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(54) **DESIGNS FOR LEFT VENTRICULAR CONDUIT**

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**Related U.S. Application Data**

(63) Continuation of application No. 10/456,488, filed on Jun. 9, 2003, which is a continuation of application No. 09/829,449, filed on Apr. 10, 2001, now Pat. No. 6,610,100, which is a continuation of application No. 09/369,048, filed on Aug. 4, 1999, now Pat. No. 6,290,728.

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

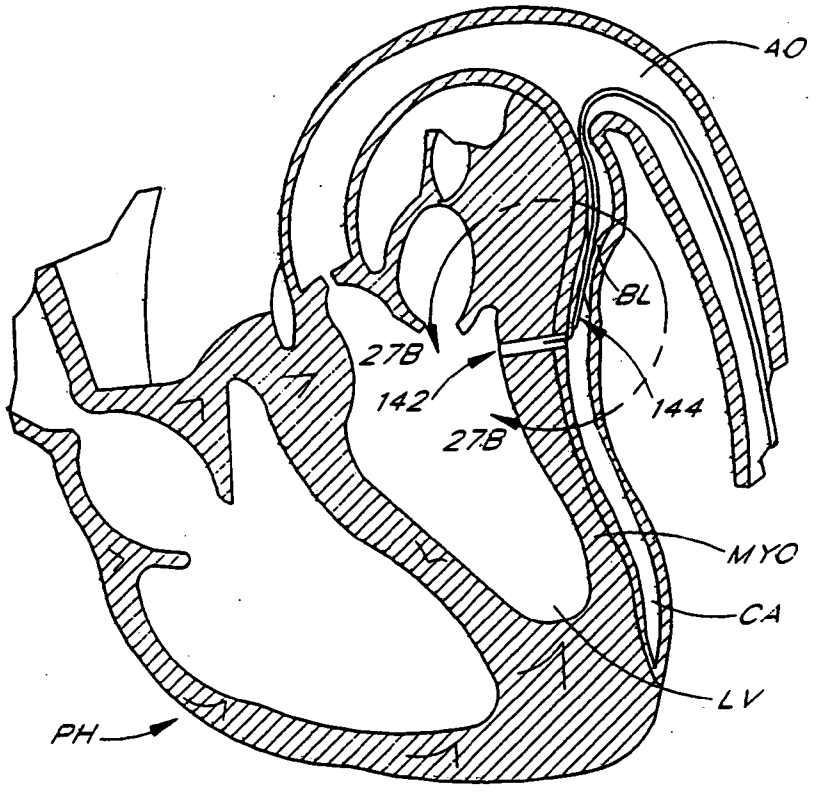
**Publication Classification**

(51) **Int. Cl.**
*A61M 5/00* (2006.01)

(52) **U.S. Cl.** ..... **604/8**; 623/1.15

(57) **ABSTRACT**

A conduit is provided to provide a bypass around a blockage in the coronary artery. The conduit is adapted to be positioned in the myocardium or heart wall to provide a passage for blood to flow between a chamber of the heart such as the left ventricle and the coronary artery, distal to the blockage. The stent is self-expanding or uses a balloon to expand the stent in the heart wall. Various attachment means are provided to anchor the stent and prevent its migration.



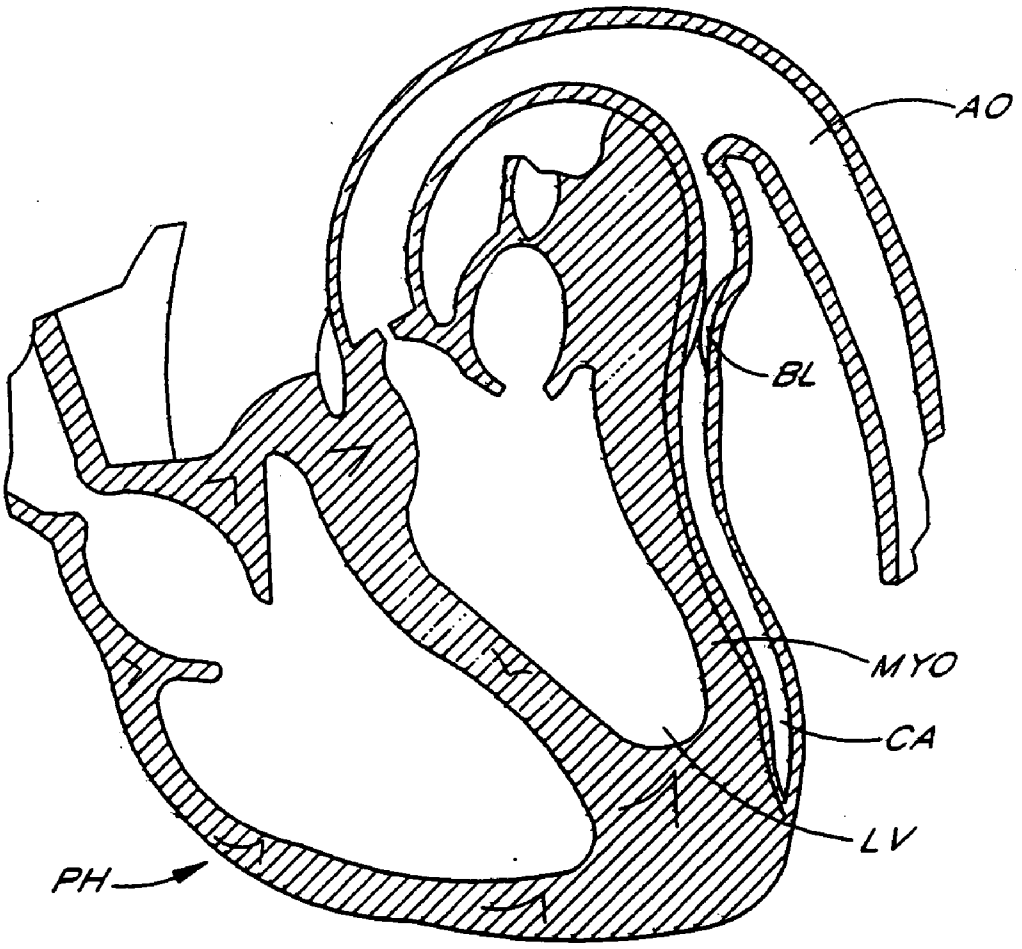



FIG. 1A

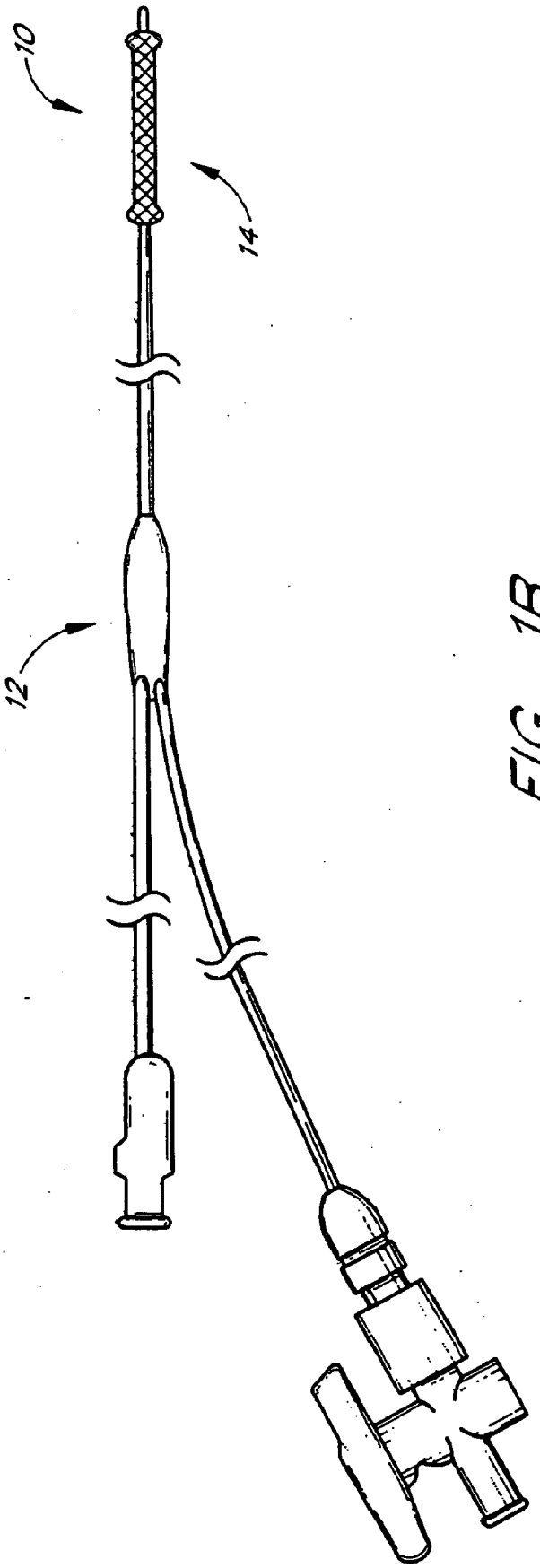



FIG. 1B

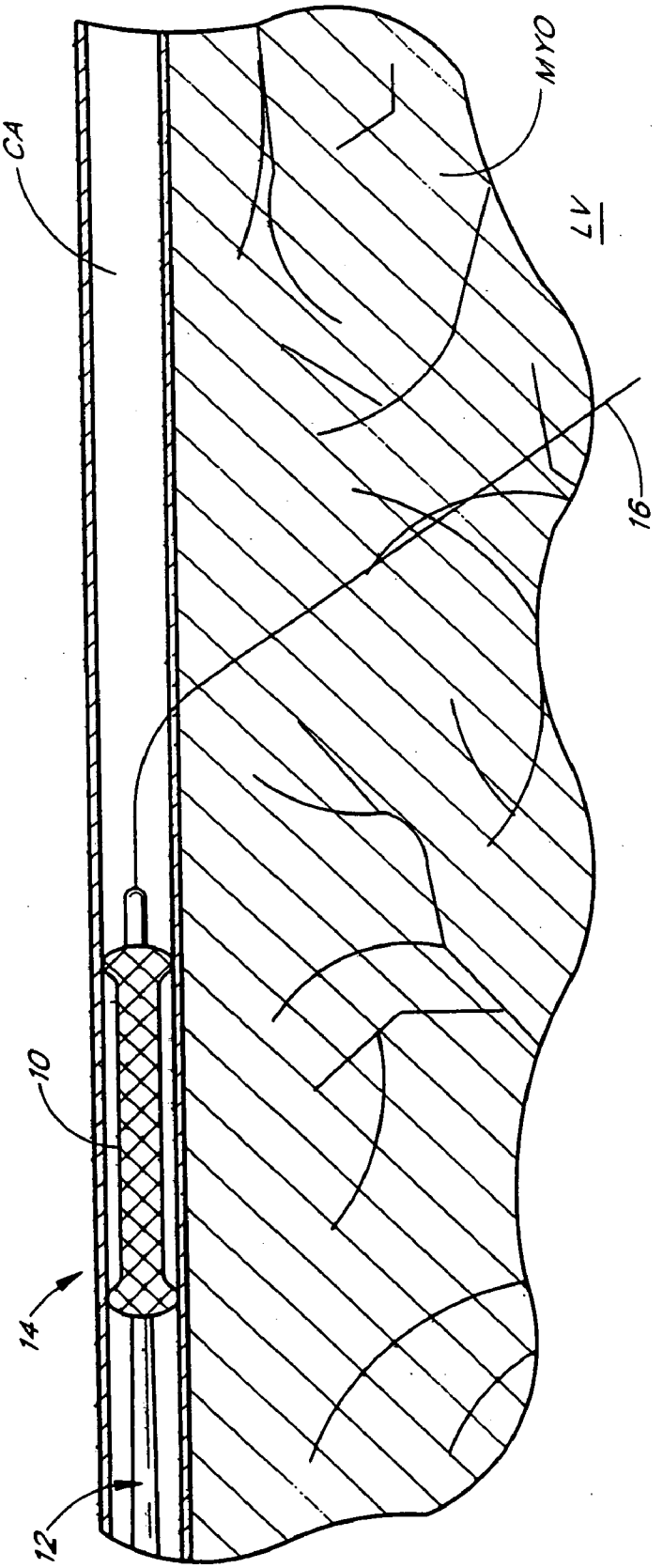



FIG. 2

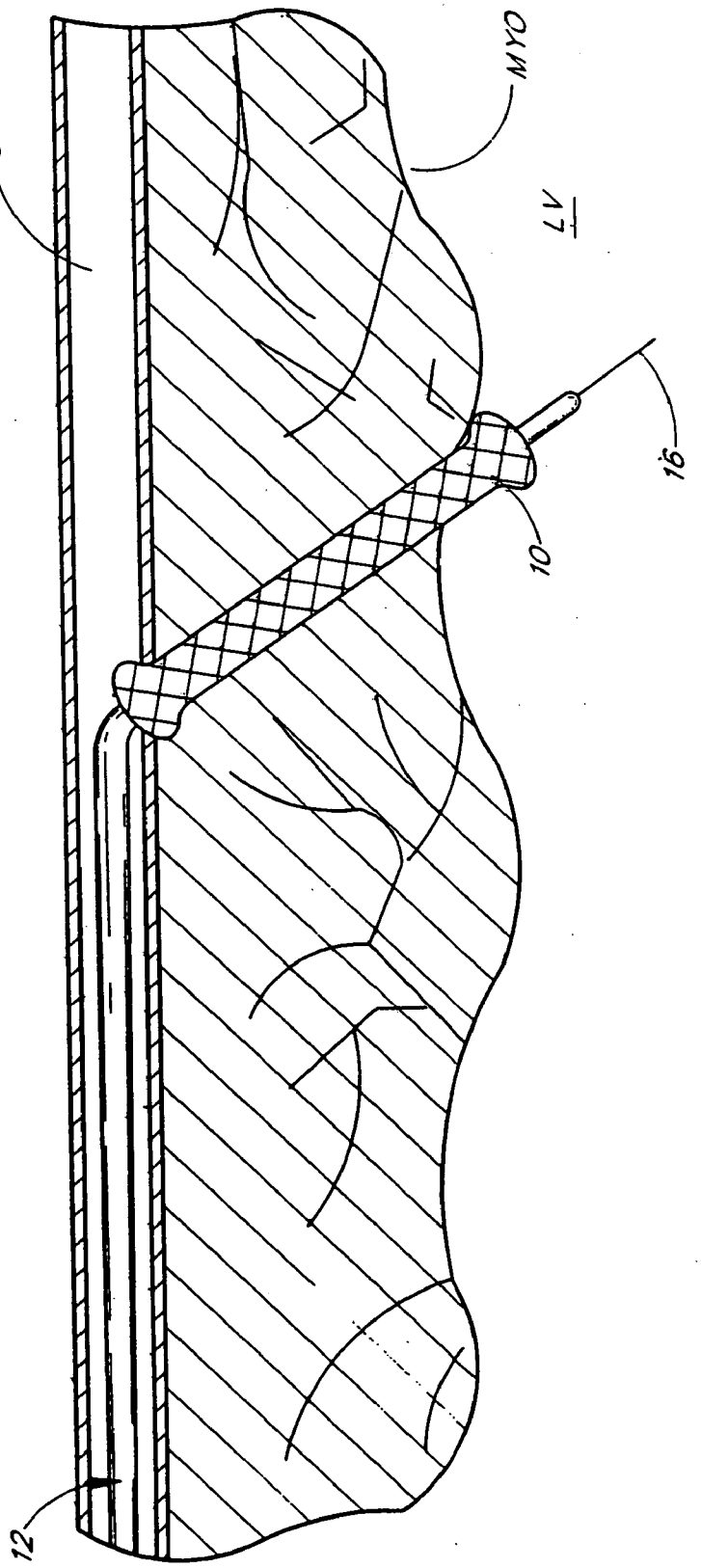



FIG. 3

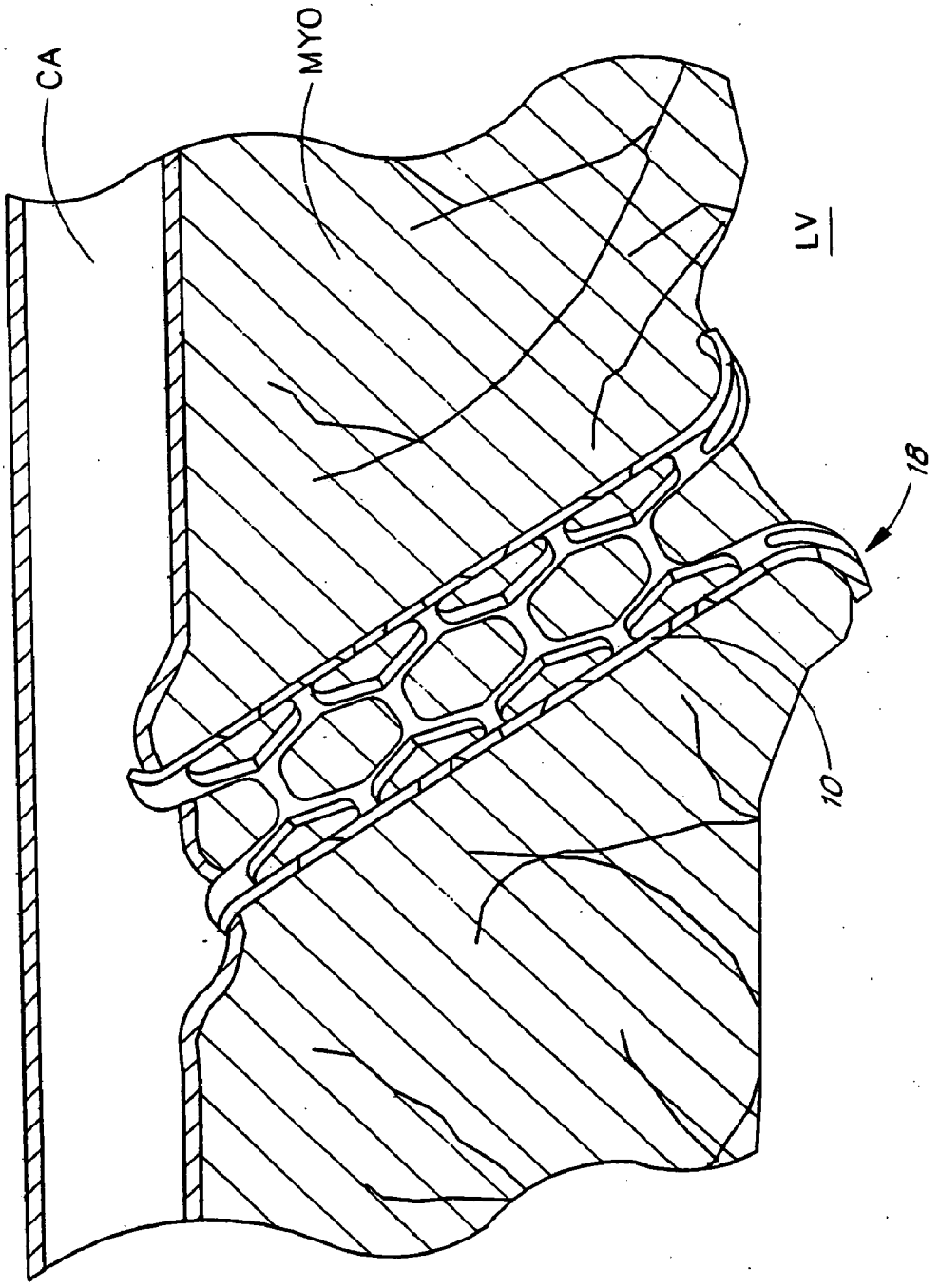



FIG. 4

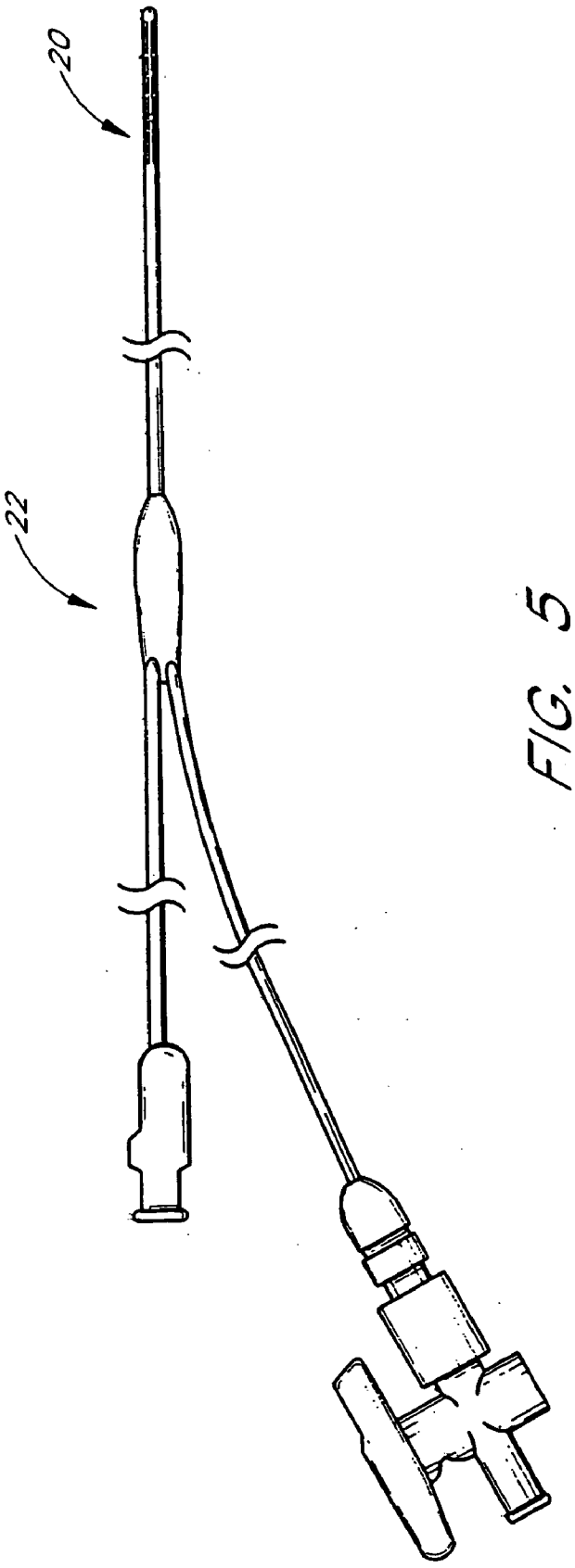



FIG. 5

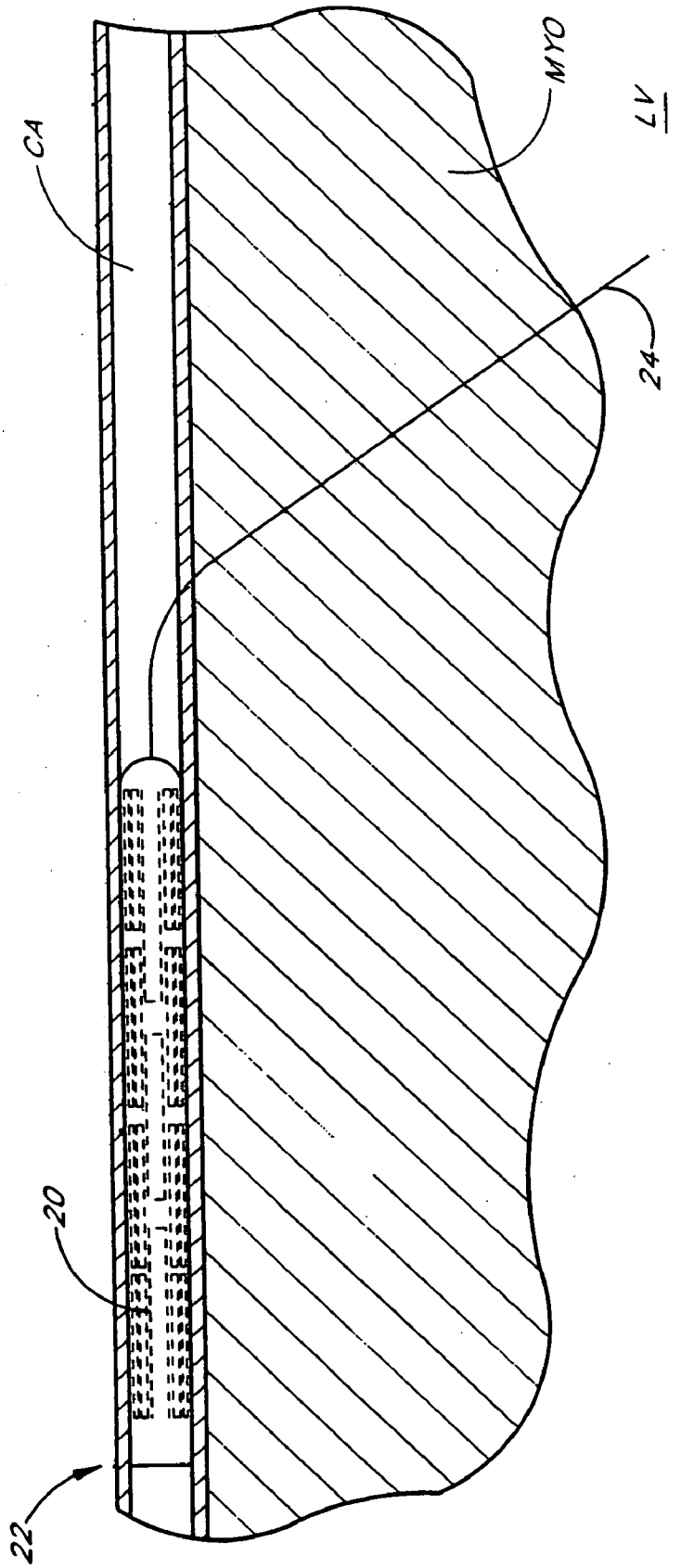



FIG. 6

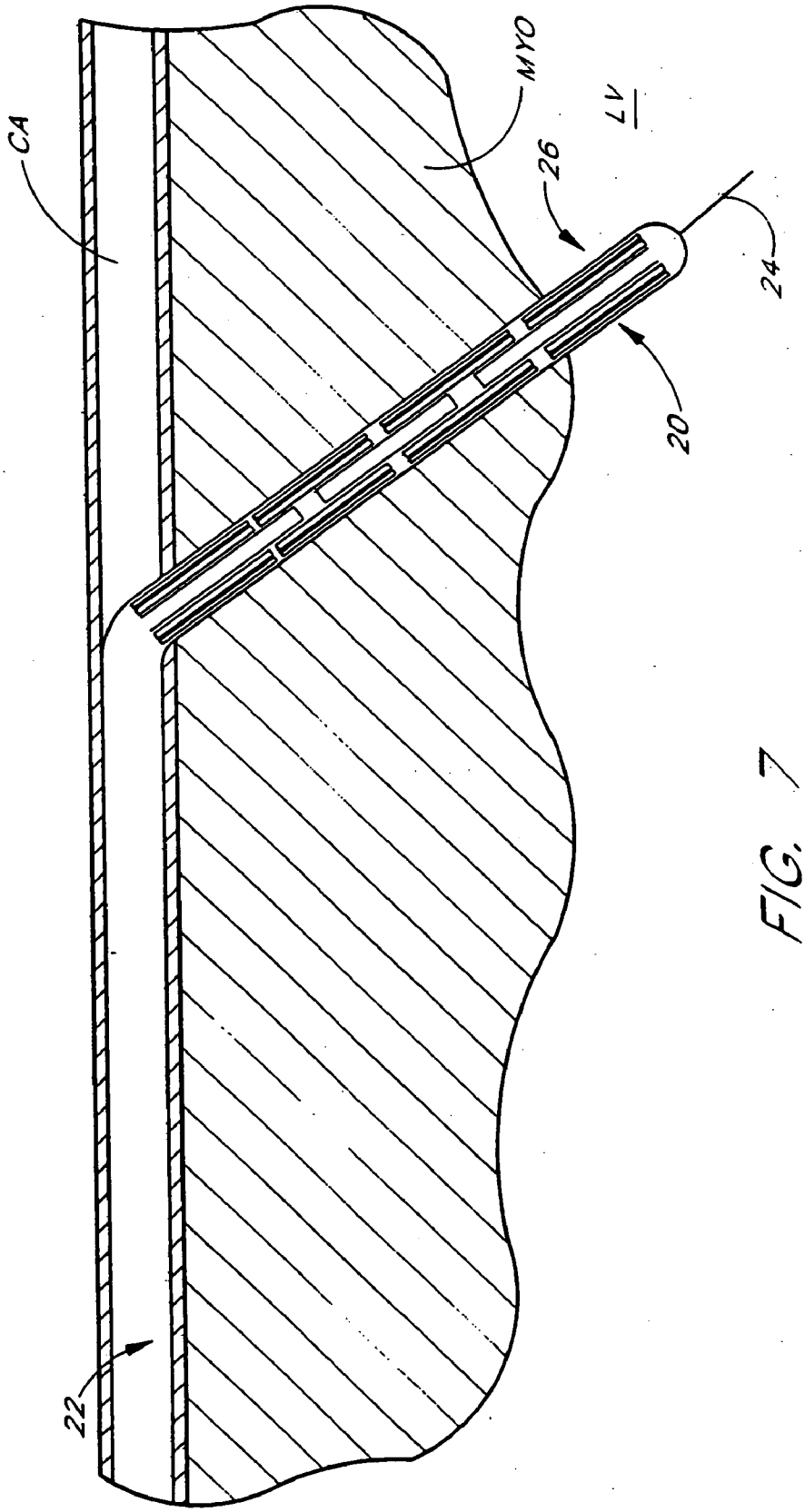



FIG. 7

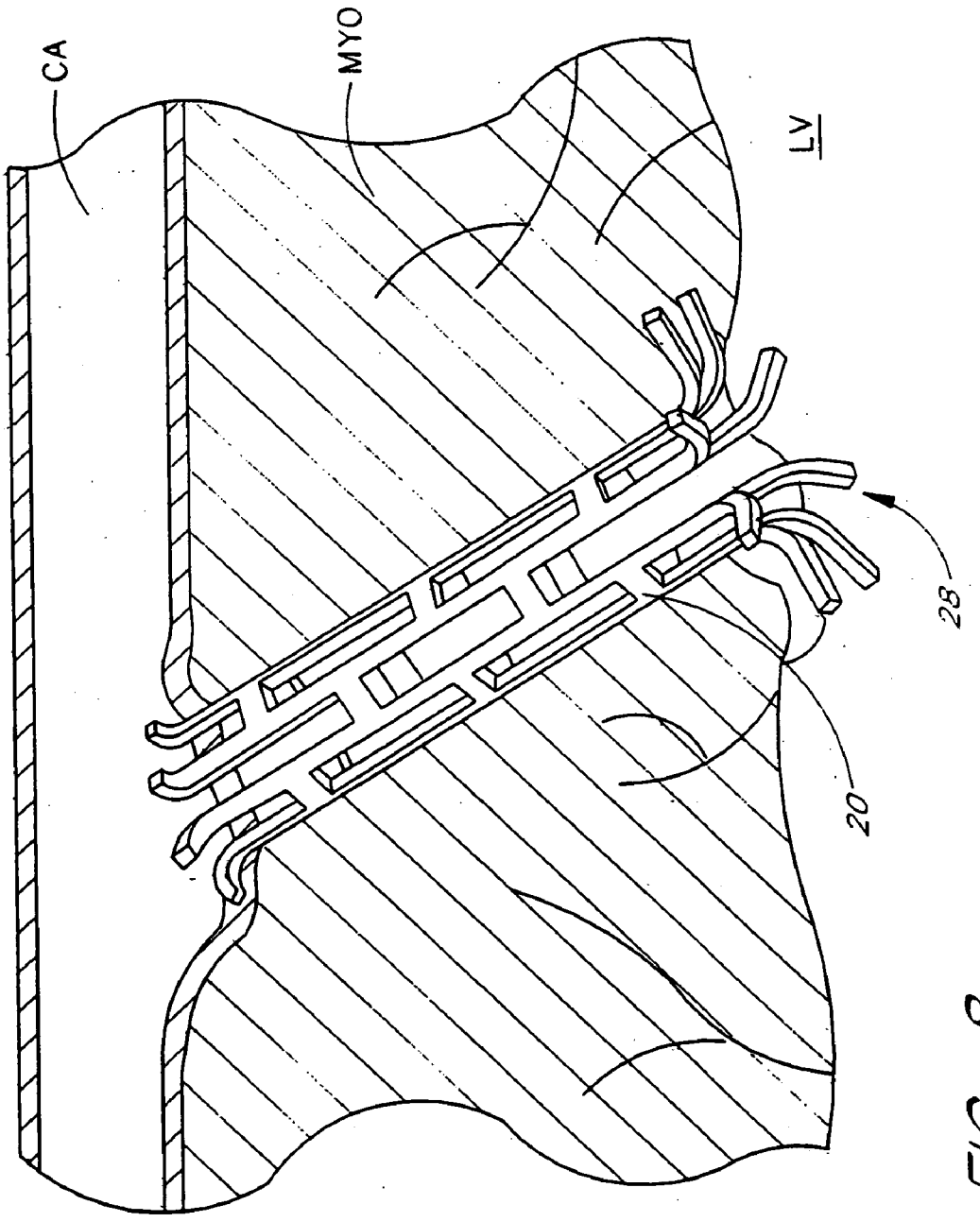



FIG. 8

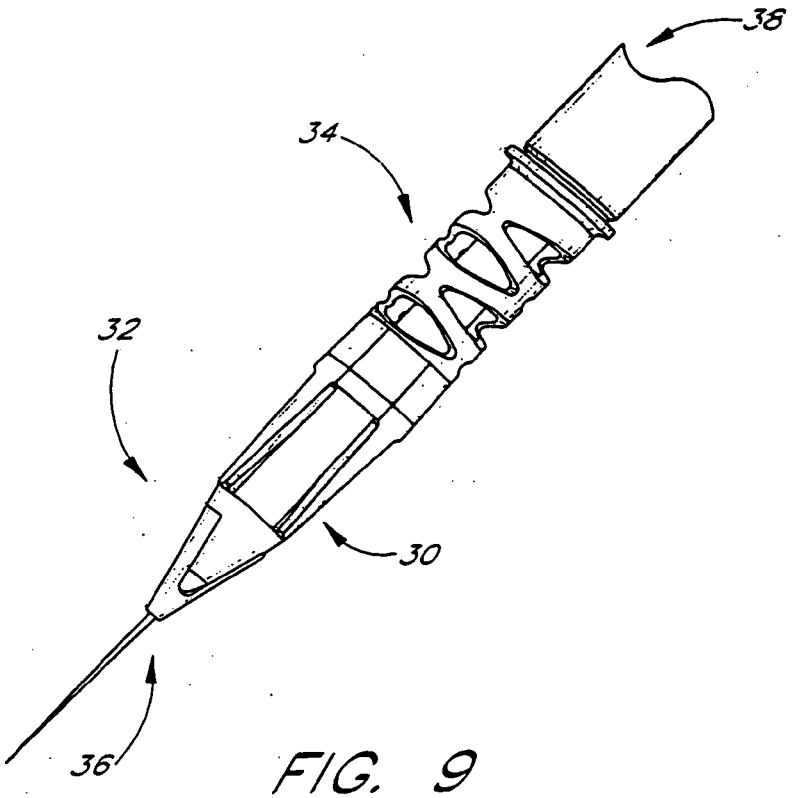



FIG. 9

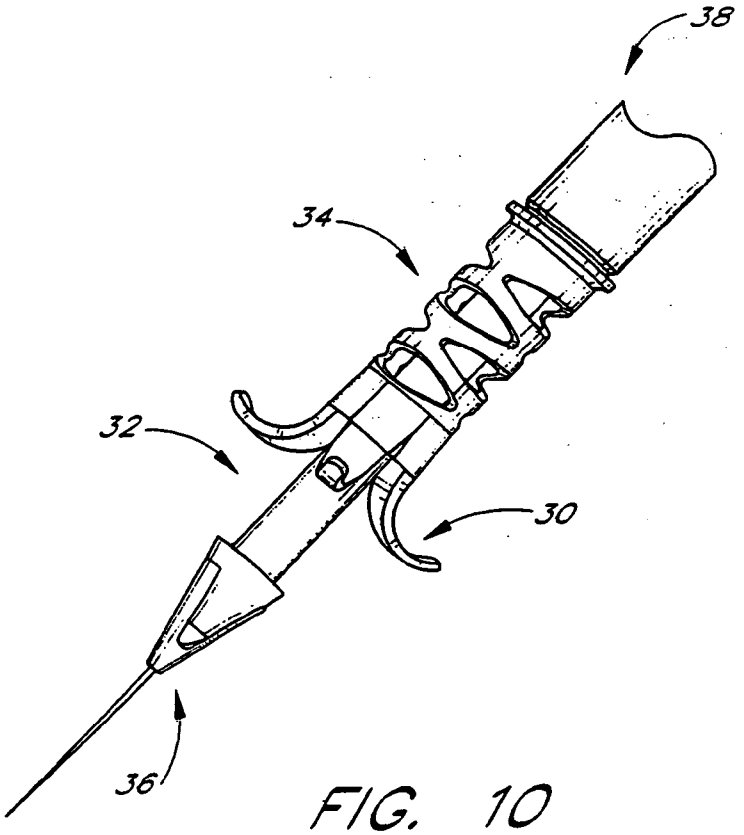



FIG. 10

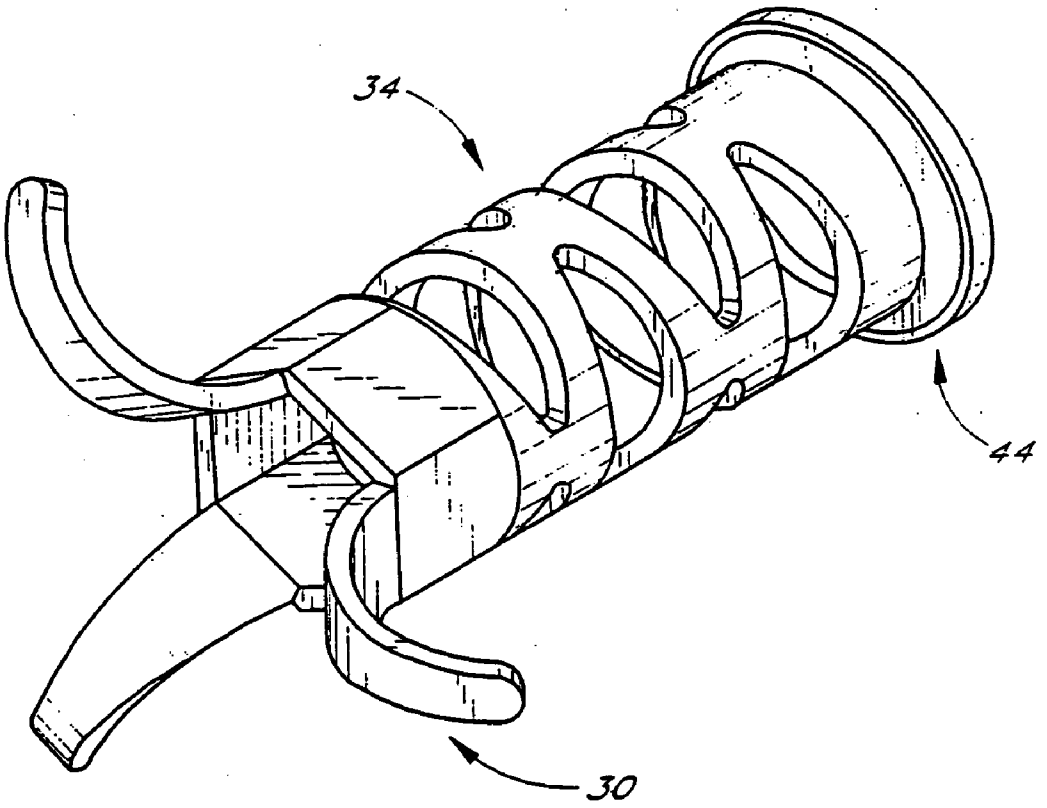



FIG. 11

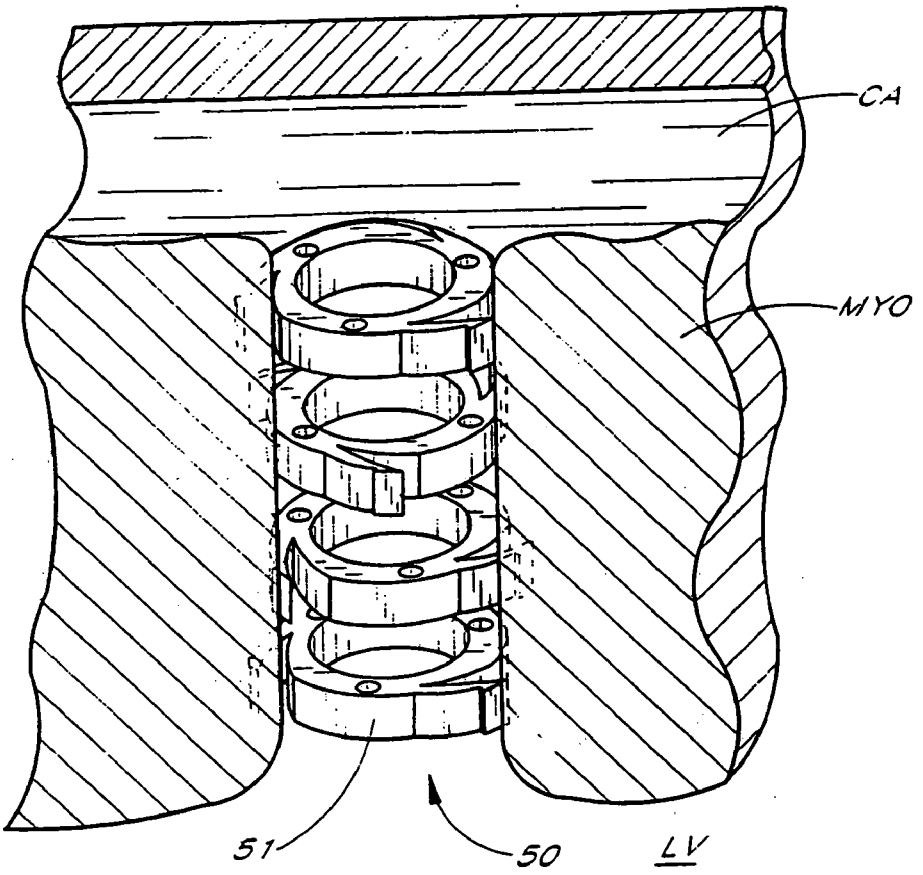



FIG. 12

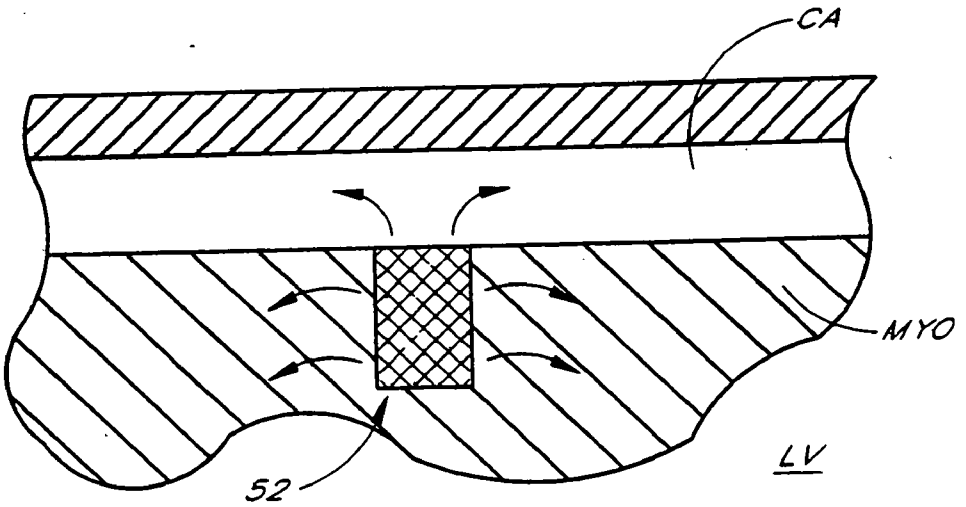



FIG. 13

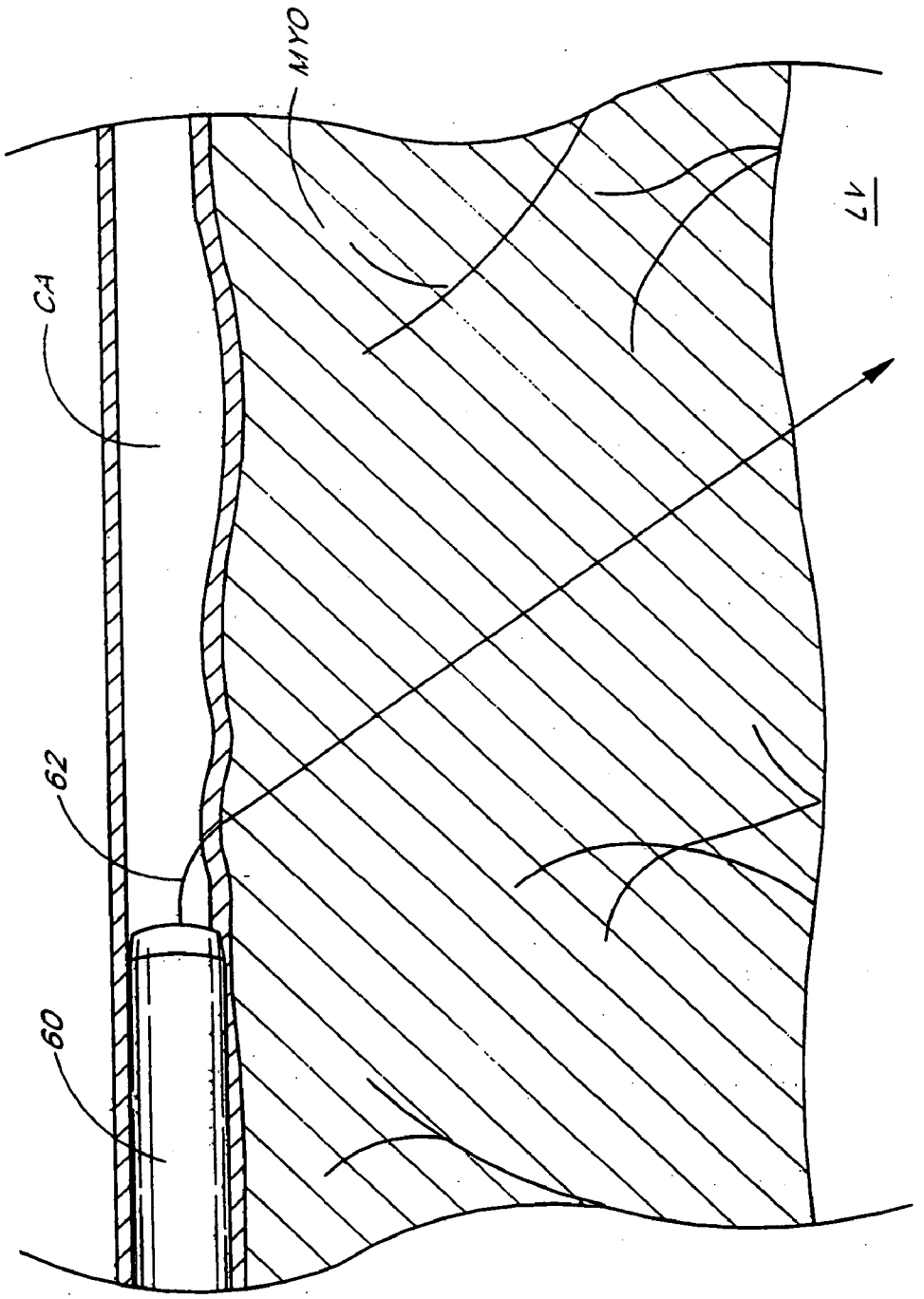



FIG. 14

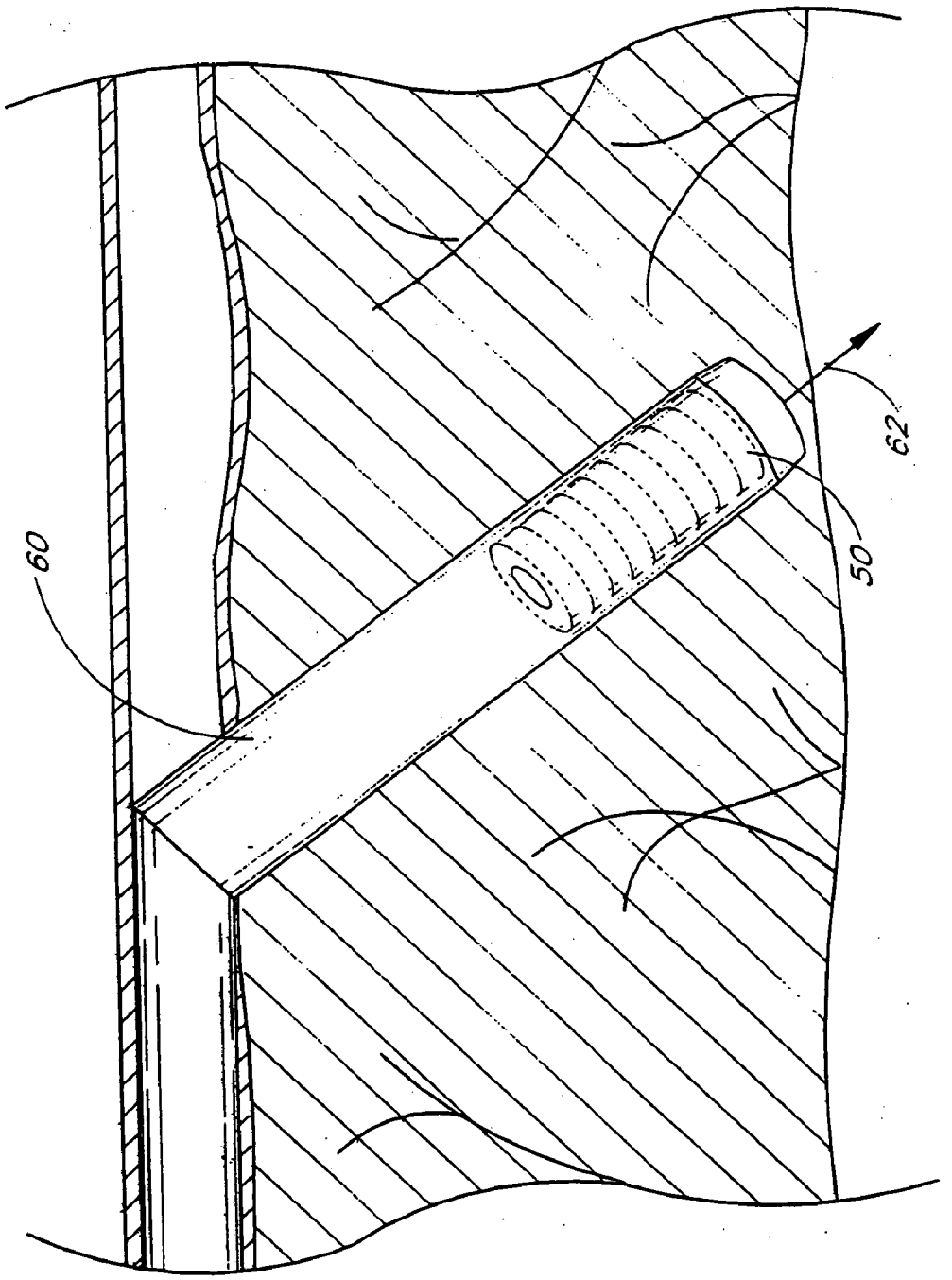



FIG. 15

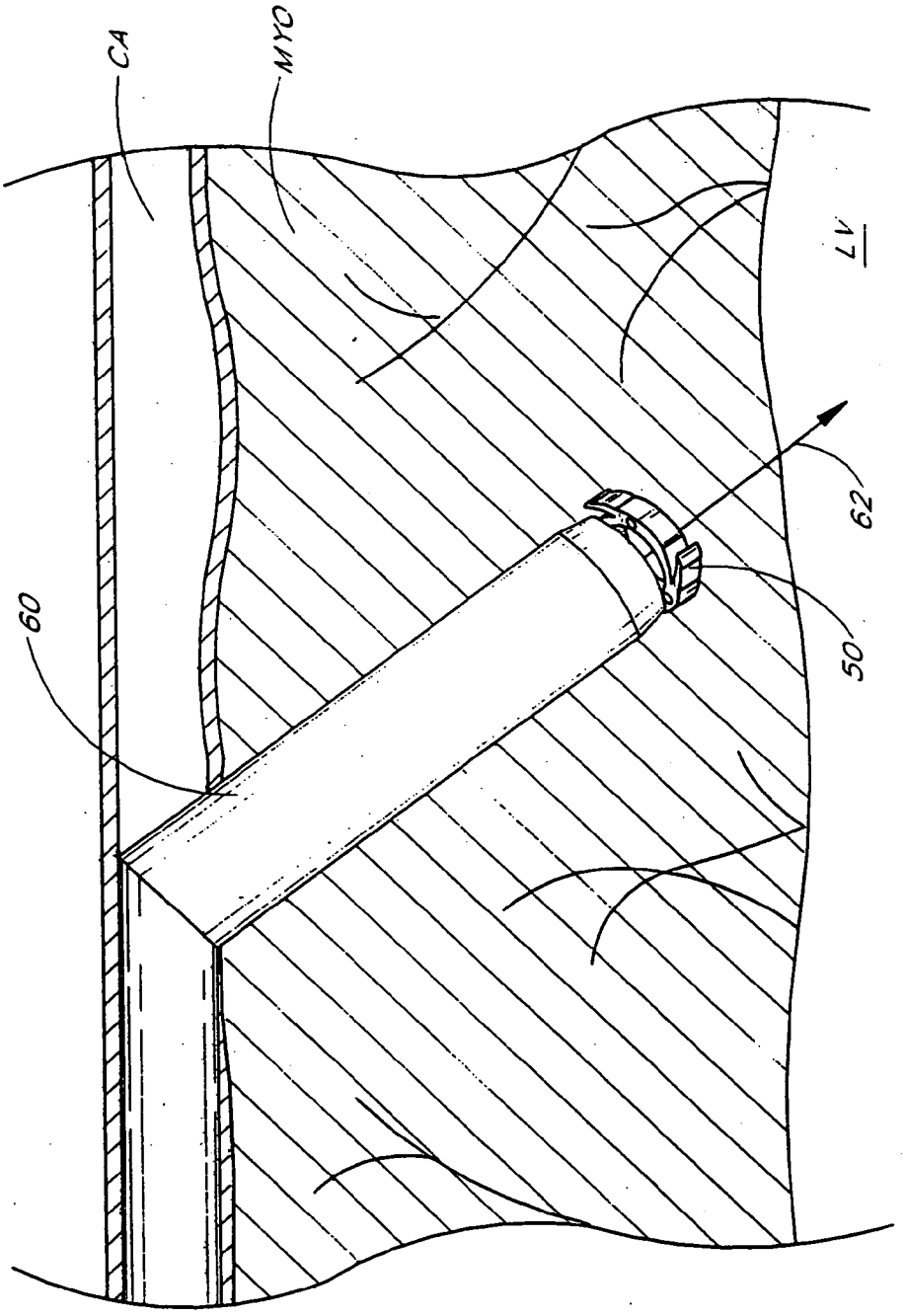



FIG. 16

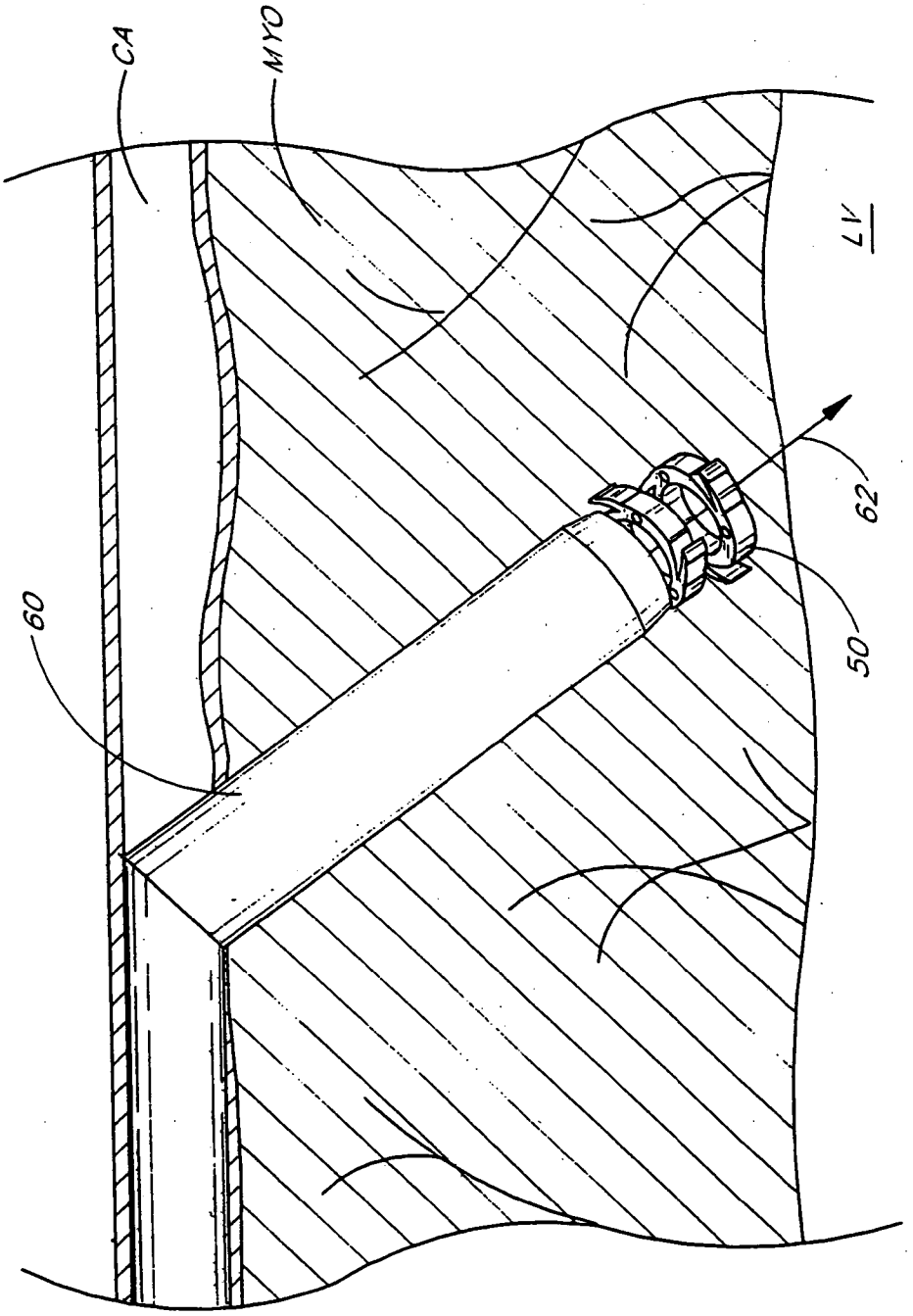



FIG. 17

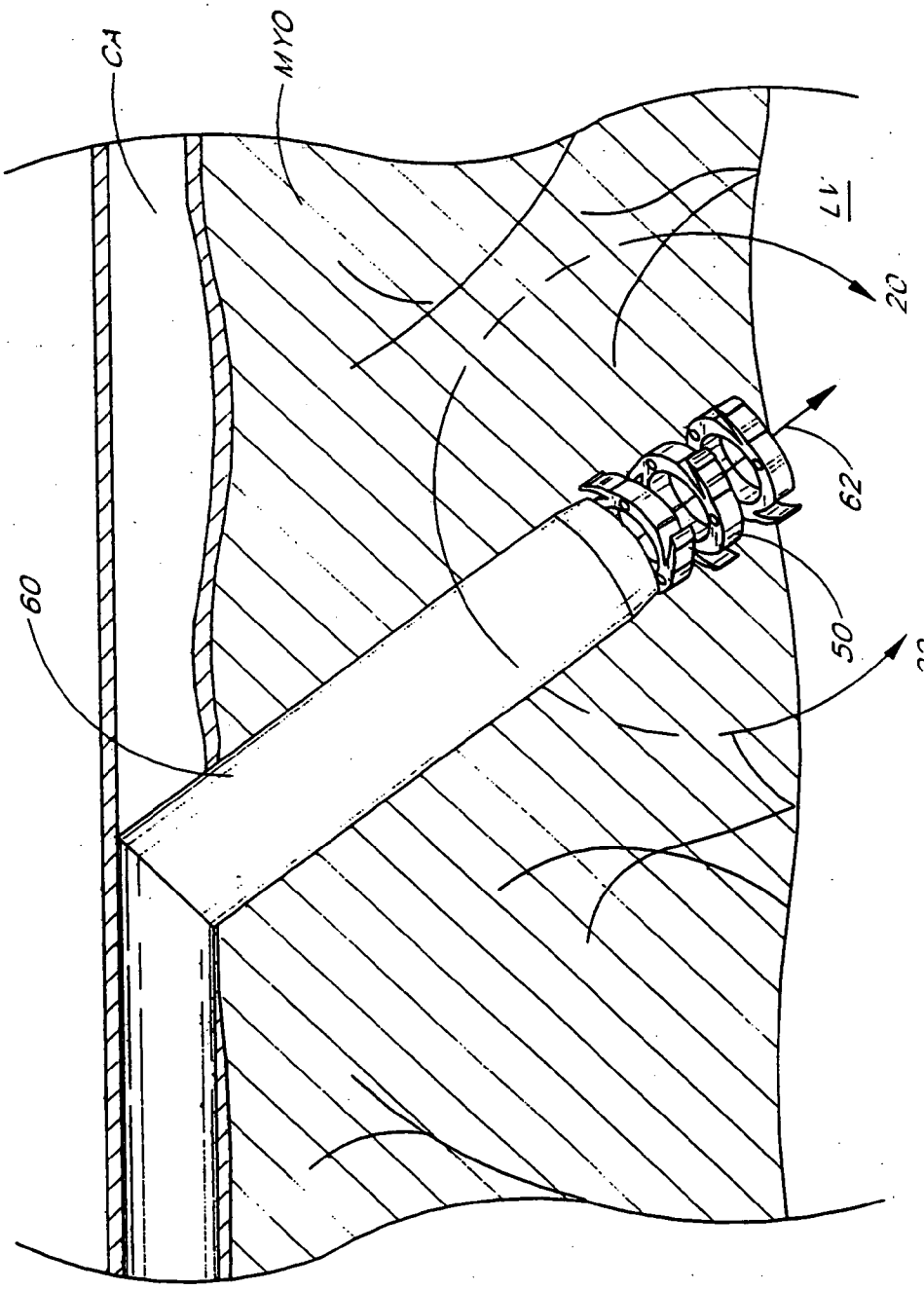



FIG. 18

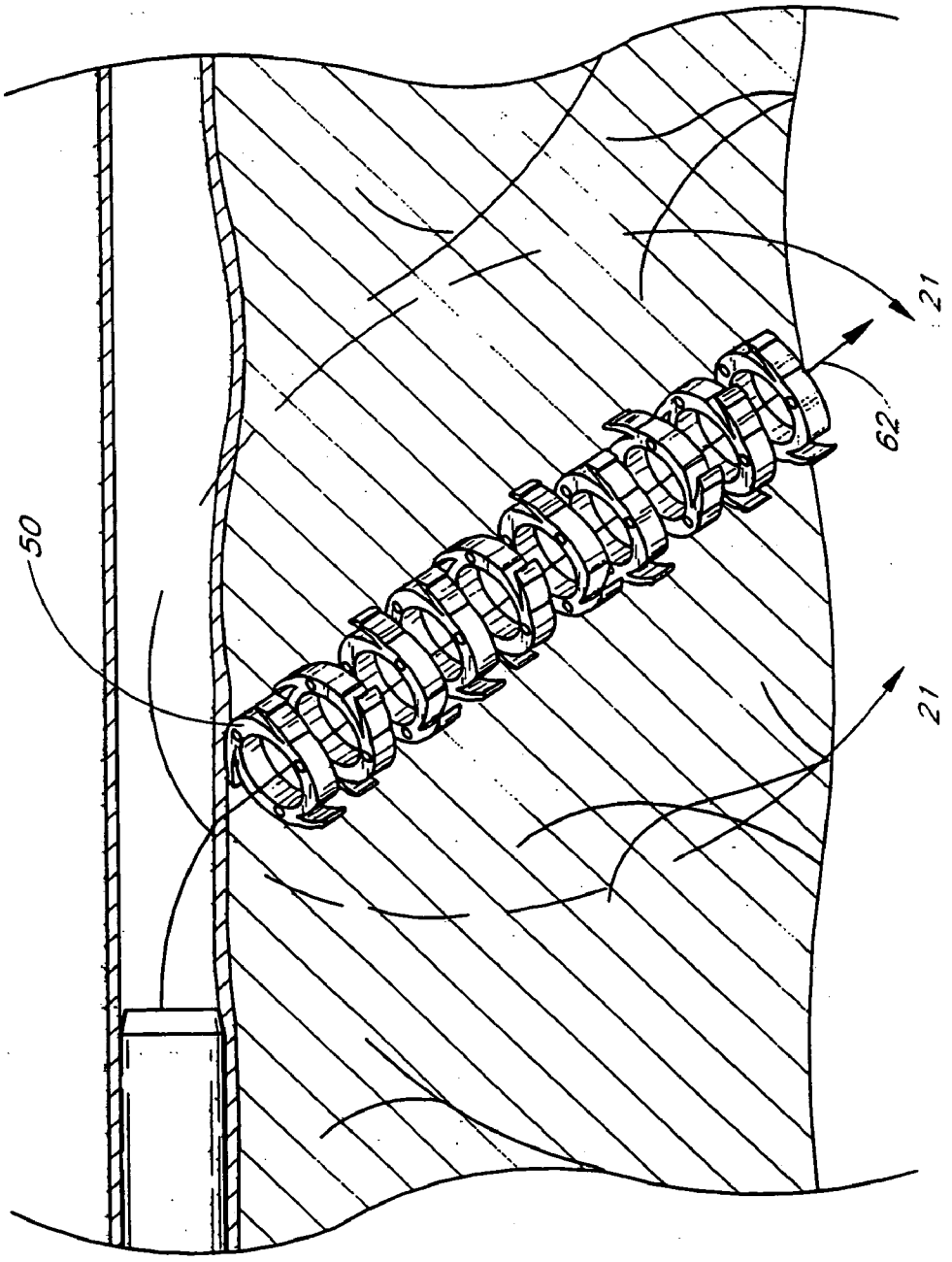



FIG. 19

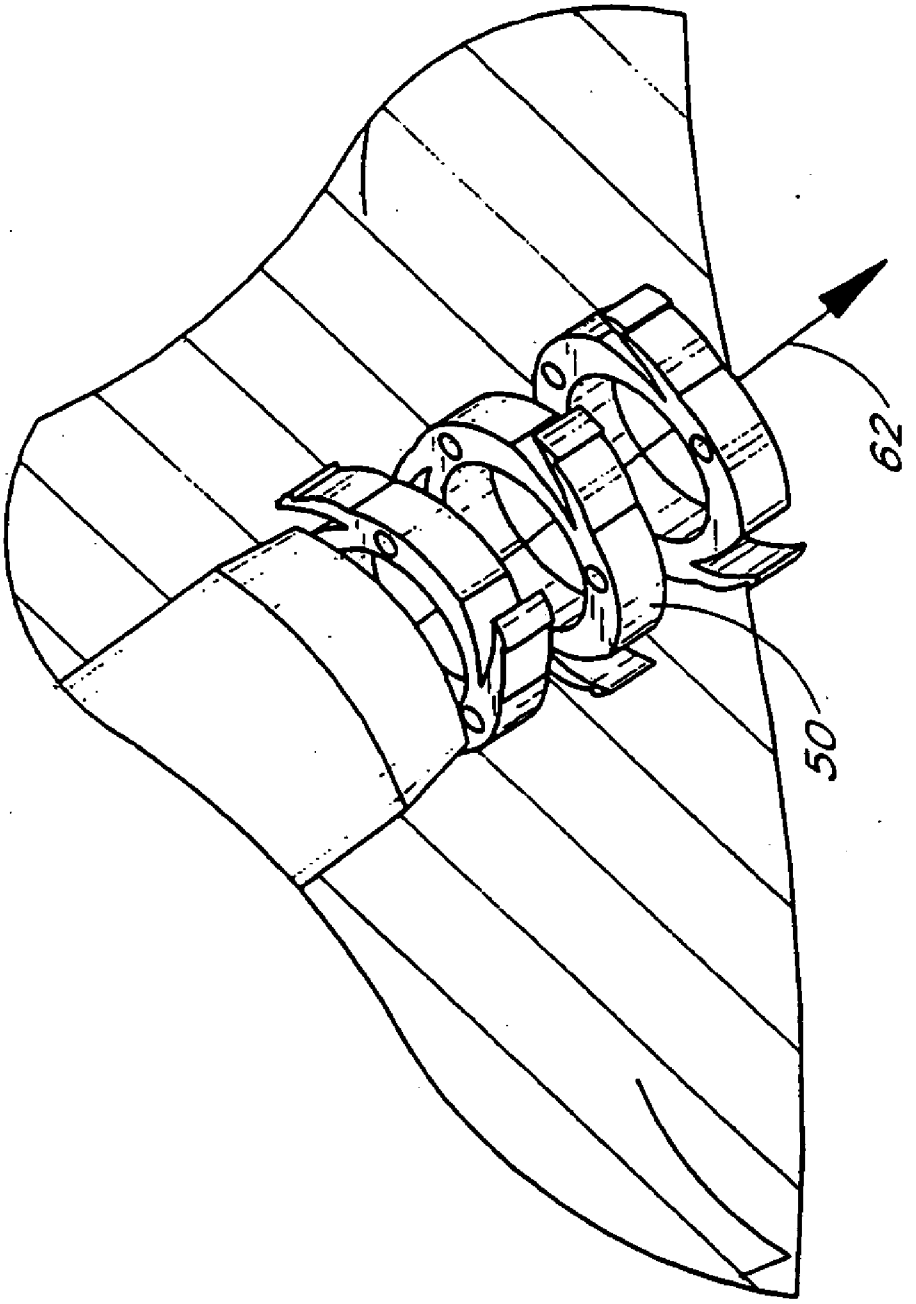



FIG. 20

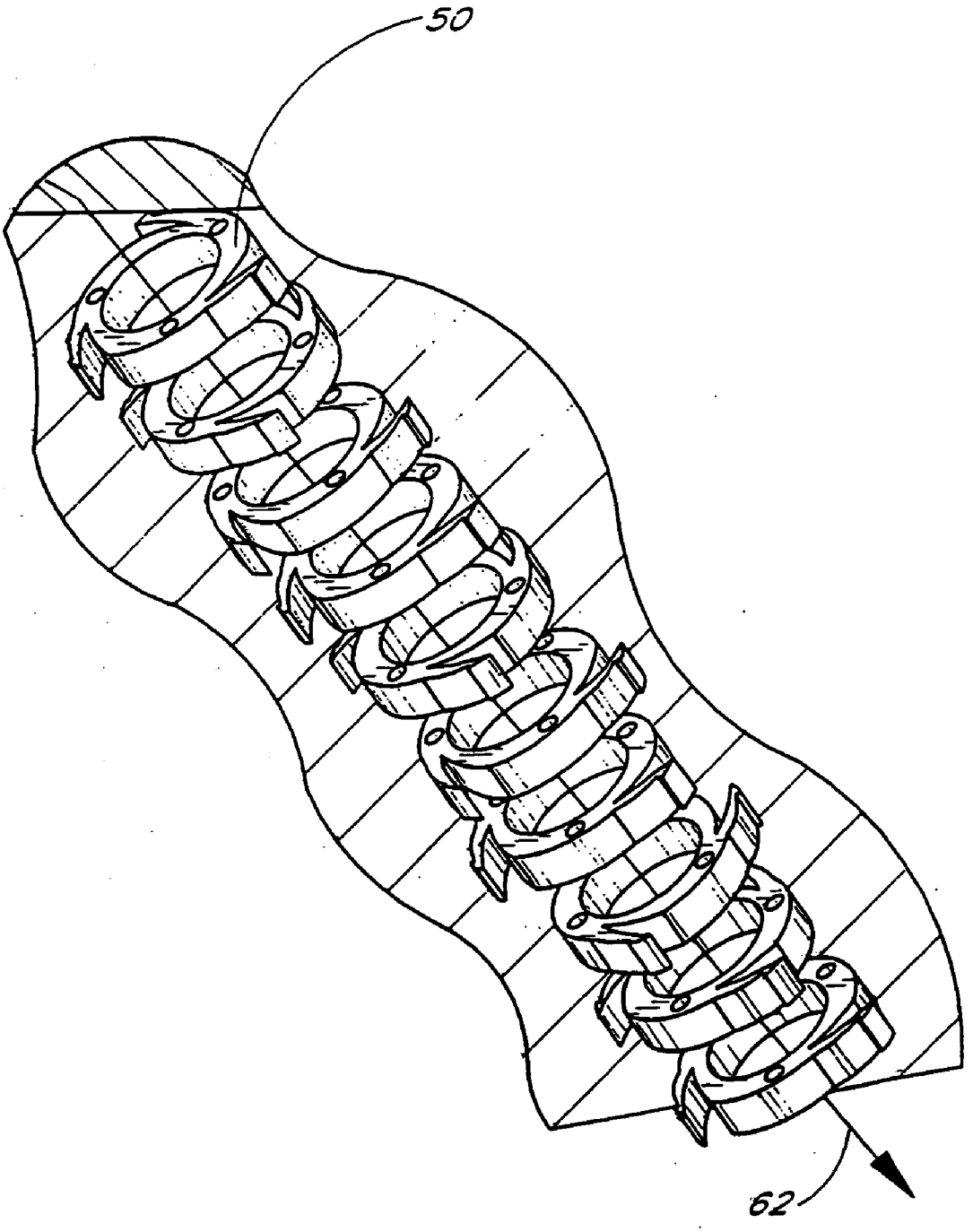



FIG. 21

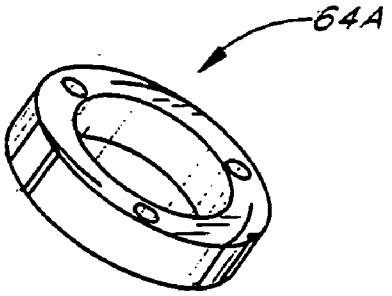



FIG. 22

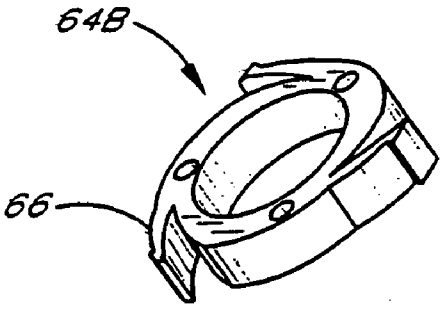



FIG. 23

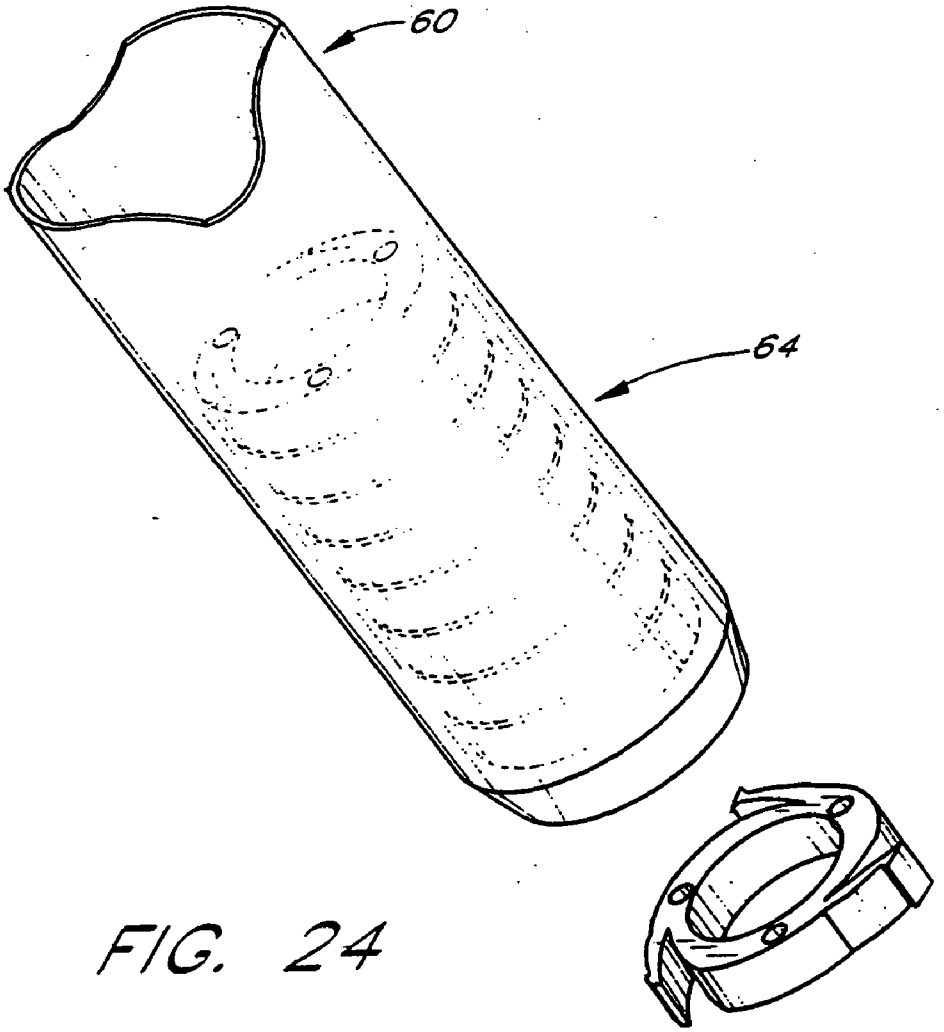



FIG. 24

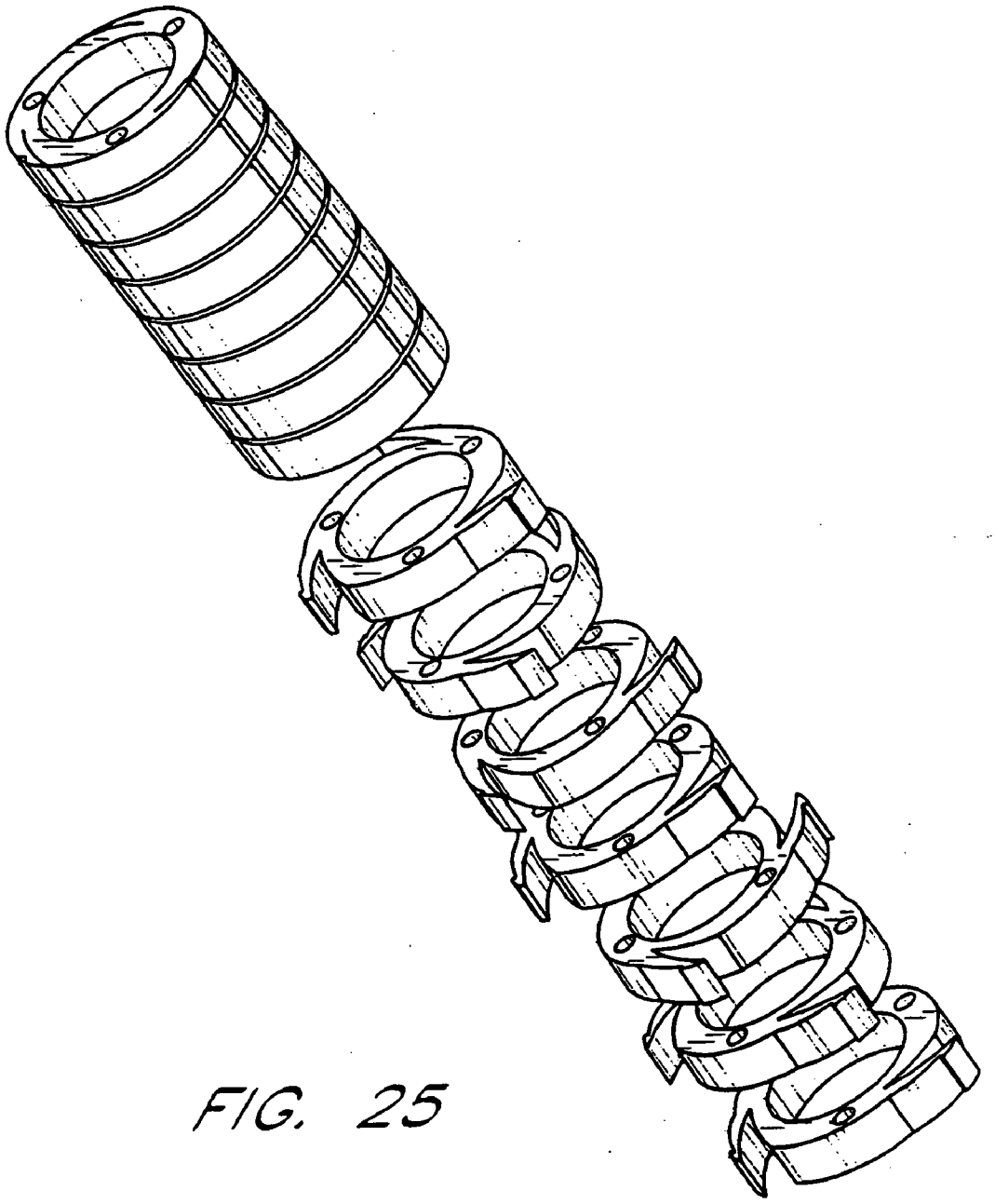


FIG. 25

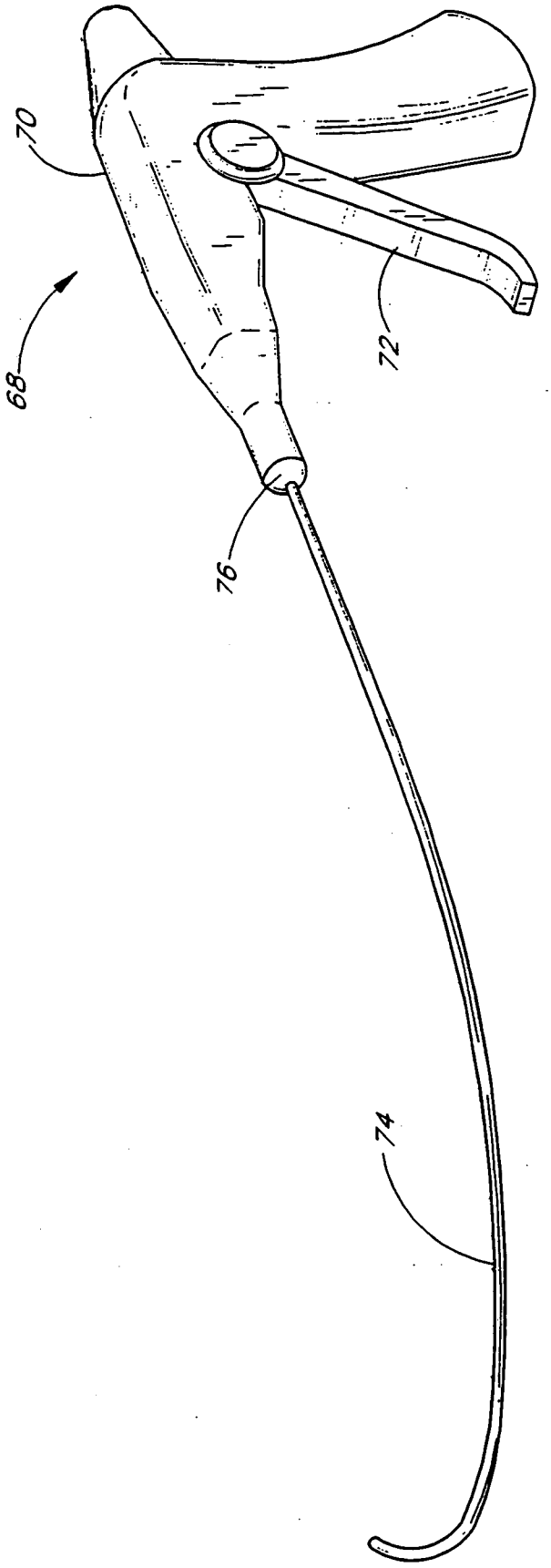



FIG. 26

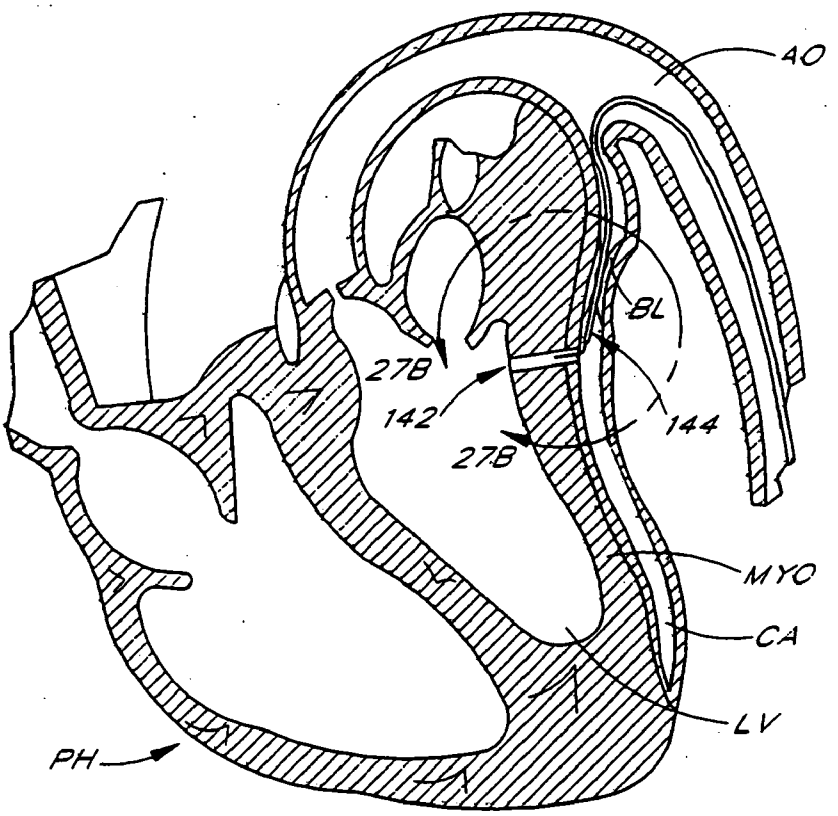



FIG. 27A

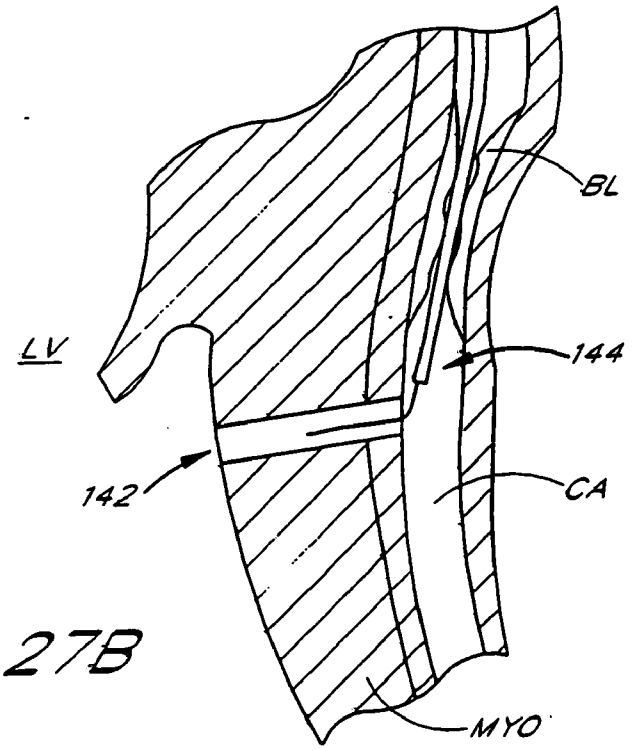
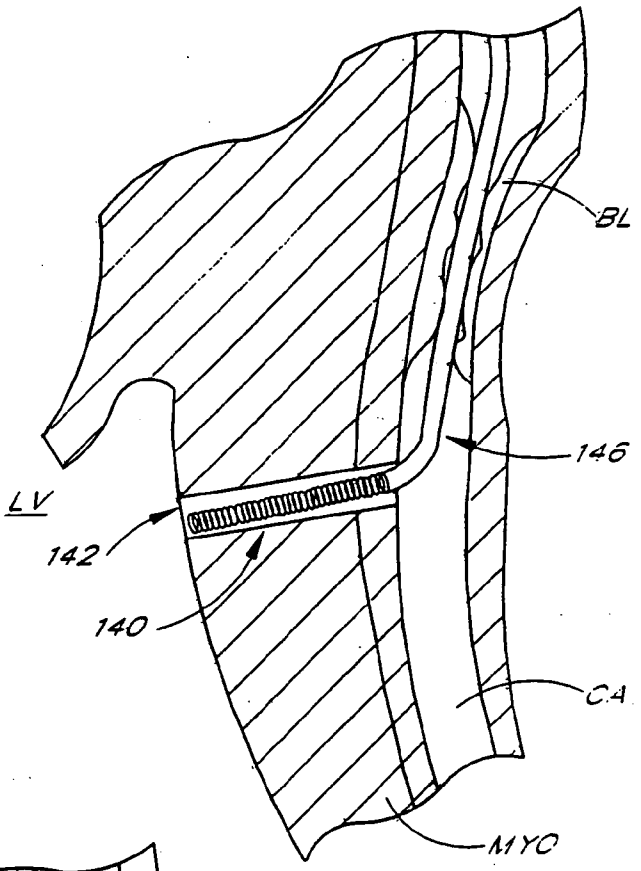



FIG. 27B

FIG. 28



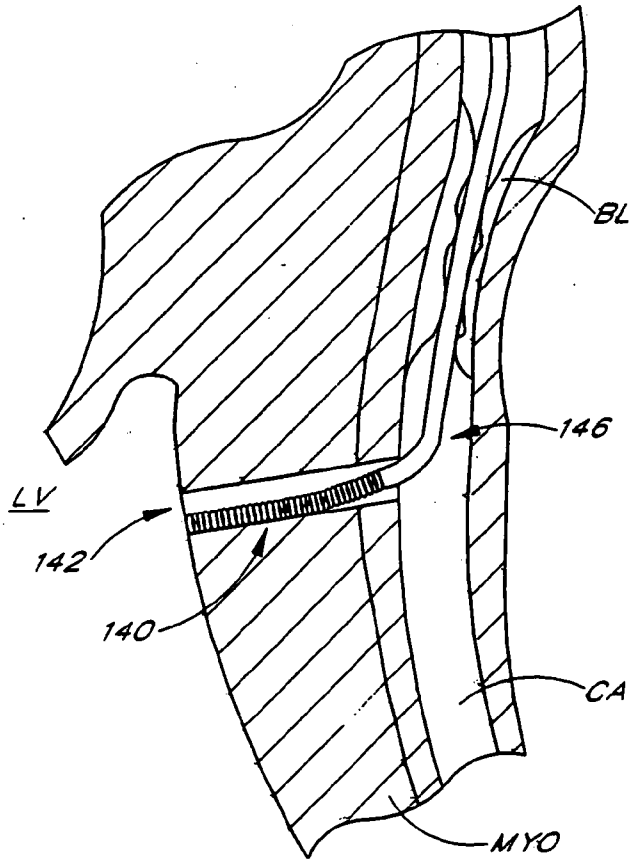




FIG. 29

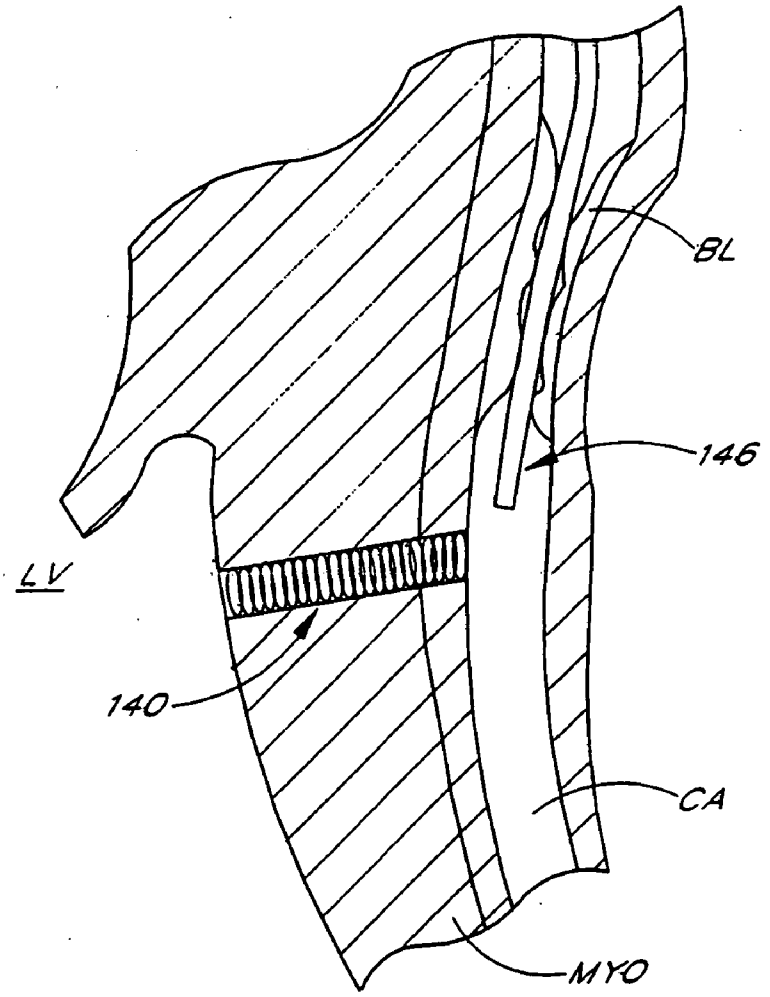



FIG. 30

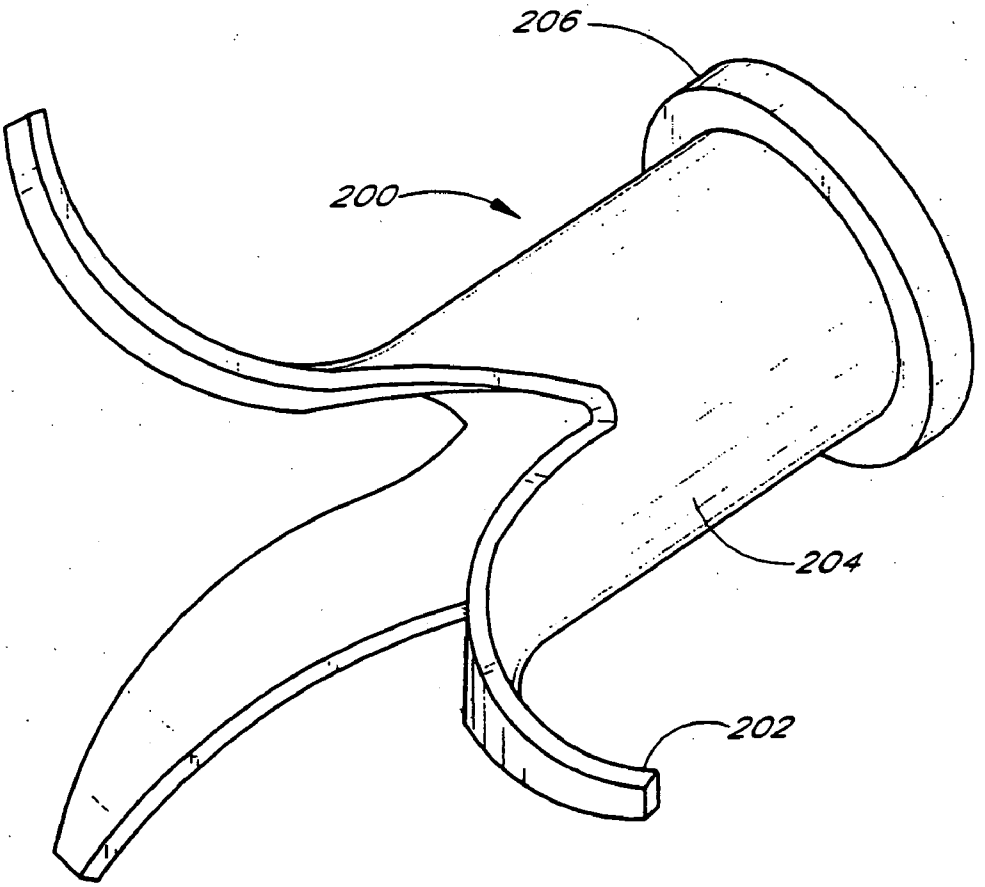



FIG. 31

# DESIGNS FOR LEFT VENTRICULAR CONDUIT

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation application of U.S. patent application Ser. No. 10/456,488, filed Jun. 9, 2003, now pending, which is a continuation application of U.S. patent application Ser. No. 09/829,449, filed Apr. 10, 2001, now U.S. Pat. No. 6,610,100, which is a continuation application of U.S. patent application Ser. No. 09/369,048, filed Aug. 4, 1999, now U.S. Pat. No. 6,290,728, and claims the benefits of priority of U.S. Provisional Patent Application No. 60/099,767, filed Sep. 10, 1998, and U.S. Provisional Patent Application No. 60/104,397, filed Oct. 15, 1998, the entirety of all of which are incorporated herein by reference.

## FIELD OF THE INVENTION

[0002] The present invention relates to an apparatus for bypassing a blocked blood vessel segment, and, more particularly, to a conduit or stent positioned between the coronary artery or other blocked vessel and a chamber of the heart, such as the left ventricle of the heart, to bypass a blocked segment of the coronary artery or other blood vessel.

## BACKGROUND OF THE INVENTION

[0003] Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque, which at the very least impairs the efficiency of the heart's pumping action, and can lead to heart attack and death. In some cases, these arteries can be unblocked through noninvasive techniques such as balloon angioplasty. In more difficult cases, a bypass of the blocked vessel is necessary.

[0004] In a bypass operation, one or more venous segments are inserted between the aorta and the coronary artery. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

[0005] Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged.

[0006] As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage, or due to the risk of emboli.

[0007] Thus, there is a need for an improved bypass system which is less traumatic to the patient.

## SUMMARY OF THE INVENTION

[0008] The preferred embodiments of the present invention address the need in the previous technology by providing a bypass system that avoids the sternotomy and other intrusive procedures normally associated with coronary bypass surgery. These embodiments also free the surgeon from the multiple anastomoses necessary in the current process.

[0009] The preferred device provides a shunt for diverting blood directly from a chamber in the heart, such as the left ventricle, to the coronary artery, distal to the blockage, therefore bypassing the blocked portion of the vessel. The shunt comprises a stent or conduit adapted to be positioned in the heart wall or myocardium between the left ventricle and the coronary artery that allows for the direct passage of blood therethrough. As used herein, the terms "stent" and "conduit" are interchangeable, and refer to a device that allows for the passage of blood therethrough. The terms "myocardium" and "heart wall" are also used interchangeably. In addition, although the left ventricle is referred to throughout the description, it should be understood that the conduit described herein can be used to provide a passageway for the flow of blood from any heart chamber, not only the left ventricle.

[0010] The stent device is delivered either externally or internally through the coronary artery to a position distal to the blockage. At that position, the coronary artery, the myocardium and the wall of the left ventricle are pierced to provide a channel completely through from the coronary artery to the left ventricle of the heart. The stent is then positioned in the channel to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage. The stent is sized so that one open end is positioned within the coronary artery, while the other open end is positioned in the left ventricle. The hollow lumen of the stent provides a passage for the flow of blood.

[0011] The stent can be self-expandable or expanded by means of a balloon or similar device, and can be provided with various means to anchor it in position within the myocardium, such as expandable legs, hooks, barbs, collars, suture holes and the like. The stent can be formed from a plurality of rings, which can be connected to provide stability. The stent can include a valve in its interior, and can also be used to deliver drugs or other pharmaceutical compounds directly into the myocardium and the coronary circulation.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1A** is a cross-sectional view of a human heart, aorta and coronary artery.

[0013] **FIG. 1B** is a side view of one embodiment of an expandable stent and the balloon catheter used for stent delivery.

[0014] **FIG. 2** is a side view of the stent of **FIG. 1B** mounted on the distal end of the catheter for delivery into the myocardium, with the coronary artery and myocardium shown cut-away.

[0015] **FIG. 3** is a side view of the distal end of the stent/catheter assembly of **FIG. 1B** positioned in the myocardium, with the coronary artery and myocardium shown cut-away.

[0016] **FIG. 4** is a cross-sectional side view of the stent of **FIG. 1B** positioned within the myocardium after removal of the catheter used for delivery.

[0017] **FIG. 5** is a side view of another embodiment of the stent and the catheter used for stent delivery.

[0018] **FIG. 6** is a cross-sectional side view of the catheter and puncture device used to introduce the self-expanding stent of **FIG. 5** into the myocardium.

[0019] **FIG. 7** is a cross-sectional side view of the stent/catheter assembly of **FIG. 5** positioned in the myocardium.

[0020] **FIG. 8** is a side view of the self-expanding stent of **FIG. 5** positioned within the myocardium after removal of the catheter and puncture device, with the coronary artery and myocardium shown cut-away.

[0021] **FIG. 9** is a perspective view of another embodiment of the stent having expandable legs, showing the stent mounted on the distal end of the introducer catheter.

[0022] **FIG. 10** is a perspective view of the stent of **FIG. 9**, showing the distal end of the introducer catheter pushed forward to allow the legs of the stent to expand.

[0023] **FIG. 11** is a perspective view of the stent of **FIG. 9**, showing the legs of the stent in an expanded position.

[0024] **FIG. 12** is a side view of another embodiment of the stent positioned within the myocardium, with the coronary artery and myocardium shown cut-away.

[0025] **FIG. 13** is a side view of a biodegradable stent positioned within the myocardium, with the coronary artery and myocardium shown cut-away.

[0026] **FIG. 14** is a side view of a catheter and puncture device used to introduce a bulkhead stent into the myocardium, with the coronary artery and myocardium shown cut-away.

[0027] **FIG. 15** is a side view of the stent/catheter assembly of **FIG. 14** positioned in the myocardium, with the coronary artery and myocardium shown cutaway.

[0028] **FIGS. 16-19** are progressive side views of the stent/catheter assembly of **FIG. 14**, showing the bulkhead stent being deployed into the myocardium.

[0029] **FIGS. 20 and 21** are enlarged views of **FIGS. 18 and 19**, respectively, showing the bulkhead stent being deployed into the myocardium.

[0030] **FIG. 22** is a perspective view of a ring of a bulkhead stent in a loaded configuration

[0031] **FIG. 23** is a perspective view of a ring of a bulkhead stent in an inserted configuration.

[0032] **FIG. 24** is a perspective view of a bulkhead stent within a delivery catheter, showing the rings of the bulkhead stent being inserted.

[0033] **FIG. 25** is a perspective view of a bulkhead stent, with the rings of the stent in loaded and inserted configurations.

[0034] **FIG. 26** is a perspective view of an inserter device used to insert a bulkhead stent.

[0035] **FIG. 27A** is a schematic, cross-sectional view of the human heart, showing a catheter used to form a channel through the myocardium and into the left ventricle inserted into the coronary artery.

[0036] **FIG. 27B** is an enlarged view of the distal end of the catheter and the channel through the myocardium in **FIG. 27A**.

[0037] **FIG. 28** is a schematic, cross-sectional view of a stent delivery catheter positioned inside the channel formed in the myocardium.

[0038] **FIG. 29** is a schematic, partial cross-sectional view of a self-expanding spring stent being positioned in the channel formed in the myocardium.

[0039] **FIG. 30** is a schematic, partial cross-sectional view of the self-expanding stent deployed within the myocardium.

[0040] **FIG. 31** is a perspective view of another embodiment of a stent having retention members which maintain the position of the stent.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0041] As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. The anatomy of the human heart is illustrated in **FIG. 1A**. Oxygenated blood flows from the heart PH to the aorta AO, on to the rest of the body, some of the blood flowing into the coronary artery CA. In some individuals, plaque builds up within the coronary artery CA, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death.

[0042] In order to restore the flow of oxygenated blood through the coronary artery, one embodiment of the present invention provides for the shunting of blood directly from the heart to a site in the coronary artery that is distal to the blockage. A channel is formed through the wall of the coronary artery and the myocardium and into the left ventricle of the heart that lies beneath the coronary artery. A stent or conduit is positioned in the passage to keep it open, and allow for the flow of oxygenated blood directly from the heart into the coronary artery. Again, it should be understood that while the insertion of the conduit in the myocardium between the left ventricle and the coronary artery is described in detail below, this is merely exemplary and use of the conduit between other chambers of the heart and the coronary artery, and between blood vessels is also contemplated.

[0043] The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

[0044] In addition, the conduits and related methods can preferably traverse various intermediate destinations and are

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

[**0045**] The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

[**0046**] The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

[**0047**] The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods may be used. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

[**0048**] In some individuals, aortic insufficiency or peripheral venous insufficiency occurs. Aortic insufficiency is the leakage of blood through the aortic valve, resulting in a backflow of blood into the left ventricle. The heart compensates for the backflow of blood by pumping harder, resulting in hypertrophy (thickening of the heart muscle) and dilation of the left ventricle wall. Left untreated, heart failure can result. In venous insufficiency, the heart valves are unable to prevent the backflow of blood. This too can result in heart failure. Accordingly, one embodiment of the invention provides for the use of a conduit placed within the heart wall to improve the flow of oxygenated blood through the body.

[**0049**] A first embodiment of the present invention is illustrated in **FIG. 1B**. This embodiment is a balloon-expanded stent **10**. The stent **10** is introduced as described below, using a high-pressure balloon catheter **12** to deploy the stent **10** once it is properly positioned in the myocardium MYO (**FIG. 2**). When the stent **10** is positioned inside the myocardial wall MYO, the balloon **14** is inflated to expand the stent **10** and open the conduit from the left ventricle LV into the coronary artery CA. The stent **10** can include attachment mechanisms not limited to hooks, barbs, flanges, large collars, suture holes and/or other means to ensure a seal is created between the coronary artery CA and the wall of the myocardium MYO and to prevent the threat of stent **10** migration. When the attachment of the stent **10** is completed, the remaining catheter assembly **12** is removed, leaving the stent **10** in place. Upon deflating the balloon **14**, the stent **10** will remain open. Because of the shape of this stent **10**, a dumbbell shaped balloon **14** is preferably used to ensure proper expansion, as described below.

[**0050**] **FIGS. 1B through 4** illustrate the introduction of the balloon-expanded stent **10** into the myocardial wall MYO. **FIG. 1B** illustrates the stent **10** mounted over the balloon **14** on the distal end of the stent introducer catheter **12**. **FIG. 2** illustrates the stent introducer catheter **12** following the path created by a puncture wire **16** extending past the distal end of the introducer catheter **12**, and used to access the left ventricle LV through the coronary artery CA and myocardium MYO. Further details regarding conduits and conduit delivery systems are described in copending patent applications entitled DELIVERY METHODS FOR LEFT VENTRICULAR CONDUIT, U.S. patent application Ser. No. 09/368,868, now U.S. Pat. No. 6,261,304, LEFT VENTRICULAR CONDUIT WITH BLOOD VESSEL GRAFT, U.S. patent application Ser. No. 09/369,061, now U.S. Pat. No. 6,254,564, VALVE DESIGNS FOR LEFT VENTRICULAR CONDUIT, U.S. patent application Ser. No. 09/368,393, now U.S. Pat. No. 6,641,610, LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS, U.S. patent application Ser. No. 09/369,039, now abandoned, and BLOOD FLOW CONDUIT DELIVERY SYSTEM AND METHOD OF USE, U.S. patent application Ser. No. 09/368,644, now U.S. Pat. No. 6,302,892, all filed on Aug. 4, 1999, and U.S. Pat. Nos. 5,429,144 and 5,662,124, the disclosures of which are all hereby incorporated by reference in their entirety.

[**0051**] **FIG. 3** illustrates the non-expanded stent **10** positioned inside the myocardial wall MYO prior to inflation of the balloon **14**. **FIG. 4** illustrates an expanded stent **10** in position, with the introducer catheter **12** removed. Because of the way the attachment mechanisms **18** expand on this stent **10**, a dumbbell shaped balloon **14** is preferably used to flare out the ends of the stent **10**. These flared edges **18** maintain the stent **10** in its proper position in the heart wall MYO and provide a seal between the coronary artery CA and the outer heart wall MYO.

[**0052**] The second embodiment of the stent or conduit incorporates a self-expanding stent **20**, illustrated in **FIGS.**

**5-8**. The stent **20**, having a retaining sheath **26** to hold it in a non-expanded configuration, is introduced into the wall of the myocardium MYO as follows. The stent delivery catheter **22** is advanced over a puncture mechanism **24** and into the wall of the myocardium MYO as described above. When the stent **20** is properly seated in the myocardial wall MYO, its retaining sheath **26** is withdrawn, allowing the stent **20** to expand and open a conduit from the ventricle LV to the coronary artery CA. This stent **20** also includes attachment mechanisms not limited to hooks, barbs, flanges, large collars, suture holes and/or other means to ensure a seal is created between the artery CA and the wall of the myocardium MYO, and to prevent the threat of stent **20** migration. When the positioning is completed, the remaining catheter assembly **22** is removed, leaving the stent **20** in place.

[**0053**] The self-expanding stent **20** mounted on the distal end of the stent introducer catheter **22** is illustrated in **FIG. 5**. **FIG. 6** illustrates the stent introducer **22** following the path created by a puncture wire **24** used to form the passage between the coronary artery CA and the left ventricle LV. **FIG. 7** illustrates a non-expanded stent **20** located in position on the stent introducer catheter **22** with the introducer catheter **22** in position in the heart wall MYO. **FIG. 8** illustrates the self-expanding stent **20** in position, with the introducing catheter **22** removed. Flared edges **28** on the stent **20** maintain its proper position in the heart wall MYO and provide a seal between the coronary vessel CA and outer surface of the heart MYO.

[**0054**] For the stent designs described above, additional anchoring methods may be desired to maintain the stent's proper position and/or create a leak-free seal in the coronary artery. Suitable attachment mechanisms include a set of barbs located on the stent body or flares and a collar on the coronary side to help seal and prevent blood from exiting the gap between the vessel and outer heart wall. The stent can also be anchored in place by applying sutures. The stent can include holes at either end to facilitate the placement of these anchoring sutures. A suture gun can be used to apply multiple sutures at the same time. In addition, the stents can be lined, if desired, with materials such as polymers, for example polytetrafluoroethylene (PTFE), silicone or GORTEX, to provide for the ease of blood flow therethrough.

[**0055**] A third embodiment of the stent design, illustrated in **FIGS. 9-11**, incorporates attachment flanges or "legs"**30** that expand after introduction into the myocardium to hold the stent **34** in place. The puncture instrument **32** and stent **34** are mated together and are advanced into the myocardial wall as a single unit. The puncture instrument's distal end **36** is shaped in a "nose-cone" configuration, which is responsible for containing the legs **30** of the stent **34** while it is being introduced into the wall of the myocardium. When the stent **34** is in the proper position in the myocardial wall, the nose cone **36** is pushed forward, releasing the attachment legs **30** of the stent **34**. The internal diameter (ID) of the stent **34** is large enough to allow the nose cone **36** to pass back through. The stent **34** is then released from the catheter **38** and the catheter **38** is removed.

[**0056**] **FIG. 9** illustrates the stent **34** mounted on the introducer catheter **38**. The expanding legs **30** of the stent **34** are held in place by the nose cone **36** on the distal end of the catheter **38** that acts as a dilator. The catheter assembly **38** is advanced over a puncture wire if desired, into proper position in the myocardium, and the nose cone **36** is pushed forward allowing the legs **30** to expand as shown in **FIG. 10**. The nosecone/puncture assembly **32**, **36** is then withdrawn through the lumen of the stent **34**. When the nose-cone/puncture assembly **32**, **36** is removed, the stent **34** can be pushed off the introducer catheter **38** and remains in the myocardium in the position shown in **FIG. 11**. **FIG. 11** also illustrates a sealing collar **44** that may be used in the interface between the coronary artery and the outer wall of the heart to prevent hemorrhaging around the stent **34** and to hold the stent **34** in place. Sutures can be used to ensure that the stent is maintained in its proper position and prevent migration.

[**0057**] **FIG. 12** illustrates a further embodiment of the present invention, a "bulkhead" stent **50**. This stent **50** consists of a plurality of rings, which are placed in the myocardium MYO. The rings **50** form a passage through which blood flows from a chamber in the heart, such as the left ventricle LV, directly into the coronary artery CA. The stent **50** is preferably formed of biocompatible material such as a metal or polymer. A gun or other suitable device can be used to implant the stent **50** in the myocardium MYO.

[**0058**] If desired, the separate units or rings of the stent **50** can be connected via a wire, suture thread, or similar means. The wire is threaded through the holes **51** located in each ring. Connecting the rings of the stent **50** in this manner serves to make the stent **50** more stable and to prevent the migration of the individual units. If desired, a valve (not shown) can be incorporated into the stent **50** to help prevent the backflow of blood into the left ventricle LV. Additional details regarding valve designs are disclosed in the above referenced copending applications entitled LEFT VENTRICULAR CONDUIT WITH BLOOD VESSEL GRAFT, U.S. patent application Ser. No. 09/369,061, now U.S. Pat. No. 6,254,564, VALVE DESIGNS FOR LEFT VENTRICULAR CONDUIT, U.S. patent application Ser. No. 09/368,393, now U.S. Pat. No. 6,641,610 and LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS, U.S. patent application Ser. No. 09/369,039, now abandoned, filed on Aug. 4, 1999, all of which are incorporated by reference in their entirety.

[**0059**] If desired, the stent or conduit of the present invention can be formed of biodegradable or bioabsorbable materials and/or used to deliver drugs directly into the myocardium and the coronary circulation. Such a stent **52** is illustrated in **FIG. 13**. The biodegradable stent **52** can extend only partially through the myocardium MYO as illustrated in **FIG. 13**, but can also extend entirely through from the left ventricle LV to the coronary artery CA. Once positioned in the myocardium MYO, the stent **52** degrades, dissolves or is absorbed over time to release drugs, genes, angiogenesis or growth factors, or other pharmaceutical compounds directly into the heart muscle MYO and the coronary artery CA, as shown by the arrows in **FIG. 13**. Bioabsorbable materials include, but are not limited to, polymers of the linear aliphatic polyester and glycolide families, such as polylactide and polyglycolide. Further details are described in the above-referenced application entitled LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS, U.S. patent application Ser. No. 09/369,039, now abandoned, filed on Aug. 4, 1999.

[0060] Turning now to **FIGS. 14-26**, there is illustrated in greater detail one preferred method and apparatus for providing a bulkhead stent **50**, as shown in **FIG. 12**, into the myocardium MYO. As shown in **FIG. 14**, a stent delivery catheter **60** is advanced over a puncture wire **62** and into the wall of the myocardium MYO as described above. The stent delivery catheter **60** follows the path created by the puncture wire **62** used to form the passage between the coronary artery CA and the left ventricle LV. **FIG. 15** illustrates a bulkhead stent **50** still located in position inside the stent delivery catheter **60** with the catheter **60** in position in the heart wall MYO. **FIGS. 16-19** show one embodiment for deploying the bulkhead stent **50** into the myocardium MYO. As the delivery catheter **60** is retracted proximally from the myocardium MYO, the rings comprising the bulkhead stent **50** are deployed into the myocardium MYO. **FIGS. 20 and 21** are enlarged views of **FIGS. 18 and 19**, showing the rings of the bulkhead stent **50** positioned within the myocardium MYO to form the passageway therethrough.

[0061] **FIGS. 22-25** illustrate more particularly the structure and deployment of the rings comprising the bulkhead stent **50**. As shown in **FIG. 24**, the bulkhead stent comprises a plurality of rings **64** that are initially loaded into the delivery catheter **60**. While inside the lumen of the catheter **60**, each ring **64** has a loaded configuration **64**A, shown in **FIGS. 22 and 25**. After ejectment from the catheter **60**, the ring **64** assumes an inserted configuration **64**B, shown in **FIGS. 23 and 25**. Preferably, the inserted configuration of ring **64**B includes a plurality of flanges **66** around the circumference of each ring **64**, thereby providing a securement mechanism to anchor each ring **64** to the myocardium MYO. Each ring **64** transforms from its loaded configuration **64**A to its inserted configuration **64**B by virtue of being released from the catheter **60**. Specifically, the catheter **60** acts as a restraint on each ring **64** to keep it in its loaded configuration **64**A. Then, once the ring **64** is released from the catheter **60**, the flanges **66** provided along the circumference of each ring **64** are allowed to extend outward to provide the securement mechanism.

[0062] **FIG. 26** illustrates an inserter device or handle **68** that may be used in deploying the bulkhead stent **50** into the myocardium. The inserter handle **68** preferably comprises a gun **70** with a trigger **72**, and a wire **74** extending from a nozzle **76**. The rings **64** (not shown) of the bulkhead stent **50** are preferably loaded onto the wire **74**, and may be deployed into the myocardium preferably one at a time by pressing the trigger **72**.

[0063] **FIGS. 27-30** illustrate another embodiment of the present invention. Here, a self-expanding spring or screw stent **140** is delivered into the myocardium MYO. As illustrated in **FIG. 27A**, a channel **142** through the wall of the myocardium MYO is first created, as described above, using a device **144** delivered through the aorta AO and coronary artery CA. The channel **142** travels from the coronary artery CA through the myocardium MYO and into the left ventricle LV as shown in **FIG. 27B**. The distal end of the stent delivery catheter **146** bearing the stent **140** is then positioned within the channel **142**, as shown in **FIG. 28**. Preferably, the position of the distal end of the delivery catheter **146** is checked radiographically, to ensure proper positioning. Next, as illustrated in **FIG. 29**, the self-expanding spring stent **140** is delivered into the channel **142** wall of the myocardium MYO. The stent **140** is cut such that it does not extend past the myocardium MYO and into either the left ventricle LV or the coronary artery CA. Again, the proper positioning and length of the stent **140** is preferably checked radiographically and any necessary adjustments made before the delivery catheter **146** is removed, as shown in **FIG. 30**.

[0064] **FIG. 31** illustrates another embodiment of the stent **200** having retention members **202**. The hollow stent body **204** is held in place in the heart wall by one or more retention members **202** which are deployed after the stent **200** is properly positioned, as described above. **FIG. 31** shows the retention members **202** in their deployed position. A flange **206** acts to seal the opening in the coronary artery, while the retention members **202** reside in the myocardium, helping to anchor the stent **200** in place.

[0065] It should be appreciated that the stents described above, and particularly the bulkhead stent, are useful in other applications in addition to stenting the myocardium. For example, these stents may also serve as other types of coronary stents, arterial or venous stents, as well as billiary and esophageal stents.

[0066] The present vascular shunt provides significant improvements in the present treatment of blockages in the coronary artery. Although the invention has been described in its preferred embodiments in connection with the particular figures, it is not intended that this description should be limited in any way.

**1-13**. (canceled)

**14**. A tissue implant device for implantation into ischemic tissue comprising:

an implant having a first configuration with a first profile and a second configuration having a second profile that is greater than the first profile whereby surrounding tissue into which the implant is placed in stress and is irritated sufficiently to cause an injury response including thrombosis formation that initiates angiogenesis;

the implant comprising a plurality of expandable members each having a free end and an end joined to the implant, each member configured to diverge away from a substantially common central longitudinal axis of the implant during self-expansion from the first configuration to the second configuration.

**15**. An implant as defined in claim 14 further comprising a flare that is resiliently expandable from the first configuration to the second configuration.

**16**. An implant device as defined in claim 14 wherein the implant defines a hollow interior.

**17**. An implant device as defined in claim 14 wherein the implant is flexible after assuming the second configuration.

**18**. An implant device as defined in claim 14 wherein the implant defines a trunk portion aligned along the longitudinal axis of the implant and defining expandable members that are legs extending from the trunk portion and that diverge away from the longitudinal axis upon expansion.

**19**. An implant device as defined in claim 14 wherein a first portion of the body aligned along the longitudinal axis of the implant remains static during and after delivery and a second portion of the body is defined by expandable members that move to a different position relative to the first portion after implantation to comprise a second configuration of the device.

**20**. An implant device as defined in claim 19 wherein the implant comprises an elastic material and the motivational energy to cause the implant to move from the first to the second configuration is the inherent resiliency of the material.

**21**. A tissue implant device for implantation into ischemic tissue comprising:

an implant having a first configuration with a first profile and a second configuration having a second profile that is greater than the first profile;

the implant comprising a plurality of expandable members each having a free end and an end joined to the implant, each member configured to diverge away from a substantially common central longitudinal axis of the implant during self-expansion from the first configuration to the second configuration.

**22**. An implant device as defined in claim 21 further comprising a flare, a leg, a flange, a hook, a barb, or a collar that is resiliently expandable from the first configuration to the second configuration.

**23**. An implant device as defined in claim 21 wherein the implant defines a hollow interior.

**24**. An implant device as defined in claim 21 wherein the implant is flexible after assuming the second configuration.

**25**. An implant device as defined in claim 21 wherein the implant defines a trunk portion aligned along the longitudinal axis of the implant and defining expandable members that are legs extending from the trunk portion and that diverge away from the longitudinal axis upon expansion.

**26**. An implant device as defined in claim 21 wherein a first portion of the body aligned along the longitudinal axis of the implant remains static during and after delivery and a second portion of the body is defined by expandable members that move to a different position relative to the first portion after implantation to comprise a second configuration of the device.

**27**. An implant device as defined in claim 26 wherein the implant comprises an elastic material and the motivational energy to cause the implant to move from the first to the second configuration is the inherent resiliency of the material.

**28**. A method for placing a conduit in the wall of a patient's heart to establish a blood flow path between a coronary vessel and a heart chamber, the method comprising steps of:

(a) positioning a guide member that extends through the coronary vessel and the heart wall into a heart chamber;

(b) using the guide member to deliver a conduit into the heart chamber; and

(c) positioning the conduit in the heart wall to establish a blood flow path between the heart chamber and the interior of the vessel;

wherein the conduit is covered by a sheath, and further comprising covering at least a portion of the conduit while placing the conduit in the heart wall and then removing the sheath.

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