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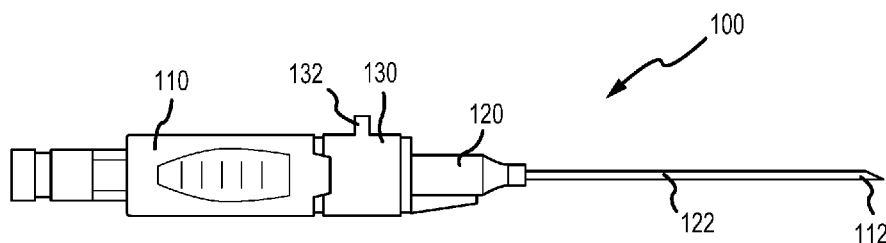


FIG. 1

(57) Abstract: The present disclosure provides for a safety catheter assembly comprising a needle hub, a catheter hub, a tip protector housing. Various embodiments can comprises a push-off tab extending radially from the tip protector housing or a portion thereof, and/or structure can be added or removed to affect compliance between a catheter assembly and a catheter insertion device.



Catheter Insertion Device with Tip Protector Housing

Background

Operators of safety catheter assemblies have historically been at risk of needle sticks. Various needle tip protectors are known in the art, however, separation of the needle tip protector from the catheter hub in connection with deployment presents challenges. For example, in some implementations, a push-off tab located on the catheter hub facilitates deployment, but becomes an obstruction post-deployment, when the catheter is in use. Making the push-off tab smaller in such implementations, so as to be less of an obstruction, makes it difficult for an operator to grip or otherwise actuate. In other implementations, there is a risk of premature separation of the needle tip protector from the catheter hub, particularly when a bending moment is introduced at or near their coupling and/or the needle is being withdrawn, thus undermining the desired protection against needle sticks.

Premature separation of the needle tip protector from the catheter hub may occur when excessive pressure is applied when gripping the needle hub with the needle tip protector positioned inside of the needle hub. Further, premature separation may occur in the event of excessive upward pull against the needle hub with the needle tip protector positioned inside of the needle hub. Still further, premature separation may occur in the event of excessive needle bend after the needle hub is pulled proximally of the needle tip protector.

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Brief Description of the Figures

The accompanying drawings are included to provide a further understanding of the present disclosure and are incorporated in, and constitute a part of, this specification, illustrate various embodiments, and together with the description, they serve to explain the principles of the disclosure.

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Figure 1 illustrates an example embodiment of a safety catheter assembly;

Figures 2A and 2B illustrate side views of an example embodiment of a safety catheter assembly, in ready and released positions, respectively;

Figures 3A and 3B illustrate top and side views, respectively, of another example embodiment of a safety catheter assembly in a ready position;

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Figures 3C and 3D illustrate top views of yet another example embodiment of a safety catheter assembly, in ready and released positions, respectively;

Figure 4 illustrates a safety catheter assembly comprising a pivoting joint in accordance with an embodiment of the present disclosure;

Figure 5 illustrates a safety catheter assembly comprising a ball joint in accordance with an embodiment of the present disclosure;

Figure 6 illustrates a cross-sectional view of a safety catheter assembly in accordance with an embodiment of the present disclosure;

5 Figure 7 illustrates yet another cross-sectional view of a safety catheter assembly in accordance with an embodiment of the present disclosure;

Figure 8 illustrates contact points at a coupling of a safety catheter assembly in accordance with an embodiment of the present disclosure;

10 Figures 9A and 9B illustrate cross-sectional and perspective views, respectively, of a tip protector housing comprising an extension in accordance with an embodiment of the present disclosure;

Figure 9C illustrates a cross-sectional view of a tip protector housing comprising an extension in accordance with an embodiment of the present disclosure;

15 Figures 9D and 9E illustrate cross-sectional and perspective views, respectively, of a tip protector housing comprising a plurality of extensions in accordance with an embodiment of the present disclosure; and

Figures 10A and 10B illustrate locked and unlocked positions, respectively, of a safety catheter assembly comprising a lock sleeve in accordance with an embodiment of the present disclosure.

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Detailed Description

The detailed description of various embodiments herein makes reference to the accompanying drawings, which show various embodiments by way of illustration. While these various embodiments are described in sufficient detail to enable those skilled in the art to practice the disclosure, it should be understood that other embodiments may be realized and that logical, chemical, mechanical and structural changes may be made without departing from the spirit and scope of the disclosure. Thus, the detailed description herein is presented for purposes of illustration only and not of limitation.

30 For example, the steps recited in any of the method or process descriptions may be executed in any order and are not necessarily limited to the order presented. Furthermore, any reference to singular includes plural embodiments, and any reference to more than one component or step may include a singular embodiment or step. Also, any reference to attached, fixed, connected, coupled or the like may include permanent (e.g., integral), removable, temporary, partial, full, and/or any other possible attachment option. Any of the

components may be coupled to each other via friction, snap, sleeves, brackets, clips or other means now known in the art or hereinafter developed. Additionally, any reference to without contact (or similar phrases) may also include reduced contact or minimal contact. As used herein, “proximal(ly)” refers to closer to the operator and further from the subject, while
5 “distal(ly)” refers to further from the operator and closer to the subject.

With reference to Figure 1, a safety catheter assembly 100 is disclosed herein. Example embodiments of safety catheter assembly 100 comprise a needle hub 110, a catheter hub 120, a tip protector housing 130, and a push-off tab 132 extending radially from tip protector housing 130 or a portion thereof. Needle hub 110, catheter hub 120, catheter 122,
10 and tip protector housing 130 can each be comprised of materials now known in the art or hereinafter developed. A catheter hub and a catheter may be referred to together herein as a catheter assembly. A needle hub, a needle and a tip protector housing may be referred to together herein as a catheter insertion device.

As disclosed herein, needle hub 110 is a structure to which a needle 112 is connected
15 or which otherwise secures needle 112. Needle 112 can extend distally from a distal end of needle hub 110. Needle 112 can be a conventional intravenous needle, a trocar or the like.

In accordance with the present disclosure, catheter hub 120 is a structure to which a catheter 122 is connected or which otherwise secures catheter 122. Catheter 122 can extend distally from a distal end of catheter hub 120. Catheter hub 120 and catheter 122 can each
20 have a lumen extending there through, the lumen of catheter hub 120 being in communication with the lumen of catheter 122.

In example embodiments, tip protector housing 130 is positioned between needle hub 110 and catheter hub 120, and is configured to protect an operator from accidental needle sticks. In example embodiments, push-off tab 132 extends radially from tip protector housing
25 130, being either coupled to or integral with tip protector housing 130. In general, push-off tab 132 extends radially in a direction away from a skin surface, for example, on the side interfaced with by an operator. Push-off tab 132 can have a height, as measured from its base at tip protector housing 130, of more than about 2mm, or more than about 4mm, or more than about 6mm.

Push-off tab 132 not located on catheter hub 120 can facilitate deployment while not
30 being an obstruction post-deployment. In accordance with example embodiments of the present disclosure, push-off tab 132 can be located proximal to, coincident with, or distal to, a proximal end of catheter hub 120.

Push-off tab 132 can be configured to be comfortable for an operator when used correctly, and/or uncomfortable for an operator when used incorrectly. For example, a proximal side of push-off tab 132 can be smooth and ergonomically suited for being pressed by an operator's finger, while a distal side of push-off tab 132 can be rough or angled to discourage contact by an operator.

In example embodiments, needle hub 110 is adjacent, but not coupled, to tip protector housing 130. In such embodiment, there may be no overlap between a distal end of needle hub 110 and a proximal end of tip protector housing 130. In other example embodiments, a distal end of needle hub 110 is passively coupled to a proximal end of tip protector housing 130. The coupling can include sliding contact with a key and keyway or the like, for example, to prevent rotational relative movement, but not axial relative movement.

In example embodiments, tip protector housing 130 is removably coupled to catheter hub 120 by a coupling that separates when a threshold force is exceeded. Such threshold force couplings can include friction fit joints, a snap fit joints, or the like. For example, a proximal end of catheter hub 120 may comprise a snap groove that removably interfaces with a snap ring on a distal end of tip protector housing.

Safety catheter assembly 100 as described herein has at least three positions. In a ready position, at least a portion of needle 112 extends through catheter 122, and a distal tip of needle 112 extends beyond a tip of catheter 122. In the ready position, a distal end of tip protector housing 130 is temporarily coupled to a proximal end of catheter hub 120.

In a safe position, catheter 122 and needle 112 (and catheter hub 120 and needle hub 110) have been moved relative to each other such that no portion of needle 112 extends through catheter 122, and the distal tip of needle 112 is securely housed within tip protector housing 130 (e.g., with or without structure being displaced in front of the distal tip of needle 112), so as to provide protection against accidental needle sticks. In the safe position, distal end of tip protector housing 130 is still temporarily coupled to proximal end of catheter hub 120.

Finally, in a released position, the distal tip of needle 112 is housed within tip protector housing 130, and distal end of tip protector housing 130 is released from proximal end of catheter hub 120.

A safety catheter assembly 200 in accordance with another embodiment of the present disclosure will now be described with reference to Figures 2A and 2B. Safety catheter assembly 200 is shown in a ready position in Figure 2A, and a portion of safety catheter assembly 200 is shown in a released position in Figure 2B. A needle hub 210 has a needle

212 extending from a distal end of needle hub 210. A catheter hub 220 has a catheter 222 extending from a distal end of catheter hub 220. A tip protector housing 230 is located between needle hub 210 and catheter hub 220. A push-off tab 232 extends radially from tip protector housing 230.

5 In the illustrated embodiment, tip protector housing 230 comprises a tab extension 234 extending distally over at least a portion of catheter hub 220, for example, over more than about 20 percent, or about 30 percent, or about 50 percent, of the overall length of catheter hub 220.

10 In the example embodiment, the overlap of tip protector housing 230 does not diminish any contact between catheter hub 220 and a skin surface. By way of non-limiting example, tab extension 234 can be located exclusively on the side of safety catheter assembly 200 interfaced with by an operator. In example embodiments, the overlap of tip protector housing 230 may absorb all or a portion of a bending moment at the coupling between catheter hub 220 and tip protector housing 230. In this regard, the overlap of tip protector housing 230 may prevent premature separation of tip protector housing 230 from the catheter hub 220.

20 Tab extension 234 can comprise a substantially flat profile or a curved profile (e.g., concave toward catheter hub 220) that substantially wraps over or otherwise follows the curvature of the overlapped portion of catheter hub 220. Tab extension 234 having a flat profile in example embodiments can have a width smaller than, about equal to, or greater than the diameter of catheter hub 220. Example embodiments of tab extension 234 having a curved profile can wrap about the catheter hub 220 by differing amounts, such 60 degrees or greater, 120 degrees or greater, 180 degrees or greater, or even up to 270 degrees or greater.

25 In example embodiments, push off-tab 232 extends radially from tab extension 234 of tip protector housing 230, push off-tab 232 being either coupled to or integral with tab extension 234. In example embodiments, push-off tab 232 is located over a portion of catheter hub 220 (i.e., push-off tab 232 is located distal to a proximal end of catheter hub 220). Positioning push-off tab 232 above catheter hub 220 may also direct forces along the axis of needle 212, which can prevent side loading and bending moments at the coupling between catheter hub 220 and tip protector housing 230.

30 A safety catheter assembly 300 in accordance with the present disclosure will now be described with reference to Figures 3A-3D. Safety catheter assembly 300 is shown in a ready position in Figures 3A-3C, and a portion of safety catheter assembly 300 is shown in a released position in Figure 3D. A needle hub 310 has a needle 312 extending from a distal

end of needle hub 310. A catheter hub 320 has a catheter 322 extending from a distal end of catheter hub 320. A tip protector housing 330 is located between needle hub 310 and catheter hub 320. A push-off tab 332 extends radially from tip protector housing 330.

In example embodiments, tip protector housing 330 is at least partially housed within or enclosed by needle hub 310 when in the ready position. In this regard, at least a portion of tip protector housing 330 has a diameter (or other cross section) smaller than at least a portion of needle hub 310. In example embodiments, needle hub 310 comprises a window 314 through which push-off tab 332 radially extends from tip protector housing 330. Stated another way, tip protector housing 330 can be substantially housed within or enclosed by needle hub 310, except for window 314 in needle hub 310 through which push-off tab 332 extends and is accessible. In example embodiments, and with momentary reference to Figure 3D, needle hub 310 comprises a plurality of windows 314, for example on opposing sides of needle hub 310. Window 314 generally extends from, and is open to, a distal end of needle hub 310.

In example embodiments, a distal end of tip protector housing 330 substantially coincides with a distal end of needle hub 310 (e.g., with reference to Figures 3A and 3B). Stated differently, tip protector housing 330 is completely circumferentially enclosed within needle hub 310 (except for push-off tab 332) in example embodiments, such that a distal end of needle hub 310 is adjacent to a proximal end of catheter hub 320. In such embodiments, the distal end of needle hub 310 and a proximal end of catheter hub 320 may not overlap.

In other embodiments, a distal end of tip protector housing 330 extends distal to a distal end of needle hub 310 (e.g., with reference to Figures 3C and 3D). In example embodiments, push-off tab 332 is not located over any portion of catheter hub 320 (i.e., push-off tab 332 is located coincident with or proximal to a proximal end of catheter hub 320).

In still other embodiments, a tip protector housing can be completely circumferentially housed within a needle hub, except for a tab extension as described with reference to Figures 2A and 2B, from which a push-off tab extends radially for an operator to grip or otherwise actuate. Such embodiment may be particularly beneficial in terms of shortening the overall length of the safety catheter assembly.

The present disclosure contemplates additional embodiments configured to lessen the risk of premature separation between the catheter assembly and the catheter insertion device.

As described above, a safety catheter assembly can comprise a catheter assembly and a catheter insertion device. The catheter assembly can comprise a catheter hub and a catheter

extending distally from the catheter hub. The catheter insertion device can comprise a needle hub, a needle extending distally from the needle hub along a longitudinal axis and having a sharp distal tip, and a tip protector housing.

In various embodiments, at least a portion of each of the catheter hub and the tip protector housing can define a coupling. In some embodiments, the coupling can be constructed and/or arranged to couple the catheter insertion device to the catheter. In some embodiments, the coupling can be configured to selectively release the catheter insertion device from the catheter when a threshold release force applied proximally along the longitudinal axis is exceeded. A threshold release force, in accordance with the present disclosure, can be below about 0.75 pounds force, or between about 0.75 and 0.25 pounds force, for example, about 0.7, 0.6, 0.5, 0.4 or 0.3 pounds force.

In some embodiments, the coupling can be configured to prevent release of the catheter insertion device from the catheter responsive to forces applied laterally to the longitudinal axis.

In various embodiments, in a ready position, the needle extends through the catheter of the catheter assembly and the tip protector housing is coupled to the catheter hub through the coupling. From the ready position in accordance with the present disclosure, retraction of the needle relative to the catheter along the longitudinal axis moves the catheter insertion device to a safe position with the sharp distal tip of the needle housed within the tip protector housing and the tip protector housing coupled to the catheter hub through the coupling. From the safe position in accordance with the present disclosure, further retraction of the needle along the longitudinal axis with a force in excess of a release force moves the catheter insertion device to a released position with the needle separated from the catheter, the distal tip of the needle housed within the tip protector housing and the tip protector housing released from the catheter hub.

In general, the risk of premature separation can be lessened by incorporating structure to increase compliance between a catheter assembly as described herein (or a portion thereof, e.g., a catheter hub) and a catheter insertion device as described herein (or a portion thereof, e.g., a tip protector housing).

With reference to Figure 4, a safety catheter assembly 400 can comprise a coupling defined by at least a portion of each of a catheter hub 420 and a tip protector housing 430. The coupling can comprise a pivoting joint 440 that allows tip protector housing 430 to pivot or rotate relative to catheter hub 420 and away from the longitudinal axis of safety catheter assembly 400, and do so in the direction shown by the arrows. Pivoting joint 440 can

comprise protrusions on the inside of tip protector housing 430 that are received in dimples on the outside of catheter hub 420, or vice versa.

Turning to Figure 5, a safety catheter assembly 500 can comprise a coupling defined by at least a portion of each of a catheter hub 520 and a tip protector housing 530. The
5 coupling can comprise a ball joint 550 that allows tip protector housing 530 to pivot or rotate relative to catheter hub 520 and away from the longitudinal axis of safety catheter assembly 500, and do so in a plurality of directions.

With reference to Figure 6, an amount of clearance 661 between an interior surface of a needle hub 610 and an exterior surface of a tip protector housing 630 can provide space for
10 movement of needle hub 610 relative to tip protector housing 630 to thereby permit a needle 612 to bend with a decreased risk of premature separation between a catheter hub 620 and tip protector housing 630.

Similarly, and with reference now to Figure 7, an amount of clearance 762 between an interior surface of a tip protector housing 730 and a needle 712 can provide space for needle
15 712 to bend with a decreased risk of premature separation between a catheter hub and tip protector housing 730. In this regard, needle 712 may be allowed to bend without initially contacting the tip protector housing, either directed or through the tip protector.

In still other embodiments, the risk of premature separation can be lessened by incorporating structure to decrease compliance between a catheter assembly as described
20 herein (or a portion thereof, e.g., a catheter hub) and a catheter insertion device as described herein (or a portion thereof, e.g., a tip protector housing).

As a non-limiting example, a needle hub can comprises a stiffness sufficient to resist temporary deformation by a user during use, such as when gripped with excessive forces by a user. This may be accomplished by molding the needle hub from a stiffer material.
25 Additionally or alternatively, the needle hub design may be altered to create a stiffer structure, such as with the addition of ribs, thicker walls and the like.

As another non-limiting example, an amount of clearance between an interior surface of a needle hub and an exterior surface of a catheter hub can be lessened. Stated differently,
30 an interior surface of a needle hub and an exterior surface of a catheter hub can be in close contact or proximity to one another. In this regard, the risk of premature separation between the catheter hub and a tip protector housing can be lessened.

In various embodiments of the present disclosure, one or more contact points between the catheter hub and the tip protector housing can counter forces that may cause unintended separation at a coupling defined by at least a portion of each of a catheter hub and a tip

protector housing. The orientation of the contact point(s) relative to the anticipated bending moment(s) can further counter forces that may cause unintended separation.

In this regard, and with reference now to Figure 8, a coupling can comprise a first contact point 871 between a catheter hub 820 and a tip protector housing oriented at 0 degrees and a second contact point 872 between catheter hub 820 and the tip protector housing oriented at 180 degrees. In general, the location of one or more contact points can be selected such that moments about a vertical plane 873 are resisted more than moments about a horizontal plane 874. In such embodiments, forces that may cause unintended separation may be countered, while not necessarily increasing the force required to intentionally separate catheter hub 820 from the tip protector housing.

In various embodiments of the present disclosure, and with reference to Figures 9A and 9B, a tip protector housing 930 can comprise an extension 931 coupled to a distal portion of tip protector housing 930 and received within a groove or recess of a proximal portion 921 of a catheter hub 920 when the safety catheter assembly is in both a ready position and a safe position. Extension 931 can be constructed as a solid, cylindrical structure (as best illustrated in Figure 9E), or comprise a plurality of tabs arranged in a circular orientation (as best illustrated in Figure 9B). Extension 931 may have a shape other than circular. Groove or recess of proximal portion 921 can generally correspond to extension 931, for example, to permit coupling of catheter hub 920 with tip protector housing 930 only when rotated relative to each other in a desired orientation.

Similarly, and with reference to Figure 9C, a tip protector housing 930 can comprise a dome extension 933 coupled to a distal portion of tip protector housing 930 and received within a recess of a proximal portion 923 of a catheter hub 920. Recess of proximal portion 923 can generally correspond to dome extension 933.

With reference now to Figures 9D and 9E, a tip protector housing 930 can comprise extensions 931, 933 coupled to distal portions of tip protector housing 930 and received within grooves or recesses of proximal portions 921, 923 of a catheter hub 920.

In various embodiments of the present disclosure, and with reference to Figures 10A and 10B, a catheter insertion device can comprise a lock sleeve 1035. Lock sleeve 1035 can be moveable within a tip protector housing 1030 from a locked position (Figure 10A) in which lock sleeve 1035 is positioned at least partially within a proximal portion of a catheter hub 1020 in the direction shown by the arrows to an unlocked position (Figure 10B) in which lock sleeve 1035 is not positioned within a proximal portion of catheter hub 1020.

In the locked position, lock sleeve 1035 may prevent inward movement of a tab 1025 on catheter hub 1020 from a gap 1037. Gap 1037 and tab 1025 can each be circumferential or at discrete positions around the circumference of tip protector housing 1030 and catheter hub 1020, respectively. Gap 1037 and tab 1025 can combine to form a snap fit joint.

5 In the unlocked position, lock sleeve 1035 may no longer prevent inward movement of tab 1025 from a gap 1037 such that tab 1025 no longer prevents separation of a coupling defined by at least a portion of each of catheter hub 1020 and tip protector housing 1030.

Lock sleeve 1025 may be formed as an integral part of the tip protector or may be a separate component that is connected to or acted on by the tip protector to move lock sleeve
10 1025 proximally. According to some examples, the lock sleeve may include features that are positioned proximally of the proximal end of the tip protector. In this respect, lock sleeve 1025 will be pulled proximally to the unlocked position by the tip protector, when the tip protector is acted on by a bump on a needle.

In other example embodiments of the present disclosure, a lock sleeve (or similar type
15 mechanisms) is rotatable relative to a tip protector housing and/or catheter hub to move between a locked and an unlocked position. Helical or ramped features may be formed directly in the needle shaft. During needle withdrawal as the needle is pulled proximally, these helical features or ramps can act to rotate a lock sleeve to cause disengagement of the tip protector housing and the catheter hub. The ramp features may be formed directly on the
20 metal material of the needle shaft. Alternatively, a separate component that includes the helical or ramp features may be secured to the needle shaft, such as with an adhesive. Including the helical or ramp features in a separate component may allow the helical / ramp features to be positioned in greater radial distance from the central needle axis, thus providing for greater mechanical advantage in moving the lock sleeve from the locked position to the
25 unlocked position.

In example embodiments of the present disclosure, a coupling defined by at least a portion of each of catheter hub 1020 and tip protector housing 1030 provides an overlap between tip protector housing 1030 and catheter hub 1020. The distance of overlap, taken in a direction that extends distally to proximally, can be increased to provide greater resistance to
30 bending moments or side loads that may cause premature separation.

Persons skilled in the art will appreciate that the foregoing embodiments comprising an lock sleeve may be used in connection with other embodiments described herein, for example, with reference to Figures 9A, 9C and 9D, which illustrate tabs and gaps similar to those described above.

It will be apparent to those skilled in the art that various modifications and variations can be made in the present disclosure without departing from the spirit or scope of the disclosure. For example, while various embodiments have been described with reference to safety catheter assemblies, the invention is not so limited. Thus, it is intended that the
5 embodiments described herein cover the modifications and variations of this disclosure provided they come within the scope of the appended claims and their equivalents.

Numerous characteristics and advantages have been set forth in the preceding description, including various alternatives together with details of the structure and function of the devices and/or methods. The disclosure is intended as illustrative only and as such is
10 not intended to be exhaustive. It will be evident to those skilled in the art that various modifications can be made, especially in matters of structure, materials, elements, components, shape, size and arrangement of parts including combinations within the principles of the invention, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. To the extent that these various
15 modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

What is claimed is:

Claims

1. A safety catheter assembly comprising:
a needle hub comprising a needle extending distally from the needle hub;
5 a tip protector housing comprising a push-off tab extending radially from the tip protector housing;
a catheter hub comprising a catheter extending distally from the catheter hub;
wherein, in a ready position, the needle extends through the catheter and the tip protector housing is coupled to the catheter hub through a threshold force coupling; and
10 wherein, in a safe position, a distal tip of the needle is housed within the tip protector housing and the tip protector housing is coupled to the catheter hub through the friction fit, and
wherein, in a released position, the distal tip of the needle is housed within the tip protector housing and the tip protector housing is released from the catheter hub.
15
2. The safety catheter assembly of claim 1, further comprising a tab extension extending distally from the tip protector housing, wherein the push-off tab extends radially from the tab extension, wherein the tab extension overlaps a proximal end of the catheter hub.
- 20 3. The safety catheter assembly of claim 2 wherein a distal end of the needle hub does not substantially overlap a proximal end of the tip protector housing.
4. The safety catheter assembly of claim 2, wherein the tab extension is flat.
- 25 5. The safety catheter assembly of claim 2, wherein the tab extension is curved at least partially around the catheter hub.
6. The safety catheter assembly of claim 2, wherein the tab extension does not diminish any contact between the catheter hub and a skin surface.
- 30 7. The safety catheter assembly of claim 1, wherein the tip protector housing is at least partially enclosed within the needle hub, and wherein the push-off tab extends through a window in the needle hub.

8. The safety catheter assembly of claim 7, wherein the push-off tab is located proximal to a proximal end of the catheter hub.
9. The safety catheter assembly of claim 6, wherein a distal end of the needle hub is adjacent to the proximal end of the catheter hub.
10. The safety catheter assembly of claim 1, wherein the tip protector housing is completely circumferentially housed within the needle hub, except for a tab extension extending distally from the tip protector housing, wherein the push-off tab extends radially from the tab extension, wherein the tab extension overlaps a proximal end of the catheter hub.
11. The safety catheter assembly of claim 1, wherein the threshold force coupling includes a friction fit joint.
12. The safety catheter assembly of claim 1, wherein the threshold force coupling includes a snap fit joint.
13. A safety catheter assembly comprising:
a catheter assembly, including:
a catheter hub; and
a catheter extending distally from the catheter hub;
a catheter insertion device, including:
a needle hub;
a needle extending distally from the needle hub along a longitudinal axis and having a sharp distal tip; and
a tip protector housing;
at least a portion of each of the catheter hub and the tip protector housing defining a coupling that is constructed and arranged to couple the catheter insertion device to the catheter, to selectively release the catheter insertion device from the catheter when a threshold release force applied proximally along the longitudinal axis is exceeded, and to prevent release of the catheter insertion device from the catheter responsive to forces applied laterally to the longitudinal axis;
wherein, in a ready position, the needle extends through the catheter of the catheter assembly and the tip protector housing is coupled to the catheter hub through the coupling,

retraction of the needle relative to the catheter along the longitudinal axis moves the catheter insertion device to a safe position with the sharp distal tip of the needle housed within the tip protector housing and the tip protector housing coupled to the catheter hub through the coupling, and further retraction of the needle along the longitudinal axis with a force in
5 excess of a release force moves the catheter insertion device to a released position with the needle separated from the catheter, the distal tip of the needle housed within the tip protector housing and the tip protector housing released from the catheter hub.

14. The safety catheter assembly of claim 13, wherein the coupling comprises a pivoting
10 joint that allows the tip protector housing to pivot relative to the catheter hub and away from the longitudinal axis.

15. The safety catheter assembly of claim 13, wherein the coupling comprises a ball joint
15 that allows the tip protector housing to pivot relative to the catheter hub and away from the longitudinal axis in a plurality of directions.

16. The safety catheter assembly of claim 13, wherein an amount of clearance between an
interior surface of the needle hub and an exterior surface of the tip protector housing provides
20 space for the needle to bend.

17. The safety catheter assembly of claim 13, wherein an amount of clearance between an
interior surface of the tip protector housing and the needle provides space for the needle to
bend.

25 18. The safety catheter assembly of claim 13, wherein an amount of clearance between an
interior surface of the needle hub and an exterior surface of the catheter hub is lessened.

19. The safety catheter assembly of claim 13, wherein the coupling comprises a first
contact point between the catheter hub and the tip protector housing oriented at 0 degrees and
30 a second contact point between the catheter hub and the tip protector housing oriented at 180
degrees.

20. The safety catheter assembly of claim 13, the tip protector housing further comprising
an extension coupled to a distal portion of the tip protector housing received within a

proximal portion of the catheter hub when the safety catheter assembly is in both the ready position and the safe position.

21. The safety catheter assembly of claim 13, further comprising:
- 5 an lock sleeve moveable within the tip protector housing from a locked position in which the lock sleeve is positioned at least partially within a proximal portion of the catheter hub to an unlocked position in which the lock sleeve is not positioned within a proximal portion of the catheter hub,
- wherein in the locked position, the lock sleeve prevents inward movement of a tab on the
- 10 catheter hub, and
- wherein in the unlocked position, the lock sleeve no longer prevents inward movement of the tab such that the tab no longer prevents separation of the coupling.

22. The safety catheter assembly of claim 21, wherein the lock sleeve is rotatable relative
- 15 to the tip protector housing.

23. The safety catheter assembly of claim 13, wherein the coupling provides an overlap between the tip protector housing and the catheter hub.

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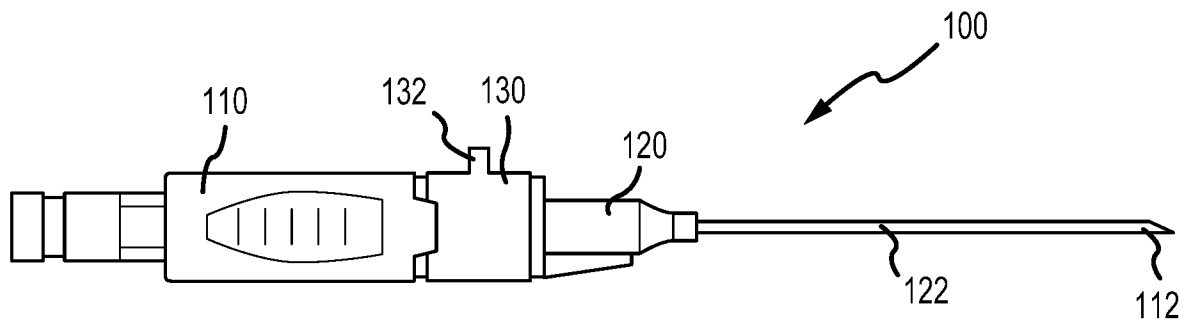


FIG. 1

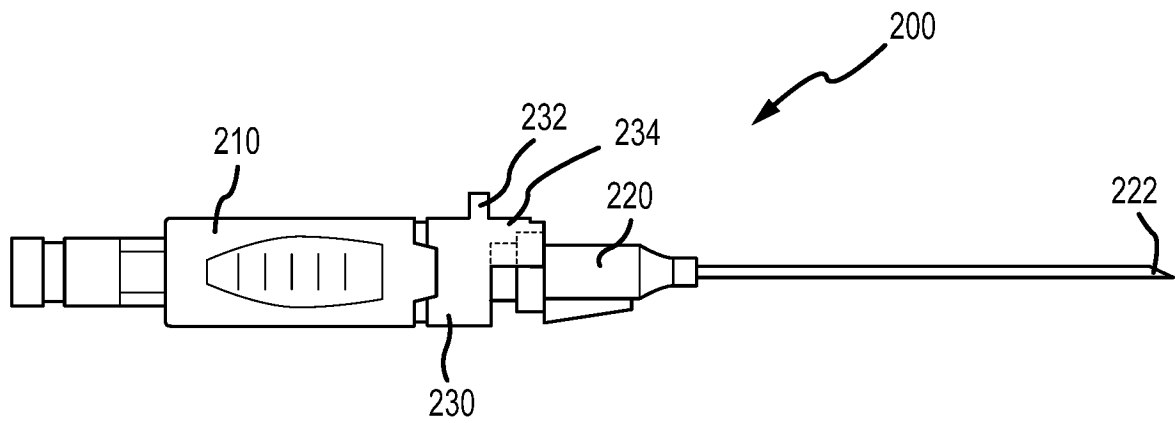


FIG. 2A

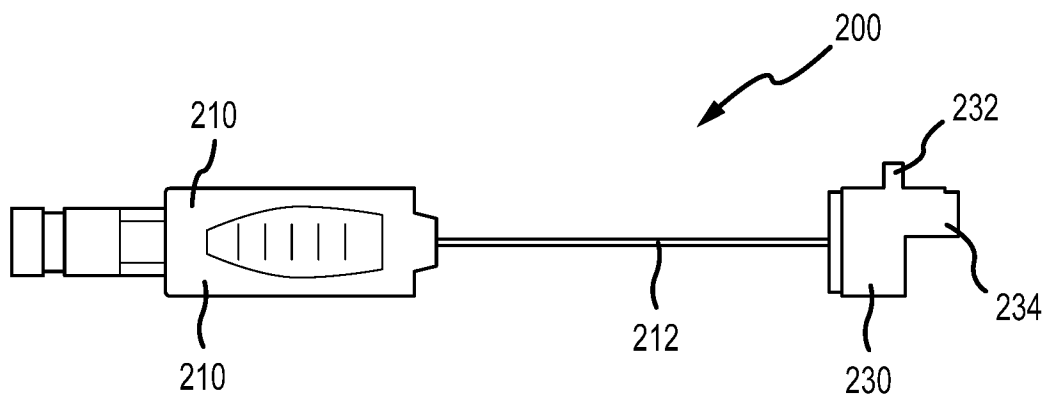


FIG. 2B

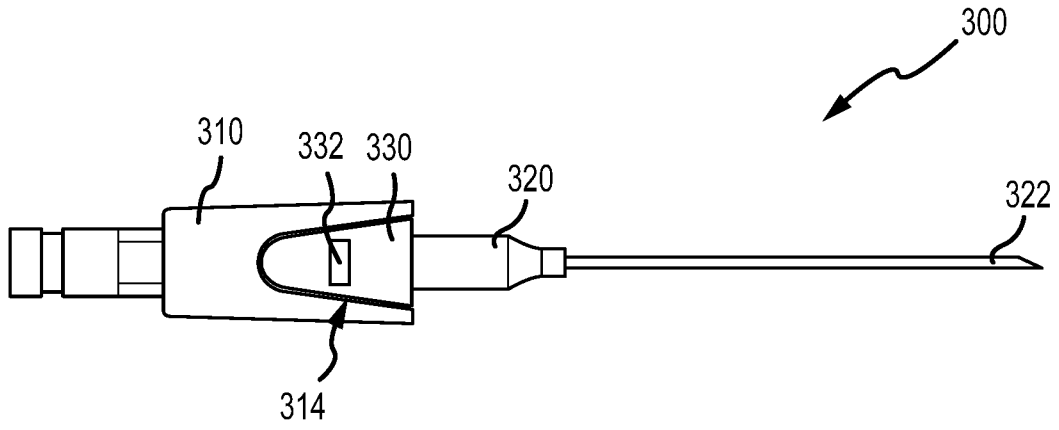


FIG.3A

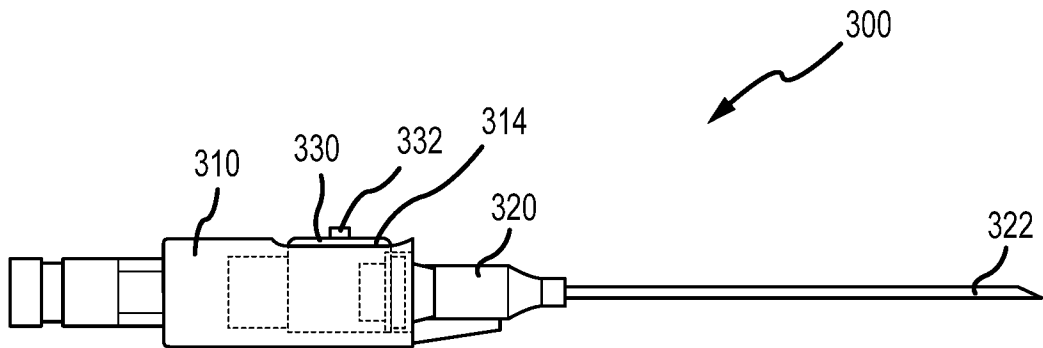


FIG.3B

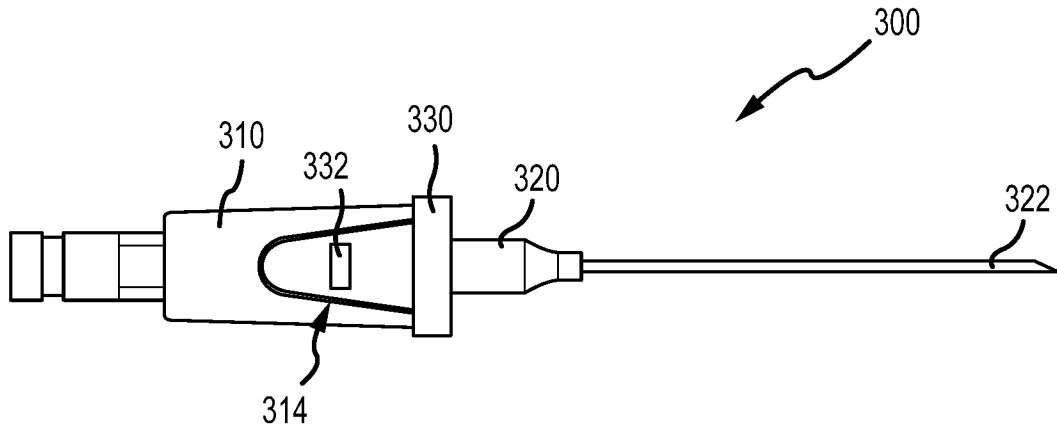


FIG.3C

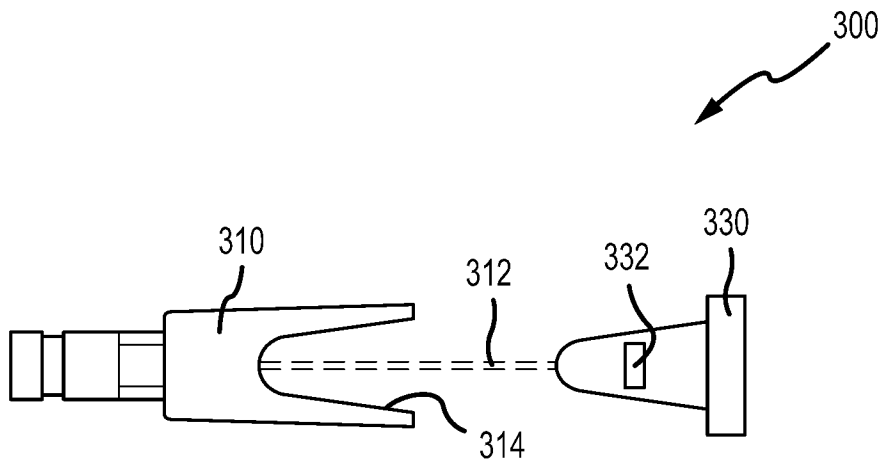


FIG.3D

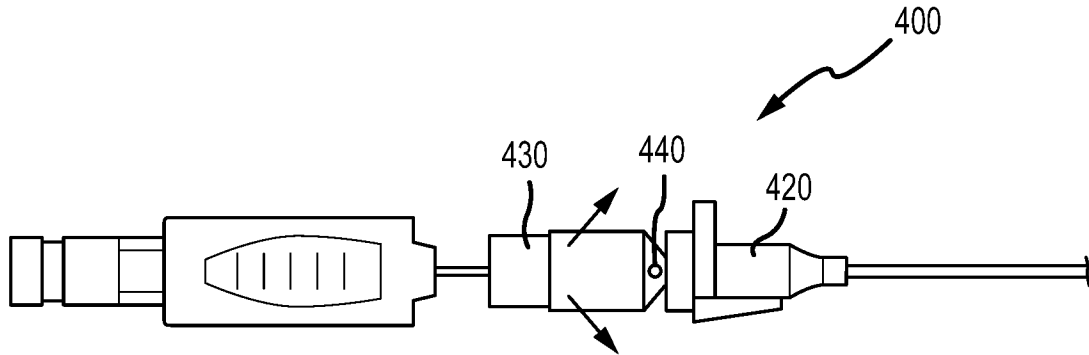


FIG. 4

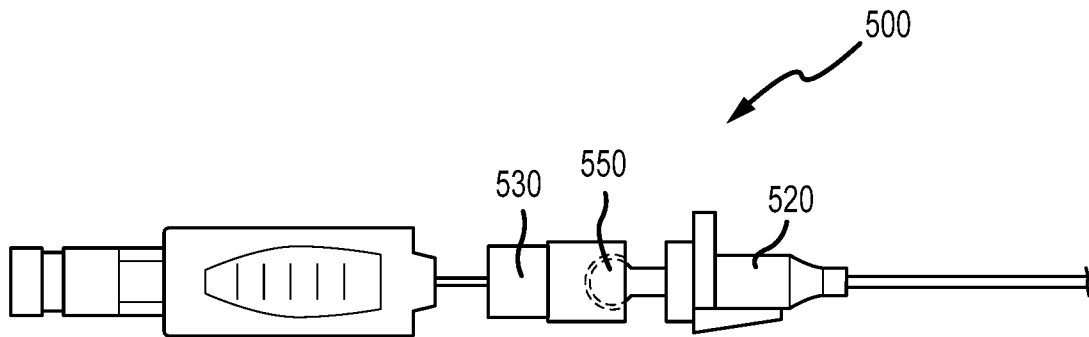


FIG. 5

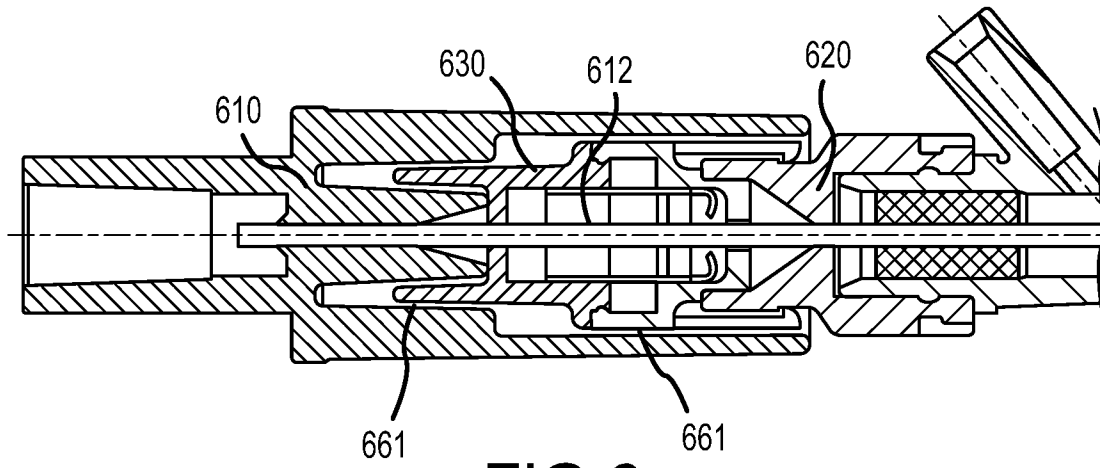


FIG.6

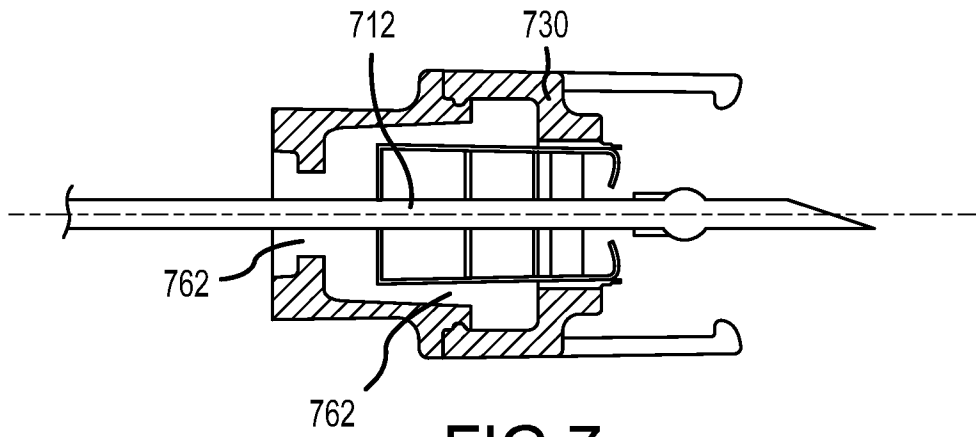


FIG.7

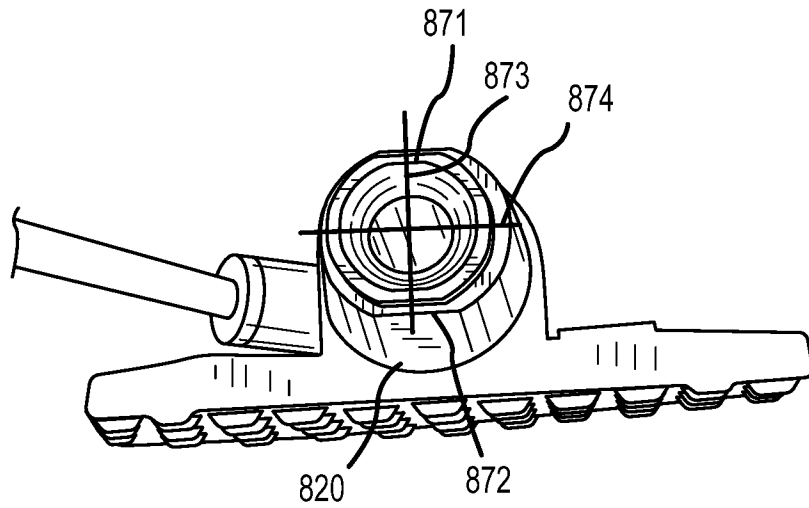


FIG.8

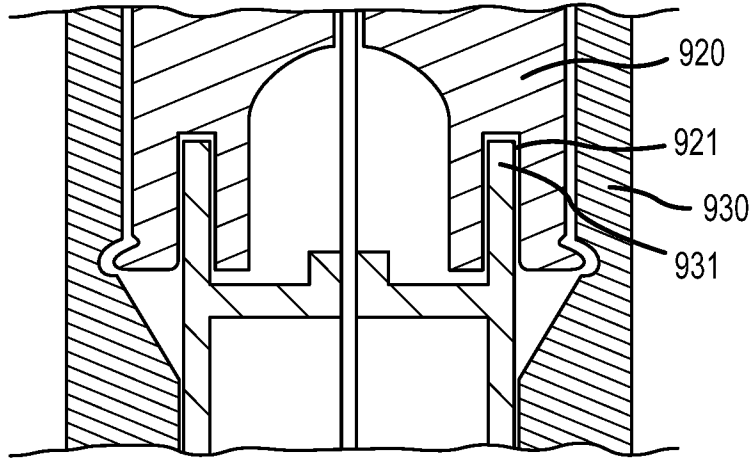


FIG.9A

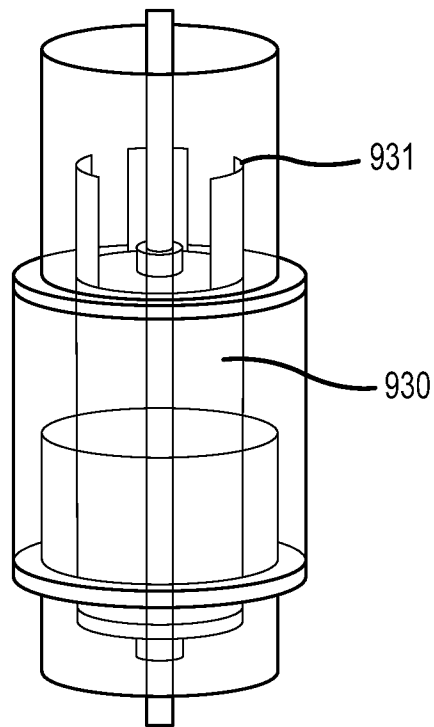


FIG.9B

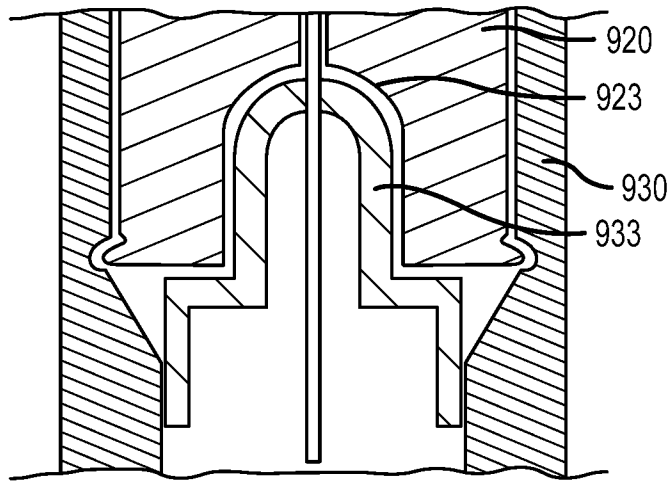


FIG.9C

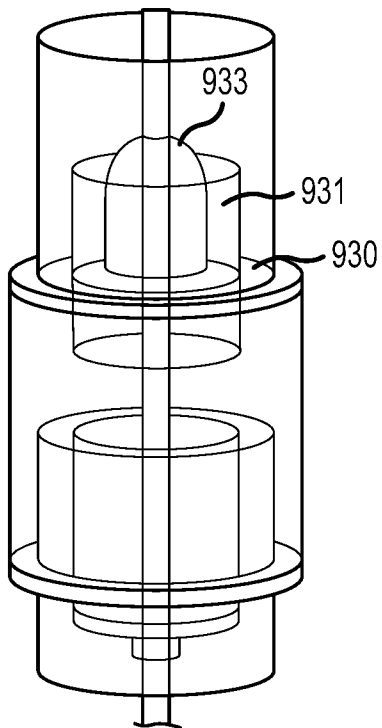


FIG.9E

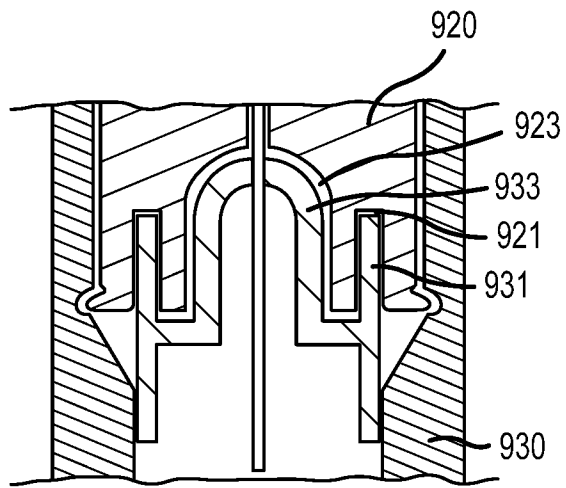


FIG.9D

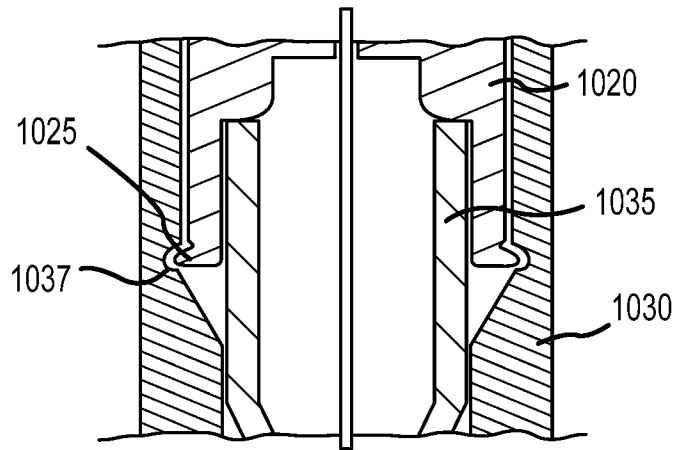


FIG.10A

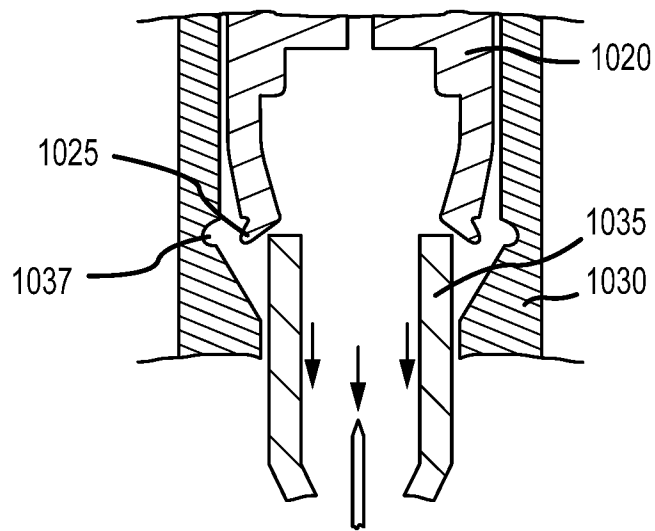


FIG.10B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/21135

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - A61M 25/00 (2018.01)
 CPC - A61M 25/00, A61M 25/06, A61M 25/0612, A61M 25/0631, A61M 5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y ----- A	US 2003/0105431 A1 (HOWELL) 5 June 2003 (05.06.2003) entire document, especially fig 1, 2; para [0021]-[0023], [0030]	1-6, 10-11, 13, 18 ----- 12 ----- 7-9, 21-22
X ----- A	US 2016/0106959 A1 (WOEHR) 21 April 2016 (21.04.2016) entire document, especially fig 4; para [0087], [0106], [0111], [0113]	13, 19, 23 ----- 14, 15
X ----- Y ----- A	US 2008/0300543 A1 (ABRILES et al) 4 December 2008 (04.12.2008) entire document, especially fig 1, 4, 6; para [0024]-[0025], [0032]	13, 16-17, 20 ----- 12 ----- 1-23
A	US 2004/0267200 A1 (CARLYON et al) 30 December 2004 (30.12.2004) entire document, especially para [0072]	1-23
A	US 7,736,337 B2 (DIEP et al) 15 June 2010 (15.06.2010) entire document, especially fig 4; col 5 ln 11-14	1-23
A	US 4,755,356 A (ROBBINS et al) 5 July 1988 (05.07.1988) entire document, especially fig 1	14-15

Further documents are listed in the continuation of Box C.

See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 April 2018

Date of mailing of the international search report

16 MAY 2018

Name and mailing address of the ISA/US

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