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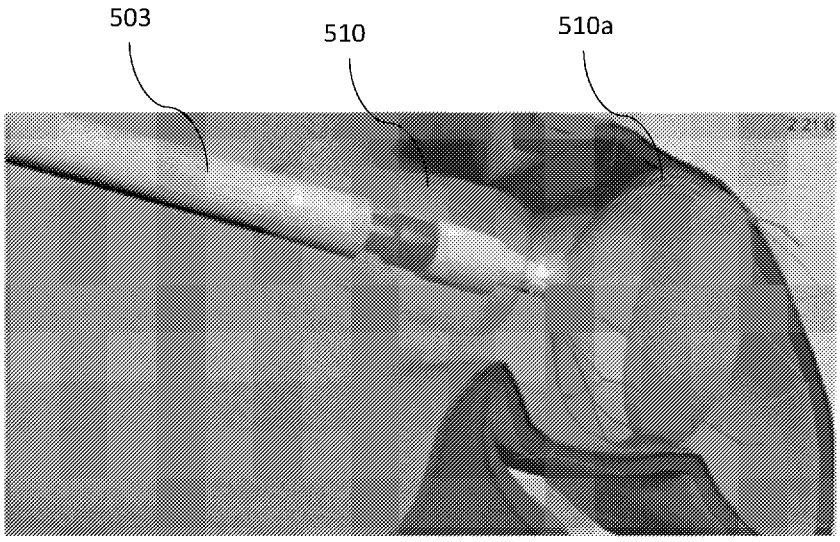

FIG. 26

(57) Abstract: The disclosed invention provides a transseptal insertion device which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial septum. The transseptal insertion device includes a sheath that defines at least one lumen therein, one or more positioning balloons that are connected to a distal end of the sheath, a puncture member movably positioned within the at least one lumen, and a puncture member balloon located on the puncture member. The positioning balloons are inflated and deflated through hypotubes, and the puncture member balloon is inflated and deflated through an additional tube. The transseptal insertion device includes a wire member movably positioned in a center lumen formed in the puncture member. The wire member may be Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter that delivers fluid or pharmaceuticals in the left atrial appendage, or a transseptal wire.

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DIRECTIONAL BALLOON TRANSSEPTAL INSERTION DEVICE FOR MEDICAL PROCEDURES WITH IMPROVED TRANSSEPTAL PUNCTURE SYSTEM WITH PUNCTURE MEMBER BALLOON SEAL

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. Provisional Application Serial No. 62/903,261, filed on September 20, 2019, which is hereby incorporated herein by reference in its entirety.

FIELD

The present invention relates generally to cardiac catheters, and more particularly, to a transseptal insertion device which is suitable for facilitating quick and safe transseptal puncture and insertion of a catheter through a cardiac septum to provide access to the left atrium in implementation of a left atrial intervention.

BACKGROUND

Cardiac catheterization is a medical procedure in which a long thin tube or catheter is inserted through an artery or vein into specific areas of the heart for diagnostic or therapeutic purposes. More specifically, cardiac chambers, vessels and valves may be catheterized.

Cardiac catheterization may be used in procedures such as coronary angiography and left ventricular angiography. Coronary angiography facilitates visualization of the coronary vessels and finding of potential blockages by taking X-ray images of a patient who has received a dye (contrast material) injection into a catheter previously injected in an artery. Left ventricular angiography enables examination of the left-sided heart chambers and the function of the left sided valves of the heart, and may be combined with coronary angiography. Cardiac catheterization can also be used to measure pressures throughout the four chambers of the heart and evaluate pressure differences across the major heart valves. In further applications, cardiac catheterization can be used to estimate the cardiac output, or volume of blood pumped by the heart per minute.

Some medical procedures may require catheterization into the left atrium of the heart. For this purpose, to avoid having to place a catheter in the aorta, access to the left atrium is generally achieved by accessing the right atrium, puncturing the interatrial septum between the left and right atria of the heart, and threading the catheter through the septum and into the left atrium. Transseptal puncture must be carried out with extreme precision, as accidental puncturing of surrounding tissue

may cause very serious damage to the heart. In addition, transseptal puncture may require complicated instruments which are not helpful in guaranteeing the precision of the puncture.

The use of devices available today present many challenges for doctors attempting to puncture the interatrial septum and perform cardiac catheterization. Locating the interatrial septum, properly placing the distal end of the puncturing device at the desired location of the septum, safely puncturing the interatrial septum, avoiding accidental punctures, and tracking and maneuvering the catheter post-puncture, are among the many challenges facing those performing cardiac catheterization today.

SUMMARY

Accordingly, there is an established need for a device that is suitable for facilitating quick and safe transseptal puncturing to provide access to the left atrium in implementation of a left atrial intervention.

These advantages and others are achieved, for example, by a transseptal insertion device which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial septum. The transseptal insertion device includes a sheath that defines at least one lumen therein, one or more positioning balloons that are connected to the distal end of the sheath, a puncture member movably positioned within the at least one lumen, and a puncture member balloon located on the distal end of the puncture member. The sheath has a distal end that is positioned toward the cardiac interatrial septum of a patient when the transseptal insertion device is in use and a proximal end that is external to the patient. The one or more positioning balloons, when inflated and the transseptal insertion device is in use, overhang and extend past the distal end of the sheath. The sheath includes one or more hypotubes respectively connected to the one or more positioning balloons to inflate and deflate the one or more positioning balloons. The puncture member has a distal end that is positioned toward the cardiac interatrial septum of the patient. The puncture member has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum. The puncture member includes at least one puncture member tube connected to the puncture member balloon to inflate and deflate the puncture member balloon.

The one or more positioning balloons may be inflated by gas or fluid supplied through the one or more hypotubes, and the one or more positioning balloons and the puncture member balloon may be inflated and deflated independently of each other. The one or more hypotubes may include one or more inflation hypotubes to inflate the one or more positioning balloons, and one or more

deflation hypotubes to deflate the one or more positioning balloons. The one or more positioning balloons, when inflated, may deliver energy in the form of heat or is used for cryoablation with fluid that is circulated through the one or more positioning balloons. The puncture member balloon, when inflated, may be positioned at a predetermined distance from a tip of the distal end of the puncture member to prevent the puncture member from being pushed beyond the predetermined distance while the puncture member is tenting the cardiac interatrial septum and the puncture member balloon is pressing against the cardiac interatrial septum.

The transseptal insertion device may further include a wire member movably positioned in a center lumen formed in the puncture member. The wire member advances beyond a tip of the distal end of the puncture member when in use. The wire member may be a Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter that delivers fluid or pharmaceuticals in the left atrial appendage, or a transseptal wire designed to and is capable of precisely puncturing the cardiac interatrial septum. The sheath may include a side port proximal to the positioning balloons. An additional catheter or wire advances into the cardiac interatrial septum through the side port and the additional catheter or wire is capable of capturing the wire member.

These advantages and others are also achieved, for example, by a method for suitably facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal insertion device. The method includes steps of inflating one or more positioning balloons connected to a distal end of a sheath of the transseptal insertion device, advancing a puncture member while the positioning balloons are inflated, positioning the puncture member against the cardiac interatrial septum, deflating the one or more positioning balloons, further advancing the puncture member to puncture the cardiac interatrial septum, and advancing the transseptal insertion device crossing the cardiac interatrial septum. The one or more positioning balloons, when inflated and the transseptal insertion device is in use, overhang and extend past the distal end of the sheath. The sheath includes one or more hypotubes respectively connected to the one or more positioning balloons to inflate and deflate the one or more positioning balloons. The puncture member is movably positioned within at least one lumen of the sheath. A puncture member balloon is located on a distal end of the puncture member and the puncture member includes at least one puncture member tube connected to the puncture member balloon to inflate and deflate the puncture member balloon.

The method may further include steps of inflating the puncture member balloon once the puncture member advances beyond the distal end of the sheath and is tenting the cardiac interatrial septum, and deflating the puncture member balloon before said further advancing the puncture member to puncture the cardiac interatrial septum. The puncture member balloon may be pressing against the cardiac interatrial septum while the puncture member is tenting the cardiac interatrial septum. The method may further include one or more of steps of re-inflating the one or more positioning balloons to navigate in an atraumatic fashion to different parts of the left atrium after the distal end of the transseptal insertion device crosses the cardiac interatrial septum, re-inflating the puncture member balloon to anchor the transseptal insertion device against the cardiac interatrial septum after the distal end of the transseptal insertion device crosses the cardiac interatrial septum, delivering, via the one or more positioning balloons, energy in the form of heat or using the one or more positioning balloons for cryoablation with fluid that is circulated through the one or more positioning balloons, advancing a wire member beyond a tip of the distal end of the puncture member after the distal end of the transseptal insertion device crosses the cardiac interatrial septum where the wire member movably positioned in a center lumen formed in the puncture member, advancing an additional catheter or wire into the cardiac interatrial septum where the sheath includes a side port proximal to the positioning balloons, and the additional catheter or wire advances through the side port, and capturing the wire member with the additional catheter or wire forming a loop with the captured wire member.

BRIEF DESCRIPTION OF THE DRAWINGS

The preferred embodiments described herein and illustrated by the drawings hereinafter be to illustrate and not to limit the invention, where like designations denote like elements.

FIG. 1A is a side perspective, cross-sectional view of an embodiment of a transseptal insertion device.

FIG. 1B is a side perspective, cross-sectional view of an embodiment of a transseptal insertion device showing a dilator extending partially through and extending out from device.

FIG. 1C is a side perspective, cross-sectional view of an embodiment of a transseptal insertion device showing a dilator extending partially through the device.

FIG. 2A is a is a perspective view of an embodiment of a transseptal insertion device with hypotube connected to one or more balloons.

FIG. 2B is a is a front view of an embodiment of a transseptal insertion device with hypotube connected to one or more balloons.

FIGS. 2C-2D are side views of embodiments of transseptal insertion device with ultrasound imaging or visualizing capability.

FIG. 3A is a is a perspective view of an embodiment of a transseptal insertion device with multiple balloons and hypotubes connected to the multiple balloons.

FIG. 3B is a is a front view of an embodiment of a transseptal insertion device with multiple balloons and hypotubes connected to the multiple balloons.

FIG. 4 is a perspective, cross-sectional view of an embodiment of a transseptal insertion device with radiofrequency energy capability.

FIG. 5 is a is a perspective view of an embodiment of a transseptal insertion device with a drive assembly coupled to dilator, and knob coupled to the drive assembly.

FIG. 6 is a perspective, cross-sectional view of an embodiment of a transseptal insertion device showing inflated overhanging balloon and dilator positioned within device and subplanar to overhanging balloon.

FIG. 7 is a cross-sectional, end view of an embodiment of a transseptal insertion device and dilator shown prior to puncturing an interatrial cardiac septum with inflated overhanging balloon.

FIG. 8 is a perspective, cross-sectional view of an embodiment of a transseptal insertion device with dilator advanced forward in order to tent an interatrial septum.

FIG. 9 is a perspective, cross-sectional view of an embodiment of a transseptal insertion device with a transseptal wire advanced post-puncture through interatrial septum.

FIGS. 10A-10C are perspective, cross-sectional views of an embodiment of a flexible transseptal insertion device with different angulations.

FIG. 11 is a side view of an embodiment of transseptal insertion device with an overhanging balloon with marking.

FIG. 12 is a side view of an embodiment of transseptal insertion device with an overhanging balloon with a marker band.

FIG. 13 is a cross-sectional side view of an embodiment of a transseptal insertion device that includes a dilator with an electrode tip.

FIG. 14 is a side view of an embodiment of a transseptal insertion device with mechanical deflection capability.

FIG. 15 is side views of embodiments of curved dilators that may be used in embodiments of a transseptal insertion device.

FIG. 16 is a perspective side view of a proximal end of an embodiment of a transseptal insertion device showing a handle and a stabilizer.

FIGS. 17A-17B are side views of an embodiment of a transseptal insertion device with balloons capable of differential inflation.

FIG. 18 is a side view of a malleable or flexible transseptal needle that may be used in embodiments of a flexible transseptal insertion device with multiple angulations.

FIGS. 19A-19C are a side view, a close side view, and a cross-sectional end view of a puncture tip of an embodiment of an improved transseptal puncture system with puncture member balloon seal with a deflated puncture member balloon.

FIGS. 20A-20C are a side view, a close side view, and a cross-sectional end view of a puncture tip of an embodiment of an improved transseptal puncture system with puncture member balloon seal with an inflated puncture member balloon.

FIGS. 21A-21B are cross-sectional side view and a close, cross-sectional side view of a puncture tip of an embodiment of an improved transseptal puncture system with puncture member balloon seal with an inflated positioning balloon.

FIGS. 22A-22B are cross-sectional side view and a close, cross-sectional side view of a puncture tip of an embodiment of an improved transseptal puncture system with puncture member balloon seal with a deflated positioning balloon.

FIGS. 23A-23C show an embodiment of an improved transseptal puncture member balloon that is inflated through the inflation port once the puncture member is outside the shaft and is tenting the septum, guidewire that is advanced into the left atrium, and the puncture member balloon that is deflated.

FIGS. 24A-24B show an embodiment of an improved positioning balloon on the shaft that has a separate hypotube for inflation and deflation.

FIGS. 25A-25C show side views of the distal end portion of the puncture member multi-lumen extension, and a cross-sectional view of the distal end portion of the puncture member multi-lumen extension of the transseptal puncture system.

FIG. 26 illustrates an embodiment of a method of using the improved transseptal puncture system.

FIG. 27 shows an embodiment of a method of using the improved transseptal puncture system for left atrial appendage thrombectomy.

FIG. 28 shows an embodiment of a method of using the improved transseptal puncture system for MitraClip or other mitral repair prosthesis device removal.

FIG. 29 shows an embodiment of a method of using the improved transseptal puncture system for laceration of a bioprosthetic valve leaflet.

FIG. 30 shows an embodiment of a method of using the improved transseptal puncture system wherein the system anchors in the pulmonary veins, performs pulmonary venous angioplasty, and deliver either radiofrequency heat energy or cryo-energy.

FIGS. 31A-31B and 32A-32B show an embodiment of a method of using the improved transseptal puncture system in which the positioning balloon anchors in the patent foramen ovale and identify multiple small atrial septal defects in a cribriform atrial septal defect.

FIG. 33 is a workflow diagram for a method for suitably facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal insertion device.

DETAILED DESCRIPTION

The following detailed description is merely exemplary in nature and is not intended to limit the described embodiments or the application and uses of the described embodiments. As used herein, the word “exemplary” or “illustrative” means “serving as an example, instance, or illustration.” Any implementation described herein as “exemplary or “illustrative” is not necessarily to be construed as preferred or advantageous over other implementations. All of the implementations described below are exemplary implementations provided to enable persons skilled in the art to make or use the embodiments of the disclosure and are not intended to limit the scope of the disclosure, which is defined by the claims. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the inventive concepts defined in the appended claims. Hence, specific dimensions and other physical characteristics relating to the

embodiments disclosed herein are not to be considered as limiting, unless the claims expressly state otherwise.

With reference to FIGS. **1A-1C**, shown is an embodiment of transseptal insertion device or catheter **10**. Shown is the distal end of transseptal insertion device **10**, *i.e.*, the end of transseptal insertion device **10** with opening through which dilator, catheter, and needle may extend, *e.g.*, to puncture interatrial cardiac septum. As shown in FIG. **1A**, transseptal insertion device **10** includes outer sheath or balloon shaft **12** and one or more balloons **14** located at distal tip **13** of transseptal insertion device **10**. Sheath **12** may contain and define a center lumen **15**. Sheath **12** may be fabricated from various materials, including, *e.g.*, polymers, including thermoplastics elastomers (TPEs) such as PEBA (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as Pellathane®, similar materials and combinations thereof. Sheath **12** may be referred to as catheter shaft and used in cardiac catheterizations. After puncture, sheath **12** may be inserted through septum into left atrium. Alternatively, sheath **12** may contain a separate catheter that is inserted through septum post puncture. Transseptal insertion device **10** also includes dilator **16**, positioned in center lumen **15**, as shown in FIG. **1B**. The one or more balloons **14** are preferably sealed, air-tight and water-tight, on both its ends to sheath **12**.

With continuing reference to FIG. **1A**, in view shown, overhanging one or more balloons **14** are uninflated. Although cross-section of balloons 14 shown on top and bottom of distal tip **13**, balloons **14** preferably extend around circumference of distal tip or end **13** of transseptal insertion device **10**. Overhanging one or more balloons **14** are of form such that balloons **14** overhang or extend from distal tip **13** of sheath **12** when inflated.

In FIG. **1B**, dilator **16** is shown positioned within and partially extending out of sheath **12**, past distal tip **13** of device **10**. Overhanging one or more balloons **14** are uninflated and dilator **16** extends past balloons **14**. It is noted that the relative sizes of sheath **12** and dilator **16** shown are for illustrative purposes as the diameter of dilator **16** may be relatively larger or smaller than shown in relation to the diameter of sheath **12**, although dilator **16** necessarily has a smaller diameter than sheath **12**. Although dilator **16** is shown to have a pointed end, dilator **16** may have a rounded or relatively flat end. Embodiments, as described herein, are designed and intended to puncture septum without use of a needle or other sharp instrument.

With reference now to FIG. **1C**, dilator **16** is shown positioned within center lumen **15** of sheath **12**. Tip of dilator **16** is positioned within distal tip **13** of transseptal insertion device **10** sub-

planar to end of transseptal insertion device **10**. The position shown is position dilator **16** may be in immediately prior to inflation of one or more balloons **14**. It is noted that the relative sizes of catheter/sheath **12** and dilator **16** shown are for illustrative purposes as the diameter of dilator **16** may be relatively larger or smaller than shown in relation to the diameter of sheath **12**. Ordinarily, dilator **16** has smaller diameter or gauge then catheter/sheath **12**, although fit of dilator **16** in catheter/sheath **12** is preferably snug enough so that dilator **16** does not move (laterally or axially) relative to position or "wobble" within transseptal insertion device **10**. Dilator **16** necessarily has a smaller diameter than sheath **12**. In embodiments, sheath **12** material may be sufficiently malleable to enable larger diameter dilators **16**, and other larger diameter devices, to be passed through sheath **12**. In such embodiments, sheath **12** will stretch to accommodate the larger diameter dilator **16** or other device.

With reference to FIG. **2A**, shown is a side perspective view of an embodiment of transseptal insertion device or catheter **200**. Shown is the distal end of transseptal insertion device **200**, *i.e.*, the end of transseptal insertion device **200** with opening through which dilator, catheter, and needle may extend, *e.g.*, to puncture interatrial cardiac septum. As shown in FIG. **2A**, transseptal insertion device **200** includes outer sheath or catheter shaft **212** and one or more balloons **214** located at distal tip **213** of transseptal insertion device **200**. Sheath **212** may contain lumen shaft **211** that defines center lumen **215**. Sheath **212** may be fabricated from various materials, including, *e.g.*, polymers, including thermoplastics elastomers (TPEs) such as PEBA (*e.g.*, Pebax®), nylons, thermoplastic polyurethanes (TPUs) such as Pellathane®, similar materials and combinations thereof. Sheath **212** may be referred to as catheter shaft and used in cardiac catheterizations. After puncture, sheath **212** may be inserted through septum into left atrium. Alternatively, sheath **212** may contain multiple lumen shafts that define multiple lumens separately. Transseptal insertion device **200** also includes dilator **216**, positioned in center lumen **215.** The one or more balloons **214** are preferably sealed, air-tight and water-tight, on both their ends to sheath **212**. Transseptal insertion device **200** includes hypotube **217** for inflation or deflation of one or more balloons **214**. Hypotube **217** may be contained in sheath or catheter shaft **212**. Transseptal insertion device **200** may further include a port (not shown) connected to hypotube **217** to supply gas or fluid to inflate one or more balloons **214**, or to remove gas or fluid from one or more balloons **214** to deflate balloons **214**. Balloons **214** may be fully inflated or deflated, or may be inflated or deflated as much as desired. With reference to FIG. 2B, shown is a front, cross-

sectional view of distal end **213** of the embodiment of transseptal insertion device **200** that shows cross-sectional views of sheath **212**, center lumen **215**, and hypotube **217**.

In the embodiment shown in FIGS. **2A-2B**, transseptal insertion device **200** may include ultrasound chips or transducers **26** for ultrasound imaging or visualizing (see FIGS. **2C-2D**). The transseptal sheath **212** or balloon **214** may house (inside or on) an ultrasound chip or transducer which may be used to guide the insertion procedure. Ultrasound chip or transducer emits and receives ultrasound energy, that may be detected by known ultrasound visualization devices, to create an image of the cardiac chambers (*e.g.*, the right atrium, fossa, interatrial septum, left atrium, atrial appendage, mitral valve, ventricle, etc.). Ultrasound chips and transducers are transducers that convert ultrasound waves to electrical signals and/or vice versa. Those that both transmit and receive may also be called ultrasound transceivers; many ultrasound sensors besides being sensors are indeed transceivers because they can both sense and transmit. Such imaging will allow the operator(s) of transseptal insertion device **200** to visualize the cardiac chambers and the determine the location of the distal end or tip **213** of transseptal insertion device **200**, enabling more precise operation of transseptal insertion device **200**. Such a ultrasound chips or transducers used may be similar to ultrasound chip or transducer described in US Pat. App. Pub. 2003/019546, which is herein incorporated by reference, or any other ultrasound transducer known to those of ordinary skill in the art that may be fabricated on scale small enough to be deployed on or in sheath **212** or balloon **214**.

With reference to FIGS. **2C-2D**, shown are embodiments of transseptal insertion device **200** with ultrasound imaging or visualizing capability. Balloon **14** shown includes one or more ultrasound chips or transducers **26** deployed in or on balloon **14**. Ultrasounds chips or transducers **26** may be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves to electrical signals, transmit the electrical signals, *e.g.*, through a wire that runs via sheath **12**. Ultrasounds chips or transducers **26** may be connected via WiFi or other wireless connection, to an external imaging device that produces images from the received signals (both still and video images).

Ultrasound chips or transducers **26** may be affixed to interior or exterior surface of balloon **14**. Ultrasound chips or transducers **26** may be arranged in a line, disc, or cross-shape. Ultrasound chips or transducers **26** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing towards interatrial septum), as shown in FIG. **2C**, or in a different direction/orientation, such as

sideways and forward facing (*e.g.*, facing towards interatrial septum and facing perpendicular to the distal or front end), as shown in FIG. **2D**. Indeed, orientation of ultrasound chips or transducers **26** may depend on whether balloon **14** is inflated or not. When balloon **14** is fully inflated, as shown in FIG. **2C**, ultrasound transducer **26** may be forward facing (or forward and perpendicularly facing as shown in FIG. **2D**). However, when balloon **14** is deflated, ultrasound transducer **26** may be folded flat and positioned on side of distal tip **13** of sheath **12**. Hence, when balloon **14** is deflated, ultrasound chip or transducer **26** may be side-facing. During inflation ultrasound transducer **26** orientation will change as balloon **14** inflates (moving from side-facing orientation to forward facing orientation with the ultrasound transducer **26** shown in FIG. **2C**). Accordingly, operator(s) of transseptal insertion device **200** may vary the inflation of balloon **14** to achieve different orientations of ultrasound transducer **26** for different imaging views.

Ultrasound chip or transducers **26** may emit and/or receive/detect ultrasound waves that may be reflect off of surfaces and structures, *e.g.*, within atrium, and then read by imaging system (not shown), *e.g.*, connected to ultrasound chips or transducers **26** via wire or cable extending through, *e.g.*, lumen **15** in sheath **12**. In this manner, ultrasound chips or transducers **26** may enable visualization of the interatrial septum and the left atrial structures.

It is also noted that ultrasound chips or transducers **26** may be deployed on distal tip **13** of sheath **12** (or elsewhere on or in sheath **12**). Ultrasound chips or transducers **26** may be installed or configured to be forward facing (facing towards distal end of sheath **12**). Alternatively, ultrasound chips or transducers **26** may be flipped to be rear facing (facing towards proximal end of sheath **12**). Varying orientations of ultrasound chips or transducers **26** may be implemented.

With reference to FIGS. **3A-3B**, shown is transseptal insertion device **300** including multiple balloons **314**, which surround center lumen shaft **311** that defines center lumen **315**, and sheath or catheter shaft **312** that includes center lumen shaft **311** and hypotubes **317** connected to multiple balloons **314**. FIG. 3A is a side view of sheath or catheter shaft **312**, and FIG. **3B** is a front cross-sectional view of sheath or catheter shaft **312**. Balloons **314** are in various shapes such as round, cylindrical, spherical, tear drop shaped or pear shaped, and are in various lengths. Balloons **314** may be with or without overhang over shaft. Balloons **314** are positioned around distal tip or end **313**, and may extend around circumference of distal tip or end **313**. Multiple balloons **314** are connected to one or more hypotubes **317**, and inflated or deflated via hypotubes **317** that are contained in sheath or catheter shaft **312**. Each of balloons **314** may be connected to

corresponding hypotube **317** to independently control the inflation and deflation of balloons **314**. Alternatively, balloons **314** may share one or more hypotubes **317**. Inflation fluid or gas may flow through hypotubes **314** to inflate or deflate balloons **314**. Outer covering **319** may cover the multiple balloons **314**.

In between balloons **314**, there are one or more ultrasound chips or transducers **326** that provide ultrasound imaging or visualizing capability. For illustrative purposes, FIG. **3B** shows ultrasound chips or transducers **326** disposed between balloons **314**, but ultrasound chips or transducers **326** may be deployed in or on balloons **314**. Ultrasound chips or transducers **326** may be affixed to interior or exterior surface of balloon **314**. Ultrasounds chips or transducers **326** may be ultrasound transceivers that both emit and receive waves, convert the ultrasound waves to electrical signals, transmit the electrical signals, *e.g.*, through wire **320** that runs inside sheath or catheter shaft **312**. However, ultrasound chips or transducers **326** may be connected wirelessly via WiFi or other wireless connection, to an external imaging device that produces images from the received signals (both still and video images).

Ultrasound chips or transducers **326** may be designed in the shape of the balloons **314**. The balloons **314** may be round, cylindrical, spherical, tear drop shaped or pear shaped with overhang or without overhang. Ultrasound chips or transducers **326** may have shapes corresponding to the shapes of balloons **314**. Alternatively, one or more ultrasound chips or transducers **326** may be deployed in a shape corresponding to the shapes of balloons **314**. Depending on the shapes of balloons **314**, ultrasound chips or transducers **326** may be side facing, front facing or back facing. Ultrasound chips or transducers **326** may be arranged in a line, disc, or cross-shape. Ultrasound chips or transducers **326** may be arranged to be forward facing (*e.g.*, on distal end of balloon facing towards interatrial septum), or in a different direction/orientation, such as sideways and forward facing (*e.g.*, facing towards interatrial septum and facing perpendicular to the distal or front end).

Orientations of ultrasound chips or transducers **326** may depend on whether balloons **314** are inflated or not. When balloons **314** are fully inflated, ultrasound chips or transducers **326** may be forward facing. However, when balloons **314** are deflated, ultrasound chips or transducer **326** may be folded flat and positioned on side of distal tip **313** of center lumen **315**. Hence, when balloons **314** are deflated, ultrasound chips or transducer **326** may be side-facing. During inflation, orientation of ultrasound chips or transducers **326** may change as balloons **314** inflate (moving from side-facing orientation to forward facing orientation). Accordingly, operator(s) of transseptal

insertion device **300** may vary the inflation of balloons **314** to achieve different orientations of ultrasound chips or transducers **326** for different imaging views.

With reference now to FIG. **4**, shown is an embodiment of transseptal insertion device **10** with radiofrequency (RF) energy capability. Transseptal insertion device **10** shown includes sheath **12**, overhanging one or more balloons **14**, and dilator **16**. Dilator **16** may include cap or crown **22**, on distal end as shown, with RF energy capability or capable of delivering RF energy. Alternatively, cap or crown may include or be an RF electrode. Dilator **16** may be connected, *e.g.*, on proximate end (not shown) to a radiofrequency energy source (not shown) at, *e.g.*, external hub, that provides RF energy to cap or crown **22**. The RF energy may be delivered through dilator **16**. So equipped with cap or crown **22**, dilator **16** may tent interaxial septum and create puncture of interaxial septum through delivery of RF energy. In this embodiment, the use of a sharp needle may be avoided. The dilator with cap or crown on distal end with RF energy capability or capable of delivering RF energy may be used for transseptal insertion devices **200** and **300** shown in FIGS. **2A-2B** and **3A-3B**.

With reference to FIG. **5**, shown is transseptal insertion device **400** including drive assembly **421**, which is coupled to dilator **416**, and knob **422** coupled to drive assembly **421** to cause dilator **416** to traverse along an axial direction of sheath or catheter shaft **412**. Dilator **416** may move backwards or forwards along the axial direction of sheath **412** while knob **422** is rotated. The drive assembly **421** may include nut assembly to drive the dilator **416**. Dilator **416** may be with or without RF energy capability.

With reference now to FIG. **6**, shown is distal end of an embodiment of transseptal insertion device **10** in which overhanging balloons **14** is inflated by supplying gas or fluid into balloon 14 through hypotube (not shown). Dilator **16** is shown positioned within center lumen **15** of sheath **12** with tip of dilator **16** positioned at distal tip **13** of transseptal insertion device **10** and sub-planar to overhanging balloon **14**. The plane that is referred to here is the plane perpendicular to the axis of transseptal insertion device **10** and dilator **16**, formed by the end of overhanging balloon **14**. Hence, dilator **16** remains sub-planar to overhanging balloon **14** until operator intends balloon **14** to be deflated and dilator **16** to tent and puncture interatrial septum **100**. As noted above, balloon **14** preferably extends completely around circumference of tip **13** of transseptal insertion device **10**. Accordingly, FIG. 7 only illustrates cross-section of inflated balloon **14**.

With reference now to FIG. **7**, shown is a front, cross-sectional view of distal end an embodiment of transseptal insertion device **10** in which overhanging balloon **14** is inflated. As shown, inflated overhanging balloon **14** preferably extends around entire circumference of sheath **12** (and, therefore, device **10**). Shown situated within lumen **15** of sheath **12** is tip of dilator **16**. Tip of dilator **16** is positioned within tip **13** of transseptal insertion device **10**, as it would be prior to being extended past tip **13** and puncturing an interatrial cardiac septum.

With reference now to FIG. **8**, shown is distal end of an embodiment of transseptal insertion device **10** with dilator **16** advanced forward in order to tent the interatrial septum **100**. Dilator **16** is shown extending through center lumen **15** of sheath **12** and past overhanging balloon **14**. At this stage, balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube. Extended as such, and pressed against interatrial septum **100**, dilator **16** tents the interatrial septum **100** away from transseptal insertion device **10**.

With reference now to FIG. **9**, shown is shown is distal end of an embodiment of transseptal insertion device **10** with dilator **16** advanced forward through interatrial septum **100**, after puncturing septal wall (*e.g.*, through application of energy through dilator 16 as described herein) and transseptal wire or wire rail **20** extending through dilator **16** and into left atrium chamber **110**. Wire rail **20** may sit in a lumen **19** of dilator **16**. Dilator **16** may be used as a conduit to advance the wire rail **20** into the left atrium.

Wire rail **20** may act as a guide for devices to enter the left atrium through the puncture in the septal wall made by transseptal insertion device **10**. For example, wire rail **20** may guide transseptal insertion device **10** or other catheters in the left atrium. In this manner, catheters may be advanced safely into the left atrium over or guided by wire rail **20**. In an embodiment, wire rail **20** may be energized (*e.g.*, to ablate or puncture the septum with energy delivered from source at proximal end of transseptal insertion device **10**).

With continued reference to FIG. **9**, dilator **16** preferably defines and includes an opening or lumen **19** extending through its tip and through which transseptal wire **20** extends. With dilator **16** extended as shown and tenting interatrial septum, septum may be punctured by energy delivered through cap or electrode at tip of dilator **16** and transseptal wire rail **20** extended through opening in tip of dilator **16** and through puncture made in interatrial septum by dilator **16** cap.

With reference to FIGS. **10A-10C**, shown are different views of an embodiment of transseptal insertion device **10** with a flexible sheath **12** flexed or angulated at different angles.

Transseptal insertion device **10** may be flexed or angulated depending on the anatomy of the atria using fixed angled dilators **16** that are inserted into lumen shaft of sheath **12**, causing sheath **12** to flex. Such fixed angled dilators **16** may be, *e.g.*, any angle from 0-270°. Alternatively, sheath **12**, lumen shaft and dilator **16** may be all flexible (preferably, hypotubes, needle and catheter inserted through such flexible sheath **12** are flexible or malleable, at least in part) and transseptal insertion device **10** may be flexed or angulated, thereby flexing or angulating sheath **12** and dilator **16**, using, *e.g.*, a handle or wire (not shown) connected to tip **13** of device **10**. Handle and/or wire may also be used to turn or flex or move tip **13** of transseptal insertion device **10**, *e.g.*, moving tip **13** of sheath "up" or "down" or "left" or "right" or angulating tip **13** relative to axis of sheath **12** as shown.

With reference now to FIG. **11**, shown is distal end of an embodiment of transseptal insertion device **10** with inflated overhanging balloon **14**. Balloon **14** shown is an embodiment with one or more markers **24**. Marker **24** may be, *e.g.*, a radiopaque and/or echogenic marker **24**. As a radiopaque or echogenic marker, marker **24** will be visible on scanners used by those performing cardiac catheterizations. The markers **24** may be in the form of letters, such as an E or a C. Marker **24** enables the appropriate positioning of balloon **14** and sheath **12** in the 3-dimensional space (*e.g.*, of the atrium) using imaging to view the marker **24** and, therefore, the position of balloon **14**.

Specifically, in operation, the less posterior distal tip **13** is positioned, the more of the E (or C) will be shown. As operator of transseptal insertion device **10** turns or rotates distal tip **13** toward posterior of patient, less of the arms of the E will be seen. In a preferred embodiment, when only the vertical portion of the E is visible (*i.e.*, appearing as an I) distal tip **13** will be rotated to its maximum posterior position.

With continuing reference to FIG. **11**, balloon **14** is shown as inflated. However, distal end of dilator **16** is shown extruding or extending distally from balloon **14**, past plane formed by distal end of inflated balloon **14**. According, dilator **16** has been moved into the tenting and puncturing position, adjacent to interaxial septum. At this stage, balloon **14** may be deflated or will soon be deflated, and puncture of the interaxial septum is imminent.

With reference now to FIG. **12**, shown is another embodiment of overhanging balloon **14** which may be deployed in embodiments of transseptal insertion device **10**. Overhanging balloon **14** may include ring or band **28** around a portion of balloon **14**. Ring or band **28** may serve as a

marker, similar to markers **24** shown in FIG. 11. Hence, ring **28** may be radiopaque or echogenic and may be view by scanning devices used for visualization in cardiac catheterizations (*e.g.*, fluoroscopic imaging devices). Similar to the letter E or C, the view of the ring **28** changes as the distal tip **13** of transseptal insertion device **10** moves more posterior. When in a least posterior position, ring **28** may appear as just a line or band positioned across axis of transseptal insertion device **10**. When device **10** is rotated so that distal tip **13** is significantly closer to the posterior, ring **28** may appear as a full "flat" circle or ring. In FIG. **12**, distal tip **13** is partially rotated so that ring **28** is partially visible.

With reference to both FIGS. **11** and **12**, the marker **24** and ring **28** are described and shown as located on balloon **14**. In embodiments, marker **24** and/or ring **28** may also be located on sheath **12** and/or dilator **16**. So located, marker **24** and/or ring **28** would operate in effectively the same manner as described above (*i.e.*, the arms of the E would disappear as the distal end was moved more to the posterior and the ring would become more visible). Markers **24** and/or rings **28** may be placed on all of balloon **14**, sheath **12**, and dilator **16**, or a combination thereof.

With reference now to FIG. **13**, shown is distal end of an embodiment of transseptal insertion device **10** that includes dilator **16** with electrode tip. Shaft of dilator **16** defines and contains a center lumen **50**. Lumen **50** may be defined in the range of, but not limited to, 0.020 to 0.040 inches. Dilator **16** may be made from a polymer material (*e.g.*, HDPE, LDPE, PTFE, or combination thereof). Dilator shaft **16** shown includes a distal electrode tip **52**. Electrode tip **52** may be comprise a metallic alloy (*e.g.*, PtIr, Au, or combination thereof). In preferred embodiments, the size and shape of electrode tip **52** is selected to be sufficient to generate a plasma for in vivo ablation of tissue in an applied power range of, but not limited to, 20-30W. Electrical conductor **54** extends from electrode tip **52** to the proximal end (not shown) of the dilator **16**. Electrical conductor **54** may run axially through an additional lumen **56** defined by and contained in dilator shaft **16**. Electrical conductor **54** may contain a coil feature **58** to accommodate lengthening during bending or flexing of dilator **16**.

Attached to distal end of sheath **12** is contains overhanging balloon **14** that is connected to hypotube **17**. Overhanging balloon **14** may be made from a polymer material (*e.g.*, PET, Nylon, Polyurethane, Polyamide, or combination thereof). Overhanging balloon **14** may be in the range of, but not limited to, 5-20 mm in diameter and 20-30 mm in length. Overhanging balloon **14** may be inflated via injection of gas or fluid through hypotube **17** connected to balloon **14**. Overhanging

balloon **14** may be deflated by removing gas or fluid in balloon **14** through hypotube **17** connected to balloon **14**. During the proper functioning or operation of transseptal insertion device **10** for puncturing the interatrial septum, balloon **14** may be deflated when dilator **16** moves out of lumen **15** by removing gas or fluid from balloon **14**. Overhanging balloon **14** is of form such balloon **14** overhangs or extends from distal end **13** of sheath **12**. Overhang or extension **60** may be in the range of, but not limited to, 0.0 mm-5.0 mm. The end of the overhang or extension **60** is the plane to which dilator **16** remains sub-planar until moving to tent and puncture the interatrial septum.

With reference now to FIG. **14**, shown is an embodiment of transseptal insertion device **10** that includes a mechanical deflection mechanism. Mechanical deflection mechanism may enable distal end of sheath **12** to be deflected or angulated to various angles with respect to axis of transseptal insertion device **10**. Mechanical deflection mechanism may include a pull wire anchor **40** affixed to distal end of sheath **12** and pull wire actuator **42** connected to pull wire anchor **40** with pull wire (not shown). Rotation of pull wire actuator **42**, as shown, may exert force on pull wire anchor **40** that deflects or angulates distal end of sheath **12**. Pull wire actuator **42** may be rotated by handle connected thereto (not shown). Deflection or angulation of distal end of sheath **12** may enable better intersection (*e.g.*, more perpendicular, flush) with interaxial septum and, therefore, better puncture and insertion by transseptal insertion device **10**.

With reference now to FIG. **15**, shown are three (3) embodiments of curved dilators **16**, each with a different curve profile (*i.e.*, different angle of deflection or curve). Curved dilators **16** may be used in embodiments of transseptal insertion device **10** with flexible or malleable sheath **12**. Such a flexible or malleable sheath **12** may be referred to as a steerable sheath **12** as it is "steered" by curved dilator **16** inserted in sheath **12**.

With reference now to FIG. **16**, shown is an embodiment of transseptal insertion device **10** with an external stabilizer **80**. Stabilizer **80** keeps proximal end of transseptal insertion device **10** stable while allowing movement of transseptal insertion device **10** towards the distal and proximal ends of device **10**, rotational/torqueing movement of proximal end of device **10**, and manipulation of dials or other controls of device **10**. In effect, stabilizer **80** substantially prevents unwanted movement of the transseptal insertion device **10** and, importantly, distal end of sheath **12**, balloon **14**, and dilator **16**.

Stabilizer **80** includes connecting rods or arms **82** that connect stabilizer **80** to handle **70** at proximal end of transseptal insertion device **10**. Connecting arms **82** are attached to stabilizer

platform **84**. Connecting arms **82** preferably hold the handle **70** securely and tightly, while permitting desired rotational movements and control manipulation. Stabilizer platform **84** is moveably attached to stabilizer base **86** so that stabilizer platform **84**, and hence handle **70** and transseptal insertion device **10**, may be slid forwards and backwards along axis of transseptal insertion device **10** towards and away from insertion point in patient (typically femoral vein at the groin of patient). Stabilizer base **86** is typically secured to a flat, stable surface, such as a table, or the leg of the patient. Configured as such, stabilizer **80** prevents unwanted vertical, rotational, or other movement of transseptal insertion device **10** and its handle **70**, keeping transseptal insertion device **10** and its handle **70** stable while permitting precise manipulation of handle **70** and its controls.

With continuing reference to FIG. **16**, as shown, proximal end of transseptal insertion device **10** may include a handle **70** for control and manipulation of transseptal insertion device **10** and, particularly, dilator **16** and distal end of dilator **16**. Handle **70** may include a dial **72** that may be used to turn or deflect distal end of dilator **16**, effectively moving the distal end of dilator **16** up or down in relation to axis of transseptal insertion device **10** (as indicated by arrows in FIG. **16**). Handle **70** may also include dial **74** for extruding/extending distal end of dilator **16** out of sheath **12** and retracting dilator **16** back into sheath **12**, effectively moving dilator **16** along axis of transseptal insertion device **10** (as indicated by arrows in FIG. **16**). Handle **70** may also be rotated, as indicated by rotational arrow in FIG. **16**, in order to deflect or turn distal end of transseptal insertion device to left or right in relation to axis of transseptal insertion device **10**, increasing or decreasing dilator **16** angle of deflection in that direction. If dial **72** moves distal end of dilator **16** along Y axis, and transseptal insertion device **10** axis is considered the Z axis, so that dial **74** moves dilator **16** along Z axis rotating handle **70** moves distal end of transseptal insertion device **10** (and hence distal end of dilator **16**) along X axis. Handle **70** includes a port through which dilator **16** and other devices inserted into transseptal insertion device **10** may be inserted. Handle **70** may also include one or more tubes or other ports permitting connection to external hubs and external energy sources, inflation liquids or gas.

In embodiments shown herein, balloon **14** and dilator **16** may be used as energy sources in the left atrium and may be used to deliver energy to the pulmonary veins, left atrial appendage, mitral valve and the left ventricle present in the left atrium. Such embodiments may include external energy sources connected to balloon **14** and/or dilator **16** through wires or other

conductors extending lumen in sheath **12**. Delivery of energy via balloon **14** or dilator **16** may be thermal/Cryo or radiofrequency, laser or electrical. The delivery of such energy could be through a metallic platform such as a Nitinol cage inside or outside balloon **14**. Transseptal insertion device **10** may also include an energy source external to the proximal end of the sheath and operatively connected to balloon **14** to deliver energy to balloon **14**.

With reference now to FIGS. **17A-17B** shown is an embodiment of transseptal insertion device **10** enabling differential expansion of balloon **14**. Differential expansion of balloon **14** enables balloon **14** inflation to be adjusted based on the needs of the device operator and the conditions present in the patient's heart. For example, the size of the fossa ovalis portion of the interatrial septum may dictate the desired size of the inflated balloon **14** needed at the puncture site (interatrial septum if often punctured through the fossa ovalis). Fossae can vary greatly in size. The larger the fossa, the harder it will be to tent the interatrial septum with balloon **14**. Large fossa tend to be saggy and more difficult to manipulate. Hence, with a large fossa, a larger distal end of balloon **14** will make proper tenting of the interatrial septum easier. Indeed, it may be ideal to have balloon **14** inflated uniformly until intersecting or passing through fossa and then differentially expanding distal end **142** of balloon **14** to move fossa out of the way. In FIG. **17A**, distal end or portion **142** of balloon **14** is smaller (less expanded) than proximal end **144** of balloon **14**.

Oppositely, the smaller the fossa, the easier it will be to tent the interatrial septum but, there will be less room to maneuver balloon **14** near interatrial septum. Consequently, a smaller distal end of balloon **14** is desired. It also may be beneficial to expand the proximal portion **144** more in order to help fix or secure balloon **14** in place. In FIG. 17B, distal end or portion of balloon **14** is larger (more expanded) than proximal end or portion of balloon **14**. In both FIGS. **17A** and **17B**, dilator **16** has extruded from sheath 12 and past distal end of balloon **14**, tenting interatrial septum **100**, and puncture is imminent.

This differential expansion of balloon **14** may be achieved, *e.g.*, by using different materials for different portions of balloon **14** (*e.g.*, a more expandable material for distal end **142** than proximal end or portion **144**, or vice versa). In general, balloon 14 may be made of either compliant or non-compliant material, or a combination thereof. Compliant material will continue expanding as more inflating liquid or gas is added to balloon **14** (at least until failure). Non-compliant material will only inflate up to a set expansion or designated inflation level. Combinations of compliant and non-compliant material may be used to provide a differentially expanding balloon **14**. For

example, distal end **142** may be formed from compliant material and proximal end **144** from non-compliant material to enable a larger distal end **142**. Oppositely, proximal end **144** may be formed from compliant material and distal end **142** from non-compliant material to enable a larger proximal end **144**. Other means for providing differential expansion of balloon **14** may be used, such as applying energy to different portions of balloon **14** to increase or decrease the compliance, and expandability, of that portion.

Balloon **14** may also be used to direct other equipment into these anatomical locations or be used as an angiographic or hemodynamic monitoring balloon. Differential expansion of balloon **14** may be utilized for proper orientation or direction of such equipment.

With reference now to FIG. **18**, shown is an embodiment of a malleable transseptal needle **90** that may be used with transseptal insertion device **10** with a flexible sheath or otherwise capable of multiple angulations. In embodiments, malleable transseptal needle **90** may be of a variety of diameters and lengths. For example, embodiments include an 18 gauge transseptal needle and that is available in 71 cm, 89 cm, and 98 cm lengths. In embodiments, the malleable transseptal needle **90** has different stiffness in a proximal segment **92**, distal segment **94**, and in a middle segment **96** between. For example, malleable transseptal needle **90** may be stiffer in the proximal segment **92** and distal segment **94** and more flexible (less stiff) in a middle segment or mid-section **96**. The mid-section may be the section where transseptal insertion device **10** and dilator **16** angulate. In an embodiment, malleable transseptal needle **90** is used and a control handle provided that enables three-dimensional movements. Malleable transseptal needle **90** shown is, preferably, malleable or flexible at least in part. Proximal end **92** of malleable transseptal needle **90** may be stiff (*e.g.*, made from a stiff material, such as a metal). Mid-section or middle **96** of malleable transseptal needle **90** may be malleable or flexible (*e.g.*, made from a flexible, malleable material, such as rubber). Accordingly, mid-section may flex or bend, enabling malleable transseptal needle **90** to pass through angulated or flexed sheath **12**.

Distal end **94** of malleable transseptal needle **90** (*i.e.*, end that punctures interatrial cardiac septum) may be stiff with a cap or electrode at its tip for delivering energy to interatrial septum to puncture interatrial septum. In embodiments, transseptal needle is able to transmit radiofrequency energy to create a controlled septal puncture. Such a transseptal needle may or may not be malleable, but is able deliver RF energy through a cap or crown (*e.g.*, an electrode) at its distal end tip. The needle **90** may be connected, *e.g.*, on proximate end (not shown) to a radiofrequency (RF)

energy source (not shown) at, *e.g.*, external hub, that provides RF energy through needle to its distal end tip. In such an embodiment, dilator **16** may tent interaxial septum and RF energy capable transseptal needle may create puncture of interaxial septum through delivery of RF energy.

Embodiments may include an additional dilator which would be able to dilate the distal end of sheath **12**, or the entire sheath length, thereby significantly increasing the French size of the sheath **12**. For example, balloons deployed within sheath **12** may be inflated to expand sheath **12**. In such embodiments, transseptal insertion device **10** may, therefore, be used to accommodate and deliver larger devices or be able to retrieve devices once they have been extruded from sheath **12** and have embolized. Such balloons may be inflated through one or more hypotubes.

In embodiments, energy, typically electrical energy, may directed through transseptal insertion device **10** may be used to increase or decrease the French size of sheath **12**. In such embodiments, sheath **12** is fabricated from materials that are known to increase in malleability and or expand when certain energies are applied. In this manner, the French size of sheath **12** may be adjusted to a size deemed necessary during a given procedure. Such energy may be applied through wires or conductive material, connected to energy source external to proximal end of transseptal insertion device **10**, attached to or fabricated within sheath **12** or other components of transseptal insertion device **10**. Likewise, parts or portions of transseptal insertion device **10** may be selectively made more rigid or more malleable/soft with the application of energy. Therefore, with the application of differential energy to different parts of transseptal insertion device **10** at different times, transseptal insertion device **10** size may be adjusted to enable various devices that are ordinarily larger and bulkier than the catheter to traverse through the catheter. In embodiments, transseptal insertion device **10** may accommodate devices up to 36 Fr.

In an embodiment of transseptal insertion device **10**, visualization of an intrathoracic region of interest using MRI techniques may be provided. Embodiments may, for example, provide a needle system comprising a hollow needle having a distal portion and a proximal portion, said distal portion having a distal-most end sharpened for penetrating a myocardial wall. The needle may include a first conductor, an insulator/dielectric applied to cover the first conductor over the proximal portion of said needle and a second conductor applied to cover the insulator/dielectric. The method may further direct the needle system into proximity to a myocardial wall, track progress of the needle system using active MRI tracking, penetrate the myocardial wall to approach

the intrathoracic region of interest, and, use the needle system as an MRI antenna to receive magnetic resonance signals from the intrathoracic region of interest.

In related embodiments, MRI antenna may be installed on distal tip **13** of sheath **12**, dilator **16** or on balloon **14**, similar to ultrasound chips or transducers **226** or **326** described above. Wires connecting such MRI antenna or other MRI components may pass through lumen in dilator **16** or sheath **12** and connect with appropriate magnetic resonance energy source on exterior of distal end of transseptal insertion device **10**.

With reference now to FIGS. **19A-22B**, shown are an embodiment of an improved transseptal puncture system **500** with puncture member balloon seal. With reference to FIGS. **19A-19C**, shown are a side view, a close-in side view of the section C, and a cross-sectional view of the section D-D of the transseptal puncture device **500**, respectively, when the puncture member balloon **504** is deflated. With reference now to FIGS. **20A-20C**, shown are a side view, a close-in side view of the section E, and a cross-sectional view of the section F-F of the transseptal puncture device **500**, respectively, when the puncture member balloon **504** is inflated.

Referring to FIGS. **19A-20C**, the transseptal puncture device **500** includes a radio-frequency (RF) generator plug **501**, Y-connector **502**, and puncture member multi-lumen extension **503** that includes sheath **514** and puncture member **515** (see FIG. **21B**). The RF generator plug **501** is connected to the puncture member multi-lumen extension **503** through a Y-connector **502**, and provides power for a RF generator (not shown) that may be positioned in the puncture member **515** located in the multi-lumen extension **503**. The puncture member **515** is located inside the sheath **514**, and has a distal end (puncture tip) **506** that is positioned toward the cardiac interatrial septum of the patient when the device **500** is in use. The puncture member balloon **504** is mounted on the puncture member **515** and is located near the distal end **506** of the puncture member **515**. The close-in side view FIG. **19B** and the cross-sectional view FIG. **19C** show deflated puncture member balloon **504**, while the close-in side view FIG. **20B** and the cross-sectional view FIG. **20C** show inflated puncture member balloon **504**.

The puncture member **515** includes an puncture member tube **507** for inflating or deflating the puncture member balloon **504**, and a lumen **508** which is connected to the puncture member tube **507** that supplies gas or fluid to the puncture member tube **507** to inflate the puncture member balloon **504**. The puncture member **515** also includes at least one RF tip **505** at the distal end **506** of the puncture member **515**. The RF tip **505** is capable of delivering RF energy. The RF generator

(not shown) produces RF energy, and the RF energy is supplied to the RF tip **505**. The puncture member **515** includes a lumen **509** for wires that delivers RF energy to the RF tip **505**.

With reference to FIGS. **21A-21B**, shown are a side view and a close-in side view of the section D of the transseptal puncture device **500**, respectively, when the positioning balloon **510** is inflated. The puncture member multi-lumen extension **503** includes the sheath **514** and the puncture member **515**. The sheath **514** may have the sheath marker band **513**, and the puncture member balloon **504**, which is mounted on the puncture member **515**, may be aligned with the sheath marker band **513**. The sheath **514** includes one or more positioning balloons **510**, one or more inflation ports **512** connected to the positioning balloons **510**, and at least one tube **516** that delivers gas or fluid to the inflation port **512** to inflate the positioning balloons **510**. The tube **516** may be the hypotube **17** (see FIG. **13**). The sheath **514** also includes one or more deflation ports **511** that is connected to the positioning balloons **510**. When the puncture member balloon **504** is inflated, the inflated puncture member balloon **504** seals the one or more deflation ports **511** in the sheath **514**, preventing leak from the positioning balloons **510** and permitting inflation of the positioning balloons **510**. The position balloons **510** are then inflated through the inflation port **512** of the sheath **514**. The non-compliant or semi-compliant puncture member balloon **504** seals off the deflation ports **511** of the sheath **514**, allowing the positioning balloons **510** to inflate and position the distal end **506** of the puncture member **515** to the fossa ovalis (see FIG. **6** for example).

With reference to FIGS. **22A-22B**, shown are a side view and a close-in side view of the section B of transseptal puncture device **500**, respectively, when the puncture member **515** advances toward fossa ovalis. Once precisely positioned, the puncture member **515** is then pushed distally towards the fossa ovalis. The inflated puncture member balloon **504** moves away from the deflation ports **511**, exposing the deflation ports **511**. The positioning balloons **510** deflate through the deflation ports **511**. However, the positioning balloons **510** may be deflated through both inflation ports **512** and the deflation ports **511**.

Additional embodiments, implementations, applications and methods of use of the above improved transseptal puncture system are possible. With reference now to FIGS. **23A-23C**, shown are a close-in side view of the section E with inflated balloon, a close-in side view of section C with deflated balloon, and a cross-sectional view of the section D-D of the transseptal puncture device **500**, respectively. With reference now to FIGS. **24A-24B**, shown are a side view of a puncture member that is advanced beyond a shaft and a side view of a puncture member with

inflated balloon **510** of the transseptal puncture device **500**, respectively. With reference to FIGS. **25A-25C**, shown are side views of the distal end portion of the puncture member multi-lumen extension **503** and a cross-sectional view of the distal end portion of the puncture member multi-lumen extension **503** of the transseptal puncture device **500** of the additional embodiment, respectively.

In these embodiments, a method of using the improved transseptal puncture system may use the puncture member balloon **504** for visibility, anchoring against the septum and preventing inadvertent advancement into the left atrium. In such an embodiment, the transseptal puncture member balloon **504** is inflated (see FIG. **23A**) through the puncture member tube **507**, once the puncture member is outside the shaft and is tenting the septum (*i.e.*, the puncture member balloon is pressing against the septum, tenting the septum away from shaft end). The puncture member balloon **504** is 5 to 8 mm (distance L in FIG. **25B**) proximal to the tip of the puncture member and prevents the puncture member from being pushed beyond the 5 to 8 mm into the left atrium. After successful puncture of the interatrial septum, a 035 (0.035") guidewire in the guide wire access lumen (or center lumen) **518** (See FIG. **23C**) is advanced into the left atrium and the puncture member balloon **504** is deflated (see FIG. **23B**) and the puncture member withdrawn back into the shaft.

In the embodiments, the positioning balloon **510** on the sheath or shaft **514** may have separate hypotubes for inflation and deflation. For example, the sheath **514** may have inflation hypotube **516a** and a deflation hypotube **516b** to inflate and deflate the positioning balloon **510**, respectively. However, the embodiment is not limited to this configuration. The positioning balloons **510** may be inflated and deflated through the same hypotube (for example, see FIG. **3A**). The puncture member **515** has a puncture member tube **507** to inflate and deflate the puncture member balloon **504**. The puncture member has a radiofrequency tip **505** at a distal end of the puncture member **506**. For the small, medium and large curl shafts, the puncture member length is small, medium and large. The curl shaft chosen depends on the size of the atrium. For example, a small curl shaft is used for small atrium. When advanced beyond the shaft **514**, the puncture member **515** can only be advanced to a max of 5 to 8 mm coming to a hard stop (see FIG. **24A**). In another embodiment, the positioning balloon **510** may be inflated through a separate hypotube, overhangs the shaft by 3 mm, and has variable dimension based on the amount of fluid or air infused or insufflated into the balloon (see FIG. **24B**). For small, medium and large curl shafts, the

puncture member **515** has a conical tip with no radiofrequency or another energy source. The puncture member may have an 0352 lumen (0.0352") to 040 (0.040") lumen **518**. Through this lumen, a wire which may or may not have radiofrequency energy capability may be advanced across the septum. Through this lumen a Brockenbrough needle or a radiofrequency tip needle could be advanced and used to cross the septum. In FIGS. **25A-25B**, the wiring member **519** may be the wire, Brockenbrough needle, or a radiofrequency tip needle. The transseptal insertion device **500** includes a sheath **514** that defines at least one lumen **517** therein, one or more positioning balloons **510** that are connected to the distal end **506** of the sheath **514**, a puncture member **515** movably positioned within the at least one lumen **517**, and a puncture member balloon **504** mounted on the puncture member **515**. The puncture member **515** defines a center lumen **518** therein, and a wire member **519**, for example, is positioned inside the center lumen **518**.

Embodiments may also include a method of performing a septostomy using the improved transseptal puncture system **500**. In such a method, once the shaft has crossed the septum, the positioning balloon **510** may be used to perform a septostomy. The positioning balloon **510** could be configured in multiple shapes and forms; for example, the positioning balloon may be shaped in a spherical, conical, reverse conical, teardrop shaped, pear-shaped, double-balloon shape with a double balloon being of varying sizes proximally or distally. Embodiments of the improved transseptal puncture system **500** may include two or more positioning balloons **510** adjacent to one another with separate micro-ports connected to the hypotube for external inflation or deflation.

Embodiments may also include methods using the improved transseptal puncture system **500** for atraumatic navigation in the left atrium. Once the shaft **514** of the improved transseptal puncture system **500** has crossed over into the left atrium, the positioning balloon **510** may be re-inflated for navigation in an atraumatic fashion to different parts of the left atrium including navigating to the left atrial appendage, to the pulmonary veins, to the mitral valve and in the left ventricle.

Embodiments may also include methods of using the improved transseptal puncture system **500** wherein the puncture member balloon **504** is used for anchoring the improved transseptal puncture system **500** against the septum. In the embodiments of the method, once the transseptal puncture system **500** is passed into the left atrium, the puncture member balloon **504** is re-inflated and then the system is pulled back. When pulled back, the puncture member balloon **504** act as an anchor against the septum.

Embodiments may also include methods of using the improved transseptal puncture system **500** wherein the shaft **514** of the system is used as a delivery guiding catheter to deliver devices. The shaft may be used as a delivery guiding catheter for delivering various devices including left atrial appendage occluder devices.

With reference now to FIG. **26**, shown is an embodiment of a method of using the improved transseptal puncture system **500** where the positioning balloon **510a** is used as an occlusion balloon. In embodiments, the positioning balloon **510a** may be used as an occlusion balloon in the left atrial appendage and pulmonary veins in case of trauma, perforation and bleeding to either the left atrial appendage or pulmonary veins. The catheter **515** may be used in the left atrial appendage with the positioning balloon **510a** being inflated such as to occlude the left atrial appendage especially in the eventuality of a perforation. The shaft positioning balloon may be inflated in the left atrial appendage such as to occlude the left atrial appendage.

With reference now to FIG. **27**, shown is an embodiment of a method of using the improved transseptal puncture system **500** for left atrial appendage thrombectomy. In the embodiment shown, the improved transseptal puncture system **500** includes a pigtail catheter **519a** that is located within the shaft of the guiding catheter. As shown, through the shaft of the guiding catheter a pigtail catheter is advanced into the distal left atrial appendage. Lavage of the left atrial appendage may be performed while injecting fluid, using the pigtail catheter **519a**, into the left atrial appendage and aspirating it through the shaft of the guiding catheter. The pigtail catheter **519a** may also be used to infuse other pharmaceuticals including thrombolytics in the left atrial appendage.

Embodiments may also include methods using the improved transseptal puncture system **500** for identifying and positioning over a paravalvular leak. The positioning balloon **510** may be used for visualization and anchoring against a prosthetic valves sewing ring annulus and stabilize the guiding catheter such that a paravalvular leak may be traversed with the guiding wire more easily.

Embodiment may also include a method of using the improved transseptal puncture system **500** for laceration of the anterior mitral leaflet. Using the positioning balloon **510**, which would be advanced to the anterior mitral leaflet, radiofrequency puncture member **515** or a radiofrequency wire is advanced through the anterior mitral leaflet and advanced into the left ventricle. Embodiments include a side port **509a** (see FIG. **25C**) in the shaft of the guiding catheter just proximal to the positioning balloon through which a small 4 French Gauge catheter may be passed

over a wire into the left ventricle over this catheter or wire. A snare may be passed into the left ventricle. The snare may be used to capture the wire which was placed in the left ventricle through the positioning balloon guide and retracted back into the left atrium. Using this radiofrequency wire which has now formed a loop traversing through the anterior mitral leaflet into the left ventricle and returning back into the left atrium and the anterior mitral leaflet could therefore be lacerated.

With reference now to FIG. **28**, shown is an embodiment of a method of using the improved transseptal puncture system **500** for MitraClip or other mitral repair prosthesis device removal. Embodiments of this method may use a technique similar to placing the positioning balloon against the mitral valve. Here, the positioning balloon **510** may be placed against a prosthesis like the MitraClip which is now forming double orifices of the mitral valve with the radiofrequency wire **519b** being advanced via one of the orifices into the left ventricle. The wire snared via a side port catheter or wire **519c** which is advanced into the left ventricle via the adjacent orifice thereby forms a reel from the left atrium into the left ventricle and back into the left atrium such as to snare the MitraClip or other percutaneous mitral repair devices. Using radiofrequency wire, the anterior mitral leaflet is then lacerated right next to the repair device such as to cause an iatrogenic single leaflet detachment. The method described herein could be repeated with the posterior aspect and including the posterior mitral leaflet.

The MitraClip device or a similar mitral repair device would be held in place with a snare or other holding devices such as an alligator clip which may be mechanical or may have magnetic properties so as to prevent embolization of the MitraClip or other repair device. Once the repair device is free, the clip may be retrieved back into the positioning balloon guiding catheter and removed from the body.

With reference now to FIG. **29**, shown is an embodiment of a method of using the improved transseptal puncture system **500** for laceration of a bioprosthetic valve leaflet. The positioning balloon **510** is placed into the base of the bioprosthetic valve leaflet using a radiofrequency puncture member **515** and a radiofrequency capable wire or a radiofrequency wire which is advanced through the bioprosthetic valve leaflet. A snare catheter over wire is then advanced via the guiding catheter to a separate hole through the orifice of the bioprosthetic valve into the adjacent chamber. The radiofrequency wire which was advanced through the bioprosthetic valve

leaflet is then snared by the snare catheter wire, thereby forming a loop or radial with the snared radiofrequency wire. Using radiofrequency energy, the bioprosthetic leaflet is then lacerated.

With reference now to FIG. **30**, shown is an embodiment of a method of using the improved transseptal puncture system **500** wherein the system anchors in the pulmonary veins, performs pulmonary venous angioplasty, and deliver either radiofrequency heat energy or cryo-energy. In embodiments, the positioning balloon **510** is used to navigate into the pulmonary veins for anchoring purposes as well as to deliver other therapeutic catheters into the pulmonary veins, such as ablation catheters. The positioning balloon **510** may also be used for balloon angioplasty of the pulmonary veins. The positioning balloon **510** may also be used itself to deliver energy in the form of heat or used for cryoablation with the use of products such as liquid nitrogen which could be circulated through the balloon via hypotubes from the outside.

With reference now to FIGS. **31A-32B**, shown is an embodiment of a method of using the improved transseptal puncture system **500** in which the positioning balloon **510** anchors in the patent foramen ovale and identify multiple small atrial septal defects in a cribriform atrial septal defect. The positioning balloon **510** may be positioned against the fossa from the right atrium and navigated to a patent foramen ovale or identify multiple small atrial septal defects in a cribriform atrial septal defect such that a patent foramen ovale or small atrial septal defects in a cribriform atrial septal defect could be easily be traversed with a wire with a stable catheter.

Other embodiments include methods of using the improved transseptal puncture system **500** to deliver occluder devices. The positioning balloon shaft may also be used as a delivery guiding catheter for delivering closure devices **519d** including atrial septal defect occluder devices, patent foramen ovale closure devices, patent ductus arteriosus, paravalvular leak closure devices etc.

With reference to FIG. **33**, shown is a workflow diagram for a method **600** for suitably facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal insertion device **500**. One or more positioning balloons **510**, which are connected to a distal end of a sheath **514** of the transseptal insertion device, are inflated, block **610**. The puncture member **515** while the positioning balloons are inflated is advanced toward cardiac interatrial septum, block **611**. The puncture member balloon **504** is inflated, once the puncture member **515** advances beyond the distal end of the sheath **514** and is tenting the cardiac interatrial septum, block **612**. The puncture member **515** is positioned against the cardiac interatrial septum, block **613**. The

puncture member balloon **504** is pressing against the cardiac interatrial septum while the puncture member **515** is tenting the cardiac interatrial septum. The puncture member balloon **504** is deflated, block **614**, and the one or more positioning balloons **510** are deflated, block **615**, before the puncture member further advances to puncture the cardiac interatrial septum. Then, the puncture member **515** advances to puncture the cardiac interatrial septum, block **616**. The transseptal insertion device **500** advances crossing the cardiac interatrial septum, block **617**.

Since many modifications, variations, and changes in detail can be made to the described preferred embodiments of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Consequently, the scope of the invention should be determined by the appended claims and their legal equivalents.

WHAT IS CLAIMED IS:

1. A transseptal insertion device which is suitable for facilitating precise and safe transseptal puncture of a cardiac interatrial septum, comprising:

a sheath that defines at least one lumen therein and has a distal end that is positioned toward the cardiac interatrial septum of a patient when the transseptal insertion device is in use and a proximal end that is external to the patient;

one or more positioning balloons that are connected to the distal end of the sheath, wherein the one or more positioning balloons, when inflated and the transseptal insertion device is in use, overhang and extend past the distal end of the sheath, wherein the sheath includes one or more hypotubes respectively connected to the one or more positioning balloons to inflate and deflate the one or more positioning balloons;

a puncture member movably positioned within the at least one lumen, wherein the puncture member has a distal end that is positioned toward the cardiac interatrial septum of the patient, wherein the puncture member has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum; and

a puncture member balloon located on the distal end of the puncture member, wherein the puncture member includes at least one puncture member tube connected to the puncture member balloon to inflate and deflate the puncture member balloon.

2. The transseptal insertion device of claim 1 wherein the one or more positioning balloons are inflated by gas or fluid supplied through the one or more hypotubes, and the one or more positioning balloons and the puncture member balloon are inflated and deflated independently of each other.

3. The transseptal insertion device of claim 1 wherein the one or more hypotubes comprises one or more inflation hypotubes to inflate the one or more positioning balloons, and one or more deflation hypotubes to deflate the one or more positioning balloons.

4. The transseptal insertion device of claim 1 wherein the one or more positioning balloons, when inflated, delivers energy in the form of heat or is used for cryoablation with fluid that is circulated through the one or more positioning balloons.

5. The transseptal insertion device of claim 1 wherein the puncture member balloon, when inflated, is positioned at a predetermined distance from a tip of the distal end of the puncture member to prevent the puncture member from being pushed beyond the predetermined distance

while the puncture member is tenting the cardiac interatrial septum and the puncture member balloon is pressing against the cardiac interatrial septum.

6. The transseptal insertion device of claim 1 wherein the puncture member includes a radiofrequency (RF) tip at the distal end of the puncture member, wherein the RF tip is capable of delivering RF energy.

7. The transseptal insertion device of claim 1 further comprising a wire member movably positioned in a center lumen formed in the puncture member, wherein the wire member advances beyond a tip of the distal end of the puncture member when in use.

8. The transseptal insertion device of claim 7 wherein the wire member is one selected from a group consisting of a Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter that delivers fluid or pharmaceuticals in the left atrial appendage, and a transseptal wire designed to and is capable of precisely puncturing the cardiac interatrial septum.

9. The transseptal insertion device of claim 7 wherein the sheath includes a side port proximal to the positioning balloons, wherein an additional catheter or wire advances into the cardiac interatrial septum through the side port and the additional catheter or wire is capable of capturing the wire member.

10. A method for suitably facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal insertion device, comprising:

inflating one or more positioning balloons connected to a distal end of a sheath of the transseptal insertion device, wherein the one or more positioning balloons, when inflated and the transseptal insertion device is in use, overhang and extend past the distal end of the sheath, and the sheath includes one or more hypotubes respectively connected to the one or more positioning balloons to inflate and deflate the one or more positioning balloons;

advancing a puncture member while the positioning balloons are inflated, wherein the puncture member is movably positioned within at least one lumen of the sheath, and wherein a puncture member balloon is located on a distal end of the puncture member and the puncture member includes at least one puncture member tube connected to the puncture member balloon to inflate and deflate the puncture member balloon;

positioning the puncture member against the cardiac interatrial septum;

deflating the one or more positioning balloons;

further advancing the puncture member to puncture the cardiac interatrial septum; and

advancing the transseptal insertion device crossing the cardiac interatrial septum.

11. The method of claim 10 wherein the one or more positioning balloons are inflated by gas or fluid supplied through the one or more hypotubes, and the one or more positioning balloons and the puncture member balloon are inflated and deflated independently of each other.

12. The method of claim 10 wherein the one or more hypotubes comprises one or more inflation hypotubes to inflate the one or more positioning balloons, and one or more deflation hypotubes to deflate the one or more positioning balloons.

13. The method of claim 10 further comprising:

inflating the puncture member balloon once the puncture member advances beyond the distal end of the sheath and is tenting the cardiac interatrial septum, wherein the puncture member balloon is pressing against the cardiac interatrial septum while the puncture member is tenting the cardiac interatrial septum; and

deflating the puncture member balloon before said further advancing the puncture member to puncture the cardiac interatrial septum.

14. The method of claim 13 wherein the puncture member balloon, when inflated, is positioned at a predetermined distance from a tip of the distal end of the puncture member to prevent the puncture member from being pushed beyond the predetermined distance while the puncture member balloon is pressing against the cardiac interatrial septum.

15. The method of claim 10 further comprising re-inflating the one or more positioning balloons to navigate in an atraumatic fashion to different parts of the left atrium after the distal end of the transseptal insertion device crosses the cardiac interatrial septum.

16. The method of claim 10 further comprising re-inflating the puncture member balloon to anchor the transseptal insertion device against the cardiac interatrial septum after the distal end of the transseptal insertion device crosses the cardiac interatrial septum.

17. The method of claim 10 further comprising delivering, via the one or more positioning balloons, energy in the form of heat or using the one or more positioning balloons for cryoablation with fluid that is circulated through the one or more positioning balloons.

18. The method of claim 10 further comprising advancing a wire member beyond a tip of the distal end of the puncture member after the distal end of the transseptal insertion device crosses the cardiac interatrial septum, wherein the wire member movably positioned in a center lumen formed in the puncture member.

19. The method of claim 18 further comprising advancing an additional catheter or wire into the cardiac interatrial septum, wherein the sheath includes a side port proximal to the positioning balloons, and the additional catheter or wire advances through the side port; and

capturing the wire member with the additional catheter or wire forming a loop with the captured wire member.

20. The method of claim 18 wherein the wire member is one selected from a group consisting of a Brockenbrough needle, a radiofrequency tip needle, a radiofrequency wire, a pigtail catheter that delivers fluid or pharmaceuticals in the left atrial appendage, and a transseptal wire designed to and is capable of precisely puncturing the cardiac interatrial septum.

FIG. 1A

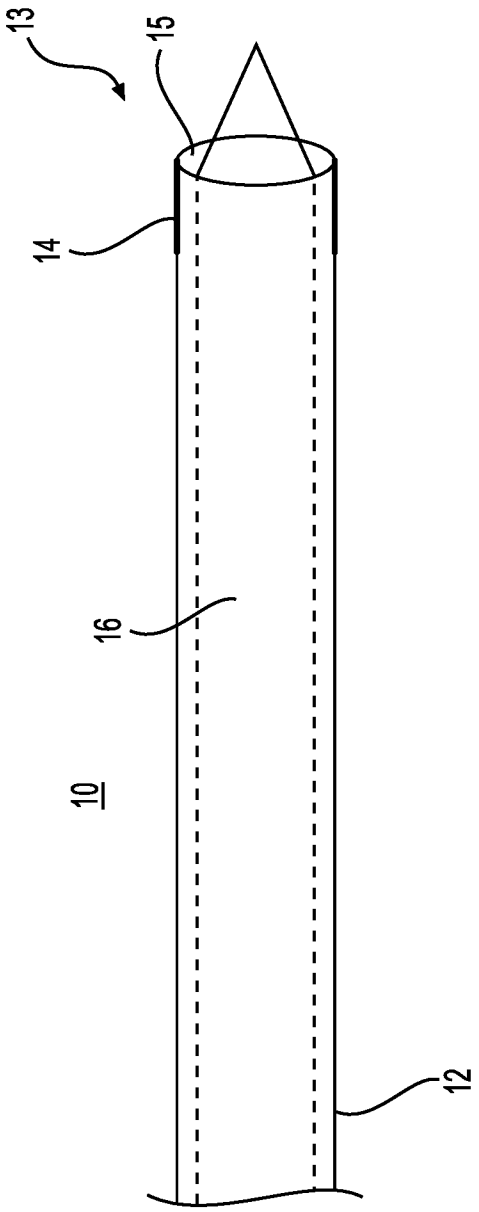


FIG. 1B

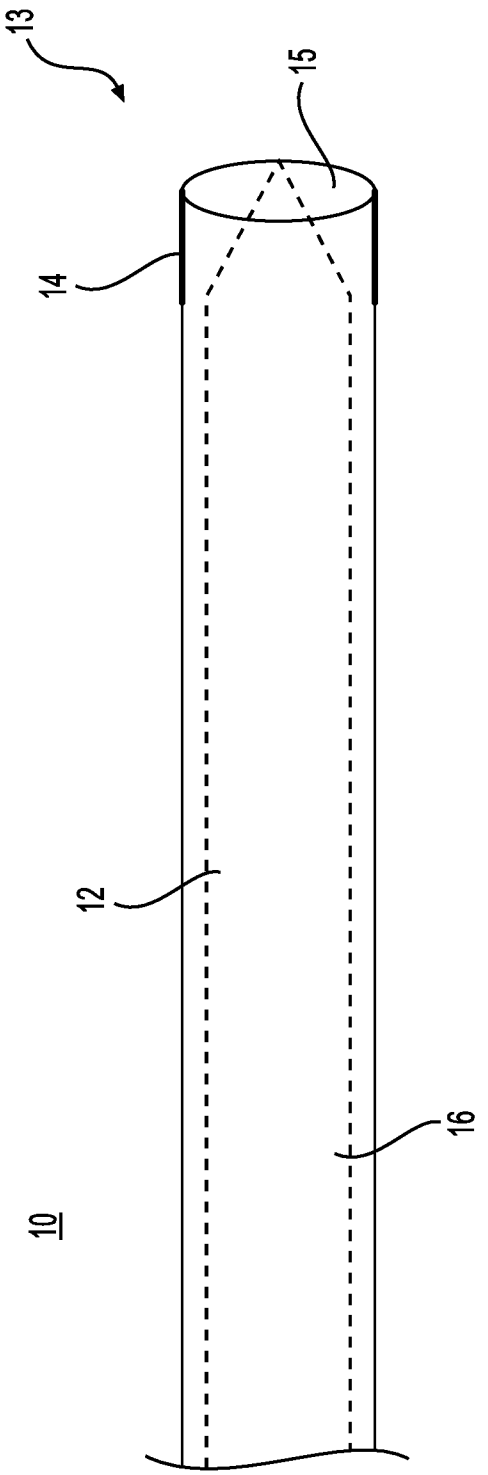


FIG. 1C

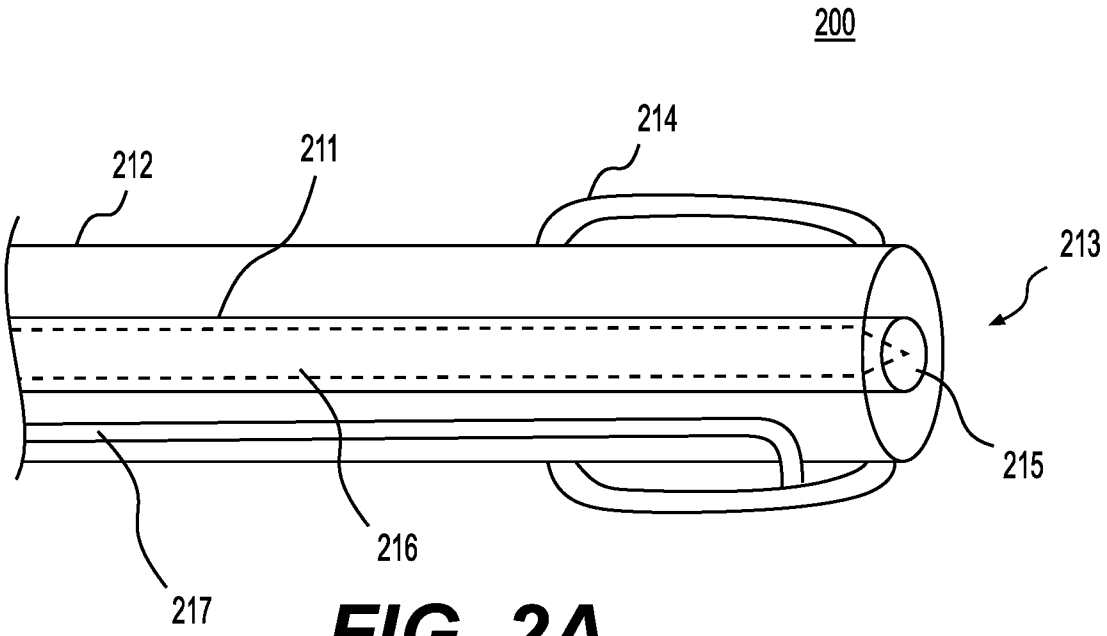


FIG. 2A

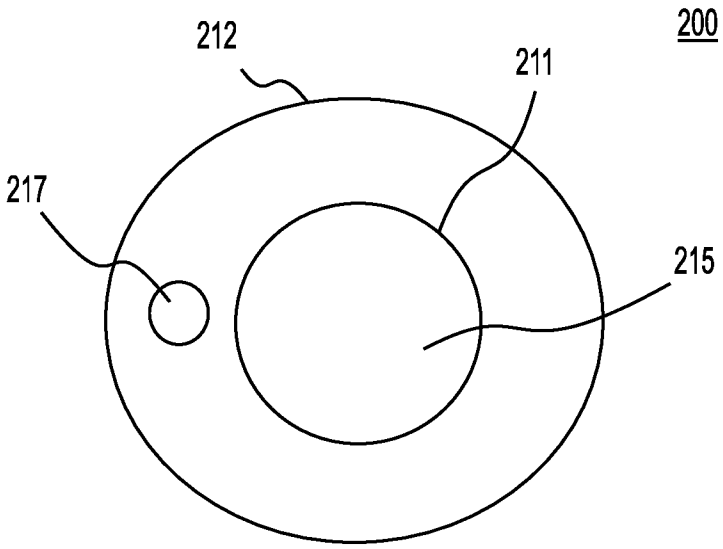


FIG. 2B

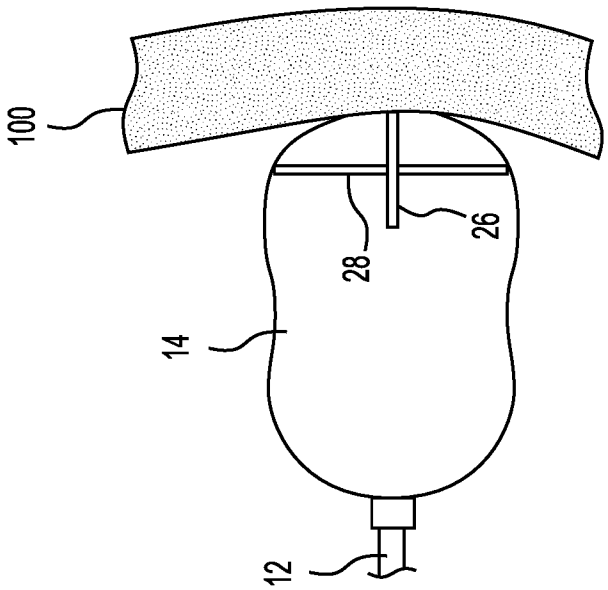


FIG. 2D

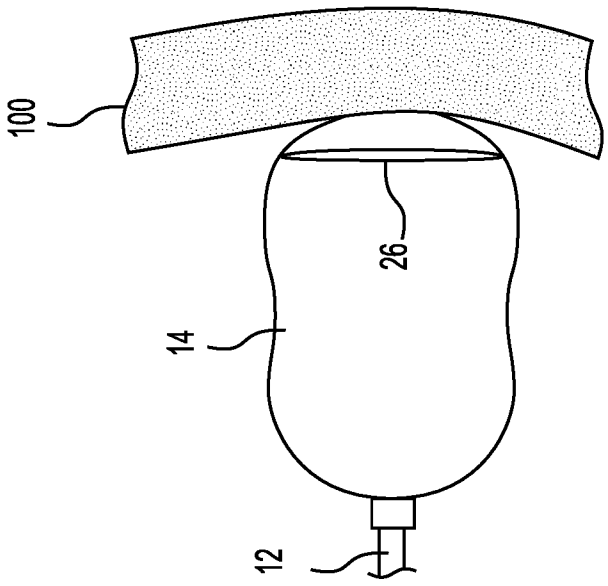


FIG. 2C

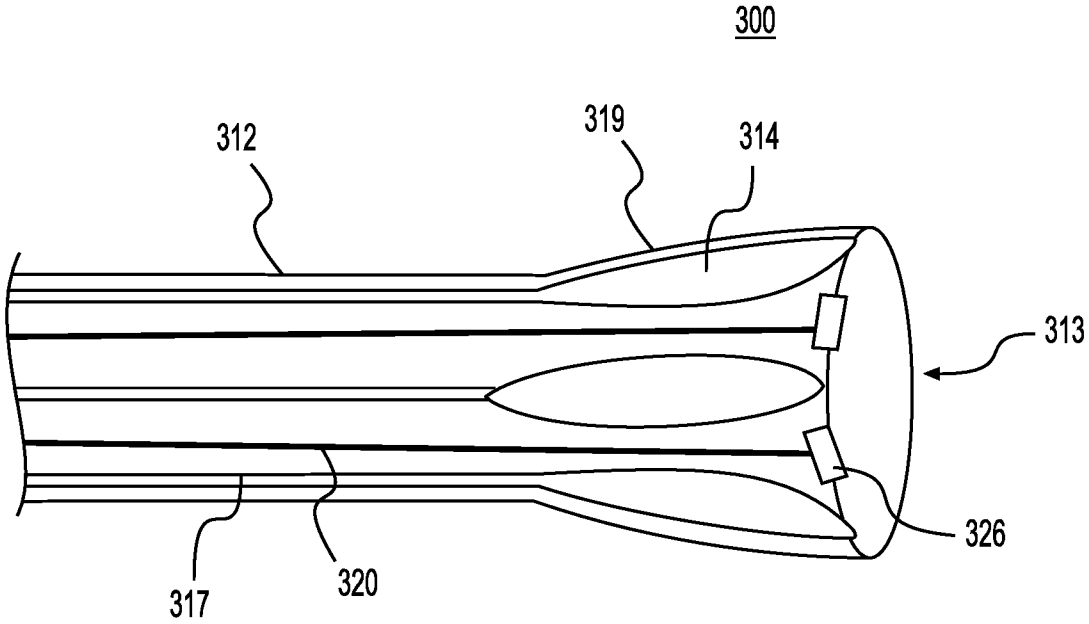


FIG. 3A

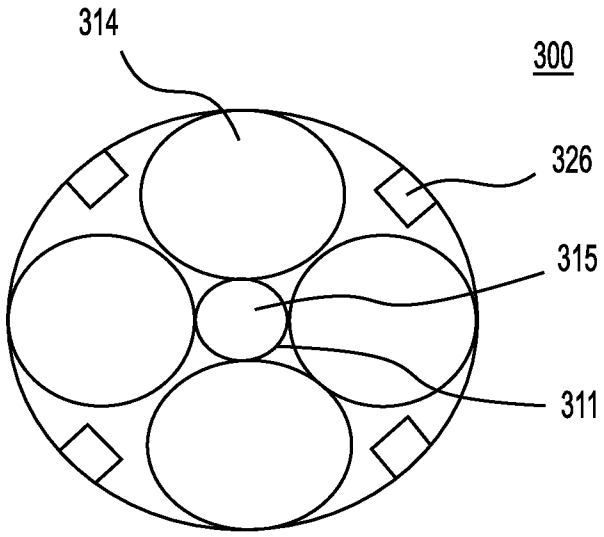


FIG. 3B

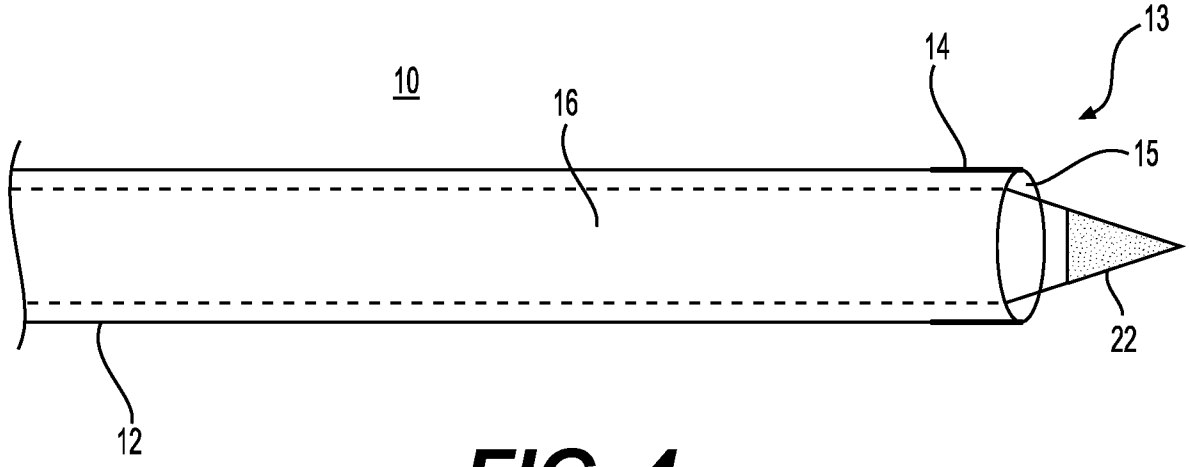


FIG. 4

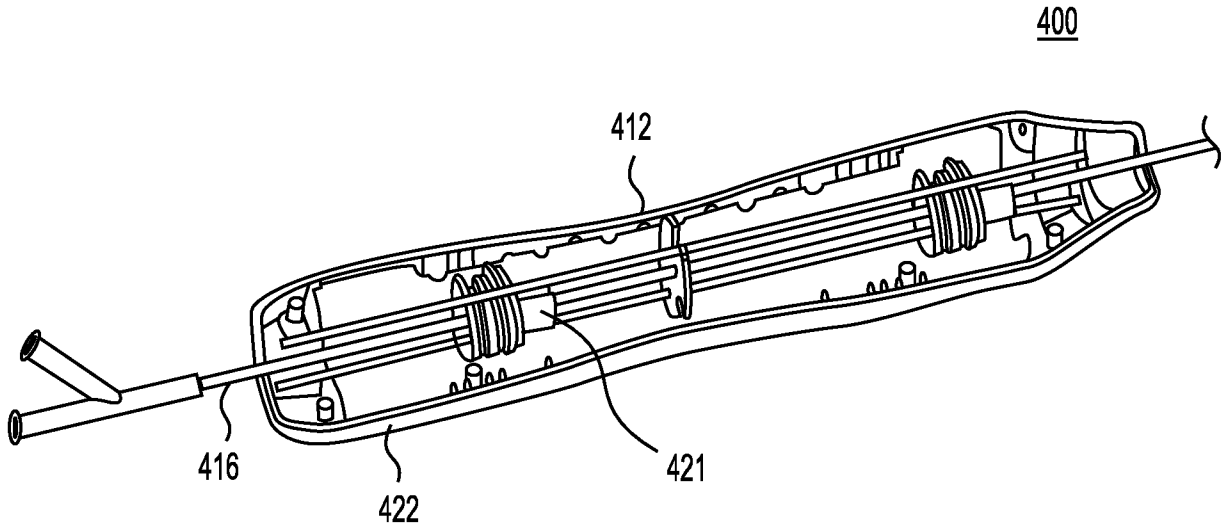


FIG. 5

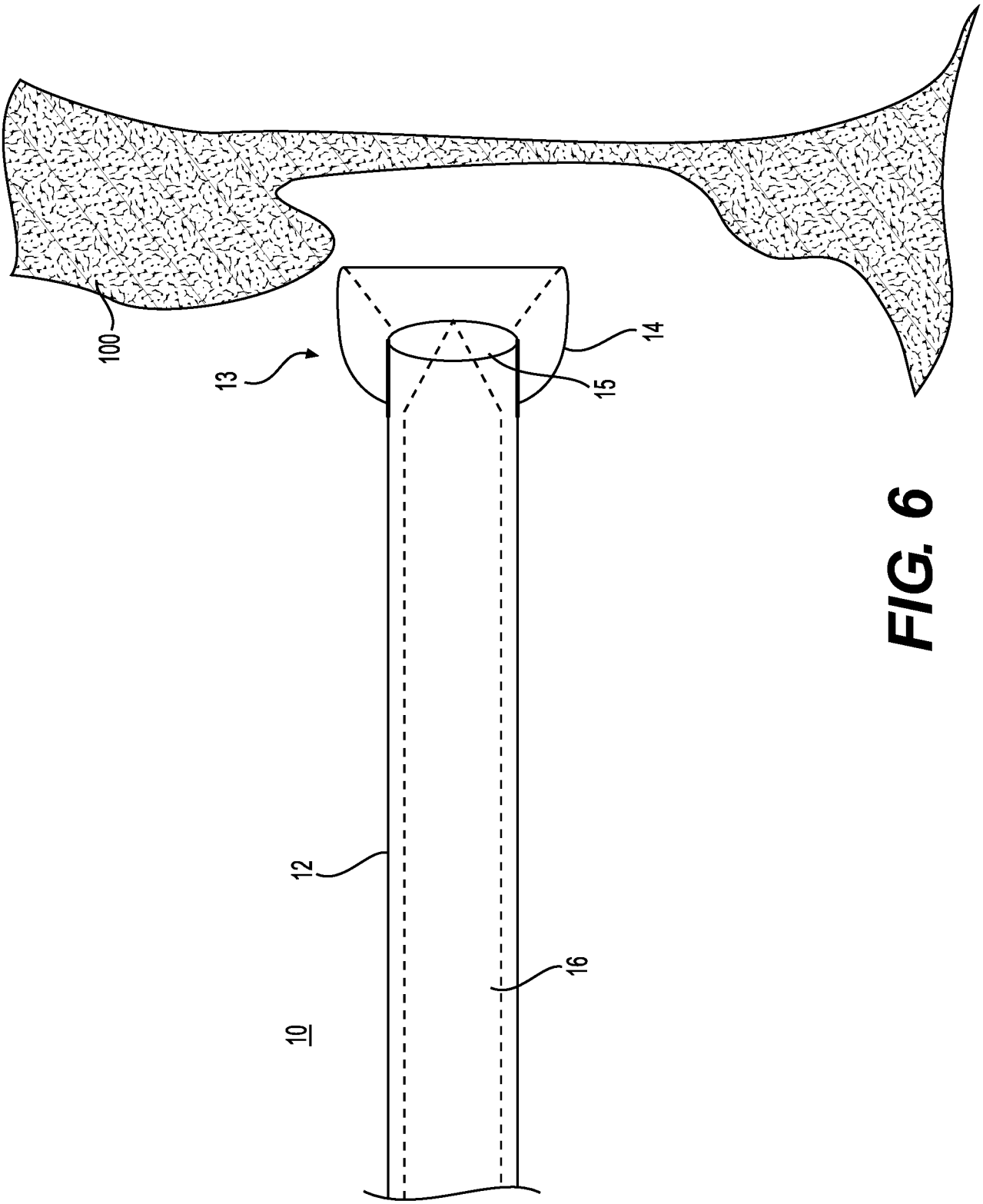


FIG. 6

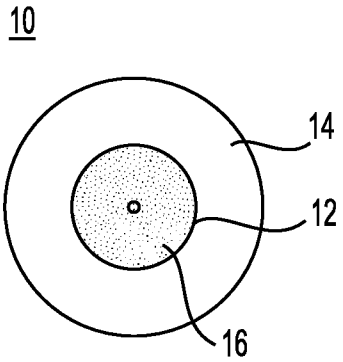


FIG. 7

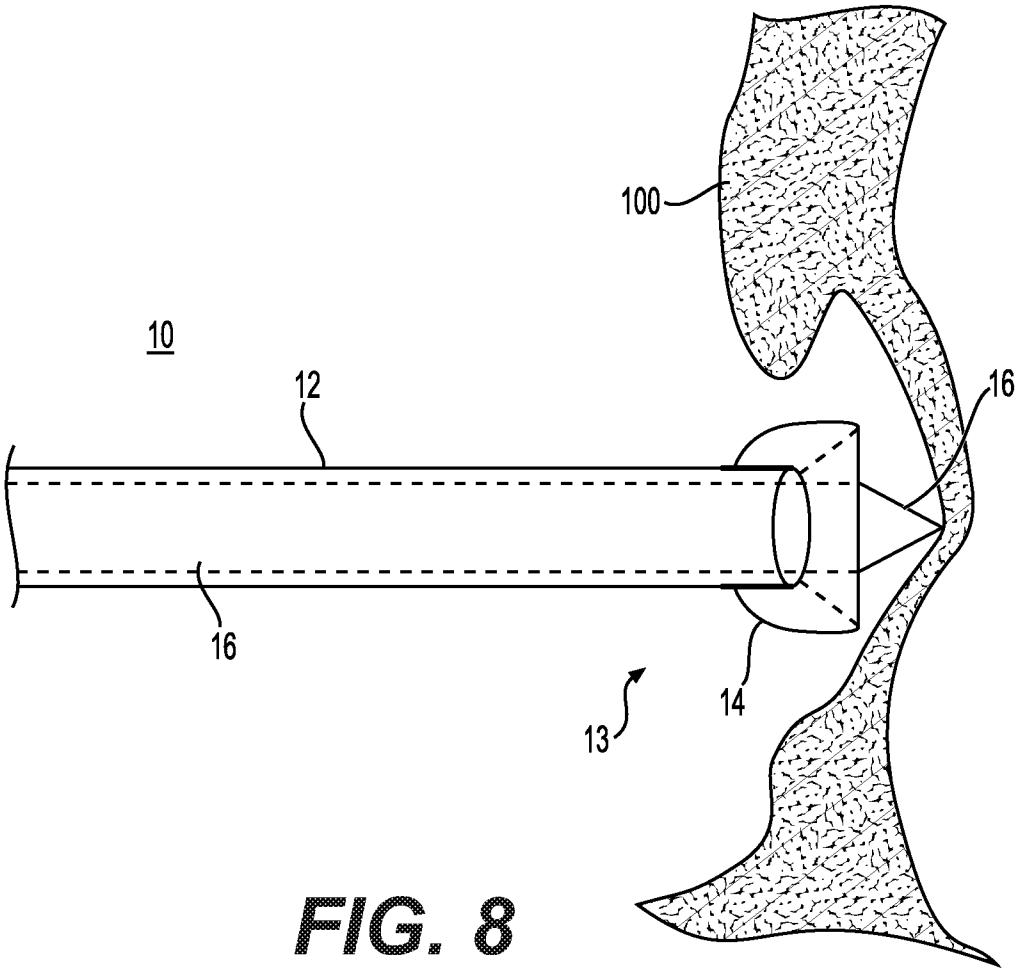


FIG. 8

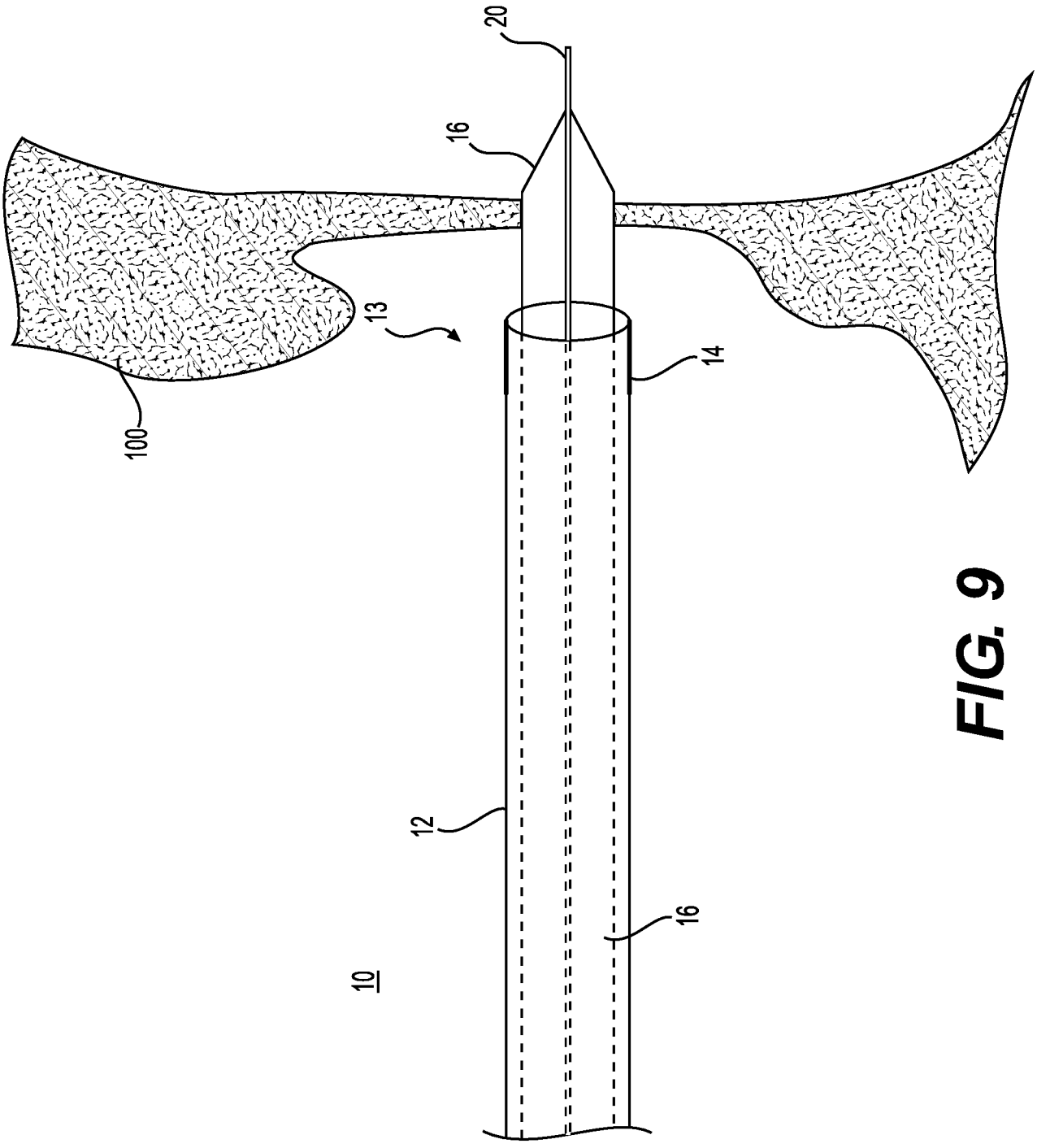


FIG. 9

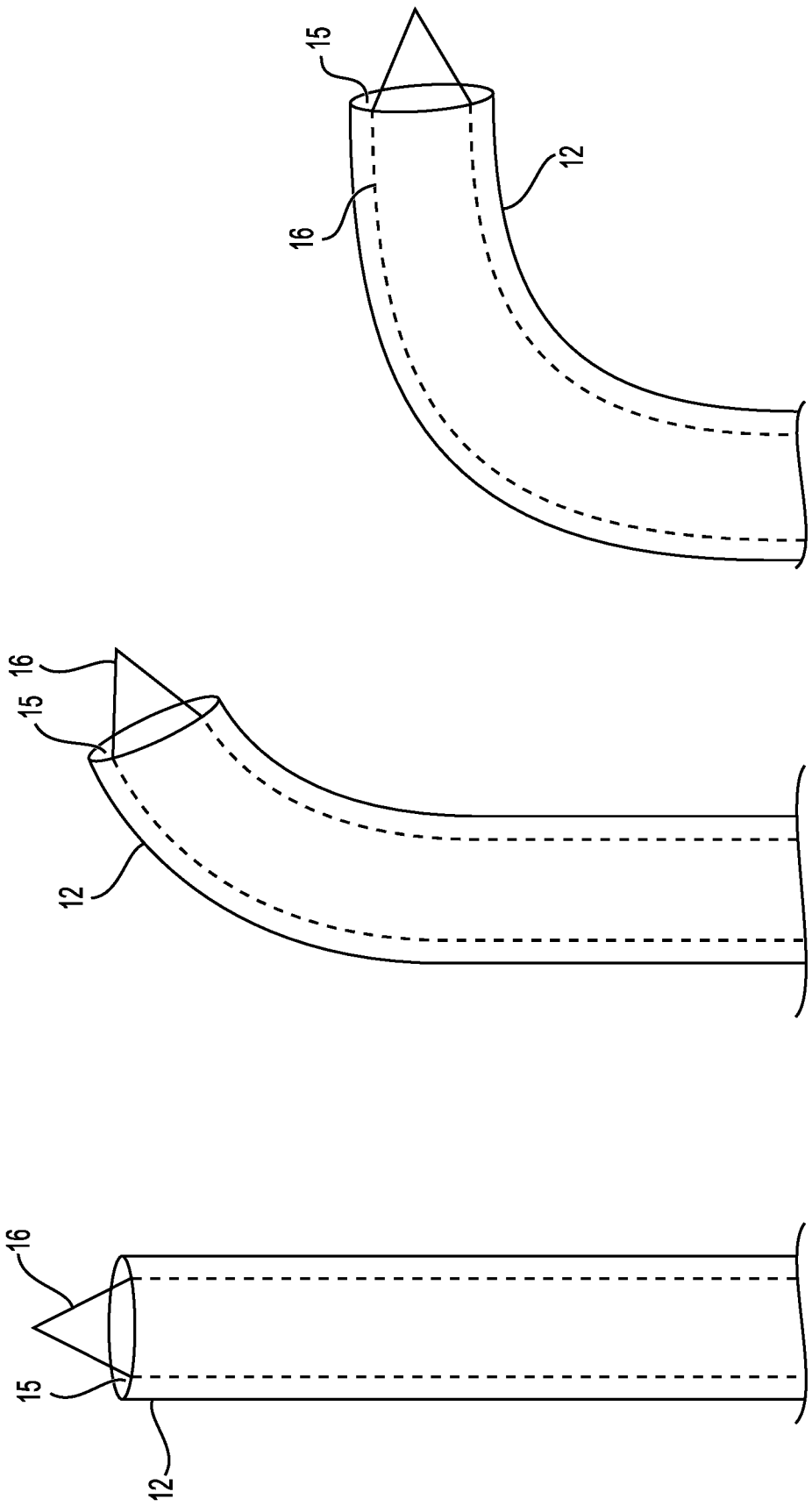


FIG. 10A

FIG. 10B

FIG. 10C

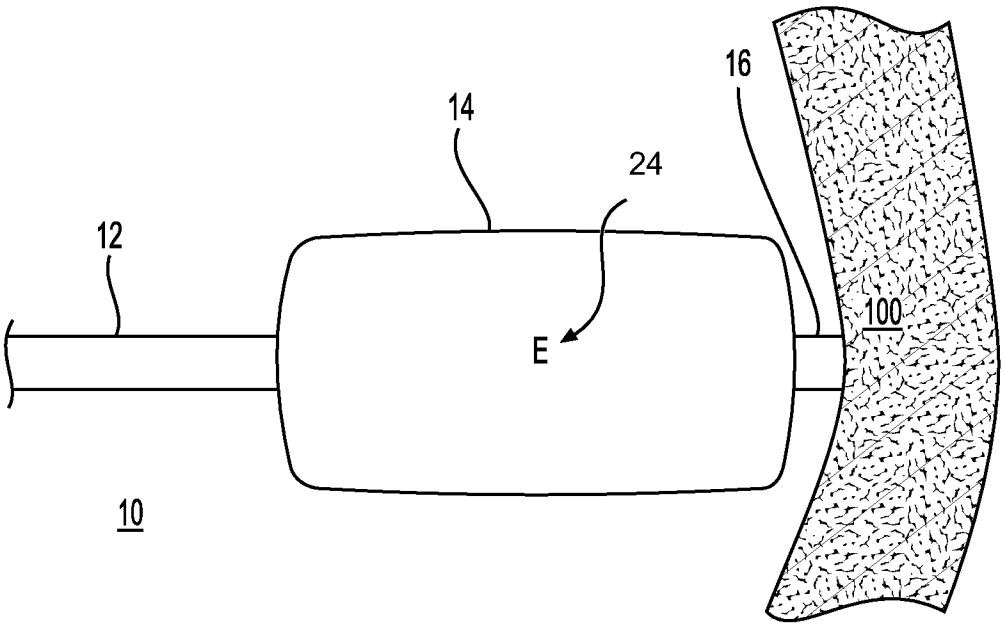


FIG. 11

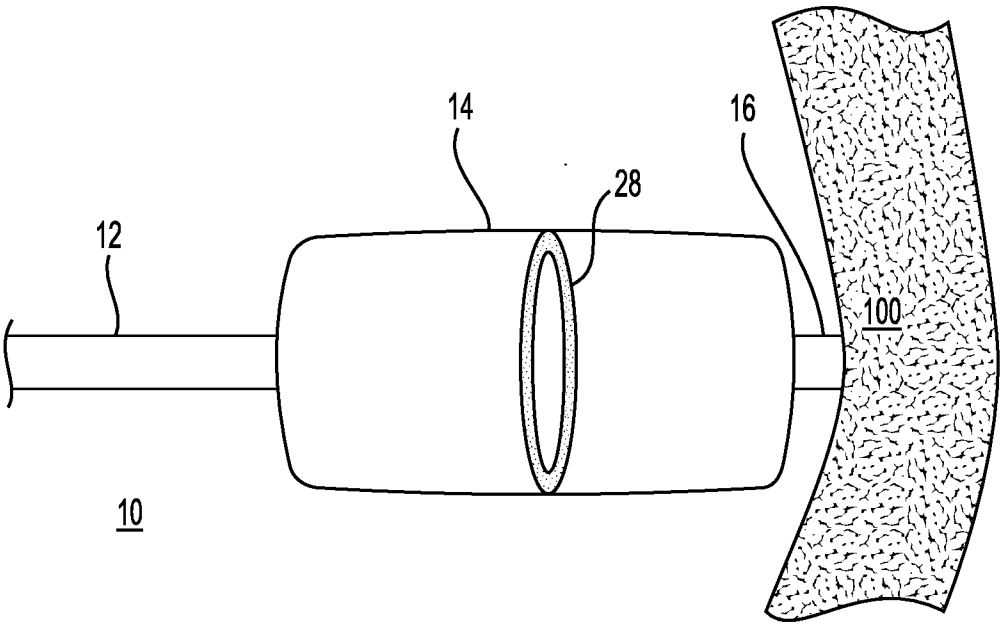


FIG. 12

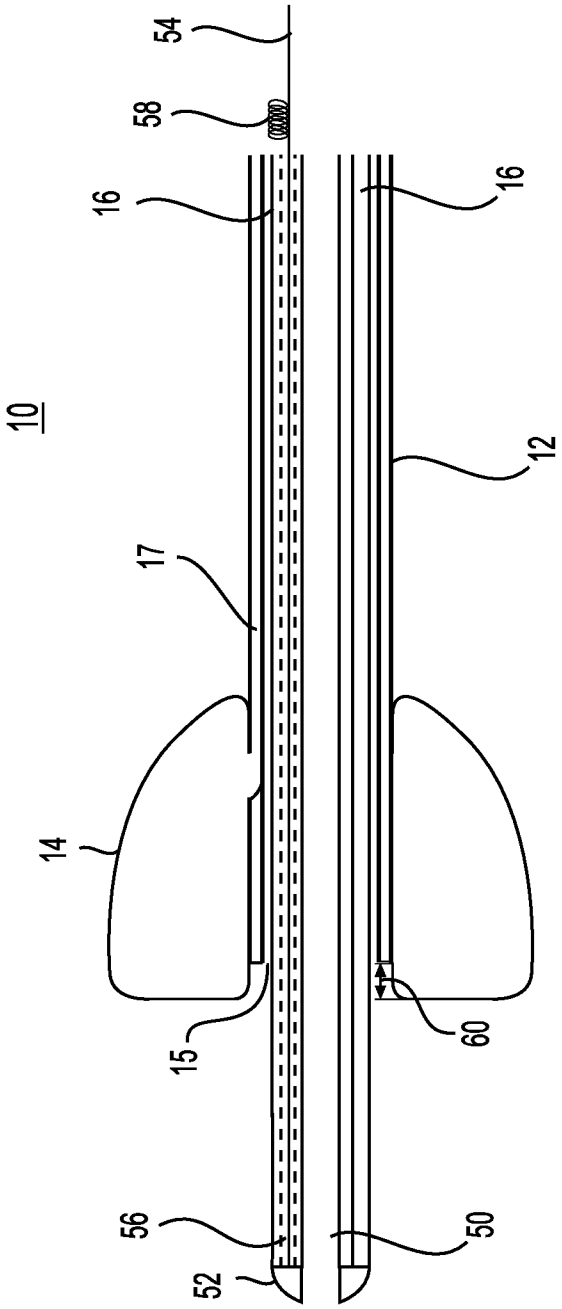


FIG. 13

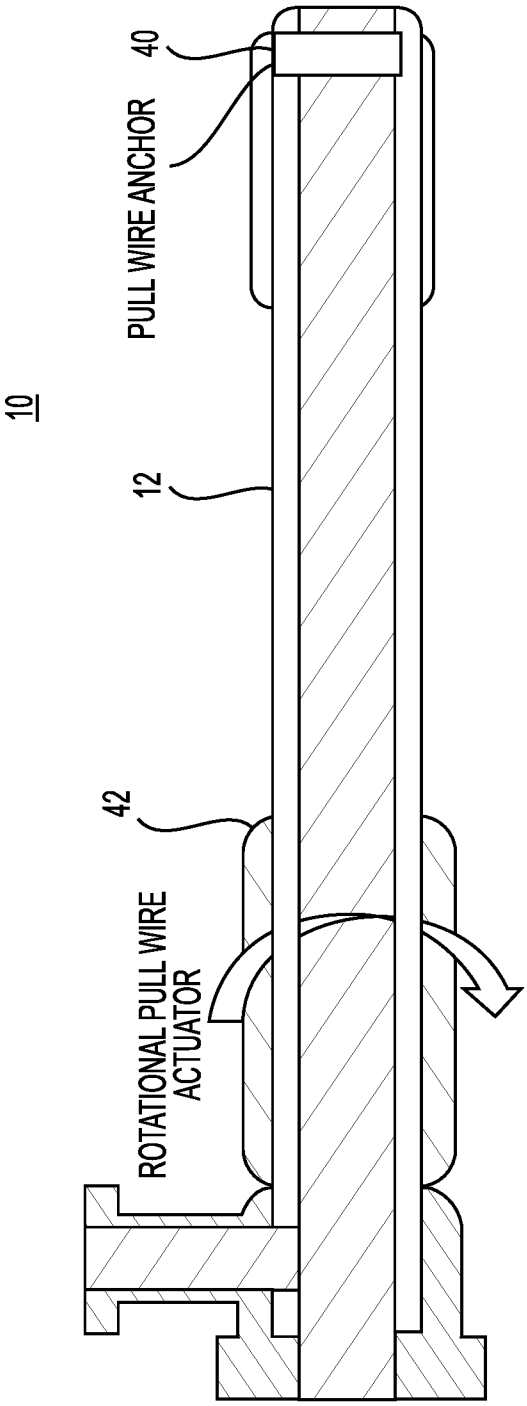


FIG. 14

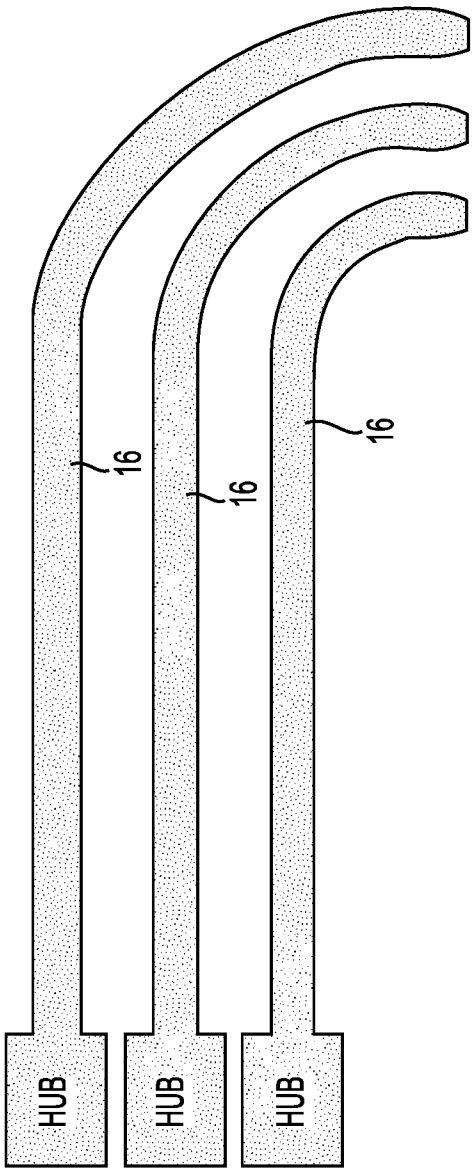


FIG. 15

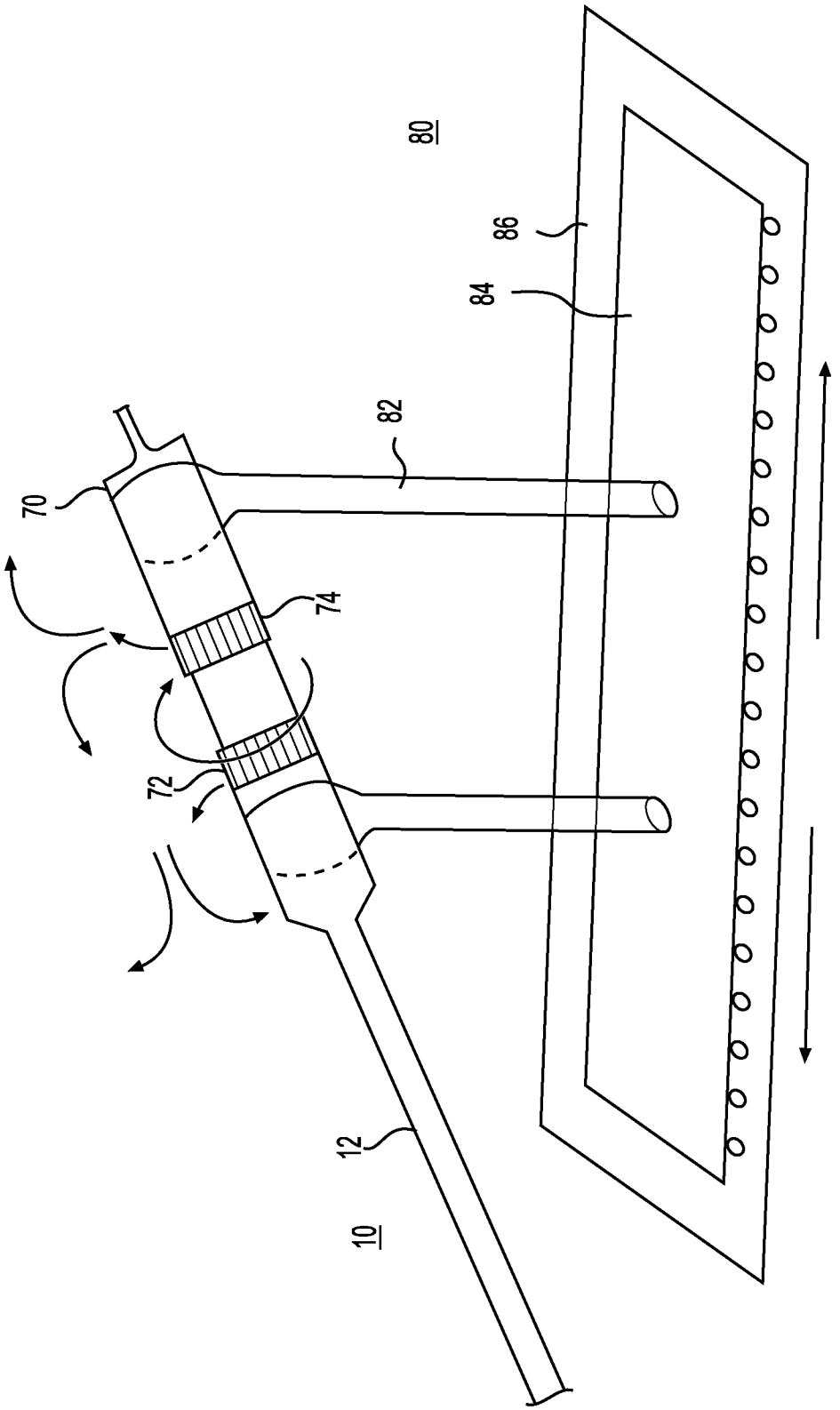


FIG. 16

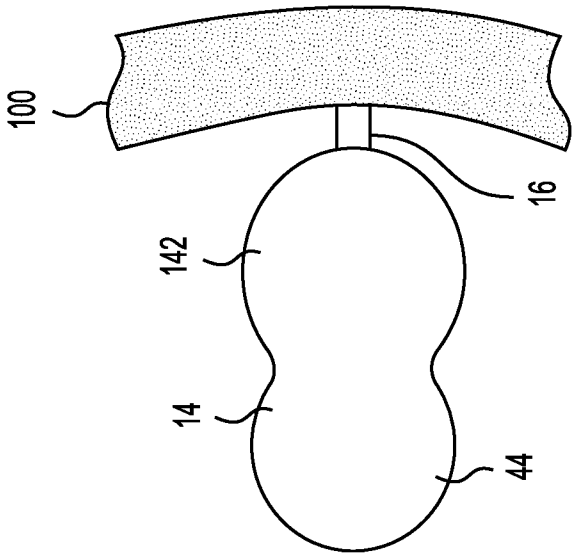


FIG. 17B

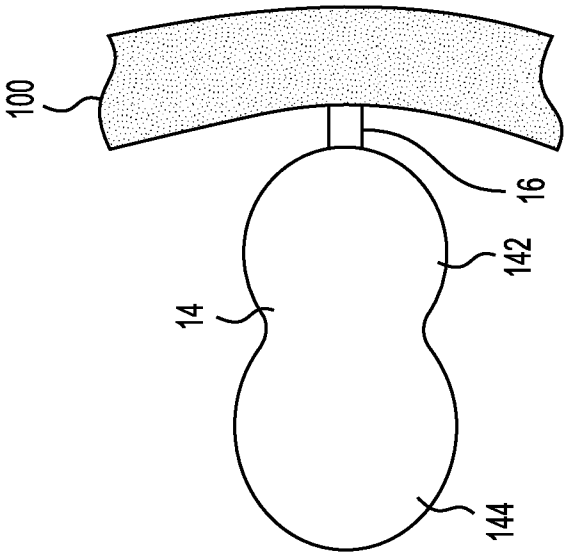


FIG. 17A

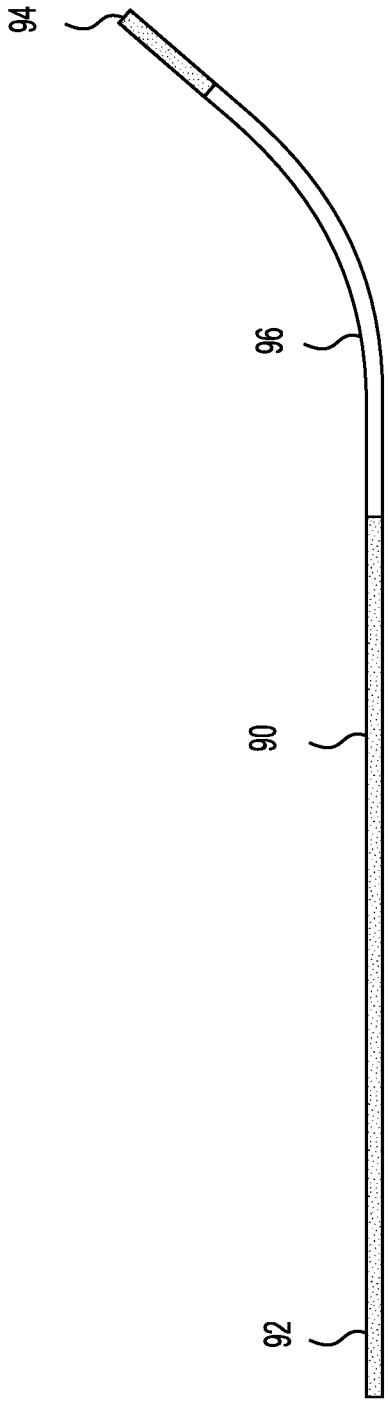


FIG. 18

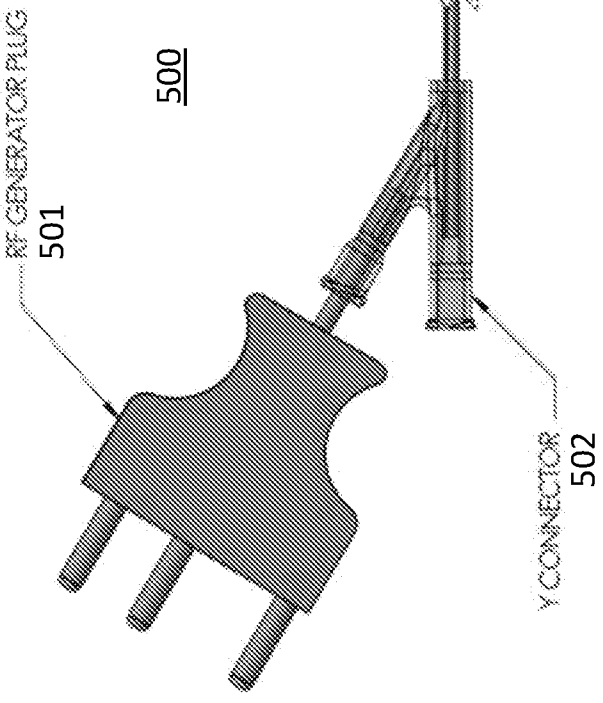


FIG. 19A

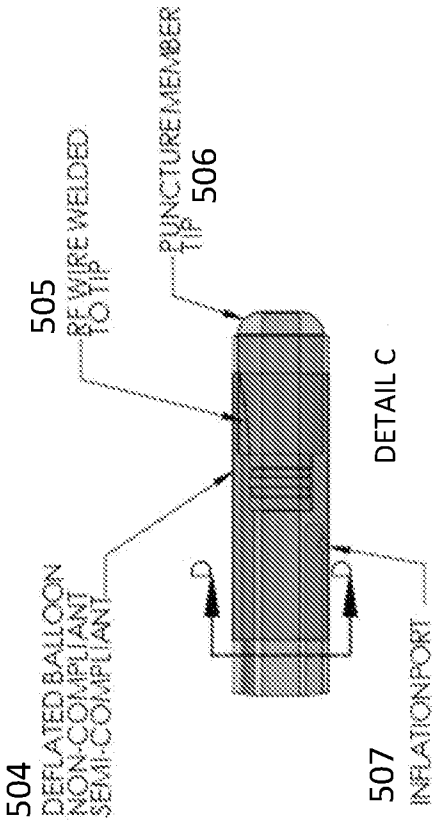


FIG. 19B

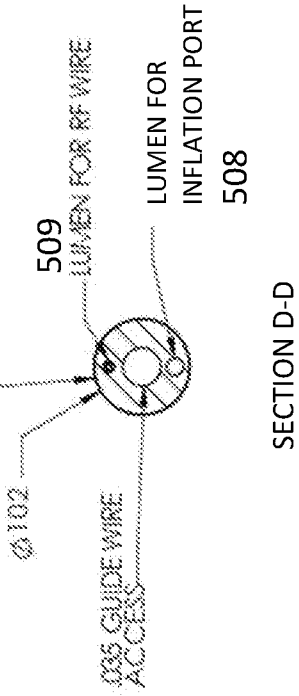


FIG. 19C

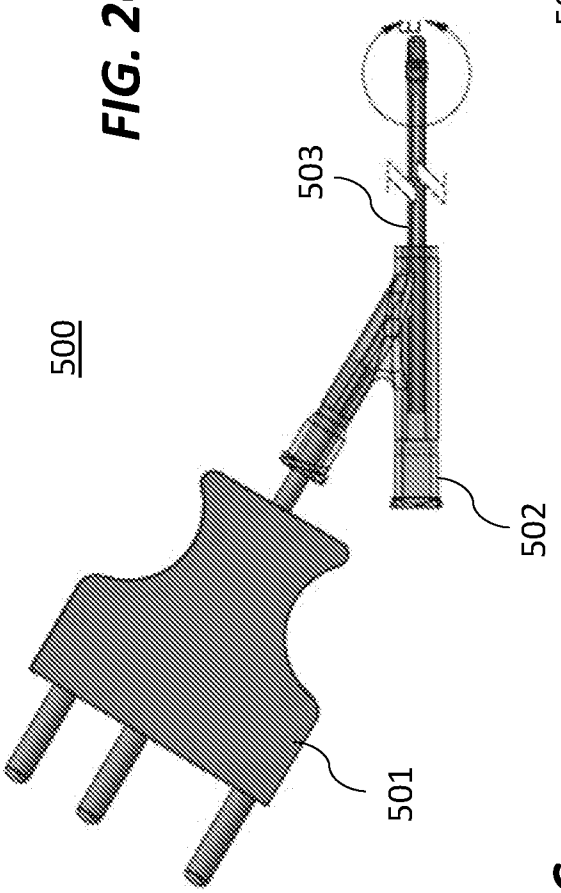


FIG. 20A

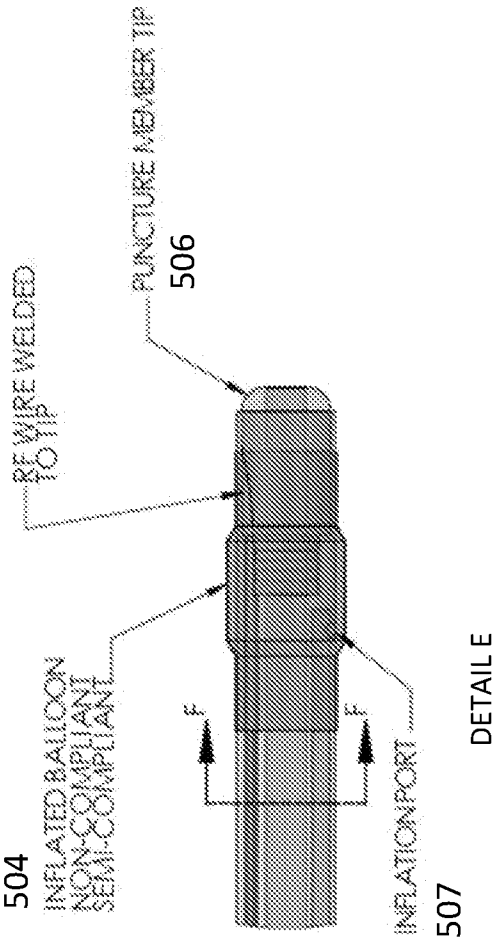


FIG. 20B

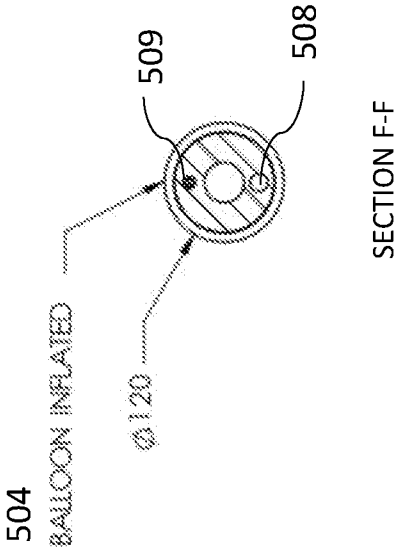


FIG. 20C

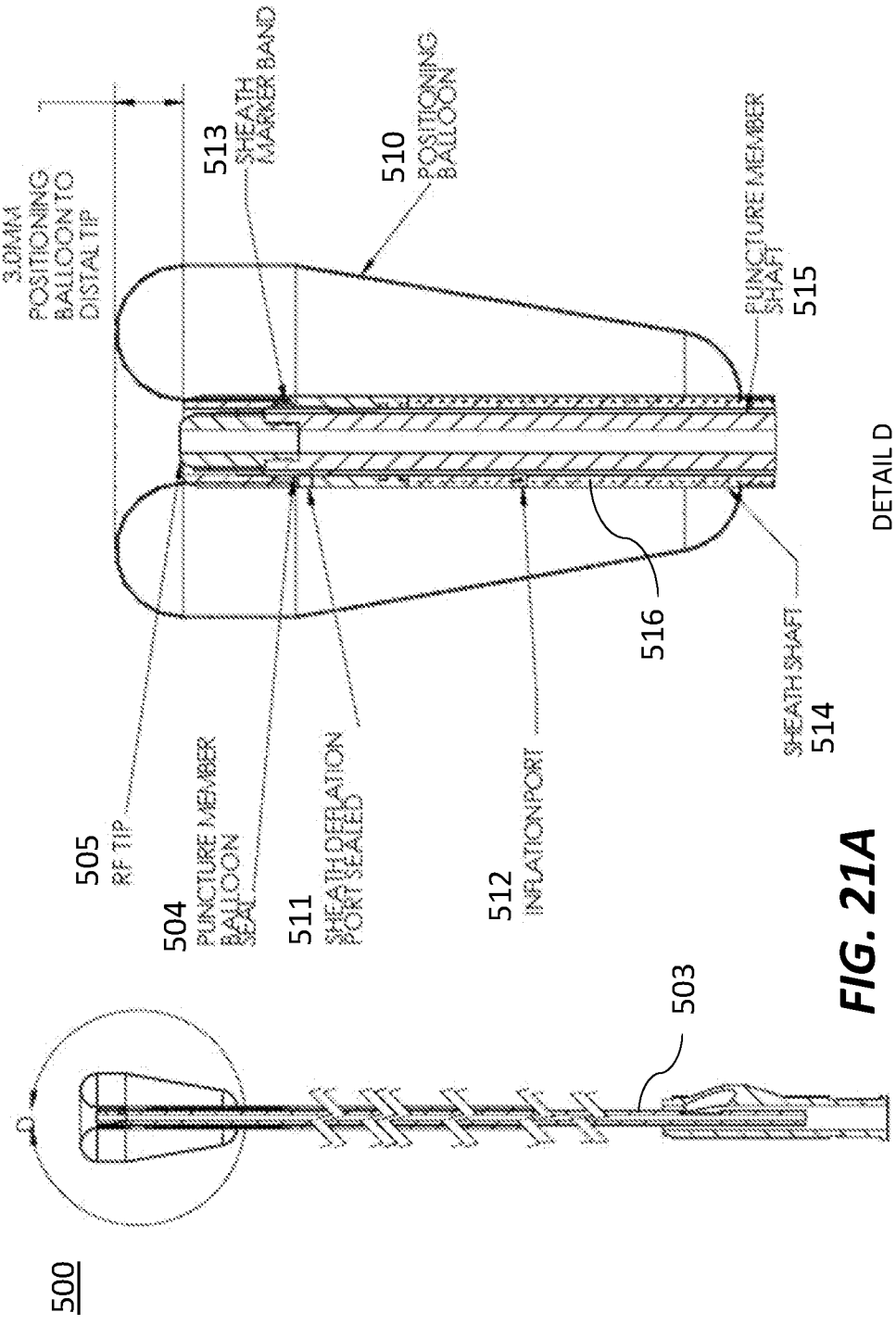


FIG. 21A

FIG. 21B

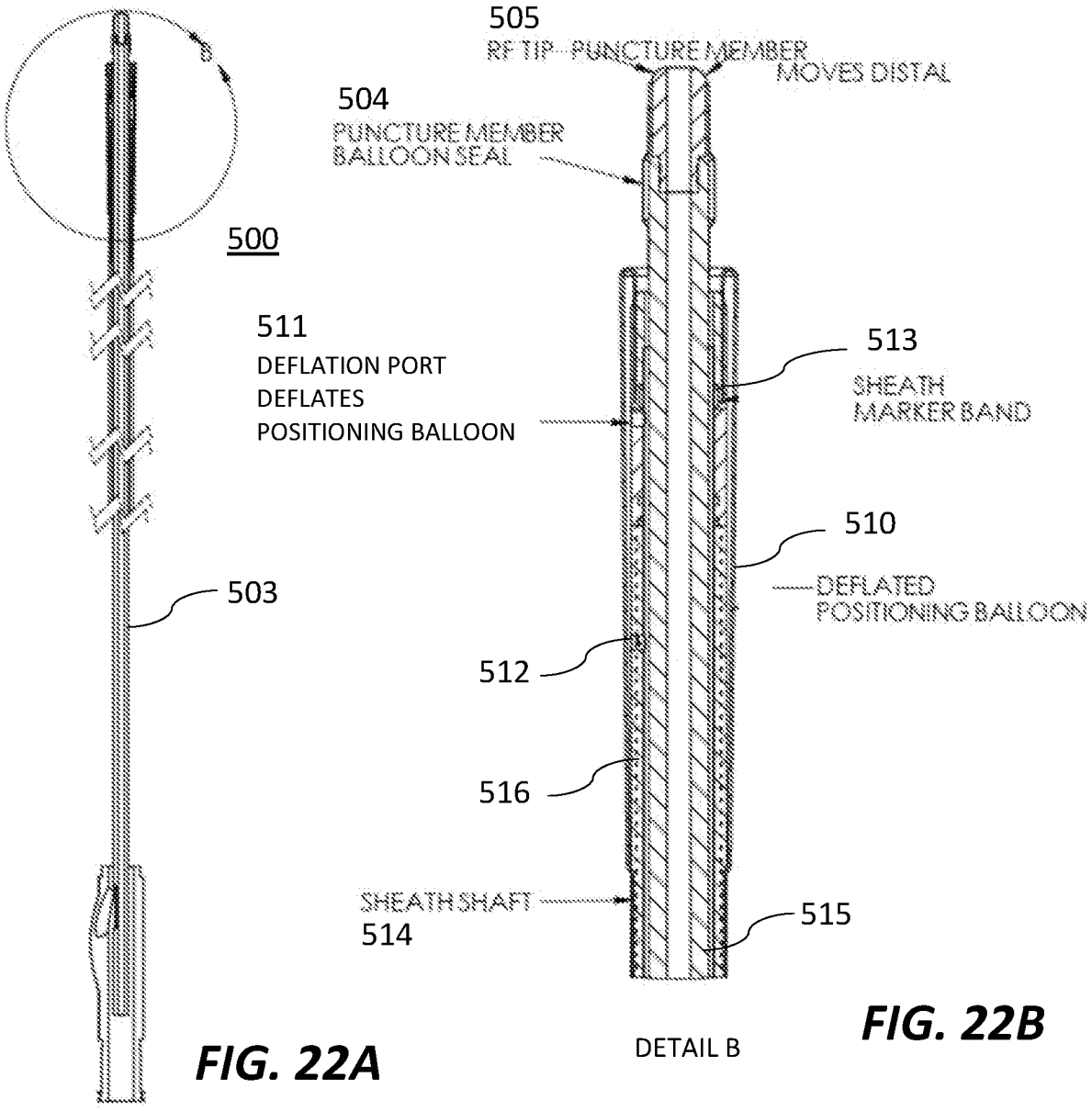


FIG. 22A

FIG. 22B

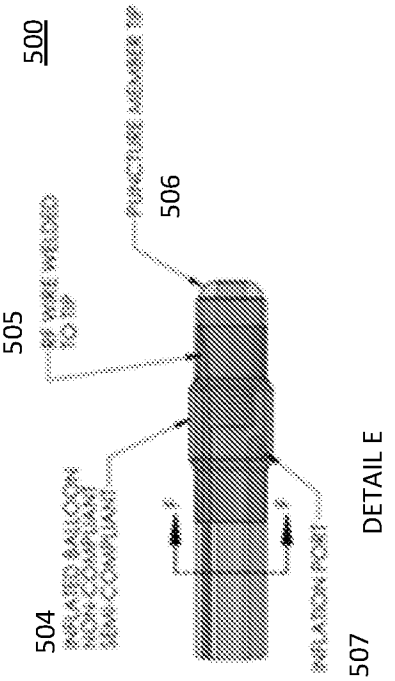


FIG. 23A

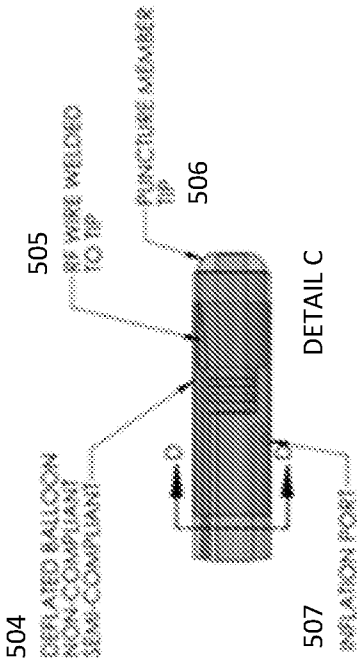


FIG. 23B

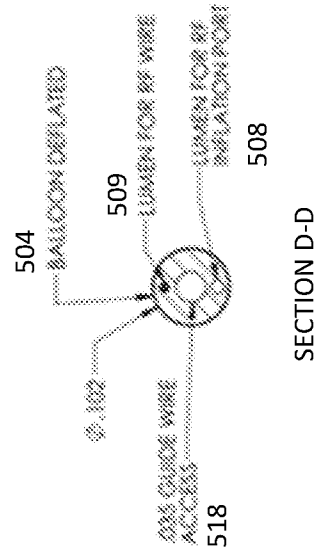
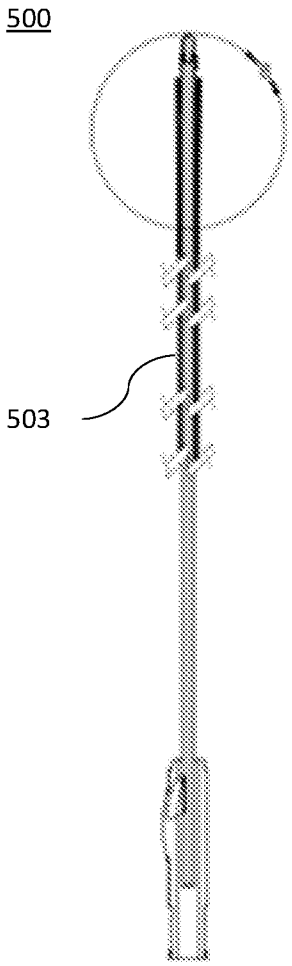
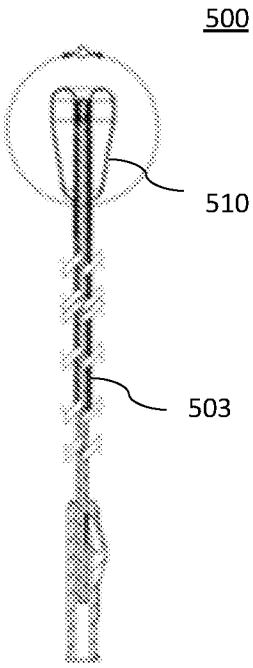


FIG. 23C



SECTION A-A

FIG. 24A



SECTION C-C

FIG. 24B

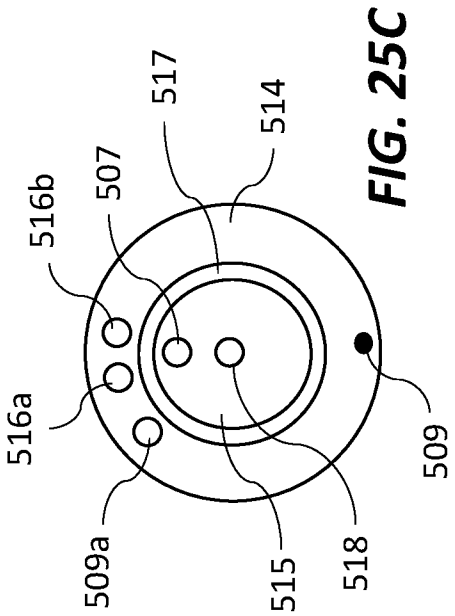


FIG. 25C

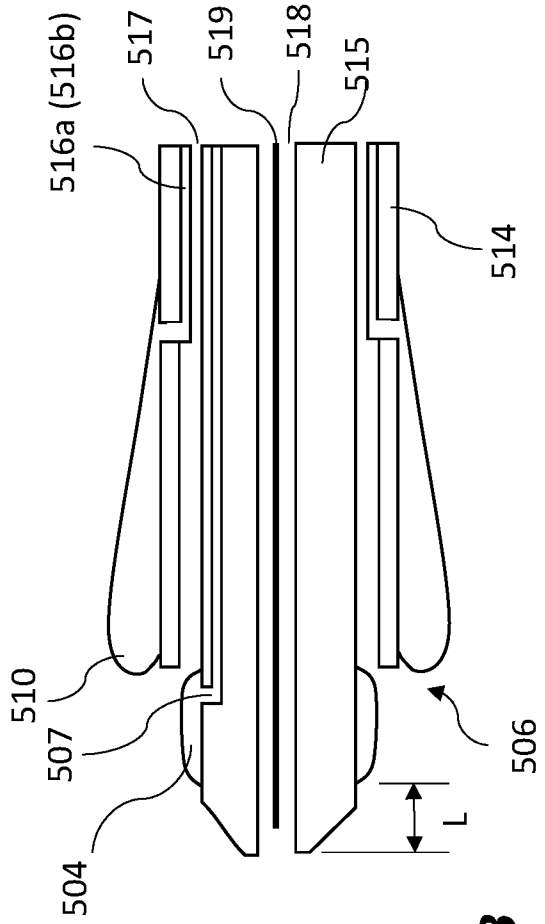


FIG. 25B

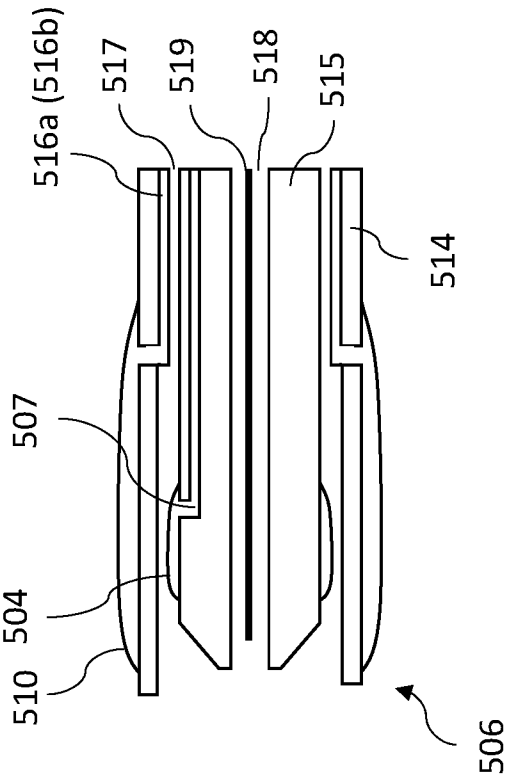


FIG. 25A

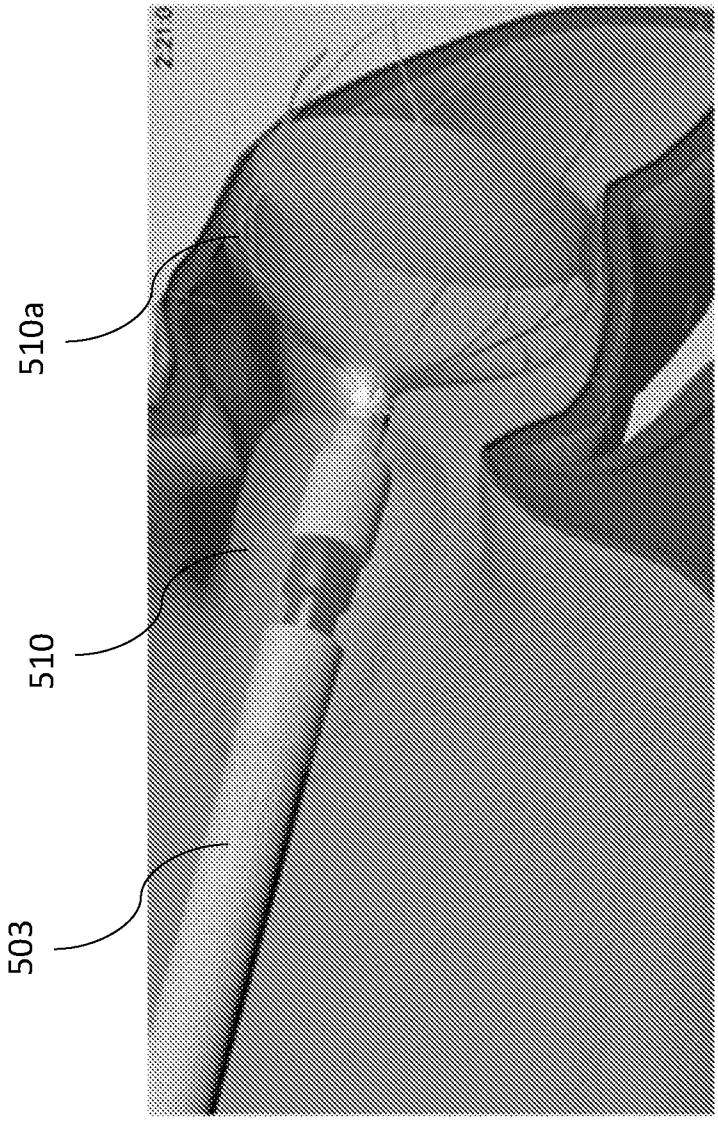


FIG. 26

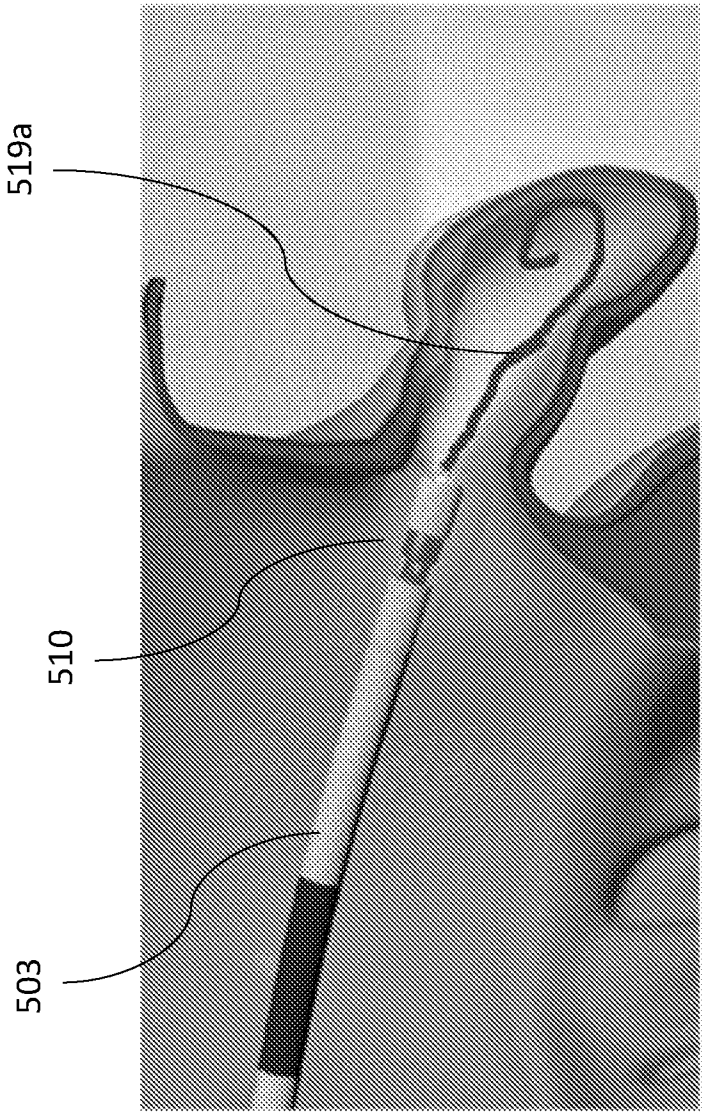


FIG. 27

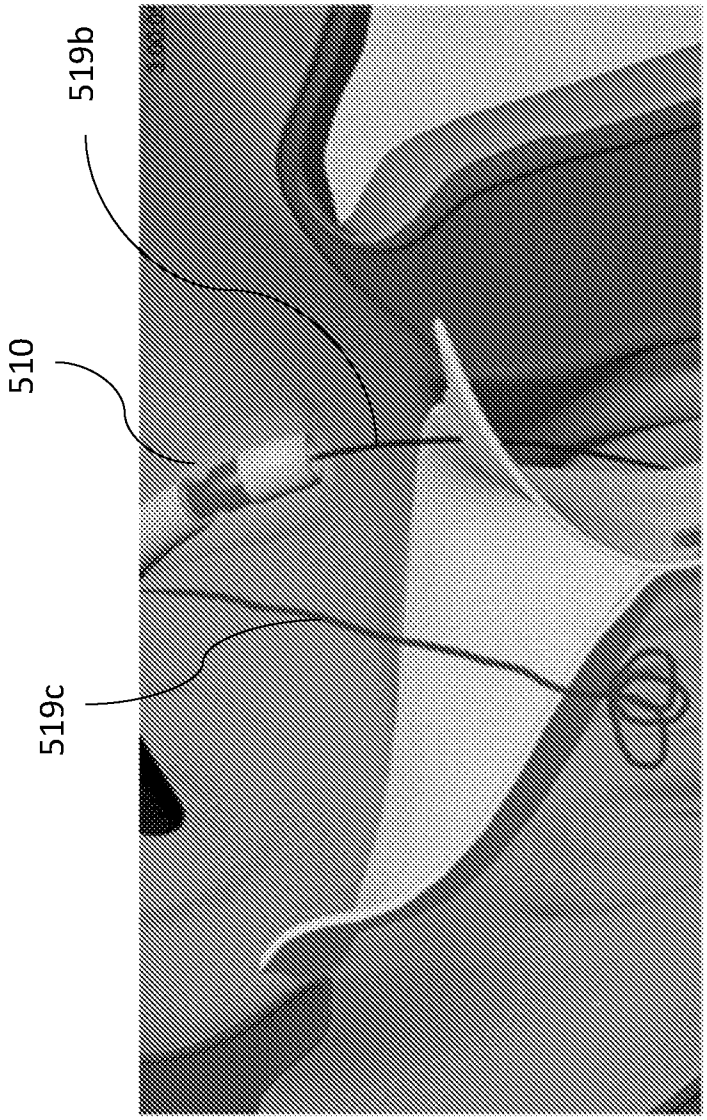


FIG. 28

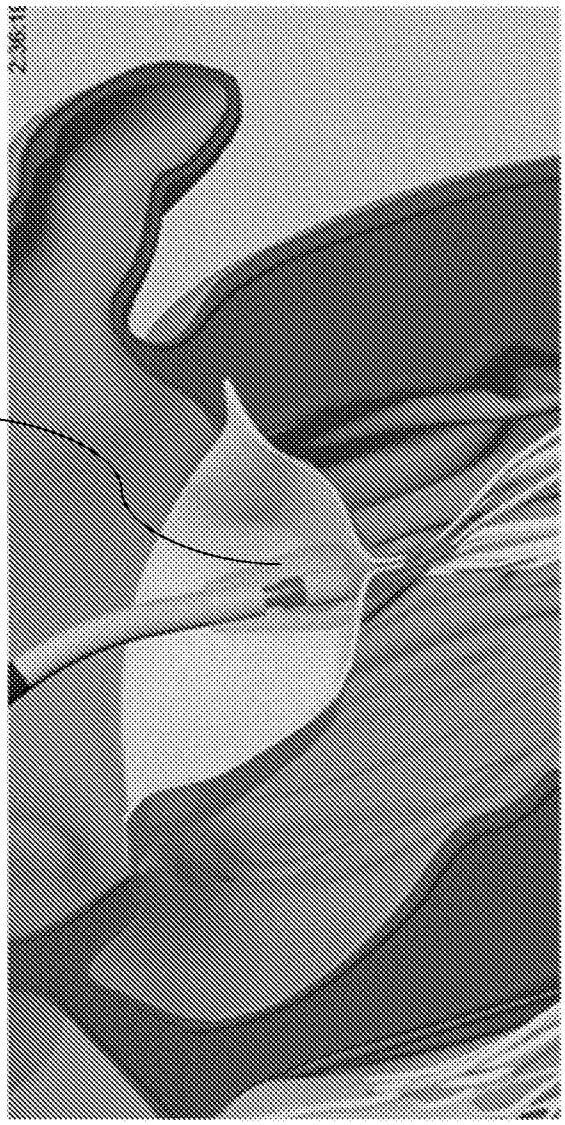


FIG. 29

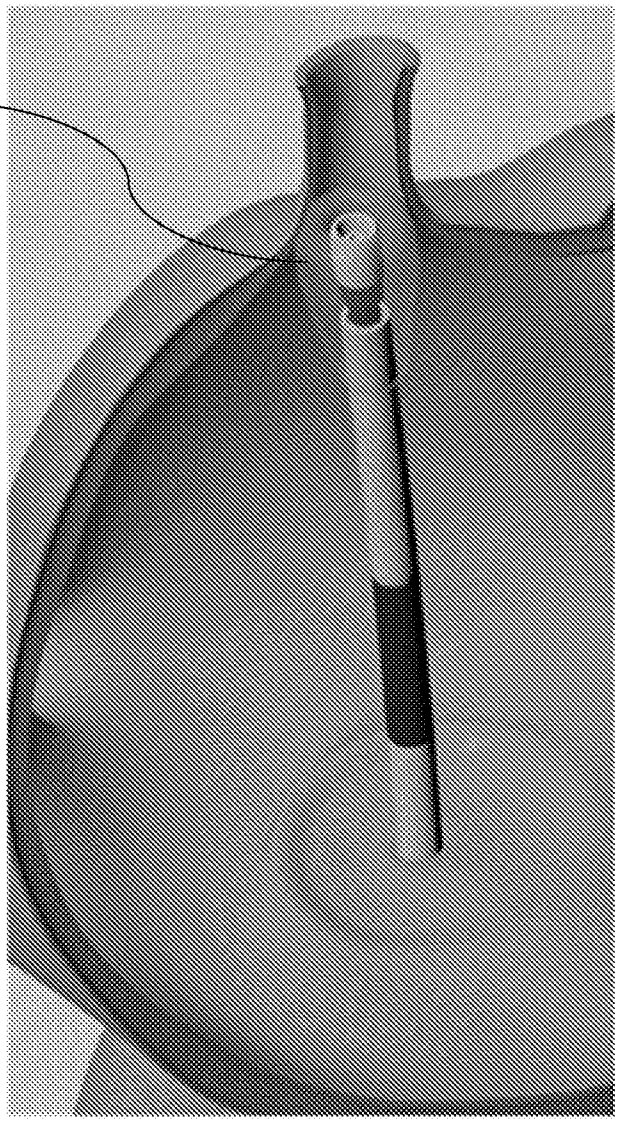


FIG. 30

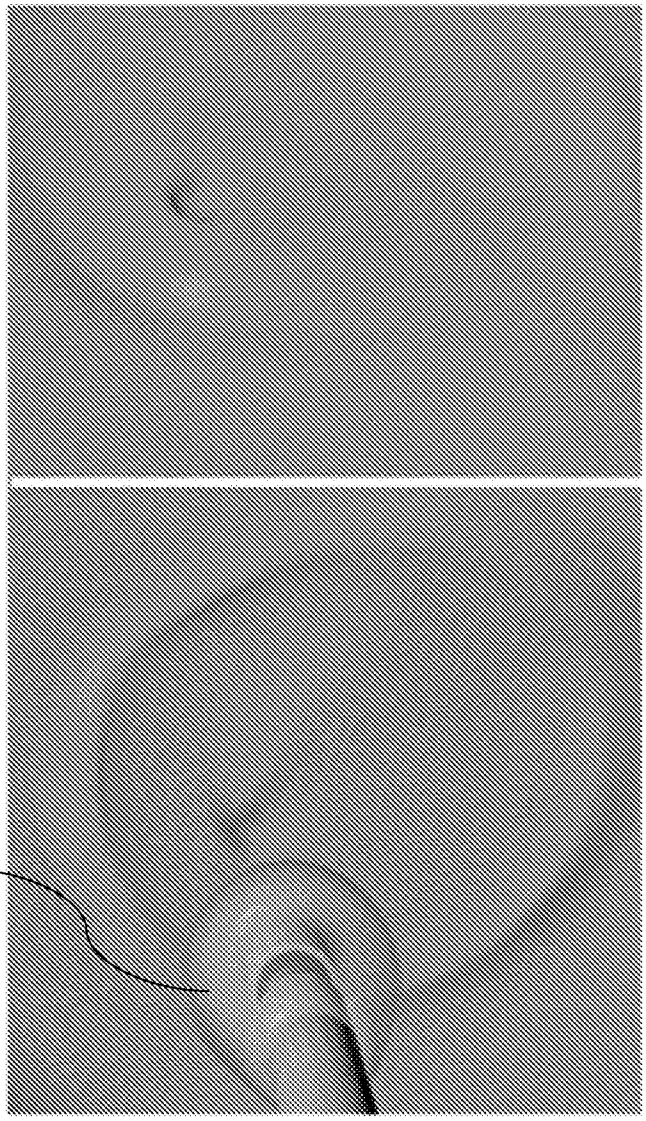


FIG. 31B

FIG. 31A

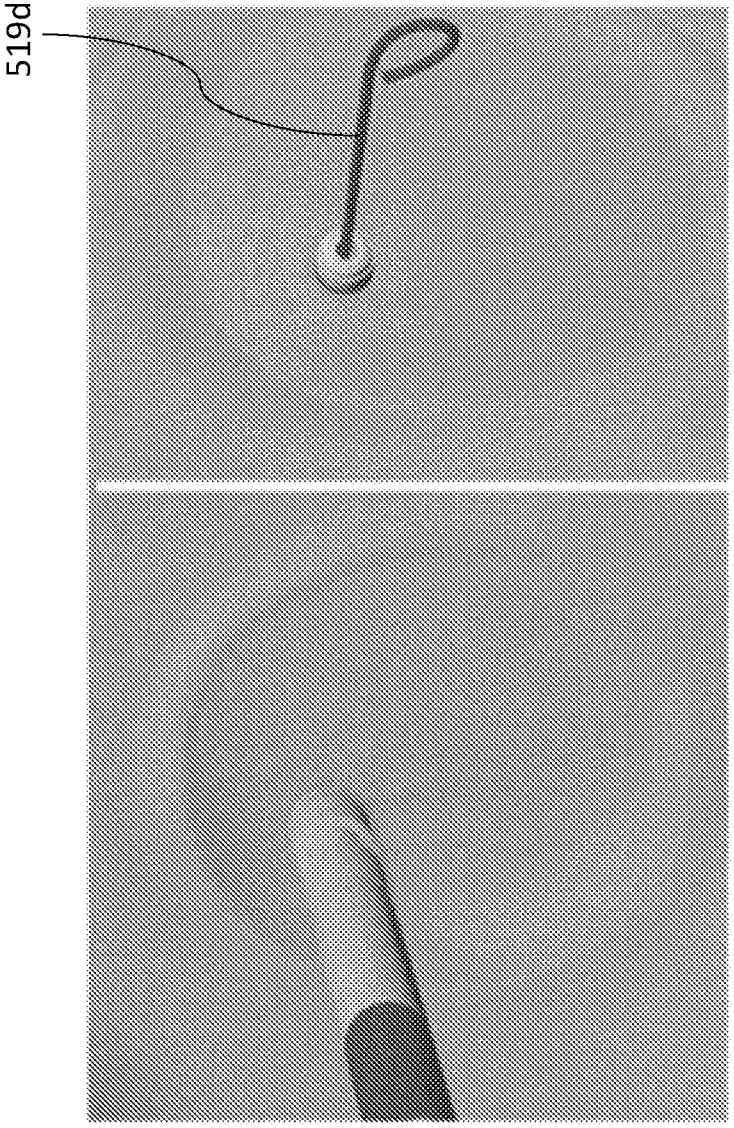


FIG. 32B

FIG. 32A

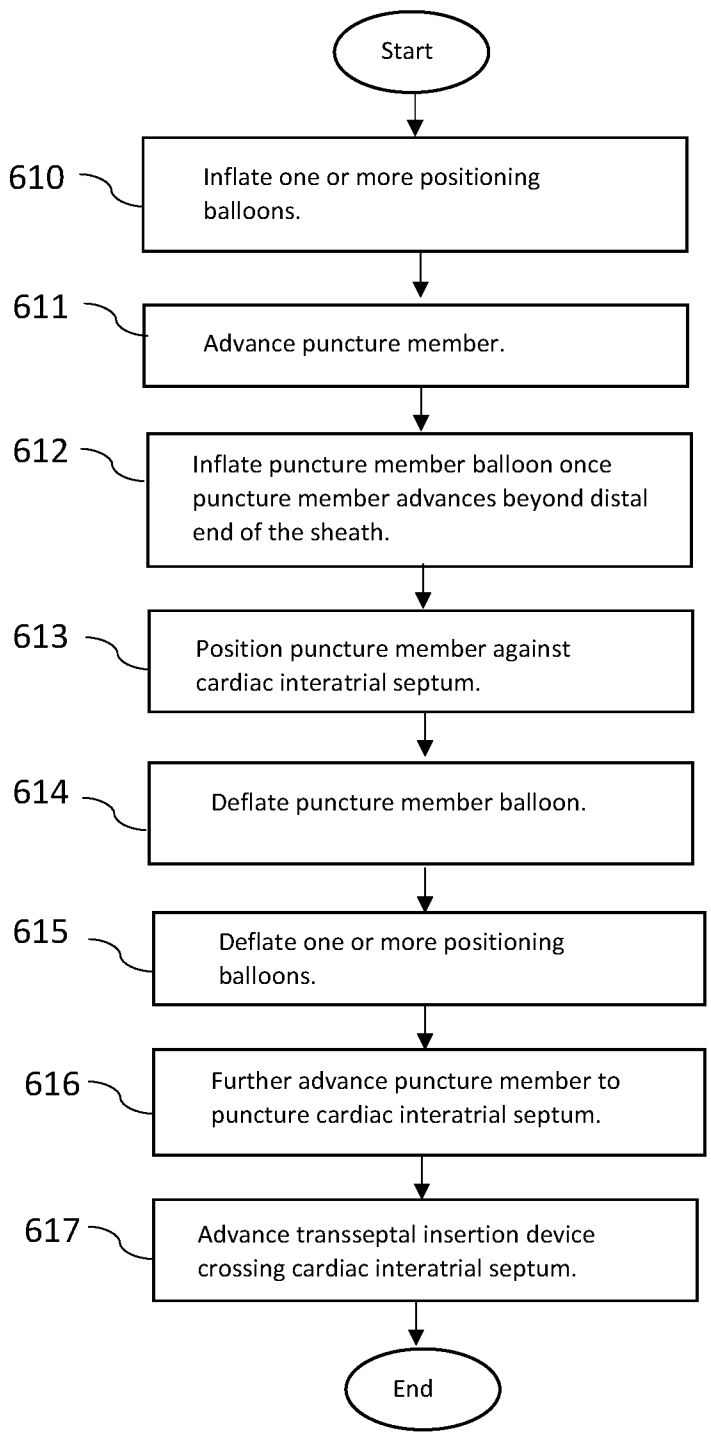

600
Start
610
Inflate one or more positioning balloons.
611
Advance puncture member.
612
Inflate puncture member balloon once puncture member advances beyond distal end of the sheath.
613
Position puncture member against cardiac interatrial septum.
614
Deflate puncture member balloon.
615
Deflate one or more positioning balloons.
616
Further advance puncture member to puncture cardiac interatrial septum.
617
Advance transseptal insertion device crossing cardiac interatrial septum.
End

FIG. 33

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/051228

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/08 A61B8/12 A61B8/00 A61B17/34 A61B18/14
A61B90/00 A61M25/00 A61M25/10
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2014/039494 A1 (KICK GEORGE F [US] ET AL) 6 February 2014 (2014-02-06) paragraphs [0070] - [0072]; claim 9; figures 5-6	1-10
Y	WO 2019/023609 A1 (EAST END MEDICAL INC [US]) 31 January 2019 (2019-01-31) paragraph [8081]; figures 12a-12b	1-10
Y	US 9 510 904 B2 (KRISHNAN SUBRAMANIAM CHITOOR [US]) 6 December 2016 (2016-12-06) claim 1	1-10
Y	US 2010/286718 A1 (KASSAB GHASSAN S [US] ET AL) 11 November 2010 (2010-11-11) figures 13a-13b	9

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 November 2020	01/12/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Gentil, Cédric

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/051228

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/149995 A1 (QUINN CHRIS [US] ET AL) 28 June 2007 (2007-06-28) figures 18-21	1-10
A	EP 2 233 169 A1 (CIRCULITE INC [US]) 29 September 2010 (2010-09-29) figures 4a-4e	1-10
A	US 2005/197530 A1 (WALLACE DANIEL T [US] ET AL) 8 September 2005 (2005-09-08) figures 3a-3e	1-10
A	US 2016/143522 A1 (RANSBURY TERRANCE J [US] ET AL) 26 May 2016 (2016-05-26) paragraph [0037]	1-10

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/051228

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11-20
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 11-20

Rule 39.1(iv) PCT - Method of treatment of the human or animal being by surgery. The method for suitably facilitating precise and safe transseptal puncture of a cardiac interatrial septum with a transseptal insertion device as defined in claims 11-20, inter-alia comprises the steps of "positioning the puncture member against the cardiac interatrial septum"; "further advancing the puncture member to puncture the cardiac interatrial septum"; and "advancing the transseptal insertion device crossing the cardiac interatrial septum of inserting a distal portion of an introducer shaft into a patient's body" and therefore involves a surgical intervention. It is hence considered that claims 11-20 define a method of treatment of the human or animal body by surgery, for which no international search needs to be carried out (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/051228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		JP 2017536891 A	14-12-2017
		KR 20170134316 A	06-12-2017
		US 2016143522 A1	26-05-2016

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/051228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
		WO 2016086160 A1	02-06-2016