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(54) Title: DIRECT AORTIC ACCESS SYSTEM FOR TRANSCATHETER AORTIC VALVE PROCEDURES

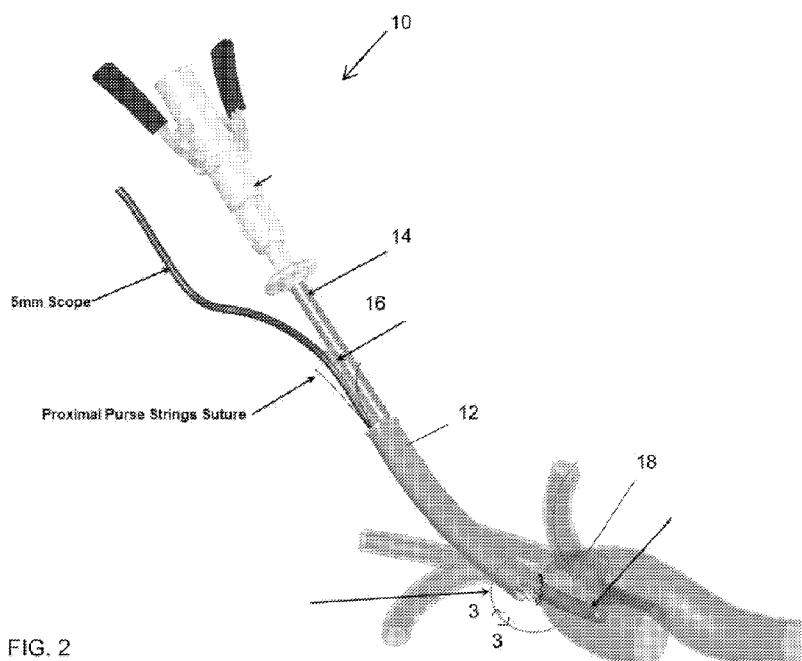


FIG. 2

(57) Abstract: Disclosed are a system and method for performing a medical procedure using direct percutaneous access of an aorta. A main sheath is introduced through an incision formed in proximity to the sternum, and positioned along (and preferable against) a posterior portion of the sternum. Instruments passed through the main sheath are used to form a purse-string suture in an exterior wall of the aorta. An opening is formed in the wall of the aorta in a region encircled by the purse-string suture, and a distal end of an introducer sheath is advanced through the opening into the aorta. A medical procedure, which may be a transcatheter aortic valve replacement, is performed using instruments passed through the introducer sheath into the aorta. After the medical procedure, the introducer sheath is withdrawn from the aorta and, as the introducer sheath is withdrawn, the purse-string suture is tightened to close the opening.



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DIRECT AORTIC ACCESS SYSTEM FOR
TRANSCATHETER AORTIC VALVE PROCEDURES

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This application claims priority to US Provisional Application No. 61/692,702, filed 23 August 2012, US Provisional Application No. 61/702,165, filed 19 September 2012, and US Provisional Application No. 61/728,679, filed 20 November 2012, each of which is incorporated herein by reference.

FIELD OF THE INVENTION

The field of the invention relates generally to the field of percutaneous access systems, and more specifically to the field of percutaneous systems for direct percutaneous access to the aorta.

BACKGROUND

Transcatheter aortic-valve implantation (TAVI) has emerged as a therapeutic option to improve symptoms and extend life in high-risk patients with severe symptomatic Aortic Stenosis.

Various approaches have been described for accessing the aortic valve during the TAVI procedure. One TAVI approach is a transfemoral (TF) route in which catheters are guided through the aorta and retrograde across the diseased valve.

A second approach, the direct transaortic (TAo) route, mimics the TF route but avoids passing instruments along the curvature of manipulating the aortic arch, reducing the risk of embolization. While TAo-TAVI is currently performed through an upper ministernotomy or a right minithoracotomy, the aortic anatomy is such that the ascending aorta could be accessed percutaneously from just above the suprasternal notch. The ascending aorta would be pierced and cannulated. In some embodiments, cannulation might occur at the level of the second

intercostal cartilage, where it lies anteromedial to the superior vena cava, although other sites might also be used.

The transition from surgical or vascular access to a direct percutaneous approach has the potential to reduce the requirement for general anesthesia, shorten procedure time, reduce the risk of wound infections, mitigate patient discomfort, reduce post-op patient immobilization, and shorten length of hospitalization. To realize the potential of percutaneous transaortic (pTAo) TAVI, however, new tools are needed for access, embolic protection, and closure.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 schematically illustrates access to the aorta using the disclosed percutaneous transaortic approach.

Fig. 2 schematically illustrates an aorta and shows components of the disclosed transaortic access system accessing the aorta.

Fig. 3 is a close-up taken from with the encircled region identified as 3-3 in Fig. 2, showing placement of the purse-string suture.

Fig. 4 is similar to Fig. 3, but shows the introducer sheath positioned through an opening formed in the wall of the ascending aorta.

Fig. 5 is a perspective view of an exemplary main sheath for the access system, with an obturator extending through the lumen of the main sheath.

Fig. 6 is a perspective view of the main sheath of Fig. 5.

Fig. 7 is a perspective view of a channel insert for the main sheath of Fig. 6.

Fig. 8 is a perspective view of the distal end of the main sheath of Fig. 6, with the insert of Fig. 7 coupled to the main sheath.

Fig. 9 is a longitudinal cross-section of the main sheath and insert assembly of Fig. 8.

Fig. 10 is a perspective view of an alternative to the main sheath of Fig. 6, with the insert assembly positioned within the sheath.

Fig. 11A is a distal perspective view of a second alternative main sheath, with the insert positioned within the sheath. Fig. 11B is a proximal perspective view of the assembly of Fig.

11A. The distal portions of the introducer sheath and an endoscope are shown disposed in the main sheath.

Fig. 12 is a perspective view of the distal portion of an exemplary articulating purse-string suture applier/needle holder.

Figs. 13A-D show a side elevation view, distal plan view, top plan view, and perspective view, respectively, of a dual dissection balloon.

Figs. 14A-D show a side elevation view, distal plan view, top plan view, and perspective view, respectively, of a thoracic dissection balloon.

Fig. 15 is a cross-section side view of an exemplary introducer sheath. Only one handle lever is shown. The sheath is shown with the handle lever in the closed position to open the valve.

Fig. 16 is similar to Fig. 2, and more clearly shows an embolic protection device in use, with the tethering wire extending through the left subclavian artery and the barrier covering the ostia of the brachiocephalic artery and the left common carotid artery.

Fig. 17 is a side view illustrating the curvature of the main sheath of Fig. 6.

DETAILED DESCRIPTION

This application discloses a system for facilitating percutaneous access directly into the aorta. As disclosed in the application, the system is particularly suitable for use in gaining access to the aortic valve for treatment. For example, the system can be used to give access to devices and instruments used for implantation of an artificial aortic valve (e.g. TAVI procedures). The system is proportioned to allow the artificial aortic valve and its delivery system to be positioned through it during the valve implantation procedure.

System

Fig. 1 schematically illustrates the access approach for which the system may be used. In particular, direct percutaneous access into the aorta is gained by forming an incision above the suprasternal notch and approaching the aorta as indicated by the illustrated arrow. The

access system is introduced through the incision and positioned behind the sternum, giving access to the aorta as indicated by the arrow in Fig. 1. Additional details of an exemplary method for using the system are described following the description of the system components.

Main Sheath

Referring to Fig. 2, an aortic access system 10 includes a main sheath 12, an introducer sheath 14 extendable through the main sheath 12, and a purse-string suture applier 16 also extendable through the main sheath. Additional components which might also be included in the system 10, including an embolic protection device 18, obturator 20, and dissection balloons 22, 24 are also shown in the drawings and will be described below.

An exemplary main sheath 12 is shown in Fig. 6. The main sheath functions to provide an access way through the skin and to accommodate the introducer sheath 14, purse-string suture applier 15 and scope in stable positions in a manner that avoids "sword fighting" between the instruments, yet preferably allows enough freedom of movement of the introducer sheath to move side-to-side if needed.

Main sheath 12 is an elongate tubular sheath having a lumen extending between its proximal and distal ends. The main sheath 12 preferably has a cross-section that is non-circular so as to include a face 26 or flattened region shaped to seat against the posterior face of the sternum when the main sheath 12 is disposed behind the sternum. The main sheath 12 of the Fig. 6 embodiment has a generally triangular cross-section, with the corner regions preferably rounded so as to avoid tissue trauma. The illustrated cross-section is equilateral although other geometries can be used. With this arrangement, the main sheath 12 has three generally rectangular faces, allowing any of the faces to seat against the sternum (or against soft tissue that is behind the sternum).

In the Fig. 6 embodiment, the main sheath 12 has a preformed curve such that, when the distal portion of the main sheath is within the body, its proximal portion curves away from the plane of the operating table (with the patient in a supine position) and thus away from the patient's head. See Figs. 16 and 17.

An alternative main sheath 12a, shown in Fig. 10, is longitudinally straight, giving the sheath the shape of a triangular prism with rounded edges. The distal end of any of the disclosed main sheaths may include a chamfered or tapered edge as shown in Fig. 10 so as to minimize tissue trauma when the main sheath is advanced into the body. The straight main sheath 12a may have a length that is approximately 3 inches or less or 2 inches or less, so as to avoid conflict with the patient's head as instruments are passed into the proximal end of the main sheath 12a.

A third main sheath 12b is shown in Figs. 11A and 11B. This sheath is similar to the main sheath 12a, but further includes flanges 28 as shown. The flanges 28 include tie-down holes that receive sutures (not shown). During use, sutures are passed through the tie-down holes and the patient's skin so as to temporarily couple the main sheath 12b to the patient.

Although main sheaths with triangular cross-sections are shown, alternative main sheaths may have other cross-sectional shapes. Preferred shapes are those which include an outer face shaped to seat against the back of the sternum (or the adjacent tissue). Preferred faces for this purpose are generally flat or planar, or have a larger radius of curvature than a circular cross-section. For example, a main sheath having an oval or elliptical cross-section can be used, with the flatter edge of the oval or ellipse positionable against the sternum or adjacent tissue. As another example, a main sheath having a rectangular or square cross-section (in each case preferably with rounded edges) would provide the desired face. Note that the face that seats along the sternum need only be present at the distal portion of the main sheath. Thus other embodiments might have a first cross-section which includes the desired face at the distal region, and a second (different) cross-section that need not extend the face at the proximal region.

Each of the illustrated main sheaths 12, 12a, and 12b includes a removable channel insert 30 for receiving a scope/camera such as a flexible or (in the case of the straight sheaths) a rigid endoscope or camera. As best shown in Fig. 7, channel insert 30 includes a proximal cap 32 or ring removably engageable with the proximal end of the main sheath 12.

A elongate member 34 extends distally from the cap 32 and includes a lumen or port 36. The lumen/port 36 is proportioned to receive a scope/camera. This arrangement allows the

distal end of the scope/camera to be positioned in a stable position at the distal end of the main sheath 12. The shape of the elongate member is preferably one that will seat in a stable relationship with adjacent walls of the main sheath – for example within a corner region of the main sheath as shown in Figs. 8, 10 and 11A-B. This position leaves the remainder of the space within the sheath available for use for the other instruments of the system. Thus the elongate member may have a generally triangular cross-section as shown in Fig. 8. The surface or wall 38 that is exposed to the interior of the main sheath (i.e. that is not in contact with a sidewall of the sheath) may be flat in its lateral dimension (or, if a straight main sheath is used, that is planar). Alternatively, referring to Figs. 10 and 11A-B, the exposed wall 38a may have a central ridge extending longitudinally – with the contour shaped to accommodate the lumen 36 – thus forming longitudinally-extending valleys extending on opposite sides of the elevated central portion. This arrangement is beneficial in that it allows instruments used through the main sheath, such as the introducer sheath 14 and the purse-string suture applier 16 (Fig. 2) to seat within the valleys during use.

In alternate embodiment, the main sheath 12, 12a, 12b includes an integrated scope channel rather than one that is removable.

Various materials are suitable for the main sheath. In some embodiments, the main sheath is rigid, and can utilize a rigid material such as stainless steel. For other embodiments, polymeric materials ranging in hardness from a stiff ABS-like material to a urethane with a hardness in Shore A scale of 40 to 100. Other suitable materials include PEEK, Delrin, Nylon, Teflon, Polyethelyne, and Polypropylene. The sheath might incorporate a lubricious lining of PTFE or other material. The sheath might be molded or extruded, with additional processing to add other features. Some designs, such as those using Pebax, might be configured to allow the physician to heat the sheath prior to use to render the sheath deformable, allowing the physician to shape the sheath to a curvature appropriate for the patient.

Similar materials as those disclosed above might also be used for the insert 30.

Obturator

Referring to Fig. 5, an obturator 40 is provided for use during advancement of the main sheath 12 through body tissue towards the aorta. The obturator 40 is proportioned to fit within

the lumen of the main sheath 12. A camera/scope lumen 42 in the obturator allows use of a scope or camera to observe the anatomy surrounding the obturator during advancement.

In the Fig. 4 embodiment, the insert 30 is not used simultaneously with the obturator 40, although in other embodiment these two components may be proportioned for simultaneous use within the main sheath, in which case the obturator may be provided without the lumen 42.

Purse-String Suture Applier

Fig. 12 shows one example of a purse-string suture applier 16. This suture applier is in the form of an articulating needle holder 44 having an end effector, in the form of a pair of jaws, supported by a shaft. The jaws are configured for holding a suture needle. The distal end of the shaft may be configured to allow axial rotation of the end effector relative to the shaft through manipulation of a manual actuator at a handle (not shown) of the suture applier. The distal end of the shaft might also include an articulation joint operable through manipulation of articulation actuators positioned at the handle. The needle holder 44 is extendable through the main sheath 12. It has features allowing the user to manipulate the jaws holding the suture needle so as to form a purse-string suture (Fig. 3) in the wall of the aorta – preferably in a manner that does not penetrate the full thickness of the vessel wall, but instead passes more shallowly (e.g. through only the adventitia of the vessel).

Another example of a purse-string suture applier 16 uses vacuum suction to engage and stabilize the outer surface of the aorta. A suture needle is then used to form the purse-string suture in the engaged and stabilized wall.

Dissection Balloons

In some instances it may be desirable to dissect tissue surrounding the incision formed at the supra-sternal notch prior to introducing the main sheath. Balloon dissectors suitable for this purpose as shown in Figs. 13A-D and 14A-D. Figs. 13A through 13D illustrate a dual dissection balloon 22 having a pair of elongate and/or cylindrical balloon chambers surrounded by an elastomeric membrane to form an expandable dissector with a generally oval-shaped lateral cross-section. Inflation catheters are fluidly coupled to the balloon chambers, which may be independently or simultaneously inflatable. An alternative dissection balloon 24,

shown in Figs. 14A – 14C, is a single chamber balloon having a generally oval-shaped cross-section.

Needle

An instrument such as a needle (not shown) is provided for penetrating the wall of the aorta within the region encircled by the purse-string suture, so as to create an access point into the aorta. A dilator advanceable over the needle may also be provided for increasing the diameter of the penetration while minimizing blood loss.

Introducer Sheath

The system includes an introducer sheath 14 having a distal portion that is delivered through the main sheath. In use, the distal portion is passed through the needle opening (e.g. over the needle and any associated dilators) formed in the aorta, thus positioning the distal end of the introducer sheath 14 within the aorta. Instruments used to carry out the procedure within the aorta, such as an artificial aortic valve and its delivery system, are delivered to the aorta via the introducer sheath 14. For this reason, the introducer sheath 14 is constructed to maintain hemostasis despite the high rate of blood flow through the aorta.

Fig. 15 shows an exemplary, prior art, introducer sheath 14, which includes a tubular shaft 50 and a valve housing 52 at the proximal end of the shaft 50. Valve 54 is disposed within the valve housing and defines an aperture 56. An instrument port 57 is located at the proximal end of the valve housing for receiving instruments to be inserted through the aperture and shaft for use within the aorta.

A slider 58 is moveable in proximal and distal directions within the valve housing 52. A spring 60 biases the slider 58 against the valve 54, compressing the valve 54 in an axial direction. Suitable springs include coil springs or wave springs.

Valve 54 is preferably made of a soft silicone material or similarly compressive material that, when axially compressed by the slider 58, will expand to fill the aperture 56, thus sealing the introducer sheath against blood loss. Because the spring 60 biases the slider 58 against the valve 54, the valve is biased in the closed position. In alternative embodiments, the spring can be positioned to bias the slider away from the valve to bias the valve in the open position.

A hard plastic material may be bonded to portions of the soft silicone. This constrains the silicone material so it cannot be pushed out of the hub of the introducer sheath.

A pair of handles 62 (one is shown) include links coupled to the slider. When the user squeezes the handles towards the valve housing 52, the links push the slider proximally against the bias of the spring, releasing some or all of the axial compression against the valve 54. With axial compression against the valve reduced, the aperture 56 opens, allowing instruments to be introduced into it, or allowing instruments already extending through it to be repositioned. When the user releases the handles, the slider returns to its biased position, compressing the valve and thus closing the aperture and causing the valve to seal around tools and instrument that are extending through it. Thus, when the valve is closed, hemostasis is maintained even with one or more devices (e.g. valve delivery system) extending through the aperture.

The introducer sheath includes features allowing the user to set a minimum diameter for the aperture opening. In the illustrated embodiment, a proximal cap 64 is engaged by threads to valve housing 52. Rotating the cap 64 in a first direction advances the cap distally relative to the valve housing, and thus limits the travel of the spring – setting a stopping point for the valve. This allows the user to pre-set the size the aperture will assume when the handles are released. This can allow the clinician to automatically apply, in a hands-free manner, a state where the valve seals down on a given diameter instrument or set of instruments with enough pressure to maintain hemostasis but minimize the drag on the inserted objects.

The introducer sheath may additionally include features allowing the user to articulate or bend the shaft 50 in one or more directions. For example, one or more tensioning elements (not shown) such as pull cables may extend through lumen in the walls of the shaft 50. In such an embodiment, the tensioning elements are coupled to one or more actuators on the proximal end of the introducer sheath, allowing the user to bend the shaft 50 through manipulation of the actuator. In some embodiments, the shaft 50 may be reinforced using a coil or braid made of NiTi or other materials, so as to maintain radial crush strength and kink resistance at thin-wall dimensions.

Embolic Protection Device

Referring to Fig. 16, an embolic protection device 18 may take the form of a shield positionable over the target ostia (i.e. the ostia of the brachiocephalic and left common carotid arteries, and optionally that of the left subclavian artery). The illustrated embodiment is formed of a flexible frame defining an open area. A barrier is supported by the perimeter of the frame. The barrier is one that will prevent passage of emboli through the frame, but at least certain regions of the barrier are porous so as to allow allowing blood to flow through it. In one embodiment, the porous barrier may be formed of porous silicone or polyurethane, or other materials such as woven materials. In one embodiment, the covering may be applied using dip, molding and/or spray techniques. The barrier preferably contacts the full inner perimeter of the frame, but in some embodiments the outer perimeter of the frame may be formed to be free of the barrier material to facilitate sliding of the diverter within the delivery and removal catheter(s). The frame is preferably made of nitinol or similar material, and is shape set to the desired shape.

The embolic protection device may be formed to have a variety of shapes. In the illustrated embodiment, the frame and barrier define a generally oval shape. The curvature is selected to approximately track the curvature of the portion of the aortic wall along which the target ostia are position, e.g. the surface of the barrier that faces into the aortic arch is concave, and the surface contacting the wall of the aorta and covering the ostia is convex – positioning the barrier away from the lumen of the aortic arch to avoid obstructing flow of blood through the arch.

A tethering wire or catheter support 19 for the embolic protection device extends from the proximal end of the frame as shown. In one method of using the third embodiment, the embolic protection device is positioning using access through the left subclavian artery as shown, leaving unimpeded access to the aortic valve by instruments being introduced through the introducer sheath. In another method, the embolic protection device is positioned using percutaneous access through a femoral artery, with the embolic protection device advanced through the descending aorta to the target ostia. Additional details of embolic protection devices suitable for use with the disclosed system are shown and described in US Provisional

Application No. 13/773,625, filed February 21, 2013, entitled Embolic Protection System and Method for Use in an Aortic Arch, which is incorporated herein by reference.

The disclosed system may be packaged together with instructions for use instructing the user to position and use the access system in accordance with the method described herein.

Method

In preparation for the procedure within the aorta, the embolic protection device 18 is deployed over the ostia of the head vessels such that any debris or other embolic material released during the procedure is diverted away from the brain. Deployment of the embolic protection device is described here as the first step in the process, although it should be understood that it may come later in the process, such as following positioning of the introducer sheath within the aorta.

The embolic protection device 18 is disposed within a catheter and introduced into the vasculature through an access port into the left subclavian artery, with the tethering wire 19 extending out of the body. The distal end of the catheter is advanced into the aorta and positioned with its distal opening upstream of the brachiocephalic artery. The embolic protection device is deployed from the catheter, thus covering the brachiocephalic artery and the left common carotid artery with the porous barrier.

In an exemplary method for using the remaining components of the system, an incision (e.g. approximately $\frac{3}{4}$ inch) is formed through the skin just above the suprasternal notch. A tunnel is formed behind the sternum using a gloved finger. If needed, balloon dilators of Figs. 13A-D or 14A-D are used to expand the tunnel formed in the tissue.

The obturator 40 is placed within the main sheath 12, and a scope or camera is passed through the scope/camera lumen 42 of the obturator. The distal end of the main sheath/obturator assembly is introduced into the incision and advanced to position the main sheath 12 behind the sternum and to position the distal end of the sheath in proximity to the aorta. Face 26 of sheath 12 is preferably seated against the surface of the sternum – such as against the posterior surface of the manubrium. The camera/scope is used during positioning

of the main sheath 12 to ensure proper placement adjacent to the aorta without causing injury to the aorta.

The obturator 40 and scope/camera are withdrawn from the main sheath 12, and the scope/camera insert 30 is coupled to the main sheath 12 as shown in Figs. 6 – 11. The scope/camera is positioned within the insert 30.

Under visualization using the scope/camera, the purse-string suture applier 16 is advanced through the main sheath, and used to form a purse-string suture as shown in Fig. 3. In a preferred method for forming the purse-string suture, the suture needle is passed partially rather than fully through the vessel wall, such as only through the adventitia of the vessel.

The introducer sheath 14 is positioned adjacent to the purse-string suture applier 16 within the main sheath 12. An introducer needle is passed through the lumen of the introducer sheath 14 and used to penetrate the aorta in the region encircled by the purse-string suture, and a guidewire is advanced into the ascending aorta. Next, the distal end of the introducer sheath 14 is advanced through the needle puncture, and into the ascending aorta. For example, the introducer may be advanced over the guidewire using a dilator, which may be a staged (e.g. 9F, 18F, 28F dilator) to expand the needle puncture.

The dilator is then removed from the introducer sheath. See Fig. 4. Note that while the purse-string suture applier 16 is shown in Fig. 4, in practice the user might choose to remove it from the main sheath prior to or after the introducer sheath is positioned. The free ends of the suture may be retained outside the body (see Fig. 1) following formation of the purse-string suture ring.

The TAVI procedure is carried out through the introducer sheath 14. Articulation of the introducer sheath allows its distal portion to be optimally oriented towards the aortic valve for valve delivery.

Once the procedure is completed, the introducer sheath is withdrawn from the aorta. The purse string suture is tightened as the introducer sheath is withdrawn from the aorta, closing the puncture opening against blood loss. Finally, the main sheath 12 is withdrawn from the percutaneous incision, and the incision is then closed.

The embolic protection device is preferably removed after the main sheath has been removed. To remove the embolic protection device, a retrieval catheter or sheath is passed over the tethering wire into the aorta, and the embolic protection device is withdrawn into the retrieval catheter or sheath, causing it to collapse.

All prior patents and patent applications referred to herein, including for purposes of priority, are incorporated herein by reference.

We Claim:

1. A method for performing a medical procedure using direct percutaneous access of an aorta, the method comprising:
 - forming a incision through skin adjacent to a sternum;
 - inserting a main sheath through the incision and positioning the main sheath against a posterior portion of the sternum;
 - forming a purse-string suture in a wall of the aorta using instruments passed through the main sheath;
 - forming an opening in the wall of the aorta in a region encircled by the purse-string suture;
 - passing a distal end of an introducer sheath through the opening into the aorta;
 - performing a procedure using instruments passed through the introducer sheath into the aorta;
 - removing the introducer sheath from the opening; and
 - while removing the introducer sheath, applying tension to free ends of the purse-string suture, thereby tightening the purse-string suture to close the opening.
2. The method of claim 1, wherein positioning the main sheath against a posterior portion of the sternum positions the main sheath against a posterior portion of a manubrium.
3. The method of claim 1, further including positioning an embolic protection device to divert emboli away from the ostia of at least the brachiocephalic and left common carotid arteries while allowing blood flow from the aorta into said arteries.
4. The method of claim 3, wherein positioning the embolic protection device includes percutaneously introducing the embolic protection device into a left subclavian artery or femoral artery and advancing the embolic protection device into the aorta.
5. A system for direct percutaneous access of an aorta, the system comprising:

a main sheath insertable through a percutaneous incision, the main sheath having a face positionable in stable contact with a posterior surface of the sternum, and a lumen;

a purse-string suture applier extendable through a lumen of the main sheath and positionable in proximity to the aorta, the purse-string suture applier having a needle and suture thereon, the purse-string suture applier manipulatable to form a purse-string suture in a wall of the aorta;

an introducer sheath extendable through a lumen of the main sheath and through an opening formed in a portion of the wall encircled by the purse-string.

6. The system of claim 5, wherein the main sheath has a generally triangular cross section.

7. The system of claim 5, wherein the main sheath has a generally elliptical cross-section.

8. The system of claim 5, further including a channel insert, the channel insert including a proximal end engagable with the proximal end of the main sheath, an elongate section extendable through the lumen of the main sheath, and a lumen through the elongate section.

9. The system of claim 5, further including an embolic protection device including a barrier positionable covering at least the ostia of the brachiocephalic and left common carotic arteries, the barrier having a surface permeable to passage of blood therethrough but impermeable to passage of embolic material.

10. The system of claim 9, wherein the embolic protection device includes a support extendable through the left subclavian artery.

11. The system of claim 5, wherein the introducer sheath includes a passage and a valve positioned to seal the passage against blood loss therethrough.

12. The system of claim 11, wherein the valve has a sealed, position in which the passage is sealed, and an unsealed position, and wherein the valve is biased in the sealed position.

13. The system of claim 12, wherein the valve in the sealed position seals against instruments extending through the passage.

14. The system of claim 12, wherein the introducer sheath includes a member manually moveable to move the valve from the sealed to the unsealed position, the member biased to return the valve to the sealed position upon release of manual force against the member.

15. The system of claim 5, further including a needle extendable through the wall of the aorta encircled by the purse string suture to form an opening in the aorta, and an introducer sheath advanceable through the opening.

16. The system of claim 5, wherein the purse string suture applier comprises a needle holder and an end effector comprising suture needle carried by the needle holder.

17. The system of claim 16 wherein the suture applier includes a shaft having a distal portion supporting the end effector, the shaft articulatable at the distal portion.

18. The system of claim 17, wherein the end effector is axially rotatable about the distal portion of the shaft.

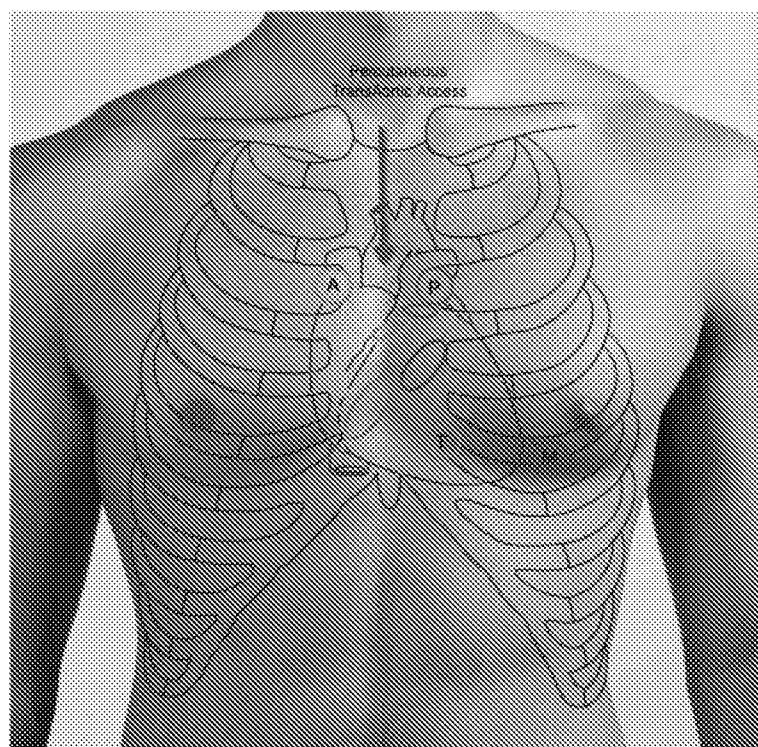


FIG. 1

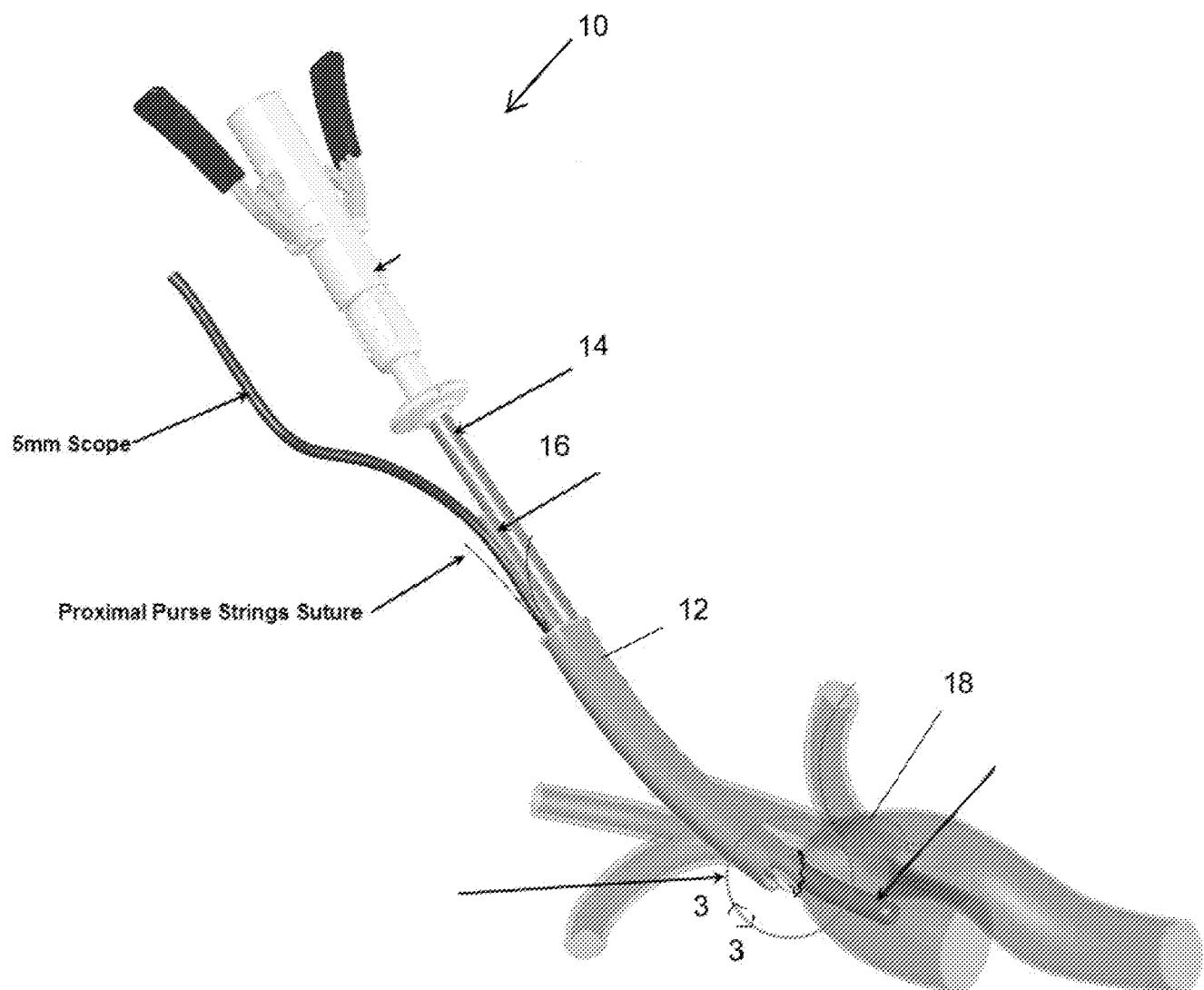


FIG. 2

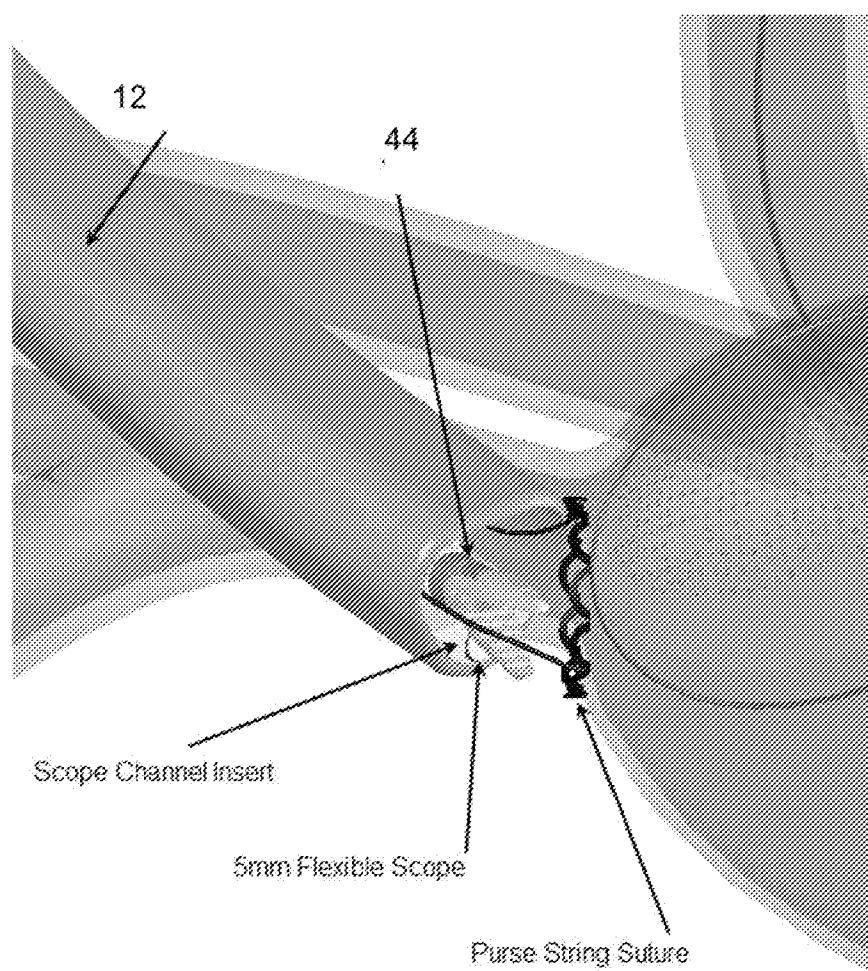


FIG. 3

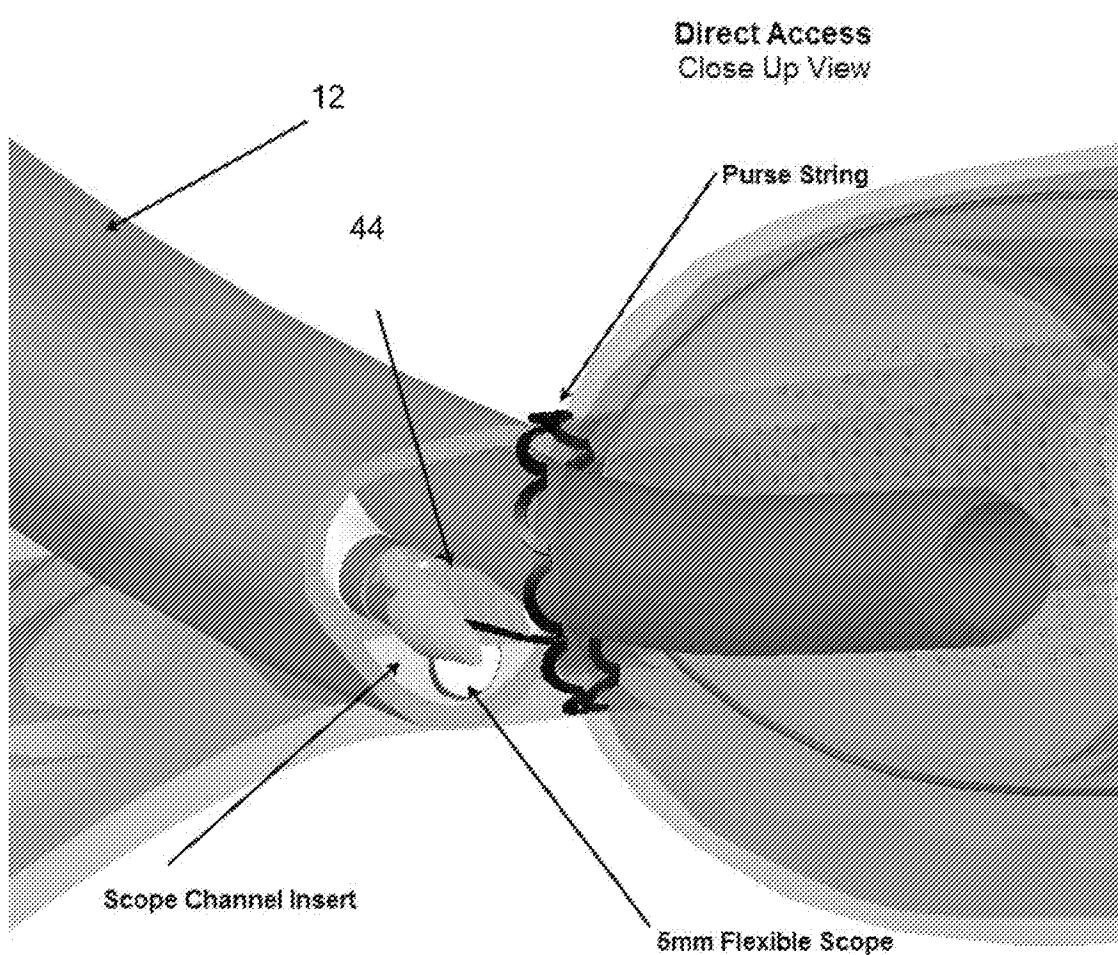


FIG. 4

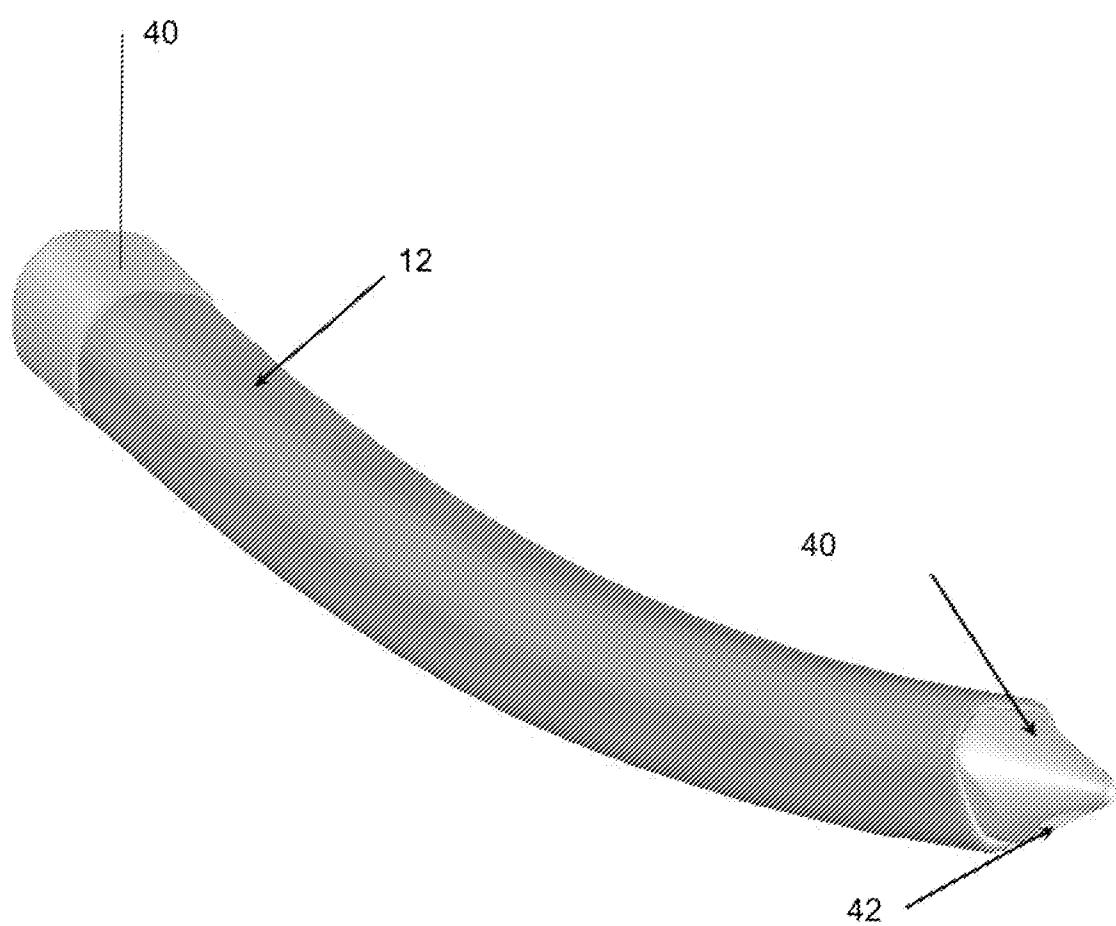
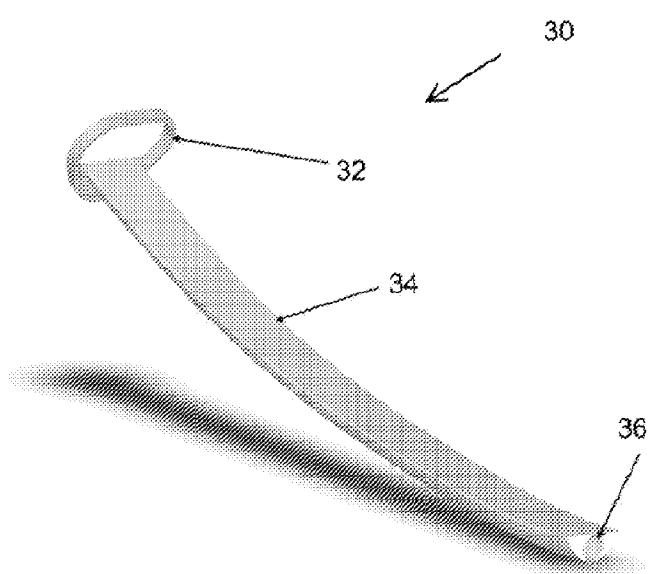
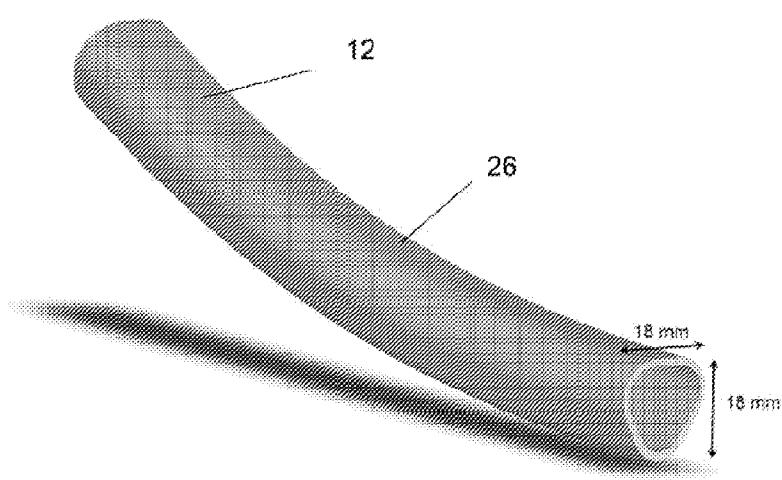


FIG. 5



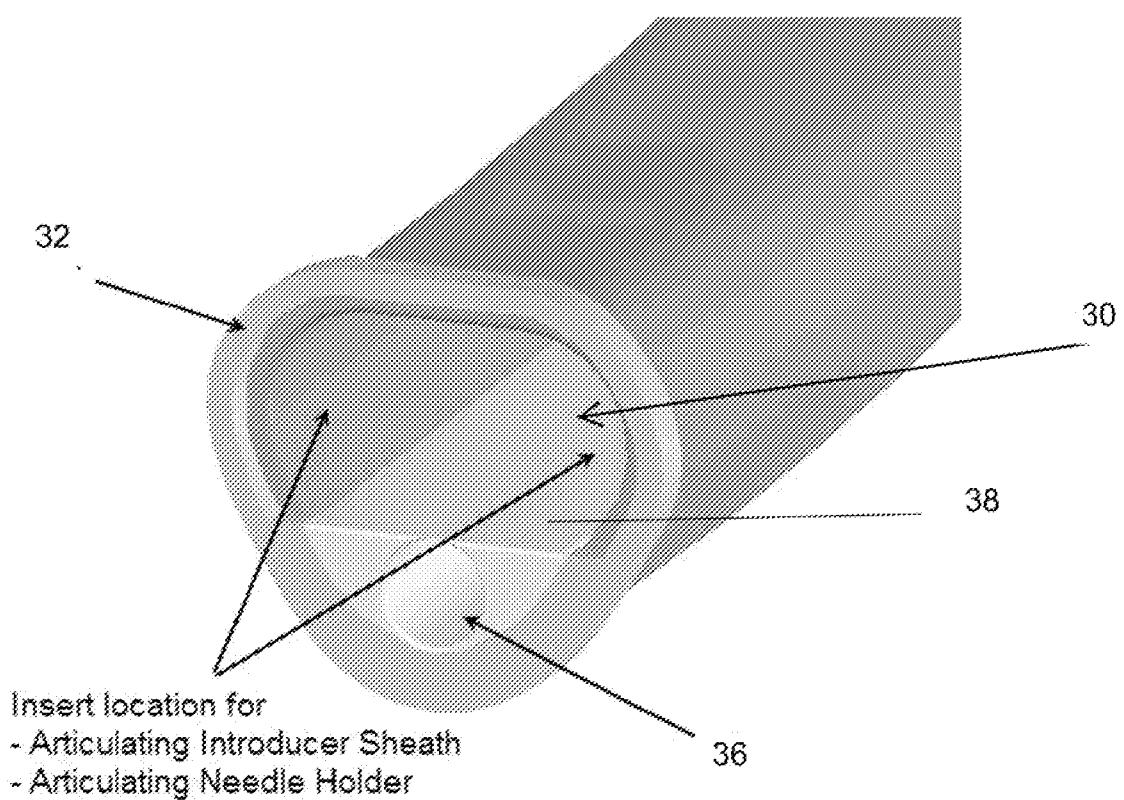


FIG. 8

32

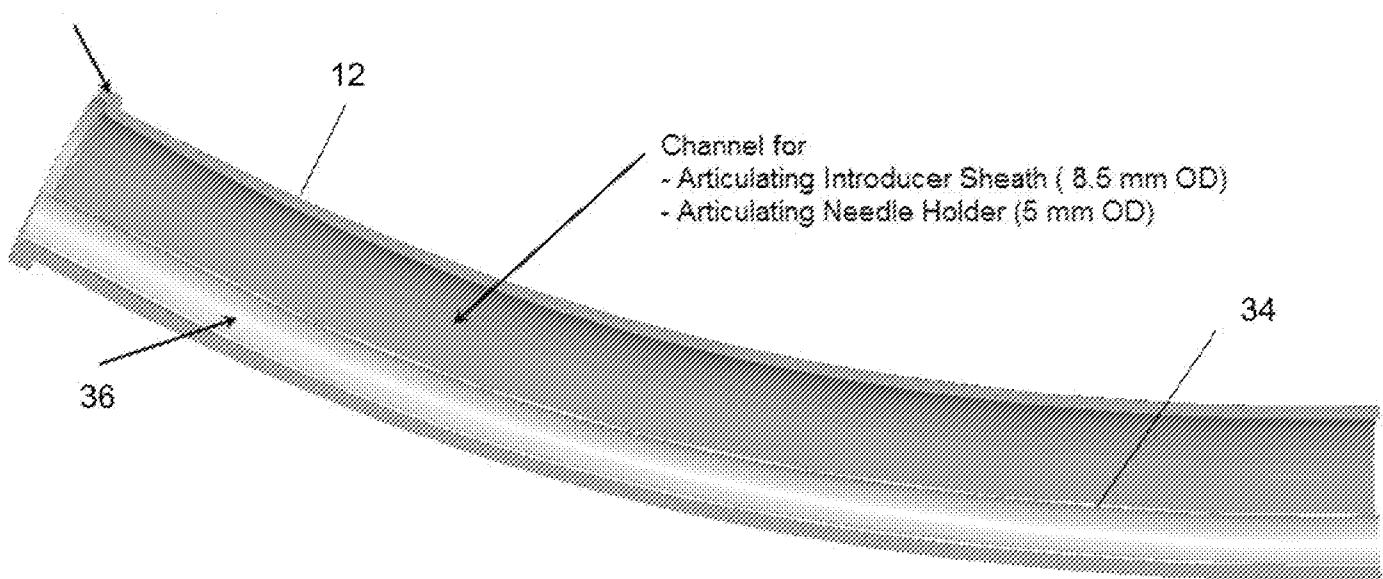


FIG. 9

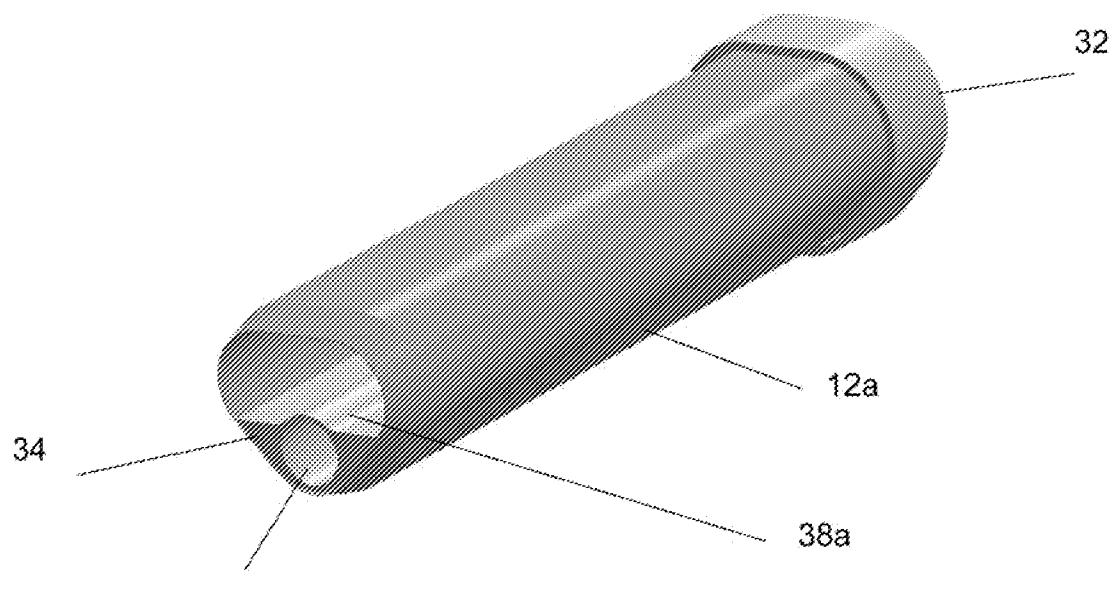


FIG. 10

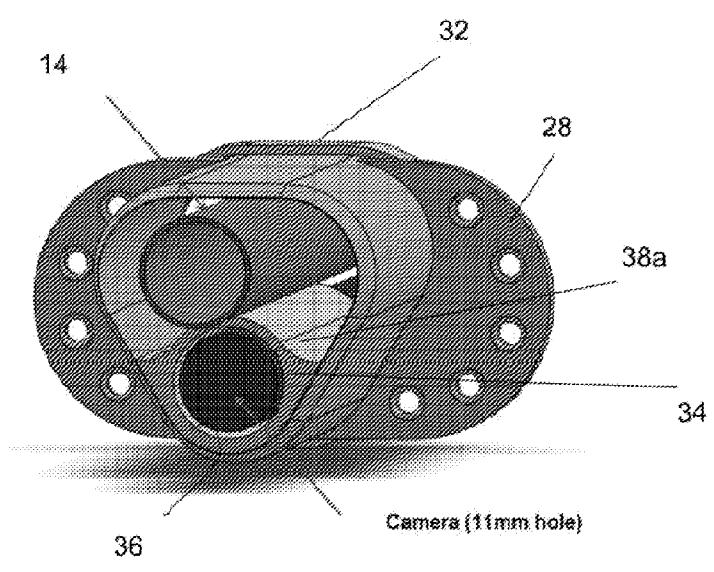


FIG. 11A

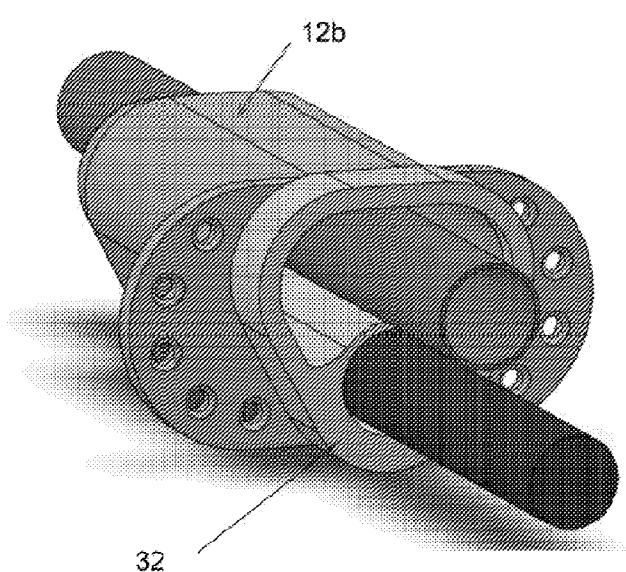


FIG. 11B

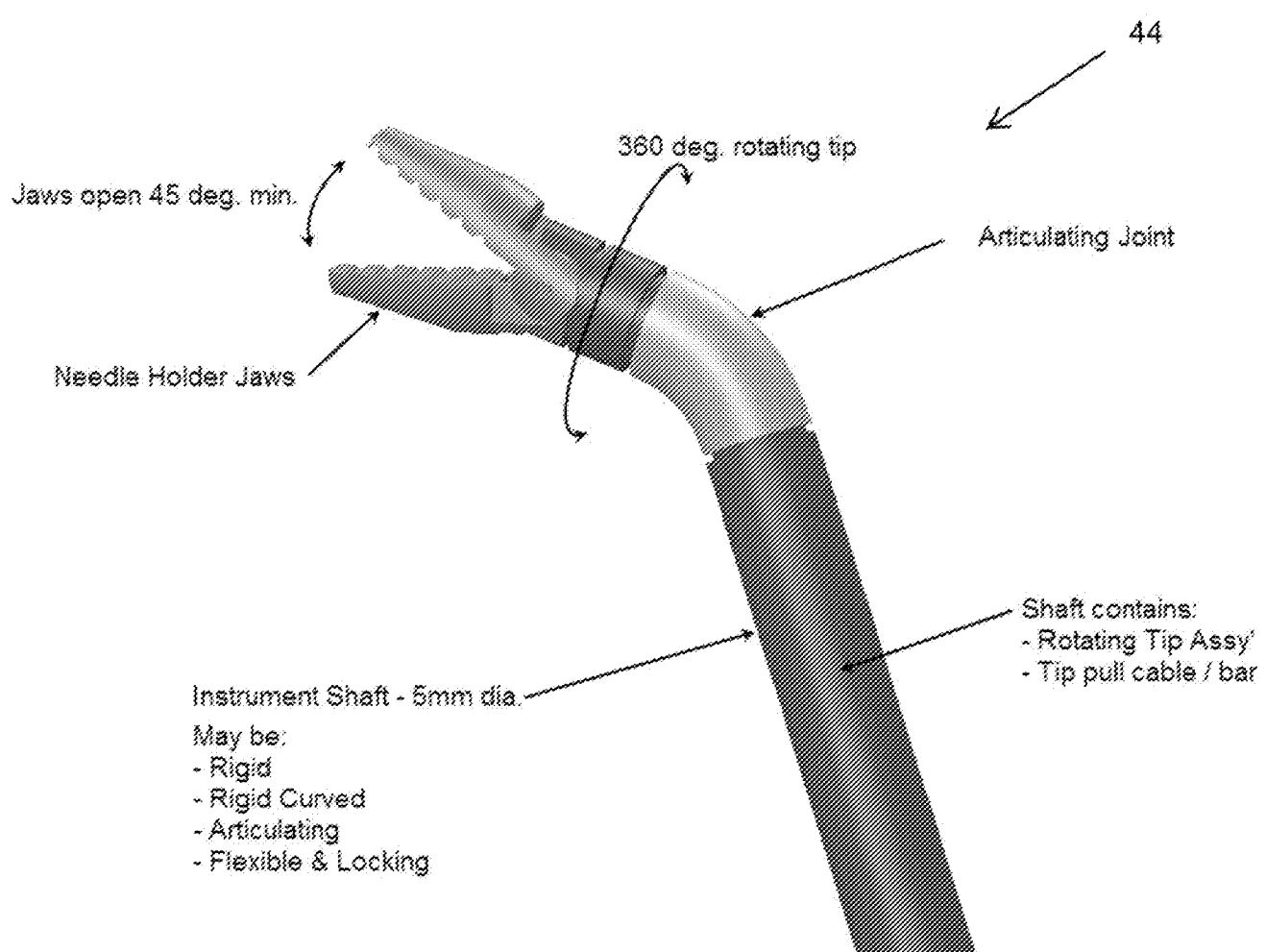
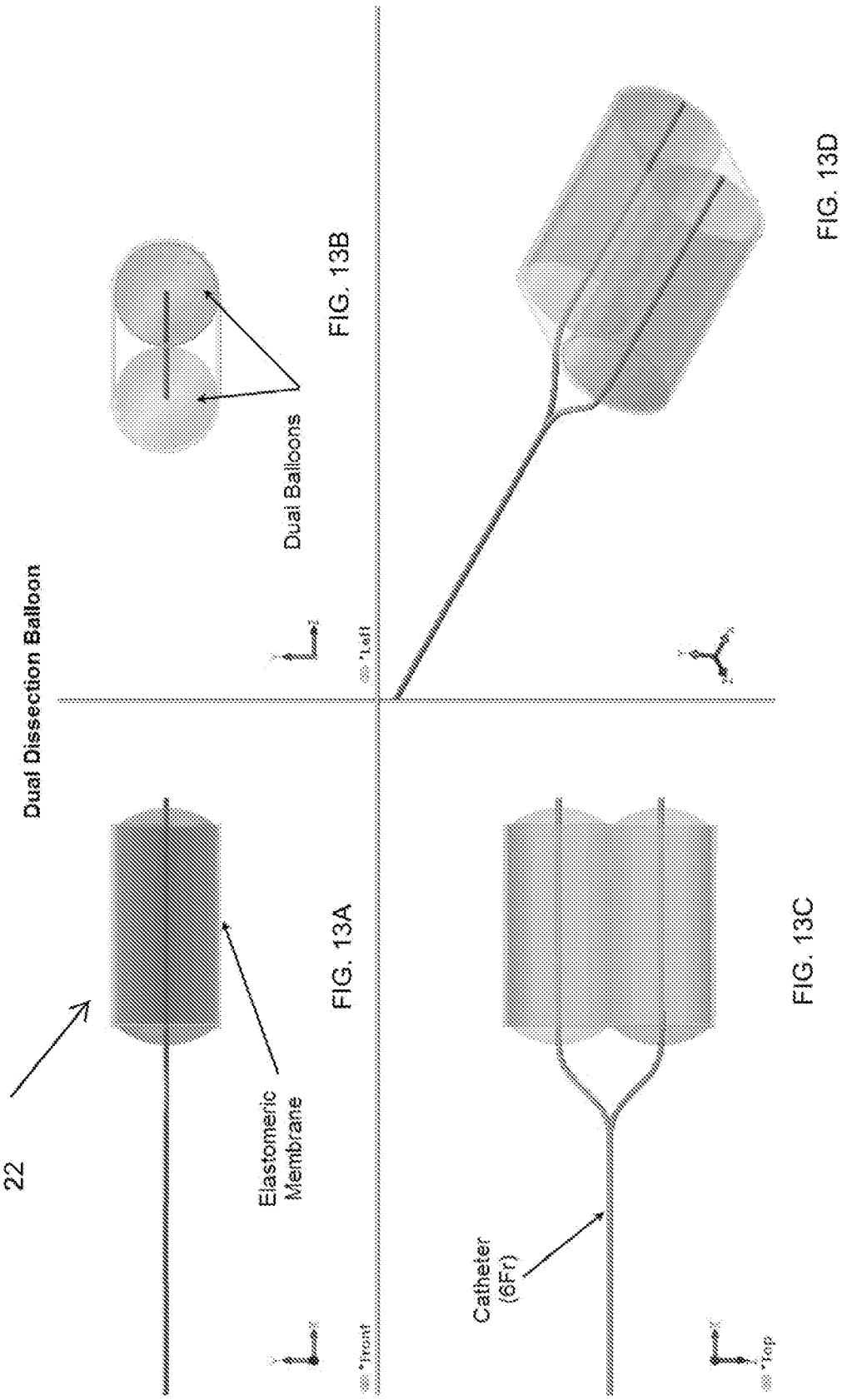


FIG. 12

22
Dual Dissection Balloon

Thoracic Balloon Dissection

24

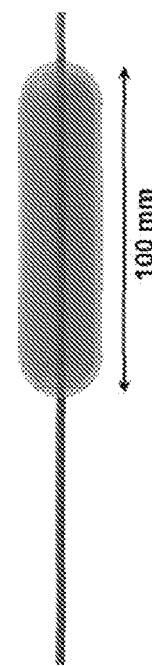


FIG. 14A

Thoracic Balloon Dissection



FIG. 14B

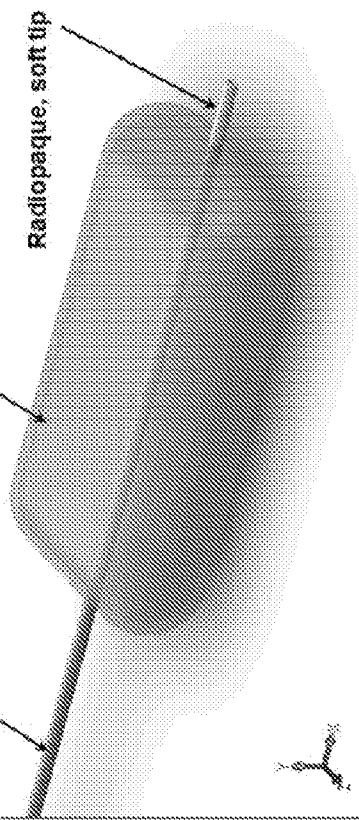
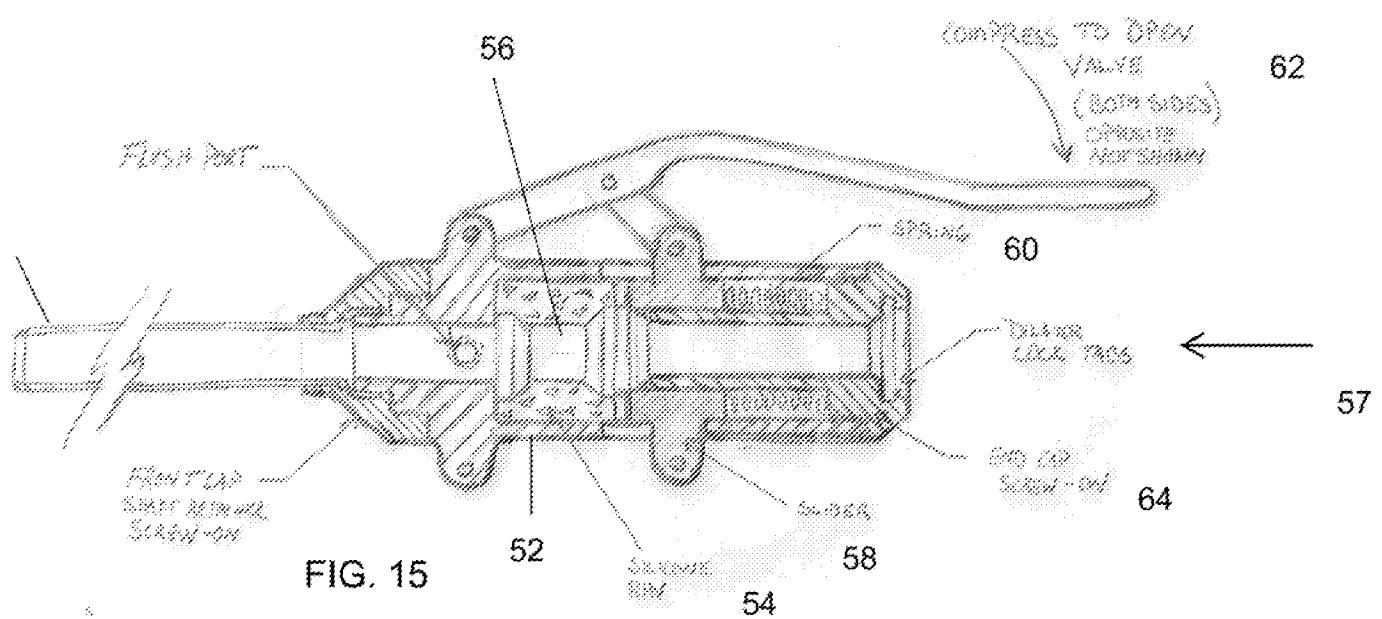
Catheter Shaft
(6 Fr - 8 Fr)

FIG. 14B

FIG. 14C

FIG. 14D



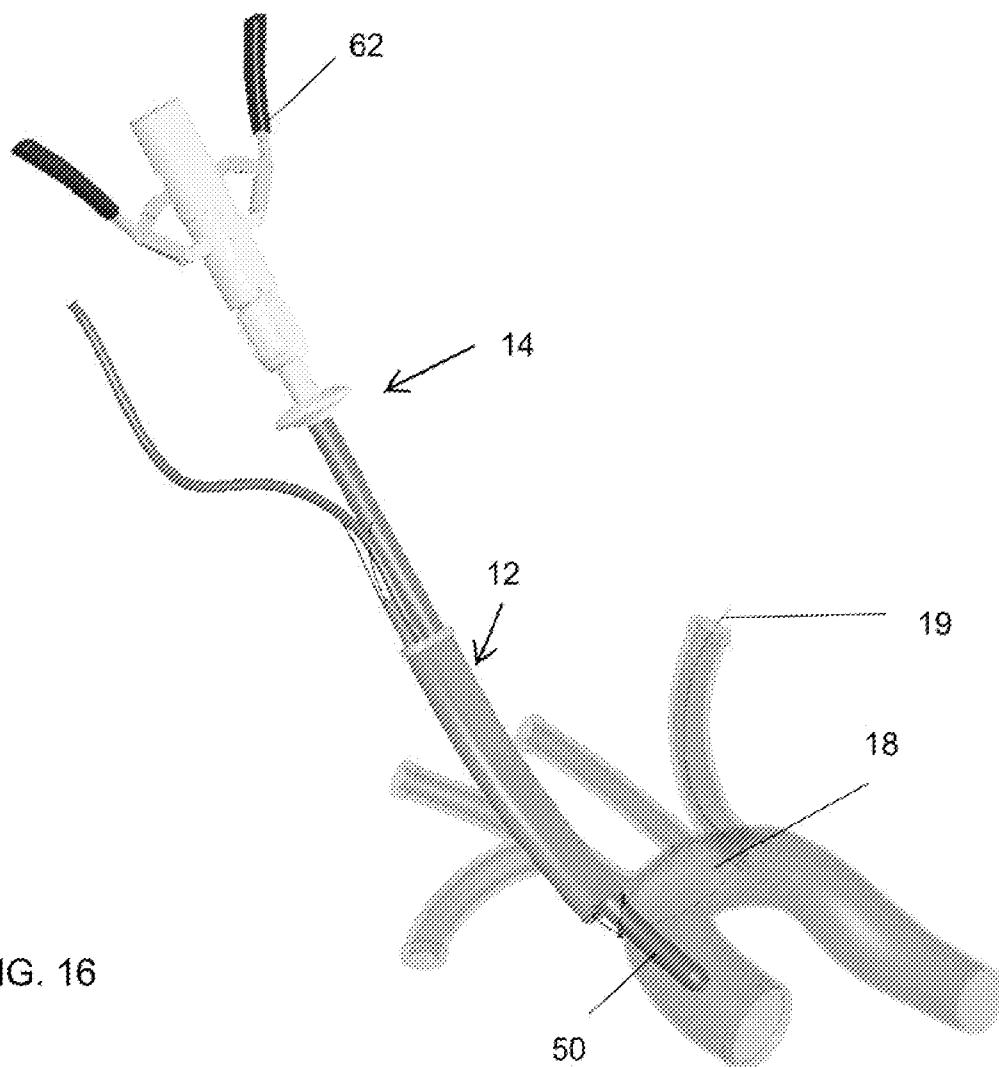
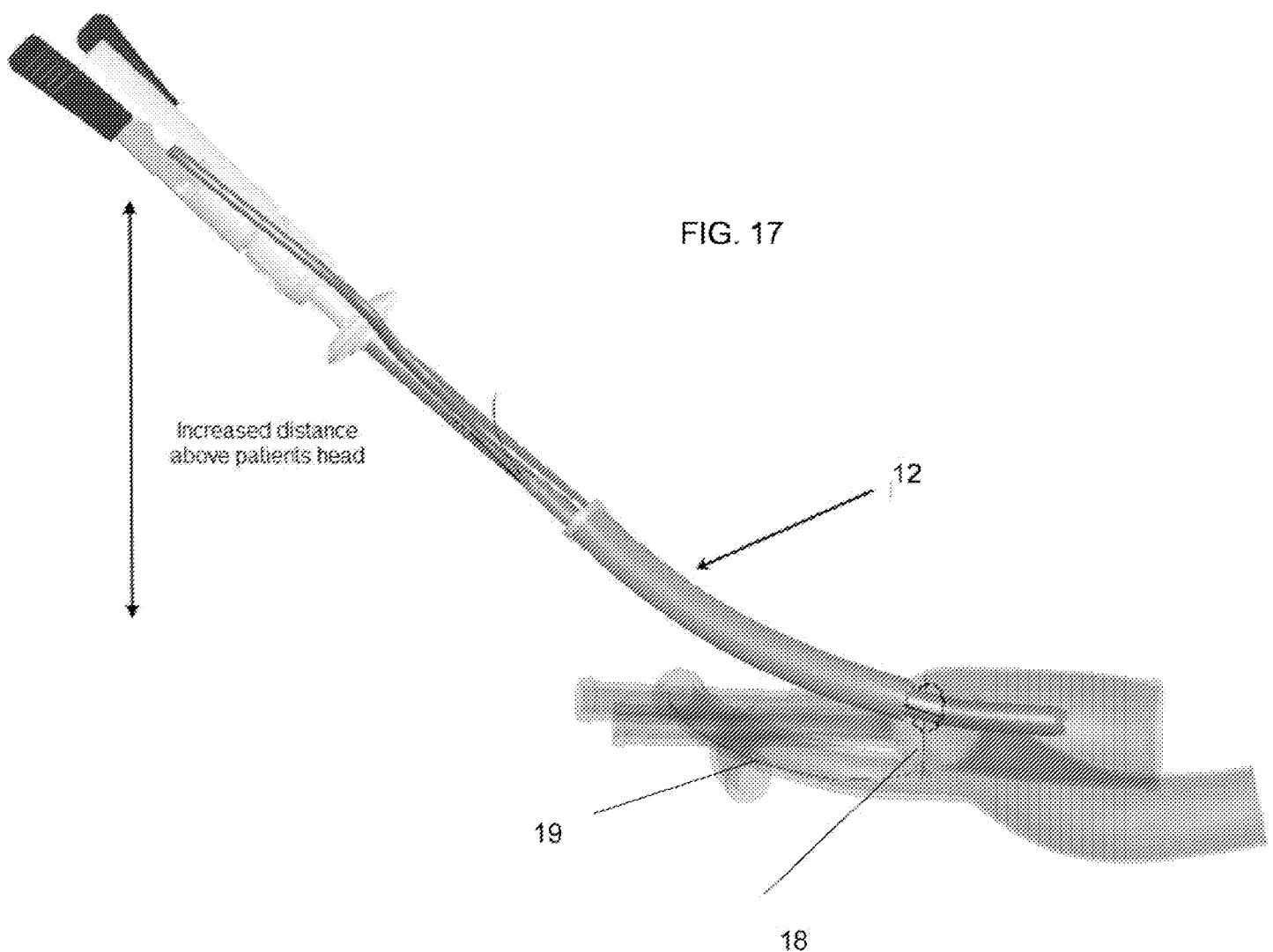


FIG. 16



A. CLASSIFICATION OF SUBJECT MATTER**A61B 17/34(2006.01)i, A61M 25/088(2006.01)i, A61F 2/24(2006.01)i, A61M 25/06(2006.01)i, A61B 17/04(2006.01)i**

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 17/34; A61B 17/068; A61B 17/04; A61M 25/088; A61F 2/24; A61M 25/06

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility modelsElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: direct percutaneous access, aorta, purse-string, sternum, chest**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	RAMLAWI, B. et al., "Transcatheter aortic valve replacement (TAVR): access planning and strategies" Methodist DeBakey Cardiovascular Journal, 2012 Apr-Jun, Vol.8, No.2, pp.22-25 See page 24, left column, lines 15-37.	5-8,11-18
A		9,10
Y	US 2003-0233108 A1 (GELLMAN, B. N. et al.) 18 December 2003 See claims 1, 2; paragraphs [0029], [0101], [0129], [0130]; figures 1-6.	5-8,11-18
A		9,10
A	US 2011-0282286 A1 (ARGENTINE, J.) 17 November 2011 See claim 1; paragraphs [0010], [0011].	5-18
A	WEBB, J. G. et al., "Current status of transcatheter aortic valve replacement" Journal of the American College of Cardiology, 2012 August 7, Vol.60, No.6, pp.483-492. See pp.486-488.	5-18
A	US 2012-0037686 A1 (HESSLER, T. R.) 16 February 2012 See abstract; claim 1; figures 1-3.	5-18

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

- * Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of 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 20 November 2013 (20.11.2013)	Date of mailing of the international search report 21 November 2013 (21.11.2013)
Name and mailing address of the ISA/KR  Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. +82-42-472-7140	Authorized officer KIM, Seung Beom Telephone No. +82-42-481-3371

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2013/056530**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. Claims Nos.: 1-4
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-4 pertain to methods for treatment of the human body by surgery, and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.
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 fee, this Authority did not invite payment of any additional fee.
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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/056530

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003-0233108 A1	18/12/2003	AU 2003-248671 A1 AU 2003-248671 B2 CA 2486550 A1 CA 2486550 C DE 60328490 D1 EP 1511429 A2 EP 1511429 B1 US 2003-233104 A1 US 2003-233107 A1 US 2007-088372 A1 US 2009-062818 A1 US 2012-283755 A1 US 6955643 B2 US 7232447 B2 US 7442198 B2 US 8257369 B2 WO 03-105701 A2	31/12/2003 26/03/2009 24/12/2003 24/05/2011 03/09/2009 09/03/2005 22/07/2009 18/12/2003 18/12/2003 19/04/2007 05/03/2009 08/11/2012 18/10/2005 19/06/2007 28/10/2008 04/09/2012 24/12/2003
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US 2012-0037686 A1	16/02/2012	AU 2011-203361 A1 CA 2746300 A1 EP 2417916 A2 JP 2012-035075 A	01/03/2012 11/02/2012 15/02/2012 23/02/2012