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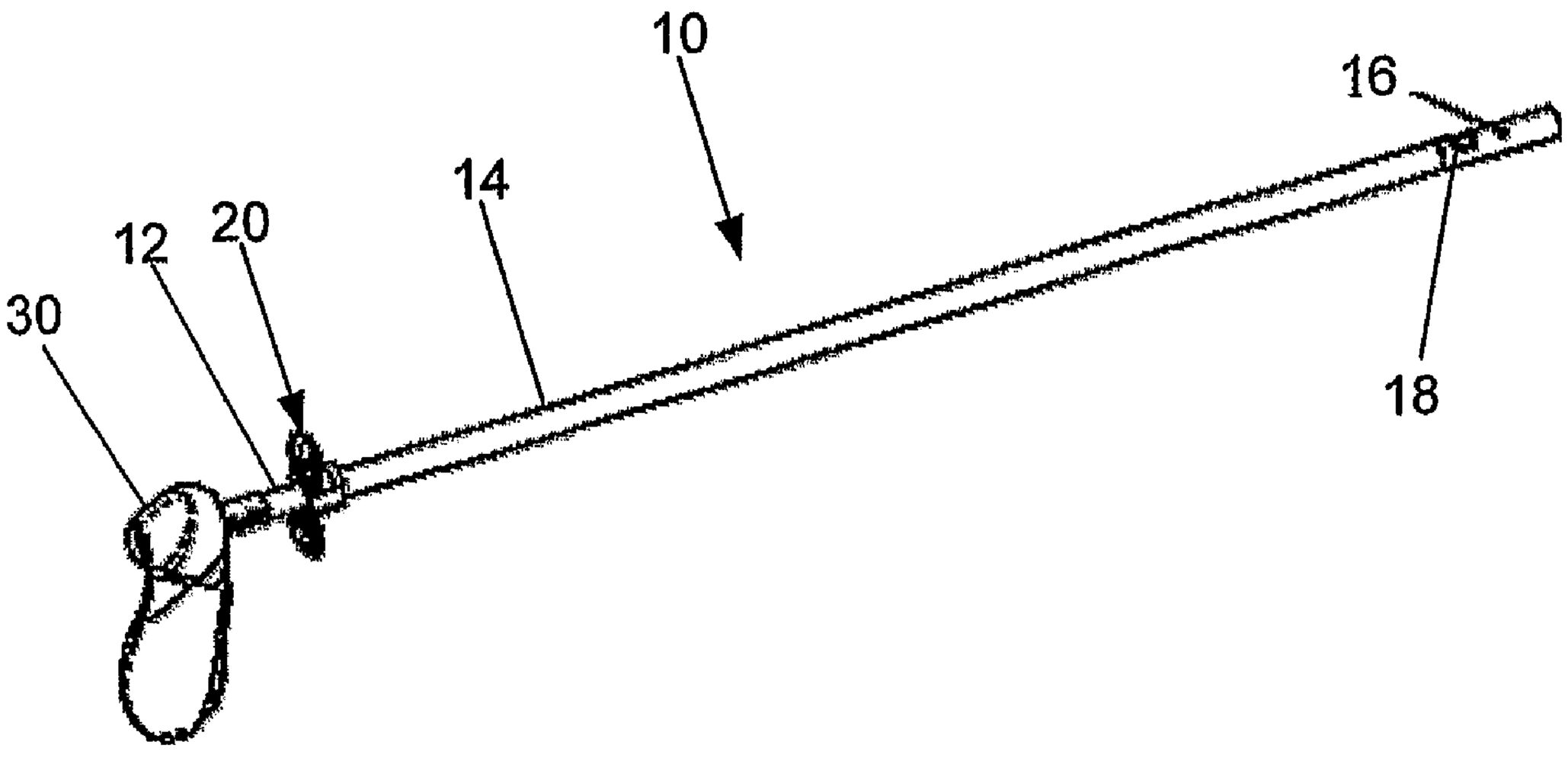

(57) Abrégé/Abstract:
A delivery device for positioning and deploying an implantable device within a lumen is provided. The device includes an inner tube positioned within an outer tube and capable of sliding therein, wherein the inner and outer tubes have proximal and distal ends. A side opening is defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening. The device includes an optical device capable of viewing at least a portion of the lumen prior to deploying the implantable device when the side openings are aligned with each other. A mechanism is coupled to at least one of the inner and outer tubes and is operable to deploy the implantable device within the lumen.

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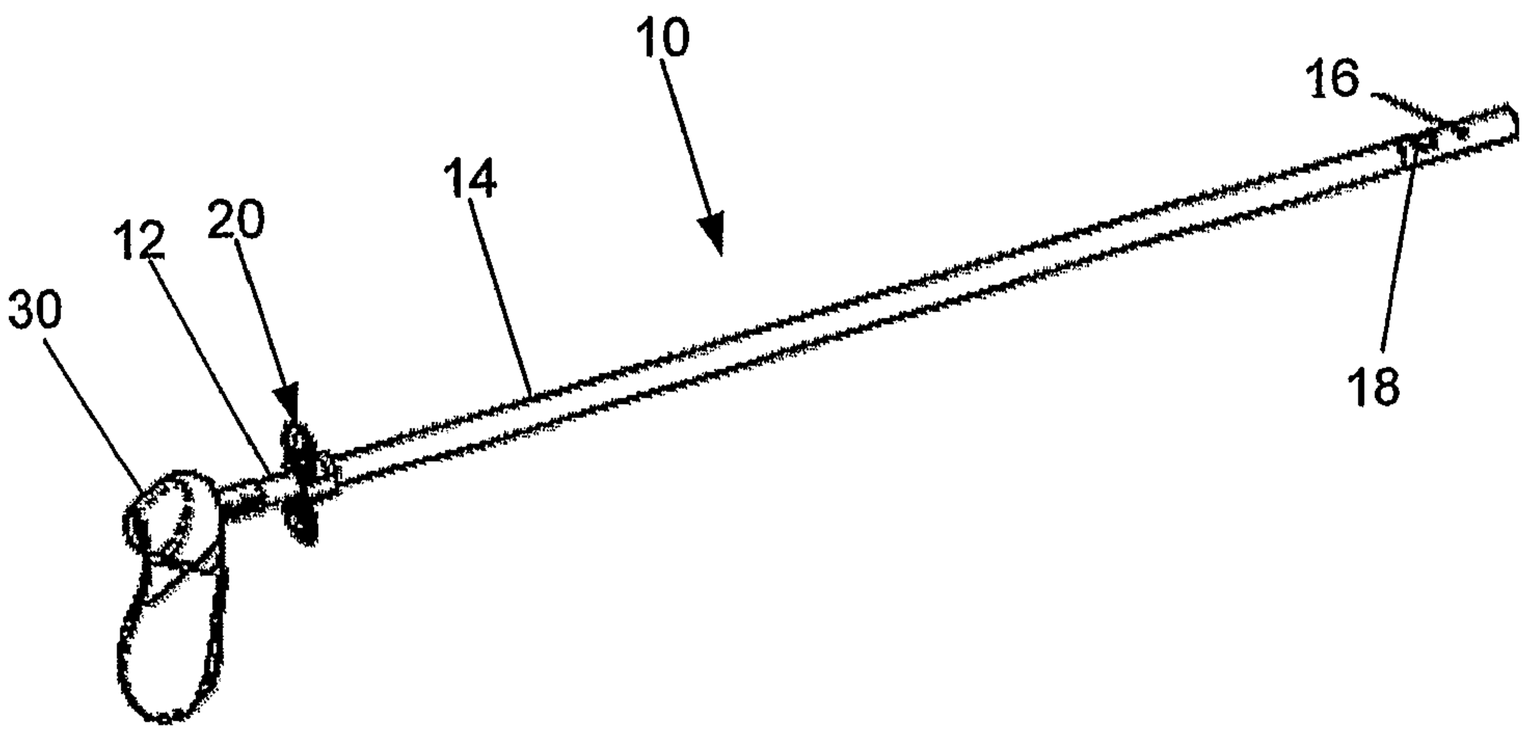

(57) **Abstract:** A delivery device for positioning and deploying an implantable device within a lumen is provided. The device includes an inner tube positioned within an outer tube and capable of sliding therein, wherein the inner and outer tubes have proximal and distal ends. A side opening is defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening. The device includes an optical device capable of viewing at least a portion of the lumen prior to deploying the implantable device when the side openings are aligned with each other. A mechanism is coupled to at least one of the inner and outer tubes and is operable to deploy the implantable device within the lumen.

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DELIVERY DEVICE WITH VIEWING WINDOW AND ASSOCIATED METHOD

BACKGROUND OF THE INVENTION

1) Field of the Invention

The present invention relates to a delivery device and, in more particular, to a delivery device that is capable of being positioned within a lumen and viewing the lumen through a window.

2) Description of Related Art

Stents are devices that are inserted into body lumina such as vessels or passages to keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, stents are commonly used to keep blood vessels open in the coronary arteries, and they are frequently inserted into the ureters to maintain drainage from the kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma, or the esophagus or airways for strictures or cancer. Vascular as well as nonvascular stenting has evolved significantly; unfortunately, there remain significant limitations with respect to effectively implanting the stents into a patient's lumen.

In order to serve its desired function, the stent must be delivered precisely and oriented correctly. Improper installation can lead to tissue luminal inflammation and tissue granulation. In order to facilitate the delivery of stents, delivery devices, such as endoscopes and catheters, have been utilized to deploy stents more precisely. Unfortunately, guidance of the stent has substantially remained a function of physician skill resulting from substantial practice. This fact has become particularly evident with the advent of radially expanding stents. The physician frequently needs to measure the length of the lesion, align a distal end of the of the delivery device, and rely on accurate deployment to ensure that the entire

lesion is covered by the stent. Moreover, delivery devices typically do not give physicians adequate visual certainty that the device has been installed at the desired target site. Optical devices are typically employed at a distal end of the delivery device, which provides limited visibility of the entire lesion with respect to the stent. If after full deployment of the stent, the physician discovers the stent has been implanted incorrectly, there is no conventional way of correcting the error short of removing the stent.

Techniques have been developed to address the problem of increasing visibility of the lesion prior to deploying the stent. For example, U.S. Patent Application Publication No. 20040193243 to Mangiardi et al. which is assigned to the present assignee and incorporated herein by reference, discloses a medical appliance optical delivery and deployment apparatus. The apparatus includes an inner tubular member disposed within an outer tubular member, where the outer tubular member is typically shorter than the inner tubular member and movable relative to the inner tubular member. A distal region of the outer tubular member surrounds the stent and maintains the stent in a crimped delivery configuration, while a distal region of the inner tubular member is surrounded by the stent. The outer tubular member may be clear so that the inner tubular member and markers are visible therethrough. An optical guidewire may extend through the inner tubular member or utility channels defined in the outer tubular member to a distal tip, or the distal tip may be configured to have a light source and lens. In addition, the inner tubular member may include optical windows proximate to the distal tip and are preferably beveled and oval to facilitate viewing with an optical instrument. The optical windows may also be staggered along the inner tubular member to increase visualization proximate to the distal tip. Once properly positioned at a site of a lesion, the outer tubular member is retracted to deploy the stent and allow the stent to radially expand.

The inner and outer tubular members, optical instruments, and optical windows provide increased visualization of the lesion prior to deploying the stent. Despite these improvements, additional innovations in positioning an implantable device and visualizing a lesion to promote more accurate delivery of the implantable device are also desired.

Therefore, there is a need in the industry for a delivery device that is capable of effectively and accurately positioning an implantable device within a patient's lumen. In addition, there is a need for a delivery device that is capable of increasing the visibility of the lumen prior to deploying the implantable device.

BRIEF SUMMARY OF THE INVENTION

The invention addresses the above needs and achieves other advantages by providing a delivery device for deploying an implantable device within a lumen. The delivery device includes a side opening in both inner and outer tubes of the device. The side openings in each of the inner and outer tubes align with one another prior to deploying the implantable device within the lumen. An optical instrument, such as a camera, is capable of being positioned proximate to the aligned side openings to view the lumen proximate to a target area. As a result, the delivery device is capable of ensuring that the proximal end of the implantable device is properly positioned proximate to the target area of the lumen.

In one embodiment of the present invention, a delivery device for positioning and deploying an implantable device within a lumen is provided. The device includes a longitudinal outer tube having proximal and distal ends, wherein the implantable device is positioned proximate to the distal end of the outer tube. The device also includes a longitudinal inner tube positioned within the outer tube and having proximal and distal ends, wherein the outer tube is capable of sliding over the inner tube. A side opening is defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening. The device further includes an optical device positioned within the inner tube and proximate to each side opening such that the optical device is capable of viewing at least a portion of the lumen prior to deploying the implantable device when the side openings are aligned with each other. A mechanism is coupled to the inner and/or outer tubes and is operable to deploy the implantable device within the lumen. The mechanism could include at least one actuator coupled to the outer tube.

In various aspects of the delivery device, a coil is positioned within each of the inner and outer tubes, wherein the side opening of each of the inner and outer tubes is defined distally of the respective coils. The side opening of the inner tube

may be defined longitudinally between the coil and the implantable device. Each of the inner and outer tubes may include a semi-transparent polymeric material, such as polytetrafluoroethylene and/or polyether block amide. In addition, the optical device is capable of viewing, through the side openings, at least a proximal end of a target area within the lumen. The optical device is also capable of extending through each of the side openings to view a target area within the lumen.

In additional aspects of the delivery device, the device includes a pusher at the distal end of the inner tube and positioned at a proximal end of the implantable device. The side opening of the inner tubular member could be defined proximally of the pusher, and each of the side openings may align with each other proximally of the pusher. Each of the side openings may include an oval having a major and a minor axis, and the major axis of each of the side openings may extend substantially parallel to a longitudinal axis of the respective inner and outer tubes. Furthermore, each of the side openings could extend less than midway about a circumference of each of the inner and outer tubes, and could align with each other proximate to the proximal end of the implantable device.

Another embodiment of the present invention includes a device for viewing a target area within a lumen. The lumen includes a longitudinal inner tube positioned within a longitudinal outer tube, where each of the inner and outer tubes having proximal and distal ends. A side opening is defined in each of the inner and outer tubes, wherein the outer tube is capable of sliding over the inner tube to substantially align each of the side openings with each other. An optical device is positioned within the inner tube and proximate to each side opening such that the optical device is capable of viewing at least a portion of the target area when the side openings are aligned with each other. The device further includes an instrument positioned within the inner tube and capable of performing a procedure while the side openings are aligned. The instrument could perform the procedure through a distal opening defined in each of the inner and outer tubes or through the side openings when the side openings are aligned.

The present invention provides another embodiment of a delivery device for positioning and deploying an implantable device within a lumen. The device includes a longitudinal outer tube having proximal and distal ends, wherein the implantable device is positioned proximate to the distal end of the outer tube. The

device also includes a longitudinal inner tube positioned within the outer tube and having proximal and distal ends, wherein the outer tube is capable of sliding over the inner tube. A side opening is defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening prior to deploying the implantable device. A mechanism is coupled to the inner and/or outer tubes and is operable to deploy the implantable device within the lumen. The device could further include an optical device positioned within the inner tube and proximate to each side opening such that the optical device is capable of viewing at least a portion of the lumen when the side openings are aligned with each other.

Furthermore, one aspect of the present invention provides a method for deploying an implantable device within a lumen proximate to a target area. The method includes positioning the implantable device within an outer tube, and sliding the outer tube over an inner tube to substantially align a pair of side openings defined in each of the inner and outer tubes. The method also includes positioning the inner and outer tubes within the lumen, and positioning an optical device within the inner tube and proximate to each of the side openings to view at least a portion of the target area. The method further includes deploying the implantable device with a mechanism proximate to the target area.

In aspects of the method, the positioning step includes positioning the optical device proximate to a proximal end of the target area. The sliding step could also include sliding the outer tube such that the side opening of the outer tube aligns with the side opening of the inner tube proximally of a pusher positioned on a distal end of the inner tube. Furthermore, the deploying step may include sliding the outer tube proximally over the inner tube with the mechanism.

A further embodiment of the present invention provides a method for manufacturing a delivery device. The method includes providing an inner tube and an outer tube, and punching a side opening through a wall in each of the inner and outer tubes. The method also includes attaching a pusher to a distal end of the inner tube, and positioning the inner tube within the outer tube such that each of the side openings is capable of aligning with one another.

Variations of the method include attaching a coil circumferentially and longitudinally within each of the inner and outer tubes. The attaching step could

include etching a surface of each of the inner and outer tubes such that the coil attaches to a respective inner and outer tube. The attaching step may include attaching a pusher at a distal end of the inner tube such that the side opening of the inner tube is positioned proximally of the pusher.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. 1 is a perspective view of a delivery device according to one embodiment of the present invention;

FIG. 2A is a side view of the delivery device shown in FIG. 1;

FIG. 2B is a side view of a delivery device according to another embodiment of the present invention;

FIG. 3 is a partial plan view of a delivery device, illustrating side windows of inner and outer tubes substantially aligned, according to one embodiment of the present invention;

FIG. 4 is another partial plan view of the delivery device shown in FIG. 3, depicting an implantable device deployed from the delivery device;

FIG. 5 is a side view of an inner tube assembly according to one embodiment of the present invention;

FIG. 6 is a partial cross-sectional view taken through line A-A of the inner tube assembly shown in FIG. 5;

FIG. 7 is a side view of an outer tube assembly according to one embodiment of the present invention;

FIG. 8 is a partial cross-sectional view taken through line A-A of the outer tube assembly shown in FIG. 7;

FIG. 9 is a side view of an additional outer tube assembly according to one embodiment of the present invention;

FIG. 10 is a partial cross-sectional view taken through line A-A of the outer tube assembly shown in FIG. 9;

FIG. 11 is side view of an outer tube according to one embodiment of the present invention; and

FIG. 12 is a partial cross-sectional view taken through line A-A of the outer tube shown in FIG. 11.

DETAILED DESCRIPTION OF THE INVENTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, this invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

With reference to FIG. 1, a delivery device **10** is shown. The delivery device **10** generally includes an inner tube **12** positioned within an outer tube **14** and capable of sliding therein. The delivery device **10** also includes a deployment mechanism **20** that is capable of deploying an implantable device **16** out of the distal end of the outer tube **14**. Side openings **18** are defined in each of the inner **12** and outer **14** tubes. Each of the side openings **18** is capable of aligning with one another such that an optical device **19** may view a target area within a lumen. Therefore, the side openings **18** provide increased visibility of the target area, especially proximal of the target region, to ensure that the implantable device **16** is properly aligned prior to deploying the implantable device within the lumen.

Thus, the delivery device **10** is capable of being deployed within a lumen proximate to a target area. "Target area," as used herein, is not meant to limiting, as the target area, could be a stricture, lesion, tumor, occlusion, fistulae, or other complication where the lumen passageway has been significantly reduced. The delivery device **10** is typically utilized to deploy the implantable device **16** within a lumen. However, the delivery device **10** is also capable of being used for surgical or endoscopic techniques to decrease the complexity of the procedure. For example, the delivery device **10** is also applicable to laparoscopy and arthrectomy.

It is understood that the delivery device **10** is applicable to a wide range of intraluminal applications. For example, the delivery device **10** could be used for implanting an implantable device within lumina of the esophagus, trachea, arteries,

or the biliary tract. The implantable device could be, for example, a stent, drug delivery device, or other medical device or drug known to those skilled in the art. Furthermore, any number of configurations of implantable devices **16** could be incorporated and still be within the present scope of the invention. An exemplary embodiment of the interstice geometry of a stent and methods of manufacturing the stent is disclosed in U.S. Patent Publication No. 20040127973, entitled "Removable Biliary Stent," which is assigned to the present assignee and is incorporated herein by reference.

Both the inner tube **12** and outer tube **14** are typically flexible for positioning and maneuvering the tubes within a lumen. Each of the inner **12** and outer **14** tubes are also typically transparent or semi-transparent, such that the inner tube is visible through the outer tube. Moreover, the inner tube **12** may include markers for positioning and deploying the implantable device **16**, although the inner and/or outer tubes could include markers if desired. For instance, the distal end of the outer tube **14** may include a marker to locate the distal end of the implantable device **16**. The inner tube **12** is slightly smaller in diameter than the outer tube **14** such that the inner tube may slide within the outer tube.

However, the inner **12** and outer **14** tubes may be various sizes and configurations to accommodate a desired implantable device **16**. For example, the inner **12** and outer **14** tubes could be about 6 to 10 mm in diameter and about 250-500 mm in length. Each of the inner **12** and outer **14** tubes could also be various diameters and wall thicknesses along the length of each tube for varying flexibility and/or aiding in securing or deploying the implantable device **16**. For example, the outer tube **14** could have an incrementally larger diameter from the coil **24** to the distal opening, and could also have a greater wall thickness proximate to the side opening **18**.

A substantial portion of each of the inner **12** and outer tubes **14** includes an assembly of polymeric materials and a metal coil **24**. For instance, the polymeric materials could be a polytetrafluoroethylene ("PTFE"), such as Teflon® (E.I. DuPont de Nemours and Co. Corp.), and a polyether block amide ("PEBA"), such as Pebax® (Atofina Corp.). Generally, a PTFE liner is placed over a mandrel, and a coil **24** is wound around the PTFE liner while positioned on the mandrel. The PEBA material is configured as a tube and slid over the wound coil **24** and the

PTFE liner while the assembly is supported on the mandrel. The assembly is then heated such that the PEBA outer sheath and the PTFE liner are adhered together over the coil to form a tube assembly. The PTFE liner is typically etched so that the PEBA material attaches or fuses to the PTFE material. During the etching process, the PTFE liner is discolored from a clear color to a yellowish brown. Because the PTFE liner is slightly discolored, the side opening **18** provides greater visibility where an optical instrument **19** would be unable to clearly view through the liner itself. The remaining portions of the inner **12** and outer **14** tubes (i.e., the distal portions of the tubes where no coil is present) are typically a combination of PTFE and PEBA materials. The interior of the inner **12** and outer **14** tubes are thus a low-friction PTFE material, which allows various devices and instruments to slide therethrough and requires lower deployment forces when retracting the outer tube **14** during deployment of the implantable device **16**. The inner tube **12** is fixedly attached at its proximal end adjacent to the handle **30**. Thus, the proximal end of the inner tube **12** may be molded or otherwise attached to a portion of the handle **30**, such as with an adhesive.

The coil **24** extends from a proximal end of the each of the inner **12** and outer **14** tubes and within each of the inner and outer tubes proximate to a respective side opening **18**. In particular, each coil **24** is positioned proximal of a respective side opening **18**. The coils **24** maintain a desired flexibility for the inner **12** and outer **14** tubes, but also preventing kinking or buckling when manipulating the inner and outer tubes within the lumen.

The deployment mechanism **20** typically includes one or more actuators **22** attached to the outer tube **14**. Depending on the length of the implantable device **16**, there could be one actuator **22** for shorter implantable devices (e.g., 20-60mm), as depicted in FIGS. 7 and 8, and two or more actuators for longer implantable devices (e.g., 80mm), as shown in FIGS. 9 and 10. When utilizing two or more actuators **22**, the actuators may be operatively connected such that the actuators cooperate to deploy the implantable device **16**. For example, FIG. 9 illustrates that a pair of actuators **22** are connected to one another with a connector **34**, where one actuator deploys the implantable device **16** partially, while the second actuator deploys the implantable device the remaining distance. The connector **34** is configured such that moving the proximal actuator **22** proximally also causes the

distal actuator to move proximally. In addition, the distal actuator **22** may slide within the connector **34** proximally to completely deploy the implantable device **16**.

This arrangement of actuators **22** allows users of the delivery device **10** to deploy the implantable device **16** with one hand if desired. For example, with reference to FIGS. 1 and 2A-B, a user would place a palm of the hand on the handle **30** of the delivery device **10** and extend his or her fingers of the same hand to pull proximally on the actuators **22** in succession. The outer tube **14** is coupled to the actuators **22** such that movement of the actuators causes concurrent sliding of the inner tube **12** within the outer tube **16**. More specifically, the proximal end of the outer tube **14** is attached to an actuator **22** such that moving the actuator proximally causes the outer tube **14** to slide proximally over the inner tube **12**, while the inner tube remains stationary.

It is understood that the deployment mechanism **20** is not meant to be limiting, as any number of techniques could be employed to deploy the implantable device **16**. As such, the deployment mechanism **20** could be any device or actuator capable of deploying the implantable device **16** distally out of the outer tube **14**. For example, the actuators **22** could be configured to slide the inner tube **12** distally within the outer tube **14** such that the outer tube remains stationary. Moreover, the mechanism **20** could be any number of sizes and configurations. For instance, although the actuators **22** are T-shaped, the actuators could be configured as a trigger to grip the actuator.

A pusher **26** is attached to a distal end of the inner tube **12**. The pusher **26** is positioned at a proximal end of the implantable device **16** when deploying the implantable device. As shown in FIGS. 5 and 6, the inner tube **12** is connected to the pusher **26** with a coupling portion **28** extending from the pusher. The coupling portion **28** is slightly larger in diameter than both the inner tube **12** and the pusher **26**. A portion of the inner tube **12** mates within the coupling portion **28** such that the inner tube and pusher **26** are operatively connected. As shown in FIG. 3, when the side openings **18** of each of the inner **12** and outer **14** tubes are aligned, the pusher **26** is positioned distally of the side openings.

A proximal end of the implantable device **16** may extend partially over a portion of the pusher **26**. The proximal end of the implantable device **16** could be

positioned adjacent to the coupling portion **28**, and the coupling portion could be colored or include a marker for identifying the proximal end of the implantable device within the lumen. In addition, the pusher **26** may include anchors **32** that extend outwardly from the pusher at spaced intervals about the circumference of the pusher. The anchors **32** could be barbs, bumps, protuberances, or the like that prevent the implantable device **16** from compressing along its length during deployment of the device. Moreover, the anchors **32** could provide frictional engagement between the inner tube **12**, implantable device **16**, and outer tube **14**, or engage openings defined in the implantable device. The pusher **26** and anchors **32** are also capable of engaging the implantable device **16** to reposition the delivery device **10** or the implantable device when the implantable device is partially deployed. For example, after partially deploying the implantable device **16**, the delivery device **10** could be moved proximally to reposition the implantable device within the lumen.

It is understood that the pusher **26** shown and described above is not meant to be limiting, as the pusher may include any number of sizes and configurations in alternative embodiments of the present invention. For instance, the pusher **26** could be integrally formed with the inner tube **12** such that pusher is not a separate component of the inner tube. In addition, the coupling portion **28** could be a separate component than the pusher **26** such that the coupling connects the inner tube **12** and pusher. It is noted that although the term "pusher" is used herein, the pusher **26** does not typically push the implantable device **16**. In contrast, the inner tube **12** and pusher **26** remain stationary while the outer tube **14** is retracted. However, the pusher **26** may be configured to advance the implantable device **16** such that the inner tube **12** may be moved distally while the outer tube **14** remains stationary or is moved concurrently in a proximal direction.

With reference to FIG. 3, the side openings **18** of each of the inner **12** and outer **14** tubes are aligned with one another. A gap is provided between the distal end of the pusher **26** and the distal end of the outer tube **14** to accommodate the implantable device **16**. The gap allows an optical device **19** to directly view the implantable device **16** for defects or position prior to or during deployment. In addition, because the inner tube **12** stops short of the distal end of the outer tube

14, the optical device **19** is also capable of viewing the target area through the outer tube within the gap.

However, there could be instances where the distal ends of the inner **12** and outer **14** tubes align, such as when a surgical procedure is performed and an implantable device **16** is not required. As such, an optical, surgical, or other instrument is capable of accessing the side openings **18** when aligned with one another. For instance, as shown in FIG. 3, an optical instrument may be positioned within the inner tube **18** and proximate to the opening to view the proximal end of the target area prior to deploying the implantable device **16**. Moreover, the optical instrument could be sized and configured to fit through the side openings **18** and view various portions of the target area or the entire target area. The optical, surgical, or other instrument may be any instrument known to those skilled in the art that is capable of accessing the side openings **18** when the side openings are aligned with one another. Thus, the instrument could extend through the distal ends of the inner **12** and outer **14** tubes and/or through the side openings **18**. Furthermore, it is understood that although the instrument is typically placed within the lumen of the inner tube **12**, the inner tube could include one or more utility channels positioned therein for accommodating various instruments.

FIGS. 5 and 6 provide further detail regarding the side opening **18** in the inner tube **12**, while FIGS. 11 and 12 provide additional details regarding the side opening in the outer tube **14**. As shown, the side openings **18** are generally oval in shape and extend less than midway about the circumference of a respective tube. The major axis of the oval side openings **18** extends approximately parallel to the longitudinal axis of the inner **12** and outer **14** tubes, while the minor axis of the side openings extends approximately perpendicular to the longitudinal axis of the inner and outer tubes. The side opening **18** of the inner tube **12** is typically slightly smaller than the outer tube **14**. For example, in one aspect of the present invention where the inner tube **12** has a diameter of about 7.5mm, and the outer tube **14** has a diameter of 8.5mm, the side openings **18** of each of the inner **12** and outer **14** tubes have about a 5mm radius (i.e., radius perpendicular to the longitudinal axis of the inner and outer tubes), while the opening of the inner tube is about 7.5mm in length, and the opening of the outer tube is about 8mm in length (i.e., length parallel to the longitudinal axis of the inner and outer tubes).

It is understood that the side openings **18** described above should not be limited to any particular size or configuration. For instance, although the side openings **18** are described as being oval, the side openings could be any shape, such as a sphere or polygon. In addition, the side openings **18** could be the same size, or the side opening of the inner tube **12** could be larger than the side opening of the outer tube **14**. Moreover, although only a single side opening **18** is shown defined in a respective tube, it is understood that there could be one or more side openings defined in each of the inner **12** and outer **14** tubes and capable of aligning with one another proximate to the target area.

The side openings **18** are typically formed in each of the inner **12** and outer **14** tubes with a punching or similar cutting tool. Because the coil **24** is positioned proximally of the side openings **18**, the tool is only required to penetrate the polymeric tubing of the inner **12** and outer **14** tubes. Each side opening **18** would generally be punched separately, although there may be instances where the side openings of both the inner **12** and outer **14** tubes are formed concurrently, such as when the same size of side opening is desired.

The implantable device **16** is deployed within a lumen and proximate to a target area using techniques known to those skilled in the art. For instance, the implantable device may be introduced orally with the delivery device **10**, through the lumen, and proximate to a target area. The implantable device **16** is typically contracted to a smaller first diameter from a relaxed position. Once contracted, the implantable device **16** is positioned within the outer tube **14** of the delivery device proximate to the distal end of the outer tube. The inner tube **12** is positioned within the outer tube **14** such that the distal end of the inner tube is positioned proximate to the proximal end of the implantable device **16**. A portion of the implantable device **16** may be positioned on the distal end of the inner tube **12** to engage the anchors **32** of the pusher **26**. Prior to deployment, the side openings **18** of each of the inner **12** and outer **14** tubes substantially align with one another.

An optical device **19** is positioned within the inner tube **12** and proximate to a proximal end of the target area and/or implantable device such that the optical device is capable of viewing at least a portion of the target area through the aligned side openings **18**. The implantable device **16** is positioned proximate to the target area such that when the implantable device is deployed from the outer tube **14**, the

implantable device, if formed from an expansible material, can expand to receive the target area and even expand the diameter of the target area. In particular, the distal end of the outer tube **14** is positioned proximate to a distal end of the target area. The outer tube **14** is then retracted over the inner tube **12** using one or more actuators **22**, while the pusher **26** supports the proximal end of the implantable device **16**. The implantable device **16** is typically deployed incrementally along its length so that a more controlled deployment and accurate position is achieved. FIG. 4 shows the implantable device **16** in a deployed and expanded state, where the pusher **26** is positioned proximate to a distal end of the outer tube **14**.

The present invention includes several advantages. For instance, the side openings **18** of the delivery device **10** facilitate increased visibility proximate to the target area. In particular, the optical device **19** is able to view the proximal end of the lesion and/or implantable device to ensure that the implantable device will be deployed to cover the entire target area. Because the implantable device is more accurately positioned within the lumen, the probability of misalignment and subsequent procedures to correct the alignment is reduced. Moreover, the delivery device **10**, including the side openings **18**, is applicable to a wide range of applications, such as deploying implantable devices and surgical procedures.

Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

THAT WHICH IS CLAIMED:

1. A delivery device for positioning and deploying an implantable device within a lumen comprising:

a longitudinal outer tube having proximal and distal ends, wherein the implantable device is positioned proximate to the distal end of the outer tube;

a longitudinal inner tube positioned within the outer tube and having proximal and distal ends, wherein the outer tube is capable of sliding over the inner tube;

a side opening defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening;

an optical device positioned within the inner tube and proximate to each side opening such that the optical device is capable of viewing at least a portion of the lumen prior to deploying the implantable device when the side openings are aligned with each other; and

a mechanism coupled to at least one of the inner and outer tubes and operable to deploy the implantable device within the lumen.

2. The delivery device according to Claim 1, further comprising a coil positioned within the inner tube, wherein the side opening of the inner tube is defined distally of the coil.

3. The delivery device according to Claim 2, wherein the side opening of the inner tube is defined longitudinally between the coil and the implantable device.

4. The delivery device according to Claim 1, further comprising a coil positioned within the outer tube, wherein the side opening of the outer tube is defined distally of the coil.

5. The delivery device according to Claim 1, wherein each of the inner and outer tubes comprises a semi-transparent polymeric material.

6. The delivery device according to Claim 5, wherein the polymeric material comprises at least one of a polytetrafluoroethylene and a polyether block amide.

7. The delivery device according to Claim 1, wherein each of the side openings comprises an oval having a major and a minor axis.

8. The delivery device according to Claim 7, wherein the major axis of each of the side openings extends substantially parallel to a longitudinal axis of the respective inner and outer tubes.

9. The delivery device according to Claim 1, wherein each of the side openings extends less than midway about a circumference of each of the inner and outer tubes.

10. The delivery device according to Claim 1, wherein each of the side openings aligns with each other proximate to the proximal end of the implantable device.

11. The delivery device according to Claim 1, wherein the optical device is capable of viewing, through the side openings, at least a proximal end of a target area within the lumen.

12. The delivery device according to Claim 1, wherein the optical device is capable of extending through each of the side openings to view a target area within the lumen.

13. The delivery device according to Claim 1, further comprising a pusher at the distal end of the inner tube and positioned adjacent to a proximal end of the implantable device.

14. The delivery device according to Claim 13, wherein each of the side openings align with each other proximally of the pusher.

15. The delivery device according to Claim 13, wherein the side opening of the inner tubular member is defined proximally of the pusher.

16. The delivery device according to Claim 1, wherein the mechanism comprises at least one actuator coupled to the outer tube.

17. A device for viewing a target area within a lumen comprising:

a longitudinal inner tube positioned within a longitudinal outer tube, each of the inner and outer tubes having proximal and distal ends;

a side opening defined in each of the inner and outer tubes, wherein the outer tube is capable of sliding over the inner tube to substantially align each of the side openings with each other;

an optical device positioned within the inner tube and proximate to each side opening such that the optical device is capable of viewing at least a portion of the target area when the side openings are aligned with each other; and

an instrument positioned within the inner tube and capable of performing a procedure when the side openings are aligned.

18. The device according to Claim 17, wherein the instrument is capable of performing the procedure through a distal opening defined in each of the inner and outer tubes.

19. The device according to Claim 17, wherein the instrument is capable of performing the procedure through the side openings when the side openings are aligned.

20. A method for deploying an implantable device within a lumen proximate to a target area comprising:

positioning the implantable device within an outer tube;

sliding the outer tube over an inner tube to substantially align a pair of side openings defined in each of the inner and outer tubes;

positioning the inner and outer tubes within the lumen;

positioning an optical device within the inner tube and proximate to each of the side openings to view at least a portion of the target area; and

deploying the implantable device with a mechanism proximate to the target area.

21. The method according to Claim 20, wherein positioning the optical device comprises positioning the optical device proximate to a proximal end of the target area.

22. The method according to Claim 20, wherein sliding comprises sliding the outer tube such that the side opening of the outer tube aligns with the side opening of the inner tube proximally of a pusher positioned on a distal end of the inner tube.

23. The method according to Claim 20, wherein deploying comprises sliding the outer tube proximally over the inner tube with the mechanism.

24. A method for manufacturing a delivery device comprising:

punching a side opening through a wall in each of an inner tube and an outer tube; and

positioning the inner tube within the outer tube such that each of the side openings is capable of aligning with one another.

25. The method according to Claim 24, further comprising attaching a coil circumferentially and longitudinally within each of the inner and outer tubes.

26. The method according to Claim 25, wherein attaching comprises etching a surface of each of the inner and outer tubes such that the coil attaches to a respective inner and outer tube.

27. The method according to Claim 24, further comprising attaching a pusher to a distal end of the inner tube such that the side opening of the inner tube is positioned proximally of the pusher.

28. A delivery device for positioning and deploying an implantable device within a lumen comprising:

a longitudinal outer tube having proximal and distal ends, wherein the implantable device is positioned proximate to the distal end of the outer tube;

a longitudinal inner tube positioned within the outer tube and having proximal and distal ends, wherein the outer tube is capable of sliding over the inner tube;

a side opening defined in each of the inner and outer tubes, wherein each side opening is defined proximate to the implantable device and is capable of substantially aligning with the other side opening prior to deploying the implantable device; and

a mechanism coupled to at least one of the inner and outer tubes and operable to deploy the implantable device within the lumen.

29. The device according to Claim 28, further comprising an optical device positioned within the inner tube and proximate to each side opening such

that the optical device is capable of viewing at least a portion of the lumen when the side openings are aligned with each other.

30. The device according to Claim 28, further comprising a pusher at the distal end of the inner tube and positioned adjacent to a proximal end of the implantable device.

31. The delivery device according to Claim 30, wherein each of the side openings align with each other proximally of the pusher.

32. The delivery device according to Claim 30, wherein the side opening of the inner tubular member is defined proximally of the pusher.

33. The delivery device according to Claim 28, further comprising a coil positioned within each of the inner and outer tubes, wherein a respective side opening of the inner and outer tubes is defined distally of the coil.

34. The delivery device according to Claim 28, wherein the side opening of the inner tube is defined longitudinally between the coil and the implantable device.

35. The delivery device according to Claim 28, wherein each of the side openings aligns with each other proximate to the proximal end of the implantable device.

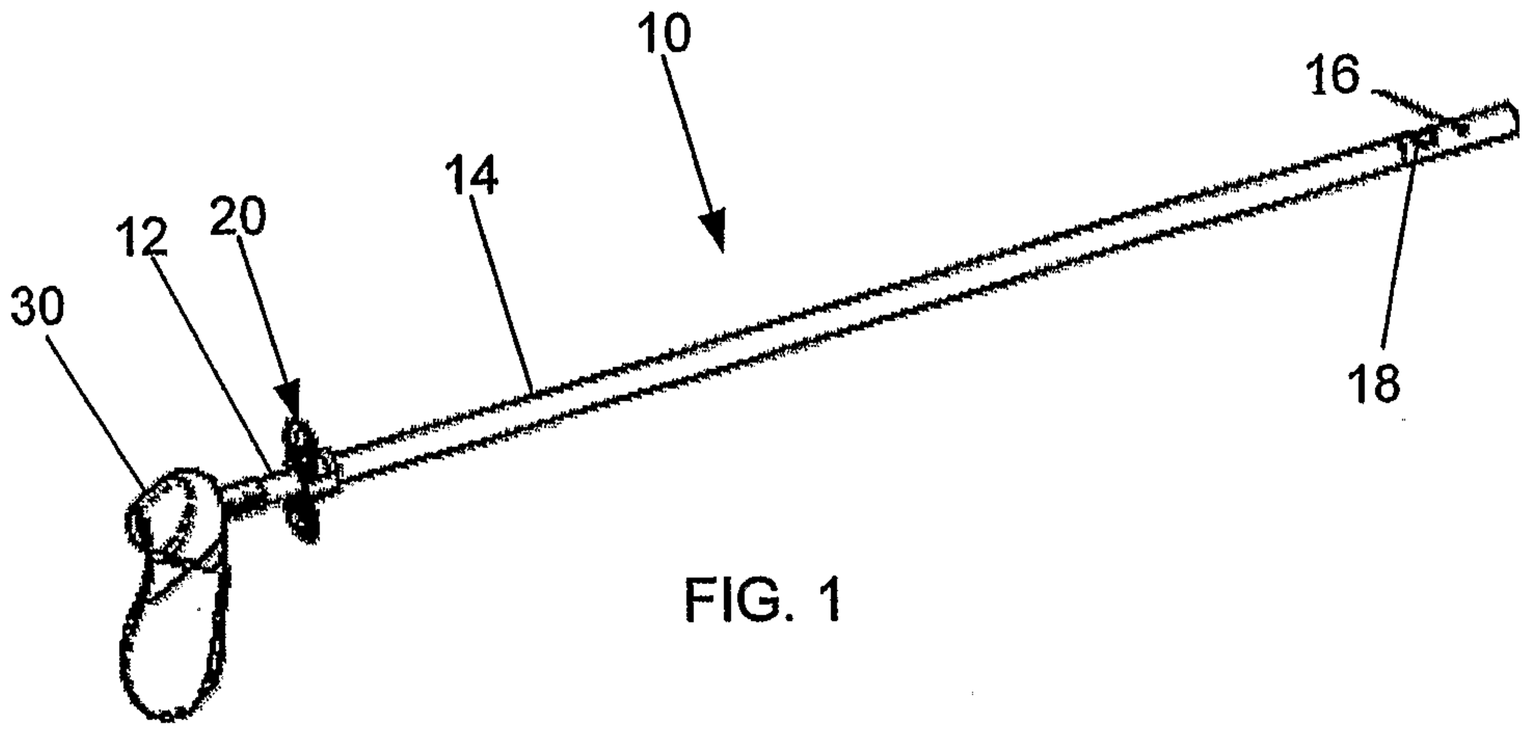


FIG. 1

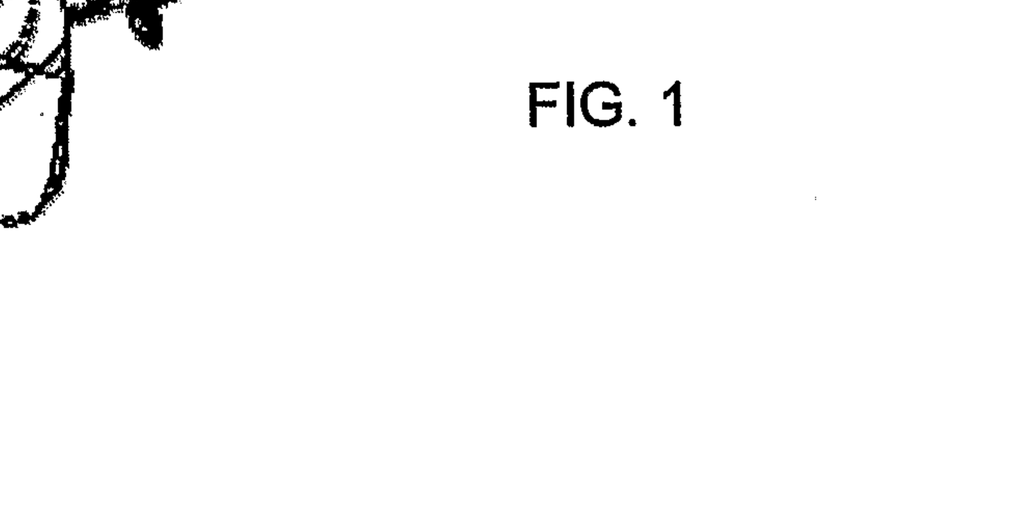


FIG. 2A

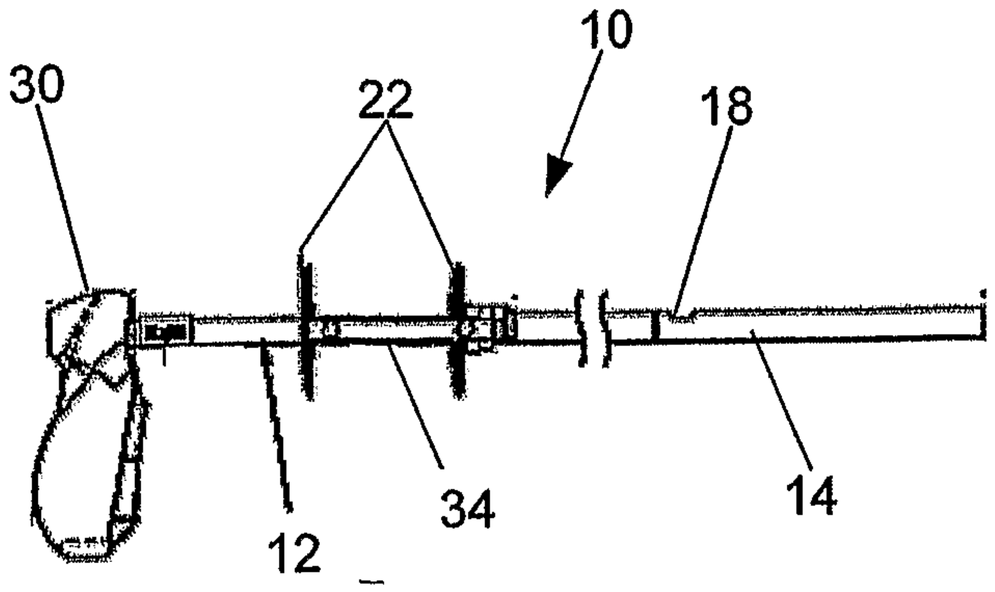


FIG. 2B

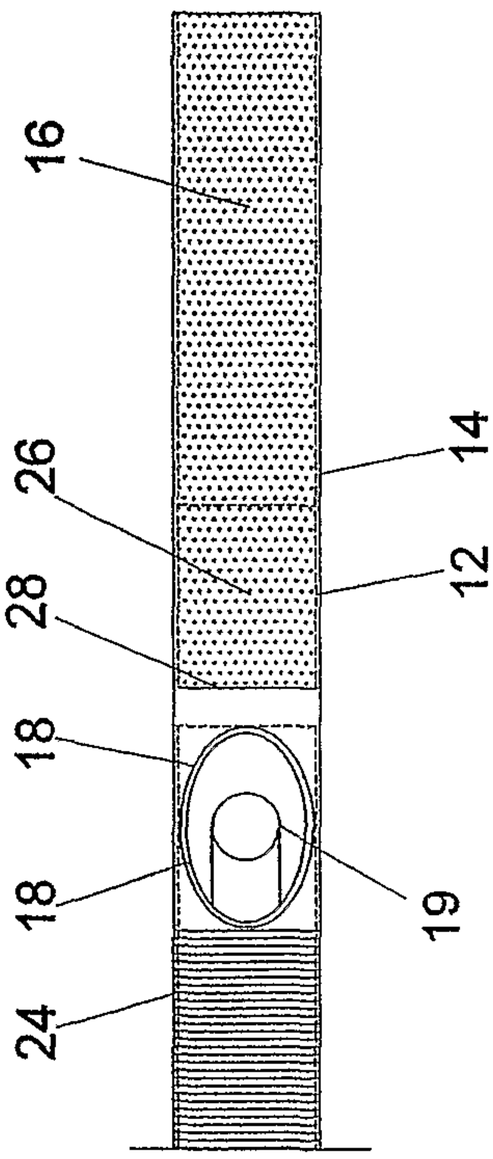


FIG. 3

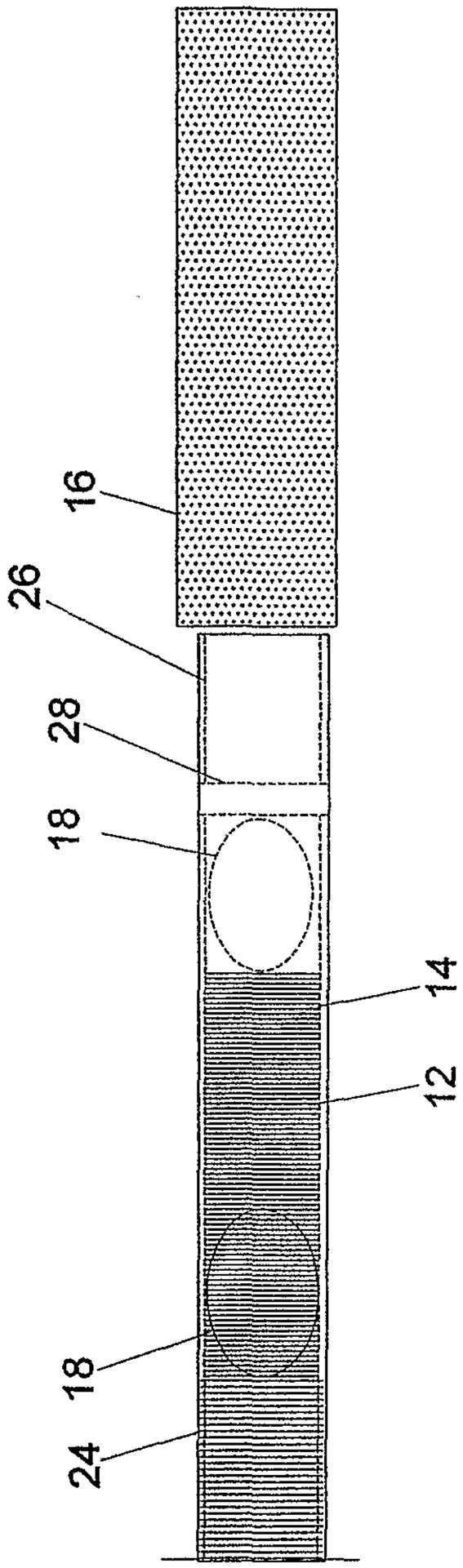


FIG. 4

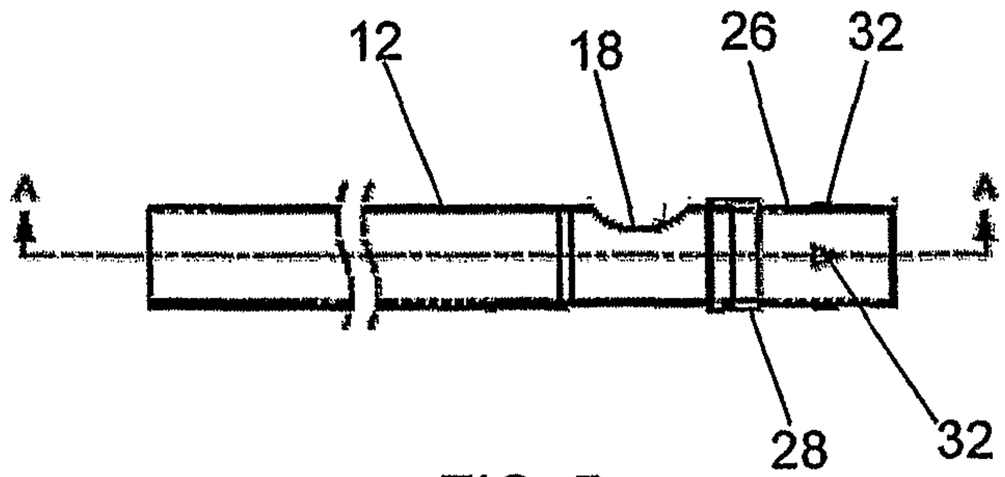


FIG. 5

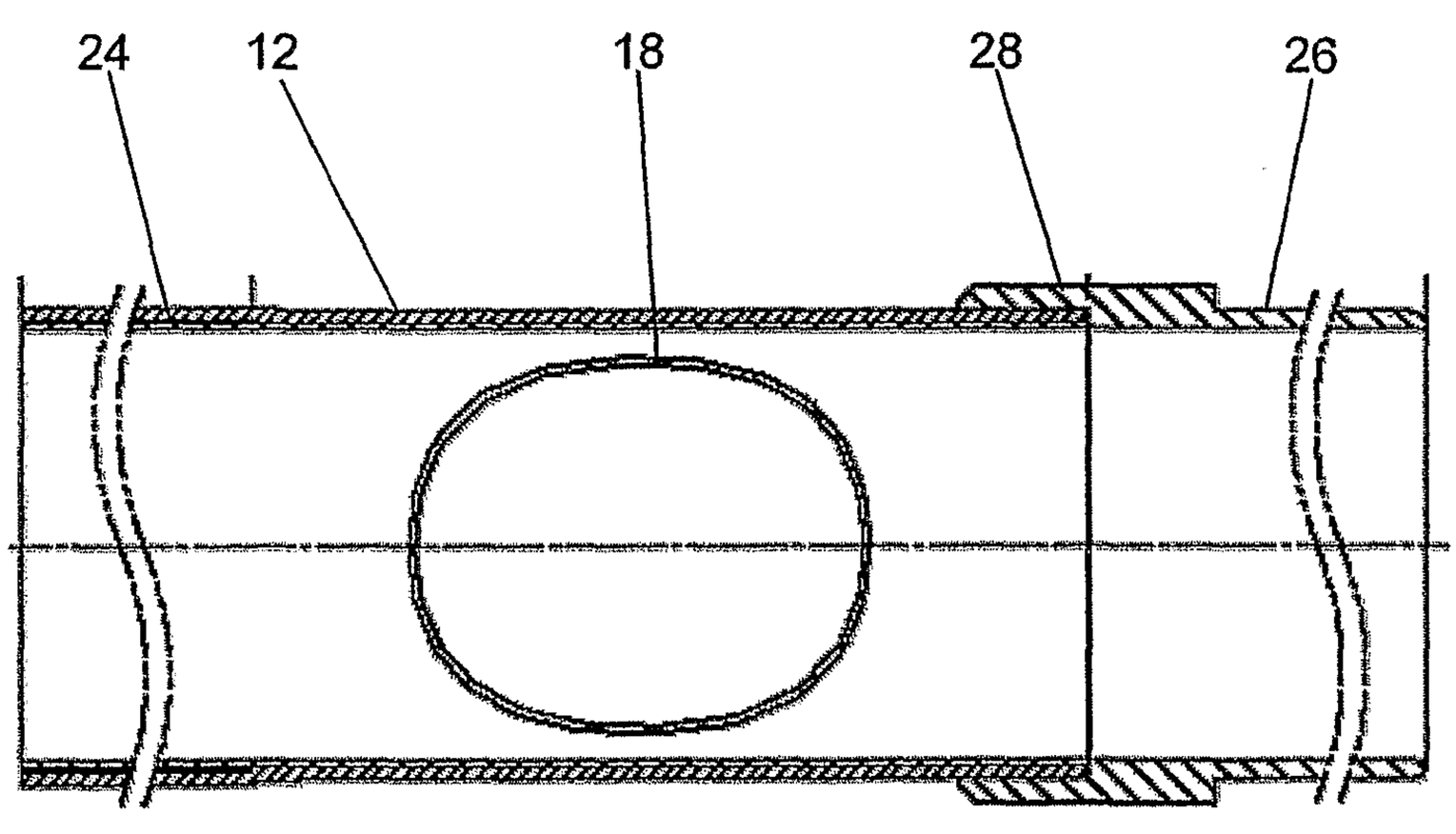


FIG. 6

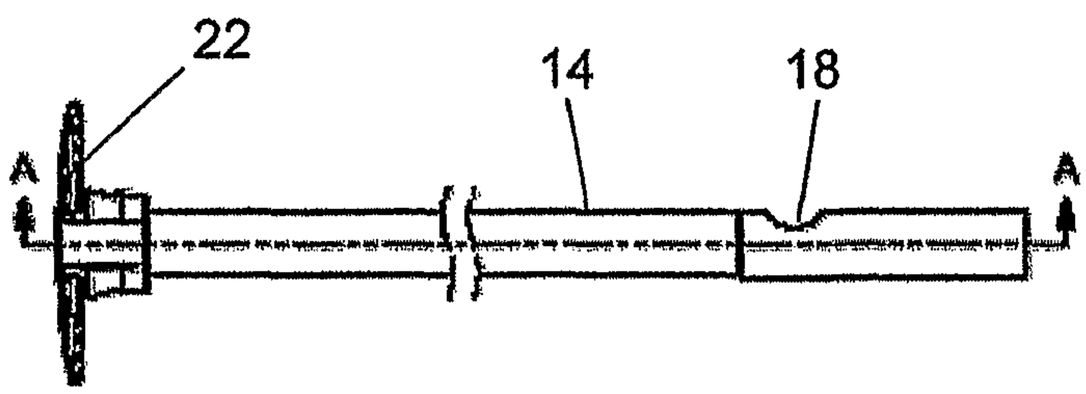


FIG. 7

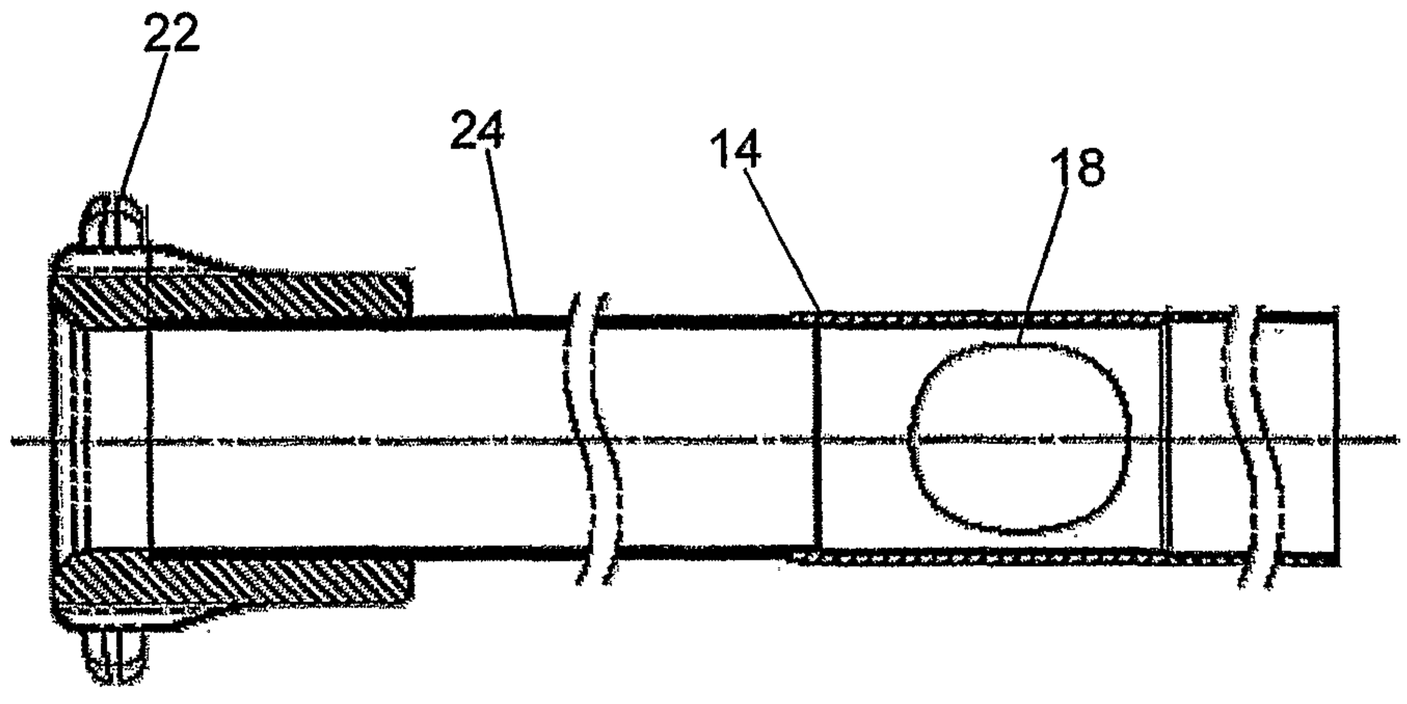


FIG. 8

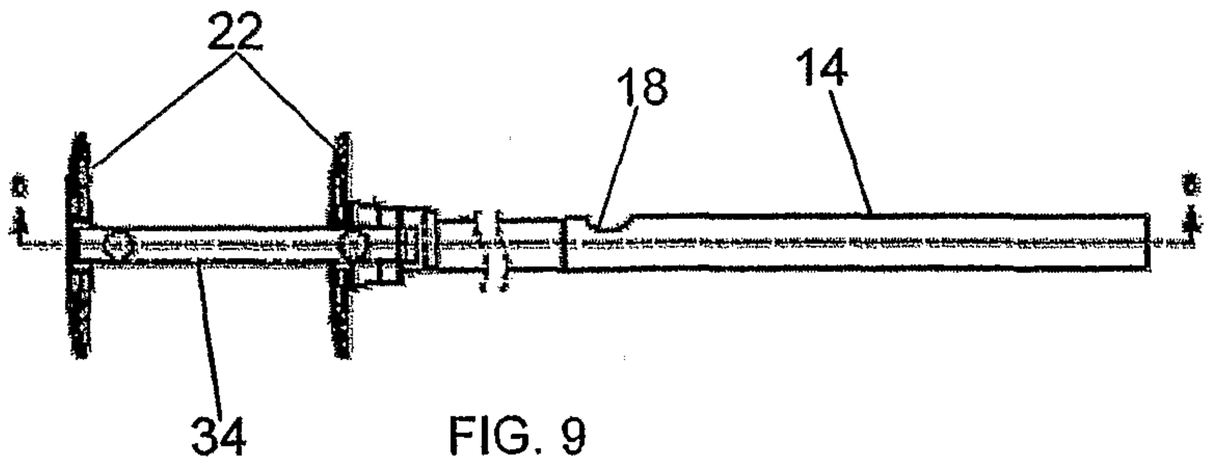


FIG. 9

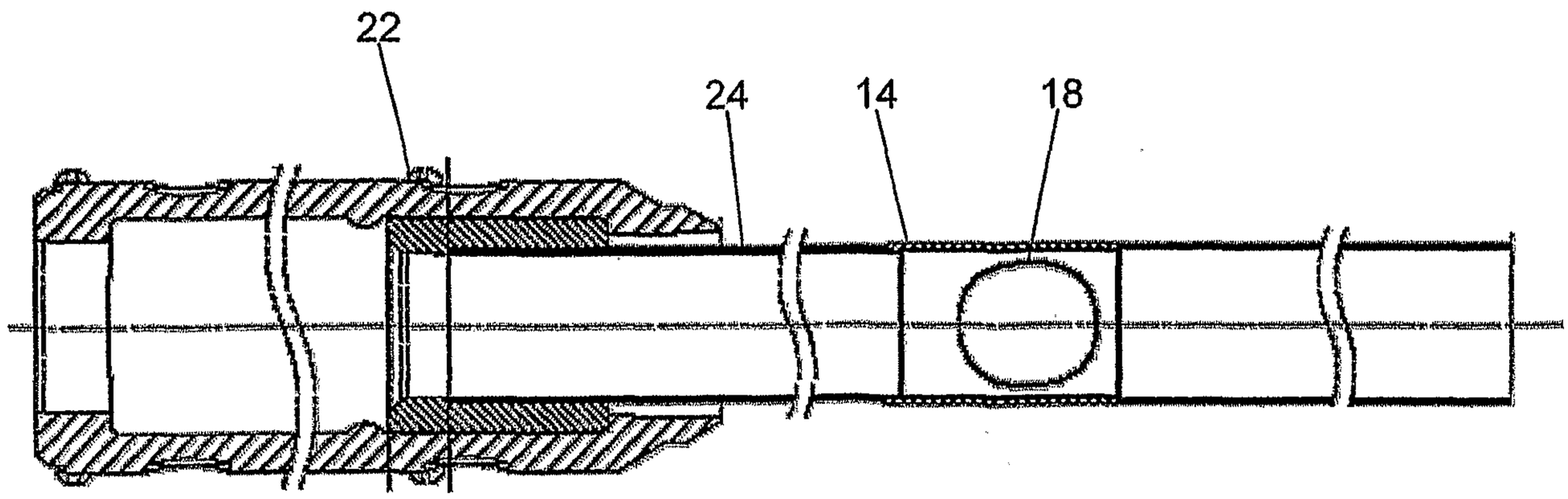


FIG. 10

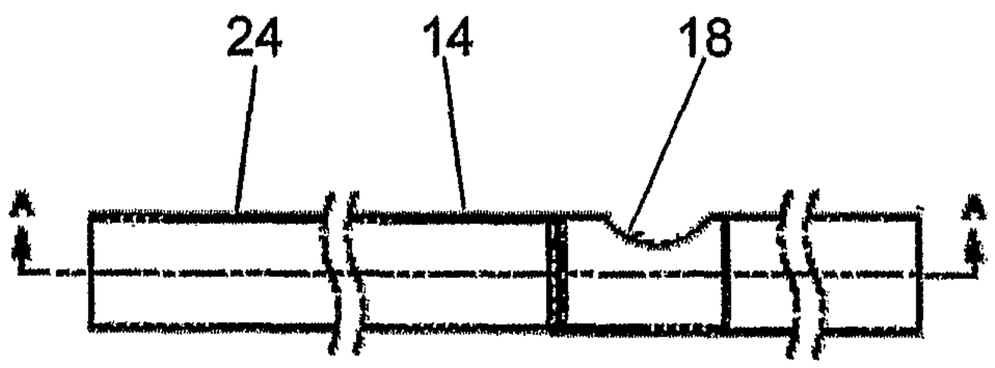


FIG. 11

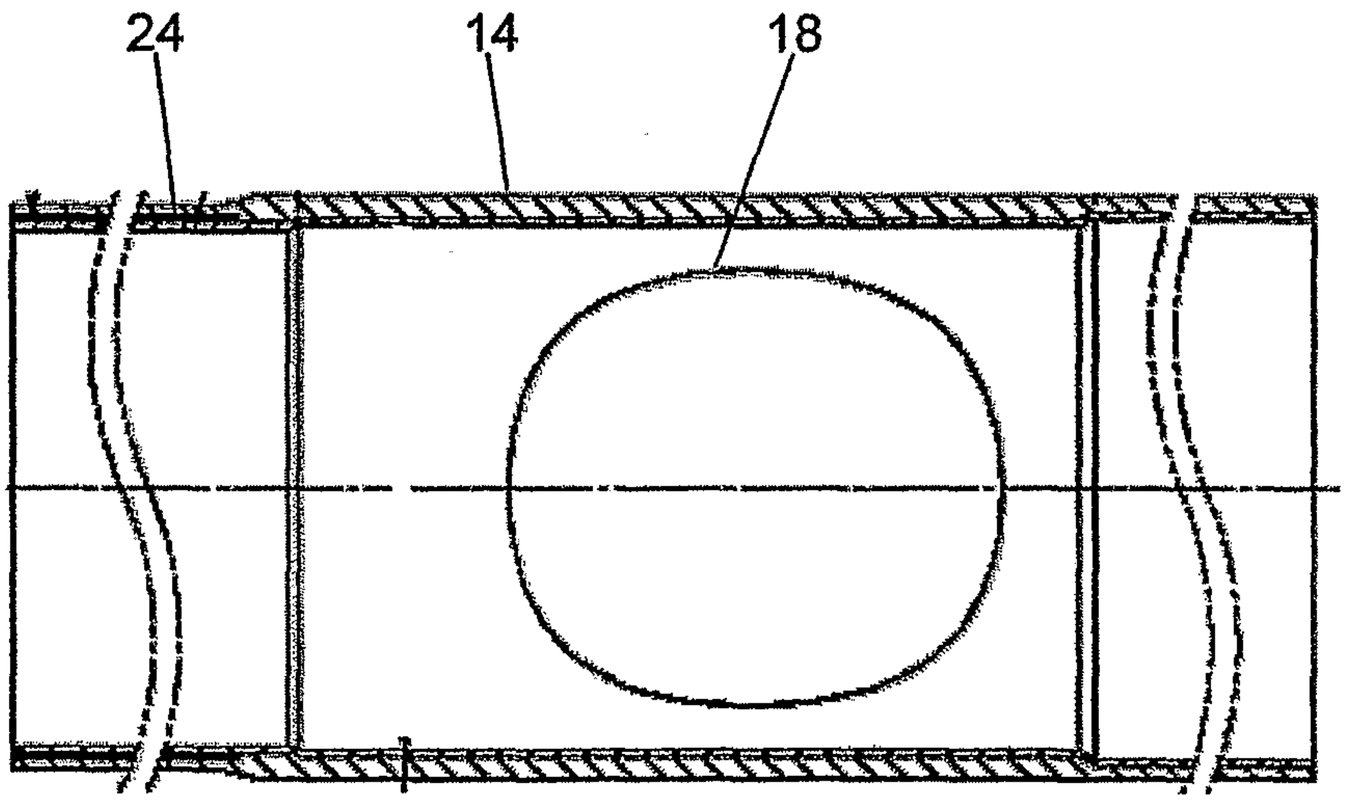
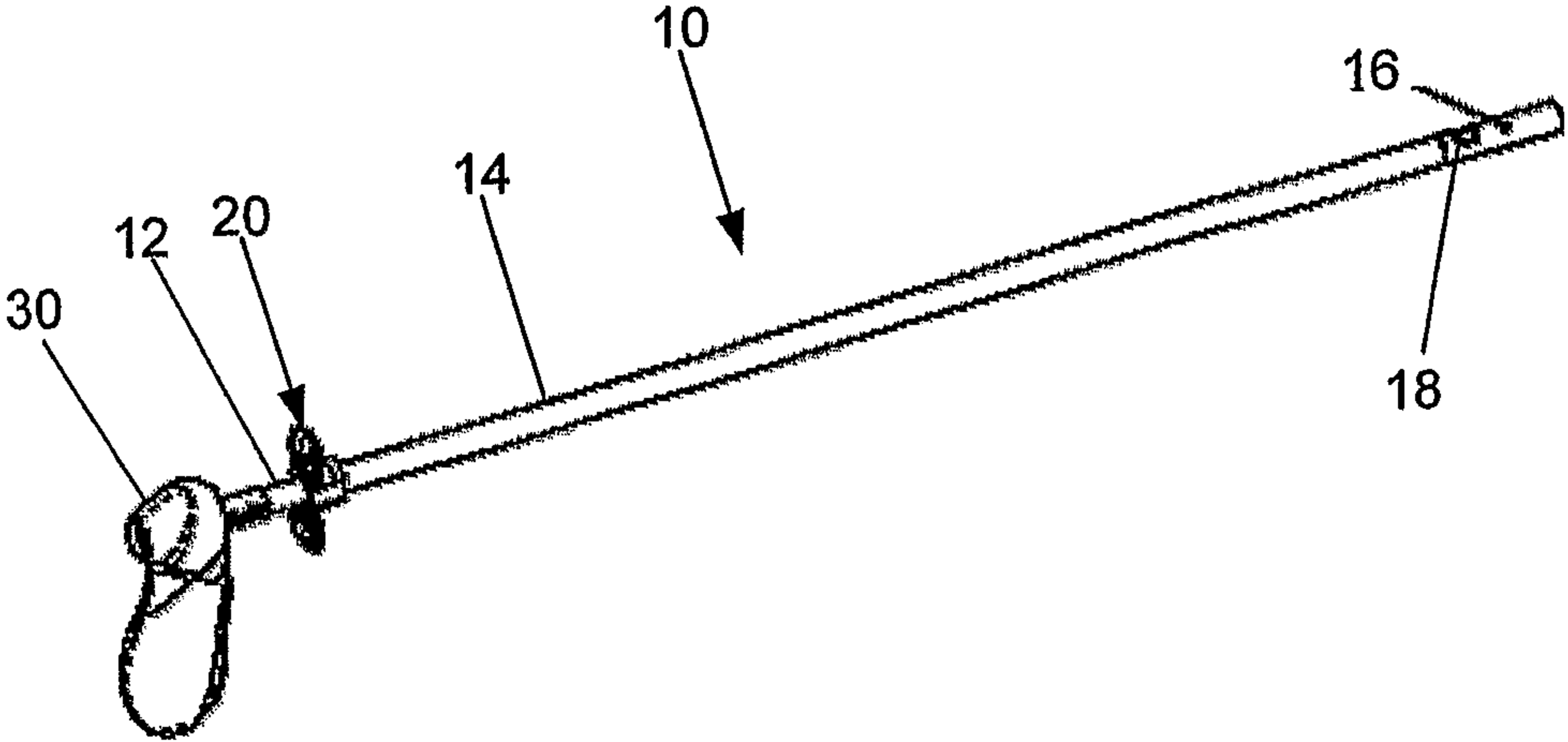


FIG. 12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