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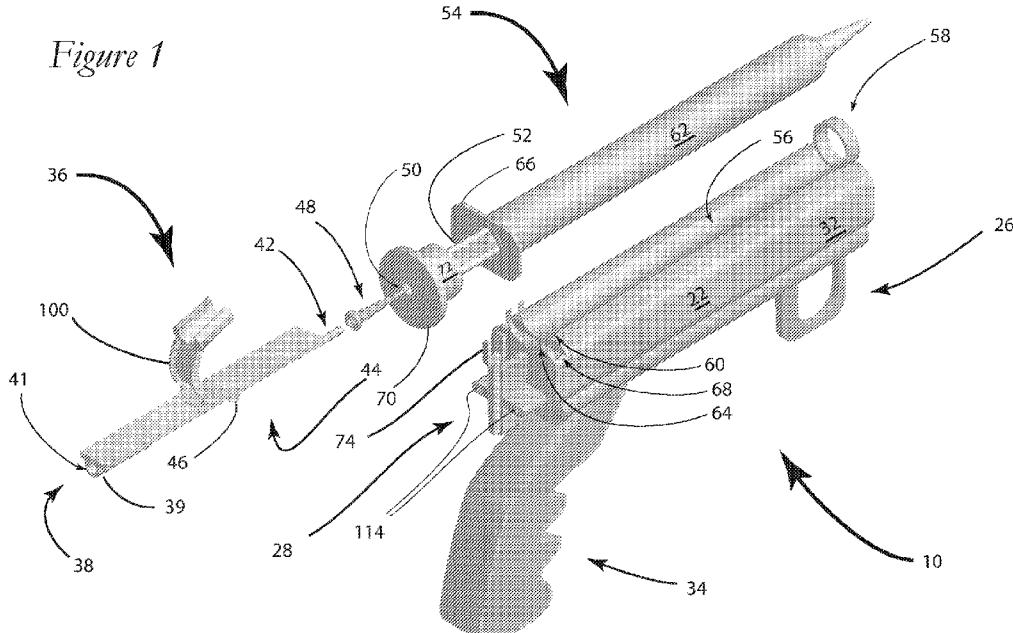
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(54) Title: INSERTION DEVICE FOR ONE-HANDED INSERTION OF A GUIDEWISE INTO THE LUMEN OF A VESSEL/CAVITY

Figure 1



(57) Abstract: A device for one-handed insertion of a guidewire into a vessel or cavity is provided. The device has a body, an actuator carriage, a guidewire feed, and a syringe. The body has a handle, a guideway, and a clip to retain the syringe. The syringe has a barrel and a plunger with a flange and a guidewire passage. The actuator carriage has a trigger and a clip to grasp the syringe plunger flange. The actuator carriage slides along the body guideway. The guidewire feed has a wire feed surface. The thumb engages wire at the wire feed surface to advance and retract the wire through the guidewire passage and a finger moves the trigger to move the syringe plunger rearwardly and/or forwardly, while the remaining fingers of the one hand grasp the handle. The device allows the user to sense resistance encountered by the tip of the wire.

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Insertion Device for One-Handed Insertion

of a

Guidewire into the Lumen of a Vessel/Cavity

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Claim for Priority

This application is based on United States Provisional Patent Application Serial No. 62/420,269, filed on November 10, 2016, the priority of which is claimed, and the disclosure of which is incorporated by reference.

Background of the Invention

10 Insertion of a guidewire, particularly a central line of considerable length, into the lumen of a vessel can be a particularly technically difficult and time consuming procedure as it must often be accomplished quite rapidly when the patient is in distress; yet the common practical procedures heretofore available have largely either required the use of an assistant with an imaging device, typically an ultrasound, and concomitant coordination therewith, or have deprived the physician inserting the guidewire of the critical sense of feel and touch for 15 the progress of the guidewire which can make a vital difference between successful and proper insertion of the guidewire into the vessel/cavity, penetrating only one wall thereof and failure occasioned by penetration of the opposite wall of the vessel/cavity or missing a critical turn in directing the wire to its desired location. Either situation can lead to an 20 adverse outcome particularly in the case of a gunshot wound, rapid blood loss or any other situation making it critical to insert a wire into a vessel or cavity quickly and accurately. This invention relates to a device enabling the practitioner to introduce the guidewire into a vessel/cavity and advance it along the desired path using one hand, freeing the other to control other equipment such as an ultrasound, while retaining the critical sense of feel and 25 touch to know both when the wire is advancing properly into the vessel/cavity and when the wire is attempting to deviate from the desired course. The ability to perceive the precise amount of resistance that the tip is experiencing, while leaving the other hand free for other devices, can be absolutely crucial to proper introduction of a guidewire and can literally make a difference between life and death. The procedure is applicable to central line 30 placement in arteries and other circulatory vessels as well as for less common procedures in which it is desired to introduce a guidewire of considerable length into other organs in a living body for a variety of therapeutic reasons. It is particularly useful in retrograde intubation as time is almost always critical when retrograde intubation is called for.

Summary of the Invention

There have been many attempts to address these issues previously. There are numerous patents directed to guidewires coiled in cassettes with a fixture at the exit to allow the practitioner to advance the guidewire into the vessel/cavity. However, these attempts cannot be considered entirely successful. In particular, where prior art devices have been claimed to make one-handed insertion and guidance possible, these often introduced gearing, drive wheels, or other devices between the operator's hand and the wire being introduced thereby degrading the operator's sense of feel for the precise amount of resistance being encountered by the guidewire. In this invention the guidewire is advanced by contact with the clinician's thumb enabling the clinician to gauge the amount of resistance being encountered while using the remainder of the hand to control advancement of the needle and manipulate the plunger of the syringe as required and leaving the other hand free to manipulate an ultrasound probe or transducer.

This invention addresses this issue by providing a device for one-handed insertion of a guidewire into the lumen of a vessel or other cavity, comprising: a body having: a rearwardly relieved handle, a guideway defined by said body, a clip mounted on said body adapted to receive and retain the barrel of a syringe; a syringe having: a barrel and a finger flange, said syringe being retained by said clip, a plunger having a plunger flange and a guidewire passage therethrough and a hollow needle co-linear with said guidewire passage through said plunger; an actuator carriage slidable along said guideway of said body, having attached thereto: a trigger, a flange trap adapted to grasp the plunger flange of said plunger of said syringe, a generally annular cassette mounted on said plunger of said syringe and having mounted therebetween a wire feed module having a receiver adapted to couple with said generally annular cassette, a rear wire control tube, a forward wire control tube, a wire feed surface between said rear wire control tube and said forward wire control tube, wherein said handle, said trigger and said feed surface are disposed such that when the handle is grasped by the digits of one hand, a digit of said one hand can urge the trigger and the plunger of said syringe rearwardly to create a slight pressure differential allowing fluid, whether liquid or gas, to flow through said needle into said syringe when said needle is properly positioned, a phenomenon often referred to as "flashback", or to withdraw fluid through said needle, if need be, while the digit of said one hand can advance and retract the wire through said syringe by engaging the wire between the digit and the feed surface, sensing resistance encountered by the tip of said wire. I term the embodiments of this invention having a downwardly extending handle as "pistol grip" fixtures. In many cases,

pistol grip fixtures will have downwardly facing wire feed surfaces where the tip of the thumb engages the wire with the clinician's hand in a "thumbs-up" posture.

In many cases, the device of the present invention will be provided as a stand-alone device to be used with standardized guidewire cassettes having attached thereto: a forward wire module adapted to couple with said finger flange and direct said guidewire into said guidewire passage through the plunger of said syringe; and a wire feed surface between said generally annular cassette and said forward guide fitting, and a line insertion syringe having a barrel, a plunger having a plunger flange and a guidewire passage therethrough and a hollow needle co-linear with said guidewire passage through said plunger. In such a case, the present invention will comprise: a device for insertion of a guidewire disposed within a generally annular cassette through a syringe into the lumen of a vessel/cavity, comprising: a body having: a rearwardly relieved handle, a guideway defined by said body, a clip mounted on said body adapted to receive and retain the barrel of a syringe; an actuator carriage slidable along said guideway of said body, having attached thereto: a trigger, a flange trap adapted to grasp the plunger flange of said plunger of said syringe, a receiver adapted to couple with said generally annular cassette, wherein said handle, said trigger and said feed surface are disposed such that when the handle is grasped by the digits of one hand, a digit of said one hand can urge the trigger of said syringe rearwardly either to create a slight pressure differential allowing fluid to flow through said needle into said syringe when said needle is properly positioned, a phenomenon often referred to as "flashback", or to withdraw fluid through said needle, if need be, while the thumb of said one hand can advance and retract the wire through said syringe by engaging the wire between the thumb of said one hand and the wire feed surface, sensing resistance encountered by the tip of said wire.

An alternative embodiment of this invention addresses this issue by providing a device for one-handed insertion of a guidewire into the lumen of a vessel/cavity, comprising: a body having: a grip defined thereupon, a guideway defined by said body, a clip mounted on said body adapted to receive and retain the barrel of a syringe; a syringe having: a barrel and a finger flange, said syringe being retained by said clip, a plunger having a plunger flange and a guidewire passage therethrough and a hollow needle co-linear with said guidewire passage through said plunger; an actuator carriage slidable along said guideway of said body, having attached thereto: a trigger, a flange trap adapted to grasp the plunger flange of said plunger of said syringe, a generally annular cassette mounted on said plunger of said syringe and having mounted therebetween a wire feed module having a receiver adapted to

couple with said generally annular cassette, a rear wire control tube, a forward wire control tube, a wire feed surface between said rear wire control tube and said forward wire control tube, wherein said grip, said trigger and said feed surface are disposed such that when the grip is grasped by the digits of one hand, a digit of said one hand can urge the trigger and the plunger of said syringe rearwardly to create a slight pressure differential allowing fluid to flow through said needle into said syringe when said needle is properly positioned, a phenomenon often referred to as "flashback", or to withdraw fluid through said needle, if need be, while the digit of said one hand can advance and retract the wire through said syringe by engaging the wire between the digit and the feed surface, sensing resistance encountered by the tip of said wire. I term the embodiments of this invention having a grip defined about the body as "hilt-handle" fixtures. In many cases, clinicians will find the hilt-handle fixtures preferable because it is easy to configure these devices such that the feed surface for the wire can be oriented facing upwardly so that the flat of the ball of the digit can be used to advance the wire giving the clinician excellent tactile feedback to the resistance that the wire is encountering while being advanced along the lumen of the vessel.

Preferred cassettes are substantially similar to those illustrated in Fleck, USP 5,125,906, Hand-Held Device for Feeding a Spring Wire Guide, issued June 30, 1992, incorporated by reference herein in its entirety.

It is of particular importance that the operator is able to manipulate the wire with the digit, usually the thumb, of the hand holding the device as well as to manipulate the plunger with a digit of the same hand. The ability to manipulate the plunger using a digit of the same hand on the trigger enables the practitioner to urge the plunger of the syringe rearwardly creating a slight pressure differential enabling the practitioner to detect flashback, the ingress of blood or other fluid or matter into the syringe when the tip of the needle has entered the vessel or other structure. At the same time, the use of an ultrasound will enable the practitioner to ascertain when the tip of the needle has been properly placed. Being able to manipulate the fixture while gripping it enables the practitioner to have precise sensation of the amount of force required to advance the wire while leaving the other hand free to manipulate an imaging or sensing device, such as an ultrasound, so that the location of the needle can be visualized and thereafter the location of the tip of the guidewire can be visualized as it is advanced into the patient

One-handed Seldinger Technique

As alluded to earlier, the *raison d'être* of the present invention is to allow clinicians to practice the Seldinger technique using only one hand for both needle placement as well as for manipulation of the guidewire while using the other to position a visualization device, such as an ultrasound, thus enabling the clinician to ensure that the ultrasound is placed properly for optimum viewing of the needle/guidewire as it enters the lumen while freeing assistants to perform other functions as needed. In many cases, where a central line is needed, time will absolutely be of the essence and the ability of the clinician to insert the line with minimal delay will be of the utmost importance. It is believed that reliable, expedient and practical methods of practicing the Seldinger technique while using only one hand to manipulate the syringe and guidewire and retaining a good haptic feel on the guidewire have not heretofore been available.

In the Seldinger technique, a syringe having a beveled needle is inserted into the body with the bevel oriented in such a fashion that the point of the bevel first enters the skin so that when the guidewire exits the bore of the syringe, it will be oriented generally parallel to the longitudinal axis of the body passageway in question or in some known other orientation if a guidewire is to be introduced into some other bodily structure. Where body conformation allows, it is usually preferable that the needle of the syringe make about a 45° angle with the surface of the skin with the point of the bevel engaging the skin first. As is well known, once the needle has entered the skin, the clinician applies slight negative pressure so as to be able to detect entry of the bore of the needle into the body passageway by flashback of blood, air, other body fluid, or even tissue into the barrel of the syringe. The fixtures of the present invention enable the clinician to apply this negative pressure by pulling back slightly on the plunger of the syringe with one hand whereas in the conventional technique the use of 2 hands can be somewhat awkward or clumsy. In many cases, the clinician will be able to manipulate the plunger using a single digit, perhaps the index finger, on the hand holding the fixture.

In those cases where an air embolism is possible, the use of the fixture of the present invention markedly decreases that danger as less effort is required to stabilize the needle, it will not be necessary to seal the pathway for air into the bore of the needle using the digit as in a conventional technique where the syringe is removed from needle. Further, as the guidewire will usually be joined to the syringe beforehand, there will be no need to

either search out or insert in the guidewire as might otherwise be required in the clamor of an urgent procedure.

Once the guidewire is passing through the bore of the needle, the clinician may have increased ability to perceive the amount of resistance being encountered by the wire while 5 also being able to more expeditiously use the ultrasound to ensure the guidewire enters into, and remains in, the lumen of the vessel or other desired location. This can be extremely significant as it avoids the contingencies in which the clinician might be tempted to withdraw the guidewire slightly to re-orient it in the lumen of the vessel. In particular, if such a withdrawal is not handled properly there is a possibility that the guidewire may be cut by 10 the bevel on the needle particularly when the guidewire is curved at the tip or is for some other reason bent. In many cases, it is of course conventional, for the guidewire to have a "J" shaped tip to guard against inadvertent perforation of a vessel wall.

After the guidewire is properly positioned, in the conventional procedure, the clinician restrains the guidewire with one hand and retracts the needle with his other hand. 15 In contrast, with the fixture of the present invention, the clinician moves the fixture rearwardly and only is required to begin using his other hand to restrain the guidewire as the bevel of the needle exits the body since the grip of surrounding tissue will often be sufficient to hold the guidewire in place while the fixture is being withdrawn, particularly if light restraint is applied above the entry point.

20 Once the guidewire has been properly positioned, and the means of inserting it have been cleared away, the clinician using the fixture of the present invention will proceed generally in accordance with the conventional procedure.

At present, Arrow/Teleflex offers a peripheral catheter styled "Endurance" extended dwell peripheral catheter adapted to be inserted with one hand. See Arrow/Teleflex's web 25 site at teleflex.com/usa/product-areas/vascular-access/vascular-access-catheters/peripheral-access/arrow-endurance-extended-dwell-peripheral-catheter-system/. It is submitted that the style of catheter insertion fixture is, as advertised, suitable for peripheral catheters but is not readily adaptable for insertion of central lines, or guidewires therefor, as the tube of the catheter is deployed around the needle during the insertion 30 procedure while the guidewire therefor may be advanced through the needle by urging a guidewire slider *rearwardly*, the interposition of the slider possibly interfering with the clinician's tactile feedback during manipulation of the wire. Thus, it is noted that, apparently, the maximum length of catheter currently offered in this format is about 8 cm, while the

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guidewires used for central line placement often have lengths of a half meter or more. In the procedure of the present invention, once the guidewire has been inserted into the vessel or other bodily structure, the fixture is removed, and the central line passed over the guidewire into the vessel, thereby allowing use of a central line of an indefinite length. Particularly in the case where the central line is being inserted through the groin and must extend into the region of the heart or coronary arteries, it is quite common to use a guidewire having a length of substantially over one meter.

Other aspects and advantages of the present invention are described in the detailed description below and in the claims.

10

Brief Description of the Drawings

The invention is described in detail below with reference to the appended drawings, wherein like numerals designate similar parts. In the Figures:

15

Figure 1 is a schematic isometric perspective of an insertion device of the present invention, partially exploded, showing the plunger of the syringe in position prior to attachment of the guidewire feed module;

Figure 2 is an exploded schematic isometric perspective of an insertion device of the present invention;

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Figure 3 is an exploded schematic isometric perspective of an insertion device of the present invention, showing details of the finger flange retention clip which retains the syringe upon the body while fixing the finger flange of the syringe in location longitudinally;

Figures 4 and 5 illustrate the details of the syringe retention ring at the front of the body;

Figures 6 and 7 illustrate the details of the syringe retention clip at the rear of the body;

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Figure 8 is a schematic isometric perspective of a wire guide feed module suitable for use with an insertion device of the present invention;

Figures 9 - 13 illustrate the details of the wire guide feed module of **Figure 8** particularly illustrating the medial salient preferred for enhanced haptics during wire manipulation;

5 **Figures 14 and 15** illustrate the lower surface of the wire guide feed of **Figures 8 – 13** when mounted in a wire guide feed mounting fixture or retainer making it possible to mount the wire guide feed and a large cassette on the actuator carriage rather than the syringe when the cassette is of a size which is less conducive to mounting on the plunger of the syringe;

Figures 16 – 21 illustrate the details of the wire guide feed mounting fixture or retainer of **Figures 14 and 15**;

10 **Figure 22** is a schematic illustrating the details of the click to fit retention mechanism for holding the wire guide feed of **Figures 8 – 13** in the wire guide feed mounting fixture or retainer of **Figures 14 - 21**;

Figure 23 is a schematic isometric perspective of an insertion device of the present invention with the syringe just above the mating clips on the body and actuating carriage;

15 **Figure 24** is a schematic isometric perspective of a wire guide feed mounting fixture illustrating mounting thereof on the actuating carriage prior to insertion of the wire guide feed;

Figure 25 is an enlarged schematic isometric perspective of the wire guide feed mounting fixture of **Figure 24** illustrating details of the mounting mechanism preventing incorrect mounting of the retainer on the actuating carriage prior to insertion of the wire guide feed module;

20 **Figure 26** is a schematic isometric perspective illustrating an alternative insertion device of the present invention which is configured to allow the operator to positively and quickly mount the syringe on the insertion device;

25 **Figure 27** is a detail drawing of the schematic isometric perspective of **Figure 26** illustrating the interaction of the finger flange on the syringe with its mating groove in the body;

Figure 28 is a detail drawing of the schematic isometric perspective of **Figure 26** illustrating the interaction of the plunger flange with the plunger flange clip;

30 **Figures 29 and 30** illustrate an alternative embodiment of the present invention which many clinicians may find preferable ergonomically as it positions the wire control surface above the trigger mechanism with the wire control surface facing upwardly so that

the wire is more easily engaged by the flat of the digit rather than the tip of the digit as in the previous embodiment;

5 **Figures 31 – 37** are respectively a plan view, a right side elevation, a rear elevation, a front elevation, a bottom view, a sectional view along line D—D in **Figure 32**, and a left side elevation of the alternative embodiment of **Figures 29 and 30**;

Figures 38 –40 are exploded views of the embodiment illustrated in **Figure 30**;

10 **Figures 41 – 55** are detail views illustrating securement of the barrel, plunger and guidewire attachments for the embodiment of **Figures 29 and 30**, in particular **Figure 48** is a detail “A” of finger flange slot **68** in **Figure 39**, while **Figure 44** is a detail “B” of **Figure 41** illustrating finger flange slot **68** with finger flange **66** *in situ*;

15 **Figures 56 and 57** illustrate how suction can be supplied to the syringe barrel by drawing finger rings rearwardly as shown in **Figure 56** and how the plunger of the syringe can be advanced by moving finger rings forwardly as in **Figure 57**, which should normally only be done with the syringe out of the body as when the clinician feels that a new start is desirable;

Figure 58 illustrates an embodiment of the invention having a “hilt handle” configuration;

20 **Figure 59** illustrates the hilt handle embodiment of the invention of **Figure 58** with the slider advanced as would be usual at the beginning of a Seldinger Procedure, while in **Figure 58**, the slider has been retracted to induce a slight vacuum in the syringe allowing the practitioner to determine when the needle has entered a fluid filled region, while in making it possible to use the other hand to manipulate an ultrasound for confirmation that the needle is properly positioned;

25 **Figures 60-66** are respectively a plan view, front elevation, a sectional view taken along D-D in **Figure 61**, a left side elevation, a right side elevation, a rear elevation, and a bottom view of the embodiments of **Figures 58 and 59**;

Figure 67 is an exploded view of the embodiment of **Figures 58 and 59**;

30 **Figures 68-76** are detail views illustrating mounting features for ensuring reliable, hold fast, snap-into-position placement of the flange on the barrel of the syringe, in particular **Figure 76** is a detail “A” of finger flange slot **68** in **Figure 67**, while **Figure 71** is a detail “B” of **Figure 68** illustrating finger flange slot **68** with finger flange **66** *in situ*;

Figures 77-83 are detail views illustrating mounting features for ensuring reliable, hold fast, snap-into-position placement of the flange on the plunger of the syringe; and

Figures 84-85 are lower perspective views illustrating the fixture of the present invention with the slider in the rearward and frontal positions respectively.

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Description of Preferred Embodiments

The invention is described in detail below with reference to several embodiments and numerous examples. Such discussion is for purposes of illustration only. Modifications to particular examples within the spirit and scope of the present invention, set forth in the appended claims, will be readily apparent to one of skill in the art. Terminology used herein is given its ordinary meaning consistent with the exemplary definitions set forth immediately below.

With respect to the various ranges set forth herein, any upper limit recited may, of course, be combined with any lower limit for selected sub-ranges.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. As used herein with respect to article claims, "consisting essentially of" and like terminology refers to the recited components and excludes other components which would substantially change the basic and novel characteristics of the article. Unless otherwise indicated or readily apparent, an article consists essentially of the recited components when the article includes 90% or more by weight of the recited components. That is, the terminology excludes more than 10% unrecited components.

In Figures 1 through 8, insertion device 10 is adapted to allow one-handed insertion of guidewire 12. Guidewire 12 is commonly disposed within generally annular cassette 14 having exit opening 16. Insertion device 10 comprises body 22 with longitudinally extending guideway 24 defined therethrough. Actuator 28 sliding within longitudinally extending guideway 24 has trigger 26 mounted thereupon which trigger 26 slides within longitudinally extending slot 30 defined in lower forward portion 32 of body 22. Rearwardly extending handle 34 attached to body 22 is highly relieved.

Guidewire 12 may be withdrawn from generally annular cassette 14 through wire guide feed module 36 mounted thereupon at exit 16. Wire guide feed module 36 comprises: receiver 38 adapted to couple with exit 16 of generally annular cassette 14; rear

wire guide **39** having rear tube **41** defined therethrough; forward guide fitting **40** comprising forward tube **42** with feed surface **44** being defined between rear tube **41** and forward tube **42**. Preferably medial ridge or salient **46** is defined on feed surface **44** to ease and facilitate handling and control of guidewire **12**. Forward guide fitting **40** is adapted to mate with 5 adapter cone **48** which is capable of penetrating and being frictionally retained within guide wire passage **50** of plunger **52** of syringe **54** which is carried in groove **56** defined atop body **22** of insertion device **10**. Syringe **54** is retained in position by forward ring **58** and barrel clip **60** grasping barrel **62** of syringe **54**. Longitudinal movement of barrel **62** of syringe **54** is restrained by finger flange stop **64** located just rearwardly of barrel clip **60** such that finger 10 flange **66** is trapped between finger flange stop **64** and barrel clip **60**. Finger flange **66** rests within finger flange slot **68**. Plunger flange **70** is joined to plunger **52** via plunger header **72**. Plunger flange clip **74** mounted on actuator **28** grasps plunger flange **70** between arms **76** and **78** defining groove **77** so that plunger **52** may be advanced or withdrawn within barrel **62** by manipulation of trigger **26**. As shown in Figures **6** and **7**, resilient arms **80** and **82** of 15 barrel clip **60** embrace more than 180° of the circumference of barrel **62** urging it downwardly into groove **56** atop body **22** of insertion device **10** while forward ring **58** further restrains both lateral and longitudinal motion of barrel **62**.

Dimensions, configuration and orientation of the foregoing parts are chosen such that when actuator **28**, sliding along guideway **24** in body **22**, is somewhat retracted from 20 body **22** of insertion device **10**, feed surface **44** for guidewire **12**, and particularly medial ridge **46**, is conveniently reachable by the digit of the hand grasping handle **34** while another digit of that same hand controls trigger **26**. (Throughout this specification and claims, where we refer to “digit” we are referring to the digits of the hand, particularly any of the fingers or the thumb.) Accordingly, guidewire **12** located within guidewire cassette **14** may be drawn 25 through guidewire exit opening **16** as the tip of the digit on the hand grasping handle **34** urges guidewire **12** forwardly or rearwardly by forward or rearward movement across medial ridge and guidewire **12** may be thereby advanced into the vessel/cavity with the operator being able to accurately sense the degree or amount of resistance guidewire **12** encounters as it is being advanced.

30 **Figure 8** is an illustration of a guidewire cassette **14** having guidewire **12** disposed therein with wire guide feed module **36** attached to exit **16** of guidewire cassette with wire **12** extending across feed surface **44** and medial ridge **46** through forward tube **42** in forward guide fitting **40** thence through adapter cone **48**.

Figures 9 through 13 illustrate a hand-held device for feeding a spring wire guide substantially similar to that described in Fleck, USP 5,125,906 which we have described as wire guide feed module **36** herein.

In many cases, it will be possible to mount wire guide feed module **36** directly on plunger **52** by insertion of adapter cone **48** into guidewire passage **50** in plunger **52**, particularly when the length of wire **12** required is relatively short and accordingly cassette **14** can be relatively light and thus be capable of being retained in position by frictional forces between forward guide fitting **40**, adapter cone **48** and plunger **52**. However, in some cases, a more robust mounting method is appropriate such as, for example when the weight of cassette **14** is too great or when pressure might be applied to wire guide feed module **36**. For such occasions, we provide retainer **88** as illustrated in **Figures 14 through 22** which is capable of being mounted on actuator **28**. In such cases, however it is necessary to ensure that the operator has open, or as near to unrestricted as may be practicable, access to wires **12** as it passes over medial ridge **46** in feed surface **44** of wire guide feed module **36**. Wire guide feed module **36** can be introduced into retainer **88** longitudinally, snapping into place when properly positioned thereby providing haptic feedback to the operator confirming completion of proper insertion.

As shown in **Figure 16**, right sidewall **90** of retainer **88** has positioning protrusions **92** placed to locate wire guide feed module **36**. **Figures 19 and 20** illustrate the configuration of positioning protrusions **92** which generally have the shape of one fourth of a sphere with relieved flanks **94** as shown in **Figure 20** which help to guide wire guide feed module **36** into position. Notably protrusion **96** will bear against forward surface **98** of cassette mounting pylon **100**, while protrusions **102** will bear against medial ridge **46** and protrusions **104** will snap into position as soon as medial ridge **46** has advanced into position. In the embodiment shown in **Figures 14 through 22**, adapter cone **48** is disposed within retainer **88**. In alternative embodiments, it may be disposed forwardly of wall **106** of retainer **88**. In **Figure 21**, retainer **88** is shown with left side wall **108** in position with crossbar **110** preventing over insertion of wire guide feed module **36** into retainer **88** by interference with pylon **100**. Notably, sidewalls **90** and **108** are highly scarfed away adjacent medial ridge **46** to allow the operator free access thereto. In **Figure 22**, it can be appreciated how crossbar **112** prevents improper insertion of wire guide feed module **36**, while crossbar **110** prevents over insertion and protrusions **102** and **104** signal complete insertion haptically to the operator. It can also be appreciated that access to medial ridge **46** and guidewire **12** passing thereover is facilitated by scarfing the way of medial portion of sidewalls **90** and **108**.

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Figure 23 illustrates an assembled insertion device **10** with syringe **54** disposed thereabove. It can be appreciated how forward end **120** of syringe **54** will be restrained by forward retention ring **58** while finger flange **66** and barrel **62** will be restrained by finger flange stop **64**, finger flange slot **68** and barrel clip **60** while plunger flange **70** is restrained by arms **76** and **78** of plunger flange clip **74**.

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In **Figures 24** and **25**, mounting recesses **114** and **115** have been provided in actuator **28** whereby pin **116** and slat **117** on mounting arms **118** may be inserted to mount retainer **88** fast to actuator **28** with details being illustrated in **Figure 25**. Inasmuch as slat **117** is too large, too wide, to be inserted into mounting recess **115**, improper mounting of retainer **88** and guidewire cassette **14** is thereby prevented. Alternatively, insertion device **10** can be provided with retainer **88** permanently attached to actuator carriage **28**.

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Figures 26 through **28** illustrate a variant of the insertion device **10** of the present invention meant for situations such as emergency rooms in which the operator may be required to assemble the insertion device **10**, syringe **54**, wire guide feed module **36** and cassette **14** with considerable urgency. It can be appreciated that retention ring **58** has been replaced by retention cone **86**, while finger flange stop **64**, barrel clip **60** and plunger flange clip **74** have been provided with exterior guides **64G**, **60G** and **74G** to facilitate rapid insertion of the mating portions of syringe **54** thereinto. **Figure 27** illustrates how finger flange **66** can be mounted either horizontally or vertically in finger flange slot **68**. Similarly, **Figure 28** illustrates mating of plunger flange **70** with plunger flange clip **74**.

25

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Figures 29 through **38** illustrate a manufacturing design for a hilt grip fixture of the present invention wherein parts performing the same function are given the same numbers as those performing that function in the conceptual design of a pistol grip fixture illustrated in **Figures 1** through **28**. It will be apparent that the primary difference between the two designs is that the grip is incorporated into body **22** of the fixture of **Figures 29 - 38** and adapter/receiver **36** for annular wire cassette **14** is oriented with feed surface **44** oriented upwardly so that a clinician holding fixture **10** is able to manipulate guidewire **12** with the flat of his digit while using his index finger to advance and retract actuator **28** while engaging plunger flange **70** of syringe **54** providing an enhanced haptic feel to evaluate resistance being met by guidewire **12** as it is advanced into the body.

In **Figure 29**, the handle of the previous embodiment is largely dispensed with leaving only trigger **26** directly connected to actuator **28** deployed directly under body **22** such that, when a digit of one hand extends through trigger **26**, the ball of the thumb of that

5

hand easily falls on medial ridge **46** over which guidewire **12** is passed allowing the clinician to advance the guidewire **12** while retaining good tactile feel for the resistance being encountered. It should be observed that in the embodiment of **Figures 29 and 30**, flanges **66** and **70** are well secured in slots **68** and **74** respectively, while barrel **62** of syringe **54** is secured by forward ring **58**, thereby providing positive location of syringe **54**. It should be noted that in the embodiment of **Figures 29-30**, the hand engages the fixture much like a hand would grasp the hilt of a sword.

10

Figures 31-37 illustrate details of the internal construction of the fixture of the present invention, note particularly “T”-shaped longitudinal channel **24** (See also **Fig.42**) formed in body **22** as shown in **Figure 36** so that actuator **28**, having mating “T” shaped portion **25** as shown in **Figure 40**, may be advanced and retracted therealong. In **Figures 38 and 39**, the fixture has been disassembled illustrating how the constituent parts are assembled.

15

Figures 41-48 illustrate other details of the constituent parts. Note longitudinally extending guideway **24** formed in body **22** to restrain movement of slider/actuator **28** thereupon. Note also undercut slot **68** in body **22** engages finger flange **66** for positive positioning thereof. In **Figures 49-55**, details of retention slot **74** having undercut groove **77** for marrying plunger flange **70** to actuator **28** are illustrated. Note again that retention slot **74** encompasses slightly more than 180° of plunger flange **70** thereby enabling positive positioning between the two by virtue of the elasticity of plunger flange **70** and, to a lesser extent, slider actuator **28**. Note also the longitudinal undercut as illustrated in **Figure 54**. As shown in **Figures 42, 44, 48**, the undercut of groove **77** accommodates the conventional cupping of plunger flange **70** further fixing the relative position thereof.

20

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Figures 56 and 57 are lower perspectives illustrating motion of slider/actuator **28** along longitudinally extending guideway **24** in body **22** with **Figure 56** illustrating actuator **28** as rearwardly positioned to induce partial vacuum in syringe **54**.

30

Figures 58 and 59 illustrate still another embodiment of the present invention in which shield/hood **97** positively prevents improper insertion of generally annular guidewire cassette **14** (not shown) when generally annular guidewire cassette **14** enters through tunnel **95**.

In **Figures 60-66**, details of the internal construction of the fixture are illustrated.

Note that longitudinally extending guideway **24** is now incorporated into slider/actuator **28** as shown in **Figure 62**.

5 In **Figure 67**, note that ramp **99** interlockingly mates with pylon **100** of wire guide feed module **36** for more positive positioning thereof back to slider/actuator **28**.

In **Figures 68-76**, details of construction of body **22** are illustrated. Particularly note that in **Figure 71**, finger flange slot **68** is longitudinally undercut with undercut groove **67** accepting finger flange **66** to positively position finger flange **66** in body **22** while flexible wall **63** serves to more positively lock finger flange **66** into position in finger flange slot **68**. Note 10 also that T-Bar **25** is formed in body **22** in this embodiment while slot **24** is formed in slider/actuator **28**.

In **Figures 77-83**, details of the construction of slider/actuator **28** are illustrated. Note particularly that groove **77** engages more than 180° of plunger flange **70** in interference fit to more positively position plunger flange **70** respect to slider/actuator **28**.

15 In **Figures 84-85**, a lower perspective illustrates slider/actuator **28** in a rearward position (**Figure 84**) as well as a forward position (**Figure 85**).

While the invention has been described in detail, modifications within the spirit and scope of the invention will be readily apparent to those of skill in the art. In view of the foregoing discussion, relevant knowledge in the art and references discussed above in 20 connection with the Background and Detailed Description, the disclosures of which are all incorporated herein by reference, further description is deemed unnecessary. In addition, it should be understood that aspects of the invention and portions of various embodiments may be combined or interchanged either in whole or in part. Furthermore, those of ordinary skill in the art will appreciate that the foregoing description is by way of example only, and is 25 not intended to limit the invention.

As our invention, we claim:

1. In a device for insertion of a guidewire initially disposed within a generally annular cassette, having an exit opening, through a syringe into a body:

5 wherein said syringe has a barrel with a finger flange, a plunger having a
plunger flange and a guidewire passage therethrough and a hollow
needle generally co-linear with said guidewire passage through said
plunger, and

wherein said generally annular cassette has attached thereto:

10 a guidewire feed having a receiver adapted to couple with said cassette and a guide fitting comprising a forward tube adapted to couple with said plunger and direct said guidewire into said guidewire passage through said plunger of said syringe, said guidewire feed having a wire feed surface between said generally annular cassette and said forward tube;

15

the improvement comprising:

an insertion device comprising:

a body,

20 a grip operably connected to said body;

a guideway defined by said body,

a barreltrap mounted on said body adapted to receive and retain the barrel of said syringe;

25 an actuator carriage slidable along said guideway of said body, said actuator carriage having attached thereto:

a trigger,

a plunger flange trap adapted to grasp the plunger flange of said plunger of said syringe,

wherein said grip, said trigger and said feed surface are disposed such that when the grip is engaged by a digits of one hand, a digit of said one hand is able to advance and retract the wire through said syringe by engaging the wire between a digit of said one hand and the wire feed surface, sensing the degree of resistance encountered by the tip of said wire, with a digit of said one hand being able to urge the trigger of said syringe rearwardly and/or forwardly, drawing said plunger rearwardly and/or forwardly while digits of said one hand continue to engage said grip.

5

10 2. The device for insertion of a guidewire of claim 1, wherein said receiver, adapted to couple with said generally annular cassette, is spaced rearwardly from said feed surface and holds the exit of said annular cassette generally in line with said feed surface, said guide fitting and said guidewire passage through said plunger of said syringe.

15 3. The device for insertion of a guidewire of claim 2, wherein said guideway is interior to said body of said device.

4. The device for insertion of a guidewire of claim 2, wherein said guideway is formed in the exterior surface of said body of said device.

5. A device for one-handed insertion of a guidewire, comprising:

20 a body having:

 a grip formed in said handle,

 a guideway defined by said body,

 a mount for a syringe having: a trap mounted on said body adapted to receive and retain a barrel of said syringe;

25 the barrel of said syringe being retained by said trap, said syringe having a plunger having a plunger flange and a guidewire passage through said plunger and a hollow needle co-linear with said guidewire passage through said plunger;

an actuator carriage slidable along said guideway of said body, having attached thereto:

5 a trigger,

a flange trap adapted to grasp the plunger flange of said plunger of said
syringe,

10 a wire guide feed mount adapted to support a generally annular cassette
mounted on said actuator carriage and having mounted thereupon:
a guide fitting adapted to couple with said plunger flange and direct
said guidewire into said guidewire passage through the
plunger of said syringe; and
a wire feed surface between said generally annular cassette and said
guide fitting,

15 a receiver adapted to couple with said generally annular cassette,
wherein said grip, said trigger and said feed surface are disposed such that
when the grip is engaged by the digits of one hand, a digit of said
one hand is able to advance the wire through said syringe by
engaging the wire between the digit of said one hand and the wire
feed surface, sensing the degree of resistance encountered by the
tip of said wire, with a digit of said one hand being able to urge the
trigger of said syringe rearwardly and/or forwardly, drawing said
plunger rearwardly and/or forwardly while digits of said one hand
20 continue to engage said grip.

25 6. The device for insertion of a guidewire of claim 5, wherein said receiver adapted to
couple with said generally annular cassette is spaced rearwardly from said flange
trap and holds the exit of said annular cassette generally in line with said wire feed
surface, said guide fitting and said guidewire passage through said plunger of said
syringe.

7. The device for insertion of a guidewire of claim 6, wherein said guideway is interior
to said body.

8. The device for insertion of a guidewire of claim 6, wherein said guideway is formed
in the exterior surface of said body.

30 9. A method of inserting a guidewire into the body of an organism, comprising the
steps of:

providing a fixture, operable with one gloved hand having digits, to:

- (a) advance a bare needle of a syringe having a plunger into said organism;
- (b) manipulate the plunger of said syringe to induce partial vacuum therein; and
- 5 (c) advance a guidewire mounted on said fixture into said organism by direct tactile contact between at least one digit of said gloved hand and said guidewire;

detecting when said needle on said syringe is entering into proper positioning by observation of entry of fluid, whether liquid, gaseous or mixture, into said 10 syringe;

stabilizing said guidewire in position within said organism using an agency other than said hand operating said fixture; and

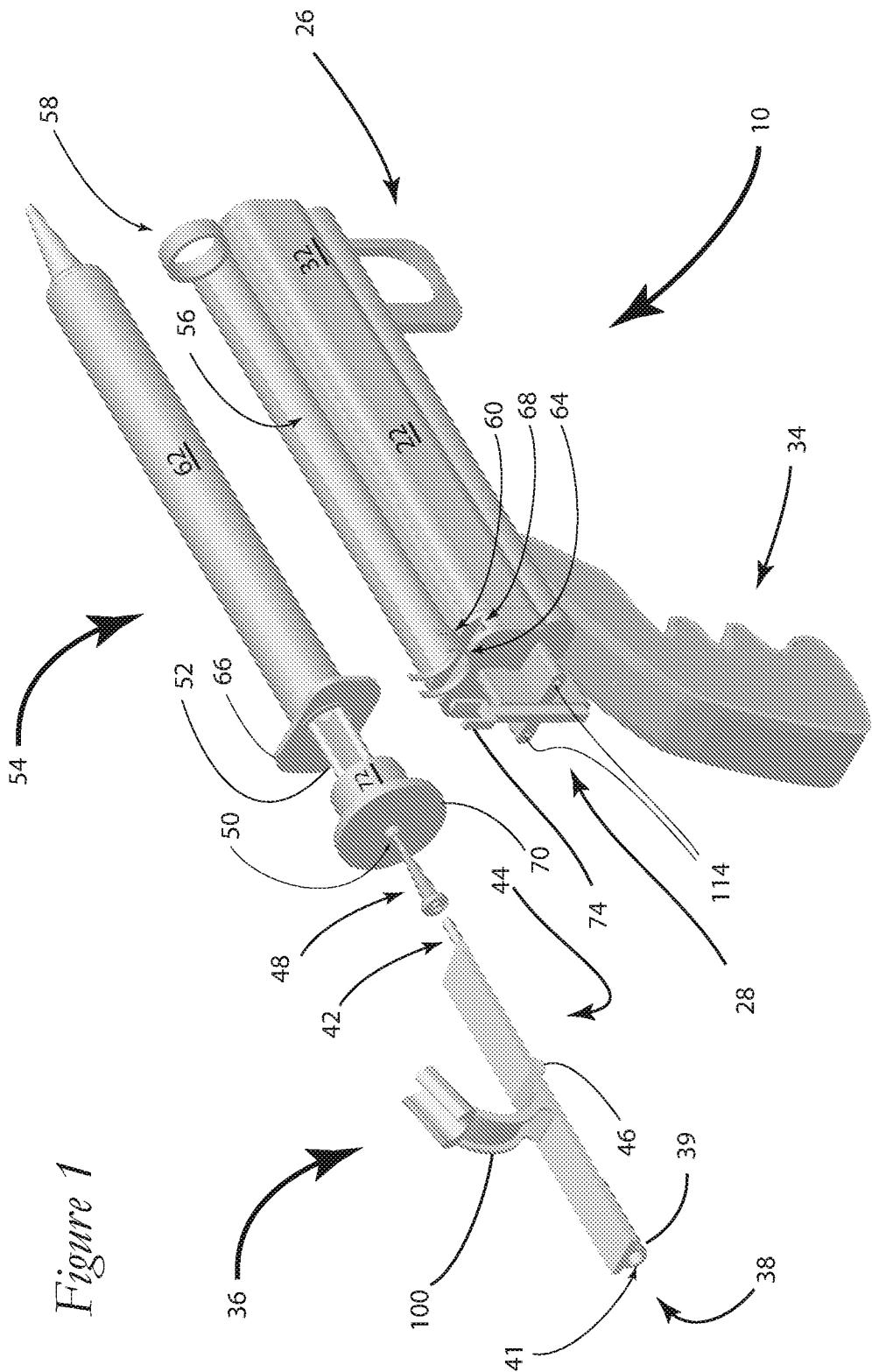
15 withdrawing said fixture;

said fixture having:

- a body with a trap capable of retaining the barrel of a syringe,
- an actuator movable with respect to said body, said actuator having a trap for the plunger of a syringe as well as a mount for receiving a feed adapter having a feed surface for a guidewire, said feed adapter being adapted to couple to a cassette having a guidewire therein.

20 10. The method of inserting a guidewire into the body of an organism of claim 9, wherein another hand of the operator of said fixture is used to manipulate a device for visualization of location of said guidewire within said organism.

11. The method of inserting a guidewire into the body of an organism of claim 9, comprising the further step of: thereafter placing a line over said guidewire and 25 passing said line into said organism after said fixture has been withdrawn.



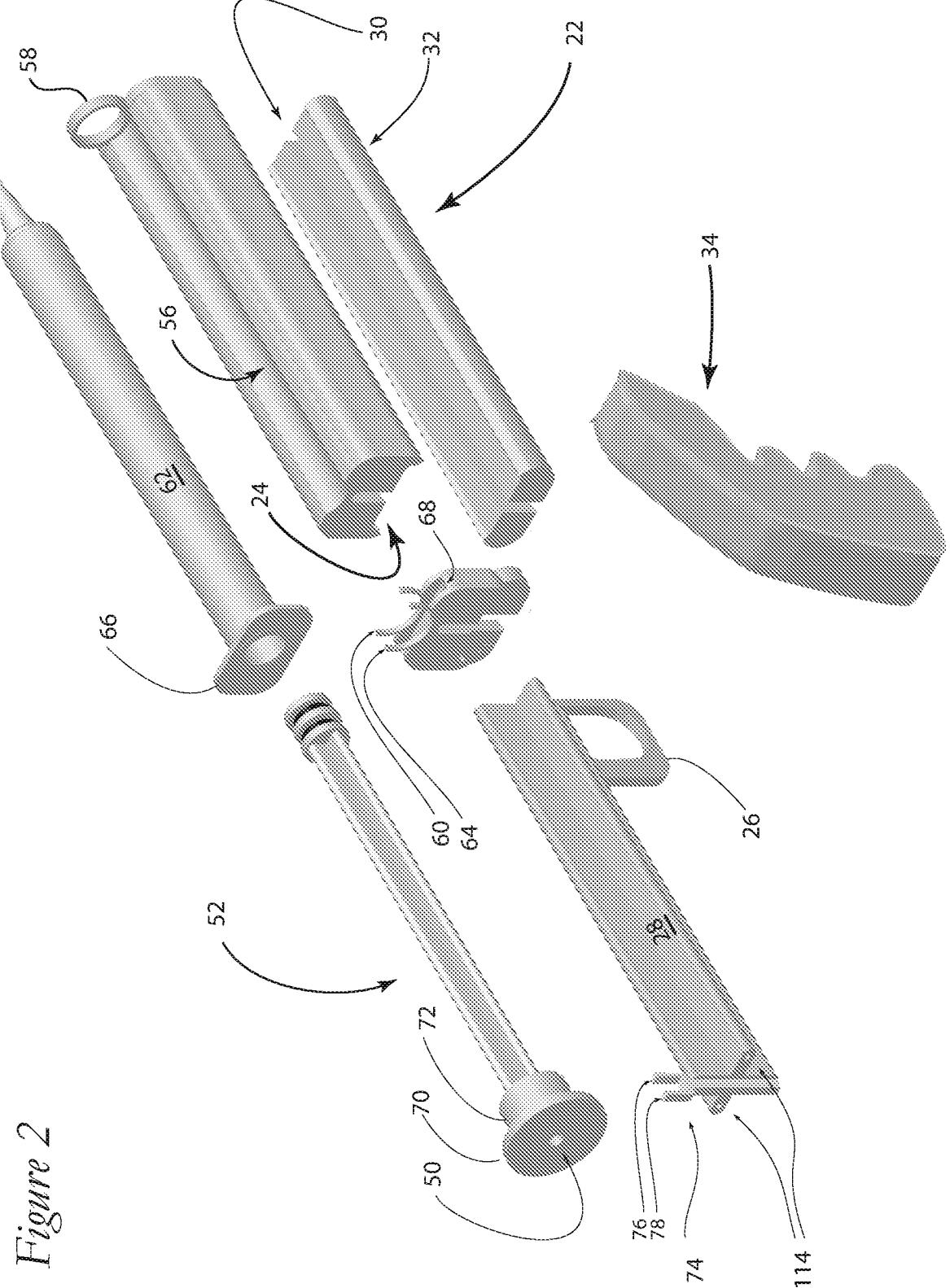


Figure 2

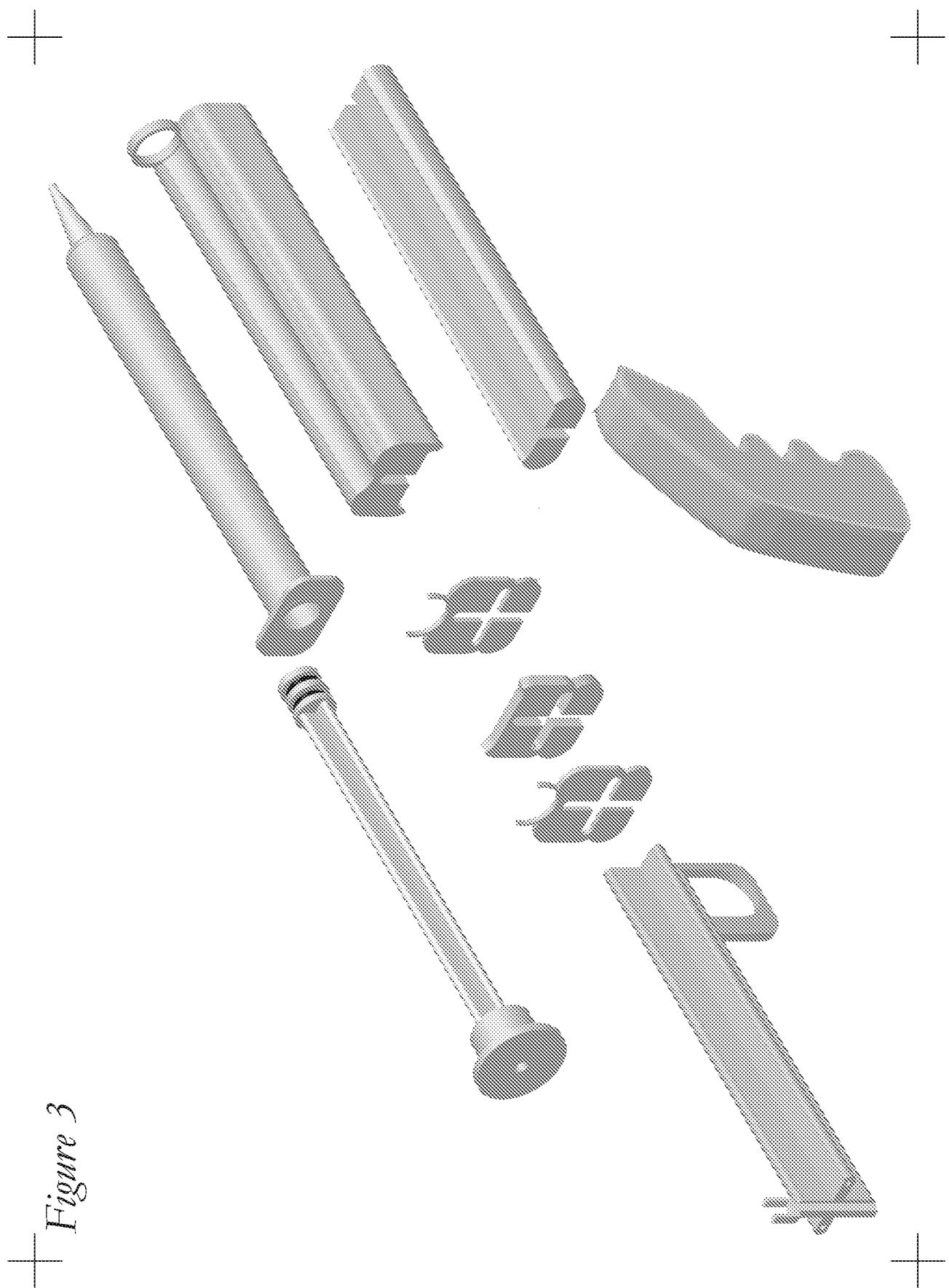




Figure 4

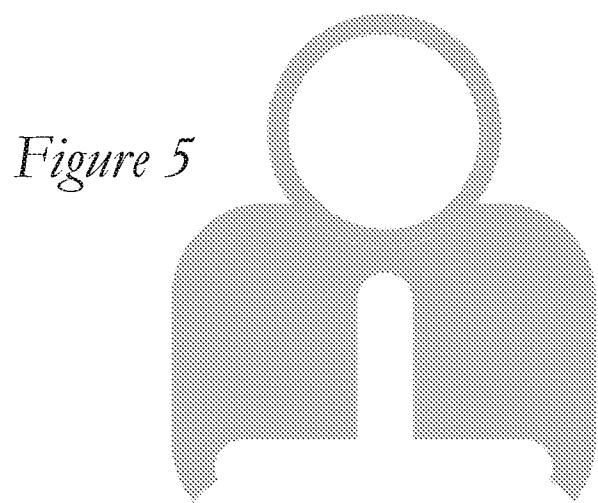


Figure 5

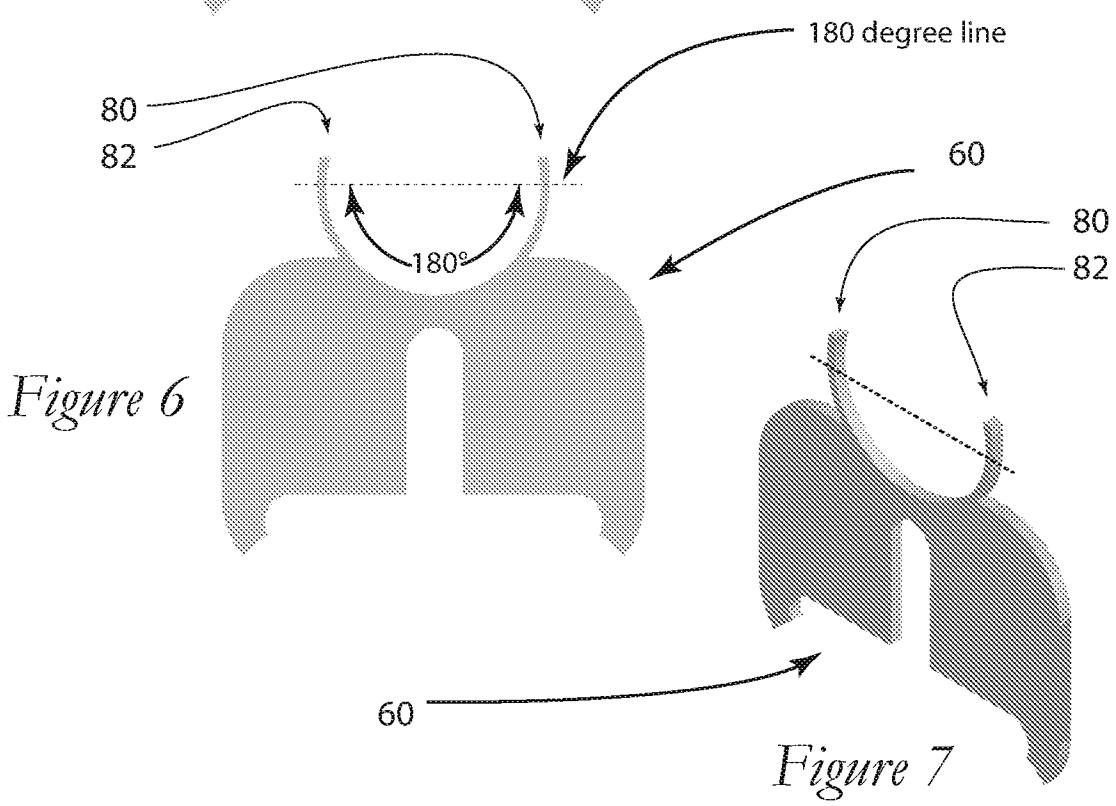


Figure 6

Figure 7

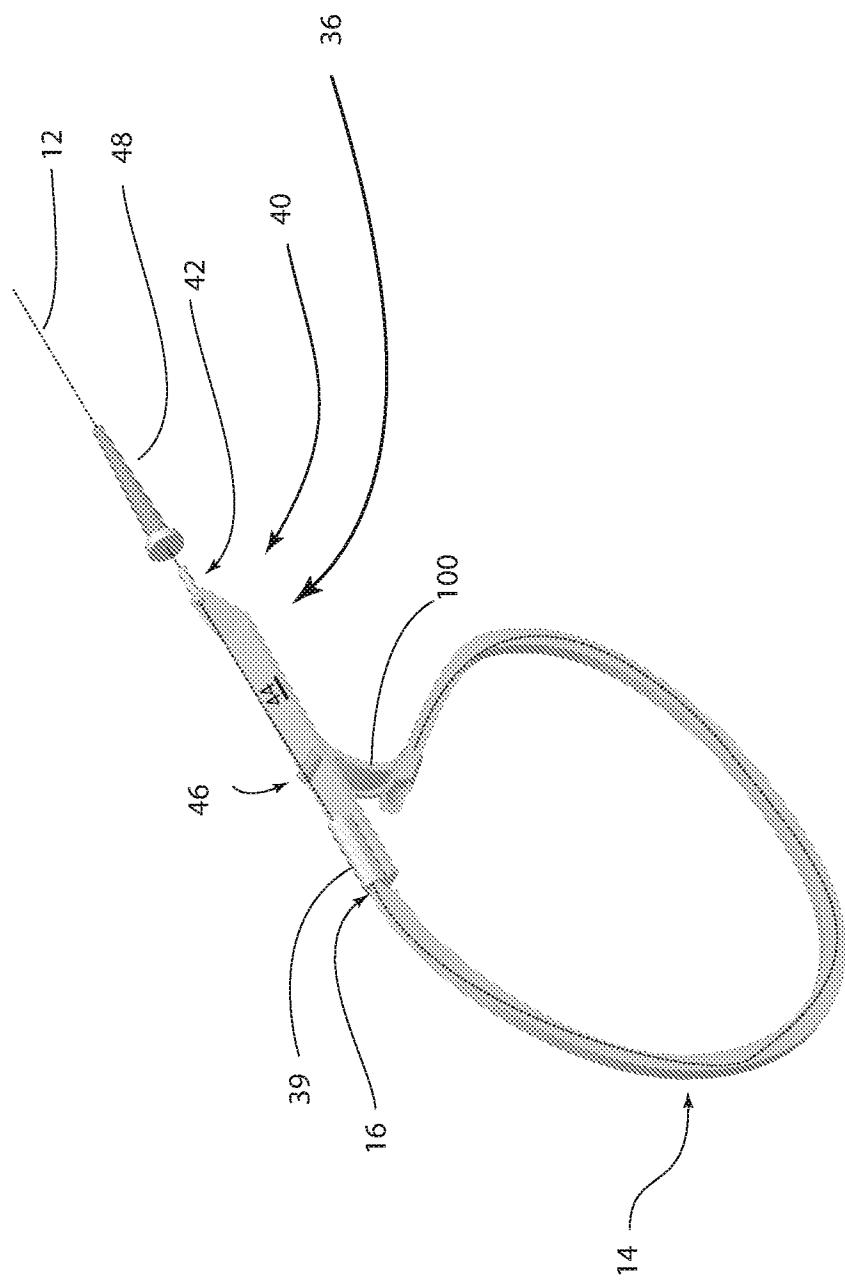


Figure 8

+

Figure 10



Figure 13+

+

Figure 9

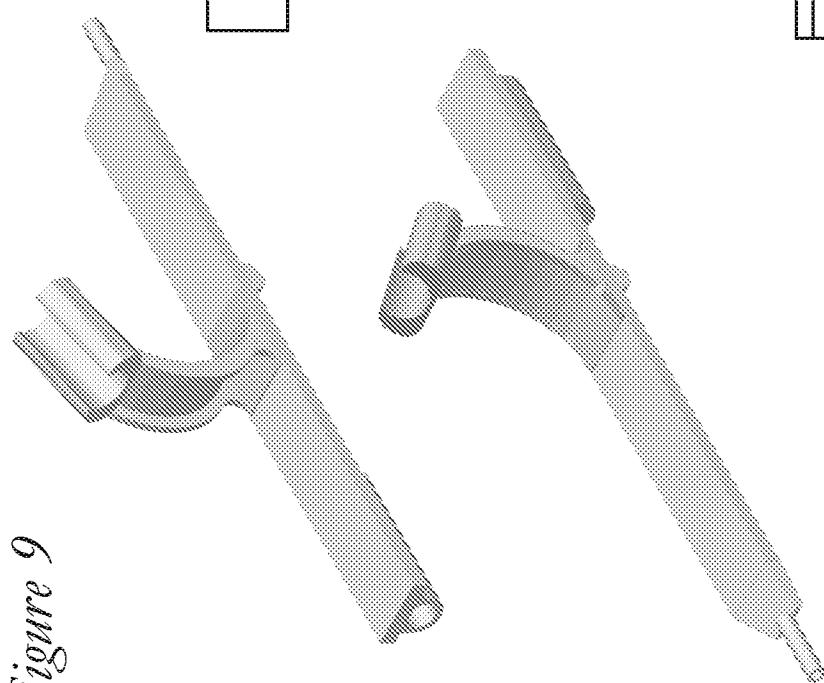


Figure 11

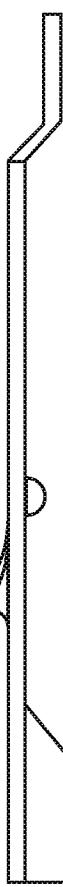
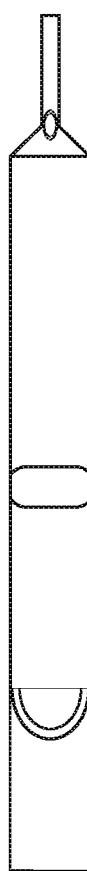


Figure 12



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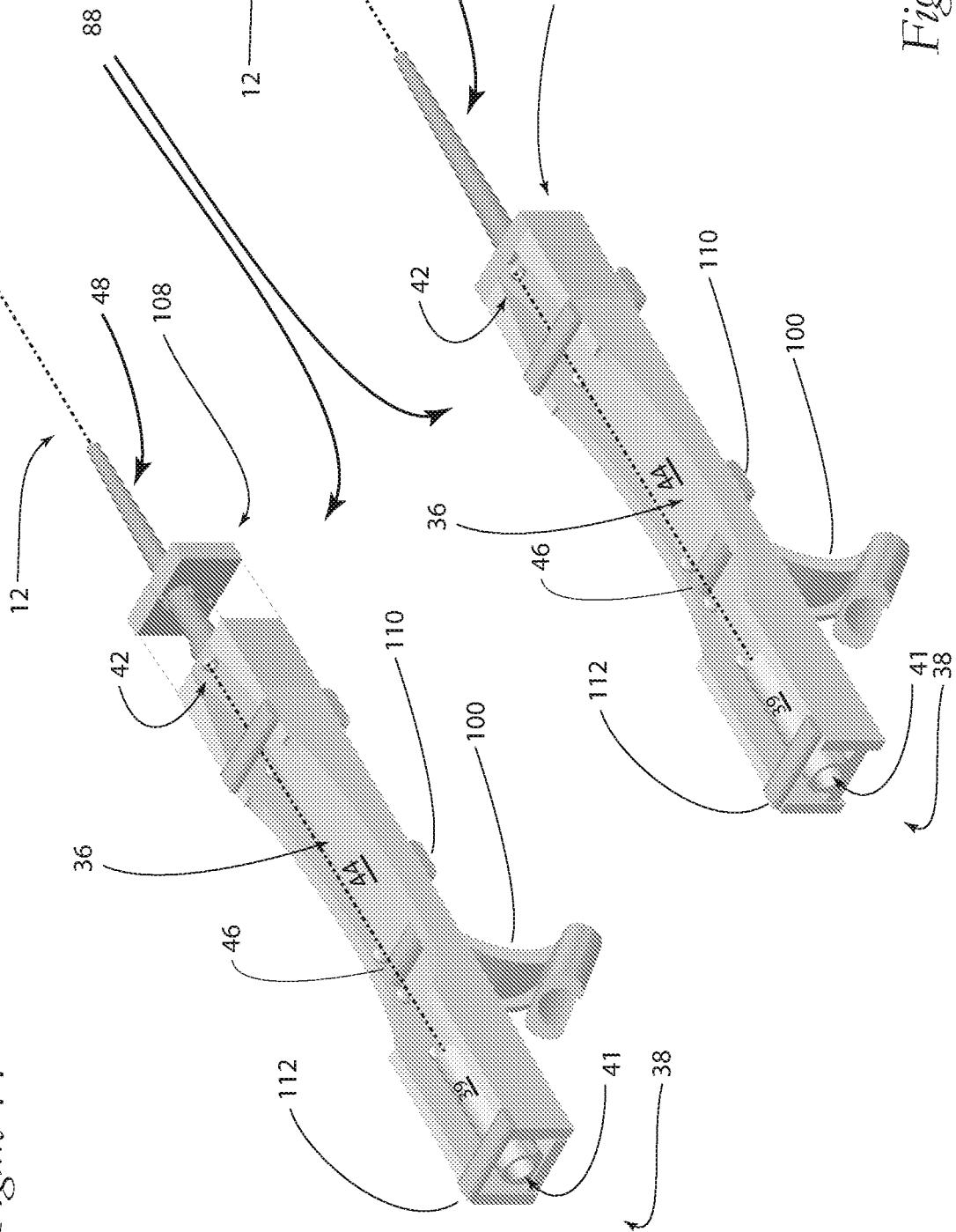


Figure 15

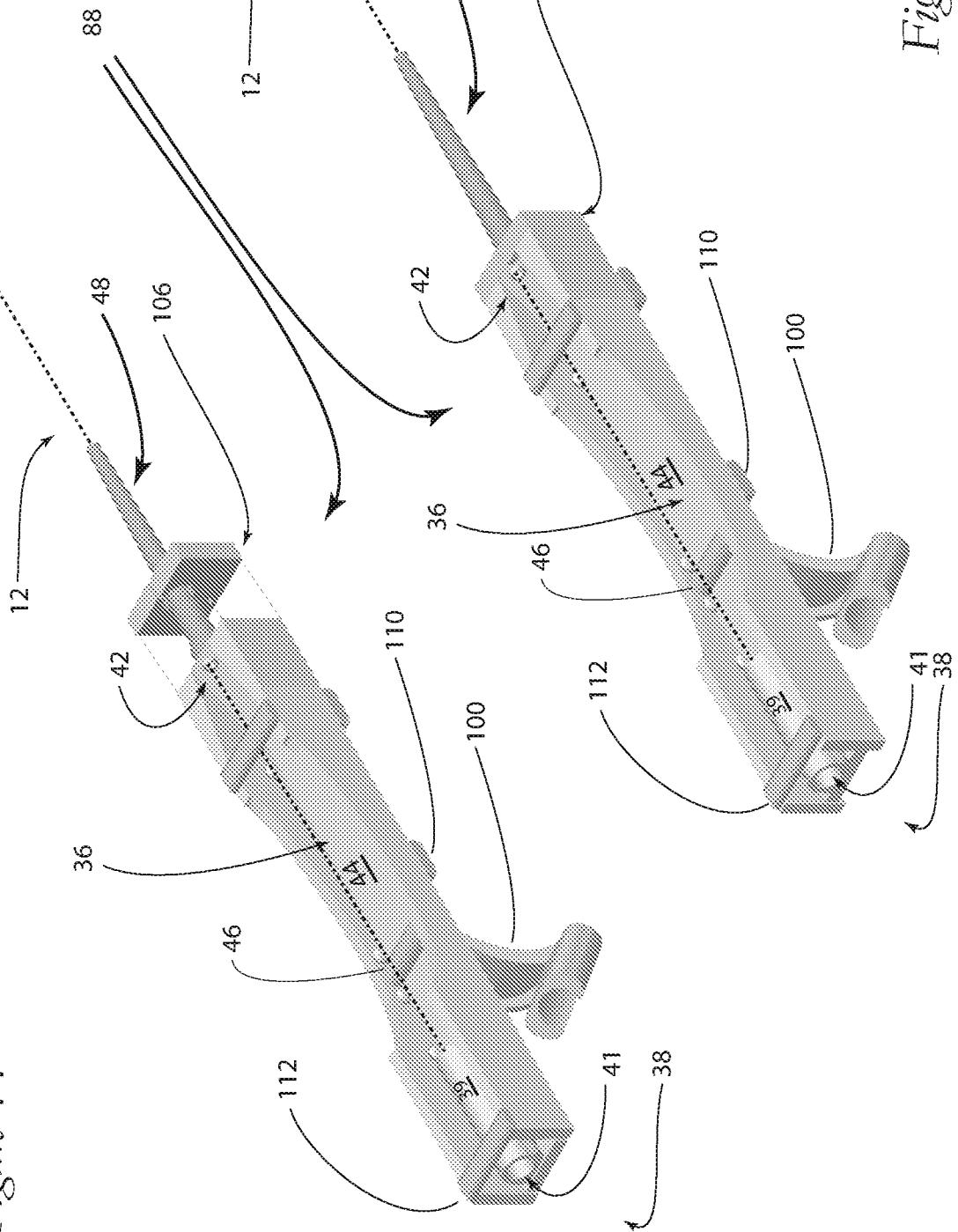


Figure 14

Figure 15

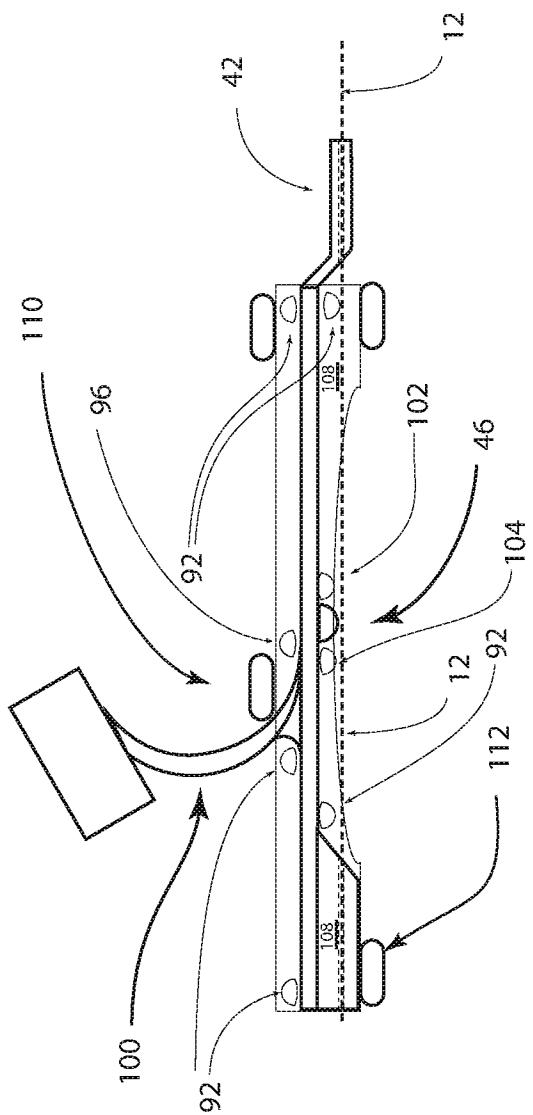


FIGURE 22

10/26

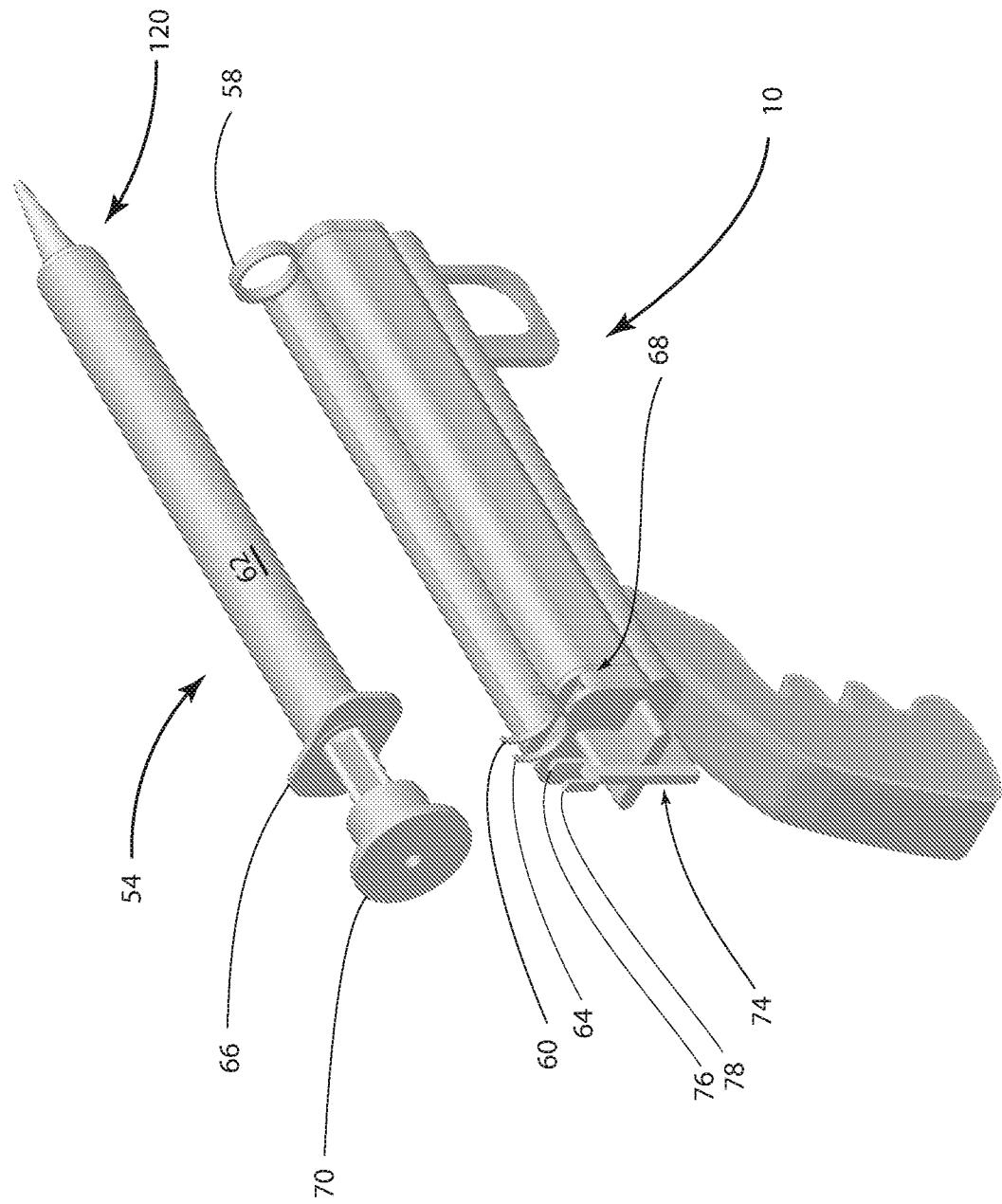


FIGURE 23

FIGURE 24

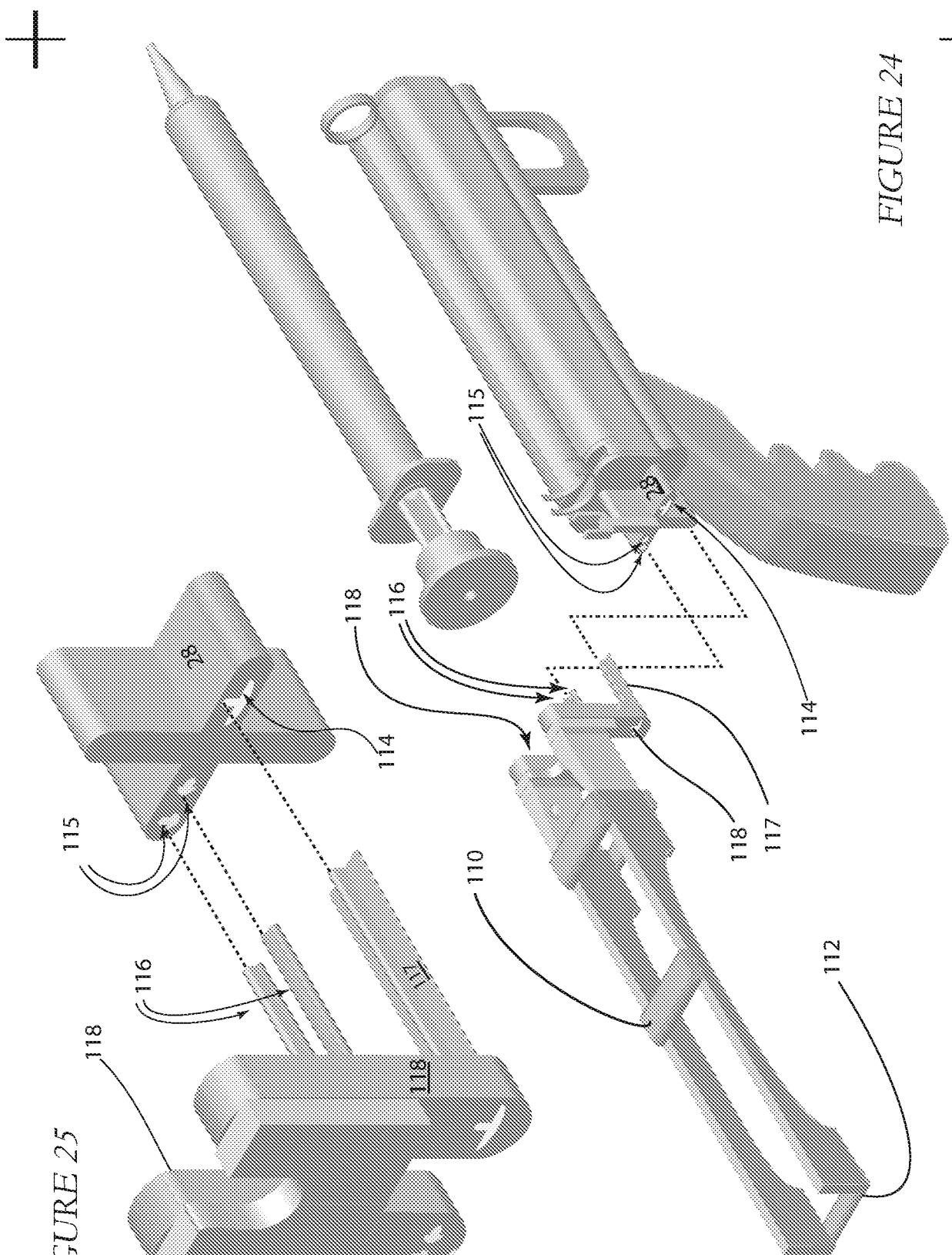


FIGURE 25

FIGURE 26

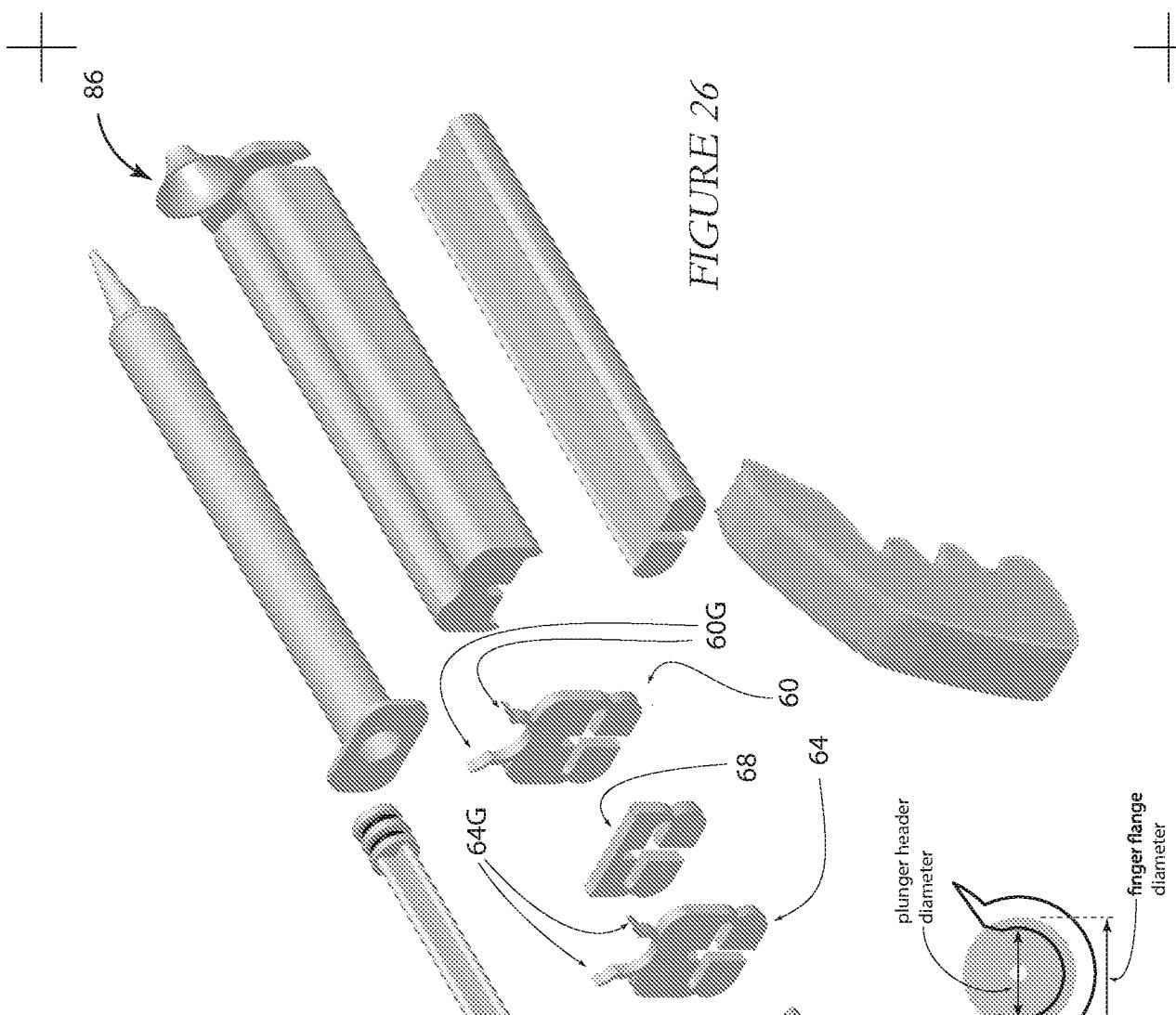


FIGURE 28

FIGURE 27

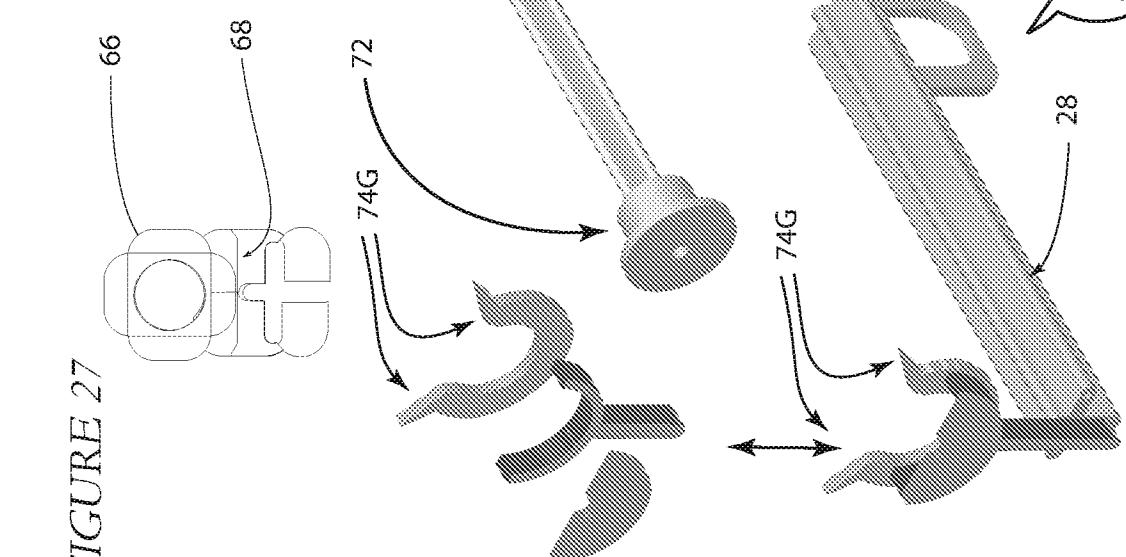


FIG. 29

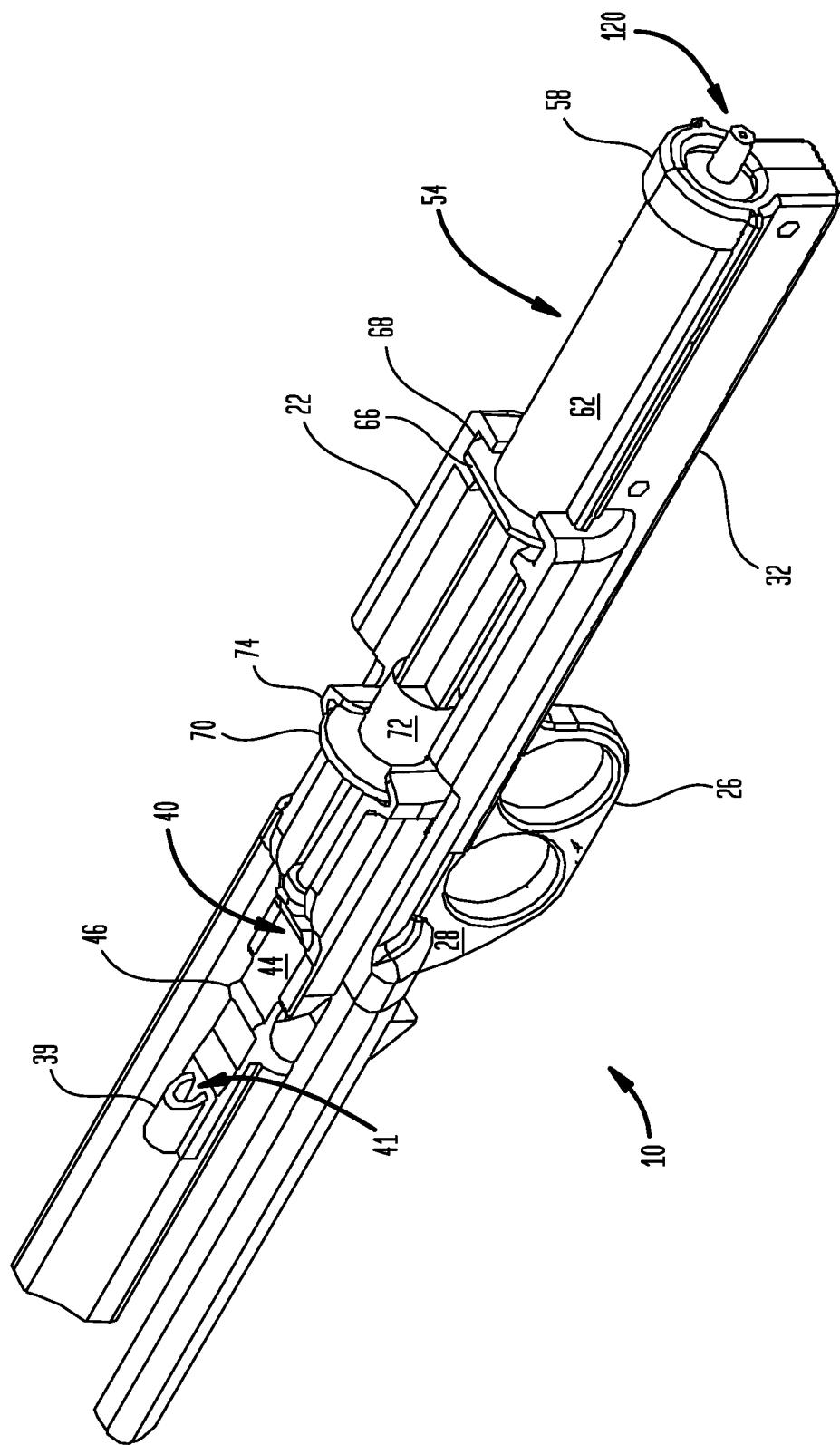


FIG. 30

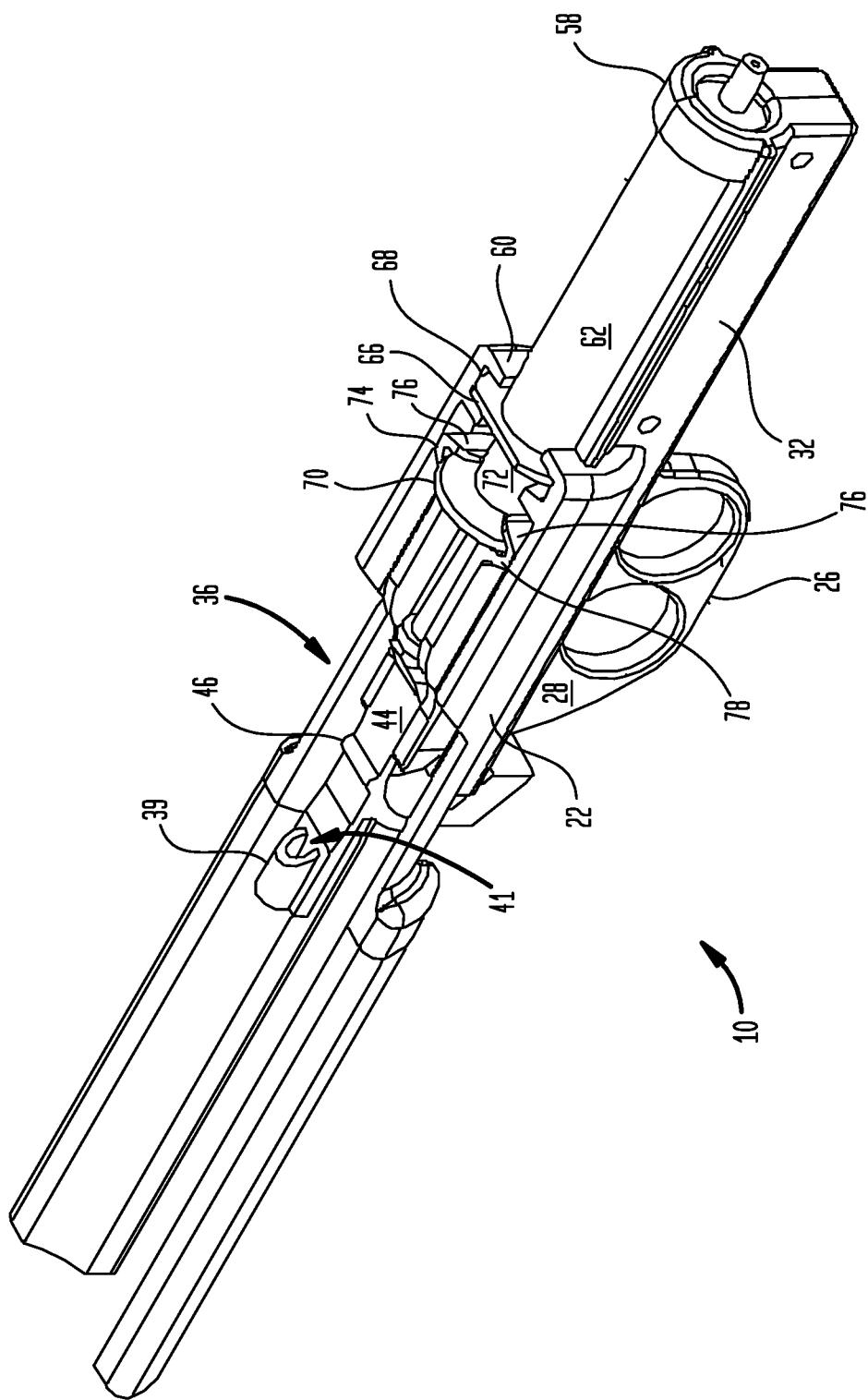
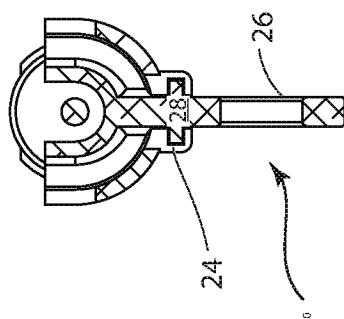


FIGURE 36



SECTION D-D

FIGURE 31

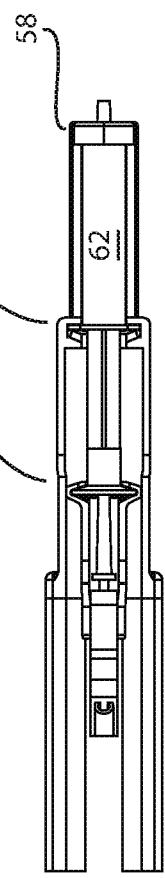


FIGURE 31

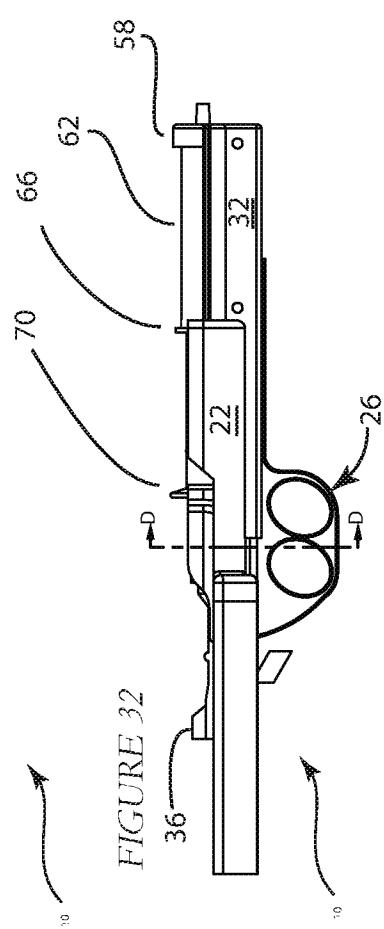


FIGURE 36

FIGURE 34

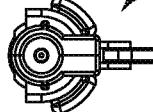


FIGURE 33

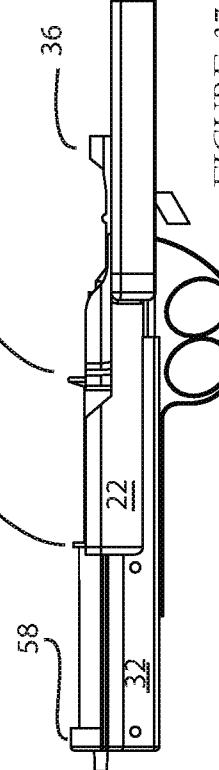
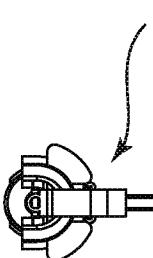


FIGURE 35

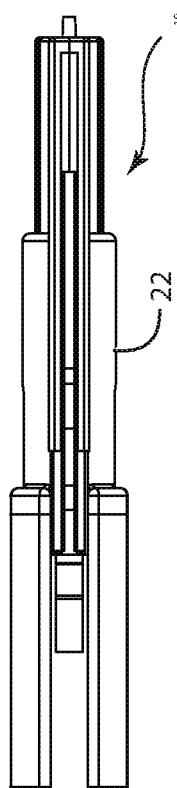


FIGURE 37

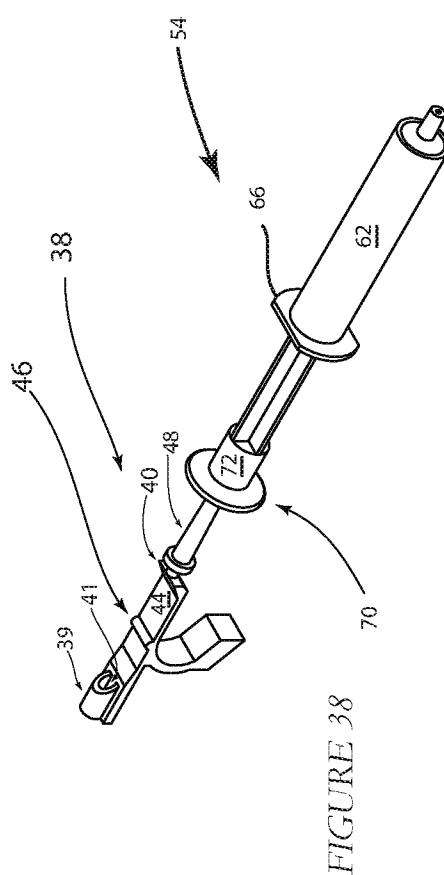


FIGURE 39

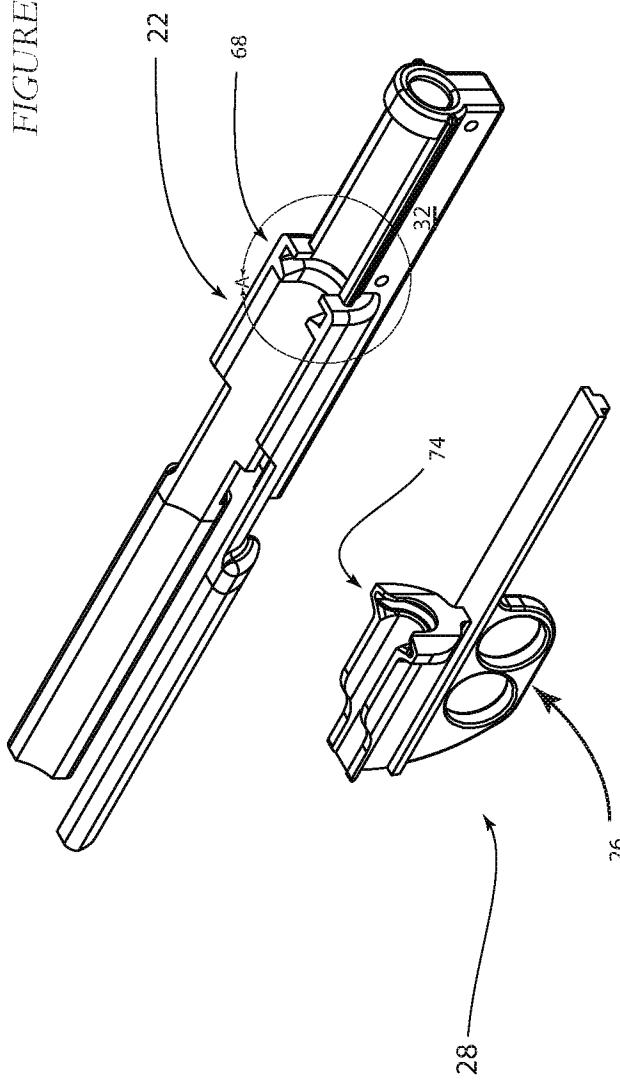


FIGURE 40

FIGURE 41

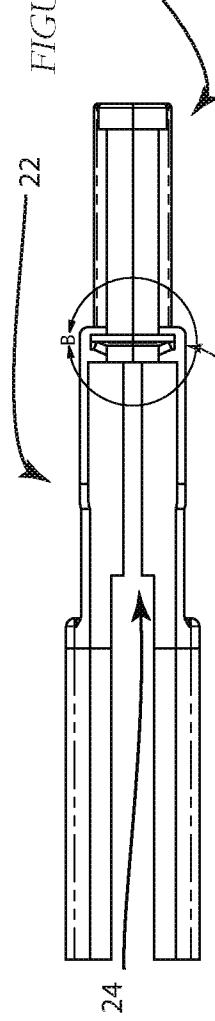


FIGURE 42

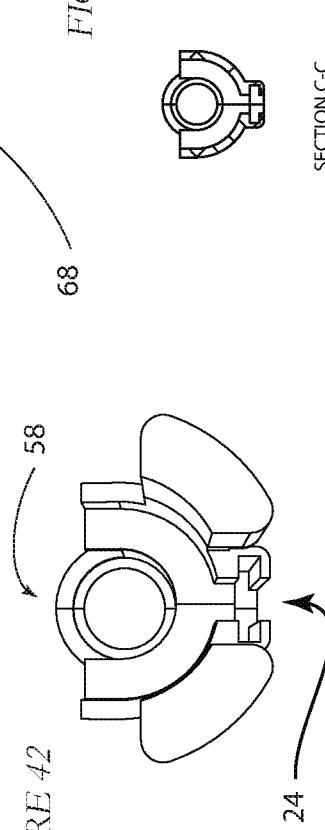


FIGURE 43

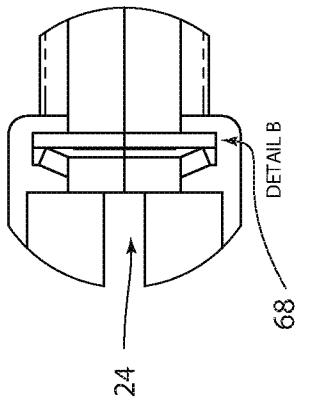


FIGURE 44

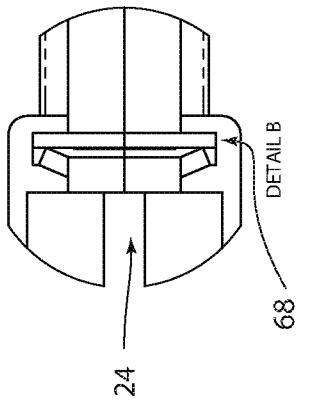


FIGURE 45

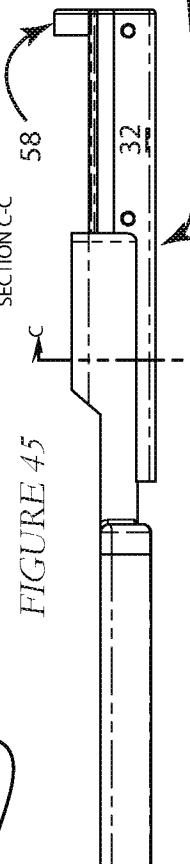


FIGURE 46

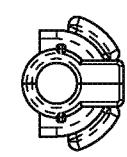


FIGURE 47

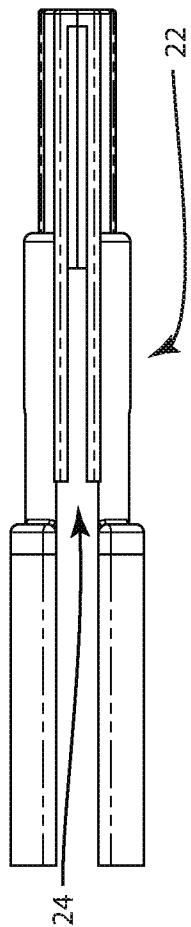


FIGURE 48

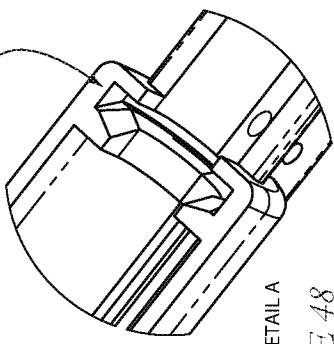
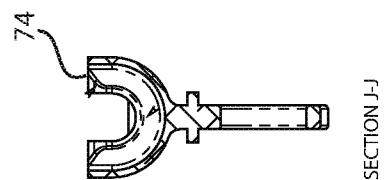


FIGURE 48



FIGURE 50



SECTION J-J

FIGURE 51

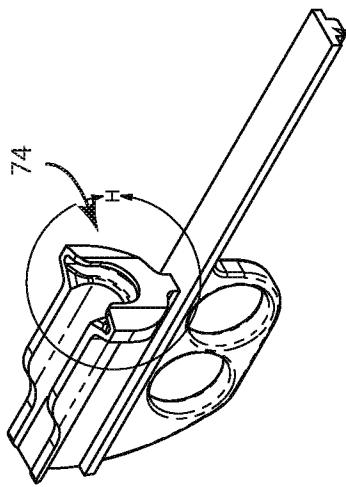
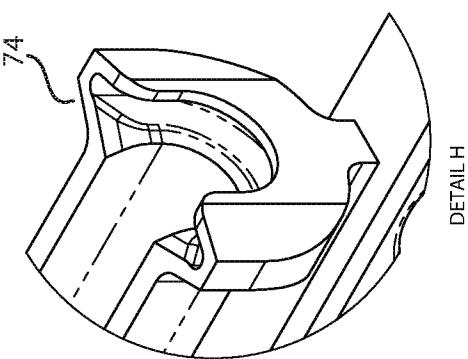


FIGURE 49



DETAIL H

FIGURE 52

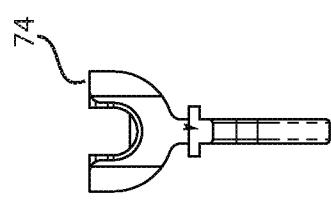
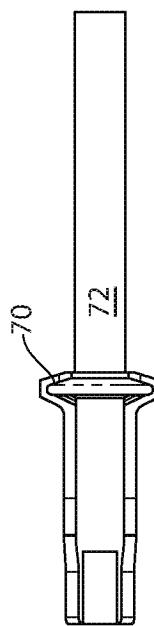


FIGURE 53

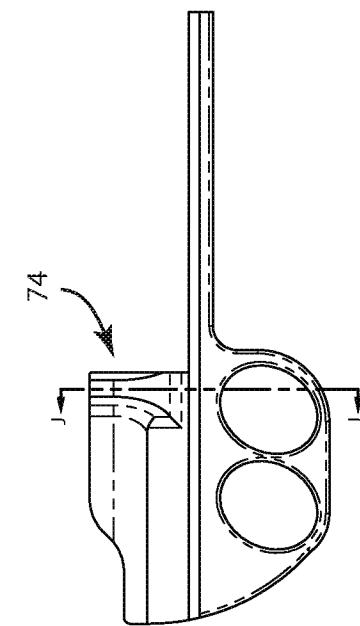


FIGURE 54

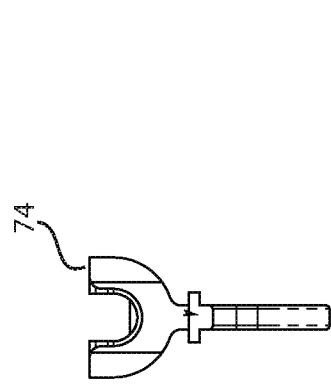


FIGURE 55

FIGURE 57

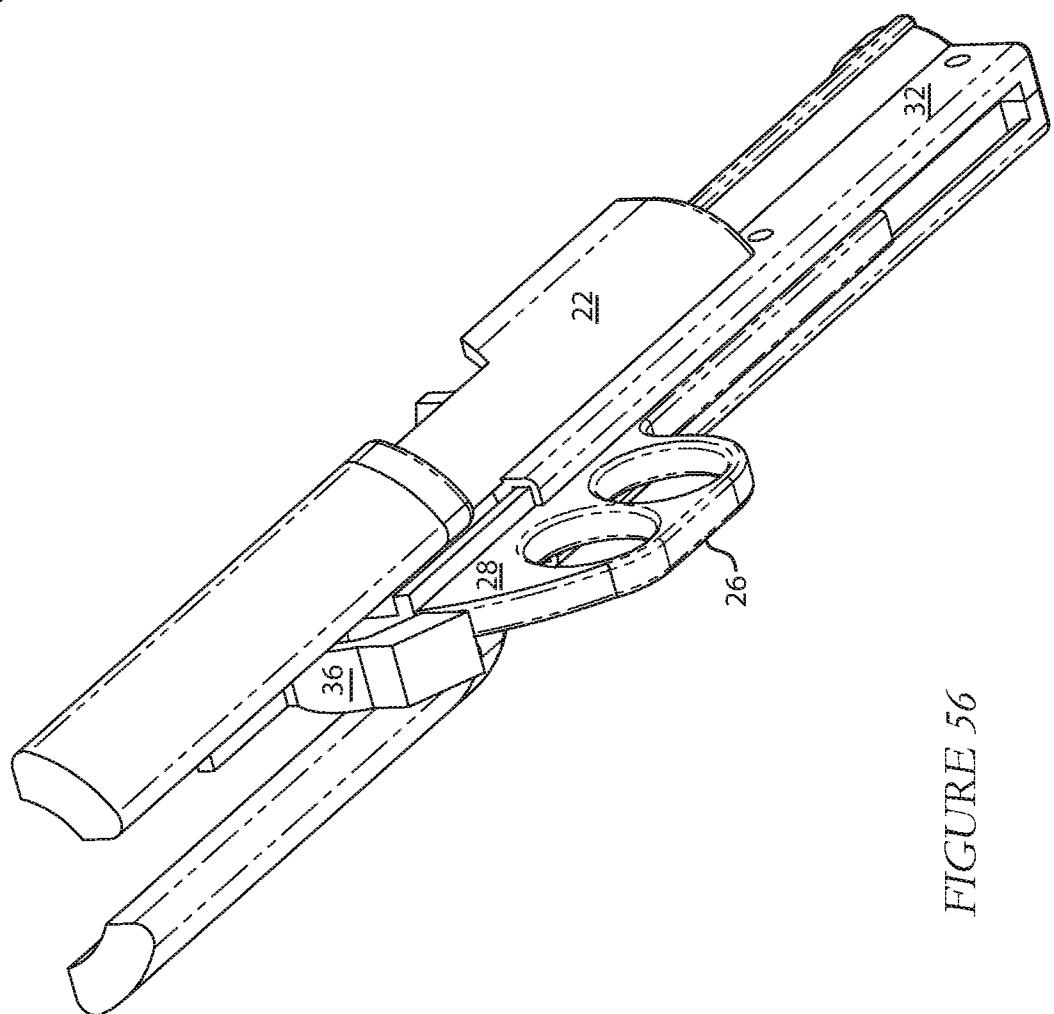
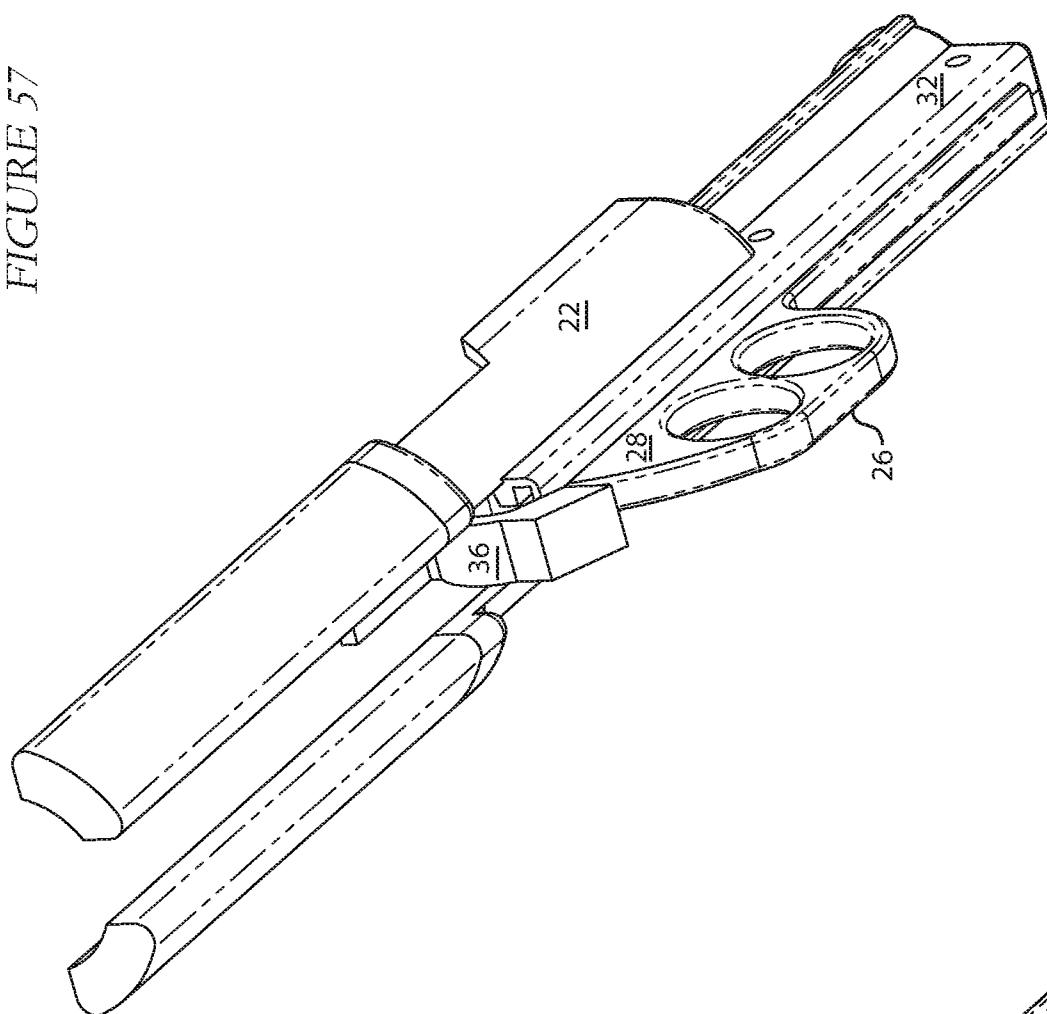
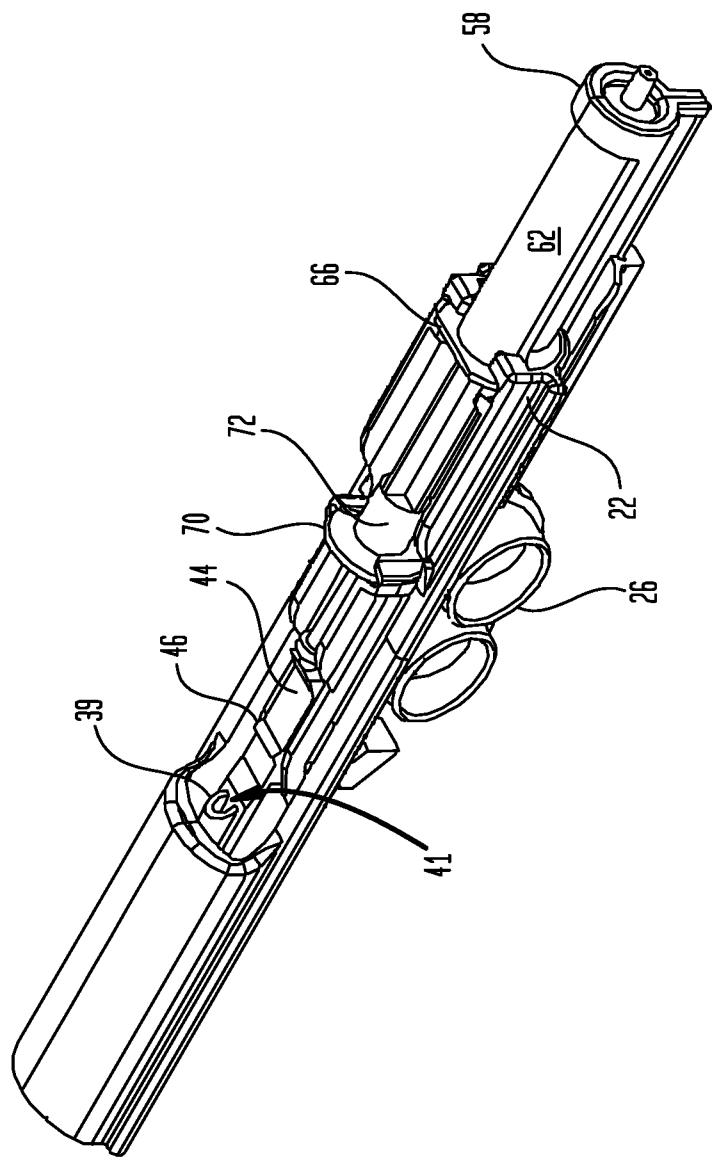


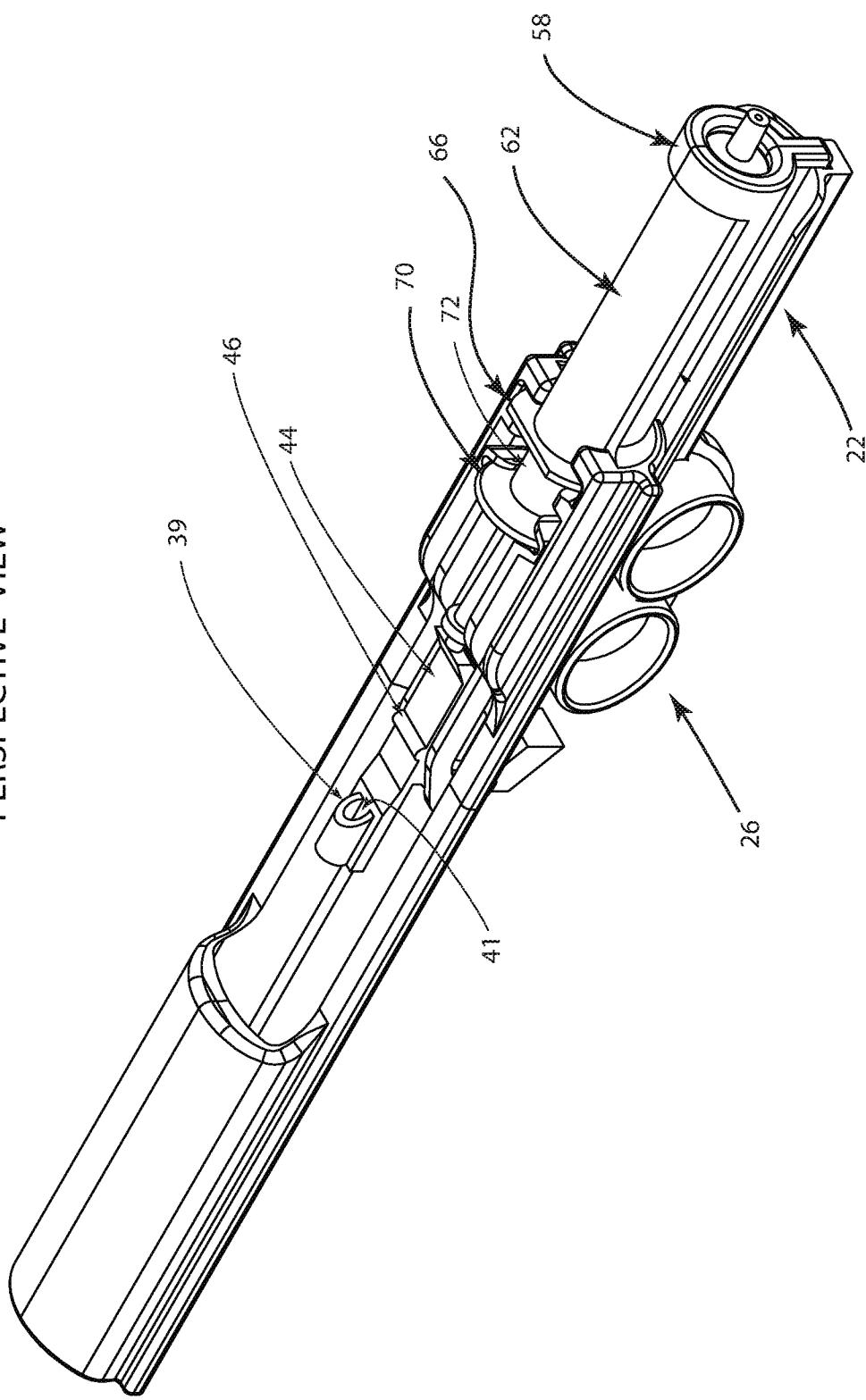
FIGURE 56

FIG. 58



VERSION 4
PERSPECTIVE VIEW

Figure 59



GENERAL VIEWS

Figure 60

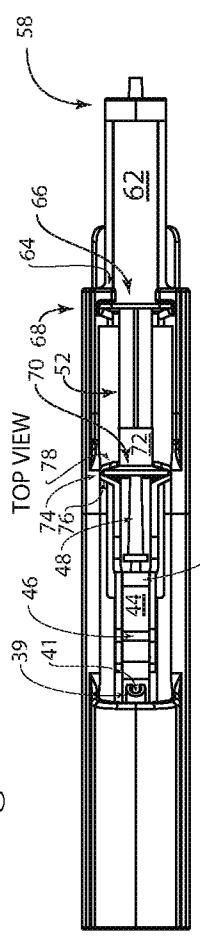


Figure 61

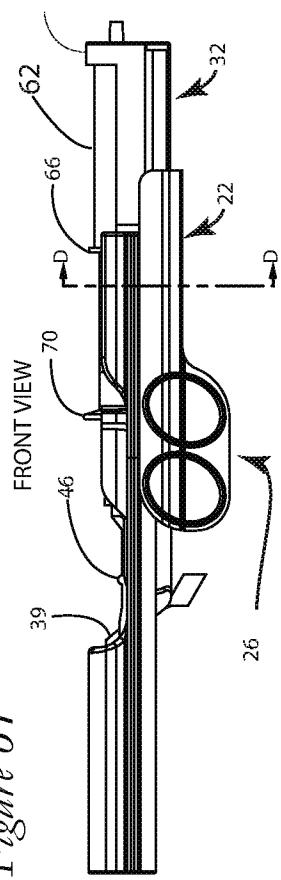


Figure 62

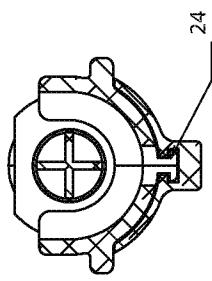
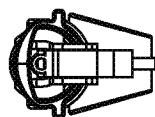
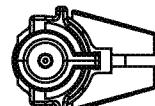
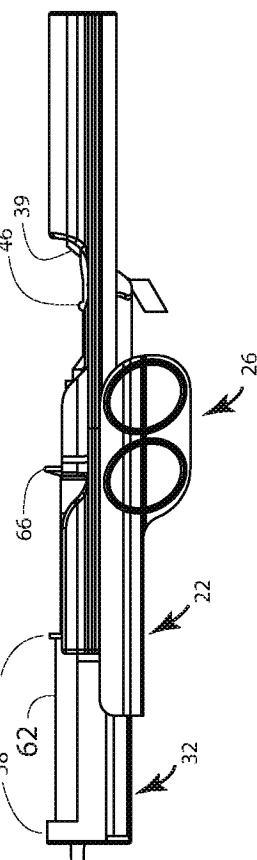
Figure 63
SIDE VIEW LEFTFigure 64
SIDE VIEW RIGHTFigure 65
BACKVIEW

Figure 66

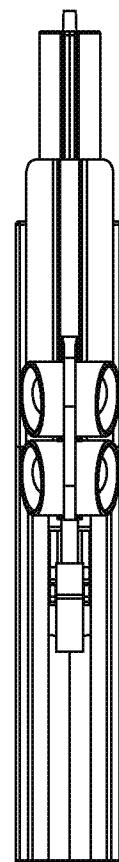


Figure 67

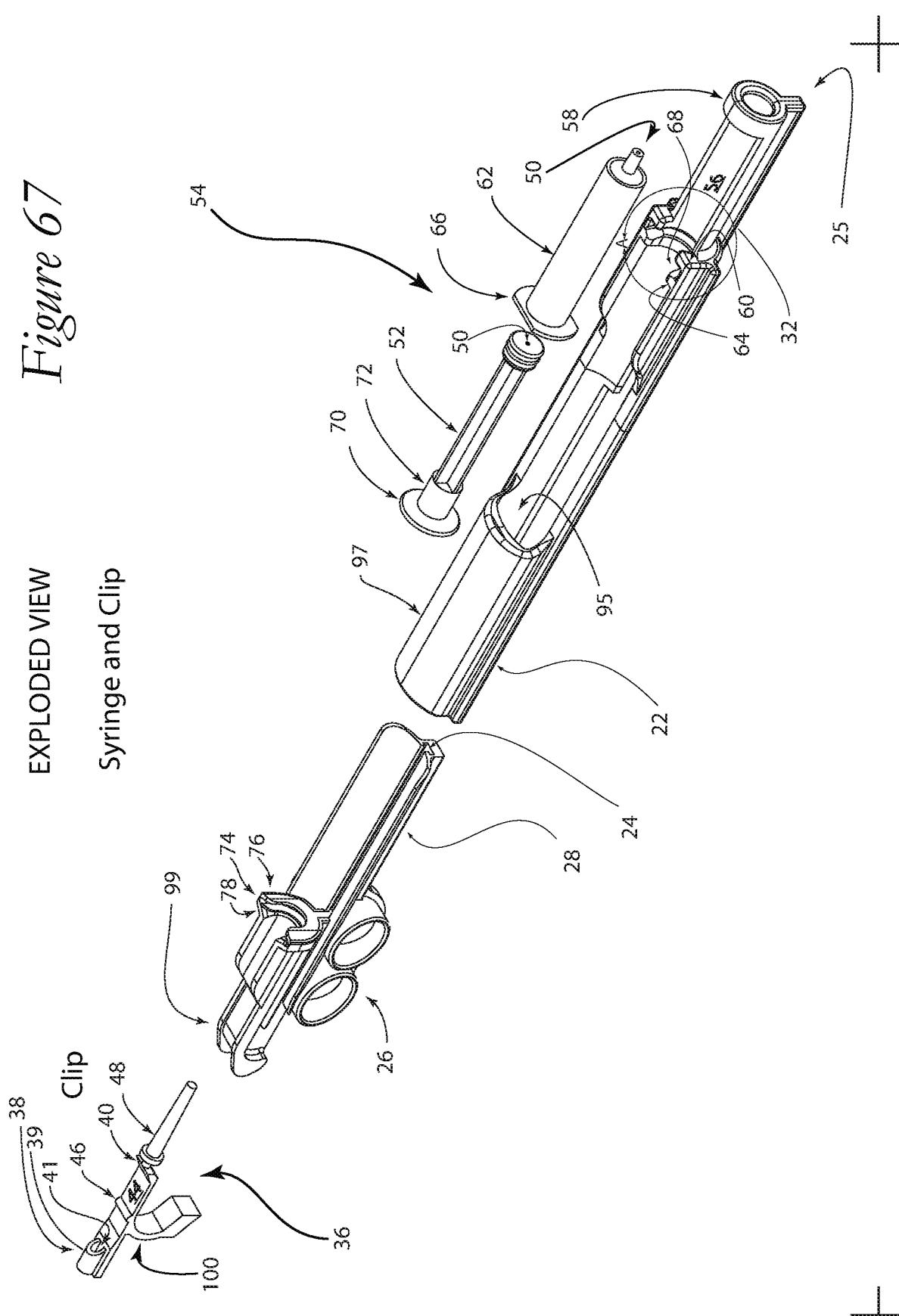
EXPLoded VIEW
Syringe and Clip

Figure 68

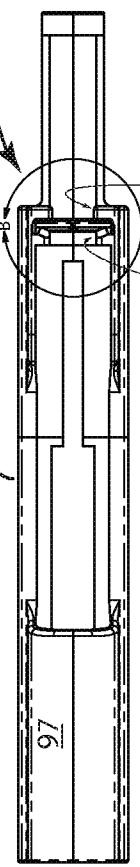


Figure 69

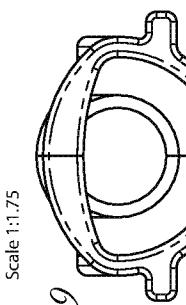


Figure 70

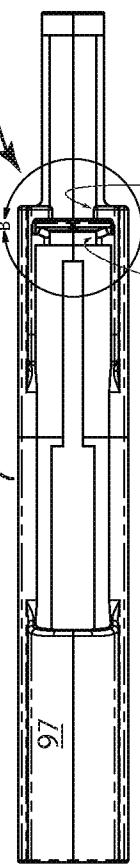


Figure 71

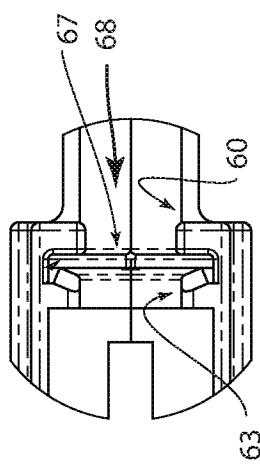
DETAIL B
SCALE 1:25:1

Figure 72

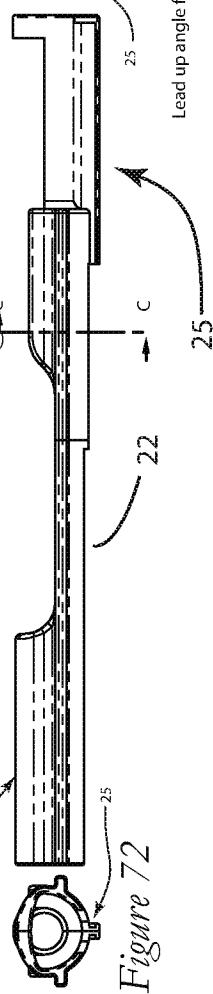


Figure 73

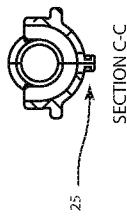
SECTION C-C
SCALE 1:25:1

Figure 74

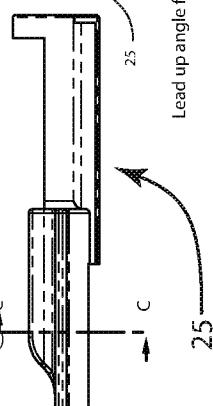
SECTION C-C
SCALE 1:25:1

Figure 75

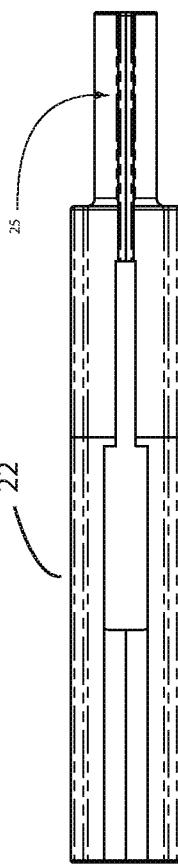
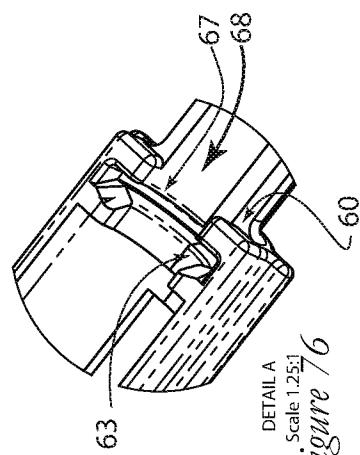


Figure 76

DETAIL A
Scale 1:25:1

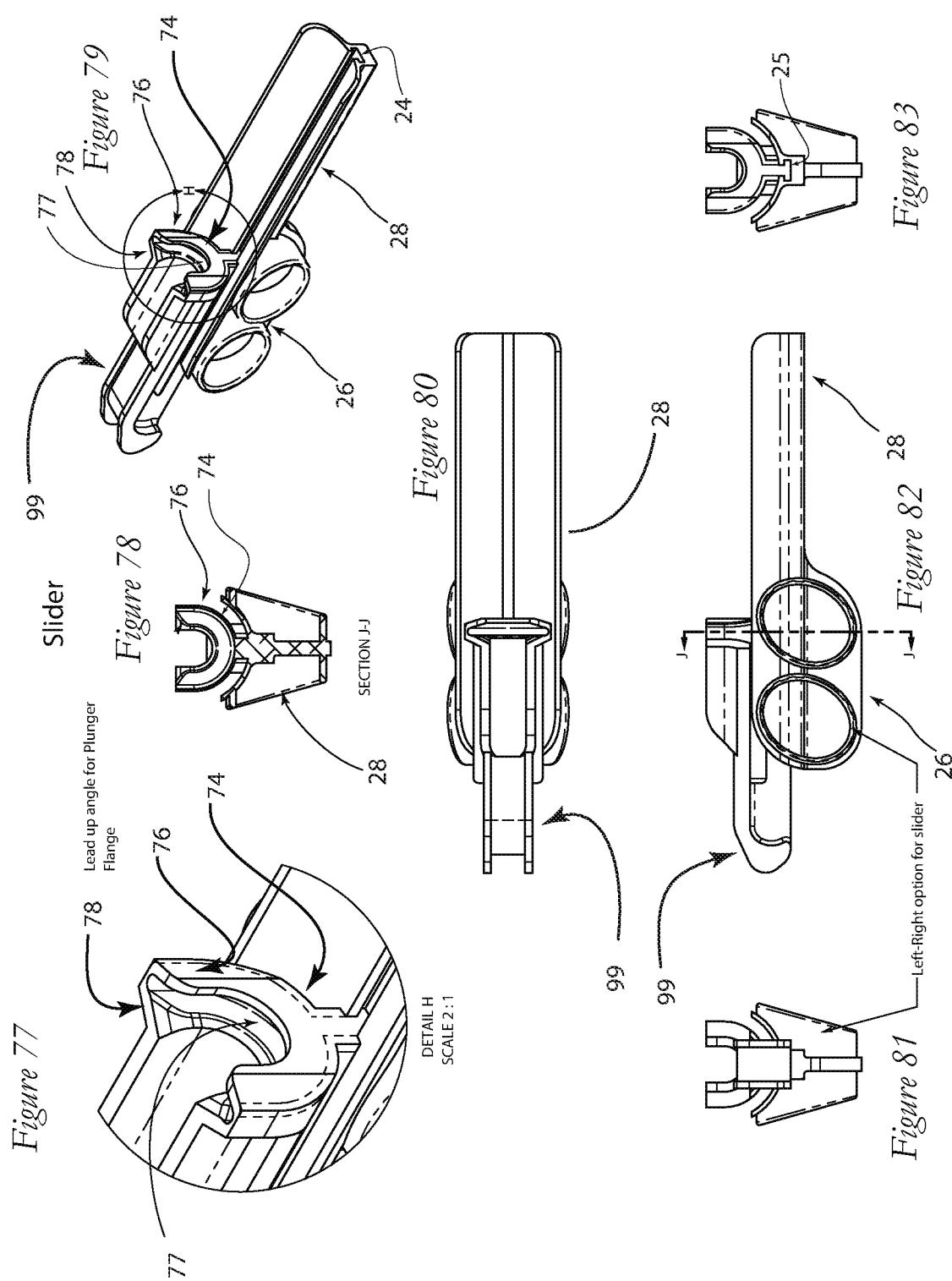
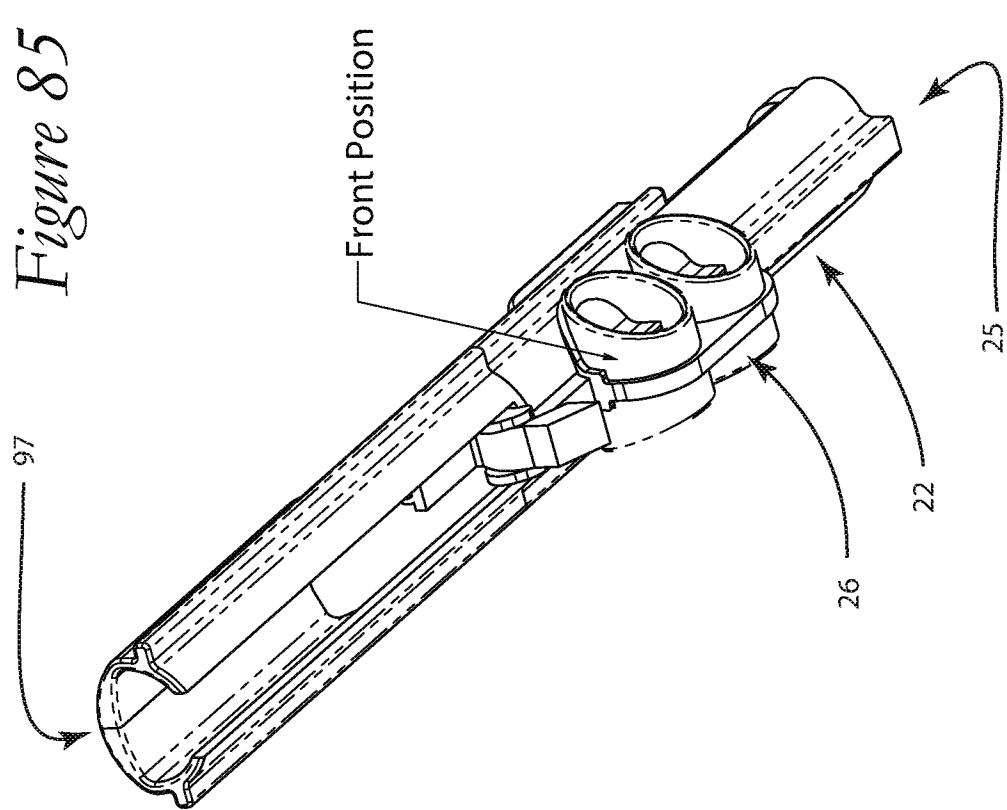


Figure 85



Slider Operation

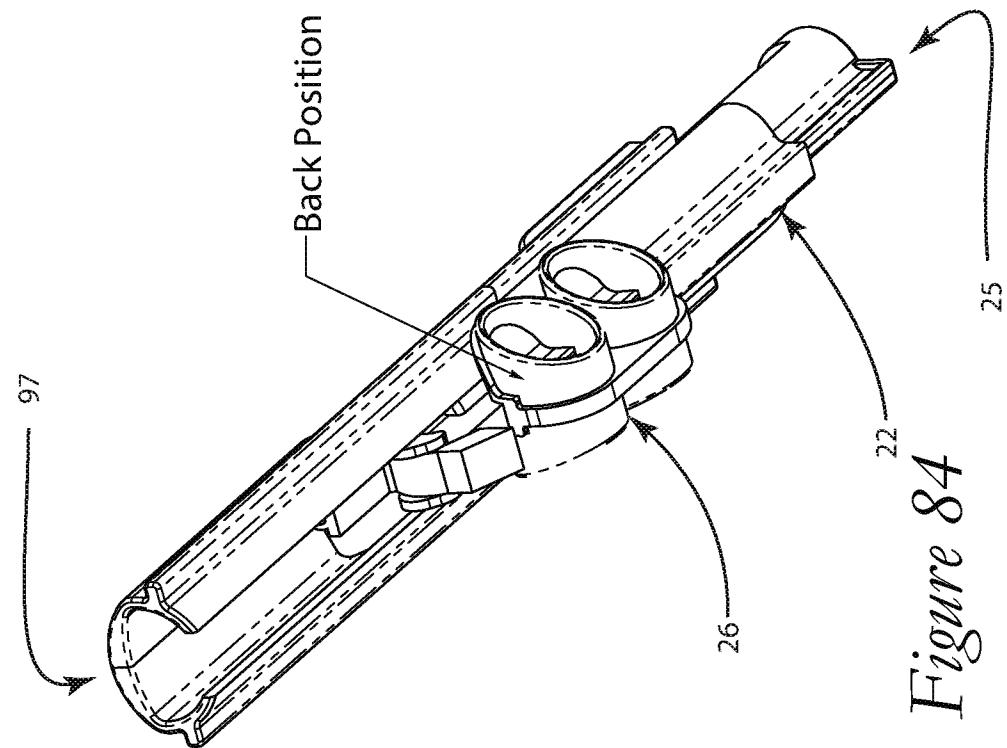


Figure 84

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/061046

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/09; A61B 17/34; A61M 25/01; A61M 39/10 (2017.01)

CPC - A61M 25/09041; A61B 17/3403; A61M 5/178; A61M 25/09 (2017.08)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 600/434; 600/585; 604/164.13; 604/164.01 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 2017/0296792 A1 (ACANTHA MEDICAL, INC.) 19 October 2017 (19.10.2017) entire document	1-11
A	US 5,125,906 A (FLECK) 30 June 1992 (30.06.1992) entire document	1-11
A	US 2015/0202414 A1 (HWANG) 23 July 2015 (23.07.2015) entire document	1-11
A	US 4,747,831 A (KULLI) 31 May 1988 (31.05.1988) entire document	1-11
A	US 2016/0242798 A1 (VASCULAR SOLUTIONS, INC.) 25 August 2016 (25.08.2016) entire document	1-11

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

28 December 2017

Date of mailing of the international search report

18 JAN 2018

Name and mailing address of the ISA/US

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