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(54) **TRANSSEPTAL DELIVERY SYSTEM FOR AORTIC VALVE THERAPEUTIC DEVICES**

Publication Classification

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(51) **Int. Cl.**

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(52) **U.S. Cl.**

CPC *A61B 17/00234* (2013.01); *A61F 2/2427* (2013.01); *A61B 2017/00358* (2013.01); *A61B 2017/00243* (2013.01); *A61B 2017/00323* (2013.01); *A61M 25/0125* (2013.01)

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(57)

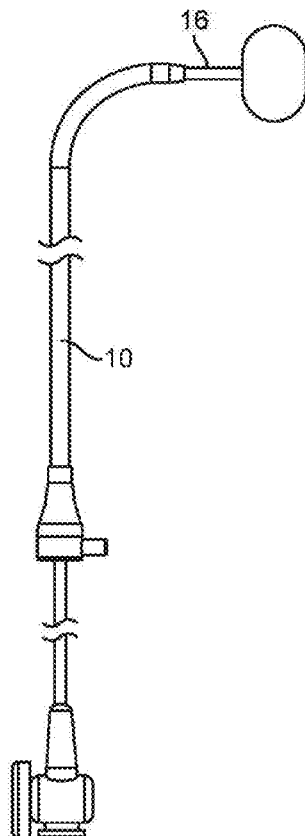
ABSTRACT

Related U.S. Application Data

(63) Continuation of application No. 16/365,601, filed on Mar. 26, 2019, now Pat. No. 11,129,603, which is a continuation-in-part of application No. PCT/US2017/062913, filed on Nov. 22, 2017, which is a continuation-in-part of application No. PCT/US2018/045445, filed on Aug. 6, 2018.

(60) Provisional application No. 62/647,894, filed on Mar. 26, 2018, provisional application No. 62/541,761, filed on Aug. 6, 2017, provisional application No. 62/567,736, filed on Oct. 3, 2017, provisional application No. 62/541,771, filed on Aug. 6, 2017, provisional application No. 62/647,894, filed on Mar. 26, 2018.

A system and method used to deliver an aortic valve therapeutic device, such as a delivery device for an aortic valve replacement, to an aortic valve site. The system includes a cable percutaneously introduced a cable into a vasculature of a patient and positioned to run from a femoral vein, through the heart via a transseptal puncture, and to a femoral artery. The therapeutic device is passed over an end of the cable at the venous side and is secured to the cable. The therapeutic device is pushed in a distal direction while the second end of the cable is pulled in the proximal direction to advance the therapeutic device to the mitral valve site. A left ventricle redirector aids in orienting the therapeutic device and preventing migration of the cable towards delicate mitral valve structures and chordae tendoneae during advancement of the therapeutic device.



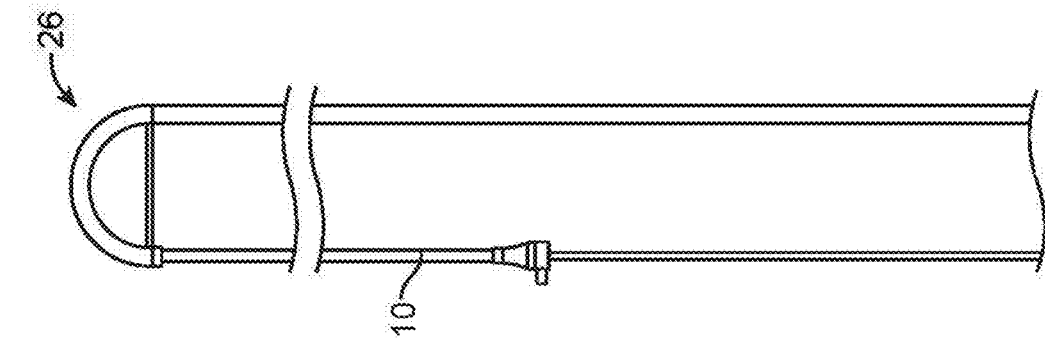


FIG. 1A

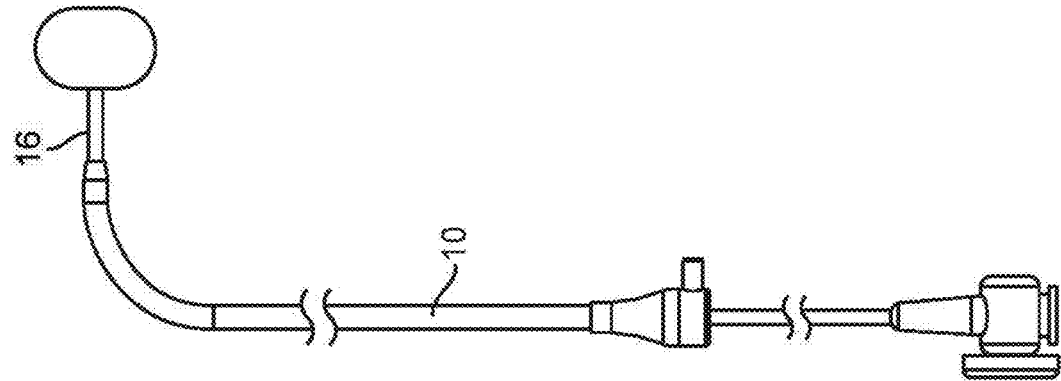


FIG. 1B

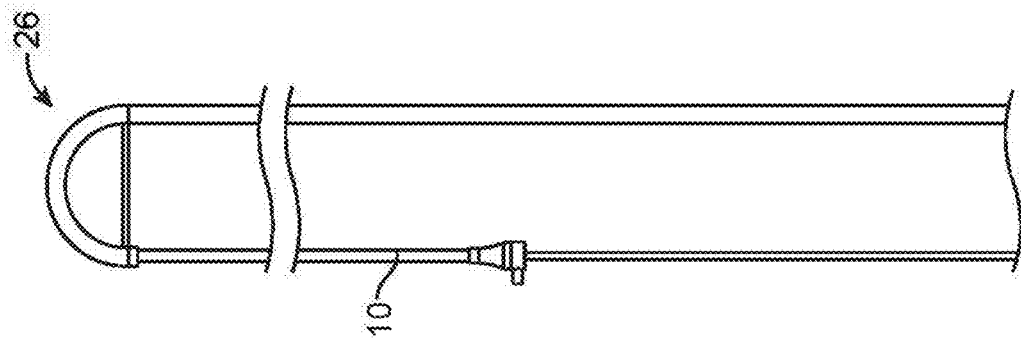


FIG. 1C

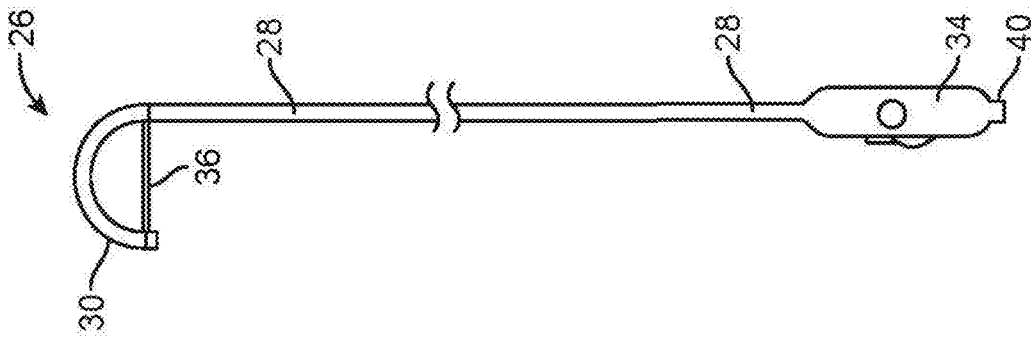


FIG. 2A

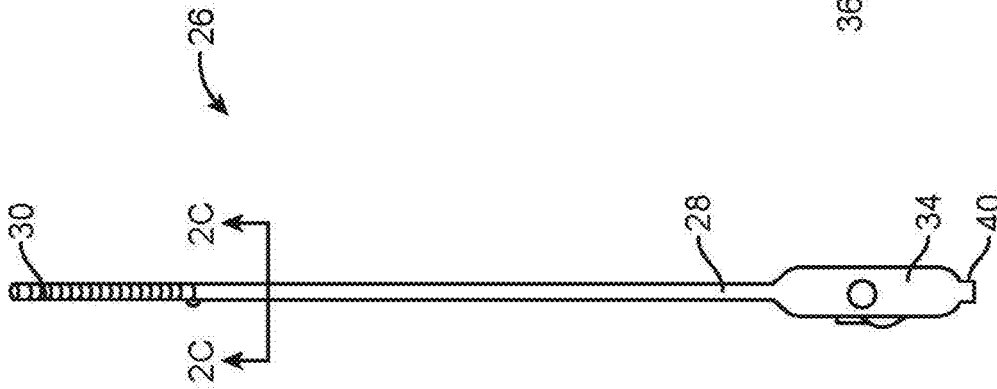


FIG. 2B

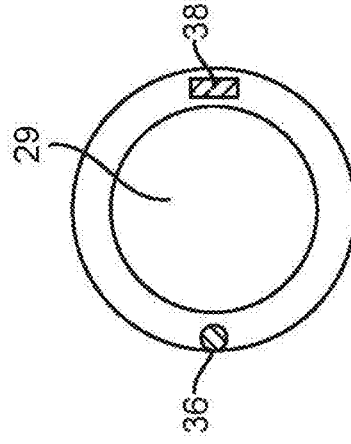


FIG. 2C

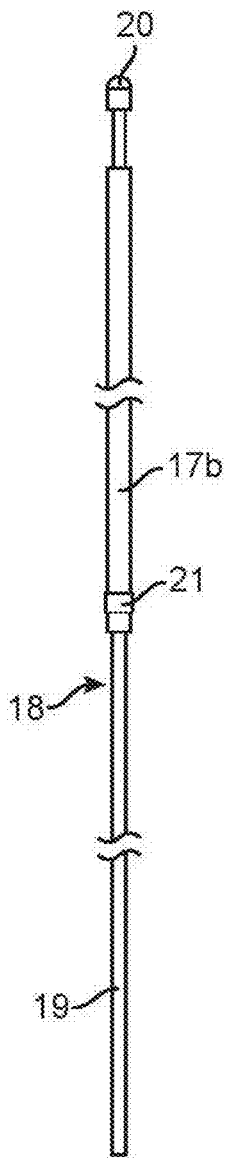


FIG. 3A

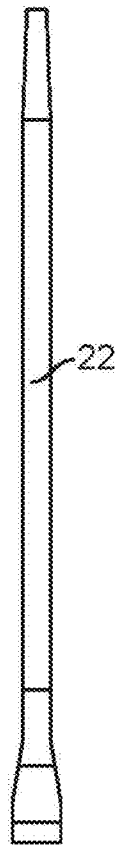


FIG. 3B

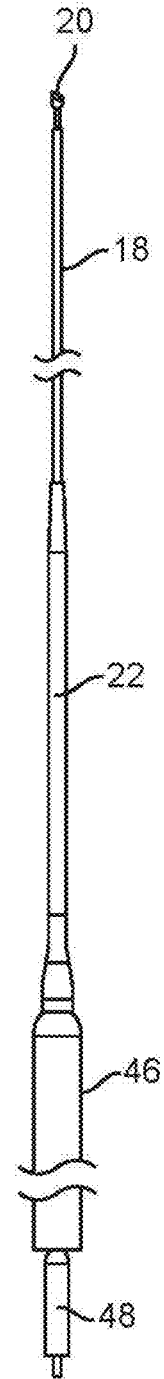


FIG. 3C

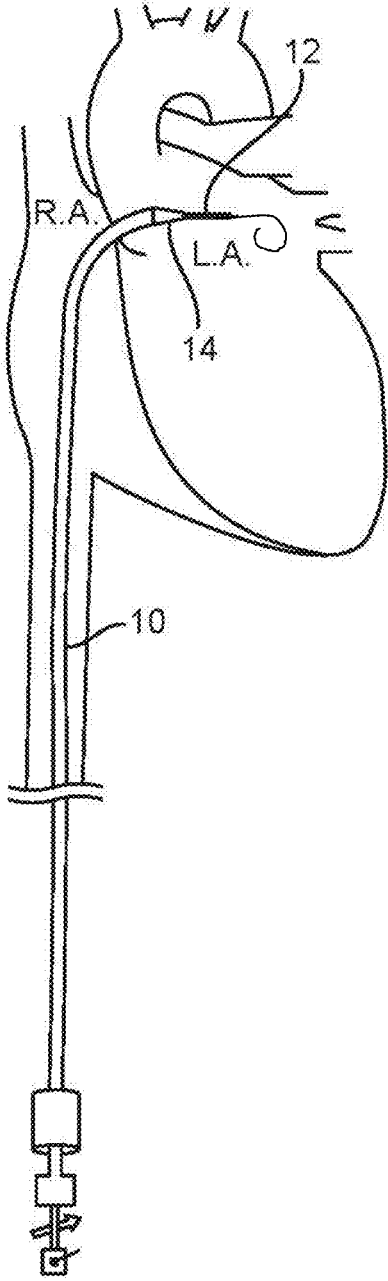


FIG. 4A

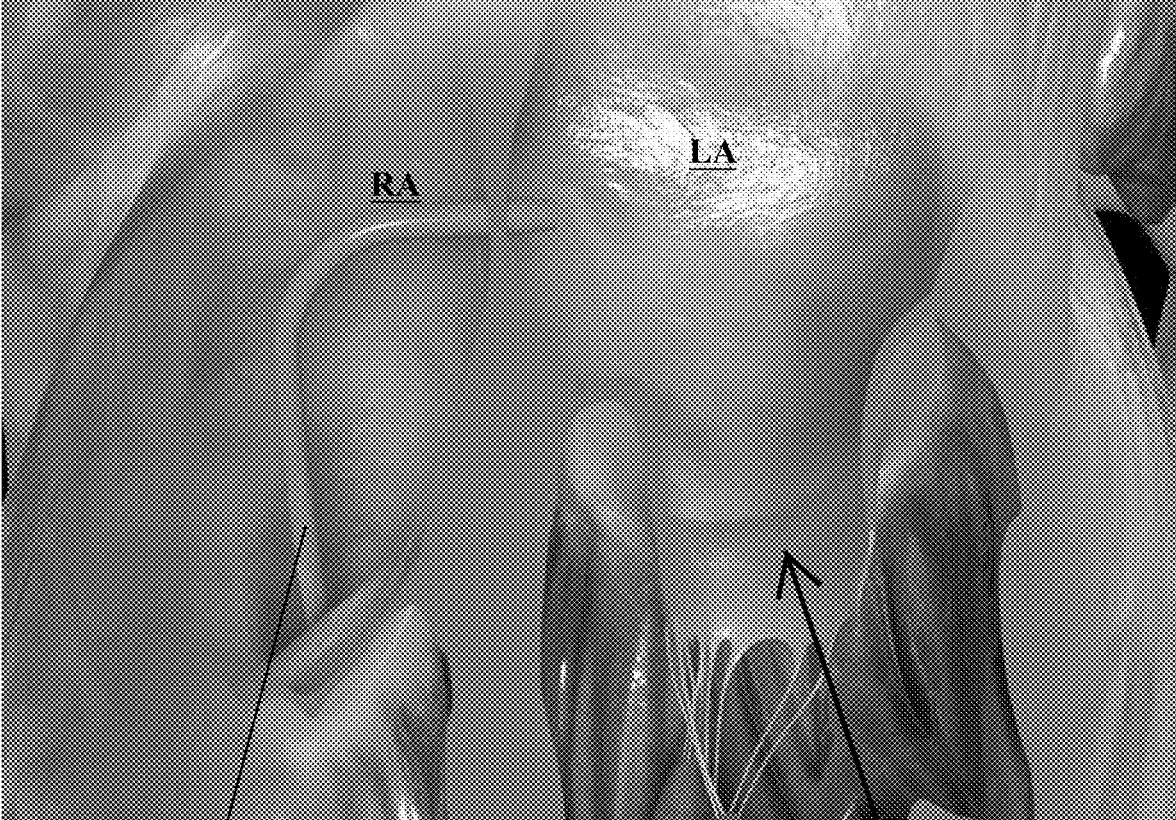
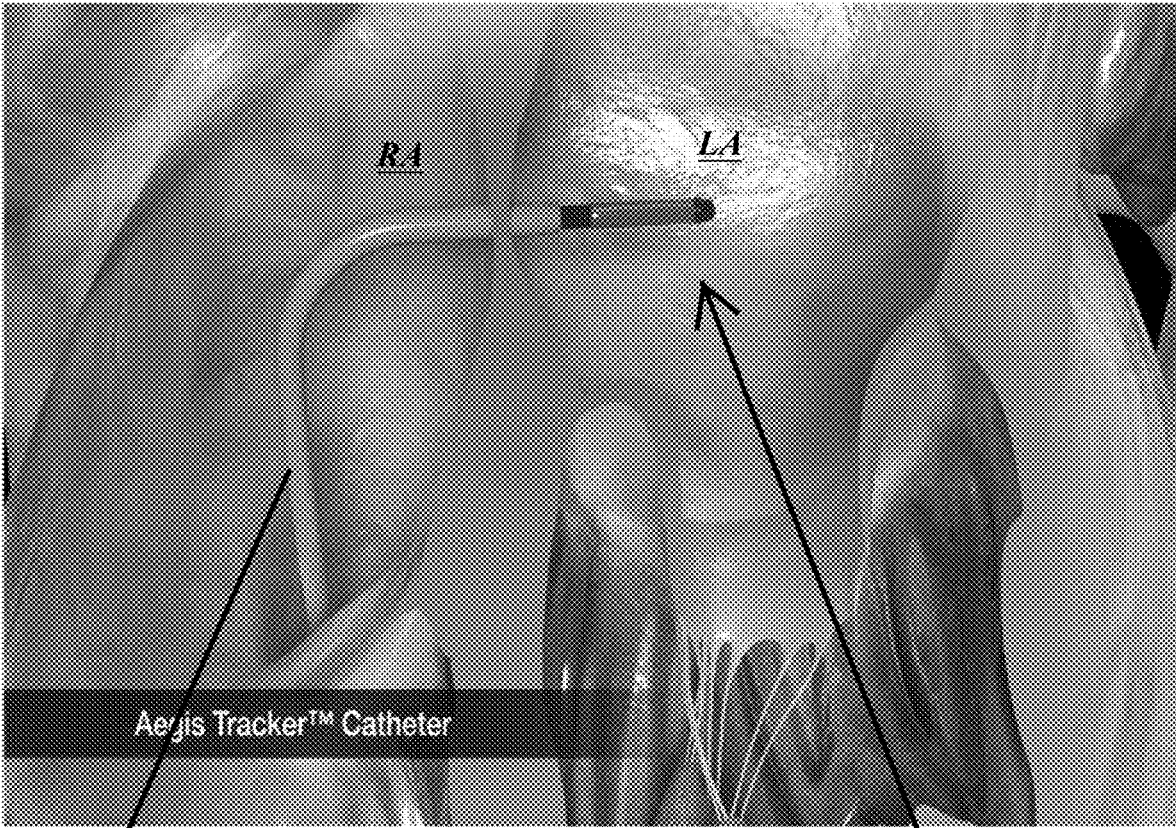


FIG. 4B

10

MV



10

FIG. 5

16

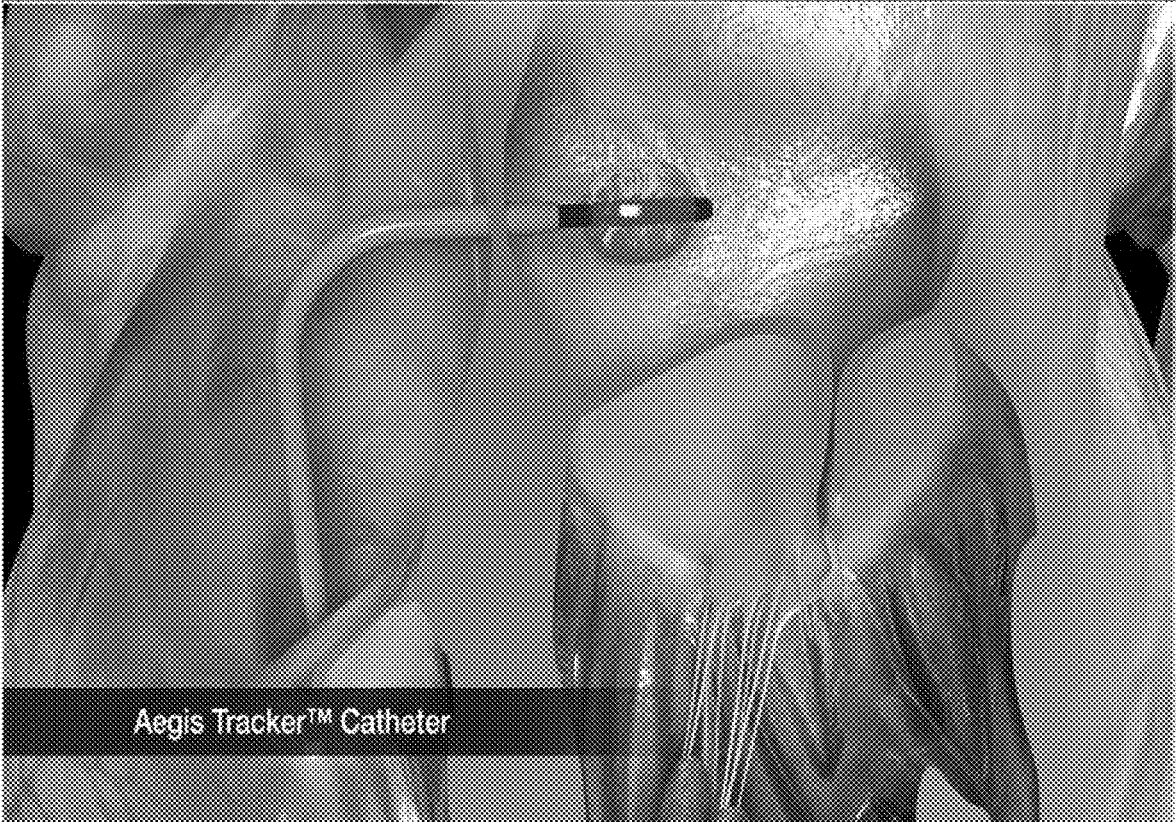


FIG. 6

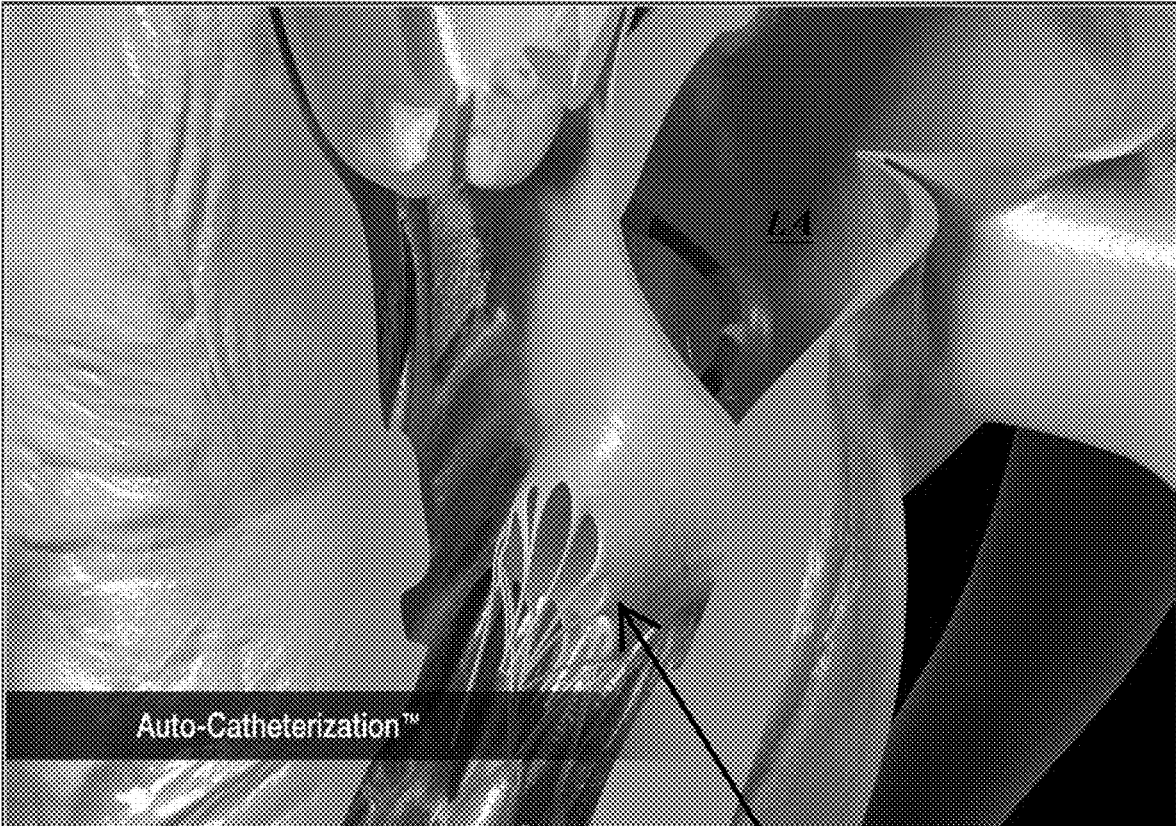


FIG. 7

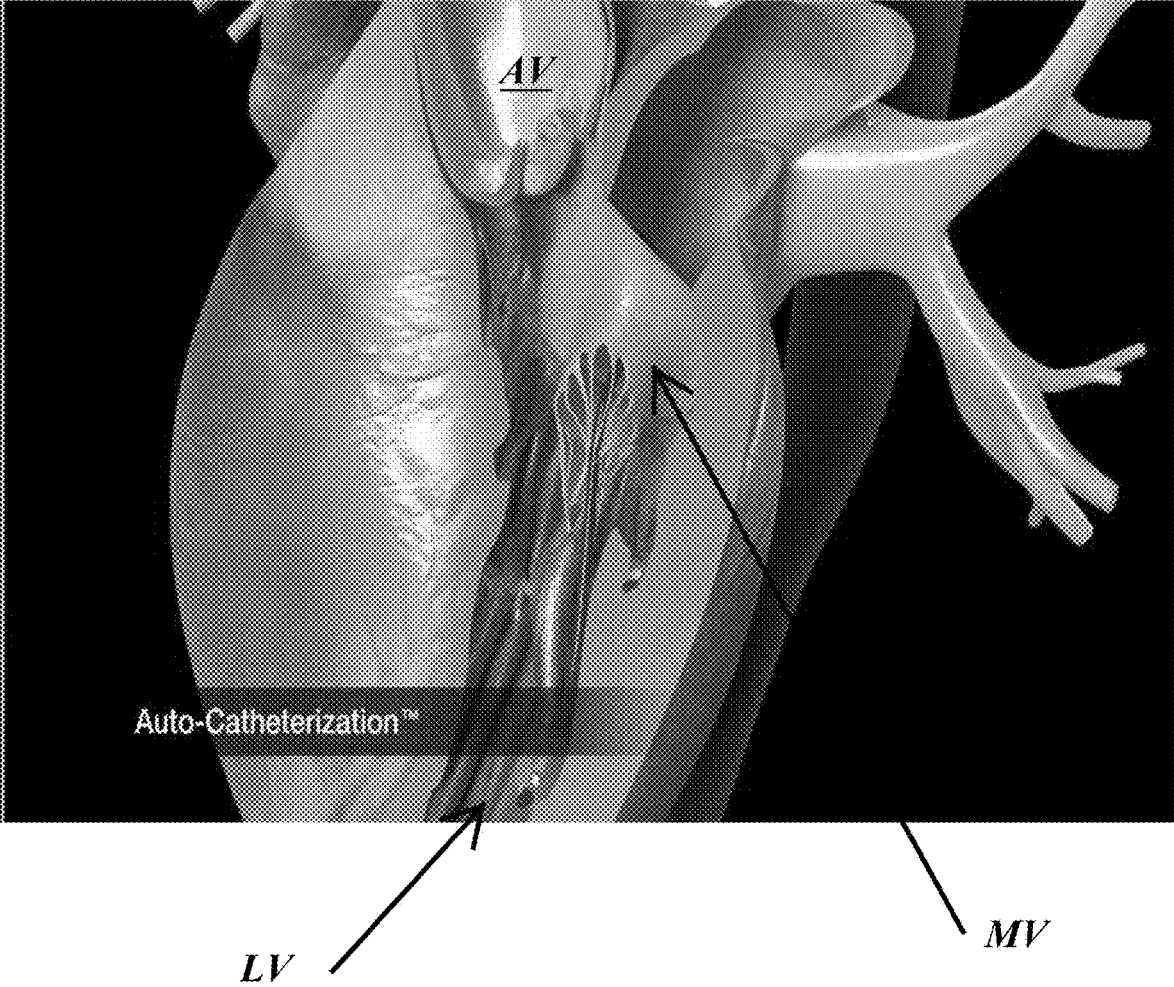


FIG. 8

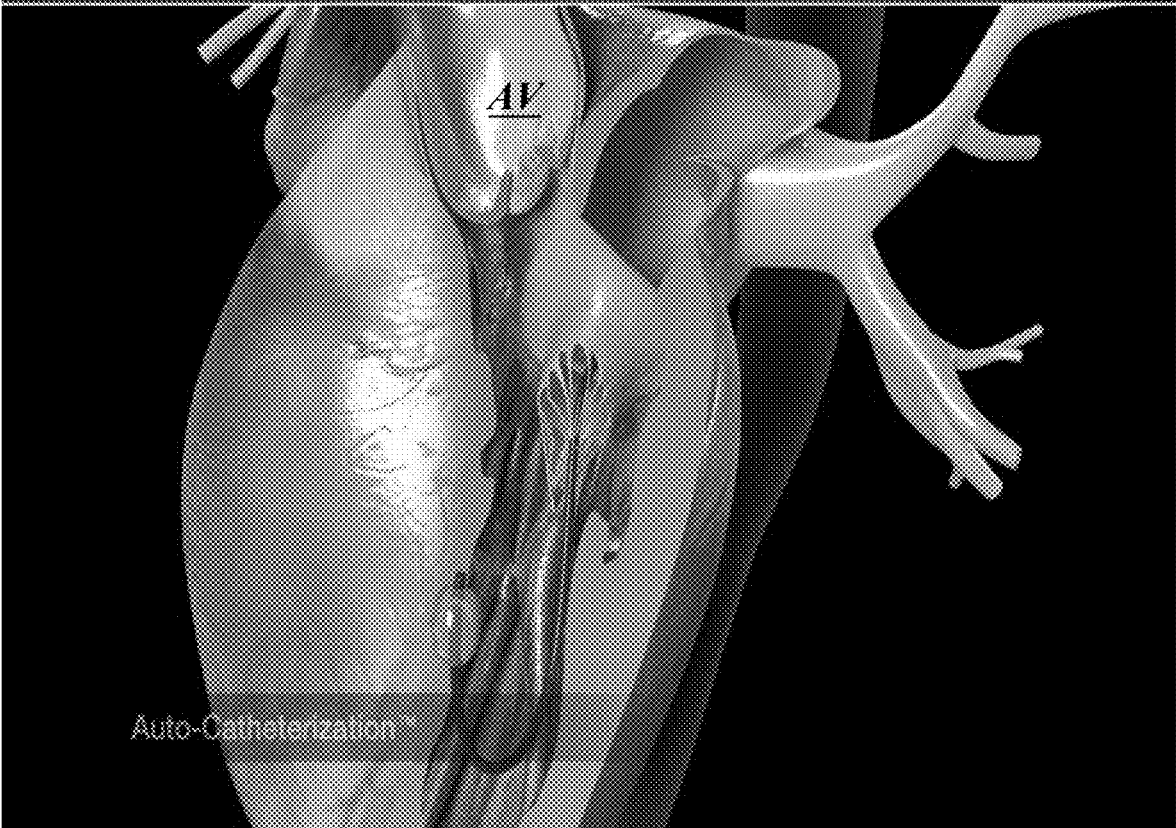


FIG. 9

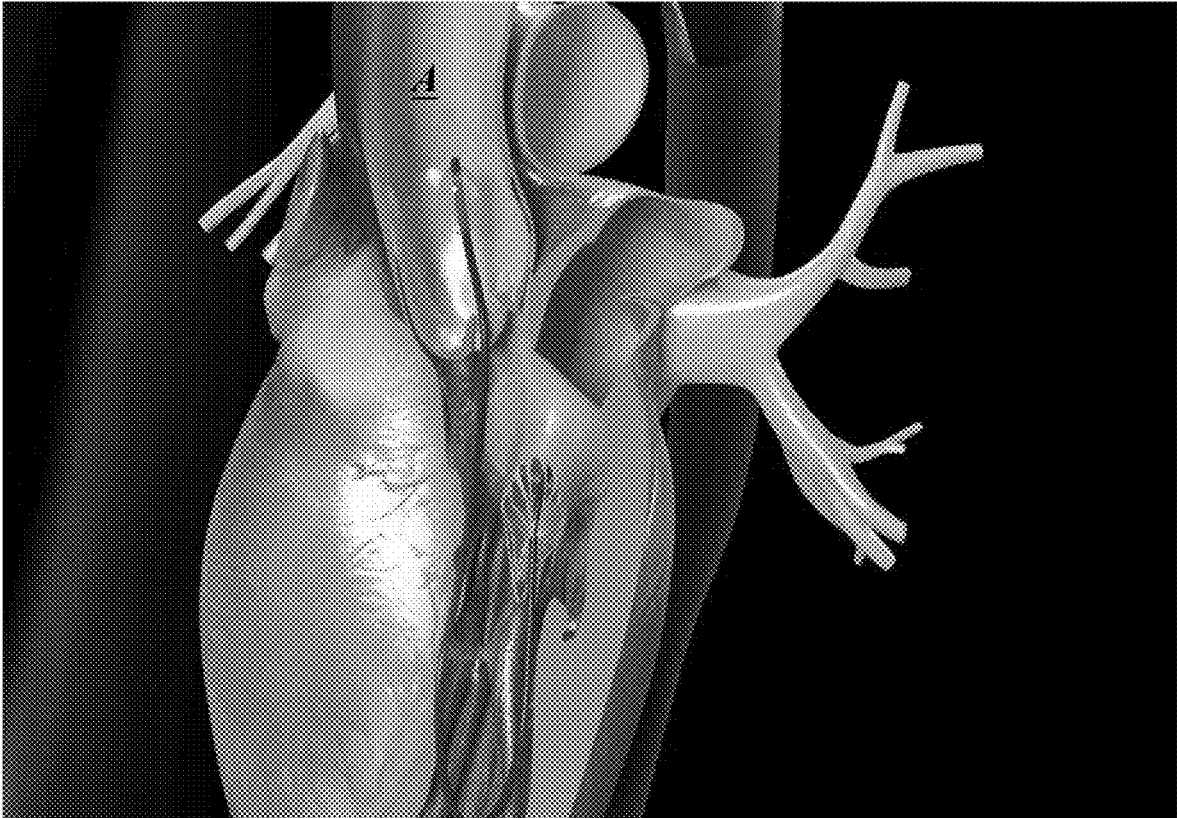
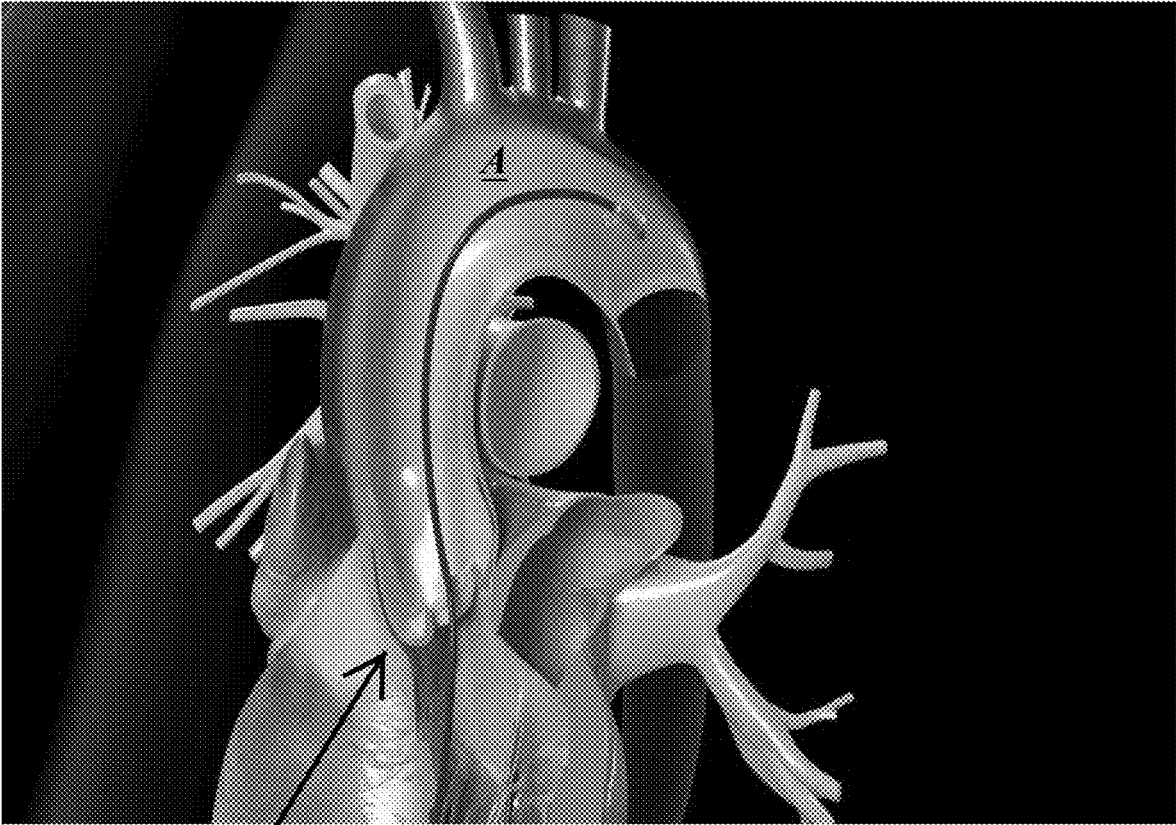


FIG. 10



AV

FIG. 11

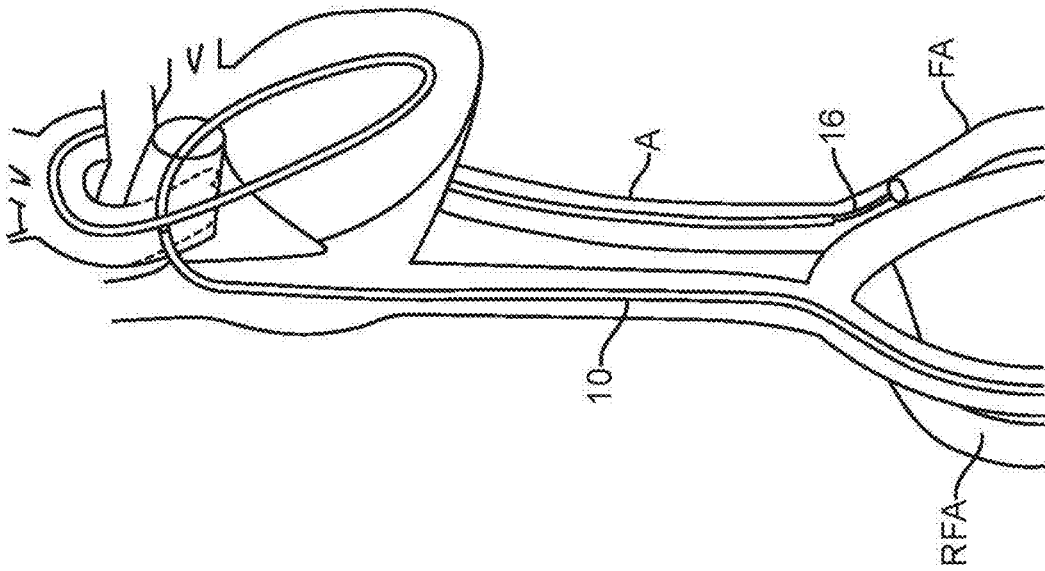


FIG. 12

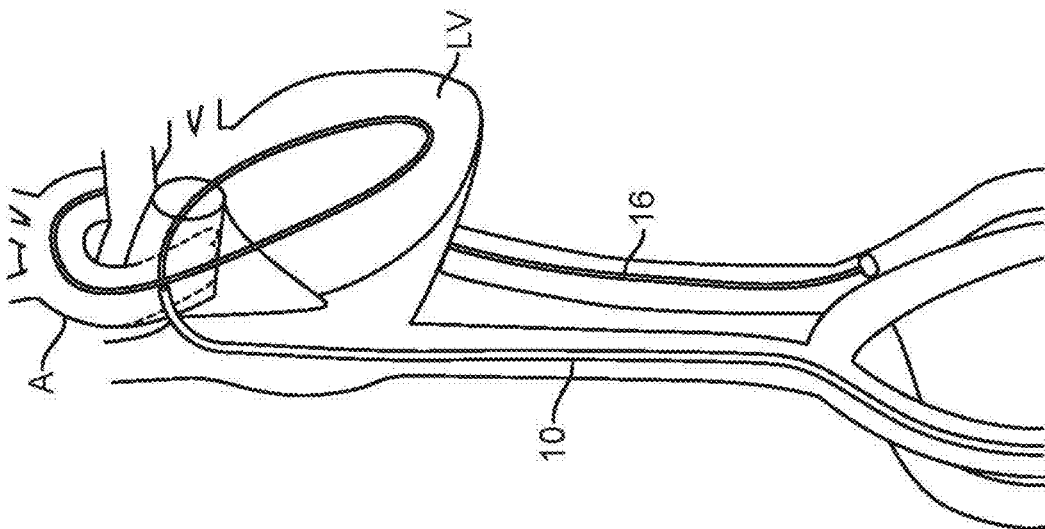


FIG. 13



FIG. 14

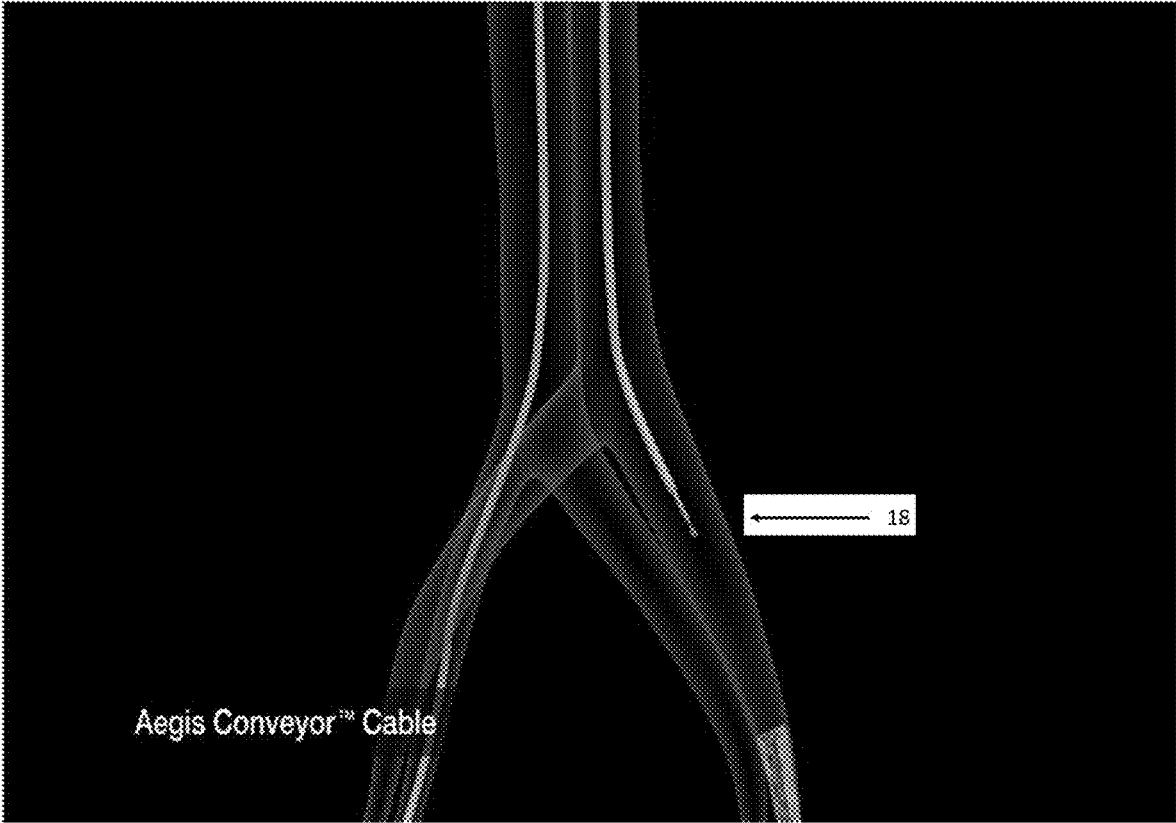


FIG. 15

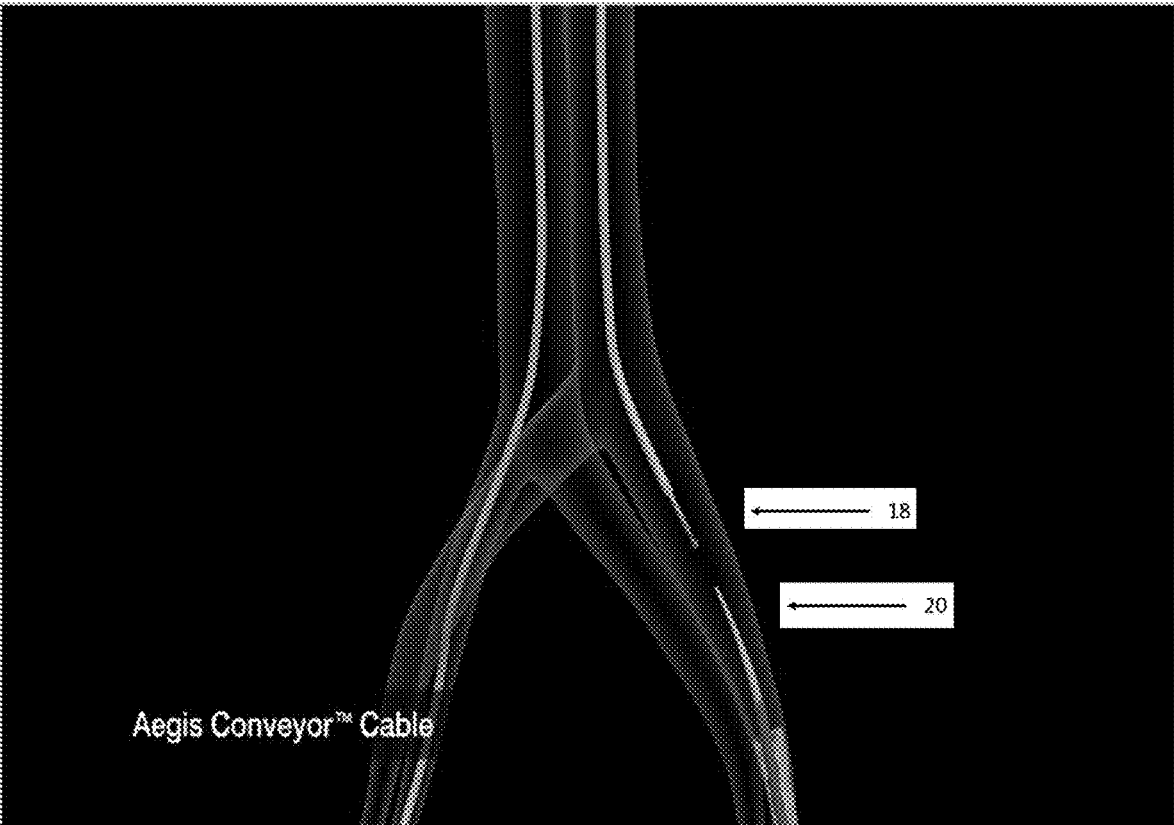


FIG. 16

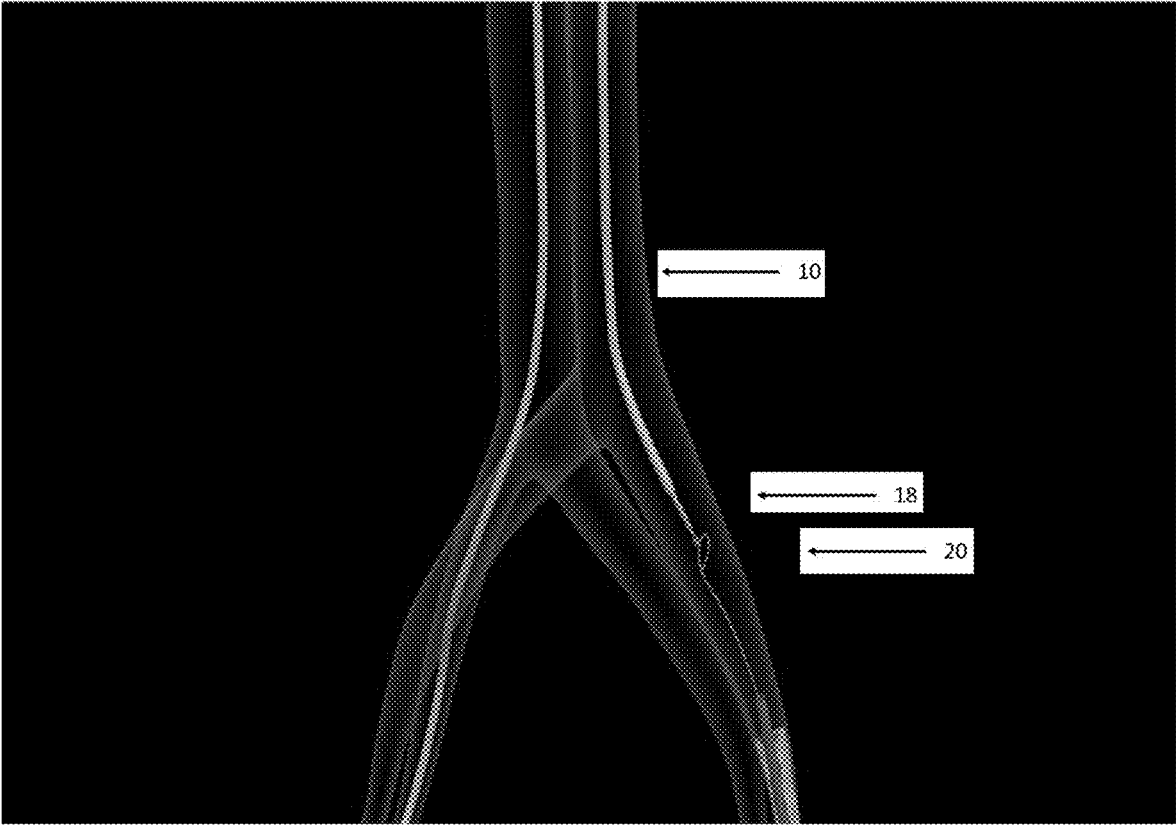


FIG. 17



FIG. 18



FIG. 19



FIG. 20



FIG. 21A

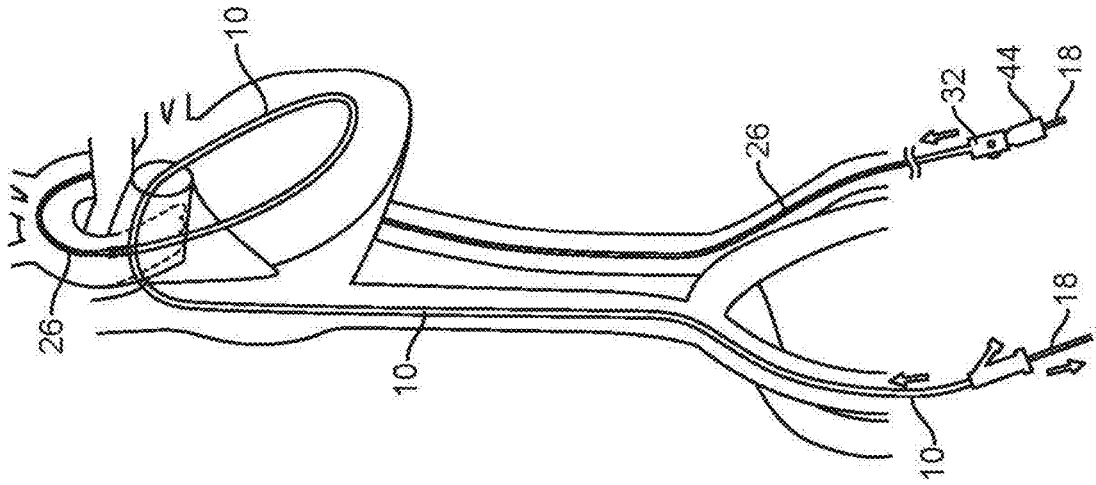


FIG. 22B

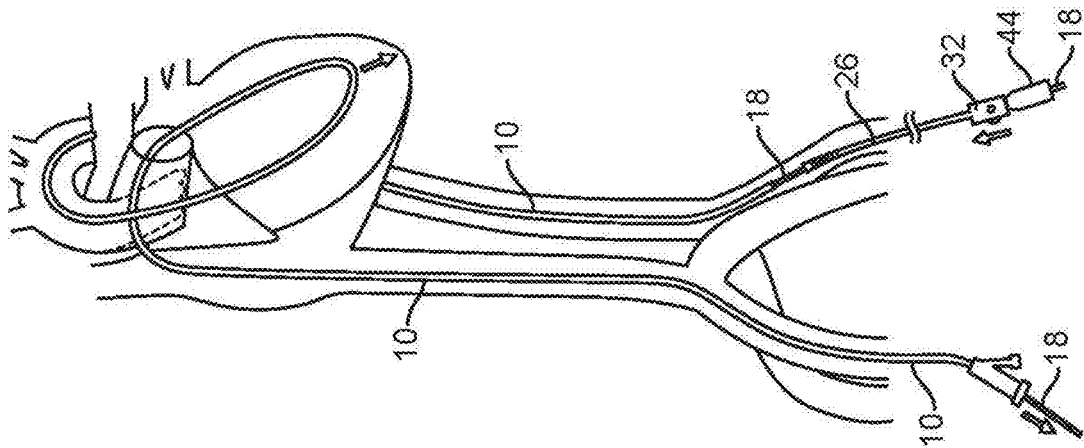


FIG. 22A

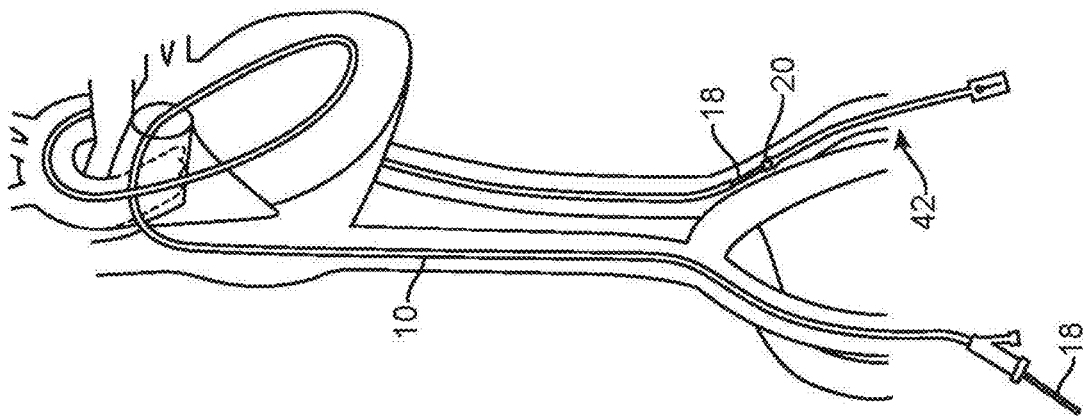


FIG. 21B

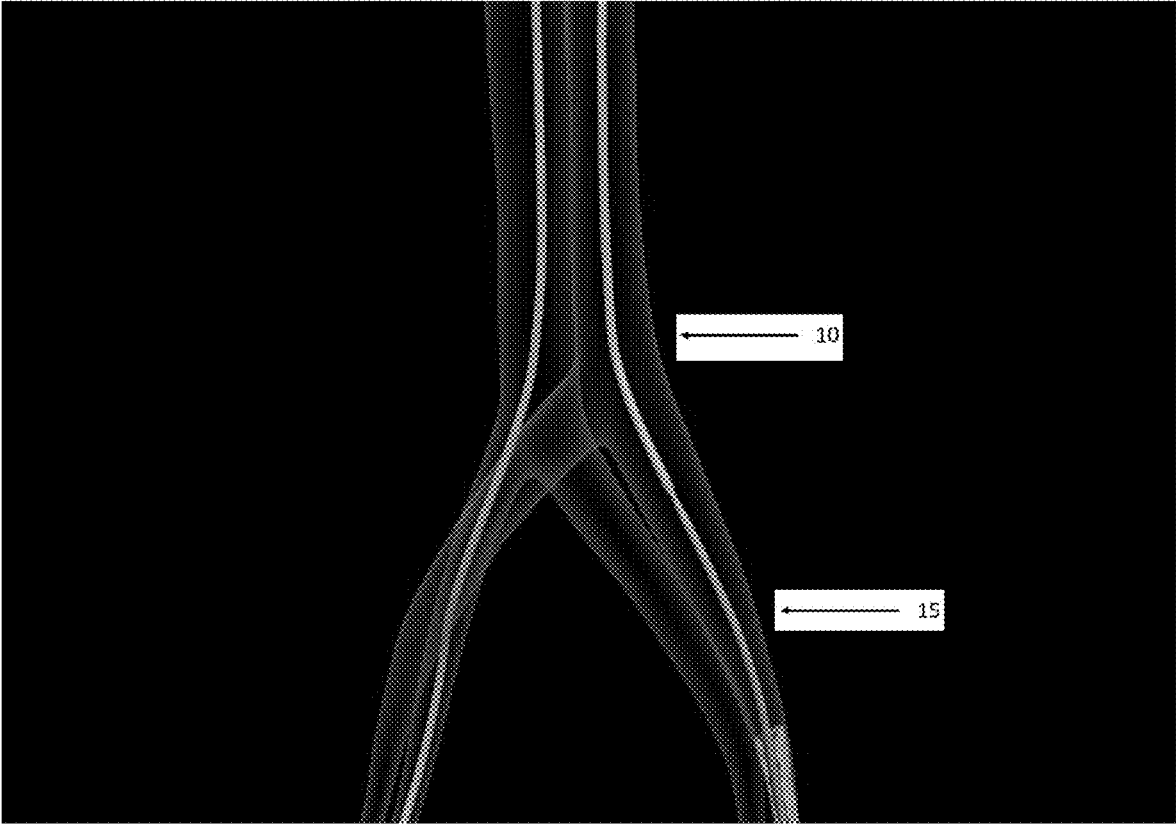


FIG. 23

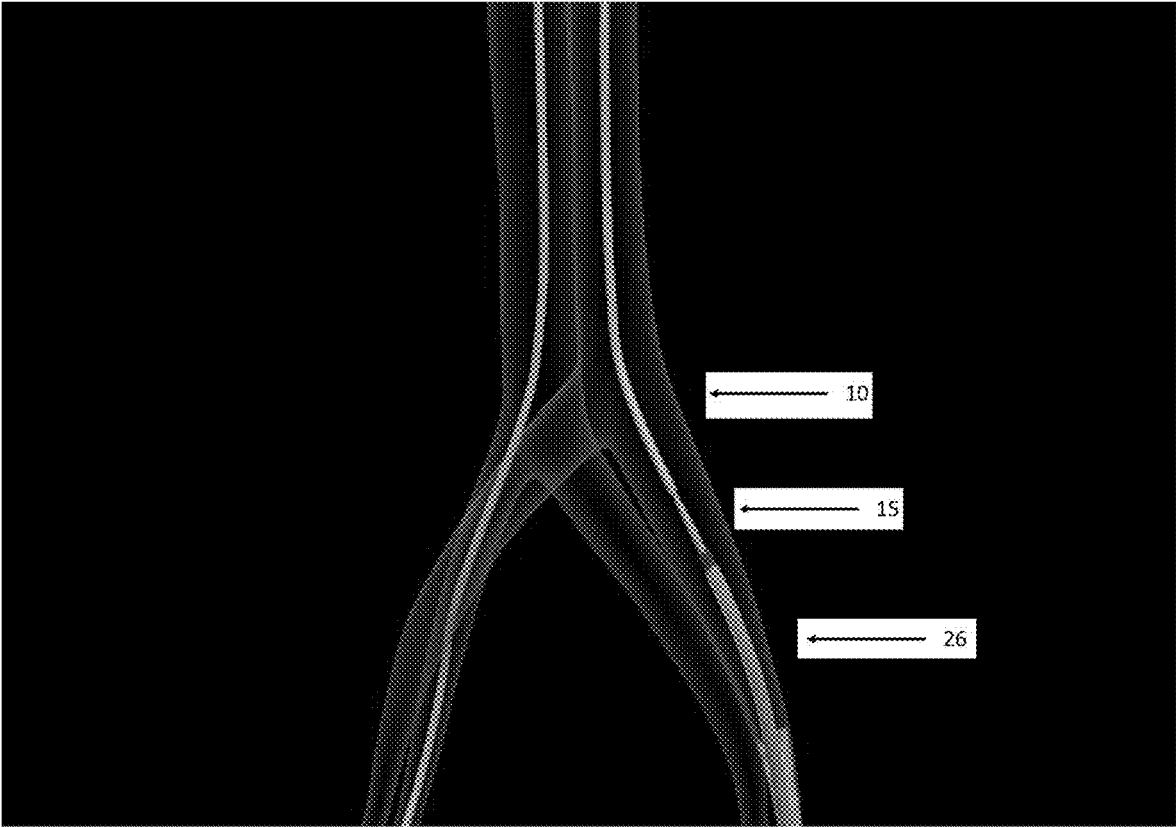


FIG. 24

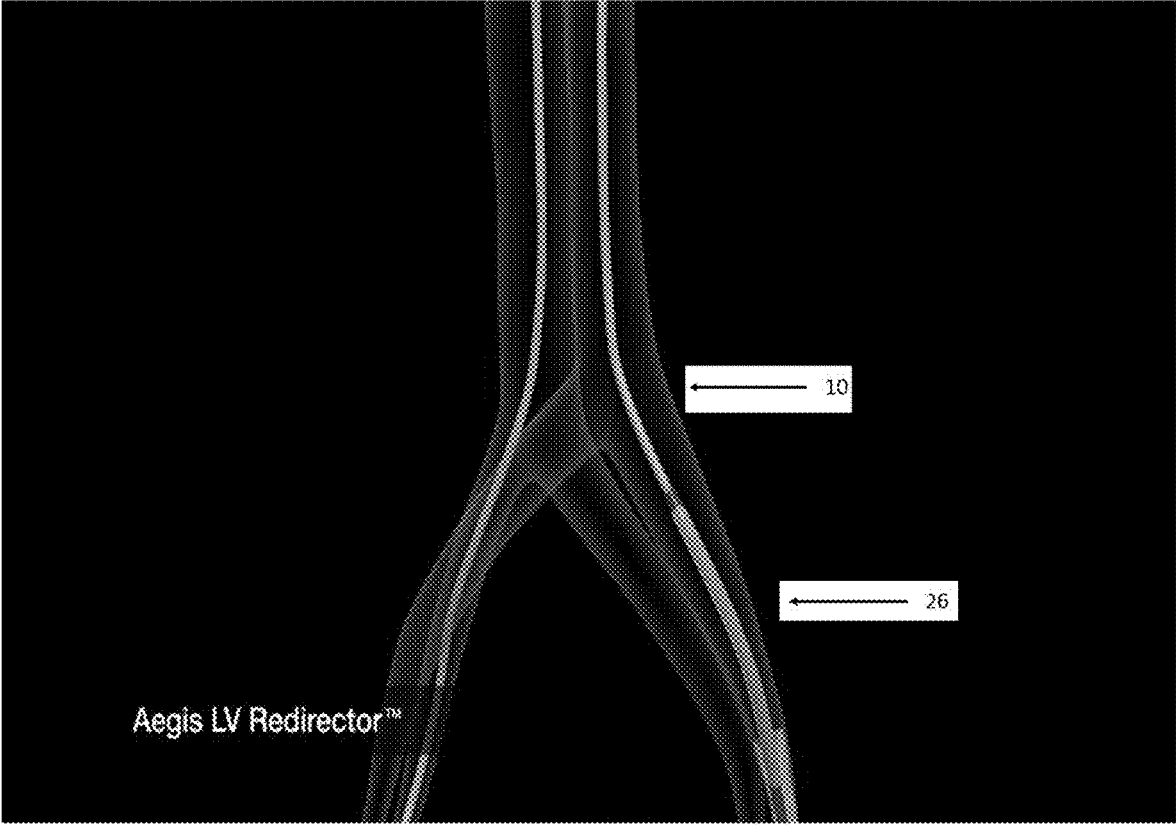


FIG. 25A

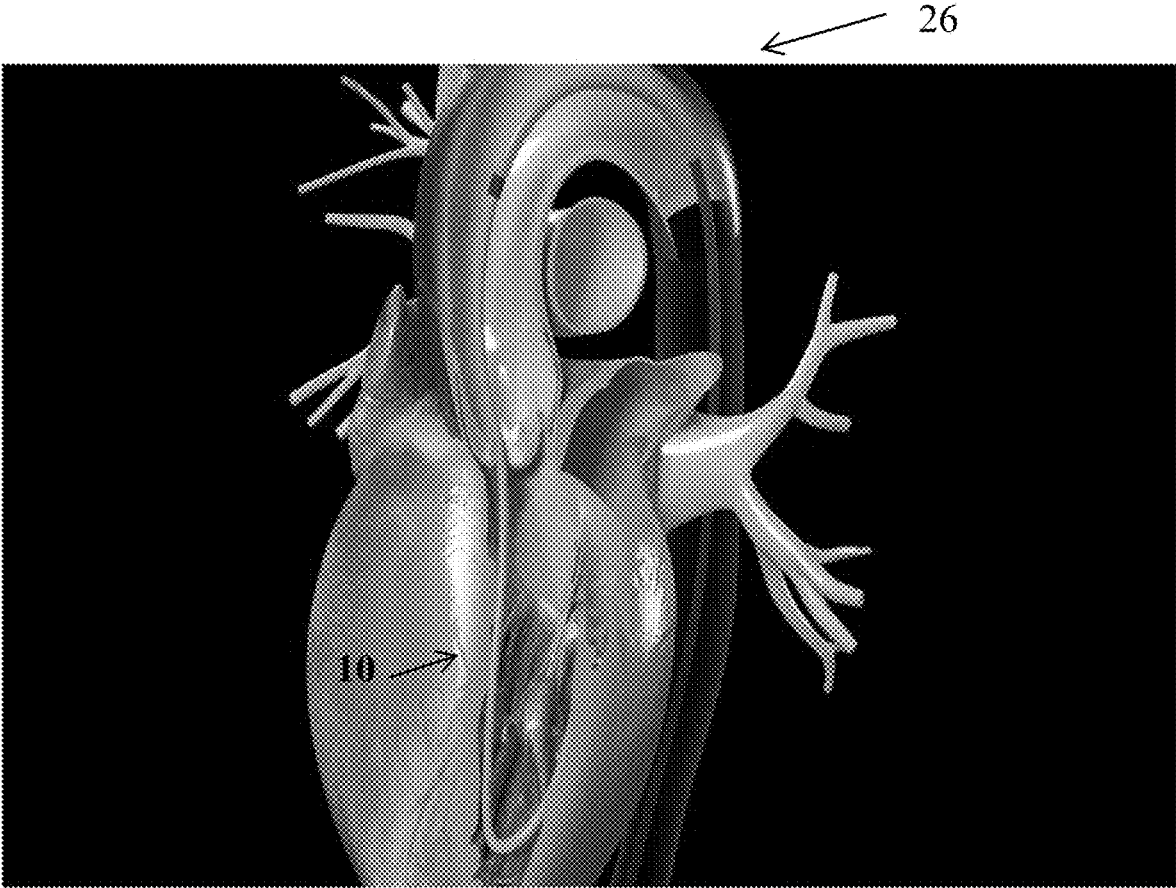


FIG. 25B

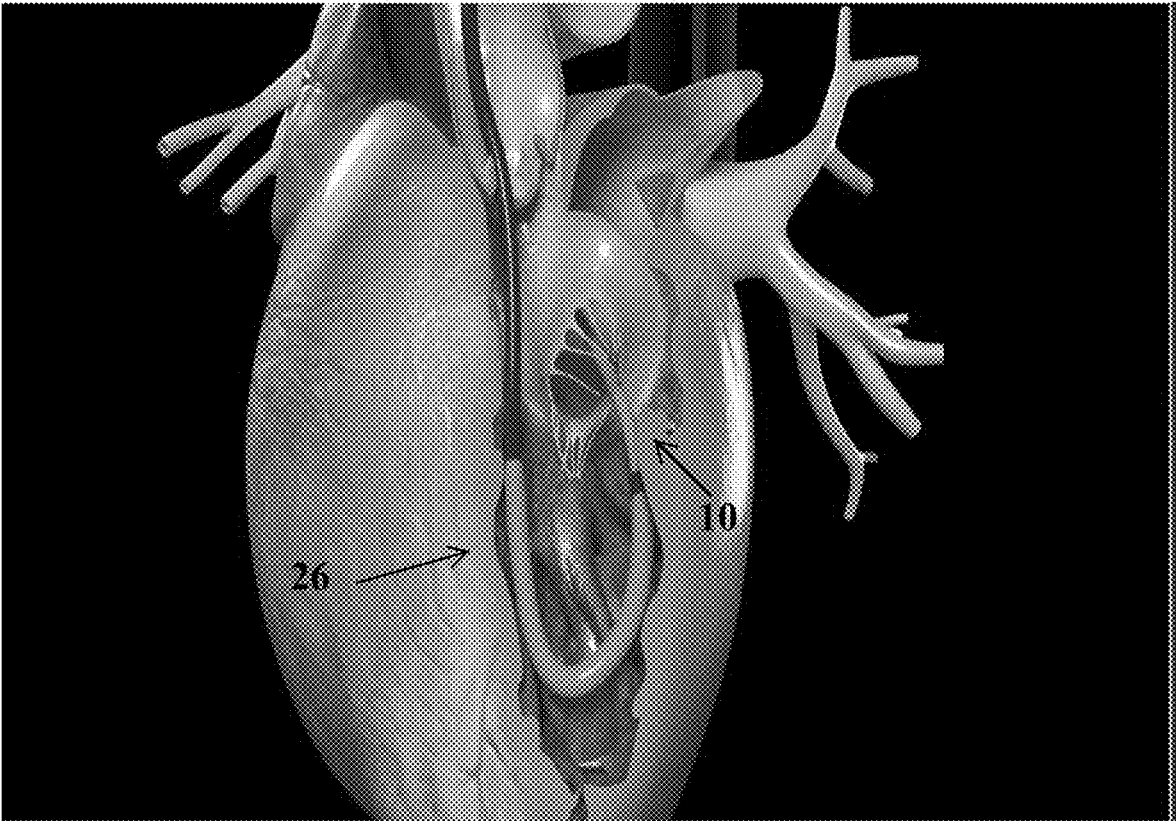


FIG. 26

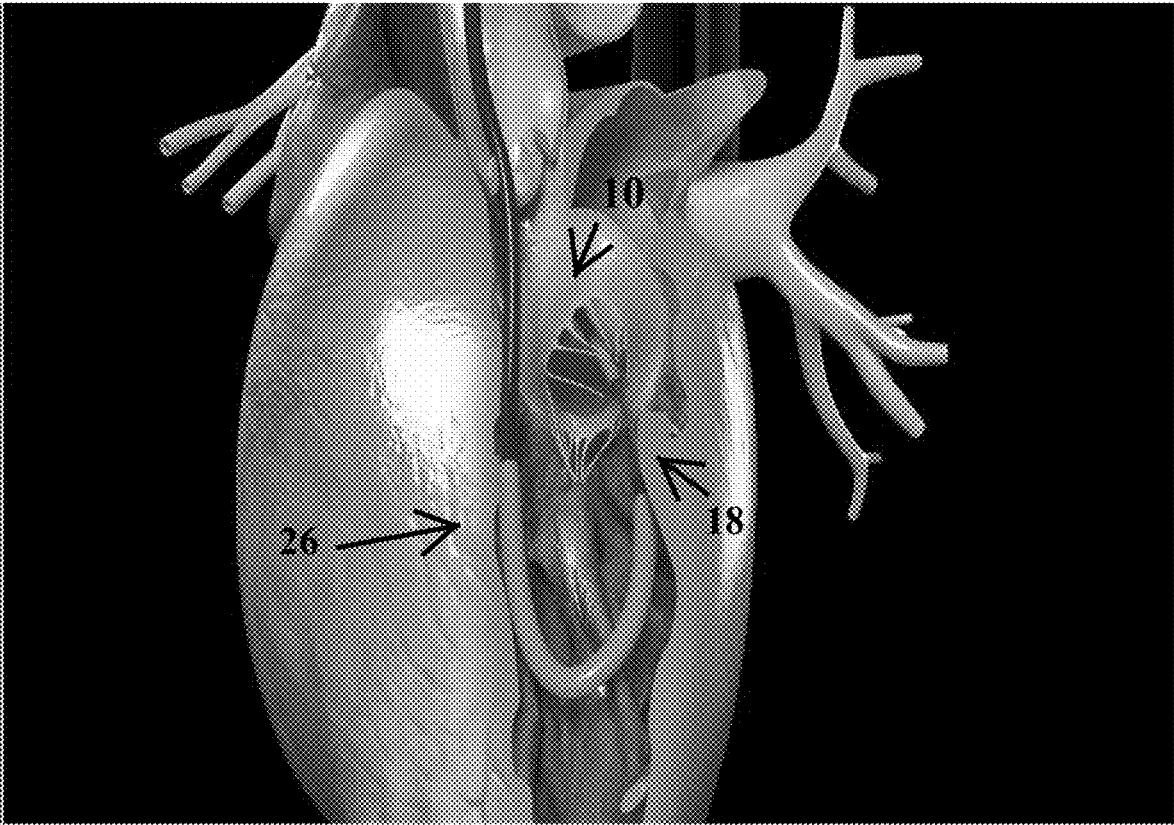


FIG. 27



FIG. 28A

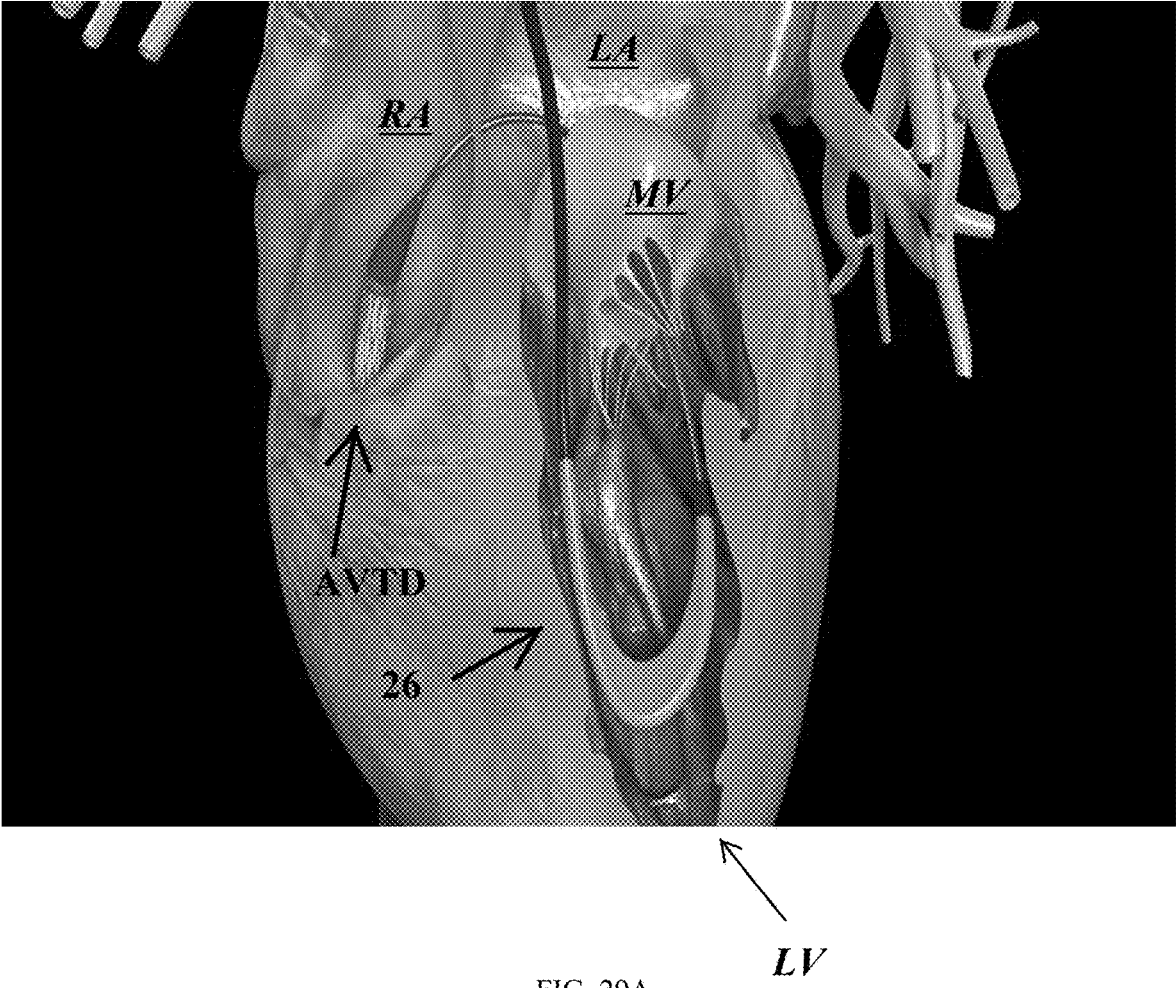


FIG. 29A

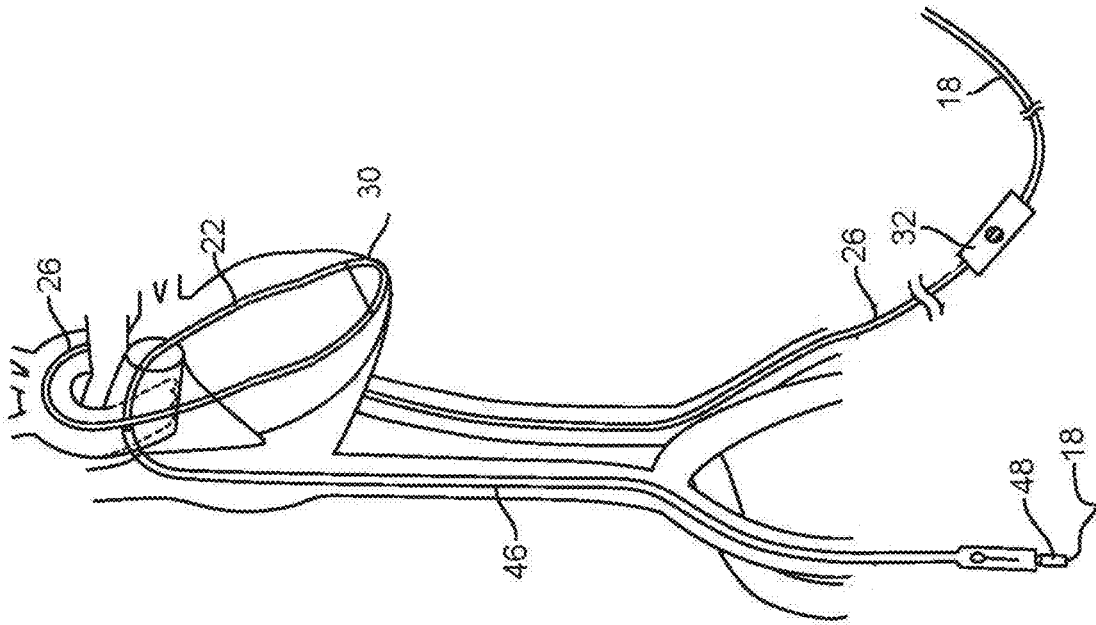


FIG. 29B

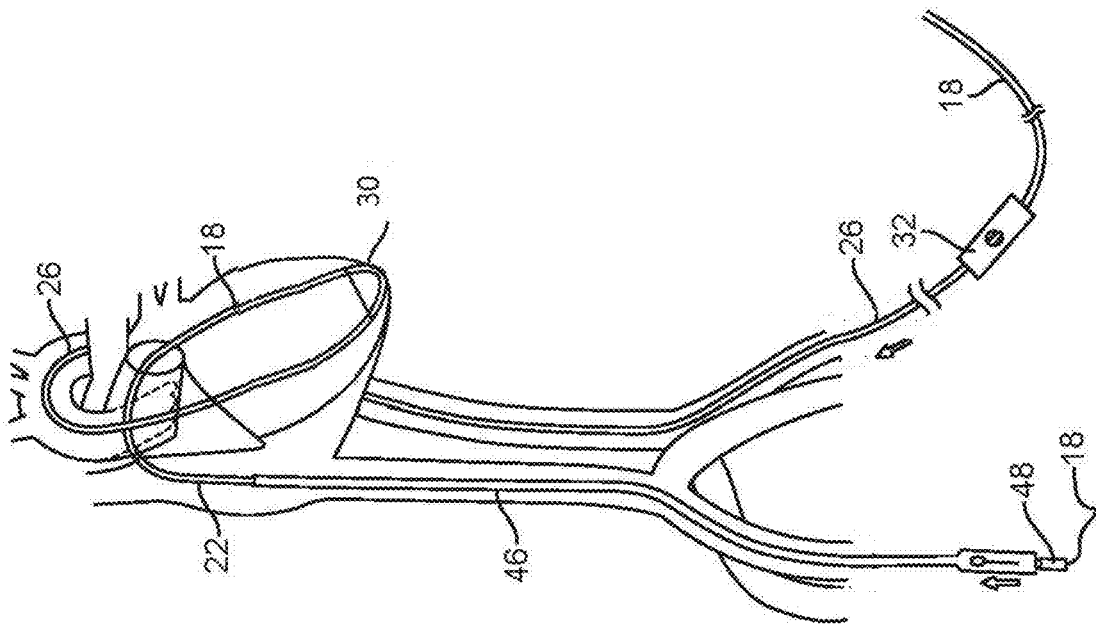


FIG. 28B

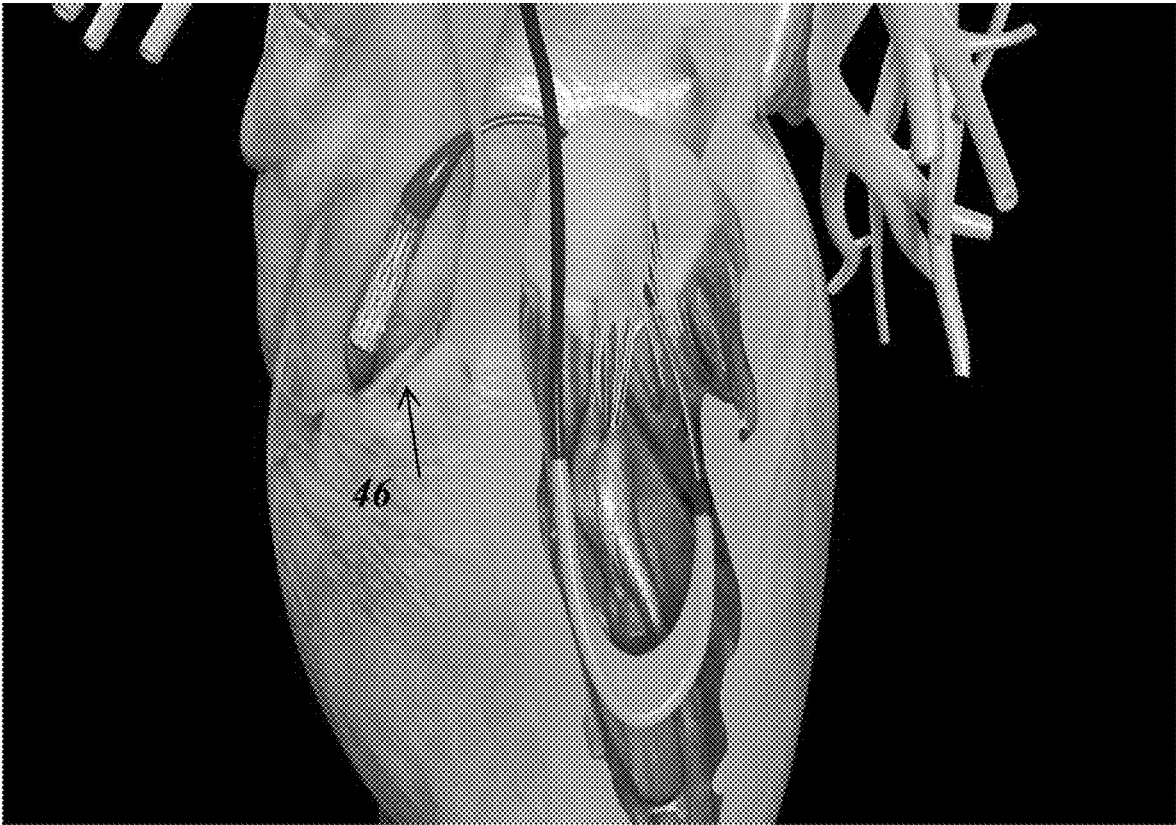


Fig. 29C

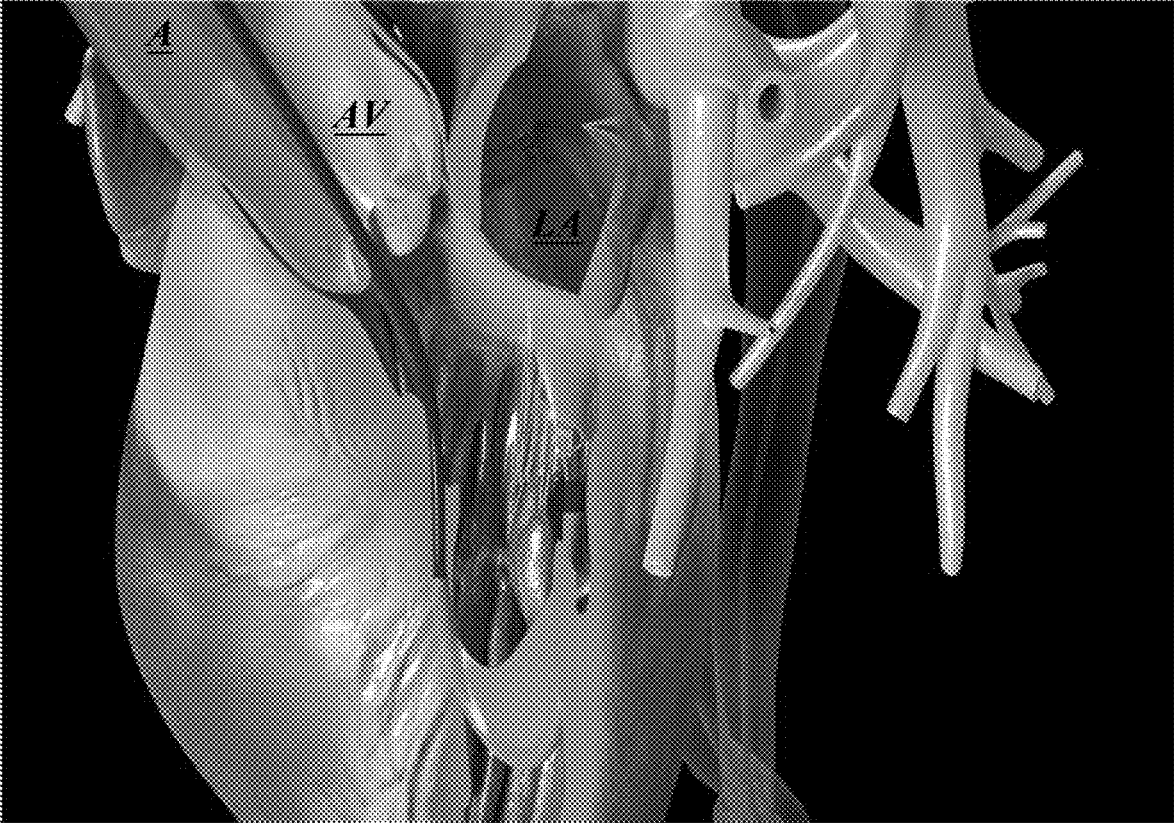


FIG. 30



FIG. 31

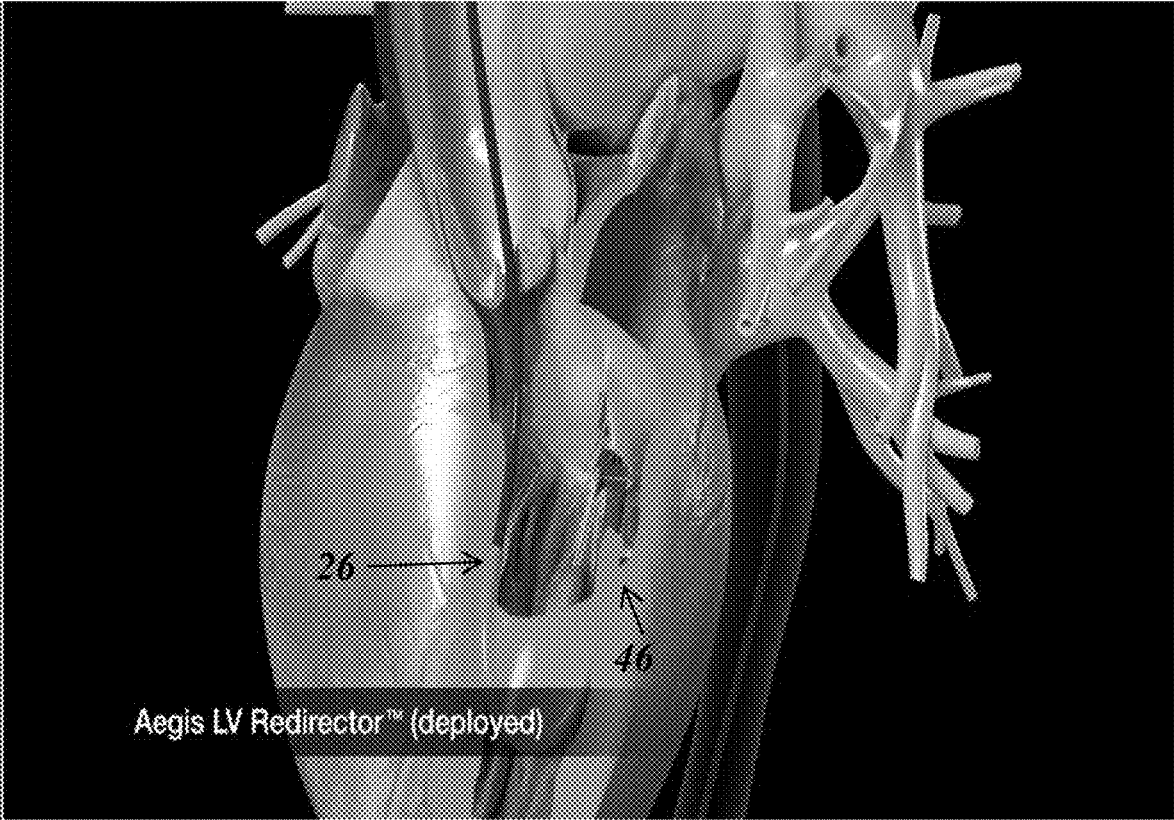


FIG. 32

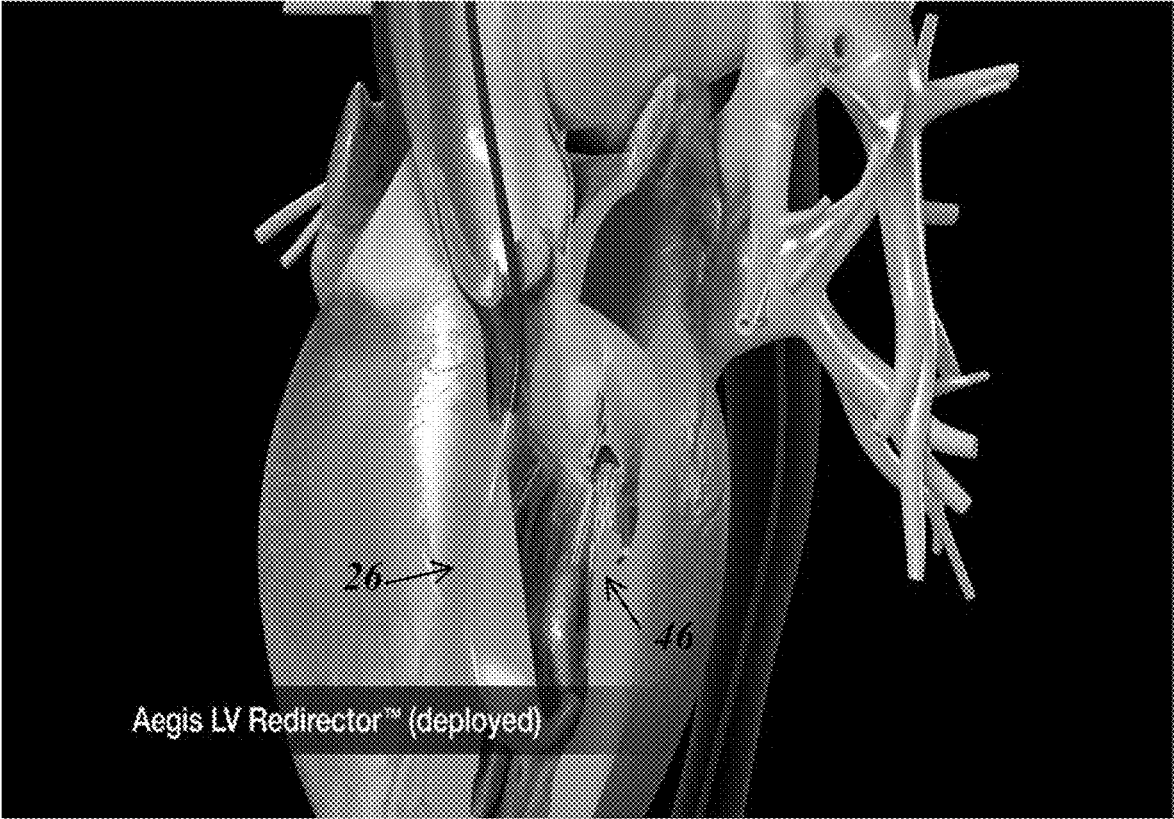


Fig. 33

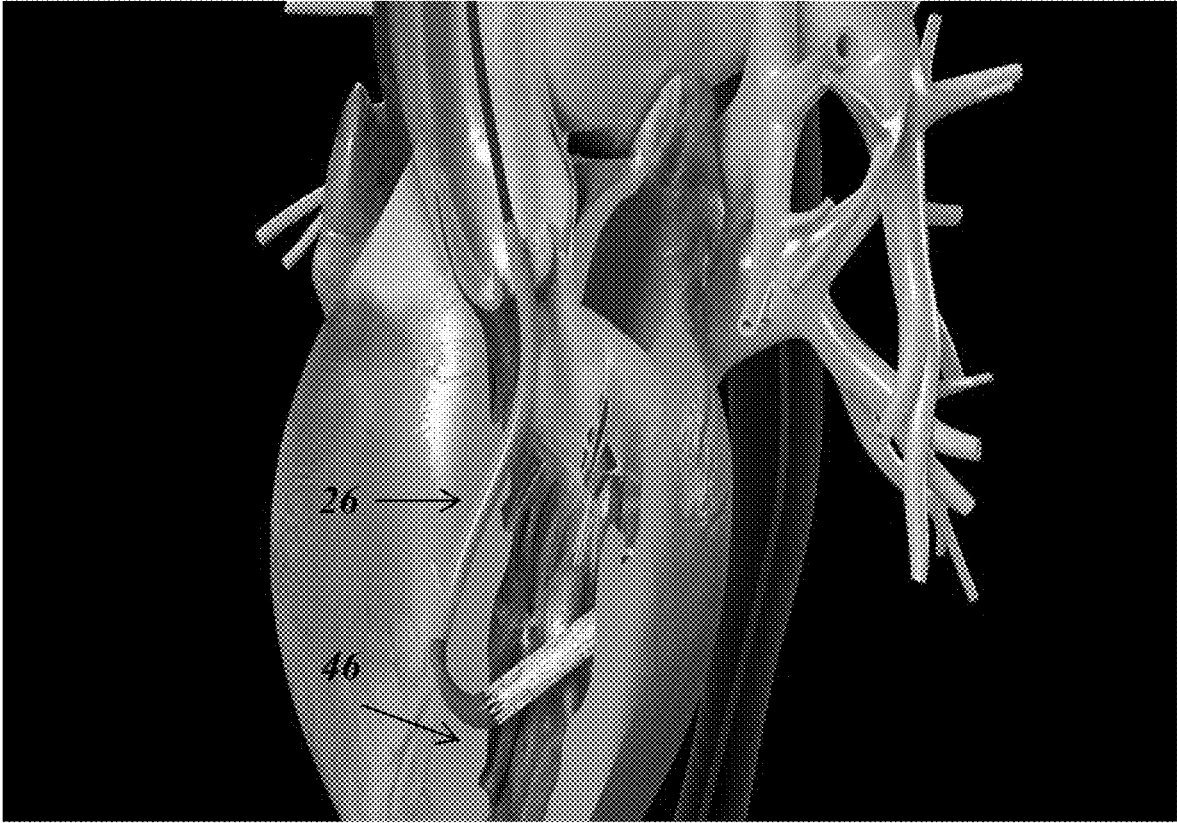


FIG. 34

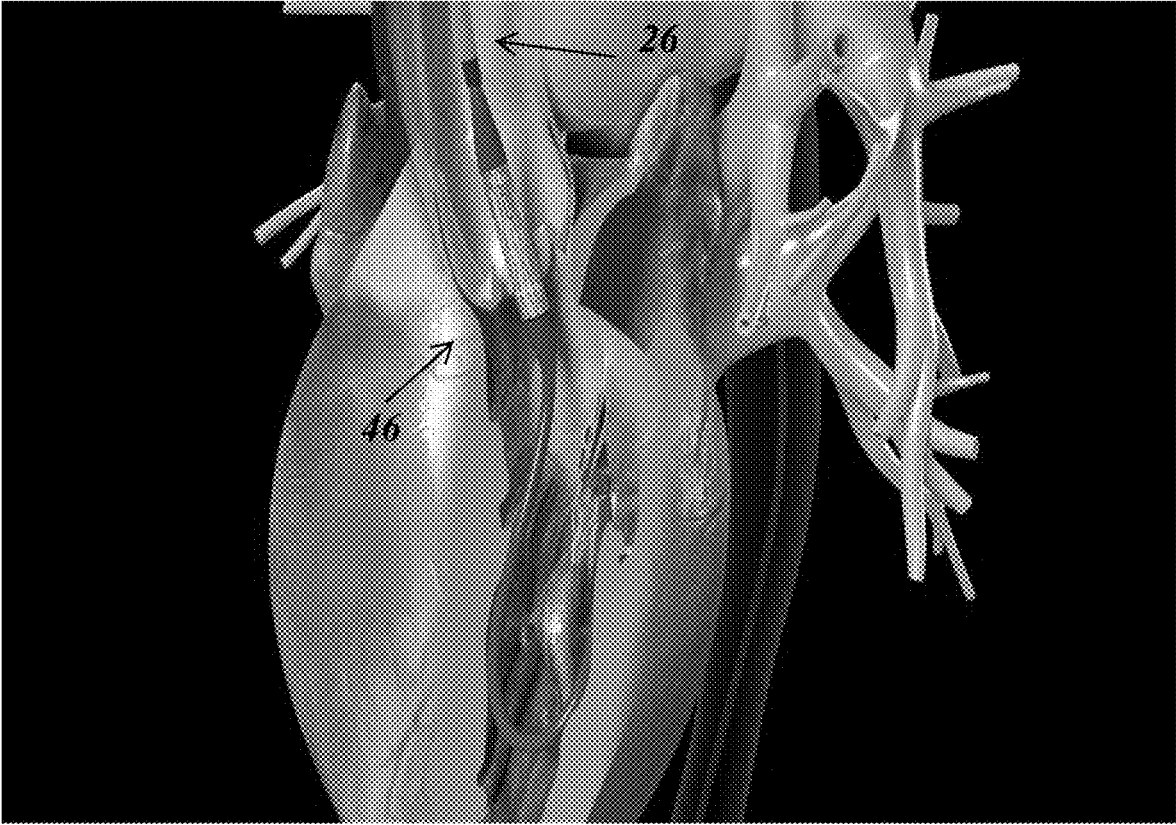


Fig. 35

TRANSEPTAL DELIVERY SYSTEM FOR AORTIC VALVE THERAPEUTIC DEVICES

[0001] This application is a continuation of U.S. application Ser. No. 16/365,601, filed Mar. 26, 2019, which claims the benefit of US Provisional Application U.S. 62/647,894, filed Mar. 26, 2018, and which is a continuation in part of PCT/US17/62913, filed Nov. 22, 2017. U.S. application Ser. No. 16/365,601 is also a continuation in part of PCT/US18/045445, filed 6 Aug. 2018, which claims the benefit of US Provisional Applications U.S. 62/541,761, filed Aug. 6, 2017, U.S. 62/541,771, filed Aug. 6, 2017, U.S. 62/567,736, filed Oct. 3, 2017, and U.S. 62/647,894, filed Mar. 26, 2018. Each of these applications is fully incorporated herein by reference.

BACKGROUND

[0002] A system that is used for transeptally driving mitral valve therapeutic devices into place is described in Applicant's co-pending PCT Application No. PCT/US17/62913 (Ref: ATR-820). A modified version of that system and method are described herein for use in implanting an aortic valve therapeutic device, such as an aortic valve replacement device or a device for repairing an aortic valve. The method described below and illustrated in the attached drawings differs from that described in PCT/US17/62913 primarily in that the aortic valve therapeutic device, once positioned in the left ventricle, is then advanced to the native aortic valve location.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] FIG. 1A is a side elevation view of a Right-to-Left conduit ("RLC") assembled with a Brockenbrough needle and dilator.

[0004] FIG. 1B is a side elevation view of the RLC of FIG. 1A assembled with a tracker balloon catheter.

[0005] FIG. 1C is a side elevation view of the RLC of FIG. 1A assembled with a Left Ventricle Redirector ("LVR").

[0006] FIG. 2A is a side elevation view of the LVR with the distal end in the curved position to deploy the protective panel.

[0007] FIG. 2B is a side elevation view of the LVR with the distal end in the straight position.

[0008] FIG. 2C is a cross-section view of the shaft of the LVR taken along the plane designated 2C-2C in FIG. 2B.

[0009] FIG. 3A is an elevation view of the cable.

[0010] FIG. 3B is an elevation view of the tensioner.

[0011] FIG. 3C shows an assembly of the cable, tensioner, MVTD and a cable lock.

[0012] FIGS. 4A-4B illustrate transeptal passage of an RLC to the left atrium. More particularly, FIG. 4A schematically illustrates a section of the heart and shows the step of transeptal catheterization from the right atrium into the left atrium, using a Brockenbrough needle assembly through the RLC, and FIG. 4B shows the tip of the RLC in the left atrium following removal of the needle assembly;

[0013] FIG. 5 shows introduction of the tracker balloon into the left atrium.

[0014] FIG. 6 shows inflation of the tracker balloon.

[0015] FIGS. 7-12 are schematic depicting the tracker balloon being carried by the flow of blood from the left atrium, into and through the aorta, to the femoral artery.

[0016] FIGS. 13-14 shows advancement of the RLC over the tracker balloon shaft and withdrawal of the balloon catheter from the RLC.

[0017] FIG. 15 shows the cable advanced through the RLC with its ball tip exposed from the end of the RLC.

[0018] FIGS. 16-21B illustrate snaring of the ball tip of the cable in the left femoral artery after the cable been passed through the RLC.

[0019] FIG. 22A illustrates the step of advancing the LVR over the cable and the locking of the LVR to the cable;

[0020] FIG. 22B illustrates the advancement of the LVR;

[0021] FIGS. 23-25B also illustrate the steps of advancing the LVR over the cable and the advancement of the LVR. Note that as shown in these drawings, a tapered dilator may be used in this step in advance of the LVR. As shown in FIG. 23, the dilator may be advanced over the cable and have its tapered tip inserted into the RLC. Then, as shown in FIG. 24, the LVR may be advanced over the dilator to the RLC.

[0022] FIG. 26 shows the LVR moved into the left ventricle.

[0023] FIG. 27 is similar to FIG. 26 and also shows the RLC beginning to be removed.

[0024] FIGS. 28A through 29C show a TAVR system being advanced over the cable from the venous side. More particularly, FIGS. 28A and 28B show the TAVR system advancing through the inferior vena cava, and FIGS. 29A through 29C show the TAVR system passing through the right atrium to the septum.

[0025] FIGS. 30 and 31 show the TAVR system being advanced across the septum into the left atrium towards the mitral valve ring.

[0026] FIG. 32 shows the LVR in the left ventricle as the TAVR system is advanced into contact with the LVR. Note that the LVR may be provided without the membrane of the LVR.

[0027] FIG. 33 shows the LVR deployed and further shows the TAVR delivery system, which is in contact with the LVR, positioned at the mitral valve as the TAVR delivery system is being centered within the valve.

[0028] FIG. 34 shows the TAVR delivery system in the left ventricle moving towards the aortic valve, the LVR has been moved out of the deployed position and is passing through the aortic valve while remaining in contact with the LVR.

[0029] FIG. 35 shows the TAVR device advanced through the aortic valve site while remaining in contact with the open end of the LVR.

DETAILED DESCRIPTION

[0030] A system and method are described herein for use in moving an aortic valve therapeutic device ("AVTD") into position for treating an aortic valve. The presently disclosed system is designed to aid in the delivery of an AVTD to an aortic valve location. The terms "aortic valve therapeutic device" or "AVTD" used here refer to any device that may be delivered to the native aortic valve site for a therapeutic purpose. In the description that follows, the AVTD is shown as an aortic valve delivery system carrying a replacement aortic valve for a TAVR procedure, but it should be understood that the system and method described may be used to deliver other types of AVTD's such as those used to repair an aortic valve.

[0031] As will be appreciated from a review of the more detailed discussion that follows, the cable system functions to both push the proximal end of the AVTD while simulta-

neously pulling on the distal nose of it with equal and coordinated force to drive the AVTD across the interatrial septum. Pulling down further on the distal nose of the AVTD using the cable provides a steering force that serves to direct the stiff, bulky AVTD into position across the interatrial septum, and into the left atrium. The AVTD is further advanced through the center of the mitral valve at an angle that is perpendicular to the MV plane by use of a steering mechanism present in a unique device referred to as the LV redirector (described in detail below). From the left ventricle, the AVTD are moved, while remaining in contact with one another, towards the native aortic valve site until the AVTD is positioned at that site.

[0032] In the description of system and method below, the access points for the components of the system are described as the right femoral vein for the venous access and the left femoral artery for the arterial access. However, the system and method can just as readily be used with a different combination of venous and arterial access. For example, venous access may be gained via the right femoral vein and arterial access may be gained via the right femoral artery. Alternatively, both access points may be on the left side. In yet another embodiment, venous access is gained via the left femoral vein and arterial access is gained via the right femoral artery.

[0033] System

[0034] Referring to FIG. 1A, the system includes a Right-to-Left conduit **10** (“RLC”), an elongate tubular catheter having a length sufficient to permit it to extend from the right femoral vein of a human adult to the right atrium, across the interatrial septum to the left atrium, through the aorta and into the femoral artery on the patient’s left or right side. The RLC **10** includes a distal portion shape set into a curved configuration to help orient the needle used for transeptal puncture towards the interatrial septum. In alternative embodiments the RLC may be steerable using pullwires or alternative means. The durometer of the RLC is relatively low (eg **55D**) as known in the art for cardiovascular catheters so as to minimize tissue trauma, although a significant length on the proximal part of the catheter is formed of a higher durometer (e.g. **70D**) to give the conduit sufficient column strength to avoid buckling when used to push during advancement of the LVR as described below. This higher durometer section may be the part of the conduit that, when the conduit fully extends between the right femoral vein and right or left femoral artery, begins at or near the proximal end of the conduit and terminates within the inferior vena, and may be as much as a third of the length of the RLC. In FIG. 1A, the RLC **10** is shown assembled with a Brockenbrough needle assembly **12** and dilator **14** for use in the transeptal catheterization step of the method.

[0035] The system further includes a tracker balloon catheter **16**, shown extending through the RLC **10** in FIG. 1B, comprising an inflatable balloon on the distal end of the catheter. The balloon catheter **16** includes a guidewire lumen. The balloon may be inflated with a fluid or gas, including CO₂ or saline, or it may be a self-expanding “vacuum balloon.”

[0036] In FIG. 1C, the RLC **10** is shown assembled with a conveyor cable **18** and a left ventricle redirector or “LVR” **26**. Details of the LVR can be seen in FIGS. 2A-2C. The LVR includes an elongate catheter shaft **28** having a proximal handle **32** with a luer port **40**. As shown in the cross-section view of FIG. 2C. The shaft includes a lumen

29 accessible via the port **40**. This lumen extends to the distal tip of the shaft. Incorporated within the wall of the LVR shaft are a pullwire **26** and a return wire **38**. The pullwire exits the sidewall of the shaft **28** near the shaft’s distal end, runs along the exterior of the shaft, and is affixed to the distal end of the shaft. Increasing tension on the pullwire **26** pulls the distal end of the shaft into a curve as shown in FIG. 2A. The handle **32** includes actuators to actuate the pull wire to bend the shaft and to actuate the return wire to return the distal end of the shaft to the generally straight configuration (as in FIG. 2B). The return wire **38** may have a rectangular diameter as shown, with the long edges oriented to aid in preferential bending of the catheter.

[0037] A membrane **30** is positioned along a portion of the distal part of the shaft and along the external portion of the pullwire **26**. When the pullwire is relaxed and the shaft is in the straight configuration, the panel and pull wire run along the distal part of the shaft. The membrane forms the D-shaped barrier shown in FIG. 2A when the distal end is drawn into the curved configuration by action of the pullwire. The barrier forms a protective panel extending between the external part of the pullwire and the shaft **28**, substantially eliminating gaps between the two. The panel may be made of an elastomeric polymer or other material.

[0038] Note that the term “pullwire” is not intended to mean that the pullwires must be formed of wire, as that term is used more broadly in this application to represent any sort of tendon, cable, or other elongate element the tension on which may be adjusted to change the shape of the LVR or other catheter in which the pullwire is used.

[0039] The conveyor cable **18**, shown in FIG. 3A comprises an elongate cable having distal cable section **17a** having a broadened distal tip **20** such as the ball tip feature shown in the drawings. The tip **20** may include a distal face having convex curvature and a cylindrical proximal part with a generally flat proximal face to facilitate engagement using a snare. A larger diameter intermediate section **17b** is proximal to the distal section **17a** and includes a polymer coating. A proximal section **19** comprises a stiff mandrel proximal to the intermediate section **17a**. The proximal section is sufficiently stiff to give column support for pushing of the cable during the RLC removal discussed below. A radiopaque marker band **21** is positioned between the proximal mandrel section **19** and the intermediate section **17b**. When the cable **18** is assembled with the segmental tensioner **22** (discussed below), the soft distal tip of the segmental tensioner mates with the marker band **21**, allowing the user to see on the fluoroscopic image the transition between the segmental tensioner and the intermediate (coated) section **17b** of the cable.

[0040] Segmental tensioner **22**, shown in FIG. 3B, is a short length (e.g. 30-35 mm) tubular component having a flexible tip section (e.g. **40D**) and a more rigid (e.g. **70D**) proximal hub section of broader diameter. The inner diameter of the hub section is proportioned to receive the distal tip of the AVTD. The segmental tensioner incorporates a deadstop within the shaft inner diameter to engage the polymer coated intermediate section **17b** of the conveyor cable and to lock the AVTD **46** in position, preventing it from advancing independently of the conveyor cable as it is moved towards the mitral valve.

[0041] Method

[0042] As an initial step, the Right-Left Catheter (RLC) **10** is introduced using the well-known technique of transseptal catheterization from the right atrium (RA) into the left atrium (LA), such as by using a Brockenbrough needle assembly **12** through the RLC, which is positioned in the right femoral vein (RFV) as shown in FIG. **1**. Once the distal end of the RLC is disposed in the left atrium (FIG. **4B**), the needle is withdrawn and the tracker balloon catheter **16** is passed through the RLC into the left atrium. See FIGS. **5** and **6**. The balloon may have a concave proximal face to increase the surface area of the balloon in the upstream direction. Once deployed within the left atrium, the flow of blood carries the tracker balloon into and through the mitral valve (MV) (FIG. **7**), left ventricle (LV) (FIGS. **8** and **9**), aortic valve (AV) and aorta (A) FIGS. **10** and **11** to the femoral artery (FIG. **12**). This description describes left side access to the arterial vasculature, but in alternative methods the tracker balloon catheter may be diverted to the right femoral artery (RFA). The RLC is then advanced over the tracker balloon catheter towards the left or right femoral artery. FIGS. **13** and **14**.

[0043] The tracker balloon catheter **16** is deflated (FIG. **14**) and then withdrawn from the RLC **10**, and the conveyor cable **18** is inserted into the RLC on the patient's right side and advanced. This directs the tip of the cable into the left femoral artery. FIG. **15**. A snare **20** introduced into the left femoral artery grasps the ball tip of the conveyor cable as shown in FIGS. **16-19**, and withdraws the ball tip out the femoral artery (FIG. **20**).

[0044] The left ventricle redirector (LVR) is introduced over the cable (FIG. **21**). The lumen of the LVR slides over the ball tip and shaft of the cable. The LVR is pushed towards the RLC while the RLC is pushed towards the LVR, causing the LVR to advance its distal end over the exterior surface of the RLC. This eliminates the exposed section of cable between the LVR and RLC, and because the conveyor cable is much more flexible than the LVR or RLC, this step removes flexibility from the assembly now extending through the vasculature and heart.

[0045] Alternatively, as shown in FIGS. **23-24**, a tapered dilator **15** may be used in this step in advance of the LVR. As shown in FIG. **23**, the dilator may be advanced over the cable and have its tapered tip inserted into the RLC. Then, as shown in FIG. **24**, the LVR may be advanced over the dilator to the RLC.

[0046] A cable lock may be used to lock the proximal end of the LVR onto the conveyor cable outside the access point to the femoral artery so that the LVR and cable will move together. The user pulls on the cable on the patient's venous side (the patient's right which is the left side of the drawings). On the patient's arterial side (the right side of the drawings), the user pushes the LVR. FIG. **22B**. Note that since the LVR is locked to the conveyor cable, the actions of pulling the cable and pushing the LVR advance the LVR into the aorta. FIGS. **22B**, **25A** and **25B**. If the system is configured such that the LVR slides over the RLC or remains engaged with the RLC by the dilator or other means, this step is accompanied by the pushing on the RLC from the venous side. Pushing the RLC during advancement of the LVR pushes the loop of the LVR into the apex of the LV, keeping it away from delicate valve structures and chordae tendineae.

[0047] Once within the heart, the LVR is pushed strongly into the apex of the left ventricle by a pushing force applied to its proximal end. FIG. **26**.

[0048] The RLC is next withdrawn from the venous side. The cable is still in place as shown. The AVTD is connected to the cable. FIG. **28**. A segmental tensioner and cable lock may be used in the manner described in PCT/US17/62913.

[0049] Once the AVTD has entered the venous circulation it is advanced toward the right atrium (FIGS. **29A** and **29B**), (optionally led by the segmental tensioner **22**), as the system is pulled by the cable while the AVTD is simultaneously pushed along at the same rate in a coordinated manner. The optional segmental tensioner leads the way as it crosses the interatrial septum (FIG. **30**) and provides a gradual transition to the bigger and stiffer AVTD.

[0050] At this point, a significant pulling force is applied to the AVTD/tensioner assembly by the cable. This force is slightly more than the "push force" force on the AVTD so as to pull the distal nose of the AVTD down and to the patient's left through the interatrial septum. FIG. **32**. Despite the pushing force of the LVR into the apex, with ever increasing pull force, there is a strong tendency to cause the loop of the cable contained in the steerable section of the LVR to be pulled upward into the valve structures above. This tendency is overcome by the synergistic downward pushing force exerted by the segmental tensioner as it enters the lumen at the distal end of the LVR in the LV apex. It ensures that the cable is positioned away from the aortic and mitral valve leaflets and chordae tendineae by maintaining the cable safely away from the valve structures within the LVR's protective sleeve.

[0051] The pullwire of the LVR is activated, placing its protective panel in the deployed position in the left ventricle. FIG. **33**. In addition to the importance of maintaining the cable loop in the apex of the ventricle, another key function of the LVR is to aid in the steering of the AVTD through the center of the mitral valve ring at an angle that is perpendicular to the mitral valve ring plane. Once through the mitral valve (FIGS. **33** and **34**) and into the left ventricle, the AVTD is further advanced to the aortic valve location as shown in FIG. **35**.

[0052] All patents and patent applications referred to herein, including for purposes of priority, are fully incorporated herein by reference.

We claim:

1. A system for of delivering an aortic valve therapeutic device to an aortic valve site, comprising:
 - a cable proportioned for introduction into a vasculature of a patient and for positioning in the vasculature to run from a femoral vein, through a heart via a transseptal puncture, and to a femoral artery such that the positioned cable has a first end external to the patient at the femoral vein and a second end external to the patient at the femoral artery;
 - an aortic valve delivery device with an aortic valve replacement device thereon, the aortic valve delivery device removably attachable to the first end of the cable and including a distal nose;
 - a left ventricle redirector (LVR) having a tubular lumen, the lumen at the distal end advanceable over the second end of the cable at the femoral artery and advanceable though an aorta and aortic valve to a left ventricle,
 - wherein the distal nose of the aortic valve delivery device is engageable with the distal end of the LVR, and

wherein the distal end of the LVR is actively steerable within the heart when engaged with the aortic valve therapeutic device to actively change an orientation of the aortic valve delivery system within the heart.

2. The system of claim 1, further including a tubular connector having a distal end and a proximal end, wherein the distal nose of the aortic valve delivery device is engageable with the proximal end of the tubular connector and the distal end of the tubular connector is engageable with the distal end of the LVR.

3. The system of claim 1, further including a right-to-left conduit (RLC) insertable from the femoral vein into an inferior vena cava into a right atrium, through an interatrial septum into a left atrium, through a mitral valve to a left ventricle, and through an aortic valve into an aorta, wherein the second end of the cable is insertable into the RLC at the femoral vein and advanceable through the RLC and out a distal end of the RLC.

4. The system of claim 3, further including:

a balloon catheter having an expandable balloon, the balloon catheter introducible into the right atrium, insertable through the interatrial septum into the left atrium, and inflatable within the left atrium such that the balloon catheter is carried by blood flow into and through the aorta to the femoral artery, wherein the RLC is introduceable over a proximal end of the balloon catheter and advanceable to position a distal end of the RLC in the left femoral artery, wherein the second end of the cable is introduceable into the RLC at the femoral vein and advanceable to the distal end of the RLC; and

a snare for capturing the second end of the cable via the femoral artery and positioning the second end external to the body.

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