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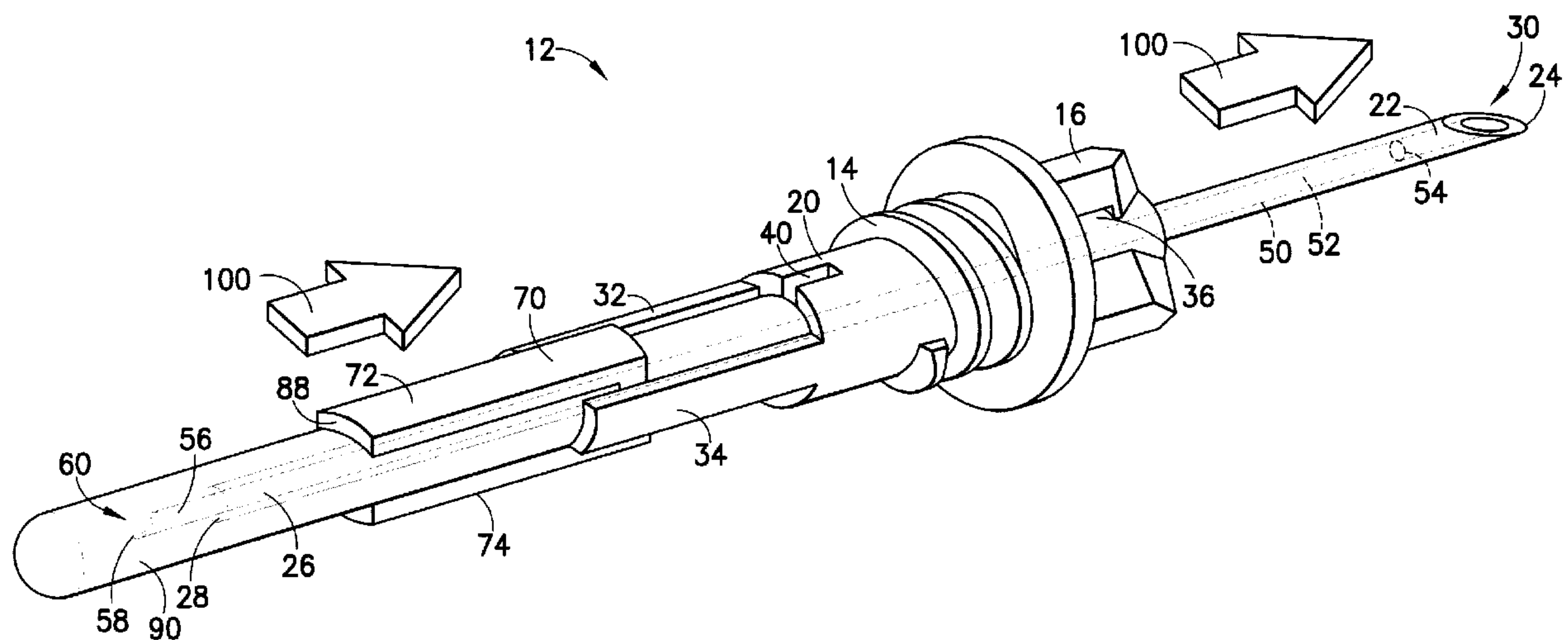
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(54) Titre : AIGUILLES DE SECURITE POUR PRELEVEMENT SANGUIN

(54) Title: SAFETY BLOOD COLLECTION NEEDLE ASSEMBLY



(57) Abrégé/Abstract:

A dual blunting needle assembly for use in blood collection procedures is provided. The needle assembly includes a hub assembly having a first external cannula with an intravenous puncture tip, a second external cannula with an external blunt tip and an internal lumen extending through the hub assembly from the intravenous puncture tip to the blunt tip. The needle assembly further includes an internal cannula extending concentrically within the internal lumen of the hub assembly. The internal cannula includes an internal blunt tip at a first end and a non-patient puncture tip at a second end. The internal cannula is adapted for axial movement within the internal lumen of the hub assembly between a first position in which the intravenous puncture tip and the non-patient puncture tip extend beyond the internal blunt tip and the external blunt tip, respectively, and a second position in which the internal blunt tip and the external blunt tip extend beyond the intravenous puncture tip and the non-patient puncture tip, respectively. The needle assembly can further be used in connection with a needle holder to provide a safety assembly.

SAFETY BLOOD COLLECTION NEEDLE ASSEMBLY

ABSTRACT OF THE DISCLOSURE

A dual blunting needle assembly for use in blood collection procedures is provided. The needle assembly includes a hub assembly having a first external cannula with an intravenous puncture tip, a second external cannula with an external blunt tip and an internal lumen extending through the hub assembly from the intravenous puncture tip to the blunt tip. The needle assembly further includes an internal cannula extending concentrically within the internal lumen of the hub assembly. The internal cannula includes an internal blunt tip at a first end and a non-patient puncture tip at a second end. The internal cannula is adapted for axial movement within the internal lumen of the hub assembly between a first position in which the intravenous puncture tip and the non-patient puncture tip extend beyond the internal blunt tip and the external blunt tip, respectively, and a second position in which the internal blunt tip and the external blunt tip extend beyond the intravenous puncture tip and the non-patient puncture tip, respectively. The needle assembly can further be used in connection with a needle holder to provide a safety assembly.

UNITED STATES PATENT APPLICATION

OF: Jamieson William Maclean Crawford

FOR: SAFETY BLOOD COLLECTION NEEDLE ASSEMBLY

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to dual end needle assemblies for use in blood collection procedures. More particularly, the present invention relates to a needle assembly having a double-ended needle for blood collection from a patient and which includes blunting elements for the double-ended needle.

2. Description of Related Art

[0002] Disposable medical devices having piercing elements are typically used for administering a medication or withdrawing a fluid, such as blood collecting needles, fluid handling needles and assemblies thereof. Current medical practice requires that the fluid containers and needle assemblies used in such systems be inexpensive and readily disposable. Consequently, existing blood collection systems, for example, typically employ some form of durable, reusable holder on which detachable and disposable needles and fluid collection tubes may be mounted. A blood collection system of this nature can be assembled prior to use and then disassembled after usage. Thus, these blood collection systems allow repeated use of the relatively expensive holder upon replacement of the relatively inexpensive needle and/or fluid collection tube. In addition to reducing the cost of collecting blood specimens, these blood collection systems also help minimize the production of hazardous medical waste.

[0003] A popular design configuration of previously available blood collection systems includes a double-ended needle assembly, an evacuated collection tube, and a holder for maintaining the needle assembly and the collection tube in fixed relation. The double-ended needle assembly, which is also referred to as a cannula, has a bore extending therethrough and a hub near a central region thereof. The evacuated fluid collection tube includes a puncturable stopper at one end thereof. In this type of blood collection system, the holder typically has a housing at one end thereof for receiving the needle assembly. Likewise, the holder also has a hollow body with an opening at an opposite end thereof for receiving the collection tube. The needle assembly is rigidly received within the housing of the holder such that a first end of the needle extends forwardly of the holder for puncturing the vein of a patient. The opposite, second end of the needle extends into the hollow body of the holder. Upon assembly of the blood collection system, the needle assembly is inserted into the housing and the collection tube is inserted through the open end of the hollow body until the second end of the needle pierces the puncturable stopper of the collection tube, thereby allowing fluid communication between the interior of the collection tube and the bore which extends through the needle assembly. To draw a blood specimen from a patient using one of these blood collection systems, the evacuated collection tube is partially inserted into one end of the holder, the first end of the needle is inserted into a patient's vein and the collection tube is fully inserted into the holder such that blood will be drawn through the bore of the needle assembly and into the fluid collection tube. After drawing the specimen, the collection tube is removed so that the blood contained therein can be analyzed and the needle assembly is detached for disposal.

[0004] In addition to being capable of accommodating blood collection tubes, the holders of some fluid transfer systems are compatible with fluid containers having a fluid to be injected into a patient. Thus, such holders can be used to inject fluid into, as well as draw blood specimens from, a patient.

[0005] In order to reduce the risk of incurring an accidental needle-stick wound, protection of the used needle tip becomes important. With concern about infection and diseases of the blood, methods and devices to enclose the used disposable needle have become very important and in great demand. Many developments have taken place for protecting used needle tips. For example, U.S. Patent No. 5,951,520 to Burzynski et al., discloses a self-blunting needle in which a rod or probe-like blunting member is disposed within the bore of a needle cannula having a puncture tip suitable for puncturing tissue. To prevent accidental needle-stick wounds from occurring after use of the device, the blunting member, which is retracted behind the puncture tip when the needle is injected into tissue, can be extended beyond the puncture tip of the needle cannula to effectively blunt the puncture tip by extending beyond it, so as to eliminate or at least greatly reduce the risk of accidental needle-stick punctures. Such a device, however, does not provide protection for the second end of the needle at the non-patient end of the assembly.

[0006] U.S. Patent No. 5,810,775 to Shaw discloses a collection assembly which provides for retraction of the intravenous needle at the patient end of the assembly, and further discloses a hinged cap at the open end of the housing of the holder. After drawing a specimen into a collection tube, the collection tube is removed, and the hinged cap is closed over the opening of the holder, thereby activating the needle retraction and blocking access to the second end of the needle at the non-patient end. Activation of the hinged cap and the retraction mechanism requires substantial manipulation by the user and cannot be conveniently accomplished with a single hand, as is ideal for typical phlebotomy practice. Furthermore, the size of the device is relatively large, and the retraction mechanism for the needle can cause splattering of blood when the tip of a used needle is accelerated during retraction, thus potentially exposing health care workers to blood borne pathogens.

[0007] Accordingly, a need exists for a needle assembly which provides for safety blunting of the needle at both the intravenous and the non-patient needle points while

minimizing aerosolization of blood particulates that may carry infectious diseases, and which is simple to manufacture, easy to operate, and does not occupy a significant amount of disposal space.

SUMMARY OF THE INVENTION

[0008] The present invention is directed to a dual blunting needle assembly which includes a safety feature for both an intravenous puncture tip and a non-patient puncture tip. The needle assembly includes a hub assembly having a first external cannula with an intravenous puncture tip extending from a first end, a second external cannula with an external blunt tip extending from a second opposing end, and an internal lumen extending through the hub assembly from the intravenous puncture tip to the blunt tip. The needle assembly further includes an internal cannula extending concentrically within the internal lumen of the hub assembly. The internal cannula includes an internal blunt tip at a first end and a non-patient puncture tip at a second end. The internal cannula is adapted for axial movement within the internal lumen of the hub assembly between a first position in which the intravenous puncture tip and the non-patient puncture tip extend beyond the internal blunt tip and the external blunt tip, respectively, and a second position in which the internal blunt tip and the external blunt tip extend beyond the intravenous puncture tip and the non-patient puncture tip, respectively.

[0009] Desirably, the first external cannula is a separate member which is connected to the hub assembly, such as through a ferrule which fits concentrically within the first end of the hub assembly. Also, the needle assembly preferably further includes a carriage concentric with the internal cannula, which is provided for slidable engagement with the hub assembly, thereby providing for axial movement of the internal cannula within the internal lumen of the aid hub assembly.

[0010] The needle assembly may further include an indicator for indicating movement of the internal cannula between the first position and the second position, and may include a locking mechanism for preventing axial displacement of the internal cannula from the second position to the first position.

[0011] The present invention is further directed to a dual blunting safety assembly which includes a needle holder as well as a needle assembly in engagement with the needle holder, with the needle assembly as described above.

DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is a perspective view of a dual blunting needle assembly in accordance with the present invention, shown in a retracted position for sampling.

[0013] FIG. 2 is a cross sectional view of the dual blunting needle assembly of FIG. 1.

[0014] FIG. 3 is a perspective view of the dual blunting needle assembly of FIG. 1 shown in an activated position.

[0015] FIG. 4 is a cross sectional view of the activated needle assembly of FIG. 3.

[0016] FIG. 5 is a cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with a needle holder and an evacuated collection tube.

[0017] FIG. 6 is a cross-sectional view of the needle assembly of the present invention shown in an activated position in use with a needle holder and an evacuated collection tube.

[0018] FIG. 7 is a perspective view of the needle assembly of the present invention shown in use with an alternate needle holder.

[0019] FIG. 8 is a cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with the needle holder of FIG. 7.

[0020] FIG. 9 is a cross-sectional view of the needle assembly of the present invention shown in an activated position in use with the needle holder of FIG. 7.

[0021] FIG. 10 is a perspective view of the needle assembly of the present invention shown in use with a further alternate needle holder.

[0022] FIG. 11 is a perspective cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with the needle holder of FIG. 10.

[0023] FIG. 12 is a perspective view of the needle assembly of the present invention shown in use with a further alternate needle holder.

[0024] FIG. 13 is a cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with the needle holder of FIG. 12.

[0025] FIG. 14 is a cross-sectional view of the needle assembly of the present invention shown in an activated position in use with the needle holder of FIG. 12.

[0026] FIG. 15 is a perspective view of the needle assembly of the present invention shown in use with yet a further alternate needle holder.

[0027] FIG. 16 is a cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with the needle holder of FIG. 15.

[0028] FIG. 17 is a cross-sectional view of the needle assembly of the present invention shown in an activated position in use with the needle holder of FIG. 15.

[0029] FIG. 18 is a perspective view of the needle assembly of the present invention shown in use with a further alternate needle holder.

[0030] FIG. 19 is a perspective view of the tab mechanism of the needle holder of FIG. 18.

[0031] FIG. 20 is a cross-sectional view of the needle assembly of the present invention shown in a retracted position in use with the needle holder of FIG. 18.

[0032] FIG. 21 is a cross-sectional view of the needle assembly of the present invention shown in an activated position in use with the needle holder of FIG. 18.

DETAILED DESCRIPTION

[0033] While the present invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail, the preferred embodiments of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. Various other embodiments will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

[0034] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 to 4 illustrate a dual blunting needle assembly in accordance with the present invention and the related features. The needle

assembly is in the form of a double-ended needle for use, for example, in combination with a needle holder for collecting blood samples. While the present invention is generally described in terms of a needle assembly, the present invention encompasses a needle assembly as well as a safety assembly which incorporates the needle assembly in combination with a needle holder, as will be discussed in more detail herein.

[0035] Needle assembly 12 of the present invention is shown generally at FIGS. 1-4. Needle assembly 12 defines a cannula assembly which is adapted for attachment to a separate needle holder, as is known in the art. As such, needle assembly 12 may be provided with means for attachment to a needle holder, such as attachment threads 14 which engage a threaded section of the needle holder. In this manner, needle assembly 12 can be provided as a disposable unit for use with a re-usable holder.

[0036] Needle assembly 12 includes a hub assembly 20 which defines a partial, generally tubular, housing for needle assembly 12. Hub assembly 20 includes a first external cannula 22 extending from a first end thereof, with an intravenous puncture tip 24 at the end of first external cannula 22. Hub assembly 20 further includes a second external cannula 26 extending from a second, opposing end thereof, with an external blunt tip 28 at the end of second external cannula 26. A central bore or internal lumen 30 extends through hub assembly 20 from intravenous puncture tip 24 to external blunt tip 28, providing for the passage of fluid therethrough, and to movably accommodate internal cannula 50, as will be discussed in more detail. External blunt tip 28 is blunted such that, under ordinary hand pressure, will not easily puncture human skin or other biological tissue. Intravenous puncture tip 24 is provided for insertion into the vein of a patient, for example, during a blood collection procedure. Accordingly, intravenous puncture tip 24 is desirably shaped to provide for ease of insertion and minimal discomfort during venipuncture, such as with a tapered pointed end, as is shown in the Figures and is known in the art.

[0037] Desirably, first external cannula 22 and second external cannula 26 are provided as separate members which are fixedly adhered to hub assembly 20, for example, using a medical grade adhesive. Desirably, first external cannula 22 is attached to hub assembly 20 through ferrule 46, which attaches directly to first external cannula 22 and fits within the first end of hub assembly 20.

[0038] As noted, hub assembly 20 includes second external cannula 26 extending from a second end thereof. As best seen in FIG. 1, hub assembly 20 includes arms 32 and 34, which extend axially along the length of needle assembly 12. Arms 32 and 34 are separate protrusions which define extensions of the generally tubular body of hub assembly 20. Arms 32 and 34 are separated, and therefore define channels therebetween for interfitting engagement with a carriage 70, as will be discussed in more detail herein.

[0039] Bridge member 42 extends between arms 32 and 34 at the second end of hub assembly 20. Such bridge member 42 further defines the general tubular body of hub assembly 20, and provides an area for attachment of second external cannula 26 to hub assembly 20. In particular, second external cannula 26 is fixedly adhered to hub assembly 20 within internal lumen 30 at bridge member 42, thereby providing second external cannula 26 as an extension of hub assembly 20. In an alternative embodiment, hub assembly 20 may have arm 32 and may not have arm 34. In a further embodiment, hub assembly 20 may consist of multiple components. These embodiments may aid assembly of the device.

[0040] Needle assembly 12 further includes internal cannula 50. Internal cannula 50 extends concentrically within internal lumen 30 of hub assembly 20. Internal cannula 50 includes first end 52, with an internal blunt tip 54 at the end of first end 52. Internal blunt tip 54 is blunted such that, under ordinary hand pressure, will not easily puncture human skin or other biological tissue. Internal cannula 50 further includes a second end 56, with a non-patient puncture tip 58 at the end of second end 56. Non-patient puncture

tip 58 is provided for puncturing of an evacuated tube, for example, during a blood collection procedure. A central bore or internal lumen 60 extends through internal cannula 50 from internal blunt tip 54 to non-patient puncture tip 58, providing for the passage of fluid therethrough.

[0041] As best depicted in FIG. 2, first end 52 of internal cannula 50 is adjacent first external cannula 22 of hub assembly 20, and second end 56 of internal cannula 50 is adjacent second external cannula 26 of hub assembly 20. Internal cannula 50 is axially slidable within the internal lumen 30 of hub assembly 20, such that internal blunt tip 54 is slidable within first external cannula 22 and non-patient puncture tip 58 is slidable within second external cannula 26. The inner diameter of first external cannula 22 is substantially the same as the outer diameter of first end 52 of internal cannula 50, and the inner diameter of second external cannula 26 is substantially the same as the outer diameter of second end 56 of internal cannula 50. As such, internal cannula 50 and hub assembly 20 are dimensioned and configured for a close fit, such that the external diameter of internal cannula 50 is a close fit with the internal diameter of hub assembly 20 so that intravenous puncture tip 24 lies flat on the external surface of first end 52 of internal cannula 50 and non-patient puncture tip 58 lies flat against the internal surface of second external cannula 26 within internal lumen 30 when needle assembly 12 is in an activated position, as shown in FIGS. 3 and 4 and described in more detail herein.

[0042] It may be desirable to lubricate the mating surfaces of internal cannula 50 and first and second external cannulas 22 and 26 of hub assembly 20, as well as to provide a seal between them to prevent the unwanted flow of air bubbles. Accordingly, a drop of viscous sealant-lubricant, such as petroleum jelly, may be provided about the mating surfaces thereof.

[0043] Internal cannula 50 is adapted for axial movement within internal lumen 30 of hub assembly 20 between a first retracted position in which intravenous puncture tip

24 and non-patient puncture tip **58** extend beyond internal blunt tip **54** and external blunt tip **28**, respectively, and a second activated position in which internal blunt tip **54** and external blunt tip **28** extend beyond intravenous puncture tip **24** and non-patient puncture tip **58**, respectively. More particularly, axial movement of internal cannula **50** within internal lumen **30** of hub assembly **20** in a direction of arrows **100** causes first end **52** of internal cannula **50** to axially displace with respect to first external cannula **22**, which causes internal blunt tip **54** to extend beyond intravenous puncture tip **24** of first external cannula **22**. In addition, such axial movement causes second end **58** of internal cannula **50** to axially displace with respect to second external cannula **26**, which causes non-patient puncture tip **58** to slide within second external cannula **26** such that external blunt tip **28** extends beyond non-patient puncture tip **58**, as depicted in FIGS. 3 and 4. As such, both intravenous puncture tip **24** and non-patient puncture tip **58** are simultaneously blunted.

[0044] Slidable engagement of internal cannula **50** and hub assembly **20** may be effected through carriage **70**. Carriage **70** is concentric with internal cannula **50**, and is provided for slidable engagement with hub assembly **20**. Carriage **70** may be integral with internal cannula **50**, or may be a separate member which is fixedly adhered to internal cannula **50** such as through the use of an adhesive. Carriage **70** is defined by a generally tubular body which includes arms **72** and **74** extending axially therealong and which are joined at nub **80**. Arms **72** and **74** slidably engage arms **32** and **34** of hub assembly **20**, such that the circumferential profile of needle assembly **12** about arms **72** and **74** of carriage **70** and arms **32** and **34** of hub assembly **20** is generally cylindrical or tubular, although other shapes or configurations may be apparent to those skilled in the art. In an alternative embodiment, carriage **70** may have arm **72** and may not have arm **74**. In a further embodiment, carriage **70** may consist of multiple components. These embodiments may aid assembly of the device.

[0045] Nub **80** of carriage **70** includes a forward portion **86** which is positioned within the interior portion of hub assembly **20** when assembled. Forward portion **86** of carriage **70** includes a surface **78** which extends circumferentially about nub **80** for interference engagement with shoulder **38** of hub assembly **20**. Such interference engagement prevents carriage **70**, and therefore internal cannula **50** which is attached thereto, from being removed or disassembled from hub assembly **20** after assembly thereof. Nub **80** also includes a tapered surface **82** extending circumferentially thereabout. Tapered surface **82** provides an interference engagement with hub assembly **20**, preventing axial displacement of carriage **70** with respect to hub assembly **20** without a force exerted thereon, as will be described in more detail herein.

[0046] Nub **80** further includes rear face **88** which is adapted for engagement with the top surface of a blood collection tube during use. As will be discussed with respect to the use and operation of needle assembly **12**, rear face **88** provides a mechanism for activating needle assembly **12**, thereby axially displacing internal cannula **50** with respect to hub assembly **20** between a first retracted position and a second activated position.

[0047] Internal cannula **50** and hub assembly **20** may be reversibly axially displaceable with respect to each other, such that internal cannula **50** may displace with respect to hub assembly **20** from either the first retracted position to the second activated position or from the second activated position to the first retracted position. In preferred embodiments, internal cannula **50** is axially displaceable with respect to hub assembly **20** in only a single direction from the first retracted position to the second activated position. As such, needle assembly **12** may be provided with means for preventing axial displacement of internal cannula **50** from the second activated position to the first retracted position once it has been activated, such as a locking mechanism. For example, nub **80** may further include a surface **84** which extends circumferentially about nub **80** for interference engagement with shoulder **38** of hub assembly **20** after activation of needle assembly **12** from the first retracted position to the second activated position. Such

interference engagement prevents axial movement of carriage 70 with respect to hub assembly 20 in a direction opposite arrows 100 after movement from the first retracted position to the second activated position.

[0048] Needle assembly 12 may be further provided with means for indicating movement of internal cannula 50 within hub assembly 20 between the first retracted position and the second extended position. Such means may be a visible, audible and/or tactile indicator, identifying movement of internal cannula 50 within hub assembly 20 between the first retracted position and the second extended position. For example, in one particular embodiment, hub assembly 20 may be provided with a channel 36 extending through the body thereof. Channel 36 is provided within hub assembly 20 and extends through the wall thereof to the external portion of needle assembly 12. Carriage 70 includes finger 76 which extends from forward portion 86 of nub 80 within channel 36 of hub assembly 20. Axial movement of carriage 70 with respect to hub assembly 20 causes finger 76 to axially slide within channel 36 of hub assembly 20. Upon axial movement of carriage 70 from the first retracted position shown in FIGS. 1-2 to the second activated position shown in FIGS. 3-4, finger 76 extends within channel 36 and through the wall of hub assembly 20, thereby providing an indication that needle assembly 12 has been activated, or blunted.

[0049] Channel 36 preferably extends through hub assembly 20 at a position which is beyond the point of attachment to a needle holder, such as threads 14, to ensure that such an indicator is visible to the user during operation and use. Moreover, finger 76 may be provided with a visual identification, such as a color code or verbiage to indicate activation of needle assembly 12.

[0050] Hub assembly 20 may further be provided with a means for attachment of a needle cover, such as shoulder 16 at the first end thereof. Shoulder 16 is provided for engagement with a needle cover (not shown), which covers intravenous puncture tip 24

of first external cannula **22** prior to use of the needle assembly **12** with a patient. Such a needle cover may be constructed of rigid polymeric material, as is known in the art. Shoulder **16** preferably includes a profile to provide for a frictional engagement with the needle cover, such that the needle cover is maintained in position about shoulder **16** in a friction fit, thereby covering and protecting first external cannula **22** and intravenous puncture tip **24** until assembly and use.

[0051] Also, needle assembly **12** may be provided with a second needle cover (not shown) for covering non-patient puncture tip **58** of second external cannula **26** prior to assembling of needle assembly **12** with a needle holder. Such a second needle cover may also be constructed of rigid polymeric material. This second needle cover may be attached to needle holder **12**, for example, by threaded engagement with external threads **14** extending about hub assembly **20**. In this manner, this second needle cover can be removed from needle assembly **12** prior to assembly with a needle holder by unthreading the needle cover from external threads **14**, and then threading external threads **14** into an internal thread of such a needle holder, as is known in the art.

[0052] Needle assembly **12** is further provided with an elastomeric sleeve **90** extending about second external cannula **26** and second end **56** of internal cannula **50**, and covering non-patient puncture tip **58**, as is generally known in the art. Elastomeric sleeve **90** is joined to bridge member **42**. This joining means may be an interference mechanism, a snap-fit, an adhesive, or other such similar means.

[0053] In a further embodiment, the present invention is directed to a safety assembly which includes needle assembly **12** in combination with a needle holder **110**, as shown in FIGS. 5 and 6. Needle holder **110** may be a conventional needle holder as is well known in the art for use in connection with double-ended needles for blood collection. For example, needle holder **110** is defined generally by hollow body **112**, which includes first end **114**, and second end **118**. First end **114** of needle holder **110**

includes an opening 116 extending therethrough, while second end 118 includes flange 122 and is generally open-ended, providing needle holder 110 with a hollow body 112 having an internal opening 120 extending therethrough. Such internal opening 120 accommodates a blood collection tube 130 during a sampling procedure, such as an evacuated collection tube, as is known in the art.

[0054] Means for attachment are provided for attaching needle assembly 12 to needle holder 110, such as within internal opening 116 at first end 114. Such attachment may be accomplished, for example, through a snap-fit engagement, or more desirably, through a threaded relation, such as through internal threads within opening 116 for engagement with external threads 14 of needle assembly 12.

[0055] Operation and use of the needle assembly of the present invention will now be described in terms of the embodiment depicted in FIGS. 1-4. In use, needle assembly 12 is provided including a first needle cover (not shown) extending over first external cannula 22, and a second needle cover (not shown) extending over second external cannula 26. When preparing the needle assembly for use in a sampling procedure, the second needle cover is removed from second external cannula 26, and needle assembly 12 is then attached to needle holder 110, such as by threading external threads 14 with internal threads provided within opening 116 of needle holder 110.

[0056] The needle cover extending over first external cannula 22 is then removed. Venipuncture is then conducted in known manner, whereby intravenous puncture tip 24 is inserted into a vein of a patient, and evacuated blood collection tube 130 having pierceable closure 132 is inserted into the needle holder, such that pierceable closure 132 of the collection tube 130 contacts sleeve 90 extending about second external cannula 26. When slight pressure is exerted on the collection tube 130, pierceable closure 132 contacting sleeve 90 causes sleeve 90 to displace, thereby causing non-patient puncture tip 58 to puncture sleeve 90 and, in turn, pierceable closure 132. At such time, the

interior of collection tube **130** and internal lumen **60** of internal cannula **50** are in fluid communication. Since the interior of collection tube is at a negative pressure, blood is drawn from the vein of the patient, through internal lumen **30** of first external cannula **22**, through internal lumen **60** of internal cannula **50** and into collection tube **130**.

[0057] When all desired samples have been drawn, activation of the dual blunting needle assembly is accomplished. Activation of the dual blunting needle assembly is desirably accomplished while venipuncture is maintained, that is while intravenous puncture tip **24** of first external cannula **22** is maintained within the vein of the patient, in order to prevent an accidental needle stick prior to blunting of the needle. Blunting of the needle assembly **12** is accomplished exerting pressure in a direction of arrows **100** on rear face **88** of carriage **70**.

[0058] In particular, during sampling, the top surface of pierceable closure **132** of collection tube **130** contacts rear face **88** of carriage **70** within the holder. When additional force is exerted against collection tube **130** in a direction of arrows **100**, rear face **88** is forced in the direction of arrows **100**. Such force causes interference engagement between tapered surface **82** of nub **80** against hub assembly **20**. Since hub assembly **20** includes groove **40** at opposed portions of the wall thereof, hub assembly **20** radially displaces to permit tapered surface **82** to pass within hub assembly **20**, thereby causing axial movement of carriage **70** with respect to hub assembly **20**. Moreover, since arms **72** and **74** of carriage **70** interfit with arms **32** and **34** of hub assembly **20**, carriage **70** is able to axially slide with respect to hub assembly **20**.

[0059] Since carriage **70** is attached to internal cannula **50**, axial displacement of carriage **70** with respect to hub assembly **20** causes axial displacement of internal cannula **50** with respect to hub assembly **20**. Moreover, since first external cannula **22** and second external cannula **26** are attached to hub assembly **20**, axial displacement of internal cannula **50** with respect to hub assembly **20** causes first end **52** and second end

56 to axially displace with respect to first external cannula **22** and second external cannula **26**. Since internal blunt tip **54** and external blunt tip **28** are positioned short of intravenous puncture tip **24** and non-patient puncture tip **58**, respectively, axial displacement of first end **52** and second end **56** with respect to first external cannula **22** and second external cannula **26** causes internal blunt tip **54** and external blunt tip **28** to axially displace to a position in which they extend beyond intravenous puncture tip **24** and non-patient puncture tip **58**, respectively. More particularly, when internal cannula **50** is axially displaced in the direction of arrows **100**, internal blunt tip **54** protrudes from the end of first external cannula **22** beyond intravenous puncture tip **24**, and non-patient puncture tip **58** slides within second external cannula **26** such that external blunt tip **28** extends beyond non-patient puncture tip **58**, as depicted in FIGS. 3 and 4. As such, both intravenous puncture tip **24** and non-patient puncture tip **58** are simultaneously blunted. Needle assembly **10** can then be removed from the patient's vein, and appropriately discarded.

[0060] As noted, the safety assembly of the present invention includes needle assembly **12** used in connection with a needle holder **110**, which may be a standard needle holder known for use with conventional double-ended needle assemblies for blood collection. Desirably, the safety assembly includes a needle holder which is particularly designed for use in connection with a needle assembly having an activation mechanism such as a blunting member adapted for axial displacement between a first retracted position and a second activated or blunted position, such as needle assembly **12** of the present invention. In particularly preferred embodiments, needle holder **110** includes a mechanism for causing axial displacement of internal cannula **50** within internal lumen **30** of hub assembly **20**.

[0061] For example, as depicted in FIGS. 7-11, the safety assembly may include a needle holder which includes a lever for preventing or permitting activation of needle assembly **12**. In particular, as shown in FIGS. 7-9, needle holder **110a** is provided.

Needle holder **110a** includes a generally tubular hollow body **112a**, including first end **114a** and second end **118a**. First end **114a** of needle holder **110a** includes an opening **116a** extending therethrough, while second end **118a** includes flange **122a** and is generally open-ended, providing needle holder **110a** with a hollow body **112a** having an internal opening **120a** extending therethrough. Such internal opening **120a** accommodates a blood collection tube **130** during a sampling procedure, such as an evacuated collection tube, as is known in the art.

[0062] Means for attachment are provided for attaching needle assembly **12** to needle holder **110a**, such as within internal opening **116a** at first end **114a**. Such attachment may be accomplished, for example, through a snap-fit engagement, or more desirably, through a threaded relation, such as through internal threads within opening **116a** for engagement with external threads **14** of needle assembly **12**.

[0063] Needle holder **110a** is further provided with a lever **140a** extending along a portion of hollow body **112a** thereof. Lever **140a** is provided as a generally elongated portion extending axially along the exterior portion of hollow body **112a**. Lever **140a** includes extension arm **142a** extending from one end thereof. Extension arm **142a** extends through the wall of hollow body **112a** of needle holder **110a**, and within internal opening **120a** of needle holder **110a**. Extension arm **142a** includes surface **148a**, which is provided for interfering engagement with a top surface of collection tube **130** such as pierceable closure **132**.

[0064] Lever **140a** is movable between a first blocking position and a second release position. More particularly, lever **140a** is provided in a first position in which lever **140a** lies flush with the outer surface of hollow body **112a** of needle holder **110a**, such that lever **140a** represents a continuation of the outer surface of hollow body **112a** of needle holder **110a**. In such a first position, extension arm **142a** extends within internal opening **120a** for interfering or abutting engagement with pierceable closure **132**

of a collection tube **130** inserted within internal opening **120a**. In such a first position, collection tube **130** is blocked from engagement with carriage **70** to prevent axial displacement of carriage **70**, and therefore prevent axial displacement of internal cannula **50** with respect to hub assembly **20** between the first retracted position and the second activated position.

[0065] Lever **140a** is movable in a direction of arrow **102a** to a second release position, in which lever **140a** protrudes from the outer surface of hollow body **112a** of needle holder **110a**. In such a second position, extension arm **142a** is moved out of interfering or abutting engagement with pierceable closure **132** of collection tube **130** within internal opening **120a**. As such, collection tube **130** is permitted to engage with carriage **70**. Application of force on collection tube **130** such as by pushing collection tube **130** further within internal opening **120a** of needle holder **110a** causes engagement of pierceable closure **132** against surface **88** of carriage **70**. Such engagement results in axial displacement of carriage **70**, and therefore axial displacement of internal cannula **50** with respect to hub assembly **20** between the first retracted position and the second activated position, as discussed above. As such, lever **140a** provides a blocking mechanism for preventing axial displacement of internal cannula **50** with respect to hub assembly **20**, and therefore for preventing blunting of needle assembly **12**, until a desired time.

[0066] Movement of lever **140a** between the first blocking position and the second release position may be provided through hinge **146a**. Hinge **146a** is depicted in FIGS. 7-9 at first end **114a** of needle holder **110a**. Lever **140a** may be provided as a separate member which is attached to hollow body **112a** of needle holder **110a** at hinge **146a**. More desirably, lever **140a** is integrally formed with hollow body **112a** of needle holder **110a**. For instance, lever **140a** may be provided as a cutaway portion of hollow body **112a**, with lever **140a** and hollow body **112a** being interconnected through hinge **146a**.

[0067] Lever **140a** further includes tab **144a**, which is provided for moving lever **140a** between the first blocking position and the second release position. Tab **144a** may be provided at a position adjacent first end **114a** of needle holder **110a**, with tab **144a** extending from hollow body **112a**, to a position adjacent the connection between needle holder **110a** and needle assembly **12**. In this manner, tab **144a** can be activated by applying pressure in a direction of arrow **102a**, such that tab **144a** deflects, thereby activating and moving lever **140a** between the first blocking position and the second release position, as shown in FIG. 9.

[0068] In a further embodiment shown in FIGS. 10 and 11, needle holder **110b** includes hollow body **112b** including first end **114b** having opening **116b** and second end **118b** having flange **122b**, and internal opening **120b** extending therethrough. Needle holder **110b** includes a pair of levers **150b** and **160b** in a similar manner as lever **140a** shown in the embodiment of FIGS. 7-9. In particular, first lever **150b** and second lever **160b** include tabs **154b** and **164b**, extension arms **152b** and **162b** and surfaces **158b** and **168b**, respectively. First lever arm **150b** and second lever arm **160b** extend along opposing sides of hollow body **112b** of needle holder **110b** within channels **124b** and **126b** respectively. In such an embodiment, first lever **150b** and second lever **160b** may extend away from hollow body **112b** in a flaring manner, with tabs **158b** and **168b** positioned adjacent second end **118b** of needle holder **110b**.

[0069] Movement of first lever **150b** and second lever **160b** between the first blocking position and the second release position can be accomplished through activation of tabs **154b** and **164b** by applying pressure in a direction of arrow **170b** and **172b**. As such, tab **154b** and **164b** deflect, thereby causing extension arms **152b** and **162b** to deflect outward in a direction of arrows **174b** and **176b**, respectively. Such deflection moves first and second levers **150b** and **160b** between the first blocking position and the second release position, thereby releasing collection tube **130** from the blocked position. As such, collection tube **130** can be forwarded in a direction of arrow **178b**, thereby

activating needle assembly **12** through engagement between pierceable closure **132** and carriage **70**, as described above. In an alternative embodiment, needle holder **110b** may have lever **150b** and may not have lever **160b**.

[0070] In a further embodiment, the needle holder may be provided with a mechanism for activating the blunting mechanism of the needle assembly, such as by axially displacing the internal cannula within the internal lumen between the first retracted position and the second activated position. For example, the needle holder may include a rotational mechanism including an internal cam assembly for blunting of an intravenous puncture tip of a needle assembly. Desirably, such a mechanism is adapted for engagement with the carriage for axially displacing the internal cannula.

[0071] Examples of particularly desirable embodiments of such needle holders are depicted in FIGS. 12-21. In the embodiment depicted in FIGS. 12-17, a needle holder **110c** includes an outer body **180c** for attachment to a needle assembly, such as needle assembly **12** as described hereinabove. Outer body **180c** includes a first end **182c** adapted for attachment to needle assembly **12**, and an open-ended second end **184c**, with an interior space **186c** within outer body **180c** extending from first end **182c** to second end **184c**. Needle holder **110c** further includes a mechanism extending within interior space **186c** of outer body **180c** for engagement with carriage **70** of needle assembly **12**, for causing said axial displacement of internal cannula **50** between the first retracted position and the second activated position. As shown in FIGS. 12-14, such a mechanism may be in the form of an inner body **190c** which is concentric with and extends within interior space **186c** of outer body **180c** through second end **184c**.

[0072] Inner body **190c** is in slidable engagement within outer body **180c**. Inner body **190c** includes first end **192c** which extends within interior space **186c** of outer body **180c**, and second end **194c** which protrudes from second end **184c** of outer body **180c**. Inner body **190c** further includes an interior space **196c**, which is adapted for

accommodating a blood collection tube therein for sampling procedures, as described hereinabove.

[0073] Activation of the blunting feature of needle assembly **12** can be accomplished in such an embodiment by sliding inner body **190c** within outer body **180c** in a direction of arrow **200**. Such sliding forces first end **192c** of inner body **190c** to engage carriage **70** at rear face **88**, thereby forcing carriage **70** to move in the direction of arrow **200**, which activates the blunting feature of needle assembly **12**, as described in detail above. Sliding of inner body **190c** within outer body **180c** can be easily accomplished by the user with slight pressure exerted on second end **194c** of inner body **190c** in the direction of arrow **200**.

[0074] It is noted that inner body **190c** may alternatively be in rotational engagement within outer body **180c**, such as through interrelating and mating threads on an outer surface of inner body **190c** and an inner surface of outer body **180c**. As such, activation of the blunting feature can be achieved by rotating inner body **190c** within outer body **180c** such as by screwing the mating threads, thereby screwing inner body **190c** within outer body **180c** in a direction of arrow **200**.

[0075] As shown clearly in FIGS. 12-14, outer body **180c** may further be provided with an opening **188c** extending through the wall thereof. In addition, inner body **190c** may be provided with a protrusion such as finger **198c**, which is adapted for engagement within opening **188c** of outer body **180c** when inner body **190c** is slidably moved in the direction of arrow **200**. Such engagement between finger **198c** and opening **188c** provides holder **100c** with a locking feature, wherein inner body **190c** is prevented from slidably moving within outer body **180c** in a reverse direction once moved in the direction of arrow **200**. As such, inner body **190c** is locked in place within outer body **180c**, which in turn locks carriage **70** of needle assembly **12** in place, thereby effectively locking needle assembly **12** in the second extended position for blunting.

[0076] Moreover, activation of the blunting feature of needle assembly 12 can be accomplished by sliding inner body 190c within outer body 180c by way of cooperating features of inner body 190c and outer body 180c. For example, outer body 180c may include a channel 202c extending axially along an outer surface thereof, as depicted in FIGS. 15-17. Channel 202c desirably includes an expanded opening 204c at first end 182c of outer body 180c. First lip 206c extends at a first position within channel 202c, while second lip 208c extends at the juncture of channel 202c and opening 204c. Inner body 190c includes tab 210c extending from an outer surface thereof. For example, inner body 190c may include a cutaway portion 212c, which flexes upon application of force. Tab 210c is integrally formed with cutaway portion 212c, with shoulder 214c extending therebetween.

[0077] Channel 202c accommodates tab 210c in slidable engagement therein. In a first position such as during sampling, shoulder 214c is in interference engagement with first lip 206c. When activation of the blunting feature of needle assembly 12 is desired, tab 210c is depressed, which flexes cutaway portion 212c within interior space 196c of inner body 190c, thereby releasing shoulder 214c from interference engagement with first lip 206c. Forward slidable movement of inner body 190c within outer body 180c can then be accomplished through movement of tab 210c. Once tab 210c is moved to a position adjacent opening 204c, tab 210c flexes upward such that tab 210c extends outward through opening 204c. Shoulder 214c is then in interference engagement with second lip 208c, thereby providing a locking feature, wherein inner body 190c is prevented from slidably moving within outer body 180c in a reverse direction.

[0078] Yet a further needle holder embodiment is depicted in FIGS. 18-21. Such a needle holder 110d includes a tubular hollow body in a similar manner as tubular hollow body 112 which is described above with respect to FIGS. 5 and 6, with a slot 220d extending therethrough. Needle holder 110d further includes a mechanism 222d which extends through slot 220d. Mechanism 222d is adapted for engagement with carriage 70

of a needle assembly, for axially displacing the internal cannula of the needle assembly as described above.

[0079] Mechanism **222d** includes a tab **224d** adapted for finger activation by a user. Mechanism **222d** further includes extension **226d** which extends from tab **224d** through slot **220d**. Extension **226d** includes surface **228d** for engagement with carriage **70** of a needle assembly. Activation of the blunting feature of needle assembly **12** can be accomplished in such an embodiment by sliding mechanism **222d** in a direction of arrow **300**. Such sliding forces surface **228d** of mechanism **222d** to engage carriage **70** at rear face **88**, thereby forcing carriage **70** to move in the direction of arrow **300**, which activates the blunting feature of needle assembly **12**, as described in detail above. Sliding of mechanism **222d** can be easily accomplished by the user with slight pressure exerted on tab **224d** in the direction of arrow **300**.

[0080] As shown clearly in FIG. 21, holder **110d** may be provided with a locking feature, wherein mechanism **222d** is prevented from slidably moving in a reverse direction once moved in the direction of arrow **300**. This may be accomplished by providing opening **230d**, and providing mechanism **222d** with a finger **232d** on an underside thereof. Such finger **232d** is provided for interference engagement with the edge of opening **230d**, thereby providing a locking feature, wherein mechanism **222d** is prevented from slidably moving in a reverse direction.

[0081] The needle assembly of the present invention may be comprised of moldable parts which can be mass produced from a variety of materials including, for example, polyethylene, polyvinyl chloride, polystyrene or the like. Materials can be selected which will provide the proper support for the structure of the invention in its use, and which will also provide a degree of resiliency for the purpose or providing the cooperative relative movement.

[0082] While the needle assembly of the present invention has been described in terms of one embodiment for use in connection with a blood collection system, it is further contemplated that the needle assembly could be used with other medical procedures, such as in conjunction with a conventional intravenous infusion set, as which are well known in the art for use with conventional needle assemblies.

[0083] The needle assembly of the present invention also could be used with needle holders that have configurations different from the needle holder illustrated in the accompanying figures.

WHAT IS CLAIMED:

1. A dual blunting needle assembly comprising:

a hub assembly having a first external cannula with an intravenous puncture tip extending from a first end, a second external cannula with an external blunt tip extending from a second opposing end, and an internal lumen extending through said hub assembly from said intravenous puncture tip to said external blunt tip; and

an internal cannula extending concentrically within said internal lumen of said hub assembly, said internal cannula having an internal blunt tip at a first end, a non-patient puncture tip at a second end, and an internal lumen extending from said internal blunt tip to said non-patient puncture tip, said internal cannula adapted for axial movement within said internal lumen of said hub assembly between a first position in which said intravenous puncture tip and said non-patient puncture tip extend beyond said internal blunt tip and said external blunt tip, respectively, and a second position in which said internal blunt tip and said external blunt tip extend beyond said intravenous puncture tip and said non-patient puncture tip, respectively.
2. A needle assembly as in claim 1, wherein said first external cannula is a separate member which is connected to said hub assembly.
3. A needle assembly as in claim 2, wherein said first external cannula is connected to said hub assembly through a ferrule.
4. A needle assembly as in claim 3, wherein said ferrule fits concentrically within said first end of said hub assembly.

5. A needle assembly as in claim 1, further comprising a carriage concentric with said internal cannula, said carriage provided for slidable engagement with said hub assembly.

6. A needle assembly as in claim 5, wherein said slidable engagement of said carriage with said hub assembly provides for said axial movement of said internal cannula within said internal lumen of said hub assembly.

7. A needle assembly as in claim 6, wherein said carriage is slidably engagable with said hub assembly between said first position and said second position.

8. A needle assembly as in claim 1, further comprising a sleeve extending about said non-patient puncture tip.

9. A needle assembly as in claim 1, further comprising means for attaching said needle assembly to a holder capable of holding blood collection tubes.

10. A needle assembly as in claim 1, wherein said means comprises threads about an external surface of said hub assembly.

11. A needle assembly as in claim 1, further comprising means for attaching a needle cover to said needle assembly.

12. A needle assembly as in claim 1, further comprising an indicator for indicating movement of said internal cannula between said first position and said second position.

13. A needle assembly as in claim 1, further comprising a locking mechanism for preventing axial displacement of said internal cannula from said second position to said first position.

14. A dual blunting safety assembly comprising:

- a) a needle holder; and
- b) a needle assembly in engagement with said needle holder, said needle assembly comprising:
 - i) a hub assembly having a first external cannula with an intravenous puncture tip extending from a first end, a second external cannula with an external blunt tip extending from a second opposing end, and an internal lumen extending through said hub assembly from said intravenous puncture tip to said external blunt tip, and
 - ii) an internal cannula extending concentrically within said internal lumen of said hub assembly, said internal cannula having an internal blunt tip at a first end, a non-patient puncture tip at a second end, and an internal lumen extending from said internal blunt tip to said non-patient puncture tip, said internal cannula adapted for axial displacement within said internal lumen of said hub assembly between a first retracted position in which said blunt tip of said internal cannula is positioned within said internal lumen of said first external cannula and said non-patient puncture tip extends beyond said blunt tip of said second external cannula and a second activated position in which said blunt tip of said internal cannula extends beyond said intravenous puncture tip of said first external cannula and said non-patient puncture tip is positioned within said second external cannula.

15. A safety assembly as in claim 14, wherein said internal cannula is axially displaceable between said first retracted position and said second activated position in a single axial direction.

16. A safety assembly as in claim 15, further comprising a locking mechanism for preventing axial displacement of said internal cannula from said second activated position to said first retracted position.

17. A safety assembly as in claim 14, further comprising a carriage concentric with said internal cannula, said carriage provided for slidable engagement with said hub assembly.

18. A safety assembly as in claim 17, wherein said needle holder is attached to said needle assembly and comprises an outer body having an internal opening therein, said needle holder adapted for accommodating a blood collection tube within said internal opening for engagement with said carriage of said needle assembly, said needle holder including a lever which is movable between a first blocking position in which said blood collection tube is blocked from engagement with said carriage to prevent axial displacement of said internal cannula between said first retracted position and said second activated position, and a second release position in which said blood collection tube is capable of engagement with said carriage to permit axial displacement of said internal cannula between said first retracted position and said second activated position.

19. A safety assembly as in claim 17, wherein said needle holder includes a mechanism for axially displacing said internal cannula within said internal lumen between said first retracted position and said second activated position.

20. A safety assembly as in claim 19, wherein said mechanism of said needle holder is adapted for engagement with said carriage for axially displacing said internal cannula within said internal lumen of said hub assembly between said first retracted position and said second activated position.

21. A safety assembly as in claim 19, wherein said needle holder comprises an outer body for attachment to said needle assembly, and a mechanism extending within said outer body for engagement with said internal cannula for causing said axial displacement of said internal cannula between said first retracted position and said second activated position.

22. A safety assembly as in claim 21, wherein said mechanism comprises an inner holder concentric with said outer body.

23. A safety assembly as in claim 21, wherein said outer body includes a channel extending axially along said outer body, and said mechanism includes an arm which projects through said channel of said outer body and is axially slidable within said channel for axial displacement of said mechanism with respect to said outer body, said axial displacement of said mechanism causing said axial displacement of said internal cannula within said internal lumen between said first retracted position to said second activated position.

24. A safety assembly as in claim 23, wherein said arm includes a locking mechanism for preventing axial displacement of said internal cannula from said second activated position to said first retracted position.

25. A safety assembly as in claim 24, further comprising a tab attached to said arm, said tab adapted for finger activation by a user for causing axial displacement of said mechanism within said outer body.

26. A needle assembly as in claim 14, further comprising an indicator for indicating movement of said internal cannula between said first position and said second position.

27. A safety assembly as in claim 14, wherein said needle assembly further comprises attachment means for attaching said needle assembly to said needle holder.

28. A safety assembly as in claim 27, wherein said attachment means comprises threads.

29. A safety assembly as in claim 14, further comprising means for attaching a needle cover to said needle assembly.

30. A safety assembly as in claim 14, further comprising a sleeve extending about said non-patient puncture tip.

31. A dual blunting safety assembly comprising:
- a) a needle assembly comprising:
 - i) a hub assembly having opposed first and second ends and an internal lumen extending therethrough;
 - ii) a first external cannula extending from a first end of said hub assembly, said first external cannula having an intravenous puncture tip and an internal lumen in fluid communication with said internal lumen of said hub assembly;
 - iii) a second external cannula extending from a second end of said hub assembly, said second external cannula having a blunt tip and an internal lumen in fluid communication with said internal lumen of said hub assembly; and
 - iv) an internal cannula disposed concentrically within said hub assembly, said internal cannula having a blunt tip at a first end adjacent said intravenous puncture tip of said first external cannula, a non-patient puncture tip at a second end adjacent said blunt tip of said second external cannula, and an internal lumen extending from said blunt tip to said non-patient puncture tip; and
 - b) a needle holder having a first end for receiving said non-patient puncture tip of said internal cannula and said blunt tip of said second external cannula, said needle holder including a mechanism for axially displacing said internal cannula within said internal lumens of said hub assembly and said first and second external cannulas from a first retracted position in which said blunt tip of said internal cannula is positioned within said internal lumen of said first external cannula and said non-patient puncture tip extends beyond said blunt tip of said second external cannula and a second activated position in which said blunt tip of said internal cannula extends beyond said

intravenous puncture tip of said first external cannula and said non-patient puncture tip is positioned within said second external cannula.

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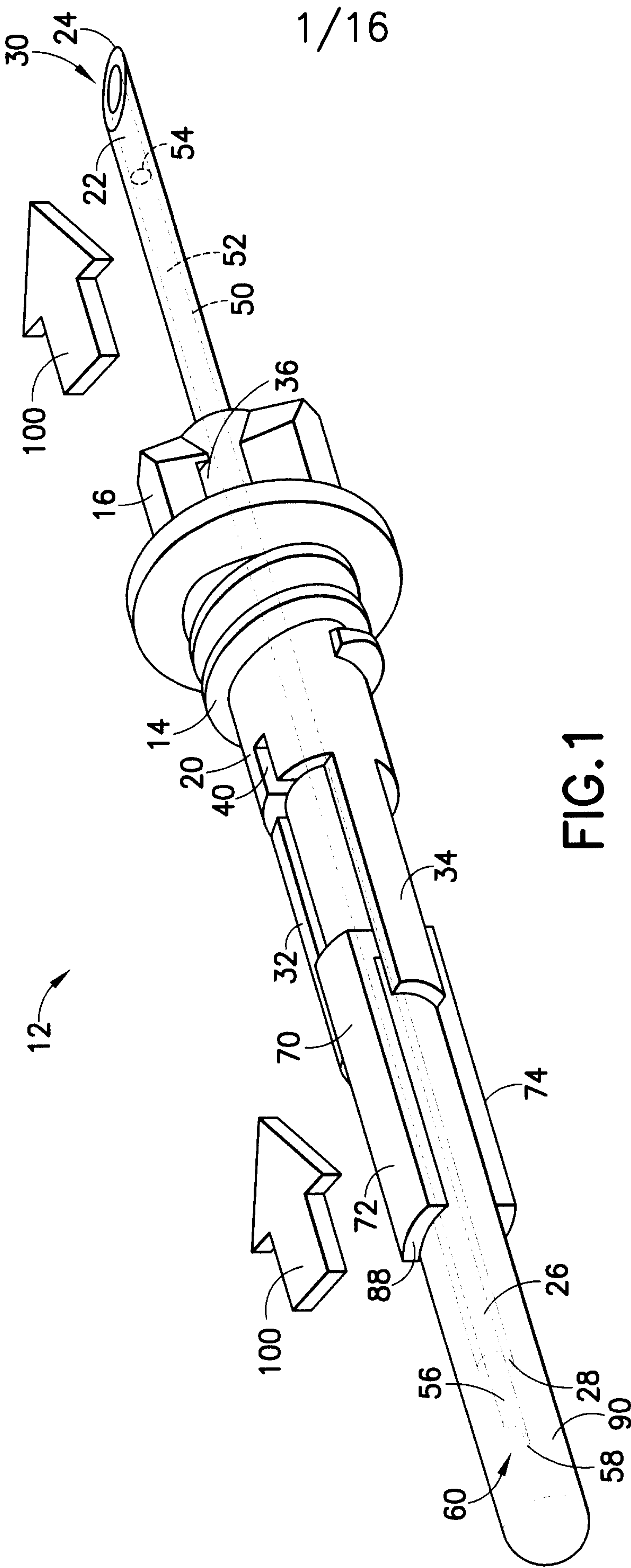


FIG. 1

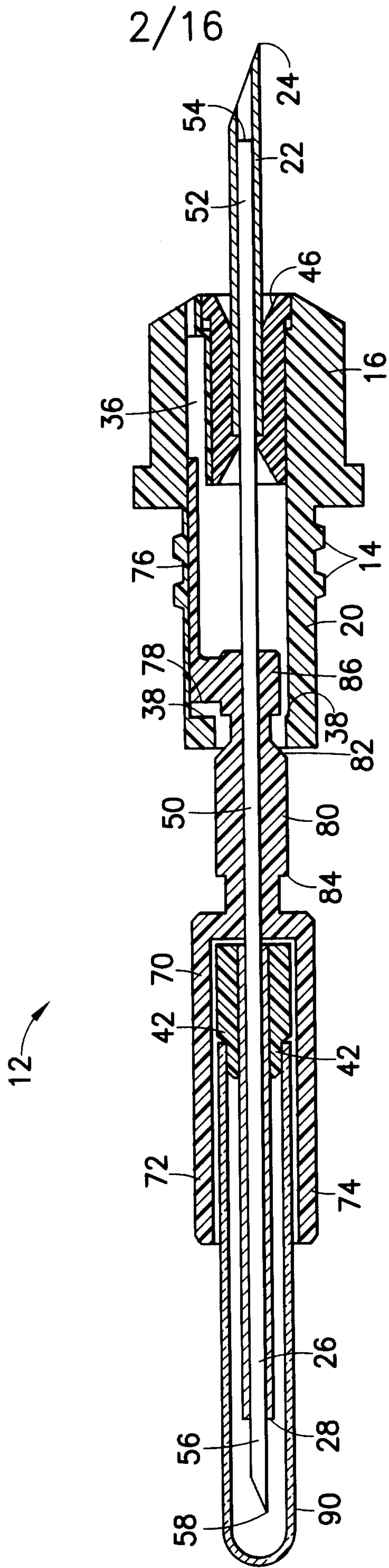
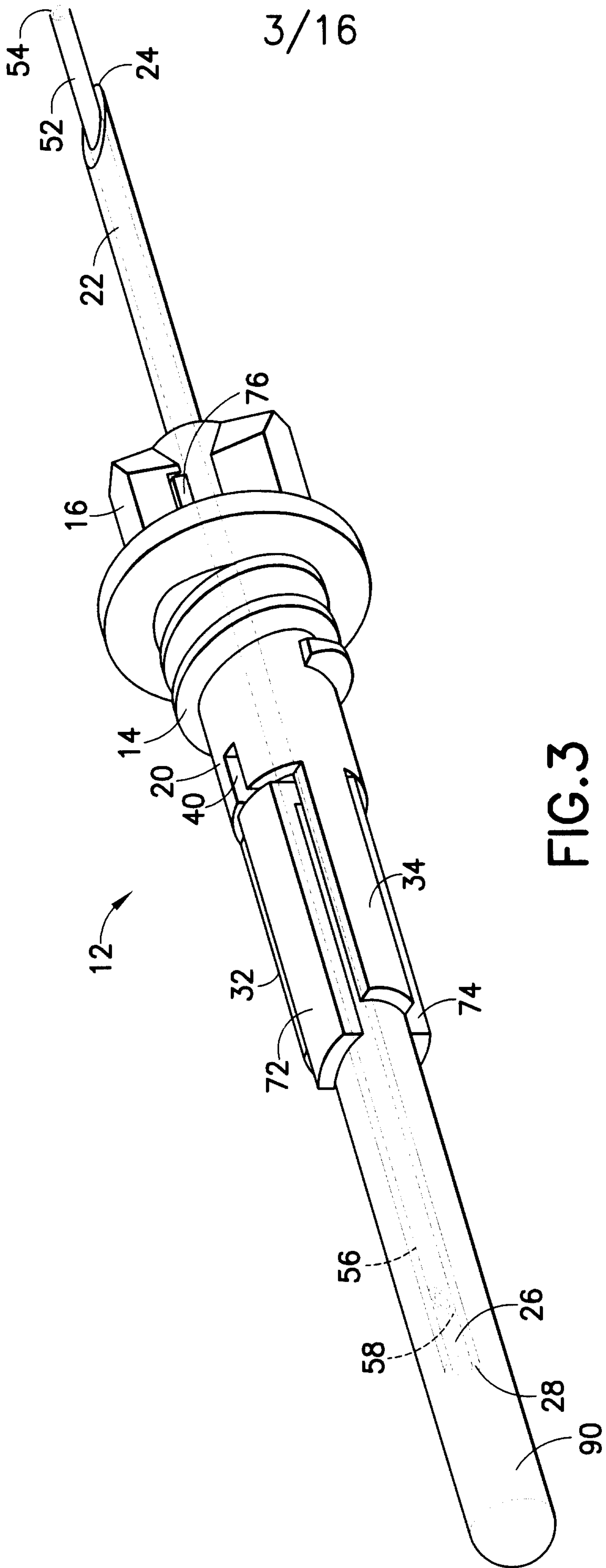


FIG.2



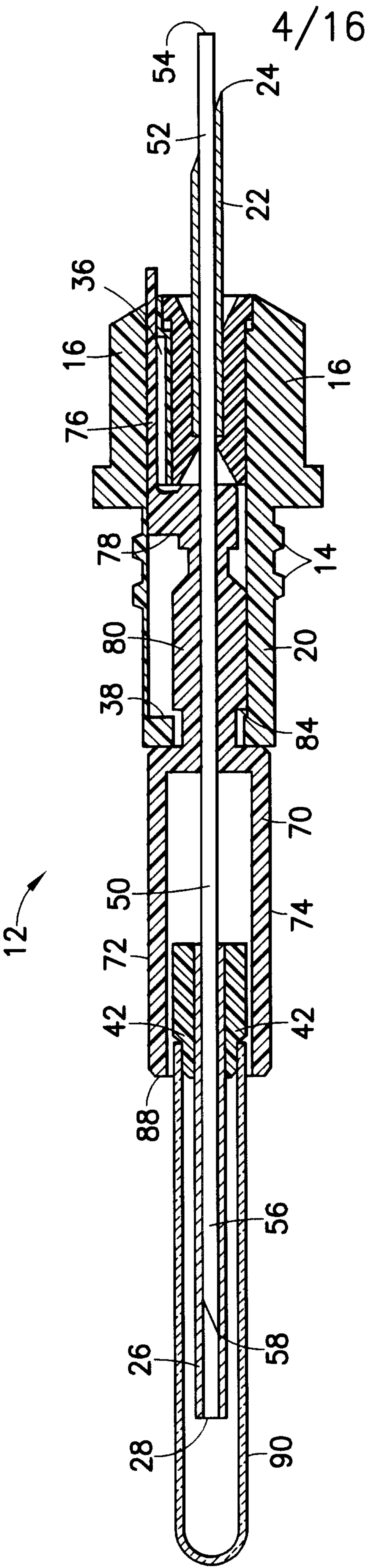


FIG.4

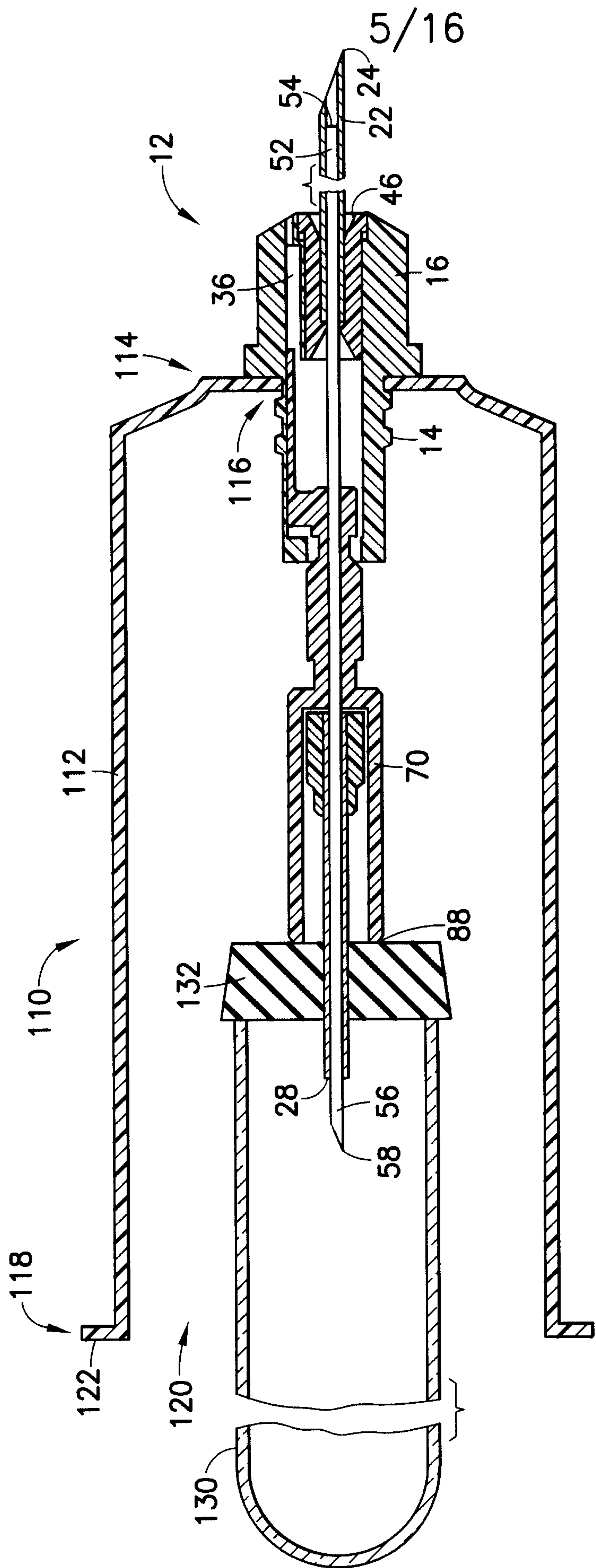


FIG.5

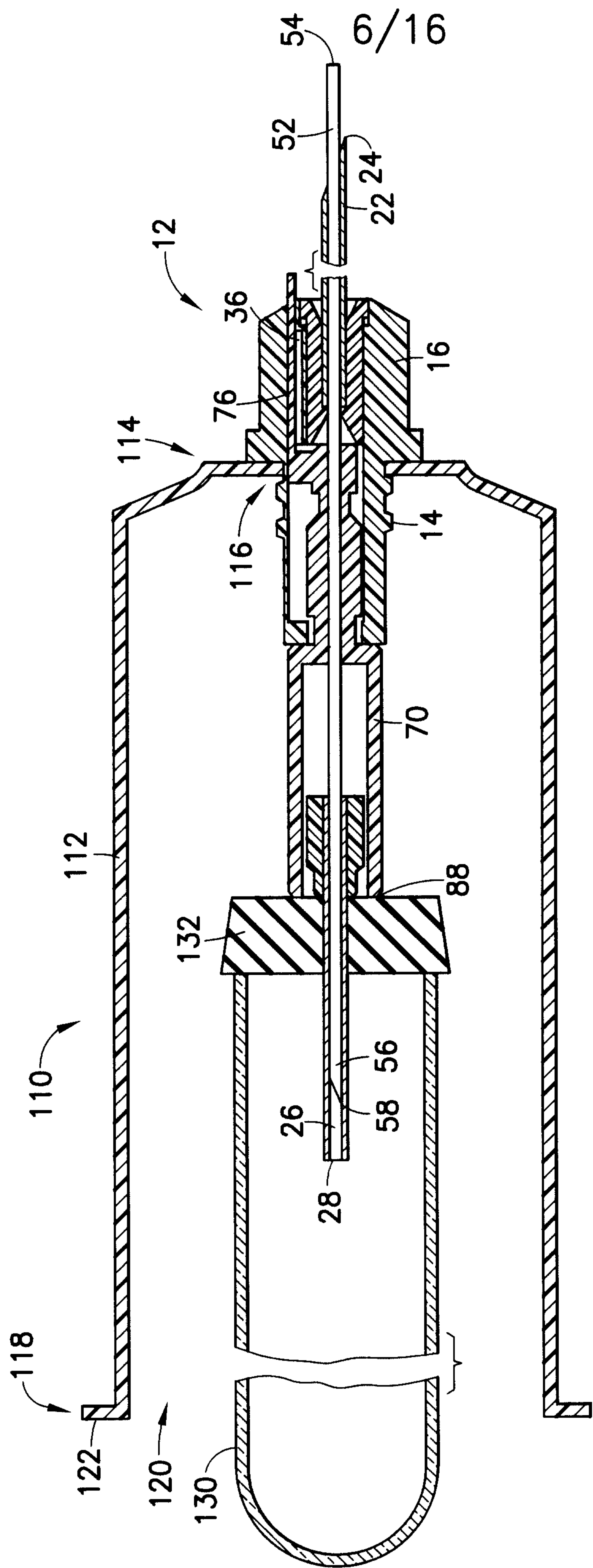


FIG.6

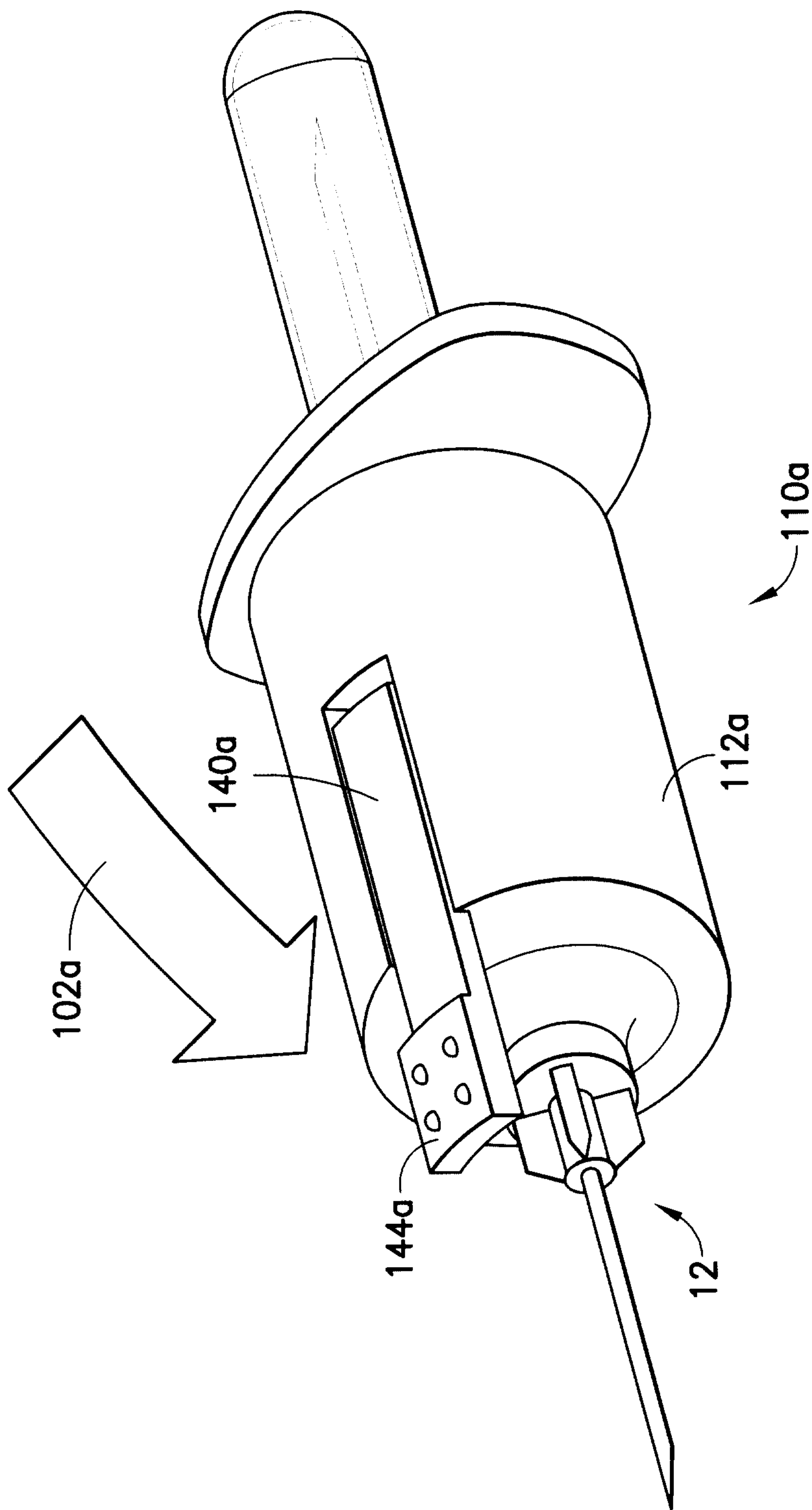


FIG. 7

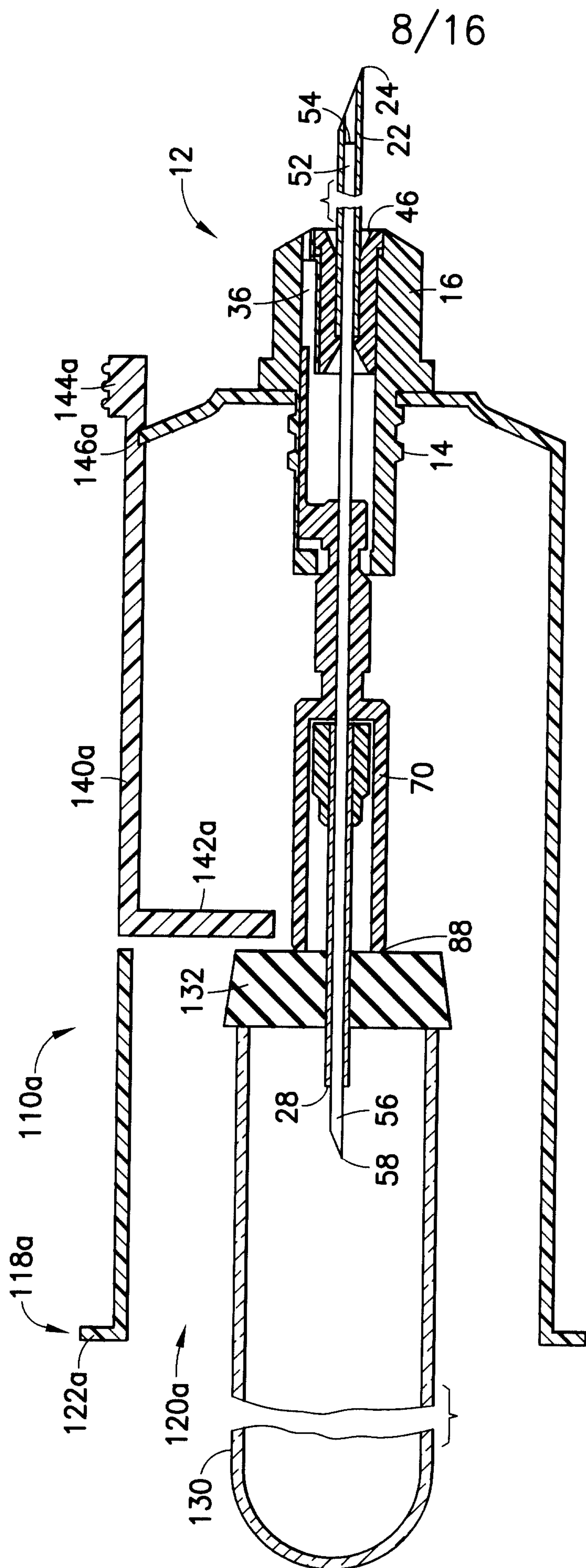


FIG. 8.

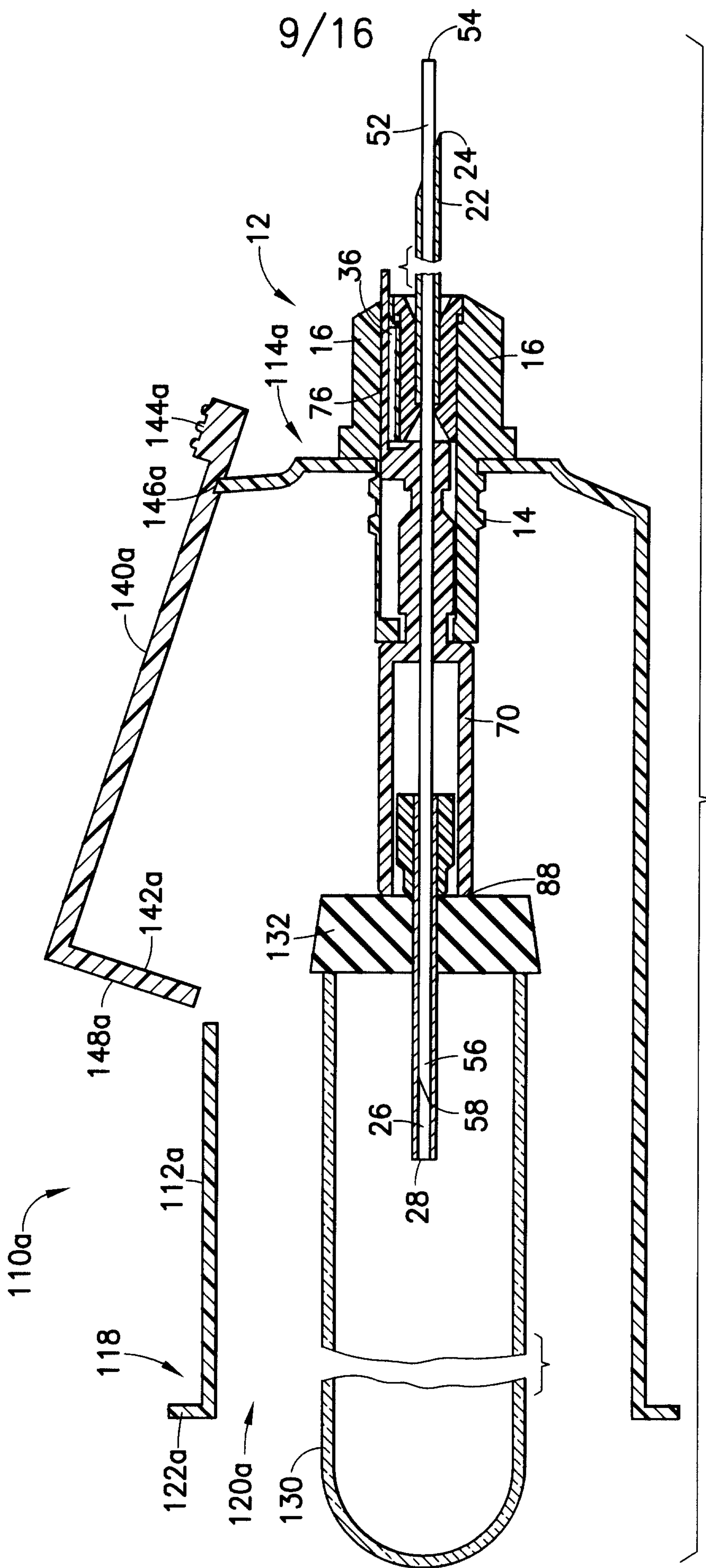


FIG. 9

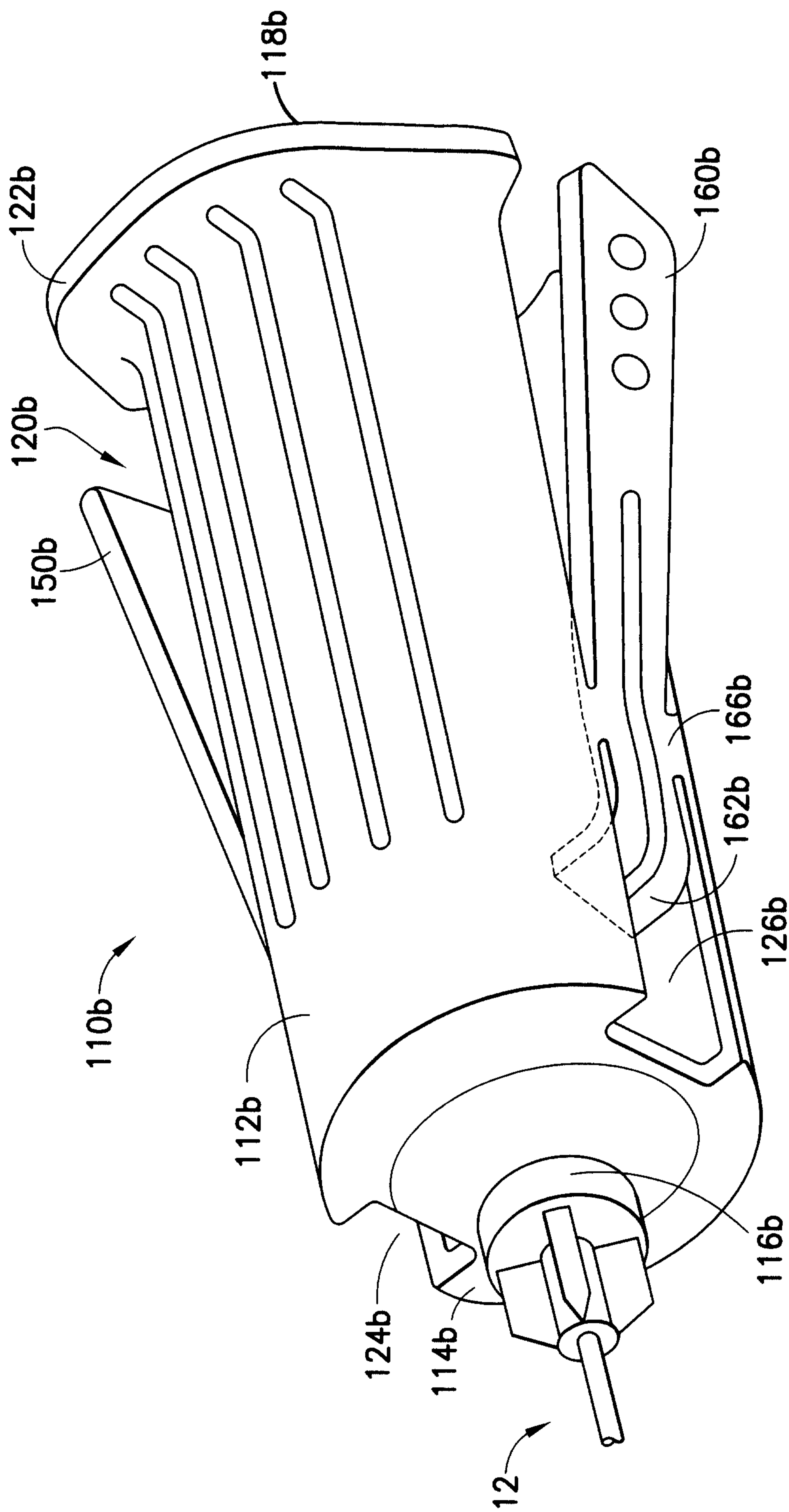


FIG.10

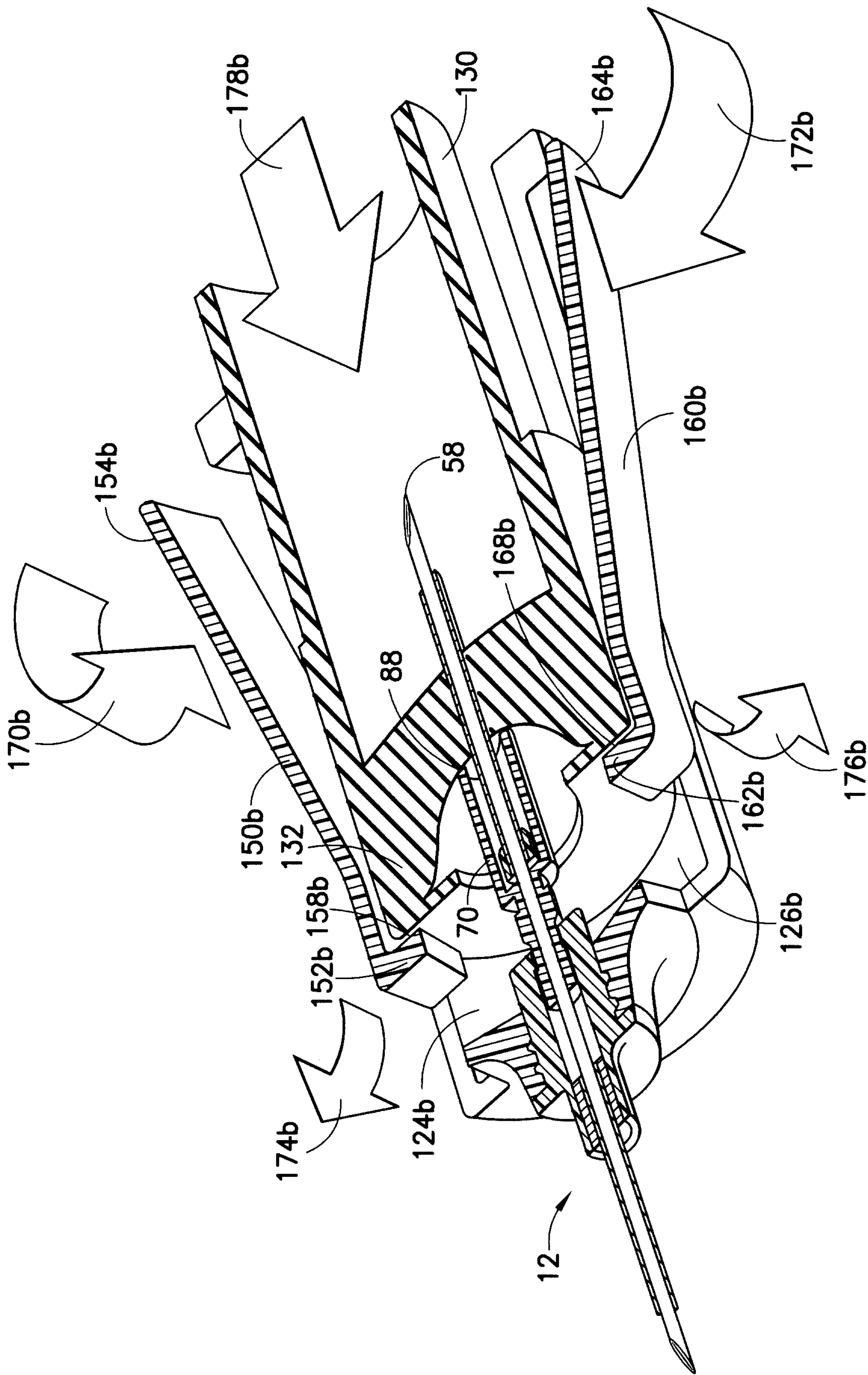


FIG. 11

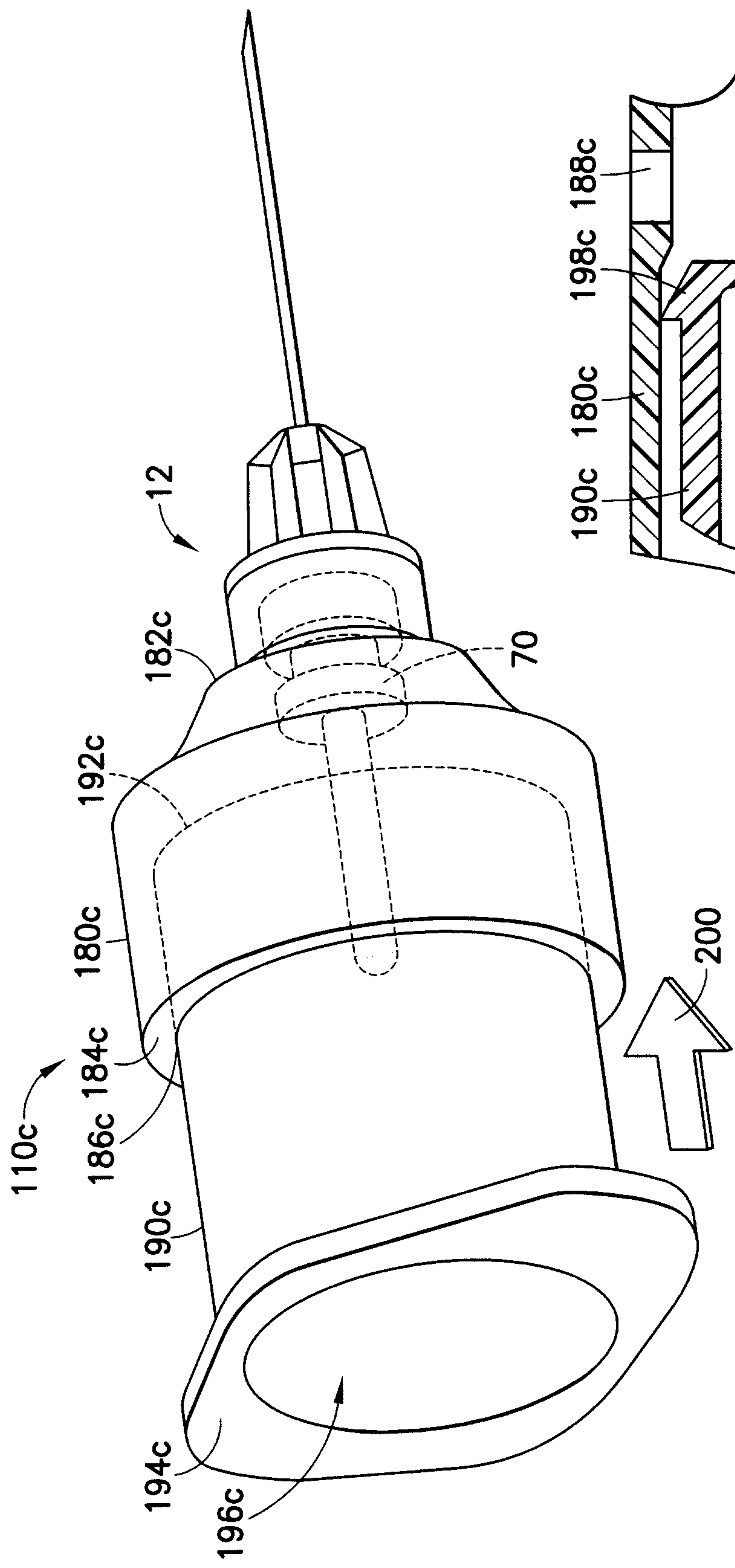


FIG. 12

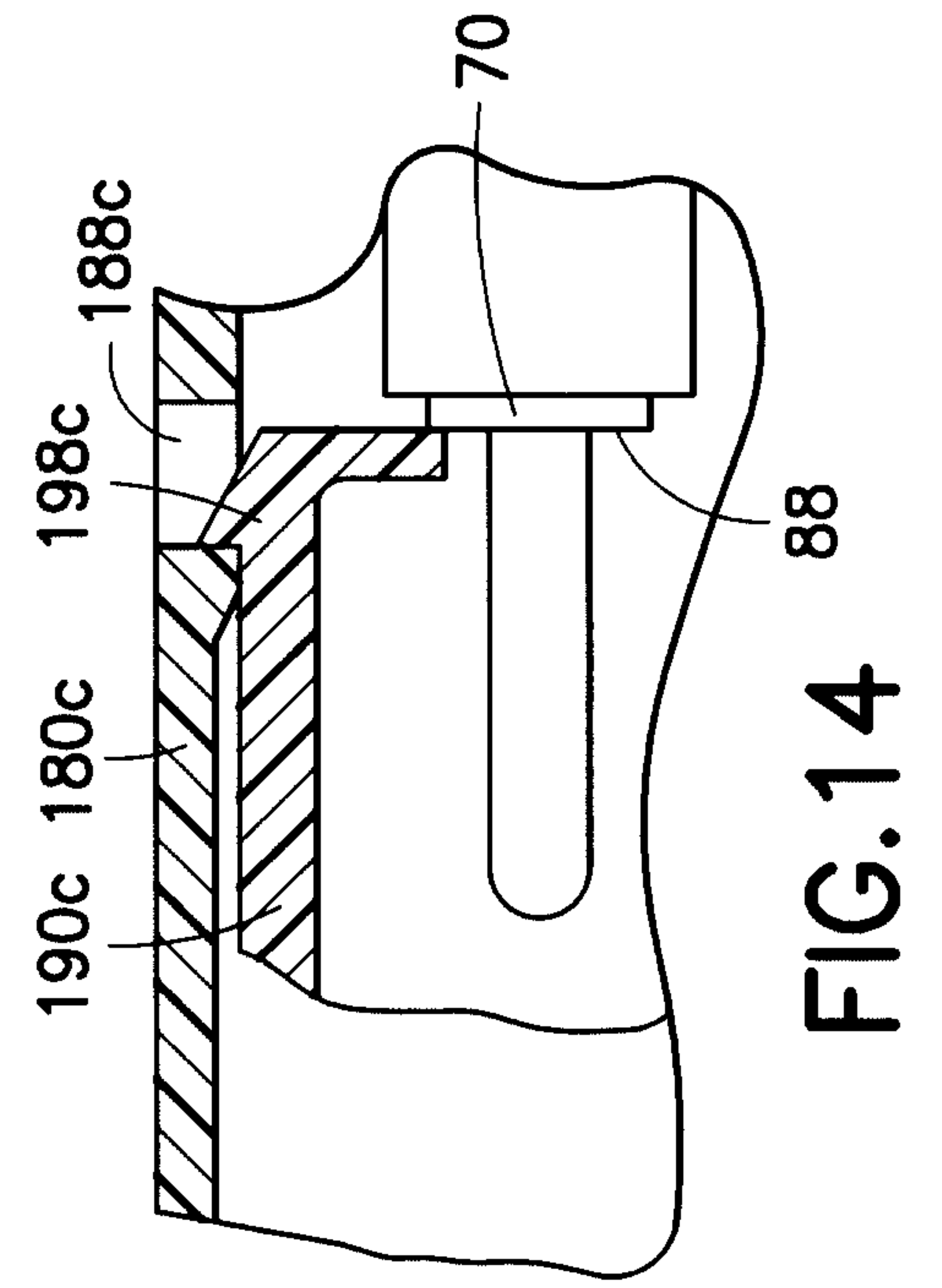


FIG. 14

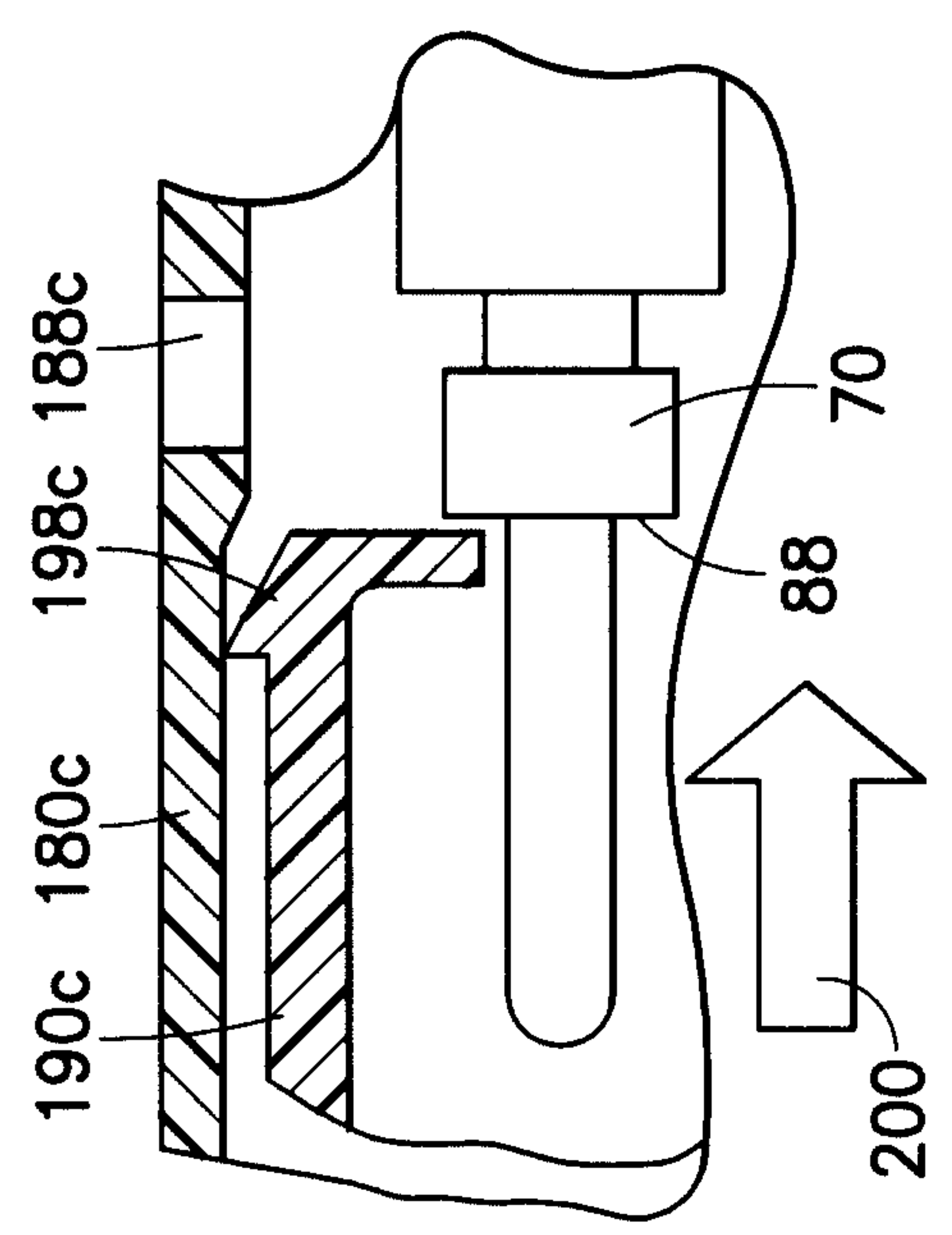


FIG. 13

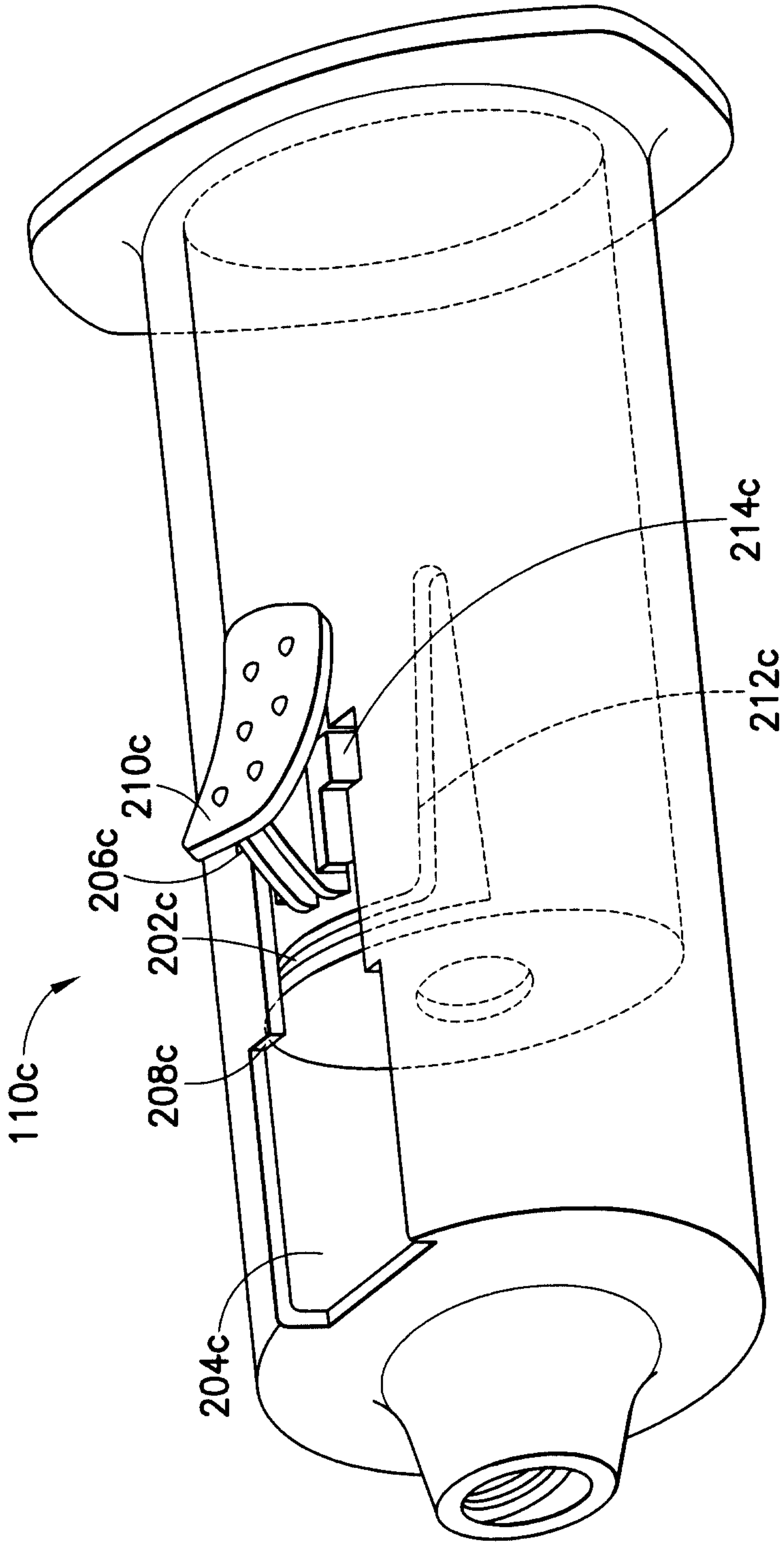


FIG.15

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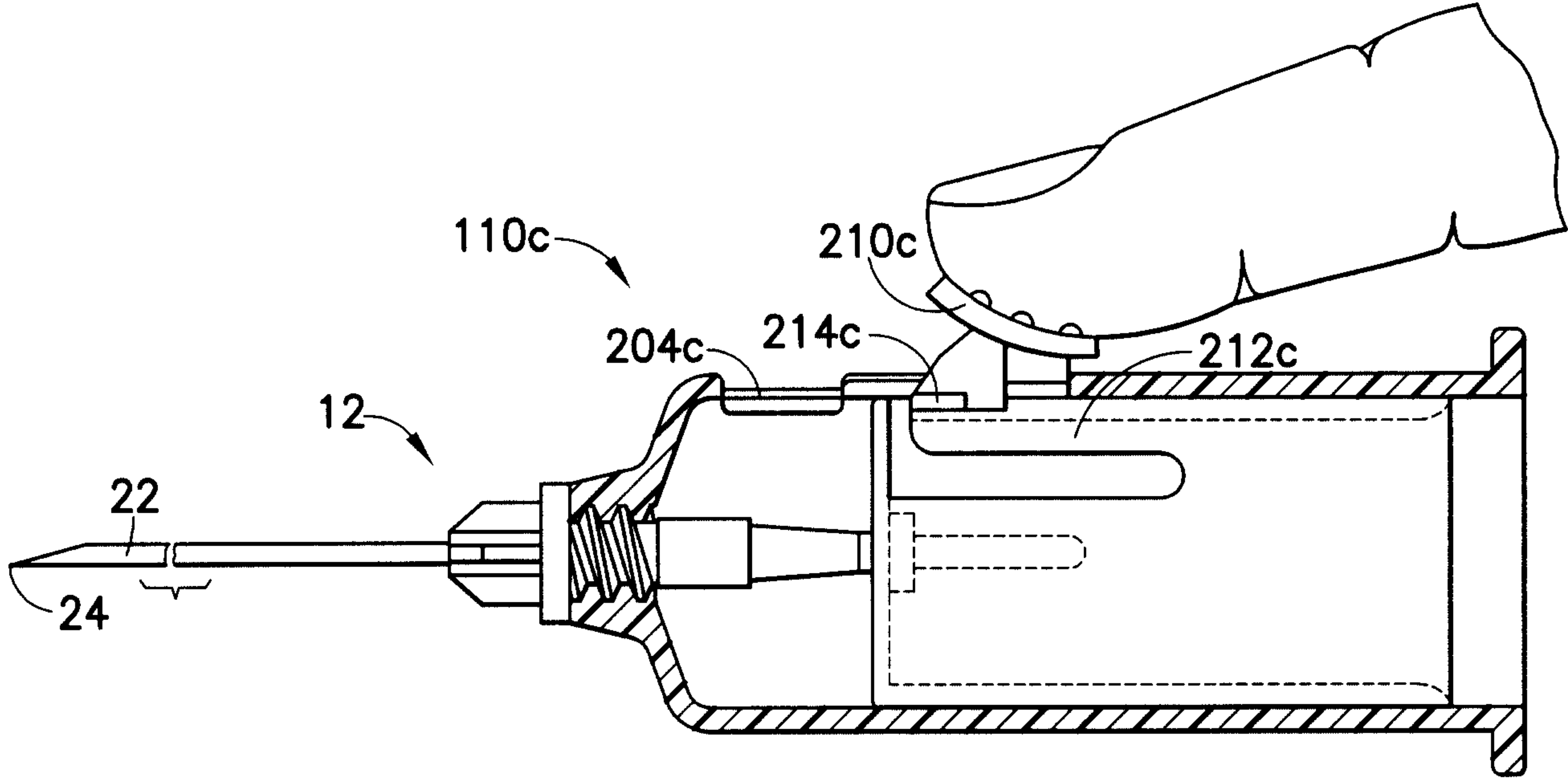


FIG.16

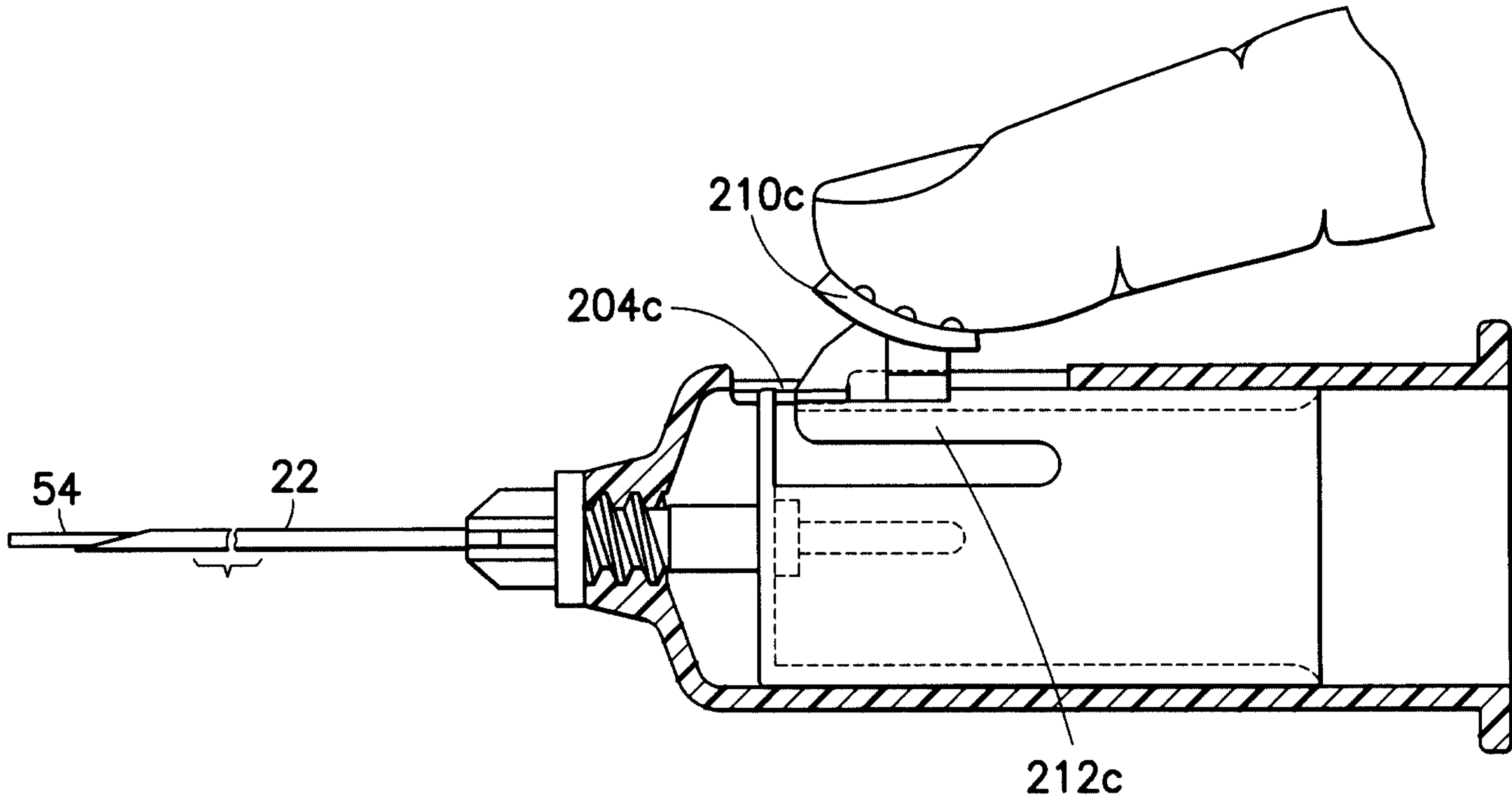


FIG.17

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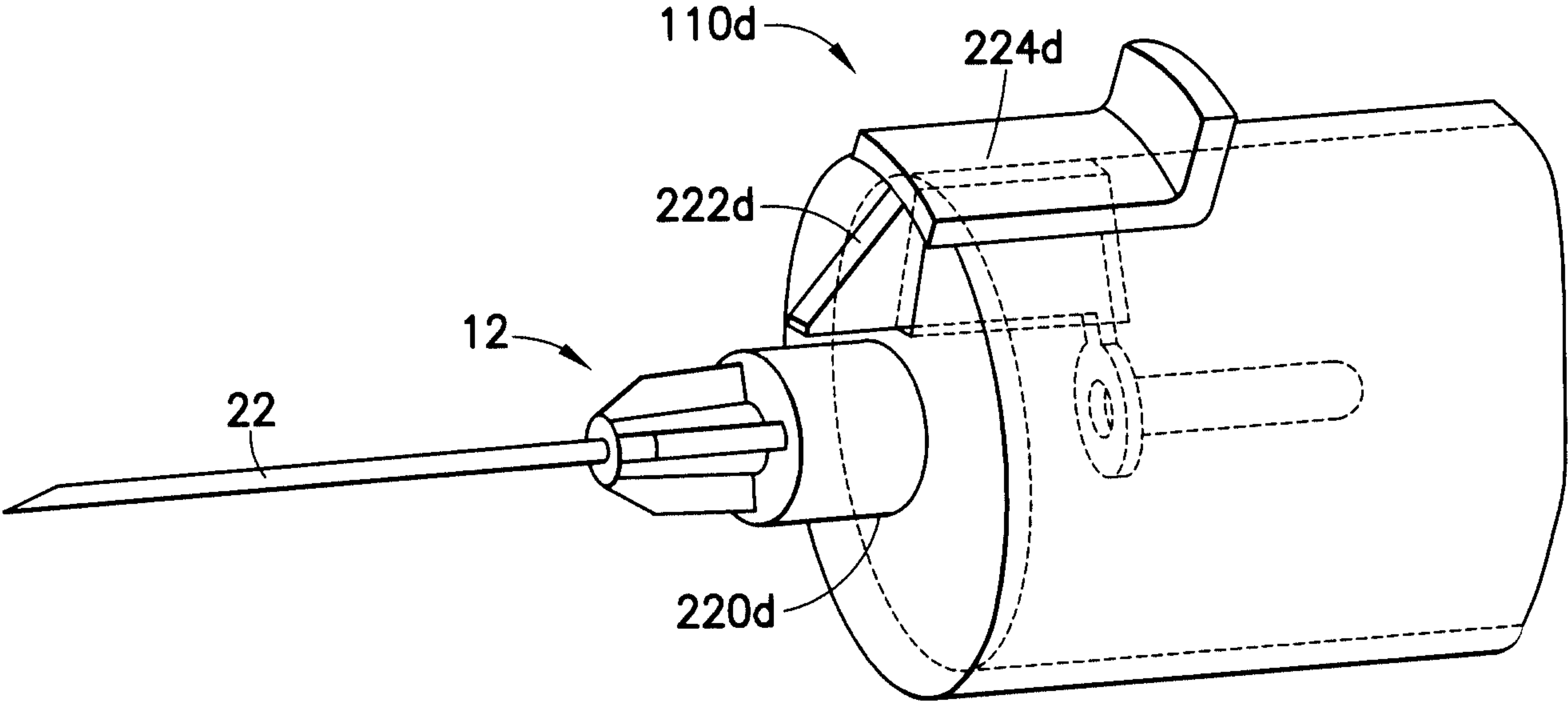


FIG.18

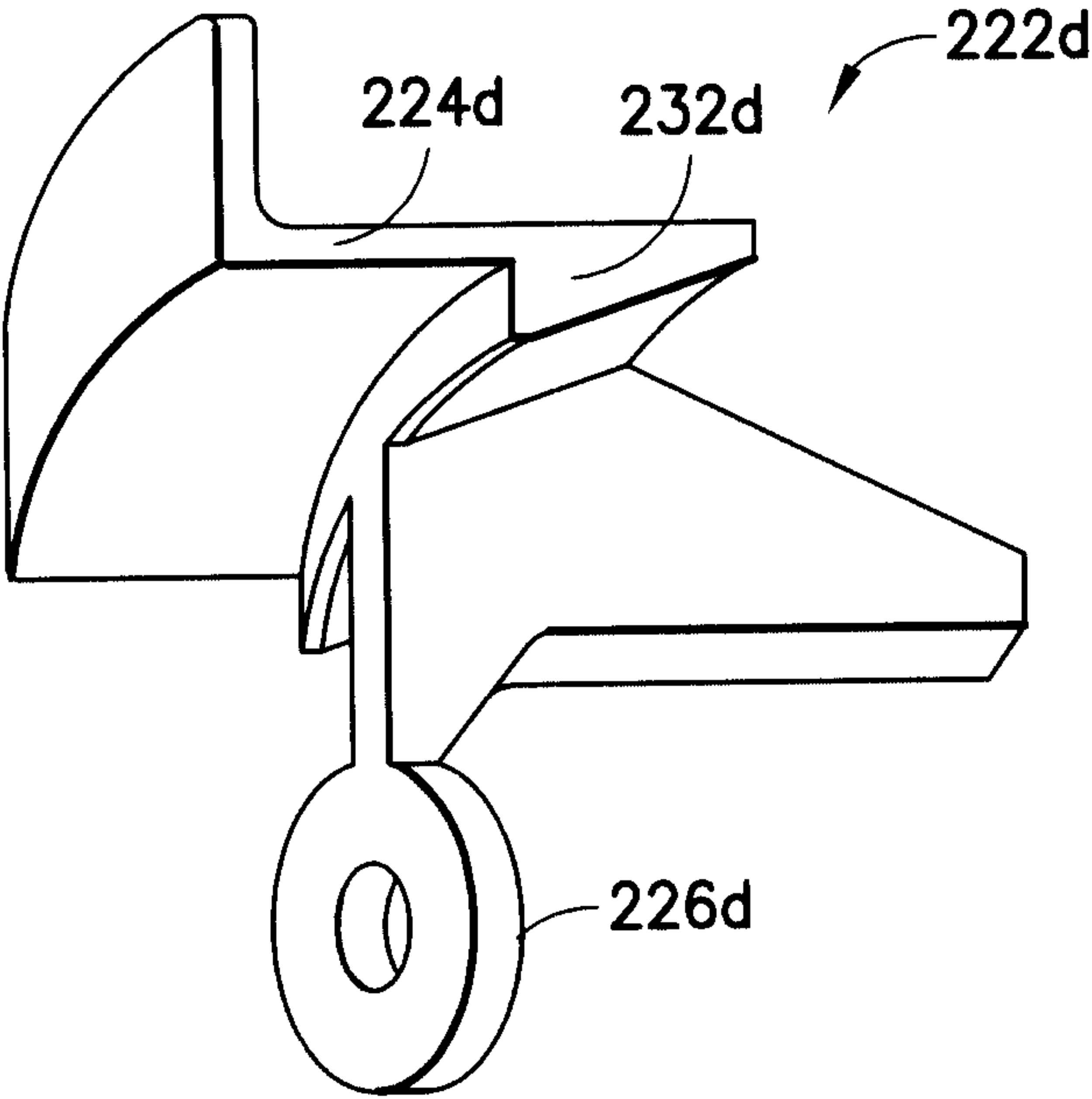


FIG.19

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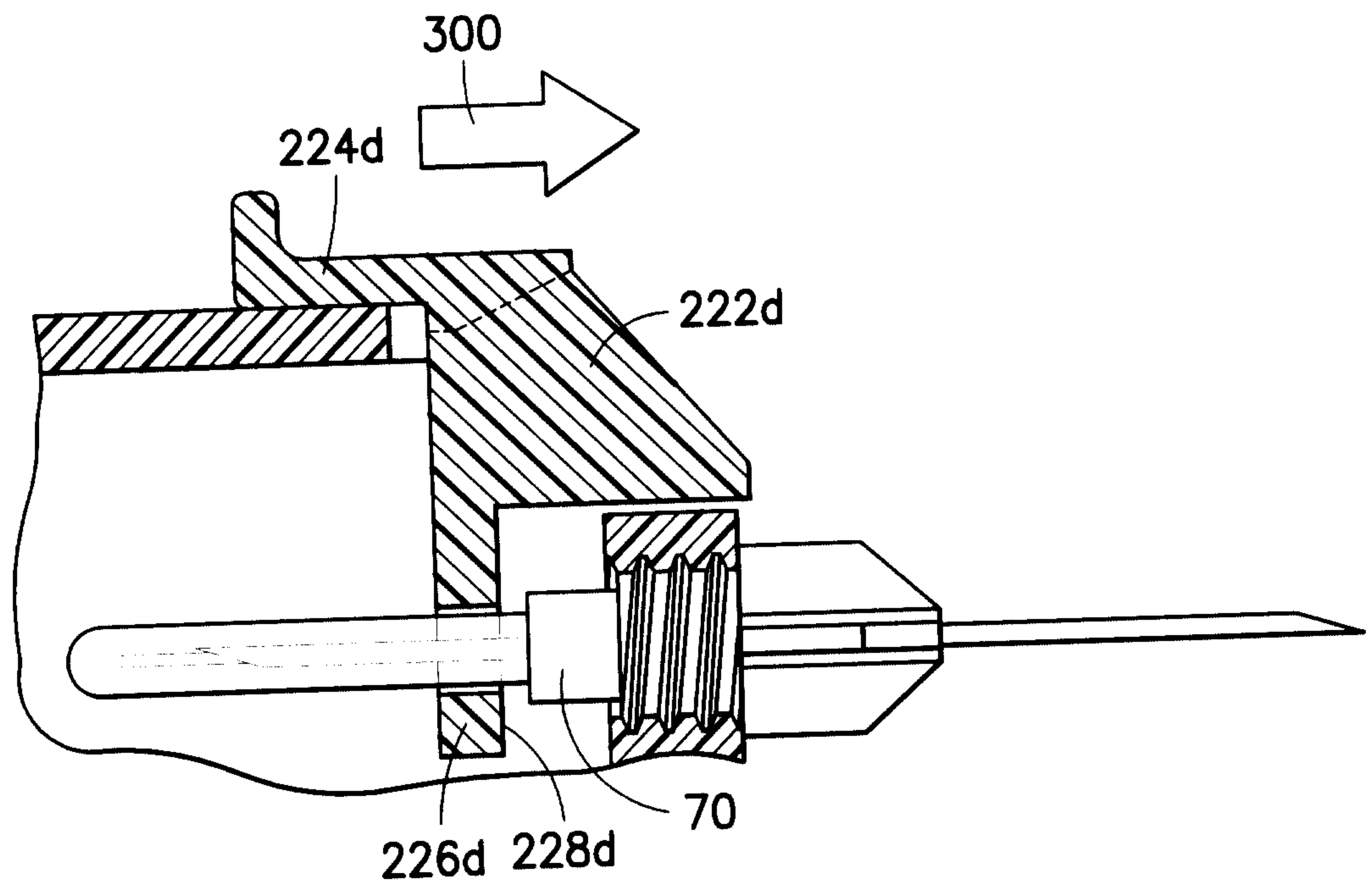


FIG. 20

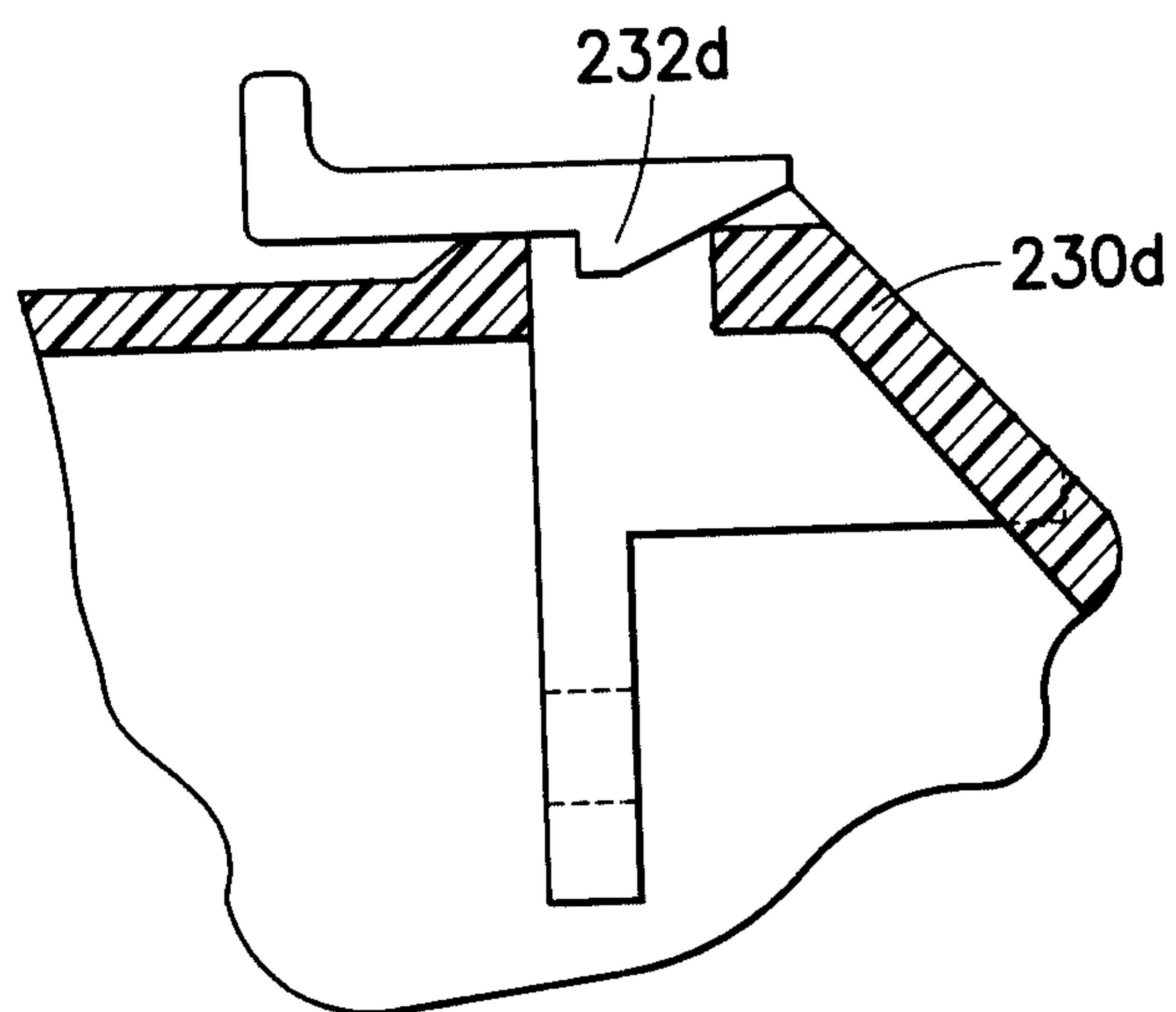


FIG. 21

