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An agency of Industry Canada

CA 2852081 A1 2013/04/25

(21) 2 852 081

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(86) Date de dépôt PCT/PCT Filing Date: 2012/10/18
(87) Date publication PCT/PCT Publication Date: 2013/04/25
(85) Entrée phase nationale/National Entry: 2014/04/11
(86) N° demande PCT/PCT Application No.: US 2012/060790
(87) N° publication PCT/PCT Publication No.: 2013/059438
(30) Priorité/Priority: 2011/10/20 (US61/549,550)

(51) Cl.Int./Int.Cl. *A61M 5/315* (2006.01), *A61B 5/15* (2006.01), *A61B 5/153* (2006.01), *A61M 5/50* (2006.01)

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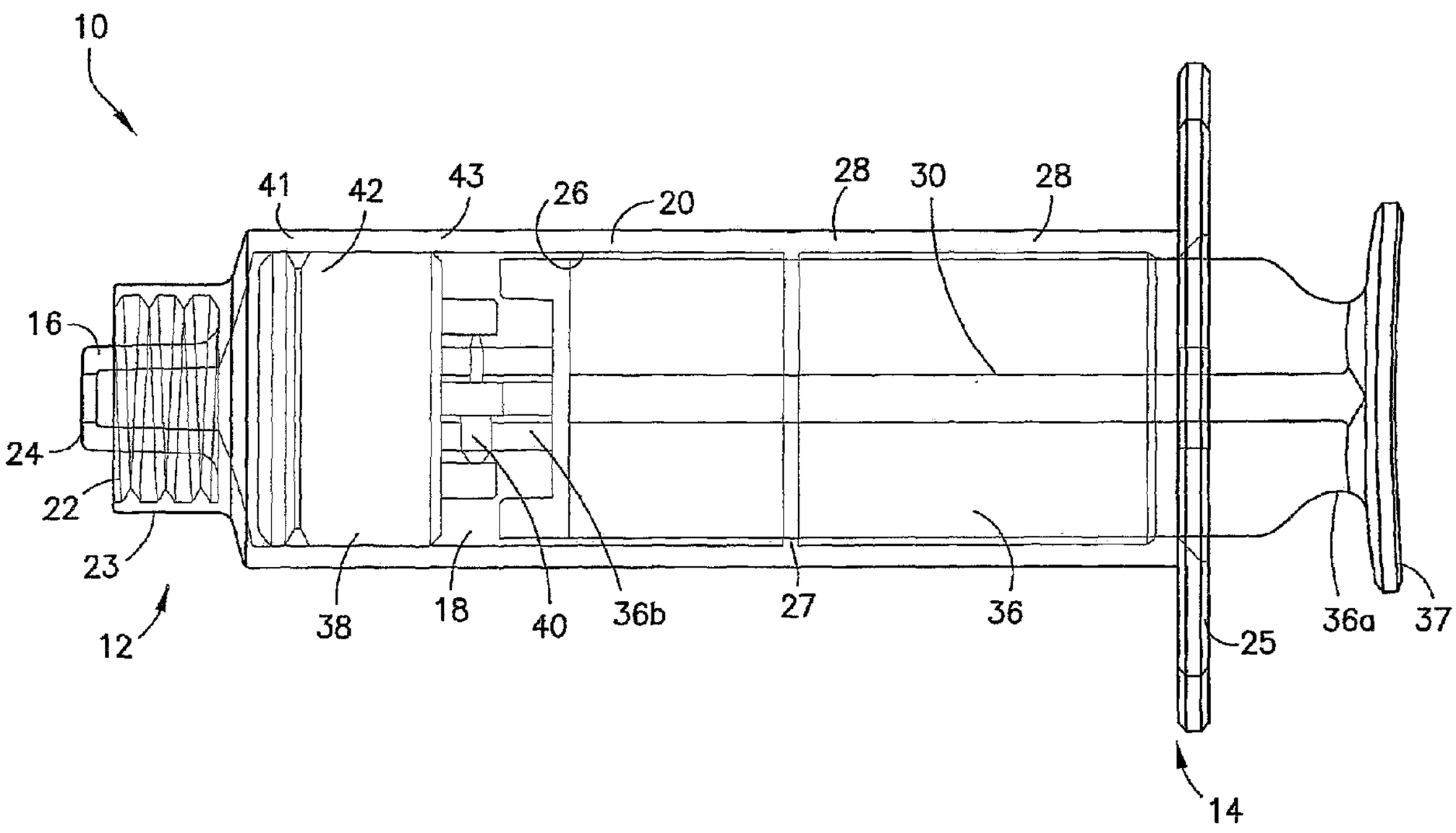
(54) Titre : SERINGUE A PISTON PLONGEUR CASSABLE DE PRELEVEMENT D'ECHANTILLON GAZEUX DE SANG ARTERIEL

(54) Title: SYRINGE WITH BREAKABLE PLUNGER FOR ARTERIAL BLOOD GAS SAMPLE COLLECTION



(57) Abrégé/Abstract:
A fluid collection assembly and method for use thereof is provided including a barrel with a plunger rod slidably inserted is disclosed. The assembly and method are particularly useful in the collection of arterial blood. The plunger rod includes a proximal portion, a distal portion with a stopper, and a breakable connector between the proximal and distal portions. In use, the assembly is primed with a liquid anticoagulant, the breakable connection is broken, and a fluid sample is collected with the arterial pressure causing the distal portion of the plunger rod to travel in a proximal direction along the barrel and contact an annular flange extending within the barrel. After collection, a tip cap can be applied to the assembly to prevent any spillage of the fluid sample during handling, storage, and transportation.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 April 2013 (25.04.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/059438 A1

(51) International Patent Classification:
A61M 5/315 (2006.01) *A61B 5/153* (2006.01)
A61M 5/50 (2006.01) *A61B 5/15* (2006.01)

(21) International Application Number:
PCT/US2012/060790

(22) International Filing Date:
18 October 2012 (18.10.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/549,550 20 October 2011 (20.10.2011) US

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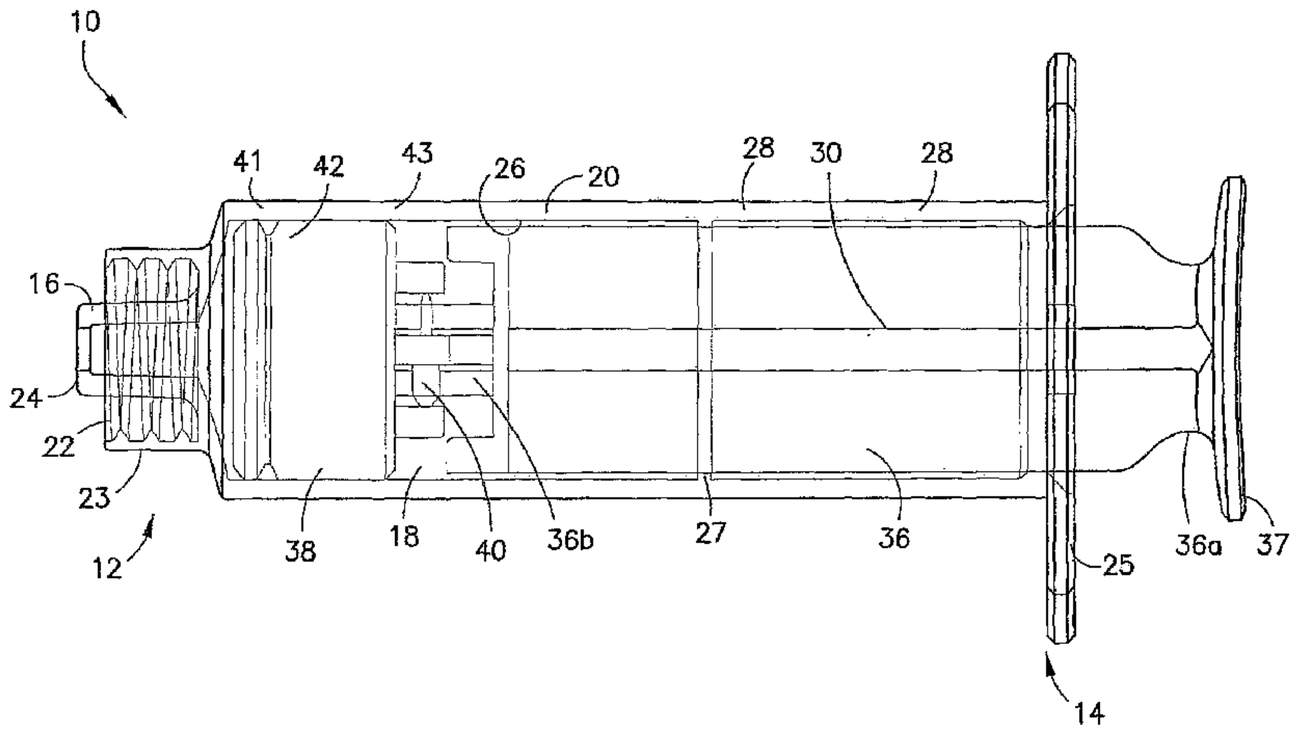
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: SYRINGE WITH BREAKABLE PLUNGER FOR ARTERIAL BLOOD GAS SAMPLE COLLECTION



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SYRINGE WITH BREAKABLE PLUNGER FOR ARTERIAL BLOOD GAS SAMPLE COLLECTION

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention is directed to a fluid collection assembly and methods for use thereof and more particularly, to a fluid collection assembly including a breakable plunger rod for use in arterial blood collection. The present invention is also directed to a fluid collection assembly configured for containing an anti-coagulant for the immediate association with a fluid sample upon collection of the sample.

Description of Related Art

[0002] Arterial blood collection syringes are used for withdrawing and collecting arterial blood samples from the body of a patient. Once the blood sample is collected, it is subjected to diagnostic analysis for gases, electrolytes, metabolites, and other elements that are indicative of a condition of a patient. Various types of syringes have been devised for collecting arterial blood samples, which mainly comprise elements from a hypodermic syringe, i.e., a plastic or glass syringe barrel, a sealing elastomeric stopper, and a plunger rod. Additionally, certain arterial blood collection syringes include a self-sealing filter that allows passage of air out of the syringe during blood collection, while still preventing the passage of blood. This latter type of syringe having a filter allows for an arterial sample to be collected without the need to aspirate the syringe, as is required with a syringe having a plunger rod and a plunger stopper.

[0003] Typical arterial blood collection syringes include a two-piece plunger rod assembly comprised of an elastomeric sealing stopper attached to a plunger rod. United States Patent No. 5,314,416 to Lewis et al. discloses a low friction syringe assembly having a typical two-piece plunger rod and a plunger tip assembly. The sealing stopper and plunger rod must be assembled together in a separate operation prior to assembly with a syringe barrel. In addition, a silicone lubricant is usually used on the interior wall of the syringe barrel to facilitate easy slidable movement of the elastomeric sealing stopper against the interior wall of the syringe barrel. Such syringes typically involve an active step for obtaining a blood sample. For example, a needle connected to such a syringe accesses a patient's blood vessel, and the syringe is thereafter aspirated by the user holding the syringe with one hand and

drawing the plunger rearwardly within the syringe barrel with the other hand so as to draw a blood sample into the syringe barrel for analysis. The need for the user to use two hands during the blood sample collection introduces unnecessary movement during the blood draw process and might cause discomfort to the patient.

[0004] Arterial blood samples can also be obtained passively through the use of a syringe having a plunger with a porous filter to collect blood by way of the blood pressure of a patient from whom the blood is being collected. In such a syringe, the plunger mechanism is typically hollow, and includes a porous filter therein. A separate elastomeric sealing stopper is typically attached to the front end of the plunger mechanism for sealing within the syringe barrel, with air channels in the stopper for air passage through the filter. In use, the plunger is set at a certain position against a graduated scale of the syringe barrel, so that the desired volume of the sample to be collected is represented by the cavity within the syringe. Once a blood vessel of a patient is accessed by an appropriate needle attached to the syringe, arterial blood will fill the syringe under its own pressure. As the cavity within the syringe fills, air within the syringe is allowed to escape from the syringe by way of a gas permeable filter. When the blood sample contacts the filter, the filter seals, thereby preventing escape of blood and ingress of air and other contaminants into the collected sample. United States Patent No. 4,821,738 to Iwasaki et al. discloses an arterial blood gas syringe including a typical two-piece assembly for use. The arterial blood gas syringe is comprised of a plunger rod and an elastomeric sealing plug having channels formed in an upper surface for use in removing air as arterial blood is received in the syringe. The channels extend in a generally radial direction and converge near the center of a sealing plug to allow the passage of air to and through a filter element contained within the sealing plug. United States Patent Nos. 5,377,689 and 5,529,738, both to Mercereau, disclose a sampling syringe including a plunger cap having an air permeable filter attached to a plunger rod, which is in slidable communication with the inner wall of a syringe barrel. However, the arterial blood collected using this type of syringe is exposed to air within the barrel interior of the syringe during the blood collection. This can affect the accuracy of the arterial blood gas analysis since oxygen and carbon dioxide can migrate into or out of the arterial blood sample depending on the partial pressure of gases in the arterial blood relative to atmospheric air.

[0005] After completion of the blood sample collection, the needle is removed and the syringe containing the collected blood sample is then transported to the laboratory. Typically blood samples collected in blood collection tubes are transported through pneumatic tubes between the ward and laboratory. However, the plunger that is protruding from the syringe

barrel makes handling and transportation of the syringe difficult and special care has to be taken not to dislodge the plunger thus preventing pneumatic tube transportation and increasing the time and resources required to transport and analyze the collected blood sample.

[0006] Attempts have been made to prevent the re-use of syringes by providing breakable plunger rods as part of the syringe assembly, examples of which being disclosed in United States Patent Number 6,217,550 (Capes), the entire content of which is incorporated herein by reference and in United States Patent Publication Number US 2006/0178625 (Lim et al.), the entire content of which is also incorporated herein by reference. Such breakable plunger rod assemblies provide a breakable connection between the main body of the plunger rod and the proximal distal portion. Such breakable connections possess sufficient structural integrity to resist breakage during normal use, but break upon application of additional force. Thus, after injection of the liquid contents of the syringe into a patient or into a suitable container or device such as through the pierceable septum of a catheter connector, a user applies additional force on the thumb press of the plunger rod. This additional force causes the breakable connection to shear, mechanically disconnecting the main body of the plunger rod from the distal portion, and hence disabling further use of the syringe.

[0007] It would therefore be desirable to provide an arterial blood collection syringe or assembly and method of use thereof which enables a single-handed blood collection technique, which does not expose the collected blood to atmospheric air prior to analysis for blood gas levels and allows the plunger to be removed to facilitate easier handling and transportation of the collected sample.

SUMMARY OF THE INVENTION

[0008] According to a first aspect, the invention is directed to a fluid collection assembly having a barrel having a proximal end, a distal end, and a sidewall extending between the proximal end and the distal end. The sidewall includes an internal surface defining an internal chamber. The fluid collection assembly also includes a stopper disposed within the barrel, a plunger rod having a proximal portion and a distal portion associated with the stopper, and a breakable connector joining the proximal portion and the distal portion of the plunger rod. The connector is adapted to break upon application of a breaking force to the plunger rod. An annular flange is provided that extends from the internal surface into the

chamber which is configured to limit proximal movement of the stopper. The internal surface of the barrel is configured for slidably receiving the stopper in fluid tight engagement therewith.

[0009] The proximal end of the barrel, at least a portion of the internal surface of the sidewall, and the stopper define an internal reservoir configured for holding at least one of a fluid treatment additive, such as anticoagulants, clotting agents, stabilization additives, and the like and a fluid sample, such as arterial blood. The proximal end of the barrel includes structure for cooperating with a medical device. One example of a medical device that can be used with the fluid collection assembly can be a needle assembly having a lumen and wherein prior to collection of a fluid sample, the plunger rod is configured to prime the lumen and the internal reservoir with the fluid treatment additive and to remove any atmospheric air therefrom. The stopper has a distal face which can be configured to cooperate with an internal proximal surface of the barrel to minimize an amount of dead space within the reservoir. The proximal portion of the plunger rod can include a thumb flange and the stopper can be a low resistance stopper. The assembly can further include a tip cap configured to cooperate with the distal end of the barrel.

[0010] After the lumen and the internal reservoir are primed and the collection assembly is ready for use, an application of a breaking force is applied to the plunger rod to disconnect the proximal portion of the plunger rod from the connector and from the distal end of the plunger rod. The proximal portion of the plunger rod is then removed from the assembly. Upon collection of a fluid sample, such as upon insertion of the needle cannula in a patient's artery, the force of the blood filling the reservoir causes the stopper and distal end of the plunger rod to move in the proximal direction during collection. The annular flange extending from the internal sidewall of the barrel is configured to limit proximal movement of the stopper after application of this breaking force to the plunger rod and during the collection of a fluid or blood sample. The tip cap can be applied to the distal end of the barrel to prevent any spillage of the fluid sample during handling, storage, and transportation.

[0011] Generally, the present invention is directed to a method of collecting an arterial blood sample including the steps of providing a collection assembly, priming the collection assembly with a liquid anticoagulant, activating the breakable connection, and collecting a blood sample, wherein the arterial pressure during blood collection causes the stopper and the distal portion of the plunger rod to travel in a proximal direction along the barrel. Specifically, the invention is directed to a method of collecting a fluid sample including providing a fluid collection assembly having a barrel having a proximal end, a distal end, and

a sidewall extending between the proximal end and the distal end, wherein the sidewall includes an internal surface defining an internal chamber, and a distal tip extending from the distal end having a passageway therethrough in fluid communication with the internal chamber. The fluid collection assembly also includes a stopper disposed within the barrel, a plunger rod having a proximal portion and a distal portion associated with the stopper, and a breakable connector joining the proximal portion and the distal portion of the plunger rod, wherein the connector is adapted to break upon application of a breaking force to the plunger rod. According to one embodiment, a needle assembly can be attached to the distal tip of said barrel. The method further includes priming the fluid collection assembly with a fluid treatment additive, breaking the breakable connector, and introducing the fluid sample into the internal chamber. The fluid sample can be a blood sample, such as arterial blood and the treatment additive can be any known blood treatment material such as an anticoagulant, a clotting agent, a stabilization additive, and the like. According to one embodiment, the fluid treatment additive can be in liquid form and can be an anticoagulant.

[0012] According to one embodiment, the proximal end of the barrel, at least a portion of the internal surface of the sidewall, and the stopper can define an internal reservoir. The step of priming the fluid collection assembly further comprises drawing a liquid anticoagulant into the internal reservoir and expelling air from the internal reservoir, the passageway, and a lumen of the needle assembly. The step of breaking the breakable connector includes exerting a force in a distal direction on the plunger rod a sufficient amount to cause the proximal portion to mechanically disconnect from the distal portion, and removing the proximal portion from the blood collection assembly.

[0013] The step of introducing the fluid sample can include inserting a distal end of the needle assembly into a source, such as a patient's artery, to cause fluid or blood to flow into the internal reservoir wherein the force of the fluid flow causes the stopper and the distal portion of the plunger rod to travel through the internal chamber toward the proximal end of the barrel until the stopper and the distal portion of the plunger rod contact an annular flange extending inwardly from the internal surface of the barrel sidewall and into the internal chamber of the barrel. After completion of fluid collection, the method further includes removing the distal end of the needle assembly from the fluid source or patient, removing the needle assembly from the distal tip of the barrel, and attaching a tip cap to the distal tip of the barrel to prevent any spillage of the fluid sample during handling, storage, and transportation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** is a schematic partially cross-sectional side view of a fluid collection assembly in accordance with an embodiment of the present invention.

[0015] **FIG. 2** is a schematic cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** in accordance with an embodiment of the present invention.

[0016] **FIG. 3** is a schematic partially cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** during the drawing of liquid anticoagulant into the fluid collection assembly in accordance with an embodiment of the present invention.

[0017] **FIG. 4** is a schematic partially cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** during the activation of the breakable connection in accordance with an embodiment of the present invention.

[0018] **FIG. 5** is a schematic partially cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** after activation of the breakable connection and prior to collection of a blood sample in accordance with an embodiment of the present invention.

[0019] **FIG. 5A** is a schematic partially cross-sectional enlarged partial view of the distal end of the plunger rod of the fluid collection assembly as shown in **FIG. 5** in accordance with an embodiment of the present invention.

[0020] **FIG. 6** is a schematic partially cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** upon completion of collection of a fluid sample in accordance with an embodiment of the present invention showing a portion of the sidewall removed.

[0021] **FIG. 7** is a schematic partially cross-sectional side view of the fluid collection assembly as shown in **FIG. 1** when prepared for transportation and testing in accordance with an embodiment of the present invention showing a portion of the sidewall removed.

[0022] **FIG. 8** is an enlarged partially cross-sectional side view of the distal end of the plunger rod of a fluid collection assembly in accordance with an embodiment of the present invention.

[0023] **FIG. 9** is an enlarged partially cross-sectional side view of the distal end of the plunger rod of a fluid collection assembly in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0024] For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives

thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices 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.

[0025] As used herein, the term "proximal" refers to a location on the blood collection assembly according to the embodiments of this invention that, during normal use, is closest to the clinician using the device and farthest from the patient in connection with whom the device is used. Conversely, the term "distal" refers to a location on the blood collection assembly of this invention that, during normal use, is farthest from the clinician using the device and closest to the patient in connection with whom the device is used. Furthermore, the term "proximal direction" indicates a direction of movement away from the patient and toward the user of the blood collection assembly, whereas the term "distal direction" indicates a direction of movement away from the user of the blood collection assembly and toward the patient.

[0026] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, **FIGS. 1-7** illustrate a fluid collection assembly, generally illustrated as **10**. According to one embodiment, the fluid collection assembly **10** can comprise an arterial blood collection assembly and thus, the present invention is generally described in terms of an arterial blood collection assembly. The fluid collection assembly includes a plunger rod **30** in slidable communication with a barrel **20** having a standard luer fitting **23** at a distal end **12** for connection to an arterial access device, such as a needle assembly, generally indicated as **50**. While described herein in terms of an arterial blood collection assembly **10** intended for use with a needle assembly **50**, the assembly **10** of the present invention may be used with or may incorporate other medical devices, such as another medical device assembly that includes a piercing element or allows for attachment to a catheter.

[0027] With continuing reference to **FIGS. 1** and **2**, the fluid collection assembly **10** includes a barrel **20**, which can be an elongated, hollow, cylindrically-shaped tube having an open proximal end **14**, a generally closed distal end **12**, and a rigid tubular sidewall **28** extending between the proximal end **14** and the distal end **12**. The sidewall **28** includes an internal surface **26** defining an internal chamber **18**.

[0028] Barrel **20** may be made of one or more than one of the following representative materials: polypropylene, polyethylene, polyethyleneterephthalate (PET), polystyrene, polycarbonate, cellulosics, glass products, or combinations thereof. More expensive plastics such as polytetrafluoroethylene and other fluorinated polymers may also be used. In addition to the materials mentioned above, examples of other suitable materials include polyolefins, polyamides, polyesters, silicones, polyurethanes, epoxies, acrylics, polyacrylates, polysulfones, polymethacrylates, PEEK, polyimide and fluoropolymers such as PTFE Teflon®, FEP Teflon®, Tefzel®, poly(vinylidene fluoride), PVDF, and perfluoroalkoxy resins. One exemplary glass product is PYREX® (available from Corning Glass, Corning, New York). Ceramic collection devices can be used according to embodiments of the invention. Cellulosic products such as paper and reinforced paper containers can also be used to form collection devices according to the invention.

[0029] Referring back to **FIGS. 1** and **2**, the fluid collection assembly also includes a stopper **38** located within the barrel **20**, a plunger rod **30** having a proximal portion **36** and a distal portion **34** associated with the stopper **38**, and a connector **40** joining the proximal portion **36** and the distal portion **34** of the plunger rod **30**. The connector **40** is adapted to break or collapse upon application of a breaking force to the plunger rod **30**. The internal surface **26** of the barrel **20** is configured for slidably receiving the stopper **38** in fluid tight engagement therewith and for receiving the breakable or collapsible plunger rod **30**. The stopper **38** is slidably positioned in fluid tight engagement with the internal surface **26**, and is able to slide distally and proximally along a longitudinal axis **32**. According to one embodiment, the stopper **38** may be a separate element connected to the distal portion **34** of the plunger rod **30**. Alternatively, the stopper **38** may be integrally molded with the distal portion **34** in a one-piece plastic construction.

[0030] According to an embodiment of the invention as shown in **FIGS. 2** and **3**, stopper **38** encloses a portion of an external surface **31** and a distal face **33** of distal portion **34**. Stopper **38** may be separately attached to distal portion **34**, or may be integrally molded over the external surface **31** and distal face **33** of distal portion **34** of plunger rod **30**. The diameter of stopper **38** is approximately equal to or only slightly bigger or smaller than that of an internal diameter **29** of the barrel **20** but is greater than an internal diameter **17** of an annular flange **27**. Stopper **38** is in slidable contact with internal surface **26** of barrel **20** and provides a fluid-tight seal between the plunger rod **30** and the internal surface **26** of the barrel **20** so that a sample can be held within an internal reservoir **13** formed within the chamber **18**

between distal end **12** of barrel **20** and distal face **33** of plunger rod **30**, thereby preventing the sample from leaking from assembly **10**.

[0031] With reference to **FIG. 6**, according to one embodiment, stopper **38** can be a low resistance stopper and as such is designed to have a relatively lower frictional resistance to movement inside of barrel **20** when compared to similar components in prior art arterial blood gas syringes such that the presence of arterial blood pressure within internal reservoir **13** will cause the distal portion **34** to slide/travel in a proximal direction toward the proximal end **14** of barrel **20** until the distal portion contacts annular flange **27** thereby limiting the proximal movement of distal portion **34**. The frictional resistance of a stopper can be lowered by either the stopper sealing profile design and/or the component material selection. In the embodiment shown in **FIG. 1**, first and second sealing rings **41**, **42** extend around the outer circumferential surface of stopper **38** near to distal face **33** to create a primary and secondary seal with internal surface **26** of barrel **20**. A third sealing ring **43** can be provided which forms a third seal and assists in the stabilization of the distal portion **34**, thereby centralizing the plunger rod **30** during slidable movement of the plunger rod **30** relative to the barrel **20**. This stopper sealing profile design lowers the amount of contact between stopper **38** and internal surface **26** thereby reducing the frictional resistance to movement of stopper **38** when compared to a stopper sealing profile in which the entire outer circumferential surface is in contact with internal surface **26**. Alternately or in combination with the stopper sealing profile design, stopper **38** is preferably made of an elastomeric material such as natural rubber, synthetic rubber, thermoplastic elastomers and combinations thereof which are formulated or synthesized to be self-lubricating or have relatively lower frictional resistance. Stopper **38** may also be made from a combination of elastomers which include a harder inner rubber core and a soft "Epilor" outer layer.

[0032] Plunger rod **30** can be constructed of a suitable polymeric material, and may be manufactured by injection molding with a suitable polymer material known in the art. It is within the purview of the present invention to include plunger rods and stoppers which are separately formed or integrally formed of the same material or different materials such as in two-color molding, or separately formed of the same or different materials and joined together by mechanical means, adhesives, ultrasonic welding, heat sealing or other suitable means.

[0033] The breakable/collapsible connector **40** is strong enough to hold the proximal portion **36** and the distal portion **34** of the plunger rod **30** together during normal use of the fluid collection assembly **10** and is breakable upon application of a breaking force to the

proximal portion **36** of the plunger rod **30**. In particular, the breakable connection **40** is manufactured to withstand typical-use shear forces generated when a user draws fluids into the fluid passageway, or expels them through an opening **24** during normal use in medical procedures. However, upon the application of a certain breaking force indicated by arrow **B** in **FIG. 4**, the breakable connection **40** activates and breaks. The breaking force should not be so small as to risk unintentional activation of breakable connection **40** during application of force during normal use or during assembly of the assembly **10**, nor too great as to place undue strain on the user. Accordingly, when a user presses down upon a thumb flange **37** with the intent to disable the syringe function of the arterial blood collection assembly **10**, proximal portion **36** mechanically disconnects from distal portion **34**. Thus, the breaking force is the total force that includes the force applied under normal use plus some additional force required to break the breakable connection. Useful breakable or collapsible plunger rods are found, for example, in U.S. Patents Nos. 6,217,550; 7,798,993; and U.S. Patent Publication Nos. US 2006/0195063 and US 2004/0064105 the contents of which are hereby incorporated by reference in their entirety.

[0034] The breaking force depends on various dimensions of the syringe barrel **20** and plunger rod **30**, the viscosity of the liquid being delivered and the mechanical and hydraulic forces encountered by the filling and delivery process. If the breakable connection **40** is too weak, the proximal portion **36** and distal portion **34** will separate during assembly or normal use of the collection assembly **10**, and if the force required to break the breakable connection **40** is too high the user may not be able to easily break the breakable connection **40** as intended. The skilled artisan can select the appropriate materials and/or connections to provide the proper breaking force to cause the connection to break and the plunger rod **30** to collapse for a particular collection assembly design and/or use.

[0035] With particular reference to **FIG. 2**, a plurality of breakable connections **40** can be provided connecting the proximal portion **36** and the distal portion **34** of the plunger rod **30**. These connections **40** may connect the proximal portion **36** of the plunger rod **30** and the distal portion **34** of the plunger rod **30** at a breakable connection point **40a**. The connections **40** can be in the form of protuberances extending in a transverse direction with respect to a longitudinal axis of the plunger rod **30**. Alternatively, the breakable connection **40** can be in the form of a circular shaped projection or protuberance which is configured to fit into a cylindrically shaped recess in the distal portion **34** of the plunger rod **30**.

[0036] With continuing reference to **FIG. 2**, according to one embodiment, the connection **40** may be molded integrally with the proximal portion **36** and the distal portion **34** of the

plunger rod **30**. A wide variety of plastic materials are suitable for molding the plunger rod **30** including polystyrene, polypropylene, and polyethylene. When molding, the modulus of elasticity of the material selected to form the connection **40** must be controlled to ensure that the breakable connection breaks or fails before the proximal portion **36** bottoms out or makes contact with the distal portion **34** of the plunger rod **30**. If the modulus is too high, the break will occur too easily, causing premature breakage. If the modulus is too low, the breakable connection may not break before the proximal portion and the distal portion contact each other. According to one embodiment, it is desirable to have a modulus of elasticity within the range of about 800 MPa to 4000 MPa.

[0037] The breakable connection point **40a** can be located anywhere along the protuberance of the connection **40** depending upon the geometry of the protuberance. As discussed above, the connection **40** can be integrally molded with the plunger rod. According to another embodiment, the connection **40** can be connected to one or both of the proximal portion **36** or the distal portion **34** with a frangible adhesive. The connection **40** can be very short and made entirely of adhesive or frangible material. According to yet another embodiment, the connection **40** can be made using a shear pin passing through the distal end **36b** of the proximal portion **36** and through the distal portion **34** of the plunger rod **30**. According to still another embodiment, the breakable connection **40** can be accomplished by using a snap-fit arrangement, a portion of which is damaged or broken when the desired force is applied. In this situation, the distal portion **34** and the proximal portion **36** can be individually molded and snapped together during the assembly process.

[0038] A proximal end **36a** of the proximal portion **36** may include a thumb flange **37** that a user may push to move the plunger rod **30** and stopper **38** distally, or pull to move the plunger rod **30** and stopper **38** proximally in relation to barrel **20**. By moving the plunger rod distally, the stopper **38** may force fluids out of the fluid passage way through opening **24** in the distal tip **16**. By moving proximally, the stopper **38** may draw fluids through the fluid passageway and into chamber **18**. The flange **37** also facilitates the application of a force to the plunger rod **30** to break the breakable connection **40**, such as by the application of a distal force thereto, as described in further detail below. An external flange **25** can also be provided at the proximal end **14** of the barrel **20** to facilitate handling of the fluid collection assembly **10** and for applying forces to the plunger rod **30** using a one-handed procedure.

[0039] An annular flange **27** is provided that extends from the internal surface **26** into the chamber **18** which is configured to limit proximal movement of the stopper **38** and the distal portion **34** of the plunger rod **30**. The internal surface **26** of the barrel **20** is configured for

slidably receiving the stopper **38** in fluid tight engagement therewith. The annular flange **27** has a diameter **17** that is less than diameter **29** of the barrel **20**.

[0040] The proximal end **14** of the barrel **20**, at least a portion of the internal surface **26** of the sidewall **28**, and a distal face **39** of the stopper **38** define an internal reservoir **13** configured for holding at least one of fluid treatment additive **45**, as shown in **FIG. 5A**, as required for particular testing procedures, such as anticoagulants, clotting agents, stabilization additives, and the like and a fluid sample, such as arterial blood. The anticoagulants may include hirudins, hirudin derivatives, chelating agents, or chelating agent derivatives. Specific anticoagulants include citrate, ethylenediaminetetraacetic acid (EDTA), heparin, CPAD, CTAD, CPDA-1, CP2D, potassium oxalate, sodium fluoride, or ACD. The anticoagulant used is liquid in form to improve the incorporation hence effectiveness of the anticoagulant upon collection of arterial blood. The liquid form can be an emulsion, solution, or dispersion of the anticoagulant in a suitable carrier. Typically prior art arterial blood sample collection methods use an arterial blood gas syringe preloaded upon manufacture with a solid form of anticoagulant such as heparin powder within the syringe barrel in order to maximize the shelf life of the syringe. The use of a solid form of anticoagulant can cause a reduction in the effectiveness of the anticoagulant as the incorporation of powdered heparin into the blood sample is difficult due to lack of agitation during the arterial blood collection process. The clotting agent may be kaolin or thrombin or silica based. Such additives may be in particle or liquid form and may be sprayed onto the internal surface **26** of the barrel **20** or located within fluid reservoir **13**.

[0041] With particular reference to **FIGS. 2-6**, the proximal end **14** of the barrel **20** includes structure for cooperating with a medical device. It will be appreciated by those skilled in the art that distal tip **16** of the blood collection assembly **10** may be releasably or permanently connected to the needle assembly **50** via a hub fitting **56** as is known in the art. Such needle assemblies include, but are not limited to, luer lock type needle assemblies and luer slip type needle assemblies. For example, a standard luer fitting including a male luer taper **21** and an internally threaded luer lock **22** may be provided at the distal end **12** of barrel **20**, as shown in **FIG. 2**, for removably receiving a corresponding fitting of an arterial access device. More particularly, an arterial access device such as a needle assembly **50** as shown in **FIGS. 3-6** may include a needle cannula **53** having a proximal end and a distal end **52** and an interior lumen **55** extending therebetween as shown in **FIG. 5A**. The distal end **52** defines a needle cannula **53** beveled at the distal end **52** to define a sharp puncture tip **54** for intravenous puncture into the blood vessel of a patient, such as an artery. Puncture tip **54** is

designed to provide ease in insertion and minimal discomfort for the patient during arterial access. The proximal end **51** of needle assembly **50** is contained within the hub fitting **56**. The hub fitting **56** includes an internal female luer taper and a pair of opposing flanges. In this manner, needle assembly **50** can be releasably attached to the distal end **12** of barrel **20** by the corresponding interfitting engagement between male luer taper **21** and female luer taper of the hub fitting **56**, as well as through the locking engagement between luer flanges and luer lock **22**, as is well known in the art. As such, fluid communication can be established between the interior lumen **55** of needle cannula **53** and chamber **18** of collection assembly **10**.

[0042] Assembly of the arterial blood collection assembly **10** is accomplished by slidably inserting plunger rod **30** within chamber **18** through proximal end **14** of barrel **20**. Breakable connection **40** has sufficient strength such that stopper **38** can be forced through annular flange **27** without the activation thereof. The assembly can then be packaged for later use. When assembled as such, fluid communication is generally established throughout the length of the assembled arterial blood collection assembly **10**. Specifically, fluid communication is provided through opening **24** at the front or distal end of barrel **20** (and likewise through needle cannula **53** attached thereto), into chamber **18**, and more particularly the fluid reservoir **13**, in barrel **20**.

[0043] In use, the fluid collection assembly **10**, according to an embodiment of the invention, is attached to needle assembly **50**. Prior to collection of a fluid sample, the plunger rod **30** is configured to prime the lumen **55** and the internal reservoir **13** with the fluid treatment additive **45**, as shown in **FIG. 5A**, and to remove any atmospheric air therefrom. The stopper **38** has a distal face **39** which can be configured to cooperate with an internal proximal surface **12a**, as shown in **FIG. 2**, of the barrel **20** to minimize an amount of dead space within the reservoir **13**. After the lumen **55** and the reservoir **13** are primed and the collection assembly **10** is ready for use, an application of breaking force is applied to the plunger rod **30** to disconnect the proximal portion **36** of the plunger rod **30** from the connector **40** and from the distal end **34** of the plunger rod **30**. The proximal portion **36** of the plunger rod **30** is then removed from the fluid collection assembly **10**. Upon collection of a fluid sample, such as upon insertion of the needle cannula **53** in a patient's artery, the force of the blood **46**, as shown in **FIGS. 6** and **7**, filling the reservoir **13** causes the stopper **38** and distal portion **34** of the plunger rod **30** to move in the proximal direction during collection. The annular flange **27** extending from the internal surface **26** of the sidewall **28** of the barrel

20 is configured to limit proximal movement of the stopper **38** after application of this breaking force to the plunger rod **30** and during the collection of a fluid or blood sample.

[0044] According to one embodiment, the fluid collection assembly can be primed by drawing a liquid anticoagulant **45**, such as heparin, from a vial, ampoule, or other suitable container using known safe procedures into fluid reservoir **13** of arterial blood collection assembly **10** by pulling the plunger rod **30** in a proximal direction indicated by arrow **A** as shown in **FIG. 3**. Air is then expelled from the fluid reservoir **13** and needle lumen by the standard techniques known in the art, e.g., holding the assembly **10** in a vertical orientation with the distal end **52** of needle cannula **53** in an upward direction and one's flicking fingers against the barrel wall **28**, then pressing plunger rod **30** in a upward or distal direction to expel any air present.

[0045] According to embodiments of the invention, plunger rod **30** can be moved back and forth along the barrel **20** as many times as necessary to properly fill the barrel **20** without activation of breakable connection **40**. For example, the barrel **20** may be filled with sterile water and then the sterile water can be injected into a vial containing a lyophilized medication which is then drawn back into the barrel **20**. Many single-use syringes in the prior art only allow one proximal motion of the plunger with respect to the barrel. With these single-use syringes, once the plunger is moved in a distal direction with respect to the barrel it can no longer be withdrawn. Therefore, repeated distal and proximal movements of the plunger as described above are not possible.

[0046] A user then presses down upon thumb flange **37** with sufficient force in a distal direction until the breakable connection **40** activates and the proximal portion **36** mechanically disconnects from distal portion **34**. The proximal portion **36** can then be separated from the distal portions as shown in **FIGS. 4-5**. With the residual liquid anticoagulant **45** present in a remaining dead space **44** within the fluid reservoir, the opening **24** in tip **16** and the lumen **55** of the needle **53** (as shown in **FIG. 5A**) should be at a concentration so as to provide sufficient anticoagulant function to prevent the clotting of the arterial blood sample upon collection. The assembly **10** is now primed with liquid heparin.

[0047] The purpose of priming assembly **10** with anticoagulant is to remove any atmospheric air, so that the partial pressure of the oxygen in the arterial blood sample will not be affected by the atmospheric air. The assembly **10** should preferably have low dead space to keep the residual volume of the heparin low in order to minimize the dilution effect of the liquid heparin on the blood sample.

[0048] Reference is now made to **FIGS. 8** and **9**, which show two stopper profiles designed to reduce the amount of residual liquid anticoagulant present after activation of breakable connection **40**. **FIG. 8** shows a stopper **138** with a finger **139** extending in a distal direction from the center of a distal face **133**. The shape of finger **139** is designed to mate with an inner surface **140** of a fluid pathway **124** in order to displace any liquid present in fluid passage **124** upon activation of breakable connection. **FIG. 9** shows a stopper **238** with a distal face **233** having a conical profile **239** which is shaped to mate with a distal internal surface **240** of a barrel **220** thereby minimizing the dead space that could occur within the fluid reservoir.

[0049] As discussed above, the present invention is directed to a method of collecting an arterial blood sample including the steps of providing a collection assembly, priming the collection assembly with a liquid anticoagulant, activating the breakable connection, and collecting a blood sample wherein the arterial pressure during blood collection causes the distal portion of the plunger rod to travel in a proximal direction along the barrel.

[0050] A method of blood collection according to an embodiment of this invention enables a single-handed technique in the blood collection process using a low resistance rubber stopper that is moved by the arterial pressure. The user grips assembly **10** as shown in **FIG. 5** with one hand and inserts puncture tip **54** into the artery. Blood at arterial pressure (which is greater than normal atmospheric or ambient pressure) will then flow through lumen **55**, opening **24** in tip **16** and into the fluid reservoir **13**, and forces stopper **38** to slide in proximal direction until the proximal face contacts flange **27** thereby defining the completion of the collection volume of the blood sample. The puncture tip **54** is then removed from the artery. The sliding motion of the rubber stopper **38** allows the liquid anticoagulant **45** and the collected arterial blood **46** to mix during the collection process, as shown in **FIG. 6**. Needle assembly **50** is then carefully replaced with a tip cap **47** that is compatible with luer connection as shown in **FIG. 7** to prevent any spillage of the blood sample during handling, storage, and transportation. The blood collection assembly **10** containing the aseptic arterial blood sample as shown in **FIG. 7** is then ready for transportation to the laboratory for Arterial Blood Gas analysis.

[0051] While the present invention is satisfied by embodiments in many different forms, there is shown in the drawings and described herein 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.

WHAT IS CLAIMED IS:

1. A fluid collection assembly comprising:

a barrel having a proximal end, a distal end, and a sidewall extending between the proximal end and the distal end, said sidewall including an internal surface defining an internal chamber;

a stopper disposed within the barrel;

a plunger rod having a proximal portion and a distal portion associated with the stopper;

a breakable connector joining the proximal portion and the distal portion of the plunger rod, said connector adapted to break upon application of a breaking force to the plunger rod; and

an annular flange extending from the internal surface into the chamber, said annular flange configured to limit proximal movement of the stopper.

2. The fluid collection assembly of claim 1, wherein the internal surface is configured for slidably receiving the stopper in fluid tight engagement therewith.

3. The fluid collection assembly of claim 1, wherein the proximal end of the barrel, at least a portion of the internal surface of the sidewall, and the stopper define an internal reservoir configured for holding at least one of a fluid treatment additive and a fluid sample.

4. The fluid collection assembly of claim 3, wherein the proximal end of the barrel includes structure for cooperating with a medical device.

5. The fluid collection assembly of claim 4, wherein the medical device comprises a needle assembly having a lumen and wherein prior to collection of a fluid sample, the plunger rod is configured to prime the lumen and the internal reservoir with the fluid treatment additive and to remove any atmospheric air therefrom.

6. The fluid collection assembly of claim 5, wherein the stopper has a distal face configured to cooperate with an internal proximal surface of the barrel to minimize an amount of dead space within the reservoir.

7. The fluid collection assembly of claim 1, wherein the annular flange is configured to limit proximal movement of the stopper after application of a breaking force to the plunger rod and during the collection of a fluid sample.

8. The fluid collection assembly of claim 1, wherein the proximal portion of the plunger rod includes a thumb flange.

9. The fluid collection assembly of claim 1, wherein the stopper is a low resistance stopper.

10. The fluid collection assembly of claim 1, including a tip cap configured to cooperate with the distal end of the barrel to prevent any spillage of a fluid sample during handling, storage, and transportation.

11. A method of collecting a fluid sample comprising:

providing a fluid collection assembly including:

a barrel having a proximal end, a distal end, and a sidewall extending between the proximal end and the distal end, said sidewall including an internal surface defining an internal chamber, and a distal tip extending from the distal end having a passageway therethrough in fluid communication with the internal chamber;

a stopper disposed within the barrel;

a plunger rod having a proximal portion and a distal portion associated with the stopper;

a breakable connector joining the proximal portion and the distal portion of the plunger rod, the connector adapted to break upon application of a breaking force to the plunger rod; and

a needle assembly attached to the distal tip of the barrel;

priming the fluid collection assembly with a fluid treatment additive;

breaking the breakable connector; and

introducing the fluid sample into the internal chamber.

12. The method of claim 11, wherein the fluid treatment additive is selected from the group consisting of anticoagulants, clotting agents and stabilization additives.

13. The method of claim 12, wherein the fluid treatment additive is in liquid form and comprises an anticoagulant.

14. The method of claim 11, wherein the proximal end of the barrel, at least a portion of the internal surface of the sidewall, and the stopper define an internal reservoir.

15. The method of claim 14, wherein priming the fluid collection assembly further comprises drawing a liquid anticoagulant into the internal reservoir and expelling air from the internal reservoir, the passageway, and a lumen of the needle assembly.

16. The method of claim 11, wherein breaking the breakable connector includes exerting a force in a distal direction on the plunger rod a sufficient amount to cause the proximal portion to mechanically disconnect from the distal portion, and removing the proximal portion from the fluid collection assembly.

17. The method of claim 14, wherein introducing the fluid sample includes inserting a distal end of the needle assembly into a source to cause fluid to flow into the internal reservoir wherein the force of the fluid flow causes the stopper and the distal portion of the plunger rod to travel through the internal chamber toward the proximal end of the barrel until the stopper and the distal portion of the plunger rod contacts an annular flange extending inwardly from the internal surface into the internal chamber.

18. The method of claim 17, including removing the needle assembly from the distal tip of the barrel and attaching a tip cap to the distal tip of the barrel.

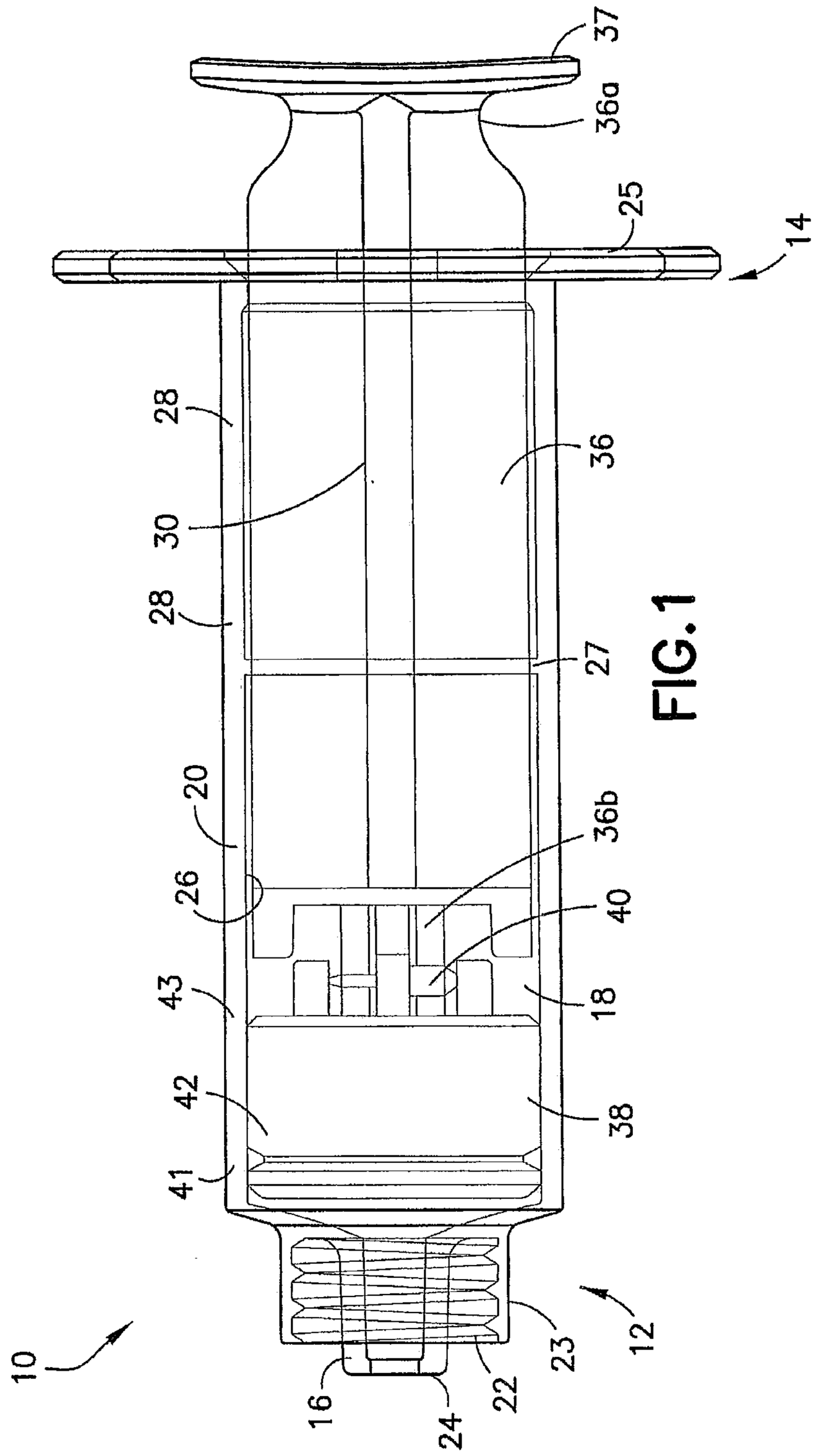
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FIG. 1

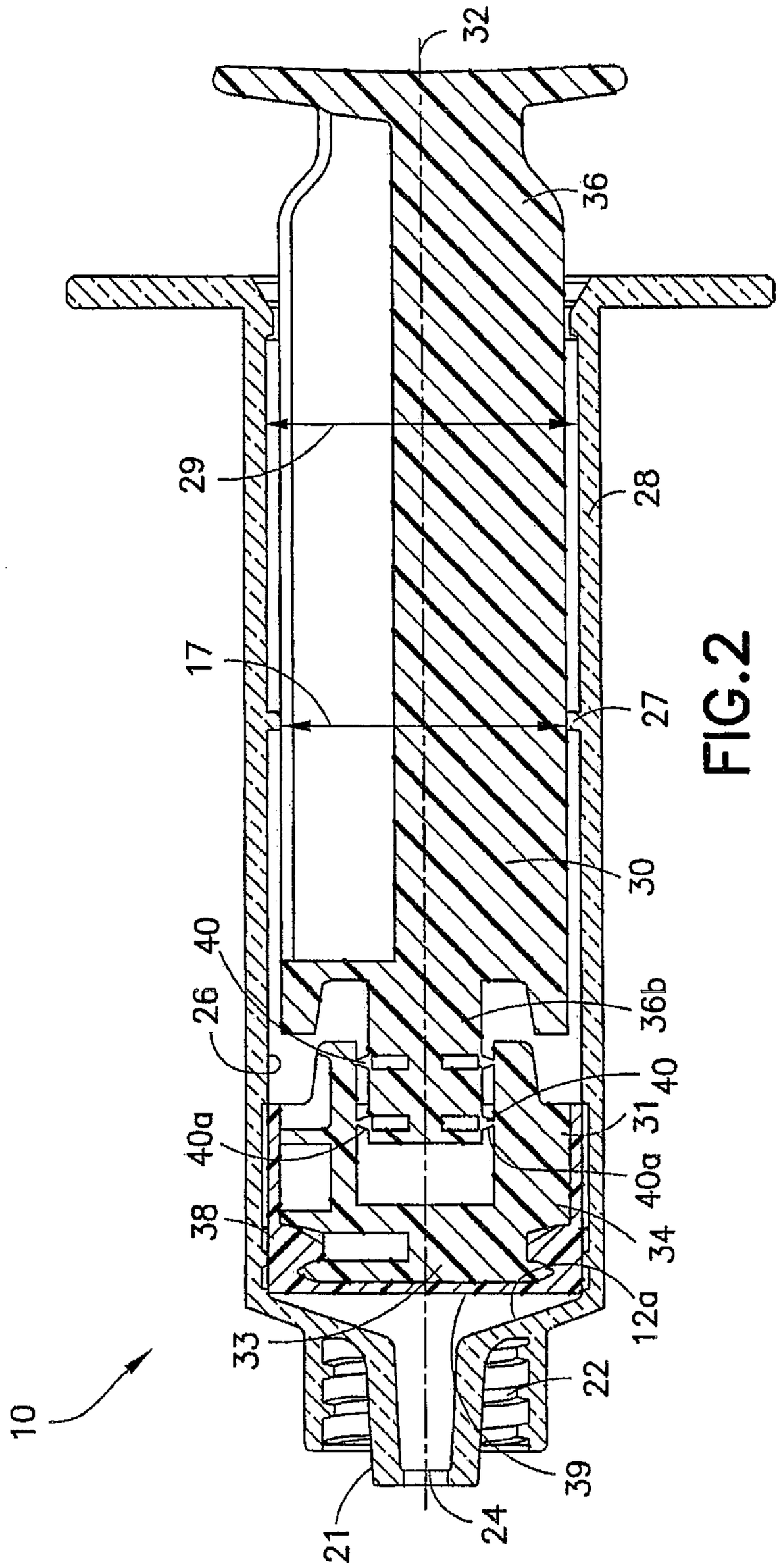

FIG.2

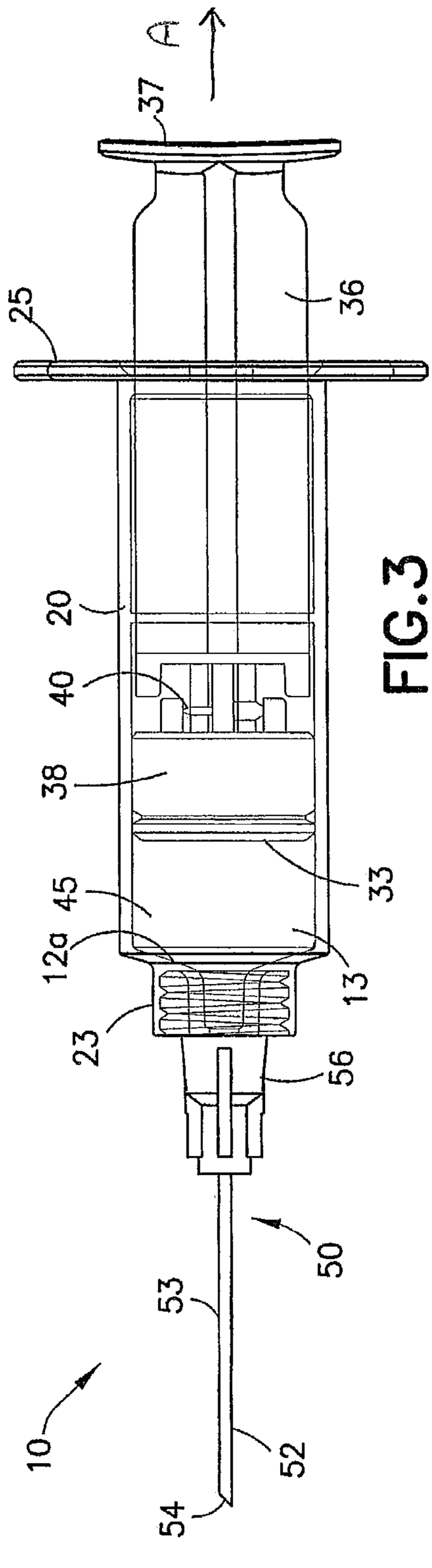
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FIG.3

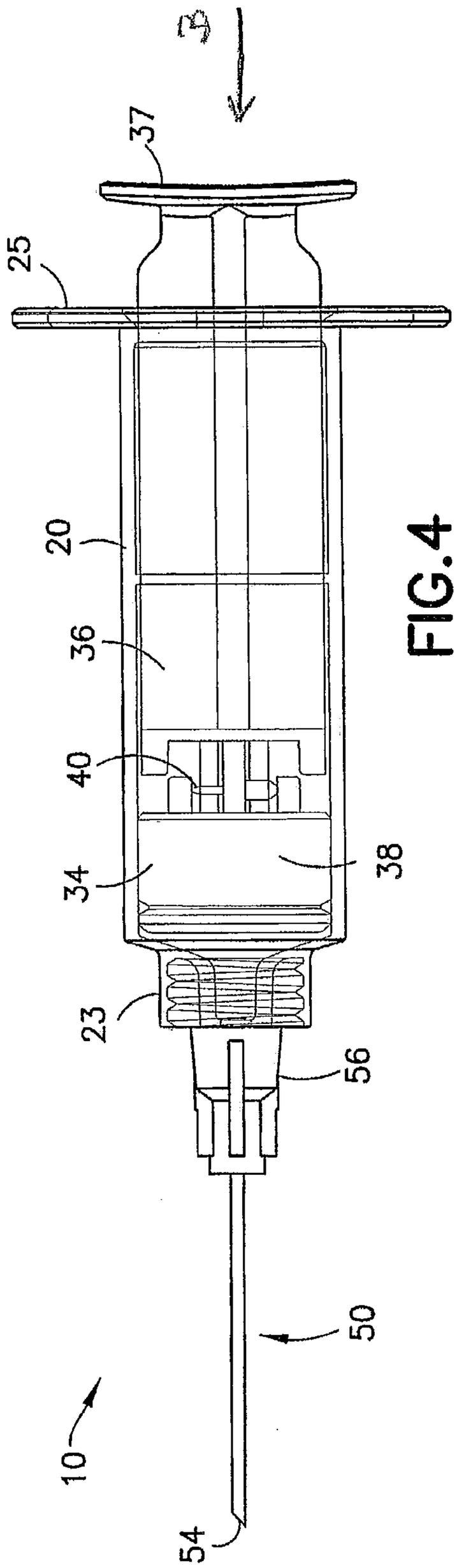
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FIG.4

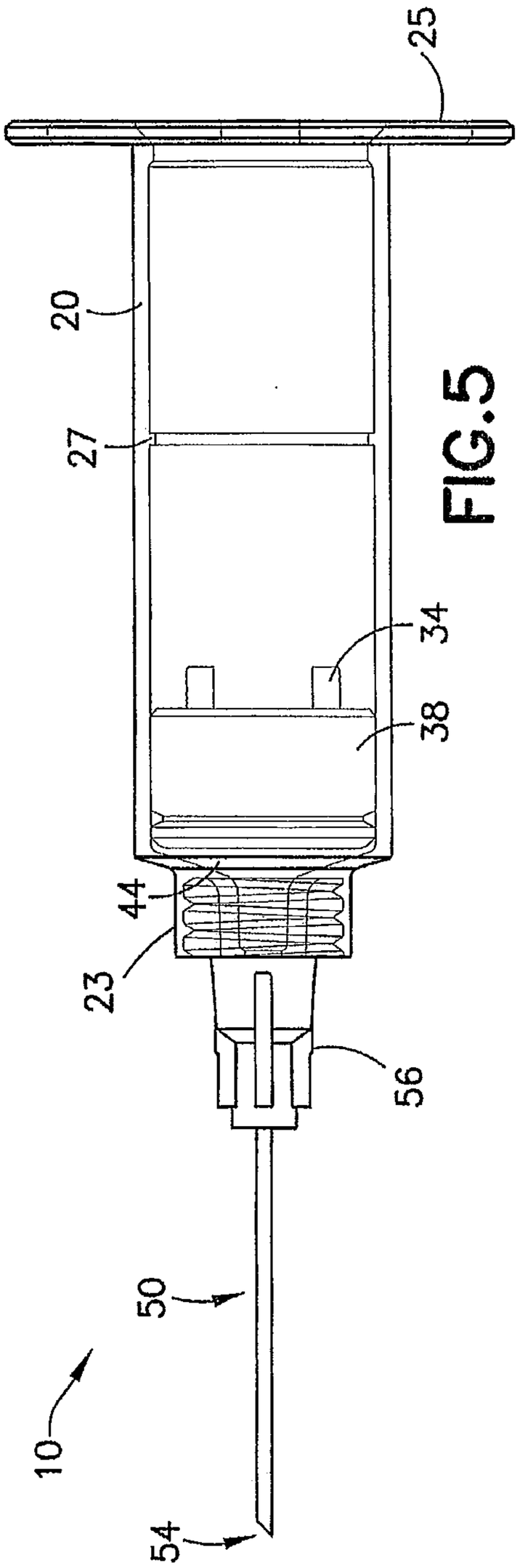


FIG.5

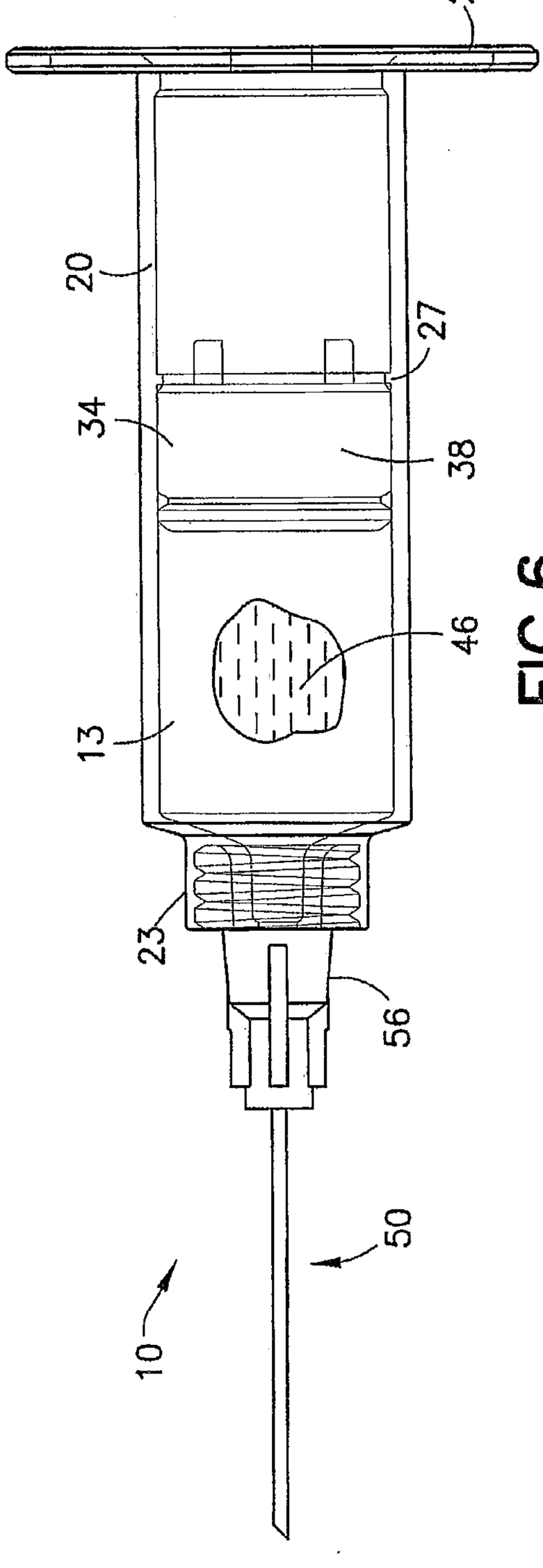


FIG.6

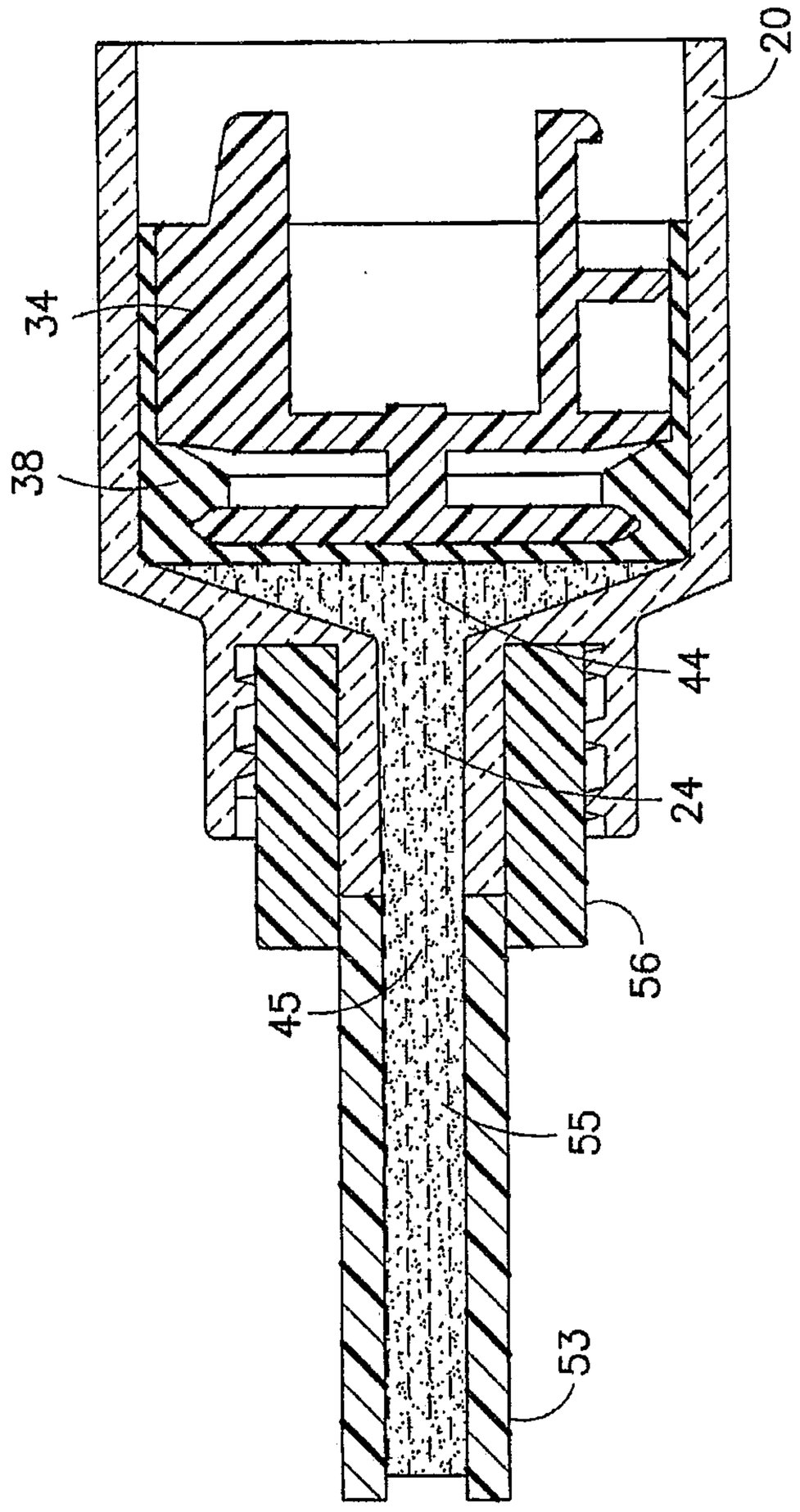


FIG.5A

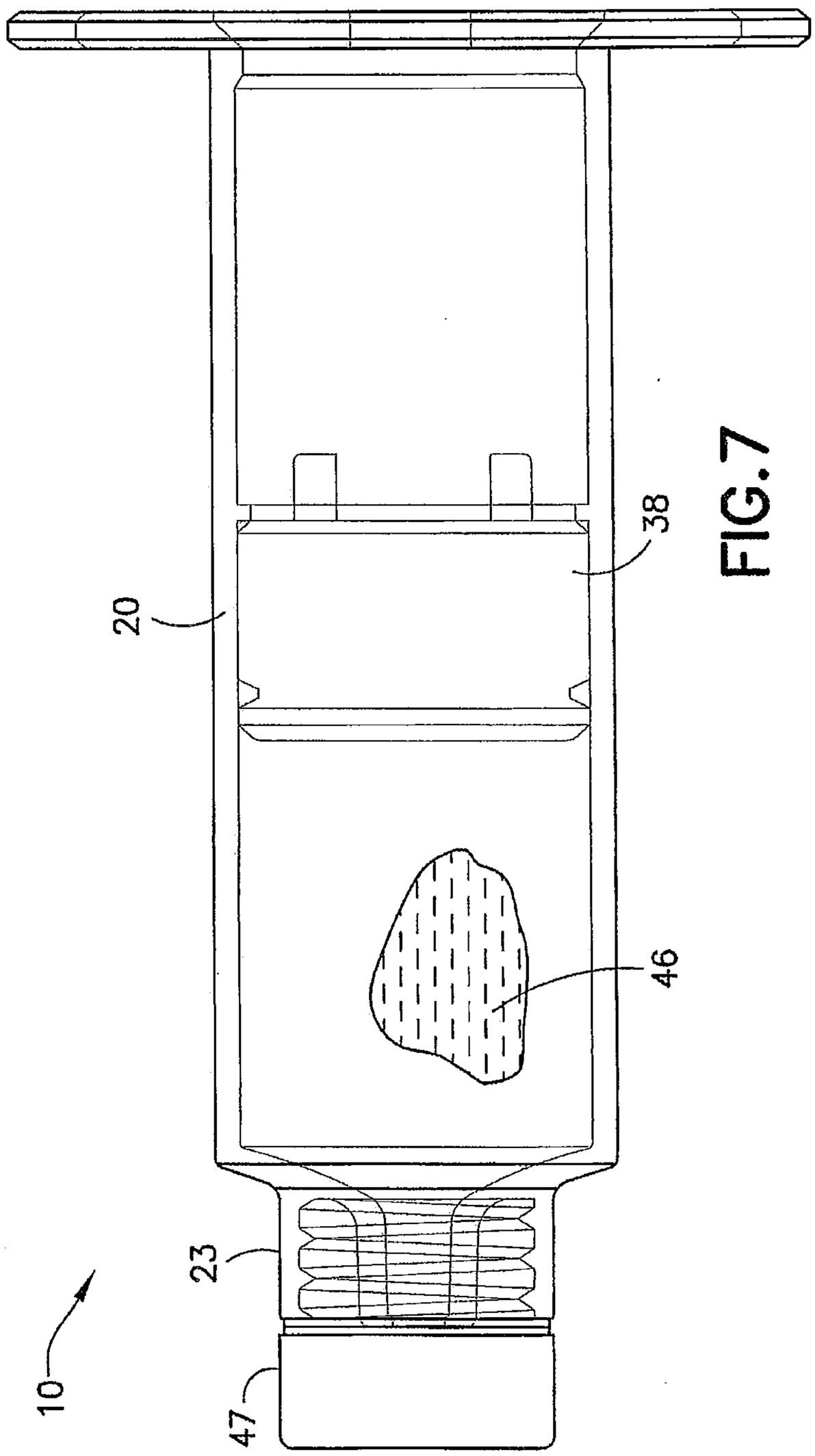


FIG.7

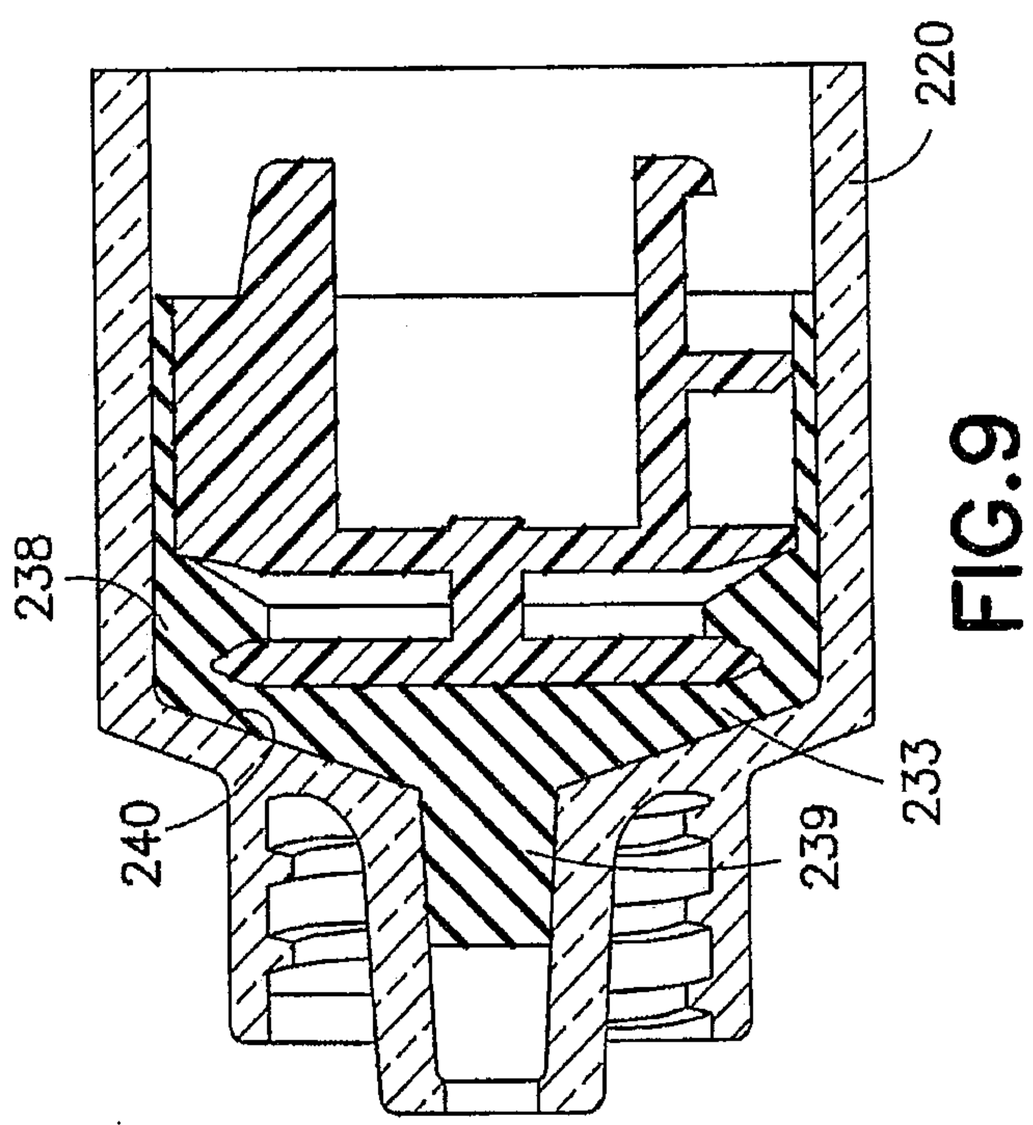


FIG.9

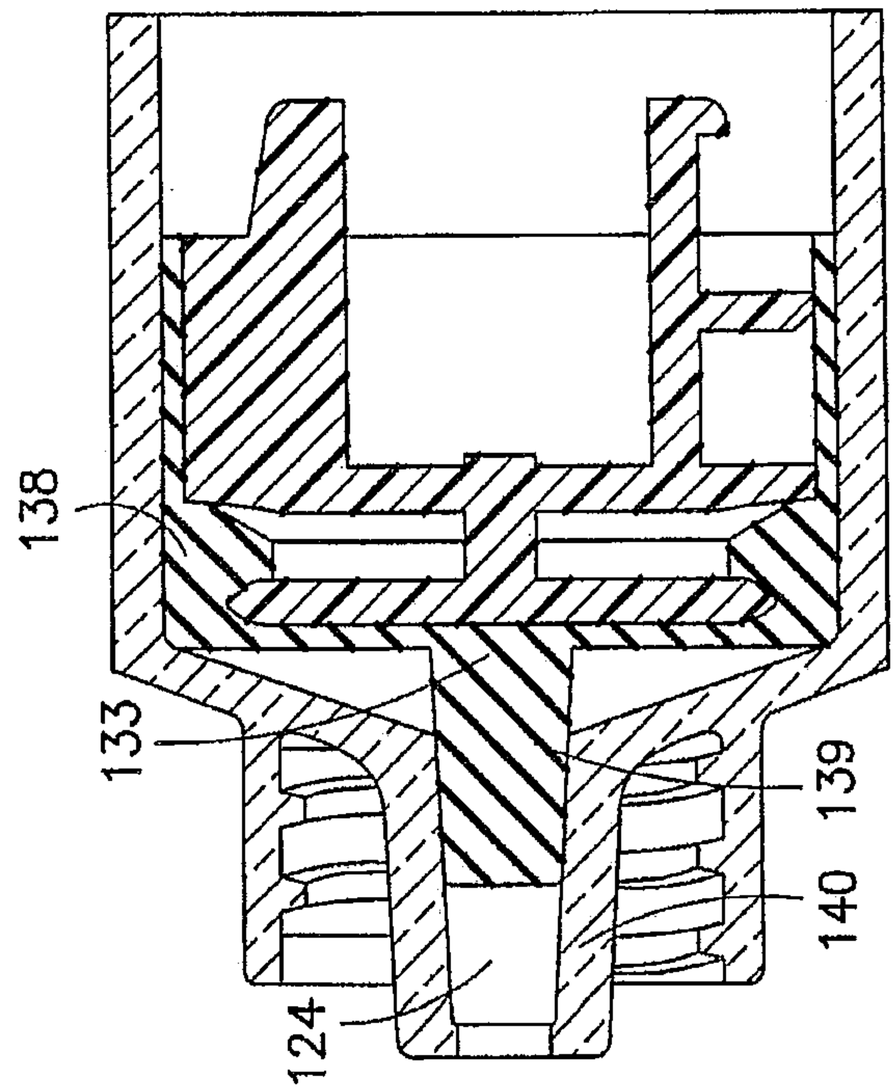
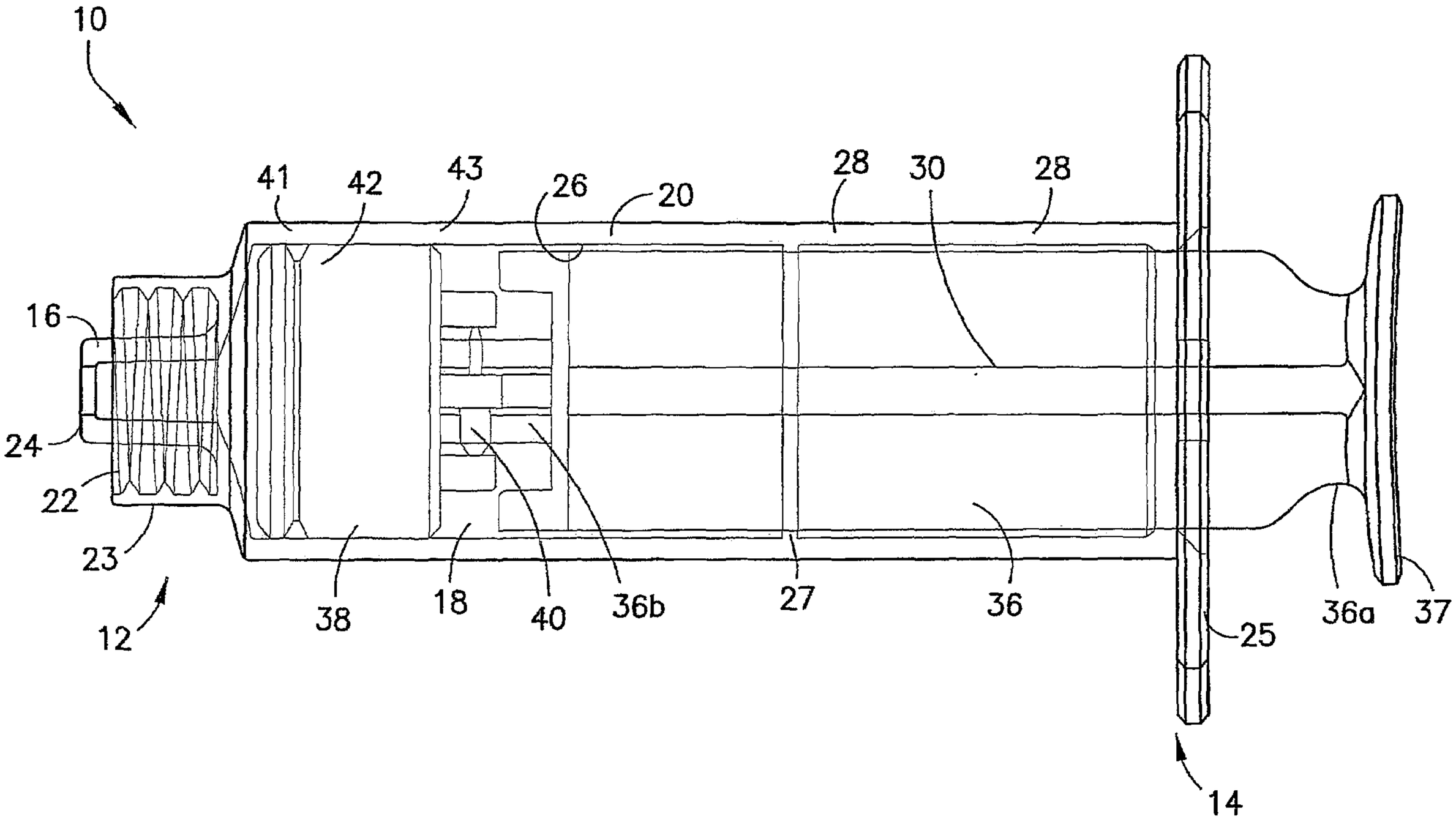


FIG.8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