(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 1 816 947 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
24.09.2014 Bulletin 2014/39

(21) Application number: **05773670.4**

(22) Date of filing: **20.07.2005**

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***B65D 81/00*** *(2006.01)*
A61B 5/15 *(2006.01)* ***A61B 5/154*** *(2006.01)*

(86) International application number:
PCT/US2005/025765

(87) International publication number:
WO 2006/014751 (09.02.2006 Gazette 2006/06)

(54) **BLOOD COLLECTION ASSEMBLY**

BLUTSAMMELANORDNUNG

ENSEMBLE DE PRELEVEMENT SANGUIN

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: **20.07.2004 US 589294 P**

(43) Date of publication of application:
15.08.2007 Bulletin 2007/33

(60) Divisional application:
14160750.7 / 2 745 769

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(56) References cited:
EP-A1- 0 364 777
EP-A1- 1 433 419
WO-A2-2004/093938
US-A- 5 181 524
US-A1- 2003 093 009

EP 1 816 947 B1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to a medical needle device and assembly for use in connection with blood collection procedures, such as a blood collection assembly that provides a snap fit connection between various components of the assembly.

2. Description of Related Art

[0002] Disposable medical needle devices having piercing elements are typically used for administrating a medication or withdrawing a fluid, such as blood, from the body of the patient. Such piercing elements include blood collection needles, fluid handling needles and assemblies thereof. Current medical practice often requires that fluid collection containers and needle assemblies used in such devices be inexpensive and readily disposable. Often, existing blood collection devices employ some form of a durable reusable holder on which detachable and disposable needle assemblies and fluid collection containers are mounted. A blood collection system of this nature may be assembled prior to use and then disassembled after use.

[0003] Known blood collection systems typically include a double-ended needle assembly attached with a holder supporting the needle assembly, with the holder capable of accommodating an evacuated fluid collection tube therein. The double-ended needle assembly includes a hub having a bore therethrough, with a needle cannula extending through the bore of the hub. The hub of the needle assembly is received through an opening at one end of the holder and maintained therein, such that a first or distal end of the needle extends outward from the holder for puncturing the vein of a patient At the opposite end, a non-patient end of the needle extends into the hollow body. To assemble the blood collection system, the needle assembly is inserted into the housing and the evacuated fluid collection tube is partially inserted through the open end of the hollow body. To draw a blood specimen from the patient using one of these systems, the distal exposed end of the needle is inserted into a patient's vein, and the collection tube is fully inserted into the holder until the second or proximal end of the needle pierces a puncturable stopper of the fluid collection tube, thereby allowing fluid communication between the interior of the fluid collection tube and the bore of the needle. Blood will then be drawn through the needle into the evacuated fluid collection tube based on the negative pressure therein. After drawing a specimen, the blood collection tube is removed so that blood contained therein may be analyzed, and the needle assembly detached for disposal.

[0004] A prior art blood collection device known in the art is disclosed in U.S. Patent No. 5,066,287 to Ryan. This patent discloses a rear adapter assembly used as part of a blood collection set. The rear adapter assembly includes a rear blood tube holder and a male connector that is inserted into the holder. The male connector includes a ratcheted ramp with a plurality of ratchet teeth that engage with an annular internal ratchet located within the holder. In particular, the annular internal ratchet is provided on a holder ramp formed in the front wall of the holder. The ratcheting connection between the male connector and the holder provides a permanent connection between these two elements.

[0005] Another blood collection device known in the art is disclosed in U.S. Patent No. 5,117,837 to Wanamaker et al. The patent is directed to a blood collection device that is generally comprised of a needle assembly and a needle holder for use with an evacuated sample collection tube. The needle assembly includes a hub which is connected to the holder through an adapter. The adapter and hub are connected together by a threaded connection, and the adapter includes a crown defining a plurality of serrated teeth. The serrated teeth on the crown are adapted to cooperate with the serrated teeth formed on a lid, which covers the distal end of the holder. The adapter engages with the lid covering the distal end of the holder.

[0006] Yet another blood collection device known in the art is disclosed in U.S. Patent No. 5,066,286 to Ryan. This patent discloses a luer adapter assembly having a male connector and a rear blood tube holder. The rearward end of the male connector includes a hollow middle portion defining a groove, which snap-fits into the forward end of the holder such that the male connector is permanently installed in the rear blood tube holder. The connector and the holder have an interrupted contacting surface, which permits slight movement between the elements. The male connector also includes a plurality of longitudinally extending protrusions spread about the connector and terminates with a stop collar. The protrusions engage with respective longitudinal grooves in the holder in order to prevent unwanted rotation of the male connector relative to the rear tube holder.

[0007] In EP 1433 419 a safety needle assembly is disclosed comprising a holder housing and a hub. The hub comprises a needle cannula and is mounted to the holder housing. Further the safety needle assembly comprises a shield that this biased towards a needle cannula covering position and is released by inserting a sample collection tube into the holder housing.

[0008] Prior art devices such as those noted typically involve complex engagement systems between the hub and/or the male luer connector and the holder. Such devices are often difficult to align, engage and otherwise assemble due to the structural limitations of the fittings.

SUMMARY OF THE INVENTION

[0009] A need exists for a blood collection assembly

that includes the requisite components, where these components are easily manufactured, engaged and assembled in a safe and efficient manner.

[0010] Accordingly, an embodiment of the present invention provides a blood collection assembly comprising a holder housing defining a receiving chamber and including a rearward end adapted to receive a sample collection tube within the chamber and a forward end including a receiving port extending into the chamber. The assembly further comprises a hub including a hub outer surface extending between a distal end and a proximal end, an internal opening extending therethrough and a puncturing element at the proximal end thereof. The hub is received within the receiving port of the holder housing such that at least a portion of the hub outer surface engages a corresponding interior surface of the receiving port. The hub is maintained within the receiving port through interfering structure extending substantially perimetrically between the hub outer surface and the interior surface of the receiving port. In this manner, a snap-fit engagement axially locks the hub to the holder housing with the puncturing element of the hub extending through the receiving port and into the chamber of the holder housing for contact with a sample collection tube received within the chamber. The engagement between the hub outer surface and the corresponding receiving port interior surface provides support against torque applied to the distal end of the hub, preventing release of the snap-fit engagement established through the interfering structure between the hub outer surface and the receiving port interior surface.

[0011] Desirably, the hub includes a needle cannula mounted through the internal opening of the hub. The needle cannula includes a forward intravenous end with a puncture tip extending from the distal end of the hub and a rearward non-patient end extending from the proximal end of the hub, with the non-patient end comprising the puncturing element. Alternatively, the distal end of the hub may include a mating surface adapted to engage a medical device having a complimentary mating surface, such as a luer adapter.

[0012] In certain embodiments, the hub may include an annular protrusion, such as an annular rib, extending substantially perimetrically about the hub outer surface at a location between the distal and proximal ends of the hub. The receiving port can include a corresponding annular groove extending perimetrically within the interior surface of the receiving port, for mating with the annular protrusion of the hub.

[0013] Moreover, the assembly includes structure for preventing rotational movement of the hub within the receiving port. The hub outer surface may comprises an anti-rotation element to prevent rotational movement of the hub within the receiving port. For example, the hub outer surface may include a nub extending from the outer surface at the proximal end, and the receiving port may be sized and shaped so as to receive and substantially abut the nub, such as through a notch portion configured to receive and substantially abut an outer surface of the nub. Moreover, the outer surface of the nub may be rounded and configured for ease of insertion within and abutment against a complimentary rounded internal surface of the notch portion of the receiving port.

[0014] In one particular embodiment, the hub includes a needle cannula having an intravenous end with a puncture tip extending from the distal end thereof, with the anti-rotation element providing a mechanism for properly aligning the hub within the receiving port of the holder so as to orient the puncture tip at the intravenous end of the needle cannula to a predetermined position, such as a bevel up orientation. Also, the rearward end of the holder housing may include a pair of flanges extending from opposing sides thereof and a bottom surface of the holder housing is configured to rest on the patient's skin. As such, the anti-rotation element may be adapted to align the bevel of the needle to a predetermined position with respect to the pair of flanges and the bottom surface of the holder housing.

[0015] It is further contemplated that the needle assembly may include shield in pivotable engagement with the hub and/or the holder housing, with the shield being adapted for pivotal movement to encompass the puncture tip of the needle cannula. A removable packaging cover may also cover the puncture tip of the needle cannula with the hub attached to the holder housing prior to use, and a rear cap element may be removably attached with the rearward end of the holder housing to seal the receiving chamber of the holder housing.

[0016] In yet a further embodiment, a method of attaching a needle assembly with a holder housing is provided. The method involves providing a needle assembly comprising a needle cannula having an intravenous end with a bevel puncture tip and a non-patient end mounted to a hub. The hub extends between a distal end and a proximal end, with a protrusion extending substantially perimetrically about an outer surface at the proximal end and an anti-rotation element extending from the outer surface at the proximal end. A holder housing defines a receiving chamber and includes a rearward end adapted to receive a sample collection tube within the chamber and a forward end including a receiving port extending therethrough and configured to receive at least a portion of the proximal end of the hub therein. The receiving port includes an internal surface for mating with said protrusion of the hub and a notch portion for engagement with the anti-rotation element of the hub. The proximal end of the hub is inserted into the receiving port of the holder housing such that the protrusion of the hub engages the corresponding mating internal surface of the receiving port substantially around an entire contacting surface therebetween to axially lock the hub with the holder housing. In this manner, insertion of the anti-rotation element within the receiving port aligns the hub, and therefore, the needle cannula to a predetermined position. Desirably, the anti-rotation element comprises a nub extending from a surface of the hub in alignment with the bevel. As

such, insertion involves aligning the nub with the notch portion, thereby aligning the bevel to a predetermined position. Moreover, insertion of the hub within the receiving port may provide a tactile indication that the hub is axially locked with the holder housing through the inter-engaging structure.

[0017] Further details and advantages of the present invention will become apparent from the following detailed description read in conjunction with the drawings, wherein like parts are designated with like reference numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018]

FIG. 1 is a perspective and exploded view of a blood collection assembly in accordance with an embodiment of the present invention.

FIG. 2 is a perspective view of a holder housing of the blood collection assembly of FIG. 1.

FIG. 3 is a further perspective view of the bottom of the holder housing of FIG. 2.

FIG. 4 is a perspective view of a hub of the blood collection assembly of FIG. 1.

FIG. 5 is a perspective view of a needle assembly engaged with a holder housing.

FIG. 6 is a side sectional view of the engaged assembly of FIG. 5.

FIG. 7 is a plan sectional view taken along lines 7-7 in FIG. 6.

FIG. 8 is a perspective view of an enclosure.

FIG. 9 is a side sectional view of the engaged enclosure surrounding the hub in FIG. 8.

FIG. 10 is a perspective view of a hub with a tapered mating surface in accordance with a further embodiment.

FIG. 11 is an exploded perspective view of a blood collection assembly and a pivotal shield in accordance with a further embodiment.

FIG. 12 is a perspective view of the hub, holder housing and pivotal shield of FIG. 11.

FIG. 13 is a side sectional view of the engaged structure of FIG. 12, together with a cap covering a portion of a needle.

FIG. 14 is the perspective view of the structure of FIG. 12, with the pivotal shield encompassing the needle.

FIG. 15 is a perspective view of a blood collection assembly in a further embodiment, with a protective cover.

FIG. 16 is an exploded perspective view of the assembly of FIG. 15.

DETAILED DESCRIPTION

[0019] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal" and derivatives thereof shall relate to embodiments of the invention as they are oriented in the drawing figures. However, it is to be understood that these embodiments may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0020] In the following description and accompanying drawings, the term "distal" refers to the forward or patient side of the device, and the term "proximal" refers to the rearward or the non-patient side of the device, respectively. These designations will become apparent from the following detailed description.

[0021] Referring generally to the figures, a blood collection assembly **10** in accordance with an embodiment of the present invention is illustrated. The blood collection assembly **10** may be used, for example, in phlebotomy (i.e., blood collection) procedures and is designed in such an instance to allow and facilitate easy and efficient connection between the various components and sub-components of the blood collection assembly **10,** as discussed hereinafter.

[0022] Referring to FIGS. 1-9, one embodiment of the blood collection assembly **10** will be discussed. The principle of operation of the blood collection assembly **10** of FIGS. 1-7 is illustrative of all the embodiments of the blood collection assembly **10** to be discussed herein. The blood collection assembly **10** is generally comprised of a needle assembly **11** attached to a holder housing **22.** The needle assembly **11** includes a hub **12,** with the hub **12** having a distal end **14,** a proximal end **16,** a hub outer surface **18** and an internal opening **20** extending through the hub **12.**

[0023] The hub **12** includes a puncturing element positioned near the proximal end **16** of the hub **12** for the passage of fluid therethrough, such as blood and the like. The puncturing element **32,** in this embodiment, is adapted for contacting and piercing a sample collection tube during use, as will be discussed in more detail herein. Desirably, the needle assembly **11** includes a needle cannula **38** mounted through the internal opening **20** of the hub **12.** The needle cannula **38** is generally a hollow needle structure having an internal lumen **40,** and extends between a distal or forward end **42** establishing an intravenous or patient needle end having a puncture tip **44** and a proximal or rearward non-patient end **46.** Desirably, the forward end **42** of the needle cannula **38** extends from the distal end **14** of the hub **12,** and the proximal or rearward end **46** of the needle cannula **38** extends from the proximal end **16** of the hub **12.** The rearward non-patient end **46** of the needle cannula **38** comprises the puncturing element **32** for contacting the sample collection tube. As shown in FIG. 6, the hub **12** may also

include an elastomeric sleeve **82** extending from the proximal end **16** about the non-patient end **46** of the needle cannula **38.** This elastomeric sleeve **82** acts as a valve for maintaining fluid within the needle cannula during use of the blood collection assembly **10,** and is adapted to be pierced by the non-patient end **46** of the needle cannula **38** during use, as is known in the art.

[0024] The blood collection assembly **10** also includes a holder housing **22,** which defines a receiving chamber **24.** The holder housing has a rearward end **26** for receiving a sample collection tube (not shown) within the chamber **24,** and a forward end **28** with a receiving port **30** extending therethrough, establishing a pathway through the holder housing **22** into the receiving chamber **24.** The receiving port **30** is sized and shaped so as to receive at least a portion of the proximal end **16** of the hub **12** of the needle assembly **11** therein.

[0025] The blood collection assembly **10,** in accordance with an embodiment of the present invention, includes interengaging structure **34** between the hub **12** and the holder housing **22.** This interengaging structure **34** is used to axially lock the hub **12** with the holder housing **22.** In particular, this interengaging structure **34** provides for a "snap fit" between the hub **12** and the holder housing **22,** such that the hub **12** may be easily attached to the holder housing **22** through an axial attachment along the longitudinal axis of the blood collection assembly **10** as opposed to a threaded or screw-on type attachment as is common within the art, thereby facilitating easy alignment and manipulation, and in many instances without the need for additional structure. Desirably, the interengaging structure **34** extends substantially around contacting or mating surfaces between the hub **12** and the holder housing **22.** This interengaging structure **34** is adapted to axially lock the hub **12** and the holder housing **22.**

[0026] In particular, the hub **12** desirably includes a protrusion **54** that extends substantially perimetrically about the hub outer surface **18** at the proximal end **16** of the hub **12.** The receiving port **30** of the holder housing **22** includes a corresponding surface **56** for mating with this protrusion **54** on the hub **12.** Accordingly, when the protrusion **54** is engaged with the corresponding surface **56,** the hub **12** is axially locked with respect to the holder housing **22.** The corresponding surface **56** includes a groove **58** that extends substantially perimetrically within the receiving port **30.** Therefore, the protrusion **54** is sized and shaped so as to lockably engage with this groove **58.** For example, the protrusion **54** may be an annular rib **60,** which mates with the groove **58.**

[0027] The blood collection assembly **10** also includes structure that prevents rotational movement of the hub **12** when positioned in the receiving port **30** of the holder housing **22.** The hub outer surface **18** includes an anti-rotation element **64** positioned adjacent the proximal end **16** of the hub **12.** In addition, the receiving port **30** of the holder housing **22** is sized and shaped so as to receive and substantially abut the anti-rotation element **64** in an interference engagement which prevents rotational movement of the hub **12** within the receiving port **30** of the holder housing **22.**

[0028] When used in connection with the above-discussed embodiment including a needle cannula **38** extending through the hub **12,** the insertion of the anti-rotation element **64** within the receiving port **30** of the holder housing **22** aligns the hub **12.** Accordingly, since the needle cannula **38** is fixed with respect to the hub **12,** insertion of the anti-rotation element **64** also aligns the needle cannula **38** to a predetermined position with respect to the holder housing **22.** In that case, insertion of the anti-rotation element **64** within the receiving port **30** occurs during the assembly process prior to the snap-fit engagement, thereby providing a mechanism for aligning the needle cannula **38** to the desired predetermined orientation before the hub **12** is snap fit into the holder housing **22.**

[0029] In one preferred embodiment, the anti-rotation element **64** includes a nub **66** that extends generally longitudinally along the hub outer surface **18** from the proximal end **16** of the hub **12.** In addition, the receiving port **30** includes a notch portion **68** for receiving and abutting against an outer surface **70** of the nub **66.** The outer surface **70** of the nub **66** may be, for example, rounded for appropriate insertion within and abutment against a complimentary rounded internal surface **72** of the notch portion **68.** Accordingly, the anti-rotation structure established through anti-rotation element **64** prevents rotation of the hub **12** with respect to the holder housing **22,** as well as the assists in the alignment of the needle cannula **38.** For example, in certain embodiments, the needle cannula **38** may include a bevel **74.** It is oftentimes desirable to orient the bevel into an appropriate position during use of the blood collection assembly **10,** such as in a "bevel up" orientation to assist in venipuncture. Desirably, the nub **66** extends from the hub **12** in longitudinal alignment with this bevel **74,** such that insertion of the nub **66** within the notch portion **68** aligns the bevel **74** to a predetermined position.

[0030] The nub **66** may be located adjacent the annular rib **60** or, in another embodiment, desirably bisects annular rib **60** as shown in **FIG.** 4. In this manner, continuous contact is achieved perimetrically between the contacting surfaces of the hub **12** and the holder housing **22** establishing the axial lock and the rotational fixation therebetween.

[0031] The rearward **end 26** of the holder housing **22** may also include a flange **76.** This flange **76** resists rolling of the holder housing **22** on a flat surface, which thereby defines an upper surface **78** of the holder housing **22.** Therefore, when the nub **66** of the holder **12** is inserted within the notch portion **68** of the holder housing **22,** the bevel **74** of the needle cannula **38** is substantially aligned with the upper surface **78** of the holder housing **22.** It is also envisioned that the rearward end **26** of the holder housing **22** includes a pair of flanges **76** that extend from opposing sides of the holder housing **22,** such that a bot-

tom surface **80** of the holder housing **22** may rest upon a patient's skin. In addition, with respect to the orientation of the bevel **74** of the needle cannula **38,** the aforementioned arrangement may achieve a bevel orientation of between about 60 degrees and about 120 degrees from the flanges **76.**

[0032] In another embodiment, the assembly **10** may include a cap element **86** that is removably attached with the rearward end **26** of the holder housing **22.** Through the attachment of this cap element **86** with the holder housing **22,** the receiving chamber **24** is sealed from the outside environment. The cap element **86** may be adhered or attached directly to the rearward end **26** of the holder housing 22, for example through an appropriate adhesive. It is further contemplated that the cap element **86** may be affixed at the rearward end **26** through a mechanical engagement, such as through interfering structure between the cap element **86** and the holder housing **22.** For example, cap element **86** may include an annular rib which snap fits within a groove within the interior surface of the holder housing **22** at the rearward end thereof. Further, the blood collection assembly **10** may be hermetically sealed with an enclosure **88** after the hub **12** has been attached to the holder housing **22** through the interengaging structure **34.** In this manner, blood collection assembly **10** can be provided as a completely assembled structure ready for use in a single prepackaged assembly.

[0033] It is envisioned that a tactile indication may be provided during insertion of the hub **12** into the holder housing **22,** where this tactile indication provides indication that the hub **12** is axially locked with the holder housing **22** through the interengaging structure **34.** Such an arrangement ensures that the holder housing **22** and the hub **12** are appropriately and effectively axially locked.

[0034] In another embodiment, as illustrated in FIG. 10, the hub **12** may include a tapered mating surface **48** extending from the distal end **14** of the hub **12.** This tapered mating surface **48** is adapted to engage a separate medical device (not shown), which includes an interengaging and complimentary tapered mating surface. This arrangement is often referred to as a "luer" fitting, as is known in the art. Further, in this embodiment, the tapered mating surface **48** of the hub **12** may be removably lockable with the complimentary taped mating surface of the medical device. Accordingly, either of the tapered mating surfaces of the hub **12** or the medical device would include appropriate structure to effect this locking arrangement.

[0035] In a further embodiment depicted in FIGS. 11-14, the blood collection assembly **10** may include a shield **84** configured to encompass the intravenous end **42** of the needle cannula **38.** This shield **84** may be removably attached to the hub **12** and/or the holder housing **22,** or may be permanently affixed thereto or formed therewith. Shield **84** is desirably a pivotal shield, which is adapted to pivot between an open position in which the intravenous end **42** of the needle cannula **38** is exposed, as shown in FIG. 12, and a closed position encompassing or shielding the intravenous end **42** of the needle cannula **38** therein, as shown in FIG. 14. In such an embodiment, enclosure **88** may also be provided for sealing the needle cannula **38** therein prior to use.

[0036] Assembly of the blood collection assembly **10** will now be described. It is contemplated that needle assembly **11** may be provided as a disposable assembly as shown in FIGS. 8-9 for attachment with holder housing **22,** which may be separate structures which are assembled immediately prior to use and disassembled after use, as is common practice in the field. As shown in FIGS. 8-9, such a needle assembly **11** may be provided with enclosure **88** covering the intravenous end **42** and affixed or fitted to hub **12,** and with a separate rear cover **87** fitted therewith, whereupon the rear cover **87** can be removed and hub **12** assembled into holder housing **22** immediately prior to use. In order to reduce the risk of disease transmission, however, it is preferable that needle assembly **11** and holder housing **22** are provided as a preassembled structure with the needle assembly **11** attached to the holder housing **22** during manufacturing and assembly and prior to packaging.

[0037] In any event, needle assembly **11** is provided including the needle cannula **38** having a bevel **74** at the forward intravenous end **42,** as discussed hereinabove, mounted to the hub **12.** The protrusion **54** in this instance is located on the hub **12** and extends substantially perimetrically around the outer surface **18** of the hub **12** at its proximal end **16.** In addition, in this embodiment, the nub **66** extends from the outer surface **18** at the proximal end **16** of the hub **12** adjacent protrusion **54,** and is in alignment with the bevel **74** of the needle cannula **38.** The holder housing **22** is provided, and this holder housing **22** may be arranged as discussed hereinabove. In particular, the receiving port **30** includes an internal surface **56** for mating with the protrusion **54,** and a notch portion **68** for engagement with the nub **66.** The proximal end **16** of the hub **12** is inserted into the receiving port **30** of the holder housing **22** through the forward end **28** thereof, with the nub **66** aligned with the notch portion **68.** The outer surface **70** of the nub **66** and the corresponding internal surface **72** of the notch portion **68** may act together to guide the hub **12** into the proper alignment with respect to the holder housing **22,** in a predetermined position. Such alignment between the nub **66** and the notch portion **68** occurs during the assembly process prior to the snap-fit engagement between the hub **12** and the holder housing **22.**

[0038] The protrusion **54** of the hub **12** thereafter engages the corresponding mating internal surface **56** of the receiving port **30** substantially around an entire contacting or mating surface therebetween. In particular, the protrusion **54** which extends around the outer perimeter of the hub outer surface **18** engages into the groove **58** extending perimetrically within the corresponding surface **56** of the receiving port **30** in an interfering manner providing a snap fit engagement, with the nub **66** also

engaged with the notch portion **68.** Accordingly, insertion of the hub **12** within the receiving port **30** aligns the hub **12,** and therefore, the needle cannula **38** to a predetermined position, such as with bevel **74** in an upright position for effective use with a patient, and also axially locks the hub **12** with the holder housing **22,** in a snap-fit engagement. The blood collection assembly **10** assembled as such may further be provided with enclosure **88** protectively surrounding the intravenous end **42,** and may be packaged in this manner for later use.

[0039] During use, the forward intravenous end **42** of the needle cannula **38** is inserted through the skin of a patient to obtain a sample using known blood collection procedures. After use, the forward intravenous end **42** of the needle cannula **38** is removed from the patient, and the pivoting shield **84,** if provided, can be pivoted thereabout to protectively shield the needle. Shield **84** may include structure therein for engaging with the needle cannula **38** when rotated or pivoted to a safety position encompassing intravenous end **42** thereof, such as a cannula lock mechanism, thereby preventing the shield **84** from pivoting out of the shielding position once it has been moved into the shielding position. After shielding, the blood collection assembly **10** can be appropriately discarded in a medical waste container.

[0040] A further embodiment is depicted in FIGS. 15-16. In such an embodiment, holder housing **22** with hub **12** attached thereto and, optionally, with shield **84** also present, can be protectively packaged or covered within a enclosure **89**. Enclosure **89** differs from enclosure **88** described above in that enclosure **89** is designed so as to attach directly to the outer surface of the holder housing **22**, encompassing intravenous end **42** of the needle cannula **38** as well as the pivoting shield **84**. The pivoting shield **84** can be contained within enclosure **89** without lockingly engaging needle cannula **38**, such that when enclosure **89** is removed, pivoting shield **84** can be moved out of the way for use, and then pivoted to a locking position with the needle cannula **38** to encompass the puncture tip at he intravenous end **42** thereof. Also, a cap element **86** may be provided at the rearward end 26 of the holder housing **22**, sealing the receiving chamber **24**. In this manner, blood collection assembly **10** can be prepackaged and sterilized as a preassembled unit ready for use, without any assembly required by the phlebotomist prior to a procedure.

[0041] The blood collection assembly **10** of the present invention allows a needle assembly including a hub **12** to be "snap fit" with a holder housing **22**. Therefore, in this manner, the structure of the blood collection assembly **10** of the present embodiments of the invention allows for a more efficient and easily engageable hub/holder housing assembly. Further, with the use of the anti-rotation element **64**, both the holder housing **22** and the needle cannula **38,** and in particular the bevel **74** of the cannula, may be appropriately aligned and also prevented from unwanted rotation. Also, the specific engagement of the interengaging structure between the hub **12** and the holder housing **22** provides support against torque applied to the hub to prevent disengagement. In particular, by providing the interengaging structure extending substantially perimetrically around the hub outer surface **18** and the surface **56** of the receiving port **30**, such as annular rib **60** in interference engagement with groove **58** around the entire perimeter of the exterior of hub outer surface **18**, continuous support is provided around the entire contacting surface. Also, the corresponding rounded profiles of the annular rib **60** and the groove **58** establish substantially continuous contacting surfaces between the hub **12** and the receiving port **30** at the point of interengagement therebetween. Moreover, with the annular rib **60** being located on the hub outer surface **18** between the distal end **14** and the proximal end **16**, a portion of the hub outer surface **18** on either side of the annular rib **60** also provides a continuous contacting surface between the hub **12** and the receiving port **30**, thereby providing further support against torque pressure. Such continuous contacting surfaces provide support at the point of engagement between the hub **12** and the annular rib **60** to retain the hub **12** secured to the holder housing **22** when torque forces are applied thereto. In particular, pivotal movement of the shield **84** to the shielding position to encompass the intravenous end **42** of the needle cannula **38** causes a torque force against needle cannula **38** which force is transferred to the distal end **14** of the hub **12**. The continuous contacting surfaces, and in particular the interfering structure extending substantially perimetrically between the hub outer surface **18** and the receiving port **30** as described above, effectively retains the hub **12** secured to the holder housing **22** without risk of release of the snap-fit engagement therebetween.

[0042] While the assembly described is generally discussed herein in terms of several embodiments, the present disclosure is to be considered as exemplary of the principals of the invention and is not intended to limit the invention to the embodiments illustrated. Various modifications may be made by those of skilled in the art without departing from the scope of the present invention. The scope of the present invention is defined by the appended claims.

Claims

1. A blood collection assembly (10), comprising:

a holder housing (22) defining a receiving chamber (24) and including a rearward end (26) adapted to receive a sample collection tube within the chamber (24) and a forward end (28) including a receiving port (30); and

a hub (12) comprising a hub outer surface (18) extending between a distal end (14) and a proximal end (16), the hub (12) further comprising an internal opening (20) extending therethrough and a puncturing element (32) at the proximal

end (16) thereof;
wherein the hub (12) is received within the receiving port (30) of the holder housing (22) such that at least a portion of the hub outer surface (18) engages a corresponding interior surface (56) of the receiving port (30), and wherein the hub (12) is maintained within the receiving port (30) through interfering structure (54, 58) extending substantially perimetrically between the hub outer surface (18) and the interior surface (56) of the receiving port (30) providing a snap-fit engagement for axially locking the hub (12) to the holder housing (22) with the puncturing element (32) of the hub (12) extending through the receiving port (30) and into the chamber (24) of the holder housing (22),
characterized in that,
the hub outer surface (18) comprises an anti-rotation element (64) positioned adjacent the proximal end (16) of the hub (12) and wherein receipt of the anti-rotation element (64) within the receiving port (30) aligns the hub (12) with the holder housing (22) and prevents rotational movement of the hub (12) within the receiving port (30).

2. The assembly of claim 1, further comprising a needle cannula (38) including an internal lumen (40) mounted through the internal opening (20) of the hub (12), the needle cannula (38) having a forward intravenous end (42) with a puncture tip (44) extending from the distal end (14) of the hub (12) and a rearward non-patient end (46) extending from the proximal end (16) of the hub (12), the non-patient end (46) comprising the puncturing element (32).

3. The assembly of claim 1, wherein the distal end (14) of the hub (12) comprises a mating surface (48) adapted to engage a medical device having a complimentary mating surface.

4. The assembly of claim 1, wherein engagement between the hub outer surface (18) and the corresponding receiving port interior surface (56) provides support against torque applied to the distal end (14) of the hub (12), thereby preventing release of the snap-fit engagement established through the interfering structure extending substantially perimetrically between the hub outer surface (18) and the receiving port interior surface (56).

5. The assembly of claim 1, wherein the hub (12) includes an annular protrusion (54) extending substantially perimetrically about the hub outer surface (18) at a location between the distal (14) and proximal (16) ends of the hub (12), and the receiving port (30) includes a corresponding annular groove (58) extending perimetrically within the interior surface (56) of the receiving port (30) for mating with the annular protrusion (54) of the hub (12).

6. The assembly of claim 5, wherein the annular protrusion (54) comprises an annular rib (60).

7. The assembly of claim 1, wherein the anti-rotation element (64) comprises a nub (66) extending from the hub outer surface (18) at the proximal end (16) of the hub (12), and wherein the receiving port (30) includes a notch portion (68) configured to receive and substantially abut an outer surface (70) of the nub (66).

8. The assembly of claim 7, wherein the outer surface (70) of the nub (66) is rounded and configured for insertion within and abutment against a complimentary rounded internal surface (72) of the notch portion (68) of the receiving port (30).

9. The assembly of claim 1, further comprising a needle cannula (38) including an internal lumen (40) mounted through the internal opening (20) of said hub (12), the needle cannula (38) having a forward intravenous end (42) with a puncture tip (44) extending from the distal end (14) of the hub (12) and a rearward non-patient end (46) extending from the proximal end (16) of the hub (12), the non-patient end (46) comprising the puncturing element (32); wherein insertion of the anti-rotation element (64) within the receiving port (30) aligns the hub (12), and therefore, the puncture tip (44) of said intravenous end (42) of the needle cannula (38) to a predetermined position.

10. The assembly of claim 9, wherein the rearward end (26) of the holder housing (22) includes a pair of flanges (76) extending from opposing sides thereof and a bottom surface (80) of the holder housing (22) is configured to rest on the patient's skin; wherein the puncture tip (44) of the intravenous end (42) of the needle cannula (38) includes a bevel (74); and wherein insertion of the anti-rotation element (64) within the receiving port (30) aligns the bevel (74) to a predetermined position with respect to the pair of flanges (76) and the bottom surface (80) of the holder housing (22).

11. The assembly of claim 10, wherein insertion of the anti-rotation element (64) within the receiving port (30) aligns the bevel (74) between about 60 degrees and about 120 degrees from at least one of the pair of flanges (76).

12. The assembly of claim 9, further comprising a shield (84) in pivotable engagement with at least one of the hub (12) and the holder housing (22) and adapted for pivotal movement to encompass the puncture tip (44) of the needle cannula (38).

13. A method of attaching a needle assembly (11) with a holder housing (22) comprising:

a) providing a needle assembly (11) comprising a needle cannula (38) having an intravenous end (42) with a bevel puncture tip (44) and a non-patient end (46) mounted to a hub (12), said hub (12) extending between a distal end (14) and a proximal end (16), with a protrusion (54) extending substantially perimetrically about an outer surface (18) at said proximal end (16) and an anti-rotation element (64) extending from said outer surface (18) at said proximal end (16);
b) providing a holder housing (22) defining a receiving chamber (24) and including a rearward end (26) adapted to receive a sample collection tube within said chamber (24) and a forward end (28) including a receiving port (30) extending therethrough and configured to receive at least a portion of said proximal end (16) of said hub (12) therein, said receiving port (30) including an internal surface (56) for mating with said protrusion (54) of said hub (12) and a notch portion (68) for engagement with said anti-rotation element (64) of said hub (12); and
c) inserting the proximal end (16) of the hub (12) into the receiving port (30) of the holder housing (22) such that the protrusion (54) of said hub (12) engages the corresponding mating internal surface (56) of said receiving port (30) substantially around an entire contacting surface therebetween to axially lock said hub (12) with said holder housing (22), and such that said insertion of said anti-rotation element (64) within said receiving port (30) aligns said hub (12) with the holder housing (22), and therefore, said needle cannula (38) to a predetermined position and prevents rotational movement of the hub (12) within the receiving port (30).

14. The method of claim 13, wherein the anti-rotation element (64) comprises a nub (66) extending from a surface (18) of the hub (12) in alignment with the bevel (74), and wherein the inserting step c) comprises aligning the nub (66) with the notch portion (68), thereby aligning the bevel (74) to a predetermined position.

15. The method of claim 13, wherein insertion of the hub (12) within the receiving port (30) provides a tactile indication that the hub (12) is axially locked with the holder housing (22) through the interengaging structure.

Patentansprüche

1. Blutaufnahmevorrichtung (10) mit:

einem Haltergehäuse (22), das eine Aufnahmekammer (24) bildet und ein hinteres Ende (26), das zum Aufnehmen eines Probenaufnahmeröhrchens in die Kammer (24) in der Lage ist, und ein vorderes Ende (28) mit einem Aufnahmedurchlass (30) aufweist; und
einem Ansatz (12) mit einer sich zwischen einem distalen Ende (14) und einem proximalen Ende (16) erstreckenden Ansatz-Außenfläche (18), wobei der Ansatz (12) ferner eine durch ihn hindurch verlaufende Innenöffnung (20) und an seinem proximalen Ende (16) ein Punktierelement (32) aufweist;
wobei der Ansatz (12) in dem Aufnahmedurchlass (30) des Haltergehäuses (22) derart aufgenommen ist, dass mindestens ein Teil der Ansatz-Außenfläche (18) mit einer entsprechenden Innenfläche (56) des Aufnahmedurchlasses (30) zusammengreift und wobei der Ansatz (12) in dem Aufnahmedurchlass (30) mittels einer Eingriffsstruktur (54,58) gehalten ist, die im Wesentlichen umfangsmäßig zwischen der Ansatz-Außenfläche (18) und der Innenfläche (56) des Aufnahmedurchlasses (30) verläuft, wobei sie einen Schnappeingriff zur axialen Verriegelung des Ansatzes (12) an dem Haltergehäuse (22) bewirkt, wobei sich das Punktierelement (32) des Ansatzes (12) durch den Aufnahmedurchlass (30) und in die Kammer (24) des Haltergehäuses (22) erstreckt,
dadurch gekennzeichnet, dass
die Ansatz-Außenfläche (18) ein Drehverhinderungselement (64) aufweist, das nahe dem proximalen Ende (16) des Ansatzes (12) positioniert ist, und dass durch Aufnahme des Drehverhinderungselements (64) in dem Aufnahmedurchlass (30) der Ansatz (12) mit dem Haltergehäuse (22) ausgerichtet ist und eine Drehbewegung des Ansatzes (12) in dem Aufnahmedurchlass (30) verhindert ist.

2. Vorrichtung nach Anspruch 1, ferner mit einer ein Innenlumen (40) aufweisenden Nadelkanüle (38), die durch die Innenöffnung (20) des Ansatzes (12) verlaufend angeordnet ist, wobei die Nadelkanüle (38) ein von dem distalen Ende (14) des Ansatzes (12) abstehendes vorderes, intravenöses Ende (42) mit einer Punktierungsspitze (44) und ein von dem proximalen Ende (16) des Ansatzes (12) abstehendes hinteres, nicht patientenseitiges Ende (46) aufweist, wobei das nicht patientenseitige Ende (46) das Punktierelement (32) aufweist.

3. Vorrichtung nach Anspruch 1, bei der das distale Ende (14) des Ansatzes (12) eine passgerechte Fläche (48) aufweist, die zum Zusammengriff mit einer medizinischen Vorrichtung in der Lage ist, welche eine komplementäre passgerechte Fläche aufweist.

4. Vorrichtung nach Anspruch 1, bei der der Zusammengriff zwischen der Ansatz-Außenfläche (18) und der entsprechenden Aufnahmedurchlass-Innenfläche (56) einen Widerhalt gegen eine auf das distale Ende (14) des Ansatzes (12) aufgebrachte Drehkraft bildet, wodurch ein Lösen des Schnappeingriffs, der durch die im Wesentlichen umfangsmäßig zwischen der Ansatz-Außenfläche (18) und der Aufnahmedurchlass-Innenfläche (56) verlaufende Eingriffsstruktur besteht, verhindert wird.

5. Vorrichtung nach Anspruch 1, bei der der Ansatz (12) einen ringförmigen Vorsprung (54) aufweist, der an einem zwischen dem distalen (14) und dem proximalen (16) Endes des Ansatzes (12) gelegenen Bereich im Wesentlichen umfangsmäßig um die Ansatz-Außenfläche (18) verläuft, und der Aufnahmedurchlass (30) eine entsprechende Ringnut (58) aufweist, die umfangsmäßig in der Innenfläche (56) des Aufnahmedurchlasses (30) verläuft, um passend mit dem ringförmigen Vorsprung (54) des Ansatzes (12) zusammenzugreifen.

6. Vorrichtung nach Anspruch 5, bei der der ringförmige Vorsprung (54) eine ringförmige Rippe (60) aufweist.

7. Vorrichtung nach Anspruch 1, bei der das Drehverhinderungselement (64) eine Noppe (66) aufweist, die an dem proximalen Ende (16) des Ansatzes (12) von der Ansatz-Außenfläche (18) absteht, und bei der der Aufnahmedurchlass (30) einen Einbuchtungsabschnitt (68) aufweist, welcher derart konfiguriert ist, dass er eine Außenfläche (70) der Noppe (66) aufnimmt und im Wesentlichen an dieser anliegt.

8. Vorrichtung nach Anspruch 7, bei der die Außenfläche (70) der Noppe (66) gerundet und zur Einführung in eine komplimentäre gerundete Innenfläche (72) des Einbuchtungsabschnitts (68) des Aufnahmedurchlasses (30) und zur Anlage gegen diese Innenfläche konfiguriert ist.

9. Vorrichtung nach Anspruch 1, ferner mit einer ein Innenlumen (40) aufweisenden Nadelkanüle (38), die durch die Innenöffnung (20) des Ansatzes (12) verlaufend angeordnet ist, wobei die Nadelkanüle (38) ein von dem distalen Ende (14) des Ansatzes (12) abstehendes vorderes, intravenöses Ende (42) mit einer Punktierungsspitze (44) und ein von dem proximalen Ende (16) des Ansatzes (12) abstehendes hinteres, nicht patientenseitiges Ende (46) aufweist, wobei das nicht patientenseitige Ende (46) das Punktierelement (32) aufweist; wobei durch die Einführung des Drehverhinderungselements (64) in den Aufnahmedurchlass (30) der Ansatz (12) und somit die Punktierungsspitze (44) des intravenösen Endes (42) der Nadelkanüle (38) in einer vorbestimmten Position ausgerichtet werden.

10. Vorrichtung nach Anspruch 9, bei der das hintere Ende (26) des Haltergehäuses (22) ein Paar von Flanschen (76) aufweist, die von einander gegenüberliegenden Seiten dieses Endes abstehen, und eine Bodenfläche (80) des Haltergehäuses (22) zur Anlage an der Haut des Patienten konfiguriert ist; wobei die Punktierungsspitze (44) des intravenösen Endes (42) der Nadelkanüle (38) einen Schliff (74) aufweist; und wobei durch die Einführung des Drehverhinderungselements (64) in den Aufnahmedurchlass (30) der Schliff (74) in eine vorbestimmte Position relativ zu dem Paar von Flanschen (76) und der Bodenfläche (80) des Haltergehäuses (22) ausgerichtet ist.

11. Vorrichtung nach Anspruch 10, bei der durch die Einführung des Drehverhinderungselements (64) in den Aufnahmedurchlass (30) der Schliff (74) in einem Bereich von ungefähr 60 Grad bis ungefähr 120 Grad von mindestens einem Flansch des Paars von Flanschen (76) ausgerichtet ist.

12. Vorrichtung nach Anspruch 9, ferner mit einem Schutzteil (84), das sich in Schwenkverbindung mit mindestens dem Ansatz (12) oder dem Haltergehäuse (22) befindet und zu einer Schwenkbewegung zwecks Umschließens der Punktierungsspitze (44) der Nadelkanüle (38) in der Lage ist.

13. Verfahren zum Befestigen einer Nadelvorrichtung (11) an einem Haltergehäuse (22), mit den Schritten:

a) Bereitstellen einer Nadelvorrichtung (11) mit einer Nadelkanüle (38), welche ein intravenöses Ende (42) mit einer angeschliffenen Punktierungsspitze (44) und ein an dem Ansatz (12) befestigtes, nicht patientenseitiges Ende (46) hat, wobei der Ansatz (12) sich zwischen einem distalen Ende (14) und einem proximalen Ende (16) erstreckt, wobei ein Vorsprung (54) an dem proximalen Ende (16) im Wesentlichen umfangsmäßig um eine Außenfläche (18) verläuft und ein Drehverhinderungselement (64) an dem proximalen Ende (16) von der Außenfläche (18) absteht;
b) Bereitstellen eines Haltergehäuses (22), das eine Aufnahmekammer (24) bildet und ein hinteres Ende (26), welches zur Aufnahme eines Probenaufnahmeröhrchens in der Kammer (24) in der Lage ist, und ein vorderes Ende (28) mit einem Aufnahmedurchlass (30) aufweist, der durch dieses Ende hindurch verläuft und zur Aufnahme mindestens eines Teils des proximalen Endes (16) des Ansatzes (12) konfiguriert ist, wobei der Aufnahmedurchlass (30) eine Innenfläche (56) zum passenden Zusammengriff

mit dem Vorsprung (54) des Ansatzes (12) und einen Einbuchtungsabschnitt (68) zum Zusammengriff mit dem Drehverhinderungselement (64) des Ansatzes (12) aufweist; und
c) Einführen des proximalen Endes (16) des Ansatzes (12) in den Aufnahmedurchlass (30) des Haltergehäuses (22) derart, dass der Vorsprung (54) des Ansatzes (12) mit der entsprechenden passgerechten Innenfläche (56) des Aufnahmedurchlasses (30) im Wesentlichen um die gesamte dazwischen verlaufende Kontaktfläche herum zusammengreift, um den Ansatz (12) axial mit dem Haltergehäuse (22) zu verriegeln, und derart, dass durch die Einführung des Drehverhinderungselements (64) in den Aufnahmedurchlass (30) der Ansatz (12) mit dem Haltergehäuse (22) ausgerichtet ist und somit die Nadelkanüle (38) in einer vorbestimmten Position ausgerichtet ist und eine Drehbewegung des Ansatzes (12) in dem Aufnahmedurchlasses (30) verhindert ist.

14. Verfahren nach Anspruch 13, bei dem das Drehverhinderungselement (64) eine Noppe (66) aufweist, die von einer Fläche (18) des Ansatzes (12) in Ausrichtung mit dem Schliff (74) absteht, und wobei der Einführ-Schritt c) das Ausrichten der Noppe (66) mit dem Einbuchtungsabschnitt (68) umfasst, wodurch der Schliff (74) in eine vorbestimmte Position ausgerichtet wird.

15. Verfahren nach Anspruch 13, bei dem beim Einführen des Ansatzes (12) in den Aufnahmedurchlass (30) ein taktiler Hinweis darauf erzeugt wird, dass der Ansatz (12) mittels der Eingriffsstruktur axial mit dem Haltergehäuse (22) verriegelt ist.

Revendications

1. Ensemble de prélèvement sanguin (10), comprenant :

un boîtier de support (22) définissant une chambre de réception (24) et comportant une extrémité arrière (26) adaptée pour recevoir un tube de prélèvement d'échantillon à l'intérieur de la chambre (24) et une extrémité avant (28) comportant un orifice de réception (30) ; et
un raccord (12) comprenant une surface externe de raccord (18) s'étendant entre une extrémité distale (14) et une extrémité proximale (16), le raccord (12) comprenant en outre une ouverture interne (20) qui le traverse et un élément de piqûre (32) au niveau de son extrémité proximale (16) ;
où le raccord (12) est reçu dans l'orifice de réception (30) du boîtier de support (22) de telle sorte qu'au moins une partie de la surface externe du raccord (18) s'engage avec une surface intérieure correspondante (56) de l'orifice de réception (30), et où le raccord (12) est maintenu à l'intérieur de l'orifice de réception (30) à travers une structure interférente (54, 58) s'étendant de manière essentiellement périmétrique entre la surface externe de raccord (18) et la surface intérieure (56) de l'orifice de réception (30) fournissant un engagement par encliquetage pour verrouiller axialement le raccord (12) au boîtier de support (22), l'élément de piqûre (32) du raccord (12) s'étendant à travers l'orifice de réception (30) et dans la chambre (24) du boîtier de support (22),
caractérisé en ce que,
la surface externe de raccord (18) comprend un élément anti-rotation (64) positionné de manière adjacente à l'extrémité proximale (16) du raccord (12) et où la réception de l'élément anti-rotation (64) à l'intérieur de l'orifice de réception (30) aligne le raccord (12) avec le boîtier de support (22) et empêche le mouvement de rotation du raccord (12) à l'intérieur de l'orifice de réception (30).

2. Ensemble de la revendication 1, comprenant en outre une canule à aiguille (38) qui comporte une lumière interne (40) montée à travers l'ouverture interne (20) du raccord (12), la canule à aiguille (38) ayant une extrémité intraveineuse avant (42) avec une pointe de ponction (44) s'étendant de l'extrémité distale (14) du raccord (12) et une extrémité arrière opposée au patient (46) s'étendant de l'extrémité proximale (16) du raccord (12), l'extrémité opposée au patient (46) comprenant l'élément de piqûre (32).

3. Ensemble de la revendication 1, dans lequel l'extrémité distale (14) du raccord (12) comprend une surface conjuguée (48) adaptée pour s'engager avec un dispositif médical ayant une surface conjuguée complémentaire.

4. Ensemble de la revendication 1, dans lequel l'engagement entre la surface externe de raccord (18) et la surface intérieure correspondante (56) de l'orifice de réception fournit un support contre un couple appliqué à l'extrémité distale (14) du raccord (12), empêchant ainsi la libération de l'engagement par encliquetage établi à travers la structure interférente s'étendant de manière essentiellement périmétrique entre la surface externe de raccord (18) et la surface intérieure (56) de l'orifice de réception.

5. Ensemble de la revendication 1, dans lequel le raccord (12) comporte une saillie annulaire (54) s'étendant de manière essentiellement périmétrique autour de la surface externe (18) du raccord à un

emplacement entre les extrémités distale (14) et proximale (16) du raccord (12), et l'orifice de réception (30) comporte une rainure annulaire correspondante (58) s'étendant de manière essentiellement périmétrique à l'intérieur de la surface intérieure (56) de l'orifice de réception (30) pour s'accoupler avec la saillie annulaire (54) du raccord (12).

6. Ensemble de la revendication 5, dans lequel la saillie annulaire (54) comprend une nervure annulaire (60).

7. Ensemble de la revendication 1, dans lequel l'élément anti-rotation (64) comprend un ergot (66) s'étendant de la surface externe (18) du raccord au niveau de l'extrémité proximale (16) du raccord (12), et dans lequel l'orifice de réception (30) comporte une partie d'encoche (68) configurée pour recevoir et venir essentiellement en butée contre une surface externe (70) de l'ergot (66).

8. Ensemble de la revendication 7, dans lequel la surface externe (70) de l'ergot (66) est arrondie et configurée pour s'insérer à l'intérieur d'une surface interne arrondie complémentaire (72) de la partie d'encoche (68) de l'orifice de réception (30) ainsi que pour venir en butée contre la surface interne arrondie complémentaire (72) de la partie d'encoche (68) de l'orifice de réception (30).

9. Ensemble de la revendication 1, comprenant en outre une canule à aiguille (38) comportant une lumière interne (40) montée à travers l'ouverture interne (20) dudit raccord (12), la canule à aiguille (38) ayant une extrémité intraveineuse avant (42) avec une pointe de ponction (44) qui s'étend de l'extrémité distale (14) du raccord (12) et une extrémité arrière (46) opposée au patient qui s'étend de l'extrémité proximale (16) du raccord (12), l'extrémité opposée au patient (46) comprenant l'élément de piqûre (32) ; où l'insertion de l'élément anti-rotation (64) à l'intérieur de l'orifice de réception (30) aligne le raccord (12), et, par conséquent, la pointe de ponction (44) de ladite extrémité intraveineuse (42) de la canule à aiguille (38) sur une position prédéterminée.

10. Ensemble de la revendication 9, dans lequel l'extrémité arrière (26) du boîtier de support (22) comporte une paire de brides (76) s'étendant depuis des côtés opposés de celle-ci et une surface inférieure (80) du boîtier de support (22) est configurée pour reposer sur la peau du patient ; où la pointe de ponction (44) de l'extrémité intraveineuse (42) de la canule à aiguille (38) comporte un biseau (74) ; et où l'insertion de l'élément anti-rotation (64) à l'intérieur de l'orifice de réception (30) aligne le biseau (74) sur une position prédéterminée par rapport à la paire de brides (76) et à la surface inférieure (80) du boîtier de support (22).

11. Ensemble de la revendication 10, dans lequel l'insertion de l'élément anti-rotation (64) à l'intérieur de l'orifice de réception (30) aligne le biseau (74) entre environ 60 degrés et environ 120 degrés à partir d'au moins l'une de la paire de brides (76).

12. Ensemble de la revendication 9, comprenant en outre un blindage (84) dans un engagement pivotant avec au moins l'un du raccord (12) et du boîtier de support (22) et adapté pour effectuer un mouvement de pivotement afin d'englober la pointe de ponction (44) de la canule à aiguille (38).

13. Procédé de fixation d'un ensemble d'aiguille (11) avec un boîtier de support (22) comprenant le fait de :

a) fournir un ensemble d'aiguille (11) comprenant une canule à aiguille (38) ayant une extrémité intraveineuse (42) avec une pointe de ponction en biseau (44) et une extrémité (46) opposée au patient montée sur un raccord (12), ledit raccord (12) s'étendant entre une extrémité distale (14) et une extrémité proximale (16), avec une saillie (54) s'étendant de manière essentiellement périmétrique autour d'une surface externe (18) au niveau de ladite extrémité proximale (16) et un élément anti-rotation (64) s'étendant de ladite surface externe (18) au niveau de ladite extrémité proximale (16);
b) fournir un boîtier de support (22) définissant une chambre de réception (24) et comportant une extrémité arrière (26) adaptée pour recevoir un tube de prélèvement d'échantillon à l'intérieur de ladite chambre (24) et une extrémité avant (28) comportant un orifice de réception (30) s'étendant à travers celui-ci et configuré pour y recevoir au moins une partie de ladite extrémité proximale (16) dudit raccord (12), ledit orifice de réception (30) comportant une surface interne (56) pour s'accoupler avec ladite saillie (54) dudit raccord (12) et une partie d'encoche (68) pour s'engager avec ledit élément anti-rotation (64) dudit raccord (12) ; et
c) insérer l'extrémité proximale (16) du raccord (12) dans l'orifice de réception (30) du boîtier de support (22) de telle sorte que la saillie (54) dudit raccord (12) s'engage avec la surface interne conjuguée correspondante (56) dudit orifice de réception (30) essentiellement autour de toute une surface de contact entre celles-ci pour verrouiller axialement ledit raccord (12) audit boîtier de support (22), et de telle sorte que ladite insertion dudit élément anti-rotation (64) à l'intérieur dudit orifice de réception (30) aligne ledit raccord (12) avec le boîtier de support (22), et par conséquent, avec ladite canule à aiguille (38) sur une position prédéterminée et empêche un mouvement de rotation du raccord (12) à l'in-

térieur de l'orifice de réception (30).

14. Procédé de la revendication 13, dans lequel l'élément anti-rotation (64) comprend un ergot (66) s'étendant d'une surface (18) du raccord (12) en alignement avec le biseau (74), et dans lequel l'étape d'insertion c) comprend l'alignement de l'ergot (66) avec la partie d'encoche (68), alignant ainsi le biseau (74) sur une position prédéterminée.

15. Procédé de la revendication 13, dans lequel l'insertion du raccord (12) à l'intérieur de l'orifice de réception (30) fournit une indication tactile qui indique que le raccord (12) est axialement verrouillé au boîtier de support (22) à travers la structure d'interconnexion.

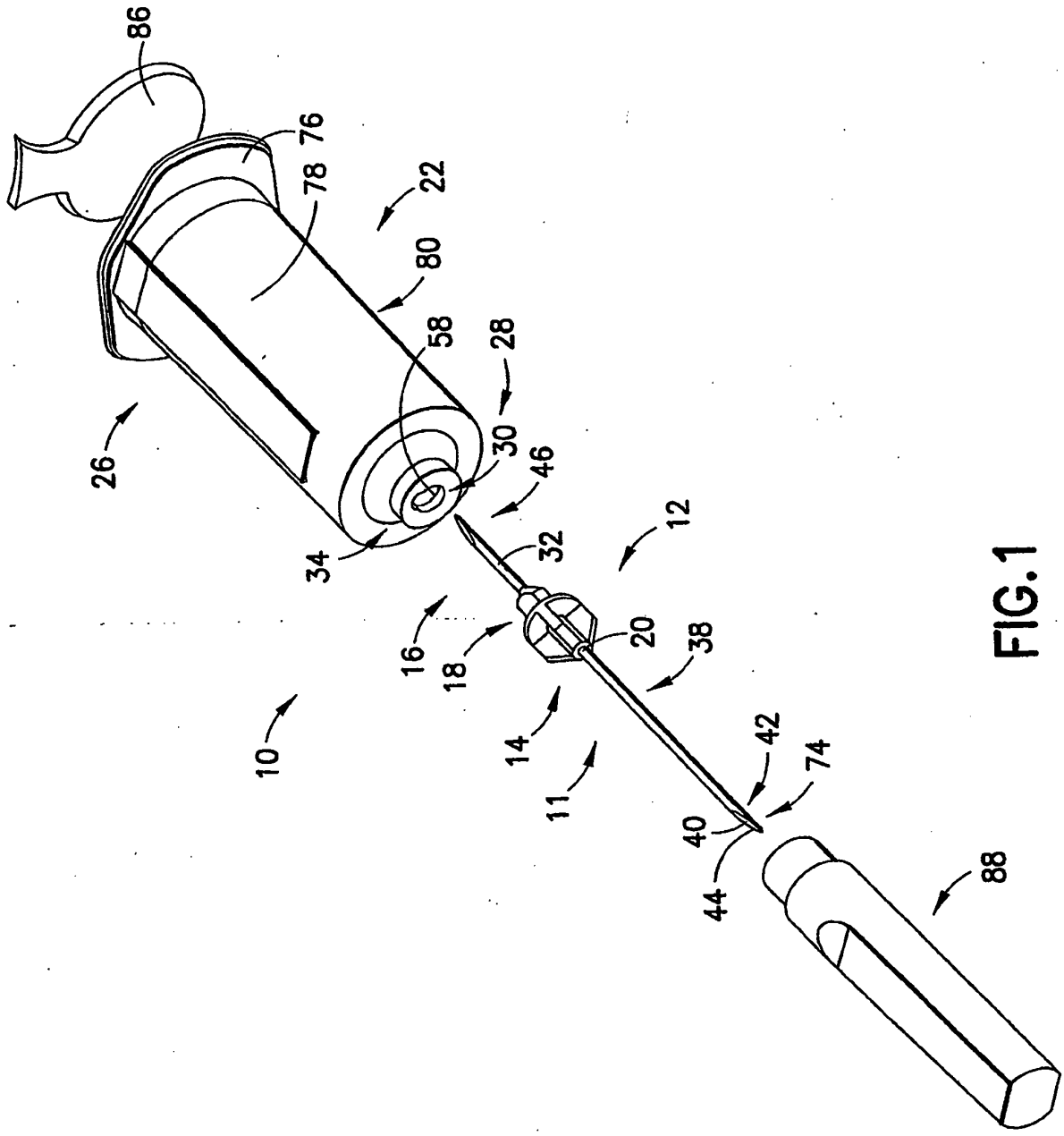
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FIG.1

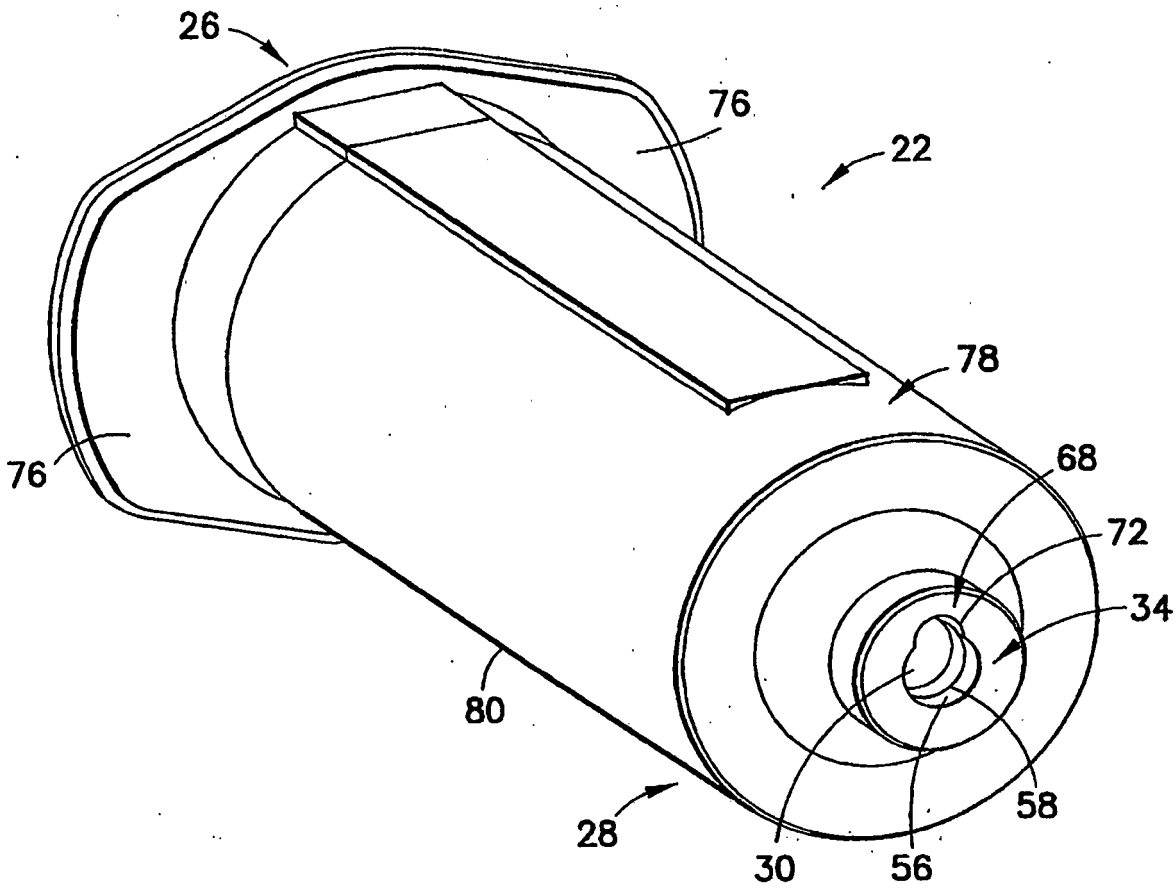

FIG.2

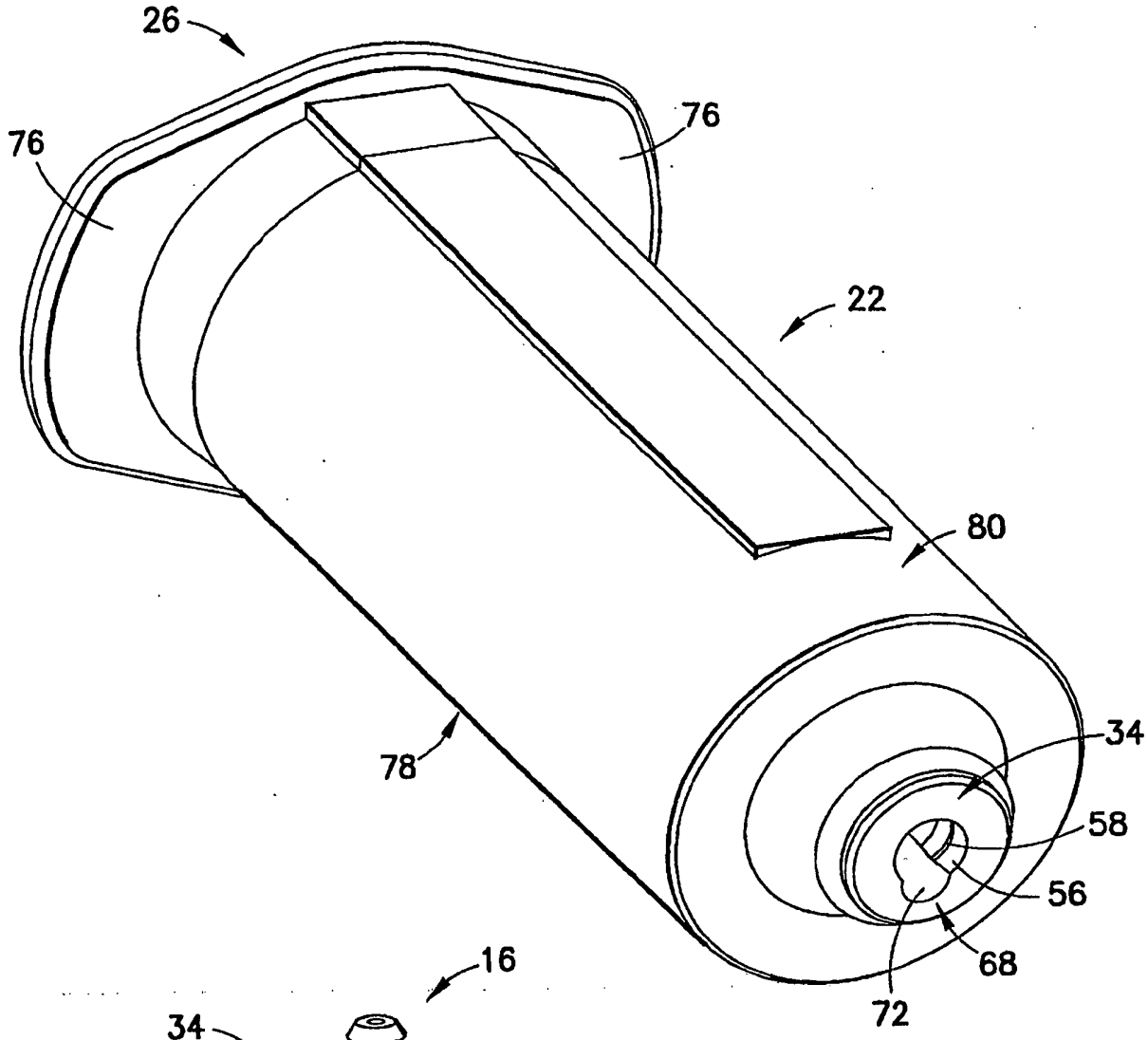

FIG.3

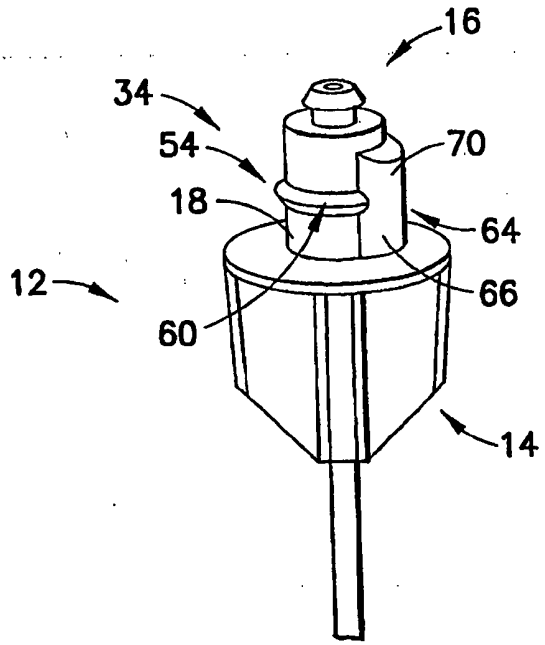

FIG.4

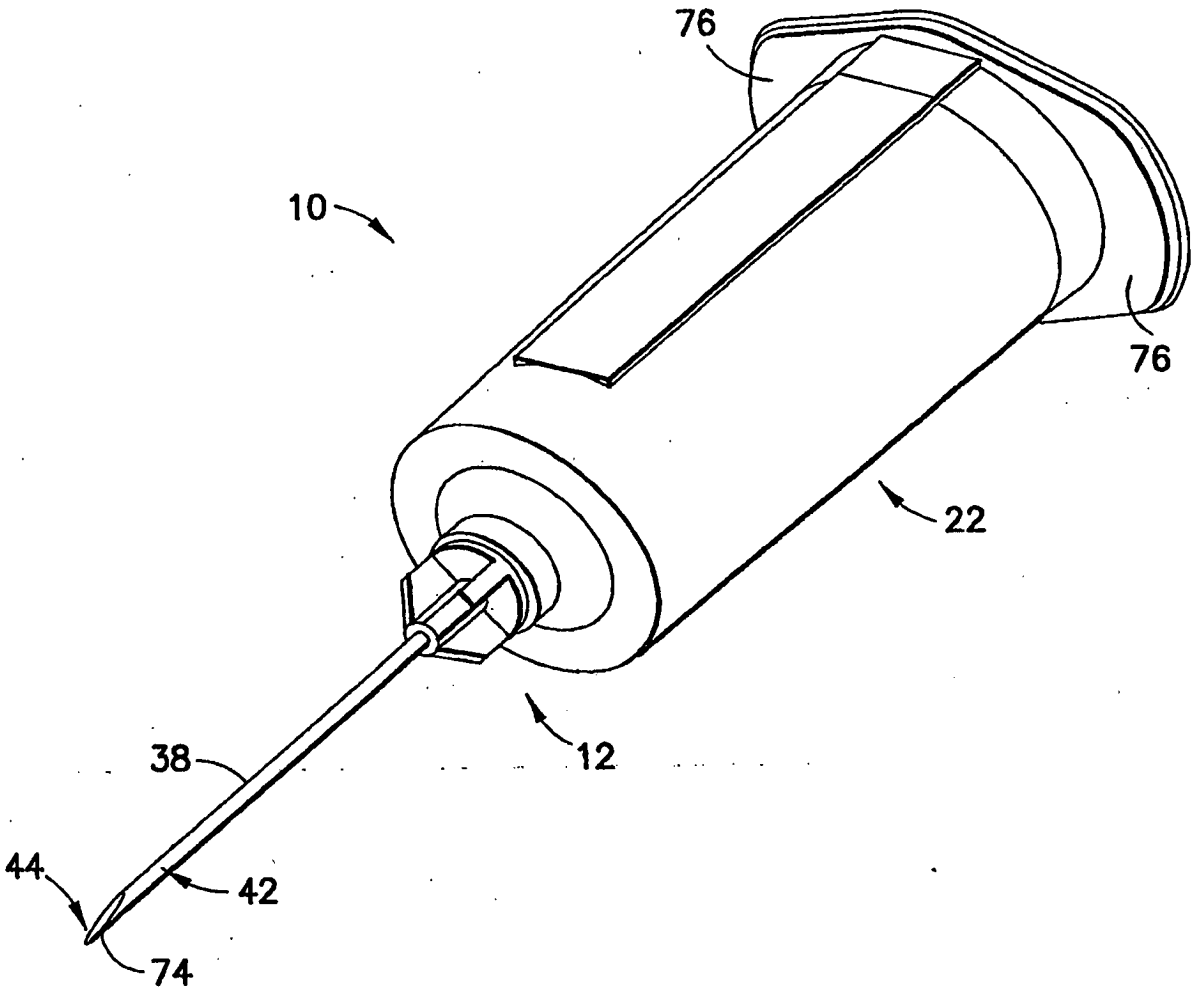

FIG.5

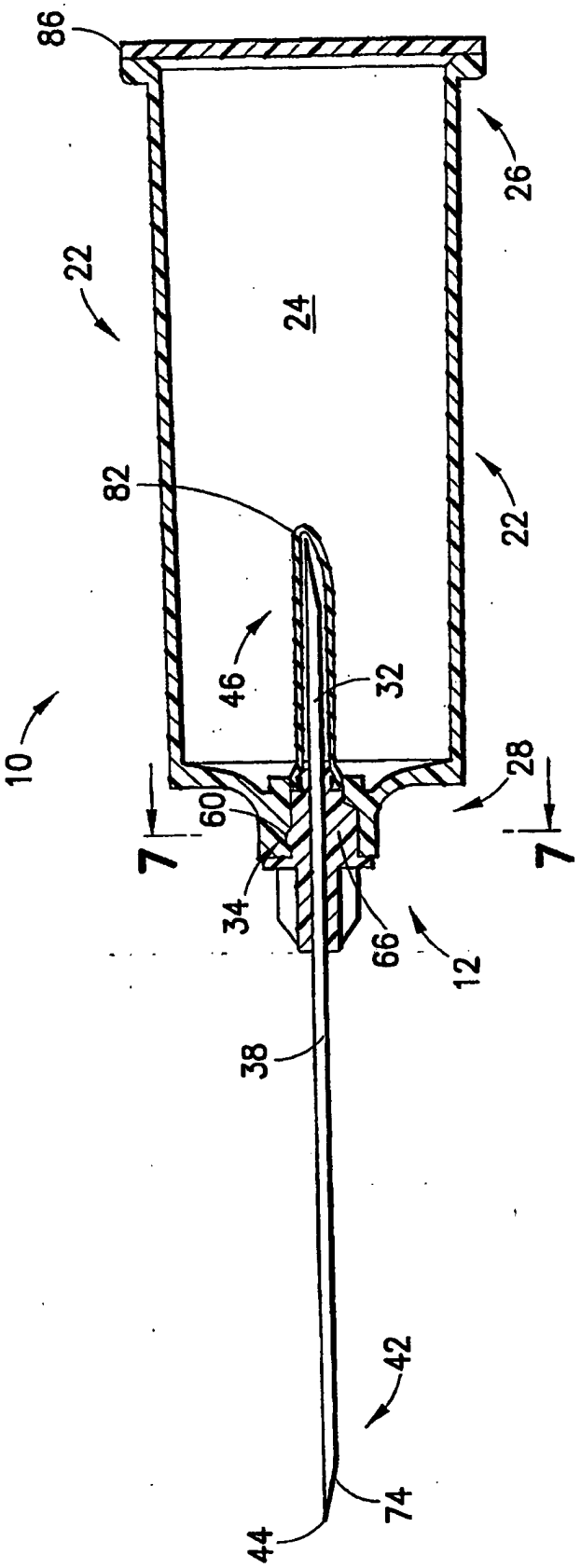

FIG.6

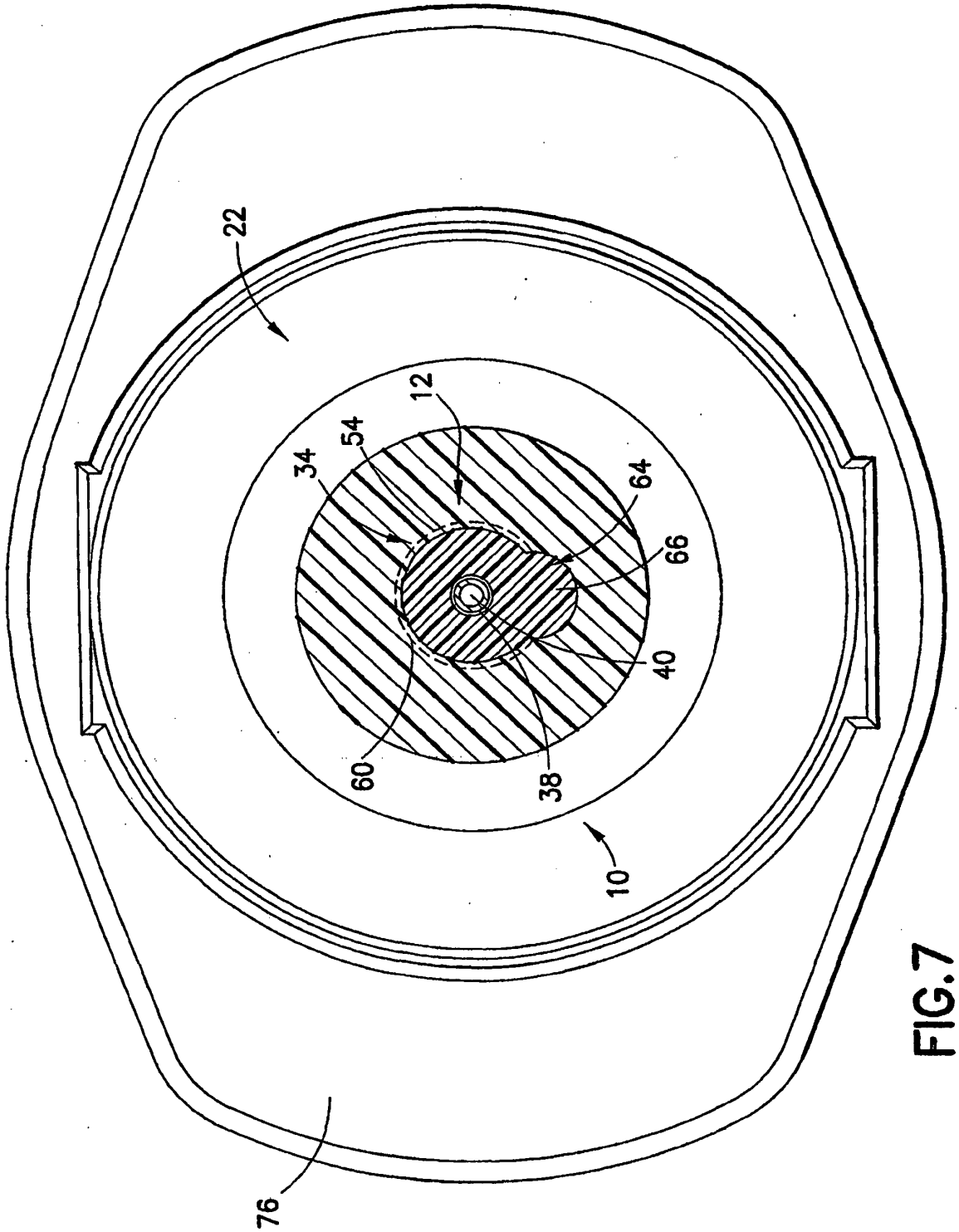

FIG.7

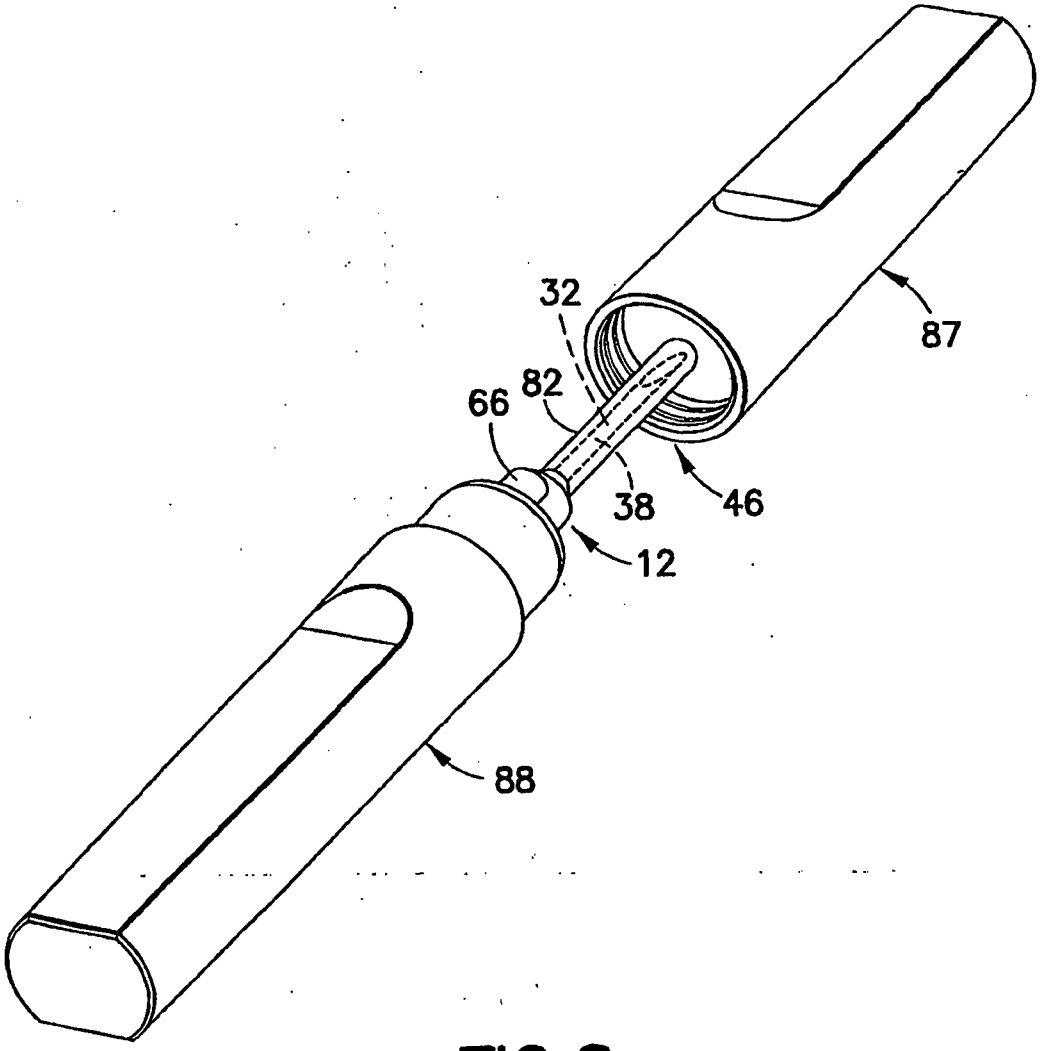

FIG.8

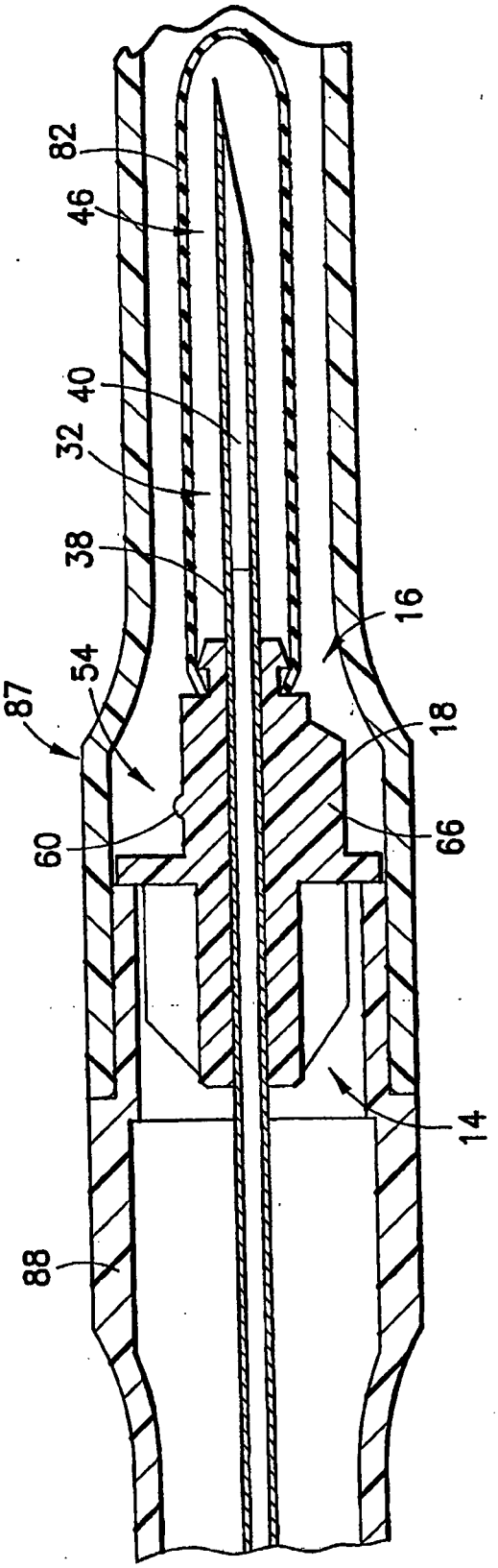

FIG.9

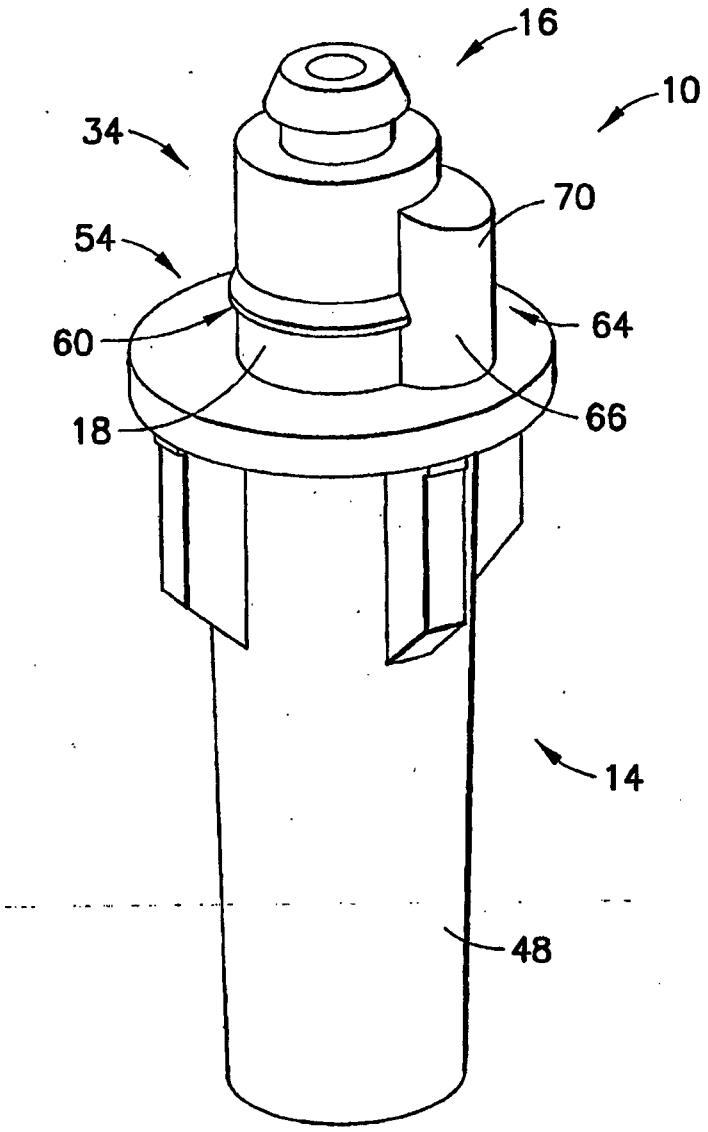

FIG.10

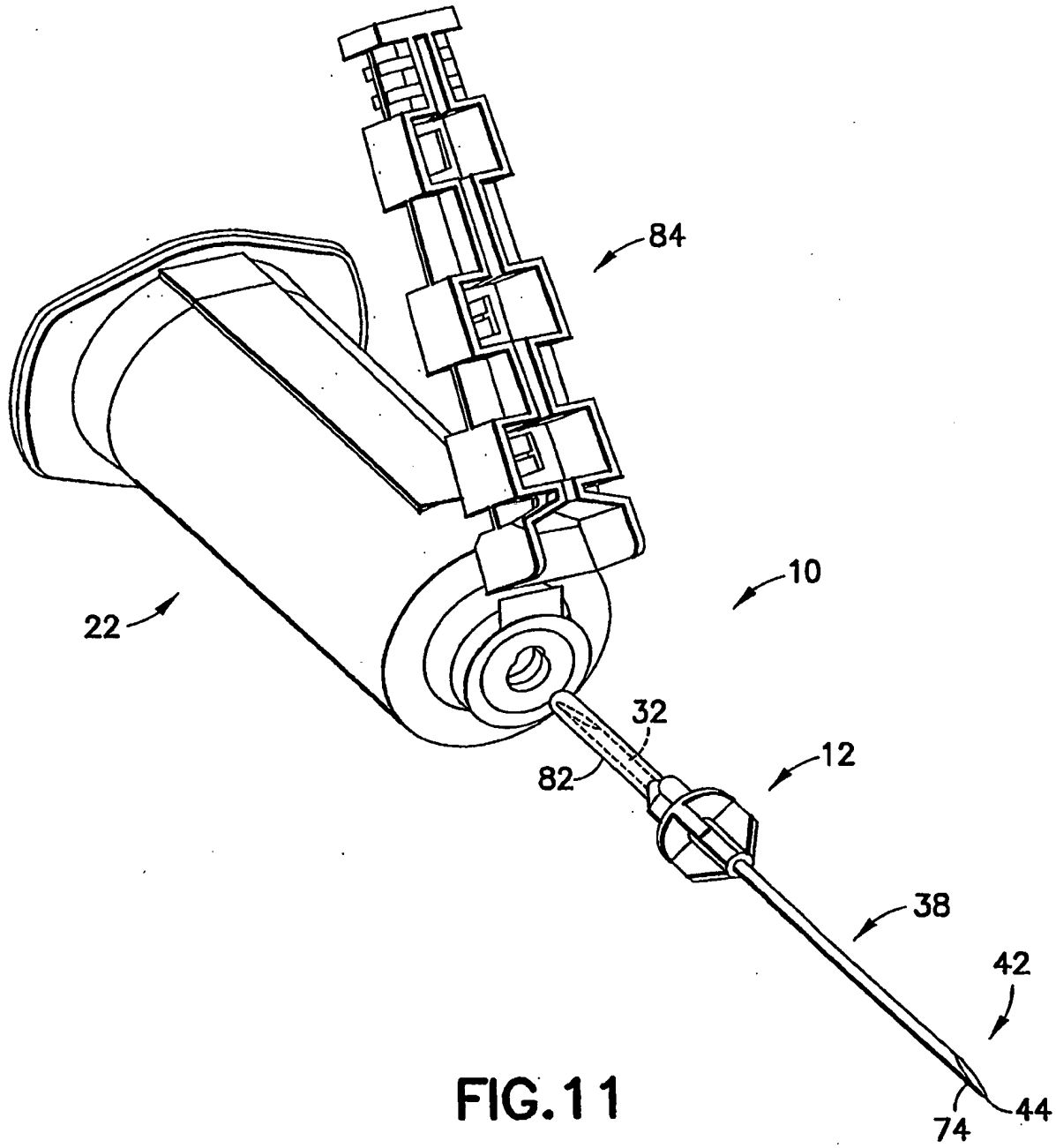

FIG. 11

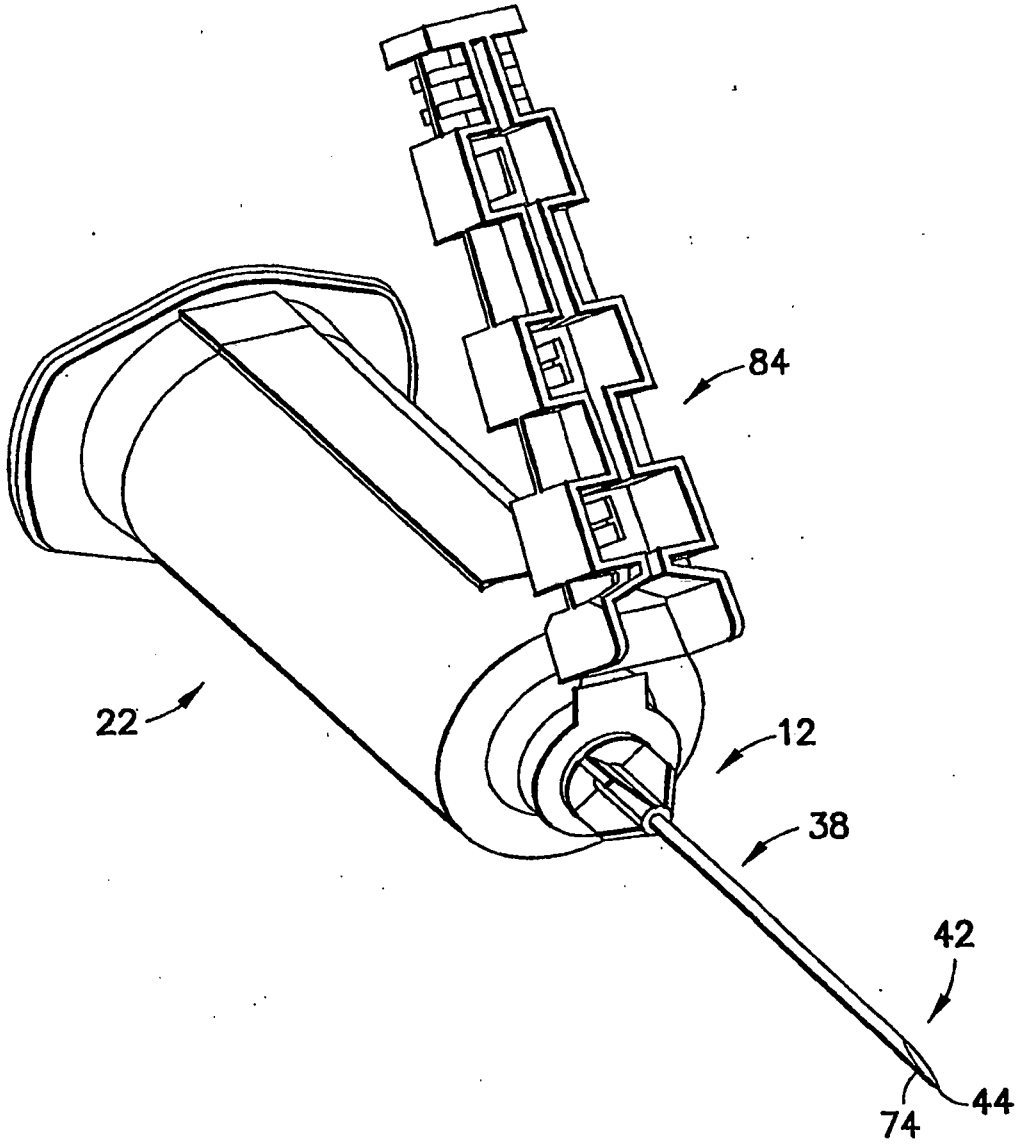

FIG.12

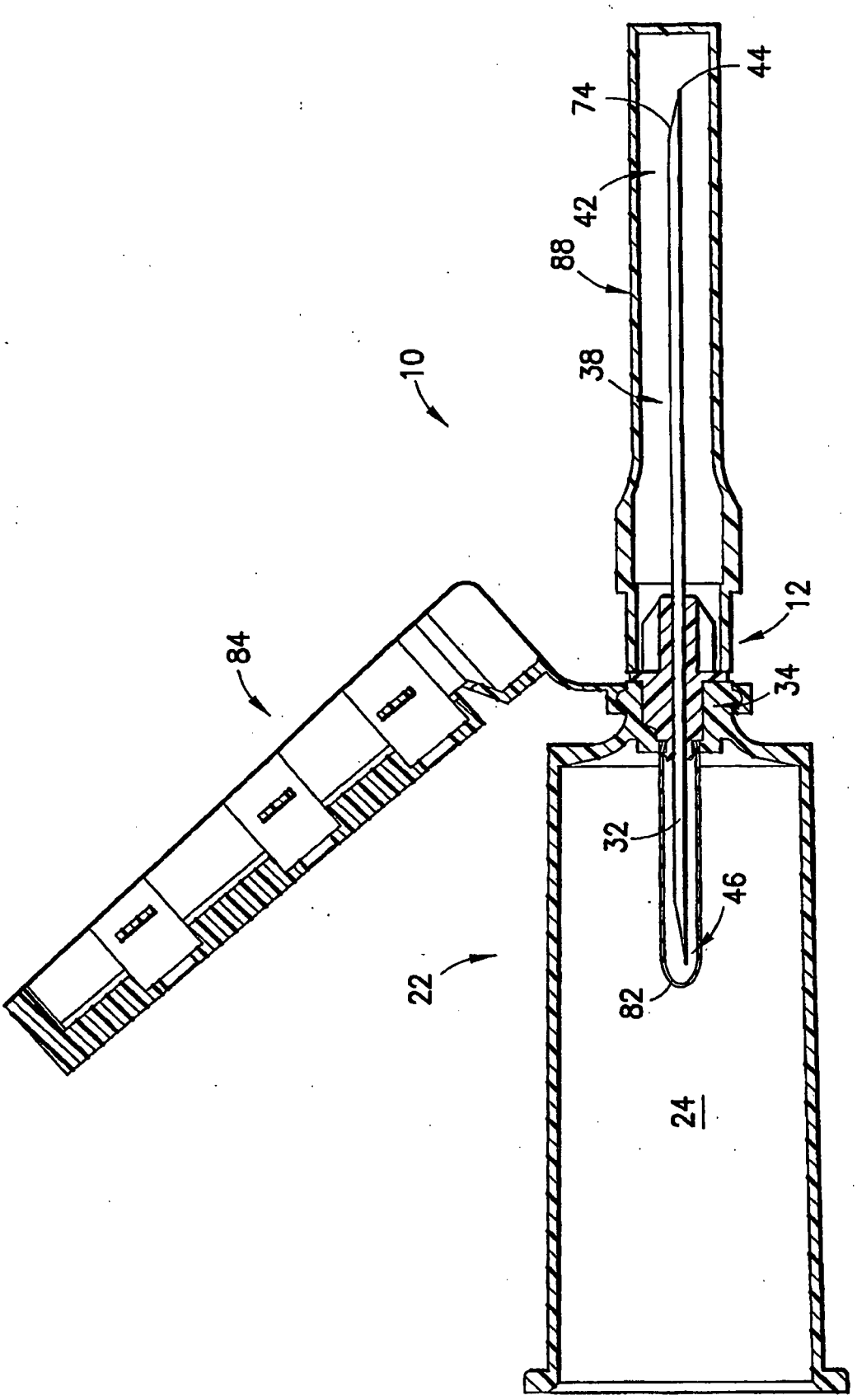

FIG.13

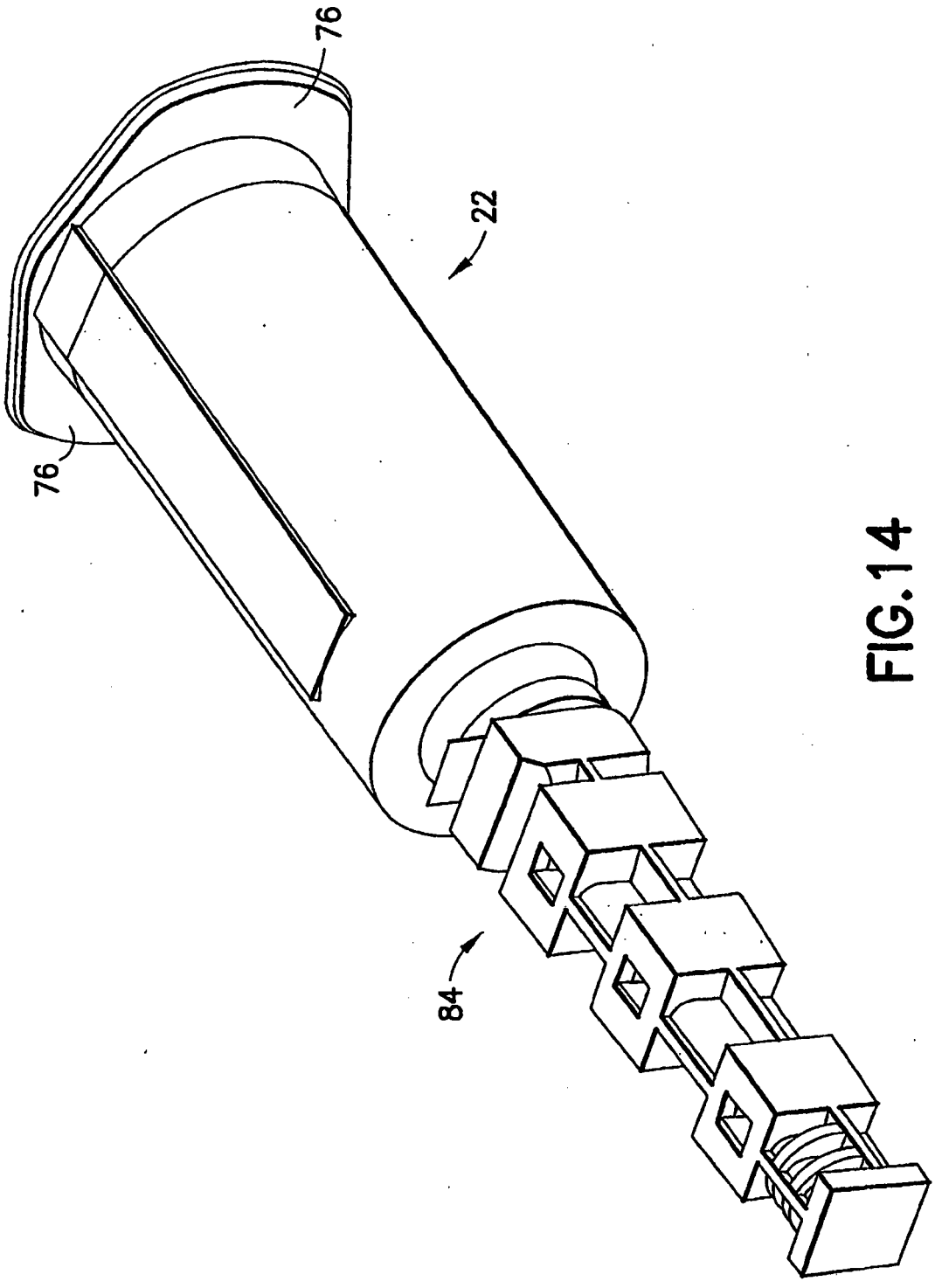

FIG.14

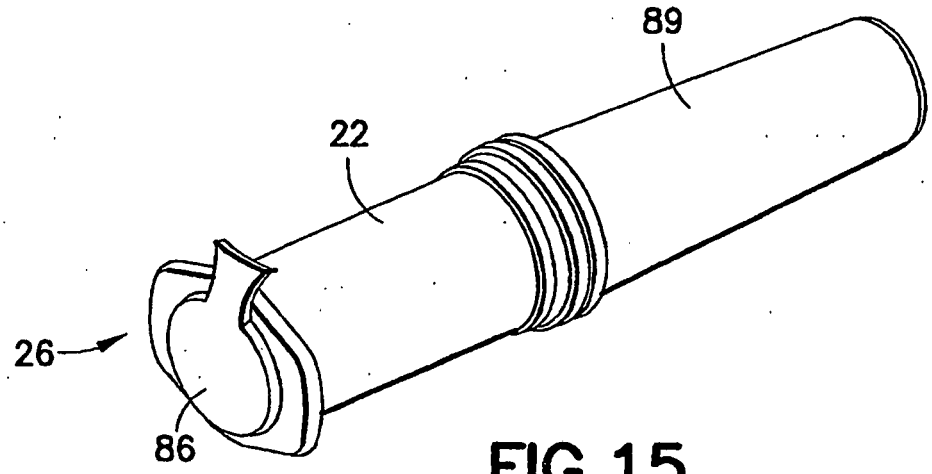

FIG.15

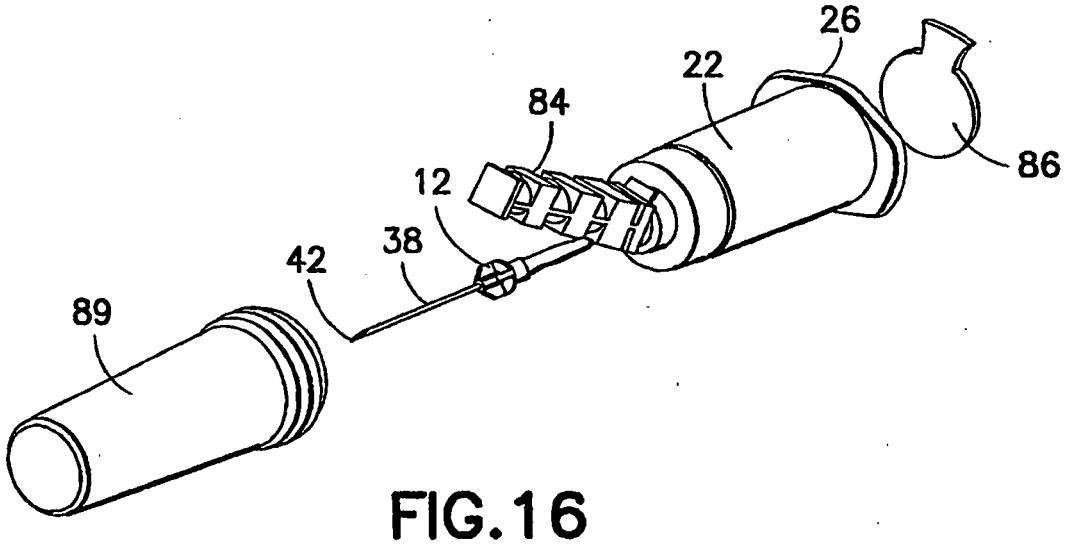

FIG.16

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5066287 A, Ryan **[0004]**
- US 5117837 A, Wanamaker **[0005]**
- US 5066286 A, Ryan **[0006]**
- EP 1433419 A **[0007]**

专利名称(译)	血液采集组件		
公开(公告)号	EP1816947A4	公开(公告)日	2012-08-22
申请号	EP2005773670	申请日	2005-07-20
[标]申请(专利权)人(译)	贝克顿·迪金森公司		
申请(专利权)人(译)	流式细胞Dickinson公司		
当前申请(专利权)人(译)	流式细胞Dickinson公司		
[标]发明人	SWENSON KIRK D		
发明人	SWENSON, KIRK, D.		
IPC分类号	A61B5/00 A61B5/15 A61B5/154 B65D81/00		
CPC分类号	A61B5/15003 A61B5/150267 A61B5/150396 A61B5/150496 A61B5/150572 A61B5/150633 A61B5/150671 A61B5/150732 A61B5/150778 A61B5/150816 A61B5/154 A61M5/348 A61M2205/6045 Y10T29/49826		
代理机构(译)	WEBER，THOMAS		
优先权	60/589294 2004-07-20 US		
其他公开文献	EP1816947B1 EP1816947A2		
外部链接	Espacenet		

摘要(译)

血液采集组件（10）包括毂（12），毂（12）具有远端（14），近端（16），毂外表面（18）和穿过其延伸的内部开口（20）。该组件还包括保持器壳体（22），其限定容纳腔室并具有适于在腔室内接收样品收集管的后端（26）和包括延伸到腔室中的接收端口（30）的前端（28）。其中接收端口在其中接收毂的近端的一部分（54）。毂的内部开口在其近端容纳穿刺元件（38），用于提供穿过其中的流体通道，并且穿刺元件接触样品收集管。轮毂和保持器壳体包括相互接合的结构（60），该结构基本上在其周围延伸，用于将轮毂与保持器壳体轴向锁定。