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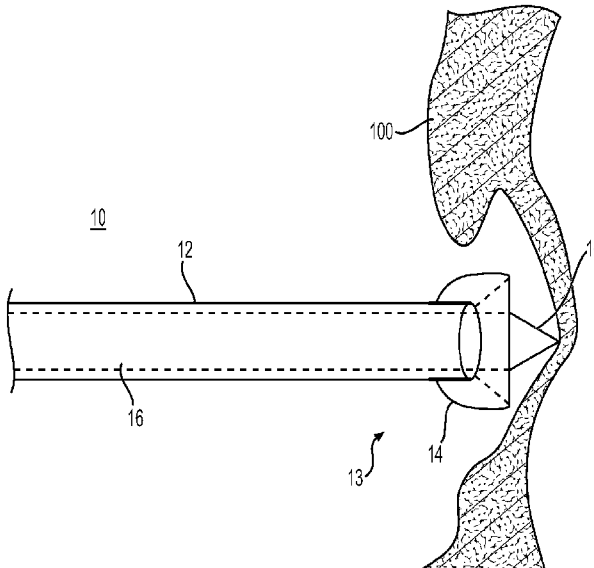

FIG. 8

(57) Abstract: A transseptal insertion device includes a sheath that defines a lumen and has a distal end that is closest to the cardiac interatrial septum of a patient, at least one balloon connected to the distal end of the sheath, in which the at least one balloon, when inflated, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum, and a dilator positioned within the lumen. The dilator has a distal end and is capable of precisely puncturing the cardiac interatrial septum without the use of a needle or other sharp instrument. The at least one balloon is connected to at least one hypotube through which the at least one balloon is inflated or deflated by gas or fluid flowing through the at least one hypotube.

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DIRECTIONAL BALLOON TRANSSEPTAL INSERTION DEVICE FOR MEDICAL PROCEDURES

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. Provisional Application Serial No. 62/821,062, filed on March 20, 2019, which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

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 and other advantages may be provided by, for example, 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 balloons, one or more ultrasound transceivers, and a dilator. The sheath has a distal end that is closest to 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 balloons are connected to the distal end of the sheath and are contained in the sheath. The balloons, when inflated and the transseptal insertion device is in use, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum. The one or more ultrasound transceivers emit and receive ultrasound waves, and convert the ultrasound waves to electrical signals. The dilator is positioned within the at least one lumen. The dilator has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

The transseptal insertion device may further include one or more hypotubes connected to the one or more balloons. The one or more balloons are inflated by gas or fluid flowing through the one or more hypotubes. The transseptal insertion device may further include at least one lumen shaft contained in the sheath. The at least one lumen shaft defines the at least one lumen and the dilator is positioned in said at least one lumen shaft. The one or more hypotubes may be contained in the sheath outside said at least one lumen shaft. The one or more ultrasound transceivers may be located on surfaces of the one or more balloons. The one or more ultrasound transceivers may be located between the balloons. The one or more ultrasound transceivers may be oriented towards the cardiac interatrial septum when the one or more balloons are inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum. The one or more ultrasound transceivers may be oriented perpendicular to the sheath when the balloons are deflated. The one or more ultrasound transceivers may be configured in the shape of a disc. The one or more ultrasound transceivers may be connected to an external imaging device wirelessly or through a wire that runs via the sheath, and may transmit the electrical signals to the external imaging device to produce images of the cardiac interatrial septum from the received electrical signals. The dilator may include cap or crown with radio frequency (RF) energy capability or capable of delivering RF energy.

These and other advantages may be provided by, for example, 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, at least one balloon, one or more ultrasound transceivers, and a dilator. The sheath has a distal end that is closest to 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 at least one balloon is connected to the distal end of the sheath. The balloon, when inflated and the transseptal insertion device is in use, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum. The one or more ultrasound transceivers emit and receive ultrasound waves, and convert the ultrasound waves to electrical signals. The dilator is positioned within the at least one lumen. The dilator has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

The transseptal insertion device may further include at least one hypotube connected to the at least one balloon. The at least one balloon is inflated by gas or fluid flowing through the at least one hypotube. The transseptal insertion device may further include at least one lumen shaft contained in the sheath. The lumen shaft may define the at least one lumen and the dilator may be positioned in said at least one lumen shaft. The hypotube may be contained in the sheath outside the at least one lumen shaft. The one or more ultrasound transceivers may be located on a surface of the at least one balloon. The one or more ultrasound transceivers may be oriented towards the distal end of the sheath when the at least one balloon is inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum. The one or more ultrasound transceivers may be oriented perpendicular to the sheath when the at least one balloon is deflated. The one or more ultrasound transceivers may be connected to an external imaging device wirelessly or through a wire that runs via the sheath, and transmit the electrical signals to the external imaging device to produce images of the cardiac interatrial septum from the received electrical signals. The dilator may include cap or crown with radio frequency (RF) energy capability or capable of delivering RF energy.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of embodiments disclosed herein are described below in connection with the accompanying 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.

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**. With reference to FIG. **2B**, 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** and **2B**, transseptal insertion device **200** may include ultrasound chips or transducers **26** for ultrasound imaging or visualizing (see FIGS. **2C** and **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 Patent Application Publication No. 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** and **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 FIGS. **2C** and **2D**, ultrasound transducer **26** may be forward facing as shown in FIG. **2C** 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 (perpendicular to an axis of the sheath). 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** and **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 **317** 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 based on 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 first 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 a second 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** and **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 may include an eighteen (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 (French size).

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**.

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 closest to 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 balloons that are connected to the distal end of the sheath and are contained in the sheath, wherein the balloons, when inflated and the transseptal insertion device is in use, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum;

one or more ultrasound transceivers that emit and receive ultrasound waves, and convert the ultrasound waves to electrical signals; and

a dilator that is positioned within the at least one lumen, wherein the dilator has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

2. The transseptal insertion device of claim 1 further comprising one or more hypotubes connected to the one or more balloons, wherein the one or more balloons are inflated by gas or fluid flowing through the one or more hypotubes.

3. The transseptal insertion device of claim 2 further comprising at least one lumen shaft contained in the sheath, wherein said at least one lumen shaft defines the at least one lumen and the dilator is positioned in said at least one lumen shaft.

4. The transseptal insertion device of claim 3 wherein the one or more hypotubes are contained in the sheath outside said at least one lumen shaft.

5. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are located on surfaces of the one or more balloons.

6. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are located between the balloons.

7. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are oriented towards the cardiac interatrial septum when the one or more balloons are inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum.

8. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are oriented perpendicular to the sheath when the balloons are deflated.

9. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are configured in the shape of a disc.

10. The transseptal insertion device of claim 1 wherein the one or more ultrasound transceivers are connected to an external imaging device wirelessly or through a wire that runs via the sheath, and transmit the electrical signals to the external imaging device to produce images of the cardiac interatrial septum from the received electrical signals.

11. The transseptal insertion device of claim 1 wherein the dilator includes cap or crown with radio frequency (RF) energy capability or capable of delivering RF energy.

12. 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 closest to 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;

at least one balloon that is connected to the distal end of the sheath, wherein the balloon, when inflated and the transseptal insertion device is in use, overhangs and extends past the distal end of the sheath, preventing accidental puncturing of the cardiac interatrial septum and stabilizing the transseptal insertion device against fossa ovalis of the cardiac interatrial septum;

one or more ultrasound transceivers that emit and receive ultrasound waves, and convert the ultrasound waves to electrical signals; and

a dilator that is positioned within the at least one lumen, wherein the dilator has a distal end and is designed to and is capable of precisely puncturing the cardiac interatrial septum.

13. The transseptal insertion device of claim 12 further comprising at least one hypotube connected to the at least one balloon, wherein the at least one balloon is inflated by gas or fluid flowing through the at least one hypotube.

14. The transseptal insertion device of claim 13 further comprising at least one lumen shaft contained in the sheath, wherein said at least one lumen shaft defines the at least one lumen and the dilator is positioned in said at least one lumen shaft.

15. The transseptal insertion device of claim 14 wherein the at least one hypotube is contained in the sheath outside the at least one lumen shaft.

16. The transseptal insertion device of claim 15 wherein the one or more ultrasound transceivers are located on a surface of the at least one balloon.

17. The transseptal insertion device of claim 12 wherein the one or more ultrasound transceivers are oriented towards the distal end of the sheath when the at least one balloon is inflated and the distal end of the sheath is oriented towards the cardiac interatrial septum.

18. The transseptal insertion device of claim 12 wherein the one or more ultrasound transceivers are oriented perpendicular to the sheath when the at least one balloon is deflated.

19. The transseptal insertion device of claim 12 wherein the one or more ultrasound transceivers are connected to an external imaging device wirelessly or through a wire that runs via the sheath, and transmit the electrical signals to the external imaging device to produce images of the cardiac interatrial septum from the received electrical signals.

20. The transseptal insertion device of claim 12 wherein the dilator includes cap or crown with radio frequency (RF) energy capability or capable of delivering RF energy.

FIG. 1A

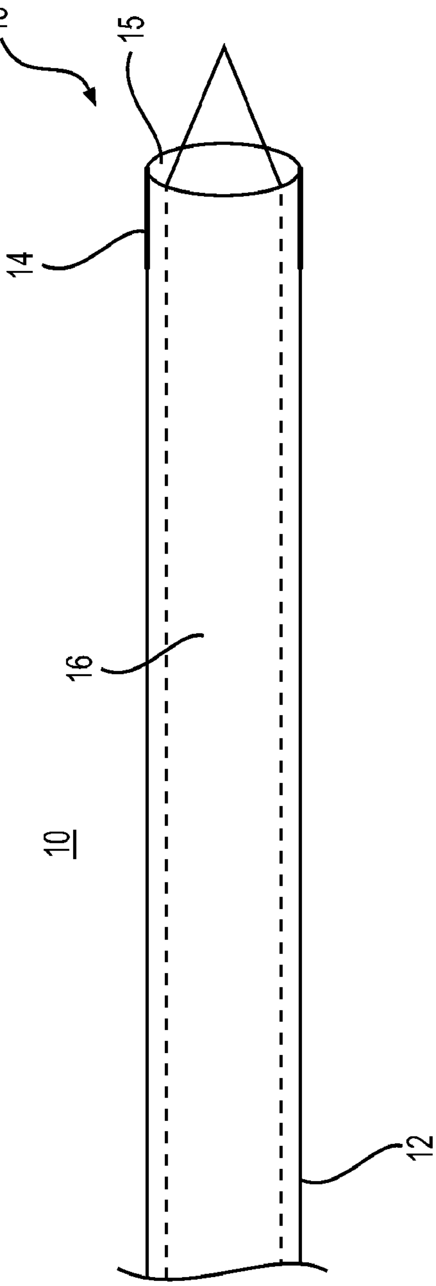

FIG. 1B

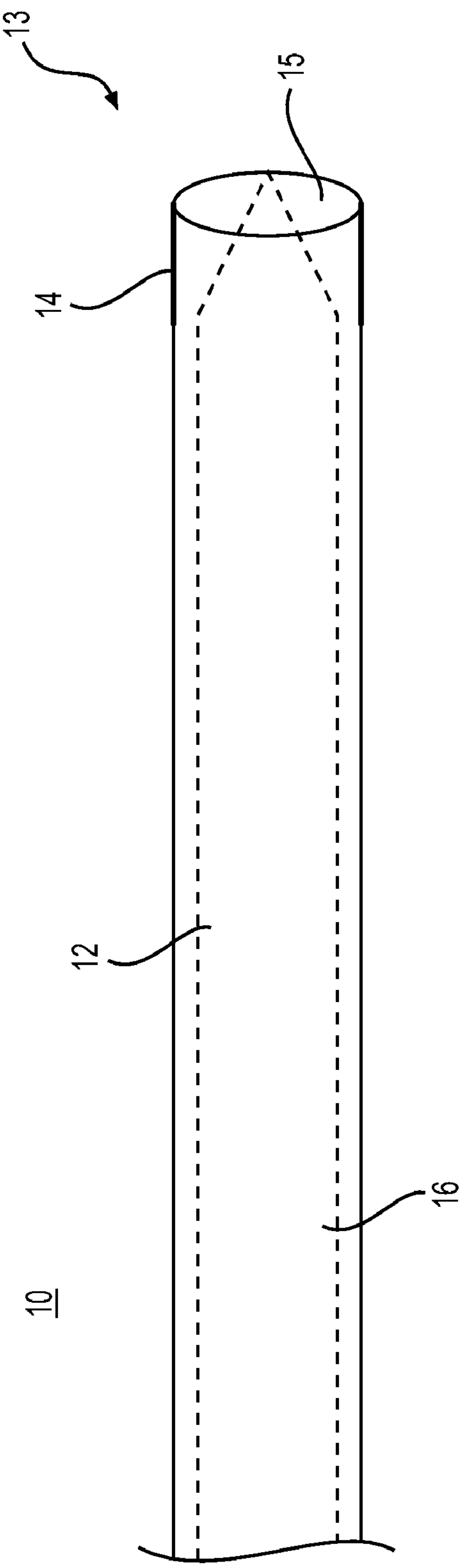

FIG. 1C

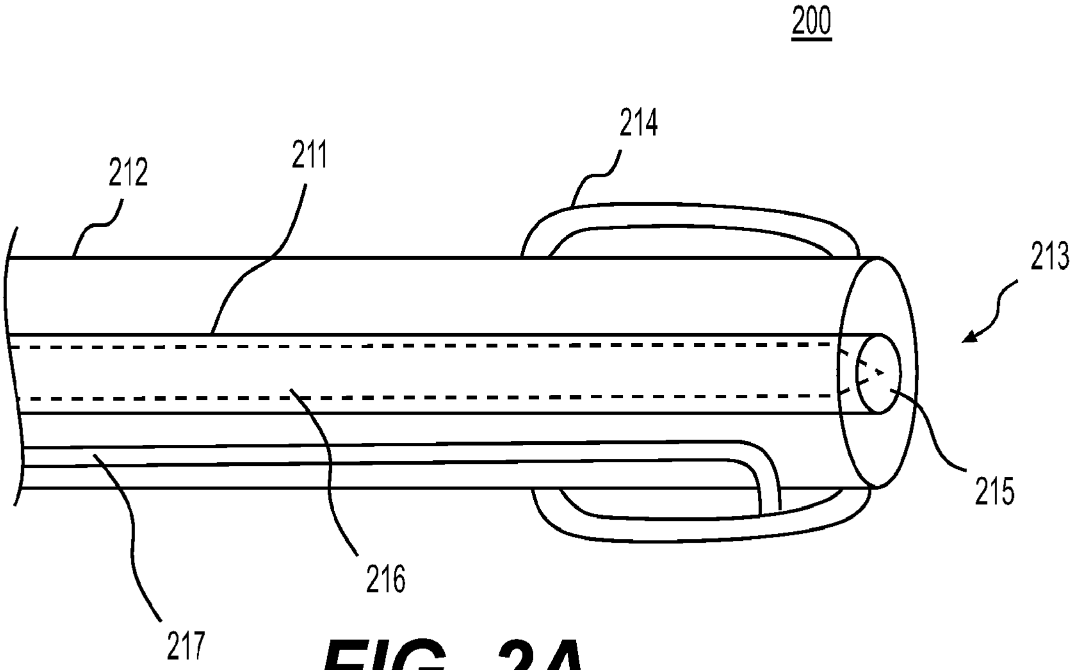

FIG. 2A

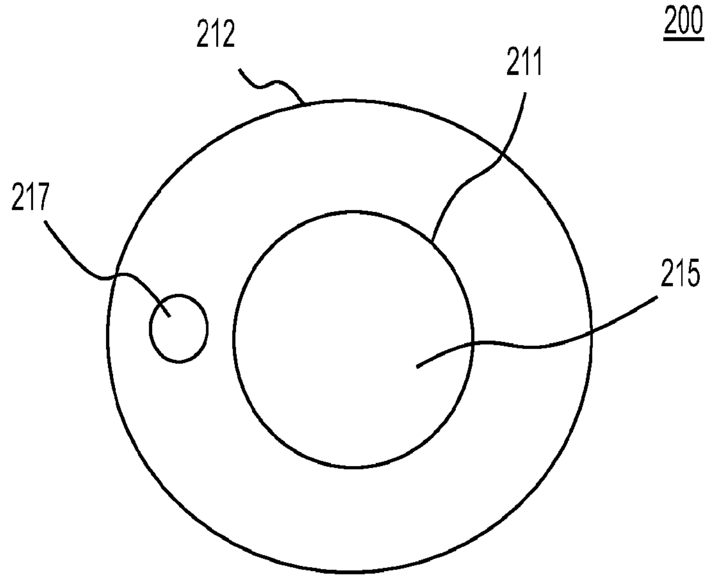

FIG. 2B

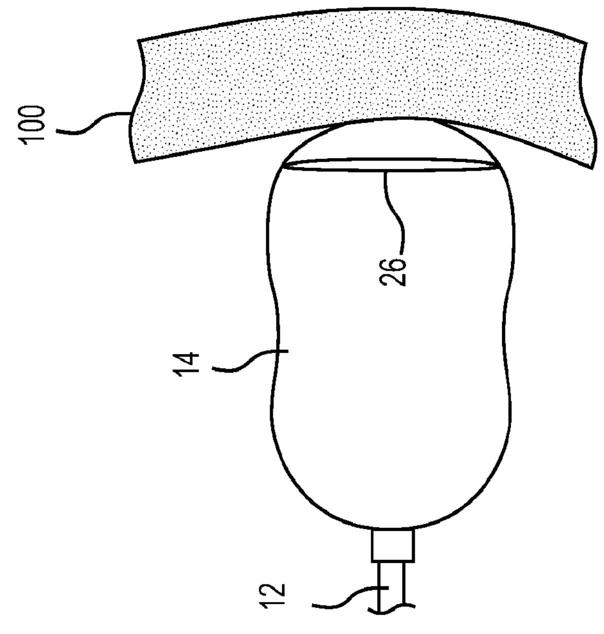

FIG. 2C

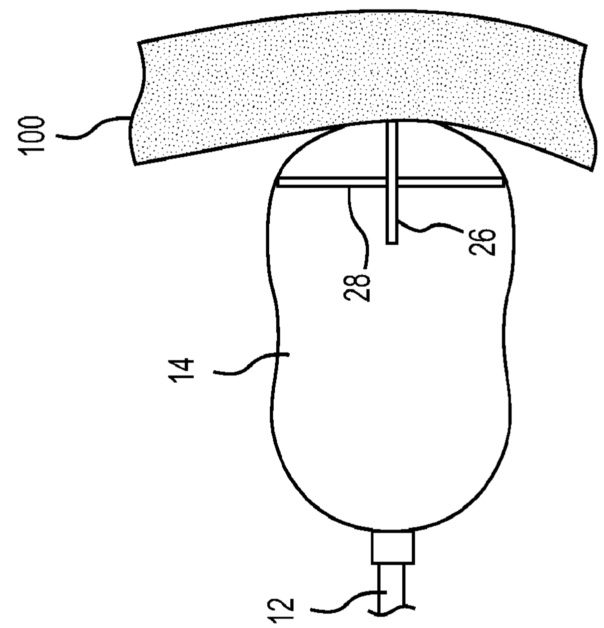

FIG. 2D

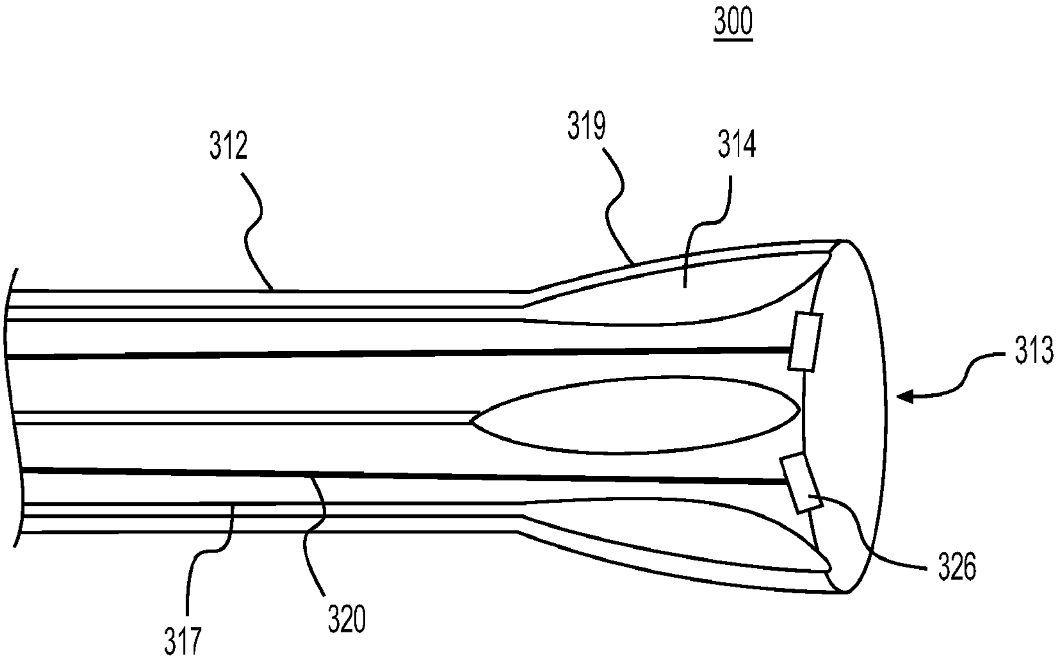

FIG. 3A

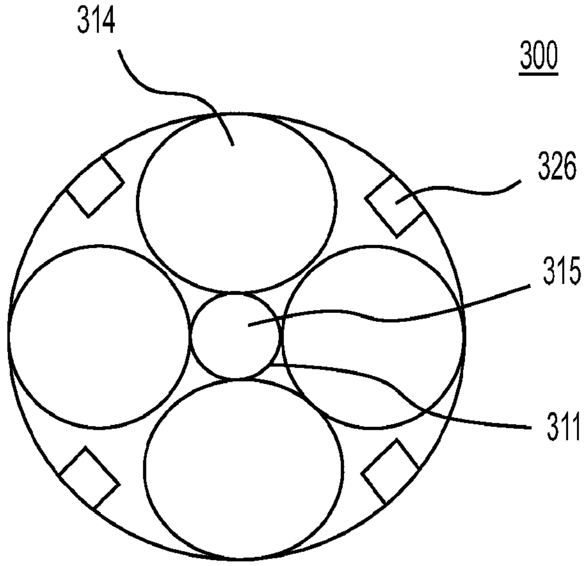

FIG. 3B

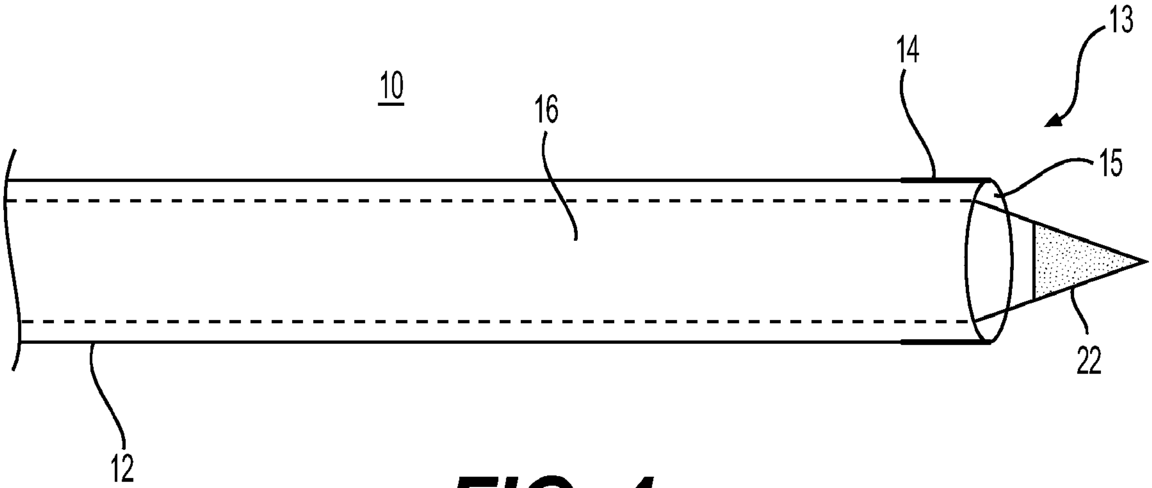

FIG. 4

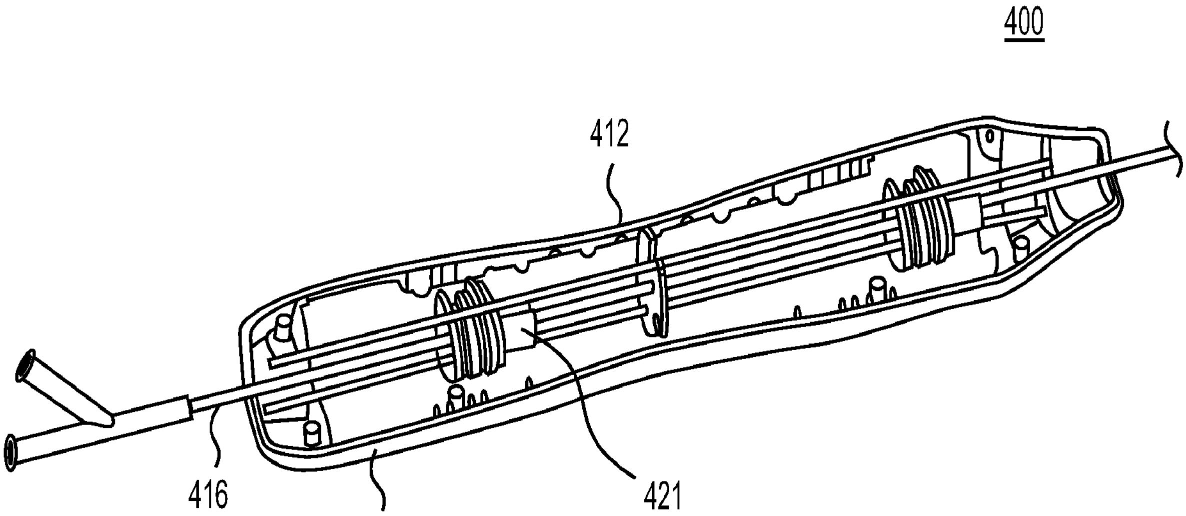

FIG. 5

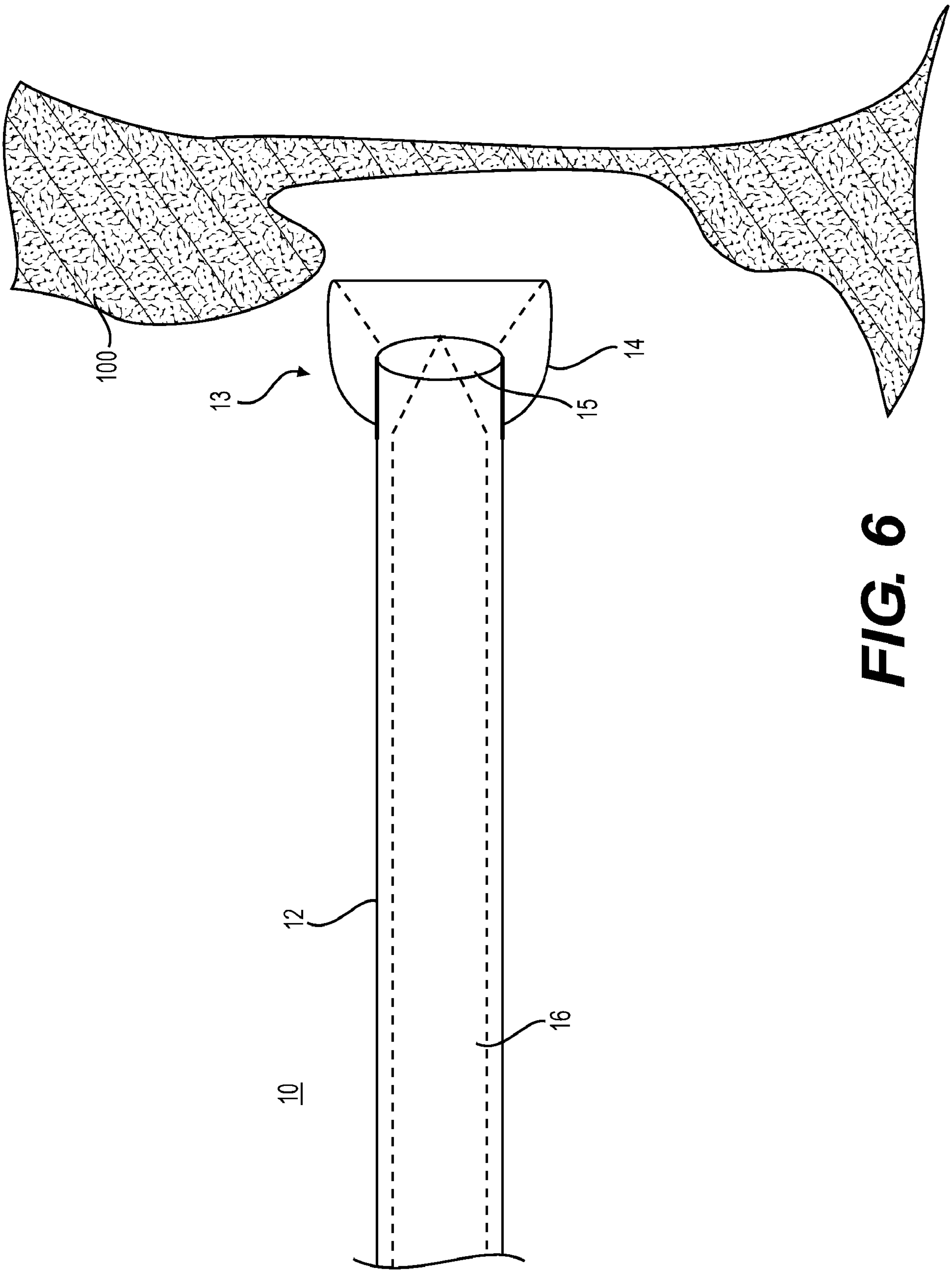

FIG. 6

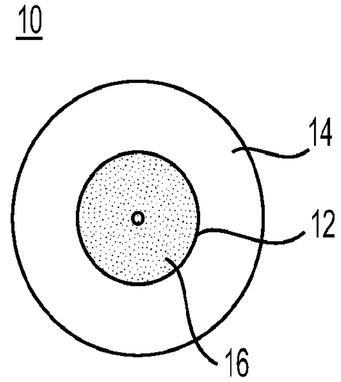

FIG. 7

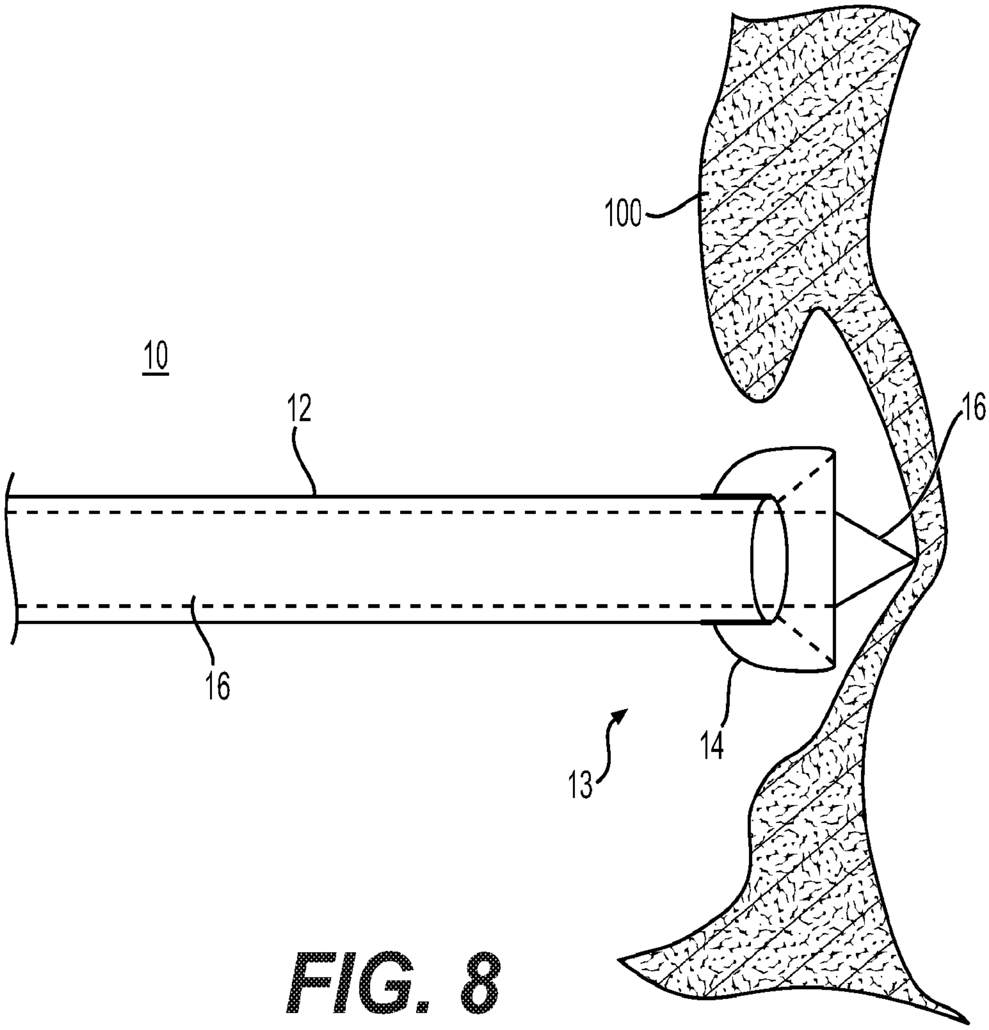

FIG. 8

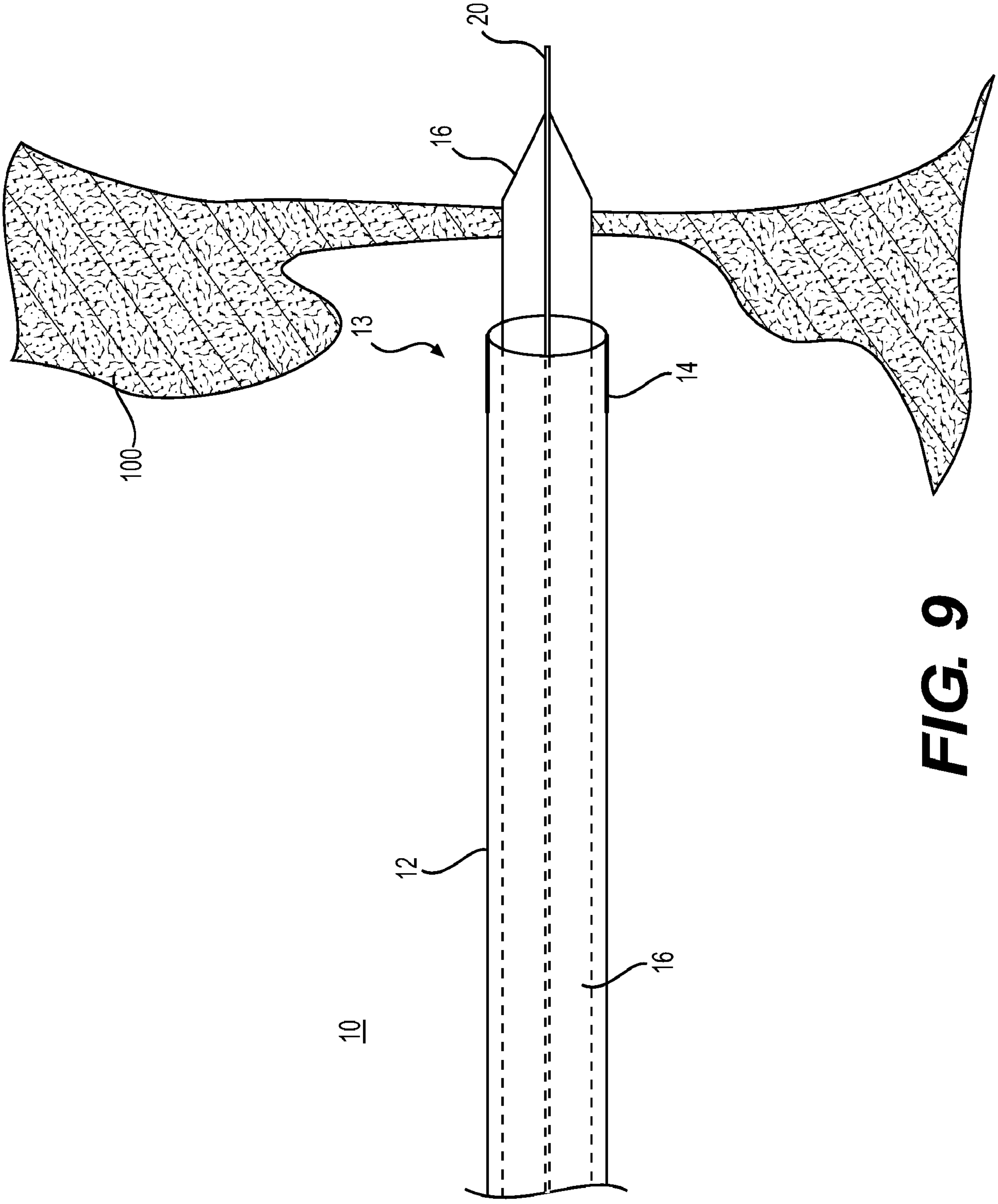

FIG. 9

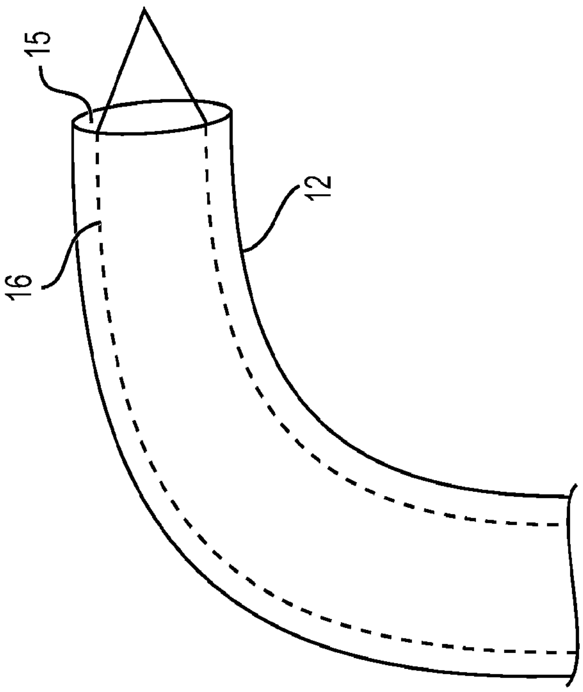

FIG. 10C

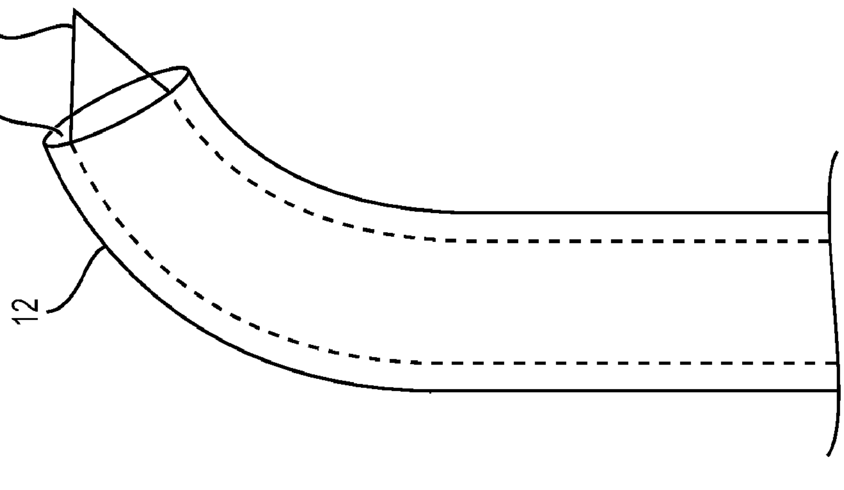

FIG. 10B

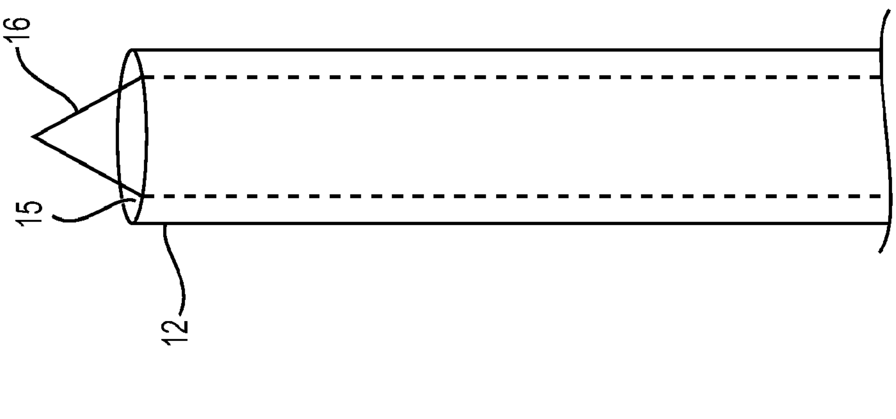

FIG. 10A

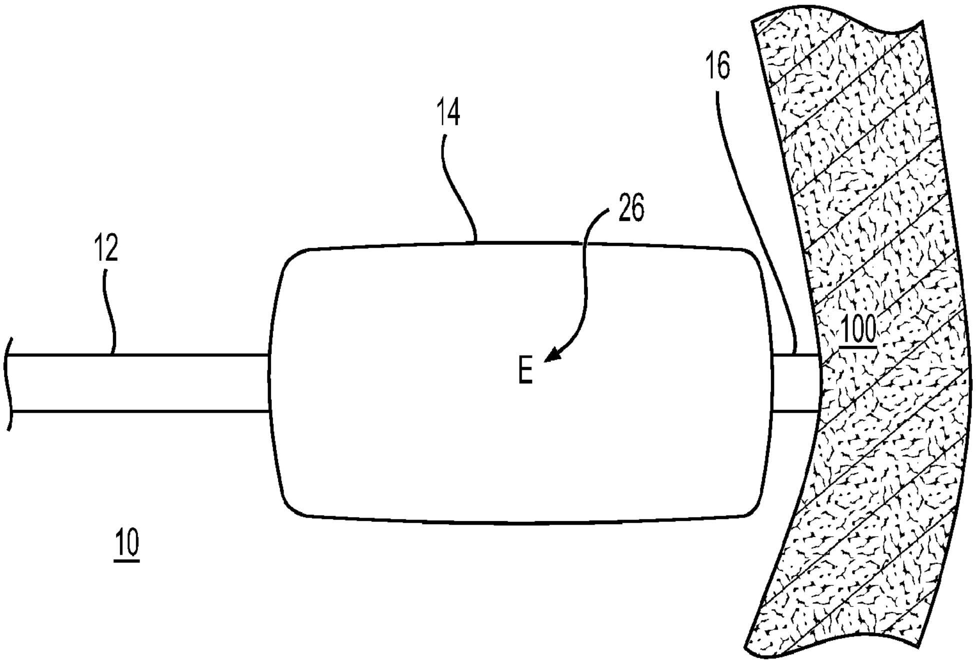

FIG. 11

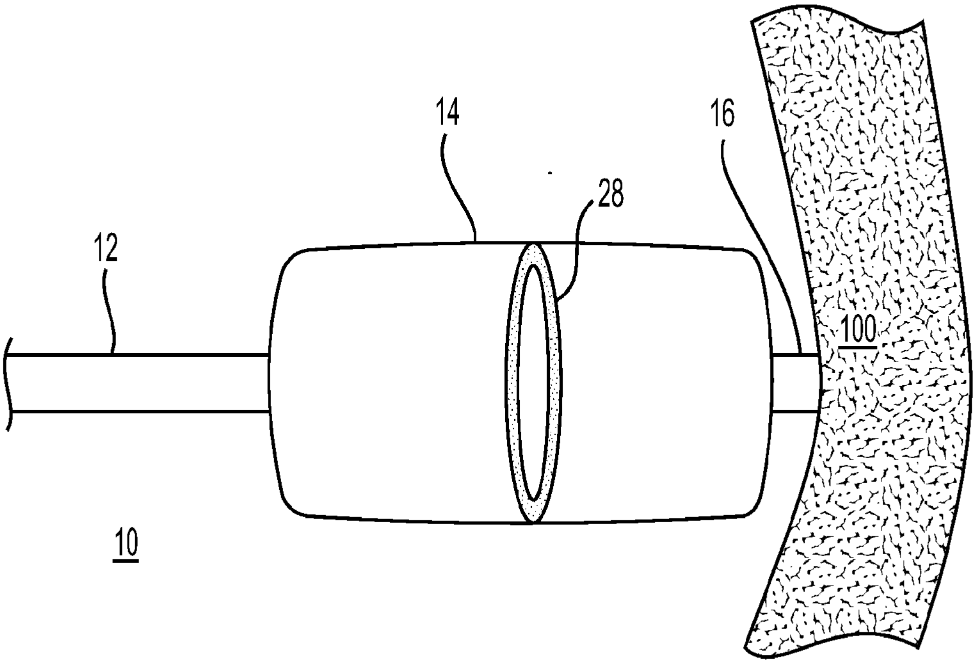

FIG. 12

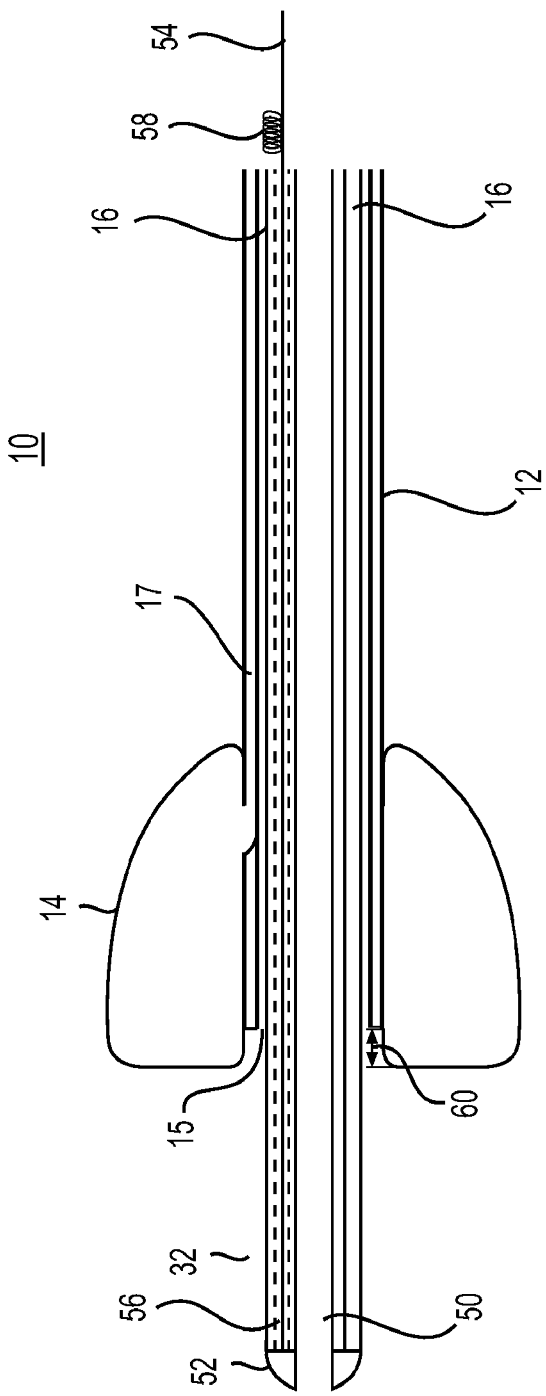

FIG. 13

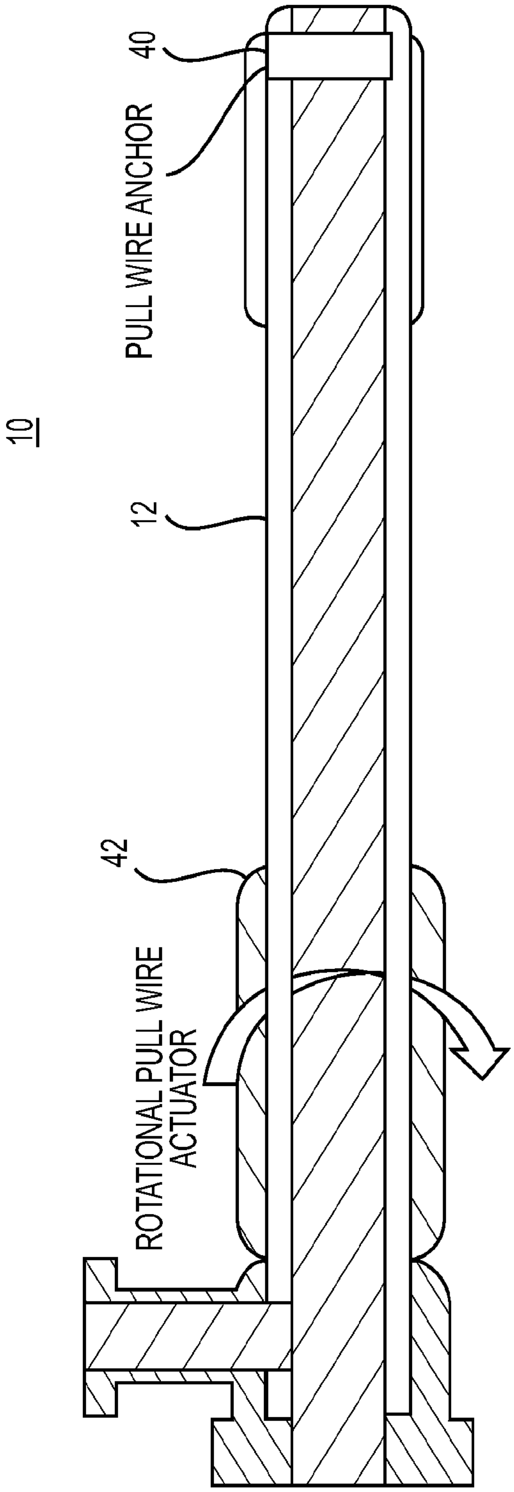

FIG. 14

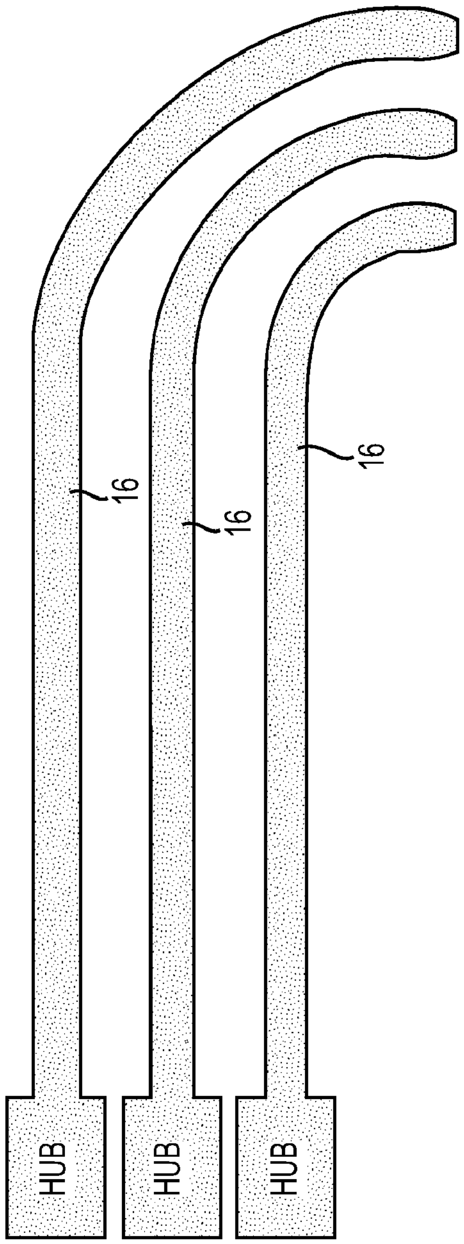

FIG. 15

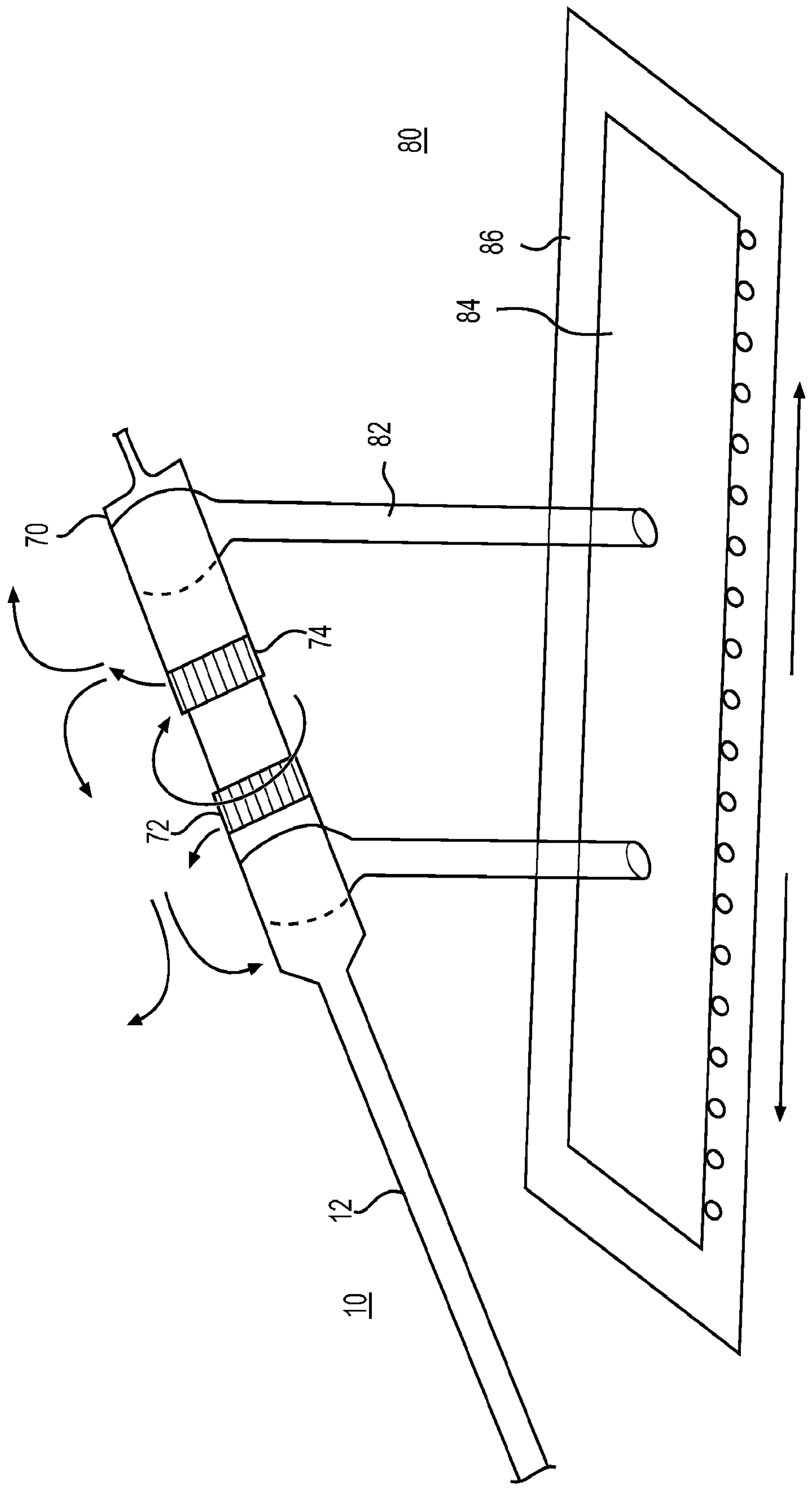

FIG. 16

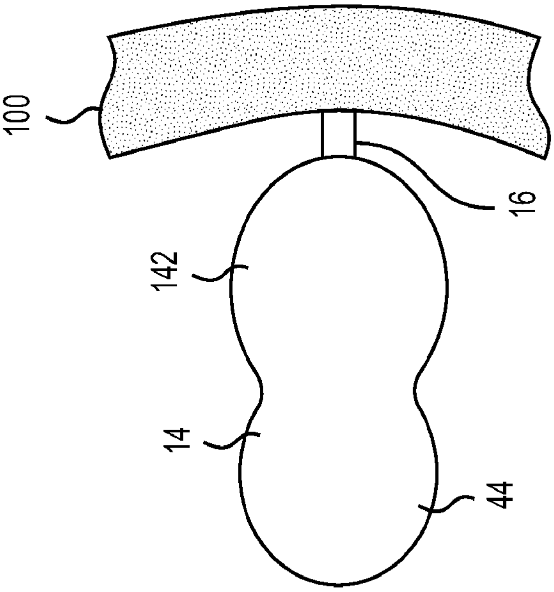

FIG. 17B

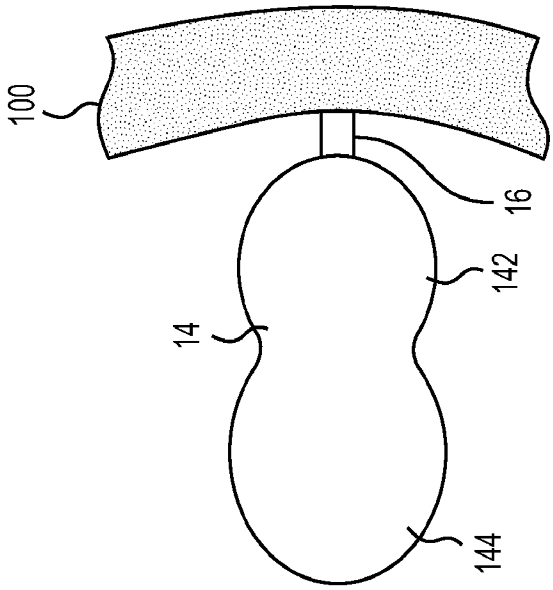

FIG. 17A

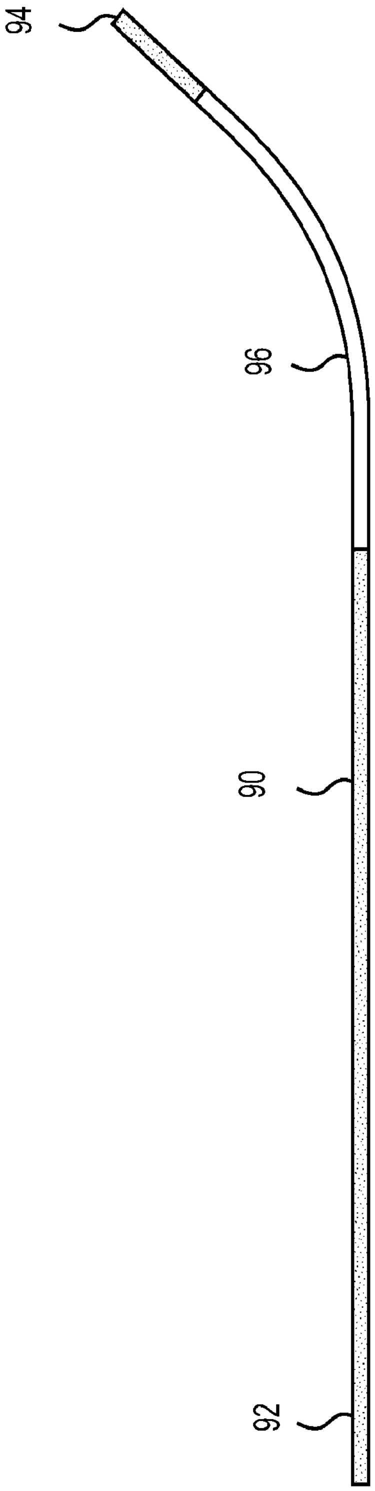

FIG. 18