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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 25/00 — A2

(11) International Publication Number: **WO 00/29056**

(43) International Publication Date: 25 May 2000 (25.05.00)

(21) International Application Number: PCT/US99/27605

(22) International Filing Date: 18 November 1999 (18.11.99)

(30) Priority Data:

09/196,636	19 November 1998 (19.11.98)	US
09/312,201	14 May 1999 (14.05.99)	US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Applications

US	09/196,636 (CIP)
Filed on	19 November 1998 (19.11.98)
US	09/312,201 (CIP)
Filed on	14 May 1999 (14.05.99)

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

Without international search report and to be republished upon receipt of that report.

(54) Title: FLUID DELIVERY APPARATUS AND METHODS

(57) Abstract

An infusion/guide catheter which is adapted to be introduced into a coronary ostium of a coronary artery of the heart of a patient through an opening in an aorta of the patient, preferably without the aid of fluoroscopic guidance, for delivery of a fluid, such as a cardioplegia solution, or passage of a catheter, into the coronary artery while still permitting blood perfusion from the aorta in to the ostium. Catheters adapted to be passed into a coronary vessel for delivery of a fluid, such as a cardioplegia solution. Preferably, the catheters can be placed without the use of fluoroscopy, although fluoroscopy may be optionally used under certain circumstances. In one embodiment, the infusion catheter generally comprises a tube having at least one lumen, a proximal end, and a distal end, the tube having at least one bend to facilitate placement of the distal end of the tube into the ostium of the coronary artery when the proximal end of the tube extends from the opening in the aorta, wherein the distal end of the tube is configured to fit within the coronary ostium while still permitting blood perfusion from the aorta into the ostium. The infusion catheter can be used as a system in conjunction with an intravascular catheter, an intraluminal shunt or similar drug delivery device which can be inserted directly into a coronary vessel, such as the right or left coronary artery or vein, following cardioplegia administration through the infusion catheter. The intravascular catheter, intraluminal shunt or similar drug delivery device can be used to deliver a fluid, such as a cardioplegia solution, more locally in the heart to enhance the efficiency of fluid or drug administration. Several embodiments include a light delivery portion capable of illuminating a distal end of the catheter for visualization thereof through the vasculature. A guidewire having a light delivery portion is also capable of illuminating a distal end of a catheter for placement of the catheter in a coronary vessel without the use of fluoroscopy.

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FLUID DELIVERY APPARATUS AND METHODS

FIELD OF THE INVENTION

The present invention generally relates to surgical or medical systems, associated devices and methods for facilitating fluid delivery, or passage of a catheter, into the coronary vasculature of the heart of a patient, and more particularly to a fluid infusion system and associated devices that will allow a surgeon to deliver a fluid such as a cardioplegia solution and/or place a drug delivery catheter for delivering the same into a coronary vessel, such as the right or left coronary artery.

BACKGROUND OF THE INVENTION

Minimally invasive surgical techniques have revolutionized cardiac surgery. Minimally invasive techniques have been developed to attempt to reduce or eliminate some of the more serious complications of conventional open-chest cardiac surgery techniques, such as the morbidity associated with the use of cardiopulmonary bypass. Minimally invasive techniques enjoy the advantages of reduced morbidity, quicker recovery times, and in some cases, improved cosmesis over conventional open-chest cardiac surgery in which the surgeon "cracks" open a patient's chest by sawing through the breastbone or sternum. Recent advances in endoscopic instruments and percutaneous access to a patient's thoracic cavity have made minimally invasive surgery possible. Reduction in morbidity, lower cost, and reduced trauma has made minimally invasive surgery desirable.

One approach to minimally invasive cardiac surgery is an endoscopic procedure in which access to the heart is gained through several small openings, or ports, in the chest wall of a patient. The endoscopic method allows surgeons to stop the heart without cracking the chest by utilizing a series of internal catheters to stop blood flow through the aorta and to administer a conventional cardioplegia solution (e.g., a potassium chloride solution) to facilitate stopping the heart. The cardioplegia solution paralyzes the electrical activity of the heart and renders the heart substantially totally motionless during the surgery. The endoscopic approach utilizes groin cannulation to establish cardiopulmonary bypass (CPB) which takes over the function of the heart and lungs by circulating oxygenated blood throughout the body. After CPB is started, an intraaortic balloon catheter that functions as an internal aortic clamp by means of an expandable balloon at its

distal end is used to occlude blood flow in the ascending aorta from within. A full description of an example of one preferred endoscopic technique is found in United States Patent No. 5,452,733, the complete disclosure of which is incorporated by reference herein. A primary drawback of endoscopic cardiac surgery procedures, however, is that such procedures do not avoid the damaging effects of CPB. CPB has been shown to be the cause of many of the complications that have been reported in conventional coronary artery bypass graft (CABG) procedures, such as stroke. The period of cardiopulmonary bypass should be minimized, if not avoided altogether, to reduce patient morbidity. An approach to minimally invasive cardiac surgery that avoids CPB is minimally invasive direct coronary artery bypass grafting (MIDCAB) on a beating heart. Using this method, the heart typically is accessed through a mini-thoracotomy (i.e., a 6 to 8 cm incision in the patient's chest) which also avoids the sternal splitting incision of conventional cardiac surgery. The anastomosis procedure is then performed under direct vision on the beating heart without the use of CPB or potassium chloride cardioplegia. However, there are many obstacles to precise coronary anastomosis during MIDCAB on a beating heart. In particular, the constant translational motion of the heart and bleeding from the opening in the coronary artery hinder precise suture placement in the often tiny coronary vessel.

In response to problems associated with the above-described minimally invasive surgical techniques, a new minimally invasive surgical platform known as the Transarrest™ platform has been developed to minimize the cardiac motion of the beating heart while avoiding the need for CPB and conventional cardioplegia. The Transarrest™ platform employs a novel pharmaceutical approach to stabilizing the heart. This revolutionary pharmaceutical approach to cardiac stabilization is fully described in International Patent Application No. PCT/US98/16469, titled "Compositions, Apparatus and Methods For Facilitating Surgical Procedures", having an International Filing Date of 7 August 1998, and invented by Francis G. Duhaylongsod, M.D, the description of the pharmaceutical approach being hereby incorporated by reference herein. As described therein, pharmaceutical compositions, devices, and methods are provided which are useful for medical and surgical procedures which require precise control of cardiac contraction, such as minimally invasive CABG procedures. Generally, the Transarrest™ platform involves the administration of a novel cardioplegia solution which provides for precise heart rate and rhythm control management while maintaining the ability of the heart to be electrically

paced (i.e., which does not paralyze the electrical activity of the heart as with conventional cardioplegia solutions). Specifically, the novel cardioplegia solution comprises a pharmaceutical composition which is capable of inducing reversible ventricular asystole in the heart of a patient, while maintaining the ability of the heart to be electrically paced. "Reversible ventricular asystole" refers to a state wherein autonomous electrical conduction and escape rhythms in the ventricle are suppressed. A state of the heart may be induced wherein the heart is temporarily slowed to at least about 25 beats per minute or less, and often about 12 beats per minute or less. The induced ventricular asystole is reversible and after reversal, the heart functions are restored, and the heart is capable of continuing autonomous function.

The pharmaceutical composition may preferably include, for example, an atrioventricular ("AV") node blocker and a beta blocker. As used herein, the term "AV node blocker" refers to a compound capable of reversibly suppressing autonomous electrical conduction at the AV node, while still allowing the heart to be electrically paced to maintain cardiac output. Preferably, the AV node blocker, or the composition comprising the AV node blocker, reduces or blocks ventricular escape beats and cardiac impulse transmission at the AV node of the heart, while the effect on depolarization of the pacemaker cells of the heart is minimal or nonexistent. The beta blocker is provided in one embodiment in an amount sufficient to substantially reduce the amount of AV node blocker required to induce ventricular asystole. For example, the AV node blocker may be present in the composition in an amount which is 50% or less by weight, or optionally about 1 to 20% by weight of the amount of AV node blocker alone required to induce ventricular asystole.

The pharmaceutical composition, such as an AV node blocker, capable of causing ventricular asystole in a preferred embodiment is a cholinergic agent such as carbachol, although other cholinergic agents may be used as well such as acetylcholine, methacholine, bethanechol, arecoline, norarecoline, neostigmine, pyridostigmine, and other agents that increase cyclic GMP levels by direct or indirect cholinergic receptor stimulation. Other exemplary AV node blockers include calcium channel blockers, adenosine A1 receptor agonists, adenosine deaminase inhibitors, cholinesterase inhibitors, monamine oxidase inhibitors, serotoninergic agonists, antiarrythmics, cardiac glycosides, and local anesthetics. Examples of these AV node blockers include verapamil, diltiazem, lidocaine, procaine, procainamide, quinidine, choloroquine, amiodarone, pilocarpine, ethmozine, propafenone,

flecainide, encainide, tranylcypromine, serotonin, adenosine, digoxin, digitalis, dipyridamole, ibutilide, zapranest, sotalol, metoclopromide and combinations thereof.

In the preferred embodiment, the beta blocker is propranolol, although other suitable beta blockers may be used as well. Other exemplary beta blockers include atenolol, acebutolol, labetalol, metoprolol, nadolol, oxprenolol, penbutolol, pindolol, sotalol and timolol, and any combinations or pharmaceutically acceptable salts thereof. Alternatively, celiprolol, betaxolol, bevantolol, bisoprolol, esmolol, alprenolol, carterolol, nadolol, or teratolol may be used. The beta blocker may be any naturally occurring or synthetic analogue capable of blocking beta-adrenergic receptor sites. The administration of the beta blocker is preferably prior to, or contemporaneously with, the administration of the cholinergic agent, and results in a synergistic effect between the beta blocker and the cholinergic agent. The use of a cholinergic agent, such as carbachol, in combination with a beta-blocker, such as propranolol, produces ventricular asystole at significantly reduced dosages of the cholinergic agent, while maintaining a short half-life and rapid onset of effect.

In one embodiment to induce reversible ventricular asystole in a patient, the beta-blocker propranolol and the AV node blocker carbachol are serially administered in an initial intracoronary bolus to induce reversible ventricular asystole of the heart, and then carbachol is administered as a periodic (e.g., one or more bolus infusions) or continuous intracoronary infusion to maintain ventricular asystole during the course of the surgical procedure. For example, an intracoronary injection of about 0.5 to 4 mg, for example about 1 mg, of propranolol is administered by intracoronary infusion over a time period of about 0.5 to 3.0 minutes, e.g., about 1 minute, preferably followed by a saline flush, such as 2 mL saline flush. This is followed by an intracoronary bolus injection of about 0.01 to 0.5 mg, e.g., about 0.025 to 0.3 mg, e.g., about 0.1 mg carbachol administered over about 0.5 to 3.0 minutes, e.g., about 1 minute, to initially induce ventricular asystole. To maintain ventricular asystole, carbachol is administered as a continuous intracoronary infusion at a rate of about 0.01 to 0.3 mg/min, e.g., about 0.025 to 0.3 mg/min, for example, about 0.01 to 0.1 mg/min, e.g., about 0.05 to 0.1 mg/min, e.g., about 0.0825 mg/min, for a time period of about 5 to 90 minutes, preferably about 30 to 90 minutes, depending on the length of the procedure. A dosage amount of about 1.0 mg of phenylephrine (or an alpha agonist such as Levofed, for example) may be administered to control the hypotensive effects associated

with carbachol administration. In some situations, atropine (about 1 mg) is used to reverse ventricular asystole and restore the heart to its normal function.

Electrical pacing wires are connected to the right ventricle and/or left ventricle and/or atria and are used to pace the heart using a novel foot-actuated pacer control system to maintain the patient's blood circulation during the periods in which the surgeon is temporarily not performing the surgical procedure. Thus, for example, in a CABG procedure, the surgeon can control the pacing of the heart with a convenient foot pedal and can controllably stop the heart as sutures are placed in the vessel walls. The pharmaceutical compositions, devices and methods for drug delivery, and systems for pacing the heart, give a surgeon complete control of the beating heart. The Transarrest™ procedure described above can be used to facilitate any surgical procedure within the thoracic cavity or other body cavity which requires intermittent stoppage of the heart or elimination of movements caused by pulsatile blood flow, whether access is gained to the body cavity via a partial or median sternotomy incision, via a mini-thoracotomy incision, or via one or more small incisions or ports in the chest wall.

In the above-described embodiment of the co-pending Transarrest™ patent application, the pharmaceutical composition is delivered locally to the AV node of the heart upon which it acts via the AV node artery of the heart. Preferably, the composition is delivered in an antegrade fashion (direction which is the normal direction of blood flow) to the right coronary artery which feeds blood to the AV node artery. In a majority of patients, the right coronary artery is the main vessel supplying blood to the right side of the heart and to the AV node. However, where the right coronary artery is substantially totally occluded, and in a small subset of about 20% of patients, the 1st septal branch of the left anterior descending artery (which originates from the left coronary artery) may be the vessel which delivers blood to the AV node and can be selected as the delivery conduit for delivering the pharmaceutical composition to the AV node. Additionally, other possible routes of administration to the AV node may include Kugel's artery and the right superior descending artery. Moreover, in certain situations, the pharmaceutical composition can be delivered in a retrograde manner (direction which is opposite to the normal blood flow direction) through a coronary vein, such as the right or left coronary vein, to the AV node.

Typically, the pharmaceutical composition is delivered to the right coronary artery (or left coronary artery) at a location near the bifurcation to the AV node artery and

proximal to the right coronary artery's bifurcation into the posterior descending artery by any one of a number of drug delivery means. For example, one method to accomplish this drug delivery is to have a cardiologist place the distal end of a drug delivery catheter within the right (or left) coronary artery via the femoral artery, or other peripheral artery, using standard fluoroscopic techniques. Catheters such as intravascular catheters which are well known for use in diagnostic and therapeutic procedures can be used to administer the drug composition to the cardiovascular system, such as a standard Target Therapeutics Tracker™ (Boston Scientific Corp.) or Ultrafuse X™ (SciMed Corp.) infusion catheter. Additionally, guide catheters are a well known form of catheter used to assist in the introduction of other catheters, guidewires and/or fluids to the arteriovenous system of a patient and can be used to facilitate proper catheter placement or drug delivery into the ostium of a coronary artery. Such guide catheters typically are also designed specifically for percutaneous or surgical (cut-down) insertion through a femoral artery (or other peripheral vessel) in the groin area of the patient and advanced into the cardiovascular system with the aid of x-ray fluoroscopy. Examples of such guide catheters are numerous with a few being disclosed in Pande U.S. Patent No. 4,596,563 and Macaulay et al. U.S. Patent No. 5,234,416.

While the use of intravascular drug delivery catheters and/or guide catheters has been shown in animal and ongoing human clinical studies to be an effective approach to administering the Transarrest™ pharmaceuticals to the cardiovascular system, the reliance of this drug delivery approach on fluoroscopy for proper catheter placement through the tortuous coronary vasculature system has its drawbacks. For example, the use of fluoroscopy is expensive, has potential adverse toxic effects on patients and doctors exposed to it if proper precautions are not taken to prevent exposure to fluoroscopic radiation, and typically is not available in the majority of operating room suites. Additionally, the cardiac surgeons performing the complex cardiac surgical procedures on the heart, great vessels and/or other internal organs using the Transarrest™ procedure, for example, typically are not well trained in fluoroscopic techniques, and thus require the assistance of a cardiologist or other trained expert to place the drug delivery catheter in a fluoroscopically equipped cardiology lab prior to the procedure, which adds to the time, expense and complexity of the procedure.

Thus, it would be advantageous to provide a drug delivery system and associated devices that can be placed surgically by a surgeon without the use of x-ray fluoroscopy.

The system preferably should include one or more devices that can be easily placed by a surgeon into the thoracic cavity of a patient who may or may not be on CPB and while the heart is beating. One drug delivery approach is to deliver the pharmaceutical composition to the coronary ostium of a coronary artery via a trans-aortic delivery approach. As used herein, the term "coronary ostium" is conventional in the art and refers to the inlet or opening to a coronary vessel such as the right or left coronary artery, for example.

Several aortic catheters or cannulas have been developed to deliver a conventional cardioplegia solution (e.g., potassium chloride (KCl)) to the heart to facilitate conventional open-chest cardiac surgical procedures in which the patient is on CPB and the aorta is cross-clamped. The cardioplegia solution is introduced into the coronary arteries to lower the temperature of the heart, to preserve the heart muscle, and to make the heart motionless (but not pacemaker dependent) during the surgery. The aortic cross-clamp prevents cardioplegia solution from exiting the coronary vessels via the aorta and prevents blood fed to the aorta from the extracorporeal CPB support apparatus from entering the heart. An example of a cannula for dispensing conventional cardioplegia solution into the heart via the aorta to facilitate conventional open-heart surgery is found in Possis et al. U.S. Pat. No. 4,610,661. A cannula of selected size is inserted through an opening in the aorta and directed to a coronary lumen of the heart. The device includes an annular member at the fluid discharge end of the tube which engages the aortic tissue that surrounds the selected coronary ostium and forms a seal therewith to prevent the entrance of air or other fluids into the coronary vessels during use of the device. Other examples of similar aortic cannulas or catheters used for open-heart surgery include those disclosed in Carpenter et al. U.S. Patent No. 4,416,280, Devries U.S. Pat. No. 4,596,552, Buckberg et al. U.S. Pat. No. 5,013,296, Jonkman U.S. Pat. No. 5,151,087, and the Coronary Artery Ostial Cannulae for antegrade infusion manufactured by Medtronic, Minneapolis, Minnesota. However, sealing the inlet opening to the coronary artery without permitting fluid perfusion around or through the cannula will not work in a beating heart procedure such as the Transarrest™ procedure in which the patient is preferably not on CPB, the aorta is not cross-clamped, and the heart itself is used to perfuse the body with blood (during the periods in which there is not an intermittent pacing interruption) to preserve the heart muscle during the surgery. In such a procedure, blood from the aorta must be allowed to continually perfuse into the coronary arteries to preserve the heart muscle during the surgery to reduce the risk of ischemia.

A device is needed, therefore, that is configured to be placed directly into the ascending aorta of a patient and the distal tip of the device positioned in the coronary ostium (i.e., the distal tip is placed immediately adjacent to the coronary ostium and/or extends through the ostium into the proximal portion of the coronary vessel) of the right or left coronary artery while still permitting blood to perfuse into the coronary artery. The device, such as an infusion catheter, should be adapted either for direct delivery of a fluid, such as a cardioplegia solution (e.g., an AV node blocker and a beta blocker), into the coronary vessel via its ostium, or for introduction of a drug delivery catheter or similar device further into the coronary vessel through which the cardioplegia solution could be delivered more locally to the heart, preferably more locally to the AV node artery. The device should be easy to place by the surgeon "blindly" with or without thoracoscopic (e.g., fluoroscopic) visualization or other guidance means. Alternatively, the device may be placed under fluoroscopic visualization, or, more preferably, another visualization arrangement that does not require the expense or necessity of fluoroscopy. Additionally, the infusion catheter should be configured to permit blood flow through the coronary ostium to the coronary vessels to preserve the heart muscle during the procedure.

Such an infusion catheter can be used, for example, to deliver both the intracoronary bolus injection and the periodic or continuous infusion of the Transarrest™ pharmaceuticals to the coronary artery via the coronary ostium to induce and maintain transient ventricular asystole during a surgical procedure. In addition, the infusion catheter can be used as a system in conjunction with a separate drug delivery device, such as an intravascular catheter, an intraluminal shunt apparatus or similar drug delivery device. For example, the infusion catheter can be used to deliver a bolus injection of a cardioplegia solution, for example an AV node blocker and a beta blocker, i.e., carbachol and propranolol, to the coronary artery to induce pacemaker dependent ventricular asystole. With the heart in ventricular asystole, the intravascular catheter, intraluminal shunt apparatus or similar drug delivery device can then easily be inserted directly into a quiescent coronary vessel, such as the coronary artery distal to the ostium for antegrade fluid infusion of a cardioplegia solution to the AV node or a coronary vein for retrograde fluid infusion to the AV node. The drug delivery device can be used to administer a cardioplegia solution, for example an AV node blocker, i.e., carbachol, more locally to the AV node to maintain ventricular asystole during the surgery. However, it is to be understood that while the infusion catheter and related devices of the present invention are

particularly well suited to facilitate a Transarrest™ procedure, the systems, devices and methods described below and set forth in the claims are not limited to their use in a Transarrest™ procedure, and can be used to facilitate any medical or surgical procedure in which it is required to deliver a fluid or drug into the coronary vasculature of the heart.

SUMMARY OF THE INVENTION

The present invention involves improvements to systems, devices and methods for local delivery of fluids or drugs, such as cardioplegia solutions, to the coronary vasculature of a heart of a patient to facilitate cardiac and other surgical procedures. In particular, the invention facilitates delivery of a cardioplegia solution to the coronary vasculature of the heart in the absence of fluoroscopic or other complex catheter guidance techniques. According to a first aspect of the present invention, an infusion catheter is disclosed which is adapted to be introduced into a coronary ostium of a coronary vessel of a heart of a patient through an opening in an aorta (i.e., transaortically) of the patient for delivery of a fluid into the coronary vessel or for passage of a drug delivery catheter therein.

The infusion catheter generally comprises an elongated tube having at least one lumen, a proximal end portion, and a distal end portion. The distal end portion is constructed to fit within the coronary ostium while permitting blood from the aorta to perfuse into the coronary vessel. The distal end portion may include a light delivery portion which facilitates placement of the distal end portion in the coronary ostium and facilitates monitoring (e.g., verification or confirmation of position) to ensure that the distal end portion does not become dislodged from the coronary ostium at any time during a procedure.

In one embodiment, blood perfusion into the ostium is allowed by having the distal end portion of the tube sized to fit within the coronary ostium while not substantially occluding blood flow around the distal end portion of the tube. For example, the distal end portion of the tube preferably has a maximum outside diameter of about 3 mm or less such that blood flow into the ostium is not substantially occluded during fluid or drug delivery through the infusion catheter. In alternative embodiments, the tube is provided with a blood perfusion capability to permit blood to perfuse from the aorta through at least a portion of the tube and into the coronary artery.

For example, according to another aspect of the invention, the infusion catheter may be provided with at least two separate and independent internal lumens. The separate lumens may be provided in a coaxial arrangement, for example, although several other configurations are possible. Specifically, the infusion catheter can include an inner fluid delivery lumen for providing a fluid delivery path between the proximal and distal ends of the device and an outer, coaxial perfusion lumen for drawing blood from the aorta and perfusing the blood through at least a portion of the device to downstream of the coronary ostium during use of the device. The perfusion lumen fluidly communicates with one or more side holes provided in the tube of the catheter near the distal end of the device through which blood is drawn and then discharged through the distal end of the device via the perfusion lumen. The blood perfusion lumen helps to supply the heart muscle with oxygenated blood during the surgical procedure in case the blood supply through the coronary ostium is partially or substantially occluded by the presence of the distal tip of the perfusion catheter in the ostium. In another embodiment, the distal end portion includes an atraumatic distal tip bonded to the distal end of the device that includes one or more perfusion channels through at least a portion of the tip. The one or more perfusion channels permit blood from the aorta to perfuse past the catheter and into the coronary ostium during the surgical procedure.

The catheter tube in the above-described embodiments may have a general J-shaped configuration to facilitate entry thereof into the ostium of a desired coronary artery, although it is to be appreciated that the tube may have a variety of shapes, such as the well-known Judkins and Amplatz configurations for both the right and left coronary arteries, as well as various other configurations, to facilitate placement of the distal end of the device into the coronary ostium. The tube is preferably made from a plastic material, such as polyurethane or nylon, for example, in a reinforced pliable polymeric composite construction, to provide enhanced flexibility to the tube. The tube may also be made from a relatively stiff, malleable material, such as stainless steel, to allow the surgeon to modify the shape of the tube, by hand or otherwise, to bend it to fit the particular anatomical situation and to assist the surgeon in palpating the tube into place in the ostium.

In alternative embodiments, the infusion catheter can have a generally straight configuration (e.g., not pre-shaped) and can be configured to releasably mate with a pre-shaped guide catheter to facilitate insertion of the catheter into a coronary vessel. The infusion catheter may also include a distally located occluding member, such as an

inflatable balloon or other expandable member, to help ensure that fluid is projected down the vessel with no back flow into the aorta. In yet another alternative embodiment, the infusion catheter can be configured so as to sealingly engage with a least a portion of the aortic tissue surrounding the coronary ostium to position a distal end of the catheter in the coronary ostium so as not to substantially extend into the coronary artery, to minimize trauma to the coronary artery. A stabilizing element, preferably including at least one suction port, is provided to apply vacuum to the aortic tissue to help stabilize and retain the distal end of the catheter in the desired location. Another variation includes a stabilizing element which engages with aortic tissue transversely away from the coronary ostium, and blood is able to continuously flow around the distal end of the catheter from the aorta into the coronary artery.

According to another aspect of the present invention, an intravascular catheter is provided for introduction into a coronary vessel for delivery of a fluid therein. The catheter generally includes an elongated tube having an outer wall, a proximal end portion, a distal end portion including a light delivery portion, and at least one lumen extending within a length of the outer wall. The light delivery portion is adapted to illuminate the distal end portion to facilitate placement in the coronary vessel without the use of fluoroscopy. The light delivery portion may be illuminated in various manners, including by a light fed optical fiber, one or more LED's, fluorescent material, etc. Optical fiber configurations may include one or more optical fibers, which may be light fed externally of the catheter, or from a light source within the catheter.

According to another aspect of the invention, an infusion catheter as described above can be used as a system in conjunction with a separate drug delivery device, such as an intravascular (or intravenous (IV)) catheter, an intraluminal shunt, or similar device, to deliver a cardioplegia solution more locally in the heart, for example more proximal to the AV node artery. To facilitate a TRANSARREST™ procedure, for example, the infusion catheter can be first used to deliver an initial intracoronary bolus of a cardioplegia solution, such as an AV node blocker and a beta blocker, e.g., carbachol and propranolol, to the coronary ostium at a sufficient dosage to induce reversible ventricular asystole of the heart. With the heart in ventricular asystole, a separate fluid delivery device, such as an intravascular (or IV catheter adapted to be appropriately placed) catheter or a shunt, may then be easily inserted directly into a quiescent coronary vessel, such as the right or left coronary artery downstream from the coronary ostium, to provide a periodic or continuous

intracoronary infusion of a cardioplegia solution, such as carbachol, directly into the artery more locally to the AV node artery at an infusion rate sufficient to maintain ventricular asystole during the procedure. The infusion catheter may then be removed from the aorta and the aorta closed to prevent blood loss.

In another aspect of the invention, an intravascular catheter as described above may be used in a surgical drug delivery system along with an infusion/guide catheter, similar to the infusion catheter described above, which is configured for insertion through an opening in an aorta of a human patient for placement into a coronary ostium of a coronary vessel, and having a proximal end portion, a distal end portion, and at least one lumen extending into the distal end portion. The infusion/guide catheter may also be used to infuse fluids, such as a saline solution to flush the catheter or a drug into the vessel. The infusion/guide catheter includes a tube which is preferably preshaped to facilitate placement of the distal end portion into the coronary ostium when the proximal end portion of the tube extends from the opening in the aorta. The intravascular catheter is configured for insertion through the preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel. In several embodiments, the intravascular catheter further includes a light delivery portion adapted to illuminate the distal end portion of the intravascular catheter to facilitate placement in the coronary vessel without the use of fluoroscopy, and also to illuminate the vessel during the procedure to allow the practitioner to confirm that the intravascular catheter remains within the vessel and does not become dislodged therefrom.

Still further, a system is provided which includes a guidewire configured for insertion through an infusion/guide catheter as described above and to guide an intravascular catheter. The guidewire comprises a light delivery portion adapted to illuminate a distal end portion of the guidewire, to facilitate placement of the guidewire and the intravascular catheter in the coronary vessel without the use of fluoroscopy.

In yet another arrangement, a surgical drug delivery system is provided which includes an intravascular catheter configured for insertion into a coronary vessel for delivery of a fluid into the coronary vessel; and a guidewire configured for insertion through a lumen of the intravascular catheter to guide the placement thereof. The guidewire comprises a light delivery portion adapted to illuminate a distal end portion of the guidewire, to facilitate placement of the guidewire and the intravascular catheter in the coronary vessel without the use of fluoroscopy.

According to another aspect of the invention, a surgical kit is disclosed to include a preshaped catheter configured for insertion into a coronary ostium of a coronary vessel through an opening in an aorta of the heart of a patient, said catheter having a tube defining at least one lumen, a proximal end, and a distal end, said tube having a shape to facilitate placement of said distal end of said tube into the ostium of the coronary vessel when the proximal end of said tube extends from an opening in the aorta; an intravascular catheter comprising a light delivery portion, said intravascular catheter configured for insertion through said preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel; and a first sealed container containing an AV node blocker compound. The kit may further include a second sealed container containing a beta blocker compound.

As an alternative arrangement, a surgical kit is provided to include a preshaped catheter configured for insertion into a coronary ostium of a coronary vessel through an opening in an aorta of the heart of a patient, an intravascular catheter, a guidewire and a first sealed container containing an AV node blocker compound. The preshaped catheter has a tube defining at least one lumen, a proximal end, and a distal end. The tube has a shape to facilitate placement of the distal end of the preshaped catheter into the ostium of the coronary vessel when the proximal end of the preshaped catheter extends from an opening in the aorta. The intravascular catheter has at least one lumen, and is configured for insertion through the preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel. The guidewire is configured for insertion through the lumen of the intravascular catheter to guide the placement thereof. The guidewire includes a light delivery portion adapted to illuminate a distal end portion of the guidewire, to facilitate placement of the guidewire and the intravascular catheter in the coronary vessel without the use of fluoroscopy. The kit may further include a second sealed container containing a beta blocker compound.

A method of preparing a patient for a surgical procedure according to the present invention is also provided, which generally includes making an opening in the aorta, introducing a distal end of a infusion catheter having at least one lumen through the opening in the aorta and advancing the distal end from the opening in the aorta into a coronary ostium of a coronary artery while still permitting blood to flow into the coronary ostium from the aorta, and delivering a cardioplegia solution into the ostium of the coronary artery with the catheter at a sufficient dosage to induce reversible ventricular asystole of the heart.

According to another aspect of the invention, a method of inducing reversible ventricular asystole in the heart of a patient undergoing a surgical procedure is disclosed which comprises delivering at least one cardioplegia solution into the coronary ostium of a coronary artery at a sufficient dosage to induce reversible ventricular asystole in the heart, and then delivering at least one cardioplegia solution directly into a coronary vessel to maintain reversible ventricular asystole in the heart. The method can include delivering a cardioplegia solution into the coronary ostium by inserting a distal end of an infusion catheter through an opening in an aorta of the patient and positioning the distal end of the catheter in the coronary ostium and delivering a cardioplegia solution through the distal end. The method can further include inserting a drug delivery device, such as an intravascular (including an appropriately configured IV catheter) catheter or an intraluminal shunt, directly into a coronary vessel of the heart, such as a coronary artery (for antegrade infusion) or a coronary vein (for retrograde infusion) proximal to the AV node artery, and periodically or continuously infusing a cardioplegia solution through the intravascular catheter (or shunt) into the coronary vessel to maintain reversible ventricular asystole during the surgical procedure.

A method of delivering a fluid or drug to within a coronary vessel of a heart of a patient according to the present invention includes making an opening in a wall of an aorta of the patient; introducing a distal portion of a guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery; positioning the distal portion of the guide catheter in the coronary ostium; advancing a distal end portion of a fluid delivery device through the guide catheter to a fluid delivery location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and passing a fluid or drug through the fluid delivery device and into the coronary artery.

When the distal end portion of the fluid delivery device includes a light delivery portion, the method of delivering further includes illuminating the light delivery portion to facilitate the advancement of the distal end portion of the fluid delivery device.

Other methods of facilitating the advancement of the distal end portion are disclosed, to include, for example, providing a fluid delivery device having a distal end portion which includes at least one electrode and electrically sensing electric signals generated by a pacemaker node of the heart using the least one electrode to facilitate advancement of the distal end portion; providing a fluid delivery device with a distal end

portion having at least one ultrasonic transducer and transmitting ultrasound signals and receiving reflections of the ultrasound signals to facilitate the advancement of the distal end portion of the fluid delivery device; providing a fluid delivery device with a distal end portion which includes at least one magnetic element and using a magnetic probe, externally of the vessel, to guide the at least one magnetic element to the fluid delivery location with the vessel, thereby facilitating advancement of the distal end portion of the fluid delivery device; and providing a fluid delivery device, the distal end portion of which includes at least one palpation member (such as an inflated balloon, for example), and palpating the palpating member, through a wall of the vessel, to facilitate the advancement of the distal end portion of the fluid delivery device.

The method of delivering can include passing at least one cardioplegia agent through the fluid delivery device. The cardioplegia agent may include an AV node blocker compound. The AV node blocker compound may include carbachol. The fluid delivery location to which the distal end portion is advanced may be proximate the AV node artery. The location may be at least about 0.5 cm downstream of the coronary ostium, preferably about 2 to 8 cm downstream and more preferably about 4 to 6 cm downstream, although preferred distances may vary from patient to patient.

According to another aspect of the present invention, a method of delivering a fluid or drug to within a coronary vessel of a heart of a patient is disclosed to include preloading at least a portion of a fluid delivery device in a guide catheter; making an opening in a wall of an aorta of the patient; introducing a distal portion of the preloaded guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery; positioning the distal portion of the guide catheter in the coronary ostium; advancing the fluid delivery device through the guide catheter to position a distal end portion of the fluid delivery device in a fluid delivery location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and passing a fluid or drug through the fluid delivery device and into the coronary artery.

The distal end portion of the fluid delivery device may include a light delivery portion, in which case the method further includes illuminating the light delivery portion to in turn illuminate the distal portion of the guide catheter to facilitate advancement of the distal portion of the guide catheter from the opening in the aorta to the coronary ostium. The method further includes delivery of one or more of the drugs identified above.

Further disclosed is a method of delivering a fluid or drug to within a coronary vessel of a heart of a patient which includes preloading a fluid delivery device over a guidewire; making an opening in a wall of an aorta of the patient; introducing a distal portion of a preshaped catheter through the opening in the aorta and advancing the distal portion from the opening in the aorta to a coronary ostium of a coronary artery; introducing a distal portion of the preloaded fluid delivery device and guidewire through the preshaped catheter and advancing the distal portion of the fluid delivery device and guidewire to a position within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and passing a fluid or drug through the fluid delivery device and into the coronary artery.

The distal portion of the guidewire may include a light delivery portion, which is illuminated to facilitate advancement of the distal portion of the fluid delivery device.

According to another aspect of the invention, a method of placement of an intravascular device within a coronary vessel of a heart of a patient is provided, to include making an opening in a wall of an aorta of the patient; introducing a distal portion of a guide catheter through the opening in the aorta and advancing the distal portion from the opening in the aorta to a coronary ostium of a coronary artery; positioning the distal portion of the guide catheter in the coronary ostium; advancing the intravascular device through the guide catheter such that a distal end portion of the intravascular device is positioned at a location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

The distal end portion of the intravascular device may be configured in various ways to facilitate the advancement thereof. For example, the distal end portion may include a light delivery portion, wherein illumination of the same facilitates advancing of the distal end portion of the intravascular device. The distal end portion may include at least one electrode, wherein electrical sensing of electric signals generated by a pacemaker node of the heart facilitates advancing of the distal end portion of the intravascular device. The distal end portion may include at least one ultrasonic transducer, wherein transmission and reception of ultrasonic signals facilitate advancing of the distal end portion of the intravascular device. Still further, the distal end portion may include at least one magnetic element, wherein use of a magnetic probe, externally of the vessel, guides the at least one magnetic element to the diagnostic or therapeutic location with the vessel, thereby facilitating advancement of the distal end portion of the intravascular device. The distal

end portion may include at least one palpation member, wherein palpating of the palpating member, through a wall of the vessel, facilitates advancing of the distal end portion of the intravascular device.

The intravascular device may be an intravascular fluid delivery device as disclosed previously. Alternatively, the intravascular device may be a catheter used to perform any one or more of a variety of different catheter-based therapies, most preferably without the use of fluoroscopy to position and locate the catheter within the vessel. Catheter-based therapies which may be used in the context of the present invention include, but are not limited to, stent placement, angioplasty, drug delivery (as described above, for example) and ablation. Additionally, a variety of diagnostic catheter techniques may be employed with the illumination methods of the present invention, including, but not limited to, radiography, angiography, endoscopic imaging, and the like.

According to another aspect of the present invention, a method of placement of a fluid delivery device within a coronary vessel of a heart of a patient includes preloading at least a portion of a fluid delivery device in a guide catheter; making an opening in a wall of an aorta of the patient; introducing a distal portion of the preloaded guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery; positioning the distal portion of the guide catheter in the coronary ostium; and advancing the fluid delivery device through the guide catheter to position a distal end portion of the fluid delivery device in a location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

In this embodiment, the distal end portion of the guide catheter may include a light delivery portion, wherein illumination of the light delivery portion illuminates the distal portion of the guide catheter to facilitate the advancement of the distal portion of the guide catheter from the opening in the aorta to the coronary ostium. Alternatively, or in addition, the distal portion of the fluid delivery device may include a light delivery portion, which, when illuminated, illuminates the distal portion of the guide catheter to facilitate placement thereof. Thus, the advancement can be viewed, through the vasculature, during the advancement, without the use of fluoroscopy.

Also, the provision of a distal end portion of the fluid delivery device to include a light delivery portion facilitates advancement of the fluid delivery device through the guide catheter to position the distal end portion of the fluid delivery device in a fluid delivery location downstream of the coronary ostium without the use of fluoroscopy.

Still further, a method is provided for placement of a fluid delivery device within a coronary vessel of a heart of a patient, which includes preloading a fluid delivery device over a guidewire; making an opening in a wall of an aorta of the patient; introducing a distal portion of a preshaped catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery; and introducing a distal portion of the preloaded fluid delivery device and guidewire through the preshaped catheter and advancing the distal portion of the fluid delivery device and guidewire to a position within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

The distal portion of the guidewire may include a light delivery portion, wherein illumination of the light delivery portion facilitates advancement of the distal portion of said fluid delivery device.

More generally, a method of placement of an intravascular device within a vessel of a patient, with or without the use of fluoroscopy, is provided, which includes providing an intravascular device having a fluorescing material provided on a distal end portion thereof; introducing the distal end portion into the vessel and advancing the distal end portion within the vessel; and passing visible light through the wall of the vessel and onto the fluorescing material to cause fluorescence of the material, thereby enabling visualization of the distal end portion externally of the vessel, by the naked eye or with filtering or electronic magnification of the optical signal.

The invention described below solves the deficiencies of the prior art and offers a number of advantages that will be apparent to one of ordinary skill in the art from the following detailed description, accompanying figures, and appended claims. Other embodiments and features of the invention are also set forth in the description, accompanying drawings and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of an infusion catheter constructed in accordance with the principles of the present invention.

Figure 1A is a side elevational view of the infusion catheter of Figure 1 showing in phantom the catheter being bent into different configurations to fit varying anatomical situations.

Figure 1B is a transverse cross-sectional view of a section of the tube of the catheter shown in Figure 1.

Figure 1C is a side elevational view of the catheter of Figure 1 with a second bend near the distal end of the catheter to facilitate placement of the catheter into a coronary ostium of a coronary artery.

Figure 2 is a side elevational view of an alternative embodiment of the infusion catheter of Figure 1 made from composite materials.

Figure 2A is a partial cut-away view showing the construction of the tube of the catheter shown in detail 2A of Figure 2 with the various sections of the tube exposed.

Figure 3A is a side elevational view of a straightening needle assembly shown removed from the infusion catheter of Figure 2 which can be used to straighten the distal portion of the catheter tube to facilitate its placement into the coronary ostium of a coronary artery.

Figure 3B is a detail view of the distal portion of the straightening needle assembly of Figure 3A.

Figure 3C is a side elevational view of the straightening needle assembly of Figure 3A shown inserted into the infusion catheter with the needle in a retracted position.

Figure 3D is a side elevational view of the straightening needle assembly of Figure 3A shown inserted into the infusion catheter with the needle in an extended position.

Figure 4A is a schematic view of the infusion catheter of Figure 1 shown being inserted through an incision in the aorta of a patient.

Figure 4B is a schematic view of the infusion catheter of Figure 2 with the straightening needle assembly inserted therein shown being inserted into the aorta of a heart of a patient.

Figure 4C is a schematic view of the infusion catheter of Figure 1C shown fluidly connected to a syringe assembly for delivering a cardioplegia solution to the coronary ostium of the right coronary artery of the heart of the patient.

Figure 5 is a schematic view of the infusion catheter of Figure 1 having been inserted through an incision in the aorta of a patient and having an adapter with hemostasis valve attached.

Figure 6 is a schematic view of an illuminated catheter according to the present invention, being inserted through an infusion catheter as positioned in Figure 5.

Figure 7 is a schematic exemplifying preloading of an illuminated catheter into an infusion catheter, prior to inserting the infusion catheter into the aorta.

Figure 8 schematically shows further advancement of an illuminated catheter, beyond the distal tip of the infusion catheter and into a coronary vessel.

Figure 9A is a transverse cross-sectional view of one embodiment of a tube of an illuminated catheter, such as that shown in Figure 8.

Figure 9B is a transverse cross-sectional view of another embodiment of a tube of an illuminated catheter, such as that shown in Figure 8.

Figure 9C is a transverse cross-sectional view of still another embodiment of a tube of an illuminated catheter, such as that shown in Figure 8.

Figure 10 schematically shows advancement of another embodiment of an illuminated catheter being inserted through an infusion catheter as positioned in Figure 5.

Figure 11 shows another embodiment of the present invention in which an illuminated guidewire is used to locate a catheter.

Figure 12 schematically shows another embodiment of an intravascular catheter according to the present invention which includes fluorescing strips or bars for locating the catheter during placement.

Figure 12A schematically shows another embodiment of an intravascular catheter according to the present invention, which includes a steering member located on a distal portion of the catheter.

Figure 13A is a side elevational view of an intravenous over the needle catheter which is adapted to be inserted directly into a coronary vessel, such as the right or left coronary artery, and which can be used in conjunction with the infusion catheter of the present invention to deliver a cardioplegia solution into a coronary vessel of the heart.

Figure 13B shows the intravenous catheter of Figure 13A inserted into the right coronary artery distal to its coronary ostium and prepared for delivery of a cardioplegia solution into the artery via an infusion pump.

Figure 14 shows an example of an intraluminal shunt inserted into the right coronary artery distal to its coronary ostium and prepared to deliver a cardioplegia solution into the artery via an infusion pump.

Figure 15 is a side elevational view of an alternative embodiment of the infusion catheter of Figure 1.

Figure 15A is a transverse cross-sectional view through a portion of the distal section of the catheter shown in Figure 15 showing the separate and independent fluid delivery and blood perfusion lumens and one of the perfusion side holes in fluid communication with the blood perfusion lumen.

Figure 16 is a side elevational view of an alternative embodiment of the infusion catheter of the present invention.

Figure 16A is a detail view of the distal tip section of the catheter of Figure 16.

Figure 16B is a transverse cross-sectional view through the distal tip section of the catheter of Figure 16 showing the blood perfusion channels through the distal tip.

Figure 17 is a side elevational view of another embodiment of an infusion catheter constructed in accordance with the principles of the present invention.

Figure 17A is a sectional view of the infusion catheter of Figure 17 taken along the section line 17A-17A in Figure 17.

Figure 17B is a sectional view of the infusion catheter of Figure 17 taken along the section line 17B-17B in Figure 17.

Figure 18A is a side elevational view of another embodiment of an infusion catheter ,according to the present invention, which includes a distally located occlusion element.

Figure 18B is a sectional view of the infusion catheter of Figure 18A taken along the section line 18B-18B in Figure 18A.

Figure 18C is a sectional view of the infusion catheter of Figure 18A taken along the section line 18C-18C in Figure 18A.

Figure 19A is a side elevational view of a relatively rigid pre-shaped guide catheter that is used to facilitate insertion of a generally straight, flexible infusion catheter.

Figure 19B is a sectional view of the guide catheter of Figure 19A taken along the section line 19B-19B in Figure 19A.

Figure 19C is a sectional view of the guide catheter of Figure 19A taken along the section line 19C-19C in Figure 19A.

Figure 19D is a top plan view of the guide catheter of Figure 19A.

Figure 20A illustrates insertion of the guide catheter and infusion catheter assembly into an aorta through an incision in the aorta, according to a method of insertion of the guide/infusion catheter assembly according to the present invention.

Figure 20B illustrates removal of the guide catheter from the infusion catheter and withdrawal from the aorta.

Figure 20C illustrates the infusion catheter in position for infusion of a fluid into the coronary ostium and downstream through the right coronary artery.

Figure 21A is a side elevational view of another embodiment of an infusion catheter according to the present invention.

Figure 21B is a side elevational view of a guide catheter used for insertion of the infusion catheter of Figure 21A.

Figure 22A shows insertion of the guide catheter/infusion catheter assembly into the aorta.

Figure 22B illustrates the infusion catheter of Figure 21A in position for infusion of a fluid into the coronary ostium and downstream through the right coronary artery.

Figure 23 is a side elevational view of another embodiment of an infusion catheter, according to the present invention, having a distal tip portion including at least one suction port to stabilize the distal tip portion and sealingly engage with aortic tissue surrounding the coronary ostium.

Figure 23A is a sectional view of the catheter of Figure 23 taken along the section line 23A-23A in Figure 23.

Figure 23B is a distal end view of the catheter of Figure 23 viewed from the line 23B-23B in Figure 23.

Figure 23C is a partial cut away view of the distal tip portion of the infusion catheter of Figure 23.

Figure 23D shows the infusion catheter of Figure 23 in sealing engagement with the aortic tissue surrounding the coronary ostium.

Figure 24 is a side elevational view of an alternative embodiment of the distal portion of the infusion catheter of Figure 23.

Figure 25 schematically shows another embodiment of an infusion catheter having an illuminated tip.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings wherein like numerals indicate like elements, various embodiments of an infusion catheter and associated fluid delivery systems are shown in accordance with the principles of the present invention.

Figure 1 depicts one embodiment of the infusion catheter 10 of the present invention, shown here in a conventional catheter configuration with a plastic luer hub 18 at

the proximal end of the catheter 10. Luer hub 18 is conventional in the medical field for making connections with other fluid carrying tubular members. Infusion catheter 10 has a proximal section 12 and a distal section 14. The catheter includes an elongated catheter tube 11 which defines an internal lumen 16 (see Figure 1B) through which a drug or other fluid, or another drug delivery catheter, passes. Delivery lumen 16 extends from luer hub 18 through tube 11 and through the distal end 20 to a distal opening 22. Bonded to the distal end 20 of tube 11 is a relatively smooth, atraumatic distal tip 24 which is preferably made from stainless steel or plastic, preferably silicon or other relatively pliable polymeric material such as polyurethane with a durometer hardness of about 90 Shore A to 55 Shore D. The distal tip 24 may also have a slightly lesser durometer hardness, such as between 50 Shore A to 70 Shore A, preferably about 70 Shore A, for example. The atraumatic distal tip 24 is intended to minimize traumatic engagement with aortic tissue surrounding the coronary ostium and the coronary vessels upon insertion of the device. As used herein, the term "coronary vessel" refers to only those vessels that directly supply blood to or remove blood from the heart tissue, e.g., the left and right coronary arteries and corresponding coronary veins, vessels interconnecting the coronary arteries and veins such as the circumflex vessels, etc.

Tube 11 is preferably pre-shaped and has at least a first bend 15 with a radius of curvature sufficient to position distal end 20 of tube 11 into the coronary ostium when the proximal end of tube 11 extends from an opening in the aorta. As shown in the drawings, tube 11 may have a general J-shaped configuration which facilitates surgical insertion of the device. However, it is to be appreciated that the tube 11 may have a variety of shapes other than J-shaped, such as the well-known Judkins and Amplatz configurations for both the right and left coronary arteries, or other configurations, to facilitate placement of the distal end 20 of the device 10 into the coronary ostium. As shown in Figure 1C, the distal section 14 of device 10 can also include a second bend 19. Bend 19 further facilitates placement of distal end 20 into the coronary ostium (as best shown in Figure 4C) and helps to minimize traumatic engagement of the distal end 20 of the device with the coronary ostium by substantially conforming the distal end 20 of the device 10 to be in registry with the longitudinal centerline of the ostium into which it is inserted. Second bend 19 is preferably a distance of about 5 to 15 mm from the distal end 20 of device 10. Second bend 19 may subtend various angles depending on patient anatomy and surgeon preference. In one embodiment, bend 19 subtends an angle of between about 20 to 90 degrees relative

to the longitudinal axis of the generally straight proximal section 12 of tube 11. Luer hub 18 includes an orientation flange 13 which is coplanar to bend 15 in tube 11 and extends in an 180 degree opposite direction to bend 15 to provide a frame of reference to the surgeon indicating the orientation of bend 15 to ease in placement of the device 10.

The tube 11 can be made from a relatively stiff material, such as stainless steel or plastic, or other similar material of like stiffness, to assist the surgeon in palpating it into place in the coronary ostium of a desired coronary artery. Preferably, the tube 11 is made from a material such as polyurethane or nylon which remains relatively stiff during insertion, yet inherently softens once placed into the body to lessen the chances of trauma when engaging with aortic tissues and the like during placement and while residing in the patient. When made of stainless steel, the tube 11 preferably is also relatively malleable to allow the surgeon to modify and shape it to fit the particular anatomical situation as shown in phantom in Figure 1A.

An example of a preferred embodiment of the infusion catheter of Figure 1 in which tube 11' is made from composite materials is shown in Figures 2 and 2A. As shown therein, the tube 11' of infusion catheter 10' can be formed (e.g., extruded) from a relatively pliable polymeric composite construction to provide enhanced flexibility. For example, the tube 11' of Figures 2 and 2A could have a relatively flexible, layered construction made from conventional plastic composite materials. Specifically, as shown in the detailed partial cut-away view of tube 11' in Figure 2A, tube 11' may include an innermost thin-walled inner lubricious layer 21 composed of a Teflon coating, for example, to allow for the smooth passage of a drug delivery device or stiff straightening needle assembly 50 through the tube and into the coronary artery as will be explained in greater detail below. The inner Teflon layer 21 may not be necessary, however, if catheter 10 is not used to pass a drug delivery catheter or similar device into the coronary artery or if sheathed needle assembly 50 is not used. The middle layer 23 includes a reinforcing matrix, preferably a braided wire matrix, preferably made from stainless steel, to provide overall stiffness and torqueability to the tube 11'. The outer layer 25 can consist of a pliable plastic material such as polyurethane, nylon, polyethylene or polyvinylchloride which enhances overall stiffness. The relative thickness' of the various composite layers may vary depending on the use of the device and the vessel anatomy into which it is placed. In one embodiment of the invention, the inner layer 21, if used, would have a thickness of about 0.002 inch (0.051 mm). The braided middle layer 23 would have a wall thickness of

between about 0.003 to 0.006 inch (0.076 to 0.152 mm), for example about 0.005 inch (0.127 mm). The outer layer 25 would have a wall thickness of between about 0.005 to 0.016 inch, preferably between about 0.005 to 0.008 inch (0.127 mm to 0.203 mm), and more preferably about 0.006 inch (0.152 mm), for example.

The tube 11' is sufficiently flexible so that bend 15' can be easily straightened (as shown in phantom in Figure 2) to assist in placement of the device through an opening in the aorta. To enhance the flexibility of tube 11' and thereby minimize vessel trauma during device insertion and placement, the tube 11' may have a gradually decreasing stiffness toward its distal end. This variability in stiffness can be accomplished by gradually or incrementally decreasing the wall thickness of the tube 11' in a direction from the proximal end to the distal end, or by gradually or incrementally decreasing the durometer hardness of one or more materials in the wall of tube 11' in a direction from the proximal end to the distal end.

To assist the surgeon in inserting the relatively flexible, shaped catheter tube 11' of Figure 2 into the aorta, a separate stiff straightening needle assembly 50, shown removed from the infusion catheter 10' in Figure 3A, is provided which is adapted to fit within lumen 16' of catheter 10' for straightening the end during insertion of the catheter into the aorta. As best shown in the detail view of the distal end of the straightening needle assembly of Figure 3B, the straightening needle assembly 50 generally includes a retractable cutting element, or needle blade 52, slidably located within a protective tube, or sheath 51, at the distal end of the sheath 51 and moveable between a retracted position and an extended position. In the retracted position of needle 52, needle 52 is shielded by sheath 51 to prevent piercing of tube 11' during insertion of the needle assembly 50 into the tube 11' (see Figure 3C). Needle 52 is fixed to an actuator member 56 by a push rod 54. The proximal handle portion 58 of sheath 51 includes lower and upper locking annular recesses 53, 55, respectively provided in an inner surface of handle portion 58. Recesses 53 and 55 are spaced apart from one another and are configured to receive in a press-fit engagement an annular locking detent 59 provided on an outside surface of actuator member 56 to secure the sheath 51 to the actuator member 56 in either the retracted or the extended position of the needle 52.

Figure 3C shows infusion catheter 10' with the straightening needle assembly 50 fully inserted therein with the needle 52 in the retracted position. In the retracted position of needle 52, locking detent 59 engages locking recess 55 to secure the needle assembly in

its retracted position. Sheath 51 can then be inserted into tube 11' of the infusion catheter 10' such that needle 52 does not pierce tube 11' of the catheter. The stiffness of straightening needle assembly 50 overcomes the intrinsic curvature of tube 11' and thus straightens the end of the catheter. In this configuration, actuation of actuator member 56 will cause locking detent 59 to move out of selective engagement with locking recess 55 and to be captured by locking recess 53. In turn, needle 52 will move axially within sheath 51 to protrude a slight distance beyond the distal end of sheath 51 and tube 11' for making a small incision in the aorta, as shown in Figures 3D and 4B. After an incision in the aorta is made with needle 52 and the assembly is introduced into the aorta, the entire straightening needle assembly 50, including sheath 51 and needle 52, can then be removed from tube 11' of infusion catheter 10' to allow the tube 11' to resume its fully curved, normal configuration. In this position, the distal end 20' of tube 11' may be advanced into the coronary ostium and readied for fluid delivery as further explained below. Although a locking mechanism in the form of a detent/recess configuration has been described in the above representative embodiment, various types of locking mechanisms may be used to fix the movement of needle 52 with respect to sheath 51 including, for example, a spring-biased plunger mechanism, a rotatable threaded knob that converts rotational motion into axial motion, and the like.

The dimensions of the tube 11 (and 11') of catheter 10 (and 10') will vary depending on the dimensions of the coronary vasculature of the patient into which the device is inserted. For most infusion catheters 10, the length of the catheter tube 11 will be between about 5 to 20 cm, preferably about 5 to 15 cm, more preferably about 10 cm, for example. The distal end 20 of the tube 11 should be constructed to fit within the coronary ostium, i.e., to be positioned directly adjacent the ostium or to extend a short distance (e.g., about 0.5 to 3 cm, preferably about 2-3 cm, for example) into the ostium, as shown in the figures. Because the tube is not provided with blood perfusion means in the above embodiments, the maximum outside diameter of the distal end 20 including distal tip 24 of tube 11 should be sufficiently smaller than the diameter of the ostium into which it is inserted to prevent occlusion of the ostium and to permit blood from the aorta to pass therethrough. Accordingly, the outside diameter of distal end 20 with distal tip 24 should be less than about 3 mm, and preferably ranges from between about 0.5 to 4.0 mm, preferably about 0.5 to 3.0 mm, more preferably about 3.0 mm, for example, to provide

maximum cross-sectional fluid flow area while also not occluding blood flow through the coronary ostium and into the coronary artery during use of the device.

The operation of the device 10 of Figure 1 for inducing reversible ventricular asystole in the heart of a patient to facilitate a cardiac or other surgical procedure will now be described. The methods herein described are used in an open chest surgical procedure where the surgeon gains access to the heart via a partial or median sternotomy by severing the sternum, or a portion of it, along its longitudinal midline to expose the thoracic cavity. A cardioplegia solution, such as a pharmaceutical composition including an AV node blocker and a beta blocker, can then be delivered to the coronary vasculature with the devices of the present invention to induce reversible ventricular asystole. However, the methods described herein are illustrative only and in no way limit the variety of procedures in which the apparatus of the present invention can be used. While the infusion catheter and related devices of the present invention are particularly well suited to facilitate a TRANSARREST™ procedure, as described above and below, the systems and devices are not limited to their use in a TRANSARREST™ procedure, and can be used to facilitate any medical or surgical procedure in which it is required to deliver a therapeutic, diagnostic, or other pharmacological agent, or other device such as a drug delivery catheter, into the coronary vasculature of the heart. For example, infusion catheter 10 can be used to deliver contrast media, e.g., radio-opaque agents, into the coronary vasculature for viewing blood vessel anatomy and blood flow characteristics in a target region, such as at an anastomosis site. In addition, infusion catheter 10 could be used in other situations to locally administer to the coronary vessels of the heart one or more of a wide variety of therapeutically useful pharmacological agents to prevent thrombus formation, smooth muscle cell proliferation, or inflammatory responses at an anastomosis site or in a stenosed region of a diseased vessel. Examples of such drugs include anti-platelet or anti-thrombus agents (such as Heparin, Hirudin, tPA, Streptokinase, Urokinase, Persantine, Aspirin, etc.), anti-inflammatory agents (such as steroidal and non-steroidal compounds), and anti-proliferative compounds (such as suramin, monoclonal antibodies for growth factors, and equivalents). In addition, other potentially useful drugs can be administered into the coronary vasculature to facilitate healing and reduce the incidence of thrombosis at an anastomosis site, such as immunosuppressant agents, glycosaminoglycans, collagen inhibitors, and endothelial cell growth promoters. Still further, infusion catheters of the type described herein could also

be easily adapted to be used in endoscopic port-access procedures, for example, by extending the length of the proximal portion of the infusion catheter tube to allow the distal end portion to be inserted into the aorta from a variety of percutaneous access points in the chest wall.

Referring now to Figures 4A-C, an exemplary use of the device 10 of the present invention for inducing reversible ventricular asystole in the heart during an open chest surgical procedure is presented. The patient undergoing the procedure, such as a coronary artery bypass graft procedure, is prepared according to known techniques for conventional open chest surgery. In this example, the heart 30 is exposed following a median sternotomy. With the heart so exposed, a slit approximately 1-3 mm in length is formed in a side wall of the aorta 32 with a scalpel or other appropriate surgical cutting instrument, such as that disclosed in co-pending patent application Serial No. 09/124,534 for "Surgical Cutting Instrument and Method of Use," filed July 29, 1998, and invented by Michael Hogendijk. Alternatively, a circular or oval punch may be used to facilitate the incision. Additionally, as noted above and in Figure 4B, in use of infusion catheter 10' having flexible tube 11', needle 52 of stiff straightening needle assembly 50 can be used to make an incision in the aorta when in its extended position. Preferably, the incision in the aorta is made on the anterior surface of the heart at a location that is substantially coplanar with the right (or left) coronary artery into which the device is inserted to facilitate placement of the distal end of the device into the coronary ostium of the artery. The infusion catheter 10 is then inserted into the opening formed in the aorta and the distal tip of the device is advanced to and inserted into the coronary ostium 38 of the right 34 (or left 36) coronary artery. One or more purse string sutures may be placed in the aorta 32 to seal the aortic incision around catheter 10 to prevent blood loss once the catheter 10 is inserted therein. The inherent stiffness of tube 11 will assist the surgeon in palpating it into place in the desired ostium from outside of the vessel, and will also cause the device to stay relatively stable in place in the ostium once it is positioned there. When made from a polyurethane or nylon material, the tube 11 will tend to soften upon insertion and contact with blood, tissue and, in general a body temperature environment. Such softening minimizes trauma to the tissues engaged by the tube, including the vessel lumen. A tube 11 made from stainless steel may be bent and shaped to facilitate placing the distal end portion thereof into the coronary ostium. Additionally, the infusion catheter 10 may also be provided with a suture flange (not shown) to assist in securing the catheter to the wall of the heart Also, the distal

portion of the catheter, including distal tip 24, may have an external fluorescent coating to allow visualization of its location during placement and once in place in the coronary ostium.

With the device 10 securely in place in the ostium, a liquid containing a cardioplegia solution is directed through the infusion catheter 10 and into the coronary ostium. The preferred cardioplegia solution is a pharmaceutical composition which is capable of reversibly inducing ventricular asystole in the heart while maintaining the ability of the heart to be electrically paced. In one embodiment, the pharmaceutical composition comprises an AV node blocker compound such as carbachol and a beta blocker compound such as propranolol. The beta-blocker propranolol and the AV node blocker carbachol can be provided as a single kit in separate pharmaceutically acceptable closed carriers and serially administered as an initial intracoronary bolus to induce reversible ventricular asystole of the heart.

For example, in one embodiment, carbachol is provided in a pharmaceutically acceptable carrier suitable for intracoronary administration. The carbachol may be provided in an aqueous carrier, such as water or saline. In the composition, which optionally may be diluted prior to local cardiac administration, the concentration of carbachol may range, for example, from about 0.01 mg/ml to 2.55 mg/ml, e.g., about 0.1 to 1.0 mg/ml. In one embodiment, propranolol may be provided in a separate pharmaceutically acceptable carrier at a concentration of about 0.5 to 6.0 mg/ml, e.g., about 0.5 to 3.0 mg/ml, or about 1.0 to 2.0 mg/ml, or about 1.0 mg/ml.

The bolus injection of propranolol and carbachol can be administered by alternately connecting luer hub 18 to a standard syringe assembly 60 containing the respective compounds and directing the compounds through the syringe into the coronary ostium via lumen 16 of the infusion catheter 10, as shown in Figure 4C (showing infusion catheter 10 with second bend 19 of Figure 1C inserted into the coronary ostium). For example, in one embodiment, an intracoronary injection of 0.5 to 4 mg, for example about 1 mg, of propranolol is administered by intracoronary infusion over a time period of about 0.5 to 3.0 minutes, e.g., about 1 minute, preferably followed by a saline flush, such as 2 mL saline flush. This is followed by an intracoronary bolus injection of about 0.01 to 0.5 mg, e.g., about 0.025 to 0.3 mg, e.g., about 0.1 mg carbachol administered over about 0.5 to 3.0 minutes, e.g., about 1 minute, to initially induce ventricular asystole in the heart. Alternatively, a drug delivery catheter, such as a Target Therapeutics Tracker™ perfusion

catheter, may be inserted through the infusion catheter 10 and advanced further into the coronary artery to serially deliver the cardioplegic compounds more locally to the AV node artery, if necessary. Additionally, a controllable infusion-hole catheter such as is fully described in patent application serial no. 09/276,312, the entire contents of which is hereby incorporated by reference herein, can be used with the transaortic insertion techniques of the present invention. The insertion of a separate drug delivery catheter like the Target Therapeutics Tracker™ through the infusion catheter 10 would likely require the use of radiographic instrumentation to guide the drug delivery catheter into a desired position in the coronary vessel.

To maintain ventricular asystole, for example, a cardioplegia solution is delivered through the infusion catheter at an infusion rate sufficient to maintain reversible ventricular asystole by periodic (e.g., one or more bolus injections) or continuous infusion. In one embodiment, carbachol is administered as a continuous intracoronary infusion through the infusion catheter 10 at a rate of about 0.01 to 0.3 mg/min, e.g., about 0.025 to 0.3 mg/min, for example, about 0.01 to 0.1 mg/min, e.g., about 0.05 to 0.1 mg/min, e.g., about 0.0825 mg/min, for a time period of about 5 to 90 minutes, preferably about 30 to 90 minutes, depending on the length of the procedure. Carbachol can also be administered as a series of bolus injections (e.g., at about 0.05 mg/bolus) through infusion catheter 10 to maintain reversible ventricular asystole. Carbachol can be periodically or continuously administered with syringe assembly 60 or by connecting luer hub 18 to a standard male luer fitting connected to the distal end of a tube which is fluidly coupled to a standard infusion pump (not shown). The infusion pump is fluidly coupled to a source of carbachol and is used to drive the carbachol through the infusion catheter 10 and into the coronary artery via infusion catheter 10. An intravascular dosage of about 1.0 mg of phenylephrine can be systemically administered to the patient to control any hypotensive effects associated with carbachol administration. In most situations, atropine (about 1 mg) is used to reverse ventricular asystole and restore the heart to its normal function following the surgical procedure. Intracoronary nitroglycerine (e.g., about 200 mcg) can also be administered to the heart to counteract any vasoconstrictive effects associated with phenylephrine administration.

With the heart in controlled ventricular asystole, the heart is appropriately prepared for a cardiac or other surgical procedure. Electrical pacing wires are connected to the right ventricle and/or left ventricle and/or atria and are used to pace the heart using a novel foot-

actuated pacer control system (as fully described in the co-pending Transarrest™ patent application Serial No. 09/131,075) to maintain the patient's blood circulation during the periods in which the surgeon is temporarily not performing the surgical procedure. Thus, for example, in a coronary artery bypass graft procedure, the surgeon can control the pacing of the heart with a convenient foot pedal and can controllably stop the heart as sutures are placed in the vessel walls. The procedures with which the systems and methods of the present invention are useful include coronary bypass surgery (with full or partial sternotomy or thoracotomy), transmyocardial laser revascularization, tachyarrythmia operations such as electrophysiology lab procedures (diagnostic and therapeutic ablation of arrhythmias), imaging procedures of the heart and great vessels such as CAT scan or MRI procedures, percutaneous transluminal coronary angioplasty, placement of stents such as coronary or aortic stents, operations where uncontrollable hemorrhage is present or anticipated or control of significant hemorrhage is required during the surgical procedure (for example, treatment of injuries to the liver, spleen, heart, lungs, or major blood vessels, including iatrogenic and traumatic injuries to such organs or structures), other procedures including percutaneous aortic aneurysm graft placement, neurosurgical procedures, such as aneurysm repair, and various other procedures that would benefit from the inducement of ventricular asystole, while maintaining the ability of the heart to be electrically paced. In addition, infusion catheter 10 can be used to infuse the coronary artery with blood from an extracorporeal CPB support system if it is necessary to connect the patient to CPB in an emergent situation, for example.

The infusion catheter described above, or one similar to it as described below, can also be used in combination with an intravascular fluid delivery device to deliver a fluid or drug to a location downstream from the coronary ostium. In the past, intravascular drug delivery catheters and/or guide catheters have typically relied on radiographic imaging, and particularly fluoroscopy for proper catheter placement through the tortuous coronary vasculature system. The use of fluoroscopy has its drawbacks, however. For example, the use of fluoroscopy is expensive, has potential adverse toxic effects on patients and doctors exposed to it if proper precautions are not taken to prevent exposure to fluoroscopic radiation, and typically is not available in the majority of operating room suites.

Figures 5-8 illustrate the use of intravascular catheters which eliminate the extra costs and procedures demanded by a required use of a fluoroscopic or other radiographic imaging technology. Additionally, these inventive devices provide advantages over the

only other method of placing intravascular catheters in a procedure of this type heretofore without the aid of radiographic imaging, i.e., "blind" placement of the catheter(s). Figure 5 is similar to Figure 4A and shows a placed catheter 10, with its distal tip in the coronary ostium 38. In the following embodiments in which catheter 10 is used in combination with an intravascular catheter for delivery of a fluid or drug to a location further downstream in the coronary artery from proximate the coronary ostium, catheter 10 serves as a guide catheter to guide and position the intravascular catheter in the coronary artery. A connector 810 having at least one hemostatic valve has been connected to the hub of the catheter 10 to close the system upon placement of the infusion/guide catheter. An IV line 812 may also be provided for inputting fluids and drugs as needed.

In Figure 6, a hemostatic valve of the connector 810 is opened to allow advancement of an illuminated intravascular catheter 800 according to the present invention. Advantageously, the catheter 800 includes an illuminated distal end portion 802 which may be illuminated according to a variety of techniques, and which, when illuminated, shines through the vessel wall of the vessel into which it has been inserted, in this case the coronary artery, allowing a surgeon or other operator to readily assess the location in the vessel of the distal end of the intravascular catheter 800. Thus, it can be seen that such a device eliminates the expense and inconvenience of the requirement to use fluoroscopy or other alternative radiographic imaging techniques, while still allowing visualization of the catheter as it is advanced into the cardiovascular system.

The illumination of the distal end portion 802 can be accomplished in a variety of different ways. One way is to provide an optical fiber to extend distally of the catheter 800, and through the length of the catheter to the distal end portion 802 as shown in Figure 6. The fiber 820 may extend to the very distal tip 804 of the catheter, or may terminate anywhere in a distal end portion 802 of the catheter, wherein it will illuminate the tip 804 as light is passed through it. In the embodiment of Figure 6, the optical fiber 802 extends distally from the hub 814 of the catheter and connects externally of the catheter with a light source (not shown). An intravascular line 816 is also connected through the hub 814 to allow the input of fluids and drugs as needed. The light source may be a laser source, a xenon light source, a white light source, an infrared light source, or other concentrated light source known in the art, and could even be optically connected to the same white light source used to illuminate the surgeon's head lamp. Where an infrared light source is used,

an infrared detection apparatus, such as an infrared camera which is conventional, can be used to visualize and confirm the location of the catheter within the vessel.

The optical fiber 820 may be arranged in the catheter 800 according to a number of different configurations. For example, the catheter 800 may simply be provided with a single lumen 806 through which the optical fiber 820 is passed, as shown in Figure 9A. The outside diameter of the optical fiber 820 in this case is much smaller than the diameter of the lumen 806, thereby allowing fluids and drugs to be transported freely through the lumen 806 even after placement of the optical fiber 820.

Figure 9B shows a two lumen configuration, in which a dedicated lumen 808 is provided for the optical fiber 820 to pass through. The optical fiber 820 may be simply slid into place through lumen 808, or, alternatively, the optical fiber 820 could be molded into place or otherwise fixed in position within the lumen 808. A dedicated lumen 806' is provided as a larger lumen than that housing the optical fiber, for the passage of fluids and drugs.

Figure 9C shows yet another variation of the arrangement of lumens that may be provided in an illuminated catheter according to the present invention. In this example, the largest lumen 806" is again provided for the passage of fluids/drugs. Similar to the embodiment in Figure 9B, a dedicated lumen 808' is also provided for housing the optical fiber 820. Additionally, a third lumen 818 is provided to allow passage of the catheter over a guidewire. Of course, Figures 9A-9C are only three examples of a large number of variations in lumen design that could be employed in the present invention. For example, one or more fibers could be wound into the wall of the catheter, extruded or embedded into the catheter or adhered against the wall of the catheter or a catheter lumen. Additionally, an illuminated catheter need not be limited to illumination by a single optical fiber, but could employ two or more optical fibers without departing from the inventive aspects of that described above. The cross-sectional configuration of the one or more lumens could also take many forms, such as circular, oval, D-shaped. crescent-shaped. or any other conventional or like configuration.

Still further alternative illumination sources may be employed. For example, one or more light emitting diodes (LED's) could be embedded, adhered or otherwise affixed to the distal end portion of the catheter and connected by a wire extending through the catheter in much the same way that the optical fiber above is passed through the catheter.

Alternatively, a wire could be molded into the wall of the catheter, eliminating the need for a dedicated lumen or the need to take up space in a single lumen.

Figures 7-8 illustrate an alternative procedure for placing the illuminated catheter 800 and particularly the preshaped catheter 10. In this example, the illuminated catheter 800 is fully inserted or preloaded into the infusion/guide catheter 10, so that the distal end portion 802 substantially aligns with the atraumatic tip 24 of the infusion/guide catheter 10 as shown in Figure 7. Illumination of the distal end portion 802 by turning on the light source (not shown) to which the optical fiber 820 is connected, will then illuminate not only the distal end portion 802, but also the tip 24, which will be visible through the vasculature as the combination of devices is passed therethrough.

Accordingly, the illuminated catheter 800 may then be used to visualize placement of the tip 24 into the coronary ostium. The placement can then proceed much in the same manner as that described above with respect to Figures 4A-4C, with the advantage being that the placement can be visualized without having to rely solely upon palpation and sensitile feedback for proper placement of the tip 24.

Once the infusion/guide catheter 10 has been properly placed, the illuminated catheter 800 is further advanced into the coronary vessel (i.e., the coronary artery 39 in Figure 8). The illuminated tip portion 802 allows constant visualization of the positioning of the end of the catheter as it is advanced, thereby assisting the operator in bypassing side branches of the vessel without unknowingly cannulating them. The catheter 800 is advanced into the coronary vessel, proximate the AV node artery, and to a location which is sufficient to substantially prevent backflow of fluids and or drugs through the coronary ostium as they are passed out of the distal end of the catheter 800. Typically, the advancement places the distal end of the catheter at least about 0.5 cm downstream from the coronary ostium, more preferably about 2 to 8 cm downstream of the coronary ostium. Although a preferred location may vary from patient to patient, a preferred placement has generally been found to occur at about 4 to 8 cm downstream of the coronary ostium.

Figure 10 illustrates a further embodiment of an illuminated catheter 800' according to the present invention. In this example, a light source 830 is contained within the hub 814' of the catheter 800' thereby rendering the catheter more wieldy, requiring less setup, and less lines to avoid during the procedure, since the entire catheter and light source can be disposed of after use in a procedure. Typically, the light source 830 would include a power source, such as a battery 832 and an illumination tube 834. Preferably, the light

source will be the standard light source that supplies light to a surgeon's headlamp to avoid the extra cost and expense of providing a separate light source. In one embodiment, for example, a light source such as a xenon light source (commercially available from Cogent Light Technologies, Santa Clara, California) can be optically coupled to the optical fiber. When a light source from Cogent Technologies is used, the optical fiber can be coupled to the light source using the apparatus and techniques disclosed in one or more of U.S. Patent Nos. 4,757,431; 4,870,952; 4,986,622; 5,414,600; 5,430,634; 5,446,818; 5,452,392; 5,509,095; and 5,598,497, the entire contents of each of which are incorporated by reference herein, to avoid the possibility of melting the fibers and to provide an adequate coupling efficiency between the fiber and the light source. A wavelength of light in the range of about 600 -700 nm is preferred, since this range will facilitate the emitted light energy to pass through blood and bodily tissues.

In yet another variation, a guidewire, preferably a floppy-tipped guidewire 900 is provided with an illuminated end portion 902, as shown in Figure 11. The end portion 902 can be illuminated in any of the manners described previously with regard to the illuminated catheters, but would obviously not include lumens for fluid delivery or other purposes. A preferred method of insertion using this embodiment is to preload an intravascular catheter onto the guidewire prior to insertion of the guidewire into the vasculature. This assembly may then be loaded into the vasculature through an infusion/guide catheter of the type described above, for example, although the insertion of the assembly is not to be limited to use with an infusion/guide catheter. Prior to insertion, the end portion 902 is left to extend distally beyond the distal end 912 of the catheter 910. the end portion 902 is illuminated prior to its insertion into the vasculature, and can be visualized during its advancement through the vasculature in much the same manner described above with regard to the illuminated catheter 800.

The operator continues advancement of the guide wire 900 until it can be visually confirmed that the illuminated end portion 902 has reached the desired location, e.g., about 0.5 to 8 cm downstream of the coronary ostium. Next the catheter 910 is advanced until the distal end 912 substantially aligns with the distal end of the guidewire 900. Catheter 910 is made of a substantially opaque material, or is at least coated at its distal end portion so as to be substantially opaque to illumination. As the distal end portion of the catheter 910 passes over the illuminated end portion 902 of the guidewire, the illumination gradually decreases, thereby confirming to the operator that the distal end of the catheter

910 has substantially aligned with the guide wire 900. This ensures accurate and proper placement of the catheter 910 and particularly, the distal end 912 of the catheter. Preferably, the catheter 910 is sufficiently opaque to diminish the illumination of the end portion 902 as described above, but not so opaque that the light emanating from end portion 902 is fully blocked when the distal end of the catheter has aligned with the distal end of the guidewire. It is preferable to have some light still pass through the wall of the catheter 910 and the vessel wall, though diminished, to allow the surgeon to confirm that the catheter has not substantially moved from its intended fluid delivery location during the course of the procedure. Delivery of fluids and drugs can be accomplished with or without removal of the guidewire 900, although preferably, the guidewire is first removed. Another variation for use of the guidewire 900, would be to insert the guidewire 900 into the infusion/guide catheter and into the position intravascularly before placing an intravascular catheter over the guidewire and into the vasculature.

Referring to Figure 12, an illuminated catheter 1000 is provided with a distal illuminated end portion 1002. In this embodiment, the distal illuminated end portion is formed by attaching fluorescene strips 1010 or strips of other material capable of illuminating or fluorescing when either white light or specific activation wavelengths are incident upon it. Aside from the manner in which the distal end portion 1002 is illuminated, the insertion procedures and variations thereof, for catheter 1000, are substantially the same as those described above with regard to catheter 800. In this embodiment however, the strips 1010 may be illuminated, after the strips 1010 have entered a vessel, by applying light externally of the vessel, which penetrates the vessel and is incident upon the strips 1010, thereby causing the strips 1010 to fluoresce. Advantageously, the illumination may be initiated by various external white light sources, including light from a surgeon's headlamp and light from an operating room lamp, etc.

In addition to the previously described illumination techniques, fluid catheters that are capable of transmitting light to a selected fluid delivery location within a vessel lumen that avoid having to use a fixed length optical fiber (or electrical circuitry associated with the use of LED's, other electrical circuitry and the like) inside the catheter tube can be used to assist in the safe and effective placement of the catheter without reliance on fluoroscopy. For example, a fluid delivery catheter that has a low refractive index cladding and an aqueous fluid core such as is fully described in U.S. Patent No. 5,267,341, the entire contents of which are expressly incorporated by reference herein, can be used with the

transaortic insertion techniques of the present invention to illuminate a fluid delivery location within a vessel to enable a surgeon to visually observe the catheter tip relative to its vessel surroundings. As described in U.S. Patent No. 5,267,341, a light transmitting catheter is disclosed having an aqueous core for transmitting light and for infusing fluid into the area to be illuminated through the open distal end of the catheter. In particular, the catheter includes a tube having an interior surface for containing an aqueous fluid wherein the interior surface has an index of refraction less than the index of refraction of water. A light source communicates with an optical fiber that is positioned at least partially in the proximal end of the catheter tube and the aqueous core. In operation, the catheter can be illuminated by passing an aqueous solution (such as any of the drug compounds described previously, for example) into the catheter tube to fill the catheter tube. Light form a light source, such as a laser or white light source, preferably a white light source, can then be passed through the aqueous solution to illuminate the fluid delivery location eternal to the distal portion of the catheter tube. Thus, the distal end portion of the catheter can be efficiently and precisely monitored during fluid or drug delivery through the catheter to ensure that the distal end portion does not become substantially dislodged from the selected fluid delivery location.

It will also be appreciated that a variety of other different catheter designs may be used with the present invention for delivering a fluid or drug to the coronary vasculature system without the use of fluoroscopy for catheter insertion and placement. Non-limiting examples of alternative catheter designs which may be used with the transaortic guide catheters of the present invention include electrode catheters, magnetically-tipped catheters, ultrasonically-guidable catheters, balloon-tipped catheters, and other catheters that can be guided to a drug delivery site within a coronary vessel without the use of fluoroscopy.

An example of an intravascular catheter that can be used with the present invention is described, for example, in U.S. Patent Nos. 5,078,678 and 5,078,714, the entire contents of which are incorporated by reference herein. An electronic catheter monitoring system is disclosed in those patents for monitoring the natural pacemaker node potentials, obtained at the distal tip of a catheter, of a pacemaker node of the heart, such as the SA node or the AV node. The catheter system includes a catheter that is provided with a set of electrodes spaced apart from each other at the distal tip of the catheter. The electrodes are used to sense electrical signals generated by a pacemaker node of the heart (such as the AV node or, in some cases, the SA node). The respective electrodes can be used in conjunction with

a conventional EKG machine for endocardial mapping as is known in the heart. The electrodes provide the user with a nonvisual indication of where the distal section of the catheter is located with respect to the AV node artery, for example, by monitoring the electrical activity of the AV node. In this way, fluid or drug delivery can be accurately targeted to the AV node artery based on the recorded electrical signals of the AV node.

In addition to electronic catheters which employ electronic means to locate a target region in a coronary vessel for fluid or drug delivery, catheters that use magnetic principles for proper catheter positioning and/or location confirmation can also be used with the present invention. An example of a magnetically guidable catheter tip and method that can be used is disclosed, for example, in U.S. Patent Nos. 3,674,014 and 5,681,260, which are incorporated by reference herein. As illustrated, for example, in U.S. Patent No. 3,674,014, a flexible catheter tip is disclosed which includes a plurality of permanent magnetic tubular sections with ball-shaped ends arranged end-to-end. Each pair of adjacent ends is provided with a tubular link formed of a non-magnetic material which provides a flexible, fluid-tight seal between the tubular sections. The flexible catheter tip may be guided to a proper place within a vessel by a controllable magnetic probe located external to the user.

Confirmation of the proper location of the catheter tip within the vessel can be confirmed also using magnetic principles as described, for example, in U.S. Patent No. 4,431,005. As described in that patent, an open-ended catheter is disclosed that includes a band of magnetic foil located near the tip of the catheter. The band of foil is made from a magnetically permeable metal. The location of the band of foil, and thus the tip of the catheter, is detected using a detecting instrument and a probe located external to the user in which the tip of the catheter is placed. The probe generates a small magnetic field. The probe is used to scan the tissue into which the catheter was inserted, until the detecting instrument detects a disturbance in the probe's magnetic field indicative of the location of the metal band.

In addition to electric and magnetic catheters, catheters that have ultrasonic visibility when used in conjunction with an ultrasonic imaging system can be used with the present invention such as the catheters disclosed in U.S. Patent Nos. 5,325,860 and 5,345,940. Disclosed in those patents is a catheter which contains an ultrasonic transducer proximate its distal end to transmit ultrasound and receive resulting echoes so as to provide a field of view within which internal features can be imaged. An electrical conductor is disposed within the catheter body for electrically connecting the transducer to control

circuitry external of the catheter. An access port is provided in the catheter which can be used as a fluid delivery conduit or for delivery of a therapeutic device or the like to a location within a vessel. The echoes received by the ultrasonic transducer can be processed to image the operation of the device within a blood vessel, for example.

In addition to using some form of energy to guide and/or verify the position of a catheter within a vessel lumen as described above, another method by which to locate a catheter within a blood vessel, such as a coronary vessel, which can be used with the present invention is to provide a small balloon, knob or other similar structure at the distal tip of the catheter to enhance the steerability of the catheter through a vessel. For example, as shown in Figure 12A, an intravascular catheter 1100 can be provided with a micro-balloon 1110 or like structure which could allow advancement of the catheter through a coronary vessel, such as the right coronary artery 34, without the use of fluoroscopy. The balloon 1110, when inflated, provides a defined mass on the catheter 1100, which can be palpated by the surgeon from external the vessel lumen to a fluid delivery location along the length of the vessel (e.g., proximal the AV node artery) for fluid or drug administration. The catheter 1100 preferably includes a conventional y-shaped adapter 1120 which includes a first side arm 1122 to permit infusion of a balloon inflation fluid, such as saline, and a second side arm 1124 that permits infusion of a fluid or drug through the catheter. The catheter 1100 can also be illuminated to aid in its positioning using any of the illumination techniques described previously.

Further alternatively, a catheter system and method that includes a pressure sensor for detecting contact/engagement with obstructions, narrowed passage, or the vessel lumen wall can be used with the present invention for precisely delivering a fluid or drug to a selected intravascular fluid delivery location within a coronary vessel. A catheter having a pressure detecting ability is described, for example, in U.S. Patent No. 5,807,265, the entire contents of which are incorporated by reference herein. As disclosed in that patent, a catheter is provided that includes a pressure sensor for detecting forces acting on the distal end of the catheter. The catheter includes a chamber that is filled with a silicon gel as well as a sensor chip and a cap. The sensor chip has a pressure sensing surface and a backside. The cap transmits the forces acting on the distal end of the catheter to the pressure sensing surfaces of the sensor chip. Further, the catheter has a pressure introducing hole. The pressure introducing hole transmits the forces acting on the periphery of the catheter to the backside of the sensor chip. The sensor chip issues signals externally of the catheter in

accordance with the pressures transmitted to its pressure sensing surface and backside. The catheter can be used, for example, with the transaortic guide catheter of the present invention (e.g., inserted into a coronary vessel through the guide catheter) for accurately sensing the state of the forward travel direction of the catheter within a coronary vessel, such as the right coronary artery, without relying on fluoroscopy to accurately position the catheter at a selected fluid delivery location within the vessel, e.g., proximate to the AV node artery.

Although many of the above-described exemplary catheter systems and surgical instruments are disclosed for specific application through a peripheral access site (such as a femoral artery) or are not otherwise described as being configured to be inserted into the coronary anatomy, it will be appreciated by those skilled in the art that such catheters and instruments can be modified to provide profiles and lengths which are suitable for application via the aortic cannulation methods of the present invention. In each of the above representative embodiments, it is preferred that the catheter or like fluid delivery device be advanced to a position within the coronary vessel, such as the right coronary artery, that is at least about 0.5 cm, for example between about 2 to 8 cm, downstream of the coronary ostium into which the transaortic guide catheter is inserted. This ensures that the majority of fluid or drug administered into the vessel will reach its intended target, e.g., the AV node artery, without being substantially diluted by collateral vessel blood flow. It is also to be appreciated that intravascular devices other than a fluid delivery device may be used with the systems and techniques of the present invention to perform a variety of therapeutic or diagnostic procedures within a coronary vessel. For example, catheter-based therapies which may be used in the context of the present invention include, but are not limited to, stent placement, angioplasty, drug delivery (as described above, for example) and ablation. Additionally, a variety of diagnostic catheter techniques may be employed with the illumination methods of the present invention, including, but not limited to, radiography, angiography, endoscopic imaging, and the like.

According to a further embodiment of the invention, the infusion catheter 10 can be used as a system in conjunction with a separate drug delivery device, such as an IV or other intravascular catheter, which can be placed directly into a coronary vessel, such as a right or left coronary artery downstream from the coronary ostium. For example, as shown in Figures 13A and 13B, infusion catheter 10 can be first used to deliver a bolus injection of a cardioplegia solution, such as an AV node blocker and a beta blocker, to the coronary

ostium 38 of right coronary artery 34 to induce reversible ventricular asystole of the heart, as in the previous embodiments. With the heart temporarily arrested, an intravascular catheter 80, for example a 24 gauge Insyte-W® IV catheter available from Becton-Dickinson, Sandy, Utah, can then be easily inserted directly into a quiescent coronary vessel, such as the right (or left) coronary artery downstream from the coronary ostium, to deliver a cardioplegia solution, such as carbachol, more locally to the AV node artery to enhance the efficiency of drug administration. The intravascular catheter can also be inserted directly into other arteries of the heart, such as Kugel's artery and the right superior descending artery, to administer a cardioplegia solution in an antegrade manner to the AV node in certain anatomical situations. Additionally, the intravascular catheter or like drug delivery device can be directly inserted into a coronary vein, such as the right coronary vein (which is a blood outlet from the AV node) or the middle cardiac vein, and used to perfuse a cardioplegia solution in a retrograde fashion to the AV node.

As shown in Figure 13A, an example of a suitable intravascular catheter 80 is shown which generally comprises a catheter hub 82 through which is removably inserted a needle assembly 84. Needle assembly 84 generally includes needle 83, a blood flashback chamber 86 and a needle plug 88. Needle assembly 84 can be used to make a small arteriotomy puncture in the coronary artery distal to the coronary ostium, as shown in Figure 13B. Upon visualization of blood return in the flashback chamber 86, the catheter hub 82 can then be advanced off the needle assembly 84 and gently moved into the coronary artery. The needle assembly 84 can then be discarded. Catheter hub 82 has a pair of suture holes 89 on opposite sides of the hub through which a suture (not shown) may be passed and secured to the fatty tissue of the heart on opposite sides of the coronary artery to help retain catheter hub 82 in place in the artery. With the catheter hub 82 securely in place in the coronary artery, a standard infusion pump 70 can be fluidly coupled to catheter hub 82. Specifically, a conventional male luer fitting 72 which is fluidly coupled to infusion pump 70 is connected to the proximal end of catheter hub 82. Infusion pump 70 is fluidly coupled to a source of a cardioplegia solution 76, such as carbachol. In this way, a periodic or continuous intracoronary infusion of a cardioplegia solution, such as carbachol, can be introduced into the artery to maintain ventricular asystole during the procedure. The infusion catheter 10 may thereafter be removed from the aorta 32 (as indicated by the arrow in Figure 13B) and the aorta closed to prevent blood loss. Radiographic techniques can be used to determine the region (i.e., the region most proximal to the AV node artery) in the

coronary artery where an incision should be made for proper placement of the intravascular catheter 80 in the artery. This two-step approach to drug delivery may help to reduce traumatic injury to the coronary ostium and/or coronary artery caused by prolonged and chronic movement and contact between infusion catheter 10 and the wall of the vessel during procedures which require manipulation and lifting of the heart, such as multi-vessel bypass procedures which require access to the posterior surface of the heart.

In a further alternative embodiment, intravascular catheter 80 can be used alone in lieu of infusion catheter 10 to deliver a cardioplegia solution locally to a coronary vessel to both induce and maintain ventricular asystole in the heart. To insert intravascular catheter 80 into a coronary vessel on a beating heart, however, it is necessary to first minimize the motion of the beating heart to facilitate its insertion. This can be accomplished with a mechanical cardiac stabilizer, for example. In one embodiment, intravascular catheter 80 can be inserted into place in a coronary vessel on the beating heart with the aid of a conventional mechanical stabilization instrument (not shown), such as the "fork-shaped" coronary vessel stabilizer manufactured by Cardiothoracic Systems, Inc., Menlo Park, California, and described in Boonstra, P.W., Grandjean, J.G., Mariani, M.A., Improved Method for Direct Coronary Grafting Without CPB Via Anterolateral Small Thoracotomy, Ann. Thor. Surg. 1997;63:567-9. The coronary vessel stabilizer in combination with an access platform in which it sits helps stabilize a coronary vessel, such as the right or left coronary artery, on the beating heart and permits a surgeon to make a fine arteriotomy incision with the intravascular catheter 80. Alternatively, the surgeon may also be able to stabilize the vessel on the beating heart to facilitate insertion of catheter 80 by using his fingers to apply slight pressure to either side of the vessel at the region where the arteriotomy incision is to be made.

In further alternative embodiments of the invention, drug delivery instruments other than intravascular catheter 80 may also be used with or without infusion catheter 10 to infuse a cardioplegia solution directly into a coronary vessel, such as the right or left coronary artery or vein. For example, as shown in Figure 14, an intraluminal shunt device 90 such as that described in co-pending patent application Serial No. 09/034,849 entitled "Intraluminal Shunt And Method of Use," and filed on March 4, 1998, can be used in combination with (or in lieu of) infusion catheter 10. For example, after the heart is temporarily arrested by delivering a bolus injection of an AV node blocker and a beta blocker into the coronary ostium using infusion catheter 10, the proximal and distal ends of

intraluminal shunt 90 can be introduced directly into a quiescent coronary vessel, such as the right or left coronary artery proximal to the AV node artery, using conventional radiographic techniques to confirm proper placement of the shunt. Shunt 90 can then be used to periodically or continuously infuse a cardioplegia solution, such as carbachol, directly into the coronary vessel at an infusion rate sufficient to maintain ventricular asystole by fluidly connecting the shunt to infusion pump 70.

Referring now to Figures 15 and 15A, an alternative embodiment of the infusion catheter of Figure 1 is shown in which the catheter tube is provided with a blood perfusion capability to permit blood perfusion through at least a portion of the tube and into the coronary ostium. The infusion catheter 100 of Figure 15 is similar in most respects to infusion catheter 10 except that the tube 111 is provided with two dedicated, separate and independent internal lumens 140 and 142, respectively, which are in a coaxial arrangement (see Figure 15A). Fluid delivery lumen 140 extends within tube 111 from the proximal end of the catheter 100 to a discharge opening in the distal end 120 of the device and is adapted to direct a fluid, such as a cardioplegia solution, from luer hub 118 through the discharge opening at the distal end of the device.

Blood perfusion lumen 142 extends about lumen 140 from a closed location just proximal to the most proximal perfusion hole 144 (described below) of the device to a separate discharge opening in the distal end 120 of the device. The tube 111 includes one or more perfusion side holes 144 in the distal section of the tube 111 which are in fluid communication with perfusion lumen 142. The number of holes and the length over which the holes are distributed can vary depending on vessel anatomy. Preferably, the perfusion side holes 144 are uniformly spaced and staggered on opposite sides of tube 111 along a portion of its length to prevent kinking of the catheter at the location of the holes, as shown in Figure 15A. The side holes 144 can also be spiraled about tube 111 to provide uniform blood perfusion through the catheter. The side holes can be formed through a portion of the outside wall of tube 111 by drilling (e.g., mechanical or laser) or by notching the exterior wall to expose the blood perfusion lumen 142. The perfusion side holes 144 allow for blood to flow through the infusion catheter 100 and down the coronary artery past the coronary ostium when the infusion catheter 100 is positioned in the coronary ostium. This is important to support the heart muscle with oxygenated blood during the surgical procedure in case the blood supply through the coronary ostium is partially or substantially occluded by the presence of the distal tip of the infusion catheter 100 in the ostium.

Alternatively, perfusion side holes 144 can be removed in an alternative embodiment, and blood and/or other fluids can be flowed into lumen 142 through luer fitting 118 to actively perfuse the coronary artery with blood from a blood supply source, for example. For instance, blood can be drawn from a needle inserted into the patient's vasculature, a catheter introducer sheath positioned in an arterial blood source, or the like, and routed to the luer fitting 118 with a standard blood pump.

Fluid delivery lumen 140 and blood perfusion lumen 142 can have any one of a number of cross-sectional configurations as would be obvious to one of ordinary skill in the art, such as a circular, oval, crescent-shaped, or a D-shaped configuration, and can be provided in a coaxial or substantially parallel, side by side arrangement, or any other suitable configuration. Generally, the fluid flow surface area of fluid delivery lumen 140 will be less than the fluid flow surface area of perfusion lumen 142 to maximize the passive perfusion of oxygenated blood into the coronary artery.

Referring now to Figures 16, 16A and 16B, a further alternative embodiment of an infusion catheter 200 having an alternative blood perfusion means is presented. Infusion catheter 200 is similar in most respects to infusion catheter 10 of Figure 1 except that the outside diameter of tube 211 is substantially smaller than the outside diameter of tube 11 of catheter 10 to provide greater flexibility. In a preferred embodiment, tube 211 has an outside diameter of between about 0.5 to 2 mm, and preferably about 0.9 mm. To provide blood perfusion past the distal end 220 of the catheter 200 to preserve the heart muscle during the surgery, one or more perfusion channels 225 are provided in the atraumatic distal tip 224 of the catheter as shown in the detail view in Figure 16A and in transverse cross-section in Figure 16B. In addition, distal tip 224 can be offset slightly from a longitudinal centerline through fluid discharge opening 216 of the device and provided with a single perfusion channel of large cross-sectional area to assist with blood perfusion past the distal end 220 of device. The perfusion channel 225 can have any one of a number of cross-sectional configurations as would be obvious to one of ordinary skill in the art, such as a circular, oval, crescent-shaped, or a D-shaped configuration.

Figures 17, 17A, and 17B show another embodiment of an infusion catheter according to the present invention. Figure 17 shows an elevational view of infusion catheter 300 which, similar to infusion catheter 10, includes a shaft 311 which includes a proximal section 312, a distal section 314, a fluid delivery lumen 316 (see Figure 17A) extending between the proximal and distal ends of the shaft 311 which defines a fluid flow

path through the shaft, and a conventional luer hub 318 and orientation flange 313 (to indicate the orientation of bend 315 in the shaft 311 to facilitate placement of the device) at the proximal end of shaft 311.

According to an important aspect of this embodiment of the invention, the distal portion 314 of shaft 311 includes a tapered section 314a which makes up about 10 to 40% of the total length of shaft 311. The reduction in diameter of the shaft 311 along its distal portion 314 provides enhanced flexibility thereto to facilitate insertion of the shaft into coronary ostia of varying anatomical configurations. The reduced diameter of the shaft at its distal end also maximizes the blood perfusion flow area around the shaft when it is positioned in a given coronary ostium. The constant diameter proximal portion 312 of the shaft provides enhanced rigidity thereto to help maintain the shaft in place in the coronary ostium during use of the device.

Figure 17B shows a sectional view of distal tip 324 which is bonded to the distal end of shaft 311. Distal tip 324 has a "star" shaped configuration in this embodiment which defines four perfusion grooves 325 therein which allow blood from the aorta to perfuse into the coronary ostium when the distal tip 324 is positioned therein. As in previous embodiments, the relatively smooth distal tip 324 minimizes traumatic engagement of the catheter with aortic tissue during placement and use of the device. The outside diameter of distal tip 324 typically will have a diameter of between about 2 to 5 mm depending on vessel anatomy.

The outer diameter of the shaft 311 may vary depending on the use thereof. Typical, non-limiting diameters of the shaft 311 range from about 0.075 to .250 inch for the constant diameter proximal portion 312 of the shaft. The shaft 311 may taper along its distal portion 314 to a diameter of about 0.035 to 0.060 at the distal end of the shaft in the representative embodiment of Figure 17. Shaft 311 can be formed from stainless steel or composite plastic materials, or a combination of those materials. For example, shaft 311 can be made from a reinforced, relatively flexible plastic material, such as nylon or polyurethane, to minimize trauma to the aortic tissue during insertion of the catheter into the coronary ostium of a coronary artery. As shown in the cross-sectional view of shaft 311 of Figure 17A, shaft 311 can be provided with a stainless steel braid 319 embedded in the plastic material to provide rigidity and torqueability to the shaft 311 to facilitate its insertion.

Figures 18A-18C show another embodiment of an infusion catheter 370 which includes a distally located inflatable member 390. The infusion catheter 370 is similar in most respects to infusion catheter 10 except that the tube 371 is provided with two dedicated, separate and independent internal lumens 380 and 382, respectively, which run preferably run substantially parallel to one another, in a coaxial arrangement as shown in Figures 18B and 18C. Fluid delivery lumen 380 extends within tube 371 from the proximal end 375 of the catheter 370 to a discharge opening in the distal end 377 of the device and is adapted to direct a fluid, such as a cardioplegia solution, from luer hub 378 through the discharge opening at the distal end of the device. Inflation lumen 382 extends from an inflation bulb 385 located near the proximal end 375 of the device to an inflatable member 390 near the distal end of the device.

The inflation bulb 385 is preferably a hand held or finger actuatable device which can be readily manually actuated by the operator of the device. Of course it would be possible to automate the inflation feature, but the hand held or finger actuatable embodiment is preferred. Placement of the infusion catheter of Figure 18A can be accomplished using any of the various techniques described above with regard to the other embodiments of the present invention. Once the infusion catheter 370 has been appropriately positioned for infusion into the coronary artery, the inflation bulb 385 is actuated to inflate inflation member 390 to occlude the coronary artery/ostium. Infusion of a fluid, preferably a cardioplegia fluid through lumen 380 can then be accomplished, while insuring that the fluid is projected down the vessel with no back flow into the aorta. Immediately after the infusion, the inflation member 390 is deflated so as to again allow blood flow from the aorta to the coronary vessel.

Alternatively, the distal end of the infusion catheter may be provided with a variety of fixation mechanisms to fixate or retain the distal tip in the artery through the ostium. For example, deployable tines, barbs or other expandable members may be formed on the distal end. Also, the bend or "J-shape" of the infusion catheter can be adjusted so as to bias the distal end portion of the catheter against the coronary vessel wall to assist in the fixation thereof.

Referring now to Figures 19A-D and 20A-C, another embodiment of the invention is shown that includes two separate members, a flexible infusion catheter 410 (see Figures 20A-C) and a relatively rigid guide catheter 430 configured to facilitate introduction of the infusion catheter 410 into a coronary ostium of a given coronary artery. Flexible infusion

catheter 410 (as shown being inserted into the aorta in Figures 20A-C) is similar in most respects to infusion catheter 10, except that it is not pre-shaped. However the inherent flexibility of catheter 410 allows it to be easily shaped to conform it to the configuration of guide catheter 430 during insertion.

Figures 19A-D illustrate a guide catheter 430 which is configured to mate with flexible infusion catheter 410 to facilitate insertion of the infusion catheter 410 into a coronary ostium of a given coronary artery. Guide catheter 430 includes a tubular shaft 432 made from a relatively rigid material such as stainless steel or a rigid plastic material. Shaft 432 is preformed into a general J-shaped configuration. Shaft 432 has a general U-shaped cross-sectional configuration defining a channel 434 along the length of the shaft as shown in Figure 19B which is shaped to releasably receive the tubular shaft of infusion catheter 410. Shaft 432 includes an arcuate, generally C-shaped retention member 436 at the distal end of the shaft, as shown in the cross-sectional view of Figure 19C, which is adapted to receive the distal end of infusion catheter 410 in a press-fit engagement to help retain the shaft within channel 434. The proximal end of shaft 432 can include a winged handle member 438 which can be grasped by a surgeon to facilitate manipulation and insertion of guide catheter 430 through the aorta.

A method of insertion of the above-described guide/infusion catheter assembly into a coronary ostium of a given coronary artery through an aortotomy or similar smaller incision will now be described with reference to Figures 20A-C. Figure 20A shows a portion of a heart 440 having an aorta 442 and a coronary ostium 444 of a right coronary artery 446. Initially, an aortotomy or similar incision is made in the aorta 442 proximal to the coronary ostium 444 with a standard scalpel or other appropriate cutting instrument. The guide catheter and infusion catheter assembly are then inserted as a unit into the aorta 442 through the incision therein as shown in Figure 20A. The guide catheter 430 is then palpated into place in the coronary ostium 444. With the guide catheter 430 firmly positioned in the coronary ostium, the guide catheter can subsequently be removed from the fluid infusion catheter 410 and withdrawn (as shown by the arrows in Figure 20B) to allow a fluid, such as a cardioplegia solution, to be injected into the coronary ostium and downstream through the right coronary artery through the infusion catheter 410 (see Figure 20C). The advantage of this embodiment of the present invention over previous embodiments is that the presence of a substantially flexible infusion catheter 410 in the coronary ostium provides less traumatic engagement of the device with aortic tissue and the

coronary vessel during use of the device. The guide catheter 430 is necessary to provide rigidity to the infusion catheter during its insertion to allow it to be easily palpated into place in the ostium, while its subsequent removal alleviates the risk of serious traumatic engagement of the device with the heart tissue.

Referring to Figures 21A-B and 22A-B, an alternative embodiment of an infusion catheter/guide catheter assembly is shown with a modification to the retention mechanism for retaining the infusion catheter 510 adjacent the guide catheter 530 during insertion and tracking of the unit through the aorta. As shown in Figure 21A, infusion catheter 510 in this embodiment includes one or more annular retention sleeves 550 at the distal portion of the catheter which are configured to slidably receive the distal portion of guide catheter 530 therein to releasably retain the guide catheter adjacent the infusion catheter 510. Retention sleeves 550 also serve to firmly position the infusion catheter 510 in the coronary artery to prevent its removal therefrom as shown in Figure 22B, which illustrates the final placement of the infusion catheter in coronary artery 546 following removal of guide catheter 530 therefrom. Retention sleeves 550 also allow adequate blood perfusion through the sleeves to supply the heart muscle with oxygenated blood from the aorta during use of the device. Guide catheter 530 may have any one of a number of cross-sectional configurations in this embodiment such as circular as shown, or other configurations such as an I-beam cross-section, square cross-section, oval cross-section, and any other suitable cross-sectional configuration.

Figures 23-23D show an alternative embodiment of an infusion catheter 710 which is constructed so as to minimize catheter extension into the coronary artery and coronary ostium during fluid delivery through the catheter 710. Infusion catheter 710 is configured to be located in sealing engagement with the aortic tissue surrounding the coronary ostium while permitting blood perfusion from the aorta through the infusion catheter and into the coronary artery to preserve the heart muscle during the surgical procedure. An important advantage of this particular embodiment is that it helps minimize the degree of traumatic engagement of the device with aortic tissue and the coronary artery during use of the device while still stabilizing the distal end of the device proximal the coronary ostium to allow accurate fluid delivery therein. Infusion catheter 710 has many of the same general features of infusion catheter 10 including a relatively flexible tube 711 having a general J-shaped configuration which is made from a plastic or stainless steel material, preferably polyurethane, a proximal luer hub 718 including an orientation flange

713 at the proximal end 712 of tube 711, and a distal tip 724 bonded to tube 711 near the distal end 714 of the tube.

Infusion catheter 710 includes a stabilizing mechanism associated with the distal end portion of the catheter which is used to stabilize the distal end of the catheter proximal to the opening of the coronary ostium. In the representative embodiment shown, distal tip 724 includes a continuous annular outer support surface 726 adapted to be located in sealing engagement with aortic tissue surrounding the inlet opening (i.e., the coronary ostium) to a coronary artery. The outer annular surface 726 engages the aortic tissue surrounding the coronary ostium and is retained in sealing engagement therewith through the generation of a suction force which is applied to the distal end of the catheter as described below. As best seen in the end view of distal tip 724 in Figure 23A and in the partial sectional view of Figure 23C, distal tip 724 preferably includes a plurality of suction ports 715 provided through annular outer surface 726 which fluidly communicate with a circumferential cavity 725 defined within distal tip 724. Of course, a functional embodiment could be successfully employed with only one such suction port, but a plurality of evenly spaced ports as shown is preferred.

An internal lumen 716 located within tube 711 fluidly communicates with cavity 725 at the distal end of the lumen 716. Lumen 716 is adapted to connect to a vacuum source (not shown) through a connector 730 near the proximal end 712 of the device. The vacuum source can be actuated to effect a suction force at the distal annular surface 726 of tip 724 of the catheter via suction ports 715 to stabilize the distal end of the device proximal the coronary ostium.

Infusion catheter 710 also includes two additional dedicated, separate and independent internal lumens 740 and 742, respectively, which run substantially parallel to one another and to lumen 716. Fluid delivery lumen 740 extends within catheter tube 711 from the proximal end 712 of the catheter to a discharge opening in the distal end 714 of the device and is adapted to direct a fluid, such as a cardioplegia solution, from luer hub 718 through the discharge opening at the distal end of the device. Blood perfusion lumen 742 is closed at the proximal-most side hole 744 (described below) and extends to a blood perfusion opening at the distal end 714' of the device. One or more blood perfusion side holes 744 in the distal section of tube 711 are provided which are in fluid communication with perfusion lumen 742. The perfusion side holes 744 allow blood flow into through the infusion catheter 710, thereby allowing the blood to pass through the coronary ostium

(while within the infusion catheter) and down the coronary artery as it exits the infusion catheter, when the infusion catheter is positioned and retained adjacent the coronary ostium.

Trans-aortic placement of the infusion catheter of Figure 23 can be accomplished using any of the various techniques described above with regard to the other embodiments of the present invention. Advantageously, very little of the infusion catheter 710 extends into the coronary artery once it is positioned proximal the coronary ostium. As shown in Figure 23D, once the annular outer surface 726 of distal tip 724 is located in alignment with the coronary ostium and the vacuum source is actuated to effect a suction force at the annular outer surface 726 to sealingly retain the surface 726 adjacent the ostium, only the distal most portion of tube 711 extends into the coronary artery. Because the device does not extend substantially into the coronary artery, it does not traumatize the sensitive lumens of the coronary arteries during use of the device. The small portion of the device 710 that does extend into the coronary artery, however, provides additional support for retaining it therein and also helps to align the device with the centerline of the vessel into which it is inserted.

With the device held in place, a fluid, such as a cardioplegia solution, is then directed under pressure through the fluid delivery lumen 740 and into the coronary artery. Annular outer surface 726 helps to ensure that the fluid is projected down the vessel with no substantial back flow into the aorta. Immediately after the infusion, the vacuum source can be turned off to allow the infusion catheter 710 to be disengaged from the coronary ostium and removed from the aorta.

Figure 24 shows an alternative embodiment 710' of the distal portion of the infusion catheter 710 of Figure 23 with alternative means for effectuating a suction force to retain the distal portion of the catheter adjacent the aortic wall. In this embodiment, the catheter does not apply a circumferential suction force around the perimeter of the coronary ostium to seal the inlet opening to the ostium as in the embodiment of Figures 23-23D. Rather, the catheter of Figure 24 includes a distally located flexible flange member 750 which applies a suction force at several points along the inner surface of the aorta in a direction away from and transverse to the coronary ostium. Flexible flange member 750 includes a plurality of suction ports 755 which communicate with vacuum lumen 716' which is adapted to connect to a vacuum source (not shown) at the proximal end of the catheter as in the previous embodiment. Flange member 750 is sufficiently flexible such

that it can be bent by a surgeon at its hinged portion 751 to assume a generally straight configuration substantially parallel to fluid delivery lumen 740' to facilitate insertion of the catheter through the aorta 762. However, after the catheter 710' is inserted into the aorta 762 and a surgeon releases pressure on the flange member 750, the flange member 750 will tend to resume its natural configuration and will extend transverse to fluid delivery lumen 740'. Alternatively, the catheter 710' can be inserted into the aorta 762 with the use of a relatively rigid guide catheter or sheath (not shown) which when inserted over the catheter 710' will overcome the intrinsic curvature of flexible flange member 750 and thus straighten the flange member. With the guide catheter/infusion catheter assembly aligned with the coronary ostium, removal of the guide catheter will cause flange member 750 to resume its normal bent configuration as shown in Figure 16 at which point suction can be applied to suction ports 755 to secure the catheter in place. The hinged portion 751 of flange member 750 serves to limit the penetration of fluid delivery lumen 740' into the coronary artery 746 and also helps to secure the position of the catheter in the aorta proximal the coronary ostium 764. Fluid delivery lumen 740' is preferably provided with a small diameter tip (e.g., about 0.5 to 3.0 mm) to allow passive blood perfusion past the tip and into the coronary artery 746 during use of the device.

Figure 25 is an embodiment of an infusion catheter 10" which is substantially the same as the infusion catheter 10 described above, with a particular difference being that the catheter 10" includes an illuminated distal end portion 1050. The distal end portion is preferably illuminated using one or more LED's 1052 which are connected and powered as described above with regard to the illuminated catheters, but the illuminated distal end portion 1050 may be illuminated in any of the above-described manners. An illuminated infusion catheter 10" is particularly useful when it is to be used for drug delivery without an intravascular catheter. In this case, the illumination can be used for proper placement of the distal tip in the coronary ostium, and, once placed, can be used to verify that dislodgment of the tip from the coronary ostium has not occurred. Illumination of any of the previously described infusion catheters can be accomplished according to any of the previously described manners of illuminating.

All references cited herein are hereby incorporated by reference.

The above is a detailed description of one or more particular embodiments of the invention. It is recognized and understood that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to

a person of ordinary skill in the art. The full scope of the invention is set out in the claims that follow and their equivalents. Accordingly, the claims and specification should not be construed to unduly narrow the full scope of protection to which the invention is entitled.

CLAIMS

1. An infusion catheter for delivery of fluid into a coronary ostium of a human patient, said catheter comprising an elongated tube having at least one lumen, a proximal end portion, and a distal end portion, said distal end portion being constructed to fit within said coronary ostium while permitting blood from the aorta to perfuse into the coronary artery.

2. The catheter of claim 1, said distal end portion further including a light delivery portion.

3. The catheter of claim 2, wherein said light delivery portion comprises at least one LED embedded in said distal end portion.

4. The catheter of claim 1 or 2, further comprising at least one bend in the tube to facilitate placement of said distal end portion into the coronary ostium when the proximal end portion of said tube extends from an opening in the aorta of the patient.

5. The catheter of claim 4, further comprising a straightening member configured for insertion into said lumen to facilitate placement of said catheter into the aorta.

6. The catheter of claim 5, wherein said straightening member includes a straightening tube and a cutting element slidably disposed within said straightening tube between a retracted position in which said straightening tube substantially covers said cutting element and an extended position in which said cutting element extends a short distance beyond a distal end of said straightening tube.

7. The catheter of claim 6, wherein said straightening member further comprises a locking mechanism configured to selectively immobilize said cutting element relative to said straightening tube in both the retracted position and the extended position of said cutting element.

8. The catheter of claim 1, wherein said tube has a substantially J-shaped configuration.

9. The catheter of claim 1 or 2, wherein said distal end portion comprises an atraumatic distal tip provided about and extending from a distal end of the tube to reduce the risk of tissue injury during insertion of the catheter.

10. The catheter of claim 1, wherein said distal end portion comprises an outside diameter of about 3 mm or less.

11. The catheter of claim 10, wherein said distal end portion comprises an outside diameter of between about 0.5 to 3.0 mm.

12. The catheter of claim 9, wherein said atraumatic distal tip includes at least one blood perfusion channel through at least a portion of the tip.

13. The catheter of claim 1, wherein said tube comprises stainless steel.

14. The catheter of claim 13, wherein said tube is hand shapeable.

15. The catheter of claim 1, wherein said tube comprises at least a first fluid delivery lumen, a second separate and independent blood perfusion lumen, and at least one perfusion opening in the tube fluidly coupled to said blood perfusion lumen.

16. The catheter of claim 15, wherein said fluid delivery lumen and said blood perfusion lumen are in a coaxial arrangement.

17. The catheter of claim 16, wherein said fluid delivery lumen is axially disposed within said blood perfusion lumen.

18. The catheter of claim 1, wherein said tube has a length of between about 5 to 15 cm.

19. The catheter of claim 1, wherein said tube comprises a polymeric composite construction.

20. The catheter of claim 19, wherein said tube includes at least a first outer plastic layer and a second inner layer comprising a reinforcing matrix.

21. The catheter of claim 4, wherein said at least one bend comprises a first bend, and a second bend distal to said first bend and near a distal end of the tube to facilitate positioning the distal end portion in the coronary ostium.

22. The catheter of claim 21, wherein the second bend is between about 5 to 15 mm from the distal end of the tube.

23. The catheter of claim 21, wherein a portion of the tube distal to the second bend forms an angle of between about 20 to 90 degrees relative to a portion of the tube proximal to the first bend.

24. The catheter of claim 1, wherein said tube comprises at least a first fluid delivery lumen and a second inflation lumen coupled to an inflatable member adapted to occlude said coronary ostium when inflated.

25. The catheter of claim 24, further comprising an inflation actuator connected to said inflation lumen proximally of said inflatable member.

26. A trans-aortic infusion catheter for introduction through an opening in an aorta of a patient for delivery of a fluid into a coronary ostium of a coronary artery, said catheter comprising:

an elongated tube having an outer wall, a proximal end portion, a distal end portion, at least first and second lumens, each extending within a length of said outer wall, and one or more blood perfusion openings in said wall which are in fluid communication with at least one of said lumens; and said tube being shaped to allow said distal end portion of said tube to be positioned in the ostium of the coronary artery when the proximal end portion of said tube extends from the opening in the aorta.

27. The catheter of claim 26, wherein blood from the aorta passes through said one or more perfusion openings and into the coronary artery when said distal end portion is positioned in the ostium.

28. The catheter of claim 26, wherein said tube has a length of between about 5 to 15 cm.

29. The catheter of claim 26, wherein said tube is hand shapeable.

30. The catheter of claim 26, wherein said first and second lumens are in a coaxial arrangement.

31. The catheter of claim 26, wherein said first lumen extends between an inlet opening associated with said proximal end portion of said tube and a fluid discharge opening associated with said distal end portion , said lumen defining a fluid flow path through the tube.

32. The catheter of claim 26, wherein said second lumen extends from a closed region near said proximal end portion of said tube to a blood discharge opening associated with said distal end portion.

33. A trans-aortic infusion catheter for introduction through an opening in an aorta of a patient, in a vicinity of a coronary ostium of a coronary artery, for delivery of a fluid into the coronary ostium, said catheter comprising :

an elongated tube having at least a first lumen, a proximal end portion, a distal end portion, and a shape to allow said distal end portion of said tube to be positioned in the coronary ostium when the proximal end portion of said tube extends from the opening in the aorta; and

blood perfusion means associated with said tube for permitting blood to perfuse from the aorta through at least a portion of the tube and into the coronary artery when said distal end portion is positioned in the coronary ostium.

34. An infusion catheter for delivery of a fluid into an inlet opening of a coronary artery of a human patient, said catheter comprising an elongated tube having at least one lumen, a proximal end portion, and a distal end portion, said distal end portion including a retention portion adapted to releasably engage aortic tissue adjacent the inlet opening of the coronary artery while permitting blood flow from the aorta to perfuse into the coronary artery.

35. The infusion catheter of claim 34, wherein said retention portion is adapted to sealingly engage the aortic tissue surrounding the inlet opening of the coronary artery, thereby preventing fluid flow through the inlet opening and external of said infusion catheter.

36. The infusion catheter of claim 35, wherein said distal end portion comprises a distal tip configured to abut against the inlet opening and said retention portion comprises a surface of said distal tip.

37. The infusion catheter of claim 36, further comprising at least one suction port through said surface of said distal tip and connectable with a vacuum source.

38. The infusion catheter of claim 37, wherein said at least one suction port comprise a plurality of suction ports circumferentially spaced about said surface of said distal tip.

39. The infusion catheter of claim 34, wherein said at least one lumen comprises at least a first fluid delivery lumen and a second separate and independent blood perfusion lumen, said catheter further comprising at least one perfusion opening in the tube fluidly coupled to said blood perfusion lumen.

40. The infusion catheter of claim 37, wherein said at least one lumen comprises at least a first fluid delivery lumen, a second separate and independent blood perfusion lumen and a third separate and independent vacuum lumen, said catheter further comprising at least one perfusion opening in the tube fluidly coupled to said blood perfusion lumen, and

said third separate and independent vacuum lumen being in fluid communication with said at least one suction port.

41. The infusion catheter of claim 34, wherein said retention portion comprises a flexible flange member adapted to engage the aortic tissue extending away from and transverse to the inlet opening of the coronary artery.

42. The infusion catheter of claim 41, further comprising at least one suction port through said flexible flange member, connectable with a vacuum source.

43. The infusion catheter of claim 34, wherein said retention portion comprises a flexible flange member extending substantially transversely from said elongated tube.

44. An intravascular catheter for introduction into a vessel of a patient's vascular system for delivery of a fluid therein, said catheter comprising an elongated tube having an outer wall, a proximal end portion, a distal end portion including a light delivery portion, and at least one lumen extending within a length of said outer wall, said light delivery portion including at least one fluorescent material which is adapted to illuminate said distal end portion to facilitate placement in the vessel, with or without the use of fluoroscopy.

45. The catheter of claim 44, wherein said fluorescent material comprises at least one fluorescene strip.

46. The catheter of claim 45, wherein said at least one fluorescene strip is adapted to be illuminated using a light source externally of the vessel, wherein the illumination causes said at least one fluorescene strip to fluoresce.

47. The catheter of claim 44, wherein said catheter is configured for insertion through a transaortic guide catheter.

48. The catheter of claim 44, wherein said catheter is configured for insertion into a coronary vessel.

49. The catheter of claim 48, wherein the coronary vessel is a right or left coronary artery.

50. The catheter of claim 46, wherein said light source comprises a white light source.

51. The catheter of claim 50, wherein said light source comprises a surgeon's head lamp.

52. A surgical drug delivery system comprising:

an infusion catheter configured for insertion through an opening in an aorta of a human patient for delivery of a fluid into a coronary ostium of a coronary artery, said catheter comprising a tube having a proximal end portion, a distal end portion, and at least one lumen extending into said distal end portion, said tube being shaped to facilitate placement of said distal end portion into the coronary ostium when the proximal end portion of said tube extends from the opening in the aorta; and

a drug delivery device configured for direct insertion into a coronary vessel of the heart for delivery of a fluid into the coronary vessel.

53. The system of claim 52, wherein said drug delivery device comprises an intravascular catheter.

54. The system of claim 52, wherein said drug delivery device comprises an intraluminal shunt.

55. The system of claim 52, wherein the fluid delivered into the coronary vessel by said drug delivery device comprises a cardioplegia solution, said system further comprising a source of a cardioplegia solution which is capable of being coupled to said drug delivery device for delivery of the cardioplegia solution into said coronary vessel.

56. The system of claim 52, wherein the coronary vessel is the coronary artery into which said infusion catheter delivers fluid.

57. The system of claim 52, wherein the coronary vessel is a coronary vessel other than the coronary artery into which said infusion catheter delivers fluid.

58. The system of claim 55, wherein the cardioplegia solution comprises an AV node blocker compound.

59. The system of claim 58, wherein said cardioplegia solution further comprises water.

60. The system of claim 58, wherein said AV node blocker compound comprises carbachol.

61. The system of claim 55, further comprising a pump fluidly coupled to said source of cardioplegia solution and adapted to be fluidly coupled to said drug delivery device for administering said cardioplegia solution into said coronary vessel via said drug delivery device.

62. A surgical drug delivery system comprising:

an infusion catheter for delivery of fluid into a coronary ostium of a coronary artery of a human patient, said catheter comprising an elongated tube having at least one lumen, a proximal end portion, and a distal end portion, said distal end portion being constructed to fit within said coronary ostium while permitting blood from the aorta to perfuse into the coronary artery; and

a source of a cardioplegia solution connectable with said catheter at said proximal end portion, for delivery of cardioplegia solution into the coronary ostium.

63. The system of claim 62, wherein said cardioplegia solution comprises an AV node blocker compound.

64. The system of claim 63, wherein said AV node blocker compound comprises carbachol.

65. The system of claim 64, wherein said cardioplegia solution further comprises a beta-blocker compound.

66. The system of claim 65, wherein said beta-blocker compound comprises propranolol.

67. The system of claim 62, further comprising a drug delivery device configured for direct insertion into a coronary vessel of the heart of the patient.

68. The system of claim 67, wherein said drug delivery device comprises an intravascular catheter.

69. The system of claim 67, wherein said drug delivery device comprises an intraluminal shunt.

70. The system of claim 62, further comprising a generally straight member sized for insertion into said at least one lumen of said infusion catheter and stiffer than said infusion catheter.

71. The system of claim 70, wherein said generally straight member includes a generally straight tube and a cutting element slidably disposed within said generally straight tube between a retracted position in which said generally straight tube substantially covers said cutting element and an extended position in which said cutting element extends a short distance beyond a distal end of said generally straight tube.

72. The system of claim 71, wherein said generally straight member further comprises a locking mechanism configured to selectively immobilize said cutting element relative to said generally straight tube in both the retracted position and the extended position of said cutting element.

73. A surgical drug delivery system comprising:

a pre-shaped catheter configured for insertion through an opening in an aorta of a human patient for placement into a coronary ostium of a coronary vessel, said preshaped

catheter comprising a tube having a proximal end portion, a distal end portion, and at least one lumen extending into said distal end portion, said tube being shaped to facilitate placement of said distal end portion into the coronary ostium when the proximal end portion of said tube extends from the opening in the aorta; and

an intravascular catheter configured for insertion through said preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel; and

an indicator configured to facilitate guidance of said intravascular catheter to a fluid delivery location within the coronary vessel without the use of fluoroscopy.

74. The system of claim 73, wherein said indicator comprises a light delivery portion adapted to illuminate a distal end portion of said intravascular catheter to facilitate placement in the coronary vessel without the use of fluoroscopy.

75. The system of claim 73, further comprising a guidewire configured for insertion through said preshaped catheter, said intravascular catheter further comprising a lumen adapted to pass said guidewire.

76. The system of claim 75, wherein said indicator comprises a light delivery portion on said guidewire, adapted to illuminate a distal end portion of said guidewire, to facilitate placement of said guidewire and said intravascular catheter in the coronary vessel without the use of fluoroscopy.

77. The system of claim 74, further comprising a light source connectable with said light delivery portion.

78. The system of claim 77, wherein said light source is optically coupled to a surgeon's head lamp.

79. A surgical drug delivery system for delivery of a fluid into a coronary artery of a heart of a patient comprising:

an infusion catheter comprising a flexible elongated shaft having a proximal end, a distal end, and a fluid delivery lumen extending from the proximal end to the distal end defining a fluid flow path through the shaft; and

a guide catheter adapted to releasably mate with the infusion catheter to position the distal end of the infusion catheter in a coronary artery through an opening in an aorta of the patient, the guide catheter having a shaft having a proximal end, a distal end, and a shape to facilitate placement of the distal end of the guide catheter shaft into a coronary artery when the proximal end of the guide catheter shaft extends from the opening in the aorta.

80. A surgical kit comprising:

an infusion catheter configured for insertion into a coronary ostium of a coronary vessel through an opening in an aorta of the heart of a patient for delivery of a cardioplegia solution into said ostium, said catheter having a tube defining at least one lumen, a proximal end, and a distal end, said tube having a shape to facilitate placement of said distal end of said tube into the ostium of the coronary vessel when the proximal end of said tube extends from an opening in the aorta; and

a first sealed container containing an AV node blocker compound.

81. The kit of claim 80, further comprising a second sealed container containing a beta blocker compound.

82. The kit of claim 80, wherein said AV node blocker compound comprises a cholinergic receptor agonist.

83. The kit of claim 82, wherein said cholinergic receptor agonist comprises carbachol.

84. The kit of claim 81, wherein said beta blocker compound comprises propranolol.

85. The kit of claim 80, further comprising an intravascular catheter sized for direct insertion into a coronary vessel.

86. The kit of claim 80, further comprising an intraluminal shunt sized for direct insertion into a coronary vessel.

87. The kit of claim 80, further comprising a drug delivery catheter sized for insertion into the infusion catheter.

88. A surgical kit comprising:

a preshaped catheter configured for insertion into a coronary ostium of a coronary vessel through an opening in an aorta of the heart of a patient, said catheter having a tube defining at least one lumen, a proximal end, and a distal end, said tube having a shape to facilitate placement of said distal end of said tube into the ostium of the coronary vessel when the proximal end of said tube extends from an opening in the aorta;

an intravascular catheter comprising a light delivery portion, said intravascular catheter configured for insertion through said preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel; and

a first sealed container containing an AV node blocker compound.

89. The kit of claim 88, further comprising a second sealed container containing a beta blocker compound.

90. The kit of claim 88, wherein said AV node blocker compound comprises a cholinergic receptor agonist.

91. The kit of claim 90, wherein said cholinergic receptor agonist comprises carbachol.

92. The kit of claim 89, wherein said beta blocker compound comprises propranolol.

93. A surgical kit comprising:

a preshaped catheter configured for insertion into a coronary ostium of a coronary vessel through an opening in an aorta of the heart of a patient, said catheter having a tube defining at least one lumen, a proximal end, and a distal end, said tube having a shape to facilitate placement of said distal end of said tube into the ostium of the coronary vessel when the proximal end of said tube extends from an opening in the aorta;

an intravascular catheter having at least one lumen, said intravascular catheter configured for insertion through said preshaped catheter and into the coronary vessel for delivery of a fluid into the coronary vessel;

a guidewire configured for insertion through said lumen of said intravascular catheter to guide the placement thereof, said guidewire comprising a light delivery portion adapted to illuminate a distal end portion of said guidewire, to facilitate placement of said guidewire and said intravascular catheter in the coronary vessel without the use of fluoroscopy; and

a first sealed container containing an AV node blocker compound.

94. The kit of claim 93, further comprising a second sealed container containing a beta blocker compound.

95. The kit of claim 93, wherein said AV node blocker compound comprises a cholinergic receptor agonist.

96. The kit of claim 95, wherein said cholinergic receptor agonist comprises carbachol.

97. The kit of claim 94, wherein said beta blocker compound comprises propranolol.

98. A method of inducing reversible ventricular asystole in the heart of a patient comprising:

making an opening in a wall of an aorta of the patient;

introducing a distal portion of an infusion catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

positioning the distal portion of the infusion catheter in the coronary ostium; and

delivering a cardioplegia solution through the infusion catheter directly into the coronary ostium, while permitting blood flow from the aorta to the coronary artery.

99. The method of claim 98, further comprising inserting a portion of a drug delivery device directly into a coronary vessel of the heart of the patient after said delivering a cardioplegia solution directly into the coronary ostium, and infusing a cardioplegia solution through the drug delivery device into the coronary vessel by periodic or continual infusion.

100. The method of claim 99, wherein said inserting comprises inserting said portion of said drug delivery device into the coronary artery leading from the coronary ostium into which the distal portion of the infusion catheter was positioned.

101. The method of claim 99, wherein said inserting said portion of said drug delivery device into a coronary vessel comprises insertion into a coronary vessel other than the coronary artery leading from the coronary ostium into which the distal portion of the infusion catheter was positioned.

102. The method of claim 99, wherein said inserting comprises inserting said portion of said drug delivery device into the right coronary artery of the heart of the patient.

103. The method of claim 99, wherein said inserting comprises inserting said portion of said drug delivery device into the left coronary artery of the heart of the patient.

104. The method of claim 99, wherein said inserting comprises inserting said portion of said drug delivery device into the right coronary vein of the heart of the patient.

105. The method of claim 99, wherein said inserting a portion of a drug delivery device into a coronary vessel comprises inserting a distal end of an intravascular catheter into the coronary vessel, and said infusing comprises infusing the cardioplegia solution through the intravascular catheter into the coronary vessel.

106. The method of claim 99, wherein said inserting a portion of a drug delivery device into a coronary vessel comprises inserting distal and proximal ends of an intraluminal shunt into the coronary vessel and said infusing comprises infusing the cardioplegia solution through the shunt into the coronary vessel.

107. The method of claim 99, further comprising discontinuing said delivering a cardioplegia solution into the coronary ostium through the infusion catheter following said inserting a portion of the drug delivery device into the coronary vessel.

108. The method of claim 98, wherein said delivering a cardioplegia solution into the coronary ostium comprises infusing an AV node blocker compound and a beta blocker compound into the ostium at a sufficient dosage to induce ventricular asystole.

109. The method of claim 108, wherein said infusing an AV node blocker and a beta blocker compound comprises administering at least one bolus injection of carbachol and propranolol into the ostium.

110. The method of claim 98, wherein said delivering a cardioplegia solution into the coronary ostium comprises infusing an AV node blocker compound and a beta blocker compound serially into the ostium at sufficient dosages to induce ventricular asystole.

111. A method of inducing reversible ventricular asystole in the heart of a patient undergoing a surgical procedure comprising:

delivering at least one cardioplegia solution into a coronary ostium of a coronary artery at a sufficient dosage to induce reversible ventricular asystole in the heart; and

delivering at least one cardioplegia solution directly into a coronary vessel by periodic or continual infusion at a sufficient dosage to maintain reversible ventricular asystole in the heart during the surgical procedure.

112. The method of claim 111, wherein said delivering at least one cardioplegia solution into the coronary ostium is performed prior to said delivering at least one cardioplegia solution directly into the coronary vessel.

113. The method of claim 111, wherein both said at least one cardioplegia solution delivered into the coronary ostium and said at least one cardioplegia solution delivered directly into the coronary vessel comprise an AV node blocker compound.

114. The method of claim 113, wherein said AV node blocker compound comprises carbachol.

115. The method of claim 113, wherein said at least one cardioplegia solution delivered into the coronary ostium further comprises a beta-blocker compound.

116. The method of claim 115, wherein the beta blocker compound comprises propranolol.

117. The method of claim 116, wherein the propranolol is administered prior to or contemporaneously with said carbachol administration into the coronary ostium.

118. The method of claim 111, further comprising inserting a distal end of an infusion catheter through an opening in an aorta of the patient and positioning the distal end of the catheter in the coronary ostium, prior to said delivering at least one cardioplegia solution into the coronary ostium; and

wherein said delivering at least one cardioplegia solution into the coronary ostium is performed by delivering the at least one cardioplegia solution through the distal end.

119. The method of claim 111, further comprising inserting a portion of a drug delivery device into the coronary vessel, and said delivering at least one cardioplegia solution directly into the coronary vessel comprises delivering the at least one cardioplegia solution through the drug delivery device into the coronary vessel.

120. The method of claim 119, wherein the coronary vessel is the coronary artery and said portion of a drug delivery device is inserted directly into the coronary artery distal to the coronary ostium.

121. The method of claim 119, wherein the coronary vessel is the right or left coronary vein.

122. The method of claim 119, wherein said inserting comprises inserting a distal end of an intravascular catheter into the coronary vessel ; and

wherein said delivering at least one cardioplegia solution directly into the coronary vessel comprises delivering the cardioplegia solution through the intravascular catheter into the coronary vessel.

123. The method of claim 119, wherein said inserting comprises inserting a distal and a proximal end of an intraluminal shunt into the coronary vessel, and said delivering at least one cardioplegia solution directly into the coronary vessel comprises delivering the cardioplegia solution through the shunt into the coronary vessel.

124. A method of inducing reversible ventricular asystole in the heart of a patient comprising inserting an intravascular catheter into a coronary vessel of the heart and infusing at least one cardioplegia solution through the intravascular catheter into the coronary vessel at a sufficient dosage to induce reversible ventricular asystole.

125. The method of claim 124, wherein the coronary vessel is a right coronary artery of the heart of the patient.

126. The method of claim 124, wherein the coronary vessel is a left coronary artery of the heart of the patient.

127. The method of claim 124, wherein the coronary vessel is a right coronary vein of the heart of the patient.

128. The method of claim 124, wherein the coronary vessel is a right coronary artery of the heart of the patient and said intravascular catheter is inserted in the right coronary artery proximal to the AV node artery.

129. The method of claim 124, wherein said at least one cardioplegia solution comprises an AV node blocker compound.

130. The method of claim 129, wherein said AV node blocker compound comprises carbachol.

131. The method of claim 129, wherein said at least one cardioplegia solution further comprises a beta-blocker compound.

132. The method of claim 131, wherein said beta blocker compound comprises propranolol.

133. The method of claim 131, wherein said at least one cardioplegia solution comprises a first solution including said carbachol and a second solution including said propanolol.

134. A method of inducing reversible ventricular asystole in the heart of a patient comprising delivering at least one cardioplegia solution directly to a coronary ostium of a coronary vessel while permitting blood flow to continue passing through the coronary ostium.

135. A method of delivering a cardioplegia solution to a coronary artery of a heart of a patient comprising:

making an opening in a wall of an aorta of the patient;

introducing a distal portion of an infusion catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

stabilizing the distal portion in or adjacent to the coronary ostium; and

delivering a cardioplegia solution through the infusion catheter directly into the coronary ostium, while permitting blood flow from the aorta to the coronary artery.

136. The method of claim 135, wherein said stabilizing comprises sealingly engaging the distal portion with an annular portion of the aorta surrounding the coronary ostium.

137. The method of claim 136, wherein said stabilizing comprises applying a suction force to the distal portion of the catheter prior to delivering a cardioplegia solution

to stabilize the distal portion in sealing engagement with said annular portion of the aorta surrounding the coronary ostium.

138. The method of claim 135, wherein said stabilizing comprises engaging a portion of the aorta in a direction transverse to the coronary ostium.

139. The method of claim 138, wherein said engaging comprises applying a suction force, through a flange member, to engage the portion of the aorta.

140. A method of delivering a fluid or drug to within a coronary vessel of a heart of a patient comprising:

making an opening in a wall of an aorta of the patient;

introducing a distal portion of a guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

positioning the distal portion of the guide catheter in the coronary ostium;

inserting a fluid delivery device into the guide catheter and advancing a distal end portion of the fluid delivery device to a fluid delivery location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and

passing a fluid or drug through the fluid delivery device and into the coronary artery.

141. The method of claim 140, wherein said distal end portion of said fluid delivery device includes a light delivery portion, said method of delivering further comprising illuminating said light delivery portion to facilitate said advancing of the distal end portion of the fluid delivery device.

142. The method of claim 141, wherein said light delivery portion comprises at least one optical fiber, and said illuminating comprises delivering light through said at least one optical fiber to said distal end portion.

143. The method of claim 141, wherein said light delivery portion comprises at least one LED, and said illuminating comprises energizing said at least one LED.

144. The method of claim 141, wherein said light delivery portion comprises a fluorescent material that fluoresces when activated with light, and said illuminating comprises shining visible light through the vessel and onto the fluorescent material to cause it to fluoresce.

145. The method of claim 140, wherein said distal end portion of said fluid delivery device includes at least one electrode, said method of delivering further comprising electrically sensing electric signals generated by a pacemaker node of the heart using said at least one electrode to facilitate said advancing of the distal end portion of the fluid delivery device.

146. The method of claim 140, wherein said distal end portion of said fluid delivery device includes at least one ultrasonic transducer, said method of delivering further comprising transmitting ultrasound signals and receive reflections of said ultrasound signals to facilitate said advancing of the distal end portion of the fluid delivery device.

147. The method of claim 140, wherein said distal end portion of the fluid delivery device includes at least one magnetic element, said method of delivering further comprising using a magnetic probe, externally of the vessel, to guide said at least one magnetic element to said fluid delivery location with the vessel, thereby facilitating said advancing of the distal end portion of the fluid delivery device.

148. The method of claim 140, wherein said distal end portion of the fluid delivery device includes at least one palpation member, said method of delivering further comprising palpating said palpating member, through a wall of the vessel, to facilitate said advancing of the distal end portion of the fluid delivery device.

149. The method of claim 148, wherein said palpation member includes a balloon.

150. The method of claim 140, wherein said passing a fluid or drug comprises passing at least one cardioplegia agent through the fluid delivery device.

151. The method of claim 150, wherein said cardioplegia agent includes an AV node blocker compound.

152. The method of claim 151, wherein said AV node blocker compound includes carbachol.

153. The method of claim 140, wherein said fluid delivery location is located proximate the AV node artery.

154. The method of claim 140, wherein said fluid delivery location is located at least about 0.5 cm downstream from the coronary ostium.

155. The method of claim 140, wherein said fluid delivery location is located between about 2 to 8 cm downstream from the coronary ostium.

156. The method of claim 155, wherein said fluid delivery location is located between about 4 to 8 cm downstream from the coronary ostium.

157. A method of delivering a fluid or drug to within a coronary vessel of a heart of a patient comprising:

preloading at least a portion of a fluid delivery device in a guide catheter;

making an opening in a wall of an aorta of the patient;

introducing a distal portion of the preloaded guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

positioning the distal portion of the guide catheter in the coronary ostium;

advancing the fluid delivery device through the guide catheter to position a distal end portion of the fluid delivery device in a fluid delivery location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and

passing a fluid or drug through the fluid delivery device and into the coronary artery.

158. The method of claim 157, wherein said distal end portion of said fluid delivery device includes a light delivery portion, said method of delivering further comprising aligning said distal end portion of said fluid delivery device with said distal portion of said guide catheter and illuminating said light delivery portion to in turn illuminate said distal portion of said guide catheter to facilitate said advancement of the distal portion of said guide catheter from said opening in the aorta to the coronary ostium.

159. The method of claim 158, further comprising viewing the illuminated light delivery portion, through the vasculature, during the positioning of the distal end portion of the fluid delivery device to facilitate proper placement in the fluid delivery location without the use of fluoroscopy.

160. The method of claim 157, wherein said distal end portion of said fluid delivery device includes a light delivery portion, said method of delivering further comprising illuminating said light delivery portion to facilitate said advancing the fluid delivery device through the guide catheter to position the distal end portion of the fluid delivery device in the fluid delivery location without the use of fluoroscopy.

161. The method of claim 157, wherein said passing a fluid or drug comprises passing at least one cardioplegia agent through the fluid delivery device.

162. The method of claim 161, wherein said cardioplegia agent includes an AV node blocker compound.

163. The method of claim 162, wherein said AV node blocker compound includes carbachol.

164. The method of claim 157, wherein said fluid delivery location is located proximate the AV node artery.

165. The method of claim 157, wherein said fluid delivery location is located at least about 0.5 cm downstream from the coronary ostium.

166. The method of claim 157, wherein said fluid delivery location is located between about 2 to 8 cm downstream from the coronary ostium.

167. The method of claim 166, wherein said fluid delivery location is located between about 4 to 8 cm downstream from the coronary ostium.

168. A method of delivering a fluid or drug to within a coronary vessel of a heart of a patient comprising:

preloading a fluid delivery device over a guidewire;

making an opening in a wall of an aorta of the patient;

introducing a distal portion of a preshaped catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

introducing a distal portion of the preloaded fluid delivery device and guidewire through the preshaped catheter and advancing the distal portion of the fluid delivery device and guidewire to a position within the coronary artery downstream of the coronary ostium without the use of fluoroscopy; and

passing a fluid or drug through the fluid delivery device and into the coronary artery.

169. The method of claim 168, wherein said distal portion of said guidewire includes a light delivery portion, said method of delivering further comprising illuminating said light delivery portion to facilitate said advancement of the distal portion of said fluid delivery device.

170. A method of placement of an intravascular device within a coronary vessel of a heart of a patient comprising:

making an opening in a wall of an aorta of the patient;

introducing a distal portion of a guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

positioning the distal portion of the guide catheter in the coronary ostium;

inserting an intravascular device into the guide catheter and advancing a distal end

portion of the intravascular device to a location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

171. The method of claim 170, wherein said distal end portion of said intravascular device includes a light delivery portion, said method of placement further comprising illuminating said light delivery portion to facilitate said advancing of the distal end portion of the intravascular device.

172. The method of claim 170, wherein said distal end portion of said intravascular device includes at least one electrode, said method of placement further comprising electrically sensing electric signals generated by a pacemaker node of the heart using said at least one electrode to facilitate said advancing of the distal end portion of the intravascular device.

173. The method of claim 170, wherein said distal end portion of said intravascular device includes at least one ultrasonic transducer, said method of placement further comprising transmitting ultrasound signals and receiving reflections of said ultrasound signals to facilitate said advancing of the distal end portion of the intravascular device.

174. The method of claim 170, wherein said distal end portion of the intravascular device includes at least one magnetic element, said method of placement further comprising using a magnetic probe, externally of the vessel, to guide said at least one magnetic element to said intravascular location within the vessel, thereby facilitating said advancing of the distal end portion of the intravascular device.

175. The method of claim 170, wherein said distal end portion of the intravascular device includes at least one palpation member, said method of placement further comprising palpating said palpating member, through a wall of the vessel, to facilitate said advancing of the distal end portion of the intravascular device.

176. A method of placement of an intravascular device within a coronary vessel of a heart of a patient comprising:

preloading at least a portion of the intravascular device in a guide catheter;

making an opening in a wall of an aorta of the patient;

introducing a distal portion of the preloaded guide catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery;

positioning the distal portion of the guide catheter in the coronary ostium;

advancing the intravascular device through the guide catheter to position a distal end portion of the intravascular device in a location within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

177. The method of claim 176, wherein said distal end portion of said intravascular device includes a light delivery portion, said method of placement further comprising illuminating said light delivery portion to in turn illuminate said distal portion of said guide catheter to facilitate said advancement of the distal portion of said guide catheter from said opening in the aorta to the coronary ostium.

178. The method of claim 177, further comprising viewing the illuminated light delivery portion, through the vasculature, during the positioning of the distal end portion of the intravascular device to facilitate proper placement in the location downstream of the coronary ostium without the use of fluoroscopy.

179. The method of claim 176, wherein said distal end portion of said intravascular device includes a light delivery portion, said method of placement further comprising illuminating said light delivery portion to facilitate said advancing the intravascular device through the guide catheter to position the distal end portion of the intravascular device in the location downstream of the coronary ostium without the use of fluoroscopy.

180. A method of placement of a fluid delivery device within a coronary vessel of a heart of a patient comprising:

preloading a fluid delivery device over a guidewire;

making an opening in a wall of an aorta of the patient;

introducing a distal portion of an infusion catheter through the opening in the aorta and advancing the distal portion from said opening in the aorta to a coronary ostium of a coronary artery; and

introducing a distal portion of the preloaded fluid delivery device and guidewire through the infusion catheter and advancing the distal portion of the fluid delivery device and guidewire to a position within the coronary artery downstream of the coronary ostium without the use of fluoroscopy.

181. The method of claim 180, wherein said distal portion of said guidewire includes a light delivery portion, said method of placement further comprising illuminating said light delivery portion to facilitate said advancement of the distal portion of said fluid delivery device.

182. A method of placement of an intravascular device within a vessel of a patient without the use of fluoroscopy, comprising:

providing an intravascular device having a fluorescing material provided on a distal end portion thereof;

introducing the distal end portion into the vessel and advancing the distal end portion within the vessel; and

passing visible light through the wall of the vessel and onto the fluorescing material to cause fluorescence of the material, thereby enabling visualization of the distal end portion externally of the vessel, by the naked eye, by the use of a filter, or by electronic amplification of the optical signal.

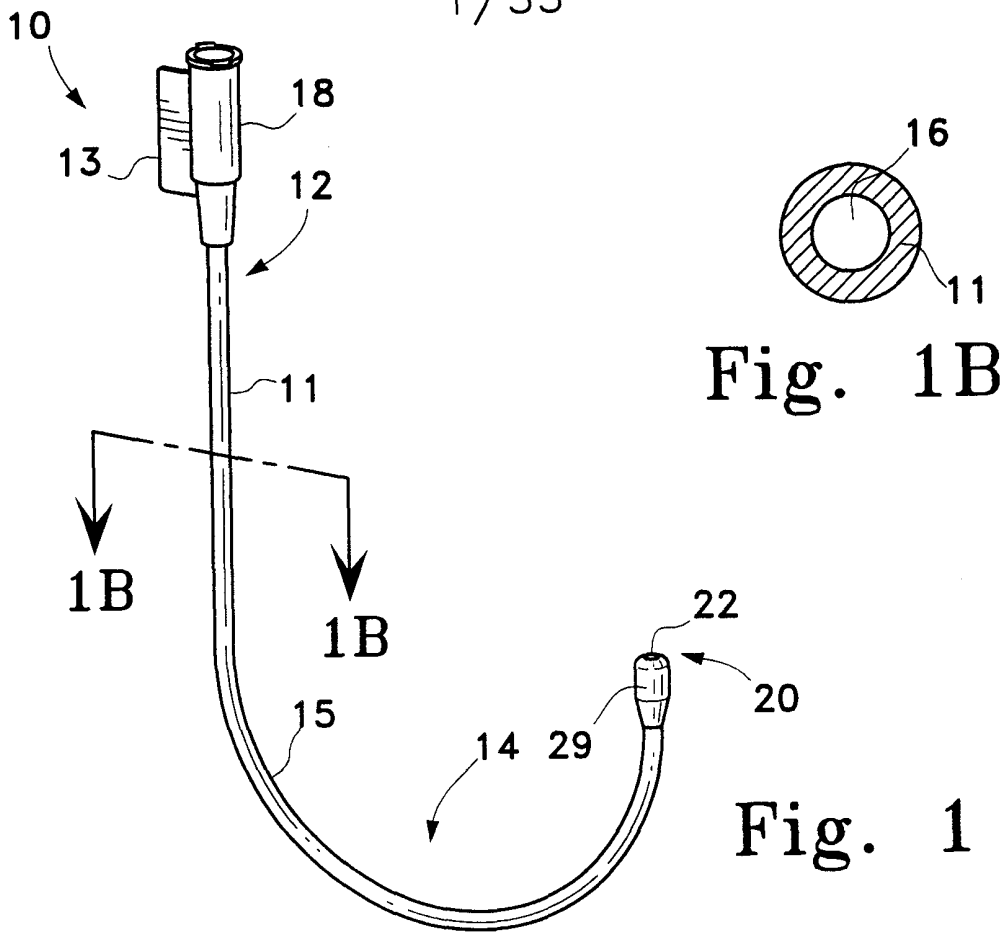


Fig. 1

Fig. 1B

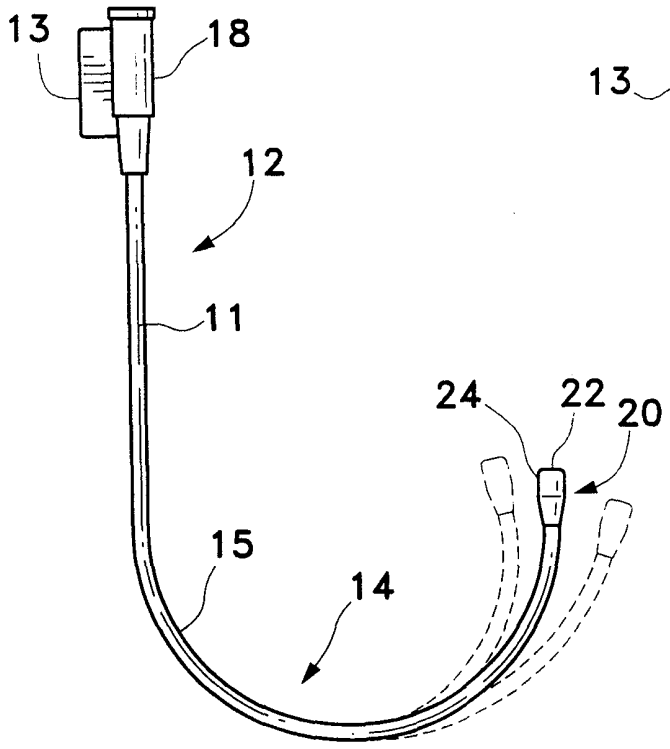


Fig. 1A

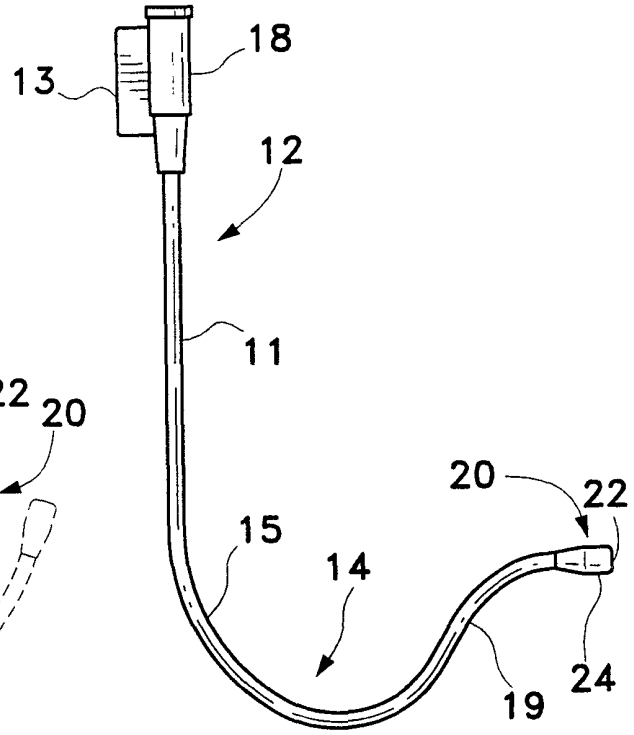


Fig. 1C

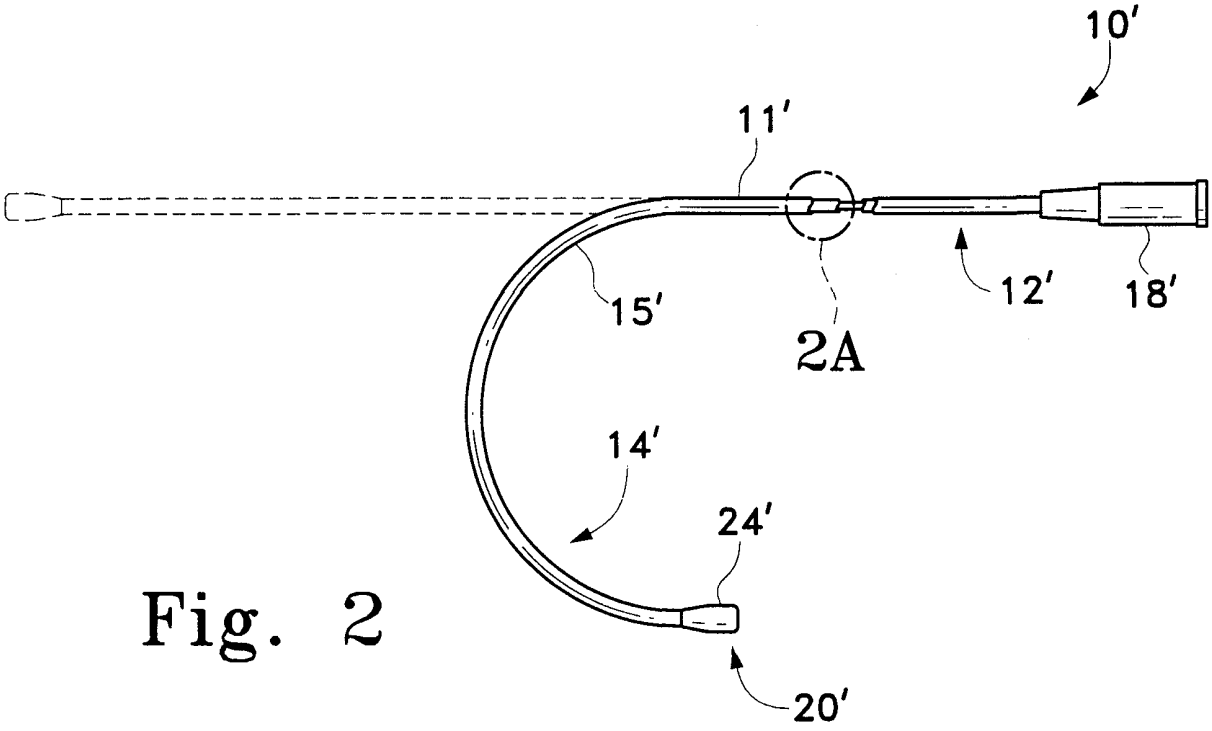


Fig. 2

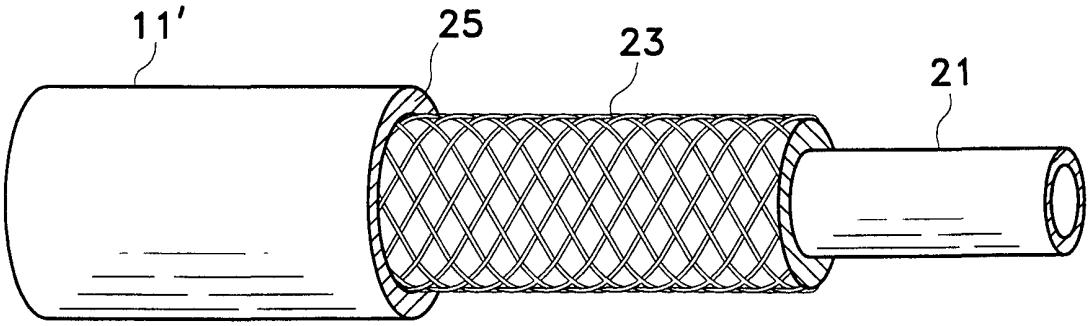


Fig. 2A

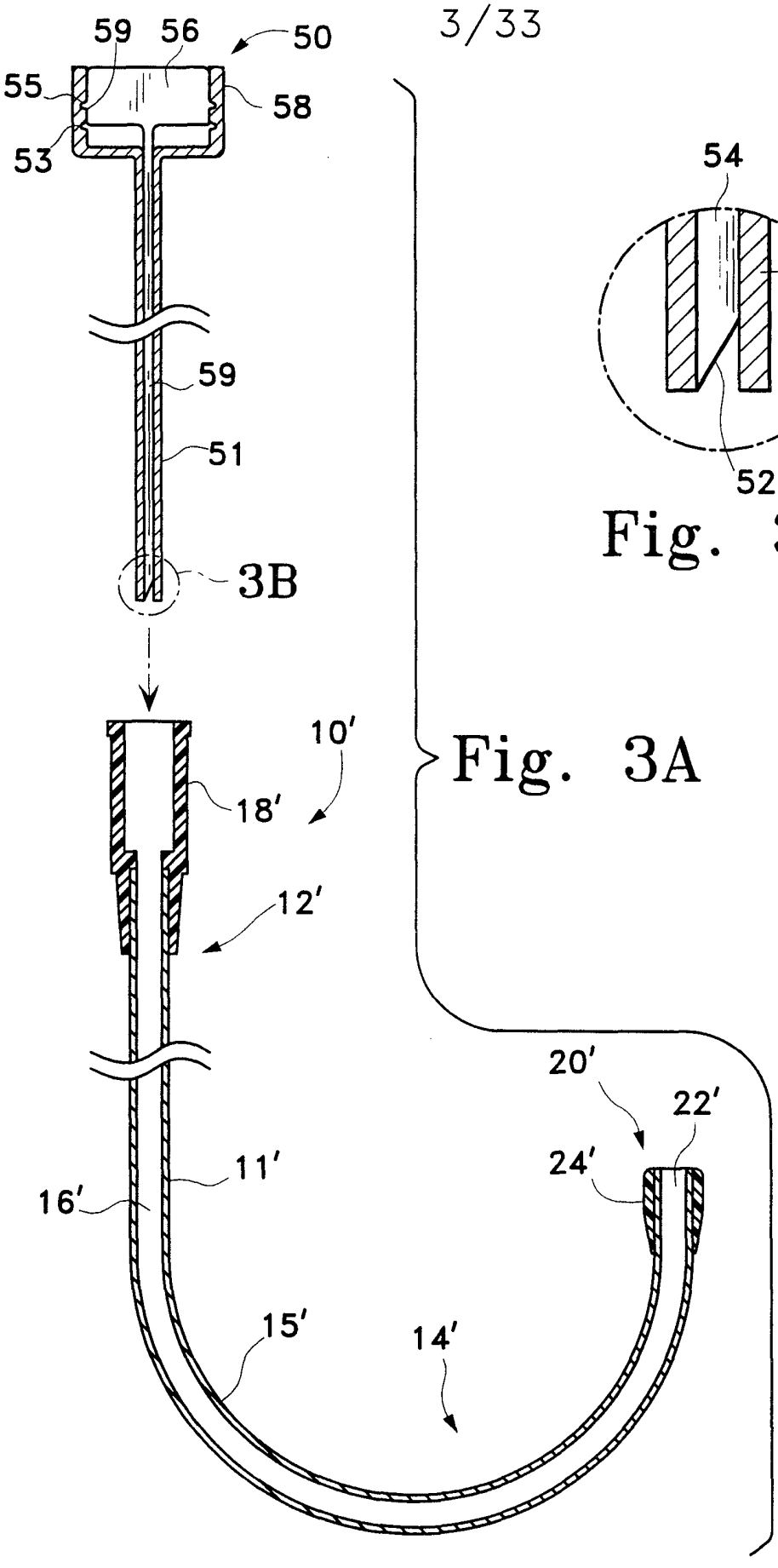


Fig. 3A

Fig. 3B

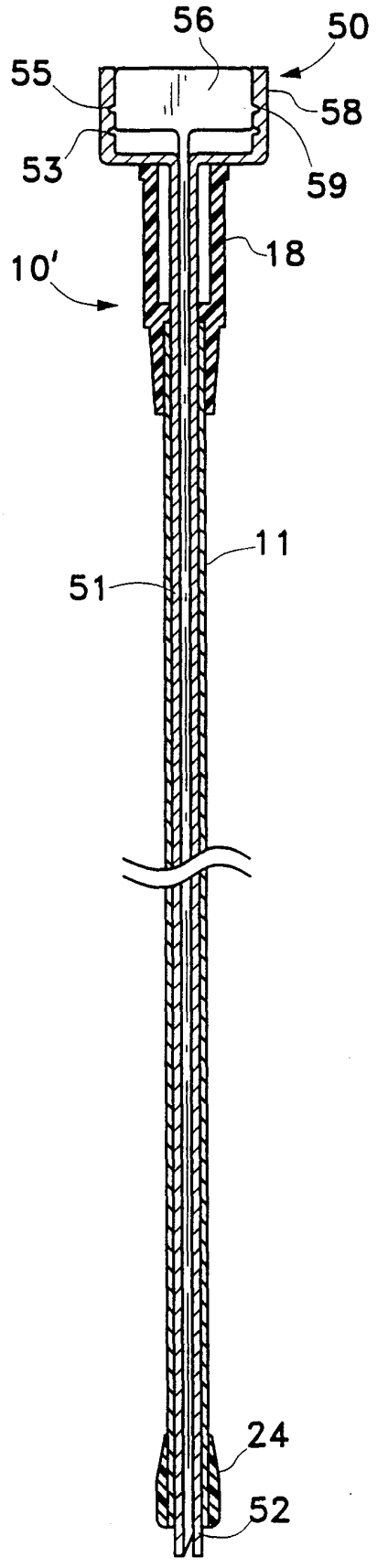


Fig. 3C

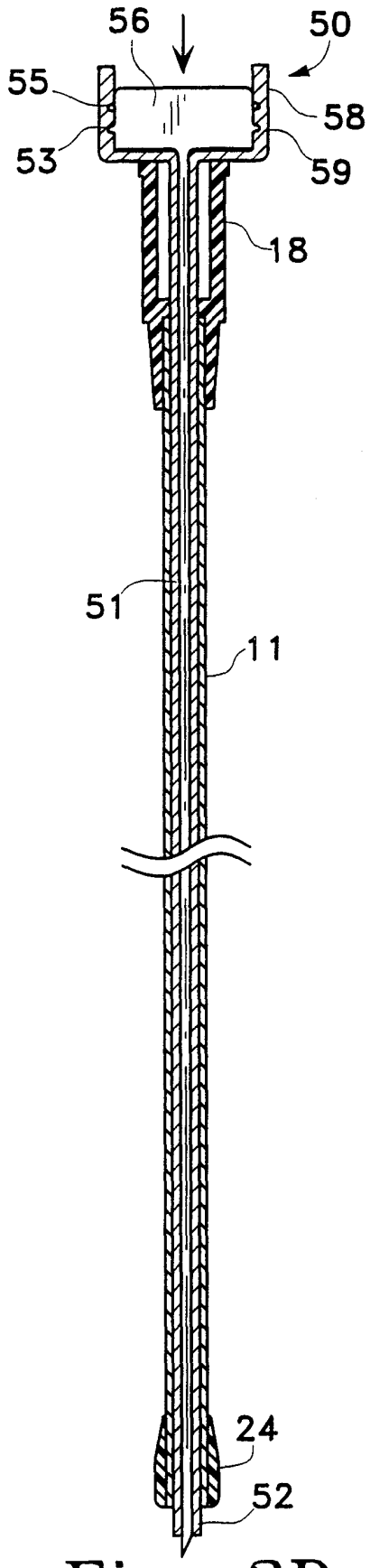


Fig. 3D

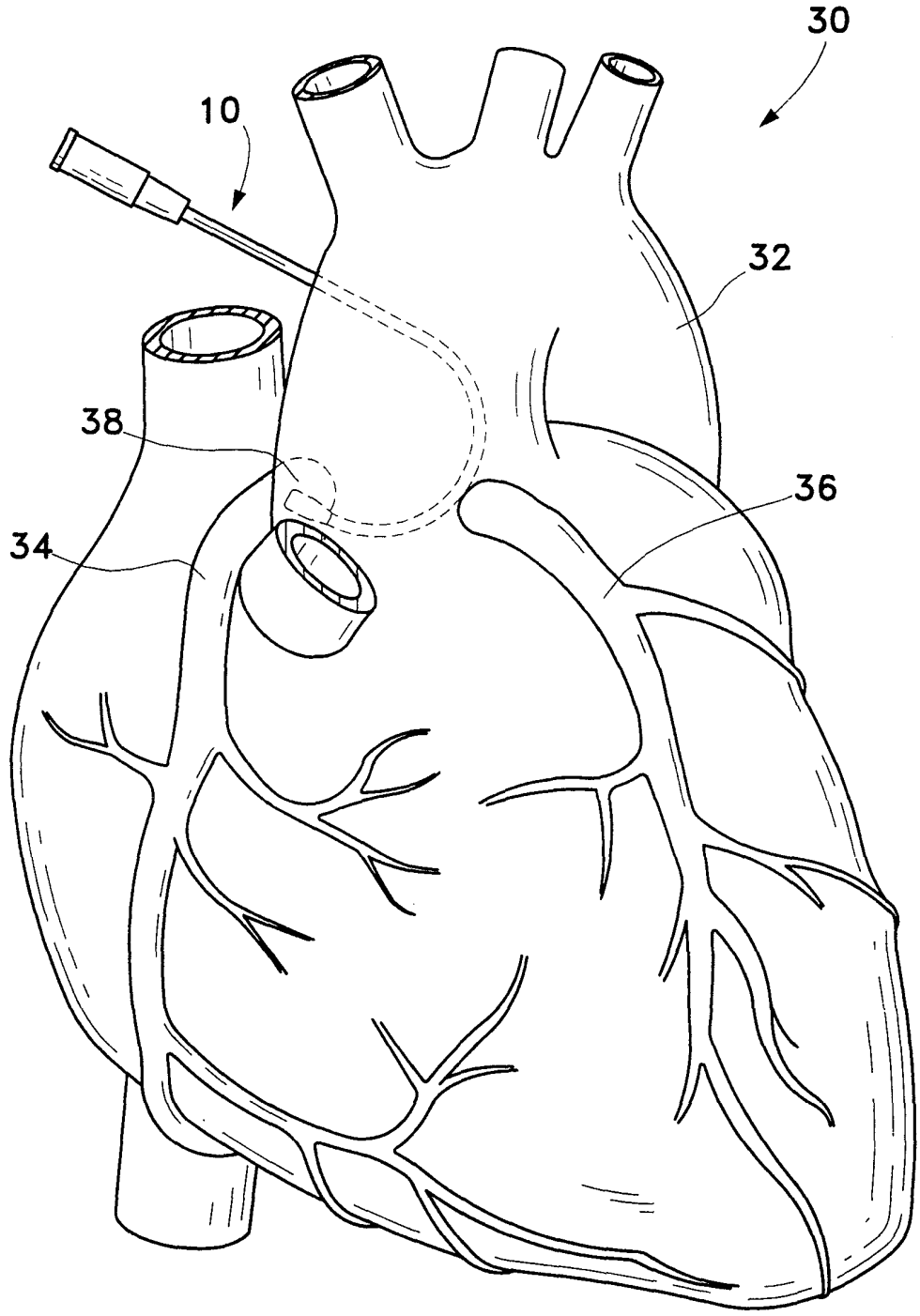


Fig. 4A

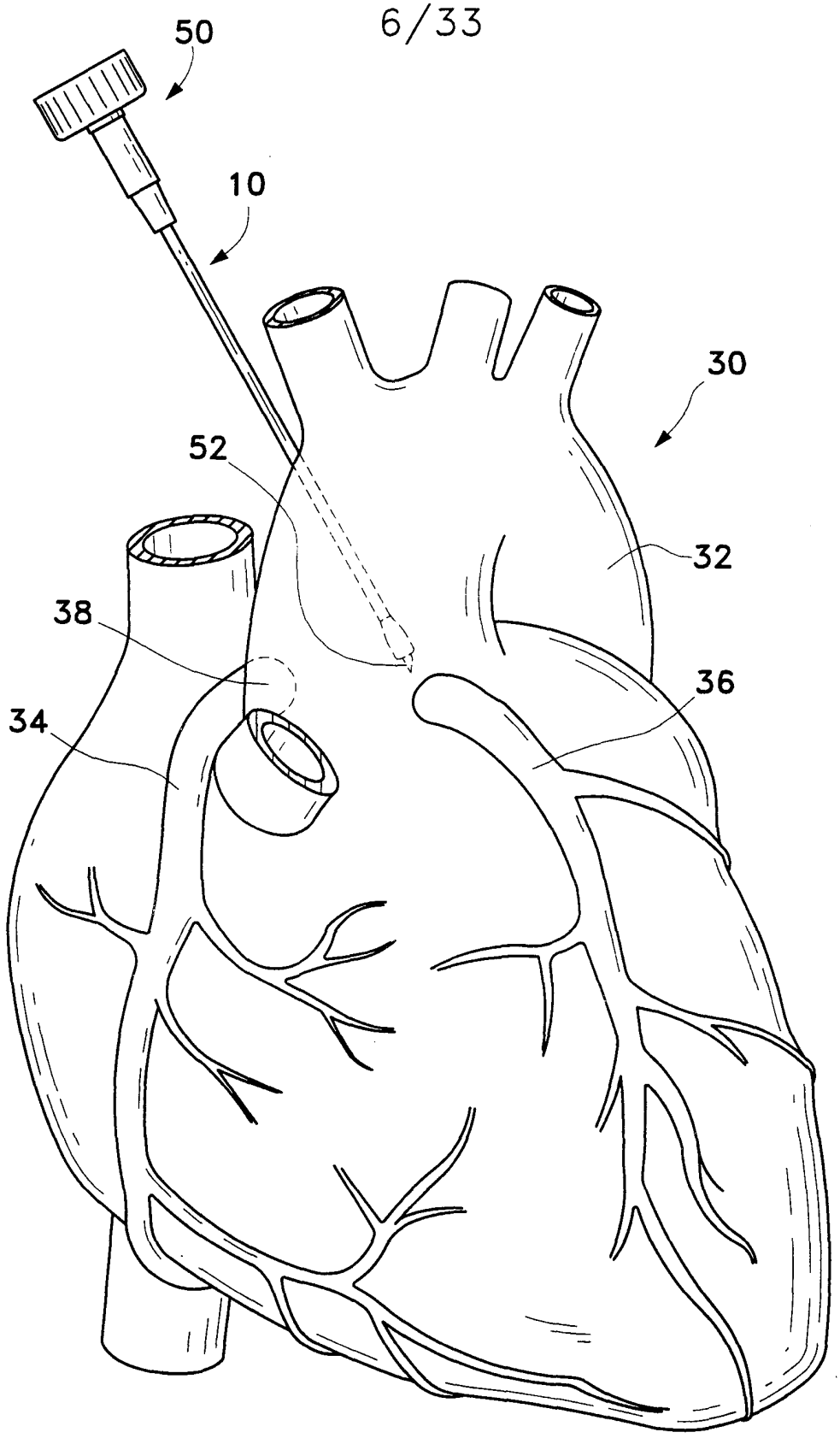


Fig. 4B

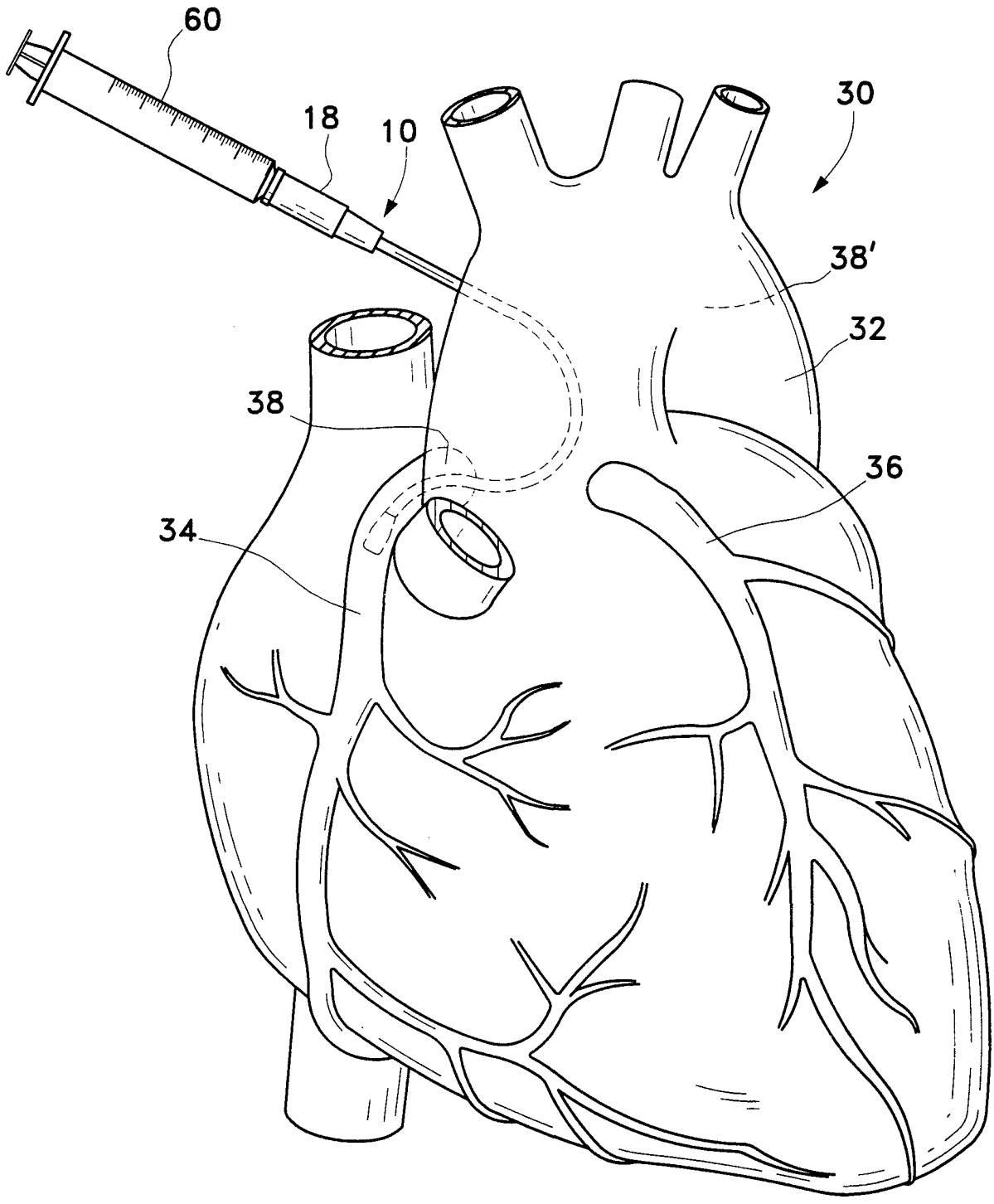


Fig. 4C

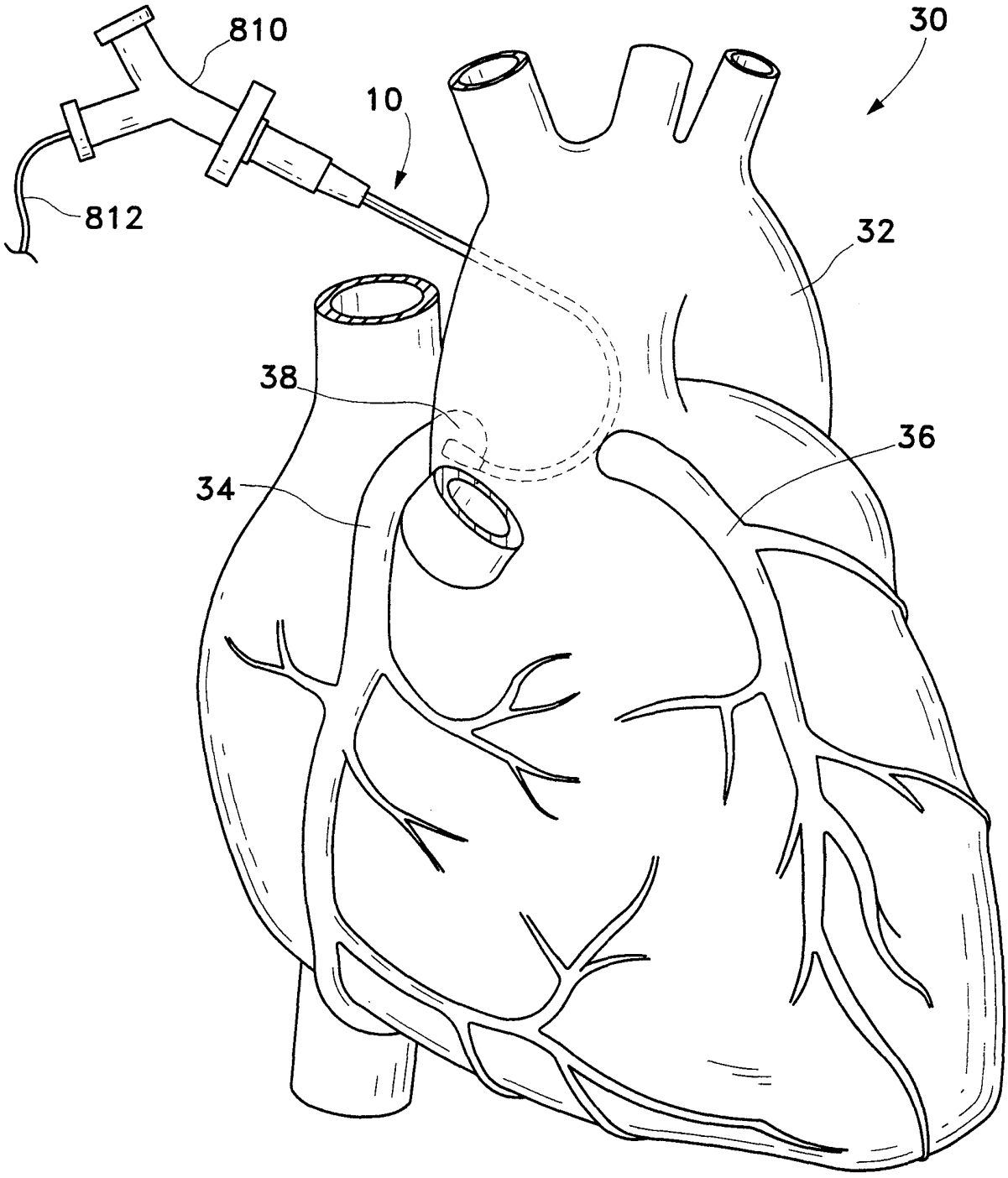


Fig. 5

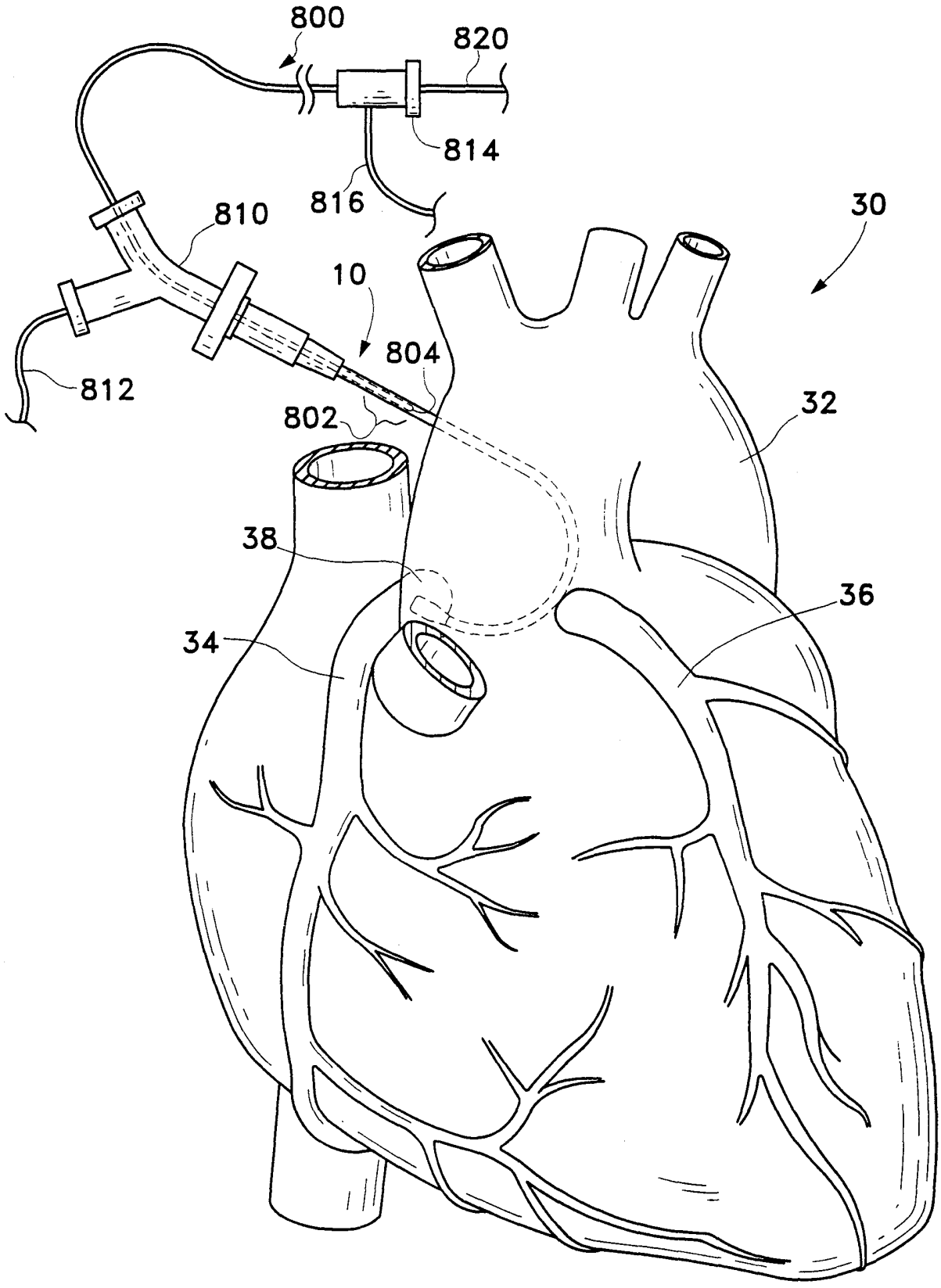


Fig. 6

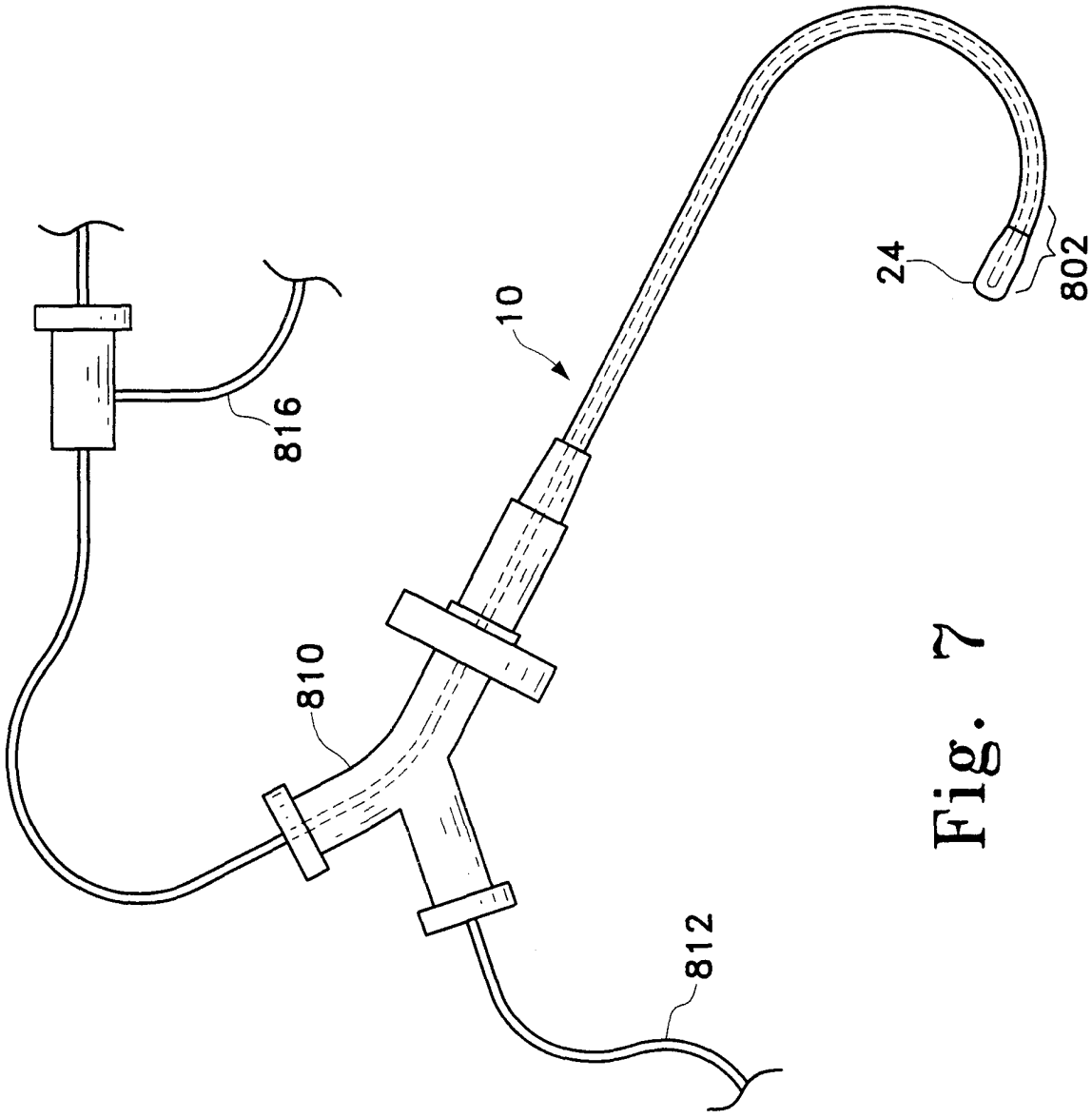


Fig. 7

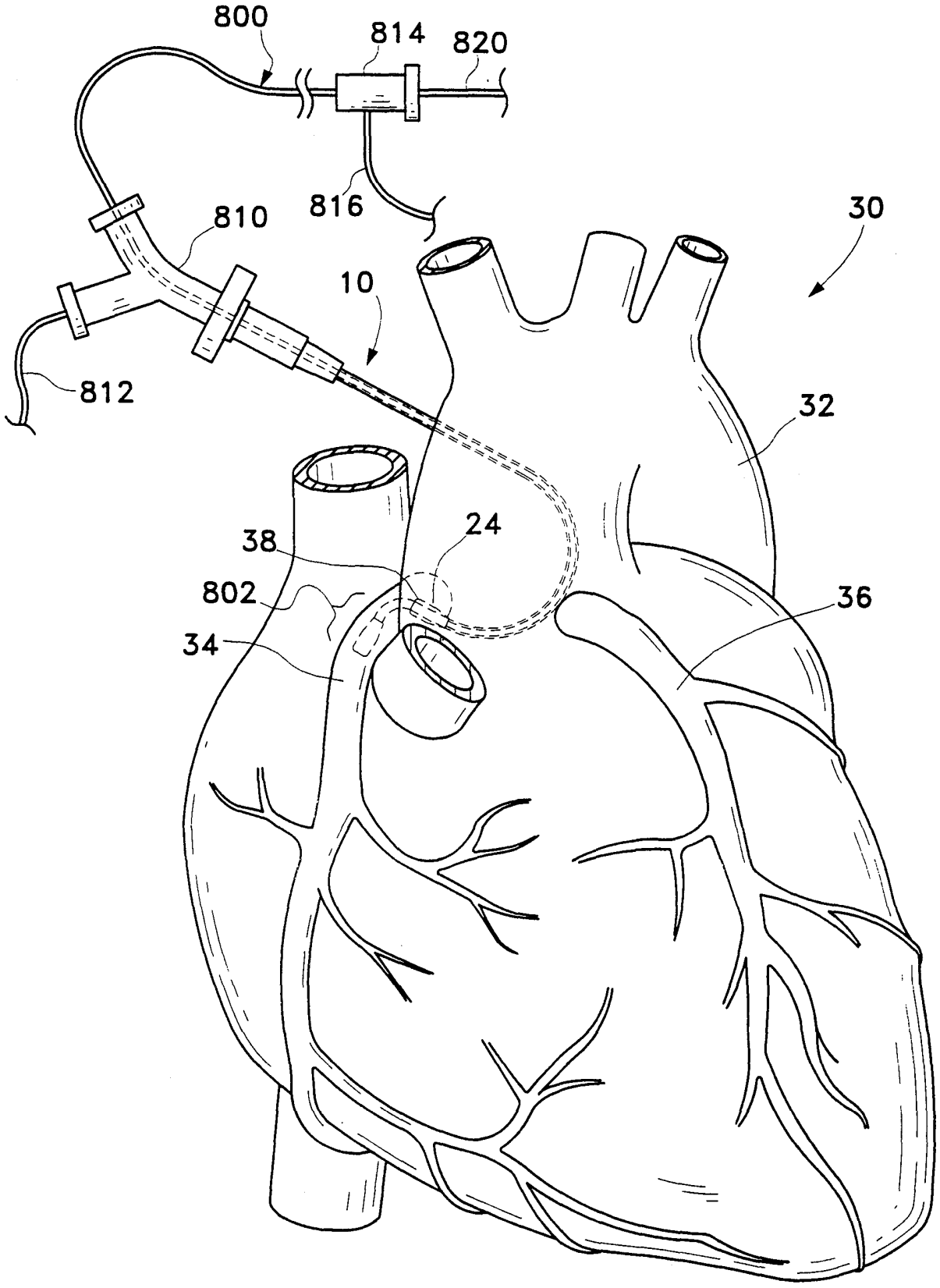


Fig. 8

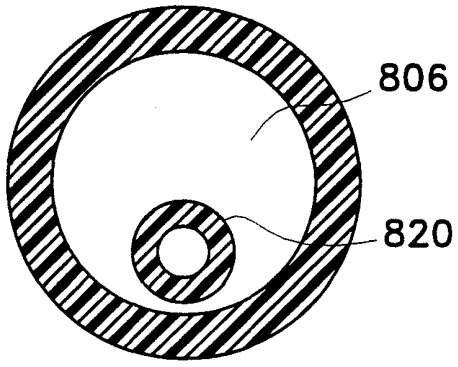


Fig. 9A

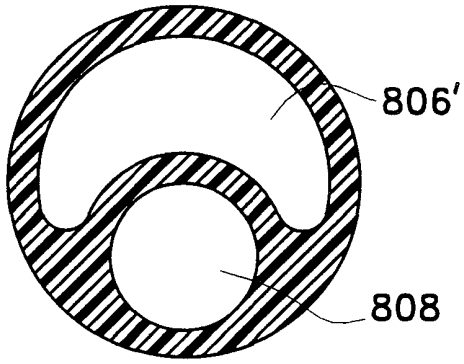


Fig. 9B

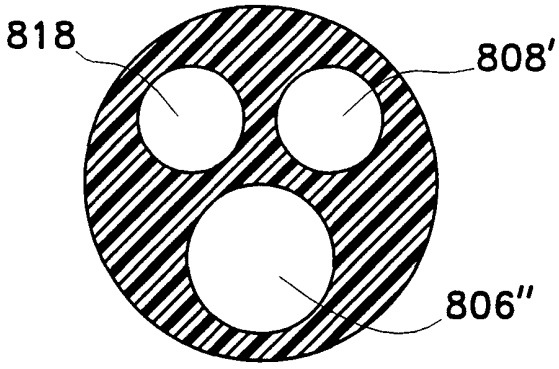


Fig. 9C

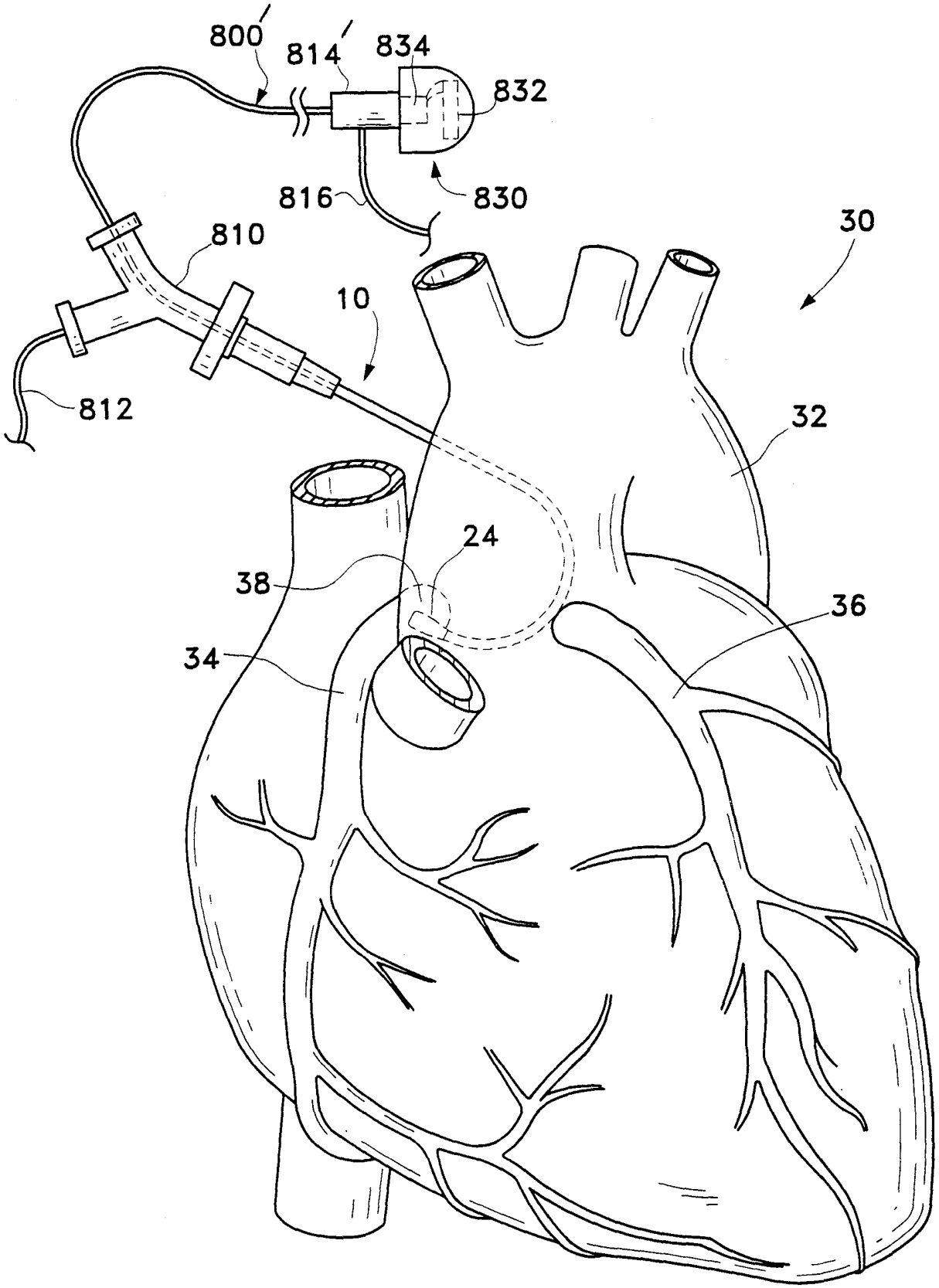


Fig. 10

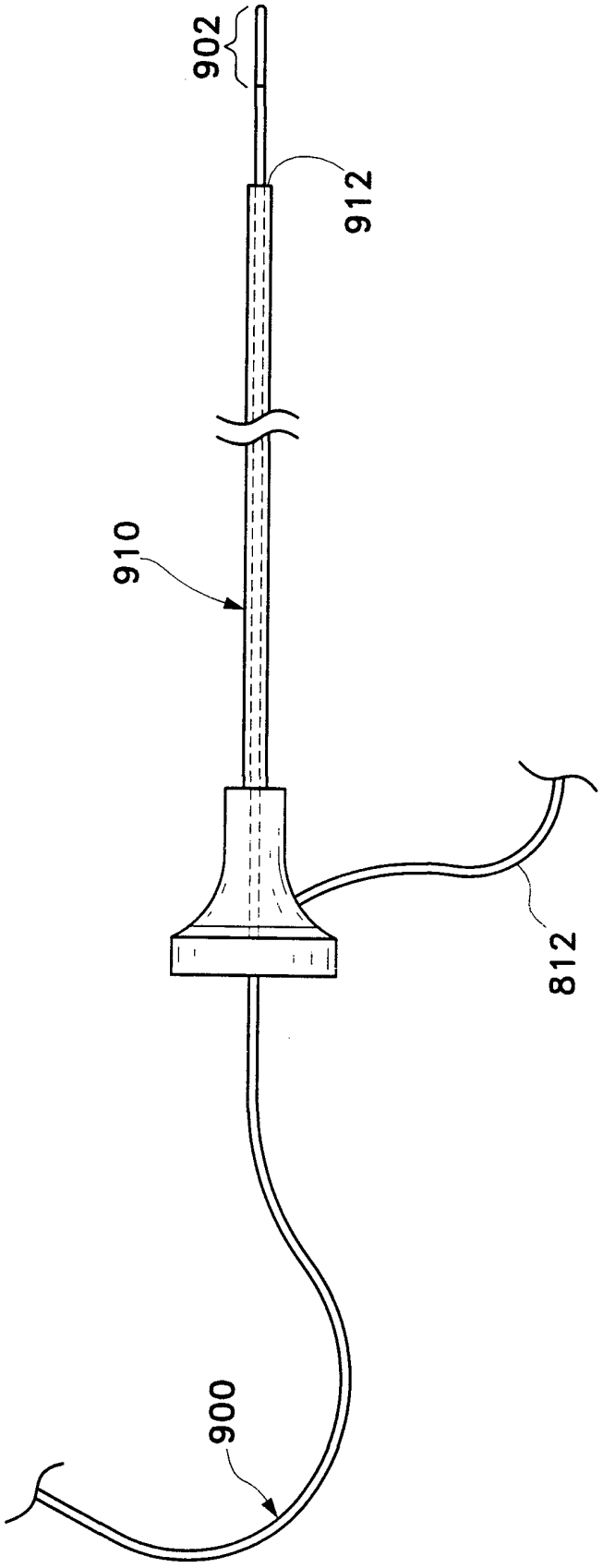


Fig. 11

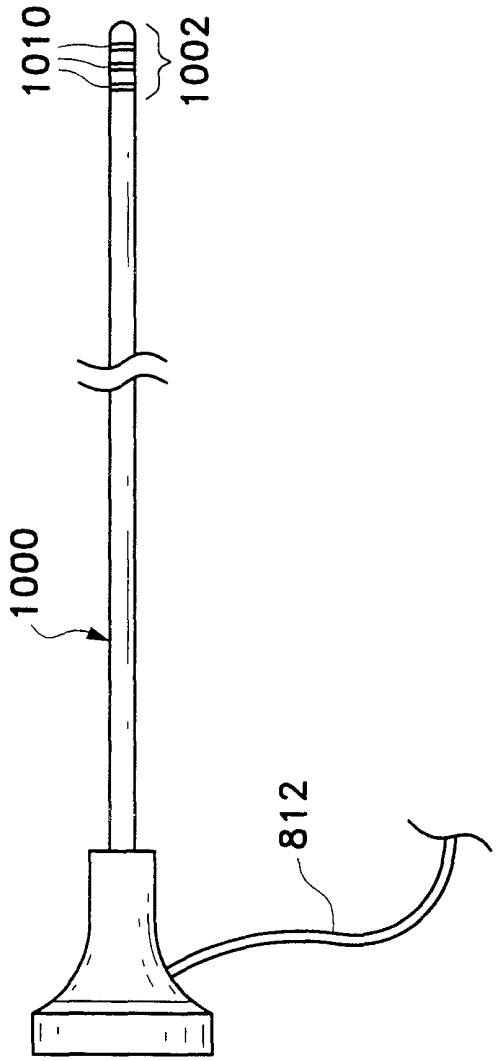


Fig. 12

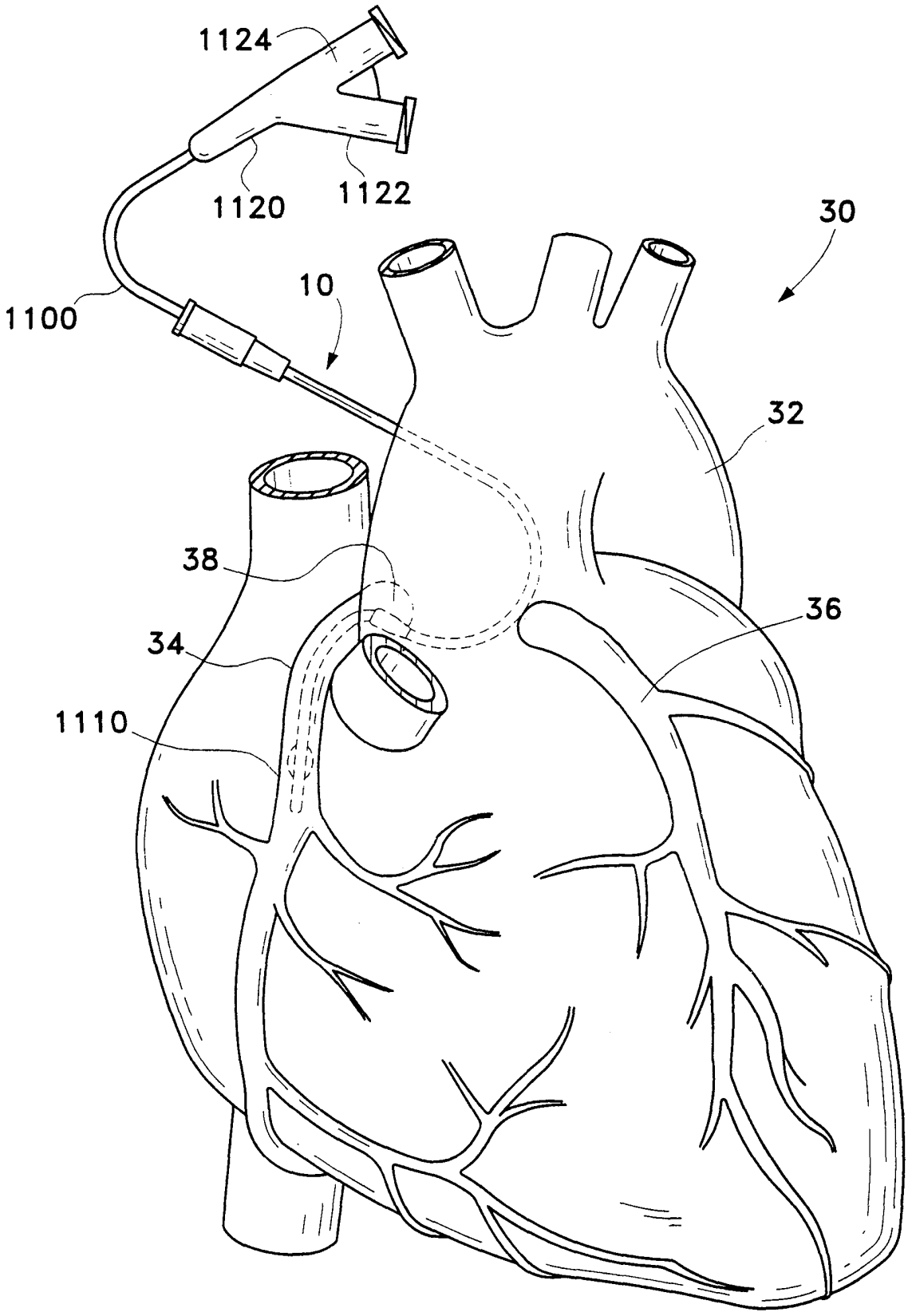


Fig. 12A

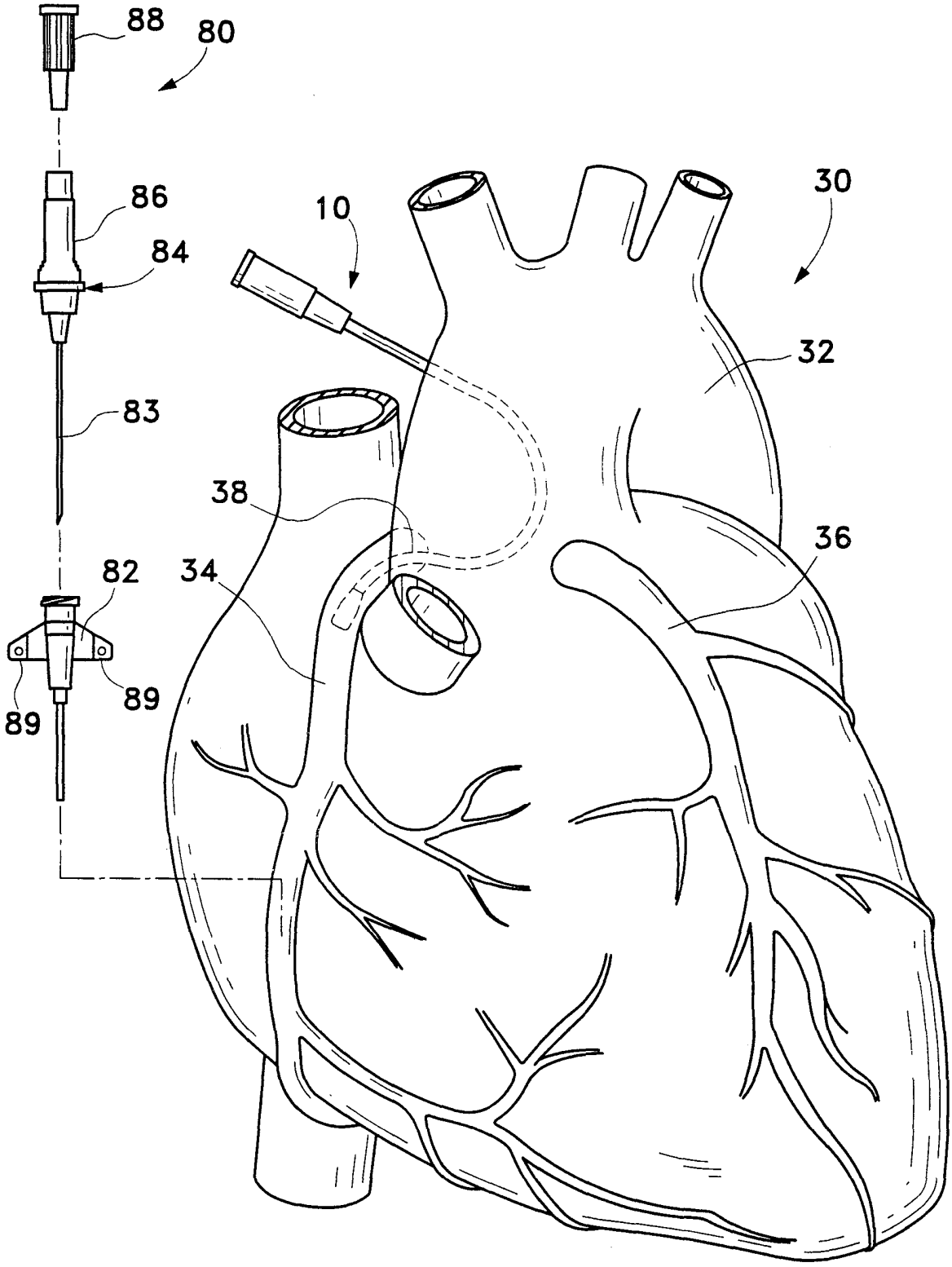


Fig. 13A

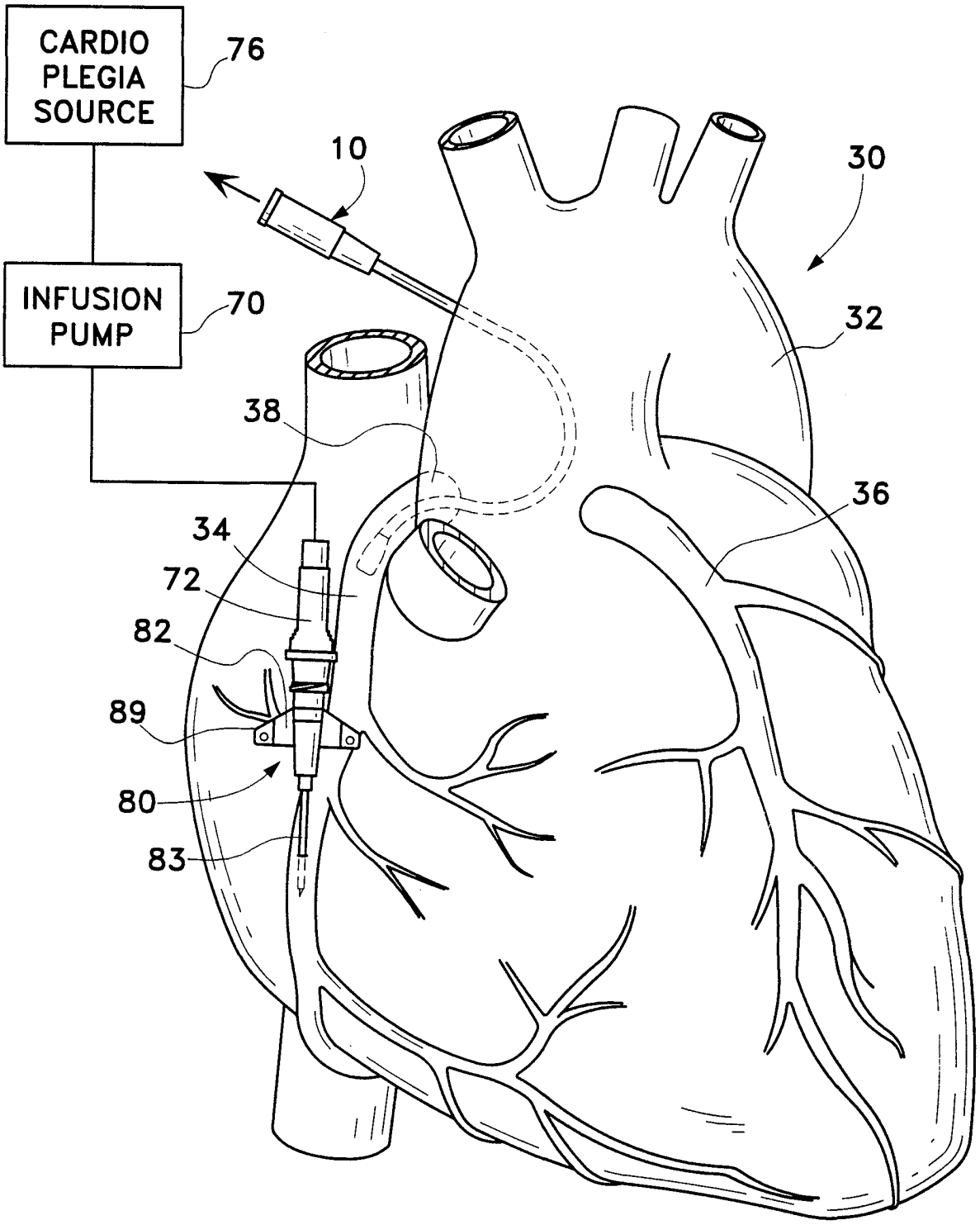

CARDIO PLEGIA SOURCE
76
10
30
INFUSION PUMP
70
32
38
36
34
72
82
89
80
83

Fig. 13B

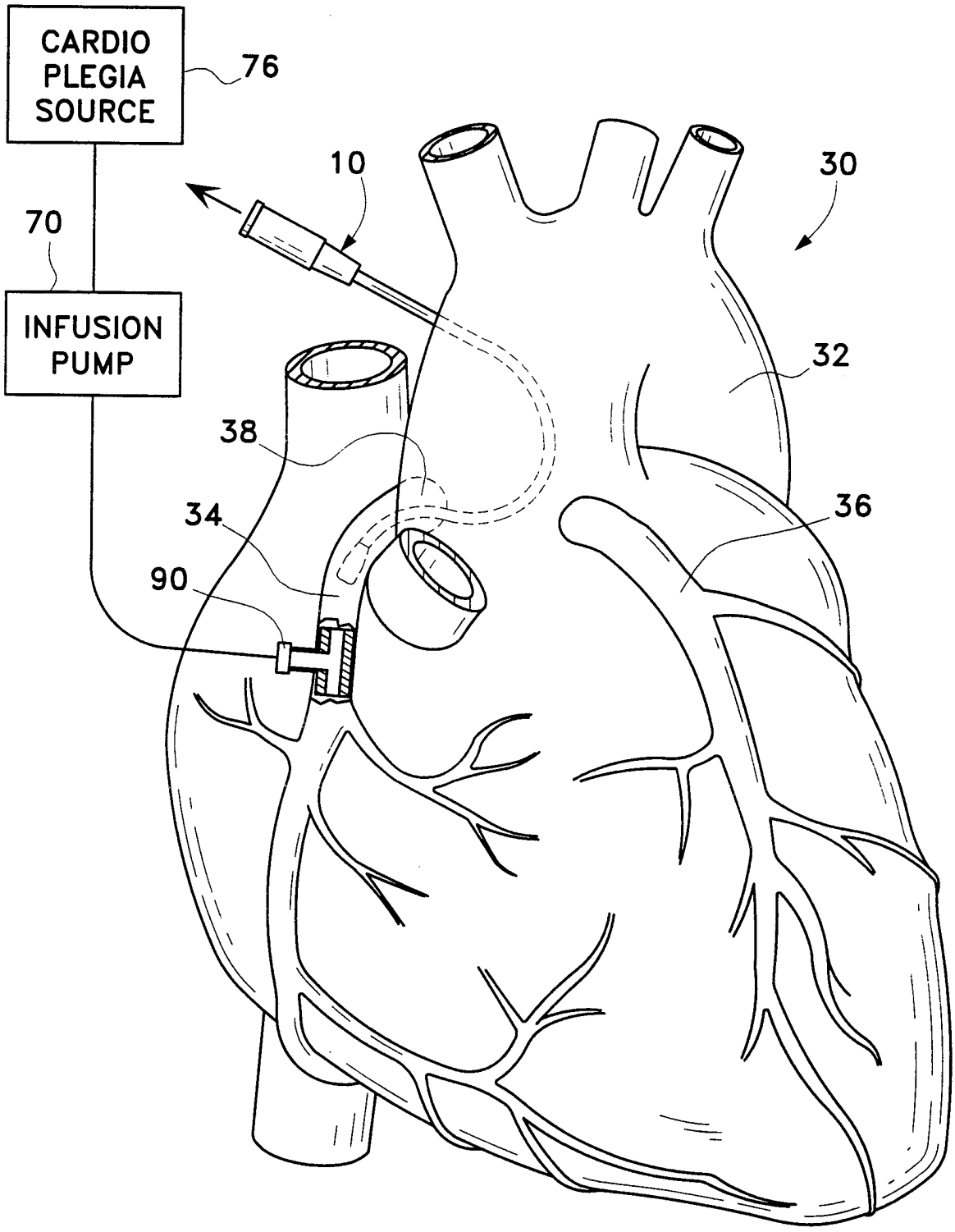


Fig. 14

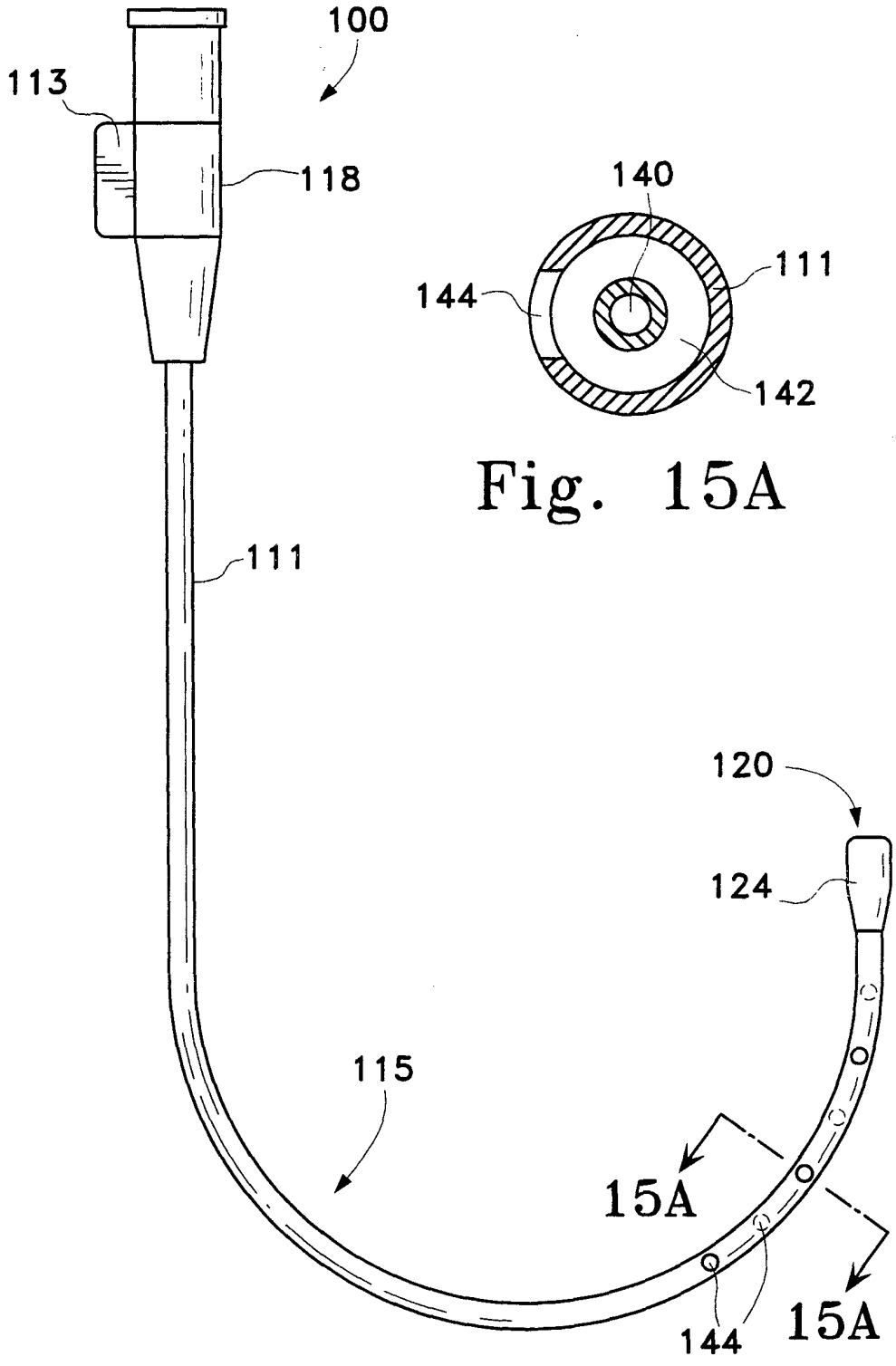


Fig. 15

Fig. 15A

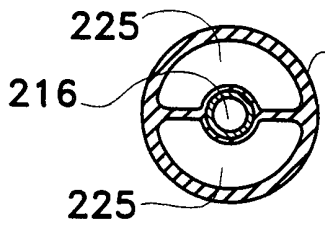


Fig. 16B

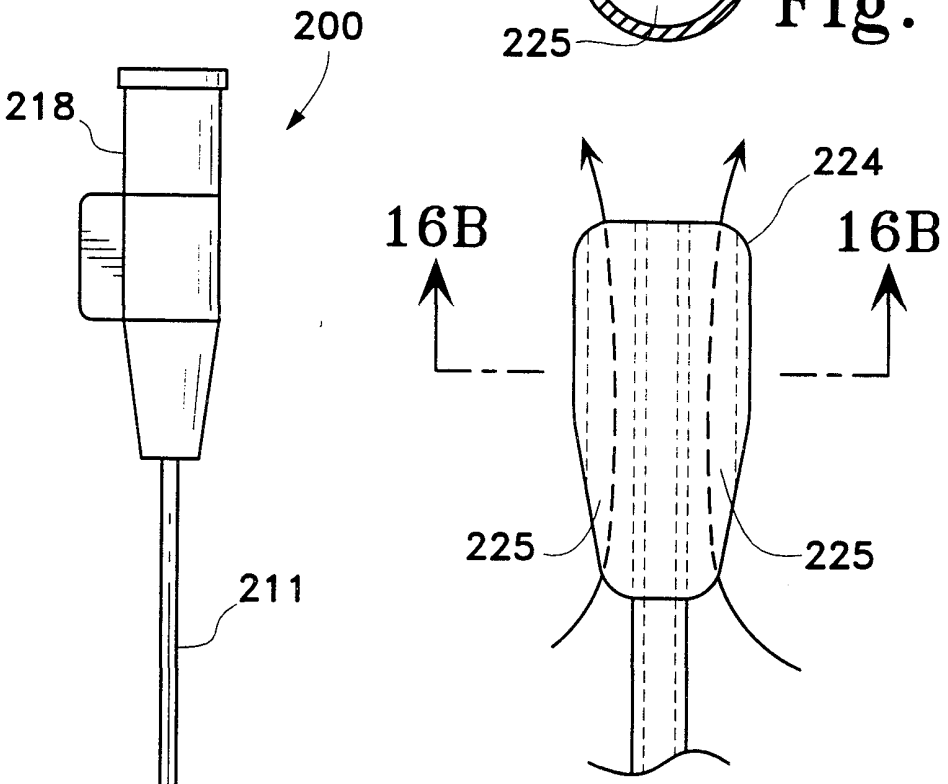


Fig. 16A

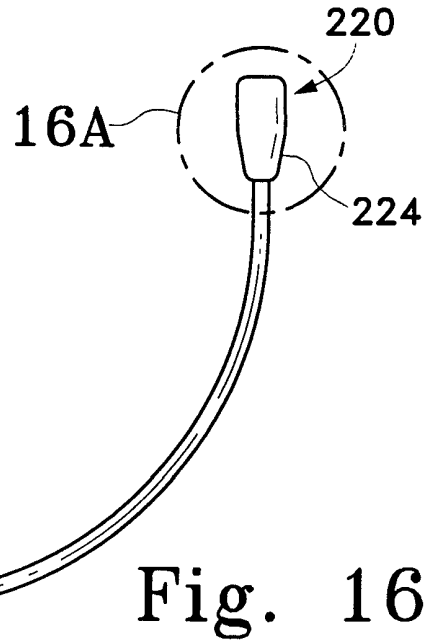


Fig. 16

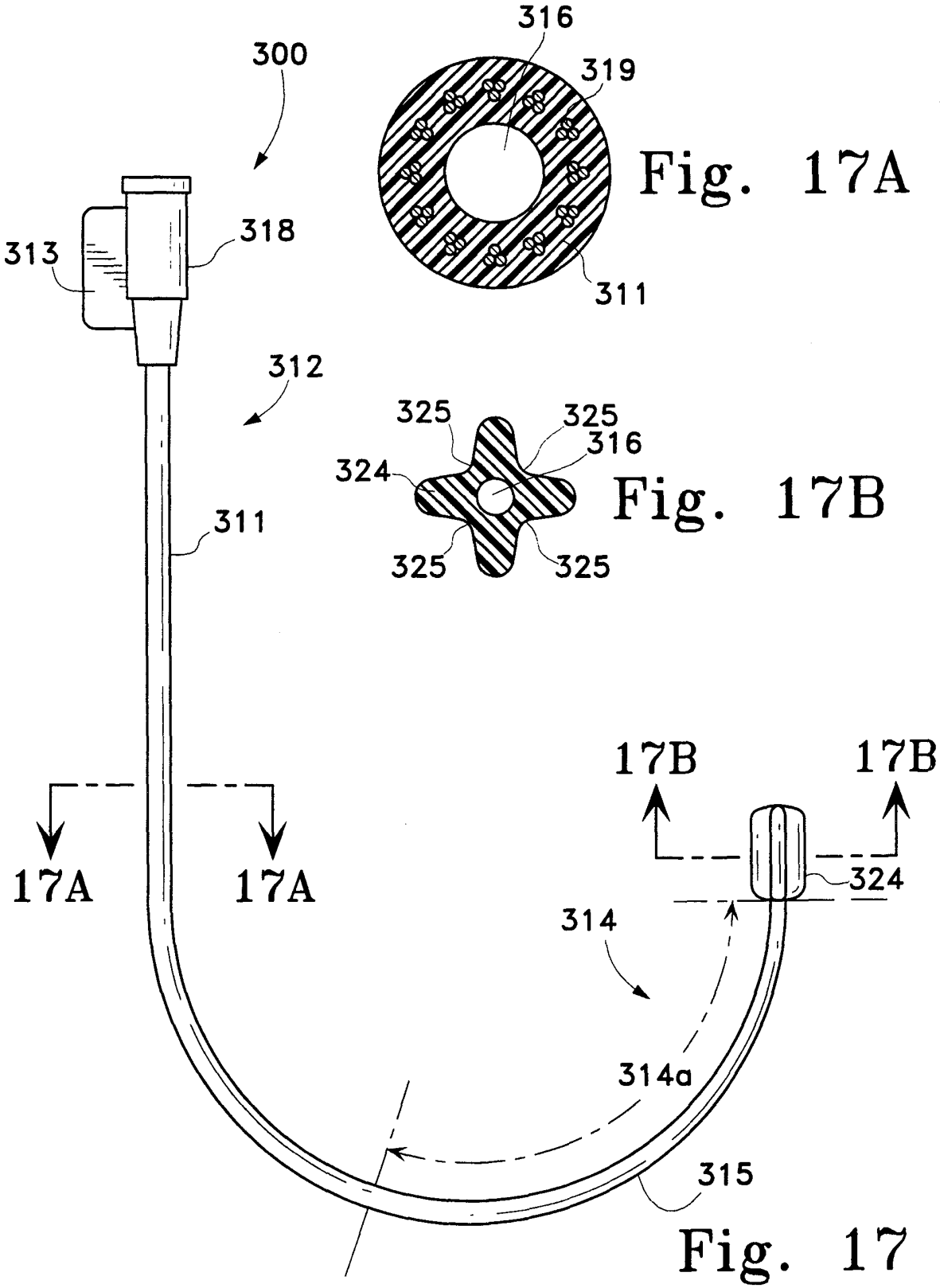
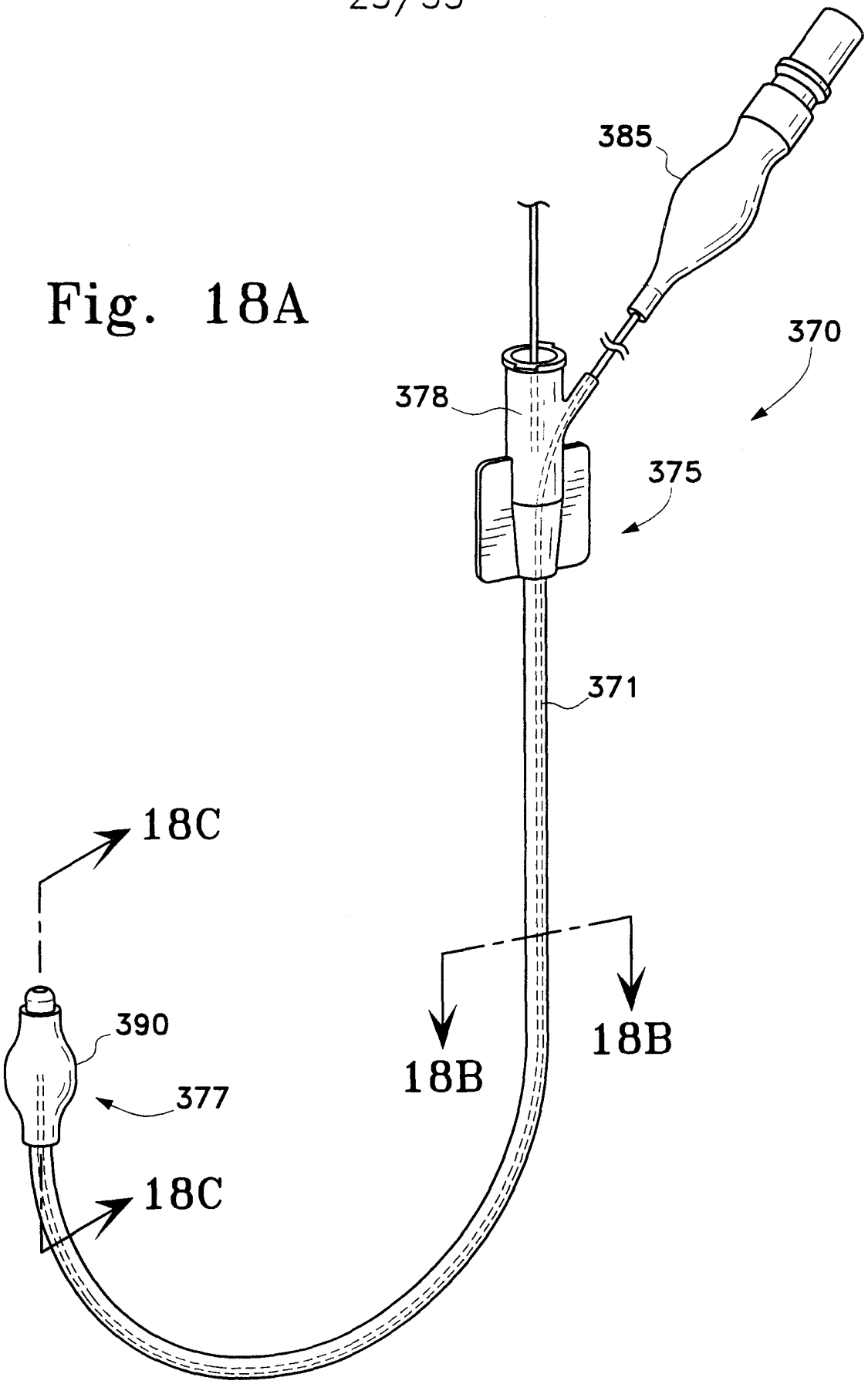


Fig. 17A

Fig. 17B

Fig. 17

Fig. 18A



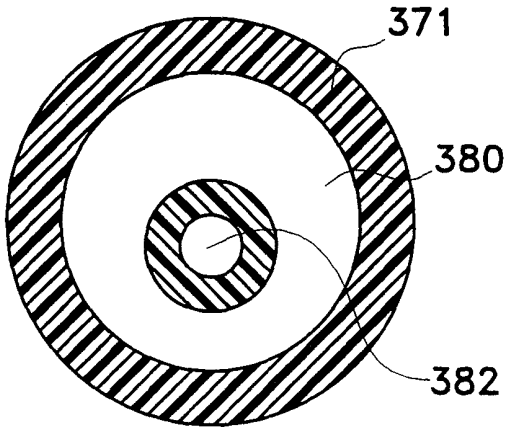


Fig. 18B

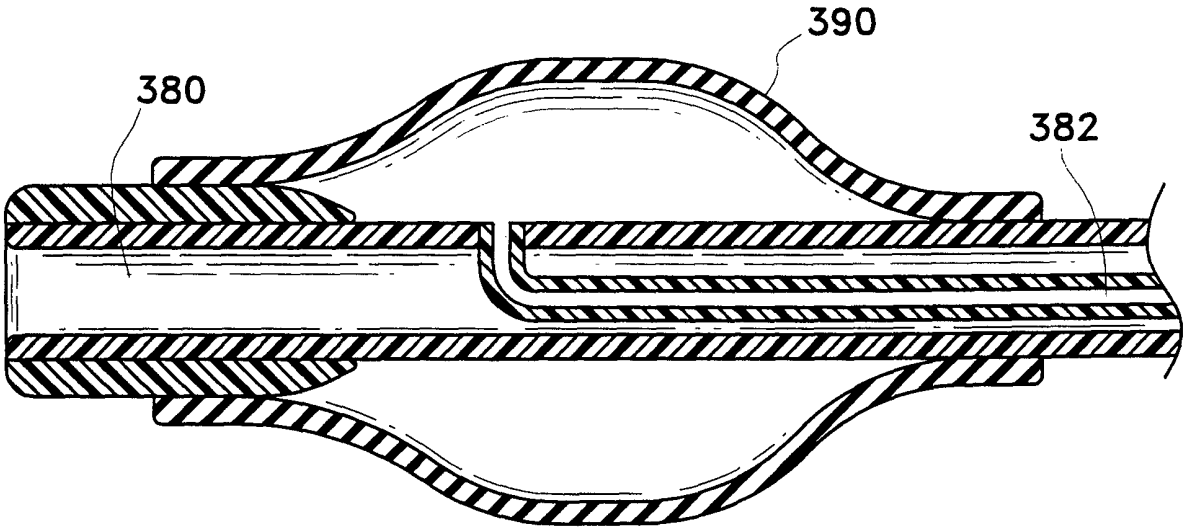


Fig. 18C

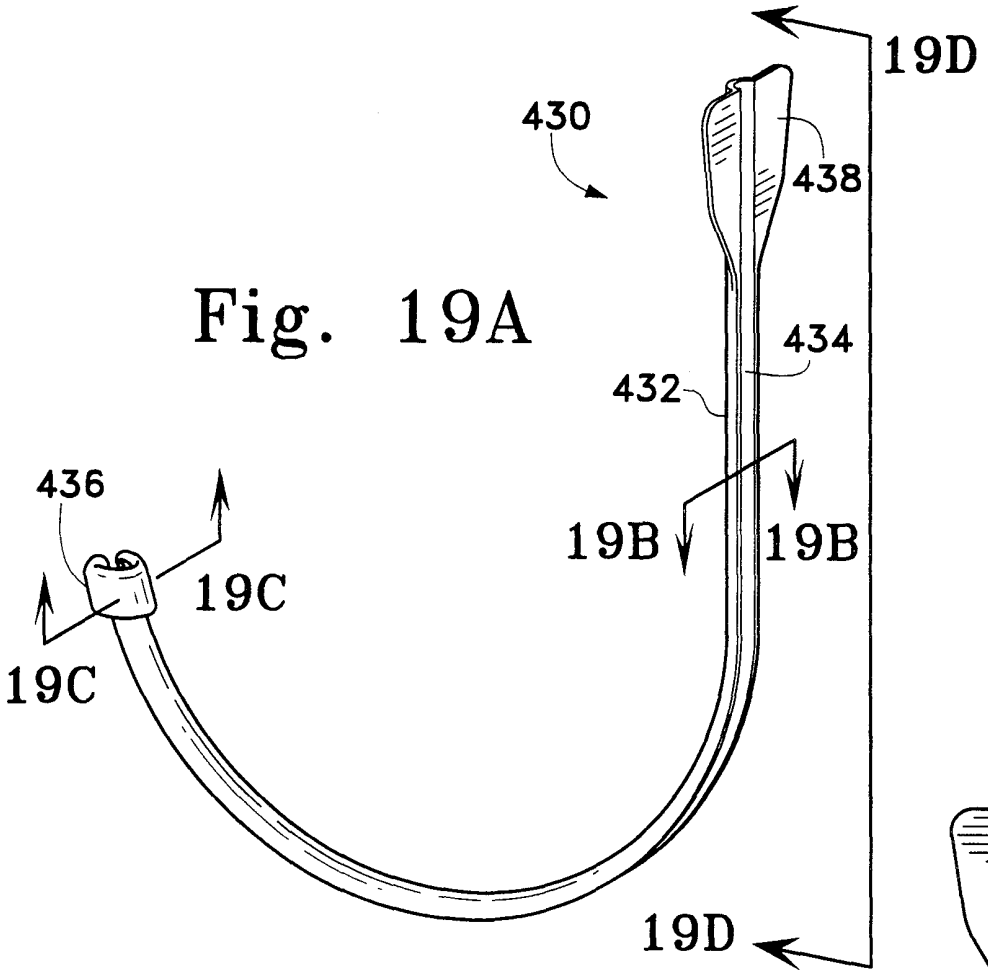


Fig. 19A

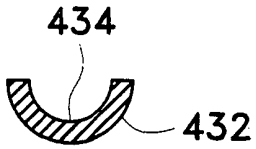


Fig. 19B

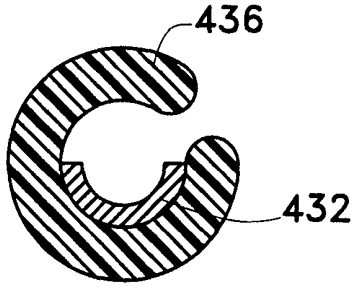


Fig. 19C

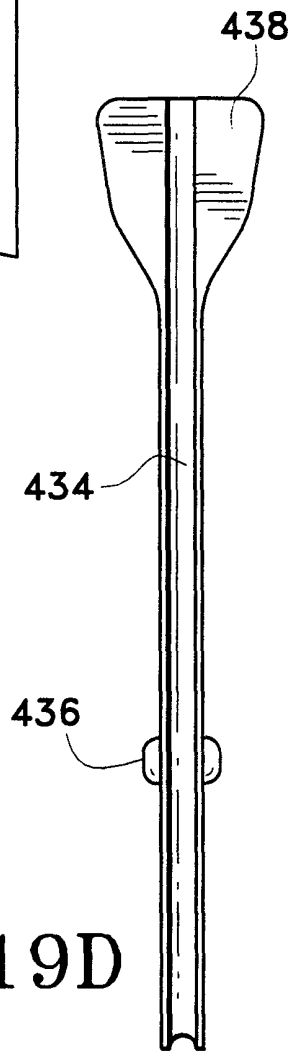


Fig. 19D

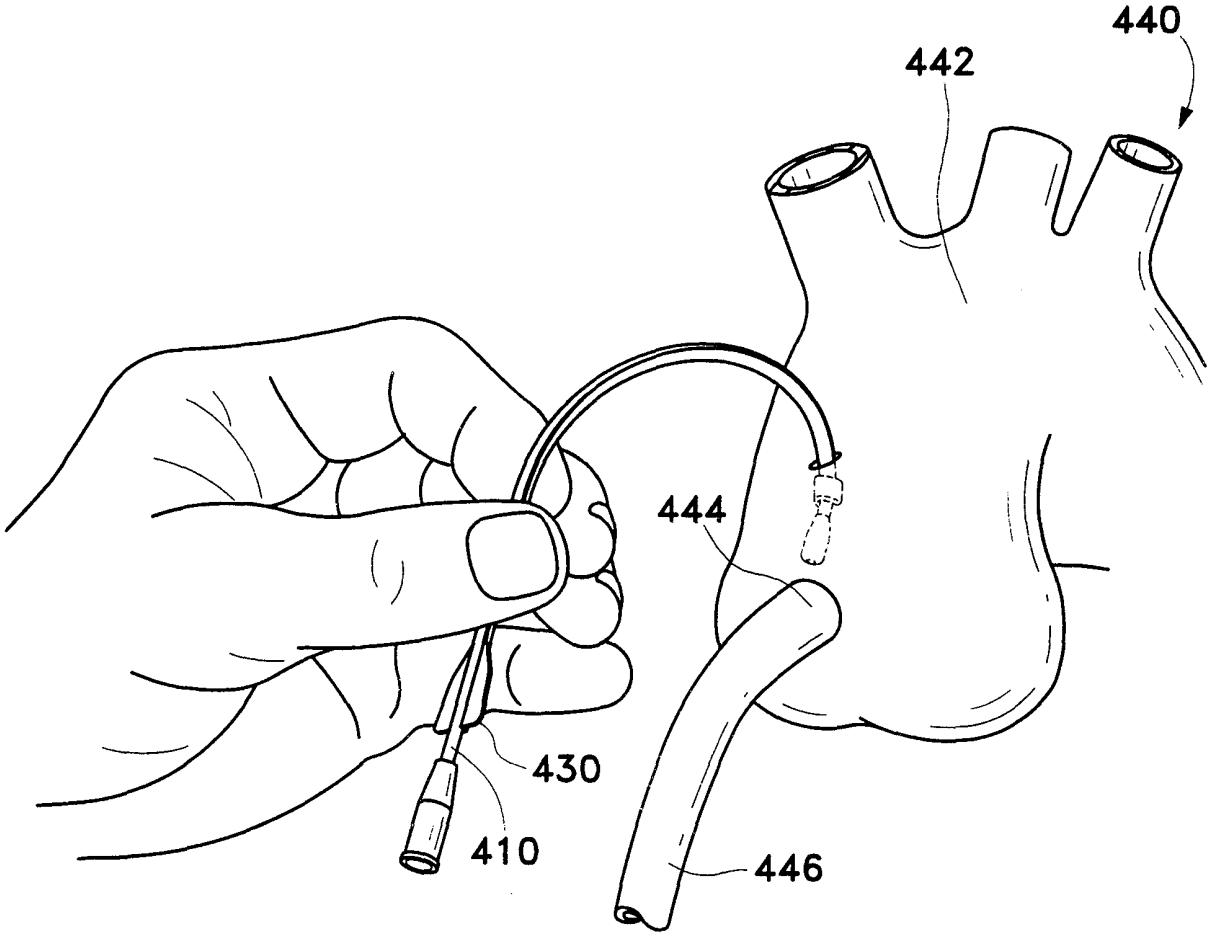


Fig. 20A

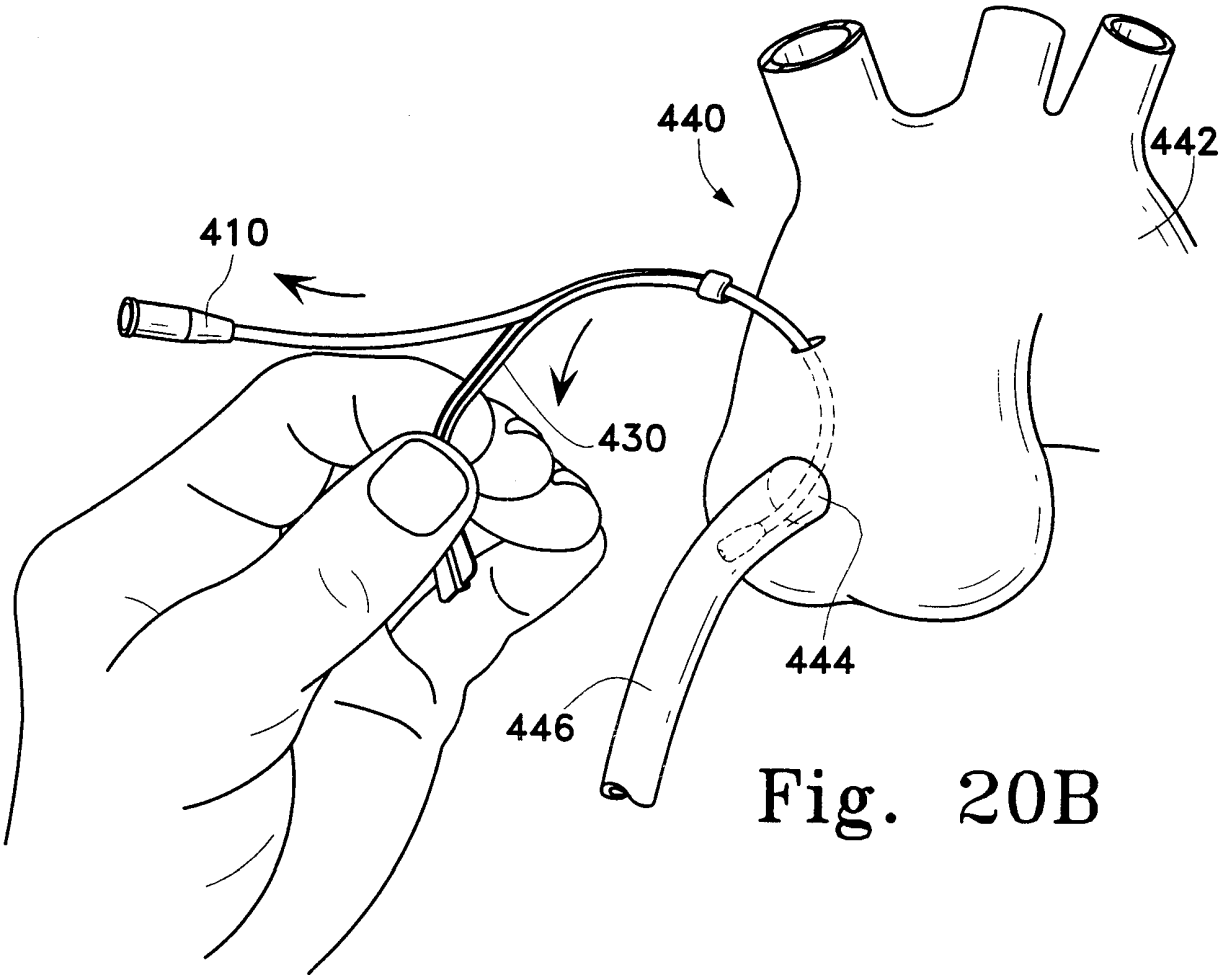


Fig. 20B

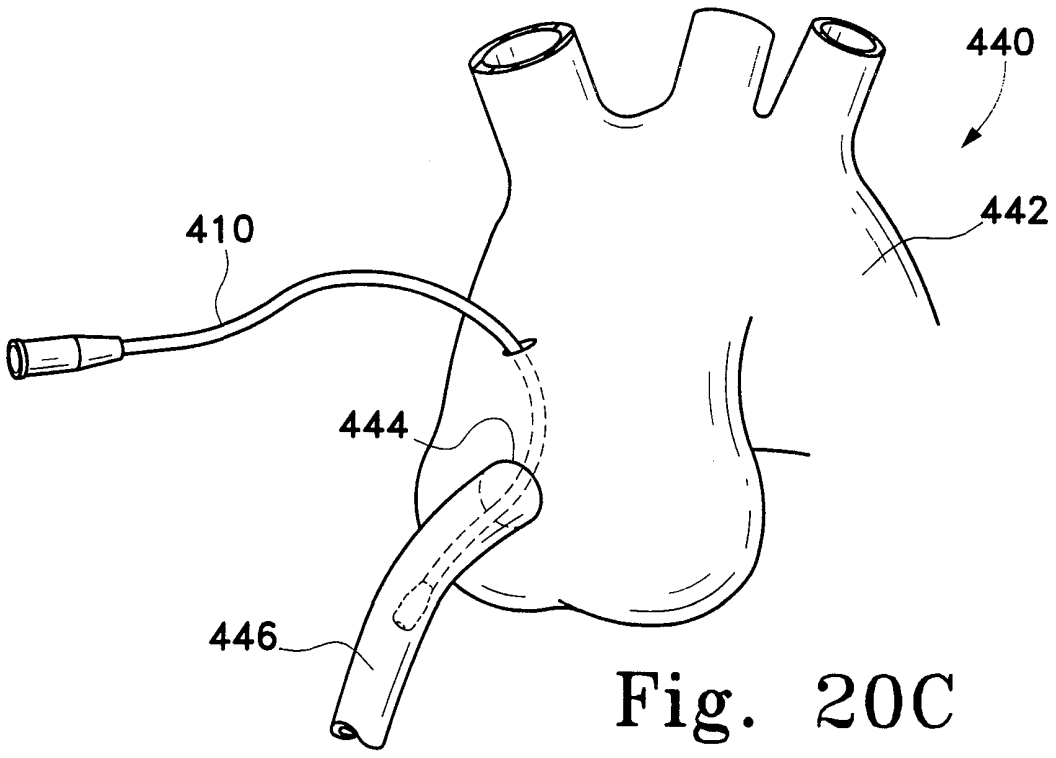


Fig. 20C

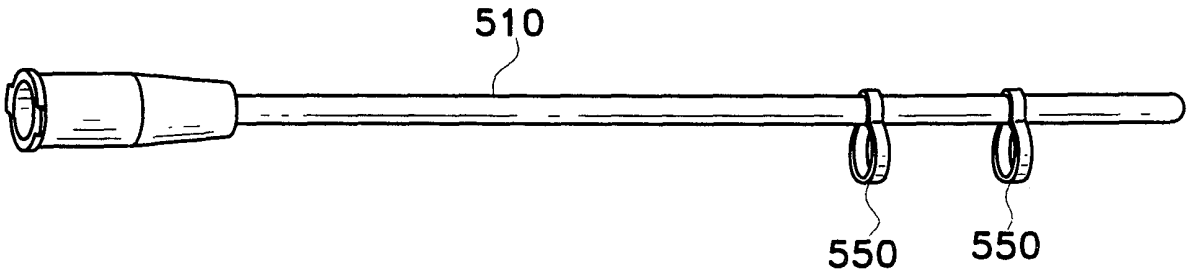


Fig. 21A

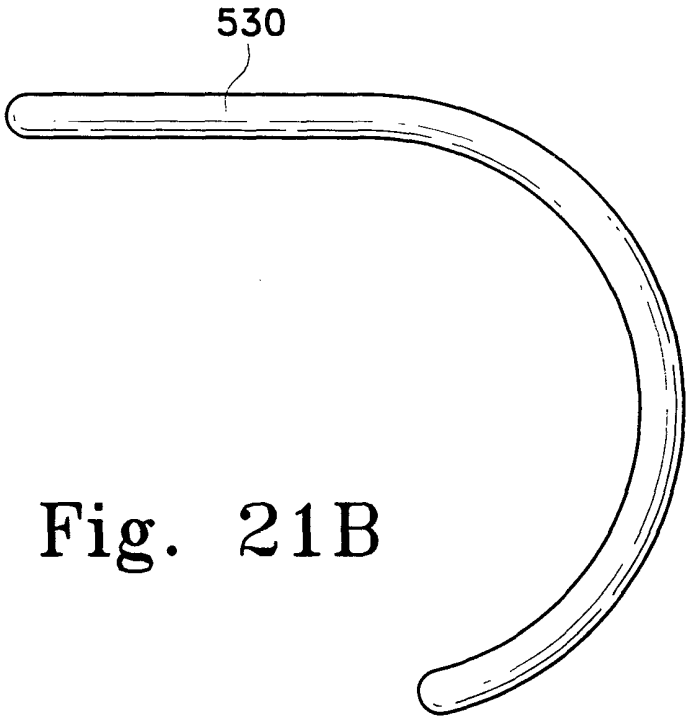


Fig. 21B

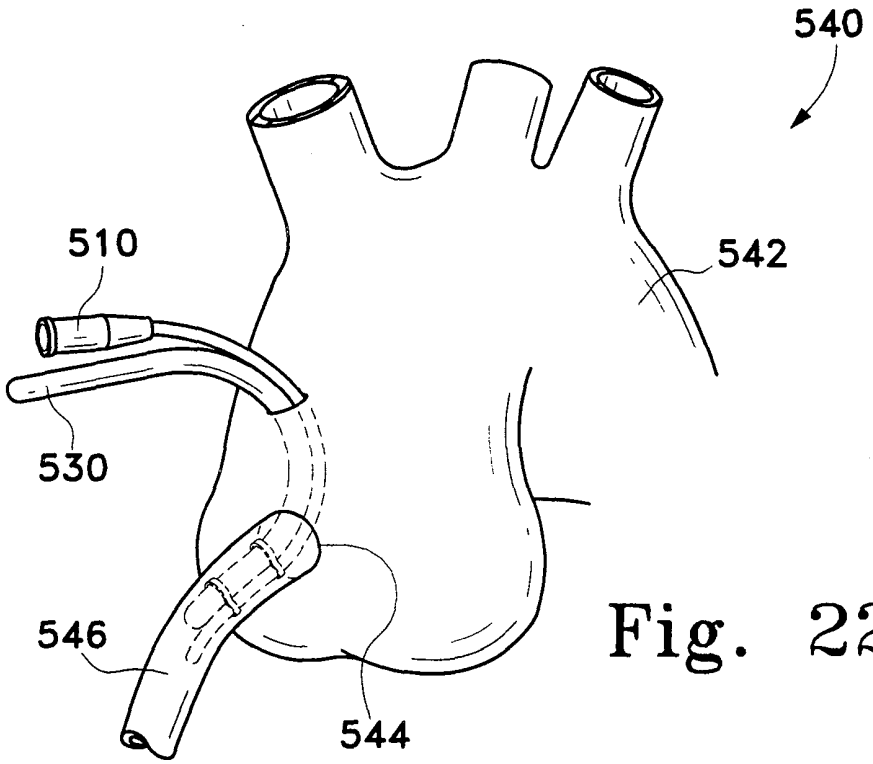


Fig. 22A

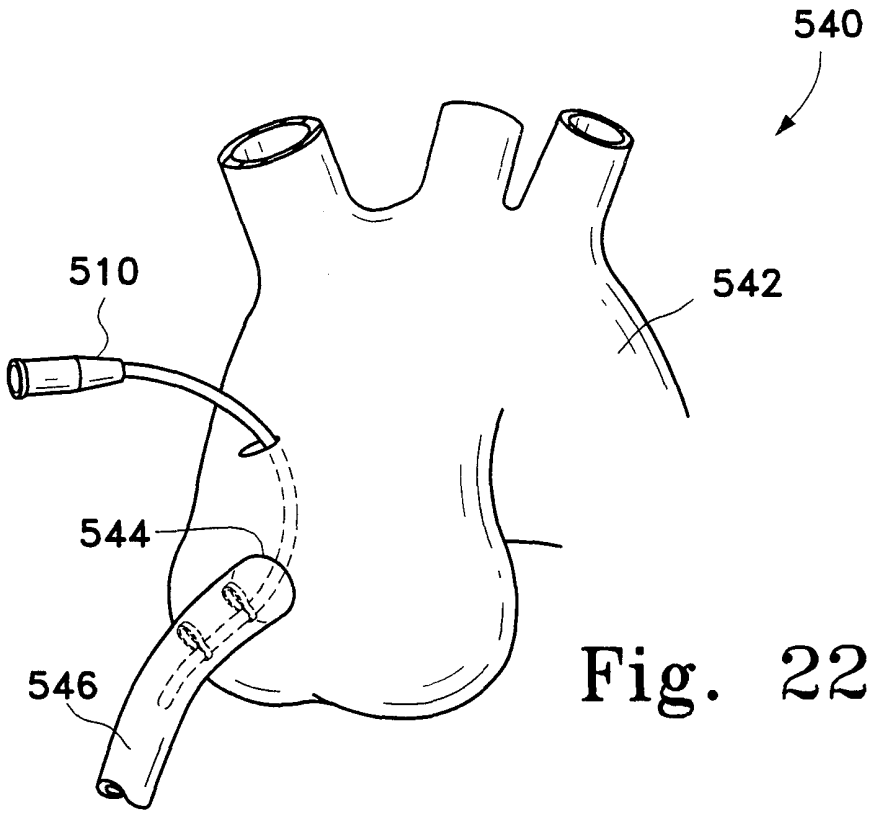


Fig. 22B

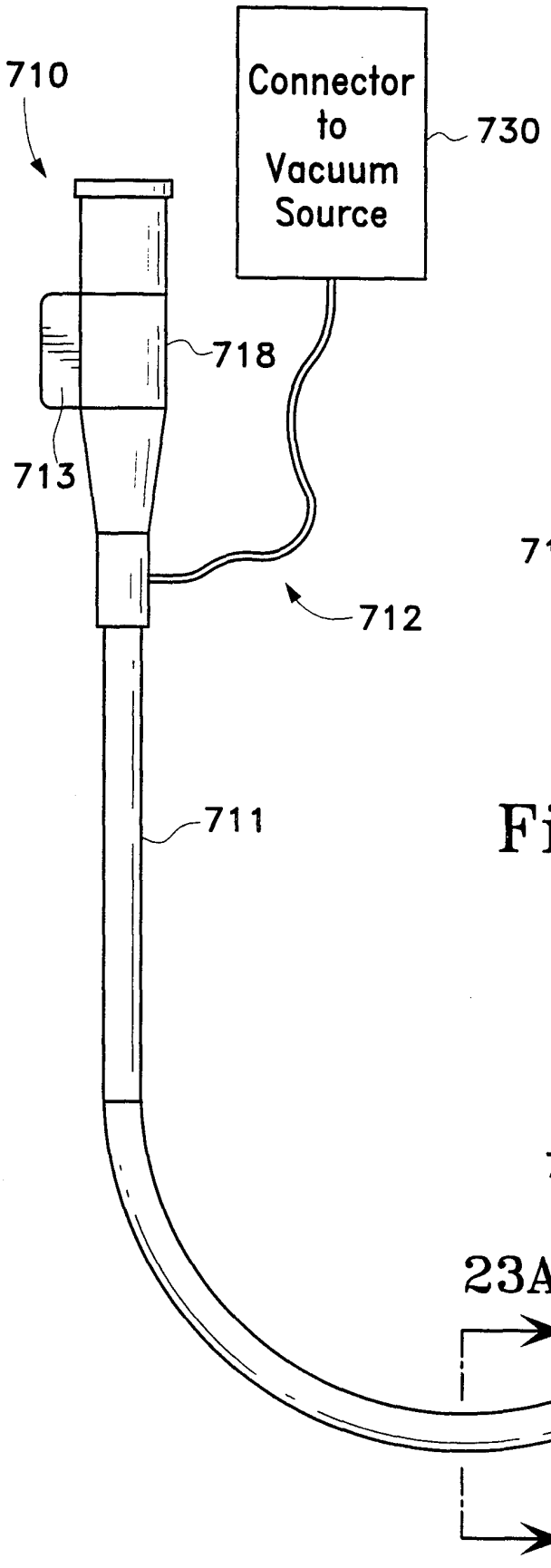


Fig. 23

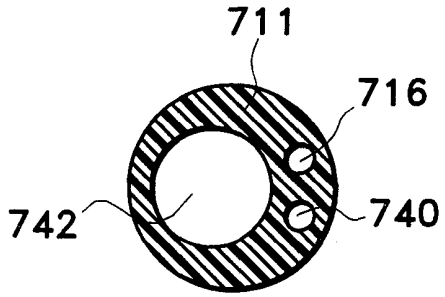


Fig. 23A

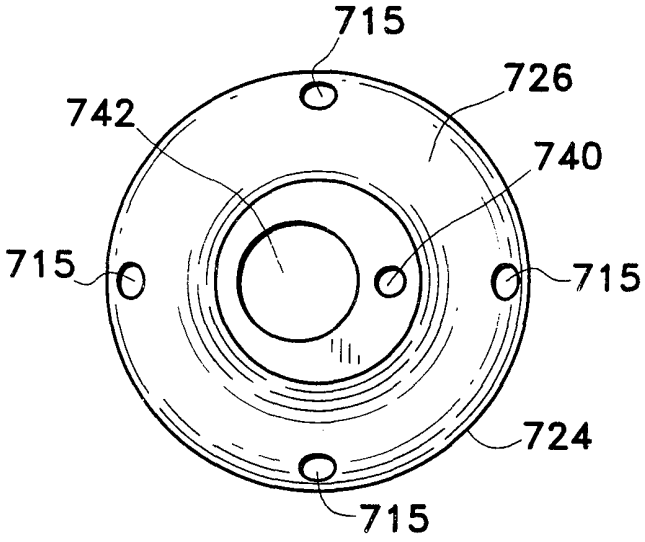


Fig. 23B

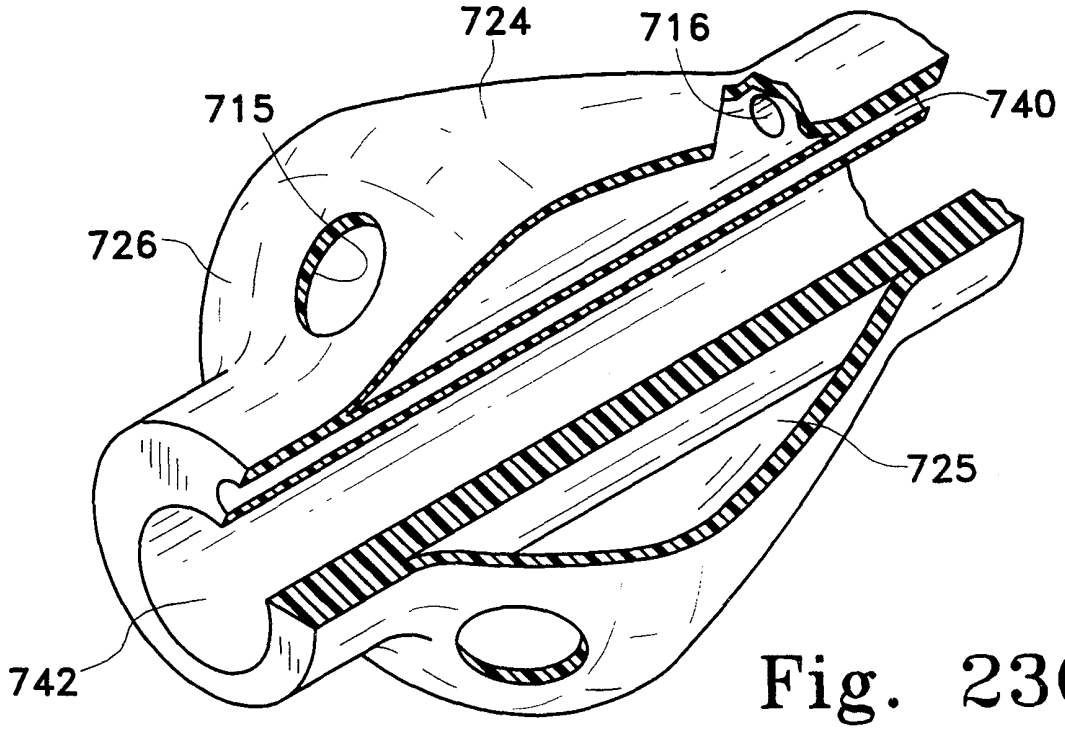


Fig. 23C

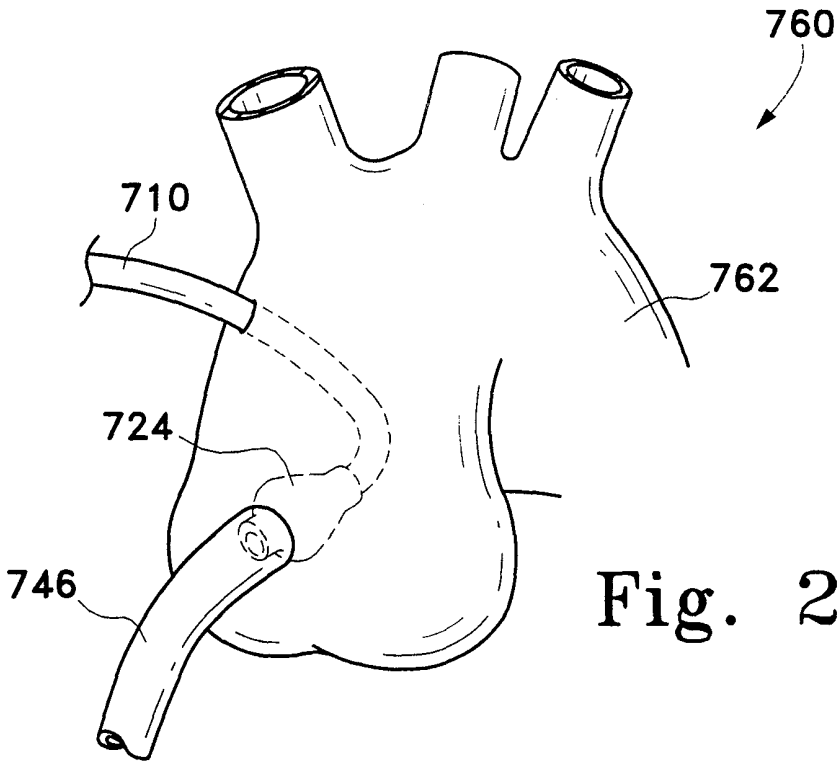


Fig. 23D

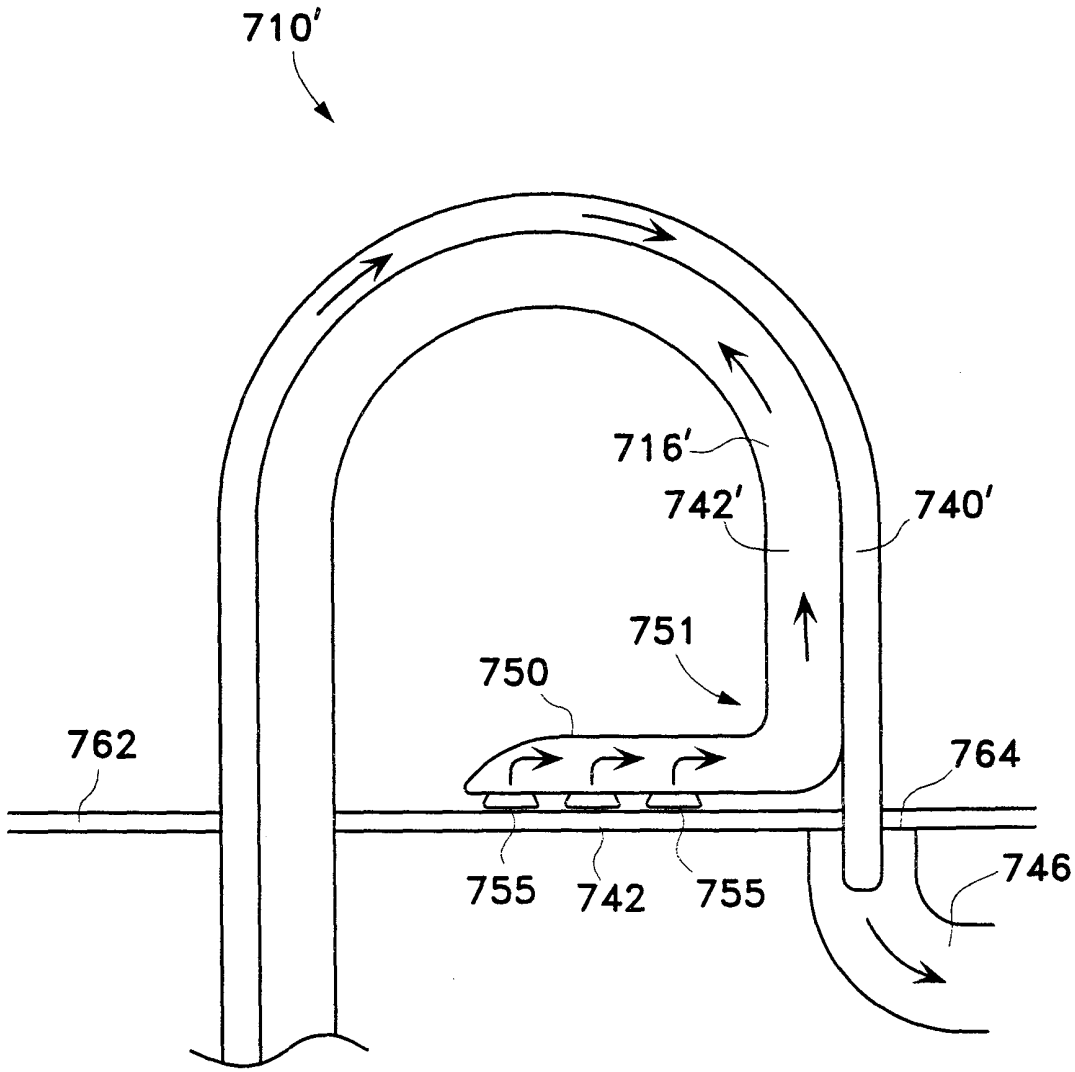


Fig. 24

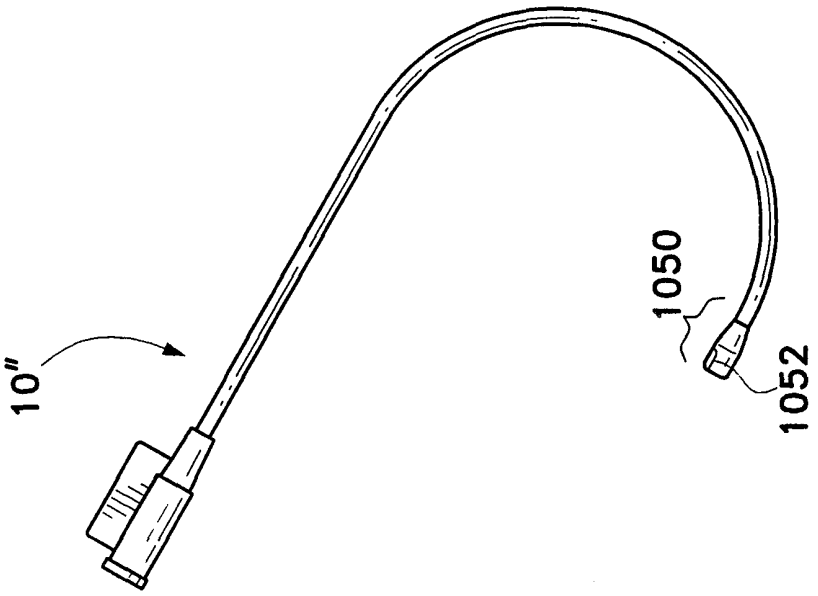


Fig. 25