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(54) **DELIVERY DEVICE APPARATUSES,  
SYSTEMS, AND METHODS**

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Simpson**, Chester, NH (US); **Daniel B.  
Finnegan**, Barrington, NH (US); **Lee A.  
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Johnson**, Salem, NH (US)

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9, 2024, provisional application No. 63/551,628, filed  
on Feb. 9, 2024, provisional application No. 63/686,  
325, filed on Aug. 23, 2024, provisional application  
No. 63/686,316, filed on Aug. 23, 2024, provisional  
application No. 63/727,877, filed on Dec. 4, 2024.

**Publication Classification**

(51) **Int. Cl.**

**A61M 37/00** (2006.01)

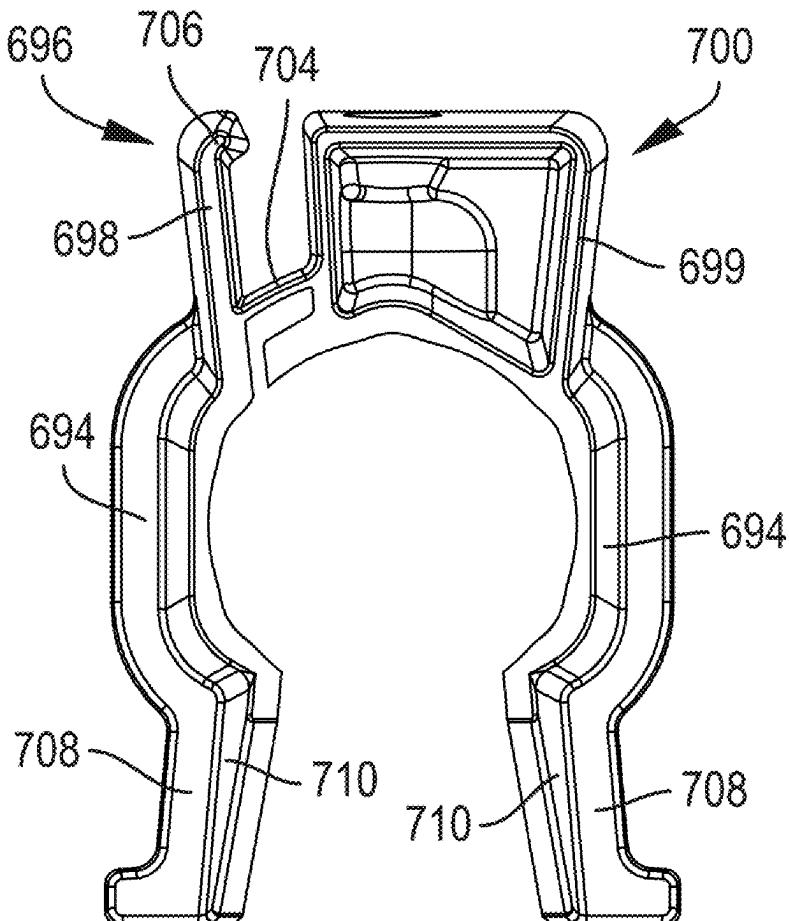
(52) **U.S. Cl.**

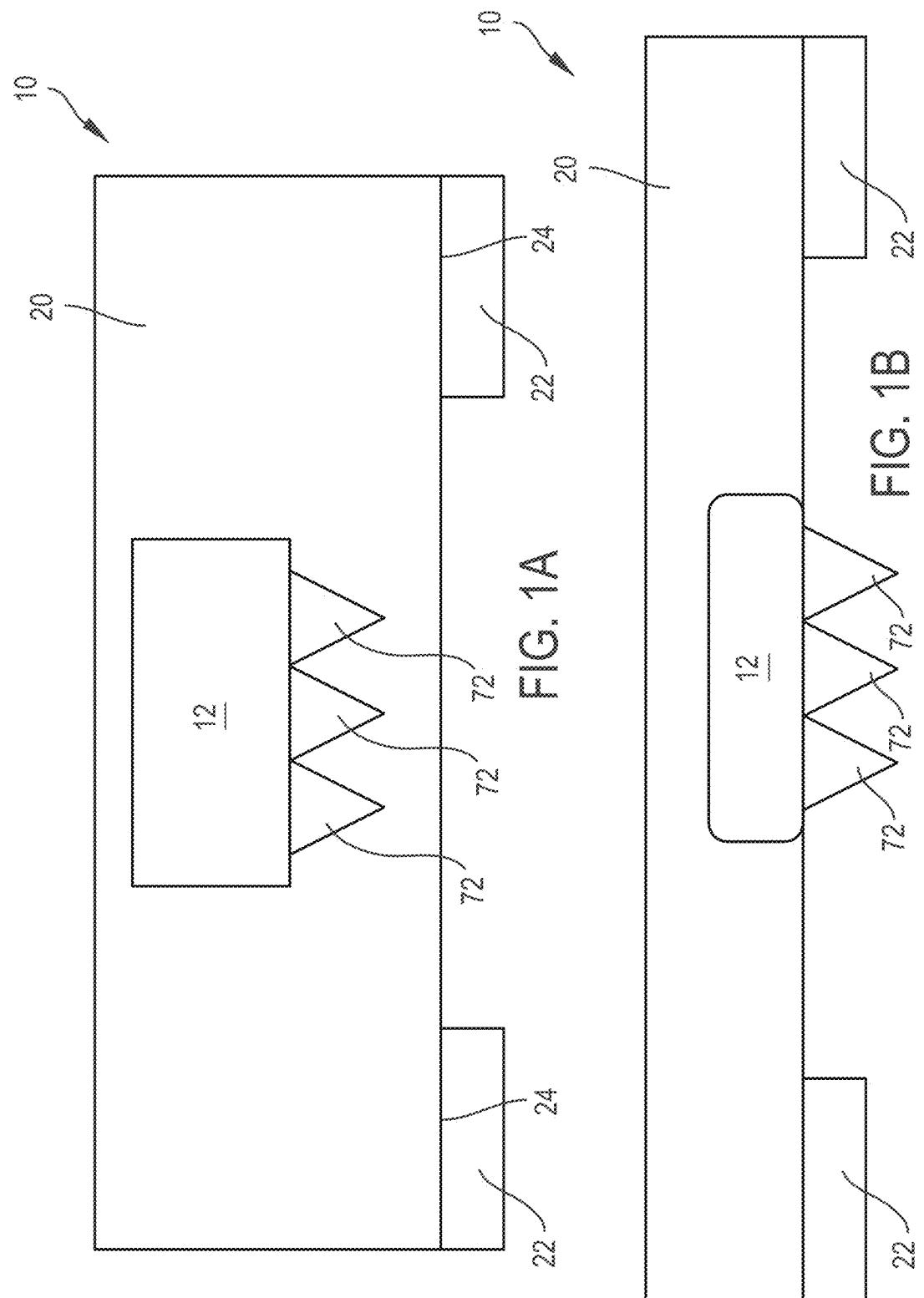
CPC . **A61M 37/0015** (2013.01); **A61M 2037/0023**  
(2013.01); **A61M 2202/0007** (2013.01); **A61M  
2205/0216** (2013.01); **A61M 2207/10**  
(2013.01)

(57)

**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.





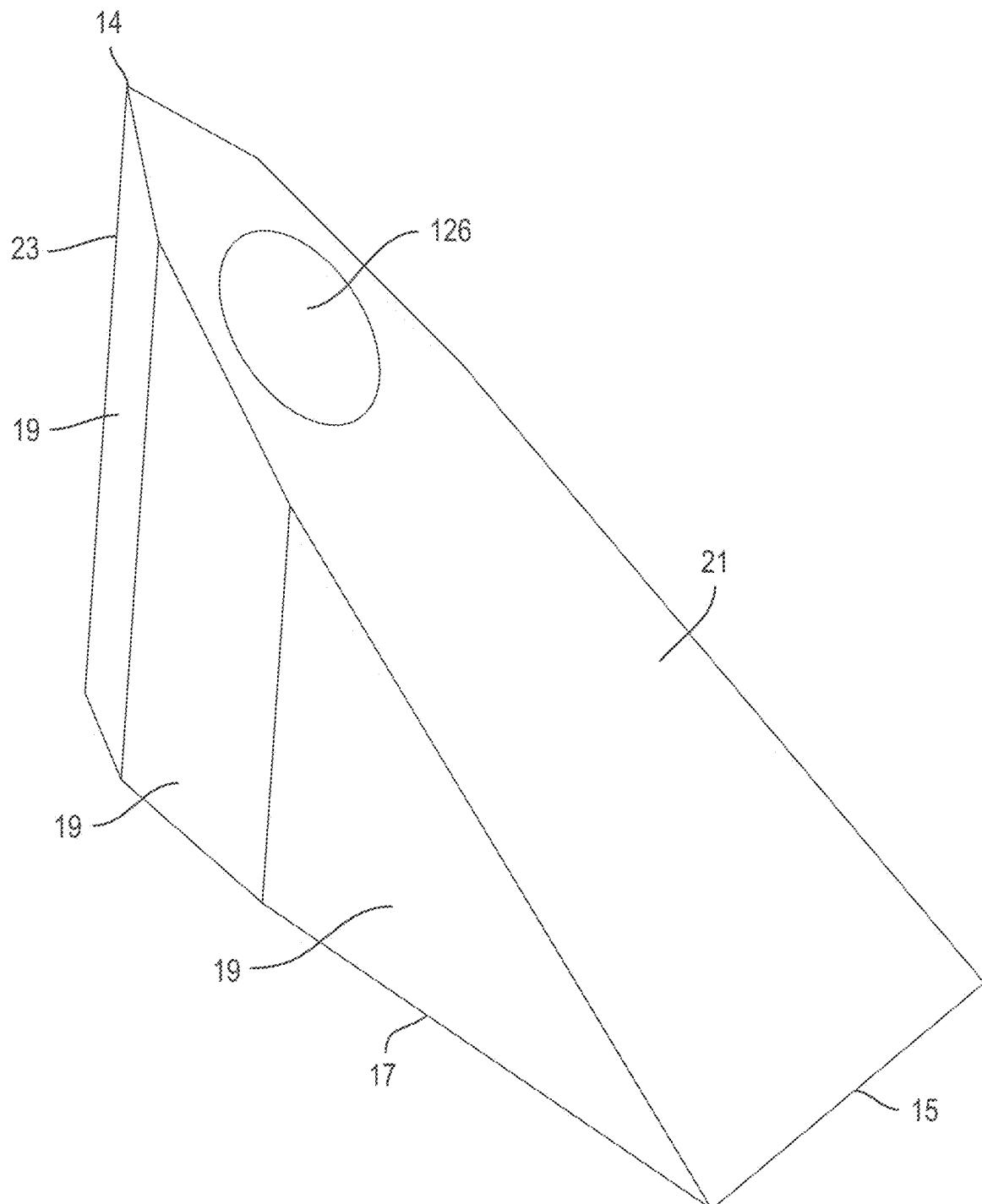


FIG. 2

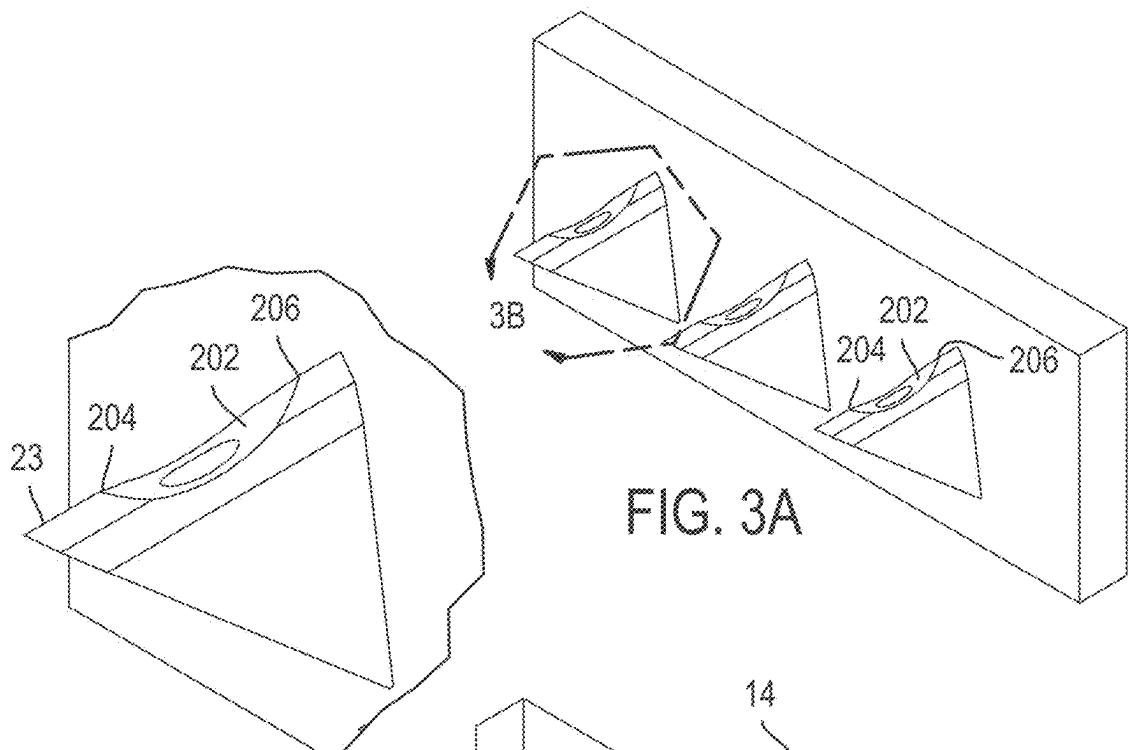


FIG. 3B

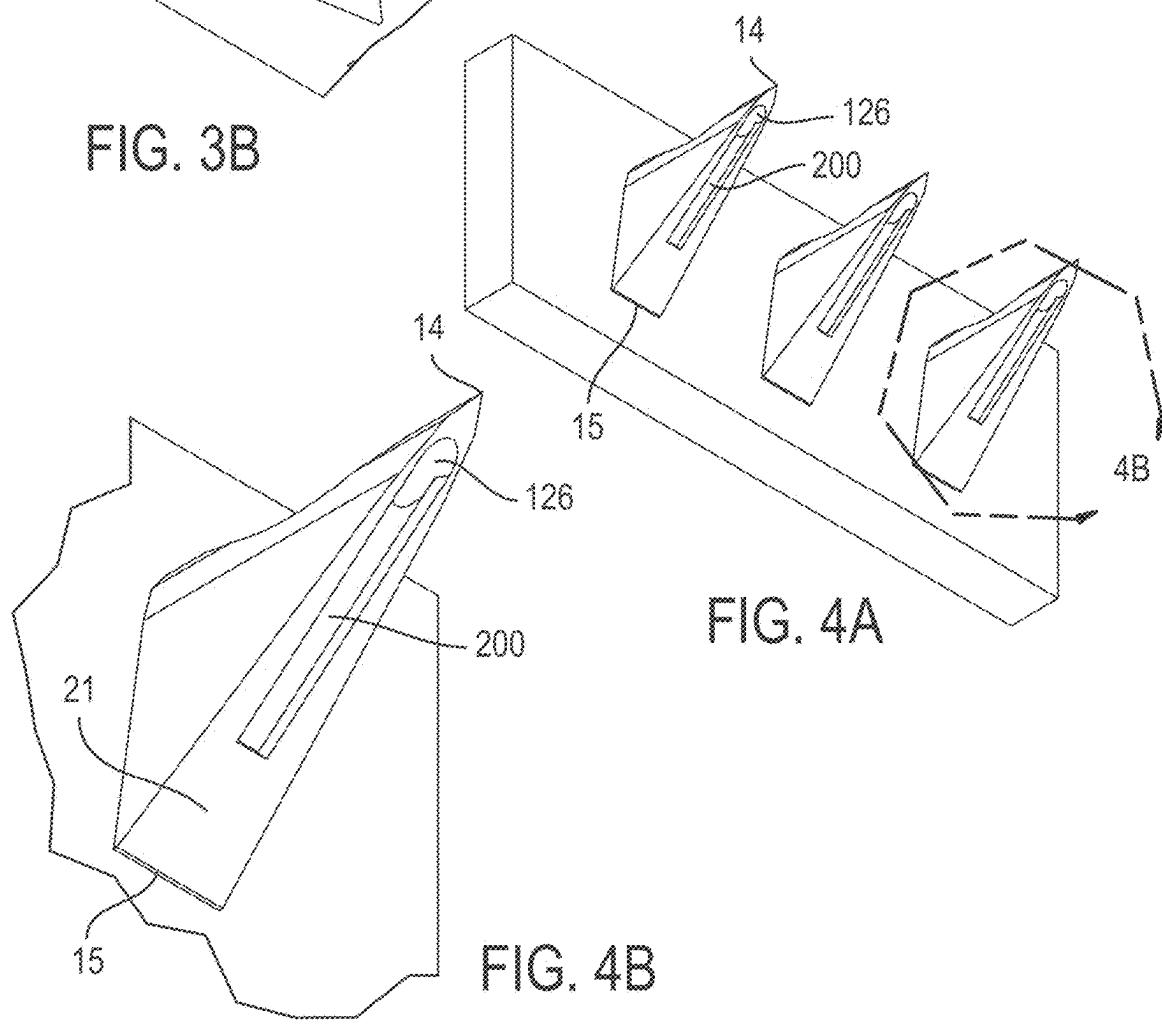
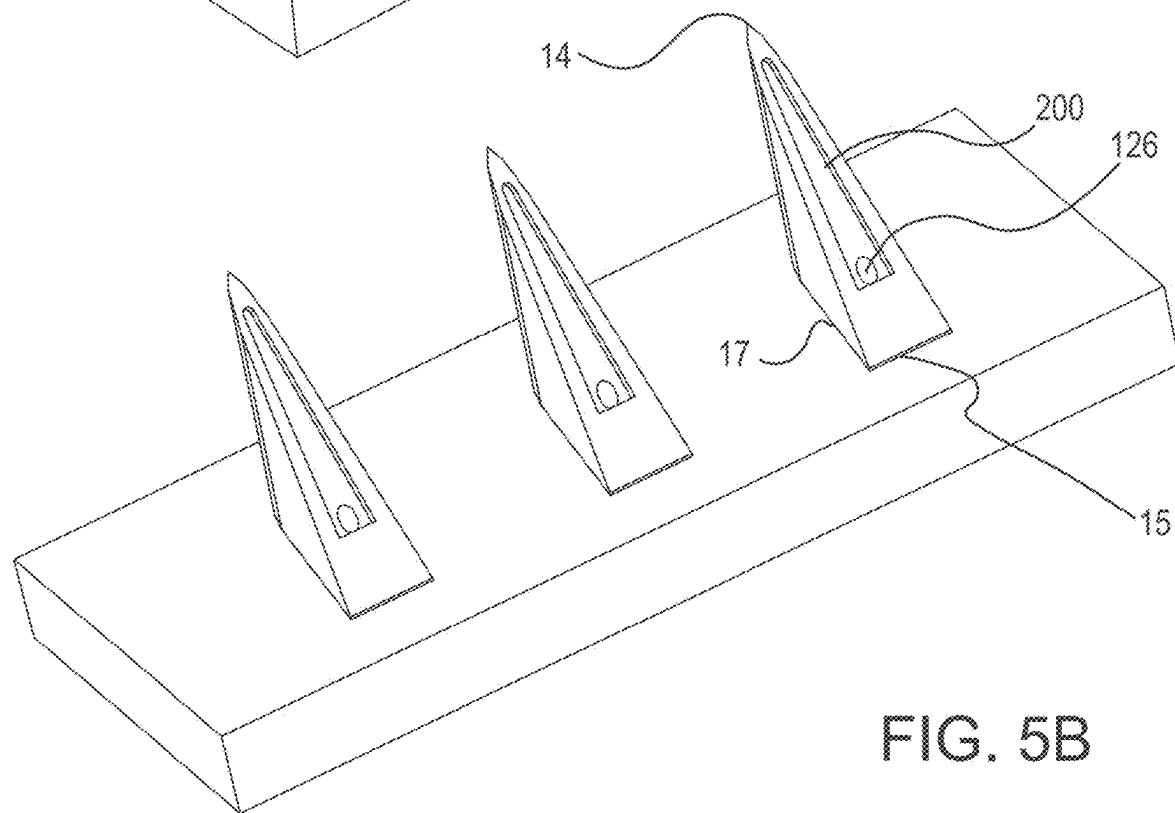
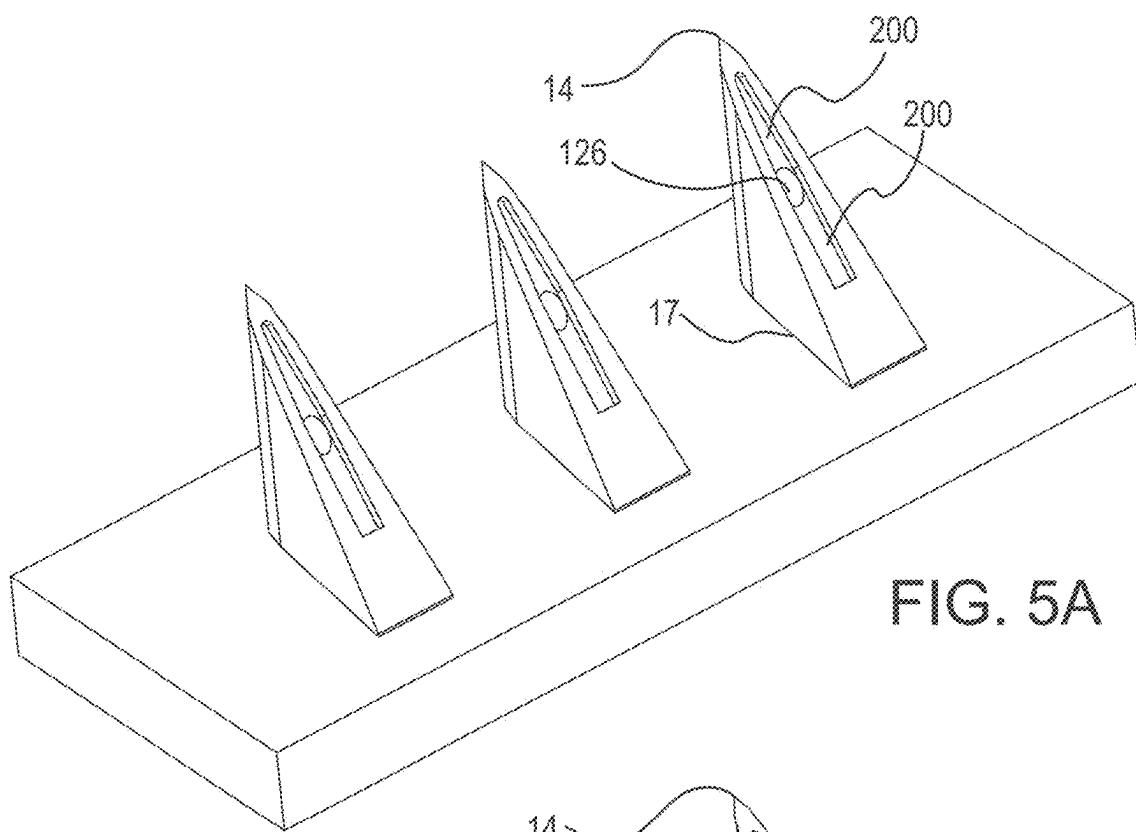


FIG. 4A

FIG. 4B



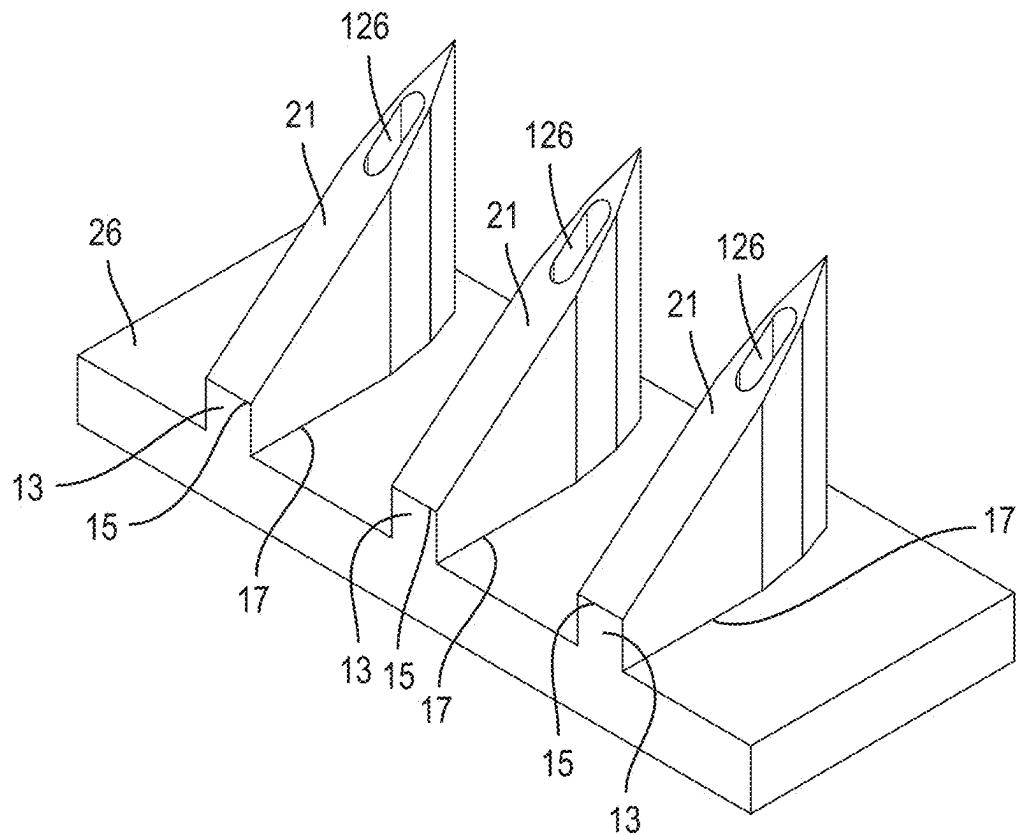


FIG. 6A

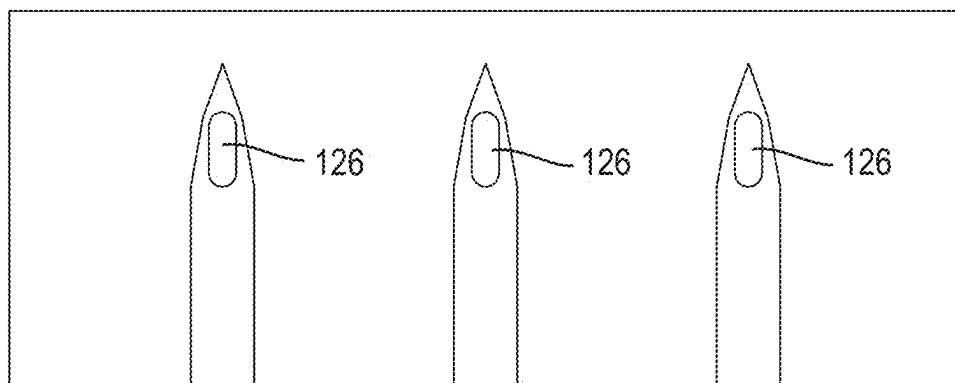


FIG. 6B

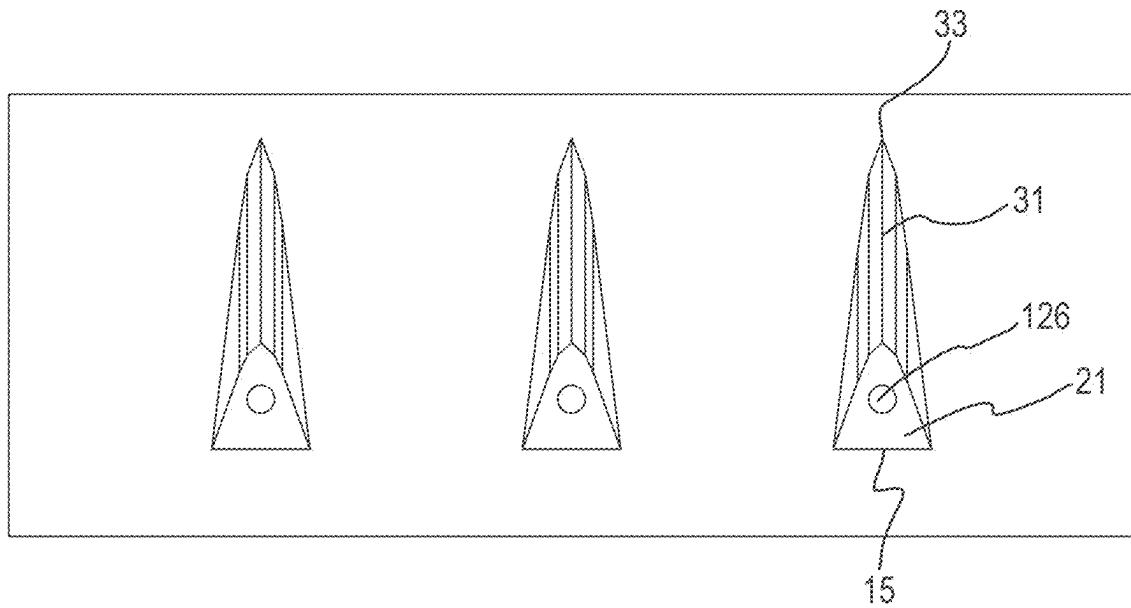


FIG. 7A

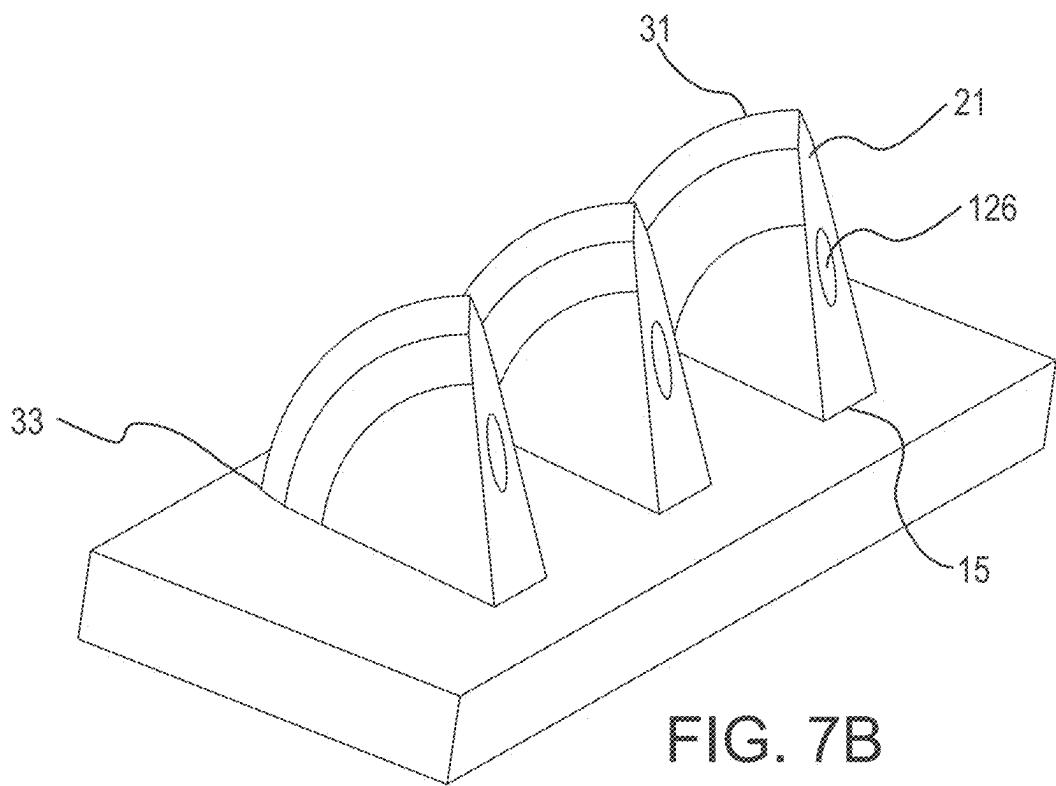


FIG. 7B

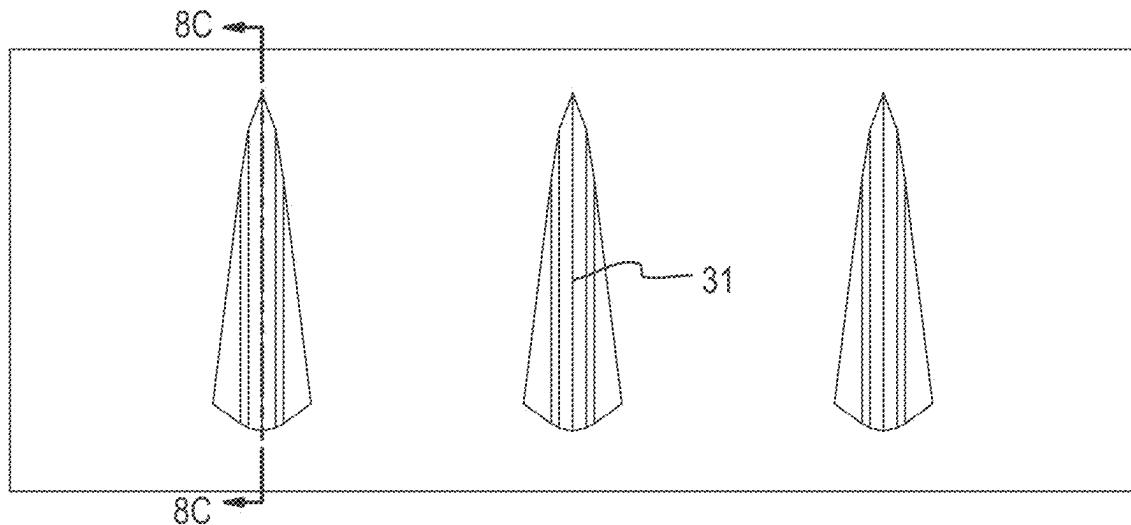


FIG. 8A

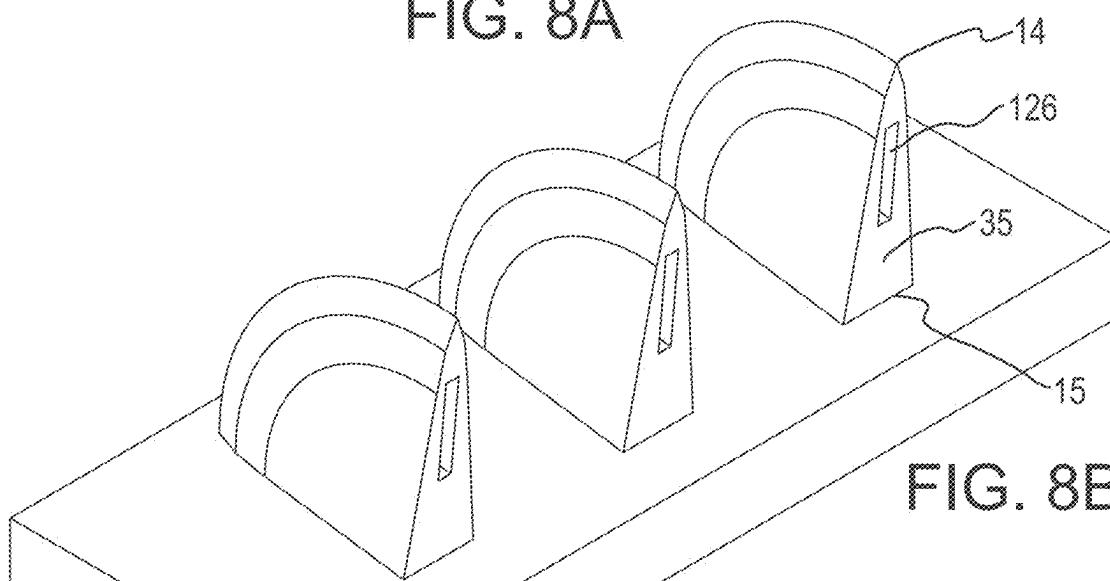


FIG. 8B

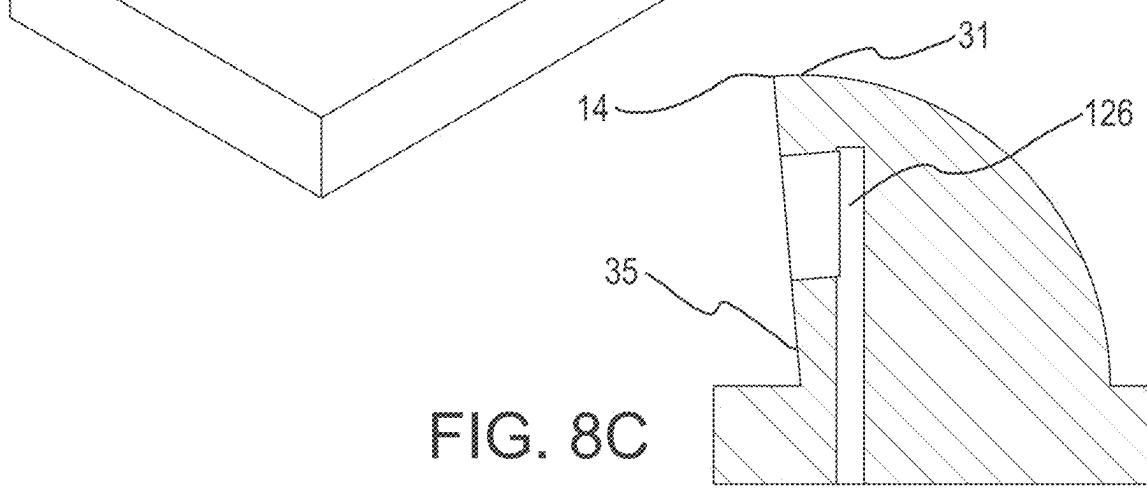


FIG. 8C

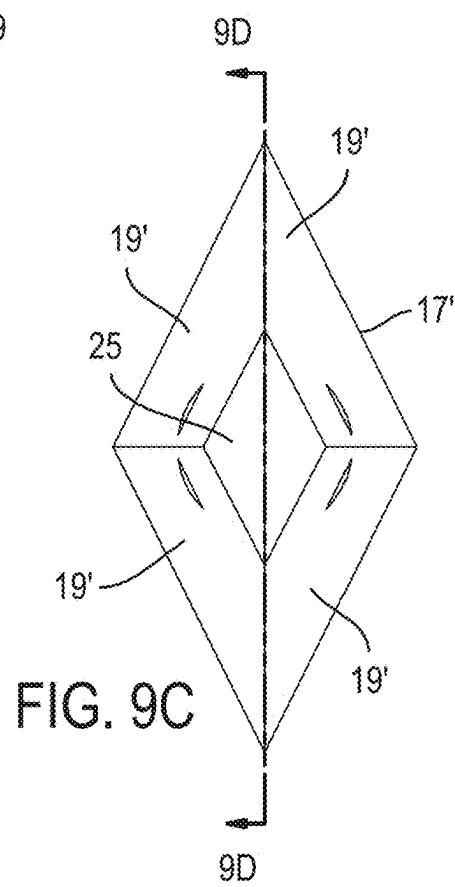
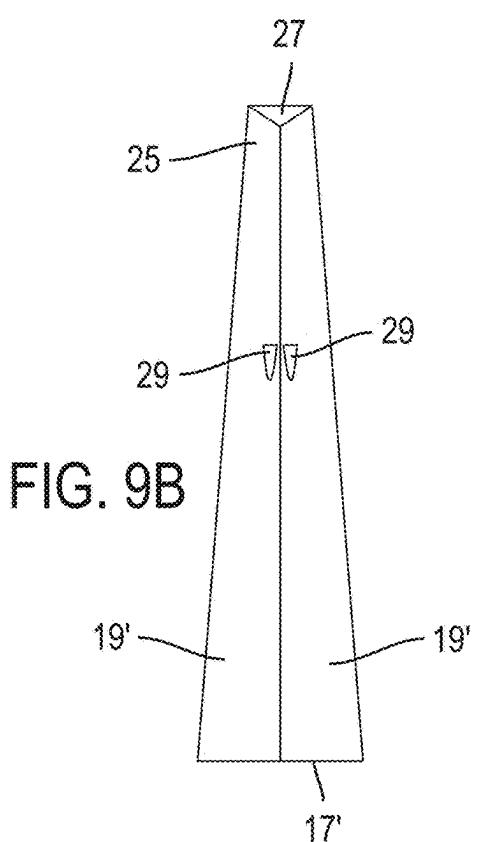
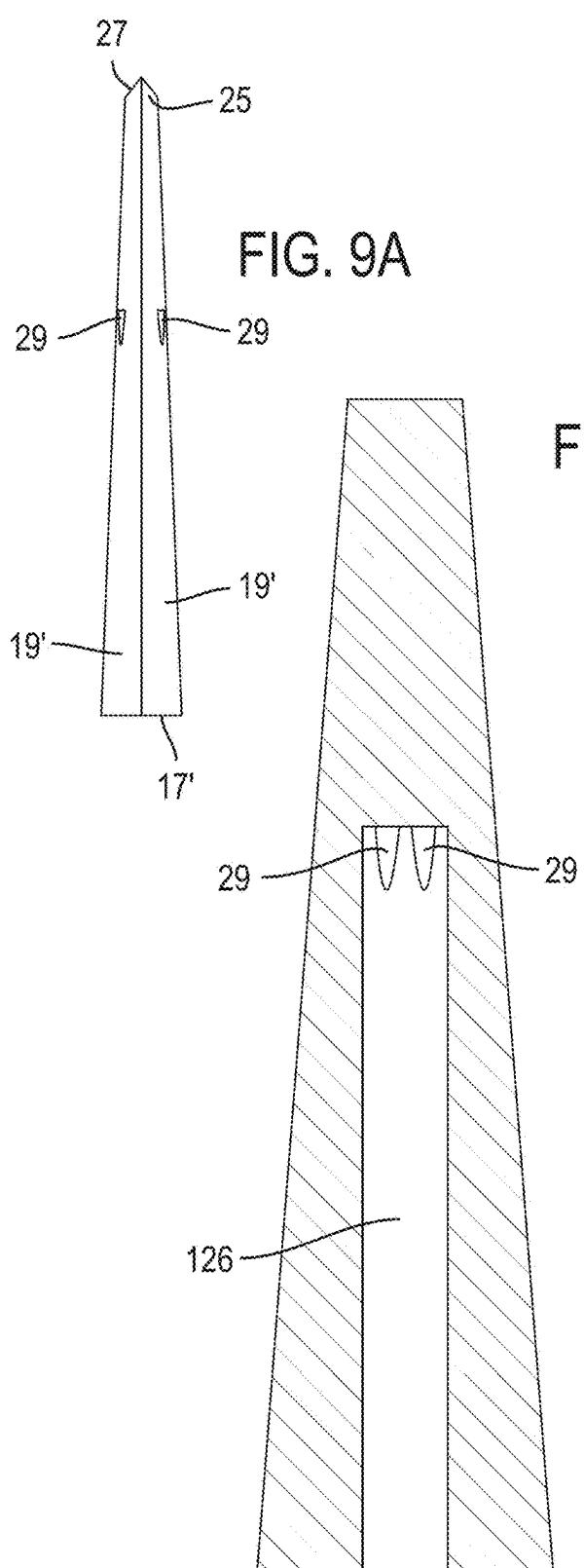
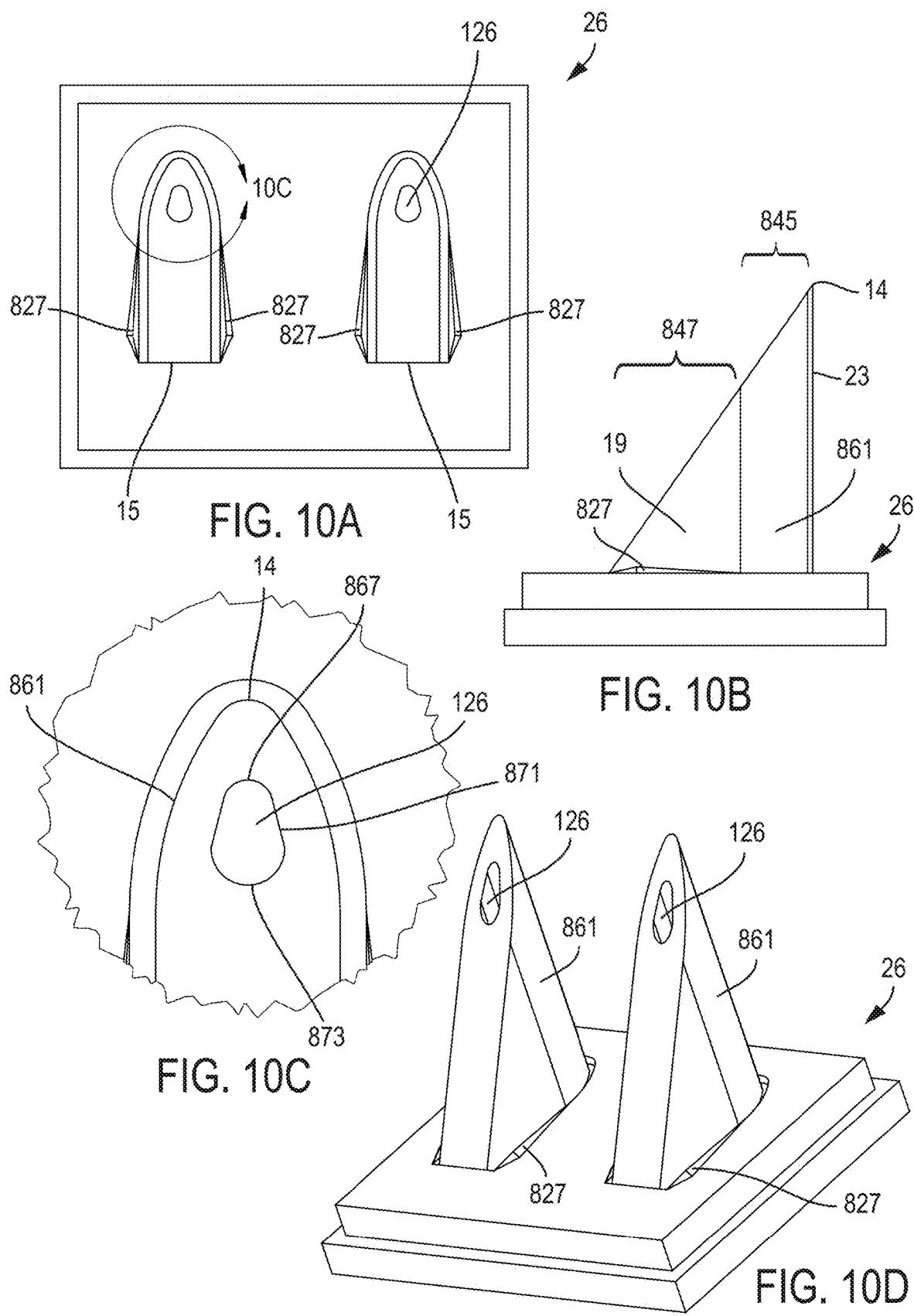
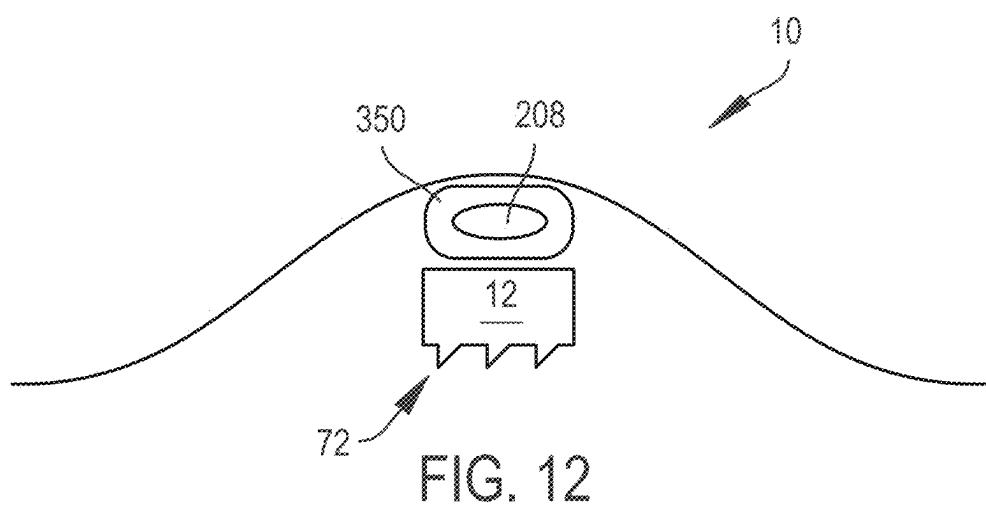
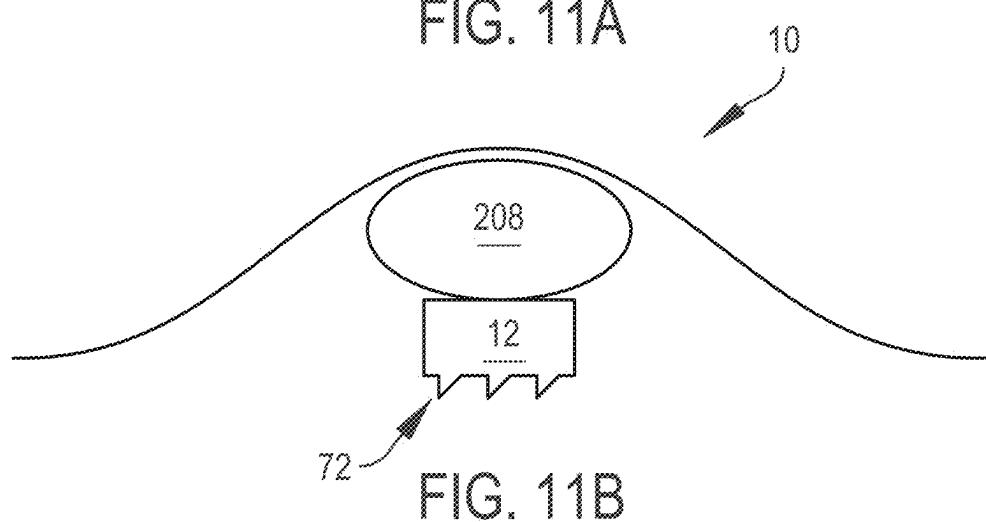
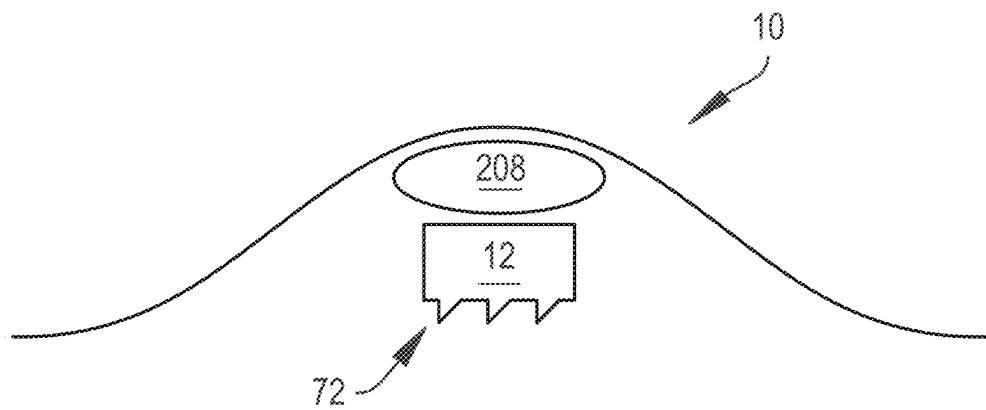
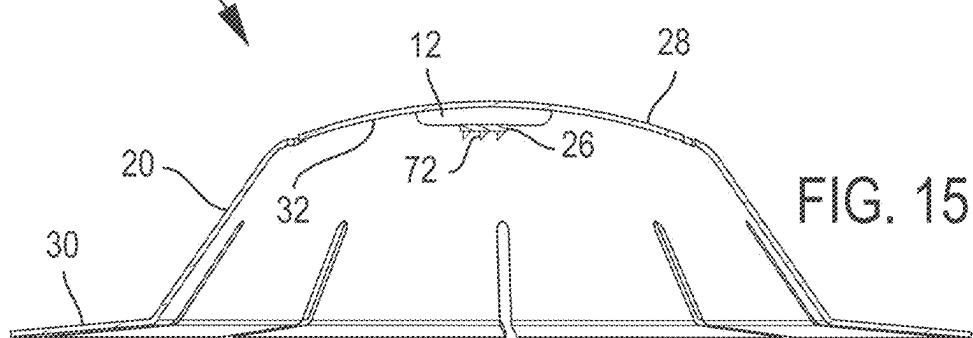
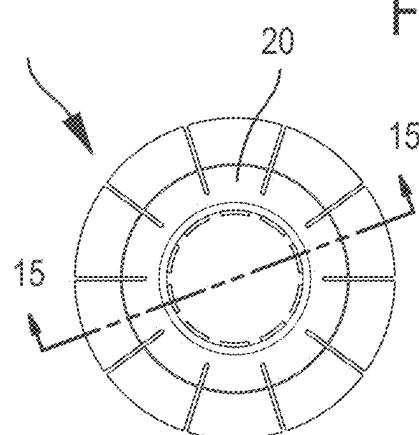
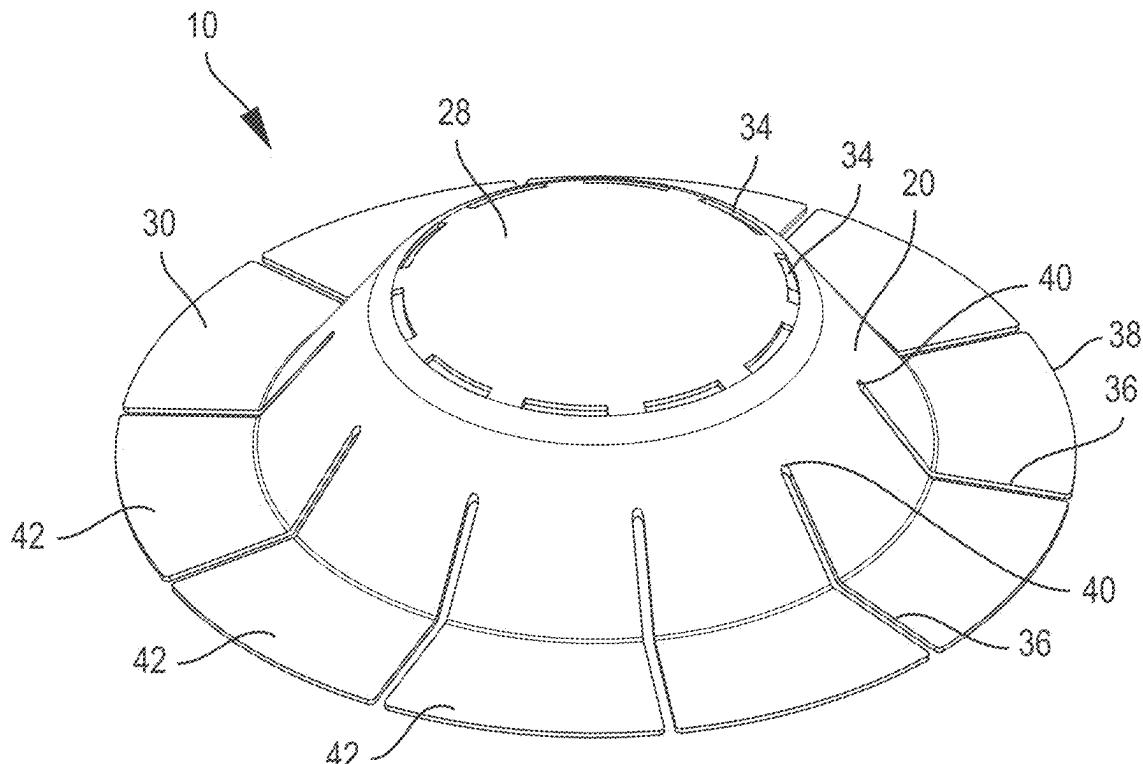


FIG. 9D







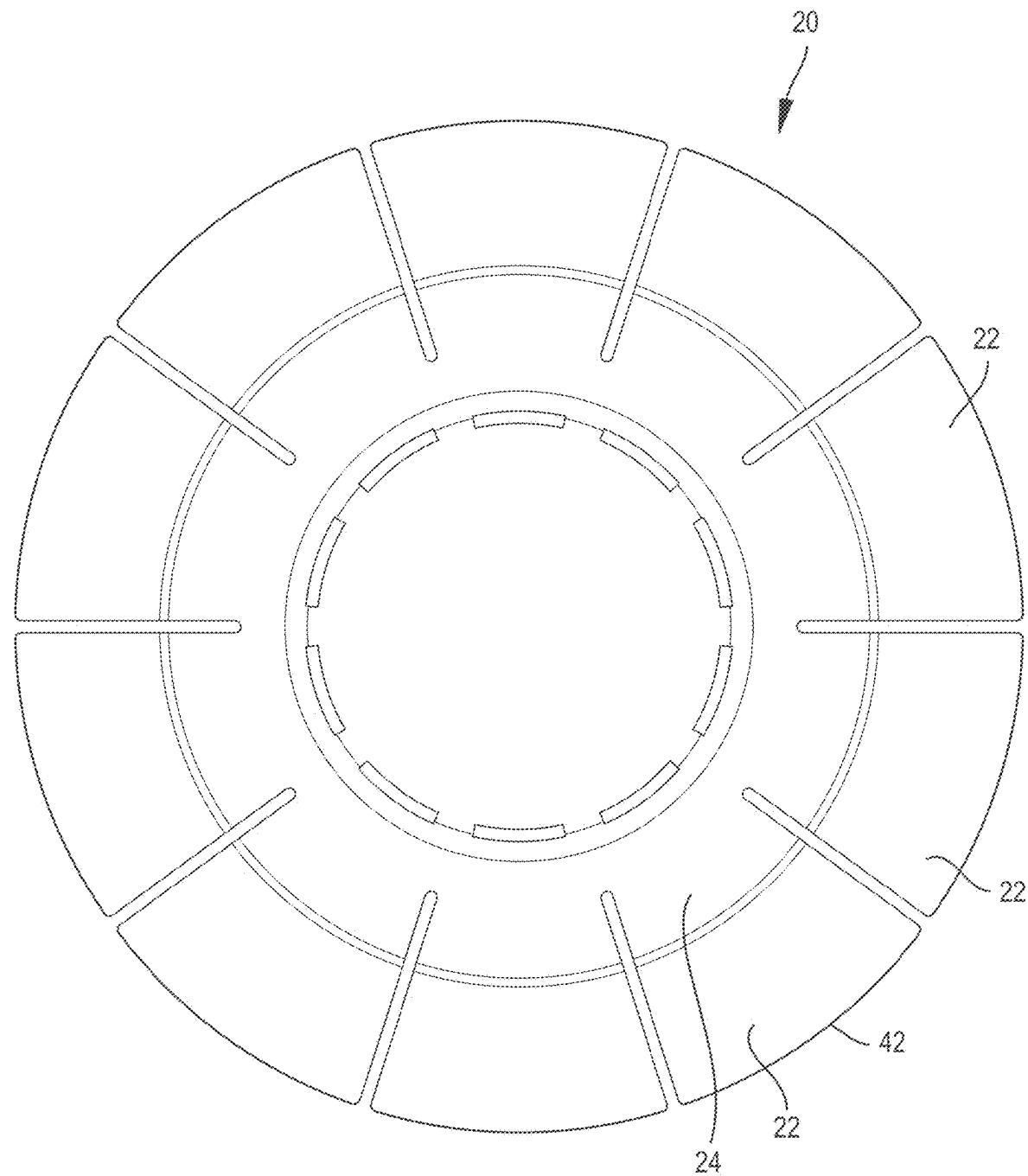
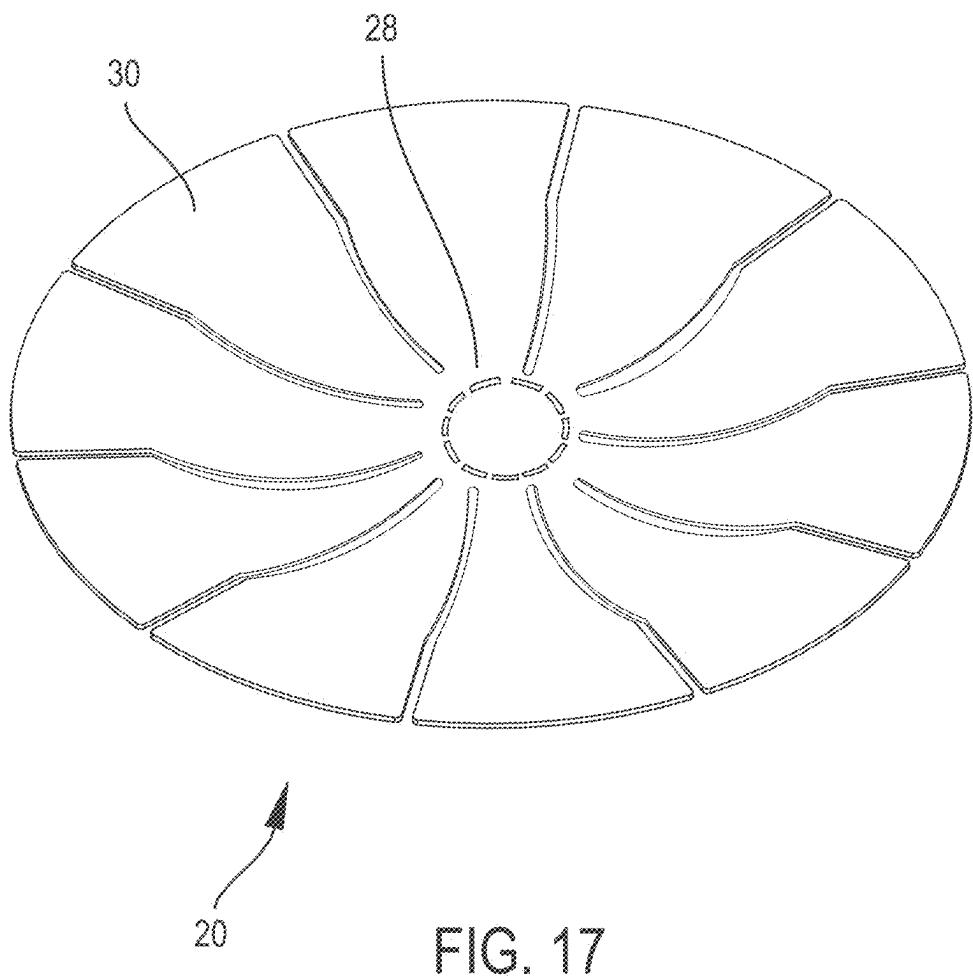
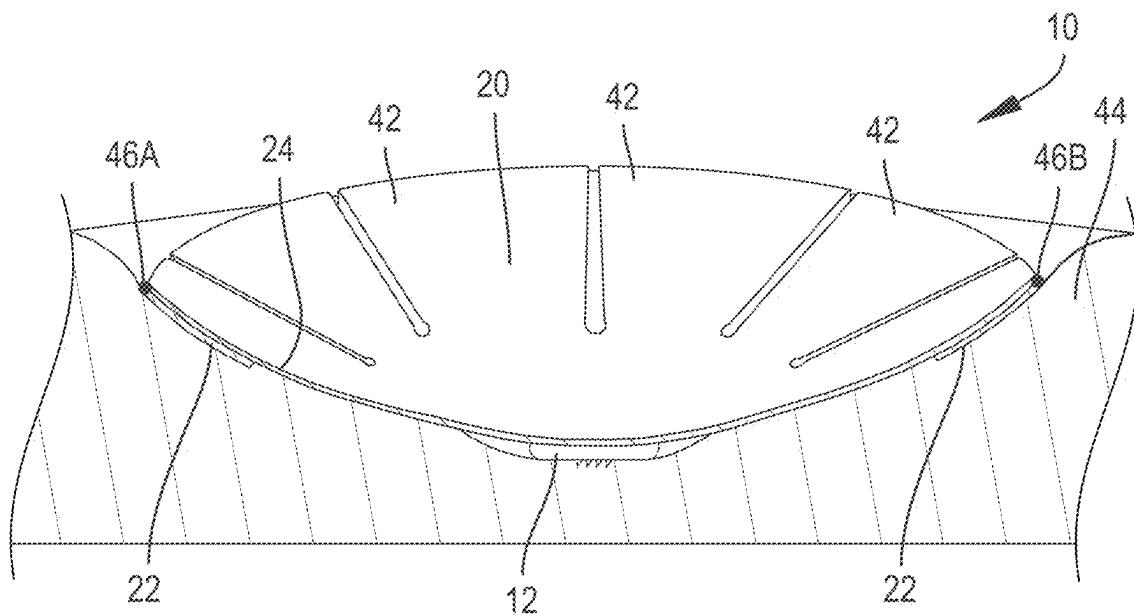
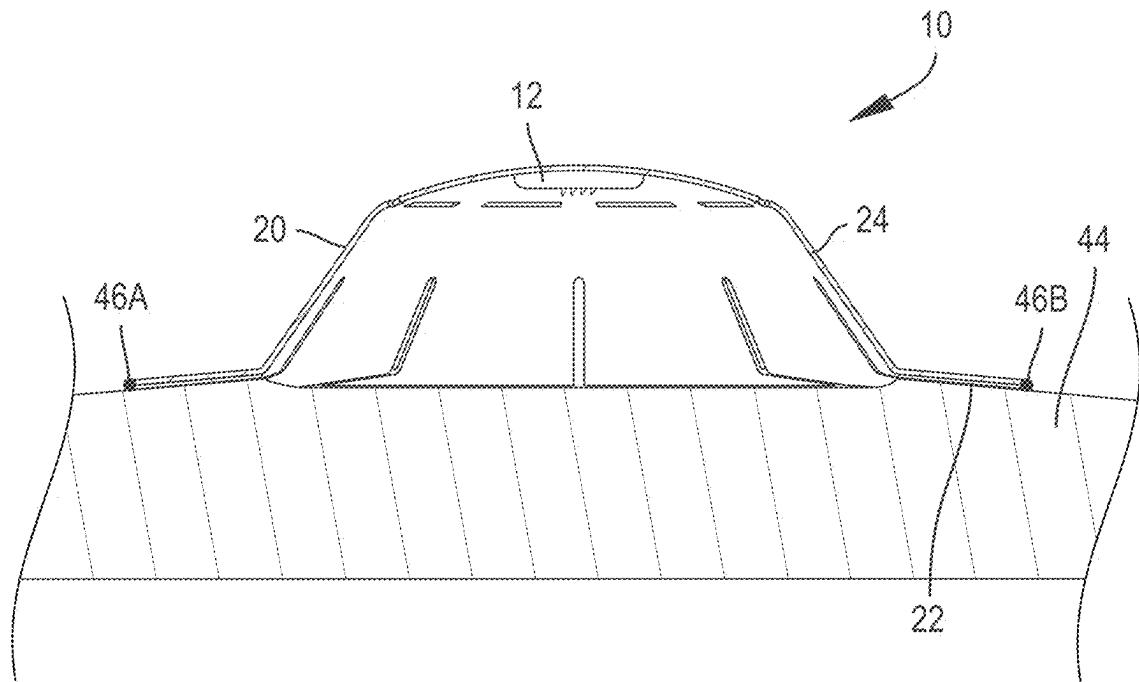


FIG. 16





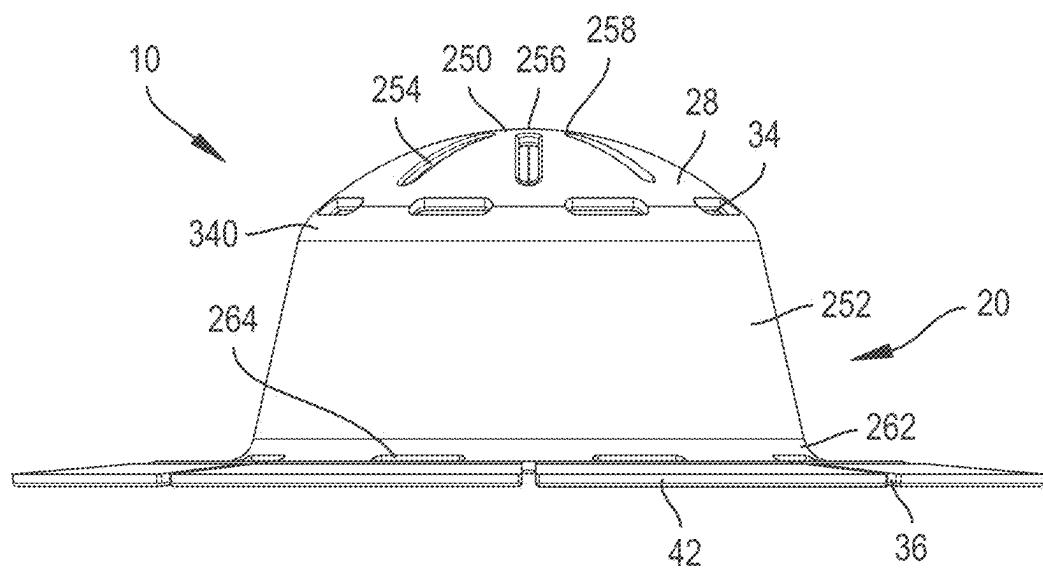


FIG. 20

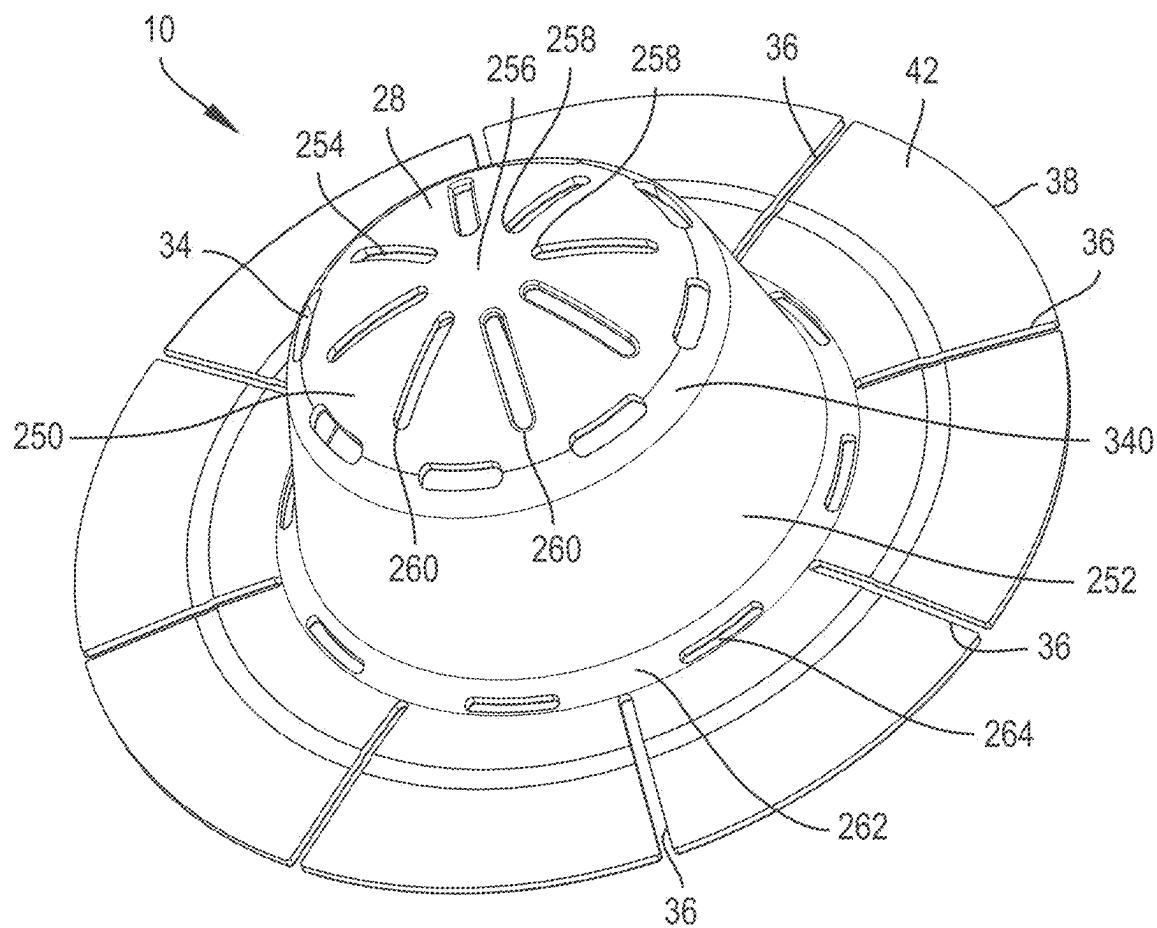


FIG. 21

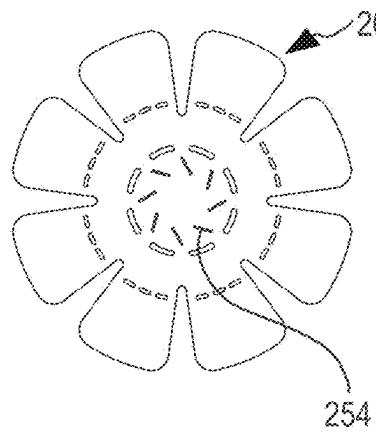


FIG. 22A

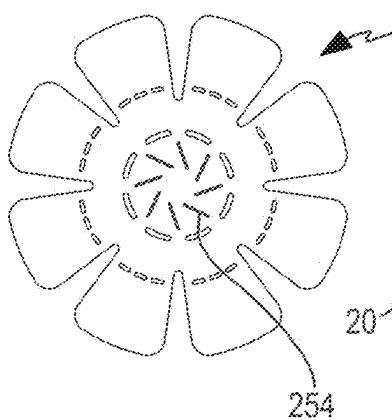


FIG. 22B

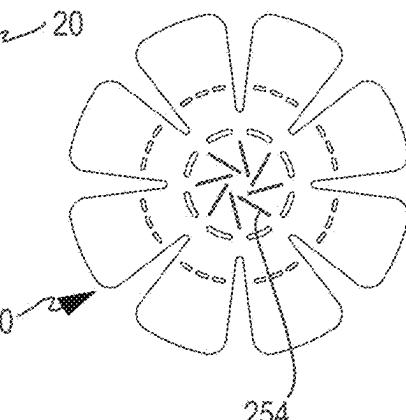


FIG. 22C

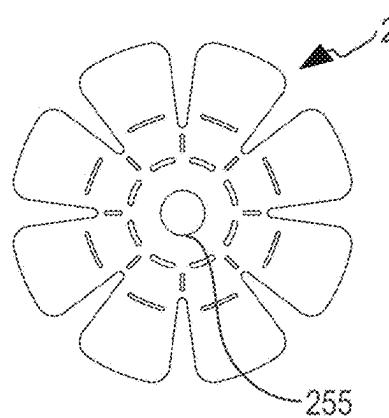


FIG. 22D

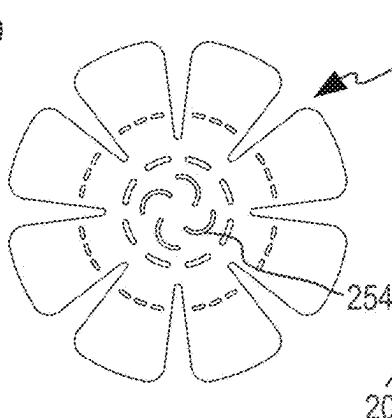


FIG. 22E

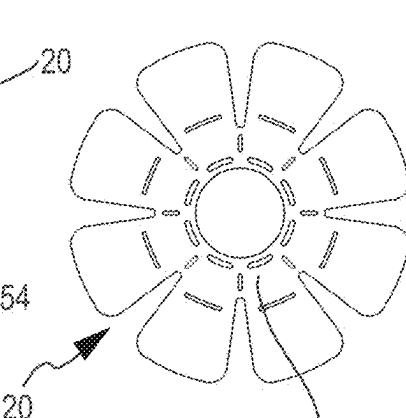


FIG. 22F

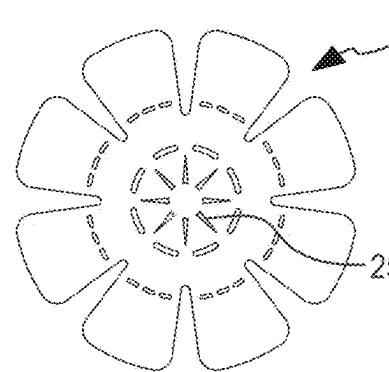


FIG. 22G

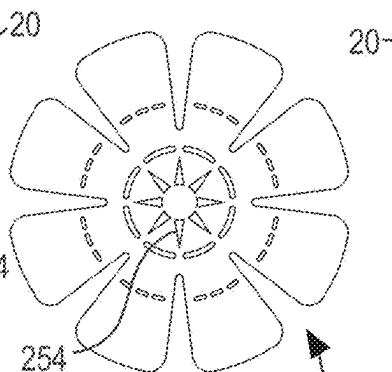


FIG. 22H

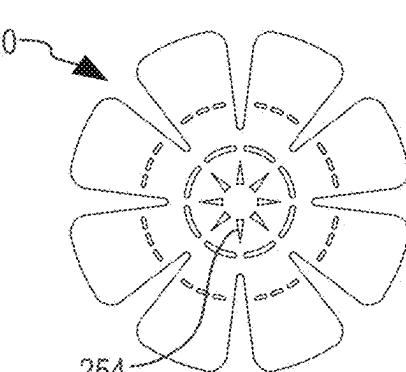


FIG. 22I

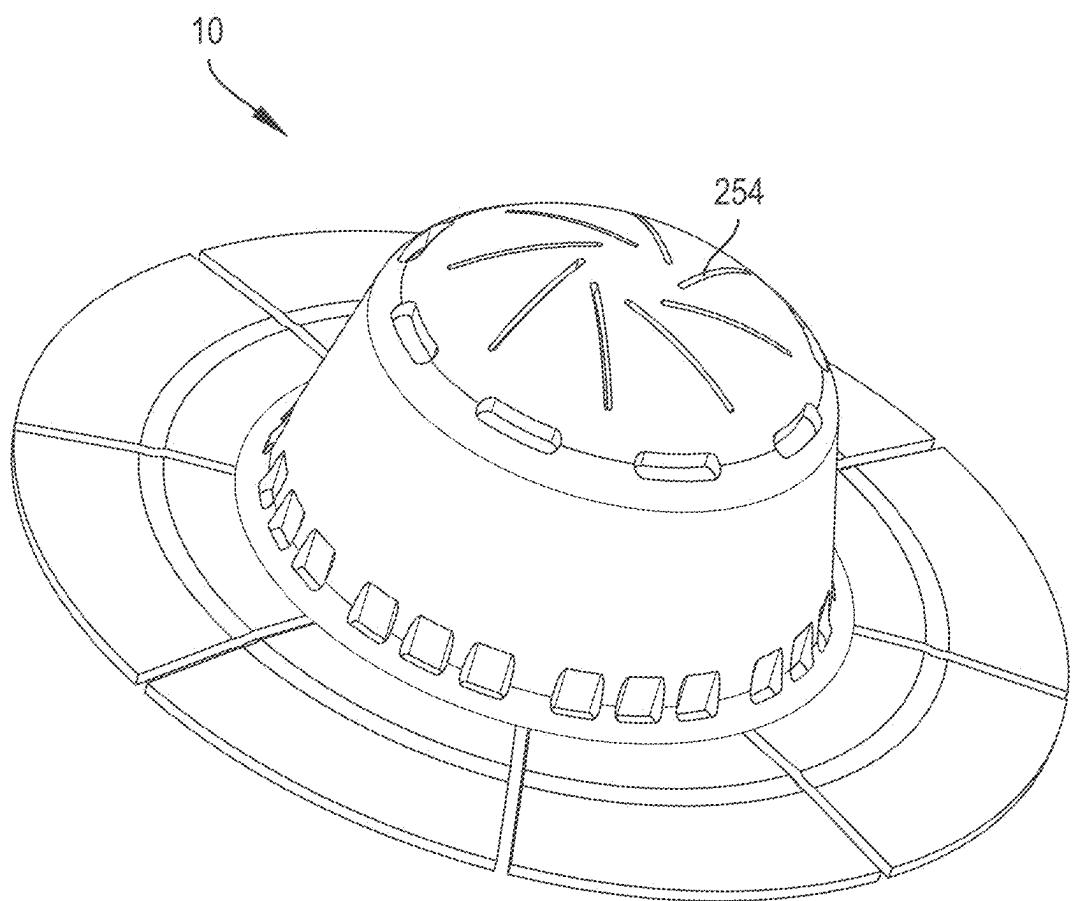


FIG. 23

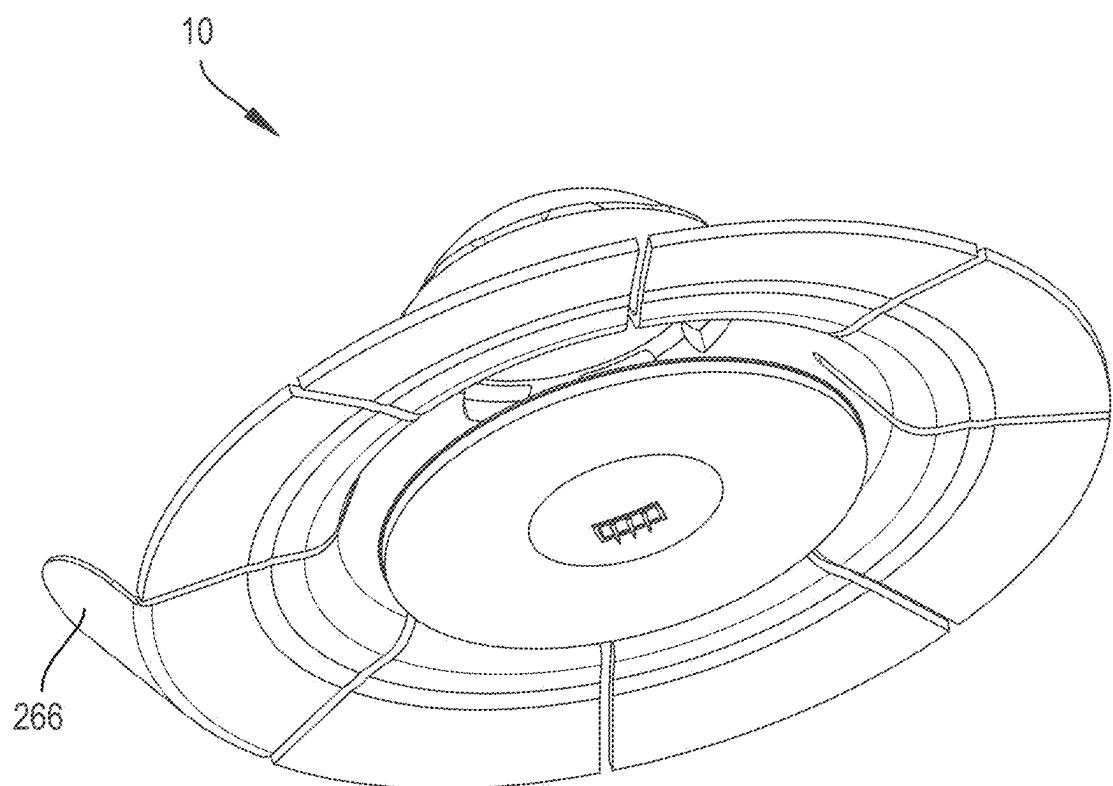


FIG. 24

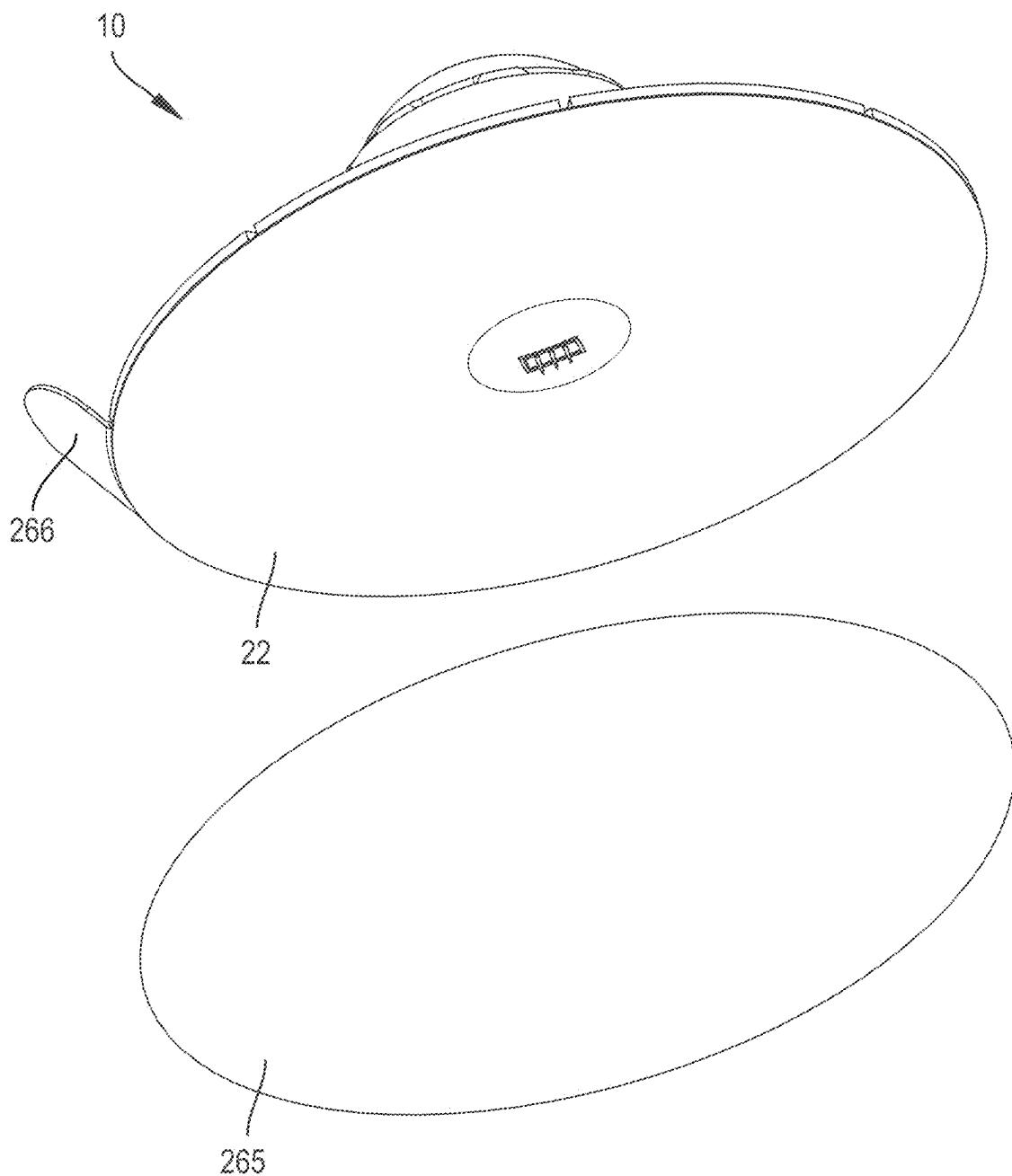


FIG. 25

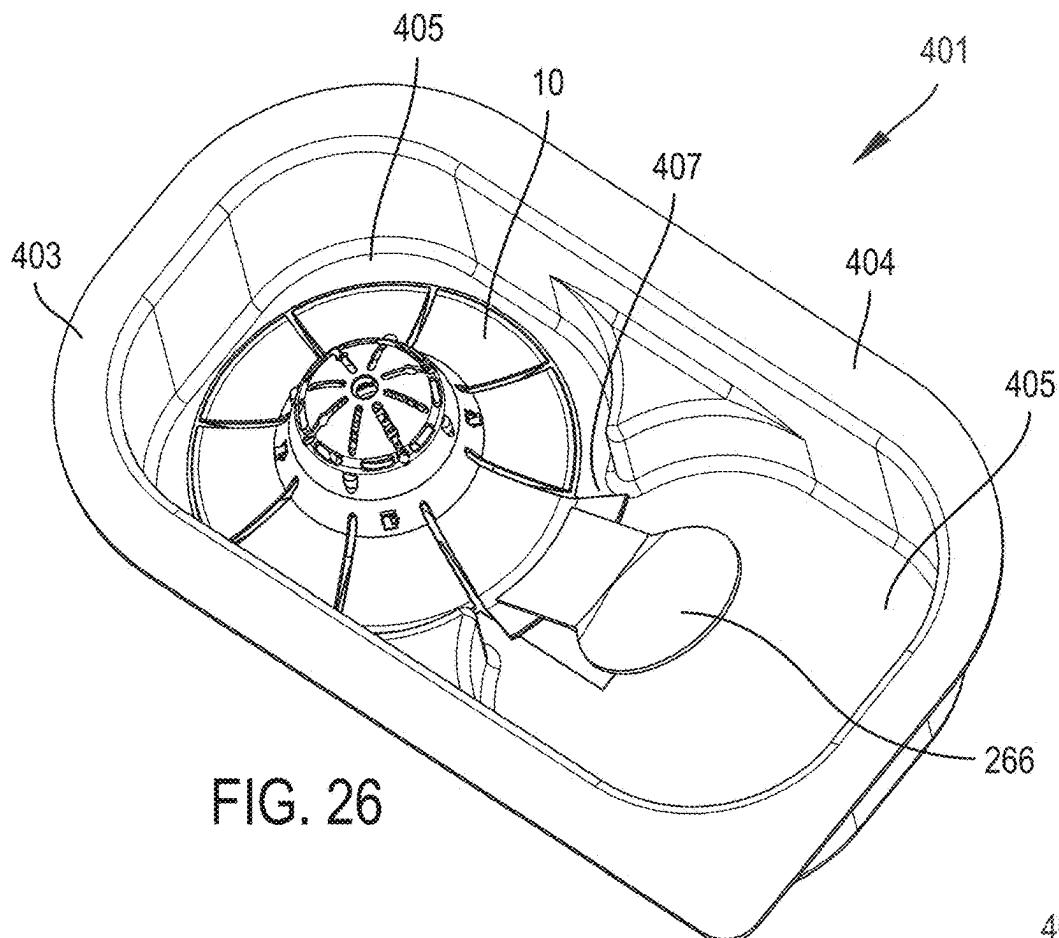


FIG. 26

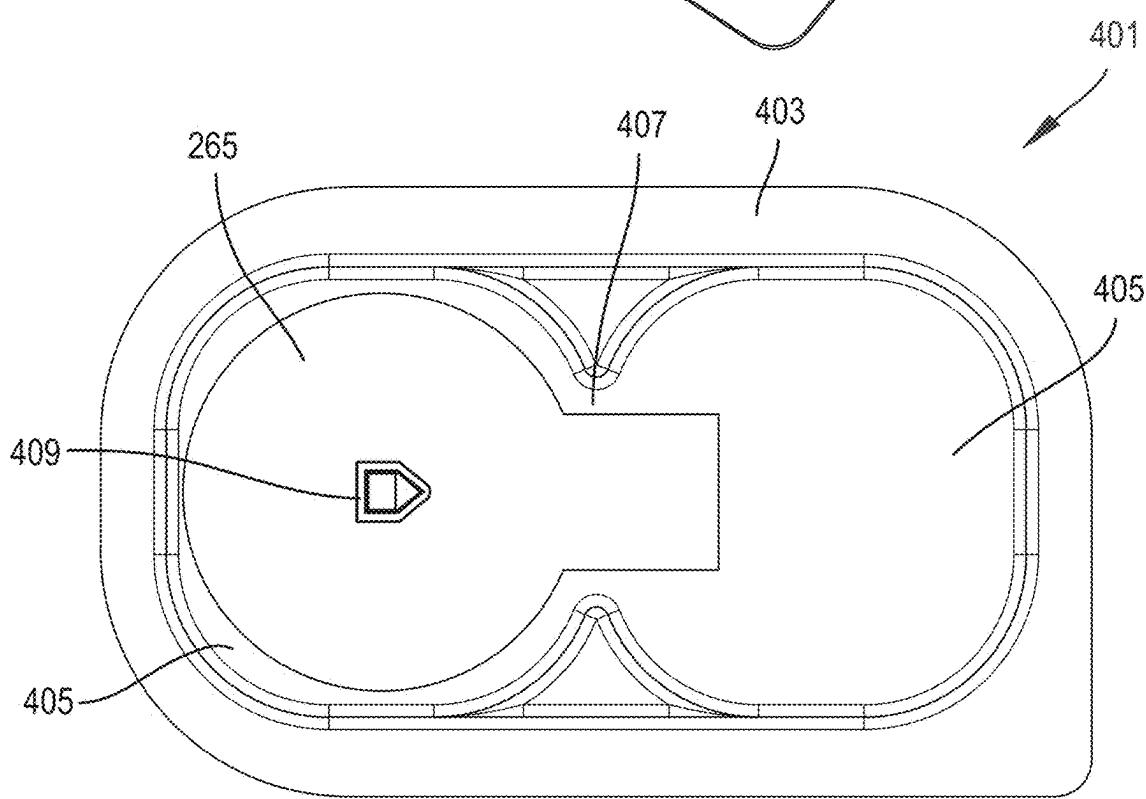


FIG. 27

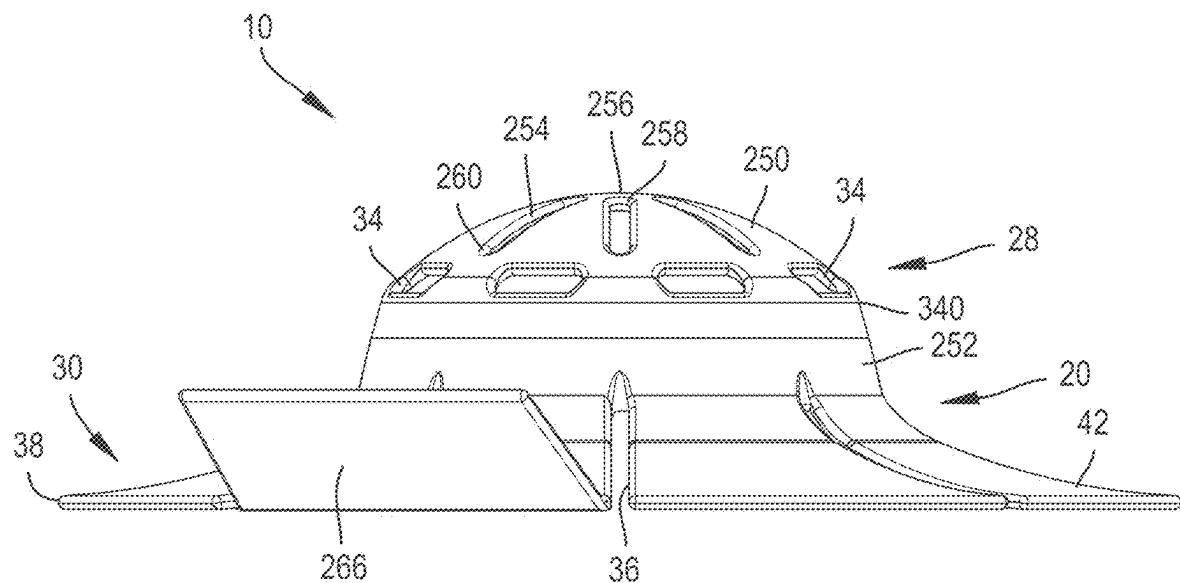


FIG. 28

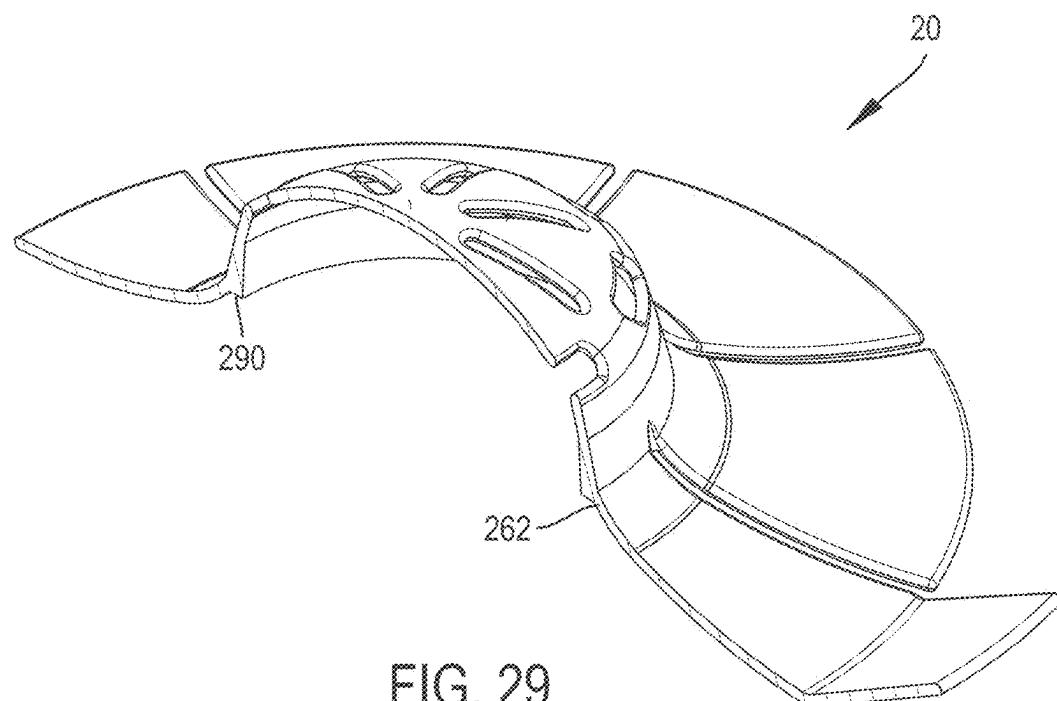
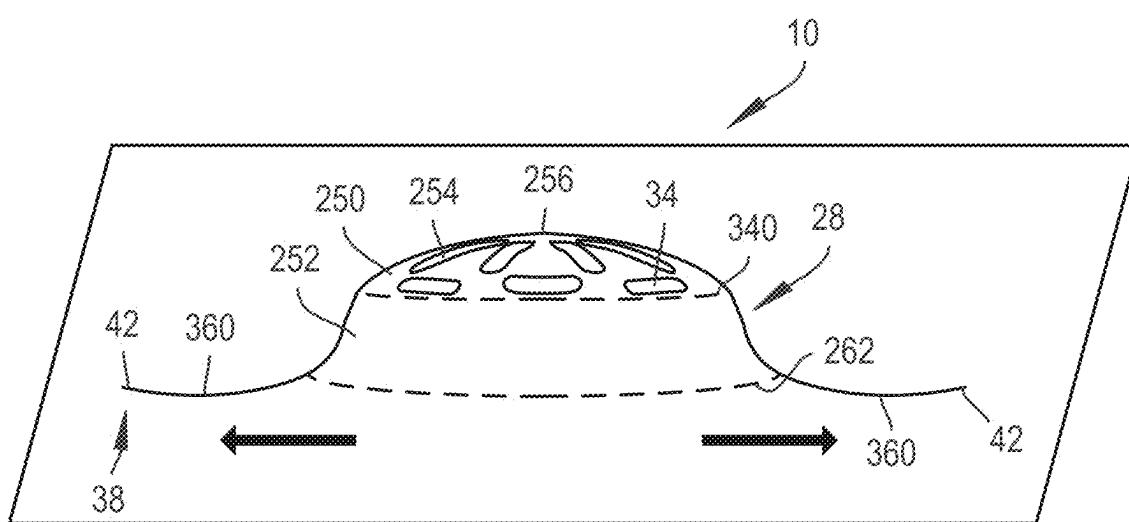
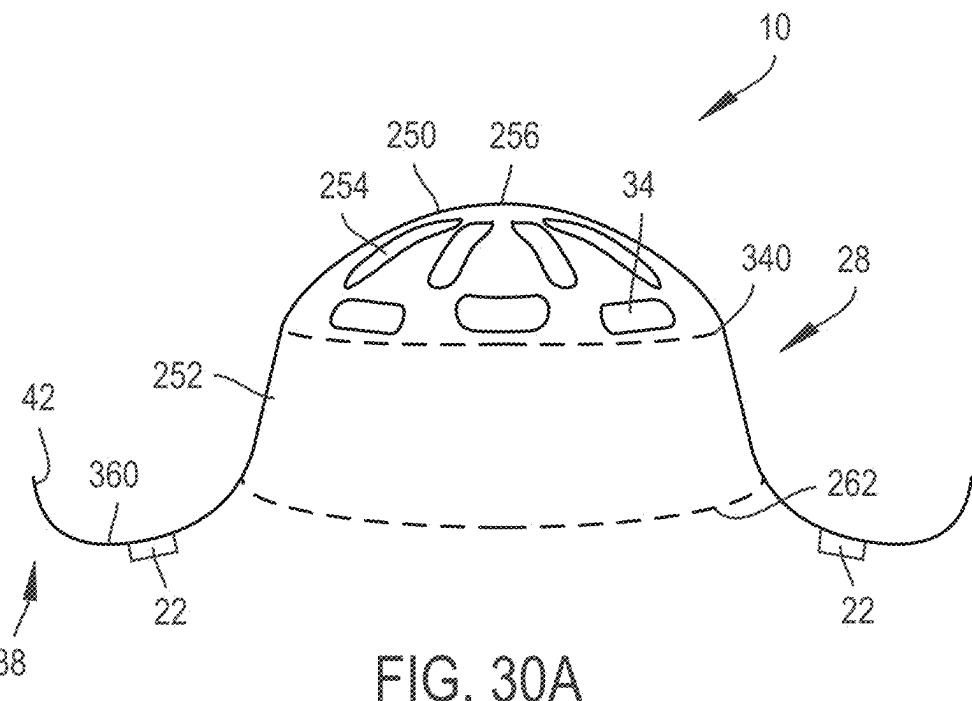
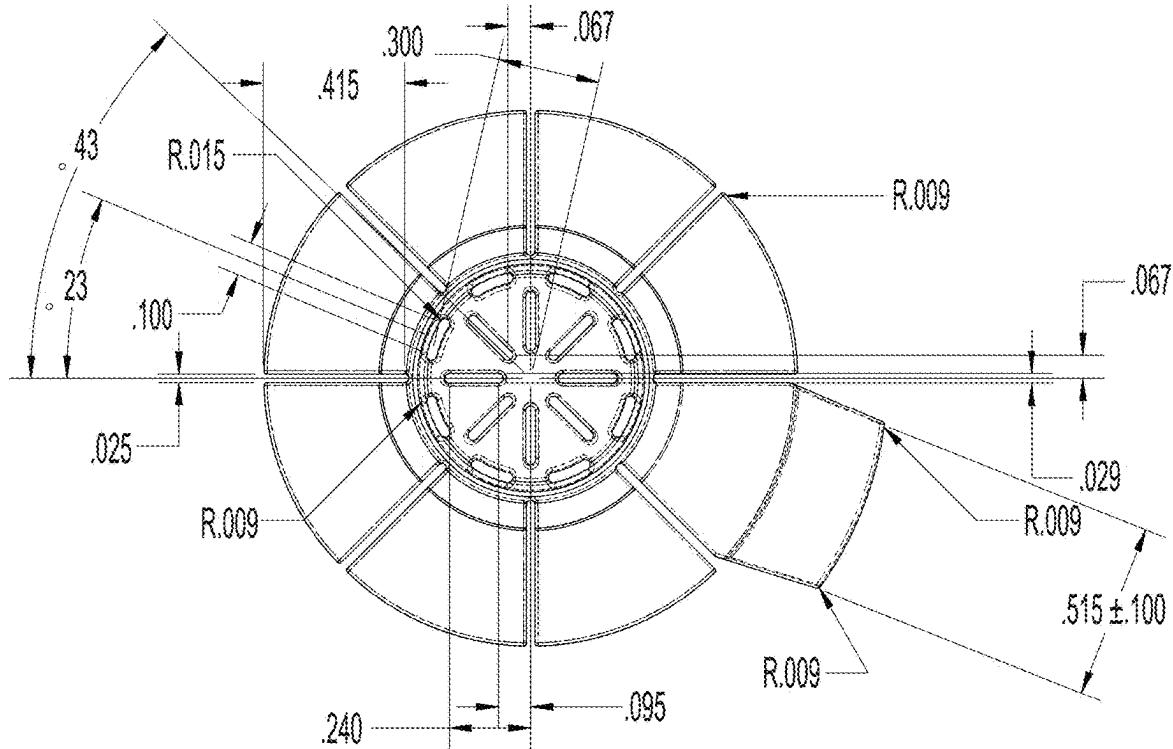


FIG. 29





**FIG. 31A**

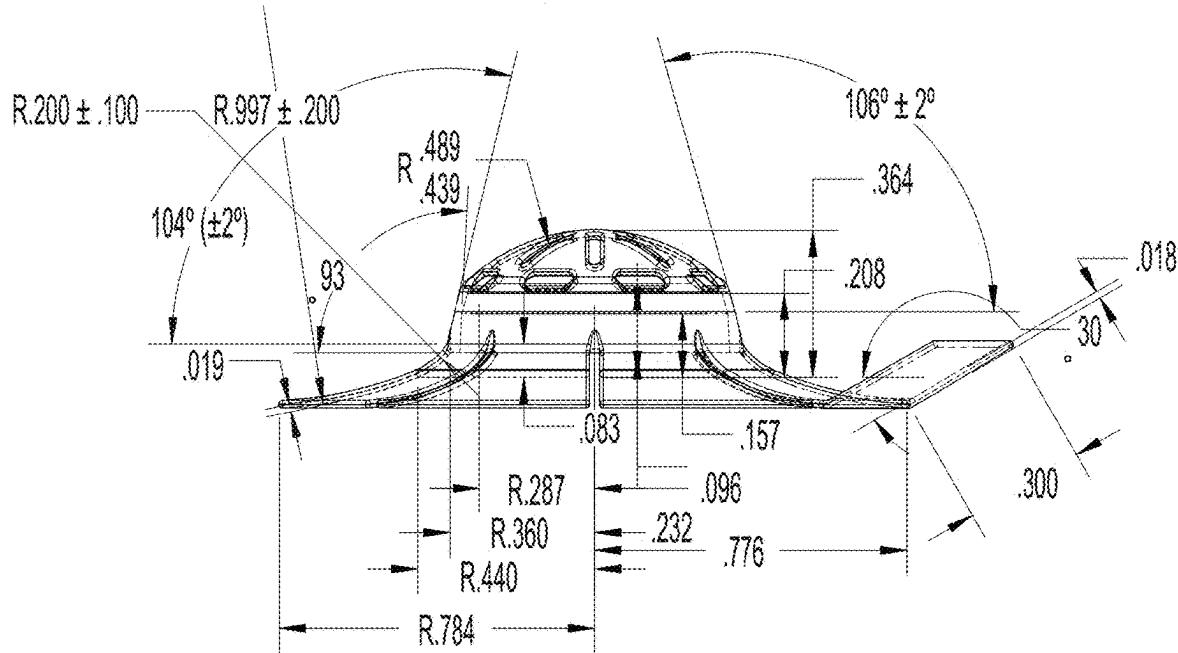
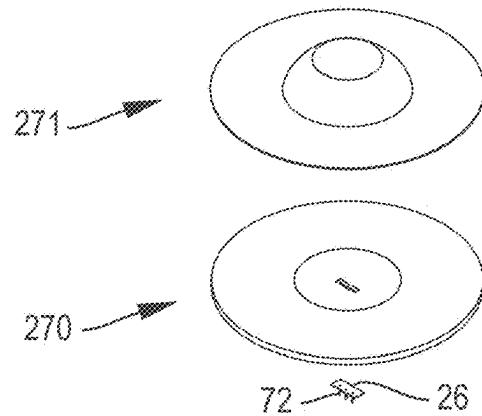
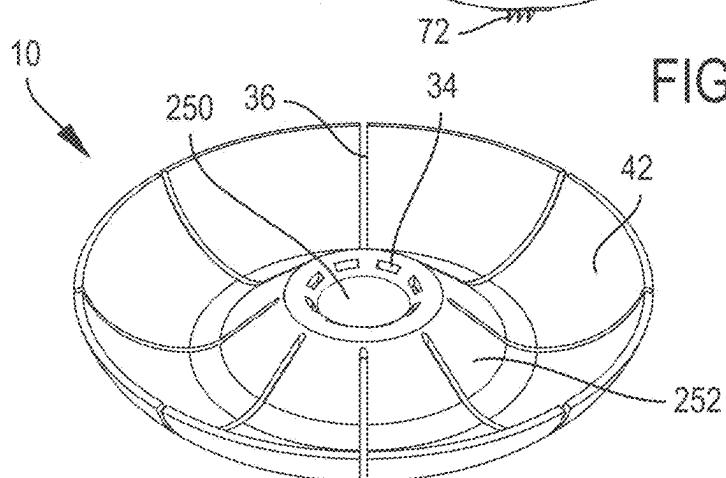
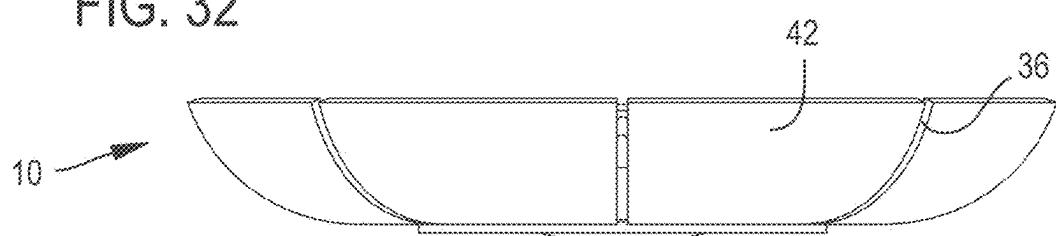
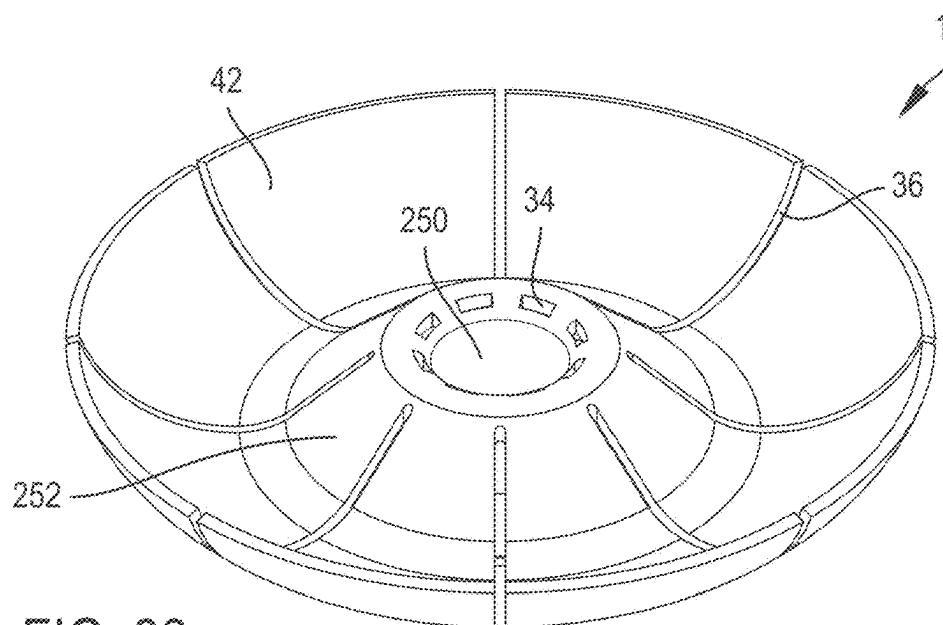


FIG. 31B



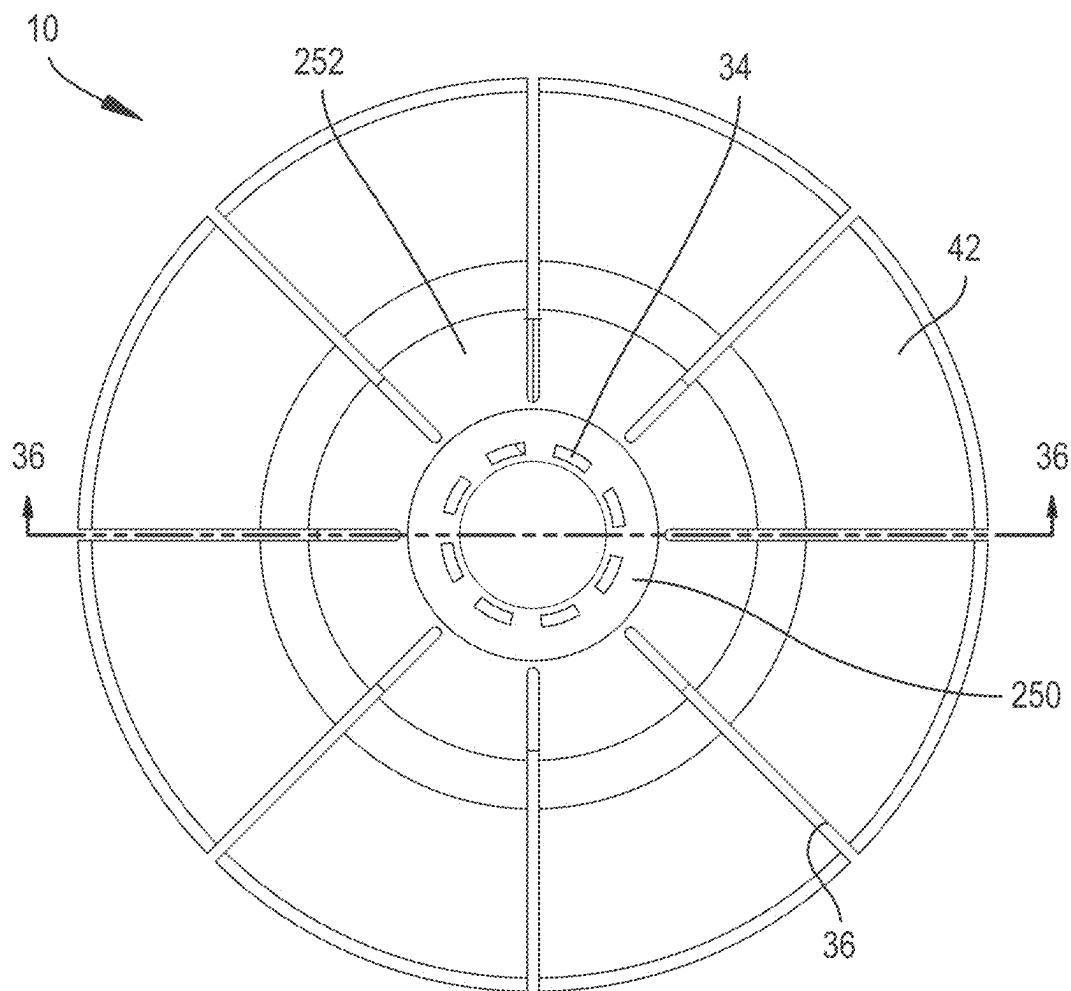


FIG. 35

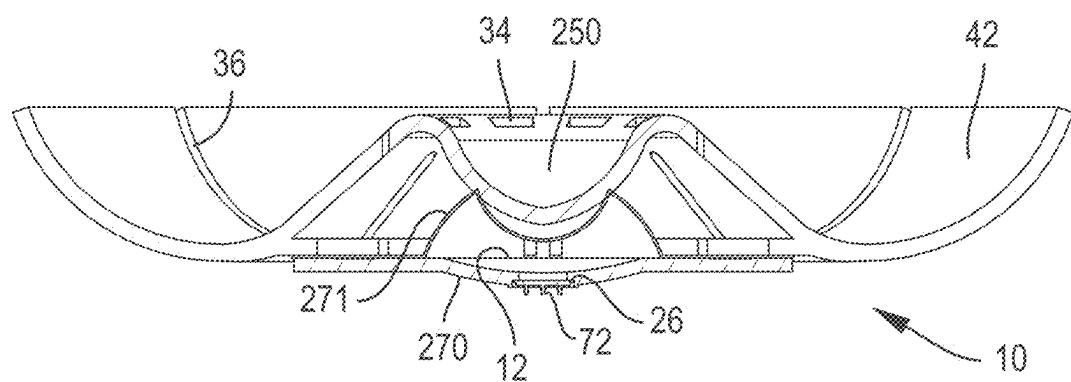
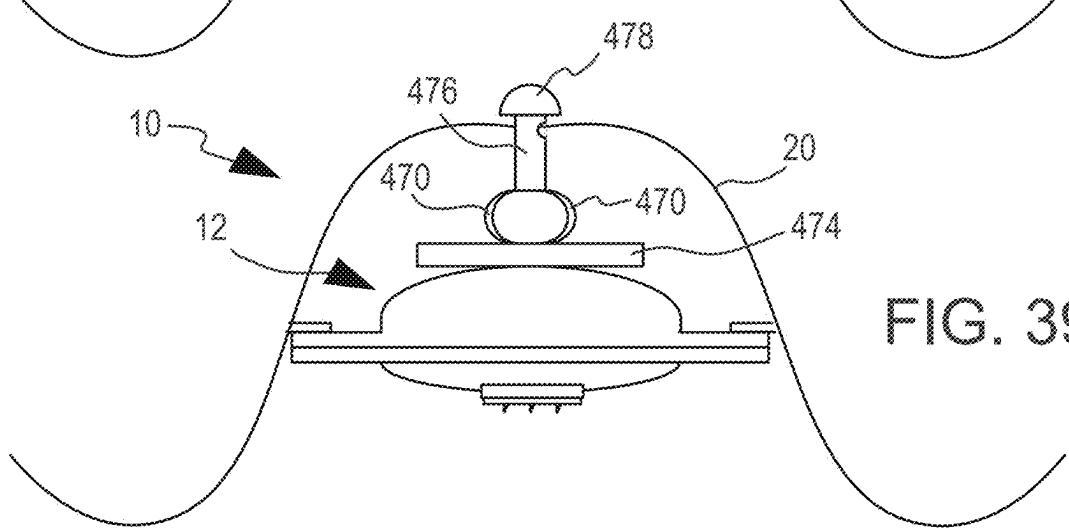
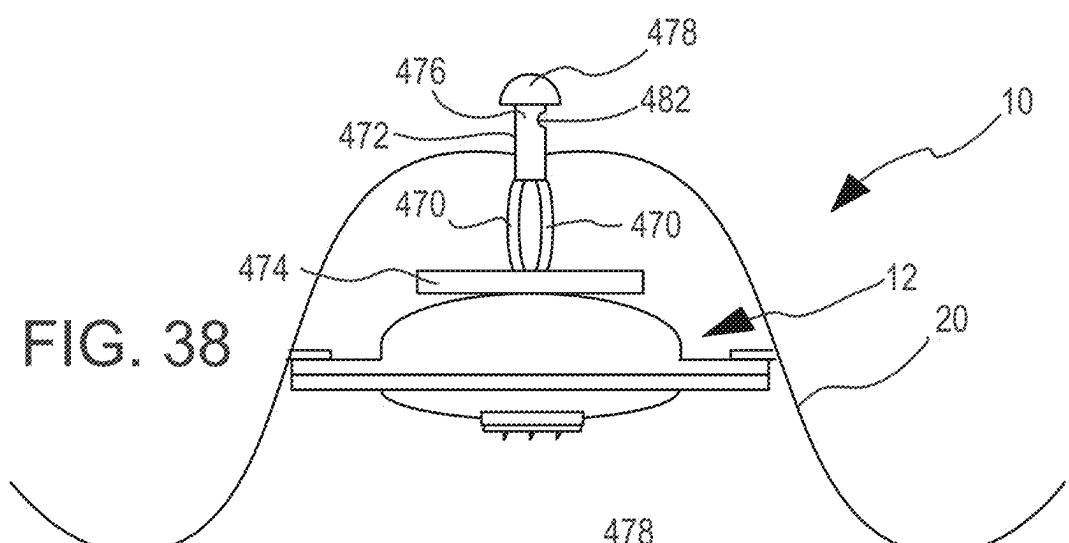
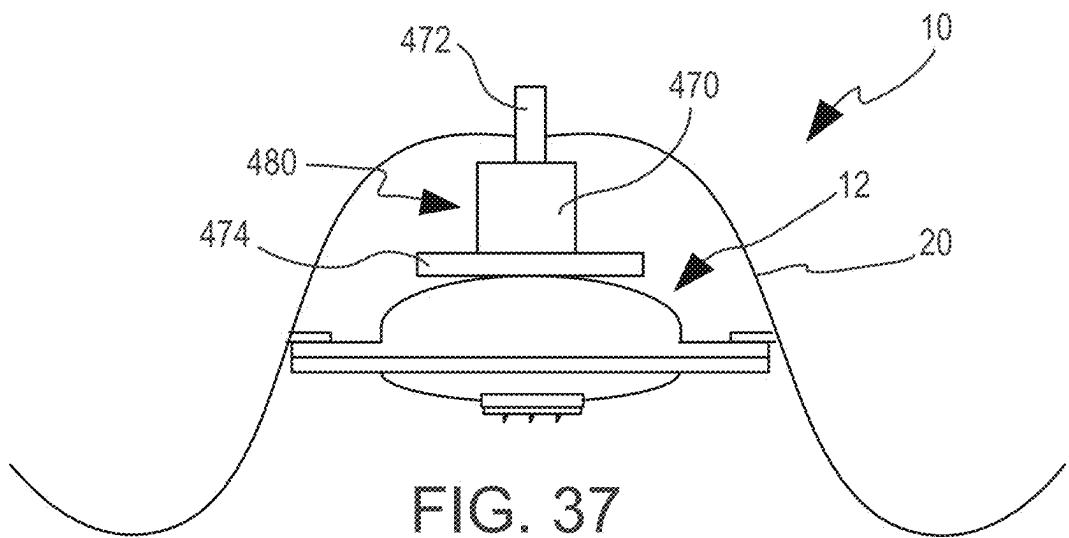


FIG. 36



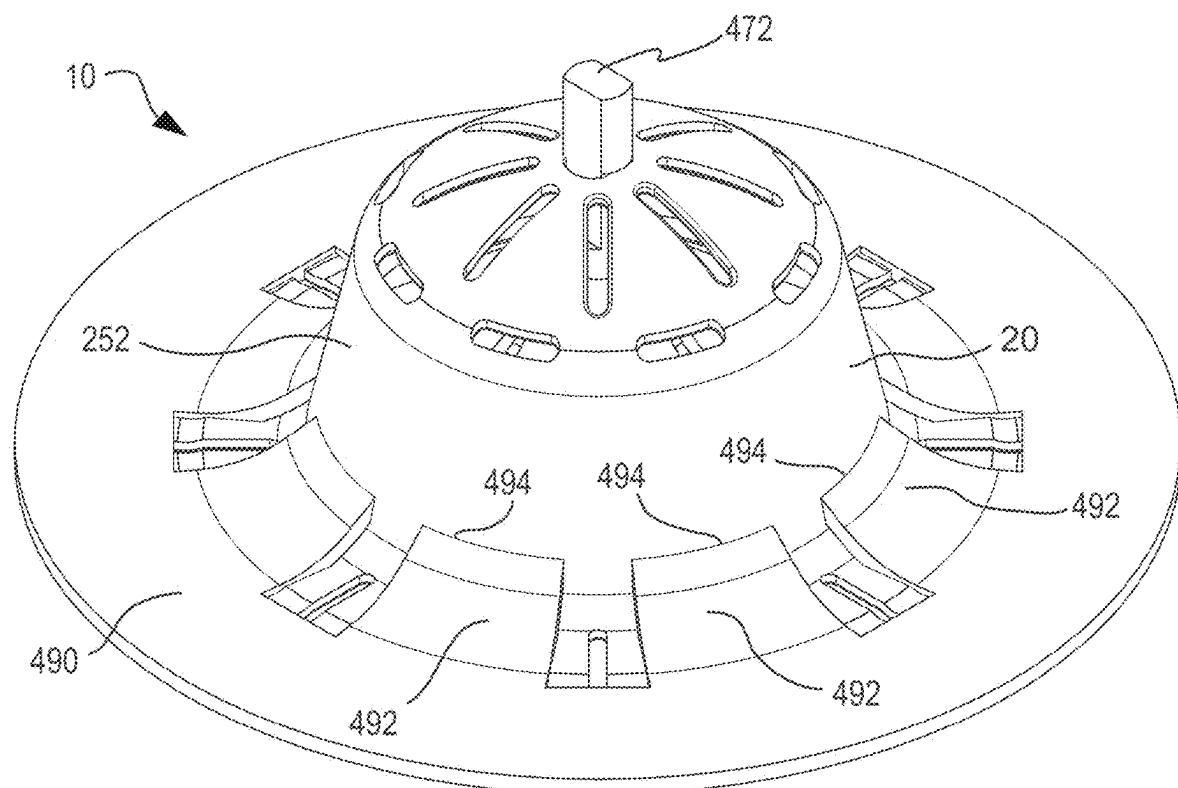


FIG. 40

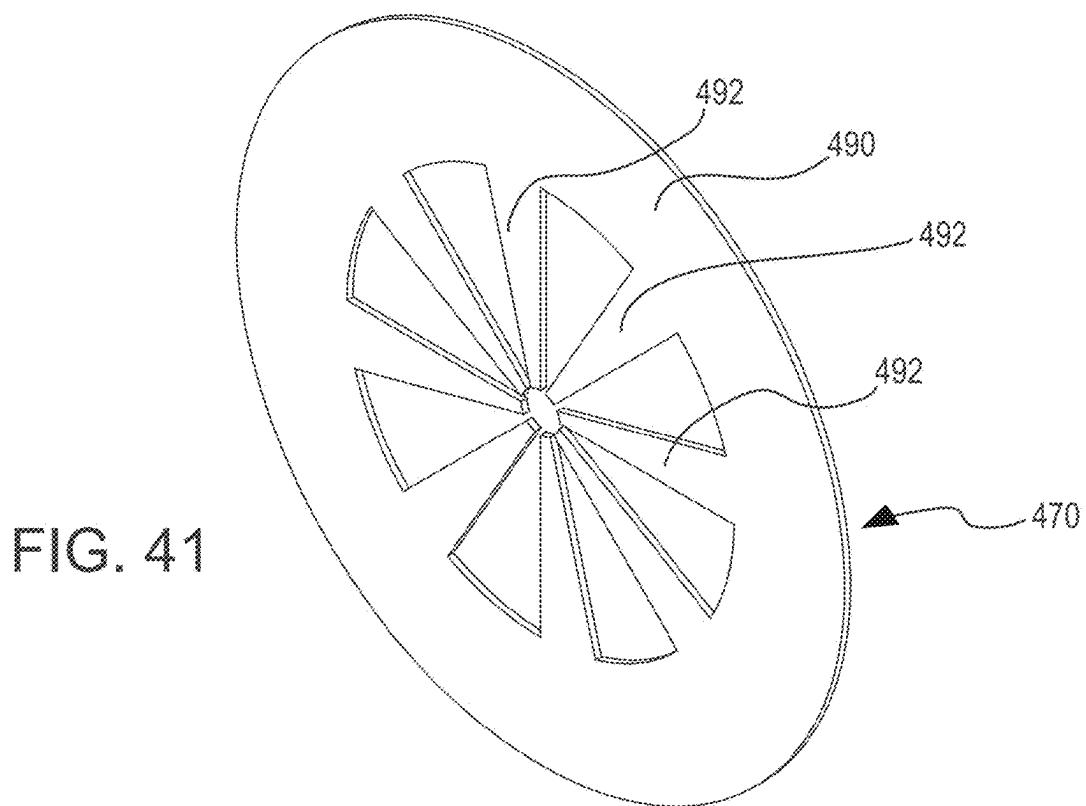


FIG. 41

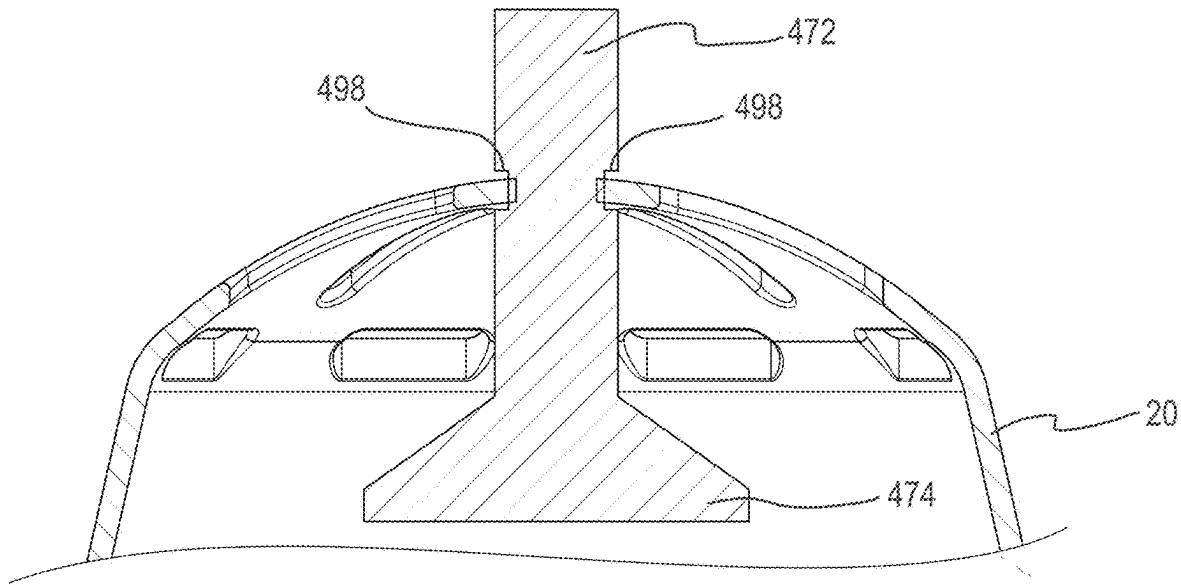


FIG. 42

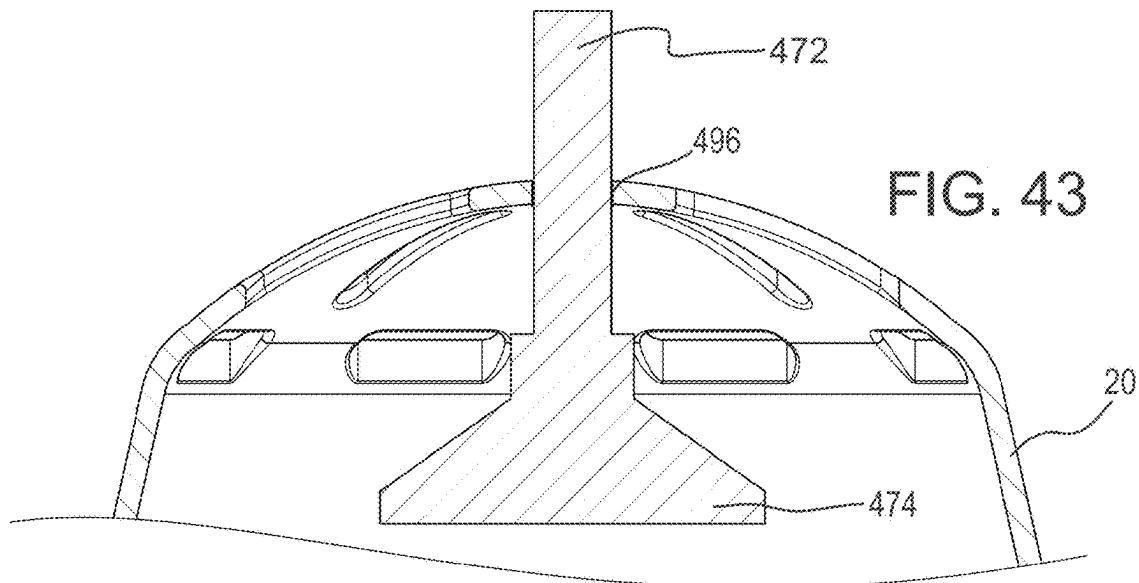
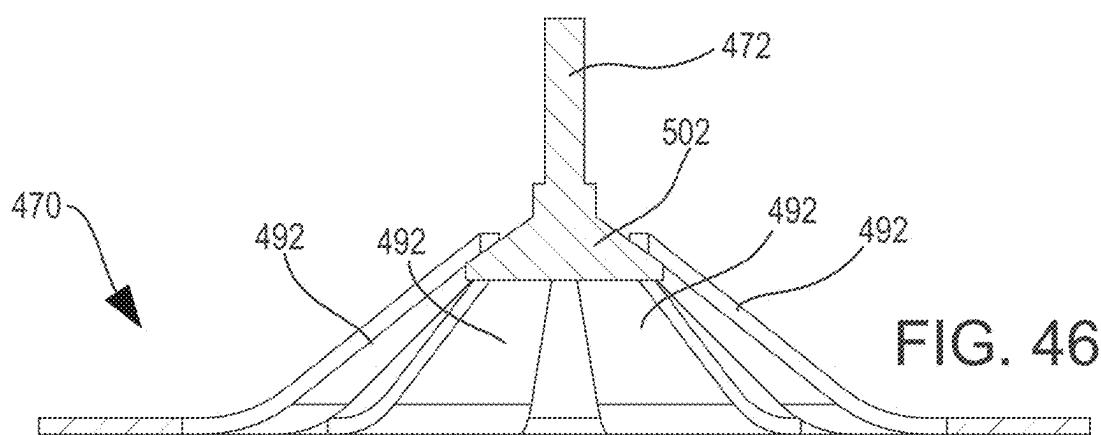
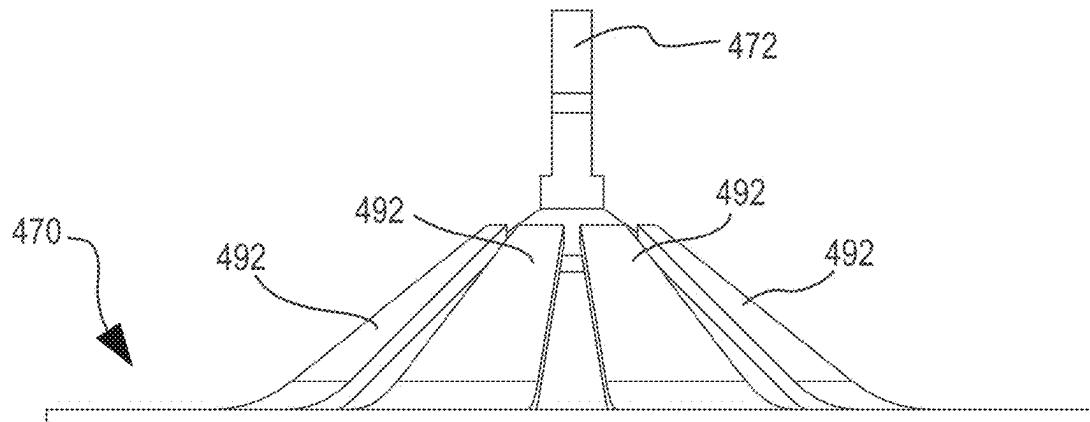
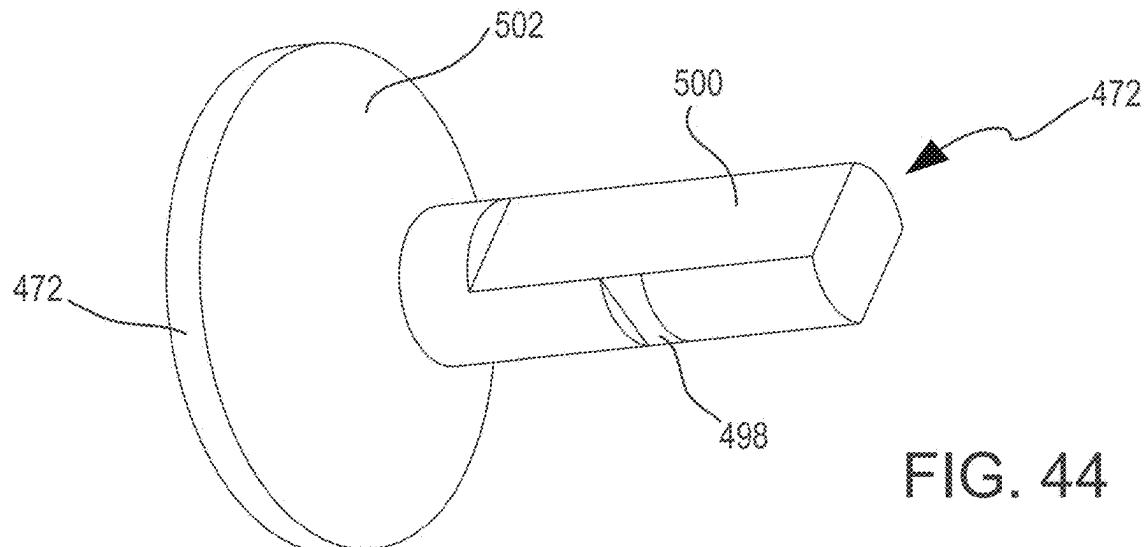


FIG. 43



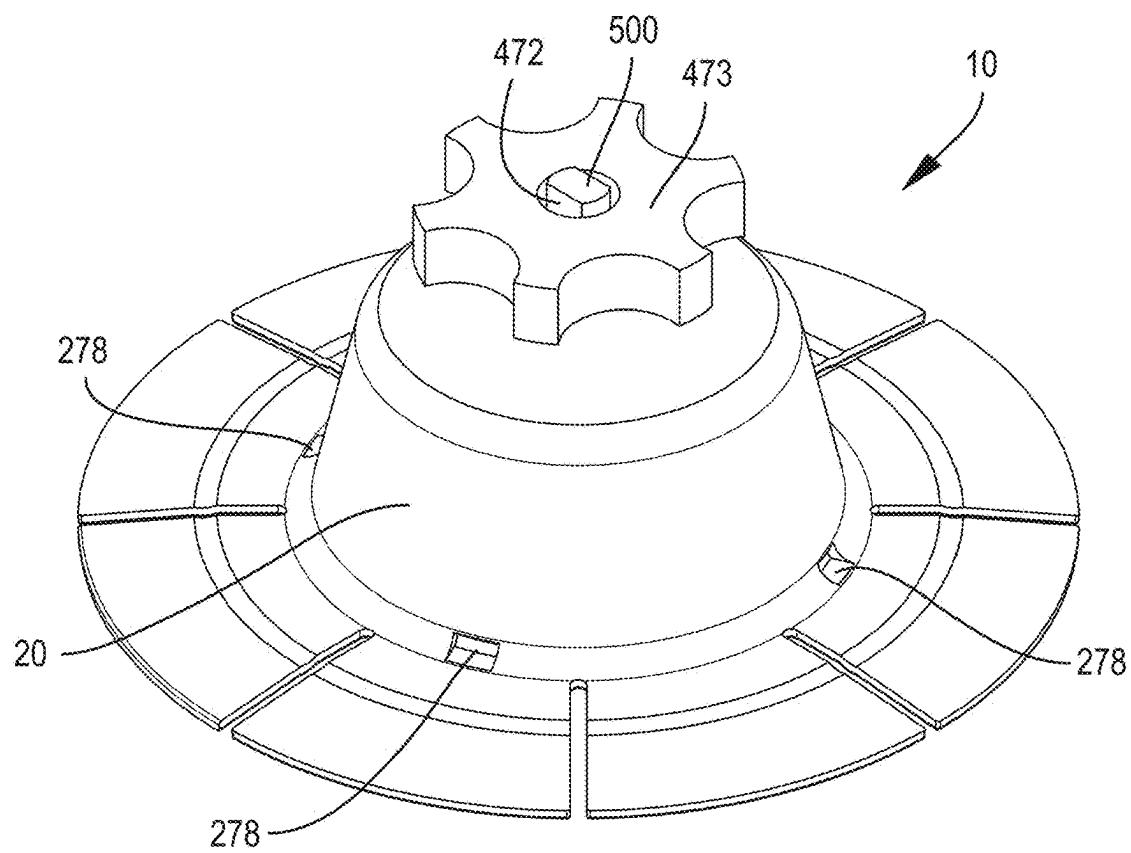


FIG. 47A

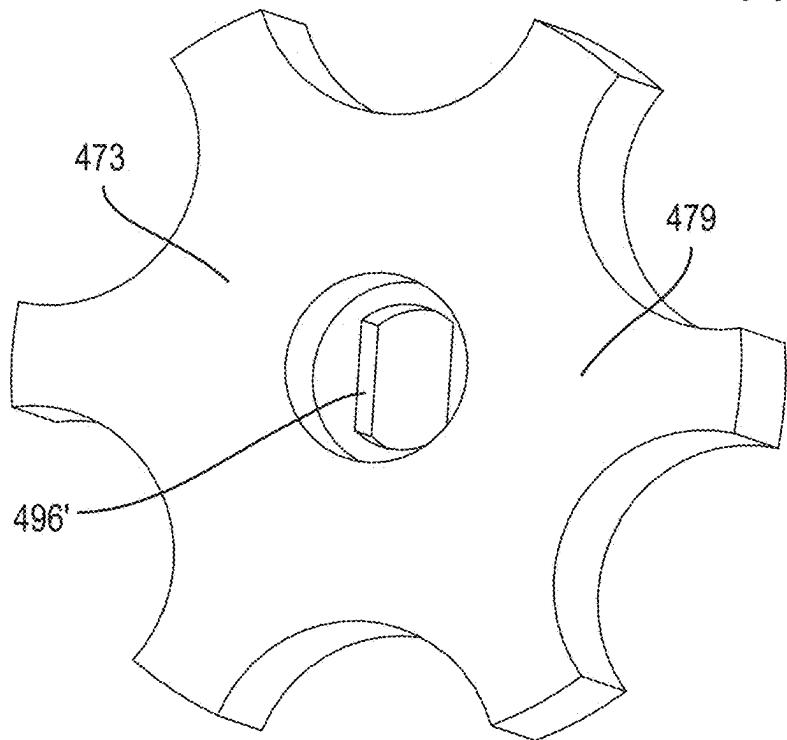


FIG. 47B

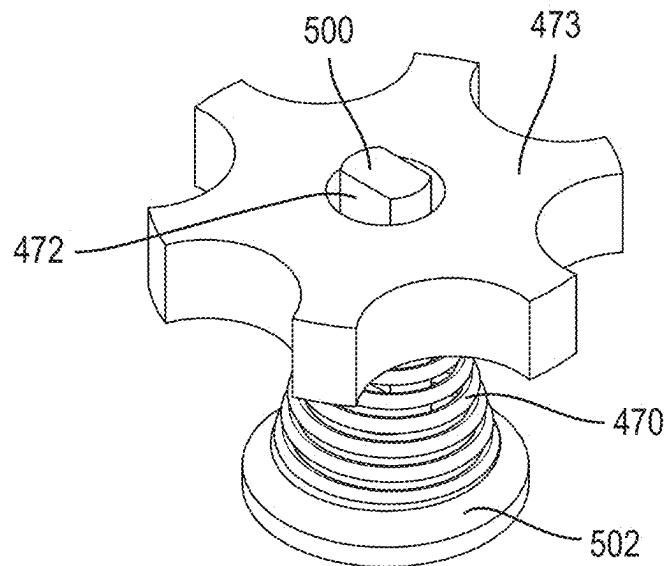


FIG. 47C

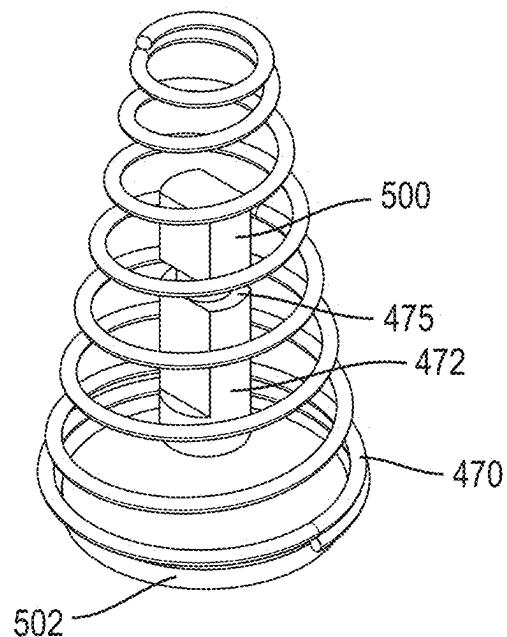
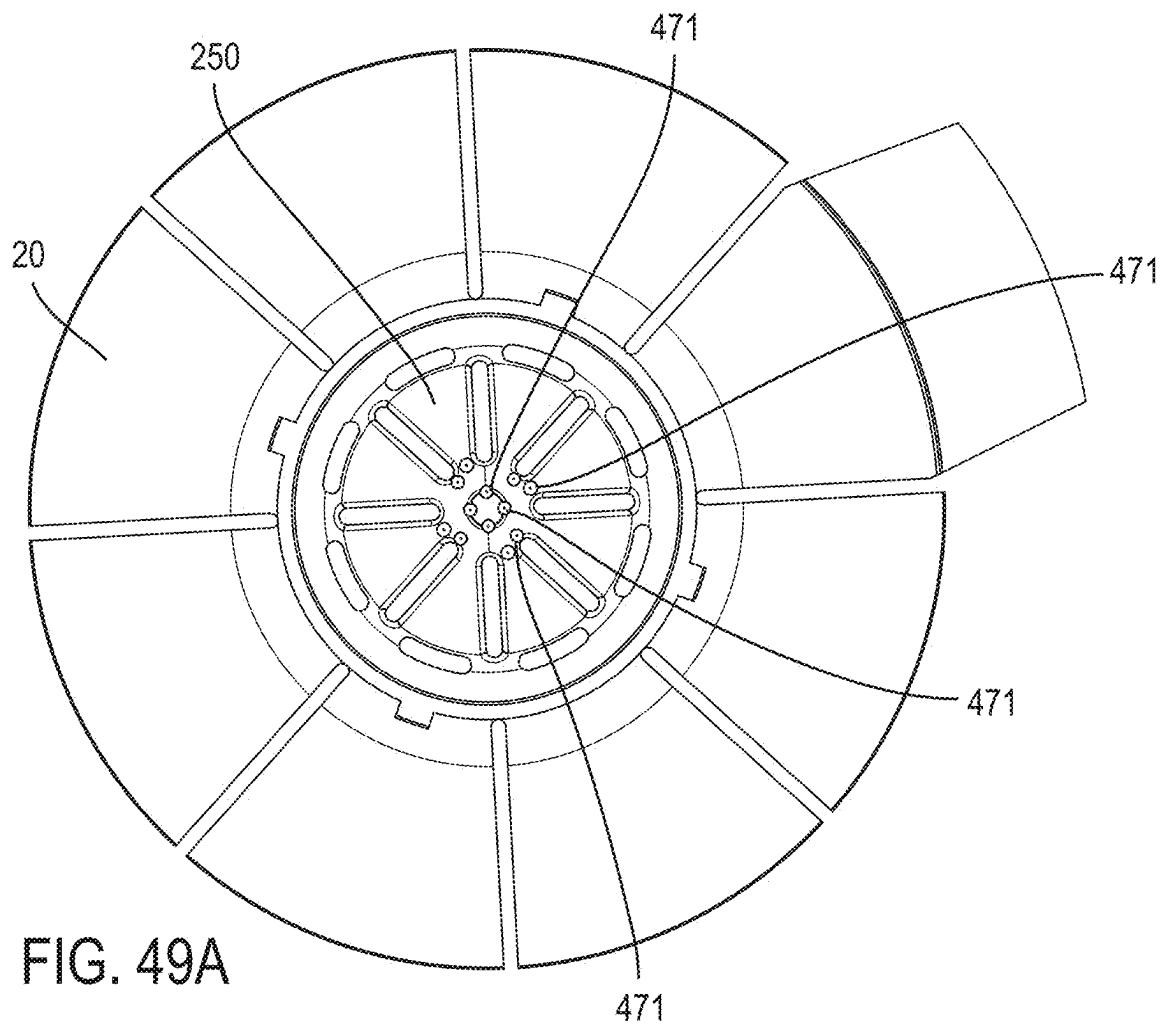
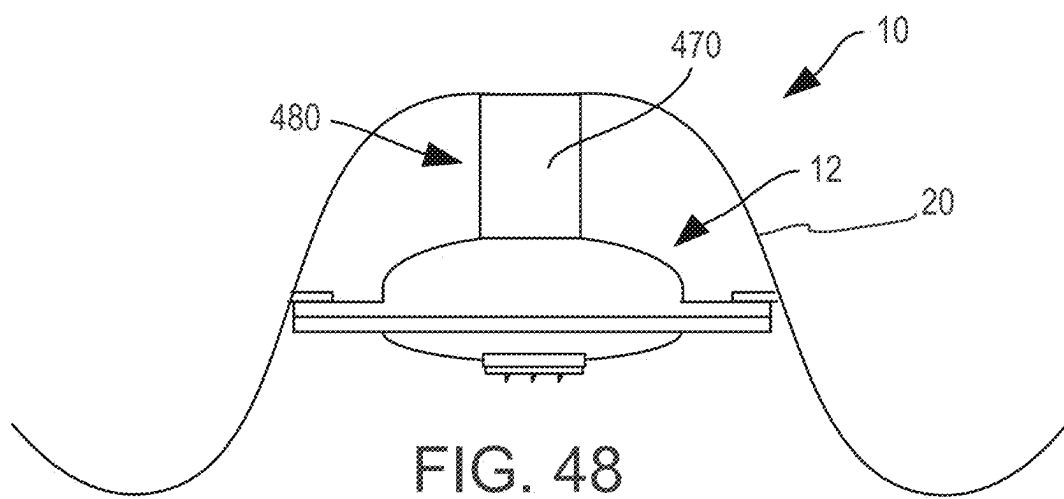
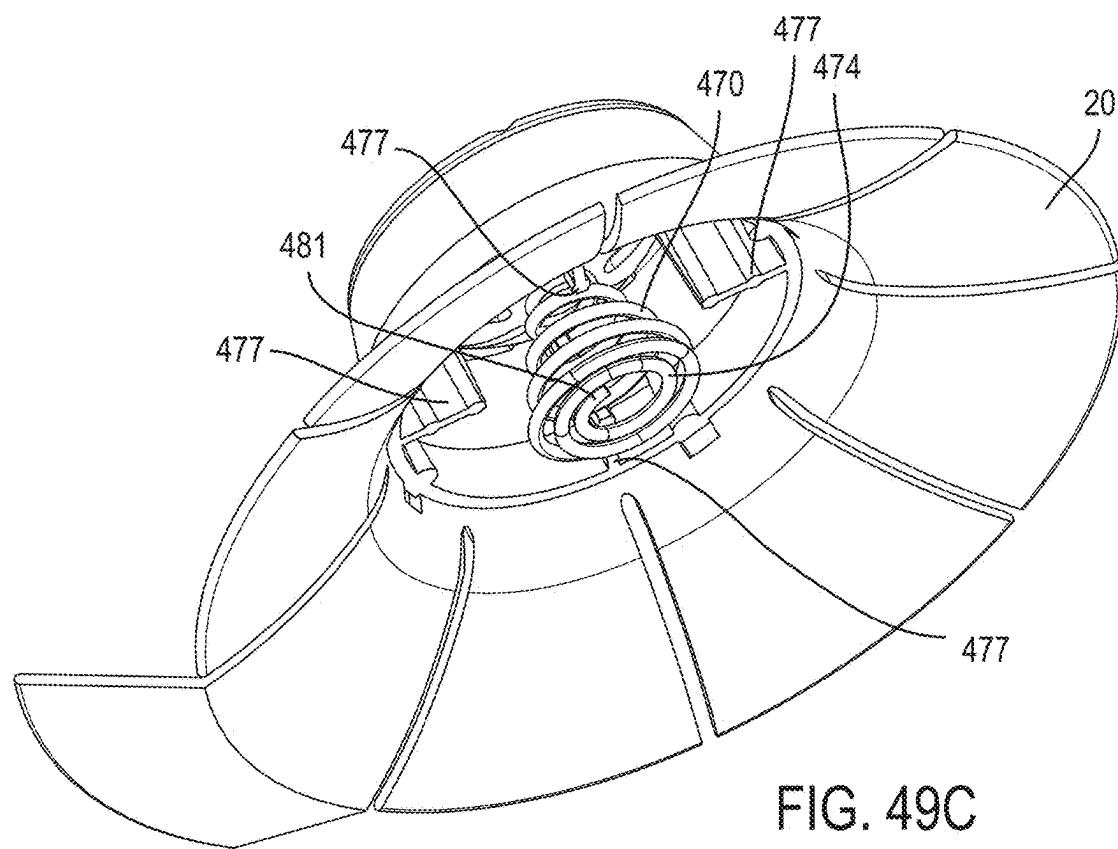
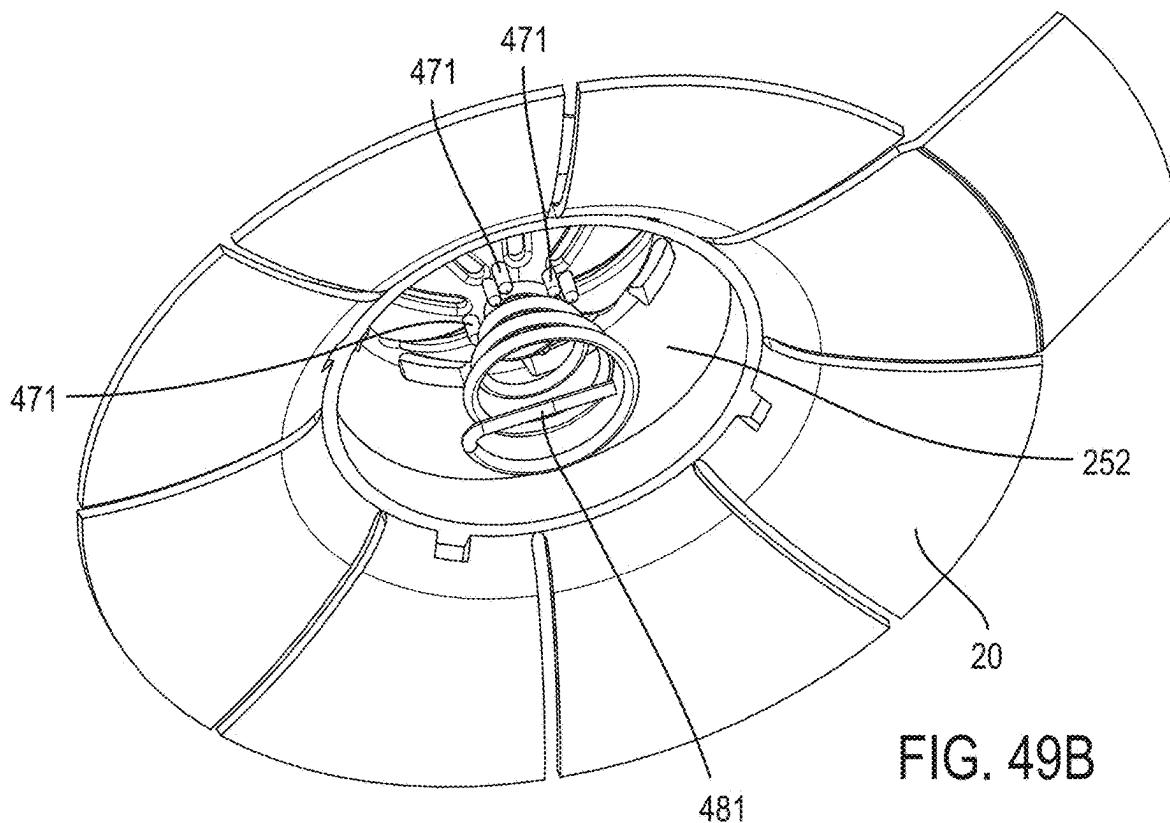


FIG. 47D





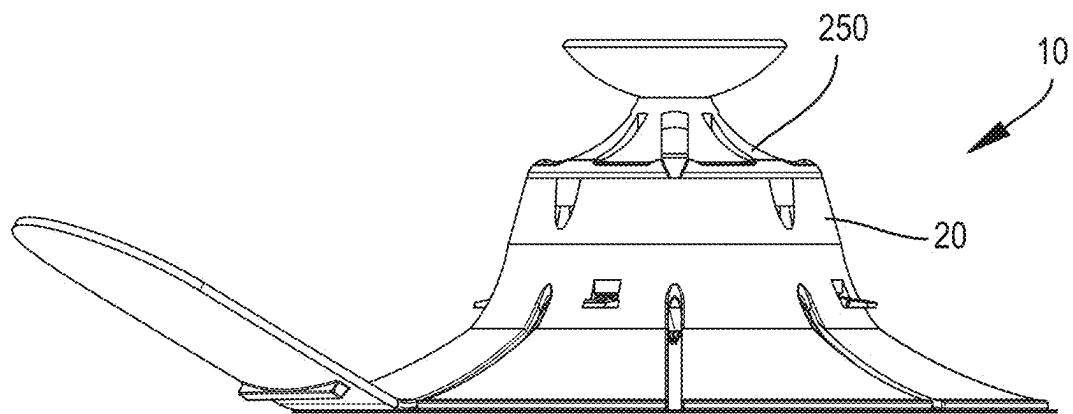


FIG. 50A

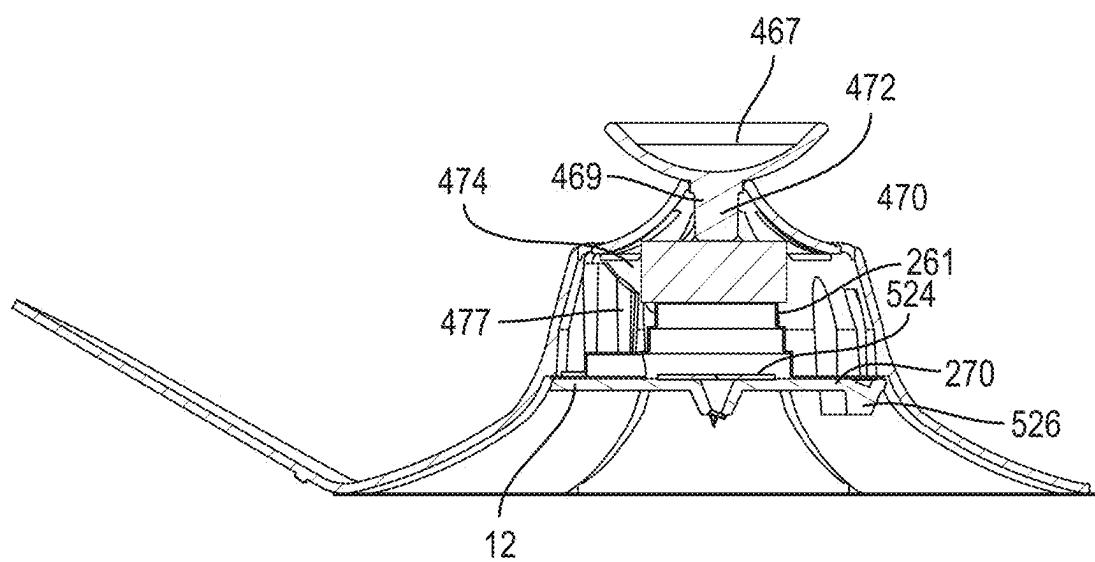


FIG. 50B

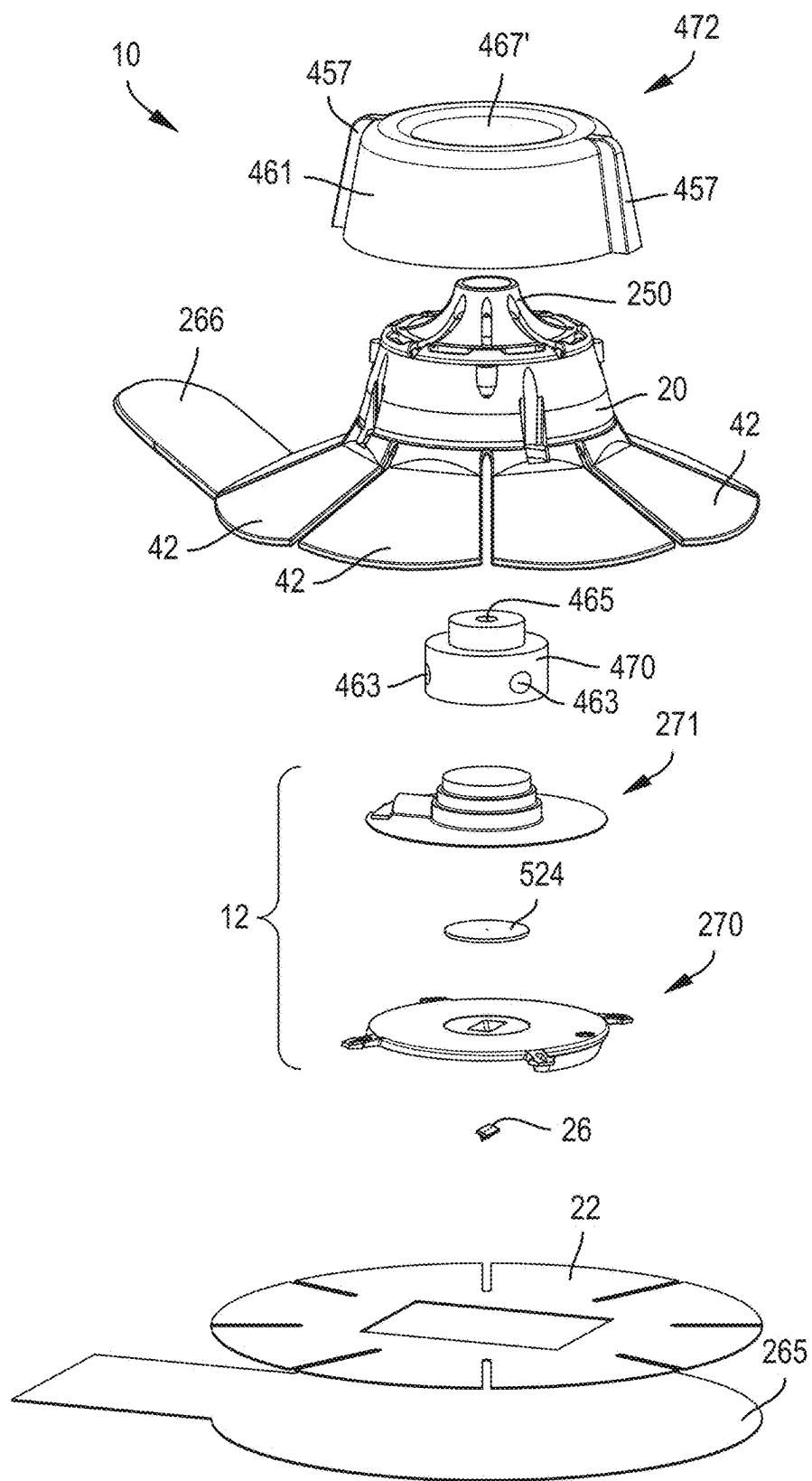


FIG. 51

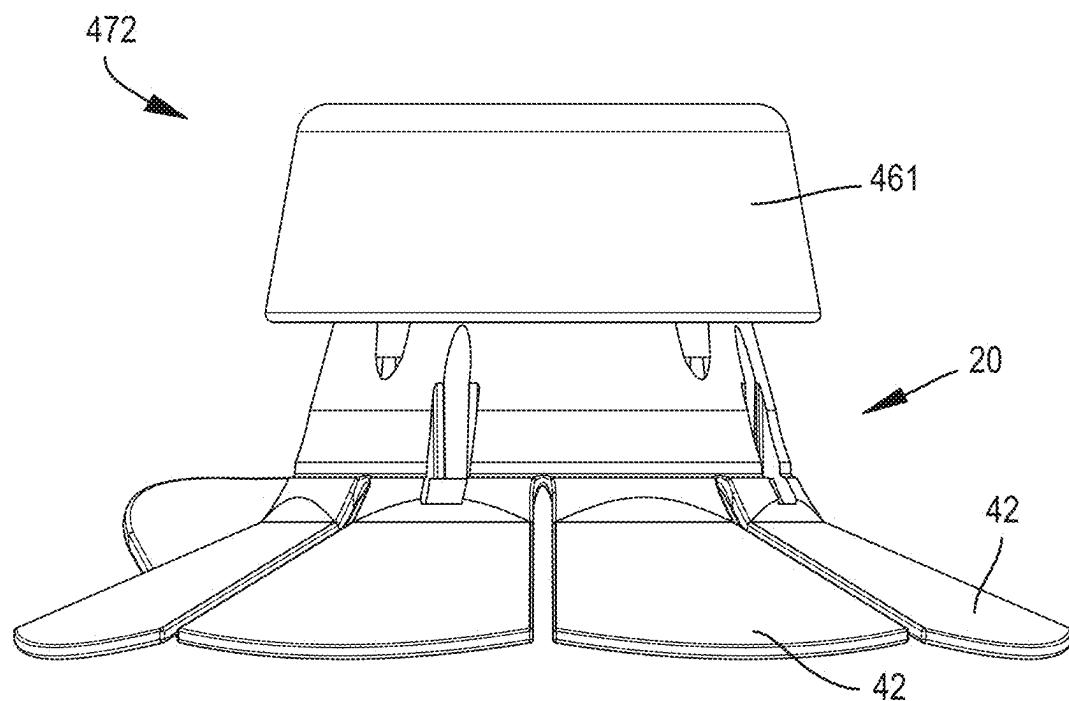


FIG. 52A

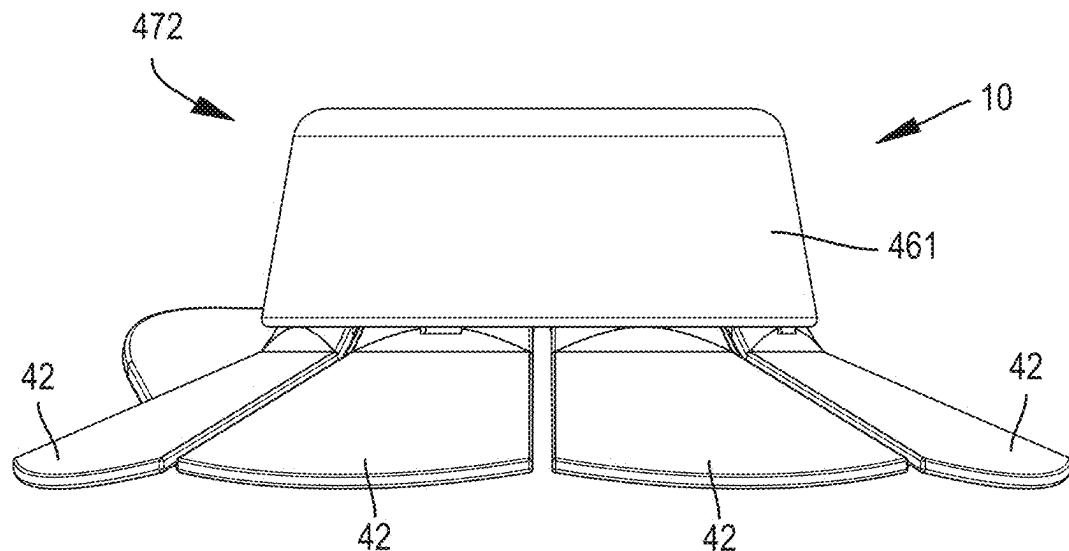


FIG. 52B

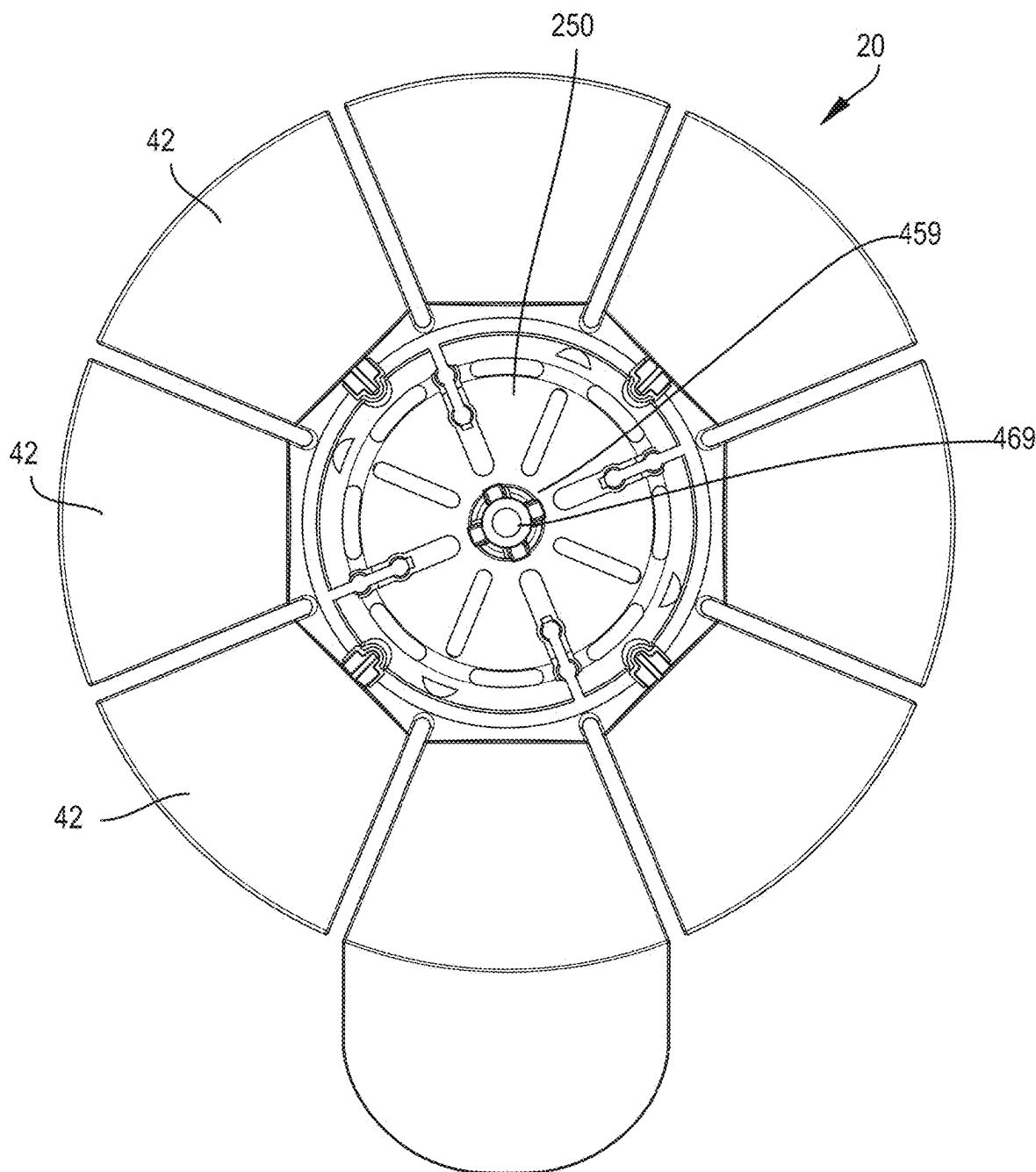
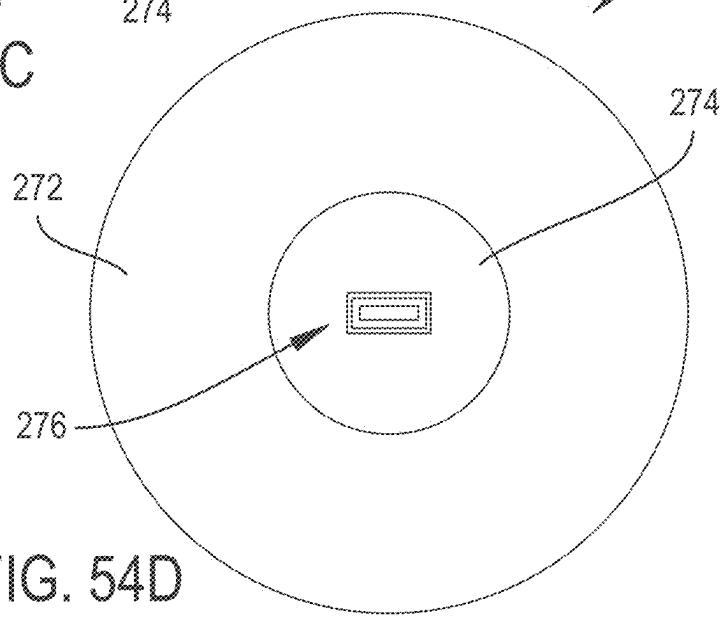
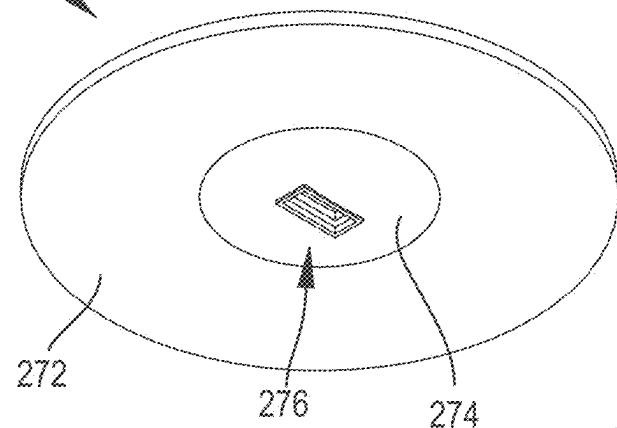
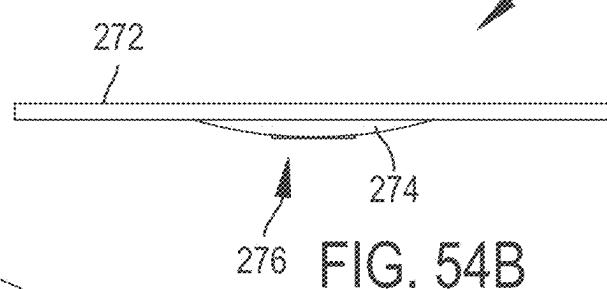
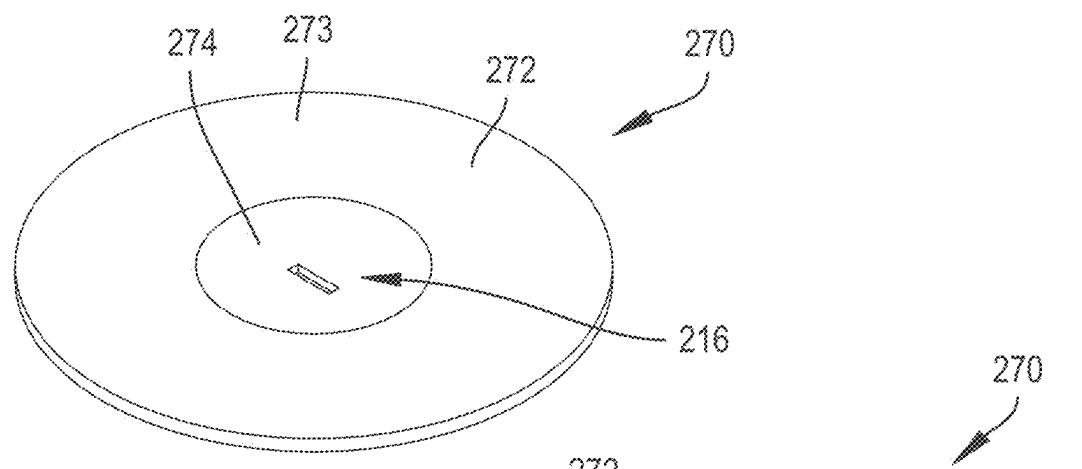


FIG. 53



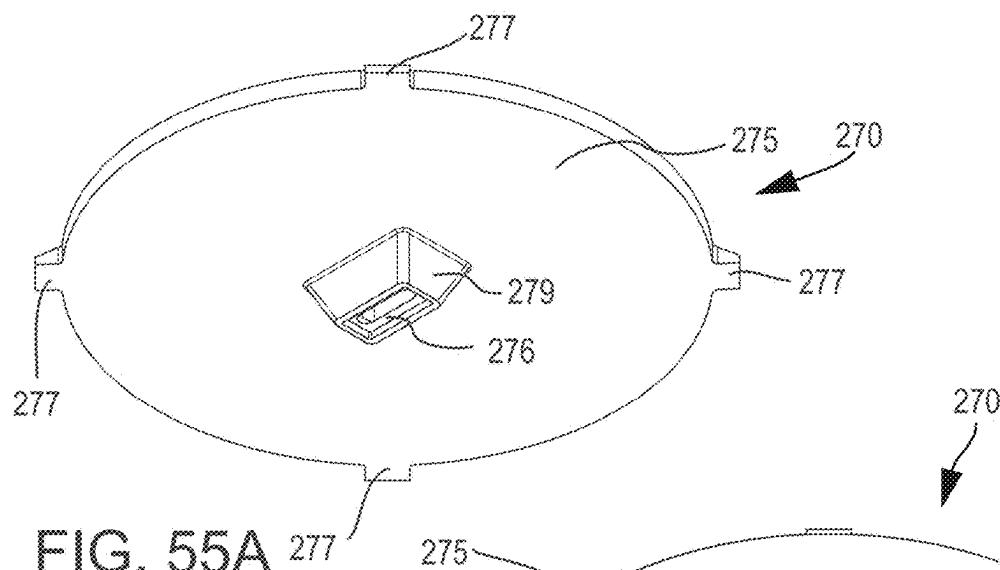


FIG. 55A

277

275

FIG. 55B

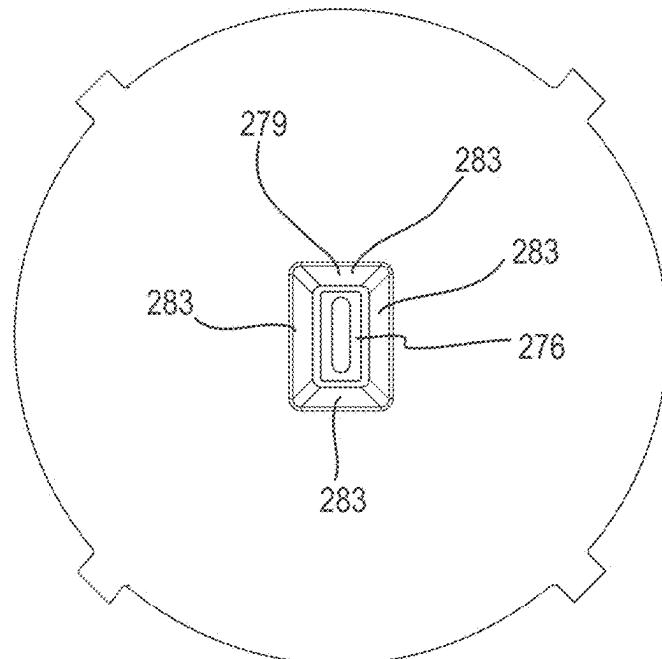
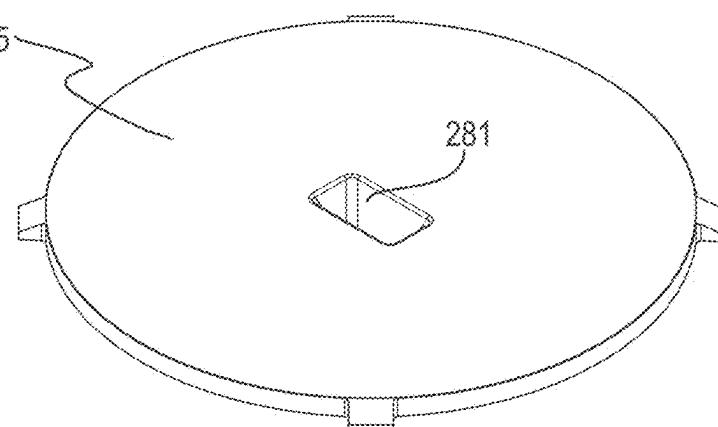
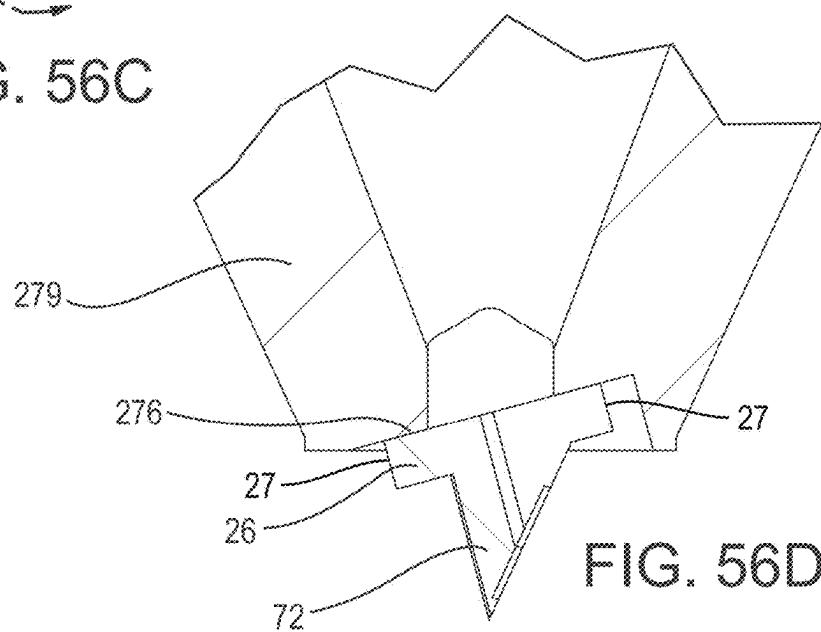
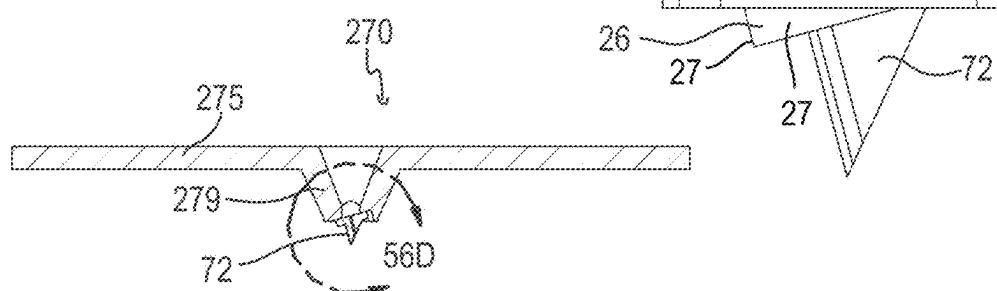
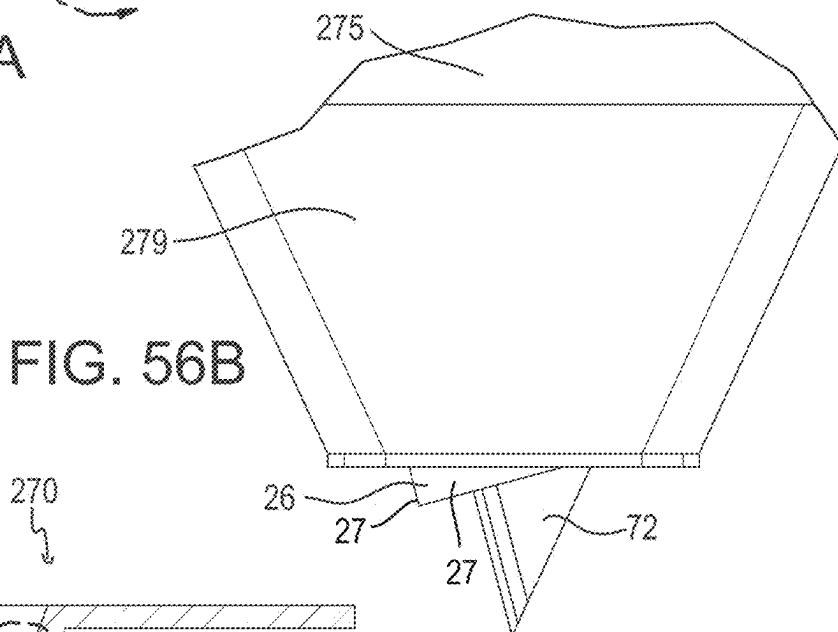
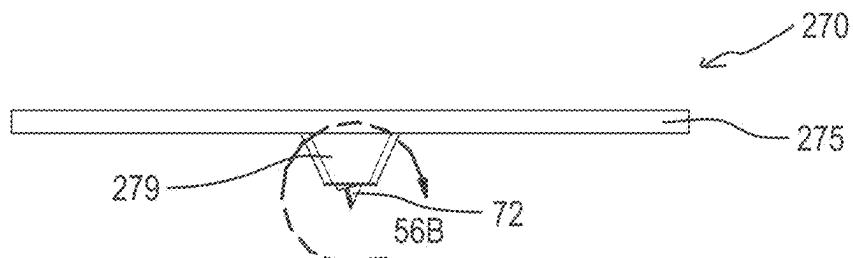


FIG. 55C



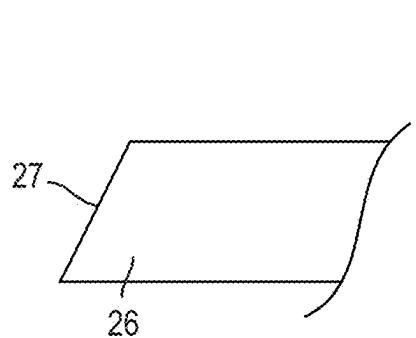


FIG. 57

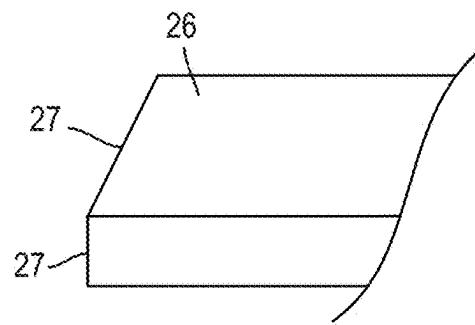


FIG. 58

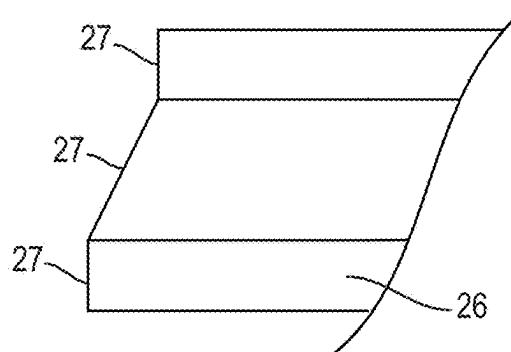


FIG. 59

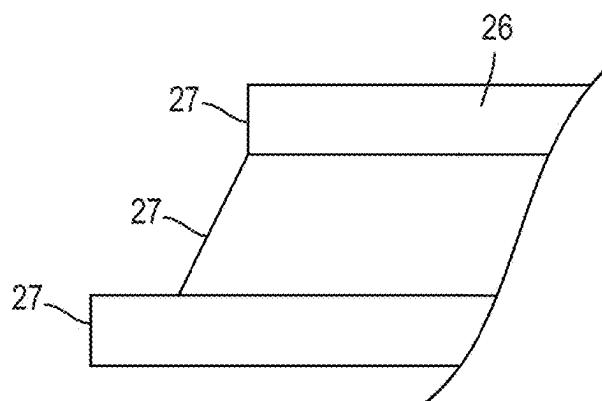


FIG. 60

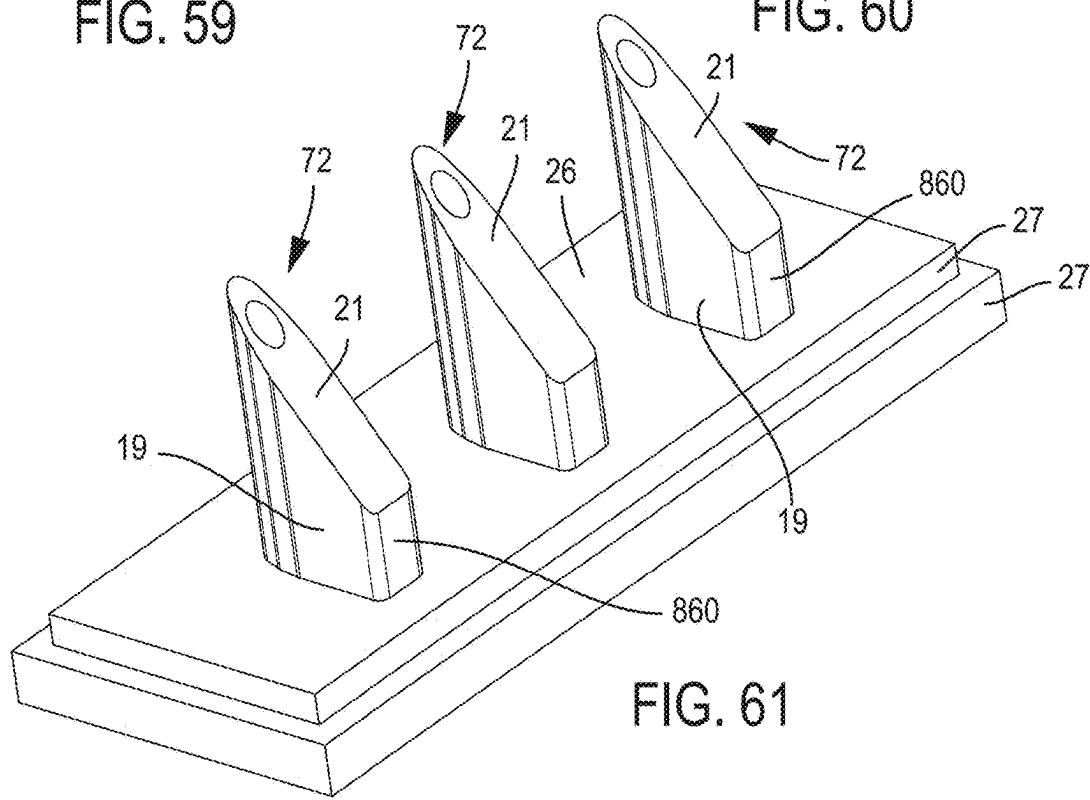


FIG. 61

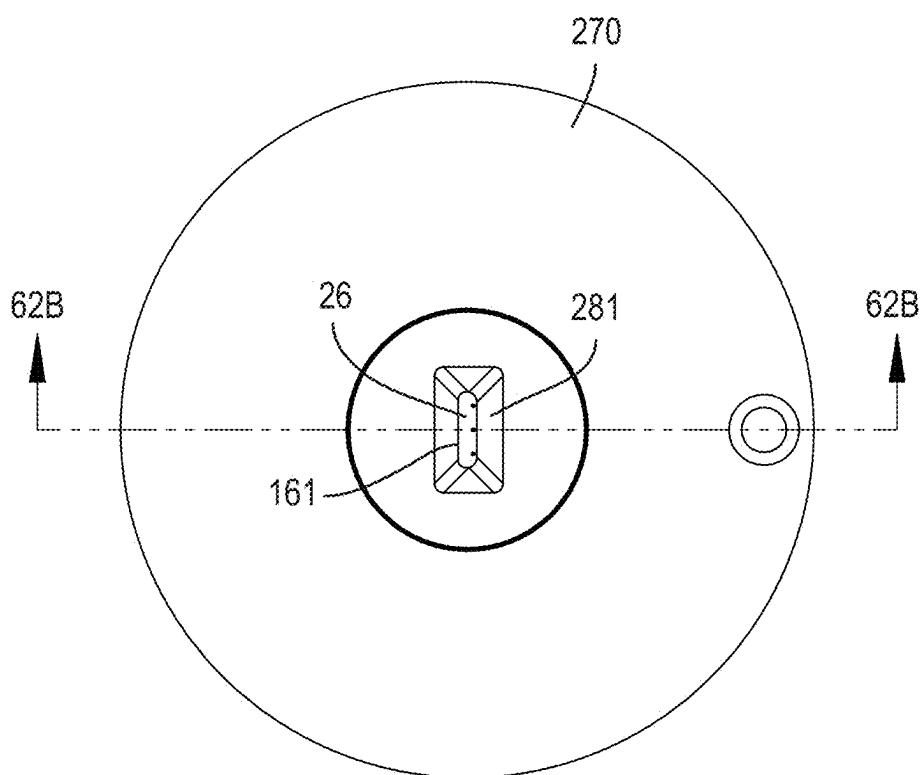


FIG. 62A

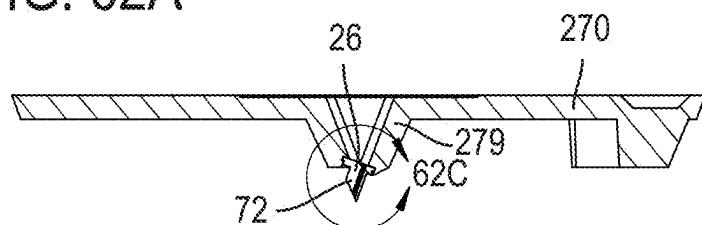


FIG. 62B

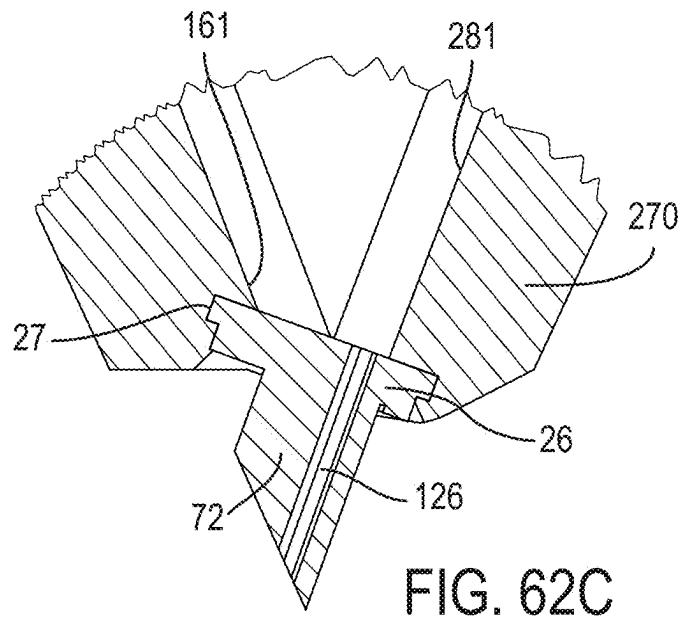


FIG. 62C

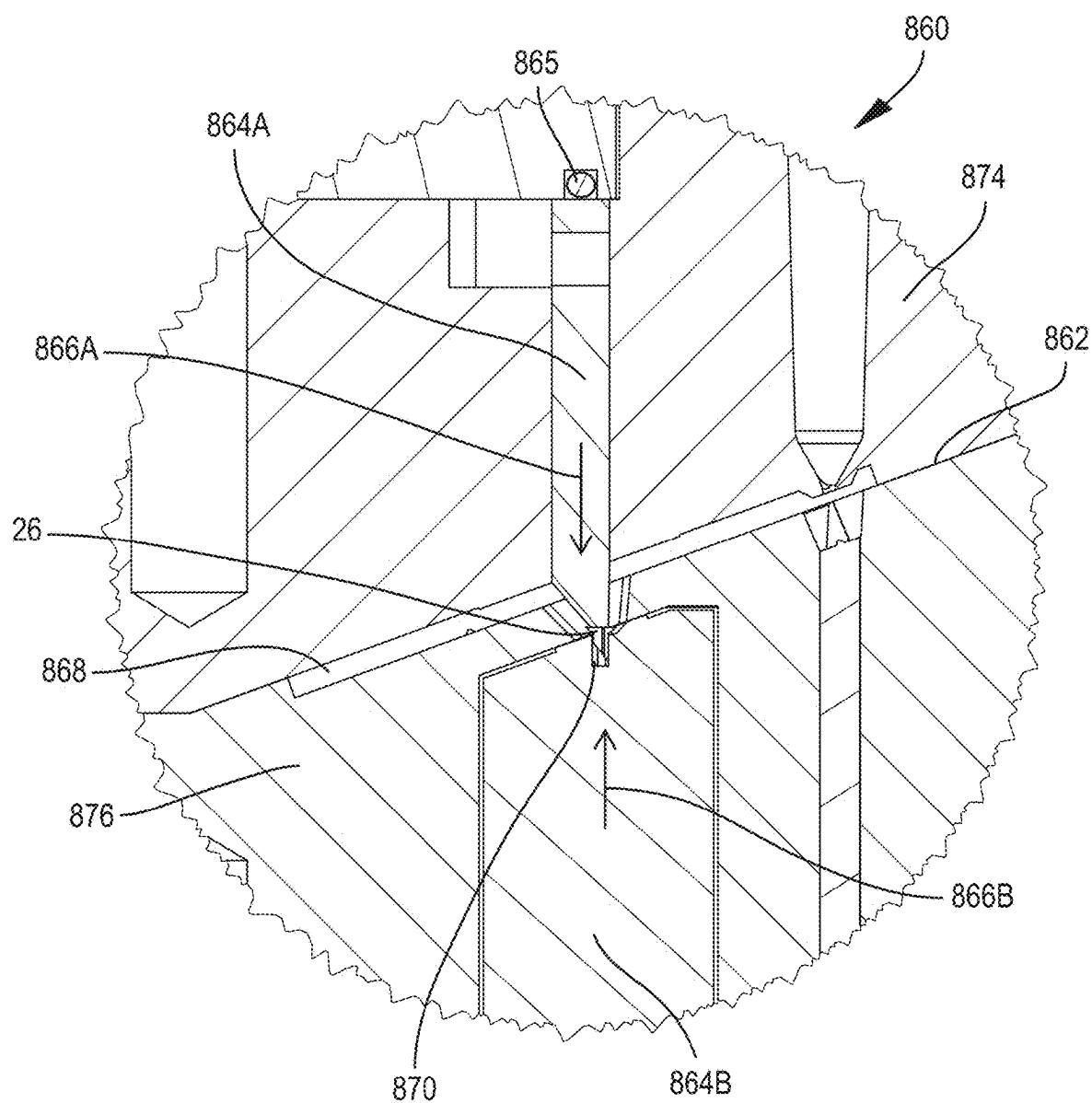


FIG. 63

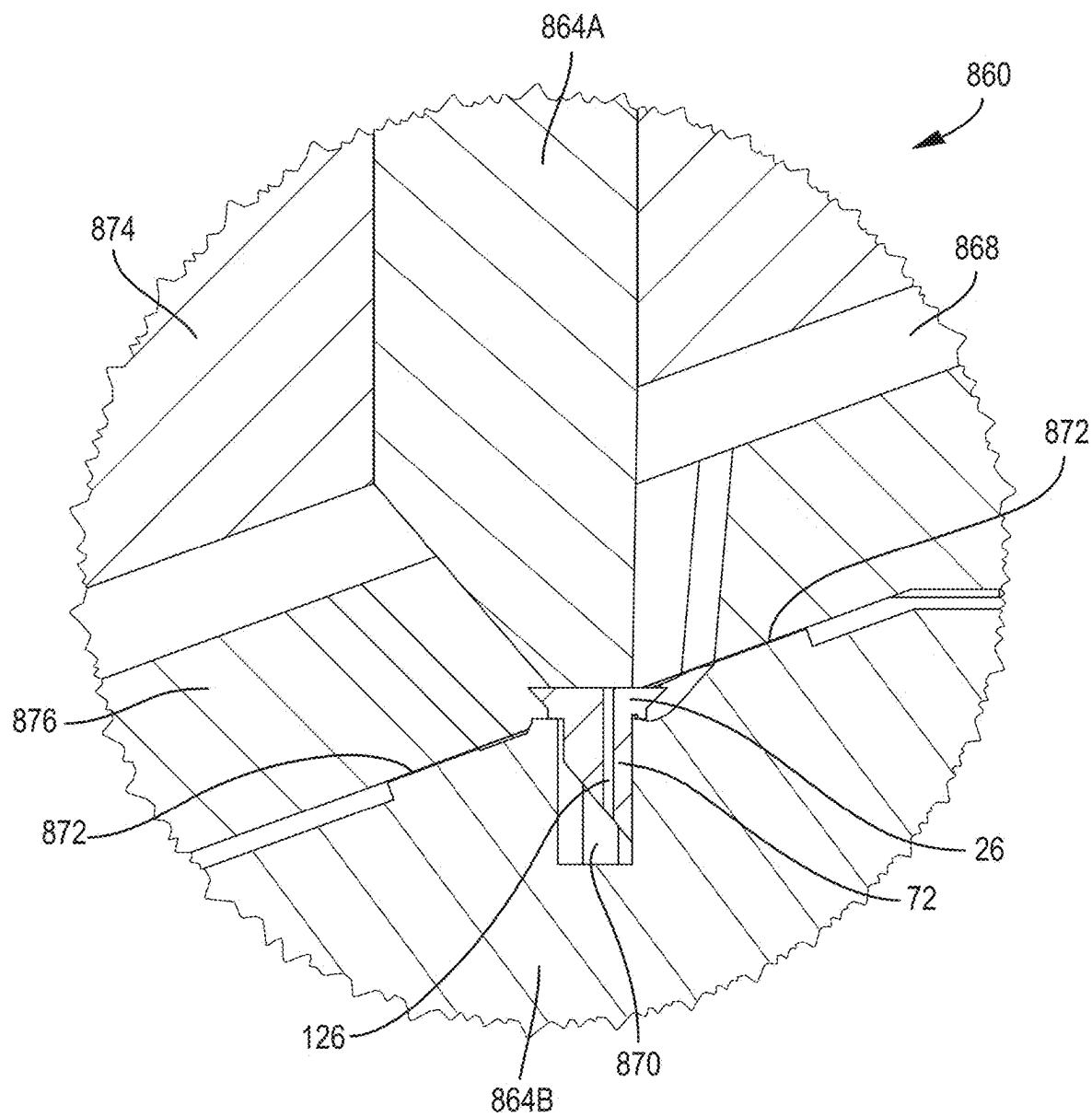


FIG. 64

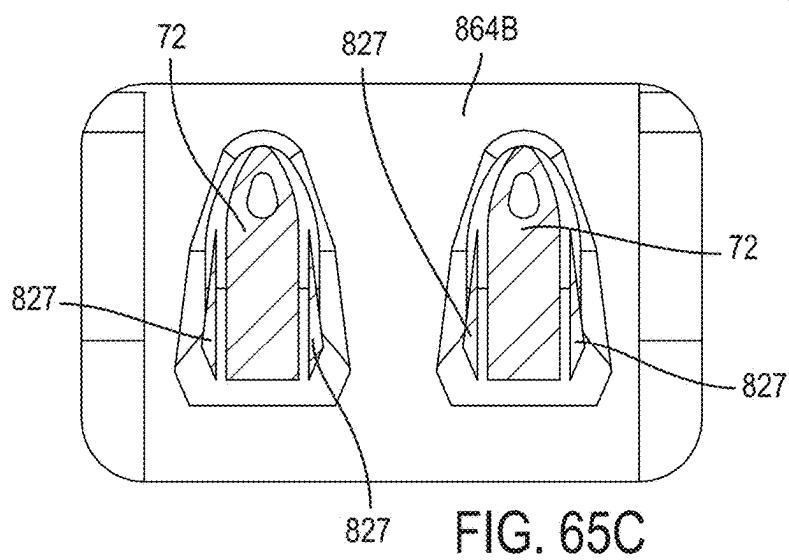
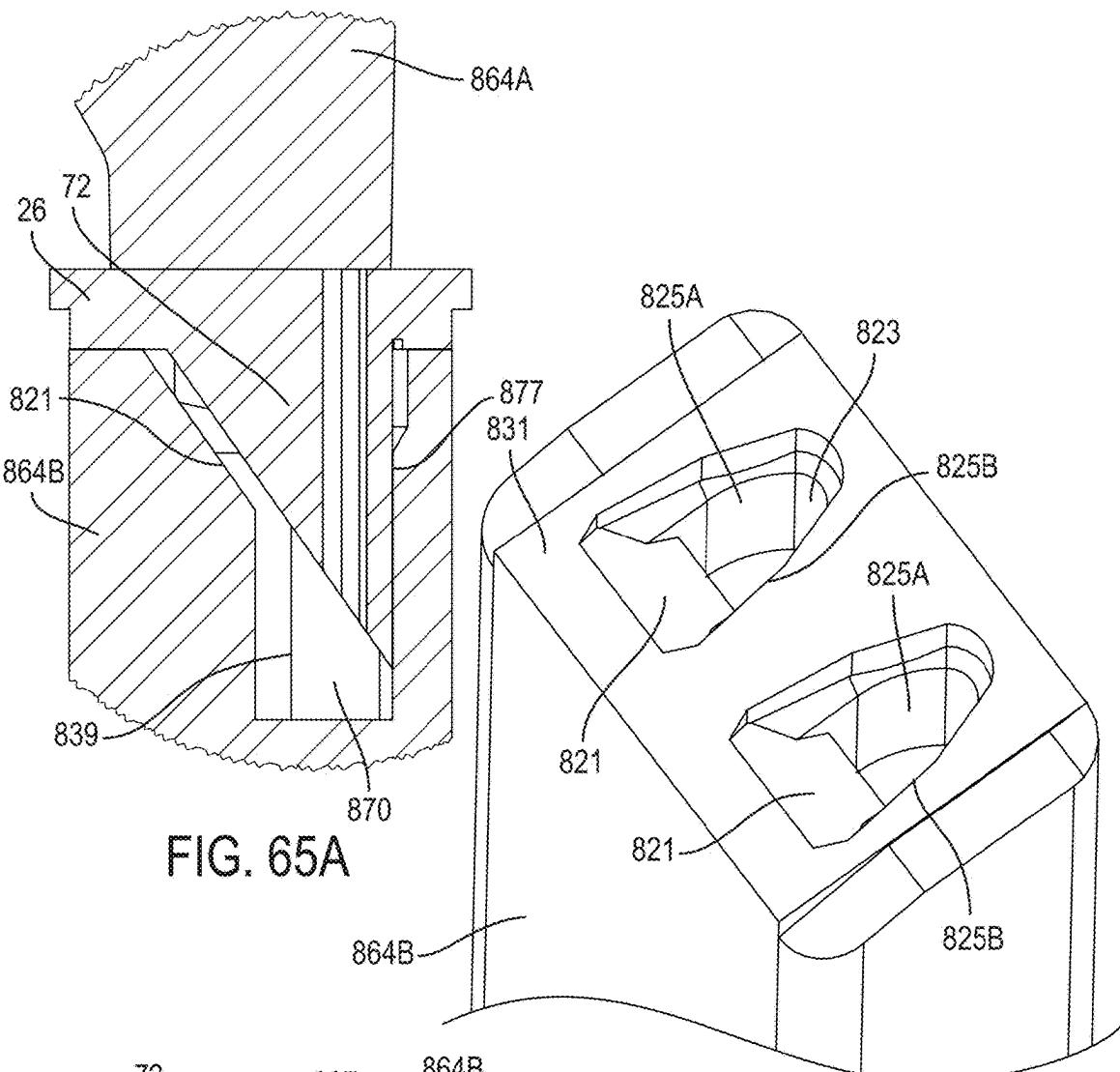


FIG. 65C

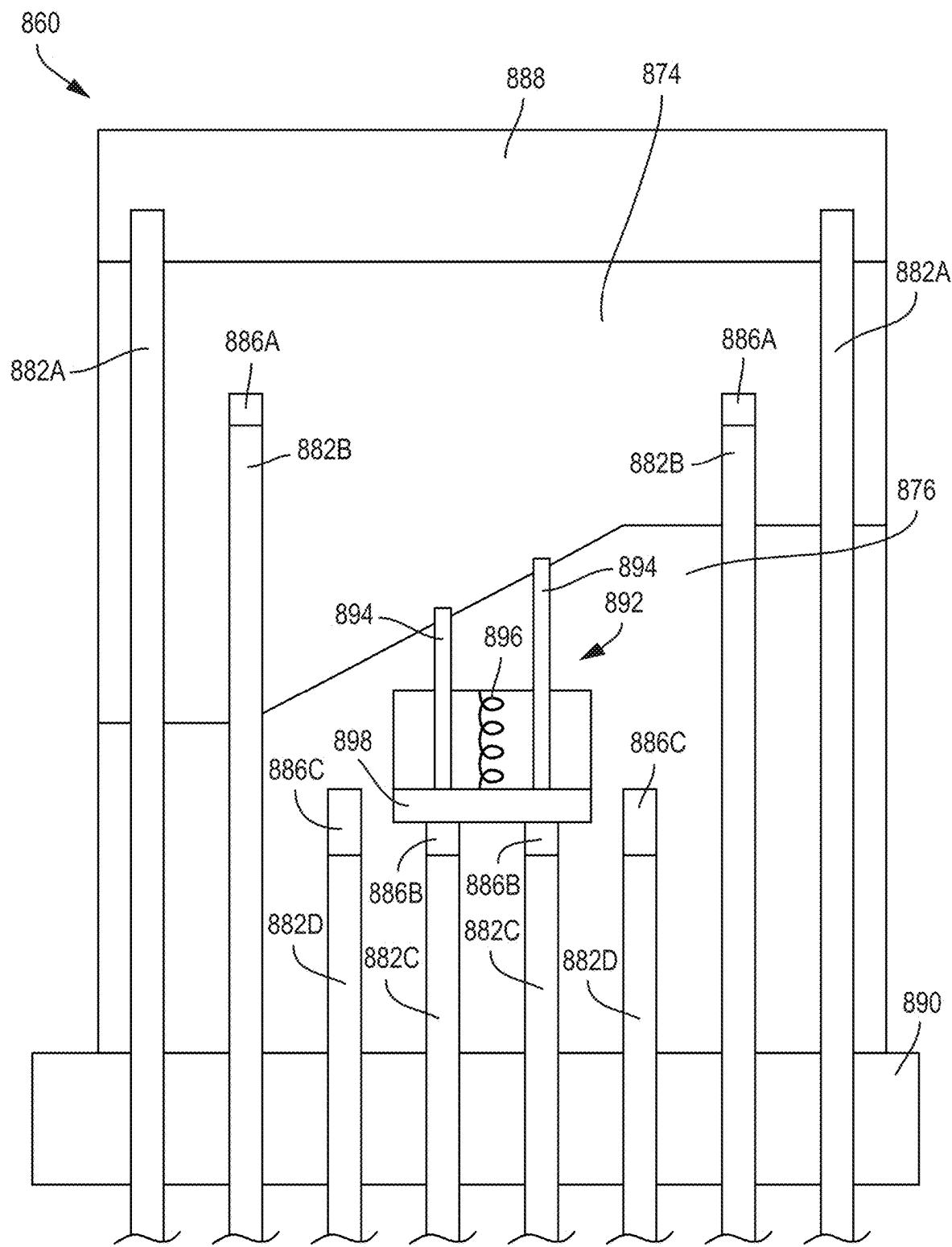


FIG. 66

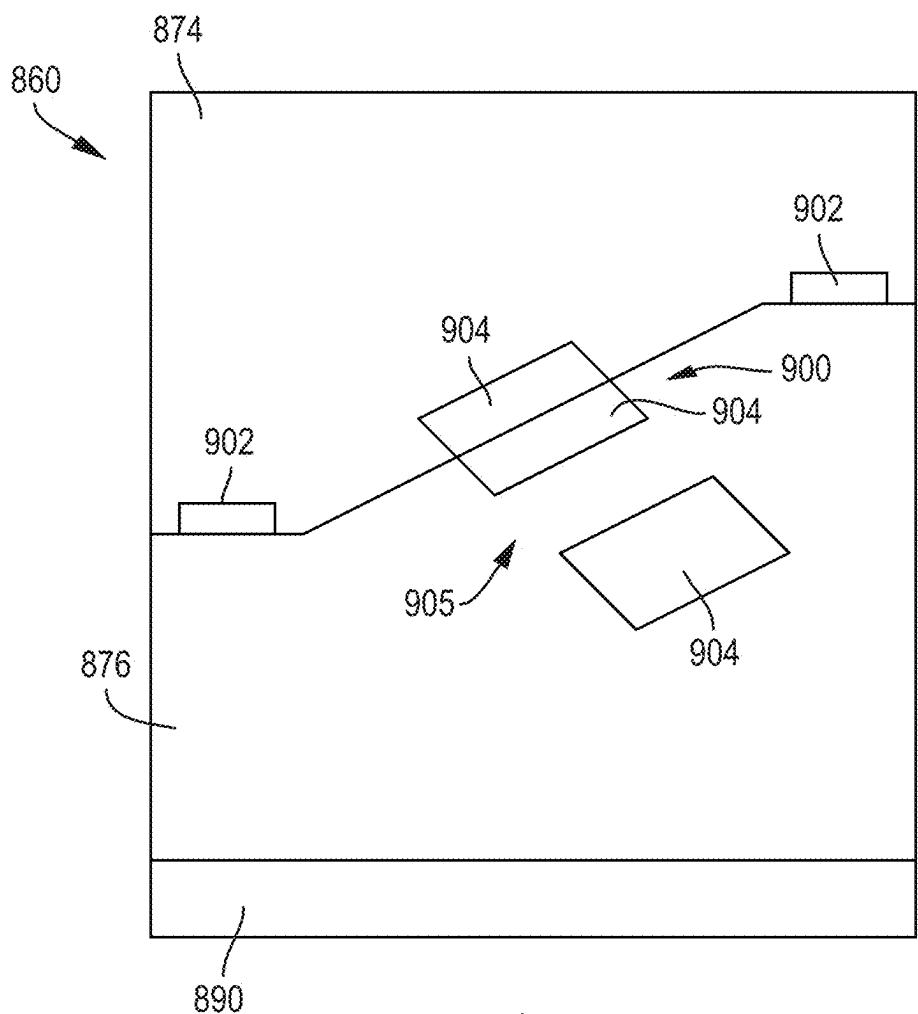


FIG. 67

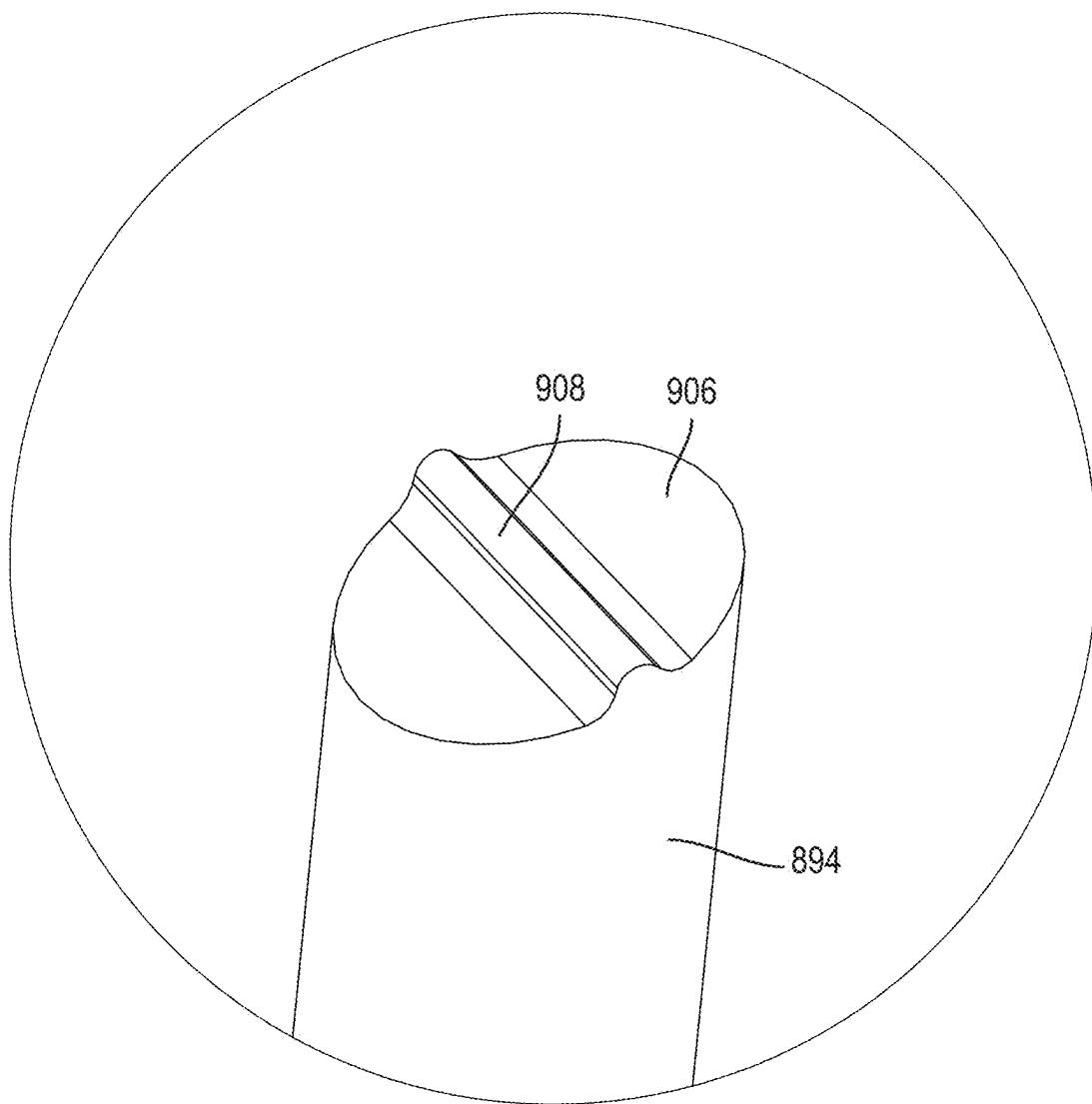


FIG. 68

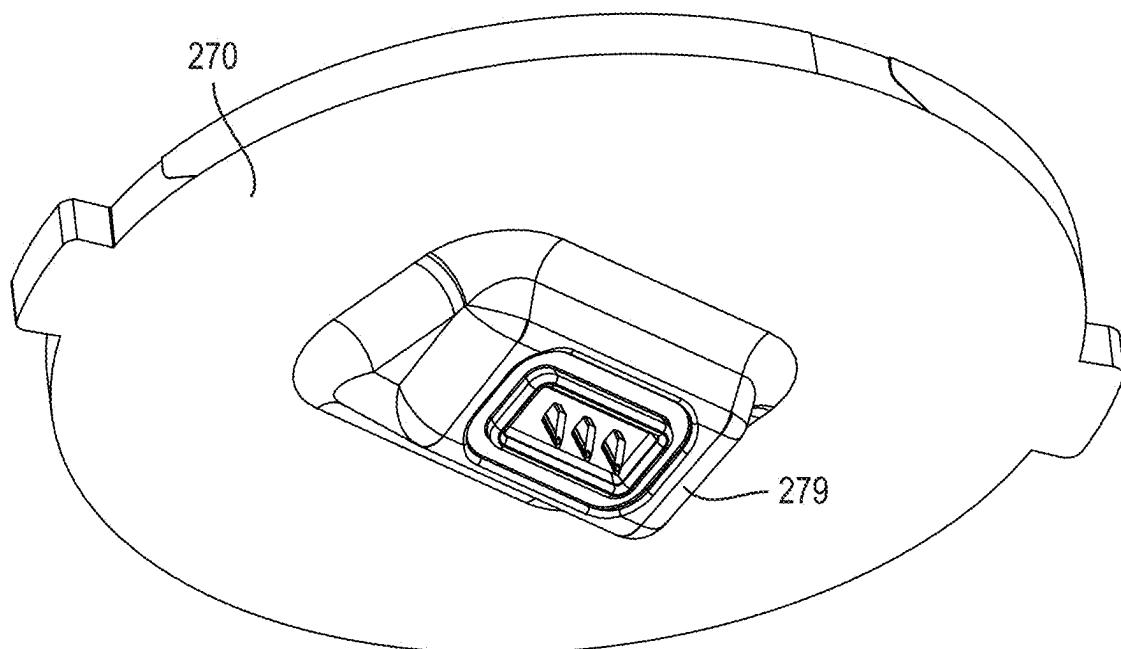


FIG. 69A

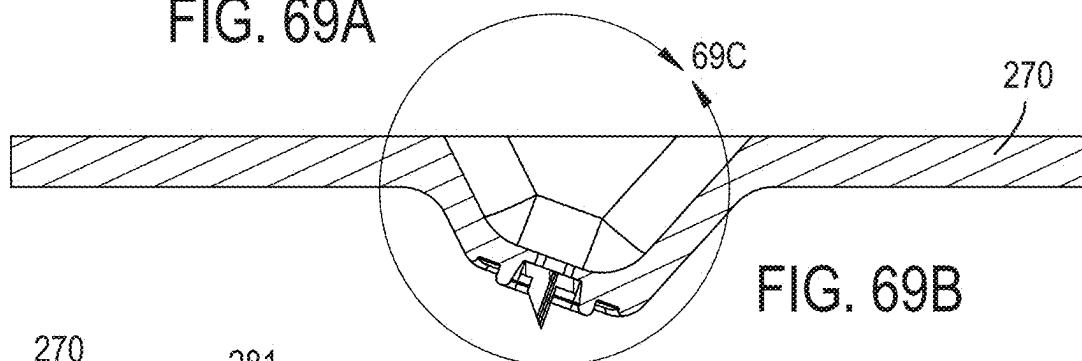


FIG. 69B

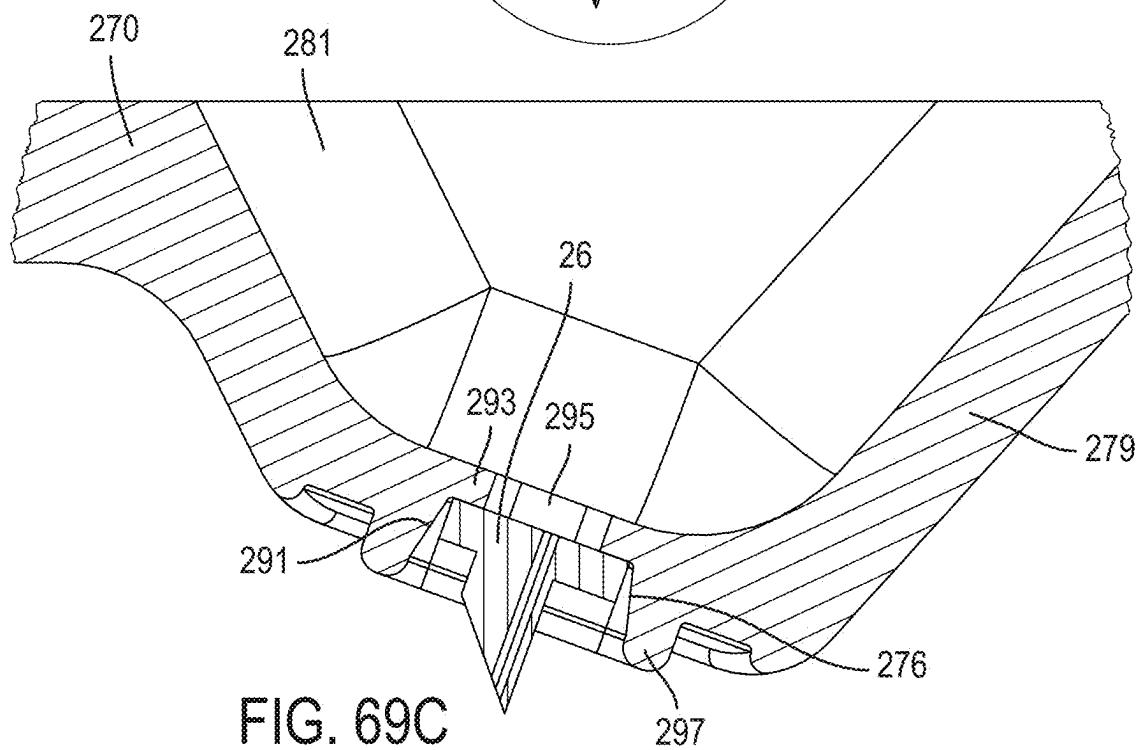
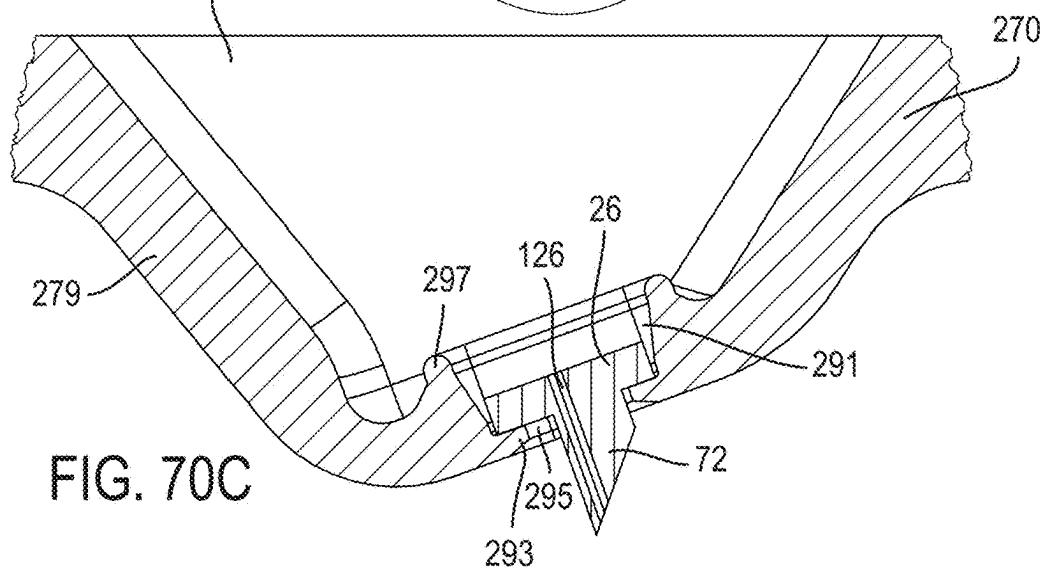
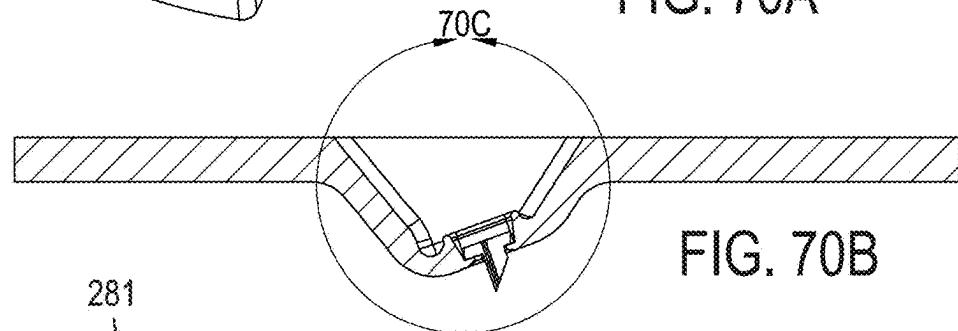
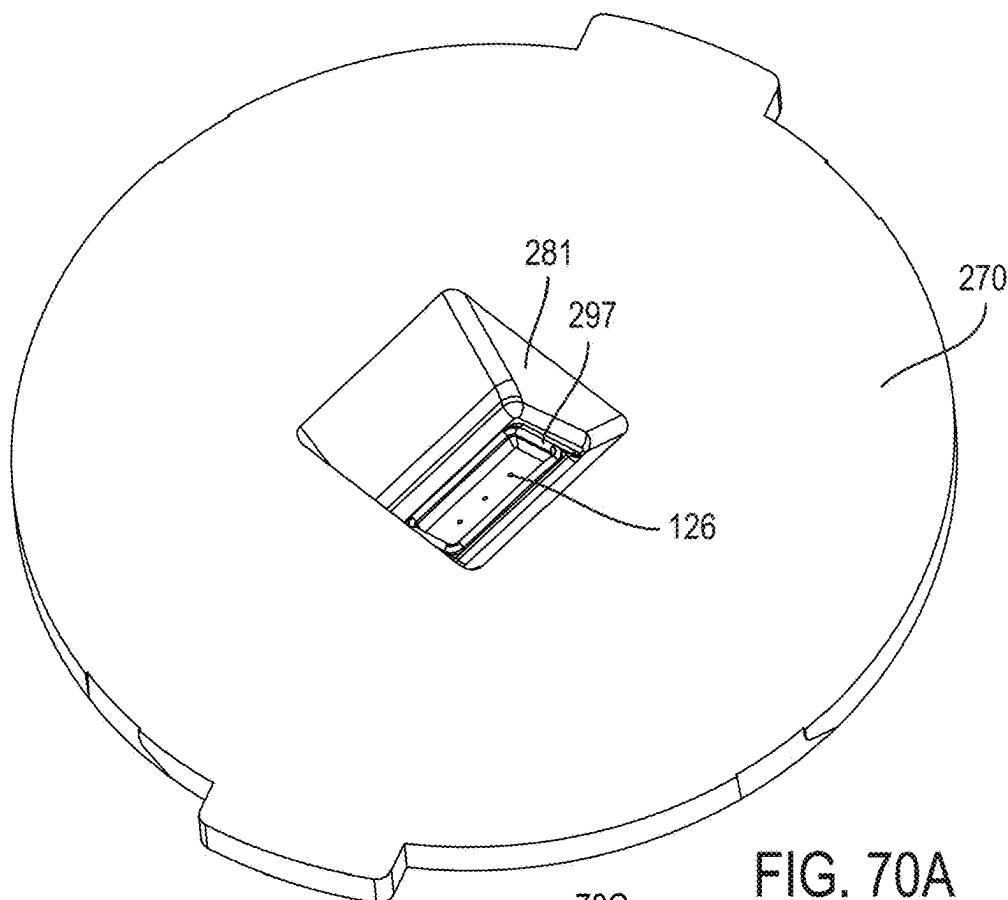


FIG. 69C



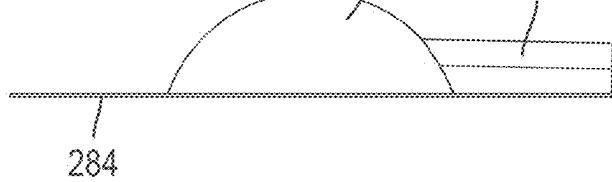
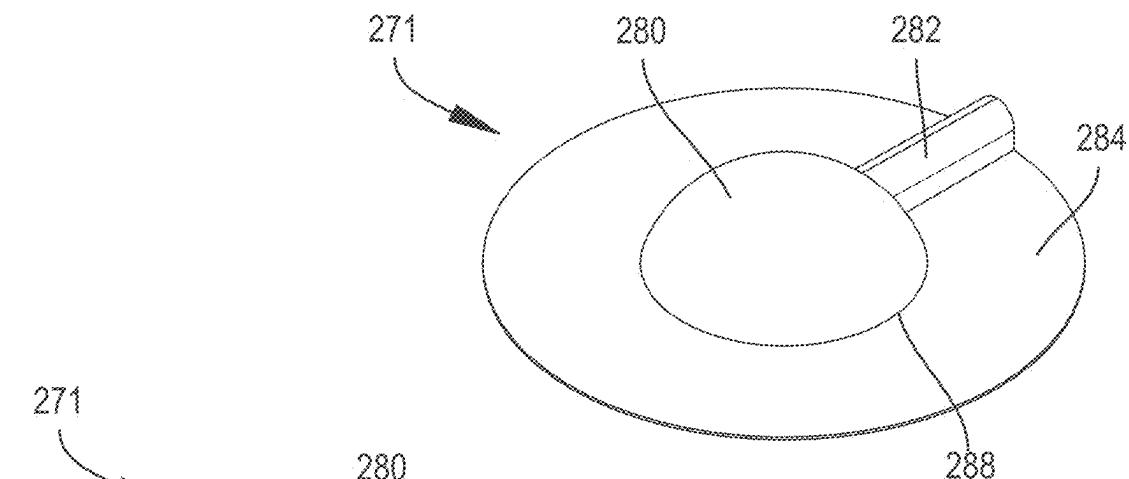


FIG. 71B

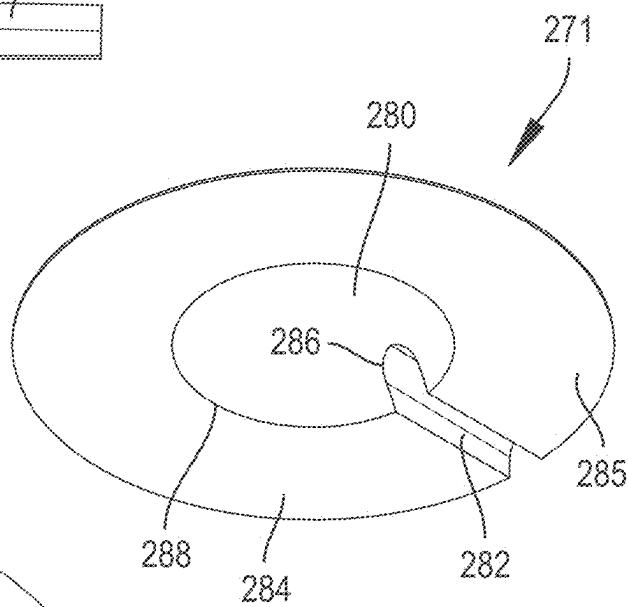


FIG. 71C

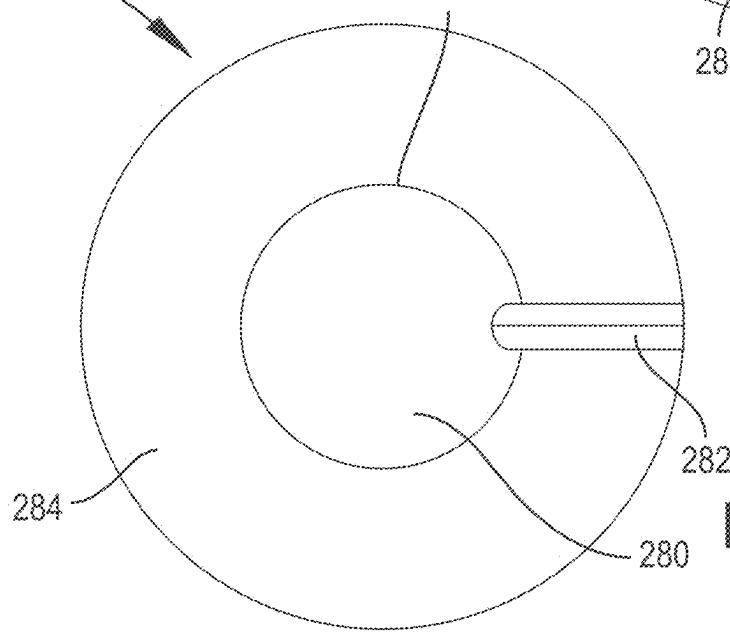


FIG. 71D

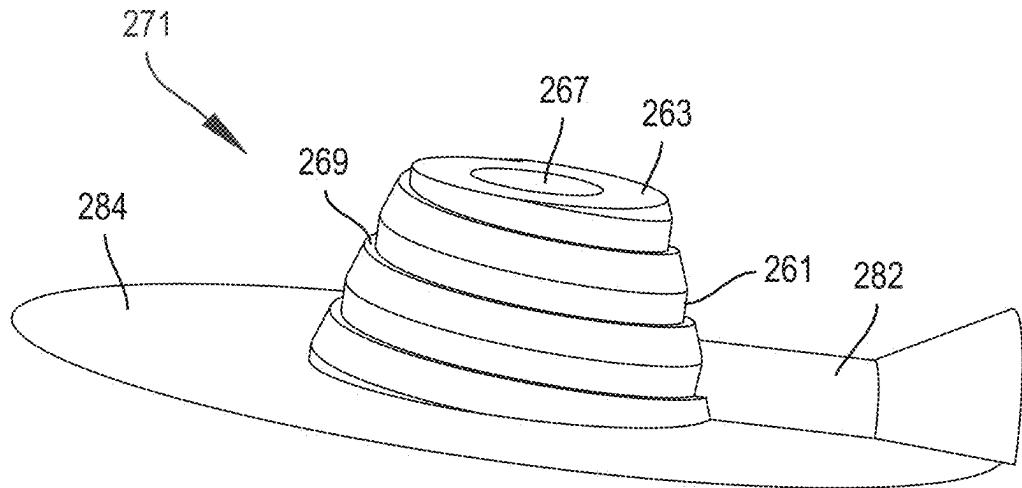


FIG. 72

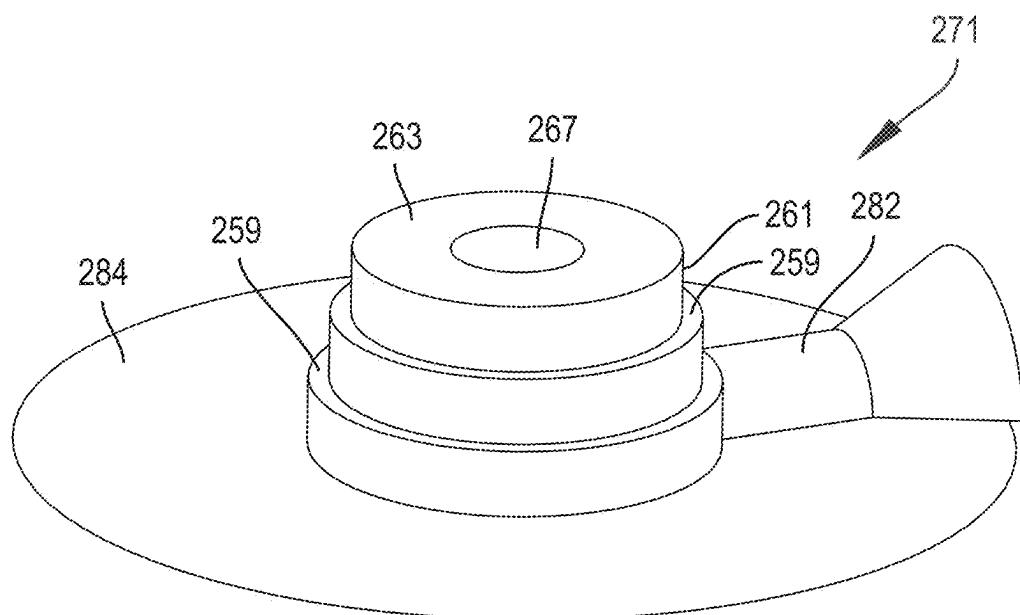


FIG. 73

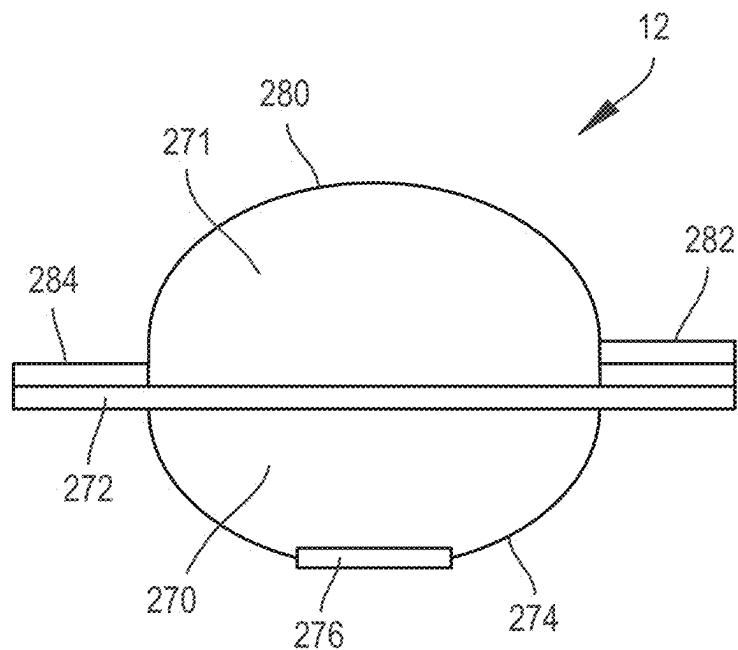


FIG. 74

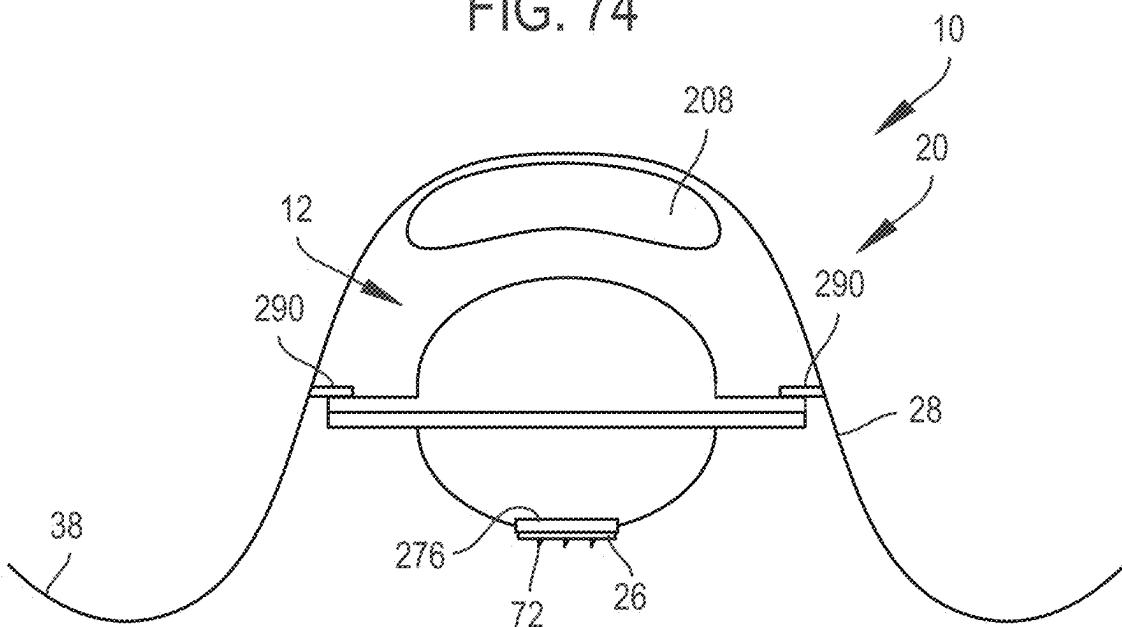


FIG. 75

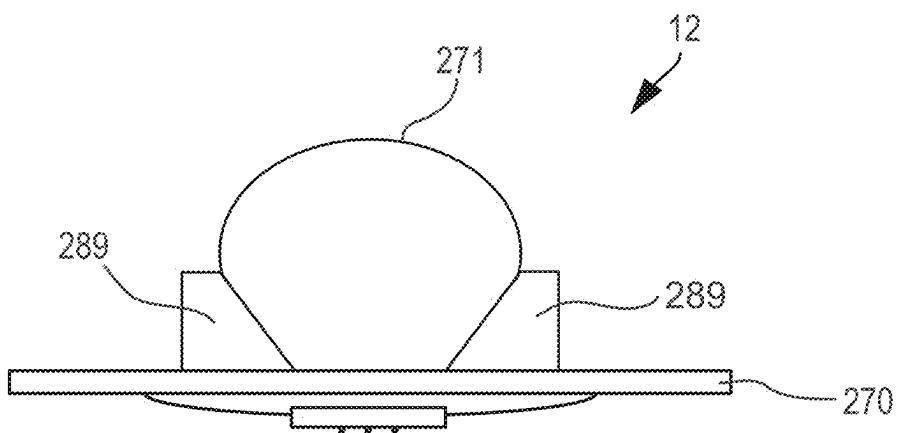


FIG. 76A

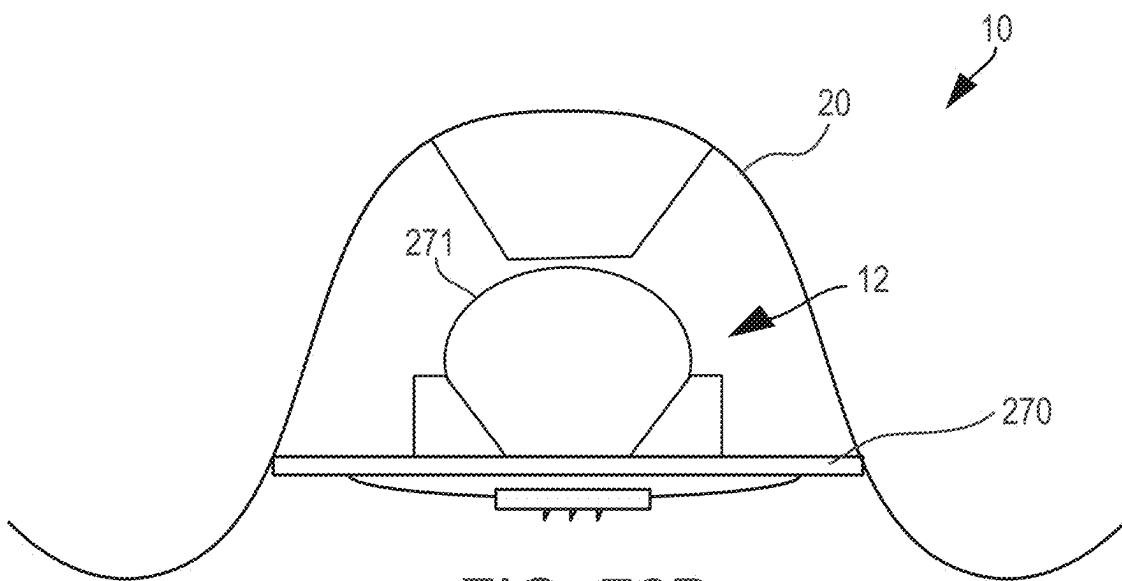


FIG. 76B

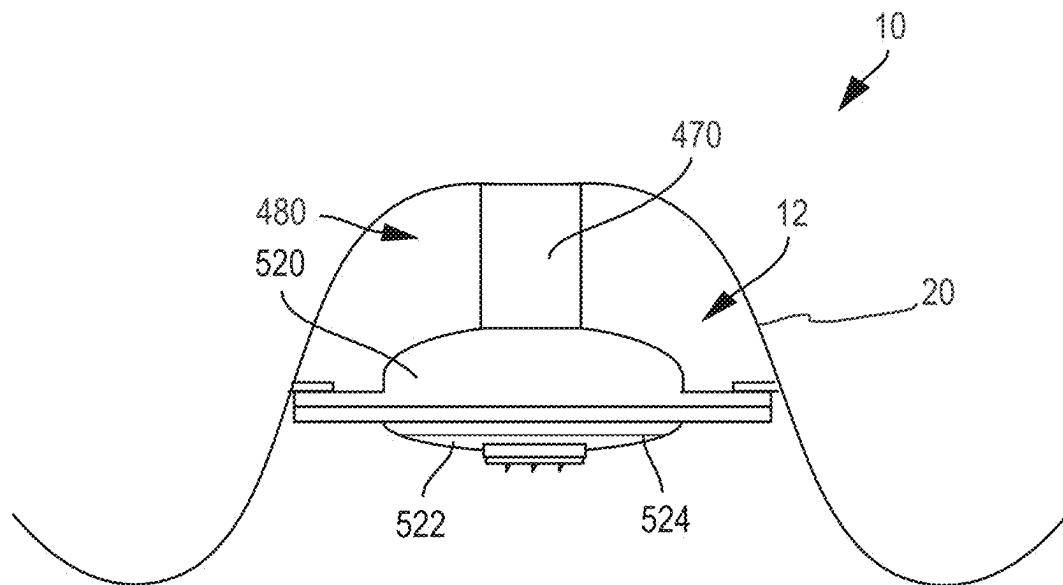


FIG. 77

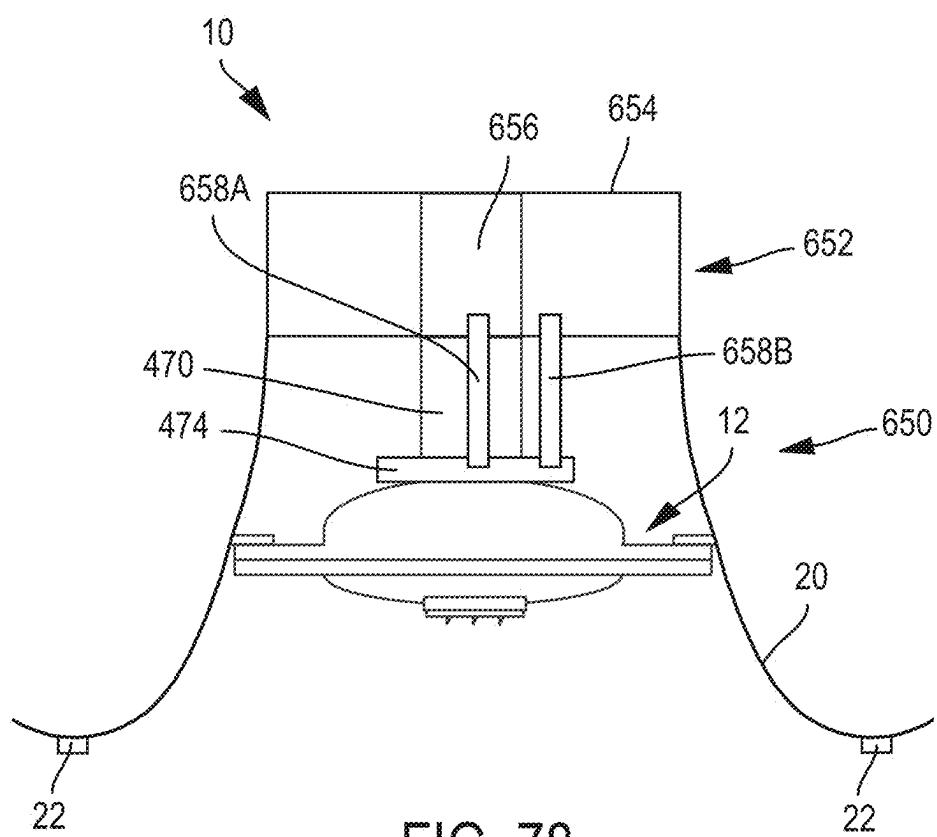


FIG. 78

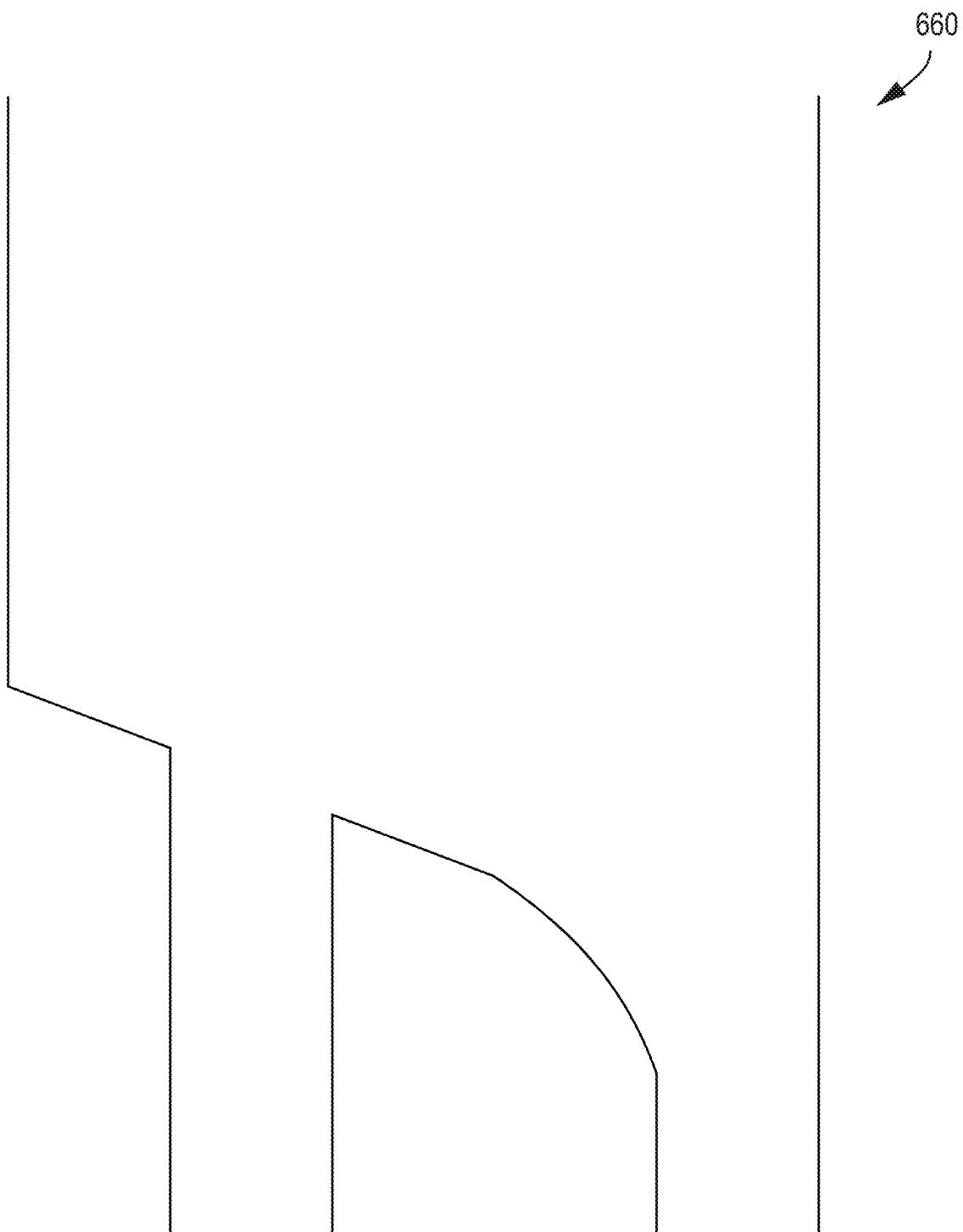


FIG. 79A

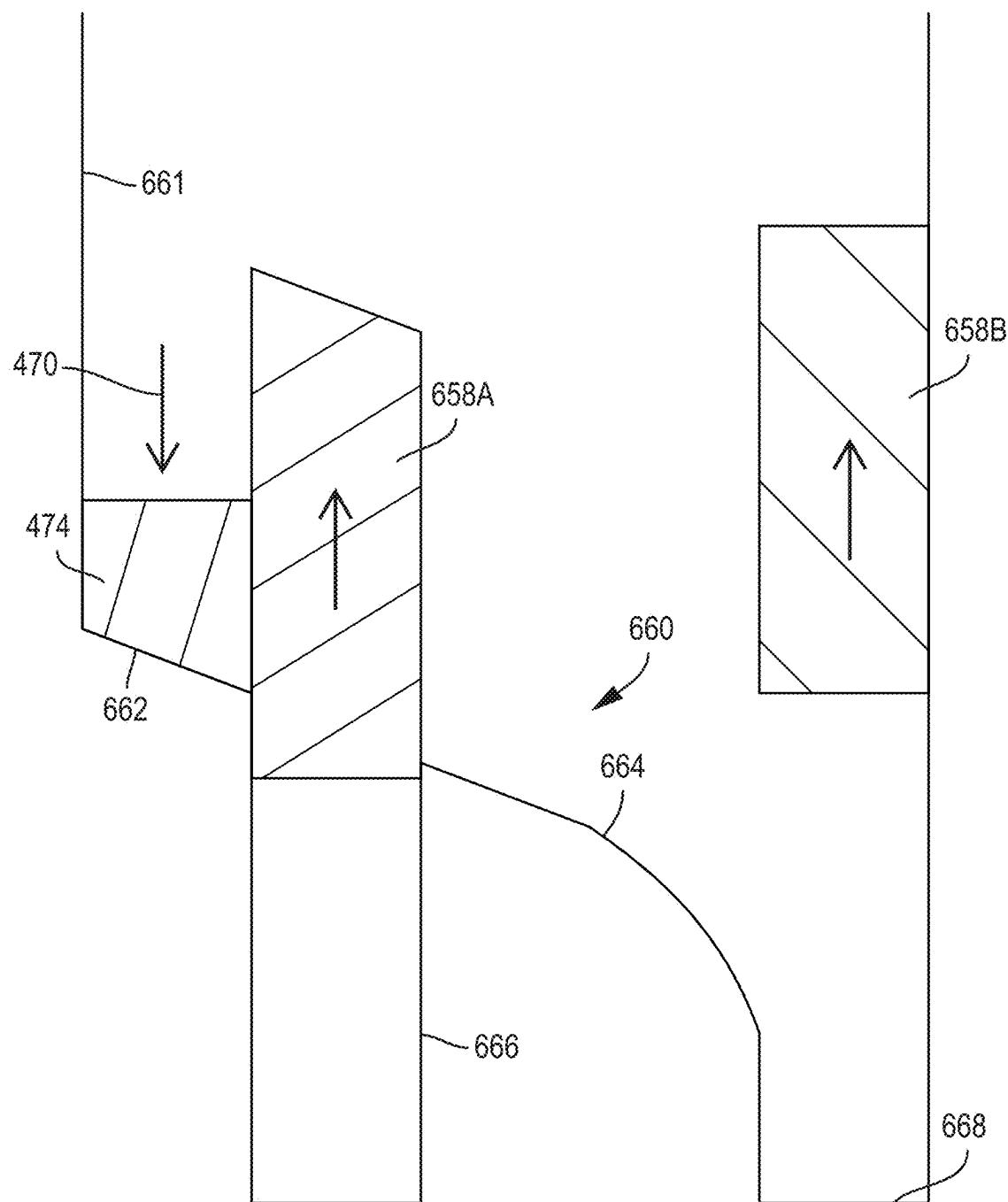


FIG. 79B

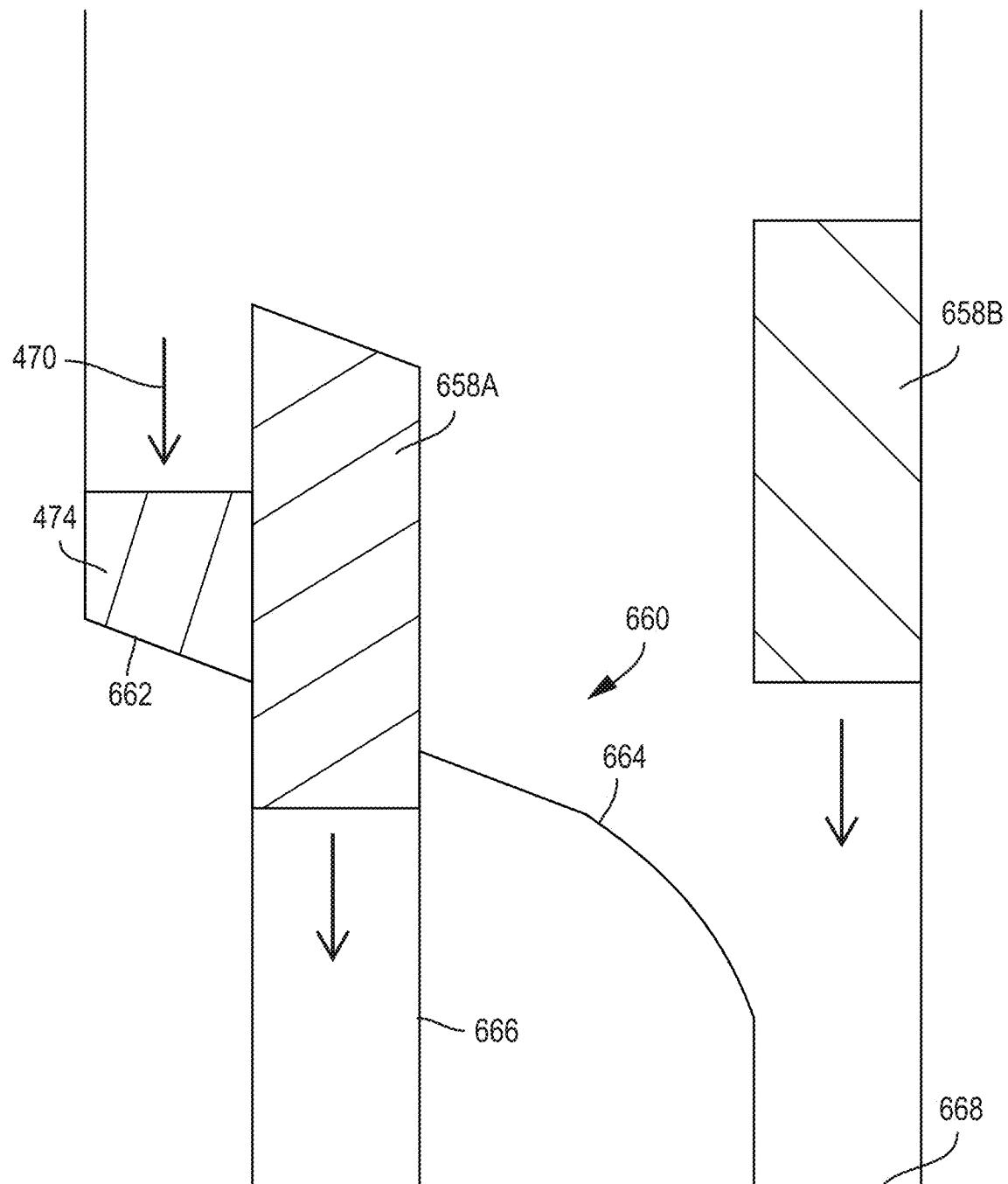


FIG. 79C

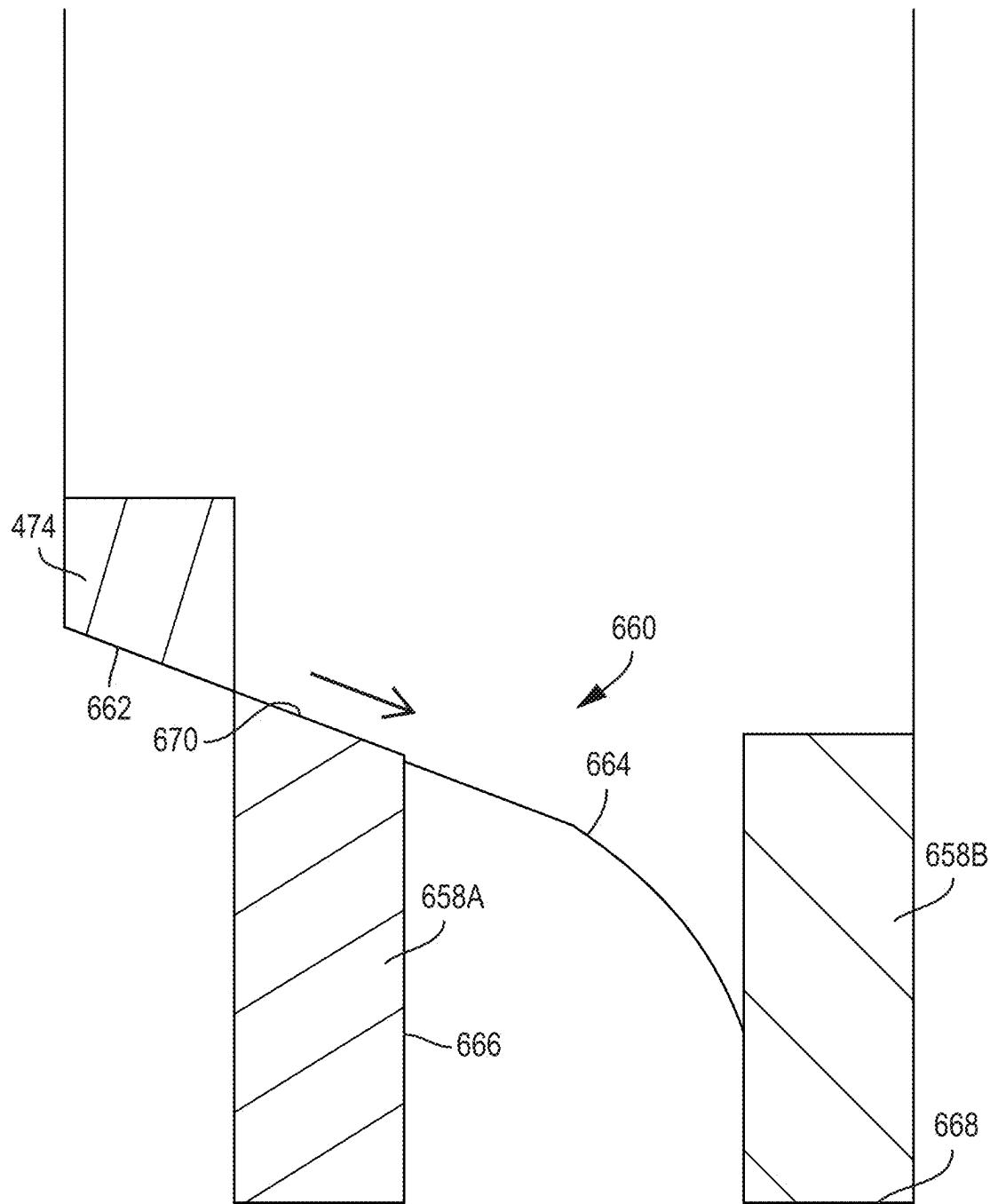


FIG. 79D

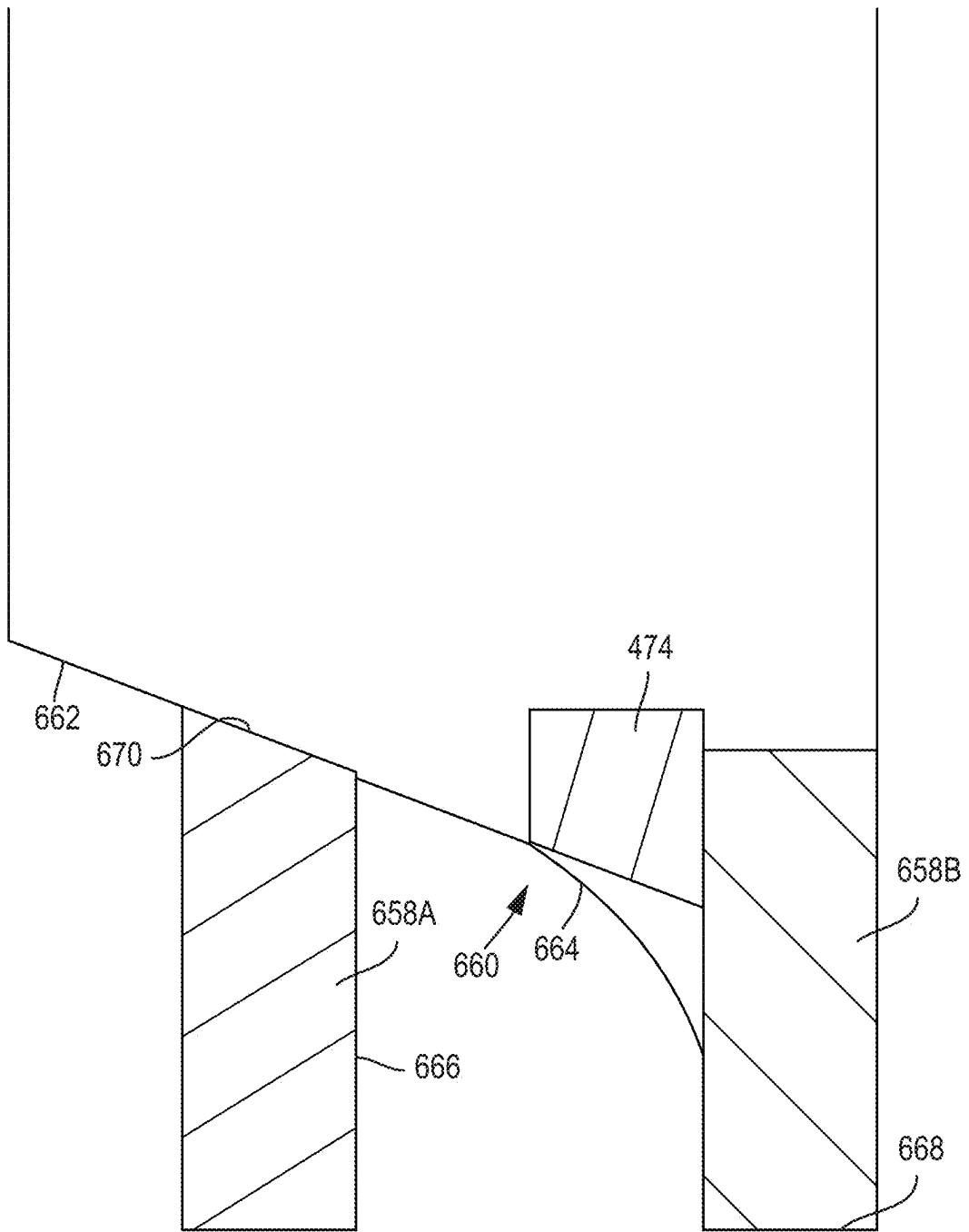


FIG. 79E

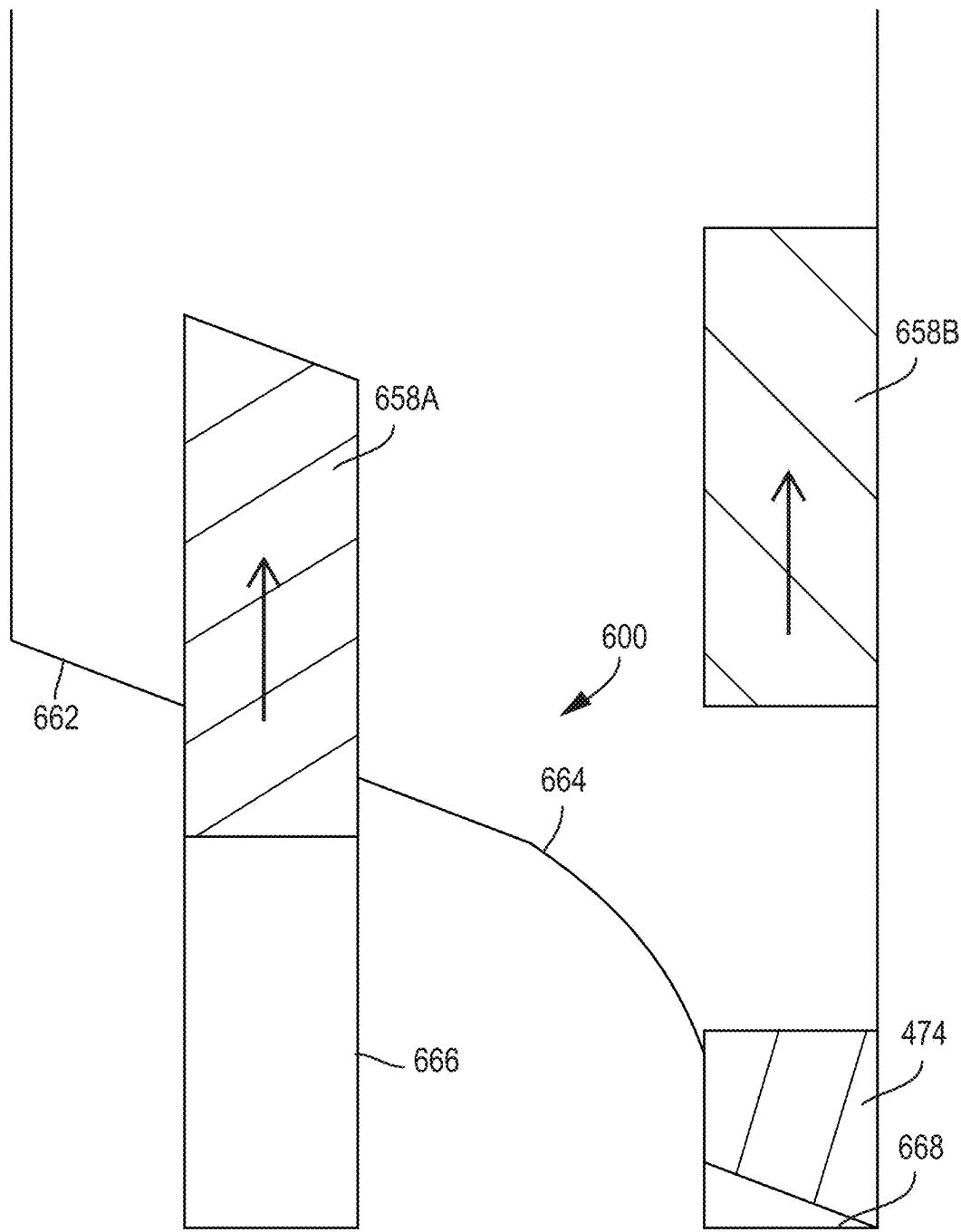


FIG. 79F

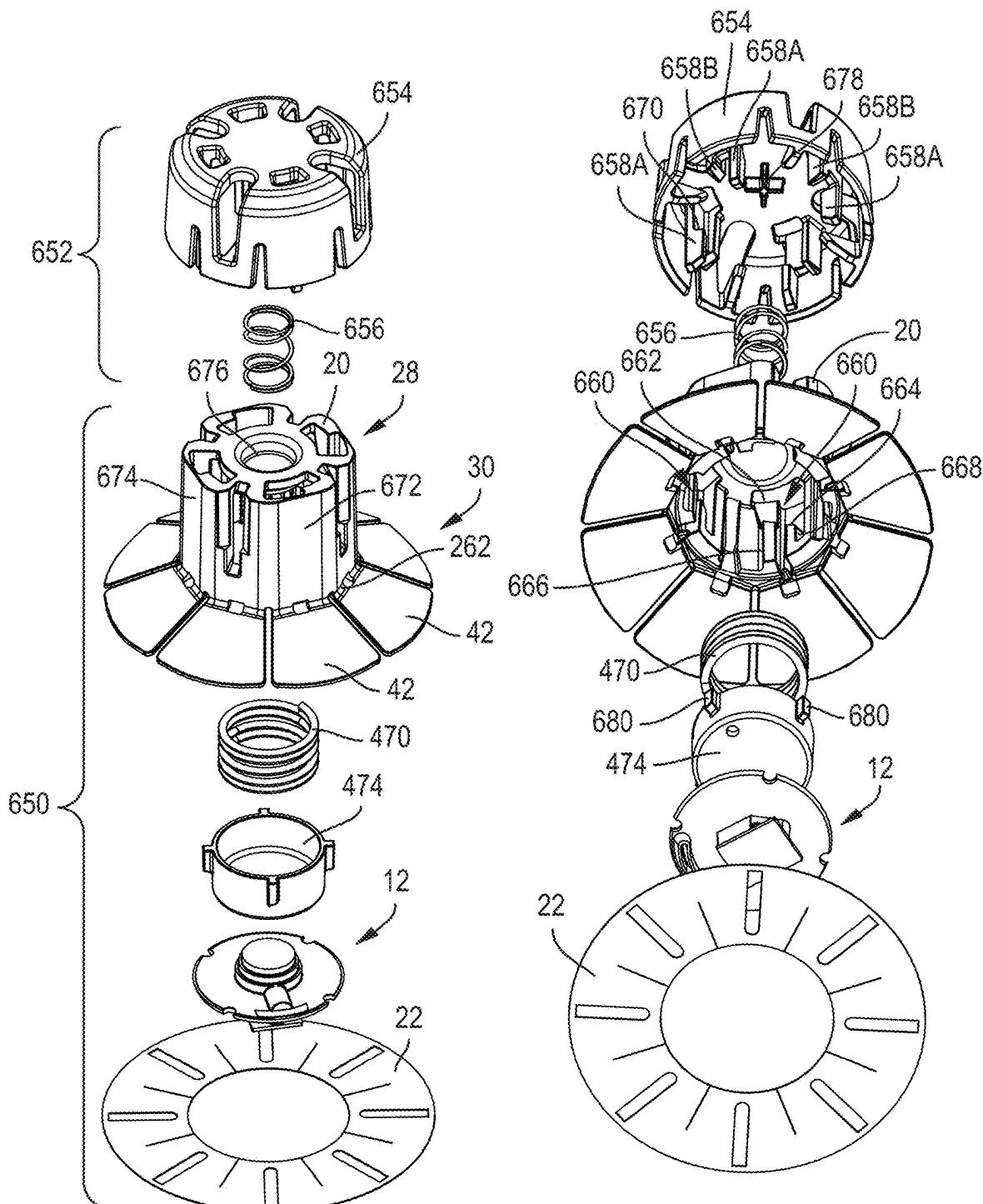


FIG. 80B

FIG. 80A

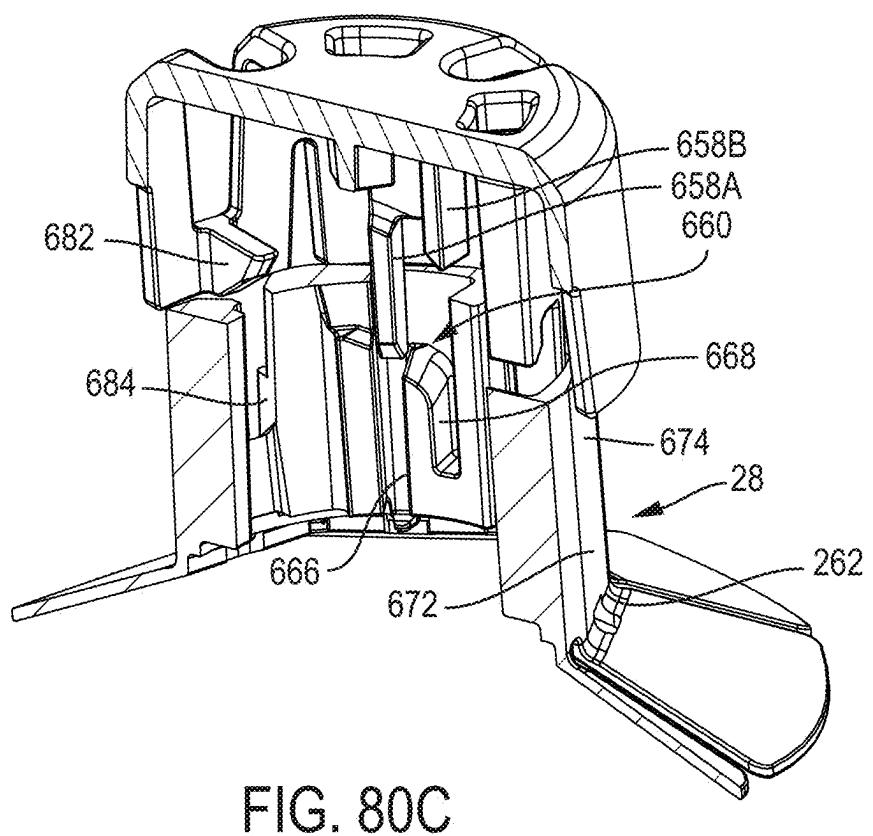
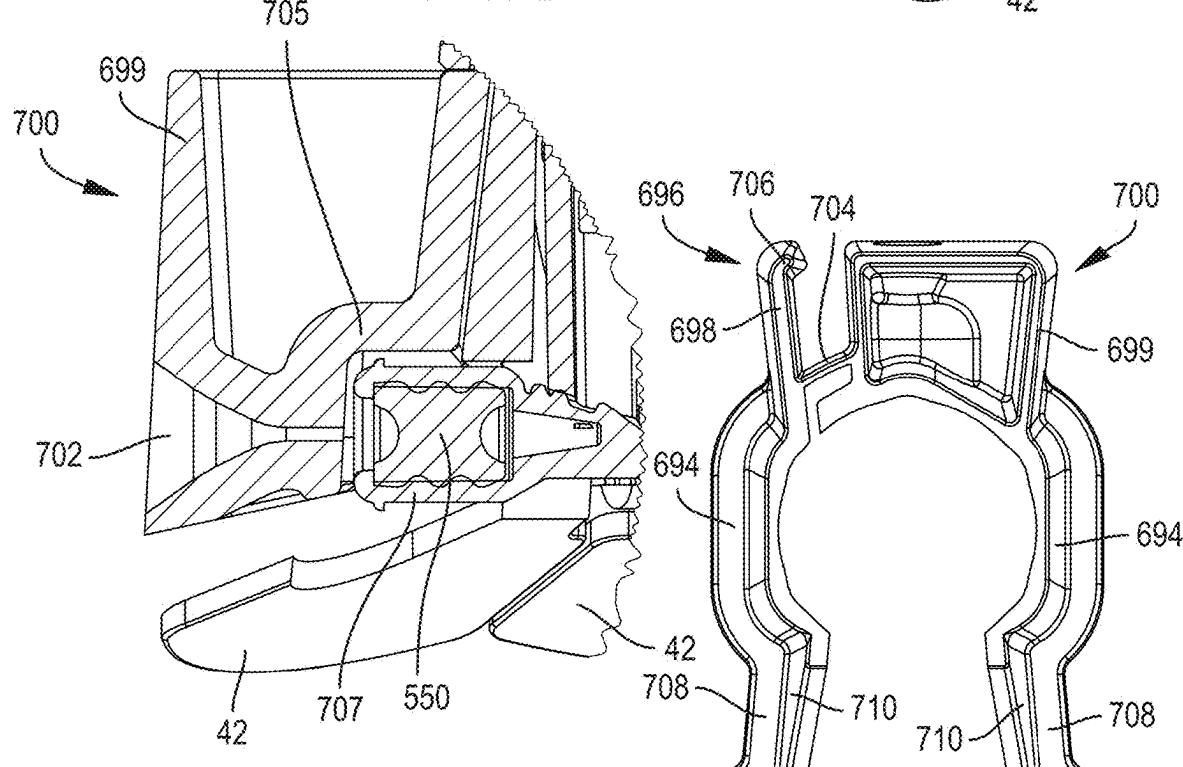
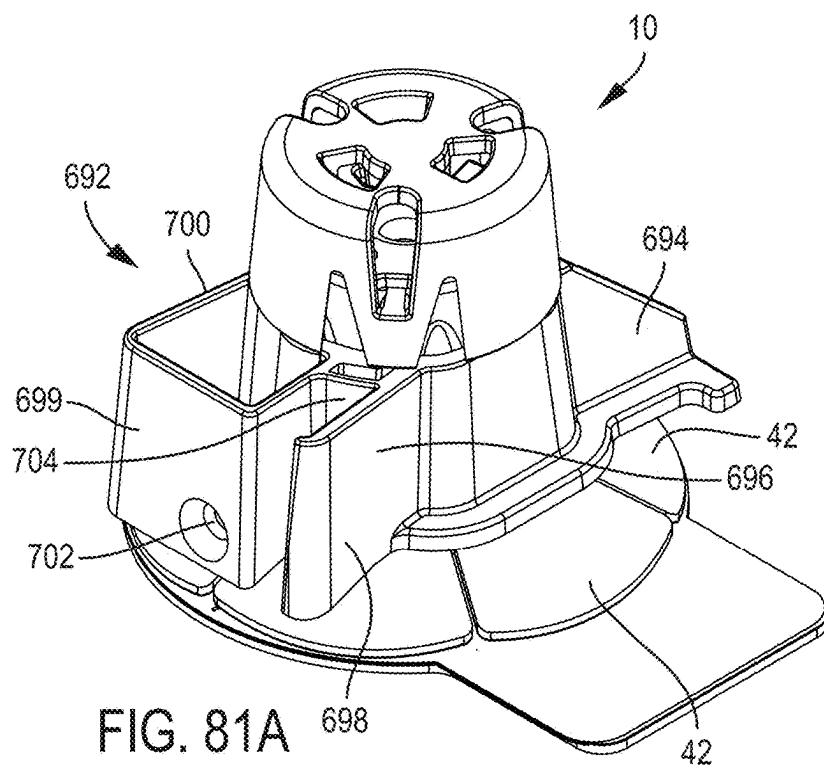


FIG. 80C



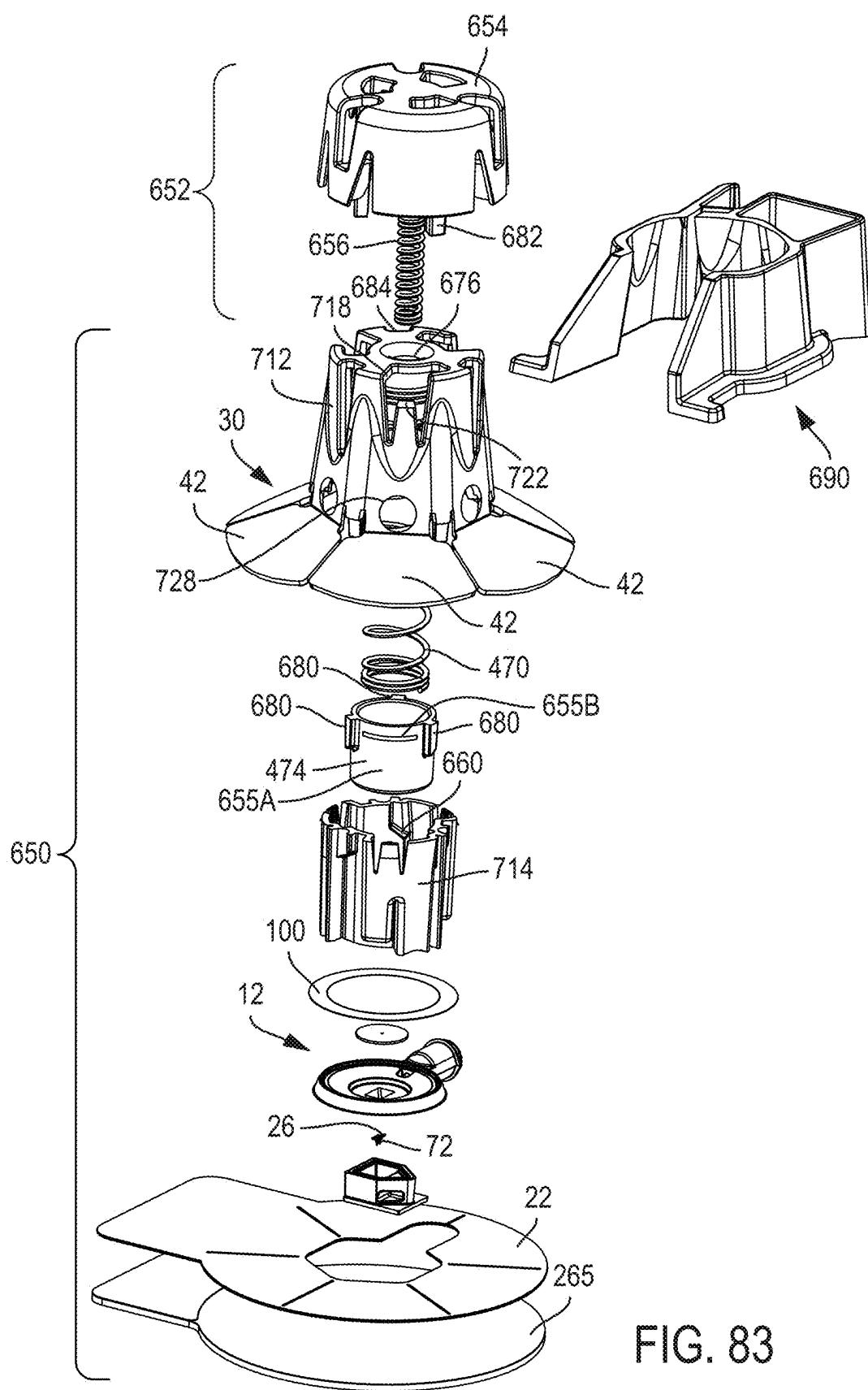
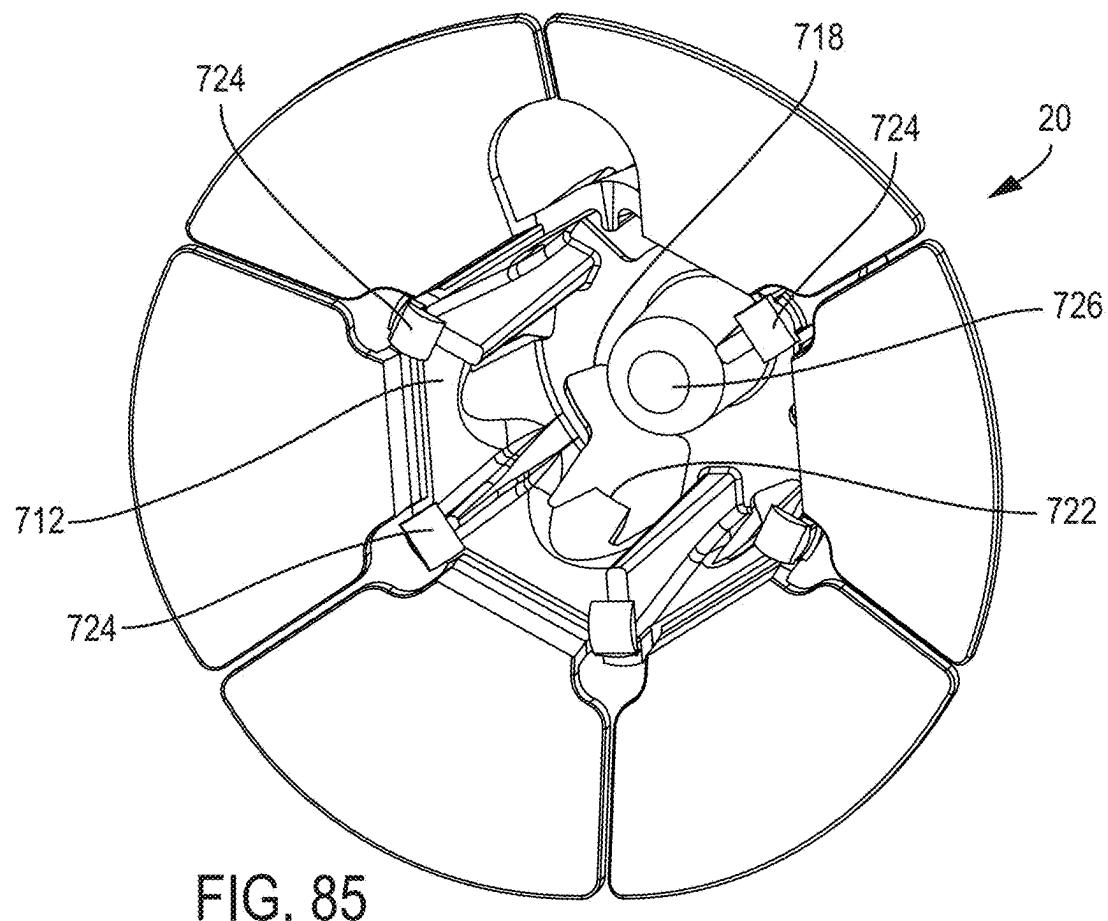
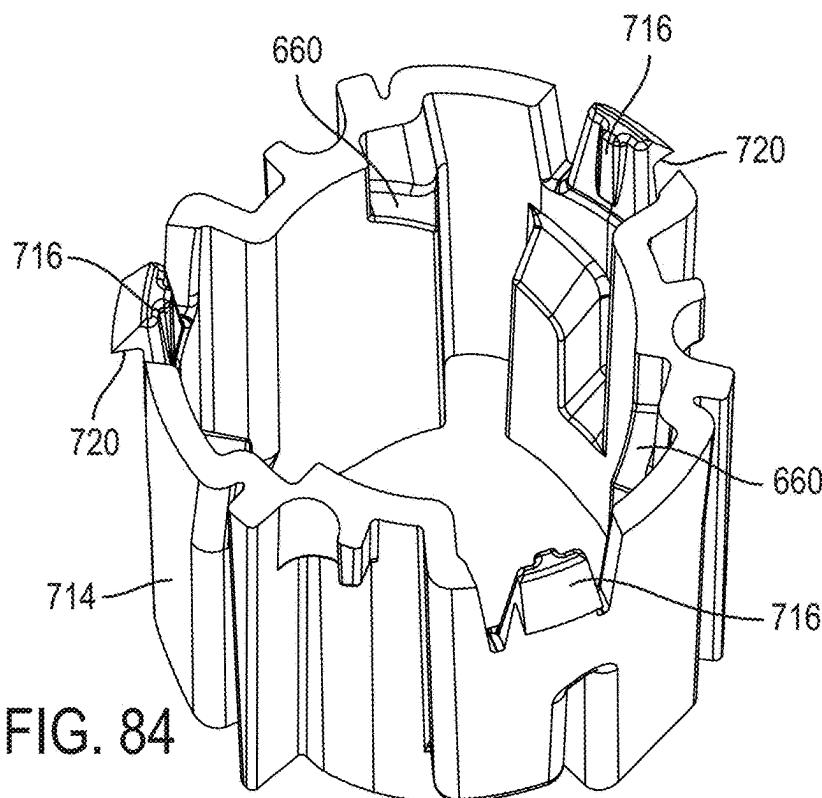


FIG. 83



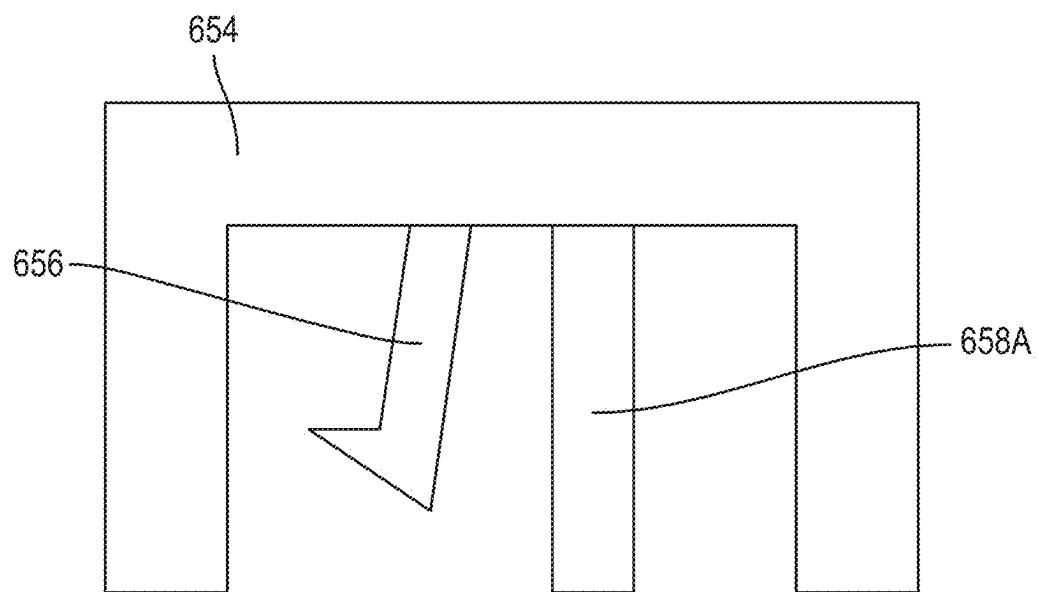


FIG. 86

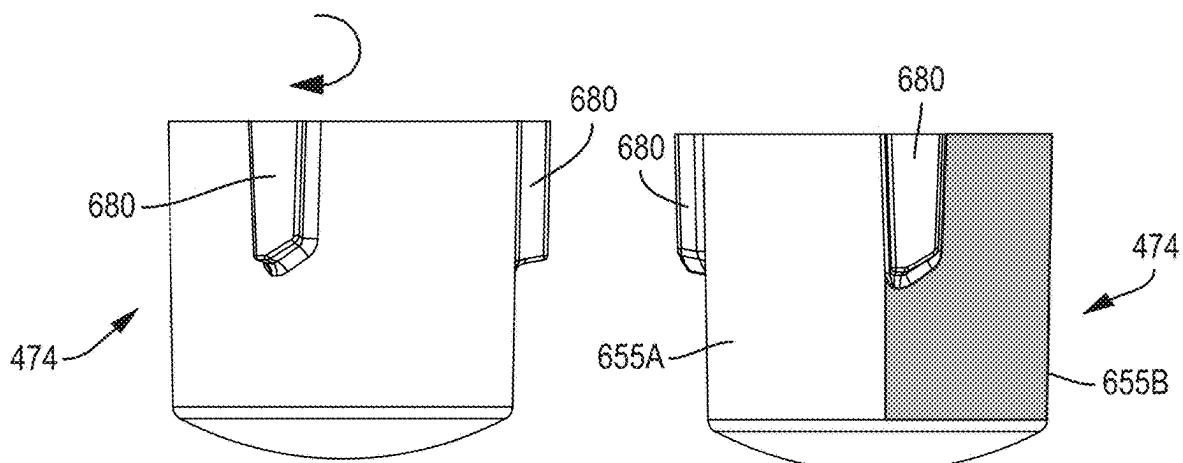


FIG. 87A

FIG. 87B

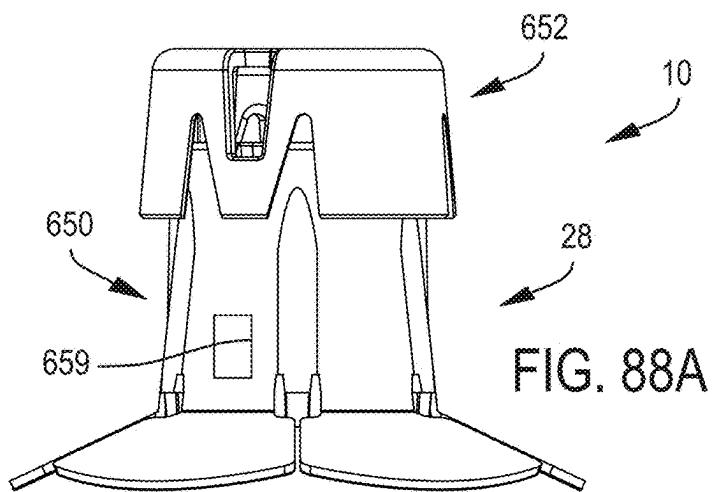


FIG. 88A

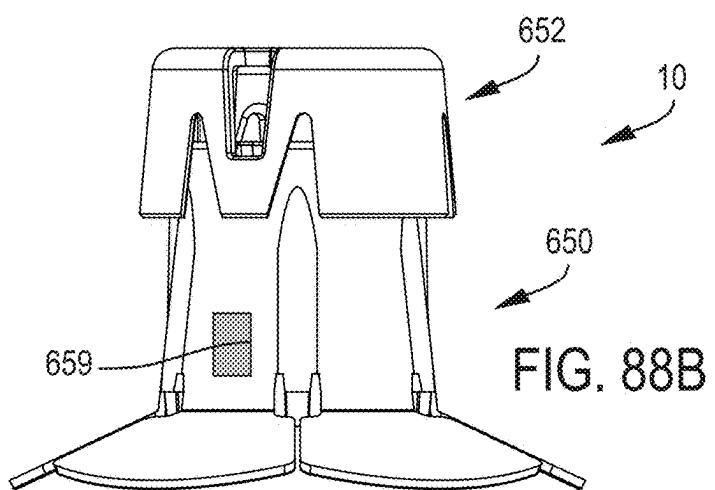


FIG. 88B

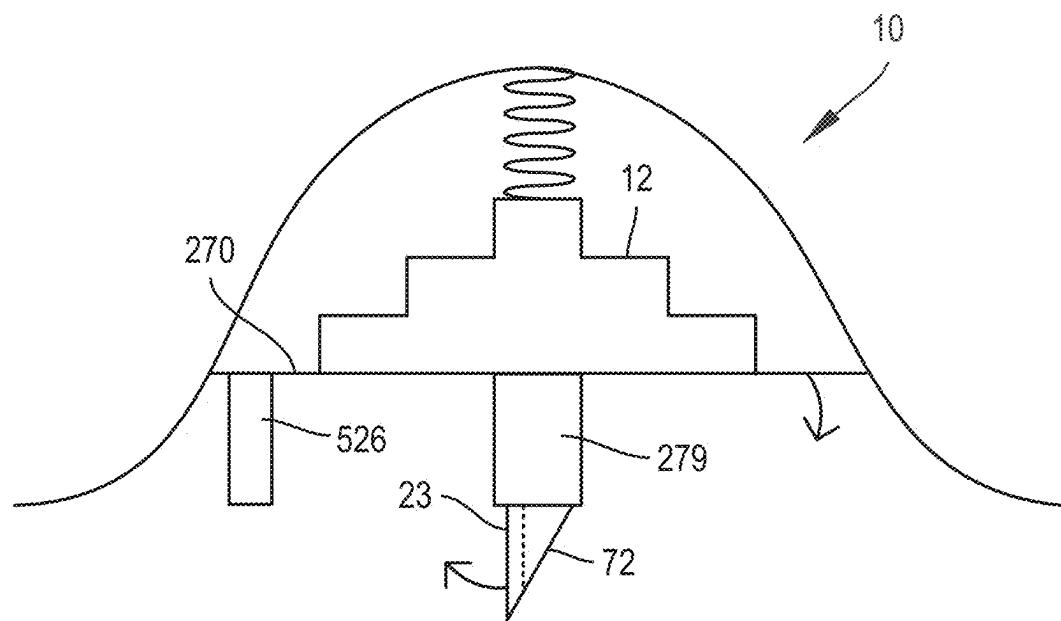


FIG. 89A

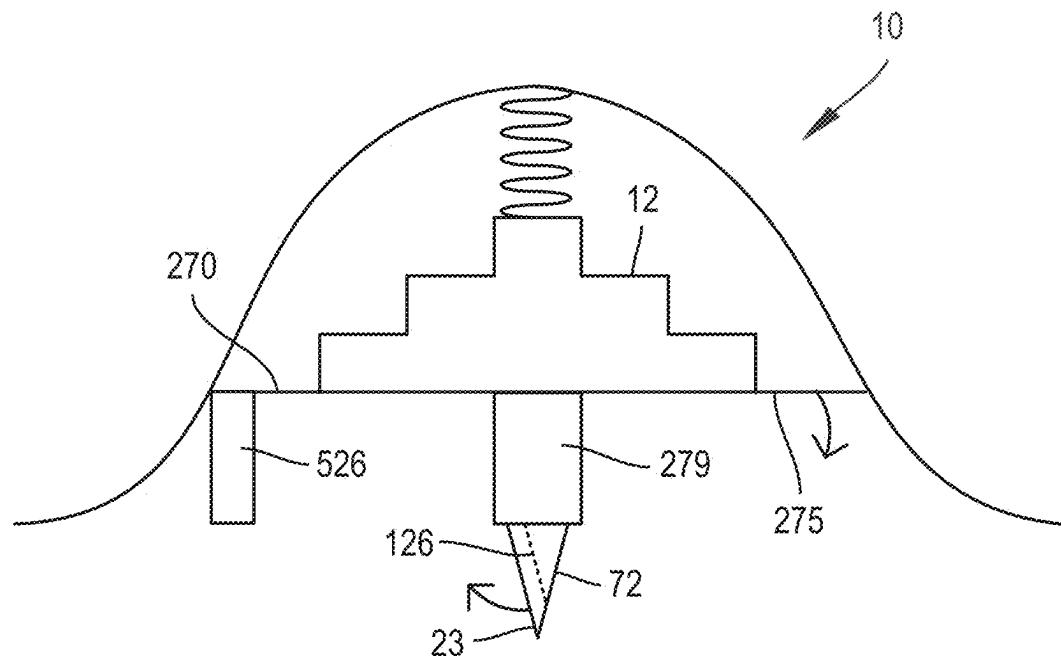


FIG. 89B

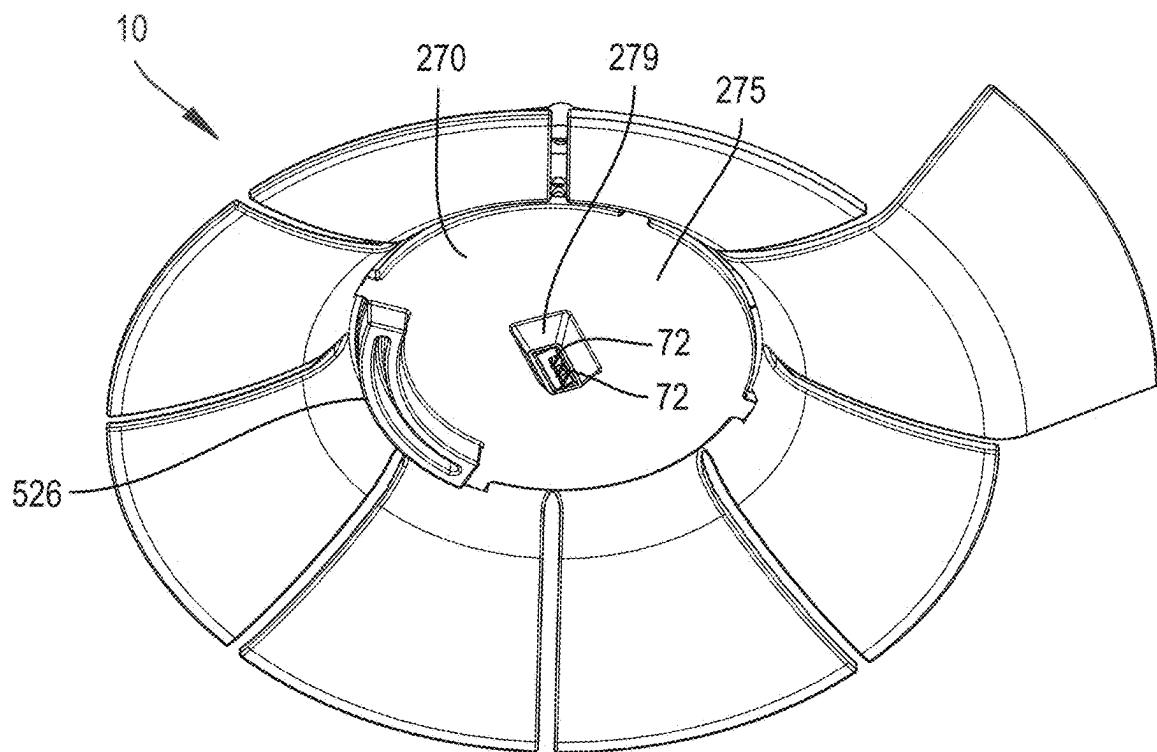


FIG. 90A

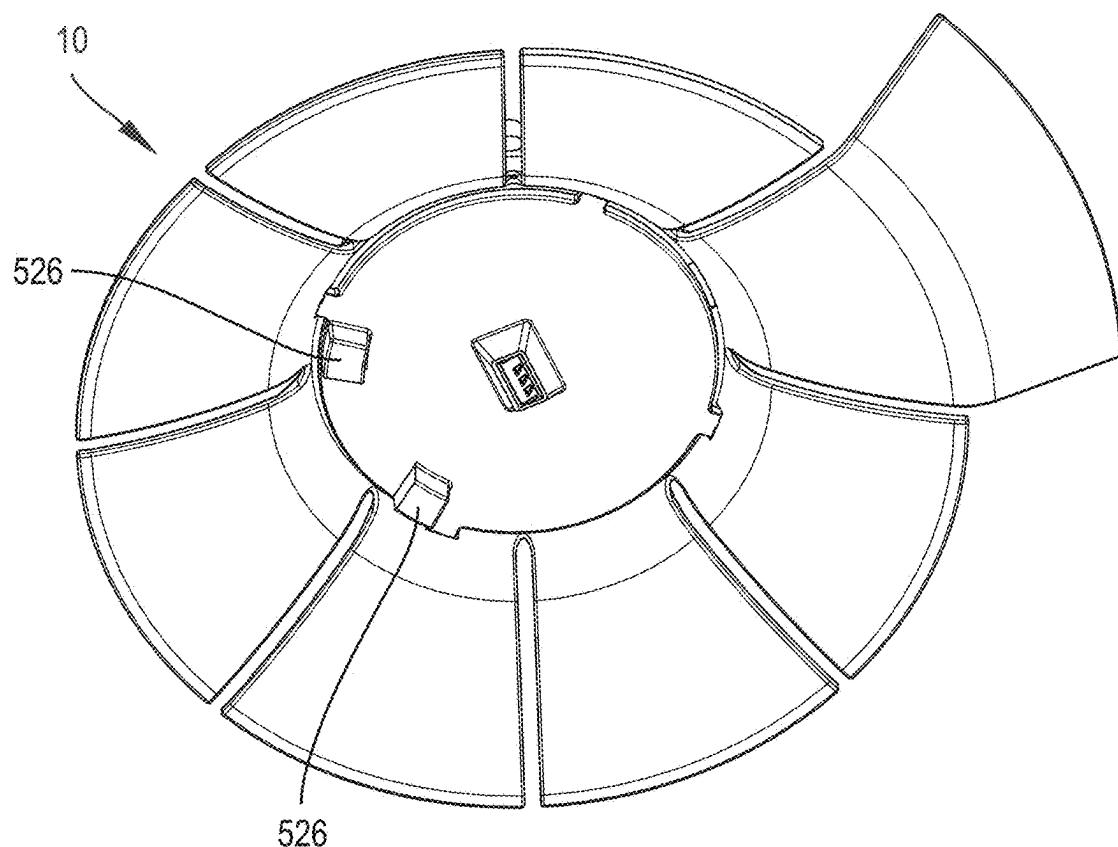


FIG. 90B

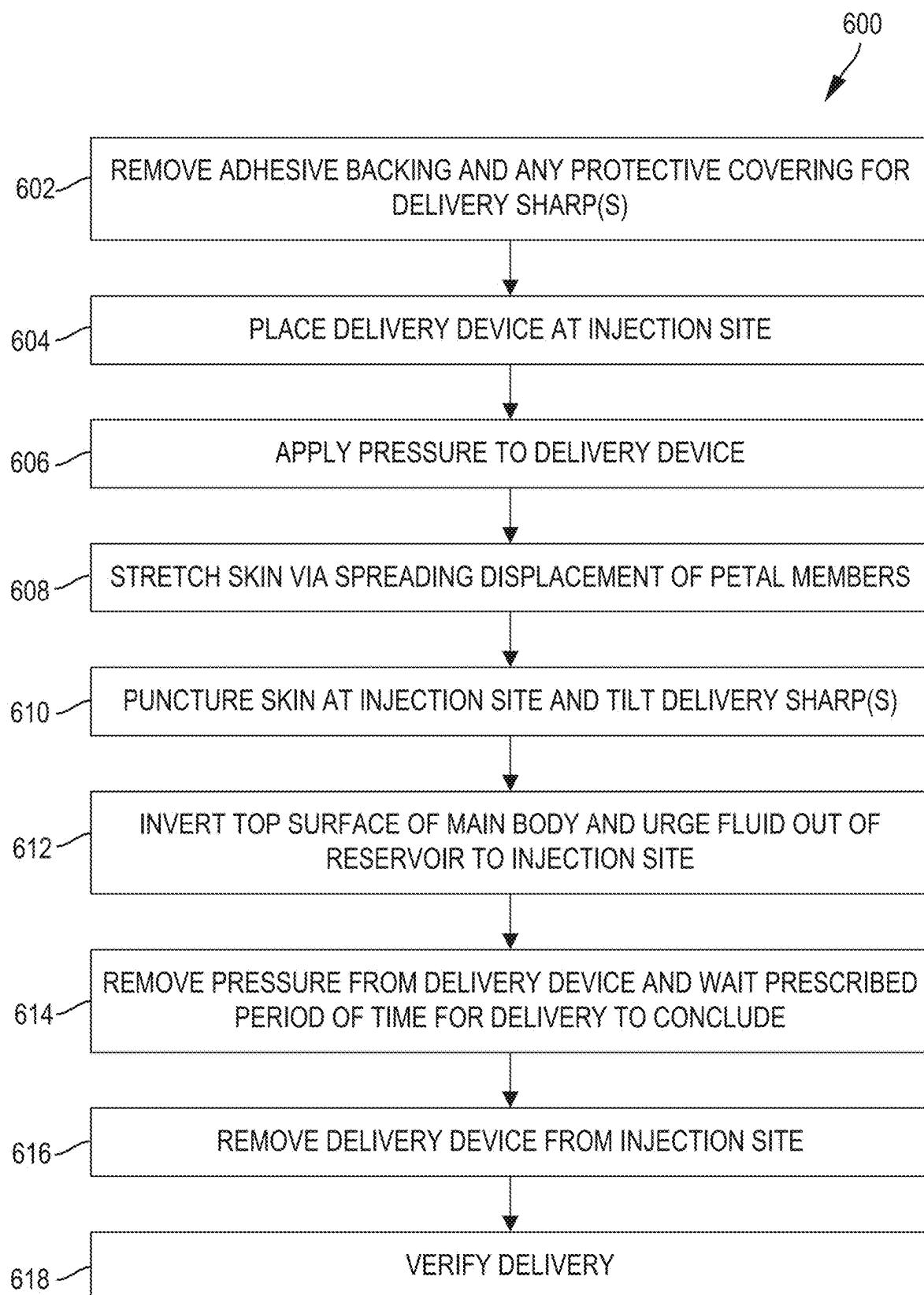
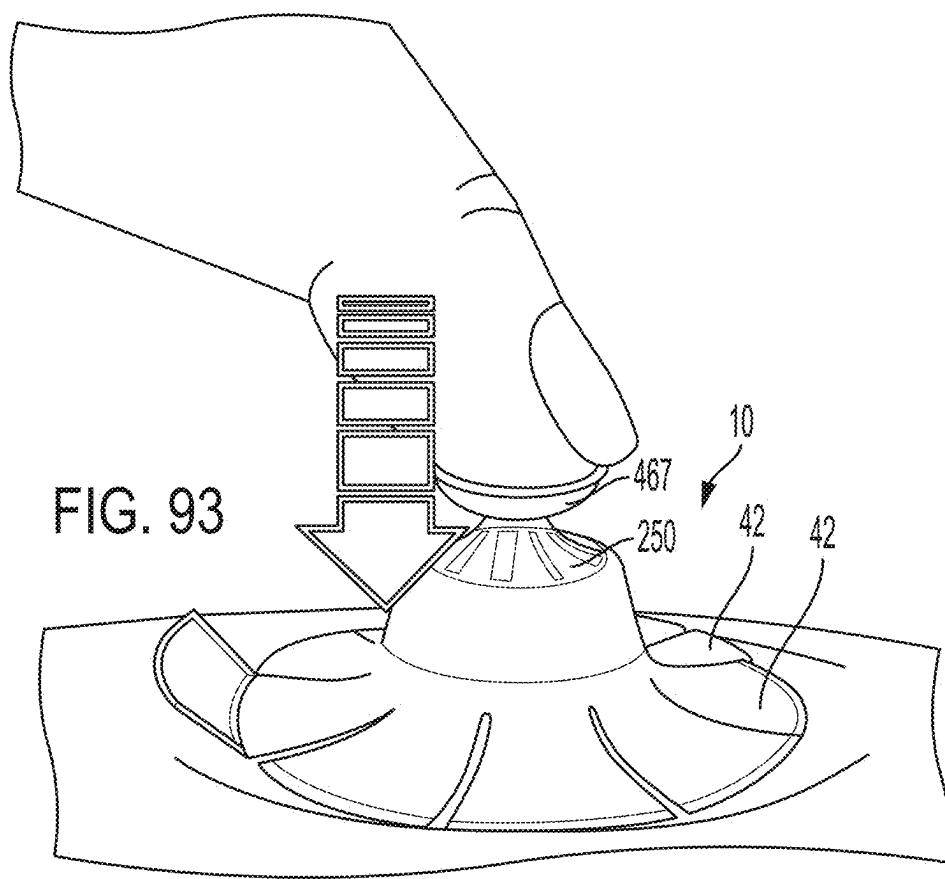
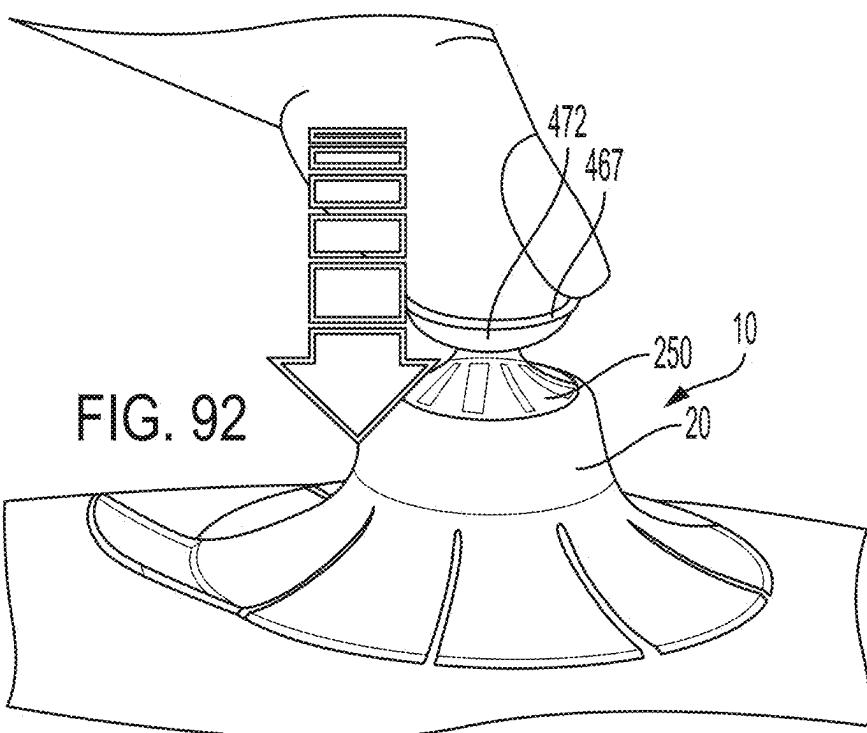


FIG. 91



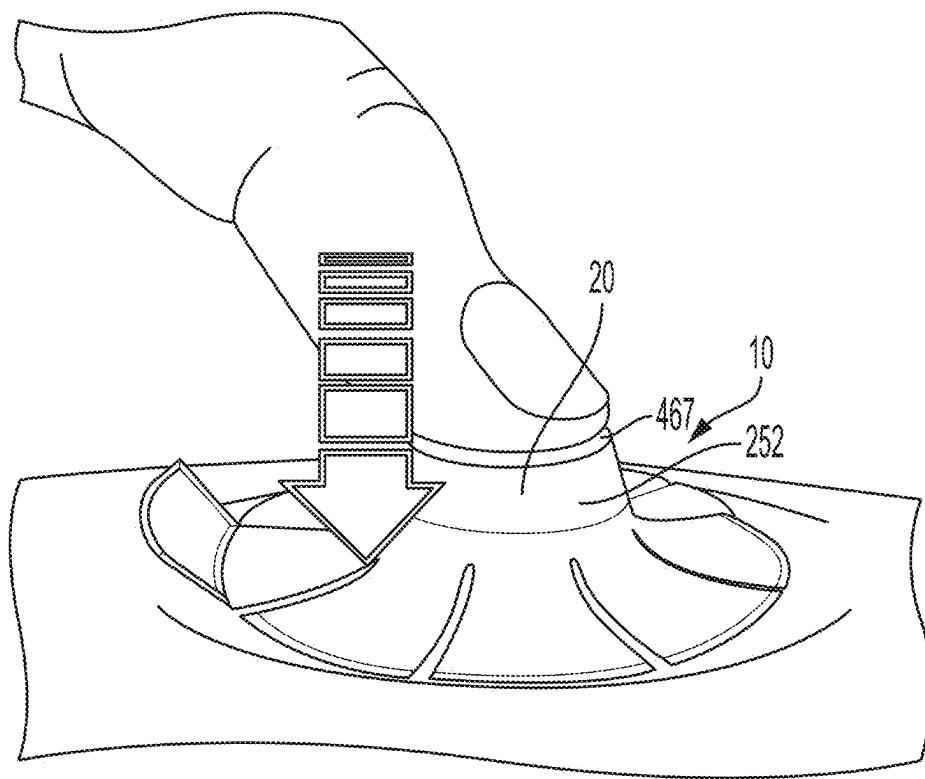


FIG. 94

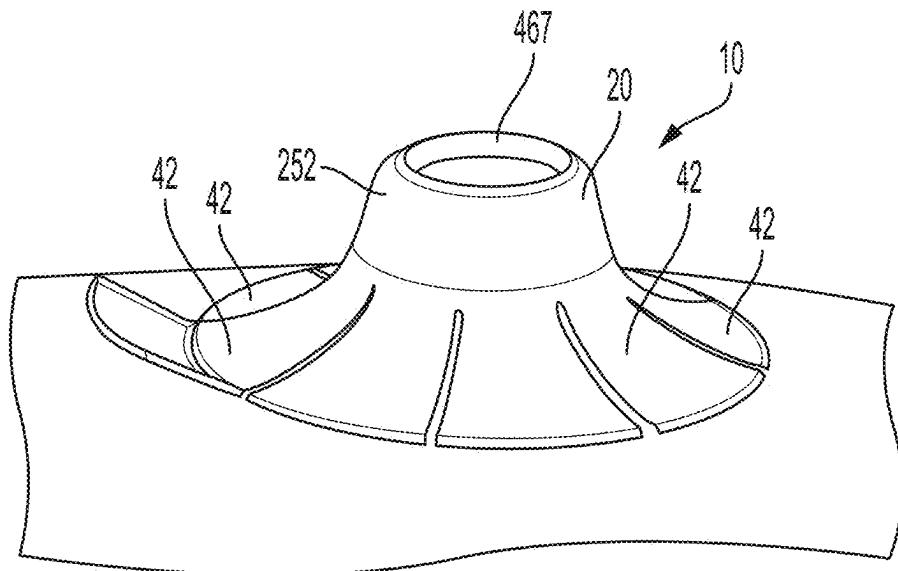


FIG. 95

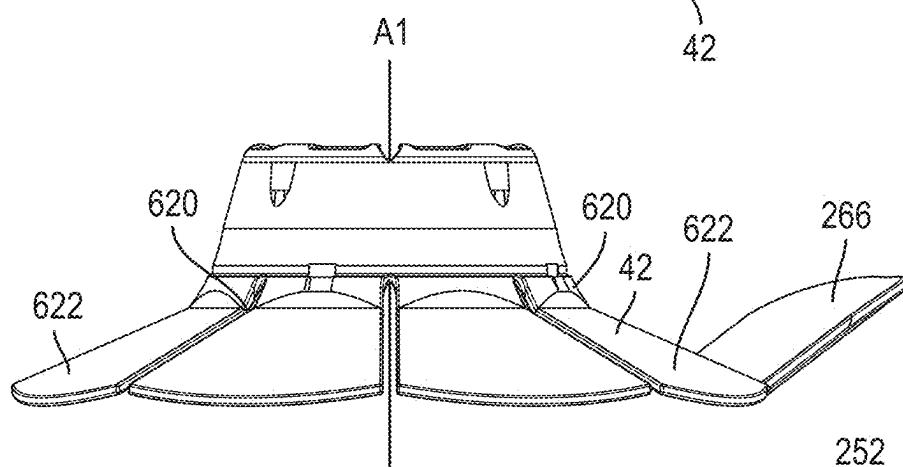
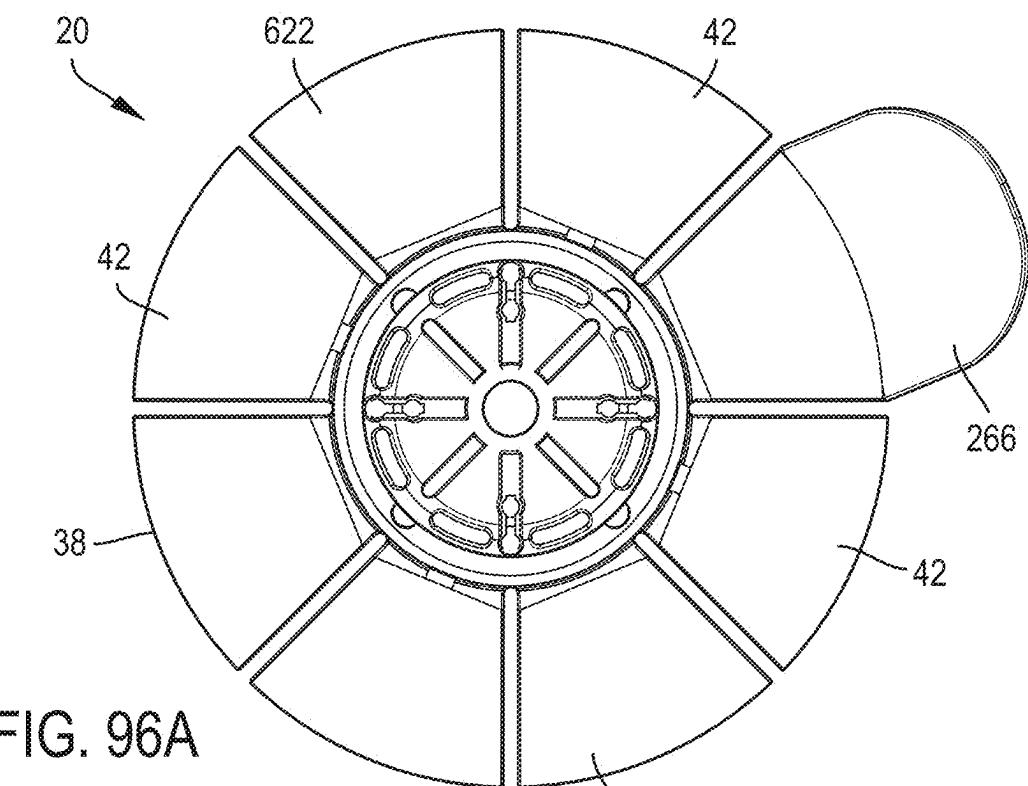


FIG. 96B

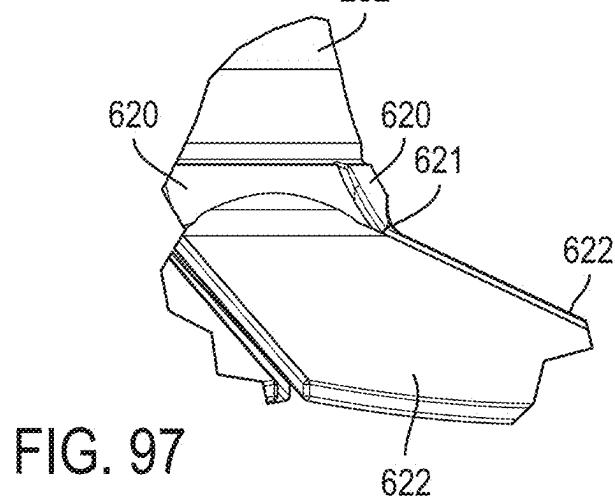


FIG. 97

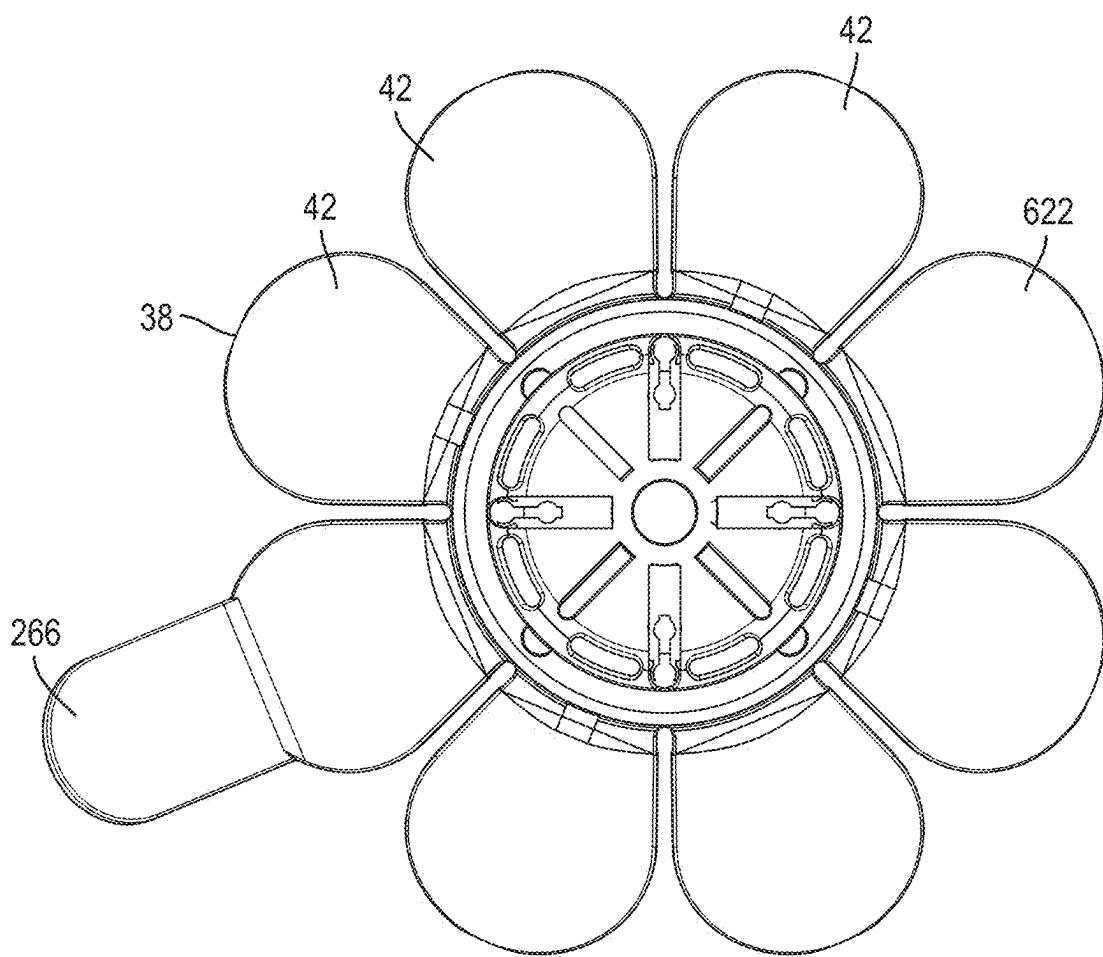


FIG. 98A

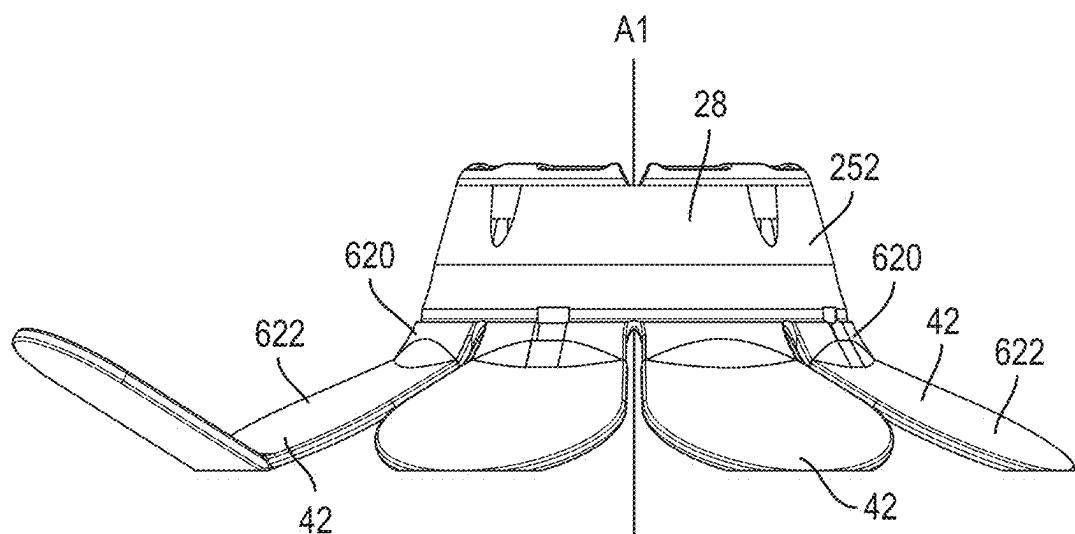


FIG. 98B

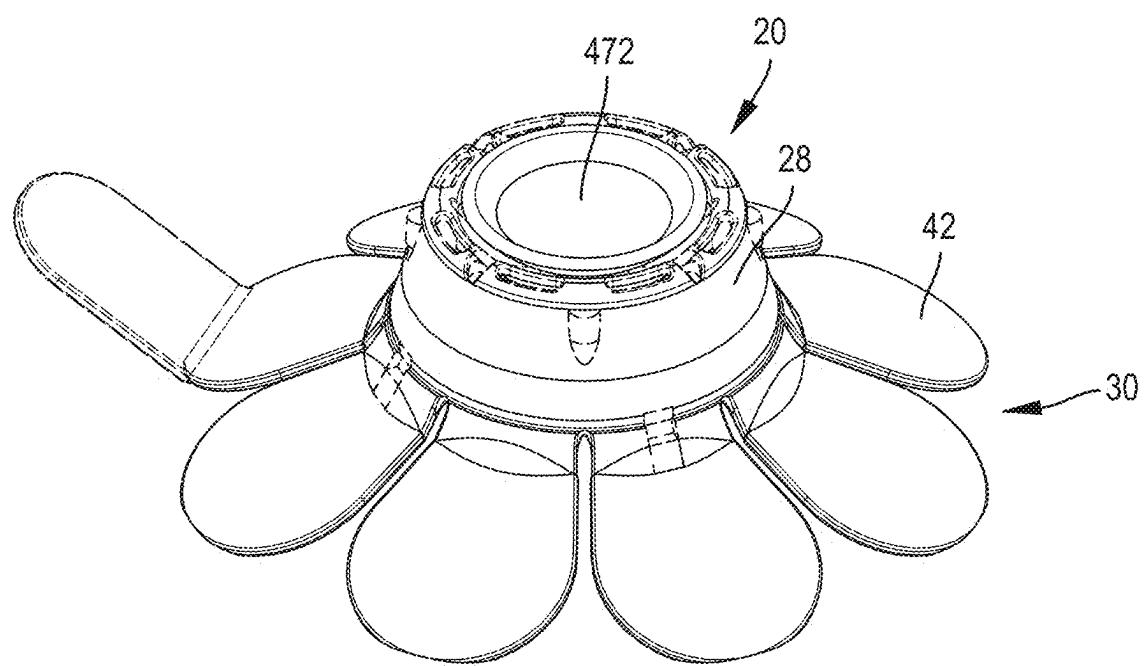
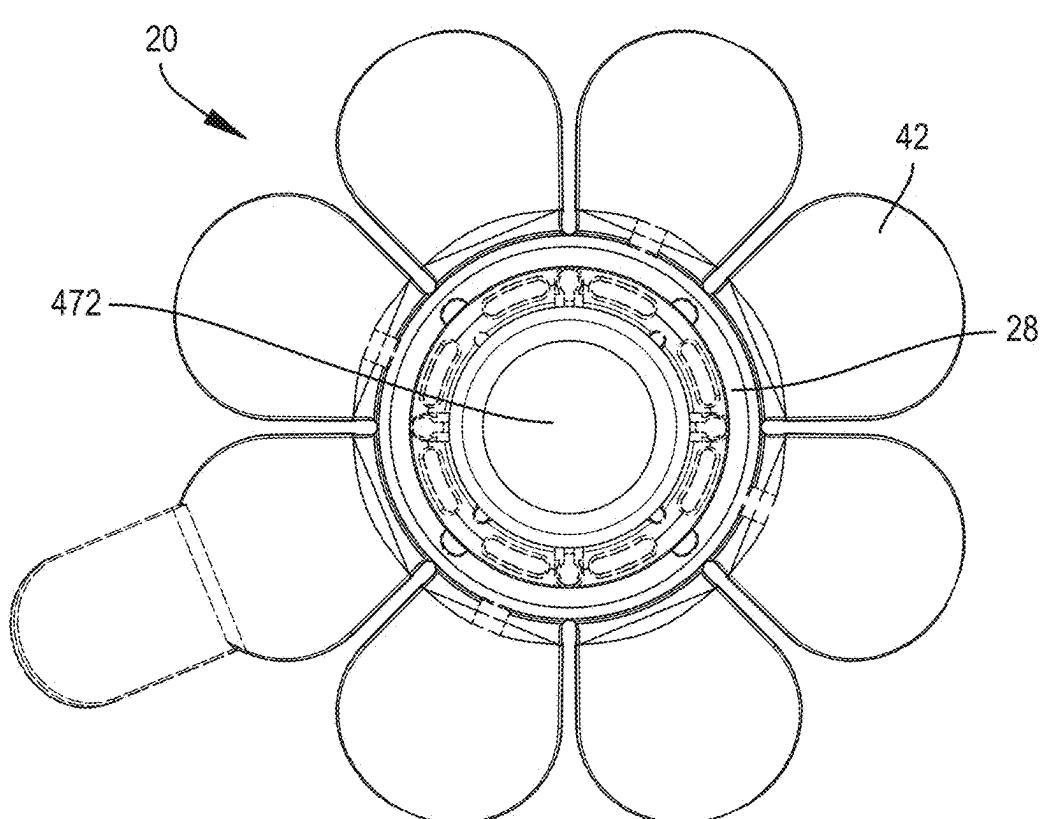
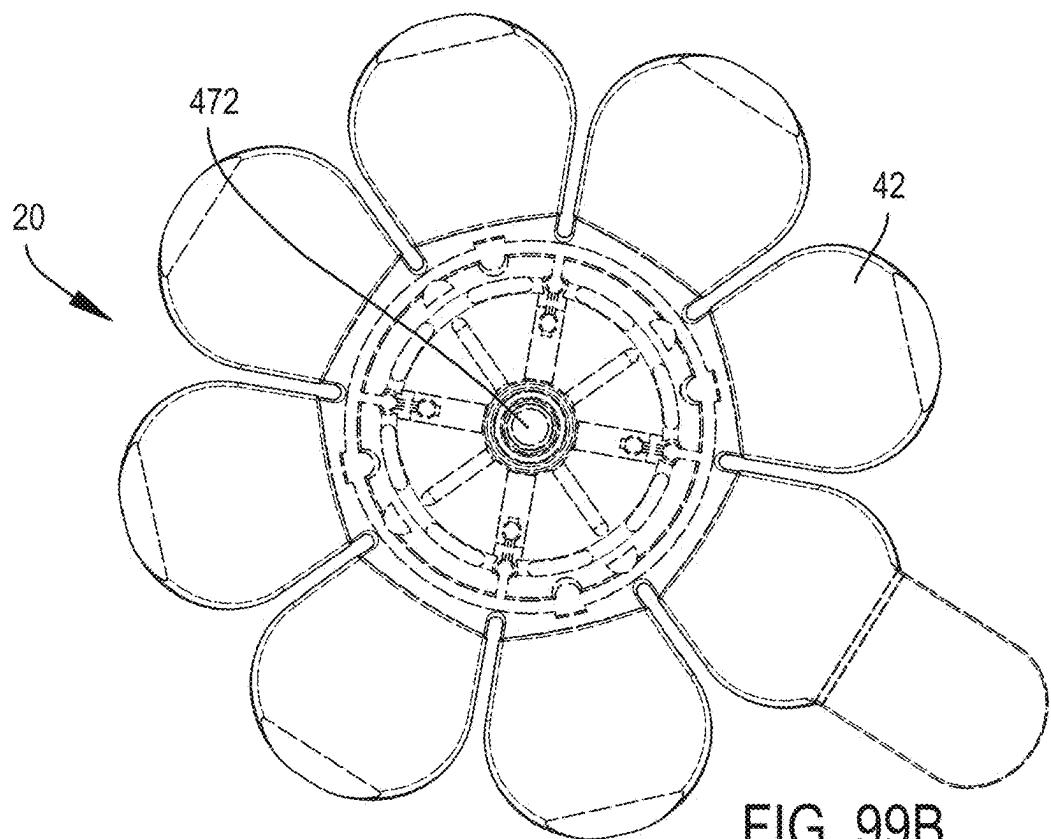


FIG. 99A



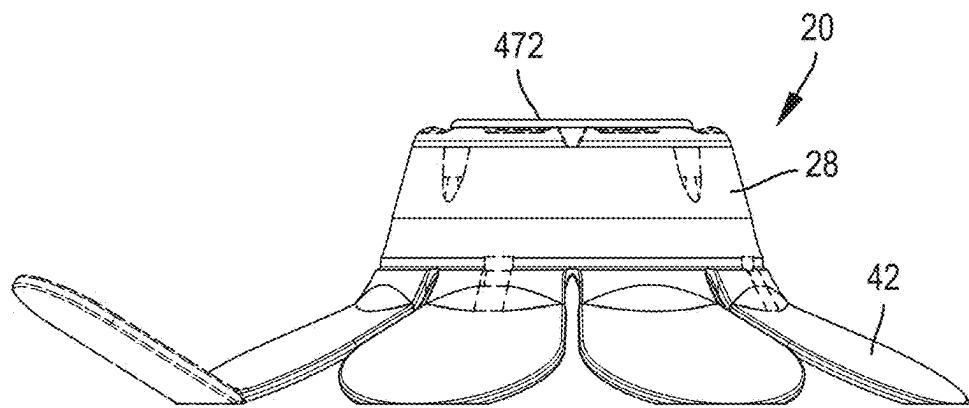


FIG. 99D

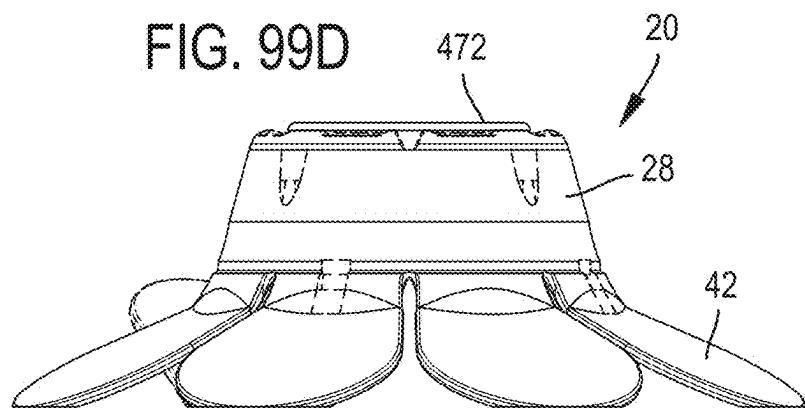


FIG. 99E

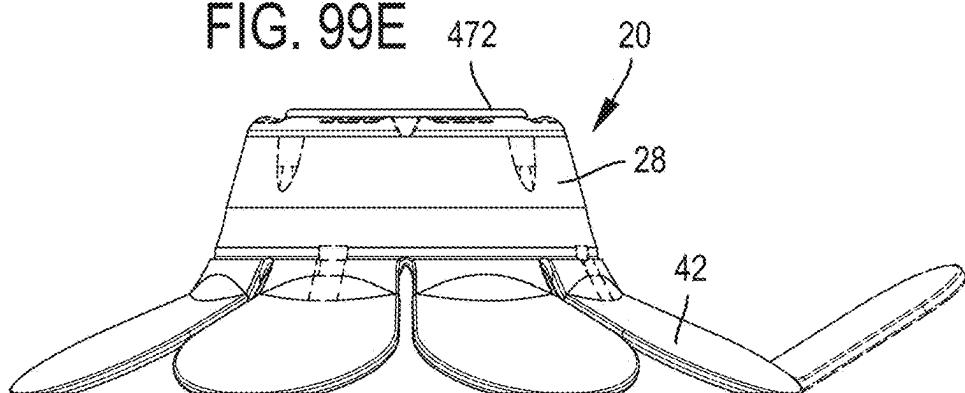


FIG. 99F

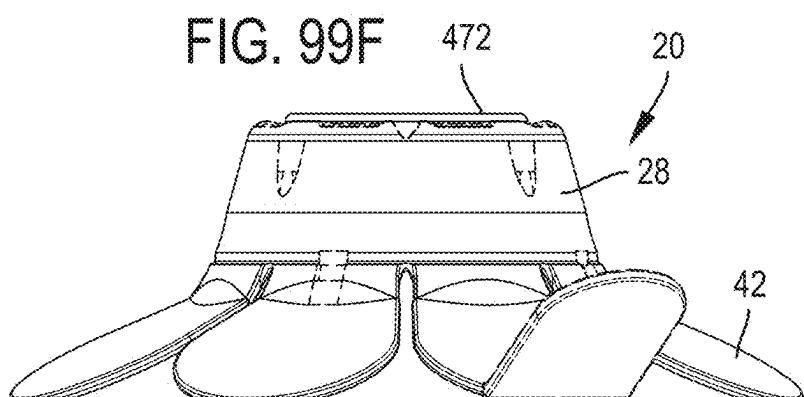


FIG. 99G

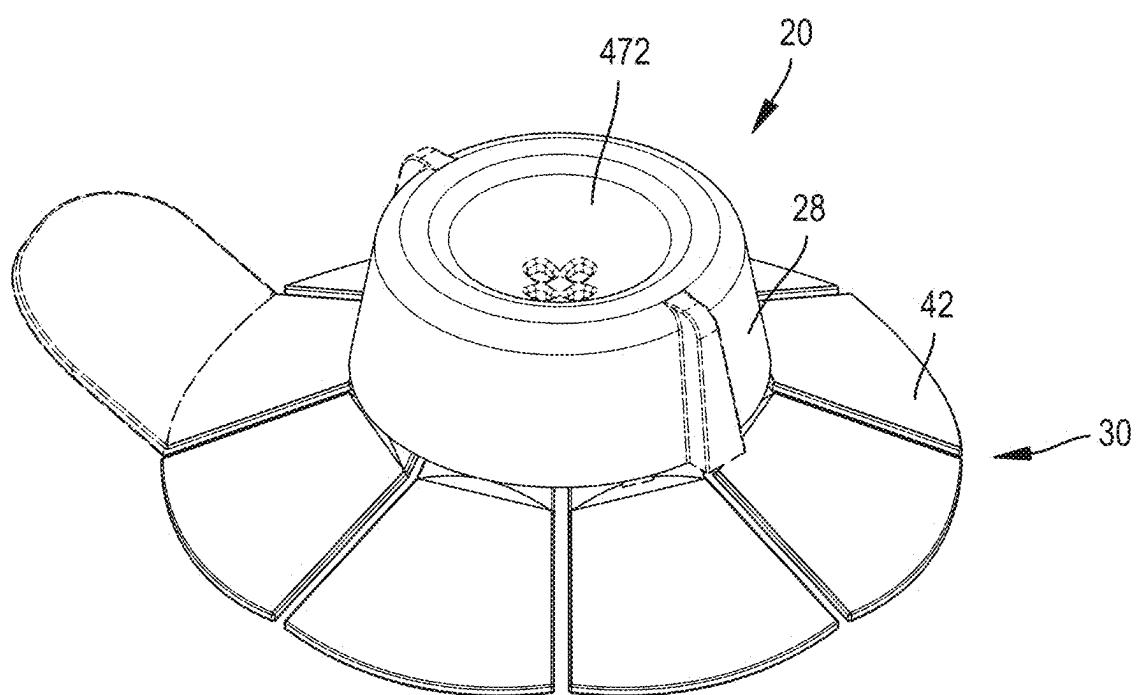
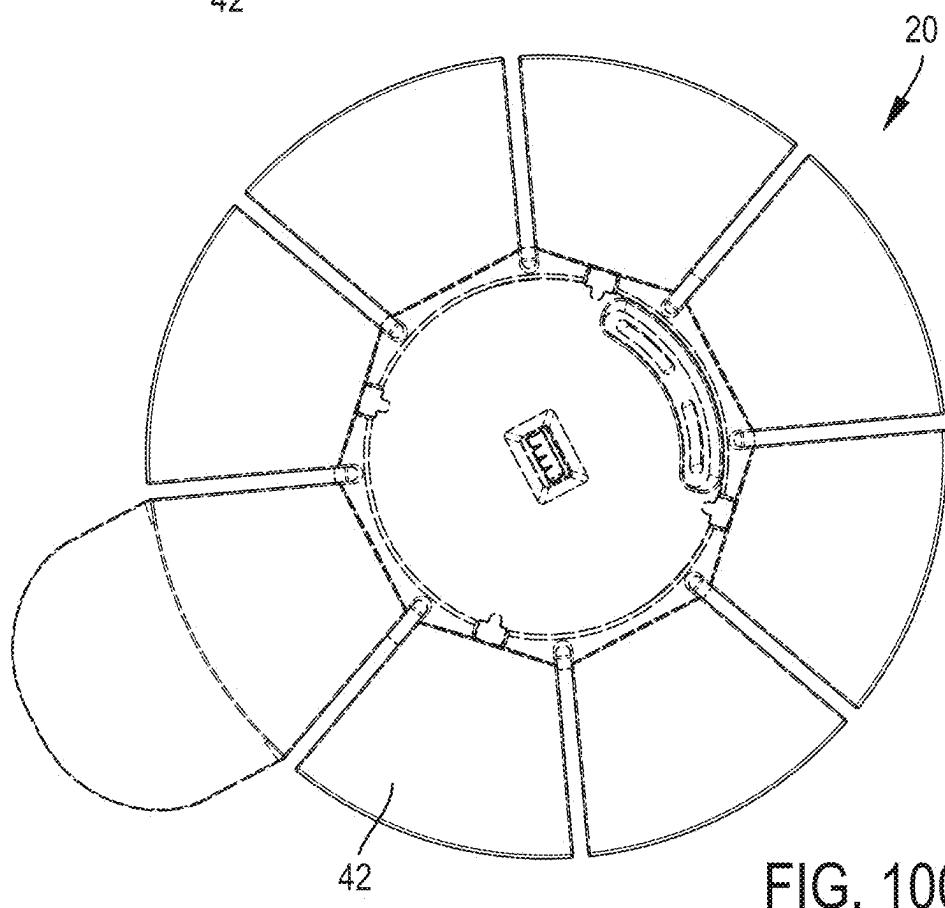
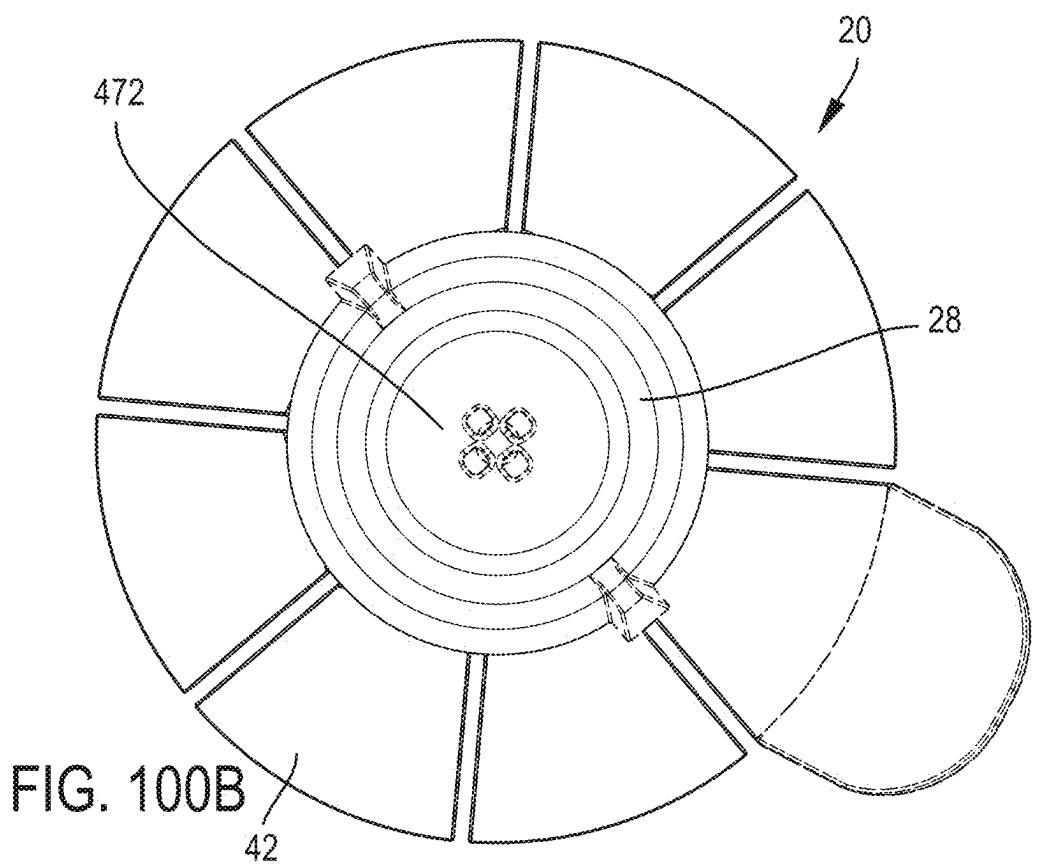
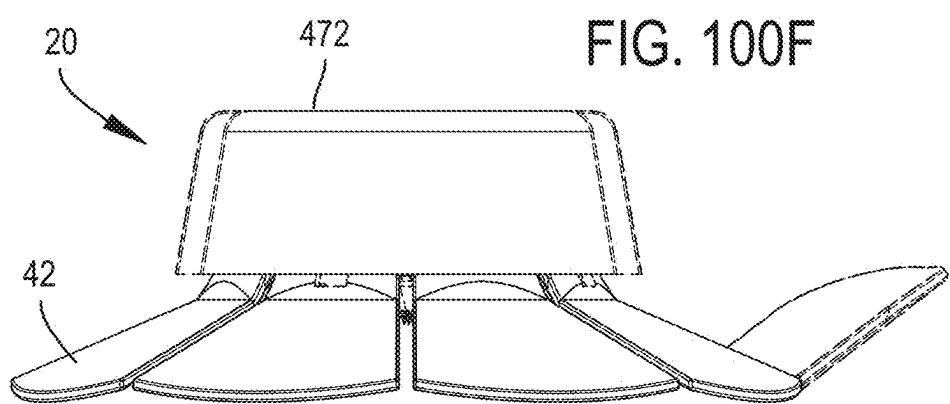
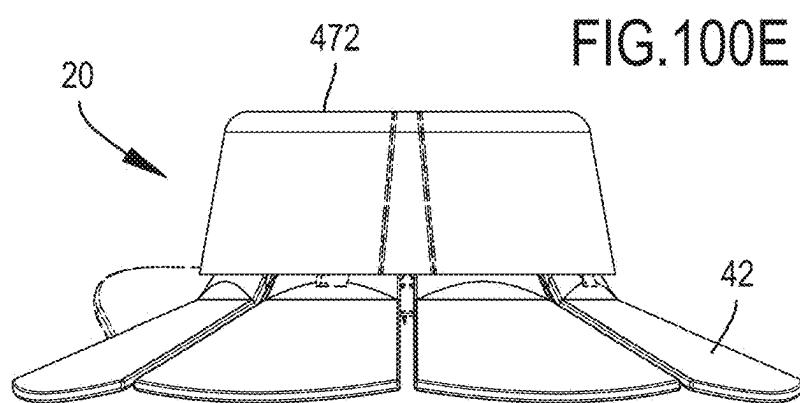
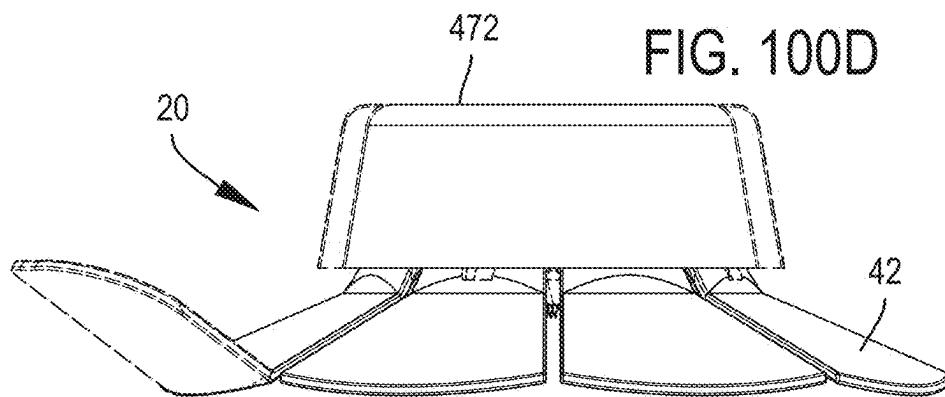
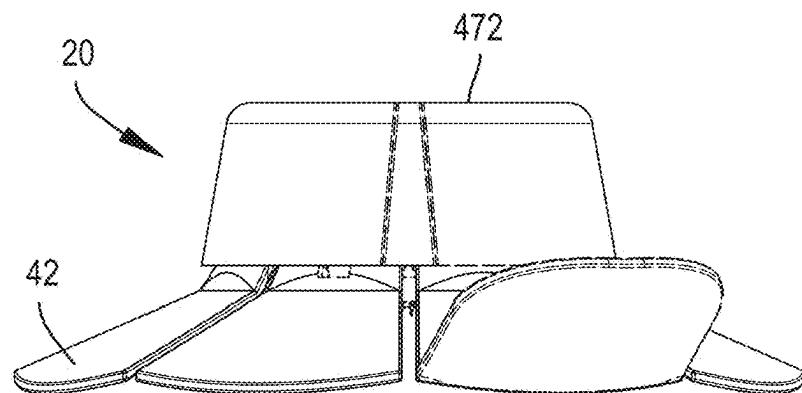


FIG. 100A





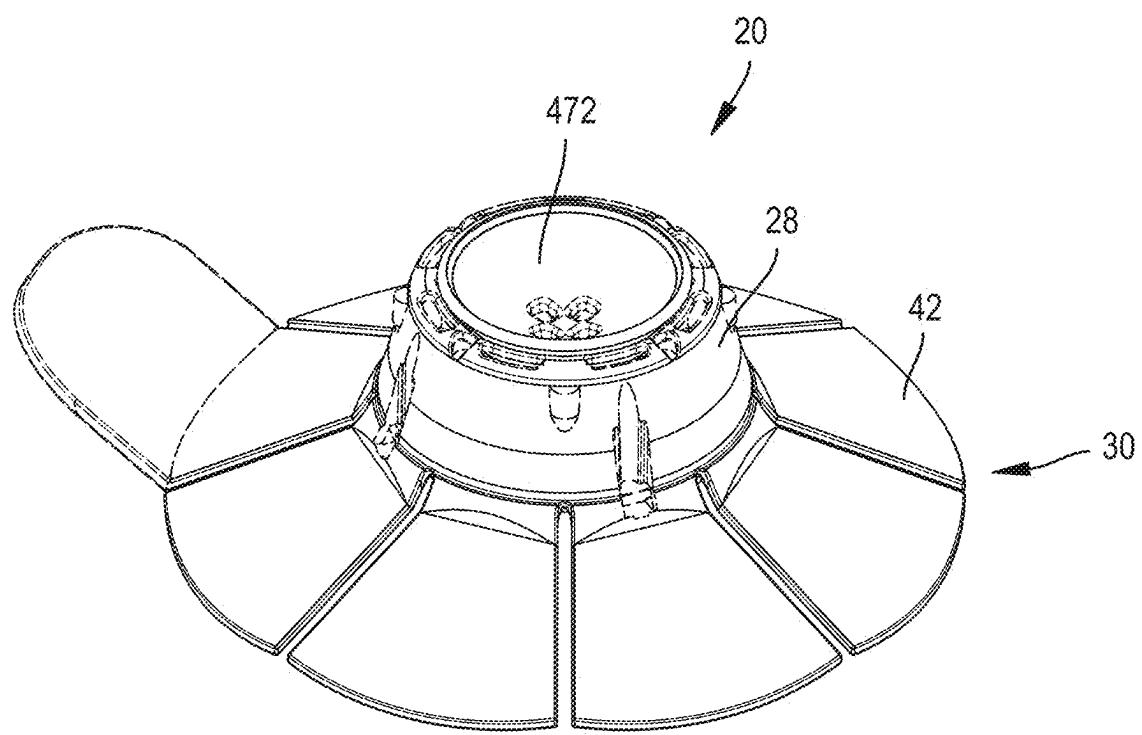
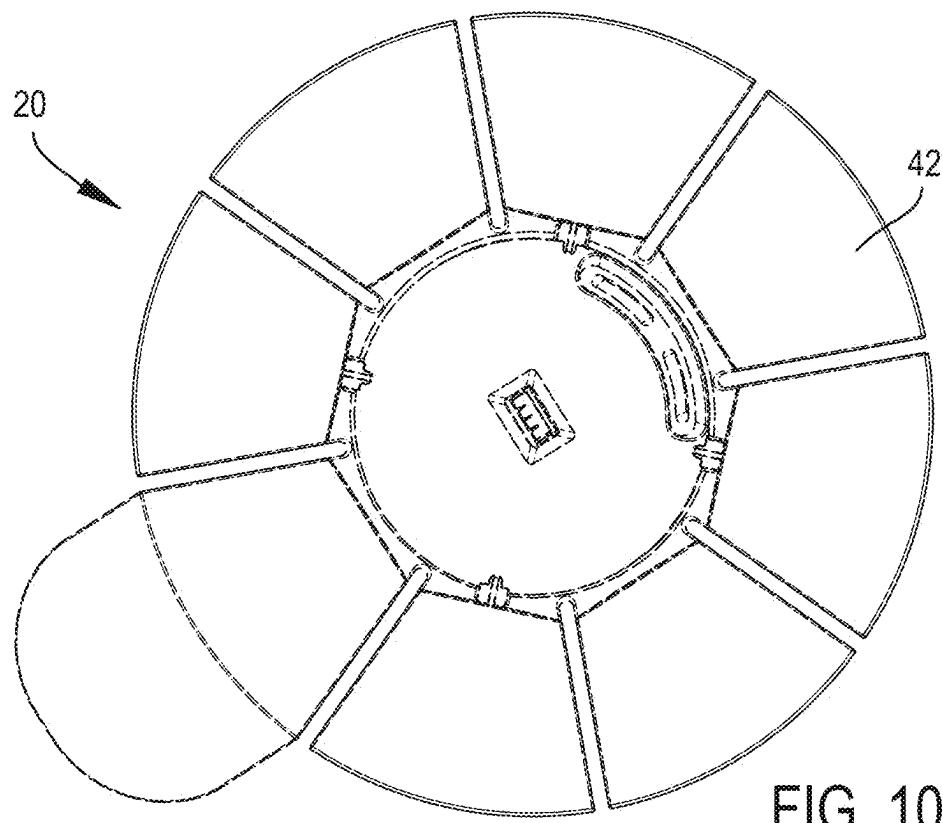
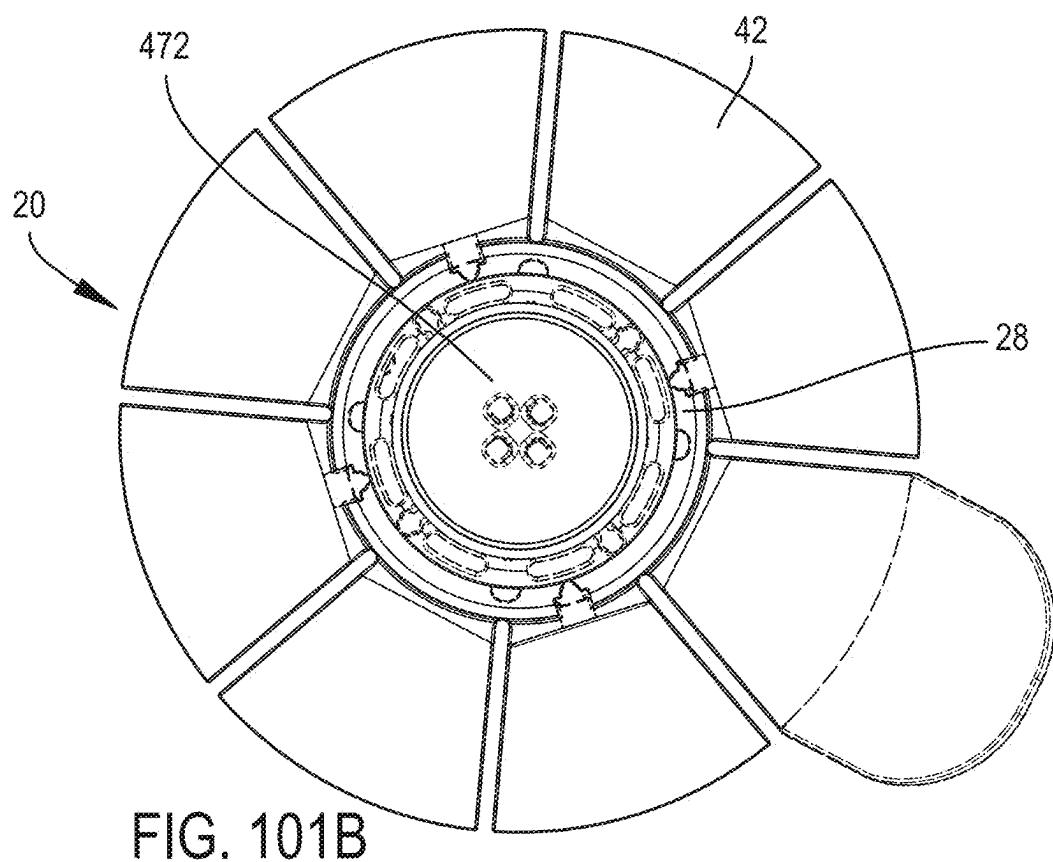


FIG. 101A



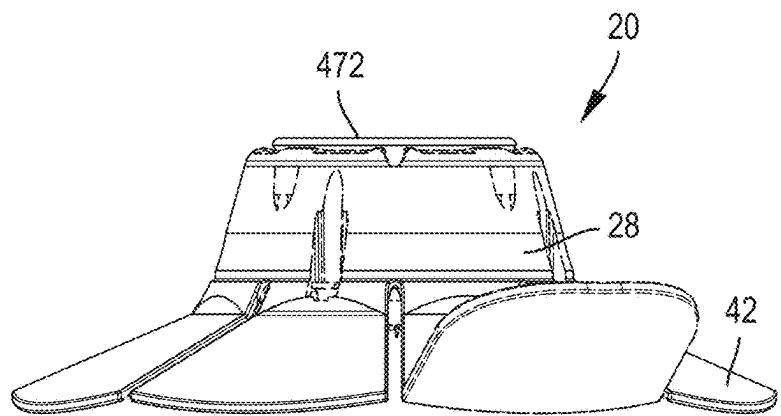


FIG. 101D

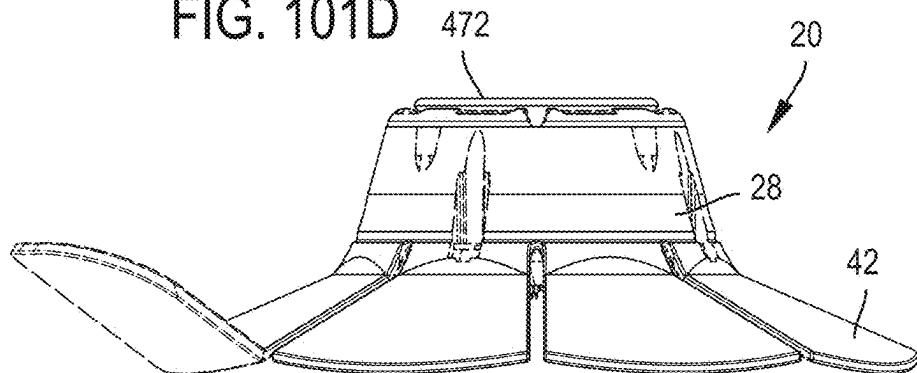


FIG. 101E

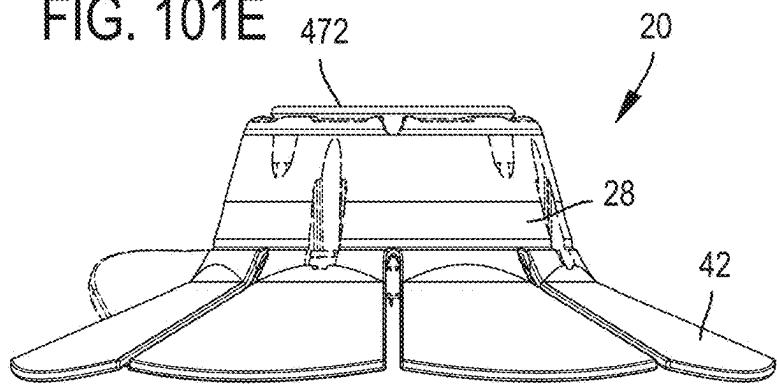


FIG. 101F

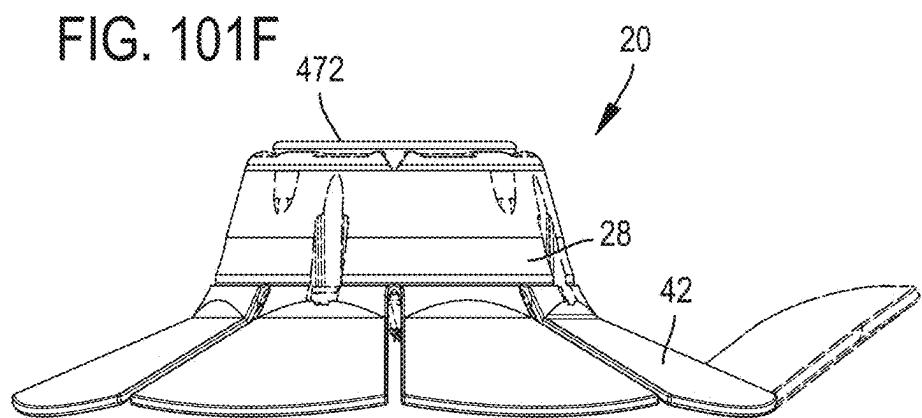


FIG. 101G

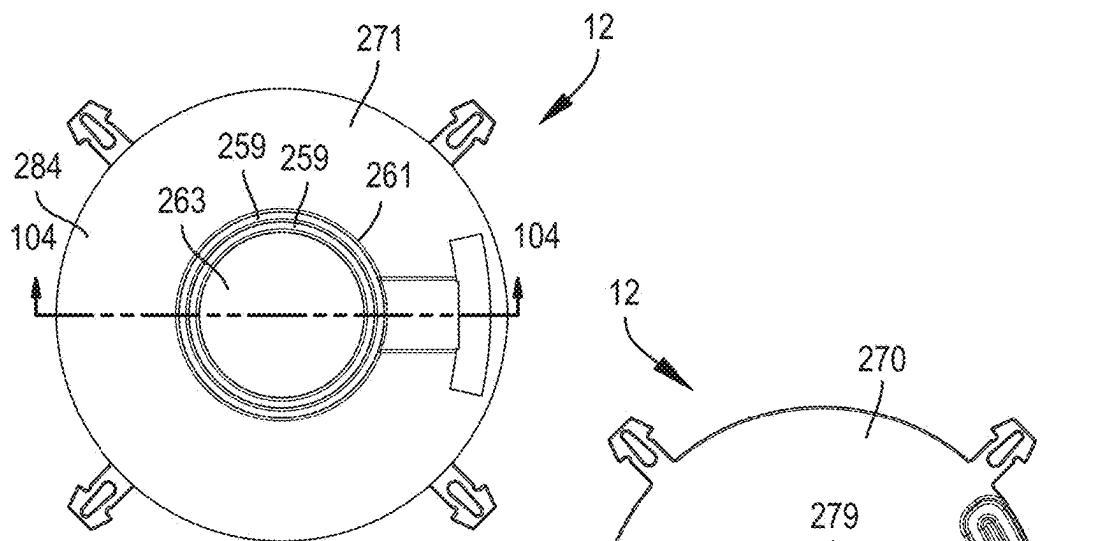


FIG. 102A

FIG. 102B

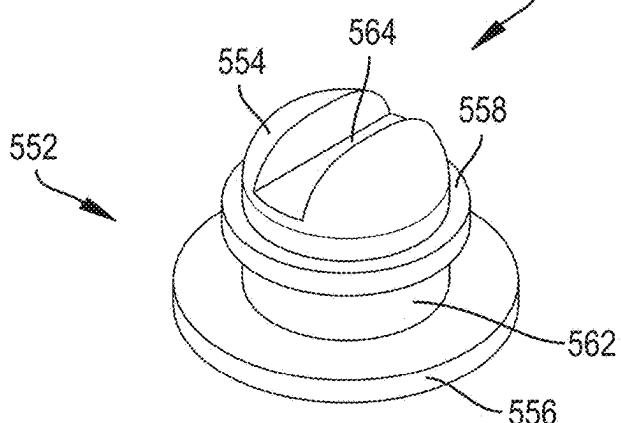


FIG. 103

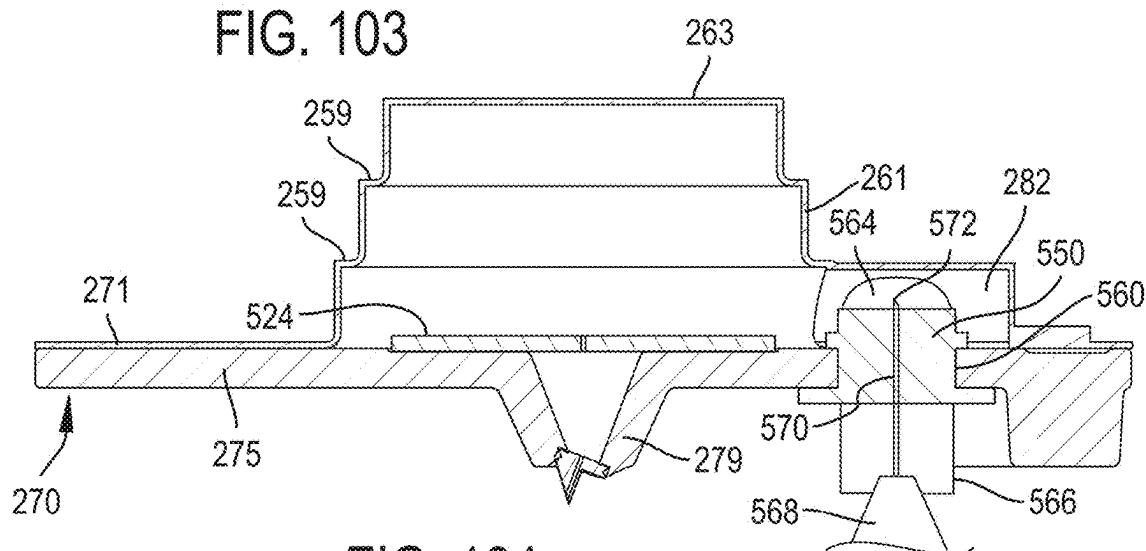


FIG. 104

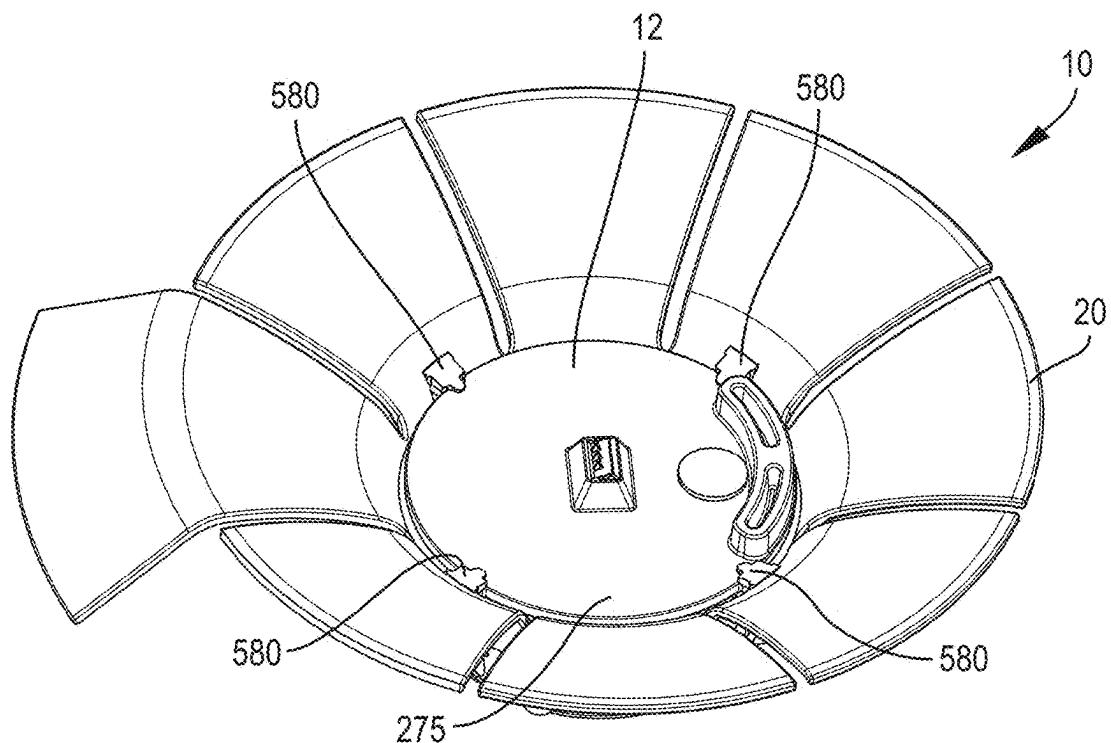


FIG. 105

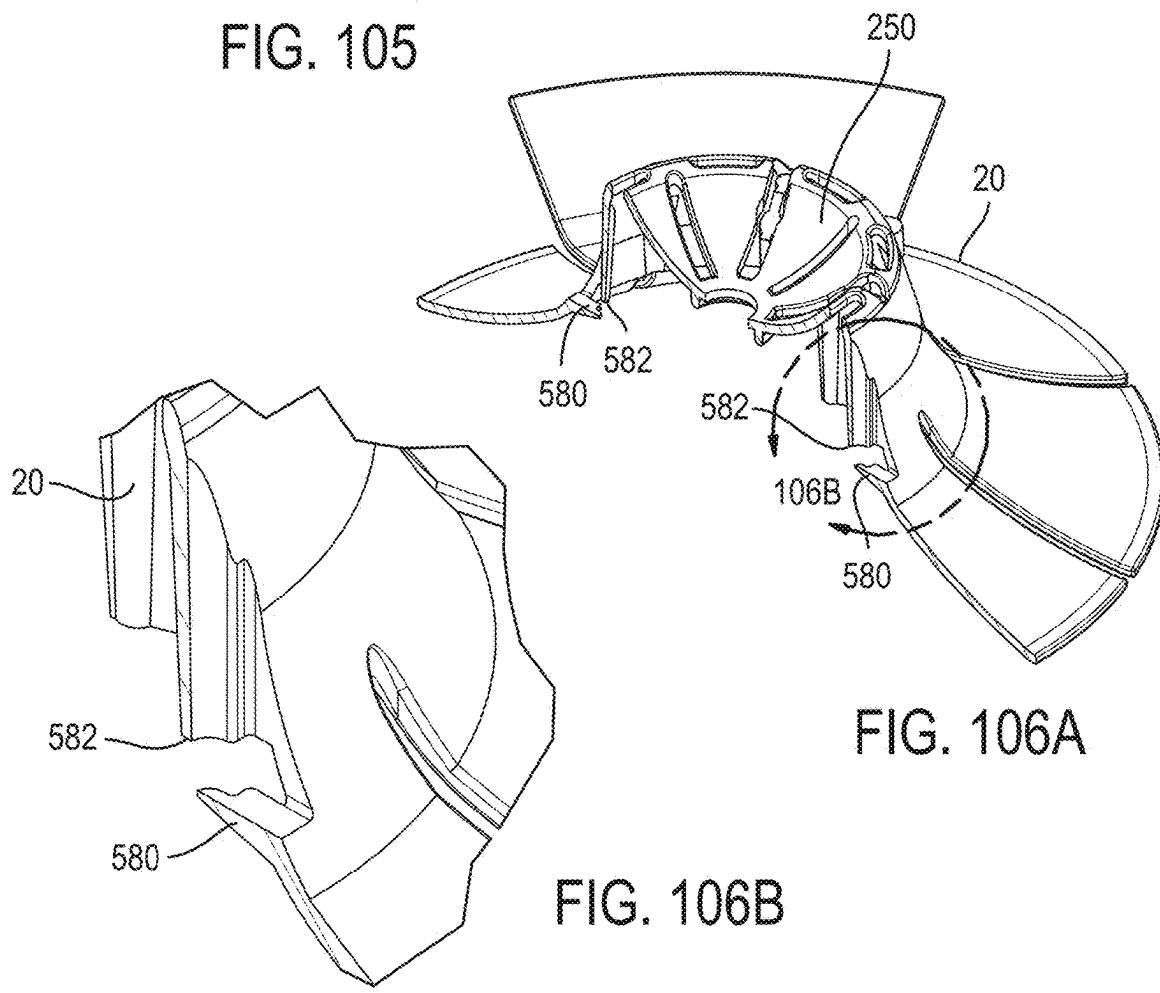
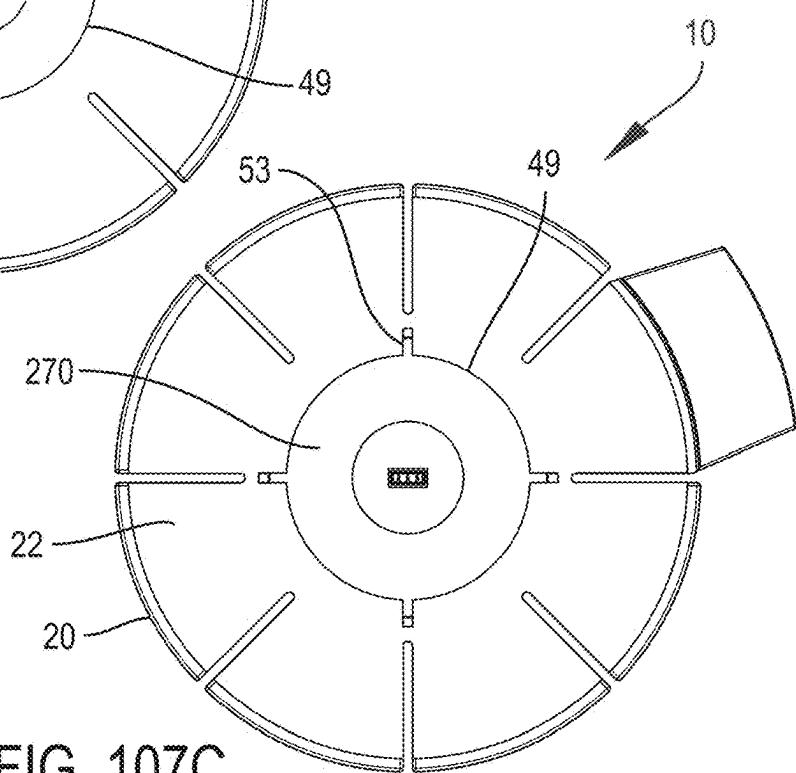
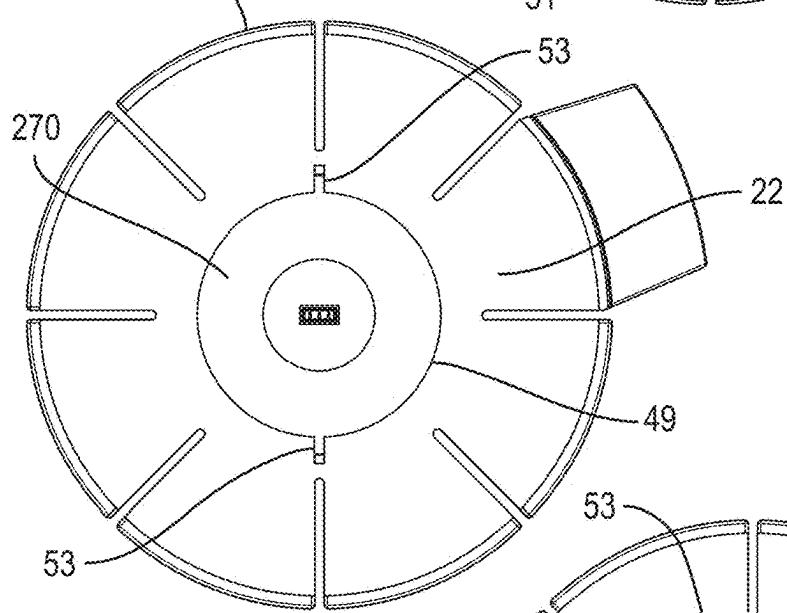
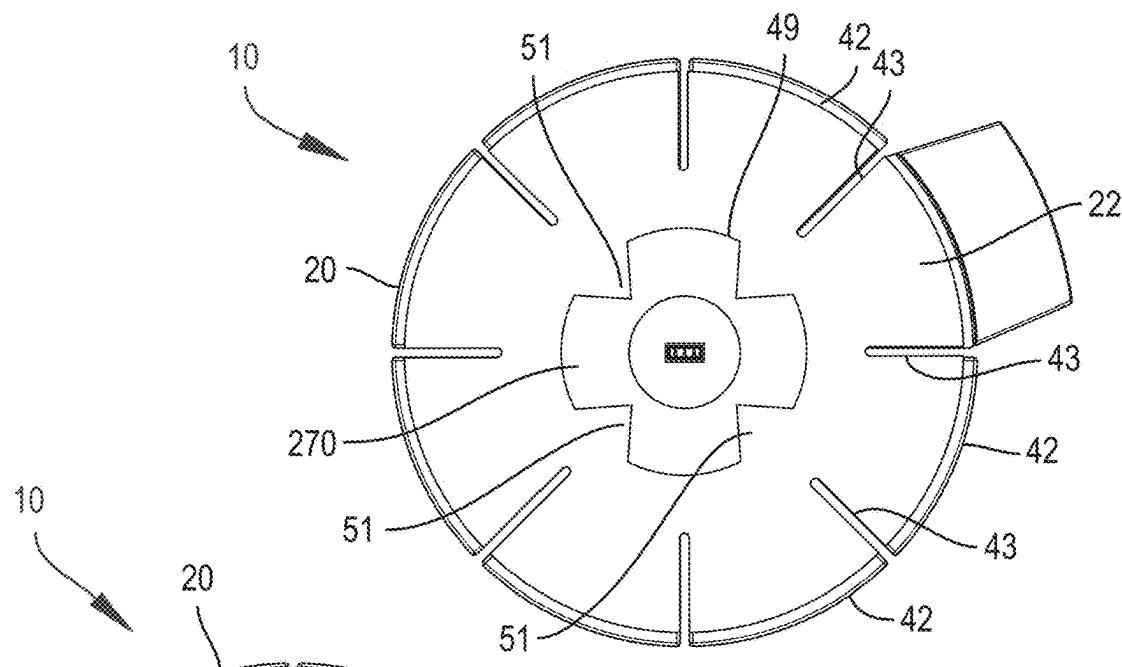
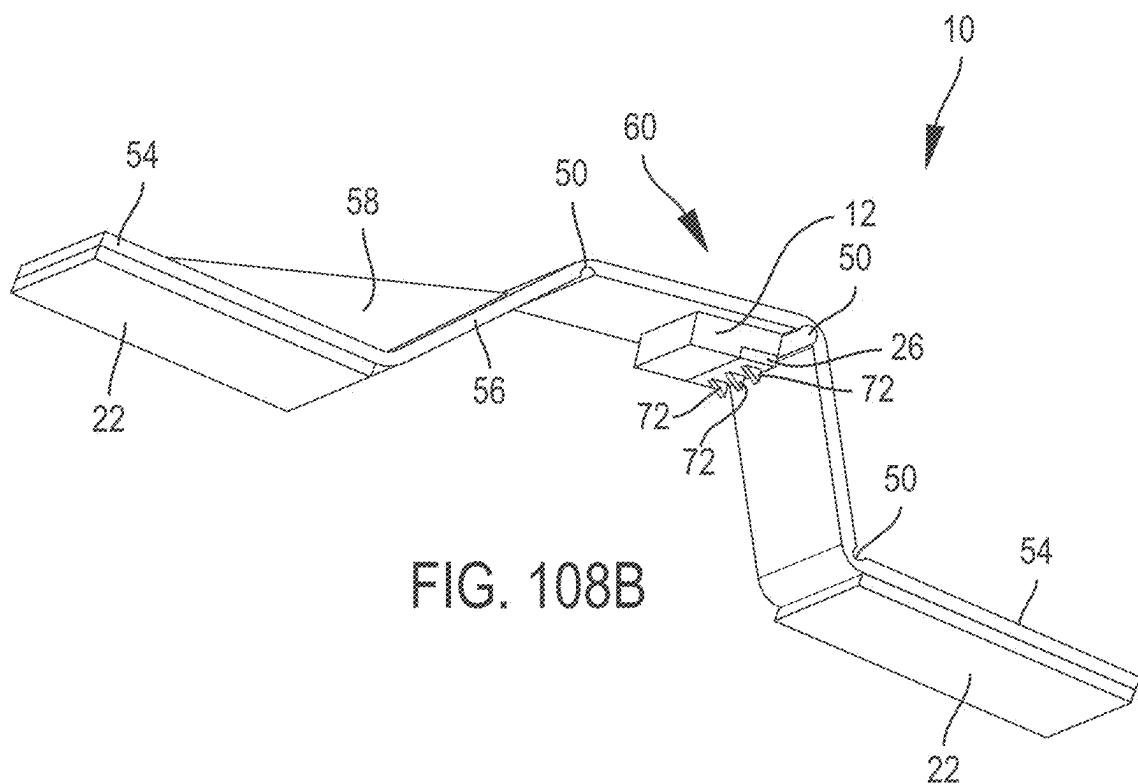
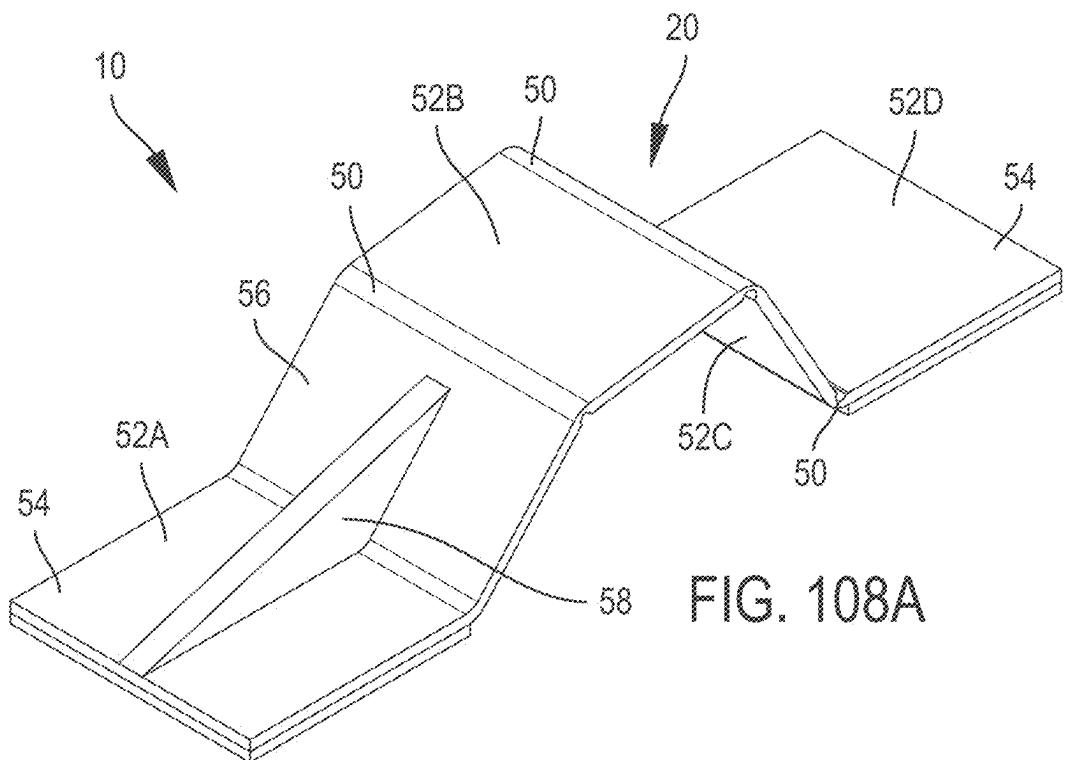


FIG. 106A

FIG. 106B





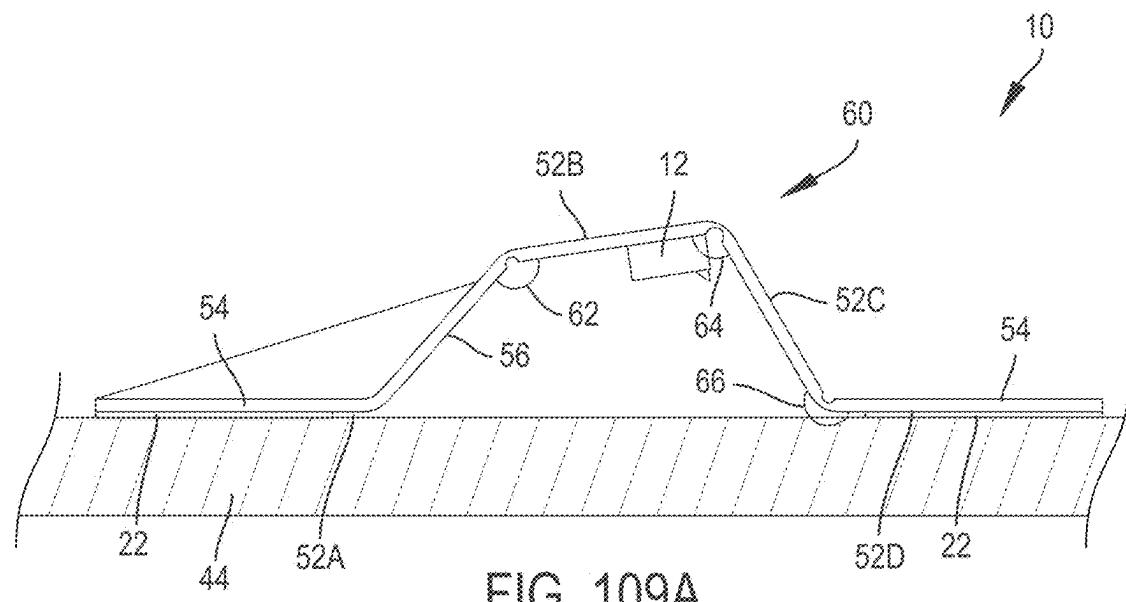


FIG. 109A

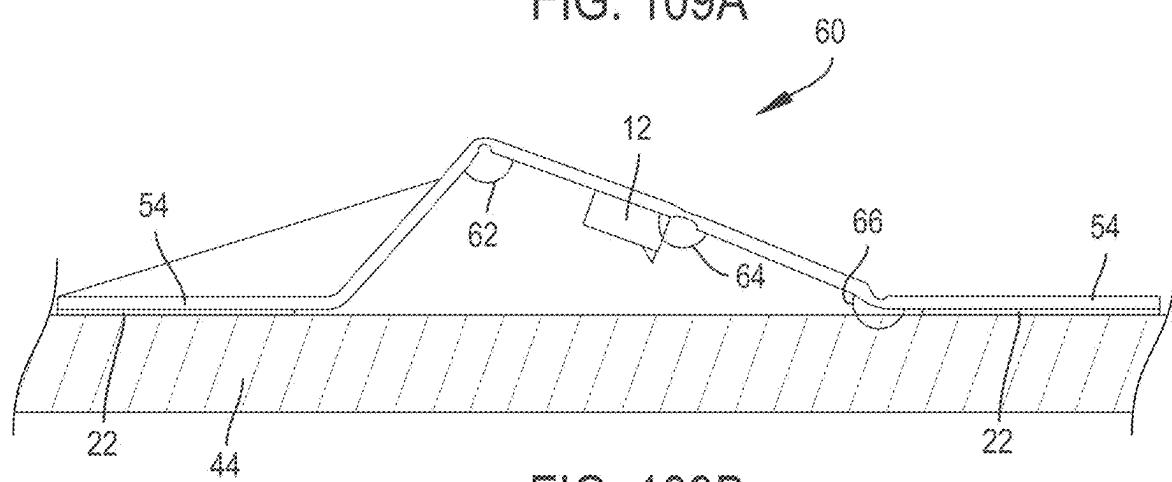


FIG. 109B

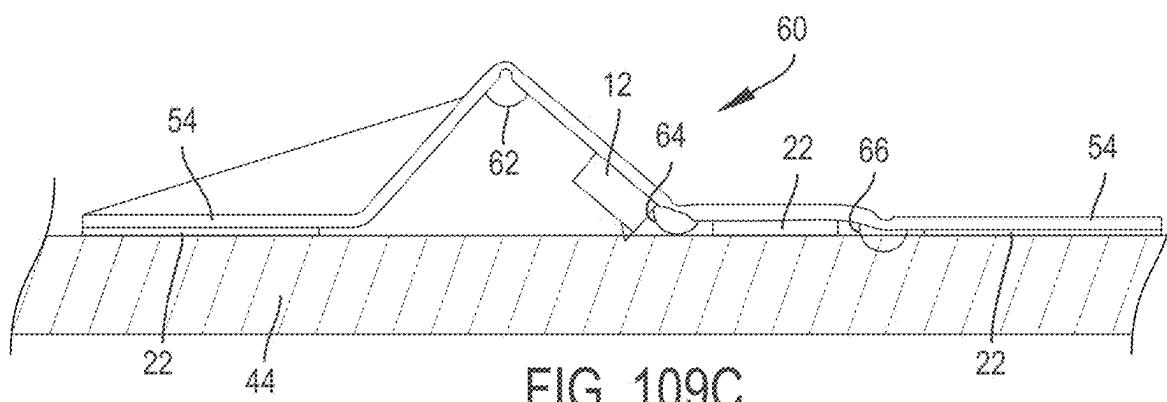
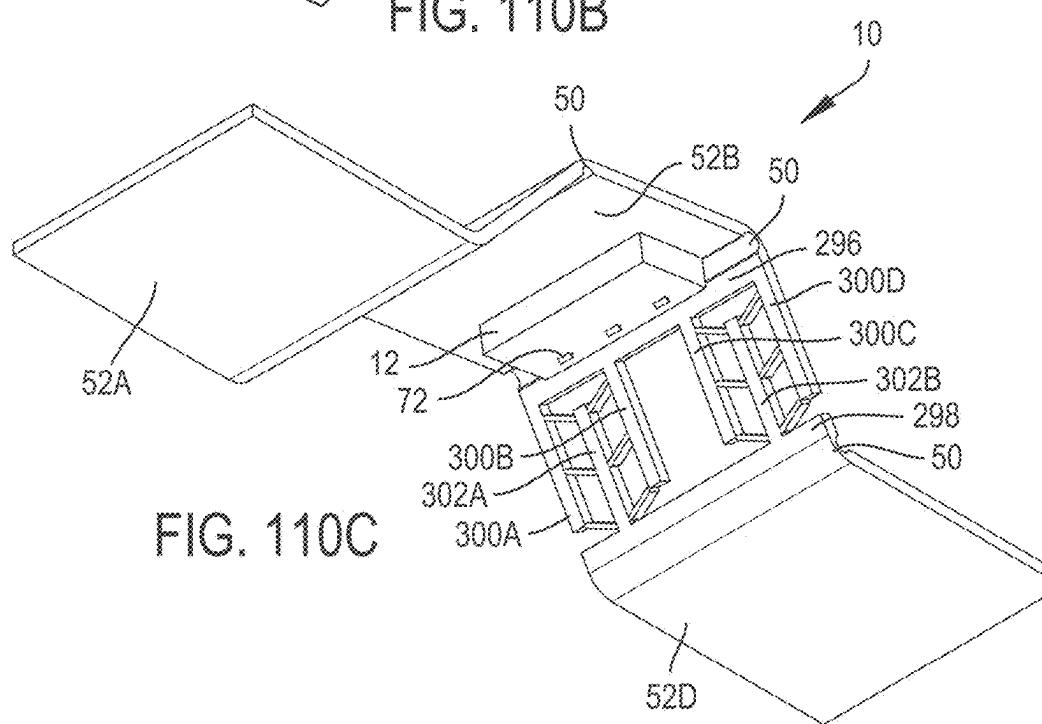
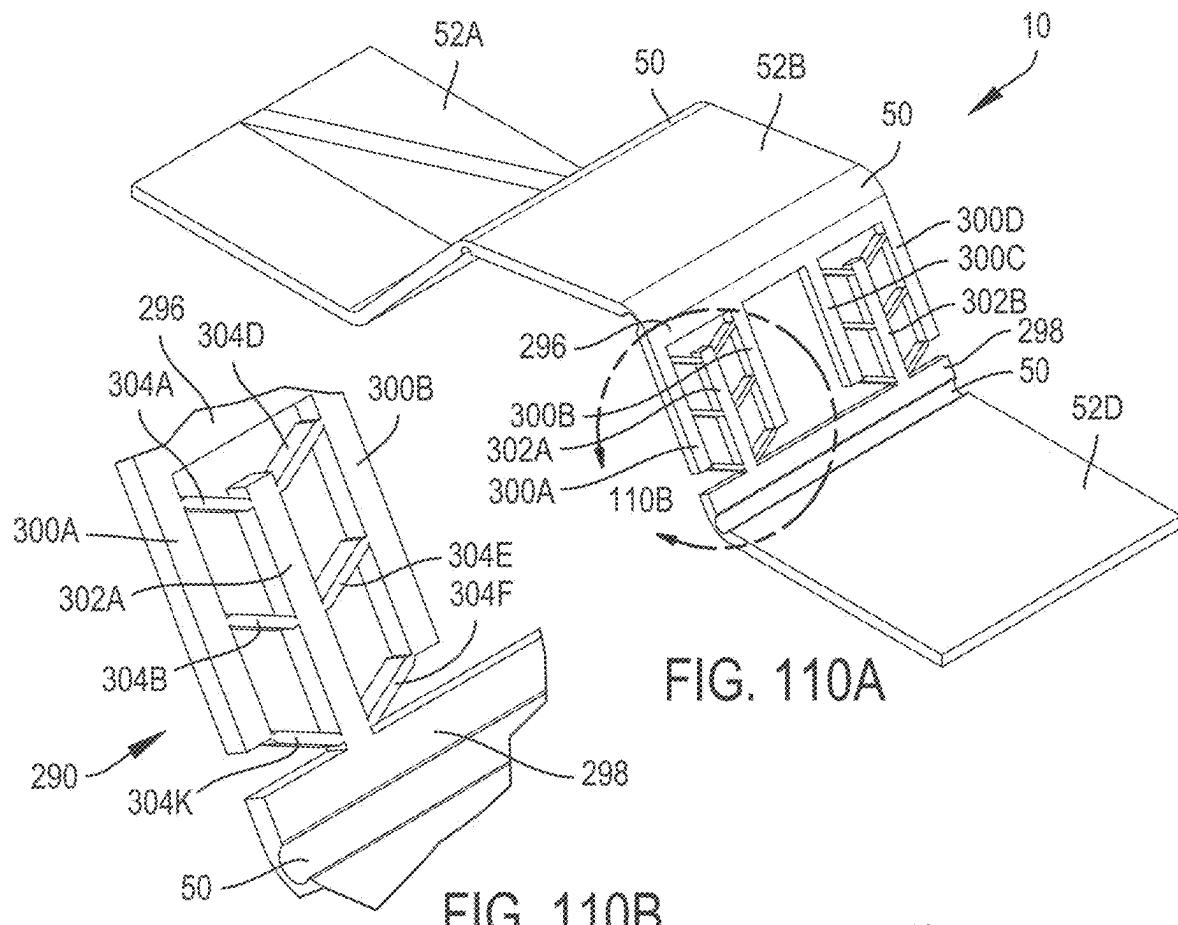


FIG. 109C



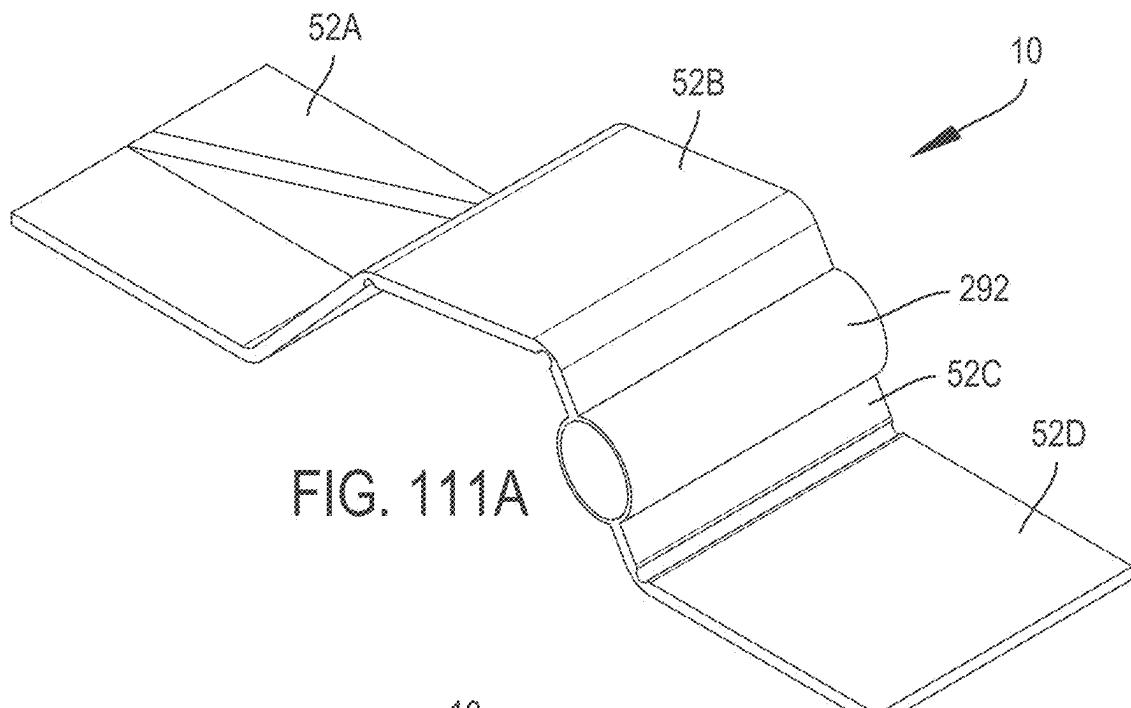


FIG. 111A

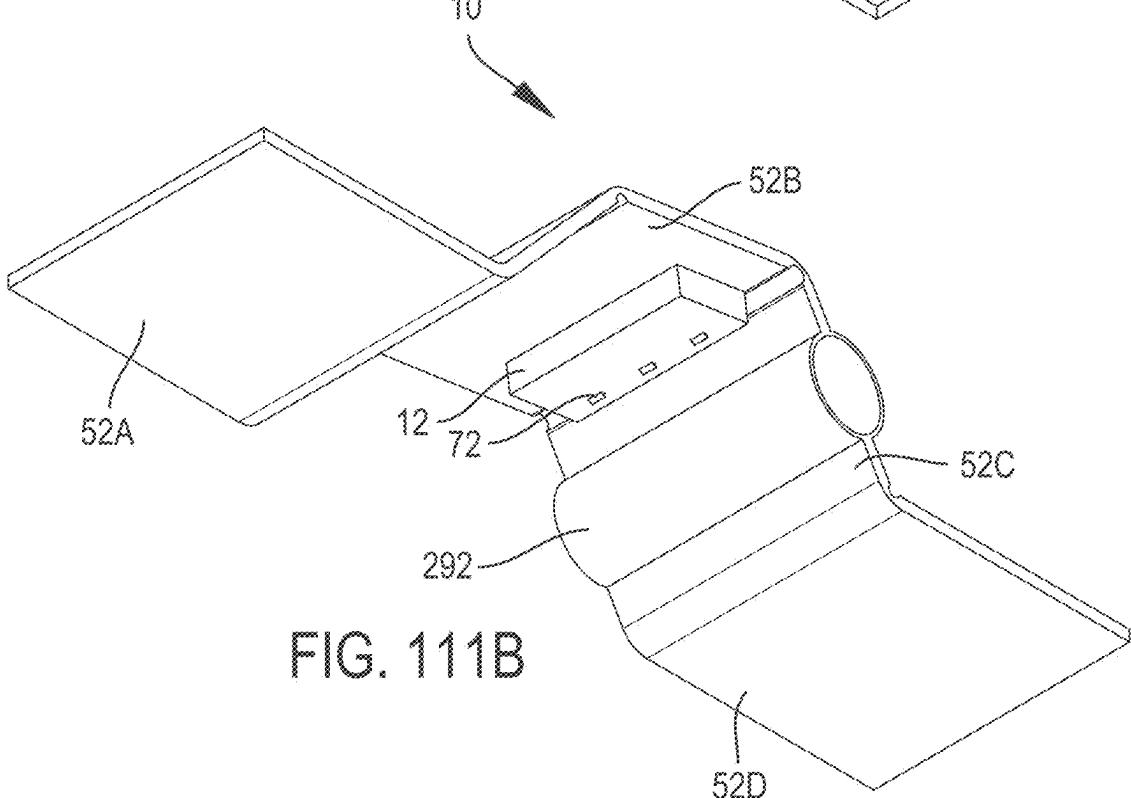


FIG. 111B

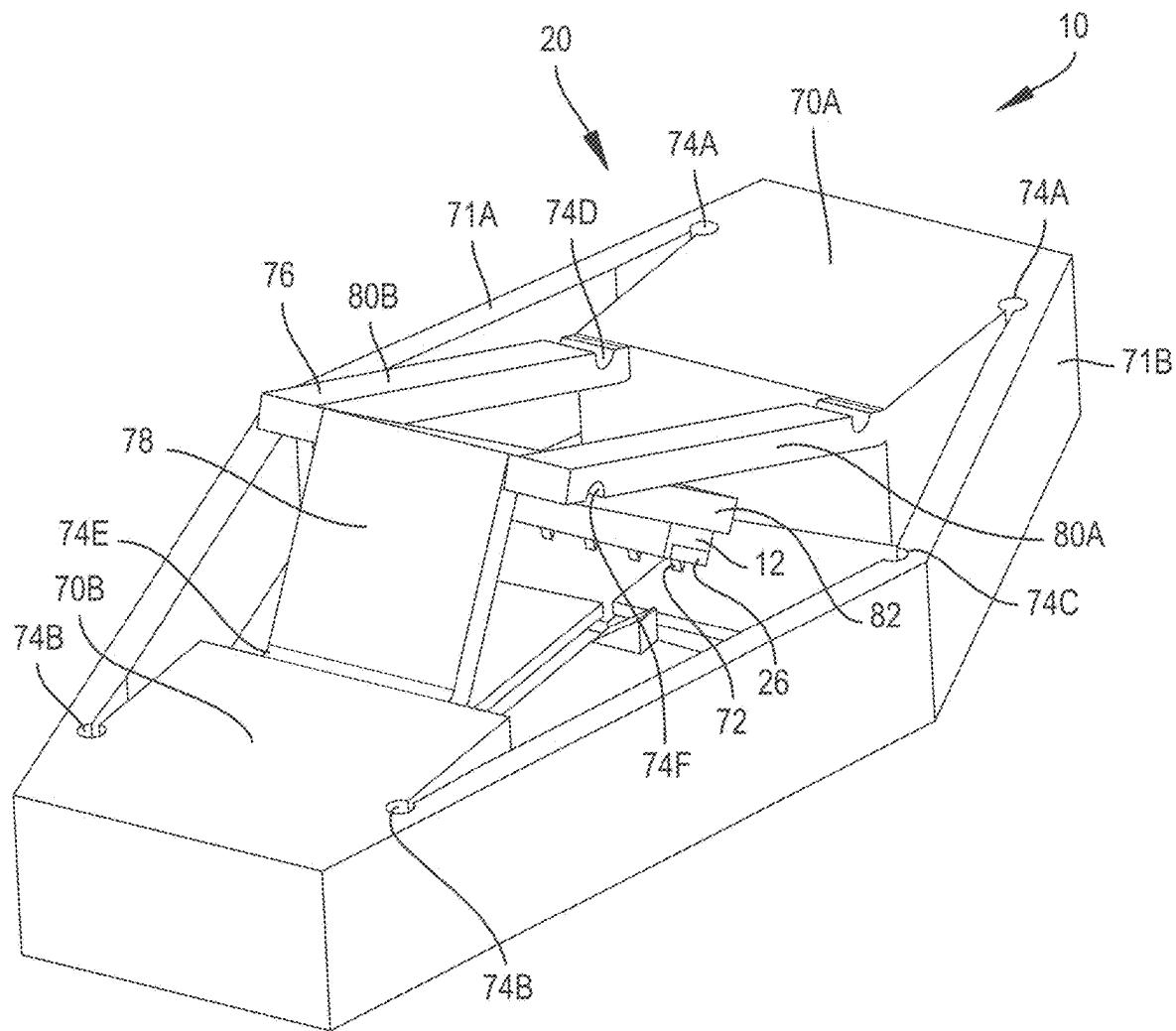


FIG. 112

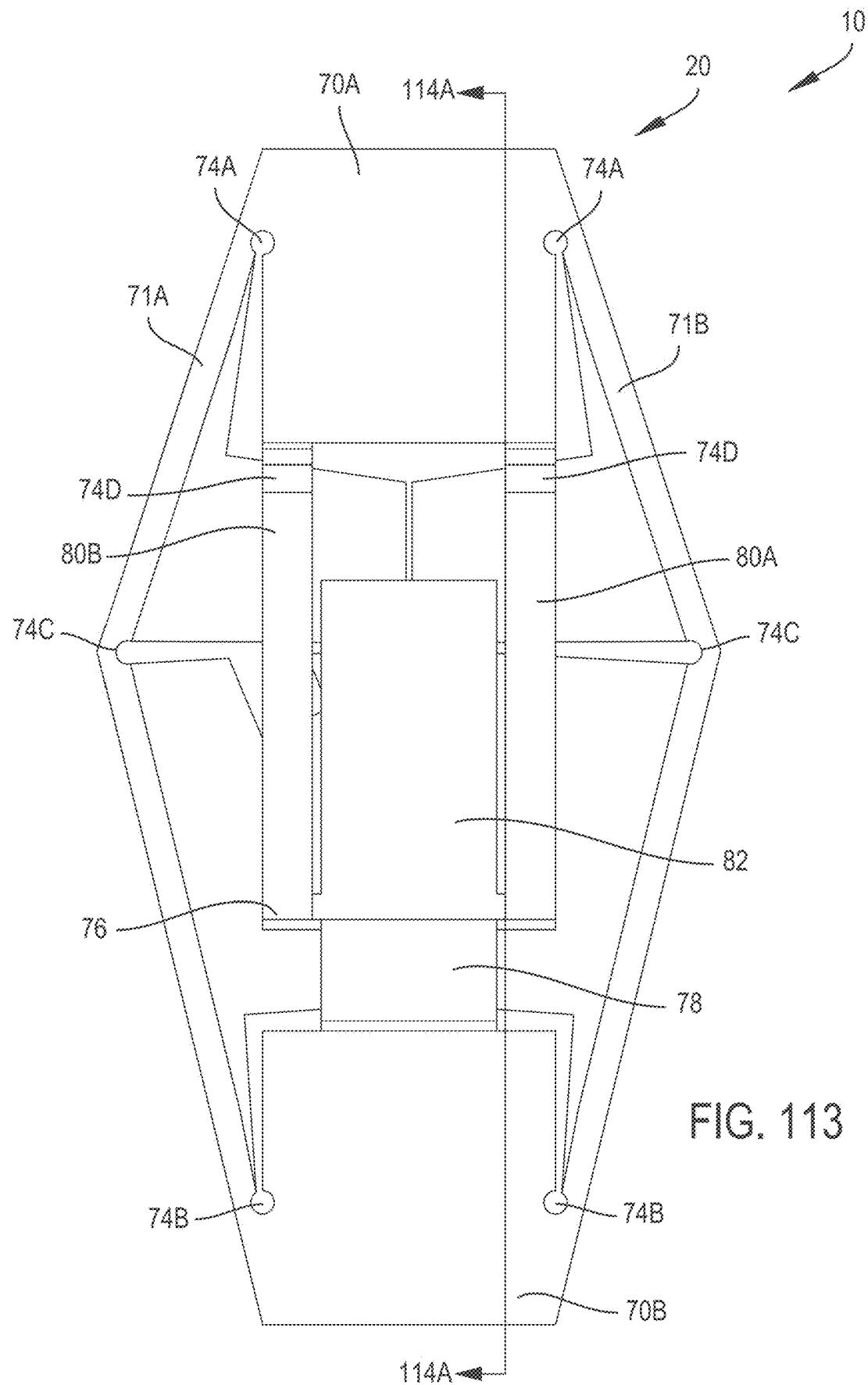


FIG. 113

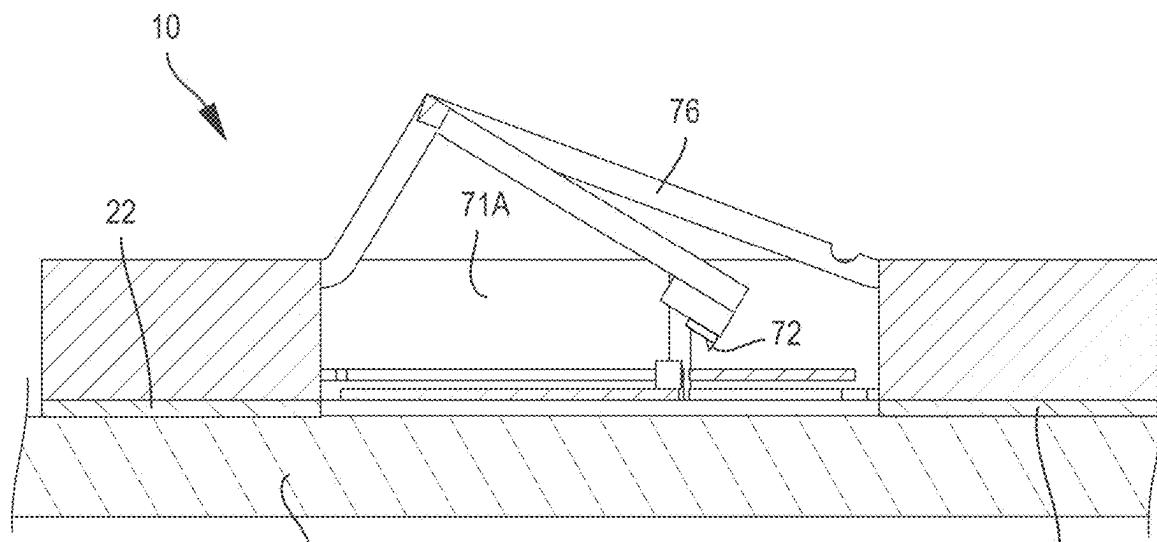


FIG. 114A

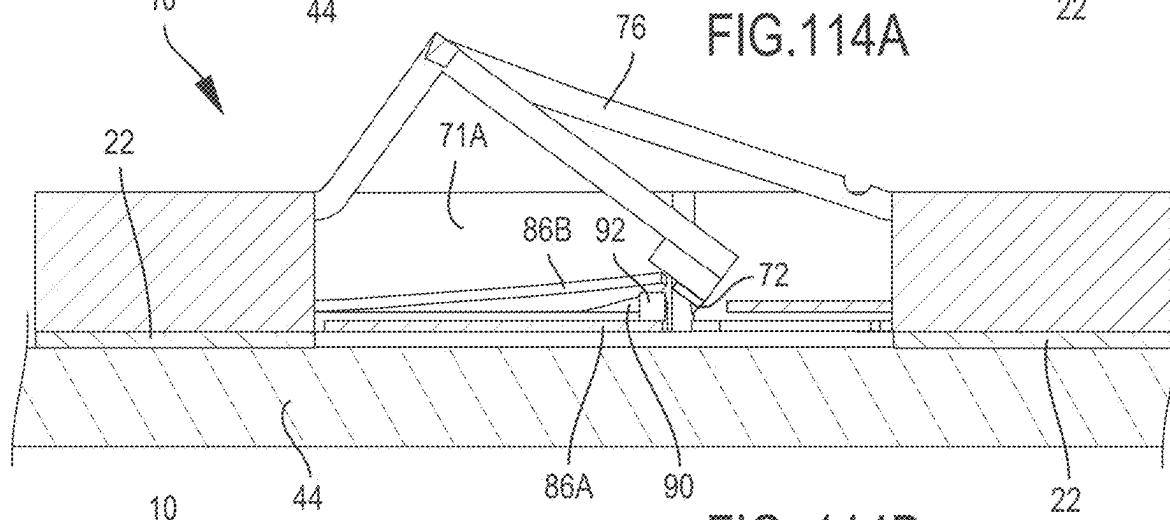


FIG. 114B

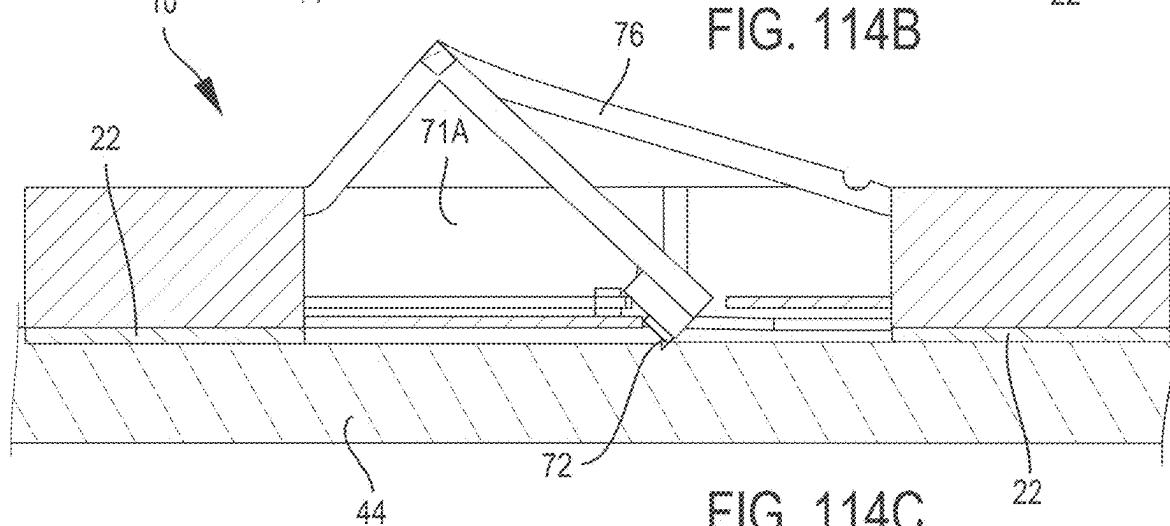


FIG. 114C

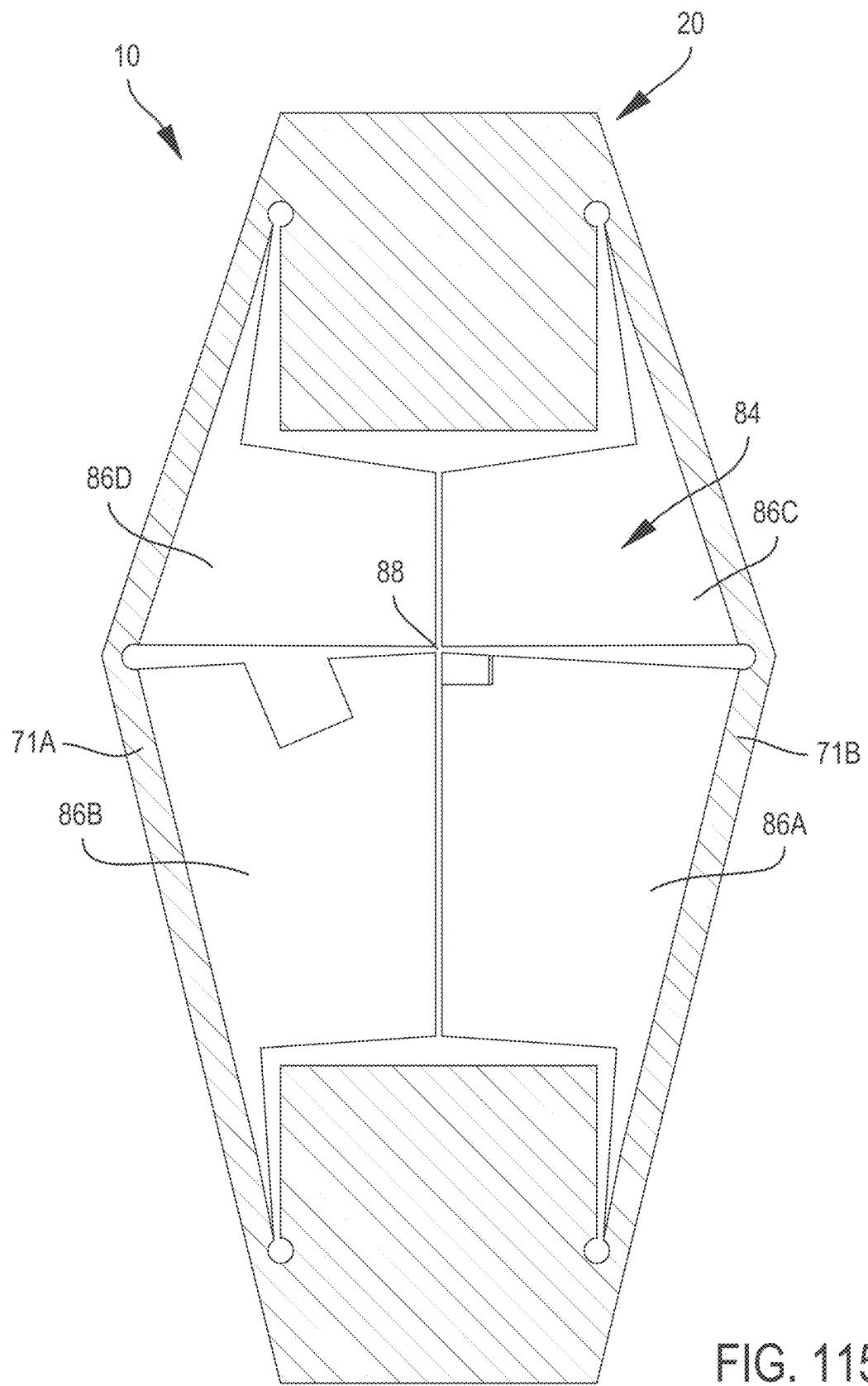


FIG. 115

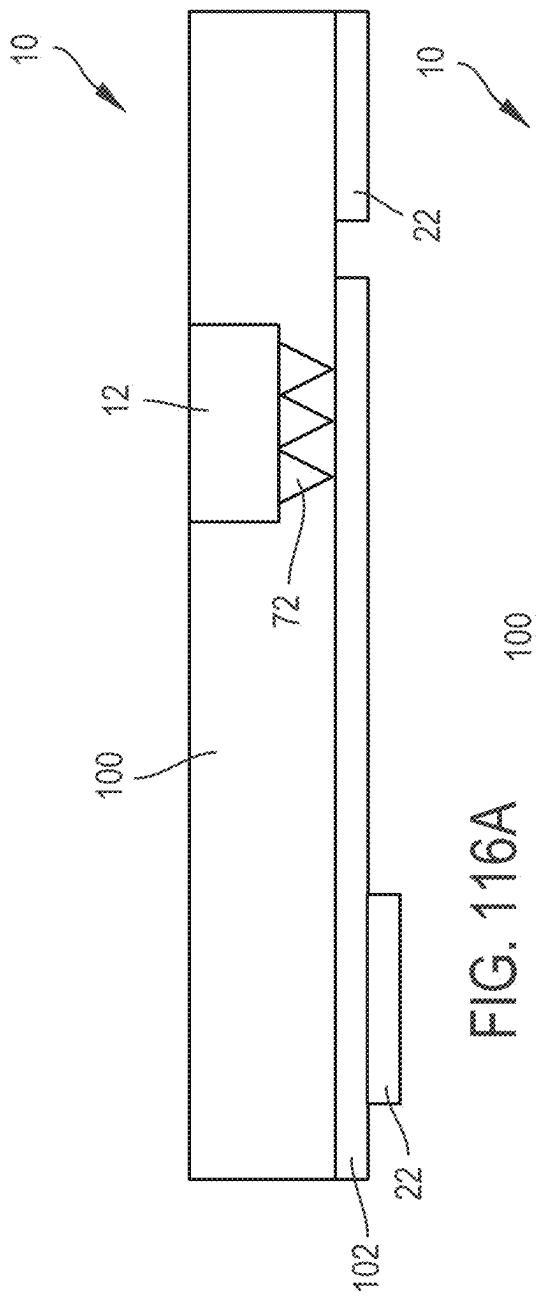
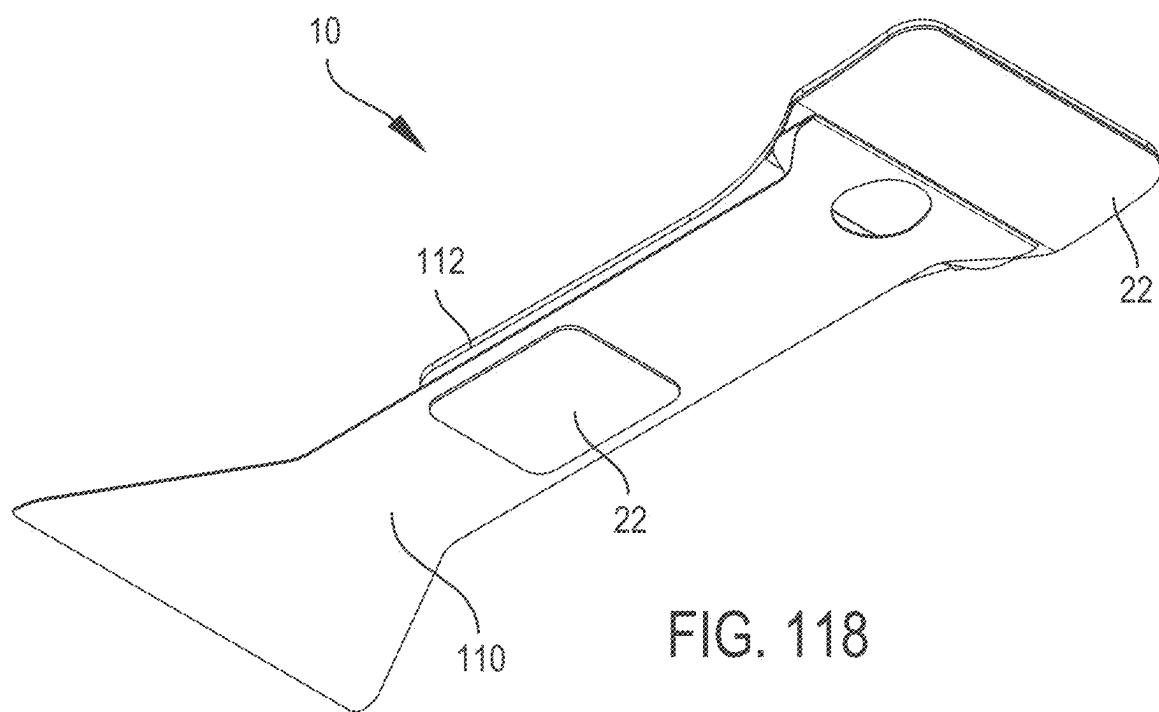
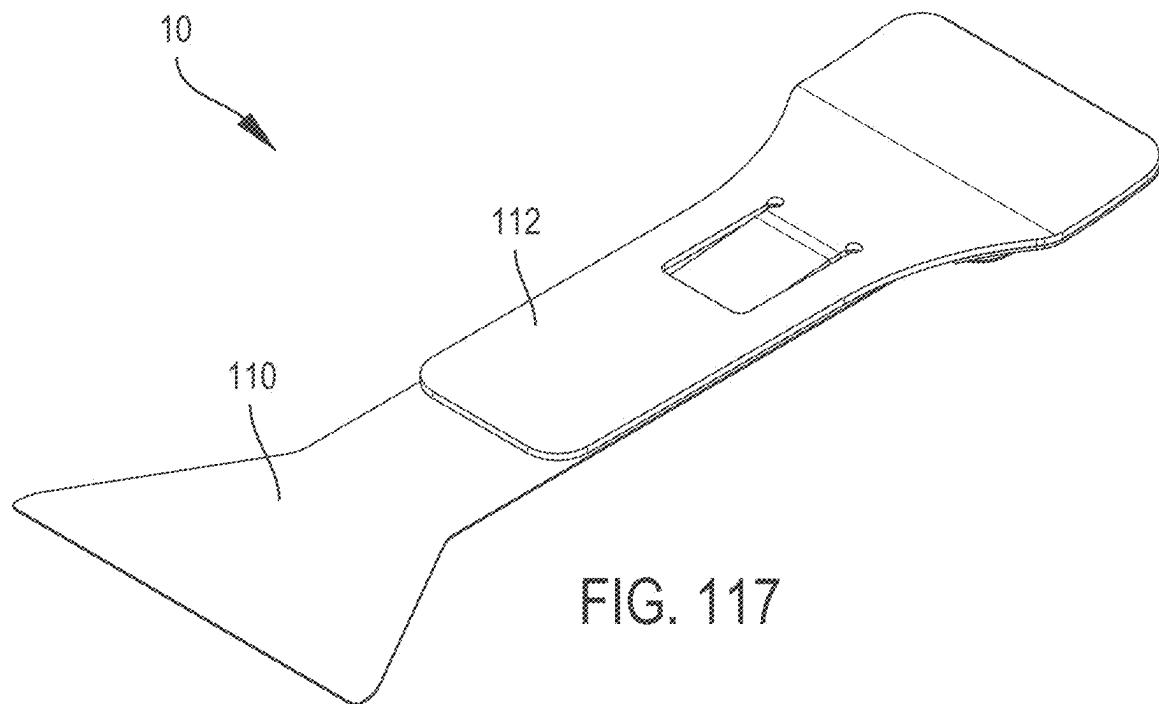


FIG. 116A



FIG. 116B



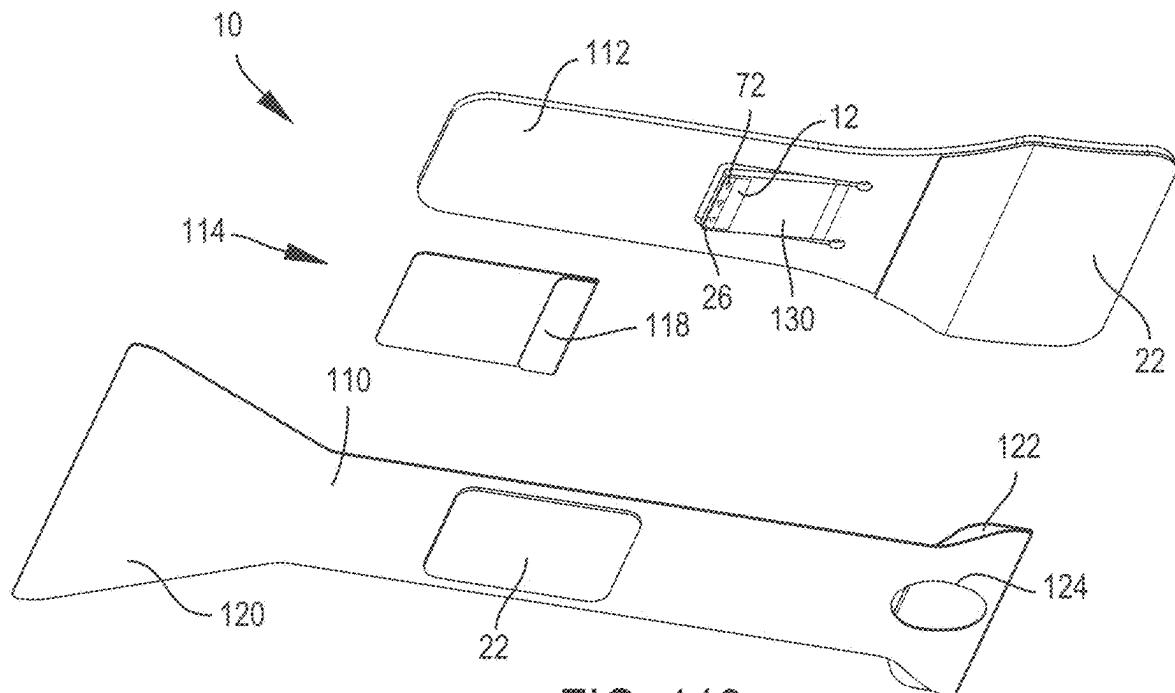


FIG. 119

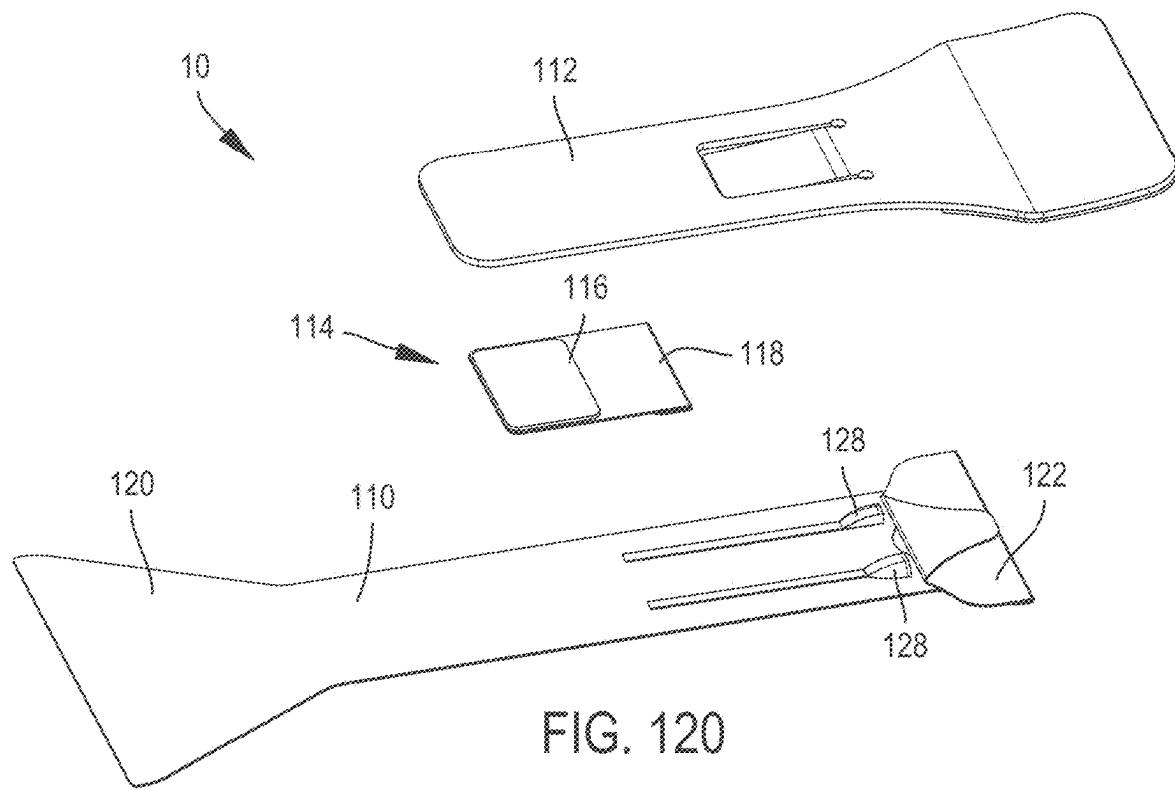
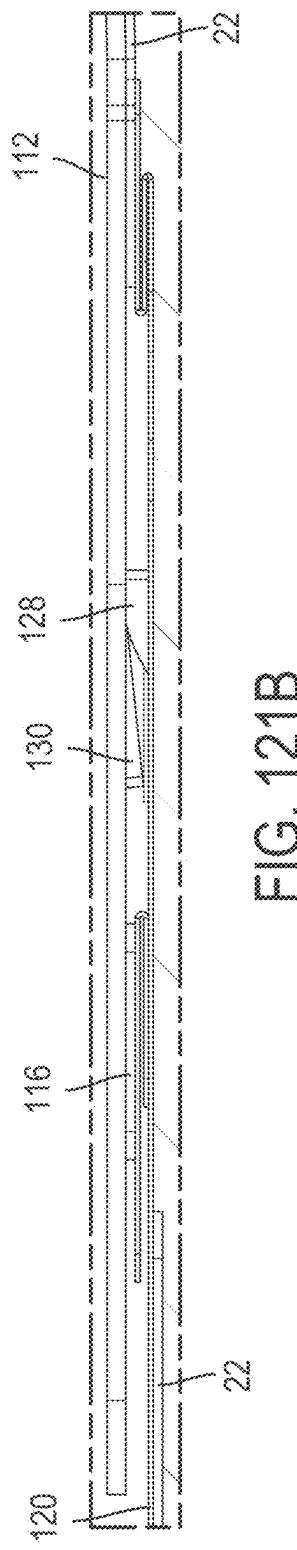
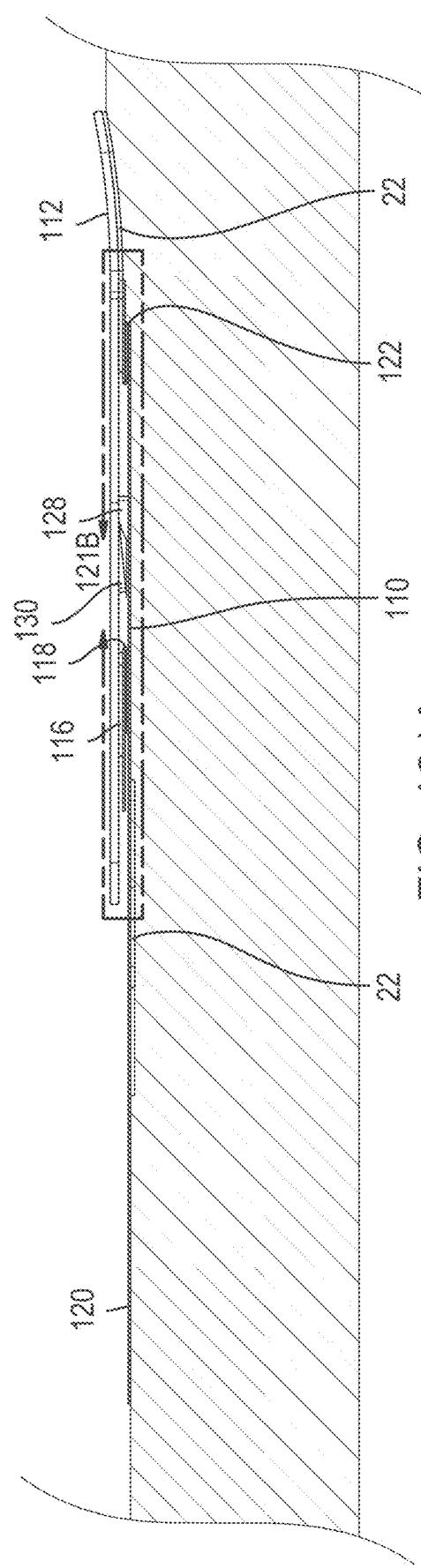


FIG. 120



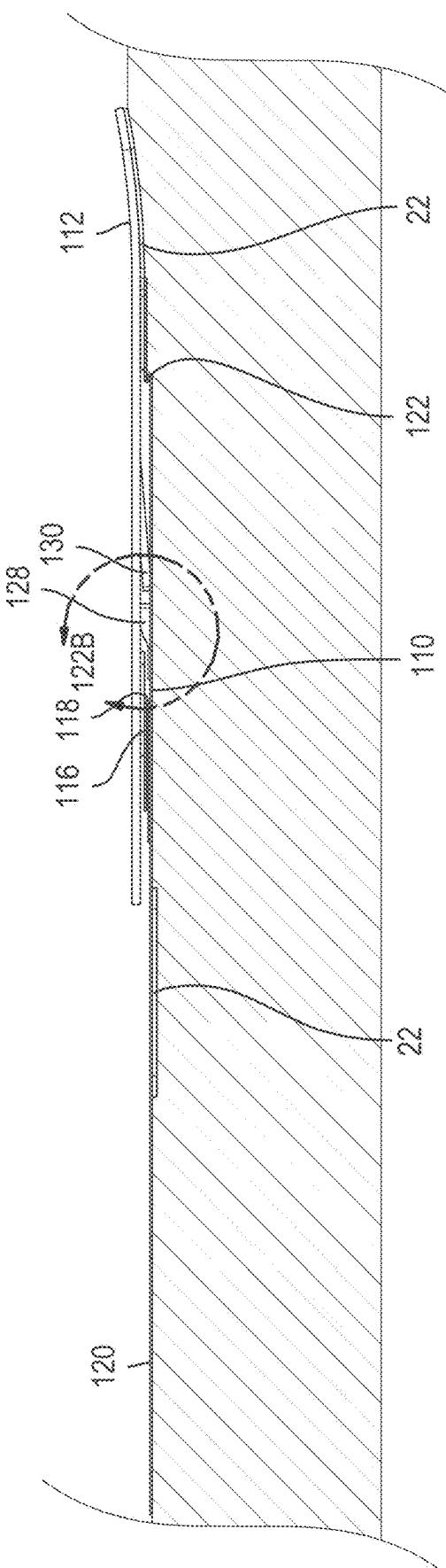


FIG. 122A

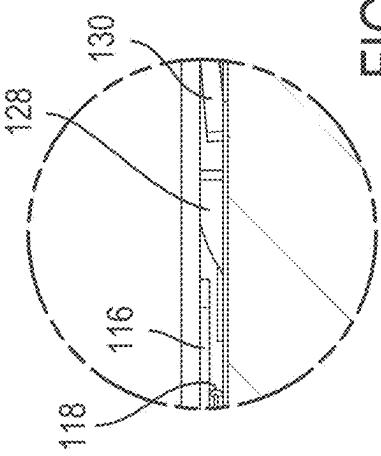


FIG. 122B

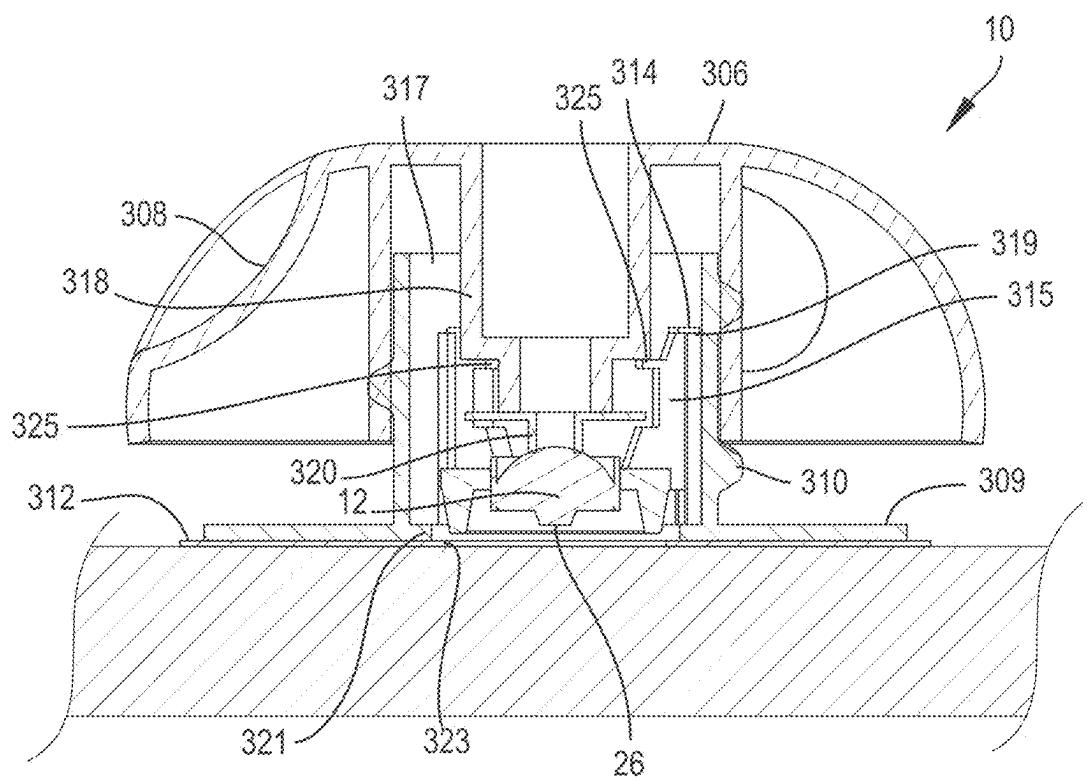


FIG. 123

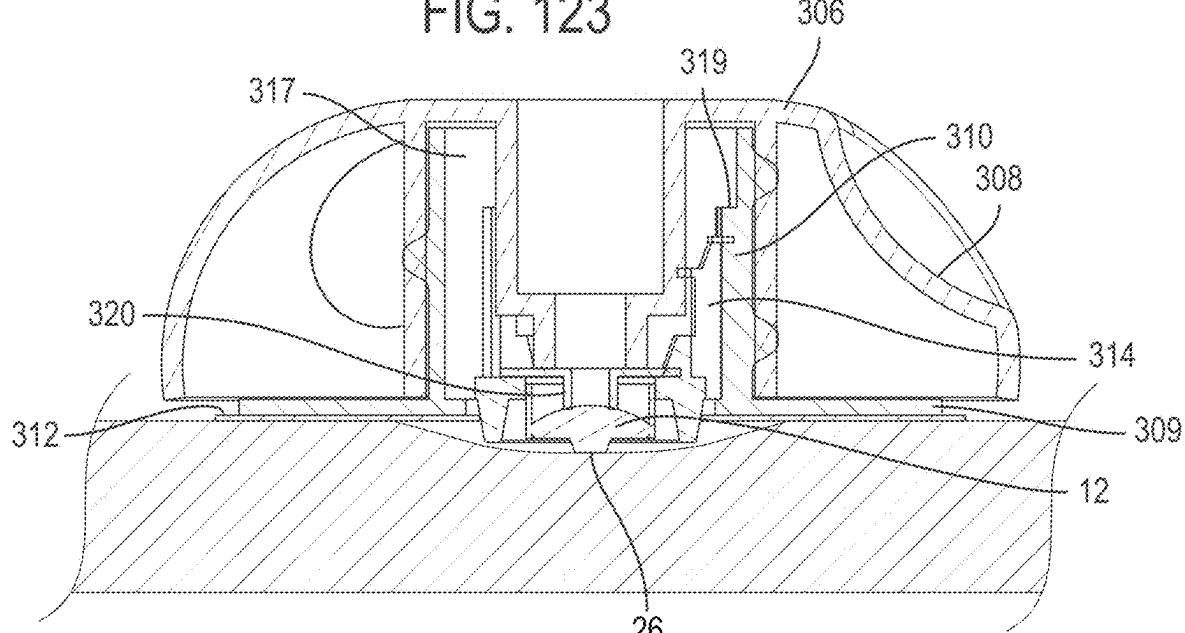


FIG. 124

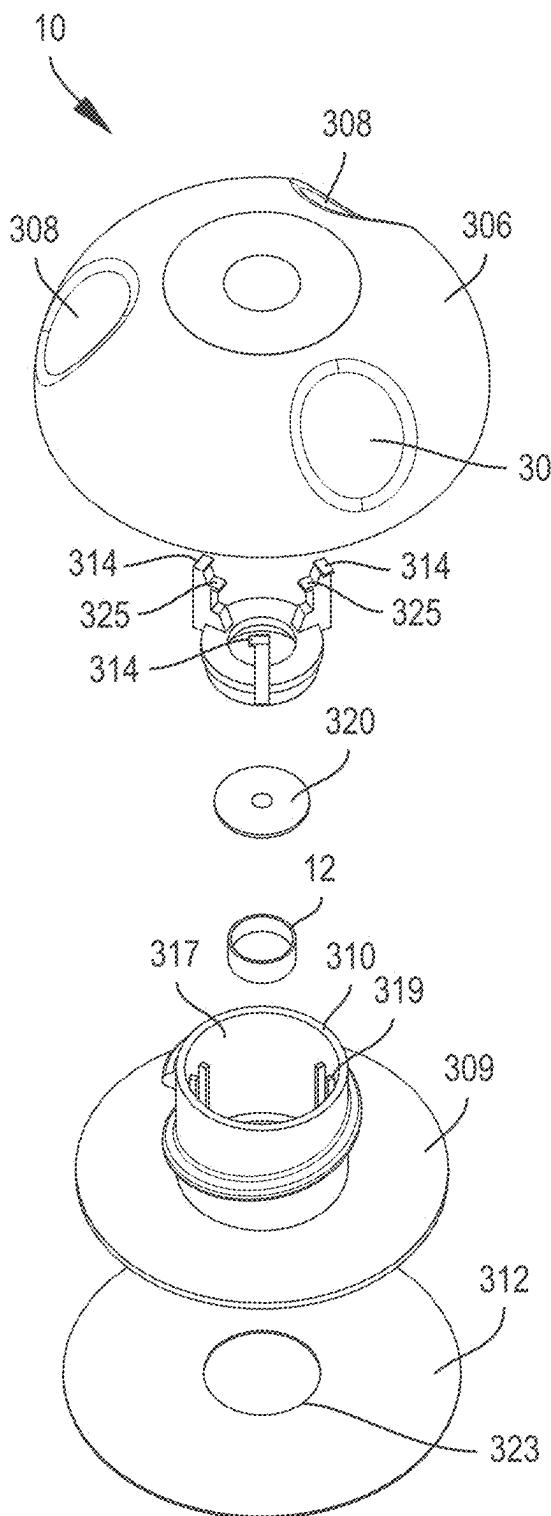


FIG. 125

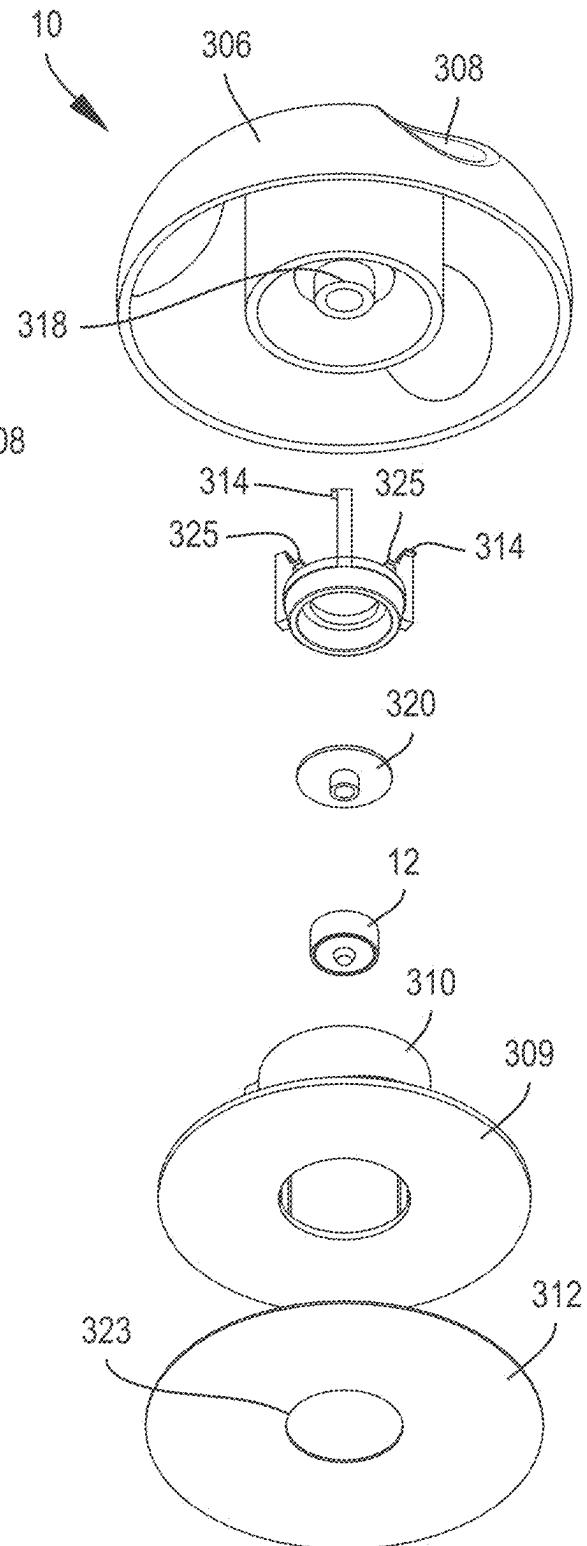
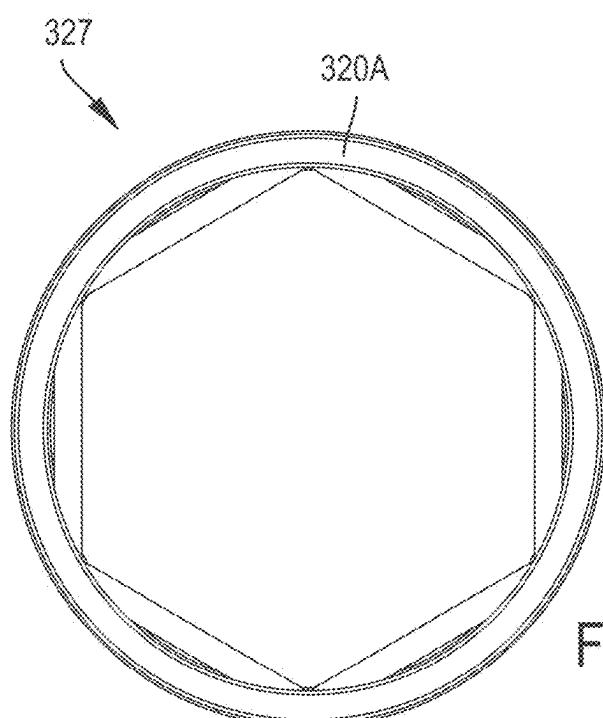
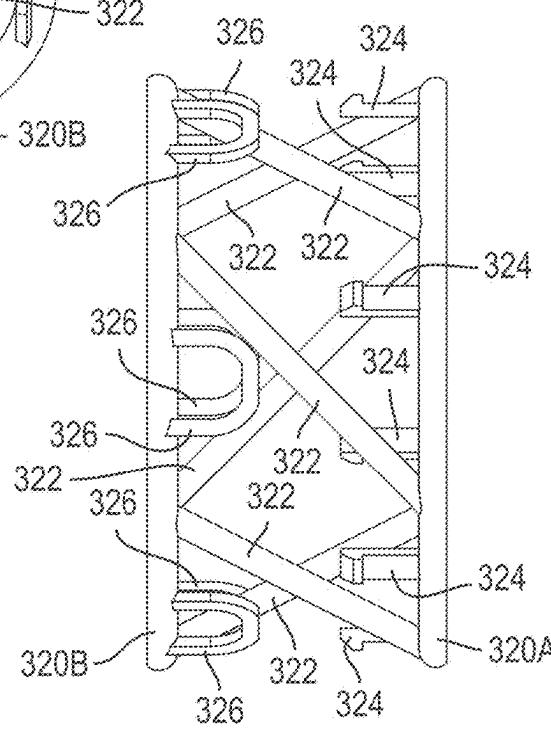
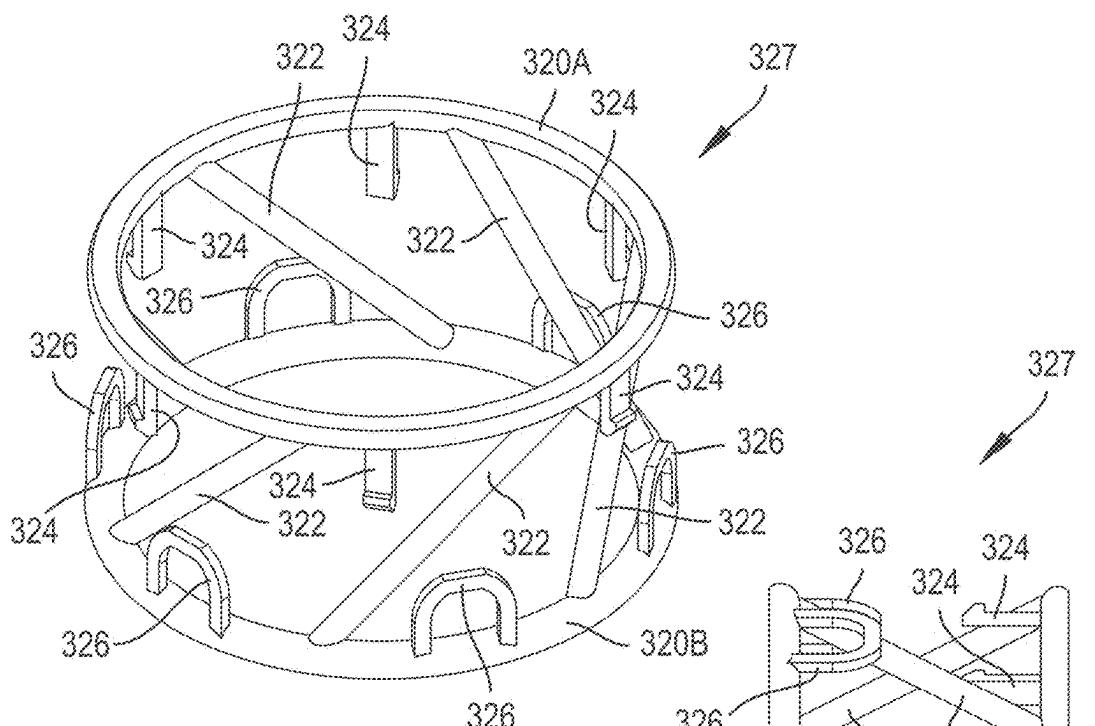


FIG. 126



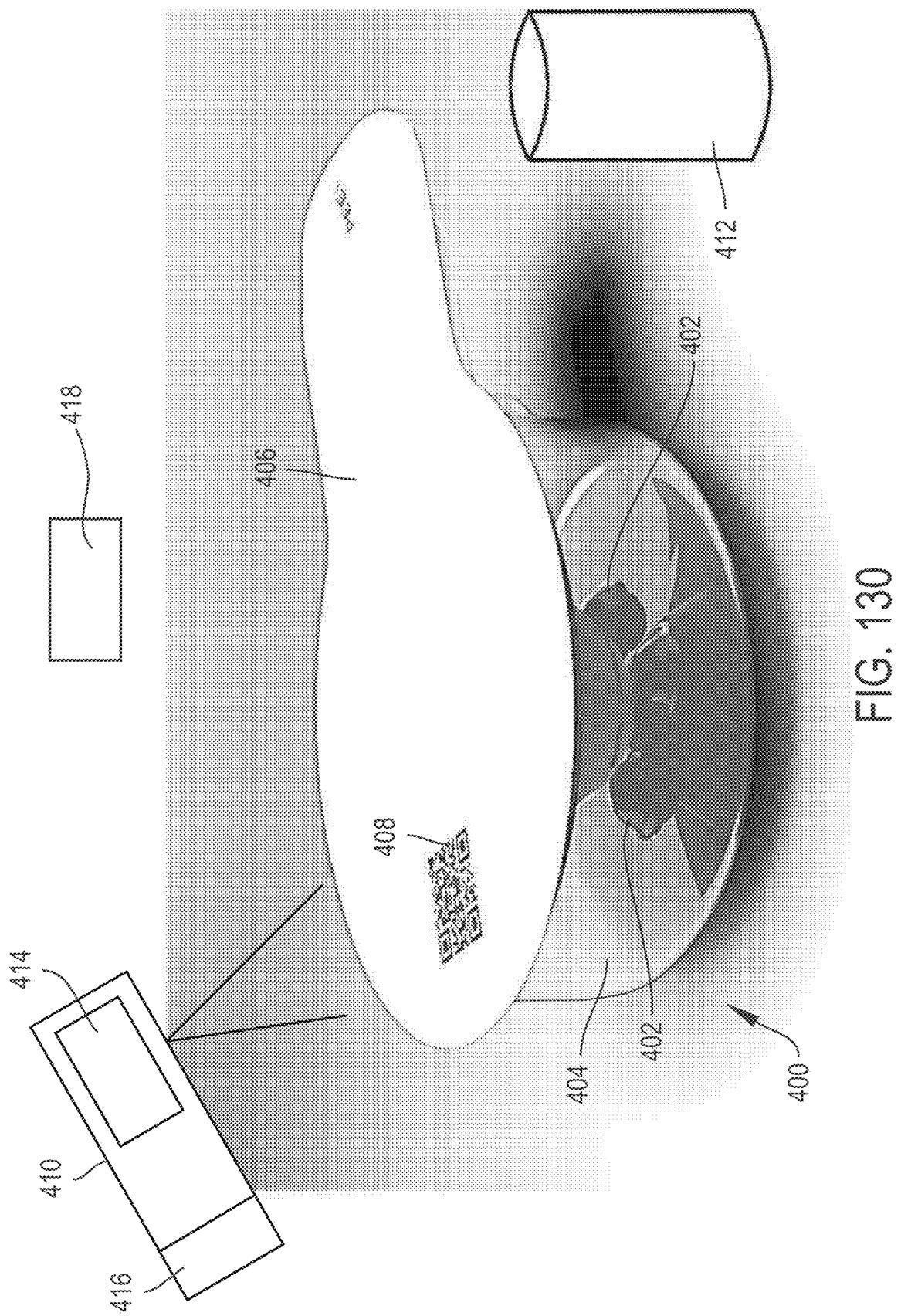


FIG. 130

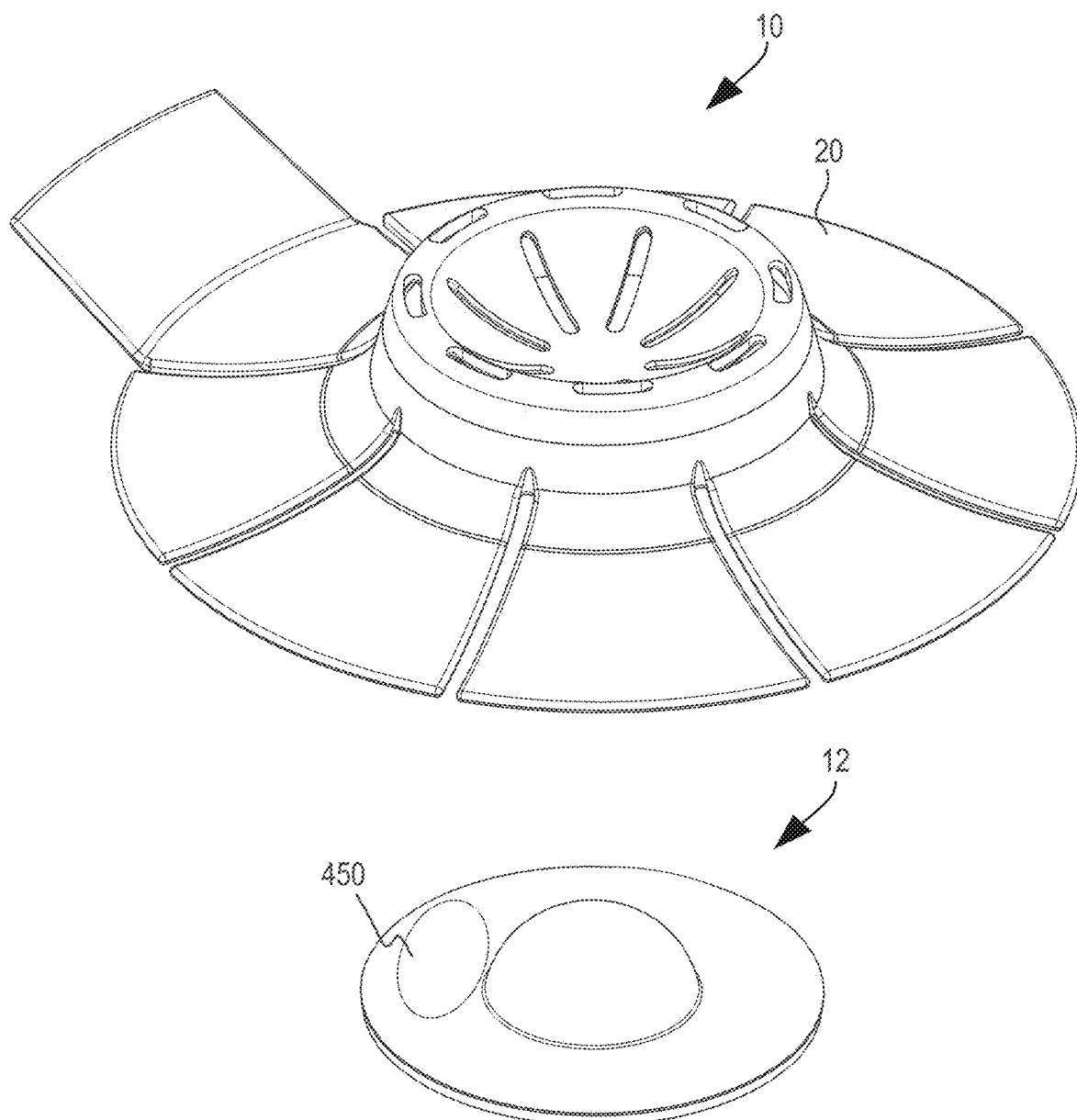


FIG. 131

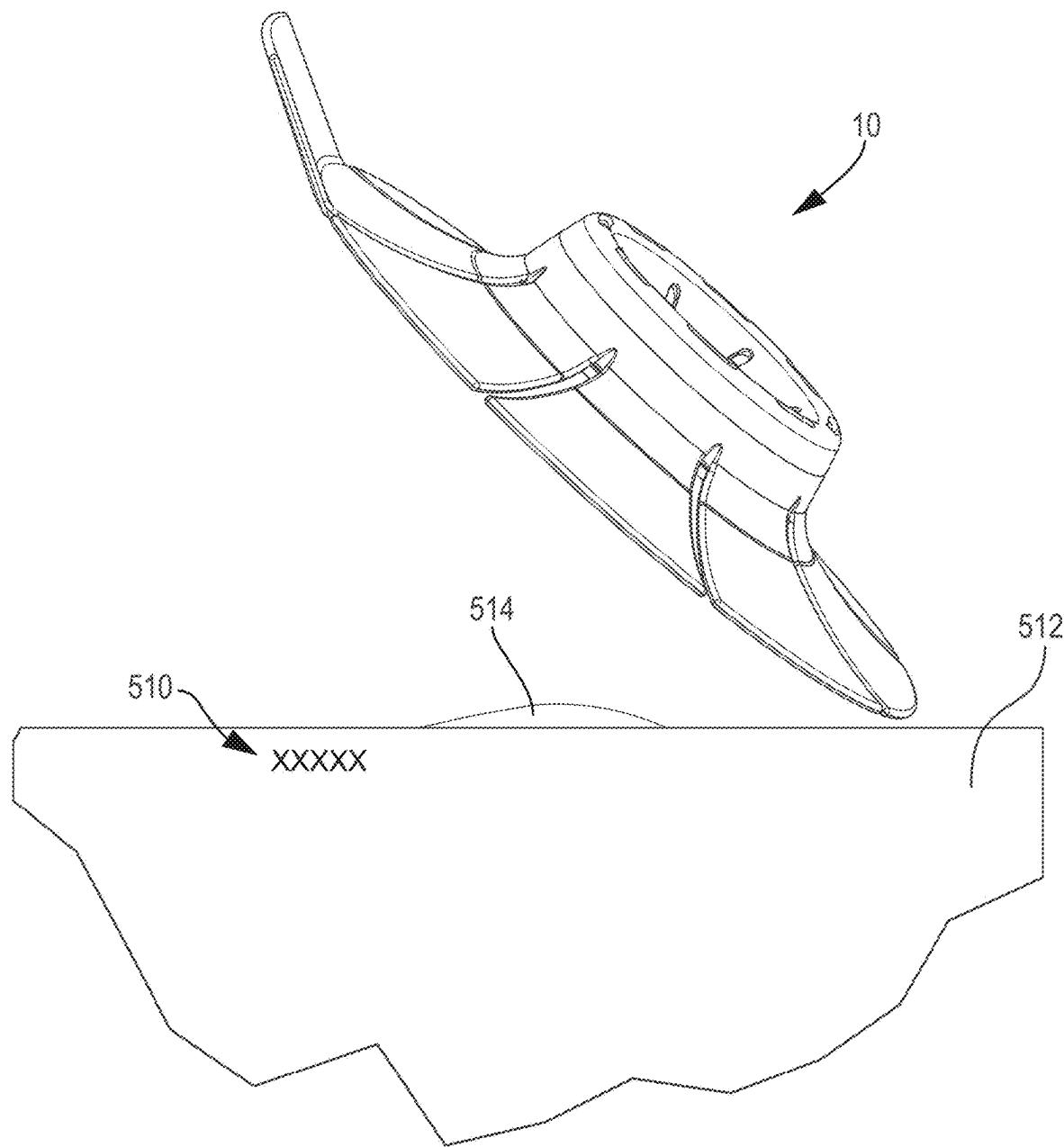


FIG. 132

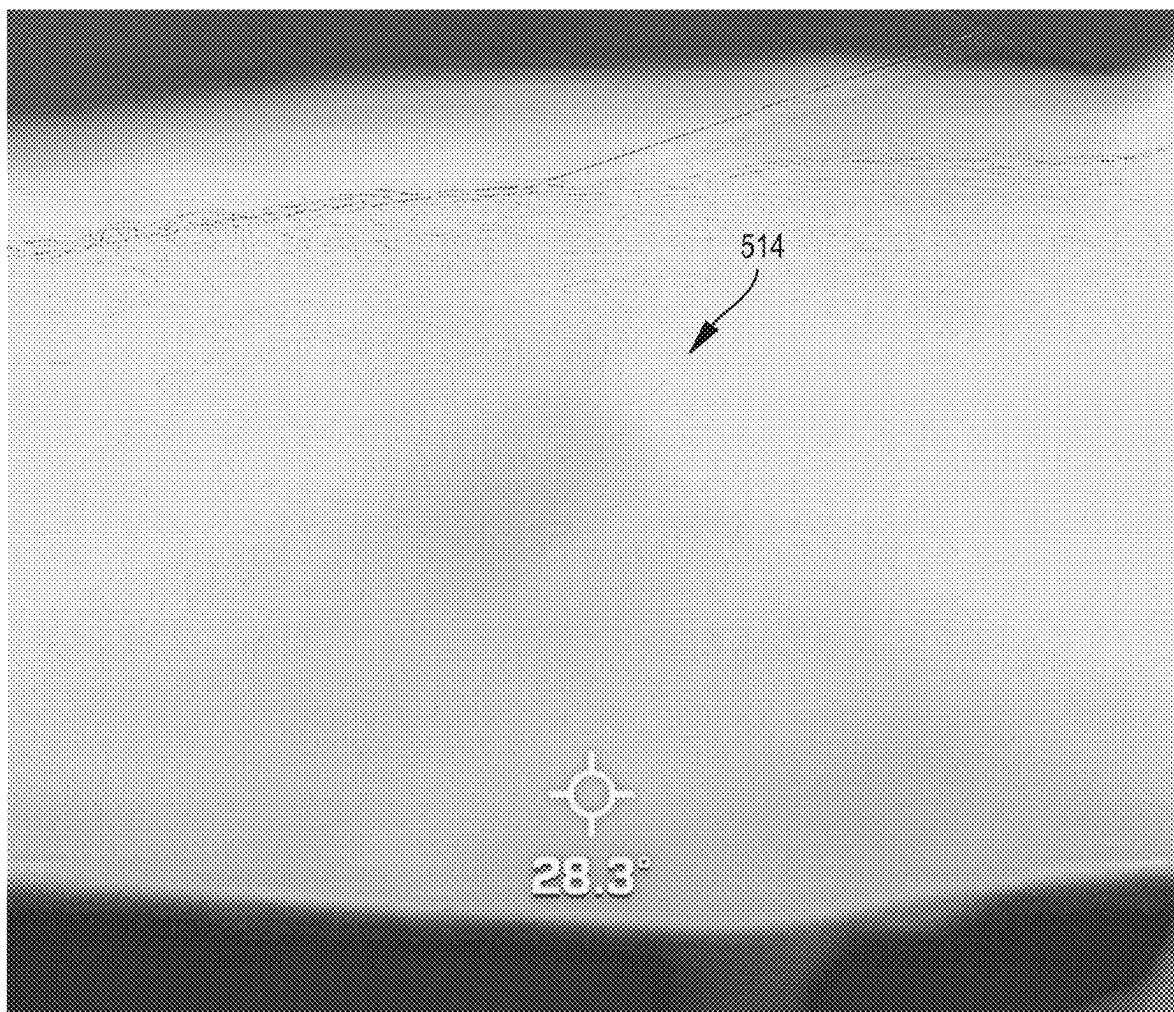


FIG. 133

## DELIVERY DEVICE APPARATUSES, SYSTEMS, AND METHODS

### 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).

### STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with Government support under Agreement W911NF-17-3-0003-CLIN 0008, awarded by ACC-APG-RTP. The Government has certain rights in the invention.

[0003] This invention was made with Government support under Agreement W911NF-17-3-0003-CLIN 0010, awarded by ACC-APG-RTP. The Government has certain rights in the invention.

### 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 protru-

sions 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 transitioning 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 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.

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

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

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

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

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

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

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

[0045] FIG. 5A 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. 5B 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. 6A 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. 6B is a top plan view of the example sharp bearing body shown in FIG. 6A in accordance with various aspects and embodiments of the present disclosure;

[0049] FIG. 7A 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. 7B 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. 8A 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. 8B 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. 8C is a cross-sectional view taken at the indicated cut plane of FIG. 8A in accordance with various aspects and embodiments of the present disclosure;

[0054] FIGS. 9A-9D depict various views of an exemplary microneedle with side ports in accordance with various aspects and embodiments of the present disclosure;

[0055] FIG. 10A depicts a top plane view of an example sharp bearing body;

[0056] FIG. 10B depicts a side view of an example sharp bearing body;

[0057] FIG. 10C depicts a detailed view of the indicated region of FIG. 10A;

[0058] FIG. 10D depicts a perspective view of an example sharp bearing body;

[0059] FIG. 11A is a block diagram of parts of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0060] FIG. 11B 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. 22A-22I 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. 30A 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. 30B 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. 31A 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. 31B 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. 47A depicts a perspective view of an exemplary delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0099] FIG. 47B 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. 47C 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. 47D 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. 49A 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. 49B 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. 49C 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. 50A depicts a side view of an example delivery device in accordance with various aspects and embodiments of the present disclosure;
- [0107] FIG. 50B 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. 52A-52B 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. 54A 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. 54B 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. 54C 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. 54D 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. 55A 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. 55B 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. 55C 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. 56A 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. 56B depicts a detailed view of the indicated region of FIG. 56A in accordance with various aspects and embodiments of the present disclosure;
- [0120] FIG. 56C 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. 56D depicts a detailed view of the indicated region of FIG. 56C 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. 62A depicts a view of a backside of a sharp bearing body overmolded into a molded component;

- [0128] FIG. 62B depicts a cross-sectional view taken at the indicated cut plane of FIG. 62A;
- [0129] FIG. 62C depicts a detailed view of the indicated region of FIG. 62B;
- [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. 65A depicts a cross-sectional view of an example sharp bearing body and set of shut-offs;
- [0133] FIG. 65B depicts a perspective view of an example mold shut-off;
- [0134] FIG. 65C 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. 69A 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. 69B depicts a cross-sectional view of the example sharp bearing body and component of FIG. 69A in accordance with various aspects and embodiments of the present disclosure;
- [0140] FIG. 69C depicts a detailed view of the indicated region of FIG. 69B in accordance with various aspects and embodiments of the present disclosure;
- [0141] FIG. 70A 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. 70B depicts a cross-sectional view of the example sharp bearing body and component of FIG. 70A in accordance with various aspects and embodiments of the present disclosure;
- [0143] FIG. 70C depicts a detailed view of the indicated region of FIG. 70B in accordance with various aspects and embodiments of the present disclosure;
- [0144] FIG. 71A 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. 71B 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. 71C 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. 71D 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. 76A depicts a block diagram of an example reservoir assembly in accordance with various aspects and embodiments of the present disclosure;
- [0153] FIG. 76B 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. 79A depicts an illustrative diagram of an example guide which may be included in a delivery unit of certain example delivery devices in accordance with various aspects and embodiments of the present disclosure;
- [0157] FIG. 79B depicts an illustrative diagram of portions of an example delivery device in an initial state in accordance with various aspects and embodiments of the present disclosure;
- [0158] FIG. 79C 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. 79D 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. 79E 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. 79F 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. 80A 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. 80B 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. 80C 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. 81A depicts a perspective view of an example delivery device with a lock installed thereon;

- [0166] FIG. 81B 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. 87A-87B depict views of an example reservoir interface member having regions of contrasting appearance.
- [0173] FIG. 88A 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. 88B 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. 89A 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. 89B 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. 90A 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. 90B 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. 96A 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. 96B 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. 98A 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. 98B 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. 99A 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. 99B 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. 99C 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. 99D 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. 99E 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. 99F 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. 99G 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. 100A 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. 100B 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. 100C 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. 100D 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. 100E 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. 100F 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. 100G 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. 101A 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. 101B 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. 101C 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. 101D 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. 101E 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. 101F 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. 101G 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. 102A depicts a top plan view of an example reservoir in accordance with various aspects and embodiments of the present disclosure;

[0211] FIG. 102B 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. 106A 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. 106B depicts a detailed view of the indicated region of FIG. 106A in accordance with various aspects and embodiments of the present disclosure;

[0217] FIG. 107A 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. 107B 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. 107C 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. 108A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0221] FIG. 108B is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0222] FIG. 109A 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. 109B 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. 109C 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. 110A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0226] FIG. 110B 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. 110C is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0228] FIG. 111A is a perspective view diagram of an example delivery device in accordance with various aspects and embodiments of the present disclosure;

[0229] FIG. 111B 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. 114A 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. 114B 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. 114C 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. 116A 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. 116B 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. 121A 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. 121B is an enlarged view of the indicated region of the delivery device of FIG. 121A in accordance with various aspects and embodiments of the present disclosure;

[0244] FIG. 122A 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. 122B is an enlarged view of the indicated region of the delivery device of FIG. 122A 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 from 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. 1A and FIG. 1B 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. 1A, the number and arrangement of delivery sharps 72 may differ in alternative embodiments. Any suitable number of rows and/or columns may be included in various examples. In various embodiments there may, for example, be a single row array of delivery sharps 72 including up to five delivery sharps 72. Preferably, the delivery sharps 72 may be arranged so as to prevent a bed of nails type scenario in which penetration of the skin via the delivery sharps 72 may be inhibited or inconsistent across users or delivery devices 10. This may occur when too many delivery sharps 72 are arranged in close proximity to one another. Thus, the array may be referred to 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. 3A-4B, in some embodiments microneedles may be constructed to include certain features that may help to reduce the pressure required to inject fluid, such as a medical agent, into the skin of a patient. In some examples, features common certain to insect stingers or biological venom administration structures may be 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. 4A-4B, a microneedle may include a channel or trough **200** on an exterior sloped face **21** leading from the flow lumen **126** toward the distal side **15**. The channel **200** may allow medical agent to flow through it along the outer side of the microneedle to find a path of least resistance, or weakest link, into the 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. 4A-4B. In some embodiments, the channel **200** may be a more meandering channel **200**. A curved channel **200** could, for example, be used provided the dimensions of the microneedle are accommodated. Moreover, there need not be only one channel **200**. More than one channel could be used provided structural integrity of the microneedle is accommodated.

[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. 5B). The width of the channel **200** may be about 20-30 percent of the width of the distal side **15** of the microneedle at the narrowest point in the channel **200**. In some embodiments, the width of the channel **200** may increase as distance to the distal side **15** decreases.

In some embodiments, at its widest, the channel 200 may have a width which is 50% or more the width of the distal side 15.

[0268] Referring now also to FIG. 5A and FIG. 5B, in other examples, the channel 200 may extend from the location of the lumen 126 toward the tip or vertex 14 of the microneedle (see, e.g., FIG. 5B). Moreover, in some examples, the channel 200 may extend both toward the vertex 14 and toward the base 17 from the location of the lumen 126. That is, the channel 200 may include a portion on both sides of the lumen 126 (see, e.g., FIG. 5A). As shown, the lumen 126 may be located substantially centrally in the sloped face 21 of the microneedle. In such embodiments, a channel 200 may extend toward the distal side 15 of the base 17 and a channel 200 may extend toward the tip or vertex 14. In other embodiments, the lumen 126 may be positioned at (or near) an end of the channel 200 most proximal the base 17.

[0269] Referring now to FIGS. 6A-6B, views of a sharp bearing body 26 including a number of microneedles are shown. In certain embodiments, a channel 200 may not be included. Instead, a microneedle may include a flow lumen 126 with an elongate cross-section (at least at the outlet, see also FIG. 7B and FIG. 8B). 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. 6A-6B. Polygonal cross-sectional shapes may also be used, such as though not limited to rectangular, trapezoidal, triangular, etc. In certain examples, the length (in the direction of elongation) of the cross-section of the lumen 126 may be up to 100-200 microns or greater (though could be less in certain examples). Where elongate lumens 126 are included, the end of the lumen 126 most proximal the distal side 15 may be spaced from the distal side 15 by at least a certain distance. The spacing may be such that, the end of the lumen 126 most proximal the distal side 15 may be at least below the stratum corneum (and perhaps one or more of the stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale) when the microneedle is inserted into the skin. In some embodiments, it may be disposed below the epidermis (e.g. in the basement membrane) or within the epidermis.

[0270] Still referring to FIGS. 6A-6B in certain embodiments, the sloped face 21 of a microneedle may not extend to the base 17 of a microneedle. There may, for example, be a vertical face 13 extending from the base 17 to the distal side 15 of a microneedle. Where a vertical face 13 is included, the vertical face 13 may be aligned with a side (e.g. distal side 15) of a sharp bearing body 26 and may form an extension thereof. Including such vertical faces 13 may aid in reducing the size of a sharp bearing body 26 and may aid in ensuring consistent fluid delivery into a target destination for certain microneedles. Though shown in relation to FIGS. 6A-6B, any of the microneedles shown herein may be arranged with vertical faces 13.

[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. 3A-3B. The depression 202 may have a maximum depth which places the depression 202 into fluid communication with the flow lumen 126 of the microneedle. The depression 202 may thus form a side port for the microneedle through which fluid may be delivered to the patient. The side port may be the only outlet of the microneedle or may be in addition to an outlet of the lumen in the face 21 of the microneedle. When the microneedle is inserted into the skin surface, fluid contained in a delivery device 10 may be delivered to the patient, at least in part, by being pumped into the depression 202. The depression 202 may be formed, for example by cutting away material during manufacture of the microneedle or the depression 202 may be formed during a molding operation. Cutting away material may be accomplished by any known suitable process such as, for instance, etching (e.g. wet etching). In some embodiments, the depression 202 may be recessed in at least one side wall 19 or edge (e.g. where two side walls 19 join) of the microneedle. In the example shown in FIGS. 3A-3B, the depression 202 is formed in a substantially vertical back facing edge 23 of the microneedles which extends from the base 17 to the vertex 14. This may establish or increase a vertical void 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. 7A and FIG. 7B, 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. 8A-8C). The rounded blade edge 31 may aid in introduction of a microneedle into skin when the microneedle is inserted at certain angles or over a variety of different angles.

[0273] In yet another embodiment, and referring now to FIGS. 8A-8C, 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. 7A-7B). As a microneedle of the variety shown in FIGS. 8A-8C is inserted, a vertical void space may be created due to the undercut. This may provide a low resistance pathway for fluid injection. Additionally, the undercut may help to mitigate potential for the lumen 126 to become obstructed by skin as the microneedle is inserted into a patient or as the delivery occurs.

[0274] In still other embodiments and referring now to FIGS. 9A-9D, the delivery sharp(s) 72 may be or include a microneedle which has a shape with a high aspect ratio. In some embodiments, microneedles may be obelisk shaped. Such microneedles may be included in an array such as any array described herein. Where obelisk type microneedles are used, the microneedles may include a base 17'. The base 17' may be any desired round or polygonal shape. For purposes of example, FIGS. 9A-9D depict a base 17' which is a quadrilateral or rhombus. The example microneedle includes a set of sidewalls 19' which extend from the base 17' to an end region 25 of the microneedle. The sidewalls 19' may be disposed at an angle which is not perpendicular to the base 17'. Thus the microneedle may taper so as to have a smaller cross-sectional area as distance from the base 17' increases. A portion of the microneedle most distal to the base 17' may include a beveled tip 27. Such a tip 27 may facilitate puncture of the skin and may aid in increasing the robustness of the end region 25. Any suitable bevel such as a single or double bevel may be used.

[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 than 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, cyclicolefin 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. 10A-10D, 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. 10A-10B could include a vertical face 460 as described in relation to FIGS. 6A-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. 1A and FIG. 1B, delivery devices **10** described herein may deliver any of a variety of medications or other medical agents to a patient. In certain embodiments, the reservoir **12** of the delivery device **10** may be filled with a vaccine. Such a delivery device **10** may deliver any suitable vaccine, though may be 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 HKU1 (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, service 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. 1A-1B, the delivery device **10** may include a main body **20**. The main body **20** may be a deformable body which may transition from a storage state (see FIG. 1A) to a delivery state (see FIG. 1B). In certain examples, this transition may be reversible, though in other embodiments the transition may result in a permanent change in the main body **20** and/or another part of the delivery device **10**. For example, once transitioned to the delivery state, the main body **20** may plastically deform such that it is permanently distorted and may not be returned to the storage state. In other examples, a frangible included in the delivery device **10** may be broken upon transition of the main body **20** to the delivery state. Alternatively or additionally, a latch, lock, or other coupling may be engaged to hold the main body **20** in the delivery state or prevent the main body **20** from returning to the storage state. Destruction of a portion of the main body **20** or a portion of the delivery device **10** engaged to the main body **20** may be required to disengage such a coupling and this destruction may render the delivery device **10** inoperative. Where a permanent change is engendered upon transition to the delivery state, this permanent change may inhibit reuse as well as provide a user perceptible (e.g. visual) indication that the delivery device **10** has been used. An indication that the transition has occurred may also be generated by the deliv-

ery 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. 11A. 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. 11B. 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. 1A and FIG. 1B. 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. 11A or FIG. 11B 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. 50A-76B and FIGS. 13-30B.

[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. 107A-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 **46A**, **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 **46A**, **B** is a straight line which does not pass through the proximal surface **24**. This straight line is roughly parallel to the surface of the skin **44**. In the delivery state, however, the shortest distance between the opposing points **46A**, **B** is a straight line which passes through the proximal surface **24**. As the skin **44** is fixed to the main body **20** via the adhesive **22** and cannot pass through the main body **20**, the skin **44** may be forced to conform to the curvature of the proximal surface **24**. Thus, the length of the skin **44** surface between the two points **46A**, **B** when the delivery device **10** is in the delivery state may be greater than the length of the skin **44** surface between the points **46A**, **B** when the delivery device **10** is in the storage state. The skin **44** may be placed under tension and stretched to accommodate this change in length. This stretching may, in turn, aid in facilitating puncture of the skin **44** by the delivery sharp(s) **72**.

[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 or more of the petal members **42** may bend or buckle at the relief region to relieve some of the tension on the skin **44**.

[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. 22A-22I, 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. 22A-22I, 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. 22A). In other embodiments, slots 254 may extend across an outer region and intermediate region of the top surface 250 (see, e.g., FIG. 22B). 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. 22C). 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. 22E, 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. 22E, 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. 22D and FIG. 22F, 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. 22D and FIG. 22F, 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. 22G-22I. 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. 22G-22I 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. 11A-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. 11A-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. 31A-31B, 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. 105-106B.

[0331] Referring now primarily to FIGS. 30A-30B, 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. 30A), 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. 31A-31B 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. 31A-31B, 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. 31A-31B, 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. 31A-31B 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. 50A-76B). 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. 50A-76B). In some embodiments, packets 208 and/or containers 350 (see, e.g., FIGS. 11A-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. 11A-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 ease 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. 47A-47D, 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. 47B, 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. 47C and FIG. 47D, 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. 49A-49B, an example embodiment of a main body 20 and a main body 20 with a bias member 470 are respectively shown. FIG. 49A depicts a bottom plan view of the main body 20. FIG. 49B 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. 49C). 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. 49C, 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. 49C, 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. 49A-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. 49B, 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. 49C).

[0360] Referring now to FIGS. 50A-50B, 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. 50A-50B 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. 50B 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. 52A-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. 52A) to the delivery state (FIG. 52B). 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. 54A-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. 54B). 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. 55A-55C. 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. 55A-55C. 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. 47A) 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. 55A-55C, 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. 54A-54D. 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. 56A-56D, 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. 56D, 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 bearing 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. 62A-62C, 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 known 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. 6A-6B, 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 864B 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 as 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  $\mu\text{m}$ . 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. **55A-55D**, 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 **864A, B** may clamp against two parallel surfaces of the sharp bearing body **26**. In the example, the shut-offs **864A, B** clamp against the sharp bearing and opposing face of the sharp bearing body **26**. Thus, the shut-offs **864A, 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 **866A, B**) applied to the shut-offs **864A, 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 **864A, 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 **864B** 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 **864B** 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 **864A, 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 **864B** as a monolithic part of the “B” block **876** of the mold **860**, the shut-off **864B** 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 **864B** as a separate component, an interface between the shut-off **864B** 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. 65A-25C a number of view of example shut-offs 864A-B are depicted. The shut-offs 864A-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 864A-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 864A-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 864A 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 864A 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 864B 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 864B 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. 65B, 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 825A, 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 825A, 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 864B increases. The slope of the taper on the lateral sidewalls 825A, B may be gentlest at the end regions of the lateral sidewalls 825A, 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 825A, B may be intermediate two straight wall segments which extend substantially perpendicular to the clamping face 831 of the shut-off 864A, 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 864B. The pockets 870 may guide the delivery sharps 72 into position within their respective pockets 870. The taper on the sidewalls 823, 825A, 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. 65A. 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 864B.

[0390] Referring primarily to FIG. 65C, a cross-sectional view of a pair of delivery sharps 72 in pockets 870 of an example shut-off 864B 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. 10A-10D) 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 864B. 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 864A, 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 repeatedly 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. 65C, 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 825A, 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 864B. 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 **882A-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 **882A-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 **882A-D** are spaced varying travel distances **886A-C** from the ends of their respective guide pockets **884**.

[0393] The ejector pins **882A** for a runner plate **888** of the mold **860** are arranged with the shortest travel distance. The ejector pins **882B** for the “A” block **874** of the mold are positioned with a first intermediate travel distance **886A**. The ejector pins **882C** for the sharp bearing body **26** and overmolded part are positioned with a second intermediate travel distance **886B** greater than the first intermediate travel distance **886A**. The ejector pins **882D** which disassociate the “B” block **876** from the mold base **890** have a longest travel distance **886C**.

[0394] As the hydraulics displace the ejector pins **882A-D**, all of the ejector pins **882A-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 **882A** 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 **882B** 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 **882B** may disassociate the “A” block **874** from the mold **860**. Subsequently, the ejector pins **882C** 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 **882C** 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 **882C**. 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 **882D** contact the ends of their respective guide pockets **884**.

[0395] In an alternative ejection arrangement, the travel distances **886A**, **886B** may be the same. Thus, the ejector pins **882B** 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 **864B** insert in the “B” block **876** in a highly controlled manner along a direction parallel to the axes of the ejector pins **882A-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 **864B** 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 **864B** 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. 69A-70C, 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. 69A-69C, 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. 70A-70C, 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. 70A-70C, however, could be a recess in a rounded depression 274 (see, e.g., FIG. 54A). 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 be 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 overmolded 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. 69A-70C 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. 69A-69C), 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. 71A-71D (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 ease 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. 49B 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. 50B. 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. 102A-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. 11A-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. 55A) which couple into receiving slits 278 (see, e.g., FIG. 47A) 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. 105-106B) which may couple the reservoir 12 in place within the delivery device 10.

[0419] In certain embodiments and referring now to FIGS. 76A-76B, 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. 76A-76B), 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. 76B, 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. 50B). 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. 53A-54C) 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. 54A-54D) 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. 54A-54D) over the rounded depression 274. In other examples, the flow restrictor 524 may separate the well 281 (see, e.g., FIGS. 55A-55C) 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. 55A-55C) 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 658A, 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 658A, 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 658A, 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) 658A, 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 658A, B may divide displacement of the reservoir interface member 474 into a number of stages. For example, a first barrier 658A (or set of first barriers 658A) may inhibit displacement of the reservoir interface member 474 until the trigger body 654 is displaced to the triggered position. A second barrier

**658B** (or set of second barriers **658B**) 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 **658B** (or set of second barriers **658B**). As pressure upon the trigger unit **652** is released, the deformable spacer **656** may restore to a less distorted state and the second barrier **658B** (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. 79A-79F, 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. 79A, 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 **658A** when the barrier **658A** 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. 79A-79F, the reservoir interface member **474** may be blocked from fully displacing along each guide track **660** by a second barrier **658B** when the trigger unit **652** is in a trigger position. As pressure on the trigger unit **652** is relieved, the second barrier **658B** 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. 79A-79F, 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. 79A). 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 **658B** 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. 79B-79F, 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. 79B, 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. 79B) 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 **658A** 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. 79B, the barrier(s) **658A** may be held in a blocking position by the deformable spacer **656**. In FIG. 79B, an arrow representing force exerted by a spring type deformable spacer **656** is shown within each barrier **658A, B**.

[0434] Referring now primarily to FIG. 79C, 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. 79D, the trigger unit **652** may displace at least until the first barrier **658A** reaches an unobstructing or stowed position. This may be a guide track completing position in which a ramp surface **670** of each first barrier **658A** 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) **658A** 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 **658B** (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) **658A** 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) **658A** 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. 79E, in embodiments where second barriers 658B 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) 658B. 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. 79F), the reservoir portion 271 may be fully collapsed and the reservoir 12 may be substantially empty or depleted. In embodiments including second barriers 658B, the intermediate point at which the reservoir interface member 474 encounters the second barriers 658B 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) 658B 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) 658B. 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. 80A-80B, 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. 80B, 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 658A, 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. 80C, a cross-sectioned view of the main body 20 and trigger body 654 of FIGS. 80A-80B 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 658A, B of the trigger body 654 may be formed monolithically with the trigger body 654. The barriers 658A, 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 658A, 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 658A, 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. 81A-83. As shown, the example delivery device 10 shown in FIG. 81A 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. 81B, 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. 81A-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. 81A 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. 81A 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. 78-80C 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. 78-80C, 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 658A, 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. 81A-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 **658A, 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. 78-80C. When the user releases the trigger body **654**, the deformable spacer **656** may urge the trigger body **654** and barrier **658A, 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. 78-80C.

[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 **658A**. This is merely illustrative, the trigger body **652** may include a first barrier **658A** for each respective guide track **660** within a delivery device **10**. The first barriers **658A** may gate displacement of the reservoir interface member **474** as described in relation to FIGS. 78-80C. The trigger body **652** may be devoid of second barrier members **658B**. 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 **658A** 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 **658A** 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. 87A-88B, 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. 88A-88B. 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 **655A, B** as shown in FIGS. 87A-87B. 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 **655A, 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. 78-80C, 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. 87A-87B, 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. 89A-89B, 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. 89A-89B, 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. 55A-56D). Shorter and taller rocker members 526 are also possible. Alternatively, where a holder 270 includes a rounded depression 274 (see, e.g., FIG. 54A), 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. 56A-D, FIG. 89B), 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. 89A-89B, 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. 90A-90B, 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. 90A 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. 90B, 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. 90A 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. 89A-89B 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. 96A-96B). 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. 89A-89B). 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. 96A-96B and FIGS. 98A-98B, 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. 96A-96B, 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 **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. 96A-96B, 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 **A1** 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. 96A-96B, 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. 96A-96B. 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 **A1** of the main body **20**. In various examples and referring now to FIGS. 98A-98B, 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 **A1** 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. 98A-98B.

**[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 accom-

modate a pull tab **266** (see, e.g., FIG. 98B) which may be included to assist in removal of the delivery device **10**.

**[0480]** Referring now to FIGS. 99A-99G, 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. 100A-101G. 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. 99A-101G 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. 99A-101G 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. 99A-101G 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. 99A-101G, 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. 102A-102B, 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. 102A-102B, 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. 56A-D) and a rocker member 526 (further described in relation to FIGS. 89A-89B).

[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. 102A-102B 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. 107A-107C) 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 554 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. 102A-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. 106A-106B, 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 **582** in place of the ridge **290**. Referring now to FIGS. 107A-107C, 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</sup>. In certain examples, the cross-sectional area of the central aperture **49** may be in a range of 0.13 in<sup>2</sup> to 0.5 in<sup>2</sup> (e.g. about 0.3 in<sup>2</sup>).

[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. 107A, 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. 107B-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. 108A and FIG. 108B, another example embodiment of a delivery device 10 is depicted. As shown, the delivery device 10 includes a main body 20 and a reservoir 12. The reservoir 12 includes a sharp bearing body 26 which includes a one dimensional array of three delivery sharps 72. Other embodiments may include any suitable number of delivery sharp(s) 72 arranged in any desired pattern. The main body 20 of the delivery device 10 may have a polygonal (e.g. rectangular) footprint and may be generally formed as a strip of material to which the reservoir 12 is attached. In the example embodiment, the main body 20 includes a number of living hinges 50 which are formed integral with the rest of the main body 20. The

living hinges 50 may each extend across a portion of the main body 20 and may partition the main body 20 into a number of panels 52A-D. The main body 20 may be injection molded.

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

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

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

[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 52A, D such that they are substantially constrained to the plane of the skin patch to which they are adhered. Application of downward pressure against the linkage 60 may displace the linkage 60 from the raised position toward the center position. As this occurs, the angle 64 between the two intermediate panels 52B, C may increase. The angle 62 between the raised projection 56 and intermediate panel 52B and the angle 66 between end panel 52D and intermediate panel 52C

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

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

**[0504]** When the delivery device **10** is in the delivery state (see FIG. 109C), the delivery sharp(s) **72** may be pressed into the skin **44** so as to puncture the skin **44** and establish fluid communication with a delivery destination in the patient. The angle **64** between the intermediate panels **52B, C** in the over-center delivery position (see FIG. 109C) 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. 109C) to the length of the intermediate panel **52B**. The reservoir **12** may also be pressed against the skin **44** when the delivery device **10** is in 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 **52C** may be covered at least partially in adhesive **22** (see, e.g., FIG. 109C). When the linkage **60** reaches the over center position at the end of the displacement range, the adhesive **22** may hold the linkage **60** in place. Additionally, in some embodiments, the main body **20** may include at least one force limiter. For example, at least one of the panels **52A, D** may include a strain relief flexure. In the example embodiment, this flexure may bend in the event that the force required to stretch the skin **44** exceeds

a threshold. Bending of the flexure may cause the linkage **60** to snap through the center position and enter an over center position such that stretching of the skin **44** is halted. This may be desirable as it may help to mitigate potential discomfort during an injection due to excessive tensioning of the skin **44**. Likewise, this may be helpful in certain patient populations as skin characteristics vary significantly across potential patients.

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

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

**[0508]** In another embodiment the intermediate panel 52C may incorporate at least one flexure 292 which may be in the form a squishable body that may deform when a threshold force applied to the body is exceeded. The flexure 292 may be round and hollow in an embodiment. As shown in FIGS. 111A-111B, 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 52C 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 70A, B. The end block 70A, B may be disposed in opposition to one another. The end blocks 70A, B may be spaced apart and connected together by a set of side panels 71A, B and a bridge 76. The side panels 71A, B may each have a first end which is connected to the first end block 70A by a hinge 74A. The side panels 71A, B may also each have a second end opposed to the first end which is connected to the second end block 70B by a hinge 74B. Each of the side panels 71A, B may also include an intermediate hinge 74C which may be disposed in an intermediate region of the side panels 71A, B between the first and second end of each side panel 71A, B.

**[0512]** Similarly to the side panels 71A, B, the bridge 76 may have a first end connected to the first end block 70A by a hinge 74D and a second end opposite the first which is connected to the second end block 70B by another hinge 75E. The bridge 76 may additionally include an intermediate hinge 74F disposed between the first and second ends of the bridge 76. The bridge 76 may include a panel body 78 and

a set of strut members 80A, B. the strut members 80A, B may be connected to the panel body 78 via the intermediate hinge 74F of the bridge 76. The bridge 76 may also include an arm member 82. The arm member 82 may be disposed between two strut members 80A, B and may extend toward a proximal face of the end blocks 70A, B. In the example embodiment, the arm member 82 extends from an end of the panel body 78 adjacent the intermediate hinge 74F of the bridge 76. The reservoir 12 may be coupled to the proximal face of the arm member 82 at an end of the arm member 82 opposite the panel body 78.

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

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

**[0515]** A pinching force which urges the side panels 71A, B toward one another may be exerted against the side panels 71A, B to displace the side panels 71A, B from the outwardly bowed position to a straightened position. It should be understood that the straightened position need not necessarily be a position in which the side panels 71A, B each extend along straight line. In some examples, the straightened position may be a position in which the side panels 71A, B are less outwardly bowed than in the outwardly 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 70A, B. The bridge 76 may be bent at the intermediate hinge 74F such that the panel body 78 and struts 80A, B extend upward from the end blocks 70A, B and away from the proximal face of the end blocks 70A, B. Some pivoting of the panel body 78 and struts 80A, B at the hinges 74D, E connecting the bridge 76 to the end blocks 70A, B may also occur to allow the bridge to assume the raised position. A force normal to the proximal faces of the end blocks 70A, B may be applied to the bridge 76 to displace the bridge from the raised position to a lowered position at the opposite end of the bridge's 76 displacement range.

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

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

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

**[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 **86A-D** which may define an aperture **88** which is variable in size from a closed to a fully open state. The iris panels **86A-D** may extend from each of the side panels **71A, B** in a direction toward the opposite side panel **71A, B**. In the example embodiment, two iris panels **86A-D** extend from each side panel **71A, B** and are disposed on either side of the intermediate hinge **74C, D** of each side panel **71A, B**. As the side panels **71A, B** are displaced from an outwardly bowed position to a straightened state, the iris panels **86A-D** may adjust the aperture **88** such that the aperture **88** provides an opening for the delivery sharp(s) **72** of the reservoir **12** to pass through. As shown in FIG. 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 **86A** includes a latch projection **90**. Another of the iris panels **86B** includes a latch catch **92** which may be formed as a notch in that iris panel **86B**. The latch projection **90** is ramped. Thus, as the iris panels **86A, B** are displaced toward one another, iris panel **86B** may deflect and ride up the ramp of the latch projection **90** (see, e.g., FIG. 114B). Upon the latch catch **92** aligning over the latch projection **90**, the iris panel **86B** including the latch catch **92** may restore to an undeflected state and the latch catch **92** may snap into engagement with the latch projection **90**. This may lock the delivery device **10** in the delivery state. The snapping action of the iris panel **86B** may generate tactile sensation perceptible, for example, via a user's finger tips. Alternatively or additionally, the snap may generate an audible click or slap. Thus, the delivery device **10** may provide an audible and/or tactile indication that the delivery device **10** has been transitioned to the delivery state. Engagement of the latch projection **90** and latch catch **92** may also aid in inhibiting reuse. As discussed in relation to other embodiments herein, the adhesive **22** may be selected so as to bond more aggressively to the skin **44** than the material forming the main body **20**. Thus, upon removal of the delivery device **10**, the adhesive **22** may peel off of the delivery device **10**. This may also aid in inhibiting reuse of the delivery device **10**.

**[0522]** Referring now to FIGS. 116A-116B, 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. 116A) to a delivery state (see FIG. 116B). 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 transitioning 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 **100, 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. 121A-122B, 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 110 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. 122A and FIG. 122B. 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 against 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 **320A**, **320B**, vertically spaced such that the first body **320A** is positioned above or in a separate plane than the second body **320B**. In the example embodiment, the first and second bodies **320A**, **B** are concentric round bodies, and are specifically shown as circles. The flexure may be made of a bendable plastic formed by injection molding or any other suitable technique as would be known to one of skill. The

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

[0547] At least one hook 324, integral to one of the bodies 320A, B may be included. The other of the bodies 320A, B may include at least one catch 326. In the example embodiment, the first body 320A includes a number of hooks 324 which extend downward therefrom toward the second body 320B. Six such hooks 324 are shown but it would be understood that the number need not be six. In the example, the hooks 324 are evenly spaced around the first circle 320A though need not necessarily be in all embodiments. At least one catch 326, integral to the second body 320B is also shown in the example embodiment. Each of the catches 326 is situated at a point on the second body 320B that is not directly beneath a hook 324 of the first body 320A. The example catches 326 extend upward from the second body 320B toward the first body 320A. Six such catches 326 are shown but it would be understood that the number need not be six. The catches 326 may be spaced around the second body 320B at even angular increments. The catches 326 may be positioned such that the respective catches 326 and hooks 324 would engage one another upon actuation of the flexure. The flexure may, for example, be actuated 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 320A is displaced toward the second body 320B at least one of the bodies 320A, B may also rotate. If one of the bodies 320A, B is rotationally constrained, only the other of the bodies 320A, B may rotate as the bodies 320A, B are displaced toward one another. With the second body 320B rotationally constrained, pushing down on the first body 320A from above may cause the flexible struts 322 to flex. The hooks 324 may rotationally (about an axis passing through the center points of the bodies 320A, B) displace. The hooks 324 and first body 320A may also translationally displace as the first body 320A approaches the second body 320B. The hooks may also translationally displace with respect to the catches 326 until the hooks 324 contact the catches 326. The hooks 324 may deflect around the catches and then resiliently restore into engagement with the catches 326. Thus, as the struts 322 attempt to resiliently restore to their undeflected state, the first and second bodies 320A, B may be held together by the engagement of the hooks 324 and catches 326. Using a single piece flexure (formed, for example, by injection molding) may allow the delivery device 10 to be manufactured at relatively lower cost. The hooks 324 engagement with the catches 326 may also help to prevent reuse of a delivery device 10 in which the flexure is included. The engaged hooks 324 may also help maintain 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 320A, B may be harnessed 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 320A. 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. 54A-54D and FIGS. 55A-55C) 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. 55B) 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. 89A-90B) may, for example, bear a marking agent. Alter-

natively, 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. 89A-90B). 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. 22A-22I) 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.

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)