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(54) Title: METHODS AND SYSTEMS FOR RAPID RETRACTION OF A TRANSCATHETER HEART VALVE DELIVERY SYSTEM

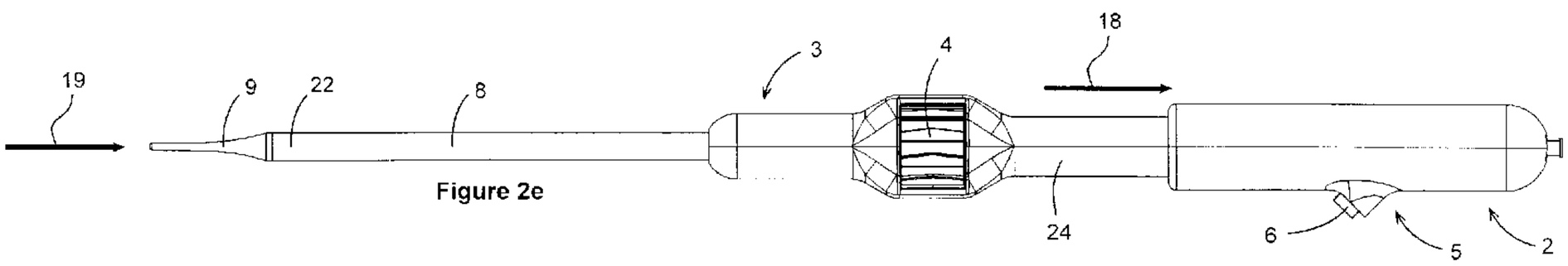

Figure 2e

(57) Abrégé/Abstract:
Methods for the rapid retraction of trans-catheter heart valve delivery systems are provided. A rapid retraction trans-catheter heart valve delivery system comprises a catheter based delivery system. The delivery system has internal mechanisms that allow for the controlled deployment of a heart valve prosthesis, as well as mechanisms that allow for quickly closing the catheter once the heart valve prosthesis has been implanted. This rapid retraction ability allows for reduced procedural durations and thus reduced risk to the patient.

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(54) **Title:** METHODS AND SYSTEMS FOR RAPID RETRACTION OF A TRANSCATHETER HEART VALVE DELIVERY SYSTEM

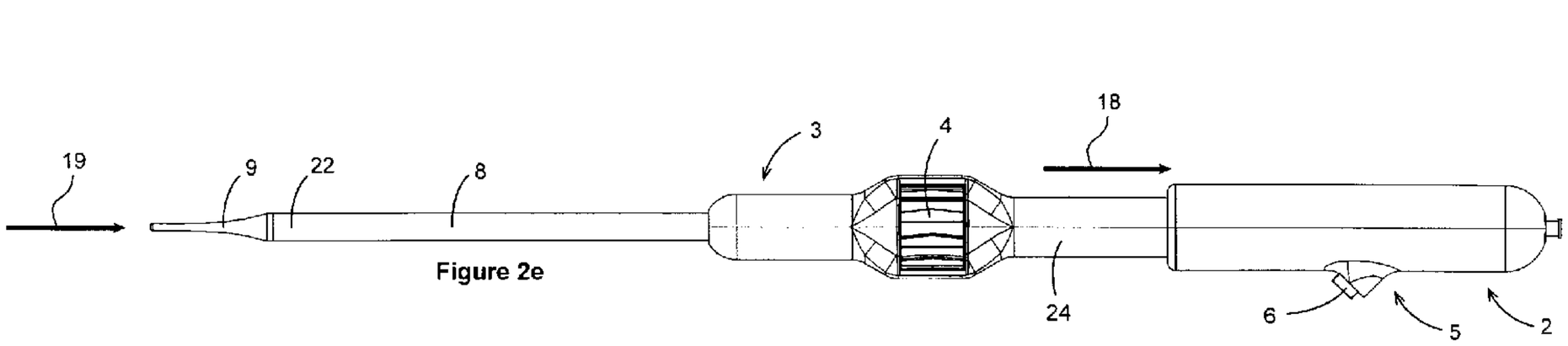

Figure 2e

(57) **Abstract:** Methods for the rapid retraction of trans-catheter heart valve delivery systems are provided. A rapid retraction trans-catheter heart valve delivery system comprises a catheter based delivery system. The delivery system has internal mechanisms that allow for the controlled deployment of a heart valve prosthesis, as well as mechanisms that allow for quickly closing the catheter once the heart valve prosthesis has been implanted. This rapid retraction ability allows for reduced procedural durations and thus reduced risk to the patient.

METHODS AND SYSTEMS FOR RAPID RETRACTION OF A TRANSCATHETER HEART VALVE DELIVERY SYSTEM

CROSS-REFERENCE

[0001] The present application claims priority to U.S. Provisional Patent Application No. 62/424,910 (Attorney Docket No. 53235-712.101), filed on November 21, 2016, which is herein incorporated by reference in its entirety.

[0002] The present application is related to: U.S. Patent No. 8,579,964 (Attorney Docket No. 53235-703.201) filed April 28, 2011; and also related to U.S. Publication Nos. 2013/0211508 (Attorney Docket No. 53235-704.201) filed November 16, 2012; 2014/0052237 (Attorney Docket No. 53235-705.201) filed February 8, 2013; 2014/0155990 (Attorney Docket No 53235-706.201) filed May 29, 2013; 2014/0257467 (Attorney Docket No. 53235-707.201) filed March 3, 2014; and 2014/0343669 (Attorney Docket No. 53235-708.201) filed April 1, 2014; the entire contents of each of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention.

[0004] Mitral regurgitation, also known as mitral insufficiency or mitral incompetence is a heart condition in which the mitral valve does not close properly thereby resulting in abnormal leakage of blood retrograde from the left ventricle through the mitral valve back upstream into the left atrium. Persistent mitral regurgitation can result in congestive heart failure, a costly and often fatal condition. Traditional surgical repair of the valve generally results in a good clinical outcome but requires open heart surgery and a lengthy and costly hospital stay along with an extended recovery period. More recently, minimally invasive procedures have been developed to deliver a prosthetic heart valve percutaneously over a catheter through the patient's vasculature to the heart, or by using a transapical procedure to introduce the prosthesis through the chest wall and through the apex of the heart to the treatment site. An exemplary prosthesis includes any of the embodiments described in U.S. Patent No. 8,579,964, the entire contents of which are incorporated herein by reference. These prostheses and delivery procedures appear to be promising, but there is yet opportunity to improve procedural outcomes by minimizing the duration of the procedure, from first

contact with the delivery system by an operator to final withdrawal of the delivery system and wound closure in the patient. Therefore, it would be desirable to provide improved devices, systems, and methods that reduce the amount of time needed to remove the delivery system from the patient, improve ease of use, speed up the procedure, and reduce risk. At least some of these objectives will be met by the exemplary embodiments described herein.

[0005] 2. Description of the Background Art. U.S. Patent No. 8,579,964 discloses an exemplary prosthetic heart valve and trans-catheter delivery system, the entire contents previously incorporated herein by reference.

BRIEF SUMMARY

[0006] The present disclosure generally relates to medical systems, devices and methods, and more particularly relates to prostheses and delivery systems such as heart valve delivery systems that may be used to implant a prosthesis such as a valve, including a prosthetic mitral valve, a heart valve, or any other valve. The present disclosure emphasizes exemplary embodiments of a prosthetic mitral valve and delivery system, but one of skill in the art will appreciate that this is not intended to be limiting.

[0007] In many embodiments, trans-catheter methods and systems of deploying prosthetic heart valves and rapid retraction of the delivery system are provided. In certain embodiments, the delivery system comprises a trans-apical delivery system that may be used to implant a prosthetic heart valve into anatomical position by way of an incision in the apex of the heart. The trans-apical delivery system may comprise a system of catheters that may be concentrically nested upon one another and that, when combined, may retain a compressed heart valve prosthesis. Removal of the constraint provided by certain catheters may then facilitate deployment of the heart valve prosthesis into the heart. Further embodiments of the trans-apical delivery system that may be used in any of the delivery systems disclose herein may allow for the closure of the delivery catheters at an enhanced speed, such as by way of translation of catheter components within each other in the opposite direction to that required for deployment operation. The operation of such delivery systems may be facilitated through the use of actuator mechanisms such as button mechanisms that may be in communication with linkage systems, or actuator mechanisms such as button mechanisms that may be in communication with flexible members, or even pin coupled components that simplify use.

[0008] Further embodiments herein may include delivery systems that allow for alternative implantation pathways such as through the inferior or superior vena cava, the aorta, or the atria.

[0009] In an aspect of the present disclosure, a method of rapidly retracting a delivery system comprises providing a delivery system, the delivery system having a plurality of catheters used to deliver a heart valve prosthesis, providing a controllable deployment mechanism, the controllable deployment mechanism having the ability to preferentially release a prosthesis from the catheter, and actuating the controllable deployment mechanism thereby releasing the prosthesis from the catheter. The method may also comprise providing a rapid retraction mechanism, the rapid retraction mechanism having the ability to rapidly close the catheter, actuating the rapid retracting mechanism thereby rapidly closing the catheter.

[0010] The method may comprise trans-apically introducing the delivery system into an apex of a heart, or transseptally delivering the delivery system to a heart, delivering the delivery system to the heart via a subclavian vein, delivering the delivery system to the heart via an aorta, or delivering the delivery system to the heart via a left atrium or a right atrium.

[0011] Actuating the rapid retraction mechanism may comprise actuating a button and linkage. The rapid retraction mechanism may comprise a threaded region and interference member, and the method may further comprise constraining movement of the rapid retraction mechanism with the threaded region and interference member. The rapid retraction mechanism may comprise a flexible interference member, and the method may further comprise deflecting the flexible interference member. The rapid retraction mechanism may comprise a pin and pin-hole link assembly, and the method may comprise removing the pin from the pin-hole link assembly.

[0012] In another aspect of the present disclosure, a delivery device for delivering a prosthesis comprises a first actuation mechanism for controlling movement of a delivery catheter, wherein the delivery catheter may be configured to carry a prosthesis therein, and wherein actuation of the first actuation mechanism may move the delivery catheter away from the prosthesis thereby at least partially removing a constraint therefrom, and a deployment mechanism for controlling release of the prosthesis from an anchoring catheter, the anchoring catheter disposed at least partially in the delivery catheter, and wherein actuation of the

deployment mechanism may move the anchoring catheter away from the prosthesis thereby releasing a constraint therefrom. The delivery system may also comprise an inner guidewire catheter having a tapered distal tip, the inner guidewire catheter disposed in the anchoring catheter, and a rapid retraction mechanism for controlling movement of the delivery catheter relative to the tapered distal tip, wherein actuation of the rapid retraction mechanism closes the delivery device such that a proximal end of the distal tip abuts against a distal end of the delivery catheter thereby forming a smooth continuous outer surface of the delivery device.

[0013] The actuation mechanism may comprise a thumbwheel. The deployment mechanism may comprise an actuatable button with a linkage coupled thereto. The rapid retraction mechanism may comprise a threaded region and interference member, a flexible interference member, or a pin and pin-hole linkage assembly.

[0014] In another aspect of the present disclosure, a system for delivering a prosthesis comprise the delivery device described above and a prosthesis such as a prosthetic mitral valve.

[0015] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0016] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The novel features of the present disclosure are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present disclosure will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the present disclosure are utilized, and the accompanying drawings of which:

[0018] FIG. 1 shows a perspective view of a trans-apical delivery system configured to allow for rapid retraction.

[0019] FIGS. 2A-2E illustrate schematic side views of an operational sequence of a trans-apical delivery system configured to allow for rapid retraction.

[0020] FIGS. 3A-3D illustrate partial cross-sectional breakout views of an operational sequence of a trans-apical delivery system configured to allow for rapid retraction.

[0021] FIGS. 4A-4B illustrate isometric partial cross-sectional breakout views of a sequence of action of an internal mechanism within a trans-apical delivery system configured to allow for rapid retraction.

[0022] FIG. 5 illustrates an exploded view and internal components of a trans-apical delivery system configured to allow for rapid retraction.

[0023] FIGS. 6A-6E illustrate schematic side views of an operational sequence of an alternate embodiment of a trans-apical delivery system configured to allow for rapid retraction.

[0024] FIGS. 7A-7D illustrate schematic side views of an operational sequence of another alternate embodiment of a trans-apical delivery system configured to allow for rapid retraction.

[0025] FIG. 8 illustrates a schematic diagram of an exemplary prosthesis

[0026] FIGS. 9A-9B illustrate exemplary cross-sections of the prosthesis in FIG. 8.

[0027] FIGS. 10A-10B illustrate a prosthesis coupled to a delivery catheter.

[0028] FIG. 11 illustrates basic human heart anatomy.

[0029] FIGS. 12A-12C illustrate exemplary delivery methods.

[0030] FIGS. 13A-13C illustrate an exemplary method of deploying a prosthesis in the heart.

DETAILED DESCRIPTION

[0031] In the following detailed description, reference is made to the accompanying figures, which form a part hereof. In the figures, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, figures, and claims are not meant to be limiting. Other embodiments may be utilized, and other changes may be made, without departing from the scope of the subject matter presented herein. It will be readily understood that the aspects of the present disclosure, as generally described herein, and illustrated in the figures, can be arranged, substituted, combined, separated, and designed in a wide variety of different configurations, all of which are explicitly contemplated herein.

[0032] Although certain embodiments and examples are disclosed below, inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses, and to modifications and equivalents thereof. Thus, the scope of the claims appended hereto is not limited by any of the particular embodiments described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain embodiments, however, the order of description should not be construed to imply that these operations are order dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components.

[0033] For purposes of comparing various embodiments, certain aspects and advantages of these embodiments are described. Not necessarily all such aspects or advantages are achieved by any particular embodiment. Thus, for example, various embodiments may be carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.

[0034] FIG. 1 shows a perspective view of a trans-apical delivery system **1** which may be configured to allow for delivery of a prosthesis such as a prosthetic heart valve with rapid retraction of the delivery system after the prosthesis has been delivered, whereby rapid retraction herein may comprise the expedient removal of the delivery catheter **8** and dilating tip **9** from the apex of a patient's heart (not shown) or other treatment region of the patient. The trans-apical delivery system **1** may be comprised of a dilating tapered tip **9** which is delivered directly into the apex of a patient's heart (not shown), a delivery catheter **8** (sometimes referred to as a sheath catheter), a handle assembly including a distal handle **3**, a proximal external handle **2**, and an actuator mechanism such as a thumbwheel **4** therebetween which may be configured to actuate said delivery catheter **8** in order to cause it to slidably translate away from the dilating tip **9** into an open configuration or open position. When the trans-apical delivery system is in the open position, a space for a prosthetic heart valve **11** or any other prosthesis may be defined between the dilating tip **9** and the distal edge of the

delivery catheter **8** (best seen in FIG. 2A). An innermost lumen can be defined between the guidewire lumen inlet **13**, located at the distal most end of the dilating tip **9**, and the guidewire lumen outlet **14** which may be located within a connector such as a needle hub **12** having a Luer connector at its proximal end, at the proximal most portion of the proximal external handle **2**. The guidewire lumen may extend through the guidewire catheter (sometimes also referred to as the dilator catheter) which may be axially and concentrically disposed under the other catheters including bell catheter **10**. The guidewire catheter may be referred to as a guidewire catheter. Any of the features describing the delivery catheter **8** may be applied to any of the delivery catheter embodiments disclosed herein. Similarly, any of the prosthetic heart valve features described for prosthetic heart valve may apply to the prostheses disclosed herein.

[0035] Also shown in **FIG. 1** is an embodiment of an actuation mechanism **5**, which can allow a user to control the final release of a prosthesis such as a prosthetic heart valve from the delivery system, and can enable further mechanical actions that will be described below. The actuation mechanism **5** may be comprised of any actuator such as a button **6**, and a disposed in a housing **7** which describes a space wherein the button **6** may translate. The mechanical details behind the translation will be further described below.

[0036] Turning now to **FIG. 2A-2E**, an operational sequence of a trans-apical delivery system **1** configured to allow for rapid retraction is presented. **FIG. 2A** shows the delivery system **1** in the closed configuration where all catheters may be concentrically disposed over one another, and the distal leading edge **22** of delivery catheter **8** may be disposed against the proximal end of dilating tip **9** to form a smooth continuous outer surface. A prosthesis such as a prosthetic heart valve may be loaded and disposed in the space **11** and constrained by the catheters. The closed configuration may be configured for trans-apical delivery of the prosthesis to the treatment region in the heart. **FIG. 2B** shows an arrow indicating translation **20** of the distal leading edge of the delivery catheter **22** in the proximal direction. An arrow indicating rotation **15** of the thumbwheel **4** is also shown, and when the thumbwheel **4** is rotated, proximal translation of the distal leading edge of the delivery catheter **8** may occur by way of internal component mechanical relationships, such as those described within U.S. Patent No. 8,579,964 (also referred to herein as the '964 patent), which is incorporated herein

by reference. For example, FIGS. 11-15C of the '964 patent describe one exemplary embodiment of a delivery system having features which may apply to the present exemplary embodiment, and FIGS. 16-20 of the '964 patent describe another exemplary embodiment having features which may apply to the present exemplary embodiment. Rotation of the thumbwheel in the opposite direction may move the delivery catheter 8 in the opposite direction, distally.

[0037] FIG. 2C shows an arrow indicating radially inward translation **16** of an actuator, here a button **6**. An arrow indicating proximal translation **21** of the distal leading edge **22** of the delivery catheter **8** is also shown, and also when the button **6** is depressed radially inwardly, the leading edge of the bell catheter **10** may translate proximally away from and off of an anchoring catheter (sometimes referred as a hub catheter), anchoring tip **23**, as further described in the '964 patent, for example, in FIGS. 16-20. By releasing the leading edge of the bell catheter **10** (similarly referred to as a bell catheter) from the anchoring catheter anchoring tip **23**, a prosthesis such as a prosthetic heart valve (not shown) may be preferentially released. The internal mechanics of this component relationship will be further described in detail below.

[0038] FIG. 2D depicts the operation of the rapid retraction functionality of the herein disclosed trans-apical delivery system **1**. By maintaining pressure on the button **6**, the proximal external handle **2** may be rotated as depicted by the arrow indicating rotation **17**. By rotating the proximal external handle **2** for one 360° rotation in a first direction (clockwise with respect to the operator), the handle can become disengaged from the middle section of the internal handle **24** and thus may be free to translate proximally over internal handle **24**, as depicted by the arrow indicating translation **18 (FIG. 2E)**. The dilator tip **9** by way of the connector such as needle hub **12 (FIG. 5)**, and anchoring catheter **50 (FIG. 5)** by way of the externally threaded portion of anchoring catheter **51 (FIG. 5)** may be mated to the proximal external handle **2**. The bell catheter proximal end **68 (FIG. 5)** may be fastened to the catheter carriage **30 (FIG. 5)**, which may be translated along with the proximal external handle **2**, and depicted by an arrow indicating translation **19 (FIG. 2E)**. This movement may allow the proximal end of the dilator tip to butt up against the distal end of the delivery catheter **8** to form a smooth continuous surface when the delivery system is in a closed configuration.

[0039] FIGS. 3A-3D more clearly illustrate some of the actuation mechanism. Turning now to **FIG. 3A**, there is illustrated the first view of a sequence of views of an operational sequence of a trans-apical delivery system that is configured to allow for rapid retraction of the delivery system **1**, depicted by way of cross-sectional breakout. The middle section of the internal handle **24** is shown, which acts as a support structure for the proximal external handle **2** to slide thereover. Specifically, an internal circular rib **25** may traverse the distal-most portion of the inner diameter of the proximal external handle **2**, and in conjunction with the external threads **27** of the middle section of the internal handle **24** as well as an external circular flange **42**, may provide support and location for the middle section of the internal handle **24** to translate within the proximal external handle **2** (shown in **FIG. 5**). In operable communication with the external threads **27** of the middle section of the internal handle **24** may be internal threads **28** of the proximal external handle **2**, which can allow for relative rotation and controlled translation between the two handles without binding or cocking, prior to disengagement. An additional feature of embodiments of this device which may be used in any embodiment of a delivery system disclosed herein, with specific regards to the external threads **27** of the middle section of the internal handle **24** is an internal slot **40** (**FIG. 4A**), the details of which will be described further below.

[0040] As previously described, a button **6** may be provided which when pushed as depicted by the arrow indicating translation **16** of the button **6**, may transmit force and motion along the shaft of the button **6**, and through a linkage arm **31**, thereby applying it to the catheter carriage **30** and causing it to translate proximally, as depicted by the arrow indicating translation **43** of the catheter carriage **30**. Directional control of the translation of the button **6** may be provided by the button housing **7,** which may be cylindrically shaped and acts as a piston chamber to guide the similarly cylindrically shaped, piston-like button **6**. Functionally, the combination of button **6**, linkage arm **31** and catheter carriage **30** may behave as a mechanical linkage. The transmission of force and motion between these components can be achieved through pin-and-hole connection of each successive component to the next; whereas a plurality of button pins **46** (**FIG. 5**) on one end of the button **6** may be concentrically mated with the distal pin-holes **32** of the linkage arm **31**, and a plurality of catheter carriage pins **47** (**FIG. 5**) on one end of the catheter carriage **30** may be concentrically mated with the

proximal pin-holes **33** of the linkage arm **31**. The catheter carriage **30** has several characteristics that may assist in its ability to translate smoothly without binding or cocking within the proximal external handle **2**. For example, the catheter carriage **30** may have a plurality of support bosses **36** (best seen in FIG. 4A) that can allow the carriage to slide within the proximal external handle **2** by contacting the inner surface of said proximal external handle **2**. The catheter carriage **30** may also have a plurality of support fins **35** that can also assist the sliding of the carriage within the proximal external handle **2** by contacting the inner surface of said proximal external handle **2**. Additionally, the plurality of support fins **35** may also provide locations for the plurality of catheter carriage pins **47** (**FIG. 5**).

[0041] In order to provide the necessary return force for appropriate valve-capturing ability through the distal end of the bell catheter **10**, a cylindrical retaining nut **38** may be in contact with both the catheter carriage **30** and a compression spring **39**. This compression spring **39** can act to push the catheter carriage **30** and bell catheter **10** proximal end **68** and distal end towards the dilating tip **9** when the button is released due to the bias provided by the compression spring **39** causing the bell catheter distal end **10** to slide over top of the anchoring catheter anchoring tip **23**.

[0042] Continuing on through the sequence of views of an operational sequence of a trans-apical delivery system that is configured to allow for rapid retraction of the delivery system **1**, by turning to **FIG. 3B** it is shown that further rotation of the proximal external handle **2** as depicted by the arrow indicating rotation **17**, may allow the external threads **27** of the middle section of the internal handle **24** and internal threads **28** of the proximal external handle **2** to further become disengaged. If this rotation is continued (arrow indicating continued rotation **41** of the proximal external handle **2**, **FIG. 3C**), the above mentioned threads may eventually completely disengage, as illustrated in **FIG. 3D**. Once the above mentioned threads are completely disengaged, the proximal external handle **2** may be free to translate away from the distal handle **3** when pulled proximally by an operator, as depicted by the arrow indicating translation **18** of the proximal external handle **2**. The proximal end of the dilator tip may now be butted up against the distal end of the delivery catheter **8** forming a smooth continuous outer surface, and all catheters may be nested within one another. This can complete the rapid retraction process, whereupon the device can safely be removed from the apex of a patient's

heart (not shown) or another treatment site. It should be noted that the internal circular rib **25** located on the distal end of the proximal external handle **2** may acts as a rigid, physical stop upon contact with the external circular flange **42** located at the proximal end of the middle section **24** of the internal handle. This limits the translation of the proximal external handle **2** and associated components relative to the internal handle, ensuring the handles do not become fully detached from one another.

[0043] As mentioned previously, there is an internal slot **40** (**FIG. 4A**) located at the proximal-most end of the middle section of the internal handle **24**. The purpose of this internal slot **40** is to provide space wherein a rectangular tab **34** of the linkage arm **31** may be placed to prevent unwanted rotation of the proximal external handle **2** relative to the inner handle **24** or distal handle **3**, and the relationships between these components is more easily appreciated when witnessed as depicted in **FIG. 4A**. The rectangular tab may be biased to rest in the slot when the button remains undepressed. One further feature of the mechanical linkage defined by the button **6**, linkage arm **31** and catheter carriage **30** that must be appreciated may be realized by the pressing of the button **6**, whereupon the rectangular tab **34** of the linkage arm **31** becomes fully removed from the internal slot **40**, and full rotation of the proximal external handle **2** relative to the inner handle **24** is thus enabled.

[0044] Turning now to **FIG. 5**, there is illustrated an exploded view with internal components of a trans-apical delivery system configured to allow for rapid retraction of delivery system **1**. While many of the elements of **FIG. 5** have been previously described herein, additional detail will now be given with emphasis to certain elements used to anchor components within the handle. The proximal external handle **2** may be comprised of two handle halves, specifically an upper section **44** and a lower section **45** which may be fastened together by way of commonly used medical device adhesives such as cyanoacrylate UV cure adhesives that may be applied to a plurality of pegs **58** for mating of said proximal external handle sections **44**, **45**. Other means for coupling the two handle halves together include but are not limited to press fits, screws, ultrasonic welding, etc. The pegs **58** are illustrated as being located within the lower section **45** of the proximal external handle **2**, and each peg may have a complementary boss having an aperture into which it fits in the upper section **44**, although it is not shown. The relative positions of the pegs and bosses may be transposed. At the

proximal-most end of each of the sections (upper **44**, and lower **45**) of the proximal external handle **2** there is illustrated a plurality of rectangular slots **60** that may act to securely locate and retain the body **59** of the connector such as needle hub **12**. Additionally, a plurality of pockets **56** for retaining the needle hub flange **57** may be provided in close proximity to the plurality of rectangular slots **60**, in order to retain and locate a specific fastening feature of the needle hub **12**, being primarily the needle hub flange **57**. Also found within the upper section **44** and lower section **45** of the proximal external handle **2** may be a plurality of rectangular pockets **55**, which serve to locate and retain the anchoring nut **48** and also provide location for an adhesive bond that secures the anchoring nut into the handle sections. It will be remembered that the anchoring nut **48** may provide mechanical fastening and location of the anchoring catheter **50** by way of an externally threaded portion **51** on the anchoring catheter **50** and an internally threaded portion **52** within the anchoring nut **48**.

[0045] FIGS. 6A-6E provide illustration of an operational sequence of an alternate embodiment of a trans-apical delivery system **1** configured to allow for rapid retraction. **FIG. 6A** depicts the first view of an operational sequence, showing another embodiment of a proximal external handle **65**. In this embodiment of a proximal external handle **65**, rapid retraction may be provided by way of a similar fashion as previously described herein, but with alternative means for disengagement of the proximal external handle **65** from another embodiment of a distal handle section **66**. Specifically, the actuator mechanism in this embodiment may include latching buttons **49** (**FIG. 6A-6C**) which may be used to maintain this embodiment of the distal handle section **66** coupled to this embodiment of the proximal external handle **65**. The latching buttons **49** may be in continuous and flexible connection with this embodiment of the distal handle section **66**, but may be typically located within a recess of the proximal external handle embodiment **65**. Thus, an interfering edge **63** of the latching buttons may be registered against another interfering edge **62** that is within the proximal external handle embodiment **65**, prior to engagement. As depicted in **FIG. 6D**, once both the latching buttons **49** are depressed (illustrated by arrows **61** indicating translation/bending of the cantilevered latching buttons **49**) the interfering edge **63** of the buttons may achieve clearance of the interfering edge **62** of the proximal external handle **65** by bending flexion (**FIG. 6E**). Clearance between the components may allow for translation

of this embodiment of the proximal external handle **65** away from this embodiment of the distal handle **66**, as depicted by directional arrow **67** indicating translation of the proximal external handle embodiment **65** (**FIG. 6E**). The remaining internal and external elements of this embodiment (**FIG. 6A-6E**) of a trans-apical delivery system **1** may be configured to allow for rapid-retraction are as that of the delivery system described in the '964 patent.

[0046] FIGS. 7A-7D provide illustration of an operational sequence of yet another alternate embodiment of a trans-apical delivery system **1** configured to allow for rapid retraction. **FIG. 7A** depicts the first view of an operational sequence, showing yet another embodiment of a proximal external handle **72**. In this embodiment of a proximal external handle **72**, rapid retraction may be provided by way of a similar fashion as previously described herein, but with alternative means for disengagement of the proximal external handle **72** from yet another embodiment of a distal handle section **73**. In the embodiment illustrated in **FIG. 7A**, a retaining pin/latch style of handle retention similar to what may be seen in the modern hand-grenade may be provided. Specifically, a retaining pin **71** which may be comprised of a preferential shaped wire-form having a grasping portion **76** and shafts **75** (**FIG. 7C**) may be used to pin a proximal external handle section embodiment **72** to a distal handle embodiment **73** by disposing the shafts **75** in receiving pin holes **77** (located on the proximal end of the distal handle embodiment **73**) and pin holes **78** (located on the proximal handle embodiment **72**). A recess **74** (**FIG. 7B**) in the handle for the retaining pin **71** may provide a location for the pin to sit flush with the outer surface of the proximal handle embodiment **72**, preventing the snagging of sterile gloves that may be adorned by the clinical user (not shown). Operation of the actuation mechanism here having a retaining pin **71** may be as follows: after final deployment of a prosthetic heart valve (not shown) by sustained rotation of the thumbwheel **4** (**FIG. 7B**), the user may then grasp the retaining pin **71** and pull it out of the recess **74** as depicted by directional arrow **69** indicating translation of the retaining pin **71**. Once the retaining pin shafts **75** are entirely removed from the pin holes **77**, **78**, the proximal external handle embodiment **72** may become free to translate away from the distal handle embodiment **73** as depicted by directional arrow **70** indicating translation of the proximal external handle embodiment **72**. The remaining internal and external elements of this embodiment (**FIG. 7A-**

7D) of a trans-apical delivery system **1** may be configured to allow for rapid-retraction are as that of the delivery system described in '964 patent.

[0047] **Prosthesis**

[0048] **FIG. 8** illustrates a schematic diagram of an exemplary prosthesis **802** which may be used with any of the delivery catheters disclosed herein. The prosthesis **802** is preferably a prosthetic valve such as a prosthetic mitral valve, although it may be a prosthetic valve for any other region in the body such as a prosthetic triscuspid valve, a prosthetic aortic valve, or a prosthetic pulmonary valve. Or it may be a prosthetic venous valve, or any other prosthetic valve, or prosthetic device. The prostheses **802** preferably includes an expandable frame **804** with a prosthetic valve mechanism **806** and preferably includes an anchor mechanism **808**. The expandable frame may be balloon expandable or self-expanding and the frame expands into engagement with the native valve. The prosthetic valve mechanism **806** may include one, two, three, or more prosthetic valve leaflets which have an open position which allows antegrade fluid flow therepast, and a closed configuration where the prosthetic valve leaflets coapt with one another to prevent or minimize retrograde fluid flow therepast. The fluid may be blood or another body fluid. The prosthetic leaflets may be pericardial tissue or other tissues, or they may be formed from synthetic materials such as polymers or metals. The anchor mechanism may be any structure configured to help enagage tissue and anchor the prosthesis with the native valve.

[0049] **FIGS. 9A-9B** illustrates taken along the line **A-A** in **FIG. 8** and show possible cross-sections of the frame **804**. **FIG. 9A** shows that the prosthesis may have a circular cross-section, and in preferred embodiments, preferably for the mitral valve, the prosthesis may have a D-shaped cross-section so that the prosthesis conforms to the native anatomy. Additional details about exemplary embodiments of a prosthesis are disclosed in the '964 patent previously incorporated herein by reference.

[0050] **FIGS. 10A-10B** illustrate a prosthesis **1008** such as the one described in **FIG. 8** coupled to a delivery catheter **1002**. In **FIG. 10A**, the prosthesis is in a collapsed configuration and being carried and constrained by the delivery catheter **1002**. The delivery catheter **1002** may be any of the delivery catheters described herein. An outer sheath **1004** constrains the prosthesis **1008** and keeps it in the collapsed configuration and disposed over

an inner shaft **1006** slidably disposed in the outer sheath **1004**. The inner shaft **1006** may be any of the inner shafts disclosed herein including the bell catheter previously disclosed. Other optional shafts in the delivery catheter are not illustrated for convenience. As the outer sheath **1004** is retracted proximally, or the bell catheter is advanced distally, the prosthesis becomes unconstrained from the outer sheath and begins to self-expand as seen in **FIG. 10B**. Once the prosthesis is completely unconstrained, is self-expands into position, preferably into engagement with a native valve.

[0051] **Delivery**

[0052] **FIG. 11** illustrates basic human heart anatomy. The heart includes four chambers, the right atrium **RA**, the right ventricle **RV**, the left atrium **LA**, and the left ventricle **LV**. Several valves prevent retrograde blood flow. The tricuspid valve **TV** controls flow from the right atrium to the right ventricle, and the pulmonary valve **PV** controls flow out of the right ventricle **RV**. The mitral valve **MV** controls flow between the left atrium **LA** and the left ventricle **LV**, and the aortic valve **AOV** controls flow out of the aorta **AO**. The major vessels coupled to the heart include the vena cava **VC** which brings venous blood back to the right atrium **RA**, and the pulmonary artery brings blood from the right ventricle **RV** to the lungs (not illustrated). Oxygenated blood from the lungs returns to the left atrium **LA** via the pulmonary veins **PVE**, and blood is delivered out of the left ventricle **LV** to the body by the aorta **AO**.

[0053] **FIG. 12A** illustrates one exemplary delivery method for treating mitral valve **MV**. In this embodiment, the delivery catheter **C** which may be any of the delivery devices disclosed herein and may have any of the prostheses disclosed herein is advanced typically from a femoral vein in the groin up into the vena cava **VC** into the right atrium **RA** and then transseptally across the atrial septal wall into the left atrium **LA** and then downward into disposition across or adjacent the native mitral valve **MV** where the prosthesis may be deployed as described herein.

[0054] **FIG. 12B** illustrates another exemplary delivery method for treating a mitral valve **MV**. In this embodiment, the delivery catheter **C** which may be any of the delivery devices disclosed herein and may have any of the prostheses disclosed herein is advanced typically from a femoral artery or other artery (e.g. radial artery) up into the aorta **AO** in to the left

ventricle **LV** and then across the mitral valve **MV** or adjacent thereto for deployment of the prosthesis as described herein.

[0055] FIG. 12C illustrates another exemplary delivery method for treating a mitral valve **MV**. In this embodiment, the delivery catheter **C** which may be any of the delivery devices described herein and may have any of the prostheses disclosed herein is typically advanced transapically from outside the body, through the chest well, into the apex of the heart into the left ventricle **LV** and then adjacent or across the mitral valve **MV** where the prosthesis is then deployed as disclosed herein.

[0056] FIGS. 13A-13C illustrate an exemplary method of deploying a prosthesis **P** in the heart using a delivery catheter **C** which may be any of the delivery devices disclosed herein. The prosthesis is preferably a mitral valve prosthesis but may be any of the prostheses disclosed herein. In **FIG. 13A**, the delivery catheter is preferably delivered transapically to the mitral valve **MV**. In **FIG. 13B**, once the prosthesis **P** has been properly positioned relative to the native mitral valve **MV**, the outer sheath is retracted proximally (or the inner bell shaft is advanced distally) so that the prosthesis is unconstrained and allowed to self-expand into engagement with the native mitral valve and anchor into position. After the prosthetic valve has been deployed and properly positioned and anchored, the delivery catheter is then retracted proximally and removed from the heart as seen in **FIG. 13C**. The prosthetic valve now takes over the function of the native mitral valve allowing antegrade flow from the left atrium to the left ventricle and preventing or minimizing regurgitation of blood from the left ventricle to the left atrium.

[0057] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A method of rapidly retracting a delivery system, the method comprising:

providing a delivery system, the delivery system having a plurality of catheters used to deliver a heart valve prosthesis;

providing a rapid retraction mechanism operably coupled with the delivery system, the rapid retraction mechanism configured to rapidly close the delivery system; and

actuating the rapid retracting mechanism thereby rapidly closing the delivery system.

2. The method of claim 1, further comprising trans-apically introducing the delivery system into an apex of a heart.

3. The method of claim 2, wherein actuating the rapid retraction mechanism comprises actuating a button and linkage.

4. The method of either claim 2 or 3, wherein the rapid retraction mechanism comprises a screw thread and interference member, and wherein the method further comprises constraining movement of the rapid retraction mechanism with the screw thread and interference member.

5. The method of any of claims 2 to 4, wherein the rapid retraction mechanism comprises a flexible interference member, the method further comprising deflecting the flexible interference member.

6. The method of any of claims 2 to 5, wherein the rapid retraction mechanism comprises a pin and pin-hole link assembly, the method further comprising removing the pin from the pin-hole link assembly.

7. The method of any of claims 1 to 6, further comprising trans-septally delivering the delivery system to a heart

8. The method of claim 7, wherein actuating the rapid retraction mechanism comprises actuating a button and linkage.

9. The method of either claim 7 or 8, wherein the rapid retraction mechanism comprises a screw and interference member, and wherein the method further comprises constraining movement of the rapid retraction mechanism with the screw and interference member.

10. The method of any of claim 7 to 9, wherein the rapid retraction mechanism comprises a flexible interference member, the method further comprising deflecting the flexible interference member.

11. The method of any of claims 7 to 10, wherein the rapid retraction mechanism comprises a pin and pin-hole link assembly, the method further comprising removing the pin from the pin-hole link assembly.

12. The method of any of claims 1 to 11, further comprising delivering the delivery system to the heart via a subclavian vein.

13. The method of claim 12, wherein actuating the rapid retraction mechanism comprises actuating a button and linkage.

14. The method of either claim 12 or 13, wherein the rapid retraction mechanism comprises a screw thread and interference member, and wherein the method further comprises constraining movement of the rapid retraction mechanism with the screw thread and interference member.

15. The method of any of claims 12 to 14, wherein the rapid retraction mechanism comprises a flexible interference member, the method further comprising deflecting the flexible interference member.

16. The method of any of claims 12 to 15, wherein the rapid retraction mechanism comprises a pin and pin-hole linkage assembly, the method further comprising removing the pin from the pin-hole linkage assembly.

17. The method of any of claims 1 to 16, further comprising delivering the delivery system to the heart via an aorta,

18. The method of claim 17, wherein actuating the rapid retraction mechanism comprises actuating a button and linkage.

19. The method of either claim 17 or 18, wherein the rapid retraction mechanism comprises a screw thread and interference member, the method further comprising constraining movement of the rapid retraction mechanism with the screw thread and interference member.

20. The method of any of claims 17 to 19, wherein the rapid retraction mechanism comprises a flexible interference member, the method further comprising deflecting the flexible interference member.

21. The method of any of claims 17 to 20, wherein the rapid retraction mechanism is comprised of a pin and pin-hole linkage assembly, the method further comprising removing the pin from the pin-hole linkage assembly.

22. The method of any of claims 1 to 21, further comprising delivering the delivery system to a heart via a right atrium or via a left atrium.

23. The method of claim 22, wherein actuating the rapid retraction mechanism comprises actuating a button and linkage.

24. The method of either claim 22 or 23, wherein the rapid retraction mechanism comprises a screw thread and interference member, the method further comprising constraining movement of the rapid retraction mechanism with the screw thread and interference member.

25. The method of any of claims 22 to 24, wherein the rapid retraction mechanism comprises a flexible interference member, the method further comprising deflecting the flexible interference member.

26. The method of any of claims 22 to 25, wherein the rapid retraction mechanism comprises a pin and pin-hole linkage assembly, the method further comprising removing the pin from the pin-hole linkage assembly.

27. The method of any of claims 1 to 26, further comprising providing a controllable deployment mechanism, the controllable deployment mechanism configured to preferentially release a prosthesis from the delivery system.

28. The method of claim 27, further comprising actuating the controllable deployment mechanism by rotating a thumbwheel operably coupled with the delivery system.

29. A delivery device for delivering a prosthesis, said device comprising:

a delivery catheter configured to carry a prosthesis therein;

a dilator catheter disposed in the delivery catheter, the dilator catheter having a tapered distal tip coupled thereto;

a rapid retraction mechanism for controlling movement of the delivery catheter relative to the tapered distal tip, wherein actuation of the rapid retraction mechanism closes the delivery device such that a proximal end of the tapered distal tip abuts against a distal end of the delivery catheter, thereby forming a smooth continuous outer surface on the delivery device.

30. The device of claim 29, further comprising a first actuation mechanism for controlling movement of the delivery catheter, wherein actuation of the first actuation mechanism moves the delivery catheter away from the prosthesis thereby at least partially removing a constraint therefrom.

31. The device of claim 30, further comprising a deployment mechanism for controlling release of the prosthesis from an anchoring catheter, the anchoring catheter disposed at least partially in the delivery catheter, and wherein actuation of the deployment mechanism moves the anchoring catheter away from the prosthesis thereby releasing a constraint therefrom.

32. The device of either claim 30 or 31, wherein the first actuation mechanism comprises a thumbwheel.

33. The device of any of claims 30 to 32, wherein the deployment mechanism comprises an actuatable button with a linkage coupled thereto.

34. The device of any of claims 29 to 33, wherein the rapid retraction mechanism comprises a screw thread and interference member.

35. The device of any of claims 29 to 34, wherein the rapid retraction mechanism comprises a flexible interference member.

36. The device of any of claims 29 to 35, wherein the rapid retraction mechanism comprises a pin and pin-hole linkage assembly.

37. A system for delivering a prosthesis, said system comprising:

the device of any of claims 29 to 36; and

the prosthesis.

38. The system of claim 37, wherein the prosthesis comprises a prosthetic mitral valve.

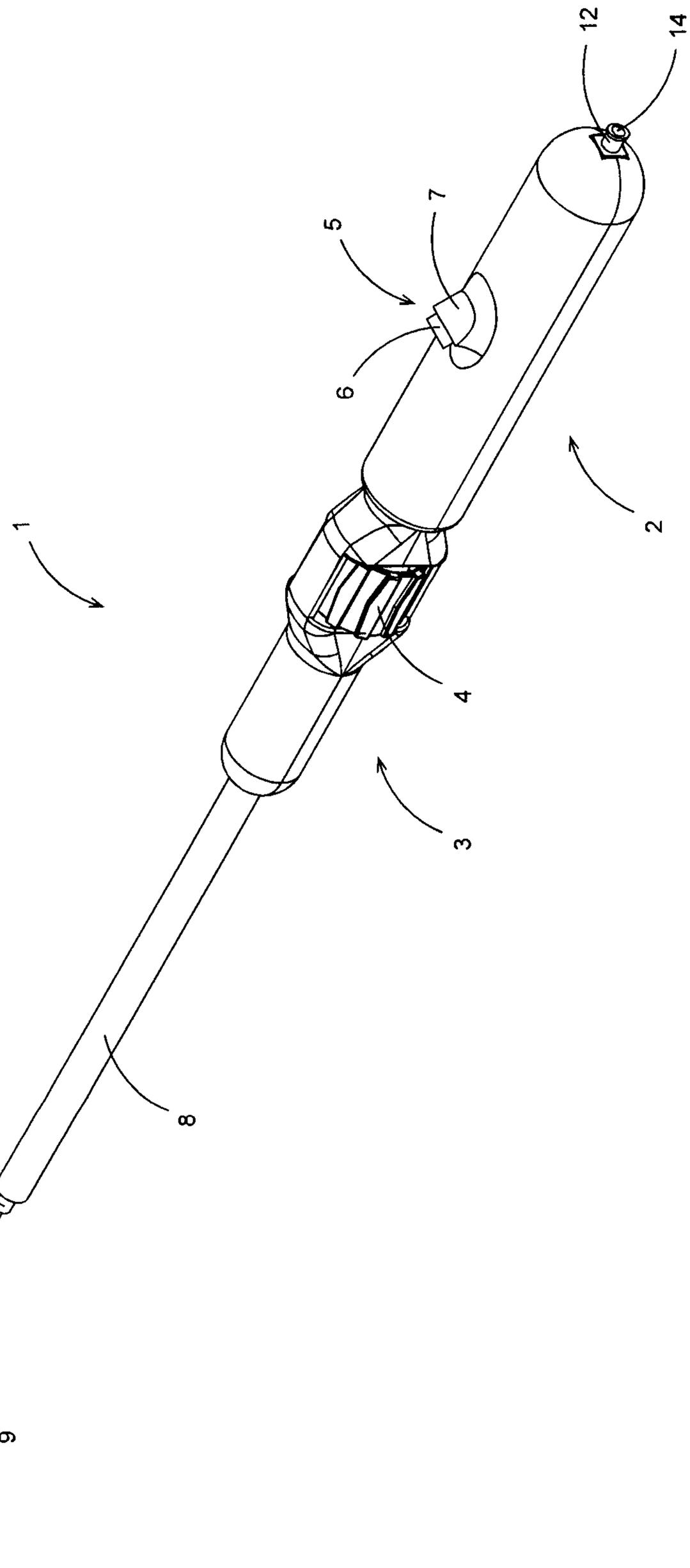

Figure 1

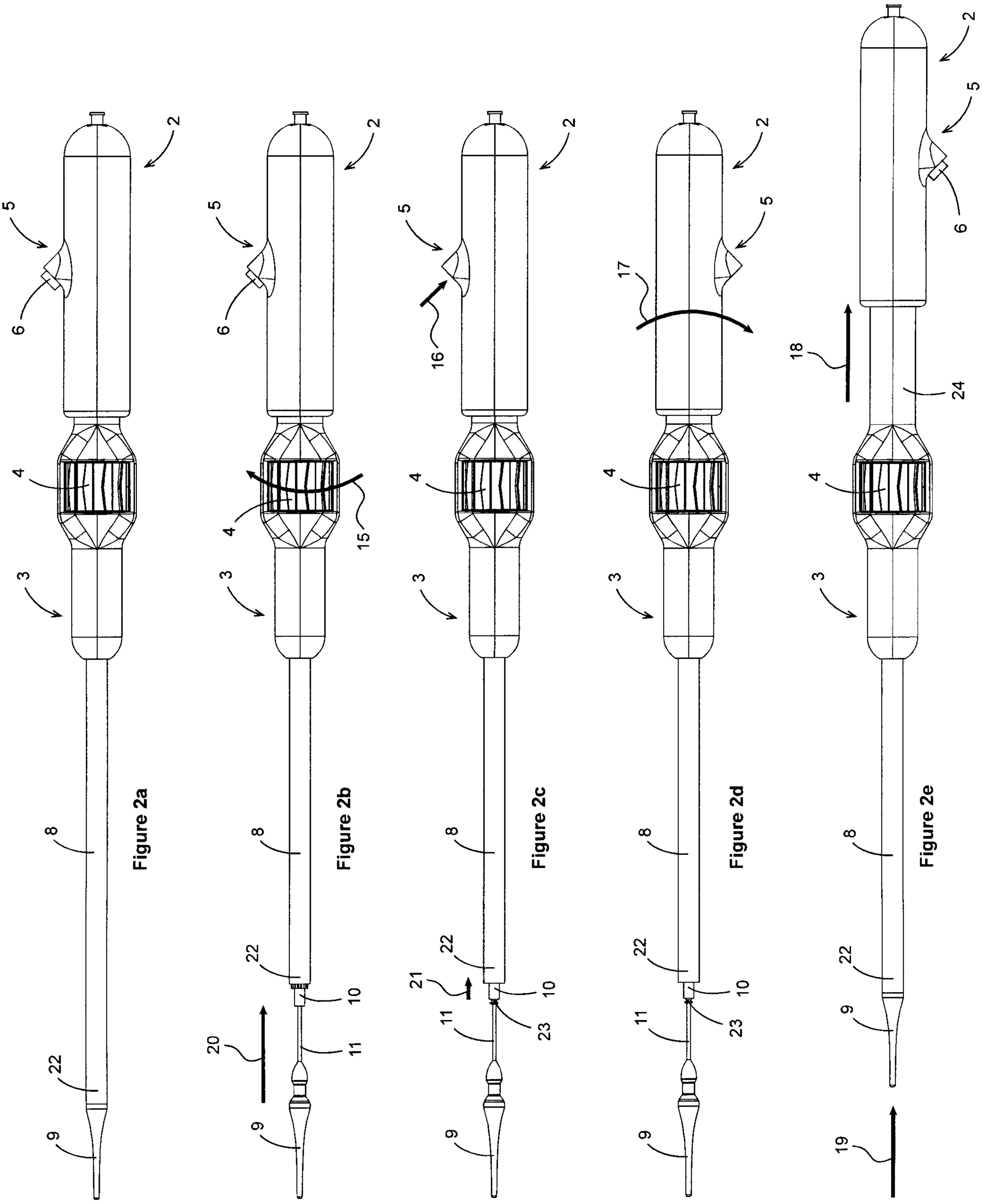
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Figure 2a
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Figure 2b
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Figure 2c
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Figure 2d
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Figure 2e
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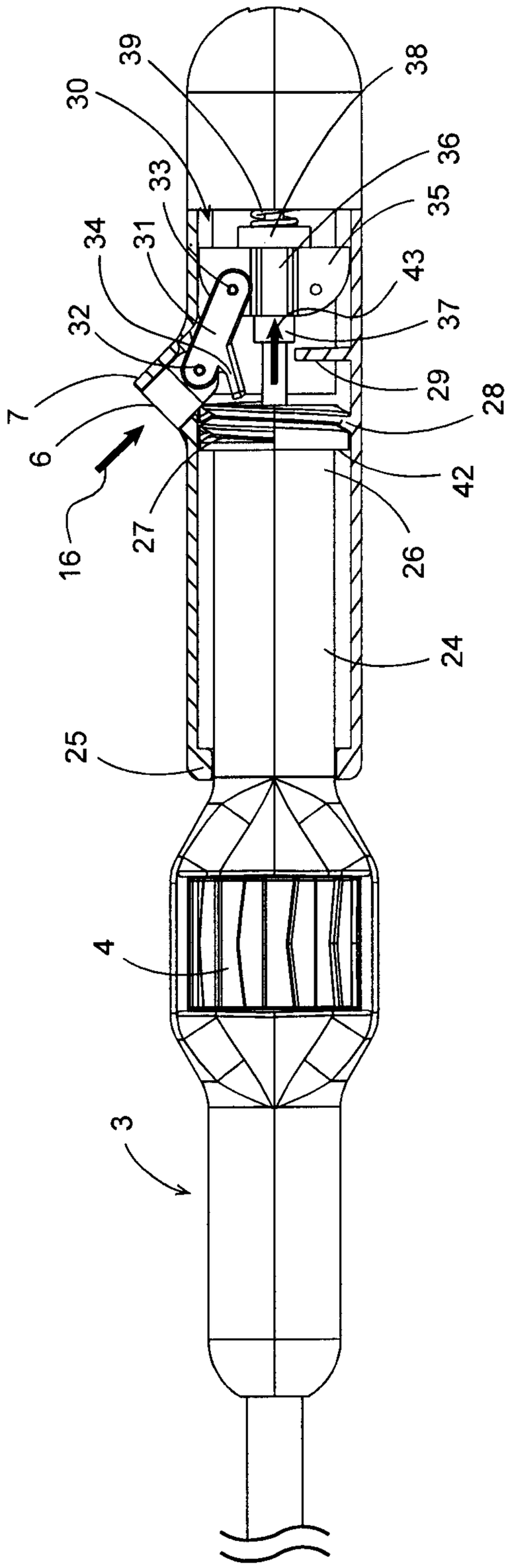

Figure 3a

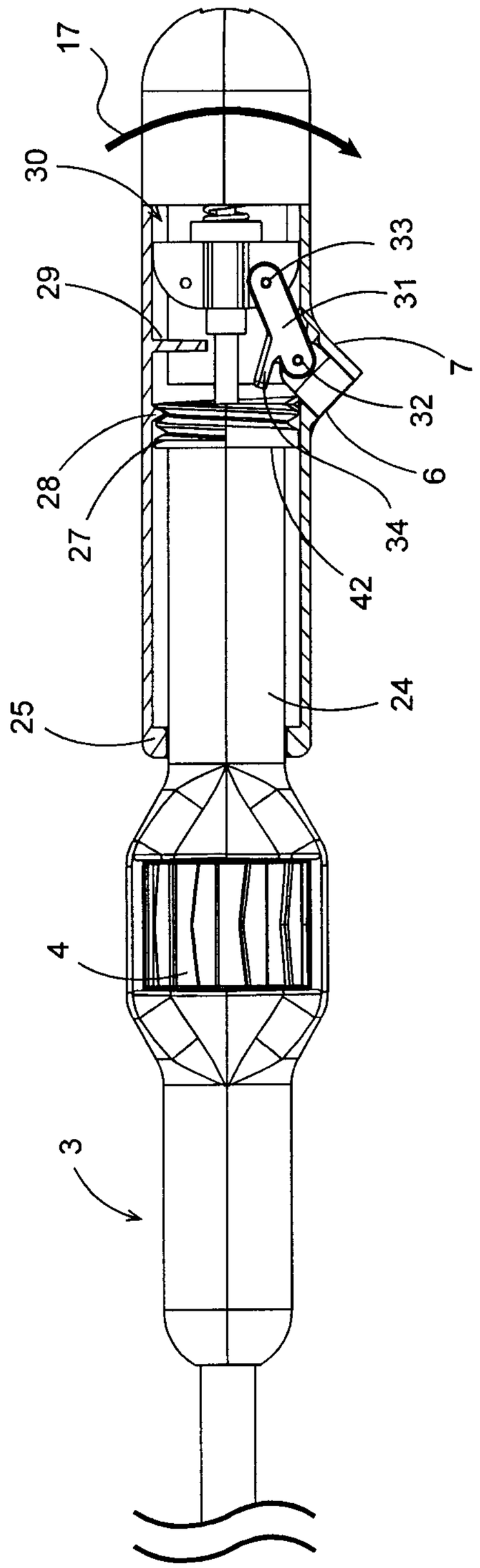

Figure 3b

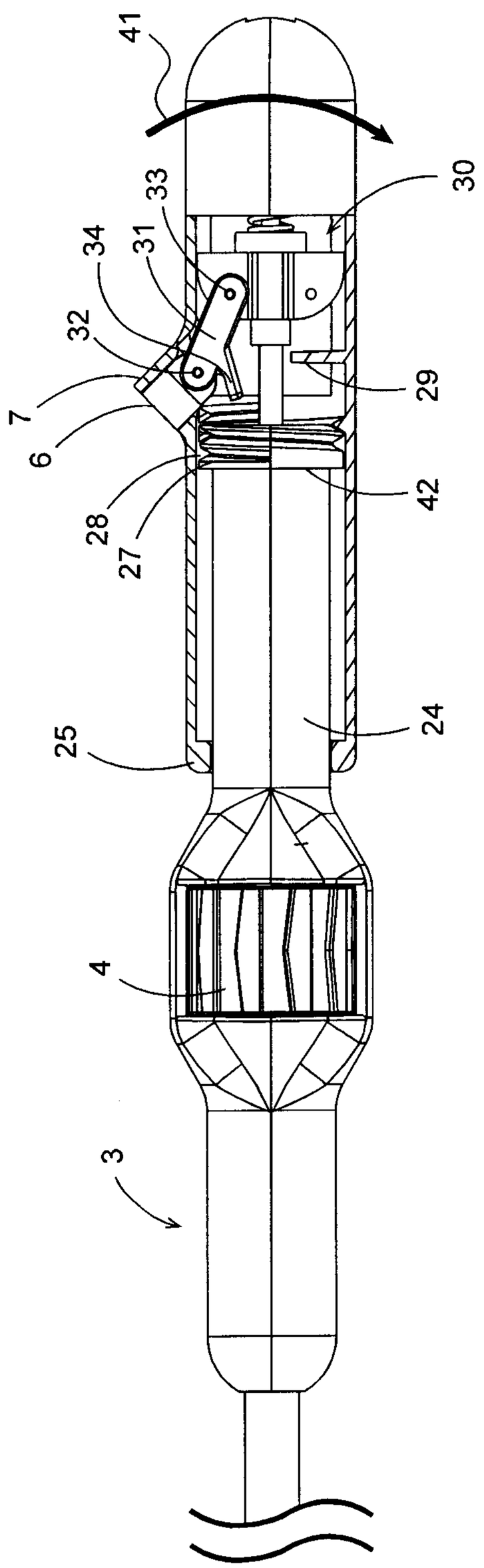

Figure 3c

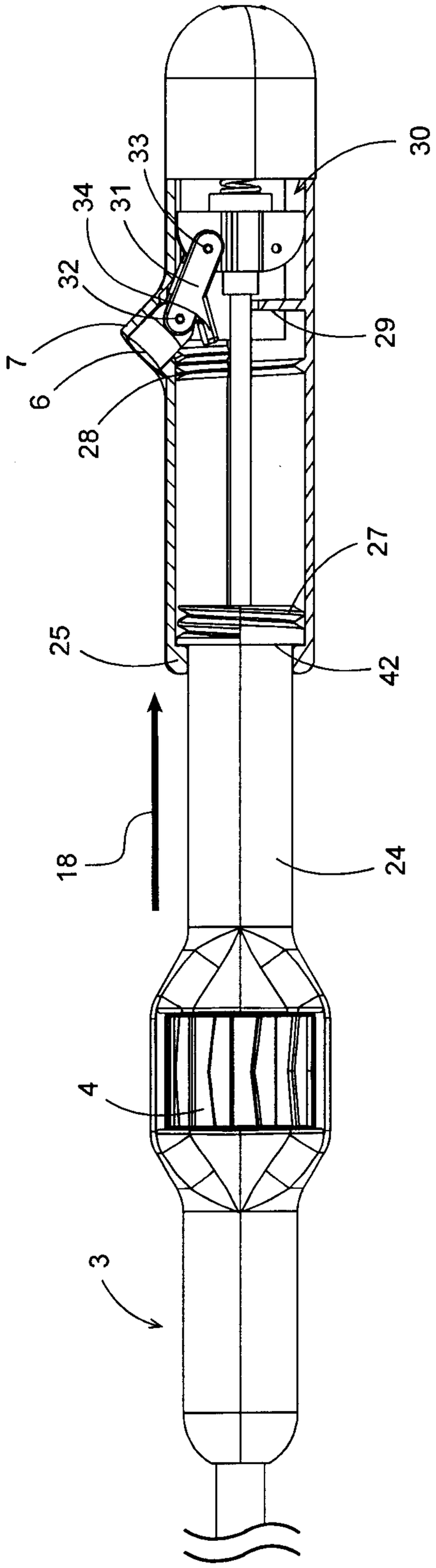

Figure 3d

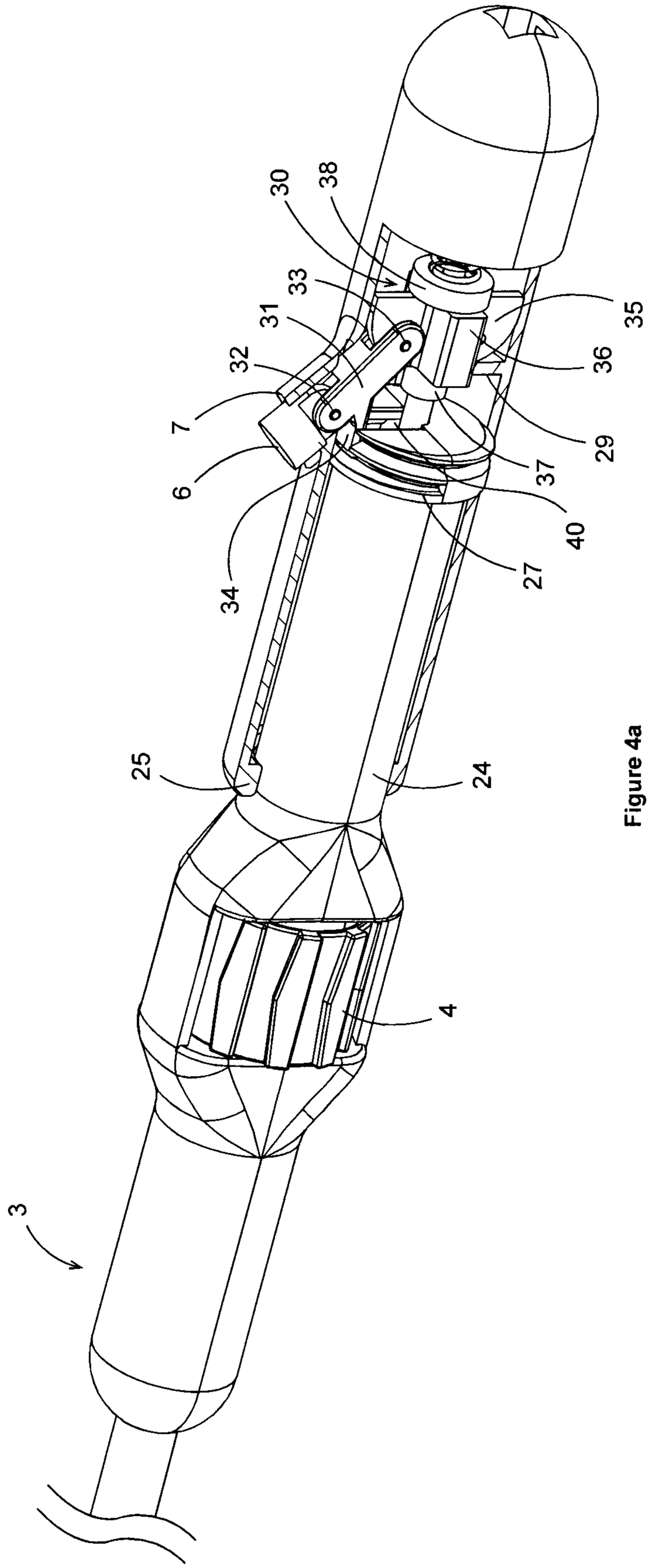

Figure 4a

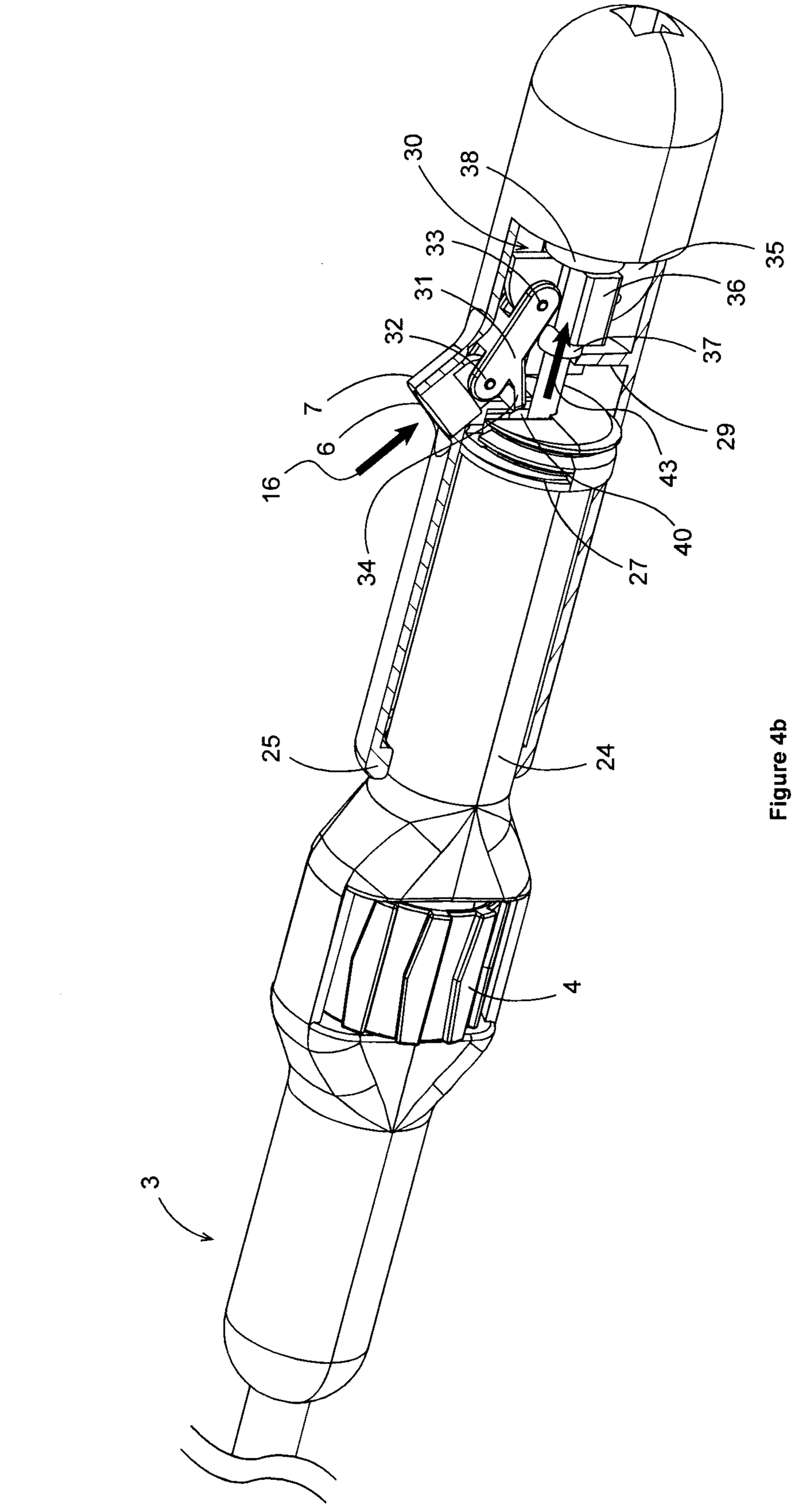

Figure 4b

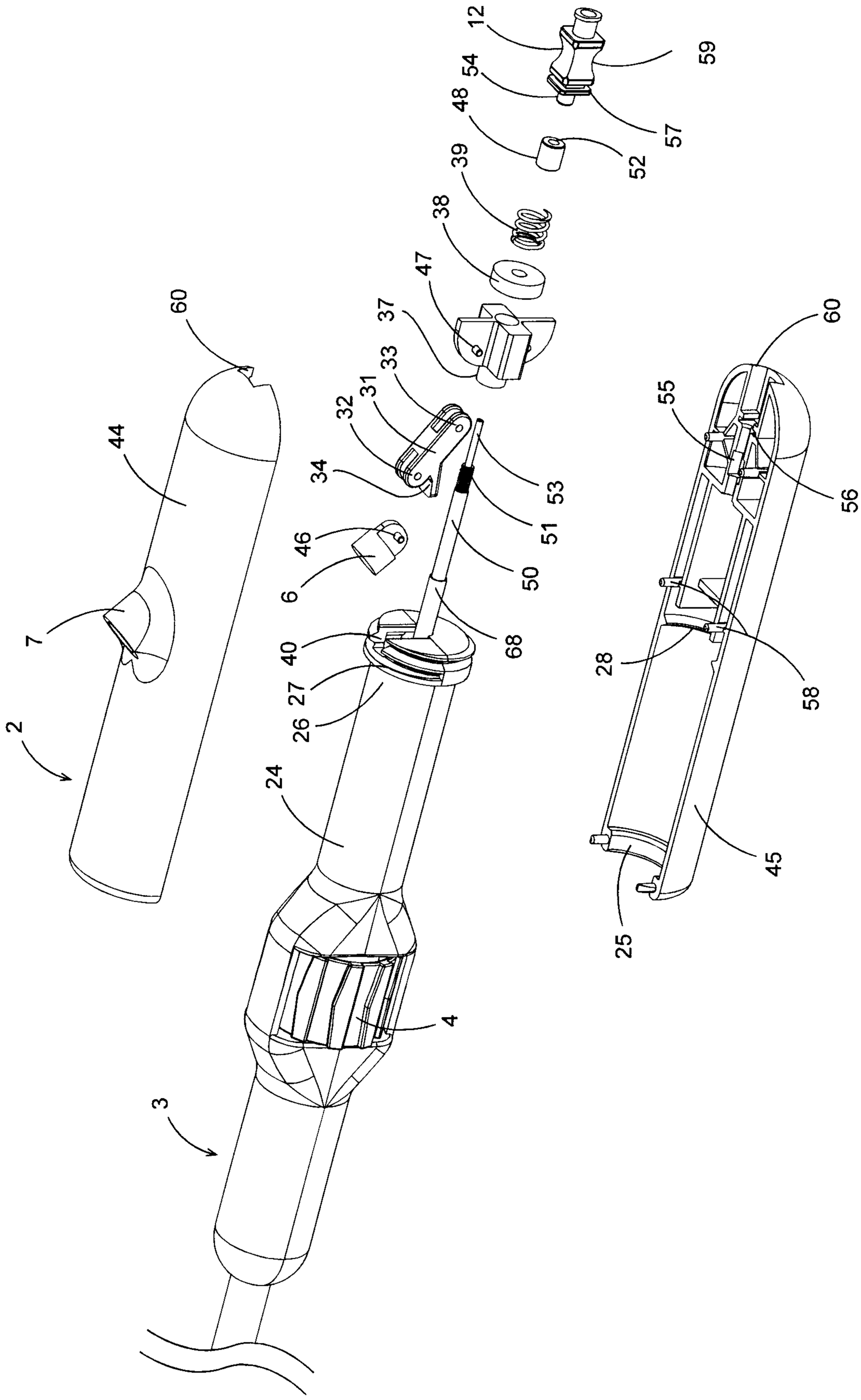
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Figure 5

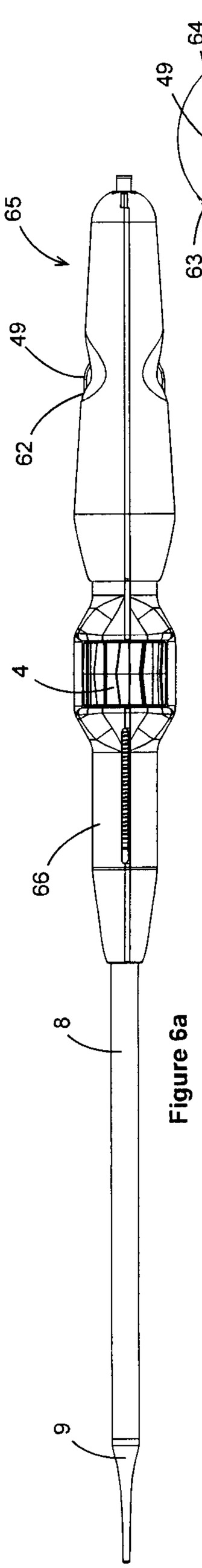

Figure 6a

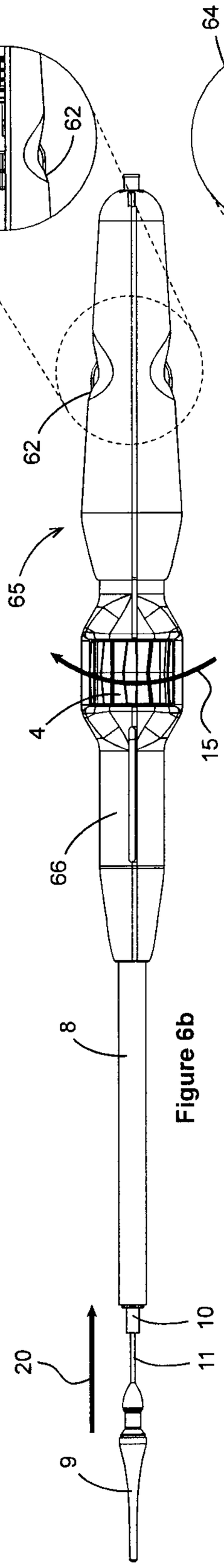

Figure 6b

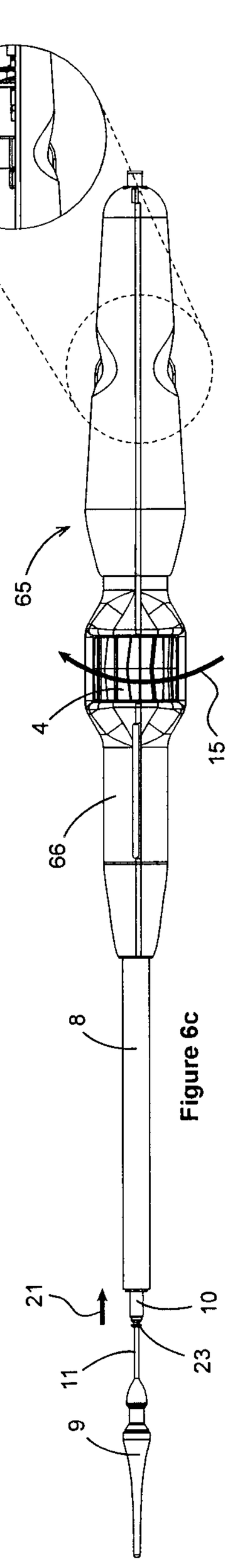

Figure 6c

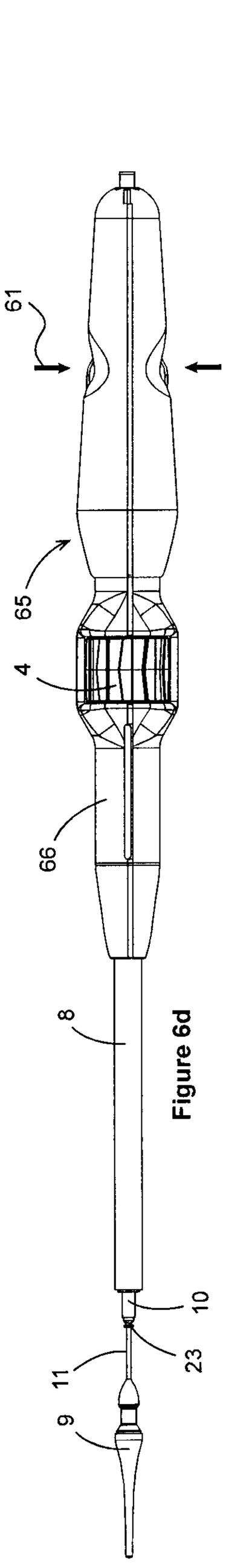

Figure 6d

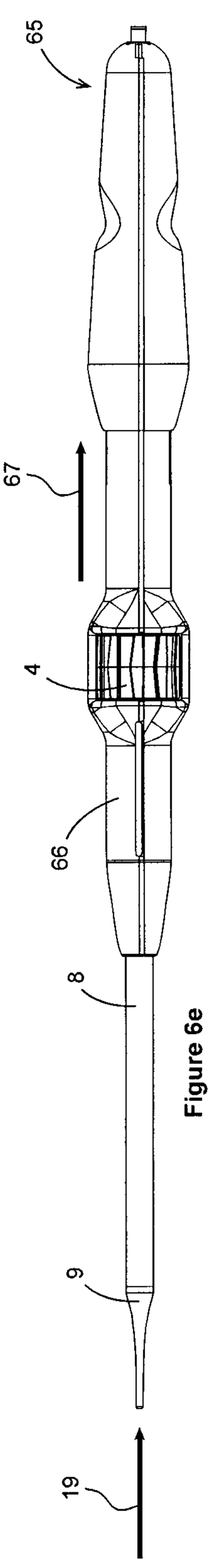

Figure 6e

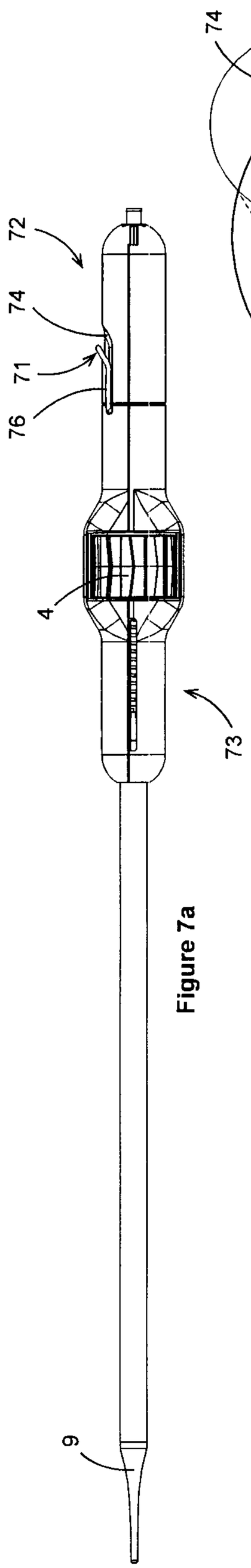

Figure 7a

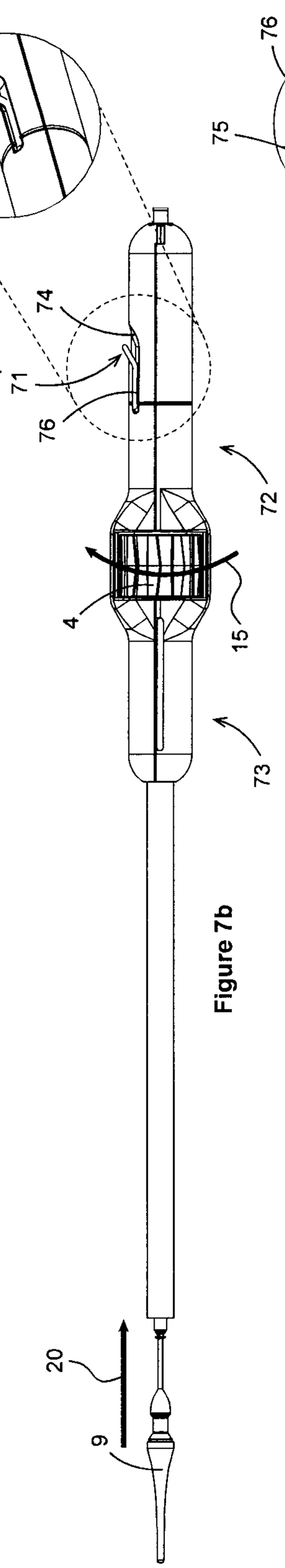

Figure 7b

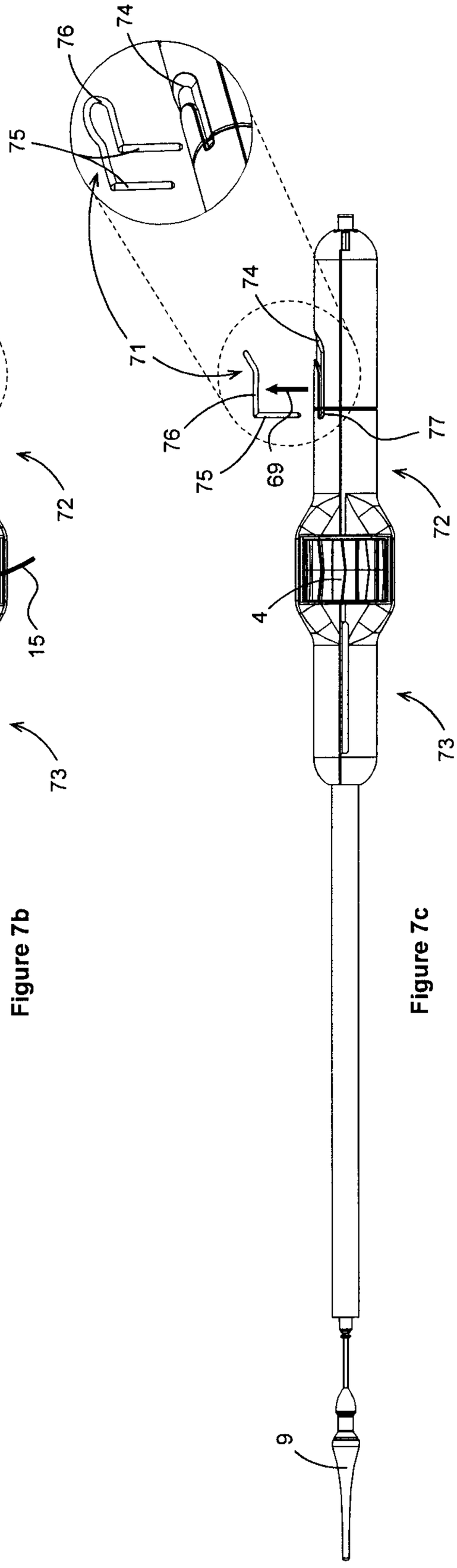

Figure 7c

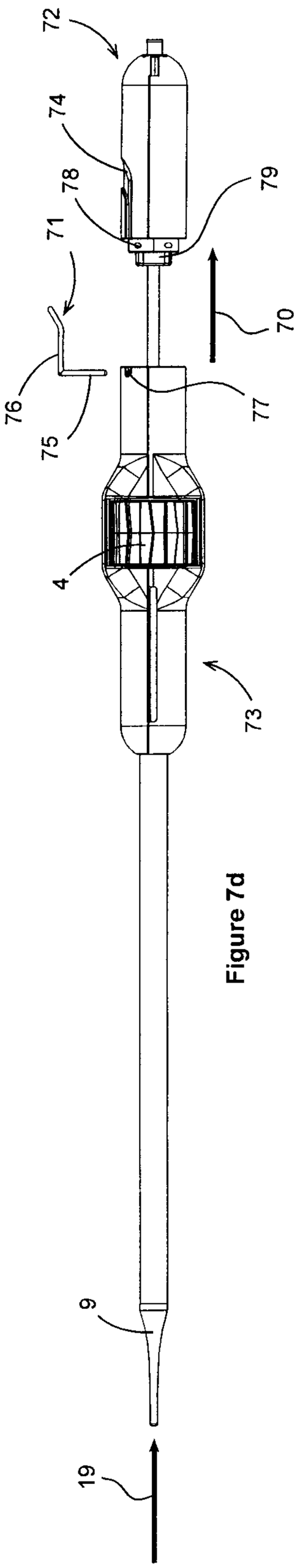

Figure 7d

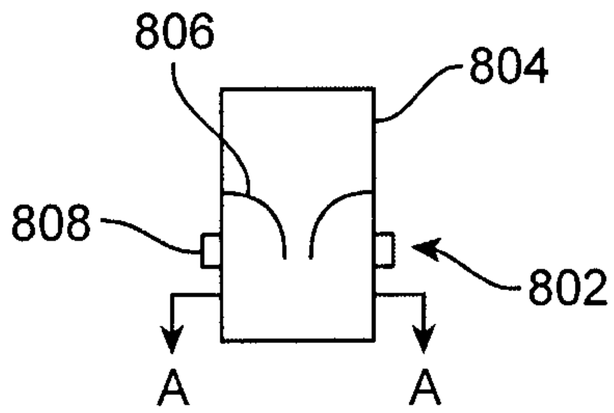

FIG. 8

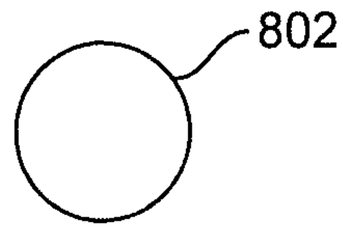

FIG. 9A

FIG. 9B

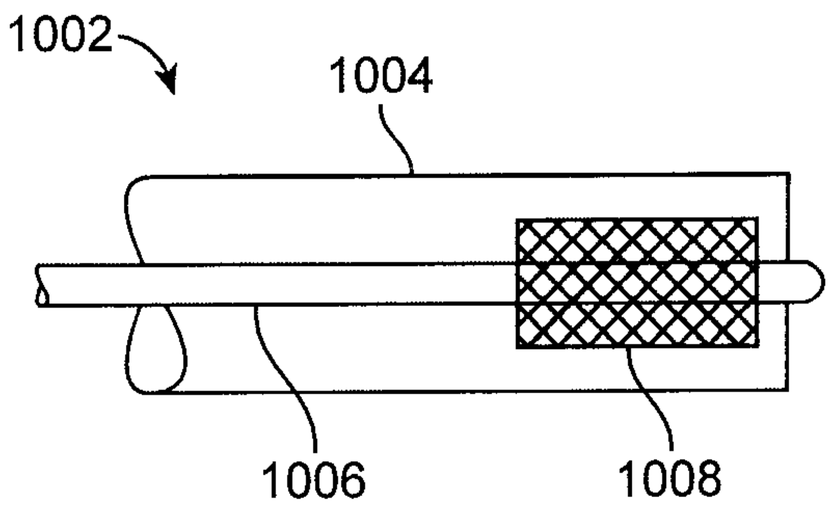

FIG. 10A

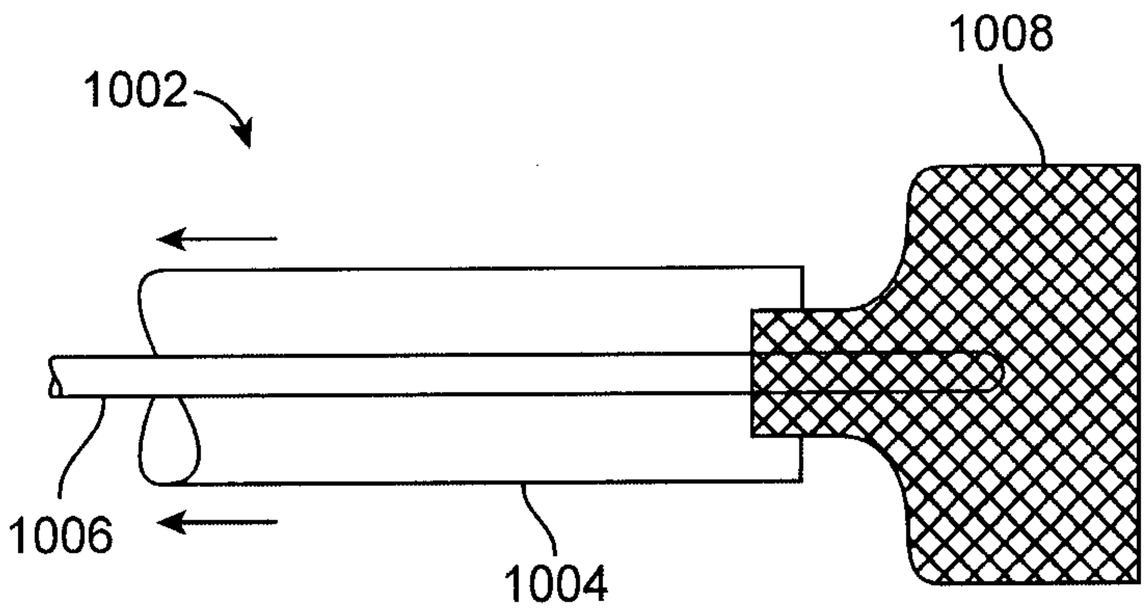

FIG. 10B

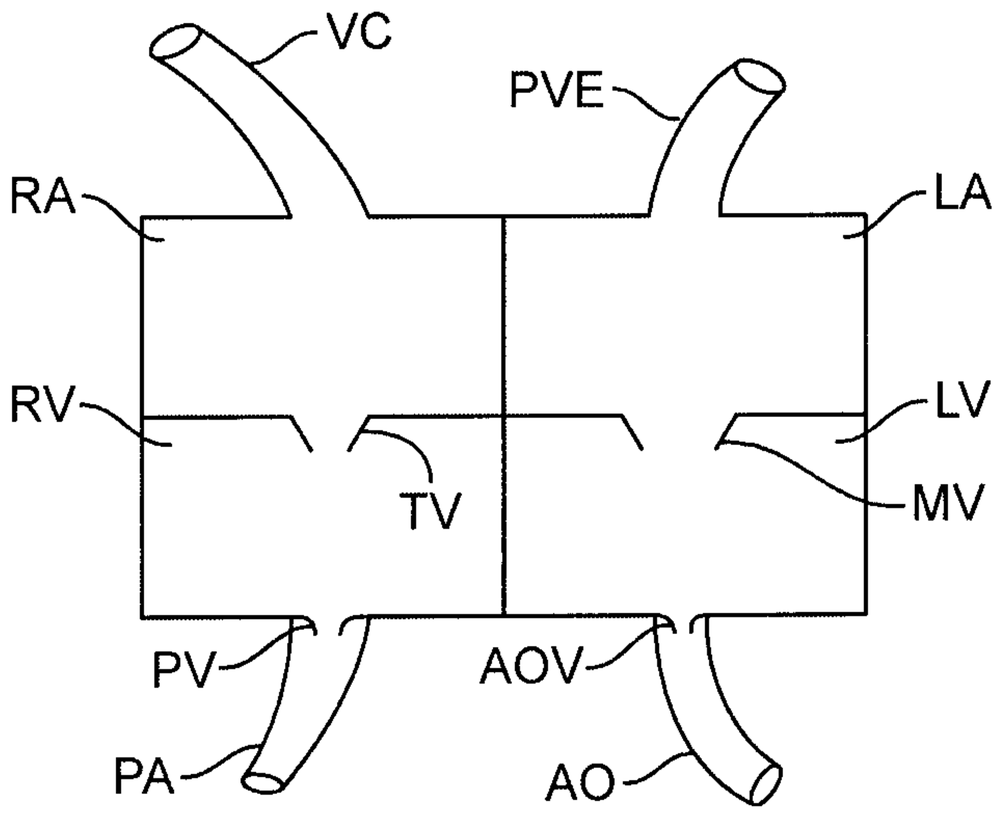

FIG. 11

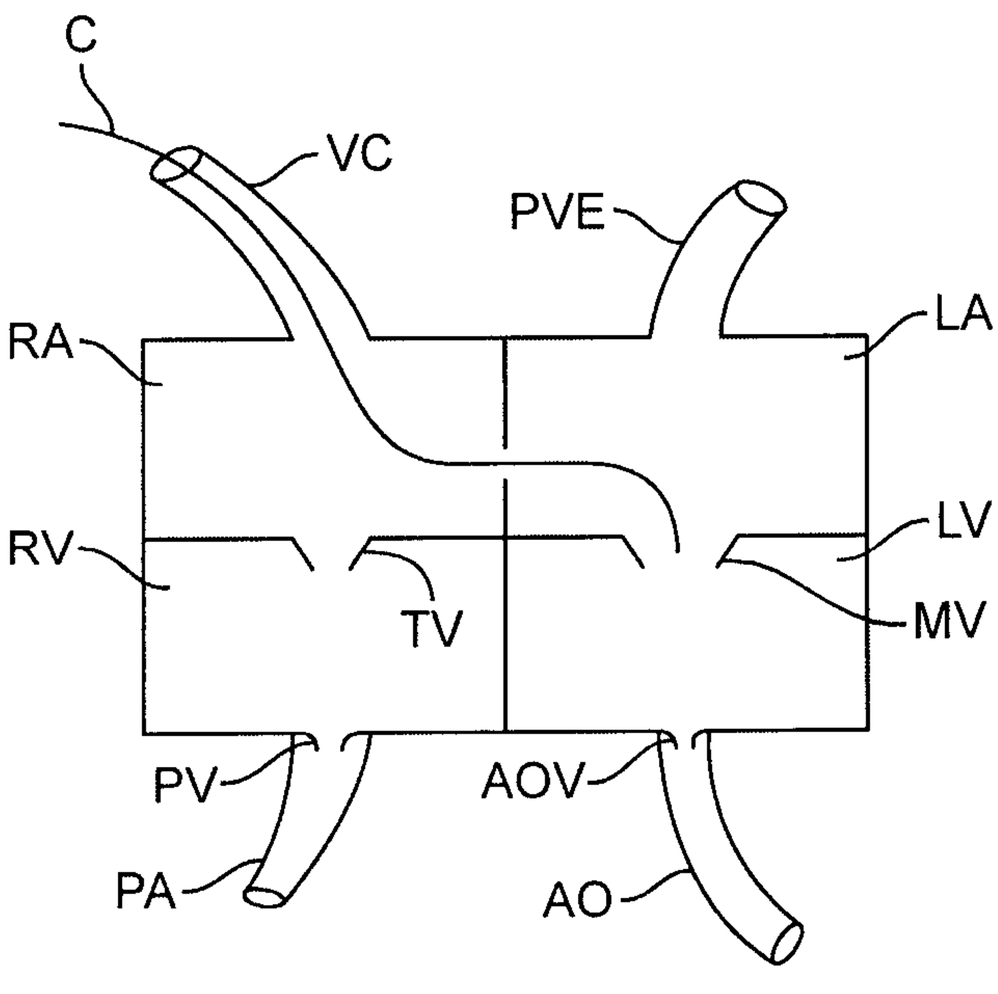

FIG. 12A

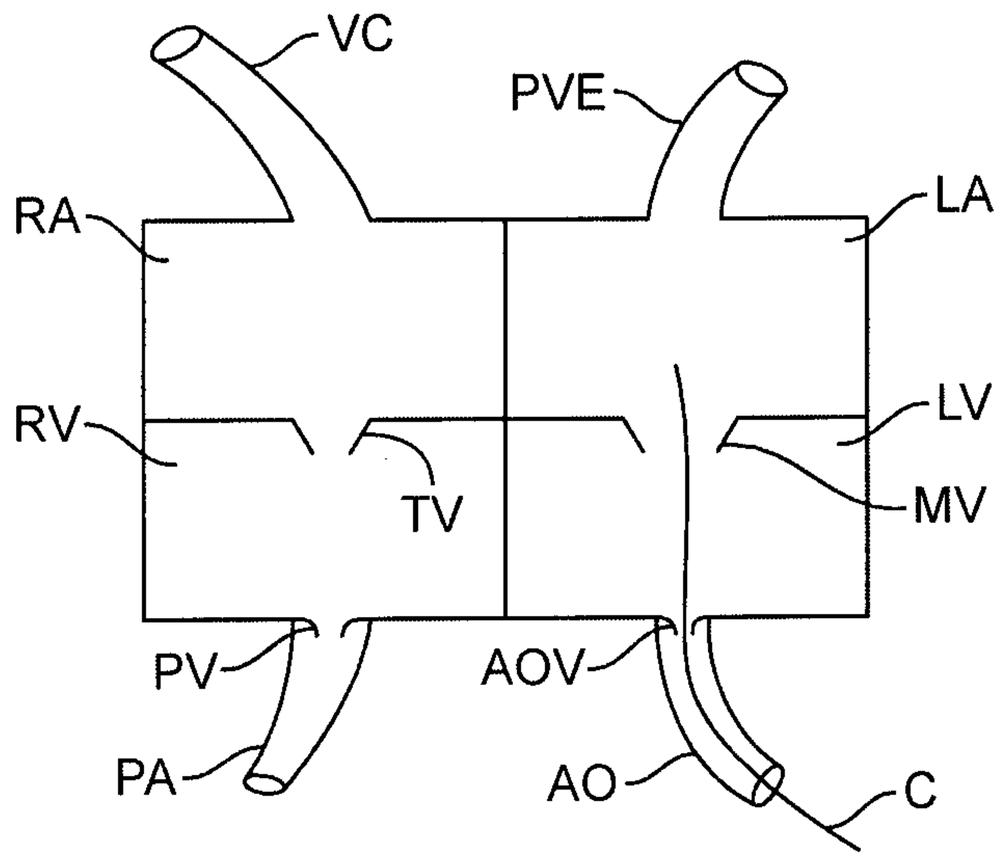

FIG. 12B

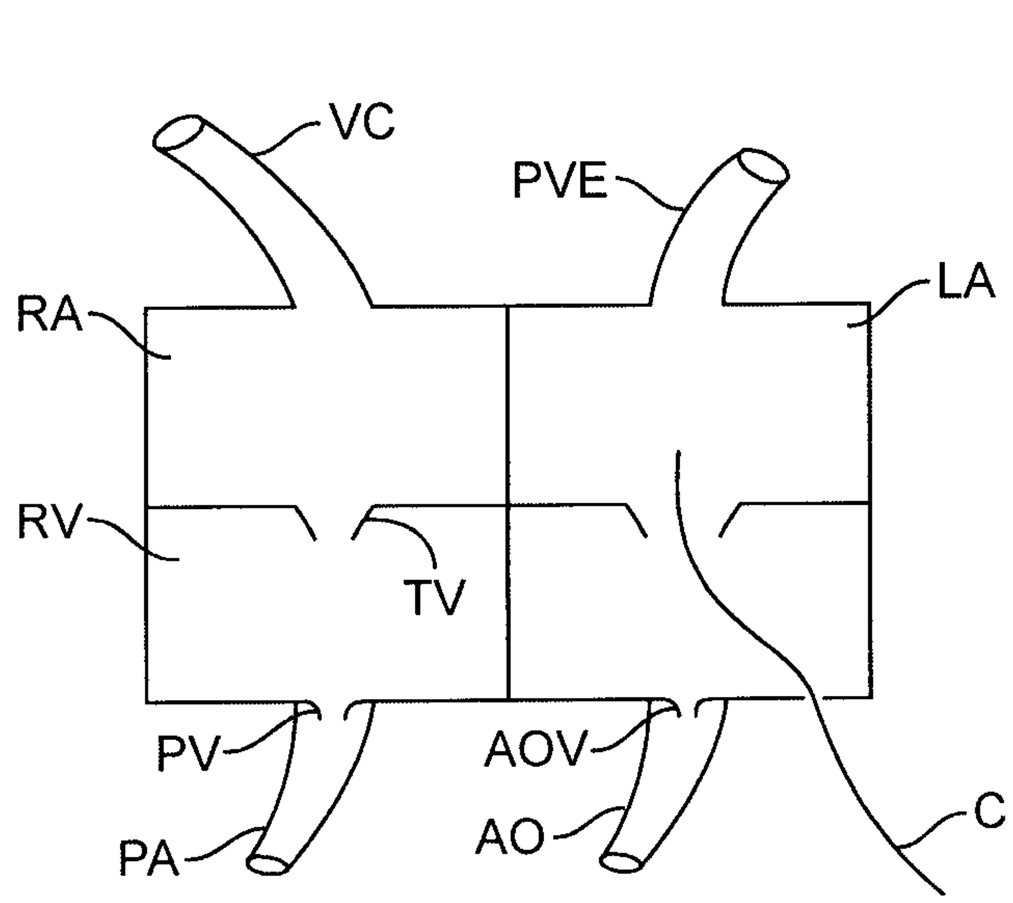

FIG. 12C

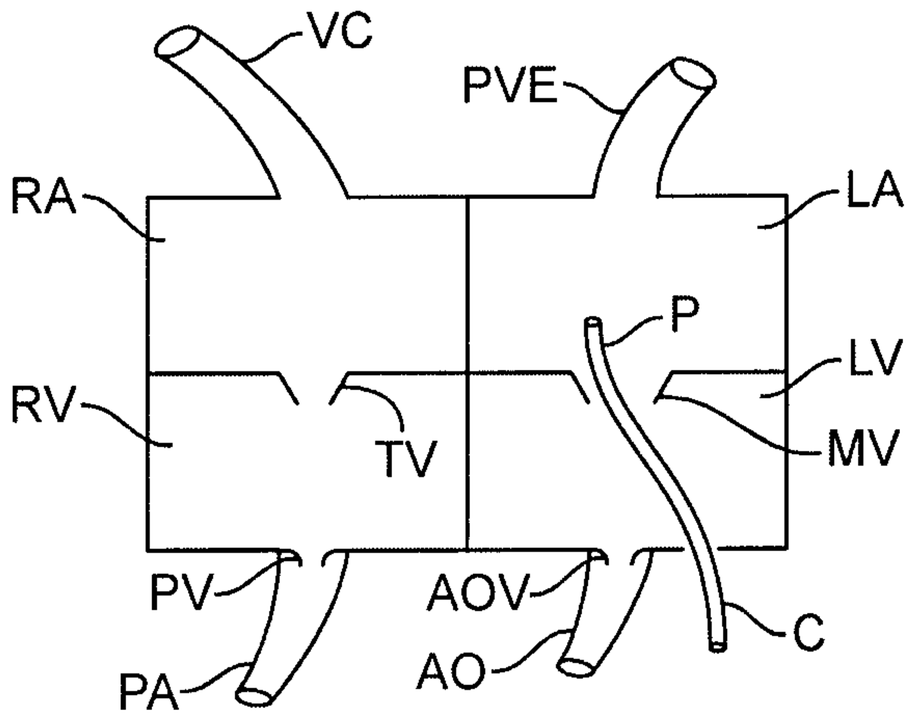

FIG. 13A

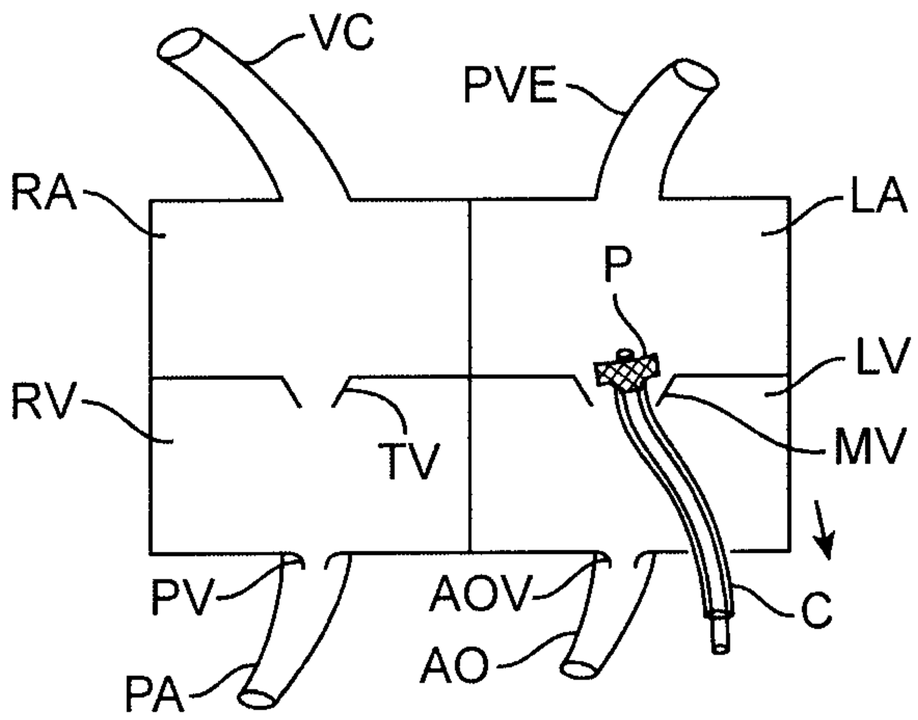

FIG. 13B

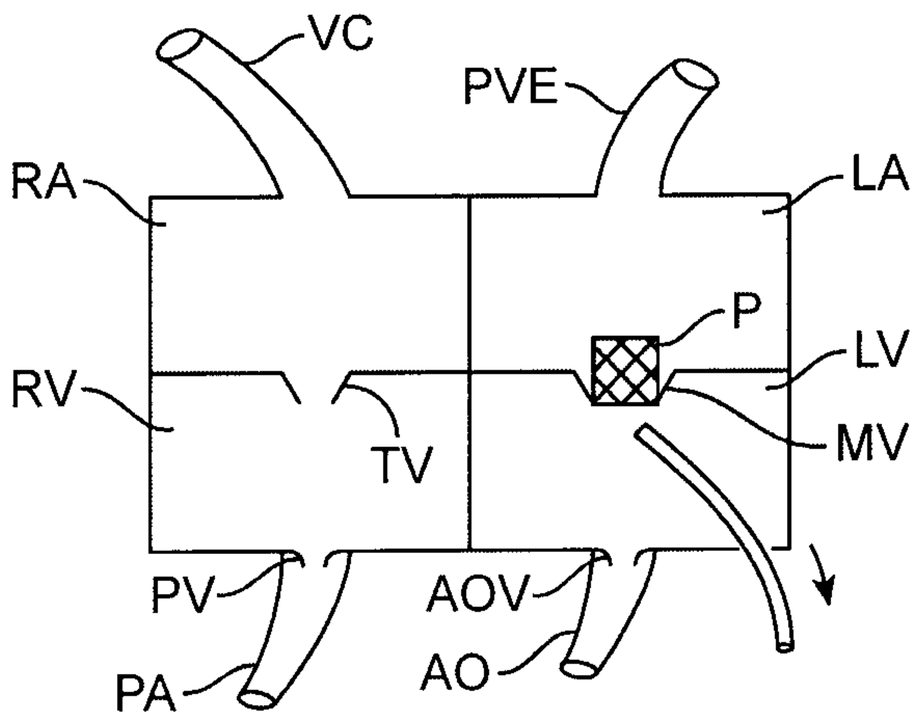

FIG. 13C

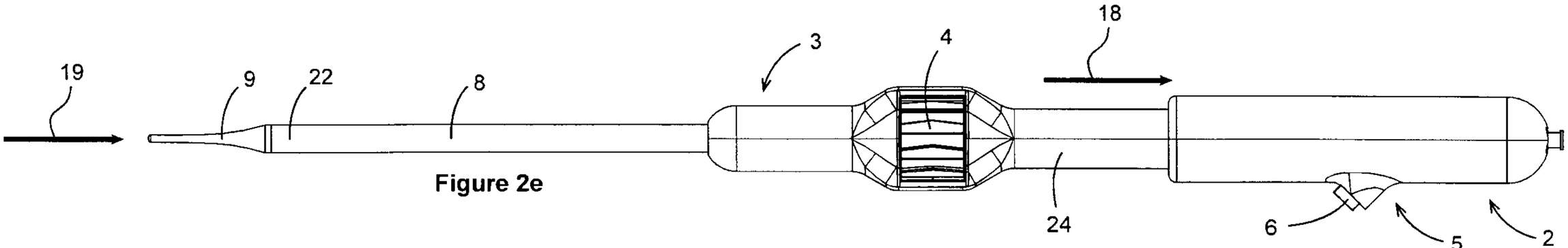

Figure 2e