

Delivery Device Apparatuses, Systems, and Methods

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

5 **[0001]** This invention was made with Government support under Agreement W911NF-17-3-0003, awarded by ACC-APG-RTP. The Government has certain rights in the invention.

BACKGROUND

10 Field of Disclosure:

[0002] This disclosure relates to medical agent delivery. More specifically, this disclosure relates to dispensers for therapeutic and other medical agents.

Description of Related Art

[0003] Novel pathogens present a variety of public health challenges which are not
15 simple to quickly overcome. From the medical perspective, existing preventive medicine infrastructure has not been and is not well suited to novel pathogens such as SARS, MERS, Zika, and COVID-19. Other pathogens for which herd immunity does not exist (e.g. Ebola), or highly dangerous pathogens which mutate quickly may present similar challenges. Vaccines typically take years to create and once a vaccine does exist, the prospect of rapidly
20 generating billions of doses would almost certainly exceed current vaccine production capabilities. Without vaccination, other preventative measures such as, testing, contact tracing, and personal protective equipment (PPE) are of elevated importance. Again, however, these preventative measures can only provide as much benefit as relevant supply chains allow. Shortages of PPE and testing kits have plagued medical systems in the United
25 States and elsewhere across the globe as they struggle to address the COVID-19 pandemic. In turn, this has hampered the potential to perform effective contact tracing which is already a vast undertaking due to the scale of the COVID-19 pandemic. Additionally, novel pathogens may refocus medical systems away from their typical functions. Secondary impacts often result when the medical community's attention is demanded by a widespread
30 pandemic. This can take the form of delayed surgeries, elective procedures, routine doctor's office visits, etc., but secondary impacts can also be much worse. As has been pointed out by the Chief of Immunizations at UNICEF, for example, during efforts to control an Ebola outbreak in the Democratic Republic of the Congo in 2019 the number of deaths due to measles was double the death toll from Ebola.

[0004] Novel pathogens also present challenges that are more psychological in nature. Put simply, such pathogens scare people. Without readily available PPE and testing, people may elect to avoid visiting medical facilities or clinics for fear of exposure to disease. Even with readily available PPE, certain individuals, such as populations in high risk demographics for a particular pathogen, may still have misgivings about visiting such facilities. Additionally, as has been the case in the United States, some may fiercely object to usage of PPE for various reasons. This presents a further public health challenge to systems attempting to deal with pandemics. Solutions to novel pathogens should seek to address and work around these challenges in order to be effective.

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SUMMARY

[0005] In accordance with an exemplary embodiment of the present disclosure an example delivery device may comprise a main body including a central region and a peripheral region. The central region may be shaped substantially as a thimble and may have a top surface and a base. The peripheral region may be defined by a plurality of petal members and a plurality of first slots therebetween. The plurality of petal members may extend outward from the base. The delivery device may further comprise an adhesive coupled to at least a part of the main body. The delivery device may further comprise a collapsible reservoir coupled to the main body and to at least one delivery sharp.

20 [0006] In some embodiments, the top surface may be convex and may include a plurality of second slots therein. In some embodiments, the central region may include a plurality of fenestrations disposed in a ring along a perimeter of the top surface. In some embodiments, the delivery device may further comprise a sharp bearing body including the at least one delivery sharp. In some embodiments, the at least one delivery sharp is a microneedle including a flow lumen with an elongate cross-section. The sharp bearing body may be coupled to the collapsible reservoir. The collapsible reservoir may be coupled to an inside surface of the central region. In some embodiments, when the delivery device is in the storage state, the collapsible reservoir may contain a fluid and the adhesive may be affixed to a penetrable surface of a member external to the delivery device. When the delivery device is in the delivery state, the penetrable surface may be stretched by the adhesive, the at least one delivery sharp may penetrate the penetrable surface, and the collapsible reservoir may be urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp. In some embodiments, the adhesive may be coupled to at least a part of at least two of the plurality

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of petal members on sides thereof most distal to the top surface. In some embodiments, when the delivery device is in the storage state, the collapsible reservoir may contain a fluid and the adhesive may be affixed to a penetrable surface of a member external to the delivery device. When the delivery device is in the delivery state, the penetrable surface may be stretched by the adhesive, the at least one delivery sharp may penetrate the penetrable surface, and the collapsible reservoir may be urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp. In some embodiments, the adhesive may be coupled to at least a part of at least two of the plurality of petal members on sides thereof most distal to the top surface. In some embodiments, the top surface may be configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave. In some embodiments, at least two of the plurality of petal members may be configured to curl in response to pressure applied on the top surface as the delivery device transitions to the delivery state. In some embodiments, the at least two of the plurality of petal members may be configured to curl so as to have a substantially constant radius of curvature in response to pressure applied on the top surface as the delivery device transitions to the delivery state. In some embodiments, at least a part of a first one of the plurality of petal members may be configured to move farther away from at least a corresponding part of a second one of the plurality of petal members during at least a part of the transition between the storage state and the delivery state, the first and second petal members being positioned opposite each other. In some embodiments, at least a part of a first one of the plurality of petal members may be configured to move farther away from at least a corresponding part of a second one of the plurality of petal members during at least a part of the transition between the storage state and the delivery state and thereby stretch a surface to which the delivery device is affixed with the adhesive, the first and second petal members being positioned opposite each other. In some embodiments, the at least one delivery sharp may be a microneedle. In some embodiments the delivery device may be an intradermal delivery device. In some embodiments, wherein the reservoir may be partitioned into a first section and a second section. In some embodiments, the first section and second section may be in fluid communication with one another through a flow restrictor. In some embodiments, the reservoir may include an orifice plate.

[0007] In accordance with another example embodiment of the present disclosure, an example method of delivering a medical agent may comprise affixing, to a skin surface,

a delivery device that includes at least one delivery sharp coupled to a collapsible reservoir containing the medical agent, the delivery device being in a storage state. The method may further comprise applying pressure to the delivery device directed at the skin surface to transition the delivery device to a delivery state, penetrate the skin surface with the at least one delivery sharp, and to cause collapse the reservoir to force the medical agent into the skin via the at least one delivery sharp.

[0008] In some embodiments, the method may further comprise stretching the skin surface as the delivery device transitions from the storage state to the delivery state. In some embodiments, the method may further comprise scratching the skin surface with at least one of the at least one delivery sharp. In some embodiments, the method may further comprise preventing reuse of the delivery device. In some embodiments, transitioning the delivery device to a delivery state may comprise at least partially inverting at least one region of a main body of the delivery device. In some embodiments, transitioning the delivery device to the delivery state may comprise deforming a main body of the delivery device out of a first stable state and into a second stable state. In some embodiments, collapsing the reservoir may comprise displacing a flexible wall of the reservoir against a rigid wall of the reservoir. In some embodiments, forcing the medical agent into the skin via the at least one delivery sharp may comprise transferring the medical agent from the reservoir to the skin via a respective flow lumen and channel in each of the at least one delivery sharp.

[0009] In accordance with another exemplary embodiment of the present disclosure an example delivery device may comprise a main body including a central region coupled to a peripheral region. The central region may be shaped substantially as a thimble and may have a top surface and a base. The peripheral region may surround the central region. The peripheral region may have an inner perimeter and an outer perimeter. The inner perimeter may be coupled to the base such that the peripheral region extends outward from the base. The peripheral region may include a plurality of first slots extending inward from the outer perimeter. The delivery device may further comprise an adhesive coupled to at least a part of the main body. The delivery device may further comprise a collapsible reservoir coupled to the main body and to at least one delivery sharp.

[0010] In some embodiments, the top surface may be convex and include a plurality of second slots therein. In some embodiments, the plurality of second slots may extend outward with respect to a center point of the top surface. In some embodiments, the central region may include a plurality of fenestrations disposed along the base. In some embodiments, the central region may include a plurality of fenestrations disposed along a

perimeter of the top surface. In some embodiments, the delivery device may further comprise a sharp bearing body including the at least one delivery sharp. The sharp bearing body may be coupled to the collapsible reservoir. The collapsible reservoir may be coupled to an inside surface of the central region. In some embodiments, the adhesive may be coupled to at least a part of a side of the peripheral region most distal to the top surface. In some embodiments, the top surface may be configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave. In some embodiments, the main body may have a footprint with an area and may be configured such that the area increases during at least a part of the transition between the storage state and the delivery state. In some embodiments, the main body may have a footprint with an area and may be configured such that the area increases during at least a part of the transition between the storage state and the delivery state and thereby stretches a surface to which the delivery device is affixed with the adhesive. In some embodiments, when the delivery device is in the storage state, the collapsible reservoir may contain a fluid and the adhesive may be affixed to a penetrable surface of a member external to the delivery device. When the delivery device is in the delivery state, the penetrable surface may be stretched by the adhesive, the at least one delivery sharp may penetrate the penetrable surface, and the collapsible reservoir may be urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp. In some embodiments, the at least a part of the side may include first and second areas between two pairs of adjacent first slots of the plurality of first slots. In some embodiments, the adhesive may be coupled to at least a part of a side of the peripheral region most distal to the top surface. In some embodiments, the at least a part of the side may include first and second areas between two pairs of adjacent first slots of the plurality of first slots. In some embodiments, when the delivery device is in the storage state, the collapsible reservoir may contain a fluid and the adhesive is affixed to a penetrable surface of a member external to the delivery device. When the delivery device is in the delivery state, the penetrable surface may be stretched by the adhesive, the at least one delivery sharp may penetrate the penetrable surface, and the collapsible reservoir may be urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp. In some embodiments, the top surface may be configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave. In some

embodiments, the main body may have a footprint with an area and may be configured such that the area of the footprint increases during at least a part of the transition between the storage state and the delivery state. In some embodiments, the main body may have a footprint with an area and may be configured such that the area of the footprint increases during at least a part of the transition between the storage state and the delivery state and thereby stretches a surface to which the delivery device is affixed with the adhesive.

[0011] In accordance with another example embodiment of the present disclosure an example actuator assembly for inhibiting reuse of a drug delivery device may comprise a flexure including first and second members and a plurality of struts which couple the first and second members together. Each strut may have a resiliency which resists displacement of the first and second member toward one another. The first member may include at least one first engagement member. The second member may include a cooperating engagement member for each of the first engagement member. The struts may be configured to deflect and engender a rotational motion of at least one of the first and second member when the first and second member are urged toward one another with more than a threshold force. The at least one first engagement member and each respective second engagement member may be configured to form a coupling when distance between the first and second member is decreased beyond a threshold distance.

[0012] In accordance with another exemplary embodiment of the present disclosure an example delivery device may comprise a first portion at least partially covered with a first adhesive and including a cantilevered arm. The delivery device may further comprise a second portion at least partially covered with a second adhesive and including at least one ramp element. The second portion may be coupled to the first portion via the first adhesive. The second portion may be configured to elongate from a first state to an elongated state. The delivery device may further comprise a collapsible reservoir including at least one delivery sharp. The reservoir may be coupled to an unsupported end of the cantilevered arm.

[0013] In some embodiments, the at least one delivery sharp may include one of a one dimensional array of microneedles and a two dimensional array of microneedles. In some embodiments, the second portion may include a delivery aperture. The delivery aperture may be out of alignment with the at least one delivery sharp when the second portion is in the first state and in alignment with the at least one delivery sharp when the second portion is in the elongated state. In some embodiments, the second portion may include a folded region in the first state. The folded region may be configured to unfurl as the second portion is transitioned to the elongated state. In some embodiments, the second

portion may include a folded region. A layer of the folded region may be coupled to the first adhesive. In some embodiments, each of the at least one ramp element may be disposed on a first side of the cantilevered arm when the second portion is in the first state and disposed on a second side of the cantilevered arm when the second portion is in the second state. In some embodiments, the second portion may be at least partly elastic. In some embodiments, the second portion may include a pull tab. In some embodiments, the delivery device may further comprise a lock adhesive disposed on a section of the first portion and the delivery device may further comprise a tether having a first end which is coupled to the second portion. In some embodiments, a second end of the tether may be coupled to the lock adhesive and cover the lock adhesive when the second portion is in the first state. The second end of the tether may be configured to at least partially disassociate from the lock adhesive when the second portion is in the elongated state to expose the lock adhesive. In some embodiments, a second end of the tether may be coupled to the lock adhesive and the tether may be doubled over upon itself when the second portion is in the first state. In some embodiments, the first adhesive and second adhesive may be disposed a first distance from one another when the second portion is in the first state and the first and second adhesive may be disposed a second distance from one another when the second portion is in the elongated state. The second distance may be greater than the first distance. In some embodiments, the at least one ramp element may be configured to resiliently deflect the cantilevered arm as the second portion is transitioned from the first state to the second state.

[0014] In accordance with an example embodiment of the present disclosure, an example delivery device may comprise a main body including first and second end blocks spaced apart by first and second side panels and a bridge. The side panels and bridge may each include first and second opposing ends. The first ends may each be connected to the first end block via respective first end living hinges. The second ends may each be connected to the second end block via respective second end living hinges. The side panels and bridge also may each include respective intermediate living hinges between their first and second ends. The delivery device may further comprise an adhesive at least partially covering a first side of the end blocks. The delivery device may further comprise a collapsible reservoir including at least one delivery sharp. The reservoir may be coupled to an end of an arm member extending from the bridge toward the first side.

[0015] In some embodiments, the side panels may each include at least one guard projection. In some embodiments, the first side panel may include a first guard projection which extends from toward the second side panel and the second side panel may include a

second guard projection which extends toward the first side panel. In some embodiments, the first guard projection may include a latch projection and the second side panel may include a latch catch. In some embodiments, the first side panel may include a third guard projection which extends toward the second side panel and the second guide panel may include a fourth guard projection which extends toward the first side panel. In some 5 embodiments, the bridge may include a first panel and a set of struts. The first panel may be connected to the struts via the intermediate living hinge of the bridge. In some embodiments, the arm member may be disposed between the struts and extend from an end of the panel adjacent the intermediate living hinge of the bridge. In some embodiments, the side panels may have a displacement range from an outwardly bowed state to a substantially straight state and the end blocks may be configured to displace away from one another when the side panels are displaced from the outwardly bowed state to the substantially straight state. In some embodiments, the side panels may be configured to displace from the outwardly bowed state to the substantially straight state upon application of a pinching force 10 to the side panels. In some embodiments, at least the intermediate living hinge of the bridge member may be configured to displace toward the first surface of the end blocks when the side panels are displaced from the outwardly bowed state to the substantially straight state. In some embodiments, the side panels may have a displacement range from an outwardly bowed state to a substantially straight state and the bridge may be configured such that the arm member may be displaced from a first position to a second position in which the at least one delivery sharp is disposed below the first surface of the end blocks when the side panels are displaced from the outwardly bowed state to the substantially straight state. In some 20 embodiments, the side panels may have a displacement range from an outwardly bowed state to a substantially straight state and the main body may include a latch projection and a latch catch. The latch projection may be configured to engage the latch catch when the side panels are displaced from the outwardly bowed state to the substantially straight state. In some embodiments, the main body may include a plurality of iris panels which extend from the side panels to create a variable aperture. In some embodiments, the aperture may be configured to vary in size as the side panels are bent about the intermediate living hinge of each side panel. 30

[0016] In accordance with another example embodiment of the present disclosure and example delivery device may comprise a main body including a set of opposed end panels and at least two intermediate panels. The panels may be separated from one another by a plurality of living hinges which each extend across the main body. The delivery device

may further comprise an adhesive covering at least a portion of a proximal side of each of the end panels. The delivery device may further comprise a collapsible reservoir including at least one delivery sharp. The reservoir may be coupled to the proximal side of one of the intermediate panels. The two intermediate panels may form a linkage displaceable between
5 a raised position and an over center position when the two end panels are constrained to a plane. A first of the intermediate panels may extend along the plane when the linkage is in the over center position.

[0017] In some embodiments, a first of the end panels may be substantially planar and a second of the end panels may include a planar portion and an angled projection
10 extending from the planar portion toward one of the intermediate linkages. In some embodiments, the second of the end panels may include a buttress which extends from the planar portion to the angled projection. In some embodiments, the at least one delivery sharp may include an array of microneedles. In some embodiments, the delivery device may be configured to transition from a storage state to a delivery state. In some embodiments, a
15 second of the intermediate panels may be at least partially covered with adhesive on a proximal side thereof. In some embodiments, the end panels may be displaced apart a first distance along the plane as the linkage displaces from the raised position to a center position and may be displaced toward one another a second distance shorter than the first distance as the linkages displaces from the center position to the over center position. In some
20 embodiments, the reservoir may be disposed on a second of the intermediate panels adjacent a living hinge of the plurality of living hinges which is between the first and second intermediate panels. In some embodiments, one of the panels may include a strain relief flexure. In some embodiments, at least a portion of the main body may be configured to plastically deform when the linkage is displaced to the over center position. In some
25 embodiments, at least one of the living hinges may be configured to break when the linkage is displaced from the raised position to the over center position and back. In some embodiments, the linkage may be at least partially inverted in the over center position with respect to the raised position. In some embodiments, an angle between the intermediate panels when the linkage is in the raised position may be an obtuse angle and an angle
30 between the intermediate panels when the linkage is in the over center may be a reflex angle. In some embodiments, one of the intermediate panels may be parallel to the skin when the linkage is in the over center position.

[0018] In accordance with yet another example embodiment of the present disclosure, an example delivery device may comprise an actuator. The delivery device may

further comprise a base including a threaded post. The actuator may be in threaded engagement with the post and may be displaceable along the threaded post from a raised state in which the actuator is most distal to the base to a delivery state in which the actuator is more proximal the base. The delivery device may further comprise a carriage disposed within a bore of the post. The carriage may include at least one first frangible supported on a respective ledge defined in the bore and at least one second frangible. The delivery device may further comprise a delivery aid disposed within the bore. The delivery device may further comprise a collapsible reservoir positioned within the bore and including at least one delivery sharp. As the actuator is displaced from the raised state to the delivery state, a portion of the actuator may be configured to apply pressure against the carriage. The pressure may break the at least one of the first frangible and free the carriage to displace within the bore as well as break the at least one of the second frangible such that pressure is exerted through the carriage and delivery aid against the reservoir. Displacement of the actuator to the delivery state may be further configured to displace the reservoir toward the base.

[0019] In some embodiments, the actuator may include a projection which may be in alignment with the axis of the post. Pressure against the carriage may be applied via the projection. In some embodiments, the delivery aid may be coupled to an end of the projection most proximal to the base. In some embodiments, the projection may extend through at least a portion of the carriage when the actuator is in at least one of the raised position and the delivery position. In some embodiments, the delivery aid may include a force concentrating protuberance. In some embodiments, the base may include a delivery aperture aligned with the bore of the post. In some embodiments, the at least one first frangible may include a set of frangibles spaced at even angular increments about the carriage. In some embodiments, the at least one second frangible may include a set of frangibles spaced at even angular increments about the carriage. In some embodiments, with the at least one first frangible in a broken state, the carriage may have a displacement range within the bore which is limited by a stop surface disposed at an end of the bore adjacent the base. In some embodiments, the carriage may extend through a delivery aperture in the base when the carriage is against the stop surface such that a skin depressor member of the carriage is external to the bore. In some embodiments, the reservoir may be disposed within a bay of the carriage and frictionally retained therein when pressure applied to the reservoir is below a threshold. In some embodiments, the carriage, delivery aid, and reservoir may be configured to displace together within the bore as a unit after the at least one first frangible

is broken. In some embodiments, the carriage delivery aid, and reservoir may be configured to cease displacement together as a unit when the at least one second frangible is broken.

[0020] In accordance with another example embodiment of the present disclosure an exemplary microneedle may comprise a base including a first edge and a plurality of second
5 edges. The microneedle may further comprise a plurality of sidewalls extending from the base in a direction substantially perpendicular thereto. The microneedle may further comprise a face extending from the first edge to a vertex at an acute angle to the base. Two adjacent sidewalls of the plurality of sidewalls may define a side edge extending from the base to the vertex in a direction substantially vertical to the base. The microneedle may
10 further comprise a flow lumen extending through the microneedle from the base to an outlet in the face. The microneedle may further comprise a channel defined in the face and connected to the flow lumen.

[0021] In some embodiments, the flow lumen may have an elongate cross-sectional shape. In some embodiments, the outlet in the face may be disposed more proximal the
15 vertex than the first edge. In some embodiments, the outlet in the face may be disposed more proximal the first edge than the vertex. In some embodiments, the outlet in the face may be disposed in a mid-region of the face intermediate a region proximal the vertex and a region proximal the first edge. In some embodiments, the channel may extend in a direction toward the first edge from the outlet in the face. In some embodiments, the channel may
20 extend in a direction toward the vertex from the outlet in the face. In some embodiments, the channel may include a first portion and a second portion. The first portion may extend in a direction toward the vertex from the outlet in the face and the second portion may extend in a direction toward the first edge from the outlet in the face. In some embodiments, the channel may have a width which is variable. In some embodiments, the channel may have a
25 substantially constant width. In some embodiments, an end of the channel most proximate the first end may be a distance of at least 50-200 microns from the base. In some embodiments, the microneedle may be constructed of silicon. In some embodiments, a height of the microneedle may be at least 600 microns.

[0022] In accordance with another example embodiment of the present disclosure,
30 an example microneedle may comprise a base including a first edge and a plurality of second edges. The microneedle may further comprise a plurality of sidewalls projecting from the second edges to an arcuate blade edge which extends from a base vertex formed by two of the second edges to a second vertex spaced from the base. The microneedle may further comprise a face extending from the first edge to the second vertex. The microneedle

may further comprise a flow lumen extending through the microneedle from the base to an outlet in the face.

[0023] In some embodiments, the blade edge may be a double beveled blade. In some embodiments, the outlet in the face may have an elongate shape. In some
5 embodiments, the first edge may be disposed such that a plane perpendicular to the base and including the first edge extends through a portion of the blade edge. In some embodiments, the first edge may be disposed such that a plane perpendicular to the base and including the first edge does not pass through the blade edge. In some embodiments, the outlet may be disposed such that at least one plane perpendicular to the base and passing through the
10 outlet also passes through the blade edge. In some embodiments, the outlet may be disposed such that any plane perpendicular to the base and passing through the outlet also passes through the blade edge. In some embodiments, the measure of the arc of the blade edge may be greater than 90°. In some embodiments, the measure of the arc of the blade edge may be less than 90°.

[0024] In accordance with yet another example embodiment of the present
15 disclosure, an example delivery device may comprise a main body including a peripheral region and a central region extending proud of the peripheral region. The peripheral region may have a top surface and a base. The peripheral region may include a number of bodies spaced apart by slits which extend from the periphery of the peripheral region toward the
20 central region. The delivery device may further comprise an adhesive coupled to at least a part of the main body. The delivery device may further comprise a collapsible reservoir coupled to the main body and to at least one delivery sharp.

[0025] In some embodiments, the main body may have a first state and a second state. The main body may include at least one partially invertible region which is in a first
25 shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region. In some embodiments, the at least one partially invertible region may include the top surface. In some embodiments, the main body may further comprise a static region which is substantially the same shape when the main body is in the first state and the second state. In some embodiments, the
30 static region may be included in the central region and may extend from a periphery of the top surface to the base. In some embodiments, the main body may be configured such that at least two of the bodies of the peripheral region spreadingly displace as the main body transitions from the first state to the second state. In some embodiments, the top surface may be convex in the first state. In some embodiments, the top surface may be concave in

the second state. In some embodiments, the reservoir may be formed as an assembly including a holder to which the microneedle is coupled and a flexible body coupled to the holder. There may be a sealed reservoir volume defined between a portion of the holder and a portion of the flexible body.

5 **[0026]** In accordance with still another example embodiment of the present disclosure, an example delivery device may comprise a main body including a central region and a peripheral region having a plurality of petal members extending outwardly from the central region. The central region may define a receptacle and having a top region and a base which are connected by a wall. The delivery device may comprise a collapsible
10 reservoir including at least one delivery sharp. The reservoir may be coupled to the main body and at least partially disposed within the receptacle. The delivery device may further comprise an adhesive disposed on at least a portion of the main body.

[0027] In some embodiments, the reservoir may comprise a rigid portion and a flexible portion coupled to the rigid portion. A sealed interior volume of the reservoir may
15 be defined between the rigid portion and the flexible portion. The at least one delivery sharp may be coupled to the rigid portion. In some embodiments, the rigid portion may include a stage projection. In some embodiments, the at least one delivery sharp may be coupled to the stage projection and may project from the stage projection at an acute angle with respect to the rigid portion. In some embodiments, the main body may include a ridge adjacent the
20 receptacle. The ridge may form a mounting surface for the reservoir. In some embodiments, the delivery device may further comprise a packet disposed in the receptacle between the top region and the reservoir. In some embodiments, the packet is a gas bladder. In some embodiments, the packet may contain a means for applying pressure to the reservoir. In some embodiments, the packet may be configured to rupture when subjected to more than a
25 threshold pressure. The packet may be disposed within a container and include a first substance. The container may contain a second substance. The first and second substances may be configured to react when combined to expand the volume of the container. In some embodiments, the packet may be configured to rupture when subjected to more than a threshold pressure. The packet may be disposed within a container and filled with a first
30 substance. The container may contain a second substance. The first and second substances may be configured to partake in a chemiluminescent reaction when combined. In some embodiments, the delivery device may further comprise a bias member disposed within the receptacle between the top region and the reservoir. In some embodiments, the bias member may be a conical spring. In some embodiments, the main body may include a plurality of

locating projections which may constrain the bias member and the bias member may be coupled to the main body. In some embodiments, the bias member may be heat staked to the main body. In some embodiments, the delivery device may further comprise a dispensing assembly including a depressor body, a reservoir interface member, and a bias member each of which being at least partially disposed within the receptacle between the reservoir and the top region. In some embodiments, the reservoir may be partitioned into a first portion and a second portion. In some embodiments, the first portion may be in fluid communication with the second portion via a flow restrictor.

[0028] In accordance with another example embodiment of the present disclosure, an example delivery device may comprise a main body including a central region and a peripheral region. The peripheral region may include a plurality of peripheral members extending outwardly from the central region. The central region may have a top region and a base which are connected by a wall. The delivery device may further comprise a reservoir portion including a reservoir with at least one delivery sharp. The reservoir portion may be detachably coupled to the main body and a least partially covered by the main body. The delivery device may further comprise an indicator disposed on a section of the reservoir portion covered by the main body. The delivery device may further comprise a first adhesive disposed on at least a portion of the main body. The delivery device may further comprise a second adhesive disposed on at least a part of the reservoir portion. The main body may obstruct line of sight to the indicator when the reservoir portion and main body are coupled together.

[0029] In some embodiments, when the delivery device is applied to a surface, the second adhesive may be configured to maintain the reservoir portion against the surface such that a removal force exerted on the main body results in separation of the main body and reservoir portion. In some embodiments, the indicator is selected from a group consisting of a barcode, data matrix, and QR code. In some embodiments, the indicator may encode information related to the contents of the reservoir. In some embodiments, the main body may be opaque. In some embodiments, the main body may be translucent. In some embodiments, the reservoir portion may be coupled to the main body via adhesive. In some embodiments, the peripheral region may include a pull tab. In some embodiments, at least one of the peripheral members may define a pull tab. In some embodiments, the main body may include a set of slots and the reservoir portion may include a number of tabs, each of the tabs extending at least partially through a respective slot to detachably couple the reservoir portion and main body.

[0030] In accordance with another example embodiment of the present disclosure and example delivery device may comprise a main body including a central region and a peripheral region. The peripheral region may have a plurality of petal members extending outwardly from the central region. The central region may define a receptacle and may have
5 a top region and a base which are connected by a wall. The delivery device may further comprise a collapsible reservoir including at least one delivery sharp. The reservoir may be coupled to the main body and at least partially disposed within the receptacle. The delivery device may further comprise a dispensing assembly at least partially disposed within the receptacle between the reservoir and the top region. The delivery device may further
10 comprise an adhesive disposed on at least a portion of the main body.

[0031] In some embodiments, the dispensing assembly may include a depressor body, at least one bias member, and a reservoir interface member. In some embodiments, the depressor body may include a portion which projects through an aperture in the top region. In some embodiments, the depressor body may include a detent. In some
15 embodiments, the portion of the depressor body may include at least one notch and may have a cross-sectional shape which is not circular and not a regular polygon. In some embodiments, the bias member may include at least one bow spring. In some embodiments, the bias member may include a peripheral region and a number of bias projection which extend inwardly from the peripheral region. The main body may include a number of slots.
20 The bias projections may extend through the slots and into the receptacle. In some embodiments, the reservoir interface member may be integral with the depressor body. In some embodiments, the dispensing assembly may include a coil spring and may include a reservoir interface member. In some embodiments, the reservoir interface member may be formed by a terminal portion of the spring which is routed in a pattern in a plane which is
25 adjacent an end of the coils of the spring. In some embodiments, the dispensing assembly may include a spring and may be out of contact with the reservoir when the delivery device is in a storage state. In some embodiments, the spring may be in an unstressed state when the delivery device is in the storage state.

[0032] In accordance with another example embodiment of the present disclosure a
30 delivery device system may comprise a package including an indicium. The system may further comprise a delivery device contained within the package. The system may further comprise a database. The system may further comprise a reader including a user interface and a controller. The reader may be in data communication with the database and may be configured to capture delivery device information from the indicium. The controller may be

configured check the delivery device information against associated data in the database. The controller may be configured to generate use instructions on the user interface when the associated data in the database indicates the device is acceptable for use. The controller may prevent use of at least one functionality of the reader until first information has been collected by the reader and a first service is enabled on the reader.

5 [0033] In some embodiments, the indicium may be selected from a group consisting of a barcode, data matrix, and QR code. In some embodiments, the reader may be a smart device and may include an imager. In some embodiments, the at least one functionality may include use of the imager. In some embodiments, the first service may be a notification service. In some embodiments, the first service may be a location service. In some
10 embodiments, the first information may be location information.

[0034] In accordance with an example embodiment of the present disclosure an example method of using of a medical delivery device may comprise capturing, with a reader, device information from an indicium on a package containing the medical delivery device. The method may further comprise applying the delivery device to skin of a patient. The method may further comprise establishing data communication between the reader and a database. The method may further comprise comparing the device information against associated device information stored on the database. The method may further comprise generating, with a controller of the reader, a set of use instructions on a user interface of the
15 reader when an acceptability for use criteria is met by the comparison. The method may further comprise capturing, with the reader, data from a post usage indicium after the medical delivery device is used. The method may further comprise updating the database to indicate that the post usage indicium of the delivery device has been captured by the reader.

[0035] In some embodiments, the method further may comprise removing a first
25 portion of the medical delivery device to reveal the post usage indicium on a second portion of the delivery device. In some embodiments, the method may further comprise marking the skin with the post usage indicium. In some embodiments, the method may further comprise generating a respective prompt on the user interface for each use instruction of the set of use instructions and preventing display of a next use instruction until a user interaction with the prompt is registered by the controller. In some embodiments, the method may further
30 comprise preventing use of at least one functionality of the reader until a notification service of the reader is enabled. In some embodiments, the at least one functionality may be use of an imager of the reader. In some embodiments, the method may further comprise generating

a confirmation of delivery for display on the user interface of the reader. In some embodiments, the reader may be a smart phone.

[0036] In accordance with yet another example embodiment of the present disclosure a method of using of a medical delivery device may comprise applying a delivery
5 device to an injection site. The method may further comprise generating, with a controller of a reader, a set of use instructions on a user interface of the reader. The method may further comprise delivering an agent into the injection site from the delivery device. The method may further comprise capturing, with the reader, image data of the injection site, the image data including image data in a spectrum outside of the visible spectrum. The method
10 may further comprise analyzing the image data to determine if the image data conforms to at least one criterion indicative of a proper injection.

[0037] In some embodiments, the method may further comprise establishing data communication between the reader and a database. In some embodiments, the method may further comprise updating the database to indicate an outcome of the analysis. In some
15 embodiments, the image data may include image data in the near infrared spectrum. In some embodiments, the image data may include image data in the infrared spectrum. In some embodiments, the image data may include thermal image data. In some embodiments, analyzing the image data may comprise analyzing thermal image data for the presence of a cool region at the injection site. In some embodiments, analyzing the image data may
20 comprise analyzing the image data to determine the presence of at least one characteristic of interest. In some embodiments, the at least one characteristic of interest may include a characteristic indicative of an intradermal bleb and a characteristic indicative of leak. In some embodiments, the reader may be a smart phone.

[0038] In accordance with another example embodiment of the present disclosure a
25 microneedle may comprise a base including a first edge and a plurality of second edges. The microneedle may further comprise a plurality of sidewalls extending from the base in a direction substantially perpendicular thereto. The microneedle may further comprise a face extending from the first edge to a vertex at an acute angle to the base. Two adjacent sidewalls of the plurality of sidewalls may define a side edge extending from the base to the
30 vertex in a direction substantially vertical to the base. The microneedle may further comprise a flow lumen extending through the microneedle from the base to an outlet in the face. The flow lumen may have a cross-section with an elongate shape.

[0039] In some embodiments, the cross-sectional shape may be obround. In some embodiments, the cross-sectional shape may have a length in a direction of elongation of up

to 100 microns. In some embodiments, the cross-sectional shape may have a length in a direction of elongation of up to 200 microns. In some embodiments, the cross-sectional shape may be polygonal. In some embodiments, the microneedle may be constructed of silicon. In some embodiments, a majority of the cross-sectional shape may have a constant width. In some embodiments, the microneedle may have a height of at least 600 microns. In some embodiments, the microneedle may have a height of up to 800 microns.

[0040] In accordance with another example embodiment of the present disclosure and example microneedle may comprise a base. The microneedle may further comprise a plurality of sidewalls extending from the base. The sidewalls may be angled such that the microneedle tapers so as to have a smaller cross-sectional area as distance from the base increases. The microneedle may further comprise a flow lumen. The microneedle may further comprise a plurality of side ports in the sidewalls. The side ports may be in fluid communication with the flow lumen. The microneedle may further comprise a tip at an end of the sidewalls opposite the base.

[0041] In some embodiments, the microneedle may have a high aspect ratio. In some embodiments, the microneedle may be substantially in the shape of an obelisk. In some embodiments, the base may be polygonal in shape and a sidewall of the plurality of sidewalls may extend from each side of the polygonal shape of the base. In some embodiments, the base may have the shape of a quadrilateral and a sidewall of the plurality of sidewalls may extend from each of the four sides of the base. In some embodiments, the flow lumen may have a substantially constant cross-section. In some embodiments, the flow lumen may extend from the base to a plane in the microneedle where the cross-section of the flow lumen is wider than the portions of the cross-section of the microneedle. In some embodiments, the microneedle may be constructed of silicon and the lumen may be etched into the microneedle. The side ports may be formed as a consequence of the etching of the lumen. In some embodiments, the flow lumen may extend substantially along the long axis of the microneedle. In some embodiments, the tip may be beveled.

[0042] In accordance with yet another example embodiment of the present disclosure, a method of delivering a medical agent may comprise affixing to a surface a delivery device that includes at least one delivery sharp which may be in fluid communication with an at least partially collapsible reservoir containing the medical agent while the delivery device is in a storage state. The method may further comprise pressing a portion of the delivery device toward the surface to transition the delivery device to a delivery state. The method may further comprise spreadingly displacing at least two

portions of the delivery device to tension the surface to which the delivery device is affixed. The method may further comprise penetrating the surface with the at least one delivery sharp. The method may further comprise transferring fluid out of the at least partially collapsible reservoir and through the at least one delivery sharp until the reservoir is in a depleted state.

5 [0043] In accordance with another example embodiment of the present disclosure, a delivery device may comprise a main body. The main body may comprise a peripheral region having a number of petal members. The main body may further comprise a central region extending proud of the peripheral region. The central region may have a top surface and a base. The delivery device may further comprise a collapsible reservoir in fluid communication with at least one delivery sharp. The at least one delivery sharp may be configured to expel fluid from the reservoir in an ejection direction. The delivery device may further comprise an adhesive member including a central aperture. The central aperture may include an increased aperture width portion aligned with the ejection direction.

10 [0044] In some embodiments, the reservoir may include a flexible portion and a rigid portion. The adhesive member may be affixed to the main body and the rigid portion. In some embodiments, the reservoir may include a flexible portion and a rigid portion. The rigid portion may have a foot print with a first area. The central aperture may encompass a second area which is between 60-100% of the first area. In some embodiments, a center of the central aperture may be coaxial with a center of the reservoir. In some embodiments, the adhesive member may include at least one spoke which projects into the central aperture from the periphery of the central aperture. In some embodiments, the adhesive member may cover at least a portion of each of the petal members. In some embodiments, the at least one delivery sharp may include a spaced array of microneedles. In some embodiments, the main body may have a first state and a second state. The main body may include at least one partially invertible region which is in a first shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region. In some embodiments, the main body may be configured such that at least two of the petal members spreadingly displace as the main body transitions from the first state to the second state. In some embodiments, the at least one delivery sharp may be displaced into communication with a delivery destination when the main body is displaced from the first state to the second state. In some embodiments, the central aperture may include, at the increased aperture width portion, at least one notch extending outward from the periphery of the central aperture and through the adhesive member.

[0045] In accordance with another example embodiment of the present disclosure a delivery device may comprise a main body. The main body may include a peripheral region having a number of petal members. The main body may further include a central region extending proud of the peripheral region and having a top surface and a base. The delivery
5 device may further comprise a collapsible reservoir coupled to the main body. The reservoir may be in fluid communication with at least one microneedle having a width, height, and length. The delivery device may further comprise an adhesive member. The adhesive member may include a central aperture having an increased aperture width portion aligned with the length dimension of the microneedle.

10 [0046] In some embodiments, the reservoir may include a flexible portion and a rigid portion. In some embodiments, the adhesive member may be affixed to the main body and the rigid portion. In some embodiments, the reservoir may include a flexible portion and a rigid portion. The rigid portion may have a foot print with a first area. The central aperture may encompass a second area which is between 60-100% of the first area. In some
15 embodiments, a center of the central aperture is coaxial with a center of the reservoir. In some embodiments, the adhesive member may include at least one spoke which projects into the central aperture from the periphery of the central aperture. In some embodiments, the adhesive member may cover at least a portion of each of the petal members. In some embodiments, the at least one delivery sharp may include a spaced array of microneedles. In
20 some embodiments, the main body may have a first state and a second state. The main body may include at least one partially invertible region which is in a first shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region. In some embodiments, the main body may be configured such that at least two of the petal members spreadingly displace as the main
25 body transitions from the first state to the second state. In some embodiments, the at least one delivery sharp may be displaced into communication with a delivery destination when the main body is displaced from the first state to the second state. In some embodiments, the central aperture may include at the increased aperture width portion at least one notch extending outward from the periphery of the central aperture and through the adhesive
30 member.

[0047] In accordance with still another exemplary embodiment of the present disclosure a delivery device may comprise a main body. The main body may include a peripheral region. The peripheral region may include a number of petal members. The main body may further include a central region. The central region may extend proud of the

peripheral region. The central region may have a top surface and a base. The delivery device may further comprise an adhesive coupled to at least a part of the main body. The delivery device may further comprise a reservoir including at least one flexible portion. The at least one flexible portion may include a cavity defined by a first wall including a collapse
5 facilitator. The delivery device may further comprise at least one delivery sharp in fluid communication with the reservoir.

[0048] In some embodiments, the collapse facilitator may include a bellows. In some embodiments, the collapse facilitator may include a pleat which extends around the wall in a spiral manner. In some embodiments, the collapse facilitator may include at least
10 one stepped region formed in the wall. In some embodiments, the first wall may extend from a flange coupled to a rigid portion of the reservoir. In some embodiments, the first wall may taper as distance from the flange increases such that the cross-sectional area of the cavity decreases with distance from the flange. In some embodiments, the cavity may also be defined by a second wall at an end of the cavity, the second wall forming a substantially
15 flat surface. In some embodiments, the second surface may include a central depression. In some embodiments, the wall may extend from a flange and may be formed integrally therewith. In some embodiments, the cavity may be defined by the first wall and a second wall at an end of the cavity, the second wall being substantially parallel to the flange. In some embodiments, the at least one delivery sharp may include a microneedle.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0049] These and other aspects will become more apparent from the following detailed description of the various embodiments of the present disclosure with reference to
25 the drawings wherein:

[0050] FIG. 1A is a block diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;

[0051] FIG. 1B is a block diagram of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;

30 [0052] FIG. 2 is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0053] FIG. 3A is a diagram of an example sharp bearing body incorporating microneedles in accordance with various aspects and embodiments of the present disclosure;

[0054] FIG. 3B is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0055] FIG. 4A is a diagram of an example sharp bearing body incorporating microneedles in accordance with various aspects and embodiments of the present disclosure;

[0056] FIG. 4B is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0057] FIG. 5A is a perspective view of an example sharp bearing body including a set of exemplary microneedles;

10 [0058] FIG. 5B is a perspective view of an example sharp bearing body including a set of exemplary microneedles;

[0059] FIG. 6A is a perspective view of an example sharp bearing body include a set of exemplary microneedles;

[0060] FIG. 6B is a top plan view of the example sharp bearing body shown in FIG. 15 6A;

[0061] FIG. 7A is a top down view of an example sharp bearing body including a set of exemplary microneedles;

[0062] FIG. 7B is a perspective view of an example sharp bearing body including a set of exemplary microneedles;

20 [0063] FIG. 8A is a top down view of an example sharp bearing body including a set of microneedles;

[0064] FIG. 8B is a perspective view of an example sharp bearing body including a set of exemplary microneedles;

[0065] FIG. 8C is a cross-sectional view taken at the indicated cut plane of FIG. 8A;

25 [0066] FIG. 9A-9D depict various views of an exemplary microneedle with side ports;

[0067] FIG. 10A is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0068] FIG. 10B is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0069] FIG. 11 is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0070] FIG. 12 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

- [0071] FIG. 13 is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0072] FIG. 14 is a side view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- 5 [0073] FIG. 15 is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0074] FIG. 16 is a conceptual representation of an exemplary delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
- 10 [0075] FIG. 17 is a diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
- [0076] FIG. 18 is a conceptual representation of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
- 15 [0077] FIG. 19 is a side view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0078] FIG. 20 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0079] FIGS. 21A-21I depicts various example embodiments of main bodies including different slot patterns and top surface apertures in accordance with various aspects and embodiments of the present disclosure;
- 20 [0080] FIG. 22 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0081] FIG. 23 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- 25 [0082] FIG. 24 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0083] FIG. 25 is a diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
- 30 [0084] FIG. 26 is a cross-section perspective view of a main body of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;

[0085] FIG. 27A is a plan view diagram of an example delivery device illustrating example dimensions of one delivery device embodiment in accordance with an embodiment of the present disclosure;

[0086] FIG. 27B is a side view diagram of an exemplary delivery device illustrating
5 example dimensions of one delivery device embodiment in accordance with an embodiment of the present disclosure;

[0087] FIG. 28A is a side view conceptual diagram of an example delivery device in transition to a delivery state in accordance with various aspects and embodiments of the present disclosure;

10 [0088] FIG. 28B is a side view conceptual diagram of an example delivery device in transition to a delivery state in accordance with various aspects and embodiments of the present disclosure;

[0089] FIG. 29 is a perspective view diagram conceptually illustrating an example delivery device in a delivery state in accordance with various aspects and embodiments of
15 the present disclosure;

[0090] FIG. 30 is a side view diagram of the example delivery device of FIG. 29 in accordance with various aspects and embodiments of the present disclosure;

[0091] FIG. 31 is an exploded view diagram of the delivery device shown in FIG. 29 in accordance with various aspects and embodiments of the present disclosure;

20 [0092] FIG. 32 is a plan view diagram of the delivery device shown in FIG. 29 in accordance with various aspects and embodiments of the present disclosure;

[0093] FIG. 33 is a cross section view diagram of the delivery device shown in FIG. 29 taken at the indicated cut plane in FIG. 32 in accordance with various aspects and embodiments of the present disclosure;

25 [0094] FIG. 34 depicts a representational illustration of an example delivery device including a dispensing assembly;

[0095] FIG. 35 depicts a representational illustration of an example delivery device including a dispensing assembly;

[0096] FIG. 36 depicts a representational illustration of an example delivery device
30 including a dispensing assembly;

[0097] FIG. 37 depicts a perspective view of an example delivery device and bias member;

[0098] FIG. 38 depicts a perspective view of an example bias member which may be included in a delivery device;

- [0099] FIG. 39 depicts a cross-sectional view of a portion of an example delivery device;
- [00100] FIG. 40 depicts a cross-sectional view of a portion of an example delivery device;
- 5 [00101] FIG. 41 depicts a perspective view of an example depressor body which may be included in a delivery device;
- [00102] FIG. 42 depicts an example depressor body and bias member where the bias member is in a stressed state;
- [00103] FIG. 43 depicts a cross-sectional view of an example depressor body and
10 bias member where the bias member is in a stressed state;
- [00104] FIG. 44A depicts a perspective view of an exemplary delivery device;
- [00105] FIG. 44B depicts a perspective view of an exemplary stop member which may be included in a delivery device;
- [00106] FIG. 44C depicts a perspective view of an example delivery assembly and
15 example stop member which may be included in a delivery device;
- [00107] FIG. 44D depicts a perspective view of an example bias member and example depressor body which may be included in a delivery device;
- [00108] FIG. 45 depicts a representational illustration of an example delivery device including a bias member;
- 20 [00109] FIG. 46A depicts a bottom plan view of an exemplary main body which may be included in a delivery device;
- [00110] FIG. 46B depicts a perspective view of an example main body and example bias member which may be included in a delivery device;
- [00111] FIG. 46C depicts a perspective view of an example main body and example
25 bias member which may be included in a delivery device;
- [00112] FIG. 47 is a perspective view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
- [00113] FIG. 48 is a side view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
- 30 [00114] FIG. 49 is a bottom-up plan view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
- [00115] FIG. 50 is a perspective view diagram of an exemplary holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;

- [00116] FIG. 51A depicts a perspective view of an example holder including a stage projection;
- [00117] FIG. 51B depicts a perspective view of an example holder including a stage projection;
- 5 [00118] FIG. 51C depicts a bottom plan view of an example holder including a stage projection;
- [00119] FIG. 52A depicts a side view of an example holder including a stage projection to which an example sharp bearing body is mounted;
- [00120] FIG. 52B depicts a detailed view of the indicated region of FIG. 52A;
- 10 [00121] FIG. 52C depicts a cross-sectional view of an example holder including a stage projection to which an example sharp bearing body is mounted;
- [00122] FIG. 52D depicts a detailed view of the indicated region of FIG. 52C;
- [00123] FIG. 53 is a side view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;
- 15 [00124] FIG. 54 is a plan view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;
- [00125] FIG. 55 is a perspective view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;
- [00126] FIG. 56 is a perspective view diagram of an exemplary portion of a reservoir
- 20 in accordance with various aspects and embodiments of the present disclosure;
- [00127] FIG. 57 depicts a perspective view of an exemplary reservoir;
- [00128] FIG. 58 depicts a perspective view of another exemplary reservoir;
- [00129] FIG. 59 is a block diagram of an example reservoir assembly in accordance with various aspects and embodiments of the present disclosure;
- 25 [00130] FIG. 60 is a block diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [00131] FIG. 61A depicts a block diagram of an example reservoir assembly;
- [00132] FIG. 61B depicts a block diagram of an example reservoir assembly;
- [00133] FIG. 62 depicts a representational illustration of an example delivery device
- 30 including a reservoir partitioned into a plurality of portions;
- [00134] FIG. 63A depicts a bottom plan view of an example delivery device with an example adhesive member;
- [00135] FIG. 63B depicts a bottom plan view of another example delivery device with another example adhesive member;

[00136] FIG. 63C depicts a bottom plan view of another example delivery device with another example adhesive member;

[00137] FIG. 64A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

5 [00138] FIG. 64B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00139] FIG. 65A is a side view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;

10 [00140] FIG. 65B is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;

[00141] FIG. 65C is a side view diagram of an example delivery device in a third state in accordance with various aspects and embodiments of the present disclosure;

[00142] FIG. 66A is a cutaway view diagram of an example flexure of a delivery device in accordance with various aspects and embodiments of the present disclosure;

15 [00143] FIG. 66B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00144] FIG. 66C is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

20 [00145] FIG. 67A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00146] FIG. 67B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00147] FIG. 68 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

25 [00148] FIG. 69 is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00149] FIG. 70A is a side view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;

30 [00150] FIG. 70B is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;

[00151] FIG. 70C is a side view diagram of an example delivery device in a third state in accordance with various aspects and embodiments of the present disclosure;

[00152] FIG. 71 is a cross section view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00153] FIG. 72A is a block diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;

[00154] FIG. 72B is a block diagram of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;

5 [00155] FIG. 73 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00156] FIG. 74 is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00157] FIG. 75 is an exploded view diagram of an example delivery device in
10 accordance with various aspects and embodiments of the present disclosure;

[00158] FIG. 76 is an exploded view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00159] FIG. 77A is a side view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;

15 [00160] FIG. 77B is an enlarged view of the indicated region of the delivery device of FIG. 77A;

[00161] FIG. 78A is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;

[00162] FIG. 78B is an enlarged view of the indicated region of the delivery device
20 of FIG. 78A;

[00163] FIG. 79 is a cross section view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;

[00164] FIG. 80 is a cross section view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;

25 [00165] FIG. 81 depicts an exploded view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00166] FIG. 82 depicts an exploded view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[00167] FIG. 83 is a perspective view diagram of an example flexure which may be
30 included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;

[00168] FIG. 84 is a side view diagram of an example flexure which may be included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;

[00169] FIG. 85 is a plan view diagram of an example flexure which may be included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;

5 [00170] FIG. 86 depicts a perspective view of an example package for a delivery device;

[00171] FIG. 87 depicts a view of an example main body of a delivery device separated for an example reservoir assembly which may be included in a delivery device;

[00172] FIG. 88 depicts a view of an example delivery device being removed from skin of a patient revealing a mark created on the skin by the delivery device; and

10 [00173] FIG. 89 depicts an example thermal image of an injection site in which a bleb from an injection into the skin is visible.

DETAILED DESCRIPTION

[00174] FIG. 1A and FIG. 1B depict an embodiment of an exemplary delivery device
15 10. The example delivery device 10 may be a low profile delivery device 10 which may be applied over the skin of a patient. The example delivery device 10 may be sized for handheld use and may be easily applied to a wide variety of injection sites over a patient's body. Additionally, the example delivery device 10 may be designed for use by a patient or relatively untrained or minimally trained individual. Thus a medical caregiver may not be
20 necessary for use of the delivery device 10.

[00175] Such delivery devices 10 may be used to dispense a medical agent from a reservoir 12 included as part of the delivery device 10 into a target delivery destination of a patient via one or more delivery sharp 72. The reservoir 12 may be at least partly flexible and may have a variable volume which may deplete as fluid is dispensed from the reservoir
25 12. As the reservoir 12 depletes, the reservoir 12 may at least partially collapse. In the example embodiment, a plurality of delivery sharps 72 are included in the delivery device 10, though other embodiments may only include a single delivery sharp 72. The exemplary plurality of delivery sharps 72 may be arranged in a one or two dimensional array and may extend from the reservoir 12. Where multiple delivery sharps 72 are included, the delivery
30 sharps 72 may be arranged in one or more rows and/or columns. Though three delivery sharps 72 arranged in a single row are depicted in FIG. 1A, the number and arrangement of delivery sharps 72 may differ in alternative embodiments. Any suitable number of rows and/or columns may be included in various examples. In various embodiments there may, for example, be a single row array of delivery sharps 72 including up to five delivery sharps

72. Preferably, the delivery sharps 72 may be arranged so as to prevent a bed of nails type scenario in which penetration of the skin via the delivery sharps 72 may be inhibited or inconsistent across users or delivery devices 10. This may occur when too many delivery sharps 72 are arranged in close proximity to one another. Thus, the array may be referred to
5 as a spaced array of delivery sharps 72.

[00176] The delivery sharps 72 may be selected based on the desired target delivery destination in a patient. In certain embodiments, the target delivery destination may be a transcutaneous location. For example, the target delivery destination may be a subcutaneous delivery destination or an intramuscular delivery destination. Alternatively, the target
10 delivery destination may be a shallow delivery destination between the stratum corneum of a patient and the subcutaneous tissue of the patient. Such shallow destinations may be referred to herein as intradermal delivery destinations. Shallow delivery destinations may include an epidermal or dermal target location or may, for example, target a junctional area between the epidermis and dermis or dermis and subcutis. In the example embodiment, the
15 delivery sharps 72 are depicted as microneedles. Such delivery sharps 72 may be present in delivery devices 10 with shallow (e.g. above subcutaneous tissue) target delivery destinations. In alternative embodiments where, for instance, the target delivery destination is a subcutaneous or intramuscular location, conventional delivery sharps (e.g. 30-gauge needle) may be utilized.

20 [00177] Referring now also to FIG. 2, where microneedles are used, the microneedles described herein may, in certain embodiments, be MEMS produced, polyhedral (e.g. pyramidal), silicon crystal microneedles. These microneedles may be no greater than 1 mm in height, e.g. 0.6 mm or 0.8mm (though longer or shorter microneedles may also be used). At least some edges of the microneedles may be rounded or filleted, though such
25 microneedles may still be referred to herein as polyhedral. In some examples and as shown in FIG. 2, the microneedles described herein may be generally in the shape of a heptagonal prism (though pentagonal, nonagonal, and other polygonal prisms may also be used as the base shape) which has been diagonally sectored to form a heptagonal ramp or pointed wedge. In such embodiments, the heptagonal prism may be sectored by a plane extending from a
30 vertex 14 of the top face of the prism through the most distal side 15 of the base 17. At least two sides of the base of the microneedle may be parallel. The side walls 19 may extend substantially perpendicularly from the base 17. The microneedle may be substantially symmetric about a line of symmetry extending from the vertex 14 to a point above the center of the most distal side 15. In other embodiments, the microneedles may be conically

shaped. Any other suitable shape may be used. In the example, the vertex 14 is shown as a point which forms a tip of the microneedle. In other embodiments, this portion of a microneedle may be rounded (though may still be referred to herein as a vertex 14 and such microneedles may still be referred to as pointed). In such embodiments, the back facing
5 edge 23 may be a round face or the back facing edge 23 and the adjacent side walls 19 may be replaced by a rounded face.

[00178] The points or tips of microneedles described herein may be solid and the flow lumens 126 through the microneedles may be offset from the points or tips (in FIG. 2 the vertex 14 forms the tip) of the microneedles. Hollow tipped microneedles in which the
10 flow lumen 126 extends to the tip of the microneedle may also be utilized. In some embodiments, the microneedles may be NanoPass hollow microneedles available from NanoPass Technologies Ltd. of 3 Golda Meir, Nes Ziona, Israel. It should be noted that microneedles (or the substrate on which they are disposed) described herein as constructed of silicon may have a surface layer of silicon dioxide (which may, for example, form with
15 exposure to air) while still being considered constructed of silicon.

[00179] With reference to FIGS. 3A-4B, in some embodiments microneedles may be constructed to include certain features that may help to reduce the pressure required to inject fluid, such as a medical agent, into the skin of a patient. In some examples, features common certain to insect stingers or biological venom administration structures may be
20 incorporated. These features may include various recesses or depressions which are formed as part of each microneedle or at least one microneedle of a delivery device 10. These recesses or depressions may fluidly communicate with the flow lumen 126 of the respective microneedle. In some embodiments, different microneedles of a delivery device 10 may include different recesses or some microneedles may include a plurality of recesses which
25 could be of different varieties (though need not be).

[00180] For example, as shown in FIGS. 4A-4B, a microneedle may include a channel or trough 200 on an exterior sloped face 21 leading from the flow lumen 126 toward the distal side 15. The channel 200 may allow medical agent to flow through it along the outer side of the microneedle to find a path of least resistance, or weakest link, into the
30 skin. In the embodiments shown, medical agent may be routed by the channel 200 to flow along the outer side of the microneedle to a weak region in the skin in the event the outlet of the flow lumen 126 has been inserted to a greater depth than the depth of the weak region. The lamina lucida junction, an intradermal delivery destination, is a weak link in the skin structure, and is difficult to consistently inject directly into due to its relative thinness (it is

typically on the order of 40 nm thick). A microneedle including a channel 200 may, for example, allow flow of medical agent to the lamina lucida junction when the lamina lucida junction has been passed by the outlet of the flow lumen 126. The channel 200 may facilitate distribution of the medical agent through a larger area of entry or injection. In some examples, incorporating a channel 200 into a microneedle may reduce the pressure required to inject a medical agent into the skin considerably. In certain examples pressure may be reduced by 600% or more (e.g. from 120 pounds per square inch (psi) to from 18 to 20 psi in certain examples).

[00181] An appropriate silicon etching technique (or mold in embodiments using polymeric microneedles) may be used to create steeper side walls of the channel 200. This may help inhibit the skin from bending into and occluding the channel 200. Etching techniques that could be used include, by way of non-limiting example, chemical etching techniques (e.g., acid). Suitable etching techniques may include ion based etching techniques (e.g. reactive ion etching). The etching process could be a wet etching process or a dry etching process. In some non-limiting embodiments, the channel 200 may be within a range of 50-60 microns wide from side to side. In some non-limiting embodiments, the flow lumen 126 may have a diameter of 50-60 microns. The channel 200 may have a width equal to the diameter or widest portion of the flow lumen 126 or the channel 200 may have a width which is less than or greater than the width of the flow lumen 126. In certain examples, the width of the channel 200 may be about 5-10 percent of the height of the microneedle.

[00182] To avoid leakage of the fluid from the channel 200, it may be desirable to ensure that the channel 200 terminates at least a certain distance beneath the surface of the skin yet also reaches the targeted skin layer (e.g., the lamina lucida junction) when the microneedle is inserted into the skin. In some embodiments the channel 200 extends from the flow lumen 126 to within at most 50 microns (e.g. 50-200 microns) of the base 17 of the microneedle. In some embodiments, the end of the channel 200 most proximal the base 17 of the microneedle may be at least below the stratum corneum (and perhaps one or more of the stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale) when the microneedle is inserted into the skin. In some embodiments, the end of the channel 200 most proximal the base 17 may be disposed below the epidermis (e.g. in the basement membrane) or within the epidermis.

[00183] The channel 200 need not be straight or shaped in the manner shown in and described with reference to FIGS. 4A-4B. In some embodiments, the channel 200 may be a

more meandering channel 200. A curved channel 200 could, for example, be used provided the dimensions of the microneedle are accommodated. Moreover, there need not be only one channel 200. More than one channel could be used provided structural integrity of the microneedle is accommodated.

5 **[00184]** The depth of the channel 200 may be about 25 microns or more (e.g. 25-50 microns) in certain examples. The depth of the channel 200 may be or be less than 5 percent the height of the microneedle. While the depth of the channel 200 may be constant along the length of the channel 200, the depth of the channel 200 need not be constant along the length of the channel 200. Likewise, the width of the channel 200 need not be constant
10 along the length of the channel 200 (see, e.g., FIG. 5B). The width of the channel 200 may be about 20-30 percent of the width of the distal side 15 of the microneedle at the narrowest point in the channel 200. In some embodiments, the width of the channel 200 may increase as distance to the distal side 15 decreases. In some embodiments, at its widest, the channel 200 may have a width which is 50% or more the width of the distal side 15.

15 **[00185]** Referring now also to FIG. 5A and FIG. 5B, in other examples, the channel 200 may extend from the location of the lumen 126 toward the tip or vertex 14 of the microneedle (see, e.g., FIG. 5B). Moreover, in some examples, the channel 200 may extend both toward the vertex 14 and toward the base 17 from the location of the lumen 126. That is, the channel 200 may include a portion on both sides of the lumen 126 (see, e.g., FIG.
20 5A). As shown, the lumen 126 may be located substantially centrally in the sloped face 21 of the microneedle. In such embodiments, a channel 200 may extend toward the distal side 15 of the base 17 and a channel 200 may extend toward the tip or vertex 14. In other embodiments, the lumen 126 may be positioned at (or near) an end of the channel 200 most proximal the base 17.

25 **[00186]** Referring now to FIGS. 6A-6B, views of a sharp bearing body 26 including a number of microneedles are shown. In certain embodiments, a channel 200 may not be included. Instead, a microneedle may include a flow lumen 126 with an elongate cross-section (at least at the outlet, see also FIG. 7B & 8B). Microneedles with channels 200 and elongate lumens 126 are also possible. When in place within the patient, an elongate lumen
30 126 may be in fluid communication with, for example, multiple layers of skin. Thus, a thin and/or weak layer of skin may be easier to target when the microneedle is advanced into a patient. Elongate lumens 126 may also help to lower pressure required to inject. Such elongate flow lumens 126 may have any suitable cross-section. In some embodiments, the cross-section may be oval or elliptical. Alternatively, a lumen 126 with an obround cross-

section may be used as is shown in FIGS. 6A-6B. Polygonal cross-sectional shapes may also be used, such as though not limited to rectangular, trapezoidal, triangular, etc. In certain examples, the length (in the direction of elongation) of the cross-section of the lumen 126 may be up to 100-200 microns or greater (though could be less in certain examples). Where elongate lumens 126 are included, the end of the lumen 126 most proximal the distal side 15 may be spaced from the distal side 15 by at least a certain distance. The spacing may be such that, the end of the lumen 126 most proximal the distal side 15 may be at least below the stratum corneum (and perhaps one or more of the stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale) when the microneedle is inserted into the skin. In some embodiments, it may be disposed below the epidermis (e.g. in the basement membrane) or within the epidermis.

[00187] Still referring to FIGS. 6A-6B in certain embodiments, the sloped face 21 of a microneedle may not extend to the base 17 of a microneedle. There may, for example, be a vertical face 13 extending from the base 17 to the distal side 15 of a microneedle. Where a vertical face 13 is included, the vertical face 13 may be aligned with a side (e.g. distal side 15) of a sharp bearing body 26 and may form an extension thereof. Including such vertical faces 13 may aid in reducing the size of a sharp bearing body 26 and may aid in ensuring consistent fluid delivery into a target destination for certain microneedles. Though shown in relation to FIGS. 6A-6B, any of the microneedles shown herein may be arranged with vertical faces 13.

[00188] Additionally or in the alternative, a microneedle may include a depression 202. The depression 202 may include first and second opposing vertices 204, 206. In some embodiments the depression 202 may be (though need not necessarily be) a rounded depression or a concave depression, as shown in FIGS. 3A-3B. The depression 202 may have a maximum depth which places the depression 202 into fluid communication with the flow lumen 126 of the microneedle. The depression 202 may thus form a side port for the microneedle through which fluid may be delivered to the patient. The side port may be the only outlet of the microneedle or may be in addition to an outlet of the lumen in the face 21 of the microneedle. When the microneedle is inserted into the skin surface, fluid contained in a delivery device 10 may be delivered to the patient, at least in part, by being pumped into the depression 202. The depression 202 may be formed, for example by cutting away material during manufacture of the microneedle or the depression 202 may be formed during a molding operation. Cutting away material may be accomplished by any known suitable process such as, for instance, etching (e.g. wet etching). In some embodiments, the

depression 202 may be recessed in at least one side wall 19 or edge (e.g. where two side walls 19 join) of the microneedle. In the example shown in FIGS. 3A-3B, the depression 202 is formed in a substantially vertical back facing edge 23 of the microneedles which extends from the base 17 to the vertex 14. This may establish or increase a vertical void
5 volume created by the microneedle as the skin is penetrated by the microneedle. That is, such a depression 202 may establish an open space in a patient into which fluid may be easily delivered from the microneedle. Positioning the depression 202 in the back facing edge 23 may provide a path of low resistance for a fluid to enter skin that the microneedle has penetrated. In embodiments wherein the microneedle includes at least one substantially
10 vertical wall, the depression 202 may be recessed into a substantially vertical wall. In the example embodiment, the maximum depth of the depression 202 may be about 130% to 110% of the distance from the back facing edge 23 to the flow lumen 126.

[00189] In certain examples, and referring now to FIG. 7A and FIG. 7B, a microneedle may include a sloped face 21 to which a lumen 126 extending through the
15 microneedle extends. A microneedle may also include a rounded blade edge 31. In the example, the rounded blade edge 31 extends from a point 33 opposite the distal side 15 and extends in an arcuate path to the vertex or tip 14 of the microneedle. In the example, the rounded blade edge 31 includes a double bevel, though other bevel types may be used. The rounded blade edge 31 may arc at a constant radius or a variable radius. The rounded blade
20 edge 31 may have an arc measure of less than 90° or, in certain examples, greater than 90° (see, e.g., FIG. 8A-8C). The rounded blade edge 31 may aid in introduction of a microneedle into skin when the microneedle is inserted at certain angles or over a variety of different angles.

[00190] In yet another embodiment, and referring now to FIGS. 8A-8C, a
25 microneedle may include a rounded blade edge 31 and a lumen outlet face 35. The lumen 126 may extend through the microneedle to the lumen outlet face 35 and may not be formed in a straight line through the microneedle. The lumen outlet face 35 may be angled from the vertex 14 to the distal side 15 so as to form an undercut. The distal edge 15 may be disposed such that a plane perpendicular to the base 17 passing through the distal edge 15 may also
30 pass through the rounded or arcuate blade edge 31. Additionally, the outlet of the flow lumen 126 in the lumen outlet face 35 may be disposed such that a plane or all planes perpendicular to the base 17 and passing through the outlet of the flow lumen 126 may also pass through the blade edge 31. This need not be true in all embodiments (see, e.g., FIGS. 7A-7B). As a microneedle of the variety shown in FIGS. 8A-8C is inserted, a vertical void

space may be created due to the undercut. This may provide a low resistance pathway for fluid injection. Additionally, the undercut may help to mitigate potential for the lumen 126 to become obstructed by skin as the microneedle is inserted into a patient or as the delivery occurs.

5 **[00191]** In still other embodiments and referring now to FIGS. 9A-9D, the delivery sharp(s) 72 may be or include a microneedle which has a shape with a high aspect ratio. In some embodiments, microneedles may be obelisk shaped. Such microneedles may be included in an array such as any array described herein. Where obelisk type microneedles are used, the microneedles may include a base 17'. The base 17' may be any desired round or polygonal shape. For purposes of example, FIGS. 9A-9D depict a base 17' which is a quadrilateral or rhombus. The example microneedle includes a set of sidewalls 19' which extend from the base 17' to an end region 25 of the microneedle. The sidewalls 19' may be disposed at an angle which is not perpendicular to the base 17'. Thus the microneedle may taper so as to have a smaller cross-sectional area as distance from the base 17' increases. A portion of the microneedle most distal to the base 17' may include a beveled tip 27. Such a tip 27 may facilitate puncture of the skin and may aid in increasing the robustness of the end region 25. Any suitable bevel such as a single or double bevel may be used.

10 **[00192]** In embodiments of microneedles which are obelisk shaped, the microneedles may include at least one side port 29 which may serve as an outlet for that microneedle. Such side port(s) 29 may be difficult to block off with tissue which that may become compressed during insertion of the microneedle into a patient. In the example embodiment, a lumen 126 may extend through the base 17' of the microneedle and have a terminal end which is more proximal the end region 15 than the base 17'. The lumen 126 may be of relatively constant cross-section. The taper of the sidewalls 19' may be such that the terminal end of the lumen 126 is wider than portions of the cross-section of the corresponding region of the microneedle. Thus, the lumen 126 may form openings in the sidewalls 19' which may serve as the side ports 29. In various examples, the lumen 126 may be centrally disposed yielding symmetrical side ports 29. In alternative embodiments, the lumen 126 need not be centrally disposed and the side ports 29 may not be symmetrical.

25 **[00193]** In various embodiments where silicon is not used to form the microneedles, microneedles described herein may be constructed of glass (e.g. silica glass, borosilicate glass), ceramic (e.g. alumina, calcium sulfate dehydrate, calcium phosphate dehydrate, organically modified ceramics such as Ormocer), polymer (e.g. polymethyl methacrylate or PMMA, polylactic acid or PLA, polylactic-co-glycolic acid or PLGA, polyglycolic acid or

PGA, polycarbonate, cyclic-olefin copolymer or COC, polyvinylpyrrolidone or PVP, polyvinyl alcohol PVA, polystyrene, polymethyl vinyl ether-co-maleic anhydride), carbohydrate, or metal (e.g. stainless steel, titanium, palladium, nickel, alloys such as palladium cobalt alloys, etc.). Any suitable microneedle constructions including dissolvable
5 microneedles may be used. Microneedles and features thereof may be manufactured in one or more of, though are not limited to, a molding process, etching process, ablative process (e.g. laser ablation), or a material additive process (e.g. 3D printed). In various embodiments, it may be desirable that microneedles be constructed of a biocompatible, non-ductile, high Young's modulus material with an indentation hardness sufficient to allow
10 penetration into skin without breakage.

[00194] Referring again primarily to FIGS. 1A and 1B, delivery devices 10 described herein may deliver any of a variety of medications or other medical agents to a patient. In certain embodiments, the reservoir 12 of the delivery device 10 may be filled with a vaccine. Such a delivery device 10 may deliver any suitable vaccine, though may be
15 particularly well suited to vaccines for novel pathogens (e.g. SARS-CoV-2) or for pathogens where herd immunity does not exist (e.g. Ebola). Additionally, such delivery devices 10 may be of particular usefulness in outbreaks of pathogens (such as measles for example) in communities which choose to forego typical vaccinations. For example, such delivery devices 10 could be distributed without requiring patients to congregate in
20 hospitals or other shared spaces. This would mitigate concern for pathogen transmission related to vaccination programs and alleviate potential worries that could dissuade people from reporting to receive a vaccination. Instead, delivery devices 10 could be picked up and used by patients without breach of social distancing, gathering size recommendations, or other safety guidelines. Alternatively, such delivery devices 10 could be distributed directly
25 to patients without requiring a patient to leave their domicile or requiring distribution personnel to interact with individuals who decline to utilize recommended PPE. Delivery devices 10 could be filled with a vaccine for a novel pathogen or could perhaps be filled with vaccines typical of a normal vaccination schedule. In the latter case, such a delivery device 10 could help to ensure that disruption of vaccination for known pathogens does not
30 occur during a novel pathogen pandemic.

[00195] Any suitable vaccine may be delivered via such a delivery device 10. For example, the vaccine may be but is not limited to, attenuated live vaccines, inactivated virus vaccines, acellular vaccines, cellular vaccines, toxoid vaccines, heterotypic or Jennerian vaccines, monovalent vaccines, polyvalent vaccines, nucleic acid vaccines (e.g. DNA,

plasmid vaccine, mRNA), virus like particle vaccines, recombinant vector vaccines (e.g. replicating, non-replicating), dendritic cell vaccines, T-cell receptor peptide vaccines, chimeric vaccines, subunit vaccines, nanoparticle vaccines, recombinant protein vaccines, polysaccharide vaccines, and conjugate vaccines. It should be noted that these are not necessarily mutually exclusive. For instance, a vaccine could be a recombinant protein nanoparticle vaccine or some other combination of the above. Vaccine may also refer to a combination vaccine (e.g. DTaP, MMR, MMRV, etc.) or a vaccination agent which targets a single pathogen or multiple strains of a single pathogen. Example vaccines may include, but are not limited to vaccines for various coronaviruses such as SARS-COV, SARS-COV-2, MERS-COV, HCoV-NL63, HCoV-229E, HCoV-OC43 and HKU1. Delivery devices 10 described herein are also not limited for use with humans. Such delivery devices 10 may be used for livestock, pets, services animals, or in other veterinary applications. In such cases, these delivery devices 10 may be filled with a vaccine for at least one non-human pathogen. Delivery devices 10 described herein may also be useful for research applications.

15 [00196] Where a delivery device 10 is filled with a vaccine, it may be desirable that the target delivery destination be a shallow delivery destination. This may be particularly desirable where the amount of available vaccine is limited. For example, such a delivery device 10 may be well suited for use with new vaccines having high demand. Vaccines for novel pathogens (e.g. SARS-CoV-2 or other coronaviruses) may, for instance, be well suited for use with delivery devices 10 described herein.

20 [00197] Evidence suggests that shallow delivery of vaccines may provoke protective immune response with smaller amounts of vaccine antigen. As a result, dose sparing may be practiced allowing the same quantity of vaccine to be effective for immunizing a greater number of people. Alternatively or additionally, injection sparing may be possible. Shallow administration with a delivery device 10 such as those shown herein may allow for a single injection protocol where other routes of administration may require multiple injections over some period of time. One or more adjuvants may be included in some vaccine formulations to further aid in facilitating dose or injection sparing, though less reliance on adjuvants could also be possible with when a vaccine is administered intradermally.

25 [00198] Particularly for new vaccines generated to combat an ongoing pandemic (e.g. a vaccine for SARS-CoV-2), the prospect of rapidly generating billions of doses would almost certainly exceed current vaccine production capabilities. Due to the injection and dose sparing potential of delivery devices 10 described herein, such delivery devices 10 may facilitate vaccination of large numbers of people even when a critically needed vaccine

is in short supply. Additionally, as a consequence of potential dose and injection sparing, delivery devices 10 such as those shown and described herein may allow injections to be more cost effective. Moreover, due to the small volume of vaccine needed, delivery devices 10 may be made relatively small. This may simplify shipping and help to facilitate rapid distribution of vaccine to a population. This may be particularly attractive for vaccines which require cold chain distribution as packing volume may be of heightened importance.

[00199] Additionally, some studies have suggested that shallow administration may be particularly helpful in certain patient populations. For example, elderly populations may receive superior protection from vaccinations received intradermally than via other routes. That said, the Mantoux technique, which is typically used for intradermal administration, can pose reliability concerns and can be difficult to perform, especially without training. Per the World Health Organization, a large factor which has limited the use of intradermal vaccination has been the lack of a delivery platform.

[00200] Delivery devices 10, such as those shown and described herein, may provide an attractive delivery platform for intradermal vaccination. Consequentially, delivery devices 10 described and shown herein may help to give better protection to vulnerable populations and may help in meeting the large demand for vaccines against, for example, novel pathogens by leveraging dose/injection sparing which may be possible with intradermal vaccination. Moreover, intradermal delivery devices 10 described herein may be painless or nearly pain free which may make the delivery devices 10 described herein user preferable over other types of injections. That said, and as mentioned above, delivery devices 10 described herein are not limited to delivery via the intradermal route. Delivery devices 10 may, for instance, be configured as transdermal (e.g. subcutaneous or intramuscular) delivery devices 10.

[00201] The example delivery devices 10 shown herein additionally are not limited to vaccine delivery devices. Such a delivery device 10 may fill a number of niches in the medical field. Other agents, for example, diagnostic or testing agents may be supplied via certain example delivery devices 10. For instance, allergens or potential allergens may be administered via the delivery device 10. Tuberculosis testing agents may be delivered via the delivery device 10. Such delivery devices 10 may also be used to deliver medication for endocrine disorders. For instance, insulin may be delivered with some exemplary delivery devices 10.

[00202] Still referring to FIGS. 1A-1B, the delivery device 10 may include a main body 20. The main body 20 may be a deformable body which may transition from a storage

state (see FIG. 1A) to a delivery state (see FIG. 1B). In certain examples, this transition may be reversible, though in other embodiments the transition may result in a permanent change in the main body 20 and/or another part of the delivery device 10. For example, once transitioned to the delivery state, the main body 20 may plastically deform such that it is permanently distorted and may not be returned to the storage state. In other examples, a frangible included in the delivery device 10 may be broken upon transition of the main body 20 to the delivery state. Alternatively or additionally, a latch, lock, or other coupling may be engaged to hold the main body 20 in the delivery state or prevent the main body 20 from returning to the storage state. Destruction of a portion of the main body 20 or a portion of the delivery device 10 engaged to the main body 20 may be required to disengage such a coupling and this destruction may render the delivery device 10 inoperative. Where a permanent change is engendered upon transition to the delivery state, this permanent change may inhibit reuse as well as provide a user perceptible (e.g. visual) indication that the delivery device 10 has been used. An indication that the transition has occurred may also be generated by the delivery device 10. For instance, an audible or tactile indication may be generated upon engagement of a latch or breaking of a frangible.

[00203] In various examples, transition of the delivery device 10 from the storage state to the delivery state may be accomplished via bending, pivoting, or deformation of one or more regions of the main body 20. In certain examples, the main body 20 may include one or more hinges (e.g. living hinge to aid in lowering part count) at which the main body 20 may bend. In other embodiments, the main body 20 may be or include a bi-stable element which may have a first stable state which corresponds to the storage state and a second stable state which corresponds to the delivery state. The main body 20 may for example substantially or partially invert (e.g. convex to concave) in shape or have one or more invertible regions which at least partially invert when the delivery device 10 is transitioned from the storage state to the delivery state. The transition may be affected via application of force throughout the entire transition. Alternatively, the transition may only require application of force throughout a portion of the transition. For example, in some embodiments a triggering force may be applied to initiate the transition and the transition may subsequently complete in the absence of any external application of force. For example, after application of the triggering force, the transition may be characterized by a snap-through buckling via which the main body 20 rapidly shifts into the delivery state.

[00204] The main body 20 may be at least partially covered with adhesive 22 over a first face 24 of the main body 20. The adhesive 22 may serve to couple the main body 20 to

a skin surface at an infusion or injection site on a patient. Thus, the first face 24 may be a skin adjacent face or proximal (proximal and distal defined in relation to a patient) face of the main body 20. The main body 20 may be adhered to the skin when the main body 20 is in the storage state and then may be transitioned to the delivery state. As the transition occurs, at least two adhesive bearing portions of the main body 20 may be displaced with respect to one another so as to stretch or spread a surface anchored to the main body 20 via the adhesive 22. As these portions may be adhered to the skin surface, the skin may be stretched as the adhesive bearing portions are displaced with respect to one another. This may be desirable as the skin may be rendered taught facilitating piercing of the skin by the delivery sharp(s) 72 as the main body 20 transitions to the delivery state. In certain examples, the adhesive bearing portions may be disposed, for example, in opposition to one another. The displacement of the two adhesive bearing portions may increase the distance between or spread apart the two adhesive bearing portions. In other embodiments, the distance between the two adhesive bearing portions may not increase or may even decrease while still causing stretching of the skin surface. This may for example occur if the transition causes a flat patch of skin to be pulled around a curve or contour of the main body 20 (see, e.g., FIGS. 17-18). A displacement of adhesive bearing portions with respect to one another that results stretching of the adhered skin (regardless of any positive or negative change in distance between the adhesive bearing portions) may be referred to as a spreading displacement. Two adhesive bearing portions which have been so displaced may be referred to as being spreadingly displaced.

[00205] Transition of the main body 20 to the delivery state may also result in a proximal displacement or lowering of the delivery sharp(s) 72 toward and into the skin. In embodiments where the delivery sharp(s) 72 are coupled to the reservoir 12, the reservoir 12 may also be proximally displaced. In some examples, the reservoir 12 may be compressed between the skin surface and a section of the main body 20 when the main body 20 is transitioned from the storage state to the delivery state. Preferably, the delivery sharp(s) 72 may be inserted into the skin prior to the reservoir 12 being substantially compressed. Compression of the reservoir 12 may serve to drive fluid out of the reservoir 12, through the delivery sharp(s) 72 and into the target delivery destination in the patient. In embodiments described herein, the delivery sharp(s) 72 may be covered prior to use. A fluid communication path from the reservoir 12 out of the delivery sharp(s) 72 may not be available prior to use.

- [00206] In some embodiments a collapsible pouch, or packet 208, may be positioned in the delivery device 10 above the reservoir 12 as shown in FIG. 10A. The packet 208 may contain a substance that, in a first condition is in a dormant state, and in a second condition transitions to a motive force applying state. In an embodiment the substance may be dormant at a first temperature and apply a motive force, e.g. upon the reservoir 12, at a second temperature. In an example embodiment, the first temperature may be colder than the second temperature. The first temperature may be a cold chain storage temperature for a vaccine. The second temperature may be room temperature or at least below average patient body temperature (e.g. 98.6°F for humans). In some embodiments, the substance may change in volume when it transitions from a dormant state to a motive force applying state. Alternatively or additionally, the substance may change from one state of matter to another state of matter when it transitions from a dormant state to a motive force applying state. In an example embodiment, the substance may change from a liquid to a gas during the transition from a dormant state to a motive force applying state.
- 15 [00207] In an embodiment where the medical agent in a reservoir 12 of a delivery device 10 must be stored at very low temperatures, such as, e.g., when the medical agent is a vaccine with such requirements, the packet 208 can contain a liquid. For example, a vaccine may be stored and/or shipped at commercial freezer temperatures, e.g., in the range of -18 degrees C (or lower, e.g. -70°C or -20°C for certain vaccines). The liquid may have a boiling point that is greater than the medical agent (e.g., vaccine) storage temperature but less than room temperature or another suitable temperature set point. Though any suitable liquid may be used, one example of a suitable liquid is butane. Butane has a boiling point of -1°C. Though the example described herein refers to butane, one skilled in the art would appreciate the description is generalizable to any suitable liquid.
- 20 [00208] The delivery device 10 may be affixed to the skin surface of a user with the reservoir 12 containing cold stored/shipped vaccine and the packet 208 containing liquid butane (or any other suitable substance). If the ambient temperature is room temperature, e.g., about 20 degrees C, the contents will warm up (heat from the patient may aid this). The liquid butane will boil and transition to gas once it reaches its boiling point of -1°C in the example embodiment. As the liquid boils and transitions to a gaseous state, the pressure in the packet 208 grows, causing it to expand and apply downward pressure on the reservoir 12 from above as shown in FIG. 10B. Butane gas, for instance, has a vapor pressure of 35.4 psi at 25°C. Accordingly, a final pressure on the reservoir 12 may be higher (e.g. around 38 psi) due to heat transfer from the patient to the packet 208. The main body 20 of the
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delivery device 10 may be sufficiently resilient to not deform under the pressure applied from the packet 208. This may aid in directing pressure against the reservoir 12.

[00209] Such an arrangement may also serve to provide visible evidence of whether the delivery device 10 had reached a temperature during storage or shipping that was too high for the medical agent. For example, if a temperature that was beyond the phase change temperature of the packet 208 contents was reached during storage, the delivery device 10 would be emptied due to the pressure applied from above by the packet 208. This may be visibly perceptible to a user. The delivery device 10 would also self-destruct when subjected to certain temperature abuse scenarios. In the event that the delivery device 10 was subjected to a temperature above the phase change temperature of the packet 208 contents, the delivery device 10 would be emptied. As a result, the delivery device 10 would prevent itself from later administering a temperature abused medical agent.

[00210] In some embodiments significant downward pressure on the reservoir 12, e.g., greater than 50 psi, may be desired to provide force to collapse the reservoir 12 and force fluid therein into the skin of a user via delivery sharps 72 as described above with reference to FIGS. 1A and 1B. In such embodiments the packet 208 may be incorporated within a squeezable container 350 as shown in FIG. 11. The container 350 may be made of a squeezable plastic or any other suitable material as would be understood by those of skill. The container 350 may be formed by injection molding, thermoforming, or any other technique known to those of skill. In addition to housing the packet 208, a first substance may be stored within the container 350. The packet 208 may hold a second substance. The first and second substances may be components of, for example, an expanding foam. The first and second substances may be selected such that they expand to create pressure when they come into contact with each other. A chemical reaction (e.g. baking soda and vinegar) which generates gas could for example be used. Upon applying the delivery device 10 to the skin surface, a user may, e.g. pinch, crush, smoosh, or squeeze the container 350. This may cause the packet 208 therein to rupture and thereby allow the first and second substances to interact and cause downward pressure on the reservoir 12 below.

[00211] In still other embodiments, the packet 208 could be a vacuum packed bias member (e.g. foam spring). In the vacuum packed state, the bias member may be in a compressed state. User interaction with the packet 208 may cause the packet 208 to break allowing the bias member to restore. As the bias member restores, pressure may be applied to the reservoir 12 to generate pressure for delivery.

[00212] In alternative embodiments, a packet 208 of FIG. 10A or FIG. 10B may be filled with contents which do not change phase when removed from cold storage. For example, the packet 208 may be a gas bladder that may serve to prevent pressure from a user's finger applied to the top of the delivery device 10 from being applied directly to the reservoir 12. Such a gas bladder may also help to make applied pressure more uniform across the reservoir 12. An example of a suitable gas which may be used to fill such a packet 208 may be nitrogen. Any other suitable gas may be used.

[00213] In other embodiments, the packet 208 may be or include a bias member. In some embodiments, the packet 208 may be a foam adhesive material sitting atop the reservoir 12. In such examples, when a user pushes down on the delivery device 10 (once the delivery device 10 is affixed to the skin surface), the foam adhesive may function like a spring that helps limit maximum pressure applied to the reservoir 12. The foam adhesive may also facilitate even distribution of pressure across the top of the reservoir 12. Assembly of the components described in connection with the above embodiments is described below with reference to FIGS. 47-61B and FIGS. 12-27B.

[00214] Referring now to FIGS. 12-14, an exemplary delivery device 10 is depicted. The example delivery device 10 is shown in a storage state in FIGS. 12-14. As shown, the delivery device 10 may include a main body 20 and a reservoir 12. The reservoir 12 may include at least one delivery sharp 72. The delivery sharp 72 may be included on a sharp bearing body 26 which may be coupled to a wall of the reservoir 12. The main body 20 of the example delivery device 10 may have a round (e.g. circular) foot print and may include a central region 28 and a peripheral region 30. The central region 28 may be a raised region of the main body 20 and the peripheral region 30 may be a substantially flat region of the main body 20 which surrounds the central region 28. The thickness of the main body 20 may be substantially uniform over the entirety of the main body 20. The main body 20 may be formed as a thin sheet or disc of material which may be thermoformed to create the raised central region 28 and flat peripheral region 30.

[00215] Alternatively, the main body 20 may be injection molded and the raised central region 28 and flat peripheral region 30 may be formed in the molding operation. In various embodiments where delivery devices 10 are or may be injection molded (e.g. the embodiments described in relation to FIGS. 12-33) the main body 20 may be injection molded so as to be in the storage state or in the delivery state. The main body 20 may transition more easily into the state in which it was molded from the opposite state. Thus, to lower the effort needed to transition a delivery device 10 from a storage state to a delivery

state, it may be desirable to mold the main body 20 of the delivery device 10 in its delivery state configuration. During assembly of a delivery device 10, the main body 20 may be brought into its storage state configuration and remain in that configuration until use.

[00216] The central region 28 may be domed and the domed shape may establish a
5 receptacle 32 on the proximal side of the main body 20 within which the reservoir 12 may be disposed. The reservoir 12 may be coupled within the receptacle 32 via adhesive or in another suitable manner. The central region 28 may also include a series of fenestrations 34 which may form a fenestrated ring in the central region 28. In the example, the fenestrations 34 are evenly spaced from one another and arranged in a circle which is generally coaxial
10 with the center of the central region 28. In alternative embodiments, fenestrations 34 may be irregularly spaced or omitted. Additionally, in some embodiments, the fenestrations 34 may instead be replaced with thinned regions or a ring where the material of the main body 20 is thinned.

[00217] The main body 20 may include a number of slots 36. The slots 36 may
15 extend from a peripheral edge 38 of the main body 20 toward a center or midpoint of the main body 20. In the example embodiment, the slots 36 extend in a radial direction. The slots 36 may extend through the entirety of the peripheral region 30. In some embodiments, and as shown, the slots 36 may additionally extend though at least a portion of the central region 28 as well. The fenestrations 34 in the central region 28 may be disposed radially
20 inward of the terminus 40 of each of the slots 36. The main body 20 may thus include a central region 28 which is circumscribed by a number of petal members 42 which are spaced apart via the slots 36.

[00218] Referring now to FIG. 15, a plan view of the proximal face 24 of the main
body 20 is depicted. As shown, adhesive 22 may be included on at least a portion of the
25 proximal face 24. The adhesive 22 may be a skin compatible adhesive and may serve to couple a delivery device 10 to a skin surface at an infusion site. In the example embodiments, adhesive 22 may be included on the peripheral region 30 of the main body 20. Though adhesive 22 is shown covering the entire surface of each of the petal members 42 in the peripheral region 30, other embodiments may differ. For example, only certain
30 petal members 42 may include the adhesive 22. In such embodiments, adhesive 22 may be included on at least one pair of oppositely disposed (e.g. diametrically opposed in the example embodiment) petal members 42. Only a portion (e.g. a majority of the surface area) of each petal member 42 included in the peripheral region 30 may be covered with adhesive 22 in some examples. Alternatively or additionally, the adhesive 22 may differ from petal

member 42 to petal member 42. Certain petal members 42 may be covered with a more aggressive adhesive 22 while other petal members 42 may be covered with a less aggressive adhesive 22. In certain examples, the entirety of the proximal surface 24 may be covered in adhesive 22. Additional adhesive members 22 are described elsewhere herein (see, e.g.,
5 FIG. 63A-C) and may be used on a delivery device 10.

[00219] Referring now to FIG. 16, a conceptual representation of a main body 20 of a delivery device 10 is depicted in a delivery state. In the delivery state, at least the central region 28 of the main body 20 may substantially invert. The fenestrations 34 may facilitate this inversion by helping to allow for increased deflection of the main body 20 at the
10 fenestrations 24. Thus, in place of a convex dome-like shape, the center region 28 of the main body 20 may take on a concave shape. As the peripheral region 30 is coupled to the center region 28, the peripheral region 30 may displace as a result of the inverting of the center region 28. In the example embodiment, the entire main body 20 takes on a bowl shape when transitioned to the delivery state. The peripheral region 30 may also spreadingly
15 displace for at least a portion of the transition. The slots 36 in the main body 20 may help to facilitate spreading displacement of the petal members 42 as the transition takes place, thereby enhancing stretching of the skin of user.

[00220] The main body 20 may be a bi-stable element or include at least one bi-stable region which may be stable in both the storage state and the delivery state. When an axial
20 load is applied on the central region 28 and the main body 20 is in the storage state, the main body 20 may deform into an unstable state. The main body 20 may then exhibit a snap through buckling action which rapidly shifts the main body 20 into the stable delivery state similar to that shown in FIG. 16. Thus, only a triggering force may be applied to initiate the transition. The rest of the shift between the storage and delivery state may be caused by the
25 snap through phenomenon.

[00221] FIG. 17 depicts a delivery device 10 in a storage state and adhered to skin 44 via adhesive 22 on a proximal face 24 of the main body 20. FIG. 18 is a conceptual representation depicting a delivery device 10 in the delivery state. As shown, the delivery device 10 may be applied to the skin 44 in the storage state. The delivery device 10 may
30 then be transitioned to the delivery state. A spreading displacement of opposed petal members 42 of the main body 20 may occur as the transition transpires.

[00222] Two opposing points 46A, B disposed at the peripheral edge of the proximal surface 24 are shown in FIGS. 17 and 18. When the delivery device 10 is in the storage state (FIG. 17), the shortest distance between the opposing points 46A, B is a straight line which

does not pass through the proximal surface 24. This straight line is roughly parallel to the surface of the skin 44. In the delivery state, however, the shortest distance between the opposing points 46A, B is a straight line which passes through the proximal surface 24. As the skin 44 is fixed to the main body 20 via the adhesive 22 and cannot pass through the main body 20, the skin 44 may be forced to conform to the curvature of the proximal surface 24. Thus, the length of the skin 44 surface between the two points 46A, B when the delivery device 10 is in the delivery state may be greater than the length of the skin 44 surface between the points 46A, B when the delivery device 10 is in the storage state. The skin 44 may be placed under tension and stretched to accommodate this change in length. This stretching may, in turn, aid in facilitating puncture of the skin 44 by the delivery sharp(s) 72.

[00223] Due to the elasticity of the skin 44, the skin 44 may exert a restoring force against the proximal surface 24 of the main body 20 as it attempts to revert to an unstretched state. The main body 20 may resist this restoring force and retain its bowl shape. The reservoir 12, however, may be compressed between the skin 44 and the main body 20. This may aid in ensuring the delivery sharp(s) 72 puncture the skin 44 and enter fluid communication with a target delivery destination in the patient. Additionally, since the reservoir 12 may be collapsible, the restoring force exerted by the skin 44 may pressurize the reservoir 12 and urge fluid to pass out of the reservoir 12 via the delivery sharp(s) 72. Thus, the restoring force exerted by the stretched skin 44 may serve to empty and collapse the reservoir 12.

[00224] As mentioned above, in certain examples, some petal members 42 may not include adhesive 22 regions or may have a proximal surface 24 which is at least partially covered in adhesive 22 that is less aggressive than adhesive 22 of on other petal members 42. In embodiments where some petal members 42 are devoid of adhesive 22, this may help to limit stretching of the skin 44. Likewise, petal members 42 with less aggressive adhesive 22 may release the patches of skin 44 to which they are affixed if force needed to stretch the skin 44 exceeds a threshold. The petal members 42 themselves may also be constructed such that at least one of the petal members 42 includes a relief region (e.g. a thin or narrow region). For example, if force needed to stretch the skin 44 is above a threshold, one or more of the petal members 42 may bend or buckle at the relief region to relieve some of the tension on the skin 44.

[00225] This may be desirable as it may help to mitigate potential discomfort during an injection due to excessive tensioning of the skin 44. Additionally, this may be helpful in

certain patient populations as skin characteristics vary significantly with age, hydration state, lifestyle (sun exposure, nutrition), etc. It may be desirable that slacker or looser skin be stretched to a greater degree than highly elastic skin. Thus, instead of providing a variety of delivery devices 10 with different adhesives 22 targeted at specified patient populations, a delivery device 10 may be made in a more universal manner.

[00226] With reference to FIGS. 19 and 20, in another embodiment, a delivery device 10 may include a central region 28 having a top surface 250 and a supporting structure 252 integral with the top surface 250. The supporting structure 252 may have a round, e.g., substantially circular, base 262. The peripheral region 30 may be roughly annular shaped and may include an inner perimeter coincident with the base 262 and an outer perimeter, or peripheral edge 38. The delivery device 10 may be constructed of a nylon material such as Nycoa 2012 nylon or other, similar nylon materials, and may be formed by injection molding. Any other suitable plastic may be used. The top surface 250 may have a round footprint, e.g., of roughly circular shape, and may be convex, forming a dome shape. The top surface 250 may have a periphery 340. The top surface 250 may include slots 254. The slots 254 may be cutouts, apertures, holes, openings, or voids in various embodiments. The slots 254 may help the delivery device 10 to transition from the storage state to the delivery state with reduced pressure from above. The slots 254 may extend radially with respect to a center point 256 of the top surface 250 such that their respective first endpoints 258 surround a region including the center point 256 of the top surface 250 and their respective second endpoints 260 may each terminate a distance (e.g., the slots 254 may each terminate the same distance) from the periphery 340 of the top surface 250. In embodiments including slots 254, the slots 254 may be disposed at regular angular increments (though need not be). In embodiments described herein including slots 254, the slots 254 may (though need not necessarily be) each be of the same length.

[00227] Referring now to FIGS. 21A-21I, a variety of different main body 20 embodiments are depicted. The exemplary main bodies 20 are shown in a flat state and may be thermoformed into a configuration such as that shown in, for example FIG. 19. Though thermoformable main bodies 20 are depicted, the features described in relation to thermoformed main bodies 20 may be included in main bodies 20 which are manufactured in any desired manner. As shown in FIGS. 21A-21I, the slots 254 may be provided in a number of different formats. Additionally, in some embodiments, slots 254 may not be included.

[00228] In some embodiments, and as also shown in FIG. 22, the slots 254 could be disposed such that they do not extend radially with respect to the center point 256. For example, the slots 254 may each extend at a common angle with respect to a radial direction. In such embodiments, slots 254 may be evenly spaced about the top surface 250 and may each be of the same length. In other embodiments, the slots 254 may not all extend at a common angle to the radial direction. At least one of the slots 254 (and perhaps all) may be disposed at a different angle to the radial direction. In some embodiments, the slots 254 may be relatively short, positioned about the periphery 340 of the top surface 250, and may be disposed within an outer region of the top surface 250 (see, e.g., FIG. 21A). In other embodiments, slots 254 may extend across an outer region and intermediate region of the top surface 250 (see, e.g., FIG. 21B). In still other embodiments, slots 254 may extend from the outer region of the top surface and into a center region of the top surface 250 (see, e.g., FIG. 21C). The angled slots 254 may aid in lowering the amount of pressure needed to transition the delivery device 10 from a storage state to a delivery state. Positioning the slots 254 at a sharper angle with respect to the radial direction may generally lower this pressure. The width of the slots 254 may slightly decrease during at least a portion of the transition from the storage state to the delivery state.

[00229] In other embodiments, and referring primarily to FIG. 21E, at least one of the slots 254 may have a curvature. The curvature may be defined by a constant or variable radius. The curvature may only be present over a segment of the slot 254. In alternative embodiments, a slot 254 may include two or more sections which are angled with respect to one another. In the example embodiment shown in FIG. 21E, four curved slots 254 are shown and are spaced apart at even angular increments. The slots 254 are arcuate and include a first end 258 and second end 260. Each example slot 254 is oriented so as to initially begin extending in a first direction from the first end 258 and curve so as to extend in a second direction as the slot 254 reaches the second end 260. The second direction may be closer to perpendicular (or may be perpendicular) to the radial direction than the first direction.

[00230] In some examples, and referring now primarily to FIG. 21D and 21F, the top surface may not include a slot 254 or slots 254 but may instead include at least one aperture 255. In the examples shown, the aperture 255 is disposed centrally within the top surface 250. The aperture 255 may extend over a minority or a majority of the top surface 250. In some embodiments, the aperture 255 may encompass nearly the entirety of the top surface 250.

[00231] As shown exemplarily in FIGS. 21D and 21F, slots 254 may also be included in other regions of a main body 20. In the example embodiment, the region of the main body 20 which would become the supporting structure 252 (when the main body 20 is thermoformed) includes slots 254. These slots 254 may be straight, curved, angled (with respect to the radial dimension) or some mix thereof as with various top surface 250 slot 254 patterns described herein. As shown, the slots 254 are spaced at regular angular intervals and are spaced between petal members 42 of the main bodies 20.

[00232] In still other embodiments, the width of one or more of the slots 254 may vary over the length of that slot 254. A number of embodiments including variable width slots 254 are depicted in FIGS. 21G-21I. The slots 254 may change in width in a continuous manner and may terminate with a pointed first or second end 258, 260. Variable width slots 254 may extend along a radial direction, though need not necessarily do so in all embodiments. In the example embodiments, each of the slots 254 are widest proximal to the center point 256 of the top surface 250 and continuously decrease in width as the slot 254 extend distally toward the periphery 340 of the top surface 250. Thus, each of the top surfaces 250 depicted in FIGS. 21G-21I have a sunburst type pattern of slots 254. In other embodiments, the slots 254 need not necessarily continuously increase or decrease in width from one end to the other.

[00233] Still referring to FIG. 22, the central region 28 may be monolithically formed with the petal members 42 comprising the regions between respective pairs of slots 36 (see also FIGS. 12-18 and the examples and embodiments described above with respect thereto). The supporting structure 252 may extend upward from the petal members 42 at a 90° angle or an angle greater than 90 degrees, e.g., 100-105 degrees, although the angle measure need not be limited to a range. The distance (vertically) from the base 262 of the supporting structure 252 to the periphery 340 of the top surface 250 may be long enough to provide a receptacle in the central region 28 for a reservoir 12 (see, e.g., FIG. 60) and, in some embodiments, any packets 208 and/or containers 350 (see, e.g., FIGS. 10A-11), springs, or foam adhesive material. The receptacle may also be sized to house portions of an actuation assembly or dispensing assembly 480 (see, e.g., FIG. 34). As described in greater detail elsewhere herein, packets 208 may include gas bladders, butane packets, or delivery force supplying packets and any associated containers 350 such those described above with respect to FIGS. 10A-11. In some embodiments the aforementioned distance may be approximately 0.3 inches (e.g. 0.315in). The slots 36 may extend from the peripheral edge 38 of the delivery device 10 to the base 262 of the supporting structure 252, but may

terminate at the base 262 and not extend into the supporting structure 252 itself. In such embodiments, rather than the entire central region 28 substantially inverting when pressure is applied from the top (e.g., by a finger), only the top surface 250 may invert, taking on a concave shape in the delivery state. The supporting structure 252 may in some embodiments include fenestrations 264 evenly spaced about the base 262. The fenestrations 264 may facilitate manufacturing of the delivery device 10 in embodiments in which the main body 20 is thermoformed.

[00234] In some embodiments and as shown in one example in FIG. 23, at least one of the petal members 42 may be made of an extended length such that an outward end of the petal member 42 may be operated by a patient or health care provider as a pull tab 266. The pull tab 266 may be grasped by a user to remove the delivery device 10 from the skin after use. The pull tab 266 may be of any suitable shape. In an example, the pull tab 266 is approximately semicircular in shape, with a first, rounded end and a second end opposite the first end, attached to a petal member 42. The second end may be attached or formed integral with the petal member 42 by injection molding or any other known technique that permits the pull tab 266 to be lifted sufficiently from the skin surface to be held by a user.

[00235] Referring now to FIG. 24, the pull tab 266 may also serve to facilitate a user peeling off a release liner 265 from the bottom of the delivery device 10 before the delivery device 10 is applied to the skin surface via an adhesive 22. A release liner 265 may be removed in a manner similar to how a release liner is peeled from a bandage before application to skin. An example delivery device 10 having a pull tab 266 and including release liner 265 and adhesive 22 is depicted in FIG. 24. The release liner 265 is exploded away from the adhesive 22 for illustrative purposes.

[00236] With reference to FIGS. 25-26 and FIGS. 28A-28B, in some embodiments, delivery devices 10 may include a central region 28 which is roughly thimble, or dome, shaped but has a relatively shorter height compared to certain other embodiments described herein. The distance (vertically) from the base 262 to the periphery 340 of the top surface 250 may be relatively shorter. In some embodiments, the aforementioned distance may be approximately 0.15 inches.

[00237] Additionally or in the alternative, the peripheral region 30 may not be a substantially flat annular shape. The peripheral region 30 may be defined by curved petal members 42 that continue in a downward direction such that their peripheral edge 38 is spaced from the plane of the base 262 of the supporting structure 252 (e.g. about the same or less than the distance from the base 262 to the periphery 340 of the top surface 250). The

peripheral edge 38 may be disposed along a plane which is more distal to the periphery 340 of the top surface 250 than the base 262. As depicted in FIG. 25, the delivery device 10 is shown in the storage state. The delivery device 10 may include slots 36 which may be disposed between the petal members 42 like other delivery device 10 embodiments described herein. An adhesive 22 (see, e.g., FIG. 24) may be affixed to at least a part of at least two of the petal members 42.

[00238] As best shown in FIG. 26, a perspective cross-sectional view of a main body 20 of a delivery device 10, the main body 20 may include an interior ridge 290. The ridge 290 may be disposed at the base 262 of the supporting structure 252. The supporting structure 252 may be thickened in a region near the base 262 so as to create the ridge 290. This may allow for the ridge 290 to be formed easily in, for example, an injection molding operation which forms the rest of a main body 20. This may also provide extra rigidity to the supporting structure 252. The ridge 290 may provide a step, ledge, or other mounting surface upon which a portion of a reservoir assembly 12 of a delivery device 10 may be mounted. Such a ridge 290 may be included in any of the delivery device embodiments described herein. Reservoir assemblies 12 and ridges 290 are further described elsewhere in the specification.

[00239] Referring now primarily to FIGS. 28A-28B, two conceptual representations of a delivery device 10 transitioning from a storage state to a delivery state are shown. When the delivery device 10 is affixed to the skin with an adhesive 22 and pressure is applied to the delivery device 10 from above, e.g., by a user's fingertip, the delivery device 10 may transition to a delivery state. When the petal members 42 are pushed against the surface of the skin, the petal members 42 may spreadingly displace outward and the skin and/or patient's body may force at least a portion of the petal members 42 to curl upward. In turn, this may cause the skin to stretch as parts of opposing petal members 42, each affixed to the skin surface by adhesive 22 (only shown in FIG. 28A), move apart from one another or spreadingly displace. As the delivery device 10 transitions to a delivery state, at least a portion of each of the curved petal members 42 may curve further or with a tighter radius of curvature. When a delivery state is reached, the curvature of the petal members 42 may be such that they may extend from the base 262 to an inflection point 360. The inflection point 360 may fall in a plane spaced from that of the base 262 and in such embodiments may also be referred to as a lowest point. In such embodiments, the lowest point 360 may be in a plane more distal to the periphery 340 of the top surface 250 than the base 262. From the inflection point 360, the petal members 42 may curve back upward so as to become

increasingly more proximal to the plane in which the periphery 340 of the top surface 250 is disposed. The peripheral edge 38 of the petal members 42 may, for example, be disposed at a point at or above (more proximal the plane of the periphery 340 of the top surface 250) the plane of the base 262. The petal members 42 may, though need not necessarily, each have a
5 constant radius of curvature from the inflection point 360 to the peripheral edge 38. The constant radii curvature back upward may enhance capability of the petal members 42 to curl upward. This may in turn enhance stretching of the skin of the user as points 360 on opposing petal members 42 (each affixed to the skin by adhesive 22) spreadingly displace. As mentioned elsewhere herein, the top surface 250 of the main body 20 may also invert as
10 the delivery device 10 is transitioned to the delivery state 10.

[00240] In some non-limiting examples, a delivery device 10 may have dimensions and radii of curvature as shown in FIGS. 27A-27B when in a storage state. It is to be understood that the dimensions shown are merely exemplary. Other delivery devices 10 of different size and having the same proportions are possible and contemplated. Additionally,
15 delivery devices 10 with different dimensions and proportions are possible and contemplated.

[00241] Referring to FIGS. 25-26 and FIGS. 28A-28B, in some embodiments, the supporting structure 252 may not include fenestrations 264 (see, e.g. FIG. 19) evenly spaced around the base 262. The main body 20 may be manufactured by injection molding. Those
20 of skill would readily appreciate that other manufacturing techniques could be used. The main body 20 may be constructed of one monolithic piece of material such that the central region 28 and peripheral region 30 are integral with respect to each other. The main body 20 may be constructed of a polymer material. In some embodiments, the main body 20 may be a nylon material such as Nycoa 2012 nylon or other, similar nylon materials. In other
25 embodiments the main body 20 may be made of a polypropylene material. The main body 20 may be manufactured of a material that serves to minimize water absorption, or a material that serves to maximize capacity to stick to an adhesive 22. A material that achieves both of these objectives to any desired degree for each may be selected. These materials may be used for any of the main bodies 20 described herein.

[00242] Still referring to FIGS. 25-26 and FIGS. 28A-28B, the top surface 250 may have a round footprint, e.g., be of roughly circular shape, and may be convex, forming a dome shape (including the periphery 340). The top surface 250 may include slots 254. The slots 254 may be cutouts, apertures, holes, openings, or voids in various embodiments. The slots 254 may extend radially with respect to a center point 256 of the top surface 250 such
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that their respective first endpoints 258 surround a region including the center point 256 of the top surface 250 and their respective second endpoints 260 may each terminate a distance (e.g., the slots 254 may each terminate the same distance) from the periphery 340 of the top surface 250. In certain embodiments, the slots 254 may be disposed at regular angular
5 increments and each be of equal length (though this need not be true to all embodiments).

[00243] Still referring to FIGS. 25-26 and FIGS. 28A-28B and as described above with reference to FIG. 22, the slots 254 could, in an alternative embodiment, be disposed such that they do not extend radially with respect to the center point 256. For example, the slots 254 may each extend at a common angle with respect to the radial direction. In such
10 embodiments, slots 254 may be evenly spaced about the top surface 250 and may each be of the same length. In other embodiments, the slots 254 may not all extend at a common angle to the radial direction. At least one of the slots 254 (and perhaps all) may be disposed at a different angle to the radial direction.

[00244] Referring now primarily to FIGS. 29-33, a number of views of a conceptual
15 representation of a delivery device 10 in a delivery state are shown. As described above (and also with reference to the embodiments of FIGS. 12-20), the delivery device 10 may, upon downward pressure being applied to the top surface 250, transition from a storage state to a delivery state in which the main body 20 of the delivery device 10 is substantially, or at least partially, inverted. A user may remove an adhesive liner 265 (see, e.g., FIG. 24)
20 from the delivery device 10 and apply the delivery device 10 to the skin. The user may then press downward (i.e., toward the skin) on the top surface 250. This may cause the petal members 42 to spreadingly displace outward and curl upward (over at least a portion thereof), stretching the skin. The top surface 250 may invert, driving delivery sharp(s) 72 into the skin, and remain inverted when the delivery device 10 attains the delivery state. The
25 peripheral region 20 may also take on an inverted shape due to the curling of the petal members 42.

[00245] In various embodiments, certain regions of the main body 20 of the delivery device 10 may remain static or may not invert. Thus, a main body 20 may include inverting regions and resilient regions. Though described as resilient regions, it is to be understood
30 that some bending or deformation may still occur as pressure is applied. These regions may, however, appear generally similar or extend/project in the general same direction in both the storage and delivery state. As shown, the peripheral region 30 and top surface 250 may invert, but a portion of the central region 28 may resist deformation to this degree. The supporting structures 252 shown in other embodiments described herein (see, e.g., FIG. 19

or FIG. 25) may also be a resilient region. Thus, certain delivery devices 10 may include a main body 20 with invertible regions which are separated from one another by a resilient region.

[00246] Still referring to FIGS. 29-33, the reservoir 12 may be formed as an assembly and may include a reservoir portion 271 and a holder 270 (described in greater detail below with reference to FIGS. 47-61B). A reservoir 12 may be compressed and/or at least partially collapsed so as to deliver a medical agent contained therein when the delivery device 10 is transitioned to the delivery state. The user may then remove the delivery device 10 from the skin. The slots 254 may aid the delivery device 10 to transition from the storage state to the delivery state with reduced pressure from above. The fenestrations 34 may also facilitate the transition. As described above with reference to the embodiments of FIGS. 12-20, there may be room in the central region 28 for a reservoir 12 and sharp bearing body 26 (see additional description with reference to the embodiments of FIGS. 12-20 and FIGS. 47-61B). In some embodiments, packets 208 and/or containers 350 (see, e.g., FIGS. 10A-11) and/or foam adhesive material may also be housed within the central region 28. As described in greater detail elsewhere herein, packets 208 may include gas bladders, butane packets, or delivery force supplying packets and any associated containers 350 such as those described above with respect to FIGS. 10A-11. In some examples, one or more petal members 42 may be constructed to incorporate a pull tab (not shown in FIGS. 29-33) such as the pull tab 266 described above with reference to FIG. 23.

[00247] Referring now to FIG. 34, a block diagram of an exemplary delivery device 10 is depicted. As shown, the delivery device 10 may include a main body 20 and a reservoir 12. The delivery device 10 may also include one or more bias member 470. The one or more bias member 470 may be included as part of a dispensing assembly 480 included in a delivery device 10. The dispensing assembly 480 may aid in applying pressure to the reservoir 12 and aid in expelling fluid from the reservoir 12 over the course of the injection. In some embodiments, the dispensing assembly 480 may include a depressor body 472 which may be coupled to or associated with the at least one bias member 470. The depressor body 472 may include or be coupled to (perhaps indirectly via the bias member 470) a reservoir interface member 474 which may also form part of a dispensing assembly 480 of a delivery device 10.

[00248] In some such embodiments, the bias member 470 may be in an unstressed state when the associated delivery device 10 is in a storage state. User interaction with the delivery device 10 to transition the delivery device 10 to a delivery state may involve

applying pressure to the depressor body 472 of the dispensing assembly 480. This may displace the depressor body 472 in the direction of the reservoir 12. The depressor body 472 may include an engagement feature (e.g. catch or detent) which may engage with a retention feature of the delivery device 10 (e.g. one defined in the main body 20) to hold the
5 depressor body 472 in the displaced position. Displacement of the depressor body 472 may in turn cause a bias to be stored in the bias member 470. With the delivery device 10 transitioned to the delivery state, the bias member 470 may restore to an unstressed state. As the bias member 470 restores, the reservoir interface member 474 of the dispensing assembly 480 may be urged against the reservoir 12 to collapse the reservoir 12 and drive
10 fluid into a patient. Thus without, for example, sustained manual pressure against the delivery device 10, pressure may be applied to the reservoir 12 over a period of time sufficient to fully deliver contents of the reservoir 12 (e.g. 5 minutes in certain embodiments).

[00249] In other embodiments, the bias member 470 may be in a stressed state when
15 the associated delivery device 10 is in a storage state and may be coupled to or associated with the depressor body 472 of the dispensing assembly 480. The depressor body 472 may interface with a portion of the delivery device 10 (e.g. the main body 20) so as to resist displacement under the restoring force exerted by the bias member 470. This may prevent the bias member 470 from restoring from its stressed state. A catch or detent in the
20 depressor body 472 may, for instance, be in engagement with the main body 20 when the delivery device 10 is in a storage state. User interaction with the delivery device 10 to transition the delivery device 10 to a delivery state may disengage the depressor body 472 such that the depressor body 472 is free to displace. Once the depressor body 472 is free to displace, the bias member 470 may restore to an unstressed or at least less stressed state and
25 drive the reservoir interface member 474 of the dispensing assembly 480 against the reservoir 12. Over a period of time, this may cause the reservoir 12 to collapse such that fluid is driven out of the reservoir 12 and into a patient.

[00250] Referring now to FIG. 35-36, a representational example of a delivery device 10 which includes a bias member 470 that is unstressed in the storage state is depicted. The
30 delivery device 10 may include a main body 20 and a reservoir 12 as with various other delivery devices 10 described above. As shown, the depressor body 472 of the dispensing assembly 480 may include an elongate member 476 such as a pin which may extend through the top surface 250 of the main body 20. In some embodiments, the elongate member 476 may include a head 478 or other surface at a distal end of the elongate member

476. The head 478 may include a rounded or tapered portion to aid in passing the head 478 through an aperture in the main body 20 during assembly. Opposite the tapered or rounded portion, the head 478 may define a step or ledge. The ledge of the head 478 may limit displacement of the elongate body 476 as the ledge may be unable to easily pass back through the aperture in the main body 20. An end of the elongate member 476 opposite the head 478 may couple to one or more bias member 470. The reservoir interface member 474 may be coupled to the one or more bias member 470 such that the one or more bias member 470 is disposed intermediate the elongate member 476 and the reservoir interface member 474. In the example embodiment, the one or more bias member 470 is depicted as a set of bow springs though any suitable number of bow springs may be used. In alternative embodiments, other bias members 470 may be used (e.g. resilient foam, coil spring, air bladder, etc.).

[00251] As pressure is applied to transition the delivery device 10 to the delivery state, the elongate body 476 may displace toward the reservoir 12. This may cause the bias members 470 to become stressed. As shown, the elongate body 476 includes a detent or notch 482. The notch 482 may engage with the main body 20 to hold the elongate body 476 in a depressed state. Engagement of the notch 482 with the main body 20 may also serve to indicate a delivery device 10 has been used.

[00252] With the elongate body 476 held in place, restoration of the bias members 470 to a less stressed state may drive displacement of the reservoir interface member 474 into the reservoir 12. As mentioned above, this may drive reservoir 12 contents out of the reservoir 12 and into the patient. It should be noted that, in various examples, at least some portion(s) of the main body 20 may spreadingly displace and/or invert as the delivery device 10 is transitioned to the delivery state (see, e.g., FIG. 29). This is not depicted in FIGS. 35-36 for ease of illustration.

[00253] Referring now to FIGS. 37 and 38, in certain embodiments, a delivery device 10 may include a bias member 470 which is in a stressed state while the delivery device 10 is in a storage state. As shown in FIG. 38, a bias member 470 (depicted in an unstressed state) may include a peripheral body 490. The peripheral body 490 may for example, be annular in shape though any suitable shape may be used. A number of bias projections 492 may extend from the peripheral body 490 toward the center of the bias member 470. The bias projection 492 may extend radially inward toward the center of the bias member 470 from the peripheral body 490. In the example embodiment, the bias projections 492 may be spaced at even angular increments though need not be in all embodiments. The peripheral

body 490 may be constructed of any suitable material and in some examples, may be a resilient plastic or a spring steel.

[00254] A main body 20 of a delivery device 10 may include a number of passages 494 which extend through the main body 20. The passages 494 may be positioned in a support structure 252 of the main body 20. The spacing of the passages 494 may correspond to the spacing of bias projections 492 on the bias member 470. When a delivery device 10 is assembled, the bias projections 492 may be introduced into and partially through respective passages 494 in the main body 20. The peripheral body 490 may rest on a distal face of the peripheral region 30 (see, e.g. FIG. 25) of the main body 20.

10 [00255] Referring now also to FIGS. 39-41, the delivery device 10 may include a depressor body 472. In the example shown, the depressor body 472 includes a reservoir interface member 474 at a proximal end thereof. The depressor body 472 may be rotationally displaceable within an aperture 496 in the main body 20. The aperture 496 may be disposed in the top surface 250 of the main body 20 as shown in FIG. 39 for instance.

15 The depressor body 472 may be rotated from a translational displacement constraining position or range of positions (see, e.g., FIG. 39) to a translational displacement permitting position or range of positions (see, e.g., FIG 38). In a translational displacement constraining position, a retention element of the depressor body 472 may be in engagement with a cooperating lock defined in the main body 20. In a translational displacement

20 permitting position the retention element of the depressor body 472 may be disengaged with the lock of the main body 20.

[00256] As best shown in FIG. 41, the exemplary depressor body 472 includes a stem 500 which extends through the aperture 496 in the main body 20 of a delivery device 10. The stem 500 may include a set of notches 498 or other recess(es) which each may serve as a retention element. The cross-sectional shape of the stem 500 may not be circular or a regular polygon. Thus, one of the width and length dimension of the cross-sectional shape of the stem 500 may be shorter than the other. In the example embodiment, the cross-sectional shape of the stem is an obround shape. Other cross-sectional shapes may be used in alternative examples. The notches 498 may be disposed so as to be recessed into the widest portion of the stem 500. The aperture 496 (see, e.g., FIG. 37) may have a shape which corresponds, though may be slightly larger than, the shape of the stem 500 cross-section. The notches 498 may be recessed to a depth such that when level with the wall of the main body 20 in which the aperture 496 is formed, the depressor body 472 may be rotated within the aperture 496.

[00257] The depressor body 472 is shown in a translational displacement constraining position in FIG. 39. In such a position, the rotational orientation of the depressor body 472 may be such that the notches 498 may overhang a portion of the main body 20 in which the aperture 496 is defined. As a result, the main body 20 may present a mechanical interference to translational displacement of the depressor body 472. Thus, the region of the main body 20 adjacent the aperture 496 may act as a lock for the depressor body 472. As shown in FIG. 40, when the depressor body 472 is rotated to a translational displacement permitting position, the rotational orientation of the depressor body 472 may be such that it may translationally displace within the correspondingly shaped aperture 496 of the main body.

[00258] Referring now also to FIGS. 42 and 43, the depressor body 472 may include an enlarged portion 502. The reservoir interface member 474 may form a proximal region of the enlarged portion 502. When a delivery device 10 is assembled, the bias projections 492 of the bias member 470 may press upon the enlarged portion 502 capturing or coupling the enlarged portion within the bias projections 492. Additionally, the bias member 470 may be substantially constrained from displacing as a whole since the bias projections may be fed through passages 494 in the main body 20. With the bias member 470 constrained in place, lifting of the depressor body 472 may cause the bias projections 492 to deflect and become stressed. Once the depressor body 472 has been lifted such that the notches 498 are even with the portion of the main body 20 in which the aperture 496 is defined, the depressor body 472 may be rotated to a translational displacement constraining position (see, e.g., FIG. 39). Thus, the bias member 470 may be held in a stressed state.

[00259] During actuation of an associated delivery device 10 from a storage state to a delivery state, the depressor body 472 may be rotated to a translational displacement permitting position. Once this position is reached, the depressor body 472 may be free to translationally displace and the bias member 470 may urge the depressor body 472 to translationally displace. As the bias member 470 restores to a less stressed state, the reservoir interface member 474 may be driven against the reservoir 12 to force fluid out of the reservoir 12 and into a patient. The amount of the depressor body 472 which extends out of the main body 20 may alter as the bias member 470 restores to a less stressed state. Thus, the amount of depressor body 472 extending out of the main body 20 may serve as an indicator that a delivery device 10 has been used.

[00260] Referring now to FIGS. 44A-44D, in some examples, a bias member 470 for a delivery device 10 may be entirely internal to the delivery device 10. Additionally, the

depressor body 472 may not latch or engage with a portion of the main body 20 to inhibit translation of the depressor body 472. In some examples of such embodiments, a stop member 473 may be included with the delivery device 10. The depressor body 472 may include a recess 475 (or alternatively set of notches 498, see, e.g., FIG. 41) which may engage with the stop member 473 instead of the main body 20. As best shown in FIG. 44B, the stop member 473 may include an aperture 496' which may have a shape which corresponds, though may be slightly larger than, cross-sectional shape of the stem 500 of the depressor body 472. The recess(es) 475 may be recessed to a depth such that when level with the aperture 496', the depressor body 472 may be rotated within the aperture 496'.

10 [00261] The stop member 473 may be rotated from a translational displacement constraining position to a translation displacement permitting position in which the depressor body 472 is free to displace translationally. In the translation displacement constraining position, the aperture 496' may be positioned such that the stem 500 overhangs a portion of the body 479 of the stop member 473. As a result, the stop member 473 may present a mechanical interference to translational displacement of the depressor body 472. 15 When the stop member 473 is rotated to a translational displacement permitting position, stem 500 may no longer overhang the body 479 of the stop member 473. In this position, the depressor body 472 may translationally displace within the correspondingly shaped aperture 496' of the stop member 473. The stop member 473 may include ridges, knurling, 20 bumps, grips, spokes, or other features to facilitate rotational displacement of the stop member 473 via interaction with a user's fingers.

[00262] Referring primarily to FIGS. 44C and 44D, the bias member 470 may be a conical spring. The conical spring may be in a stressed (e.g. compressed state) when a delivery device 10 is in a storage state and the stop member 473 is in a translational displacement constraining position. When the stop member 473 is moved to the translational displacement permitting position, the bias member 470 may be free to drive displacement of the depressor body 472 against the reservoir 12 as described above with respect to FIGS. 42-43. As the depressor body 472 is displaced via relaxation of the bias member 470, the stem 500 of the depressor body 472 may fully pass through the aperture 496' of the stop member 473. The stop member 473 may thus be disassociated from the rest of the delivery device 10. The depressor body 472 may also translate to a position in which the recess(es) 475 are internal to the delivery device 10. Thus, the stop member 473 may be inhibited from being recoupled to the depressor body 472. When a delivery device 10 is observed absent a stop member 473, it may provide a visual cue that the particular delivery 30

device 10 has already been used. Thus, the stop member 473 may also serve as an indicator which conveys that a particular delivery device 10 is available for use.

[00263] Referring now to FIG. 45, a block diagram of another exemplary delivery device 10 is depicted. As shown, the delivery device 10 may include a main body 20 and a reservoir 12. The delivery device 10 may also include one or more bias member 470. The one or more bias member 470 may form the entire dispensing assembly 480. The one or more bias member 470 may directly contact the reservoir 12 and may aid in applying pressure to the reservoir 12 in order to deliver fluid out of the reservoir 12. In certain examples, a reservoir interface member 474 (see, e.g., FIG. 34) may be included. Where included, the reservoir interface member 474 may (though need not necessarily be) be formed as a part of the at least one bias member 470 and may be integral therewith. The reservoir interface member 474 may directly contact the reservoir 12. The at least one bias member 470 may be or include a spring, compression spring, conical spring, resilient foam, air bladder, any other suitable bias member, or some combination thereof.

[00264] Still referring to FIG. 45, the bias member 470 may be in an unstressed state when the associated delivery device 10 is in a storage state. No pressure may be applied to the reservoir 12 in the storage state. In certain examples, the at least one bias member 470 (and optionally any reservoir interface member 474) may be entirely out of contact with the reservoir 12 in the storage state (e.g. by .05-2mm). When the delivery device 10 is used, the delivery device 10 may be transitioned to the delivery state as described elsewhere herein. As with various embodiments discussed herein, when transitioned to a delivery state, at least a portion of the delivery device 10 may at least partially invert. For example, at least the domed top surface 250 of the central region 28 may invert or partially invert. The distance between the reservoir 12 and the inverted top surface 250 in the delivery state may be less than the distance between the reservoir 12 and the top surface 250 in the storage state. This may in turn cause a bias to be stored in the bias member 470. The at least one bias member 470 may, in the example, be compressed when the top surface 250 is inverted. Additionally, where the at least one bias member 470 is spaced from the reservoir 12 in the storage state, the at least one bias member 470 or reservoir interface member 474 (which may be a part of the bias member 470) may be displaced into contact with the reservoir 12. The inverted top surface 250 may be sufficiently strong in the inverted state to withstand any force exerted by the at least one bias member 470. As the at least one bias member 470 restores, the at least one bias member (and/or reservoir interface member 474 if included) may press against the reservoir 12 to collapse the reservoir 12 and drive fluid into a patient.

Thus without, for example, sustained manual pressure against the delivery device 10, pressure may be still applied to the reservoir 12 over a period of time sufficient to fully deliver contents of the reservoir 12 (e.g. 5 minutes in certain embodiments).

[00265] Referring now to FIGS. 46A-46B, an example embodiment of a main body 20 and a main body 20 with a bias member 470 are respectively shown. FIG. 46A depicts a bottom plan view of the main body 20. FIG. 46B depicts a perspective view of the main body 20 and bias member 470. The main body 20 is shown with the top surface inverted for illustrative purposes. As shown, the main body 20 may include a number of locating projections 471. There may be a set of locating projections 471 which are disposed in a center region of the top surface 250. A second set of locating projections 471 may be spaced outwardly from the center region may optionally be included. In the example embodiment, the second set of locating projections 471 extend from the top surface 250. In other examples, location projections 471 may extend radially inward from the supporting structure 252 of the central region 28. An end of the bias member 470 may be centered by the locating projections 471 as the bias member 470 is placed into the delivery device 10 assembly. In certain examples, the end of the bias member 470 may be coupled into place. For example, the end of the bias member 470 adjacent the top surface 250 may be heat staked once the bias member 470 is properly positioned (see, e.g., FIG. 46C). When the delivery device 10 is fully assembled, the heat stake may retain the bias member 470 in place against the main body 20. As a result, the bias member 470 may be held out of contact with the reservoir 12 until the delivery device 10 is transitioned to the delivery state. The locating projections 471 may also aid in ensuring that the bias member 470 transitions to the stressed state in a desired manner. For example, where a compression spring is used, the second set of locating projections 471 may constrain the bias member 470 such that the bias member 470 is compressed substantially along the axis of the bias member 470.

[00266] Referring now also to FIG. 46C, in some examples, the bias member 470 may be constrained from displacement by one or more guide body 477. The one or more guide body 477 may extend from the supporting structure 252 of the central region 28 of the main body 20 toward the axis of the bias member 470. In the example shown in FIG. 46C, four guide bodies 477 are included and are spaced at even angular increments. In other embodiments, the number of guide bodies 477 may differ and/or the guide bodies could be irregularly spaced. The guide bodies 477 may aid in ensuring that the bias member 470 compresses substantially along its axis and may help inhibit tilting of the bias member 470 during use of a delivery device 10.

[00267] Still referring to FIGS. 46A-C, where the bias member 470 is a compression spring, a terminal end 481 of the bias member 470 may form a reservoir interface member 474. The terminal end 481 bias member 470 may be routed in a manner which helps spread pressure more uniformly over the reservoir 12. The terminal end 481 of the bias member
5 470 may be routed in a direction or desired pattern. The terminal end 481 may also be disposed substantially within a plane disposed even with or adjacent an end of the bias member 470. In the example embodiment in FIG. 46B, the terminal end 481 of the coil is bent so that it extends between opposing points on the bias member 470. In the example, the terminal end 481 extends substantially diametrically across the end of the bias member 470
10 proximal the reservoir 12. In other embodiments, the terminal end 481 of the bias member 470 may be routed in a spiral or other pattern (see, e.g., FIG. 46C).

[00268] In some embodiments, as shown in FIGS. 47-50 (respectively a perspective view from the top, view from the side, view from the bottom, and perspective view from below, relative to an application surface for a delivery device 10 such as the skin surface),
15 an example holder 270 for a sharp bearing body 26 (see, e.g., FIG. 31) including delivery sharp(s) 72 (see, e.g., FIG. 31), may be formed as an annulus or annular body 272 integral with a rounded depression 274. The rounded depression 274 may be centrally disposed. In one example, the rounded depression 274 may have the shape of a spherical segment. The annulus 272 may have an inner edge, and the rounded depression 274 may have a perimeter.
20 The inner edge of the annulus 272 may be coincident to the perimeter of the rounded depression 274. When a delivery device 10 incorporating a holder 270 is affixed to the skin surface of a user, the rounded depression 274 extends below the plane of the annulus 272 (see FIG. 48).

[00269] The rounded depression 274 may include a pocket 276 formed therein. The
25 pocket 276 may be formed in a proximal face of the holder 270. The pocket 276 may be situated at a center, and lowest (with respect to the skin surface when the delivery device 10 is affixed thereto) point of the rounded depression 274. The pocket 276 may be sized to fit and accept a sharp bearing body 26 with delivery sharp(s) 72 thereon such as, e.g., the sharp bearing body 26 including delivery sharps 72 of FIG. 31. The sharp bearing body 26
30 including delivery sharp(s) 72 may be mated into the pocket 276 by, e.g., injection molding or adhesive. The holder 270 may be over molded around the sharp bearing body 26 so as to couple the components together. In various embodiments, the delivery device 10 may be arranged such that pressure from above (e.g., from a finger) on the delivery device 10 may be distributed evenly over the area of the holder 270. In some embodiments, the depression

274 may act as a force concentrating protuberance from the holder 270 which serves to ensure force applied to a delivery device 10 is concentrated upon the delivery sharp(s) 72 aiding in insertion of the delivery sharp(s) 72 into the skin.

[00270] In an example embodiment, the width (e.g. diameter) of the holder 270 may be approximately 0.7 inches (e.g. 0.744 inches). The footprint area of an exemplary holder 270 may be approximately 0.45 square inches (e.g. 0.44 square inches). The holder 270 may be manufactured by any technique known to those of skill including, e.g., injection molding or thermoforming.

[00271] Another exemplary holder 270 is depicted in FIGS. 51A-51C. As shown, a holder 270 may include a disk body 275. The disk body 275 may be substantially flat and may include a number of peripherally disposed tab projections 277. The tab projections 277 may be symmetrically disposed about the disk body 275 and may be spaced at regular angular intervals as shown in FIGS. 51A-51C. In alternative embodiments, the tab projections 277 may be asymmetrically disposed about the base or disposed at irregular angular intervals. The tab projections 277 may engage with receiving slits 278 (see, e.g., FIG. 44A) disposed in a main body 20 of a delivery device 10. Thus, the tab projections 277 may be used to couple the holder 270 into place in a delivery device 10. Asymmetric or irregularly spaced tab projections 277 may allow for the holder 270 to be coupled to a main body 20 in a prescribed orientation which may be desirable in some examples.

[00272] Still referring primarily to FIGS. 51A-51C, a holder 270 may include at least one stage projection 279. The stage projection 279 may be included in addition or instead of the rounded depression 272 and spherical segment of the embodiment described above in relation to FIGS. 47-50. The stage projection 279 may provide a well 281 on the distal side of the disk body 277. The stage projection 279 may extend proud of the proximal side of the disk body 277 by a height which may, in certain examples, be at least equal to the height of a microneedle (e.g. 600 microns) of the delivery device 10. The stage projection 279 may generally extend from the disk at a perpendicular angle. The side walls 283 of the stage projection 279 may be chamfered so as to extend in a non-perpendicular direction with respect to the proximal face of the disk body 279. The stage projection 279 may include a pocket 276. The pocket 276 may be sized to fit and accept a sharp bearing body 26 with delivery sharp(s) 72 thereon as described elsewhere herein.

[00273] Referring now to FIGS. 52A-52D, in some embodiments, the pocket 276 of the stage projection 279 may be in a non-parallel orientation with respect to the plane of the disk body 275. As best shown in FIG. 52D, when a sharp bearing body 26 is mounted to the

pocket 276, the orientation of the pocket 276 may ensure that the delivery sharp(s) 72 (e.g. microneedles) extend at a prescribed angle with respect to the disk body 275. In the example embodiment, the pocket 276 may be oriented such that the delivery sharp(s) 72 extend at a 10-20° angle (e.g. 15°) with respect to the plane of the disk body 275. In other
5 embodiments, the pocket 276 may be oriented such that the delivery sharp(s) 72 project at a 45° or 60° angle or some angle therebetween. Any suitable angle may be used. In alternative embodiments, the entire stage projection 279 may project at the desired angle from the disk body 275. Thus, the delivery sharp(s) 72 may extend at that angle when coupled to the pocket 276.

10 **[00274]** In some embodiments, as shown in FIGS. 53-56 (respectively a view from the side, view from the top, perspective view looking down from above, and perspective view looking up from below relative to an application surface for a delivery device 10 such as e.g., the skin surface), a reservoir portion 271 is depicted. A reservoir portion 271 may be shaped to incorporate, as an integrated structure, a dome shaped portion 280, a tunnel or
15 side channel 282, and a flange or annular portion 284. That is, these features may be included in a single monolithic piece of material. In some embodiments the dome shaped portion 280 may be shaped approximately as a hemisphere or other spherical segment though any other suitable shape is possible. In examples where the reservoir portion 271 includes a rounded shape which forms a cavity (e.g. the dome shaped portion 280), there
20 may be a plateau or flat surface included at the portion of the rounded shape most distal the flange 284. The flat surface may be generally parallel to the flange 284. In some examples, a central depression 267 (see, e.g. FIG. 57) may also be included in the flat surface. The tunnel 282 may be shaped in some examples as a half-pipe or half cylinder that may be formed from the annular portion 284. Any suitable cross-sectional shape may be used in
25 alternative embodiments. The side channel or tunnel 282 may communicate with the dome shaped portion 280 via an arch 286 such that the combination of dome shaped portion 280 and tunnel 282 form a structure shaped approximately as an igloo. In some embodiments, the end of the tunnel 282 opposite the dome shaped portion 280 may flare or taper outwardly to increase ease of filling. The annular portion 284 may have an inner edge that is
30 coincident with a base perimeter 288 of the dome shaped portion 280. The reservoir portion 271 may be manufactured by, e.g., thermoforming a flat sheet of material (e.g., plastic or layers of various plastic or other material). Where a multilayer sheet is used, the sheet may include a drug or agent compatible layer, barrier layer, tie layer, etc. In some embodiments vacuum forming may be used to manufacture the reservoir portion 271. Other known

techniques such as injection molding could be used. The reservoir portion 271 may be formed of a polycarbonate material or other suitable materials and may be coated with a Cyclic Olefin Polymer (COP) or any other suitable coating material. The dome shaped portion 280 may be collapsible when pressure is applied thereto.

5 **[00275]** Referring now to FIGS. 57, a perspective view of an exemplary reservoir portion 271 is shown. In certain examples, reservoir portions 271 may include at least one cavity with one or more built in collapse facilitator. The collapse facilitator may encourage the cavity to collapse in a prescribed manner and may lower the force needed to collapse the cavity. The collapse facilitator may also aid in ensuring that the cavity collapses such that
10 any dead volume is minimized. Likewise, inclusion of a collapse facilitator may help to mitigate potential for fluid contained in a reservoir 12 to become trapping or pocketed in a region of the reservoir 12 that becomes blocked out of communication with an outlet during collapse of the cavity. Other reservoirs 12 described herein may include at least one collapse facilitator.

15 **[00276]** A collapse facilitator may be a pleated, bellows shaped, accorded, creased, ruffled, stepped, or concertina shaped wall 261 which extends upward from the flange 284. The wall 261 may extend proud of the flange 284 and may taper (e.g. continuously or in stepwise manner) as distance from the flange 284 increases. A top wall 263 may span across the portion of the wall 261 most distal the flange 284. Thus, the wall
20 261 and top wall 263 may together form a cavity in the reservoir portion 271. The top wall 263 may be generally planar and extend parallel to the flange 284 in certain examples. The top wall 263 may in certain examples include a central depression 267. The central depression 267 may serve to aid in locating a reservoir interface member 474 (see, e.g., FIG. 34) or a portion of a bias member 470, 481 (see, e.g., FIG. 35 and FIG. 46B
25 respectively). Flat top walls 263 and/or central depressions 267 may be included in other reservoirs 12 described herein. The cavity formed by the wall 261 and top wall 263 may have a generally round, circular, elliptical, oval, obround, or polygonal cross-section.

30 **[00277]** Though any pleating, bellows, accordion, crease, or ruffling pattern may be used, in certain embodiments, the wall 261 may include at least one pleat 269 in a spiral pattern. The at least one spiral pleat 269 may extend from a point adjacent the flange 284 and end at a point adjacent the top wall 263. Where the wall 261 tapers as distance from the flange 284 increases, the any spiral pleats 269 may have a conical type spiral to accommodate the taper. Any spiraling pleat(s) 269 may have a pitch which causes each pleat(s) 269 to wrap around the wall 261 a plurality of times. In the example embodiment

shown in FIG. 57, the spiral pleat 269 wraps around the wall 261 about three times. Such a pleat 269 may aid in assisting collapse of the cavity while fluid is urged out of a reservoir 12 during operation of a delivery device 10. Thus minimal force may be needed to deform and deplete such a reservoir 12 during use. Additionally, such a pleat 269 may assist in
5 ensuring that little dead volume remains in the reservoir 12 after a delivery has completed. Use of a flat top wall 263 may also assist in collapse of the cavity.

[00278] Referring now to FIG. 58, the wall 261 may be stepped and include at least one step region 259. The cross-sectional area of the cavity may change at each step region 259. In the example, the cross-sectional area of the cavity is largest adjacent the flange 284
10 and decreases in a stepwise manner as distance from the flange 284 increases. The wall 261 includes two step regions 259 in the example shown in FIG. 58, though any suitable number may be included in alternative embodiments. As in the examples discussed above, the stepped wall 261 may aid in lowering force needed to collapse the cavity and help to direct the collapse in a prescribed manner.

15 [00279] In an embodiment, the reservoir 12 may be formed by attaching the reservoir portion 271 to the holder 270, as shown in FIG. 59. The reservoir portion 271 may be positioned above the holder 270 in the example shown, and the lower surface area 285 of the annular portion 284 may be affixed to the upper surface area 273 of the annulus 272 or disk body 275. In an embodiment, the reservoir portion 271 may be attached to the holder
20 270 by ultrasonic welding, although any form of welding or any other coupling technique known to those of skill could be used. For example, the reservoir portion 271 and the holder 270 may be sealed together with a double sided adhesive. Other suitable techniques for sealing the reservoir portion 271 and the holder 270 together include, by way of non-limiting examples, using an ultraviolet curable adhesive, heat staking, and laser welding.

25 [00280] A medical agent, such as, e.g., a vaccine, may be inserted into the reservoir 12 via the side channel 282, after which the side channel 282 may be sealed closed by any known technique such as, e.g., sonic welding or any other suitable technique described here. The sharp bearing body 26 (see, e.g., FIG. 31) including the delivery sharp(s) 72 (see, e.g., FIG. 31) may be inserted into the pocket 276 and fixed therein by any suitable technique
30 such as, e.g., welding, prior to insertion of the medical agent (e.g., vaccine) into the reservoir 12. Alternatively, and as mentioned above, the holder 270 may be formed around the sharp bearing body 26. As mentioned elsewhere herein, the delivery sharp(s) 72 may be one or more microneedle in various examples.

[00281] In one example embodiment, the reservoir 12 may hold approximately two microliters of vaccine or other medical agent. After a medical agent (e.g., a vaccine) has been inserted, the reservoir 12 may be placed in cold chain storage separately and subsequently installed in the delivery device 10 shortly before use. This may serve to help
5 maximize the yield of vaccine doses per unit volume in cold chain storage. The reservoir 12 may be inserted into the delivery device 10 with a packet 208 and/or container 350 or foam adhesive (such as the packet or foam adhesive material described above with reference to FIGS. 10A-11). The packet 208 and/or container 350 or foam adhesive may be disposed
10 between the reservoir 12 and the underside of the top surface 250 of the delivery device 10 when the delivery device 10 is fully assembled. Alternatively and as discussed above, a dispensing assembly 480 (see, e.g., FIG. 34) or at least one bias member 470 (see, e.g., FIG. 45) may be disposed between the underside of the top surface 250 and the reservoir 12 once the reservoir 12 is installed.

[00282] With reference to FIG. 60, a reservoir 12 (e.g., a reservoir 12 such as that
15 described above with reference to FIG. 59) may be affixed to the inside of a delivery device 10. Though a representational example delivery device 10 is depicted, a reservoir 12 may be similarly installed in a main body 20 of any delivery device 10 embodiments described herein. The reservoir 12 may contain a medical agent (e.g., a vaccine) prior to being assembled into the delivery device 10. The reservoir 12 may be removed from cold storage
20 prior to being attached to the inside of the main body 20 of a delivery device 10.

[00283] Still referring to FIG. 60, in one embodiment, a ridge 290 may be formed in an inside surface of the central region 28 of the delivery device 10 such that the ridge 290 may serve as a seating structure upon or against which a section or region of the reservoir 12 may be positioned or coupled. In one example, the annulus 272 or the holder 270 may be
25 adhered to the ridge 290 with an adhesive. It would be understood by one of skill that any suitable coupling technique could be used. In other embodiments, the distal face of the reservoir portion 271 may attach to the proximal face of the ridge 290. A distal face of a reservoir portion 271 may for example be coupled to the ridge 290 of the main body 20 of the delivery device 10 shown in FIG. 26. Tab projections 277 (see, e.g., FIG. 51A) which
30 couple into receiving slits 278 (see, e.g., FIG. 44A) defined in the main body 20 may alternatively or additionally be used.

[00284] In certain embodiments and referring now to FIGS. 61A-61B, the shape of the reservoir portion 271 may be adjusted to alter the maximum cross-sectional area of the reservoir portion 271. This may aid in achieving a desired delivery pressure. For example,

in some embodiments, the reservoir portion 271 may be formed so as to have a balloon like (shown in FIG. 61A-61B), cylindrical, polygonal prism shape, etc. The height of the reservoir portion 271 may be adjusted to achieve the desired interior volume given a preselected maximum cross-sectional area. As shown, the holder 270 may include at least one buttress 289. The at least one buttress 289 may at least partially surround the reservoir portion 271. The at least one buttress 289 may aid in holding the reservoir portion 271 in a desired position within a delivery device 10. The at least one buttress 289 may also aid in directing collapse the reservoir portion 271 as delivery occurs.

[00285] As shown in FIG. 61B, the main body 20 may include a nesting projection 287. As the delivery device 10 is transitioned into a delivery state (see, e.g., FIG. 29) the nesting projection 287 may press against the reservoir portion 271. As delivery progresses, the nesting projection 287 may press the reservoir portion 271 against the at least one buttress 289. In the example embodiment, the nesting projection 287 may be disposed between the exemplary buttresses 289 and may aid in ensuring minimal dead space remains in the reservoir 12 after delivery is complete.

[00286] Referring now to FIG. 62, in certain embodiments, it may be desirable that delivery pressure ramp up relatively slowly when the delivery device 10 is transitioned to a delivery state. For example, it may be desirable that fluid injection begin at a relatively low pressure or at or about the lowest pressure at which injection is possible for a particular patient. The delivery pressure may be ramped up until this delivery initiation pressure is reached for a particular patient. Ramping up pressure slowly may allow for the delivery initiation pressure to be reached for a wide variety of patients using the same delivery device 10 design. Additionally, once the injection begins, it may be desirable that the delivery pressure is held at or near the delivery initiation pressure. Additionally, and as shown in FIG. 62, it may be desirable that such embodiments use at least one bias member 470 to facilitate delivery. For example, a compression spring made of a Hookean material may be used.

[00287] As shown in FIG. 62, in such embodiments, the reservoir 12 may be partitioned into a first portion 520 and a second portion 522. The first portion 520 and the second portion 522 may be in fluid communication with one another via a flow restrictor 524. The flow restrictor 524 may be disposed between a portion of the reservoir 12 proximal to the microneedles and a portion of the reservoir 12 more distal to the microneedles. The flow restrictor 524 may be an orifice plate with one or more orifice extending therethrough in certain embodiments. In some embodiments a flow restrictor 524

with a 15-25 micron orifice may be included. In other embodiments, an orifice may be up to 100 microns in diameter (e.g. 70-80 microns or 75 microns). In some embodiments, the orifice may have diameter greater than 100 microns. The orifice size may be selected based on considerations such as the viscosity and/or surface tension of the agent(s) filled into the reservoir, the desired speed of injection and how quickly it is desired to ramp up injection pressure. An orifice plate may be an injection molded component though could be formed in any other suitable manner.

[00288] Still referring to FIG. 62, the first portion 520 of the reservoir 12 may include a majority of the reservoir 12. The second portion 522 of the reservoir 12 may be disposed proximal to the delivery sharp(s) 72 relative to the first portion 520. Thus, the flow restrictor 524 may separate a large first portion 520 from a smaller second portion 522 which is most proximal the delivery sharp(s) 72. The first portion 520 may have a volume substantially equal to the fill volume of the reservoir 12 in certain examples. The flow restrictor 524 may be disposed upstream of at least the pocket 276 (see, e.g., FIGS. 47-51C) into which a sharp bearing body 26 may be coupled. In example embodiments, the flow restrictor 524 may separate a rounded depression 274 (see, e.g., FIGS. 47-50) from the remainder of the reservoir 12. In such embodiments, the flow restrictor 524 may be coupled to the distal face of the annular body 272 (see, e.g. FIGS. 47-50) over the rounded depression 274. In other examples, the flow restrictor 524 may separate the well 281 (see, e.g., FIGS. 51A-51C) from the remainder of the reservoir 12. In such embodiments, the flow restrictor 524 may be coupled to the distal face of the disk body 275 (see, e.g. FIGS. 51A-51C) over the well 281.

[00289] In certain examples, the first and second portion 520, 522 of a partitioned reservoir 12 may be filled with different fluids. For example, the first portion 520 may be filled with an agent desired to be delivered (drug, vaccine, medical agent, etc.). The portion proximal the delivery sharp(s) 72 may be filled with a gas (e.g. sterile or cleanroom air from the manufacturing environment, inert gas, etc.). The orifice may be sized such that the properties of the agent (e.g. surface tension, viscosity) prevent the agent from passing to the second portion 522 without addition of pressure on the reservoir 12. Thus, despite the first and second portions 520, 522 being in fluid communication, the second portion 522 may remain unwetted by any agent filled into the reservoir 12 during manufacture until use. When the delivery device 10 is used, there may be a latency period during which fluid is forced into the second portion 522 from the first portion 520. Pressure in the second portion 522 may then ramp up until a pressure at which the patient's anatomy begins to accept the

delivery. The pressure may remain relatively steady (or at least not spike considerably) once delivery begins.

[00290] When a delivery device 10 including a partitioned reservoir 12 is transitioned to a delivery state, at least one bias member 470 (e.g. a conical spring) may cause pressure to be exerted against the first portion 520 of the reservoir 12. Depending on the embodiment, the at least one bias member 470 may directly contact the reservoir 12 or pressure may be exerted through a reservoir interface member 474 (see, e.g., FIG. 34) or other components of a delivery assembly 280 (see, e.g., FIG. 34). The flow restrictor 524 may cause the pressure of fluid in the second portion 522 of the reservoir 512 to slowly ramp up to a pressure at which injection into a patient begins. Thereafter, the flow restrictor 524 may limit build-up of pressure in the second portion 522 as the injection progresses. Thus the injection will tend to occur at or near the lowest pressure at which the patient will accept the delivery. This may facilitate use of a more aggressive spring and may limit discomfort associated with the delivery. Moreover, it may allow for a single delivery device 10 design to be used on a wide range of patient populations (e.g. any patient) or with a wide variety of different agents. Additionally, this may have an effect on bleb formation resulting from the delivery. As the delivery may tend to occur relatively slowly and at a relatively low pressure, a more diffuse shallow (e.g. intradermal) injection may tend result. Adjustment of the size of any orifice in the flow restrictor 524 may alter the duration of the delivery and characteristics of the bleb.

[00291] Referring now to FIGS. 63A-C, a number of example adhesive members 22 are depicted on exemplary delivery devices 10. As shown, a single adhesive member 22 is included for each of the example delivery devices 10. In alternative embodiments, the adhesive member 22 may be broken into a plurality of individual adhesive members 22. This may facilitate use of different adhesives or perhaps leaving certain petal member 42 devoid of adhesive. As shown, each adhesive member 22 may include a plurality of slits 43 extending radially inward from a periphery of the adhesive member 22 so as to create petal portions which align with the petal members 42 of the main body 20. The adhesive member 22 may also include a central aperture 49 through which the delivery sharp(s) 72 of the delivery device 10 may access a patient.

[00292] The shape and size of the central aperture 49 may have an effect on bleb formation resulting from delivery when a delivery device 10 is used. Additionally, the shape and size of the central aperture 49 may play a role in helping to facilitate certain shallow deliveries or shallow deliveries into skin having certain characteristics. In various

exemplary delivery devices 10, it may be desirable that the central aperture 49 have a cross sectional area which is 60-100% the area of the footprint of the holder 270. It may also be desired that the central aperture 49 be shaped such that at least a portion of the adhesive member 22 is attached to a portion of a holder 270 or other rigid portion of the reservoir 12.

5 In certain examples, the cross-sectional area of the central aperture 49 may be greater than 0.13in^2 . In certain examples, the cross-sectional area of the central aperture 49 may be in a range of 0.13in^2 to 0.5in^2 (e.g. about 0.3in^2).

[00293] Additionally, it may be desired that the central aperture 49 be wider in certain directions compared to others. For instance, each delivery sharp 72 (e.g. one or more
10 microneedle) may tend to dispense fluid in an ejection direction which extends from the outlet of the respective delivery sharp 72 (e.g. along the axis of the lumen of the delivery sharp 72). It may be desired that the central aperture 49 have a larger or increased width in a direction which aligns or substantially aligns with the ejection direction. For example, the greatest width (or at least a comparatively large width portion) of the central aperture 49
15 may be along a direction that is parallel to a plane that includes the ejection direction. Using a delivery device 10 including one or more microneedle similar to that shown in FIG. 2, an increased width portion of the central aperture 49 may be aligned with the front to back (distal side 15 to back facing edge 23, may also be referred to herein as length) direction or line of symmetry of the microneedle. For example, the central aperture 49 could be obround
20 and be widest in a direction parallel to the front to back direction of the microneedles. This may help to create a more diffuse shallow (e.g. intradermal) injection as opposed to a concentrated bleb. This may, in turn, be desirable as it may help to increase the effectiveness of the injection. For instance, a more diffuse intradermal injection of a vaccine may expose more of the immune related cells in the intradermal region to the vaccine
25 potentially augmenting the immune response.

[00294] Referring now primarily to FIG. 63A, the central aperture 49 may generally be a round (e.g. circular) aperture with the exception of a number of inwardly extending teeth or spokes 51 of adhesive member 22 material. In the example embodiment, the adhesive member 22 includes a central aperture 49 with four spokes 51 spaced at regular
30 angular increments from one another. The number of spokes 51 may differ and the spacing of the spokes 51 may be irregular in certain examples. The spokes 51 may be disposed such that the central aperture 49 has a comparatively large width in a direction aligned with the ejection direction. Though the central aperture 49 may have a comparatively large width in this direction, this does not preclude other wide regions of equal, lesser, or perhaps even

greater width. In the example shown, the central aperture 49 is about equal in width when measured in a direction perpendicular to the front to back direction of the microneedles. In certain examples, spokes 51 may assist in attachment to a holder 270 or other rigid reservoir 12 portion. Thus, the adhesive member 22 may be firmly attached to both the main body and the holder 270 for example. In certain examples, the spokes 51 may be the only portion of the adhesive member 22 which is adhered to the holder 270.

[00295] Referring now primarily to FIG. 63B-C, in certain examples, the central aperture 49 may include notches 53 which extend outwardly from the periphery of the rest of the central aperture 49. The notches 53 may be included to widen the central aperture 49 where desired. Though rectangular notches 53 are included in the examples, the shape of the notches may differ in alternative embodiments. The notches 53 could be any suitable polygonal shape or could be round for example.

[00296] Referring now to FIG. 64A and FIG. 64B, another example embodiment of a delivery device 10 is depicted. As shown, the delivery device 10 includes a main body 20 and a reservoir 12. The reservoir 12 includes a sharp bearing body 26 which includes a one dimensional array of three delivery sharps 72. Other embodiments may include any suitable number of delivery sharp(s) 72 arranged in any desired pattern. The main body 20 of the delivery device 10 may have a polygonal (e.g. rectangular) footprint and may be generally formed as a strip of material to which the reservoir 12 is attached. In the example embodiment, the main body 20 includes a number of living hinges 50 which are formed integral with the rest of the main body 20. The living hinges 50 may each extend across a portion of the main body 20 and may partition the main body 20 into a number of panels 52A-D. The main body 20 may be injection molded.

[00297] The panels 52A-D may include a pair of opposed end panels 52A, D. Each of the end panels 52A, D may include a planar portion 54. The planar portions 54 may be parallel or coplanar. In the example, the planar portions 54 are coplanar. One of the end portions 52A may include an angled projection 56 which extends from planar portion 54. The angled projection may extend from the planar portion 54 such that an obtuse angle is formed between the distal faces of the planar portion 54 and angled projection 56. The angled projection 56 may be resilient and resist deflection or bending so as to extend at a fixed angle with respect to the planar portion 54. In some examples, a buttress 58 may be included and may extend from the planar portion 54 to the angled projection 56 to aid in preventing displacement of the angled projection 56 with respect to the planar portion 54.

Each of the planar portions may have a proximal face which is at least partially covered in adhesive 22.

[00298] The panels 52A-D may also include at least two intermediate panels 52B, C which may extend between and couple together the end panels 52A, D. One of the panels
5 52B may be coupled to an end of the raised projection 56 via one of the living hinges 50. The other of the intermediate panels 52C may be coupled to the planar end panel 52D via another of the living hinges 50. Each of the intermediate panels 52B, C may be coupled to one another via a living hinge 50 so as to form a linkage 60 between the end panels 52A, D.

[00299] Referring now to FIGS. 65A-65C, the linkage 60 may be displaceable
10 between a raised position (see FIG. 65A), through a center position (see FIG. 65B) and into an over center position (see FIG. 65C). The linkage 60 may be in the raised position when the delivery device 10 is in the storage state. In the raised position, the intermediate panel 52B connected to the raised projection 56 may extend from the raised projection 56 at an angle 62 (angles 62, 64, 66) measured between proximal faces of recited components). The
15 angle 62 may be selected such that the intermediate panel 52B becomes progressively more distant from the plane of the planar portions 54 as distance from the raised projection 56 increases. In the example shown, angle 62 is an obtuse angle when the linkage 60 is in the raised position. The intermediate panels 52B, C may also be disposed at an angle 64 to one another. This angle 64 is also an obtuse angle in the example embodiment when the linkage
20 60 is in the raised position. The intermediate panel 52C and end panel 52D may form an angle 66 with respect to one another which may be a reflex angle when the linkage 60 is in the raised position. Additionally, in the raised position each of the end panels 52A, D may be at a closest distance to one another.

[00300] The delivery device 10 may be applied to the skin 44 over an infusion site in
25 the storage state with the linkage 60 in the raised position. This may fix the end panels 52A, D such that they are substantially constrained to the plane of the skin patch to which they are adhered. Application of downward pressure against the linkage 60 may displace the linkage 60 from the raised position toward the center position. As this occurs, the angle 64 between the two intermediate panels 52B, C may increase. The angle 62 between the raised
30 projection 56 and intermediate panel 52B and the angle 66 between end panel 52D and intermediate panel 52C may decrease. To accommodate the change in the angle 64 between the two intermediate panels 52B, C the end panels 52A, D may spread apart. When the linkage 60 reaches a center position (see FIG. 65B) the angle 64 may be 180° and the end

panels 52, D may be at a greatest distance from one another. The skin 44 may be stretched and rendered taught as the end panels 52A, D displace apart.

[00301] As the linkage 60 is further displaced the linkage 60 may enter an over center state. The elasticity of the stretched skin 44 may exert a restoring force which tends to drive
5 the end panels 52A, D toward one another. Thus, once the linkage 60 is displaced through the center position the linkage 60 may automatically be displaced to an over center position at an end of the displacement range of the linkage 60. When the linkage 60 is displaced into this over center position, the delivery device 10 may be transitioned into the delivery state. As the linkage shifts to the over center position shown in FIG. 65C, the distance between
10 the end panels 52A, D may decrease. The distance between the end panels 52A, D may still, however, be greater than the distance between the end panels 52A, D when the linkage 60 is in the raised position. In the over center position at the end of the displacement range, the angle 62 between the raised projection 56 and intermediate panel 52B may be about 90° (e.g. 80°-110°). The angle 64 between the intermediate panels 52B, C may be a reflex angle.
15 Thus, the linkage 60 may be partially inverted with respect to its position in the raised position. The angle 66 between intermediate panel 52C and end panel 52D may be substantially 180°. As shown, when the linkage 60 reaches the over center position at the end of its displacement range a proximal face of the intermediate panel 52C may contact the skin 44.

20 [00302] When the delivery device 10 is in the delivery state (see FIG. 65C), the delivery sharp(s) 72 may be pressed into the skin 44 so as to puncture the skin 44 and establish fluid communication with a delivery destination in the patient. The angle 64 between the intermediate panels 52B, C in the over-center delivery position (see FIG. 65C) may be selected to cause the delivery sharp(s) 72 to pierce into the skin 44 at a prescribed
25 angle (e.g. 45° to the skin 44 surface). The angle 64 may be selected to be in the range of 30° to 60°. Alternatively, the angle 64 may be established by setting within a desired range the ratio of the shortest distance between the angle 62 and the surface of the skin 44 in the over-center delivery position (see FIG. 65C) to the length of the intermediate panel 52B. The reservoir 12 may also be pressed against the skin 44 when the delivery device 10 is in
30 the delivery state 10. This may pressurize the reservoir 12 and force fluid out of the reservoir 12 through the delivery sharp(s) 72 and into the patient. Restoring force exerted by the stretched skin 44 may serve to supply a continuous pressure against the reservoir 12 and aid in ensuring that the reservoir 12 is completely depleted as the delivery occurs.

[00303] In some embodiments, the proximal face of the intermediate panel 52C may be covered at least partially in adhesive 22 (see, e.g., FIG. 65C). When the linkage 60 reaches the over center position at the end of the displacement range, the adhesive 22 may hold the linkage 60 in place. Additionally, in some embodiments, the main body 20 may include at least one force limiter. For example, at least one of the panels 52A, D may include a strain relief flexure. In the example embodiment, this flexure may bend in the event that the force required to stretch the skin 44 exceeds a threshold. Bending of the flexure may cause the linkage 60 to snap through the center position and enter an over center position such that stretching of the skin 44 is halted. This may be desirable as it may help to mitigate potential discomfort during an injection due to excessive tensioning of the skin 44. Likewise, this may be helpful in certain patient populations as skin characteristics vary significantly across potential patients.

[00304] In an embodiment, one of the intermediate panels 52B, 52C, for example the intermediate panel 52C, may be implemented as a flexure or including at least one flexure that incorporates a gap and at least one bias member. The gap may be urged to a widened state by the bias member (which may, in some embodiments, be formed integrally with and of the same material as the panel 52B, C). Applying sufficient pressure to the bias member may overcome the bias member and allow the flexure to give. Thus, an intermediate panel 52B, 52C may be formed so as to have a variable length which decreases as force exceeds some predefined threshold.

[00305] The intermediate panel 52C (though any intermediate panels 52B, 52C may include such features) may be implemented as or to include at least one lattice-structured flexure 290, as shown in FIGS. 66A-66B. The flexure(s) 290 may be formed by injection molding. The intermediate panel 52C may include a first member 296 adjacent the living hinge 50 connection to the other intermediate panel 52B. The first member 296 may have at least one support arm 300. In the example shown, there are four support arms 300A-D extending from the first member 296 at substantially ninety degree angles toward a second member 298 of the intermediate panel 52C. The second member 298 may be adjacent the living hinge 50 connection to the end panel 52D. The second member 298 may be disposed parallel to and opposing the first member 296 and have at least one arm 302. In the example shown there are two arms 302A-B extending from the second member 298 at substantially ninety degree angles toward the first member 296. Each of the two arms 302A-B may be positioned substantially parallel to and extend between a respective pair of the four support arms 300A-D. Each of the two arms 302A-B may be coupled to at least one of the

associated two support arms 300A-B, 300C-D disposed on each side of the respective arm 302A-B by at least one buttress 304 (e.g., three buttresses 304). In the example, each of the two arms 302A, B is connected to each of the associated support arms 302A-B. Only six of twelve buttresses 304A-F are shown in FIG. 66A for ease of illustration. Applying pressure
5 that exceeds a threshold level will cause the gaps between the first and second members 296, 298, the support arms 300A-D, the arms 302A-B, and the buttresses 304A-F to at least partially close. The number of buttresses 304A-F may be altered to adjust the threshold at which that flexure 290 gives way. Additionally or alternatively, the amount of material or thickness of the buttresses 340A-F may be adjusted for this purpose. The buttresses 304A-F
10 may be disposed substantially parallel with each other and extend from the respective arm 302A-B at acute angles relative to the first member 296. The buttresses 304A-F may couple to the respective support arms 300A-D at obtuse angles relative to the first member 296. The flexures 290 are shown by way of non-limiting example and may be incorporated using any suitable shapes, angles, and/or numbers of structures and/or parts.

15 **[00306]** In another embodiment the intermediate panel 52C may incorporate at least one flexure 292 which may be in the form a squishable body that may deform when a threshold force applied to the body is exceeded. The flexure 292 may be round and hollow in an embodiment. As shown in FIGS. 67A-67B, the exemplary flexure 292 may be roughly cylindrical in shape. It would be understood that the flexure 292 shown is one of many
20 possible examples and need not be limited to the structure or shape shown. The flexure 292 may be integral to the intermediate panel 52C and may be formed in an injection molding process that forms the main body 20 of the delivery device 10.

[00307] In some embodiments, at least a portion of the main body 20 may plastically deform after the delivery device 10 is transitioned from the storage state to the delivery
25 state. For example, one of the living hinges 50 may be plastically deformed. Alternatively, one or more of the living hinges 50 may break when an attempt to transition the delivery device 10 back to the storage state from the delivery state is made. Thus, the transition from the storage state to the delivery state may be rendered irreversible and reuse of the delivery device 10 may be prevented. In some examples, the adhesive 22 may be selected so as to
30 bond more aggressively to the skin 44 than the material forming the main body 20. Thus, upon removal of the delivery device 10, the adhesive 22 may peel off of the delivery device 10. This may also aid in inhibiting reuse of the delivery device 10. In embodiments described herein where the adhesive 22 peels off the delivery device 10, the adhesive 22

may include a pull tab or similar feature which would facilitate subsequent removal from the skin 44.

[00308] Referring now to FIGS. 68-69, another example embodiment of a delivery device 10 is depicted. As shown, the delivery device 10 includes a main body 20 and a reservoir 12. The reservoir 12 includes a sharp bearing body 26 which includes a one dimensional array of delivery sharps 72. Other embodiments may include any suitable number of delivery sharp(s) 72 arranged in any desired pattern. The main body 20 of the delivery device 10 may have a polygonal footprint which may change from a first polygonal shape (e.g. a hexagonal shape) to a second polygonal shape (e.g. a rectangular shape) when the delivery device 10 is transitioned from a storage state to a delivery state.

[00309] The main body 20 may include a first and second end block 70A, B. The end block 70A, B may be disposed in opposition to one another. The end blocks 70A, B may be spaced apart and connected together by a set of side panels 71A, B and a bridge 76. The side panels 71A, B may each have a first end which is connected to the first end block 70A by a hinge 74A. The side panels 71A, B may also each have a second end opposed to the first end which is connected to the second end block 70B by a hinge 74B. Each of the side panels 71A, B may also include an intermediate hinge 74C which may be disposed in an intermediate region of the side panels 71A, B between the first and second end of each side panel 71A, B.

[00310] Similarly to the side panels 71A, B, the bridge 76 may have a first end connected to the first end block 70A by a hinge 74D and a second end opposite the first which is connected to the second end block 70B by another hinge 75E. The bridge 76 may additionally include an intermediate hinge 74F disposed between the first and second ends of the bridge 76. The bridge 76 may include a panel body 78 and a set of strut members 80A, B. the strut members 80A, B may be connected to the panel body 78 via the intermediate hinge 74F of the bridge 76. The bridge 76 may also include an arm member 82. The arm member 82 may be disposed between two strut members 80A, B and may extend toward a proximal face of the end blocks 70A, B. In the example embodiment, the arm member 82 extends from an end of the panel body 78 adjacent the intermediate hinge 74F of the bridge 76. The reservoir 12 may be coupled to the proximal face of the arm member 82 at an end of the arm member 82 opposite the panel body 78.

[00311] In the example embodiment shown in FIGS. 68-69, the hinges 74A-F are depicted as living hinges. In alternative embodiments, at least one of the hinges 74A-F may be conventional hinges and the main body 20 may be constructed as an assembly of a

plurality of components which are coupled to one another via the hinges 74A-F. In still other examples, the main body 20 may be constructed of at least two components. Instead of using a hinge to join the components, the two or more components of the main body 20 may be joined together via welding, heat bonding, solvent bonding, etc.

5 **[00312]** The side panels 71A, B of the delivery device 10 may be displaceable through a displacement range to transition the delivery device 10 between a storage state (shown in FIGS. 68-69) to a delivery state. In the storage state, the side panels 71A, B of the delivery device 10 may be in an outwardly bowed position. The side panels 71A, B may be bent at the intermediate hinges 74C of each of the side panes 71A, B such that the side
10 panels 71A, B may assume this outwardly bowed position. Some pivoting of the side panels 71A, B at the hinges 74A, B connecting the side panels 71A, B to the end blocks 70A, B may also occur to allow the side panels 71A, B to be placed in the outwardly bowed position.

[00313] A pinching force which urges the side panels 71A, B toward one another
15 may be exerted against the side panels 71A, B to displace the side panels 71A, B from the outwardly bowed position to a straightened position. It should be understood that the straightened position need not necessarily be a position in which the side panels 71A, B each extend along straight line. In some examples, the straightened position may be a position in which the side panels 71A, B are less outwardly bowed than in the outwardly
20 bowed position.

[00314] The bridge 76 may also be displaceable through a displacement range to transition the delivery device 10 between a storage state (shown in FIGS. 68-69) to a delivery state. In the storage state, the bridge 76 may be in a raised state in which at least the delivery sharp(s) 72 of the reservoir 12 coupled to the arm member 82 are disposed
25 above the proximal faces of the end blocks 70A, B. The bridge 76 may be bent at the intermediate hinge 74F such that the panel body 78 and struts 80A, B extend upward from the end blocks 70A, B and away from the proximal face of the end blocks 70A, B. Some pivoting of the panel body 78 and struts 80A, B at the hinges 74D, E connecting the bridge 76 to the end blocks 70A, B may also occur to allow the bridge to assume the raised
30 position. A force normal to the proximal faces of the end blocks 70A, B may be applied to the bridge 76 to displace the bridge from the raised position to a lowered position at the opposite end of the bridge's 76 displacement range.

[00315] In various embodiments, actuation of the bridge 76 through its displacement range may transition the delivery device 10 from the storage state to the delivery state.

Additionally, actuation of the side panels 71A, B from the outwardly bowed state to the straightened state may transition the delivery device 10 from the storage state to the delivery state. Actuation of the bridge 76 through its displacement range may result in displacement of the side panels 71A, B through their displacement range since the bridge 76 and side
5 panels 71A, B are coupled to one another through the end blocks 70A, B. Likewise, actuation of the side panels 71A, B through their displacement range may result in displacement of the bridge 76 through its displacement range.

[00316] It may be left up to the user whether actuation of the side panels 71A, B or bridge 76 is used to transition the delivery device 10. Alternatively, whether the bridge 76 is
10 actuated or the side panels 71A, B are actuated may depend upon the patient population to which the user belongs. For example, actuation of the bridge 76 may result in a greater amount of pressure being exerted against the arm member 82. This may aid in ensuring puncture of the delivery sharp(s) 72 into the skin. Thus, it may be desirable that patient populations with certain skin characteristics be instructed to actuate the delivery device 10
15 via the bridge as opposed to the side panels 71A, B.

[00317] Referring now also to FIGS. 70A-70C, with the side panels 71A, B in the outwardly bowed position and the bridge 76 in the raised position (see FIG. 70A), the end blocks 70A, B may be at a first distance from one another. As the side panels 71A, B are displaced toward the straightened position and the bridge 76 is displaced to the lowered
20 position (see FIGS. 70B-70C), the end blocks 70A, B may be displaced apart from one another. As the delivery device 10 may be attached to the skin 44 via adhesive 22 included on the end blocks 70A, B, the spreading of the end blocks 70A, B may cause the skin 44 to be stretched and rendered taught. This may help to facilitate piercing of the skin 44 by the delivery sharp(s) 72 included on the reservoir 12. As shown in FIG. 70C, when the side
25 panels 71A, B reach the straightened position and the bridge 76 reaches the lowered position, the delivery sharp(s) 72 may puncture the skin 44 and the delivery device 10 may be in the delivery state. The reservoir 12 may be compressed between the skin 44 and the arm member 82 to drive fluid out of the reservoir 12 and into the patient. The reservoir 12 may collapse as delivery occurs.

[00318] Referring now also to FIG. 71, a cross section of the delivery device 10 in
30 FIGS. 68-69, a delivery device 10 may include an iris assembly 84 in certain examples. The iris assembly 84 may include a set of iris panels 86A-D which may define an aperture 88 which is variable in size from a closed to a fully open state. The iris panels 86A-D may extend from each of the side panels 71A, B in a direction toward the opposite side panel

71A, B. In the example embodiment, two iris panels 86A-D extend from each side panel 71A, B and are disposed on either side of the intermediate hinge 74C, D of each side panel 71A, B. As the side panels 71A, B are displaced from an outwardly bowed position to a straightened state, the iris panels 86A-D may adjust the aperture 88 such that the aperture 88 provides an opening for the delivery sharp(s) 72 of the reservoir 12 to pass through. As shown in FIG. 71, the aperture 88 may be substantially closed when the delivery device 10 is in the storage state. Such an iris assembly 84 may thus serve as a guard which may aid in preventing inadvertent contact with the delivery sharp(s) 72 during handling of the delivery device 10.

10 [00319] In the example embodiment, one of the iris panels 86A includes a latch projection 90. Another of the iris panels 86B includes a latch catch 92 which may be formed as a notch in that iris panel 86B. The latch projection 90 is ramped. Thus, as the iris panels 86A, B are displaced toward one another, iris panel 86B may deflect and ride up the ramp of the latch projection 90 (see, e.g., FIG. 70B). Upon the latch catch 92 aligning over the latch projection 90, the iris panel 86B including the latch catch 92 may restore to an undeflected state and the latch catch 92 may snap into engagement with the latch projection 90. This may lock the delivery device 10 in the delivery state. The snapping action of the iris panel 86B may generate tactile sensation perceptible, for example, via a user's finger tips. Alternatively or additionally, the snap may generate an audible click or slap. Thus, the delivery device 10 may provide an audible and/or tactile indication that the delivery device 10 has been transitioned to the delivery state. Engagement of the latch projection 90 and latch catch 92 may also aid in inhibiting reuse. As discussed in relation to other embodiments herein, the adhesive 22 may be selected so as to bond more aggressively to the skin 44 than the material forming the main body 20. Thus, upon removal of the delivery device 10, the adhesive 22 may peel off of the delivery device 10. This may also aid in inhibiting reuse of the delivery device 10.

[00320] Referring now to FIGS. 72A-72B, another exemplary embodiment of a delivery device 10 is depicted. The delivery device 10 may include a first portion 100 and a second portion 102. One of the first and second portion 100, 102 may translationally displace with respect to the other of the first and second portion 100, 102 to transition the delivery device 10 from a storage state (see FIG. 72A) to a delivery state (see FIG. 72B). In some embodiments, only a part of the first or second portion 100, 102 may translationally displace with respect to the other. For example, one of the first or second portions 100, 102 may stretch and/or elongate. In certain examples, the transition to the delivery state may be

reversible, though in other embodiments the transition may be a one-way transition that is irreversible. For example, a latch, lock, or other coupling may be engaged to hold the first and second portion 100, 102 in the delivery state or prevent the first and second portion 100, 102 from returning to the storage state. Alternatively, the first and second portion 100, 102 may be bonded together when the delivery device 10 is transitioned into the storage state. Destruction of a portion of the delivery device 10 may be required to disengage the coupling or bonding between the first and second portion 100, 102 once the delivery device 10 is transitioned to the delivery state. This destruction may render the delivery device 10 inoperative. This may inhibit reuse as well as provide a user perceptible (e.g. visual) indication that the delivery device 10 has been used.

[00321] The proximal face of each of the first and second portion 100, 102 may be at least partially covered with adhesive 22. The adhesive 22 may serve to couple the first and second portion 110, 102 to a skin surface at an infusion site on a patient. The delivery device 10 may be adhered to the skin when delivery device 10 is in the storage state and then may be transitioned to the delivery state. As the transition occurs, an adhesive bearing section of the first portion 100 may be displaced with respect to an adhesive bearing section of the second portion 102. Thus, the distance between these adhesive bearing sections may be increased so as to stretch or spread the underlying skin. This may be desirable as the skin may be rendered taught facilitating piercing of the skin by at least one delivery sharp 72 of a reservoir 12 included in the delivery device 10.

[00322] Transition of the delivery device 10 to the delivery state may also result in a proximal displacement or lowering of the delivery sharp(s) 72 toward and into the skin. In embodiments where the delivery sharp(s) 72 are coupled to the reservoir 12, the reservoir 12 may also be proximally displaced. In some examples, the reservoir 12 may be compressed between the skin surface and a section of one of the first and second portions 100, 102 when the delivery device 10 is transitioned from the storage state to the delivery state. Compression of the reservoir 12 may serve to drive fluid out of the reservoir 12, through the delivery sharp(s) 72 and into the target delivery destination in the patient. Additionally, in some embodiments, at least one of an audible or tactile indication may be generated when the delivery sharp(s) 72 are displaced toward the skin.

[00323] Referring now to FIGS. 73-74, an exemplary delivery device 10 is depicted. As shown, the delivery device 10 may be a thin, low profile assembly which is substantially planar. The delivery device 10 may include a proximal portion 110 and a distal portion 112. The proximal portion 110 may be formed of flexible material and in some embodiments

may be elastic so as to allow the proximal portion 110 or at least a portion of the proximal portion 110 to be stretched. The distal portion 112 may be rigid. The proximal face of both the proximal portion 110 and the distal portion 112 may have at least one region which is covered with adhesive 22. The proximal portion 110 may be coupled to the distal portion 112 via the adhesive 22 on the proximal face of the distal portion 112. Such an embodiment may be desirable as the delivery device 10 may be amenable to production via a reel to reel fabrication process in high volume.

[00324] Referring now also to FIGS. 75-76, the proximal portion 110 and the distal portion 112 may also be coupled together via an adhesive locking assembly 114. As shown, the adhesive locking assembly 114 may include a region of locking adhesive 116 which may be disposed on a portion of the proximal face of the distal portion 112. The adhesive locking assembly 114 may include a tether member 118. The tether member 118 may be coupled at a first end to the proximal portion 110 of the delivery device 10 and coupled, at a second opposing end, to the locking adhesive 116 on the distal portion 112. The tether member 118 may be heat staked, welded, or otherwise fixedly coupled to the proximal portion 110 while being relatively lightly coupled to the locking adhesive 116. In some embodiments, the tether member 118 may be constructed of an adhesive liner or backing material which adheres, but is easily peeled from the locking adhesive 116. As shown, the tether member 118 may be at least partially doubled over when the delivery device 10 is in the storage state.

[00325] The proximal portion 110 may include a pull tab 120 which may be disposed at a first end of the proximal portion 110. The pull tab 120 may be an enlarged or widened section of the proximal portion 110. In some embodiments, the pull tab 120 may include a roughened surface or may include bumps, ridges, or the like to facilitate grasping. In alternative embodiments, the pull tab 120 may include a cut out so as form a pull ring.

[00326] The proximal portion 110 may also include at least one ramp element 128 and a folded region 122 at an end of the proximal portion 110 opposite the pull tab 120. In the example embodiment, the proximal portion 110 includes two ramp elements 128 disposed abreast of one another. The folded region 122 may be folded over upon itself a number of times. In the example, the folded region 122 is folded upon itself twice. Thus, when a pulling force is exerted on the pull tab 120, the folded region 122 may unfurl and spool out proximal portion 110 material to allow the proximal portion 110 to elongate. The at least one ramp element 128 may also be displaced as the folded region 122 feeds out material. The number of folds in the folded region 122 may be adjusted to change the

amount that the proximal portion 110 elongates as it is transitioned to the elongated state. The folded region 122 may taper from a larger width to a smaller width over at least a section of the folded region 122. In the example embodiment, the layer of the folded region 122 most proximal to the distal portion 112 tapers to a rounded end. The layer of the folded region 112 most proximal to the distal portion 112 may be substantially immobile and anchored in place by the adhesive 22 of the distal portion 112 as the folded region 122 unfurls.

[00327] As best shown in FIG. 75, the delivery device 10 may include a reservoir 12 which may include at least one delivery sharp 72. Any suitable number of delivery sharp(s) 72 may be included in any desired number of rows and/or columns. Any delivery sharp(s) 72 described herein may be used. The delivery sharp(s) 72 may be included on a sharp bearing body 26 which is coupled to the reservoir 12. The reservoir 12 may be disposed on a resilient cantilevered arm 130 defined in the distal portion 112 of the delivery device 10. The folded region 122 of the proximal portion 110 may include a delivery aperture 124. As shown, when the delivery device 10 is in a storage state the delivery aperture 124 may be out of alignment with the delivery sharp(s) 72. Thus, the proximal portion 110 may cover the delivery sharp(s) 72 and block or guard against inadvertent contact with the delivery sharp(s) 72 when the delivery device 10 is in the storage state. The delivery aperture 124 may, however, allow for the delivery sharp(s) 72 of the delivery device 10 to pass through the delivery aperture 124 and access the skin of a user when the delivery device 10 is transitioned to the delivery state.

[00328] Referring now to FIGS. 77A-78B, to transition the delivery device 10 from the storage state to a delivery state, a pulling force may be exerted on the pull tab 120. The distal portion 112 of the delivery device 10 may be anchored to the skin 44 via the adhesive 22 on the proximal face of the distal portion 112. Thus, the distal portion 112 of the delivery device 10 may be substantially stationary as the transition transpires. The proximal portion 110 may transition from a first state to an elongated state as the delivery device 10 passes from the storage state to the delivery state. As shown, the folded region 122 of the proximal portion 110 may unfurl such that the proximal portion 110 may elongate as the pull tab 120 is pulled. Additionally, in certain embodiments, the proximal portion 110 may stretch allowing for further elongation. The segment of the proximal portion 110 including the adhesive 22 may displace relative to the distal portion 112 of the delivery device 10 as the pull tab 120 is pulled. The adhesive 22 on the proximal portion 110 and distal portion 112 may be displaced apart when the proximal portion 110 is pulled from the first state to the

elongated state. As a result, the skin 44 between the adhesive 22 on the proximal portion 110 and the adhesive 22 on the distal portion 112 may become stretched and taut to facilitate puncture.

5 [00329] As the folded region 122 unfurls, proximal portion 110 material may be fed out such that the proximal portion 110 elongates and the delivery aperture 124 is displaced into alignment with the delivery sharp(s) 72. The at least one ramp element 128 may be displaced in the direction of the pull tab 120. The at least one ramp element 128 may keep the cantilevered arm 130 slightly deflected toward the distal portion 112 as the proximal portion elongates. This may keep the delivery sharp(s) 72 of the reservoir from dragging
10 against the proximal portion 110 as the proximal portion 110 is transitioned to the elongated state. As the at least one ramp element 128 is further displaced, the cantilevered arm 130 may ride over a sloped region of the at least one ramp element 128 and be further deflected toward the distal portion 112 of the delivery device 10. As the folded region 122 continues to unfurl, the at least one ramp element 128 may advance past the cantilevered arm 130.

15 [00330] Once the at least one ramp element 128 has cleared the cantilevered arm 130, the cantilevered arm 130 may restore to an undeflected state as shown in FIGS. 78A and 78B. The delivery device 10 may enter the delivery state when the cantilevered arm 130 is clear of the at least one ramp element 128 and restores to its undeflected state. As the cantilevered arm 130 springs back to an undeflected state, the delivery sharp(s) 72 may be
20 displaced through the delivery aperture 124 and may puncture the skin 44. This may establish fluid communication between the delivery sharp(s) 72 and a target delivery destination in the patient. Additionally, the reservoir 12 may be compressed between the skin 44 and the cantilevered arm 130 when the cantilevered arm 130 restores to its undeflected state. This compression may serve to drive fluid out of the reservoir 12 and into
25 the patient via the delivery sharp(s) 72. The compression may also help to ensure that the reservoir 12 is fully emptied during delivery.

[00331] As shown, the tether member 118 may be peeled from the lock adhesive 116 as the delivery device 10 transitions from the storage state to the delivery state. Once the delivery device 10 reaches the delivery state, the tether member 118 may be at least
30 partially separated from the lock adhesive 116. The exposed lock adhesive 116 may then adhere to the proximal portion 110 to bond the proximal portion 110 in place. The lock adhesive 116 may aggressively adhere to the proximal portion 110. An attempt to separate the proximal portion 110 and lock adhesive 116 may result in damage to one of the components of the delivery device 10. This may help to ensure that the transition of the

delivery device 10 to the delivery state is irreversible. The lock adhesive 116 may also inhibit restoring force exerted by the stretched skin from causing the proximal portion 110 to crumple. Thus, the lock adhesive 116 may hold the adhesive 22 on the proximal portion 110 in place such that the skin remains stretched when the proximal portion 110 is in the elongated state and the user releases the pull tab 120.

[00332] With reference to FIGS. 79-82, another example embodiment of a delivery device 10 is depicted. FIG. 79 depicts the example delivery device 10 in a storage state. FIG. 80 depicts the example delivery device 10 in a delivery state. FIG. 81 and FIG. 82 depict exploded views of the example delivery device 10. As shown, the example delivery device 10 may comprise an actuator. In some embodiments the actuator may form a top 306, or cap, having at least one depression or concavity 308 therein (three such concavities 308 are shown but it would be understood that the number need not be three). The concavities 308 may serve to facilitate twisting of the top 306 by a user via fingertip placement therein. The top 306 may be of a hooded, or convex shape, and may be made of a plastic formed by injection molding or any other suitable technique as would be known to one of skill. One of skill would appreciate that the top 306 need not be limited to any particular shape provided that it can be twisted by a user.

[00333] As shown, the exemplary top 306 sits on a base body 309. The top 306 engage with a threaded post or screw 310 included as part of the base body 309. In some non-limiting examples, the threaded screw 310 may be made of a plastic material formed by injection molding and may be formed integrally with the rest of the base body 309. One of skill would appreciate that other materials and manufacturing techniques could be used to construct the threaded screw 310.

[00334] In an example embodiment, a user may first remove an adhesive liner 265 (see, e.g., FIG. 24) from the delivery device 10. In addition to covering an adhesive bearing pad 312 of the delivery device 10, the adhesive liner 265 may, in some embodiments, have been attached to cover and maintain a previously sanitized state of the delivery device 10. Such a state may be created prior to attaching the adhesive liner 265 to any of the delivery devices 10 described herein. In some examples, the user may peel off the adhesive liner 265 similarly to the manner in which a user peels a liner off a bandage prior to applying the bandage. Once the liner 265 is removed, a user may then apply the delivery device 10 to the skin. As in the example shown, the adhesive pad 312 may be annular in shape. In some embodiments, the adhesive pad 312 may be ultrasonically welded to the delivery device 10.

Those of skill would understand that other suitable techniques to adhere the adhesive pad 312 to the delivery device 10 may be used.

5 **[00335]** After affixing the delivery device 10 to the skin, the user may then twist the top 306 of the delivery device 10 and thereby cause the top 306 to advance proximally (e.g., toward the skin) along the threads of the threaded screw 310. Inside the threaded screw 310 a breakable material, or frangible 314 may be housed. The frangible 314 may inhibit displacement of the top 306 and other components of the delivery device 10 until a sufficient force is applied to the top 306. This may aid in preventing transition of the delivery device 10 to a delivery state during storage.

10 **[00336]** In the example embodiment, the frangible 314 is provided as at least one tab which projects from a carriage 315 that may be disposed within the bore 317 of the threaded post 310. In some embodiments, the carriage 315 may include a set of three frangibles 314 which are disposed at even angular increments about a first end of the carriage 315. The bore 317 may include a ledge 319 to support at least one of the frangibles 315 and preferably a ledge 319 to support each frangible 314. With the frangibles 314 resting on the ledge(s) 319, the carriage 315 may be inhibited from displacing within the bore 317 and twisting motion of the top 306 may be impeded. In certain examples, the ledge(s) 319 may each be an end of a track or rail (best shown in FIG. 81) disposed in the bore 317 which may help to guide displacement of the carriage 315 within the bore 315.

20 **[00337]** The top 306 may incorporate a central projection 318 (e.g. column or stepped column as shown) that rests upon a portion of the carriage 315. As the top 306 screws downward or proximally toward the skin surface, the projection 318 may cause the frangible(s) 314 may be pressed against the respective ledges 319. The pressure exerted against the frangible(s) 314 may cause the frangible(s) 314 to break off, allowing the carriage 315 to travel proximally within the bore 317. The carriage 315 may displace proximally and eventually a second end of carriage 315 (opposite the first end from which the frangibles 314 project) may contact the skin surface. It would be understood by one of skill that once the frangible(s) 314 have broken, reuse of the delivery device 10 may be inhibited.

30 **[00338]** The adhesive pad 312 of the delivery device 10 may have a central aperture 323 through which a portion of the carriage 315 may extend. Skin may not be retained in position against the delivery device 10 in the region of the central aperture 323. Thus, as the carriage 315 continues to displace proximally, the skin in this region may be pressed and stretched as it is displaced by the carriage 315. This may render the skin aligned with the

central aperture 323 taut. The base body 309 may include a shelf 321 which extends into the bore 317 at the proximal end of the bore 317 and acts as a stop surface. The carriage 315 may cease proximal displacement upon contacting the shelf 321.

[00339] The top 306 may be at an intermediate point in its travel along the post 310
5 when the carriage 315 contacts the shelf 321. As shown, the carriage 315 may include a second frangible 325 or set of frangibles 325. In some embodiments, there may be three second frangibles 325 spaced at even angular intervals about the carriage 315. The first frangible(s) 314 may be weaker (e.g. thinner) than the second frangible(s) 325. Thus, the second frangible(s) 325 may only break after the first frangible(s) 314. The projection 318
10 from the top 306 may abut the second frangible(s) 325 when in the carriage 315 is against the stop provided by the shelf 321. The second frangible(s) 325 may impede displacement of the top 306. Further actuation of the top may exert force against the second frangible(s) 325 and result in breaking of the second frangible(s) 325. With the second frangible(s) 325 broken, the top 306 may be free to move proximally while the carriage 315 remains
15 stationary (against the stop provided by the shelf 321). It would be understood by one of skill that once the frangible(s) 325 have broken, reuse of the delivery device 10 may be inhibited.

[00340] As shown, the delivery device 10 may also include a delivery aid 320. The delivery aid 320 may be a flat plate from which a column extends, as shown in the example.
20 The delivery aid 320 may be made of a plastic material formed by injection molding. One of skill would appreciate that other materials and manufacturing techniques could be used to construct the delivery aid 320. The delivery aid 320 may be positioned atop a reservoir 12 that contains a fluid such as, e.g., a medical agent (e.g., a vaccine) and incorporates on an underside a sharp bearing body 26 (see, e.g., FIG. 31) including at least one delivery sharp
25 72 (see, e.g., FIG. 31).

[00341] In some embodiments, the delivery aid 320 may be attached to the proximal end of the projection 318 via adhesive. In some embodiments, the delivery aid 320 may rest upon a shelf within the carriage 315. The reservoir 12 may be retained via friction or via a slip fit within an aperture of the carriage 315 as shown. In some examples, a weak adhesive
30 may hold the reservoir 12 in place within the aperture. In other embodiments, the friction fit may be augmented by a gasket member (e.g. O-ring) disposed between the reservoir 12 sides and the aperture of the carriage 315.

[00342] With the second frangible(s) 325 broken, the delivery aid 320 may concentrate force generated as the top 306 is actuated against a reservoir 12 of the delivery

device 10. In embodiments where the delivery aid 320 rests upon a shelf in the carriage 315 a portion of the delivery aid 320 may deform or break to allow movement beyond the shelf. The delivery aid 320 and reservoir 12 may move downward as the top 306 continues to advance along the post 310. The force exerted by the top 306 may be sufficient to overcome
5 friction or adhesive holding the reservoir 12 in place. The delivery aid 320 moving downward may cause the reservoir 12 to move downward until the delivery sharp(s) 72 (see, e.g., FIG. 31) penetrate into the skin surface. At that point, as shown in FIG. 80, the reservoir 12 may be sandwiched between the skin and the projection 318 of the top 306. As the top 306 continues to displace proximally, pressure from the delivery aid 320 builds in
10 the reservoir 12, causing delivery of the fluid contained within the reservoir 12 through the delivery sharp(s) 72 and into the patient. At that point the top 306 stops twisting and may have reached the end of its displacement range. The top 306 may abut against the base body 309 at the end of the displacement range and the base body 309 may present a mechanical interference to further displacement. Once the top 306 stops moving, the user may remove
15 the delivery device 10 from the skin.

[00343] As previously discussed, it may be desirable to prevent reuse of the delivery device 10. It may also be desirable to provide a delivery device 10 in which the delivery sharp(s) 72 scratch across the surface of the skin prior to penetrating the skin surface. In an embodiment, a delivery device 10 may include an actuation assembly which may include
20 first and second displaceable members. The members may be displaceable from a separated state to a proximal state with relation to each other. The members may transition from the separated state to the proximal state when the delivery device 10 is actuated and/or when the delivery device 10 delivers its contents. The members may include cooperating coupling features that may engage with each other upon the members approaching or reaching the
25 proximal state. Once the cooperating coupling features are engaged, the coupling features may inhibit separation of the members and may maintain the members in the proximal state.

[00344] With reference to FIGS. 83-85, an example embodiment of such a portion of an actuation assembly 327 for a delivery device 10 is depicted. The delivery device 10 may comprise a one-piece or monolithically formed flexure. The flexure may be formed as a pair
30 of first and second bodies 320A, 320B, vertically spaced such that the first body 320A is positioned above or in a separate plane than the second body 320B. In the example embodiment, the first and second bodies 320A, B are concentric round bodies, and are specifically shown as circles. The flexure may be made of a bendable plastic formed by injection molding or any other suitable technique as would be known to one of skill. The

bodies 320A, 320B may be coupled by at least two flexible struts 322 integral to the flexure. In the example, six such flexible struts 322 are shown but it would be understood that the number need not be six. The struts 322 may be disposed at even angular increments though need not be in all embodiments. The struts 322 may extend between the bodies 320A, 320B
5 at an angle to the bodies 320A, 320B that is not perpendicular.

[00345] At least one hook 324, integral to one of the bodies 320A, B may be included. The other of the bodies 320A, B may include at least one catch 326. In the example embodiment, the first body 320A includes a number of hooks 324 which extend downward therefrom toward the second body 320B. Six such hooks 324 are shown but it
10 would be understood that the number need not be six. In the example, the hooks 324 are evenly spaced around the first circle 320A though need not necessarily be in all embodiments. At least one catch 326, integral to the second body 320B is also shown in the example embodiment. Each of the catches 326 is situated at a point on the second body 320B that is not directly beneath a hook 324 of the first body 320A. The example catches
15 326 extend upward from the second body 320B toward the first body 320A. Six such catches 326 are shown but it would be understood that the number need not be six. The catches 326 may be spaced around the second body 320B at even angular increments. The catches 326 may be positioned such that the respective catches 326 and hooks 324 would engage one another upon actuation of the flexure. The flexure may, for example, be actuated
20 by applying pressure on the flexure via a portion of the delivery device 10 within which it is assembled. The catches 326 may be substantially shaped in the form of an upside down Latin character "U".

[00346] As the first body 320A is displaced toward the second body 320B at least one of the bodies 320A, B may also rotate. If one of the bodies 320A, B is rotationally
25 constrained, only the other of the bodies 320A, B may rotate as the bodies 320A, B are displaced toward one another. With the second body 320B rotationally constrained, pushing down on the first body 320A from above may cause the flexible struts 322 to flex. The hooks 324 may rotationally (about an axis passing through the center points of the bodies 320A, B) displace. The hooks 324 and first body 320A may also translationally displace as
30 the first body 320A approaches the second body 320B. The hooks may also translationally displace with respect to the catches 326 until the hooks 324 contact the catches 326. The hooks 324 may deflect around the catches and then resiliently restore into engagement with the catches 326. Thus, as the struts 322 attempt to resiliently restore to their undeflected state, the first and second bodies 320A, B may be held together by the engagement of the

hooks 324 and catches 326. Using a single piece flexure (formed, for example, by injection molding) may allow the delivery device 10 to be manufactured at relatively lower cost. The hooks 324 engagement with the catches 326 may also help to prevent reuse of a delivery device 10 in which the flexure is included. The engaged hooks 324 may also help maintain
5 pressure against a reservoir 12 of a delivery device 10 needed to ensure delivery of a medical agent (e.g., a vaccine) into a patient through one or more delivery sharp 72 (see, e.g., FIG. 31).

[00347] The rotational displacement of one of the bodies 320A, B may be harness to help drive the delivery sharp(s) (see, e.g., FIG. 31) across the skin surface to scratch it prior
10 to piercing the skin. In the example embodiment described above, the delivery sharp(s) 72 (see, e.g., FIG. 31) may be constrained to move in tandem with the first body 320A. Thus, the delivery sharp(s) 72 (see, e.g., FIG. 31) would rotate as they are displaced against the skin.

[00348] Referring now to FIG. 86, an example package 400 is depicted. The package
15 400 may house a delivery device 10 during distribution and shipping. The package 400 may also include other components such as printed instructions and/or a medical wipe which may be used for injection site preparation. The package 400 may hold the delivery device 10 and perhaps other contents in place during distribution and may help to prevent premature or inadvertent actuation of the delivery device 10. The package 400 may include
20 an interior cavity (a portion of the package 400 is depicted as transparent in FIG. 86) which may have one or more receivers 402 for a delivery device 10. The receivers 402 may constrain the delivery device 10 within the package 400 such that the delivery device 10 does not shift or jostle excessively during handling. The package 400 may also protect a delivery device 10 from exposure to the surrounding environment. In some embodiments,
25 the package 400 and delivery device 10 may be sterilized (e.g. via EtOx) and the package 400 may maintain the delivery device 10 in this state until just prior to use.

[00349] The package 400 itself may be constructed of a first component 404 and a second component 406. The first component 404 may be a rigid base. The rigid base may include a well in which a delivery device 10 (e.g. similar to that shown in FIG. 25) may be
30 housed. The rigid base may be a plastic component. The second component 406 may be a peelable cover which may be coupled to a face of the first component 404. The peelable cover may be removed by a user to access the delivery device 10 just prior to use.

[00350] As shown, the package 400 may include at least one unique identifier 408. In other embodiments, a unique identifier 408 may instead or additionally be included on a

delivery device 10 or component thereof. Any suitable unique identifier(s) 408 and combinations thereof may be used. In some embodiments, an RFID may be used. In other examples, the unique identifier 408 may be implemented as a printed indicium such as a bar code, data matrix, QR code, etc. The unique identifier 408 may encode various information
5 about the delivery device 10 or contents of the reservoir 12 of the delivery device 10. For example, the unique identifier 408 may include product identity information, product lot information, product serial number, dose size information, etc.

[00351] The unique identifier 408 may be read by a reader 410. The reader 410 may be a dedicated reader or a device such as, e.g., a smart phone, tablet, smart device, laptop, or
10 other portable device in some embodiments. Where a smart phone or the like is utilized, a dedicated delivery device app may run on the smart phone. Where a smart phone or the like is used, the reader 410 may include multiple pieces of hardware which may be used to read a unique identifier 408 (e.g. one or more front facing imager and one or more rear facing imager). The reader 410 used may depend on whether the delivery device 10 is intended for
15 use at home by an individual user or in a clinical setting (e.g. vaccination center, hospital, clinic, or other care facility). A smart phone may be convenient for a use as a reader 410 if delivery via the delivery device 10 is to be, for example, self-administered by a patient (e.g. at home).

[00352] The reader 410 may communicate with a database 412 (e.g. via internet, other network, cloud platform, etc.). Prior to use of the delivery device 10, a user may read the unique identifier 408 with the reader 410. The identifier 408 for the delivery device 10 may be checked against the database 412 to ensure the unique identifier 408 is not associated with a delivery device 10 which has already been used, subject to recall, expired, etc. The database 412 may also be updated to indicate that the delivery device 10 associated
25 with the unique identifier 408 has been used. Thus, the reader 410 and database 412 may aid in inventory management. Other usage information may also be saved. In some embodiments, geolocation data indicating the location of the package 400 when the unique identifier 408 is read may also be saved to the database 412.

[00353] Depending on the infrastructure available, the data may be stored offline in a memory of the reader 410 until a robust connection to the internet or another suitable network is formed. Thereafter, data may be uploaded to the database 412. Alternatively, data may be sent to the database 412 as it is acquired at the reader 410.
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[00354] In some embodiments, a patient may be required to pre-register in order to receive a delivery device 10. In some embodiments, the reader 410 may be used to register

(e.g. where an app on a smart phone is used). Where the reader 410 uses a smart phone app, the smart phone app may inhibit usage of the reader 410 for the delivery in the event that certain services are not enabled. Such an app may generate a unique identifier or code when predefined requisite services (e.g. location tracking, push notifications) have been enabled.

5 This code may be provided to the database 412 and may be referred to as a registration code. A patient may be required to provide the code in order to receive a delivery device 10. The code may be input to a dispenser or provided to distribution personnel and checked against the database 412. A delivery device 10 may be provided to the patient in the event that the code matches a registration code stored on the database 412. In other embodiments, 10 the controller 416 of the reader 410 may generate a manual input screen to collect desired information in the event that the user elects not to enable one or more service or otherwise provide desired user information. For example, when location tracking is not enabled the app may generate a location data input screen. Input of information into any such screens may be required before a code is generated and provided to the database 412.

15 **[00355]** In some embodiments, when the unique identifier 408 on the package 400 is read, a controller 416 of the reader 410 may generate instructions on a user interface 414 of the reader 410. The instructions may include text, images, animations, videos, etc. detailing how to use the delivery device 10. The instructions may guide a user, step-by-step, from opening of the package 400 to discarding of a delivery device 10 after use. In some 20 embodiments, each step of the instructions set may be followed by generation, via the controller 416, of a prompt on the user interface 414. The user may be required to interact with the prompt to proceed to the next set of instructions. User interactions may be logged and stored in a database 412. This may aid in confirming that a particular delivery device 10 was not only received by a patient, but also applied and used. In some embodiments, the 25 controller 416 may generate a notification (e.g. visual, tactile, audio, or some combination thereof) in the event that not all steps have been completed. In other embodiments, one or more message may be generated in the event that a user is unresponsive to prompts. For example, where a smart phone or the like is used, the messages may be push notifications generated by the app for the delivery device 10.

30 **[00356]** In other embodiments, at least one message generator 418 in data communication with the database 412 may generate, for instance, a text message, email, phone call (e.g. automated message or connect the user to a human operator) which may be sent to a telephone number or email address provided by the user. In the event that a delay greater than a predefined period of time has occurred since a previous prompt has been

interacted with by the user, the message generator 418 may send a communication to the patient. The type of communication triggered may escalate if no response is received after a communication is sent by a message generator 418. The communication may initially be a text message or push notification. In some embodiments, a push message may preferably be
5 sent or may be sent instead of a text message in the event that cellular service is unacceptable or below a threshold. If no user interaction is received after a predefined escalation period, a message generator 418 may generate a more obtrusive communication (e.g. a phone call). Any suitable number of escalation tiers may be used.

[00357] In some embodiments, a patient may also provide additional data via the
10 reader 410. This data may be stored in the database 412 and analyzed (e.g. via a cloud analytics tool or tool set). For example, users may indicate via the reader 410 that a problem with their delivery device 10 has occurred. This data may be checked against data associated with other delivery devices 10 from the same lot. If more than a predetermined threshold of problematic delivery devices 10 are deemed to exist within a lot, the lot may be
15 flagged for investigation and prevented from being distributed or used. Alternatively or additionally, a patient may be prompted to provide certain post injection information via the reader 410. For example, the patient may be requested to fill out a side-effect questionnaire or other form which may be generated by the controller 416 of the reader 410 on the user interface 414. Side-effect data may be analyzed to identify patterns common to certain
20 patient types or delivery devices 10 (e.g. delivery devices 10 of the same lot or holding the same contents). Analysis may be conducted via a cloud analytics tool or toolset.

[00358] In certain examples and referring now also to FIG. 87, a delivery device 10 may include a revealing indicator 450 or identifier which may be hidden when the delivery device 10 is in a storage state. Upon or after use of such a delivery device 10, the revealing
25 indicator 450 may become accessible. The revealing indicator 450 may then be scanned by a reader 410 and confirmation of the scan or scan data captured during the scan may be sent to the database 412. The revealing indicator 450 may encode a unique identifier (e.g. barcode, QR code, data matrix, etc.) specific to the delivery device 10 in certain examples. Thus, the revealing indicator 450 may serve as a confirmation that a delivery was performed
30 with a specific delivery device 10. In some examples, the database 412 or certain data within the database 412 may also be accessible via a payment provider (e.g. governmental body, insurer, etc.). In order to help ensure that the revealing identifier 450 is scanned to document delivery via a delivery device 10, reimbursement or payment may be tied to scanning of the revealing identifier 450. For example, a payment service may query the

database 412 to determine usage status of a delivery device 10 and only allow payment in the event that a delivery device 10 has been used. Indication in the database 412 that the revealing indicator 450 has been scanned may flag a delivery device 10 as used.

[00359] Referring now to FIG. 87, in some examples, a delivery device 10 may include a first portion and a second portion which may become disassociated when a user removes the delivery device 10 from the skin. In the example embodiment, a delivery device 10 including a main body 20 and a reservoir assembly 12 similar to that shown in FIG. 25 for instance is depicted. A revealing indicator 450 may also be included in other delivery device 10 embodiments described herein. In the example illustrated in FIG. 87, the exemplary first portion is the reservoir assembly 12 (see, e.g., FIG. 59) and the exemplary second portion is the main body 20. In such an example, a revealing indicator 450 may be placed on a distal side of the reservoir assembly 12. View of the revealing indicator 450 may be obstructed by the main body 20 when the first and second portion are coupled together (the main body 20 may be opaque or at least sufficiently translucent). As shown, when the main body 20 and reservoir assembly 12 become disassociated, the revealing indicator 450 may become visible and may be scanned to aid in confirming that that delivery device 10 has been used.

[00360] In some examples, the holder 270 (see, e.g., FIGS. 47-50 and FIGS. 51A-51C) of the reservoir assembly 12 may include an adhesive on at least a portion of the proximal face of the holder 270. In various embodiments where the of the holder 270 reservoir assembly 12 includes tabs 277 (see, e.g., FIG. 51B) which couple into slits of the main body 20, the tabs 277 may disengage with the slits 278 (see, e.g., FIG. 45) of the main body 20 when the user attempts to remove the delivery device 10 from the skin. The bond between the adhesive on the holder 270 and the skin may be sufficient to overcome or disengage the coupling between the tabs 277 and the main body 20 when the patient pulls on the main body 20 to remove the delivery device 10. That is, the adhesive may withstand any forces applied to disassociate the main body 20 from the rest of the delivery device 10 when a user pulls on the main body 20. Thus, the reservoir portion 12 may remain adhered to the skin and the main body 20 may be removed. The revealing indicator 450 included on the reservoir 12 may become visible and may be scanned by a reader 410 (see, e.g., FIG. 86). The reservoir assembly 12 may then be peeled off the skin by the patient. In examples where the reservoir assembly 12 is adhered to the main body 20, an adhesive connection between the skin and reservoir assembly 12 may be stronger than the adhesive connection between the reservoir assembly 12 and main body 20. Thus, as a patient pulls on the main

body 20, the main body 20 may decouple from the reservoir assembly 12 to reveal the revealing indicator 450.

[00361] In other embodiments, and referring now to FIG. 88, a delivery device 10 may provide a mark 510 on the skin when the delivery device 10 is applied or applied for at least a predetermined period of time. In some embodiments, a marking agent such as an ink or the like may be included on a portion of the delivery device 10 adjacent the skin 512. Alternatively, the marking agent may be manufactured into a skin compatible adhesive for coupling the delivery device 10 to the skin during use. In examples where pressure sensitive adhesive is used, pressure applied when the delivery device 10 is used may activate the adhesive and also release the marking agent. The marking agent may at least partially transfer to the skin 512 or otherwise mark the skin 512 when the delivery device 10 is applied. Alternatively, the delivery device 10 may apply a temporary tattoo over the course of the injection. In some embodiments, the mark 510 created may have a pattern which encodes certain information about the delivery device 10. In the example embodiment, a series of "X"'s are shown though any suitable mark 510 may be produced. As indicated by the injection bleb 514, the mark 510 may become visible after the injection is completed and the delivery device 10 is removed from the skin 512.

[00362] When the delivery device 10 is removed, the mark 510 left on the skin 512 may be imaged by a reader 410 (see, e.g., FIG. 86). This mark 510 may help to verify that an injection has been administered to a patient by a delivery device 10. In some embodiments, the controller 416 (see, e.g., FIG. 86) of the reader 410 may analyze the image to determine whether the mark 510 is present. When the controller 416 determines an appropriate mark 510 is present, the database 412 (see, e.g., FIG. 86) may then be updated to indicate that the delivery device 10 associated with the previously scanned unique identifier 408 has been used. It should be understood that in embodiments mentioned herein where the controller 416 is described as performing image analysis or other analysis, this need not be the case. For example, the image may be communicated to the database 412 by the reader 410 and a cloud analytics tool may be utilized to verify that the image indicates a delivery has occurred. Regardless of where analysis is performed, the image may be uploaded to the database 412.

[00363] Referring now primarily to FIG. 89, in certain embodiments the reader 410 (see, e.g., FIG. 86) may include at least one image sensor which is sensitive to one or more wavelength(s) outside of the visible spectrum. The non-visible spectrum wavelength or spectrum to which the image sensor is sensitive may be a wavelength which has a higher

penetration depth into skin than light in the visible spectrum. The reader 410 may include at least one image sensor which is sensitive to various wavelengths in the infrared spectrum (e.g. near infrared). A CCD or CMOS image sensor may be included in various embodiments. Any such capable sensor in the reader 410 may not include an IR filter (e.g. IR blocking film) which is commonly applied to typical consumer imaging equipment. The sensor may be associated with a filter which blocks visible light. In some embodiments, the imager may be a thermographic or thermal imaging imager. Multiple imagers which capture images in different non-visible spectrums may be included (e.g. at least one for near infrared and at least one for longer infrared wavelengths).

10 **[00364]** After a delivery device 10 has been used, the reader 410 may be used to capture at least one image of the injection site. At least one image may be captured or generated based on light other than that in the visible spectrum. Image data in the visible spectrum may also be captured in some embodiments. A controller 416 (see, e.g., FIG. 86) of the reader 410 (see, e.g., FIG. 86) may generate a prompt (e.g. within an app) to capture
15 the image(s). In certain embodiments, the controller 416 may also automatically open an image capture program. The controller 416 may enable image capture with an appropriate imager of the reader 410 (e.g. if multiple imagers are included in a reader 410).

[00365] The image data may be analyzed to determine the presence of a bleb 514 formed within the skin during the delivery. Analysis may be automated or may be
20 conducted by a human operator viewing images via a network connection to a database 412 (see, e.g., FIG. 86). As light outside of the visible spectrum may have greater penetration into the skin, the use of such light for imaging purposes may make certain subsurface features in the skin discernable or more easily discernable. This may help to, for example, facilitate detection of the bleb 514. Additionally, the injected agent may differ in
25 temperature from the patient. An area with a temperature that differs from the surrounding area on the patient may be discernable. The injection site may, for example, be cooler than the surrounding regions of the patient. FIG. 89, for instance, depicts a thermal image of an arm after injection. As shown, a cool region (darker gray) is discernable in the image and corresponds to the location of a bleb 514 on the skin.

30 **[00366]** In the event that the image(s) contain characteristics of a bleb 514, it may be concluded that a delivery was actually performed with the delivery device 10 and was successful. In some embodiments, the image(s) may be required to comply with at least one predefined characteristic of interest. For example, in certain implementations, it may be required that a bleb 514 is detected and is of a certain size (e.g. in relation to a marking

510). Additionally, the image(s) may be required to be devoid of characteristics indicative of an improper injection. For example, where a thermal imager is used, a cool region corresponding to a bleb 514 with one or more adjacent cool region or a cool region 514 or a size beyond a certain limit may be flagged as having characteristics of a leak. In such an example, the analysis may indicate an unsuccessful delivery from a delivery device 10.

[00367] The analysis may be performed by the controller 416 (see, e.g., FIG. 86) of the reader 410 (see, e.g., FIG. 86). Alternatively, the analysis may be conducted on a networked server such as a cloud server. As mentioned above, human analysis may be used. The outcome of the analysis and optionally the image(s) may be provided to and stored on at least one database 412 (see, e.g., FIG. 86). In the event that the image(s) indicate an improper delivery or no delivery, a notification for the user may be generated for display on the reader 410 (e.g. by the controller 416 see, e.g., FIG. 86). In the event that a proper delivery has been documented, a confirmation may be generated that the injection was successful.

[00368] In examples where the reader 410 is a smart phone, any app used may generate a confirmation that injection with a delivery device 10 was performed upon request by a user. The controller 416 of the reader 410 may generate an option (e.g. displayed button) which may be interacted with by the user to display a conformation notice regarding the injection. Where a delivery device 10 is used to perform a vaccination, the app may provide a proof of vaccination or virtual vaccination record or card which is automatically populated with various information about the user's vaccination. The vaccination record may be stored in a memory of the reader 410 or may be stored in a database 412 (see, e.g., FIG. 86) accessible via the reader 410 (or stored in multiple locations). Thus, the reader 410 may be used to provide proof of injection if necessary. For example, the reader 410 could be used to prove vaccination in order to access certain spaces (restaurants, stadiums, workplaces, other venues, airplanes or airports, ships, public transportation, etc.).

[00369] In still other embodiments, a container 350 which houses a packet 208 may be included in a delivery device 10 as described elsewhere herein (see, e.g., FIG. 11). One of the packet 208 and container 250 may include a first chemical or chemicals while the other may include a second chemical or chemical. A dye or dyes may also be included in one of the container 350 and packet 208. When pressure is applied to the delivery device 10 to shift the delivery device from the storage state to the delivery state, the packet 208 may rupture and the first and second chemicals may mix. The chemicals may react and produce a visually perceptible effect. A chemiluminescent reaction may, for example, be initiated

when the first and second chemicals are mixed. In examples of such embodiments, chemicals commonly used in glow sticks may, for instance, be filled into the container 350 and packet 208.

5 [00370] The delivery device 10 may include one or more window (e.g. slots 254 or apertures 255 in a main body 20 like the example shown in FIGS. 21A-21I) through which light generated by the reaction may be perceived. A reader 410 (see, e.g., FIG. 86) may image the delivery device 10 as it is injecting and a controller 416 (see, e.g., FIG. 86) may analyze the image(s) to verify presence of the light from the reaction. When the controller 416 determines that a chemiluminescent reaction is documented in the image(s), the
10 controller 416 may communicate with the database 412 and the database 412 may be updated to indicate the delivery device 10 has been used.

[00371] In some alternative embodiments where two (or more) chemicals are combined to produce a visibly perceptible effect, the first chemical or chemicals may be included in the medical wipe. The user may wipe the injection site during preparation and
15 some of the first chemical or chemicals may be deposited on the skin surface. The second chemical or chemicals may be carried by or released by the delivery device 10 during the course of the injection. The first and second chemicals may interact by the time the injection has completed and may, for instance, result in a color change to a delivery indicating color. An image of the injection site may be taken by the reader 410 and analyzed (e.g. locally by
20 the controller 416 or via a cloud analytic tool after the image is uploaded to the database 412) to confirm presence of the delivery indicating color. In the event that the color change is documented in the image, the database 412 may be updated to indicate that the delivery device 10 has been used.

[00372] Various alternatives and modifications can be devised by those skilled in the
25 art without departing from the disclosure. Accordingly, the present disclosure is intended to embrace all such alternatives, modifications and variances. Additionally, while several embodiments of the present disclosure have been shown in the drawings and/or discussed herein, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read
30 likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. And, those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto. Other elements, steps, methods and techniques that are insubstantially different from those described above and/or in the appended claims are also intended to be within the scope of the disclosure.

[00373] The embodiments shown in drawings are presented only to demonstrate certain examples of the disclosure. And, the drawings described are only illustrative and are non-limiting. In the drawings, for illustrative purposes, the size of some of the elements may be exaggerated and not drawn to a particular scale. Additionally, elements shown
5 within the drawings that have the same numbers may be identical elements or may be similar elements, depending on the context.

[00374] Where the term "comprising" is used in the present description and claims, it does not exclude other elements or steps. Where an indefinite or definite article is used when referring to a singular noun, e.g. "a" "an" or "the", this includes a plural of that noun
10 unless something otherwise is specifically stated. Hence, the term "comprising" should not be interpreted as being restricted to the items listed thereafter; it does not exclude other elements or steps, and so the scope of the expression "a device comprising items A and B" should not be limited to devices consisting only of components A and B.

[00375] Furthermore, the terms "first", "second", "third" and the like, whether used in
15 the description or in the claims, are provided for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances (unless clearly disclosed otherwise) and that the embodiments of the disclosure described herein are capable of operation in other sequences and/or arrangements than are described or
20 illustrated herein.

What is claimed is:

1. A delivery device comprising:
 - a main body including a central region and a peripheral region, the central region having a top surface spaced apart from and connected to a base, the peripheral region being defined by a plurality of petal members and a plurality of first slots therebetween, the plurality of petal members extending outward from the base;
 - an adhesive coupled to at least a part of the main body; and
 - a collapsible reservoir coupled to at least one delivery sharp.
2. The delivery device of claim 1, wherein the top surface is convex, and wherein the top surface includes a plurality of second slots therein.
3. The delivery device of claim 1, wherein the central region includes a plurality of fenestrations disposed in a ring along a perimeter of the top surface.
4. The delivery device of claim 1, further comprising a sharp bearing body including the at least one delivery sharp, the sharp bearing body being coupled to the collapsible reservoir, wherein the collapsible reservoir is coupled to an inside surface of the central region.
5. The delivery device of claim 4, wherein when the delivery device is in the storage state, the collapsible reservoir contains a fluid and the adhesive is affixed to a penetrable surface of a member external to the delivery device, and wherein when the delivery device is in the delivery state, the penetrable surface has been stretched by the adhesive, the at least one delivery sharp has penetrated the penetrable surface, and the collapsible reservoir has been urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp.
6. The delivery device of claim 4, wherein the adhesive is coupled to at least a part of at least two of the plurality of petal members on sides thereof most distal to the top surface.
7. The delivery device of claim 6, wherein when the delivery device is in the storage state, the collapsible reservoir contains a fluid and the adhesive is affixed to a penetrable surface of a member external to the delivery device, and wherein when the delivery device is in the delivery state, the penetrable surface has been stretched by the adhesive, the at least one delivery sharp has penetrated the penetrable surface, and the collapsible reservoir has been urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp.
8. The delivery device of claim 4, wherein the at least one delivery sharp is a microneedle including a flow lumen with an elongate cross-section.
9. The delivery device of claim 1, wherein an interior volume of the reservoir is partitioned into a first section and a second section.
10. The delivery device of claim 9, wherein the first section and second section are in fluid communication with one another through at least one flow restrictor.

11. The delivery device of claim 9, wherein the first section has a variable interior volume and the second section has a fixed interior volume smaller than the variable interior volume.
12. The delivery device of claim 11, wherein the fixed interior volume is more proximal the at least one delivery sharp than the variable interior volume.
13. The delivery device of claim 9, wherein at least two of the plurality of petal members are configured to curl in response to pressure applied on the top surface as the delivery device transitions to the delivery state.
14. The delivery device of claim 13, wherein the at least two of the plurality of petal members are configured to curl so as to have a substantially constant radius of curvature in response to pressure applied on the top surface as the delivery device transitions to the delivery state.
15. The delivery device of claim 9, wherein at least a part of a first one of the plurality of petal members is configured to move farther away from at least a corresponding part of a second one of the plurality of petal members during at least a part of the transition between the storage state and the delivery state, the first and second petal members being positioned opposite each other.
16. The delivery device of claim 9, wherein at least a part of a first one of the plurality of petal members is configured to move farther away from at least a corresponding part of a second one of the plurality of petal members during at least a part of the transition between the storage state and the delivery state and thereby stretch a surface to which the delivery device is affixed with the adhesive, the first and second petal members being positioned opposite each other.
17. The delivery device of claim 1, wherein the adhesive is coupled to at least a part of at least two of the plurality of petal members on sides thereof most distal to the top surface.
18. The delivery device of claim 1, wherein the top surface is configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave.
19. The delivery device of claim 1, wherein the reservoir includes an orifice plate.
20. A method of delivering a medical agent comprising:
 - affixing to a skin surface a delivery device that includes at least one delivery sharp coupled to a collapsible reservoir containing the medical agent, the delivery device being in a storage state; and
 - applying pressure to the delivery device directed at the skin surface to transition the delivery device to a delivery state and penetrate the skin surface with the at least one delivery sharp, and to cause collapse the reservoir to force the medical agent into the skin via the at least one delivery sharp.

21. The method of claim 20, wherein the method further comprises stretching the skin surface as the delivery device transitions from the storage state to the delivery state.
22. The method of claim 21, wherein the method further comprises scratching the skin surface with at least one of the at least one delivery sharp.
23. The method of claim 20, wherein the method further comprises preventing reuse of the delivery device.
24. A delivery device comprising:
a main body including a central region coupled to a peripheral region, the central region being shaped substantially as a thimble having a top surface and a base, the peripheral region surrounding the central region and having an inner perimeter and an outer perimeter, the inner perimeter being coupled to the base such that the peripheral region extends outward from the base, the peripheral region including a plurality of first slots extending inward from the outer perimeter;
an adhesive coupled to at least a part of the main body; and
a collapsible reservoir coupled to the main body and to at least one delivery sharp.
25. The delivery device of claim 24, wherein the top surface is convex and includes a plurality of second slots therein.
26. The delivery device of claim 25, wherein the plurality of second slots extend outward with respect to a center point of the top surface.
27. The delivery device of claim 24, wherein the central region includes a plurality of fenestrations disposed along the base.
28. The delivery device of claim 24, wherein the central region includes a plurality of fenestrations disposed along a perimeter of the top surface.
29. The delivery device of claim 24, further comprising a sharp bearing body including the at least one delivery sharp, the sharp bearing body being coupled to the collapsible reservoir, wherein the collapsible reservoir is coupled to an inside surface of the central region.
30. The delivery device of claim 29, wherein the adhesive is coupled to at least a part of a side of the peripheral region most distal to the top surface.
31. The delivery device of claim 30, wherein the top surface is configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave.
32. The delivery device of claim 31, wherein the main body has a footprint with an area and is configured such that the area increases during at least a part of the transition between the storage state and the delivery state.
33. The delivery device of claim 31, wherein the main body has a footprint with an area and is configured such that the area increases the during at least a part of the transition between

the storage state and the delivery state and thereby stretches a surface to which the delivery device is affixed with the adhesive.

34. The delivery device of claim 30, wherein when the delivery device is in the storage state, the collapsible reservoir contains a fluid and the adhesive is affixed to a penetrable surface of a member external to the delivery device, and wherein when the delivery device is in the delivery state, the penetrable surface has been stretched by the adhesive, the at least one delivery sharp has penetrated the penetrable surface, and the collapsible reservoir is urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp.

35. The delivery device of claim 30, wherein the at least a part of the side includes first and second areas between two pairs of adjacent first slots of the plurality of first slots.

36. The delivery device of claim 24, wherein the adhesive is coupled to at least a part of a side of the peripheral region most distal to the top surface.

37. The delivery device of claim 36, wherein the at least a part of the side includes first and second areas between two pairs of adjacent first slots of the plurality of first slots.

38. The delivery device of claim 36, wherein when the delivery device is in the storage state, the collapsible reservoir contains a fluid and the adhesive is affixed to a penetrable surface of a member external to the delivery device, and wherein when the delivery device is in the delivery state, the penetrable surface has been stretched by the adhesive, the at least one delivery sharp has penetrated the penetrable surface, and the collapsible reservoir is urged to at least partially collapse, enabling the fluid to enter the member through the penetrable surface via the at least one delivery sharp.

39. The delivery device of claim 24, wherein the top surface is configured to transition the delivery device, in response to pressure applied thereon, from a storage state in which the top surface is convex, to a delivery state in which the top surface is concave.

40. The delivery device of claim 39, wherein the main body has a footprint with an area and is configured such that the area of the footprint increases during at least a part of the transition between the storage state and the delivery state.

41. The delivery device of claim 40, wherein the main body has a footprint with an area and is configured such that the area of the footprint increases during at least a part of the transition between the storage state and the delivery state and thereby stretches a surface to which the delivery device is affixed with the adhesive.

42. An actuator assembly for inhibiting reuse of a drug delivery device, comprising:
a flexure including first and second members, and a plurality of struts which couple the first and second members together, each strut having a resiliency which resists displacement of the first and second member toward one another, the first member including at least one first engagement member, the second member including a cooperating engagement member for each of the first engagement member, the struts configured to deflect and engender a rotational motion of at least one of the first and second member when the first and second member are urged toward one another with more than a threshold

force, the at least one first engagement member and each respective second engagement member configured to form a coupling when distance between the first and second member is decreased beyond a threshold distance.

43. A delivery device comprising:

a first portion at least partially covered with a first adhesive and including a cantilevered arm;

a second portion at least partially covered with a second adhesive and including at least one ramp element, the second portion coupled to the first portion via the first adhesive, the second portion configured to elongate from a first state to an elongated state; and

a collapsible reservoir including at least one delivery sharp, the reservoir coupled to an unsupported end of the cantilevered arm.

44. The delivery device of claim 43, wherein the at least one delivery sharp includes one of a one dimensional array of microneedles and a two dimensional array of microneedles.

45. The delivery device of claim 43, wherein the second portion includes a delivery aperture, the delivery aperture being out of alignment with the at least one delivery sharp when the second portion is in the first state and in alignment with the at least one delivery sharp when the second portion is in the elongated state.

46. The delivery device of claim 43, wherein the second portion includes a folded region in the first state, the folded region configured to unfurl as the second portion is transitioned to the elongated state.

47. The delivery device of claim 43, wherein the second portion includes a folded region, a layer of the folded region being coupled to the first adhesive.

48. The delivery device of claim 43, wherein each of the at least one ramp element is disposed on a first side of the cantilevered arm when the second portion is in the first state and disposed on a second side of the cantilevered arm when the second portion is in the second state.

49. The delivery device of claim 43, wherein the second portion is at least partly elastic.

50. The delivery device of claim 43, wherein the second portion includes a pull tab.

51. The delivery device of claim 43, wherein the delivery device further comprises a lock adhesive disposed on a section of the first portion and the delivery device further comprises a tether having a first end which is coupled to the second portion.

52. The delivery device of claim 51, wherein a second end of the tether is coupled to the lock adhesive and covers the lock adhesive when the second portion is in the first state, the second end of the tether configured to at least partially disassociate from the lock adhesive when the second portion is in the elongated state to expose the lock adhesive.

53. The delivery device of claim 51, wherein a second end of the tether is coupled to the lock adhesive and the tether is doubled over upon itself when the second portion is in the first state.

54. The delivery device of claim 43, wherein the first adhesive and second adhesive are disposed a first distance from one another when the second portion is in the first state and the first and second adhesive are disposed a second distance from one another when the second portion is in the elongated state, the second distance being greater than the first distance.

55. The delivery device of claim 43, wherein the at least one ramp element is configured to resiliently deflect the cantilevered arm as the second portion is transitioned from the first state to the second state.

56. A delivery device comprising:

- a main body including first and second end blocks spaced apart by first and second side panels and a bridge, the side panels and bridge each including first and second opposing ends, the first ends each connected to the first end block via respective first end living hinges, the second ends each connected to the second end block via respective second end living hinges, the side panels and bridge also each including respective intermediate living hinges between their first and second ends;

- an adhesive at least partially covering a first side of the end blocks; and

- a collapsible reservoir including at least one delivery sharp, the reservoir coupled to an end of an arm member extending from the bridge toward the first side.

57. The delivery device of claim 56, wherein the side panels each include at least one guard projection.

58. The delivery device of claim 56, wherein the first side panel includes a first guard projection which extends from toward the second side panel and the second side panel includes a second guard projection which extends toward the first side panel.

59. The delivery device of claim 58, wherein the first guard projection includes a latch projection and the second side panel includes a latch catch.

60. The delivery device of claim 58, wherein the first side panel includes a third guard projection which extends toward the second side panel and the second guide panel includes a fourth guard projection which extends toward the first side panel.

61. The delivery device of claim 56, wherein the bridge includes a first panel and a set of struts, the first panel connected to the struts via the intermediate living hinge of the bridge.

62. The delivery device of claim 61, wherein the arm member is disposed between the struts and extends from an end of the panel adjacent the intermediate living hinge of the bridge.

63. The delivery device of claim 56, wherein the side panels have a displacement range from an outwardly bowed state to a substantially straight state and the end blocks are configured to displace away from one another when the side panels are displaced from the outwardly bowed state to the substantially straight state.

64. The delivery device of claim 63, wherein the side panels are configured to displace from the outwardly bowed state to the substantially straight state upon application of a pinching force to the side panels.

65. The delivery device of claim 64, wherein at least the intermediate living hinge of the bridge member is configured to displace toward the first surface of the end blocks when the side panels are displaced from the outwardly bowed state to the substantially straight state.

66. The delivery device of claim 56, wherein the side panels have a displacement range from an outwardly bowed state to a substantially straight state and the bridge is configured such that the arm member is displaced from a first position to a second position in which the at least one delivery sharp is disposed below the first surface of the end blocks when the side panels are displaced from the outwardly bowed state to the substantially straight state.

67. The delivery device of claim 56, wherein the side panels have a displacement range from an outwardly bowed state to a substantially straight state and the main body includes a latch projection and a latch catch, the latch projection configured to engage the latch catch when the side panels are displaced from the outwardly bowed state to the substantially straight state.

68. The delivery device of claim 56, wherein the main body includes a plurality of iris panels which extend from the side panels to create a variable aperture.

69. The delivery device of claim 68, wherein the aperture is configured to vary in size as the side panels are bent about the intermediate living hinge of each side panel.

70. A delivery device comprising:

- a main body including a set of opposed end panels and at least two intermediate panels, the panels separated from one another by a plurality of living hinges which each extend across the main body;

- an adhesive covering at least a portion of a proximal side of each of the end panels;

and

- a collapsible reservoir including at least one delivery sharp, the reservoir coupled to the proximal side of one of the intermediate panels;

- wherein the two intermediate panels form a linkage displaceable between a raised position and an over center position when the two end panels are constrained to a plane, a first of the intermediate panels extending along the plane when the linkage is in the over center position.

71. The delivery device of claim 70, wherein a first of the end panels is substantially planar and a second of the end panels includes a planar portion and an angled projection extending from the planar portion toward one of the intermediate linkages.

72. The delivery device of claim 71, wherein the second of the end panels includes a buttress which extends from the planar portion to the angled projection.

73. The delivery device of claim 70, wherein the at least one delivery sharp includes an array of microneedles.

74. The delivery device of claim 70, wherein the delivery device is configured to transition from a storage state to a delivery state.
75. The delivery device of claim 70, wherein a second of the intermediate panels is at least partially covered with adhesive on a proximal side thereof.
76. The delivery device of claim 70, wherein the end panels are displaced apart a first distance along the plane as the linkage displaces from the raised position to a center position and are displaced toward one another a second distance shorter than the first distance as the linkages displaces from the center position to the over center position.
77. The delivery device of claim 70, wherein the reservoir is disposed on a second of the intermediate panels adjacent a living hinge of the plurality of living hinges which is between the first and second intermediate panels.
78. The delivery device of claim 70, wherein one of the panels includes a strain relief flexure.
79. The delivery device of claim 70, wherein at least a portion of the main body is configured to plastically deform when the linkage is displaced to the over center position.
80. The delivery device of claim 70, wherein at least one of the living hinges is configured to break when the linkage is displaced from the raised position to the over center position and back.
81. The delivery device of claim 70, wherein the linkage is at least partially inverted in the over center position with respect to the raised position.
82. The delivery device of claim 70, wherein an angle between the intermediate panels when the linkage is in the raised position is an obtuse angle and an angle between the intermediate panels when the linkage is in the over center is a reflex angle.
83. The delivery device of claim 70, wherein one of the intermediate panels is parallel to the skin when the linkage is in the over center position.
84. A delivery device comprising:
 an actuator;
 a base including a threaded post, the actuator in threaded engagement with the post and displaceable along the threaded post from a raised state in which the actuator is most distal to the base to a delivery state in which the actuator is more proximal the base;
 a carriage disposed within a bore of the post, the carriage including at least one first frangible supported on a respective ledge defined in the bore and at least one second frangible;
 a delivery aid disposed within the bore;
 a collapsible reservoir positioned within the bore and including at least one delivery sharp;
 wherein as the actuator is displaced from the raised state to the delivery state, a portion of the actuator is configured to apply pressure against the carriage, the pressure: breaking the at least one of the first frangible and freeing the carriage to displace within the

bore, as well as breaking the at least one of the second frangible such that pressure is exerted through the carriage and delivery aid against the reservoir, displacement of the actuator to the delivery state further configured to displace the reservoir toward the base.

85. The delivery device of claim 84, wherein the actuator includes a projection which is in alignment with the axis of the post, pressure against the carriage being applied via the projection.

86. The delivery device of claim 85, wherein the delivery aid is coupled to an end of the projection most proximal to the base.

87. The delivery device of claim 85, wherein the projection extends through at least a portion of the carriage when the actuator is in at least one of the raised state and the delivery state.

88. The delivery device of claim 84, wherein the delivery aid includes a force concentrating protuberance.

89. The delivery device of claim 84, wherein the base includes a delivery aperture aligned with the bore of the post.

90. The delivery device of claim 84, wherein the at least one first frangible includes a set of frangibles spaced at even angular increments about the carriage.

91. The delivery device of claim 84, wherein the at least one second frangible includes a set of frangibles spaced at even angular increments about the carriage.

92. The delivery device of claim 84, wherein with the at least one first frangible in a broken state, the carriage has a displacement range within the bore which is limited by a stop surface disposed at an end of the bore adjacent the base

93. The delivery device of claim 92, wherein the carriage extends through a delivery aperture in the base when the carriage is against the stop surface such that a skin depressor member of the carriage is external to the bore.

94. The delivery device of claim 84, wherein the reservoir is disposed within a bay of the carriage and frictionally retained therein when pressure applied to the reservoir is below a threshold.

95. The delivery device of claim 84, wherein the carriage, delivery aid, and reservoir are configured to displace together within the bore as a unit after the at least one first frangible is broken.

96. The delivery device of claim 95, wherein the carriage delivery aid, and reservoir are configured to cease displacement together as a unit when the at least one second frangible is broken.

97. A microneedle comprising:
a base including a first edge and a plurality of second edges;

a plurality of sidewalls extending from the base in a direction substantially perpendicular thereto;
a face extending from the first edge to a vertex at an acute angle to the base, two adjacent sidewalls of the plurality of sidewalls defining a side edge extending from the base to the vertex in a direction substantially vertical to the base;
a flow lumen extending through the microneedle from the base to an outlet in the face; and
a channel defined in the face and connected to the flow lumen.

98. The microneedle of claim 97, wherein the outlet in the face is disposed more proximal the vertex than the first edge.

99. The microneedle of claim 97, wherein the outlet in the face is disposed more proximal the first edge than the vertex.

100. The microneedle of claim 97, wherein the outlet in the face is disposed in a mid-region of the face intermediate a region proximal the vertex and a region proximal the first edge.

101. The microneedle of claim 97, wherein the channel extends in a direction toward the first edge from the outlet in the face.

102. The microneedle of claim 97, wherein the channel extends in a direction toward the vertex from the outlet in the face.

103. The microneedle of claim 97, wherein the channel includes a first portion and a second portion, the first portion extending in a direction toward the vertex from the outlet in the face and the second portion extending in a direction toward the first edge from the outlet in the face.

104. The microneedle of claim 97, wherein the channel has a width which is variable.

105. The microneedle of claim 97, wherein the channel has a substantially constant width.

106. The microneedle of claim 97, wherein an end of the channel most proximate the first end is a distance of at least 50-200 microns from the base.

107. The microneedle of claim 97, wherein the microneedle is constructed of silicon.

108. The microneedle of claim 97, wherein a height of the microneedle is at least 600 microns.

109. The delivery device of claim 97, wherein the flow lumen has an elongate cross-sectional shape.

110. A microneedle comprising:
a base including a first edge and a plurality of second edges;
a plurality of sidewalls projecting from the second edges to an arcuate blade edge which extends from a base vertex formed by two of the second edges to a second vertex spaced from the base;

a face extending from the first edge to the second vertex;
a flow lumen extending through the microneedle from the base to an outlet in the face.

111. The microneedle of claim 110, wherein the blade edge is a double beveled blade.

112. The microneedle of claim 110, wherein the outlet in the face has an elongate shape.

113. The microneedle of claim 110, wherein the first edge is disposed such that a plane perpendicular to the base and including the first edge extends through a portion of the blade edge.

114. The microneedle of claim 110, wherein the first edge is disposed such that a plane perpendicular to the base and including the first edge does not pass through the blade edge.

115. The microneedle of claim 110, wherein the outlet is disposed such that at least one plane perpendicular to the base and passing through the outlet also passes through the blade edge.

116. The microneedle of claim 110, wherein the outlet is disposed such that any plane perpendicular to the base and passing through the outlet also passes through the blade edge.

117. The microneedle of claim 110, wherein the measure of the arc of the blade edge is greater than 90° .

118. The microneedle of claim 110, wherein the measure of the arc of the blade edge is less than 90° .

119. A delivery device comprising:

a main body including a peripheral region and a central region extending proud of the peripheral region and having a top surface and a base, the peripheral region including a number of bodies spaced apart by slits which extend from the periphery of the peripheral region toward the central region;

an adhesive coupled to at least a part of the main body; and

a collapsible reservoir coupled to the main body and to at least one delivery sharp.

120. The delivery device of claim 119, wherein the main body has a first state and a second state, the main body including at least one partially invertible region which is in a first shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region.

121. The delivery device of claim 120, wherein the at least one partially invertible region includes the top surface.

122. The delivery device of claim 120, wherein the main body further comprises a static region which is substantially the same shape when the main body is in the first state and the second state.

123. The delivery device of claim 122, wherein the static region is included in the central region and extends from a periphery of the top surface to the base.

124. The delivery device of claim 120, wherein the main body is configured such that at least two of the bodies of the peripheral region spreadingly displace as the main body transitions from the first state to the second state.

125. The delivery device of claim 120, wherein the top surface is convex in the first state.

126. The delivery device of claim 120, wherein the top surface is concave in the second state.

127. The delivery device of claim 119, wherein the reservoir is formed as an assembly including a holder to which the microneedle is coupled and a flexible body coupled to the holder, there being a sealed reservoir volume defined between a portion of the holder and a portion of the flexible body.

128. A delivery device comprising:

- a main body including a central region and a peripheral region having a plurality of petal members extending outwardly from the central region, the central region defining a receptacle and having a top region and a base which are connected by a wall;

- a collapsible reservoir including at least one delivery sharp, the reservoir coupled to the main body and at least partially disposed within the receptacle; and

- an adhesive disposed on at least a portion of the main body.

129. The delivery device of claim 128, wherein the reservoir comprises a rigid portion and a flexible portion coupled to the rigid portion, a sealed interior volume of the reservoir being defined between the rigid portion and the flexible portion, the at least one delivery sharp being coupled to the rigid portion.

130. The delivery device of claim 129, wherein the rigid portion includes a stage projection.

131. The delivery device of claim 130, wherein the at least one delivery sharp is coupled to the stage projection and projects therefrom at an acute angle with respect to the rigid portion.

132. The delivery device of claim 128, wherein the main body includes a ridge adjacent the receptacle, the ridge forming a mounting surface for the reservoir.

133. The delivery device of claim 128, wherein the delivery device further comprises a packet disposed in the receptacle between the top region and the reservoir.

134. The delivery device of claim 133, wherein the packet is a gas bladder.

135. The delivery device of claim 133, wherein the packet contains a means for applying pressure to the reservoir.

136. The delivery device of claim 133, wherein the packet is configured to rupture when subjected to more than a threshold pressure, the packet disposed within a container and

including a first substance, the container containing a second substance, the first and second substances configured to react when combined to expand the volume of the container.

137. The delivery device of claim 133, wherein the packet is configured to rupture when subjected to more than a threshold pressure, the packet disposed within a container and filled with a first substance, the container containing a second substance, the first and second substances configured to partake in a chemiluminescent reaction when combined.

138. The delivery device of claim 128, wherein the delivery device further comprises a bias member disposed within the receptacle between the top region and the reservoir.

139. The delivery device of claim 138, wherein the bias member is a conical spring.

140. The delivery device of claim 138, wherein the main body includes a plurality of locating projections which constrain the bias member and the bias member is coupled to the main body.

141. The delivery device of claim 128, wherein the delivery device further comprises a dispensing assembly including a depressor body, a reservoir interface member, and a bias member each of which being at least partially disposed within the receptacle between the reservoir and the top region.

142. The delivery device of claim 128, wherein an interior volume of the reservoir is partitioned into a first portion and a second portion.

143. The delivery device of claim 142, wherein the first portion and second portion are in fluid communication via at least one flow restrictor.

144. The delivery device of claim 142, wherein the first and second portion are in fluid communication via at least one orifice in an orifice plate separating the first and second portion.

145. The delivery device of claim 142, wherein the first portion has a variable interior volume and the second portion has a substantially fixed interior volume, the second portion being adjacent the at least one delivery sharp.

146. The delivery device of claim 128, wherein the at least one delivery sharp includes a spaced array of microneedles.

147. A delivery device comprising:

- a main body including a central region and a peripheral region including a plurality of peripheral members extending outwardly from the central region, the central region having a top region and a base which are connected by a wall;

- a reservoir portion including a reservoir with at least one delivery sharp, the reservoir portion detachably coupled to the main body and at least partially covered by the main body;

- an indicator disposed on a section of the reservoir portion covered by the main body;
- and

- a first adhesive disposed on at least a portion of the main body;

a second adhesive disposed on at least a part of the reservoir portion;
wherein the main body obstructs line of sight to the indicator when the reservoir portion and main body are coupled together.

148. The delivery device of claim 147, wherein when the delivery device is applied to a surface, the second adhesive is configured to maintain the reservoir portion against the surface such that a removal force exerted on the main body results in separation of the main body and reservoir portion.

149. The delivery device of claim 147, wherein the indicator is selected from a group consisting of a barcode, data matrix, and QR code.

150. The delivery device of claim 147, wherein the indicator encodes information related to the contents of the reservoir.

151. The delivery device of claim 147, wherein the main body is opaque.

152. The delivery device of claim 147, wherein the main body is translucent.

153. The delivery device of claim 147, wherein the reservoir portion is coupled to the main body via adhesive.

154. The delivery device of claim 147, wherein the peripheral region includes a pull tab.

155. The delivery device of claim 147, wherein at least one of the peripheral members defines a pull tab.

156. The delivery device of claim 147, wherein the main body includes a set of slots and the reservoir portion includes a number of tabs, each of the tabs extending at least partially through a respective slot to detachably couple the reservoir portion and main body.

157. A delivery device comprising:

a main body including a central region and a peripheral region having a plurality of petal members extending outwardly from the central region, the central region defining a receptacle and having a top region and a base which are connected by a wall;

a collapsible reservoir including at least one delivery sharp, the reservoir coupled to the main body and at least partially disposed within the receptacle;

a dispensing assembly at least partially disposed within the receptacle between the reservoir and the top region; and

an adhesive disposed on at least a portion of the main body.

158. The delivery device of claim 157, wherein the dispensing assembly includes a depressor body, at least one bias member, and a reservoir interface member.

159. The delivery device of claim 157, wherein the depressor body includes a portion which projects through an aperture in the top region.

160. The delivery device of claim 159, wherein the depressor body includes a detent.

161. The delivery device of claim 159, wherein the portion of the depressor body includes at least one notch and has a cross-sectional shape which is not circular and not a regular polygon.

162. The delivery device of claim 157, wherein the bias member includes a bow spring.

163. The delivery device of claim 157, wherein the bias member includes a peripheral region and a number of bias projection extending inwardly therefrom, the main body including a number of slots, the bias projections extending through the slots and into the receptacle.

164. The delivery device of claim 157, wherein the reservoir interface member is integral with the depressor body.

165. The delivery device of claim 157, wherein the dispensing assembly includes a coil spring and a reservoir interface member.

166. The delivery device of claim 165, wherein the reservoir interface member is formed by a terminal portion of the spring which is routed in a pattern in a plane adjacent an end of the coils of the spring.

167. The delivery device of claim 157, wherein the dispensing assembly includes a spring and the dispensing assembly is out of contact with the reservoir when the delivery device is in a storage state.

168. The delivery device of claim 167, wherein the spring is in an unstressed state in the storage state.

169. A delivery device system comprising;
A package including an indicium;
A delivery device contained within the package;
A database; and
A reader including a user interface and a controller, the reader being in data communication with the database and configured to capture delivery device information from the indicium, the controller configured check the delivery device information against associated data in the database, and the controller configured to generate use instructions on the user interface when the associated data in the database indicates the device is acceptable for use; and

Wherein the controller prevents use of at least one functionality of the reader until first information has been collected by the reader and a first service is enabled on the reader.

170. The system of claim 169, wherein the indicium is selected from a group consisting of a barcode, data matrix, and QR code.

171. The system of claim 169, wherein the reader is a smart device and includes an imager and wherein the at least one functionality includes use of the imager.

172. The system of claim 169, wherein the reader includes a plurality of imagers.

173. The system of claim 169, wherein the first service is selected from a group consisting of a notification service and a location service.

174. The system of claim 169, wherein the delivery device comprises a reservoir in fluid communication with one or more microneedles.

175. The system of claim 169, wherein the first information is location information.

176. A method of using of a medical delivery device comprising:

- Capturing, with a reader, device information from an indicium on a package containing the medical delivery device;
- Applying the delivery device to skin of a patient;
- Establishing data communication between the reader and a database;
- Comparing the device information against associated device information stored on the database;

- Generating, with a controller of the reader, a set of use instructions on a user interface of the reader when an acceptability for use criteria is met by the comparison;

- Capturing, with the reader, data from a post usage indicium after the medical delivery device is used; and

- Updating the database to indicate that the post usage indicium of the delivery device has been captured by the reader.

177. The method of claim 176, wherein the method further comprises removing a first portion of the medical delivery device to reveal the post usage indicium on a second portion of the delivery device.

178. The method of claim 176, wherein the method further comprises marking the skin with the post usage indicium.

179. The method of claim 176, wherein the method further comprises generating a respective prompt on the user interface for each use instruction of the set of use instructions and preventing display of a next use instruction until the controller registers a user interaction with the prompt.

180. The method of claim 176, wherein the method further comprises preventing use of at least one functionality of the reader until a notification service of the reader is enabled.

181. The method of claim 180, wherein the at least one functionality is use of an imager of the reader.

182. The method of claim 176, wherein the method further comprises generating a confirmation of delivery for display on the user interface of the reader.

183. The method of claim 176, wherein the reader is a smart phone.

184. A microneedle comprising:

- a base including a first edge and a plurality of second edges;

a plurality of sidewalls extending from the base in a direction substantially perpendicular thereto;
a face extending from the first edge to a vertex at an acute angle to the base, two adjacent sidewalls of the plurality of sidewalls defining a side edge extending from the base to the vertex in a direction substantially vertical to the base; and
a flow lumen extending through the microneedle from the base to an outlet in the face, the flow lumen having a cross-section with an elongate shape.

185. The microneedle of claim 184, wherein the cross-sectional shape is obround.

186. The microneedle of claim 184, wherein the cross-sectional shape has a length in a direction of elongation of up to 100 microns.

187. The microneedle of claim 184, wherein the cross-sectional shape has a length in a direction of elongation of up to 200 microns.

188. The microneedle of claim 184, wherein the cross-sectional shape is polygonal.

189. The microneedle of claim 184, wherein the microneedle is constructed of silicon.

190. The microneedle of claim 184, wherein a majority of the cross-sectional shape has a constant width.

191. The microneedle of claim 184, wherein the microneedle has a height of at least 600 microns.

192. The microneedle of claim 184, wherein the microneedle has a height of up to 800 microns.

193. A microneedle comprising:
a base;
a plurality of sidewalls extending from the base, the sidewalls angled such that the microneedle tapers so as to have a smaller cross-sectional area as distance from the base increases;
a flow lumen;
a plurality of side ports in the sidewalls, the side ports being in fluid communication with the flow lumen; and
a tip at an end of the sidewalls opposite the base.

194. The microneedle of claim 193, wherein the microneedle has a high aspect ratio.

195. The microneedle of claim 193, wherein the microneedle is in the shape of an obelisk.

196. The microneedle of claim 193, wherein the base is polygonal in shape and a sidewall of the plurality of sidewalls extends from each side of the polygonal shape of the base.

197. The microneedle of claim 193, wherein the base has the shape of a quadrilateral and a sidewall of the plurality of sidewalls extends from each of the four sides of the base.

198. The microneedle of claim 193, wherein the flow lumen has a substantially constant cross-section.
199. The microneedle of claim 198, wherein the flow lumen extends from the base to a plane in the microneedle where the cross-section of the flow lumen is wider than the portions of the cross-section of the microneedle.
200. The microneedle of claim 193, wherein microneedle is constructed of silicon and the lumen is etched into the microneedle, the side ports being formed as part of the etching of the lumen.
201. The microneedle of claim 193, wherein the flow lumen extends substantially along the long axis of the microneedle.
202. The microneedle of claim 193, wherein the tip is beveled.
203. A method of using of a medical delivery device comprising:
Applying a delivery device to an injection site;
Generating, with a controller of a reader, a set of use instructions on a user interface of the reader;
Delivering an agent into the injection site from the delivery device;
Capturing, with the reader, image data of the injection site, the image data including image data in a spectrum outside of the visible spectrum; and
Analyzing the image data to determine if the image data conforms to at least one criterion indicative of a proper injection.
204. The method of claim 203, wherein the method further comprises establishing data communication between the reader and a database.
205. The method of claim 204, wherein the method further comprises updating the database to indicate an outcome of the analysis.
206. The method of claim 203, wherein the image data includes image data in the near infrared spectrum.
207. The method of claim 203, wherein the image data includes image data in the infrared spectrum.
208. The method of claim 203, wherein the image data includes thermal image data.
209. The method of claim 203, wherein analyzing the image data comprises analyzing thermal image data for the presence of a cool region at the injection site.
210. The method of claim 203, wherein analyzing the image data comprises analyzing the image data to determine the presence of at least one characteristic of interest.
211. The method of claim 210, wherein the at least one characteristic of interest includes a characteristic indicative of an intradermal bleb and a characteristic indicative of leak.

212. The method of claim 203, wherein the reader is a smart phone.

213. A method of delivering a medical agent comprising:

Affixing to a surface a delivery device that includes at least one delivery sharp in fluid communication with an at least partially collapsible reservoir containing the medical agent while the delivery device is in a storage state;

Pressing a portion of the delivery device toward the surface to transition the delivery device to a delivery state;

Spreadingly displacing at least two portions of the delivery device to tension the surface to which the delivery device is affixed;

Penetrating the surface with the at least one delivery sharp;

Transferring fluid out of the at least partially collapsible reservoir and through the at least one delivery sharp until the reservoir is in a depleted state.

214. A delivery device comprising:

a main body comprising:

a peripheral region having a number of petal members; and

a central region extending proud of the peripheral region having a top surface and a base;

a collapsible reservoir in fluid communication with at least one delivery sharp configured to expel fluid from the reservoir in an ejection direction; and

an adhesive member including a central aperture having an increased aperture width portion aligned with the ejection direction.

215. The delivery device of claim 214, wherein the reservoir includes a flexible portion and a rigid portion, the adhesive member being affixed to the main body and the rigid portion.

216. The delivery device of claim 214, wherein the reservoir includes a flexible portion and a rigid portion, the rigid portion having a foot print with a first area, the central aperture encompassing an second area which is between 60-100% of the first area.

217. The delivery device of claim 214, wherein a center of the central aperture is coaxial with a center of the reservoir.

218. The delivery device of claim 214, wherein the adhesive member includes at least one spoke which projects into the central aperture from the periphery of the central aperture.

219. The delivery device of claim 214, wherein the adhesive member covered at least a portion of each of the petal members.

220. The delivery device of claim 214, wherein the at least one delivery sharp includes a spaced array of microneedles.

221. The delivery device of claim 214, wherein the main body has a first state and a second state, the main body including at least one partially invertible region which is in a first shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region.

222. The delivery device of claim 221, wherein the main body is configured such that at least two of the petal members spreadingly displace as the main body transitions from the first state to the second state.

223. The delivery device of claim 223, wherein the at least one delivery sharp is displaced into communication with a delivery destination when the main body is displaced from the first state to the second state.

224. The delivery device of claim 214, wherein the central aperture includes at the increased width portion at least one notch extending outward from the periphery of the central aperture and through the adhesive member.

225. A delivery device comprising:

- a main body including a peripheral region having a number of petal members and a central region extending proud of the peripheral region and having a top surface and a base;
- a collapsible reservoir coupled to the main body in fluid communication with at least one microneedle having a width, height, and length; and
- an adhesive member including a central aperture having an increased width portion aligned with the length dimension of the microneedle.

226. The delivery device of claim 225, wherein the reservoir includes a flexible portion and a rigid portion, the adhesive member being affixed to the main body and the rigid portion.

227. The delivery device of claim 225, wherein the reservoir includes a flexible portion and a rigid portion, the rigid portion having a foot print with a first area, the central aperture encompassing an second area which is between 60-100% of the first area.

228. The delivery device of claim 225, wherein a center of the central aperture is coaxial with a center of the reservoir.

229. The delivery device of claim 225, wherein the adhesive member includes at least one spoke which projects into the central aperture from the periphery of the central aperture.

230. The delivery device of claim 225, wherein the adhesive member covered at least a portion of each of the petal members.

231. The delivery device of claim 225, wherein the at least one delivery sharp includes a spaced array of microneedles.

232. The delivery device of claim 225, wherein the main body has a first state and a second state, the main body including at least one partially invertible region which is in a first shape in the first state and in the second state is substantially inverted with respect to the first shape over at least a portion of the of the invertible region.

233. The delivery device of claim 232, wherein the main body is configured such that at least two of the petal members spreadingly displace as the main body transitions from the first state to the second state.

234. The delivery device of claim 233, wherein the at least one delivery sharp is displaced into communication with a delivery destination when the main body is displaced from the first state to the second state.

235. The delivery device of claim 225, wherein the central aperture includes at the increased width portion at least one notch extending outward from the periphery of the central aperture and through the adhesive member.

236. A delivery device comprising:
a main body including a peripheral region having a number of petal members and a central region extending proud of the peripheral region and having a top surface and a base;
an adhesive coupled to at least a part of the main body;
a reservoir including at least one flexible portion, the at least one flexible portion including a cavity defined by a first wall including a collapse facilitator; and
at least one delivery sharp in fluid communication with the reservoir.

237. The delivery device of claim 236, wherein the collapse facilitator includes a bellows.

238. The delivery device of claim 236, wherein the collapse facilitator includes a pleat which extends around the wall in a spiral manner.

239. The delivery device of claim 236, wherein the collapse facilitator includes at least one stepped region formed in the wall.

240. The delivery device of claim 236, wherein the first wall extends from a flange coupled to a rigid portion of the reservoir.

241. The delivery device of claim 240, wherein the first wall tapers as distance from the flange increases such that the cross-sectional area of the cavity decreases with distance from the flange.

242. The delivery device of claim 236, wherein the cavity is also defined by a second wall at an end of the cavity, the second wall forming a substantially flat surface.

243. The delivery device of claim 242, wherein the second surface includes a central depression.

244. The delivery device of claim 236, wherein the wall extends from a flange and is formed integrally therewith, the cavity being defined by the first wall and a second wall at an end of the cavity, the second wall being substantially parallel to the flange.

245. The delivery device of claim 236, wherein the at least one delivery sharp includes a microneedle.

246. Any of the systems, methods, or apparatuses shown or described herein.