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(72) Inventeur/Inventor:
CHOON MENG, LAU STEVEN, SG

(73) Propriétaire/Owner:
BECTON, DICKINSON AND COMPANY, US

(74) Agent: PIASETZKI NENNIGER KVAS LLP

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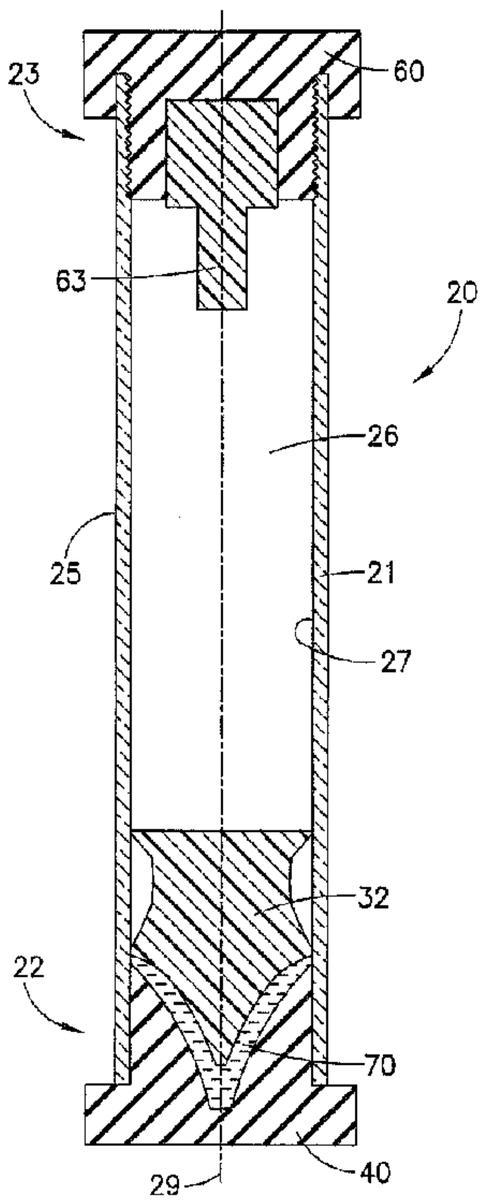

(57) Abrégé/Abstract:
A blood collection cartridge (2) has a distal end (22), a proximal end (23), and defines a container interior (26). The cartridge includes a resealable closure (40) sealing the distal end of the container, having a closure distal end (41) and a closure proximal end (42). The cartridge also includes a cap (60) sealing the proximal end of the container, having a cap distal end and a cap proximal end. The cartridge further includes a stopper (32) disposed within the container interior sized relative to the container to provide sealing engagement with the side- wall (25) of the container, the stopper having a stopper distal end (34) and a stopper proximal end (35). A first fluid reservoir (28) is bounded by the sidewall between the closure proximal end and the stopper distal end, and a second fluid reservoir is bounded by the sidewall between the cap distal end and the stopper proximal end. An anticoagulant is disposed within the first fluid reservoir.

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(71) Applicant: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417 (US).

(72) Inventor: **CHOON MENG, Lau Steven**; 1A Ontario Avenue, #03-02 The Windsor, Singapore 576190 (SG).

(74) Agents: **MILES, Kirk, M.** et al.; The Webb Law Firm, One Gateway Center, 420 Fort Duquesne Boulevard, Suite 1200, Pittsburgh, Pennsylvania 15222 (US).

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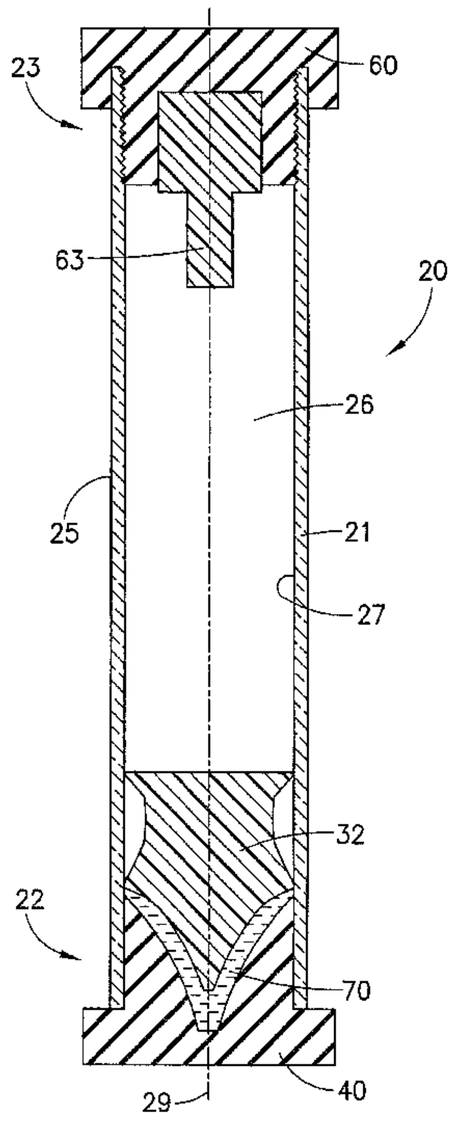

FIG.2

(57) Abstract: A blood collection cartridge (2) has a distal end (22), a proximal end (23), and defines a container interior (26). The cartridge includes a resealable closure (40) sealing the distal end of the container, having a closure distal end (41) and a closure proximal end (42). The cartridge also includes a cap (60) sealing the proximal end of the container, having a cap distal end and a cap proximal end. The cartridge further includes a stopper (32) disposed within the container interior sized relative to the container to provide sealing engagement with the side- wall (25) of the container, the stopper having a stopper distal end (34) and a stopper proximal end (35). A first fluid reservoir (28) is bounded by the sidewall between the closure proximal end and the stopper distal end, and a second fluid reservoir is bounded by the sidewall between the cap distal end and the stopper proximal end. An anticoagulant is disposed within the first fluid reservoir.

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BLOOD COLLECTION ASSEMBLY

BACKGROUND OF THE INVENTION

1. Field of the Disclosure

[0001] The present disclosure relates generally to arterial blood collection assemblies. More particularly, the present disclosure relates to an arterial blood collection assembly with a blood collection cartridge and methods for use thereof.

2. Description of the 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 anaerobic 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 or the sealing stopper is composed of a self-lubricating polymeric material 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 arterial blood collection 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] It would be therefore desirable to provide an arterial blood collection assembly and method of use thereof which is compatible with current clinical practice, which does not expose the collected blood to atmospheric air prior to analysis for blood gas levels.

SUMMARY OF THE INVENTION

[0007] The present disclosure provides a blood collection cartridge, a blood collection system, and a method of collecting a blood sample from a blood vessel. The present disclosure provides a blood collection cartridge with a stopper slidably disposed within a container, the stopper sized relative to the container to provide sealing engagement with a sidewall of the container. In one configuration, the stopper contacts the sidewall of the container at a first point and a second point spaced from the first point and no other portion of the stopper contacts the sidewall of the container. In this manner, frictional resistance between the stopper and the container, which restricts movement of the stopper within the interior of the container, only exists at the first point and the second point.

[0008] In accordance with an embodiment of the present invention, a blood collection cartridge includes a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior. The blood collection cartridge includes a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end, a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, and a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end. The blood collection cartridge further includes a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end, a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end, and an anticoagulant disposed within the first fluid reservoir.

[0009] In one configuration, the stopper contacts the sidewall of the container at a first point and a second point spaced from the first point, wherein no other portion of the stopper contacts the sidewall of the container. In another configuration, the presence of arterial blood pressure in the first fluid reservoir forces the stopper to move towards the proximal end of the container. In yet another configuration, the stopper includes at least one sealing ring extending around an outer circumferential surface of the stopper. In one configuration, the stopper includes a first sealing ring and a second sealing ring each extending around an outer circumferential surface of the stopper. In another configuration, the anticoagulant disposed

within the first fluid reservoir is in a liquid form. In yet another configuration, the blood collection cartridge includes a spacing member having a protruding portion extending from the distal end of the cap into the container interior. In one configuration, the spacing member is connected to the cap. In another configuration, the cap is rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap breaks the seal with the proximal end of the container allowing air to vent from the container interior.

[0010] In accordance with another embodiment of the present invention, a blood collection cartridge includes a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior. The blood collection cartridge includes a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end, a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, and a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end, the stopper contacting the sidewall of the container at a first point and a second point spaced from the first point, wherein no other portion of the stopper contacts the sidewall of the container. The blood collection cartridge further includes a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end, a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end, and an anticoagulant disposed within the first fluid reservoir.

[0011] In one configuration, frictional resistance between the stopper and the container, which restricts movement of the stopper within the container interior of the container, only exists at the first point and the second point. In another configuration, the first point of the stopper includes a first sealing ring which creates a first seal with the sidewall of the container. In yet another configuration, the second point of the stopper includes a second sealing ring which creates a second seal with the sidewall of the container.

[0012] In accordance with another embodiment of the present invention, a blood collection cartridge includes a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior. The blood collection cartridge includes a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end, a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed

position in which the cap seals the proximal end of the container and an open position in which the cap breaks the seal with the proximal end of the container allowing air to vent from the container interior, a spacing member having a protruding portion extending from the distal end of the cap into the container interior, and a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end. The blood collection cartridge further includes a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end, a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end, and an anticoagulant disposed within the first fluid reservoir, wherein the stopper is slidable between a distal position in which the stopper is adjacent the closure proximal end such that the anticoagulant completely fills the first fluid reservoir and a proximal position in which the stopper abuts the spacing member.

[0013] In one configuration, with the stopper in the distal position the second fluid reservoir is larger than the first fluid reservoir. In another configuration, with the stopper in the proximal position the first fluid reservoir is larger than the second fluid reservoir. In yet another configuration, the spacing member is connected to the distal end of the cap. In one configuration, the spacing member is integral with the cap.

[0014] In accordance with another embodiment of the present invention, a blood collection system includes a blood collection cartridge including a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior, a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end, a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, and a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end. The blood collection cartridge further includes a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end, a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end, and an anticoagulant disposed within the first fluid reservoir. The blood collection system further includes a needle assembly including a translucent hub configured to provide a visual indication of flashback of a fluid flowing into the hub and at least one cannula having a cannula distal end and a cannula proximal end, a portion of the at least one cannula mounted within the hub. The blood collection system further includes a

holder attached to the needle assembly, with the blood collection cartridge inserted within the holder and connected with the needle assembly such that the cannula proximal end pierces the closure of the blood collection cartridge, the first fluid reservoir of the blood collection cartridge and the at least one cannula of the needle assembly are in fluid communication.

[0015] In accordance with another embodiment of the present invention, a method of collecting a blood sample from a blood vessel includes: obtaining a blood collection assembly including a needle assembly and a holder attached to the needle assembly; inserting a distal end of the needle assembly into the blood vessel; obtaining a blood collection cartridge including: a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior; a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end; a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap breaks the seal with the proximal end of the container allowing air to vent from the container interior; a spacing member having a protruding portion extending from the distal end of the cap into the container interior; a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end; a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end; a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end; and an anticoagulant disposed within the first fluid reservoir; inserting the blood collection cartridge into the holder such that blood flows into the first fluid reservoir and forces the stopper to travel in a proximal direction along a longitudinal axis of the container; removing the blood collection cartridge from the holder when the stopper contacts the spacing member; and removing the distal end of the needle assembly from the blood vessel.

[0016] In one configuration, the anticoagulant disposed within the first fluid reservoir is in a liquid form. In another configuration, the method further includes rotating the cap to the open position prior to or after insertion of the blood collection cartridge into the holder to allow air to vent from the container interior of the container. In yet another configuration, the method further includes rotating the cap to the closed position prior to the removal of the blood collection cartridge from the holder to seal the proximal end of the container of the

blood collection cartridge. In one configuration, the method further includes attaching a luer adapter to the distal end of the container of the blood collection cartridge.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of embodiments of the disclosure taken in conjunction with the accompanying drawings.

[0018] **FIG. 1** is an exploded, cross-sectional view of a blood collection system in accordance with an embodiment of the present invention.

[0019] **FIG. 2** is a cross-sectional view of a blood collection cartridge in accordance with an embodiment of the present invention.

[0020] **FIG. 3** is a fragmentary, cross-sectional view of the distal end of the blood collection cartridge of **FIG. 2** in accordance with an embodiment of the present invention.

[0021] **FIG. 4** is a fragmentary, cross-sectional view of the proximal end of the blood collection cartridge of **FIG. 2** in accordance with an embodiment of the present invention.

[0022] **FIG. 5** is a cross-sectional view of a needle assembly in accordance with an embodiment of the present invention.

[0023] **FIG. 6** is a cross-sectional view of the needle assembly of **FIG. 5** attached to a holder and inserted into an artery in accordance with an embodiment of the present invention.

[0024] **FIG. 7** is a cross-sectional view of the needle assembly and the holder of **FIG. 6** with a blood collection cartridge inserted within the holder and in fluid communication with the needle assembly, upon completion of the collection of a blood sample from the artery, in accordance with an embodiment of the present invention.

[0025] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the disclosure, and such exemplifications are not to be construed as limiting the scope of the disclosure in any manner.

DETAILED DESCRIPTION

[0026] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and

alternatives are intended to fall within the spirit and scope of the present invention. Before describing several exemplary embodiments of the invention, it is to be understood that the invention is not limited to the details of construction or process steps set forth in the following description and drawings. The invention is capable of other embodiments and of being practiced or carried out in various ways.

[0027] 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.

[0028] In the following discussion, "distal" refers to a location on the blood collection assembly of the present disclosure that is, during normal use, closest to a patient who is receiving treatment and farthest from a clinician administering the treatment to the patient and "proximal" refers to the opposite direction of distal, i.e., farthest from the patient who is receiving treatment and closest to the clinician administering the treatment to the patient. Furthermore, in the following discussion, "proximal direction" refers to a direction of movement away from the patient who is receiving treatment and toward the clinician administering the treatment to the patient, and "distal direction" refers to a direction of movement toward the patient who is receiving treatment and away from the clinician administering the treatment to the patient. For purposes of this disclosure, the above-mentioned references are used in the description of the components of a blood collection assembly in accordance with the present disclosure.

[0029] Referring to **FIGS. 1-7** an arterial blood collection assembly or blood collection system **10** includes a needle assembly **11**, a tube holder **13**, and a blood collection cartridge **20**. The present invention is generally described in terms of an arterial blood collection assembly **10**. While described herein in terms of a preferred embodiment of an arterial blood collection cartridge **20** intended for use with a needle assembly **11**, the cartridge **20** of the present disclosure 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 or arterial lines.

[0030] Referring to **FIGS. 1-4**, arterial blood collection cartridge **20** include a closure **40**, an anticoagulant **70**, a stopper **32** that is slidably disposed within a container **21**, a collection volume spacer or spacing member **63**, and a cap **60**. Referring to **FIG. 2**, blood collection cartridge **20** includes a tube or container **21** having an open distal end **22** and an opposing, open proximal end **23**. Container **21** defines a container longitudinal axis **29**. In one embodiment, tube **21** is an elongated, hollow, cylindrically-shaped container. In other embodiments, tube **21** may include other shapes and sizes. For example, tube **21** may have other multi-sided polygon cross-sectional shapes, such as square or rectangular cross-sectional shapes. Container **21** has a rigid tubular wall or sidewall **25** that defines an internal chamber or container interior **26** extending between distal end **22** and proximal end **23**. The rigid tubular wall **25** of tube **21** defines an internal surface **27** for slidably receiving a low resistance stopper **32**.

[0031] Tube **21** 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.

[0032] Referring to **FIGS. 2-4**, arterial blood collection cartridge **20** includes a low resistance stopper **32** slidably received within the chamber **26** defined by tubular sidewall **25** of container **21**. Stopper **32** is in sealing contact with the internal surface of sidewall **25** of container **21** and stopper **32** is slidably positioned in fluid tight engagement with internal surface **27**, and is able to slide distally and proximally along longitudinal axis **29** of container **21**. Stopper **32** includes a distal face or stopper distal end **34** and opposing proximal face or stopper proximal end **35**. The diameter of stopper **32** is approximately equal to or only slightly smaller than the internal diameter '**a**' (**FIG. 3**) of container **21**. Stopper **32** is in slidable contact with internal surface **27** of tube **21** and provides a fluid-tight seal with the internal surface **27** of the tube **21** so that a sample can be held within a fluid reservoir or first

fluid reservoir **28** formed within the chamber **26** between distal end **22** of tube **21** and distal face **34** of stopper **32**, thereby preventing the sample from leaking from the proximal end **23** of tube **21**. In one embodiment, first fluid reservoir **28** is located within sidewall **25** between a proximal end of closure **40** and the distal end **34** of stopper **32**. Stopper **32** is sized relative to container **21** to provide sealing engagement with the interior surface of sidewall **25** of container **21**. In alternative embodiments, stopper **32** may include one or more annular ribs extending around the periphery of stopper **32** to increase the sealing engagement between stopper **32** and the interior surface of sidewall **25** of container **21**. In other alternate embodiments, a singular O-ring or a plurality of O-rings may be circumferentially disposed about stopper **32** to increase the sealing engagement with the interior surface of sidewall **25**.

[0033] Referring to **FIGS. 3** and **7**, stopper **32** is slidable between a distal position (**FIG. 3**) in which stopper **32** is adjacent a closure proximal end **42** such that anticoagulant **70** completely fills first fluid reservoir **28**, and a proximal position (**FIG. 7**) in which stopper **32** abuts spacing member **63**.

[0034] In some embodiments, stopper **32** is a low resistance stopper and as such is designed to have a relatively lower frictional resistance to movement inside of tube **21** when compared to similar components in prior art arterial blood gas syringes such that the presence of arterial blood pressure (approximately 100 to 160 mmHg) within fluid reservoir **28** will cause the stopper **32** to slide/travel in a proximal direction toward the proximal end **23** of tube **21** until the proximal face **35** contacts collection volume spacer **63** thereby limiting the proximal movement of stopper **32**. The frictional resistance of a stopper can be lowered by either of a combination of stopper sealing profile design and/or component material selection.

[0035] Referring to **FIG. 3**, a first **36** sealing ring and a second **37** sealing ring extend around the outer circumferential surface of stopper **32** adjacent distal face **34** and proximal face **35** respectively to create a primary and secondary seal with internal surface **27** of tube **21**. This stopper sealing profile design lowers the amount of contact between stopper **32** and internal surface **27** thereby reducing the frictional resistance to movement of stopper **32** when compared to a stopper sealing profile in which the entire outer circumferential surface is in contact with internal surface **27**. Alternately or in combination with the stopper sealing profile design, stopper **32** 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 **32** may also be made from a combination of elastomers which include a harder inner rubber core and a soft self-lubricating polymeric material outer layer. A self-lubricating

polymeric material has a lubricant incorporated into the polymeric material, an example of which is Epilor.

[0036] Referring to **FIGS. 2** and **3**, stopper **32** only contacts sidewall **25** of container **21** at a first point **82** and a second point **84** spaced from the first point **82**. Importantly, no other portion of stopper **32** contacts sidewall **25** of container **21**. In this manner, frictional resistance between stopper **32** and container **21**, which restricts movement of stopper **32** within the container interior **26** of container **21**, only exists at first point **82** and second point **84**. Referring to **FIG. 3**, first point **82** where stopper **32** contacts sidewall **25** of container **21** includes first sealing ring **36** which creates a first seal with sidewall **25** of container **21**. Referring again to **FIG. 3**, second point **84** where stopper **32** may also contact sidewall **25** of container **21** includes second sealing ring **37** which creates a second seal with sidewall **25** of container **21**. In this manner, the contact area between stopper **32** and sidewall **25** of container **21** is reduced, thereby reducing the frictional resistance which restricts movement of stopper **32** within container **21**.

[0037] Referring to **FIGS. 2-4**, stopper **32** is in slidable contact with internal surface **27** of tube **21** and provides a fluid-tight seal with the internal surface **27** of the tube **21** so that a sample can be held within a fluid reservoir or first fluid reservoir **28** formed within the chamber **26** between distal end **22** of tube **21** and distal face **34** of stopper **32**, thereby preventing the sample from leaking from the proximal end **23** of tube **21**. First fluid reservoir **28** is located within sidewall **25** between closure proximal end **42** and stopper distal end **34**. A second fluid reservoir **38** is formed within the chamber **26** of container **21** and is located within sidewall **25** between the distal end of cap **60** and stopper proximal end **35**. With stopper **32** in the distal position (**FIGS. 2** and **3**), the second fluid reservoir **38** is larger than the first fluid reservoir **28**. With stopper **32** in the proximal position (**FIG. 7**), the first fluid reservoir **28** is larger than the second fluid reservoir **38**.

[0038] Distal end **22** of tube **21** is sealed by closure **40** to form a liquid impermeable seal to contain the blood sample. The closure **40** includes an external end or closure distal end **41** and an internal end or closure proximal end **42** structured to be at least partially received within the tube **21**. Portions of the closure **40** adjacent the open distal end **22** of the tube **21** define a maximum outer diameter which exceeds the inside diameter '**a**' (**FIGS. 3** and **4**) of the tube **21**. The inherent resiliency of closure **40** can ensure a sealing engagement with the internal surface **27** of the wall **25** of the tube **21**. Portions of the closure **40** extending downwardly from the internal end **42** may taper from a minor diameter which is approximately equal to, or slightly less than, the inside diameter '**a**' (**FIGS. 3** and **4**) of the

tube **21** to a major diameter that is greater than the inside diameter '**a**' of the tube **21** adjacent the distal end **22**. Thus, the internal end **42** of the closure **40** may be urged into a portion of the tube **21** adjacent the distal open end **22**. In an alternative embodiment, a luer lock feature can be incorporated to enhance the seal between the internal surface **27** of tube **21** and closure **40**. Closure **40** is such that it can be pierced by a needle or other cannula to introduce a biological sample into tube **21** as is known in the art. Preferably, closure **40** is resealable. The closure **40** can also be formed to define at a cavity **43** extending into the internal end **42**. The cavity **43** may be sized to receive at least a corresponding profile **44** extending distally from the distal face **34** of stopper **32**. Suitable materials for closure **40** include, for example, elastomers such as silicone rubber, natural rubber, styrene butadiene rubber, ethylene-propylene copolymers and polychloroprene, and thermoplastic elastomers.

[0039] Proximal end **23** of tube **21** is sealed by a cap or twist cap **60** having mating screw threads located on the internal surface **27** of tube **21** and an outer surface **62** of an internal end **61** of cap **60** to form a liquid and gaseous impermeable seal when in the closed position. Rotating twist cap **60** in an anti-clockwise direction to an open position breaks the gaseous seal and allows air to escape or vent from chamber **26** proximal to stopper **32** into the surrounding atmosphere. This venting of air from chamber **26** eases the proximal movement of stopper **32** during the blood collection process as a back pressure is prevented from forming in chamber **26** between proximal face **35** of stopper **32** and twist cap **60**. A back pressure in this location could prevent the collection of the intended volume of blood by prematurely retarding the proximal movement of stopper **32**. Rotating twist cap **60** in a clockwise direction to the closed position, reforms a liquid and gaseous impermeable seal. In other words, cap **60** is rotatable between a closed position in which cap **60** seals the proximal end **23** of container **21** and an open position in which cap **60** breaks the seal with the proximal end **23** of container **21** allowing air to vent from the container interior **26** of container **21**. In one embodiment, cap **60** has a cap distal end and an opposing, cap proximal end.

[0040] Collection volume spacer or spacing member **63** limits the proximal movement of stopper **32** thereby limiting the blood collection volume of container **21**. The length '**L**' (**FIG. 4**) that a projection or protruding portion **64** protrudes into chamber **26** can be designed to provide the desired blood collection volume of container **21**. In current clinical practice, 2 ml of blood is collected for arterial blood gas analysis, therefore the length of protrusion **64** is preset such that when the proximal face **35** of stopper **32** contacts projection **64**, a volume of 2 ml of blood is present within fluid reservoir **28** as shown in **FIG. 7**. Collection volume

spacer **63** also maintains the position of stopper **32** during subsequent transportation and storage of the collected blood sample. Referring to **FIGS. 1-4**, collection volume spacer **63** is press-fitted into a recess **65** in the internal end **61** of twist-cap **60**; however, collection volume spacer **63** and twist cap **60** may be connected by any method know in the art or may optionally be formed as a unitary or integral element.

[0041] According to an embodiment of the present disclosure, the arterial blood collection cartridge **20** may contain additional additives as required for particular testing procedures, such as anticoagulants, clotting agents, stabilization additives, and the like. Such additives may be sprayed onto the internal surface **27** of the tube **21** or located within fluid reservoir **28**. 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 is used in a liquid 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.

[0042] For the above reasons, first fluid reservoir **28** is completely filled with an anticoagulant **70** in liquid form (e.g., heparin) in order to remove any atmospheric air, so that the partial pressure of the oxygen in the arterial blood sample will not be affected by contact to any atmospheric air. The combination of cavity **43** in the internal end **42** of closure **40** and profile **44** extending from distal face **34** of stopper **32** provides a minimized "dead space" volume within fluid reservoir **28** prior to blood collection to minimize volume of liquid anticoagulant required to fill fluid reservoir **28**, hence, minimize the dilution effect of the liquid heparin on the blood sample. In other words, as discussed above, when stopper **32** is located in the distal position (**FIG. 3**) in which stopper **32** is adjacent the closure proximal end **42**, the anticoagulant **70** completely fills first fluid reservoir **28**.

[0043] Referring to **FIGS. 1** and **5-7**, arterial blood collection system **10** includes a flashback needle assembly **11**, a holder **13**, and blood collection cartridge **20**. Flashback needle assembly **11** could be a flashback needle assembly in accordance with the flashback

needle assemblies described in United States Patent Number 6,533,760, the entire disclosure of which is hereby expressly incorporated herein by reference.

[0044] Referring to **FIG. 5**, needle assembly **11** includes a distal cannula **50** with a pointed distal end **51** and a proximal cannula **52** having a pointed proximal end **53** in axial alignment with one another to provide an axial fluid flow path **58** and each cannula having a lumen extending between the ends. The needle assembly **11** further comprises a clear/ translucent hub **54** having a proximal end **55**, a distal end **56**, and a passage extending between the ends. Translucent hub **54** is configured to provide a visual indication of flashback of a fluid flowing into the hub **54**. Both cannulas **50** and **52** are mounted securely in the passage of the hub **54**. Thus, proximal end **53** of proximal cannula **52** projects proximally beyond the hub **54** and the pointed distal end **51** of distal cannula **50** projects distally beyond the hub **54**. An external vent **59** through the wall of the plastic hub allows venting of air inside the distal cannula **50** and hub **54** which will be displaced by incoming blood. Flashback is produced when blood flows along the axial fluid flow path **58** between the two cannulas and provides visual confirmation of needle entry into the artery. External surface regions of the hub **54** near the proximal end **55** of the hub **54** may be formed with mounting structures, such as an array of external threads, at least one annular groove, or at least one annular rib. The mounting structure enables the needle hub **54** to be secured to a holder **13** that is configured to slidably receive a blood collection cartridge **20** according to an embodiment of the invention. The needle assembly **11** further includes a multiple sample sleeve **57** mounted over the proximal portions of the needle cannula **50** and secured to the proximal end **55** of the hub **54**. The proximal portions of the needle cannula **50** and the multiple sample sleeve **57** project into the holder **13** when the hub **54** of the needle assembly **11** is mounted to the holder **13**.

[0045] Assembly of the arterial blood collection cartridge **20** is accomplished by slidably inserting stopper **32** within chamber **26** through distal end **22** of tube **21**. Liquid anticoagulant **70** such as heparin is then added to fill fluid reservoir **28** before distal end **22** is sealed by the insertion of closure **40**. Collection volume spacer **63** is attached to twist cap **60** before twist cap **60** is screwed into the proximal end **23**. The assembly can then be packaged for later use.

[0046] A method of blood collection according to an embodiment of this invention is described as follows. Needle assembly **11** is attached to holder **13**. The user may then grip needle assembly **11** with holder **13** attached and insert pointed distal end **51** into an artery **80** of a patient. Blood at arterial pressure (which is greater than normal atmospheric or ambient pressure) will then flow through lumen of distal cannula **50** and into hub **54** via axial flow

path **58** thereby providing visual indication of flashback confirming that distal end **51** is located in artery **80** as shown in **FIG. 6**. Blood collection cartridge **20** is then inserted in holder **13** such that pointed proximal end **53** of proximal needle **52** pierces multiple sample sleeve **57** and closure **40** once flashback is observed (i.e., blood is observed in hub **54**). Blood flows through the lumen into the fluid reservoir **28** and forces stopper **32** to slide in a proximal direction until the proximal face **35** of stopper **32** contacts projection **64** of collection volume spacer **63** thereby defining the completion of the collection volume of the blood sample as shown in **FIG. 7**. The sliding motion of the rubber stopper **32** allows the liquid anticoagulant **70** and collected arterial blood **46** to mix during the collection process. Twist cap **60** can be opened prior to insertion of the blood cartridge into the holder or during blood collection to allow air to vent from chamber **26** to further facilitate the proximal movement of stopper **32**. Blood collection cartridge **20** is then removed from the multi-sample needle assembly **11** and holder **13** prior to the withdrawal of distal end **51** from the artery. The blood collection cartridge **20** containing the arterial blood sample is then ready for transportation to the laboratory for arterial blood gas analysis.

[0047] A luer adapter may then be inserted through closure **40** of the cartridge **20** to provide the cartridge with an interface connection that is compatible with a blood gas analyzer. A range of different luer adaptors can be provided to allow the arterial blood collection cartridge **20** to connect to all different types of the blood gas analyzer interfaces. The luer adaptor may also be supplied with a luer tip cap to seal the arterial blood collection cartridge **20** when the luer adapter is connected.

[0048] While this disclosure has been described as having exemplary designs, the present disclosure can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the disclosure using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this disclosure pertains and which fall within the limits of the appended claims.

CLAIMS:

1. A blood collection cartridge, comprising:

a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior;

a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end;

a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap allows air to vent from the container interior;

a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end;

a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end;

a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end; and

an anticoagulant disposed within at least one of the first fluid reservoir and the second fluid reservoir.

2. The blood collection cartridge of claim 1, wherein the stopper contacts the sidewall of the container at a first point and a second point spaced from the first point, wherein no other portion of the stopper contacts the sidewall of the container.

3. The blood collection cartridge of claim 1, wherein the presence of arterial blood pressure in the first fluid reservoir forces the stopper to move towards the proximal end of the container.

4. The blood collection cartridge of claim 1, the stopper further comprising at least one sealing ring extending around an outer circumferential surface of the stopper.

5. The blood collection cartridge of claim 1, the stopper further comprising a first sealing ring and a second sealing ring each extending around an outer circumferential surface of the stopper.

6. The blood collection cartridge of claim 1, wherein the anticoagulant disposed within the first fluid reservoir is in a liquid form.

7. The blood collection cartridge of claim 1, further comprising a spacing member having a protruding portion extending from the distal end of the cap into the container interior.

8. The blood collection cartridge of claim 7, wherein the spacing member is connected to the cap.

9. A blood collection cartridge, comprising:

a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior;

a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end;

a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap allows air to vent from the container interior;

a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end, the stopper contacting the sidewall of the container at a first point and a second point spaced from the first point, wherein no other portion of the stopper contacts the sidewall of the container;

a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end; and

a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end.

10. The blood collection cartridge of claim 9, further comprising an anticoagulant within the first fluid reservoir.

11. The blood collection cartridge of claim 9, wherein frictional resistance between the stopper and the container, which restricts movement of the stopper within the container interior of the container, only exists at the first point and the second point.

12. The blood collection cartridge of claim 9, wherein the first point of the stopper comprises a first sealing ring which creates a first seal with the sidewall of the container.

13. The blood collection cartridge of claim 12, wherein the second point of the stopper comprises a second sealing ring which creates a second seal with the sidewall of the container.

14. A blood collection cartridge, comprising:

a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior;

a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end;

a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap breaks the seal with the proximal end of the container allowing air to vent from the container interior;

a spacing member having a protruding portion extending from the distal end of the cap into the container interior;

a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end;

a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end;

a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end; and

an anticoagulant disposed within the first fluid reservoir, wherein the stopper is slidable between a distal position in which the stopper is adjacent the closure proximal end such that the anticoagulant completely fills the first fluid reservoir and a proximal position in which the stopper abuts the spacing member.

15. The blood collection cartridge of claim 14, wherein with the stopper in the distal position the second fluid reservoir is larger than the first fluid reservoir.

16. The blood collection cartridge of claim 14, wherein with the stopper in the proximal position the first fluid reservoir is larger than the second fluid reservoir.

17. The blood collection cartridge of claim 14, wherein the spacing member is connected to the distal end of the cap.

18. The blood collection cartridge of claim 14, wherein the spacing member is integral with the cap.

19. A blood collection system, comprising:

a blood collection cartridge, comprising:

a container having a distal end, a proximal end, and a sidewall extending therebetween and defining a container interior,

a resealable closure sealing the distal end of the container, the resealable closure having a closure distal end and a closure proximal end,

a cap sealing the proximal end of the container, the cap having a cap distal end and a cap proximal end, the cap rotatable between a closed position in which the cap seals the proximal end of the container and an open position in which the cap allows air to vent from the container interior,

a stopper slidably disposed within the container interior of the container, the stopper sized relative to the container to provide sealing engagement with the sidewall of the container, the stopper having a stopper distal end and a stopper proximal end,

a first fluid reservoir located within the sidewall between the closure proximal end and the stopper distal end,

a second fluid reservoir located within the sidewall between the cap distal end and the stopper proximal end, and

an anticoagulant disposed within the first fluid reservoir; and

a needle assembly, comprising:

a hub configured to provide a visual indication of flashback of a fluid flowing into the hub, and

at least one cannula having a cannula distal end and a cannula proximal end, a portion of the at least one cannula mounted within the hub, and

a holder attached to the needle assembly, such that with the blood collection cartridge inserted within the holder and connected with the needle assembly the cannula proximal end pierces the closure of the blood collection cartridge, thereby providing the first fluid reservoir and the at least one cannula in fluid communication.

20. The blood collection system of claim 19, further comprising a spacing member having a protruding portion extending from the distal end of the cap into the container interior.

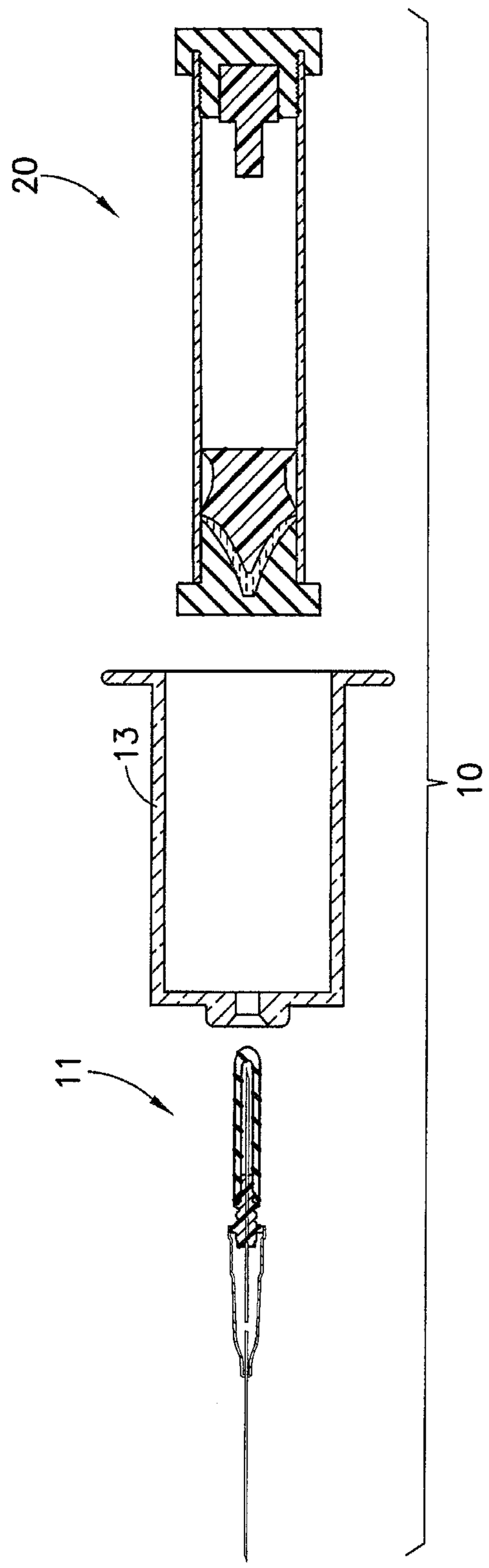


FIG.1

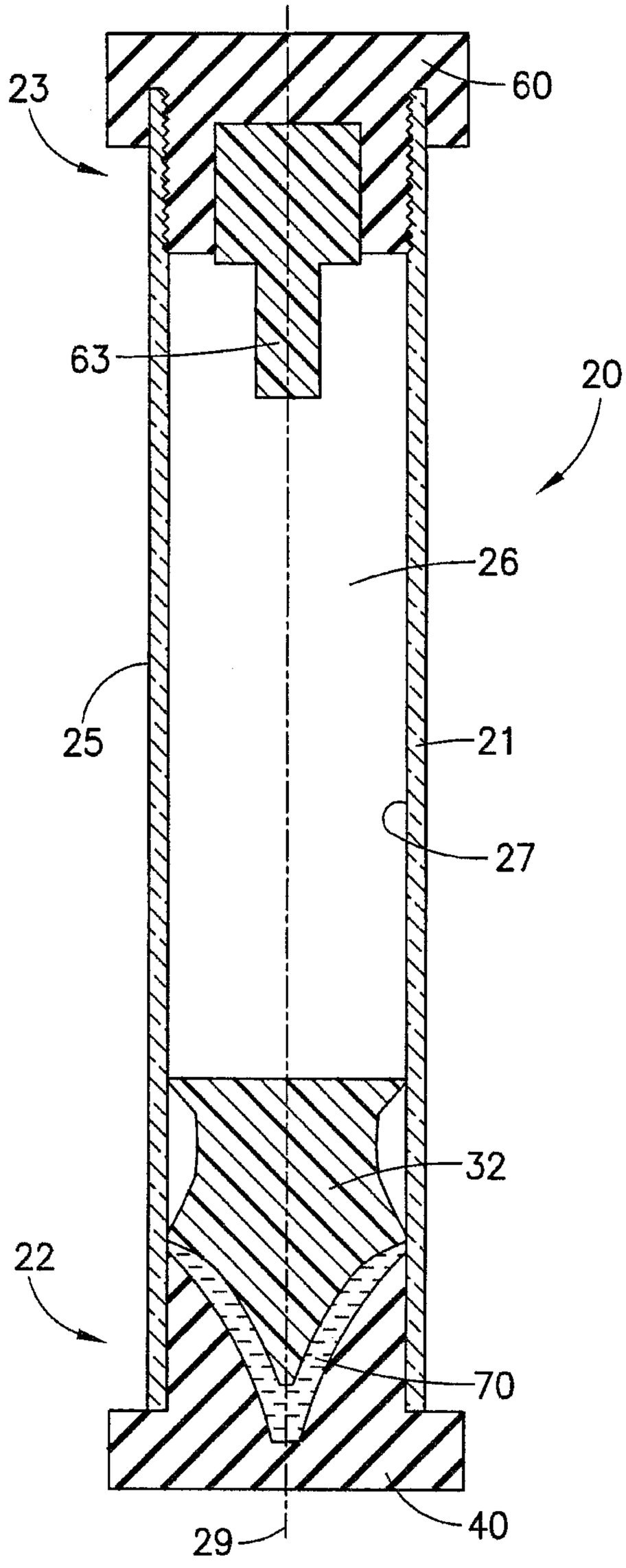


FIG.2

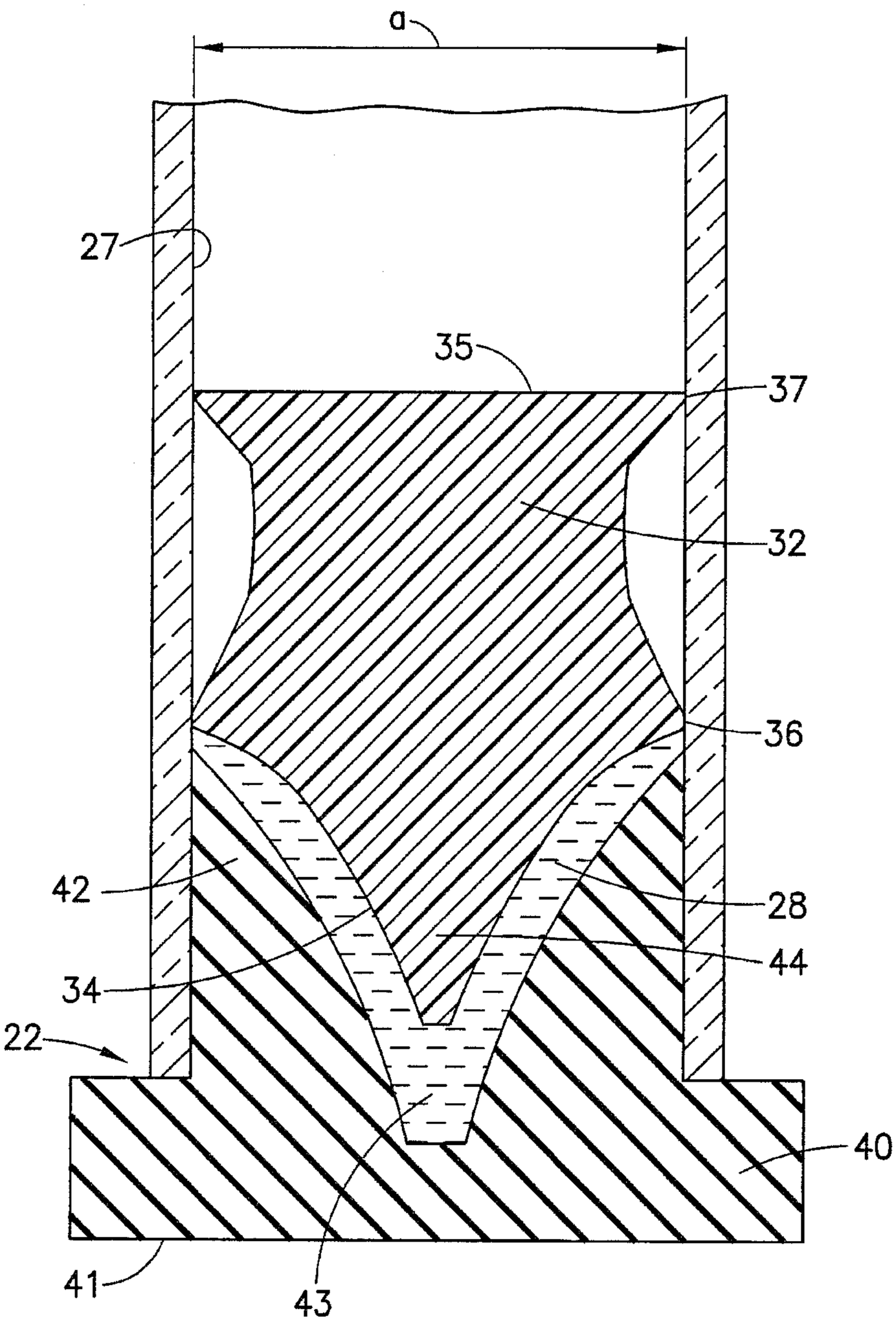


FIG.3

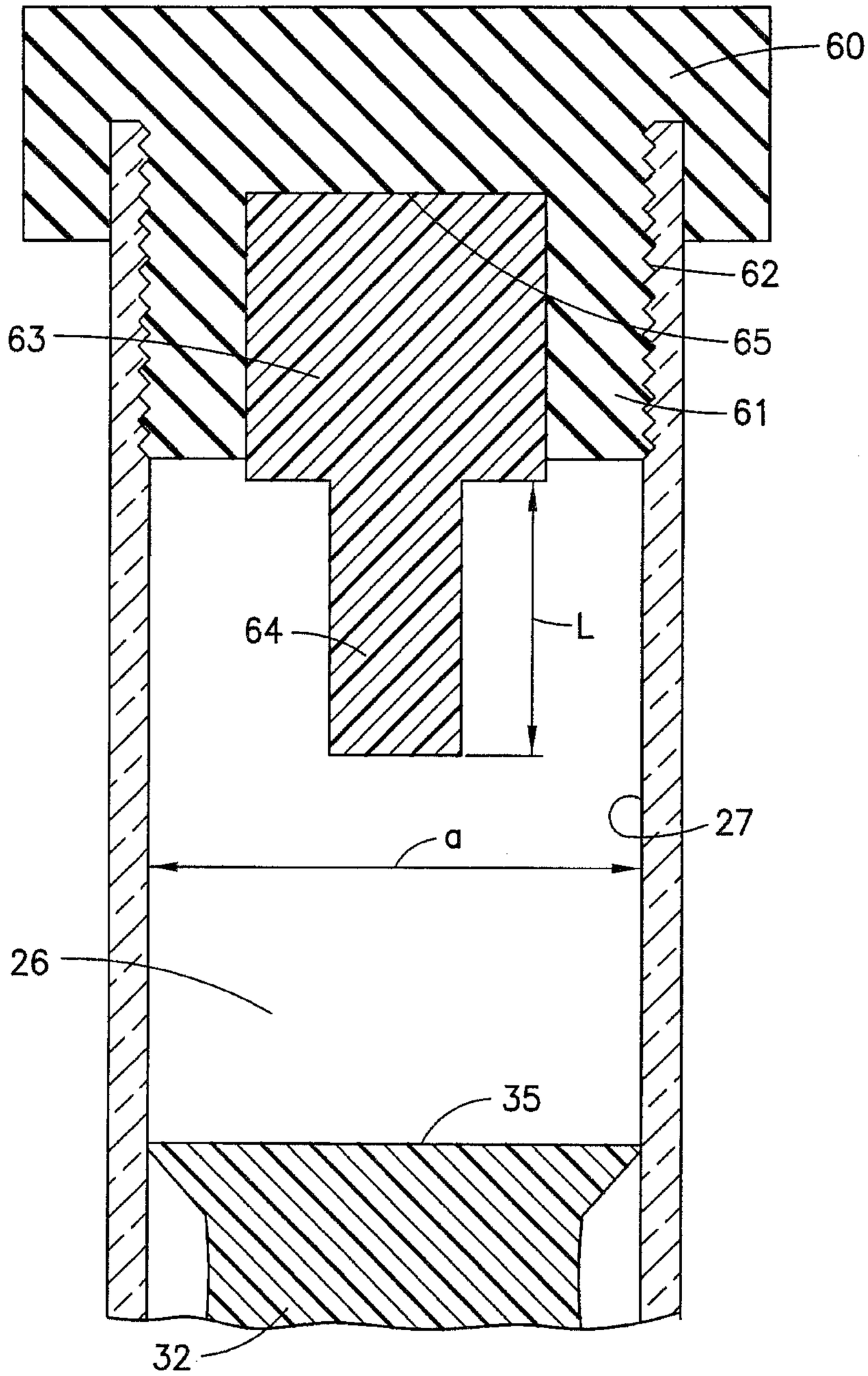


FIG.4

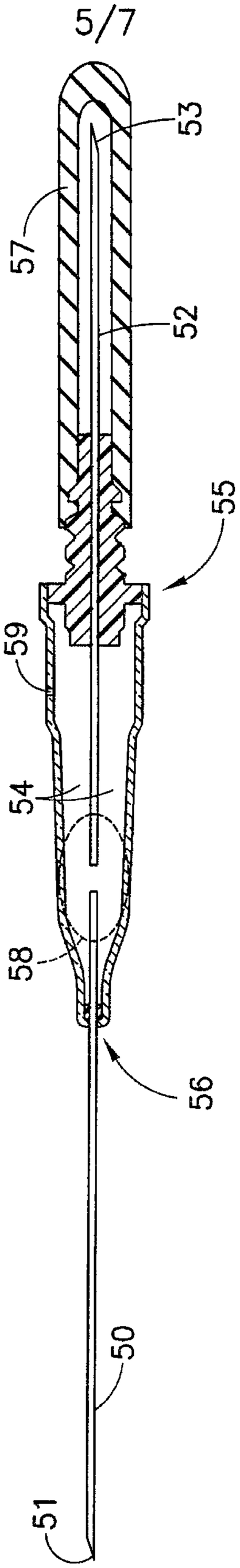
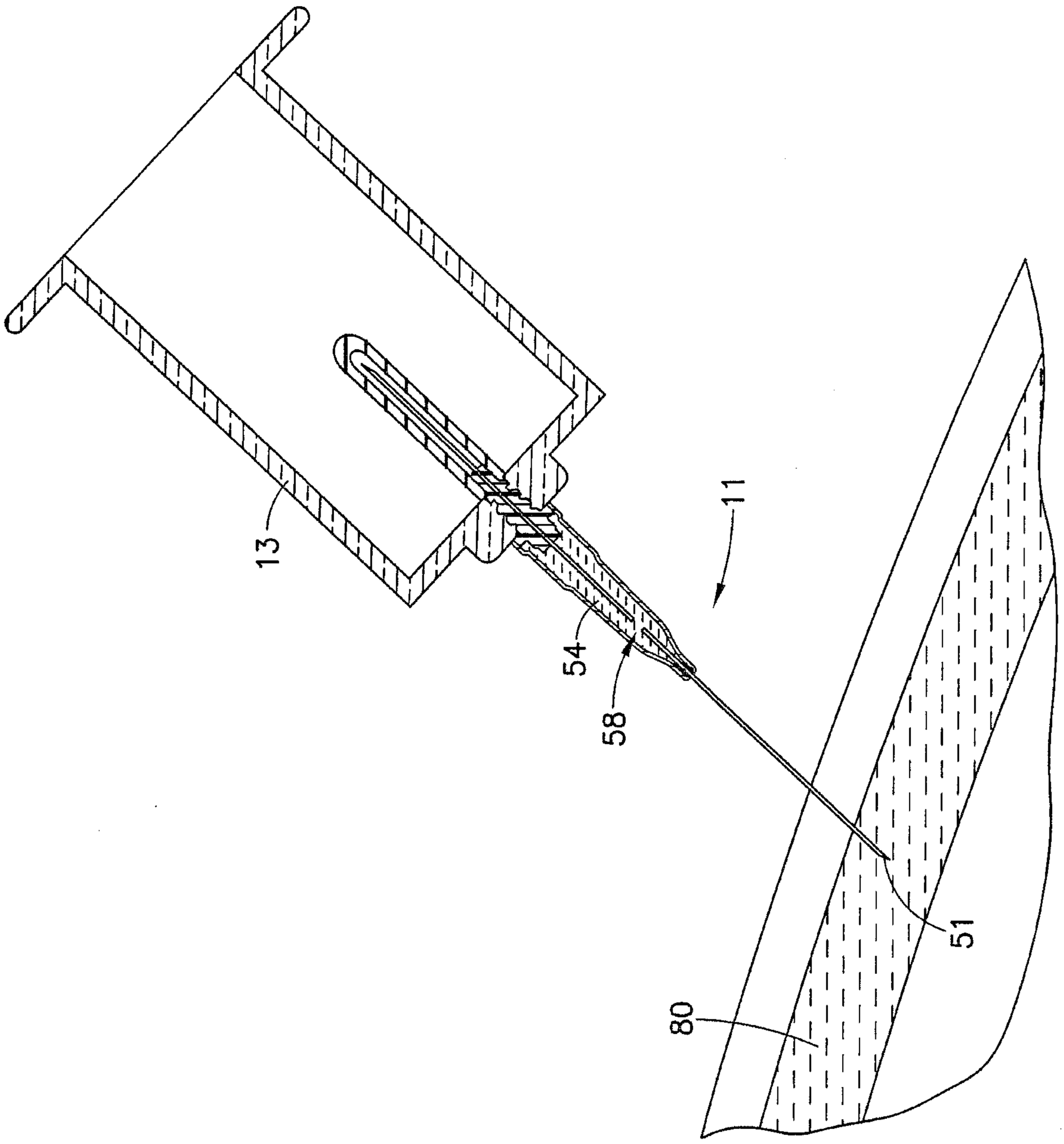


FIG.5

FIG.6



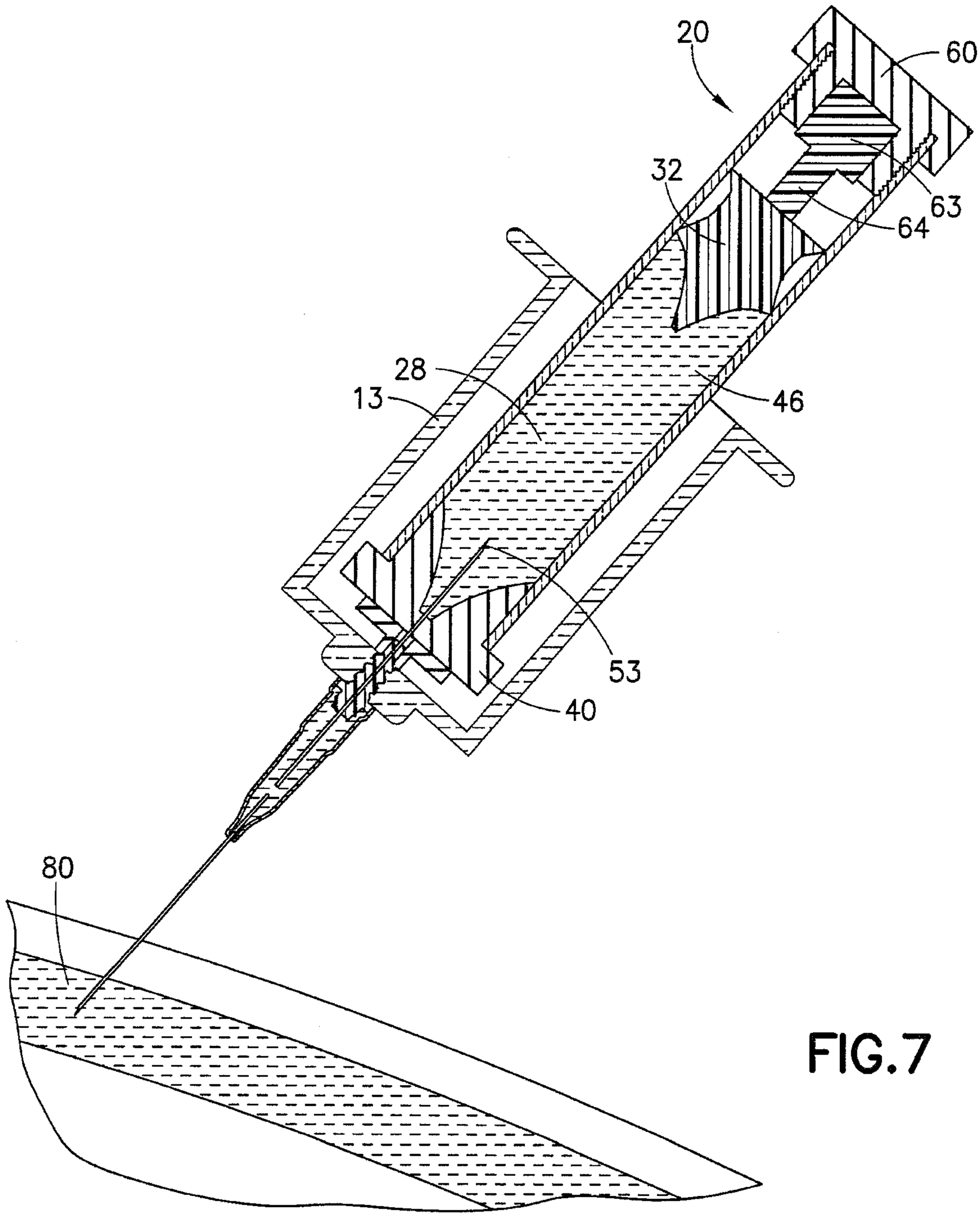
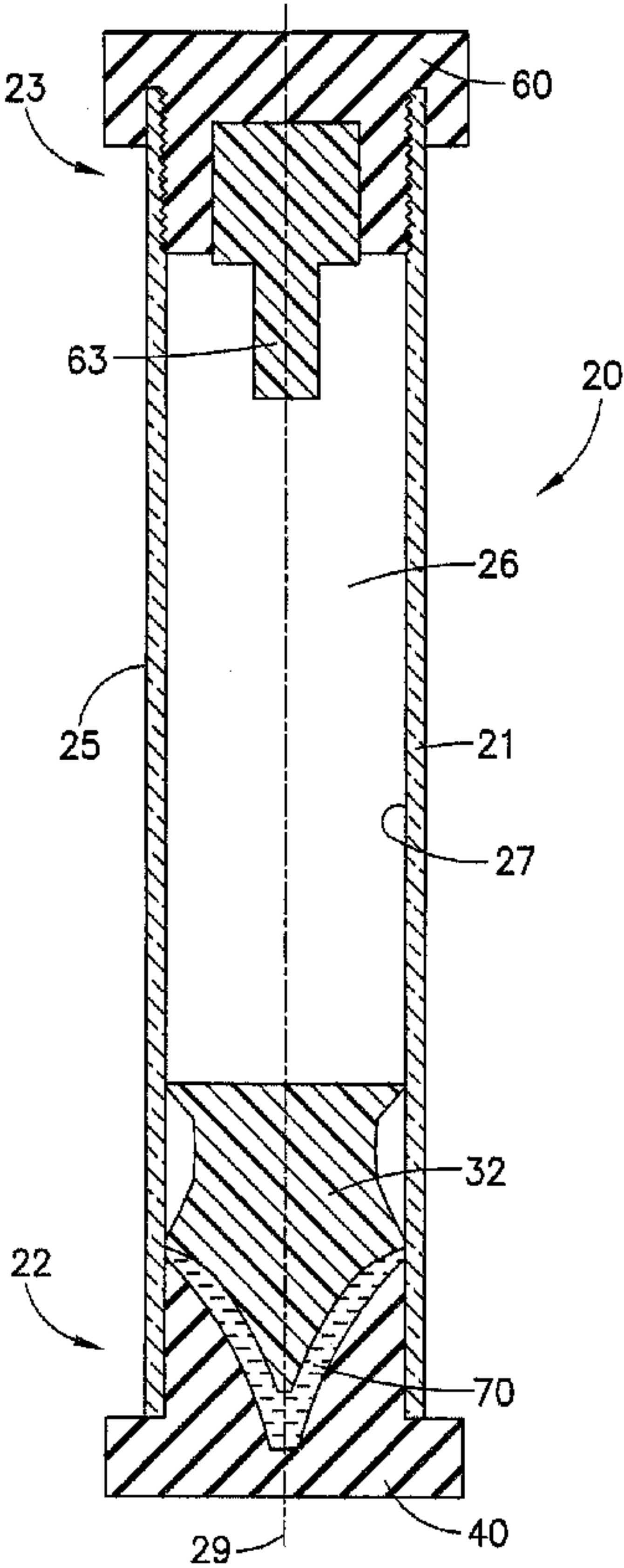


FIG.7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