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# (54) LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS

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**Related U.S. Application Data**

(63) Continuation of application No. 09/534,038, filed on Mar. 24, 2000, which is a continuation of application No. 09/369,039, filed on Aug. 4, 1999, now abandoned, which is a continuation-in-part of application No. 09/016,485, filed on Jan. 30, 1998, now abandoned, and which is a continuation-in-part of application No. PCT/US99/03484, filed on Feb. 17, 1999.

(60) Provisional application No. 60/099,720, filed on Sep. 10, 1998. Provisional application No. 60/099,691, filed on Sep. 10, 1998. Provisional application No. 60/099,767, filed on Sep. 10, 1998. Provisional application No. 60/104,397, filed on Oct. 15, 1998.

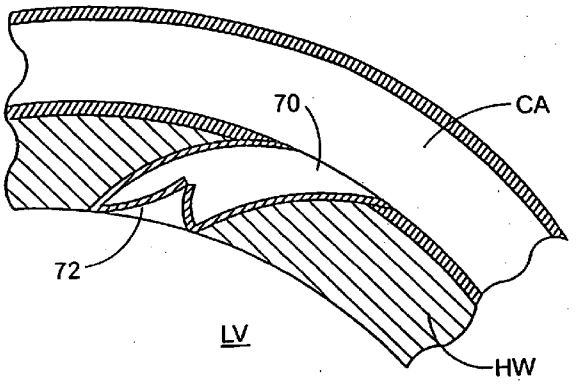
**Publication Classification**

(51) **Int. Cl.**[7] ..... **A61M 5/00**; A61F 11/00

(52) **U.S. Cl.** ..... **604/8**; 606/108

## (57) ABSTRACT

Left ventricular conduits and related methods are disclosed for achieving bypass of a partially or completely occluded coronary artery. More broadly, conduits for allowing communication of bodily fluids from one portion of a patient's body to another and related methods are disclosed, including conduits for forming a blood flow path from a chamber of the heart to a vessel or from one vessel to another. In other embodiments, the conduits achieve a coronary artery bypass by allowing blood communication between the left ventricle and the coronary artery or between a proximal portion of the coronary artery and a distal portion of the coronary artery. The conduits may be placed completely through the heart wall or extend only partially therein. Conduits may take on a variety of configurations for allowing the control of blood flow therethrough, including curved or tapered shapes. The conduits may also follow a variety of paths, including direct transmyocardial communication between the left ventricle and the coronary artery, or through the myocardium and into the intrapericardial space and then into the coronary artery. The conduits may be implanted through a variety of methods, including minimally invasive techniques. Also disclosed are various preferred embodiments of medical devices and related methods for implanting the conduits including rigid delivery rods for penetrating bodily tissue. The delivery rods may be solid, thus being trocar-like, or hollow to form a self-implantable conduit. Other preferred rod embodiments may have the conduits mounted thereon and take the form of a stylet or the like. The conduits may be one-piece, continuous conduits or made up of a number of plural sections joined together. Disclosures of various anastomosis devices are provided.



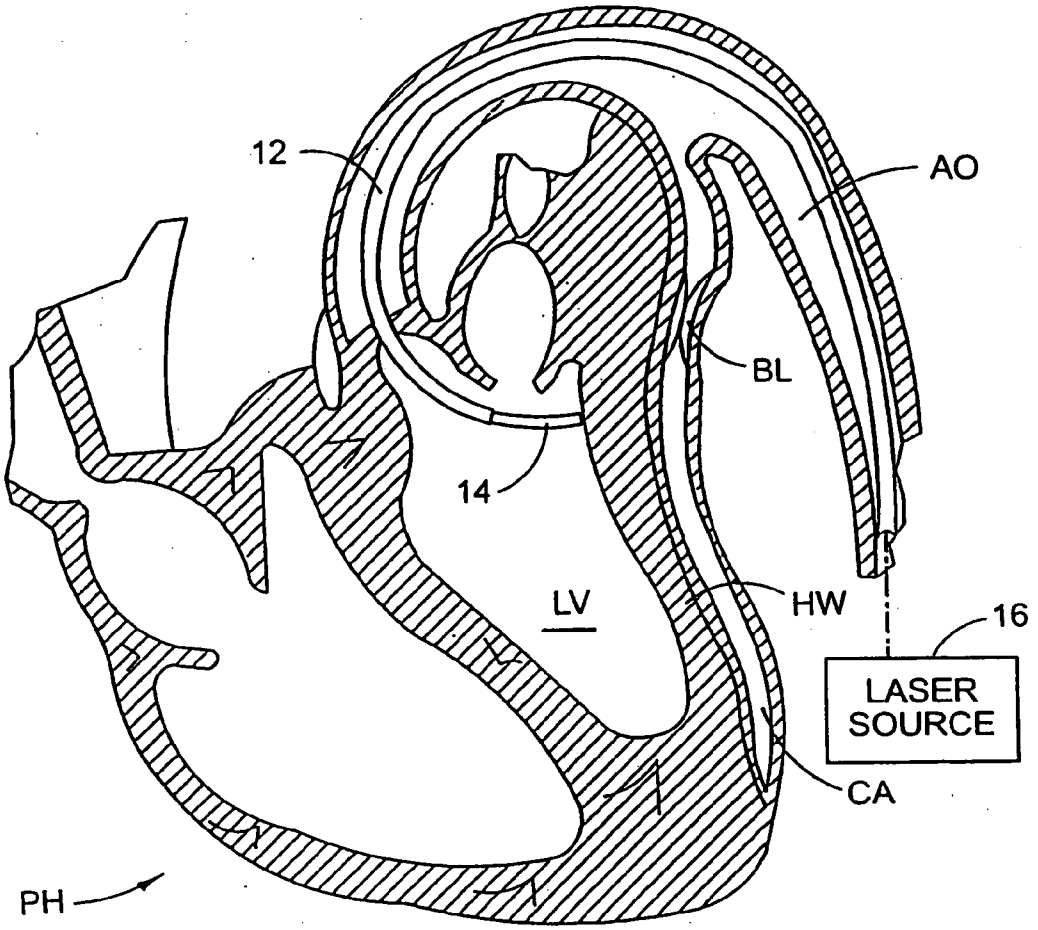



FIG. 1A

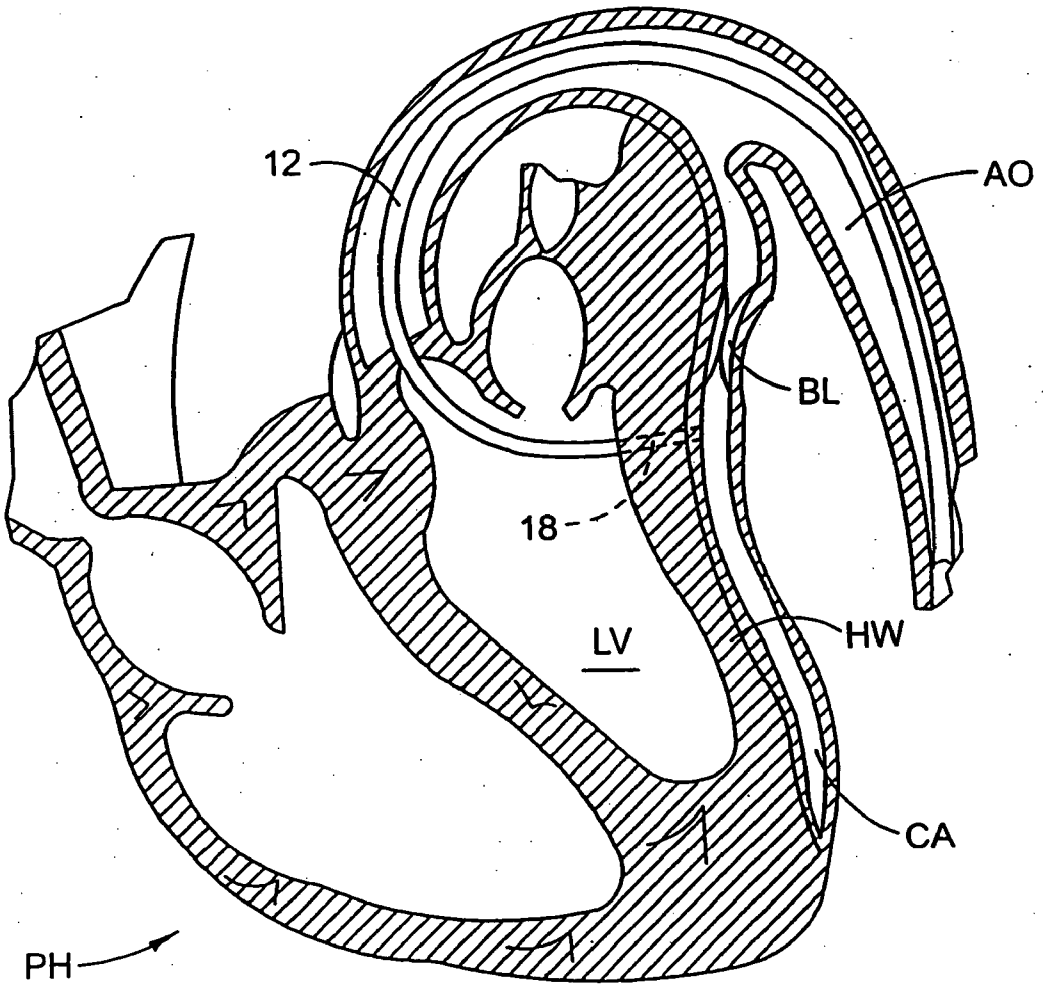



FIG. 1B

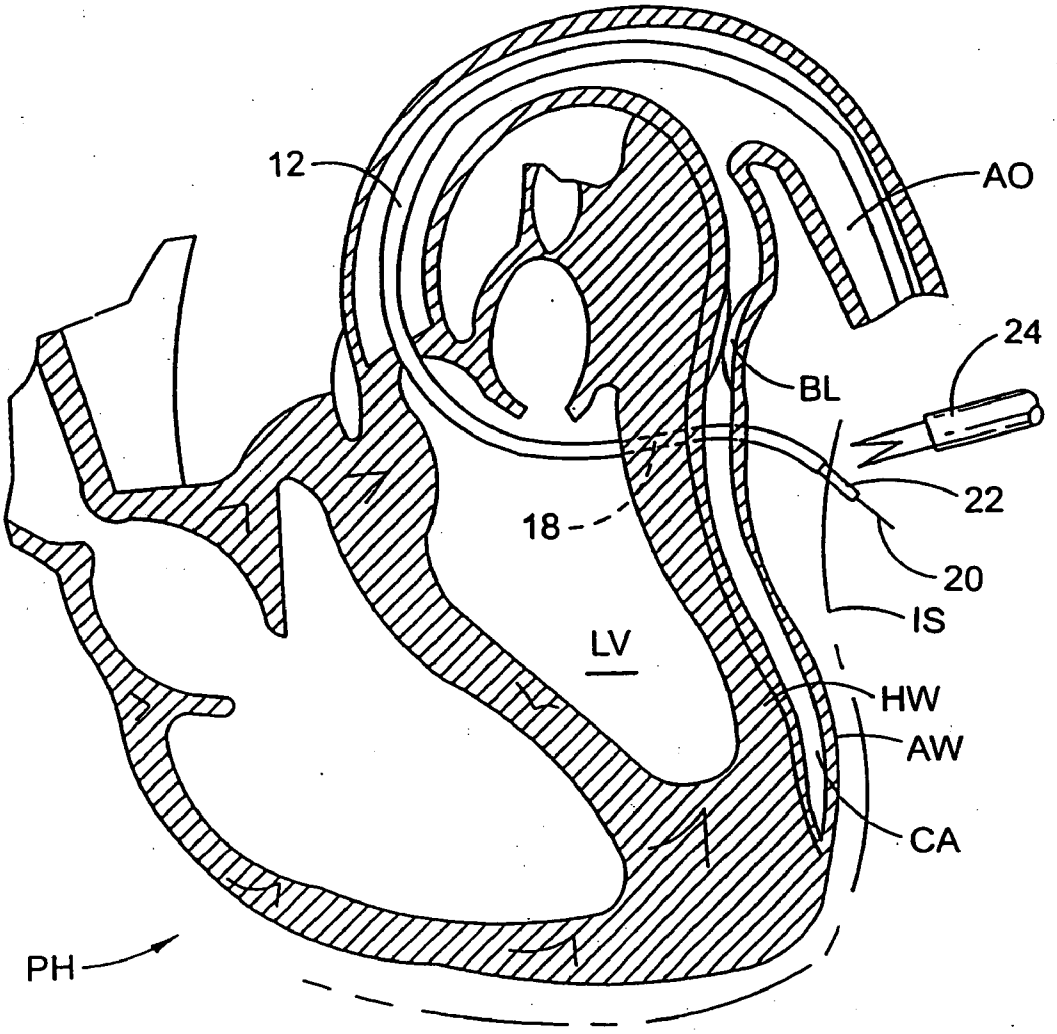



FIG. 1C

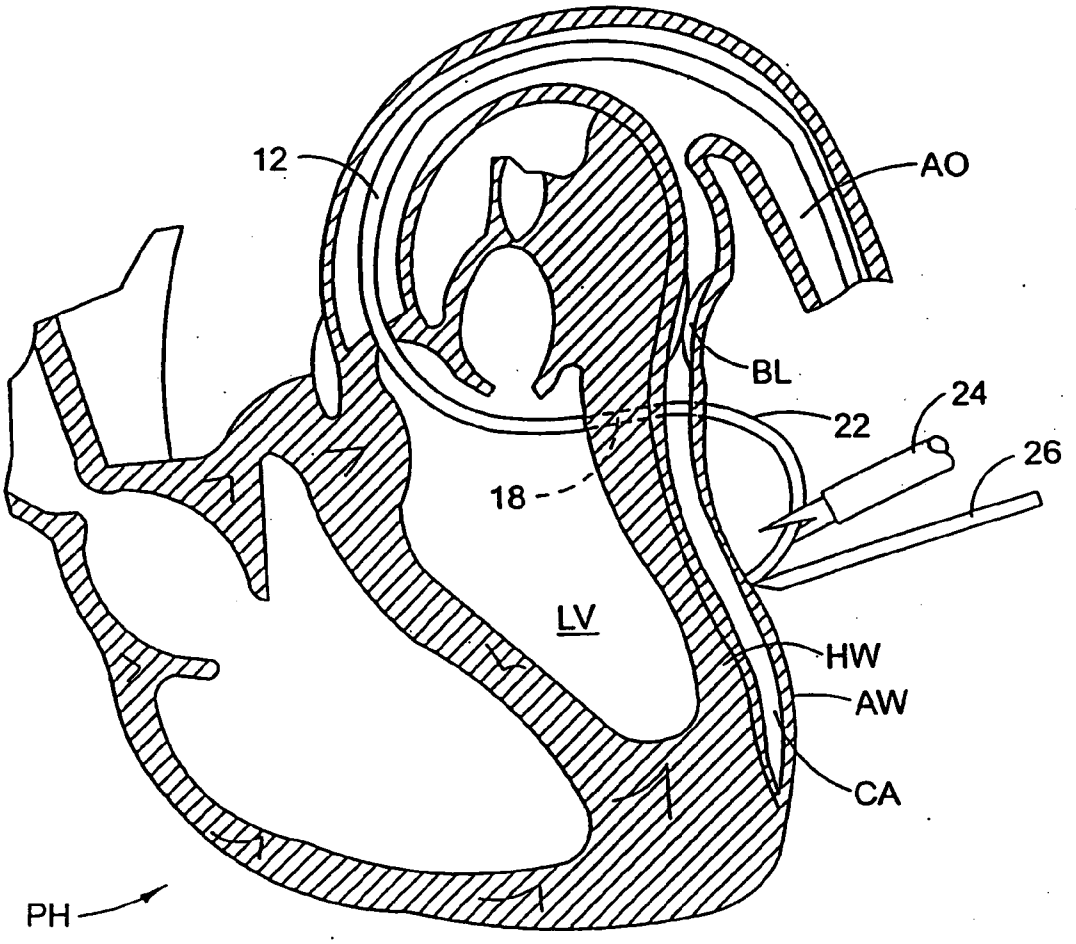



FIG. 1D

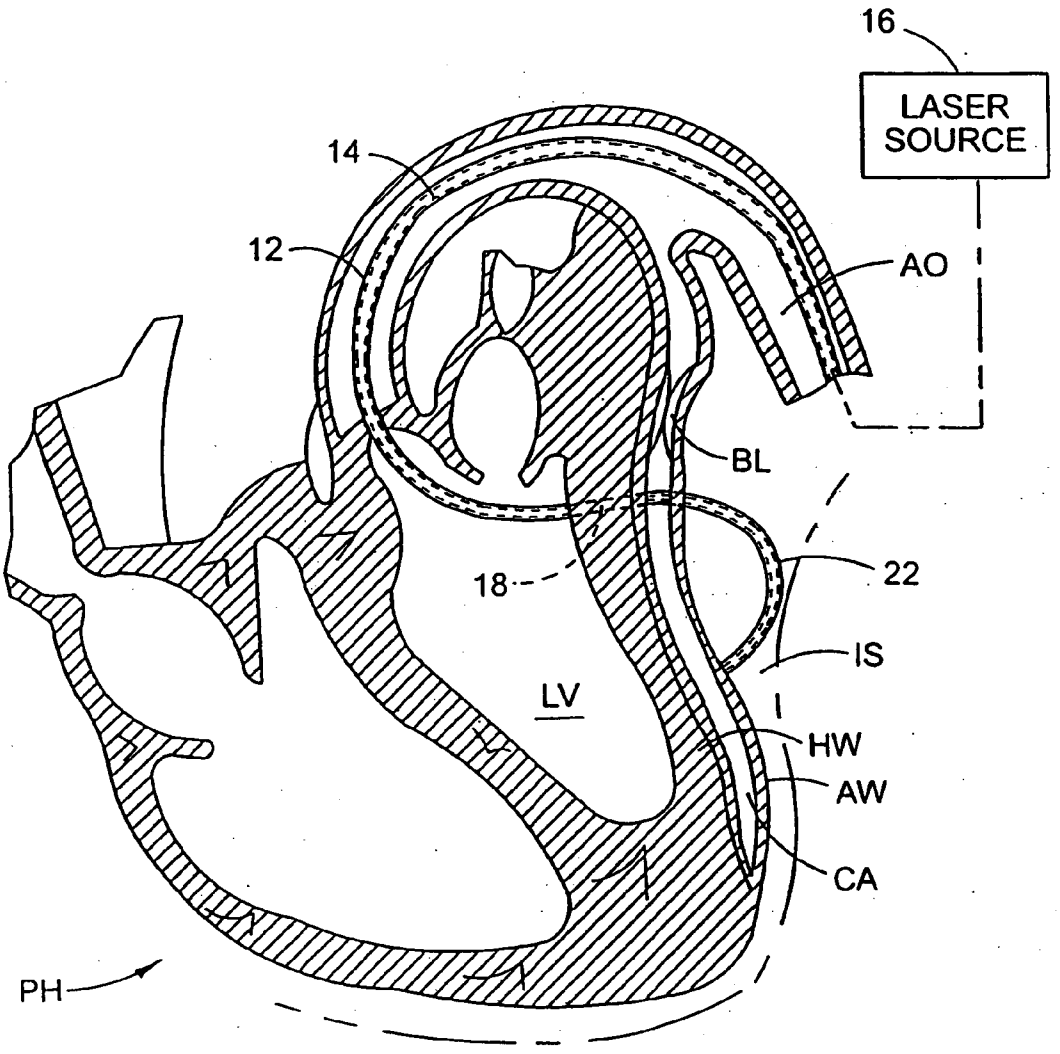



FIG. 1E

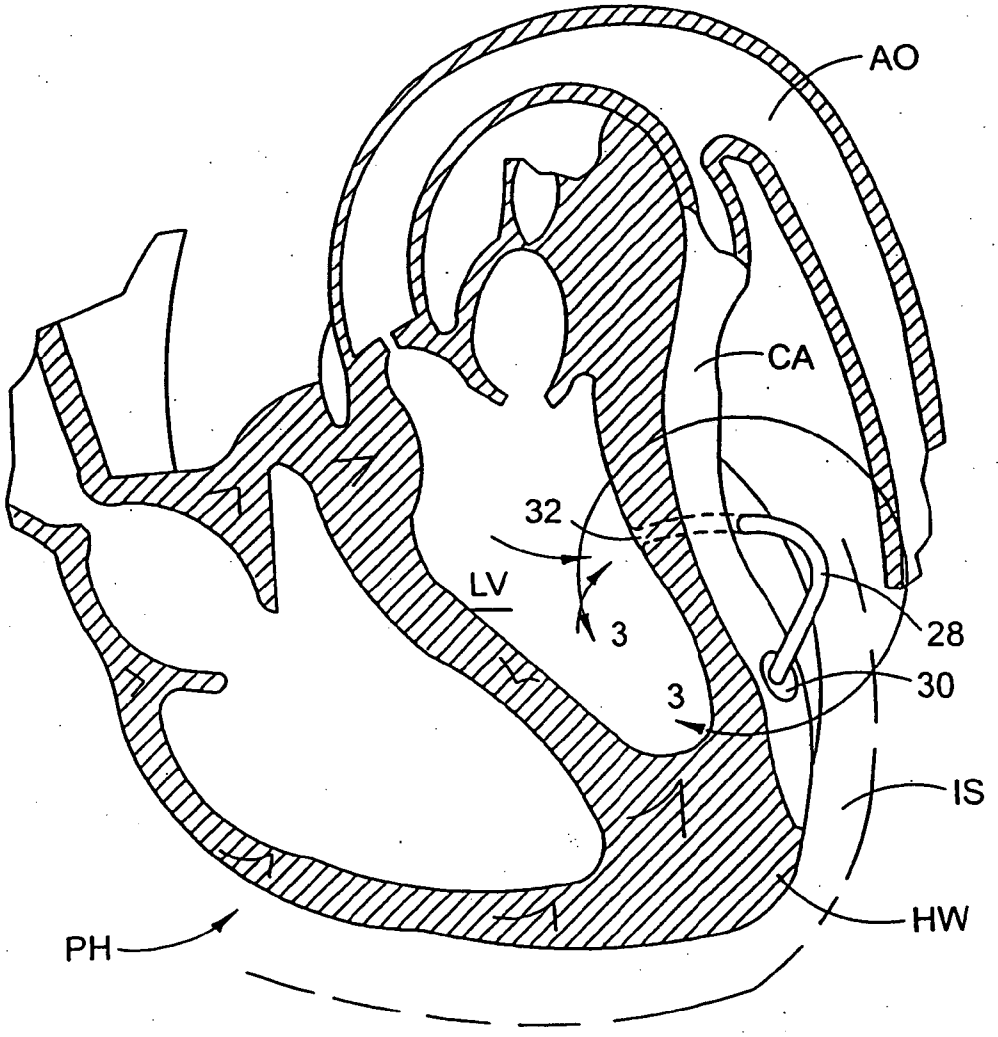



FIG. 2

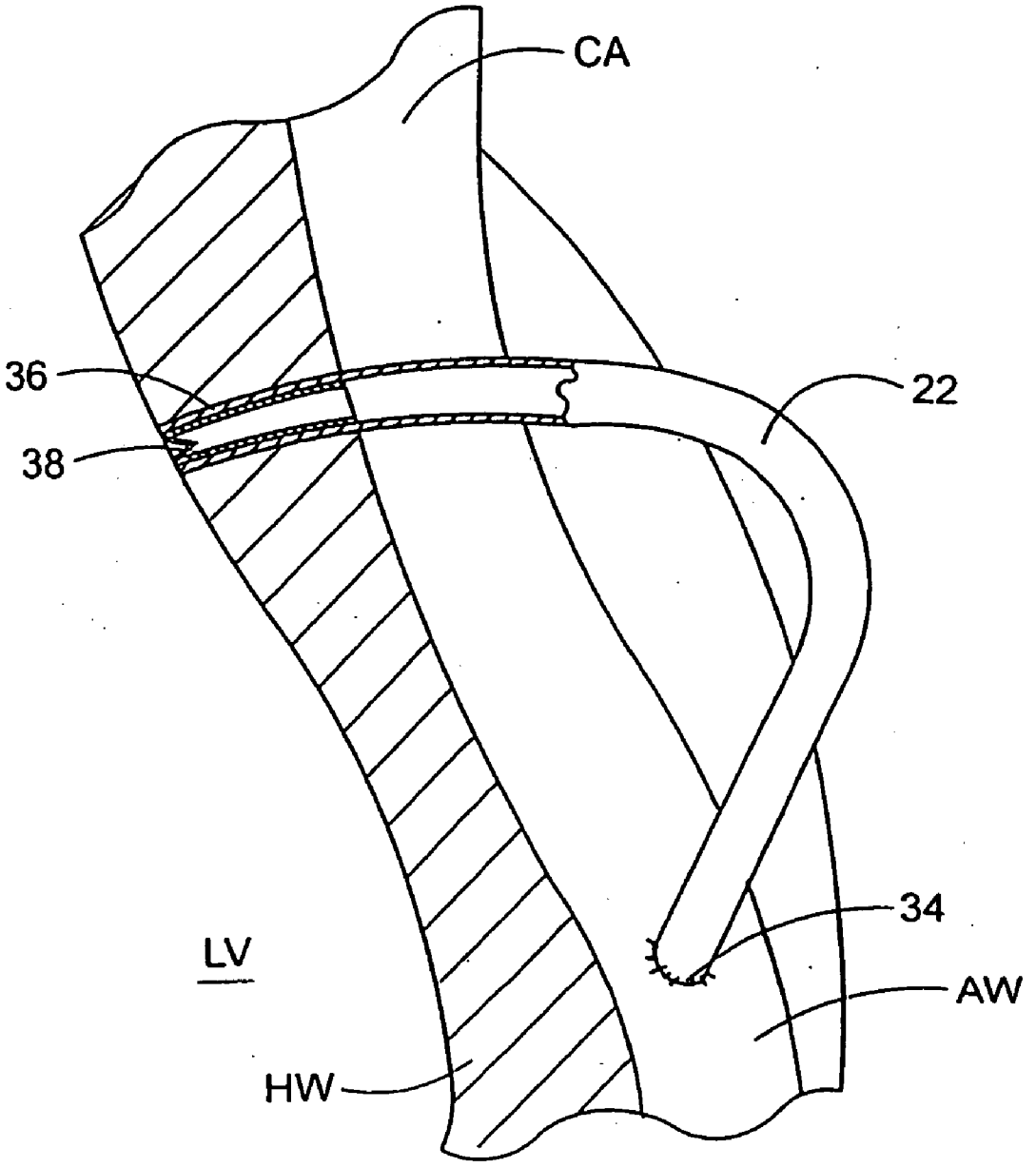



FIG. 3

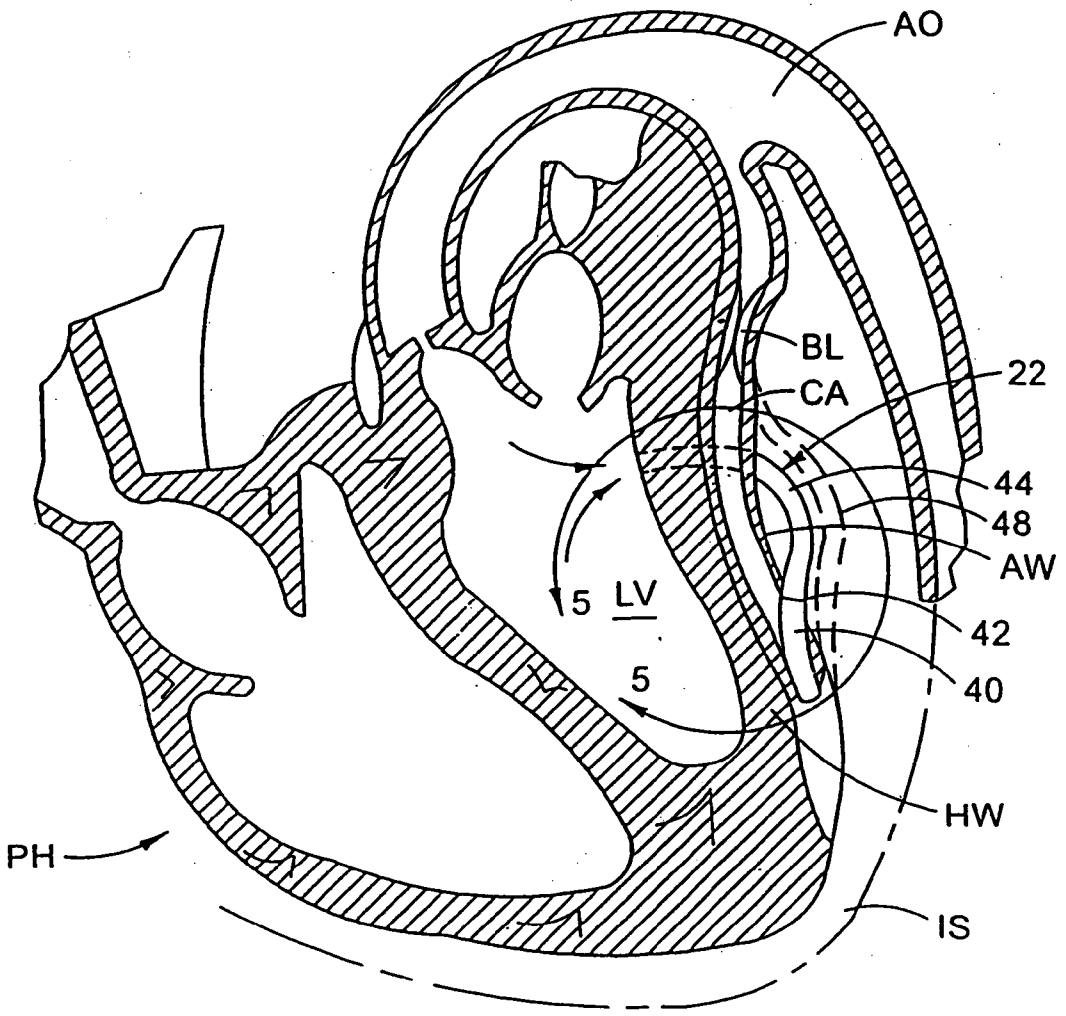



FIG. 4

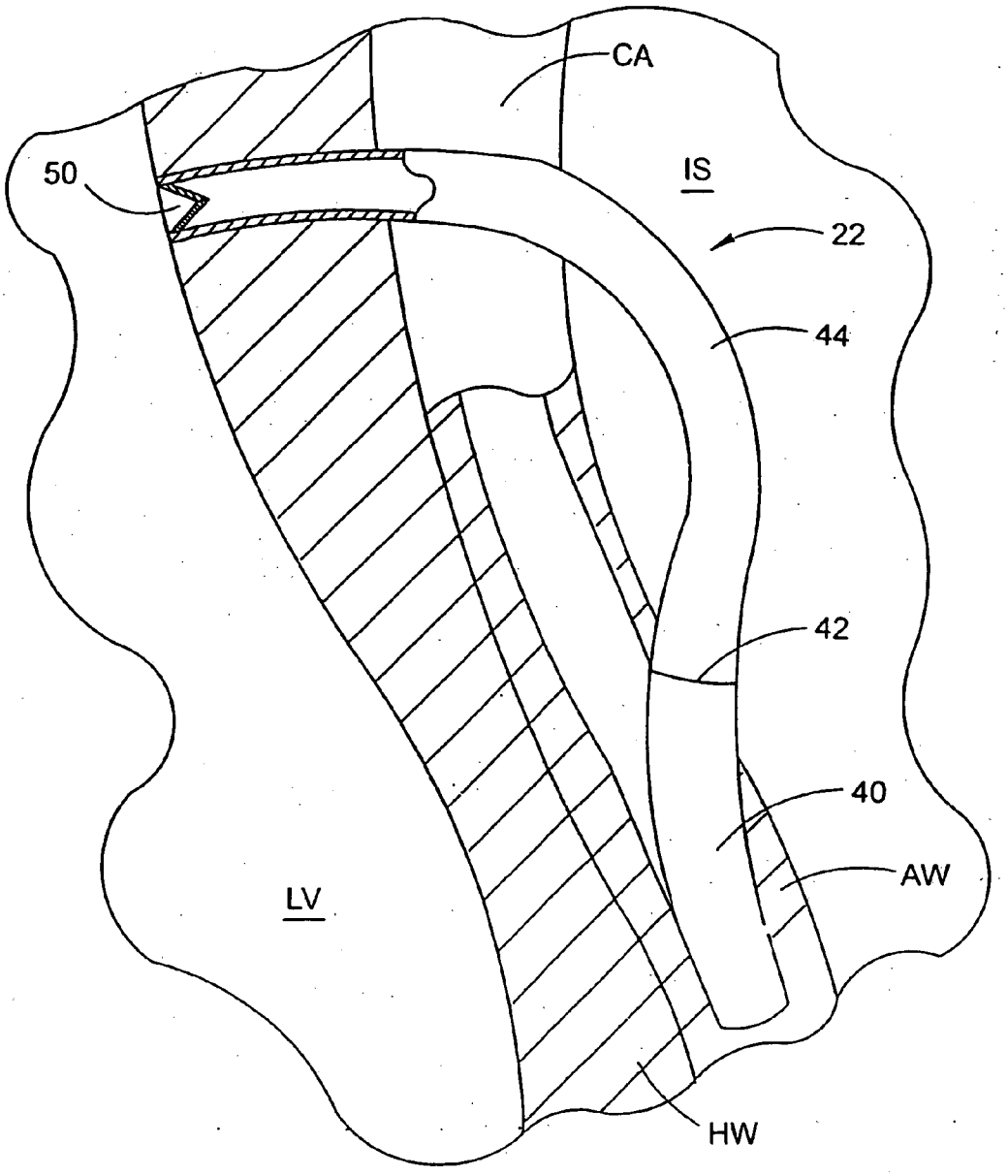



FIG. 5

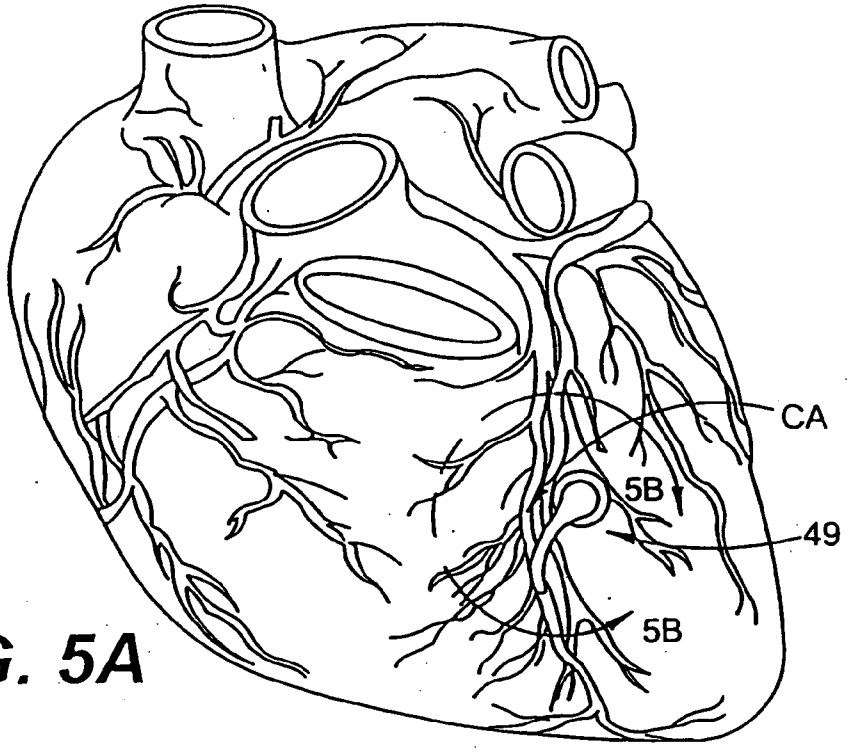



FIG. 5A

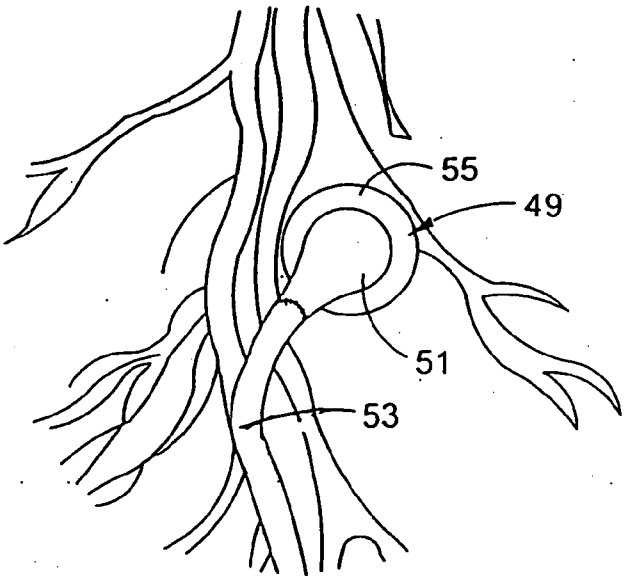



FIG. 5B

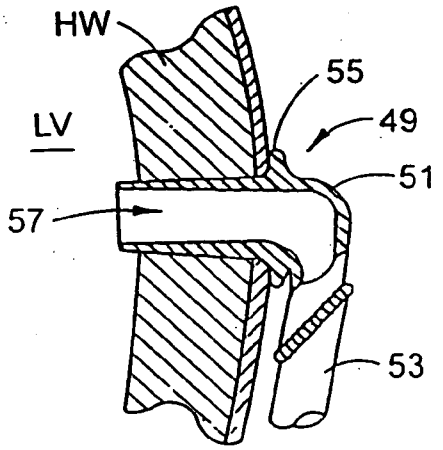



FIG. 5C

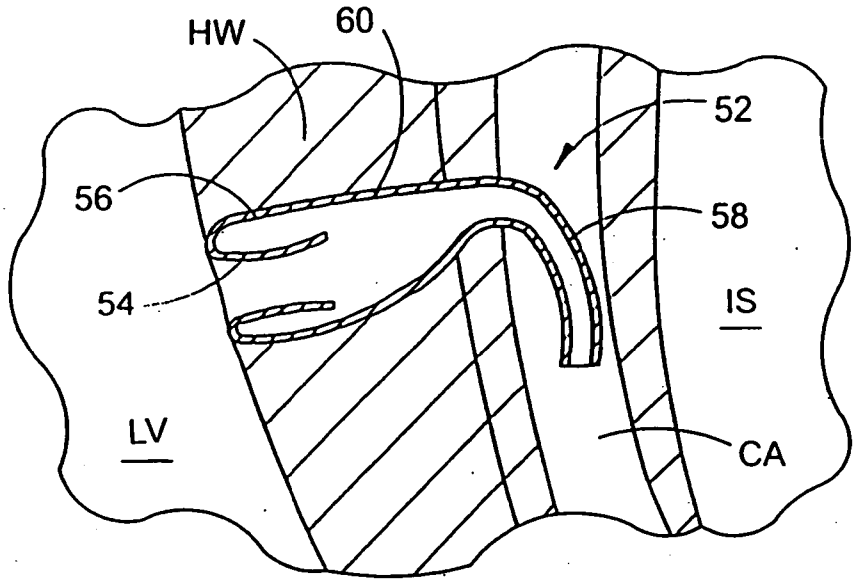



FIG. 6A

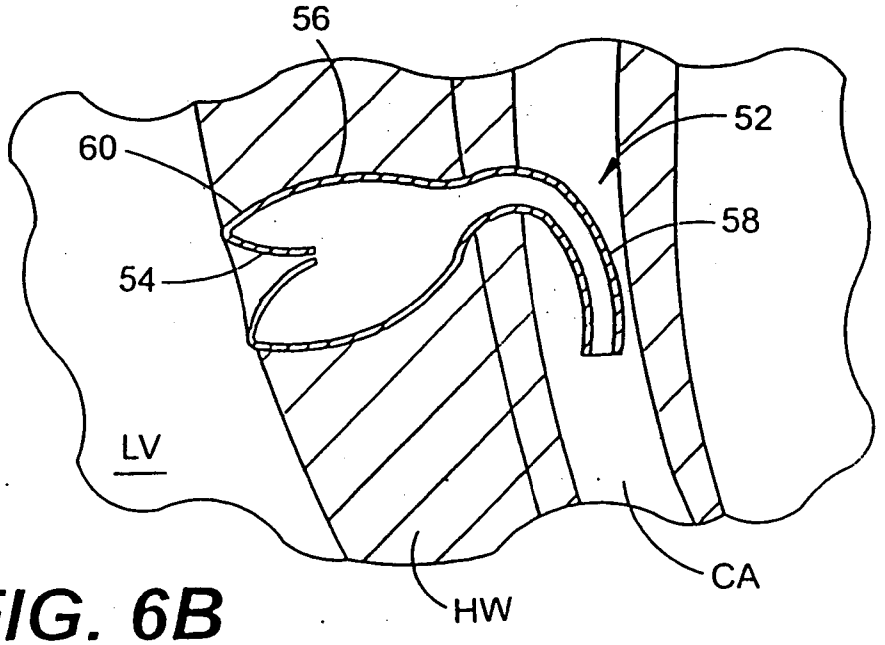



FIG. 6B

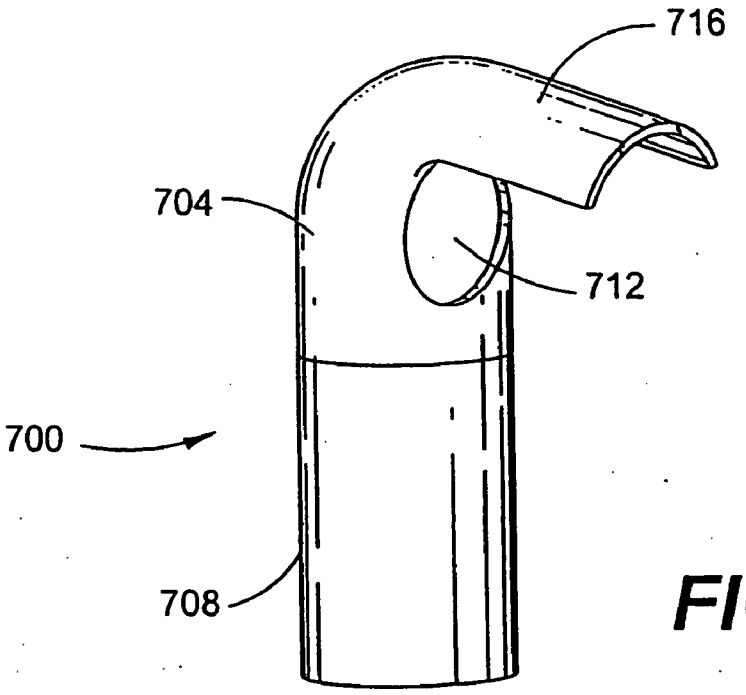



FIG. 6C

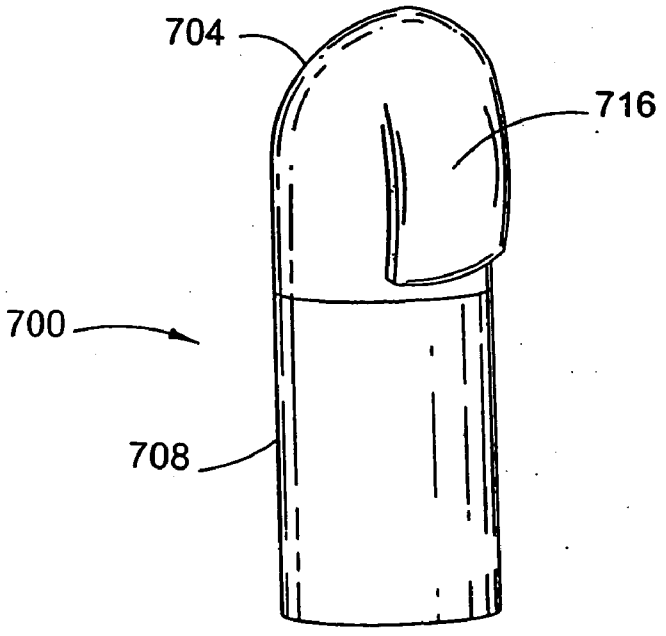



FIG. 6D

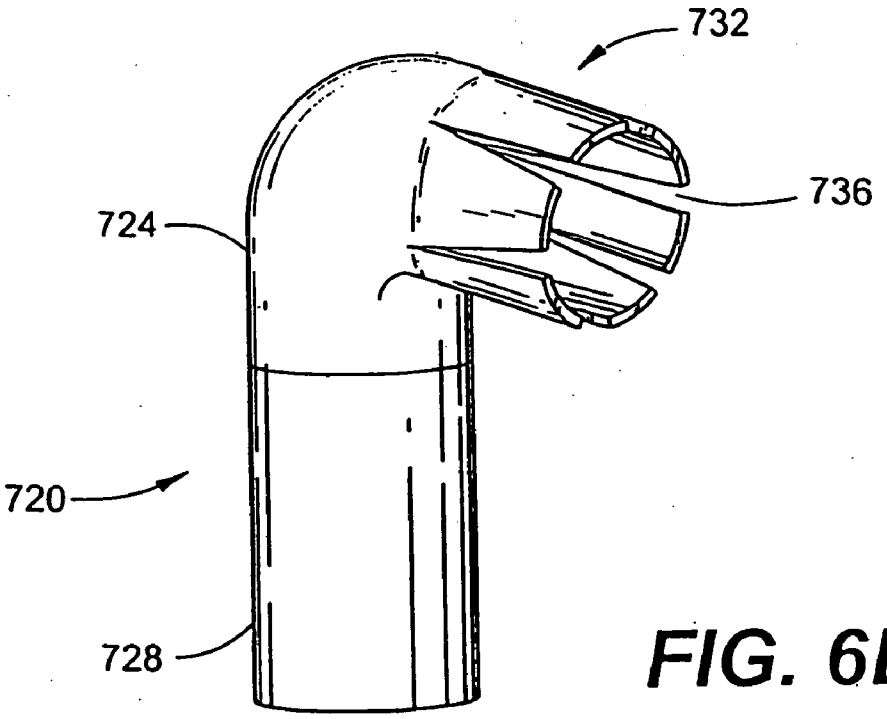



FIG. 6E

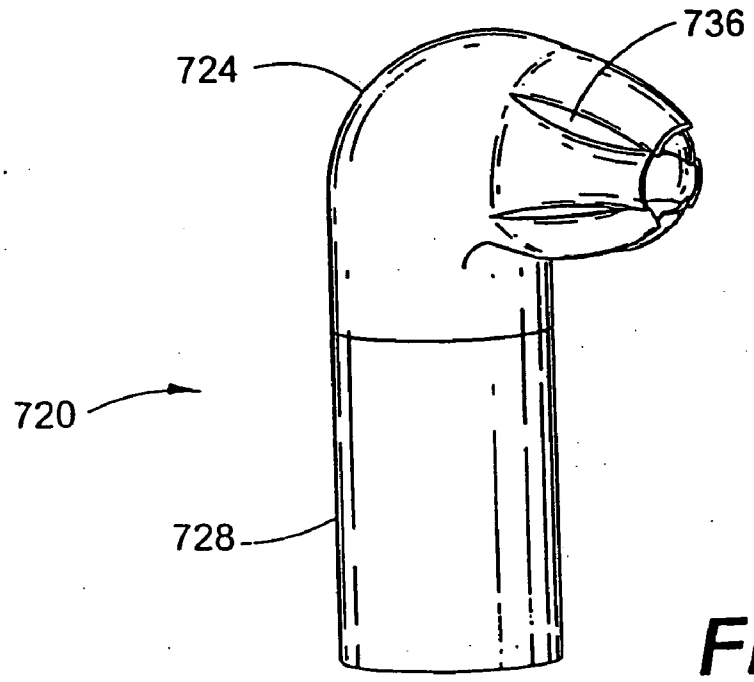



FIG. 6F

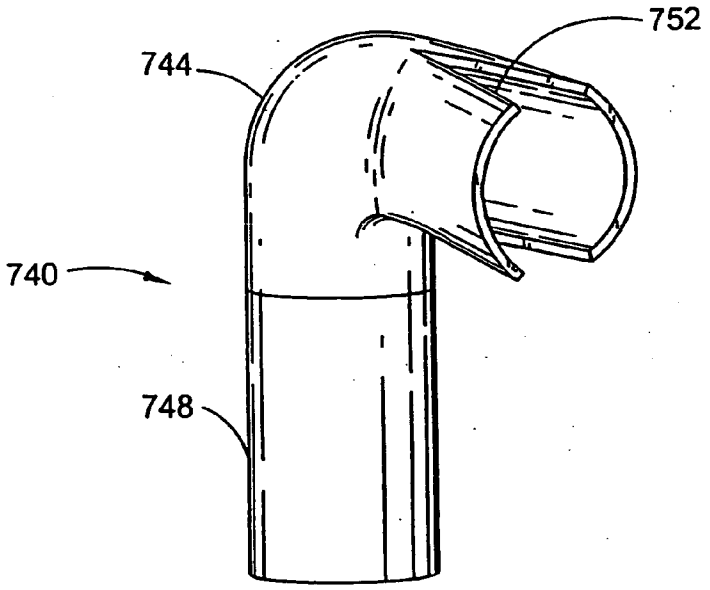



FIG. 6G

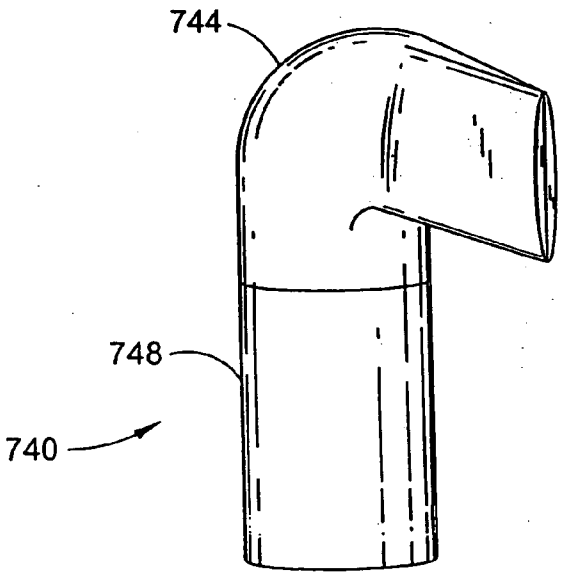
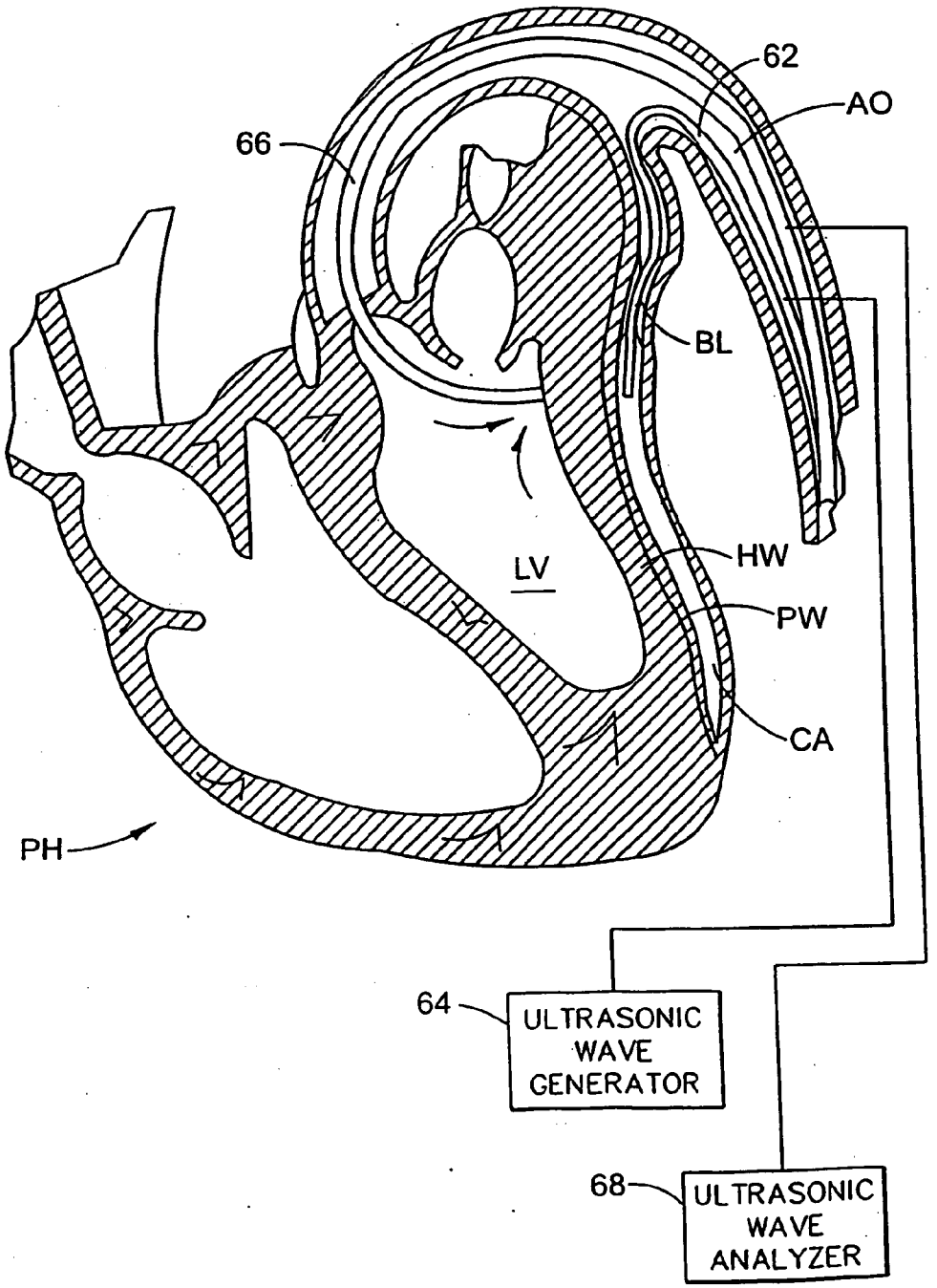



FIG. 6H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AO
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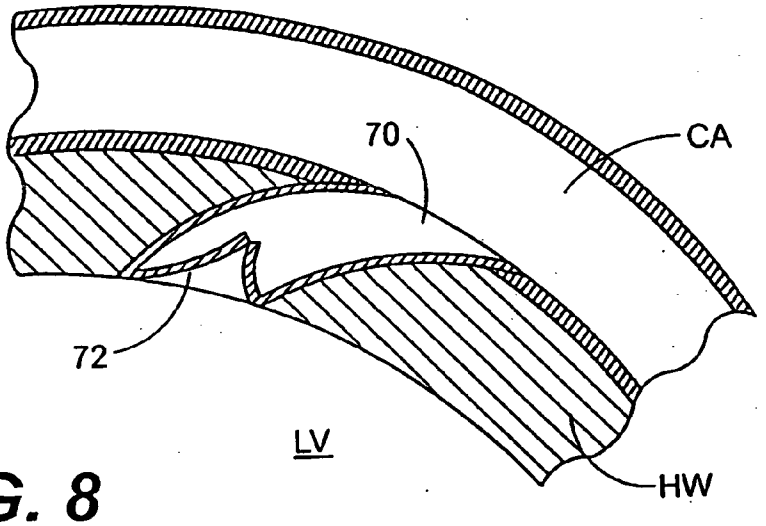
LV
PW
CA
PH
64
ULTRASONIC WAVE GENERATOR
68
ULTRASONIC WAVE ANALYZER

FIG. 7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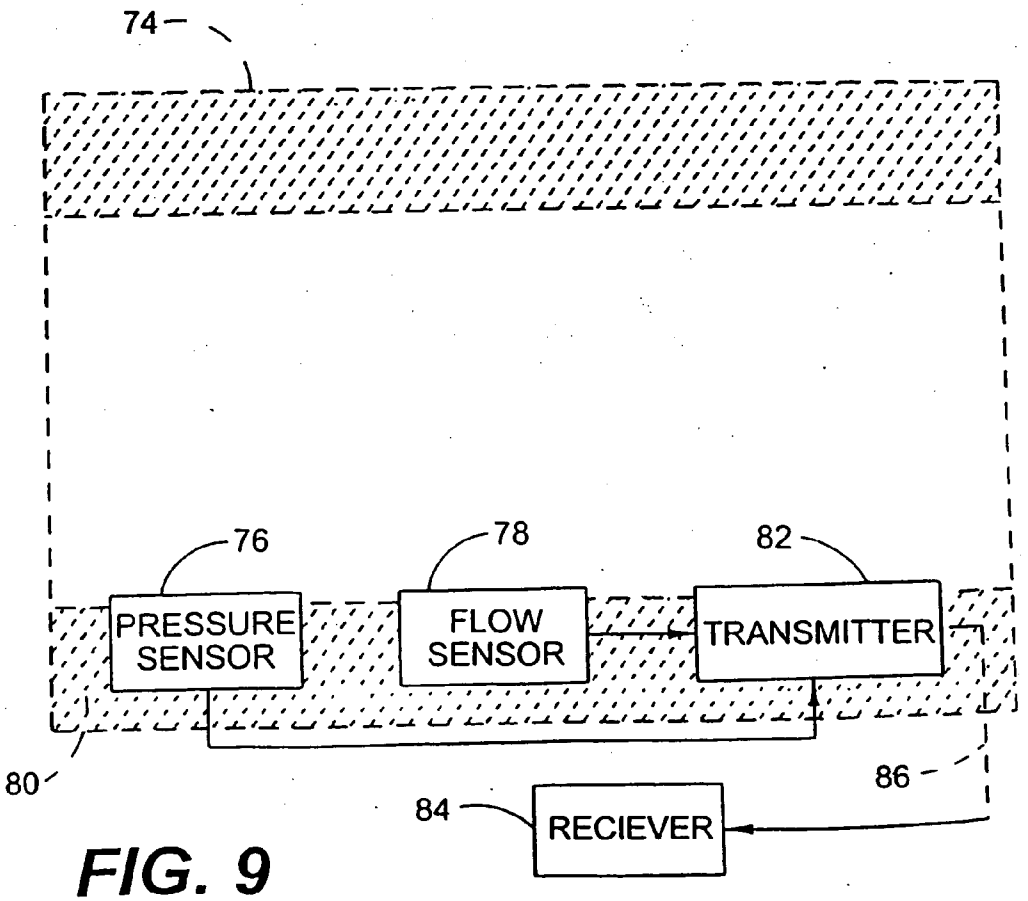
LV
HW

FIG. 8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FLOW SENSOR
TRANSMITTER
80
86
84
RECIEVER

FIG. 9

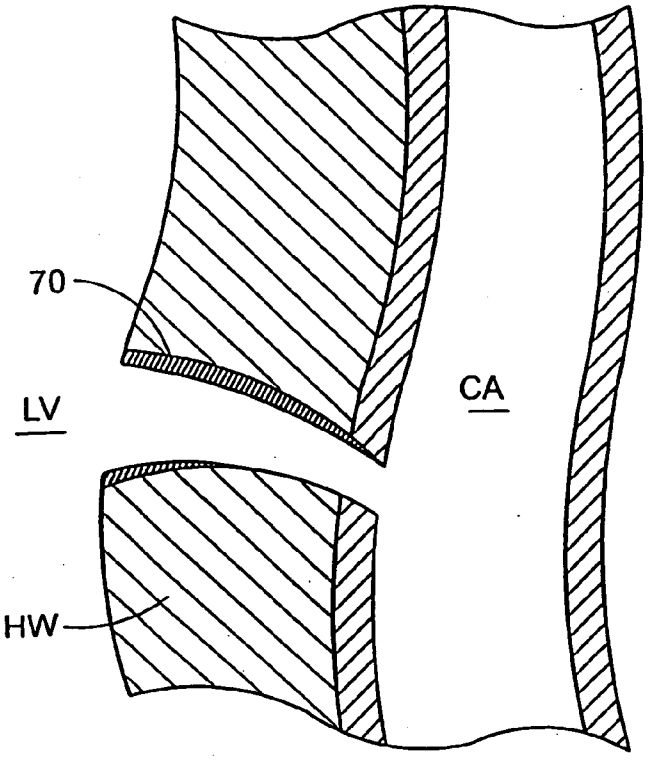



FIG. 8A

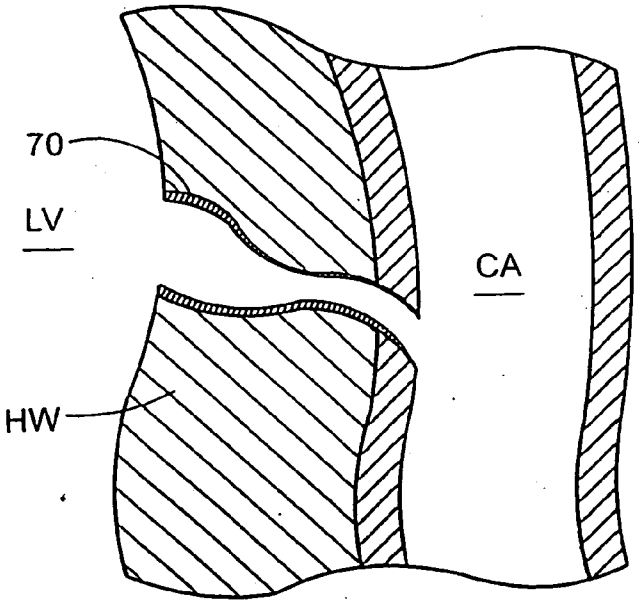
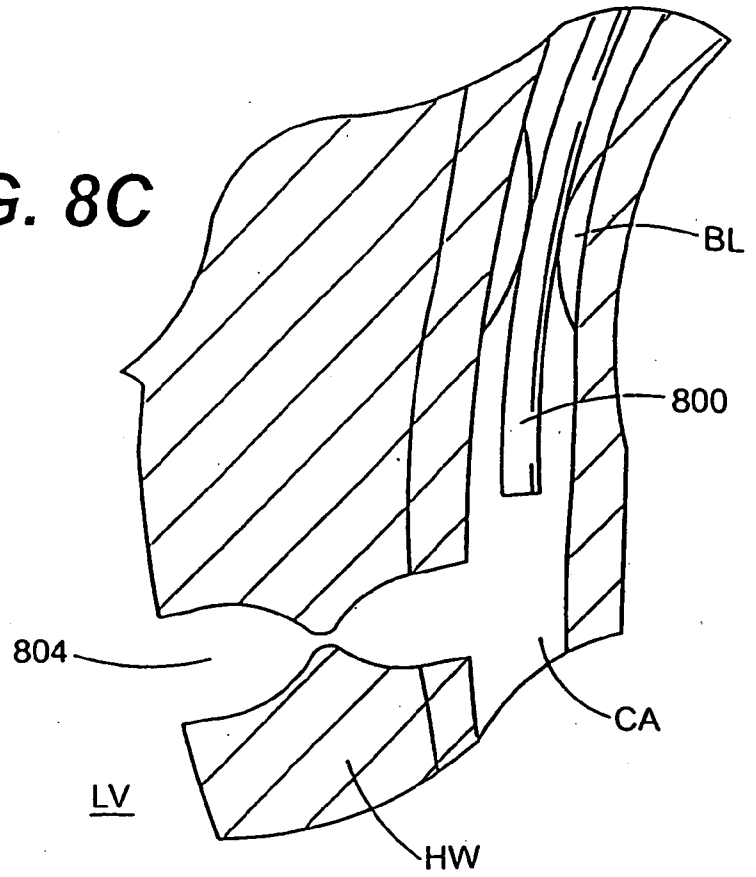



FIG. 8B

FIG. 8C



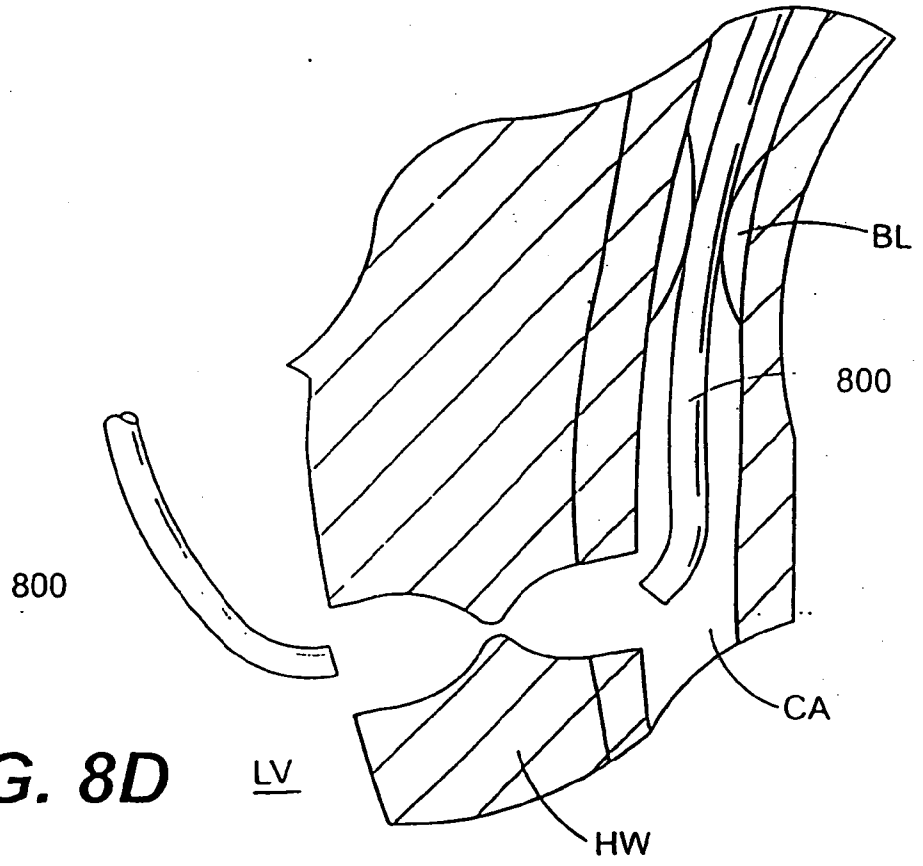
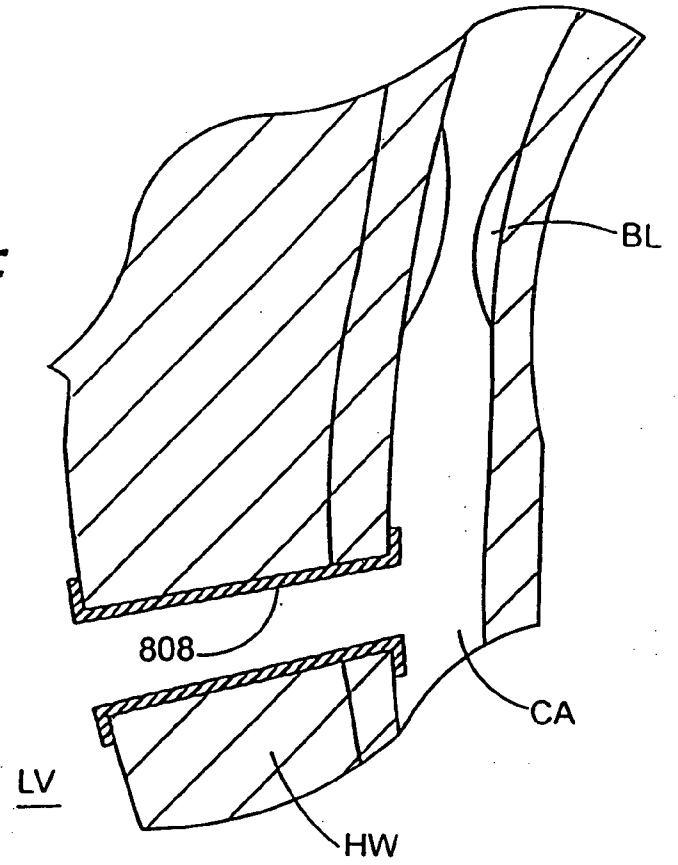




FIG. 8D

FIG. 8F

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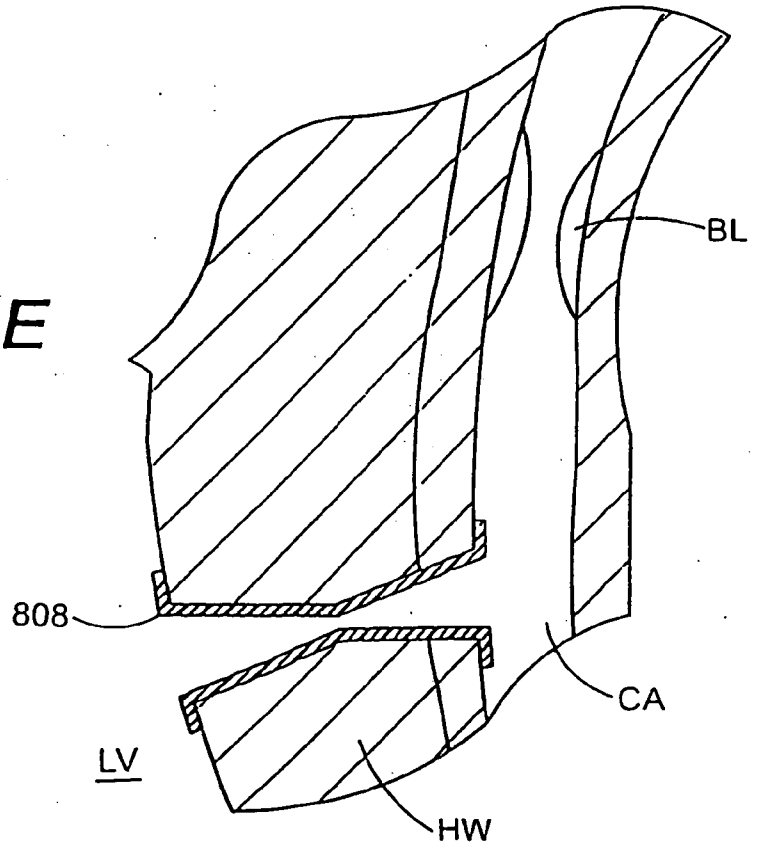
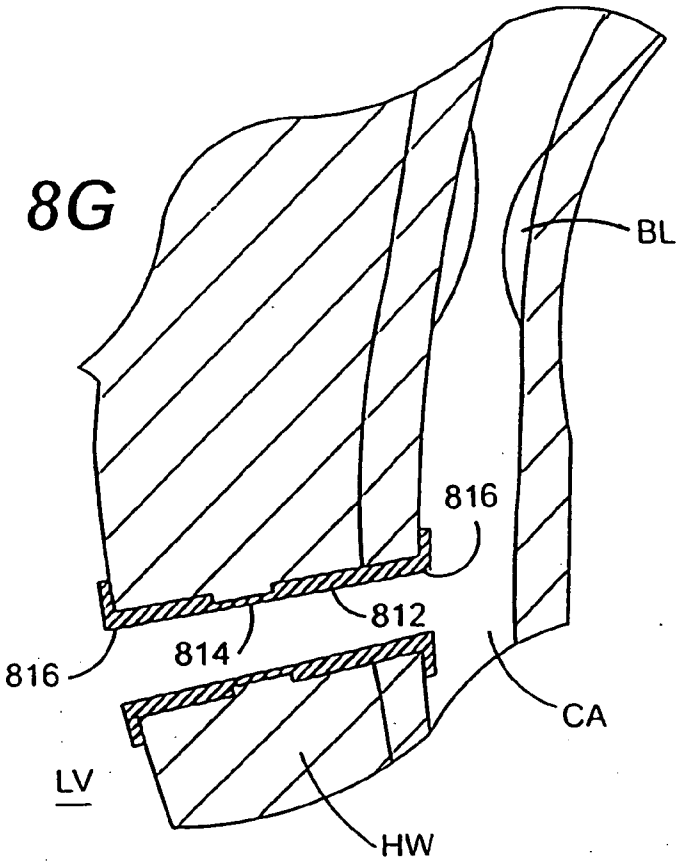


FIG. 8G



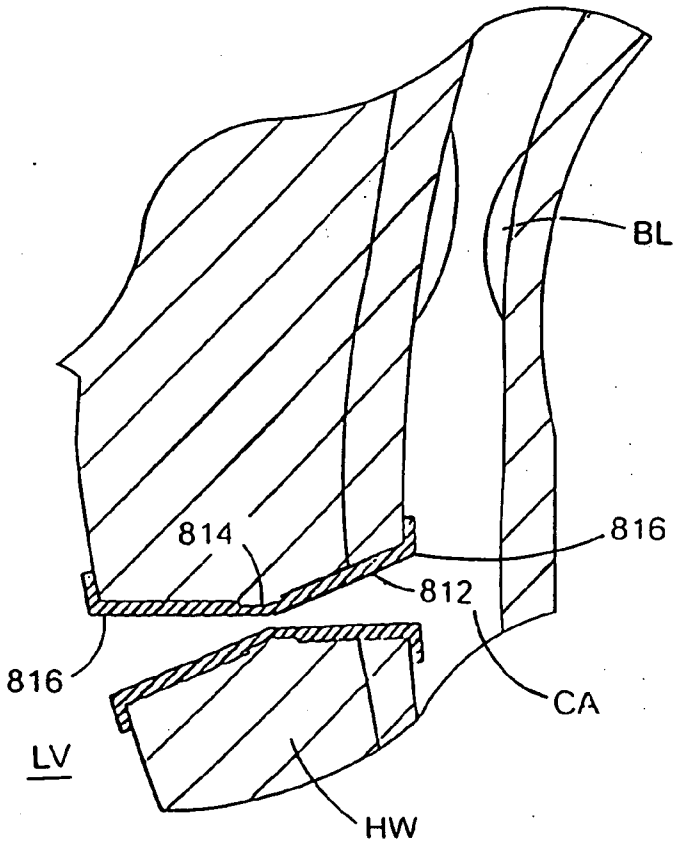




FIG. 8H

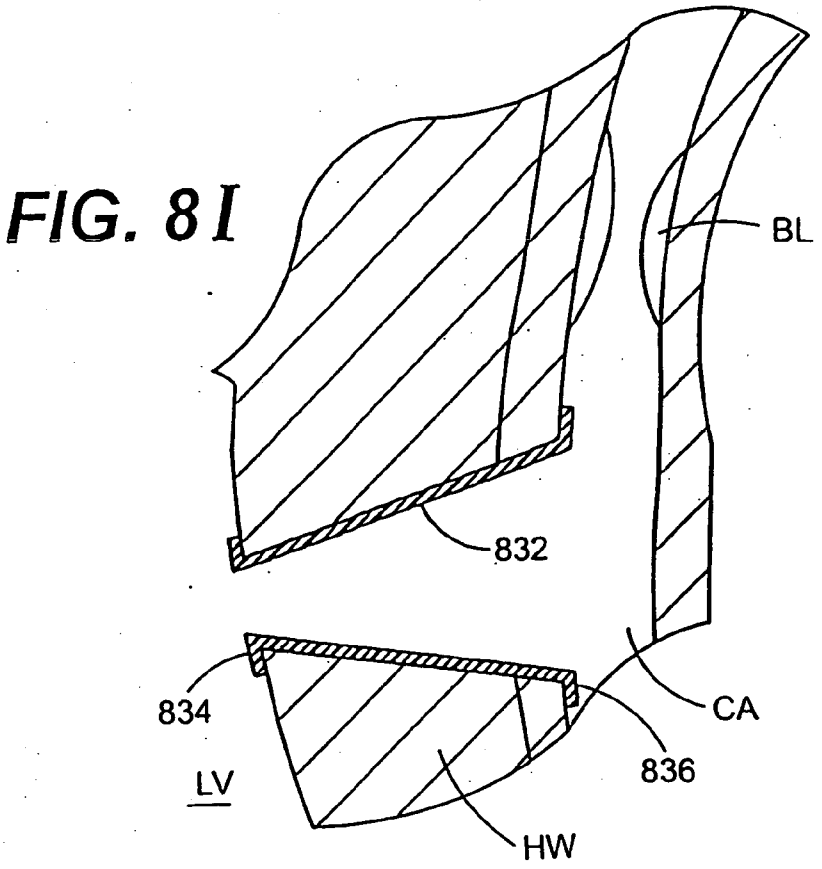



FIG. 8I

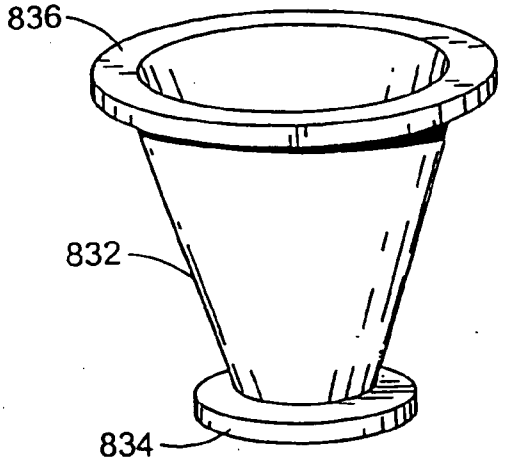
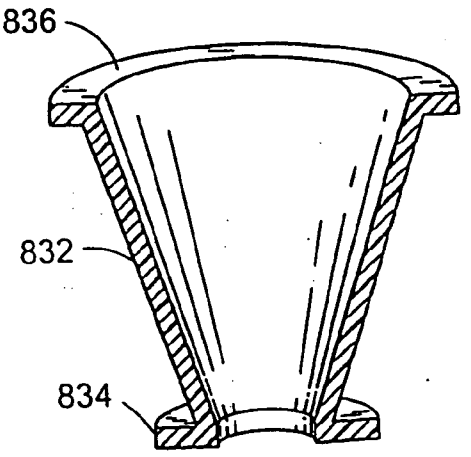



FIG. 8J

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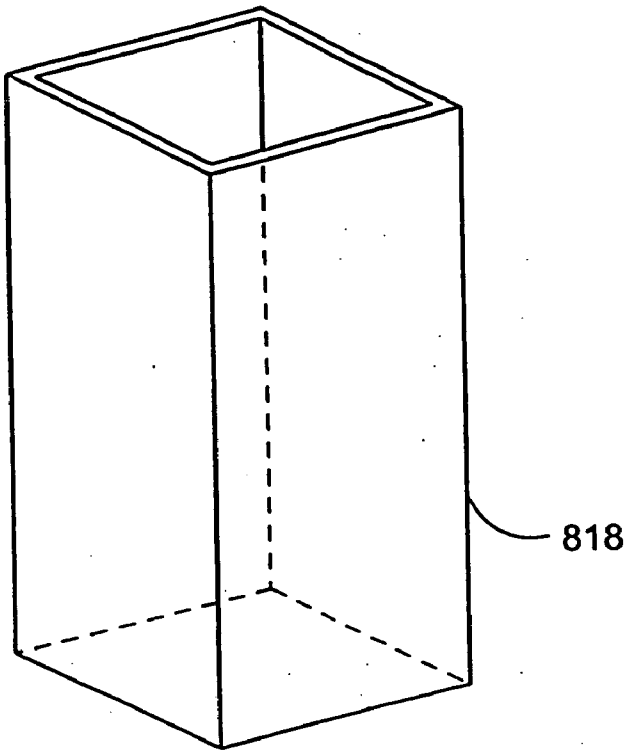



FIG. 8L

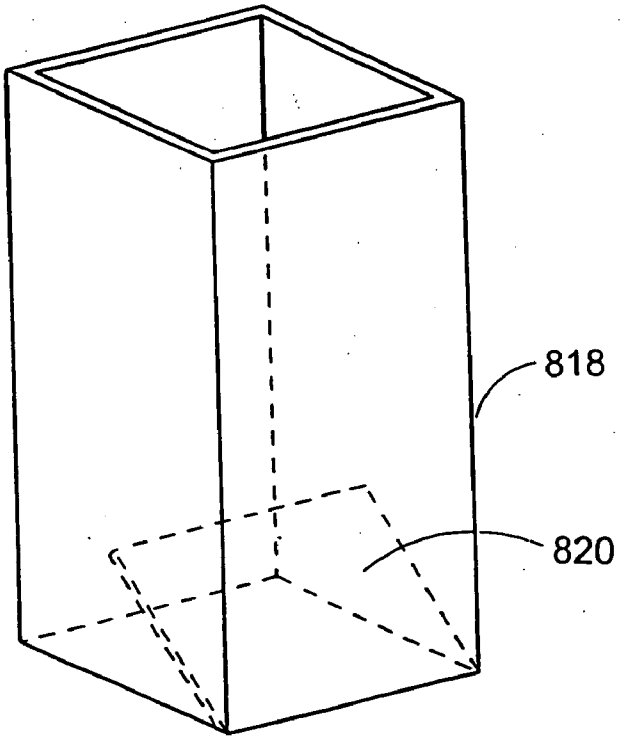
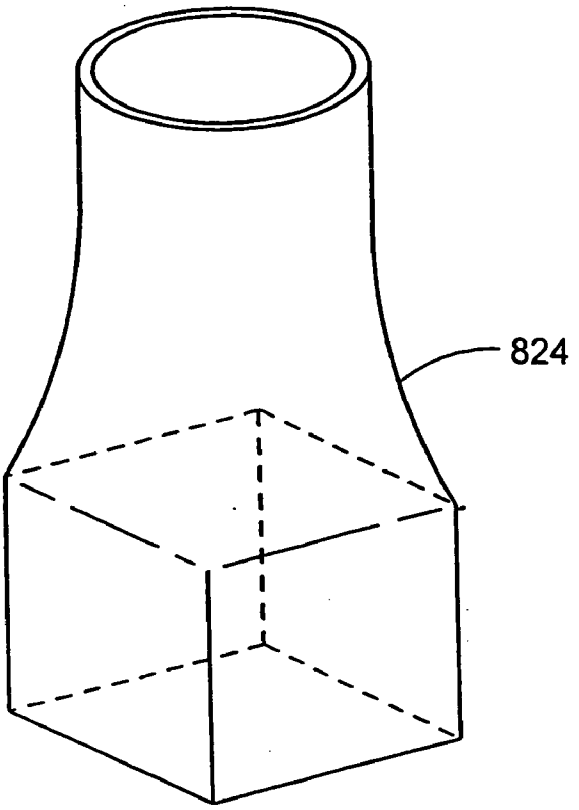



FIG. 8M

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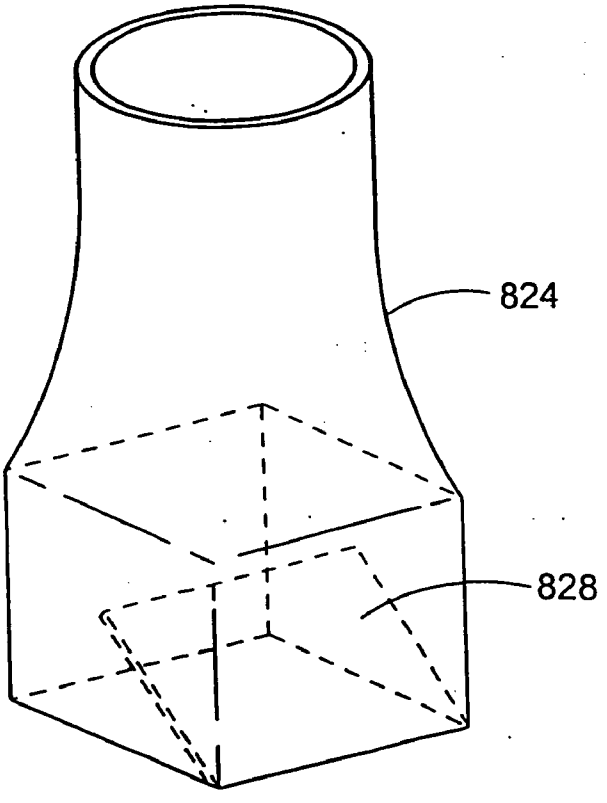
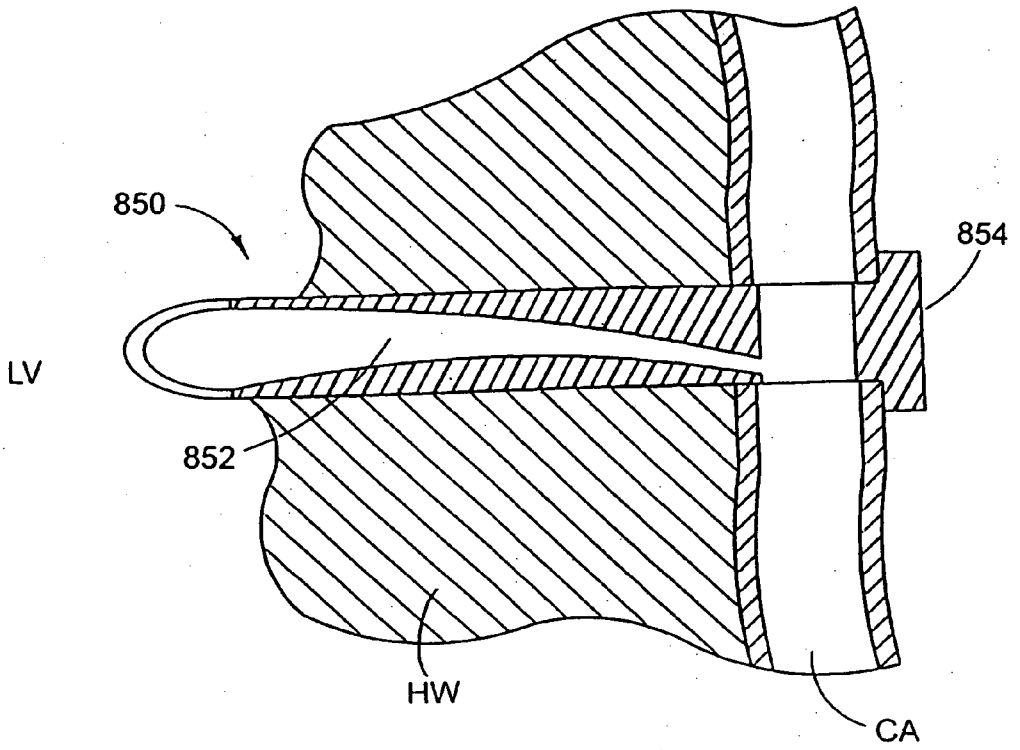



FIG. 8 0

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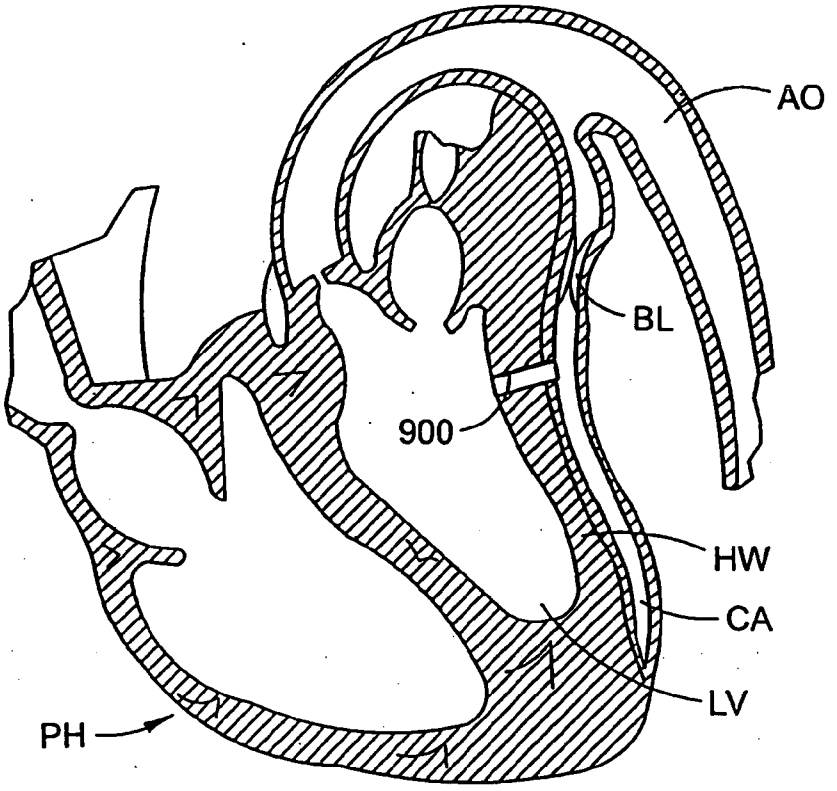



FIG. 9A

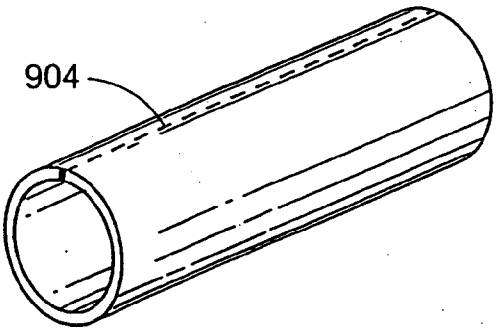



FIG. 9B

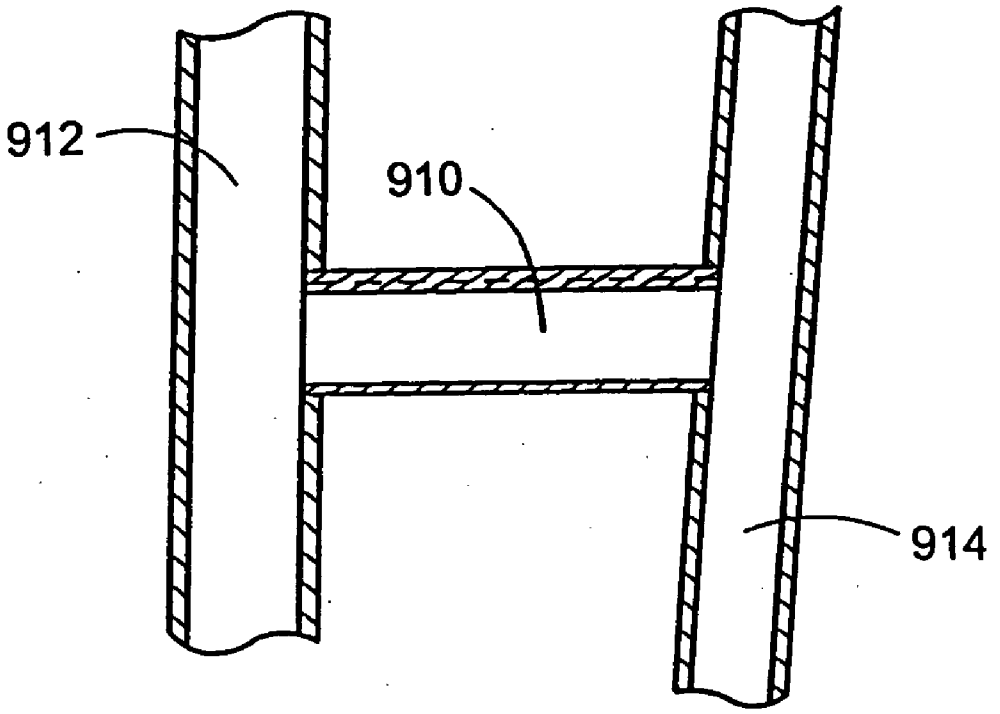



FIG. 9C

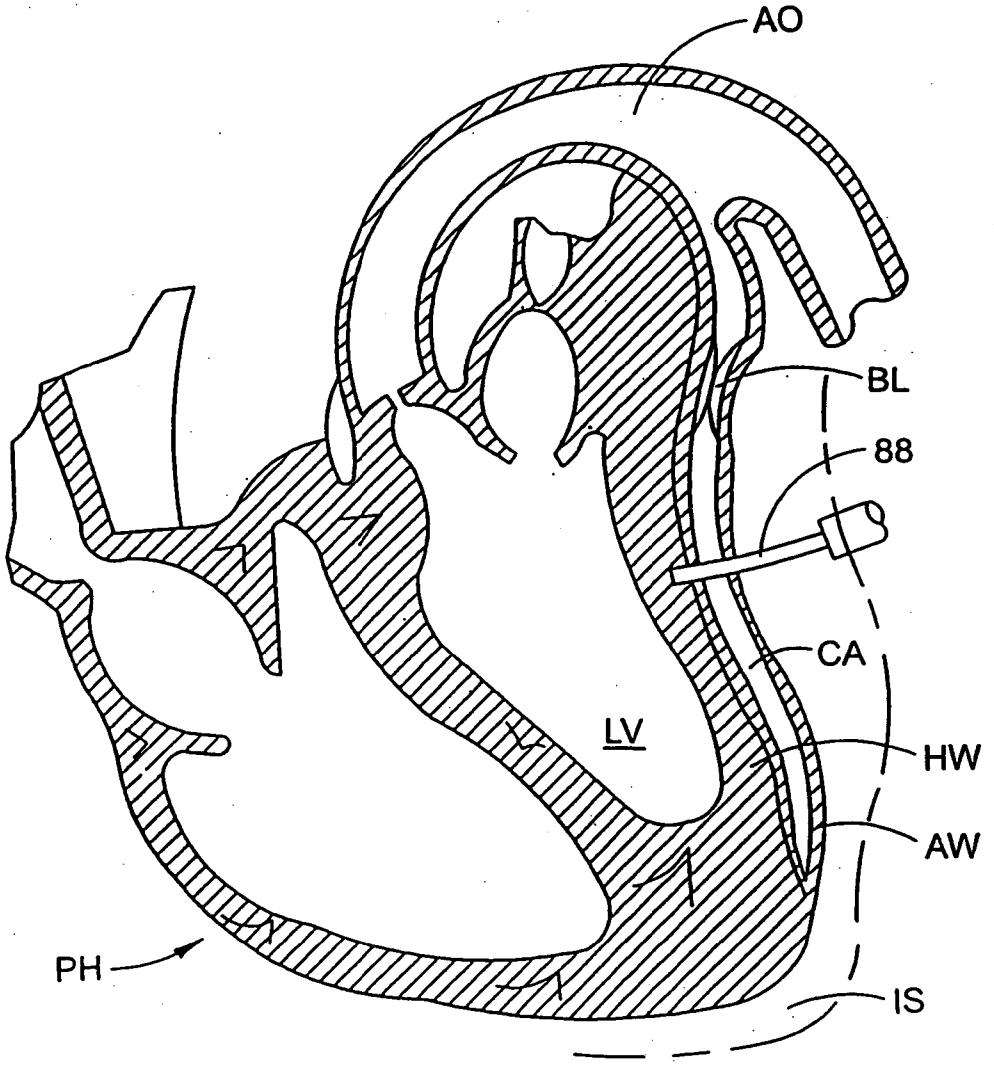



FIG. 10A

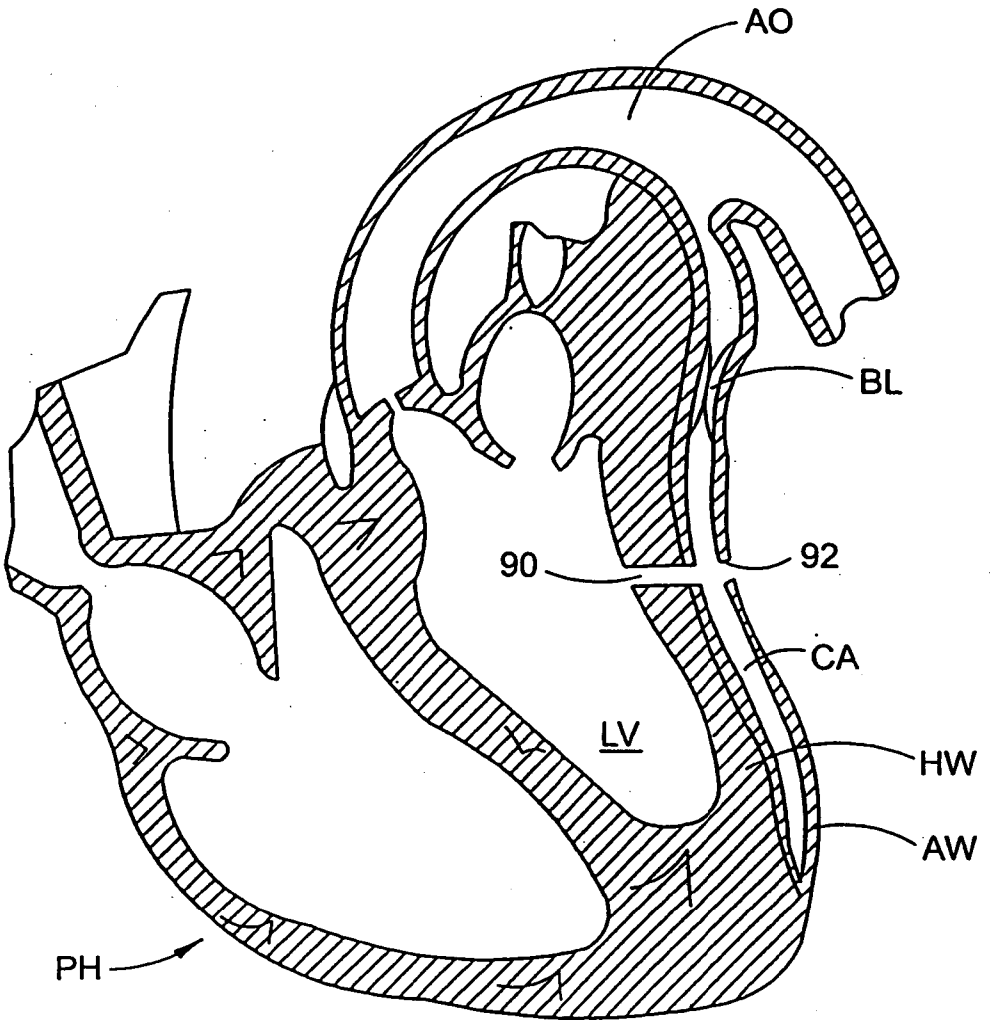
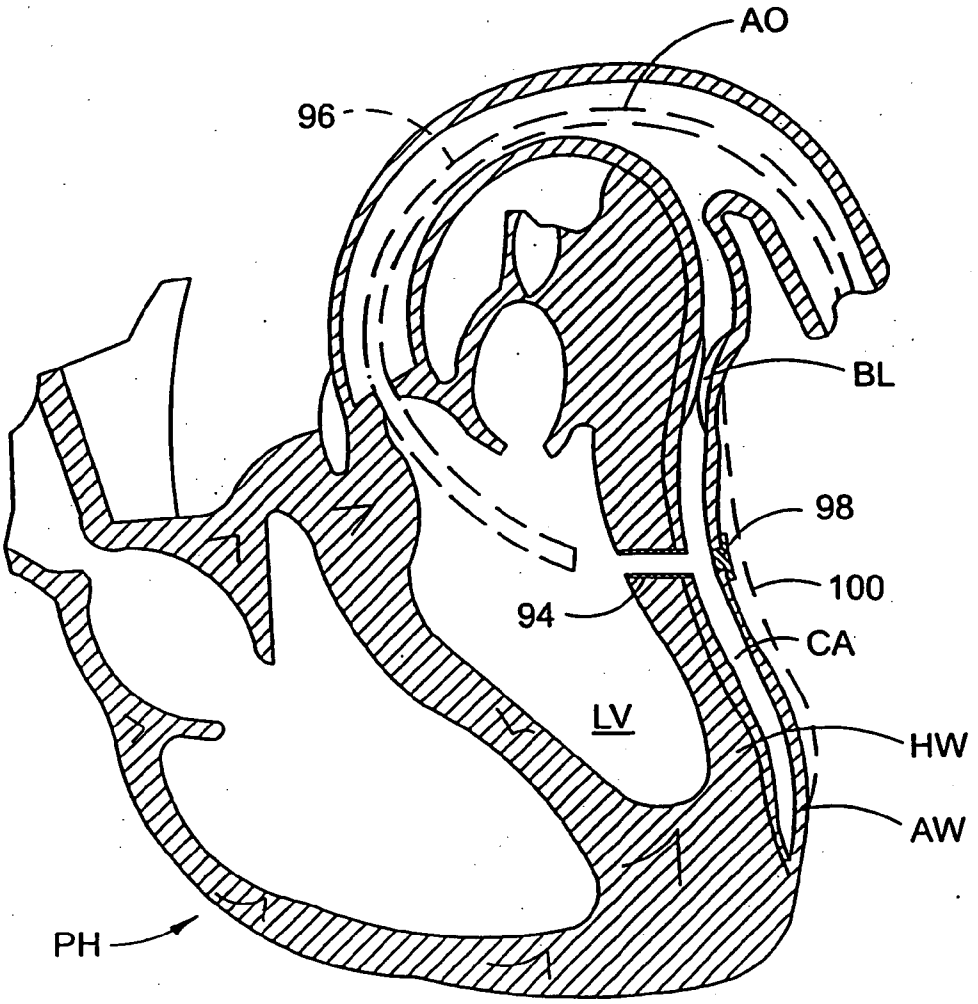



FIG. 10B

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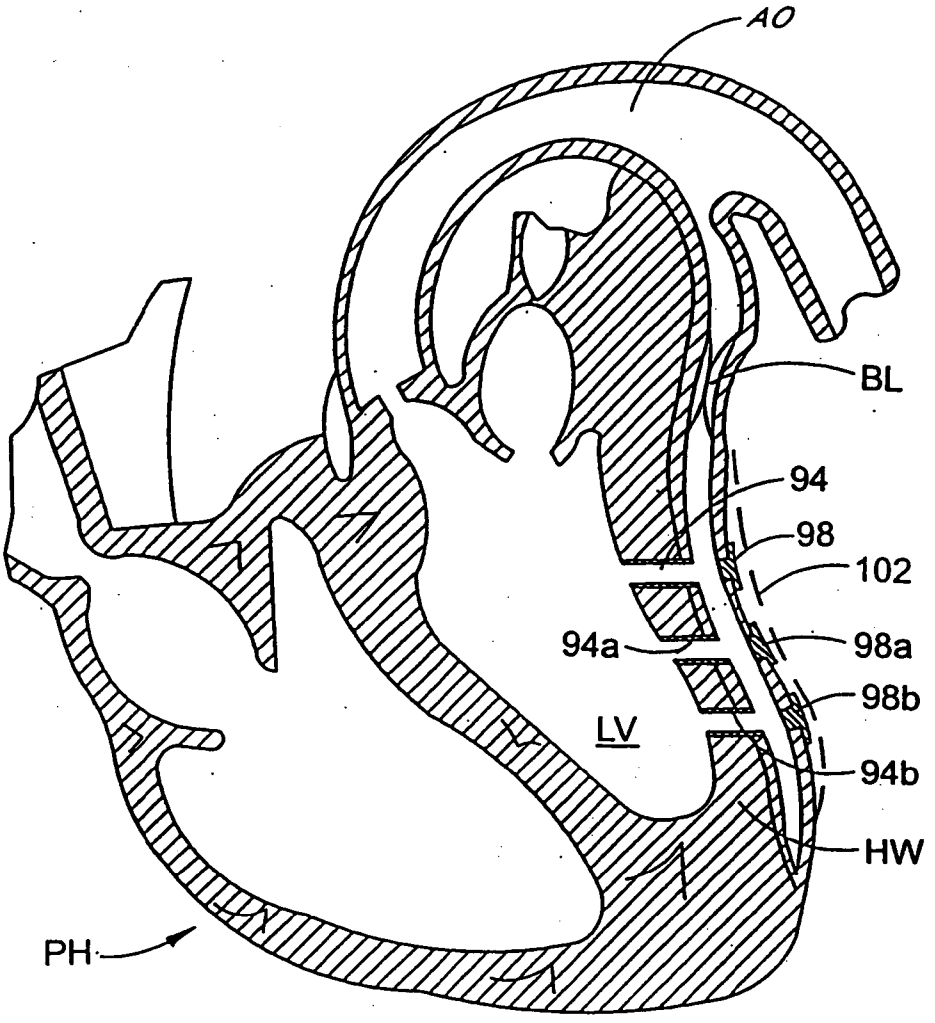
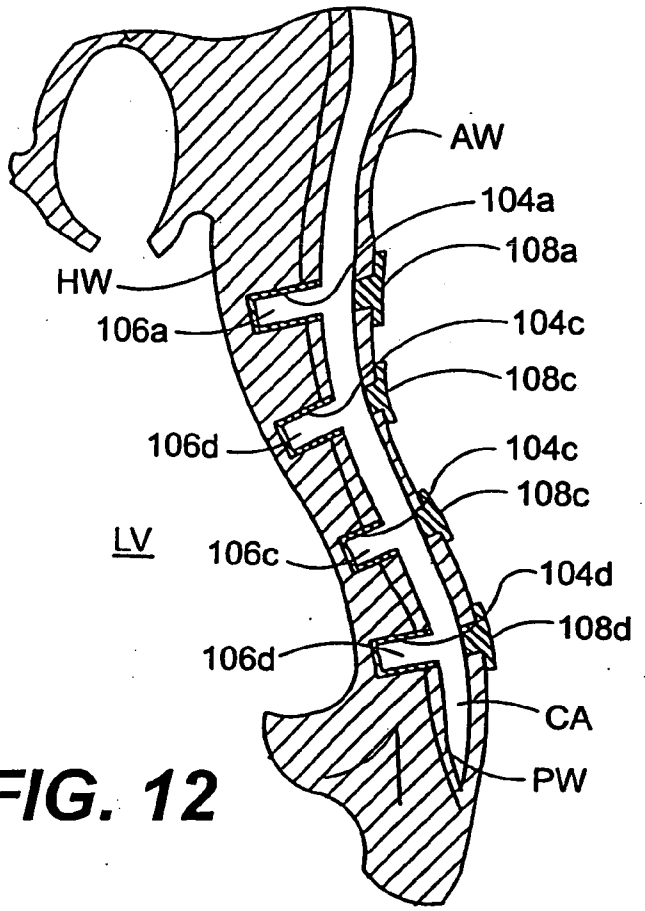



FIG. 11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PW

FIG. 12

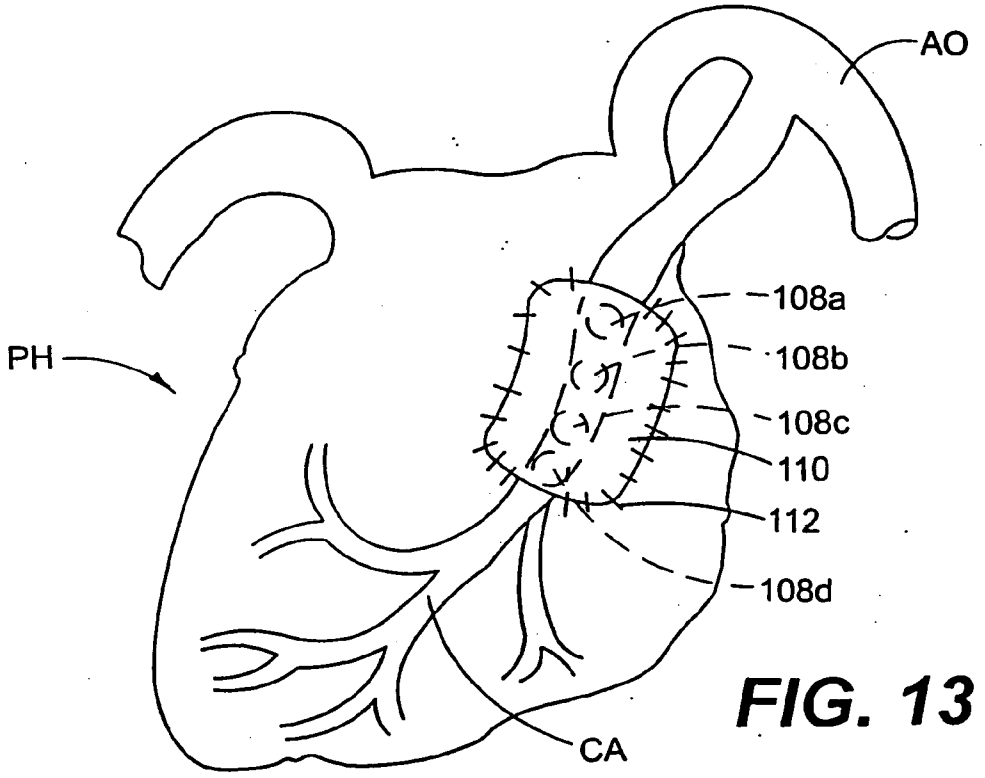
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FIG. 13

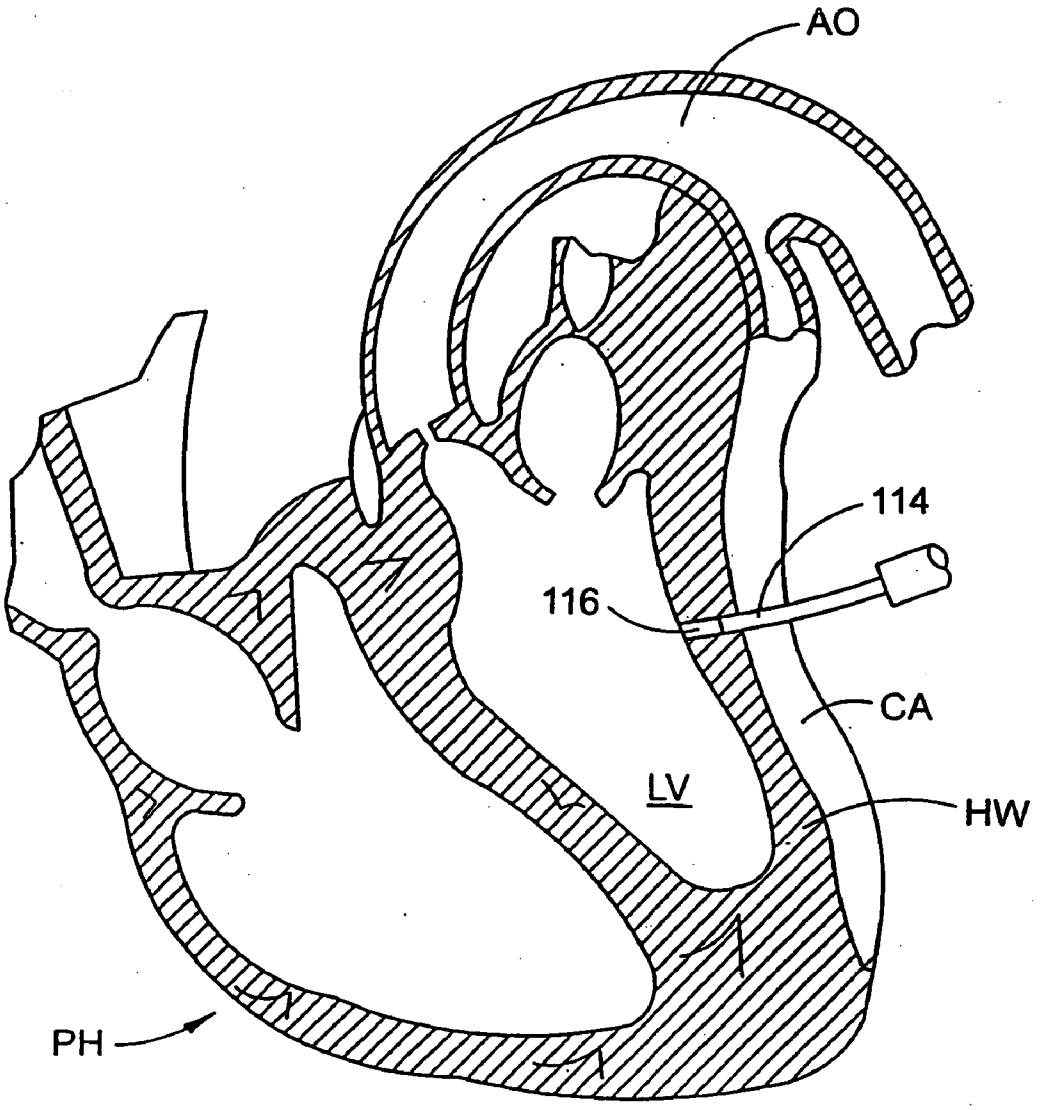



FIG. 14A

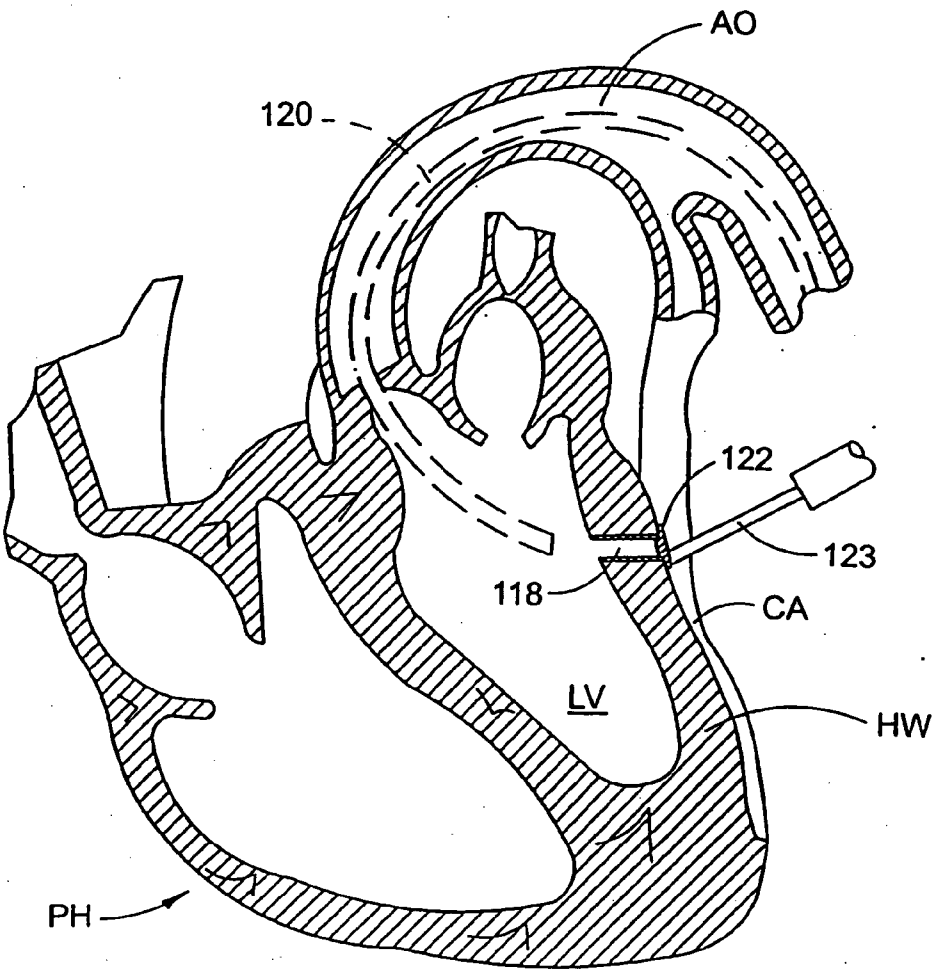



FIG. 14B

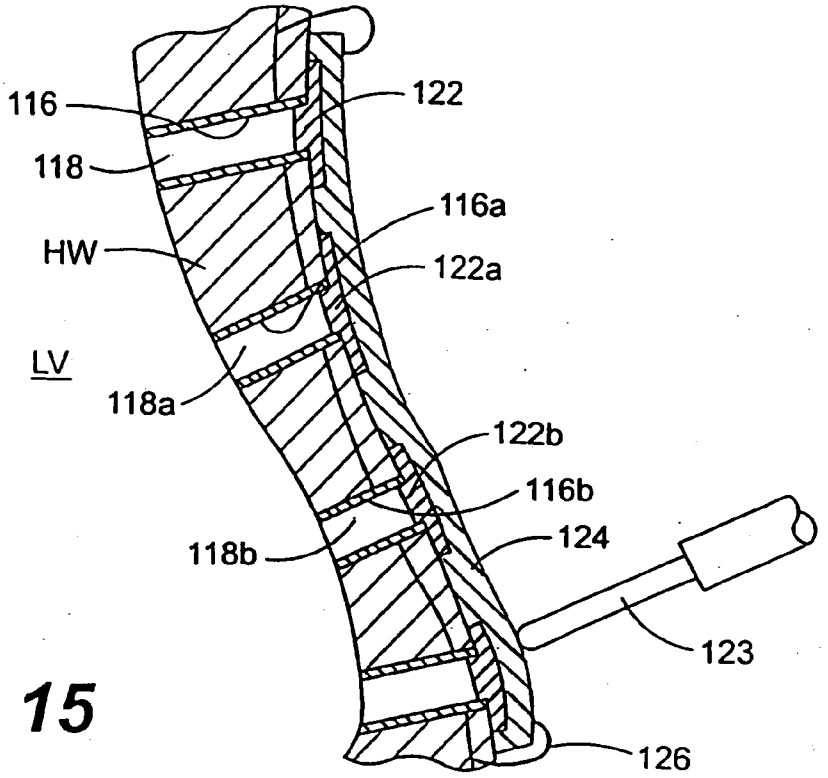



FIG. 15

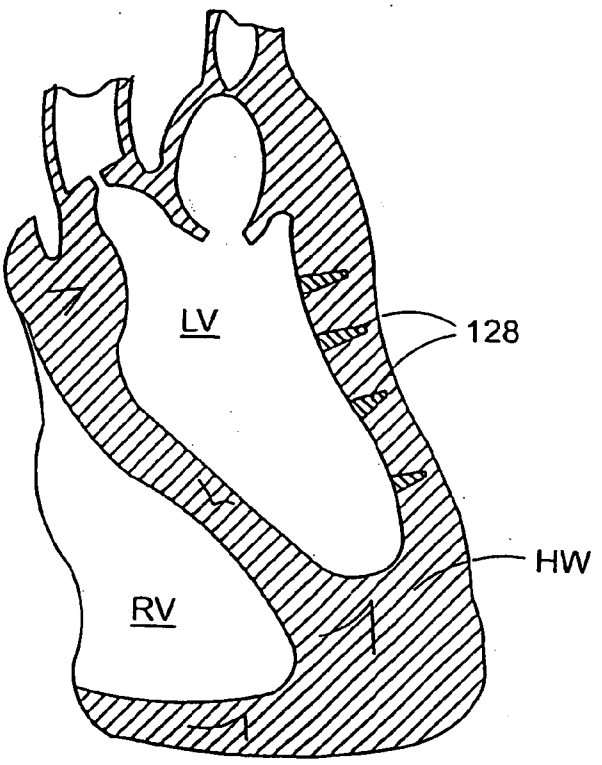



FIG. 16

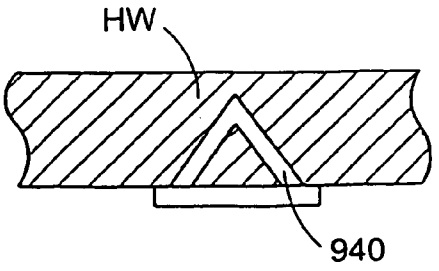



FIG. 16A

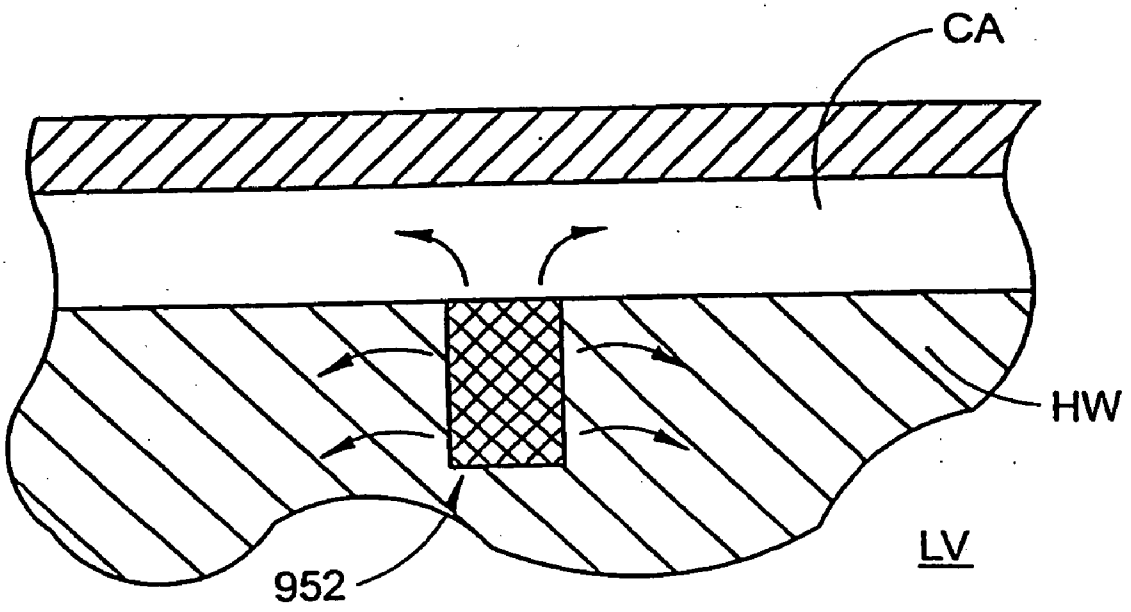



FIG. 16B

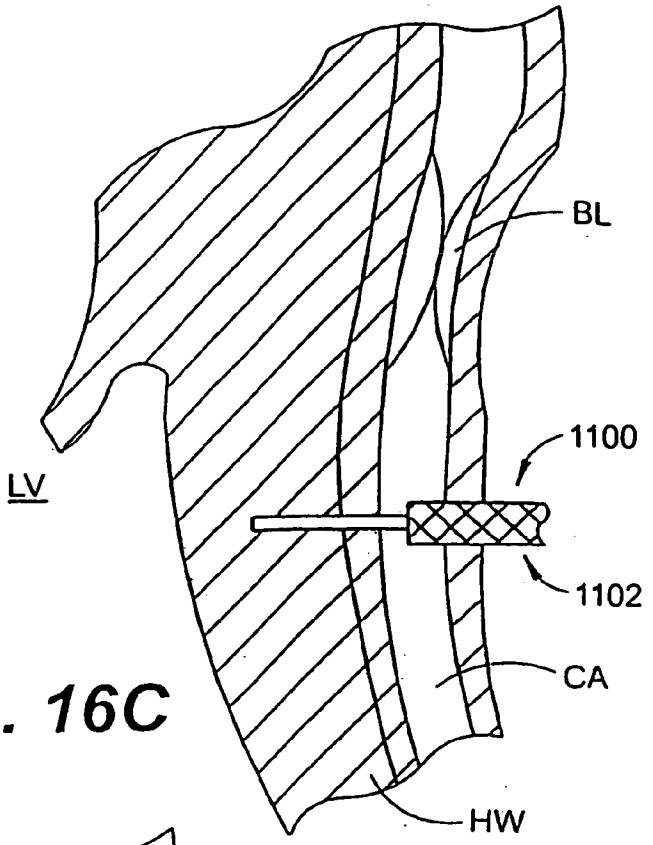



FIG. 16C

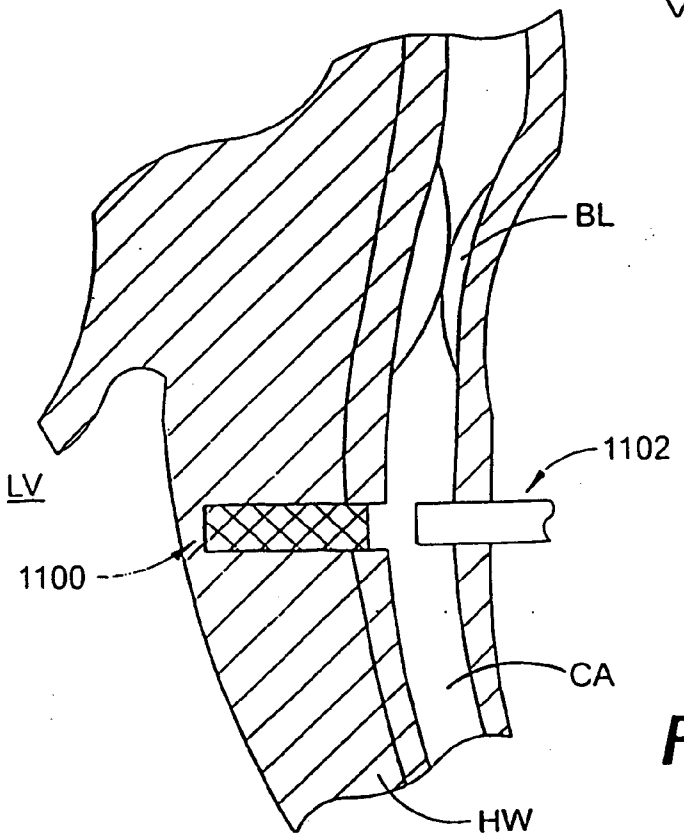



FIG. 16D

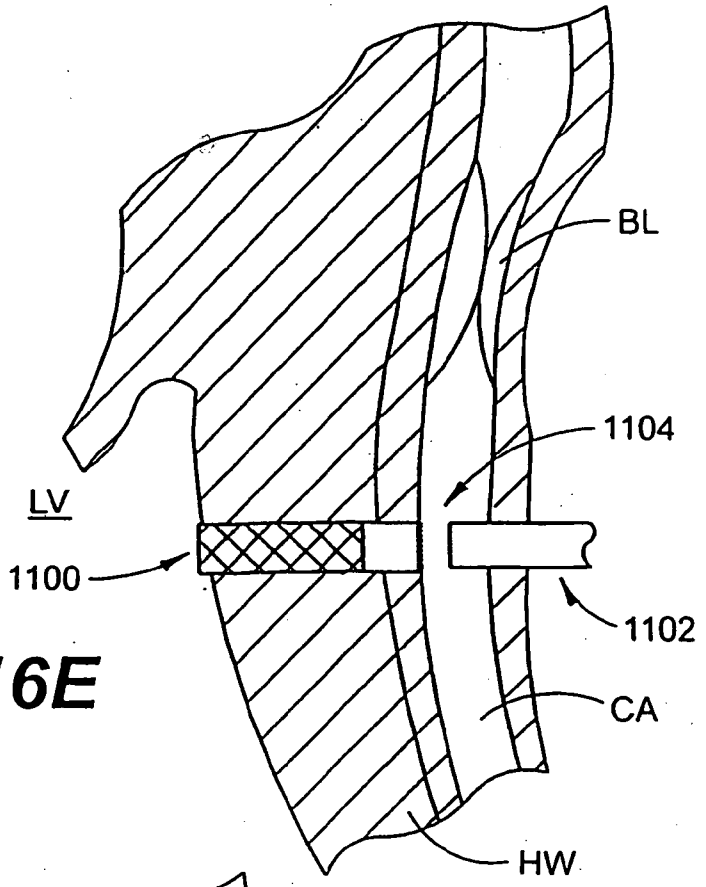



FIG. 16E

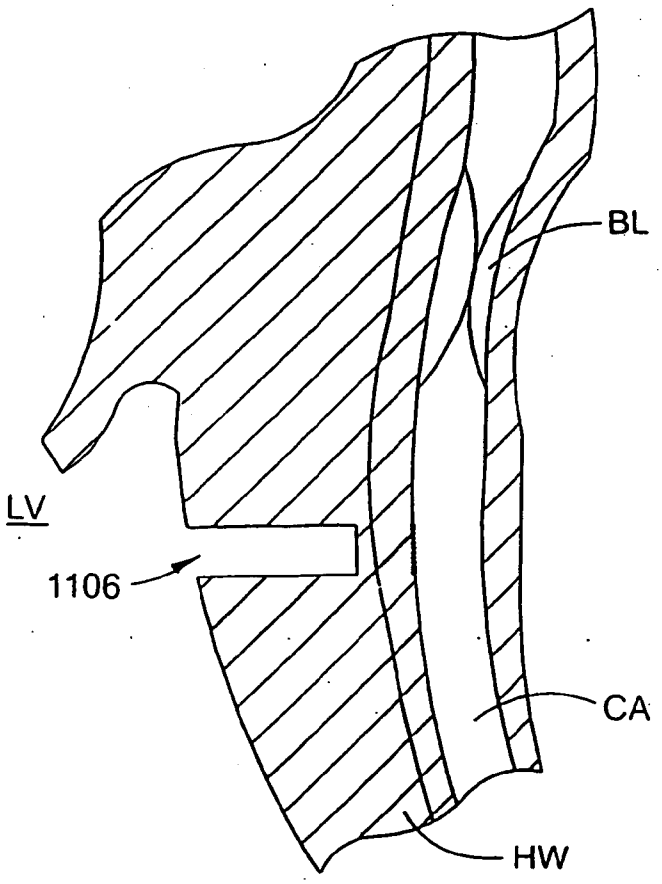



FIG. 16F

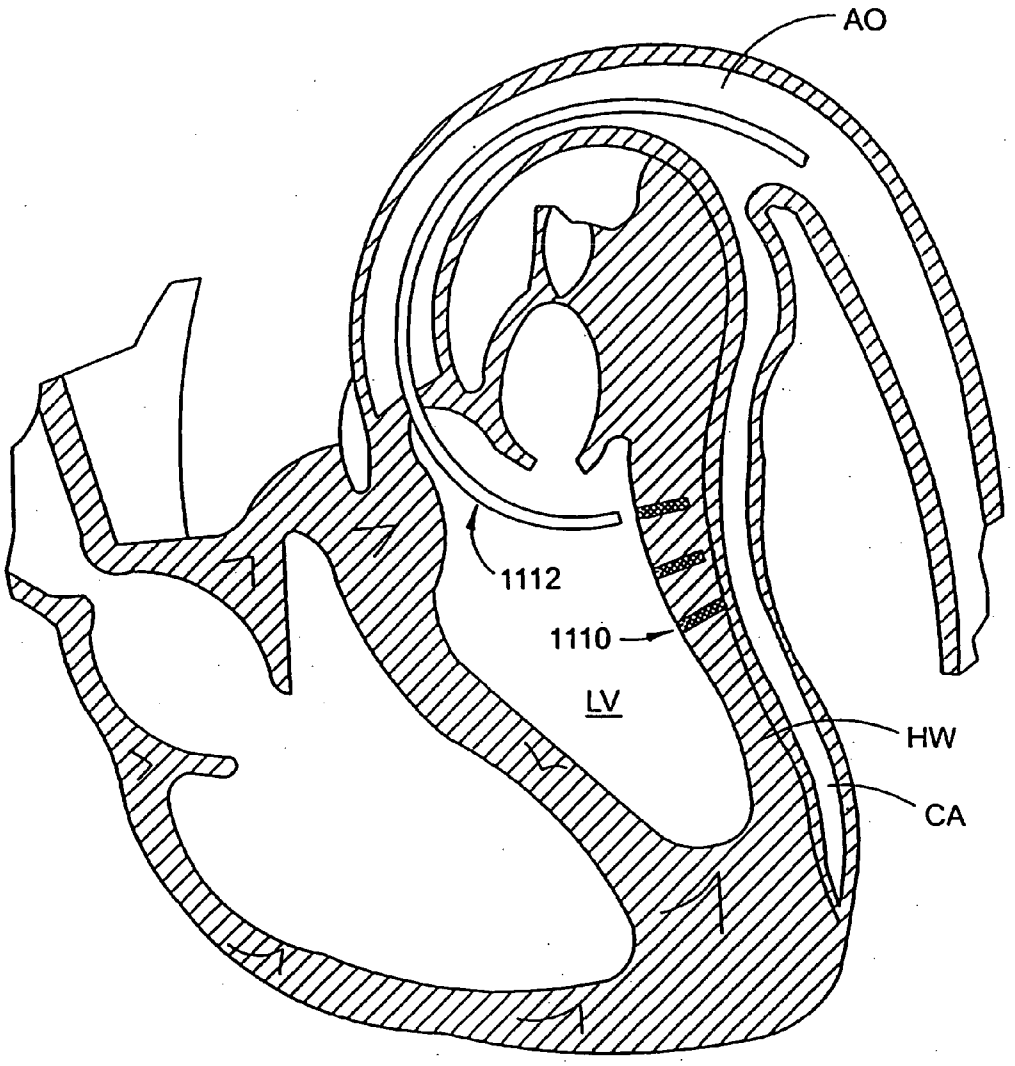



FIG. 16G

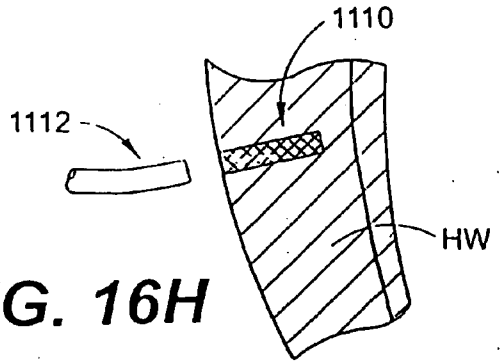



FIG. 16H

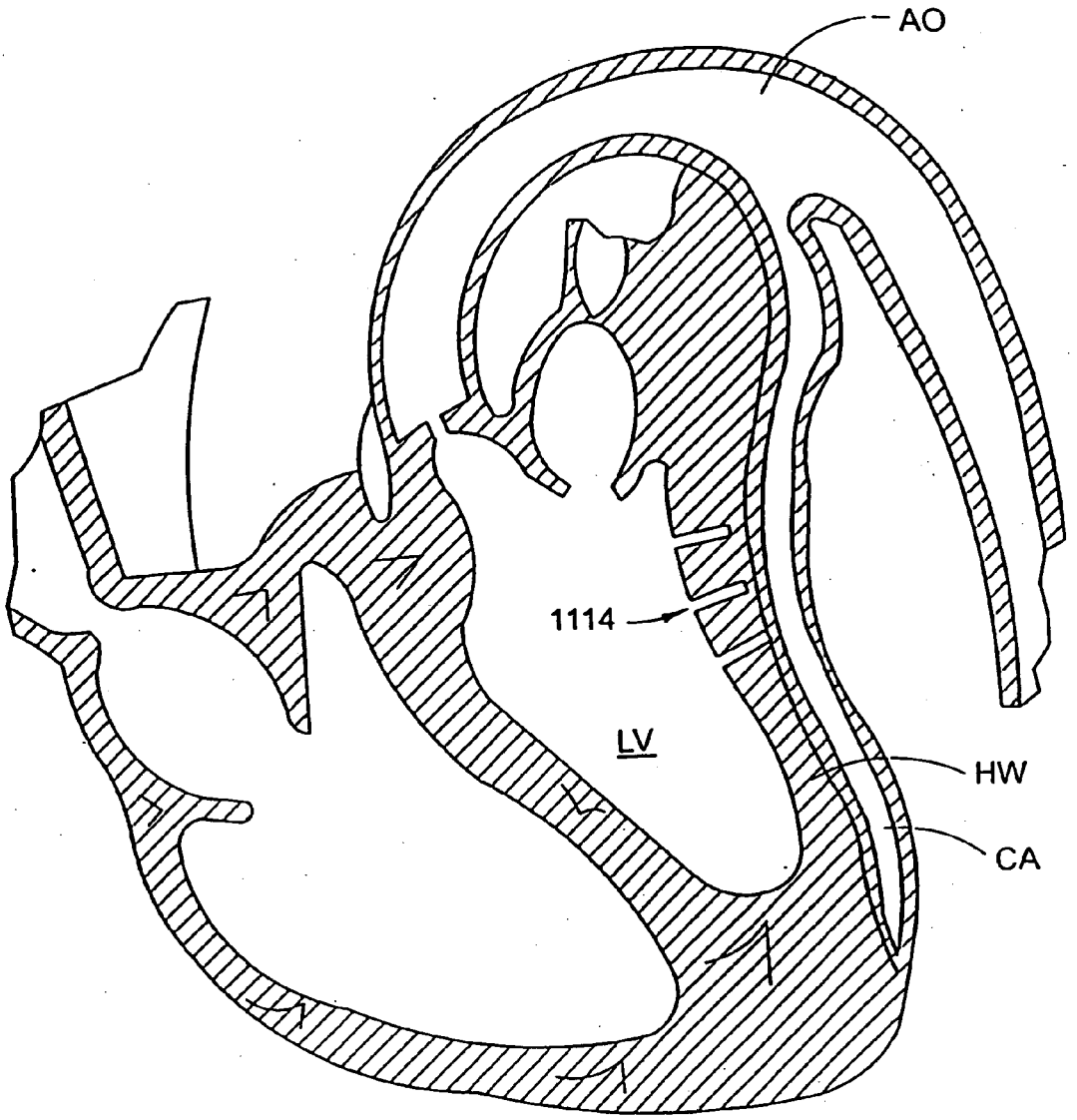



FIG. 16I

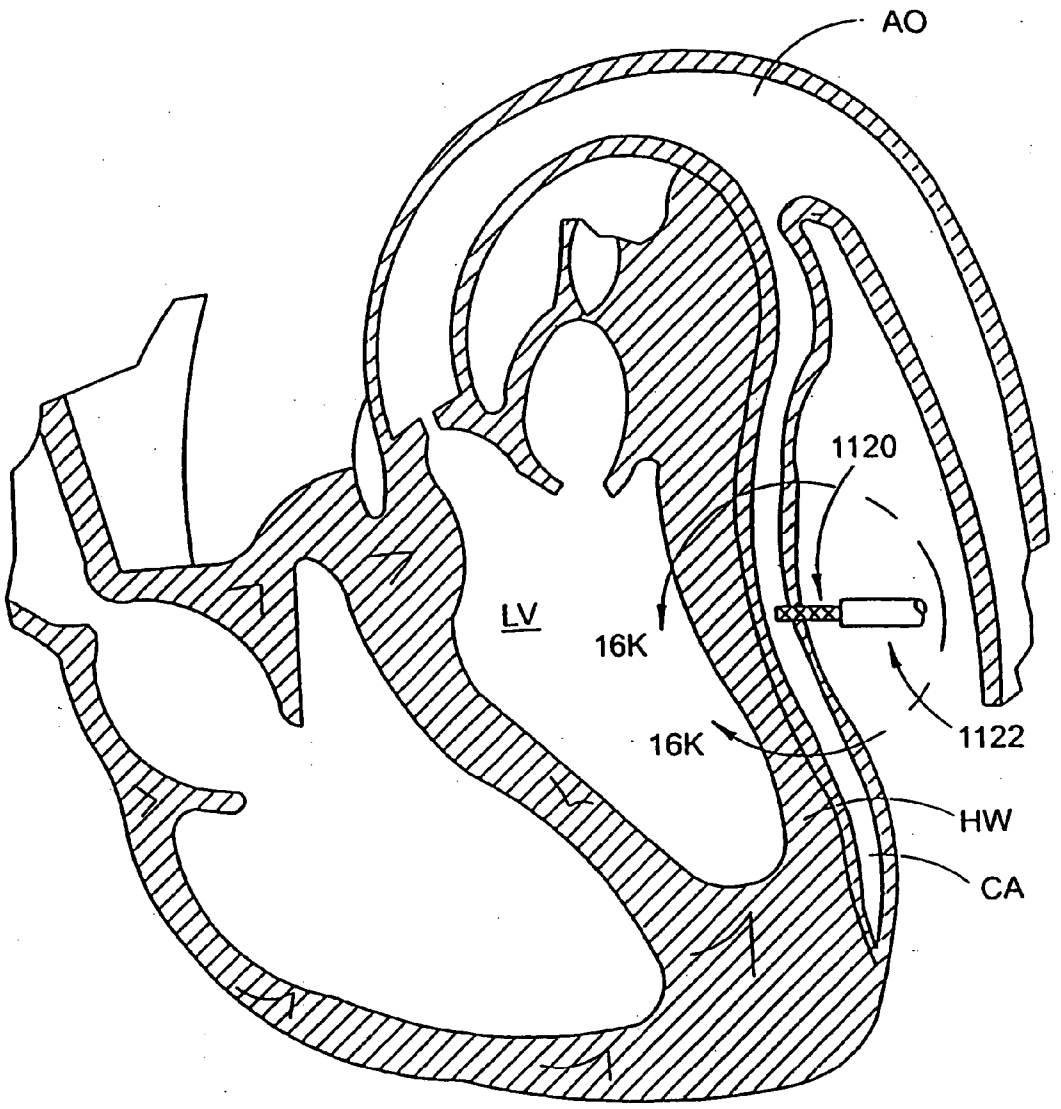



FIG. 16J

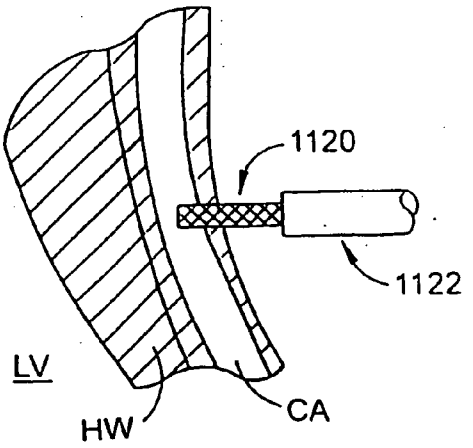



FIG. 16K

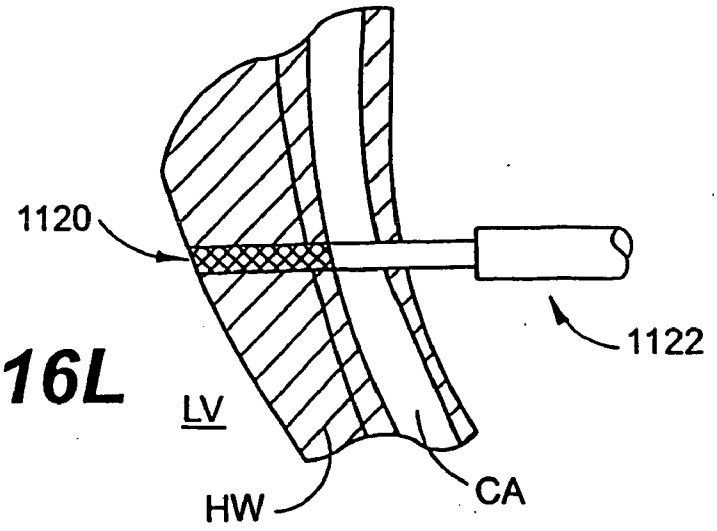



FIG. 16L

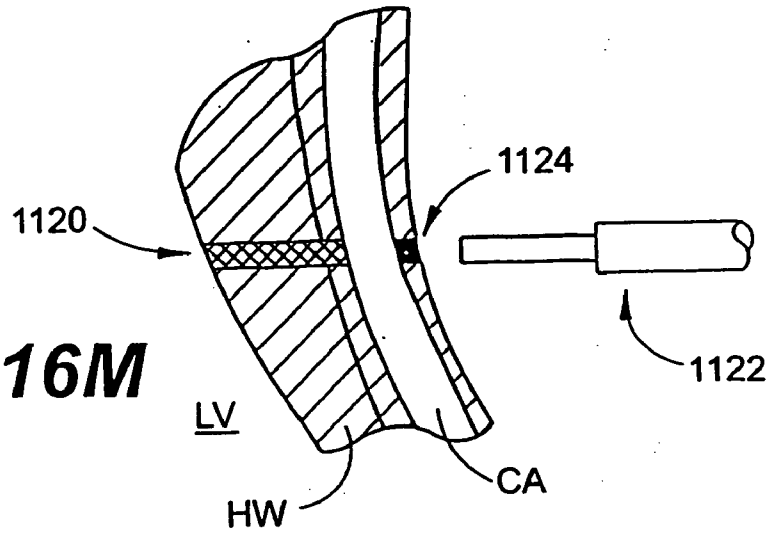



FIG. 16M

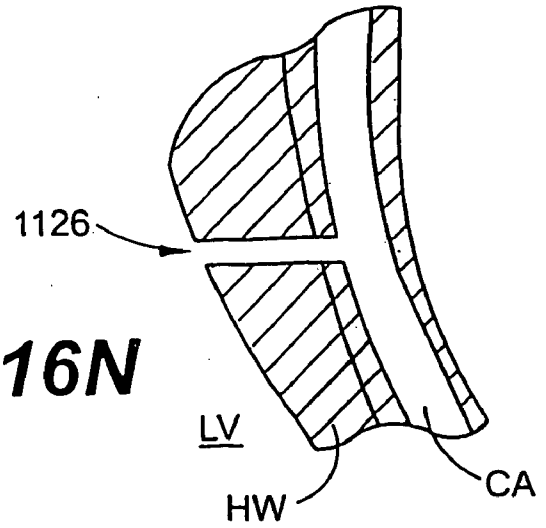



FIG. 16N

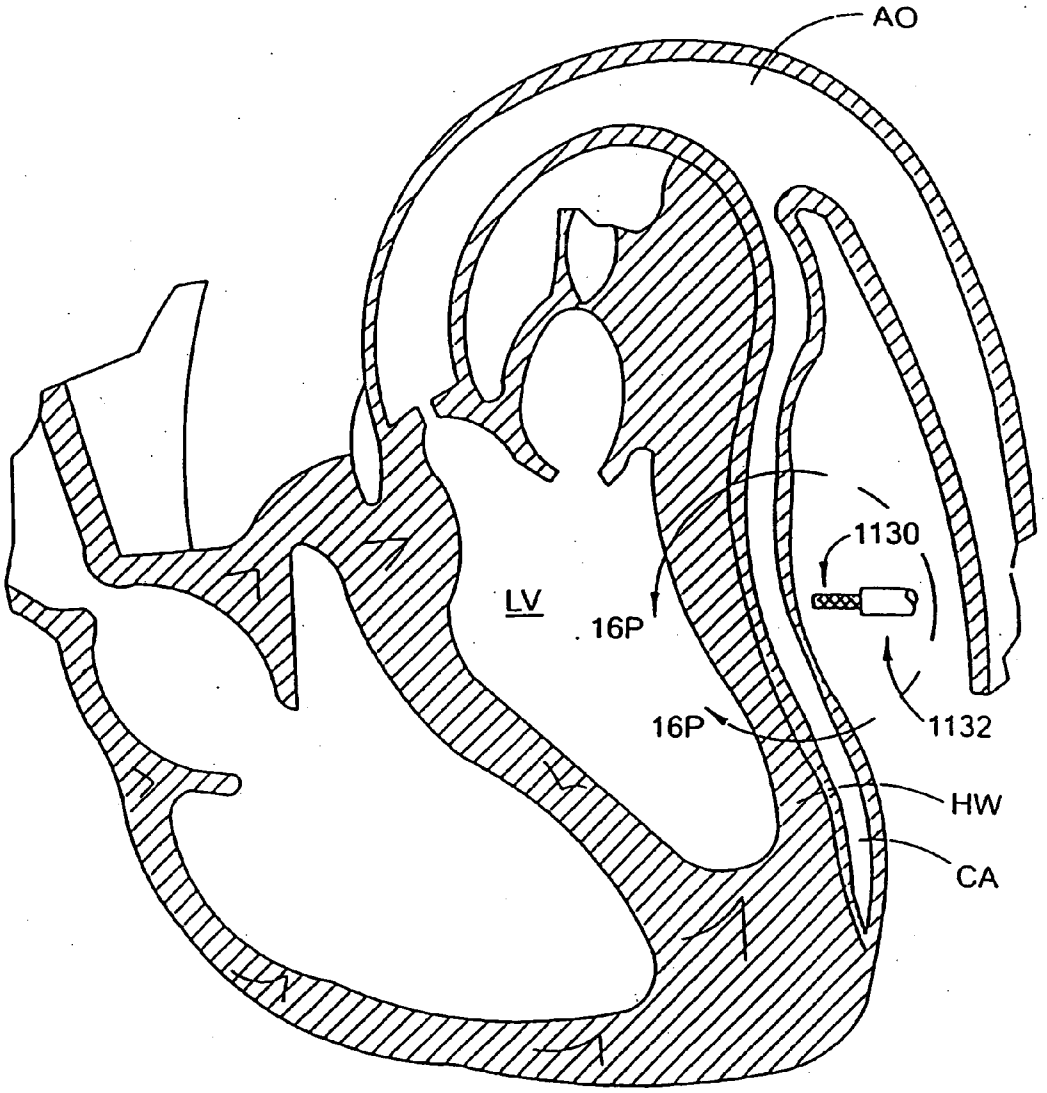



FIG. 16O

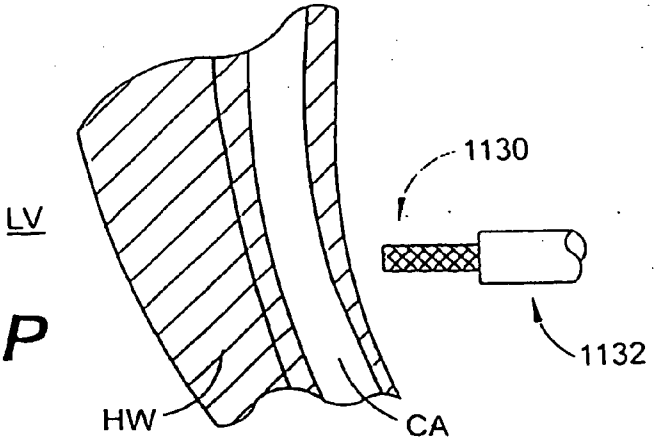



FIG. 16P

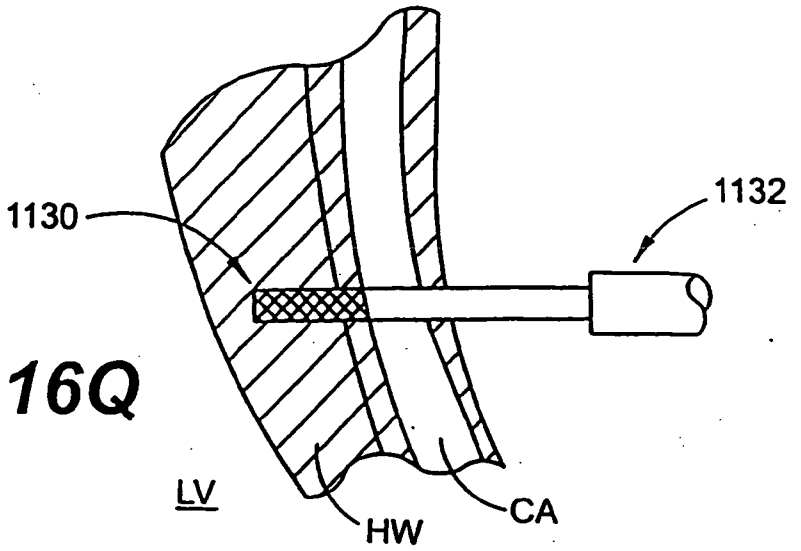



FIG. 16Q

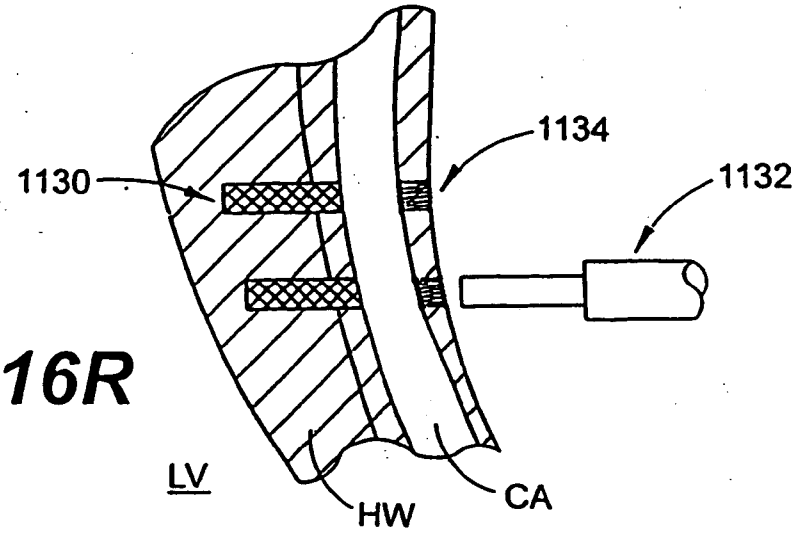



FIG. 16R

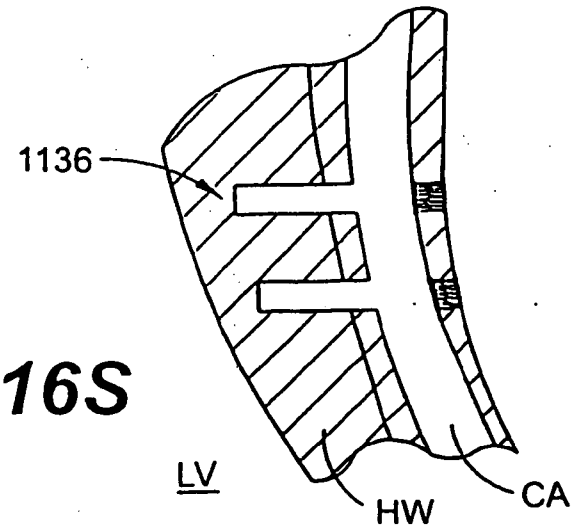



FIG. 16S

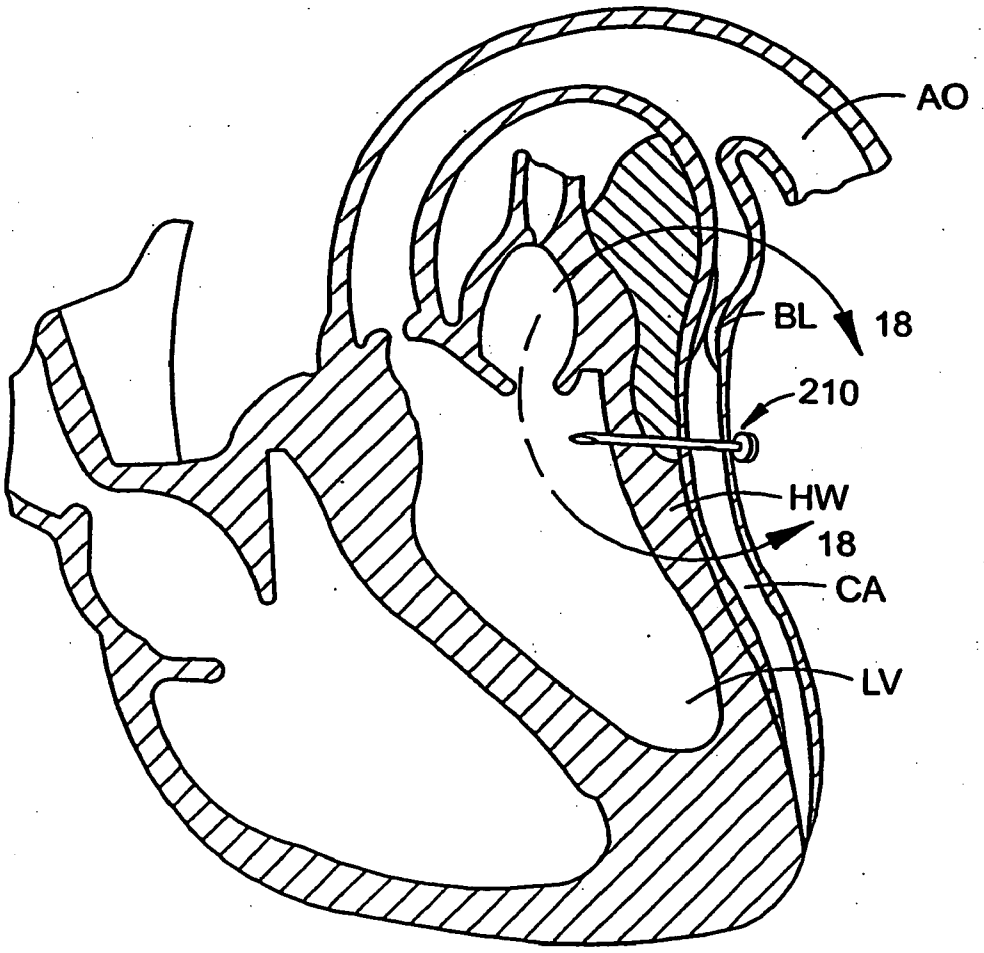



FIG. 17

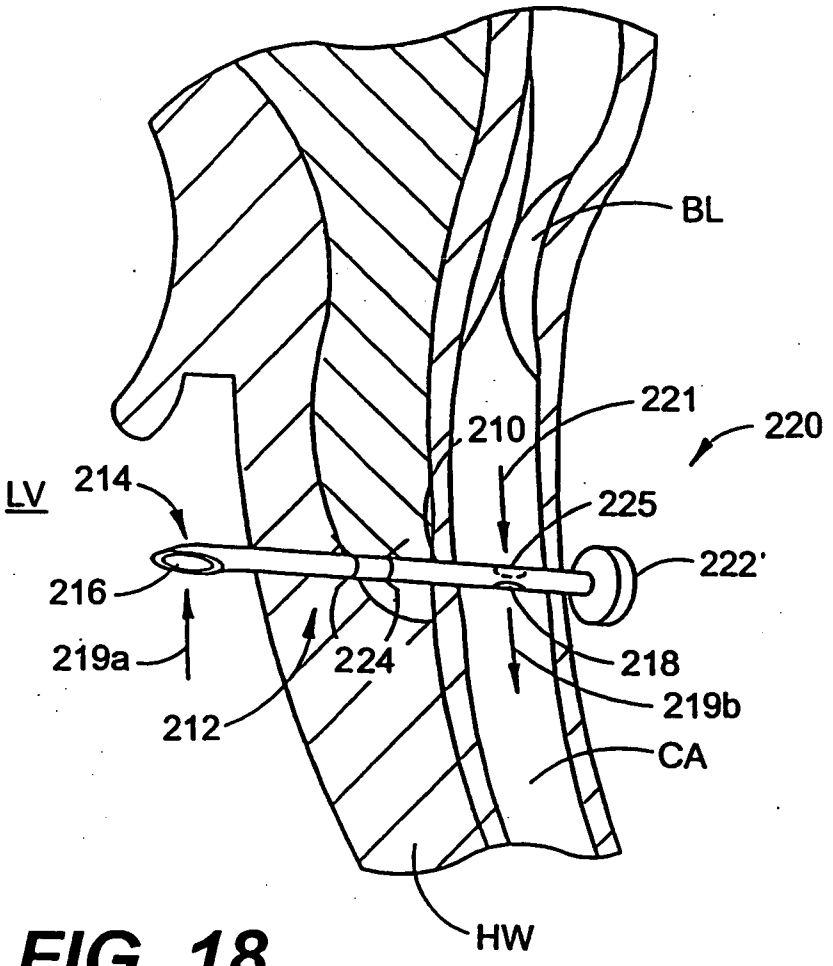



FIG. 18

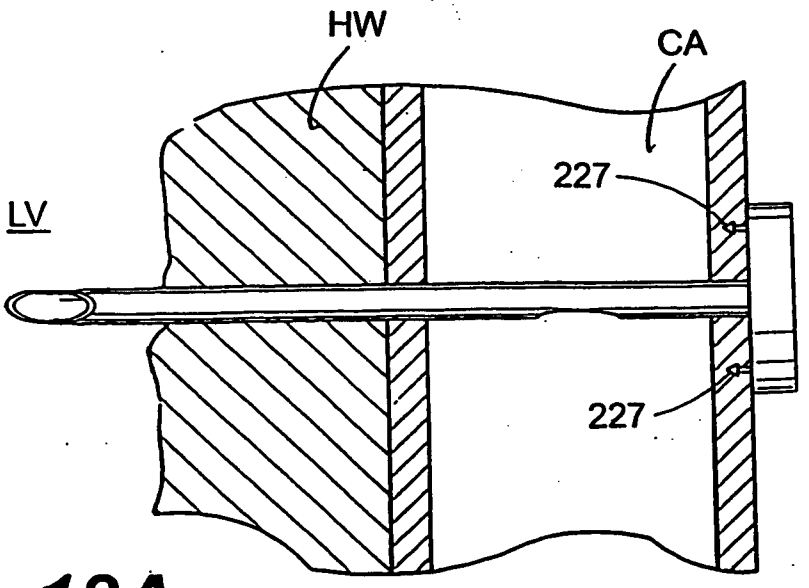



FIG. 18A

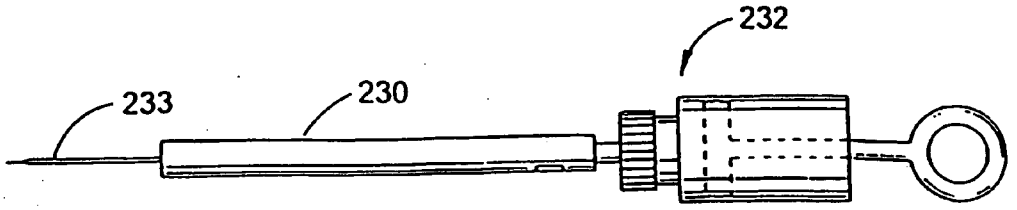



FIG. 19A

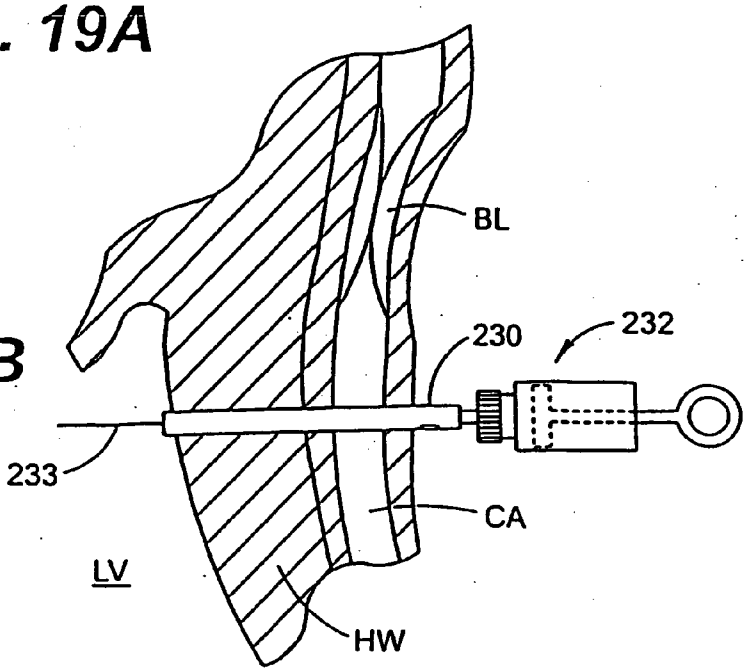



FIG. 19B

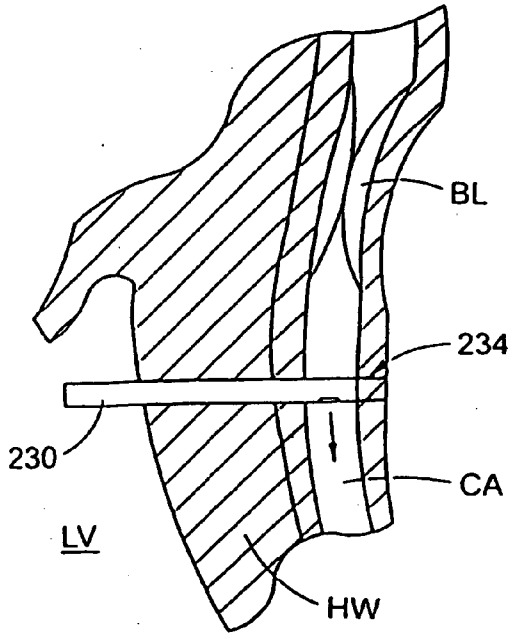
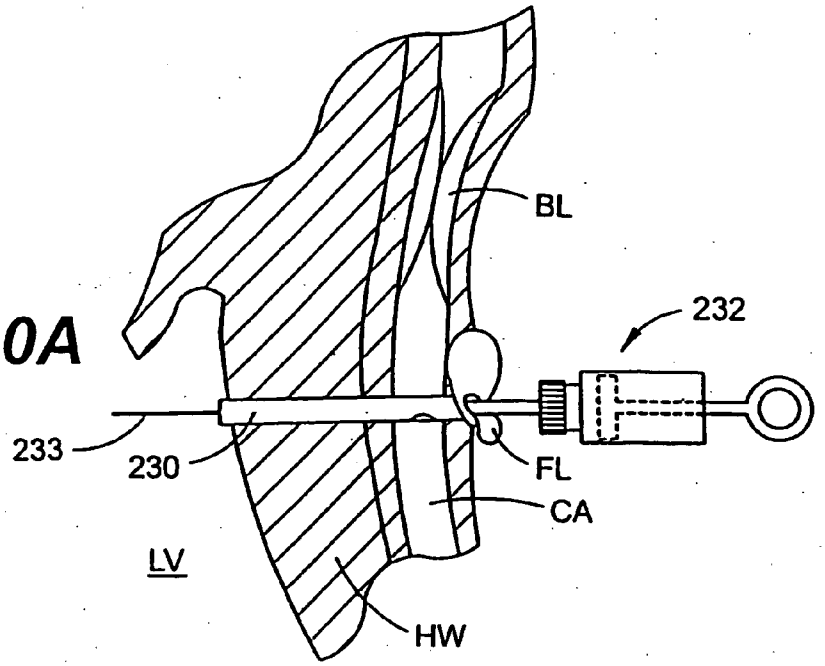



FIG. 19C

FIG. 20A



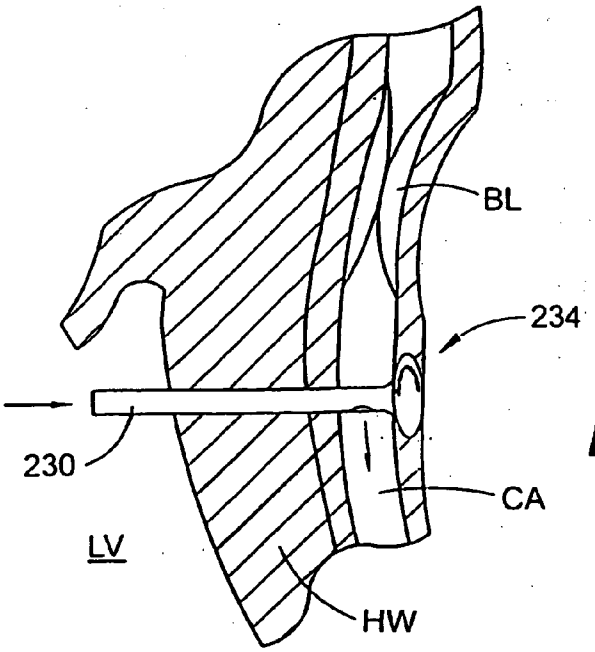




FIG. 20B

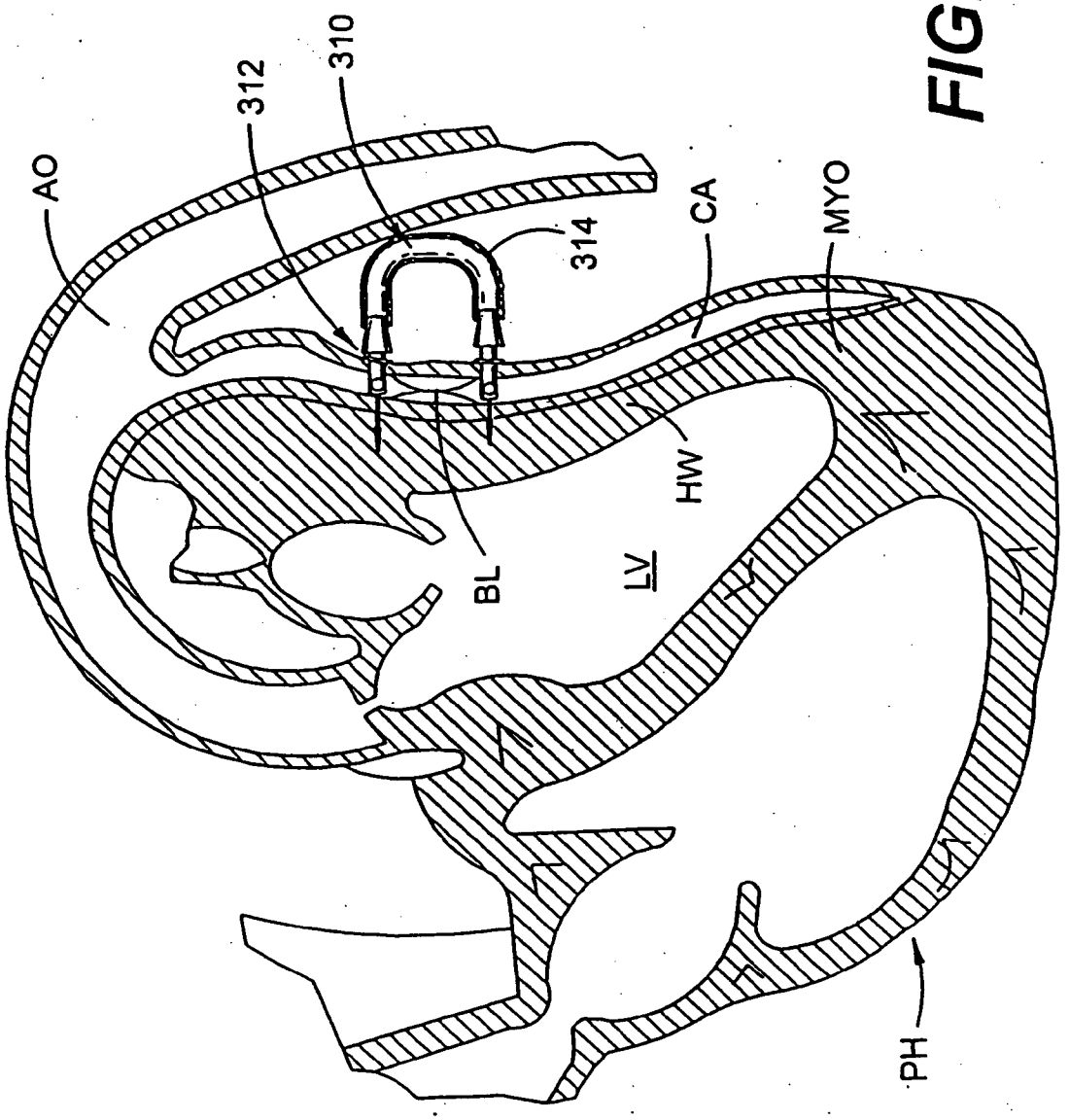



FIG. 21

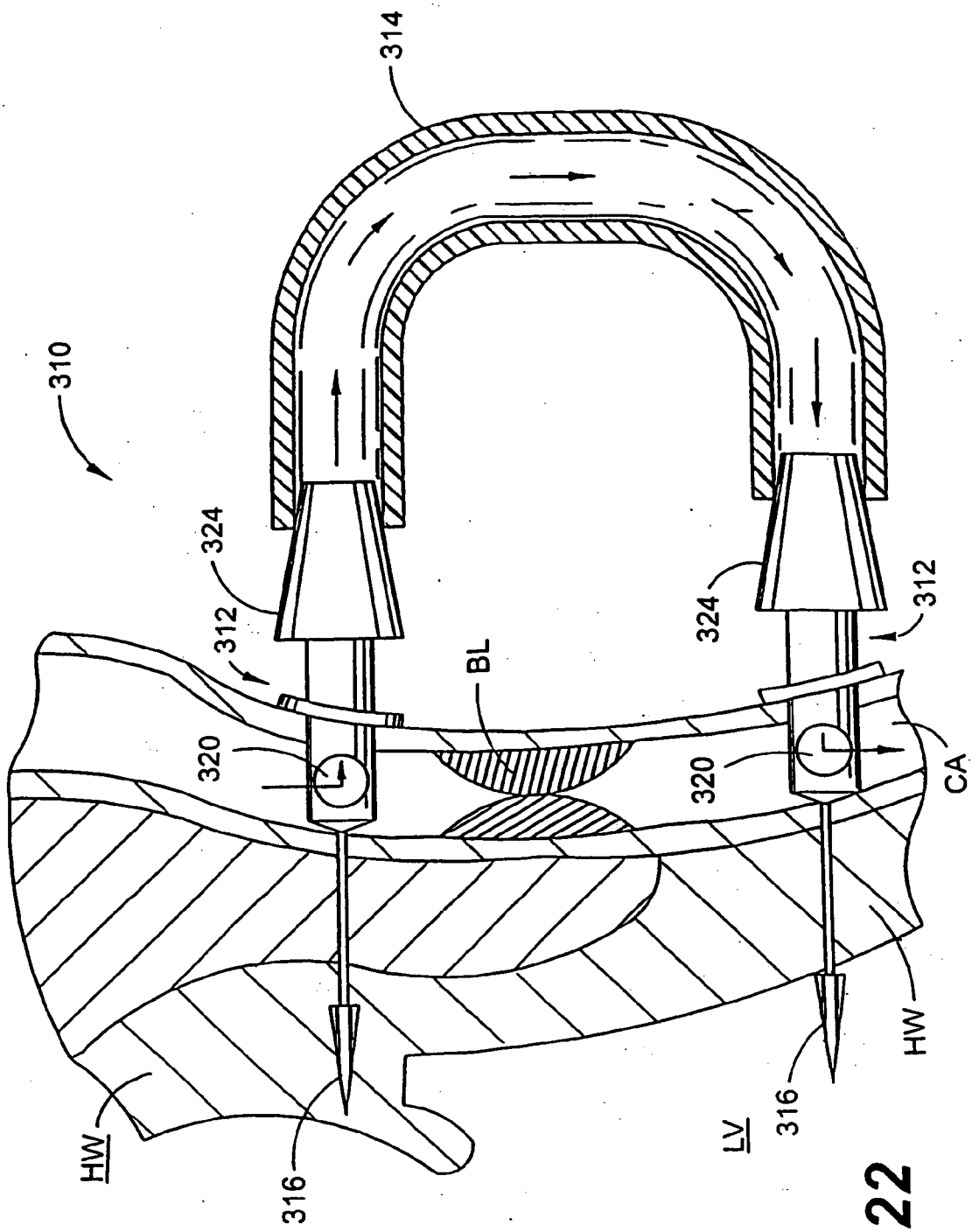



FIG. 22

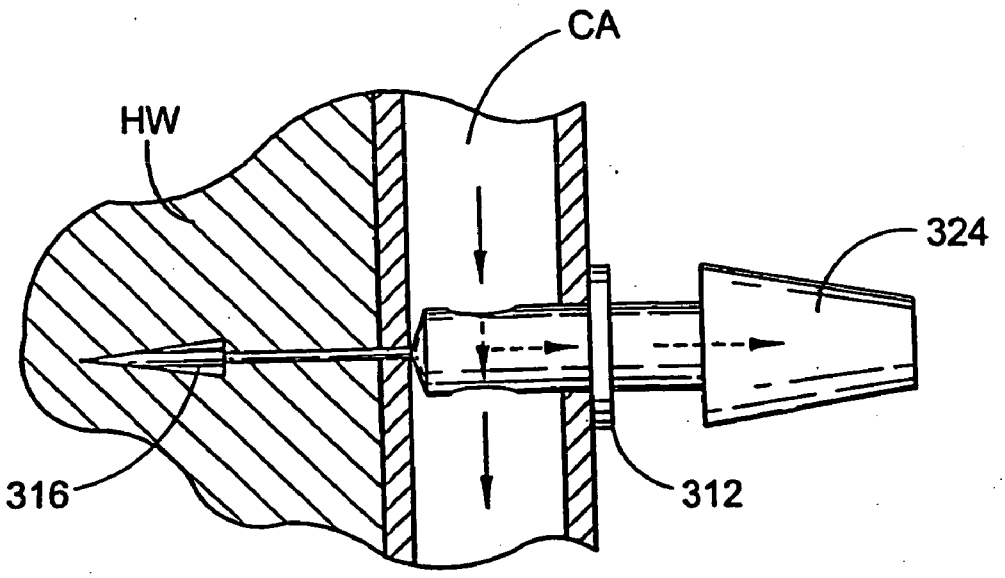



FIG. 22A

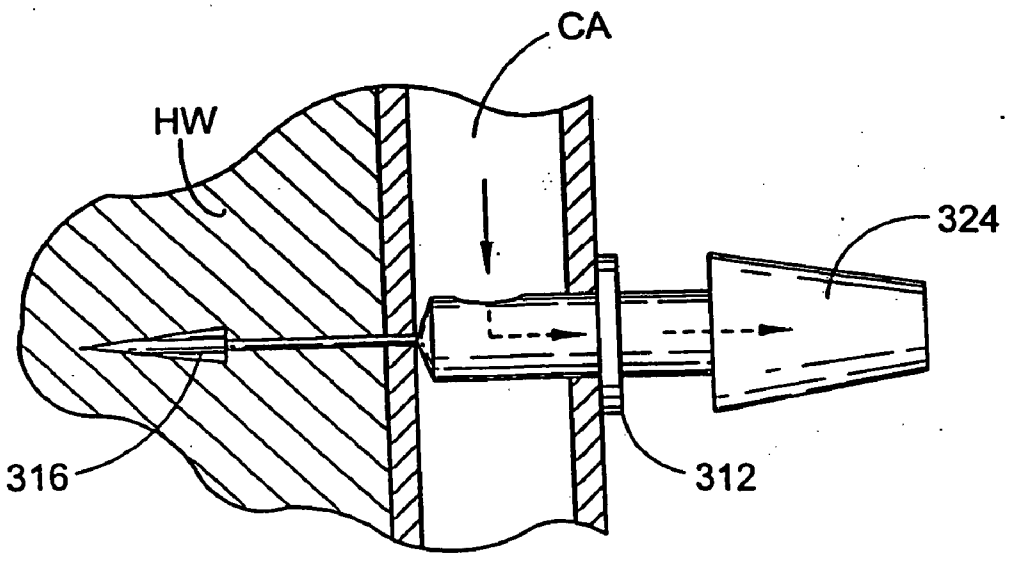



FIG. 22B

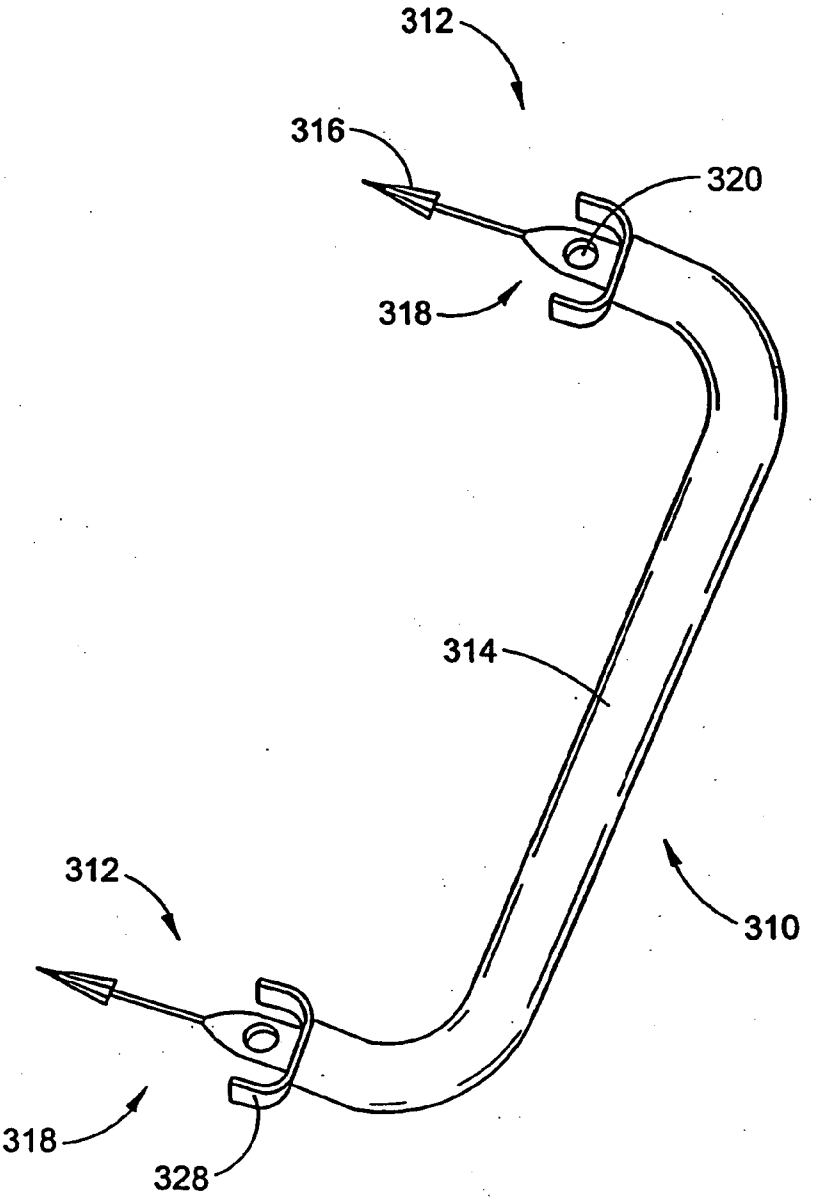



FIG. 23

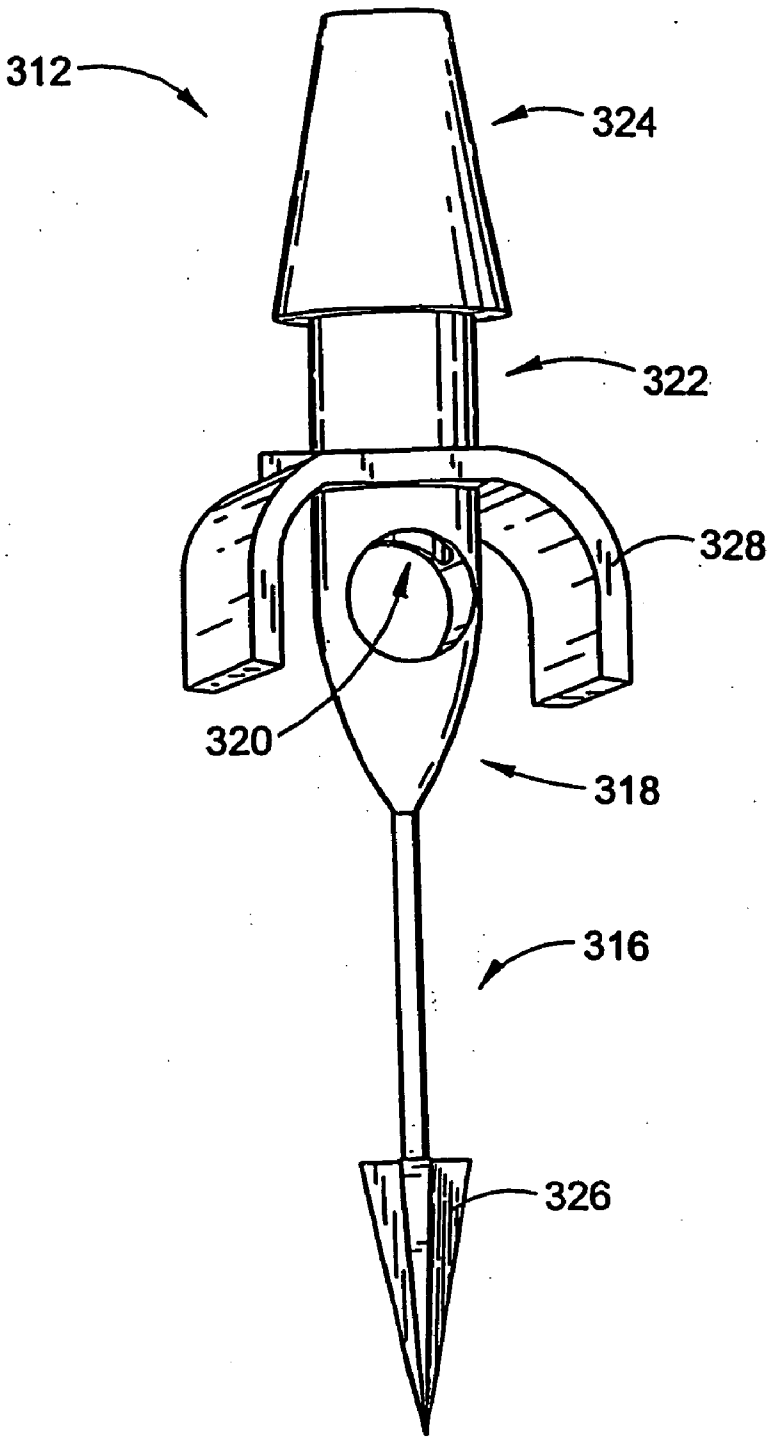



FIG. 24

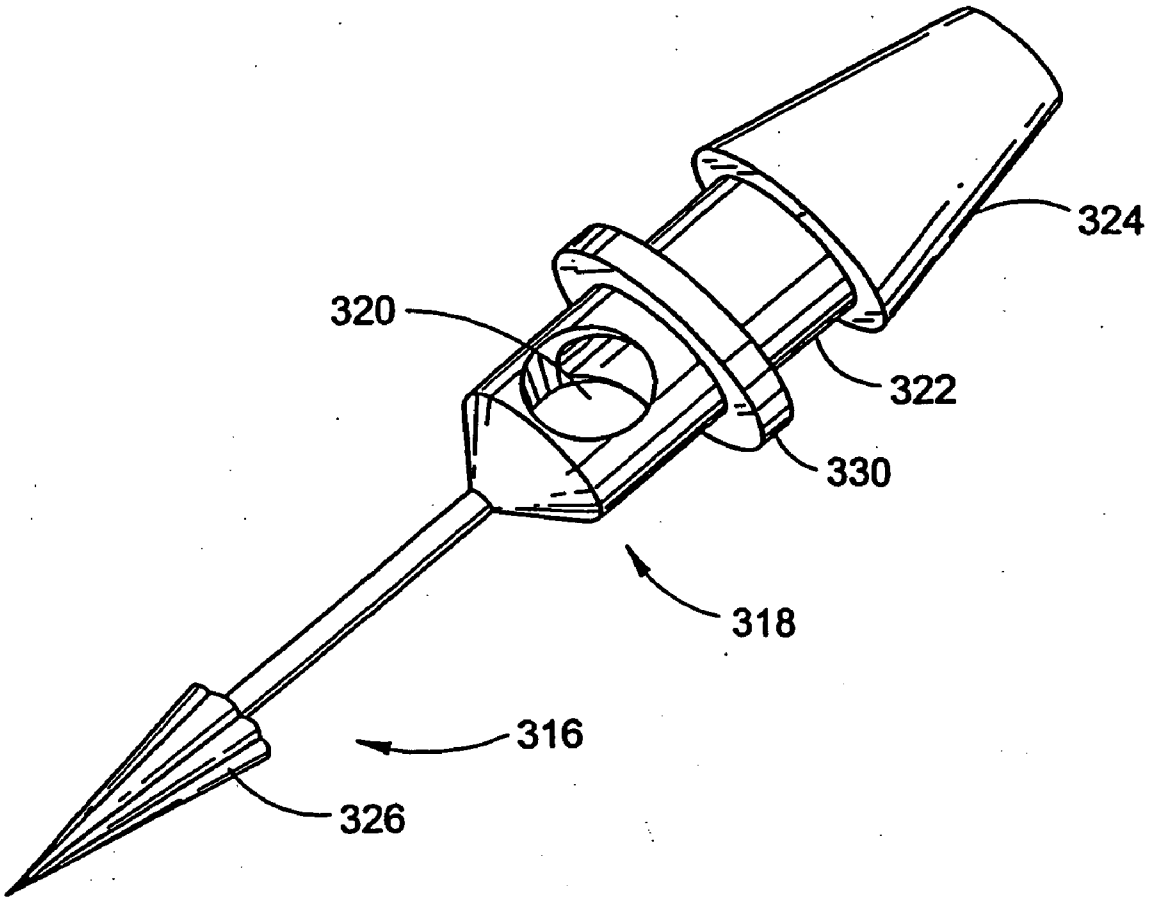



FIG. 25

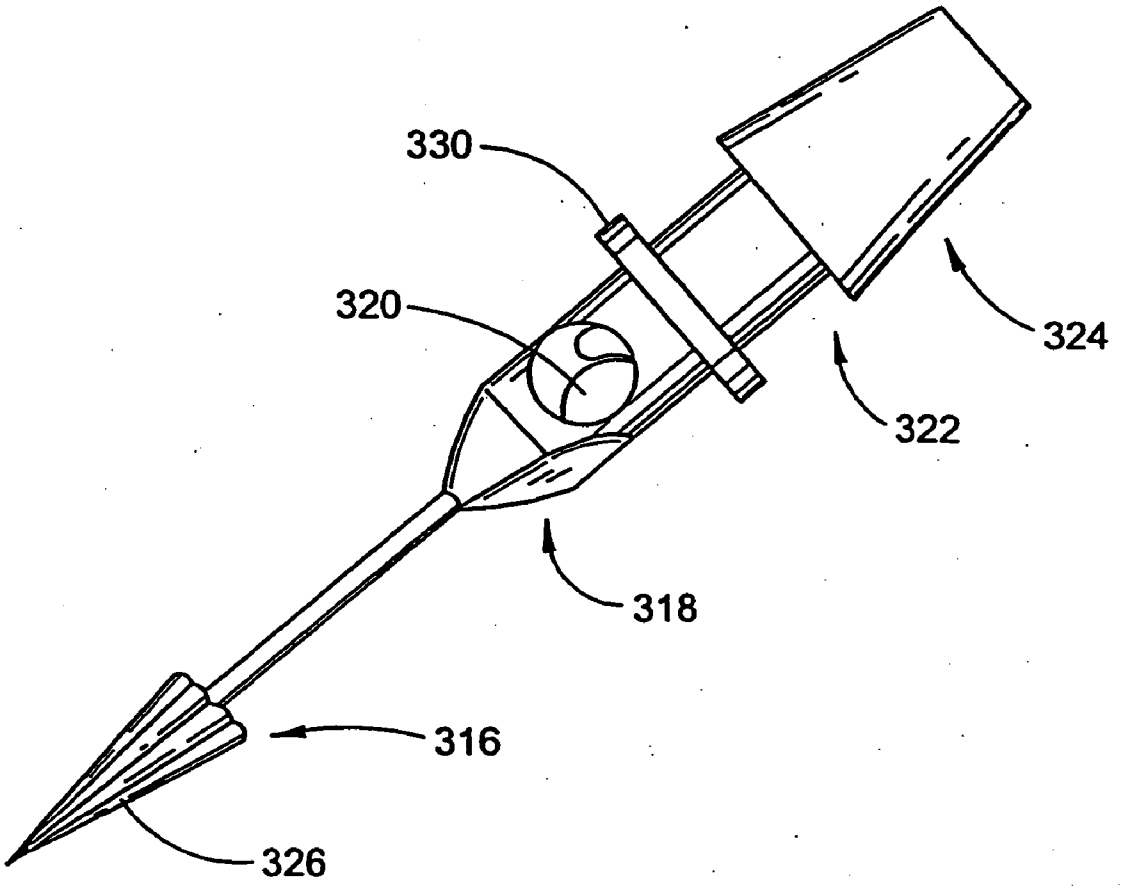



FIG. 27

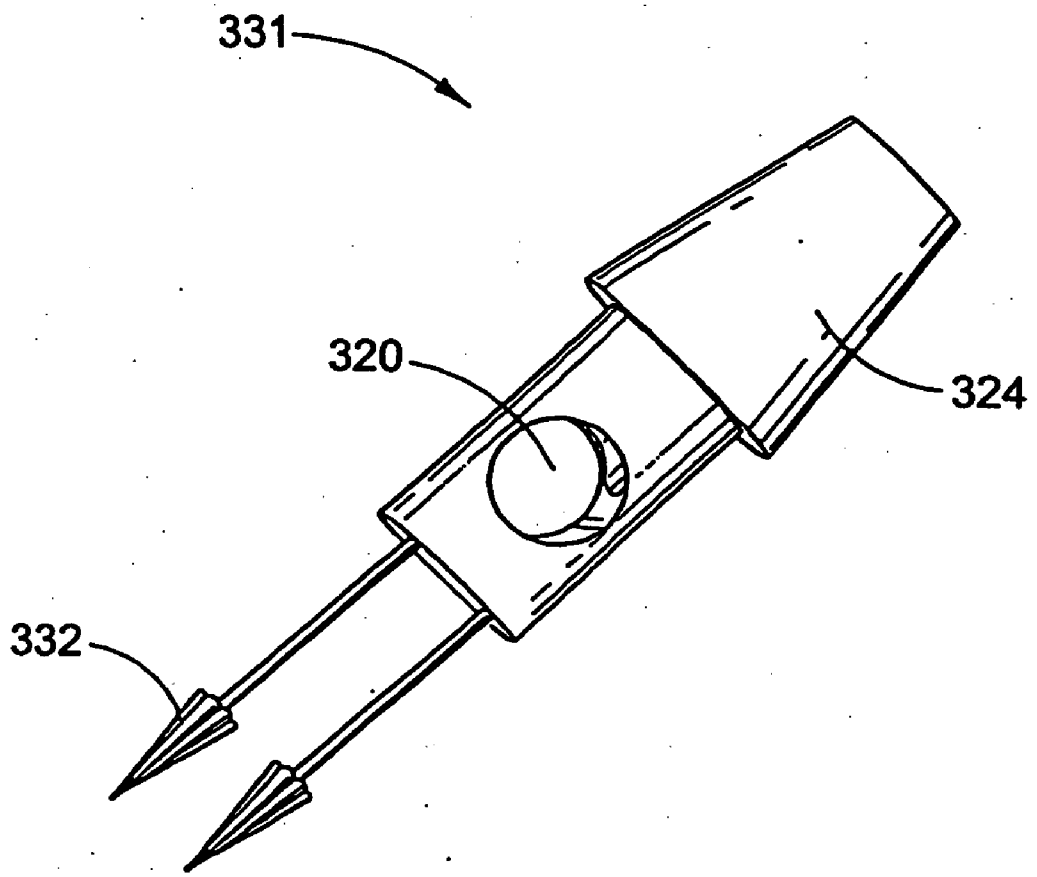



FIG. 28

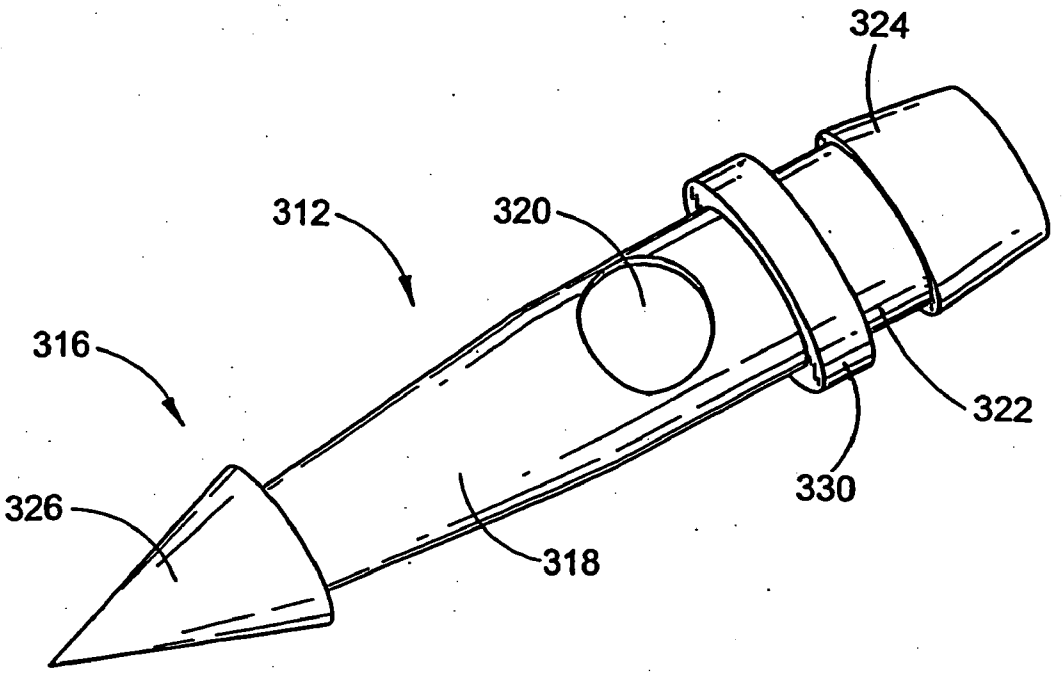



FIG. 29

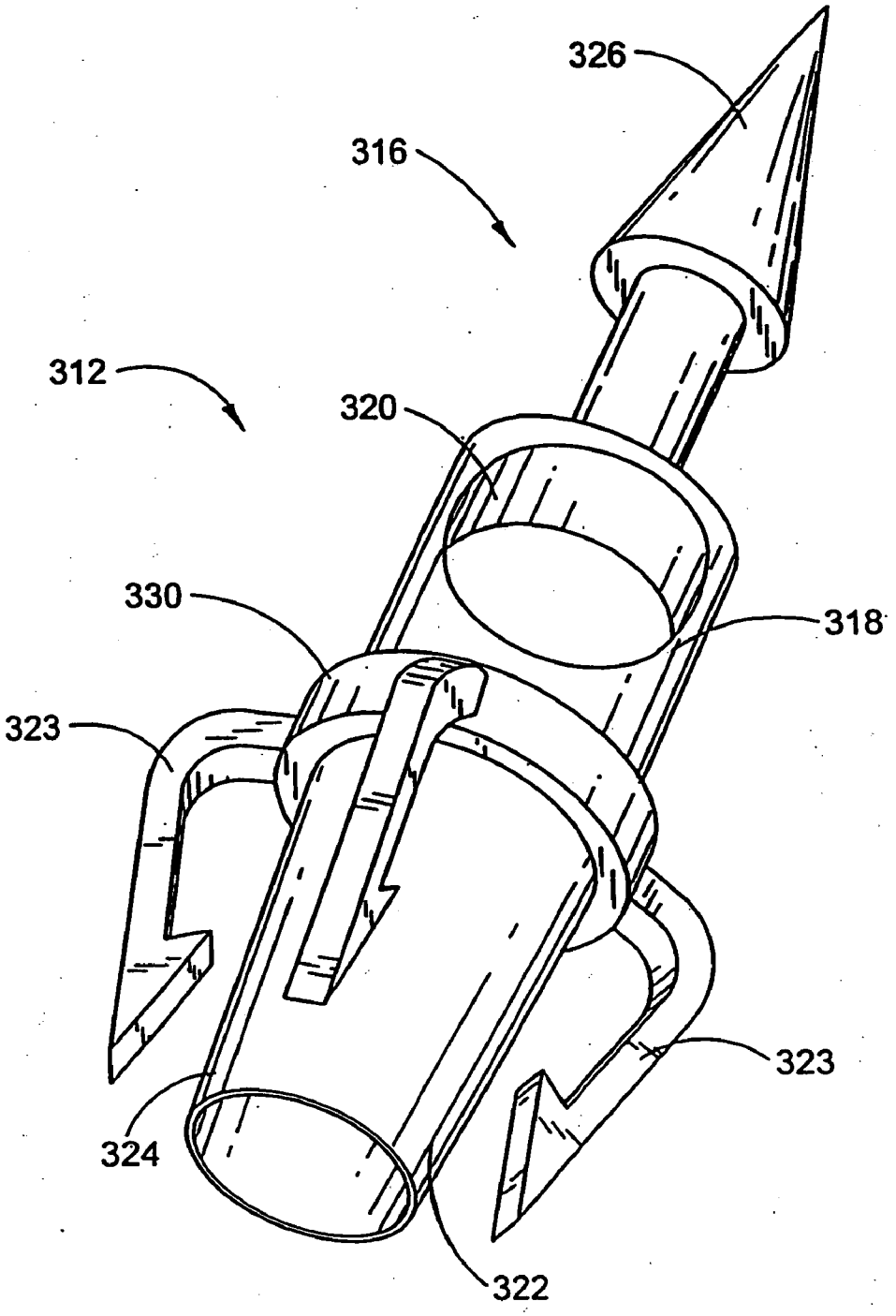



FIG. 30

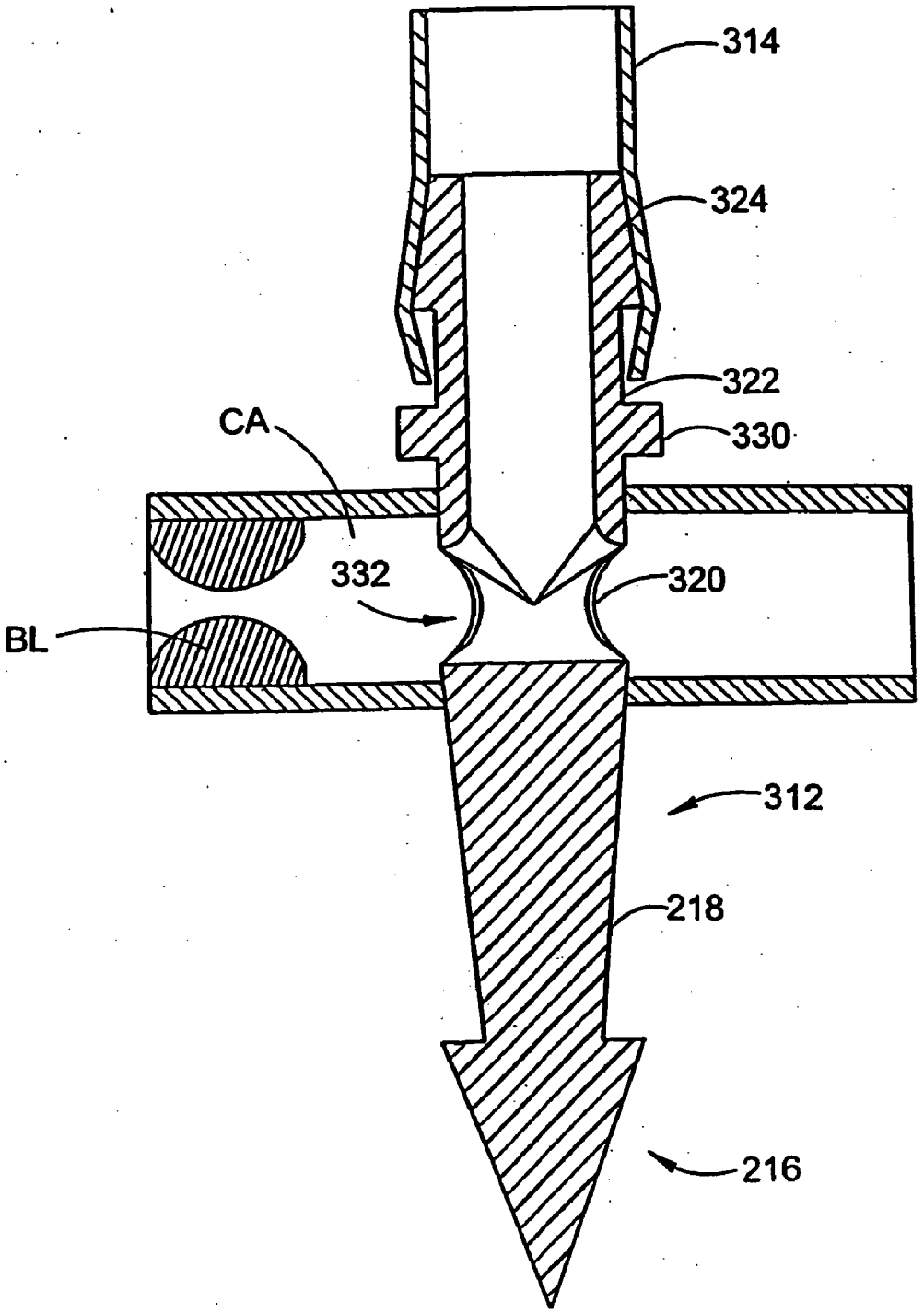



FIG. 31

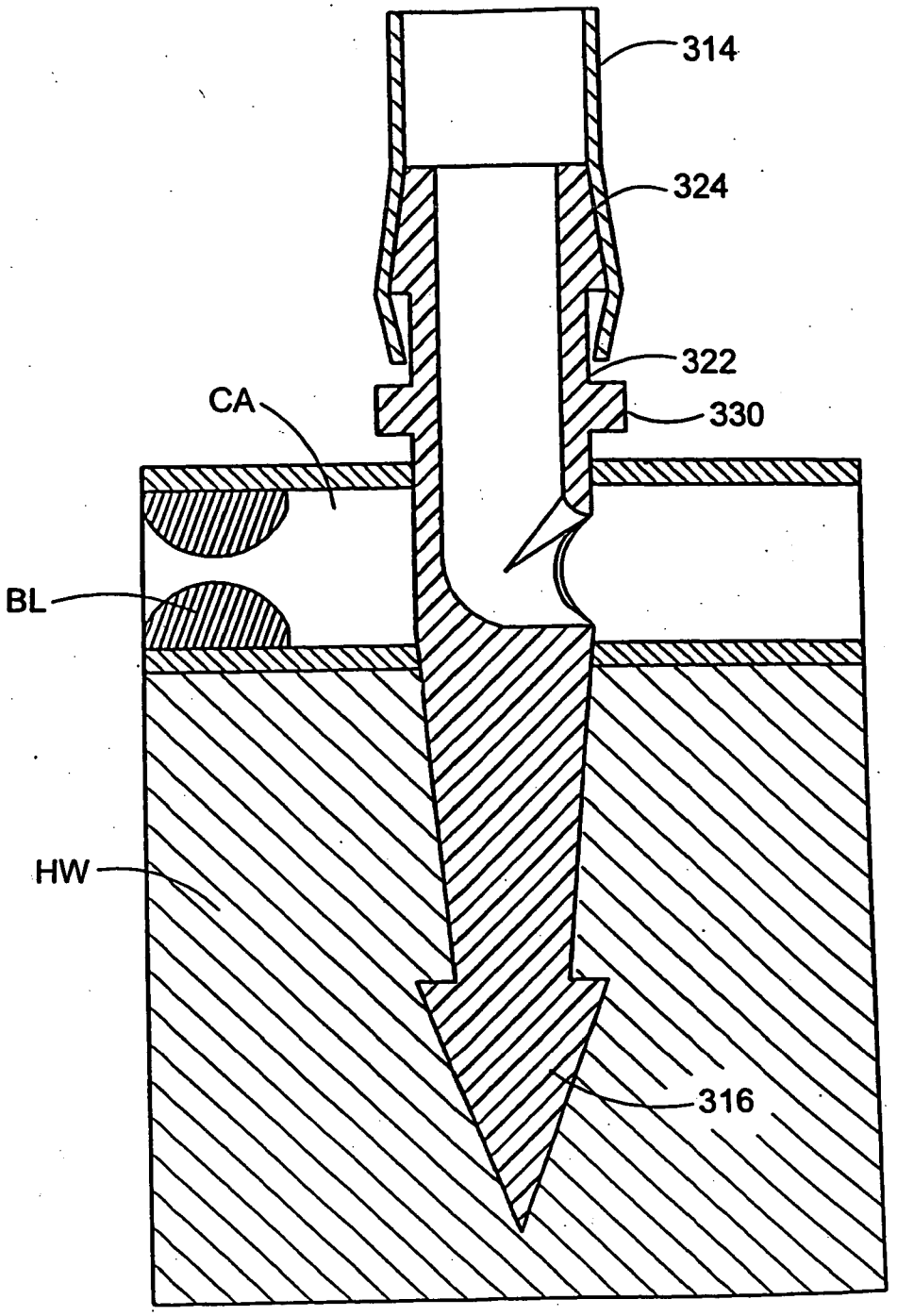



FIG. 32

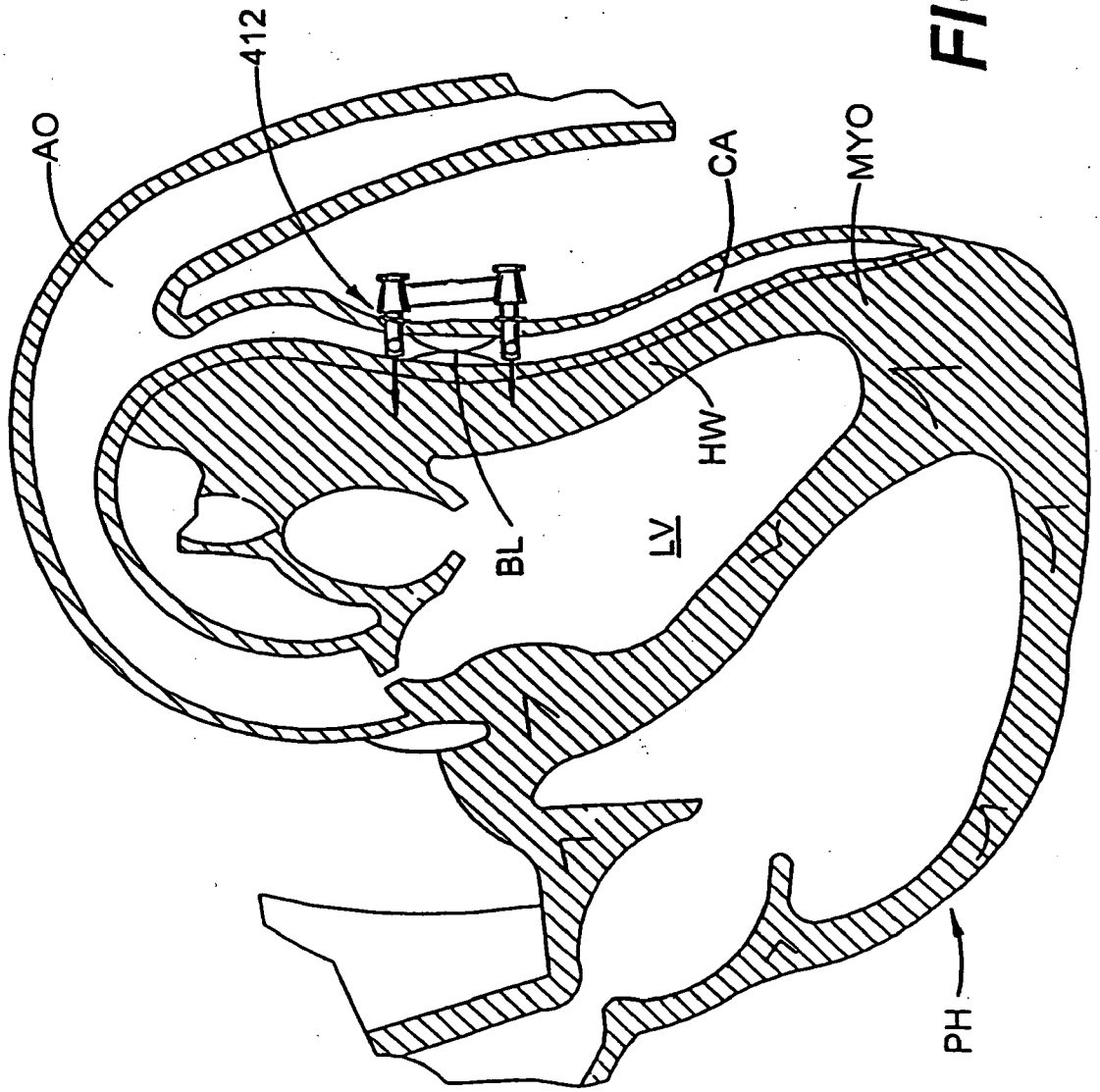



FIG. 33A

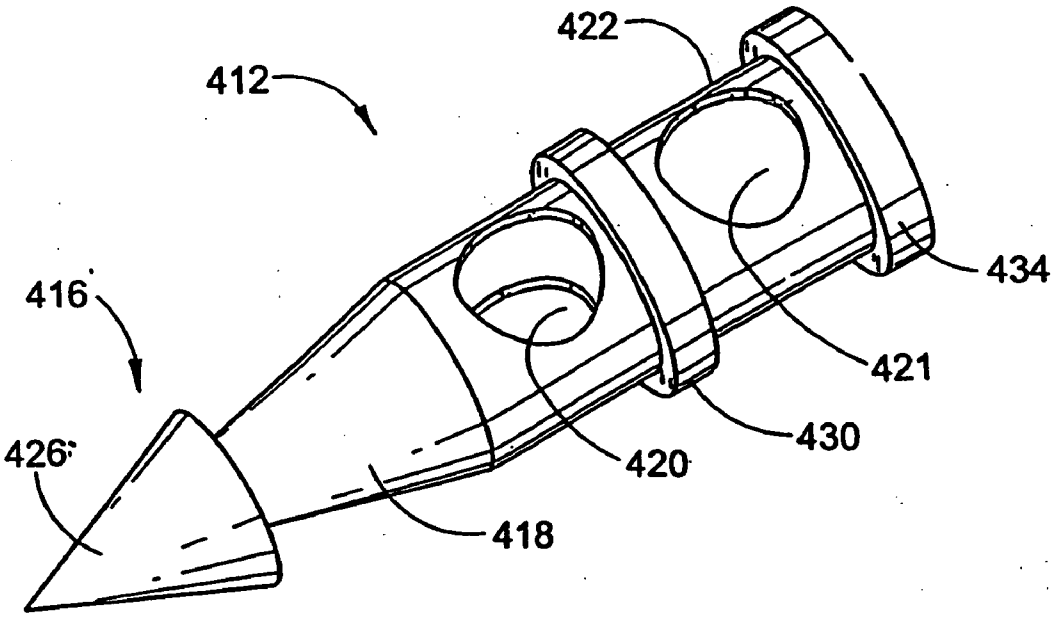



FIG. 33

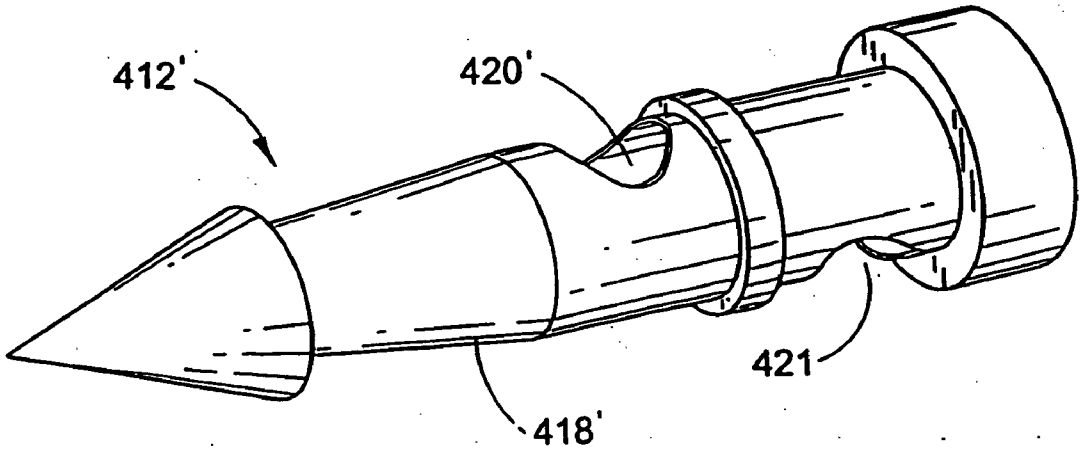



FIG. 34

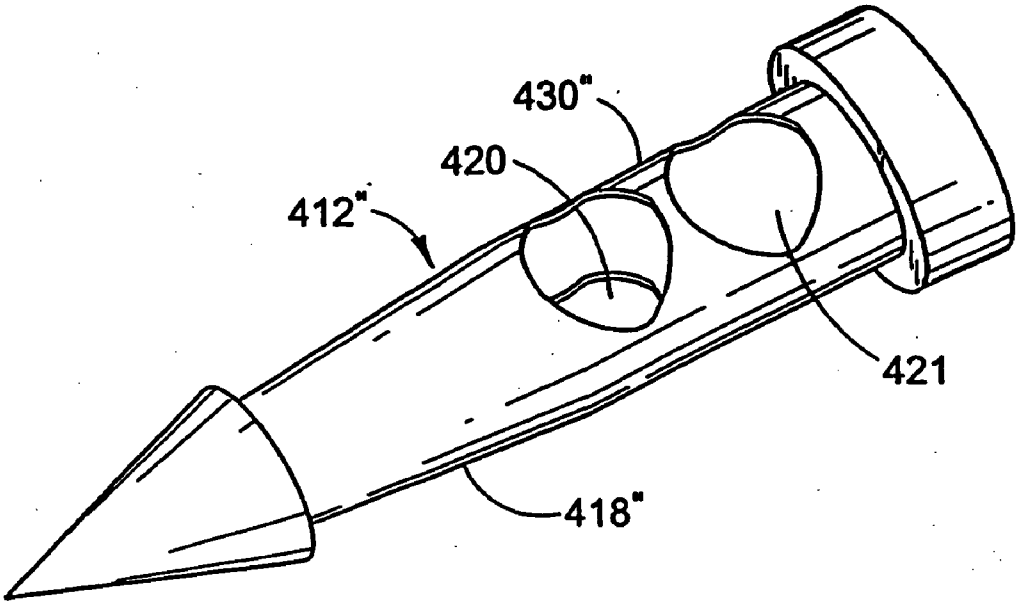



FIG. 35

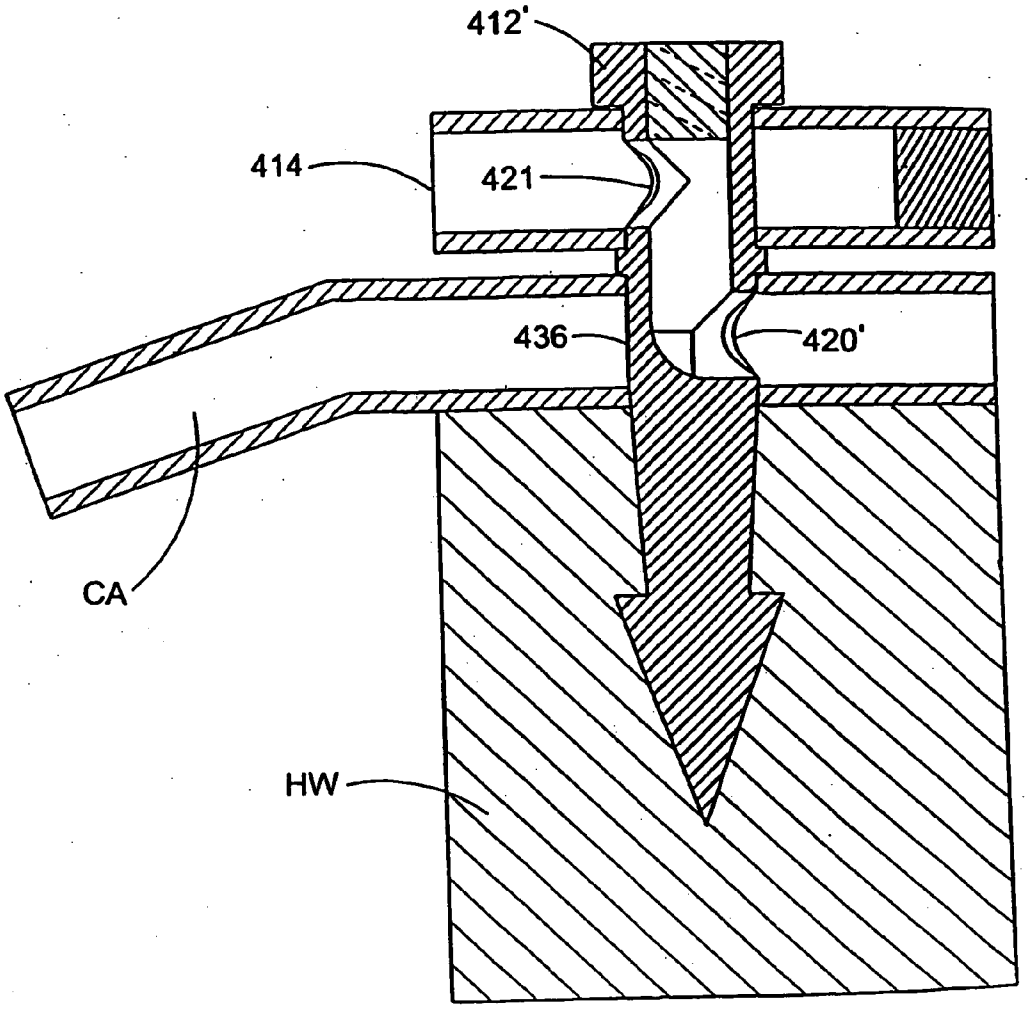



FIG. 37

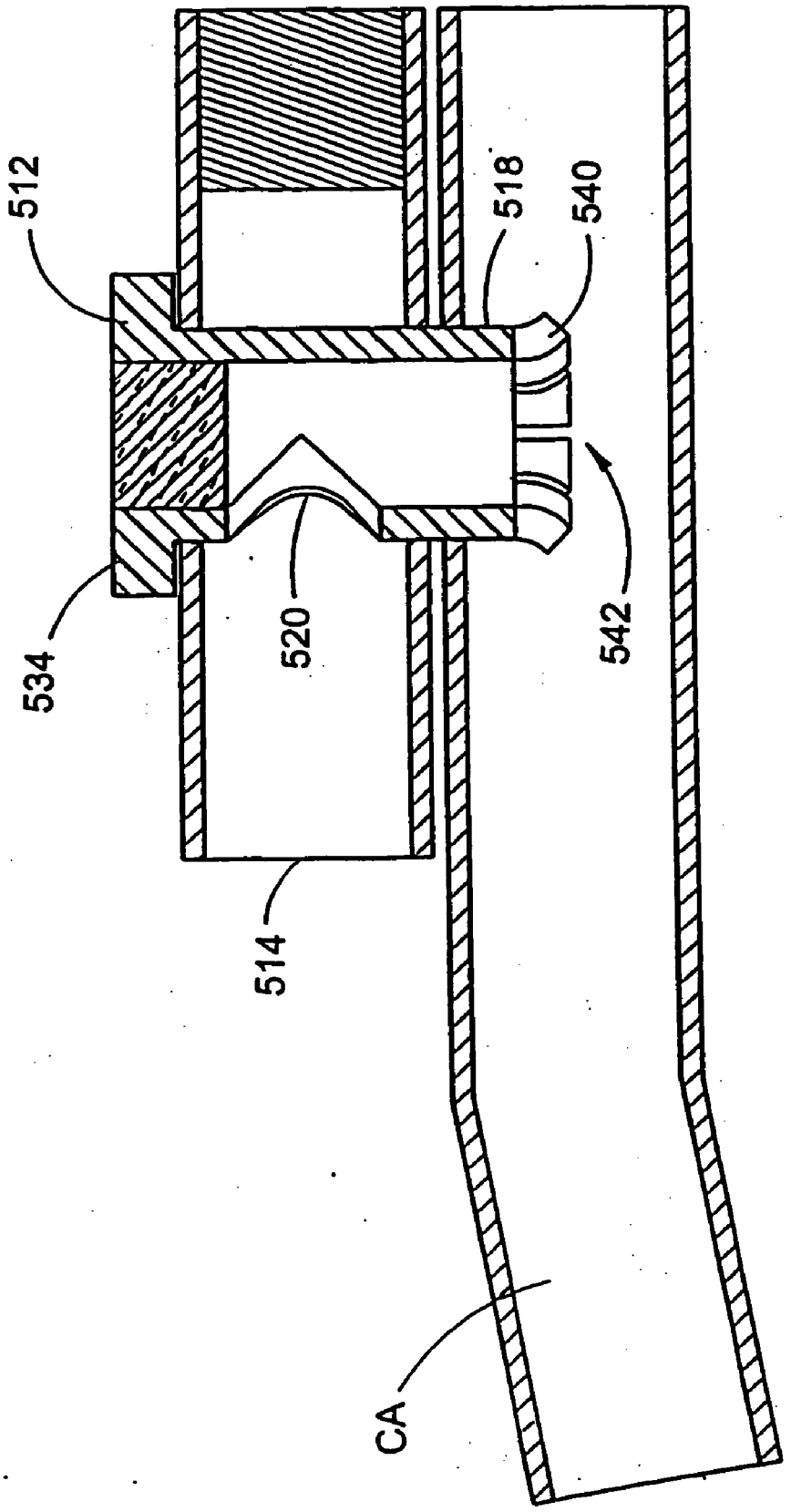



FIG. 38

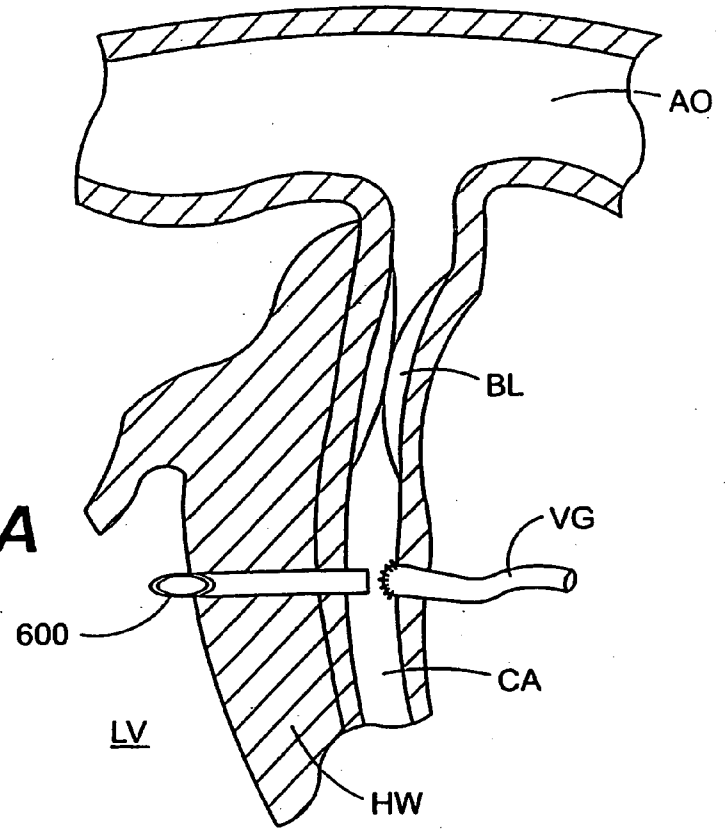



FIG. 39A

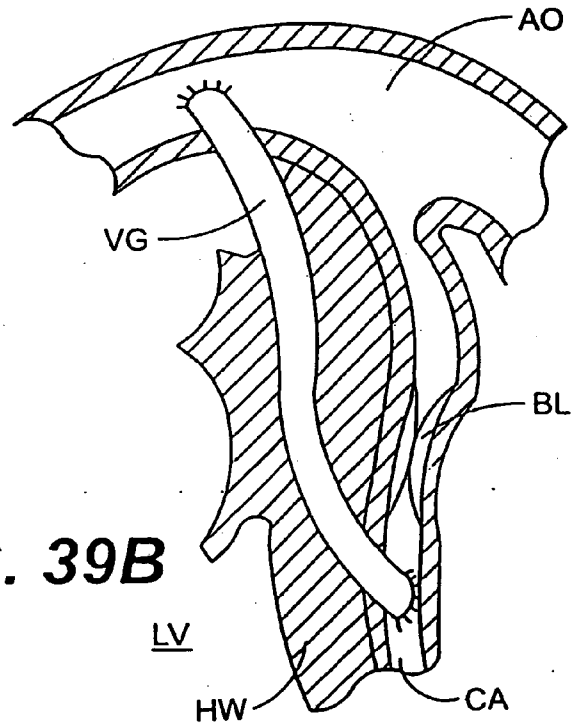



FIG. 39B

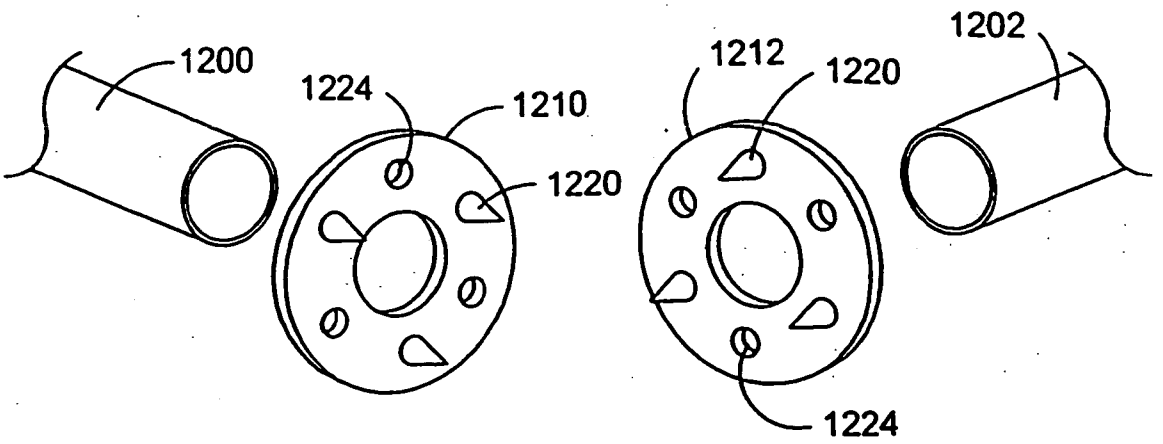



FIG. 40

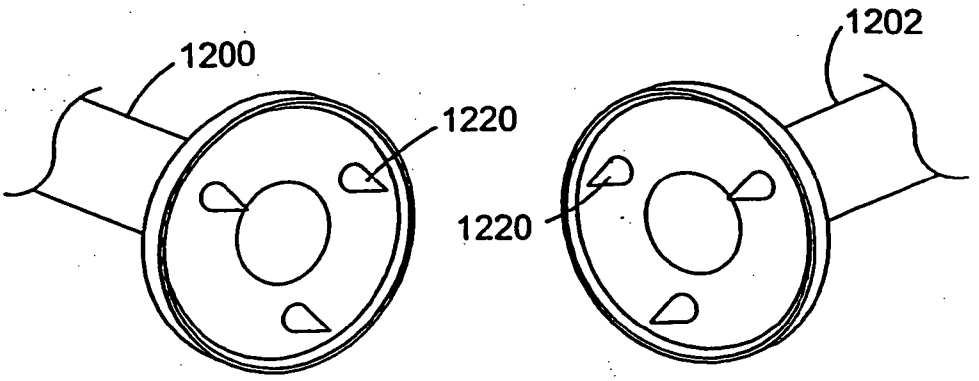



FIG. 40A

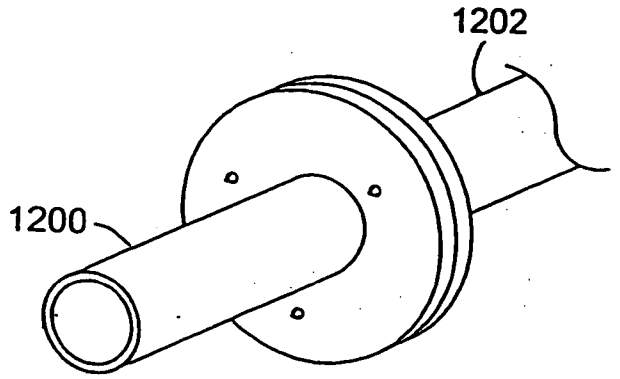



FIG. 40B

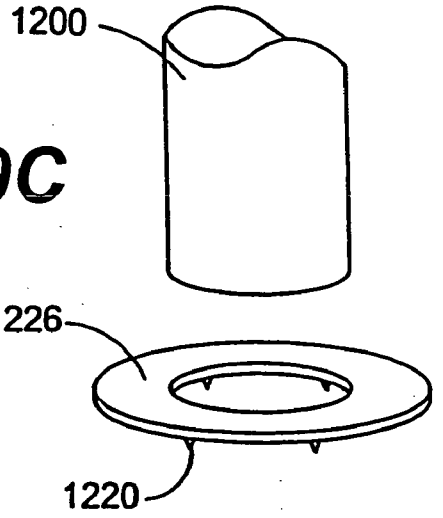



FIG. 40C

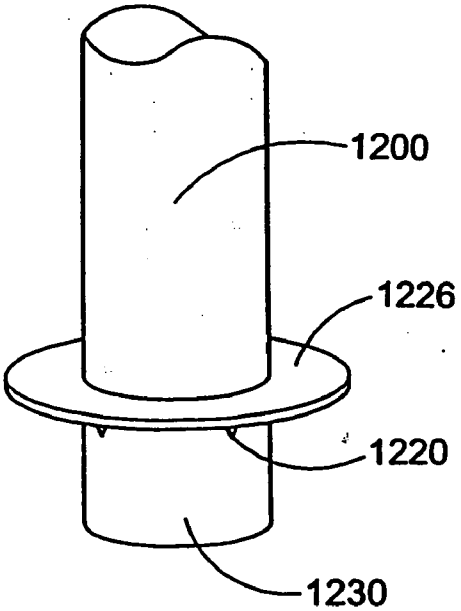



FIG. 40D

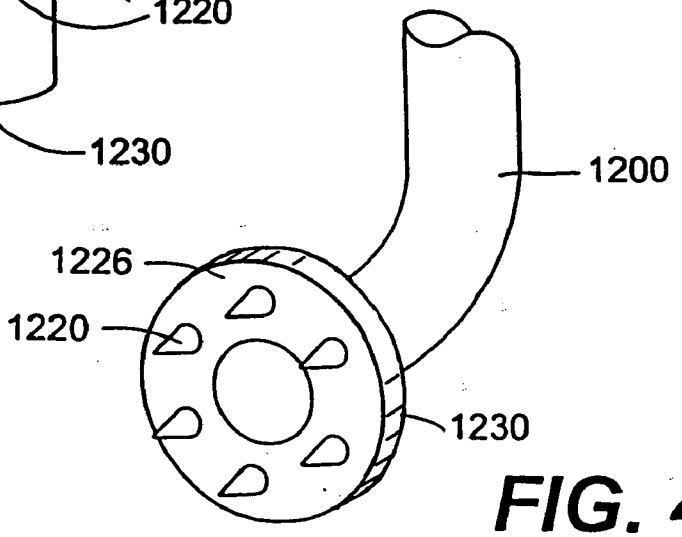



FIG. 40E

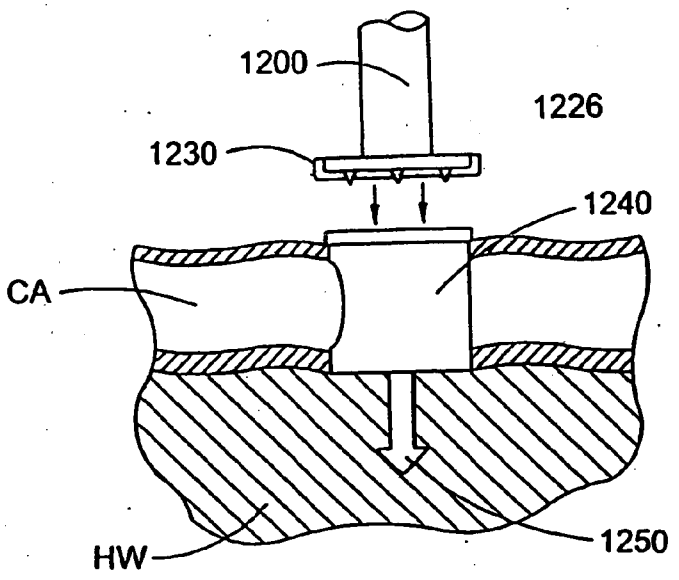



FIG. 40F

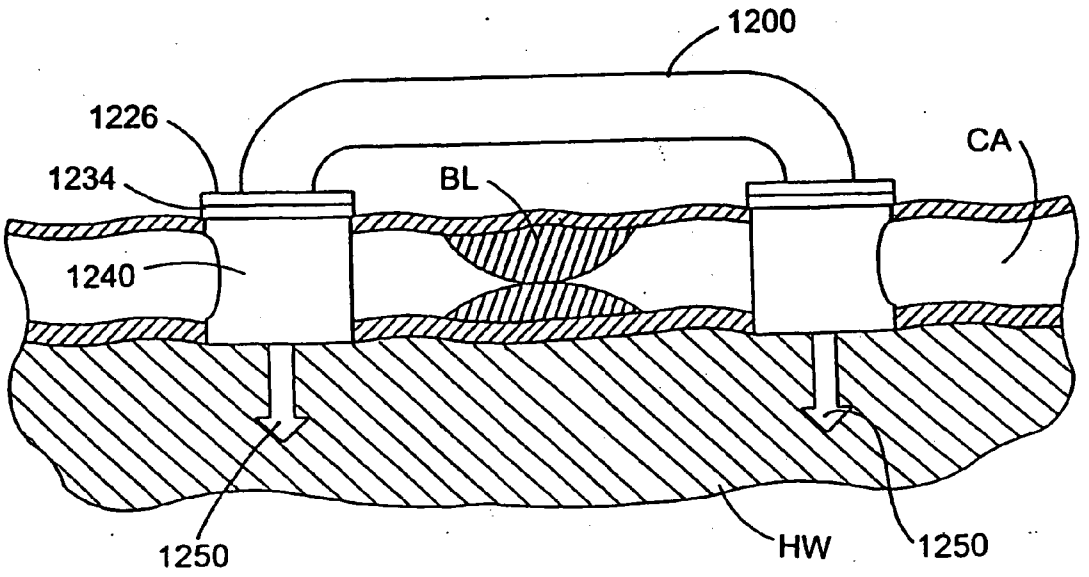



FIG. 40G

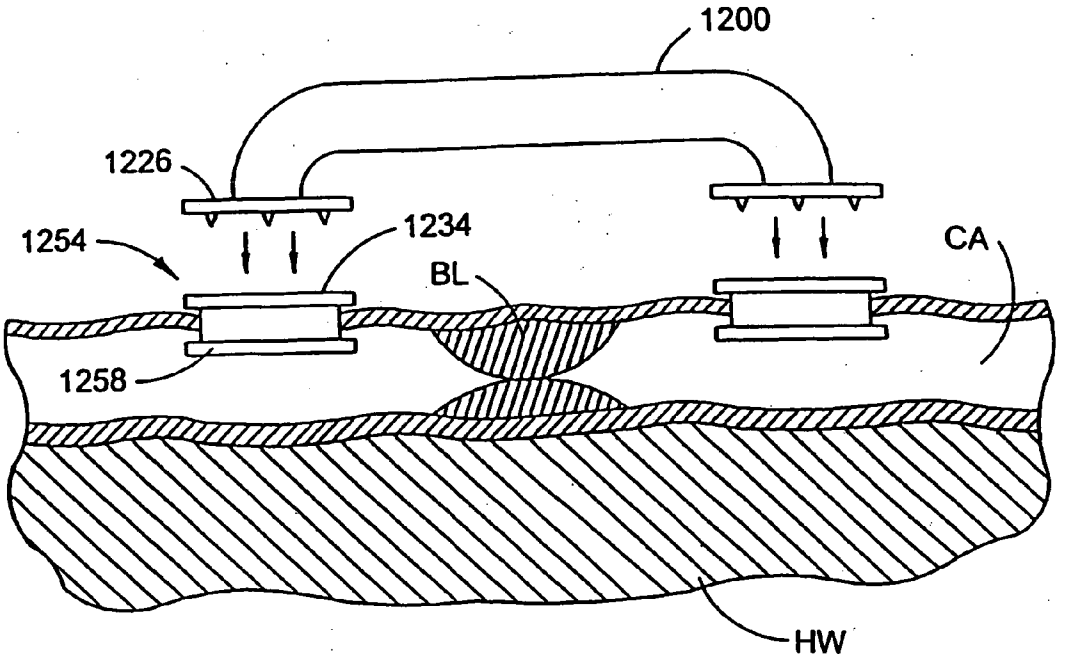



FIG. 40H

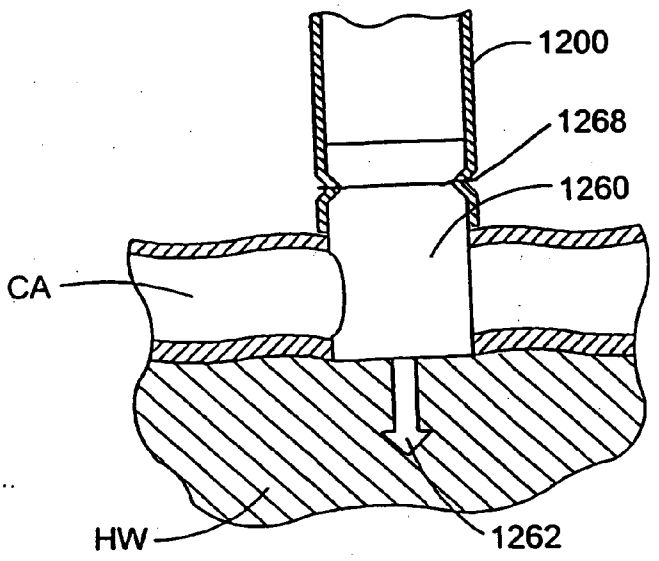



FIG. 40I

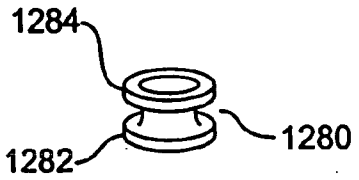



FIG. 40J

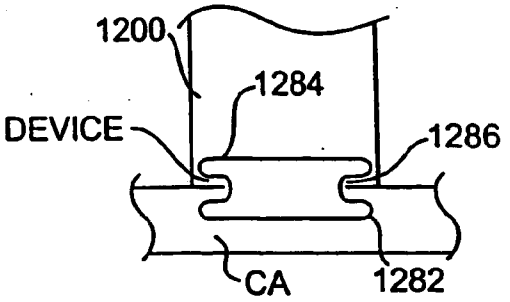



FIG. 40K

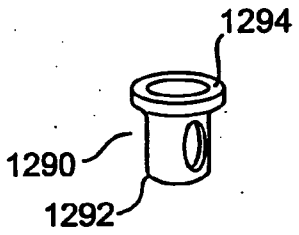



FIG. 40L

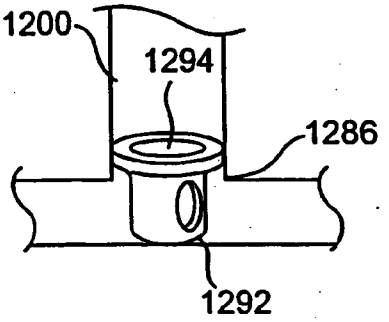



FIG. 40M

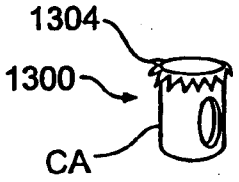



FIG. 40N

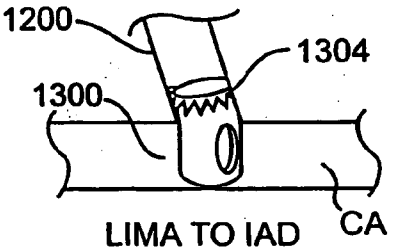



FIG. 40O

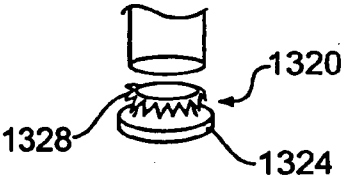



FIG. 40P

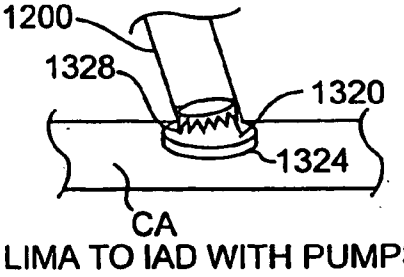



FIG. 40Q

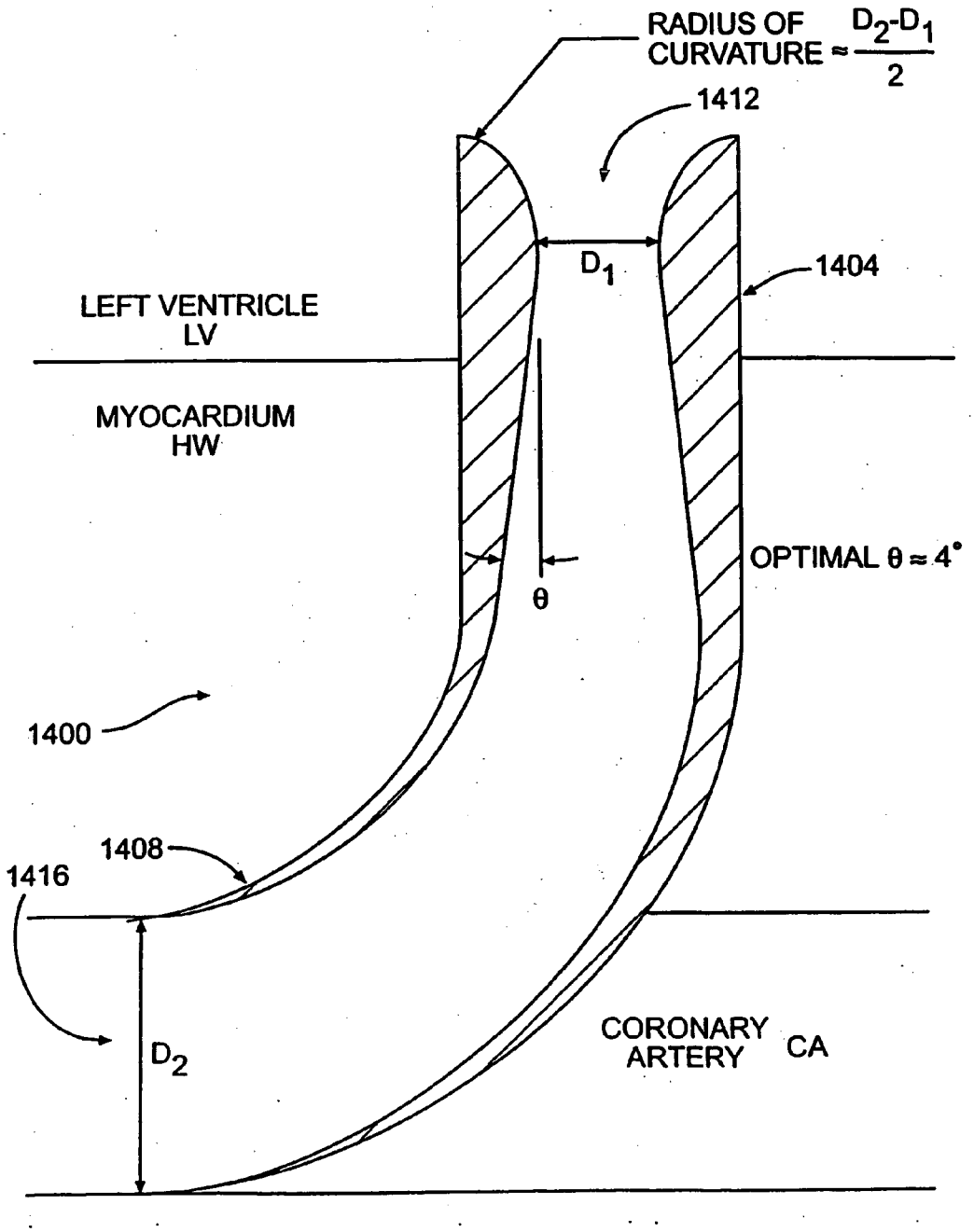

RADIUS OF CURVATURE ≈ $\frac{D_2-D_1}{2}$
1412
$D_1$
1404
LEFT VENTRICLE
LV
MYOCARDIUM
HW
OPTIMAL θ ≈ 4°
θ
1400
1408
1416
$D_2$
CORONARY ARTERY CA

FIG. 41

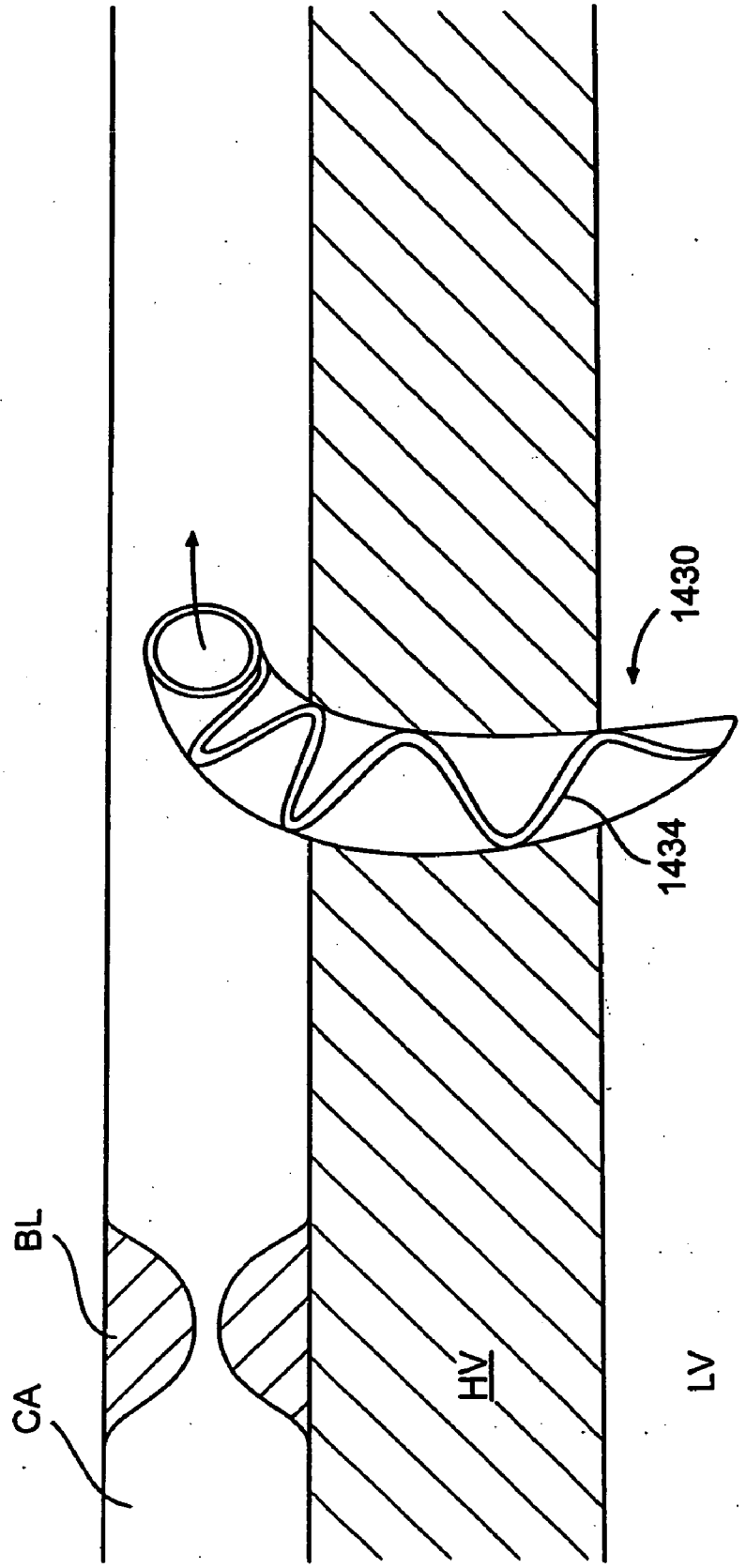



FIG. 42

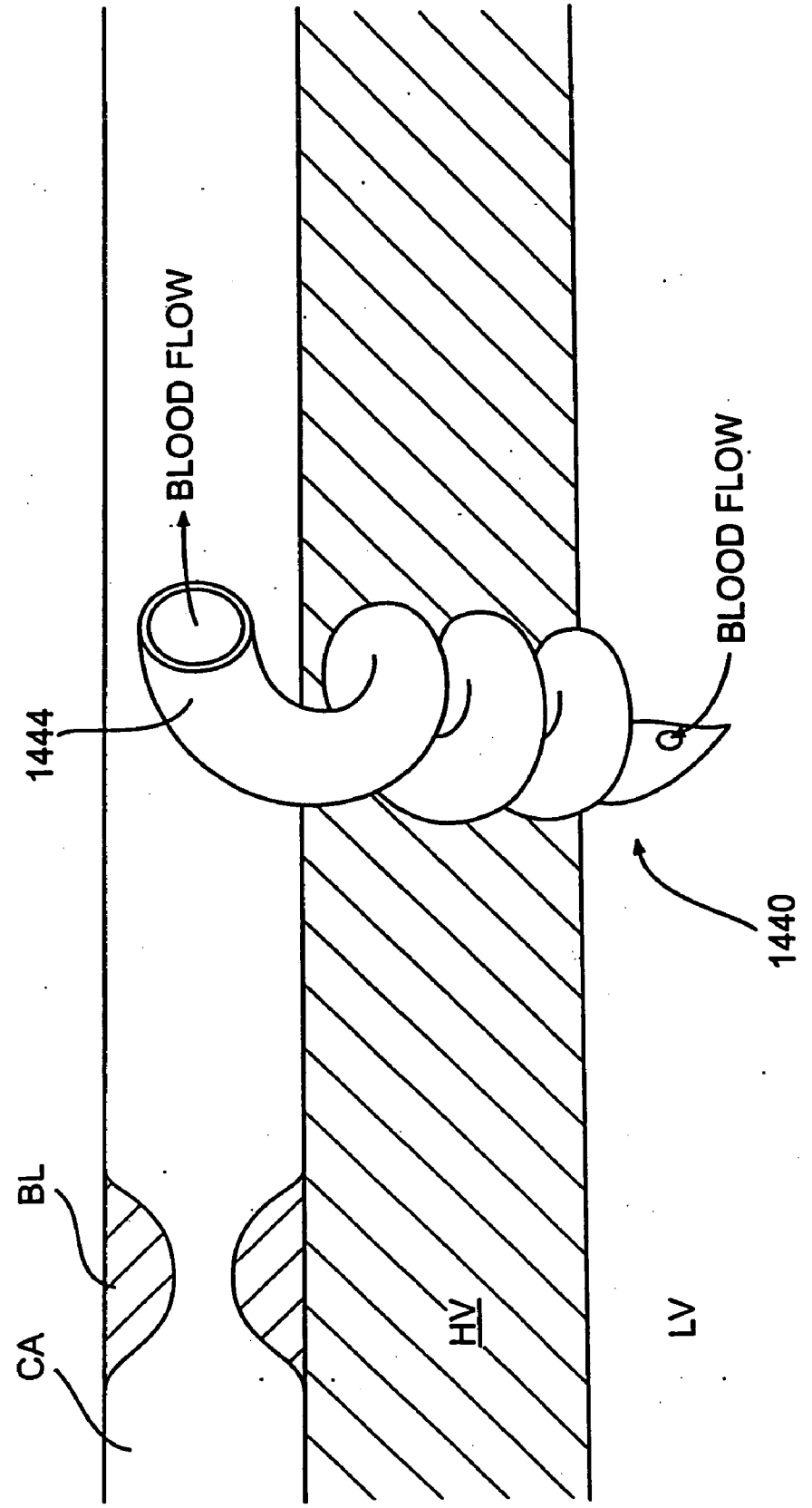



FIG. 43

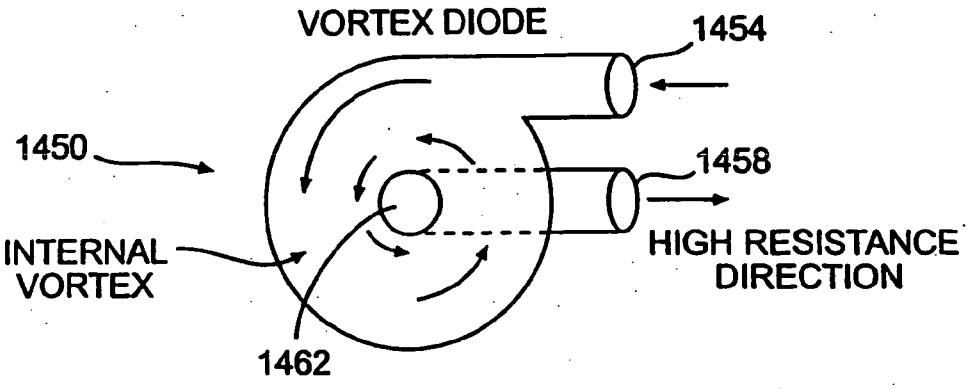



FIG. 44A

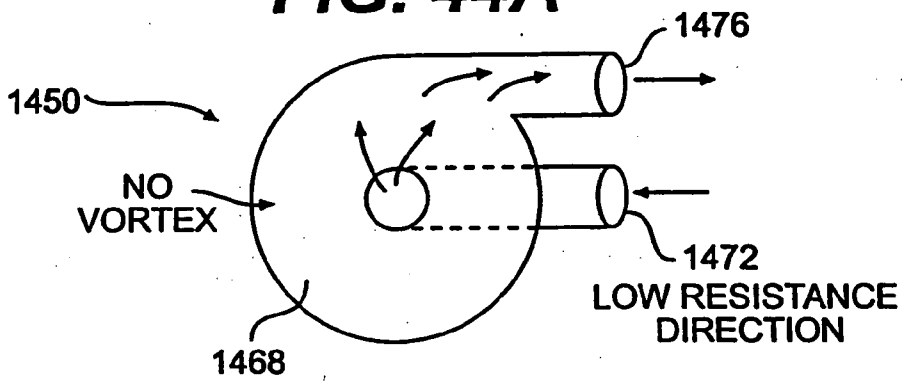



FIG. 44B

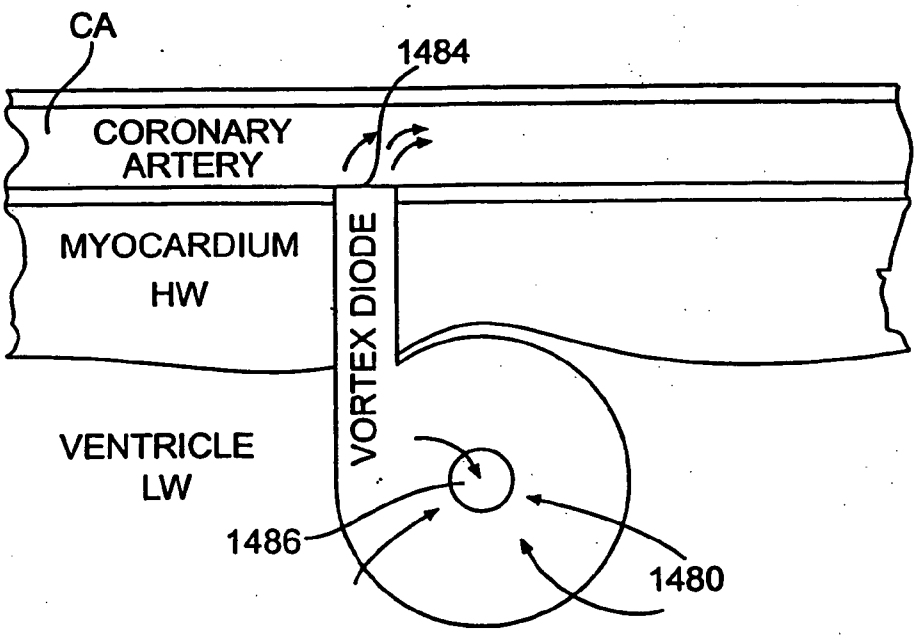



FIG. 44C

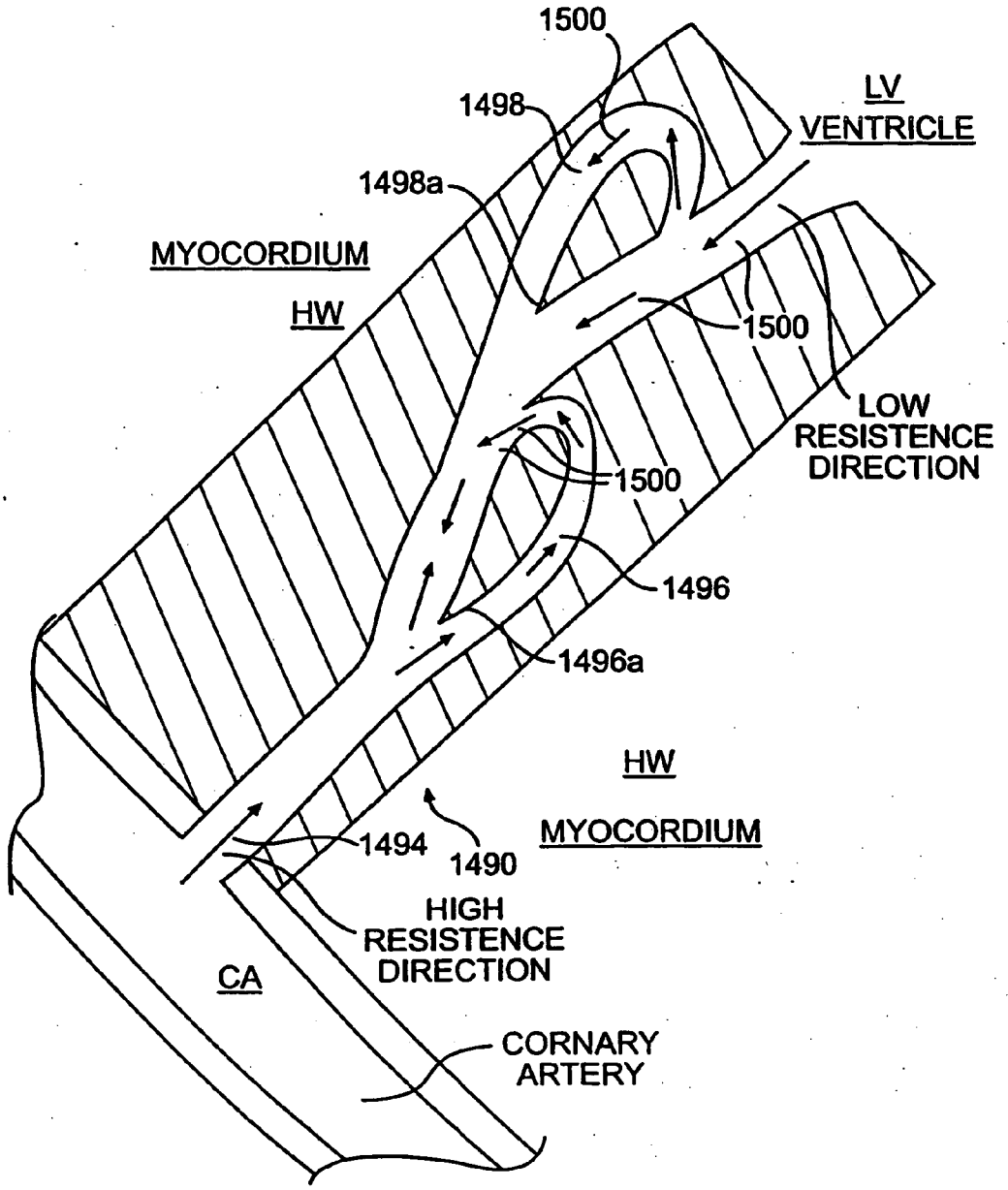

1500
1498
LV
VENTRICLE
1498a
MYOCORDIUM
HW
1500
LOW
RESISTENCE
DIRECTION
1500
1496
1496a
HW
MYOCORDIUM
1494
1490
HIGH
RESISTENCE
DIRECTION
CA
CORNARY
ARTERY

FIG. 45

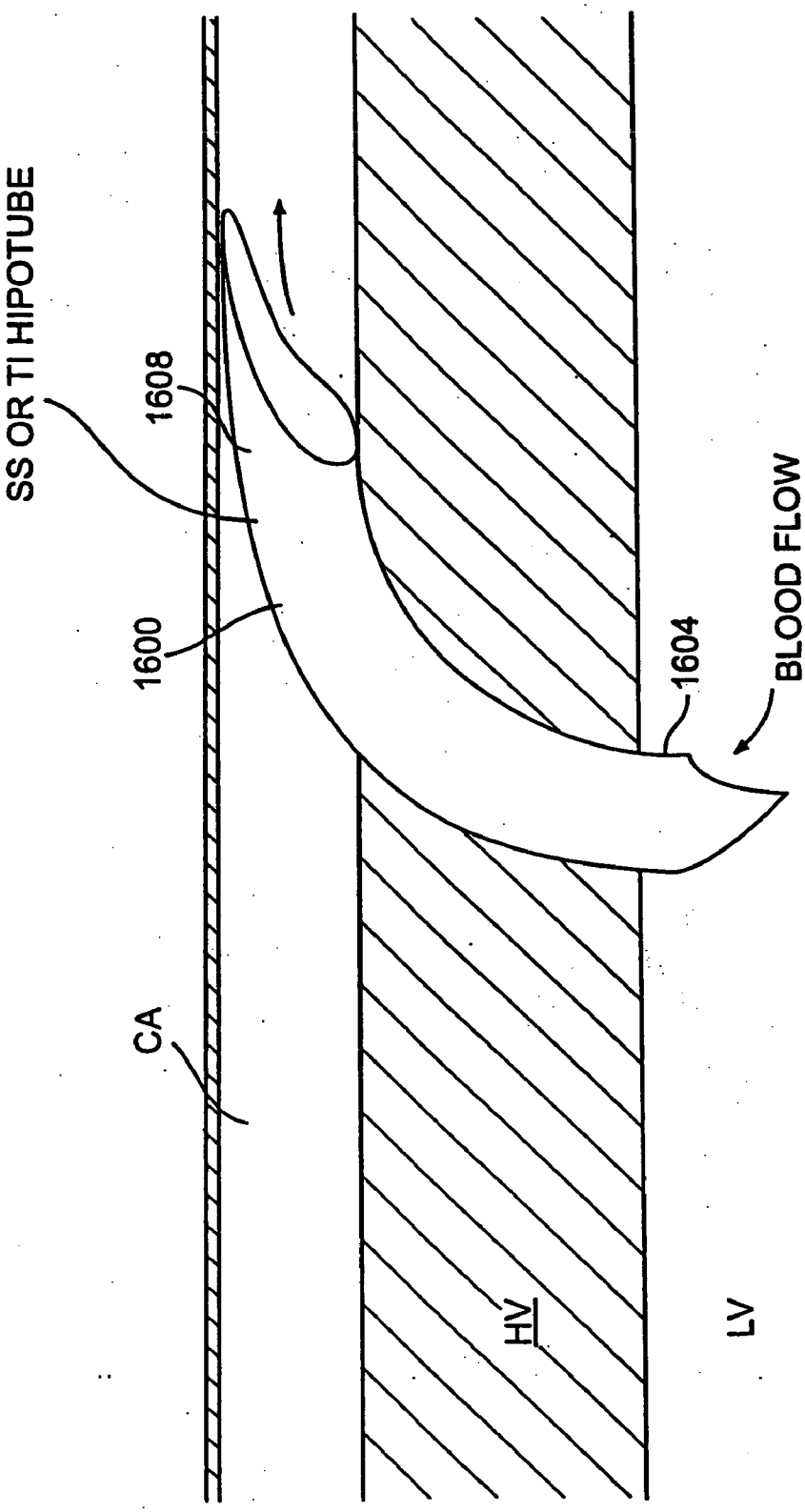



FIG. 46

INSERTION STEPS

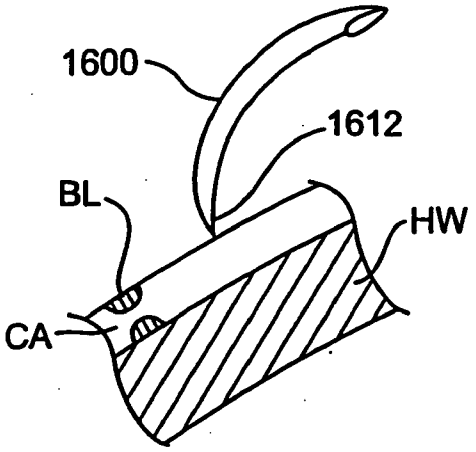



FIG. 47A

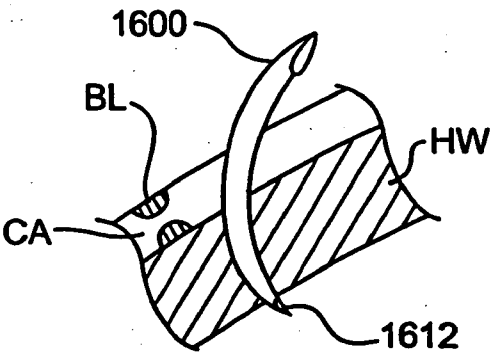



FIG. 47B

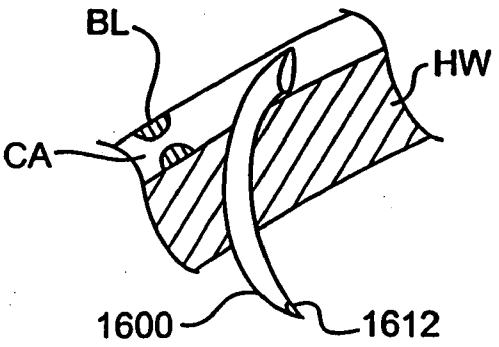



FIG. 47C

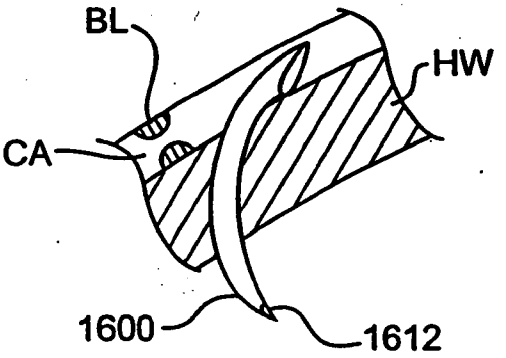



FIG. 47D

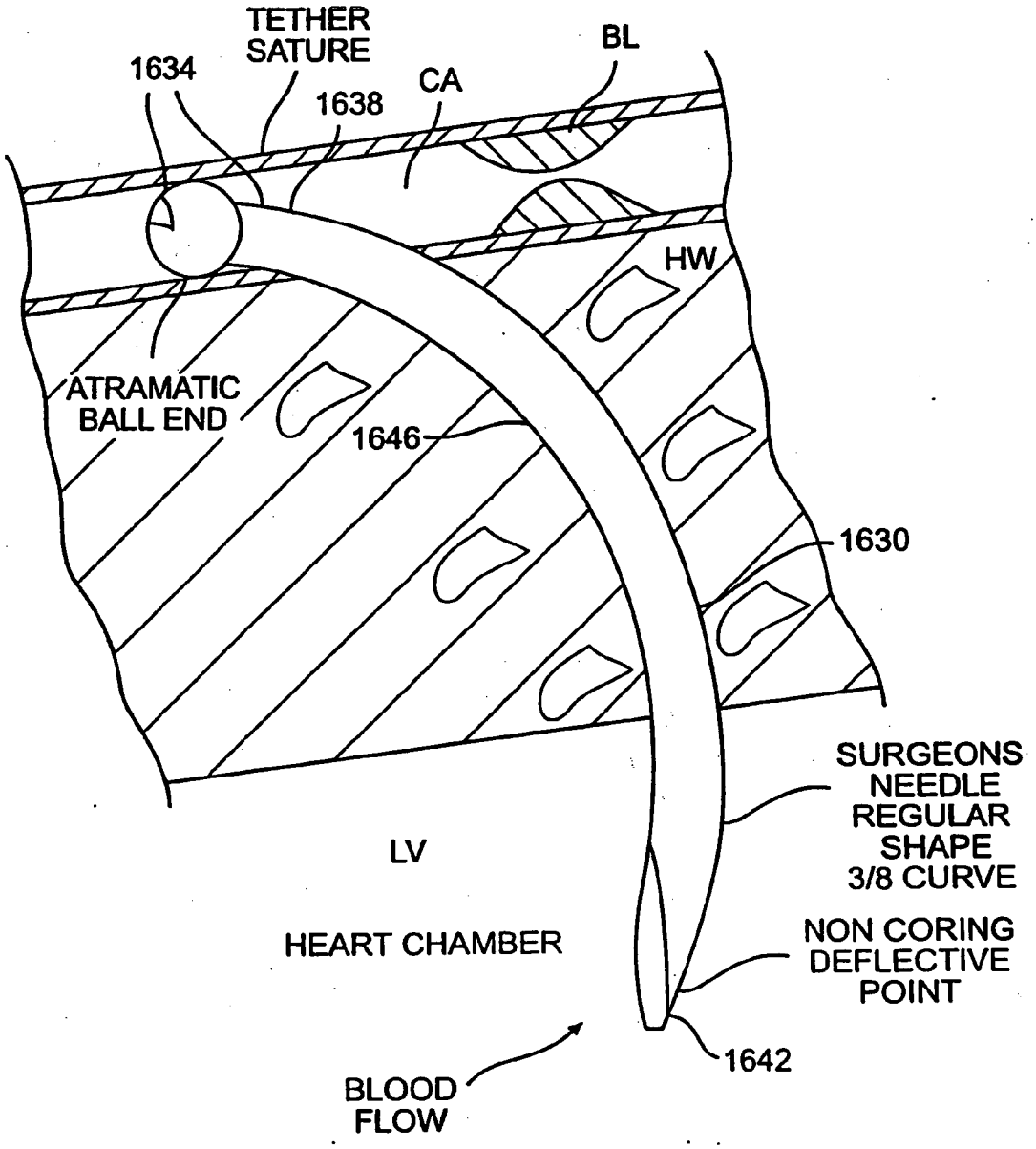

TETHER SATURE
1634
1638
CA
BL
HW
ATRAMATIC BALL END
1646
1630
SURGEONS NEEDLE REGULAR SHAPE 3/8 CURVE
LV
HEART CHAMBER
NON CORING DEFLECTIVE POINT
1642
BLOOD FLOW

FIG. 48

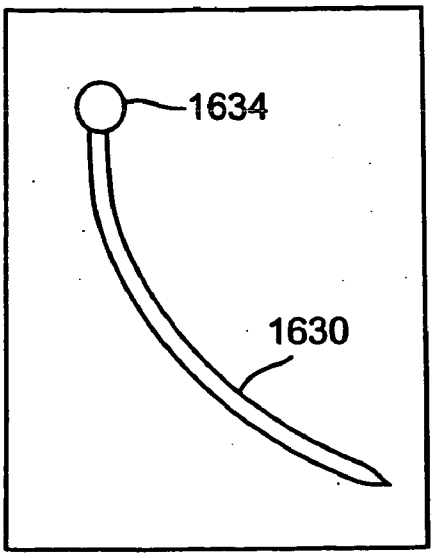



FIG. 48A

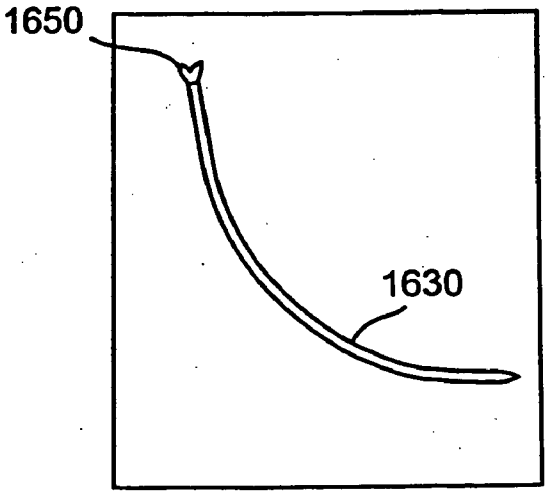



FIG. 48B

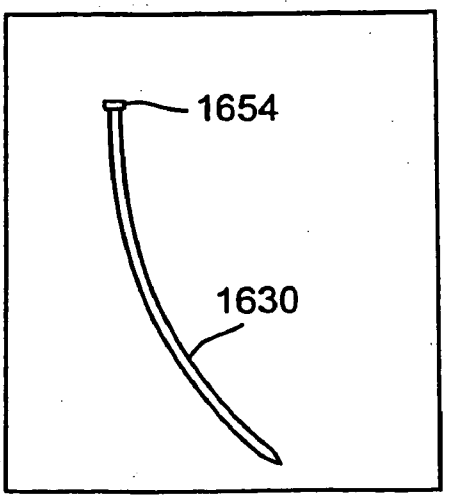



FIG. 48C

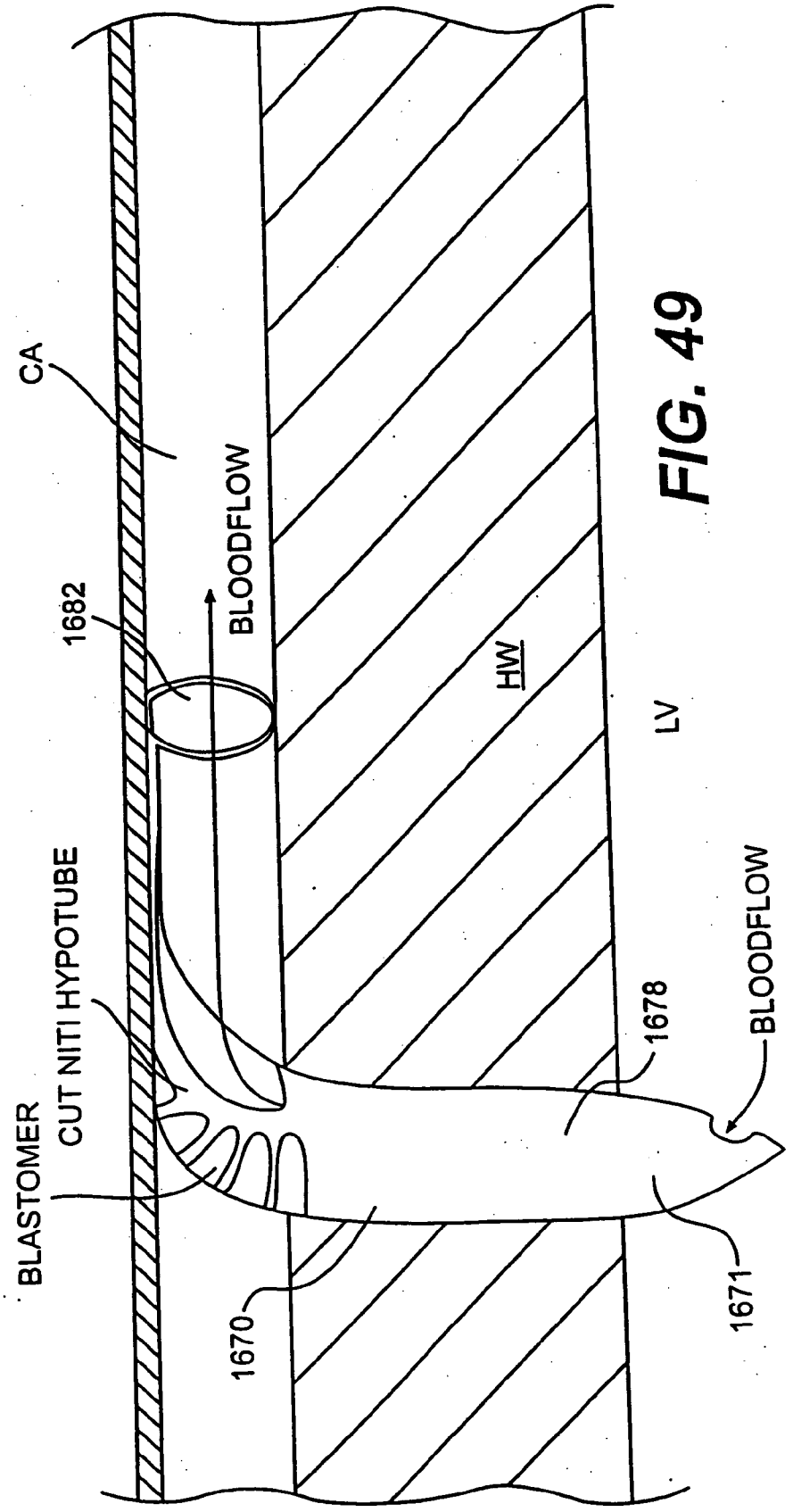

CA
BLOODFLOW
1682
HW
LV
BLOODFLOW
1678
CUT NITI HYPOTUBE
BLASTOMER
1670
1671

FIG. 49

FIG. 50A

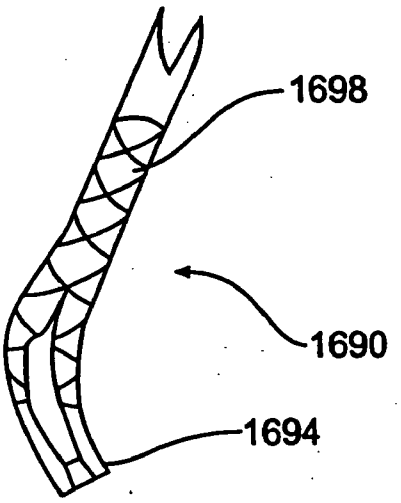



FIG. 50B

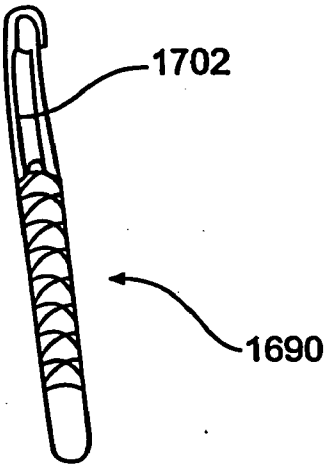
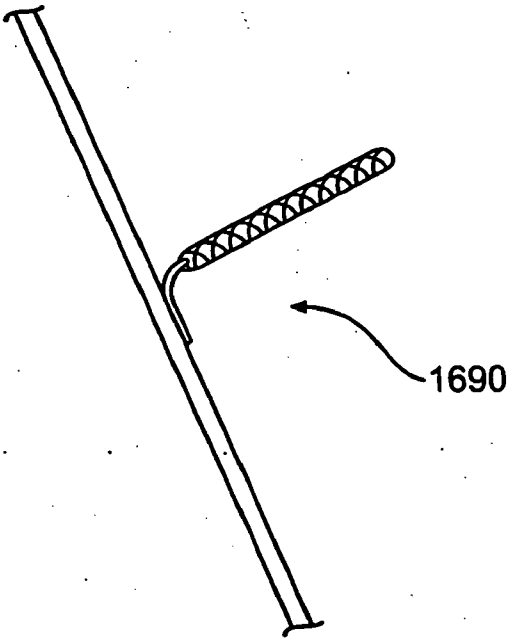



FIG. 50C



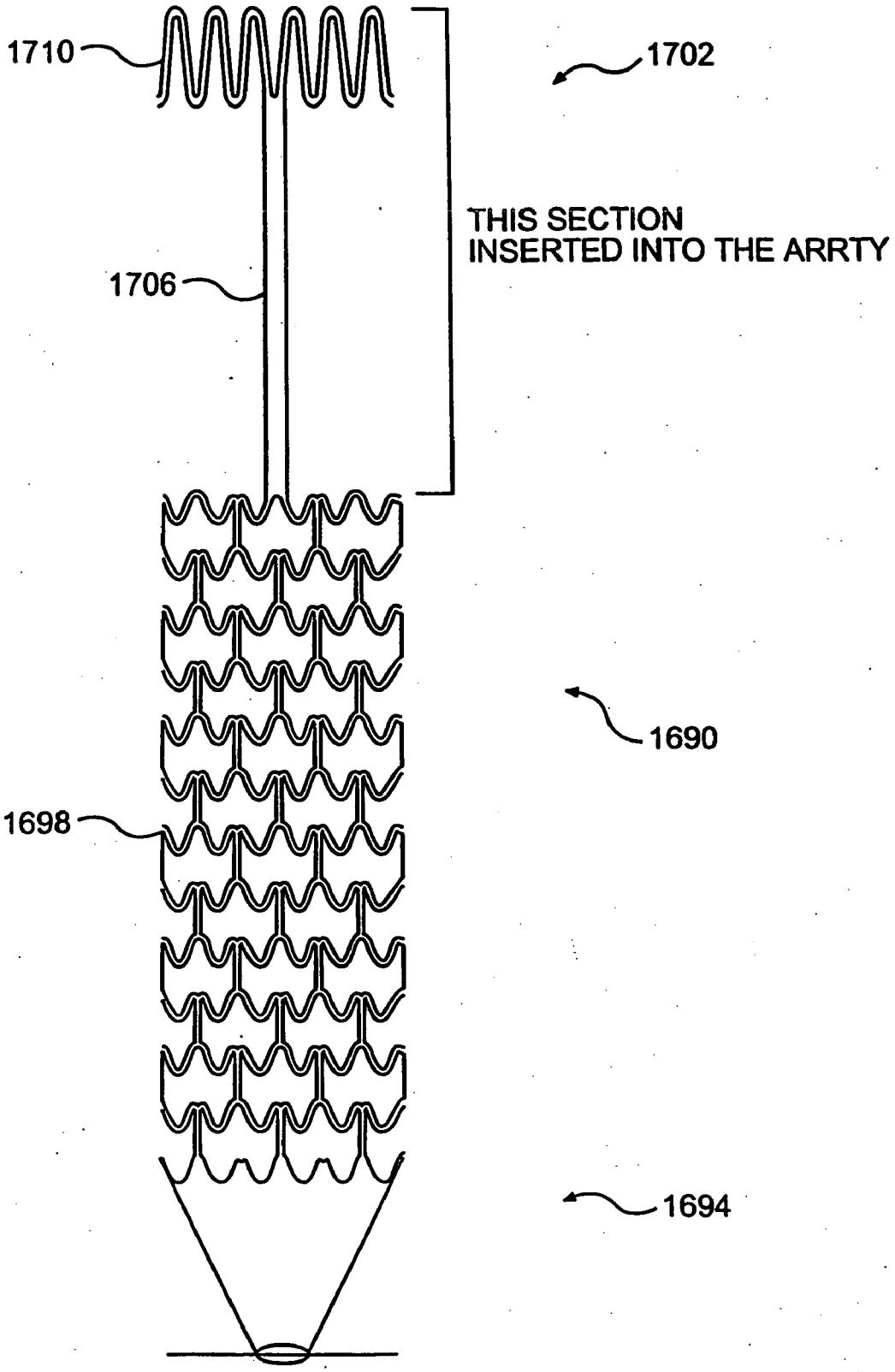

1710
1702
THIS SECTION
INSERTED INTO THE ARRTY
1706
1690
1698
1694

FIG. 51A

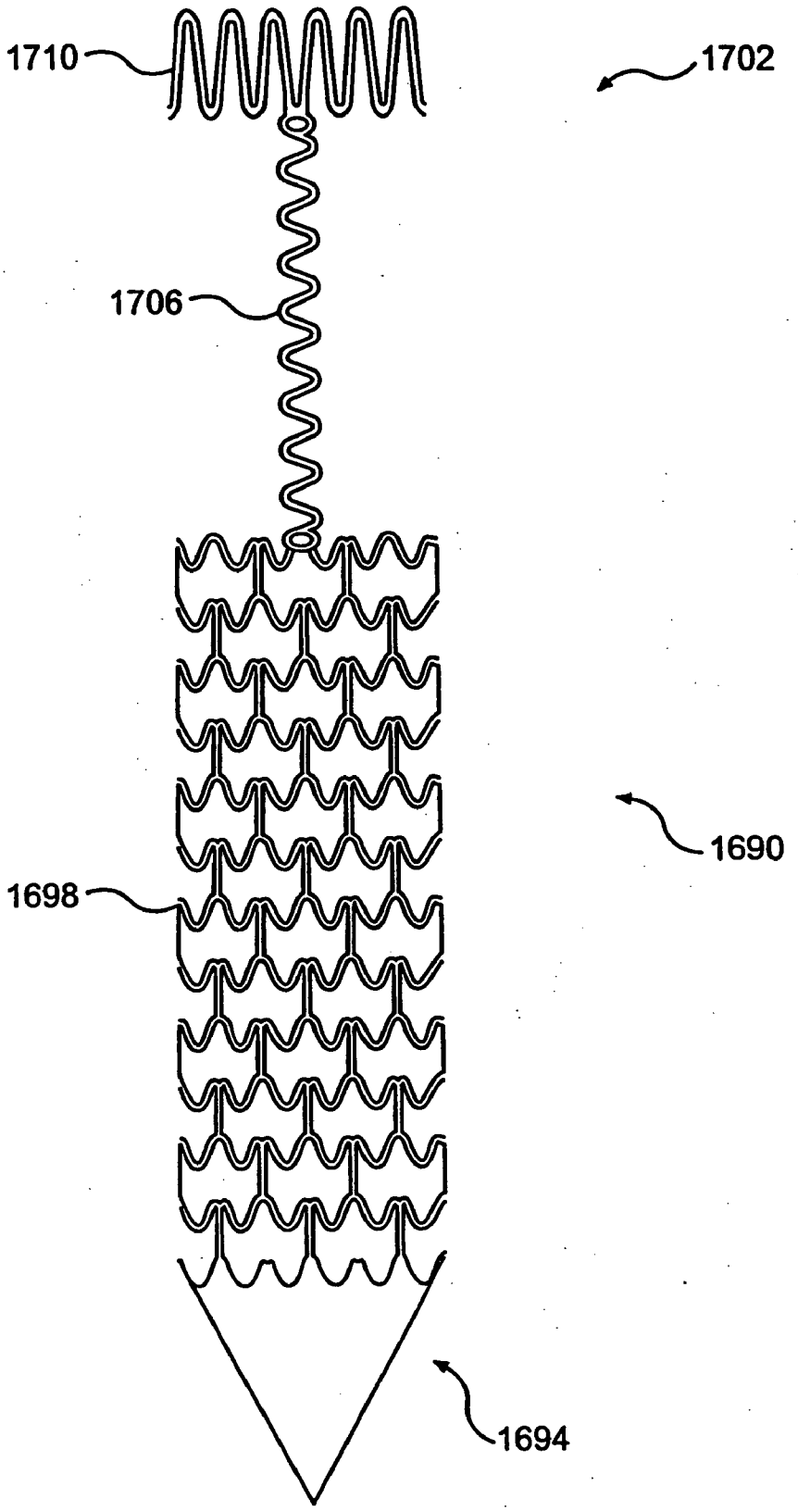



FIG. 51B

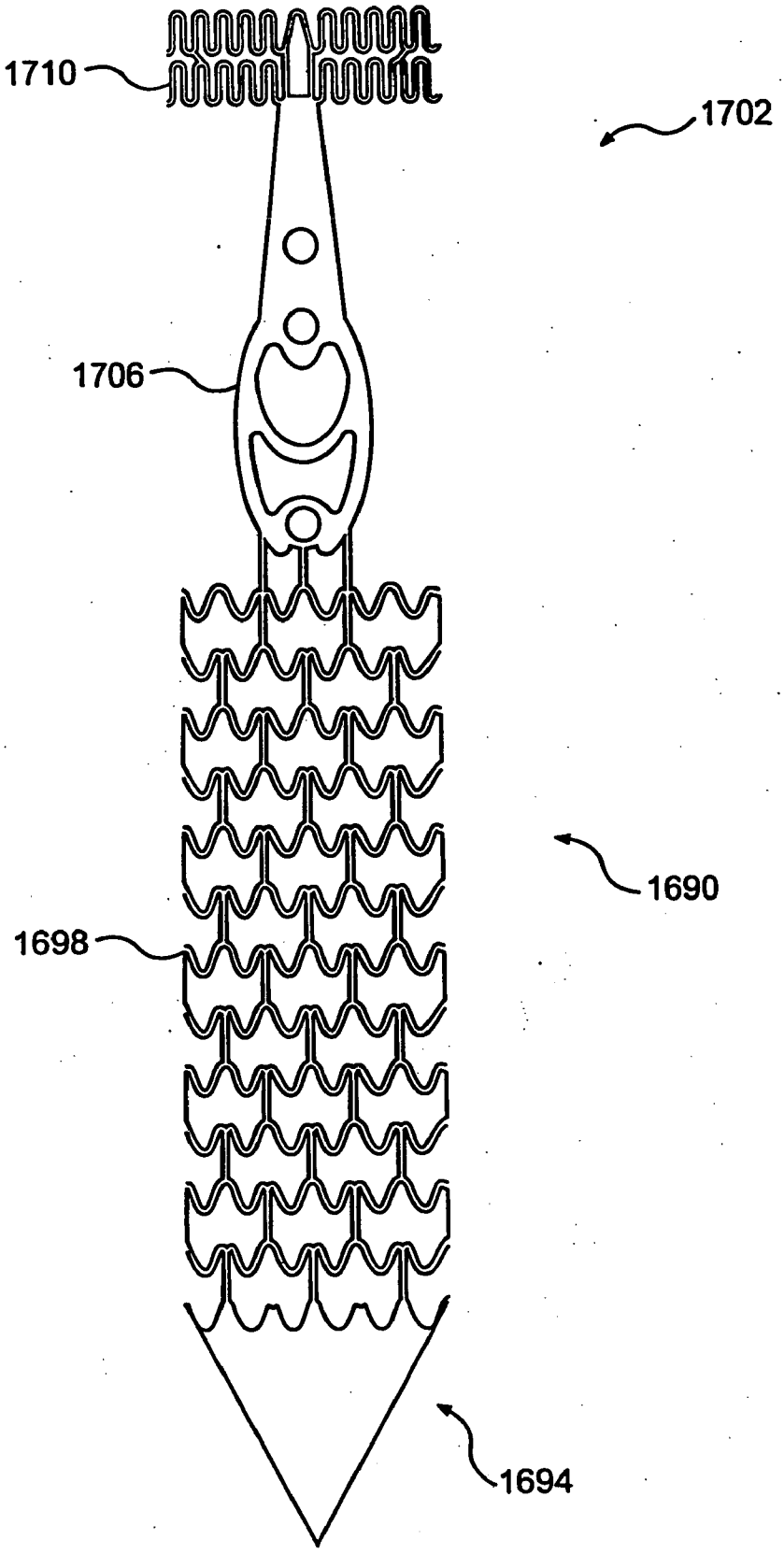



FIG. 51C

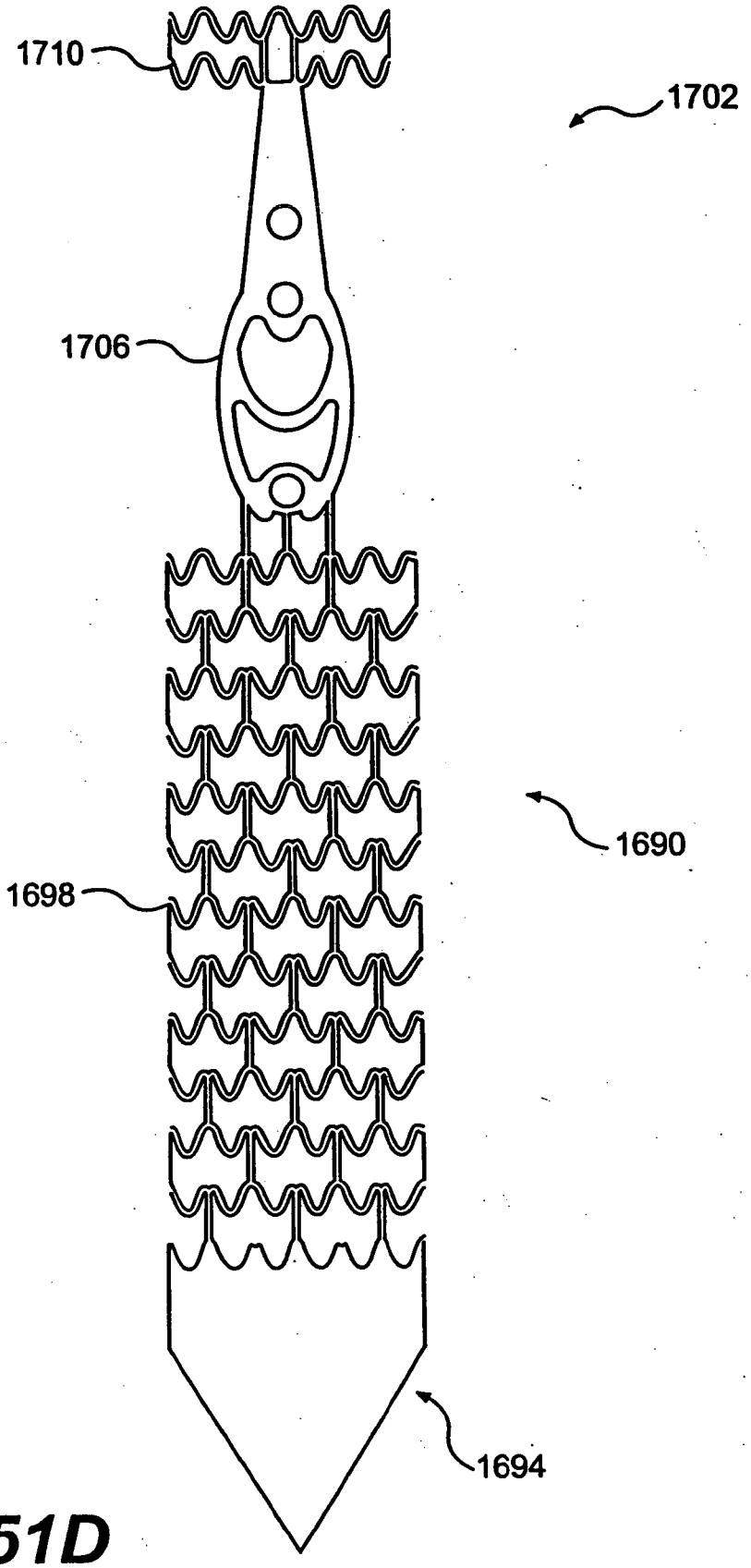



FIG. 51D

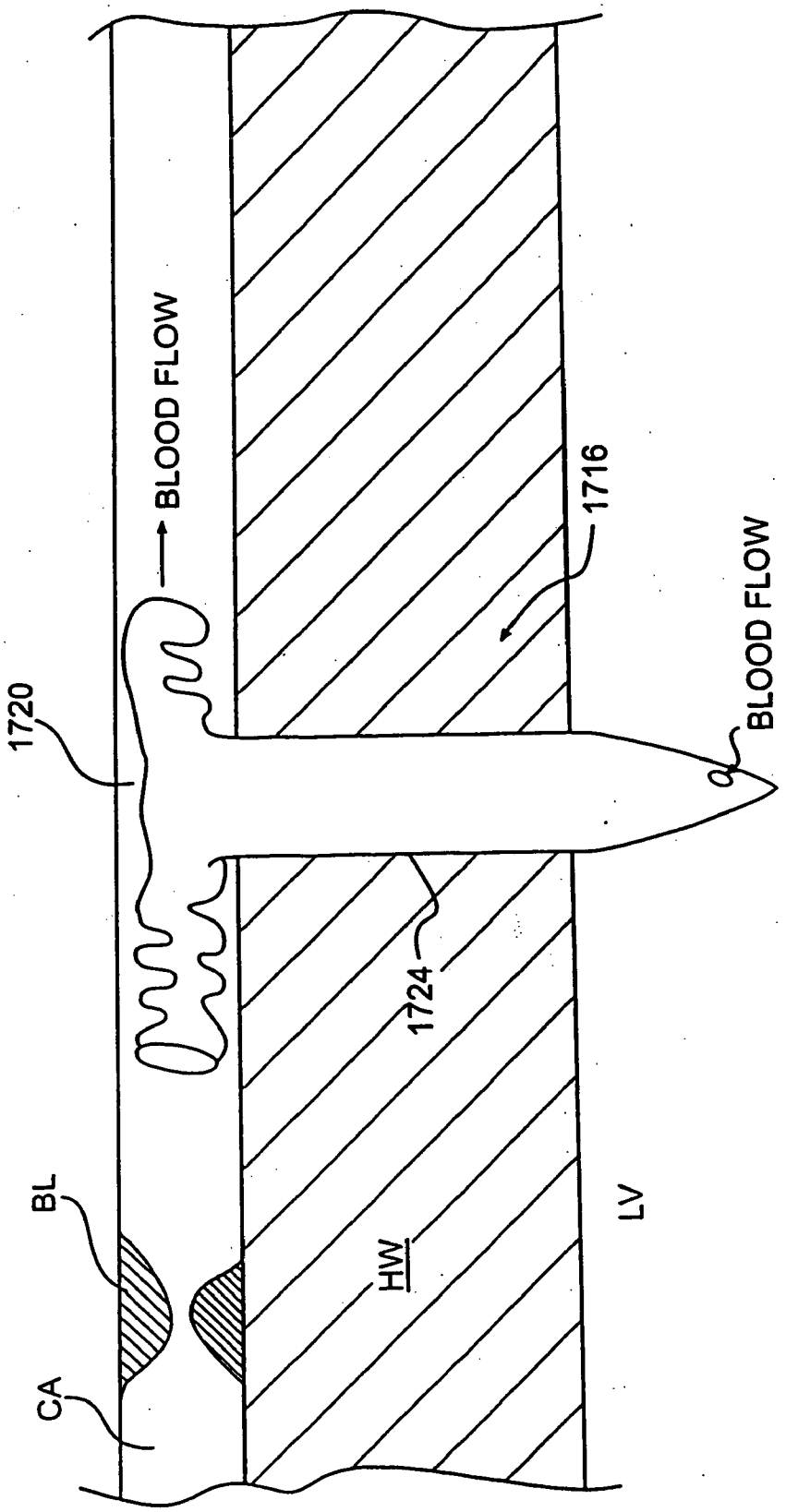



FIG. 52

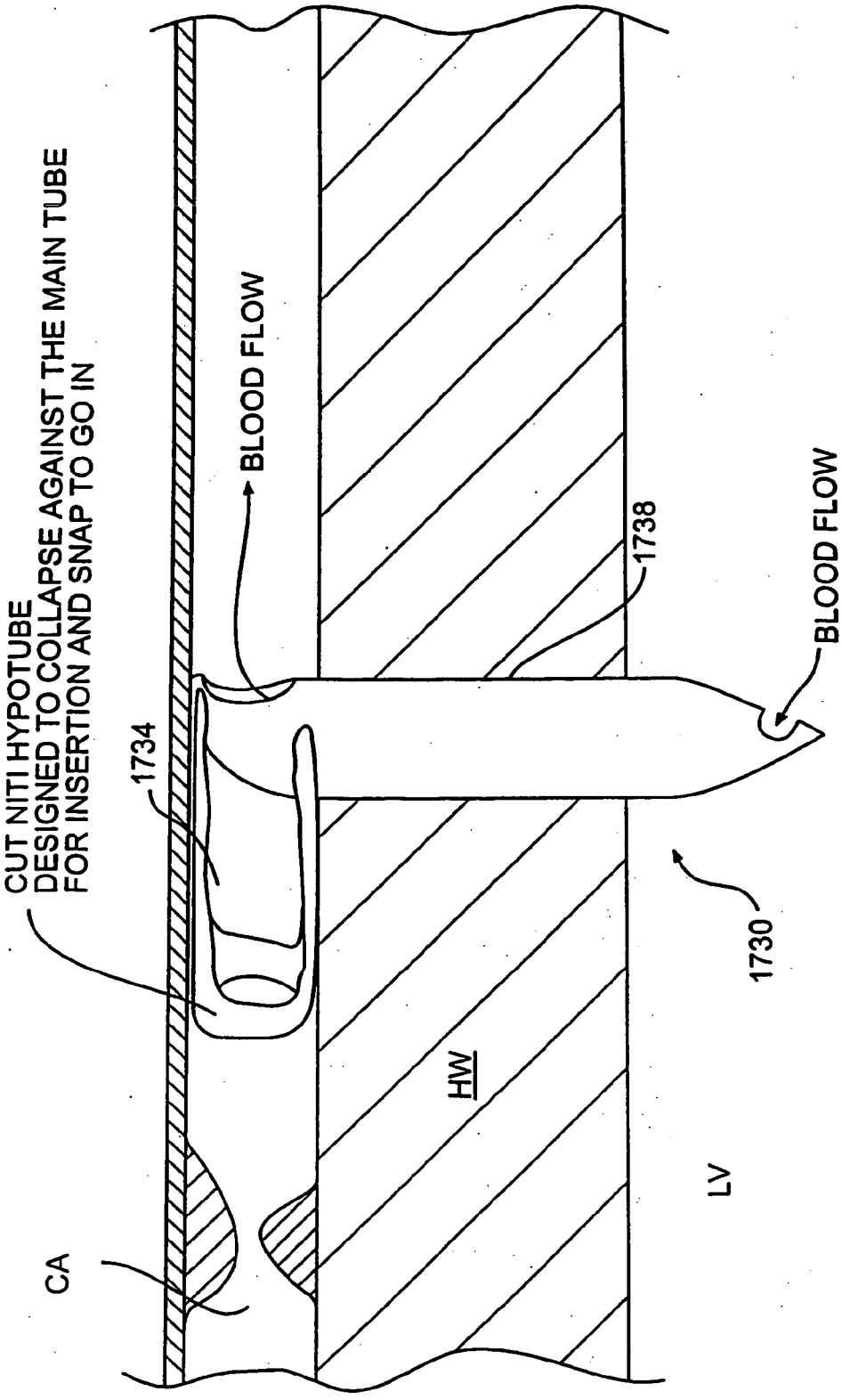

CUT NITI HYPOTUBE
DESIGNED TO COLLAPSE AGAINST THE MAIN TUBE
FOR INSERTION AND SNAP TO GO IN
BLOOD FLOW
1734
1738
BLOOD FLOW
1730
HW
LV
CA

FIG. 53

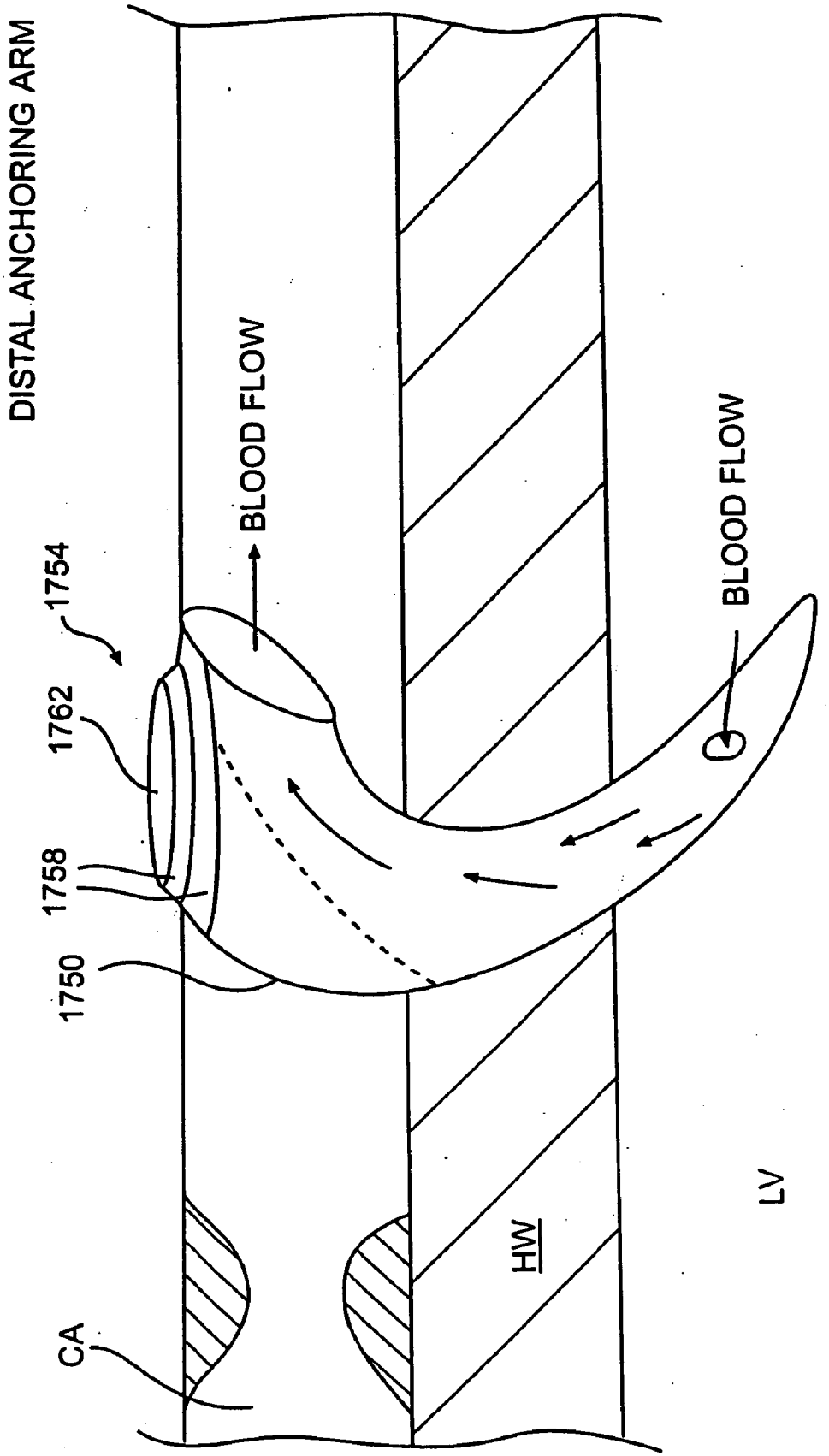

DISTAL ANCHORING ARM
BLOOD FLOW
BLOOD FLOW
1754
1762
1758
1750
CA
HW
LV

FIG. 54

# LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/099,691, filed Sep. 10, 1998, U.S. Provisional Application No. 60/099,720, filed Sep. 10, 1998, U.S. Provisional Application 60/104,397, filed Oct. 15, 1998, and U.S. Provisional Application 60/099,767 filed Sep. 19, 1998, and is a continuation-in-part of application Ser. No. 09/016,485, filed Jan. 30, 1998, and International Application No. PCT/US99/03483, filed Feb. 17, 1999, all of which are hereby incorporated by reference herein in their entirety.

## BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to an apparatus and method for implanting a conduit to allow communication of fluids from one portion of a patient's body to another; and, more particularly, to a blood flow conduit to allow communication from a heart chamber to a vessel or vice versa, and/or vessel to vessel. Even more particularly, the invention relates to a left ventricular conduit and related conduit configurations for controlling the flow of blood through the conduit to achieve bypass of an occluded coronary artery.

[0004] 2. Description of Related Art

[0005] Coronary artery disease is a major problem in the U.S. and throughout the world. In fact, about 1.1 million "open heart" procedures are performed each year, and current estimates are that approximately 4.8 million people suffer from some degree of congestive heart failure.

[0006] When coronary arteries or other blood vessels become clogged with plaque, the results are at the very least impairment of the efficiency of the heart's pumping action. On the more severe side of the scale are heart attack and death. In some cases, clogged arteries can be unblocked through minimally invasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

[0007] In a bypass operation, one or more arterial or venous segments are harvested from the body and then surgically inserted between the aorta and the coronary artery. The inserted vessel segments, or transplants, act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

[0008] Coronary artery bypass grafting (CABG) has been used for more than 30 years. Initially, the saphenous vein (SV) served as the principal conduit for coronary bypass, but studies over the last dozen years have shown a 3540% increase in 10-year patency rate for the internal thoracic artery (ITA) compared with the SV. The SV, in fact, has only been shown to have a 10-year patency rate of 50%. Since the mid 1980's, not only the ITA, but also the alternative arterial conduits have been increasingly used. These conduits include the grastroepiploic artery (GEA), inferior epigastric artery (IEA), and radial artery (RA), which have been used primarily as supplements to both the right and left ITA.

[0009] Although the use of arterial conduits results in demonstrably better long-term patency, use of arteries in place of the SV often requires complex technical challenges, such as free grafts, sequential anastomosis, and conduit-to-conduit anastomosis. Some of the reasons for the difficulty in using arterial conduits reside in the fact that they are much more fragile than the SV and therefore easier to damage, and due to their smaller size, easier to occlude completely or partially through technical error during grafting.

[0010] Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence periods are prolonged.

[0011] As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage, or due to the risk of the emboli formation.

[0012] One bypass technique employed in the prior art is taught by Wilk (U.S. Pat. Nos. 5,287,861, 5,409,019, 5,662,124, and 5,429,144, the entirety of each of which is hereby incorporated herein by this reference). These Wilk references teach the use of a stent which is introduced through the myocardial wall from an adjacent coronary artery to provide a bypass conduit between the left ventricle and the adjacent coronary artery. In one embodiment, this technique teaches the delivery of a transmyocardial bypass shunt in a collapsed, reduced-profile configuration, which requires radial expansion subsequent to delivery in a bore pre-formed in the myocardial wall. The bore is formed, for example, by a drill, needle, Seldinger wire, dilating wires or catheters, or other devices prior to stent placement and expansion.

[0013] In another embodiment, Wilk discloses the disposition of a stent in the myocardium so that the stent extends only in the myocardium. The stent may extend only partially through the myocardium, from the left ventricle of the heart or from a coronary artery, upstream of a vascular obstruction. Alternatively, the stent may extend completely through the myocardium to establish a blood flow path or conduit from the left ventricle to a coronary artery, downstream of a vascular obstruction.

[0014] Where stents are used in the Wilk cardiac revascularization techniques to guide blood from the left ventricle, the stents may be designed to lock upon opening from collapsed insertion configurations. Such stents enable the infusion of blood into the myocardium during systole. The stents may be provided with one-way valves to regulate or control the backflow of blood during diastole.

[0015] Thus, there is a continuing need for improved bypass methods and apparatus that allow for the realization

of increased long-term patency rates, and that are less physically traumatic to the patient.

## SUMMARY OF THE INVENTION

[0016] Thus, in one preferred embodiment there is provided a new apparatus and method for performing a coronary artery by-pass operation which is less invasive and less traumatic to the patient than conventional by-pass surgery. Another advantage of this embodiment is that it requires no incision through the chest wall. In another embodiment there is provided a catheter assembly for use in performing the method of the invention.

[0017] Conduit Utilizing Intrapericardial Space

[0018] In another embodiment, there is provided methodology and related medical devices for effectively bypassing a blocked or partially blocked coronary artery and providing oxygenated blood to the myocardium. In accordance with this embodiment, a coronary artery bypass method utilizes a fluid communication conduit or shunt member. An upstream end portion of the shunt member is disposed in the myocardium of a patient's heart so that the upstream end portion communicates with the left ventricle of the patient's heart. An opposite downstream end portion of the shunt member is placed in communication with a coronary artery of the patient downstream of a blockage in the coronary artery, so that an intermediate or middle portion of the shunt member is disposed in an intrapericardial space of the patient, outside of the myocardium and outside of the coronary artery. The downstream end portion of the shunt is inserted into the coronary artery or, alternatively, attached to a generally anterior wall of the coronary artery.

[0019] Where the downstream end portion of the shunt is attached to the anterior wall of the coronary artery, the method further comprises forming an aperture in the anterior wall of the coronary artery after attaching the downstream end portion of the shunt member to the anterior wall, thereby opening communication between the shunt member and the coronary artery. The shunt member is preferably delivered intravascularly into the left ventricle of the patient's heart. The downstream end portion of the shunt member is then passed completely through the myocardium and the intrapericardial space to the anterior wall of the coronary artery. The aperture in the coronary artery is formed by inserting a free end portion of an incising instrument intravascularly and through the shunt member after disposition of the upstream end portion of the shunt member in the myocardium and after attaching of the downstream end portion of the shunt member to the coronary artery. The incising instrument is operated, after inserting thereof, to perforate the anterior wall of the coronary artery.

[0020] The incising instrument may be a laser instrument including an optical fiber. The incising instrument is operated in part by transmitting monochromatic or laser radiation through the optical fiber to the anterior wall of the coronary artery.

[0021] The method utilizing the shunt member further comprises forming a passageway through the myocardium prior to the disposing of the upstream end portion of the shunt member in the myocardium. The passageway is formed by inserting a surgical instrument intravascularly into the left ventricle of the patient and operating the instrument from outside the patient to bore or tunnel through the myocardium. The upstream end portion of the shunt member is disposed in the passageway and subsequently the downstream end portion of the shunt member is placed in communication with the coronary artery of the patient.

[0022] The shunt member may be deployed in a pericardioscopic operation wherein pericardioscopic surgical instruments are operated from outside the patient to manipulate the downstream end portion of the shunt member and to place the downstream end portion of the shunt member into communication with the coronary artery of the patient after passing of the downstream end portion of the shunt member through the passageway in the myocardium.

[0023] Where the downstream end portion of the shunt member is inserted into the coronary artery, the sequence of operations is similar to the case where the shunt member is attached to the anterior wall of the coronary artery. The shunt member is delivered intravascularly into the left ventricle of the patient's heart and subsequently the downstream end portion of the shunt member is passed through the myocardium; the downstream end portion of the shunt member is then inserted into the coronary artery. In this case, as well, the shunt member may be deployed in a pericardioscopic operation wherein pericardioscopic surgical instruments are operated from outside the patient to place the downstream end portion of the shunt member in communication with the coronary artery.

[0024] Generally, in the above-described procedure, the downstream end portion of the shunt member communicates with the coronary artery downstream of a blockage. During systole, blood travels from the patient's left ventricle through the shunt member to the coronary artery and then to the myocardium along natural vessels. It may be necessary, in some patients, to provide two or more shunt members, depending on the number of blockages and their locations along the coronary artery.

[0025] Conduit Construction

[0026] The shunt or conduit member comprises a generally tubular, rounded or circumferential member having a length greater than a width of the myocardium. The shunt member is made of a biocompatible material such as polyethylene or GORTEX™ and is flexible at least along the middle or intermediate portion thereof. Accordingly, the intermediate or middle portion of the shunt member may be bent into an arc to facilitate the formation of a proper junction between the downstream end portion of the shunt member and the coronary artery of the patient. The tubular shunt member may be provided with a one-way valve preventing back flow of blood from the coronary artery into the ventricle. In a specific embodiment of the invention, the upstream end portion of the tubular shunt member is wider than the downstream end portion.

[0027] As discussed above, an upstream end portion of a generally tubular shunt member may be disposed in a myocardium of a patient's heart so that the upstream end portion communicates with a left ventricle of the patient's heart, while a downstream end portion of the shunt member is inserted into a coronary artery of the patient downstream of a blockage in the coronary artery so that the downstream end portion is disposed inside the coronary artery. In a variation of the present invention, the shunt member is

deployed so as to be disposed only inside the myocardium and the coronary artery. In contrast to the above-described methodology, no portion of the shunt member lies in the intrapericardial space. In this variation of the method, the shunt member is again delivered intravascularly into the left ventricle of the patient's heart, with the downstream end portion being passed through the myocardium. However, in this variation, the downstream end portion is inserted directly into the coronary artery through a posterior wall thereof in contact with the myocardium.

[0028] Posterior Wall Access

[0029] A method for performing a myocardial revascularization comprises, in accordance with another embodiment of the present invention, forming a passageway at least partially through a myocardium of a patient from an outer surface of the patient's heart, and performing a surgical operation at an outer end of the passageway to permanently close the passageway at the outer end. In a particular implementation of this embodiment of the invention, the passageway includes a portion extending though a posterior wall of a coronary artery and is produced by forming an aperture in an anterior wall of the coronary artery and forming the passageway in substantial alignment with the aperture. In this case, the closure of the passageway is effectuated particularly by closing the aperture in the anterior wall of the coronary artery. The closing of the aperture in the anterior wall of the coronary artery may be effectuated by one or more of several techniques, including suturing, plugging, and laser coagulation. To reinforce the closure of the artery wall, a brace may be placed over the closure. The brace may take the form of a biocompatible patch attached to the heart via suturing or laser welding.

[0030] Conduit Configurations

[0031] Pursuant to another feature of a myocardial revascularization technique, in accordance with yet another embodiment of the present invention, a stent is inserted into the passageway formed at least partially through the patient's myocardium. The inserting of the stent is preferably performed prior to the performing of the surgical operation to close the passageway at the outer end. The myocardial revascularization technique, including the insertion of the stent, may be performed in open heart surgery or in a pericardioscopic operation. In either case, the aperture in the anterior wall of the coronary artery and the passageway in the myocardium are formed by operating an instrument taken from the group consisting of a surgical drill and a surgical laser.

[0032] The passageway formed to communicate at an inner end with a left ventricle of the patient may communicate at an outer end with a coronary artery or, alternatively, may terminate in the myocardium after closure of the outer end of the passageway. In the former case, blood flows from the left ventricle through the passageway, the coronary artery and blood vessels communicating with the coronary artery. In the latter case, the myocardium is revascularized directly by the passageway, rater than indirectly through the coronary artery and its tributaries.

[0033] In a myocardial revascularization technique in accordance with another embodiment of the present invention, the passageway may be one of a plurality of similarly formed passageways extending from the coronary artery into the myocardium of the patient. Each passageway is produced by forming a plurality of openings in the anterior wall of the coronary artery and forming the passageways in alignment with respective ones of the openings. The passageways are effectively closed from the external environment (the intrapericardial space) by closing the openings in the anterior wall of the coronary artery. Where a myocardial passageway formed in accordance with this embodiment does not extend through or into a coronary artery, the closure of the passageway is effectuated on an epicardium of the patient.

[0034] A stent for a coronary artery bypass or myocardium revascularization procedure in accordance with another embodiment of the present invention has a collapsed configuration and an expanded configuration. The expanded configuration may have an arcuate form, to provide a curved flow path for blood upon implantation of the stent into a myocardium of a patient. This curved flow path smoothly redirects blood flow and minimizes possible adverse effects that the impulsive force of the blood might have on the patient's coronary artery and other layers of heart tissue. The stent may have a one-way valve for preventing retrograde flow of blood.

[0035] Another stent in accordance with another embodiment has a collapsed configuration and an expanded configuration and is provided with a sensor and means for transmitting signals from the sensor to a receiver external to the stent. The sensor is taken from the group consisting of a pressure sensor and a flow sensor.

[0036] Self-Inserting Conduits

[0037] In yet another embodiment of the present bypass apparatus there is provided a self-inserting conduit for diverting blood directly from the left ventricle of the heart to the coronary artery at a point distal to the blockage, therefore bypassing the blocked portion of the vessel. The shunt comprises a stent in the form of a single conduit having an opening at either end, and adapted to be positioned in the myocardium. The coronary artery, the myocardium and the wall of the left ventricle of the heart are pierced by the conduit from an outside space or tissue in a transverse manner to provide a channel completely through from the coronary artery to the left ventricle of the heart. An opening located on the distal end of the conduit is positioned in the coronary artery. Oxygenated blood is pumped from the left ventricle, through the distal opening, through the hollow central portion of the conduit, out of the proximal opening and into the coronary artery distal to the blockage. The conduit is anchored in the myocardium to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage.

[0038] The apparatus of the present invention is preferably implanted in a minimally invasive manner using thoroscopy or another endoscopic procedure, although open surgery or other means of vascular access are also possible.

[0039] Coronary Bypass

[0040] The present system preferably utilizes a combination conduit comprising an access and shunt device for forming a diversion of the blood from the coronary and proximally to the stenosis. A similar access and shunt device is located in the vessel distal of the stenosis to receive the diverted blood and allow it to continue on its course down-

stream. The combination access/shunt device comprises a conduit element for providing access to the vessel and anchoring the system in place. The conduit pierces the artery from the outside and travels completely through it and into the myocardium or other heart tissue adjacent the coronary artery. The conduit has a conduit or barb or series of barbs on its distal end and is otherwise designed so that it has substantial resistance to pull back or exit from the vessel. As noted, the conduit pierces through the vessel from an outside space or tissue in a transverse manner. Mounted on top of the conduit is a shunt device which comprises an aperture and a diversion conduit. With the conduit in its anchoring position, the shunt device is located partially in the vessel and partially outside of the vessel from the direction in which the conduit entered. The aperture resides in the vessel to allow blood to enter therein and from there to the diversion tube which is in fluid communication with the aperture. This provides the shunt of blood into the diversion tube of the combination access/shunt device. Mounted on top of the diversion tube is a connector piece which mates with a bypass conduit. These elements are also in fluid communication to allow the blood to bypass the blockage and to be shunted to a location distal thereof.

[0041] At such distal location, another similar combination access/shunt device is placed to allow the shunted blood to re-enter the artery in a free-graft configuration, and continue on its path downstream. However, a single device can be used distal of the restriction and connected to an appropriate graft for revascularization.

[0042] The apparatus of the present invention is preferably implanted in a minimally invasive manner using thoroscopy or other endoscopic procedure, although open surgery or other means of vascular access are also possible. The apparatus can be implanted permanently, or can be used temporarily to provide a bypass system during various surgical procedures, including coronary bypass procedures.

[0043] Thus, the present system is used to direct the flow of blood around the blocked portion of the vessel. In one embodiment, a shunt is used to direct blood directly from the left ventricle of the heart to the coronary artery at a point distal to the blockage. According to one aspect of the invention, the shunt comprises a rigid, generally elongated stent in the form of a single conduit having an opening at either end, and adapted to be positioned in the myocardium. The coronary artery, the myocardium and the wall of the left ventricle of the heart are pierced by the conduit from an outside space or tissue in a transverse manner to provide a channel completely through from the coronary artery to the left ventricle of the heart. An opening located on the distal end of the conduit is positioned within the left ventricle. An opening on the proximal end of the conduit is positioned in the coronary artery. Oxygenated blood is pumped from the left ventricle, through the distal opening, through the hollow central portion of the conduit, out of the proximal opening and into the coronary artery distal to the blockage. The conduit is anchored in the myocardium to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage.

[0044] Alternatively, the conduit can be used temporarily to maintain blood flow through the coronary artery during therapeutic procedures, such as coronary bypass. The conduit can be used to deliver a vein graft, and to provide for the passage of blood around the blockage until the anastomosis of the graft is complete.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0045] FIGS. **1A-1E** are schematic cross-sectional views of a human heart, showing successive steps in a transmyocardial coronary artery bypass operation in accordance with one conduit embodiment of the present invention.

[0046] **FIG. 2** is a schematic cross-sectional view of a human heart showing an alternative conduit to that used in the operation of FIGS. **1A-1E**.

[0047] **FIG. 3** is a schematic partial cross-sectional view, on a larger scale, showing a modification of the coronary artery bypass produced by the operation of FIGS. **1A-1E**.

[0048] **FIG. 4** is a schematic cross-sectional view of a human heart showing a modification of the coronary artery bypass operation depicted in FIGS. **1A-1E**.

[0049] **FIG. 5** is a schematic partial cross-sectional view, on a larger scale, showing a variation of the coronary artery bypass of **FIG. 4**.

[0050] **FIG. 5A** is a schematic view of a human heart showing a two piece conduit connecting the left ventricle to the left anterior descending coronary artery.

[0051] **FIG. 5B** is an enlarged view of the two piece conduit of **FIG. 5A**.

[0052] **FIG. 5C** is a schematic cross-sectional view of the two piece conduit of **FIG. 5B**.

[0053] **FIG. 6A** is a schematic partial cross-sectional view of another coronary artery bypass showing a conduit or shunt with a one-way valve opened during systole.

[0054] **FIG. 6B** is a schematic partial cross-sectional view similar to **FIG. 6A**, illustrating the shunt of **FIG. 6A** with the valve closed during diastole.

[0055] FIGS. **6C-6H** are perspective views of conduits or stents with openings into the coronary artery having hoods, valves, or other flow direction/flow control devices.

[0056] **FIG. 7** is a schematic cross-sectional view of a human heart showing instrumentation used for implanting the shunt of **FIGS. 6A and 6B**.

[0057] **FIG. 8** is a schematic partial cross-sectional view of an arcuate conduit or stent with a one-way valve utilized in a further coronary artery technique.

[0058] FIGS. **8A-8B** are schematic partial cross-sectional views of arcuate conduits or stents having narrow openings into the coronary artery.

[0059] FIGS. **8C-8P** are schematic partial cross-sectional views of conduits or stents having a variety of configurations to achieve flow control therethrough and to minimize backflow.

[0060] **FIG. 9** is a block diagram of operational components with feedback as to operational parameters.

[0061] FIGS. **9A-9B** illustrate a conduit having a flow sensor for measuring various blood flow parameters incorporated therein.

[0062] **FIG. 9C** is a schematic partial cross-sectional view of a conduit having the flow sensor **FIG. 9B** as installed between two vessels.

[0063] FIGS. **10A-10C** are schematic cross-sectional views of a human heart, showing successive steps in a transmyocardial coronary artery bypass operation utilizing a penetrating rod for implanting a conduit.

[0064] **FIG. 11** is a schematic cross-sectional view similar to **FIG. 10C**, showing three transmyocardial conduits or stents implanted pursuant to the procedure of FIGS. **10A-10C**.

[0065] **FIG. 12** is a schematic partial cross-sectional view of an artificial myocardial revascularization showing a plurality of partial conduits or stents extending from a coronary artery partially into the myocardium.

[0066] **FIG. 13** is a schematic front elevational view of a human heart, showing an improvement in the myocardial revascularization of **FIG. 12**.

[0067] **FIGS. 14A and 14B** are schematic cross-sectional views of a human heart, showing successive steps in an artificial myocardial revascularization procedure, resulting in a plurality of conduits or stents extending from a left ventricle of the heart at least partially into the myocardium.

[0068] **FIG. 15** is a schematic partial cross-sectional view of a human heart, illustrating a modification to the artificial myocardial revascularization of **FIG. 14B**.

[0069] **FIG. 16** is a schematic partial cross-sectional view of a human heart, illustrating a heart provided in a left ventricle with implants or plugs.

[0070] **FIG. 16A** is a schematic partial cross-sectional view of a conduit or plug, having therapeutic materials applied thereto.

[0071] **FIG. 16B** is a side view of a biodegradable conduit or stent positioned within the myocardium, with the coronary artery and myocardium shown cut-away.

[0072] FIGS. **16C-16F** are schematic, cross-sectional views of the external insertion of an absorbable intramyocardial plug in the myocardium.

[0073] FIGS. **16G-16I** are schematic, cross-sectional views of the insertion of absorbable intramyocardial plugs in the myocardium via the left ventricle.

[0074] FIGS. **16J-16N** are schematic, cross-sectional views of the external insertion of absorbable intramyocardial plugs used to form a conduit or shunt through the myocardium from the left ventricle to the coronary artery.

[0075] FIGS. **16O-16S** are schematic, cross-sectional views of the external insertion of absorbable intramyocardial plugs in the myocardium.

[0076] **FIG. 17** is a small scale cross-sectional view of a heart with a blockage in the coronary artery and illustrating a self-inserting conduit.

[0077] **FIG. 18** is a close-up perspective view of one embodiment of the device of **FIG. 17** shown implanted in the myocardium, with the coronary artery, myocardium and left ventricle of the heart shown cut-away.

[0078] **FIG. 18A** is a schematic partial cross-sectional view of a self-inserting conduit, having dual prongs in the head or flange thereof to prevent rotation.

[0079] FIGS. **19A-C** illustrate a method for implanting the conduit device of **FIG. 17**.

[0080] FIGS. **20A-B** illustrate an alternate method for implanting the conduit device of **FIG. 17**.

[0081] **FIG. 21** is a small scale cross-sectional view of a heart with a blockage in the coronary artery, and further illustrating another embodiment of the bypass device of this embodiment;

[0082] **FIG. 22** is a close-up cross-sectional view of the blockage in the coronary artery and illustrating in greater detail the bypass device of the present invention;

[0083] FIGS. **22A-22B** are schematic partial cross-sectional views of conduits similar to that described in **FIG. 22** illustrating alternative blood flow embodiments.

[0084] **FIG. 23** is a perspective view of the bypass device and conduit;

[0085] **FIG. 24** is a close-up view of a combination access/shunt conduit device having a distal tip;

[0086] **FIG. 25** is a perspective view of an alternative embodiment of a combination access/shunt device conduit;

[0087] [**FIG. 26** is reserved]

[0088] **FIG. 27** is a perspective view of a third combination access/shunt embodiment which has a tapered configuration;

[0089] **FIG. 28** is a perspective view of a fourth combination access/shunt embodiment with dual distal tips.

[0090] **FIG. 29** is a perspective view of a conduit or shunt device according to a fifth embodiment of a combination access/shunt;

[0091] **FIG. 30** is a perspective view of a conduit or shunt device according to a sixth embodiment of a combination access/shunt;

[0092] **FIG. 31** shows the shunt device of **FIG. 29** in cross-section;

[0093] **FIG. 32** is a close-up cross-sectional view of a coronary artery blockage and the myocardium of a patient and the shunt device according to **FIG. 29**;

[0094] **FIG. 33** is a perspective view of a side-by-side bypass device;

[0095] **FIG. 33A** is a schematic cross-sectional view illustrating the coronary bypass system which is more parallel to the coronary artery.

[0096] **FIG. 34** is a perspective view of another side-by-side bypass embodiment;

[0097] **FIG. 35** is a perspective view of a third side-by-side bypass embodiment;

[0098] [**FIG. 36** is reserved]

[0099] **FIG. 37** is a close-up cross-sectional view of a coronary artery and the myocardium of a patient and the shunt device according to **FIG. 34**;

[0100] **FIG. 38** is a close-up cross-sectional view of a coronary artery of a patient and the shunt device according to **FIG. 36**.

[0101] FIGS. **39**A-B illustrate the temporary use of a stent during a coronary bypass procedure.

[0102] **FIGS. 40 and 40**A-**40**Q show a variety of members for securing segments of tissue to each other, as well as conduit members.

[0103] **FIG. 41** shows a conduit of variable wall thickness.

[0104] **FIGS. 42, 43**, **44**A-**44**C, and **45** show conduits designed to take advantage of flow resistance to facilitate flow control.

[0105] FIGS. **46**, **47**A-**47**D, **48**, **48**A-**48**C, and **49** show curved conduits that direct blood flow downstream in a direction that is substantially parallel to the bloodstream in the vessel.

[0106] FIGS. **50**A-**50**C and **51**A-**51**D show a variety of conduits of a lattice construction.

[0107] **FIG. 52** shows a conduit having a T-like distal portion.

[0108] **FIG. 53** shows a conduit that has an articulating distal portion.

[0109] **FIG. 54** shows a conduit that has an elastomeric distal anchoring arm.

[0110] In the drawings, the same reference designations are used to designate the same objects. The word "distal" when used herein designates an instrument end which is spaced from the surgeon, radiologist or other operator. The physical relation of the instrument to the patient is not determinative.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0111] The principles of the present invention are not limited to left ventricular conduits, and apply to conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

[0112] In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the intrapericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

[0113] The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

[0114] The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

[0115] The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. In this regard, the anastomotic devices and methods utilized in connection with the various embodiments of the present invention are to be broadly construed to relate to connections of these various components. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods are disclosed. In one embodiment, the delivery rod is solid and trocar like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. The delivery rod may be an incising instrument such as a laser or a drill. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably removed leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

[0116] Further details regarding conduits and conduit delivery systems are described in copending patent applications entitled DELIVERY METHODS FOR LEFT VENTRICULAR CONDUIT [Attorney Docket No. PERCAR.003CP1], DESIGNS FOR LEFT VENTRICULAR CONDUIT [Attorney Docket No. PERCAR.013A], LEFT VENTRICULAR CONDUIT WITH BLOOD VESSEL GRAFT [Attorney Docket No. PERCAR.005A], VALVE DESIGNS FOR LEFT VENTRICULAR CON-

DUIT [Attorney Docket No. PERCAR.006A], and BLOOD FLOW CONDUIT DELIVERY SYSTEM AND METHOD OF USE [Attorney Docket No. PERCAR.040A], filed on the same day as the present application, and U.S. Pat. Nos. 5,429,144 and 5,662,124, the disclosures of which are all hereby incorporated by reference in their entirety.

[0117] Conduits Utilizing Intrapericardial Space

[0118] In a transmyocardial coronary artery bypass operation illustrated in FIGS. **1A-1E**, a catheter **12** is inserted over a guidewire (not illustrated) through the vasculature of a patient and particularly through the aorta AO into the left ventricle LV of the patient's heart PH. (Although the embodiments described herein are discussed with respect to the left ventricle LV, they may also be applied to the right ventricle RV and the right and left atria.) Upon arrival of a distal end of catheter **12** in left ventricle LV, the guidewire is withdrawn and a surgical incising instrument **14** such as a light-transmitting optical fiber is inserted through catheter **12**. The catheterization procedure is monitored via conventional radiographic techniques or, alternatively, via a CAT scanner or MRI machine.

[0119] Upon ejection of a distal tip of optical fiber **14** from catheter **12** into left ventricle LV, the fiber tip is placed into contact with a heart wall HW of the patient at a predetermined location downstream of an arterial blockage BL in the coronary artery CA of the patient, as illustrated in **FIG. 1A**. A laser source **16** is then activated to transmit monochromatic electromagnetic radiation along optical fiber **14** to heart wall HW. The distal end of fiber **14** is pushed through heart wall HW, with the radiation being continuously or periodically transmitted through optical fiber **14**, thereby forming a transmyocardial passageway **18** in heart wall HW **(FIG. 1B)**.

[0120] After the formation of passageway **18**, optical fiber **14** is withdrawn from catheter **12** and replaced with a guidewire **20 (FIG. 1C)**. In addition, catheter **12** is pushed in a forward direction through passageway **18** so that a distal end portion of the catheter extends outwardly from passageway **18** into an intrapericardial space IS. A shunt **22** made of flexible biocompatible material such as polyethylene or GORTEX™ is then passed over guidewire **20** and through catheter **12**. At this juncture, a forceps instrument **24 (FIGS. 1C and 1D)** inserted into the patient via a pericardioscopic cannula or port (not shown) or through an open incision (not shown) is used to grasp shunt **22** and direct a free end of the shunt to an anterior wall AW of coronary artery CA, as illustrated in **FIG. 1D**. A laser instrument **26** is then used to attach the free end of shunt **22** to the anterior wall AW of coronary artery CA. At this point in the operation, there is no avenue of communication between left ventricle LV and coronary artery CA.

[0121] After the attachment of shunt **22** to anterior wall AW of coronary artery CA, optical fiber **14** is again inserted through catheter **12** and through shunt **22** to anterior wall AW of coronary artery CA. Laser source **16** is temporarily activated to form an aperture in anterior wall AW of coronary artery CA inside shunt **22**, thereby establishing a transmyocardial coronary artery bypass path from left ventricle LV into the coronary artery downstream of blockage BL as illustrated in **FIG. 1E**. After the formation of the aperture in coronary artery CA, fiber **14** is withdrawn from shunt **22** and catheter **12** is withdrawn from heart wall HW. Optical fiber **14** may be used at that time (or previously) to attach an upstream end of shunt **22** to heart wall HW at left ventricle LV. The optical fiber **14** and catheter **12** are then extracted from the patient. The deployed shunt **22** extends from left ventricle LV through heart wall or myocardium HW to anterior wall AW of coronary artery CA, with a middle or intermediate portion (not separately designated) of shunt **22** being disposed in intrapericardial space IS.

[0122] **FIG. 2** depicts a transmyocardial coronary artery bypass similar to that shown in **FIG. 1E**, except that a different shunt **28** is used. Shunt **28** is provided at opposite ends with flanges **30** and **32** in the form of annular disks. These flanges **30** and **32** facilitate the attachment of shunt **28** to the heart wall HW at left ventricle LV and to anterior wall AW of coronary artery CA, respectively. The attachment of flanges **30** and **32** to heart wall HW and coronary artery CA may be effectuated by laser instrument **26** and/or by other techniques including gluing and suturing. Shunt **28** is installed in the manner described above with reference to FIGS. **1A-1E**.

[0123] The structure of shunt **28**, as well as different uses thereof, is described and illustrated in U.S. Pat. No. 5,470,320, the disclosure of which is hereby incorporated by reference.

[0124] **FIG. 3** shows a modification of the transmyocardial coronary artery bypass of **FIG. 1E**. The downstream end of shunt **22** is attached to anterior wall AW of coronary artery CA via sutures **34**. A stent **36** with a one-way valve **38** is placed inside an upstream portion of shunt **22** located within heart wall or myocardium HW. Stent **36** functions to clamp the upstream end of shunt **22** to heart wall HW. One-way valve **38** permits blood to flow from ventricle LV to coronary artery CA during systole and prevents backflow to ventricle LV during diastole. Where shunt **22** is installed without stent **36**, shunt **22** may be provided with an integral one-way valve (not illustrated). Stent **36** is generally introduced into heart PH in a collapsed configuration through a catheter. Stent **36** may be predisposed inside the upstream end portion of shunt **22** and inserted therewith into heart PH. Alternatively, stent **36** may be inserted into shunt **22** after the shunt has been passed through passageway **18** and before or after the attachment of the downstream end of shunt **22** to anterior wall AW of coronary artery CA. Stent **36**, and other stents and shunts disclosed herein, may be provided with outwardly projecting barbs (not illustrated) for anchoring the stent or shunt to the myocardium.

[0125] In another variation (not illustrated) of the transmyocardial coronary artery bypass of **FIG. 1E**, shunt **22** has an upstream portion which is a stent. The stent is substantially coextensive with or smaller than passageway **18** and is accordingly lodged completely within passageway **18** upon installation of the shunt **22**. The remainder of the shunt **22** is made of a continuous, essentially impermeable biocompatible film material, as in the embodiment discussed above.

[0126] As illustrated in **FIG. 4**, another modification of the transmyocardial coronary artery bypass of **FIG. 1E** includes the insertion of a downstream end portion **40** of shunt **22** through an aperture **42** formed in anterior wall AW of coronary artery CA downstream of blockage BL. Clearly, in this bypass procedure, aperture **42** is formed in coronary artery CA prior to the joining of the downstream end portion **40** of shunt **22** and coronary artery CA. Aperture **42** is

formed by an incising instrument (not shown) such as a laser or a scalpel blade which is inserted into intrapericardial space IS either through a pericardioscopic cannula or port (not shown) or through an open incision. Shunt **22** may be attached, by laser welding, glue or sutures, to coronary artery CA at aperture **42**. As discussed hereinabove with respect to the embodiment of **FIG. 1**E, an intermediate or middle portion **44** of shunt **22** is disposed inside intrapericardial space IS upon deployment of shunt **22**. A brace **48**, for example, in the form of a patch (compare with **FIG. 13**), may be disposed over middle portion **44** of shunt **22** and attached to heart PH, to support the shunt **22** against possible dislodgment owing to the hydraulic forces of blood flow and the mechanical forces of myocardium contraction. Brace or patch **48**, and similar braces or patches disclosed herein, is made of a strong biocompatible material such as KEVLAR™, polytetrafluoroethylene, silicone, etc.

[**0127**] **FIG. 5** illustrates the shunt-implemented transmyocardial coronary artery bypass of **FIG. 4**, with a one-way valve **50** being provided at the upstream end of shunt **22** for permitting blood flow from ventricle LV into coronary artery CA during systole and for preventing blood flow from coronary artery CA toward ventricle LV during diastole.

[**0128**] Conduit Configurations

[**0129**] **FIG. 5A** illustrates a human heart PH, showing more particularly the left anterior descending coronary artery CA. The technical challenge presented herein is placing a conduit accurately and aligned properly between the left ventricle LV and the coronary artery CA. A conduit **49** is shown in FIGS. **5**A-**5**C comprising two separate pieces, namely an access port **51** which punctures through the heart wall HW, including the myocardium, to the left ventricle LV, and an anastomosed segment **53**. To place the conduit **49**, the access port **51** is inserted into the heart wall HW from the outside of the heart PH, preferably adjacent but not necessarily through the coronary artery CA. Flange **55** determines the position of the port **51** by pressing against the outside of the heart PH, and the port extends into the left ventricle LV with a lumen **57** extending therethrough. The end of the port **51** on the outside of the heart wall HW may be curved as shown in **FIG. 5C**. After the port **51** is inserted, the port is connected to the artery CA preferably using a segment **53** which is more preferably an artificial graft. The location where the segment **53** is anastomosed to the coronary artery may preferably be downstream of a blockage (not shown) in the coronary artery CA.

[**0130**] The embodiment of FIGS. **5**A-**5**C is advantageous in that it does not require extremely accurate placement of the port **51** into the heart PH. This is especially important because during a beating heart procedure placement of a device through the heart PH may be difficult. More specifically, as shown in FIGS. **5**A-**5**C, the port **541** need not be positioned at a very precise position through or adjacent the coronary artery CA. Rather, the port **51** need only be placed near the coronary artery CA, and the graft segment **53** is used to connect the port **51** to the coronary artery CA. It will be appreciated that multiple conduits may be made to the artery CA.

[**0131**] As depicted in **FIGS. 6A and 6B**, a transmyocardial coronary artery bypass is implemented by a conduit or shunt member **52** provided at an upstream end with a one-way valve **54**. Shunt member **52** extends directly from left ventricle LV through heart wall HW into coronary artery CA and includes an upstream portion **56** disposed within heart wall or myocardium HW and a downstream portion **58** disposed in coronary artery CA. Shunt member **52** may have a tapered form which narrows down in a downstream direction so that downstream portion **58** is of smaller cross-section than upstream portion **56**. Upstream portion **56** may take the form of a stent which is expanded from a collapsed insertion configuration to an expanded use configuration to lock or clamp shunt member **52** to a passageway **60** formed in heart wall or myocardium HW prior to the insertion of shunt member **52**. Downstream portion **58** is made of a continuous, essentially impermeable biocompatible film material. In addition, upstream portion **56** may be flexible to an extent so as to expand, if necessary, during diastole (**FIG. 6B**) to accommodate some backflow. It will also be noted in connection with **FIG. 6**B, the upstream portion **56** also acts as a reservoir to accumulate blood during systole which is then passed into the coronary artery CA during diastole.

[**0132**] Shunt **52** is curved and bears the force of the blood ejected from left ventricle LV through passageway or channel **60** during systole.

[**0133**] Other one way valve embodiments are shown in FIGS. **6**C-**6**H and are particularly useful for directing laminar flow and controlling the flow of blood. **FIGS. 6C and 6D** show the open and closed positions, respectively, of a conduit **700**. The conduit comprises a relatively soft, pliable portion **704** and a harder, firmer portion **708**. In the open configuration (**FIG. 6C**), blood flows out of a hole **712** in the conduit **700** and into the left ventricle LV. The softer portion **704** has a resiliency such that a hood or flap portion **716** closes during diastole, thereby blocking the flow of blood.

[**0134**] **FIGS. 6E and 6F** show another one way valve conduit embodiment **720** that comprises soft and hard portions **724** and **728**, respectively. The soft portion **724** includes a flap portion **732** having a series of slits **736** therein which may be spaced equidistantly from each other as shown, or alternatively, the slits may be spaced unequally from each other. The resiliency of the conduit **720** is such that it is open during systole (**FIG. 6F**) but closes partially during diastole (**FIG. 6F**).

[**0135**] **FIGS. 6G and 6H** show another one way valve conduit embodiment **740** comprising soft and hard portions **744** and **748**, in which a single slit **752** is formed in the soft portion **744**. As in embodiments **6**C-**6**D and **6**E-**6**F, the resiliency of the soft portion is such that the conduit **740** acts as a one-way valve, with the conduit opening during systole and partially closing during diastole. Further, conduits (not shown) having an opening for blood flow, but no slits, may be used in which the portion of the conduit around the opening partially or completely collapses (closes) during diastole, but is at least partially open during systole.

[**0136**] As illustrated in **FIG. 7**, the deployment or installation of shunt **52** in an intravascular procedure requires instrumentation for enabling the precise locating of the coronary artery CA with respect to possible insertion points in left ventricle LV. To that end, a first catheter **62** is utilized which is provided at a distal end with an electroacoustic transducer (not illustrated) for converting an electrical signal of ultrasonic frequency to a mechanical pressure wave which is transmitted through a posterior wall PW of coronary artery CA and heart wall or myocardium HW. Catheter

62 and particularly the electroacoustic transducer (not shown) is operatively connected to an ultrasonic wave generator 64. Another catheter 66 is also inserted through aorta AO (and over a conventional guidewire, not illustrated). This second catheter 66 is introduced into left ventricle LV and is provided at a free end with an acousto-electric transducer (not shown) for detecting pressure waves in an ultrasonic frequency range. Catheter 66 and its acoustoelectric transducer are operatively connected to an ultrasonic wave analyzer 68 which calculates the location of the distal tip of catheter 62 relative to the distal tip of catheter 66 and thus provides feedback to a surgeon or an insertion device for determining an insertion point and insertion angle for surgical incising instrument such as optical fiber 14 (FIG. 1A).

[0137] Several shunt members 22 or 52 may be necessary in cases of multiple coronary artery blockages. These multiple shunt members each tap into the coronary artery at a point downstream of a respective blockage.

[0138] As depicted in FIG. 8, a transmyocardial stent 70 for maintaining a circulation path between left ventricle LV of patient's heart PH and coronary artery CA is curved in the longitudinal or flow direction to provide an arcuate flow path. This curvature serves to deflect the hydraulic forces from a direction substantially perpendicular to coronary artery CA to a direction substantially parallel to coronary artery CA. This deflection serves to prevent coronary artery dilatation and to protect anterior wall AW of artery CA from the substantial hydraulic forces generated during systole. Thus, this deflection serves to control the flow of the blood through the stent 70 during systole. Moreover, since the stent 70 narrows and curves towards the coronary artery CA, it serves to prevent or minimize backflow into the stent 70 during diastole, thus obviating the need for a valve 72. Stent 70 may be optionally provided with a one-way valve 72 and may be deployed as discussed above with reference to FIG. 7. Curved stent 70 may be used as upstream portion 56 of shunt member 52 or in place of stent 36 (FIG. 3) or as an upstream portion of shunt 22. FIGS. 8A and 8B illustrate further arcuate stent embodiments for maintaining circulation between the left ventricle LV and the coronary artery CA. As in FIG. 8, the embodiments of FIGS. 8A and 8B include a transmyocardial stent 70 that is curved in the longitudinal or flow direction to provide an arcuate flow path.

[0139] FIGS. 8C and 8D illustrate how a catheter 800 may be introduced into the coronary artery CA (FIG. 8C) or on both sides of the heart wall (FIG. 8D) for boring out a portion of the heart wall HW to form an hourglass-shaped portion 804 within the heart wall HW. The hourglass shaped portion 804 acts to create a valve effect so that blood is at least partially blocked during diastole.

[0140] As seen in FIGS. 8E and 8F, a stent 808 may be positioned within the heart wall HW. As shown in FIG. 8E, the stent 808 is driven towards a closed position during diastole, whereas FIG. 8F shows the open position of the stent during systole. FIGS. 8G and 8H show an embodiment analogous to FIGS. 8E-F, except that a stent 812 is used that has a varying thickness. Using a stent 812 of nonconstant thickness has the effect of accentuating the deflection of the stent 812 at its central portion 814 relative to that at the outer portions 816 of the stent (at its ends).

[0141] Other stent designs may be used like the parallelpiped shaped stents 818 of FIGS. 8L-M (which may include a movable flap portion 820 for controlling the flow of blood) or the stents 824 illustrated in FIGS. 8N-O (which likewise may include a movable flap 828 for controlling the flow). FIGS. 81-8K show another embodiment which includes a conically-shaped stent 832 whose base is located on the coronary artery side. The stent 832 includes rims 834 and 836 for securing the stent 832 to the heart wall HW.

[0142] FIG. 8P illustrates an embodiment of a stent 850 which, like the embodiment of FIG. 8, maintains a circulation path between the left ventricle LV of patient's heart PH and coronary artery CA. The stent 850 has a lumen 852 therein which is curved, thereby deflecting hydraulic forces to control the flow of the blood through the stent 850 during systole. Further, the lumen 852 narrows and curves towards the coronary artery CA, which reduces backflow into the stent 850 during diastole and reduces the need for a valve. Nevertheless, the stent 850 may be optionally provided with a one-way valve 72 and may be deployed as discussed above with reference to FIG. 7. Further, the stent 850 may be used as upstream portion 56 of shunt member 52 or in place of stent 36 (FIG. 3) or as an upstream portion of shunt 22. Unlike its counterpart in FIG. 8, however, the lumen 852 of FIG. 8P is oriented within the stent 850 such that the lumen 852 joins the coronary artery CA at an oblique angle when the stent 850 is oriented perpendicular to the coronary artery CA. This aids the practitioner in the proper positioning of the lumen 852, and insures that the lumen 852 will be oriented with respect to the coronary artery CA as shown in FIG. 8P when a flange 854 of the stent 850 is positioned against the coronary artery CA. Further, the stent 850 of FIG. 8P may advantageously have an outer dimension that is substantially constant in cross section.

[0143] A shunt or stent 74 may be provided with a pressure sensor 76 and/or a flow sensor 78, as illustrated in FIG. 9. Sensors 76 and 78 are attached to or incorporated into a wall 80 of shunt or stent 74 and have outputs operatively connected to a transmitter 82 which is also attached to or incorporated into shunt or stent wall 80. Output signals from sensors 76 and 78 which encode data pertaining to pressures and flow rates are relayed to a receiver 84 via transmitter 82. Transmitter 82 may be wireless or connected by a wire 86 to receiver 84. The pressure and flow rate data collected via sensors 76 and 78 are useful for monitoring the effectiveness of the implanted stents or shunts for any particular patient and thereby determining whether additional stents or shunts may be necessary for that patient. Receiver 84 may be physically located on a chest of the patient or otherwise nearby.

[0144] FIG. 9A illustrates a cross-section of the heart illustrating a stent 900 having incorporated therein a sensor 904 (shown in FIG. 9B) similar to the sensors described above in connection with FIG. 9. The sensor may be incorporated into the wall of the stent 900 as illustrated in FIG. 9B or may be associated with a stent in some other fashion. The sensor 904 may advantageously transmit an output signal which encodes data with respect to pressures and flow rates. For example, blood pressure during both systole and diastole may be monitored, and the sensor 904 may be used to indicate when the blood flow (or pressure) is decreasing or when the blood flow (or pressure) falls beneath a certain level. As shown in FIG. 9C, a conduit 910

having a sensor therein may be used between two vessels, such as an aorta **912** and a vein **914**.

[**0145**] Posterior Wall Access

[**0146**] As illustrated in FIGS. **10**A-**10**C, a transmyocardial coronary artery bypass may be performed from outside the patient's vascular system. An incising instrument **88** such as a laser or a drill is inserted pericardioscopically or through an open incision into the intrapericardial space IS and is operated to bore a passageway **90** in the heart wall or myocardium HW via the coronary artery CA, as shown in **FIG. 10A**. Passageway **90** (**FIG. 10B**) extends through heart wall HW and posterior wall PW of coronary artery CA and is aligned with an aperture **92** formed in anterior wall AW of coronary artery CA by the incising instrument **88**.

[**0147**] Upon the formation of passageway **90**, a stent **94** (**FIG. 10C**) is inserted in a collapsed configuration into the passageway and then expanded. Stent **94** may be inserted from outside the patient's vascular system, either through an open incision in the patient's chest or through a pericardioscopic cannula or port. Alternatively, stent **94** may be placed via a catheter **96** inserted through the vascular system including the aorta AO and the left ventricle LV. As in all cases of stent implantation described herein, stent **94** serves to maintain passageway **90** in an open state, i.e., prevents the closure of passageway **90** by muscular contraction forces during systole and, in the longer term, by natural healing processes of the myocardium.

[**0148**] After the formation of passageway **90** and after the installation of stent **94** via an extravascular operation, aperture **92** is closed, via sutures (not shown) and/or via a plug **98** (**FIG. 10C**) or patch which is stitched or laser bonded to anterior wall AW of coronary artery CA. If stent **94** is placed via an intravascular operation, aperture **92** is preferably closed prior to the disposition of the stent inside passageway **90**. A brace **100** in the form of a patch is optionally placed over plug **98** and fastened to heart PH via sutures, glue or welding to support the plug against possible dislodgment under blood pressure forces.

[**0149**] **FIG. 11** illustrates a triple transmyocardial coronary artery bypass wherein a plurality of stents **94**, **94***a* and **94***b* are placed in respective passageways (not separately designated) extending through heart wall or myocardium HW and posterior wall PW of coronary artery CA. The passageways are formed and the stents **94**, **94***a* and **94***b* inserted as described hereinabove with reference to FIGS. **10**A-**10**C. Plugs **98**, **98***a* and **98***b* are positioned in respective apertures (not separately designated) which are formed, as discussed above, in alignment with the passageways of stents **94**, **94***a* and **94***b*. A brace **102** in the form of a patch is optionally placed over plugs **98**, **98***a* and **98***b* and fastened to heart PH via sutures, glue or laser welding.

[**0150**] **FIG. 12** depicts a modification of the transmyocardial coronary artery bypass of **FIG. 11**, wherein passageways **104***a*, **104***b*, **104***c* and **104***d* are formed by the extravascular technique discussed above with reference to FIGS. **10**A-**10**C but which extend through posterior coronary artery wall PW and only part of the heart wall or myocardium HW from coronary artery CA. Stents **106***a*, **106***b*, **106***c* and **106***d* are inserted into respective passageways **104***a*, **104***b*, **104***c* and **104***d* via an extravascular operation. Thereafter, plugs **108***a*, **108***b*, **108***c* and **108***d* are inserted into or over respective apertures in anterior coronary artery wall AW aligned with passageways **104***a*, **104***b*, **104***c* and **104***d* and stents **106***a*, **106***b*, **106***c* and **106***d*. As illustrated in **FIG. 13, a** patch **110** may be placed over coronary artery CA and particularly over plugs **108***a*, **108***b*, **108***c*, **108***d* and attached via sutures **112** to heart PH to brace the plugs against dislodgment under systolic and diastolic blood pressures.

[**0151**] **FIGS. 14A and 14B** depict steps in a transmyocardial revascularization procedure. An incising instrument **114** such as a laser fiber or a drill is inserted in an extravascular procedure through an open chest incision or a pericardioscopic cannula or port and is used to form a channel or passageway **116** in heart wall or myocardium HW through the epicardium (not shown). A stent **118** is inserted into channel **116** in a collapsed configuration via an intravascularly deployed catheter **120** or in an extravascular operation. A plug **122** is inserted into an outer end of channel **116** to close off that outer end. Plug **122** may be attached to the epicardium of heart PH via a laser instrument **123** or via sutures (not shown). Several channels **116**, **116***a* and **116***b* may be formed and provided with respective stents **118**, **118***a* and **118***b* and respective plugs **122**, **122***a* and **122***b*, as illustrated in **FIG. 15**. A patch **124** may be placed over plug **122** or plugs **122**, **122***a* and **122***b* and attached via sutures **126** to heart wall HW.

[**0152**] Myocardial Plugs

[**0153**] The various conduits or stents disclosed herein may be provided with a layer of polymeric material carrying a biochemical composition, e.g., angiogenesis factor or the nucleic acid instructions therefor, for generating, stimulating, and enhancing blood vessel formation. As illustrated in **FIG. 16**, plugs **128** may be inserted into a patient's heart wall or myocardium HW from inside the left ventricle LV or right ventricle RV via an intravascularly deployed catheter (not shown). Alternatively, the plugs may be inserted into the heart wall or myocardium HW from outside of the heart in an open incision or pericardioscopic operation (not shown). In either case, the plugs carry angiogenesis factor, or the nucleic acid instructions therefor, for generating, stimulating, and enhancing vascular generation and growth. The angiogenesis factor is gradually released from the plugs, or stents, in time release fashion, to optimize the stimulation of vascular growth.

[**0154**] **FIG. 16A** is a schematic partial cross-sectional view of a triangular-shaped conduit comprising a plug **940** or stent or the like and having, for example, multiple factors applied thereto such as growth factors, genes, drugs, etc. The rate at which an applied factor is released may be controlled through appropriate configuration of the plug **940**, e.g., by controlling its porosity.

[**0155**] If desired, the stent or conduit of the present invention can be formed of biodegradable or bioabsorbable materials and/or used to deliver drugs directly into the myocardium and the coronary circulation. Such a stent **952** is illustrated in **FIG. 16B**. The biodegradable stent **952** can extend only partially through the heart wall HW as illustrated in **FIG. 16**B, but can also extend entirely through from the left ventricle LV to the coronary artery CA. Once positioned in the heart wall HW, the stent **952** degrades, dissolves or is absorbed over time to release drugs, genes, angiogenesis or growth factors, or other pharmaceutical compounds directly into the heart wall HW and the coronary

artery CA, as shown by the arrows in **FIG. 16B**. Bioabsorbable materials include, but are not limited to, polymers of the linear aliphatic polyester and glycolide families, such as polylactide and polyglycolide.

**[0156]** Such a stent is also illustrated in FIGS. **16C-16F**. **FIG. 16C** illustrates the external insertion of a solid, but absorbable stent or plug **1100**. A delivery device **1102**, such as a thoroscope bearing the intramyocardial plug **1100** is inserted into the heart wall HW at a site distal to the blockage BL in the coronary artery CA as shown in **FIG. 16D**. The insertion site in the heart wall HW is permanently closed using sutures **1104**, a plug, laser coagulation or similar means, as shown in **FIG. 16E**. This allows for myocardial revascularization. As the plug **1100** is absorbed, blood flows from the coronary artery CA into the passageway formed by the absorbed plug **1100**. This results in the ischemic myocardial area being revascularized. Alternatively, as illustrated in **FIGS. 16E and 16F**, the intramyocardial plug **1100** can be inserted through the heart wall HW such that it extends into the left ventricle LV. As the plug **100** is absorbed by the body, there remains a space or channel **1106** in the heart wall HW that perfuses with oxygenated blood from the left ventricle LV. This channel **1106** acts as do the channels formed in the heart during percutaneous transmyocardial revascularization (PTMR), allowing the heart muscle to be exposed to additional oxygenated blood.

**[0157]** FIGS. **16G-16I** illustrate an alternative means for delivering an absorbable plug **1110** into the heart wall HW. **FIG. 16G** illustrates the delivery of multiple plugs **1110** using a catheter **1112** threaded through the patient's vasculature and into the left ventricle LV of the heart. The plug **1110** is inserted into the myocardial wall as shown is **FIG. 16H**. The plug **1110** is absorbed over time, leaving an opening or channel **1114** in the heart wall HW (**FIG. 16I**) that perfuses with oxygenated blood from the left ventricle LV. This channel **1114** acts as do the channels formed in the heart during percutaneous transmyocardial revascularization (PTMR), allowing the heart muscle to be exposed to additional oxygenated blood.

**[0158]** Turning now to FIGS. **16J-16N**, there is shown the insertion of an absorbable intramyocardial plug **1120** that achieves the same result as a stent. The plug **1120** is inserted through the posterior wall of the coronary artery CA, either externally as described below, or internally using a delivery catheter threaded through the aorta AO and the coronary artery CA. External insertion is illustrated in FIGS. **16J-M**. In **FIG. 16J**, there is illustrated a thoroscope **1122** having the absorbable plug **1120** at its distal end inserted into the chest of the patient, until it reaches the heart. The plug **1120** is inserted through the posterior wall of the coronary artery CA and into the heart wall HW (**FIGS. 16K and 16L**). As the delivery device **1122** is removed, the hole in the anterior wall of the coronary artery CA is closed, using sutures **1124**, staples, laser coagulation, plugs such as GELFOAM, adhesives such as cyanoacrylate, or similar closure means, as illustrated in **FIG. 16M**. As the plug **1120** is absorbed, a shunt **1126** is formed between the left ventricle LV and the coronary artery CA, which allows for the passage of blood (**FIG. 16N**).

**[0159]** FIGS. **16O-16S** illustrate the insertion of absorbable intramyocardial plugs **1130** which result in the perfusion of the heart wall HW with blood flowing through the coronary artery CA. In **FIG. 16O**, there is illustrated a thoroscope **1132** having the absorbable plug **1130** at its distal end being inserted into the chest of the patient, until it reaches the heart. The plug **1130** is inserted through the posterior wall of the coronary artery CA, and only partially through the heart wall HW such that it stops before reaching the left ventricle LV of the heart (**FIG. 16Q**). As the delivery device **1132** is removed, the hole in the anterior wall of the coronary artery CA is closed, using sutures **1134**, staples laser coagulation, plugs, such as GELFOAM, adhesives such as cyanoacrylate or similar closure means, as illustrated in **FIG. 16R**. The plug **1130** is absorbed over time, leaving an opening or channel **1136** in the heart wall HW (**FIG. 16S**) that perfuses with oxygenated blood from the coronary artery CA. The channel **1130** acts as do the channels formed in the heart during percutaneous transmyocardial revascularization (PTMR), allowing the heart muscle to be exposed to additional oxygenated blood.

**[0160]** It is to be appreciated that the drawings herein are schematic. The stents and shunt portions in the forms of stents described herein may have a conventional wire infrastructure not shown in the drawings. Alternatively, the stents may be made of an elastic material having an internal spring constant permitting the stent to be temporarily collapsed and then returned to an opened configuration.

**[0161]** Intravascular or extravascular incising instruments disclosed herein for use in forming passageways or channels in the myocardium may be contact lasers or rotating or reciprocating drills. Other drilling or cutting instruments suitable for forming channels or tunnels may be used alternatively or additionally. Such instruments may take the form of ultrasonic cavitation devices, chemical devices for dissolving tissues, or heat treatment (electrocautery) devices.

**[0162]** Although suturing, gluing and laser welding are discussed herein for attaching plugs and reinforcement patches or braces to the cardiac tissues, equivalent alternatives to these techniques include stapling and tacking. Also, apertures in the epicardium or coronary artery may be closed without plugs or patches, for example, by the direct application of sutures or staples or by coagulation (electrical, thermal or laser).

**[0163]** It is to be understood that stents are preferred for maintaining open blood flow passageways in or through the myocardium. However, in some cases, stents may be omitted, for example, in the embodiments of **FIGS. 10C, 11, 12, 14A** and **14B** and **15**, depending on the needs of the patient.

**[0164]** Generally, stent **36** (**FIG. 3**), upstream portion **56** (**FIGS. 6A, 6B**) when in the form of a stent, stent **70** (**FIG. 8**), plugs **98**, **98***a*, **98***b* (**FIG. 11**), stents **106***a*-**106***d* (**FIG. 12**), and plugs **122**, **122***a*, **122***b* (**FIG. 15**) have lengths which are predetermined by measuring the thickness of the myocardium. Procedures for such measurements are described in U.S. Pat. Nos. 5,429,144 and 5,662,124, the disclosures of which are hereby incorporated by reference in their entirety.

**[0165]** Self-Inserting Conduits

**[0166]** As is well known, the coronary artery CA branches off the aorta AO and is positioned along the external surface of the heart wall HW. Oxygenated blood flows from the heart PH to the aorta AO, into the coronary artery CA, and

on to the rest of the body. In some individuals, plaque builds up within the coronary artery CA, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death.

[0167] In view of restoring the flow of oxygenated blood through the coronary artery CA, embodiments are disclosed which provide for the shunting of blood directly from the heart to a site in the coronary artery CA which is distal to the blockage BL. In a similar manner to that described above, a single rod-like conduit may utilize posterior heart wall access in order to be inserted through the walls of the coronary artery CA and the heart wall HW, and from there into the left ventricle LV of the heart PH which lies beneath the coronary artery CA. The hollow conduit is positioned such that the openings on either end of the conduit are within the coronary artery CA and the left ventricle LV. Blood flows through the opening in the left ventricle LV, through the hollow conduit and out of the opening positioned in the coronary artery CA distal to the site of the blockage BL. Thus, the self-inserting conduit is preferably rigid or at least semi-rigid in order to provide the ability to pierce through the heart wall or other tissue of the patient and to install the conduit as described above. In this case, the conduit is preferably a delivery rod in that it provides for its own delivery.

[0168] Referring to **FIG. 17**, there is shown a cross-sectional view of a typical heart PH, aorta AO, and the coronary artery CA having a blockage BL therein. The coronary artery CA lies along the external surface of the wall of the heart HW. As is well known, the coronary artery CA supplies oxygenated blood pumped from the left ventricle of the heart LV and through the aorta AO to the heart muscle or heart wall HW.

[0169] **FIG. 17** also illustrates in schematic fashion a bypass device **210** implanted distal to the blockage BL in the coronary artery CA. It should be noted that only the presently preferred embodiments of the bypass devices are described herein and only then in accordance with certain figures. However, arteries and vessels other than the coronary artery CA may be treated. As used herein, the term "vessel" shall be deemed to embrace any body organ, vessel, space or vasculature, including artificial members or prior implants, which contains or can contain bodily fluid. In addition, other types of blockages or vascular defects can be treated, including, for example, vascular bypass in other areas to alleviate problems such as aneurysms, deep vein thrombosis, or other types of calcified or stenosed vessels. Embodiments described herein may be used to bypass obstructed bile ducts in the liver, or to direct the blood supply away from tumors in an effort to destroy them. Access devices using configurations other than conduit devices as herein described, may also be implemented. Thus, the following description should not be construed to be limiting in any way.

[0170] Referring to **FIG. 18**, there is shown in greater detail one preferred embodiment of the bypass apparatus **210** of the present invention. The apparatus **210** is preferably formed of a biocompatible material, such as metal or a polymer. The apparatus **210** is shown piercing the coronary artery CA distal to the site of the blockage BL. The details of this conduit device **210** are described below. In connection with the somewhat schematic representation of **FIG. 18**, it will be noted that the device **210** pierces completely through the coronary artery CA, with the central portion **212** of the device **210** positioned within the myocardium HW and the distal portion **214** of the device **210** implanted in the left ventricle of the heart LV.

[0171] Each shunt device **210** (**FIG. 18**) is comprised of a central portion **212** formed by a hollow lumen having respective aperture or openings **216**, **218** on each end. One opening **216** receives blood from the left ventricle LV and shunts it through the lumen and out the other opening **218** which is positioned in the coronary artery CA. The conduit **210** therefore allows oxygenated blood to flow directly from the left ventricle LV and into the coronary artery CA, as indicated by the arrows **219***a* and **219***b* in **FIG. 18**.

[0172] The distal end of the conduit **214** may be blunt (**FIG. 20B**) or tapered if desired (**FIG. 18**) to aid in the insertion of the device **210** through the coronary artery CA, the heart wall HW and the left ventricle LV. The proximal end **220** of the conduit **210** is preferably provided with a head portion **222** that is larger than the diameter of the lumen (**FIG. 18**), to help anchor the conduit **210** in place and prevent it from migrating or passing completely through the coronary artery CA. This head portion **222** also acts to seal the puncture in the coronary artery CA formed by the distal tip **214** of the conduit **210**. The blood therefore flows through the conduit **210** and downstream within the coronary artery CA and not out through the puncture opening. If desired, the head portion **222** of the device **210** may be sutured into the surrounding tissue to prevent the device **210** from migrating from its proper position. Additional anchoring in the form of sutures or other means **224** is also preferably provided along the central portion **212** of the conduit **210**. Anchoring the device **210** into the myocardium HW prevents migration of the conduit **210** from its proper position.

[0173] As illustrated in **FIG. 18**, the conduit **210** may also include a second opening **225** at its proximal end **220** opposite from the first opening **218**. This second opening **225** allows for the perfusion of blood from the coronary artery CA as shown by the arrow **221** in **FIG. 18, i**.e., if the blockage BL does not completely block the coronary artery CA, blood may perfuse past the blockage BL and through the second opening **225**. **FIG. 18A** illustrates a self-inserting conduit having a flange or head with dual prongs **227** to prevent rotation of the conduit in the coronary, to ensure proper blood flow through the opening **218**.

[0174] In installing the device of this embodiment, the surgeon may make a small incision of a keyhole type in order to gain access to the blocked vessel. Visual access may be obtained through thoroscopy or similar endoscopic procedure. Such access is very minimally invasive. Once the area of blockage is located (through fluoroscopy, etc.), the conduit **210** is implanted in the body in the manner described above. The conduit device **210** is preferably introduced by way of an automatic gun or needle in order to reduce procedure time and avoid bleeding, but the conduit **210** may be implanted in other ways as well.

[0175] One method for implanting the device is illustrated in FIGS. **19**A-C. The conduit **230** is first mounted over a needle **232** (**FIG. 19A**), and the needle **232** is used to puncture the coronary artery CA, heart wall HW and left ventricle LV (**FIG. 19B**). The distal end of the needle **232** is

indicated by reference numeral **233**. The needle **232** is then removed (**FIG. 19C**) and the anterior hole in the coronary artery CA is closed using sutures **234** or other suitable methods.

[**0176**] In an alternate method illustrated in **FIGS. 20A and 20B**, a flap FL is first cut in the wall of the coronary artery CA and the needle **232** bearing the conduit **230** is inserted through the flap FL and through the other side of the coronary artery CA, through the heart wall HW, and into the left ventricle LV. The needle **232** is withdrawn, leaving the conduit **230** in place. The flap FL is then closed using sutures **234** or other suitable means.

[**0177**] The conduit **230** is preferably anchored in place in the heart wall HW as described above to prevent migration and to ensure that the free flow of blood from the left ventricle LV to the coronary artery CA is maintained.

[**0178**] Coronary Bypass

[**0179**] Referring to **FIG. 21**, there is shown a cross-sectional view of a typical heart anatomy including the aorta AO with a blockage BL or stenosis in the coronary artery CA which is positioned along the external surface of the heart wall HW. As is well known, the coronary artery CA supplies blood pumped from the left ventricle LV to the aorta AO and into the heart muscles or myocardium HW.

[**0180**] **FIG. 21** also illustrates in schematic fashion a bypass device **310** mounted both proximally and distally of the blockage BL by means of conduit combination access/shunt devices **312** and bypass conduit **314**, described in more detail below.

[**0181**] Referring to **FIG. 22**, there is shown in greater detail one preferred embodiment of the bypass apparatus **310**. The apparatus **310** is preferably formed of a biocompatible material, such as metal or a polymer. A pair of combination access/shunt devices **312** is shown proximally and distally of the blockage BL. The details of these conduit devices **312** are described below and shown in connection with **FIGS. 24 and 25**. In connection with **FIG. 22**, it will be noted that each access/shunt device **312** pierces completely through the coronary artery CA on the outside, leaving the conduit portion **316** of the device **312** implanted in the wall of the heart wall HW. The conduit portion **316** pierces not only through the coronary artery CA, but also into the tissue to provide anchoring and stabilization of the artery. The conduit portion **316** can be embedded in a tissue or passed completely through the tissue and into the left ventricle LV as shown in the portion of the device distal to the blockage BL.

[**0182**] FIGS. **22**A-**22**B illustrate two alternative embodiments for conduits of the nature described above. In **FIG. 22**A, the conduit is preferably placed proximally in the coronary artery CA to preferably allow some of the proximal flow in the coronary artery CA through the conduit and past the blockage BL to a downstream location in the coronary artery CA. This embodiment is preferably utilized in connection with blockages which are not complete, and yet advantageously also allows for bypass flow as described above. The conduit of **FIG. 22**B, however, does not allow any proximal flow through the coronary and all flow is diverted through the bypass.

[**0183**] Each access/shunt device **312** (e.g., see also **FIG. 24**) is comprised of a shunt portion **318** having an aperture **320** which, in the case of the proximal device, receives blood from the coronary artery CA and shunts it into a diversion tube **322** mounted proximally with respect to the conduit portion **316** and the aperture **320**. The diversion tube **322** is in fluid communication with the aperture **320** to allow blood flow from the coronary artery CA into the aperture **320** and into the diversion tube **322** as indicated by the arrows in **FIG. 22**. Mounted proximally with respect to the diversion tube **322** is a connector piece **324** which is also in fluid communication therewith. The combination access/shunt device **312** which is distal of the blockage BL may be constructed in a similar fashion or may have another configuration in which blood flows in the direction opposite that indicated by the arrows in **FIG. 22**. The bypass conduit **314**, which is hollow, is mounted on the two connector portions **324** of the devices **312**, as shown in **FIG. 22**, to allow blood to bypass the blockage BL. The conduit **314** may be constructed from a vein or artery graft taken from the patient or a donor, an artificial vein graft, or any other biocompatible tubing including one made from a metal or polymer. All these connections are fluid-tight, as described below in more detail, to avoid hemorrhaging. **FIG. 22** illustrates the conduit portion **314** somewhat exploded away from the connector portions **324** in order to illustrate the manner in which the complete bypass system can be assembled.

[**0184**] **FIG. 23** illustrates the conduit portion **314** of the bypass system **310** completely press-fit or snapped-down over the connector portions **324** (not shown in **FIG. 23**), as is the case in the final installation of the system.

[**0185**] **FIG. 24** illustrates the combination access/shunt device **312** in greater detail. The distal conduit portion **316**, as described above, provides access to the coronary artery CA by piercing completely through and into the surrounding tissue. A barbed distal portion **326** having one or more barbs provides anchoring for the entire device. The proximal shunt portion **318** which resides in the vessel comprises the aperture **320** to allow blood to flow therein and from there, at a right angle, into the diversion tube **322** mounted proximally with respect to the aperture **320**, as indicated by the arrow in **FIG. 24**. The proximal shunt portion **318** may be tapered if desired to aid in the insertion of the device **312** through the coronary artery CA and into the heart wall HW. Mounted on top of the-diversion tube **322** is a connector tube **324** for receiving the bypass conduit **314** as described above. It will be noted that the connector tube **324** is frusto-conical in order to provide a fluid-tight press-fit for the bypass.

[**0186**] In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device. This fabric or mesh helps to seal the vessel to prevent bleeding and provides a structure which allows endothelial cells to infiltrate the device **312** and incorporate it into the surrounding tissues.

[**0187**] Likewise, **FIG. 24** illustrates an inverted U-shaped saddle portion **328** of the device **312** which serves a dual purpose. This saddle portion **328** fits over the artery when the combination access/shunt device **312** is installed therein, thereby stabilizing the artery. In addition, this saddle device **328** acts as a flange for self-sealing the puncture in the coronary artery CA formed by the barbed distal tip **326**. In addition, the collar or saddle that may help contain the artery and mitigate any possible migration problems. Thus, blood flows through the diversion tube **322** and not out through the

puncture opening. If desired, a loop may be added to the saddle portion **328** to allow the device to be sutured into the myocardium HW to prevent the device from migrating from its proper position.

[**0188**] **FIG. 25** is an alternative embodiment of the conduit access/shunt device of **FIG. 24** in which a planar flange **330** serves to stabilize the artery and to self-seal the puncture therein.

[**0189**] **FIGS. 27 and 28** show views of two additional embodiments for device **312**. **FIG. 27** shows device **312** having a tapered configuration to aid in the insertion of the device **312**. **FIG. 28** shows a device **331** having dual distal tips to prevent rotation of the device when installed in the tissues of the patient.

[**0190**] In installing the device **310**, the surgeon may make a small incision of a keyhole type in order to gain access to the blocked vessel. Visual access may be obtained through thoracoscopy or similar endoscopic procedure. Such access is very minimally invasive. Once the area of blockage is located (through fluoroscopy, etc.), one or both of the combination access/shunt devices **312** are installed in the artery in the manner described above. The conduit devices **312** would preferably be introduced by way of an automatic gun which would implant both conduit devices **312** and the conduit **314** at the same time in order to reduce procedure time and avoid bleeding. Alternatively, the conduits **312** could be introduced individually, provided that bleeding is controlled.

[**0191**] The device **310** can be sutured in place to provide for permanent bypass; alternatively, the device can be implanted temporarily to maintain the flow of blood through the coronary artery CA during bypass surgery. The device **310** is implanted as described above. A vein graft is sutured in place, with one end anastomosed to the aorta, and the other end to the coronary artery CA at a site distal to the blockage. The device **310** provides blood flow from the aorta to the coronary artery CA at a site distal to the blockage BL during the anastomosis. Once blood flow has been established through the vein graft, the bypass device may be removed.

[**0192**] **FIG. 29** illustrates a further embodiment of the combination access/shunt device **312**. The distal conduit portion **316**, as described above, provides access to the coronary artery CA by piercing completely therethrough and into the surrounding tissue. The barbed distal portion **326** having one or more barbs provides anchoring for the entire device. The proximal shunt portion **318** which resides in the vessel comprises an aperture **320** to allow blood to flow therein and from there, at a right angle, into the diversion tube **322** mounted proximally with respect to the aperture **320**. The proximal shunt portion **318** may be tapered if desired to aid in the insertion of the device **312** through the coronary artery CA and into the heart wall HW. Mounted on top of the diversion tube **322** is a connector tube **324** for receiving a bypass conduit as described above. It will be noted that the connector tube **324** can be frusto-conical in order to provide a fluid-tight press-fit for the bypass. In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device. This fabric or mesh helps to seal the vessel to prevent bleeding and provides a structure that allows endothelial cells to infiltrate the device **312** and incorporate it into the surrounding tissues. A planar flange **330** serves to stabilize the artery and to self-seal the puncture therein.

[**0193**] **FIG. 30** illustrates a further embodiment of the combination access/shunt device **312**. The distal conduit portion **316**, as similar to that described above with respect to other embodiments, and has a barbed distal portion **326** having one or more barbs for anchoring the device. The proximal shunt portion **318** which resides in the vessel comprises an aperture **320** to allow blood to flow into the diversion tube **322**. The proximal shunt portion **318** may be tapered. The top of the diversion tube **322** forms a tapered connector portion **324** for receiving a bypass conduit as described above. It will be noted that the connector portion **324** can be frusto-conical. In a preferred embodiment, a biocompatible fabric or mesh (not shown) is incorporated into the structure of the device, as above. A planar flange **330** serves to stabilize the artery and to self-seal the puncture therein. Attached to the planar flange and distributed thereabout are one or more retaining members **323**, which can comprise detents at the end thereof for engaging the bypass conduit. The detents can be in the form of hooks, clasps, split rings, pads, or the like in order to mechanically retain the bypass conduit onto the connector portion **324** of the diversion tube **322**.

[**0194**] Referring now to **FIG. 31**, the shunt device **312** of **FIG. 29** is depicted in cross-section, where like features are referred to by the same reference numerals. The view depicts the device **312** inserted into an artery, such as the coronary artery CA of a patient, and further depicts a blockage BL therein. A bypass conduit, for example, a vein or artery graft **314**, is secured to the connector tube **324** of the diversion tube **322** above the flange **330**. Optionally, an access port or hole may be placed along the shunt body opposite the aperture **320** at portion **332** to increase total flow and to maintain blood perfusion through the vessel bypassed. It also should be noted that although the figure depicts the device **312** inserted perpendicular to the artery CA, the geometry of the device **312** allows it to be inserted at an angle without affecting its performance. This feature advantageously allows for more flexible application of the device during surgery, where perpendicular access to a vessel is not always available or convenient. **FIG. 32** presents a view similar to that of **FIG. 31**, showing the barb **326** of the conduit device implanted in the myocardium HW of a patient for perfusing the coronary artery CA.

[**0195**] A side-by-side bypass device **412** is depicted in **FIG. 33**, and **FIG. 33A** illustrates in schematic fashion the bypass achieved with the conduit of **FIG. 33**. In this case, the bypass conduit runs more parallel to the coronary artery CA and therefore utilizes less space within the intrapericardial space. In this device, the distal conduit portion **416** is similar to that described above with respect to other embodiments, and has a barbed distal portion **426** having one or more barbs for anchoring the device. The proximal shunt portion **418** which resides in a vessel comprises an aperture **420** to allow blood to flow into the diversion tube **422**. The aperture **420** passes through the shunt portion **418**, and allows communication with the diversion tube to either side of the shunt portion **418**. The proximal shunt portion **418** may be tapered. The top of the diversion tube **422** forms a connector portion with a second aperture **421** for communicating with a bypass conduit, such as an artery or vein graft. As above, a biocompatible fabric or mesh (not shown)

can be incorporated into the structure of the device. A planar flange **430** serves to stabilize the artery and to self-seal the puncture therein. Similarly, a flange **434** is provided at the end of the diversion tube **422** to self-seal the puncture in the artery or vein graft.

[**0196**] **FIG. 34** depicts an alternative embodiment **412'** similar to the device of **FIG. 33**. The device of **FIG. 34** has an aperture **420'**, which extends through only one side of the shunt portion **418'**. It should be understood that the apertures of this and the preceding embodiment may be selectively placed and sized according to the desired application, the orientation of the blood vessels employed, and the location of anatomical features, blockages, etc.

[**0197**] **FIG. 35** depicts a further alternative embodiment **412"** that is similar to the embodiment depicted in **FIGS. 33 and 34** except that there is no flange between the apertures **420** and **421**, but rather a smooth transition area **430"**. The shunt body **418"** is shown to have a gentle taper.

[**0198**] **FIG. 37** is a cutaway schematic representation of the shunt device **412'** depicted in **FIG. 34** mounted within the patient, with the conduit end resident within the myocardium HW. The coronary artery CA and the bypass graft **414** are shown to be placed in fluid communication by the apertures **420'**, **421** in the shunt **412'**. This illustration is illustrative of all side-by-side instant anastomosis devices described herein. Further, it should be noted that a hole may be located at position **436** to allow additional perfusion of the coronary artery CA, and that the aperture **420'** could pass through both sides, as in devices **412** and **412"**. Further, it should be noted that the device could be mounted at an angle, as discussed hereinabove.

[**0199**] **FIG. 38** is a cutaway schematic representation of a "rivet" type shunt device **512** mounted within the patient, with the retention members **540** deployed. A flange **534** seals the incision and maintains a bearing surface against the bypass graft **514**, which could be venous or arterial. An aperture **520** opens a channel into the hollow stent body **518**, which terminates in an open end **542**. In this illustrative arrangement, the open end **542** is resident within the coronary artery CA.

[**0200**] For illustrative purposes, it has been found that an anastomosis shunt device of the type depicted in **FIG. 29** can be dimensioned to have a height of 12.5 mm, with a body width of about 2 mm, a flange diameter of about 2.8 mm, and an inside diameter of the diversion tube of about 1.4 mm. The conduit can be dimensioned to be about 3 mm in height tapering to a width of about 2.1 mm. The aperture can be dimensioned to be about 1.4 mm in diameter, and can have an edge radius about the periphery of about 0.10 mm all around. An anastomosis shunt device of the type depicted in **FIG. 33** can be dimensioned to have a height of 12.65 mm, with a body width of about 2.8 mm, a flange diameter of about 3.4 mm, and an inside diameter of the diversion tube of about 2.0 mm. The conduit can be dimensioned to be about 3 mm in height tapering to a width of about 2.6 mm. The apertures can be dimensioned to be about 2.0 mm in diameter, and can have an edge radius about the periphery of about 0.10 mm all around.

[**0201**] Anastomosis Devices and Methods

[**0202**] It will be noted in connection with the coronary bypass devices, systems, and methods described above that various connections from one conduit to another are necessary. The term "anastomosis" refers to the joining of two conduits or two vessels in a similar fashion; although, in the context of the present application, that term should not be limited to a particular medical definition or practice, but refers broadly to the connection of various conduits in connection with bypass systems. Thus, as described above, prefit connections from one conduit onto a hub of another conduit are possible, although other anastomosis configurations are described below.

[**0203**] As shown in **FIGS. 39A and 39B**, a conduit **600** can be used to provide temporary blood flow during therapeutic procedures. For example, in typical coronary artery bypass surgery, a section of vein VG taken from the leg of the patient is attached at one end to the aorta AO and at the other end to a point distal to the blockage in the coronary artery CA. This surgery requires the delicate procedure of joining the vein graft VG to the aorta AO and to the coronary artery CA. This joining of the blood vessels is known as anastomosis. Normally, the patient is placed on a heart-lung machine to keep the blood oxygenated and flowing during this procedure, and the blood is diverted from the coronary artery CA to allow the physician to complete the anastomosis.

[**0204**] In one embodiment of the present invention, the conduit **600** is used to maintain blood flow through the coronary artery CA during bypass surgery (**FIG. 39A**). The vein graft VG is loaded on top of the stent **600** prior to implantation. The conduit **600** is implanted as described above, at the point of the vein graft VG anastomosis. The vein graft VG is sutured to the aorta and to the CA at a point distal to the blockage BL. If desired, the sutures can be preloaded onto the graft VG to facilitate the anastomosis. Once the vein graft VG has been attached, the conduit **600** is removed, and blood flow occurs from the aorta AO, through the vein graft VG, and down the coronary artery CA. The conduit **600** can be sutured in place during the anastomosis procedure for permanent attachment, if desired.

[**0205**] Other embodiments for connecting vessels or segments of vessels together are shown in FIGS. **40**-**40**G. **FIG. 40** illustrates two vessels **1200** and **1202** to be connected to respective disc members **1210** and **1212**. Each of the disc members **1210** and **1212** includes a plurality of prongs **1220** which are configured to mate with opposing holes **1224**. After the disc members **1210**, **1212** are secured to the vessels **1200** and **1202** (**FIG. 40A**), the vessels **1200** and **1202** may be effectively joined by snapping or locking the disc members together. As illustrated in **FIG. 40**B, this may be done by aligning the prongs **1220** with the holes **1224**, so that the prongs pass through and are accepted by the holes.

[**0206**] A technique for securing the vessels **1200** and **1202** to the disc members is illustrated in FIGS. **40**C-**40**G. **FIG. 40C** shows the vessel **1200** (e.g., a left internal mammary artery or "LIMA") being brought into proximity with a disc member **1226**, which, as shown in **FIG. 40**D, is brought over the vessel **1200**, so that a portion **1230** of the vessel **1200** extends beyond the disc member **1226**. As shown in **FIG. 40**E, the portion **1230** may then be advantageously everted over the disc member **1226**, so that the prongs **1220** of the disc member **1226** pierce through the vessel portion **1230**. As illustrated in **FIGS. 40F and 40G**, the disc member **1226** may then be mated with another disc member **1234** having

a plurality of holes **1224** therein. The disc member **1234** may advantageously be part of a larger integrally formed conduit device **1240** for redirecting the flow of blood around a blockage BL (not shown in **FIG. 40F**) within the coronary artery CA. A spike **1250** may be used to secure the conduit device **1240** within the heart wall HW. Although the disc member **1226** is shown as having several prongs **1220** that mate with respective holes **1224** in another disc member **1234**, it will be understood that disc members having alternate holes and prongs (like those in FIGS. **40**-**40**B) may be used.

[**0207**] Another conduit device **1254** is shown in **FIG. 40**H, in which the device **1254** includes a disc member **1234** that mates with another disc member **1226**. The conduit device **1254** is held snugly within the coronary artery CA by a rim element **1258** of the device **1254**. In **FIG. 40I** a conduit device **1260** is shown that includes a spike **1262** for securing the device **1260** into the heart wall HW. A vessel **1200** fits around a cylindrical portion **1264** of the conduit device **1260** and is held around the cylindrical portion **1264** by friction or with a ligature **1268**.

[**0208**] **FIG. 40J** shows a conduit member **1280** having a pair of rings **1282** and **1284**. As shown in **FIG. 40**K, one of the rings **1282** fits snugly inside and against the wall of the coronary artery CA, while the other ring **1284** sits above and on top of the coronary artery CA. A vessel **1200** fits over the ring **1284** and may be held in place with a suture **1286**.

[**0209**] **FIG. 40L** shows another conduit member **1290**, a base **1292** of which rests on the coronary artery CA, as illustrated in **FIG. 40M**. A suture **1286** may be used to secure the vessel **1200** to a ring **1294** of the conduit member **1290**.

[**0210**] **FIG. 40N** shows another conduit member **1300** which functions similar to its counterpart in **FIG. 40**L, except that instead of a ring **1294**, a plurality of teeth **1304** are used for holding the conduit member **1300** in place. Specifically, a vessel is brought over the conduit member so that the vessel slides beyond the teeth **1304**. As the vessel **1200** is then retracted, the teeth **1304** engage the vessel **1200**, thereby securing the vessel **1200** to the conduit member **1300**, as shown in FIGURE O.

[**0211**] Another conduit member **1320** is shown in FIGURE P. The member **1320** includes a ring **1324** and a plurality of teeth **1328**. When in use, the ring **1324** contacts the inside of the coronary artery CA, whereas the teeth **1328** engage the vessel **1200** in a manner analogous to the embodiment of FIGS. **40**N-O.

[**0212**] Conduits With Flow Resistance

[**0213**] One of the advantages of certain embodiments of the present conduits is that they can be designed to optimize fluid or blood flow through them. That is, the design or configuration of a conduit may be such that it automatically achieves flow control without microvalves, check valves, or other moving devices. (See, for example, the conduits of FIGS. **6**A-H and **8**-**8**P.) Such moving or articulating devices may be complicated or expensive to manufacture, particularly on the small scales required in this context. Thus, in one embodiment, flow control is achieved by maximizing flow through the conduit in one direction (preferably from the left ventricle to the coronary artery), but minimizing flow through the conduit in the opposite direction. Since flow rate through the conduit is a function of friction or drag, turbulence, and other fluid dynamic parameters, it may be convenient to discuss flow rate through the conduit in terms of resistance of the conduit to such flow. In other words, in one embodiment, it is advantageous to have a low conduit resistance in the forward direction (from the left ventricle to the coronary artery), but a higher resistance in the opposite direction. In that sense, the conduit acts as a type of choke device having a higher reversed flow resistance or diastolic resistance than the forward flow or systolic resistance.

[**0214**] Experimentation has shown, however, that the above characteristics may not necessarily produce optimized flow rate in the coronary artery. Thus, it should be remembered that flow rate through the conduit should be controlled such that it enhances total coronary flow rate, which total coronary flow rate is essential for perfusion of the heart tissues. Thus, experimentation has shown that the degree of proximal occlusion may have an effect on total coronary flow rate. It has been determined that, where a proximal occlusion is only partial, the total flow rate in the distal coronary artery may increase with greater systolic resistance in the conduit. This may be due, at least in part, to the back pressure which the flow through the conduit sees as a result of the partial occlusion. Thus, optimization under these circumstances must take into consideration the degree of proximal occlusion. In this regard, it has been determined that total coronary flow rate is increased with increasing systolic resistance through the conduit. Preferably, diastolic resistance remains high. For example, it has been found that with mild systolic resistance, an increase in coronary flow rate was achieved with approximately zero negative diastolic flow.

[**0215**] Thus, referring to **FIG. 41**, there is shown in schematic, cross-sectional view a conduit **1400** which has been designed to achieve flow optimization under certain circumstances, and which acts as an asymmetrical flow resistor. In this case, the conduit **1400** is generally curved with varying wall thickness, and has a proximal end **1404** which extends into the left ventricle LV and a distal end **1408** which curves so that its exit is approximately transverse to the direction of flow in the distal portion of the coronary artery CA. In this context, the term "distal" is used with respect to direction of flow and represents a location downstream from a given point in the flow path. It will be observed that the proximal portion of the conduit **1400** shown in **FIG. 41** extends into the left ventricle LV to take into consideration the changing wall thickness of the myocardium. Thus, the proximal portion of the conduit **1400** may extend into the ventricle LV roughly 5%-30% to accommodate for such changing wall thicknesses. Thus, during systole, the myocardium HW contracts and goes into tension, thus increasing the thickness of the myocardium. The conduit **1400** of **FIG. 41** is designed to accommodate such a thickening such that its entrance **1412** will be approximately flush with the internal surface of the myocardium HW during systole.

[**0216**] It will also be observed at the proximal end **1404** of the conduit **1400** that the entrance **1412** is shaped so as to have a high radius of curvature, which is approximately ½ of the difference between the diameter at the exit **1416** and the diameter of the conduit **1400** at the entrance **1412**. This curvature tends to reduce flow losses (or in other words, decreases resistance to flow) at the entrance **1412**, thereby

maximizing flow through the conduit during systole. At the same time, it will be observed that the decreased diameter at the entrance **1412** increases the resistance to reverse diastolic flow at that location, thus tending to decrease negative flow through the conduit **1400** or flow from the coronary artery CA back into the ventricle LV. Thus, the proximal portion of the conduit **1400** is designed so as to achieve an abrupt expansion resulting in large exit losses and consequently high resistance to diastolic flow.

[**0217**] At the distal end **1408**, on the other hand, flow losses are minimized, so as to minimize flow resistance. Such exit losses are essentially zero because the exit diameter of the conduit **1400** proximates or matches the diameter of the coronary artery CA. Moreover, during diastolic flow, there will be an "entrance" losses at the exit of the conduit **1400**, thus increasing the resistance to such negative flow. Moreover, the curved configuration of the distal end **1408** of the conduit **1400** minimizes flow loss during diastole which results from proximal flow through a partial occlusion. In other words, the distal end **1408** of the conduit **1400** can be constructed so as to allow a proximal flow passing a partial occlusion and contributing to the flow through the conduit **1400** to produce an advantageous total coronary flow rate. Such distal designs for the conduit **1400** are described elsewhere herein and are compatible with the conduit of **FIG. 41**. Moreover, the conduit **1400** can be constructed from a rigid or flexible material, it may be a solid wall or lattice structure (e.g., stent-like) as described below.

[**0218**] Thus, the conduit **1400** of **FIG. 41** can be designed so as to optimize total flow rate by designing a certain flow resistance through the conduit **1400** in accordance with the conditions indicated by the patient. In this embodiment, the wall thickness of the conduit **1400** varies by a taper ($\theta$) of approximately 4°, thus producing the differences in entrance and exit diameters. This degree of taper tends to minimize losses in a gradual conical expansion region.

[**0219**] Referring to FIGS. **42-45**, it can be seen that other conduit configurations can result in advantageous flow resistance. These conduit designs may or may not embody the design characteristics of the conduit **1400** of **FIG. 41**. For example, shown in **FIG. 42** is a schematic view of a curved conduit **1430**, similar to that of **FIG. 41**, except having a spiral flow path **1434** therethrough. This spiral flow path **1434** increases the resistance to negative or diastolic flow. By the same token, during systole, the pressures available are sufficient to overcome the resistance presented by the spiral flow path **1434**. In this case, the conduit **1430** may be of solid configuration and having a spiral flow path cut or bored therethrough. On the other hand, the conduit **1430** may be manufactured in a spiral fashion comprising a hollow flow path through the spiral.

[**0220**] Similarly, as shown in **FIG. 43**, there is shown a conduit **1440** with a helical flow path **1444**. Again, this conduit **1440** takes advantage of the increased flow resistance in the negative or reverse flow direction during diastole. The side walls of these conduits may be straight or tapered, as shown in **FIG. 41**, to further effect the degree of resistance. Thus, not only does the blood flow see a larger pressure differential between the vessel and the ventricle, but it may also see an increasing pressure due to a gradually tapered, smaller diameter blood flow path in the reverse direction. Again, however, this design may be reversed (in order to increase forward resistance) where only a partial occlusion is presented.

[**0221**] FIGS. **44A-44C** utilize an alternate method of flow resistance which comprises a type of fluidic vortex diode. Referring to **FIG. 44A**, there is shown a conduit **1450** having an entrance **1454** and an exit **1458**. It will be appreciated that the entrance **1454** and exit **1458** can be positioned in the ventricle LV and coronary artery CA, respectively, and that this illustration is only schematic with respect to the placement of the conduit **1450** in the heart tissues of the patient. Furthermore, as discussed above, the entrance **1454** and exit **1458** may be placed in the ventricle LV and coronary artery CA, respectively, or vice versa, depending upon patient indications and the desired flow optimization. Thus, it is convenient with respect to **FIGS. 44A and 44B** to discuss them in terms of a high resistance direction (shown in **FIG. 44A**) and a low resistance direction (shown in **FIG. 44B**). Both such flow resistances are achieved in a single device by providing a chamber or housing (preferably circular) with a tangential flow port and a central axial flow port. If the direction of flow is such that fluid enters the tangential flow port and exits the axial flow port, as shown in **FIG. 44A, a** vortex **1462** is created in the circular chamber. This vortex **1462** greatly impedes the flow of fluid through the device and provides for a high resistance fluid flow conduit. The fluid dynamics behind this result are such that the rotation of the fluid in the chamber generates centrifugal forces that cause the fluid to push outward toward the periphery of the chamber. Since fluid is entering the chamber at the periphery where the resulting centrifugal forces react, the outward push of the rotating fluid impedes the flow.

[**0222**] When the flow direction is reversed, such as that shown in **FIG. 44B**, fluid flows into the chamber **1468** from the central axial flow port **1472** and from there to the tangential flow port **1476**. However, no vortex is created. Thus, the resistance of conduit **1450** to the flow of fluid in this direction is relatively low.

[**0223**] A conduit **1480** utilizing this type of vortex diode device is shown in **FIG. 44C**. Thus, in this embodiment, the tangential flow port **1484** is placed in the coronary artery CA such that a high resistance to reverse flow is generated. On the other hand, the entrance **1486** to the axial flow port is placed in the ventricle LV so that blood flow into the conduit **1480** sees low resistance.

[**0224**] **FIG. 45** illustrates an alternate embodiment of a conduit **1490** utilizing flow resistance. In this case, the conduit **1490** is in the nature of a tesla valvular conduit. The geometry of the flow path in this device is such that flow entering the conduit **1490** from one direction **1494**, which is generally likely to occur during diastole, is bifurcated at several locations with part of the flow being conducted into passages **1496**, **1498** that redirect portions of the flow back into the main flow stream **1494** in a direction **1500** that is essentially reversed to the direction **1494** of the main flow stream. This reversed direction **1500** flow impedes the main flow stream **1494** and sets up a high resistance to fluid flow. On the other hand, when fluid enters in the opposite direction **1502**, such as is likely to occur during systole, no such bifurcation and no resulting flow impedance occurs. Thus, as shown in **FIG. 45**, the higher resistance flow direction is

from the coronary artery CA toward the ventricle LV. Flow in that direction **1494** experiences at least two bifurcations **1496***a*, **1498***a* with resulting reverse flow **1500** to impede diastolic blood flow. On the other hand, flow **1502** from the ventricle LV toward the coronary CA does not experience any bifurcations, thus resulting in lower flow resistance.

[**0225**] Conduits With Proximal Extensions

[**0226**] As discussed above, flow resistance in the direction of ventricle LV to coronary artery CA can be reduced by an increased exit diameter at the conduit distal portion which opens into the coronary artery CA. At this location, a conduit exit diameter which approximates or matches the diameter of the coronary will result in decreased flow losses and minimize flow resistance. Due to the curvature of the conduit, the flow at the conduit exit is approximately parallel to the axial flow in the coronary. Thus, this distal conduit portion may serve not only as an advantageous controller of the flow, but the extension nature of the distal portion can also serve to anchor or support the conduit in its position. Furthermore, as noted above, this distal portion of the conduit can be designed to allow proximal flow past a partial occlusion, past the distal portion of the conduit, and into the lower coronary regions for profusion of the heart.

[**0227**] Thus, referring to **FIG. 46**, there is shown a schematic, partial cross-sectional view of a curved conduit **1600** having an extension portion **1604** at its proximal end (to take into consideration changes in myocardial thickness) and a distal extension **1608** at the conduit distal end extending into the coronary artery CA. Besides minimizing flow losses and anchoring the conduit **1600** in place, this distal extension **1608** also reduces trauma to the coronary artery CA by directing flow downstream in a substantially parallel direction.

[**0228**] The conduit **1600** of **FIG. 46** may be installed in one embodiment, in accordance with FIGS. **47**A-D. Thus, with reference to **FIG. 47**A, the curved tubular conduit **1600** may have a sharpened or pointed proximal tip **1612** to allow it to penetrate the heart tissues, including at least the coronary artery CA and the myocardium HW so that the proximal end extends into the ventricle LV, as shown in **FIG. 47B**. The curved conduit **1600** is advanced in a rotational or curved fashion, as shown in **FIG. 47**C, so that it extends well into the ventricle LV. In fact, the conduit **1600** can be of such a length and constructed from a material to allow it to bend and curve into the coronary artery CA in a downstream fashion, as shown in **FIG. 47C**. Thus, the curved conduit **1600** actually is placed so as to bypass its final destination to allow it to be curved and then inserted in a downstream fashion as shown in **FIG. 47D**.

[**0229**] An alternate embodiment of the conduit **1600** of **FIG. 46** is shown in **FIG. 48**. In this case, the hollow, curved, tubular conduit **1630** is provided with an atraumatic ball configuration **1634** at the distal end of the conduit **1630**. This configuration allows for reduced flow losses at the exit, while at the same time providing a proximal extension which secures the conduit **1630** in place without damaging the sensitive linings of the vessel. Alternatively, the neck of the conduit **1630** just proximal the end having the atraumatic ball **1634** provides a location for an anchoring suture or tether **1638**, as shown in **FIG. 48**. The proximal end of the conduit **1630** can be provided with a non-coring, deflective point **1642**, and the tubular section **1646** can be constructed from a surgeon's needle having a ⅜ inch radius of curvature. As with all the conduits depicted herein, they can be installed in a variety of vascular or surgical procedures, depending upon patient indications. Thus, the conduit **1630** of **FIG. 48** may be implanted in the manner illustrated in FIGS. **47**A-**47**D. Alternatively, it may be inserted by means of a curved trocar or stylet, or may even travel over a thin guidewire. The conduit **1630** may be constructed from a rigid or semi-rigid material, it may have solid walls or a lattice stent-like construction as discussed below.

[**0230**] **FIG. 48A** illustrates the conduit **1630** of **FIG. 48** in its uninstalled condition. FIGS. **48**B-C illustrate alternate embodiments in which the atraumatic ball end at the distal end of the conduit **1630** is replaced with a partial ball **1650** or semi-spherical section, shown in **FIG. 48**B, or a flange-type structure **1654** as shown in **FIG. 48C**.

[**0231**] Another embodiment of a conduit **1670** having a proximal extension is shown in **FIG. 49**. In this case, the proximal portion **1674** of the conduit **1670** and the main body **1678** portion thereof which extends to the myocardium HW are relatively stiff or rigid regions. These portions of the conduit **1670** can be constructed from a smooth material, such as a metallic stainless steel or nitinol hypotube. Thus, a laminar flow pattern is generated in the conduit **1670** in these regions.

[**0232**] On the other hand, as the flow approaches the artery CA, the conduit **1670** can be constructed from a combination of laser cut hypotube and elastomer to provide a flexible distal portion which extends proximally into the coronary artery CA. In the embodiment of **FIG. 49**, the curved section of the conduit **1670** is stent-like or is of a lattice construction. It can be manufactured by laser cutting of a nitinol hypotube with elastomeric sections joining the lattice portions. The proximal extension **1674** may comprise at least a unitary arm with a circular flow exit **1682**, as illustrated in **FIG. 49**.

[**0233**] Alternatively, as shown in FIGS. **50**A-**50**C, the conduit of **FIG. 49** can be constructed so that it is substantially entirely of a lattice construction or stent-like. In this case, the term stent-like is used to refer to coronary stents which are often implanted following angioplasty, and is thus in an illustrated manner only and not to be restrictive in any sense of the term. Thus, as shown in **FIG. 50**A, there is a conduit **1690** having a solid or smooth proximal end **1694** which extends into the ventricle LV and a main body section **1698** which is of a lattice-type construction. This section likewise can be constructed from the laser cutting or other cutting of a nitinol hypotube or other material. **FIG. 50B** illustrates the conduit **1690** of **FIG. 50A** prior to having its distal portion **1702** bent so as to extend into the distal regions of the coronary artery CA. **FIG. 50**C, on the other hand, illustrates the conduit **1690** of **FIG. 50A** as installed in the heart tissues with the distal portion **1702** curved so as to align with the coronary artery CA.

[**0234**] The lattice construction of the conduit **1690** of FIGS. **50**A-C may be constructed from a variety of materials. FIGS. **51**A-**51**D illustrate various constructions for the conduit **1690** in **FIG. 50**. which includes a single arm with an opening at its end. In each case, the conduit **1690** is comprised essentially of a tapered or pointed proximal section **1694** which extends into the ventricle LV, a main body **1698** of a lattice construction, and an extension arm

**1706** and distal anchor **1710** which extends into the coronary artery CA. The distal extension arm **1706** and exit portion can take on a variety of shapes as shown in FIGS. **51**A-**51**D. These conduits **1690** can be constructed, preferably, from a nitinol tubing of approximately 0.060 inches in outer diameter with an inner diameter of approximately 0.048 inches. Another advantage of these conduits **1690** is their flexibility in the main body region **1698** in response to changes in myocardial thickness. Also, due to the lattice construction at the distal end, proximal flow through the coronary CA is not impeded.

[**0235**] **FIG. 52** illustrates an alternate embodiment **1716** with a distal extension **1720** extending both distally in the coronary artery CA as well as proximally. Thus, the distal portion **1720** of the conduit **1716** has a T-like configuration. As shown in **FIG. 52**, this T-like distal portion **1720** of the conduit **1716** may have a lattice construction such as the conduit **1690** shown in **FIGS. 50 and 51**. The main body **1724** of the conduit **171**-**6** of **FIG. 52** may be a smooth tubular structure, or may be of a lattice construction as shown in **FIGS. 50 and 51**.

[**0236**] The conduit **1730** of **FIG. 53** has an articulating distal portion **1734** which may fold down either in a manner so as to either extend distally with respect to the coronary artery CA or proximally, as shown in **FIG. 53**. In this case, the distal extension **1734** of the conduit **1730** is preferably of a lattice construction made from a nitinol hypotube as discussed above. This distal portion **1734** is designed to collapse against the main body **1738** of the conduit **1730** for insertion and then extend to an approximately 90° position, as shown in **FIG. 53**, within the coronary lumen after insertion. Thus, the distal portion **1734** of the conduit **1730** serves as an articulating or anchor arm for positioning the device within the heart tissues.

[**0237**] **FIG. 54** illustrates an alternate embodiment **1750** having an elastomeric distal anchoring arm **1754** for the conduit **1750**. In this case, the distal portion of the conduit **1750** is provided with a sealing portion **1758** and a shoulder portion **1762**. Both of these may preferably be constructed from elastomeric material or some other soft material. The sealing portion **1758** extends through a hole in the coronary artery CA which is used to implant the conduit **1750** of **FIG. 54**. The shoulder portion **1762** supports the sealing portion **1758** and seals the opening against the coronary wall. The distal portion of the conduit **1750** itself may be constructed from a metallic or other flexible material such that the bias or bending characteristic of the conduit **1750** causes it to push slightly at the distal end against the coronary wall, thus providing the seal.

[**0238**] The bypass devices and methods herein provide significant improvements in the treatment of vascular blockages. It should be understood that while various anatomical features have been discussed herein for ease of reference, the anastomosis devices described herein can also be used in connection with vessels other than coronary artery, etc. Thus, it is intended that the present invention is applicable to a wide range of uses where vascular anastomosis is indicated. It is further intended that the present invention may applicable during a wide variety of surgical techniques, from conventional sternotomy or "open chest" procedures, to minimally-invasive direct coronary artery bypass (MDCAB) and even vascular approaches.

[**0239**] Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

**1**. An implantable body fluid shunt device for providing fluid communication between body vessels of a patient, said device comprising:

a generally elongated shunt body having proximal and distal ends, said shunt body being formed of a rigid, biocompatible material;

said shunt body having:

a first proximal aperture and at least one second aperture longitudinally spaced along said shunt body from said first aperture; and

a diversion tube having a predetermined shape providing fluid communication between said first aperture and said at least one second aperture;

wherein, in use, said device is implanted in a patient such that said first aperture is disposed within a first vessel, and said at least one second aperture is disposed in a second vessel.

**2**. The implantable shunt device of claim 1, wherein said shunt body further comprises a spike portion at a distal end thereof.

**3**. The implantable shunt device of claim 1, wherein said shunt body further comprises expansible retention members at a distal end thereof.

**4**. The implantable shunt device of claim 1, wherein said device provides transmyocardial blood perfusion, and wherein said second aperture is adjacent said distal end of said shunt body and in use is disposed within the left ventricle of a patient.

**5**. The implantable shunt device of claim 4, wherein the first aperture is adjacent said proximal end of said shunt body and in use is disposed within a coronary artery of a patient.

**6**. The implantable shunt device of claim 2, wherein the second aperture in use is situated within the coronary artery of a patient and wherein said spike portion is disposed within the myocardium.

**7**. The implantable shunt device of claim 6, wherein the first aperture is adjacent said proximal end of said shunt body, wherein said first aperture is disposed within a venous or arterial graft.

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