



US 20120203072A1

(19) **United States**(12) **Patent Application Publication**
Lattouf et al.(10) **Pub. No.: US 2012/0203072 A1**(43) **Pub. Date: Aug. 9, 2012**(54) **APICAL INSTRUMENT PORT**(75) Inventors: **Omar M. Lattouf**, Atlanta, GA (US); **Dirk Hoyns**, Social Circle, GA (US); **Larry Hall**, Atlanta, GA (US); **Amin Rahme**, Atlanta, GA (US)(73) Assignee: **Transcardiac Therapeutics, Inc.**(21) Appl. No.: **13/247,304**(22) Filed: **Sep. 28, 2011****Related U.S. Application Data**

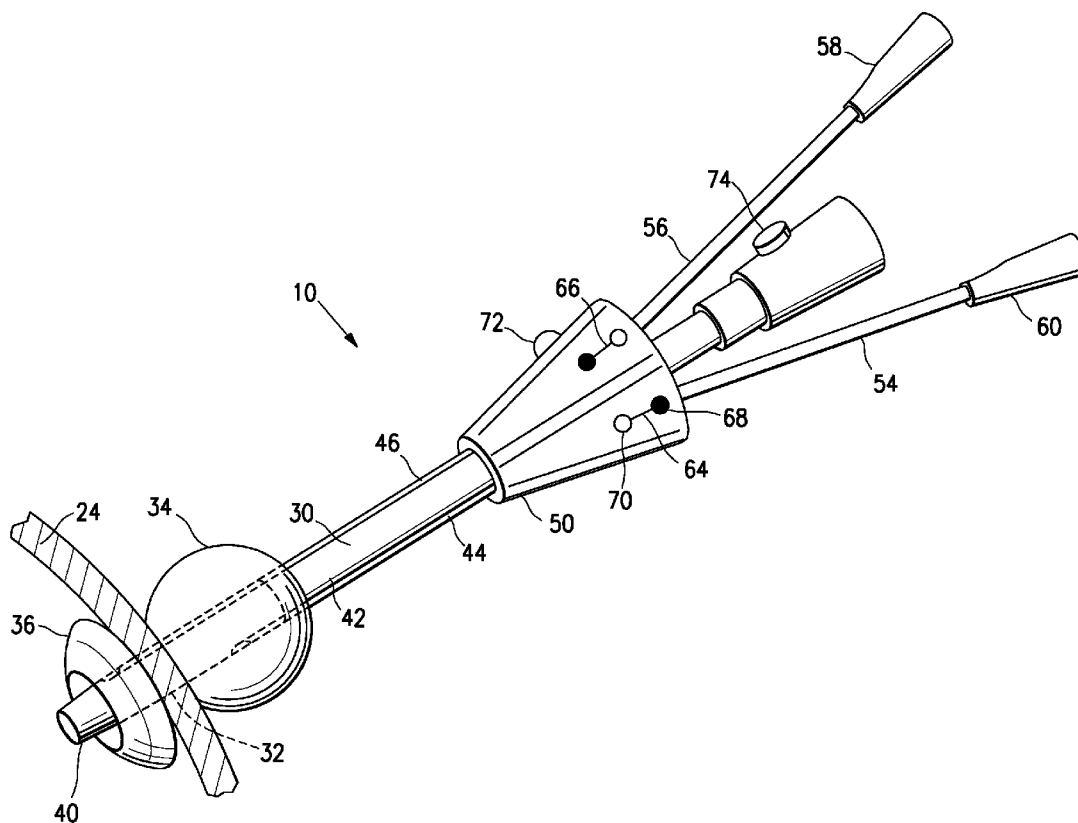
(63) Continuation of application No. 12/006,967, filed on Jan. 8, 2008, which is a continuation-in-part of application No. 11/784,385, filed on Apr. 6, 2007, now abandoned, which is a continuation-in-part of application No. 10/313,198, filed on Dec. 6, 2002, now Pat.

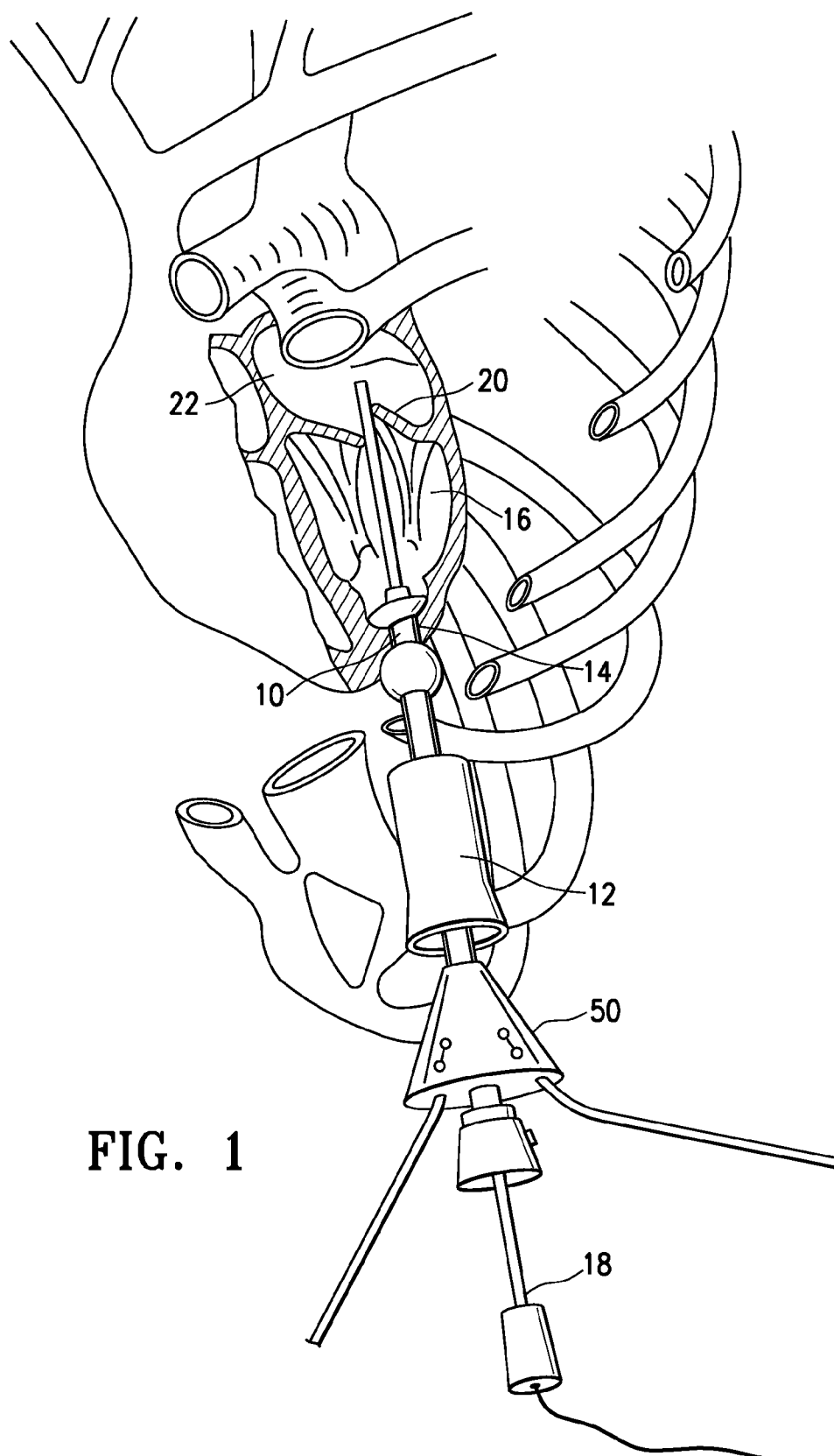
No. 7,373,207, which is a continuation-in-part of application No. 10/295,390, filed on Nov. 15, 2002, now Pat. No. 6,978,176.

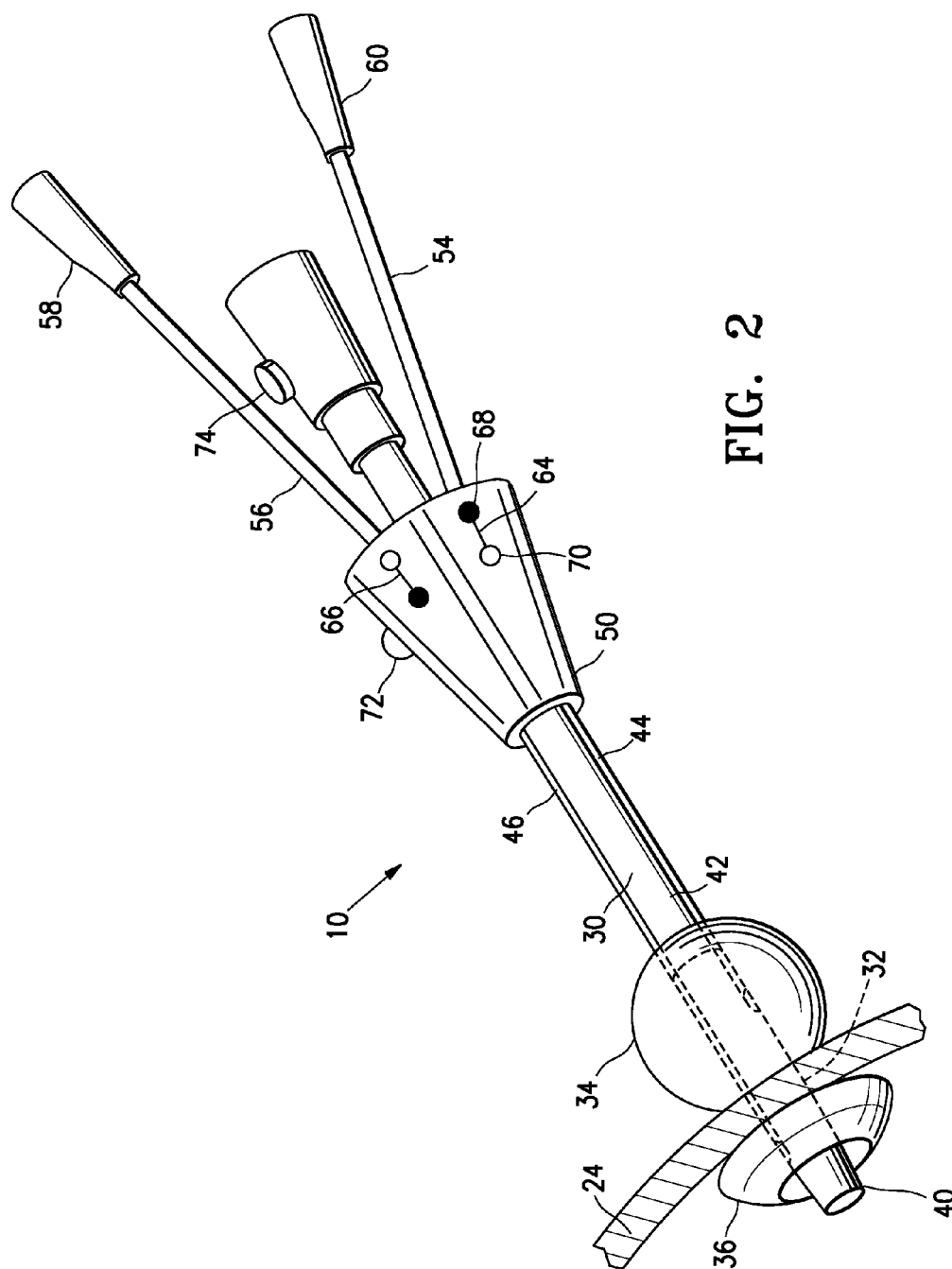
(60) Provisional application No. 60/340,062, filed on Dec. 8, 2001, provisional application No. 60/365,918, filed on Mar. 20, 2002, provisional application No. 60/369,988, filed on Apr. 4, 2002.

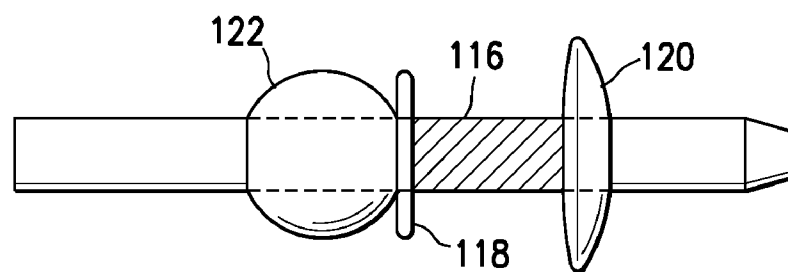
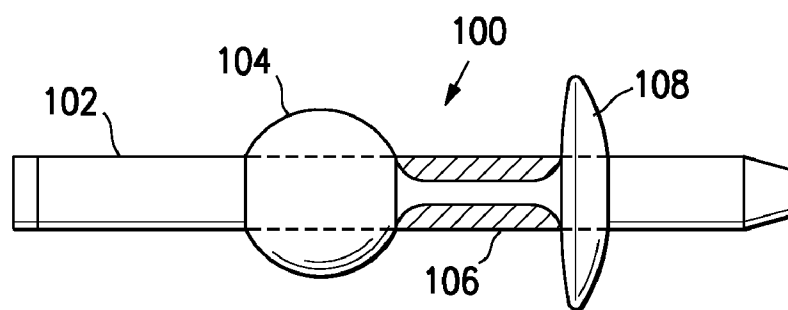
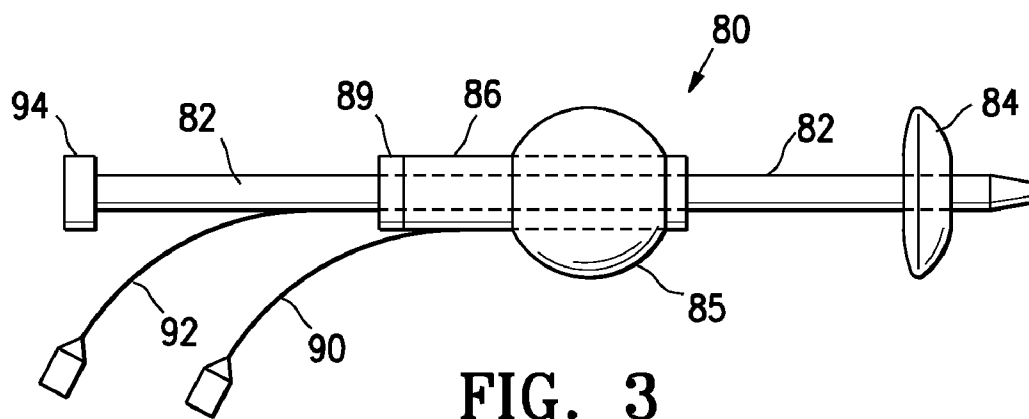
Publication Classification(51) **Int. Cl.**
A61B 1/32 (2006.01)(52) **U.S. Cl.** **600/208**(57) **ABSTRACT**

The invention is directed to a method of treating a patient's heart. In this method an instrument port is secured within a passageway through a wall of an apical region of the patient's heart to allow the passage of a treatment instrument. A number of minimally invasive procedures may be performed within the patient's heart









APICAL INSTRUMENT PORT

RELATED APPLICATIONS

[0001] This application is a continuation of application Ser. No. 12/006,967, filed Jan. 8, 2008, which is a continuation in part of application Ser. No. 11,784,385, filed on Apr. 6, 2007, which is a continuation in part of application Ser. No. 10/313,198, filed on Dec. 6, 2002 (now U.S. Pat. No. 7,373,207), which is a continuation in part of application Ser. No. 10/295,390, filed on Nov. 15, 2002 (now U.S. Pat. No. 6,978,176) which is related to and claims priority from provisional applications, Ser. No. 60/340,062, filed Dec. 8, 2001, Ser. No. 60/365,918, filed Mar. 20, 2002 and Ser. No. 60/369,988, filed Apr. 4, 2002. All of these applications are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

[0002] The invention is generally directed to the field of minimally invasive methods of surgical procedures and particularly, to such procedures with an instrument port that facilitates access for a medical instrument into the interior of a patient's heart through an apical region of a wall of the patient's heart.

BACKGROUND OF THE INVENTION

[0003] Medical procedures on the heart can be performed inside the heart (endocardial) and on the outside of the heart (epicardial). Endocardial procedures require access to the interior of the heart, which can be accomplished percutaneously through the vasculature or directly, through the patient's chest and heart wall.

[0004] For percutaneous access, a catheter is typically inserted at the femoral or carotid artery and threaded into the heart via the vasculature. Travel of the catheter is monitored using a fluoroscope. Percutaneous treatment has several issues that make it less than desirable. For one thing, the catheters and tools that are used for percutaneous cardiac procedures are limited in size because they must be threaded through the vasculature into the heart. When a guide catheter is used, only tools that are smaller than the guide catheter can be threaded through the catheter to the intended site of use. In cases where more than one type of tool is used, each tool must be threaded separately, adding to the length of the process.

[0005] Maneuverability of a catheter which is threaded such a long distance is limited, which means that it is difficult and sometimes impossible to locate the working end of the catheter exactly at the area in the heart where treatment is needed. This also adds to the total length of the procedure. Another issue with percutaneous access can be various vascular complications such as bleeding, dissection, and rupture of a blood vessel. Moreover, some areas of the heart are simply difficult to access percutaneously.

[0006] For direct access to the interior of the heart, physicians have traditionally used open heart surgical procedures. This involves a gross thoracotomy, usually in the form of a median sternotomy, to gain access to the thoracic cavity. A saw or other cutting instrument is used to cut the sternum longitudinally, allowing the rib cage to be spread apart. A large opening into the thoracic cavity is thus created, through which the surgeon can directly visualize and operate upon the heart. Of course, such an invasive procedure has consequences, such as typically an extended hospital stay and an increased risk of complications and pain.

[0007] Once the surgeon has accessed the thoracic cavity, and the exterior of the heart, he must gain access to the interior of the heart for endocardiac procedures. Opening up the heart surgically can only be done after placing the heart under cardioplegic arrest and maintaining circulation using cardiopulmonary bypass. Stopping the heart invites serious complications.

[0008] To avoid cardiac bypass, the surgeon must have a way to penetrate the heart wall with an instrument without losing a tremendous amount of blood. A hemostatic seal must be created around the instrument passed through the wall. One way to create a hemostatic seal is by using a purse-string suture around the instrument inserted through the heart wall. However, purse-string sutures are not always effective and do not easily allow the insertion of more than one instrument through a single incision.

[0009] From the above discussion it is apparent that there is a need for devices and methods to access the inside of the heart other than percutaneously and directly via open heart surgery. There is a need for methods and devices to access the interior of the heart minimally invasively. There is further a need for devices that allow instruments that have already been developed for percutaneous use to be used in minimally invasive endocardiac procedures.

[0010] Accordingly, to avoid the disadvantages of both open heart surgery and percutaneous access, the present invention provides a method for minimally invasive access to the interior of the heart (and to other areas and organs of the body). An area of the heart that is preferably accessed is the ventricular apex of the heart, which is the rounded inferior extremity of the heart formed by the left and right ventricles. In normal healthy humans it generally lies beneath the fifth left intercostal space from the mid-sternal line.

SUMMARY OF THE INVENTION

[0011] The present invention is directed to devices and methods for accessing the interior of the heart without having to stop the heart from beating and while minimizing blood loss. The devices and methods are useful for performing endocardiac treatments. The methods rely upon access to the interior of the heart through the heart wall using an instrument port.

[0012] In a preferred method, the instrument port is implanted into the heart wall using a minimally invasive opening in the chest wall. However, the port could also be installed after a more invasive procedure to open the chest wall and access the heart, such as a gross thoracotomy. The instrument port is installed in the heart wall and allows passage of instruments therethrough into a heart chamber. The port is anchored by a sealing device which also serves to reduce blood loss from the heart.

[0013] When the instrument port is implanted into the apical wall of the patient's heart a number of procedures may be performed. For example, a treatment instrument having an operative distal portion which is configured to repair a mitral valve in the patient's heart as described in U.S. Pat. No. 6,978,176 to Lattouf but the method taught therein is described as being useful for other procedures such as ablation.

[0014] In another example, the operative distal portion of the treatment instrument is configured to repair an aortic valve in the patient's heart. In yet another embodiment, the operative distal portion of the treatment instrument is configured to deliver a stent prosthesis through the interior of the

patient's heart into the patient's aorta for aneurysm repair or partial aorta replacement. In a further embodiment, the operative distal portion of the treatment instrument is configured to repair a para valvular leak. Another embodiment has a treatment instrument with an operative distal portion configured to extract clots or masses from the interior of the patient's heart. In another exemplary embodiment, the operative distal portion of the treatment instrument is configured to deliver stem cells to an interior wall of the patient's heart. In yet another embodiment, the operative distal portion of the treatment instrument is configured to form a thermal or energy based ablation lesion to treat rhythm disturbances of the patient's heart. In other embodiments one or more treatment instrument is inserted through the inner lumen of the instrument port in order to advance a first portion of an artificial chordae tendinae into the left ventricle of the patient's heart, securing the first portion of the artificial chordae tendinae to a free edge of a valve leaflet with a torn or damaged chordae tendinae from within the patient's heart; and securing a second portion of the artificial chordae tendinae to a ventricular wall of the patient's heart

[0015] The invention will become more apparent from the following detailed description and accompanying exemplary drawings. These and other advantages of the invention will become more apparent from the following detailed description of embodiments when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is a perspective view of a patient's chest with the patient's heart exposed and an instrument port penetrating an apical region of the patient's heart wall providing instrument access into the interior of the patient's heart to perform a minimally invasive surgical procedure.

[0017] FIG. 2 is a perspective view of the instrument port shown in FIG. 1.

[0018] FIG. 3 illustrates another embodiment of an instrument port.

[0019] FIG. 4 illustrates another embodiment of an instrument port.

[0020] FIG. 5 illustrates yet another embodiment of an instrument port.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0021] The instrument port embodying features of the invention allows a physician to gain access to the interior of the heart in a minimally invasive manner, so that a surgical procedure can be performed in the interior of the patient's heart. The instrument port is designed to be temporarily implanted through an apical region of the patient's heart wall and to allow passage of one or more instruments into the heart while minimizing blood loss out of the heart.

[0022] FIG. 1 illustrates the instrument port 10 as used to facilitate delivery of an ablation catheter or other instrument into or through the left atrium of a patient's heart. The instrument port is shown inserted through the apex of the left ventricle of the patient's heart to facilitate access to the left ventricle and left atrium. Although the instrument port 10 is shown for delivery of an ablation catheter, it can be used with a wide variety of instruments and in a wide variety of minimally invasive procedures.

[0023] As described in more detail below and shown in FIG. 1, the instrument port 10 is preferably installed into the heart wall through a minimally invasive opening made in the patient's chest. In FIG. 1, this minimally invasive opening is maintained using a chest trocar 12. However the instrument port is not limited to use in minimally invasive treatments and could be used after a more invasive opening is made in the patient's chest. After a trocar 12 is inserted through the patient's chest and the heart is exposed, a series of dilators and one or more guide wires can be used to form a passageway through the apical region of the heart wall and the instrument port 10 may be inserted through the passageway made in the apex 14 of the left ventricle 16 as shown in FIG. 1.

[0024] After the instrument port 10 is inserted through the heart wall, the sealing members 34 and 36 are activated (described below in detail), anchoring the instrument port 10 in place and sealing the opening to reduce blood loss there-through. Any of a number of instruments can then be inserted through the instrument port and into the interior of the patient's heart.

[0025] As schematically shown in FIG. 1, an ablation catheter 18 is inserted through the instrument port 10, into the left ventricle 16, past the mitral valve 20, and into the left atrium 22. The tip of ablation catheter 18 is thus placed in the left atrium.

[0026] If desired, the ablation catheter 18, or any other tool, can be used with an instrument guide, such as that described in application Ser. No. 11/784,385 incorporated herein. The instrument guide can help deliver the instrument to the desired area within the patient's heart or aorta.

[0027] FIG. 2 illustrates the instrument port 10 in greater detail and shows the port inserted through an apical wall 24. Instrument port 10 desirably has an elongated cylindrical tubular body 30 with a heart wall portion 32 that generally is as long as the thickness of the apical heart wall 24. The width of the apical heart wall 24 can be varied, as discussed further below.

[0028] Sealing members 34 and 36 are located on either side of the heart wall portion 32 of the instrument port 10. In the embodiment shown the sealing devices 34 and 36 are two inflatable balloons. The proximal sealing member 34 (a balloon) is on the outside of the apical heart wall 24 and the distal sealing member 36 (a balloon) is on the inside of the apical heart wall 24. The sealing members may however be a single balloon crimped in the middle, where the crimped part of the balloon is generally through the apical heart wall 24 and a portion of the balloon extends from either side of the heart wall. In another embodiment the sealing device of the port is a single balloon on the side of the port on the inside of the heart wall. Instead of a balloon sealing device on the outer side of the heart wall portion, the port can have a flange or other structure that serves to stabilize the device. In any case the sealing devices are desirably expandable balloons, wherein the inside balloon 36 is flat or pancake shaped and the outer balloon 34 may also be disc-shaped or more desirably is substantially spherical. This embodiment is particularly advantageous for use in the heart, and other places where interior space is limited, since the flat disc-shaped balloon 36 requires less space. The flat disc-shaped balloon 36 also provides better sealing against the tissue wall 24 to prevent blood from leaving the heart chamber. The sealing devices may also serve to hold the port in place within the heart wall.

[0029] In a preferred embodiment, the interior balloon 36 ranges in size in diameter from about 0.5 to 2.5 cm in diameter

and in thickness from about 0.1 to 1.5 cm, although it may be smaller or larger, depending upon the application. The exterior balloon ranges in size up to about 3 cm in diameter. The balloons are desirably made of polyurethane, although they may be made of any suitable biocompatible material. They can be fastened to the port body by any suitable means. For example, one method of fastening the balloons to the port body is using an adhesive.

[0030] The instrument port cylindrical body **30** desirably measures from about 5 to 25 cm in length. The distal tip **40** of the port, measuring about 0.5 to 1 cm in length, is desirably tapered and is radiopaque for visualization.

[0031] Wall portion **32** of the instrument port **10** is defined by the sealing devices on either side, the balloons **34** and **36** as shown in FIG. 2. The width of wall portion **32** is desirably about the same as the thickness of the wall through which the port **10** is inserted. In most cases this will be from about 5 to 40 mm. The instrument port can have a wall portion of a set length or, in an alternate embodiment, the instrument port may have a variable length wall portion. Designs for instrument ports **10** having variable length wall portions are discussed below.

[0032] As shown in FIG. 2, the instrument port **10** has three lumens, one central instrument lumen **42**, and one for inflating each of the balloons **34**, **36**. In other embodiments, the port **10** could have more or less lumens. For example, a single lumen could be used to inflate both balloons **34**, **36**. As another example, the port **10** could have more than one delivery lumen, such as one lumen for a tool and one lumen for a viewing scope, or a second tool.

[0033] The outer diameter of the instrument port **10** is desirably from about 1 to 20 mm and the inner diameter of the instrument lumen is desirably about 1 to 15 mm. This allows passage of an instrument guide or instrument through the port of up to 15 mm (45 Fr). Various sized ports may be desirable for ports employed for different purposes. The port **10** includes a one way valve (not shown) in the inner lumen so that blood is prevented from exiting the heart but an instrument can be inserted through the inner lumen. The valve is desirably a hemostatic valve, such as a duck-bill valve, and is desirably made of silicon although other types of valves and materials can be used.

[0034] The instrument port is desirably made of polyether block amides known as PEBAX® polymers or other plasticizer-free thermoplastic elastomers.

[0035] The balloon lumens **44**, **46** lead to balloons **34** and **36** respectively, and to inflation tubes **54** and **56**, respectively. A manifold **50** serves as a comfortable grip for the port **10** and also organizes the inflation tubes **54** and **56**. The manifold desirably includes raised markings **64** and **66**, that indicate which balloon is inflated with the corresponding inflation tube. This safety feature is shown in FIG. 2 as two barbell shaped markings, wherein (for the raised marking **64**) one of the barbell ends **68** is a raised and filled (colored) circle and the other barbell end **70** is a non raised open (non colored or filled) circle. The colors of the raised barbell ends correspond to the colors of the fittings **58** and **60**, respectively.

[0036] In addition, the manifold may have a raised bump **72** on one side, to indicate to the handler which balloon he is inflating. This bump is shown in FIG. 2 on the side of the manifold holding the inflation tube **56** for the inside balloon **36**. The raised markings **64** and **66** and raised bump **72** are safety features, providing the surgeon with an indication of which inflation tube leads to which balloon.

[0037] As stated, the balloons **34** and **36** are filled via inflation tubes **54** and **56** via lumens **44** and **46**. The embodiment is shown with separate inflation lines for each balloon but they could alternatively be filed via the same inflation port.

[0038] Cylindrical body **30** is held by manifold **50** and extends to the proximal end of manifold **50**. A purge valve **74** on the proximal end of the port **10** is in fluid communication with the instrument lumen **42**. This purge valve **74** can be used to flush the port **10** with saline or blood prior to insertion, or to allow air removal from the port **10** during insertion. Purge valve **74** could also be used for infusion of saline, blood, or active agents during the use of the port for the medical procedure, if desired.

[0039] Various alternative designs for the instrument port are described below.

[0040] FIGS. 3-7 illustrate alternate embodiments of the instrument port. As discussed above, the length of the wall portion is desirably about the same as the thickness of the wall through which the port is inserted. The thickness of the heart wall varies from about 5 to 40 mm so an instrument port having a variable length wall portion would be useful.

[0041] In FIG. 3, the instrument port **80** is two cylindrical tube pieces assembled in a slidable coaxial relationship. An inner piece **82** includes a first, distal, balloon **84**. An outer piece **86** includes a second, proximal, balloon **88**. The pieces **82** and **86** are assembled in a coaxial sliding assembly so that the distance between the balloons **84** and **88** can be varied. A locking nut **89** on the proximal end of the second, outer piece **86** keeps the tubes **82** and **86** from sliding once they are in position. Inflation ports **90** and **92** are used to fill the balloons **88** and **84**, respectively. Balloon **84** is flat, as described above for balloon **36** of FIG. 2.

[0042] Rather than the internal one-way valve as shown in FIG. 2 above, this embodiment has a hemostatic valve **94** on the proximal tip of the first inner piece **82**. Either arrangement is possible for all embodiments described herein. Preferably both pieces **82** and **86** are long enough to extend out of the patient's chest so they can be easily manipulated.

[0043] FIG. 4 illustrates an instrument port **100** having a cylindrical body portion **102** and a single balloon **104**. The balloon **104** is constrained with a spacer **106** of a certain length. The spacer **106** length approximates the heart wall thickness where the port **100** is to be installed. The spacer can be slid over one end of the port or may be made of a material that allows it to be spread open so that it can be placed on the port and then contracted once it is in place. The spacer **106** may optionally be crimped or glued in place or otherwise attached to the balloon. The balloon is designed so that the distal end **108** of the balloon is flat. A similar port (not shown) has two balloons and uses a spacer to define a set distance between the balloons when they are inflated.

[0044] In the embodiment shown in FIG. 5, the spacer **116** includes a stop **118** on the proximal end thereof, so that as the port is inserted into the heart wall it will only be inserted as far as the stop **118**. A stop can be incorporated into any of the instrument ports described in this application. The distal end **120** of the balloon **122** is again flat or pancake shaped.

[0045] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. Additional details of the instrument port and methods may be found in the patents and applications incorporated herein. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

[0046] Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

[0047] Terms such as “element”, “member”, “component”, “device”, “means”, “portion”, “section”, “steps” and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms “means for” or “step for” followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

What is claimed is:

1. A minimally invasive method of accessing an interior portion of a patient's heart, comprising:

- a. providing an elongated treatment instrument having an operative distal portion;
- b. providing an accessing port having an inner lumen and a valve within the inner lumen, said valve reducing proximal passage of blood through the inner lumen and allowing distal passage of the treatment instrument through the inner lumen;
- c. forming a small passageway through a ventricular wall in an apical region of the patient's heart;
- d. seating the accessing port within the passageway formed in the apical region of the patient's ventricular wall;
- e. advancing the treatment instrument having an operative distal portion through the inner lumen of the seated accessing port into an interior of the patient's heart until the operative distal portion of the treatment instrument is located in a desired treatment area within the patient's heart;
- f. treating the patient's heart with the operative distal portion of the treatment instrument; and
- g. withdrawing the treatment instrument after treating the patient's heart through the accessing port.

2. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to repair a valve in the patient's heart.

3. The method of claim 2 wherein the operative distal portion of the treatment instrument is configured to repair an aortic valve in the patient's heart.

4. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to deliver a

stent prostheses through the interior of the patient's heart into the patient's aorta for aneurysm repair or partial aorta replacement.

5. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to repair a para valvular leak.

6. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to extract clots or masses from the interior of the patient's heart.

7. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to deliver stem cells to an interior wall of the patient's heart.

8. The method of claim 1 wherein the operative distal portion of the treatment instrument is configured to form a thermal or energy based ablation lesion to treat rhythm disturbances of the patient's heart.

9. The method of claim 1 wherein one or more treatment instruments are inserted through the inner lumen of the instrument port in order to advance a first portion of an artificial chordae tendinae into the left ventricle of the patient's heart, securing the first portion of the artificial chordae tendinae to a free edge of a valve leaflet with a torn or damaged chordae tendinae from within the patient's heart; and securing a second portion of the artificial chordae tendinae to a ventricular wall of the patient's heart.

10. The method of claim 9 wherein a grasping device is advanced through the inner lumen of the instrument port in the ventricular wall into the left ventricle and grasps a free edge of a valve leaflet with a torn or damaged chordae tendinae and positions the free edge of the valve leaflet in a grasping location.

11. The method of claim 10 wherein the first portion of the artificial chordae tendinae is secured to the free edge of the valve leaflet with a torn or damaged chordae tendinae when the free edge thereof is grasped by the grasping device.

12. The method of claim 11 wherein the grasping device is withdrawn from the interior of the patient's heart and the second portion of the artificial chordae tendinae is then secured to the wall of the patient's heart.

13. The method of claim 12 wherein the second portion of the artificial chordae tendinae extends through the passageway in the patient's ventricular wall and is secured to an exterior surface thereof.

14. The method of claim 11 wherein the free edge of the valve leaflet which has a torn or damaged chordae tendinae and a free edge of an adjacent valve leaflet are secured together.

* * * * *