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Medical Agent Dispensing Apparatuses, Systems, and Methods

Abstract

An example agent administration device may comprise a housing. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be reciprocally displaceable along a guide channel of the housing. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly configured drive the sharp assembly, via urging of a single bias member, from a storage state in which the delivery sharp is within the housing, through a first extended position in which the delivery sharp extends a maximum distance from the housing and to a partially retracted position in which the delivery sharp extends a lesser distance from the housing.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] The present application is a divisional of U.S. Ser. No. 17/566,818, entitled Medical Agent Dispensing Apparatuses, Systems, and Methods, filed Dec. 31, 2021, Attorney Docket No. 00101.00329.AA770 which claims the benefit of U.S. Provisional Application Ser. No. 63/154,931, entitled Medical Agent Dispensing Apparatuses, Systems, and Methods, filed Mar. 1, 2021, Attorney Docket No. 00101.00312.AA380 each of which being incorporated herein by reference in their entireties.

BACKGROUND
Field of Disclosure
[0003] This disclosure relates to medical agent delivery. More specifically, this disclosure relates to dispensers for therapeutic and other medical agents.
Description of Related Art
[0004] Novel pathogens present a variety of public health challenges which are not 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 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 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 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.
[0005] 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.
SUMMARY
[0006] In accordance with an embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a housing cover. The delivery device may further comprise a base coupled to the housing cover. The base may include a first side with a skin adhering face and a second side including a reservoir portion and a guide portion. The delivery

device may further comprise a plunger sled including a plunger portion and an aperture through which the guide portion extends. The plunger sled may be displaceable between a delivered position in which the plunger portion is adjacent an outlet of the reservoir portion and a retracted position in which the plunger is at an end of the reservoir portion opposite the outlet. The delivery device may further comprise at least one delivery sharp in fluid communication with a flow path in an insert at the outlet of the reservoir portion. The delivery device may further comprise a plug displaceable between a first position in which the plug blocks all flow through the insert and second position in which the plug blocks flow through a portion of the insert. The at least one delivery sharp may be in fluid communication with the reservoir portion via the insert when the plug is in the second position. The delivery device may further comprise a first bias member configured to urge the plug to the second position. The delivery device may further comprise a second bias member configured to urge the plunger sled to displace toward the delivered position. The delivery device may further comprise a removable locking member which blocks displacement of the plug and plunger sled until being removed from the delivery device.

[0007] In some embodiments, the plunger portion may be at least partially formed of elastomeric material. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a microneedle. In some embodiments, the at least one delivery sharp may be an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented substantially perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the first and second bias member may be compression springs. In some embodiments, the insert may be at least partially elastomeric. In some embodiments, the plunger sled may be a rectilinear frame having a first end from which the plunger portion projects, an opposing second end in which the aperture is disposed, and side panels including guides. In some embodiments, the plunger sled may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, and opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the locking member may include at least one portion which may be configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the second bias member which occurs as the plunger sled is displaced from the retracted position to the delivered position may be 10-20% of the total displacement range of the second bias member. In some embodiments, the plug and first bias member may be disposed within the guide portion and the second bias member may surround the guide portion. In some embodiments, the plug may include a head portion and a pin portion which extends from the head portion. In some embodiments, the locking member may extend through an orifice in the head portion when the locking member is installed within the delivery device.

[0008] In accordance with an embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a housing cover. The delivery device may further comprise a base coupled to the housing cover. The base may include a first side with a skin adhering face and a second side including a reservoir portion and a guide portion. The delivery device may further comprise a displaceable plunger sled including a plunger portion and an

aperture through which the guide portion extends. Displacement of the plunger sled may cause displacement of the plunger portion toward an outlet of the reservoir. The delivery device may further comprise at least one delivery sharp in fluid communication with a flow path in an insert at the outlet of the reservoir portion. The delivery device may further comprise a displaceable plug configured to block all flow through the insert in a first position. The delivery device may further comprise a first bias member configured to urge the plug to a second position in which a flow path through the insert to the at least one delivery sharp is established. The delivery device may further comprise a second bias member configured to urge displacement of the plunger sled. The delivery device may further comprise a removable locking member which may block displacement of the plug and plunger sled until being removed from the delivery device.

[0009] In some embodiments, the plunger portion may be at least partially formed of elastomeric material. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a microneedle. In some embodiments, the at least one delivery sharp may be an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the first and second bias member may be compression springs. In some embodiments, the insert may be at least partially elastomeric. In some embodiments, the plunger sled may be a rectilinear frame having a first end from which the plunger portion projects, an opposing second end in which the aperture is disposed, and side panels including guides. In some embodiments, the plunger sled may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the locking member may include a least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the second bias member which occurs as the plunger sled is displaced along the reservoir portion to fully deliver the contents of the reservoir portion may be 10-20% of the total displacement range of the second bias member. In some embodiments, the plug and first bias member may be disposed within the guide portion and the second bias member surrounds the guide portion. In some embodiments, the plug may include a head portion and a pin portion which extends from the head portion.

[0010] In accordance with another embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a base including a first side with a skin adhering face and a second side including a reservoir portion. The delivery device may further comprise a housing cover coupled to the base. The delivery device may further comprise a plunger displaceable within the reservoir portion. The delivery device may further comprise at least one delivery sharp in fluid communication with a fluid pathway in an insert disposed at a reservoir outlet of the reservoir portion. The delivery device may further comprise a plug configured to block all flow through the insert in a first position. The delivery device may further comprise a first bias member configured to urge the plug to a second position in which a flow path through the insert to the at least one delivery sharp is established. The delivery device may further comprise a second

bias member configured to urge the plunger toward the reservoir outlet. The delivery device may further comprise a lock which blocks displacement of the plug and plunger until the lock is actuated out a locking state.

[0011] In some embodiments, the plunger may be at least partly elastomeric. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a pyramid shaped, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may comprise an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the first and second bias member may be compression springs. In some embodiments, the insert may be at least partially elastomeric. In some embodiments, the plunger may be coupled to a frame having a first end from which the plunger projects, an opposing second end, and side panels including guides. In some embodiments, the frame may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the lock may include at least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the second bias member which occurs as the plunger is displaced to fully deliver the contents of the reservoir portion may be 10-20% of the total displacement range of the second bias member. In some embodiments, the plug and first bias member may be disposed within a guide portion of the base and the second bias member may surround the guide portion. In some embodiments, the plug may include a head portion and an occluder member.

[0012] In accordance with yet another embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a base including a first side with a skin adhering face and a second side including a reservoir portion. The delivery device may further comprise a housing cover coupled to the base. The delivery device may further comprise a plunger displaceable within the reservoir portion. The delivery device may further comprise at least one delivery sharp in fluid communication with a fluid pathway in an insert disposed at a reservoir outlet of the reservoir portion. The delivery device may further comprise an activation assembly configured to be actuated from an inactive state where flow from the reservoir portion is blocked and the plunger is inhibited from displacing to an activated state where a flow path through the insert to the delivery sharp is established and the plunger is free to displace. The delivery device may further comprise a bias member configured to urge the plunger toward the reservoir outlet.

[0013] In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. In some embodiments, the activation assembly may include a displaceable plug. In some embodiments, the activation assembly may include a bias member disposed between a head of the plug and the insert. In some embodiments, the activation assembly may include a plug having a first position in which the plug blocks all flow through the insert and a second position in which a flow path through the insert to the at least one delivery sharp is established. In some

embodiments, the activation assembly may include a plug bias member configured to urge the plug from the first position to the second position. The activation assembly may further comprise a lock which prevents displacement of the plug to the second position until the lock is actuated. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a pyramid shaped, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may be a pointed, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may comprise an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the at least one delivery sharp may have a length of about 0.6 millimeters. In some embodiments, the plunger may be coupled to a frame having a first end from which the plunger projects, an opposing second end, and side panels including guides. In some embodiments, the frame may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. The lock may include a least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the bias member which occurs as the plunger is displaced to fully deliver the contents of the reservoir portion is may be 10-20% of the total displacement range of the second bias member.

[0014] In accordance with an embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a base including a first side with a skin adhering face and a second side including a reservoir portion. The delivery device may further comprise a housing cover coupled to the base. The delivery device may further comprise a plunger. The delivery device may further comprise at least one delivery sharp. The delivery device may further comprise an activation assembly configured to be actuated between an inactive state where flow from the reservoir portion to the at least one delivery sharp is blocked and the plunger is inhibited from displacing to an activated state where a flow path to the delivery sharp is established and the plunger is free to displace. The delivery device may further comprise a bias member configured to urge the plunger toward the reservoir outlet.

[0015] In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. In some embodiments, the activation assembly may include a displaceable plug. In some embodiments, the activation assembly may include a bias member disposed between a head of the plug and an insert disposed at an outlet of the reservoir portion. In some embodiments, the activation assembly may include a plug having a first position in which the plug blocks all flow through an insert disposed at an outlet of the reservoir portion and a second position in which a flow path through the insert to the at least one delivery sharp is established. In some embodiments, the activation assembly includes a plug bias member configured to urge the plug from the first

position to the second position, the activation assembly further comprising a lock which prevents displacement of the plug to the second position until the lock is actuated. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a pyramid shaped, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may be a pointed, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may comprise an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the plunger may be coupled to a frame having a first end from which the plunger projects, an opposing second end, and side panels including guides. In some embodiments, the frame may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. The lock may include a least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the bias member which occurs as the plunger is displaced to fully deliver the contents of the reservoir portion may be 10-20% of the total displacement range of the second bias member.

[0016] In accordance with an embodiment of the present disclosure a delivery device for administering a medical agent to a patient may comprise a base including a first side with a skin adhering face and a second side including a reservoir portion. The delivery device may further comprise a housing cover coupled to the base. The delivery device may further comprise a plunger displaceable within the reservoir portion. The delivery device may further comprise an infusion set connector in fluid communication with a fluid pathway in an insert disposed at a reservoir outlet of the reservoir portion. The delivery device may further comprise an activation assembly configured to be actuated from an inactive state where flow from the reservoir portion is blocked and the plunger is inhibited from displacing to an activated state where a flow path through the insert to the delivery sharp is established and the plunger is free to displace. The delivery device may further comprise a bias member configured to urge the plunger toward the reservoir outlet.

[0017] In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. In some embodiments, activation assembly may include a displaceable plug. In some embodiments, the activation assembly may include a bias member disposed between a head of the plug and an insert disposed at an outlet of the reservoir portion. In some embodiments, the activation assembly may include a plug having a first position in which the plug blocks all flow through an insert disposed at an outlet of the reservoir portion and a second position in which a flow path through the insert to the at least one delivery sharp is established. In some embodiments, the activation assembly may include a plug bias member configured to urge the plug from the first position to the second position, the activation assembly further comprising a lock which prevents displacement of the plug to the second position until the lock is actuated. In some embodiments,

the infusion set connector may form a portion of the base and include a face which is coplanar with the skin adhering face of the base. In some embodiments, the infusion set connector may be coupled to the rest of the delivery device via an expanse of infusion tubing. In some embodiments, the infusion tubing may between an inch and a meter long. In some embodiments, the infusion tubing may be at least a meter long. In some embodiments, the infusion set connector may include a connector sharp configured to pierce a septum of an infusion set. In some embodiments, the infusion site connector may include at least one coupling projection. In some embodiments, the infusion site connector may include a removable cap member. In some embodiments, the infusion site connector may be configured to mate with an infusion set assembly. The reservoir portion may be placed into fluidic communication with a delivery destination in the patient via the infusion set assembly when the infusion site connector is mated to the infusion set assembly. In some embodiments, the plunger may be coupled to a frame having a first end from which the plunger projects, an opposing second end, and side panels including guides. In some embodiments, the frame may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device further comprises a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. The lock may include a least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the bias member which occurs as the plunger is displaced to fully deliver the contents of the reservoir portion may be 10-20% of the total displacement range of the second bias member.

[0018] In accordance with another embodiment of the present disclosure, a delivery device for administering a medical agent to a patient may comprise a base including a first side with a skin adhering face and a second side including a reservoir portion. The delivery device may further comprise a housing cover coupled to the base. The delivery device may further comprise a plunger displaceable within the reservoir portion. The delivery device may further comprise at least one delivery sharp which may be actuatable from a stowed position in the at least one delivery sharp is disposed in recessed relationship to the skin adhering face of the base to a deployed position in which at least a portion of the at least one delivery sharp extends proud of the skin adhering face of the base. The delivery device may further comprise an activation assembly configured to be actuated from an inactive state where flow from the reservoir portion is blocked and the plunger is inhibited from displacing to an activated state where a flow path through the insert to the delivery sharp is established and the plunger is free to displace. The delivery device may further comprise a bias member configured to urge the plunger toward the reservoir outlet.

[0019] In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. In some embodiments, the activation assembly may include a displaceable plug. In some embodiments, the activation assembly may include a bias member disposed between a head of the plug and an insert disposed at an outlet of the reservoir portion. In some embodiments, the activation assembly ay include a plug having a first position in which the plug blocks all flow through an insert disposed at an outlet of the reservoir portion and a second position in which a flow path through the insert to the at least one delivery sharp is established. In some embodiments, the activation assembly includes a plug bias member configured to urge the plug from the first

position to the second position. The activation assembly may further comprise a lock which prevents displacement of the plug to the second position until the lock is actuated. In some embodiments, the at least one delivery sharp may be selected from a group consisting of an intramuscular delivery needle and a subcutaneous delivery needle. In some embodiments, the at least one delivery sharp may comprise an array of delivery sharps. In some embodiments, the at least one delivery sharp may be a pyramid shaped, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may be a pointed, silicon crystal, microneedle. In some embodiments, the at least one delivery sharp may comprise an array of microneedles. In some embodiments, the at least one delivery sharp may be oriented perpendicular to the skin adhering face of the delivery device. In some embodiments, the at least one delivery sharp may be oriented at an acute angle to the skin adhering face of the base. In some embodiments, the at least one delivery sharp may have a length of no more than one millimeter. In some embodiments, the plunger may be coupled to a frame having a first end from which the plunger projects, an opposing second end, and side panels including guides. In some embodiments, the frame may include at least one coupling lip configured to engage a drive element of a filling fixture. In some embodiments, the reservoir portion may be filled with a medical agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, the delivery device may further comprise a cover member coupled to the base and covering the at least one delivery sharp. In some embodiments, the activation assembly may include a lock which presents a mechanical interference to displacement of the plunger when the activation assembly is in the inactive state. The lock may include a least one portion which is configured to displace from a stowed state against the housing cover to a second state where the at least one portion extends a greater distance from the housing cover compared to the its position in the stowed state. In some embodiments, the delivery device may further comprise a flow limiter restriction upstream of the at least one delivery sharp. In some embodiments, the displacement of the bias member which occurs as the plunger is displaced to fully deliver the contents of the reservoir portion may be 10-20% of the total displacement range of the second bias member.

[0020] In accordance with an embodiment of the present disclosure a method of delivering a medical agent may comprise applying a delivery device to a patient. The method may further comprise penetrating the skin of the patient with at least one delivery sharp of the delivery device. The method may further comprise actuating a lock of the delivery device. The method may further comprise driving a plug, via a plug driver, from a flow preventing position, to a second position in which a flow path from a reservoir portion of the delivery device to the at least one delivery sharp is established. The method may further comprise dispensing contents of the reservoir portion out of the at least one delivery sharp by driving a plunger sled, via plunger sled driver, from a retracted position to a delivered position in which a plunger on the plunger sled is adjacent an outlet of the reservoir portion.

[0021] In some embodiments, the plug driver and plunger sled driver may be coil springs. In some embodiments, the plug driver and the plunger sled driver may be compression springs. In some embodiments, driving the plunger sled from the retracted position to the delivered position may comprise displacing the plunger sled along a guide portion of a base of the delivery device. In some embodiments, the plunger sled may be a rectilinear frame having a first end from which the plunger extends, and an opposing end including an aperture and driving the plunger sled from the retracted position to the delivered position may comprise displacing the aperture along a guide portion of the base of the delivery device. In some embodiments, the plunger sled may further comprise side panels with guides and driving the plunger sled from the retracted position to the delivered position may comprise displacing the guides along a guide surface formed as part of the base. In some embodiments, dispensing the contents of the reservoir portion may comprise dispensing an agent

selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, penetrating the skin with the at least one delivery sharp comprises puncturing the skin with a delivery sharp selected from a list consisting of a subcutaneous needle and an intramuscular needle. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with a microneedle array. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with a plurality of pyramid sharped, silicon crystal microneedles no longer than one millimeter in length. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating at least the stratum corneum and epidermis with the at least one delivery sharp. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an angle substantially perpendicular to the skin surface. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an acute angle relative to the skin surface. In some embodiments, actuating the lock may comprise removing the lock from the delivery device. In some embodiments, actuating the lock comprises displacing a portion of the lock from a stowed state in which the portion is against a housing of the delivery device to a second state in which the portion projects a greater distance from the housing and removing the lock from the delivery device. In some embodiments, driving the plug to the second position may comprise urging the plug against a stop surface provided by an interior face of a portion of a housing for the delivery device. In some embodiments, displacing the plug to the second position may comprise displacing a pin of the plug along a portion of a flow path in an elastomeric insert disposed at the outlet of the reservoir. In some embodiments, the plunger sled driver may be a coil spring and driving the plunger sled from the retracted position to the delivered position may comprise relaxing the coil spring over 10-20% of its total displacement range. In some embodiments, the method may further comprise removing a cover member and an adhesive backing from the delivery device. In some embodiments, the method may further comprise limiting the flow rate of fluid out of the at least one delivery sharp with a flow limiting restriction in the flow path from the reservoir to the at least one delivery sharp. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise actuating the at least on delivery sharp from a stowed state within the delivery device to an exposed state in which at least a portion of the at least one delivery sharp extends out of the delivery device.

[0022] In accordance with another embodiment of the present disclosure a method of delivering opioid antagonist to an overdose victim may comprise applying a delivery device to a patient. The method may further comprise penetrating the skin of the patient with at least one delivery sharp of the delivery device to at least subcutaneous tissue. The method may further comprise actuating a lock of the delivery device. The method may further comprise driving a plug, via a plug driver, from a flow preventing position, to a second position in which a flow path from a reservoir portion of the delivery device to the at least one delivery sharp is established. The method may further comprise dispensing the opioid antagonist from the reservoir portion out of the at least one delivery sharp by driving a plunger sled, via plunger sled driver, from a retracted position to a delivered position in which a plunger on the plunger sled is adjacent an outlet of the reservoir portion.

[0023] In some embodiments, the method may further comprise applying a second delivery device to the victim and dispensing the opioid antagonist from the reservoir portion to the user. The flow rate from the second delivery device being a faction of the flow rate from the first delivery device. In some embodiments, the plug driver and plunger sled driver may be compression springs. In some embodiments, the plug driver and plunger sled driver may be coil springs. In some embodiments, driving the plunger sled from the retracted position to the delivered position may comprise displacing the plunger sled along a guide portion of a base of the delivery device. In some embodiments, the plunger sled may be a rectilinear frame having a first end from which the plunger

extends, and an opposing end including an aperture and driving the plunger sled from the retracted position to the delivered position comprises displacing the aperture along a guide portion of the base of the delivery device. In some embodiments, the plunger sled may further comprise side panels with guides and driving the plunger sled from the retracted position to the delivered position may comprise displacing the guides along a guide surface formed as part of the base. In some embodiments, dispensing the opioid antagonist from the reservoir portion may comprise dispensing naloxone from the reservoir portion. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise puncturing the skin with a delivery sharp selected from a list consisting of a subcutaneous needle and an intramuscular needle. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with an array of delivery sharps. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an angle substantially perpendicular to the skin surface. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an acute angle relative to the skin surface. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise actuating the at least on delivery sharp from a stowed state within the delivery device to an exposed state in which at least a portion of the at least one delivery sharp extends out of the delivery device. In some embodiments, actuating the lock may comprise removing the lock from the delivery device. In some embodiments, actuating the lock may comprise displacing a portion of the lock from a stowed state in which the portion is against a housing of the delivery device to a second state in which the portion projects a greater distance from the housing and removing the lock from the delivery device. In some embodiments, driving the plug to the second position may comprise urging the plug against a stop surface provided by an interior face of a portion of a housing for the delivery device. In some embodiments, displacing the plug to the second position may comprise displacing a pin of the plug along a portion of a flow path in an elastomeric insert disposed at the outlet of the reservoir. In some embodiments, the plunger sled driver may be a coil spring and driving the plunger sled from the retracted position to the delivered position may comprise relaxing the coil spring over 10-20% of its total displacement range. In some embodiments, the method may further comprise removing a cover member and an adhesive backing from the delivery device. In some embodiments, the method may further comprise limiting the flow rate of fluid out of the at least one delivery sharp with a flow limiting restriction in the flow path from the reservoir to the at least one delivery sharp.

[0024] In accordance with an embodiment of the present disclosure a method of delivering a medical agent may comprise applying a delivery device to a patient. The method may further comprise coupling an infusion set connector to an infusion set base in the skin of the patient. The method may further comprise actuating a lock of the delivery device. The method may further comprise driving a plug, via a plug driver, from a flow preventing position, to a second position in which a flow path from a reservoir portion of the delivery device to the at least one delivery sharp is established. The method may further comprise dispensing contents of the reservoir portion out of the at least one delivery sharp by driving a plunger sled, via plunger sled driver, from a retracted position to a delivered position in which a plunger on the plunger sled is adjacent an outlet of the reservoir portion.

[0025] In some embodiments, the plug driver and plunger sled driver may be compression springs. In some embodiments, the plug driver and the plunger sled drive may be coil springs. In some embodiments, driving the plunger sled from the retracted position to the delivered position may comprise displacing the plunger sled along a guide portion of a base of the delivery device. In some embodiments, the plunger sled may be a rectilinear frame having a first end from which the plunger extends, and an opposing end including an aperture and driving the plunger sled from the retracted position to the delivered position comprises displacing the aperture along a guide portion of the base of the delivery device. In some embodiments, the plunger sled may further comprise side

panels with guides and driving the plunger sled from the retracted position to the delivered position may comprise displacing the guides along a guide surface formed as part of the base. In some embodiments, dispensing the contents of the reservoir portion may comprise dispensing an agent selected from a list consisting of a vaccine, an antiviral, a retroviral, a peptide, an endocrine disorder drug, insulin, a diagnostic agent, an allergen, an overdose intervention drug, an opioid antagonist, naloxone, and a tuberculosis testing agent. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise puncturing the skin with a delivery sharp selected from a list consisting of a subcutaneous needle and an intramuscular needle. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with a microneedle array. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with a plurality of pyramid sharped, silicon crystal microneedles no longer than one millimeter in length. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating at least the stratum corneum and epidermis with the at least one delivery sharp. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an angle substantially perpendicular to the skin surface. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise penetrating the skin with the at least one delivery sharp at an acute angle relative to the skin surface. In some embodiments, actuating the lock may comprise removing the lock from the delivery device. In some embodiments, actuating the lock may comprise displacing a portion of the lock from a stowed state in which the portion is against a housing of the delivery device to a second state in which the portion projects a greater distance from the housing and removing the lock from the delivery device. In some embodiments, driving the plug to the second position may comprise urging the plug against a stop surface provided by an interior face of a portion of a housing for the delivery device. In some embodiments, displacing the plug to the second position may comprise displacing a pin of the plug along a portion of a flow path in an elastomeric insert disposed at the outlet of the reservoir. In some embodiments, the plunger sled driver may be a coil spring and driving the plunger sled from the retracted position to the delivered position may comprise relaxing the coil spring over 10-20% of its total displacement range. In some embodiments, the method may further comprises removing a cover member and an adhesive backing from the delivery device. In some embodiments, the method may further comprise limiting the flow rate of fluid out of the at least one delivery sharp with a flow limiting restriction in the flow path from the reservoir to the at least one delivery sharp. In some embodiments, penetrating the skin with the at least one delivery sharp may comprise actuating the at least one delivery sharp from a stowed state within the delivery device to an exposed state in which at least a portion of the at least one delivery sharp extends out of the delivery device.

[0026] In accordance with another embodiment of the present disclosure an agent administration device may comprise a housing. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be reciprocally displaceable along a guide channel of the housing. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly configured drive the sharp assembly, via urging of a single bias member, from a storage state in which the delivery sharp is within the housing, through a first extended position in which the delivery sharp extends a maximum distance from the housing and to a partially retracted position in which the delivery sharp extends a lesser distance from the housing.

[0027] In some embodiments, the housing may include a base portion in which the guide channel is defined and the housing may include a cover portion. The access port may be included as part of the cover portion. In some embodiments, the guide channel may define an insertion angle of the delivery sharp. In some embodiments, the insertion angle may be 5°-45°. In some embodiments, the insertion angle may be no greater than 35°. In some embodiments, the access port may include a piercable septum. In some embodiments, the delivery sharp may be a needle of no larger than 30

gauge. In some embodiments, the bias member may be a torsion spring. In some embodiments, the delivery sharp may include a point which may be rotationally clocked to a 12 o'clock position. In some embodiments, the maximum distance may be sufficient to penetrate transcutaneously into a patient. In some embodiments, the lesser distance may correspond to a penetration depth in a patient suitable for intradermal administration of agent. In some embodiments, the agent may include at least one vaccine. In some embodiments, the agent may include at least one SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine. In some embodiments, the device may further comprise a removable lock member configured to hold the sharp assembly in the storage state when installed in the device. In some embodiments, the lock member may be coupled to a removable cover strip attached to the housing and covering the access port. In some embodiments, the actuation assembly may include the single bias member, a pivot pin pivotally retained in the housing, and a guide pin coupled to the pivot pin and the sharp assembly. In some embodiments, the housing may define a guide track, the guide pin being displaceable along the guide track.

[0028] In accordance with yet another embodiment of the present disclosure, an agent administration device may comprise a housing including a guide channel. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be reciprocally displaceable along the guide channel. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly coupled to the sharp assembly and including a guide pin displaceable along an arcuate path from a first position to a stop. The sharp assembly may be displaced from a storage state in which the delivery sharp is within the housing, to an administration position in which the delivery sharp extends a target distance out of the housing as the guide pin displaces from the first position to the stop. The delivery sharp may extend a distance greater than the target distance as the guide pin is displaced along an intermediate portion of the path.

[0029] In some embodiments, the housing may include a base portion in which the guide channel is defined and the housing may include a cover portion. The access port may be included as part of the cover portion. In some embodiments, the guide channel may define an insertion angle of the delivery sharp. In some embodiments, the insertion angle may be 5°-45°. In some embodiments, the insertion angle may be no greater than 35°. In some embodiments, the access port may include a piercable septum. In some embodiments, the delivery sharp may be a needle of no larger than 30 gauge. In some embodiments, the delivery sharp may include a point which is rotationally clocked to a 12 o'clock position. In some embodiments, the distance greater than the target distance may be a distance sufficient to penetrate transcutaneously into a patient. In some embodiments, the target distance may correspond to a penetration depth in a patient suitable for intradermal administration of agent. In some embodiments, the agent may include at least one vaccine. In some embodiments, the agent may include at least one SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine. In some embodiments, the device may further comprise a removable lock member configured to hold the sharp assembly in the storage state when installed in the device. In some embodiments, the lock member may be coupled to a removable cover strip attached to the housing and covering the access port. In some embodiments, the actuation assembly may include a bias member, a pivot pin pivotally retained in the housing, the guide pin and a

linkage coupling which couples the actuation assembly to the sharp assembly. In some embodiments, the housing may define a guide track within which a portion of the guide pin is disposed, the guide track defining the arcuate path.
[0030] In accordance with yet another embodiment of the present disclosure an agent administration device may comprise a housing. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be reciprocally displaceable along a guide channel of the housing. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly including a guide pin coupled to the sharp assembly. The actuation assembly may be configured to drive the sharp assembly from a storage state in which the delivery sharp is within the housing, through a first extended position in which the delivery sharp extends a maximum distance from the housing and to a partially retracted position in which the delivery sharp extends a lesser distance from the housing via spring loaded displacement of the guide pin along an arcuate path.
[0031] In some embodiments, the housing may include a base portion in which the guide channel is defined and the housing may include a cover portion. The access port may be included as part of the cover portion. In some embodiments, the guide channel may define an insertion angle of the delivery sharp. In some embodiments, the insertion angle may be 5°-45°. In some embodiments, the insertion angle may be no greater than 35°. In some embodiments, the access port may include a piercable septum. In some embodiments, the delivery sharp may be a needle of no larger than 30 gauge. In some embodiments, the delivery sharp may include a point which is rotationally clocked to a 12 o'clock position. In some embodiments, the maximum distance may be a distance sufficient to penetrate transcutaneously into a patient. In some embodiments, the target distance may correspond to a penetration depth in a patient suitable for intradermal administration of agent. In some embodiments, the agent may include at least one vaccine. In some embodiments, the agent may include at least one SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine. In some embodiments, the device may further comprise a removable lock member configured to hold the sharp assembly in the storage state when installed in the device. In some embodiments, the lock member may be coupled to a removable cover strip attached to the housing and covering the access port. In some embodiments, the actuation assembly may include the guide pin, a bias member configured to assert a spring load on the guide pin, and a pivot pin pivotally retained in the housing and coupled to the guide pin. In some embodiments, the housing may define a guide track within which a portion of the guide pin is disposed. The guide track may define the arcuate path.
[0032] In accordance with yet another embodiment of the present disclosure an agent administration device may comprise a housing including a guide. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be reciprocally displaceable along the guide. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly coupled to the sharp assembly and including a guide pin continuously displaceable along a path from a starting position to a stop. The sharp assembly may be displaced from a storage state as the guide pin displaces from the first position, to an administration state when the guide pin contacts the stop in which the delivery sharp extends a target distance out of the housing. The delivery sharp may extend a distance greater than the target distance as the guide pin is displaced along an intermediate portion of the path.
[0033] In some embodiments, the housing may include a base portion in which the guide is defined and the housing may include a cover portion. The access port may be included as part of the cover

portion. In some embodiments, the guide may define an insertion angle of the delivery sharp. In some embodiments, the insertion angle may be 5°-45°. In some embodiments, the insertion angle may be no greater than 35°. In some embodiments, the access port may include a piercable septum. In some embodiments, the delivery sharp may be a needle of no larger than 30 gauge. In some embodiments, the delivery sharp may include a point which is rotationally clocked to a 12 o'clock position. In some embodiments, the distance greater than the target distance may be a distance sufficient to penetrate transcutaneously into a patient. In some embodiments, the target distance may correspond to a penetration depth in a patient suitable for intradermal administration of agent. In some embodiments, the agent may include at least one vaccine. In some embodiments, the agent may include at least one SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine. In some embodiments, the device may further comprise a removable lock member configured to hold the sharp assembly in the storage state when installed in the device. In some embodiments, the lock member may be coupled to a removable cover strip attached to the housing and covering the access port. In some embodiments, the actuation assembly may include the guide pin, a bias member configured to assert a bias force on the guide pin, and a pivot pin pivotally retained in the housing and coupled to the guide pin. In some embodiments, the housing may define an arcuate guide track within which a portion of the guide pin is disposed. The portion of the guide pin may displace along the arcuate track as the guide pin displaces along the path from the starting position to the stop.

[0034] In accordance with another embodiment of the present disclosure an agent administration device may comprise a housing including a guide. The device may further comprise a sharp assembly including at least one delivery sharp. The sharp assembly may be reciprocally displaceable along the guide. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuation assembly coupled to the sharp assembly and including a guide pin. The sharp assembly may be displaced from a storage state to an administration state in which the at least one delivery sharp extends a target distance out of the housing as the guide pin displaces from a starting position to a stop in a single direction. The at least one delivery sharp may extend a distance greater than the target distance as the guide pin is displaced along an intermediate portion of the path.

[0035] In some embodiments, the single direction may be selected from a group consisting of a clockwise direction and a counterclockwise direction. In some embodiments, the single direction may be a direction of rotational motion. In some embodiments, the housing may include a base portion in which the guide is defined and the housing may include a cover portion. The access port may be included as part of the cover portion. In some embodiments, the guide may define an insertion angle of the delivery sharp. In some embodiments, the insertion angle may be 5°-45°. In some embodiments, the insertion angle may be no greater than 35°. In some embodiments, the access port may include a piercable septum. In some embodiments, the delivery sharp may be a needle of no larger than 30 gauge. In some embodiments, the delivery sharp may include a point which is rotationally clocked to a 12 o'clock position. In some embodiments, the distance greater than the target distance may be a distance sufficient to penetrate transcutaneously into a patient. In some embodiments, the target distance may correspond to a penetration depth in a patient suitable for intradermal administration of agent. In some embodiments, the agent may include at least one vaccine. In some embodiments, the agent may include at least one SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based

vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine. In some embodiments, the device may further comprise a removable lock member configured to hold the sharp assembly in the storage state when installed in the device. In some embodiments, the lock member may be coupled to a removable cover strip attached to the housing and covering the access port. In some embodiments, the actuation assembly may include the guide pin, a bias member configured to assert a bias force on the guide pin, and a pivot pin pivotally retained in the housing and coupled to the guide pin. In some embodiments, the housing may define an arcuate guide track within which a portion of the guide pin is disposed. The portion of the guide pin may displace along the arcuate track as the guide pin displaces along the path from the starting position to the stop.

[0036] In accordance with another embodiment of the present disclosure a drug delivery device may comprise a housing. The device may further comprise a sharp assembly including a delivery sharp. The sharp assembly may be displaceable through an actuation sequence from a storage state in which the delivery sharp is within the housing, through a first extended position in which the delivery sharp extends a maximum distance from the housing and to a second extended position in which the delivery sharp extends a lesser distance from the housing. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuator assembly having a bias member, a guide pin configured for displacement along a guide track, and a linkage coupling the actuation assembly to the sharp assembly such that displacement of the guide pin engenders displacement of the sharp assembly. When the sharp assembly is in the storage state, the bias member may urge the guide pin to a terminus of the guide track. The sharp assembly may be displaced through the actuation sequence as the guide pin is displaced to the terminus via the linkage.

[0037] In accordance with yet another embodiment of the present disclosure a drug delivery device may comprise a housing including a base portion and a cover portion. The device may further comprise a sharp assembly displaceable along a guide channel and including a delivery sharp. The device may further comprise an access port in fluid communication with the delivery sharp. The device may further comprise an actuator assembly having a bias member, a guide pin configured for displacement along a guide track, and a linkage coupling the actuation assembly to the sharp assembly such that displacement of the guide pin engenders displacement of the sharp assembly. The device may further comprise a lock member including a portion that projects into the guide channel. The lock member may block displacement of the sled and may hold the bias member in a stressed state when the delivery sharp is in a storage state. Upon removal of the lock member, the bias member may be configured to restore to a less stressed state and urge the guide pin along the guide track to a terminus of the guide track. The sharp assembly displacing through a first extended position in which the delivery sharp extends a maximum distance from the housing and to a second extended position in which the delivery sharp extends a second distance from the housing as the guide pin displaces to the terminus of the guide track.

[0038] In accordance with another embodiment of the present disclosure an agent administration device may comprise a housing including a base body and a slide body displaceable relative to the base body from a first position to a second position. The slide body may include a cam. The device may further comprise an elastomeric housing and including a chamber. The device may further comprise a pressurized agent containing ampoule including a frangible which is disposed within the chamber. The elastomeric housing may form a seal against the ampoule upstream of the frangible. The device may further comprise an outlet assembly including a ram, a cam follower, and a nozzle portion having at least one microneedle in fluid communication with the chamber. The outlet assembly may be configured to displace from a storage state to a deployed state via interaction of the cam and cam follower as the slide body displaces from the first position to the second position. The ram may be configured to be driven into the elastomeric housing and break the frangible as the outlet assembly is displaced toward the deployed state.

[0039] In some embodiments, the elastomeric housing may include a port with a receptacle. The outlet assembly may include a portion which is coupled into the receptacle. In some embodiments, the base body may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the base body may include at least one guide track and the slide body may include at least one rail which moves along the guide track with displacement of the slide body. In some embodiments, the base body may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the slide body when in the first state and permit displacement of the slide body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the slide body may comprise a pair of cams and a cross piece extending between the cams. In some embodiments, the slide body may further comprise a second cam and the outlet assembly may include a second cam follower. In some embodiments, the outlet assembly may be configured to pivot from the storage state to the deployed state. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the base portion configured to be adhered to the skin of a patient as the slide body is displaced from the first position toward the second position. In some embodiments, when the slide body is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit further displacement of the cam follower. In some embodiments, the plateau portion may present a mechanical interference to further displacement of the cam follower. In some embodiments, the base portion may include a skin depressor. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.

[0040] In accordance with yet another embodiment of the present disclosure an agent administration device may comprise a base body. The device may further comprise a slide body coupled to the base body and displaceable relative to the base body from a first position to a second position. The slide body may include a cam. The device may further comprise an elastomeric housing and including a chamber. The device may further comprise a pressurized agent containing ampoule including a frangible which is disposed within the chamber. The elastomeric housing may form a seal against the ampoule upstream of the frangible. The device may further comprise an outlet assembly including a ram, a cam follower, and a nozzle portion having at least one microneedle in fluid communication with the chamber. The outlet assembly may be configured to displace from a storage state to a deployed state via interaction of the cam and cam follower as the slide body displaces from the first position to the second position. The ram may be configured to be driven into the elastomeric housing and break the frangible as the outlet assembly is displaced toward the deployed state.

[0041] In some embodiments, the elastomeric housing may include a port with a receptacle. The outlet assembly may include a portion which is coupled into the receptacle. In some embodiments, the base body may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the base body may include at least one guide track and the slide body may include at least one rail which moves along the guide track with displacement of the slide body. In some embodiments, the base body may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the slide body when in the first state and permit displacement of the slide body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the slide body may comprise a pair of cams and a cross piece

extending between the cams. In some embodiments, the slide body may further comprise a second cam and the outlet assembly may include a second cam follower. In some embodiments, the outlet assembly may be configured to pivot from the storage state to the deployed state. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the base portion configured to be adhered to the skin of a patient as the slide body is displaced from the first position toward the second position. In some embodiments, when the slide body is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit further displacement of the cam follower. In some embodiments, the base portion may include a skin depressor. In some embodiments, the ampoule may be constructed out of glass. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.

[0042] In accordance with another embodiment of the present disclosure an agent administration device may comprise a pressurized agent containing ampoule including a frangible. The device may further comprise an elastomeric housing surrounding and forming a seal against a portion of the ampoule including the frangible. The device may further comprise an outlet assembly including a ram, a cam follower, and a nozzle portion having at least one microneedle in fluid communication with the chamber. The device may further comprise a housing including a displaceable body having a cam. The outlet assembly may be configured to displace from a storage state to a deployed state via interaction of the cam and cam follower as the displaceable body displaces from a first position to a second position relative to a base portion of the housing. The ram may be configured to be driven into the elastomeric housing and break the frangible as the outlet assembly is displaced toward the deployed state.

[0043] In some embodiments, the elastomeric housing may include a port with a receptacle. The outlet assembly may include a portion which is coupled into the receptacle. In some embodiments, the base body may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the base portion may include at least one guide track and the displaceable body may include at least one rail which moves along the guide track with displacement of the displaceable body. In some embodiments, the housing may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the displaceable body when in the first state and may permit displacement of the displaceable body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the displaceable body may comprise a pair of cams and a cross piece extending between the cams. In some embodiments, the cross piece may be disposed over a portion of the ampoule downstream of the frangible when the displaceable body is in the first position and may be displaced over a portion of the ampoule upstream of the frangible as the displaceable body is displaced to the second position. In some embodiments, the outlet assembly may include a second cam follower and the displaceable body may further comprise a second cam configured to interact with the second cam follower as the displaceable body is displaced from the first position to the second position. In some embodiments, the outlet assembly may be configured to pivot from the storage state to the deployed state. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the base portion configured to be adhered to the skin of a patient as the displaceable body is displaced from the first position toward the second position. In some embodiments, when the displaceable body is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit

further displacement of the cam follower. In some embodiments, the housing may include a skin depressor. In some embodiments, the ampoule is constructed out of glass. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.

[0044] In accordance with another embodiment of the present disclosure an agent administration device may comprise a pressurized agent containing ampoule including a frangible. The device may further comprise an elastomeric housing having a chamber surrounding and forming a seal against a portion of the ampoule that includes the frangible. The device may further comprise an outlet assembly pivotally displaceable between a storage state and a deployed state and including a ram, a cam follower, and a nozzle having at least one microneedle in fluid communication with the chamber. The device may further comprise a housing including a displaceable body having a cam. The cam may be configured to engender displacement of the cam follower and pivoting of the outlet assembly to the deployed state as the displaceable body is displaced from a first position to a second position on the housing. At least a portion of the elastomeric housing may be in a displacement path of the ram as the outlet assembly is pivoted to the deployed state. The ram may be configured exert a frangible breaking force on the ampoule as the ram is driven into the at least a portion of the elastomeric housing.

[0045] In some embodiments, the elastomeric housing may include a port with a receptacle. The outlet assembly may include a portion which may be coupled into the receptacle. In some embodiments, the housing may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the housing may include at least one guide track and the displaceable body may include at least one rail which moves along the guide track with displacement of the displaceable body. In some embodiments, the housing may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the displaceable body when in the first state and may permit displacement of the displaceable body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the displaceable body may comprise a pair of cams and a cross piece extending between the cams. In some embodiments, the cross piece may be disposed over a portion of the ampoule downstream of the frangible when the displaceable body is in the first position and is displaced over a portion of the ampoule upstream of the frangible as the displaceable body is displaced to the second position. In some embodiments, the outlet assembly may include a second cam follower and the displaceable body may further comprise a second cam configured to interact with the second cam follower as the displaceable body is displaced from the first position to the second position. In some embodiments, the outlet assembly may be configured to pivot about a pivot axis which extends through a portion of the nozzle. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the housing configured to be adhered to the skin of a patient as the displaceable body is displaced from the first position toward the second position. In some embodiments, when the displaceable body is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit further displacement of the cam follower. In some embodiments, the housing may include a skin depressor. In some embodiments, the ampoule may be constructed out of glass. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable

from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.
[0046] In accordance with another embodiment of the present disclosure an agent administration device may comprise a pressurized agent containing ampoule including a frangible. The device may further comprise an elastomeric boot disposed on and sealing against a region of the ampoule that includes the frangible. The device may further comprise an outlet assembly including a ram, a cam follower, a nozzle in communication with the region via a flow path extending through the boot, and a delivery sharp extending from the nozzle. The device may further comprise a housing including a first portion and a second portion that includes a cam and is displaceable relative to the first portion from a first position to a second position. The cam may be configured to direct displacement of the outlet assembly from a storage state to a deployed state as the second portion is displaced to the second position and the cam is displaced over the cam follower. The ram may be configured exert a frangible breaking force on the ampoule through the boot as the outlet assembly is displaced to the deployed state.
[0047] In some embodiments, the boot may include a port with a receptacle. The outlet assembly may include a portion which is coupled into the receptacle. In some embodiments, the first portion of the housing may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the first portion of the housing may include at least one guide track and the displaceable body may include at least one rail which moves along the guide track with displacement of the displaceable body. In some embodiments, the housing may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the displaceable body when in the first state and may permit displacement of the displaceable body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the second portion of the housing may comprise a pair of cams and a cross piece extending between the cams. In some embodiments, the cross piece may be disposed over a portion of the ampoule downstream of the frangible when the second portion of the housing is in the first position and is displaced over a portion of the ampoule upstream of the frangible as the second portion of the housing is displaced to the second position. In some embodiments, the outlet assembly may include a second cam follower and the second portion of the housing may further comprise a second cam configured to interact with the second cam follower as the second portion of the housing is displaced from the first position to the second position. In some embodiments, the outlet assembly may be configured to pivot from the storage state to the deployed state. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the housing configured to be adhered to the skin of a patient as the second portion of the housing is displaced from the first position toward the second position. In some embodiments, when the second portion of the housing is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit further displacement of the cam follower. In some embodiments, the housing may include a skin depressor. In some embodiments, the ampoule may be constructed out of glass. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.
[0048] In accordance with an embodiment of the present disclosure an agent administration device may comprise a housing including a base body and a slide body including a cam which displaces along a displacement path as the slide body is displaced from a first position to a second position. The device may further comprise a pressurized agent containing ampoule including a frangible.

The device may further comprise an elastomeric housing covering and scaling against a portion of the ampoule and including a chamber. The frangible may be disposed in the chamber. The device may further comprise an outlet assembly including a nozzle portion having at least one microneedle and being in fluid communication with the chamber, a ram, and a cam follower at least partially disposed in the displacement path of the cam when the outlet assembly is in a storage state. The outlet assembly may be configured to pivot from the storage state to a deployed state in which the at least one microneedle is outside of the housing via interaction of the cam and cam follower as the slide body displaces from the first position to the second position. The ram may be driven into the elastomeric housing breaking the frangible as the outlet assembly is pivoted toward the deployed state.

[0049] In some embodiments, the elastomeric housing may include a port with a receptacle. The outlet assembly may include a portion which may be coupled into the receptacle. In some embodiments, the base body may define a holster and at least a portion of the ampoule may be disposed within the holster. In some embodiments, the base body may include at least one guide track and the slide body may include at least one rail which moves along the guide track with displacement of the slide body. In some embodiments, the housing may include a latch configured for actuation between a first state and a second state. The latch may block displacement of the displaceable body when in the first state and may permit displacement of the displaceable body in the second state. In some embodiments, the latch may be configured to resiliently deflect from the first state to the second state. In some embodiments, the slide body may comprise a pair of cams and a cross piece extending between the cams. In some embodiments, the cross piece may be disposed over a portion of the ampoule downstream of the frangible when the slide body is in the first position and may be displaced over a portion of the ampoule upstream of the frangible as the slide body is displaced to the second position. In some embodiments, the outlet assembly may include a second cam follower and the slide body may further comprise a second cam configured to interact with the second cam follower as the slide body is displaced from the first position to the second position. In some embodiments, the outlet assembly may be configured to pivot about a pivot axis which extends through a portion of the nozzle. In some embodiments, the cam may include a ramped section and a plateau section. The ramped section may be configured to drive the cam follower towards a face of the housing configured to be adhered to the skin of a patient as the slide body is displaced from the first position toward the second position. In some embodiments, when the slide body is in the second position, the cam follower may be in contact with the plateau portion and the plateau portion may inhibit further displacement of the cam follower. In some embodiments, the base body may include a skin depressor. In some embodiments, the ampoule may be constructed out of glass. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The device may further comprise an elastomeric sleeve surrounding a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection portion from the first position to the second position.

[0050] In accordance with yet a further embodiment of the present disclosure an agent delivery device may comprise a reservoir assembly including a panel having an agent filled collapsible blister and a flow path extending from the blister. The device may further comprise an infusion site connector coupled to the panel and in fluid communication with the blister via the flow path. The infusion site connector may have a connector sharp and a pair of cantilevered arms flanking the connector sharp. Each of the arms may include a ledge configured to engage a retention catch of an infusion site assembly.

[0051] In some embodiments, the panel may be constructed of rigid material. In some embodiments, the reservoir assembly may include a check valve which inhibits flow of fluid along

the flow path to the blister. In some embodiments, the infusion site connector may include at least one guard projection which extends alongside the connector sharp. In some embodiments, the agent may be a vaccine. In some embodiments, the agent may be a SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine.

[0052] In accordance with yet another embodiment of the present disclosure a delivery device may comprise a housing. The device may further comprise a reservoir assembly including a panel having an agent filled collapsible blister and a flow path extending from the blister. The device may further comprise a displaceable lock member. The device may further comprise a bias member configured to receive the lock member in a stressed state. The lock member may hold the bias member in the stressed state when received by the bias member. The bias member may be configured to transition to a less stressed state and exert a collapsing force on the blister upon displacement of the lock member to a disengaged state. The device may further comprise a septum. The device may further comprise an outlet assembly including a sharp displaceable from a first position to a second position. The sharp may pierce through the septum and establish fluid communication with the fluid path upon displacement to the second position.

[0053] In some embodiments, the outlet assembly may include an infusion site connector. The sharp may be mounted on a hub displaceable along a channel defined in the infusion site connector. In some embodiments, the hub may include a shoulder. The shoulder may abut a stop and prevent further displacement of the hub in at least one direction when the sharp is displaced to the second position. In some embodiments, the lock member may be a removable pin. In some embodiments, the lock member may include a button which extends through the housing. In some embodiments, the button may include at least one arm including a bar extending therefrom. The bias member may be configured to receive a portion of the bar. In some embodiments, the device may further comprise a pressure plate disposed against the blister and coupled to the bias member. The pressure plate may be urged against the panel upon transition of the bias member to the less stressed state. In some embodiments, the bias member may be a cantilevered spring. In some embodiments, the outlet assembly may include an infusion site connector having a pair of cantilevered arms flanking the sharp. Each of the arms may include a ledge configured to engage a retention catch of an infusion site assembly. In some embodiments, the reservoir assembly may include a check valve configured to prevent refilling of the blister. In some embodiments, the agent may be a vaccine. In some embodiments, the agent may be a SARS-COV-2 vaccine. In some embodiments, the SARS-COV-2 vaccine may be selected from a group consisting of an attenuated live virus vaccine, inactivated virus vaccine, non-replicating viral vector vaccine, nucleic acid based vaccine, RNA based vaccine, mRNA based vaccine, saRNA based vaccine DNA based vaccine, DNA plasmid vaccine, recombinant protein vaccine, protein subunit vaccine, spike protein based vaccine, nanoparticle vaccine, and virus like particle vaccine.

[0054] In accordance with another embodiment of the present disclosure a delivery device may comprise a base. The device may further comprise a main body displaceable relative to the base. The device may further comprise a reservoir having a variable interior volume. The reservoir may be defined by a convex surface on the main body and a membrane covering the convex surface which is sealed to the main body around the periphery of the convex surface. The membrane may be in a first stretched state against the convex surface to accommodate the shape of the convex surface when the reservoir is in an empty state. The membrane may be distensible away from the convex surface to a second stretched state to accommodate fluid when the reservoir is in a filled state. The device may further comprise a port in fluid communication with the reservoir. The device may further comprise an outlet in fluid communication with the reservoir. The outlet may include at

least one delivery sharp and may be displaceable with the main body such that the at least one delivery sharp extends out of an aperture in the base when the main body is displaced against the base. Stretching of the membrane between the first stretched state and second stretched state may be over a steady pressure stretching range of the membrane.
[0055] In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the at least one delivery sharp may include a microneedle array. In some embodiments, the base may include a skin depressor. In some embodiments, the convex surface on the main body may be a spherical segment. In some embodiments, the membrane may be configured to assume a flat shape when unstressed. In some embodiments, the port may include a piercable septum. In some embodiments, the base and the main body may include cooperating retention features. The retention features may be configured to engage upon movement of the main body against the base to hold the main body against the base. In some embodiments, the device may further comprise a bandage mounted on the base for adhering the device to a patient. In some embodiments, the main body may be pivotally displaceable relative to the base body.
[0056] In accordance with still another embodiment of the present disclosure a delivery device may comprise a base. The delivery device may further comprise a main body displaceable relative to the base. The delivery device may further comprise a reservoir defined by a raised surface on the main body and a membrane covering the raised surface which is sealed to the main body around the periphery of the raised surface. The membrane may be in a first stretched state against the raised surface when the reservoir is in an empty state. The membrane may be distensible away from the raised surface to a second stretched state to accommodate fluid when the reservoir is in a filled state. The device may further comprise a filling port in fluid communication with the reservoir. The device may further comprise an outlet in fluid communication with the reservoir. The outlet may include at least one delivery sharp. Stretching of the membrane between the first stretched state and second stretched state may be over a steady pressure stretching range of the membrane.
[0057] In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the at least one delivery sharp may include a microneedle array. In some embodiments, the base may include a skin depressor. In some embodiments, the raised surface on the main body may be a round protuberance. In some embodiments, the membrane may be configured to assume a flat shape when unstressed. In some embodiments, the port may include a piercable septum. In some embodiments, the base and the main body may include cooperating retention features. The retention features may be configured to engage upon movement of the main body against the base to hold the main body against the base. In some embodiments, the device may further comprise a bandage mounted on the base for adhering the device to a patient. In some embodiments, the main body may be pivotally displaceable relative to the base body.
[0058] In accordance with another embodiment of the present disclosure a delivery device may comprise a base having a locking recess. The device may further comprise an outlet assembly including at least one delivery sharp and an access sharp on opposing ends of the outlet assembly. The access sharp may be in fluid communication with the at least one delivery sharp. The device may further comprise a reservoir assembly including a barrel having an outlet sealed by a septum, a plunger and an insert both displaceable within the barrel. The insert may have an end adjacent the plunger and a projection. The barrel may be displaceable from a sealed state to an accessed state in which the septum is pierced by the access sharp. The device may comprise a bias member configured to, when transitioned from a stressed state to a less stressed state, urge the reservoir assembly toward the accessed state. The bias member may be further configured to urge the insert and plunger toward the outlet once the barrel is in the accessed state. The bias member may be held in the stressed state when the projection of the insert is engaged with the locking recess.
[0059] In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the at least one delivery sharp may include an array of microneedles. In some embodiments, the at least one delivery sharp may be clocked such that the tip of the at least one

delivery sharp is in a controlled orientation. In some embodiments, barrel may be constructed of an inert material. In some embodiments, the projection may be included on a cap portion of the insert. In some embodiments, the projection may be a radially extending flange. The insert may be rotatable about a long axis of the insert between a state in which the projection is in engagement with the recess and a state in which the projection is free of the recess when the barrel is in the sealed state. In some embodiments, the projection may be included on a second end of the insert opposite the end adjacent the plunger. In some embodiments, the septum may be crimped in place on the barrel. In some embodiments, the bias member may be a compression spring. In some embodiments, the insert may include a cap body on a second end of the insert opposite the end adjacent the plunger. The at least a portion of the cap body may be configured to displace over an exterior surface of the barrel as the insert and plunger are displaced toward the outlet. In some embodiments, the at least one delivery sharp may be surrounded by a pressure chamber operatively coupled to a pressure source. In some embodiments, the pressure source may be a negative pressure source.

[0060] In accordance with another embodiment of the present disclosure a delivery device may comprise a base having a locking recess. The device may further comprise an outlet assembly including at least one delivery sharp on a first end of the outlet assembly and an access sharp on an opposing end of the outlet assembly. The access sharp may be in fluid communication with the at least one delivery sharp. The device may further comprise a reservoir assembly including a barrel having an outlet sealed by a septum, a plunger displaceable along the barrel and having a first side proximal to the outlet and a second side distal to the outlet, and an insert displaceable within the barrel and having an end adjacent the second side of the plunger. The insert may further include a projection. The device may further comprise a bias member configured to urge the reservoir portion from a first position to a second position in which the septum is punctured by the access sharp. The bias member may further be configured to urge the insert and plunger toward the outlet once the reservoir assembly has been driven to the second position. The bias member may be held in a stressed state when the projection of the inserter is engaged with the locking recess.

[0061] In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the at least one delivery sharp may include an array of microneedles. The array may be a one dimensional or a two dimensional array of microneedles. In some embodiments, the at least one delivery sharp may be clocked such that the tip of the at least one delivery sharp is in a controlled orientation. In some embodiments, the barrel may be constructed of an inert material. In some embodiments, the projection may be included on a cap portion of the insert. In some embodiments, the projection may be a radially extending flange. The insert may be rotatable about a long axis of the insert between a state in which the projection is in engagement with the recess and a state in which the projection is free of the recess when the barrel is in the sealed state. In some embodiments, the projection may be included on a second end of the insert opposite the end adjacent the plunger. In some embodiments, the septum may be crimped in place on the barrel. In some embodiments, the bias member may be a compression spring. In some embodiments, the insert may include a cap body on a second end of the insert opposite the end adjacent the plunger. The at least a portion of the cap body may be configured to displace over an exterior surface of the barrel as the insert and plunger are displaced toward the outlet. In some embodiments, the at least one delivery sharp may be surrounded by a pressure chamber operatively coupled to a pressure source. In some embodiments, the pressure source may be a negative pressure source.

[0062] In accordance with yet another embodiment of the present disclosure a delivery device may comprise a base. The delivery device may further comprise an axel supported by the base and including an inlet flow channel and an outlet flow channel recessed into an outer face of the axel. The delivery device may further comprise a fluid handling portion. The fluid handling portion may comprise a port assembly. The fluid handling portion may further comprise a reservoir assembly including a barrel and a plunger within the barrel biased toward an outlet of the barrel. The fluid

handling portion may further comprise an outlet assembly including at least one delivery sharp. The fluid handling portion may further comprise a hub body disposed and pivotally displaceable about the axel. Each of the port assembly, reservoir assembly, and outlet assembly may extend from the hub body. The fluid handling portion may be displaceable from a filling orientation in which the port assembly is in fluid communication with the barrel via the inlet flow channel to a delivery orientation in which the outlet assembly is in fluid communication with the barrel via the outlet flow channel.

[0063] In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the at least one delivery sharp may include an array of microneedles. In some embodiments, the base may include a stop. The outlet assembly may abut the stop when fluid handling portion is in the filling orientation. In some embodiments, the base may include a deflectable cradle configured to displace against the skin of a patient when the fluid handling portion is displaced from the filling orientation to the delivery orientation. In some embodiments, the cradle may be cantilevered from a main body of the base. In some embodiments, the delivery sharp may be configured to extend through an aperture in the base when the fluid handling portion is displaced from the filling orientation to the delivery orientation. In some embodiments, the base may include a catch. The catch may be configured to engage the reservoir portion when the fluid handling portion is displaced from the filling orientation to the delivery orientation. The catch may inhibit displacement of the fluid handling portion when engaged with the reservoir portion. In some embodiments, the port assembly may include a piercable septum. In some embodiments, the device may further comprise an inlet and an outlet. The inlet may be in communication with the inlet flow path when the fluid handling portion is in the filling orientation. The outlet may be in communication with the outlet flow path when the fluid handling portion is in the delivery orientation.

[0064] In accordance with an embodiment of the present disclosure a method for accessing a target delivery depth of a patient may comprise applying an administration device to a patient. The method may further comprise displacing a lock member from a locking state to a disengaged state. The method may further comprise propelling a guide pin along a displacement path. The method may further comprise transmitting, via a linkage, motion of the guide pin to a sharp assembly to extend at least one delivery sharp of the sharp assembly a first distance out of a housing of the administration device and retract the at least one delivery sharp to a delivery position in which the at least one delivery sharp extends a second distance out of the housing which is less than the first distance.

[0065] In some embodiments, the displacement path may be an arcuate displacement path. In some embodiments, propelling the guide pin may comprise exerting a bias force on the guide pin with a single bias member. In some embodiments, propelling the guide pin may comprise propelling the guide pin along the displacement path to a stop in a single direction along the guide path. In some embodiments, the single direction may be a single rotational direction. In some embodiments, propelling the guide pin along the displacement path may comprise displacing a portion of the guide pin along a guide track defined in the housing. In some embodiments, the first distance may correspond to a transcutaneous puncture depth in the patient. In some embodiments, the second distance may correspond to an intradermal puncture depth in the patient. In some embodiments, the method may further comprise constraining the at least one delivery sharp to displace at a predefined angle relative to a skin surface of the patient to which the administration device is adhered. In some embodiments, the predefined angle may be 5°-45°. In some embodiments, displacing the lock member may comprise removing a strip to which the lock member is attached from the delivery device. In some embodiments, displacing the lock member may comprise removing the lock member. In some embodiments, propelling the guide pin along the displacement path may comprise propelling the guide pin in a single fluid motion along the displacement path. In some embodiments, the delivery sharp may be a needle of no larger than 30 gauge. In some

embodiments, the propelling the guide pin along the displacement track may comprise propelling the guide pin along a first portion of the displacement path in which the guide pin increases in proximity to a delivery sharp aperture in the housing and along a second portion of the displacement path shorter than the first portion in which the guide pin decreases in proximity to the delivery sharp aperture.

[0066] In accordance with another embodiment of the present disclosure an agent administration device may comprise a housing including a first portion that includes at least one guide surface and a rigid shelf. The housing may include a second portion displaceable relative to the first portion between a storage state and a delivery state. The second portion may have at least one guide projection which slides along and is directed by the at least one guide surface as the second portion is displaced between the storage and delivery states. The device may further comprise at least one delivery sharp extending from the second portion. The at least one delivery sharp may be within the housing in the storage state and extending out of the housing in the delivery state. The device may further comprise a pressurized agent containing ampoule including a frangible retained within the second portion. The device may further comprise an elastomeric boot disposed on and scaling against a region of the ampoule that includes the frangible. Displacement of the second portion from the storage state to the delivery state may be configured displace at least a portion of the ampoule into the rigid shelf and exert a frangible breaking force on the ampoule through the boot as the second portion is displaced to the deployed state.

[0067] In some embodiments, the boot may include a port with a receptacle. The second portion may include a flow pathway projection which is coupled into the receptacle. The flow pathway projection may include a flow channel which communicates with the at least one delivery sharp. In some embodiments, the second portion of the housing may define a holster clamshell with at least one foldable portion. The foldable portion may be displaceable between a molding configuration in which the holster clamshell is open and an assembly configuration in which the holster clamshell is closed. In some embodiments, the second portion of the housing may define a holster clamshell. The ampoule may be retained within the holster clamshell when the clamshell is in a closed state. In some embodiments, the first portion of the housing may include a ratcheting wall including a plurality of ratcheting interfaces. In some embodiments, the ratcheting interfaces may be recessed into a face of the ratcheting wall. In some embodiments, the ratcheting interfaces may be raised from a face of the ratcheting wall. In some embodiments, the second portion of the housing may include a foldable section coupled to a main portion of the second portion via a living hinge. In some embodiments, the foldable section may include a pawl projection and a clip. The ratcheting wall may be held between the clip and a remainder of the foldable section. The pawl projection may engage a first ratcheting interface when the second portion is in the storage state and a second ratcheting interface when the second portion is in the delivery state. In some embodiments, the foldable section may include a pawl projection and a clip. The ratcheting wall being held between the clip and a remainder of the foldable section. The foldable section may be configured to displace in a direction parallel to a plane of the ratcheting wall as the second portion is displaced between the storage state and the delivery state. In some embodiments, the agent administration device may further comprise a support means for inhibiting breakage of the ampoule at locations other than the frangible. In some embodiments, the at least one delivery sharp may include a microneedle. In some embodiments, the second portion may include a skin depressor. In some embodiments, the ampoule may be constructed out of glass. In some embodiments, at least a portion of the housing may include at least one foldable portion monolithically formed with the at least a portion of the housing. Each of the at least one foldable portion may be displaceable between a molding configuration and an assembly configuration. In some embodiments, the each of the at least one foldable portion may be coupled to the at least a portion of the housing via a living hinge. In some embodiments, the at least one foldable portion may include at least one latch projection and the at least a portion of the housing may include at least one retention slot configured to accept one of the

at least one latch projection. In some embodiments, the device may further comprise an injection port. The injection port may be disposed over a tail including a second frangible that extends from the ampoule. The elastomeric boot may surround a portion of the injection port, the tail, and a main body of the ampoule. In some embodiments, the injection port may be pivotally displaceable from a first position to a second position. The second frangible may be configured to break with displacement of the injection port from the first position to the second position.
[0068] In accordance with another embodiment of the present disclosure a method of delivering an intradermal injection may comprise puncturing, with at least one delivery sharp, to an intradermal delivery destination. The method may further comprise dispensing a first fluid through the at least one delivery sharp to the delivery destination. The method may further comprise dispensing a second fluid through the at least one delivery sharp to the delivery destination. One of the first and second fluid may be a vaccine and the other of the first and second fluid is a gas.
[0069] In some embodiments, the at least one delivery sharp may comprise an array of microneedles. In some embodiments, the puncturing to an intradermal delivery destination may comprise driving the at least one delivery sharp to a first depth and subsequently retracting the at least one delivery sharp to the intradermal delivery destination. In some embodiments, driving the at least one delivery sharp to a first depth and subsequently retracting the at least one delivery sharp to the intradermal delivery destination may be executed in a single reciprocating fluid motion. In some embodiments, the at least one delivery sharp may comprise a needle of no greater than 30 gauge. In some embodiments, the method may further comprise stimulating blood flow in the vicinity of the intradermal delivery destination. In some embodiments, the gas is a gas selected to stimulate blood flow to the intradermal delivery destination.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0070] These and other aspects will become more apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:
[0071] FIG. **1** depicts a perspective view of an example delivery device;
[0072] FIG. **2** depicts a perspective view of an example delivery device having a locking member which may be flexed to transition between a first state and a second state;
[0073] FIG. **3** depicts a bottom perspective view of an example delivery device and cover member;
[0074] FIG. **4** depicts a bottom perspective view of the delivery device of FIG. **3** with the cover member removed;
[0075] FIG. **5** depicts a perspective view of an example cover member;
[0076] FIG. **6** depicts a perspective view of an example delivery device with a portion of the housing exploded away from the remainder of the delivery device;
[0077] FIG. **7** depicts an exploded view of an example delivery device;
[0078] FIG. **8** depicts a top plan view of an example delivery device;
[0079] FIG. **9** depicts a cross sectional view of an example delivery device taken at the indicated cut plane of FIG. **8**;
[0080] FIG. **10** depicts a cross-sectional view of an example insert which may be included in a delivery device;
[0081] FIG. **11** depicts a cross-sectional view of an example delivery device with a locking member of the delivery device being removed from the delivery device;
[0082] FIG. **12** depicts another cross-sectional view of another delivery device with a turnkey;
[0083] FIG. **13** depicts another cross-sectional view of another delivery device with a teethed locking member;
[0084] FIG. **14** depicts a cross-sectional view of an example delivery device with a plug of the

delivery device being displaced against a stop surface included in the delivery device;
[0085] FIG. **15** depicts a cross-sectional view of an example delivery device in a partially dispensed state;
[0086] FIG. **16** depicts a cross-sectional view of an example delivery device in a fully dispensed state;
[0087] FIG. **17** depicts an enlarged view of the indicated portion of the cross-sectional view depicted in FIG. **9**;
[0088] FIG. **18** depicts a top plan view of an example delivery device;
[0089] FIG. **19** depicts a cross-sectional view of an example delivery device taken at the indicated cut plane in FIG. **18**;
[0090] FIG. **20** depicts a perspective view of a portion of a housing of a delivery device;
[0091] FIG. **21** depicts a cross-sectional view of a portion of a delivery device being filled via a filling implement;
[0092] FIG. **22** depicts a bottom perspective view of an example delivery device;
[0093] FIG. **23** depicts a perspective view of an example cover member for a delivery device;
[0094] FIG. **24** depicts a bottom perspective view of a delivery device with its cover member removed;
[0095] FIG. **25** depicts a detailed view of the indicated region of FIG. **24**;
[0096] FIG. **26** depicts a view of an example microneedle;
[0097] FIG. **27** depicts a cross-sectional view of an example delivery device including an actuatable delivery sharp where the actuatable delivery sharp is in a stowed state;
[0098] FIG. **28** depicts a detailed view of the indicated region of FIG. **27**;
[0099] FIG. **29** depicts a cross-sectional view of an example delivery device including an actuatable delivery sharp where the actuatable delivery sharp is in a deployed state;
[0100] FIG. **30** depicts a detailed view of the indicated region of FIG. **29**;
[0101] FIG. **31** depicts a top plan view of an example delivery device including an infusion site connector;
[0102] FIG. **32** depicts a cross-sectional view of an example delivery device including an infusion site connector taken at the indicated cut plane in FIG. **31**;
[0103] FIG. **33** depicts a top plan view of an example delivery device which is connected to an infusion site connector via a run of infusion tubing;
[0104] FIG. **34** depicts a cross sectional view of an example delivery device taken at the indicated cut plane in FIG. **33**;
[0105] FIG. **35** depicts an example delivery device including an infusion site connector;
[0106] FIG. **36** depicts another example delivery device including an infusion site connector;
[0107] FIG. **37** depicts a top down plan view of another example embodiment of a delivery device;
[0108] FIG. **38** depicts a cross-sectional view of the example delivery device of FIG. **37** taken at the indicated cut plane of FIG. **37**;
[0109] FIG. **39** depicts a perspective view of an example delivery device and example infusion site assembly;
[0110] FIG. **40** depicts a top down plan view of another example embodiment of a delivery device;
[0111] FIG. **41** depicts a cross-sectional view of the example delivery device of FIG. **40** taken at the indicated cut plane of FIG. **40**;
[0112] FIG. **42** depicts a perspective view of an example delivery device;
[0113] FIG. **43** depicts another top down plan view of another example embodiment of a delivery device;
[0114] FIG. **44** depicts a perspective view of an example delivery device.
[0115] FIG. **45** depicts a side view of an example delivery device;
[0116] FIG. **46** depicts a perspective view of a delivery device with a fluid handling portion of the delivery device removed;

[0117] FIG. **47** depicts a cross-sectional view of the delivery device depicted in FIG. **43** at the cut plane indicated in FIG. **43**.
[0118] FIG. **48** depicts an exploded view of an example delivery device;
[0119] FIG. **49** depicts a side view of an example delivery device in a delivery state;
[0120] FIG. **50** depicts a cross-sectional view of the delivery device shown in FIG. **49** taken along a longitudinally extending mid plane of the delivery device shown in FIG. **49**;
[0121] FIG. **51** depicts a detailed view of the indicated region of FIG. **49**;
[0122] FIG. **52** depicts a top down plan view of another example delivery device;
[0123] FIG. **53** depicts a cross-sectional view of the example delivery device of FIG. **52** taken at the cut plane superimposed over FIG. **52**;
[0124] FIG. **54** depicts another cross-sectional view of the example delivery device of FIG. **52** where the delivery device has been transitioned into a delivery state;
[0125] FIG. **55** depicts a side view of an example embodiment of yet another delivery device;
[0126] FIG. **56** depicts a detailed view of the indicated region of FIG. **55**;
[0127] FIG. **57** depicts a top down plan view of an example delivery device embodiment;
[0128] FIG. **58** depicts a cross-sectional view of the example delivery device depicted in FIG. **57** taken at the indicated cut plane in FIG. **57**;
[0129] FIG. **59** depicts an exploded view of an example delivery device;
[0130] FIG. **60** depicts a perspective view of an example delivery device in a storage state;
[0131] FIG. **61** depicts a perspective view of an example delivery device which has been unlocked such that it may be transitioned out of a storage state;
[0132] FIG. **62** depicts a side view of an example delivery device in a delivery state;
[0133] FIG. **63** depicts a cross-sectional view of the example delivery device shown in FIG. **62** taken along a longitudinally extending mid plane of the delivery device shown in FIG. **62**;
[0134] FIG. **64** depicts another perspective view of an example delivery device embodiment;
[0135] FIG. **65** depicts a cross-sectional view of the example delivery device shown in FIG. **64** taken along a longitudinally extending mid plane of the delivery device shown in FIG. **65**;
[0136] FIG. **66** depicts a top down plan view of yet another example embodiment of a delivery device;
[0137] FIG. **67** depicts a cross-sectional view of the delivery device shown in FIG. **66** taken at the indicated cut plane in FIG. **66**;
[0138] FIGS. **68-70** depict a views of yet another example embodiment of a delivery device;
[0139] FIG. **71** depicts example plot depicting pressure versus volume characteristics of an example stretchable membrane based reservoir;
[0140] FIG. **72** depicts a view of an example ampoule;
[0141] FIG. **73** depicts a top down plan view of an example embodiment of a delivery device including an ampoule;
[0142] FIG. **74** depicts a cross-sectional view of the example delivery device of FIG. **73** taken at the indicated cut plane of FIG. **73**;
[0143] FIG. **75** depicts a perspective view of an example activation assembly which may be included in a delivery device such as that shown in FIG. **74**;
[0144] FIG. **76** depicts a perspective view of an example delivery device;
[0145] FIG. **77** depicts a detailed view of the indicated region of FIG. **76**;
[0146] FIG. **78** depicts a view of another example ampoule and an elastomeric housing;
[0147] FIG. **79** depicts a cross sectional view of the example ampoule and elastomeric housing of FIG. **78**;
[0148] FIG. **80** depicts a perspective view of yet another example delivery device embodiment;
[0149] FIG. **81** depicts a perspective view of an example delivery device;
[0150] FIG. **82** depicts a perspective view of a slide body which may be included in an example delivery device such as that shown in FIG. **80**;

[0151] FIG. **83** depicts a perspective view of an outlet assembly which may be included in an example delivery device such as that shown in FIG. **80**;
[0152] FIG. **84** depicts a top down plan view of an example delivery device;
[0153] FIG. **85** depicts a cross-sectional view of the example delivery device shown in FIG. **84** taken at the indicated cut plane of FIG. **84**;
[0154] FIG. **86** depicts a perspective view of yet another example embodiment of a delivery device;
[0155] FIG. **87** depicts another perspective view of an example embodiment of a delivery device;
[0156] FIG. **88** depicts a top down plan view of an example embodiment of a delivery device which is in a delivery state;
[0157] FIG. **89** depicts a cross-sectional view of the example delivery device of FIG. **88** taken at the indicated cut plane of FIG. **88**;
[0158] FIG. **90** depicts a perspective view of yet another embodiment of a delivery device which includes an injection port;
[0159] FIG. **91** depicts another perspective view of an embodiment of a delivery device including an injection port;
[0160] FIG. **92** depicts a perspective view of an embodiment of a delivery device with a syringe introducing fluid into the delivery device via an injection port included in the delivery device;
[0161] FIG. **93** depicts a view of an exemplary ampoule which may be included in certain delivery device embodiments including an injection port;
[0162] FIG. **94** depicts a cross-sectional view of an example delivery device including an injection port where the injection port is covered with a cap member;
[0163] FIG. **95** depicts a cross-sectional view of an example delivery device including an injection port with the cap member removed;
[0164] FIG. **96** depicts a cross-sectional view of an example delivery device including an injection port which has been displaced so as to break a frangible of an ampoule disposed in the delivery device in order to access the interior of the ampoule of the delivery device;
[0165] FIG. **97** depicts a cross-sectional view of an example injection port and a portion of an example ampoule;
[0166] FIG. **98** depicts a perspective view of yet another example embodiment of a delivery device;
[0167] FIG. **99** depicts another perspective view of an example embodiment of a delivery device;
[0168] FIG. **100** depicts a cross-sectional view of an exemplary delivery device where the delivery device is in a storage state;
[0169] FIG. **101** depicts a cross-sectional view of an example delivery device where the delivery device is in a delivery state;
[0170] FIG. **102** depicts a view of an exemplary slide body which may be included in an example delivery device such as that shown in FIG. **98**, the slide body being in a molding configuration;
[0171] FIG. **103** depicts a view of the exemplary slide body of FIG. **102** after being transitioned to an assembly configuration in which foldable portion of the slide body have been bent and an example ampoule has been captured within a holster clamshell of the slide body;
[0172] FIG. **104** depicts a cross-sectional view of an example delivery device embodiment where the delivery device is in a storage state;
[0173] FIG. **105** depicts another cross-section view of an example delivery device embodiment where the delivery device is in a delivery state;
[0174] FIG. **106** depicts a flowchart detailing a number of example actions which may be executed to deliver fluid into a patient via a delivery device;
[0175] FIG. **107** depicts another flowchart detailing a number of example actions which may be executed to deliver fluid into a patient via a delivery device;
[0176] FIG. **108** depicts a perspective view of yet another embodiment of an example delivery device;
[0177] FIG. **109** depicts a perspective view of an example delivery device with a flexible strip and

locking member removed;
[0178] FIG. **110** depicts a cross-sectional view of an example delivery device in a storage state;
[0179] FIG. **111** depicts a cross-sectional view of a delivery device in which a delivery sharp of the delivery device has been extended to a first position;
[0180] FIG. **112** depicts a cross-sectional view of a delivery device in which a delivery sharp has been retracted from a first position to a second position in which the delivery sharp extends a lesser distance from the housing than in the first position;
[0181] FIG. **113** depicts a top down plan view of an example delivery device with a sharp assembly and actuation assembly removed;
[0182] FIG. **114** depicts a cross-sectional view of the example delivery device of FIG. **113** taken at the indicated cut plane of FIG. **113**;
[0183] FIG. **115** depicts a perspective view of an example sharp assembly and example actuation assembly which may be included in a delivery device such as that shown in FIG. **113**;
[0184] FIG. **116** depicts a perspective view of another example embodiment of a delivery device;
[0185] FIG. **117** depicts another perspective view of the delivery device in FIG. **116**;
[0186] FIG. **118** depicts a perspective view of a delivery device having a bandage with a cover included therein;
[0187] FIG. **119** depicts a cross-sectional view of a delivery device having a bandage with a cover, the bandage being folded such that the cover is positioned over the delivery sharps; and
[0188] FIG. **120** depicts a flowchart detailing a number of example actions which may be executed to position a delivery sharp at a target delivery depth in a patient.

DETAILED DESCRIPTION

[0189] Referring to FIG. **1**, an example delivery device **10** is depicted. The delivery device **10** may be a vaccine delivery device in certain example. The example delivery device **10** may be designed for patient or other untrained use. Thus, a medical caregiver would not be necessary to administer any contents of the delivery device **10**. This would aid in the ability to rapidly perform a mass vaccination campaign, especially in scenarios where a medical care system is already stretched thinly. Additionally, it would help to free up caregivers to focus on other medical issues thus reducing secondary impacts of a pandemic. As the delivery device **10** may be designed for patient use, the delivery device **10** may significantly limit consumption of PPE related to vaccination. Moreover, it may aid in limiting opportunities for exposure as less interaction between various parties (some of which may elect not to use PPE when available) may be needed to administer vaccine from the delivery device **10**.
[0190] Such a delivery device **10** may deliver any suitable vaccine, though may be 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 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 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 occur during a novel pathogen pandemic.
[0191] Vaccine may refer to any type of vaccine such as, though 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, in other veterinary applications, or in research settings. In such cases, these delivery devices **10** may be filled with a vaccine for at least one non-human pathogen.

[0192] Delivery devices **10**, such as the example shown in FIG. **1** may also be advantageous in circumstances where the amount of available vaccine is limited. Evidence suggests that intradermal delivery of certain 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. Intradermal 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 vaccines to further aid in facilitating dose or injection sparing.

[0193] 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.

[0194] Additionally, some studies have suggested that intradermal 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.

[0195] 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 to novel pathogens by leveraging dose/injection sparing 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, 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**.

[0196] The example delivery devices **10** shown herein additionally are not limited to vaccine

delivery devices. As explained elsewhere herein, such a delivery device **10** may fill a number of niches in the medical field. The delivery devices **10** shown and described herein may deliver any suitable therapeutic agent as a bolus or as a basal delivery depending on the embodiment. Such delivery devices **10** may, for example, be used to deliver medication for endocrine disorders. For instance, insulin may be delivered with some exemplary delivery devices **10**.

[0197] Delivery devices **10** described and shown herein may also be well suited to deliver drugs for overdose intervention such as opioid antagonists (e.g. Naloxone). Delivery devices **10** such as that shown in FIG. **1** may be easily used at the site of an overdose by a non-medically trained bystander. Alternatively, delivery devices **10** may be used by emergency medical services (EMS) personnel responding to an overdose. Such delivery devices **10** may provide rapid access and delivery to, for instance, a subcutaneous space in the overdose victim. While absorption may be slower when delivered, e.g., subcutaneously, this may be balanced out by the fact that no time would be needed to attempt establishing an intravenous access (which may be especially difficult in intravenous drug users). Additionally, slower onset of the antagonist may blunt the onset of withdrawal symptoms. This may contribute to greater adoption in addict communities and may provide safety benefits for EMS personnel.

[0198] Other agents, for example, diagnostic or testing agents may also 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**. Nutrients such as vitamins may also be delivered using delivery device **10** embodiments described herein. Additionally, the delivery devices **10** described herein may be arranged so as to be applied in serial fashion. For example, a first delivery device **10** may be configured to relatively rapidly supply a loading dose or bolus of an agent while a second, subsequently applied delivery device **10** may provide, for example, a basal injection of that agent or a different agent over a prolonged period of time (e.g. anywhere from 30-90 minutes or longer).

[0199] As shown in FIG. **1**, a delivery device **10** may include a housing **12**. The delivery device **10** may be sized so as to be handheld and easily applied to a variety of possible injection sites over a patient's body. The housing **12** may be ergonomically shaped so as to easily be held in the hand of a user. In the example embodiment, the housing **12** is contoured similarly to a computer mouse. Preferably, the delivery device **10** may be free from corners or edges which may catch on items such as clothing. The housing **12** may be formed of a rigid material which may be a polymer, metal, metal alloy, other material, or combination thereof.

[0200] The delivery device **10** may have a face which is intended to be adhered to the patient's skin. This face may be substantially planar or may be contoured or flexible to cooperate with the curvature of a desired patient injection site. This patient adhering face may be covered with a skin compatible adhesive. For example, an adhesive pad may be attached to the patient adhering face of the delivery device **10**. The adhesive may be covered by a removable (e.g. peel off) backing **14**. The adhesive backing **14** may include a protuberance **16** in certain examples. Such a protuberance **16** may facilitate removal of the backing **14** from the delivery device **10**. In some embodiments, a portion of the adhesive bearing pad on the delivery device **10** may also project away from the rest of the delivery device **10** in the location of the backing protuberance **16**. Thus, when the delivery device **10** is applied to a patient, the adhesive pad projection may be grasped by a user to facilitate removal of the delivery device **10**.

[0201] In the example embodiment shown in FIG. **1**, the delivery device **10** may also include a lock. The lock may be a locking member **18** or locking mechanism. The locking member **18** or mechanism may be included as part of an activation assembly of the delivery device **10**. Such a locking member **18** or mechanism may inhibit delivery of therapeutic agent from a delivery device **10** until the locking member **18** or mechanism is acted on by a user. Thus, the locking member **18** or mechanism may prevent the delivery device **10** from inadvertently activating and delivering therapeutic agent during shipping, storage, preparation for use, etc. Upon actuation or displacement

of the locking member **18** or mechanism, the delivery device **10** may transition to a usage state. For example, the delivery device **10** may begin dispensing of medication when the delivery device **10** is transitioned to the usage state. Alternatively, a delivery button or other interface may be made functional due to actuation or displacement of the locking member **18** or mechanism. Prior to actuation or displacement of the locking member **18** or mechanism, interaction with delivery button or other interface may have no effect.

[0202] As shown in the example embodiment depicted in FIG. **1**, the delivery device **10** includes a removable locking member **18**. The removable locking member **18** may include two arms **20**A, B. The arms **20**A, B may extend orthogonally to the longitudinal midplane of the delivery device **10** as shown in FIG. **1**. The arms **20**A, B may have a curvature which facilitates grasping by fingers of the user. In the example embodiment, each arm **20**A, B is arcuate and bends downward toward the skin adhering face of the delivery device **10** as distance from the arm's **20**A, B attachment point to the stem **22** increases. In other embodiments, locking members **18** may have alternative grasping features. In some examples, a locking member **18** may include one or more of a pull ring, flange, tab, nub, textured surface, etc. in place of or in addition to the arms **20**A, B.

[0203] The exemplary locking member **18** may also include a stem portion **22** which may be installed into the delivery device **10** through an aperture **24** (best shown in FIG. **6**) in the housing **12**. In the example, the aperture **24** is disposed along the longitudinal midplane of the delivery device **10**. The stem portion **22** may present a mechanical interference to displacement of internal components of the delivery device **10** active in dispensing of the contents of the delivery device **10**. When the locking member **18** is disassociated with the delivery device **10**, the mechanical interference may be removed allowing the interior components of the delivery device **10** to displace and cause delivery of therapeutic agent from the delivery device **10**. Where a second button or other interface is used, removal of the locking member **18** may remove a mechanical interference which would otherwise block dispensing of drug when the button or other interface was actuated by a user. That is, when the locking member **18** is in place, the mechanical interference it presents may render the button or other interface impotent.

[0204] Referring now to FIG. **2**, in certain embodiments, a locking member **18** may include one or more flexible component. In such embodiments, the locking member **18** may have a shipping or storage configuration. For use, the locking member **18** may be transitioned (e.g. via flexing or bending a portion of the locking member **18**) from its storage configuration to a grasping configuration in which the locking member **18** may easily be grasped by a user. Using the example locking member **18** shown in FIG. **1**, in some embodiments, the arms **20**A, B may be at least partially flexible. For example, the arms **20**A, B may be joined to the stem portion **22** via living hinges. To remove the locking member **18**, the arms **20**A, B may be displaced upward from their orientation in FIG. **1** (what would be the storage state for the arms **20**A, B) to their position in FIG. **2**. When in the graspable state the arms **20**A, B may extend upward substantially parallel to the axis of the stem portion **22**. Thus, the user may have a long surface over which to grasp the locking member **18**. Additionally, the terminal ends of the arms **20**A, B opposite their connection to the stem portion **22** may include nubs **30**. The nubs **30** may further increase case of removal of the locking member **18**. Other embodiments may differ. For example, instead of arms **20**A, B another suitable grasping element may be coupled to the stem portion **22**. This grasping element may be close to (perhaps against) the housing **12** in its storage state and displaced to an easily graspable position during use. For instance, a pull ring which is folded against the housing **12** and hinged (e.g. via a living hinge) to the stem portion **22** may be used in some examples.

[0205] Use of a locking member **18** which has a storage state and grasping state may allow for the delivery device **10** to have a low profile when shipped and stored. As the locking member **18** may be transitioned into a state in which it protrudes a greater degree from the housing **12**, case of removal of the locking member **18** may not be sacrificed in order to make the delivery device **10** lower profile. Limiting the volume of packaged delivery devices **10** in the shipping state may help

maximize the amount of delivery devices **10** which may be transported. This may be particularly useful in delivery devices **10** which require a cold chain type supply chain (e.g. delivery devices **10** loaded with heat labile vaccines). Many regions of the world may lack extensive cold chain infrastructure, thus a higher density of delivery devices **10** in a given storage volume may aid in limiting the demands on cold chain resources in these regions.

[0206] Referring now also to FIG. **3**, a delivery device **10** may also include a cover member **26**. A cover member **26** may engage with the housing **12** or another component of the delivery device **10** so as to be retained in place on the delivery device **10**. The cover member **26** may act as a barrier which prevents the ingress of detritus, fingers, etc. into the interior of the delivery device **10**. Where a fixed delivery sharp **88** (see, e.g. FIG. **4**) is present in a delivery device **10**, the cover member **26** may also inhibit inadvertent contact of the sharp **88** with a user and aid in maintaining sterility of the delivery sharp **88**. In use, the cover member **26** may be removed and the delivery device **10** may be placed on the skin of the patient after removal of any adhesive backing **14**. The locking member **18** or mechanism may be displaced or actuated to then begin delivery of therapeutic agent.

[0207] Referring primarily to FIGS. **4** and **5**, the skin adhering face of the delivery device **10** may include a recess **28** through which at least one delivery sharp **88** may project. In the example embodiment, only one delivery sharp **88** is shown. The example delivery sharp **88** may be suitable for subcutaneous or intramuscular injection for example. In other embodiments, multiple delivery sharps **88** may be included. In some embodiments, the delivery device **10** may include a plurality of delivery sharps **88** in the form of a microneedle array (or alternatively a single microneedle). In such embodiments, the delivery device **10** may be suited to intradermal delivery of medication.

[0208] As shown, the example sharp **88** is oriented roughly perpendicular to the skin adhering face of the housing **12**. In alternative embodiments, a sharp **88** or sharps **88** may be oriented at an angle other than a right angle. For example, in certain embodiments, the sharp **88** may be oriented at, e.g., 60°, 45°, or 30° with respect to the skin adhering face of the housing **12**.

[0209] The adhesive and the adhesive backing **14** may include an interruption in the region where the recess **28** is present. The recess **28** may include at least one capture interface **32** which is configured to cooperate with a portion of the cover member **26** in order to retain the cover member **26** on the delivery device **10**. In the example embodiment, the recess **28** includes a pair of fenestrations through the skin adhering face of the delivery device **10**. The exemplary cover member **26** includes cooperating upstanding cantilevered projections **34**. Each of the cantilevered projections **34** may include a ramped segment **36** at a terminal unsupported end thereof. The ramped segments **36** are included on the lateral faces of the cantilevered projections **34** in the example embodiment. The cantilevered projections **34** may further include a catch ledge **38** adjacent the ramped segments **36**. To couple the cover member **26** to the delivery device **10**, the cantilevered projections **34** may be pushed into the fenestrations. The ramped segments **36** may contact the edge wall of the fenestrations and facilitate deflection of the cantilevered projections **34** as the cover member **26** is advanced toward the rest of the delivery device **10**. When the ramped segments **36** are advanced fully through the fenestrations, the cantilevered projections **34** may have a resiliency sufficient to cause the cantilevered projections **34** to return to an undeflected state. When the cantilevered projections **34** return to the undeflected state, the catch ledges **38** may rest on an interior facing side of the material in which the fenestrations are formed. Thus, cover member **26** may snap fit onto the delivery device **10** and the catch ledges **38** may inhibit inadvertent removal of the cover member **26**.

[0210] As shown in FIGS. **3-5**, the cover member **26** may include a flange **40** which surrounds a substantially centrally disposed well **42**. The well **42** may accommodate the delivery sharp **88** or sharps **88**. The well **42** may also provide a grasping surface for a user to aid in removal of the cover member **26**. The flange **40** may provide a shield which helps to block a user's fingers from coming into contact with the delivery sharp(s) **88** during manipulation of the cover member **26**.

Additionally, as best shown in FIGS. **4** and **5**, a raised rim **44** may be provided around the perimeter of the well **42**. The cantilevered projections **34** may extend from the rim **44** in some embodiments. The recess **28** may have a trough **46** which corresponds with the rim **44**. In the example embodiment, the well **42** is substantially circular and the trough **46** is substantially annular and includes the capture interfaces **32**. The rim **44** and trough **46** may aid in alignment of the cover member **26** with the recess **28** during installation of the cover member **26** to the delivery device **10**.
[0211] Though a snap fit engagement of the cover member **26** with the delivery device **10** is shown, any number of other retention arrangements may be used. For example, in some embodiments, the cover member **26** may couple to the delivery device **10** via an interference fit, threaded engagement, bayonet mount type engagement, adhesive, magnetic engagement, tape, etc. In some embodiments, the adhesive backing **14** may couple to the cover member **26** such that removal of the adhesive backing **14** will also remove the cover member **26**.
[0212] Referring now to FIG. **6** and FIG. **7**, a partially exploded view and exploded view of an exemplary delivery device **10** are respectively depicted. As shown, the housing **12** of the delivery device **10** may include a first portion **50** and a second or base portion **52**. The first portion **50** may couple to the second portion **52** and act as a housing cover or cap which encloses the internal components of the delivery device **10**. The first portion **50** may be contoured for easy grasping. The second portion **52** of the housing **12**, in the example embodiment, may include the skin adhering face of the delivery device **10**. The second portion **52** may be substantially planar or may be at least partially flexible or contoured so as to accommodate placement against a cooperatively shaped section of a user's body.
[0213] The second portion **52** may also include stationary internal components of the delivery device **10**. For example, the second portion **52** may also include a reservoir portion **54** and a guide portion **56**. The reservoir portion **54** and guide portion **56** may be formed integrally with the second portion **52** of the housing **12** in certain embodiments. Thus, the reservoir portion **54**, guide portion, and second portion **52** of the housing **12** may be constructed together as, for example, a single molded part. In other embodiments, one or more of the reservoir portion **54** and guide portion **56** may be discrete separate components which are assembled into place within a delivery device **10**. For example, the reservoir portion **54** may be a separate component such as a syringe barrel which mates onto the second portion **52** of the housing **12**. Housing retention members **58** may also be included and may, in some embodiments, be formed integrally with the second portion **52** of the housing **12**. The housing retention members **58** may cooperate with features of the first portion **50** of the housing **12** so as to couple the first and second portions **50**, **52** of the housing **12** together.
[0214] Still referring to FIGS. **6** and **7**, a delivery device **10** may also include a plunger sled **60**. The plunger sled **60** in the example embodiment has the form of a rectilinear frame with opposing first and second ends **64**, **66** connected to one another via side panels **68**. A plunger sled **60** may also be coupled to a plunger member **62**. In the example embodiment, the plunger member **62** is included on the second end **66** of the plunger sled **60**. The plunger member **62** may extend substantially perpendicularly from the interior face of the second end **66** and into the space surrounded by the plunger sled **60**. The plunger member **62** may be constructed of or covered at least partially with an elastomeric material. In some embodiments, the elastomeric material of the plunger member **62** may be over molded onto a base body **70** of the plunger member **62**. Alternatively, the terminal portion the plunger member **62** may be an elastomeric or partially elastomeric insert which is mounted (e.g. pressed into or onto and/or bonded or adhered to, see FIG. **9**) to a base body **70** of the plunger member **62**.
[0215] When the delivery device **10** is assembled, the plunger member **62** may be at least partially disposed within the reservoir portion **54** of the delivery device **10**. The plunger member **62** may form a fluidic seal which inhibits fluid from passing out of the reservoir portion **54** and past the plunger member **62**. Example plunger members **62** may include at least one radial rib **72** which extends proud of the side surface of the plunger member **62**. The radial rib(s) **72** may compress

against the interior wall of the reservoir portion **54** to aid in generating a robust fluid tight seal between the reservoir portion **54** and plunger member **62**.

[0216] The first end **64** of the plunger sled **60** may include an aperture **74**. The aperture **74** may be sized so as to accept the guide portion **56** of the delivery device **10**. Thus, as the plunger sled **60** is displaced during operation, the aperture **74** may ride along the guide portion **56** helping to direct the displacement of the plunger sled **60** along a desired axis.

[0217] The side panels **68** of the plunger sled **60** may include protruding rails **76**. These rails **76** may be disposed such that the rails **76** ride along the housing retention members **58** as the plunger sled **60** is displaced (best shown in FIG. **19**). Again, this may aid in helping to constrain displacement of the plunger sled **60** to a desired path. Although the side panels **68** are shown as having protruding rails **76** in the example embodiment, in alternative embodiments, the side panels **68** may instead each include a groove or channel. In such embodiments, a projection or rail may be defined in one or more of the housing retention members **58** to guide the displacement of the plunger sled **60** during operation.

[0218] Referring now to FIG. **8** and FIG. **9**, a top view of an example delivery device **10** and a cross section of a delivery device **10** are respectively shown. The cross section in FIG. **9** is taken at the cut plane indicated in FIG. **8**. As shown, the delivery device **10** is in a locked state with its reservoir portion **54** in a fluid filled state. The plunger member **62** is disposed partially within the reservoir portion **54** of the delivery device **10** and forms a seal which prevents fluid from displacing past the plunger member **62** and out of the reservoir portion **54**. Opposite the plunger member **62**, the reservoir portion **54** includes a reservoir outlet **80**.

[0219] Referring now also to FIG. **10**, an insert **82** (shown in cross-section in FIG. **10**) is disposed within the reservoir outlet **80** in the example embodiment. Though referred to as an insert **82**, the insert **82** may not necessarily be physically inserted into the reservoir outlet **80** during assembly. The insert **82** may be, for example, created in place as part of a molding operation or other manufacturing operation. The insert **82** may be constructed of a compliant material such as an elastomer. The insert **82** may include at least one fluid pathway **84**, **86** defined therein. In the example embodiment, the insert **82** includes a fluid pathway **84** which extends through the insert **82** substantially along the longitudinal axis of the insert **82**. The insert **82** also includes a second fluid pathway **86** which branches from the first fluid pathway **84**. The second fluid pathway **86** may communicate with one or more fluid delivery sharp **88** (in this example a needle for subcutaneous delivery).

[0220] The delivery device **10** may include a plug **90**. The plug **90** may include a head portion **92** from which an occluding member **94** may extend. The occluding member **94** may extend into a fluid pathway **84**, **86** of the insert **82** and prevent flow from the reservoir portion **54** to the delivery sharp(s) **88** when disposed within the fluid pathway **84**. In the example embodiment, the occluding member **94** is a pin which projects from the head portion **92** of the plug **90**. The fluid pathway **84** of the insert **82** which interacts with the occluding member **94** may include one or more reduced diameter portions **96** (best shown in FIG. **10**). The reduced diameter portions **96** may be arranged such that their diameter is less than that of the occluding member **94** ensuring that these segments of the fluid pathway **84** will be compressed against the exterior of the occluding member **94** when the occluding member **94** is present. This may aid in ensuring a robust fluid seal is formed when the occluding member **94** is in place within the fluid pathway **84**. In the example embodiment, the fluid pathway **84** extending through the longitudinal axis of the insert **82** includes two reduced diameter sections **96**. One of the reduced diameter sections **96** is disposed upstream of the branch fluid pathway **86** leading to the delivery sharp(s) **88**. The other of the reduced diameter sections **96** is disposed downstream of the branch fluid pathway **86** leading to the delivery sharp(s) **88**. The reduced diameter sections **96** may be included as stepwise changes in the diameter of the fluid pathway **84** or the fluid pathway **84** may have a continuous gradual change in diameter over the extent of the reduced diameter sections **96** as shown.

[0221] Referring primarily to FIG. **9**, the delivery device **10** may include a plug driver and a plunger sled driver. In the example embodiment, the plug driver is shown as a first bias member **100** and the plunger sled driver is shown as a second bias member **102**. Specifically, the exemplary bias members **100**, **102** shown in FIG. **9** are compression springs. Any other suitable bias member such as other springs, gas bladders, compressible compliant members, etc. may be used. The first bias member **100** may be disposed between the head portion **92** of the plug **90** and the insert **82**. Together with the locking member **18**, the plug **90** and first bias member **100** may from an activation assembly of the delivery device **10**. In some embodiments, a resilient body **104** (e.g. a washer or disk) may be disposed intermediate the inserter **82** and an end of the first bias member **100**. The second bias member **102** may be disposed between the first end **64** of the plunger sled **60** and a radial flange **106** at an end of the guide portion **56** most proximal the reservoir portion **54** of the delivery device **10**.
[0222] When the delivery device **10** is in a locked state, the first and second bias members **100**, **102** may be in an energy storing state. The locking member **18** may be present and may extend at least partially through a receiving slot **108** in the head portion **92** of the plug **90**. As the locking member **18** extends through the head portion **92** of the plug **90**, the locking member **18** may block the plug **90** from displacing under restoring force supplied from the first bias member **100**. The first end **64** of the plunger sled **60** may also be in contact with a face of the locking member **18**. Thus, the locking member **18** may present a mechanical interference which prevents movement of the plunger sled **60** under restoring force supplied by the second bias member **102**.
[0223] Referring now to FIG. **11**, when a user is ready to deliver the contents of the delivery device **10** to a patient, the cover member **26** (see, e.g., FIG. **5**) may be doffed and the locking member **18** may be displaced. With the locking member **18** displaced out of a locking state (in the example, fully removed from the delivery device **10**), the plug **90** and the plunger sled **60** may be free to move under the urging of the first and second bias member **100**, **102**.
[0224] In some embodiments, and referring now to FIG. **12**, the first bias member **100** may not be used. Instead, the plug **90** may be arranged to be manually extracted. In the example shown in FIG. **12**, the plug **90** includes a turnkey portion **91** (which may be a knob, dial, lever, etc. in alternative embodiments) which is accessible via the exterior of the housing. The plug **90** also include a threaded section **93** which may interface with cooperating threads included in a receiving bore **95** of the guide portion **56**. Rotation of the turnkey portion **91** may displace the plug **90**. In other embodiments, a threaded section **93** may not be used. In such embodiments, the turnkey portion **91** may be replaced with a pull ring or other graspable interface and the plug **90** may be displaced by a manual pulling force exerted on the pull ring.
[0225] Referring now to FIG. **13**, in other embodiments which do not include the first bias member **100**, the lock member **18** may be teethed with at least one tooth **97**. The plug **90**, may include a pinion portion **99**. When installed in the delivery device **10**, the at least one tooth **97** of the lock member **18** may interdigitate with the teeth of the pinion portion **99** of the plug **90**. As the lock member **18** is extracted, the teethed interface between the lock member **18** and pinion portion **99** of the plug **90** may convert translational displacement of the lock member **18** into rotation of the plug **90**. As mentioned above, the plug **90** may include a threaded section **93** (see, e.g., FIG. **12**). Thus, as the plug **90** is rotated, the plug **90** may translationally displace due to interaction between the threaded section **93** of the plug **90** and the cooperating threads of the receiving bore **95** of the guide portion **56**. The pinion portion **99** of the plug **90** may have a length sufficient to accommodate this translational displacement. Thus the pinion portion **99** may not only rotate, but also slide across the at least one tooth **97** of the lock member **18** as the plug **90** is translationally displaced along the axis of the receiving bore **95** of the guide portion **56**.
[0226] Referring now to FIG. **14**, with the locking member **18** removed from the locking state, the bias members **100**, **102** may begin to displace the plug **90** and the plunger sled **60**. The first bias member **100** may quickly transition to a relaxed state and drive the plug **90** in a direction opposite

the insert **82**. In alternative embodiments, the plug **90** may be manually displaced (e.g. via a turnkey portion **91** of the plug **90**, see, e.g., FIG. **12**, via a rack and pinion arrangement between the plug **90** and lock member **18** see, e.g., FIG. **13**, or any other suitable arrangement). As shown, the head portion **92** of the plug **90** may abut against a stop surface **110** on the interior face of the first portion **50** of the housing **12**. The displacement distance of the plug **90** may be chosen such that the interior volume of the reservoir portion **54** may be placed into communication with the delivery sharp(s) **88** of the delivery device **10** when the plug **90** is driven into the stop surface **110**. When the plug **90** is displaced against the stop surface **110**, the occluding member **94** may be moved so as to establish a flow path through the insert **82** to the delivery sharp(s) **88**, yet block fluid from passing fully through the first fluid pathway **84**. Though the first bias member **100** is described as being in a relaxed state in FIG. **14**, it should be understood that the first bias member **100** may not be fully restored to its unstressed configuration once the plug **90** is driven into the stop surface **110**. This may be desirable as the plug **90** may be firmly held against the stop surface **110** if the first bias member **100** is still at least slightly stressed.

[0227] Referring now also to FIGS. **15** and **16**, the second bias member **102**, while free to transition to a more relaxed state when the locking member **18** is removed, may do so more slowly. This may be a result of any resistance to fluid flow from the reservoir portion **54** to the delivery sharp(s) **88**.

[0228] In some examples, the second bias member **102** may be selected such that the relaxation of the second bias member **102** as the plunger sled **60** is driven from its position in FIG. **14** to its position in FIG. **16** only partially relaxes the second bias member **102**. The displacement of the second bias member **102** as this relaxation occurs may be selected such that it occurs over a portion of the second bias member's **102** force v. displacement plot which has a characteristic of interest. For example, the displacement may be selected such that it occurs over a linear portion of the force v. displacement plot. Alternatively, the displacement may be selected to occur over a portion of the force v. displacement plot that is relatively constant. For example, the displacement of the second bias member **102** needed to deliver the contents of the reservoir portion **54** may be a small fraction (e.g. 10-15% or up to 20%) of the total spring displacement. The characteristic of interest for the force v. displacement plot may be selected to inform the flow rate of fluid from the delivery device **10** or its derivatives during operation.

[0229] Referring now to FIG. **17**, in certain embodiments, the resistance to fluid flow from the reservoir **54** may be manipulated to control the delivery rate from the delivery device **10**. For example, in certain embodiments, a restriction **98** may be placed in the fluid flow path between the reservoir portion **54** and the delivery sharp(s) **88** to lower the flow rate. The length of the flow path between the reservoir portion **54** and the delivery sharp(s) **88** may also be altered to adjust the flow rate. Thus, delivery devices **10** may be constructed so as to support a bolus delivery of the contents of the reservoir portion **54** or a slower basal delivery of the reservoir portion **54** contents.

[0230] Referring now to FIGS. **18** and **19** a top down view of an example delivery device **10** and a cross section of a delivery device **10** taken at the indicated cut plane in FIG. **18** are respectively shown. As shown, during displacement of the plunger sled **60** the rails **76** of the plunger sled **60** may travel along a face of the housing retention members **58**. In the example, the rails **76** travel along and may be guided by a face of the housing retention members **58** which is most distal to the main body of the second housing portion **52**.

[0231] Referring now also to FIG. **20**, the first housing portion **50** may include a number of coupling members **120**. The coupling members **120** are shown as snap projections which are cantilevered from an interior face of the first housing portion **50** in the example embodiment. As the first housing portion **50** and second housing portion **52** are joined, the coupling members **120** may resiliently deflect around the housing retention members **58**. As the first and second housing portions **50**, **52** are further advanced toward one another, the coupling members **120** may reach a latch slot **122** in each of the housing retention members **58**. The coupling members **120** may restore

to their undeflected state upon reaching the latch slot **122**. Upon restoring to their relaxed state, a ledge **124** on each coupling member **120** may abut against a wall of the latch slot **122** preventing inadvertent disassociation of the first and second housing portion **50**, **52**. As the coupling is inaccessible from the exterior of the delivery device **10**, the connection between the first housing portion **50** and second housing portion **52** may be difficult for a user to disengage which may be desirable.

[0232] Referring now to FIG. **21**, example delivery devices **10** may be filled in a variety of ways. For example, in certain examples, a filling implement **130** may be brought into fluid communication with the reservoir **54** via the insert **82**. Fluid from a source **132** connected to the filling implement **130** may then be transferred into the interior volume of the reservoir portion **54**. In certain embodiments, fluid from the source **132** may be driven into the reservoir portion **54** and the hydraulic pressure of the fluid may displace the plunger sled **60** and compress the second bias member **102** as needed to accommodate the fluid. In other examples, the plunger sled **60** may be driven so as to displace the plunger member **62** away from the outlet **80** of the reservoir portion **54** and compress the second bias member **102**. In such embodiments, the negative pressure generated due to the displacement of the plunger member **62** within the reservoir portion **54** may draw fluid into the reservoir portion **54** through the filling implement **130**. In still other embodiments, hydraulic pressure may force fluid into the reservoir portion **54** while the plunger sled **60** is be driven so as to suck fluid into the reservoir portion **54**.

[0233] Where the plunger sled **60** is driven to aid in drawing of fluid into the reservoir portion **54**, the plunger sled **60** may include at least one coupling **134** to which a drive element **136** may be coupled. Coupling **134** may, for example, be a hitch, hook, yoke, catch, or, as shown in FIG. **21**, a lip. The drive element **136**, which may be part of a filling fixture in a manufacturing setting, may be coupled to the plunger sled **60** via the coupling **134** and be actuated so as to displace the plunger sled **60** against the force exerted by the second bias member **102**. In the example embodiment, the drive element **136** may include a protruding ridge **138** which may be brought into abutment with the lip **134** to pull back the plunger sled **60**.

[0234] In alternative examples, the plunger sled **60** may be pushed so as to displace the plunger sled **60** against the force exerted by the second bias member **102**. For example, a drive element **136** be press against a face **137** of the plunger sled **60** opposite the plunger **62**. In such embodiments, the guide portion **56** may act as a locating projection which may help to position the drive element in place against the face **137** of the plunger sled **60**.

[0235] After the reservoir portion **54** has been filled as desired, the plunger sled **60** may be held in position. As mentioned above, in some embodiments, the plunger sled **60** may include a coupling **134** which may engage with a portion of a filling fixture. This engagement may be used to hold the plunger sled **60** in position against the restoring force of the second bias member **102**. While the plunger **60** is held in a withdrawn position, the first bias member **100** and plug **90** may be introduced into the delivery device **10** assembly. As shown in FIG. **9**, the plug **90** may block flow through the outlet **80** of the reservoir portion **54**. During filling the outlet **80** may be the highest portion of the reservoir portion **54** so as to prevent any egress of fluid prior to installation of the plug **90**. A locking member **18** may be installed so as to block movement of the plug **90** and plunger sled **60**. With the locking member **18** in a locking state, the plunger sled **60** may be disengaged from the drive element **136** of the filling fixture. The first portion **50** of the housing **12** may be coupled to the second portion **52** to enclose the internal components of the delivery device **10**. As described in reference to FIG. **2**, in certain examples, locking members **18** may be partially flexible. In the grasping configuration (see, e.g., FIG. **2**) of such a locking member **18**, the locking member **18** may be able to pass through the aperture **24** in the first portion **50** of the housing **12** as the first and second portions **50**, **52** are coupled to one another.

[0236] Filling of the delivery device **10** and introduction of the plug **90** may occur in a tightly controlled environment. Once the plug **90** has been installed, the fluid paths of the delivery device

10 may be sealed or protected from the ambient environment (the cover member **26** may be present). Thus, remaining components of the delivery device **10** need not be provided in a sterile state. Additionally, such components may be assembled into place in a less stringently controlled environment.

[0237] Referring now to FIG. **22**, another exemplary embodiment of a delivery device **10** is depicted. The example delivery device **10** may be an intradermal delivery device **10** which is arranged to automatically deliver fluid to an intradermal location of a patient's body. As shown, the delivery device **10** includes a cover member **26**. The cover member **26** may cover the majority or the entirety of the skin adhering surface of the delivery device **10**. Referring now also to FIG. **23**, the cover member **26** may have a concavely curved wall which forms a basin. When coupled to the housing **12** of the delivery device **10**, the delivery sharp(s) **88** may be enclosed by the cover member **26**.

[0238] Referring now to FIGS. **24-25**, the delivery device **10** may include an array of delivery sharps **88** which in the example embodiment are microneedles. In the example embodiment, an array of three microneedles is depicted for exemplary purposes. The three microneedles are arranged in a single row in the example. As with other embodiments described herein, any suitable number of microneedles may be included and in some examples a single microneedle may be included. Additionally, any suitable number of rows and/or columns or microneedles may be included where an array is used in an embodiment described herein. Preferably, the arrangement of microneedles may not produce a bed of nails type effect in which penetration of the skin is inhibited. The microneedles may be appropriately spaced in a spaced array to prevent this.

[0239] Microneedles included herein may be constructed of a biocompatible, non-ductile, high Young's modulus material with an indentation hardness sufficient to allow penetration into skin without breakage. 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 (though longer microneedles may also be used). At least some edges of the microneedles may be rounded or filleted, though such microneedles may still be considered polyhedral. In other embodiments, the microneedles may be conically shaped. Any suitable shape may be used. The points or tips of microneedles described herein may be solid and the flow lumens through the microneedles may be offset from the points or tips of the microneedles. Hollow tipped microneedles in which the flow lumen is 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 described herein as constructed of silicon may have a surface layer of silicon dioxide which may, for example, form with exposure to air. In other embodiments, 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, carbohydrate, or metal (e.g. stainless steel, titanium, palladium, nickel, alloys such as palladium cobalt alloys, etc.). Any suitable microneedle constructions including dissolvable microneedles may be used. Microneedles 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).

[0240] Referring still to FIGS. **24-25**, in the example, the microneedles are disposed substantially perpendicular to the skin adhering face of the delivery device **10**. In alternative embodiments, the microneedles may extend at an acute angle (e.g. 30°, 45°, 60°) with respect to the skin adhering face of the delivery device **10**. The microneedles may be provided on a portion of the delivery device **10** which is raised with respect the remainder of the skin adhering face of the delivery device **10**. In the example embodiment, the microneedles are disposed on a platform **150**. A platform **150** may not be used in all embodiments. For example, the delivery sharps **88** may be included on a portion of a convex bump raised from the skin adhering face. Disposing the delivery

sharps **88** in raised relationship to the skin adhering surface of the delivery device **10** may ensure that pressure applied to the delivery device **10** when the delivery device **10** is placed on a patient's body is concentrated on the delivery sharps **88**. Additionally, it may aid in stretching the skin at the puncture site. This may help to ensure that the delivery sharps **88** appropriately puncture into the patient's skin. Thus, the delivery device **10** may provide intradermal delivery access without need for a medical professional to utilize Mantoux technique. Additionally, the delivery device **10** may simply be applied to the skin obviating the need for a medical professional to hold an injection instrument at their estimate of a prescribed angle relative to the skin surface. Thus, intradermal injection via a delivery device **10** may be more precise and consistent.

[0241] Referring now to FIG. **26**, another example microneedle is depicted. As shown, in some examples, the microneedles described herein may be generally in the shape of a heptagonal prism (in alternative embodiments the base shape may be a pentagonal, nonagonal, and so on type prism) which has been diagonally sected to form a heptagonal ramp or pointed wedge. In such embodiments, the heptagonal prism may be sected by a plane extending from a vertex **13** of the top face of the prism to 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**. The flow lumen **21** in the example embodiment is offset from the point of the microneedle and may thus be referred to a solid pointed microneedle.

[0242] Referring now again primarily to FIGS. **24-25**, when the locking member **18** is removed from the delivery device **10** the second bias member **102** (see, e.g., FIG. **9**) of the delivery device **10** may force fluid from a reservoir portion **54** (see, e.g., FIG. **9**) out of the microneedle array of delivery sharps **88**. No manual sustained pressure or other user interaction may be required as the delivery occurs. This may ensure that no medical personnel are needed to complete the delivery. This may be particularly desirable as the flow rate of fluid into the patient may be relatively slow due to the small apertures of the microneedles. Thus sustained manual pressure would be needed for a relatively long period of time to complete delivery if fluid was to be manually driven from the delivery device **10**. From the perspective of the user, the user need only to wait a predefined period of time after applying the delivery device **10** and displacing the locking member **18** to effect the delivery.

[0243] Referring now to FIG. **27** and FIG. **28**, another embodiment of an example delivery device **10** is shown. As shown, the delivery device **10** includes an actuatable delivery sharp assembly **170**. The delivery sharp assembly **170** may include at least one delivery sharp **88**. In some embodiments, a subcutaneous or intramuscular delivery sharp **88** may be included in the delivery sharp assembly **170**. In other embodiments, the delivery sharp(s) **88** included in the deliver sharp assembly **170** may be a microneedle or microneedle array. In such delivery devices **10**, the delivery device **10** may be applied to the injection site. The delivery sharp(s) **88** may be subsequently advanced from a stowed position inside the delivery device **10** to an extended position in which the delivery sharp(s) **88** establish fluid communication into the user's body. After injection, the delivery sharp(s) **88** may be actuated to a retracted state in which the tip(s) of the delivery sharp(s) **88** are recessed with respect to the skin adhering face of the delivery device **10**. Thus, the delivery sharp(s) **88** may be substantially inaccessible to the user after the delivery device **10** has been used.

[0244] The delivery sharp assembly **170** may include a head **172** which may be disposed external to the housing **12** of the delivery device **10**. The head **172** may be a nub, flange, or other surface against which a user may exert manual pressure. A flow lumen **174** may extend from the head **172**. The flow lumen **174** may extend through the insert **82** and into a channel **176** which extends to the skin adhering face of the delivery device **10**. The flow lumen **174** may terminate in a needle tip in some embodiments, or may have a terminal end coupled to a microneedle or microneedle array.

[0245] As best shown in FIG. **28**, the flow lumen **174** may also include a side port **178**. When the

delivery sharp assembly **170** is in the stowed state, the side port **178** may be disposed in the elastomeric material of the insert **82**. No flow path from the reservoir portion **54** of the delivery device **10** into the flow lumen **174** may be available with the delivery sharp assembly **170** in the stowed state.

[0246] Referring now to FIG. **29** and FIG. **30**, the delivery sharp assembly **170** is depicted in an extended state. To actuate the delivery sharp assembly **170** to the extended state, a user may manually press the head **172** of the delivery sharp assembly **170** against the housing **12**. The housing **12** may provide a stop surface for the nub **172** which prevents the delivery sharp(s) **88** from displacing past their desired penetration depth in the patient. As the delivery sharp assembly **170** is actuated to the extended state, the side port **178** of the flow lumen **174** may pass into fluid communication with an atrium **182** of the insert **82** which is in communication with the reservoir portion **54**. Thus, a flow pathway from the reservoir portion **54** and into the patient may be established once the delivery sharp assembly **170** has been transitioned to the extended position. As mentioned above, after delivery has completed, the delivery sharp assembly **170** may be actuated to a retracted state in which the delivery sharp(s) **88** is/are withdrawn out of the skin and disposed within the delivery device **10**. In some embodiments, the delivery sharp assembly **170** may include a stop projection **180** which inhibits the delivery sharp assembly **170** from being displaced beyond a predetermined amount. This may prevent a user from removing the delivery sharp assembly **170** from the delivery device **10**. In the example embodiment shown in FIG. **29-30**, the delivery sharp **88** is shown as a microneedle. In certain embodiments, the delivery sharp **88** may instead be a conventional needle or a microneedle array.

[0247] Referring now to FIG. **31** and FIG. **32**, another exemplary delivery device **10** is depicted. As shown, the delivery device **10** is delivery sharp **88** free. Instead, the example delivery device **10** depicted in FIG. **31** includes an infusion site connector **190**. The delivery device **10** may include an internal flow channel **192** which extends from a branched fluid pathway **86** of the insert **82** to an inlet of the infusion site connector **190**. The infusion site connector **190** may have a bottom face which is substantially even with the skin adhering face of the delivery device **10**.

[0248] The infusion site connector **190** may include a connector sharp **194**. The infusion site connector **190** may also include at least one coupling interface. In the example embodiment, the infusion site connector **190** includes a pair of cantilevered arms **196**. The infusion site connector **190** may be docked with an infusion set assembly **205** (see, e.g. FIG. **35**) which has been previously inserted into the skin of a user. The cantilevered arms **196** may have a ledge which snaps into place against a catch surface of the infusion set assembly **205** to maintain coupling of the infusion site connector **190** and the infusion set assembly **205**. The infusion set assembly **205** may include a cannula **207** (see, e.g., FIG. **39**) which extends into a desired delivery destination in the patient (e.g. subcutaneous tissue). During docking of the infusion site connector **190** with the infusion set assembly **205**, the connector sharp **194** may puncture a barrier such as a septum in the infusion site assembly **205**. This may place the outlet of the connector sharp **194** into sealed fluid communication with the cannula **207** of the infusion set assembly **205**. The infusion site connector **190** may include guard projections which extend alongside the connector sharp **194** to inhibit contact of the connector sharp **194** with a user. The cantilevered arms **196** may help guard against contact with the connector sharp **194**.

[0249] With fluid communication to the cannula **207** (see, e.g., FIG. **39**) of the infusion set assembly **205** (see, e.g. FIG. **35**) established, the locking member **18** of the delivery device **10** may be actuated and fluid may be delivered from the reservoir portion **54**, through the insert **82** and interior flow channel **192**, and into the cannula **207** via the connector sharp **192**. Once the injection has completed, the coupling interfaces may be disengaged and the delivery device **10** along with the infusion site connector **190** may be discarded. In some embodiments, a cap member **198** may be placed over the infusion site connector **190** to prevent user interaction with the connector sharp **192**. The infusion site assembly **205** may remain in place or may be removed if no longer needed.

[0250] The infusion site assembly **205** (see, e.g., FIG. **35**) may be any suitable infusion site assembly **205**. In some embodiments, the infusion site assembly **205** may be any of those shown and described in U.S. patent application Ser. No. 16/797,624, to Lanigan et al., entitled Infusion set and Inserter Assembly Systems and Methods, filed Feb. 21, 2020 incorporated herein by reference in its entirety. The infusion site assembly **205** may be installed on the user using any suitable inserter assembly. In some embodiments, an inserter assembly which lifts the skin from underlying tissue prior to triggering insertion may be used. Any inserter assembly described in the above mentioned U.S. patent application Ser. No. 16/797,624 may for example be used. Various infusion set connectors described in the above mentioned U.S. patent application Ser. No. 16/797,624 may be included as the infusion set connector **190** of delivery devices **10** described and shown herein.
[0251] Referring now to FIG. **33** and FIG. **34**, another delivery device **10** embodiment which is delivery sharp **88** free is depicted. As shown, the delivery device **10** is connected to an infusion site connector **190** via an expanse of infusion tubing **200**. The length of infusion tubing **200** may be anywhere from a few inches to a meter or more. As in the above described embodiment, the infusion site connector **190** may couple to an infusion site assembly **205** (see, e.g., FIG. **35**) which may include a cannula **207** (see, e.g., FIG. **39**) that extends into a delivery destination in a patient. The infusion tubing **200** may allow a user to place the infusion site assembly **205** in a wider variety of locations over a patient's body. The delivery device **10** may be applied to a different location on the patient's body. Alternatively, the delivery device **10** may be placed in a pocket, handbag, on a desk, tray, or other surface, etc. as the fluid is delivered from the delivery device **10** and into the patient through the infusion set assembly **205**. Though described in relation to the delivery device **10** embodiment shown in FIG. **1**, infusion site connectors **190** and/or infusion tubing **200** may be included on any of the delivery devices **10** described and shown herein. Thus any of the delivery devices **10** shown or described herein may be constructed as delivery sharp **88** free devices which may deliver to an external infusion site assembly **205**.
[0252] Referring now to FIG. **35** and FIG. **36**, two additional exemplary embodiments of a delivery devices **10** including an infusion site connector **190** which may couple to an infusion site assembly **205** are shown. As shown, the infusion site connector **190** may be coupled to a reservoir assembly **650**. The reservoir assembly **650** may include an agent filled collapsible blister **652**. The agent filled blister **652** may be included on a panel **656** of material which may include a flow path **654** therein. The material forming the panel **656** may be rigid. In various examples the reservoir assembly **650** may also include a check valve to prevent refilling of the blister **652** once the delivery device **10** is used. The panel **656** may be provided in a variety of orientations. For example, the panel **656** may define a plane which is generally parallel to the skin (see FIG. **35**). Alternatively, the panel **656** may define a plane which is transverse to the skin surface (e.g. substantially perpendicular as shown in FIG. **36**). Once the infusion site connector **190** is coupled to the infusion site assembly **205**, a user may manually press against the blister **652** to drive fluid out of the blister **652** and into the patient via the cannula **207** (see, e.g., FIG. **39**) of the infusion site assembly **205**. The infusion site connector **190** may be decoupled from the infusion site assembly **205** once the blister **652** has been fully collapsed and the infusion site connector **190** and reservoir assembly **650** may be discarded.
[0253] Referring now to FIG. **37** and FIG. **38** (a cross-section at the indicated plane of FIG. **37**) another example delivery device **10** is depicted. As shown, the delivery device **10** may include a housing **660**. The delivery device **10** may further include an infusion site connector **190**. The infusion site connector **190** may couple to an infusion site assembly **205** as described elsewhere herein. The infusion site connector **190** is depicted as connected to the housing **660** in the example embodiment, though may alternatively be connected to the housing **660** via tubing **200** (see, e.g., FIG. **34**). In alternative embodiments, the outlet of the delivery device **10** may be a delivery sharp (e.g. conventional needle, microneedle, microneedle array) which delivers agent directly to the patient instead of via an infusion site assembly **205**.

[0254] As shown best in FIG. **38**, a reservoir assembly **650** may be contained within the housing **660**. The reservoir assembly **650** may include an agent containing collapsible blister **652**. The blister **652** may be included on a panel **656**. The interior volume of the blister **652** may be placed into communication with the infusion site connector **190** via a flow path **654** provided from the blister **652** along a portion of the panel **656**. As shown, the infusion site connector **190** may include a connection sharp **662**. The connection sharp **662** may be displaceable between a first position and a second position. In the example embodiment, the connection sharp **662** is mounted in a hub **666** which may displace within a channel **664** of the infusion site connector **190**. The hub **666** may include a shoulder portion **668** which may limit travel of the hub **666** within the channel **664**. The connection sharp **662** may include a needle point on each of the opposing ends of the connection sharp **662**. During coupling of the infusion site connector **190** to an infusion site assembly **205**, the hub **666** and connection sharp **662** may be displaced toward and through a septum **670**. The connection sharp **662** may be in the second position when the connection sharp **662** has been displaced through the septum **670**. The septum **670** may prevent fluid communication from the blister **652** to the connection sharp **662** until the septum **670** has been punctured by the connection sharp **662**. When the connection sharp **662** is in the second position, the connection sharp **662** may be in fluid communication with the blister **652**.
[0255] Still referring to FIG. **38**, the delivery device **10** may include an actuator **672**. The actuator **672** may be coupled to a pressure plate **676** which may be positioned atop the blister **652**. In the example embodiment, the actuator **672** is depicted as a bias member which is provided in a stressed state. Specifically, a cantilevered spring is depicted with the pressure plate **676** being coupled to the spring near the unsupported end of the spring. The actuator **672** also includes a locking member interface **674**. The locking member interface **674** may be a loop of material, slot, or other receptacle for a locking member **18**. Referring now also to FIG. **38**, in the example embodiment, the locking member **18** is depicted as a removable pin which may be received in the locking member interface **674** of the actuator **672**. With the infusion site connector **190** coupled to an infusion site assembly **205** and the septum **670** breached by the connection sharp **662**, the locking member **18** may be removed (e.g. pulled out in the example embodiment). The actuator **672** may resiliently restore to an unstressed state (or at least less stressed state) with the locking member **18** removed or displaced to a state in which it is disengaged from the actuator **672**. This in turn may urge the pressure plate **676** against the blister **652** and toward the panel **656** so as to drive fluid from the blister **652** through the delivery device **10** and into the patient via the infusion site assembly **205**. The reservoir assembly **650** may include a check valve which may prevent refilling of the reservoir assembly **650** in order to prevent reuse.
[0256] Referring now to FIGS. **40-42**, another exemplary delivery device **10** similar to that depicted in FIGS. **37-39** is shown. As shown, the delivery device **10** may include a housing **680**. The delivery device **10** may further include an infusion site connector **190**. As shown, the infusion site connector **190** may couple to an infusion site assembly **205** which may provide access to a delivery destination in a patient via a cannula **207** for example. The infusion site connector **190** is depicted as connected to the housing **680** in the example embodiment, though may alternatively be connected to the housing **680** via tubing **200** (see, e.g., FIG. **34**). The delivery device **10** may include a reservoir assembly **650** including a collapsible agent filled blister **652** on a panel **656**. A flow path **654** may lead from the blister **652** to the infusion site connector **190**. As the infusion site connector **190** is depicted coupled to an infusion site assembly **205**, the connection sharp **662** and hub **666** have been driven along the channel **664** of the infusion site connector **190** such that the septum **670** is breached by the connection sharp **662**.
[0257] As in FIGS. **37-39**, the actuator **672** in the embodiment of FIGS. **40-42** may be a bias member such as a cantilevered spring which is provided in a stressed state. A pressure plate **676** may be coupled to the actuator **672** near the unsupported end of the actuator **672**. The actuator **672** of the delivery device **10** may include a hook **678** which may interface with a locking member **18**.

In the example shown in FIGS. **40-42**, the locking member **18** is depicted as a button **686** which includes a portion that is accessible from the exterior of the housing **680**. The button **686** may include at least one arm **682** which may be attached to a bar **684**. The bar **684** may be captured by the hook **678** and when engaged with the hook **678** may prevent the actuator **672** from restoring from its stressed state. A user may depress the button **686** to drive the bar **684** out of engagement with the hook **678**. This may allow the actuator **672** to resiliently restore toward an unstressed state. As the actuator **672** restores, the pressure plate **676** may be forced against the blister **652** driving fluid from the blister **652** and into the patient via the cannula **207**. The reservoir assembly **650** may include a check valve which may prevent refilling of the reservoir assembly **650** in order to prevent reuse.

[0258] Referring now to FIGS. **43-44**, another embodiment of an example delivery device **10** is depicted. The example delivery device **10** may include a base portion **250**. The base portion **250** may be constructed of plastic material and may be mounted on an adhesive member **252**. The adhesive member **252** may be a bandage or Band-Aid type member with the gauze portion omitted. As shown, the base portion **250** may be attached to a fluid handling portion **254**. The fluid handling portion **254** may be pivotally attached to the base portion **250** in certain examples. The fluid handling portion **254** may be displaceable from a loading position (shown) to a delivery position (see, e.g. FIG. **49**). The delivery device **10** may be shipped with the fluid handing portion **254** in the delivery position to minimize size of the delivery device **10**. During filling, the fluid handling portion **254** may be in the loading position and rotated away from the base portion **250**. Once the fluid handling portion **254** has been filled, the fluid handling portion **254** may be rotationally displaced toward the base portion **250**. Referring now to FIG. **46**, a perspective view of an example base portion **250** is depicted. The base portion **250** may include a flat member **312**. The flat member **312** may be constructed of a plastic. The plastic chosen may be slightly flexible so as to allow the flat member **312** to bend with the adhesive member **252** to conform to various contours of a user's body. As shown, the base portion **250** may include a catch **256** which may capture the fluid handling portion **254** once the fluid handling portion **254** has been rotated against the base portion **250**. Any suitable catch may be used. In the example, the catch **256** is defined on a body which extends upward from the flat member **312** at a substantially perpendicular angle. The base portion **250** may also include a projection **310** which may extend upward from the flat member **312**. The projection **310** may be contoured so as to form a cradle against which part of the fluid handling portion **254** of the delivery device **10** may rest. In the example embodiment, the projection **310** is included on a portion of the flat member **312** which is hinged with respect to the rest of the flat member **312**. As shown, the portion of the flat member **312** including the projection **310** is attached to the remainder of the flat member **312** via a living hinge **314**.

[0259] Referring now primarily to FIG. **47**, a cross-sectional view taken at the indicated cut plane in FIG. **43** is shown. As shown, the fluid handling portion **254** of the delivery device **10** may include a port assembly **258**. The port assembly **258** may be used to access an interior volume of a reservoir portion **280** of the fluid handling portion **254**. As shown, the port assembly **258** may include a septum **260** which may be constructed of an elastomeric material which may be punctured and self-seal upon removal of a filling implement (e.g. needle of a syringe). Alternatively, any suitable barrier may be used. Some embodiments may include a luer lock fitting and split septum for example. In the exemplary embodiment, the port assembly **258** may also include a septum retainer **262** which may be attached to a port wall **264** that surrounds a well **268** in which the septum **260** is located. The septum retainer **262** may sandwich the septum **260** between a face of the septum retainer **262** and a bottom of the well **268**. A flow channel **266** of the port assembly **258** may also be included and may extend to the bottom face of the well **268**. In certain examples, a check valve **263** may be included to prevent removal of fluid from the delivery device **10**. Such a check valve **263** may also relieve pressure on the septum **260** when the delivery device **10** is filled.

[0260] The fluid handling portion **254** of the delivery device **10** may also include an outlet assembly **270**. The outlet assembly **270** may include an outlet flow channel **274** which extends to a micro needle **272**, an array of microneedles **272**, or other delivery sharp. As shown in FIG. **47**, the outlet assembly **270** may be in abutment with a stop projection **318** of the base portion **250** when the fluid handing portion **254** is in the loading position. This may present a mechanical interference which inhibits rotation of the fluid handling portion **254** beyond the loading position.
[0261] The reservoir portion **280** is depicted as a syringe type reservoir. The reservoir portion **280** includes a barrel portion **282**. Within the barrel **282**, a plunger **284** may be included. The plunger **284** may include an elastomeric member **286** which may be molded to or attached to a head portion of the plunger **284**. The elastomeric member **286** may aid in generating a robust fluid seal against the interior wall of the barrel **282**. The plunger **284** may include a plunger stem **288** which extend away from the head portion of the plunger **284**. A bias member **292** may be included in the reservoir portion **280**. The bias member **292** may store energy which tends to drive fluid out of the reservoir portion **280** by urging the plunger **284** to advance toward an outlet **296** of the barrel **282**. Any suitable bias member **292** such as gas bladders, compressible elastomer, various springs, etc. may be used. In the example embodiment, the bias member **292** is depicted as a coil spring which surrounds the stem **288** of the plunger **284**. The bias member **292** may be captured between the head portion of the plunger **284** and a rear of the barrel **282**. In the example embodiment a clip **294** is installed at the rear of the barrel **282** to capture the bias member **292** and plunger **284** within the barrel **282**.
[0262] Referring now to FIG. **47** and FIG. **48**, in the example embodiment, the port assembly **258**, outlet assembly **270**, and the reservoir portion **280** may also be included as features which extend from an exterior face of a hub body **276**. The hub body **276** may be round and may be coaxial with and rotate about an axel **300**. In the example embodiment, the hub body **276** is generally cylindrical. The axel **300** may be supported by the base portion **250** and may be included as a part of the base portion **250**. As shown, the base portion **250** may include a first section **320** and a second section **322**. The first section may include the axel **300**. The fluid handling portion **254** may be installed on the axel **300** and the second portion **322** may then be joined to the first portion **320** of the base portion **250** to retain the fluid handing portion **254** in place in the delivery device **10**. In the example embodiment, the second portion **322** includes a pin **324** which may couple into a receptacle of the axel **300** via interference fit. Other coupling schemes may be used in other embodiments. For example, a snap fit, adhesive, solvent bonding, welding, fasteners, etc. may be used to couple the first and second portion **320**, **322** together during assembly. In alternative embodiments, the first portion **320** and second portion **322** may be molded together as a monolithic part. In such embodiments, a living hinge may be present between the first portion **320** and second portion **322**. The second portion **322** may be folded via bending at the living hinge during assembly.
[0263] The axel **300** may include a number of fluid flow channels. The fluid flow channels may be formed as troughs which are recessed into an outer or external face of the axel **300**. In the example embodiment, a filling or inlet flow channel **302** and a delivery flow channel **304** are included. A gasket member may be included in certain embodiments as well. The filling flow channel **302** and delivery flow channel **304** may be stationary with respect to the fluid handling portion **254** of the delivery device **10**. When the fluid handling portion **254** of the delivery device **10** is in the loading position (shown in FIG. **47**) the flow channel **266** of the port assembly **258** may be in fluid communication with an inlet **298** of the reservoir portion **280** via the filling flow channel **302**. Fluid may be loaded into the reservoir portion **280** via delivery of fluid (e.g. vaccine, opioid antagonist, or other types of medical agents depicted as stippling in FIG. **47**) into the port assembly **258** (e.g. via syringe or other filling implement). As the reservoir portion **280** is filled, the plunger **284** may be pushed toward the rear of the barrel **282** to allow the volume of fluid dispensed into the port assembly **258** to be accommodated. This may also cause the bias member **292** to become stressed

and store energy which may be used to drive later delivery of the fluid.
[0264] Referring now to FIGS. **49-50**, once the reservoir portion **280** has been filled, the fluid handling portion **254** of the delivery device **10** may be displaced to the delivery state. As the reservoir portion **280** is displaced toward the base portion **250** the reservoir portion **280** may contact the projection **310**. The reservoir portion **280** may contact the projection **310** at an intermediate position and prior to the fluid handling portion **254** of the delivery device **10** reaching its delivery position. As the reservoir portion **280** continues to pivot toward the flat member **312** of the base portion **250**, the section of the flat member **312** including the projection **310** may begin to deflect about the living hinge **314** connecting it to the remainder of the flat member **312**. This deflection may continue until the fluid handling portion **254** reaches its delivery state and is captured by the catch **256** on the base portion **250**. The deflection of the section of the flat member **312** including the projection **310** may press against the skin of a user. In turn, this may cause stretching of the skin in the area where the section of the flat member **312** including the projection contacts the skin. As shown, pivotal displacement of the fluid handing portion **254** of the delivery device **10** toward the delivery state may also cause the microneedle(s) **316** (other embodiments may be outfitted with different delivery sharps) to be pivoted into the patient's skin. The bandage **252** may include apertures for the section of the flat member **312** including the projection **310** and the outlet assembly **270**. Stretching of the skin as the microneedle(s) **316** is/are advanced into contact with the skin may facilitate consistent penetration into the intradermal space. Once the fluid handling portion **254** of the delivery device **10** reaches the delivery position, the interior volume of the reservoir may be placed into communication with the microneedle(s) **316** via the outlet flow channel **304** of the axel **300**. The bias member **292** may then relax over a period of time forcing fluid from the reservoir portion **280** into the intradermal space of the patient. The patient may wait a predetermined period of time for the delivery to complete and then the delivery device **10** may be removed and discarded.
[0265] Referring now to FIG. **52**, a top down view of another example embodiment of a delivery device **10** is depicted. As shown, the delivery device **10** may include a reservoir portion **350**. The reservoir portion **350** may include a port assembly **360**. Any suitable port assembly **360** may be used. The port assembly **360** may be similar to that shown in FIG. **47** and may include a septum through which the interior volume of the reservoir portion **350** may be accessed for filling of the reservoir portion **350**. The reservoir portion **350** may be attached to the bandage **252** via a base member **352** coupled to the reservoir portion **350** in some embodiments.
[0266] Referring now also to FIG. **53** and FIG. **54**, the delivery device **10** may include a stopcock assembly **370**. The stopcock assembly **370** may include a lever **372**. The lever **372** may be connected to the spindle **374** of the stopcock assembly **370**. During loading of the reservoir portion **350** the bore **376** through the spindle **374** may be out of communication with the outlet **356** of the reservoir portion **350**. The reservoir portion **350** shown in FIGS. **53-54** includes a barrel **354** with a plunger **358** therein. As with the embodiment described in relation to FIG. **47**, during loading of the reservoir portion **350**, a bias member **359** may become stressed when fluid is loaded into the interior volume of the reservoir portion **350** via the port assembly **360**.
[0267] When the user is ready to deliver fluid from the delivery device **10**, the lever **372** may be displaced to rotate the spindle **374**. In the example embodiment, the lever **372** may be displaced toward the skin. As the spindle **374** rotates in response to displacement of the lever **372**, the bore **376** may be brought into fluid communication with the outlet **356** of the reservoir portion **350**. Additionally, during displacement of the lever **372**, an outlet assembly **378** include a microneedle **380** or microneedle array may be driven into the skin of the user to access an intradermal space of the user. The bias member **359** may begin to relax and force fluid out of the reservoir portion **350** and into the intradermal space of the user.
[0268] The delivery device **10** may also include a cover **362**. The cover **362** may seat over the reservoir portion **350** and stopcock assembly **370** and may include an aperture through which the

port assembly **360** may extend. The lever **372** may also extend outside of the cover **362** so as to allow operation via a hand of the user.

[0269] Referring now to FIG. **55-56**, another example embodiment of a delivery device **10** is depicted. The example delivery device **10** may include a first base portion **500** and a second base portion **502**. The base portions **500**, **502** may be constructed of plastic material and may be mounted on an adhesive member **252**. The adhesive member **252** may be bandage or a Band-Aid type member with the gauze portion omitted. As shown, the base portions **500**, **502** may accept a reservoir portion **504** which may be included as part of a fluid handling portion **254** of the delivery device **10**. The fluid handling portion **254** may be actuatable from a storage state (shown) to a delivery state (see, e.g. FIG. **65**). The delivery device **10** may be shipped with the fluid handing portion **254** in the storage state and may be prefilled (e.g. via a manufacturer or at a pharmacy) in certain examples. As shown, the example delivery device **10** is depicted with a microneedle **506** or microneedle array. In alternative embodiments, transcutaneous delivery sharps such as subcutaneous or intramuscular needles may be included.

[0270] Referring now to FIGS. **57-58**, the first base portion **500** may include an outlet assembly **510** which may form part of the fluid handling portion **254** of the delivery device **10**. The outlet assembly **510** may include the microneedle **506** or microneedle array (or other delivery sharp(s)). The outlet assembly **510** may also include a reservoir access sharp **508** which may be disposed on an end of the outlet assembly opposite the microneedle(s) **506**. The reservoir access sharp **508** and microneedle **506** may each be included on respective support bodies **512**, **514** or hubs and may be in fluid communication with one another via a coupler **516** and flow channels in the support bodies **512**, **514**. As shown, each of the support bodies **512**, **514** includes a female mating interface which couples to respective male interfaces on opposing sides of the coupler **516**. In alternative embodiments, each support body **512**, **514** may include a male interface which mates into a respective female mating interface of the coupler **516**. In certain embodiments, a coupler **516** may be omitted and the support bodies **512**, **514** may be formed as a single monolithic component. The outlet assembly **510** may be included within a housing receptacle **518** which extends from a flat member **520** of the first base portion **500**. The outlet assembly **510** may be fixedly retained within the housing receptacle housing **518**. For example, the outlet assembly **510** may be fixedly retained within the housing receptacle housing **518** via adhesive, solvent bonding, snap fit, interference fit, etc. In some examples, the receptacle housing **518** may be keyed such that the outlet assembly **510** may only be installed within the receptacle housing **518** in a particular orientation. This may ensure that the microneedle(s) **506** are clocked to a prescribed orientation once assembled into the delivery device **10**.

[0271] Still referring primarily to FIG. **58**, the reservoir assembly **504** may include a barrel **530**. The reservoir assembly **504** may further include a plunger head **532** and a bias member **534** which may urge the plunger **532** toward an outlet **536** of the reservoir assembly **504**. The bias member **534** may be disposed within an insert **562** to which the plunger head **532** may be mounted. The bias member **534** may be captured between a wall of the insert **562** adjacent the plunger head **532** and a bias member locating projection **564** included on the second base portion **502**. The bias member locating projection **564** may aid in keeping the bias member **534** in proper position during assembly and operation. In the example embodiment, the bias member **534** is depicted as a coil type compression spring, though other suitable bias members **534** including other types of springs, gas bladders, etc. may be utilized in alternative embodiments.

[0272] In the example embodiment, the outlet **536** of the reservoir portion **504** is depicted as a vial closure. The example vial closure includes a septum **538** and a retainer **540** (e.g. a crimp) which retains the septum **538** in place on the outlet end of the barrel **530**. In certain embodiments, the barrel **530** may be constructed of an inert material. The barrel **530** may, for example, be a glass vial with an open end opposite the outlet **536**. As shown, the outlet of the barrel **530** is sealed from communication with the outlet assembly **510**. Translational displacement of the reservoir assembly

504 or at least a portion including the outlet **536** (e.g. the barrel **530**) may cause the reservoir access sharp **508** to puncture through the septum **538** and establish a flow path from the outlet **536** of the reservoir assembly **504** to the microneedle(s) **506**.

[0273] Referring now to FIG. **59**, an exploded view of the base portions **500**, **502** of an example delivery device **10** is depicted. As shown, the second base portion **502** of the delivery device **10** may include a projection **542** with a fenestration **544** or alternatively a recess. The first base portion **500** may include a protruding member **546** which includes a slot **548** therein. The slot **548** may be sized to accept the projection **542** of the second base portion **502**. In the example embodiment, the protruding member **546** of the first base portion **500** includes a cantilever arm **550** which forms a portion of the wall of the slot **548**. The cantilevered arm **550** may include a coupling interface (e.g. catch, nub, hook, etc.) which extends into the slot **548**. As the projection **542** is introduced to the slot **548**, the slot **548** may contact the coupling interface and the cantilevered arm **550** may deflect so as to allow further advance of the projection **542** into the slot **548**. Once the projection **542** is fully advanced into the slot **548**, the fenestration **544** may be in alignment with the coupling interface of the cantilevered arm **550**. The cantilevered arm **550** may then snap into engagement with the fenestration **544** so as to retain the projection **542** within the slot **548** and hold the first and second base portion **500**, **502** together.

[0274] Referring now to FIG. **60**, the insert **562** (see, e.g., FIG. **58**) may include a cap body **552** on an end of the insert **562** opposite the outlet **536**. The cap body **552** may include a flange **554**. As shown, the cap body **552** includes a radially extending flange **554** which is present around a portion of the exterior of the cap body **552**. The second base portion **502** may include a notch or recess **556** within which the flange **554** may be located. With the flange **554** disposed within the recess **556**, components attached or coupled to the cap body **552** may be prevented from displacing.

[0275] Referring now to FIG. **61** and FIG. **62**, the reservoir assembly **504**, insert **562**, or at least the cap body **552** may be rotatable about the longitudinal axis of the reservoir assembly **504**. As shown, this may allow the cap body **552** to be rotated such that the flange **554** may be displaced from a state in which it is in engagement with the recess **556** to a state in which it is free of the recess **556** in the second base portion **502**. As shown, once the flange **554** is released from the recess **556**, the reservoir portion **504** may be driven toward the receptacle housing **518** via urging of the bias member **534**.

[0276] Referring now to FIG. **63**, with the reservoir portion **504** free to displace, the reservoir portion **504** may advance, under urging of the bias member **534**, into abutment with a wall **560** of the receptacle housing **518**. This may cause the outlet **536** of the reservoir assembly **504** to be accessed via the reservoir access sharp **508**. In the example embodiment, the reservoir access sharp **508** may access the interior volume of the reservoir via a septum **538**. Further displacement of the barrel **530** of the reservoir portion **504** may be inhibited by the interference presented by the wall **560** of the receptacle housing **518**. Thus, the reservoir portion **504** may be driven via the bias member **534** (in this case a coil spring) from a sealed state into an accessed state.

[0277] Referring now to FIG. **64** and FIG. **65**, actuation of the delivery device **10** may be a two stage process. As shown, once the reservoir portion **504** has reached the accessed state, fluid contained within the reservoir portion **504** may be able to be driven out of the reservoir portion **504** through the access sharp **508** and into the patient via the microneedle(s) **506**. The bias member **534** may urge the insert **562** and plunger head **532** toward the outlet **536** to force fluid out of the reservoir portion **504** over a delivery stage of actuation. At the conclusion of this stage, the delivery device **10** may be in a delivered state and the plunger head **532** may be at its most proximal to the outlet **536**. The bias member **534** is shown in its compressed state for case of illustration. In practice, and as would be understood by one of skill in the art, the bias member **534** would expand during actuation.

[0278] As shown, the cap body **552** may include a recess **566** in which a terminal end of the barrel **530** may be disposed. During the delivery stage, the recess **566** may displace over a segment of the

terminal end of the barrel **530**. In some embodiments, this may serve as an indicator of delivery progress. In some examples, the portion of the barrel **530** to be covered received in the recess **566** may include graduations, markings, coloration, or various indicia that indicate delivery progress. This may facilitate communication to a user that the delivery has completed and the delivery device **10** may be removed and discarded.

[0279] Referring now to FIGS. **66-67**, in some embodiments, the injection site may be pressurized as agent in a delivery device **10** is dispensed. As shown, a delivery device **10** may include a chamber **630**. When the delivery device **10** is applied to a patient, the chamber **630** may cover and surround the delivery site and the microneedle(s) **506** (or other delivery sharp or sharps). The chamber **630** may include a peripheral flange **632** which may be attached to a portion of the bandage **252**. The peripheral flange **632** and bandage **252** surrounding the chamber **630** may aid in creating a seal against the skin of the patient. Also as shown, the chamber **630** may include a port **634**. The port **634** may be provided with a mating interface (luer lock, barbed fitting, etc.) which may couple to a pressure source **636** or tubing **638** extending therefrom. In various embodiments, the pressure source **636** may include a pump, manual squeeze bulb, pressure reservoir, combination thereof and any associated check valves or other valving. The pressure source **636** may be operated to bring the chamber **630** to a negative pressure. The chamber **630** may also be outfitted with a relief valve (not shown) to ensure pressure does not drop below a predefined cracking pressure of the relief valve. Negatively pressurizing the chamber **630** may aid in drawing fluid out of the microneedle(s) **506** and into an intradermal space. Though shown in relation to the delivery device **10** depicted in FIGS. **55-65**, such a pressure chamber **630** may be included in other varieties of delivery devices **10** depicted herein. For example, delivery devices **10** including ampoules **440** or the delivery device **10** described in relation to FIGS. **68-70** may include a chamber **630** which may be pressurized during delivery of agent to the patient. Any other delivery device **10** described herein may similarly include a pressure chamber **630** which may seal around an injection site so as to allow pressurization (positive or negative) of the injection site.

[0280] Referring now to FIG. **68**, another example embodiment of a delivery device **10** is depicted. As shown, the delivery device **10** may include a base portion **390**. The base portion **390** may be coupled to a bandage **252**. The base portion **390** may be constructed of a plastic which may be rigid or slightly flexible so as to allow the delivery device **10** to adapt to contours of a user's body. The base portion **390** may include a displaceable section **392**. The displaceable section **392** may be coupled to the rest of the base portion **390** at a hinge or may be integral with the rest of the base portion **390** and hinged via a living hinge. Alternatively, the displaceable section **392** may be arranged to displace substantially translationally. In such embodiments, the displaceable section **392** may include flanges on opposing edges. The flanges may overhang a channel within which the displaceable section **392** is configured to displace. At least one of these flanges may be flexible such that it may deflect as the displaceable section **392** is pressed into the channel during assembly. This flange would then restore to an undeflected state such that the displaceable section **392** cannot be removed without exertion of significant force. The displaceable section **392** may have a thickness which is thicker than the rest of the base portion **390**.

[0281] The delivery device **10** may also include a fluid handling portion **400**. The fluid handling portion **400** may be coupled to the base portion **390** at a hinge **402**. The fluid handling section **400** may include a port assembly **404**. The port assembly **404** may be any suitable port assembly such as port assembly **258** described in relation to FIG. **47**. The fluid handling section **400** may also include a reservoir **415**. In the example embodiment, the fluid handling section **400** includes a raised protuberance **406**. In the example embodiment, the raised protuberance **406** is shown as a round or convex bump which provides a convex surface on the fluid handling section **400**. In some embodiments, this convex surface presented by the raised protuberance **406** may be hemispherical or some other spherical segment. Other convex surfaces such as those presented by round raised protuberances **406** with egg-like, elliptical, oval, obround, etc. type footprints may also be included

in alternative embodiments. The convex surface provided by the raised protuberance **406** may be covered via a membrane **408** which is fluidically sealed to a main body **410** of the fluid handling portion **400** at the periphery of the raised protuberance **406**. In some embodiments, a retention ring may be attached to the main body **410** (ultrasonic welded, laser welded, adhered with adhesive, etc.) compressing the membrane **408** into sealing relationship with the main body. The membrane **408** may have an unstressed shape which differs from the shape of the raised protuberance **406**. In various embodiments, the membrane **408** may be flat in its unstressed state. Thus, when in place over the raised protuberance **406**, the membrane **408** may be said to be in a pre-stressed state as it may be stretched to accommodate the contour of the convex surface of raised protuberance **406**. A fluid flow path **416** from the port assembly **404** to the sealed space between the membrane **408** and the raised protuberance **406** may be included. The space between the surface of the raised protuberance **406** and the membrane **408** may function as the reservoir **415** and the membrane **408** may stretch as fluid is loaded into the reservoir **415** to allow for filling of the reservoir **415**.

[0282] The fluid handling portion **400** may also include an outlet assembly **412**. The outlet assembly **412** may extend from a face of the main body **410** opposing that on which the raised protuberance **406** is included. The outlet assembly **412** in the example embodiment includes a microneedle **414** or an array of microneedles **414** (other delivery sharps such as subcutaneous or intramuscular needles may be used in alternative embodiments). A fluid flow path **418** from the sealed space between the membrane **408** and the raised protuberance **406** to the microneedle(s) **414** may be included.

[0283] The fluid handling portion **400** may be pivotal about the hinge **402** from a withdrawn position shown in FIG. **68** to a deployed position shown in FIGS. **69** and **70**. The delivery device **10** may be applied to a user with the fluid handling portion **400** in the withdrawn position. In the withdrawn position, the fluid handling portion **400** may be raised with respect to the base portion **390**. The fluid handling portion **400** may then be displaced to the deployed position. As the fluid handling portion **400** is displaced to the deployed position, the main body **410** (which may be rigid) may contact the displaceable portion **392** of the base portion **390**. Further displacement of the fluid handling portion **400** toward the deployed position may cause the displaceable portion **392** to displace against the skin of the user. Thus the displaceable portion **392** may act as a skin depressor. This may cause the skin near the displaceable portion **392** to be stretched. Other embodiments described herein may include translationally displaceable skin depressors like that shown in FIGS. **68-70**. The microneedle(s) **414** of the fluid handling portion **400** may puncture the stretched skin gaining access to an intradermal space in the user as the fluid handling portion **400** is fully displaced into the deployed position. In various embodiments, the fluid handling portion **400** and base portion **390** may include cooperating retention features which allow the fluid handling portion **400** to be retained in the deployed position once the fluid handling portion **400** has been fully rotated against the base portion **390**. For example, the fluid handling portion **400** may snap into place on the base portion **390** upon displacement to the deployed position.

[0284] With the fluid handling portion **400** in the deployed position, a user may load fluid into the delivery device **10**. The space between the raised protuberance **406** and the membrane **408** may function as a reservoir and may be variable in volume due to stretching of the membrane **408**. As shown in FIG. **70**, the membrane **408** may stretch to accommodate a volume of medical agent. As this stretching may stress the membrane **408**, the membrane **408** may exert a pressure on the fluid which forces fluid into the patient through the fluid flow path **418** and microneedle(s) **414**. The amount of pressure exerted by the membrane **408** may be related to the volume contained in the reservoir **415** defined by the membrane **408** and convex surface of the raise protuberance **406**.

[0285] Referring now to FIG. **71**, an example plot **420** depicting pressure versus volume characteristics of a stretchable membrane based reservoir is shown. As fluid is initially loaded into the reservoir, the reservoir may begin to balloon out through an initial stretching range of the reservoir. A relatively large pressure build up (see regions C and A) is required to begin stretching

the membrane to accommodate the change in volume over the initial stretching range. There is a point at which the first derivative of pressure over volume becomes zero for the first time (**430** in FIG. **71**). Once the initial stretching has been completed, the pressure tends to remain relatively constant as further increase in volume occurs (see region B). Stretching of the membrane that occurs here may be said to occur over a steady pressure stretching range of the membrane.

[0286] Referring now also to FIGS. **68**-**70**, the membrane **408** may be attached to the delivery device **10** over the raised protuberance **406** in a pre-stressed or a first stressed state. When the membrane **408** is snug against the raised protuberance **406**, the volume of the reservoir **415** may be substantially zero and the reservoir **415** may be in an empty state. The membrane **408** may, however, be stretched to assume a shape which, absent the raised protuberance **406**, would correspond to a volume in region B of the plot **420**. Thus, as the reservoir **415** increases in volume as it is brought to a filled state, the pressure exerted by the membrane **408** on the fluid contained in the reservoir **415** may remain relatively stable. In certain embodiments, a change in pressure may be less than 10% or less than 5% may occur as the reservoir is brought to a filled state. As a result, delivery out of the delivery device **10** may occur at a substantially constant rate. This may be particular desirable where the delivery device **10** is used to deliver a fluid to a user at a basal delivery rate. In alternative embodiments, the raised protuberance **406** may be omitted. In such embodiments, the pressure may change, perhaps significantly, over the course of filling and delivery.

[0287] Referring now to FIG. **72**, in certain embodiments, a delivery device **10** may include a breakable or fracturable reservoir which contains a medical agent. For example, delivery devices **10** may include a glass or plastic ampoule **440** which serves as the reservoir for the medical agent **442** (e.g. vaccine). Glass may be advantageous as it is inert and may lessen the amount of compatibility testing needed for the delivery device **10**. This may help a delivery device **10** to be made available for a vaccine quickly which may be of particular interest where the delivery device **10** is intended to deliver a vaccine for a novel pathogen and time is of the essence. The ampoule **440** or other fracturable reservoir may be pressurized such that upon rupture, the pressure in the ampoule **440** may deliver fluid through the delivery device **10** and into the patient. In certain embodiments, the ampoule **440** may be pressurized with a volume of inert gas **444** (e.g. to 10 psi). The ampoule **440** may include a frangible **446** which may be thinned and/or scored (as shown) to provide a weak point in the ampoule **440** and allow the ampoule **440** to be cleanly snapped open. In the example embodiment, the ampoule **440** includes a neck portion **445** which extends from a main body **443** of the ampoule **440**. The frangible **446** is located in the neck portion **445** in the example embodiment.

[0288] Referring now to FIG. **73** and FIG. **74** (a cross-section taken at the indicated plane of FIG. **73**), when installed in a delivery device **10**, the portion of the ampoule **440** including the frangible **446** may be contained in an elastomeric boot or housing **450**. The elastomeric housing **450** may include a chamber **452** in which the frangible **446** is disposed. The chamber **452** may include a port **458** via which the chamber **452** is in communication with a microneedle **454** or array of microneedles **454** included as part of an outlet assembly **456**. Alternatively, a conventional delivery sharp (e.g. needle) may be used. The elastomeric housing **450** may from a fluid and pressure tight seal around the exterior of another portion of the ampoule **440** upstream of the frangible **446**. Additionally, in some embodiments, the ampoule **440** may include a step or notch which aids in ensuring that the elastomeric housing **450** is retained in place on the ampoule **440** and cannot easily be removed. As shown, the ampoule **440** may be placed in a holster **460** formed in a base portion **480** of the delivery device **10**. The base portion **480** may be coupled to a bandage **252** which may be applied to the skin of a user. In some embodiments, a delivery device **10** may be packaged separate from the ampoule **440** (and perhaps elastomeric housing **450**). The ampoule **440** (and perhaps elastomeric housing **450**) may be inserted into the delivery device **10** prior to use (e.g. by a pharmacy, clinician, trained vaccination staff, user). Alternatively, the delivery device **10** may come

with the ampoule **440** pre-assembled and ready for use.
[0289] Referring now to FIG. **74** and FIG. **75**, the elastomeric housing **450** may seat into a receptacle **472** of an activation assembly **470**. The activation assembly **470** may include a tab **474** which surrounds the receptacle **472**. The tab **474** may be configured so as to be easily grasped by a user. In operation, the user may grasp the tab **474** and displace the tab **474** upward. Thus, the activation assembly **470** may be actuated from an inactive state to an active state. During this transition, the frangible **446** may be ruptured and a fluid flow path from the interior volume of the ampoule **440** to the microneedle(s) **454** may be established. As the ampoule **440** may be pressurized, agent disposed within the ampoule **440** may be driven out of the ampoule **440** and out of the delivery device **10** to the patient.
[0290] Referring now also to FIG. **76** and FIG. **77** (depicting a detailed view of the indicated region of FIG. **76**), the activation assembly **470** may also include a number of wings **476**. The wings **476** may be disposed within detent interfaces **482** included on walls **484** extending from a main body **486** of a base portion **480** of the delivery device **10**. As shown, the detent interfaces **482** may be configured to allow the wings **476** to be locked in a first position and a second position. In the example embodiment shown in FIG. **76**, the wings **476** are locked in the first position. The wings **476** may be in the first position when the activation assembly **470** is in an inactive state. Upon transition of the activation assembly **470** to the active state, the wings **476** may snap out of a first detent **488**A of the detent interfaces **482** and snap into a second detent **488**B of the detent interfaces **482**. The wings **476** may be firmly retained in the second detent **488**B maintaining the delivery device **10** in the active state.
[0291] Referring again primarily to FIG. **74** and FIG. **75**, upon transition of the activation assembly **470** to the active state, a tail member **490** of the activation assembly **470** may be displaced forward. The tail member **490** may be hingedly connected to the rest of the activation assembly **470**. In the example embodiment, the tail member **490** may be molded integrally with the rest of the activation assembly **470** and may be connected to the rest of the activation assembly via a living hinge **492**. In alternative embodiments, a physical hinge may be used. As the tab **474** is displaced upward and the outlet assembly **476** pivots into the skin, the tail member **490** may translationally displace toward the forward end of the delivery device **10**. As shown, the tail member **490** may include at least one raised portion **494** (e.g. a ramp, nub, bump, etc.). As the tail member **490** translationally displaces, the raised portion **494** may abut against a stationary portion of the delivery device **10**. In the example embodiment, the raised portion **494** may abut against a bottom of the holster **460**. Further displacement of the tail member **490** may force the tail member **490** downward toward the skin. The tail member **490** may press against a portion of the main body **486** of the base portion **480** which is hinged (e.g. connected via living hinge) with respect to the rest of the base portion **480**. This portion may be pressed against the skin causing the skin in the vicinity to be stretched. This may facilitate puncture of the stratum corneum and access to an intradermal space of the user via the microneedle(s) **454**.
[0292] In certain alternative embodiments, the ampoule **440** may be replaced by a biased plunger. In such embodiments, a reservoir portion similar to reservoir portion **280** shown in FIG. **47** may be used, however, the end of the reservoir portion **280** may be terminated in a closed frangible seal as described above. Embodiments of delivery devices **10** shown in FIGS. **80-89** and FIGS. **98-103** may similarly include such a biased plunger and reservoir in place of an ampoule **440**. The plunger may begin to advance when the frangible is broken and a flow path to the patient is established. In other embodiments, the entire ampoule **440** may be encased in an elastomeric housing **450**. In such embodiments, the entire ampoule **440** may be smashed within the elastomeric housing **450** and the pressure stored in the ampoule **440** may serve to drive fluid into the patient.
[0293] Use of microneedles may be attractive in embodiments with frangible seals as the microneedles may have a very small aperture through which agent is dispensed. These apertures may effectively act as filters which prevent any pieces of glass generated during fracture of the

frangible from passing to the patient. Thus, a microneedle array may double as a filter assembly. Various delivery devices **10** may also include other filter elements for this purpose as well.
[0294] Referring now to FIGS. **78-79**, another example ampoule **440** and elastomeric housing **450** are depicted. The ampoule **440** may be pressurized (e.g. with inert gas) such that upon rupture, the pressure in the ampoule **440** may cause the medicinal agent (e.g. a vaccine) in the ampoule **440** to be expelled. The ampoule **440** may include a frangible **446** which may be thinned and/or scored (as shown) to provide a weak point in the ampoule **440** and may allow the ampoule **440** to be cleanly snapped open at a prescribed location. The portion of the ampoule **440** including the frangible **446** may be contained in an elastomeric housing **450**. The elastomeric housing **450** may include a chamber **452** in which the frangible **446** is disposed. The chamber **452** may include a port **458** via which the chamber **452** may fluidically communicate with an outlet assembly **594** (see, e.g. FIG. **83**). The elastomeric housing **450** may from a fluid and pressure tight seal around the exterior of another portion of the ampoule **440** upstream of the frangible **446** (or the ampoule **440** may be complete encased in an elastomeric housing). Additionally, in some embodiments, the ampoule **440** may include a step or notch which engages a corresponding feature of the ampoule **440**. This may aid in ensuring that the elastomeric housing **450** is retained in place on the ampoule **440** and cannot easily be removed. The elastomeric housing **450** may also include a receptacle **496** which may receive an outlet assembly. The receptacle may be in fluid communication with the port **458**. As the elastomeric housing **450** may be made of a flexible material, the receptacle **496** may bend or flex relative to the remainder of the elastomeric housing **450**.
[0295] Referring now to FIGS. **80-81** another example delivery device **10** is depicted. The example delivery device **10** may accept and deliver fluid from an ampoule **440** as described in relation to FIGS. **78** and **79** in certain embodiments. As shown, the example delivery device **10** may include a base **570** and a slide body **572**. The base **570** and slide body **572** may cooperate to form a housing **574** for the delivery device **10**. As shown in FIG. **80**, the base **570** may be mounted on a bandage **252** (omitted in FIG. **81**). When shipped or in storage, portions of the bandage **252** outside the footprint of the housing **574** may be folded up against the sides of the housing **574** to minimize the size of the delivery device **10** during shipping. As shown, the base **570** (and bandage **252**) may include an aperture **576**. The aperture **576** may allow for displacement of at least one delivery sharp (e.g. microneedle, transcutaneous delivery sharp, etc.) from the interior of the housing **574** and into the skin of a patient.
[0296] As shown, the base **570** may also include a skin depressor **578**. The skin depressor or stretcher **578** may be pressed against the skin of a patient as the delivery device **10** is applied to a patient. In certain examples, the skin depressor **578** may be molded so as to be cantilevered and have at least a portion which extends below a face of the base **570** to which the bandage **252** is attached. In the example embodiment, the unsupported end of the skin depressor **578** may be most distal to the face of the base **570** to which the bandage **252** is attached. Thus, when the delivery device **10** is in place on a patient, the skin depressor **578** may resiliently deflect and exert a restoring force against the patient's skin. Alternatively, the skin depressor **578** may be sufficiently rigid to displace skin without deflection. This may cause the skin aligned with the aperture **576** to be stretched when the delivery device **10** is coupled to a user. Other delivery devices **10** described herein may include such a skin depressor **578**.
[0297] The base **570** and the slide body **572** may include cooperating guide interfaces. As shown, the base **570** of the delivery device **10** may include a set of tracks **580**. These tracks **580** may accept guide projections **582** included in the slide body **572**. The tracks **580** may act as guides which direct displacement of the slide body **572** via interaction with guide projections **582** on the slide body **572**. In alternative embodiments, the base **570** may include guide projections **582** (e.g. rails) and the slide body **572** may include tracks **580**. The slide body **572** may be displaceable from a first position (shown in FIGS. **80-81**) to a second position (see, e.g., FIG. **86**). The slide body **572** may be in the first position when the delivery device **10** is in a shipping or storage state. The delivery

device **10** may be in a delivery state when the slide body **572** is displaced to the second position.
[0298] In certain embodiments, the tracks **580** may include a stop which may prevent displacement of the slide body **572** from the first position to a position in which the slide body **572** would be more distal to the second position. As shown, the base **570** may also include a latch **584**. The latch **584** may prevent displacement of the slide body **572** toward the second position until actuation of the latch **584**. In the example embodiment, the latch **584** is flanked by slots **587** such that the latch **584** is cantilevered from a side wall **586** of the base **570**. To actuate the latch **584**, a user may press the latch **584** out of a blocking position to an actuated position in which the slide body **572** may pass by the latch **584**. The latch **584** would resiliently bend at its attachment point to the side wall **586** of the base **570** such that the latch **584** would be entirely below a top wall **588** of the slide body **572** in the example embodiment. In this position, the slide body **572** would be free to pass over that latch **584** as displacement toward the second position occurs. The resiliency of the latch **584** may help to prevent inadvertent actuation of the latch **584**. The slide body **572** may include one or more stop projections **604** which may abut the side wall **586** of the base **570** to prevent displacement of the slide body **572** beyond the second position.
[0299] Referring now to FIG. **82**, a perspective view of an example slide body **572** is depicted. The slide body **572** may include a number of ramp section **600**. In the example embodiment, the ramp section **600** may include a sloped portion **601**A and a plateau portion **601**B which may be substantially flat. A cross piece **602** may extend between the two ramp segments **600**. Additionally, the slide body **572** may include a set of stop projections **604** (described above in relation to FIG. **80**). Notches **606** may be cut into the slide body **572** to allow portions of the walls of the slide body **572** to deflect around the base **570** during assembly. In the example embodiment, the notches **606** may allow the portions of the slide body **572** including the guide projections **582** to deflect around a portion of the base **570** and snap into the tracks **580** as the delivery device **10** is assembled. As shown, the guide projections **582** may include ramped or sloped faces to aid in deflecting the walls as the delivery device **10** is assembled.
[0300] Referring now to FIG. **83**, a perspective view of an example outlet assembly **594** is depicted. As shown, the outlet assembly **594** includes a nozzle **596** which may include one or more microneedle **592** (see, e.g., FIG. **85**). The example outlet assembly **594** also includes a pair of actuation members **598**. The actuation members **598** in the example embodiment are arm like projections which extend from pivot bearings **610** of the outlet assembly **594**. In some embodiments, only a single actuation member **598** may be included. The outlet assembly **594** may also include a ram body **612**. In the example embodiment, the ram body **612** extends from the pivot bearings **610**. The nozzle **596** may be disposed between the pivot bearings **610**.
[0301] Referring now to FIGS. **84** and **85** (a cross-section taken at the indicated cut plane of FIG. **84**), an example delivery device **10** is shown with the slide body **572** in the first position. As shown, the latch **584** may include at least one raised section which may catch against the top wall **588** of the slide body **572** inhibiting displacement toward the second position. With the slide body **572** in the first position, a microneedle or microneedles **592** (though other embodiments may use alternative delivery sharps described elsewhere herein) of the delivery device **10** may be disposed within the housing **574** of the delivery device **10**.
[0302] The ampoule **440** may be located at least partially within a holster **568** defined in the base **570**. The holster **568** may hold the ampoule **440** in place within the delivery device **10**. The base **570** may also include a support rest **616**. A side of the tip of the elastomeric housing **450** may seat on the support rest **616**. Additionally, the cross piece **602** of the slide body **572** may be disposed slightly above the opposing side of the elastomeric housing **450**. The support rest **616** and the cross piece **602** may help to ensure that the frangible **446** of the ampoule **440** is protected from breakage during storage or shipping.
[0303] The microneedle(s) **592** may form part of an outlet assembly **594**. As mentioned above, the outlet assembly **594** may include a nozzle **596**. The nozzle **596** may mate into the receptacle **496** of

the elastomeric housing **450**. The nozzle **596** may be retained in the receptacle **496** via friction fit, adhesive, or any other suitable manner. In some embodiments, the nozzle **596** may include a stepped region or barb which may aid in holding the nozzle **596** in place within the receptacle **496**. The nozzle **596** may be coupled to at least one actuation member **598** which forms a portion of the outlet assembly **594**. The at least one actuation member **598** may interact with a portion of the slide body **572** as the slide body **572** is displaced to the second position so as to displace (e.g. rotate) the nozzle **596** toward the skin and displace the microneedle(s) **592** into the patient.

[0304] In the example embodiment shown in FIG. **85**, when the delivery device **10** is in the shipping or storage state, the outlet assembly **594** may be prevented from displacing. As shown, the ram body **612** may rest against an interior face of the base **570**. As the base **570** is in the way, the base **570** may block rotation of the outlet assembly **594** in a first direction since the ram body **612** cannot displace through the base **570** material. Additionally, the ends of the actuation members **598** most distal to the pivot bearings **610** may be adjacent an interior side wall **618** of the slide body **572**. This may prevent rotation of the outlet assembly **594** in a second direction opposite the first direction as the actuation members **598** may not pass through the solid side wall **618**. Thus, the outlet assembly **594** may be rotationally locked when the delivery device **10** is in the shipping/storage state. When in the storage state, the microneedle(s) **592** may be within the housing **574** of the delivery device **10** and protected from inadvertent contact with a user.

[0305] When the slide body **572** is displaced toward the second position (see, e.g., FIG. **86**) the ramp sections **600** of the slide body **572** may contact the actuation members **598**. The ramp sections **600** may interact with the actuation members **598** to cause displacement of the outlet assembly **594** as the slide body **572** is displaced. The actuation members **598** may, for instance, act as cam followers and the ramp sections **600** may present a cam which may direct displacement of the actuation members **598** as the slide body **572** is displaced. Translational displacement of the slide body **572** may result in rotational displacement of the outlet assembly **594** through this interaction.

[0306] As the slide body **572** is displaced, the interior side wall **618** of the slide body **572** may also be displaced out of the outlet rotation preventing position described above as the slide body **572** is displaced. With the interior side wall **618** out of the rotation preventing position, further displacement of the slide body **572** may cause the actuation members **598** to displace as the ramp segments **600** are driven into the actuation members **598**. Over the course of the displacement of the slide body **572** to the second position, the interaction of the ramp segments **600** and the actuation members **598** may cause the outlet assembly **594** to displace to a deployed position in which the microneedle(s) **592** extend out of the housing **574** and puncture into communication with an intradermal space of the patient.

[0307] Referring now to FIGS. **86**-**89**, an example delivery device **10** is depicted with the slide body **572** in the second position. As best shown in FIG. **89**, as the outlet assembly **594** is rotated during displacement of the slide body **572**, the ram body **612** may be driven into the elastomeric housing **450** and exert a breaking or snapping force on the ampoule **440**. As this occurs, the ampoule **440** may be snapped open at the location of the frangible **446**. To aid in ensuring the ampoule **440** breaks at the frangible **446**, the cross piece **602** may be displaced to a location upstream of the frangible **446** as the slide body **572** is moved to the second position. Thus, the cross piece **602** may provide support to this portion of the ampoule **440** as the ram body **612** is driven into the unsupported end of the ampoule **440** downstream of the frangible **446**. This may help to ensure that any break in the ampoule **440** occurs at the location of the frangible **446**. With the frangible **446** broken, the interior volume of the ampoule **440** may be placed into communication with the microneedle(s) **592** and the pressure within the ampoule **440** may drive the contents of the ampoule **440** into the patient via the microneedle(s) **592**.

[0308] Referring now also to FIG. **82**, with the slide body **572** in the second position, the plateau regions **601**B of the ramp segments **600** on the slide body **572** may be positioned against at least a

portion of the actuation members **598**. This may block any additional rotation of the outlet assembly **594** about the pivot bearings **610** as the plateau regions **601**B may present a mechanical interference to such rotation. Thus, once transitioned to the deployed state, the outlet assembly **594** may be locked in position such that the microneedle(s) **592** are robustly held in place within the patient.

[0309] Referring now to FIGS. **90**, **91**, and **92**, an alternative embodiment of the delivery device **10** shown in FIGS. **80**-**89** is depicted. The delivery device **10** may include an additional injection port **800**. The injection port **800** may be covered by a removable cap **802** (exploded away from injection port **800** in FIG. **90**). The injection port **800** may allow for a user to deliver fluid manually from a fluid administration implement **804** (e.g. syringe, injection pen, etc.) into the patient via the delivery device **10**. In some embodiments, the outlet assembly **594** of the delivery device **10** may be in communication with the injection port **800** via tubing. Alternatively, the injection port **800** be used to access the interior volume of the ampoule **440**.

[0310] The injection port **800** may be utilized to deliver a second agent to a patient after a first agent contained in the ampoule **440** in the delivery device **10** has already been expelled. Alternatively, the injection port **800** may allow for the ampoule **440** to be repressurized with a gas (e.g. via a syringe or other implement). Thus, in the event that agent remains in the delivery device **10** after actuation, pressure may be manually applied to drive the remaining agent from the ampoule **440**.

[0311] Referring now to FIG. **93** an example ampoule **440** which may be used in a delivery device **10** including an injection port **800** is depicted. As with other ampoules **440** described herein, the ampoule **440** may include a neck portion **445** which extends from the main body **443** of the ampoule **440**. This neck portion **445** may include a frangible **446** which may be broken to establish fluid communication from the interior volume of the ampoule **440** to an outlet of a delivery device **10**. The example ampoule **440** shown in FIG. **93** may further include a tail portion **447**. The tail portion **447** may be disposed on an end of the main body **443** of the ampoule **440** which is opposite that from which the neck portion **445** extends. A tail frangible **449** may be included in the tail portion **447** of the ampoule **440**. The tail frangible **449** may be a weakened and/or scored area of the tail portion **447** which may facilitate breaking of the tail portion **447** at the location of the tail frangible **449**.

[0312] Referring now to FIGS. **94**-**96** a number of cross sectional view of an example delivery device **10** including an injection port **800** and the ampoule **440** of FIG. **93** are shown. As shown, the delivery device **10** is depicted with the slide body **572** in the second position. As the slide body **572** is in the second position, the outlet assembly **594** is displaced to a deployed state and the frangible **446** (see, e.g., FIG. **79**) of the ampoule **440** has been broken. The neck portion **445** of the ampoule **440** is covered by an elastomeric housing **450** like that shown in FIG. **79**. The ampoule **440** may also be housed in an elastomeric sleeve **806** which surrounds the remainder of the ampoule **440**. In the example embodiment, the elastomeric housing **450** and elastomeric sleeve **806** are depicted as separate components. In alternative embodiments, the elastomeric housing **450** and the elastomeric sleeve **806** may be a single elastomeric article which is created as a monolithic component. The elastomeric sleeve **806** may surround the main body **443** of the ampoule **440**. The elastomeric sleeve **806** may also contact and establish a scal against the elastomeric housing **450** (where the elastomeric sleeve **806** and elastomeric housing **450** are not a monolithic component).

[0313] As shown, the injection port **800** may include a tail receptacle **810**. The tail portion **447** of the ampoule **440** may seat within the tail receptacle **810** when the delivery device **10** is assembled. The elastomeric sleeve **806** may include an injection port receiver portion **808**. The injection port receiver portion **808** may surround the tail portion **447** of the ampoule **440** and the tail receptacle **810**. The injection port receiver portion **808** may form a fluid tight seal against the tail receptacle **810**.

[0314] In use, the slide body **572** of the delivery device **10** may be displaced to the second position

on the base body **570** (as shown). This may break the frangible **446** of the ampoule **440** and cause the outlet assembly **594** to displace into a deployed state. Pressure in the ampoule **440** may drive the agent contained in the ampoule **440** into the patient through the outlet assembly **594**. If desired, the cap **802** (which may protect the injection port **800** from contamination) on the injection port **800** may then be doffed from the injection port **800** (see FIG. **95**) so that the ampoule **440** may be repressurized or another agent may be delivered. With the cap **802** removed from the delivery device **10**, an agent dispensing implement **804** (see, e.g. FIG. **92**) may be introduced to the injection port **800**. In some embodiments, the injection port **800** may include a fitting such as a luer lock, bayonet mount, threaded fitting, etc. which may mate with an agent dispensing implement **804**.

[0315] A user may pivot the agent dispensing implement **804** once it is introduced to the injection port **800**. Pivoting of the agent dispensing implement **804** may cause the injection port **800** to pivot in tandem with the agent dispensing implement **804**. The base body **570** may include an aperture **812** through which the injection port **800** extends. The aperture **812** may surround the injection port **812** and may present a stop which limits pivoting of the injection port **800** beyond a certain amount. The elastomeric sleeve **806** may bend to accommodate the pivoting of the injection port **800**. The interior end **814** of the injection port **800** may be aligned with the tail frangible **449**. Consequentially, stress on the tail portion **447** of the ampoule **440** (which may be constrained from moving within the delivery device **10**) due to pivoting of the injection port **800** may be concentrated at the tail frangible **449**. Thus, pivoting of the injection port **800** may cause the tail frangible **449** to break. With the tail frangible **449** broken, fluid communication with the interior of the main body **443** of the ampoule **440** may be established via the injection port **800**. Fluid (e.g. repressurization gas or a second agent) may then be delivered into the delivery device **10** via the injection port **800**.

[0316] Referring now to FIG. **97**, a cross section through an injection port **800** and tail portion **447** of an ampoule **440** is depicted. As shown, the injection port **800** may include an interior channel **820** within which the tail portion **447** is received. The interior channel **820** may include a number of protrusions **822** which project radially inward from the wall of the interior channel **820**. The protrusions **822** may be spaced at regular or irregular intervals about the interior channel **820**. In the example embodiment, six protrusions **822** are included and are spaced at regular angular intervals (every 60° in the example) about the interior channel **820**. The number of protrusions **822** may differ in alternative embodiments. The protrusions **822** may abut against the tail portion **447**. In some embodiments, the protrusions **822** may be slightly compressed against the tail portion **447** establishing an interference fit. As shown, when the injection port **800** is installed over the tail portion **447** the gaps between protrusions **822** may provide flow pathways **824** between the tail portion **447** and wall of the interior channel **820**. The protrusions **822** may also ensure that upon breakage of the tail portion **447** at the tail frangible **449** (see, e.g., FIG. **96**) the tail portion **447** is held in a prescribed position relative to the injection port **800**. This may ensure that when the tail frangible **449** is broken a flow path through the injection port **800** into the interior of the main body **443** of the ampoule **440** remains patent.

[0317] Referring now to FIGS. **98-99**, another exemplary embodiment of a delivery device **10** is depicted. The example delivery device **10** may accept and deliver fluid from an ampoule **440** such as those described elsewhere herein. As shown, the example delivery device **10** may include a base **870** and a slide body **872**. The base **870** and slide body **872** may cooperate to form a housing **874** for the delivery device **10**. As shown, the base **870** may be mounted on a bandage **252**. When shipped or in storage, portions of the bandage **252** outside the footprint of the housing **874** may be folded up against the sides of the housing **874** to minimize the size of the delivery device **10** during shipping. As shown, the base **870** may include an aperture **876**. The bandage **252** may also include a bandage aperture **877** which surrounds the aperture **876** of the base **870**. The aperture **876** may allow for displacement of at least one delivery sharp **892** (e.g. microneedle, transcutaneous delivery

sharp, etc.) from the interior of the housing **874** and into the skin of a patient.
[0318] The example delivery device **10** may be transitioned from a storage state (see, e.g., FIG. **104**) to a delivery state. This may be accomplished by displacing the slide body **872** from a first position to a second position relative to the base body **870**. The delivery device **10** is depicted in a delivery state in FIGS. **98-99**. In the delivery state, at least a portion of an outlet assembly **894** may protrude from the housing **874** such that microneedles **892** (or any other delivery sharp) extend into skin of a patient to access an intradermal space of the patient. As shown, a skin depressor or stretcher **878** may be included and also extends out of the housing **874** via the aperture **876** when the delivery device **10** is in the delivery state. In the example, the skin depressor **878** is included as part of the slide body **872** and extends to a point adjacent the microneedles **894** on the outlet assembly **892**. The skin depressor **878** may also double as a support rib which buttresses the outlet assembly **894**.
[0319] The skin depressor or stretcher **878** may be pressed against the skin of a patient as the delivery device **10** is transitioned from a storage/shipping state to a delivery state. This may cause stretching of the skin at the puncture location of the microneedle(s) **894** facilitating access to an intradermal space of the patient. In certain examples, the skin depressor **878** may include one or more projection **879** on the skin contacting side of the skin depressor **878**. Such a projection **879** may further aid in causing stretching of the skin. Other skin depressors described herein may include similar projections for this purpose. In the example, the projection **879** is depicted as a bump though ribs or ridges may be used in alternative embodiments. In some examples, the projection **879** may be a tooth or barb which may catch on skin and aid in tugging on the skin as the delivery device **10** is transitioned into a delivery state. Multiple projections **879** may be included in alternative examples.
[0320] In alternative examples, and referring now to FIGS. **100** and **101**, a cantilevered skin depressor or stretcher **878** may be included. Such a skin depressor **878** may, for example, be cantilevered from a portion of the base **870**. The skin depressor or stretcher **878** may be deflected so as to be pressed against the skin of a patient as the delivery device **10** is transitioned from a storage/shipping state to a delivery state. This may cause stretching of the skin at the puncture location of the microneedle(s) **894** facilitating access to an intradermal space of the patient. In the example, the slide body **872** may include a support rib **895** which buttresses the outlet assembly **894**. The support rib **895** may include a projection **879** thereon. The projection **879** may contact the skin depressor **878** as the delivery device **10** is transitioned to the delivery state and concentrate a deflecting force on an unsupported end of the skin depressor **878** to facilitate deflection of the skin depressor **878** against the skin. In the example embodiment, the projection **879** is shown as a rounded bump though any suitable shape (e.g. pin, rib, ridge, pointed tooth, etc.) may be used in other examples.
[0321] Referring now to FIGS. **102-103**, a view of the slide body **872** of the example delivery device **10** shown in FIGS. **98-99** is depicted. The slide body **872** may be constructed as a single monolithic component. This may help to minimize the number of components needed to construct a delivery device **10**. The slide body **872** in the view depicted in FIG. **102** is shown in a molding configuration. The slide body **872** may be manipulated from the molding configuration into an assembly configuration for installation into a delivery device **10** during the manufacturing process. The slide body **872** is depicted in the assembly configuration in FIG. **103**.
[0322] As shown, the slide body **872** may include a main portion **900** and one or more foldable section **902**, **904**. In the example embodiment, the slide body **872** includes two foldable sections **902**, **904**. The foldable sections **902**, **904** may be connected to the main portion **900** of the slide body **872** via living hinges **906**. These foldable sections **902**, **904** may be displaced into their assembly configuration via bending of the living hinges **906**. The main portion **900** of the slide body **872** may include notches **908** or other retention interfaces. The notches **908** may cooperate with latch projections **910** of one or more of the foldable section **902**, **904** to hold the one or more

foldable sections **902**, **904** in the assembly configuration. The latch projections **910** may include a ramped face to facilitate displacement of the latch projections **910** into the notches **908** during assembly. In other delivery device **10** embodiments shown and described herein, housing components may similarly be constructed with foldable sections which may be displaced between a molding configuration an assembly configuration.

[0323] Foldable sections **902**, **904** may allow for certain portions of a delivery device **10** to bend or move in a facile manner relative to other physically connected portions of the delivery device **10**. Such foldable sections **902**, **904** may not be latched into place during assembly. Duc to the living hinge **906** connection, different portion of the same monolithic component may displace relative to one another, displace along different axes, or in different manners (e.g. translationally, rotationally).

[0324] Still referring primarily to FIGS. **102-103**, in the molding configuration, the foldable sections **902**, **904** may be positioned so as to facilitate molding of the slide body **872** in a single molding operation. Foldable sections **902**, **904** may also be included in a slide body **872** so as to allow molding via a minimally complicated molding operation. That is, even in delivery device **10** embodiments where a slide body **872** (or other housing component) could be molded in a single molding operation, foldable sections **902**, **904** may still be included as they may allow the mold or molding operation to be simplified.

[0325] Additionally, including one or more foldable section **902**, **904** may allow for other components of a delivery device **10** to be placed into the slide body **872** (or other housing component). This may be done prior to manipulation of the slide body **872** into its assembly configuration where clearance or a pathway to insert these other components may not exist. In the example embodiment shown in FIGS. **102** and **103**, the slide body **872** includes a holster **912** for supporting an ampoule **440** and its elastomeric housing **450** (only the elastomeric housing is visible in FIG. **103**). The example holster **912** is constructed as a clamshell style retainer for the ampoule **440**. In the molding configuration, the holster **912** may be in an open state. An ampoule **440** may be placed in one portion of the holster **912** clamshell while the slide body **872** is in the molding configuration. When the slide body **872** is folded into the assembly configuration, the holster **912** may be brought to a closed state in which the ampoule **440** is retained and locked within the slide body **872**. In the example embodiment, this may be accomplished by displacing a foldable section **904** of the slide body **872** against the ampoule **440** and driving the latch projections **910** into the notches **908** of the main portion **900** of the slide body **872**.

[0326] As shown, the holster **912** may also include a flow pathway projection **913** which includes a flow channel that communicates with the delivery sharp(s) **892**. The elastomeric housing **450** may include a receptacle **917** (see, e.g., FIG. **105**) which mates onto the projection **913**. As the foldable section **904** is brought to the closed state the foldable section **904** may slightly compress the material of the elastomeric housing **450** aiding in sealing around the projection **913**.

[0327] Still referring to FIGS. **102** and **103**, the first foldable section **902** may include a pawl projection **880**. Additionally, the first foldable section **902** may include a clip member **882**. The clip member **882** may include a cantilevered tab **884** which extends toward the pawl projection **880**. As will be explained in greater detail later in the specification, the pawl projection **880** and clip member **882** may cooperate with a portion of the base body **870** to direct displacement of the slide body **872** relative to the base body **870** as the delivery device **10** is transitioned form the storage state to the delivery state. The main portion **900** of the slide body **872** may include guide projections **886**. The guide projections **886** may include a rounded surface which may be configured to slide against an abutting surface of the base body **870** when the delivery device **10** is assembled.

[0328] Referring now to FIG. **104**, a cross section of the example delivery device **10** shown in FIGS. **98-99** is depicted. The cross-section is taken along a longitudinal midplane of the example delivery device **10**. The delivery device **10** is depicted in an assembled state with the slide body **872** folded into its assembly configuration and installed in the delivery device **10**. The delivery

device **10** is arranged in a storage or shipping state in FIG. **104**. As shown, when the delivery device **10** is in the storage state, the microneedle(s) **892** may be disposed within the housing **874** of the delivery device **10**.

[0329] A ratcheting wall **890** of the base body **870** may be captured between the clip **882** and the remainder of the first foldable section **902** of the slide body **872**. The ratcheting wall **890** may include a number of ratchet interfaces **892**. These ratchet interfaces **892**A, B may be raised off the main surface of the ratchet wall **890** or recessed into the ratchet wall **890** as shown in FIG. **104**. The pawl projection **880** may engage with a first ratchet interface **892**A when the slide body **872** is in a first position corresponding to the delivery device **10** being in a storage state. This may help to hold the delivery device **10** in the storage state during shipping and preparation for use. Additionally, the pawl projection **880** may prevent the slide body **872** from being removed from the delivery device **10** as the pawl projection **880** may catch against ratcheting interface **892**A. The base body **870** may also include a stop **922** (see, e.g., FIG. **98**) which a tab **924** (see, e.g., FIG. **98**) of the slide body **872** may contact to inhibit removal of the slide body **872**.

[0330] Referring now to FIG. **105**, the slide body **872** may be displaced toward or into the base body **870** to transition the delivery device **10** from the storage state to the delivery state shown in FIG. **105**. As the ratcheting wall **890** is captured between the clip **882** and the remainder of the first foldable section **902**, the ratcheting wall **890** may constrain displacement of the first foldable section **902** to an axis substantially parallel to the ratcheting wall **890**. The pawl projection **880** may pass out of the first ratchet interface **892**A and engage a second ratcheting interface **892**B when the slide body **872** has been displaced to a second position and the delivery device **10** is in the delivery state. The interaction of the pawl projection **880** and the second ratchet interface **892**B may hold the delivery device **10** in the delivery state.

[0331] The base portion **870** may include a guide surface **896** against which the guide projections **886** (see FIG. **102**) of the slide body **872** may ride as the slide body **872** is displaced. The guide surface **896** may direct displacement of the main portion **900** of the slide body **872** as the slide body **872** is driven to the second position. Thus the contour of the guide surface **896** may define the displacement path of the main portion **900** of the slide body **872**. In the example embodiment, the guide surface **896** is a curved surface. As shown, when the slide body **872** is displaced from the first position to the second position, the main body **900** may displace into the base portion **870** and rotate such that the outlet assembly **894** and microneedle(s) **892** project out of the housing **874**. The base body **870** may include a shelf **920** which extends into the interior of the housing **874**. The neck portion **445** of the ampoule **440** may be driven into the shelf as the slide body **872** is moved to the second position. This may exert a breaking force on the frangible **446**. As shown in FIG. **105**, further advancement of the slide body **872** may cause the ampoule **440** to break at the frangible **446** of the ampoule **440**. Once broken, pressure within the ampoule **440** may drive agent out of the ampoule **440**, through the outlet assembly **894** and into an intradermal space (or other delivery destination depending on the type of delivery sharp) of a patient via the microneedle(s) **892**.

[0332] The second foldable portion **904** may support the ampoule **440** against displacement relative to the slide body **872** as the slide body **872** is driven to the second position. Additionally, a segment **905** of the second foldable portion **904** may extend over a section of the neck **445** of the ampoule **440** which is upstream of the frangible **446**. This may prevent breakage of the ampoule **440** in this region and help ensure that breakage occurs at the location of the frangible **446** as the slide body **872** is displaced to the second position.

[0333] In certain examples, the example delivery device **10** may include an ampoule **440** such as that shown and described in relation to FIGS. **90**-**97**. In such embodiments, the delivery device **10** would also include an injection port **800** as shown in FIGS. **90**-**97**. Thus, a second agent could be delivered through the delivery device **10** or the ampoule **440** could be repressurized if desired via the injection port **800**.

[0334] Referring now to FIG. **106**, a flowchart **930** detailing a number of example actions which

may be executed to deliver fluid from a delivery device to a patient is depicted. As shown, in block **932**, a delivery device may be applied to the skin of a patient. In block **934**, a slide body of the delivery device may be actuated. In block **936**, the frangible of a pressurized ampoule contained in the delivery device may be broken. The delivery sharp(s) of the delivery device may puncture into the skin of the patient in block **938**. In block **940**, fluid from the ampoule may be driven into the patient via the pressure stored in the ampoule.

[0335] Referring now to FIG. **107**, another flowchart **950** detailing a number of example actions which may be executed to deliver fluid from a delivery device to a patient is depicted. As shown, in block **952**, a delivery device may be applied to the skin of a patient. In block **954**, a slide body of the delivery device may be actuated. In block **956**, the frangible of a pressure ampoule contained in the delivery device may be broken. The delivery sharp(s) of the delivery device may puncture into the skin of the patient in block **958**. In block **960**, a first fluid may be driven into the patient via the pressure. A second fluid may be driven into the patient in block **962**. The first fluid may be an agent stored in the ampoule. The second fluid may be an agent which is administered via an injection port included in the delivery device. For example, this fluid may be delivered via an injection port **800** as shown and described in relation to FIGS. **90-97**.

[0336] Alternatively, in certain embodiments, one of the first or second fluid may be a gas. This may be particularly useful in instance where the other of the first or second fluid is a vaccine. Gas may be introduced to the delivery device via a port such as injection port **800** (see FIGS. **90-97**). In other examples, an ampoule of a delivery device may be pressurized to a degree that some gas may be delivered along with another agent contained in the ampoule. Other embodiments described herein may also deliver a gas as well as another agent (e.g. vaccine) to a patient. For example, when loading the reservoir portion **280** of the delivery device **10** described in FIG. **47**, a liquid agent and a gas may be transferred into the reservoir portion **280**. Each of these fluids may then be administered when delivery occurs. Similarly, a liquid agent and a gas may be loaded into the delivery device **10** described in relation to FIGS. **52-54** via port assembly **360**. The reservoir portions of the delivery devices **10** shown in FIGS. **1-34**, **55-65**, and **66-67** may be loaded with a liquid agent and a gas. Likewise, the blister **652** reservoirs shown in FIGS. **35-42** may be filled with both a liquid and a gas. The reservoir **415** of the delivery device **10** shown in FIGS. **68-70** may also be filled with both a liquid agent and a gas via port assembly **400**. Both a liquid agent and a gas may be delivered via the delivery device **10** shown in FIGS. **108-115** via access port **708**.

[0337] Upon entry into the patient, the gas may aid in generating a space within the tissue to accommodate agent administered into the patient. For example, the gas may help to enlarge the area taken up by an agent depot delivered into the patient and/or increase the surface area of tissue which is exposed to the agent. In an intradermal delivery, the gas may encourage larger diameter blebs for a given volume of delivered agent. This may help to expose more cells which play a role in immune response to the agent when the agent is administered. This may be particular desirable intradermal injections due to the density of antigen presenting cells (e.g. macrophages and phagocytic immune cells such as dendritic or Langerhans cells). As a result, such gas delivery may aid in augmenting dose or injection sparing by helping to elevate the immunogenicity of the vaccination. Additionally, certain gases (e.g. carbon dioxide) have been observed to increase skin microcirculation which may aid in generating a robust immune response.

[0338] Referring now to FIG. **108** and FIG. **109**, another example embodiment of a delivery device **10** is depicted. As shown, the delivery device **10** may include a housing **700**. The housing **700** may be mounted on a bandage **252** which may be used to secure the delivery device **10** to the skin of a user. The housing **700** may be generally triangular in shape with the point of the triangle most distal to the bandage **252** being rounded. Housings **700** having alternative shapes may also be used. The housing **700** may include a base portion **702** and a cover portion **704**. The base **702** may be attached to the bandage **252**. As shown, the cover portion **704** may couple to the base portion **702** to enclose internal components of the delivery device **10**.

[0339] A flexible strip **706** of material may be coupled to the housing **700**. The strip **706** may include one end which may be attached to the cover portion **704** and may include an opposing end which may be coupled to the base portion **702**. As shown, the cover portion **704** may include an access port **708**. Any suitable access port **708** may be provided. In the example embodiment, an access port **708** including a piercable septum **710** is shown. Alternatively, the access port **708** could, for example, include a luer connector, needleless connector, quick connect fitting, split septum, protective cover/cap, or combination thereof. The flexible strip **706** may extend over the access port **708** when the strip **706** is attached to the housing **700**. Thus, the flexible strip **706** may act as a protective strip which prevents the access port **708** from coming into contact with detritus, fingers, etc. during storage and handling. The flexible strip **706** may also provide a visual indicator that the delivery device **10** has not been previously used.
[0340] As best shown in FIG. **109**, a lock member **712** may be coupled to the flexible strip **706** in some embodiments. The lock member **712** may seat in a recess **714** defined in the base portion **702** of the housing **700**. The lock member **712** may include a protuberance **716** which may extend through an aperture **718** in the recess **714**. When in place within the recess **714**, the protuberance **716** of the lock member **712** may extend into the interior of the housing **700** and prevent actuation of the delivery device **10**. As the lock member **712** is coupled to the flexible strip **706**, the lock member **712** may be extracted from the housing **700** when the flexible strip **706** is removed. In alternative embodiments, the lock member **712** need not be coupled to the flexible strip **706**. Instead, the lock member **712** may be manually removed by the user in a separate operation and may include a grip feature, pull ring, interface for a removal tool, etc. to facilitate removal of the lock member **712**. Once the lock member **712** is removed, an insertion stroke may commence and a delivery sharp **732** (see, e.g., FIG. **110**) within the delivery device **10** may be deployed into the skin of a patient. In some embodiments, the insertion stroke may commence upon actuation of a button interface or the like after removal of the lock member **712**.
[0341] Once the delivery sharp **732** is inserted, a fluid administration implement (e.g. syringe) may then be used to administer fluid into the patient via the access port **708**. In some embodiments, fluid may be forced out the fluid administration implement and into the patient through the delivery sharp **732**. Alternatively, the delivery device **10** may include and interior reservoir which may be filled by fluid loaded in from the fluid administration implement. For example, a spring biased syringe (see e.g. FIGS. **14-16**, FIG. **47**, FIG. **58**) may be loaded via fluid loaded into the delivery device. Alternatively, a reservoir with an elastomeric wall (see, e.g. FIGS. **68-70**) may be loaded with fluid from the fluid administration implement. Fluid may then be dispensed out of the reservoir of the delivery device **10** into the patient via the delivery sharp **732**.
[0342] Referring now to FIGS. **110-112**, a number of cross-sectional views of the example delivery device **10** depicted in FIGS. **108-109** are shown. FIGS. **110-112** depict a progression of views showing the example delivery device **10** transitioning through an actuation sequence which displaces the delivery sharp **732** into the body of a patient and positions the tip **750** of the delivery sharp **732** at a target destination in the patient. In some embodiments, and as shown in the example embodiment, a delivery device **10** may use a conventional delivery sharp **732** (e.g. a 30-gauge needle or smaller) to establish access to a shallow (e.g. epidermal, dermal, junctional areas between the epidermis and dermis or dermis and subcutis) delivery destination. This shallow (e.g. intradermal) positioning may be achieved by starting from a deeper insertion of the delivery sharp **732**. The delivery sharp **732** may be inserted into the patient and then withdrawn, for example, almost all the way out so as to locate the tip **750** of the delivery sharp **732** in a targeted shallow delivery location. Thus, the delivery sharp **732** may be advanced out of the housing **700** for a first portion of the actuation sequence and retracted in the opposing direction for a second, subsequent portion of the actuation sequence. This deep insertion and withdrawal may be accomplished via an insertion stroke which drives the delivery sharp **732** into the skin and then withdraws the delivery sharp **732** in a single fluid motion in certain embodiments. Thus the same delivery stroke may

include a puncturing portion and a withdrawal portion.
[0343] Though embodiments described herein may target a shallow delivery destination, other embodiments may target deeper tissues. For example, in some embodiments, subcutaneous tissue may be targeted and the delivery sharp **732** may be advanced to an intramuscular location and withdrawn to the targeted subcutaneous tissue during the insertion stroke. In general, a delivery sharp **732** may be advanced to a first depth and withdrawn to a delivery destination at a second depth. The tissue or structure at the first depth and second depth may be the same or the tissue or structure at each depth may differ.
[0344] Still referring to FIGS. **110**-**112**, in a storage state, the delivery sharp **732** of the delivery device **10** may be within the housing **700** of the delivery device **10**. This may prevent inadvertent contact with the delivery sharp **732** and facilitate placement of the delivery device **10** on the skin. When actuated, an actuator assembly **734** of the delivery device **10** may drive the delivery sharp **732** from a storage state (see FIG. **110**) to a first extended position (see FIG. **111**). In the first extended position the delivery sharp **732** may project out of the delivery device **10** a maximum distance ("L"). In this position, the tip **750** of the delivery sharp **732** may extend into the patient at a depth which is greater than a final target depth. For an intradermal delivery device **10**, the delivery sharp **732** may extend transcutaneously into the patient. In some examples, the tip **750** of the delivery sharp **732** may be in muscle or subcutaneous tissue for example. As the actuator assembly **734** of the delivery device **10** continues to drive the delivery sharp **732**, the delivery sharp **732** may be withdrawn to a second extended position (see FIG. **112**). The second extended position may be a final or a delivery position. In the second extended position, the delivery sharp **732** may extend from the delivery device **10** a distance which is less than in the first extended position. In the second extended position, the tip **750** of the delivery sharp **732** may extend a target distance from the housing **700** such that the tip **750** may be positioned at the target delivery depth (e.g. an intradermal location). Thus, when being withdrawn, the delivery sharp **732** may be withdrawn "L" less the target delivery depth "D.sub.t" (e.g. 100-1500 microns, for example 500 or 600 microns). The target delivery depth may vary by embodiment, but may be below the stratum corneum.
[0345] By driving the delivery sharp **732** past a target location and reaching the target location on a withdrawal portion of the actuation sequence, the delivery sharp **732** may be reliably placed at a target penetration depth in a patient. Certain challenges related to precise positioning of the tip **750** may be avoided with such an approach. For example, elasticity of the skin (and variations thereof related to age, hydration state, location on the body, etc.) may not present a positioning challenge. Moreover, any bunching, bulging, wrinkling, or other deformation of the skin resulting from introduction of the delivery sharp **732** may be at least partially relieved during the withdrawal portion of the insertion stroke. This may facilitate delivery of fluid and may aid in minimizing pain associated with the injection. The withdrawal portion of the insertion stroke may also help to ensure that the skin is at an expected position. For example, in the event that the skin is pulled away from the bandage **252** (see, e.g., FIG. **108**) during insertion into the skin, withdrawal of the delivery sharp **732** may help to pull the skin back into contact with the adhesive **252**. Thus, the skin may be in a prescribed location helping to ensure that the tip **750** of the delivery sharp **732** is at the expected depth. In some embodiments, the delivery sharp **732** may have a treatment on its exterior surface which roughens the external face of the delivery sharp **732**. This may aid in ensuring the skin is pulled back as the withdrawal portion of the insertion stroke occurs. Such an insertion sequence may also aid in minimizing any leaking of agent out of a patient during/after injection. This may be due to the outlet of the delivery sharp **732** reliably being inserted in its entirety into the patient regardless of any skin deformation at the puncture site. Additionally, such an insertion sequence may aid in establishing a seal between the tissue and the outer surface of the delivery sharp **732**.
[0346] Referring primarily to FIG. **112**, once the delivery sharp **732** is positioned in the second extended state, a user may introduce a fluid administration implement (e.g. syringe) to the access

port **708**. As shown, the example access port **708** includes a piercable septum **710** which may self-seal after being punctured. The access port **708** may be in fluid communication with the outlet of the delivery sharp **732**. The cover portion **704** of the body may include a sharp receiving cavity **780** which in the example embodiment is depicted as a funnel cavity. Preferably this cavity **780** may have a minimal dead volume. The cover portion **704** may also define a conduit receptacle **782** which may communicate (e.g. via a connecting passage) with the sharp receiving cavity **780**. A conduit **784** which extends from the conduit receptacle **782** into fluid communication with the delivery sharp **732** may be included. In the example, the conduit extends from the conduit receptacle **782** to an end of the delivery sharp **732** opposite the tip **750**. A user may deliver fluid from the fluid administration implement into the delivery device **10** through the access port **708** and this fluid may be driven through the conduit and into the patient via the delivery sharp **732**. The conduit **784** may be flexible and may include an amount of slack so as to allow the conduit **784** to spool out or displace as needed over the course of the insertion stroke.

[0347] Though the example embodiment includes an access port **708** through which agent may be introduced, delivery devices **10** which insert a delivery sharp **732** to a first depth and withdraw it to its target depth may receive agent from a pressurized ampoule **440**, a spring loaded syringe like reservoir, or any other reservoir type. The outlet of a syringe like reservoir may be in fluid communication with the delivery sharp **732** via a conduit for example. Any spring loaded syringe type reservoir such as those described herein (see, e.g., FIGS. **55-65**) may be included in such a delivery device **10**. Similarly, a port **458** (see, e.g. FIGS. **78-79**) in an elastomeric housing **450** (see, e.g. FIGS. **78-79**) surrounding an ampoule **440** (see, e.g. FIGS. **78-79**) may be plumbed into communication with a delivery sharp **732** via a conduit. The ampoule **440** may, for example, be broken via displacement of a neck **445** (see, e.g., FIG. **104**) portion of the ampoule **440** into a rigid shelf defined in the housing or may be broken by driving a ram body **612** (see, e.g. FIG. **89**) or other ramming element into the neck portion **445**. Any arrangements described herein for breaking an ampoule **440** frangible **446** may be incorporated into a delivery device **10** including an insertion mechanism such as that described in FIGS. **108-115**. Alternatively, a reservoir with an elastomeric wall (see, e.g. FIGS. **68-70**) may be connected to the access port **708**. Such a reservoir may communicate with the delivery sharp **732** via a conduit.

[0348] Referring now to FIG. **113** and FIG. **114** (a cross-sectional perspective view taken at the indicated cut plane of FIG. **114**), an example base portion **702** is depicted. As shown, the base portion **702** may include a pivotal bearing **720**. The base portion **702** may also include a number of guides. In the example embodiment, the base portion **702** includes an arcuate guide track **722**. The base portion **702** may also include a guide channel **724** which may be shaped so as to accept a sharp assembly **731**. The sharp assembly **731** in the example embodiment includes the delivery sharp **732** and a sled **730** on which the delivery sharp **732** is borne. In other embodiments, a sharp assembly **731** may include a plurality of delivery sharps **732**. Each of the delivery sharps **732** may be mounted on the sled **730** in, for example, a row. In the example embodiment, the guide channel **724** extends through the base portion **702** to a delivery sharp aperture **726** through which a delivery sharp **732** may extend to access a patient. As shown, the bandage **252** may also include an aperture **727**. The bandage aperture **727** may preferably have a diameter only slightly larger (e.g. up to ˜30% or 40%) than the outer diameter of the delivery sharp **732**. This may aid in holding the skin in place at the puncture location during the insertion stroke.

[0349] As shown, the aperture **718** of the recess **714** extends through the wall of the base portion **702** to the guide channel **724**. When the lock member **712** is installed within the recess **714**, the protuberance **716** of the lock member **712** may obstruct passage of the sled **730** of the sharp assembly **731** along the guide channel **724** (see, e.g., FIG. **110**). In certain examples, the delivery device **10** may be automatically actuated upon removal of the lock member **712**.

[0350] Referring now also to FIG. **115**, a perspective view of a delivery sharp **732** bearing sled **730** and actuator assembly **734** are shown. In the example embodiment, the delivery sharp **732** is

depicted as a 30-gauge needle (higher or lower gauge needles may also be used in alternative embodiments) which has an insertable length suitable for subcutaneous or intramuscular agent administration. The delivery sharp **732** may be made of a metal such as stainless steel though other metals, polymers, or any other suitable material may be used. In certain embodiments, a plurality of such delivery sharps **732** (e.g. two, three, four, or more) may be included. The delivery sharp(s) **732** may be rotationally clocked to a prescribed orientation when installed within the sled **730**. In the example embodiment, the delivery sharp **732** is rotationally clocked such that the point **750** of the delivery sharp **732** is most proximal to the wall of the base portion **702** where the recess **714** is defined. This position may be referred to as a 12 o'clock position. It should be understood that the delivery sharp **732** may be rotationally clocked such that the point **750** of the delivery sharp **732** is in alternative rotational orientations (e.g. in a 6 o'clock position or any other o'clock position). Where multiple delivery sharps **732** are included, each delivery sharp **732** may be clocked to any desired rotational position. In some embodiments, each delivery sharp **732** may be clocked to the same position as at least one other delivery sharp **732**. Alternatively, all delivery sharps **732** may be clocked to different positions. Use of multiple delivery sharps **732** may aid in distributing agent delivered to the patient over a large area at the target depth.

[0351] As shown, the sled **730** of the sharp assembly **731** includes two wing bodies **736** which flank a main body **738** in which the delivery sharp **732** may be mounted. The delivery sharp **732** may be coupled into the main body **738** via friction fit, adhesive, or in any other suitable manner. The sled **730** may also include a hitch portion **740** via which the sled **730** may be coupled to the actuator assembly **734**. Any suitable linkage to couple the hitch portion **740** and actuator assembly **734** may be used. The guide channel **724** of the base portion **702** of the housing **700** may be shaped so as to accept the sled **730**. The guide channel **724** may, for example, have wing receiving slots **742**, a hitch receiving channel **744** and a main body receiving slot **746**. The guide channel **724** may constrain movement of the sled **730** substantially to a direction parallel to the axis of the delivery sharp **732**. Thus, the guide channel **724** may define the insertion angle of the delivery sharp **732** into the patient. This angle may be from 5° and 45° (though steeper and shallower angles are possible) in various embodiments. In some embodiments the angle may be 5°-15°. In some embodiments, the angle may be no greater than 35°. In the example embodiment, the guide channel **724** defines an insertion angle for the delivery sharp **732** at 35°. The end of the main body **738** of the sled **730** most proximal the tip or point **750** of the delivery sharp **732** may include an angled face **748** which may be roughly parallel to the face of the base portion **702** which is secured to the bandage **252** (see, e.g., FIG. **108**). This face **748** may act as a stop which prevents the delivery sharp **732** from being deployed beyond a certain amount.

[0352] Still referring primarily to FIG. **115**, the actuation assembly **734** may include a pivot pin **760**. The pivot pin **760** may include a first end **764** which may seat within the pivotal bearing **720** of the base portion **702**. The cover portion **704** of the housing **700** may include a second bearing **762** (see, e.g., FIG. **110**) which may accept a second end **766** of the pivot pin **760**. A boom plate **768** may extend from a portion of the pivot pin **760** proximal the second end **766**. The boom plate **768** may support a guide pin **770** which may project from the boom plate **768**. As the pivot pin **760** is rotated about its longitudinal axis, the guide pin **770** may be displaced along an arcuate path. The guide pin **770** may include an end opposite the boom plate **768** which rides within the arcuate guide track **722** of the base portion **702**. The guide pin **770** may receive a bias member **772**. The bias member **772** may couple to the pivot pin **760** as well as the hitch **740** of the sled **730**. Thus the bias member **772** may double as the linkage coupling the sharp assembly **731** and the actuation assembly **734**. In the example embodiment, the bias member **772** is depicted as a torque producing bias member. A torsion spring is shown in the exemplary embodiment. The torsion spring is disposed on the guide pin **770** such that the guide pin **770** extends through the central void of the torsion spring. The example bias member **772** includes a first arm **774** which may be assembled into a notch **776** defined in the first end **764** of the pivot pin **760**. The exemplary bias member **772**

also includes a second arm **778** which is coupled into an orifice **780** of the hitch **740**.
[0353] The bias member **772** may be held in a stressed state when the delivery sharp **732** is within the delivery device **10**. The lock member **712** may prevent the bias member **772** from transitioning to an unstressed state. As the pivot pin **760** is confined within the pivotal bearing **720** and second bearing **762**, displacement of the pivot pin **760** may be constrained to rotation about the long axis of the pivot pin **760**. When the bias member **772** is released (e.g. via removal of the lock member **712**) and allowed to restore to a less stressed state, the bias member **772** may drive the guide pin **770** along an arcuate displacement path. The guide pin **770** may be displaced toward the sharp aperture **726** during displacement along a first portion of the arcuate displacement path and may be displaced away from the sharp aperture **726** as it displaces along a subsequent portion of the arcuate displacement path. The guide pin **770** may also be urged along the arcuate guide track **722** as displacement along the arcuate displacement path occurs. Since the bias member **772** in the example embodiment couples the guide pin **770** to the sled **730** via the hitch **740**, movement of the guide pin **770** may cause the sharp assembly **731** to displace along the guide channel **724** of the base portion **702** in a reciprocating motion. This reciprocating motion of the sharp assembly **731** may occur without any reciprocating motion or doubling back of the guide pin **770** along its displacement path. The reciprocating motion of sharp assembly **731** may be driven via a single, continuous, fluid motion of the guide pin **770** in a single rotational direction (clockwise or counterclockwise depending upon the embodiment) along its arcuate displacement path.
[0354] As the guide pin **770** is urged to displace along the arcuate guide track **722** from a starting position, the guide pin **770** may reach a point at which it is closest to the delivery sharp aperture **726** of the base portion **702** (see, e.g., FIG. **111**). The delivery sharp **732** may extend its maximum extent from the housing **700** (the first extended state) at this point. The arcuate guide track **722** may be asymmetric about the midplane (see cut plane **114-114** of FIG. **113**) of the delivery device **10**. As the guide pin **770** continues along the arcuate guide track **722**, the guide pin **770** may become more distant from the delivery sharp aperture **726**. Thus, the delivery sharp **732** may begin to withdraw from the skin. The guide track **722** may be shorter on the withdraw portion of the insertion stroke. Due to the asymmetry of the arcuate guide track **722**, the delivery sharp **732** may be prevented from fully withdrawing into the housing **700** of the delivery device **10**. In the example, the arcuate guide track **722** may include a terminus **788** which presents a stop that blocks further displacement of the guide pin **770** and defines an end of the displacement range of the guide pin **770** along its arcuate displacement path. The terminus **788** may be a rigid, non-compliant wall of the guide track **722**. The insertion stroke may complete when the guide pin **770** contacts the stop presented by the terminus **788** of the arcuate guide track **722**. The terminus **788** may be positioned such that the delivery sharp **732** may be at the target depth (the second extended position) in the skin when the guide pin **770** reaches the terminus **788**. Thus, via urging of a single bias member **772**, the sharp assembly **731** may be driven in a reciprocating motion along the guide channel **724** to advance the delivery sharp **732** to the first extended position and then partially retract the delivery sharp **732** to its target position. At this point, the delivery device **10** may be ready for administration of agent into the patient.
[0355] The bias member **772** may still be partially stressed when the delivery sharp **732** is in its target position. This may ensure that the sharp assembly **731** does not move after the insertion stroke completes. In the example embodiment, the boom plate **768** includes a nock **790**. The nock **790** may at least partially receive the hitch **740** of the sled **730** (or potentially another portion of sharp assembly **731**) when the delivery sharp **732** is in the second extended position. This may aid in holding the sharp assembly **731** in place during administration of agent to the patient. The hitch **740** is depicted as received within the nock **790** in FIG. **112**.
[0356] Referring now to FIGS. **116-117**, in certain examples, the delivery device **10** may be arranged such that the delivery sharp **732** may be completely retracted into the housing **700** once delivery into the patient is complete. For example, the terminus **788** may be a displaceable barrier

(e.g. pivotal). When injection is complete, the terminus **788** may be displaced (e.g. via interaction with a lever/button/knob accessible via the exterior of the housing **700**) allowing the guide pin **770** to be displaced further away from the delivery sharp aperture **726**. Thus, the delivery sharp **732** may be fully retracted into the delivery device **10** after infusion of fluid has completed.

[0357] As shown in FIGS. **116-117**, an example delivery device **10** including a knob **970** is shown. Various components of the delivery device **10** have been hidden for sake of illustration. As shown, the knob **970** may include a lever **972**, turnkey, dial, or other user-graspable feature which is accessible on the exterior of the delivery device **10**. When the delivery device **10** is actuated, the guide pin **770** may displace along the guide track **722** and into contact with a stop surface **974** defined on a pin portion **976** of the knob **970** which extends into the delivery device **10**. The stop surface **974** may act as the terminus **788** of the guide track **722** described above. Once delivery has completed, the knob **970** may be rotated to a stowing position (see FIG. **117**). As shown, the pin portion **976** of the knob **970** may include a channel **978** recessed therein. This channel **978** may be sized to accept the guide pin **770**. As shown, when the knob **970** has been rotated to the stowing position, the stop surface **974** may be rotated out of contact with the guide pin **770** and the channel **978** may be rotated into a position in which it may accept the pin **770**. This may allow the bias member **772** to drive the guide pin **770** into the channel **978**. As a result, the delivery sharp **732** may be further withdrawn and be located entirely within the delivery device **10**. In turn, the delivery sharp **732** may be retracted into the delivery device **10** to stow the delivery sharp **732** out of potential contact with a user.

[0358] Referring now to FIGS. **118-119**, a cross-section of an example delivery device **10**, in certain examples, a sharp cover **980** may be included as part of the bandage **252** of a delivery device **10**. Though the embodiment shown in FIGS. **118-119** is depicted as a delivery device **10** of the variety illustrated in FIGS. **108-115**, such a sharp cover **980** may be included on the bandage **252** of any delivery device **10** described herein. As shown, the sharp cover **980** may be a resilient well which is included in a portion of the bandage **252** outside of the footprint of the housing of the delivery device **10**. The portion of the bandage **252** including the sharp cover **980** may be flexible or connected to the remainder of the bandage **252** via a bendable region. Once the delivery device **10** has been used, the bandage **252** may be folded over such that the tip of the delivery sharp **732** is positioned within the well formed by the sharp cover **980**. As the bandage **252** may be adhesive bearing, the bandage **252** may stick to itself when folded over. Thus, the sharp cover **980** may be coupled in place around the delivery sharp **732** preventing inadvertent contact with the delivery sharp **732**. Though the sharp cover **980** is coupled in place via the adhesive of the bandage **252** in the example embodiments, in other embodiments, the sharp cover **980** may additionally or alternatively snap into place around the delivery sharp **732**.

[0359] Referring now to FIG. **120**, a flowchart **840** depicting a number of exemplary actions which may be executed to deliver fluid to a target depth in a patient are shown. As shown, in block **842**, the delivery device **10** may be applied to a patient. In certain examples, the delivery device **10** may be adhered to the patient via an adhesive member. In block **844**, a lock member may be displaced to a state in which it is disengaged. In some examples, the lock member may be removed from the delivery device **10**. In block **846**, a guide pin may be urged along a displacement path. Movement of the guide pin along the displacement path may occur in a single fluid motion. The guide pin may be acted on by a single bias member which displaces the guide pin in a single direction along an arcuate displacement path in various examples. The guide pin may be displaced along the displacement path until abutting a stop which halts movement of the guide pin. In block **848**, motion of the guide pin may be transmitted to a sharp assembly of the delivery device **10** such the sharp assembly is displaced in a reciprocating motion. In the example detailed in FIG. **120**, the sharp assembly may be displaced such that at least one delivery sharp of the sharp assembly is advanced a first distance out of a housing of the delivery device **10** and then retracted to a delivery position. In the delivery position, the at least one delivery sharp may extend a second distance from

the housing which is less than the first. When the at least one delivery sharp is retracted to the second position the outlet(s) of the at least one delivery sharp may be at the target depth (e.g. intradermal) in a patient. In block **850**, a fluid administration implement may be introduced into a fill port of the delivery device **10**. Fluid may be expelled from the fluid administration implement, driven through the delivery device **10**, and out of the at least one delivery sharp in block **852**. In alternative embodiments, fluid from another reservoir such as a pressurized ampoule or a spring loaded syringe type reservoir may be delivered through the delivery sharp into the patient.
[0360] Various alternatives and modifications can be devised by those skilled in the 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 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.
[0361] 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 within the drawings that have the same numbers may be identical elements or may be similar elements, depending on the context.
[0362] 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 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.
[0363] Furthermore, the terms “first”, “second”, “third” and the like, whether used in 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 illustrated herein.

Claims

1. A method for accessing a target delivery depth of a patient comprising: applying an administration device to a patient; displacing a lock member from a locking state to a disengaged state; propelling a guide pin along a displacement path; and transmitting, via a linkage, motion of the guide pin to a sharp assembly to extend at least one delivery sharp of the sharp assembly a first distance out of a housing of the administration device and retract the at least one delivery sharp to a delivery position in which the at least one delivery sharp extends a second distance out of the housing which is less than the first distance.
2. The method of claim 1, wherein propelling the guide pin comprises propelling the guide pin along the displacement path to a stop in a single direction along the guide path.
3. The method of claim 2, wherein the single direction is a single rotational direction.
4. The method of claim 1, wherein the first distance corresponds to a transcutaneous puncture depth

in the patient.
5. The method of claim 1, wherein the second distance corresponds to an intradermal puncture depth in the patient.
6. The method of claim 1, wherein displacing the lock member comprises removing the lock member.
7. A method of locating a delivery sharp at a target depth within a patient comprising: applying an administration device to a patient; removing a lock from the device; propelling a guide along a track; and transmitting, via a linkage, motion of the guide to a body to which the delivery sharp is coupled to extend the delivery sharp a first distance out of a housing of the administration device and retract the delivery sharp to a delivery position in which the delivery sharp extends a second distance out of the housing which is less than the first distance.
8. The method of claim 7, wherein the track is an arcuate.
9. The method of claim 7, wherein the propelling the guide comprises exerting a bias force on the guide with a single bias member.
10. The method of claim 7, wherein propelling the guide comprises propelling the guide along the track to a stop in a single direction along the guide path.
11. The method of claim 10, wherein the method further comprises displacing the stop to a stowed position and further propelling the guide to a final position, motion of the guide being transmitted through the linkage to the body to displace the delivery sharp to a housed position as the guide reaches the final position.
12. The method of claim 10, wherein the single direction is a single rotational direction.
13. The method of claim 7, wherein propelling the guide pin along the displacement path comprises propelling the guide pin in a single fluid motion along the displacement path.
14. The method of claim 7, wherein the propelling the guide along the track comprises propelling the guide along a first portion of the track in which the guide increases in proximity to a delivery sharp aperture in the housing and along a second portion of the track shorter than the first portion in which the guide decreases in proximity to the delivery sharp aperture.
15. The method of claim 7, wherein the first distance corresponds to a transcutaneous puncture depth in the patient.
16. The method of claim 7, wherein the second distance corresponds to an intradermal puncture depth in the patient.
17. The method of claim 7, wherein the method further comprises constraining the at least one delivery sharp to displace at a predefined angle relative to a skin surface of the patient to which the administration device is applied.
18. The method of claim 7, wherein the method further comprises constraining the at least one delivery sharp to displace at a predefined angle of 5°-45° with respect to a surface of the housing of the administration device.
19. The method of claim 7, wherein removing the lock comprises disassociating a strip to which a portion of the lock is attached from the delivery device.
20. The method of claim 7, wherein the delivery sharp is a needle of no larger than 30 gauge.
21. A method for positioning the tip of a delivery sharp relative to a housing of an administration device comprising: applying the administration device to a surface; removing a lock from the administration device; displacing a body from which the delivery sharp extends in a reciprocal motion along a guide defined by the housing in a single fluid motion with a single bias member from a first position in which the delivery sharp is within the housing, through an intermediate position in which the delivery sharp is maximally extended from the housing, to a partially retracted position in which the tip of the delivery sharp is in a target position relative to the housing.
22. The method of claim 21, wherein the tip of the delivery sharp is spaced from the housing a distance corresponding to a transcutaneous puncture depth in a patient when the delivery sharp is

maximally extended from the housing and the tip of the delivery sharp is spaced from the housing a distance corresponding to an intradermal puncture depth in the patient when the tip of the delivery sharp is in the target position.