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# Delivery Device Apparatuses, Systems, and Methods


## Abstract

A device for delivery of agent to a biological barrier may comprise a petal bearing main body having a set of guides each having an upstream and downstream portion. The device may further comprise a reservoir including at least one delivery sharp. The device may further comprise a plunger having a set of plunger protrusions each disposed in a respective guide. The device may further comprise a first bias member urging the plunger toward a position in which the protrusions are at an end of the downstream portions. The device may further comprise a trigger body with a first and second set of barriers. The trigger body may be displaceable between a position in which the second barriers are stowed and the first barriers obstruct displacement of the protrusions and another position in which the first barriers are stowed and the second barriers obstruct travel of the protrusions.



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## Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] The present application claims the benefit of U.S. Provisional Application Ser. No. 63/551,596, entitled Delivery Device Apparatuses, Systems, and Methods, filed Feb. 9, 2024 (Attorney Docket No. 00101.00372.AB267), and claims the benefit of U.S. Provisional Application Ser. No. 63/551,628, entitled Delivery Device Apparatuses, Systems, and Methods, filed Feb. 9, 2024 (Attorney Docket No. 00101.00384.AB308), and claims the benefit of U.S. Provisional Application Ser. No. 63/686,325, entitled Delivery Device Apparatuses, Systems, and Methods, filed Aug. 23, 2024 (Attorney Docket No. 00101.00430.AB551), and claims the benefit of U.S. Provisional Application Ser. No. 63/686,316, entitled Delivery Device Apparatuses, Systems, and Methods, filed Aug. 23, 2024 (Attorney Docket No. 00101.00429.AB550), and also claims the benefit of U.S. Provisional Application Ser. No. 63/727,877, entitled Components and Methods for Use in Production of Fluid Delivery Devices, filed Dec. 4, 2024 (Attorney Docket No. 00101.00469.AB680).

BACKGROUND
Field of Disclosure
[0004] This disclosure relates to medical agent delivery. More specifically, this disclosure relates to dispensers for therapeutic and other medical agents.
Description of Related Art
[0005] 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.

[0006] 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

[0007] In accordance with an embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological barrier may comprise a rigid guide body. The rigid guide body may comprise a plurality of petal members extending outwardly from a first end thereof. The rigid guide body may further comprise a sloped guide track partitioned into an upstream portion and downstream portion by an interrupt channel. The delivery device may further comprise a reservoir including at least one delivery sharp, the reservoir may be coupled to the rigid guide body. The delivery device may further comprise a plunger partially disposed in the guide track. The delivery device may further comprise a bias member intermediate the plunger and a wall at a second end of the rigid guide body. The bias member may exert a force compelling the plunger along the guide track when in a distorted state. The delivery device may further comprise a trigger body with a first barrier projection. The first barrier projection may present an interference to displacement of the plunger along the guide track when the trigger body is in a blocking position. The first barrier projection may be disposed within the channel with a track completing surface aligned with the upstream and downstream portion when the trigger body is in a trigger position. The delivery device may further comprise a deformable spacer having a first state in which the trigger body is held in the blocking position. The deformable spacer may transition to a deformed state upon displacement of the trigger body to the trigger position.

[0008] In some embodiments, the sloped guide track may be a ledge on the interior sidewall of the rigid guide body. In some embodiments, the sloped guide track may include a terminal channel at a downstream end of the guide track. In some embodiments, the trigger body may include a second barrier projection. The second barrier projection may be disposed within the terminal channel when the trigger body is in the trigger position. The second barrier may be in an unobstructing position relative to the terminal channel when the trigger body is in the blocking position. In some embodiments, the deformable spacer may be a spring. In some embodiments, the deformable spacer may be a flexure of the trigger body which extends from a portion of the trigger body to the second end of the rigid guide body. In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the delivery device may further comprise an adhesive coupled to the petal members. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the portion of the plunger disposed in the guide track is in the upstream portion of the guide track. In some embodiments, the reservoir may include a septum.

[0009] In accordance with another embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological barrier may comprise a petal bearing main body. The main body may comprise a set of cam tracks each partitioned into an upstream portion and downstream portion by an interrupt channel. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective cam track. The plunger may be biased by a first bias member from a first position in which the protrusions are disposed at the upstream portions toward a second position in which the protrusions are disposed at the downstream portions. The delivery device may further comprise a button with a first set of barriers.

The button may be displaceable between a blocking position in which the first set of barriers obstruct travel of the protrusions along the respective cam tracks and a trigger position in which the first set of barriers fill the interrupt channel and complete the cam track.
[0010] In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the button. In some embodiments, the deformable spacer may be a flexure extending from one of the main body and button. In some embodiments, the deformable spacer may be a second bias member. In some embodiments, the delivery device may further comprise a deformable spacer which transitions from a home state to a deformed state upon displacement of the button to the trigger position. In some embodiments, the deformable spacer may transition to the deformed state upon application of more than a threshold force urging the button toward the trigger position. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiments, the delivery device may further comprise a deformable spacer intermediate the button and main body. The button may displace from the blocking position to the trigger position and deform the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force. In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the button may be biased to the blocking position by a second bias member. In some embodiments, the button may include a second set of barriers which obstruct travel of the protrusions to a terminal region of the downstream portions when the button is in the trigger position. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective cam tracks. In some embodiments, the reservoir may include a septum.
[0011] In accordance with another embodiment of the present disclosure and example delivery device for delivery of medical agent to a biological barrier may comprise a petal bearing main body. The main body may comprise a set of guides each having an upstream portion and downstream portion. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective guide. The plunger may be biased by a first bias member from a first position in which the protrusions are disposed at the upstream portions toward a second position in which the protrusions are disposed at the downstream portions. The delivery device may further comprise a trigger body with a first set of barriers. The trigger body may be displaceable between a blocking position in which the first set of barriers obstruct displacement of the protrusions between the upstream and downstream sections of the respective guides and a trigger position in which the first set of barriers are in a stowed state.
[0012] In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the trigger body. In some embodiments, the deformable spacer may be a flexure extending from one of the main body and trigger body. In some embodiments, the deformable spacer may be a second bias member. In some embodiments, the delivery device may further comprise a deformable spacer which transitions from a home state to a deformed state upon displacement of the trigger body to the trigger position. In some embodiments, the deformable spacer may transition to the deformed state upon application of more than a threshold force urging the trigger body toward the trigger position. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiments, the delivery device may further comprise a spacer intermediate the trigger body and main body. The trigger body may displace from the blocking position to the trigger position and deform the spacer upon application of a threshold deforming force which is greater

than the threshold petal spreading force. In some embodiments, the trigger body may be biased to the blocking position by a second bias member. In some embodiments, the trigger body may include a second set of barriers which obstruct travel of the protrusions to a terminal region of the downstream portions when the trigger body is in the trigger position. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective guides.

[0013] In accordance with another embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological may comprise a petal bearing main body having a set of guides. Each guide may comprise an upstream portion and downstream portion. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective guide. The delivery device may further comprise a first bias member urging the plunger toward a position in which the protrusions are at an end of the downstream portions. The delivery device may further comprise a trigger body with a first and second set of barriers. The trigger body may be displaceable between a blocking position in which the second set of barriers may be stowed and the first set of barriers may obstruct displacement of the protrusions between the upstream and downstream portions of the respective guides and a trigger position in which the first set of barriers may be stowed and the second set of barriers may obstruct travel of the protrusions to the end of the downstream portions.

[0014] In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, each of the guides may be a sloped track. In some embodiments, each of the first set of barriers may be within an interrupt channel defined in each guide when the trigger body is in blocking position. In some embodiments, each of the guides may be a cam track. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective guides. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiment, the delivery device may further comprise a spacer intermediate the trigger body and main body. The trigger body may displace from the blocking position to the trigger position and deform the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force. In some embodiments the trigger body may be biased to the blocking position by a second bias member. In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the trigger body. In some embodiments, the deformable spacer may be a flexure extending from one of the main body and trigger body.

[0015] In accordance with another embodiments of the present disclosure an example method of expelling an agent from a delivery device may comprise applying the delivery device to a barrier. The method may further comprise generating a spreading displacement of petal members of a main body of the delivery device by exerting a first threshold force on a trigger body of the delivery device. The method may further comprise displacing the trigger body toward the main body to a trigger position by exerting a second threshold force greater than the first on the trigger body. The method may further comprise displacing at least one first barrier of the trigger body from an obstructing position to a stowed position. In some embodiments, expelling the agent from a reservoir of the delivery device by collapsing the reservoir with a spring biased plunger when each of the at least one first barrier is in the stowed position. The method may further comprise guiding displacement of the spring biased plunger with at least one guide track.

[0016] In some embodiments, applying the delivery device to the barrier may comprise adhering at least the petal members of the delivery device to the barrier. In some embodiments, the method

may further comprise preventing displacement of the trigger body to the trigger position with a deformable spacer when the first threshold force is exerted on the trigger body. In some embodiments, the method may further comprise biasing the trigger body in a direction away from the main body with at least one bias member. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise driving each of the at least one first barrier into an interrupt channel of a respective guide track. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise displacing a surface of each of the at least one first barrier into a guide track completing position. The surface of each of the at least one first barrier may define a span of a respective guide track of the at least one guide track in the guide track completing position. In some embodiments, each of the at least one guide track may be a cam track and guiding the displacement of the spring bias plunger may comprise engendering rotation of the plunger as the advances along the at least one guide track. In some embodiments, the method may further comprise displacing at least one second barrier from a retracted position to a guide track terminus obstructing position as the trigger body is displaced to the trigger position. Each of the at least one second barrier may block a terminal end of a respective one of the at least one guide track in the guide track terminus obstructing position. In some embodiments, the method may further comprise displacing the plunger into contact with the at least one second barrier. In some embodiments, the method may further comprise ceasing exertion of force on the trigger body after the trigger body is in the trigger position and driving the trigger body away from the main body via a bias member until the at least one second barrier is returned to the retracted position and the method further comprises displacing the plunger to an end of a displacement range of the plunger.

[0017] In accordance with an embodiment of the present disclosure a method of expelling an agent from a delivery device may comprise adhering petal members of a main body of the delivery device to a barrier. The method may further comprise generating a spreading displacement of the petal members and puncturing the barrier with at least one delivery sharp of a reservoir of the delivery device by exerting a first threshold force on a trigger body of the delivery device. The method may further comprise displacing the trigger body to a trigger position by exerting a second threshold force greater than the first on the trigger body. The method may further comprise freeing a spring biased plunger to collapse the reservoir by displacing at least one first barrier of the trigger body from an obstructing position to a stowed position. The method may further comprise guiding displacement of the spring biased plunger with at least one guide track.

[0018] In some embodiments, the method may further comprise preventing displacement of the trigger body to the trigger position with a deformable spacer when the first threshold force is exerted on the trigger body. In some embodiments, the method may further comprise biasing the trigger body in a direction away from the main body with at least one bias member. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise driving each of the at least one first barrier into an interrupt channel of a respective guide track. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise displacing a surface of each of the at least one first barrier into a guide track completing position. The surface of each of the at least one first barrier may define a span of a respective guide track of the at least one guide track in the guide track completing position. In some embodiments, each of the at least one guide track may be a cam track and guiding the displacement of the spring bias plunger may comprise engendering rotation of the plunger as the advances along the at least one guide track. In some embodiments, the method may further comprise displacing at least one second barrier from a retracted position to a guide track terminus obstructing position as the trigger body is displaced to the trigger position. Each of the at least one second barrier may block a terminal end of a respective one of the at least one guide track in the guide track terminus obstructing position. In some embodiments, the method may further comprise displacing the plunger into contact with the at least one second barrier. In some

embodiments, the method may further comprise ceasing exertion of force on the trigger body after the trigger body is in the trigger position and driving the trigger body away from the main body via a bias member until the at least one second barrier is returned to the retracted position and the method may further comprise displacing the plunger to an end of a displacement range of the plunger.

[0019] In accordance with another example embodiment of the present disclosure an example rigid reservoir portion of a medical agent administration device may comprise a proximal face. The reservoir portion may further comprise a distal face opposite the proximal face. The reservoir portion may further comprise a sharp bearing body. The sharp bearing body may comprise a sharp bearing face with at least one delivery sharp projecting therefrom. The sharp bearing face may further comprise a sharp free face opposite the sharp bearing face. The sharp bearing body may further comprise at least one lumen. Each of the at least one lumen may extend through a respective one of the at least one delivery sharp to the sharp free face. The reservoir portion may further comprise a receptacle located on one of the proximal and distal face of the rigid reservoir portion. The sharp bearing body may seated in the receptacle with a portion of the at least one delivery sharp protruding beyond the proximal face of the rigid reservoir portion. The reservoir portion may further comprise a bead of a swaged material circumscribing and at least partially overlaying a peripheral portion of the sharp bearing body.

[0020] In some embodiments, the swaged material may be a material selected to absorb an output wavelength from a swaging laser. In some embodiments, the swaged material may be laser swaged. In some embodiments, the swaged material is a heat swaged. In some embodiments, the swaged material may be a material which is different than a second material which forms at least a majority of the remainder of the rigid reservoir portion. In some embodiments, the swaged material may be a material which is the same as a material forming at least a majority of a remainder of the rigid reservoir portion. In some embodiments, the swaged material may be an elastomer. In some embodiments, the sharp bearing body may further comprise a set of sidewalls between the sharp bearing face and the sharp free face. In some embodiments, each of sidewalls may comprise a step disposed intermediate the sharp bearing face and the sharp free face. A first cross-sectional area of the sharp bearing body proximate the sharp free face may be larger than the area of the sharp bearing face. In some embodiments, the sidewalls may each include at least one tapered span and the area of the sharp free face may be larger than the area of the sharp bearing face.

[0021] In accordance with another example embodiment of the present disclosure, a method for securing a sharp bearing body to a rigid reservoir portion of a medical agent administration device may comprise locating a receptacle on a face of the rigid reservoir portion. The method may further comprise seating the sharp bearing body in a position in the receptacle so that at least one sharp of the sharp bearing body is protruding from the rigid reservoir portion. The method may further comprise forming a bead of a material in a position circumscribing the receptacle. The method may further comprise temporarily applying a bead displacing condition that changes the position of at least a portion of the bead into a sharp bearing body retaining position. The method may further comprise setting the at least a portion of the bead in the sharp bearing body retaining position.

[0022] In some embodiments, temporarily applying the displacing condition may comprise applying a heat swage tool. In some embodiments, temporarily applying the displacing condition may comprise illuminating the bead with a swaging laser. In some embodiments, the sharp bearing body retaining position may be a position in which the at least of portion of the bead is on a sharp bearing face of the sharp bearing body. In some embodiments, the sharp bearing body retaining position may be a position in which the at least of portion of the bead is on at least a portion of a sidewall of the sharp bearing body. In some embodiments, the sharp bearing body retaining position may be a position in which the at least a portion of the bead is on the sharp free face of the sharp bearing body. In some embodiments, forming the bead of material may comprise depositing the bead around the receptacle. In some embodiments, forming the bead of material may comprise

overmolding the bead of material in position around the receptacle.
[0023] In accordance with an embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological barrier may comprise a main body having a housing with a plurality of petal members extending outwardly from a first end thereof. The delivery device may further comprise a guide insert coupled into the housing with a sloped guide track which is partitioned into an upstream portion and downstream portion by an interrupt channel. The delivery device may further comprise a reservoir including at least one delivery sharp coupled to the housing and enclosing the guide insert within the housing. The delivery device may further comprise a plunger partially disposed in the guide track. The delivery device may further comprise a bias member intermediate the plunger and a wall at a second end of the housing. The bias member may exert a force compelling the plunger to displace along the guide track. The delivery device may further comprise a trigger body with a first barrier projection. The first barrier projection may present an interference to displacement of the plunger along the guide track when the trigger body is in a blocking position and may be disposed within the channel with a track completing surface aligned with the upstream and downstream portion in when the trigger body is in a trigger position. The delivery device may further comprise a deformable spacer having a first state in which the trigger body is held in the blocking position. The deformable spacer may transition to a deformed state upon displacement of the trigger body to the trigger position.
[0024] In some embodiments, the sloped guide track may be a ledge on the interior sidewall of the guide insert. In some embodiments, the sloped guide track includes a terminal channel at a downstream end of the guide track. In some embodiments, the trigger body may include a second barrier projection. The second barrier projection may be disposed within the terminal channel when the trigger body is in the trigger position and may be in an unobstructing position relative to the terminal channel when the trigger body is in the blocking position. In some embodiments, the deformable spacer may be a spring. In some embodiments, the deformable spacer may be a flexure of the trigger body which extends from a portion of the trigger body to the second end of the rigid guide body. In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the delivery device may further comprise an adhesive coupled to the petal members. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the portion of the plunger disposed in the guide track is in the upstream portion of the guide track. In some embodiments, the reservoir may include a septum.
[0025] In accordance with another embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological barrier may comprise a petal bearing main body. The delivery device may further comprise an insert within the main body having a set of cam tracks each partitioned into an upstream portion and downstream portion by an interrupt channel. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective cam track. The plunger biased by a first bias member from a first position in which the protrusions are disposed at the upstream portions toward a second position in which the protrusions are disposed at the downstream portions. The delivery device may further comprise a button with a first set of barriers. The button may be displaceable between a blocking position in which the first set of barriers obstruct travel of the protrusions along the respective cam tracks and a trigger position in which the first set of barriers fill the interrupt channel and complete the cam track.
[0026] In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the button. In some embodiments, the deformable spacer may be a flexure extending from one of the main body and button. In some embodiments, the deformable spacer may be a second bias member. In some embodiments, the delivery device may further comprise a deformable spacer which transitions from a home state to a deformed state upon

displacement of the button to the trigger position. In some embodiments, the button may include at least one latch projection and the main body may include a respective catch for each of the at least one latch projection. Each of the at least one latch projection may engage its respective catch when the button is displaced to from the blocking position toward the trigger position. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiments, the delivery device may further comprise a deformable spacer intermediate the button and main body. The button may displace from the blocking position to the trigger position and may deform the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force. In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the button may be biased to the blocking position by a second bias member. In some embodiments, the button may include a second set of barriers which obstruct travel of the protrusions to a terminal region of the downstream portions when the button is in the trigger position. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective cam tracks.

[0027] In accordance with another embodiment of the present disclosure, an example delivery device for delivery of medical agent to a biological barrier may comprise a petal bearing main body. The delivery device may further comprise an insert coupled within the main body with a set of guides each having an upstream portion and downstream portion. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective guide. The plunger biased by a first bias member from a first position in which the protrusions are disposed at the upstream portions toward a second position in which the protrusions are disposed at the downstream portions. The delivery device may further comprise a trigger body with a first set of barriers. The trigger body may be displaceable between a blocking position in which the first set of barriers obstruct displacement of the protrusions between the upstream and downstream sections of the respective guides and a trigger position in which the first set of barriers are in a stowed state.

[0028] In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the trigger body. In some embodiments, the deformable spacer may be selected from a group consisting of a flexure extending from one of the main body and trigger body and a second bias member. In some embodiments, the deformable spacer may be a latch projection. The latch projection may extend from the trigger body. The main body may include a catch. The latch projection may enter into engagement with the catch as the trigger body is transitioned to the trigger position. In some embodiments, the delivery device may further comprise a deformable spacer which transitions from a home state to a deformed state upon displacement of the trigger body to the trigger position. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiments, the delivery device may further comprise a spacer intermediate the trigger body and main body. The trigger body may displace from the blocking position to the trigger position and may deform the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force. In some embodiments, the main body may include a window. The plunger may include a region of contrasting appearance. The region of contrasting appearance may be aligned with the window when the protrusions are disposed at the downstream portions. In some embodiments, the trigger body may include a second set of barriers which obstruct travel of the protrusions to a terminal region of the downstream portions when the trigger body is in the trigger position. In some embodiments, the reservoir may include a displaceable wall defining a portion of

a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective guides. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The displaceable wall may have a first state when the reservoir is filled with agent and a second state when the reservoir is depleted. The main body may include a fill verification aperture through which at least a portion of the displaceable wall is visible when the displaceable wall is in the first state.

[0029] In accordance with still another embodiment of the present disclosure an example delivery device for delivery of medical agent to a biological barrier may comprise a petal bearing main body. The delivery device may further comprise a guide bearing body defining a set of guides each having an upstream portion and downstream portion. The delivery device may further comprise a reservoir including at least one delivery sharp. The delivery device may further comprise a plunger having a set of plunger protrusions each disposed in a respective guide. The delivery device may further comprise a first bias member urging the plunger toward a position in which the protrusions are at an end of the downstream portions. The delivery device may further comprise a trigger body with a first and second set of barriers. The trigger body may be displaceable between a blocking position in which the second set of barriers are stowed and the first set of barriers obstruct displacement of the protrusions between the upstream and downstream portions of the respective guides and a trigger position in which the first set of barriers are stowed and the second set of barriers obstruct travel of the protrusions to the end of the downstream portions.

[0030] In some embodiments, each of the at least one delivery sharp may be a microneedle. In some embodiments, each of the guides may be a sloped track. In some embodiments, each of the first set of barriers may be within an interrupt channel defined in each guide when the trigger body is in blocking position. In some embodiments, each of the guides is a cam track. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The plunger may be out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective guides. In some embodiments, the petal bearing main body may comprise a plurality of petal members. The petal members may displace from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied. In some embodiments, the delivery device may further comprise a spacer intermediate the trigger body and main body. The trigger body may displace from the blocking position to the trigger position and may deform the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force. In some embodiments, the reservoir may include a displaceable wall defining a portion of a main interior volume of the reservoir. The displaceable wall may have a first state when the reservoir is filled with agent and a second state when the reservoir is depleted. The main body may include a fill verification aperture through which at least a portion of the displaceable wall is visible when the displaceable wall is in the first state.

[0031] In some embodiments, the delivery device may further comprise a deformable spacer between the main body and the trigger body. The deformable spacer may be selected from a list consisting of a bias member, a compression spring, a flexure, and a latching projection extending from the trigger body. In some embodiments, the main body may include a window and the plunger may include a region of contrasting appearance. The region of contrasting appearance being aligned with the window when the protrusions are disposed at the downstream portions.

[0032] In accordance with a further embodiment of the present disclosure an example method of expelling an agent from a delivery device may comprise applying the delivery device to a barrier. The method may further comprise generating a spreading displacement of petal members of a main body of the delivery device by exerting a first threshold force on a trigger body of the delivery device. The method may further comprise displacing the trigger body toward the main body to a trigger position by exerting a second threshold force greater than the first on the trigger body. The

method may further comprise displacing at least one first barrier of the trigger body from an obstructing position to a stowed position. The method may further comprise expelling the agent from a reservoir of the delivery device by collapsing the reservoir with a spring biased plunger when each of the at least one first barrier is in the stowed position. The method may further comprise guiding displacement of the spring biased plunger with a guide insert coupled to the main body.

[0033] In some embodiments, applying the delivery device to the barrier may comprise adhering at least the petal members of the delivery device to the barrier. In some embodiments, the method may further comprise resisting displacement of the trigger body to the trigger position with a deformable spacer when the first threshold force is exerted on the trigger body. In some embodiments, the method may further comprise biasing the trigger body in a direction away from the main body with at least one bias member. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise driving each of the at least one first barrier into an interrupt channel of a respective guide track defined in the guide insert. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise displacing a surface of each of the at least one first barrier into a guide track completing position. The surface of each of the at least one first barrier may define a span of a respective guide track of the guide insert in the guide track completing position.

[0034] In some embodiments, the guide insert may include at least one plunger guide track. Each of the at least one guide track may be a cam track and guiding the displacement of the spring biased plunger comprises engendering rotation of the plunger as the plunger advances along the at least one guide track. In some embodiments, the method may further comprise displacing at least one second barrier from a retracted position to an obstructing position as the trigger body is displaced to the trigger position. Each of the at least one second barrier may block a terminal end of a respective guide track defined in the guide insert in the obstructing position. In some embodiments, the method may further comprise displacing the plunger into contact with the at least one second barrier. In some embodiments, the method may further comprise ceasing exertion of force on the trigger body after the trigger body is in the trigger position and driving the trigger body away from the main body via a bias member until the at least one second barrier is returned to the retracted position. The method may further comprise displacing the plunger to an end of a displacement range of the plunger.

[0035] In accordance with still another example embodiment of the present disclosure a method of expelling an agent from a delivery device may comprise adhering petal members of a main body of the delivery device to a barrier. The method may further comprise generating a spreading displacement of the petal members and puncturing the barrier with at least one delivery sharp of a reservoir of the delivery device by exerting a first threshold force on a trigger body of the delivery device. The method may further comprise displacing the trigger body to a trigger position by exerting a second threshold force greater than the first on the trigger body. The method may further comprise freeing a spring biased plunger to collapse the reservoir by displacing at least one first barrier of the trigger body from an obstructing position to a stowed position. The method may further comprise guiding displacement of the spring biased plunger with a guide insert coupled to the main body.

[0036] In some embodiments, the method may further comprise inhibiting displacement of the trigger body to the trigger position with a deformable spacer when the first threshold force is exerted on the trigger body. In some embodiments, the method may further comprise biasing the trigger body in a direction away from the main body with at least one resilient spacer. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise driving each of the at least one first barrier into an interrupt channel of a respective guide track of the guide insert. In some embodiments, displacing the at least one first barrier from the obstructing position to the stowed position may comprise displacing a surface of

each of the at least one first barrier into a guide track completing position. The surface of each of the at least one first barrier defining a span of a respective guide track of the guide insert in the guide track completing position. In some embodiments, the guide insert may include at least one plunger guide track. Each of the at least one guide track may be a cam track and guiding the displacement of the spring biased plunger may comprise engendering rotation of the plunger as the advances along the at least one guide track. In some embodiments, the method may further comprise displacing at least one second barrier from a retracted position to an obstructing position as the trigger body is displaced to the trigger position. Each of the at least one second barrier may block a terminal end of a respective guide track defined in the guide insert in the obstructing position. In some embodiments, the method further may comprise displacing the plunger into contact with the at least one second barrier. In some embodiments, the method may further comprise ceasing exertion of force on the trigger body after the trigger body is in the trigger position and driving the trigger body away from the main body via a bias member until the at least one second barrier is returned to the retracted position. The method may further comprise displacing the plunger to an end of a displacement range of the plunger.

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## Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] 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:

[0038] FIG. **1**A is a block diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;

[0039] FIG. **1**B is a block diagram of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;

[0040] FIG. **2** is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0041] FIG. **3**A is a diagram of an example sharp bearing body incorporating microneedles in accordance with various aspects and embodiments of the present disclosure;

[0042] FIG. **3**B is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0043] FIG. **4**A is a diagram of an example sharp bearing body incorporating microneedles in accordance with various aspects and embodiments of the present disclosure;

[0044] FIG. **4**B is a diagram of an example microneedle in accordance with various aspects and embodiments of the present disclosure;

[0045] FIG. **5**A is a perspective view of an example sharp bearing body including a set of exemplary microneedles in accordance with various aspects and embodiments of the present disclosure;

[0046] FIG. **5**B is a perspective view of an example sharp bearing body including a set of exemplary microneedles in accordance with various aspects and embodiments of the present disclosure;

[0047] FIG. **6**A is a perspective view of an example sharp bearing body include a set of exemplary microneedles in accordance with various aspects and embodiments of the present disclosure;

[0048] FIG. **6**B is a top plan view of the example sharp bearing body shown in FIG. **6**A in accordance with various aspects and embodiments of the present disclosure;

[0049] FIG. **7**A is a top down view of an example sharp bearing body including a set of exemplary microneedles in accordance with various aspects and embodiments of the present disclosure;

[0050] FIG. **7**B is a perspective view of an example sharp bearing body including a set of exemplary microneedles in accordance with various aspects and embodiments of the present

disclosure;
[0051] FIG. **8**A is a top down view of an example sharp bearing body including a set of microneedles in accordance with various aspects and embodiments of the present disclosure;
[0052] FIG. **8**B is a perspective view of an example sharp bearing body including a set of exemplary microneedles in accordance with various aspects and embodiments of the present disclosure;
[0053] FIG. **8**C is a cross-sectional view taken at the indicated cut plane of FIG. **8**A in accordance with various aspects and embodiments of the present disclosure;
[0054] FIGS. **9**A-**9**D depict various views of an exemplary microneedle with side ports in accordance with various aspects and embodiments of the present disclosure;
[0055] FIG. **10**A depicts a top plane view of an example sharp bearing body;
[0056] FIG. **10**B depicts a side view of an example sharp bearing body;
[0057] FIG. **10**C depicts a detailed view of the indicated region of FIG. **10**A;
[0058] FIG. **10**D depicts a perspective view of an example sharp bearing body;
[0059] FIG. **11**A is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0060] FIG. **11**B is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0061] FIG. **12** is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0062] FIG. **13** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0063] FIG. **14** is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0064] FIG. **15** is a side view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0065] FIG. **16** is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0066] FIG. **17** is a conceptual representation of an exemplary delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0067] FIG. **18** is a diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
[0068] FIG. **19** is a conceptual representation of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0069] FIG. **20** is a side view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0070] FIG. **21** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0071] FIGS. **22**A-**22**I depicts various example embodiments of main bodies including different slot patterns and top surface apertures in accordance with various aspects and embodiments of the present disclosure;
[0072] FIG. **23** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0073] FIG. **24** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0074] FIG. **25** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0075] FIG. **26** depicts a perspective view of an example delivery device package in accordance with various aspects and embodiments of the present disclosure;
[0076] FIG. **27** depicts a top plan view of an example delivery device package with the delivery

device removed in accordance with various aspects and embodiments of the present disclosure;
[0077] FIG. **28** is a diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
[0078] FIG. **29** is a cross-section perspective view of a main body of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
[0079] FIG. **30**A is a side view conceptual diagram of an example delivery device in transition to a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0080] FIG. **30**B is a side view conceptual diagram of an example delivery device in transition to a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0081] FIG. **31**A is a plan view diagram of an example delivery device illustrating example dimensions of one delivery device embodiment in accordance with an embodiment of the present disclosure;
[0082] FIG. **31**B is a side view diagram of an exemplary delivery device illustrating example dimensions of one delivery device embodiment in accordance with an embodiment of the present disclosure;
[0083] FIG. **32** is a perspective view diagram conceptually illustrating an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0084] FIG. **33** is a side view diagram of the example delivery device of FIG. **32** in accordance with various aspects and embodiments of the present disclosure;
[0085] FIG. **34** is an exploded view diagram of the delivery device shown in FIG. **32** in accordance with various aspects and embodiments of the present disclosure;
[0086] FIG. **35** is a plan view diagram of the delivery device shown in FIG. **32** in accordance with various aspects and embodiments of the present disclosure;
[0087] FIG. **36** is a cross section view diagram of the delivery device shown in FIG. **32** taken at the indicated cut plane in FIG. **35** in accordance with various aspects and embodiments of the present disclosure;
[0088] FIG. **37** depicts a representational illustration of an example delivery device including a dispensing assembly in accordance with various aspects and embodiments of the present disclosure;
[0089] FIG. **38** depicts a representational illustration of an example delivery device including a dispensing assembly in accordance with various aspects and embodiments of the present disclosure;
[0090] FIG. **39** depicts a representational illustration of an example delivery device including a dispensing assembly in accordance with various aspects and embodiments of the present disclosure;
[0091] FIG. **40** depicts a perspective view of an example delivery device and bias member in accordance with various aspects and embodiments of the present disclosure;
[0092] FIG. **41** depicts a perspective view of an example bias member which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0093] FIG. **42** depicts a cross-sectional view of a portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0094] FIG. **43** depicts a cross-sectional view of a portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0095] FIG. **44** depicts a perspective view of an example depressor body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0096] FIG. **45** depicts an example depressor body and bias member where the bias member is in a stressed state in accordance with various aspects and embodiments of the present disclosure;
[0097] FIG. **46** depicts a cross-sectional view of an example depressor body and bias member where the bias member is in a stressed state in accordance with various aspects and embodiments of the present disclosure;

[0098] FIG. **47**A depicts a perspective view of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;
[0099] FIG. **47**B depicts a perspective view of an exemplary stop member which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0100] FIG. **47**C depicts a perspective view of an example delivery assembly and example stop member which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0101] FIG. **47**D depicts a perspective view of an example bias member and example depressor body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0102] FIG. **48** depicts a representational illustration of an example delivery device including a bias member in accordance with various aspects and embodiments of the present disclosure;
[0103] FIG. **49**A depicts a bottom plan view of an exemplary main body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0104] FIG. **49**B depicts a perspective view of an example main body and example bias member which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0105] FIG. **49**C depicts a perspective view of an example main body and example bias member which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0106] FIG. **50**A depicts a side view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0107] FIG. **50**B depicts a cross-section view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0108] FIG. **51** depicts an exploded view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0109] FIGS. **52**A-**52**B depict views of portions of an example delivery device respectively in a storage state and a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0110] FIG. **53** depicts a bottom view of an example main body of a delivery device and a portion of a depressor body in accordance with various aspects and embodiments of the present disclosure;
[0111] FIG. **54**A is a perspective view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
[0112] FIG. **54**B is a side view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
[0113] FIG. **54**C is a bottom-up plan view diagram of an example holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
[0114] FIG. **54**D is a perspective view diagram of an exemplary holder for a sharp bearing body in accordance with various aspects and embodiments of the present disclosure;
[0115] FIG. **55**A depicts a perspective view of an example holder including a stage projection in accordance with various aspects and embodiments of the present disclosure;
[0116] FIG. **55**B depicts a perspective view of an example holder including a stage projection in accordance with various aspects and embodiments of the present disclosure;
[0117] FIG. **55**C depicts a bottom plan view of an example holder including a stage projection in accordance with various aspects and embodiments of the present disclosure;
[0118] FIG. **56**A depicts a side view of an example holder including a stage projection to which an example sharp bearing body is mounted in accordance with various aspects and embodiments of the present disclosure;
[0119] FIG. **56**B depicts a detailed view of the indicated region of FIG. **56**A in accordance with various aspects and embodiments of the present disclosure;

[0120] FIG. **56**C depicts a cross-sectional view of an example holder including a stage projection to which an example sharp bearing body is mounted in accordance with various aspects and embodiments of the present disclosure;
[0121] FIG. **56**D depicts a detailed view of the indicated region of FIG. **56**C in accordance with various aspects and embodiments of the present disclosure;
[0122] FIG. **57** depicts a view of a portion of an example sharp bearing body;
[0123] FIG. **58** depicts a view of a portion of another example sharp bearing body;
[0124] FIG. **59** depicts a view of a portion of another example sharp bearing body;
[0125] FIG. **60** depicts a view of a portion of another example sharp bearing body;
[0126] FIG. **61** depicts a perspective view of another example sharp bearing body having a plurality of example microneedles projecting therefrom;
[0127] FIG. **62**A depicts a view of a backside of a sharp bearing body overmolded into a molded component;
[0128] FIG. **62**B depicts a cross-sectional view taken at the indicated cut plane of FIG. **62**A:
[0129] FIG. **62**C depicts a detailed view of the indicated region of FIG. **62**B;
[0130] FIG. **63** depicts a cross-sectional view of an example mold which may be used to overmold a component onto a sharp bearing body;
[0131] FIG. **64** depicts another cross-sectional view of an example mold which may be used to overmold a component onto a sharp bearing body;
[0132] FIG. **65**A depicts a cross-sectional view of an example sharp bearing body and set of shut-offs;
[0133] FIG. **65**B depicts a perspective view of an example mold shut-off;
[0134] FIG. **65**C depicts cross-sectional view depicting a set of microneedles positioned in pockets of an example shut-off;
[0135] FIG. **66** depicts a block diagram depicting various portions of an example mold and a number of ejector pins;
[0136] FIG. **67** depicts a block diagram of an example mold;
[0137] FIG. **68** depicts a view of a portion of an example ejector pin with a cleat;
[0138] FIG. **69**A depicts a perspective view of an example sharp bearing body in an example component surrounded by a bead of material which may be deformed via swaging to couple the sharp bearing body to the component in accordance with various aspects and embodiments of the present disclosure;
[0139] FIG. **69**B depicts a cross-sectional view of the example sharp bearing body and component of FIG. **69**A in accordance with various aspects and embodiments of the present disclosure;
[0140] FIG. **69**C depicts a detailed view of the indicated region of FIG. **69**B in accordance with various aspects and embodiments of the present disclosure;
[0141] FIG. **70**A depicts a perspective view of an example sharp bearing body in an example component surrounded by a bead of material which may be deformed via swaging to couple the sharp bearing body to the component in accordance with various aspects and embodiments of the present disclosure;
[0142] FIG. **70**B depicts a cross-sectional view of the example sharp bearing body and component of FIG. **70**A in accordance with various aspects and embodiments of the present disclosure;
[0143] FIG. **70**C depicts a detailed view of the indicated region of FIG. **70**B in accordance with various aspects and embodiments of the present disclosure;
[0144] FIG. **71**A is a perspective view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure
[0145] FIG. **71**B is a side view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;
[0146] FIG. **71**C is a perspective view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;

[0147] FIG. **71**D is a plan view diagram of an exemplary portion of a reservoir in accordance with various aspects and embodiments of the present disclosure;
[0148] FIG. **72** depicts a perspective view of an exemplary reservoir in accordance with various aspects and embodiments of the present disclosure;
[0149] FIG. **73** depicts a perspective view of another exemplary reservoir in accordance with various aspects and embodiments of the present disclosure;
[0150] FIG. **74** is a block diagram of an example reservoir assembly in accordance with various aspects and embodiments of the present disclosure;
[0151] FIG. **75** is a block diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0152] FIG. **76**A depicts a block diagram of an example reservoir assembly in accordance with various aspects and embodiments of the present disclosure;
[0153] FIG. **76**B depicts a block diagram of an example reservoir assembly in accordance with various aspects and embodiments of the present disclosure;
[0154] FIG. **77** depicts a representational illustration of an example delivery device including a reservoir partitioned into a plurality of portions in accordance with various aspects and embodiments of the present disclosure;
[0155] FIG. **78** depicts a block diagram of an example delivery device having a delivery unit and a trigger unit in accordance with various aspects and embodiments of the present disclosure;
[0156] FIG. **79**A depicts an illustrative diagram of an example guide which may be including in a delivery unit of certain example delivery devices in accordance with various aspects and embodiments of the present disclosure;
[0157] FIG. **79**B depicts and illustrative diagram of an portions of an example delivery device in an initial state in accordance with various aspects and embodiments of the present disclosure;
[0158] FIG. **79**C depicts an illustrative diagram of portions of an example delivery device in a state in which pressure has been applied to a trigger body of the example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0159] FIG. **79**D depicts an illustrative diagram of an example delivery device transitioned into a trigger state in accordance with various aspects and embodiments of the present disclosure;
[0160] FIG. **79**E depicts an illustrative diagram of an example delivery device at the end of a first stage of actuation of the delivery device in accordance with various aspects and embodiments of the present disclosure;
[0161] FIG. **79**F depicts an illustrative diagram of an example delivery device at the end of a second stage of actuation of the delivery device in accordance with various aspects and embodiments of the present disclosure;
[0162] FIG. **80**A depicts an exploded perspective view of an exemplary delivery device with a trigger unit and a delivery unit in accordance with various aspects and embodiments of the present disclosure;
[0163] FIG. **80**B depicts another exploded perspective view of an exemplary delivery device with a trigger unit and a delivery unit in accordance with various aspects and embodiments of the present disclosure;
[0164] FIG. **80**C depicts cross-sectioned view of a main body and trigger body of an example delivery device with a portion of a rigid guide body of the main body removed in accordance with various aspects and embodiments of the present disclosure;
[0165] FIG. **81**A depicts a perspective view of an example delivery device with a lock installed thereon;
[0166] FIG. **81**B depicts a cross-sectional view of a portion of an example delivery device and lock;
[0167] FIG. **82** depicts a top plan view of an example lock;
[0168] FIG. **83** depicts an exploded view of an example delivery device with a lock;

[0169] FIG. **84** depicts a perspective view of an exemplary guide insert;
[0170] FIG. **85** depicts a perspective view of an example main body of a delivery device;
[0171] FIG. **86** depicts a diagrammatic view of an example trigger body for a delivery device;
[0172] FIGS. **87**A-**87**B depict views of an example reservoir interface member having regions of contrasting appearance.
[0173] FIG. **88**A depicts a view of an example delivery device having a window with which a first region of a reservoir interface member is aligned; and
[0174] FIG. **88**B depicts a view of an example delivery device having a window with which a second region of a reservoir interface member is aligned;
[0175] FIG. **89**A depicts a block diagram view of an example delivery device with an example rocker member in accordance with various aspects and embodiments of the present disclosure;
[0176] FIG. **89**B depicts a block diagram view of an example delivery device with an example rocker member in accordance with various aspects and embodiments of the present disclosure;
[0177] FIG. **90**A depicts a perspective view of an example delivery device including an example rocker member in accordance with various aspects and embodiments of the present disclosure;
[0178] FIG. **90**B depicts a perspective view of another example delivery device including a plurality of example rocker members in accordance with various aspects and embodiments of the present disclosure;
[0179] FIG. **91** depicts a flowchart detailing a number of example actions which may be executed to delivery agent with a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0180] FIG. **92** depicts an illustration of an example delivery device after being applied to a user in accordance with various aspects and embodiments of the present disclosure;
[0181] FIG. **93** depicts an illustration of an example delivery device in process of transitioning from a storage state to a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0182] FIG. **94** depicts an illustration of an example delivery device in process of transitioning from a storage state to a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0183] FIG. **95** depicts an illustration of a delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0184] FIG. **96**A depicts a view of an example main body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0185] FIG. **96**B depicts a side view of an example main body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0186] FIG. **97** depicts a detailed view of a portion of an exemplary main body in accordance with various aspects and embodiments of the present disclosure;
[0187] FIG. **98**A depicts a view of an example main body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0188] FIG. **98**B depicts a side view of an example main body which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0189] FIG. **99**A depicts a top front right perspective view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0190] FIG. **99**B depicts a bottom plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0191] FIG. **99**C depicts a top plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0192] FIG. **99**D depicts a front side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0193] FIG. **99**E depicts a right side view of an example portion of an example delivery device in

accordance with various aspects and embodiments of the present disclosure;
[0194] FIG. **99**F depicts a back side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0195] FIG. **99**G depicts a left side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0196] FIG. **100**A depicts a top front right perspective view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0197] FIG. **100**B depicts a top plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0198] FIG. **100**C depicts a bottom plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0199] FIG. **100**D depicts a front side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0200] FIG. **100**E depicts a right side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0201] FIG. **100**F depicts a back side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0202] FIG. **100**G depicts a left side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0203] FIG. **101**A depicts a top front right perspective view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0204] FIG. **101**B depicts a top plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0205] FIG. **101**C depicts a bottom plan view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0206] FIG. **101**D depicts a front side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0207] FIG. **101**E depicts a right side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0208] FIG. **101**F depicts a back side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0209] FIG. **101**G depicts a left side view of an example portion of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0210] FIG. **102**A depicts a top plan view of an example reservoir in accordance with various aspects and embodiments of the present disclosure;
[0211] FIG. **102**B depicts a bottom plan view of an example reservoir in accordance with various aspects and embodiments of the present disclosure;
[0212] FIG. **103** depicts a perspective view of an example septum in accordance with various aspects and embodiments of the present disclosure;
[0213] FIG. **104** depicts a cross-sectional view of an example reservoir including a septum in accordance with various aspects and embodiments of the present disclosure;
[0214] FIG. **105** depicts a perspective view of an example delivery device including a septum in accordance with various aspects and embodiments of the present disclosure;
[0215] FIG. **106**A depicts a perspective cross-sectional view of an example main body including retention tabs in accordance with various aspects and embodiments of the present disclosure;
[0216] FIG. **106**B depicts a detailed view of the indicated region of FIG. **106**A in accordance with various aspects and embodiments of the present disclosure;
[0217] FIG. **107**A depicts a bottom plan view of an example delivery device with an example adhesive member in accordance with various aspects and embodiments of the present disclosure;
[0218] FIG. **107**B depicts a bottom plan view of another example delivery device with another

example adhesive member in accordance with various aspects and embodiments of the present disclosure;
[0219] FIG. **107**C depicts a bottom plan view of another example delivery device with another example adhesive member in accordance with various aspects and embodiments of the present disclosure;
[0220] FIG. **108**A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0221] FIG. **108**B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0222] FIG. **109**A is a side view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;
[0223] FIG. **109**B is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;
[0224] FIG. **109**C is a side view diagram of an example delivery device in a third state in accordance with various aspects and embodiments of the present disclosure;
[0225] FIG. **110**A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0226] FIG. **110**B is a cutaway view diagram of an example flexure of a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0227] FIG. **110**C is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0228] FIG. **111**A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0229] FIG. **111**B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0230] FIG. **112** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0231] FIG. **113** is a plan view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0232] FIG. **114**A is a side view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;
[0233] FIG. **114**B is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;
[0234] FIG. **114**C is a side view diagram of an example delivery device in a third state in accordance with various aspects and embodiments of the present disclosure;
[0235] FIG. **115** is a cross section view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0236] FIG. **116**A is a block diagram of an example delivery device in a storage state in accordance with various aspects and embodiments of the present disclosure;
[0237] FIG. **116**B is a block diagram of an example delivery device in a delivery state in accordance with various aspects and embodiments of the present disclosure;
[0238] FIG. **117** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0239] FIG. **118** is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0240] FIG. **119** is an exploded view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0241] FIG. **120** is an exploded view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0242] FIG. **121**A is a side view diagram of an example delivery device in a first state in

accordance with various aspects and embodiments of the present disclosure;
[0243] FIG. **121**B is an enlarged view of the indicated region of the delivery device of FIG. **121**A in accordance with various aspects and embodiments of the present disclosure;
[0244] FIG. **122**A is a side view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;
[0245] FIG. **122**B is an enlarged view of the indicated region of the delivery device of FIG. **122**A in accordance with various aspects and embodiments of the present disclosure;
[0246] FIG. **123** is a cross section view diagram of an example delivery device in a first state in accordance with various aspects and embodiments of the present disclosure;
[0247] FIG. **124** is a cross section view diagram of an example delivery device in a second state in accordance with various aspects and embodiments of the present disclosure;
[0248] FIG. **125** depicts an exploded view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0249] FIG. **126** depicts an exploded view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
[0250] FIG. **127** is a perspective view diagram of an example flexure which may be included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;
[0251] FIG. **128** is a side view diagram of an example flexure which may be included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;
[0252] FIG. **129** is a plan view diagram of an example flexure which may be included as or as part of an actuation assembly of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;
[0253] FIG. **130** depicts a perspective view of an example package for a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0254] FIG. **131** depicts a view of an example main body of a delivery device separated for an example reservoir assembly which may be included in a delivery device in accordance with various aspects and embodiments of the present disclosure;
[0255] FIG. **132** depicts a view of an example delivery device being removed from skin of a patient revealing a mark created on the skin by the delivery device in accordance with various aspects and embodiments of the present disclosure; and
[0256] FIG. **133** depicts an example thermal image of an injection site in which a bleb from an injection into the skin is visible in accordance with various aspects and embodiments of the present disclosure.

DETAILED DESCRIPTION

[0257] FIG. **1**A and FIG. **1**B depict an embodiment of an exemplary delivery device **10**. The example delivery device **10** may be a low profile delivery device **10** which may be applied over the skin of a patient. The example delivery device **10** may be sized for handheld use and may be easily applied to a wide variety of injection sites over a patient's body. Additionally, the example delivery device **10** may be designed for use by a patient or relatively untrained or minimally trained individual. Thus a medical caregiver may not be necessary for use of the delivery device **10**.
[0258] Such delivery devices **10** may be used to dispense a medical agent from a reservoir **12** included as part of the delivery device **10** into a target delivery destination of a patient via one or more delivery sharp **72**. The reservoir **12** may be at least partly flexible and may have a variable volume which may deplete as fluid is dispensed from the reservoir **12**. As the reservoir **12** depletes, the reservoir **12** may at least partially collapse. In the example embodiment, a plurality of delivery sharps **72** are included in the delivery device **10**, though other embodiments may only include a single delivery sharp **72**. The exemplary plurality of delivery sharps **72** may be arranged in a one or two dimensional array and may extend from the reservoir **12**. Where multiple delivery sharps **72**

are included, the delivery sharps **72** may be arranged in one or more rows and/or columns. Though three delivery sharps **72** arranged in a single row are depicted in FIG. **1**A, the number and arrangement of delivery sharps **72** may differ in alternative embodiments. Any suitable number of rows and/or columns may be included in various examples. In various embodiments there may, for example, be a single row array of delivery sharps **72** including up to five delivery sharps **72**. Preferably, the delivery sharps **72** may be arranged so as to prevent a bed of nails type scenario in which penetration of the skin via the delivery sharps **72** may be inhibited or inconsistent across users or delivery devices **10**. This may occur when too many delivery sharps **72** are arranged in close proximity to one another. Thus, the array may be referred to as a spaced array of delivery sharps **72**.

[0259] The delivery sharps **72** may be selected based on the desired target delivery destination in a patient. In certain embodiments, the target delivery destination may be a transcutaneous location. For example, the target delivery destination may be a subcutaneous delivery destination or an intramuscular delivery destination. Alternatively, the target delivery destination may be a shallow delivery destination between the stratum corneum of a patient and the subcutaneous tissue of the patient. Such shallow destinations may be referred to herein as intradermal delivery destinations. Shallow delivery destinations may include an epidermal or dermal target location or may, for example, target a junctional area between the epidermis and dermis or dermis and subcutis. In the example embodiment, the delivery sharps **72** are depicted as microneedles. Such delivery sharps **72** may be present in delivery devices **10** with shallow (e.g. above subcutaneous tissue) target delivery destinations. In alternative embodiments where, for instance, the target delivery destination is a subcutaneous or intramuscular location, conventional delivery sharps (e.g. 30-gauge needle) may be utilized.

[0260] Referring now also to FIG. **2**, where microneedles are used, the microneedles described herein may, in certain embodiments, be MEMS produced, polyhedral (e.g. pyramidal), silicon crystal microneedles. These microneedles may be no greater than 1 mm in height, e.g. 0.6 mm or 0.8 mm (though longer or shorter microneedles may also be used). At least some edges of the microneedles may be rounded or filleted, though such microneedles may still be referred to herein as polyhedral. In some examples and as shown in FIG. **2**, the microneedles described herein may be generally in the shape of a heptagonal prism (though pentagonal, nonagonal, and other polygonal prisms may also be used as the base shape) which has been diagonally 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 **14** of the top face of the prism through the most distal side **15** of the base **17**. At least two sides of the base of the microneedle may be parallel. The side walls **19** may extend substantially perpendicularly from the base **17**. The microneedle may be substantially symmetric about a line of symmetry extending from the vertex **14** to a point above the center of the most distal side **15**. In other embodiments, the microneedles may be conically shaped. Any other suitable shape may be used. In the example, the vertex **14** is shown as a point which forms a tip of the microneedle. In other embodiments, this portion of a microneedle may be rounded (though may still be referred to herein as a vertex **14** and such microneedles may still be referred to as pointed). In such embodiments, the back facing edge **23** may be a round face or the back facing edge **23** and the adjacent side walls **19** may be replaced by a rounded face.

[0261] The points or tips of microneedles described herein may be solid and the flow lumens **126** through the microneedles may be offset from the points or tips (in FIG. **2** the vertex **14** forms the tip) of the microneedles. Hollow tipped microneedles in which the flow lumen **126** extends to the tip of the microneedle may also be utilized. In some embodiments, the microneedles may be NanoPass hollow microneedles available from NanoPass Technologies Ltd. of 3 Golda Meir, Nes Ziona, Israel. It should be noted that microneedles (or the substrate on which they are disposed) described herein as constructed of silicon may have a surface layer of silicon dioxide (which may, for example, form with exposure to air) while still being considered constructed of silicon.

[0262] With reference to FIGS. **3**A-**4**B, in some embodiments microneedles may be constructed to include certain features that may help to reduce the pressure required to inject fluid, such as a medical agent, into the skin of a patient. In some examples, features common certain to insect stingers or biological venom administration structures may be incorporated. These features may include various recesses or depressions which are formed as part of each microneedle or at least one microneedle of a delivery device **10**. These recesses or depressions may fluidly communicate with the flow lumen **126** of the respective microneedle. In some embodiments, different microneedles of a delivery device **10** may include different recesses or some microneedles may include a plurality of recesses which could be of different varieties (though need not be).
[0263] For example, as shown in FIGS. **4**A-**4**B, a microneedle may include a channel or trough **200** on an exterior sloped face **21** leading from the flow lumen **126** toward the distal side **15**. The channel **200** may allow medical agent to flow through it along the outer side of the microneedle to find a path of least resistance, or weakest link, into the skin. In the embodiments shown, medical agent may be routed by the channel **200** to flow along the outer side of the microneedle to a weak region in the skin in the event the outlet of the flow lumen **126** has been inserted to a greater depth than the depth of the weak region. The lamina lucida junction, an intradermal delivery destination, is a weak link in the skin structure, and is difficult to consistently inject directly into due to its relative thinness (it is typically on the order of 40 nm thick). A microneedle including a channel **200** may, for example, allow flow of medical agent to the lamina lucida junction when the lamina lucida junction has been passed by the outlet of the flow lumen **126**. The channel **200** may facilitate distribution of the medical agent through a larger area of entry or injection. In some examples, incorporating a channel **200** into a microneedle may reduce the pressure required to inject a medical agent into the skin considerably. In certain examples pressure may be reduced by 600% or more (e.g. from 120 pounds per square inch (psi) to from 18 to 20 psi in certain examples).
[0264] An appropriate silicon etching technique (or mold in embodiments using polymeric microneedles) may be used to create steeper side walls of the channel **200**. This may help inhibit the skin from bending into and occluding the channel **200**. Etching techniques that could be used include, by way of non-limiting example, chemical etching techniques (e.g., acid). Suitable etching techniques may include ion based etching techniques (e.g. reactive ion etching). The etching process could be a wet etching process or a dry etching process. In some non-limiting embodiments, the channel **200** may be within a range of 50-60 microns wide from side to side. In some non-limiting embodiments, the flow lumen **126** may have a diameter of 50-60 microns. The channel **200** may have a width equal to the diameter or widest portion of the flow lumen **126** or the channel **200** may have a width which is less than or greater than the width of the flow lumen **126**. In certain examples, the width of the channel **200** may be about 5-10 percent of the height of the microneedle.
[0265] To avoid leakage of the fluid from the channel **200**, it may be desirable to ensure that the channel **200** terminates at least a certain distance beneath the surface of the skin yet also reaches the targeted skin layer (e.g., the lamina lucida junction) when the microneedle is inserted into the skin. In some embodiments the channel **200** extends from the flow lumen **126** to within at most 50 microns (e.g. 50-200 microns) of the base **17** of the microneedle. In some embodiments, the end of the channel **200** most proximal the base **17** of the microneedle may be at least below the stratum corneum (and perhaps one or more of the stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale) when the microneedle is inserted into the skin. In some embodiments, the end of the channel **200** most proximal the base **17** may be disposed below the epidermis (e.g. in the basement membrane) or within the epidermis.
[0266] The channel **200** need not be straight or shaped in the manner shown in and described with reference to FIGS. **4**A-**4**B. In some embodiments, the channel **200** may be a more meandering channel **200**. A curved channel **200** could, for example, be used provided the dimensions of the microneedle are accommodated. Moreover, there need not be only one channel **200**. More than one

channel could be used provided structural integrity of the microneedle is accommodated.
[0267] The depth of the channel **200** may be about 25 microns or more (e.g. 25-50 microns) in certain examples. The depth of the channel **200** may be or be less than 5 percent the height of the microneedle. While the depth of the channel **200** may be constant along the length of the channel **200**, the depth of the channel **200** need not be constant along the length of the channel **200**. Likewise, the width of the channel **200** need not be constant along the length of the channel **200** (see, e.g., FIG. **5**B). The width of the channel **200** may be about 20-30 percent of the width of the distal side **15** of the microneedle at the narrowest point in the channel **200**. In some embodiments, the width of the channel **200** may increase as distance to the distal side **15** decreases. In some embodiments, at its widest, the channel **200** may have a width which is 50% or more the width of the distal side **15**.
[0268] Referring now also to FIG. **5**A and FIG. **5**B, in other examples, the channel **200** may extend from the location of the lumen **126** toward the tip or vertex **14** of the microneedle (see, e.g., FIG. **5**B). Moreover, in some examples, the channel **200** may extend both toward the vertex **14** and toward the base **17** from the location of the lumen **126**. That is, the channel **200** may include a portion on both sides of the lumen **126** (see, e.g., FIG. **5**A). As shown, the lumen **126** may be located substantially centrally in the sloped face **21** of the microneedle. In such embodiments, a channel **200** may extend toward the distal side **15** of the base **17** and a channel **200** may extend toward the tip or vertex **14**. In other embodiments, the lumen **126** may be positioned at (or near) an end of the channel **200** most proximal the base **17**.
[0269] Referring now to FIGS. **6**A-**6**B, views of a sharp bearing body **26** including a number of microneedles are shown. In certain embodiments, a channel **200** may not be included. Instead, a microneedle may include a flow lumen **126** with an elongate cross-section (at least at the outlet, see also FIG. **7**B and FIG. **8**B). Microneedles with channels **200** and elongate lumens **126** are also possible. When in place within the patient, an elongate lumen **126** may be in fluid communication with, for example, multiple layers of skin. Thus, a thin and/or weak layer of skin may be easier to target when the microneedle is advanced into a patient. Elongate lumens **126** may also help to lower pressure required to inject. Such elongate flow lumens **126** may have any suitable cross-section. In some embodiments, the cross-section may be oval or elliptical. Alternatively, a lumen **126** with an obround cross-section may be used as is shown in FIGS. **6**A-**6**B. Polygonal cross-sectional shapes may also be used, such as though not limited to rectangular, trapezoidal, triangular, etc. In certain examples, the length (in the direction of elongation) of the cross-section of the lumen **126** may be up to 100-200 microns or greater (though could be less in certain examples). Where elongate lumens **126** are included, the end of the lumen **126** most proximal the distal side **15** may be spaced from the distal side **15** by at least a certain distance. The spacing may be such that, the end of the lumen **126** most proximal the distal side **15** may be at least below the stratum corneum (and perhaps one or more of the stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale) when the microneedle is inserted into the skin. In some embodiments, it may be disposed below the epidermis (e.g. in the basement membrane) or within the epidermis.
[0270] Still referring to FIGS. **6**A-**6**B in certain embodiments, the sloped face **21** of a microneedle may not extend to the base **17** of a microneedle. There may, for example, be a vertical face **13** extending from the base **17** to the distal side **15** of a microneedle. Where a vertical face **13** is included, the vertical face **13** may be aligned with a side (e.g. distal side **15**) of a sharp bearing body **26** and may form an extension thereof. Including such vertical faces **13** may aid in reducing the size of a sharp bearing body **26** and may aid in ensuring consistent fluid delivery into a target destination for certain microneedles. Though shown in relation to FIGS. **6**A-**6**B, any of the microneedles shown herein may be arranged with vertical faces **13**.
[0271] Additionally or in the alternative, a microneedle may include a depression **202**. The depression **202** may include first and second opposing vertices **204**, **206**. In some embodiments, the depression **202** may be (though need not necessarily be) a rounded depression or a concave

depression, as shown in FIGS. **3**A-**3**B. The depression **202** may have a maximum depth which places the depression **202** into fluid communication with the flow lumen **126** of the microneedle. The depression **202** may thus form a side port for the microneedle through which fluid may be delivered to the patient. The side port may be the only outlet of the microneedle or may be in addition to an outlet of the lumen in the face **21** of the microneedle. When the microneedle is inserted into the skin surface, fluid contained in a delivery device **10** may be delivered to the patient, at least in part, by being pumped into the depression **202**. The depression **202** may be formed, for example by cutting away material during manufacture of the microneedle or the depression **202** may be formed during a molding operation. Cutting away material may be accomplished by any known suitable process such as, for instance, etching (e.g. wet etching). In some embodiments, the depression **202** may be recessed in at least one side wall **19** or edge (e.g. where two side walls **19** join) of the microneedle. In the example shown in FIGS. **3**A-**3**B, the depression **202** is formed in a substantially vertical back facing edge **23** of the microneedles which extends from the base **17** to the vertex **14**. This may establish or increase a vertical void volume created by the microneedle as the skin is penetrated by the microneedle. That is, such a depression **202** may establish an open space in a patient into which fluid may be easily delivered from the microneedle. Positioning the depression **202** in the back facing edge **23** may provide a path of low resistance for a fluid to enter skin that the microneedle has penetrated. In embodiments wherein the microneedle includes at least one substantially vertical wall, the depression **202** may be recessed into a substantially vertical wall. In the example embodiment, the maximum depth of the depression **202** may be about 130% to 110% of the distance from the back facing edge **23** to the flow lumen **126**.

[0272] In certain examples, and referring now to FIG. **7**A and FIG. **7**B, a microneedle may include a sloped face **21** to which a lumen **126** extending through the microneedle extends. A microneedle may also include a rounded blade edge **31**. In the example, the rounded blade edge **31** extends from a point **33** opposite the distal side **15** and extends in an arcuate path to the vertex or tip **14** of the microneedle. In the example, the rounded blade edge **31** includes a double bevel, though other bevel types may be used. The rounded blade edge **31** may arc at a constant radius or a variable radius. The rounded blade edge **31** may have an arc measure of less than 90° or, in certain examples, greater than 90° (see, e.g., FIG. **8**A-**8**C). The rounded blade edge **31** may aid in introduction of a microneedle into skin when the microneedle is inserted at certain angles or over a variety of different angles.

[0273] In yet another embodiment, and referring now to FIGS. **8**A-**8**C, a microneedle may include a rounded blade edge **31** and a lumen outlet face **35**. The lumen **126** may extend through the microneedle to the lumen outlet face **35** and may not be formed in a straight line through the microneedle. The lumen outlet face **35** may be angled from the vertex **14** to the distal side **15** so as to form an undercut. The distal edge **15** may be disposed such that a plane perpendicular to the base **17** passing through the distal edge **15** may also pass through the rounded or arcuate blade edge **31**. Additionally, the outlet of the flow lumen **126** in the lumen outlet face **35** may be disposed such that a plane or all planes perpendicular to the base **17** and passing through the outlet of the flow lumen **126** may also pass through the blade edge **31**. This need not be true in all embodiments (see, e.g., FIGS. **7**A-**7**B). As a microneedle of the variety shown in FIGS. **8**A-**8**C is inserted, a vertical void space may be created due to the undercut. This may provide a low resistance pathway for fluid injection. Additionally, the undercut may help to mitigate potential for the lumen **126** to become obstructed by skin as the microneedle is inserted into a patient or as the delivery occurs.

[0274] In still other embodiments and referring now to FIGS. **9**A-**9**D, the delivery sharp(s) **72** may be or include a microneedle which has a shape with a high aspect ratio. In some embodiments, microneedles may be obelisk shaped. Such microneedles may be included in an array such as any array described herein. Where obelisk type microneedles are used, the microneedles may include a base **17**′. The base **17**′ may be any desired round or polygonal shape. For purposes of example,

FIGS. **9**A-**9**D depict a base **17**′ which is a quadrilateral or rhombus. The example microneedle includes a set of sidewalls **19**′ which extend from the base **17**′ to an end region **25** of the microneedle. The sidewalls **19**′ may be disposed at an angle which is not perpendicular to the base **17**′. Thus the microneedle may taper so as to have a smaller cross-sectional area as distance from the base **17**′ increases. A portion of the microneedle most distal to the base **17**′ may include a beveled tip **27**. Such a tip **27** may facilitate puncture of the skin and may aid in increasing the robustness of the end region **25**. Any suitable bevel such as a single or double bevel may be used.
[0275] In embodiments of microneedles which are obelisk shaped, the microneedles may include at least one side port **29** which may serve as an outlet for that microneedle. Such side port(s) **29** may be difficult to block off with tissue which that may become compressed during insertion of the microneedle into a patient. In the example embodiment, a lumen **126** may extend through the base **17**′ of the microneedle and have a terminal end which is more proximal the end region **15** than the base **17**′. The lumen **126** may be of relatively constant cross-section. The taper of the sidewalls **19**′ may be such that the terminal end of the lumen **126** is wider than portions of the cross-section of the corresponding region of the microneedle. Thus, the lumen **126** may form openings in the sidewalls **19**′ which may serve as the side ports **29**. In various examples, the lumen **126** may be centrally disposed yielding symmetrical side ports **29**. In alternative embodiments, the lumen **126** need not be centrally disposed and the side ports **29** may not be symmetrical.
[0276] In various embodiments where silicon is not used to form the microneedles, microneedles described herein may be constructed of glass (e.g. silica glass, borosilicate glass), ceramic (e.g. alumina, calcium sulfate dehydrate, calcium phosphate dehydrate, organically modified ceramics such as Ormocer), polymer (e.g. polymethyl methacrylate or PMMA, polylactic acid or PLA, polylactic-co-glycolic acid or PLGA, polyglycolic acid or PGA, polycarbonate, cyclic-olefin copolymer or COC, polyvinylpyrrolidone or PVP, polyvinyl alcohol PVA, polystyrene, polymethyl vinyl ether-co-maleic anhydride), carbohydrate, or metal (e.g. stainless steel, titanium, palladium, nickel, alloys such as palladium cobalt alloys, etc.). Any suitable microneedle constructions including dissolvable microneedles may be used. Microneedles and features thereof may be manufactured in one or more of, though are not limited to, a molding process, etching process, ablative process (e.g. laser ablation), or a material additive process (e.g. 3D printed). In various embodiments, it may be desirable that microneedles be constructed of a biocompatible, non-ductile, high Young's modulus material with an indentation hardness sufficient to allow penetration into skin without breakage.
[0277] Referring now to S. **10**A-**10**D, views of a sharp bearing body **26** including a pair of microneedles are depicted. Such sharp bearing bodies **26** may be preferable for certain fluid delivery applications such as those in which relatively slow delivery of fluid is acceptable or in scenarios where fluid is not delivered via a sustained, manually applied force. Such sharp bearing bodies **26** may also be particularly well suited where a user does not manually maintain the orientation of a delivery implement (e.g. syringe). By including only a pair of microneedles on a sharp bearing body **26**, more sharp bearing bodies **26** may be created out the same wafer of silicon material even while increasing the height of the microneedles. This may also make such sharp bearing bodies **26** more cost efficient without adversely impacting delivery in devices where the orientation of the device is not manually maintained and relatively slow delivery is acceptable.
[0278] As shown, the sharp bearing body **26** is arranged such that the cross-sectional area of the sharp bearing body **26** increases as distance from the sharp bearing face of the sharp bearing body **26** increases. In the example, the sharp bearing body **26** has a stepped appearance, though any arrangement described in relation to FIGS. **57**-**61** may be used. Though not shown, the example microneedles depicted in FIGS. **10**A-**10**B could include a vertical face **460** as described in relation to FIGS. **6**A-B and FIG. **61**. Other features such as any channels **200** described herein may also be included.
[0279] As shown, each of the microneedles includes a tip region **845** and a trailing region **847**. The

tip region **845** includes a rounded vertex **31** and back facing edge **23**. The vertex **31** and back facing edge may in certain examples have a radius of 25-40 microns (e.g. 34 microns). At least one additional radiused region **861** may connect the back facing edge **23** to the trailing region **847** on each side of the microneedle. In the example the at least one additional radiused region is a single constant radiused region on each side of the microneedle. In certain examples, the radius of this region may be 310-335 microns (e.g. 324 microns). Thus, the entire tip region **845** may be rounded with the sidewalls **19** in this region being devoid of straight spans or corners. This may generate a microneedle with a particularly robust tip region **845**. The sidewalls **19** on each side of the microneedle in the trailing region **847** may be planar. In certain examples, the sidewall segments on each side of the microneedle may be oriented parallel to one another. In alternative examples, the sidewall segments in the trailing region **847** may be at a slight angle to one another (e.g. less than 25° to one another). Greater angles are also possible.

[0280] The lumen **126** for the microneedle may be disposed in the tip region **845** in a central position with respect to the sidewalls **19** on each side of the microneedle. The lumen **126** may be defined by a first radiused wall **867** most proximal the vertex **31** and back facing edge **23**. The distance between the back facing edge **23** and the closest portion of the first radiused wall **867** may be 65-80 microns. The lumen **126** may also be defined by a second radiused wall **873** forming the portion of the lumen **126** most distal to the vertex **31** and back facing edge **23**. The first radiused wall **867** may have a tighter radius than the second radiused wall **873**. In some examples, the first radiused wall **867** may have a radius of 23.5-33.5 microns and the second radiused wall **873** may have a radius of 35-42.5 microns. Straight spans **871** may be present on each side of the lumen **126** to connect the ends of the first radiused wall **867** to respective ends of the radiused wall **873**. The minimum distance between the sidewall of the microneedle and the closest wall of the lumen **126** may be 25-30 microns.

[0281] Referring again primarily to FIG. **1**A and FIG. **1**B, delivery devices **10** described herein may deliver any of a variety of medications or other medical agents to a patient. In certain embodiments, the reservoir **12** of the delivery device **10** may be filled with a vaccine. Such a delivery device **10** may deliver any suitable vaccine, though may be 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.

[0282] Any suitable vaccine may be delivered via such a delivery device **10**. For example, the vaccine may be but is not limited to, attenuated live vaccines, inactivated virus vaccines, acellular vaccines, cellular vaccines, toxoid vaccines, heterotypic or Jennerian vaccines, monovalent vaccines, polyvalent vaccines, nucleic acid vaccines (e.g. DNA, plasmid vaccine, mRNA), virus like particle vaccines, recombinant vector vaccines (e.g. replicating, non-replicating), dendritic cell vaccines, T-cell receptor peptide vaccines, chimeric vaccines, subunit vaccines, nanoparticle vaccines, recombinant protein vaccines, polysaccharide vaccines, and conjugate vaccines. It should

be noted that these are not necessarily mutually exclusive. For instance, a vaccine could be a recombinant protein nanoparticle vaccine or some other combination of the above. Vaccine may also refer to a combination vaccine (e.g. DTaP, MMR, MMRV, etc.) or a vaccination agent which targets a single pathogen or multiple strains of a single pathogen. Example vaccines may include, but are not limited to vaccines for various coronaviruses such as SARS-COV, SARS-COV-2, MERS-COV, HCOV-NL63, HCOV-229E, HCoV-OC43 and HKUI (and any variants or sub-variants thereof). Delivery devices **10** described herein are also not limited for use with humans. Such delivery devices **10** may be used for livestock, pets, services animals, or in other veterinary applications. In such cases, these delivery devices **10** may be filled with a vaccine for at least one non-human pathogen. Delivery devices **10** described herein may also be useful for research applications.

[0283] Where a delivery device **10** is filled with a vaccine, it may be desirable that the target delivery destination be a shallow delivery destination. This may be particularly desirable where the amount of available vaccine is limited. For example, such a delivery device **10** may be well suited for use with new vaccines having high demand. Vaccines for novel pathogens (e.g. SARS-COV-2 or other coronaviruses) may, for instance, be well suited for use with delivery devices **10** described herein.

[0284] Evidence suggests that shallow delivery of vaccines may provoke protective immune response with smaller amounts of vaccine antigen. As a result, dose sparing may be practiced allowing the same quantity of vaccine to be effective for immunizing a greater number of people. Alternatively or additionally, injection sparing may be possible. Shallow administration with a delivery device **10** such as those shown herein may allow for a single injection protocol where other routes of administration may require multiple injections over some period of time. One or more adjuvants may be included in some vaccine formulations to further aid in facilitating dose or injection sparing, though less reliance on adjuvants could also be possible with when a vaccine is administered intradermally.

[0285] Particularly for new vaccines generated to combat an ongoing pandemic (e.g. a vaccine for SARS-COV-2), the prospect of rapidly generating billions of doses would almost certainly exceed current vaccine production capabilities. Due to the injection and dose sparing potential of delivery devices **10** described herein, such delivery devices **10** may facilitate vaccination of large numbers of people even when a critically needed vaccine is in short supply. Additionally, as a consequence of potential dose and injection sparing, delivery devices **10** such as those shown and described herein may allow injections to be more cost effective. Moreover, due to the small volume of vaccine needed, delivery devices **10** may be made relatively small. This may simplify shipping and help to facilitate rapid distribution of vaccine to a population. This may be particularly attractive for vaccines which require cold chain distribution as packing volume may be of heightened importance.

[0286] Additionally, some studies have suggested that shallow administration may be particularly helpful in certain patient populations. For example, elderly populations may receive superior protection from vaccinations received intradermally than via other routes. That said, the Mantoux technique, which is typically used for intradermal administration, can pose reliability concerns and can be difficult to perform, especially without training. Per the World Health Organization, a large factor which has limited the use of intradermal vaccination has been the lack of a delivery platform.

[0287] Delivery devices **10**, such as those shown and described herein, may provide an attractive delivery platform for intradermal vaccination. Consequentially, delivery devices **10** described and shown herein may help to give better protection to vulnerable populations and may help in meeting the large demand for vaccines against, for example, novel pathogens by leveraging dose/injection sparing which may be possible with intradermal vaccination. Moreover, intradermal delivery devices **10** described herein may be painless or nearly pain free which may make the delivery devices **10** described herein user preferable over other types of injections. That said, and as

mentioned above, delivery devices **10** described herein are not limited to delivery via the intradermal route. Delivery devices **10** may, for instance, be configured as transdermal (e.g. subcutaneous or intramuscular) delivery devices **10**.

[0288] The example delivery devices **10** shown herein additionally are not limited to vaccine delivery devices. Such a delivery device **10** may fill a number of niches in the medical field. Other agents, for example, diagnostic or testing agents may be supplied via certain example delivery devices **10**. For instance, allergens or potential allergens may be administered via the delivery device **10**. Tuberculosis testing agents may be delivered via the delivery device **10**. Such delivery devices **10** may also be used to deliver medication for endocrine disorders. For instance, insulin may be delivered with some exemplary delivery devices **10**.

[0289] 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** described herein 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 shallow destination in the overdose victim. This may allow agent to be supplied to an overdose victim in a rapid manner. Additionally, it may obviate the need to establish an intravenous access which can be particularly difficult for users of intravenous drugs.

[0290] Still referring to FIGS. **1**A-**1**B, the delivery device **10** may include a main body **20**. The main body **20** may be a deformable body which may transition from a storage state (see FIG. **1**A) to a delivery state (see FIG. **1**B). In certain examples, this transition may be reversible, though in other embodiments the transition may result in a permanent change in the main body **20** and/or another part of the delivery device **10**. For example, once transitioned to the delivery state, the main body **20** may plastically deform such that it is permanently distorted and may not be returned to the storage state. In other examples, a frangible included in the delivery device **10** may be broken upon transition of the main body **20** to the delivery state. Alternatively or additionally, a latch, lock, or other coupling may be engaged to hold the main body **20** in the delivery state or prevent the main body **20** from returning to the storage state. Destruction of a portion of the main body **20** or a portion of the delivery device **10** engaged to the main body **20** may be required to disengage such a coupling and this destruction may render the delivery device **10** inoperative. Where a permanent change is engendered upon transition to the delivery state, this permanent change may inhibit reuse as well as provide a user perceptible (e.g. visual) indication that the delivery device **10** has been used. An indication that the transition has occurred may also be generated by the delivery device **10**. For instance, an audible or tactile indication may be generated upon engagement of a latch or breaking of a frangible.

[0291] In various examples, transition of the delivery device **10** from the storage state to the delivery state may be accomplished via bending, pivoting, or deformation of one or more regions of the main body **20**. In certain examples, the main body **20** may include one or more hinges (e.g. living hinge to aid in lowering part count) at which the main body **20** may bend. In other embodiments, the main body **20** may be or include a bi-stable element which may have a first stable state which corresponds to the storage state and a second stable state which corresponds to the delivery state. The main body **20** may for example substantially or partially invert (e.g. convex to concave) in shape or have one or more invertible regions which at least partially invert when the delivery device **10** is transitioned from the storage state to the delivery state. In some embodiments, the main body **20** may include one or more regions which may invert while also including one or more regions which distort and at least partially restore as a result of the delivery device being transitioned to a delivery state.

[0292] The transition may be affected via application of force throughout the entire transition. Alternatively, the transition may only require application of force throughout a portion of the transition. For example, in some embodiments a triggering force may be applied to initiate the

transition and the transition may subsequently complete in the absence of any external application of force. For example, after application of the triggering force, the transition may be characterized by a snap-through buckling via which the main body **20** rapidly shifts into the delivery state.
[0293] The main body **20** may be at least partially covered with adhesive **22** over a first face **24** of the main body **20**. The adhesive **22** may serve to couple the main body **20** to a skin surface at an infusion or injection site on a patient. Thus, the first face **24** may be a skin adjacent face or proximal (proximal and distal defined in relation to a patient) face of the main body **20**. The main body **20** may be adhered to the skin when the main body **20** is in the storage state and then may be transitioned to the delivery state. As the transition occurs, at least two adhesive bearing portions of the main body **20** may be displaced with respect to one another so as to stretch or spread a surface anchored to the main body **20** via the adhesive **22**. As these portions may be adhered to the skin surface, the skin may be stretched as the adhesive bearing portions are displaced with respect to one another. This may be desirable as the skin may be rendered taught facilitating piercing of the skin by the delivery sharp(s) **72** as the main body **20** transitions to the delivery state. In certain examples, the adhesive bearing portions may be disposed, for example, in opposition to one another. The displacement of the two adhesive bearing portions may increase the distance between or spread apart the two adhesive bearing portions. In other embodiments, the distance between the two adhesive bearing portions may not increase or may even decrease while still causing stretching of the skin surface. This may for example occur if the transition causes a flat patch of skin to be pulled around a curve or contour of the main body **20** (see, e.g., FIGS. **18**-**19**). A displacement of adhesive bearing portions with respect to one another that results stretching of the adhered skin (regardless of any positive or negative change in distance between the adhesive bearing portions) may be referred to as a spreading displacement. Two adhesive bearing portions which have been so displaced may be referred to as being spreadingly displaced.
[0294] Transition of the main body **20** to the delivery state may also result in a proximal displacement or lowering of the delivery sharp(s) **72** toward and into the skin. In embodiments where the delivery sharp(s) **72** are coupled to the reservoir **12**, the reservoir **12** may also be proximally displaced. In some examples, the reservoir **12** may be compressed between the skin surface and a section of the main body **20** when the main body **20** is transitioned from the storage state to the delivery state. Preferably, the delivery sharp(s) **72** may be inserted into the skin prior to the reservoir **12** being substantially compressed. Compression of the reservoir **12** may serve to drive fluid out of the reservoir **12**, through the delivery sharp(s) **72** and into the target delivery destination in the patient. In embodiments described herein, the delivery sharp(s) **72** may be covered prior to use. A fluid communication path from the reservoir **12** out of the delivery sharp(s) **72** may not be available prior to use.
[0295] In some embodiments a collapsible pouch, or packet **208**, may be positioned in the delivery device **10** above the reservoir **12** as shown in FIG. **11**A. The packet **208** may contain a substance that, in a first condition is in a dormant state, and in a second condition transitions to a motive force applying state. In an embodiment the substance may be dormant at a first temperature and apply a motive force, e.g. upon the reservoir **12**, at a second temperature. In an example embodiment, the first temperature may be colder than the second temperature. The first temperature may be a cold chain storage temperature for a vaccine. The second temperature may be room temperature or at least below average patient body temperature (e.g. 98.6° F. for humans). In some embodiments, the substance may change in volume when it transitions from a dormant state to a motive force applying state. Alternatively or additionally, the substance may change from one state of matter to another state of matter when it transitions from a dormant state to a motive force applying state. In an example embodiment, the substance may change from a liquid to a gas during the transition from a dormant state to a motive force applying state.
[0296] In an embodiment where the medical agent in a reservoir **12** of a delivery device **10** must be stored at very low temperatures, such as, e.g., when the medical agent is a vaccine with such

requirements, the packet **208** can contain a liquid. For example, a vaccine may be stored and/or shipped at commercial freezer temperatures, e.g., in the range of −18 degrees C. (or lower, e.g. −70° C. or −20° C. for certain vaccines). The liquid may have a boiling point that is greater than the medical agent (e.g., vaccine) storage temperature but less than room temperature or another suitable temperature set point. Though any suitable liquid may be used, one example of a suitable liquid is butane. Butane has a boiling point of −1° C. Though the example described herein refers to butane, one skilled in the art would appreciate the description is generalizable to any suitable liquid.

[0297] The delivery device **10** may be affixed to the skin surface of a user with the reservoir **12** containing cold stored/shipped vaccine and the packet **208** containing liquid butane (or any other suitable substance). If the ambient temperature is room temperature, e.g., about 20 degrees C., the contents will warm up (heat from the patient may aid this). The liquid butane will boil and transition to gas once it reaches its boiling point of −1° C. in the example embodiment. As the liquid boils and transitions to a gaseous state, the pressure in the packet **208** grows, causing it to expand and apply downward pressure on the reservoir **12** from above as shown in FIG. **11**B. Butane gas, for instance, has a vapor pressure of 35.4 psi at 25° C. Accordingly, a final pressure on the reservoir **12** may be higher (e.g. around 38 psi) due to heat transfer from the patient to the packet **208**. The main body **20** of the delivery device **10** may be sufficiently resilient to not deform under the pressure applied from the packet **208**. This may aid in directing pressure against the reservoir **12**.

[0298] Such an arrangement may also serve to provide visible evidence of whether the delivery device **10** had reached a temperature during storage or shipping that was too high for the medical agent. For example, if a temperature that was beyond the phase change temperature of the packet **208** contents was reached during storage, the delivery device **10** would be emptied due to the pressure applied from above by the packet **208**. This may be visibly perceptible to a user. The delivery device **10** would also self-destruct when subjected to certain temperature abuse scenarios. In the event that the delivery device **10** was subjected to a temperature above the phase change temperature of the packet **208** contents, the delivery device **10** would be emptied. As a result, the delivery device **10** would prevent itself from later administering a temperature abused medical agent.

[0299] In some embodiments significant downward pressure on the reservoir **12**, e.g., greater than 50 psi, may be desired to provide force to collapse the reservoir **12** and force fluid therein into the skin of a user via delivery sharps **72** as described above with reference to FIG. **1**A and FIG. **1**B. In such embodiments the packet **208** may be incorporated within a squeezable container **350** as shown in FIG. **12**. The container **350** may be made of a squeezable plastic or any other suitable material as would be understood by those of skill. The container **350** may be formed by injection molding, thermoforming, or any other technique known to those of skill. In addition to housing the packet **208**, a first substance may be stored within the container **350**. The packet **208** may hold a second substance. The first and second substances may be components of, for example, and an expanding foam. The first and second substances may be selected such that they expand to create pressure when they come into contact with each other. A chemical reaction (e.g. baking soda and vinegar) which generates gas could for example be used. Upon applying the delivery device **10** to the skin surface, a user may, e.g., pinch, crush, smoosh, or squeeze the container **350**. This may cause the packet **208** therein to rupture and thereby allow the first and second substances to interact and cause downward pressure on the reservoir **12** below.

[0300] In still other embodiments, the packet **208** could be a vacuum packed bias member (e.g. foam spring). In the vacuum packed state, the bias member may be in a compressed state. User interaction with the packet **208** may cause the packet **208** to break allowing the bias member to restore. As the bias member restores, pressure may be applied to the reservoir **12** to generate pressure for delivery.

[0301] In alternative embodiments, a packet **208** of FIG. **11**A or FIG. **11**B may be filled with contents which do not change phase when removed from cold storage. For example, the packet **208** may be a gas bladder that may serve to prevent pressure from a user's finger applied to the top of the delivery device **10** from being applied directly to the reservoir **12**. Such a gas bladder may also help to make applied pressure more uniform across the reservoir **12**. An example of a suitable gas which may be used to fill such a packet **208** may be nitrogen. Any other suitable gas may be used.
[0302] In other embodiments, the packet **208** may be or include a bias member. In some embodiments, the packet **208** may be a foam adhesive material sitting atop the reservoir **12**. In such examples, when a user pushes down on the delivery device **10** (once the delivery device **10** is affixed to the skin surface), the foam adhesive may function like a spring that helps limit maximum pressure applied to the reservoir **12**. The foam adhesive may also facilitate even distribution of pressure across the top of the reservoir **12**. Assembly of the components described in connection with the above embodiments is described below with reference to FIGS. **50**A-**76**B and FIGS. **13**-**30**B
[0303] Referring now to FIGS. **13-15**, an exemplary delivery device **10** is depicted. The example delivery device **10** is shown in a storage state in FIGS. **13-15**. As shown, the delivery device **10** may include a main body **20** and a reservoir **12**. The reservoir **12** may include at least one delivery sharp **72**. The delivery sharp **72** may be included on a sharp bearing body **26** which may be coupled to a wall of the reservoir **12**. The main body **20** of the example delivery device **10** may have a round (e.g. circular) foot print and may include a central region **28** and a peripheral region **30**. The central region **28** may be a raised region of the main body **20** and the peripheral region **30** may be a substantially flat region of the main body **20** which surrounds the central region **28**. The thickness of the main body **20** may be substantially uniform over the entirety of the main body **20**. The main body **20** may be formed as a thin sheet or disc of material which may be thermoformed to create the raised central region **28** and flat peripheral region **30**.
[0304] Alternatively, the main body **20** may be injection molded and the raised central region **28** and flat peripheral region **30** may be formed in the molding operation. In various embodiments where delivery devices **10** are or may be injection molded (e.g. the embodiments described in relation to FIGS. **13-36**) the main body **20** may be injection molded so as to be in the storage state or in the delivery state. The main body **20** may transition more easily into the state in which it was molded from the opposite state. Thus, to lower the effort needed to transition a delivery device **10** from a storage state to a delivery state, it may be desirable to mold the main body **20** of the delivery device **10** in its delivery state configuration. During assembly of a delivery device **10**, the main body **20** may be brought into its storage state configuration and remain in that configuration until use.
[0305] The central region **28** may be domed and the domed shape may establish a receptacle **32** on the proximal side of the main body **20** within which the reservoir **12** may be disposed. The reservoir **12** may be coupled within the receptacle **32** via adhesive or in another suitable manner. The central region **28** may also include a series of fenestrations **34** which may form a fenestrated ring in the central region **28**. In the example, the fenestrations **34** are evenly spaced from one another and arranged in a circle which is generally coaxial with the center of the central region **28**. In alternative embodiments, fenestrations **34** may be irregularly spaced or omitted. Additionally, in some embodiments, the fenestrations **34** may instead be replaced with thinned regions or a ring where the material of the main body **20** is thinned.
[0306] The main body **20** may include a number of slots **36**. The slots **36** may extend from a peripheral edge **38** of the main body **20** toward a center or midpoint of the main body **20**. In the example embodiment, the slots **36** extend in a radial direction. The slots **36** may extend through the entirety of the peripheral region **30**. In some embodiments, and as shown, the slots **36** may additionally extend through at least a portion of the central region **28** as well. The fenestrations **34** in the central region **28** may be disposed radially inward of the terminus **40** of each of the slots **36**.

The main body **20** may thus include a central region **28** which is circumscribed by a number of petal members **42** which are spaced apart via the slots **36**.

[0307] Referring now to FIG. **16**, a plan view of the proximal face **24** of the main body **20** is depicted. As shown, adhesive **22** may be included on at least a portion of the proximal face **24**. The adhesive **22** may be a skin compatible adhesive and may serve to couple a delivery device **10** to a skin surface at an infusion site. In the example embodiments, adhesive **22** may be included on the peripheral region **30** of the main body **20**. Though adhesive **22** is shown covering the entire surface of each of the petal members **42** in the peripheral region **30**, other embodiments may differ. For example, only certain petal members **42** may include the adhesive **22**. In such embodiments, adhesive **22** may be included on at least one pair of oppositely disposed (e.g. diametrically opposed in the example embodiment) petal members **42**. Only a portion (e.g. a majority of the surface area) of each petal member **42** included in the peripheral region **30** may be covered with adhesive **22** in some examples. Alternatively or additionally, the adhesive **22** may differ from petal member **42** to petal member **42**. Certain petal members **42** may be covered with a more aggressive adhesive **22** while other petal members **42** may be covered with a less aggressive adhesive **22**. In certain examples, the entirety of the proximal surface **24** may be covered in adhesive **22**. Additional adhesive members **22** are described elsewhere herein (see, e.g., FIGS. **10**7A-C) and may be used on a delivery device **10**.

[0308] Referring now to FIG. **17**, a conceptual representation of a main body **20** of a delivery device **10** is depicted in a delivery state. In the delivery state, at least the central region **28** of the main body **20** may substantially invert. The fenestrations **34** may facilitate this inversion by helping to allow for increased deflection of the main body **20** at the fenestrations **24**. Thus, in place of a convex dome-like shape, the center region **28** of the main body **20** may take on a concave shape. As the peripheral region **30** is coupled to the center region **28**, the peripheral region **30** may displace as a result of the inverting of the center region **28**. In the example embodiment, the entire main body **20** takes on a bowl shape when transitioned to the delivery state. The peripheral region **30** may also spreadingly displace for at least a portion of the transition. The slots **36** in the main body **20** may help to facilitate spreading displacement of the petal members **42** as the transition takes place, thereby enhancing stretching of the skin of the user.

[0309] The main body **20** may be a bi-stable element or include at least one bi-stable region which may be stable in both the storage state and the delivery state. When an axial load is applied on the central region **28** and the main body **20** is in the storage state, the main body **20** may deform into an unstable state. The main body **20** may then exhibit a snap through buckling action which rapidly shifts the main body **20** into the stable delivery state similar to that shown in FIG. **17**. Thus, only a triggering force may be applied to initiate the transition. The rest of the shift between the storage and delivery state may be caused by the snap through phenomenon.

[0310] FIG. **18** depicts a delivery device **10** in a storage state and adhered to skin **44** via adhesive **22** on a proximal face **24** of the main body **20**. FIG. **19** is a conceptual representation depicting a delivery device **10** in the delivery state. As shown, the delivery device **10** may be applied to the skin **44** in the storage state. The delivery device **10** may then be transitioned to the delivery state. A spreading displacement of opposed petal members **42** of the main body **20** may occur as the transition transpires.

[0311] Two opposing points **46**A, B disposed at the peripheral edge of the proximal surface **24** are shown in FIG. **18** and FIG. **19**. When the delivery device **10** is in the storage state (FIG. **18**), the shortest distance between the opposing points **46**A, B is a straight line which does not pass through the proximal surface **24**. This straight line is roughly parallel to the surface of the skin **44**. In the delivery state, however, the shortest distance between the opposing points **46**A, B is a straight line which passes through the proximal surface **24**. As the skin **44** is fixed to the main body **20** via the adhesive **22** and cannot pass through the main body **20**, the skin **44** may be forced to conform to the curvature of the proximal surface **24**. Thus, the length of the skin **44** surface between the two

points **46**A, B when the delivery device **10** is in the delivery state may be greater than the length of the skin **44** surface between the points **46**A, B when the delivery device **10** is in the storage state. The skin **44** may be placed under tension and stretched to accommodate this change in length. This stretching may, in turn, aid in facilitating puncture of the skin **44** by the delivery sharp(s) **72**.
[0312] Due to the elasticity of the skin **44**, the skin **44** may exert a restoring force against the proximal surface **24** of the main body **20** as it attempts to revert to an unstretched state. The main body **20** may resist this restoring force and retain its bowl shape. The reservoir **12**, however, may be compressed between the skin **44** and the main body **20**. This may aid in ensuring the delivery sharp(s) **72** puncture the skin **44** and enter fluid communication with a target delivery destination in the patient. Additionally, since the reservoir **12** may be collapsible, the restoring force exerted by the skin **44** may pressurize the reservoir **12** and urge fluid to pass out of the reservoir **12** via the delivery sharp(s) **72**. Thus, the restoring force exerted by the stretched skin **44** may serve to empty and collapse the reservoir **12**.
[0313] As mentioned above, in certain examples, some petal members **42** may not include adhesive **22** regions or may have a proximal surface **24** which is at least partially covered in adhesive **22** that is less aggressive than adhesive **22** of on other petal members **42**. In embodiments where some petal members **42** are devoid of adhesive **22**, this may help to limit stretching of the skin **44**. Likewise, petal members **42** with less aggressive adhesive **22** may release the patches of skin **44** to which they are affixed if force needed to stretch the skin **44** exceeds a threshold. The petal members **42** themselves may also be constructed such that at least one of the petal members **42** includes a relief region (e.g. a thin or narrow region). For example, if force needed to stretch the skin **44** is above a threshold, one of more of the petal members **42** may bend or buckle at the relief region to relieve some of the tension on the skin **44**.
[0314] This may be desirable as it may help to mitigate potential discomfort during an injection due to excessive tensioning of the skin **44**. Additionally, this may be helpful in certain patient populations as skin characteristics vary significantly with age, hydration state, lifestyle (sun exposure, nutrition), etc. It may be desirable that slacker or looser skin be stretched to a greater degree than highly elastic skin. Thus, instead of providing a variety of delivery devices **10** with different adhesives **22** targeted at specified patient populations, a delivery device **10** may be made in a more universal manner.
[0315] With reference to FIG. **20** and FIG. **21**, in another embodiment, a delivery device **10** may include a central region **28** having a top surface **250** and a supporting structure **252** integral with the top surface **250**. The supporting structure **252** may have a round, e.g., substantially circular, base **262**. The peripheral region **30** may be roughly annular shaped and may include an inner perimeter coincident with the base **262** and an outer perimeter, or peripheral edge **38**. The delivery device **10** may be constructed of a nylon material such as Nycoa 2012 nylon or other, similar nylon materials, and may be formed by injection molding. Any other suitable plastic may be used. The top surface **250** may have a round footprint, e.g., of roughly circular shape, and may be convex, forming a dome shape. The top surface **250** may have a periphery **340**. The top surface **250** may include slots **254**. The slots **254** may be cutouts, apertures, holes, openings, or voids in various embodiments. The slots **254** may help the delivery device **10** to transition from the storage state to the delivery state with reduced pressure from above. The slots **254** may extend radially with respect to a center point **256** of the top surface **250** such that their respective first endpoints **258** surround a region including the center point **256** of the top surface **250** and their respective second endpoints **260** may each terminate a distance (e.g., the slots **254** may each terminate the same distance) from the periphery **340** of the top surface **250**. In embodiments including slots **254**, the slots **254** may be disposed at regular angular increments (though need not be). In embodiments described herein including slots **254**, the slots **254** may (though need not necessarily be) each be of the same length.
[0316] Referring now to FIGS. **22**A-**22**I, a variety of different main body **20** embodiments are depicted. The exemplary main bodies **20** are shown in a flat state and may be thermoformed into a

configuration such as that shown in, for example FIG. **20**. Though thermoformable main bodies **20** are depicted, the features described in relation to thermoformed main bodies **20** may be included in main bodies **20** which are manufactured in any desired manner. As shown in FIGS. **22**A-**221**, the slots **254** may be provided in a number of different formats. Additionally, in some embodiments, slots **254** may not be included.

[0317] In some embodiments, and as also shown in FIG. **23**, the slots **254** could be disposed such that they do not extend radially with respect to the center point **256**. For example, the slots **254** may each extend at a common angle with respect to a radial direction. In such embodiments, slots **254** may be evenly spaced about the top surface **250** and may each be of the same length. In other embodiments, the slots **254** may not all extend at a common angle to the radial direction. At least one of the slots **254** (and perhaps all) may be disposed at a different angle to the radial direction. In some embodiments, the slots **254** may be relatively short, positioned about the periphery **340** of the top surface **250**, and may be disposed within an outer region of the top surface **250** (see, e.g., FIG. **22**A). In other embodiments, slots **254** may extend across an outer region and intermediate region of the top surface **250** (see, e.g., FIG. **22**B). In still other embodiments, slots **254** may extend from the outer region of the top surface and into a center region of the top surface **250** (see, e.g., FIG. **22**C). The angled slots **254** may aid in lowering the amount of pressure needed to transition the delivery device **10** from a storage state to a delivery state. Positioning the slots **254** at a sharper angle with respect to the radial direction may generally lower this pressure. The width of the slots **254** may slightly decrease during at least a portion of the transition from the storage state to the delivery state.

[0318] In other embodiments, and referring primarily to FIG. **22**E, at least one of the slots **254** may have a curvature. The curvature may be defined by a constant or variable radius. The curvature may only be present over a segment of the slot **254**. In alternative embodiments, a slot **254** may include two or more sections which are angled with respect to one another. In the example embodiment shown in FIG. **22**E, four curved slots **254** are shown and are spaced apart at even angular increments. The slots **254** are arcuate and include a first end **258** and second end **260**. Each example slot **254** is oriented so as to initially begin extending in a first direction from the first end **258** and curve so as to extend in a second direction as the slot **254** reaches the second end **260**. The second direction may be closer to perpendicular (or may be perpendicular) to the radial direction than the first direction.

[0319] In some examples, and referring now primarily to FIG. **22**D and FIG. **22**F, the top surface may not include a slot **254** or slots **254** but may instead include at least one aperture **255**. In the examples shown, the aperture **255** is disposed centrally within the top surface **250**. The aperture **255** may extend over a minority or a majority of the top surface **250**. In some embodiments, the aperture **255** may encompass nearly the entirety of the top surface **250**.

[0320] As shown exemplarily in FIG. **22**D and FIG. **22**F, slots **254** may also be included in other regions of a main body **20**. In the example embodiment, the region of the main body **20** which would become the supporting structure **252** (when the main body **20** is thermoformed) includes slots **254**. These slots **254** may be straight, curved, angled (with respect to the radial dimension) or some mix thereof as with various top surface **250** slot **254** patterns described herein. As shown, the slots **254** are spaced at regular angular intervals and are spaced between petal members **42** of the main bodies **20**.

[0321] In still other embodiments, the width of one or more of the slots **254** may vary over the length of that slot **254**. A number of embodiments including variable width slots **254** are depicted in FIGS. **22**G-**221**. The slots **254** may change in width in a continuous manner and may terminate with a pointed first or second end **258**, **260**. Variable width slots **254** may extend along a radial direction, though need not necessarily do so in all embodiments. In the example embodiments, each of the slots **254** are widest proximal to the center point **256** of the top surface **250** and continuously decrease in width as the slot **254** extend distally toward the periphery **340** of the top surface **250**.

Thus, each of the top surfaces **250** depicted in FIGS. **22**G-**22**I have a sunburst type pattern of slots **254**. In other embodiments, the slots **254** need not necessarily continuously increase or decrease in width from one end to the other.

[0322] Still referring to FIG. **23**, the central region **28** may be monolithically formed with the petal members **42** comprising the regions between respective pairs of slots **36** (see also FIGS. **13**-**19** and the examples and embodiments described above with respect thereto). The supporting structure **252** may extend upward from the petal members **42** at a 90° angle or an angle greater than 90 degrees, e.g., 100-105 degrees, although the angle measure need not be limited to a range. The distance (vertically) from the base **262** of the supporting structure **252** to the periphery **340** of the top surface **250** may be long enough to provide a receptacle in the central region **28** for a reservoir **12** (see, e.g., FIG. **75**) and, in some embodiments, any packets **208** and/or containers **350** (see, e.g., FIGS. **11**A-**12**), springs, or foam adhesive material. The receptacle may also be sized to house portions of an actuation assembly or dispensing assembly **480** (see, e.g., FIG. **37**). As described in greater detail elsewhere herein, packets **208** may include gas bladders, butane packets, or delivery force supplying packets and any associated containers **350** such those described above with respect to FIGS. **11**A-**12**. In some embodiments the aforementioned distance may be approximately 0.3 inches (e.g. 0.315 in). The slots **36** may extend from the peripheral edge **38** of the delivery device **10** to the base **262** of the supporting structure **252**, but may terminate at the base **262** and not extend into the supporting structure **252** itself. In such embodiments, rather than the entire central region **28** substantially inverting when pressure is applied from the top (e.g., by a finger), only the top surface **250** may invert, taking on a concave shape in the delivery state. The supporting structure **252** may in some embodiments include fenestrations **264** evenly spaced about the base **262**. The fenestrations **264** may facilitate manufacturing of the delivery device **10** in embodiments in which the main body **20** is thermoformed.

[0323] In some embodiments and as shown in one example in FIG. **24**, at least one of the petal members **42** may be made of an extended length such that an outward end of the petal member **42** may be operated by a patient or health care provider as a pull tab **266**. The pull tab **266** may be grasped by a user to remove the delivery device **10** from the skin after use. The pull tab **266** may be of any suitable shape. In an example, the pull tab **266** is approximately semicircular in shape, with a first, rounded end and a second end opposite the first end, attached to a petal member **42**. The second end may be attached or formed integral with the petal member **42** by injection molding or any other known technique that permits the pull tab **266** to be lifted sufficiently from the skin surface to be held by a user.

[0324] Referring now to FIG. **25**, the pull tab **266** may also serve to facilitate a user peeling off a release liner **265** from the bottom of the delivery device **10** before the delivery device **10** is applied to the skin surface via an adhesive **22**. A release liner **265** may be removed in a manner similar to how a release liner is peeled from a bandage before application to skin. An example delivery device **10** having a pull tab **266** and including release liner **265** and adhesive **22** is depicted in FIG. **25**. The release liner **265** is exploded away from the adhesive **22** for illustrative purposes.

[0325] Referring now to FIGS. **26**-**27**, an example embodiment of a package **401** for a delivery device **10** is depicted. The delivery device **10** is depicted in place within the package **401** in FIG. **26**. The package **401** may include a first component **404** and a second component **406** (not shown in FIGS. **26**-**27**, see, e.g., FIG. **130**). The first component **404** may be a rigid component such as a plastic. The second component **406** may be a flexible component (e.g. EtOx permeable sheet) which may be peeled from the first component **404** to access the delivery device **10**. The interior of the package **401** may be a protected environment (e.g. sterilized via EtOx or any other suitable manner) until the second component **406** is removed from the first component. The second component **406** may releasably couple to a rim **403** included on the first component.

[0326] The first component **404** may include one or more wells **405**. The delivery device **10** may be disposed in one of the wells **405**. The pull tab **266** of the delivery device **10** may project along a

passage **407** connecting the two wells **405**. To remove the delivery device **10** a user may reach into the well **405** unoccupied by the delivery device **10** to grasp a portion of the pull tab **266** extending into that well **405**. The delivery device **10** may then easily be lifted out of the package **401** by pulling on the pull tab **266**.

[0327] As shown in FIG. **27**, the liner **265** for the adhesive **22** (see, e.g., FIG. **25**) may be coupled to the surface of one of the wells **405**. This may aid in limiting any movement of a delivery device **10** within a package **401** during transport and handling. As the delivery device **10** is removed, the liner **265** may remain behind in the package **401**. Thus the delivery device **10** may be rendered ready for use when removed from a package **401**. A cap or cover **409** (e.g. receptacle that surrounds the delivery sharp(s) **72**) for the delivery sharp(s) **72** of the delivery device **10** may be included in some examples. The cover **409** may also be coupled to the package **401** and stay behind when the delivery device **10** is removed from the package **401**. Again, this may aid in rendering a delivery device **10** ready for use when taken out of the package **401**.

[0328] With reference to FIGS. **28**-**29** and FIGS. **31**A-**31**B, in some embodiments, delivery devices **10** may include a central region **28** which is roughly thimble, or dome, shaped but has a relatively shorter height compared to certain other embodiments described herein. The distance (vertically) from the base **262** to the periphery **340** of the top surface **250** may be relatively shorter. In some embodiments, the aforementioned distance may be approximately 0.15 inches.

[0329] Additionally or in the alternative, the peripheral region **30** may not be a substantially flat annular shape. The peripheral region **30** may be defined by curved petal members **42** that continue in a downward direction such that their peripheral edge **38** is spaced from the plane of the base **262** of the supporting structure **252** (e.g. about the same or less than the distance from the base **262** to the periphery **340** of the top surface **250**). The peripheral edge **38** may be disposed along a plane which is more distal to the periphery **340** of the top surface **250** than the base **262**. As depicted in FIG. **28**, the delivery device **10** is shown in the storage state. The delivery device **10** may include slots **36** which may be disposed between the petal members **42** like other delivery device **10** embodiments described herein. An adhesive **22** (see, e.g., FIG. **25**) may be affixed to at least a part of at least two of the petal members **42**.

[0330] As best shown in FIG. **29**, a perspective cross-sectional view of a main body **20** of a delivery device **10**, the main body **20** may include an interior ridge **290**. The ridge **290** may be disposed at the base **262** of the supporting structure **252**. The supporting structure **252** may be thickened in a region near the base **262** so as to create the ridge **290**. This may allow for the ridge **290** to be formed easily in, for example, an injection molding operation which forms the rest of a main body **20**. This may also provide extra rigidity to the supporting structure **252**. The ridge **290** may provide a step, ledge, or other mounting surface upon which a portion of a reservoir assembly **12** of a delivery device **10** may be mounted. Such a ridge **290** may be included in any of the delivery device **10** embodiments described herein. Reservoir assemblies **12** and ridges **290** are further described elsewhere in the specification. Any embodiments including ridges **290** may alternatively include retention tabs **580** and stop surfaces **582** such as those shown in FIGS. **105**-**106**B.

[0331] Referring now primarily to FIGS. **30**A-**30**B, two conceptual representations of a delivery device **10** transitioning from a storage state to a delivery state are shown. When the delivery device **10** is affixed to the skin with an adhesive **22** and pressure is applied to the delivery device **10** from above, e.g., by a user's fingertip, the delivery device **10** may transition to a delivery state. When the petal members **42** are pushed against the surface of the skin, the petal members **42** may spreadingly displace outward and the skin and/or patient's body may force at least a portion of the petal members **42** to curl upward. In turn, this may cause the skin to stretch as parts of opposing petal members **42**, each affixed to the skin surface by adhesive **22** (only shown in FIG. **30**A), move apart from one another or spreadingly displace. As the delivery device **10** transitions to a delivery state, at least a portion of each of the curved petal members **42** may curve further or with a tighter radius

of curvature. When a delivery state is reached, the curvature of the petal members **42** may be such that they may extend from the base **262** to an inflection point **360**. The inflection point **360** may fall in a plane spaced from that of the base **262** and in such embodiments may also be referred to as a lowest point. In such embodiments, the lowest point **360** may be in a plane more distal to the periphery **340** of the top surface **250** than the base **262**. From the inflection point **360**, the petal members **42** may curve back upward so as to become increasingly more proximal to the plane in which the periphery **340** of the top surface **250** is disposed. The peripheral edge **38** of the petal members **42** may, for example, be disposed at a point at or above (more proximal the plane of the periphery **340** of the top surface **250**) the plane of the base **262**. The petal members **42** may, though need not necessarily, each have a constant radius of curvature from the inflection point **360** to the peripheral edge **38**. The constant radii curvature back upward may enhance capability of the petal members **42** to curl upward. This may in turn enhance stretching of the skin of the user as points **360** on opposing petal members **42** (each affixed to the skin by adhesive **22**) spreadingly displace. As mentioned elsewhere herein, the top surface **250** of the main body **20** may also invert as the delivery device **10** is transitioned to the delivery state **10**.

[0332] In some non-limiting examples, a delivery device **10** may have dimensions and radii of curvature as shown in FIGS. **31**A-**31**B when in a storage state. It is to be understood that the dimensions shown are merely exemplary. Other delivery devices **10** of different size and having the same proportions are possible and contemplated. Additionally, delivery devices **10** with different dimensions and proportions are possible and contemplated.

[0333] Referring to FIGS. **28**-**29** and FIGS. **31**A-**31**B, in some embodiments, the supporting structure **252** may not include fenestrations **264** (see, e.g. FIG. **20**) evenly spaced around the base **262**. The main body **20** may be manufactured by injection molding. Those of skill would readily appreciate that other manufacturing techniques could be used. The main body **20** may be constructed of one monolithic piece of material such that the central region **28** and peripheral region **30** are integral with respect to each other. The main body **20** may be constructed of a polymer material. In some embodiments, the main body **20** may be a nylon material such as Nycoa 2012 nylon or other, similar nylon materials. In other embodiments the main body **20** may be made of a polypropylene material. The main body **20** may be manufactured of a material that serves to minimize water absorption, or a material that serves to maximize capacity to stick to an adhesive **22**. A material that achieves both of these objectives to any desired degree for each may be selected. These materials may be used for any of the main bodies **20** described herein.

[0334] Still referring to FIGS. **28**-**29** and FIGS. **31**A-**31**B, the top surface **250** may have a round footprint, e.g., be of roughly circular shape, and may be convex, forming a dome shape (including the periphery **340**). The top surface **250** may include slots **254**. The slots **254** may be cutouts, apertures, holes, openings, or voids in various embodiments. The slots **254** may extend radially with respect to a center point **256** of the top surface **250** such that their respective first endpoints **258** surround a region including the center point **256** of the top surface **250** and their respective second endpoints **260** may each terminate a distance (e.g., the slots **254** may each terminate the same distance) from the periphery **340** of the top surface **250**. In certain embodiments, the slots **254** may be disposed at regular angular increments and each be of equal length (though this need not be true to all embodiments).

[0335] Still referring to FIGS. **28**-**29** and FIGS. **31**A-**31**B and as described above with reference to FIG. **23**, the slots **254** could, in an alternative embodiment, be disposed such that they do not extend radially with respect to the center point **256**. For example, the slots **254** may each extend at a common angle with respect to the radial direction. In such embodiments, slots **254** may be evenly spaced about the top surface **250** and may each be of the same length. In other embodiments, the slots **254** may not all extend at a common angle to the radial direction. At least one of the slots **254** (and perhaps all) may be disposed at a different angle to the radial direction.

[0336] Referring now primarily to FIGS. **32**-**36**, a number of views of a conceptual representation

of a delivery device **10** in a delivery state are shown. As described above (and also with reference to the embodiments of FIGS. **13**-**21**), the delivery device **10** may, upon downward pressure being applied to the top surface **250**, transition from a storage state to a delivery state in which the main body **20** of the delivery device **10** is substantially, or at least partially, inverted. A user may remove an adhesive liner **265** (see, e.g., FIG. **25**) from the delivery device **10** and apply the delivery device **10** to the skin. The user may then press downward (i.e., toward the skin) on the top surface **250**. This may cause the petal members **42** to spreadingly displace outward and curl upward (over at least a portion thereof), stretching the skin. The top surface **250** may invert, driving delivery sharp(s) **72** into the skin, and remain inverted when the delivery device **10** attains the delivery state. The peripheral region **20** may also take on an inverted shape due to the curling of the petal members **42**.

[0337] In various embodiments, certain regions of the main body **20** of the delivery device **10** may remain static or may not invert. Thus, a main body **20** may include inverting regions and resilient regions. Though described as resilient regions, it is to be understood that some bending or deformation may still occur as pressure is applied. These regions may, however, appear generally similar or extend/project in the general same direction in both the storage and delivery state. As shown, the peripheral region **30** and top surface **250** may invert, but a portion of the central region **28** may resist deformation to this degree. The supporting structures **252** shown in other embodiments described herein (see, e.g., FIG. **20** or FIG. **28**) may also be a resilient region. Thus, certain delivery devices **10** may include a main body **20** with invertible regions which are separated from one another by a resilient region.

[0338] Still referring to FIGS. **32**-**36**, the reservoir **12** may be formed as an assembly and may include a reservoir portion **271** and a holder **270** (described in greater detail below with reference to FIGS. **50**A-**76**B). A reservoir **12** may be compressed and/or at least partially collapsed so as to deliver a medical agent contained therein when the delivery device **10** is transitioned to the delivery state. The user may then remove the delivery device **10** from the skin. The slots **254** may aid the delivery device **10** to transition from the storage state to the delivery state with reduced pressure from above. The fenestrations **34** may also facilitate the transition. As described above with reference to the embodiments of FIGS. **13**-**21**, there may be room in the central region **28** for a reservoir **12** and sharp bearing body **26** (see additional description with reference to the embodiments of FIGS. **13**-**21** and FIGS. **50**A-**76**B). In some embodiments, packets **208** and/or containers **350** (see, e.g., FIGS. **11**A-**12**) and/or foam adhesive material may also be housed within the central region **28**. As described in greater detail elsewhere herein, packets **208** may include gas bladders, butane packets, or delivery force supplying packets and any associated containers **350** such as those described above with respect to FIGS. **11**A-**12**. In some examples, one or more petal members **42** may be constructed to incorporate a pull tab (not shown in FIGS. **32**-**36**) such as the pull tab **266** described above with reference to FIG. **24**.

[0339] Referring now to FIG. **37**, a block diagram of an exemplary delivery device **10** is depicted. As shown, the delivery device **10** may include a main body **20** and a reservoir **12**. The delivery device **10** may also include one or more bias member **470**. The one or more bias member **470** may be included as part of a dispensing assembly **480** included in a delivery device **10**. The dispensing assembly **480** may aid in applying pressure to the reservoir **12** and aid in expelling fluid from the reservoir **12** over the course of the injection. In some embodiments, the dispensing assembly **480** may include a depressor body **472** which may be coupled to or associated with the at least one bias member **470**. The depressor body **472** may include or be coupled to (perhaps indirectly via the bias member **470**) a reservoir interface member **474** which may also form part of a dispensing assembly **480** of a delivery device **10**. In certain examples, a reservoir interface member **474** may be omitted and the bias member **470** may directly contact the reservoir **12**.

[0340] In some embodiments, the bias member **470** may be in an unstressed state when the associated delivery device **10** is in a storage state. User interaction with the delivery device **10** to

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

[0341] In other embodiments, the bias member **470** may be in a stressed state when the associated delivery device **10** is in a storage state and may be coupled to or associated with the depressor body **472** of the dispensing assembly **480**. The depressor body **472** may interface with a portion of the delivery device **10** (e.g. the main body **20**) so as to resist displacement under the restoring force exerted by the bias member **470**. This may prevent the bias member **470** from restoring from its stressed state. A catch or detent in the depressor body **472** may, for instance, be in engagement with the main body **20** when the delivery device **10** is in a storage state. User interaction with the delivery device **10** to transition the delivery device **10** to a delivery state may disengage the depressor body **472** such that the depressor body **472** is free to displace. Once the depressor body **472** is free to displace, the bias member **470** may restore to an unstressed or at least less stressed state and drive the reservoir interface member **474** of the dispensing assembly **480** against the reservoir **12**. Over a period of time, this may cause the reservoir **12** to collapse such that fluid is driven out of the reservoir **12** and into a patient.

[0342] Referring now to FIGS. **38-39**, a representational example of a delivery device **10** which includes a bias member **470** that is unstressed in the storage state is depicted. The delivery device **10** may include a main body **20** and a reservoir **12** as with various other delivery devices **10** described above. As shown, the depressor body **472** of the dispensing assembly **480** may include an elongate member **476** such as a pin which may extend through the top surface **250** of the main body **20**. In some embodiments, the elongate member **476** may include a head **478** or other surface at a distal end of the elongate member **476**. The head **478** may include a rounded or tapered portion to aid in passing the head **478** though an aperture in the main body **20** during assembly. Opposite the tapered or rounded portion, the head **478** may define a step or ledge. The ledge of the head **478** may limit displacement of the elongate body **476** as the ledge may be unable to easily pass back through the aperture in the main body **20**. An end of the elongate member **476** opposite the head **478** may couple to one or more bias member **470**. The reservoir interface member **474** may be coupled to the one or more bias member **470** such that the one or more bias member **470** is disposed intermediate the elongate member **476** and the reservoir interface member **474**. In the example embodiment, the one or more bias member **470** is depicted as a set of bow springs though any suitable number of bow springs may be used. In alternative embodiments, other bias members **470** may be used (e.g. resilient foam, coil spring, air bladder, rubber body, elastomeric body, etc.).

[0343] As pressure is applied to transition the delivery device **10** to the delivery state, the elongate body **476** may displace toward the reservoir **12**. This may cause the bias members **470** to become stressed. As shown, the elongate body **476** includes a detent or notch **482**. The notch **482** may engage with the main body **20** to hold the elongate body **476** in a depressed state. Engagement of the notch **482** with the main body **20** may also serve to indicate a delivery device **10** has been used.

[0344] With the elongate body **476** held in place, restoration of the bias members **470** to a less stressed state may drive displacement of the reservoir interface member **474** into the reservoir **12**. As mentioned above, this may drive reservoir **12** contents out of the reservoir **12** and into the

patient. It should be noted that, in various examples, at least some portion(s) of the main body **20** may spreadingly displace and/or invert as the delivery device **10** is transitioned to the delivery state (see, e.g., FIG. **32**). This is not depicted in FIGS. **38-39** for case of illustration.

[0345] Referring now to FIGS. **40-41**, in certain embodiments, a delivery device **10** may include a bias member **470** which is in a stressed state while the delivery device **10** is in a storage state. As shown in FIG. **41**, a bias member **470** (depicted in an unstressed state) may include a peripheral body **490**. The peripheral body **490** may for example, be annular in shape though any suitable shape may be used. A number of bias projections **492** may extend from the peripheral body **490** toward the center of the bias member **470**. The bias projections **492** may extend radially inward toward the center of the bias member **470** from the peripheral body **490**. In the example embodiment, the bias projections **492** may be spaced at even angular increments though need not be in all embodiments. The peripheral body **490** may be constructed of any suitable material and in some examples, may be a resilient plastic or a spring steel.

[0346] A main body **20** of a delivery device **10** may include a number of passages **494** which extend through the main body **20**. The passages **494** may be positioned in a support structure **252** of the main body **20**. The spacing of the passages **494** may correspond to the spacing of bias projections **492** on the bias member **470**. When a delivery device **10** is assembled, the bias projections **492** may be introduced into and partially through respective passages **494** in the main body **20**. The peripheral body **490** may rest on a distal face of the peripheral region **30** (see, e.g. FIG. **28**) of the main body **20**.

[0347] Referring now also to FIGS. **42-44**, the delivery device **10** may include a depressor body **472**. In the example shown, the depressor body **472** includes a reservoir interface member **474** at a proximal end thereof. The depressor body **472** may be rotationally displaceable within an aperture **496** in the main body **20**. The aperture **496** may be disposed in the top surface **250** of the main body **20** as shown in FIG. **42** for instance. The depressor body **472** may be rotated from a translational displacement constraining position or range of positions (see, e.g., FIG. **42**) to a translational displacement permitting position or range of positions (see, e.g., FIG. **41**). In a translational displacement constraining position, a retention element of the depressor body **472** may be in engagement with a cooperating lock defined in the main body **20**. In a translational displacement permitting position the retention element of the depressor body **472** may be disengaged with the lock of the main body **20**.

[0348] As best shown in FIG. **44**, the exemplary depressor body **472** includes a stem **500** which extends through the aperture **496** in the main body **20** of a delivery device **10**. The stem **500** may include a set of notches **498** or other recess(es) which each may serve as a retention element. The cross-sectional shape of the stem **500** may not be circular or a regular polygon. Thus, one of the width and length dimension of the cross-sectional shape of the stem **500** may be shorter than the other. In the example embodiment, the cross-sectional shape of the stem is an obround shape. Other cross-sectional shapes may be used in alternative examples. The notches **498** may be disposed so as to be recessed into the widest portion of the stem **500**. The aperture **496** (see, e.g., FIG. **40**) may have a shape which corresponds, though may be slightly larger than, the shape of the stem **500** cross-section. The notches **498** may be recessed to a depth such that when level with the wall of the main body **20** in which the aperture **496** is formed, the depressor body **472** may be rotated within the aperture **496**.

[0349] The depressor body **472** is shown in a translational displacement constraining position in FIG. **42**. In such a position, the rotational orientation of the depressor body **472** may be such that the notches **498** may overhang a portion of the main body **20** in which the aperture **496** is defined. As a result, the main body **20** may present a mechanical interference to translational displacement of the depressor body **472**. Thus, the region of the main body **20** adjacent the aperture **496** may act as a lock for the depressor body **472**. As shown in FIG. **43**, when the depressor body **472** is rotated to a translational displacement permitting position, the rotational orientation of the depressor body

**472** may be such that it may translationally displace within the correspondingly shaped aperture **496** of the main body.

[0350] Referring now also to FIG. **45** and FIG. **46**, the depressor body **472** may include an enlarged portion **502**. The reservoir interface member **474** may form a proximal region of the enlarged portion **502**. When a delivery device **10** is assembled, the bias projections **492** of the bias member **470** may press upon the enlarged portion **502** capturing or coupling the enlarged portion within the bias projections **492**. Additionally, the bias member **470** may be substantially constrained from displacing as a whole since the bias projections may be fed through passages **494** in the main body **20**. With the bias member **470** constrained in place, lifting of the depressor body **472** may cause the bias projections **492** to deflect and become stressed. Once the depressor body **472** has been lifted such that the notches **498** are even with the portion of the main body **20** in which the aperture **496** is defined, the depressor body **472** may be rotated to a translational displacement constraining position (see, e.g., FIG. **42**). Thus, the bias member **470** may be held in a stressed state.

[0351] During actuation of an associated delivery device **10** from a storage state to a delivery state, the depressor body **472** may be rotated to a translational displacement permitting position. Once this position is reached, the depressor body **472** may be free to translationally displace and the bias member **470** may urge the depressor body **472** to translationally displace. As the bias member **470** restores to a less stressed state, the reservoir interface member **474** may be driven against the reservoir **12** to force fluid out of the reservoir **12** and into a patient. The amount of the depressor body **472** which extends out of the main body **20** may alter as the bias member **470** restores to a less stressed state. Thus, the amount of depressor body **472** extending out of the main body **20** may serve as an indicator that a delivery device **10** has been used.

[0352] Referring now to FIGS. **47**A-**47**D, in some examples, a bias member **470** for a delivery device **10** may be entirely internal to the delivery device **10**. Additionally, the depressor body **472** may not latch or engage with a portion of the main body **20** to inhibit translation of the depressor body **472**. In some examples of such embodiments, a stop member **473** may be included with the delivery device **10**. The depressor body **472** may include a recess **475** (or alternatively set of notches **498**, see, e.g., FIG. **44**) which may engage with the stop member **473** instead of the main body **20**. As best shown in FIG. **47**B, the stop member **473** may include an aperture **496**′ which may have a shape which corresponds, though may be slightly larger than, cross-sectional shape of the stem **500** of the depressor body **472**. The recess(es) **475** may be recessed to a depth such that when level with the aperture **496**′, the depressor body **472** may be rotated within the aperture **496**′.

[0353] The stop member **473** may be rotated from a translational displacement constraining position to a translation displacement permitting position in which the depressor body **472** is free to displace translationally. In the translation displacement constraining position, the aperture **496**′ may be positioned such that the stem **500** overhangs a portion of the body **479** of the stop member **473**. As a result, the stop member **473** may present a mechanical interference to translational displacement of the depressor body **472**. When the stop member **473** is rotated to a translational displacement permitting position, stem **500** may no longer overhang the body **479** of the stop member **473**. In this position, the depressor body **472** may translationally displace within the correspondingly shaped aperture **496**′ of the stop member **473**. The stop member **473** may include ridges, knurling, bumps, grips, spokes, or other features to facilitate rotational displacement of the stop member **473** via interaction with a user's fingers.

[0354] Referring primarily to FIG. **47**C and FIG. **47**D, the bias member **470** may be a conical spring. The conical spring may be in a stressed (e.g. compressed state) when a delivery device **10** is in a storage state and the stop member **473** is in a translational displacement constraining position. When the stop member **473** is moved to the translational displacement permitting position, the bias member **470** may be free to drive displacement of the depressor body **472** against the reservoir **12** as described above with respect to FIGS. **45-46**. As the depressor body **472** is displaced via relaxation of the bias member **470**, the stem **500** of the depressor body **472** may fully pass through

the aperture **496**′ of the stop member **473**. The stop member **473** may thus be disassociated from the rest of the delivery device **10**. The depressor body **472** may also translate to a position in which the recess(es) **475** are internal to the delivery device **10**. Thus, the stop member **473** may be inhibited from being recoupled to the depressor body **472**. When a delivery device **10** is observed absent a stop member **473**, it may provide a visual cue that the particular delivery device **10** has already been used. Thus, the stop member **473** may also serve as an indicator which conveys that a particular delivery device **10** is available for use.

[0355] Referring now to FIG. **48**, a block diagram of another exemplary delivery device **10** is depicted. As shown, the delivery device **10** may include a main body **20** and a reservoir **12**. The delivery device **10** may also include one or more bias member **470**. The one or more bias member **470** may form the entire dispensing assembly **480**. The one or more bias member **470** may directly contact the reservoir **12** and may aid in applying pressure to the reservoir **12** in order to deliver fluid out of the reservoir **12**. In certain examples, a reservoir interface member **474** (see, e.g., FIG. **37**) may be included. Where included, the reservoir interface member **474** may (though need not necessarily be) be formed as a part of the at least one bias member **470** and may be integral therewith. The reservoir interface member **474** may directly contact the reservoir **12**. The at least one bias member **470** may be or include a spring, compression spring, conical spring, resilient foam, air bladder, rubber body, elastomeric body, any other suitable bias member, or some combination thereof.

[0356] Still referring to FIG. **48**, the bias member **470** may be in an unstressed state when the associated delivery device **10** is in a storage state. No pressure may be applied to the reservoir **12** in the storage state. In certain examples, the at least one bias member **470** (and optionally any reservoir interface member **474**) may be entirely out of contact with the reservoir **12** in the storage state (e.g. by 0.05-2 mm). Alternatively, the bias member **470** may contact, but not press against the reservoir **12**. When the delivery device **10** is used, the delivery device **10** may be transitioned to the delivery state as described elsewhere herein. As with various embodiments discussed herein, when transitioned to a delivery state, at least a portion of the delivery device **10** may at least partially invert. For example, at least the domed top surface **250** of the central region **28** may invert or partially invert. The distance between the reservoir **12** and the inverted top surface **250** in the delivery state may be less than the distance between the reservoir **12** and the top surface **250** in the storage state. This may in turn cause a bias to be stored in the bias member **470**. The at least one bias member **470** may, in the example, be compressed when the top surface **250** is inverted. Additionally, where the at least one bias member **470** is spaced from the reservoir **12** in the storage state, the at least one bias member **470** or reservoir interface member **474** (which may be a part of the bias member **470**) may be displaced into contact with the reservoir **12**. The inverted top surface **250** may be sufficiently strong in the inverted state to withstand any force exerted by the at least one bias member **470**. As the at least one bias member **470** restores, the at least one bias member (and/or reservoir interface member **474** if included) may press against the reservoir **12** to collapse the reservoir **12** and drive fluid into a patient. Thus without, for example, sustained manual pressure against the delivery device **10**, pressure may be still applied to the reservoir **12** over a period of time sufficient to fully deliver contents of the reservoir **12** (e.g. five minutes in certain embodiments).

[0357] Referring now to FIGS. **49**A-**49**B, an example embodiment of a main body **20** and a main body **20** with a bias member **470** are respectively shown. FIG. **49**A depicts a bottom plan view of the main body **20**. FIG. **49**B depicts a perspective view of the main body **20** and bias member **470**. The main body **20** is shown with the top surface inverted for illustrative purposes. As shown, the main body **20** may include a number of locating projections **471**. In alternative embodiments, the locating projections **471** may be replaced with a round or annular locating wall. There may be a set of locating projections **471** which are disposed in a center region of the top surface **250**. A second set of locating projections **471** may be spaced outwardly from the center region may optionally be

included. In the example embodiment, the second set of locating projections **471** extend from the top surface **250**. In other examples, location projections **471** may extend radially inward from the supporting structure **252** of the central region **28**. An end of the bias member **470** may be centered by the locating projections **471** as the bias member **470** is placed into the delivery device **10** assembly. In certain examples, the end of the bias member **470** may be coupled into place. For example, the end of the bias member **470** adjacent the top surface **250** may be heat staked once the bias member **470** is properly positioned (see, e.g., FIG. **49**C). When the delivery device **10** is fully assembled, the heat stake may retain the bias member **470** in place against the main body **20**. As a result, the bias member **470** may be held out of contact with the reservoir **12** until the delivery device **10** is transitioned to the delivery state. The locating projections **471** may also aid in ensuring that the bias member **470** transitions to the stressed state in a desired manner. For example, where a compression spring is used, the second set of locating projections **471** may constrain the bias member **470** such that the bias member **470** is compressed substantially along the axis of the bias member **470**.

[0358] Referring now also to FIG. **49**C, in some examples, the bias member **470** may be constrained from displacement by one or more guide body **477**. The one or more guide body **477** may extend from the supporting structure **252** of the central region **28** of the main body **20** toward the axis of the bias member **470**. In the example shown in FIG. **49**C, four guide bodies **477** are included and are spaced at even angular increments. In other embodiments, the number of guide bodies **477** may differ and/or the guide bodies **477** could be irregularly spaced. The guide bodies **477** may aid in ensuring that the bias member **470** compresses substantially along its axis and may help inhibit tilting of the bias member **470** during use of a delivery device **10**.

[0359] Still referring to FIGS. **49**A-C, where the bias member **470** is a compression spring, a terminal end **481** of the bias member **470** may form a reservoir interface member **474**. The terminal end **481** bias member **470** may be routed in a manner which helps spread pressure more uniformly over the reservoir **12**. The terminal end **481** of the bias member **470** may be routed in a direction or desired pattern. The terminal end **481** may also be disposed substantially within a plane disposed even with or adjacent an end of the bias member **470**. In the example embodiment in FIG. **49**B, the terminal end **481** of the coil is bent so that it extends between opposing points on the bias member **470**. In the example, the terminal end **481** extends substantially diametrically across the end of the bias member **470** proximal the reservoir **12**. In other embodiments, the terminal end **481** of the bias member **470** may be routed in a spiral or other pattern (see, e.g., FIG. **49**C).

[0360] Referring now to FIGS. **50**A-**50**B, in other examples, the bias member **470** may be block of compressible material such as rubber or elastomer. The surface of the bias member **470** adjacent the reservoir **12** may serve as the reservoir interface member **474** and may be substantially flat or planar in certain embodiments. Thus, various delivery devices **10** may include a reservoir interface member **474** which is compliant. The delivery device **10** depicted in FIGS. **50**A-**50**B is shown in a storage state. As shown, the delivery device **10** may include a depressor body **472** which may be coupled to the top surface **250** of the main body **20**. The top surface **250** of the main body **20** may have an infundibuliform or trumpet shape when in the storage state in certain examples. Such top surfaces **250** may be included in various other embodiments described herein. As shown, the depressor body **472** includes a post **469**. The post **469** may extend through and be coupled to the top surface **250** (e.g. via a heat stake, adhesive, a dogged central aperture **459**, etc.). The depressor body **472** may further include a dish body **467** coupled to the post **469**. The dish body **467** may be disposed above the top surface **250** of the main body **20**. The dish body **467** may provide an ergonomic location for a user to press against when transitioning the delivery device **10** to the delivery state. When the delivery device **10** is transitioned to the delivery state, top surface **250** may substantially invert and the bias member **470** may be compressed against the reservoir **12**. This may urge fluid to be dispensed from the reservoir **12**. In some embodiments, the bias member **470** may be coupled to an end of the post **469** opposite the dish body **467**. For example, the bias

member **470** may include a receiving recess **465** (see, e.g., FIG. **51**) into which the end of the post **469** may be mated. Though a dish body **467** in the form of a concave dish is depicted, a dish like body need not be included in all embodiments. For example, the dish body **467** may be replaced by a relatively planar body or plate in certain embodiments.

[0361] Referring now to FIG. **51**, an exploded view of a delivery device **10** similar to that illustrated in FIG. **50**B is depicted. As shown, some delivery devices **10** may include a bias member **470** which changes in width along its height dimension and is constructed of an elastomeric material such as a silicone material. For example, the bias member **470** may be tiered. In the example shown, the bias member **470** includes two tiers. Additionally, the bias member **470** may include one or more hollow region. In the example embodiment, the bias member **470** includes a plurality of passages **463** which extend through the bias member **470** to form hollow regions. The passages **463** may extend through at least one of the tiers and in the example embodiment, both are disposed in the first or base tier of the bias member **470**. The passages **463** may be evenly spaced about the bias member **470** and are disposed such that the bias member **470** has a plane of symmetry in the example shown. As noted above, when the top surface **250** of the main body **20** is transitioned from its storage state position to the delivery state position, the bias member **470** may become compressed. Fluid may be driven out of the reservoir **12** as the bias member **470** restores to a less compressed state. The passages **463** may make the initial application of force by the bias member **470** against the reservoir **12** more gentle and less abrupt. This may make reservoirs **12** more robust during use while still ensuring reservoirs **12** are substantially emptied during delivery.

[0362] Referring now also to FIGS. **52**A-**53**, various views of a main body **20** and a depressor body **472** are shown. The depressor body **472** of the delivery device **10** may include a dish region **467**′ from which a skirt **461** extends. The skirt **461** may include a set of cars **457** extending outwardly therefrom such as those shown in FIG. **51**. Any cars **457** may be spaced at regular angular intervals. The dish region **467** may be shaped similar to dish bodies **467** described elsewhere herein. The skirt **461** may be sized to nest over the supporting structure **252** of the main body **20** when the delivery device **10** is transitioned from the storage state (FIG. **52**A) to the delivery state (FIG. **52**B). Thus, the supporting structure **252** may act as a guide which helps inhibit tilting of the depressor body **472** and assists in ensuring that the depressor body **472** displaces substantially along an axis as pressure is applied. When transitioned fully to the delivery state, the end of the skirt **461** opposite the dish region **467**′ may be near the petal members **42**, but sufficiently spaced from the petals members **42** so as not to restrict movement of petal members **42**. As shown best in FIG. **53**, the depressor body may include a post **469**. The post **469** may extend through a dogged aperture **459** in the central portion of the top surface **250** of the main body **20**. As the depressor body **472** is pulled in a direction away from the main body **20**, the dogs of the dogged aperture **459** may pivot and bite into the post **469** inhibiting the depressor body **472** from being disassociated from the rest of the delivery device **10**. When the delivery device **10** is assembled, the post **469** may project into the receiving recess **465** in the bias member **470**.

[0363] In some embodiments, as shown in FIGS. **54**A-D (respectively a perspective view from the top, view from the side, perspective view from the bottom, and view from below, relative to an application surface for a delivery device **10** such as the skin surface), an example holder **270** for a sharp bearing body **26** (see, e.g., FIG. **34**) including delivery sharp(s) **72** (see, e.g., FIG. **34**), may be formed as an annulus or annular body **272** integral with a rounded depression **274**. The rounded depression **274** may be centrally disposed. In one example, the rounded depression **274** may have the shape of a spherical segment. The annulus **272** may have an inner edge, and the rounded depression **274** may have a perimeter. The inner edge of the annulus **272** may be coincident to the perimeter of the rounded depression **274**. When a delivery device **10** incorporating a holder **270** is affixed to the skin surface of a user, the rounded depression **274** extends below the plane of the annulus **272** (see FIG. **54**B). Thus the rounded depression **274** may also form a bump extending proud of the proximal face of the holder **270**.

[0364] The rounded depression **274** may include a pocket **276** formed therein. The pocket **276** may be formed in a proximal face of the holder **270** (e.g. in the bump). The pocket **276** may be situated at a center, and lowest (with respect to the skin surface when the delivery device **10** is affixed thereto) point of the rounded depression **274**. The pocket **276** may be sized to fit and accept a sharp bearing body **26** with delivery sharp(s) **72** thereon such as, e.g., the sharp bearing body **26** including delivery sharps **72** of FIG. **34**. The sharp bearing body **26** including delivery sharp(s) **72** may be mated into the pocket **276** by, e.g., injection molding or adhesive. The holder **270** may be over molded around the sharp bearing body **26** so as to couple the components together. In various embodiments, the delivery device **10** may be arranged such that pressure from above (e.g., from a finger) on the delivery device **10** may be distributed evenly over the area of the holder **270**. In some embodiments, the depression **274** may act as a force concentrating protuberance from the holder **270** which serves to ensure force applied to a delivery device **10** is concentrated upon the delivery sharp(s) **72** aiding in insertion of the delivery sharp(s) **72** into the skin.
[0365] In an example embodiment, the width (e.g. diameter) of the holder **270** may be approximately 0.7 inches (e.g. 0.744 inches). The footprint area of an exemplary holder **270** may be approximately 0.45 square inches (e.g. 0.44 square inches). The holder **270** may be manufactured by any technique known to those of skill including, e.g., injection molding or thermoforming.
[0366] Another exemplary holder **270** is depicted in FIGS. **55**A-**55**C. As shown, a holder **270** may include a disk body **275**. The disk body **275** may be substantially flat and may include a number of peripherally disposed tab projections **277**. The tab projections **277** may be symmetrically disposed about the disk body **275** and may be spaced at regular angular intervals as shown in FIGS. **55**A-**55**C. In alternative embodiments, the tab projections **277** may be asymmetrically disposed about the base or disposed at irregular angular intervals. The tab projections **277** may engage with receiving slits **278** (see, e.g., FIG. **47**A) disposed in a main body **20** of a delivery device **10**. Thus, the tab projections **277** may be used to couple the holder **270** into place in a delivery device **10**. Asymmetric or irregularly spaced tab projections **277** may allow for the holder **270** to be coupled to a main body **20** in a prescribed orientation which may be desirable in some examples.
[0367] Still referring primarily to FIGS. **55**A-**55**C, a holder **270** may include at least one stage projection **279**. The stage projection **279** may be included in addition or instead of the rounded depression **272** and spherical segment of the embodiment described above in relation to FIGS. **54**A-**54**D. The stage projection **279** may provide a well **281** on the distal side of the disk body **277**. The stage projection **279** may extend proud of the proximal side of the disk body **277** by a height which may, in certain examples, be at least equal to the height of a microneedle (e.g. 600 microns) of the delivery device **10**. The stage projection **279** may generally extend from the disk at a perpendicular angle. The side walls **283** of the stage projection **279** may be chamfered so as to extend in a non-perpendicular direction with respect to the proximal face of the disk body **279**. The stage projection **279** may include a pocket **276**. The pocket **276** may be sized to fit and accept a sharp bearing body **26** with delivery sharp(s) **72** thereon as described elsewhere herein.
[0368] Referring now to FIGS. **56**A-**56**D, in some embodiments, the pocket **276** of the stage projection **279** may be in a non-parallel orientation with respect to the plane of the disk body **275**. As best shown in FIG. **56**D, when a sharp bearing body **26** is mounted to the pocket **276**, the orientation of the pocket **276** may ensure that the delivery sharp(s) **72** (e.g. microneedles) extend at a prescribed angle with respect to the disk body **275**. In the example embodiment, the pocket **276** may be oriented such that the delivery sharp(s) **72** extend at a 10-20° angle (e.g. 15°) with respect to a plane perpendicular to the disk body **275**. In other embodiments, the pocket **276** may be oriented such that the delivery sharp(s) **72** project at a 45° or 60° angle or some angle therebetween. Any suitable angle may be used. In alternative embodiments, the entire stage projection **279** may project at the desired angle from the disk body **275**. Thus, the delivery sharp(s) **72** may extend at that angle when coupled to the pocket **276**.
[0369] The sharp bearing body **26** may be coupled to any of the holders **270** described herein

during a molding operation or via an adhesive. Sharp bearing bodies **26** may be coupled to any of the holders **270** described herein during a molding operation or via an adhesive. Where the sharp bearing body **26** is joined to any of the holders **270** described herein during molding, some material may be molded up the sidewalls **27** of the sharp bearing body **26** and over onto the face of the sharp bearing body **26** from which the delivery sharp(s) **72** project to capture the sharp bearing body **26**. In alternative embodiments, the sidewalls **27** of the sharp bearing body **26** may be chamfered or at an angle which is not perpendicular to the face of the sharp bearing body **26** from which the delivery sharp(s) **72** extend. The footprint or cross-section of the sharp bearing body **26** may increase in area as distance from the sharp bearing face of the sharp bearing body **26** increases. Where the delivery sharp(s) **72** are silicon, a number of sets of delivery sharp(s) **72** may typically be formed on a large wafer and sharp bearing bodies **26** including the desired number of delivery sharp(s) **72** may be diced out of the wafer. To form the chamfered sidewalls **27**, the dicing saw may have angled faces such that dicing process creates the desired chamfer or angle on the sidewalls **27**. In certain embodiments, sidewalls **27** which are between 30-60° (e.g. 45°) may be used. Where chamfered sidewalls **27** are present, material may be molded up only a portion of the sidewall **27** to couple the sharp bearing body **26** to a holder **270**. This may allow for a sharp bearing body **26** to be captured in a holder **270** (or any other molded component, e.g., a part of a delivery implement or an adapter for a syringe or other delivery implement which couples to that delivery implement via a luer lock or the like) without material being molded over onto the sharp bearing face of the sharp bearing body **26** (though this could optionally be done). Thus no molded material may act as a stand-off on the sharp bearing face blocking the full height of any delivery sharp(s) **72** from penetrating into the skin. Description in relation to a holder **270** may be generalized to other components and discussion of the holder **270** is merely exemplary.

[0370] In certain examples, and referring now to FIGS. **57**-**61**, the peripheral region of a sharp bearing body **26** may be formed in a series of material removal operations. Where the sharp bearing body **26** is constructed of silicon, the sidewall **27** may be formed by dicing, etching, or some combination thereof. The sidewall **27** of the sharp bearing body **26** may include a number of regions which may be some combination of straight regions where the cross-sectional area of the sharp bearing body **26** is constant and chamfered or angled regions over which the cross-sectional area varies. In some embodiments, the sidewall **27** may be tiered and have a stepped appearance with one or more plateau regions. Such sidewalls **27** may make a sharp bearing body **26** amenable to being coupled into a component via molding without material being molded over onto the sharp bearing face. Such sidewalls **27** may also allow for more versatility in molding. For example, materials with a larger variety of shrinkage values after molding may be used to construct a holder **270** or other component (e.g. syringe adapter) to which a sharp bearing body **26** is to be coupled. Sharp bearing bodies **26** with such sidewalls **27** may be particularly robust against stress due to shrinkage loading during molding. Additionally, such sharp bearing bodies **26** may accommodate greater ejection loading when the molded component is ejected from the mold cavity. Sharp bearing bodies **26** with such sidewalls **27** may also facilitate creation of high quality, fluid tight interfaces between overmolded material and sharp bearing body **26** material. Such sidewalls **27** may increase the pressure at which an overmolded component such as a holder **270** or other component remains leak proof. Stepped sidewalls **27** may also help facilitate flow of injection molding material into cracks which may be formed in sharp bearing bodies **26** during handling by automation equipment and thus assisting in limiting rejection percentage.

[0371] In some examples, at least two sets of dicing cuts may be made to form the sidewalls **27** of the sharp bearing body **26**. The sidewalls **27** may include a chamfered section extending from the sharp bearing face of the sharp bearing body **26** (see, e.g., FIG. **58**). The chamfered section may be formed by a first set of cuts and may be oriented such that the cross-sectional area of the sharp bearing body **26** decreases as proximity to the sharp bearing face increases. The sidewalls **27** may also include a straight region where the cross-sectional area of the sharp bearing body **26** is

substantially constant. The straight region of the sidewall **27** may be formed in a second set of dicing cuts and may define the remainder of the sidewall **27**. In some embodiments, the sidewall **27** may include two straight regions and an intermediate chamfered region (see, e.g., FIG. **59**). The straight regions of the sidewalls **27** may respectively be adjacent the sharp baring face and the opposing face of the sharp bearing body **26**. A set of angled dicing cuts may be made to form the intermediate section and a second set of dicing cuts may be made to cut back a segment of the resulting chamfered face to form a straight region. The second straight region may be created with another set of dicing cuts. In alternative examples, at least one of the straight regions of the sidewall **27** may be a precision sidewall segment as described below.

[0372] In still other embodiments, and referring now to FIG. **61**, the chamfer may be replaced by a stepwise change in cross-sectional area of the sharp bearing body **26**. The stepwise change may be provided such that the footprint or cross-sectional area of the sharp bearing body **26** increases as distance from the sharp bearing face of increases. In some examples, the stepwise change in height may be created with a series of dicing cuts. One set of cuts may form a partial cut through the wafer material while another set of cuts may singulate each sharp bearing body **72** from the rest of the wafer. When forming the holder **270**, material may be molded over the larger cross section portion of the sharp bearing body **26** and onto the step intermediate the large and small cross-sectional area portions of the sharp bearing body **26**. Thus, the larger cross-sectional area region of the sharp bearing body **26** may be encased in the holder **270** (or other component) material and a portion of the peripheral side wall most proximal the sharp bearing face of the sharp bearing body **26** may be only partially covered. Alternatively, the peripheral sidewall may be covered to a height even with the sharp bearing face. As shown in FIG. **60**, in some examples there may be a small chamfer or radiused region where the step transitions to the sidewall **27** for the smaller cross-sectional area portion of the sharp bearing body **26**. Such a step may be created by a dicing saw. Though described as a chamfer or radiused region any shape created by the dicing saw kerf may be present. The chamfer or radiused region may only be present for a fraction of the height of the smaller cross-sectional area region of the sharp bearing body **26** (e.g. less than 50% or less than 25%).

[0373] Referring primarily to FIG. **61**, in various examples, the height of the large and small cross-sectional area portions of the sharp bearing body **26** may be substantially equal. The small cross-sectional area portion of the sharp bearing body **26** may be at least 50% of the height of the sharp bearing body **26**. The width of the step between the large cross-sectional area portion of the sharp bearing body **26** and the small cross-sectional area portion of the sharp bearing body **26** may be less than the height of the small or large cross-sectional area portion of the sharp bearing body **26**. In some embodiments, the width of the step may be no more than 50% of the height of the small cross-sectional area portion of the sharp bearing body **26**. The width of the step may be greater than 50% of the height of the small cross-sectional area of the sharp bearing body **26** in other embodiments. In other examples, the width of the step may be at least 100% of the height of the small or large cross-sectional area portion of the sharp bearing body **26**. The width of the step may be the same on each side of the sharp bearing body **26**, though may differ in alternative examples. In some embodiments, the width of the step may be the same for each opposing side of the sharp bearing body **26**.

[0374] Though sharp bearing bodies **26** described above may be particularly amenable to being attached to a holder **270** (or other component) via overmolding, sharp bearing bodies **26** may also be attached to a holder **270** (or other component) in other suitable manners. For example, sharp bearing bodies **26** described herein may be coupled to a holder **270** (or other component) via swaging (e.g. heat swaging or laser swaging operation).

[0375] Referring now to FIG. **62**A-**62**C, a view of a backside and two cross-sectional views of a sharp bearing body **26** coupled to a holder **270** via injection molding are respectively depicted. While material may be molded over a chamfered or stepped portion (or both) of the sidewall **27** of

a sharp bearing body **26**, it may also be desirable that material is also molded over a portion of the rear face of sharp bearing body **26**. As shown, in some examples, material may be permitted to flow at least over the peripheral edges of the rear face of the sharp bearing body **26** to create a frame **161** over the rear face. In some embodiments, material for the frame **161** may be allowed to flow over other regions of the rear face (and perhaps a majority of the rear face), but be blocked from reaching the lumens **126** of the sharp bearing body **26**. This may be accomplished by including a shutoff in the mold for the holder **270** (or other component) which obstructs flow of material over portions of the rear face which are desired to be bare. Including some compliance (see, e.g., compliant member **865** of FIG. **64**) in the portion of the mold **860** including the shutoff may be desirable as it may aid in maintaining the integrity of the sharp bearing body **26** during the molding operation. By embedding a section of the sidewall **27** and portion of the rear face of the sharp bearing body **26** in the molded material, a sharp bearing body **26** may be robustly retained in a holder **270** or other component. Additionally, the interface between the sharp bearing body **26** and the holder **270** or other component may be leak resistant up to relatively high pressures.

[0376] Where sharp bearing bodies **26** are singulated from a wafer in a series of material removal operations, the manner in which the material is removed may be leveraged to assist in placement of the sharp bearing body **26** into a mold cavity. It may be desirable to have features on the sidewalls **27** which are positionally defined with a high degree of precision (+/−1-3 microns). These features may be referred to as precision sidewall segments. Such segments may allow for automation equipment to place a sharp bearing body **26** substantially blindly into a target destination in a mold cavity. This may be particularly important where the vision system's field of view is obstructed by the sharp bearing body **26** and/or end effector holding the sharp bearing body **26** when the sharp bearing body **26** is placed. The precision sidewall **27** segments may allow the sharp bearing body **26** to be in a highly know position relative to the automation equipment. Inclusion of precision sidewall segments may decrease time required to place the sharp bearing body **26** in a mold cavity. In such examples a portion of the sidewall **27** of a sharp bearing body **26** defining a substantially constant cross-section portion of the sharp bearing body **26** may be formed via an etching process. For example, a highly anisotropic etch such as a deep reactive ion etch may be utilized to form a portion of the sidewall **27** for the sharp bearing body **26**. A second portion or portion(s) of the sidewall **27** may be formed in a set of dicing cuts which may be used to singulate the sharp bearing body **26** from the wafer. In some examples precision sidewall **27** segments may form the bounds of a constant cross-sectional area portion of the sharp bearing body **26** on two opposing sides of the sharp bearing body **26**. The remainder of the sidewalls **27** may be formed via dicing. Additionally, etched side wall **27** portions may allow for sidewalls **27** which are defined (at least in part) by non-straight line segments. In some examples, only a small portion of the sidewall **27** may be etched. For example, for each sharp bearing body **26** which is to be individualized from a larger wafer, at least one passage may be etched through (or at least partially through) the wafer material in a precise position. The position chosen for the hole may ensure that a portion of the hole forms a section of the sidewall **27** of the sharp bearing body **26** when the sharp bearing body **26** is diced from the wafer. There may for example be sidewall **27** portions defined by remnants of holes on at least two opposing sides of a sharp bearing body **26**. Two such precision sidewall **27** segments defined by hole remnants may be included on each of the opposing sides in certain non-limiting examples. Thus, the small divot or notch (e.g. a semi-circle or half-moon shape) in the sidewall **27** may act as a precision sidewall **27** segment which may assist in automated placement of the sharp bearing body **26** into other equipment (e.g. molds).

[0377] As mentioned above in relation to FIGS. **6**A-**6**B, certain delivery sharps **72** may be formed with vertical faces **860**. In some embodiments, and still referring primarily to FIG. **61**, vertical faces **860** of any delivery sharp(s) **72** included on a sharp bearing body **26** may be disposed inboard of the periphery of the sharp bearing body **26**. Thus, the footprint of each delivery sharp **72** may be surrounded on all sides by a portion of the sharp bearing face of the sharp bearing body **26**. By

positioning the delivery sharps(s) **72** inboard of the periphery of a sharp bearing body **26**, coupling of the sharp bearing body **26** to a holder **270** during an injection molding operation may be facilitated. This may allow for an edge surface (e.g. chamfered or stepped) to be included such that the sharp bearing body **26** may be robustly coupled to a holder **270** without molding material onto the sharp bearing face of the sharp bearing body **26**. Additionally, it avoids having vertical faces **860** of the delivery sharp(s) **72** which are continuous with the outermost portion of the sidewall **27** that may present scaling issues when a sharp bearing body **26** is coupled to a holder **270** via injection molding. Additionally, it may allow for a shut-off **864**B to contact the sharp bearing face of the sharp bearing body **26** around all sides of the delivery sharps **72**. Where the delivery sharp(s) **72** are one or more microneedles formed of silicon, sharp bearing bodies **26** with arrays of microneedles may generally be diced out of a wafer including a relatively large number of microneedle arrays. When the microneedles are formed, the microneedles may be formed such that their sloped faces **21** extend all the way to sharp bearing face of the sharp bearing body **26**. The angle of the sloped face **21** may be defined by a crystallographic plane (e.g. 1 1 1) of the wafer. A dicing saw may be used to both separate individual sharp bearing bodies **26** from the larger wafer and to remove a portion of the microneedle to form the vertical face **860** at the desired position. The dicing saw may be moved at high speed over the sharp bearing face and across the portion of the microneedles to be removed. A portion of the sharp bearing face may be removed as this occurs such that the sharp bearing face in this region may be recessed after the vertical faces **860** for the microneedles are formed. This may allow a sharp bearing body **26** with silicon microneedles to maintain a small footprint even with tall microneedles despite the sloped face **21** having an angle defined by the crystallographic plane of the wafer. Additionally, this may facilitate use of sidewalls **27** described above which may make a sharp bearing body **26** highly amenable to being coupled to a holder **270** (or other component such an adapter which is part of or couples to a delivery implement) via injection molding.

[0378] Still referring to FIG. **61** the sidewalls **456** of the delivery sharp(s) **72** on a sharp bearing body **26** may be angled or rounded such that the width of the delivery sharp(s) **72** decreases adjacent the vertical face **860**. The etch used to define the outline of the delivery sharp(s) **72** may be made such that the width of the delivery sharp(s) **72** decreases as proximity to the sacrificial portion of the delivery sharp(s) **72**. In some embodiments, the decrease in width may continue into sacrificial portion or the portion of the delivery sharp(s) **72** to be removed. When the vertical face **860** is formed, this may allow the transition from the sidewalls **27** to the vertical face **860** to be less sharp and thus more robust.

[0379] Though sharp bearing bodies **26** may be coupled to other components via adhesives, this can be a time consuming process which is poorly suited to high volume manufacturing. Molding arrays of microneedles into other components allows for efficient high volume mass manufacture of microneedle based fluid delivery platforms. Overmolding of material onto arrays of microneedles to form larger components is a particular challenge in the implementation of microneedles in fluid delivery devices. A fluid tight seal between the sharp bearing body **26** and overmolded material needs to be reliably formed without compromising the integrity of the sharp bearing body **26**. Silicon wafer material, from which certain delivery sharps **72** and sharp bearing bodies **26** may be formed is brittle and can break fairly easily. This material is subjected to a number of stresses (ejection loading, thermal expansion and contraction of materials, etc.) during an overmolding process. Moreover, slight misalignment can result in chips, cracks, or other undesired marring of sharp bearing bodies **26** or delivery sharps **72**. Additionally, the distance from the sharp bearing face to the opposing face of various sharp bearing bodies **26** may typically be about 200 μm. Thus, the available space for formation of an interface between the overmolded component and the sharp bearing body **26** which is fluid tight up to high pressures (e.g. at least 90 p.s.i.) is relatively small. Additionally, depending on the design of the overmolded component, such pressures may elastically distort the overmolded material in the vicinity of the sharp bearing body

**26** presenting further sealing challenges. Moreover, a strong bond between an initial part and the second material used in the overmolding procedure is typically considered critical. Sharp bearing bodies **26** may typically be formed of a material that is dissimilar to material used to form the overmold. Silicon wafer material, for example, will not melt during the overmolding procedure and will not chemically bond with the overmolded material.

[0380] Components may be overmolded to sharp bearing bodies **26** as described below in relation to FIGS. **63**-**68**. Though the below description is provided in the context of a holder **270** for a delivery device **10**, it should be appreciated that the description is generalizable for use with components other than holders **270**. For example, adapters for delivery implements such as syringes may be formed similarly to as described herein. Additionally, infusion sets for prolonged delivery of agent to a shallow delivery destination (similar to subcutaneous insulin infusion sets for instance) or subcomponents thereof may be formed as described across FIGS. **63**-**68**. Such components may, for example, include any of those shown and described in U.S. Publication No. US20230277759A1, filed Mar. 3, 2023, and entitled "Systems, Methods, and Apparatuses for Medical Agent Administration", (Attorney Docket No. 00101.00359.AB108) which is hereby incorporated by reference in its entirety. Any other drug delivery hardware which interfaces with patient anatomy via one or more microneedle may be formed similarly to as described herein.

[0381] As mentioned in relation to FIGS. **55**A-**55**D, it may be desirable that the delivery sharps **72** of a component be coupled into that component in a tilted orientation. The sharp bearing body **26** and delivery sharps **72** may be tilted about a tilt axis that extends perpendicular to an axis of the component into which they are molded. For example the delivery sharps **72** may be tilted 15-25° from the orientation in which they would extend parallel to an axial dimension of the component. Though it adds complexity to the mold **860** (multiple shut off planes, part ejection systems not perpendicular to part geometry, etc.), it may be desirable to overmold the material with a mold **660** incorporating a stepped parting line.

[0382] Referring now to FIGS. **63**-**64**, the parting plane **862** for the mold **860** may be oriented such that the sharp bearing body **26** may be deposited into the mold **860** in an orientation in which the force of gravity is normal to the sharp bearing face of the sharp bearing body **26**. This may assist in retaining the sharp bearing body **26** in a stable resting orientation within the mold **860** prior to clamping.

[0383] Still referring to FIGS. **63**-**64**, preferably, the shut-offs **864**A, B may clamp against two parallel surfaces of the sharp bearing body **26**. In the example, the shut-offs **864**A, B clamp against the sharp bearing and opposing face of the sharp bearing body **26**. Thus, the shut-offs **864**A, B may block material from being molded over the sharp bearing face or into openings to the lumens **126** on the opposing face. The clamping force (indicated by arrows **866**A, B) applied to the shut-offs **864**A, B may be kept normal to the sharp bearing face and opposing face of the sharp bearing body **26** by incorporating a stepped parting line. This will help to ensure that the shut-offs **864** A, B do not deflect or have a tendency to misalign on the sharp bearing body **26** once pressure is applied to clamp the sharp bearing body **26** between the shut-offs **864**A, B. This may facilitate repeatable and reliable seal creation around the periphery of the sharp bearing body **26** when material is injected into the mold cavity **868**. Additionally, it may assist in maintaining the integrity of the sharp bearing body **26** and delivery sharps **72**. For example, the shut-off **864**B which clamps against the sharp bearing face of the sharp bearing body **26** will include at least one pocket **870** for the delivery sharps **72** on the sharp bearing body **26**. The sharp pocket(s) **870** entirely surround the delivery sharps **72**. With deflection or misalignment, the walls sharp pocket **870** on the shut-off **864**B may contact and damage the delivery sharps **72**. The stepped parting line may also help to constrain the nature of any misalignment of the sharp bearing body **26** within the mold **860** such that any misalignment from the ideal position may be kept substantially within a plane. That is, any misalignment may tend to be in a fore/aft, left/right, or rotational yaw type manner. As a result, despite any potential misalignment, the surfaces of the sharp bearing body **26** against which the

shut-offs **864**A, B press may still be substantially within the plane in which they are anticipated to be. Thus, any misalignment may be kept substantially in directions where the greatest degree of forgiveness is present. This may help inhibit damage to the sharp bearing body **26** and delivery sharps **72** which could be incurred in the event that pitch or roll type misalignment was present during clamping.

[0384] Still referring to FIGS. **63**-**64**, as mentioned above creation of a good seal between the overmolded component and the sidewalls **27** of the sharp bearing body **26** is challenging. This seal is formed over a very small region and is required to be fluid tight even when exposed to high pressure (e.g. 90 p.s.i. or greater). The mold **860** may be constructed such that vents **872** in the mold cavity **868** are included adjacent the interface to be formed between the sharp bearing body **26** and the material filled into the mold **860**. Instead of incorporating the shut-off **864**B as a monolithic part of the "B" block **876** of the mold **860**, the shut-off **864**B shown in the example embodiment is part of an insert which is deposited in the "B" block **876** of the mold **860**. By including the shut-off **864**B as a separate component, an interface between the shut-off **864**B insert and the surrounding "B" block **876** material is created. This interface may be leveraged to create a number of appropriately sized venting pathways directly abreast the interface between the sharp bearing body **26** sidewalls **27** and the component to be overmolded. This ensures that the mold breathes particularly well in this region and that material fills at this interface in a predictable, consistent, and repeatable manner without any dieseling.

[0385] Referring now to FIGS. **65**A-**25**C a number of view of example shut-offs **864**A-B are depicted. The shut-offs **864**A-B may clamp against a sharp bearing body **26** during an injection molding operation where a component is overmolded to the sharp bearing body **26**. The shut-offs **864**A-B may ensure that a robust fluid tight seal (e.g. up to at least 90 psi) is formed by the overmolded material. At the same time, the shut-offs **864**A-B may be arranged to help assist in ensuring a highly reliable positioning of the sharp bearing body **26** while mitigating any potential for damage to the delivery sharps **72** or sharp bearing body **26**.

[0386] As shown, shut-off **864**A clamp may clamp against a central region of the rear face of the sharp bearing body **26**. The exterior surface walls of the shut-off **864**A in the vicinity of the sharp bearing body **26** may be smooth and devoid of steps. The exterior walls may also extend in a direction substantially perpendicular to the clamped rear face of the sharp bearing body **26**. This may help to ensure good flow of material to the regions immediately adjacent the sharp bearing body **26**. In turn, this may ensure that a reliable seal is formed by the material overmolded onto the sharp bearing body **26**.

[0387] Shut-off **864**B may include a pocket **870** for each delivery sharp **72** present on the sharp bearing body **26**. In the example embodiment, two pockets **870** are depicted, however, additional pockets **870** of the same type may be included in shut-offs **864**B for sharp bearing bodies **26** with a greater number of delivery sharps **72**. The pockets **870** may be constructed to encourage a highly repeatable and reliable sharp bearing body **26** position within a mold **860**. The pockets **870** may also bestow this reliable positioning while mitigating potential to damage the delivery sharp **72** or sharp bearing body **26** as the sharp bearing body **26** is installed in a mold **860**.

[0388] As best shown in FIG. **65**B, the pockets **870** each include a ramped sidewall **821**. Opposite the ramped sidewall **821** the pockets **670** include a rounded sidewall section **823**. Lateral sidewalls **825**A, B connecting the rounded sidewall section **823** to the ramped sidewall **821** may also be present. The width of the pocket **870** may generally increase as distance from the rounded sidewall section **823** increases. The rounded sidewall section **823** and lateral sidewalls **825**A, B may taper such that the cross-sectional area of the pocket **870** decreases as distance from the clamping face **831** of the shut-off **864**B increases. The slope of the taper on the lateral sidewalls **825**A, B may be gentlest at the end regions of the lateral sidewalls **825**A, B most proximal the ramped sidewall **821**. The width of the pocket **870** may be greatest where the distal side **15** of the base **17** of the delivery sharp **72** is positioned. The tapered region of the rounded sidewall **823** and lateral sidewalls **825**A,

B may be intermediate two straight wall segments which extend substantially perpendicular to the clamping face **831** of the shut-off **864**A, B.

[0389] As the sharp bearing body **26** is installed in the mold **860**, the delivery sharps **72** may be placed into the pockets **870** of the shut-off **864**B. The pockets **870** may guide the delivery sharps **72** into position within their respective pockets **870**. The taper on the sidewalls **823**, **825**A, B may serve to gently funnel the delivery sharps **72** such that they self-center within the pockets **870**. Additionally, the sloped face **21** of the delivery sharp **72** may slide along the ramped sidewall **821** of the respective pocket **870**. This may tend to bring the back facing edge **23** of the delivery sharp **72** into contact with the rounded sidewall section **823** as shown best in FIG. **65**A. The pockets **870** may also include a pit region **839**. The pit region **839** may be sized to accept the tip **31** of the delivery sharp **72** when the delivery sharp **72** is introduced into the pocket **870** over any of a range of positions. Thus, the tip **31** of the delivery sharp **72** may generally be out of contact with the pocket **870** in the event of minor misalignment and may only contact the pocket **870** as the delivery sharp **72** self-aligns with further advancement into the pocket **870**. Thus, the deliver sharp **72** may be substantially protected against damage when the sharp bearing body **26** is located on the shut-off **864**B.

[0390] Referring primarily to FIG. **65**C, a cross-sectional view of a pair of delivery sharps **72** in pockets **870** of an example shut-off **864**B is depicted. The cross-section is taken at the plane of the sharp bearing face of a sharp bearing body **26** to illustrate the position of the delivery sharps **72** within the respective pockets **870**. As shown, each delivery sharp **72** has associated kerf regions **827** (see also FIGS. **10**A-**10**D) which are artefacts of the etching process used to form silicon delivery sharps **72**. It is desirable to carefully accommodate the kerf regions **827** in any shut-off **864**B. The kerf regions **827** are relatively delicate and prone to chipping. Particulate formation in the mold **860** may be undesired for a number of reasons. For example, silicon is quite hard and silicon particulate may negatively impact mold **860** longevity. Additionally, particulate trapped between the shut-offs **864**A, B and the sharp bearing body **26** may damage the sharp bearing body **26** when clamping force is applied. Silicon particulate may also become entrapped in the overmold material. This may further complicate the challenge of repeatably and reliably generating a fluid tight high pressure seal at the interface of the sharp bearing body **26** and the overmolded material.

[0391] Still referring to FIG. **65**C, the width of the open ends of the pockets **870** directly lateral to where the distal side **15** of the base **17** of the delivery sharp **72** is received may be selected to be about double (e.g. 85-115%) the width of the distal side **17** of the delivery sharp **72**. This may help to ensure that the kerf regions **827** are accommodated within the pocket **870** for an associated delivery sharp **72**. The tapered region of the lateral sidewalls **825**A, B may begin at a depth greater than the maximum height of the kerf regions **827**. Thus, the cross-sectional area of the pocket **870** may be at its greatest throughout the volume of the pocket **870** where the kerf regions **727** may be positioned. As mentioned above, the pockets **870** may substantially self-center respective delivery sharps **72** as a sharp bearing body **26** is installed in the shut-off **864**B. The self-centering of the respective delivery sharp **72** may be substantially complete before the kerf regions **827** are advanced into the volume of the pocket **870** helping to ensure the kerf regions **827** maximum clearance from the walls of the pocket **870**. By self-centering the respective delivery sharps **72** prior to the kerf regions **827** advancing into the pocket **870** the cross-sectional area at the open end of the pockets **870** may be kept relatively small. This may help to maximize the amount of the sharp bearing body **26** available for use as a shut-off surface.

[0392] Referring now to FIG. **66**, an example block diagram **880** of a mold **860** is depicted. The example mold **860** includes a multi-stage ejection arrangement with a variety of ejector pins **882**A-D disposed within guide pockets **884** defined in the mold **860**. The hydraulics of the molding machine may be used to drive the ejector pins **882**A-D to remove components of the mold **860** and the molded assembly in a controlled and repeatable sequence. The terminal ends of the ejector pins **882**A-D are spaced varying travel distances **886**A-C from the ends of their respective guide pockets

**884**.
[0393] The ejector pins **882**A for a runner plate **888** of the mold **860** are arranged with the shortest travel distance. The ejector pins **882**B for the "A" block **874** of the mold are positioned with a first intermediate travel distance **886**A. The ejector pins **882**C for the sharp bearing body **26** and overmolded part are positioned with a second intermediate travel distance **886**B greater than the first intermediate travel distance **886**A. The ejector pins **882**D which disassociate the "B" block **876** from the mold base **890** have a longest travel distance **886**C.
[0394] As the hydraulics displace the ejector pins **882**A-D, all of the ejector pins **882**A-D may move in tandem with one another. The runner plate **888** of the mold **860** is initially ejected from the mold **860**. The ejector pins **882**A for runner plate **888** may have no travel distance (as shown) to cover and may be in contact with the ends of their respective guide pockets **884** when in their initial position. As the runner plate **888** is ejected, the molded component may be automatically de-gated. The ejector pins **882**B for the "A" block **874** of the mold **860** may then contact the ends of their respective guide pockets **884**. Further displacement of the ejector pins **882**B may disassociate the "A" block **874** from the mold **860**. Subsequently, the ejector pins **882**C for the sharp bearing body **26** and the molded component contact the bottoms of their respective guide pockets **884** driving the overmolded assembly out of the mold **860**. The ejector pins **882**C for the overmolded assembly may act on a knockout subassembly **892** within the mold **860**. This subassembly **892** may include a set of part side ejector pins **894** on a sled **898** which are driven by the hydraulic side ejector pins **882**C. The subassembly **892** is biased (e.g. via one or more compression spring **896**) to a home position. After ejection, the bias drives the subassembly **892** back to the home position within the "B" block **876**. A final ejection step drives the "B" block **876** of the mold **860** off of the mold base **890** as the ejector pins **882**D contact the ends of their respective guide pockets **884**.
[0395] In an alternative ejection arrangement, the travel distances **886**A, **886**B may be the same. Thus, the ejector pins **882**B for the "A" block **874** of the mold **860** and those acting on the knockout subassembly **892** may begin to displace their respective portions of the mold **860** at the same time. The knockout subassembly **892** thus chases the "A" block **874** of the mold **860** in lock step as the "A" block **874** of the mold **860** is separated from the "B" block **876**. The overmolded assembly would then stick on the "A" block **876** of the mold **860** when the knockout subassembly **892** is driven back to its home position. A vacuum grabber (or other suitable picking end-effector) could be used to remove the overmolded assembly. The overmolded assembly could be separated from the "A" block **874** in any other suitable manner. The delivery sharps **72** on the sharp bearing body **26** will be displaced out of the sharp pocket(s) **870** of the shut-off **864**B insert in the "B" block **876** in a highly controlled manner along a direction parallel to the axes of the ejector pins **882**A-D. This limits opportunity for the delivery sharps **72** on the sharp bearing body **26** come into contact with the pocket(s) **870** in the shut-off **864**B and may help to inhibit damage to the delivery sharps **72** during the molding process.
[0396] Referring now also to FIG. **67**, the molds **860** described herein may include a resting clamping assembly **900** which may provide a resting clamping force that holds the "A" block **874** and "B" block **876** firmly against one another. A resting clamping force may assist in keeping the sharp bearing body **26** and delivery sharps **72** firmly in place when mold **860** is initially closed before the injection molding machine hydraulics are pressing on clamping platens of the machine. In the example shown in FIG. **67**, the resting clamping assembly **900** include a set of rare earth magnets **904** disposed in the "A" block **874** of the mold **860** and the "B" block **876** of the mold **860**. When the mold **860** is initially closed, the attraction between the magnets **904** may clamp the sharp bearing body **26** in place. Elastomer cushions **902** may be built into the parting line. These elastomer cushions **902** add some compliance which mitigates potential shock on the sharp bearing body **26** when the magnets **904** drive the "A" block **874** and "B" block **876** of the mold **860** together. Though magnets **904** are used, this clamping may be accomplished in any other suitable manner.

[0397] The mold **860** may also include a retainer assembly **905** that maintains the "B" block **876** of the mold **860** against the mold base **890** for at least a portion of the ejection sequence. For example the retainer assembly **905** may hold the "B" block **876** of the mold **860** in place as the "A" block **874** of the mold **860** is ejected. Thus the "B" block **876** will be held in a tightly controlled position as relative displacement of the "A" block **874** occurs. This may help to prevent movement of the delivery sharps **72** within the sharp pocket(s) **870** of the shut-off **864**B minimizing potential for the delivery sharps **72** to be compromised. In the example embodiment, the retainer assembly **905** is provided by the magnets **904** in the "B" block **876**. As shown, a greater number of magnets **904** are installed in the "B" block **876** than the "A" **874**. In the example embodiment, the "B" block **876** includes double the number of magnets **904** than the "A" block **874**. This ensures that the "B" block **876** is attracted to the mold base **890** strongly enough to be retained against the mold base **890** as the "A" block **874** is ejected.

[0398] Referring now to FIG. **68** a detailed view of a terminal end **906** of a part side ejector pin **894** of a knockout subassembly **892** which may be included in a mold **860** is depicted. Due to the stepped parting line incorporated into the mold **860**, the overmolded component needs to be ejected on a wedge. With a flat terminal end **906**, some of the linear ejection force will be translated into lateral deflection force. This may lead to an overmolded component not ejecting cleanly or may place side loads on the part side ejection pins **894** which may damage the part side ejection pins **894**. As shown, the terminal end of part side ejector pins **894** may be arranged such that the molded component and the part side ejector pins **894** have interlocking features. As shown, a cleat **908** may be placed in the terminal end **906** of each part side ejector pin **894**. Thus, as material is injected into the mold **860**, the material may be overmolded onto the cleats **908** and the terminal ends of the part side ejector pins **894** may be embedded into the molded component. The overmolded material will buttress the part side ejector pins **894** against any side loading ensuring that the molded assembly ejects cleanly.

[0399] As shown, the cleats **908** may be included as raised ridges which span across the terminal end **906** of each part side ejector pin **894**. The ridges may run in a direction perpendicular to the lateral deflection force which would be experienced by each of the part side ejector pins **894**. Additionally, the ridges forming the cleats **908** may be rounded. Thus, the cleats **908** may easily (e.g. automatically) release from the molded assembly as the ejection sequence transpires. Though shown as a ridge, other generously drafted raised features may be included in alternative embodiments. The part side ejector pins **894** could alternatively include a recessed feature or features which would interlock with material of the molded component. It may, however, be preferred that raised features be used in order to avoid creating protrusions on the patient contacting side of the overmolded component.

[0400] In other embodiments and referring now to FIGS. **69**A-**70**C, a sharp bearing body **26** may be coupled to a holder **270** via a material swaging operation. Though described in relation to a holder **270**, a sharp bearing body **26** may be coupled to other components which form part of or couple to a delivery implement (e.g. an adapter with a luer fitting) in like manner. Description in relation to a holder **270** may be generalized to other such components and discussion of the holder **270** is merely exemplary. Additionally, the holder **270** shown is merely exemplary and sharp bearing bodies **26** may be coupled to any holder **270** depicted or described herein via a material swaging operation.

[0401] As shown, a holder **270** may include a receptacle **291** for a sharp bearing body **26**. The receptacle **291** may be defined on a proximal or distal face of a holder **270** depending on the embodiment. As depicted in FIGS. **69**A-**69**C, the receptacle **291** is included on the proximal side of the holder **270**. The receptacle **291** may, for instance, be a pocket **276** on a stage projection **279** or bump of a holder **270**. The receptacle **291** may include a shelf **293** which surrounds a passage **295** disposed in a central region of the receptacle **291** which extends through the holder **270**. The face of a sharp bearing body **26** opposite the sharp bearing face may be placed on the shelf **293**. The

passage **295** may provide a fluid communication channel through the holder **270** to the lumen(s) **126** of the delivery sharp(s) **72** of the sharp bearing body **26**.
[0402] As shown in FIGS. **70**A-**70**C, a receptacle **291** may alternatively be formed as a recess in the distal face of the holder **270**. The example receptacle **291** is shown as a recess in a well **281** of an example stage projection **279** in FIGS. **70**A-**70**C, however, could be a recess in a rounded depression **274** (see, e.g., FIG. **54**A). The receptacle **291** may include a shelf **293** surrounding a passage **295** extending through the holder **270**. The sharp bearing face of a sharp bearing body **26** may be seated against the shelf **293** and the delivery sharp(s) **72** may project through the passage **295** proud of the holder **270** such that they may puncture into a patient.
[0403] The receptacle **291** may be surrounded by a bead **297** of material. In some embodiments, the bead **297** may be formed integrally with the remainder of the holder **270** in a single molding operation (as shown). In alternative embodiments, the bead **297** may formed of a material which differs from that the majority of the holder **270**. For example, the bead **297** may be formed in a piece of material that is over molded to a first portion of the holder **270**. In such embodiments, the bead **297** may be formed of elastomer while the first portion of the holder **270** may be formed of a comparatively rigid plastic.
[0404] When a sharp bearing body is **26** installed in a receptacle **291**, the bead **297** of material may be swaged over a portion of the sharp bearing body **26** to couple the sharp bearing body **26** in place on the holder **270**. In some embodiments, the bead **297** may be heat swaged over a portion of the sharp bearing body **26**. In some embodiments, the bead **297** may be laser swaged over a portion of the sharp bearing body **26**. Where laser swaging is used, the bead **297** may be constructed of a material which absorbs wavelengths of the laser used to perform the swage. A thermoplastic with a high melt index (e.g. 10 or higher).
[0405] Though the examples shown in FIGS. **69**A-**70**C depict sharp bearing bodies **26** with sidewalls **27** formed as a single straight surface which is substantially perpendicular to the sharp bearing face, other sidewall **27** arrangements may be used. Where the bead **297** of material is disposed nearest the sharp bearing face of the sharp bearing body (FIGS. **69**A-**69**C), various sidewall **27** arrangements may be utilized. The sidewalls **27** may, for example, be arranged such that the cross-sectional area of the sharp bearing body **26** increases as distance from the sharp bearing face increases. This may assist in ensuring that the swaged material does not displace over the sharp bearing face of the sharp bearing body **26**, but instead covers only a portion of the sidewalls **27** or substantially the entire sidewall **27** depending on the embodiment. In alternative examples, the microneedle height may be increased and some material may be allowed to displace over the sharp bearing face of the sharp bearing body **26**.
[0406] Where the bead **297** of material is disposed closest the face of the sharp bearing body **26** opposite the sharp bearing face, similar sidewall **27** arrangements cut in the opposite fashion may be used. That is, any of the sidewall **27** profiles described above may be used, however, material may be removed such that the cross-sectional area of the sharp bearing body **26** decreases as proximity to the sharp bearing face decreases. This may assist in ensuring that the swaged material does not displace over the face of the sharp bearing body **26** where the upstream end of the lumens **126** are disposed, but instead covers a portion or substantially all of the sidewalls **27**. This helps to keep the swaged material from impeding access to lumens **126** of the sharp bearing body **26**.
[0407] Retaining a sharp bearing body **26** in a holder **270** or other component via a swaging operation may be advantageous for a variety of reasons. For example, where laser swaging is used, the bead **297** of material may be swaged into a retaining position relatively rapidly (less than a second). Additionally, ejection stress loading of the sharp bearing body **26** may be absent. The sharp bearing body **26** may also be placed in a holder **270** (or other component) with relatively loose tolerances.
[0408] In some embodiments, as shown in FIGS. **71**A-**71**D (respectively a perspective view looking down from above, view from the side, perspective view looking up from below, and view

from the top relative to an application surface for a delivery device **10** such as e.g., the skin surface), a reservoir portion **271** is depicted. A reservoir portion **271** may be shaped to incorporate, as an integrated structure, a dome shaped portion **280**, a tunnel or side channel **282**, and a flange or annular portion **284**. That is, these features may be included in a single monolithic piece of material. In some embodiments the dome shaped portion **280** may be shaped approximately as a hemisphere or other spherical segment though any other suitable shape is possible. In examples where the reservoir portion **271** includes a rounded shape which forms a cavity (e.g. the dome shaped portion **280**), there may be a plateau or flat surface included at the portion of the rounded shape most distal the flange **284**. The flat surface may be generally parallel to the flange **284**. In some examples, a central depression **267** (see, e.g. FIG. **72**) may also be included in the flat surface. The tunnel **282** may be shaped in some examples as a half-pipe or half cylinder that may be formed from the annular portion **284**. Any suitable cross-sectional shape may be used in alternative embodiments. The side channel or tunnel **282** may communicate with the dome shaped portion **280** via an arch **286** such that the combination of dome shaped portion **280** and tunnel **282** form a structure shaped approximately as an igloo. In some embodiments, the end of the tunnel **282** opposite the dome shaped portion **280** may flare or taper outwardly to increase case of filling. The annular portion **284** may have an inner edge that is coincident with a base perimeter **288** of the dome shaped portion **280**. The reservoir portion **271** may be manufactured by, e.g., thermoforming a flat sheet of material (e.g., plastic or layers of various plastic or other material). Where a multilayer sheet is used, the sheet may include a drug or agent compatible layer, barrier layer, tie layer, etc. In some embodiments vacuum forming may be used to manufacture the reservoir portion **271**. Other known techniques such as injection molding could be used. The reservoir portion **271** may be formed of a polycarbonate material or other suitable materials and may be coated with a Cyclic Olefin Polymer (COP) or any other suitable coating material. The dome shaped portion **280** may be collapsible when pressure is applied thereto.

[0409] Referring now to FIGS. **72**, a perspective view of an exemplary reservoir portion **271** is shown. In certain examples, reservoir portions **271** may include at least one cavity with one or more built in collapse facilitator. The collapse facilitator may encourage the cavity to collapse in a prescribed manner and may lower the force needed to collapse the cavity. The collapse facilitator may also aid in ensuring that the cavity collapses such that any dead volume is minimized. Likewise, inclusion of a collapse facilitator may help to mitigate potential for fluid contained in a reservoir **12** to become trapped or pocketed in a region of the reservoir **12** that becomes blocked out of communication with an outlet during collapse of the cavity. Other reservoirs **12** described herein may include at least one collapse facilitator.

[0410] A collapse facilitator may be a pleated, bellows shaped, accordioned, creased, ruffled, stepped, or concertina shaped wall **261** which extends upward from the flange **284**. The wall **261** may extend proud of the flange **284** and may taper (e.g. continuously or in stepwise manner) as distance from the flange **284** increases. A top wall **263** may span across the portion of the wall **261** most distal the flange **284**. Thus, the wall **261** and top wall **263** may together form a cavity in the reservoir portion **271**. The top wall **263** may be generally planar and extend parallel to the flange **284** in certain examples. The top wall **263** may in certain examples include a central depression **267**. The central depression **267** may serve to aid in locating a reservoir interface member **474** (see, e.g., FIG. **37**) or a portion of a bias member **470**, **481** (see, e.g., FIG. **38** and FIG. **49**B respectively). Flat top walls **263** and/or central depressions **267** may be included in other reservoirs **12** described herein. The cavity formed by the wall **261** and top wall **263** may have a generally round, circular, elliptical, oval, obround, or polygonal cross-section.

[0411] Though any pleating, bellows, accordion, crease, or ruffling pattern may be used, in certain embodiments, the wall **261** may include at least one pleat **269** in a spiral pattern. The at least one spiral pleat **269** may extend from a point adjacent the flange **284** and end at a point adjacent the top wall **263**. Where the wall **261** tapers as distance from the flange **284** increases, any spiral pleats **269**

may have a conical type spiral to accommodate the taper. Any spiraling pleat(s) **269** may have a pitch which causes each pleat(s) **269** to wrap around the wall **261** a plurality of times. In the example embodiment shown in FIG. **72**, the spiral pleat **269** wraps around the wall **261** about three times. Such a pleat **269** may aid in assisting collapse of the cavity while fluid is urged out of a reservoir **12** during operation of a delivery device **10**. Thus minimal force may be needed to deform and deplete such a reservoir **12** during use. Additionally, such a pleat **269** may assist in ensuring that little dead volume remains in the reservoir **12** after a delivery has completed. Use of a flat top wall **263** may also assist in collapse of the cavity.

[0412] Referring now to FIG. **73**, the wall **261** may be stepped and include at least one step region **259**. The cross-sectional area of the cavity may change at each step region **259**. In the example, the cross-sectional area of the cavity is largest adjacent the flange **284** and decreases in a stepwise manner as distance from the flange **284** increases. The wall **261** includes two step regions **259** in the example shown in FIG. **73**, though any suitable number may be included in alternative embodiments. As in the examples discussed above, the stepped wall **261** may aid in lowering force needed to collapse the cavity and help to direct the collapse in a prescribed manner. One example delivery device **10** embodiment including a reservoir **12** with such a stepped wall **261** is depicted in FIG. **50**B. An example reservoir **12** including a stepped wall **261** is depicted in FIG. **104**.

[0413] In an embodiment, the reservoir **12** may be formed by attaching the reservoir portion **271** to the holder **270**, as shown in FIG. **74**. The reservoir portion **271** may be positioned above the holder **270** in the example shown, and the lower surface area **285** of the annular portion **284** may be affixed to the upper surface area **273** of the annulus **272** or disk body **275**. In an embodiment, the reservoir portion **271** may be attached to the holder **270** by ultrasonic welding, although any form of welding or any other coupling technique known to those of skill could be used. For example, the reservoir portion **271** and the holder **270** may be sealed together with a double sided adhesive. Other suitable techniques for sealing the reservoir portion **271** and the holder **270** together include, by way of non-limiting examples, using an ultraviolet curable adhesive, heat staking, and laser welding.

[0414] A medical agent, such as, e.g., a vaccine, may be inserted into the reservoir **12** via the side channel **282**, after which the side channel **282** may be sealed closed by any known technique such as, e.g., sonic welding, heat staking, or any other suitable technique described herein. In alternative embodiments, the reservoir **12** may include a septum **550** (see, e.g., FIGS. **102**A-**104**) through which agent may be transferred into the reservoir **12**. In such examples, the side channel **282** may be omitted and the periphery of the flange **284** of the reservoir portion **217** may be completely sealed to the upper surface **273**.

[0415] The sharp bearing body **26** (see, e.g., FIG. **34**) including the delivery sharp(s) **72** (see, e.g., FIG. **34**) may be inserted into the pocket **276** and fixed therein by any suitable technique such as, e.g., welding, prior to insertion of the medical agent (e.g., vaccine) into the reservoir **12**. Alternatively, and as mentioned above, the holder **270** may be formed around the sharp bearing body **26**. As mentioned elsewhere herein, the delivery sharp(s) **72** may be one or more microneedle in various examples.

[0416] In one example embodiment, the reservoir **12** may hold approximately two microliters of vaccine or other medical agent. After a medical agent (e.g., a vaccine) has been inserted, the reservoir **12** may be placed in cold chain storage separately and subsequently installed in the delivery device **10** shortly before use. This may serve to help maximize the yield of vaccine doses per unit volume in cold chain storage. The reservoir **12** may be inserted into the delivery device **10** with a packet **208** and/or container **350** or foam adhesive (such as the packet or foam adhesive material described above with reference to FIGS. **11**A-**12**). The packet **208** and/or container **350** or foam adhesive may be disposed between the reservoir **12** and the underside of the top surface **250** of the delivery device **10** when the delivery device **10** is fully assembled. Alternatively and as discussed above, a dispensing assembly **480** (see, e.g., FIG. **37**) or at least one bias member **470**

(see, e.g., FIG. **48**) may be disposed between the underside of the top surface **250** and the reservoir **12** once the reservoir **12** is installed.

[0417] With reference to FIG. **75**, a reservoir **12** (e.g., a reservoir **12** such as that described above with reference to FIG. **74**) may be affixed to the inside of a delivery device **10**. Though a representational example delivery device **10** is depicted, a reservoir **12** may be similarly installed in a main body **20** of any delivery device **10** embodiments described herein. The reservoir **12** may contain a medical agent (e.g., a vaccine) prior to being assembled into the delivery device **10**. The reservoir **12** may be removed from cold storage prior to being attached to the inside of the main body **20** of a delivery device **10**.

[0418] Still referring to FIG. **75**, in one embodiment, a ridge **290** may be formed in an inside surface of the central region **28** of the delivery device **10** such that the ridge **290** may serve as a seating structure upon or against which a section or region of the reservoir **12** may be positioned or coupled. In one example, the annulus **272** or the holder **270** may be adhered to the ridge **290** with an adhesive. It would be understood by one of skill that any suitable coupling technique could be used. In other embodiments, the distal face of the reservoir portion **271** may attach to the proximal face of the ridge **290**. A distal face of a reservoir portion **271** may for example be coupled to the ridge **290** of the main body **20** of the delivery device **10** shown in FIG. **29**. Tab projections **277** (see, e.g., FIG. **55**A) which couple into receiving slits **278** (see, e.g., FIG. **47**A) defined in the main body **20** may alternatively or additionally be used. In place of ridges **290**, main bodies **20** may include retention tabs **580** and stop surfaces **582** (see, e.g., FIGS. **105**-**106**B) which may couple the reservoir **12** in place within the delivery device **10**.

[0419] In certain embodiments and referring now to FIGS. **76**A-**76**B, the shape of the reservoir portion **271** may be adjusted to alter the maximum cross-sectional area of the reservoir portion **271**. This may aid in achieving a desired delivery pressure. For example, in some embodiments, the reservoir portion **271** may be formed so as to have a balloon like (shown in FIG. **76**A-**76**B), cylindrical, polygonal prism shape, etc. The height of the reservoir portion **271** may be adjusted to achieve the desired interior volume given a preselected maximum cross-sectional area. As shown, the holder **270** may include at least one buttress **289**. The at least one buttress **289** may at least partially surround the reservoir portion **271**. The at least one buttress **289** may aid in holding the reservoir portion **271** in a desired position within a delivery device **10**. The at least one buttress **289** may also aid in directing collapse the reservoir portion **271** as delivery occurs.

[0420] As shown in FIG. **76**B, the main body **20** may include a nesting projection **287**. As the delivery device **10** is transitioned into a delivery state (see, e.g., FIG. **32**) the nesting projection **287** may press against the reservoir portion **271**. As delivery progresses, the nesting projection **287** may press the reservoir portion **271** against the at least one buttress **289**. In the example embodiment, the nesting projection **287** may be disposed between the exemplary buttresses **289** and may aid in ensuring minimal dead space remains in the reservoir **12** after delivery is complete.

[0421] Referring now to FIG. **77**, in certain embodiments, it may be desirable that delivery pressure ramp up relatively slowly when the delivery device **10** is transitioned to a delivery state. For example, it may be desirable that fluid injection begin at a relatively low pressure or at or about the lowest pressure at which injection is possible for a particular patient. The delivery pressure may be ramped up until this delivery initiation pressure is reached for a particular patient. Ramping up pressure slowly may allow for the delivery initiation pressure to be reached for a wide variety of patients using the same delivery device **10** design. Additionally, once the injection begins, it may be desirable that the delivery pressure is held at or near the delivery initiation pressure. Additionally, and as shown in FIG. **77**, it may be desirable that such embodiments use at least one bias member **470** to facilitate delivery. For example, a compression spring made of a Hookean material may be used.

[0422] As shown in FIG. **77**, in such embodiments, the reservoir **12** may be partitioned into a first portion **520** and a second portion **522**. The first portion **520** and the second portion **522** may be in

fluid communication with one another via a flow restrictor **524** (see, also FIG. **50**B). The flow restrictor **524** may be disposed between a portion of the reservoir **12** proximal to the microneedles and a portion of the reservoir **12** more distal to the microneedles. The flow restrictor **524** may be an orifice plate with one or more orifice extending therethrough in certain embodiments. In some embodiments a flow restrictor **524** with a 15-25 micron orifice may be included. In other embodiments, an orifice may be up to 100 microns in diameter (e.g. 70-80 microns or 75 microns). In some embodiments, the orifice may have diameter greater than 100 microns. The orifice size may be selected based on considerations such as the viscosity and/or surface tension of the agent(s) filled into the reservoir, the desired speed of injection and how quickly it is desired to ramp up injection pressure. An orifice plate may be an injection molded component though could be formed in any other suitable manner.

[0423] In some embodiments, the width of the orifice may vary. For example, the orifice may taper from a wider aperture to a smaller aperture as distance to toward the proximal side of the orifice plate increases (the opposite is also possible). Such a tapered arrangement may be preferable depending on the agent to be delivered from the delivery device **10**.

[0424] Still referring to FIG. **77**, the first portion **520** of the reservoir **12** may include a majority of the reservoir **12**. The second portion **522** of the reservoir **12** may be disposed proximal to the delivery sharp(s) **72** relative to the first portion **520**. Thus, the flow restrictor **524** may separate a large first portion **520** from a smaller second portion **522** which is most proximal the delivery sharp(s) **72**. The first portion **520** may have a volume substantially equal to the fill volume of the reservoir **12** in certain examples. The flow restrictor **524** may be disposed upstream of at least the pocket **276** (see, e.g., FIGS. **53**A-**54**C) into which a sharp bearing body **26** may be coupled. In example embodiments, the flow restrictor **524** may separate a rounded depression **274** (see, e.g., FIGS. **54**A-**54**D) from the remainder of the reservoir **12**. In such embodiments, the flow restrictor **524** may be coupled to the distal face of the annular body **272** (see, e.g. FIGS. **54**A-**54**D) over the rounded depression **274**. In other examples, the flow restrictor **524** may separate the well **281** (see, e.g., FIGS. **55**A-**55**C) from the remainder of the reservoir **12**. In such embodiments, the flow restrictor **524** may be coupled to the distal face of the disk body **275** (see, e.g. FIGS. **55**A-**55**C) over the well **281**.

[0425] In certain examples, the first and second portion **520**, **522** of a partitioned reservoir **12** may be filled with different fluids. For example, the first portion **520** may be filled with an agent desired to be delivered (drug, vaccine, medical agent, etc.). The portion proximal the delivery sharp(s) **72** may be filled with a gas (e.g. sterile or cleanroom air from the manufacturing environment, inert gas, etc.). The orifice may be sized such that the properties of the agent (e.g. surface tension, viscosity) prevent the agent from passing to the second portion **522** without addition of pressure on the reservoir **12**. Thus, despite the first and second portions **520**, **522** being in fluid communication, the second portion **522** may remain unwetted by any agent filled into the reservoir **12** during manufacture until use. When the delivery device **10** is used, there may be a latency period during which fluid is forced into the second portion **522** from the first portion **520**. Pressure in the second portion **522** may then ramp up until a pressure at which the patient's anatomy begins to accept the delivery. The pressure may remain relatively steady (or at least not spike considerably) once delivery begins.

[0426] When a delivery device **10** including a partitioned reservoir **12** is transitioned to a delivery state, at least one bias member **470** (e.g. a conical spring, foam body, rubber body, elastomeric body) may cause pressure to be exerted against the first portion **520** of the reservoir **12**. Depending on the embodiment, the at least one bias member **470** may directly contact the reservoir **12** or pressure may be exerted through a reservoir interface member **474** (see, e.g., FIG. **37**) or other components of a delivery assembly **280** (see, e.g., FIG. **37**). The flow restrictor **524** may cause the pressure of fluid in the second portion **522** of the reservoir **512** to slowly ramp up to a pressure at which injection into a patient begins. Thereafter, the flow restrictor **524** may limit build-up of

pressure in the second portion **522** as the injection progresses. Thus the injection will tend to occur at or near the lowest pressure at which the patient will accept the delivery. This may facilitate use of a more aggressive spring and may limit discomfort associated with the delivery. Moreover, it may allow for a single delivery device **10** design to be used on a wide range of patient populations (e.g. any patient) or with a wide variety of different agents. Additionally, this may have an effect on bleb formation resulting from the delivery. As the delivery may tend to occur relatively slowly and at a relatively low pressure, a more diffuse shallow (e.g. intradermal) injection may tend result. Adjustment of the size of any orifice in the flow restrictor **524** may alter the duration of the delivery and characteristics of the bleb.

[0427] Referring now to FIG. **78**, in some examples, delivery devices **10** may include a delivery unit **650** and a trigger unit **652**. The delivery unit **650** may be formed of a first set of components and the trigger unit **652** may at least include a trigger body **654**. The trigger body **654** may displace relative to the delivery unit **650** to transition the delivery device **10** from its storage state to a delivery state. The delivery unit **650** may, for example, include a main body **20**, reservoir **12**, adhesive **22**, bias member **470**, and a reservoir interface member **474**. The trigger unit **652** may, for example, include the trigger body **654** and a deformable spacer **656** (though the spacer **656** may form part of the delivery unit **650** in certain examples).

[0428] The trigger body **654** may be a button and may include or be coupled to at least one barrier **658**A, B which may block displacement of a portion of the delivery unit **650** until the trigger body **654** is displaced by a user. For example, the at least one barrier **658**A, B may impede movement of the reservoir interface member **474** in the direction of the reservoir **12**. In some embodiments, there may be a set of barriers **658**A, B which displace in tandem and block movement of different sections of a reservoir interface member **474** (e.g. sections on opposite sides of the reservoir interface member **474** or sections spaced about the reservoir interface member **474** perhaps at regular angular intervals). The deformable spacer **656** may hold the trigger body **654** in a blocking position and may deform upon application of pressure to make way for the trigger body **654** and barrier(s) **658**A, B to displace to a trigger position. The deformable spacer **656** may be a spring, elastomeric body, gas bladder, or any other compliant member in various examples. Alternatively, the deformable spacer **656** may be a flexure formed integral to the trigger body **654** or a portion of the main body **20**. The deformable spacer **656** may also be a frangible in certain implementations which may permanently distort or break upon application of pressure. Once the trigger unit **652** has reached the trigger position, the bias member **470** may propel the reservoir interface member **474** in the direction of the reservoir **12** to expel the contents of the reservoir **12**.

[0429] In some embodiments, a series of barriers **658**A, B may divide displacement of the reservoir interface member **474** into a number of stages. For example, a first barrier **658**A (or set of first barriers **658**A) may inhibit displacement of the reservoir interface member **474** until the trigger body **654** is displaced to the triggered position. A second barrier **658**B (or set of second barriers **658**B) may be displaced to a blocking position as the trigger unit **652** is driven to the trigger position. The reservoir interface member **474** may partially displace to an intermediate point in its displacement range due to the presence of the second barrier **658**B (or set of second barriers **658**B). As pressure upon the trigger unit **652** is released, the deformable spacer **656** may restore to a less distorted state and the second barrier **658**B (or set thereof) may be urged to an unobstructing position. This may free the reservoir interface member **474** to displace to a second end of its displacement range allowing the reservoir interface member **474** to bring the reservoir **12** to its depleted state under the urging of the bias member **470**.

[0430] Referring now to FIGS. **79**A-**79**F, a number of diagrams of portions of an example delivery device **10** of the variety described in relation to FIG. **78** are depicted. With reference to FIG. **79**A, a portion of a delivery unit **650** is depicted alone. As shown, certain exemplary delivery units **650** may include at least one guide track **660**. Each of the at least one guide track **660** may be defined as a recess or ledge included in a side wall of a portion of the main body **20**. Each guide track **660**

may generally slope or ramp from a first end of the main body **20** toward an end of the main body **20** including the peripheral region **30**. A barrier channel **666** may be disposed somewhere in the intermediate region of each guide track **660** and may accept the barrier **658**A when the barrier **658**A is in the trigger position. The reservoir interface member **474** may be propelled by a bias member **470** to displace along the guide track(s) **660** upon triggering of the delivery device **10**. As mentioned above, and as shown in FIGS. **79**A-**79**F, the reservoir interface member **474** may be blocked from fully displacing along each guide track **660** by a second barrier **658**B when the trigger unit **652** is in a trigger position. As pressure on the trigger unit **652** is relieved, the second barrier **658**B may retract allowing the reservoir interface member **474** to continue displacement to a terminal point in its displacement range. Thus, such a delivery device **10** may be triggered over two stages. In the first stage, the reservoir interface member **474** may traverse an upstream portion of each guide track **660** and in the second stage the reservoir interface member **474** may proceed to the end of its displacement range along a downstream region of each guide track **660**.

[0431] In the embodiment depicted in FIGS. **79**A-**79**F, the guide track **660** shown includes an initial region **662** which is separated from a knoll region **664** of the guide track **660** by the barrier channel **666**. The exemplary guide track **660** may also include a terminal region downstream of the knoll region **664**. The initial region **662** may be sloped so as to form a ramp. Upstream of the initial region **662** may be a wall or backstop **661** which blocks motion of the reservoir interface member **474** in that direction. The portion of the knoll region **664** most proximal the initial region **662** may be positioned substantially at a point falling on a line at the same angle as the initial region **662** which bridges the barrier channel **666** (line shown in phantom in FIG. **79**A). Alternatively, the portion of the knoll region **664** most proximate the initial region **662** may be below this point (that is, closer to the bottom of the barrier channel **666**). The terminal region **668** may be a track which extends at a sharp angle or is substantially parallel to the barrier channel **666**. The terminal region **668** may also act as a barrier channel for a respective second barrier **658**B included in the delivery device **10**. The knoll region **664** may be at a constant angle or, as shown, may transition from the angle of the initial portion **662** to the angle of the terminal portion **668**. Though the knoll region **664** displays a rounded transition in the example, the transition may be formed of a series of increasingly steeply angled guide track segments **660** in alternative embodiments.

[0432] Referring now primarily to the progression of FIGS. **79**B-**79**F, the portion of the delivery device **10** is shown as the delivery device **10** is transitioning from a storage state to a delivery state. As shown in FIG. **79**B, in the storage state, the reservoir interface member **474** of the delivery unit **650** may be positioned over the initial region **662** of the example guide track **660**. Where multiple guide tracks **660** are included, each may be identical and a portion of the reservoir interface member **474** may be positioned in the initial region **662** of each guide track **600**.

[0433] The bias member **470** (represented by an arrow in FIG. **79**B) may supply a bias against the reservoir interface member **474** which tends to drive the reservoir interface member **474** along the guide track **660** in the direction of the terminal portion **668**. A first barrier **658**A may be partially within the barrier channel **666** of each guide track **600** and inhibit displacement of the reservoir interface member **474** along the guide track **660** under the urging of the bias member **470**. As shown in FIG. **79**B, the barrier(s) **658**A may be held in a blocking position by the deformable spacer **656**. In FIG. **79**B, an arrow representing force exerted by a spring type deformable spacer **656** is shown within each barrier **658**A, B.

[0434] Referring now primarily to FIG. **79**C, the reservoir interface member **474** may remain static relative to the guide track(s) **660** as a user begins to apply pressure to the trigger unit **652**. The pressure exerted through the trigger body **652** may cause the main body **20** to press against an injection site. As this occurs at least two adhesive bearing portions (e.g. petal member **42**) of the main body **20** may be displaced with respect to one another so as to stretch or spread a surface anchored to the main body **20** via the adhesive **22**. As these portions may be adhered to the skin surface, the skin may be stretched as the adhesive bearing portions are displaced with respect to

one another rendering it taut for piercing by the delivery sharp(s) **72** of the delivery device **10**. The delivery sharp(s) **72** may also displace toward and pierce the skin (or other surface) as this occurs.
[0435] Referring now to FIG. **79**D, the trigger unit **652** may displace at least until the first barrier **658**A reaches an unobstructing or stowed position. This may be a guide track completing position in which a ramp surface **670** of each first barrier **658**A is advanced to a position in which it is at least even with the respective guide track **660**. Thus, in the trigger position, the first barrier(s) **658**A may not present an interference to displacement of the reservoir interface member **474** along the guide track under urging of the bias member **470**. As shown, a second barrier **658**B (where included) may be displaced into the terminal portion **668** of each guide track **660** when the trigger unit **652** is in the trigger position. With the first barrier(s) **658**A in their trigger position(s), the bias member **470** may drive the reservoir interface member **474** over the ramp surface(s) **670** of the first barrier(s) **658**A and along the guide track **660** toward the terminal region **668**. Though in the example embodiment the ramped portion **670** is displaced even with the guide track **660** it could be displaced to a position in which it is recessed with respect to the initial portion **662** in certain examples.
[0436] Referring now primarily to FIG. **79**E, in embodiments where second barriers **658**B are included, the reservoir interface member **474** may progress to an intermediate point in its displacement range at which it contacts the second barrier(s) **658**B. At some point after the reservoir interface member **474** has progressed beyond the initial region **662** of the guide track(s) **660**, the reservoir interface member **474** may come into contact with the reservoir **12**. Further progress of the reservoir interface member **474** along the guide track(s) **660** may cause a reservoir portion **271** of the reservoir **12** to collapse expelling fluid from the reservoir **12** and out of the delivery sharp(s) **72** of the delivery device **10**. When the reservoir interface member **474** reaches the terminal region **668** of the guide track **660** (see FIG. **79**F), the reservoir portion **271** may be fully collapsed and the reservoir **12** may be substantially empty or depleted. In embodiments including second barriers **658**B, the intermediate point at which the reservoir interface member **474** encounters the second barriers **658**B may be a point at which the reservoir interface member **474** comes into contact with the reservoir portion **271**. Pressure may need to be relieved on the trigger unit **652** allowing the second barrier(s) **658**B to retract before the reservoir interface member **474** may pass to the terminal region **668** of the guide track **660**.
[0437] Use of such a delivery device **10** may provide a number of potential advantages. For example, the guide track **660** may prevent the full force of the bias member **470** from being exerted on the reservoir **12** in a binary manner. Thus, the pressure applied on the reservoir **12** via the bias member **470** may be decreased during an initial portion of the delivery by inclusion of a guide track **660**. The steepness or angle of the guide track **660** may be adjusted to increase or decrease the component of force exerted by the bias member **470** which is aligned with the direction of motion of the reservoir interface member **474** toward the reservoir **12**. Thus, the pressure exerted by the bias member **470** upon commencement of delivery may be altered. Such a guide track **660** may also be used in conjunction with a flow restrictor **524** (see, e.g., FIG. **77**) in certain implementations.
[0438] Such a delivery device **10** may also facilitate positioning the reservoir interface member **474** in spaced relation to the reservoir **12** when the delivery device **10** is in a storage state. Upon transition of the trigger unit **652** to the trigger position, the reservoir interface member **474** may be brought into contact with the reservoir portion **271**, but prevented from aggressively driving into and impacting the reservoir **12** by the presence of the second barrier(s) **658**B. This may assist in initiating the expulsion of fluid from the reservoir **12** in a more gentle manner. Additionally, it may allow for a greater range of reservoir portion **271** materials or material thicknesses to be used in a delivery device **10**.
[0439] Referring now to FIGS. **80**A-**80**B, exploded views of an example embodiment of a delivery device **10** are depicted. The delivery device **10** may include a delivery unit **650** and a trigger unit

**652**. The main body **20** of the delivery unit **650** may include a peripheral region **30** and a central region **28**. The peripheral region **30** may include a plurality of petal members **42**. Any of the petal members **42** shown or described herein may be used. The central region **28** may include a rigid guide body **672**. The rigid guide body **672** may include a sidewall **674** extending from a base **262** of the central region **28**. As best shown in FIG. **80**B, the interior face of the sidewall **674** may include a number of guide tracks **660**. The guide tracks **660** are depicted as cam type tracks, thus the reservoir interface member **474** will rotate as it progresses through its displacement range along the tracks **660**. The face of the rigid guide body **672** most distal the peripheral region **30** may include a central depression or cup **676**. The cup **676** may be a locating recess which may assist in locating the deformable spacer **656** of the trigger unit **652** (a compression spring in the example depicted). The trigger body **654** may also include a locating projection **678** for the deformable spacer **656**. A number of apertures may be included to allow for passage of the barriers **658**A, B of the trigger body **654** into the interior of the rigid guide body **672**.

[0440] The delivery unit **650** may include a bias member **470** (e.g. compression spring as shown). The opposing side of the cup **676** may provide a projection which may help locate the bias member **470** within the delivery unit **650**. The reservoir interface member **474** may be a plunger having a number of outwardly (e.g. radially) extending protrusions **680**. Each of the protrusions **680** may interface with one of the guide tracks **660** defined on the sidewall **674** of the rigid guide body **672**. The guide tracks **660** and the protrusions **680** may be spaced at regular angular intervals.

[0441] Referring now also to FIG. **80**C, a cross-sectioned view of the main body **20** and trigger body **654** of FIGS. **80**A-**80**B are depicted. The portion of the rigid guide body **672** most distal to the base **262** of the central region **28** has also been removed for illustrative purposes. As shown, the barriers **658**A, B of the trigger body **654** may be formed monolithically with the trigger body **654**. The barriers **658**A, B depicted in the example embodiment are formed as peg like projections extending from an end surface of the trigger body **654**. In the example, each barrier **658**A, B is defined as a region of the same projection though discrete projections for each barrier **658** A, B could be included in alternative embodiments. The barriers **658**A, B may be aligned with the barrier channel **666** and terminal region **668** of a respective guide track **660** such that they may displace into these features when the trigger body **654** is brought to a trigger position. Additionally, the trigger body **654** may include at least one guide fin **682**. The guide fin **682** may displace along a slot **684** defined in the rigid guide body **672**. This may assist in directing displacement of the trigger body **654** during operation and may inhibit rotational displacement of the trigger body **654**. The guide fin(s) **682** may also assist in retaining the trigger body **654** in relation with the main body **20** and may thus be referred to as a retention fin or projection herein.

[0442] An alternative embodiment a delivery device **10** including a delivery unit **650** and a trigger unit **652** is shown in FIGS. **81**A-**83**. As shown, the example delivery device **10** shown in FIG. **81**A includes a lock **690** (shown in isolation in FIG. **82**). The lock **690** may preferably be formed of a single piece of injection molded material. In the example embodiment, the lock **690** includes a base portion **692** from which a set of arm members **694** extend. The base portion **692** may include a first segment **696** having a protuberance **698**. The base portion **692** may also include a second segment **700**. The second segment **700** may include a peripheral wall **699** along its edges. The second segment **700** may also include a passage **702** defined therein which extends from an exterior face of the base portion **692**, through the lock **690**, to an interior face of the base portion **692**. The passage **702** may taper from a first cross-section area to a second cross-sectional area smaller than the first as distance from the exterior face increases. In the example, the first and second segments **696**, **700** are connected by a living hinge **704**.

[0443] As best shown in FIG. **81**B, the second segment **700** may include a receptacle **705**. The receptacle may accept a protruding body **707** of the reservoir assembly **12** in which a septum **550** is retained. When the lock **690** is engaged with the delivery device **10** and the protruding body **707** is in the receptacle **705**, the passage **702** may be aligned with the septum **550**. The passage **702** may

thus form a sharp guide which may direct a dispensing sharp **570** (e.g. a needle attached to a syringe or automated filling station) into alignment with the septum **550**. The receptacle **705** may also help ensure that the delivery device **10** is placed into the lock **690** in a prescribed orientation.
[0444] Still referring to FIGS. **81**A-**83**, as shown the height of the arm members **694** may be selected such that the trigger unit **652** rests on or is in close proximity to a face of the lock **690**. The opposite side of lock **690** may rest on the peripheral region **30** of the main body **20** which may support the lock **690**. With the lock **690** supported by the peripheral region **30**, the trigger unit **652** may be blocked from displacing due to the interference presented by the lock **690**. As shown, the base portion **692** may also include a wall which blocks displacement of the trigger unit **652** relative to the delivery unit **650**. As the lock **690** may prevent displacement of the trigger unit **652**, the lock **690** may inhibit inadvertent actuation of the delivery device **10** during handling or shipping. It may be required that the lock member **690** be removed from the delivery device **10** before use.
[0445] The arm members **694** may be displaceable relative to one another so as to alter the gap between the arm members **694**. When the arm members **694** are in a home position, the shape of the arm members **694** may cradle the central region **28** of the main body **20** of the delivery device **10** retaining it in place between the arm members **694**. The arm members **694** may be displaced to a spread state in which the delivery device **10** is released from the lock **690**. When the arm members **694** are in a spread position, the arm members **694** may be biased toward the home position (shown in FIG. **81**A and FIG. **82**). In the example embodiment, a user may press on the protuberance **698** and displace it toward the most proximal face of the peripheral wall **699** of the second segment **700**. This may distort the base member **690** at the living hinge **704** spreading the arm members **694** apart from one another. The material forming the lock **690** may be selected so as to elastically distort as this occurs. When force is relieved, the material may restore to a resting state and the arm members **694** may return to a home position. Alternatively, the lock **690** may be formed of multiple pieces and the living hinge **704** may be replaced by a hinge coupling the first and second segments **696**, **700** of the base portion **692**.
[0446] The protuberance **698** may include a serif **706** at its unsupported end. The serif **706** may collide with the wall **699** of the second segment **700** when the user pinches the protuberance **698** towards the second segment **700**. Thus the serif **706** may provide a stop which inhibits excess deformation of the lock **690** when the arm members **694** are spread. The unsupported ends of the arm members **694** may form a lead in feature which assists in installing the lock **690** on the delivery device **10** during manufacture or packaging. In the example, the interior faces **710** of the end regions **708** of the arm members **694** are angled such that the gap between the arm members **694** increases as proximity to the ends of the arms members **694** increases. Thus, the end regions **708** of the arm members **694** may guide the delivery device **10** into place as it is pressed into the lock **690**.
[0447] Referring now primarily to FIG. **83**, an exploded view of the example delivery device **10** depicted in FIG. **81**A is shown. As mentioned above, the example delivery device **10** includes a delivery unit **650** and a trigger unit **652**. The central region **28** of the main body **20** may define a housing **712**. Referring now also to FIG. **84**, a guide insert **714** may also be included in the delivery unit **650**. The interior face of the guide insert **714** may include a number of guide tracks **660**. The guide tracks **660** are depicted as cam type tracks, thus the reservoir interface member **474** will rotate as it progresses through its displacement range along the tracks **660**. The guide insert **714** may include a number of cantilevered latch projections **716**. When the guide insert **714** is advanced into the housing **712** during assembly, the latch projections **716** may deflect toward the longitudinal axis of the guide insert **714**. Referring now also to FIG. **85**, after the guide insert **714** has been advanced beyond a certain distance into the housing **712**, the latch projections **716** may reach respective fenestrations **718** in the housing **712** allowing them to restore outward from their deflected states. The latch projections **716** may each include a step **720** which may latch into place against a ledge **722** defined in the wall of the fenestration **718**. This may retain the guide insert **714**

in place within the housing **712**. Use of a guide insert **714** in place of a rigid guide body of the type described in relation to FIGS. **78-80**C may simply manufacture of the delivery device **10**.
[0448] Still referring to FIG. **85**, the main body may include a number of swaged posts **724**. The swaged posts **724** may be molded as pegs and the reservoir assembly **12** may be inserted into the main body **20**. The molded pegs may be disposed at various positions around the periphery of the reservoir assembly **12**. With the reservoir assembly **12** in place, the molded pegs may then be swaged (e.g. heat swaged) over a face of the reservoir assembly **12**. Once this is completed, the swaged posts may retain the reservoir assembly **12** in place within the delivery device **12**.
[0449] The end of the housing **712** most distal the peripheral region **30** includes a central depression or cup **676**. The cup **676** may be a locating recess which may assist in locating the deformable spacer **656** of the trigger unit **652** (a compression spring in the example depicted). As with embodiments described in relation to FIGS. **78-80**C, the trigger body **654** may also include a locating projection **678** for the deformable spacer **656**. A number of apertures may be included in the housing **712**. Barriers **658**A, B of the trigger body **654** (described above) may displace into the interior of the housing **712** through the apertures. The trigger body **654** may additionally include at least one guide fin **682** which may displace along a slot **684** defined in the housing **712**. This guide fin **682** may assist in directing displacement of the trigger body **654** relative to the delivery unit **650** and prevent rotational displacement of the trigger body **654**.
[0450] Still referring to FIG. **85**, the opposing side of the cup **676** in the housing **712** may provide a projection **726**. The projection **726** may help locate a bias member **470** of the delivery unit **650** in place. The example delivery device **10** includes a plunger as the reservoir interface member **474**. The plunger includes a number of outwardly extending protrusions **680** which may interface with one of the guide tracks **660** of the guide insert **714**. The example embodiment shown in FIGS. **81**A-**83** includes a plunger with three outwardly extending protrusions **680** at regular angular intervals. In other examples, and as shown elsewhere herein, four evenly spaced protrusions **680** may be included. The bias member **470** may press the protrusions **680** against respective guide tracks **660**. This in turn, may prevent the guide insert **714** from advancing further into the housing **712**.
[0451] As the trigger body **654** is displaced toward the delivery unit **650**, the barriers **658**A, B of the trigger body **654** may move relative to the guide tracks **660**. This may allow the plunger to advance toward the reservoir assembly **12** along the guide tracks **660** as further described in to as further described in relation to FIGS. **78-80**C. When the user releases the trigger body **654**, the deformable spacer **656** may urge the trigger body **654** and barrier **658**A, B to again displace in relation to the guide tracks **660**. This may allow the plunger to further advance toward the reservoir assembly **12** and expel fluid from the delivery device **10** as further described in relation to FIGS. **78-80**C.
[0452] As shown best in FIG. **83**, the main body **20** may include at least one reservoir fill verification aperture **728**. The aperture(s) **728** may be positioned so as to provide a line of sight to the reservoir portion **100** of the reservoir assembly **12**. When the reservoir assembly **12** is in a filled state, the reservoir portion **100** may be in a raised state. After the reservoir assembly **12** is loaded with agent, the delivery device **10** may be positioned such that an imager may view the reservoir portion **100** via a fill verification aperture **728**. An image may be taken of the delivery device **10** through the fill verification aperture **728**. A controller may analyze the image to determine whether the reservoir portion **100** is in a position consistent with the reservoir assembly **10** being in an appropriate filled state. The delivery device **10** may be associated with a unique identifier (e.g. data matrix) on an exterior of the delivery device **10**. The image from the imager and a pass/fail determined by the controller may be associated with a record of the unique identifier for that delivery device **10** which is stored in a database (e.g. cloud database). In the event the image analysis performed by the controller indicates that the reservoir assembly **12** is not properly filled, an alert may be generated by the controller and the delivery device **10** may be separated to prevent its use. Other sensing hardware may be used in alternative embodiments. For example, a beam

break sensor could utilized to monitor for the raising of the reservoir portion **100** when the reservoir assembly **12** is brought to a filled state.

[0453] Referring now also to FIG. **86**, a diagrammatic representation of an example trigger body **652** is depicted. As shown, the trigger body **652** includes only a single first barrier **658**A. This is merely illustrative, the trigger body **652** may include a first barrier **658**A for each respective guide track **660** within a delivery device **10**. The first barriers **658**A may gate displacement of the reservoir interface member **474** as described in relation to FIGS. **78**-**80**C. The trigger body **652** may be devoid of second barrier members **658**B. The trigger body **652** may also include at least one integral deformable spacer **656**. In the example embodiment, the deformable spacer **656** is a cantilevered latch projection. The latch projection includes a step **730** at the unsupported end thereof. The latch projection is disposed at a non-parallel angle to the long axis of the trigger body **652**.

[0454] When the trigger body **652** is displaced toward a delivery unit **650**, the cantilevered projection may collide with a wall of the main body **20** and deflect. For example, the cup **676** of the housing **712** may have a chamfered or filleted opening (see, e.g. FIG. **83**) which guides the deflection such that the cantilevered latch projection is directed into the cup **676**. As the trigger body **652** reaches the end of its displacement range, the step **730** of the cantilevered latch projection may reach a ledge defined on the main body **20** and the latch projection may restore to a less deflected state and into engagement with the ledge. The may be an opening in the wall of the cup **676** and a sidewall of the opening may serve as the ledge **676** for instance. With the latch projection in the engaged position, the first barriers **658**A may be in unobstructing states and the reservoir interface member **474** of the delivery device **10** may be driven along the guide tracks **660** and against the reservoir assembly **12** by the bias member **470**. The trigger body **652** may be held in a depressed state by the engagement of the step **730** with the ledge. Additionally, the force required to deflect the cantilevered latch projection may ensure that the petal members **42** spreadingly displace before the trigger body **652** is pressed to the end of its displacement range and the first barriers **658**A reach an unobstructing position. This may prevent reuse and serve as an indicator that a delivery device **10** has already been consumed.

[0455] Though the cantilevered latch projection is shown extending from the trigger body **652** it could be included as part of the main body **20** in other embodiments. In such examples, the trigger body **652** would define the ledge on which the step **730** engages.

[0456] Referring now to FIGS. **87**A-**88**B, in some embodiments, a delivery device **10** may include an indicator which communicates whether the delivery device **10** has been used. An example delivery device **10** with a trigger unit **652** and delivery unit **650** is depicts in FIGS. **88**A-**88**B. As with the embodiments described in FIGS. **78**-**85**, example delivery devices **10** may include a reservoir interface member **474** such as a plunger. The reservoir interface member **474** may include regions of contrasting appearance **655**A, B as shown in FIGS. **87**A-**87**B. For example, a first portion of the reservoir interface member **474** may be a first color and another region may be a second color. In some embodiments, the contrasting appearance may be accomplished through use of an applique, paint, or the like which is applied after the reservoir interface member **474** is manufactured. Alternatively, the reservoir interface member **474** may be given regions of contrasting appearance **655**A, B during molding. For example, a different color material may be overmolded onto a precursor reservoir interface member **474** to complete the reservoir interface member **474**. Multi-shot molding or any other suitable method may be used.

[0457] As mentioned above and further described in relation to FIGS. **78**-**80**C, when the delivery device **10** is used, the reservoir interface member **474** may translationally displace against the reservoir assembly **12** and may rotationally displace along the guide tracks **660**. The main body **20** of the delivery device **10** may include one or more window **659** in the central region **28**. When the delivery device **10** is in the storage state, a portion of the reservoir interface member **474** having a first appearance may be in alignment with the window(s) **659**. As the reservoir interface member

**474** is displaced to its post usage position, a portion of the reservoir interface member **474** having a second appearance may displace into alignment with the window(s) **659**. In some examples, a bottom region of the reservoir interface member **474** may have the first appearance and the top region may have a second appearance. The translational displacement of the reservoir interface member **474** may cause the bottom region to displace out of the field of view of the window **659** while the top region displaces into the field of view of the window **659**. Alternatively and as shown in FIGS. **87**A-**87**B, the side wall of the reservoir interface member **474** may have a least one strip or section having a second appearance while the remainder of the side wall has the first appearance. As the reservoir interface member **474** rotates while it travels along the guide tracks **660**, the section(s) having the second appearance may rotate into alignment with the window(s) **659**. In still other embodiments, the indicator may be a line (see, e.g., FIG. **83**) included on the reservoir interface member **474** which passes into alignment with a window **659** when the reservoir interface member **474** displaces. Regardless of the indicator used, a user or caregiver may look at the window(s) **659** to quickly determine if a particular delivery device **10** has been used. A user or caregiver may also monitor the window **659** when a delivery device **10** is applied to a user and triggered. This may allow a user to verify that the delivery device **10** properly actuated and that agent should have been delivered from the reservoir assembly **12**.

[0458] Referring now to FIGS. **89**A-**89**B, various of the delivery devices **10** described herein may include a reservoir **12** with at least one rocker member **526**. When such a delivery device **10** is applied to a user and transitioned to a delivery state, skin may be rendered taught due to spreading displacement of portions of the delivery device **10** and the at least one delivery sharp **72** of the delivery device **10** may displace into the stretched skin. Movement of the delivery sharp(s) **72** may generally be in a first direction which is substantially perpendicular to the surface of the skin and the delivery sharp(s) **72** may generally puncture downwardly into the skin. The at least one rocker member **526** may cause the reservoir **12** to tilt or rock as a consequence of the delivery device **10** being transitioned to a delivery state. The at least one rocker member **526** may cause the delivery sharp(s) **72** to displace slightly in a second direction substantially opposite the first direction when pressure is relieved from the delivery device **10**. Tilting as well as displacement in the second direction may occur.

[0459] In some embodiments, portions of the delivery device **10** may also deform or adjust in response to the rocking of the reservoir **12** in order to accommodate the rocking of the reservoir **12**. The tilting of the reservoir **12** may cause the delivery sharp(s) **72** to displace in a non-straight path. For example the delivery sharp(s) **72** may rotate or swing along an arcuate path during at least a portion of the transition of a delivery device **10** to the delivery state. In example embodiments, the tilting may occur automatically as a consequence of the transition of a delivery device **10** to a delivery state. No linkages or interactions with guide elements may be needed in order to achieve the tilting. Example reservoirs **12** may tilt together as a single unit due to the presence of the one or more rocker member **526**. Such tilting of a reservoir **12** may lower the pressure at which injection may begin to occur and/or increase delivery flow rate in certain delivery device **10** embodiments. Additionally, the inclusion of one or more rocker member **526** may impact characteristics of bleb formation during delivery. Tilting may also help to facilitate delivery where delivery sharps **72** are initially advanced into skin at an angle substantially perpendicular to the skin.

[0460] Still referring to FIGS. **89**A-**89**B, a rocker member **526** may be a protrusion which extends from a proximal face of a holder **270**. In various examples, a rocker member **526** may be disposed at or inward of the peripheral edge of the holder **270**. A rocker member **526** may have a height which is approximately the height of a stage projection **279** (see, e.g., FIGS. **55**A-**56**D). Shorter and taller rocker members **526** are also possible. Alternatively, where a holder **270** includes a rounded depression **274** (see, e.g., FIG. **54**A), the rocker member **526** may have a height which sets it approximately even with the height of a bump corresponding with the rounded depression **274**. Again, shorter and taller rocker members **526** may be provided in such embodiments.

[0461] When delivery devices **10** including at least one rocker member **526** are transitioned to a delivery state, the rocker member(s) **526** may come into contact with the user and impede further displacement of the portion of the reservoir **12** including the rocker member(s) **526**. The opposing side may be free of any rocker members **526** and the reservoir **12** may tilt or rock to accommodate continued displacement of the opposing side toward the user. In certain examples, the delivery sharp(s) **72** (e.g. microneedles) may tilt 3-5° (e.g. 4°) with respect to their initial orientation. In other examples, the delivery sharp(s) **72** may tilt lesser or greater amounts. Height of a rocker member **526** may alter the point at which the delivery sharp(s) **72** begin to rotate or swing during the transition of the delivery device **10** to the delivery state. Rocker members **526** even with the height of a stage **279** may, for example, tend to initiate tilting after the delivery sharp(s) **72** have punctured the skin.
[0462] In certain examples, the delivery sharp(s) **72** may be microneedles such as any of those described herein. Where the delivery sharp(s) **72** is/are microneedle(s), the rocker member(s) **526** may be disposed on a side of the reservoir **12** closest the back facing edge **23** (see, e.g., FIG. **2**) of the microneedle(s). The rocker member(s) **526** may be positioned such that back facing edge **23** of the microneedle(s) is the portion of the microneedle(s) most proximal the rocker member(s) **526**. As rocking of the reservoir **12** transpires, the displacement path followed by the microneedle(s) may be such that the back facing edge(s) **23** may be driven through the skin. The beveled surfaces leading to the back facing edge **23** may facilitate cutting of the skin as the microneedle(s) are displaced. Thus, the back facing edge **23** may be a cutting edge. Additionally, this may cause a face of each microneedle in which an outlet of the lumen **126** of that microneedle is disposed to be displaced away from skin contacted during the initial puncture. For example, the lumen(s) **126** of any microneedles may be displaced away from skin contacted by the sloped face(s) **21** during the initial puncture where a microneedle such as that shown in FIG. **2** is utilized. Such displacement of the microneedle(s) may aid in ensuring fluid may easily flow out of the lumen(s) **126** and into the skin as delivery occurs. The above described displacement may also create a small receiving volume in the skin into which fluid may be delivered from the lumen(s) **126**. When pressure applied to the delivery device **10** to transition the delivery device **10** to the delivery state is relieved, the delivery sharp(s) **72** may displace slightly in a direction away from the patient. This may create a small receiving volume in the skin and displace the lumen **126** away from skin contacted during initial puncture. The rocker member **526** may help to encourage this.
[0463] In some examples (see, e.g., FIGS. **56**A-D, FIG. **89**B), delivery sharp(s) **72** may be mounted to a stage **279** having a mounting area (e.g. a pocket **256**) which is non-parallel with respect to a disk body **275** of the holder **270**. In such examples, the delivery sharp(s) **72** may extend from the stage **279** at a prescribed angle (e.g. 15°) with respect to a plane normal to the disk body **275**. The disk body **275** and skin may be generally parallel when various example delivery devices **10** are first applied to a user. Delivery sharp(s) **72** may thus be angled with respect to a plane normal to the skin. As the reservoir **12** tilts, the delivery sharp(s) **72** may be displaced to a position in which they are closer (e.g. 3-5°) to a normal orientation with respect to the skin. Depending on the mounting angle of the delivery sharp(s) **72**, the delivery sharp(s) **72** may be brought to or nearly to a normal orientation with respect to the skin as the reservoir **12** tilts. In other embodiments, the delivery sharp(s) **72** may be 10° or more (e.g. 11-12°) away from a normal orientation.
[0464] Still referring to FIGS. **89**A-**89**B, in some examples, a reservoir **12** may include at least one marking member. The at least one marking member may contact or press against the skin as the delivery device **10** is dispensing agent to a user. In some embodiments, any rocker member(s) **526** may double as marking members though dedicated marking members may also be present in some embodiments. Marking members may also be used in embodiments which do not include a rocker member **526**. When a delivery device **10** is used, one or more marking member may leave a perceptible marking on the skin. This marking may be a temporary impression or depression in the skin resulting from the marking member pressing on the skin as a delivery occurs. Alternatively or

additionally, the marking member (e.g. rocker member **526**) may bear a marking agent (e.g. ink) which at least partially transfers to the skin when the delivery device **10** is used. As the contact surface of the marking member may be of a known size, the perceptible marking may serve as a fiducial reference. The delivery site may, in some examples, be imaged after a delivery device **10** is removed and an image of the delivery site may be analyzed (e.g. any suitable image processing such as edge detection may be used) by a controller to identify the perceptible marking. In certain examples, it may be required that an image be taken within some preset time after a delivery device **10** is removed. The perceptible marking may aid in confirming a delivery device **10** has been used when identified in an image. Additionally, the perceptible marking could aid in determining, for example, one or more attribute related to the delivery (e.g. bleb presence, size, area, relative location of the bleb to the mark). For example, a controller may analyze an area of an image a defined distance from the marking for the one or more attribute related to the delivery or the controller may ensure that an attribute of interest conforms to an expected relationship with the marking (e.g. is within some range of distances from the marking). The mark left by a marking member or the arrangement of marking members on the delivery device **10** could be selected to leave a perceptible mark having a particular pattern. Any suitable pattern could be used. The pattern could be selected to assist in image analysis or perhaps could be selected to provide a patient friendly delivery confirmation marking (e.g. smiley face or the like).

[0465] Referring now to FIGS. **90**A-**90**B, bottom perspective views of exemplary delivery devices **10** (with adhesive members **22** hidden) including rocker members **526** are depicted. As shown, a rocker member **526** may be a protuberance from the disk body **275** which may extend along the peripheral edge of the disk body **275**. The rocker member **526** in the example shown in FIG. **90**A is arcuate, though rocker members **526** extending in a straight, zigzag, undulating, meandering or other path may also be used. In other examples such as that shown in FIG. **90**B, multiple (two are shown, though more could be included) rocker members **526** may be included. Rocker members **526** may for example be included as a set of bumps or nubs which extend proud of the proximal face of the disk body **275**. Rocker member(s) **526** may be sized and/or positioned such that rocking or tilting of the reservoir **12** occurs generally along a desired plane (e.g. a plane including or parallel to a desired displacement path taken by one or more delivery sharp **72** of the delivery device **10** as tilting occurs). The position and/or size of the rocker member(s) **526** may impact characteristics of a bleb formed during delivery for some delivery devices **10**. For example, the rocker member **526** of FIG. **90**A may tend to encourage a bleb to spread more in directions left and right of the center of the rocker member **526**.

[0466] Referring now to FIG. **91**, a flowchart **600** depicting a number of exemplary actions which may be executed to deliver agent from a delivery device **10** to an injection site is shown. As shown, in block **602**, an adhesive backing **265** (see, e.g., FIG. **25** and FIG. **27**) may be removed from a delivery device **10**. Additionally, any covering (e.g. cover **409** of FIG. **27**) protecting the delivery sharp(s) **72** may be removed from the delivery device **10** in block **602**. In block **604**, the delivery device **10** may be placed at a desired injection site.

[0467] Referring now also to FIG. **92**, pressure may be applied to the delivery device **10** in block **606**. In some examples, pressure may be applied to the top surface **250** of a main body **20** of a delivery device **10**. Alternatively, and as shown in the illustration in FIG. **92**, pressure may be applied to a depressor body **472** (e.g. a dish body **467**) of the delivery device **10**. Pressure may be applied manually, for example, with a single finger of a user.

[0468] Referring now primarily to FIG. **91** in combination with FIG. **93**, in block **608**, the skin coupled to the delivery device **10** via adhesive **22** of the delivery device **10** may be stretched. At least two portions of the delivery device **10** adhered to the skin may distort from their initial state so as to spreadingly displace and stretch the skin. For example, this may occur as petal members **42** of the main body **20** distort under pressure being applied to the delivery device **10**. As described elsewhere herein, when the petal members **42** distort, the reservoir **12** and delivery sharp(s) **72**

coupled thereto may displace toward the skin. The delivery sharp(s) **72** may puncture the skin and may optionally tilt (e.g. due to the presence of a rocker member **526**, see FIGS. **89**A-**89**B and related description) in block **610**. As shown in FIG. **93**, the top surface **250** of the delivery device **10** may resist deformation at least as the petal members **42** initially begin to spreadingly displace.
[0469] The petal members **42** may be constructed to have a stiffness selected to help ensure that this occurs. The petal members **42** may for example be substantially or primarily planar and project from the rest of the delivery device **10** at a constant angle (see, e.g., FIGS. **96**A-**96**B). This may allow the petal members **42** to deflect relatively easily as pressure is applied to the delivery device **10**. In alternative embodiments, the petal members **42** may have curvature at least in certain regions. Any curvature in the petal members **42** may be selected to ensure that at least a desired amount of distortion of the petal members **42** occurs prior to deformation of the top surface **250**. In preferred embodiments, the main body **20** may be constructed such that the petal members **42** distort an amount sufficient to stretch the skin and allow the delivery sharp(s) **72** to penetrate the skin prior to the top surface **250** substantially deforming.
[0470] Referring now primarily to FIG. **91** in combination with FIG. **94**, the top surface **250** of the main body **20** may flip from a protruding state to a depressed state or invert in block **612**. Fluid may also be urged out of the reservoir **12** in block **612**. As described elsewhere herein, a bias member **470** may become compressed upon flipping of the top surface **250**. Fluid may be driven out of the reservoir **12** into the injection site via the delivery sharp(s) **72** as the bias member **470** restores to less distorted state. As shown in FIG. **94**, in embodiments including a depressor body **472** with a dish body **467**, the dish body **467** may seat against an end of the supporting structure **252** when the top surface **250** inverts. The dish body **467** may obstruct view of the top surface **250** when the top surface **250** is inverted giving a visual cue the delivery device **10** has been used (see also FIG. **95**).
[0471] Referring now primarily to FIG. **91** in combination with FIG. **95**, in block **614**, pressure may be removed from the delivery device **10** and a predetermined period of time may be allowed to elapse. The period of time may be selected to be at least as long as and preferably greater than an expected delivery time. In certain examples, the wait time may be (1-5 minutes).
[0472] In certain examples and as shown in FIG. **95**, when pressure is removed, one or more portion of the delivery device **10** may at least partially restore from its distorted state. Thus, the main body **20** may have at least one invertible region, at least one resilient region, and at least one region which elastically deforms as a delivery device **10** is transitioned to a delivery state. The at least one region which elastically deforms may be distorted from an initial state, to an intermediate state, and then elastically restore at least partially from the intermediate state during the course of the transition to the delivery state. The intermediate state may be a state during the transition in which the region is maximally distorted. The region may restore from this state back towards the initial state. The petal members **42** may, for example, at least partially restore from their distorted state. As the petal members **42** of the delivery device **10** are adhered to the skin via the adhesive **22** of the delivery device **10**, the skin may be pulled away from the underlying anatomy as the petal members **42** restore. As the petal members **42** restore, the reservoir **12** may also displace slightly in a direction away from the skin (it is possible a rocker member **526** may assist this see e.g. discussion of FIGS. **89**A-**89**B). Where adhesive **22** is present on portions of the reservoir **12** (e.g. the holder **270**) skin may also be pulled away from underlying anatomy as the reservoir **12** displaces. This may relieve some pressure on the injection site which otherwise tends to compress anatomy at the injection site. This decreased compression at the injection site may allow fluid to be more readily be transferred from the delivery sharp(s) **72** into the delivery destination. Additionally, depending on the orientation of the delivery sharp(s) **72**, the delivery sharp(s) **72** may tug the skin into which they have punctured upward away from underlying anatomy as the petal members **42** restore. Again, this may help to facilitate delivery as the compactedness of the anatomy at the delivery destination may be reduced. The shape of the petal members **42** and material used to

construct the main body **20** may be selected to help encourage this at least partial restoration or recoil of the petal members **42** when pressure is removed.

[0473] In block **616**, the delivery device **10** may be removed from the injection site. In certain examples, delivery may be verified in block **618**. In certain embodiments, this verification may be manual. Staff at a vaccination site or clinic may verify by eye that a bleb is present after injection and no leaks are seen. In other embodiments, an image of the injection site may be taken, analyzed, and perhaps documented in electronic records as described elsewhere herein. Image analysis may, for example, determine whether an expected marking is present at the injection site or whether characteristics of interest are present in the image (or have a desired relationship with a fiducial marking). In other examples, an image may be analyzed for the presence of a cool region in the skin (see, e.g., FIG. **133** and related description).

[0474] Referring now to FIGS. **96**A-**96**B and FIGS. **98**A-**98**B, two exemplary main bodies **20** which may be used in various delivery devices **10** described herein are respectively shown. In various embodiments where delivery devices **10** are or may be injection molded, portions of the main body **20** may be injection molded so as to be in the storage state or in the delivery state. Portions of the main body **20** may transition more easily or tend to restore into the configuration in which they were molded. Such portions may also have a tendency to stay in the configuration in which they were molded. In the examples in FIGS. **96**A-**96**B, the top surface **250** is molded in a delivery state position. The petal members **42** are molded in a storage state position. During assembly of a delivery device **10**, the various portions of the main body **20** may be brought into a storage state configuration and remain in that configuration until use. Molding the top surface **250** in the delivery state position may lower the effort needed to transition a delivery device **10** from a storage state to a delivery state. Likewise, molding the petal members **42** in their storage state positions encourages the petal members to **42** to restore toward their storage state positions (see, e.g., FIG. **95** and related description) when a user relieves pressure on the delivery device **10** during use.

[0475] As mentioned above, in certain embodiments, petal members **42** may be relatively devoid of curvature. For example, petal members **42** be substantially flat and/or extend from the rest of a main body **20** at an angle or angles thereto. This may assist in making the force required to cause deflection in the petal members **42** relatively low as pressure is applied to the delivery device **10**. In turn, this may help to assist in generating spreading displacement of the petal members **42** and help ensure puncture of the skin with the delivery sharp(s) **72** prior to deformation of the top surface **250** of the main body **20**.

[0476] As shown in FIGS. **96**A-**96**B, the petal members **42** of example main bodies **20** may each include first regions **620** adjacent the supporting structure **252** and second regions **622** which form the more peripheral portions of the petal members **42**. As shown, the first regions **620** may be arced roughly similar to that of the adjacent portion of the supporting structure **252**. The second regions **622** may be oriented at a constant angle to the center axis A**1** of the main body **20**. The second regions **622** may form the majority of the petal members **42**. In some examples, the petal members **42** may have a curved region or surface, while being predominantly flat. In various embodiments, a small curved transition **621** between the first and second regions **620**, **622** of the petal members **42** may be included (see, e.g., FIG. **97**).

[0477] A living hinge may be formed at the transition between the first and second regions **620**, **622**. As pressure is applied to the top surface **250** of a main body **20**, the living hinge may allow the second regions **622** of the petal members **42** to displace relative to the first regions **620**. The first regions **620** may distort to a lesser degree than the second regions **622** throughout the transition of the delivery device **10** to the delivery state. In some examples, the first regions **620** may resist substantial deformation and remain generally undistorted throughout the transition. Thus, the first regions **620** may behave as stops which may help to limit spreading displacement of the petal members **42** after a desired amount of spreading displacement has been achieved. Curved

transitions **621** may be included to assist in encouraging the petal members **42** to at least partially restore once pressure on the delivery device **10** has been relieved. In examples including petal members **42** such as those in FIGS. **96**A-**96**B, it may be preferred that, in the storage state, the base of any stage projection **279** be substantially even with the end of the second region **622** of the petal members **42** most proximal the central region **28**.

[0478] The main body **20** may have a round, substantially circular footprint in examples such as that shown in FIG. **96**A-**96**B. The portion of each petal member **42** at the peripheral edge **38** of the main body **20** may arc along a radius extending from the center axis A**1** of the main body **20**. In various examples and referring now to FIGS. **98**A-**98**B, the width of the portions of the petal bodies **42** forming the peripheral edge **38** may decrease as distance from the central region **28** of the main body **20** increases. For instance, the portion of the petal members **42** forming the peripheral edge **38** of the main body **20** may be arced other than along a radius extending from a center point within the center axis A**1** of the main body **20**. For example, a radius defining the curve of the periphery of each petal member **42** may be extended from a center point within the respective petal member **42** or within the second portion **622** of the respective petal member **42**. The outermost region of each of the petal members **42** may disposed more distal the central region **28** than the ends of the slits **36** most distal the central region **28**. The outermost regions may decrease in width as distance from the central region **28** increases. In certain examples, the portion of each petal body **42** forming the peripheral edge **38** may taper to a point or be rounded as shown in FIGS. **98**A-**98**B.

[0479] This may assist in removal of a delivery device **10** as it may decrease the surface area of adhesive which a user is attempting to dissociate from the skin during initial portions of the removal action. Though each petal member **42** may be described as having the same shape, it should be understood that such description may be inclusive of at least one petal member **42** differing in shape slightly to accommodate a pull tab **266** (see, e.g., FIG. **98**B) which may be included to assist in removal of the delivery device **10**.

[0480] Referring now to FIGS. **99**A-**99**G, various views of a portion of an example delivery device **10** are shown. Various views of example delivery devices **10** are also shown in FIGS. **100**A-**101**G. As shown, compared to typical syringe and needle based injections, delivery devices **10** of the type shown and described herein possess ornamentality which may, for instance, make them more approachable. This may be particularly true in populations with a high prevalence of needle anxiety such as children. In some though not all examples, portions of a delivery device **10** may be shaped and or colored to resemble a flower (e.g. daisy). A depressor body **472** (and perhaps at least part of the center region **28** of a main body **20**) may have a first appearance (e.g. color, material, pattern) while at least the petal members **42** of the main body **20** may have a second appearance (e.g. color, material, pattern) which differs from the first. Depressor bodies **472** may, for example, have the appearance of the center portion of a flower. The petal members **42** may have a flower petal like appearance. Certain features may differ or be optional as indicated by dashed lines in FIGS. **99**A-**101**G while still retaining a delivery device **10** or portion thereof having desirable ornamental aspects. Additionally, parts of the delivery devices **10** and portions thereof shown and described in relation to FIGS. **99**A-**101**G possess desirable ornamental aspects in isolation (e.g. depressor bodies **472**, main bodies **20**, sections of main bodies **20** such peripheral regions **30**, petal members **42**, sets of petal members **42**). Additionally, delivery devices **10** and portions thereof shown and described in relation to FIGS. **99**A-**101**G may be modified to, for example, include greater or fewer petal members **42**. In some implementations, petal members **42** may be separated by slits in the peripheral region **30** of the identical to those shown in FIGS. **99**A-**101**G, however, the size of the petal members **42** may differ to accommodate inclusion of the desired number of petal members **42**. In such examples, the petal members **42** may have the same cross-sectional shape as those shown, however, that cross-sectional shape may be revolved along a larger or smaller arc depending on the number of petal members **42** desired. The gaps between petal members **42**

formed by the slits in the peripheral region **30** may be wider or smaller in some alternative embodiments.

[0481] Referring now to FIGS. **102**A-**102**B, a top plan and bottom plan view of an example reservoir **12** are depicted. The example reservoir **12** may, for example, be included in various delivery devices **10** such as any of the exemplary delivery device **10** embodiments described above. As shown, various example reservoirs **12** may include at least one septum **550**. A septum **550** may be disposed in an off-center location in the reservoir **12** adjacent a rocker member **526** in certain examples. When the reservoir **12** is assembled, the septum **550** may have a first portion which may be in fluid communication with the interior volume of the reservoir **12**. The septum **550** may also include an externally accessible portion. In some embodiments, the reservoir **12** may include a flow channel which is in fluid communication with the main fluid holding volume of the reservoir **12**, but is sealed from the exterior environment by the septum **550**. The flow channel may extend from a space adjacent the first portion of the septum **550** to the main fluid containing volume of the reservoir **12**. The flow channel may be defined by a portion of the disk body **275** and the reservoir portion **271**. The reservoir **12** may be filled through the septum **550** (e.g. via a dispensing sharp **570**) and fluid may flow through the flow channel (if included) to the main interior cavity of the reservoir **12**. Though shown in relation to the embodiment depicted in FIGS. **102**A-**102**B, septa **550** may be included in other example reservoirs **12** described herein.

[0482] The example reservoir **12** includes a reservoir portion **271** with a wall **261** having a collapse facilitator (see, e.g., FIGS. **72**-**73**). The wall **261** in the example embodiment includes a number of step regions **259** similarly to as described in relation to FIG. **73**. Thus, the wall **261** may have a tiered appearance. The main interior volume of the example reservoir **12** is a step pyramid or ziggurat shaped volume in the example depicted. As shown, the reservoir **12** is in a filled state. The holder **270** includes a stage projection **279** (further described in relation to FIGS. **56**A-D) and a rocker member **526** (further described in relation to FIGS. **89**A-**89**B).

[0483] In the example shown, a side channel **282** of the reservoir portion **271** has been sealed closed by heat staking the reservoir portion **271** material to the holder **270**. The portion of the side channel **282** at the periphery of the flange **284** is sealed against the holder **270** leaving the remaining portion of the side channel **282** open. In alternative embodiments, the reservoir portion **271** may not include a side channel **282**. The entire peripheral region of the flange **284** may be coupled to the disk body **275** during manufacture. In certain example embodiments, the wall **261** forming the cavity in the reservoir portion **271** may include an offshoot or a node which extends away from the main portion of the cavity.

[0484] Reservoirs **12** including a septum **550** such as that shown in FIGS. **102**A-**102**B may be shipped in an unfilled state. The reservoir **12** may be filled at a pharmacy, hospital, physician's office, vaccination site, or other patient care setting. Alternatively, reservoirs **12** may be filled at a local distribution center from which they may be subsequently disseminated to the surrounding population. The reservoir **12** may be filled temporally proximate use of a delivery device **10**. Thus, agent may only be contained in the delivery device **10** for a short period of time (e.g. minutes to weeks). This may allow for reservoirs **12** or delivery devices **10** to be shipped without need for cold chain distribution networks. Additionally, this may help limit need for prolonged agent compatibility testing and facilitate a more nimble response to public health crises.

[0485] Referring now also to FIGS. **103**-**104**, when desired, example reservoirs **12** may be filled by establishing fluid communication between an interior fluid holding volume of the reservoir **12** and a filling implement (not shown). In various examples, a filling implement such as a syringe may be used and may include a dispensing sharp **570**. The dispensing sharp **570** may be advanced through the septum **550** and fluid may be transferred from the filling implement into the interior volume of the reservoir **12** via the dispensing sharp **570**. Any adhesive member **22** (see, e.g., FIGS. **107**A-**107**C) on the delivery device **10** may include an open region to allow access to the septum **550** via the dispensing sharp **570** (or the adhesive member **22** may be coupled to the delivery device **10**

after filling). Once a desired volume of fluid has been transferred into the reservoir **12**, the dispensing sharp **570** may be withdrawn from the septum **550**. The septum **550** may be constructed of a self-scaling material such that when the dispensing sharp **570** is withdrawn, the septum **550** provides a robust seal between the interior volume of the reservoir **12** and the external environment. In some examples, prior to transferring fluid into the reservoir **12**, a vacuum may be pulled on the reservoir **12** via the filling implement (e.g. by withdrawing the plunger of a syringe). The dispensing sharp **570** may be removed from the septum **550** and any gas sucked out of the reservoir **12** may be expelled from the filling implement. This may help to ensure a minimal volume of gas is present in the reservoir **12** prior to filling.

[0486] In certain examples, the reservoir **12** may include a guard which helps to inhibit contact of the reservoir portion **271** with the tip **572** of a dispensing sharp **570**. The guard may help keep the reservoir portion **271** in spaced relation to the dispensing sharp **570** during filling of the reservoir **12**. The guard may, for example, block a portion of the reservoir portion **271** from displacing into a sharp receiving region of the reservoir **12** where the tip **572** of a dispensing sharp **570** may be disposed during filling.

[0487] Referring primarily to FIG. **103**, an example embodiment of a septum **550** is depicted. As shown, the septum **550** includes a plug portion **552** and a standoff **554** which may act as a guard. The plug portion **552** may include a first end **556** and a second end **558**. The first and second ends **556**, **558** may be connected by a stem body **562**. The stem body **562** may be narrower (e.g. have a smaller diameter) than either of the first and second ends **556**, **558**. The first end **556** may be wider (e.g. larger diameter) than the second end **558**. The standoff **554** may project from the second end **558**. In the example shown, the standoff **554** is shaped substantially as a hemisphere and includes a recessed channel **564**. The recessed channel **564** may extend across the width of the standoff **554** forming a canyon type feature in the standoff **554**.

[0488] Referring primarily to FIG. **104**, as shown, the holder **270** may include an aperture **560** which extends through the disk body **275** of the holder **270**. The septum **550** may be a fluid tight plug for this aperture **560** when the reservoir **12** is assembled. For example, the septum **550** may be installed in the reservoir **12** by advancing the standoff **554** and first end **556** through the aperture **560**. The standoff **544** may have a shape (e.g. a spherical segment) which helps guide the septum **550** into the aperture **560**. When installed, the stem body **562** may be disposed within the bore of the aperture **560**. The first end **556** may be disposed against the face of the holder **270** from which the stage projection **279** extends. The second end **558** may be disposed within the side channel **282** (or in an offshoot or node projecting from the main cavity of the interior volume of the reservoir **12**). Thus the plug portion **552** may establish a fluid tight seal between the exterior environment and the interior volume of the reservoir **12**. The stem body **562** of the septum **550** may have a width (e.g. diameter) which is slightly larger than that of the aperture **560** such that the stem body **562** is under compression when the septum **550** is installed within the reservoir **12**.

[0489] When installed within the reservoir **12**, the section of the reservoir portion **271** in which the side channel **282** (or offshoot or node from the main cavity of the reservoir **12**) is formed may be inhibited from displacing into the recessed channel **564** by the remainder of the standoff **554**. The portions of the standoff **554** adjacent the recessed channel **564** may hold the reservoir portion **271** above the recessed channel **564**. Thus, the recessed channel **564** may form a sharp receiving volume within the reservoir **12**. The tip **572** of a dispensing sharp **570** may be advanced into the recessed channel **564** while being kept spaced away from the material forming the reservoir portion **271**.

[0490] In certain embodiments, an adapter **566** may be utilized with any suitable filling implement to ensure that the dispensing sharp **570** is prevented from advancing into the septum **550** beyond a certain distance. The adapter **566** may, for example, couple to a filling implement or hub **568** to which the dispensing sharp **570** is attached. The adapter **566** may extend along a portion of the dispensing sharp **570** shortening the exposed length of the dispensing sharp **570**. The adapter **566**

may contact or bottom out against the reservoir **12** as the dispensing sharp **570** is introduced into the septum **550** and inhibit further displacement of the dispensing sharp **570** into the septum **550**. The adapter **566** may ensure that the tip **572** of the dispensing sharp **570** is limited from displacing out of the recessed channel **564**. In alternative embodiments, an adapter **566** may be omitted. The dispensing sharp **570** may have an exposed length (e.g. extending from a hub **568**) which is shorter than a height of the septum **550**, but longer than a distance between the first end **556** of the septum **550** and the most proximate point of the recessed channel **564**. Thus, when inserted, the tip **572** of the dispensing sharp **570** may be disposed within the recessed channel **564**.

[0491] Referring now to FIG. **105**, the example reservoir **12** of FIGS. **102**A-**104** is depicted assembled into an exemplary delivery device **10**. Depending on the embodiment, the reservoir **12** may be filled while installed in a delivery device **10** or may be filled and subsequently installed in a delivery device **10**. Where the reservoir **12** is filled separate from the delivery device **10**, a user may install the reservoir **12** into the delivery device **10** after filling and then couple an adhesive member **22** to the delivery device **10**. Where the delivery device **10** is filled in a pharmacy or the like, a fixture may be provided to assist in positioning the adhesive member **22** and delivery device **10** when coupling the two together.

[0492] In certain examples, and referring now also to FIGS. **106**A-**106**B, the main body **20** of the delivery device **10** may include one or more retention tabs **580**. The retention tabs **580** may form ledges extending from the interior sidewall of the main body **20** which may be spaced from respective stop surfaces **582** above each retention tab **580**. In various examples, the main body **20** may be formed as a monolithic body with the retention tabs **580** and stop surfaces **582** in a single molding operation without use of side actions in the mold. The retention tabs **580** may be created by incorporating bypass shutoffs in the mold. The retention tabs **580** may allow the reservoir **12** to be coupled to the main body **20** via a snap fit. To install a reservoir **12** into the delivery device **10**, the reservoir **12** may be displaced against an underside (a side which would be most proximal a patient when the delivery device **10** is in use) of the retention tabs **580** and pressed toward the top surface **250** of the main body **20**. The retention tabs **580** may deflect to allow passage of the disk body **275** of the reservoir **12** beyond the retention tabs **580** and into abutment with a stop surface **582**. The retention tabs **580** may resiliently restore to hold the reservoir **12** in place within the delivery device **10**. Retention tabs **580** and stop surfaces **582** may be incorporated into various delivery devices **10** described herein (e.g. any of those described above). Embodiments including a ridge **290** (see, e.g., FIG. **29**) may, for example, be modified to include retention tabs **580** and stop surfaces **528** in place of the ridge **290**. Referring now to FIGS. **107**A-**107**C, a number of example adhesive members **22** are depicted on exemplary delivery devices **10**. As shown, a single adhesive member **22** is included for each of the example delivery devices **10**. In alternative embodiments, the adhesive member **22** may be broken into a plurality of individual adhesive members **22**. This may facilitate use of different adhesives or perhaps leaving certain petal member **42** devoid of adhesive. As shown, each adhesive member **22** may include a plurality of slits **43** extending radially inward from a periphery of the adhesive member **22** so as to create petal portions which align with the petal members **42** of the main body **20**. The adhesive member **22** may also include a central aperture **49** through which the delivery sharp(s) **72** of the delivery device **10** may access a patient.

[0493] The shape and size of the central aperture **49** may have an effect on bleb formation resulting from delivery when a delivery device **10** is used. Additionally, the shape and size of the central aperture **49** may play a role in helping to facilitate certain shallow deliveries or shallow deliveries into skin having certain characteristics. In various exemplary delivery devices **10**, it may be desirable that the central aperture **49** have a cross sectional area which is 60-100% the area of the footprint of the holder **270**. It may also be desired that the central aperture **49** be shaped such that at least a portion of the adhesive member **22** is attached to a portion of a holder **270** or other rigid portion of the reservoir **12**. In certain examples, the cross-sectional area of the central aperture **49**

may be greater than 0.13 in.sup.2. In certain examples, the cross-sectional area of the central aperture **49** may be in a range of 0.13 in.sup.2 to 0.5 in.sup.2 (e.g. about 0.3 in.sup.2).
[0494] Additionally, it may be desired that the central aperture **49** be wider in certain directions compared to others. For instance, each delivery sharp **72** (e.g. one or more microneedle) may tend to dispense fluid in an ejection direction which extends from the outlet of the respective delivery sharp **72** (e.g. along the axis of the lumen of the delivery sharp **72**). It may be desired that the central aperture **49** have a larger or increased width in a direction which aligns or substantially aligns with the ejection direction. For example, the greatest width (or at least a comparatively large width portion) of the central aperture **49** may be along a direction that is parallel to a plane that includes the ejection direction. Using a delivery device **10** including one or more microneedle similar to that shown in FIG. **2**, an increased width portion of the central aperture **49** may be aligned with the front to back (distal side **15** to back facing edge **23**, may also be referred to herein as length) direction or line of symmetry of the microneedle. For example, the central aperture **49** could be obround and be widest in a direction parallel to the front to back direction of the microneedles. This may help to create a more diffuse shallow (e.g. intradermal) injection as opposed to a concentrated bleb. This may, in turn, be desirable as it may help to increase the effectiveness of the injection. For instance, a more diffuse intradermal injection of a vaccine may expose more of the immune related cells in the intradermal region to the vaccine potentially augmenting the immune response.
[0495] Referring now primarily to FIG. **107**A, the central aperture **49** may generally be a round (e.g. circular) aperture with the exception of a number of inwardly extending teeth or spokes **51** of adhesive member **22** material. In the example embodiment, the adhesive member **22** includes a central aperture **49** with four spokes **51** spaced at regular angular increments from one another. The number of spokes **51** may differ and the spacing of the spokes **51** may be irregular in certain examples. The spokes **51** may be disposed such that the central aperture **49** has a comparatively large width in a direction aligned with the ejection direction. Though the central aperture **49** may have a comparatively large width in this direction, this does not preclude other wide regions of equal, lesser, or perhaps even greater width. In the example shown, the central aperture **49** is about equal in width when measured in a direction perpendicular to the front to back direction of the microneedles. In certain examples, spokes **51** may assist in attachment to a holder **270** or other rigid reservoir **12** portion. Thus, the adhesive member **22** may be firmly attached to both the main body and the holder **270** for example. In certain examples, the spokes **51** may be the only portion of the adhesive member **22** which is adhered to the holder **270**.
[0496] Referring now primarily to FIG. **107**B-C, in certain examples, the central aperture **49** may include notches **53** which extend outwardly from the periphery of the rest of the central aperture **49**. The notches **53** may be included to widen the central aperture **49** where desired. Though rectangular notches **53** are included in the examples, the shape of the notches may differ in alternative embodiments. The notches **53** could be any suitable polygonal shape or could be round for example.
[0497] Various main bodies **20**, as well as petal members **42**, central regions **28**, top surfaces **250**, ridges **290**, retention tabs **580** thereof are described above. It shall be understood that various delivery devices **10** described herein are exemplary. Any main body **20** described above may be used in any of the above delivery devices **10**. Similarly, any main body **20** features described above may be incorporated into any of the main bodies **20** described above. Various adhesive members **22** are described herein. Any adhesive members **22** described above may be utilized in any of the delivery devices **10** described above. Any of the delivery sharps **72** or sharp bearing bodies **26** described herein may be used in any of the delivery devices **10** described above. Any of the dispensing assemblies **480** or portions thereof (e.g. bias members **470**, depressor bodies **474**) described herein may be used in any of the delivery devices **10** described above. Various reservoirs **12** and features thereof (e.g. holders **270**, rocker members **526**, reservoir portions **271**, reservoir

walls **261**, stage projections **279**, flow restrictors **524**) are described above and may be used in any of the delivery devices **10** described above.

[0498] Referring now to FIG. **108**A and FIG. **108**B, another example embodiment of a delivery device **10** is depicted. As shown, the delivery device **10** includes a main body **20** and a reservoir **12**. The reservoir **12** includes a sharp bearing body **26** which includes a one dimensional array of three delivery sharps **72**. Other embodiments may include any suitable number of delivery sharp(s) **72** arranged in any desired pattern. The main body **20** of the delivery device **10** may have a polygonal (e.g. rectangular) footprint and may be generally formed as a strip of material to which the reservoir **12** is attached. In the example embodiment, the main body **20** includes a number of living hinges **50** which are formed integral with the rest of the main body **20**. The living hinges **50** may each extend across a portion of the main body **20** and may partition the main body **20** into a number of panels **52**A-D. The main body **20** may be injection molded.

[0499] The panels **52**A-D may include a pair of opposed end panels **52**A, D. Each of the end panels **52**A, D may include a planar portion **54**. The planar portions **54** may be parallel or coplanar. In the example, the planar portions **54** are coplanar. One of the end portions **52**A may include an angled projection **56** which extends from planar portion **54**. The angled projection may extend from the planar portion **54** such that an obtuse angle is formed between the distal faces of the planar portion **54** and angled projection **56**. The angled projection **56** may be resilient and resist deflection or bending so as to extend at a fixed angle with respect to the planar portion **54**. In some examples, a buttress **58** may be included and may extend from the planar portion **54** to the angled projection **56** to aid in preventing displacement of the angled projection **56** with respect to the planar portion **54**. Each of the planar portions may have a proximal face which is at least partially covered in adhesive **22**.

[0500] The panels **52**A-D may also include at least two intermediate panels **52**B, C which may extend between and couple together the end panels **52**A, D. One of the panels **52**B may be coupled to an end of the raised projection **56** via one of the living hinges **50**. The other of the intermediate panels **52**C may be coupled to the planar end panel **52**D via another of the living hinges **50**. Each of the intermediate panels **52**B, C may be coupled to one another via a living hinge **50** so as to form a linkage **60** between the end panels **52**A, D.

[0501] Referring now to FIGS. **109**A-**109**C, the linkage **60** may be displaceable between a raised position (see FIG. **109**A), through a center position (see FIG. **109**B) and into an over center position (see FIG. **109**C). The linkage **60** may be in the raised position when the delivery device **10** is in the storage state. In the raised position, the intermediate panel **52**B connected to the raised projection **56** may extend from the raised projection **56** at an angle **62** (angles **62**, **64**, **66**) measured between proximal faces of recited components). The angle **62** may be selected such that the intermediate panel **52**B becomes progressively more distant from the plane of the planar portions **54** as distance from the raised projection **56** increases. In the example shown, angle **62** is an obtuse angle when the linkage **60** is in the raised position. The intermediate panels **52**B, C may also be disposed at an angle **64** to one another. This angle **64** is also an obtuse angle in the example embodiment when the linkage **60** is in the raised position. The intermediate panel **52**C and end panel **52**D may form an angle **66** with respect to one another which may be a reflex angle when the linkage **60** is in the raised position. Additionally, in the raised position each of the end panels **52**A, D may be at a closest distance to one another.

[0502] The delivery device **10** may be applied to the skin **44** over an infusion site in the storage state with the linkage **60** in the raised position. This may fix the end panels **52**A, D such that they are substantially constrained to the plane of the skin patch to which they are adhered. Application of downward pressure against the linkage **60** may displace the linkage **60** from the raised position toward the center position. As this occurs, the angle **64** between the two intermediate panels **52**B, C may increase. The angle **62** between the raised projection **56** and intermediate panel **52**B and the angle **66** between end panel **52**D and intermediate panel **52**C may decrease. To accommodate the

change in the angle **64** between the two intermediate panels **52**B, C the end panels **52**A, D may spread apart. When the linkage **60** reaches a center position (see FIG. **109**B) the angle **64** may be 180° and the end panels **52**, D may be at a greatest distance from one another. The skin **44** may be stretched and rendered taught as the end panels **52**A, D displace apart.

[0503] As the linkage **60** is further displaced the linkage **60** may enter an over center state. The elasticity of the stretched skin **44** may exert a restoring force which tends to drive the end panels **52**A, D toward one another. Thus, once the linkage **60** is displaced through the center position the linkage **60** may automatically be displaced to an over center position at an end of the displacement range of the linkage **60**. When the linkage **60** is displaced into this over center position, the delivery device **10** may be transitioned into the delivery state. As the linkage shifts to the over center position shown in FIG. **109**C, the distance between the end panels **52**A, D may decrease. The distance between the end panels **52**A, D may still, however, be greater than the distance between the end panels **52**A, D when the linkage **60** is in the raised position. In the over center position at the end of the displacement range, the angle **62** between the raised projection **56** and intermediate panel **52**B may be about 90° (e.g. 80°-110°). The angle **64** between the intermediate panels **52**B, C may be a reflex angle. Thus, the linkage **60** may be partially inverted with respect to its position in the raised position. The angle **66** between intermediate panel **52**C and end panel **52**D may be substantially 180°. As shown, when the linkage **60** reaches the over center position at the end of its displacement range a proximal face of the intermediate panel **52**C may contact the skin **44**.

[0504] When the delivery device **10** is in the delivery state (see FIG. **109**C), the delivery sharp(s) **72** may be pressed into the skin **44** so as to puncture the skin **44** and establish fluid communication with a delivery destination in the patient. The angle **64** between the intermediate panels **52**B, C in the over-center delivery position (see FIG. **109**C) may be selected to cause the delivery sharp(s) **72** to pierce into the skin **44** at a prescribed angle (e.g. 45° to the skin **44** surface). The angle **64** may be selected to be in the range of 30° to 60°. Alternatively, the angle **64** may be established by setting within a desired range the ratio of the shortest distance between the angle **62** and the surface of the skin **44** in the over-center delivery position (see FIG. **109**C) to the length of the intermediate panel **52**B. The reservoir **12** may also be pressed against the skin **44** when the delivery device **10** is in the delivery state **10**. This may pressurize the reservoir **12** and force fluid out of the reservoir **12** through the delivery sharp(s) **72** and into the patient. Restoring force exerted by the stretched skin **44** may serve to supply a continuous pressure against the reservoir **12** and aid in ensuring that the reservoir **12** is completely depleted as the delivery occurs.

[0505] In some embodiments, the proximal face of the intermediate panel **52**C may be covered at least partially in adhesive **22** (see, e.g., FIG. **109**C). When the linkage **60** reaches the over center position at the end of the displacement range, the adhesive **22** may hold the linkage **60** in place. Additionally, in some embodiments, the main body **20** may include at least one force limiter. For example, at least one of the panels **52**A, D may include a strain relief flexure. In the example embodiment, this flexure may bend in the event that the force required to stretch the skin **44** exceeds a threshold. Bending of the flexure may cause the linkage **60** to snap through the center position and enter an over center position such that stretching of the skin **44** is halted. This may be desirable as it may help to mitigate potential discomfort during an injection due to excessive tensioning of the skin **44**. Likewise, this may be helpful in certain patient populations as skin characteristics vary significantly across potential patients.

[0506] In an embodiment, one of the intermediate panels **52**B, **52**C, for example the intermediate panel **52**C, may be implemented as a flexure or including at least one flexure that incorporates a gap and at least one bias member. The gap may be urged to a widened state by the bias member (which may, in some embodiments, be formed integrally with and of the same material as the panel **52**B, C). Applying sufficient pressure to the bias member may overcome the bias member and allow the flexure to give. Thus, an intermediate panel **52**B, **52**C may be formed so as to have a variable length which decreases as force exceeds some predefined threshold.

[0507] The intermediate panel **52**C (though any intermediate panels **52**B, **52**C may include such features) may be implemented as or to include at least one lattice-structured flexure **290**, as shown in FIGS. **110**A-**110**B. The flexure(s) **290** may be formed by injection molding. The intermediate panel **52**C may include a first member **296** adjacent the living hinge **50** connection to the other intermediate panel **52**B. The first member **296** may have at least one support arm **300**. In the example shown, there are four support arms **300**A-D extending from the first member **296** at substantially ninety degree angles toward a second member **298** of the intermediate panel **52**C. The second member **298** may be adjacent the living hinge **50** connection to the end panel **52**D. The second member **298** may be disposed parallel to and opposing the first member **296** and have at least one arm **302**. In the example shown there are two arms **302**A-B extending from the second member **298** at substantially ninety degree angles toward the first member **296**. Each of the two arms **302**A-B may be positioned substantially parallel to and extend between a respective pair of the four support arms **300**A-D. Each of the two arms **302**A-B may be coupled to at least one of the associated two support arms **300**A-B, **300**C-D disposed on each side of the respective arm **302**A-B by at least one buttress **304** (e.g., three buttresses **304**). In the example, each of the two arms **302**A, B is connected to each of the associated support arms **302**A-B. Only six of twelve buttresses **304**A-F are shown in FIG. **110**B for case of illustration. Applying pressure that exceeds a threshold level will cause the gaps between the first and second members **296**, **298**, the support arms **300**A-D, the arms **302**A-B, and the buttresses **304**A-F to at least partially close. The number of buttresses **304**A-F may be altered to adjust the threshold at which that flexure **290** gives way. Additionally or alternatively, the amount of material or thickness of the buttresses **340**A-F may be adjusted for this purpose. The buttresses **304**A-F may be disposed substantially parallel with each other and extend from the respective arm **302**A-B at acute angles relative to the first member **296**. The buttresses **304**A-F may couple to the respective support arms **300**A-D at obtuse angles relative to the first member **296**. The flexures **290** are shown by way of non-limiting example and may be incorporated using any suitable shapes, angles, and/or numbers of structures and/or parts.

[0508] In another embodiment the intermediate panel **52**C may incorporate at least one flexure **292** which may be in the form a squishable body that may deform when a threshold force applied to the body is exceeded. The flexure **292** may be round and hollow in an embodiment. As shown in FIGS. **111**A-**111**B, the exemplary flexure **292** may be roughly cylindrical in shape. It would be understood that the flexure **292** shown is one of many possible examples and need not be limited to the structure or shape shown. The flexure **292** may be integral to the intermediate panel **52**C and may be formed in an injection molding process that forms the main body **20** of the delivery device **10**.

[0509] In some embodiments, at least a portion of the main body **20** may plastically deform after the delivery device **10** is transitioned from the storage state to the delivery state. For example, one of the living hinges **50** may be plastically deformed. Alternatively, one or more of the living hinges **50** may break when an attempt to transition the delivery device **10** back to the storage state from the delivery state is made. Thus, the transition from the storage state to the delivery state may be rendered irreversible and reuse of the delivery device **10** may be prevented. In some examples, the adhesive **22** may be selected so as to bond more aggressively to the skin **44** than the material forming the main body **20**. Thus, upon removal of the delivery device **10**, the adhesive **22** may peel off of the delivery device **10**. This may also aid in inhibiting reuse of the delivery device **10**. In embodiments described herein where the adhesive **22** peels off the delivery device **10**, the adhesive **22** may include a pull tab or similar feature which would facilitate subsequent removal from the skin **44**.

[0510] Referring now to FIGS. **112**-**113**, another example embodiment of a delivery device **10** is depicted. As shown, the delivery device **10** includes a main body **20** and a reservoir **12**. The reservoir **12** includes a sharp bearing body **26** which includes a one dimensional array of delivery sharps **72**. Other embodiments may include any suitable number of delivery sharp(s) **72** arranged in any desired pattern. The main body **20** of the delivery device **10** may have a polygonal footprint

which may change from a first polygonal shape (e.g. a hexagonal shape) to a second polygonal shape (e.g. a rectangular shape) when the delivery device **10** is transitioned from a storage state to a delivery state.

[0511] The main body **20** may include a first and second end block **70**A, B. The end block **70**A, B may be disposed in opposition to one another. The end blocks **70**A, B may be spaced apart and connected together by a set of side panels **71**A, B and a bridge **76**. The side panels **71**A, B may each have a first end which is connected to the first end block **70**A by a hinge **74**A. The side panels **71**A, B may also each have a second end opposed to the first end which is connected to the second end block **70**B by a hinge **74**B. Each of the side panels **71**A, B may also include an intermediate hinge **74**C which may be disposed in an intermediate region of the side panels **71**A, B between the first and second end of each side panel **71**A, B.

[0512] Similarly to the side panels **71**A, B, the bridge **76** may have a first end connected to the first end block **70**A by a hinge **74**D and a second end opposite the first which is connected to the second end block **70**B by another hinge **75**E. The bridge **76** may additionally include an intermediate hinge **74**F disposed between the first and second ends of the bridge **76**. The bridge **76** may include a panel body **78** and a set of strut members **80**A, B. the strut members **80**A, B may be connected to the panel body **78** via the intermediate hinge **74**F of the bridge **76**. The bridge **76** may also include an arm member **82**. The arm member **82** may be disposed between two strut members **80**A, B and may extend toward a proximal face of the end blocks **70**A, B. In the example embodiment, the arm member **82** extends from an end of the panel body **78** adjacent the intermediate hinge **74**F of the bridge **76**. The reservoir **12** may be coupled to the proximal face of the arm member **82** at an end of the arm member **82** opposite the panel body **78**.

[0513] In the example embodiment shown in FIGS. **112**-**113**, the hinges **74**A-F are depicted as living hinges. In alternative embodiments, at least one of the hinges **74**A-F may be conventional hinges and the main body **20** may be constructed as an assembly of a plurality of components which are coupled to one another via the hinges **74**A-F. In still other examples, the main body **20** may be constructed of at least two components. Instead of using a hinge to join the components, the two or more components of the main body **20** may be joined together via welding, heat bonding, solvent bonding, etc.

[0514] The side panels **71**A, B of the delivery device **10** may be displaceable through a displacement range to transition the delivery device **10** between a storage state (shown in FIGS. **112**-**113**) to a delivery state. In the storage state, the side panels **71**A, B of the delivery device **10** may be in an outwardly bowed position. The side panels **71**A, B may be bent at the intermediate hinges **74**C of each of the side panes **71**A, B such that the side panels **71**A, B may assume this outwardly bowed position. Some pivoting of the side panels **71**A, B at the hinges **74**A, B connecting the side panels **71**A, B to the end blocks **70**A, B may also occur to allow the side panels **71**A, B to be placed in the outwardly bowed position.

[0515] A pinching force which urges the side panels **71**A, B toward one another may be exerted against the side panels **71**A, B to displace the side panels **71**A, B from the outwardly bowed position to a straightened position. It should be understood that the straightened position need not necessarily be a position in which the side panels **71**A, B each extend along straight line. In some examples, the straightened position may be a position in which the side panels **71**A, B are less outwardly bowed than in the outwardly bowed position.

[0516] The bridge **76** may also be displaceable through a displacement range to transition the delivery device **10** between a storage state (shown in FIGS. **112**-**113**) to a delivery state. In the storage state, the bridge **76** may be in a raised state in which at least the delivery sharp(s) **72** of the reservoir **12** coupled to the arm member **82** are disposed above the proximal faces of the end blocks **70**A, B. The bridge **76** may be bent at the intermediate hinge **74**F such that the panel body **78** and struts **80**A, B extend upward from the end blocks **70**A, B and away from the proximal face of the end blocks **70**A, B. Some pivoting of the panel body **78** and struts **80**A, B at the hinges **74**D, E

connecting the bridge **76** to the end blocks **70**A, B may also occur to allow the bridge to assume the raised position. A force normal to the proximal faces of the end blocks **70**A, B may be applied to the bridge **76** to displace the bridge from the raised position to a lowered position at the opposite end of the bridge's **76** displacement range.

[0517] In various embodiments, actuation of the bridge **76** through its displacement range may transition the delivery device **10** from the storage state to the delivery state. Additionally, actuation of the side panels **71**A, B from the outwardly bowed state to the straightened state may transition the delivery device **10** from the storage state to the delivery state. Actuation of the bridge **76** through its displacement range may result in displacement of the side panels **71**A, B through their displacement range since the bridge **76** and side panels **71**A, B are coupled to one another through the end blocks **70**A, B. Likewise, actuation of the side panels **71**A, B through their displacement range may result in displacement of the bridge **76** through its displacement range.

[0518] It may be left up to the user whether actuation of the side panels **71**A, B or bridge **76** is used to transition the delivery device **10**. Alternatively, whether the bridge **76** is actuated or the side panels **71**A, B are actuated may depend upon the patient population to which the user belongs. For example, actuation of the bridge **76** may result in a greater amount of pressure being exerted against the arm member **82**. This may aid in ensuring puncture of the delivery sharp(s) **72** into the skin. Thus, it may be desirable that patient populations with certain skin characteristics be instructed to actuate the delivery device **10** via the bridge as opposed to the side panels **71**A, B.

[0519] Referring now also to FIGS. **114**A-**114**C, with the side panels **71**A, B in the outwardly bowed position and the bridge **76** in the raised position (see FIG. **114**A), the end blocks **70**A, B may be at a first distance from one another. As the side panels **71**A, B are displaced toward the straightened position and the bridge **76** is displaced to the lowered position (see FIGS. **114**B-**114**C), the end blocks **70**A, B may be displaced apart from one another. As the delivery device **10** may be attached to the skin **44** via adhesive **22** included on the end blocks **70**A, B, the spreading of the end blocks **70**A, B may cause the skin **44** to be stretched and rendered taught. This may help to facilitate piercing of the skin **44** by the delivery sharp(s) **72** included on the reservoir **12**. As shown in FIG. **114**C, when the side panels **71**A, B reach the straightened position and the bridge **76** reaches the lowered position, the delivery sharp(s) **72** may puncture the skin **44** and the delivery device **10** may be in the delivery state. The reservoir **12** may be compressed between the skin **44** and the arm member **82** to drive fluid out of the reservoir **12** and into the patient. The reservoir **12** may collapse as delivery occurs.

[0520] Referring now also to FIG. **115**, a cross section of the delivery device **10** in FIGS. **112**-**113**, a delivery device **10** may include an iris assembly **84** in certain examples. The iris assembly **84** may include a set of iris panels **86**A-D which may define an aperture **88** which is variable in size from a closed to a fully open state. The iris panels **86**A-D may extend from each of the side panels **71**A, B in a direction toward the opposite side panel **71**A, B. In the example embodiment, two iris panels **86**A-D extend from each side panel **71**A, B and are disposed on either side of the intermediate hinge **74**C, D of each side panel **71**A, B. As the side panels **71**A, B are displaced from an outwardly bowed position to a straightened state, the iris panels **86**A-D may adjust the aperture **88** such that the aperture **88** provides an opening for the delivery sharp(s) **72** of the reservoir **12** to pass through. As shown in FIG. **115**, the aperture **88** may be substantially closed when the delivery device **10** is in the storage state. Such an iris assembly **84** may thus serve as a guard which may aid in preventing inadvertent contact with the delivery sharp(s) **72** during handling of the delivery device **10**.

[0521] In the example embodiment, one of the iris panels **86**A includes a latch projection **90**. Another of the iris panels **86**B includes a latch catch **92** which may be formed as a notch in that iris panel **86**B. The latch projection **90** is ramped. Thus, as the iris panels **86**A, B are displaced toward one another, iris panel **86**B may deflect and ride up the ramp of the latch projection **90** (see, e.g., FIG. **114**B). Upon the latch catch **92** aligning over the latch projection **90**, the iris panel **86**B

including the latch catch **92** may restore to an undeflected state and the latch catch **92** may snap into engagement with the latch projection **90**. This may lock the delivery device **10** in the delivery state. The snapping action of the iris panel **86**B may generate tactile sensation perceptible, for example, via a user's finger tips. Alternatively or additionally, the snap may generate an audible click or slap. Thus, the delivery device **10** may provide an audible and/or tactile indication that the delivery device **10** has been transitioned to the delivery state. Engagement of the latch projection **90** and latch catch **92** may also aid in inhibiting reuse. As discussed in relation to other embodiments herein, the adhesive **22** may be selected so as to bond more aggressively to the skin **44** than the material forming the main body **20**. Thus, upon removal of the delivery device **10**, the adhesive **22** may peel off of the delivery device **10**. This may also aid in inhibiting reuse of the delivery device **10**.

[0522] Referring now to FIGS. **116**A-**116**B, another exemplary embodiment of a delivery device **10** is depicted. The delivery device **10** may include a first portion **100** and a second portion **102**. One of the first and second portion **100**, **102** may translationally displace with respect to the other of the first and second portion **100**, **102** to transition the delivery device **10** from a storage state (see FIG. **116**A) to a delivery state (see FIG. **116**B). In some embodiments, only a part of the first or second portion **100**, **102** may translationally displace with respect to the other. For example, one of the first or second portions **100**, **102** may stretch and/or elongate. In certain examples, the transition to the delivery state may be reversible, though in other embodiments the transition may be a one-way transition that is irreversible. For example, a latch, lock, or other coupling may be engaged to hold the first and second portion **100**, **102** in the delivery state or prevent the first and second portion **100**, **102** from returning to the storage state. Alternatively, the first and second portion **100**, **102** may be bonded together when the delivery device **10** is transitioned into the storage state. Destruction of a portion of the delivery device **10** may be required to disengage the coupling or bonding between the first and second portion **100**, **102** once the delivery device **10** is transitioned to the delivery state. This destruction may render the delivery device **10** inoperative. This may inhibit reuse as well as provide a user perceptible (e.g. visual) indication that the delivery device **10** has been used.

[0523] The proximal face of each of the first and second portion **100**, **102** may be at least partially covered with adhesive **22**. The adhesive **22** may serve to couple the first and second portion **110**, **102** to a skin surface at an infusion site on a patient. The delivery device **10** may be adhered to the skin when delivery device **10** is in the storage state and then may be transitioned to the delivery state. As the transition occurs, an adhesive bearing section of the first portion **100** may be displaced with respect to an adhesive bearing section of the second portion **102**. Thus, the distance between these adhesive bearing sections may be increased so as to stretch or spread the underlying skin. This may be desirable as the skin may be rendered taught facilitating piercing of the skin by at least one delivery sharp **72** of a reservoir **12** included in the delivery device **10**.

[0524] Transition of the delivery device **10** to the delivery state may also result in a proximal displacement or lowering of the delivery sharp(s) **72** toward and into the skin. In embodiments where the delivery sharp(s) **72** are coupled to the reservoir **12**, the reservoir **12** may also be proximally displaced. In some examples, the reservoir **12** may be compressed between the skin surface and a section of one of the first and second portions **100**, **102** when the delivery device **10** is transitioned from the storage state to the delivery state. Compression of the reservoir **12** may serve to drive fluid out of the reservoir **12**, through the delivery sharp(s) **72** and into the target delivery destination in the patient. Additionally, in some embodiments, at least one of an audible or tactile indication may be generated when the delivery sharp(s) **72** are displaced toward the skin.

[0525] Referring now to FIGS. **117-118**, an exemplary delivery device **10** is depicted. As shown, the delivery device **10** may be a thin, low profile assembly which is substantially planar. The delivery device **10** may include a proximal portion **110** and a distal portion **112**. The proximal portion **110** may be formed of flexible material and in some embodiments may be elastic so as to

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

[0526] Referring now also to FIGS. **119-120**, the proximal portion **110** and the distal portion **112** may also be coupled together via an adhesive locking assembly **114**. As shown, the adhesive locking assembly **114** may include a region of locking adhesive **116** which may be disposed on a portion of the proximal face of the distal portion **112**. The adhesive locking assembly **114** may include a tether member **118**. The tether member **118** may be coupled at a first end to the proximal portion **110** of the delivery device **10** and coupled, at a second opposing end, to the locking adhesive **116** on the distal portion **112**. The tether member **118** may be heat staked, welded, or otherwise fixedly coupled to the proximal portion **110** while being relatively lightly coupled to the locking adhesive **116**. In some embodiments, the tether member **118** may be constructed of an adhesive liner or backing material which adheres, but is easily peeled from the locking adhesive **116**. As shown, the tether member **118** may be at least partially doubled over when the delivery device **10** is in the storage state.

[0527] The proximal portion **110** may include a pull tab **120** which may be disposed at a first end of the proximal portion **110**. The pull tab **120** may be an enlarged or widened section of the proximal portion **110**. In some embodiments, the pull tab **120** may include a roughened surface or may include bumps, ridges, or the like to facilitate grasping. In alternative embodiments, the pull tab **120** may include a cut out so as form a pull ring.

[0528] The proximal portion **110** may also include at least one ramp element **128** and a folded region **122** at an end of the proximal portion **110** opposite the pull tab **120**. In the example embodiment, the proximal portion **110** includes two ramp elements **128** disposed abreast of one another. The folded region **122** may be folded over upon itself a number of times. In the example, the folded region **122** is folded upon itself twice. Thus, when a pulling force is exerted on the pull tab **120**, the folded region **122** may unfurl and spool out proximal portion **110** material to allow the proximal portion **110** to elongate. The at least one ramp element **128** may also be displaced as the folded region **122** feeds out material. The number of folds in the folded region **122** may be adjusted to change the amount that the proximal portion **110** elongates as it is transitioned to the elongated state. The folded region **122** may taper from a larger width to a smaller width over at least a section of the folded region **122**. In the example embodiment, the layer of the folded region **122** most proximal to the distal portion **112** tapers to a rounded end. The layer of the folded region **112** most proximal to the distal portion **112** may be substantially immobile and anchored in place by the adhesive **22** of the distal portion **112** as the folded region **122** unfurls.

[0529] As best shown in FIG. **119**, the delivery device **10** may include a reservoir **12** which may include at least one delivery sharp **72**. Any suitable number of delivery sharp(s) **72** may be included in any desired number of rows and/or columns. Any delivery sharp(s) **72** described herein may be used. The delivery sharp(s) **72** may be included on a sharp bearing body **26** which is coupled to the reservoir **12**. The reservoir **12** may be disposed on a resilient cantilevered arm **130** defined in the distal portion **112** of the delivery device **10**. The folded region **122** of the proximal portion **110** may include a delivery aperture **124**. As shown, when the delivery device **10** is in a storage state the delivery aperture **124** may be out of alignment with the delivery sharp(s) **72**. Thus, the proximal portion **110** may cover the delivery sharp(s) **72** and block or guard against inadvertent contact with the delivery sharp(s) **72** when the delivery device **10** is in the storage state. The delivery aperture **124** may, however, allow for the delivery sharp(s) **72** of the delivery device **10** to pass through the delivery aperture **124** and access the skin of a user when the delivery device **10** is transitioned to the delivery state.

[0530] Referring now to FIGS. **121**A-**122**B, to transition the delivery device **10** from the storage state to a delivery state, a pulling force may be exerted on the pull tab **120**. The distal portion **112** of the delivery device **10** may be anchored to the skin **44** via the adhesive **22** on the proximal face of the distal portion **112**. Thus, the distal portion **112** of the delivery device **10** may be substantially stationary as the transition transpires. The proximal portion **110** may transition from a first state to an elongated state as the delivery device **10** passes from the storage state to the delivery state. As shown, the folded region **122** of the proximal portion **110** may unfurl such that the proximal portion **110** may elongate as the pull tab **120** is pulled. Additionally, in certain embodiments, the proximal portion **110** may stretch allowing for further elongation. The segment of the proximal portion **110** including the adhesive **22** may displace relative to the distal portion **112** of the delivery device **10** as the pull tab **120** is pulled. The adhesive **22** on the proximal portion **110** and distal portion **112** may be displaced apart when the proximal portion **110** is pulled from the first state to the elongated state. As a result, the skin **44** between the adhesive **22** on the proximal portion **110** and the adhesive **22** on the distal portion **112** may become stretched and taut to facilitate puncture.

[0531] As the folded region **122** unfurls, proximal portion **110** material may be fed out such that the proximal portion **110** elongates and the delivery aperture **124** is displaced into alignment with the delivery sharp(s) **72**. The at least one ramp element **128** may be displaced in the direction of the pull tab **120**. The at least one ramp element **128** may keep the cantilevered arm **130** slightly deflected toward the distal portion **112** as the proximal portion elongates. This may keep the delivery sharp(s) **72** of the reservoir from dragging against the proximal portion **110** as the proximal portion **110** is transitioned to the elongated state. As the at least one ramp element **128** is further displaced, the cantilevered arm **130** may ride over a sloped region of the at least one ramp element **128** and be further deflected toward the distal portion **112** of the delivery device **10**. As the folded region **122** continues to unfurl, the at least one ramp element **128** may advance past the cantilevered arm **130**.

[0532] Once the at least one ramp element **128** has cleared the cantilevered arm **130**, the cantilevered arm **130** may restore to an undeflected state as shown in FIG. **122**A and FIG. **122**B. The delivery device **10** may enter the delivery state when the cantilevered arm **130** is clear of the at least one ramp element **128** and restores to its undeflected state. As the cantilevered arm **130** springs back to an undeflected state, the delivery sharp(s) **72** may be displaced through the delivery aperture **124** and may puncture the skin **44**. This may establish fluid communication between the delivery sharp(s) **72** and a target delivery destination in the patient. Additionally, the reservoir **12** may be compressed between the skin **44** and the cantilevered arm **130** when the cantilevered arm **130** restores to its undeflected state. This compression may serve to drive fluid out of the reservoir **12** and into the patient via the delivery sharp(s) **72**. The compression may also help to ensure that the reservoir **12** is fully emptied during delivery.

[0533] As shown, the tether member **118** may be peeled from the lock adhesive **116** as the delivery device **10** transitions from the storage state to the delivery state. Once the delivery device **10** reaches the delivery state, the tether member **118** may be at least partially separated from the lock adhesive **116**. The exposed lock adhesive **116** may then adhere to the proximal portion **110** to bond the proximal portion **110** in place. The lock adhesive **116** may aggressively adhere to the proximal portion **110**. An attempt to separate the proximal portion **110** and lock adhesive **116** may result in damage to one of the components of the delivery device **10**. This may help to ensure that the transition of the delivery device **10** to the delivery state is irreversible. The lock adhesive **116** may also inhibit restoring force exerted by the stretched skin from causing the proximal portion **110** to crumple. Thus, the lock adhesive **116** may hold the adhesive **22** on the proximal portion **110** in place such that the skin remains stretched when the proximal portion **110** is in the elongated state and the user releases the pull tab **120**.

[0534] With reference to FIGS. **123-126**, another example embodiment of a delivery device **10** is depicted. FIG. **123** depicts the example delivery device **10** in a storage state. FIG. **124** depicts the

example delivery device **10** in a delivery state. FIG. **125** and FIG. **126** depict exploded views of the example delivery device **10**. As shown, the example delivery device **10** may comprise an actuator. In some embodiments the actuator may form a top **306**, or cap, having at least one depression or concavity **308** therein (three such concavities **308** are shown but it would be understood that the number need not be three). The concavities **308** may serve to facilitate twisting of the top **306** by a user via fingertip placement therein. The top **306** may be of a hooded, or convex shape, and may be made of a plastic formed by injection molding or any other suitable technique as would be known to one of skill. One of skill would appreciate that the top **306** need not be limited to any particular shape provided that it can be twisted by a user.

[0535] As shown, the exemplary top **306** sits on a base body **309**. The top **306** engage with a threaded post or screw **310** included as part of the base body **309**. In some non-limiting examples, the threaded screw **310** may be made of a plastic material formed by injection molding and may be formed integrally with the rest of the base body **309**. One of skill would appreciate that other materials and manufacturing techniques could be used to construct the threaded screw **310**.

[0536] In an example embodiment, a user may first remove an adhesive liner **265** (see, e.g., FIG. **25**) from the delivery device **10**. In addition to covering an adhesive bearing pad **312** of the delivery device **10**, the adhesive liner **265** may, in some embodiments, have been attached to cover and maintain a previously sanitized state of the delivery device **10**. Such a state may be created prior to attaching the adhesive liner **265** to any of the delivery devices **10** described herein. In some examples, the user may peel off the adhesive liner **265** similarly to the manner in which a user peels a liner off a bandage prior to applying the bandage. Once the liner **265** is removed, a user may then apply the delivery device **10** to the skin. As in the example shown, the adhesive pad **312** may be annular in shape. In some embodiments, the adhesive pad **312** may be ultrasonically welded to the delivery device **10**. Those of skill would understand that other suitable techniques to adhere the adhesive pad **312** to the delivery device **10** may be used.

[0537] After affixing the delivery device **10** to the skin, the user may then twist the top **306** of the delivery device **10** and thereby cause the top **306** to advance proximally (e.g., toward the skin) along the threads of the threaded screw **310**. Inside the threaded screw **310** a breakable material, or frangible **314** may be housed. The frangible **314** may inhibit displacement of the top **306** and other components of the delivery device **10** until a sufficient force is applied to the top **306**. This may aid in preventing transition of the delivery device **10** to a delivery state during storage.

[0538] In the example embodiment, the frangible **314** is provided as at least one tab which projects from a carriage **315** that may be disposed within the bore **317** of the threaded post **310**. In some embodiments, the carriage **315** may include a set of three frangibles **314** which are disposed at even angular increments about a first end of the carriage **315**. The bore **317** may include a ledge **319** to support at least one of the frangibles **315** and preferably a ledge **319** to support each frangible **314**. With the frangibles **314** resting on the ledge(s) **319**, the carriage **315** may be inhibited from displacing within the bore **317** and twisting motion of the top **306** may be impeded. In certain examples, the ledge(s) **319** may each be an end of a track or rail (best shown in FIG. **125**) disposed in the bore **317** which may help to guide displacement of the carriage **315** within the bore **315**.

[0539] The top **306** may incorporate a central projection **318** (e.g. column or stepped column as shown) that rests upon a portion of the carriage **315**. As the top **306** screws downward or proximally toward the skin surface, the projection **318** may cause the frangible(s) **314** may be pressed against the respective ledges **319**. The pressure exerted against the frangible(s) **314** may cause the frangible(s) **314** to break off, allowing the carriage **315** to travel proximally within the bore **317**. The carriage **315** may displace proximally and eventually a second end of carriage **315** (opposite the first end from which the frangibles **314** project) may contact the skin surface. It would be understood by one of skill that once the frangible(s) **314** have broken, reuse of the delivery device **10** may be inhibited.

[0540] The adhesive pad **312** of the delivery device **10** may have a central aperture **323** though

which a portion of the carriage **315** may extend. Skin may not be retained in position against the delivery device **10** in the region of the central aperture **323**. Thus, as the carriage **315** continues to displace proximally, the skin in this region may be pressed and stretched as it is displaced by the carriage **315**. This may render the skin aligned with the central aperture **323** taut. The base body **309** may include a shelf **321** which extends into the bore **317** at the proximal end of the bore **317** and acts as a stop surface. The carriage **315** may cease proximal displacement upon contacting the shelf **321**.

[0541] The top **306** may be at an intermediate point in its travel along the post **310** when the carriage **315** contacts the shelf **321**. As shown, the carriage **315** may include a second frangible **325** or set of frangibles **325**. In some embodiments, there may be three second frangibles **325** spaced at even angular intervals about the carriage **315**. The first frangible(s) **314** may be weaker (e.g. thinner) than the second frangible(s) **325**. Thus, the second frangible(s) **325** may only break after the first frangible(s) **314**. The projection **318** from the top **306** may abut the second frangible(s) **325** when the carriage **315** is against the stop provided by the shelf **321**. The second frangible(s) **325** may impede displacement of the top **306**. Further actuation of the top may exert force against the second frangible(s) **325** and result in breaking of the second frangible(s) **325**. With the second frangible(s) **325** broken, the top **306** may be free to move proximally while the carriage **315** remains stationary (against the stop provided by the shelf **321**). It would be understood by one of skill that once the frangible(s) **325** have broken, reuse of the delivery device **10** may be inhibited.

[0542] As shown, the delivery device **10** may also include a delivery aid **320**. The delivery aid **320** may be a flat plate from which a column extends, as shown in the example. The delivery aid **320** may be made of a plastic material formed by injection molding. One of skill would appreciate that other materials and manufacturing techniques could be used to construct the delivery aid **320**. The delivery aid **320** may be positioned atop a reservoir **12** that contains a fluid such as, e.g., a medical agent (e.g., a vaccine) and incorporates on an underside a sharp bearing body **26** (see, e.g., FIG. **34**) including at least one delivery sharp **72** (see, e.g., FIG. **34**).

[0543] In some embodiments, the delivery aid **320** may be attached to the proximal end of the projection **318** via adhesive. In some embodiments, the delivery aid **320** may rest upon a shelf within the carriage **315**. The reservoir **12** may be retained via friction or via a slip fit within an aperture of the carriage **315** as shown. In some examples, a weak adhesive may hold the reservoir **12** in place within the aperture. In other embodiments, the friction fit may be augmented by a gasket member (e.g. O-ring) disposed between the reservoir **12** sides and the aperture of the carriage **315**.

[0544] With the second frangible(s) **325** broken, the delivery aid **320** may concentrate force generated as the top **306** is actuated against a reservoir **12** of the delivery device **10**. In embodiments where the delivery aid **320** rests upon a shelf in the carriage **315** a portion of the delivery aid **320** may deform or break to allow movement beyond the shelf. The delivery aid **320** and reservoir **12** may move downward as the top **306** continues to advance along the post **310**. The force exerted by the top **306** may be sufficient to overcome friction or adhesive holding the reservoir **12** in place. The delivery aid **320** moving downward may cause the reservoir **12** to move downward until the delivery sharp(s) **72** (see, e.g., FIG. **34**) penetrate into the skin surface. At that point, as shown in FIG. **124**, the reservoir **12** may be sandwiched between the skin and the projection **318** of the top **306**. As the top **306** continues to displace proximally, pressure from the delivery aid **320** builds in the reservoir **12**, causing delivery of the fluid contained within the reservoir **12** through the delivery sharp(s) **72** and into the patient. At that point the top **306** stops twisting and may have reached the end of its displacement range. The top **306** may abut against the base body **309** at the end of the displacement range and the base body **309** may present a mechanical interference to further displacement. Once the top **306** stops moving, the user may remove the delivery device **10** from the skin.

[0545] As previously discussed, it may be desirable to prevent reuse of the delivery device **10**. It

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

[0546] With reference to FIGS. **127-129**, an example embodiment of such a portion of an actuation assembly **327** for a delivery device **10** is depicted. The delivery device **10** may comprise a one-piece or monolithically formed flexure. The flexure may be formed as a pair of first and second bodies **320**A, **320**B, vertically spaced such that the first body **320**A is positioned above or in a separate plane than the second body **320**B. In the example embodiment, the first and second bodies **320**A, B are concentric round bodies, and are specifically shown as circles. The flexure may be made of a bendable plastic formed by injection molding or any other suitable technique as would be known to one of skill. The bodies **320**A, **320**B may be coupled by at least two flexible struts **322** integral to the flexure. In the example, six such flexible struts **322** are shown but it would be understood that the number need not be six. The struts **322** may be disposed at even angular increments though need not be in all embodiments. The struts **322** may extend between the bodies **320**A, **320**B at an angle to the bodies **320**A, **320**B that is not perpendicular.

[0547] At least one hook **324**, integral to one of the bodies **320**A, B may be included. The other of the bodies **320**A, B may include at least one catch **326**. In the example embodiment, the first body **320**A includes a number of hooks **324** which extend downward therefrom toward the second body **320**B. Six such hooks **324** are shown but it would be understood that the number need not be six. In the example, the hooks **324** are evenly spaced around the first circle **320**A though need not necessarily be in all embodiments. At least one catch **326**, integral to the second body **320**B is also shown in the example embodiment. Each of the catches **326** is situated at a point on the second body **320**B that is not directly beneath a hook **324** of the first body **320**A. The example catches **326** extend upward from the second body **320**B toward the first body **320**A. Six such catches **326** are shown but it would be understood that the number need not be six. The catches **326** may be spaced around the second body **320**B at even angular increments. The catches **326** may be positioned such that the respective catches **326** and hooks **324** would engage one another upon actuation of the flexure. The flexure may, for example, be actuated by applying pressure on the flexure via a portion of the delivery device **10** within which it is assembled. The catches **326** may be substantially shaped in the form of an upside down Latin character “U”.

[0548] As the first body **320**A is displaced toward the second body **320**B at least one of the bodies **320**A, B may also rotate. If one of the bodies **320**A, B is rotationally constrained, only the other of the bodies **320**A, B may rotate as the bodies **320**A, B are displaced toward one another. With the second body **320**B rotationally constrained, pushing down on the first body **320**A from above may cause the flexible struts **322** to flex. The hooks **324** may rotationally (about an axis passing through the center points of the bodies **320**A, B) displace. The hooks **324** and first body **320**A may also translationally displace as the first body **320**A approaches the second body **320**B. The hooks may also translationally displace with respect to the catches **326** until the hooks **324** contact the catches **326**. The hooks **324** may deflect around the catches and then resiliently restore into engagement with the catches **326**. Thus, as the struts **322** attempt to resiliently restore to their undeflected state, the first and second bodies **320**A, B may be held together by the engagement of the hooks **324** and catches **326**. Using a single piece flexure (formed, for example, by injection molding) may allow the delivery device **10** to be manufactured at relatively lower cost. The hooks **324** engagement with

the catches **326** may also help to prevent reuse of a delivery device **10** in which the flexure is included. The engaged hooks **324** may also help maintain pressure against a reservoir **12** of a delivery device **10** needed to ensure delivery of a medical agent (e.g., a vaccine) into a patient through one or more delivery sharp **72** (see, e.g., FIG. **34**).

[0549] The rotational displacement of one of the bodies **320**A, B may be harness to help drive the delivery sharp(s) **72** (see, e.g., FIG. **34**) across the skin surface to scratch it prior to piercing the skin. In the example embodiment described above, the delivery sharp(s) **72** (see, e.g., FIG. **34**) may be constrained to move in tandem with the first body **320**A. Thus, the delivery sharp(s) **72** (see, e.g., FIG. **34**) would rotate as they are displaced against the skin.

[0550] Referring now to FIG. **130**, an example package **400** is depicted. The package **400** may house a delivery device **10** during distribution and shipping. The package **400** may also include other components such as printed instructions and/or a medical wipe which may be used for injection site preparation. The package **400** may hold the delivery device **10** and perhaps other contents in place during distribution and may help to prevent premature or inadvertent actuation of the delivery device **10**. The package **400** may include an interior cavity (a portion of the package **400** is depicted as transparent in FIG. **130**) which may have one or more receivers **402** for a delivery device **10**. The receivers **402** may constrain the delivery device **10** within the package **400** such that the delivery device **10** does not shift or jostle excessively during handling. The package **400** may also protect a delivery device **10** from exposure to the surrounding environment. In some embodiments, the package **400** and delivery device **10** may be sterilized (e.g. via EtOx) and the package **400** may maintain the delivery device **10** in this state until just prior to use.

[0551] The package **400** itself may be constructed of a first component **404** and a second component **406**. The first component **404** may be a rigid base. The rigid base may include a well in which a delivery device **10** (e.g. similar to that shown in FIG. **28**) may be housed. The rigid base may be a plastic component. The second component **406** may be a peelable cover which may be coupled to a face of the first component **404**. The peelable cover may be removed by a user to access the delivery device **10** just prior to use.

[0552] As shown, the package **400** may include at least one unique identifier **408**. In other embodiments, a unique identifier **408** may instead or additionally be included on a delivery device **10** or component thereof. Any suitable unique identifier(s) **408** and combinations thereof may be used. In some embodiments, an RFID may be used. In other examples, the unique identifier **408** may be implemented as a printed indicium such as a bar code, data matrix, QR code, etc. The unique identifier **408** may encode various information about the delivery device **10** or contents of the reservoir **12** of the delivery device **10**. For example, the unique identifier **408** may include product identity information, product lot information, product serial number, dose size information, etc. An alternative package **401** is depicted in FIGS. **26-27** and may also include a unique identifier **408** as described in relation to FIG. **130**.

[0553] The unique identifier **408** may be read by a reader **410**. The reader **410** may be a dedicated reader or a device such as, e.g., a smart phone, tablet, smart device, laptop, or other portable device in some embodiments. Where a smart phone or the like is utilized, a dedicated delivery device app may run on the smart phone. Where a smart phone or the like is used, the reader **410** may include multiple pieces of hardware which may be used to read a unique identifier **408** (e.g. one or more front facing imager and one or more rear facing imager). The reader **410** used may depend on whether the delivery device **10** is intended for use at home by an individual user or in a clinical setting (e.g. vaccination center, hospital, clinic, or other care facility). A smart phone may be convenient for a use as a reader **410** if delivery via the delivery device **10** is to be, for example, self-administered by a patient (e.g. at home).

[0554] The reader **410** may communicate with a database **412** (e.g. via internet, other network, cloud platform, etc.). Prior to use of the delivery device **10**, a user may read the unique identifier **408** with the reader **410**. The identifier **408** for the delivery device **10** may be checked against the

database **412** to ensure the unique identifier **408** is not associated with a delivery device **10** which has already been used, subject to recall, expired, etc. The database **412** may also be updated to indicate that the delivery device **10** associated with the unique identifier **408** has been used. Thus, the reader **410** and database **412** may aid in inventory management. Other usage information may also be saved. In some embodiments, geolocation data indicating the location of the package **400** when the unique identifier **408** is read may also be saved to the database **412**.

[0555] Depending on the infrastructure available, the data may be stored offline in a memory of the reader **410** until a robust connection to the internet or another suitable network is formed. Thereafter, data may be uploaded to the database **412**. Alternatively, data may be sent to the database **412** as it is acquired at the reader **410**.

[0556] In some embodiments, a patient may be required to pre-register in order to receive a delivery device **10**. In some embodiments, the reader **410** may be used to register (e.g. where an app on a smart phone is used). Where the reader **410** uses a smart phone app, the smart phone app may inhibit usage of the reader **410** for the delivery in the event that certain services are not enabled. Such an app may generate a unique identifier or code when predefined requisite services (e.g. location tracking, push notifications) have been enabled. This code may be provided to the database **412** and may be referred to as a registration code. A patient may be required to provide the code in order to receive a delivery device **10**. The code may be input to a dispenser or provided to distribution personnel and checked against the database **412**. A delivery device **10** may be provided to the patient in the event that the code matches a registration code stored on the database **412**. In other embodiments, the controller **416** of the reader **410** may generate a manual input screen to collect desired information in the event that the user elects not to enable one or more service or otherwise provide desired user information. For example, when location tracking is not enabled the app may generate a location data input screen. Input of information into any such screens may be required before a code is generated and provided to the database **412**.

[0557] In some embodiments, when the unique identifier **408** on the package **400** is read, a controller **416** of the reader **410** may generate instructions on a user interface **414** of the reader **410**. The instructions may include text, images, animations, videos, etc. detailing how to use the delivery device **10**. The instructions may guide a user, step-by-step, from opening of the package **400** to discarding of a delivery device **10** after use. In some embodiments, each step of the instructions set may be followed by generation, via the controller **416**, of a prompt on the user interface **414**. The user may be required to interact with the prompt to proceed to the next set of instructions. User interactions may be logged and stored in a database **412**. This may aid in confirming that a particular delivery device **10** was not only received by a patient, but also applied and used. In some embodiments, the controller **416** may generate a notification (e.g. visual, tactile, audio, or some combination thereof) in the event that not all steps have been completed. In other embodiments, one or more message may be generated in the event that a user is unresponsive to prompts. For example, where a smart phone or the like is used, the messages may be push notifications generated by the app for the delivery device **10**.

[0558] In other embodiments, at least one message generator **418** in data communication with the database **412** may generate, for instance, a text message, email, phone call (e.g. automated message or connect the user to a human operator) which may be sent to a telephone number or email address provided by the user. In the event that a delay greater than a predefined period of time has occurred since a previous prompt has been interacted with by the user, the message generator **418** may send a communication to the patient. The type of communication triggered may escalate if no response is received after a communication is sent by a message generator **418**. The communication may initially be a text message or push notification. In some embodiments, a push message may preferably be sent or may be sent instead of a text message in the event that cellular service is unacceptable or below a threshold. If no user interaction is received after a predefined escalation period, a message generator **418** may generate a more obtrusive communication (e.g. a phone call).

Any suitable number of escalation tiers may be used.
[0559] In some embodiments, a patient may also provide additional data via the reader **410**. This data may be stored in the database **412** and analyzed (e.g. via a cloud analytics tool or tool set). For example, users may indicate via the reader **410** that a problem with their delivery device **10** has occurred. This data may be checked against data associated with other delivery devices **10** from the same lot. If more than a predetermined threshold of problematic delivery devices **10** are deemed to exist within a lot, the lot may be flagged for investigation and prevented from being distributed or used. Alternatively or additionally, a patient may be prompted to provide certain post injection information via the reader **410**. For example, the patient may be requested to fill out a side-effect questionnaire or other form which may be generated by the controller **416** of the reader **410** on the user interface **414**. Side-effect data may be analyzed to identify patterns common to certain patient types or delivery devices **10** (e.g. delivery devices **10** of the same lot or holding the same contents). Analysis may be conducted via a cloud analytics tool or toolset.
[0560] In certain examples and referring now also to FIG. **131**, a delivery device **10** may include a revealing indicator **450** or identifier which may be hidden when the delivery device **10** is in a storage state. Upon or after use of such a delivery device **10**, the revealing indicator **450** may become accessible. The revealing indicator **450** may then be scanned by a reader **410** and confirmation of the scan or scan data captured during the scan may be sent to the database **412**. The revealing indicator **450** may encode a unique identifier (e.g. barcode, QR code, data matrix, etc.) specific to the delivery device **10** in certain examples. Thus, the revealing indicator **450** may serve as a confirmation that a delivery was performed with a specific delivery device **10**. In some examples, the database **412** or certain data within the database **412** may also be accessible via a payment provider (e.g. governmental body, insurer, etc.). In order to help ensure that the revealing identifier **450** is scanned to document delivery via a delivery device **10**, reimbursement or payment may be tied to scanning of the revealing identifier **450**. For example, a payment service may query the database **412** to determine usage status of a delivery device **10** and only allow payment in the event that a delivery device **10** has been used. Indication in the database **412** that the revealing indicator **450** has been scanned may flag a delivery device **10** as used.
[0561] Referring now to FIG. **131**, in some examples, a delivery device **10** may include a first portion and a second portion which may become disassociated when a user removes the delivery device **10** from the skin. In the example embodiment, a delivery device **10** including a main body **20** and a reservoir assembly **12** similar to that shown in FIG. **28** for instance is depicted. A revealing indicator **450** may also be included in other delivery device **10** embodiments described herein. In the example illustrated in FIG. **131**, the exemplary first portion is the reservoir assembly **12** (see, e.g., FIG. **74**) and the exemplary second portion is the main body **20**. In such an example, a revealing indicator **450** may be placed on a distal side of the reservoir assembly **12**. View of the revealing indicator **450** may be obstructed by the main body **20** when the first and second portion are coupled together (the main body **20** may be opaque or at least sufficiently translucent). As shown, when the main body **20** and reservoir assembly **12** become disassociated, the revealing indicator **450** may become visible and may be scanned to aid in confirming that that delivery device **10** has been used.
[0562] In some examples, the holder **270** (see, e.g., FIGS. **54**A-**54**D and FIGS. **55**A-**55**C) of the reservoir assembly **12** may include an adhesive on at least a portion of the proximal face of the holder **270**. In various embodiments where the of the holder **270** reservoir assembly **12** includes tabs **277** (see, e.g., FIG. **55**B) which couple into slits of the main body **20**, the tabs **277** may disengage with the slits **278** (see, e.g., FIG. **48**) of the main body **20** when the user attempts to remove the delivery device **10** from the skin. The bond between the adhesive on the holder **270** and the skin may be sufficient to overcome or disengage the coupling between the tabs **277** and the main body **20** when the patient pulls on the main body **20** to remove the delivery device **10**. That is, the adhesive may withstand any forces applied to disassociate the main body **20** from the rest of the

delivery device **10** when a user pulls on the main body **20**. Thus, the reservoir portion **12** may remain adhered to the skin and the main body **20** may be removed. The revealing indicator **450** included on the reservoir **12** may become visible and may be scanned by a reader **410** (see, e.g., FIG. **130**). The reservoir assembly **12** may then be peeled off the skin by the patient. In examples where the reservoir assembly **12** is adhered to the main body **20**, an adhesive connection between the skin and reservoir assembly **12** may be stronger than the adhesive connection between the reservoir assembly **12** and main body **20**. Thus, as a patient pulls on the main body **20**, the main body **20** may decouple from the reservoir assembly **12** to reveal the revealing indicator **450**.

[0563] In other embodiments, and referring now to FIG. **132**, a delivery device **10** may provide a mark **510** on the skin when the delivery device **10** is applied or applied for at least a predetermined period of time. In some embodiments, a marking agent such as an ink or the like may be included on a portion of the delivery device **10** adjacent the skin **512**. In certain examples, a rocker member **526** (see, e.g., FIGS. **89**A-**90**B) may, for example, bear a marking agent. Alternatively, the marking agent may be manufactured into a skin compatible adhesive for coupling the delivery device **10** to the skin during use. In examples where pressure sensitive adhesive is used, pressure applied when the delivery device **10** is used may activate the adhesive and also release the marking agent. The marking agent may at least partially transfer to the skin **512** or otherwise mark the skin **512** when the delivery device **10** is applied. Alternatively, the delivery device **10** may apply a temporary tattoo over the course of the injection. In still other embodiments, no marking agent may be included and the mark **510** may be a temporary impression left on the skin due to a portion of a delivery device **10** pressing against the skin during delivery (further described in relation to FIGS. **89**A-**90**B). In some embodiments, the mark **510** created may have a pattern which encodes certain information about the delivery device **10**. In the example embodiment, a series of “X”'s are shown though any suitable mark **510** may be produced. As indicated by the injection bleb **514**, the mark **510** may become visible after the injection is completed and the delivery device **10** is removed from the skin **512**.

[0564] When the delivery device **10** is removed, the mark **510** left on the skin **512** may be imaged by a reader **410** (see, e.g., FIG. **130**). This mark **510** may help to verify that an injection has been administered to a patient by a delivery device **10**. In some embodiments, the controller **416** (see, e.g., FIG. **130**) of the reader **410** may analyze the image to determine whether the mark **510** is present. When the controller **416** determines an appropriate mark **510** is present, the database **412** (see, e.g., FIG. **130**) may then be updated to indicate that the delivery device **10** associated with the previously scanned unique identifier **408** has been used. Additionally, the mark **510** may be of a known size and may be in a known position relative to other components (e.g. any delivery sharp(s) **72** of a delivery device **10**. Thus, the mark **510** may serve as a fiducial reference which may facilitate various image analysis via a controller **416**. For example, the mark **510** may be used to ensure other identified features in an image (e.g. an injection bleb) correspond to an expected range of positions and/or sizes using the mark **510** as a reference. It should be understood that in embodiments mentioned herein where the controller **416** is described as performing image analysis or other analysis, this need not be the case. For example, the image may be communicated to the database **412** by the reader **410** and a cloud analytics tool may be utilized to verify that the image indicates a delivery has occurred. Regardless of where analysis is performed, the image may be uploaded to the database **412**.

[0565] Referring now primarily to FIG. **133**, in certain embodiments the reader **410** (see, e.g., FIG. **130**) may include at least one image sensor which is sensitive to one or more wavelength(s) outside of the visible spectrum. The non-visible spectrum wavelength or spectrum to which the image sensor is sensitive may be a wavelength which has a higher penetration depth into skin than light in the visible spectrum. The reader **410** may include at least one image sensor which is sensitive to various wavelengths in the infrared spectrum (e.g. near infrared). A CCD or CMOS image sensor may be included in various embodiments. Any such capable sensor in the reader **410** may not

include an IR filter (e.g. IR blocking film) which is commonly applied to typical consumer imaging equipment. The sensor may be associated with a filter which blocks visible light. In some embodiments, the imager may be a thermographic or thermal imaging imager. Multiple imagers which capture images in different non-visible spectrums may be included (e.g. at least one for near infrared and at least one for longer infrared wavelengths).

[0566] After a delivery device **10** has been used, the reader **410** may be used to capture at least one image of the injection site. At least one image may be captured or generated based on light other than that in the visible spectrum. Image data in the visible spectrum may also be captured in some embodiments. A controller **416** (see, e.g., FIG. **130**) of the reader **410** (see, e.g., FIG. **130**) may generate a prompt (e.g. within an app) to capture the image(s). In certain embodiments, the controller **416** may also automatically open an image capture program. The controller **416** may enable image capture with an appropriate imager of the reader **410** (e.g. if multiple imagers are included in a reader **410**).

[0567] The image data may be analyzed to determine the presence of a bleb **514** formed within the skin during the delivery. Analysis may be automated or may be conducted by a human operator viewing images via a network connection to a database **412** (see, e.g., FIG. **130**). As light outside of the visible spectrum may have greater penetration into the skin, the use of such light for imaging purposes may make certain subsurface features in the skin discernable or more easily discernable. This may help to, for example, facilitate detection of the bleb **514**. Additionally, the injected agent may differ in temperature from the patient. An area with a temperature that differs from the surrounding area on the patient may be discernable. The injection site may, for example, be cooler than the surrounding regions of the patient. FIG. **133**, for instance, depicts a thermal image of an arm after injection. As shown, a cool region (darker gray) is discernable in the image and corresponds to the location of a bleb **514** on the skin.

[0568] In the event that the image(s) contain characteristics of a bleb **514**, it may be concluded that a delivery was actually performed with the delivery device **10** and was successful. In some embodiments, the image(s) may be required to comply with at least one predefined characteristic of interest. For example, in certain implementations, it may be required that a bleb **514** is detected and is of a certain size (e.g. in relation to a marking **510**). Additionally, the image(s) may be required to be devoid of characteristics indicative of an improper injection. For example, where a thermal imager is used, a cool region corresponding to a bleb **514** with one or more adjacent cool region or a cool region **514** or a size beyond a certain limit may be flagged as having characteristics of a leak. In such an example, the analysis may indicate an unsuccessful delivery from a delivery device **10**.

[0569] The analysis may be performed by the controller **416** (see, e.g., FIG. **130**) of the reader **410** (see, e.g., FIG. **130**). Alternatively, the analysis may be conducted on a networked server such as a cloud server. As mentioned above, human analysis may be used. The outcome of the analysis and optionally the image(s) may be provided to and stored on at least one database **412** (see, e.g., FIG. **130**). In the event that the image(s) indicate an improper delivery or no delivery, a notification for the user may be generated for display on the reader **410** (e.g. by the controller **416** see, e.g., FIG. **130**). In the event that a proper delivery has been documented, a confirmation may be generated that the injection was successful.

[0570] In examples where the reader **410** is a smart phone, any app used may generate a confirmation that injection with a delivery device **10** was performed upon request by a user. The controller **416** of the reader **410** may generate an option (e.g. displayed button) which may be interacted with by the user to display a conformation notice regarding the injection. Where a delivery device **10** is used to perform a vaccination, the app may provide a proof of vaccination or virtual vaccination record or card which is automatically populated with various information about the user's vaccination. The vaccination record may be stored in a memory of the reader **410** or may be stored in a database **412** (see, e.g., FIG. **130**) accessible via the reader **410** (or stored in multiple locations). Thus, the reader **410** may be used to provide proof of injection if necessary. For

example, the reader **410** could be used to prove vaccination in order to access certain spaces (restaurants, stadiums, workplaces, other venues, airplanes or airports, ships, public transportation, etc.).

[0571] In still other embodiments, a container **350** which houses a packet **208** may be included in a delivery device **10** as described elsewhere herein (see, e.g., FIG. **12**). One of the packet **208** and container **250** may include a first chemical or chemicals while the other may include a second chemical or chemical. A dye or dyes may also be included in one of the container **350** and packet **208**. When pressure is applied to the delivery device **10** to shift the delivery device from the storage state to the delivery state, the packet **208** may rupture and the first and second chemicals may mix. The chemicals may react and produce a visually perceptible effect. A chemiluminescent reaction may, for example, be initiated when the first and second chemicals are mixed. In examples of such embodiments, chemicals commonly used in glow sticks may, for instance, be filled into the container **350** and packet **208**.

[0572] The delivery device **10** may include one or more window (e.g. slots **254** or apertures **255** in a main body **20** like the example shown in FIGS. **22**A-**221**) through which light generated by the reaction may be perceived. A reader **410** (see, e.g., FIG. **130**) may image the delivery device **10** as it is injecting and a controller **416** (see, e.g., FIG. **130**) may analyze the image(s) to verify presence of the light from the reaction. When the controller **416** determines that a chemiluminescent reaction is documented in the image(s), the controller **416** may communicate with the database **412** and the database **412** may be updated to indicate the delivery device **10** has been used.

[0573] In some alternative embodiments where two (or more) chemicals are combined to produce a visibly perceptible effect, the first chemical or chemicals may be included in the medical wipe. The user may wipe the injection site during preparation and some of the first chemical or chemicals may be deposited on the skin surface. The second chemical or chemicals may be carried by or released by the delivery device **10** during the course of the injection. The first and second chemicals may interact by the time the injection has completed and may, for instance, result in a color change to a delivery indicating color. An image of the injection site may be taken by the reader **410** and analyzed (e.g. locally by the controller **416** or via a cloud analytic tool after the image is uploaded to the database **412**) to confirm presence of the delivery indicating color. In the event that the color change is documented in the image, the database **412** may be updated to indicate that the delivery device **10** has been used.

[0574] The delivery devices **10** shown and described herein may be modified to include features of the delivery device **10** shown or described herein. The sharp bearing bodies **26** or delivery sharps **72** of any delivery devices or reservoirs **12** described or shown herein may be substituted with any others shown or described herein. Any of the petal members **42** shown and described in herein may be used in any of the delivery devices **10** of the present disclosure. The delivery devices **10** shown and described herein may be modified to utilize any of the various reservoirs **12** shown and described herein. Portions of reservoirs **12** described herein may be interchanged with the corresponding components of other reservoirs **12** shown or described herein. The delivery devices **10** described herein may be modified to use any of the example bias members shown or described herein.

[0575] 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.

[0576] 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.

[0577] 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.

[0578] 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 delivery device for delivery of medical agent to a biological barrier comprising: a rigid guide body having a plurality of petal members extending outwardly from a first end thereof and a sloped guide track partitioned into an upstream portion and downstream portion by an interrupt channel; a reservoir including at least one delivery sharp coupled to the rigid guide body; a plunger partially disposed in the guide track; a bias member intermediate the plunger and a wall at a second end of the rigid guide body the bias member exerting a force compelling the plunger along the guide track when in a distorted state; a trigger body with a first barrier projection, the first barrier projection presenting an interference to displacement of the plunger along the guide track when the trigger body is in a blocking position and disposed within the interrupt channel with a track completing surface aligned with the upstream and downstream portion in when the trigger body is in a trigger position; and a deformable spacer having a first state in which the trigger body is held in the blocking position, the deformable spacer transitioning to a deformed state upon displacement of the trigger body to the trigger position.

**2**. The delivery device of claim 1, wherein the sloped guide track includes a ledge on the interior sidewall of the rigid guide body and a terminal channel, the terminal channel disposed in the downstream portion of the guide track.

**3**. (canceled)

**4**. The delivery device of claim 2, wherein the trigger body includes a second barrier projection, the second barrier projection being disposed within the terminal channel when the trigger body is in the trigger position and in an unobstructing position relative to the terminal channel when the trigger body is in the blocking position.

**5**. The delivery device of claim 1, wherein the deformable spacer is selected from a list consisting of, an additional bias member, a spring, and a flexure of the trigger body which extends from a portion of the trigger body toward the second end of the rigid guide body.

**6**. (canceled)

**7**. The delivery device of claim 1, wherein each of the at least one delivery sharp is a microneedle, each of the at least one delivery sharp extending from a sharp bearing body having a stepped side

wall.
**8**. The delivery device of claim 1, wherein the delivery device further comprises an adhesive coupled to the petal members.
**9**. The delivery device of claim 1, wherein the reservoir includes a displaceable wall defining a portion of a main interior volume of the reservoir, the plunger out of contact with the displaceable wall when the portion of the plunger disposed in the guide track is in the upstream portion of the guide track.
**10**. The delivery device of claim 1, wherein the reservoir includes a septum disposed in a protruding body which extends outwardly from a periphery of the reservoir.
**11-22**. (canceled)
**23**. A delivery device for delivery of medical agent to a biological barrier comprising: a petal bearing main body having a set of guides each having an upstream portion and downstream portion; a reservoir including at least one delivery sharp; a plunger having a set of plunger protrusions each disposed in a respective guide, the plunger biased by a first bias member from a first position in which the protrusions are disposed at the upstream portions toward a second position in which the protrusions are disposed at the downstream portions; and a trigger body with a first set of barriers, the trigger body displaceable between a blocking position in which the first set of barriers obstruct displacement of the protrusions between the upstream and downstream sections of the respective guides and a trigger position in which the first set of barriers are in a stowed state.
**24**. The delivery device of claim 23, wherein each of the at least one delivery sharp is a microneedle.
**25**. The delivery device of claim 23, wherein the delivery device further comprises a spacer between the main body and the trigger body.
**26-29**. (canceled)
**30**. The delivery device of claim 23, wherein the petal bearing main body comprises a plurality of petal members, the petal members displacing from a relaxed position to a spreadingly displaced position when a threshold petal spreading force is applied.
**31**. The delivery device of claim 30, wherein the delivery device further comprises a spacer intermediate the trigger body and main body, the trigger body displacing from the blocking position to the trigger position and deforming the spacer upon application of a threshold deforming force which is greater than the threshold petal spreading force.
**32**. The delivery device of claim 23, wherein the trigger body is biased to the blocking position by a second bias member.
**33**. The delivery device of claim 23, wherein the trigger body includes a second set of barriers which obstruct travel of the protrusions to a respective terminal region of each of the downstream portions when the trigger body is in the trigger position.
**34**. The delivery device of claim 23, wherein the reservoir includes a displaceable wall defining a portion of a main interior volume of the reservoir, the plunger out of contact with the displaceable wall when the protrusions are disposed at the upstream portion of the respective guides.
**35-45**. (canceled)
**46**. A method of expelling an agent from a delivery device comprising; applying the delivery device to a barrier; generating a spreading displacement of petal members of a main body of the delivery device by exerting a first threshold force on a trigger body of the delivery device; displacing the trigger body toward the main body to a trigger position by exerting a second threshold force greater than the first on the trigger body; displacing at least one first barrier of the trigger body from an obstructing position to a stowed position; expelling the agent from a reservoir of the delivery device by collapsing the reservoir with a spring biased plunger after each of the at least one first barrier has been displaced to the stowed position; and guiding displacement of the spring biased plunger with at least one guide track.

**47**. The method of claim 46, wherein applying the delivery device to the barrier comprises adhering at least the petal members of the delivery device to the barrier.
**48**. The method of claim 46, wherein the method further comprises preventing displacement of the trigger body to the trigger position with a deformable spacer when the first threshold force is exerted on the trigger body.
**49**. (canceled)
**50**. The method of claim 46, wherein, displacing the at least one first barrier from the obstructing position to the stowed position comprises driving each of the at least one first barrier into an interrupt channel of a respective guide track.
**51**. (canceled)
**52**. The method of claim 46, wherein each of the at least one guide track is a cam track and guiding the displacement of the spring bias plunger comprises engendering rotation of the plunger as the advances along the at least one guide track.
**53**. The method of claim 46, wherein the method further comprises displacing at least one second barrier from a retracted position to a guide track terminus obstructing position as the trigger body is displaced to the trigger position, each of the at least one second barrier blocking a terminal end of a respective one of the at least one guide track in the guide track terminus obstructing position.
**54**. The method of claim 53, wherein the method further comprises displacing the plunger into contact with the at least one second barrier.
**55**. The method of claim 54, wherein the method further comprises ceasing exertion of force on the trigger body after the trigger body is in the trigger position and driving the trigger body away from the main body via a bias member until the at least one second barrier is returned to the retracted position and the method further comprises displacing the plunger to an end of a displacement range of the plunger.
**56-64**. (canceled)
**65**. A rigid reservoir portion of a medical agent administration device comprising: a proximal face; a distal face opposite the proximal face; a sharp bearing body comprising: a sharp bearing face with at least one delivery sharp projecting therefrom; a sharp free face opposite the sharp bearing face; and at least one lumen, each of the at least one lumen extending through a respective one of the at least one delivery sharp to the sharp free face; a receptacle located on one of the proximal and distal face of the rigid reservoir portion, the sharp bearing body seated in the receptacle with a portion of the at least one delivery sharp protruding beyond the proximal face of the rigid reservoir portion; and a bead of a swaged material circumscribing and at least partially overlaying a peripheral portion of the sharp bearing body.
**66-145**. (canceled)