

of the skin, but short enough not to puncture nerve endings, thus reducing or eliminating pain upon insertion. However, the penetration of microneedles to precise levels within the skin tissue and with good reproducibility is often a challenging task. Therefore, unlike the application of traditional patch-based delivery systems, some existing MTSs require the assistance of external energy to ensure efficient and reproducible penetration of microneedles into biological tissue at desired depths. This assistance can be achieved by utilizing an apparatus device, which can either be used after positioning the microneedle array on the skin surface, or the apparatus device can be integrated with an array of microneedles and, upon activation, can deliver the microneedle array into the skin. The microneedles help to create microchannels in the skin, which in some embodiments, can facilitate delivering an active ingredient. In some constructions, active component(s) may be coated on the microneedle array and delivered directly through the skin when the stratum corneum is punctured by the microneedles. One advantage of MTS systems over other skin treatment methods is a reduced-pain mode of delivery.

SUMMARY

Some embodiments of the present disclosure provide a microneedle injection and infusion apparatus that can include a housing having a base and a cavity that extends through the base to define an opening in the base, wherein the base of the housing is configured to be positioned toward a skin surface. The apparatus can further include a microneedle array holder configured to hold a microneedle array and located in the housing, the microneedle array holder movable with respect to the opening in the base of the housing between (i) a retracted position in which the microneedle array is recessed within the housing such that the microneedle array does not contact the skin surface when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder, and (ii) an extended position in which at least a portion of the microneedle array is positioned to contact the skin surface via the opening when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder. The apparatus can further include a shuttle configured to hold and carry a cartridge. The cartridge can define a reservoir configured to contain an active agent. The shuttle can be movable between a first position in which the reservoir of the cartridge is not in fluid communication with a fluid path and a second position in which the reservoir is in fluid communication with the fluid path. The apparatus can further include an actuator movable between a first position and a second position, wherein movement of the actuator to the second position releases the shuttle from its first position and allows the shuttle to move toward its second position, and wherein movement of the shuttle toward its second position releases the microneedle array holder from the retracted position and allows the microneedle array holder to move to the extended position. When the actuator is in the first position, at least a portion of the actuator protrudes from the opening in the base of the housing and defines a base of the actuator configured to be coupled to the skin surface, wherein the base of the actuator includes a skin-contact adhesive.

Some embodiments of the present disclosure provide a method of using a microneedle injection apparatus. The method can include providing a microneedle injection apparatus. The apparatus can include a housing having a base and a cavity that extends through the base to define an opening in the

base, wherein the base of the housing is configured to be positioned toward a skin surface. The apparatus can further include a microneedle array holder configured to hold a microneedle array and located in the housing, the microneedle array holder movable with respect to the opening in the base of the housing between (i) a retracted position in which the microneedle array is recessed within the housing such that the microneedle array does not contact the skin surface when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder, and (ii) an extended position in which at least a portion of the microneedle array is positioned to contact the skin surface via the opening when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder. The apparatus can further include a shuttle configured to hold and carry a cartridge. The cartridge can define a reservoir configured to contain an active agent. The shuttle can be movable between a first position in which the reservoir is not in fluid communication with a fluid path and a second position in which the reservoir is in fluid communication with the fluid path. The apparatus can further include an actuator movable between a first position and a second position. The method can further include moving the actuator to its second position to allow the shuttle to move toward its second position, wherein movement of the shuttle toward its second position allows the microneedle array holder to move to its extended position. When the actuator is in the first position, at least a portion of the actuator protrudes from the opening in the base of the housing and defines a base of the actuator configured to be coupled to the skin surface, wherein the base of the actuator includes a skin-contact adhesive.

Other features and aspects of the present disclosure will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front assembled top perspective view of a microneedle injection and infusion apparatus according to one embodiment of the present disclosure, the apparatus including a cover, and injection assembly, and an infusion assembly.

FIG. 2 is a side view of the apparatus of FIG. 1.

FIG. 3 is a side cross-sectional view of the apparatus of FIGS. 1 and 2.

FIG. 4 is a front, top, partially exploded perspective view of the apparatus of FIGS. 1-3.

FIG. 5 is a front, bottom, partially exploded perspective view of the apparatus of FIGS. 1-4.

FIG. 6 is a front, top, exploded perspective view of the apparatus of FIGS. 1-5.

FIG. 7 is a side cross-sectional view of the apparatus of FIGS. 1-6, the apparatus shown in a first condition with the cover removed.

FIG. 8 is a close-up, rear, top, partial perspective view of the apparatus of FIGS. 1-7, the apparatus shown in the first condition with the cover removed.

FIG. 9 is a side cross-sectional view of the apparatus of FIGS. 1-8, the apparatus shown in a second condition.

FIG. 10 is a close-up, rear, top, partial perspective view of the apparatus of FIGS. 1-9, the apparatus shown in the second condition.

What is claimed is:

1. A microneedle injection and infusion apparatus comprising:

a housing having a base and a cavity that extends through the base to define an opening in the base, wherein the base of the housing is configured to be positioned toward a skin surface;

a microneedle array holder configured to hold a microneedle array and located in the housing, the microneedle array holder movable with respect to the opening in the base of the housing between

a retracted position in which the microneedle array is recessed within the housing such that the microneedle array does not contact the skin surface when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder, and

an extended position in which at least a portion of the microneedle array is positioned to contact the skin surface via the opening when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder;

a shuttle configured to hold and carry a cartridge, the cartridge defining a reservoir configured to contain an active agent, the shuttle being movable between a first position in which the reservoir of the cartridge is not in fluid communication with a fluid path and a second position in which the reservoir is in fluid communication with the fluid path; and

an actuator movable between a first position and a second position, wherein movement of the actuator to the second position releases the shuttle from its first position and allows the shuttle to move toward its second position, and wherein movement of the shuttle toward its second position releases the microneedle array holder from the retracted position and allows the microneedle array holder to move to the extended position;

wherein, when the actuator is in the first position, at least a portion of the actuator protrudes from the opening in the base of the housing and defines a base of the actuator configured to be coupled to the skin surface, wherein the base of the actuator includes a skin-contact adhesive.

2. A method of using a microneedle injection apparatus, the method comprising:

providing a microneedle injection apparatus comprising:

a housing having a base and a cavity that extends through the base to define an opening in the base, wherein the base of the housing is configured to be positioned toward a skin surface;

a microneedle array holder configured to hold a microneedle array and located in the housing, the microneedle array holder movable with respect to the opening in the base of the housing between

a retracted position in which the microneedle array is recessed within the housing such that the microneedle array does not contact the skin surface when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder, and

an extended position in which at least a portion of the microneedle array is positioned to contact the skin surface via the opening when the apparatus is positioned on the skin surface and the microneedle array is coupled to the microneedle array holder;

a shuttle configured to hold and carry a cartridge, the cartridge defining a reservoir configured to contain an active agent, the shuttle being movable between a first position in which the reservoir is not in fluid communication with a fluid path and a second position in which the reservoir is in fluid communication with the fluid path; and

an actuator movable between a first position and a second position;

moving the actuator to its second position to allow the shuttle to move toward its second position, wherein movement of the shuttle toward its second position allows the microneedle array holder to move to its extended position;

wherein, when the actuator is in the first position, at least a portion of the actuator protrudes from the opening in the base of the housing and defines a base of the actuator configured to be coupled to the skin surface, wherein the base of the actuator includes a skin-contact adhesive.

3. The apparatus of claim 1 or the method of claim 2, wherein the microneedle array includes a plurality of hollow microneedles, and wherein the fluid path is configured to deliver the active agent to the plurality of hollow microneedles when the microneedle array is coupled to the microneedle array holder.

4. The apparatus of claim 1 or 3 or the method of claim 2 or 3, wherein the microneedle array includes a first side comprising a first major surface and a plurality of hollow microneedles that protrude from the first major surface, wherein the microneedle array includes a second side opposite the first side, wherein the plurality of hollow microneedles are in fluid communication with the second side, and wherein the microneedle array is configured to be coupled to a base of the microneedle array holder such that the second side of the microneedle array and the base of the microneedle array holder are spaced a distance apart to define a manifold for the plurality of hollow microneedles.

5. The apparatus of any of claims 1 and 3-4 or the method of any of claims 2-4, wherein the shuttle is biased in the second position, and wherein the microneedle array holder is biased in the extended position.

6. The apparatus of any of claims 1 and 3-5 or the method of any of claims 2-5, wherein the microneedle array holder is held in the retracted position by the shuttle, when the shuttle is in its first position.

7. The apparatus of any of claims 1 and 3-6 or the method of any of claims 2-6, wherein at least a portion of the shuttle is configured to hold the actuator in the second position after the actuator has been moved to the second position.

when the actuator is in the first position, an outermost surface of the actuator extends beyond the base of the housing by a first distance, and

when the actuator is in the second position, the outermost surface of the actuator does not extend beyond the base of the housing, or extends beyond the base of the housing by a second distance that is less than the first distance.

14. The apparatus of any of claims 1 and 3-8 or the method of any of claims 2-8, wherein the actuator is movable between the first position and the second position along a first actuation axis, wherein the microneedle array holder is movable between the retracted position and the extended position along a second actuation axis, and wherein the first actuation axis and the second actuation axis are substantially parallel with respect to one another.

15. The apparatus or method of claim 14, wherein at least a portion of the actuator extends beyond the base of the housing when the actuator is in the first position.

16. The apparatus or method of claim 14 or 15, wherein the shuttle is movable between the first position and the second position along a third axis, and wherein the third axis is oriented substantially perpendicularly with respect to at least one of the first actuation axis and the second actuation axis.

17. The apparatus of any of claims 1 and 3-16 or the method of any of claims 2-16, wherein the actuator includes a base and an opening formed in the base, and wherein at least a portion of the microneedle array extends through the opening in the actuator and beyond the base of the actuator when the microneedle array holder is in the extended position, and wherein the base of the actuator is configured to be coupled to the skin surface.

18. The apparatus of any of claims 1 and 3-17 or the method of any of claims 2-17, wherein the shuttle is biased toward the second position, and wherein the shuttle is restrained from moving to the second position by the actuator, until the actuator is moved to the second position.

19. The apparatus of any of claims 1 and 3-9 and 14-16 or the method of any of claims 2-9 and 14-16, further comprising a stored energy device configured to drive the shuttle toward the second position.

20. The apparatus of any of claims 1 and 3-9 and 14-16 or the method of any of claims 2-9 and 14-16, further comprising an active agent and a piston located in the reservoir of the cartridge, the piston movable between a first position in which the active agent is not being forced out of the reservoir and moved into the fluid path and a second position in which the active agent is being forced out of the reservoir and moved into the fluid path.

21. The apparatus or method of claim 20, further comprising a first stored energy device configured to initiate movement of the shuttle toward the second position and a second stored energy device configured to assist in moving the shuttle toward the second position and further configured to drive the piston toward its second position.

22. The apparatus or method of claim 20, further comprising an indicator that is movable with the piston between the first position and the second position of the piston, wherein the indicator is visible from outside the housing to indicate the position of the piston with respect to the housing.

23. The apparatus or method of claim 22, wherein the indicator is movable with the shuttle from the first position of the shuttle to the second position of the shuttle, and wherein the indicator is further movable with the piston and with respect to the shuttle when the shuttle is in the second position.

24. The apparatus of any of claims 1 and 3-23 or the method of any of claims 2-23, wherein the fluid path includes or is in fluid communication with a piercing element configured to provide fluid communication between the reservoir of the cartridge and the fluid path, and further comprising a deformable sterility seal positioned to enclose the piercing element and configured to be pierced by the piercing element, and wherein the sterility seal is further configured to be changed from a first state in which the sterility seal defines a sterile chamber within which the piercing element is located to a second state in which the sterility seal has been pierced by the piercing element and the sterility seal is collapsed.