

the patient. Depending upon the angle, depth, and stiffness of the needle, this can cause patient discomfort and the anxiety of seeing the needle afterward.

[0006] As a result, insertion mechanisms have been disposed within drug delivery devices to accomplish insertion and/or retraction movements of the needle. Such an insertion mechanism, however, may increase the overall size, complexity, and/or cost of the drug delivery device.

SUMMARY

[0007] In accordance with a first aspect, a wearable drug delivery device comprises a main housing having a container, a fluid pathway connector coupled to the container, and a pressure supply device. The drug delivery device further comprises an insertion mechanism disposed within the main housing and operatively coupled to the pressure supply device, the fluid pathway connector defining a fluid flow path between the container and the insertion mechanism. The insertion mechanism includes a housing having a proximal end, a distal end, a first opening disposed near the proximal end, and a second opening disposed in the distal end, the first opening coupled to the pressure supply device. A needle or cannula assembly is disposed within the housing and moveable between a retracted position and an extended position. The needle or cannula assembly includes a base having a proximal surface and a distal surface, and a needle or cannula coupled to the distal surface of the base. The base divides the housing into a proximal chamber and a distal chamber. A retraction member is disposed within the housing to maintain the needle or cannula assembly in the retracted position before movement to the extended position. The retraction member is in contact with the base and applies a resistive force. The insertion mechanism further includes a flexible fluid path member having a first end operatively coupled to a first connector upwardly extending from the proximal surface of the base and a second end operatively coupled to a second connector downwardly extending from the proximal end of the housing, the flexible fluid path member moveable with the needle assembly.

The pressure supply device is adapted to supply pressure through the first opening and into the proximal chamber until an amount of pressure P_1 in the proximal chamber applies an application force to the proximal surface of the base that surpasses the resistive force of the retraction member to move the needle assembly from the retracted position to the

extended position. The needle is disposed through the opening in the distal end of the housing in the extended position to deploy the needle.

[0008] In accordance with a second aspect, an insertion mechanism for a drug delivery device comprises a housing having a proximal end, a distal end, a first opening disposed in the housing near the proximal end, the first opening adapted to be operatively coupled to a pressure supply device, and a second opening disposed in the distal end of the housing. A needle or cannula assembly is disposed within the housing and moveable between a retracted position and an extended position. The needle or cannula assembly includes a base having a proximal surface and a distal surface, and a needle or cannula is attached to the base. A retraction member is in contact with the base and applies a resistive force to maintain the needle or cannula assembly in the retracted position before movement to the extended position. The insertion mechanism further comprises a flexible fluid path member having a first end operatively coupled to a connector extending from the proximal surface of the base and a second end operatively coupled to a connector extending from the proximal end of the housing, the flexible fluid path member moveable between the retracted position and the extended position corresponding to the retracted position and the extended position of the needle or cannula assembly. Pressure is supplied through the first opening until an amount of pressure P_1 applies an application force to the proximal surface of the base of the needle or cannula assembly that exceeds the resistive force of the retraction member to move the needle or cannula assembly from the retracted position to the extended position, the needle extending through the second opening in the distal end of the housing in the extended position.

[0009] There is disclosed a method of deploying a needle of an insertion mechanism from a drug delivery device is disclosed. The method comprises maintaining a retracted position of a needle or cannula assembly disposed within a housing of the insertion mechanism by a

retraction member. The method also comprises supplying pressure to a first opening of the housing of the insertion mechanism until an amount of pressure P_1 in a proximal chamber of the housing imparts an application force on a base of the needle or cannula assembly that exceeds a resistive force applied to the base by one or more of the retraction member or a pressure P_2 in a distal chamber of the housing. The method also comprises moving the needle assembly from the retracted position to the extended position

What is Claimed:

1. A wearable drug delivery device comprising:

a main housing having a container, a fluid pathway connector coupled to the container, and a pressure supply device; and

an insertion mechanism disposed within the main housing and operatively coupled to the pressure supply device, the fluid pathway connector defining a fluid flow path between the container and the insertion mechanism, the insertion mechanism including:

a housing having a proximal end, a distal end, a first opening disposed near the proximal end, and a second opening disposed in the distal end, the first opening coupled to the pressure supply device,

a needle or cannula assembly disposed within the housing and moveable between a retracted position and an extended position, the needle or cannula assembly including a base having a proximal surface and a distal surface, and a needle or cannula coupled to the distal surface of the base, the base dividing the housing into a proximal chamber and a distal chamber, and

a retraction member disposed within the housing to maintain the needle or cannula assembly in the retracted position before movement to the extended position, the retraction member in contact with the base and applying a resistive force, and

a flexible fluid path member having a first end operatively coupled to a first connector upwardly extending from the proximal surface of the base and a second end operatively coupled to a second connector downwardly extending from the proximal end of the housing, the flexible fluid path member moveable with the needle assembly,

wherein the pressure supply device is adapted to supply pressure through the first opening and into the proximal chamber until an amount of pressure P1 in the proximal chamber

applies an application force to the proximal surface of the base that surpasses the resistive force of the retraction member to move the needle or cannula assembly from the retracted position to the extended position, the needle disposed through the opening in the distal end of the housing in the extended position to deploy the needle.

2. The wearable drug delivery device of claim 1, wherein the retraction member comprises a biasing mechanism, the biasing mechanism including ~~one or more of: a spring having a first end attached to the base and a second end attached to the distal end of the housing, or a~~the flexible fluid path member having a first end attached to the base and a second end attached to the proximal end of the housing, and wherein the biasing mechanism retracts the needle into the retracted position after release of pressure P1 in the proximal chamber.

~~3. The wearable drug delivery device of claim 2, wherein the insertion mechanism further comprises a first connector upwardly extending from the proximal surface of the base, and a flexible fluid path member having a first end operatively coupled to the connector upwardly extending from the proximal surface of the base and a second end operatively coupled to a second connector downwardly extending from the proximal end of the housing, the flexible fluid path member moveable with the needle assembly.~~

43. The wearable drug delivery device of claim ~~31~~, wherein the flexible fluid path member is in an extended position when the needle assembly is in the extended position and in a compressed position when the needle assembly is in the retracted position.

54. The wearable drug delivery device of any one of claims ~~2-41-3~~, further comprising a step disposed on the housing sidewall near the distal end of the housing, the step having a sealing mechanism, wherein the sealing mechanism is an o-ring, and the distal surface of the base contacts the o-ring to soften the impact when the needle or cannula assembly moves from the retracted position to the extended position.

65. The wearable drug delivery device of any one of claims 2-~~54~~, wherein the housing includes a sidewall having a threaded inside surface, and the base further includes a side surface in contact with the inside surface of the sidewall, the side surface of the base having a threaded surface corresponding to the threaded inside surface of the sidewall of the housing.

76. The wearable drug delivery device of claim 65, wherein the threaded inside surface of the sidewall of the housing and the threaded surface of the side surface of the base are one of coarse threading or fine threading, the coarse threading allowing the needle to rotate at least two to three times during deployment, and the fine threading allowing the needle to rotate at least eight to ten times during deployment.

87. The wearable drug delivery device of claim 1, wherein the retraction member comprises at least one frictional element, the frictional element in contact with a sidewall of the base and comprising one or more of at least one sealing mechanism or o-ring.

98. The wearable drug delivery device of claim 87, wherein, upon one of applying negative pressure through the first opening or supplying positive pressure to a third opening disposed in a sidewall of the housing near the distal end of the housing, a pressure P2 in the distal chamber surpasses the pressure P1 in the proximal chamber causing the needle or cannula assembly to move back into the retracted position after needle deployment.

109. The wearable drug delivery device of claim 87, wherein the needle or cannula assembly is secured back into the retracted position by one or more of: (1) at least one spring-loaded directional latch, or (2) at least one groove disposed on the sidewall of the housing, the at least one groove for receiving the at least one sealing mechanism disposed on the sidewall of the base to prevent the needle assembly from being activated again into the extended position.

1110. The wearable drug delivery device of claim 109, wherein the at least one spring-loaded directional latch includes a first spring-loaded directional latch disposed on one area of

the sidewall of the housing and a second spring-loaded latch disposed on another area of the sidewall of the housing, each latch having an angled side surface that contacts a corresponding angled side surface of the base on either side of the base to lock the base of the needle or cannula assembly, preventing redeployment.

1211. The wearable drug delivery device of claim 109, wherein the at least one groove includes a first groove disposed on one area of the sidewall of the housing and a second groove disposed on another area of the sidewall of the housing, each groove adapted to receive a corresponding frictional element to secure the base of the needle or cannula assembly, preventing redeployment.

1312. The wearable drug delivery device of claim 87, wherein the housing further includes a guide member downwardly extending from the proximal end of the housing and having a central bore, and the base further includes a shaft extending from a center of the proximal surface of the base into the central bore, the central bore to guide the shaft of the base when the needle assembly moves between the retracted and extended positions and reduce the volume of the proximal chamber.

1413. An insertion mechanism for a drug delivery device, the insertion mechanism comprising:

a housing having a proximal end, a distal end, a first opening disposed in the housing near the proximal end, the first opening adapted to be operatively coupled to a pressure supply device, and a second opening disposed in the distal end of the housing;

a needle or cannula assembly disposed within the housing and moveable between a retracted position and an extended position, the needle or cannula assembly including a base having a proximal surface and a distal surface, and a needle or cannula attached to the base;

and

a retraction member in contact with the base and applying a resistive force to maintain the needle or cannula assembly in the retracted position before movement to the extended position; and

a flexible fluid path member having a first end operatively coupled to a connector extending from the proximal surface of the base and a second end operatively coupled to a connector extending from the proximal end of the housing, the flexible fluid path member moveable between the retracted position and the extended position corresponding to the retracted position and the extended position of the needle or cannula assembly,

wherein, pressure is supplied through the first opening until an amount of pressure P1 applies an application force to the proximal surface of the base of the needle or cannula assembly that exceeds the resistive force of the retraction member to move the needle or cannula assembly from the retracted position to the extended position, the needle extending through the second opening in the distal end of the housing in the extended position.

1514. The insertion mechanism of claim **1413**, wherein the base divides the housing into a proximal chamber and a distal chamber, such that when a pressure P1 in the proximal chamber exceeds a pressure P2 in the distal chamber, the needle or cannula assembly moves from the retracted position to the extended position.

1615. The insertion mechanism of any one of claims **1413** and **1514**, further comprising a pair of sealing mechanisms disposed on the housing sidewall near the distal end of the housing, such that the distal surface of the base contacts the sealing mechanisms when the needle assembly is in the extended position.

1716. The insertion mechanism of any one of claims **1413-1615**, wherein the housing includes a sidewall having a threaded inside surface, and the base further includes a side surface in contact with the inside surface of the sidewall, the side surface of the base having a threaded surface corresponding to the threaded inside surface of the sidewall of the housing,

and wherein the threaded inside surface of the sidewall of the housing and the threaded surface of the side surface of the base are one of coarse threading or fine threading, the coarse threading allowing the needle to rotate at least two to three times during insertion, and the fine threading allowing the needle to rotation at least eight to ten times during insertion.

~~18. The insertion mechanism of any one of claims 14-16, further comprising a flexible fluid path member having a first end operatively coupled to a connector extending from the proximal surface of the base and a second end operatively coupled to a connector extending from the proximal end of the housing, the flexible fluid path member moveable between the retracted position and the extended position corresponding to the retracted position and the extended position of the needle or cannula assembly.~~

1917. The insertion mechanism of any of claims 1413-1816, wherein the base includes a pair of side surfaces minimally spaced from the sidewall of the housing to minimize flow-around when pressure is supplied.

2018. The insertion mechanism of claim 1813, wherein the flexible fluid path member is the retraction member that biases the needle assembly in the retracted position.