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Reichenbach et al.

(54) **ATTACHMENT METHOD**

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Related U.S. Application Data

(63) Continuation of application No. 12/945,890, filed on Nov. 14, 2010, which is a continuation-in-part of application No. 12/590,863, filed on Nov. 15, 2009, which is a continuation-in-part of application No. 12/590,864, filed on Nov. 15, 2009.

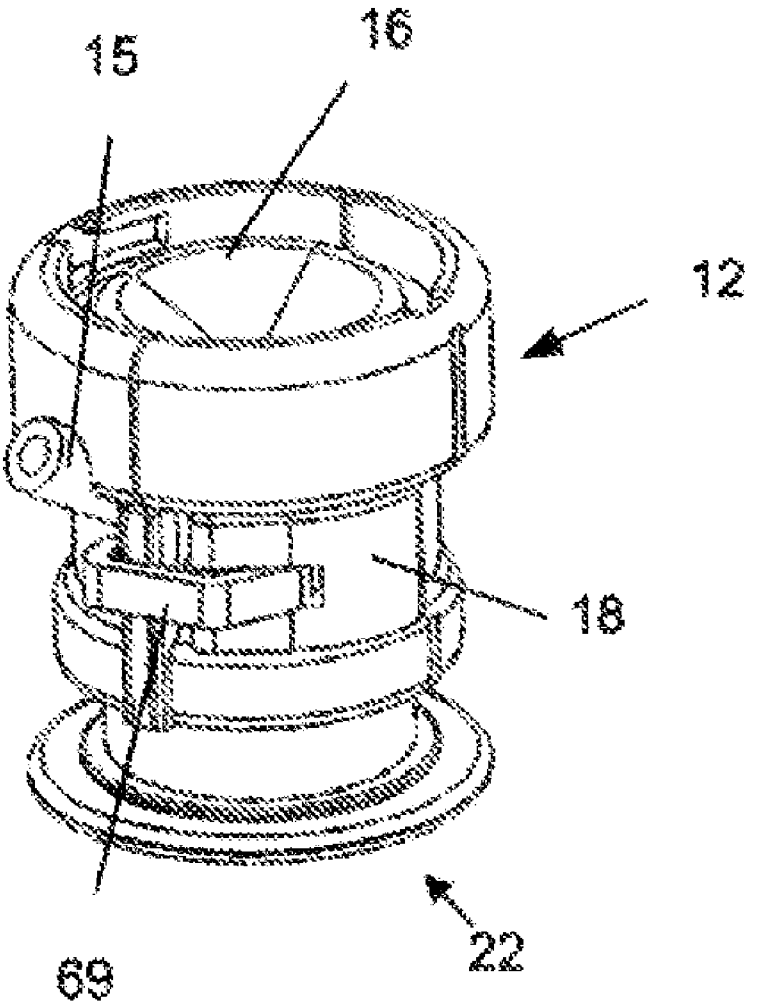
Publication Classification

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(52) **U.S. Cl.** **600/16**

(57) **ABSTRACT**

Preparing the heart for connection with a ventricular assist device (VAD) can include attaching an attachment ring to a ventricular apex of the heart. The attachment ring optionally includes a seal or a valve to allow the procedure to be performed with or without a heart-lung bypass. A valve can be temporarily attached to the attachment ring. Tissue is removed from the ventricular apex through the attachment ring to form a hole through which an inflow conduit of the VAD can be inserted. A slit can first be made in the ventricular apex to facilitate removal of the tissue. A clamp can be closed around the attachment ring to secure the inflow conduit.



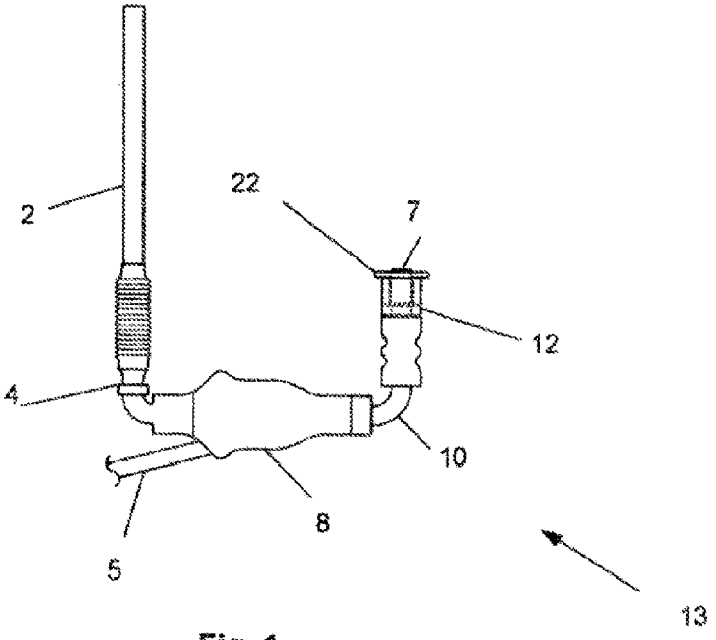


Fig. 1

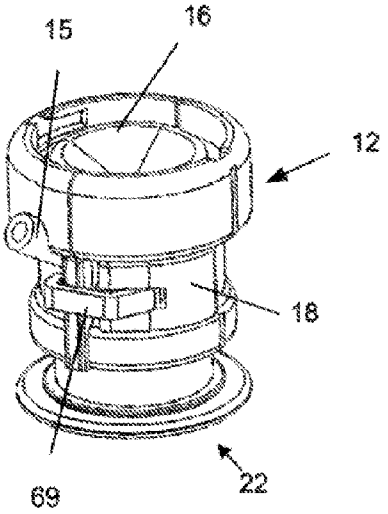


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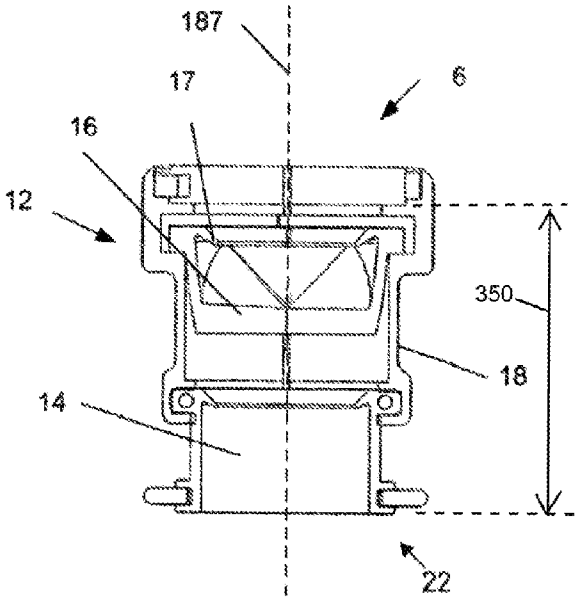


Fig. 2b

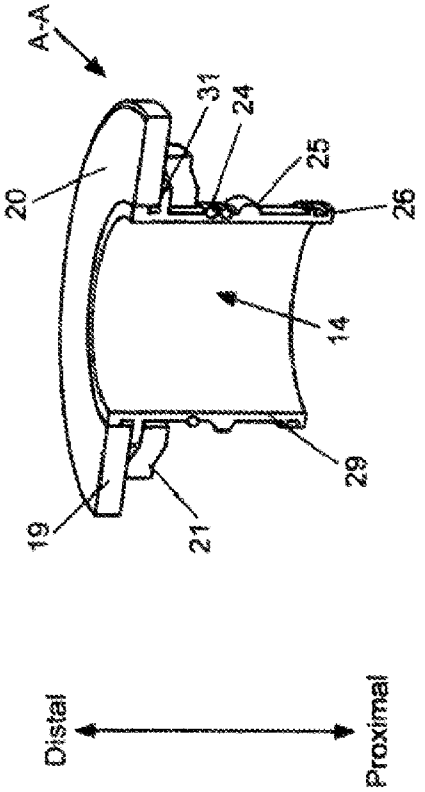


Fig. 3b

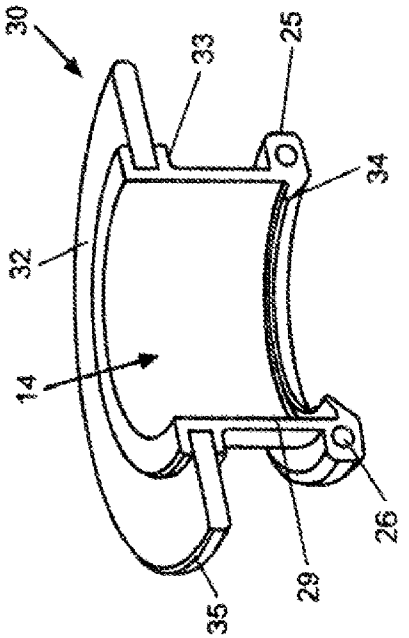


Fig. 4b

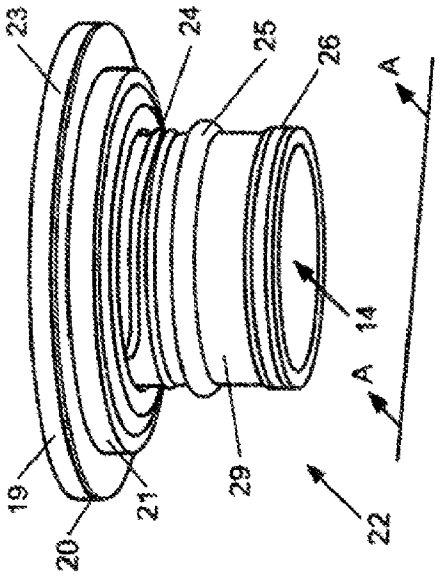


Fig. 3a

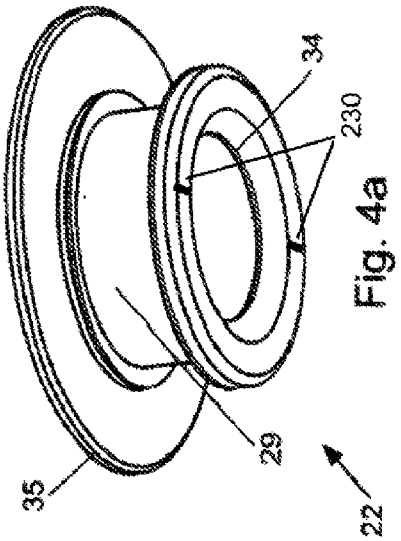


Fig. 4a

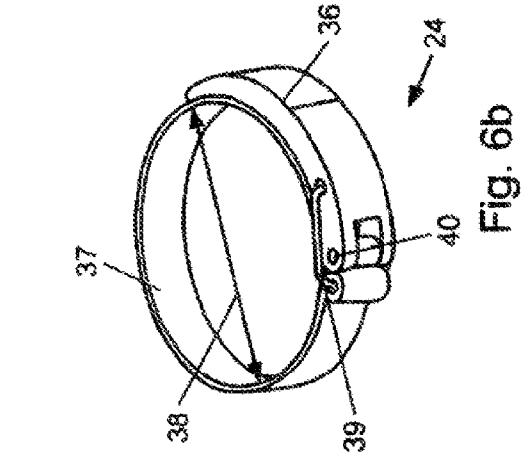


Fig. 6b

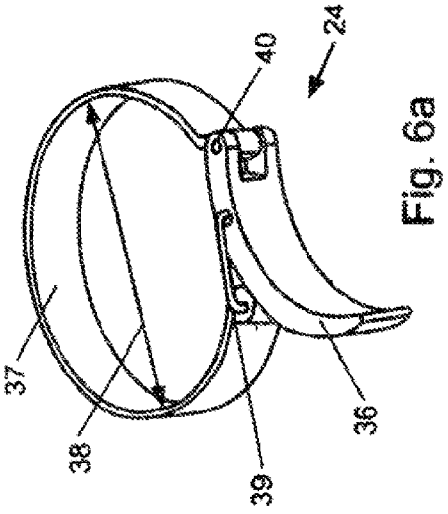


Fig. 6a

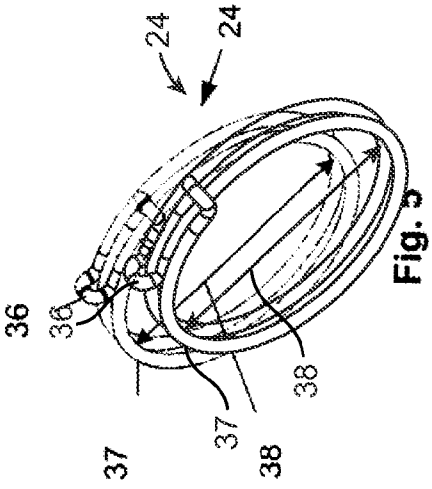


Fig. 5

FIG. 5

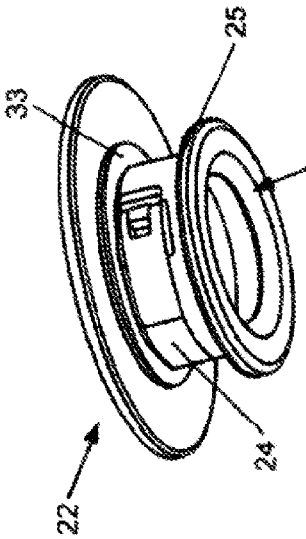


Fig. 7b

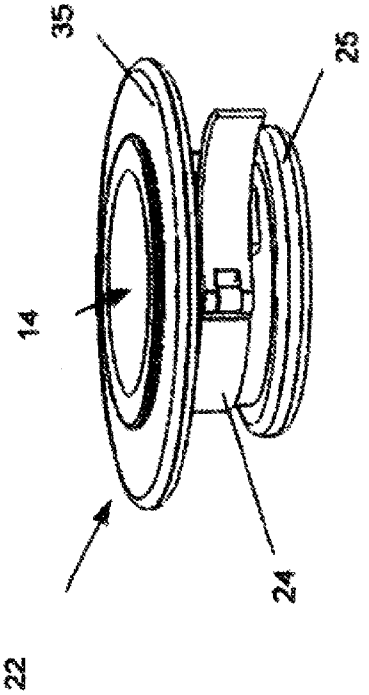


Fig. 7a

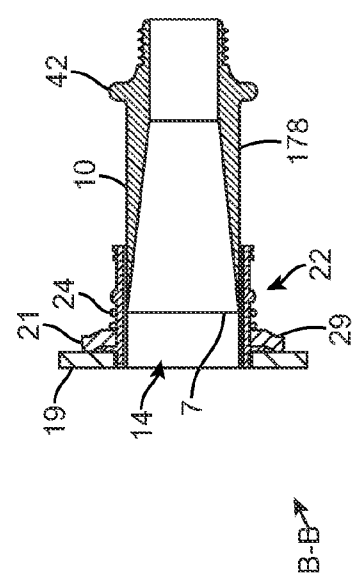


FIG. 8c

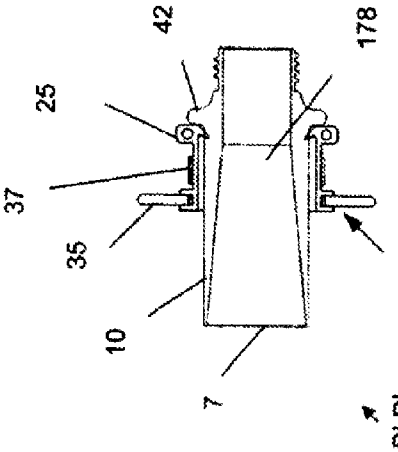


Fig. 9c

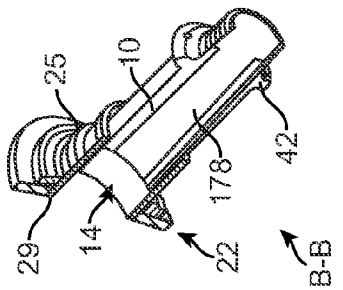


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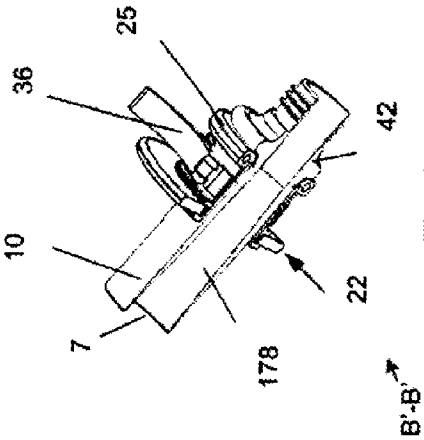


Fig. 9b

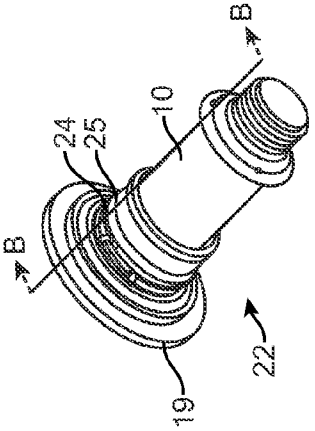


FIG. 8a

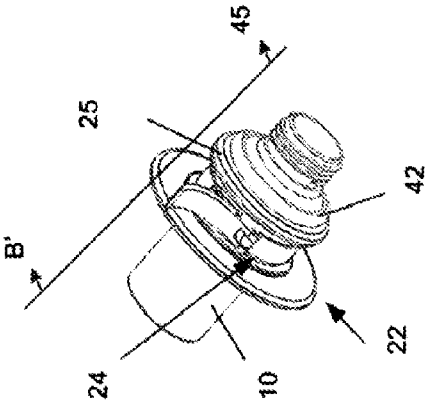


Fig. 9a

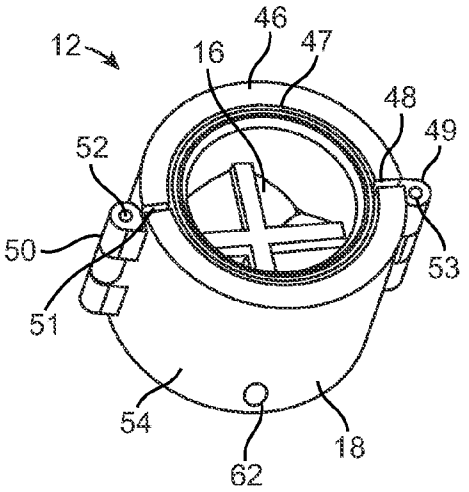


FIG. 10a

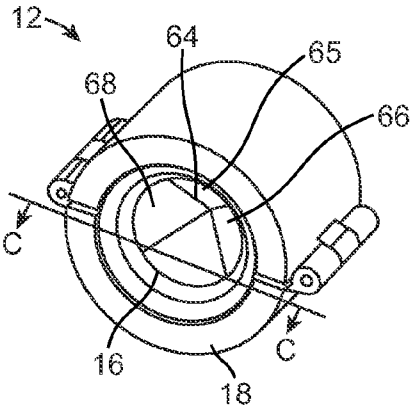


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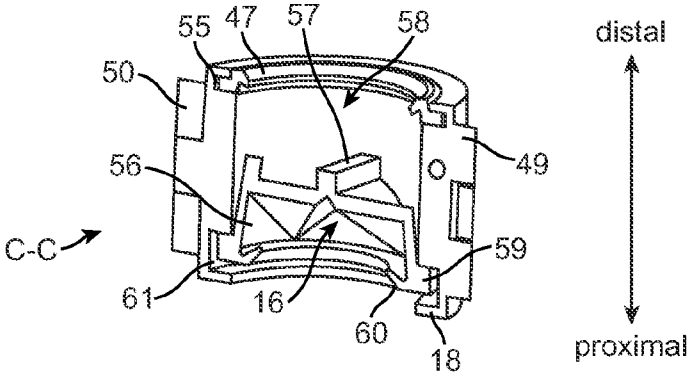


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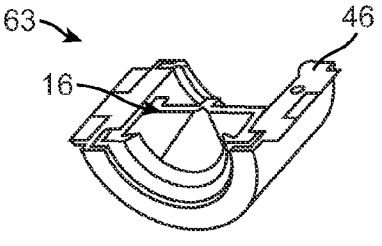


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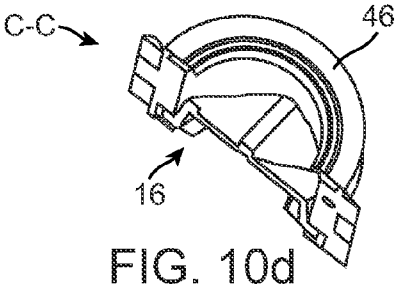


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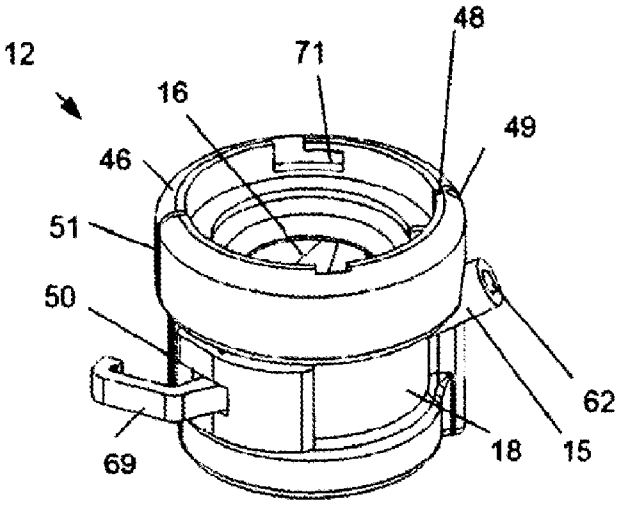


Fig. 11a

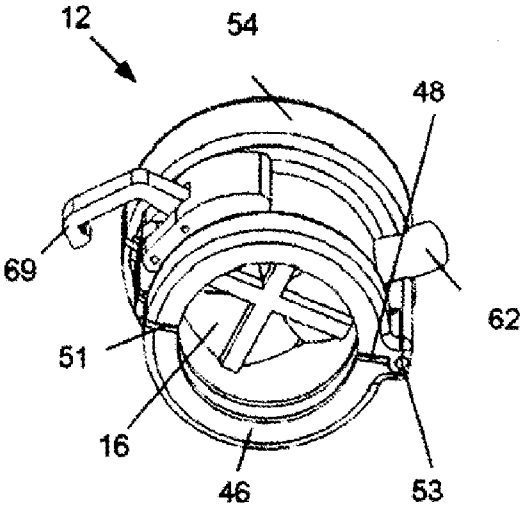


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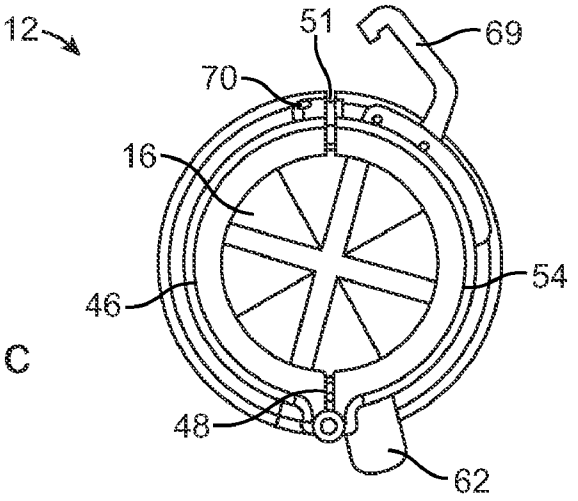


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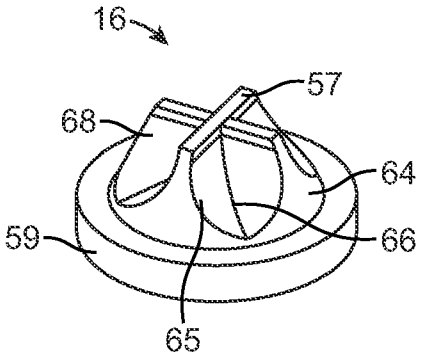


FIG. 12a

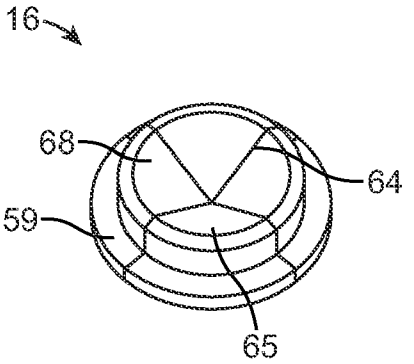


FIG. 13a

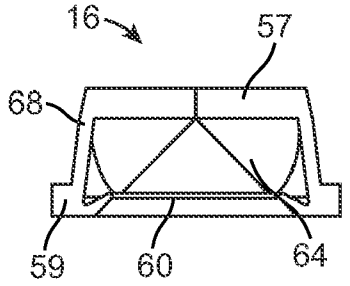


FIG. 12b

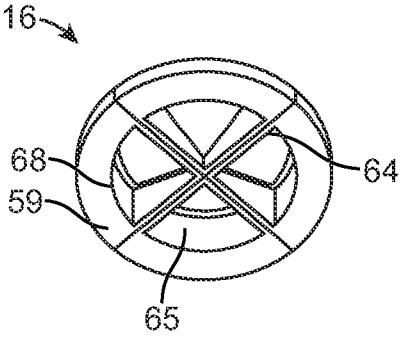


FIG. 13b

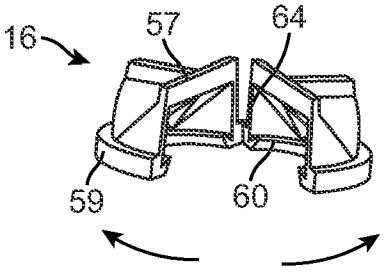


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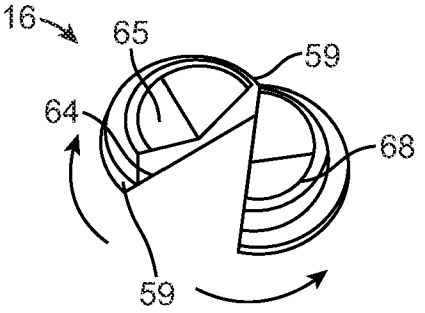


FIG. 13c

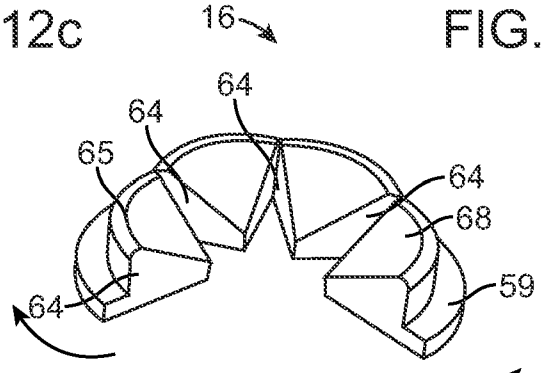


FIG. 13D

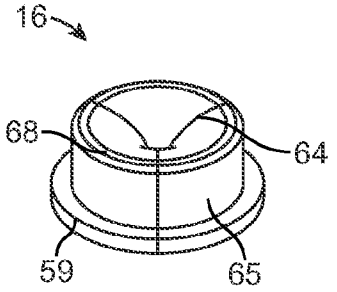


FIG. 14a

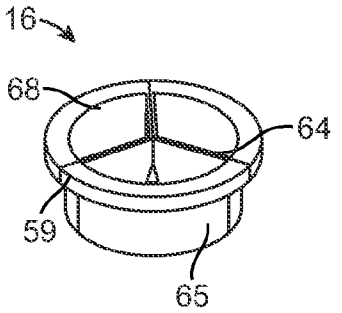


FIG. 14b

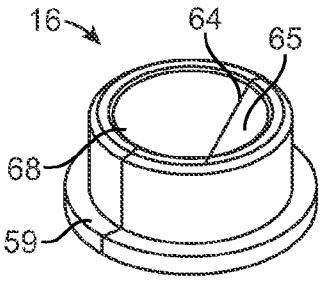


FIG. 15a

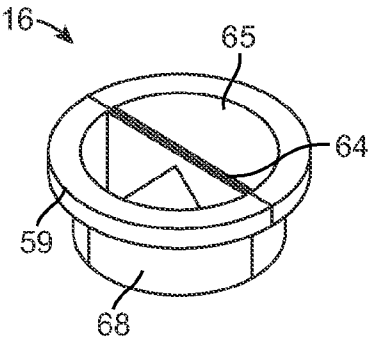


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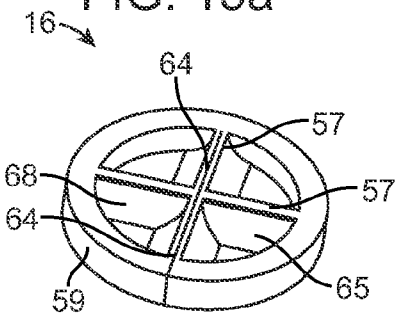


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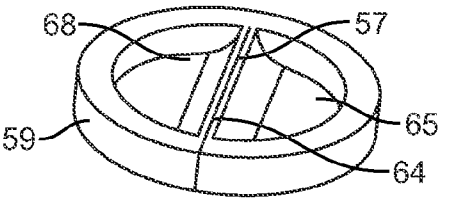


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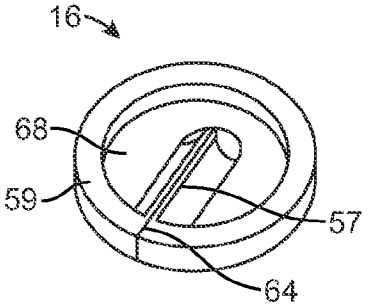


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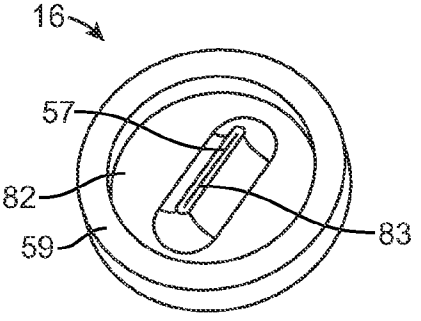


FIG. 15f

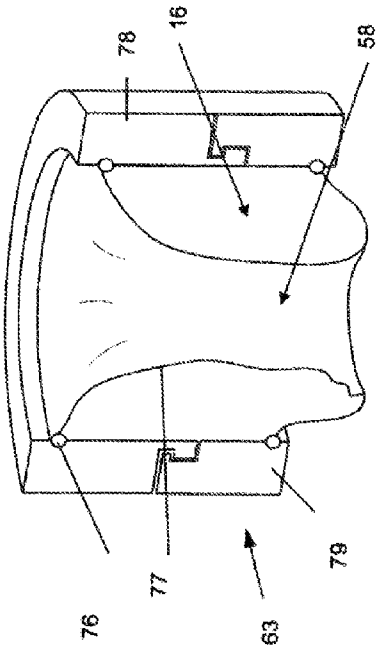


Fig. 17a

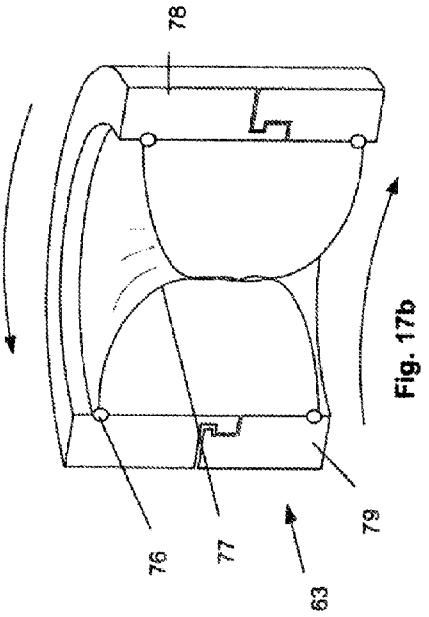


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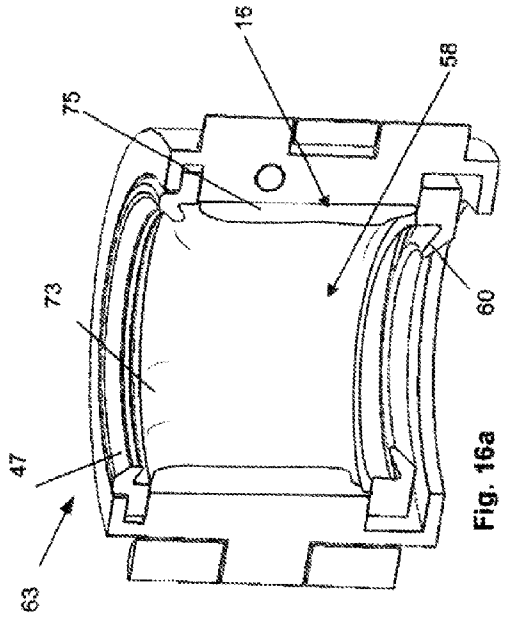


Fig. 16a

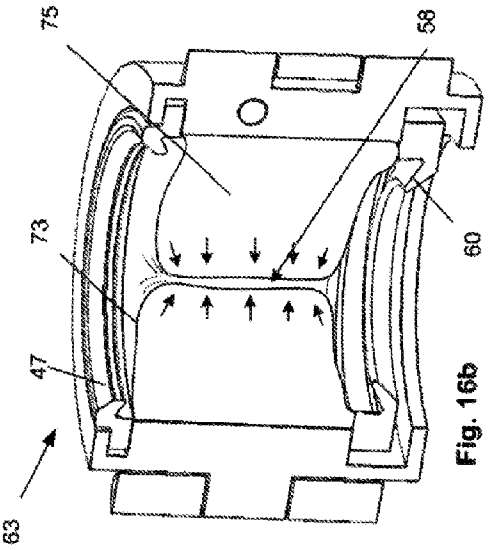


Fig. 16b

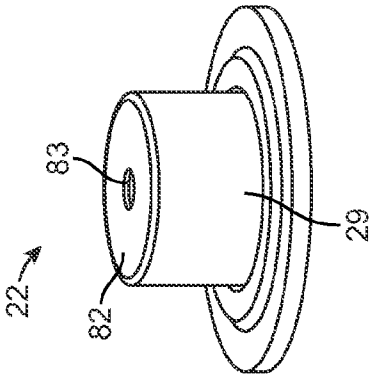


FIG. 19a

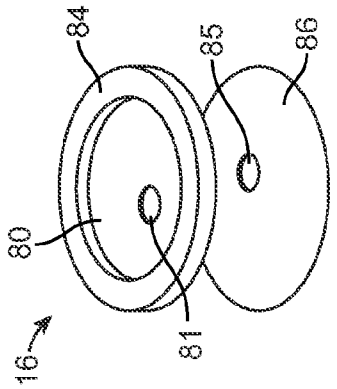


FIG. 18a

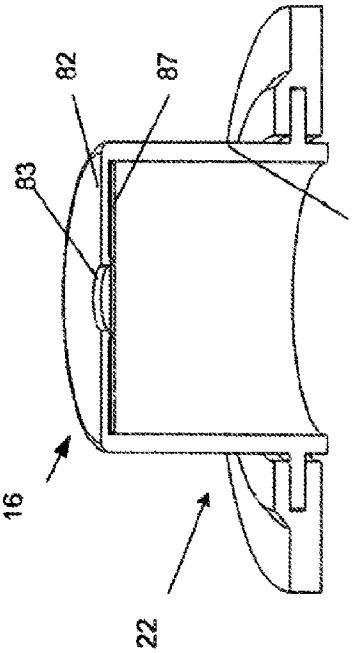


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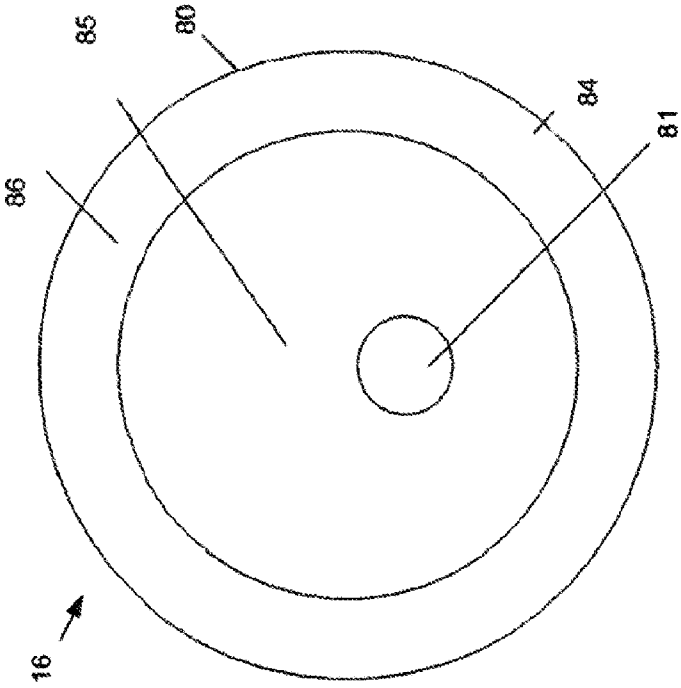


Fig. 18b

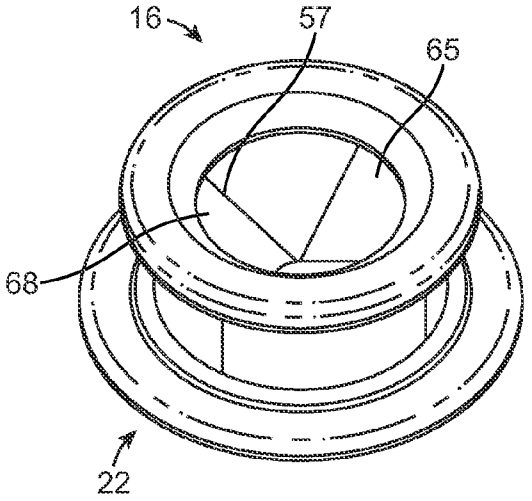


FIG. 19c

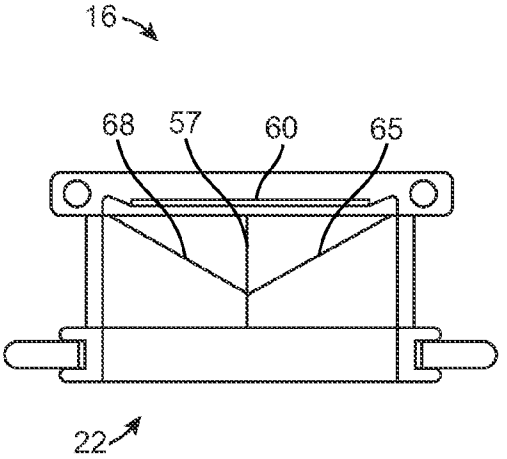


FIG. 19d

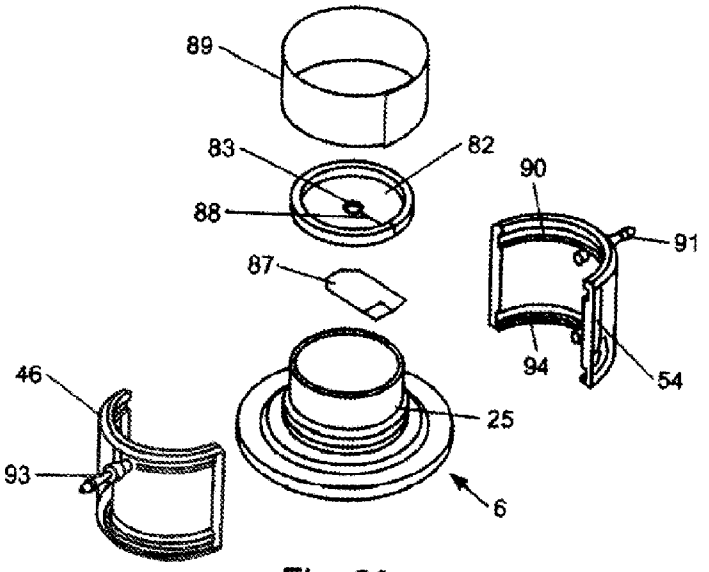


Fig. 20

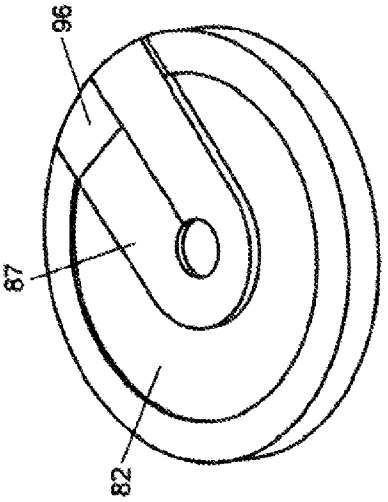


Fig. 21b

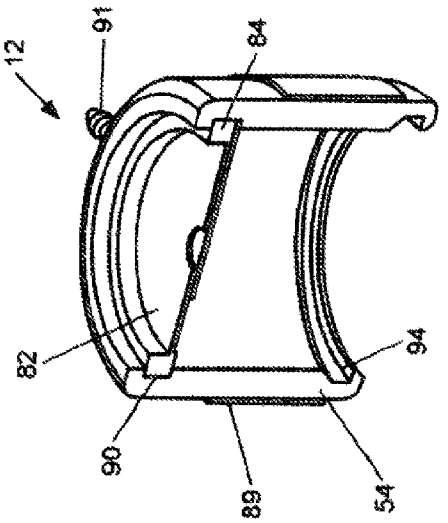


Fig. 22

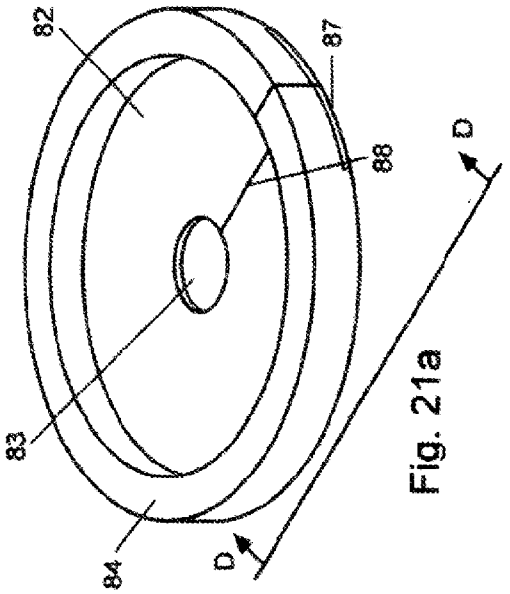


Fig. 21a

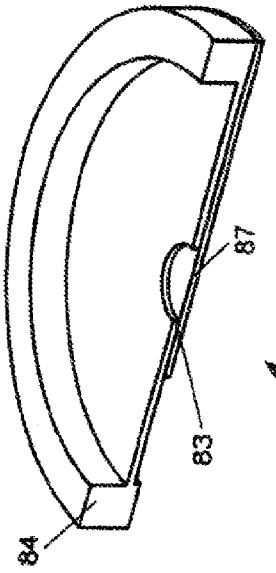


Fig. 21c

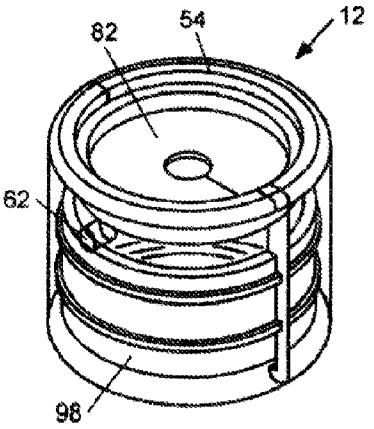


Fig. 23

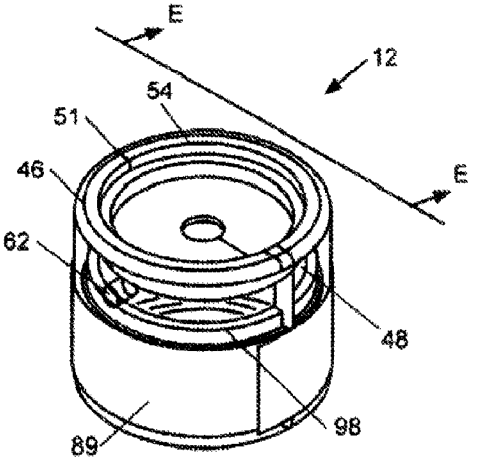


Fig. 24

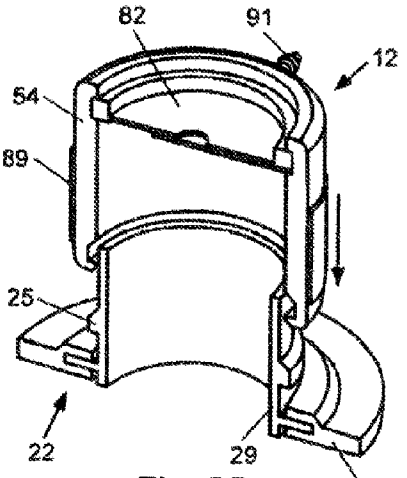


Fig. 25

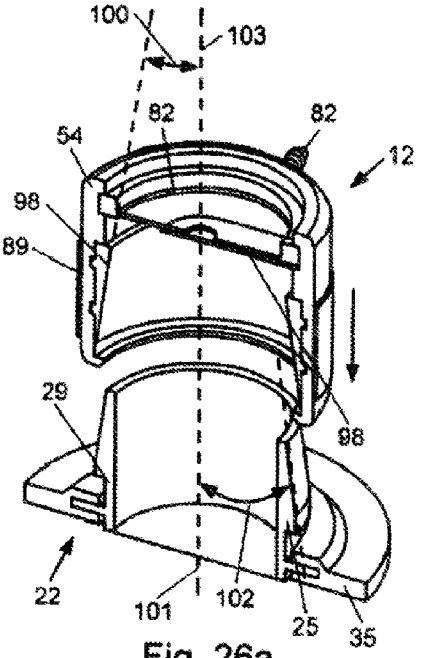


Fig. 26a

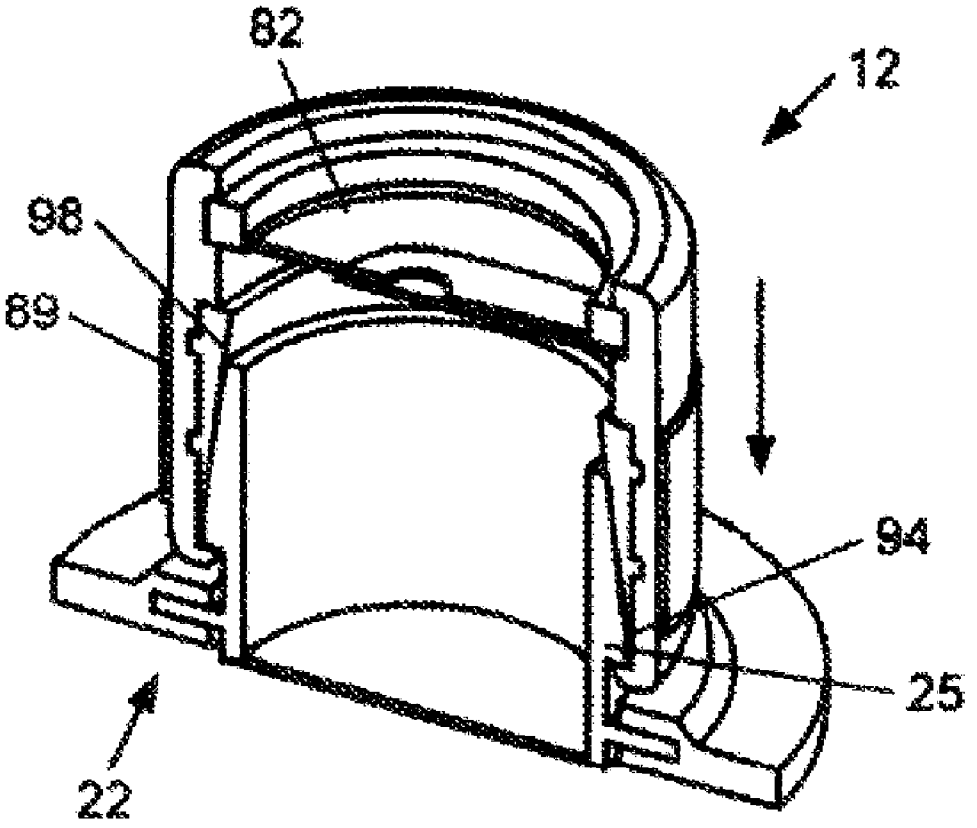


Fig. 26b

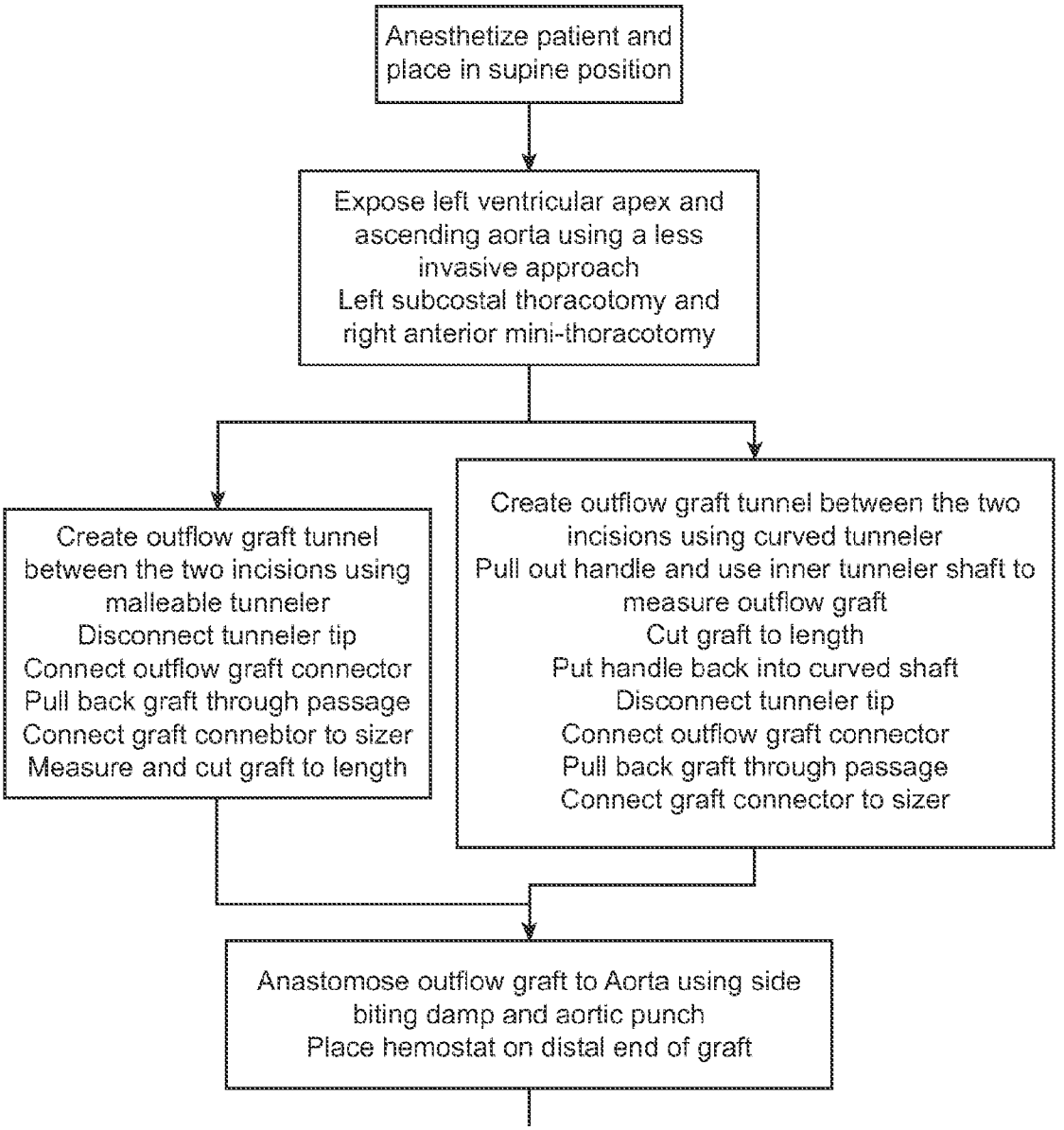

Anesthetize patient and place in supine position
Expose left ventricular apex and ascending aorta using a less invasive approach
Left subcostal thoracotomy and right anterior mini-thoracotomy
Create outflow graft tunnel between the two incisions using malleable tunneler
Disconnect tunneler tip
Connect outflow graft connector
Pull back graft through passage
Connect graft connebtor to sizer
Measure and cut graft to length
Create outflow graft tunnel between the two incisions using curved tunneler
Pull out handle and use inner tunneler shaft to measure outflow graft
Cut graft to length
Put handle back into curved shaft
Disconnect tunneler tip
Connect outflow graft connector
Pull back graft through passage
Connect graft connector to sizer
Anastomose outflow graft to Aorta using side biting damp and aortic punch
Place hemostat on distal end of graft

FIG. 27a

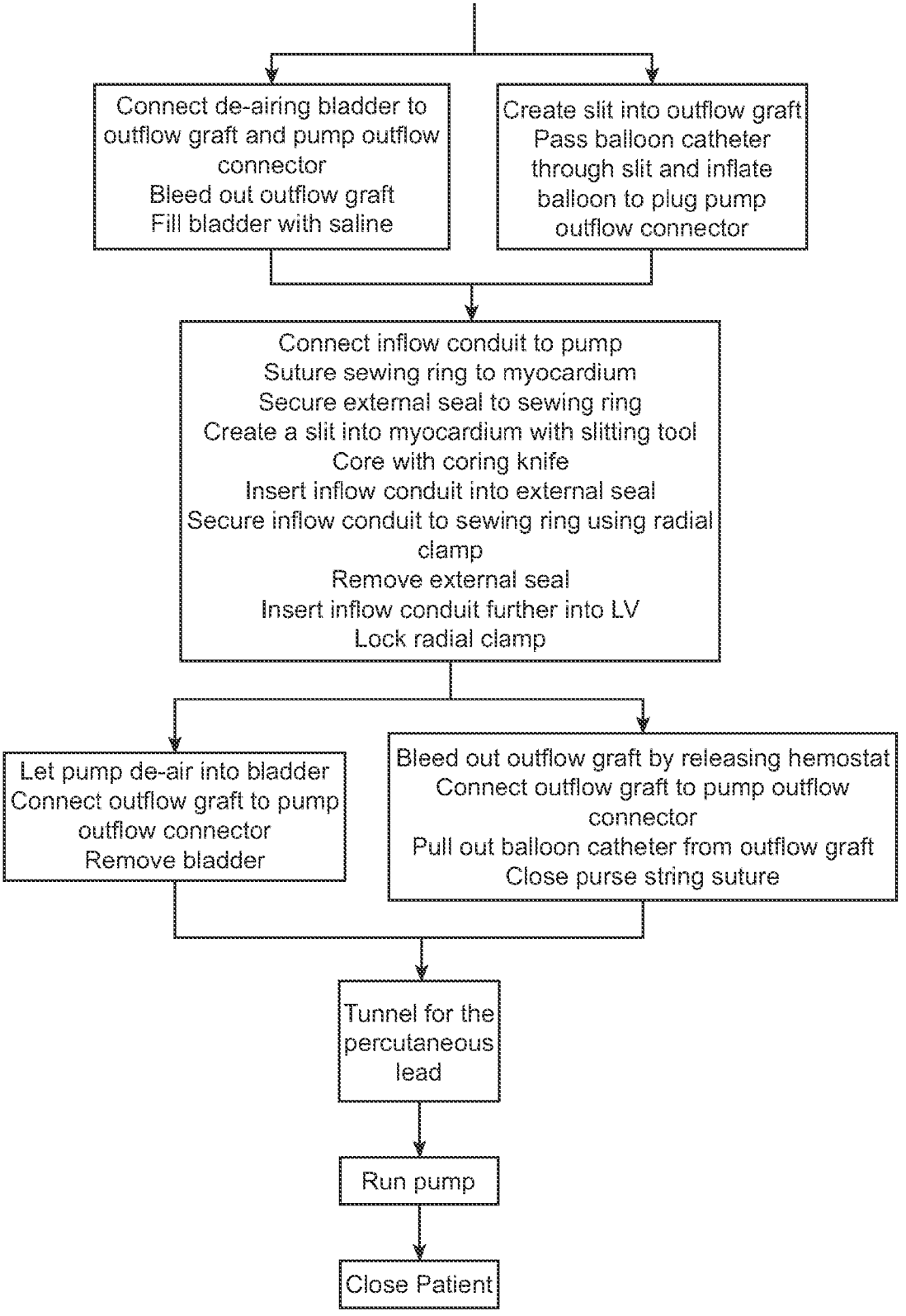

Connect de-airing bladder to outflow graft and pump outflow connector
Bleed out outflow graft
Fill bladder with saline
Create slit into outflow graft
Pass balloon catheter through slit and inflate balloon to plug pump outflow connector
Connect inflow conduit to pump
Suture sewing ring to myocardium
Secure external seal to sewing ring
Create a slit into myocardium with slitting tool
Core with coring knife
Insert inflow conduit into external seal
Secure inflow conduit to sewing ring using radial clamp
Remove external seal
Insert inflow conduit further into LV
Lock radial clamp
Let pump de-air into bladder
Connect outflow graft to pump outflow connector
Remove bladder
Bleed out outflow graft by releasing hemostat
Connect outflow graft to pump outflow connector
Pull out balloon catheter from outflow graft
Close purse string suture
Tunnel for the percutaneous lead
Run pump
Close Patient

FIG. 27b

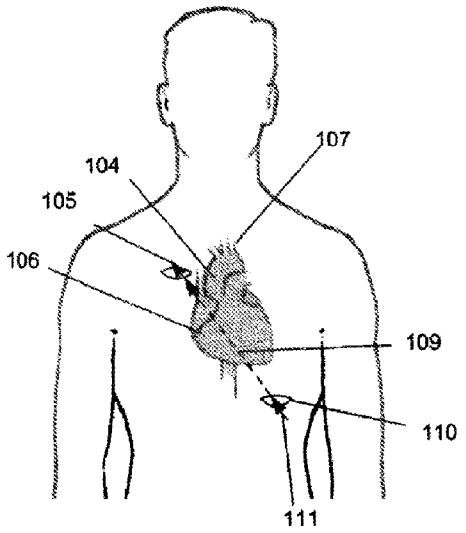


Fig. 28a

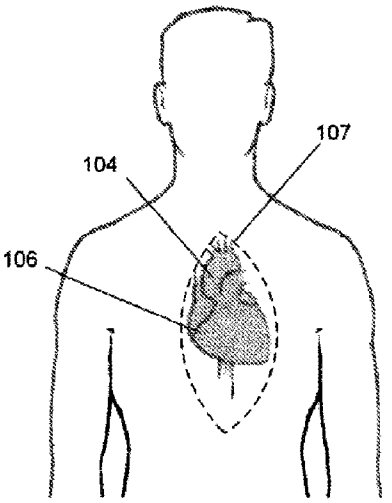


Fig. 28b

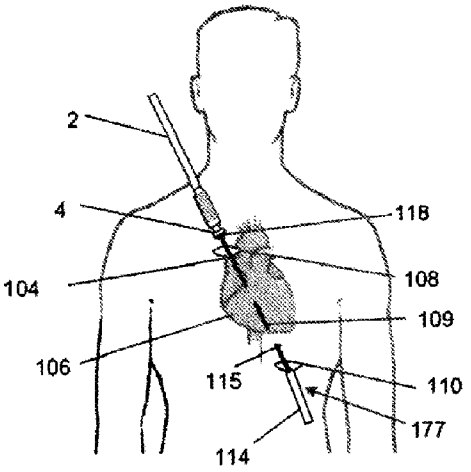


Fig. 32

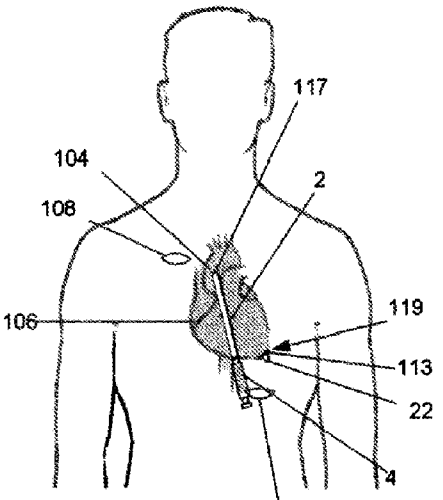


Fig. 35

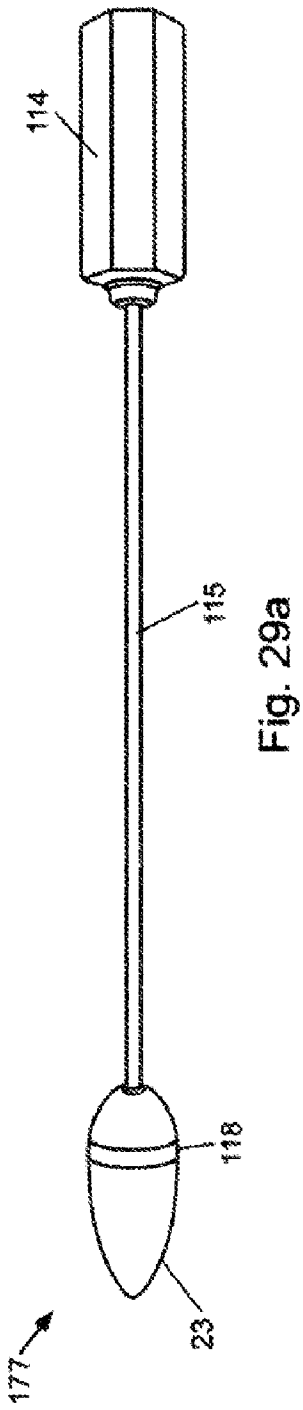


Fig. 29a

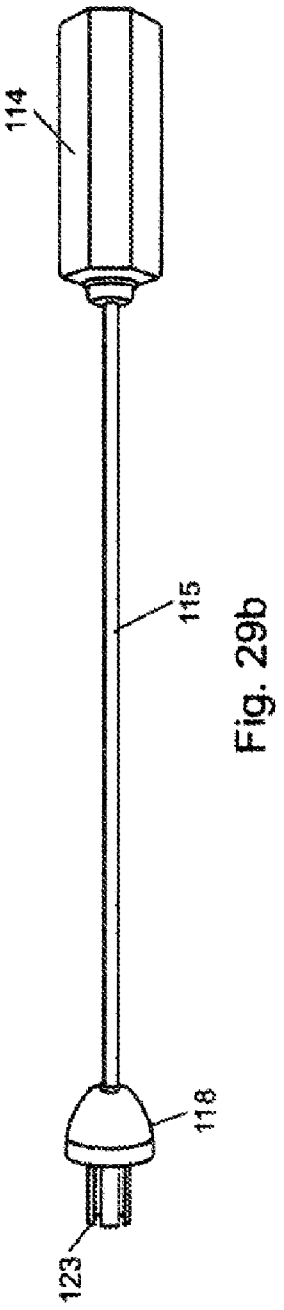


Fig. 29b

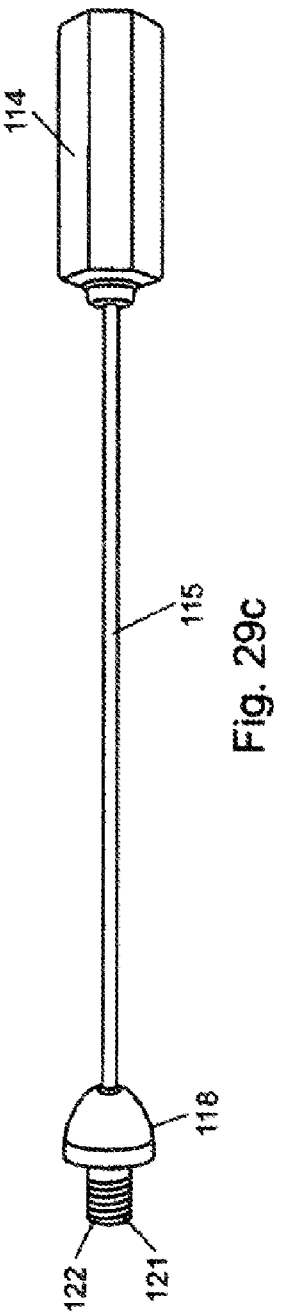


Fig. 29c

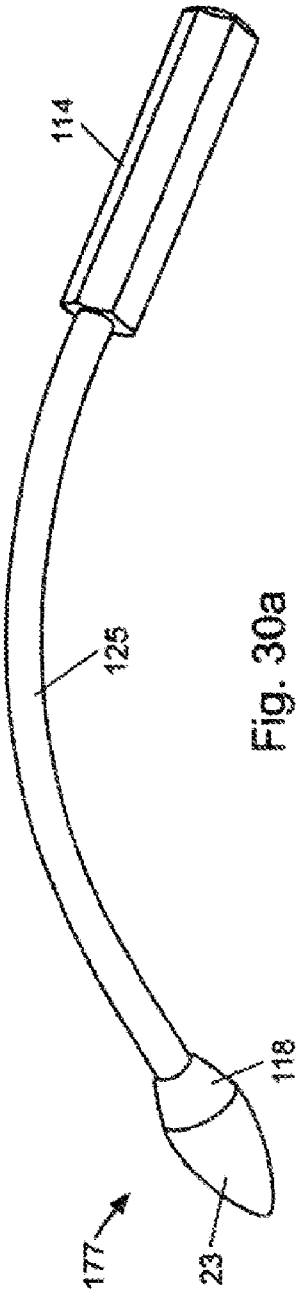


Fig. 30a

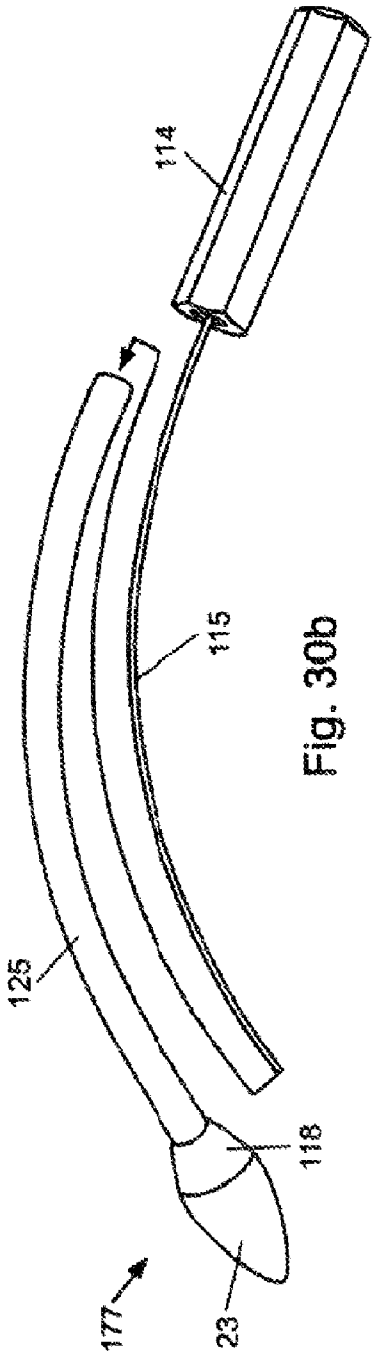


Fig. 30b

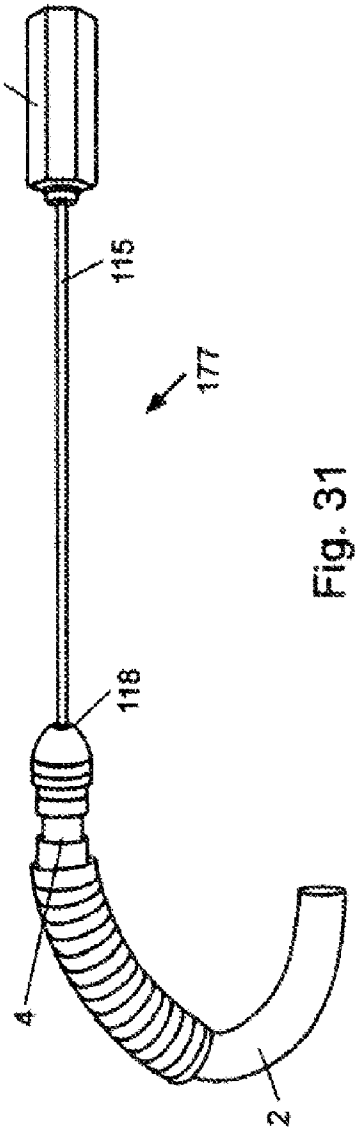


Fig. 31

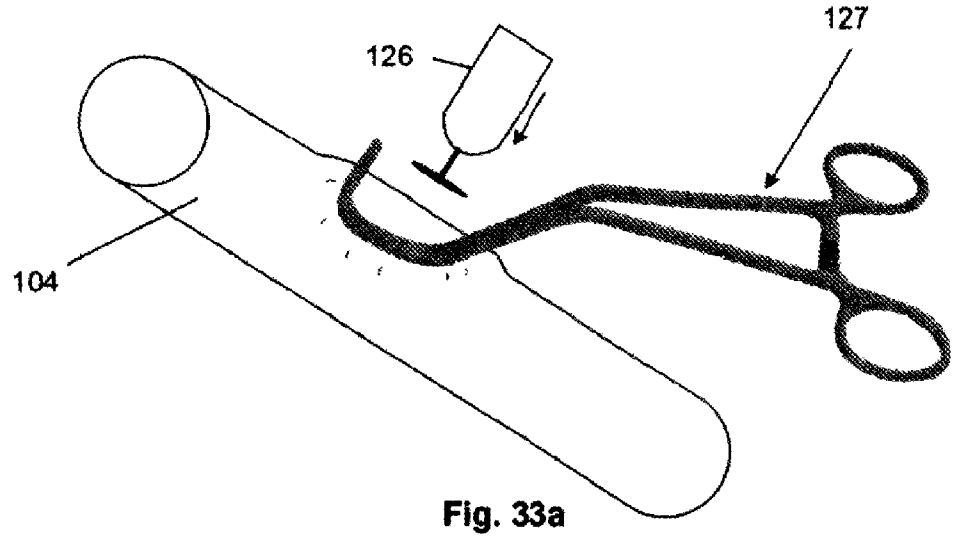


Fig. 33a

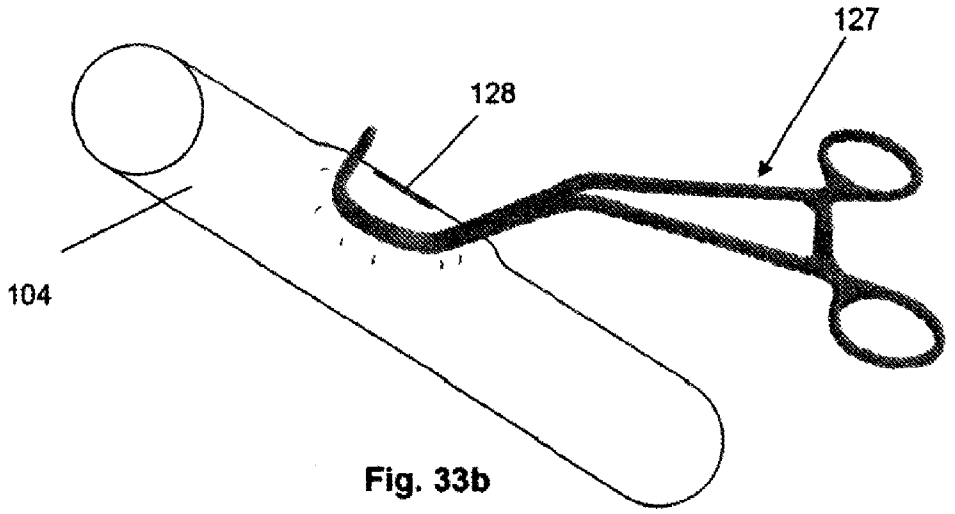


Fig. 33b

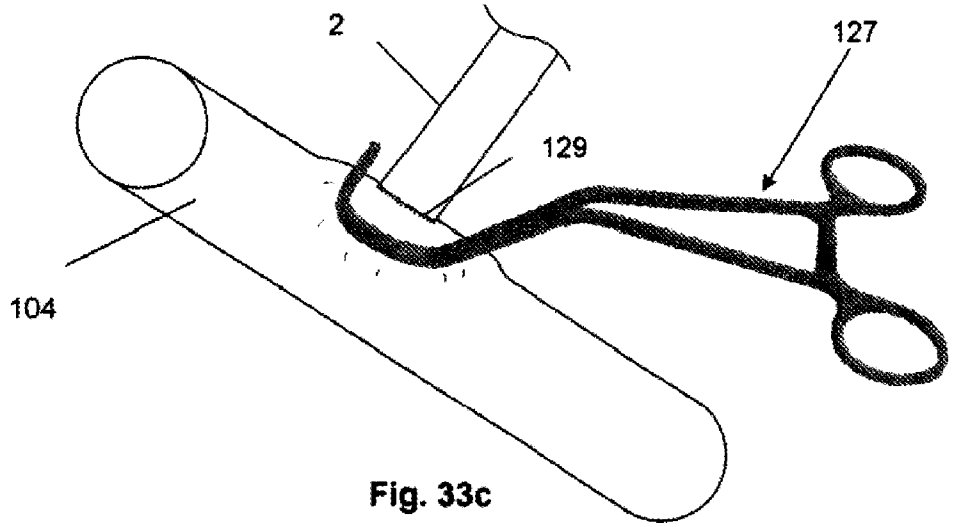


Fig. 33c

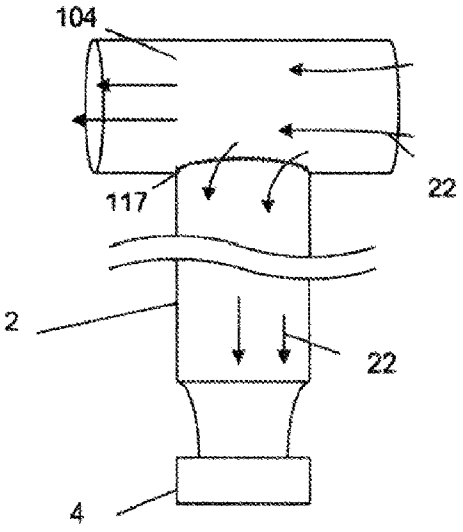


Fig. 34a

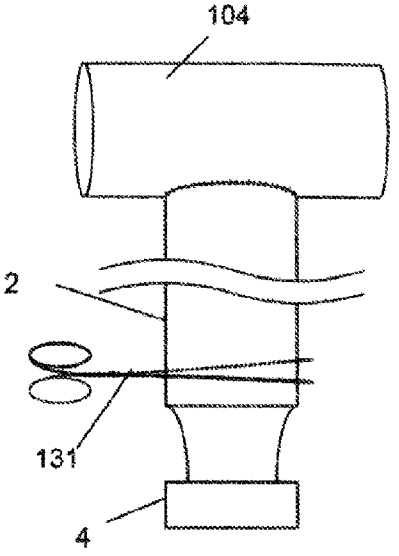


Fig. 34b

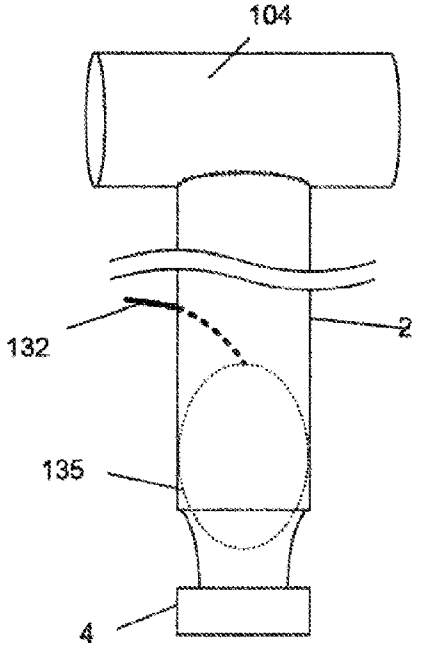


Fig. 34c

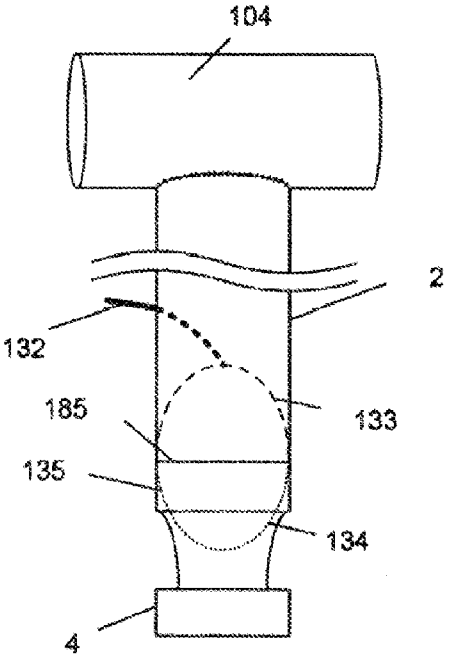
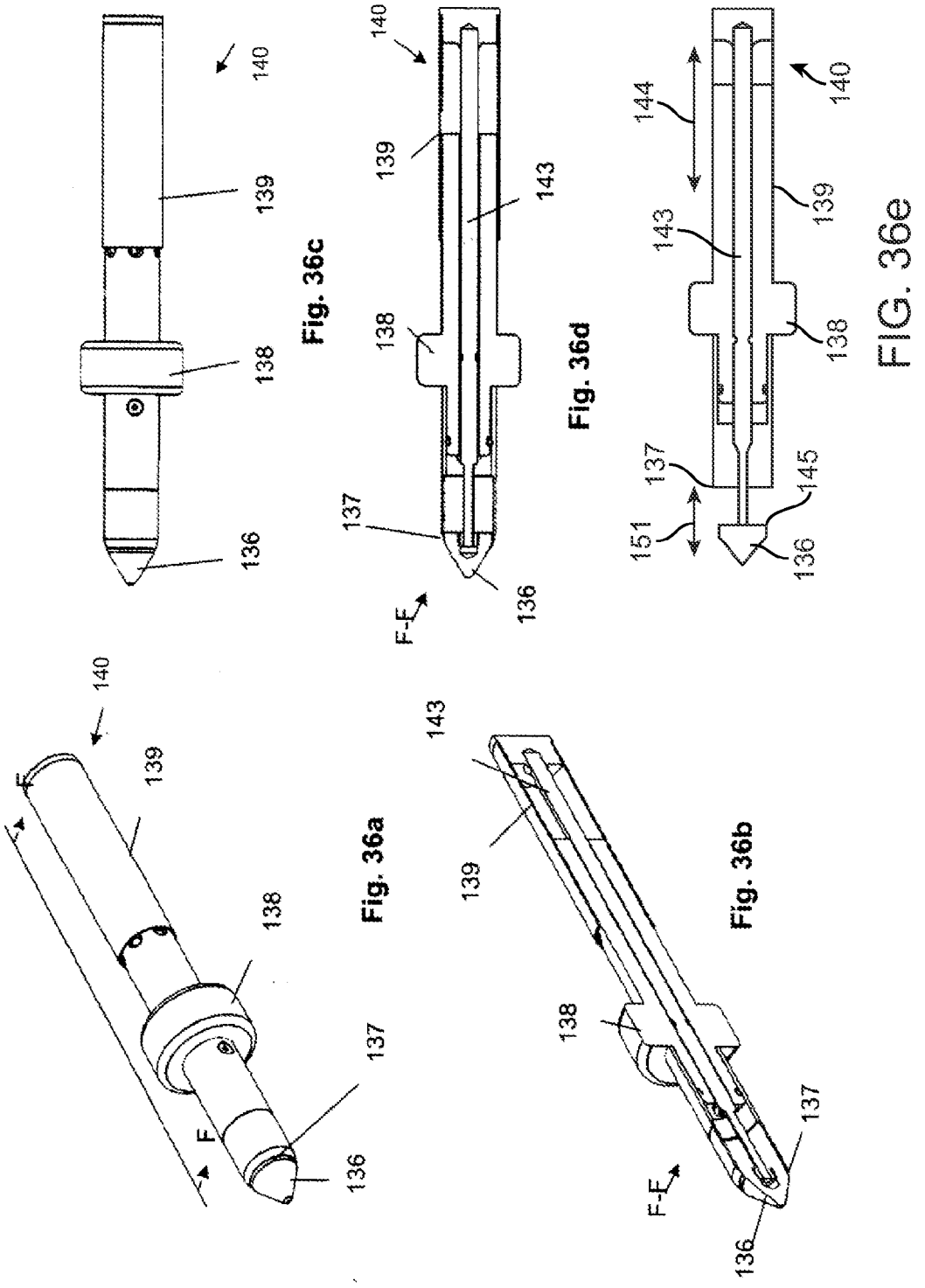


Fig. 34d


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Fig. 36c
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Fig. 36d
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FIG. 36e
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Fig. 36a
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F-F
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Fig. 36b

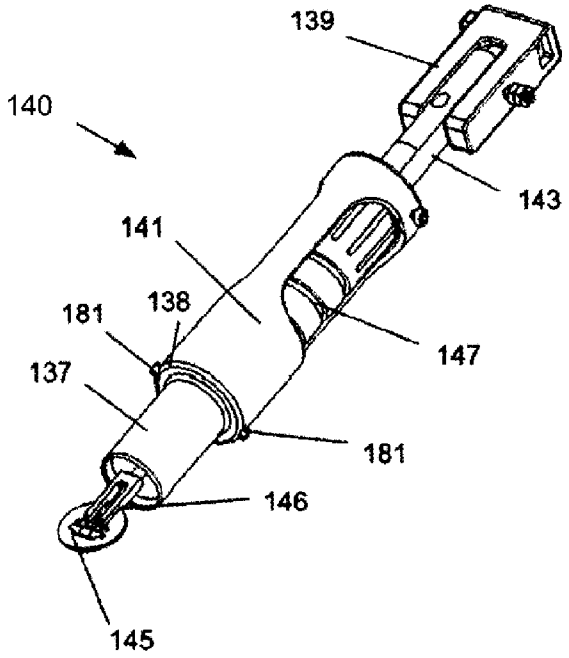


Fig. 37a

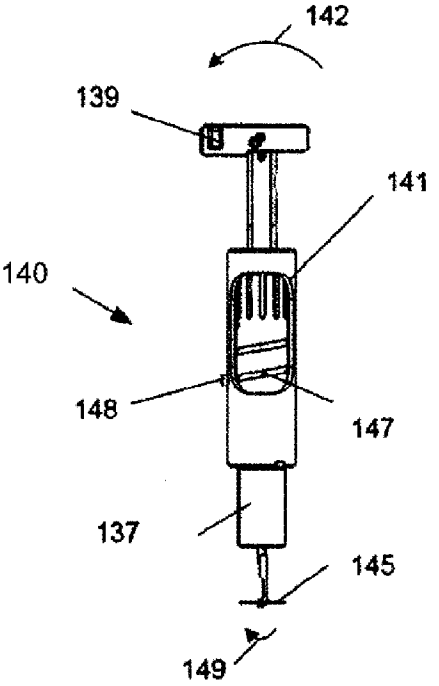


Fig. 37c

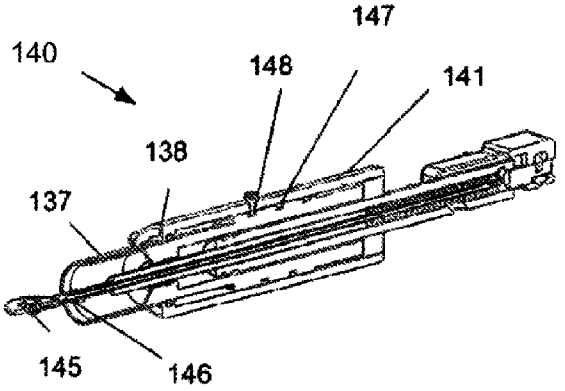


Fig. 37b

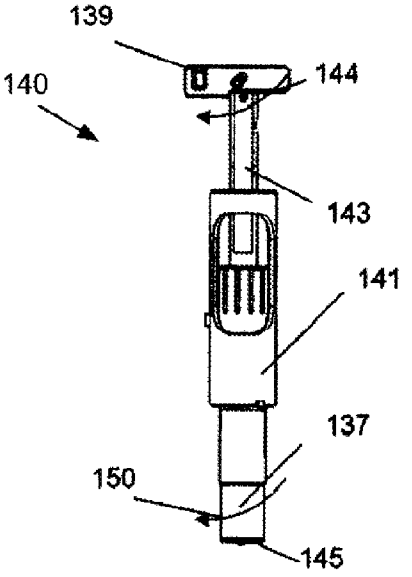


Fig. 37d

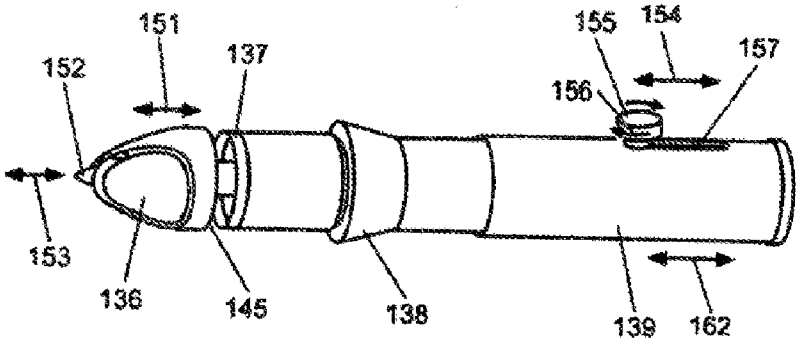


Fig. 38

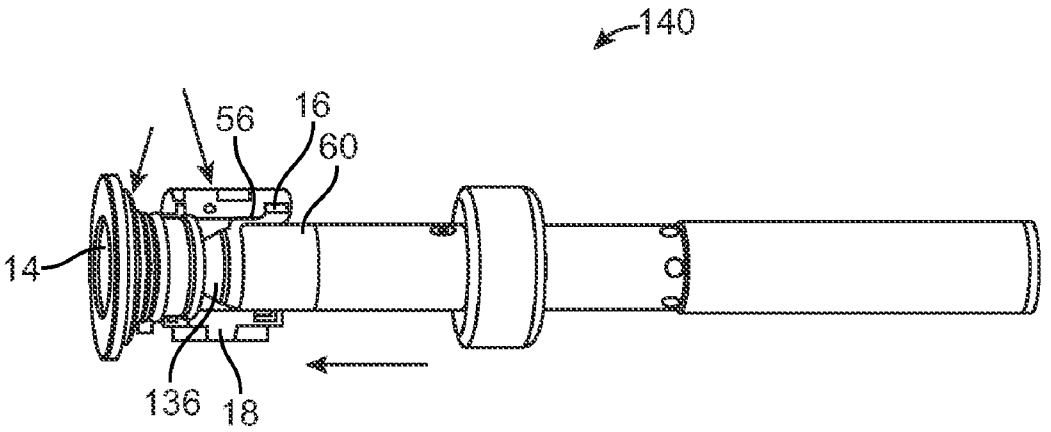


FIG. 39a

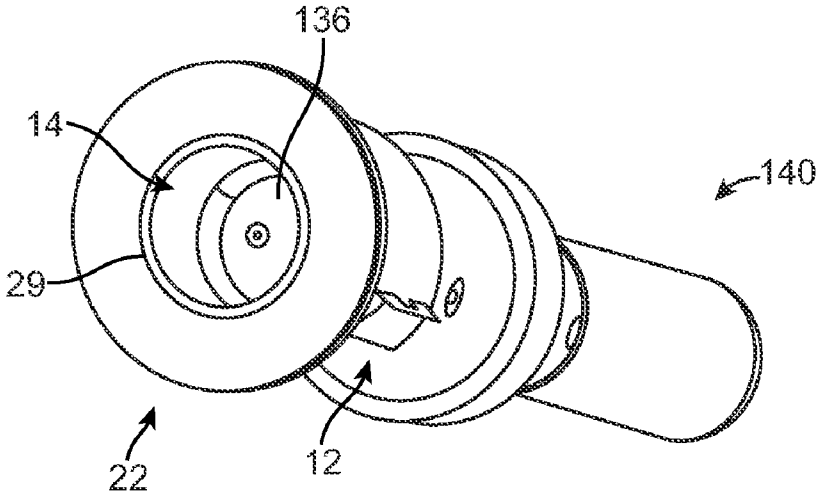


FIG. 39b

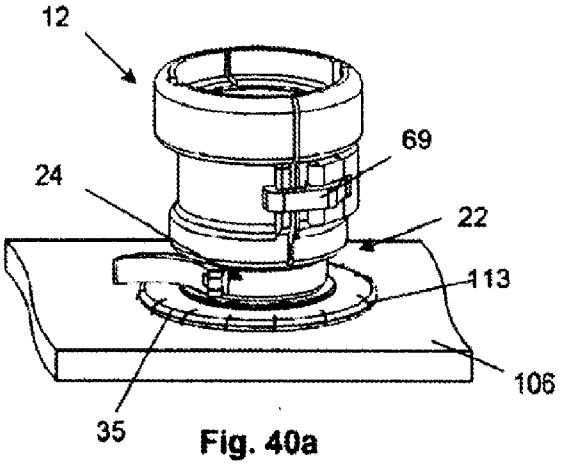


Fig. 40a

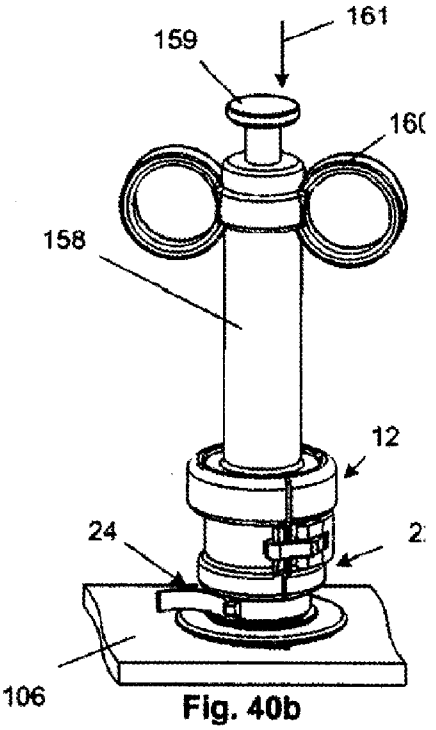


Fig. 40b

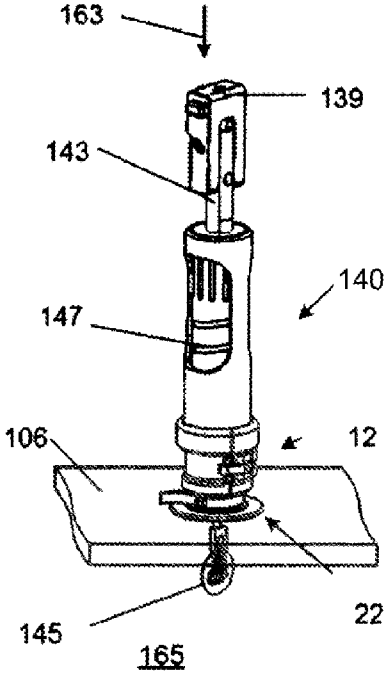


Fig. 40c

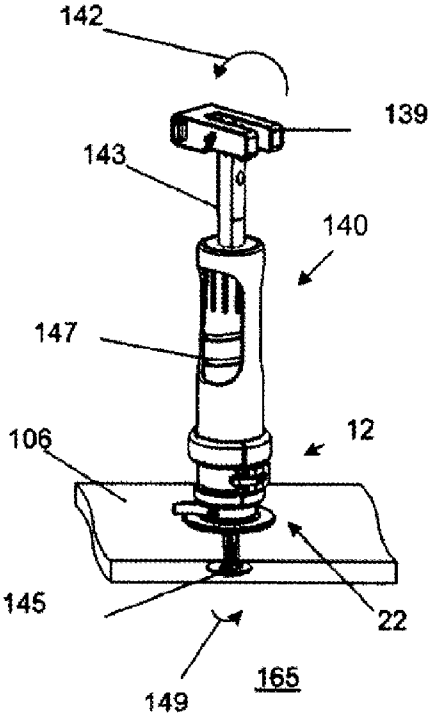


Fig. 40d

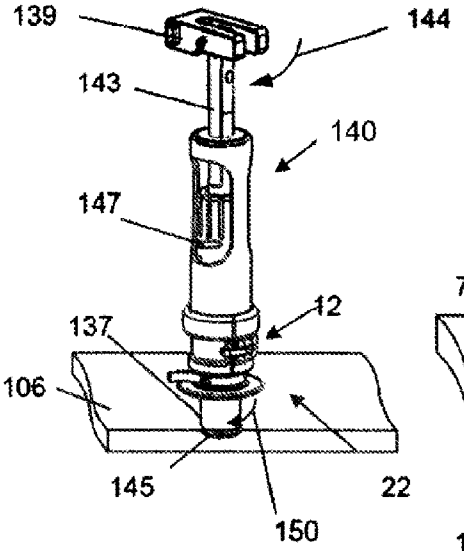


Fig. 40e

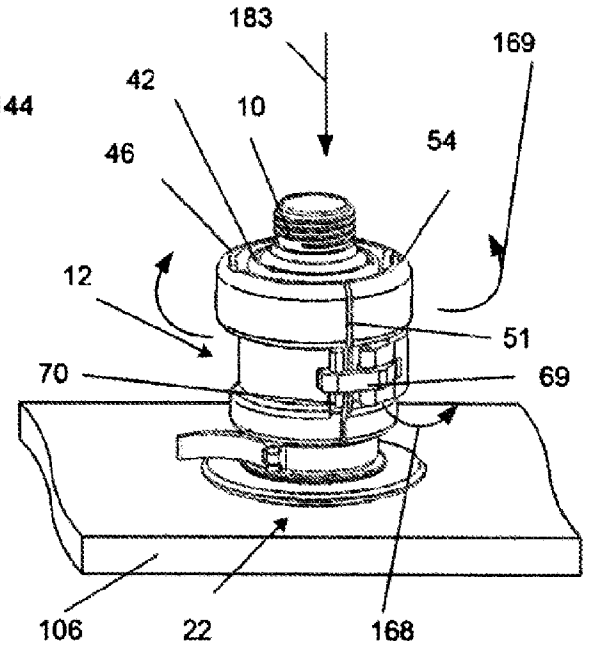


Fig. 40f

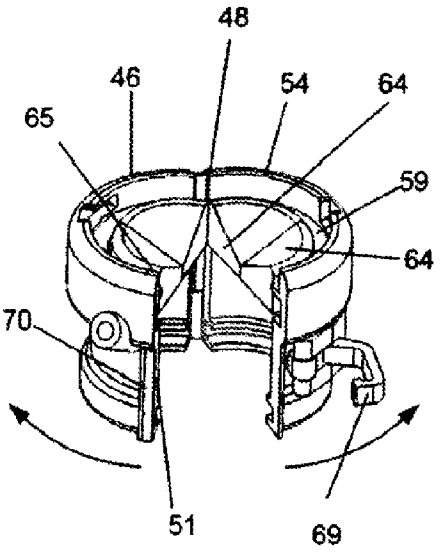


Fig. 40g

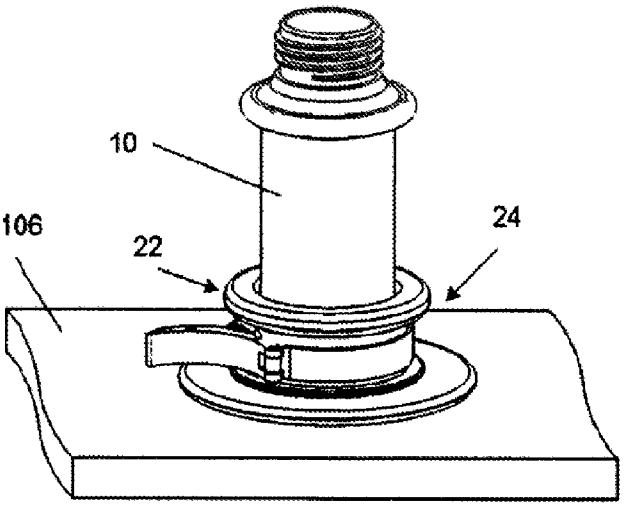


Fig. 40h

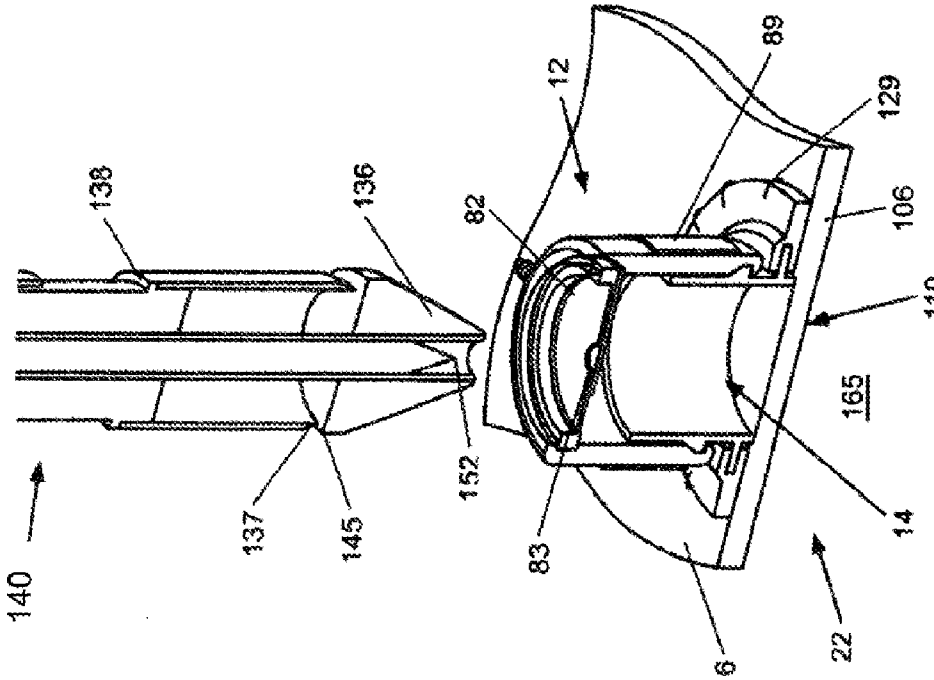


Fig. 41a

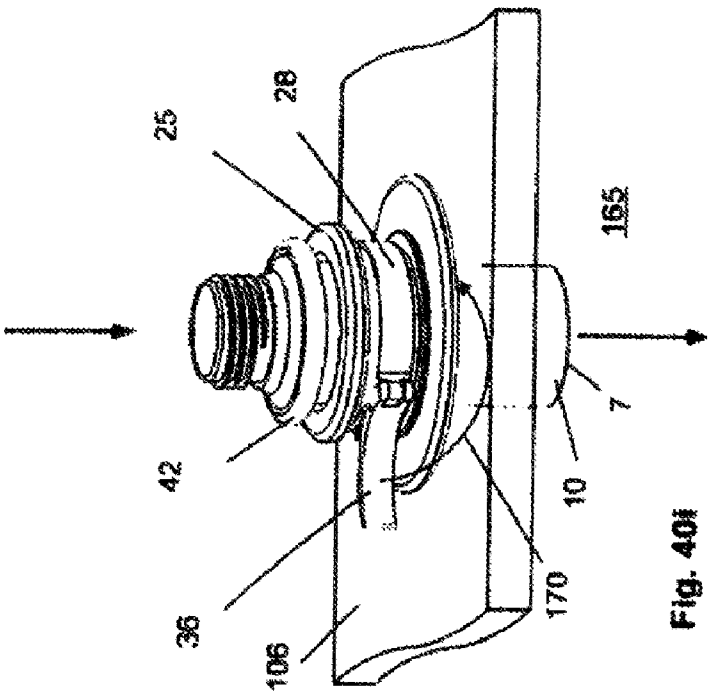


Fig. 40i

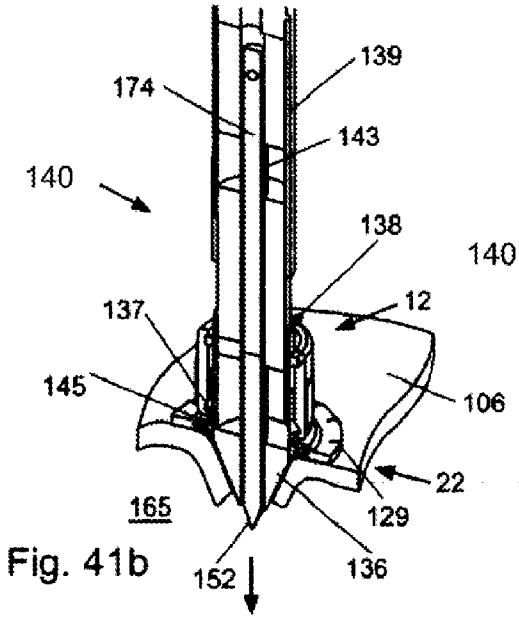


Fig. 41b

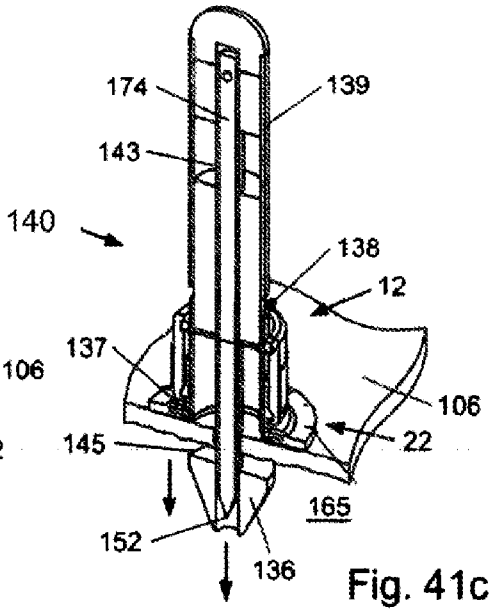


Fig. 41c

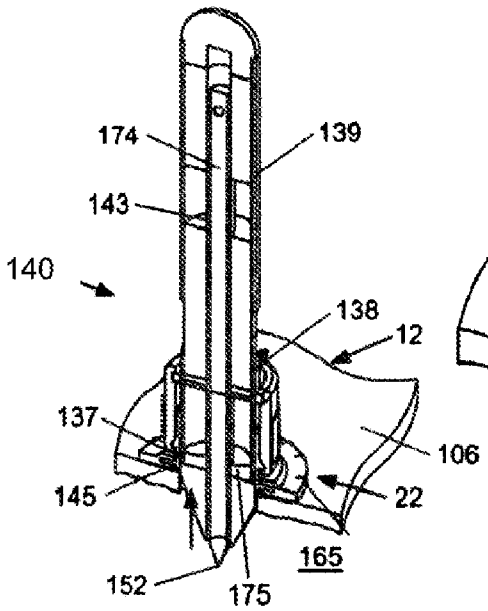


Fig. 41d

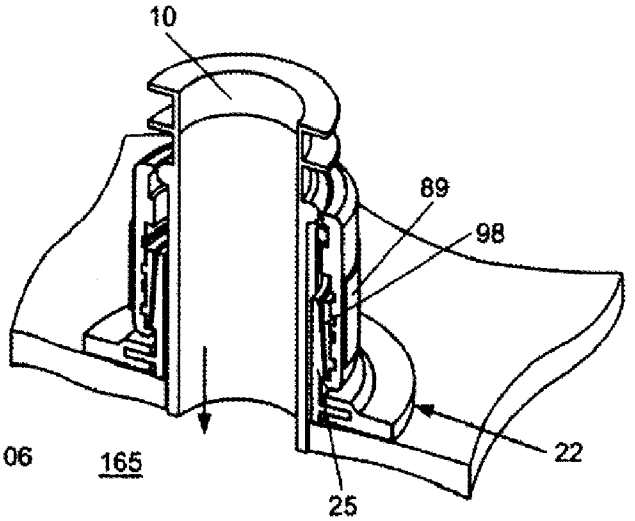


Fig. 42a

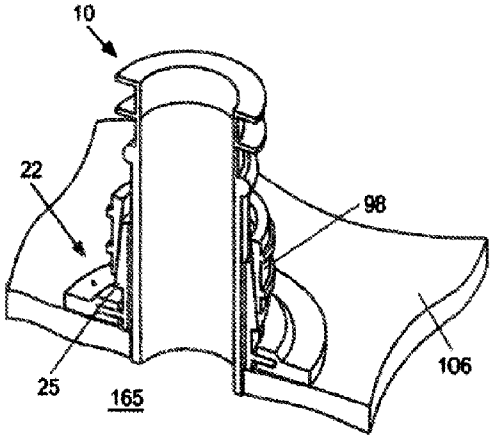


Fig. 42b

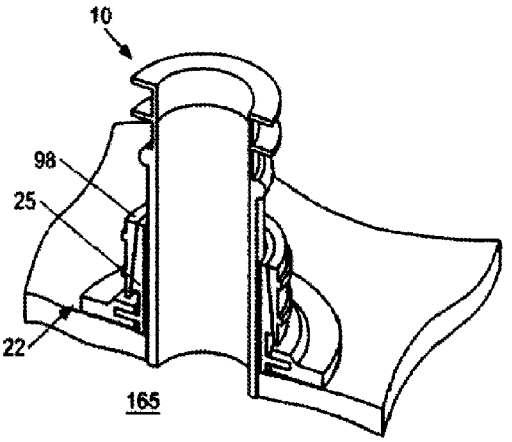


Fig. 42c

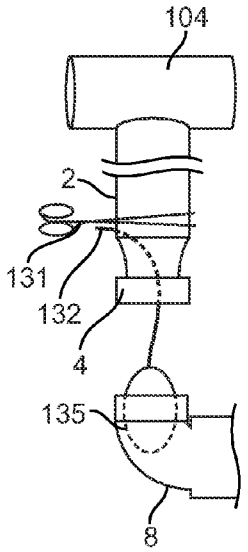


FIG. 43a

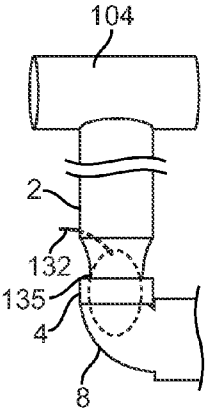


FIG. 43b

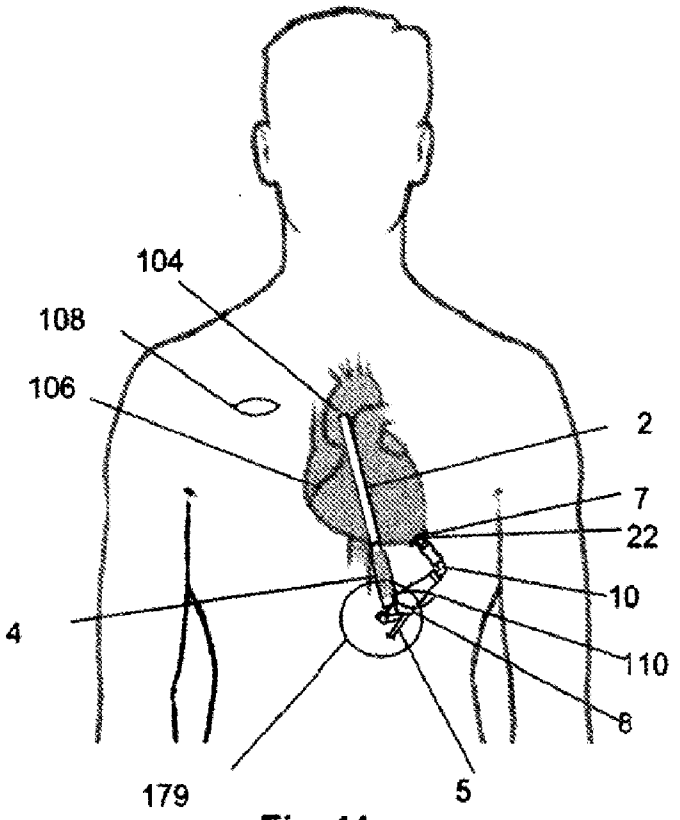


Fig. 44

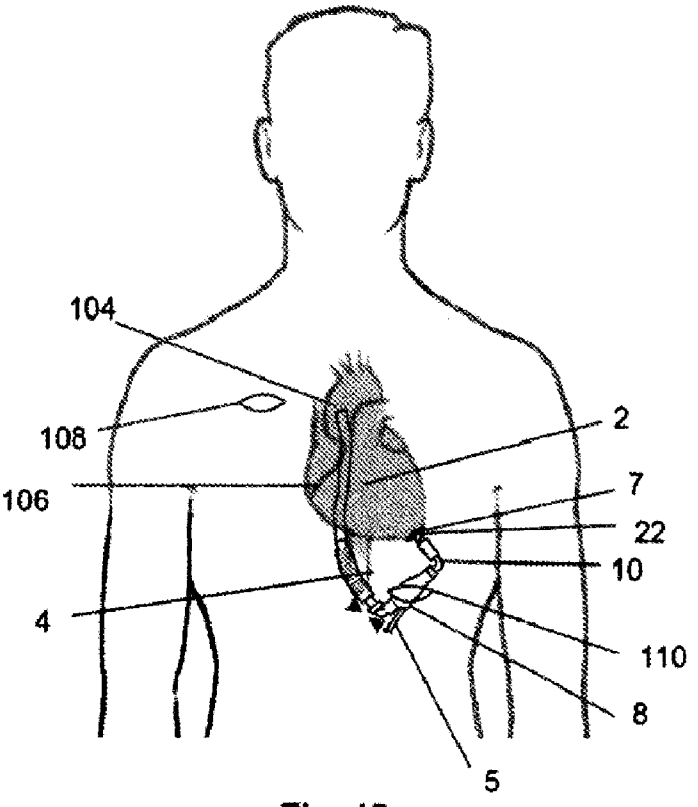


Fig. 45

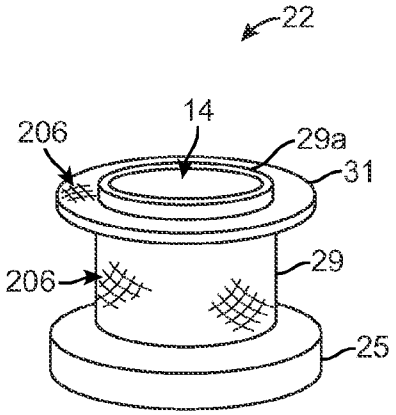


FIG. 46a

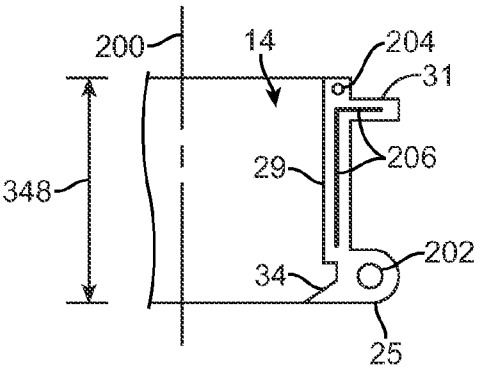


FIG. 46b

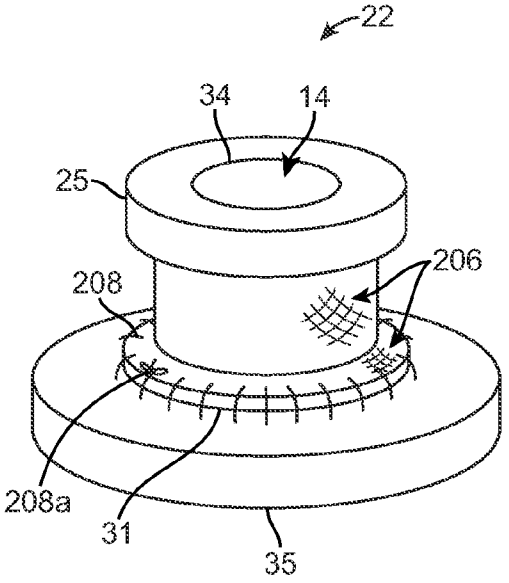


FIG. 46c

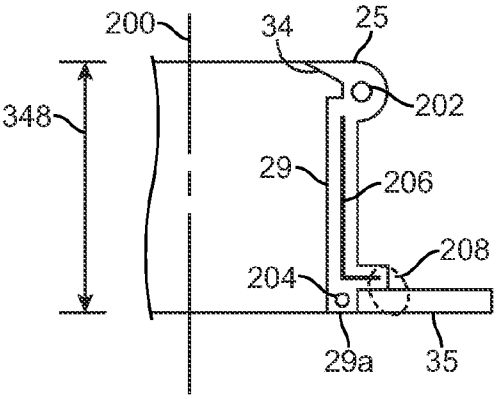


FIG. 46d

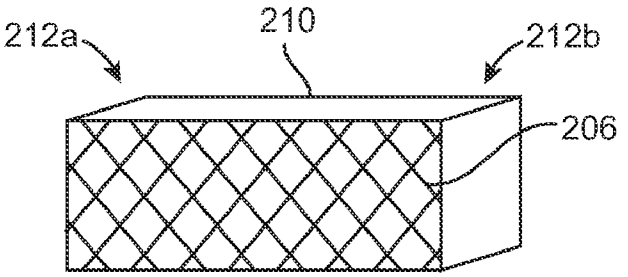


FIG. 47a

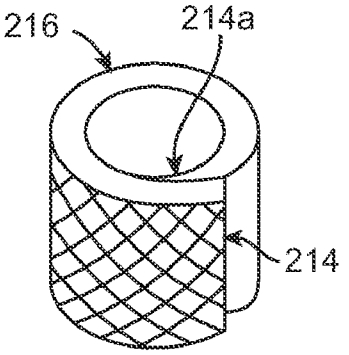


FIG. 47b

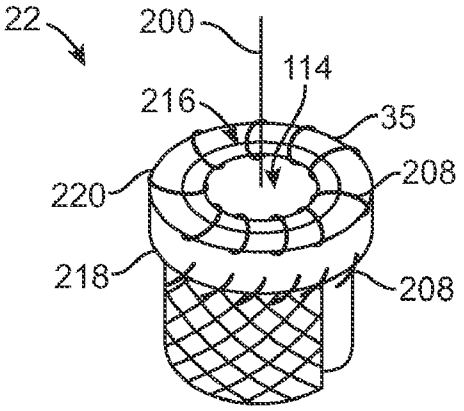


FIG. 47c

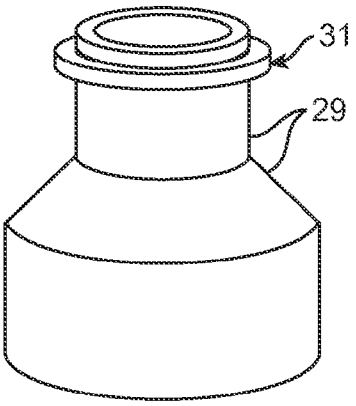


FIG. 48a

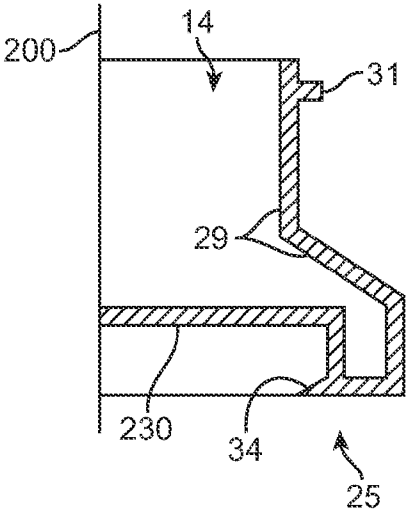


FIG. 48b

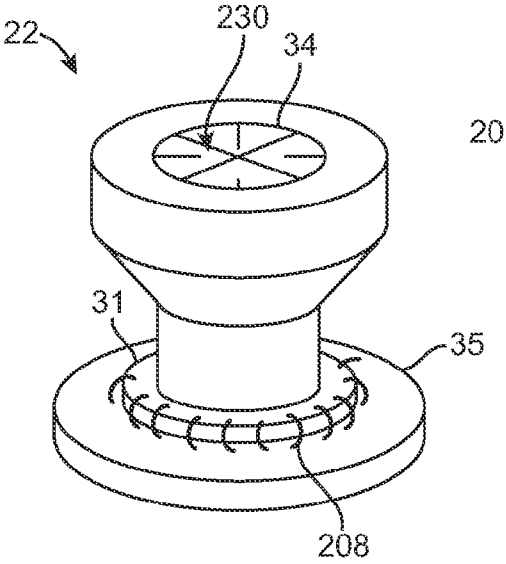


FIG. 48c

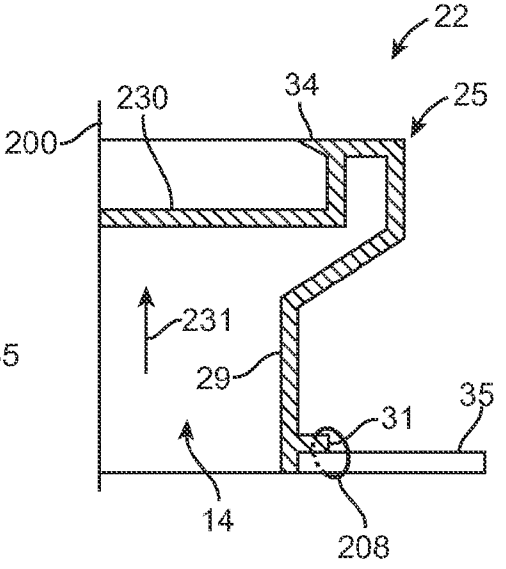


FIG. 48d

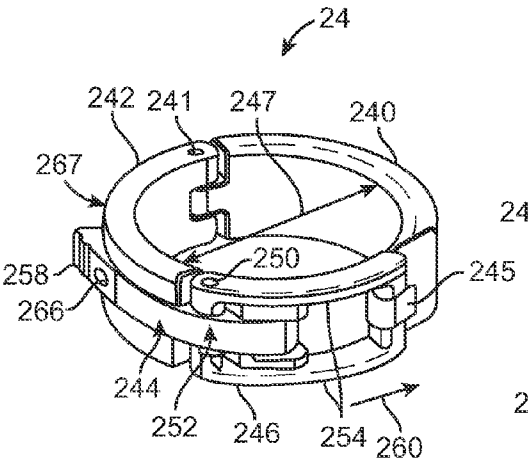


FIG. 49a

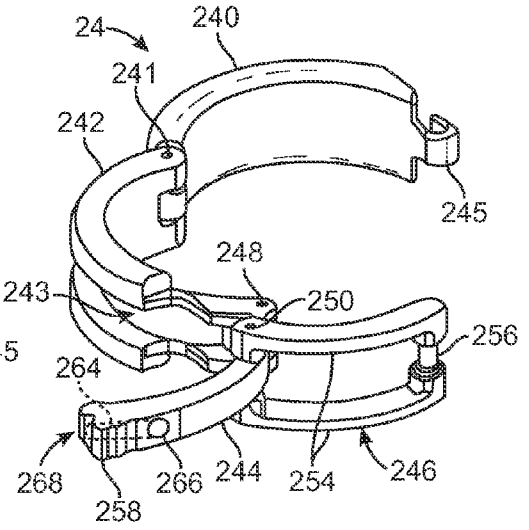


FIG. 49b

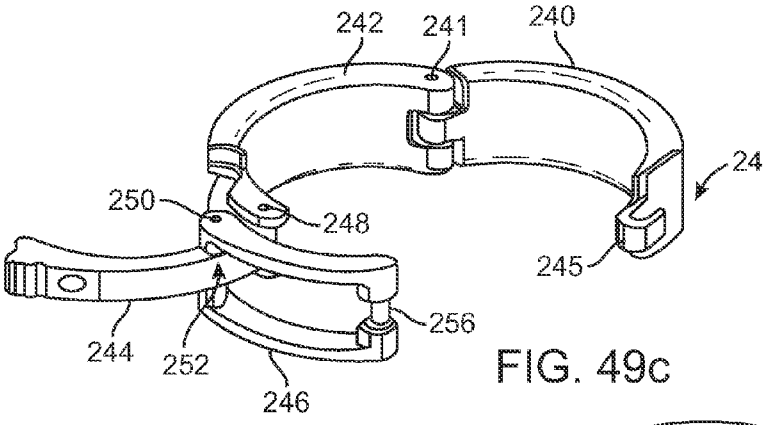


FIG. 49c

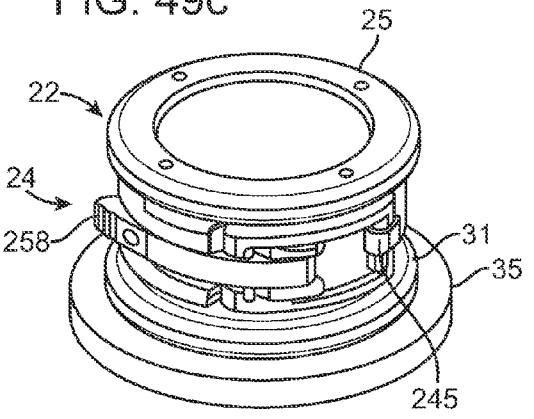


FIG. 49d

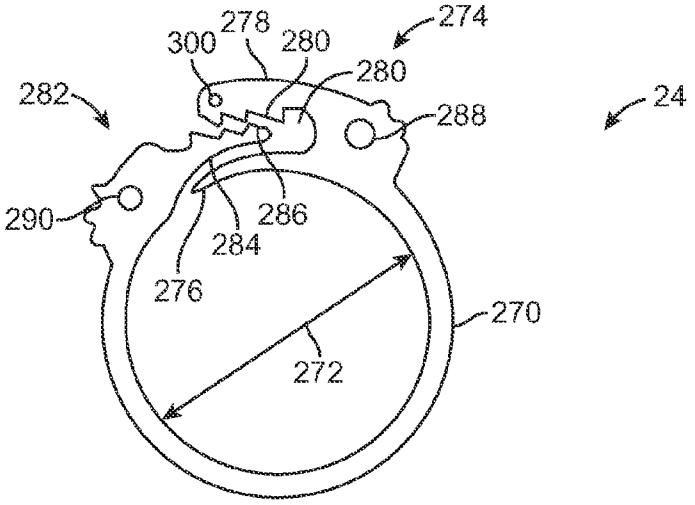


FIG. 50a

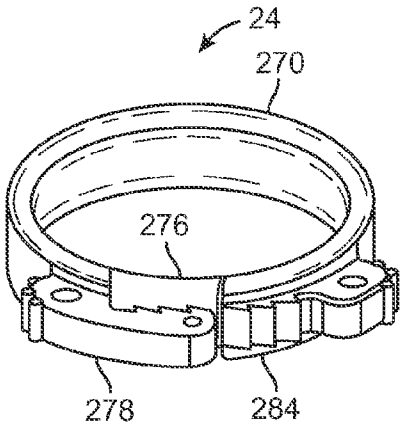


FIG. 50b

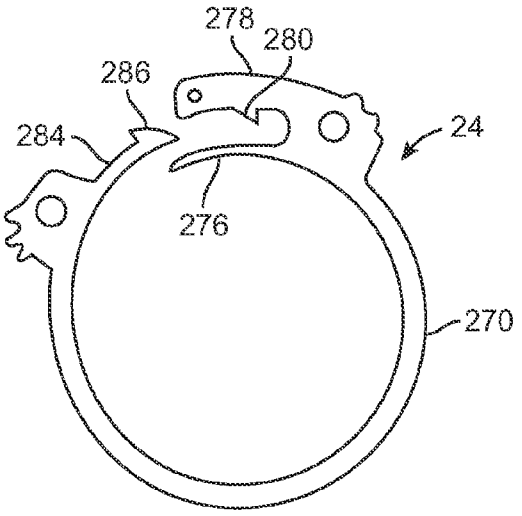


FIG. 51

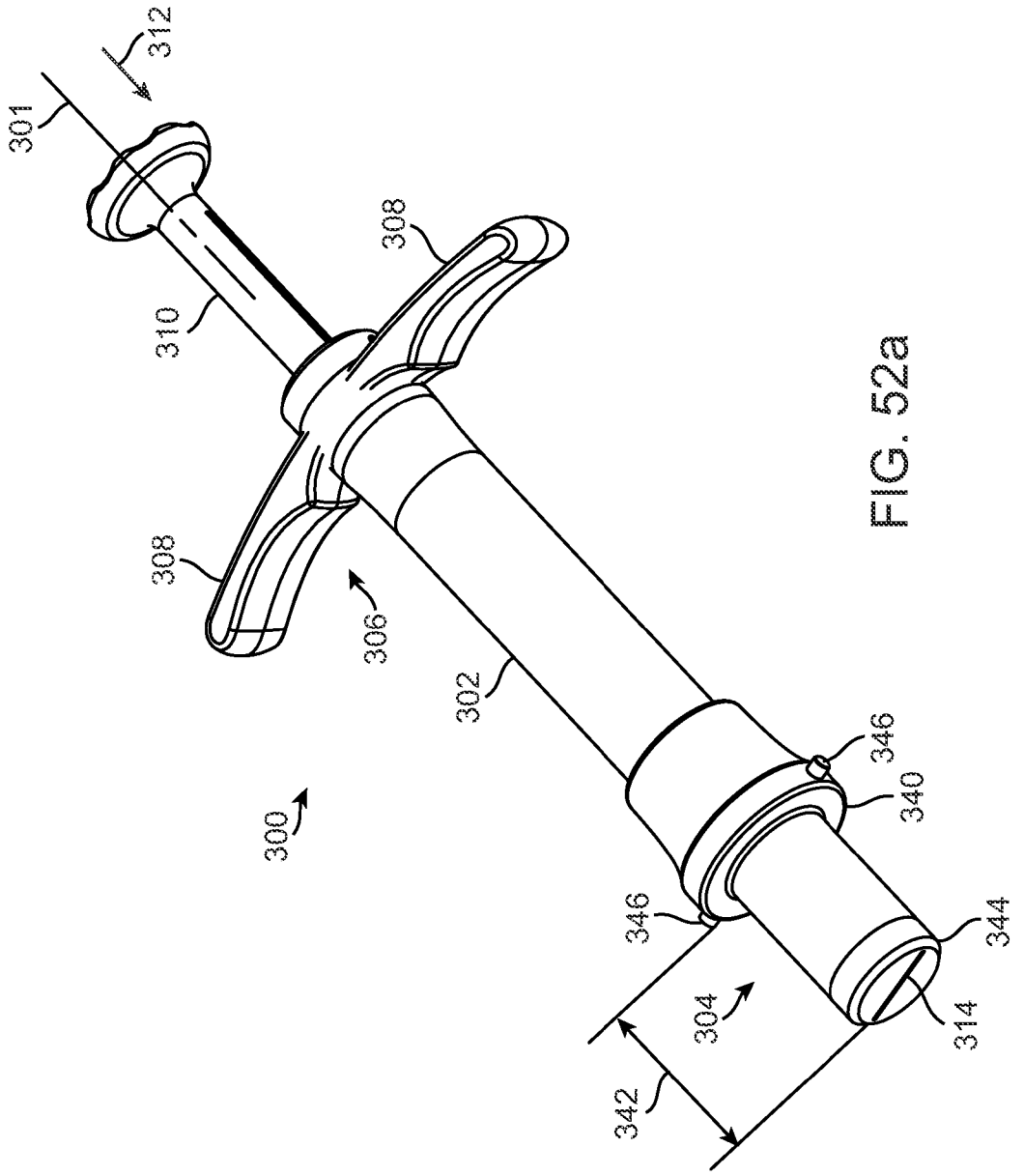


FIG. 52a

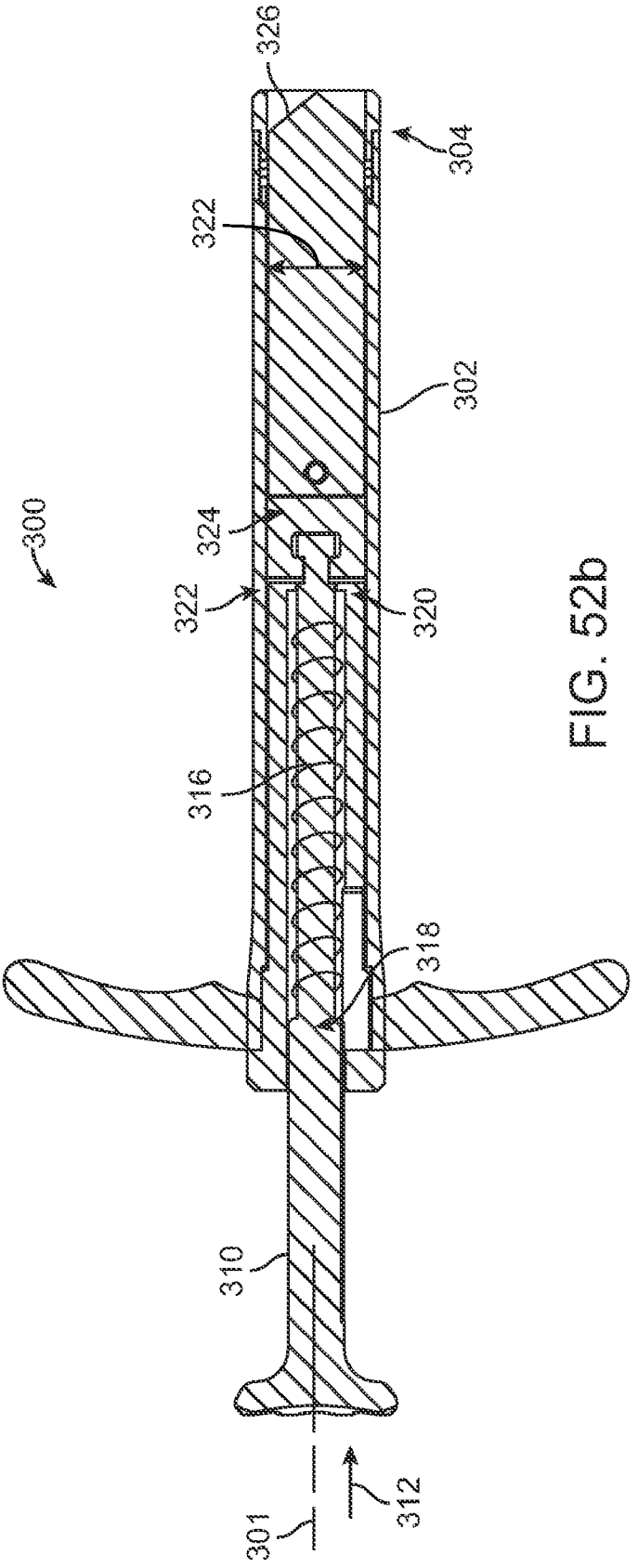


FIG. 52b

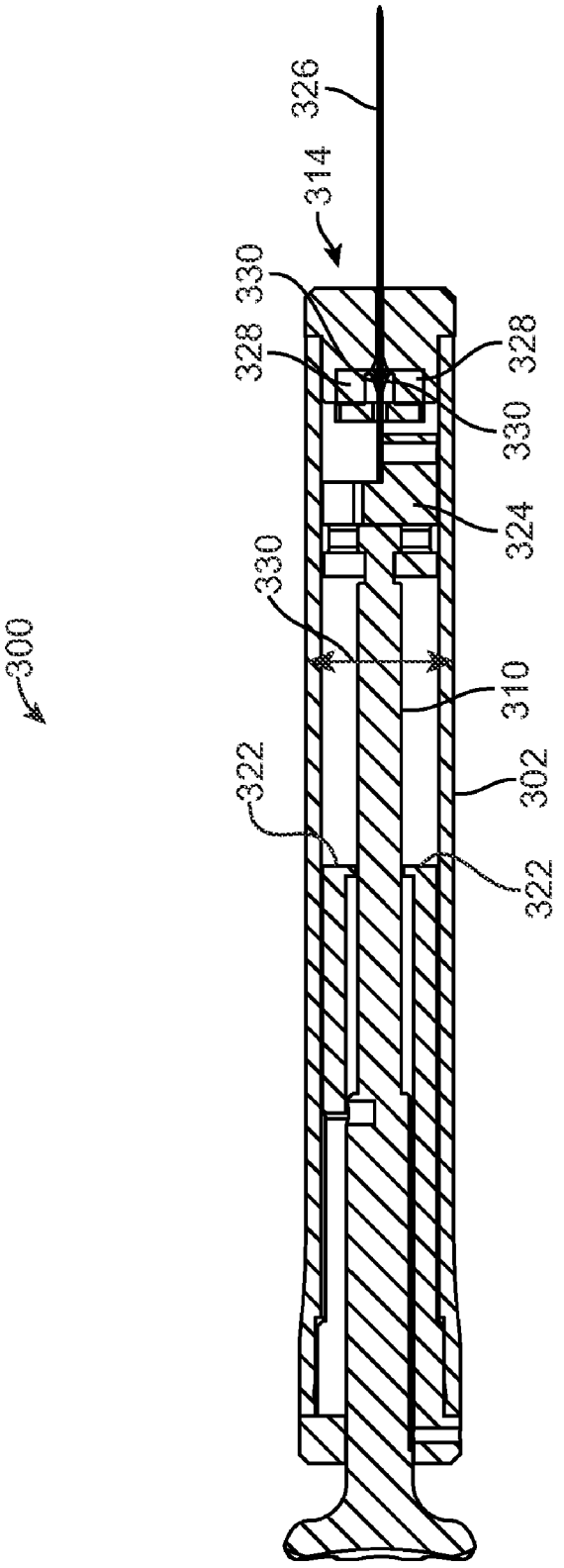


FIG. 52c

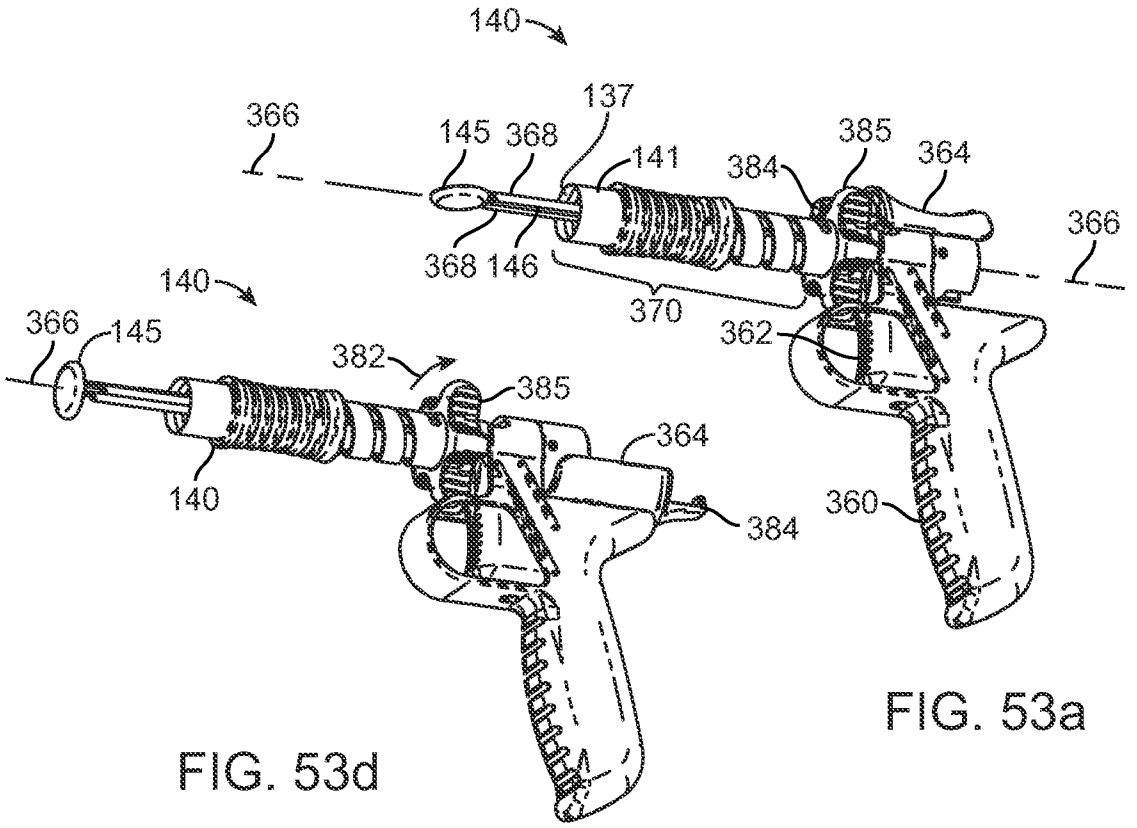


FIG. 53d

FIG. 53a

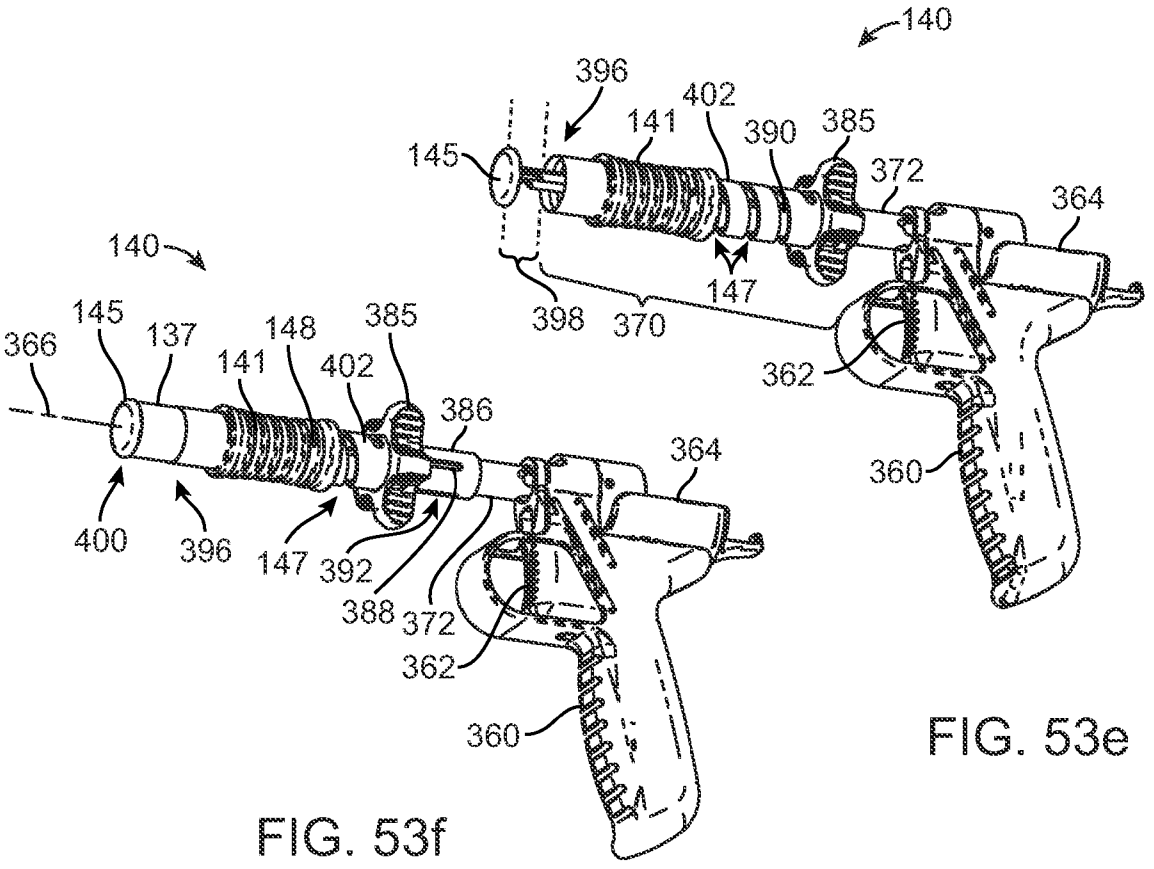


FIG. 53e

FIG. 53f

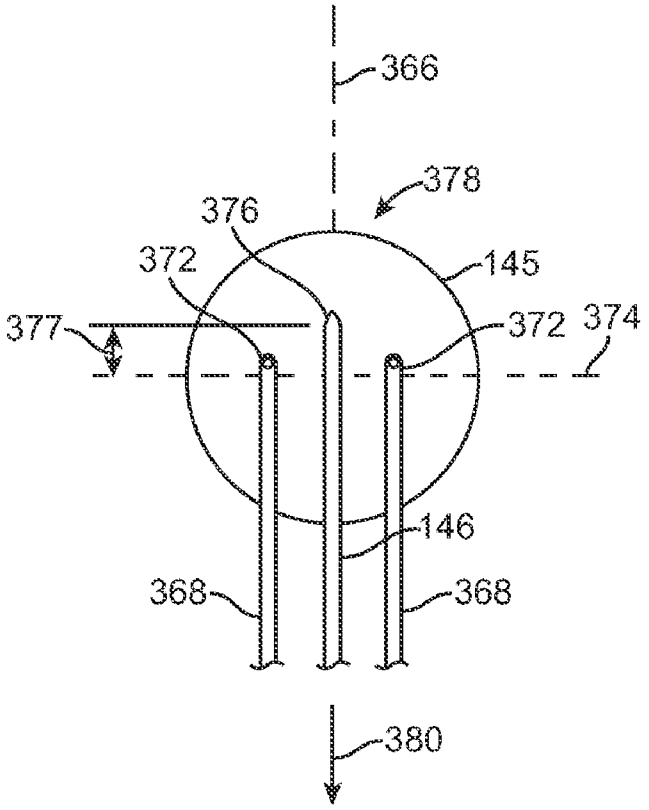


FIG. 53b

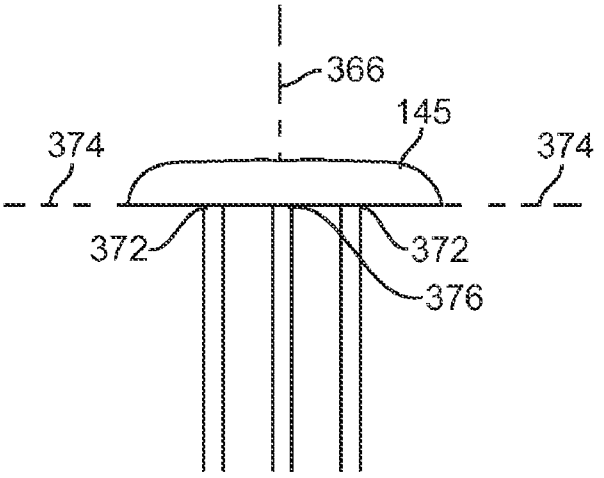


FIG. 53c

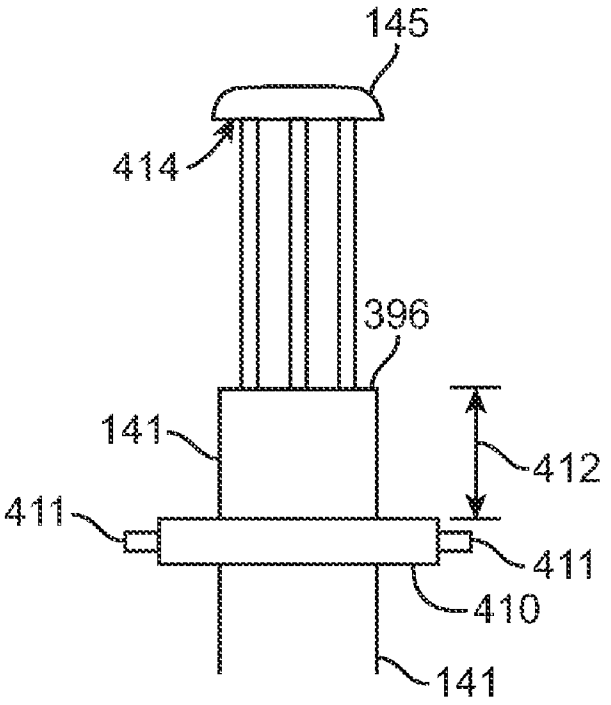


FIG. 54

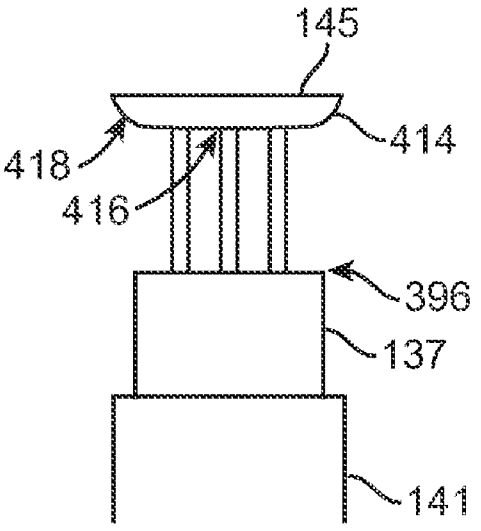


FIG. 55

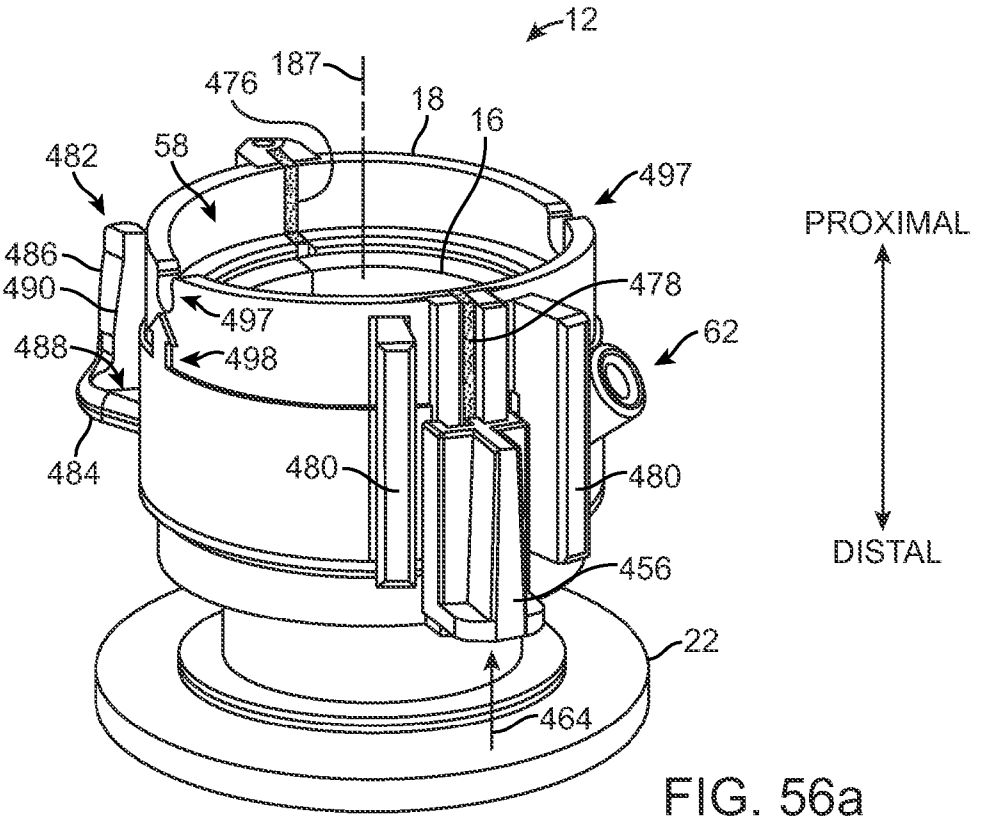


FIG. 56a

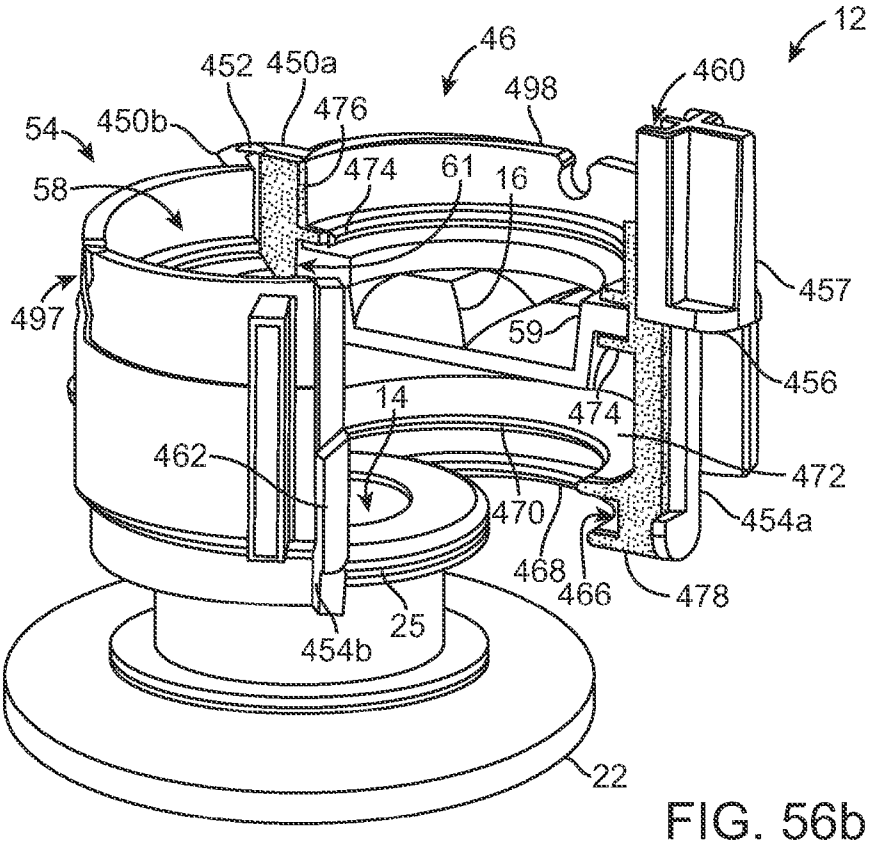


FIG. 56b

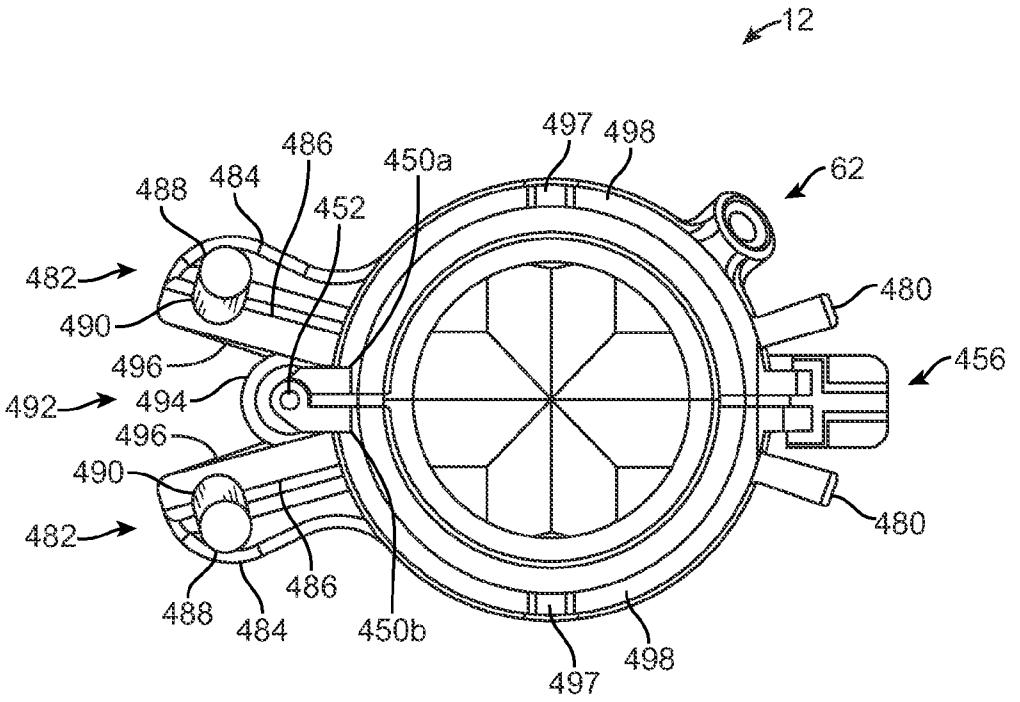


FIG. 56c

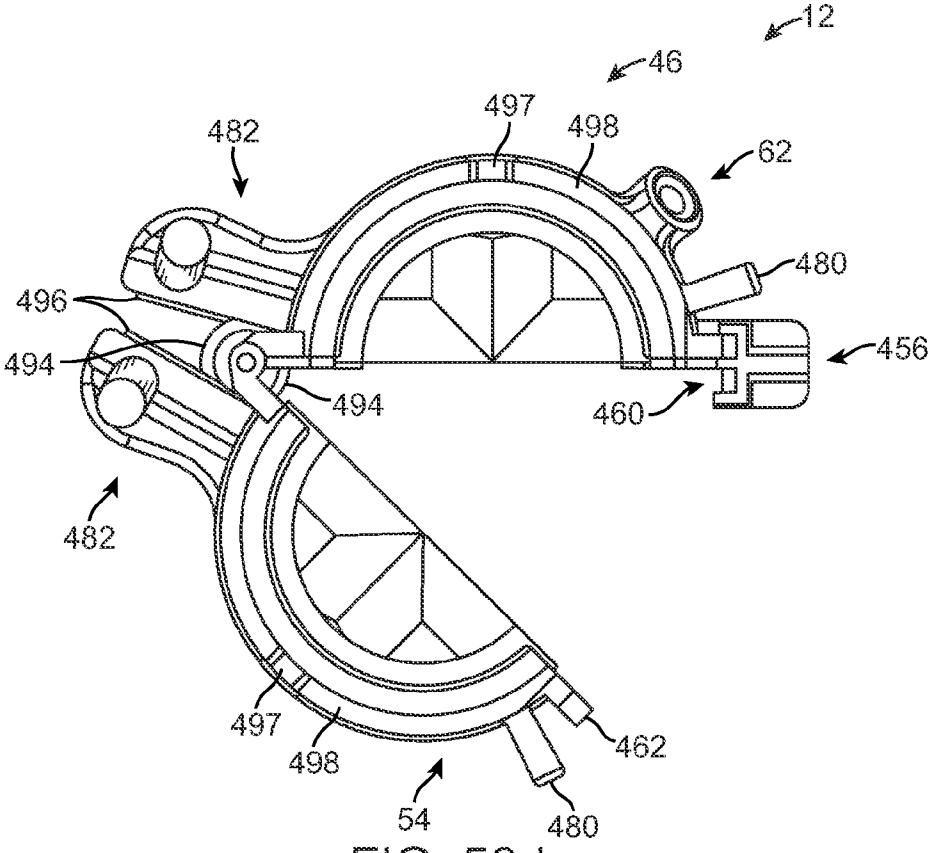


FIG. 56d

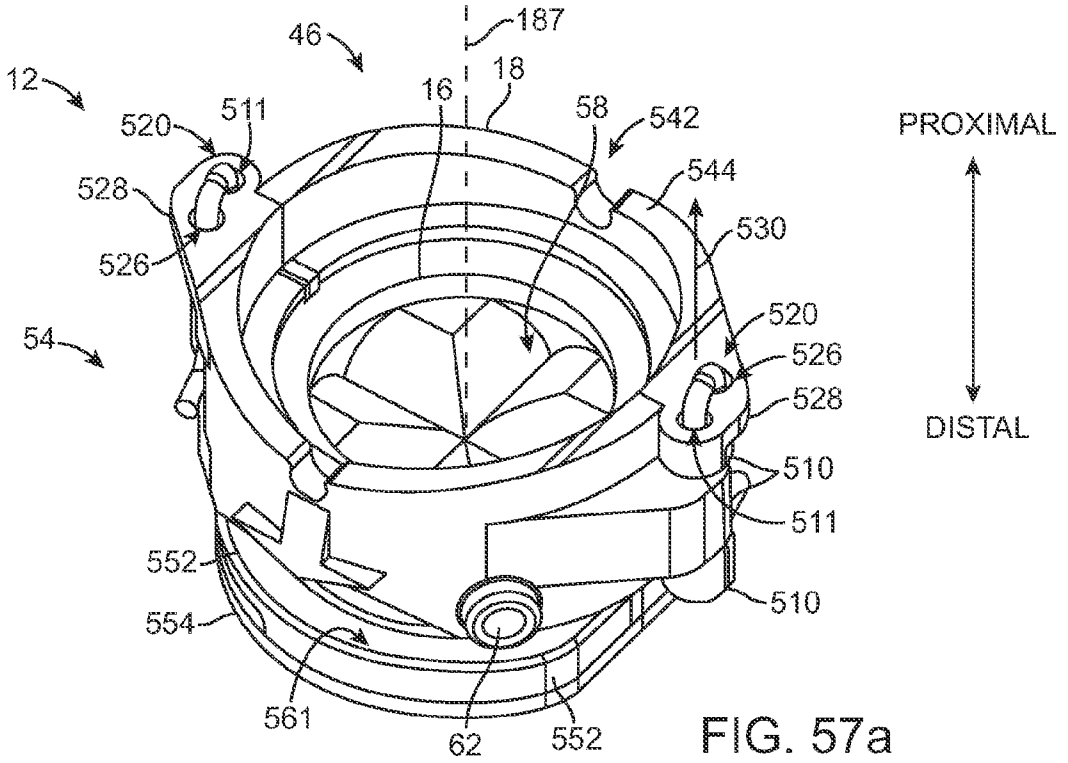


FIG. 57a

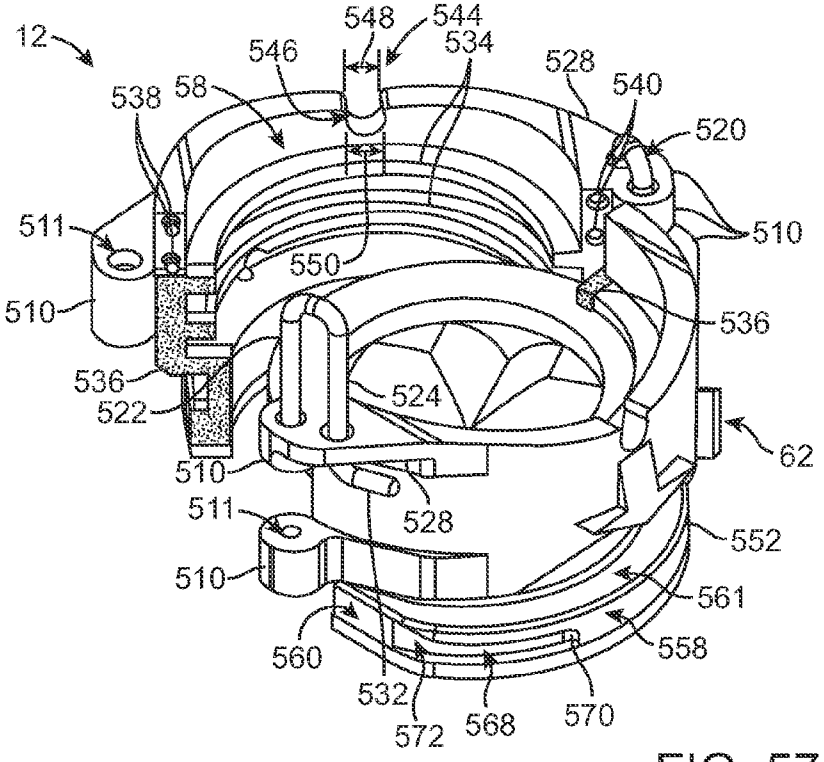


FIG. 57b

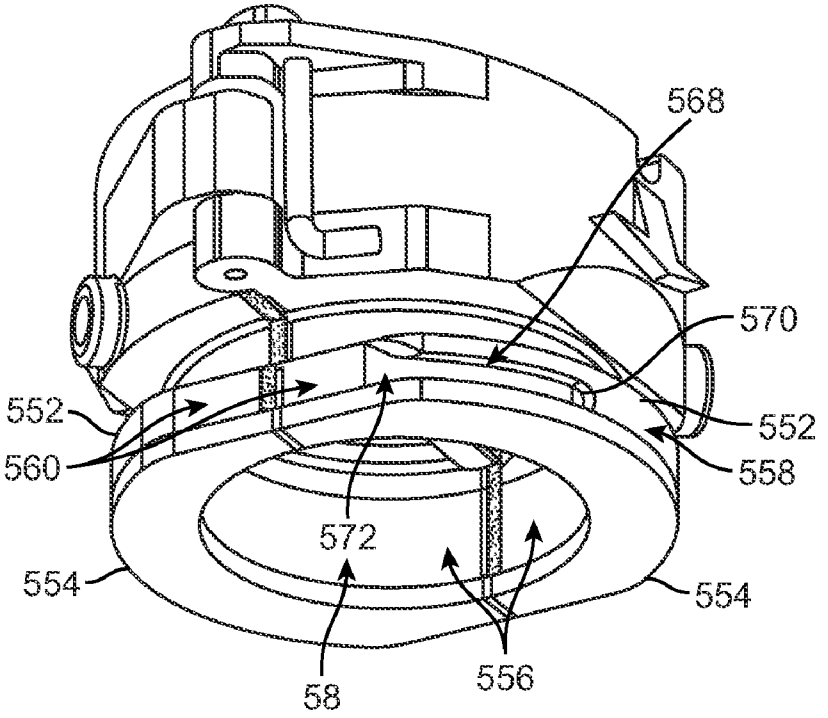


FIG. 57c

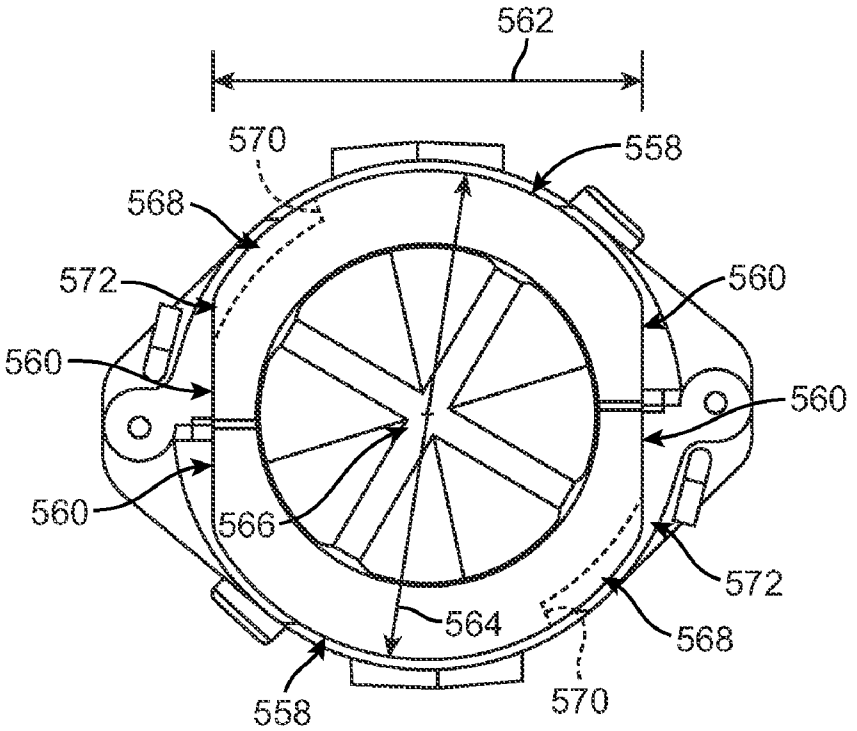


FIG. 57d

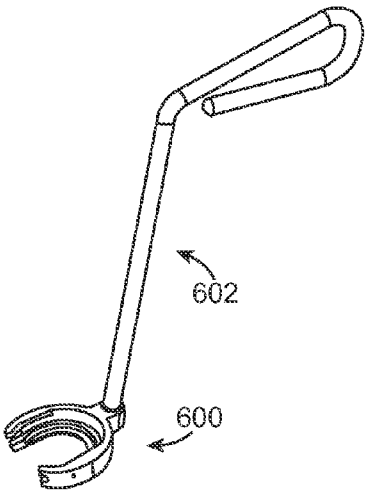


FIG. 58a

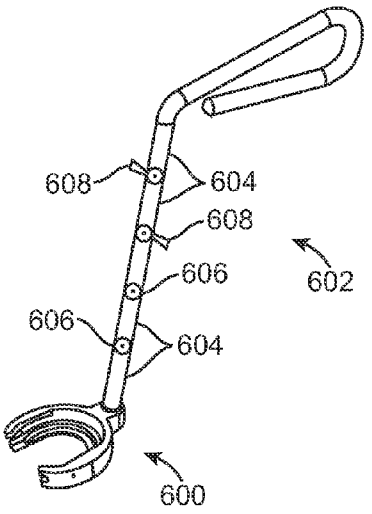


FIG. 58b

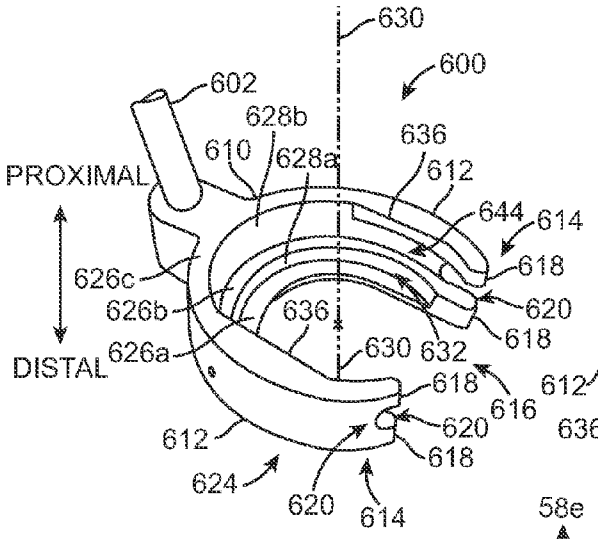


FIG. 58c

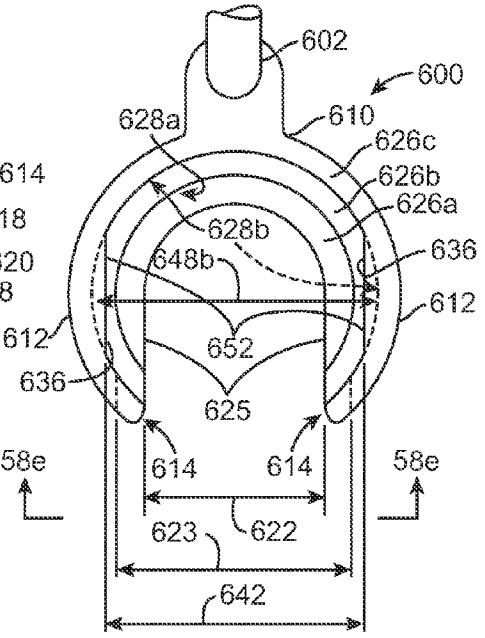


FIG. 58d

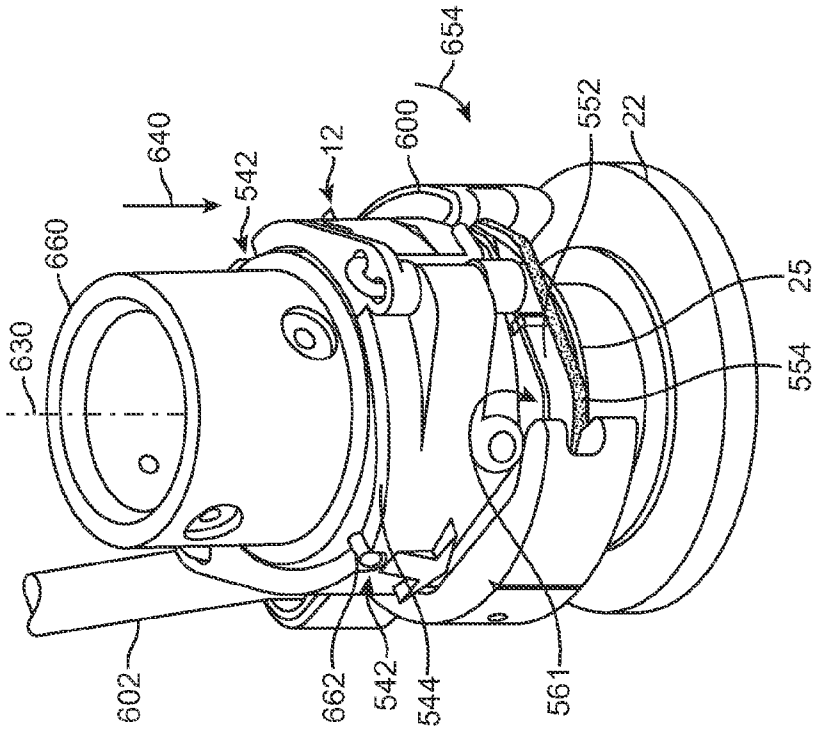


FIG. 59b

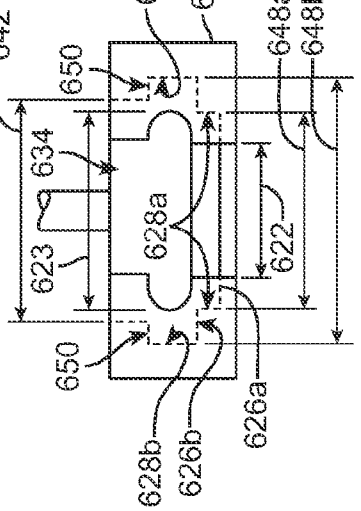


FIG. 58e

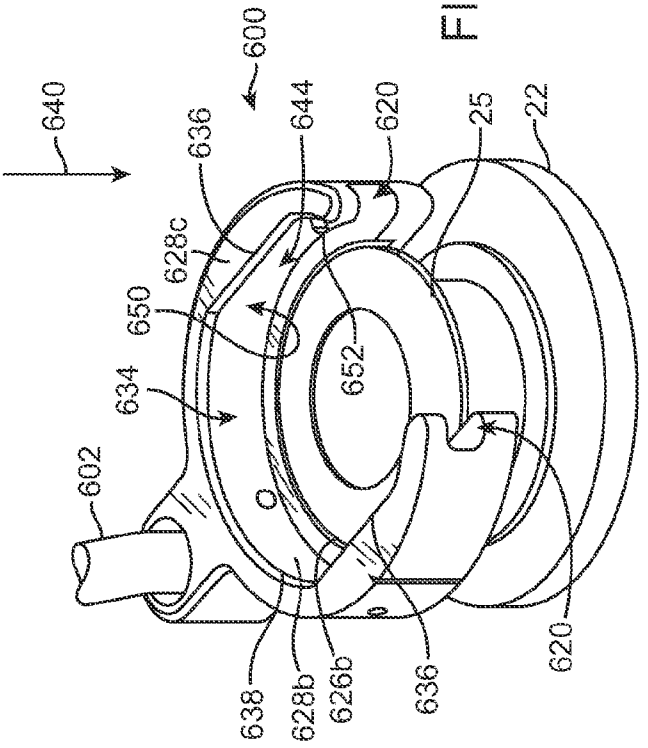


FIG. 59a

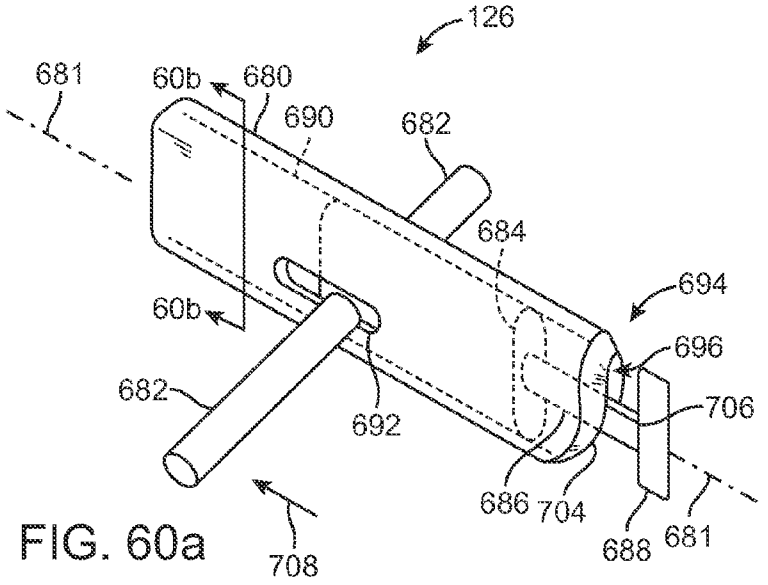


FIG. 60a

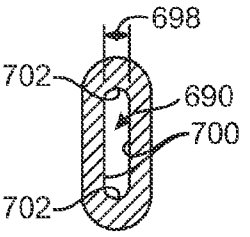


FIG. 60b

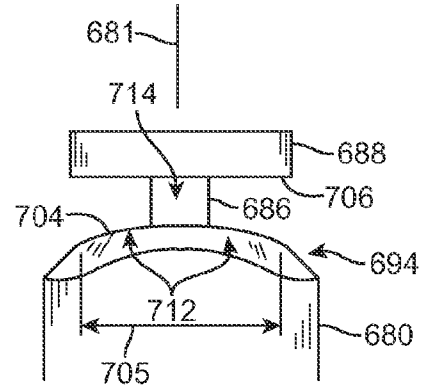


FIG. 60c

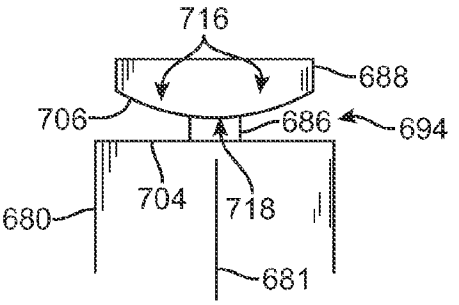


FIG. 60d

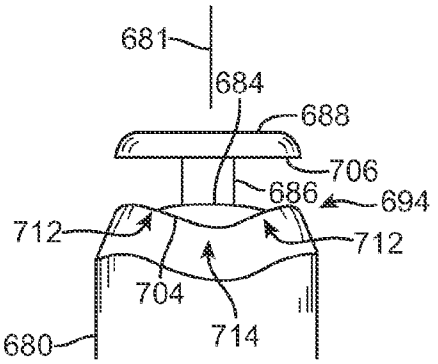


FIG. 60e

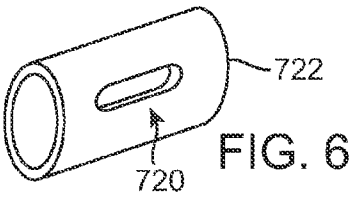


FIG. 61a

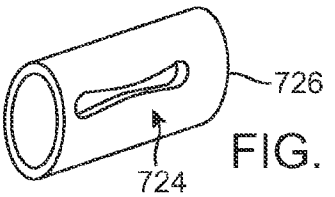


FIG. 61b

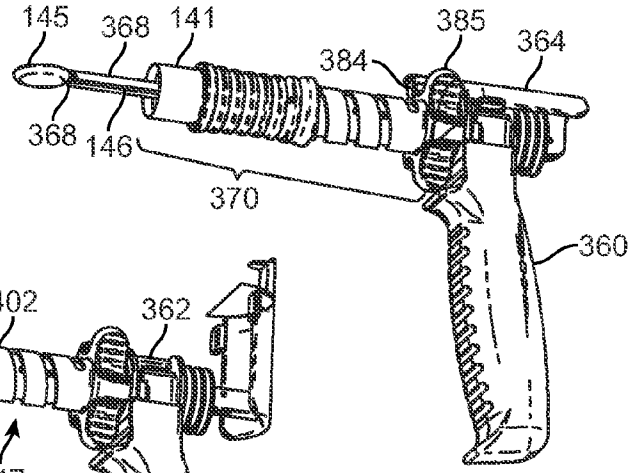


FIG. 62a

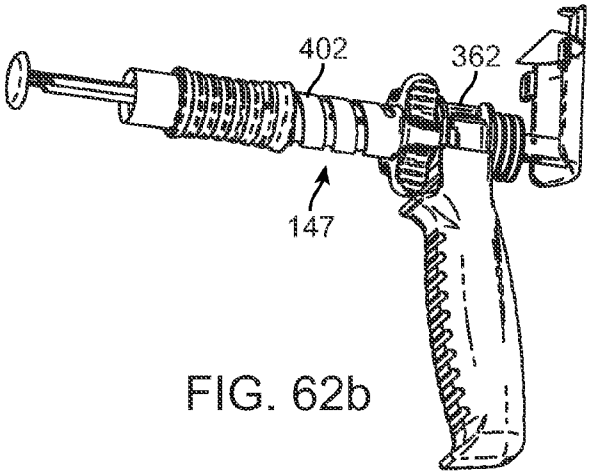


FIG. 62b

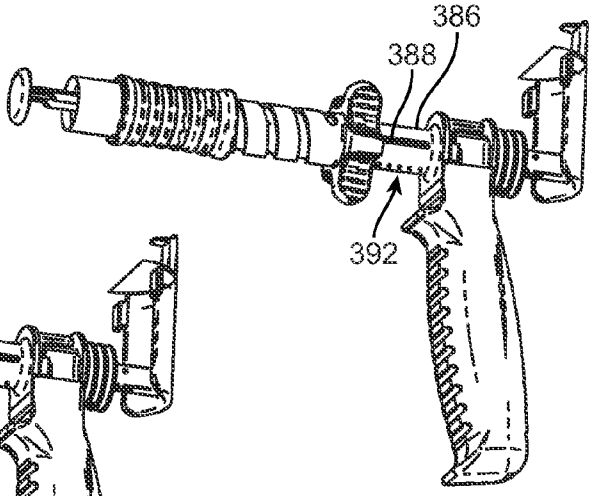


FIG. 62c

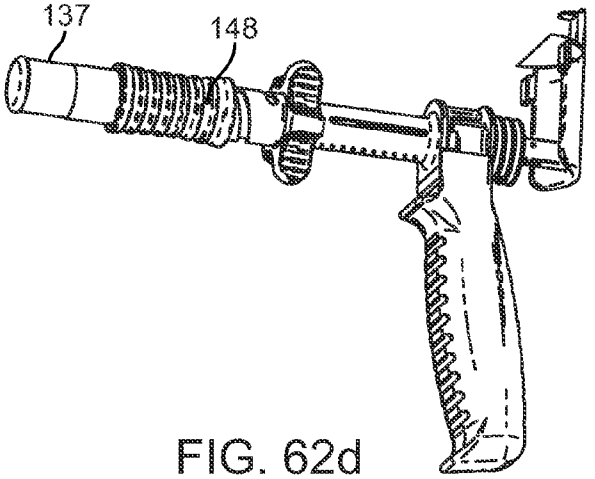


FIG. 62d

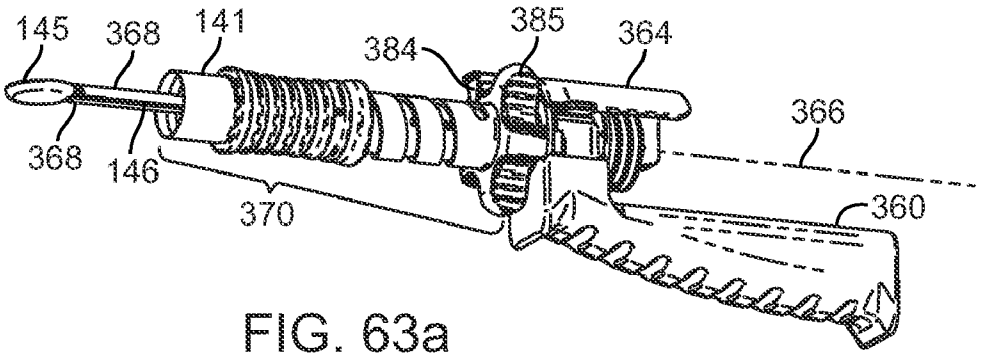


FIG. 63a

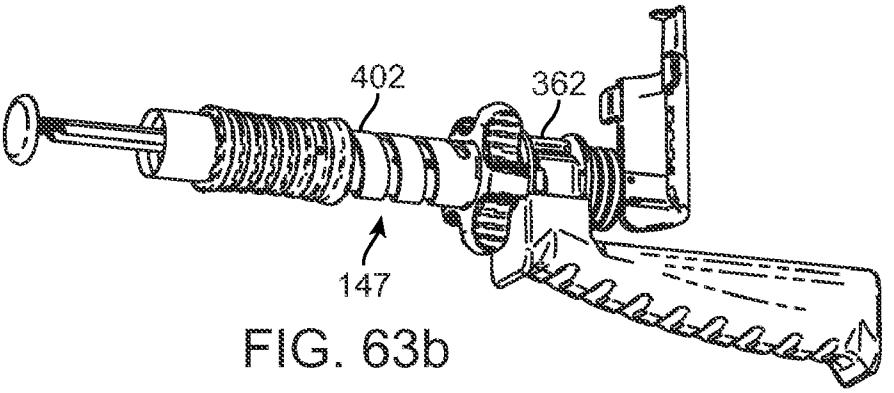


FIG. 63b

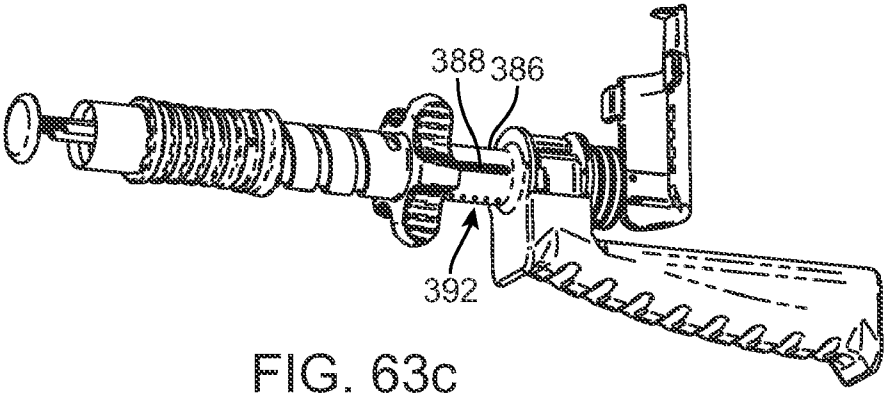


FIG. 63c

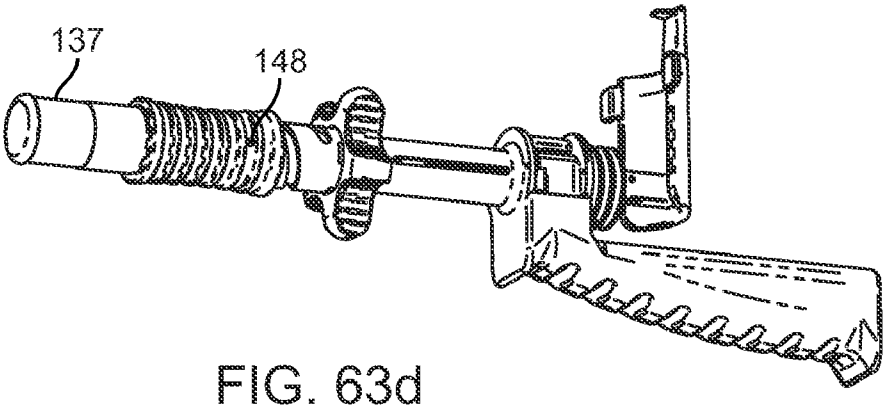


FIG. 63d

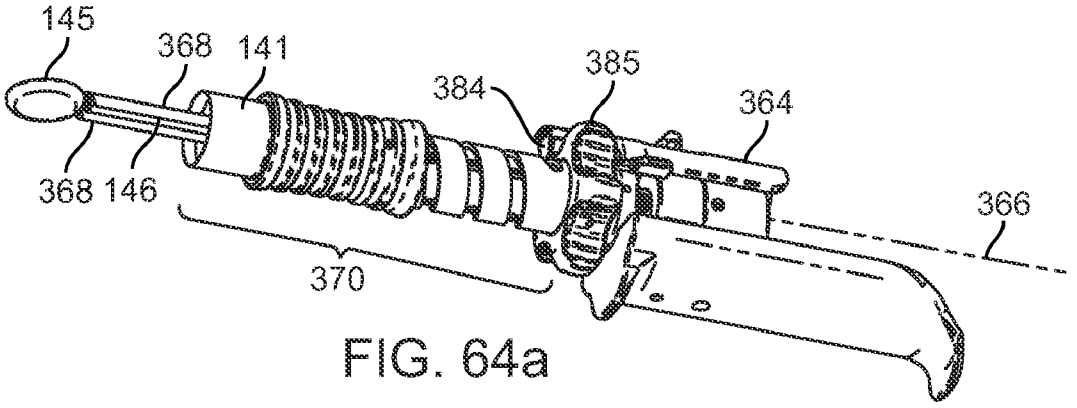


FIG. 64a

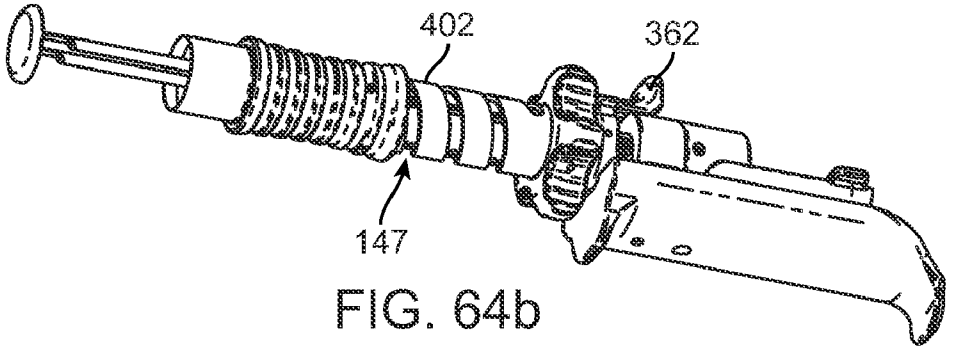


FIG. 64b

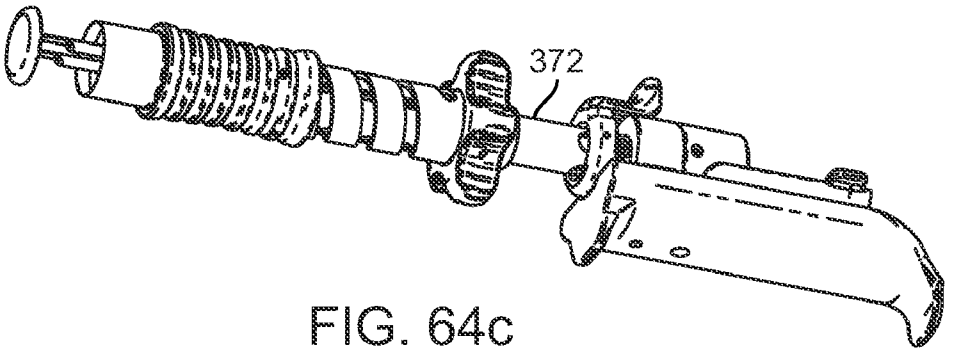


FIG. 64c

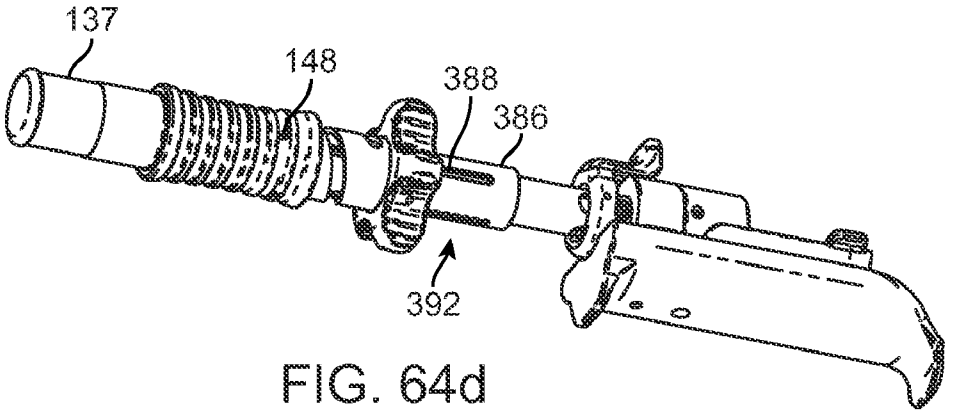


FIG. 64d

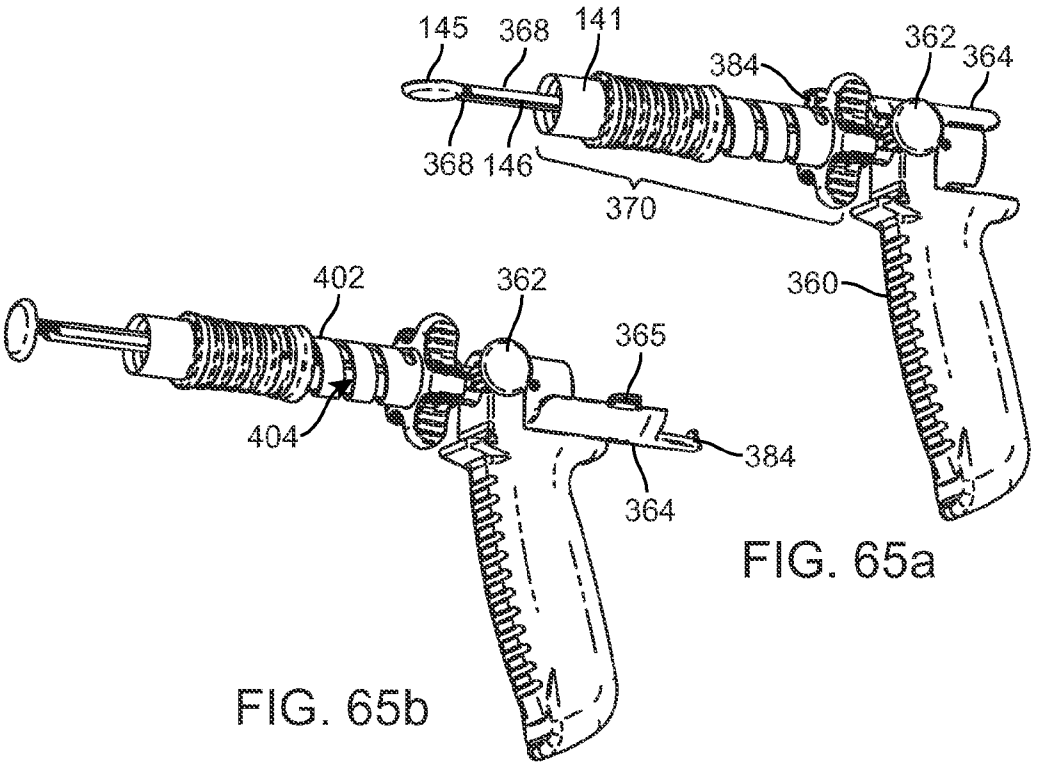


FIG. 65a

FIG. 65b

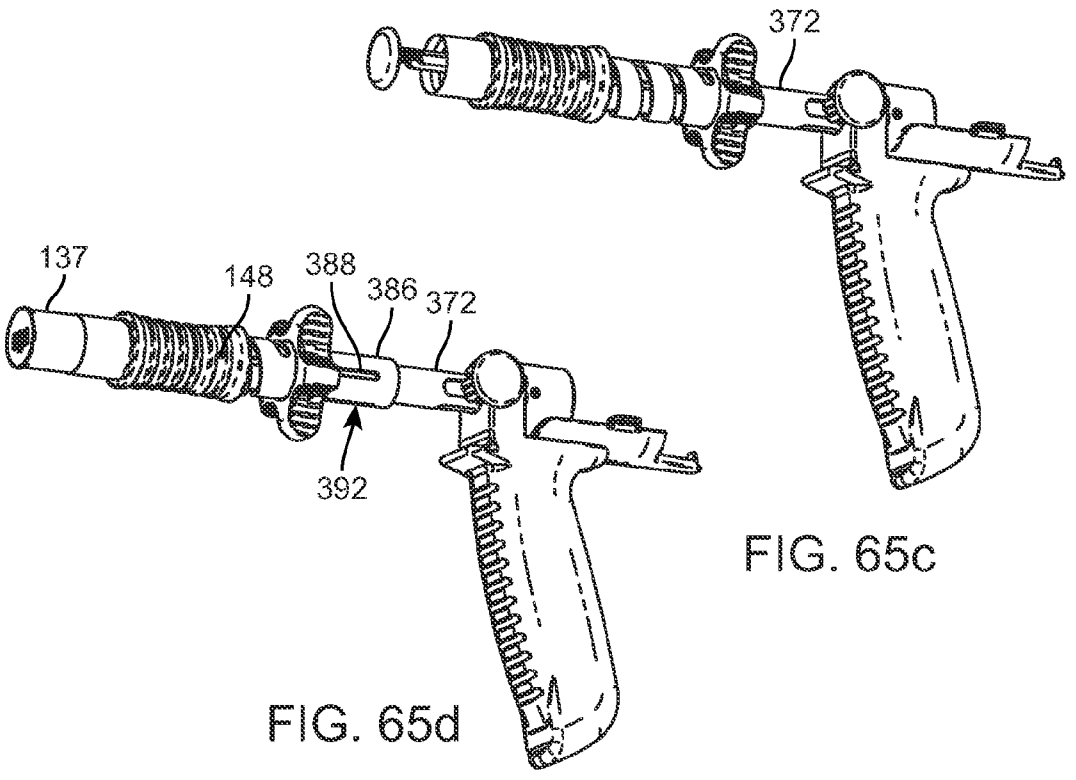


FIG. 65c

FIG. 65d

ATTACHMENT METHOD

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of Ser. No. 12/945,890, filed Nov. 14, 2010, which is a continuation-in-part of application Ser. Nos. 12/590,863, filed Nov. 15, 2009, and 12/590,864, filed Nov. 15, 2009, which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to the field of heart assist devices and methods, devices and systems for the in vivo implantation of VADs and its attachment to the heart.

[0004] 2. Description of the Related Art

[0005] Heart assist devices are implantable devices that assist the heart in circulating blood in the body. A ventricular assist device (VAD) is an example of a heart assist device that is used to assist one or both ventricles of the heart to circulate blood. For patients suffering from heart failure, assisting the left ventricle with a VAD is more common. Currently, VADs are commonly used as a treatment option or a bridge to transplant for patients with heart failure.

[0006] The procedure to implant VADs carries many risks and side effects. The implantation procedure is invasive as surgeons need to access the heart directly by opening the chest with a sternotomy or a thoracotomy. Generally, a heart-lung bypass machine is used during the procedure, but a beating heart procedure may minimize side effects associated with using a heart-lung bypass machine in such a major invasive surgery. However, a beating heart procedure can potentially lead to significant blood loss during the process of implanting the VAD if great care is not exercised.

[0007] While procedural related issues during the implantation process can directly impact the success of the implantation, some of these procedural issues may also impact patients' recovery. When complications arise during the implantation process, the recovery time for these very ill patients can be extended. Procedural issues may result in major detrimental side effects for patients, directly increasing the recovery time. The recovery time and risk factors are often compounded by the originally poor health of the heart failure patient in need of the VAD.

[0008] A system and method for implanting a ventricular assist device without a sternotomy is desired. Furthermore, a system and method for safely implanting a VAD without requiring heart-lung bypass is desired. Additionally, a system and method for implanting a ventricular assist device in a beating-heart procedure is desired.

SUMMARY OF THE INVENTION

[0009] Briefly and in general terms, the present invention is directed to a method of preparing a heart for connection with a ventricular assist device. In aspects of the present invention, a method comprises attaching an attachment ring to a ventricular apex of the heart, the attachment ring including a seal or a valve and configured to receive an inflow conduit, removing tissue, through the attachment ring, from the heart to form a hole in the ventricular apex, and closing a clamp around the attachment ring to secure an inflow conduit, inserted through the attachment ring, against the attachment ring, wherein the inflow conduit is configured to attach to or form a part of the ventricular assist device.

[0010] In other aspects of the present invention, a method comprises attaching an attachment ring to a ventricular apex of the heart, the attachment ring including a valve or a seal, forming a slit in the ventricular apex, the forming of the slit performed with use of a slitting tool aligned relative to and passed through the attachment ring, and removing tissue around the slit to form a hole in the ventricular apex, the removing of the tissue performed through the attachment ring.

[0011] In other aspects of the present invention, a method comprises attaching an attachment ring to a left ventricular apex of the heart, and attaching a valvular structure to the attachment ring using a clamp device, wherein a valvular structure has a closed position, and when in the closed position blood from an aperture in the left ventricular apex is substantially prevented from flowing out of the valvular structure.

[0012] The features and advantages of the invention will be more readily understood from the following detailed description which should be read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

[0013] FIG. **1** illustrates a variation of the ventricular assist system.

[0014] FIGS. **2***a* and **2***b* are perspective and sectional views of a variation of the attachment ring attached to the valvular structure.

[0015] FIG. **3***a* is a perspective view of a variation of the attachment ring.

[0016] FIG. **3***b* is a cross-sectional view of A-A of FIG. **3***a*.

[0017] FIG. **4***a* is a perspective view of a variation of the attachment ring.

[0018] FIG. **4***b* is a cross-sectional view of FIG. **4***a*.

[0019] FIG. **5** illustrates a variation of the clamp.

[0020] FIGS. **6***a* and **6***b* illustrate a variation of the clamp in opened and closed configurations, respectively.

[0021] FIGS. **7***a* and **7***b* illustrate a variation of the clamp on the attachment ring with the clamp in opened and closed configurations, respectively.

[0022] FIG. **8***a* illustrates a variation of the attachment ring attached to the inflow conduit.

[0023] FIG. **8***b* is a perspective view of section B-B of FIG. **8***a*.

[0024] FIG. **8***c* is the variation of cross-section B-B of FIG. **8***a* shown in FIG. **8***b*.

[0025] FIG. **9***a* illustrates a variation of the attachment ring attached to the inflow conduit.

[0026] FIG. **9***b* is a perspective view of section B'-B' of FIG. **9***a*.

[0027] FIG. **9***c* is the variation of cross-section B'-B' of FIG. **9***a* shown in FIG. **9***b*.

[0028] FIGS. **10***a* and **10***b* are a perspective views of a variation of the valvular structure.

[0029] FIGS. **10***c*-**10***e* are perspective views of a variation of section C-C.

[0030] FIGS. **11***a* through **11***c* are bottom perspective, top perspective, and top views, respectively, of a variation of the valvular structure.

[0031] FIGS. **12***a* and **12***b* illustrate perspective and section views, respectively, of a variation of the valve in a closed configuration.

[0032] FIG. **12***c* is a perspective view of the valve of FIGS. **12***a* and **12***b* in an open configuration.

[0033] FIGS. **13***a* and **13***b* are top perspective and bottom perspective views of a variation of the valve in a closed configuration.

[0034] FIGS. **13***c* and **13***d* are top perspective views of the valve of FIGS. **13***a* and **13***b* in open configurations.

[0035] FIGS. **14***a* and **14***b* are top perspective and bottom perspective views of a variation of the valve.

[0036] FIGS. **15***a* and **15***b* are top perspective and bottom perspective views of a variation of the valve.

[0037] FIGS. **15***c* through **15***e* illustrate variations of miter valves.

[0038] FIG. **15***f* illustrates a variation of a duckbill diaphragm valve.

[0039] FIGS. **16***a* and **16***b* illustrate open and closed configurations, respectively, of a variation of the valvular structure of section C-C.

[0040] FIGS. **17***a* and **17***b* illustrate open and closed configurations, respectively, of a variation of the valvular structure of section C-C.

[0041] FIGS. **18***a* and **18***b* are exploded and top views of a variation of the valve.

[0042] FIGS. **19***a* and **19***b* are perspective and sectional views of a variation of the valve integrated with an attachment ring.

[0043] FIGS. **19***c* and **19***d* are perspective and sectional views of a variation of the valve integrated with an attachment ring.

[0044] FIG. **20** illustrates a variation of the attachment ring and an exploded view of a variation of the valvular structure.

[0045] FIG. **21***a* is a top perspective view of a variation of the valve.

[0046] FIG. **21***b* is a variation of cross-section D-D of the valve.

[0047] FIG. **21***c* is a bottom perspective view of the valve of FIG. **21** a with the diaphragm flap shown in see-through.

[0048] FIG. **22** is a sectional view of a variation of the valvular structure.

[0049] FIG. **23** illustrates a variation of the valvular structure with the housing shown in see-through.

[0050] FIG. **24** illustrates a variation of the valvular structure with the housing in see-through.

[0051] FIG. **25** is a sectional view of a variation of a method for attaching the valvular structure to the attachment ring.

[0052] FIGS. **26***a* and **26***b* are sectional views of a variation of a method for attaching the valvular structure to the attachment ring.

[0053] FIGS. **27***a* and **27***b* illustrate a variation of the method process flow for implanting a variation of the ventricular assist system.

[0054] FIGS. **28***a* and **28***b* illustrate variations of a method for accessing the target site.

[0055] FIG. **29***a* illustrates a variation of the tunneler.

[0056] FIGS. **29***b* and **29***c* illustrate variations of the tunneler of FIG. **29***a* with the bullet tip removed.

[0057] FIG. **30***a* illustrates a variation of the tunneler.

[0058] FIG. **30***b* illustrates the tunneler of FIG. **30***a* with the outer sheath removed from the tunneler shaft.

[0059] FIG. **31** illustrates a variation of the tunneler attached to the outflow conduit.

[0060] FIG. **32** illustrates a variation of inserting the outflow conduit in the target site.

[0061] FIG. **33***a* through **33***c* illustrate a variation of a method for anastomosing the aorta to the outflow conduit.

[0062] FIG. **34***a* illustrates blood flow through the outflow conduit after aortic anastomosis.

[0063] FIGS. **34***b* through **34***d* illustrate variations of methods for stanching blood flow through the outflow conduit.

[0064] FIG. **35** illustrates a variation of a method of attaching the attachment ring to the apex of the heart.

[0065] FIGS. **36***a* and **36***c* are perspective and side views, respectively, of a variation of the coring knife.

[0066] FIGS. **36***b* and **36***d* are perspective and side views of a variation of section F-F of FIG. **36***a*.

[0067] FIG. **36***e* is a side view of a variation of section F-F of FIG. **36***a* with the coring blade in a retracted configuration.

[0068] FIGS. **37***a* and **37***b* are perspective and sectional views, respectively, of a variation of the coring knife.

[0069] FIGS. **37***c* and **37***d* are front views of the coring knife with the coring abutment in a rotated configuration, and the coring blade in an extended configuration, respectively.

[0070] FIG. **38** illustrates a variation of the coring knife.

[0071] FIG. **39***a* is a side view with the valvular structure shown in cut-away, of a variation of a method of using the coring knife with the valvular structure.

[0072] FIG. **39***b* is a perspective end view of FIG. **39***a*.

[0073] FIGS. **40***a* through **40***i* illustrate a variation of a method for using a variation of the ventricular assist device system.

[0074] FIGS. **41***a* through **41***d* illustrate a variation of a method for coring.

[0075] FIGS. **42***a* through **42***c* illustrate a variation of inserting the inflow conduit through the attachment ring.

[0076] FIGS. **43***a* and **43***b* illustrate a variation of a method for stanching blood flow through the pump outflow elbow and de-airing the pump.

[0077] FIG. **44** illustrates a variation of a method for de-airing the ventricular assist device.

[0078] FIG. **45** illustrates a variation of attaching the pump to the outflow conduit.

[0079] FIGS. **46***a*-**46***d* show an attachment ring, FIGS. **46***b* and **46***d* being partial cross-sectional sectional views.

[0080] FIGS. **47***a*-**47***c* show an attachment ring, FIG. **47***a* showing a flat sheet of material used for making the attachment ring.

[0081] FIGS. **48***a*-**48***d* show an embodiment an attachment ring with an integral valve.

[0082] FIGS. **49***a*-**49***d* are perspective views of a clamp for use on an attachment ring, FIG. **49***d* showing clamp closed on an attachment ring.

[0083] FIGS. **50***a* and **50***b* are plan and perspective views of a clamp for use on an attachment ring, showing ratcheting teeth for locking the clamp closed.

[0084] FIG. **51** is a plan view of a clamp for use on an attaching ring with one pair of teeth.

[0085] FIGS. **52***a*-**52***c* are perspective and cross-sectional views of a slitting tool for making a linear incision in the heart, the linear incision allow for a subsequent circular incision.

[0086] FIGS. **53***a*-**53***f* are perspective and partial plan views of a coring knife for making a circular incision in the heart.

[0087] FIG. **54** is a partial plan view of a portion of a coring knife, showing a variation on the coring knife casing.

[0088] FIG. **55** is a partial plan view of a portion of a coring knife, showing a variation on the coring knife abutment.

[0089] FIGS. **56***a*-**56***d* are perspective and proximal plan views of a valvular structure having a spring-loaded hinge.

[0090] FIGS. **57***a*-**57***d* are perspective and plan views of a valvular structure having two identical halves, FIGS. **57***c* and **57***d* showing view of the distal end.

[0091] FIGS. **58***a*-**58***e* are perspective, plan and side views of a C clamp for engaging a valvular structure onto an attachment ring.

[0092] FIGS. **59***a* and **59***b* are perspective views showing the C-clamp with an attachment ring and valvular structure.

[0093] FIGS. **60***a*-**60***e* are perspective, cross-sectional and partial side views of various aortic punches.

[0094] FIGS. **61***a* and **61***b* are perspective views of anatomical vessels with holes made by aortic punches.

[0095] FIGS. **62***a*-**62***d*, **63***a*-**63***d*, **64***a*-**64***d* and **65***a*-**65***d* are perspective views of various coring knives.

DETAILED DESCRIPTION

[0096] As used herein, any term of approximation such as, without limitation, near, about, approximately, substantially, essentially and the like mean that the word or phrase modified by the term of approximation need not be exactly that which is written but may vary from that written description to some extent. The extent to which the description may vary will depend on how great a change can be instituted and have one of ordinary skill in the art recognize the modified version as still having the properties, characteristics and capabilities of the modified word or phrase. For example without limitation, something that is described as "substantially circular" in shape refers to a shape that is perfectly circular and a shape that one skilled in the art would readily recognize as being circular even though diameters measured at multiple locations on the circle are not exactly the same. As another non-limiting example, a first structure that is described as "substantially parallel" in reference to a second structure encompasses an orientation that is perfectly parallel and an orientation that one skilled in the art would readily recognize as being parallel even though distances between corresponding locations on the two respective structures are not exactly the same. In general, but with the preceding discussion in mind, a numerical value herein that is modified by a word of approximation may vary from the stated value by ±15%, unless expressly stated otherwise.

[0097] Variations of a system and method for implanting a VAD during a beating-heart procedure are disclosed. The system can minimize or prevent blood loss from the heart during the system implantation procedure, notably during the steps of coring a portion of the epicardial wall and insertion of the inflow conduit through the epicardial wall. The system can provide a fluid-tight seal around the surgical tools used to access or come into contact with the internal fluid volume of the heart. Throughout this disclosure, one should appreciate that references made to VADs equally applies to all heart assist devices. Similarly, the system and surgical tools may apply to a similar procedure of cannulation to other parts of the heart or of the cardiovascular system.

[0098] FIG. **1** illustrates a ventricular assist device (VAD) system **13** with a pump **8**. All locations described as proximal or distal, herein, are relative to the location of the pump **8**. The pump **8** can draw blood from the left ventricle, and deliver the blood to the aorta at a higher pressure to assist the pumping of the heart. The pump **8** is configured to direct blood flow from one location (e.g., the heart) to a second location (e.g., target vasculature like an aorta) in the vascular system to provide mechanical circulatory support/assistance. For example, the pump **8** can be configured as a unidirectional turbine pump **8** to direct blood from the inflow side of the pump **8** (e.g., from the heart) to the outflow side of the pump **8** (e.g., to the aorta). A percutaneous lead **5** having insulated wires can be used for transmission and/or receiving of data and/or power between the pump **8** and a controller and/or a remote device for controlling the operation of the pump **8**. In one variation, a controller or remote is outside of the patient's body. The pump **8** can have any configuration including but not limited to having axial flow or centrifugal flow.

[0099] The pump **8** can be directly attached to or have an inflow conduit **10** at a first end of the pump **8** and directly attached to or have an outflow conduit **2** at a second end of the pump **8**. The inflow conduit **10** can be coupled with the pump **8** by a helically threaded coupler configured to attach to the inflow port **7** of the pump **8**.

[0100] The inflow conduit **10** can have a hollow channel for fluid communication such as directing blood from a first location (e.g., the heart) to the pump **8**. In one variation, the inflow conduit **10** can be flexible. In another variation, the inflow conduit **10** can be rigid, such as a metal tube. In yet another variation, the inflow conduit **10** may have a combination of rigid and flexible elements such as having a proximal (relative to the pump **8**) rigid elbow for coupling with the pump **8** that is connected to a flexible middle portion to accommodate for bending and a distal rigid portion (relative to the pump **8**) for coupling with the heart. The inflow conduit may also be formed by a portion of the pump body.

[0101] As illustrated in FIG. **1**, the inflow conduit **10** has a distal end that can be placed through the valvular structure **12** and the attachment ring **22** before entering into the heart after implantation. A flexible middle portion of the inflow conduit **10** provides strain relief between the distal end and the proximal end. The proximal end is coupled with the pump **8**. Blood can enter the inflow conduit **10** through its distal opening, travel along the length of the inflow conduit **10**, and enter the pump **8** at the inflow port **7** of the pump **8** after exiting the proximal opening of the inflow conduit **10**. The inflow conduit **10** can be integral with, or separate and attachable to, the pump **8**.

[0102] The valvular structure **12** is configured to prevent or minimize blood loss from the heart during the implantation of the VAD. The valvular structure **12** can be removed from the system and the patient once the inflow conduit **10** is properly positioned relative to the heart, for example, after the inflow conduit **10** has been inserted into the attachment ring **22**. The valvular structure **12** can seal against a coring knife and/or the inflow conduit **10** which passes through a channel through the valvular structure **12**. The valvular structure **12** can minimize or prevent blood flow out from the heart during the implantation of the VAD. Additionally the valvular structure **12** can provide for passage of other instruments during the procedure while preventing blood loss out of the heart.

[0103] The valvular structure **12** can be directly attached to an attachment ring **22**, for example, indirectly attaching the valvular structure **12** to the apex of the heart during use. The attachment ring **22** can be configured to connect to a ventricle. The attachment ring **22** can fix and seal against the inflow conduit **10** once the VAD is implanted. The attachment ring **22** can be a ventricle or heart connector. The attachment ring **22** can fixedly attach to the VAD to the wall of the heart. Thus,

the attachment ring **22** is configured to be secured against the heart, and is also configured to be secured against the inflow conduit **10**.

[0104] An outflow conduit is coupled to the second end (e.g., outflow port) of the pump **8** where the blood or fluid exits the pump **8**. In an axial flow pump arrangement, the outflow conduit **2** is approximately linear and opposite to the inflow conduit **10**. Similar to the inflow conduit **10**, a proximal end (relative to the pump **8**) of the outflow conduit **2** is coupled to the pump **8**, whereas the distal end (relative to the pump **8**) of the outflow conduit **2** is for coupling to a target vasculature (e.g., aorta) where blood re-enters the circulatory system after exiting the pump **8**.

[0105] Similar also to the inflow conduit **10**, the proximal end of the outflow conduit **2** can be rigid for coupling to the pump **8**. The middle portion of the outflow conduit **2** can be made from a flexible material for bend relief. In one variation, the distal portion of the outflow conduit **2** (relative to the pump **8**) can be a flexible sealed graft that can be sewn onto a target vasculature (e.g., aorta) by way of an anastomosis, for blood to re-enter the circulatory system.

[0106] The ventricular assist system can have fluid communication between the inflow port **7**, the inflow conduit **10**, the pump **8**, the outflow conduit **2** and the outflow port. The components of the ventricular assist system shown in FIG. **1**, except for the valvular structure **12**, can all or partially be from a Heartmate II Left Ventricular Assist Device (from Thoratec Corporation, Pleasanton, Calif.).

[0107] FIGS. **2***a* and **2***b* illustrate a valvular structure **12**. In conjunction with other components in a system, this valvular structure **12** helps to prevent or otherwise minimize blood loss out of the heart during the implantation or cannulation procedure, for example, when an opening is created in the heart while the heart is beating, or when a heart-lung by-pass machine is not used. The valvular structure **12** has a housing **18** that can be substantially cylindrical with a valve **16** and/or one or more seals **17** coupled to the inside wall of the structure. The valve **16** can act as either a complete or a partial seal for the valvular structure **12**. The valve **16** can allow the flow of fluid or entry of an element in a distal direction and substantially impair or completely prevent the flow of fluid or entry of an element in a proximal direction. The housing **18** and valve **16** can be configured to be attachable to and removable from the attachment ring **22**. The housing **18** can be separatable and removable from the valve **16**. The housing **18** can have an attachment ring channel **14** around the inner circumference of the housing **18**. The attachment ring **22** can be positioned inside of the attachment ring channel **14** and at or near one end of the housing **18**. The attachment ring **22** and valvular structure **12** can have longitudinal axes **187**. The longitudinal axis of the attachment ring **22** and the longitudinal axis of the valvular structure **12** can be co-axial.

[0108] A de-airing channel **15** can be configured through the wall of the housing **18**. In the process of cannulation or implantation, air can be introduced into the valvular structure **12**. Air entering the circulatory system can cause air embolism and can be harmful to a patient. The de-airing channel **15** can be used for purging all the air from the valvular structure **12** prior to insertion of the inflow conduit **10** into the heart thus preventing air from entering the circulatory system. In one variation, suction can be applied to and/or a fluid such as saline and/or blood can be delivered through the de-airing channel **15** to remove air from the system before the system is completely assembled. The de-airing channel **15** can place the environment radially external to the surface of the housing **18** in fluid communication with the attachment ring channel **14**.

[0109] FIGS. **3***a* and **3***b* illustrate an attachment ring **22**. The attachment ring **22** can be attached to the epicardial wall, for example, by sutures through the cuffs **19** and **21** and the epicardial wall. After being sutured to the heart, the cuffs **19** and **21** can provide at least mechanical support on the heart wall for the attachment ring **22**, which serves as an anchoring point for securing of the inflow conduit **10** after it has been inserted into the heart for fluid (e.g., blood) communication. The attachment ring **22** can have an attachment ring wall **29** that defines an attachment ring channel **14**. The attachment ring channel **14** can be open at both ends. The inflow conduit **10** can be passed through the attachment ring channel **14**, accessing the chamber inside the ventricle. The attachment ring **22** can have a substantial or nominal height. The attachment ring wall **29** can be made from a silicone molded body with ABS, Delrin, or combinations thereof. The attachment ring **22** can have polypropylene ring inserts (e.g., to provide circular structure to facilitate tool and inflow conduit **10** insertion) and reinforced polyester mesh (e.g., to prevent tearing). The attachment ring wall **29** can be sutured to the cuff **19** and/or **21**. The cuff pad **20** can be made from PTFE felt. titanium, silicone, or combinations thereof. The attachment ring **22** can be from about 5 mm to about 25 mm tall. The attachment ring wall **29** can have a thickness from about 1 to about 3 mm (e.g., not including flanges). The diameter of the attachment ring channel **14** can range from about 10 mm to about 25 mm.

[0110] The attachment ring wall **29** can have a distal band **31** extending radially from the attachment ring wall **29** at or near the distal terminus of the attachment ring wall **29**. The distal band **31** can be integral with the attachment ring wall **29**. The distal band **31** can attach to the distal and/or proximal cuff **21**. The attachment ring wall **29** can have a proximal band **26** at or near the proximal terminus of the attachment ring wall **29** to maintaining a substantially circular cross-section adjacent to where the inflow conduit **10** is inserted into the attachment ring channel **14**. The proximal band **26** can be a rigid metal or plastic. The proximal band **26** can structurally reinforce the proximal end of the attachment ring wall **29**. The attachment ring wall **29** can be flexible or rigid. These proximal and distal bands **26** and **31** can be used as anchors, attachment points, visual alignment indicators and/or locks to other structures, components, or tools used in the implantation process.

[0111] The attachment ring **22** can be attached to the heart by stitching, suturing, or stapling one or more regions on the cuff **19** and/or **21** of the attachment ring **22** to the heart. The attachment ring wall **29** is attached to the cuff **19** and/or **21** having an annular shape with a distal cuff **19** or sewing region and a proximal cuff **21** or sewing region. For example, the cuffs **19** and/or **21** can be attached to the attachment ring **22** by sutures, thread, staples, brads, welding, adhesive, epoxy, or combinations thereof. The cuffs **19** and **21** extend radially from the attachment ring wall **29** outward. The distal cuff **19** can extend radially more outward than the proximal cuff **21**, for example, the proximal cuff **21** can structurally support the distal cuff **19** and provide a thicker layer through which sutures can be stitched. The distal cuff **19** and the proximal cuffs **21** can form the shape of cylindrical discs with hollow centers (i.e., where the attachment ring wall **29** and attachment ring channel **14** are located). The distal cuff **19** can be on

the distal side of the distal band **31**, and the proximal cuff **21** can be on the proximal side of the distal band **31** and attached to the distal band **31** and/or the attachment ring wall **29**. The distal and proximal cuffs **21** can be stacked. The distal cuff **19** can be attached to the proximal cuff **21**, for example, at the radially outer circumference of the proximal cuff **21**.

[0112] The cuffs **19** and/or **21** can each have a cuff pad **20** through which the sutures can be passed. The cuff pads **20** can be made from a mesh or fabric material that can be configured to allow penetration by a typical surgical needle and suture. The material of the cuff pad **20** can be strong enough such that the cuff **19** and/or **21** can be secured by sutures against the epicardial wall without easily tearing should a small force be exerted on the attachment ring **22** by accidentally tugging the attachment ring **22** away from the epicardial wall. The cuff pads **20** can be flexible. The cuff pads **20** can be configured to affix to sutures passed through the cuff pads **20**.

[0113] The cuffs **19** and/or **21** can have cuff frames **23** that maintain the planar shape of the cuffs. The cuff frames **23** can also prevent the suture from tearing through the cuff pad **20** and radially exiting and detaching from the cuff. The cuff frames **23** can be rigid circular bands attached to the external circumference of the cuff pads **20**. The cuff frames **23** can be metal and/or hard plastic. The suture can be passed through the cuff pad **20** radially inside of the cuff frame **23**.

[0114] The attachment ring wall **29** can have a ring wall interface lip **25** that can prevent the clamp **24** from shifting, slipping, or otherwise coming off the attachment ring wall **29**. The ring wall interface lip **25** can extend radially from the attachment ring wall **29** proximal from the cuffs **19** and **21**.

[0115] An integral or separately attached clamp **24** can be on the attachment ring wall **29** distal to ring wall interface lip **25** and proximal to the cuffs **19** and/or **21**. The clamp **24** can apply an inward radial force against the attachment ring wall **29**. The clamp **24** can exert a compressive radially force around the attachment ring wall **29**, for example, to pressure-fit the inner surface of the attachment ring wall **29** to the outer surface of an inflow conduit **10** when the inflow conduit **10** is passed through the attachment ring channel **14**. The compressive force from the clamp **24** can hold and seal the attachment ring **22** against the inflow conduit **10**. The attachment ring seal **34** can prevent blood flow from the heart from exiting between the attachment ring **22** and the inflow conduit **10**. The inflow conduit **10** can separately seal around the cored hole in the epicardium. The clamp **24** can be on the radial outside of the attachment ring wall **29** between the ring wall interface lip **25** and the cuffs.

[0116] FIGS. **4***a* and **4***b* illustrate that the attachment ring **22** can have an attachment ring seal **34** at the proximal end of the attachment ring wall **29**. The attachment ring seal **34** can extend radially inward from the attachment ring wall **29** into the attachment ring channel **14**. The attachment ring seal **34** can be flexible. The attachment ring seal **34** (and any other seals disclosed herein) can be made from a soft, resilient elastomer or other polymer. The attachment ring seal **34** can be integral with or separate and attached to the attachment ring wall **29**. The attachment ring seal **34** can produce a fluid-tight seal against elements placed in the attachment ring channel **14**, when the element in the attachment ring channel **14** has an outer diameter larger than the inner diameter of the attachment ring seal **34**.

[0117] The proximal band **26** can be inside of the ring wall interface lip **25**. The ring wall interface lip **25** can extend radially outward from the attachment ring wall **29**. The ring wall interface lip **25** can interference fit against the clamp **24** to prevent the clamp **24** from translating proximally off the attachment ring wall **29**. The ring wall interface lip **25** can be attached to and/or abutted against by an element adjacent to the attachment ring **22**. For example, the inflow conduit **10** can abut against the ring wall interface to prevent the inflow conduit **10** from passing too far through the attachment ring channel **14**. Also for example, the valvular structure **12** can attach to the ring wall interface lip **25**. The proximal band **26** also provides structural support and a hemostatic seal when the attachment ring wall interface lip **25** and valvular structure housing **18** are joined together.

[0118] The attachment ring **22** can have one cuff **35**. The attachment ring wall **29** can have a first distal band **32** on a distal side of the cuff **35** and a second distal band **33** on a proximal side of the cuff **35**. The cuff **35** can be attached to, or pressure fit between, the first distal band **32** and the second distal band **33**.

[0119] FIG. **5** illustrates that the clamp **24** can be made of a single, continuous wire of material. The clamp **24** can be made from a metal and/or polymer (e.g., plastic). The clamp **24** can have a clamp frame **37** to transmit the radially compressive force and clamp handles **36** that can be used to open and/or close the clamp frame **37**. The clamp frame **37** can be resiliently deformable. The clamp frame **37** can have a clamp diameter **38**. When the clamp **24** is in a substantially or completely relaxed or unbiased configuration, the clamp diameter **38** can be smaller than the outer diameter of the attachment ring wall **29** to which the clamp **24** attaches.

[0120] The clamp handles **36** can extend radially from the remainder of the clamp frame **37**. Compressive, squeezing force can be applied to the opposite clamp handles **36** to move the clamp handles **36** toward each other. The compressive force applied to the clamp handles **36** can expand the clamp diameter **38**, placing the clamp **24** in an open configuration.

[0121] When the clamp **24** is in an open configuration, the clamp **24** can be loaded onto and/or removed from the attachment ring **22**. In the open configuration, an inflow conduit **10** can be passed through or retracted from the attachment ring channel **14**.

[0122] FIGS. **6***a* and **6***b* illustrate another variation of the clamp **24**. FIG. **6***a* illustrates the clamp **24** in an open configuration. The clamp **24** can have a frame made from a band of ribbon with a clamp handle **36** to loosen or tighten the clamp **24**. The configuration as shown illustrates that a first end of the clamp lever **39** is rotatably attached to a first terminus of the clamp frame **37** and with the second end of the clamp lever **39** rotatably attached to the clamp handle **36**. The clamp handle **36** can be rotatably attached to the second terminus of the clamp frame **37** that is not attached to the clamp lever **39**. The clamp handle **36** can be attached to the clamp frame **37** at a clamp hinge **40**.

[0123] FIG. **6***b* illustrates the clamp **24** in a closed configuration. In this illustration, the clamp handle **36** is rotated to cause the clamp frame **37** to tighten the clamp frame **37** in the closed configuration. The clamp handle **36** can lie flush against the outer circumference of a length of the clamp frame **37**. The clamp lever **39** can position a first terminus of the clamp frame **37** toward the second terminus of the clamp frame **37** when the clamp handle **36** is closed.

[0124] The clamp diameter **38** can be smaller when the handle is closed than when the handle is open. When the handle is closed, the clamp diameter **38** can be smaller than the outer diameter of the attachment ring wall **29** to which the

clamp **24** attaches. When the handle is open (as shown in FIG. **6***a*), the clamp diameter **38** can be larger than the outer diameter of the attachment ring wall **29** to which the clamp **24** attaches. When the handle is open, the clamp diameter **38** can be larger than the outer diameter of the ring wall interface lip **25**.

[0125] FIG. **7***a* illustrates that the clamp **24** can be on the attachment ring **22** in an open configuration over the attachment ring external wall **29**. With the clamp **24** in an open configuration, elements such as a coring knife, inflow conduit **10** or other surgical tools, can pass through the attachment ring channel **14**. The clamp **24** can be against the outer surface of the attachment ring wall **29** between the ring wall interface lip **25** and the cuff **35**.

[0126] FIG. **7***b* illustrates that the clamp **24** can be in a closed configuration over the attachment ring external wall **29**. With the clamp **24** in a closed configuration, the attachment ring wall **29** can compress onto and seal against elements placed in the attachment ring channel **14**, such as the inflow conduit **10**. The clamp **24** can be between the second distal band **33** and the ring wall interface lip **25**. The clamp **24** can exert a radially inward force against the attachment ring wall **29**. The closed clamp **24** can reduce the diameter of the attachment ring wall **29** and the diameter of the attachment ring channel **14**.

[0127] FIGS. **8***a* through **8***c* illustrate that the inflow conduit **10** can be inserted into the attachment ring **22** to access the heart with the inflow conduit **10** and route blood through an inflow conduit channel **178** from the heart to the pump **8**. The inflow conduit **10** can have an inflow conduit stop **42** configured to abut against or attach to other elements, for example, to preventing the inflow conduit **10** from over-insertion through the attachment ring **22**. The inflow conduit **10** distal to the inflow conduit stop **42** can have an outer diameter smaller than the inner diameter of the attachment ring channel **14**. The inflow conduit stop **42** can have an outer diameter larger than the inner diameter of the attachment ring channel **14**.

[0128] The clamp **24** can be biased open (e.g., by compressing the clamp handles **36** toward each other) when the inflow conduit **10** is inserted into the attachment ring channel **14**, for example, to allow the inflow conduit **10** to pass freely through the attachment ring channel **14**. The clamp **24** can be released and returned to a compressive state around the attachment ring wall **29** when the inflow conduit **10** is in a desired location within the attachment ring **22**, for example, to clamp **24** the attachment ring **22** onto the inflow conduit **10** and hold the inflow conduit **10** in place.

[0129] FIGS. **9***a* through **9***c* illustrate that the variation of the clamp **24** of FIGS. **6***a* and **6***b* can be in an open configuration when the inflow conduit **10** is inserted into the attachment ring channel **14**, allowing the inflow conduit **10** to be inserted freely through the attachment ring **22**. The clamp handle **36** can be rotated open.

[0130] The inflow conduit **10** can be advanced through the attachment ring channel **14** until the inflow conduit stop **42** abuts the proximal end of the attachment ring wall **29**, for example at the ring wall interface lip **25**. The inflow conduit **10** can extend out of the distal end of the attachment ring **22**, for example into and within fluid communication with the chamber of the heart.

[0131] When the inflow conduit **10** is in a desired location within the attachment ring **22**, the clamp **24** can be closed or released, for example, compressing the attachment ring wall **29** onto the inflow conduit **10**. The inflow conduit **10** can then pressure fit against the inner surface of the attachment ring wall **29**, for example holding the inflow conduit **10** in place relative to the attachment ring **22**.

[0132] FIGS. **10***a* through **10***e* illustrate a variation of the valvular structure **12** that can have a clamshell housing **18**. The valvular structure **12** can have a housing **18** with a housing first portion **46** separatably attached to a housing second portion **54**. The housing first portion **46** can have a rotatable clamshell attachment to the housing second portion **54** and can be rotated open and removed from the remainder of the ventricular assist system. In a closed configuration, the housing portions **46** and **54** can define a housing channel **58** longitudinally through the housing **18** and open on each end. The housing first portion **46** can attach to the housing second portion **54** at a housing first seam **51** and a housing second seam **48**. The housing first seam **51** can have a housing first joint **50**. The housing second seam **48** can have a housing second joint **49**.

[0133] The housing joints **49** and **50** can be pinned hinges. For example, the first and/or second housing joints **49** and/or **50** can have first and/or second joint pins **52** and/or **53**, respectively. The housing portions **46** and **54** can rotate about the housing joints **49** and **50**. The respective pins **52** and **53** can be removed from the housing joints **49** and **50** and the housing portions **46** and **54** can be separated from each other at the housing joint **49** and **50**. After separation, the housing portions **46** and **54** can be reassembled at the housing joints **49** and **50** and the joint pins **52** and **53** can be reinserted into the housing joints **49** and **50**. When the housing **18** is separated at one or both joints **49** and **50**, the valve **16**, which is a discrete and separate element from the housing **18**, can come out of the housing **18** or otherwise be removed or detached from the housing **18**.

[0134] One or both of the housing portions **46** and **54** can have de-airing ports **62**. The de-airing ports **62** can be the ends of the de-airing channels **15**. Air can be suctioned out of the de-airing ports **62** and/or saline or blood can be delivered from inside the housing **18** through the de-airing ports **62** to remove the air from the volume between the valve **16** and the heart wall during the de-airing process.

[0135] The valve **16** can have first, second, third, and fourth valve leaflets **56**. The leaflets **56** can be flexible and resilient. The leaflets **56** can be made from an elastomer. The valve **16** can have inter-leaflet seams **64** between adjacent leaflets **56**. Each leaflet **56** can have an intra-leaflet fold **66**. Each leaflet **56** can have a leaflet rib **57** or reinforcement on the inter-leaflet seam **64** or intra-leaflet fold **66**, for example to reinforce the leaflet **56** at the seam **64** or fold **66**. The leaflets **56** can allow fluids and solids to move in the distal direction through the housing channel **58**. The leaflets **56** can oppose fluids and solids moving in the proximal direction through the housing channel **58**. The leaflets **56** can close against pressure from the distal side of the leaflets **56**, for example, preventing the flow of blood from the heart out of the valvular structure **12**.

[0136] The valve **16** can have a valve seal **60** proximal to the leaflets **56**. The valve seal **60** can extend radially into the housing channel **58**. The valve seal **60** can be resilient. The valve seal **60** can seal against an element, such as the coring knife or inflow conduit **10**, located in the housing channel **58**. When the leaflets **56** are spread open, the valve seal **60** between the seal and the coring knife or inflow conduit **10** can

prevent the flow of blood from the heart past the valve seal **60** and out of the valvular structure **12**.

[0137] The housing **18** can have a housing seal **47** distal to the valve **16**. The housing seal **47** can seat in, and attach to the housing **18**, via a circumferential housing seal groove **55** in the housing **18**. The housing seal **47** can extend radially into the housing channel **58**. The housing seal **47** can be resilient. Similar to the valve seal **60**, the housing seal **47** can seal against an element, such as the coring knife or inflow conduit **10**, located in the housing channel **58**. When the leaflets **56** are spread open, the seal between the housing seal **47** and the coring knife or inflow conduit **10** can prevent the flow of blood from the heart out past the housing seal **47**.

[0138] The valve **16** can have a valve shoulder **59** that extends radially from the base of the valve leaflets **56**. The valve shoulder **59** can seat and interference fit into a valve groove **61** recessed in the inner surface of the housing **18**. The valve shoulder **59** can hold the valve **16** in the valve groove **61**.

[0139] FIGS. **11***a* through **11***c* illustrate another variation of the valvular structure **12** that can have a latching closure configuration. The housing **18** of this variation of the valvular structure **12** can latch closed, as shown in FIGS. **2***a* and **2***b*, locking the housing first portion **46** to the housing second portion **54** in a closed configuration. The housing **18** can also be opened by unlatching the housing first portion **46** to the housing second portion **54**.

[0140] The housing **18** can have a first joint that can have a first joint latch **69**. The joint latch can be rotated open (as shown), decoupling the housing first portion **46** and the housing second portion **54** at the housing first seam **51**. The first joint latch **69** can be rotated closed, laying substantially flush with the outer wall of the housing **18**. In a closed configuration, the first joint latch **69** can be closed onto and attach to a first joint catch **70**. The first joint latch **69** can be on the housing second portion **54**, the first joint catch **70** can be on the housing first portion **46**.

[0141] When the housing first portion **46** is separated from the housing second portion **54**, the housing **18** can be removed from the valve **16**. The valve **16** is destructible and can be torn away from the ventricular assist structure by hand or with a knife and removed from the target site after the housing **18** is removed. For example, after the inflow conduit **10** is inserted through the attachment ring **22** and the housing **18** is removed, the valve **16** can be torn away from the inflow conduit **10**.

[0142] The housing first portion **46** and/or housing second portion **54** can each have coupling grooves **71** proximal to the valve **16**. The coupling grooves **71** can be configured to slidably and lockably interface with radially extending locking tabs **181** on other components that can interact with the housing **18** such as the slitting blade case **158**, coring knife, inflow conduit **10**, or combinations thereof. The locking tabs **181** and couple groove can interface to hold, fix, or otherwise releasably couple the component inserted through the housing **18** to the housing **18** and to align the component inserted through the housing **18** to the housing **18**. For example, the locking tabs **181** and coupling groove **71** can cause a slit from a slitting blade case **158** to be at the same angular orientation and position as a coring abutment disc later-inserted through the slit, as shown in FIGS. **40***b* and **40***c*.

[0143] FIGS. **12***a* through **15***b* illustrate variations of the valve **16** with different configurations. FIGS. **12***a* and **12***b* illustrate that the valve **16** shown in FIGS. **10***a* through **10***e* can be a four-leaflet valve **16**. The inter-leaflet seams **64** can extend radially from the center of the valve **16** to the valve shoulder **59** with no inter-leaflet seam extending through the valve shoulder **59** or through the valve shoulder **59** to the outer circumference of the valve **16**, or combinations thereof. For example, as shown in FIG. **12***c*, one of the inter-leaflet seams **64** can extend through the valve shoulder **59** while the remainder of the inter-leaflet seams **64** can extend to the valve shoulder **59** without extending through the valve shoulder **59**, and the one inter-leaflet seam **64** that extends through the valve shoulder **59** can be aligned with one of the housing seams **51** or **48** when loaded in the housing **18**.

[0144] The inter-leaflet seams **64** can be completely separated seams, perforations, or combinations thereof along the length of the seam (e.g., complete separation between the leaflets **56** and perforation as the seam extends through the valve shoulder **59**). The valve **16** can be tearable by hand, for example along the inter-leaflet seam **64**. For valves **16** with a completely separated inter-leaflet seam **64**, no tearing is necessary to separate the valve **16** from an element which the valve **16** surrounds, such as the inflow conduit **10**. As shown in FIG. **12***c*, the valve can be rotated open, as shown by arrows, in a clamshell configuration to release the valve **16** from an inner element or component which the valve **16** surrounds.

[0145] FIGS. **13***a* through **13***c* show another variation of the valve **16**. The valve **16** can be a quadcuspid (i.e., four-leaflet) valve that can have inter-leaflet seams **64** that can extend through the valve shoulder **59** to the outer circumference of the valve **16**. FIG. **13***c* illustrates that the valve **16** can be rotated open, as shown by arrows, at a first interleaflet seam **64** that extends through the valve shoulder **59** between the first leaflet **68** and the second leaflet **65**. The opposite inter-leaflet seam **64** can extend to, but not through the valve shoulder **59**, acting as a hinge around which the valve halves can rotate. FIG. **13**D illustrates that the remaining inter-leaflet seams **64**—other than the inter-leaflet seam **64** that extends through the valve shoulder **59** between the first leaflet **68** and second leaflet **65**—can extend to but not through the valve shoulder **59**. The valve **16** can be further rotated open to spread open each inter-leaflet seam **64**, for example when removing the valve **16** from the coring tool or inflow conduit **10** placed through the valve **16**.

[0146] FIGS. **14***a* and **14***b* illustrate yet another variation of the valve **16** that can be a tricuspid valve (i.e., having three leaflets). FIGS. **15***a* and **15***b* illustrate yet another variation of the valve **16** that can be a bicuspid valve (i.e., having two leaflets).

[0147] FIGS. **15***c* through **15***e* illustrate variations of the valve **16** that can have opposite inter-leaflet seams **64** that extend through the shoulder on a first side of the valve **16**, and not through the shoulder on a second side of the valve **16**, opposite to the first side of the valve **16**. The opposite inter-leaflet seams **64** can converge in the middle of the valve **16** to form a single slit along a diameter of the valve **16**. The valves **16** can be miter valves. The leaflets can join together at miters or bevels at the inter-leaflet seams **64**. The leaflets can pucker or duckbill at the inter-leaflet seams **64**.

[0148] FIG. **15***c* illustrates a quadcuspid valve **16**. FIG. **15***d* illustrates a bicuspid valve **16**. FIG. **15***e* illustrates a unicuspid valve **16** (i.e., having one leaflet) that can have a seam that does not extend to the valve shoulder. A unicuspid valve is a type of diaphragm valve. A diaphragm valve can have no

more than one seam extending to the shoulder. The seam can be similar in length to the diaphragm seam **88** shown in FIGS. **21***a* and **21***b*.

[0149] FIG. **15***f* illustrates a diaphragm valve **16** that can have a diaphragm **82** but no leaflets. The seam in the valve **16** can be a straight slit or port **83** that can be closed in a relaxed an unbiased configuration. The slit or port **83** can extend along a diameter of the valve **16**, but not extend to the valve shoulder **59**. The valve **16** can duckbill, pucker or miter around the port **83**.

[0150] FIGS. **16***a* and **16***b* illustrate a variation of the valvular structure **12** that can have a valve **16** that can be an inflatable membrane **73**. The valve **16** can be inflated and deflated to close and open, respectively, the valve **16**. The valve **16** can have an inflatable valvular chamber **75** between the inflatable membrane **73** and the housing **18**. The inflatable membrane **73** can be resilient. The inflatable membrane **73** can be in a deflated and open configuration, as shown in FIG. **16***a*.

[0151] FIG. **16***b* illustrates that the inflatable membrane **73** can be in an inflated and closed configuration. The inflatable valvular chamber **75** can be pressurized, as shown by arrows, with a liquid (e.g., saline) or gas (e.g., carbon dioxide) to inflate the inflatable membrane **73**. The inflatable membrane **73** can seal around elements in the housing channel **58**, such as the coring knife or inflow conduit **10**. The inflatable membrane **73** can have a high-friction surface facing the housing channel **58** that can pressure-fit against the coring knife or inflow conduit **10**, fixing the coring knife or inflow conduit **10** in the housing channel **58**. Alternatively, the inflatable membrane **73** can have a low-friction surface facing the housing channel **58** that can allow the coring knife of inflow conduit **10** to slide within the housing channel **58** against the inflated inflatable membrane **73**.

[0152] The pressure in the inflatable valvular chamber **75** can be released, returning the inflatable membrane **73** to the open configuration and releasing the pressure-fit against any elements in the housing channel **58**.

[0153] FIG. **17***a* illustrates a variation of the valvular structure **12** that can have a valve **16** that can be a torsioning or twisting membrane **77**. The top and bottom of the housing **18** can be counter-rotated to open or close the twisting membrane **77**. The twisting membrane **77** can be loose and non-resilient or taught and resilient and elastic. The housing first portion **46** and second portion can each have a top rotatably attached to a bottom. The twisting membrane **77** can be attached to housing tops **78** (the housing first potion top is shown) and bottoms **79** (the housing first potion bottom is shown) by a membrane anchor ring **76**. The twisting membrane **77** can be in an untwisted and open configuration, as shown.

[0154] FIG. **17***b* illustrates that the housing tops **78** can be rotated with respect to the housing bottoms **79**, as shown by arrows, for example, to partially or completely close the valve **16**. The twisting membrane **77** can twist upon itself and around elements in the housing channel **58**. The twisting membrane **77** can be in a twisted and closed configuration. The tops and bottoms can be counter-rotated to untwist and open the twisting membrane **77**.

[0155] FIGS. **18***a* and **18***b* illustrate another variation of the valve **16** that can be a diaphragm valve that can be closed in an unbiased configuration and stretched open when the inflow conduit **10** or coring knife is pushed through the diaphragm valve. The valve **16** can have a first diaphragm **80** and a second diaphragm **86**. The diaphragms can be made from resilient material, such as an elastomer, or combinations thereof. For example, the diaphragm can be made from silicone, polyurethane or other blood compatible polymers. The first diaphragm **80** can be in contact with and attached to the second diaphragm **86**.

[0156] The first diaphragm **80** can have a first diaphragm port **81** that can receive the inflow conduit **10** or coring knife. The second diaphragm **86** can have a second diaphragm port **85** that can also receive the inflow conduit **10** or coring knife. The diaphragm ports can be circular. The diaphragm ports can be resiliently expandable. For example, when a solid element, such as the inflow conduit **10** or coring knife, with a diameter larger than the diaphragm ports is forced through the diaphragm ports the diaphragm ports can expand in shape and size to allow the solid element to pass through the ports and can seal against the solid element. When the solid element is removed from the diaphragm ports, the diaphragm ports can return to the relaxed, unbiased, shape and size of the diaphragm port.

[0157] The first diaphragm **80** can have a diaphragm interface lip **84**. The diaphragm interface lip **84** can be used to hold to diaphragm in the valve groove **61** in the housing **18**. The diaphragm interface lip **84** can be a ring around the outer circumference of the first diaphragm **80** that can be raised or thickened compared to the remainder of the first diaphragm **80**. The diaphragm interface lip **84** can be formed a result of the attachment of the second diaphragm **86** and the first diaphragm **80**. For example the diaphragm interface lip **84** can be a rib formed by fusing, gluing or welding, or a reinforcement.

[0158] The second diaphragm **86** can have a diameter smaller than the diameter of the first diaphragm **80**. The second diaphragm **86** can be attached to the first diaphragm **80** at or near the outer circumference of the second diaphragm **86**. The second diaphragm **86** can attach to the first diaphragm **80** on the diaphragm interface lip **84** or on the face of the first diaphragm **80** on the opposite side of the diaphragm interface lip **84**.

[0159] When the first diaphragm **80** and the second diaphragm **86** are attached, the first diaphragm port **81** can be incongruous from (i.e., not overlapping with) the second diaphragm port **85** when the first and second diaphragms **80** and **86** are in relaxed, unbiased configurations. When the diaphragm valve **16** is in a relaxed, unbiased configuration, the first diaphragm port **81** and the second diaphragm port **85** can overlap completely, partially or not at all (as shown). The diaphragm valve **16** can have a substantially fluid-tight seal in a relaxed configuration.

[0160] The diaphragm valve **16**, or other valve variations such as the leaflet valves, can allow a check flow, for example a small amount of blood flow used to test or confirm if positive blood pressure exists on the opposite side of the valve **16**. For example, the pressure between the first diaphragm **80** and the second diaphragm **86** can be insufficient to completely seal when pressurized blood from the heart is in contact with the diaphragm valve **16**, and a small trickle or drip-flow of blood can pass through the diaphragm ports **81** and **85**. In an alternative variation, the leaflets can have a check flow channel, a small channel longitudinally aligned in the inter-leaflet seam that can allow check flow to flow between adjacent leaflets in a direction opposite to the low-resistance orientation of valve.

[0161] FIGS. **19***a* and **19***b* illustrate a variation of the attachment ring **22** with an integrated diaphragm valve **16**. The first diaphragm **80** can be integral with the attachment

ring wall **29**. The first diaphragm **80** can substantially close the end of the of the attachment ring channel **14**. The second diaphragm **86** can be attached to the first diaphragm **80** and/or the attachment ring wall **29**. Similarly, the other valve types described can also be integrated with the attachment ring **22**. For example, FIGS. **19***c* and **19***d* illustrates a variation of the attachment ring **22** integrated with a quadcuspid valve **16**. FIG. **20** illustrates the exploded assembly of a variation of the diaphragm valve **16** in a valvular structure **12** attached to an attachment ring **22**. The valve **16** can be separate and detachable from the attachment ring **22**. The diaphragm **82** can be attached to a diaphragm flap **87**. The housing first portion **46** and housing second portion **54** can have a diaphragm groove **90** circumferentially around the radially inner surface of the housing **18**. The diaphragm interface lip **84** can seat in and attach to the diaphragm groove **90**.

[0162] The housing first portion **46** and housing second portion **54** can have a ring groove **94** circumferentially around the radially inner surface of the housing **18**. The ring wall interface lip **25** can seat in and attach to the ring groove **94**.

[0163] The housing first portion **46** can have a housing first handle **93**. The housing second portion **54** can have a housing second handle **91**. The housing handles **91** and **93** can be pulled to separate the housing first portion **46** from the housing second portion **54**. For example, the housing first seam **51** and the housing second seam **48** can be completely separated or perforated.

[0164] The tape **89** can be a substantially unresilient, flexible polymer strip tightly wrapped around the radial outer surface of the housing **18**. The tape **89** can radially compress the housing first portion **46** and the housing second portion **54**, keeping the housing first portion **46** attached to the housing second portion **54**. The tape **89** can have an adhesive applied to the radial inner surface. The tape **89** can be wound once or more around the housing **18** and can stick to the housing **18** and to inner layers of the tape **89** itself.

[0165] Alternatively, the tape **89** can be an elastomeric hollow cylinder or band. The tape **89** can be placed onto the housing **18** by stretching the tape **89** over the housing **18** and releasing the tape **89** from the stretching force, resiliently radially compressing the housing **18**.

[0166] FIGS. **21** a through **21***c* illustrate another variation of the diaphragm valve **16**. FIG. **21** b illustrates that the diaphragm **82** can have a diaphragm seam **88** extending from the diaphragm port **83** to the external circumference of the diaphragm **82**. The diaphragm seam **88** can be a complete split separating each side of the diaphragm seam **88**, allowing an element, such as the inflow conduit **10** or coring knife, to pass through the diaphragm **82** at the diaphragm port **83** and/or the diaphragm seam **88**. The diaphragm port **83** can be in the radial center of the diaphragm **82**. The diaphragm flap **87** can cover the diaphragm port **83**.

[0167] FIG. **21***c* illustrates that the diaphragm flap **87** can attach to the diaphragm **82** at an attachment area **96**. The diaphragm flap **87** can be unattached to the diaphragm **82** except for at the attachment area **96**, allowing the diaphragm flap **87** to open out of the way when an element is pushed through the diaphragm port **83** and/or diaphragm seam **88**. The diaphragm flap **87** can be rigid or flexible. The diaphragm flap **87** can be resilient. The diaphragm flap **87** can be made from the same materials as the diaphragm **82**.

[0168] The diaphragm flap **87** can extend to the external circumference. The diaphragm flap **87** can cover the diaphragm port **83** and the diaphragm seam **88**. The diaphragm flap **87** can cover a portion of the side of the diaphragm **82** and leave a portion of the side of the diaphragm **82** exposed (as shown) or can cover the entire side of the diaphragm **82**.

[0169] When the fluid pressure on the side of the diaphragm **82** of the diaphragm flap **87** exceeds the fluid pressure on the side of the diaphragm **82** opposite the diaphragm flap **87**, the diaphragm flap **87** can press against the diaphragm seam **88** and diaphragm port **83**, further sealing the diaphragm **82**.

[0170] When an element, such as the coring knife or inflow conduit **10**, is forced through the diaphragm **82** from the side of the diaphragm **82** opposite of the diaphragm flap **87**, the element can press open the diaphragm **82** at the diaphragm port **83** and diaphragm seam **88**, and the diaphragm flap **87** can be pressed aside as the element moves through the diaphragm **82**.

[0171] FIG. **22** illustrates that when the valvular structure **12** is assembled the diaphragm interface lip **84** can be seated in the diaphragm groove **90** of the housing **18**. The housing first portion (not shown) and the housing second portion **54** can be compressed together by tape **89** wound around the external circumference of the housing **18**.

[0172] FIG. **23** illustrates that the valvular structure **12** can have a locking ring **98** that can be used to compress the attachment ring **22** against an inflow conduit **10** placed in the attachment ring channel **14**. For example, the locking ring **98** can be used in lieu of or in addition to the clamp **24**. The locking ring **98** can be releasably attached to the radially internal surface of the housing **18**. The locking ring **98** can be separably attached to the housing **18** with circumferential rails and interfacing grooves on the radially outer surface of the locking ring **98** and the radially inner surface of the housing **18**.

[0173] The de-airing ports **62** (as shown) can act as handle ports and/or be used to de-air the valvular structure **12**. The handle ports can attach to housing handles or can be open to be used for de-airing, as described herein.

[0174] FIG. **24** illustrates that the tape **89** can be wound radially around the outer surface of the housing **18**. The tape **89** can compress the housing first portion **46** to the housing second portion **54**. The tape **89** can have adhesive, for example, on the side of the tape **89** facing the housing **18**. The tape **89** can have no adhesive and be elastic, for example, attaching to the outer surface of the housing **18** by a friction-fit from the tape **89** elastically compressing against the housing **18**.

[0175] FIG. **25** illustrates that the valvular structure **12** can be attached to the attachment ring **22**, for example, by snapping the valvular structure **12** onto the attachment ring **22**. The valvular structure **12** can be attached to the attachment ring **22** before or during the VAD implant procedure.

[0176] The valvular structure **12** can be translated, as shown by arrow, over the attachment ring wall **29**. The ring wall interface lip **25** can have a sloped side facing in the direction of the on-loading valvular structure **12**. As the valvular structure **12** is being pressed onto the attachment ring **22**, the portion of the housing **18** that is distal to the ring groove **94** can deform over the sloped side of the ring wall interface lip **25**. The ring wall interface lip **25** can then seat and interference fit into the ring groove **94**.

[0177] FIGS. **26***a* and **26***b* illustrate another variation of snapping the valvular structure **12** onto the attachment ring **22**. In this variation, the valvular structure **12** can have a locking ring **98**. The locking ring **98** can have a locking ring wall angle **100** with respect to the housing channel longitu-

dinal axis **103**. The locking ring wall angle **100** can be, for example, from about 3° to about 15°, for example about 10°.

[0178] The ring wall interface lip **25** can have a sloped side facing in the direction of the on-loading valvular structure **12**. The sloped side of the ring wall interface lip **25** can form a ring wall angle **102** with the attachment ring channel longitudinal axis **101**. The ring wall angle **102** can be from about 3° to about 15°, for example about 10°. The ring wall angle **102** can be substantially equal to the locking ring wall angle **100**.

[0179] The valvular structure **12** can be pressed onto the attachment ring **22**, over the attachment ring wall **29**, as shown by arrow. As the valvular structure **12** is being pressed onto the attachment ring **22**, the portion of the housing **18** distal to the ring groove **94** can deform over the sloped side of the ring wall interface lip **25**.

[0180] FIG. **26***b* illustrates that the valvular structure **12** can be pressed onto the assembly ring, as shown. The ring wall interface lip **25** can seat and interference fit into the ring groove **94**.

[0181] Method of Using

[0182] FIGS. **27***a* and **27***b* illustrate a process for surgically implanting a ventricular assist system. It should be appreciated to a person with ordinary skills in the art that the surgical, preparation, and implantation processes described can be performed in a different order as presented. The surgical process for implanting the ventricular assist system can begin by anesthetizing the patient and placing the patient in a supine position. The left ventricular apex and ascending aorta **104** can then be exposed using a less invasive approach, such as a left subcostal incision and a second right anterior mini-thoracotomy, or a common sternotomy which is typically more invasive but allows more space for a surgeon to operate.

[0183] The method can include space for placement of an outflow conduit **2**/graft by tunneling from a subcostal position to an aortic location. For example, an outflow graft tunnel can be created between the two incisions (e.g., the left subcostal incision and the right anterior mini-thoracotomy) with a malleable tunneler and/or a curved tunneler. The tunneler **177** can begin at the left subcostal thoracotomy and tunnel to the right anterior mini-thoracotomy.

[0184] The tunneler **177** can have a tunneler tip that can then be removed from the tunneler once the tunneler has reached the right anterior mini-thoracotomy. The outflow graft connector can then be attached to the end of the tunneler and pulled back through the tunnel created between the incisions. The outflow graft can then be connected to a pump sizer at the target site for the pump **8**. The pump sizer is a plastic element the size and shape or the pump **8** that can be used to check the fit of the finally deployed pump **8** by inserting the pump sizer at the target site before inserting the pump **8**.

[0185] With the outflow graft attached to the pump sizer, the outflow graft can be measured and cut to length to fit the space between the pump **8** and the aorta **104** with enough slack in the outflow conduit **2** to allow movement of the pump **8** and organs, but not too much slack to enable kinking of the outflow conduit **2**.

[0186] If the process does not include the use of a heart-lung by-pass machine and is performed while the heart **106** is pumping, the outflow graft can then be anastomosed to the aorta **104** using a side biting clamp to hold the aorta **104** and an aortic punch **126** to make the incision in the aorta **104**.

[0187] After blood is allowed to flow into the outflow graft for purging air from inside the outflow graft or conduit **2**, a clamp **131**, such as a hemostat, can then be placed on the outflow graft **2**, or a balloon **135** can be inflated in the outflow graft to stanch the flow of blood from the aorta **104** through the outflow graft **2**. The control of blood from the heart **106** and de-airing can also or additionally be performed by creating a slit into the wall of the outflow graft **2**. A balloon catheter **132** can then be delivered into the outflow graft **2** through the slit. The balloon **135** can then be positioned in the pump outflow connector and inflated to plug the pump outflow connector. End and or side ports on the balloon catheter **132** can be used for de-airing.

[0188] The pump **8** and the inflow conduit **10** or inflow graft can be prepared prior to connection of the inflow conduit **10** to the heart **106**. The proximal end of the inflow conduit **10** is connected to the pump **8** in a saline bath to purge all air from the inflow conduit **10** and the pump **8** prior to having the distal end of the inflow conduit **10** connected to the heart **106**. In this preparation process, the entire inflow conduit **10** and the pump **8** can both be submerged into a saline bath and connected. A blockage at the outflow end of the pump **8** is placed to prevent blood from escaping after the distal end of the inflow conduit **10** is connected to the heart **106**.

[0189] Prior to connection of the inflow conduit **10** to the heart **106**, the attachment ring **22** can be sewed onto the epicardial surface of the target connection area on the heart **106**. In one variation, sutures can be used to secure the cuff **35** of the attachment ring **22** onto the heart **106**. The valvular structure **12** or external seal can then be secured against the attachment ring **22**, for example, by placing and securing the valvular structure **12** over the walls forming the attachment ring channel **14**. A slitting blade or tool can be inserted through the valvular structure **12** and the attachment ring **22** to create a slit into the myocardium at the target connection area. A coring knife **140** can then be inserted through the slit and used to core a portion of the myocardium. The inflow conduit **10** can then be inserted through the valvular structure **12** and the attachment ring **22** to into the opening of the heart **106** created by the coring knife. The inflow conduit **10** can be secured to the attachment ring **22** with the radial clamp **24**. The valvular structure **12** including the external seal can then be removed. The inflow conduit **10** can be inserted further into the left ventricle. The radial clamp **24** can then be radially compressed (e.g., released from a radially expanded configuration) and/or locked to secure the inflow conduit **10** to the attachment ring **22**.

[0190] The entire system can be completely de-aired in the process of connecting the outflow graft to the pump **8**. De-airing or the removal of all the air from the outflow graft and the pump **8** can be performed with the use of a de-airing bladder, enclosure or a bath of saline. The unconnected end of the outflow graft can be submerged into the bath of saline along with the outflow end of the pump **8** that has the blockage. The clamp or balloon **135** can be removed from the outflow graft and all the air in the outflow graft and pump **8** can be allowed to escape or pushed by the flow of blood from the aorta **104** into the bladder, enclosure, or the bath of saline, for de-airing. Similarly, the outflow end of the pump **8** with the blockage is also submerged into the saline bath. Once the hemostatic outflow graft clamp **131** is removed from the outflow graft and the blockage is removed from the outflow end of the pump **8**, any air remaining in either the outflow graft or in the pump **8** will be allowed to escape into the saline bath or enclosure. If the balloon **135** had previously been inserted into the pump outflow connector, the de-airing can occur by releasing the hemostatic clamp **131** from the outflow

graft **2** resulting in blood from the aorta **104** flooding and bleeding out the outflow graft **2**. The outflow graft **2** can then be connected to the pump outflow connector. The balloon **135** can be deflated and the balloon catheter **132** can then be pulled out from outflow graft **2**. The hole in the site of the outflow graft **2** used for introducing the balloon catheter **132** can then be closed with a purse string suture. The outflow graft **2** is connected to the outflow end of the pump **8** after air is removed from the system.

[0191] A tunnel can be formed for the percutaneous lead **5** to extend from the pump **8** out of the body. The pump **8** can then be turned on to run and assist the blood flow from the left ventricle. The surgical wounds on the patient can then be closed.

[0192] FIGS. **28** to **35** will collectively illustrate the process of accessing the heart **106** and target implantation vasculature and the tools used to create a tunnel for an outflow conduit **2**. FIGS. **28**, **32** and **35** illustrate the process of creating a tunnel and implanting an outflow conduit **2** in the tunnel, and FIGS. **29***a* through **31** illustrate the variations of tools used for this tunnel creation process. FIGS. **33***a* through **33***c* illustrate the process and tools for creating an aortotomy **128** in the target vasculature for an anastomotic connection with the outflow conduit **2**. FIGS. **34***a* through **34***b* illustrate the processes and tools for preventing blood from spilling out of the outflow conduit **2** after it is connected to the target vasculature.

[0193] FIG. **28***a* illustrates the creation of a tunnel for the outflow conduit **2** without a sternotomy. FIG. **28***b* illustrates that when a sternotomy is performed, creating a sternotomy opening **107**, there is no need to tunnel.

[0194] In a less invasive variation of the procedure, as shown in FIG. **28***a*, the target site can be accessed by making a first incision **110** caudally or inferior to the target site, for example just below the apex on the left side of the heart **106**. A second incision **108** can be made cranial to the target site, on an opposite side of the target site from the first incision **110**. The second incision **108** can be made near the right second intercostal to provide access to the aorta **104**. The tunneler **177** can then be inserted, as shown by arrow **111**, into the first incision **110** and tunneled between the first and second incision **110** and **108**, as shown by arrow **109**. The end of the tunneler **177** can then exit, as shown by arrow **105**, from the patient at the second incision **108**, or be inside the patient but accessible from the second incision **108**.

[0195] FIGS. **29***a* to **30***b* illustrate variations of a tunneler **177** that can be used for creating the outflow conduit tunnel. FIG. **29***a* illustrates one example of a tunneler **177** that can have an elongated tunneler shaft **115**. The tunneler **177** can have a tunneler handle **114** at a proximal end of the tunneler shaft **115**. The tunneler shaft **115** can be straight when in a torsionally unstressed state. The tunneler shaft **115** is of a substantially smaller diameter than the distal attachment cone **118** so that it can be malleable or flexible for shaping into a configuration that fits the anatomy of the patient. The tunneler **177** can have a distal attachment cone **118** at the distal end of the tunneler shaft **115**. In one variation, this distal attachment can be a bullet tip **124** at the distal end of the tunneler **177**. The bullet tip **124** can have a smooth or flush seam with the distal attachment cone **118**. The bullet tip **124** can be removed from the distal attachment cone **118** and expose or be replaced with different distal attachment interface configurations. For example, the bullet tip **124** can be attached to, or replaced with, a distal attachment collet **123** extending distally from the distal attachment cone **118**, as shown in FIG. **29***b*. Similarly, the bullet tip **124** can be attached to, or replaced with, a distal attachment bolt **122** extending distally from the distal attachment cone **118**, as shown in FIG. **29***c*. The distal attachment bolt **122** can have helical thread **121**. The objective of the distal attachment bolt **122** and the distal attachment collet **123** are for attachment with a proximal end of the outflow graft as will be illustrated further below.

[0196] FIGS. **30***a* and **30***b* illustrate another variation of the tunneler **177** that can have an outer sheath **125** attached to the distal attachment cone **118**. The tunneler shaft **115** can be separate from the outer sheath **125** and distal attachment cone **118**. The outer sheath **125** can be of a diameter that is similar to the diameter of the distal attachment cone **118** and can be hollow. While the diameter of the tunneler shaft **115** and the outer sheath **125** differs, the outer sheath **125** and the tunneler shaft **115** can have substantially equal radii of curvature. The tunneler shaft **115** and outer sheath **125** can be rigid. The tunneler shaft **115** can be slidably received by the outer sheath **125**.

[0197] The tunneler **177** can be inserted through the first incision **110** at a desired location in the abdomen and/or thorax to create the tunnel for ultimate placement of the outflow conduit **2**. The bullet tip **124** can be configured with a blunt tip to atraumatically separate or create a path through tissue when the tunneler **177** is being inserted through the patient.

[0198] FIG. **31** illustrates that the bullet tip **124** can be removed and the outflow conduit coupler **4** can be attached to the distal attachment interface. The outflow conduit **2** can extend from the terminus of the tunneler **177**. The tunneler **177** can be used to manipulate the location and orientation (i.e., rotate, twist, translate, steer) of the outflow conduit **2**.

[0199] The outflow conduit **2** can be attached to the tunneler **177** after the distal end of the tunneler **177** is passed through the patient and out of, or adjacent to, the second incision site, such as a surgical opening near the aorta **104** like a right anterior mini thoracotomy or a mini sternotomy near the aorta **104**. FIG. **32** illustrates that when the distal attachment interface is positioned at the distal end of the tunnel or out of the second incision **108**, the bullet tip **124** can be removed from the distal attachment interface and the outflow conduit coupler **4** can be attached to the distal attachment interface. The tunneler handle **114** can then be pulled to draw the outflow conduit coupler **4** and outflow conduit **2** through the tunnel.

[0200] FIG. **33***a* illustrates the use of an aortic clamp **127** to clamp a portion of the wall of the aorta **104**. This aortic clamp **127** can be a side-biting clamp of any shape, and is typically used when the vasculature (e.g., aorta **104**) is still filled with blood, for example, when a heart-lung by-pass machine is not used. An aortic punch **126**, or scalpel or other tool can be applied to the clamped portion of the aorta **104** to create a small opening in the vasculature or target vessel (e.g., aorta **104**), as shown in FIG. **33***b*. FIG. **33***c* illustrates that the outflow conduit **2** can then be attached to the target vessel by attaching the circumferential edge of the distal end of the outflow graft/conduit around the opening with sutures (as shown), staples, clips, brads, glue, or combinations thereof.

[0201] FIG. **34***a* illustrates removal of the aortic clamp **127** from the aorta **104**. Once the aortic clamp **127** is removed, blood flow **130** through the aorta **104** will branch off and flow through the outflow conduit **2**, as shown by arrows. If the outflow conduit **2** is not obstructed, the blood flow **130** from

the aorta **104** can flow through the outflow conduit **2** and exit through the (proximal) open end of the outflow conduit **2**.

[0202] FIG. **34***b* illustrates a variation of a method for stanching the blood flow **130** through the outflow conduit **2**. A vascular clamp **131** can be placed on the outflow conduit **2** to compress the outflow conduit **2**, closing and obstructing the outflow conduit **2** and stanching the flow of blood from the aorta **104** through the outflow conduit **2**.

[0203] FIG. **34***c* illustrates another variation of a method for stanching blood flow **130** through the outflow conduit **2**. An inflatable balloon **135**, similar to an angioplasty balloon, can be inserted through the wall of the outflow conduit **2**. The balloon **135** can be in fluid communication with a catheter **132**. The balloon **135** can be inflated with a gas (e.g., carbon dioxide) or liquid (e.g., saline.) The balloon **135** can be inflated when in the outflow conduit **2**, closing the outflow conduit **2** and stanching the flow of blood from the aorta **104** through the outflow conduit **2**. The balloon **135** can be made of a single material along the entire surface of the balloon **135**.

[0204] FIG. **34***d* illustrates yet another variation of a method for stanching blood flow **130** through the outflow conduit **2**. The balloon **135** can be covered with two or more materials. In a first variation, the balloon **135** can be a composite balloon made of two sub-balloons, the first sub-balloon covered with a first material and having a first volume, and the second sub-balloon covered with the second material and having a second volume. In a second variation, the balloon **135** cave have a first volume covered by the first material and separated by a balloon septum **185** from the second volume covered in the second material. The first volume can be in fluid communication with a first channel in the catheter **132**, and the second volume can be in fluid communication with a second channel in the catheter **132** or a second catheter. The first material can be on the balloon distal surface **133** and the second material can be on the balloon proximal surface **134**. The first material on the balloon distal surface **133** can be gas impermeable. The second material on the balloon proximal surface **134** can be made from a material that can be gas permeable, but not liquid permeable (i.e., a breathable membrane such as PTFE or acrylic copolymer). The balloon distal surface **133** can face the aorta **104** and the balloon proximal surface **134** can face away from the aorta **104** when the balloon **135** is inserted in the outflow conduit **2** and inflated.

[0205] When de-airing the outflow conduit **2**, fluid (e.g., blood and residual air) can be pumped from the pump **8** through the outflow conduit coupler **4**. Air in the VAD can pass through the balloon proximal surface **134** and into the balloon **135**. The balloon distal surface **133** and first volume can be inflated to obstruct the air from flowing through the vessel and force the air into the balloon proximal surface **134** while allowing the blood and/or saline to flow through the outflow conduit **2** and into the aorta **104**. The air captured in the balloon **135** can be withdrawn through the catheter **132**.

[0206] FIG. **35** illustrates that the outflow conduit **2** can be drawn through the tunnel, for example, positioning the outflow conduit coupler **4** near the first incision **110** or otherwise at or adjacent to the target site for the pump **8**. As described above, the outflow conduit **2** can be connected to the aorta **104** (i.e., aortic anastomosis) with an aortic attachment device, such as aortic sutures **117**. The aortic anastomosis can occur before or after the outflow conduit **2** is drawn into and/or through the thorax, for example, by the tunneler **177**.

[0207] After the outflow conduit **2** is drawn through the thorax, the attachment ring **22** can be sutured to the heart apex **119** with an apical attachment device, such as apical sutures **113**. The attachment ring **22** can be placed against, and attached to, either the left (e.g., at the apex) or right ventricles or the left or right atria. The apical sutures **113** can be the same or different suture material and size as the aortic sutures **117**. The attachment ring **22** can be attached to the apex with or without the valvular structure **12** attached to the attachment ring **22**.

[0208] FIGS. **36***a* through **38** illustrate variations of a cutting tool, such as the coring knife **140**, that can be used to core a piece of the epicardial tissue while the heart **106** is beating. FIGS. **36***a* through **36***e* illustrate a variation of the coring knife **140** with a cylindrical coring blade **137** configured to chop or shear heart tissue against an abutment surface on the proximal side of a conical knife head **136**. FIGS. **37***a* through **37***d* illustrate another variation of the coring knife **140** that can have a rotatable coring abutment **145** to insert through a small slit in the heart **106** and then rotate to squeeze against and compress the heart tissue which is desired to be cored. FIG. **38** illustrates a yet another variation of the coring knife **140** that has a foreblade **152** that is independently deployable from the knife head **136**.

[0209] FIGS. **36***a* through **36***d* illustrate a variation of the coring knife **140**. The coring knife **140** can have a hollow cylindrical coring blade **137**. The coring knife **140** can have a conical or bullet-shaped knife head **136**. The knife head **136** can be shaped to push apart a pre-cut slit in epicardial tissue to introduce the knife head **136** into the left ventricle. The proximal surface of the knife head **136** can be a coring abutment **145** that the coring blade **137** can cut against.

[0210] The coring knife **140** can have a knife handle **139** at the proximal end of the coring knife **140**. The knife handle **139** can be fixed to a coring control shaft **143**. The coring control shaft **143** can be fixed to the knife head **136**. Translation of the knife handle **139** can directly control translation of the knife head **136**. The knife can have a knife stop **138** radially extending from the body of the coring knife **140**. The knife stop **138** can limit the extent of the translation of the knife handle **139**, and therefore the knife head **136**, with respect to the coring blade **137**. The knife stop **138** can prevent over insertion of the coring blade **137** into tissue. For example, in use the knife stop **138** can abut the attachment ring **22** or valvular structure housing **18** preventing or minimizing the risk of inserting the coring blade **137** through the heart wall and into the septum.

[0211] FIG. **36***e* illustrates that the knife handle **139** can be translated distally, as shown by arrow, to translate the knife head **136** distally (i.e., extend), as shown by arrow, away from the coring blade **137**. The knife handle **139** can be translated proximally, as shown by arrow, to translate the knife head **136** proximally (i.e., retract), as shown by arrow, toward the coring blade **137**. The coring abutment **145** can interference fit against the distal cutting edge of the coring blade **137**. The coring abutment **145** can move within and adjacent to the coring blade **137**, for example when the outer diameter of the coring abutment **145** is smaller than the inner diameter of the distal end of the coring blade **137**. In this configuration, the coring abutment **145** can shear tissue against the coring blade **137**.

[0212] FIGS. **37***a* and **37***b* illustrate a variation of the coring knife **140** that can have a rotatable coring abutment **145** that can be passed through a slit in the heart wall and then rotated to face the coring blade **137**. The coring abutment **145** can be a circular disc. If the slit in the heart wall is not already created

when the coring abutment **145** is passed through the heart wall and/or the slit is not large enough for the coring abutment **145** to pass, the circular disc of the coring abutment **145** can be used to create the slit in the heart wall. The coring abutment **145** can be rotatably attached to a control arm **146**. The control arm **146** can be attached to the knife handle **139** in a configuration allowing the knife handle **139** to rotate the coring abutment **145** through manipulation of the control arm **146**. The knife handle **139** can be rotatably attached to the proximal end of the coring control shaft **143**.

[0213] The outside surface of the coring control shaft **143** can have a helical coring groove, for example along the length of the coring control shaft **143** that passes through the coring knife case **141**. The coring knife case **141** can have a guide peg **148** that extends radially inward from the coring knife case **141**. The guide peg **148** can be fixed to the coring knife case **141**. The guide peg **148** can seat in the helical coring groove, controlling the movement of the coring control shaft **143** with respect to the coring knife case **141**. For example, the coring blade **137** can be rotated helically with respect to the coring knife case **141**.

[0214] FIG. **37***c* illustrates that the knife handle **139** can be rotated, as shown by arrow **142**, rotating the coring abutment **145**, as shown by arrow **149**. The plane defined by the coring abutment **145** in a rotated configuration can be parallel to the plane defined by the cutting edge of the coring blade **137**.

[0215] FIG. **37***d* illustrates that the knife handle **139** can be moved in a helical motion, as shown by arrow **144**, helically moving the coring control shaft **143** and coring blade **137**, as shown by arrow **150**. The helical motion of the knife handle **139** can be constrained by the guide peg **148** slidably fitting into the helical coring guide **147**. The coring blade **137** can be helically rotated and translated to abut the proximal surface of the coring abutment **145**. The coring blade **137** can be rotated and translated until the coring blade **137** abuts the coring abutment **145**.

[0216] FIG. **38** illustrates that the coring knife **140** can have a foreblade **152** that can be used to create a slit in the epicardial tissue through which the coring knife **140** can be inserted into the ventricle. The coring knife **140** with a rotatable coring abutment **145** can also be configured with an integral foreblade **152**. The foreblade **152** can be controllably extended distally out of the distal surface of the knife head **136**. The coring knife **140** can have a foreblade control knob **155** that can be used to extend and retract the foreblade **152**. The foreblade control knob **155** can be fixed to the foreblade **152** by a foreblade control shaft **174**, shown in FIGS. **41***b* through **41***d*. The foreblade control knob **155** can be translated proximally and distally, as shown by arrows **154**, within a knob port **157** to translate the foreblade **152** proximally and distally, respectively, as shown by arrows **153**, with respect to the knife head **136**.

[0217] Translating the knife handle **139**, as shown by arrows **162**, can translate the knife head **136**, as shown by arrows **151**, independently of the foreblade **152**. Translating the knife handle **139** can extend and retract the coring blade **137**. The foreblade control knob **155** can be rotated, shown by arrows **156**, to lock or unlock the translation of the foreblade **152** to the translation of the knife handle **139**.

[0218] The knife head **136** can have a chisel-tipped configuration. The distal end of the knife head **136** can be traumatic or atraumatic.

[0219] FIGS. **39***a* and **39***b* illustrate that the coring knife **140** can be inserted, as shown by arrow, through the housing **18** of the valvular structure **12** and the attachment ring **22**. The leaflets **56** of the valve **16** can resiliently deform away from the coring knife **140**. The leaflets **56**, valve seal **60**, housing seal **47**, or combinations thereof, can form fluid-tight seals around the coring knife **140**, for example to prevent or minimize the flow of blood from the heart **106** and out of the valvular structure **12** during use of the coring knife **140**.

[0220] FIGS. **40***a* through **40***i* illustrate a variation of a method for coring the heart **106** and attaching the inflow conduit **10** to the heart **106** while the heart **106** is beating. FIG. **40***a* illustrates that the attachment ring **22** can be placed against the wall of the heart **106**. One or more sutures **113** can be sewn through the cuff **35** and the heart **106**, fixing the attachment ring **22** to the heart **106**. The clamp **24** can be attached to the attachment ring **22** in an open configuration, as shown. The valvular structure **12** can be attached to the attachment ring **22** before or after the attachment ring **22** is attached to the heart **106**. The air can be removed from the attachment ring channel **14** and/or housing channel **58** at any time by inserting blood and/or saline into the de-airing port **62** and/or by applying suction to the de-airing port **62**, for example before slitting or coring an opening into the heart wall.

[0221] FIG. **40***b* illustrates that the initial slit in the heart wall can be made by a slitting blade. The slitting blade can be contained in a slitting blade case **158** and configured to extend from and retract into the slitting blade case **158**. The slitting blade case **158** can be inserted through the valvular structure **12** and attachment ring **22**. The slitting blade case **158** can have slitting blade handles **160** and a slitting blade plunger **159**. The slitting blade plunger **159** can control a sharp, linear slitting blade (not shown) at the distal end of the slitting blade case **158**. The slitting blade plunger **159** can be translated, as shown by arrow **161**, inserting the slitting blade through the heart **106** and forming a slit in the heart **106**. The valve **16** and seals in the valvular structure **12** can form a fluid-tight seal against the slitting blade case **158**, preventing blood from flowing out of the heart **106** through the valvular structure **12**. The slitting blade case **158** can be removed from the valvular structure **12** and the procedure site after the slit is formed. Instead of a slitting blade, the slit can be formed by a foreblade **152** extended from a coring knife **140**, as shown and described in FIGS. **41***a* through **41***d*.

[0222] FIG. **40***c* illustrates that the coring knife **140** can be translated, as shown by arrow **163**, into the valvular structure **12** and attachment ring **22**. The coring knife **140** engages with the valvular structure **12** with locking tabs **181** and locking slots or coupling grooves **71** to provide a reliable connection and a depth marker and locator. The coring abutment **145** can be inserted through the slit in the heart **106** formed by the slitting blade. The coring abutment **145** can be pushed into the left ventricle **165** while the heart **106** continues to beat. The seals and valve **16** can produce a seal around the coring knife **140** preventing blood from flowing out of the beating heart **106** through the valvular structure **12**.

[0223] FIG. **40***d* illustrates that the knife handle **139** can be rotated, as shown by arrow **142**, rotating the coring abutment **145**, as shown by arrow **149**, for example, to prepare the coring knife **140** to core a portion of the heart **106**. The coring abutment **145** can be in a plane substantially parallel with, and adjacent to, the internal side of the adjacent heart wall in the left ventricle **165**.

[0224] FIG. **40***e* illustrates twisting the coring blade **137** to cut a cylinder of the heart wall away from the rest of the heart

wall. The handle can be helically moved, as shown by arrow **144**, helically extending the coring blade **137**, as shown by arrow **150**, through the heart wall. The distal edge of the coring blade **137** can be sharpened and/or serrated and can cut the heart wall as the coring blade **137** moves through the heart wall. The coring abutment **145** can resist motion of the heart wall away from the coring blade **137**, compressing the heart wall between the coring blade **137** and the coring abutment **145**. The coring blade **137** can be extended until the coring blade **137** contacts the coring abutment **145**, coring the heart wall. The heart wall can be cored coaxial (i.e., along substantially the same longitudinal axis) with the valvular structure **12** and/or attachment ring **22**.

[0225] In an alternative variation of the coring knife **140** with the coring abutment **145** having a smaller outer diameter than the inner diameter of the cutting edge of the coring blade **137**, the coring blade **137** can be extended until the coring blade **137** passes adjacent to the coring abutment **145**, shearing the cored tissue **175** between the coring blade **137** and the outer circumference of the coring abutment **145**.

[0226] The coring knife **140** can be withdrawn and removed from the heart **106**, attachment ring **22** and valvular structure **12** with the coring blade **137** pressed against the coring abutment **145** to form a closed volume in the coring blade **137**. The core of heart tissue formed by the coring blade **137** can be stored within the coring blade **137** and removed from the target site with the coring knife **140**.

[0227] FIG. **40***f* illustrates that the inflow conduit **10** of the pump **8** (pump **8** not shown in FIG. **40***f*) can be translated, as shown by arrow **183**, into the valvular structure **12** and the attachment ring **22**. The inflow conduit stop **42** can abut and interference fit against the housing **18**, stopping translation of the inflow conduit **10**.

[0228] The valvular structure **12** and attachment ring **22** can be de-aired by applying suction to the de-airing port **62** of the valvular structure **12** and/or injecting saline or blood into the de-airing port **62**. The valvular structure **12** can be de-aired once during the implantation of the ventricular assist system or multiple times throughout the implantation, for example immediately before and/or after insertion of the inflow conduit **10** through the valvular structure **12**.

[0229] After the inflow port **7** of the inflow conduit **10** is located in the heart **106** and/or past a fluid tight seal formed against the attachment ring **22** (e.g., with the attachment ring seal **34**) and/or the valvular structure **12** (e.g., with the housing seal **47** and/or valve **16**), the valvular structure **12** can be removed from the attachment ring **22**. For example, the first joint latch **69** can be opened, as shown by arrows **168**. The housing first portion **46** and housing second portion **54** can then be rotated open and removed from the attachment ring **22**, as shown by arrows **169**.

[0230] FIG. **40***g* illustrates the valvular structure **12** in a configuration when being opened and in the process of being removed from the inflow conduit **10**. A first portion of the valvular structure **12** can be rotated away from a second portion of the valvular structure **12**. For example, the interleaflet seam **64** can open at a lateral perimeter surface of the valve **16**, splitting open the valve **16** along the respective housing seam **51** or **49**, and the housing first portion **46** can rotate open away from the housing second portion **54** at a hinge at the housing second seam **48**. When the housing **18** is removed, the valve **16** can separate from the housing **18** and remain on the inflow conduit **10**. The valve **16** can then be rotated open at the end of an interleaf seam that extends to but not through the valve shoulder **59** (with the valve shoulder **59** acting as a hinge), as shown in FIG. **40***g*, and/or cut or torn at the interleaf seam and pulled away from the inflow conduit **10**. The valve **16** can be removed with the housing **18** from the inflow conduit **10**, as shown in FIG. **40***g*, or after the housing **18** is removed from the inflow conduit **10**. FIG. **40***h* illustrates the inflow conduit **10** and attachment ring **22** following the removal of the valvular structure **12**. The pump **8** is not shown but is attached to the distal end of the inflow conduit **10**. The inflow conduit **10** can have an indicator that the pump **8** should be attached to the distal end of the inflow conduit **10**.

[0231] FIG. **40***i* illustrates that the inflow conduit **10** can be further translated, as shown by arrows, into the left ventricle **165**. The inflow conduit **10** can be translated until the inflow conduit stop **42** interference fits against the ring wall interference lip. The clamp handle **36** can then be closed, as shown by arrow **170**, reducing the diameter of the clamp **24** and pressure fitting or compressing the inside of the attachment ring **22** against the outside of the inflow conduit **10**, reducing or preventing translation of the inflow conduit **10** with respect to the attachment ring **22**. The outside surface of the inflow conduit **10** can form a fluid-tight seal against the inside surface of the attachment ring **22** for example at the attachment ring seal **34**. The inflow conduit **10** can be removed or repositioned, for example, by opening the clamp handle **36**, removing or repositioning the inflow conduit **10**, and then closing the clamp handle **36**.

[0232] The heart **106** can pump blood during the creation of the slit, insertion of the coring abutment **145** into the ventricle, coring, insertion of the inflow conduit **10** into the heart **106**, removal of the valvular structure **12**, tightening of the clamp **24** around the attachment ring **22**, or combinations or all of the above.

[0233] FIGS. **41***a* through **41***d* illustrate a method of coring a portion of the heart wall using a variation of the coring knife **140** similar to the variation shown in FIG. **38**. FIG. **41***a* illustrates that the coring knife **140** can be placed adjacent to a valvular structure **12** with a diaphragm valve **16**. FIG. **41***b* illustrates that the coring knife **140** can be inserted through the diaphragm port **83**. The diaphragm port can elastically deform to accommodate the coring knife **140** passing through the diaphragm port. The diaphragm can form a fluid-tight seal around the coring knife **140** as the coring knife **140** is inserted into the diaphragm port. The foreblade **152** can be extended out of the distal end of the knife head **136** and pressed into the heart wall, as shown by arrow. The foreblade **152** can cut or slit the heart **106**. The knife head **136** can be pushed into the slit or cut in the heart wall made by the foreblade **152**.

[0234] FIG. **41***c* illustrates that the knife handle **139** can be translated toward the heart **106**, extending the knife head **136** into the left ventricle **165**, as shown by arrow. The coring abutment **145** can be facing the inner surface of the heart wall. The foreblade **152** can be retracted to be atraumatically covered by the knife head **136**.

[0235] FIG. **41***d* illustrates that the knife handle **139** can be translated away from the heart **106**, retracting the knife head **136** toward the coring abutment **145**, as shown by arrow. The coring abutment **145** and coring blade **137** can cut tissue away from the heart wall. The coring abutment **145** and coring blade **137** can shear (if the coring abutment **145** has a smaller diameter than the diameter of the coring blade **137**) or chop (if the coring abutment **145** has a diameter larger than or equal to the diameter of the coring blade **137**) the tissue. Cored tissue **175** can be stored within the internal volume of the coring

blade **137** until after the coring knife **140** is removed from the valvular structure **12**. When the coring knife **140** is removed from the valvular structure **12**, the diaphragm can close, preventing or minimizing blood flow from the heart **106** from exiting the valvular structure **12**.

[0236] FIGS. **42***a* through **42***c* illustrate a method of using a valvular structure **12** having a locking ring **98** to clamp the attachment ring **22** to the inflow conduit **10**. FIG. **42***a* illustrates that the inflow conduit **10** can be inserted, as shown by arrow, through the valvular structure **12** having a diaphragm valve **16** (the diaphragm can be elastically deformed out of the way of the inflow conduit **10** but is not shown for illustrative purposes). The diaphragm port **83** can elastically expand to accommodate the inflow conduit **10**. The diaphragm port **83** can form a fluid-tight seal around the inflow conduit **10**, preventing blood from flowing from the heart **106** out the valvular structure **12**.

[0237] FIG. **42***b* illustrates that the tape **89** can then be removed from the valvular structure **12**. The housing **18** can then be separated into the housing first portion **46** and the housing second portion **54** components and removed from the target site. The diaphragm valve **16** can then be removed, such as by being torn or cut away from the inflow conduit **10** or removed with the housing **18** when the diaphragm seam **88** opens.

[0238] FIG. **42***c* illustrates that the locking ring **98** can be forced toward the heart **106**, as shown by arrow. In the configuration shown in FIG. **42***c*, the locking ring **98** can compress the ring wall **29**. The inner diameter of the ring wall **29** can be reduced by the compressive pressure from the locking ring **98**. The radially inner surface of the attachment ring wall **29** can compress against and press-fit to the radially outer wall of the inflow conduit **10**, forming a fluid-tight seal. The locking ring **98** can be pulled away from the heart **106**, relaxing and expanding the attachment ring wall **29**, for example reducing the force of or completely eliminating the press fit between the radially inner surface of the attachment ring wall **29** and the radially outer surface of the inflow conduit **10**.

[0239] FIGS. **43***a* and **43***b* illustrate a variation of a method for de-airing the outflow conduit **2**. FIG. **43***a* illustrates that when the blood flow in the outflow conduit **2** is stanched by a clamp **131** (as shown) or balloon **135**, a balloon catheter **132** can be inserted through the wall of the outflow conduit **2**. The pump **8** can be de-aired, for example the pump **8** can be run when in fluid communication with the ventricle, or the pump **8** can be pre-loaded with saline or blood. The balloon **135** can then be inserted into the terminal outflow end of the pump **8** and inflated, for example maintaining the pump **8** and inflow conduit **10** in a de-aired condition (i.e., with no air within the fluid channel of the pump **8** or the inflow conduit **10**).

[0240] FIG. **43***b* illustrates that the outflow conduit **2** can be joined to the pump **8** at the outflow conduit coupler **4**. The clamp **131** can be removed from the outflow conduit **2** before coupling the outflow conduit **2** to the pump **8**, allowing blood from the aorta **104** to de-air the outflow conduit **2** and then the outflow conduit **2** can be joined to the pump **8**.

[0241] Alternatively, the outflow conduit clamp **131** can remain on the outflow conduit **2** after the outflow conduit **2** is joined to the pump **8**. The balloon **135** can then be removed from the pump **8** and outflow conduit **2**, and the pump **8** can be run. The air from the outflow conduit **2** between the outflow conduit clamp **131** and the pump **8** can be forced out through the hole in the side wall of the outflow conduit **2** directly or drawn out via a needle inserted into the outflow conduit **2**. If a balloon catheter with side ports is used, the catheter ports can be used to withdraw air instead of using the hole in the graft or an additional needle.

[0242] Once the outflow conduit **2** and the remainder of the system is de-aired, the balloon **135** (as shown) and/or outflow conduit clamp **131** can be removed from the outflow conduit **2**. If a catheter **132** was removed from the wall of the outflow conduit **2**, a suture can be sewn if needed, such as by a purse stitch, into the outflow conduit **2** to close the hole in the outflow conduit wall.

[0243] Alternatively, when the outflow conduit **2** is occluded by the balloon **135** or clamp **131**, the pump **8** can be attached to the outflow conduit **2** and operated. Excess air in the ventricular assist system can be withdrawn with a catheter **132** or the bi-material balloon described herein.

[0244] FIG. **44** illustrates another variation of a method for de-airing the system using a liquid-filled de-airing bladder, enclosure or pouch to prevent air from entering the VAD components during assembly of the outflow conduit **2** and the pump **8**. The outflow conduit coupler **4**, outflow end of the pump **8** and the end of the outflow conduit **2** to be attached to the pump **8** can be placed in the de-airing pouch **179**. The de-airing pouch **179** can be filled with saline before or after placing the VAD components in the de-airing pouch **179**. The attachment ring **22** can be previously de-aired through the de-airing port **62** on the valvular structure **12**. The outflow conduit **2** can be previously de-aired with blood flow from the aorta **104** and stanching, for example, with an outflow conduit clamp **131** or balloon **135**. The pump **8** and inflow conduit **10** can be pre-filled with saline or blood before delivery into the target site. The outflow port of the pump **8** can be plugged before the pump **8** is delivered into the target site.

[0245] When the outflow end of the pump **8** and the inflow end of the conduit are located in the de-airing pouch **179**, the balloon **135** in the outflow conduit **2** can be deflated and removed or the outflow conduit clamp **131** on the outflow conduit **2** can be removed. The blood flowing from the aorta **104** can de-air the outflow conduit **2**, purging air in the outflow conduit **2** into the de-airing pouch **179**. The purged air can then escape from the de-airing pouch **179** or travel to a portion of the de-airing pouch **179** away from the openings of the VAD components. The pump **8** can be driven to pump blood through the inflow conduit **10** and pump **8** to drain any additional air from the pump **8** and inflow conduit **10**. The outflow conduit **2** can then be attached to the pump **8** in the de-airing pouch **179** or without a de-airing pouch **179**, as shown in FIG. **43***b* or **45**.

[0246] The percutaneous lead **5** can be attached to the pump **8** and to external power, control and data transmission devices as known in the art.

[0247] The system can be implanted when the heart **106** is beating and the patient is not on cardio-pulmonary bypass. However, the system can be implanted with the patent on cardio-pulmonary bypass and the heart **106** slowed or stopped. The system can be implanted using less invasive techniques described herein, but can be implanted with a full thoracotomy and sternotomy.

[0248] In FIGS. **46***a* and **46***b*, another embodiment of attachment ring **22** is formed by injection molding a polymer in a mold containing reinforcement elements which are to be imbedded or encased within the polymer. The mold cavity includes geometric features that simultaneously form interface lip **25**, cylindrical ring wall **29** which forms a tubular fluid passageway, distal band **31**, and ring seal **34** as a single,

unitary structure. Ring seal **34** forms the circular, inner edge of the proximal opening to ring channel **14**.

[0249] Attachment ring **22** is flexible. The polymer used for molding can be silicone rubber, although other polymers suitable for implantation may be used. When completely cooled and/or cured after molding, the polymer is flexible and elastic to allow ring seal **34** to flex, conform, and seal against a cylindrical object that is inserted through ring channel **14**. The reinforcement elements include proximal reinforcement band **202**, distal reinforcement band **204**, and fiber mesh **206**. Proximal and distal reinforcement bands **202**, **204** can be made of a material that is more rigid than the polymer injected into the mold and which forms the remainder of attachment ring **22**. The additional rigidity provided proximal and distal reinforcement bands **202**, **204** help openings at the opposite ends of ring channel **14** maintain a circular shape. Proximal and distal reinforcement bands **202**, **204** can be made of Nylon, acetal, polycarbonate, HDPE, PP, PET, PEEK, titanium or stainless steel. Fiber mesh **206** can be made of polyester fibers that have been braided to form a mesh tube which is then placed in the mold as part of the molding process. Other types of fibers and mesh configurations can be used. Fiber mesh **206** can be distributed within distal band **31** and ring wall **29**. Fiber mesh **206** helps prevent the polymer from tearing due to mechanical stress, such as may be arise from sutures used later to attach cuff **35** to distal band **31**. Flared ends of fiber mesh **206** provide positive fixation of sutures to the polymer substrate of distal band **31**.

[0250] Attachment ring **22** can be rotationally symmetric about longitudinal axis **200**, so that interface lip **25**, ring wall **29**, distal band **31**, ring seal **34**, proximal reinforcement band **200**, and distal reinforcement band **202** are each annular in shape.

[0251] After molding, cuff **35** can be attached to distal band **31** by passing a needle with suture **208** through cuff **35** and distal band **31**. Suture **208** can be a continuous, non-bioerodable fiber or thread that is looped in a helical manner through the outer perimeter of distal band **31**. Opposite ends of suture **208** can be tied in a knot **208***a* to prevent loosening. Portion **29***a* of ring wall **29** extends distally beyond distal band **31**. Portion **29***a* helps to center the hole in cuff **35** with ring channel **14** so that no portion of cuff **35** obstructs ring channel **14**. In subsequent clinical use of attachment ring **22**, cuff **35** is attached to a patient's heart and ring clamp **24** can be used to secure inflow conduit **10** within ring channel **14**.

[0252] The molding process allows ring seal **34** to be formed, in a consistent manner, with a diameter and round shape that corresponds to the size of inflow conduit **10**, so that a fluid-tight seal between attachment ring **22** and exterior surfaces of inflow conduit **10** results when inflow conduit **10** is disposed within attachment ring **22**

[0253] In FIGS. **47***a*-**47***c*, another embodiment of attachment ring **22** is formed by molding a polymer into a sheet in which fiber mesh **206** is embedded or encased. Suitable materials for the polymer and fiber mesh can be as described for FIGS. **46***a*-**46***d*. As shown in FIGS. **47***a* and **47***b*, attachment ring **22** can be made by cutting out a rectangular strip **210** from the flat sheet, rolling strip **210** so that opposite ends **212** of the strip overlap, and bonding ends **212** together to form a fluid-tight seam **214**.

[0254] Next, cuff **35** can be attached around distal portion **216** of the rolled strip by passing a needle with suture **208** through cuff **35** and distal portion **216**. A single, continuous piece or several pieces of suture **208** can be used to secure proximal edge **218** and distal edge **220** of cuff **35** to distal portion **216** of the rolled strip. In subsequent clinical use of attachment ring **22**, cuff **35** is attached to a patient's heart and ring clamp **24** can be used to secure inflow conduit **10** within ring channel **14**. Interior edge **214***a* of seam **214** extends through the entire length of ring channel **14**. End **212***a* of the strip which forms interior edge **214***a* can be tapered in cross-section so as to form a smooth interface with opposite end **212***b*. Material can also be added at interior edge **214***a* to form the smooth interface. The smooth interface allows the inner surface of ring channel **14** to form a fluid-tight seal against inflow conduit **10**.

[0255] In FIGS. **48***a* and **48***d*, another embodiment of attachment ring **22** is formed by injection molding a polymer in a mold cavity having geometric features that simultaneously form ring wall **29**, distal band **31**, ring seal **34**, and ring valve **230** as a single, unitary structure. Suitable materials for the polymer can be as described for FIGS. **46***a*-**46***d*. FIGS. **48***a* and **48***c* show views of the distal end and proximal end, respectively. FIGS. **48***a* and **48***b* show attachment ring **22** without cuff to better show features of distal band **31**.

[0256] Attachment ring **22** can be rotationally symmetric about longitudinal axis **200**, so ring wall **29**, distal band **31**, and ring seal **34** are each annular in shape. In the illustrated embodiment, ring valve **230** is a quadcuspid (i.e., four-leaflet) valve similar in configuration to valve **16** described in connection with FIGS. **12***a* and **15***c*. Other configurations for valve **230** can be implemented, for example and without limitation a tricuspid valve (similar to FIG. **14***a*), a bicuspid valve (similar to FIG. **15***a*), a dome valve, a diaphragm valve (similar to FIG. **15***f*), and combinations thereof. Ring seal **34** forms the circular, inner edge of the proximal opening of ring channel **14**. When a cylindrical object (for example, slitting tool **300** and coring knife **140**) is inserted into the proximal opening of ring channel **14**, ring seal **34** seals against the cylindrical object and ring valve **230** flexes open. When the cylindrical object is removed, ring valve **230** closes autonomously to reduce, prevent or inhibit fluid from flowing distally through ring valve **230** in the direction of arrow **231**. With attachment ring **22** attached to the heart, ring valve **230** can allow slitting and coring of heart tissue while the heart is beating and pumping without the use of valvular structure **12**.

[0257] After molding, cuff **35** can be attached to distal band **31** by passing a needle with suture **208** through cuff **35** and distal band **31**, such as described for FIGS. **46***c* and **46***d*. In subsequent clinical use of attachment ring **22**, cuff **35** is attached to a patient's heart and ring clamp **24** can be used to secure inflow conduit **10** within ring channel **14**.

[0258] Attachment ring **22**, in any of the embodiments described above, may include an alignment feature that allows a slitting tool and coring knife **140** to share common alignment. A slitting tool is shown in FIGS. **52***a*-**52***c*. In use, the slitting tool can be inserted into attachment ring **22**. When inserting the slitting tool into attachment ring **22**, the alignment feature ensures that the flat blade of the slitting tool is oriented in a particular way, as will be described in more detail below. Once aligned, the flat blade extends to form a slit in the heart tissue, then the slitting tool is removed from attachment ring **22**. The slit functions as a passage through which elements of coring knife **140** can be inserted. When inserting coring knife **140** into attachment ring **22**, the alignment feature ensures that rotatable coring abutment **145**, such as shown in FIGS. **37***a*-**37***d*, is oriented along the same line as

the slit previously formed by the slitting tool and thereby allows of easy entry of coring abutment **145** into the heart cavity.

[0259] Alignment feature can take the form of a structural feature, such as two indentations **230** (FIG. **4***a*) formed into interface lip **25** at the proximal end of attachment ring **22**. Indentations **230** can be shaped and sized to receive protrusions **346** on the exterior surface of the slitting tool (see FIG. **52***a*) and protrusions **411** on the exterior surface of the coring knife (see FIG. **54**). Indentations **230** allow for "blind" alignment whereby engagement of indentations and protrusions provide tactile feedback to the surgeon or other user which indicates proper alignment. Alignment feature can also take the form of a visual indicator, such as indelible markings **232** (FIG. **46***c*) in a contrasting color and/or an embossed marking applied on interface lip **25**. In use, a pair of protrusions or markings on the exterior surface of the slitting tool can be aligned with markings **232** during insertion of the slitting tool into attachment ring **22**. Subsequently, a pair of protrusions or markings on the exterior surface of coring knife **140** can be aligned with markings **232** during insertion of coring knife **140** into attachment ring **22**.

[0260] Referring again back to FIG. **7***a*, clamp **24** can be disposed around the central portion of attachment ring wall **29** located between interface lip **25** and cuff **35**. Clamp **24** can be installed and removed from attachment ring **25** by translating it axially, in a direction along longitudinal axis **200**, onto attachment ring **22** until it reaches the central portion of attachment ring wall **29**. However, in cases where clamp **24** has limited ability enlarge its clamp diameter **38**, interface lip **25** and cuff **35** could interfere with axial translation of attachment ring **22**, making installation and removal of attachment ring **22** difficult especially after attachment ring **22** has been secured to heart tissue.

[0261] In FIGS. **49***a*-**49***d*, another embodiment of clamp **24** is shown having multiple linkages that allow clamp **24** to be easily installed and removed from attachment ring **22**, either before or after attachment ring **22** has been secured to heart tissue. The linkages are in the form of first curved piece **240**, second curved piece **242**, lever **244**, and third curved piece **246**. When clamp **24** is closed (FIG. **49***a*), inner surfaces of first, second and third curved pieces **240**, **242**, **246** form a circle having diameter **247** needed to allow the curved pieces to apply pressure to attachment ring wall **29** in order to secure inflow conduit **10** to attachment ring **22**. Diameter **247** can be about the same as or slightly smaller (for example, 5%, 10%, or 20% smaller) than the outer diameter of attachment ring wall **29**. The linkages can be pivoted relative to each other so as to create an opening that is larger that the outer diameter of attachment ring wall **29**. With this ability, attachment ring **22** can be installed and removed from attachment ring **22** in a manner that avoids interference from interface lip **25** and cuff **35**.

[0262] Referring to FIG. **49***b*, the ends of first curved piece **240** and second curved piece **242** are pivotally connected to each other by primary hinge **241**. The opposite end of first curved piece **240** has hook **245**. The opposite end of second curved piece **242** is connected to lever **244** by first lever hinge **248**. Second lever hinge **250** connects medial part **252** of lever **244** to one end of third curved piece **246**. Medial part **252** is disposed between two legs **254** of third curved piece **246**. The opposite end of curved piece **246** has cylindrical catch **256**. Cylindrical catch **256** connects legs **254** together and is sized and shaped to fit within hook **245**.

[0263] FIG. **49***a* shows clamp **24** when closed. Lever **244** is disposed within groove **243** (FIG. **49***b*) formed within second curved piece **242** and between legs **254** of third curved piece **246**. Cylindrical catch **256** is seated within hook **245**. First lever hinge **248** is positioned adjacent hook **245**.

[0264] When clamp **24** is closed, movement of third curve piece **246** along the direction of arrow **260** is prevented by the presence of attachment ring wall **29** and inflow conduit **10** within clamp **24**. That is, attachment ring wall **29** and inflow conduit **10** prevent inner diameter **247** of clamp **24** from getting smaller.

[0265] To open clamp **24**, a person can pull protrusion **258** at the free end of lever **244** radially outward in the direction of arrow **262**, as shown in FIG. **49***b*. Movement of protrusion **258** along arrow **260** causes cylindrical catch **256** to move along arrow **260**, without requiring inner diameter **247** to get smaller. Thus, the presence of attachment ring wall **29** and inflow conduit **10** within clamp **24** does not prevent cylindrical catch **256** from disengaging hook **245** when protrusion **258** is pulled along arrow **260**. Once disengaged first curve piece **240** can be pivoted about primary hinge **241** to create an opening that is substantially larger than diameter **247**, as shown in FIG. **49***c*.

[0266] Clamp **24** can have a provision for locking lever **244** in the closed position. Through hole **264** is formed through the free end of lever **244**. When in the closed position, as shown in FIG. **49***a*, first opening **266** of the through hole is exposed and second opening **268** (FIG. **49***b*) is disposed within groove **243** in second curved piece **242**. Second opening **268** faces the opening of through hole **267** in second curved piece **242** which extends to the outer surface of second curved piece **242**. Through hole **264** and through hole **267** can be aligned so as to be coaxial, which allows a suture to be looped through both through holes. The suture prevents lever **244** from moving out in direction of arrow **262** and thereby keeps clamp **24** closed. Opposite ends of the suture can be tied together in a knot to keep the suture in place. The suture can be cut to allow its removal and to allow clamp **24** to be opened.

[0267] In FIGS. **50***a* and **50***b*, another embodiment of clamp **24** is shown having a single, unitary structure in the form of ring **270** with detachable ends. The ends have ratchet features that interlock with each other and allow inner diameter **272** of ring **270** to become smaller. First end **274** includes guard member **276** and ratchet member **278** with a plurality of radially inward facing teeth **280**. Second end **282** includes ratchet member **284** with a plurality of radially outward facing teeth **286**. Ratchet member **284** is disposed within an open channel between guard member **276** and ratchet member **278**. When clamp **24** is open, as shown in FIGS. **50***a* and **50***b*, gap **280** exists between the free end of ratchet member **284** and the end of the open channel between guard member **276** and ratchet member **278**. Gap **280** allows first end **274** and second end **282** to pushed together, which causes teeth **280** and teeth **286** to engage each other. Teeth **280** and teeth **286** are configured to slip past each other when first end **274** and second end **282** are pushed together and are configured to engage each other to prevent first end **274** and second end **282** from subsequently moving apart from each other. In use, clamp **24** can be disposed around attachment ring wall **29** of attachment ring **22**. Guard member **276** prevents attachment ring wall **29** from being pinched within gap **280**.

[0268] Ring **270** functions like a spring in that it stores spring energy when first end **274** and second end **282** are pushed together. Ring **270** can be formed by injecting a poly-

mer into a mold cavity that includes geometric features that simultaneously form guard member **276**, ratchet member **278**, teeth **280**, ratchet member **284**, and teeth **286** as a single, unitary structure. Through hole **288** is formed in first end **274**. Through hole **290** is formed in second end **282**. Through hole **288** and through hole **290** can receive tips of a tool for pushing first end **274** and second end **282** together. Through hole **300** is formed in ratchet member **278**. Opposing teeth **280**, **286** can be disengaged from each other by inserting a tool in through hole **300** and pulling radially outward. When opposing teeth **280**, **286** disengage, first end **274** and second end **282** autonomously move apart from each other due to the spring energy stored in ring **270**.

[0269] After pushing first end **274** and second end **282** together, a suture can be looped into through hole **300** and through hole **290** as a security measure to prevent the ratchet members from inadvertently disengaging. Opposite ends of the suture can be tied together in a knot to keep the suture in place. The suture can be cut to allow its removal and to allow ratchet members to disengage and inner diameter **272** to enlarge.

[0270] When clamp **24** is open, as shown in FIGS. **50***a* and **50***b*, inner diameter **272** is larger than the outer diameter of attachment ring wall **29** of attachment ring **22**. When clamp **24** is closed by pushing the first end **274** and second end **282** together, inner diameter **272** corresponds to the size of inflow conduit **10** plus the thickness of attachment ring wall **29**, so that a fluid-tight seal between attachment ring **22** and exterior surfaces of inflow conduit **10** results when inflow conduit **10** is disposed within attachment ring **22**.

[0271] In FIG. **51**, another embodiment of clamp **24** is shown having ratchet members **278**, **284**, each with only one tooth **286**, **280**. Other embodiments may have any number of teeth, as may be needed, to provide additional engagement and/or to allow clamp **24** to be used with attachment rings **22** and inflow conduits **10** of different sizes.

[0272] After attachment ring **22** is attached to heart apex **119**, foreblade **152** of coring knife **140** of FIG. **38** can be used to form a slit through the epicardium and into the myocardium at heart apex **119**. Alternatively, slitting tool **300** of FIGS. **52***a*-**52***c* can be used to form the slit into the heart.

[0273] As shown in FIG. **52***a*, cylindrical housing **302** has front end **304** and rear end **306**. Rear end **306** includes radially protruding handles **308**. Spring-loaded actuator **310** protrudes axially out of rear end **306** and is connected to a flat blade contained within housing **302**. Pushing actuator **310** axially forward in the direction of arrow **312** causes the flat blade to extend out of slit opening **314** at front end **304**.

[0274] As shown in FIG. **52***b*, spring **316** is contained within a rear segment of housing **302**. Rear end **318** of spring **316** is attached to a medial segment of actuator **310**. Forward end **320** of spring **316** abuts wall **322** within housing **302**. Spring **316** and flat blade **326** are contained within housing **302** at opposite sides of wall **322**. Spring **316** is under compression and keeps the flat blade completely retracted within housing **302** until a user pushes actuator **310**. Actuator **310** extends through a hole in wall **322**. Forward end **324** of actuator **310** is connected to flat blade **326**. As actuator **310** is translated forward in the direction of arrow **312**, actuator **310** compresses spring **316** against wall **322** and forward end **324** pushes blade **326** out of front end **304** of housing **302**.

[0275] FIG. **52***c* shows flat blade **326** extending out of slit opening **314** after actuator **310** has been pushed forward. Blade seal **328** is contained within housing **302** and is located adjacent slit opening **314** at front end **304**. Flat blade **326** passes through blade seal **328** which includes a pair of flexible wipers **330** that face each other. Wipers **330** extend across the entire blade width **332** (FIG. **52***b*) and press against opposite sides of flat blade **326**, thereby preventing blood from flowing into the rear segment of housing **302**. Blade seal **328** can be made of silicone rubber or other resilient polymer. In other embodiments, blade seal **328** is a strip of polymer foam with a slit equivalent in size to blade width **332**.

[0276] In use, front end **304** of housing **302** is inserted into attachment ring **22** or the combination of valvular structure **12** and attachment ring **22**. Outer diameter **330** of housing **302** and ring seal **34** of attachment ring **22** can be sized such that a substantially fluid-tight seal is formed between the exterior surface of housing **302** and ring seal **304** when front end **304** is inserted into through attachment ring **22**. When flat blade **326** punctures a beating heart and is retracted, blood from the heart may flow into attachment ring **22** and into slit opening **314** of housing **302**. Blade seal **328** minimizes blood loss by preventing or inhibiting blood from flowing through and out of slitting tool **300**.

[0277] In some embodiments, outer diameter **330** of housing **302** and housing seal **47** (FIG. **10***a*) of valvular structure **12** can be sized such that a substantially fluid-tight seal is formed between the exterior surface of housing **302** and housing seal **47** when front end **304** is inserted into valvular structure **12** which has been attached to attachment ring **22**. When flat blade **326** punctures a beating heart and is retracted, blood from the heart may flow into attachment ring **22**, valvular structure **12**, and slit opening **314** of housing **302**. Blade seal **328** minimizes blood loss by preventing or inhibiting blood from flowing through and out of slitting tool **300**.

[0278] Referring again to FIG. **52***a*, stop feature **340** is located on housing **320** at a predetermined distance **342** from the forward most tip **344** of slitting tool **300**. Stop feature **340** prevents tip **344** from pushing into the heart when slitting tool **340** is being positioned within attachment ring. Stop feature **340** includes a pair of protrusions **346** sized and shaped to fit within alignment features on attachment ring **22** and/or valvular structure **12**.

[0279] In some embodiments, predetermined distance **342** is equivalent to or a few millimeters less than the longitudinal height of attachment ring **22**. The longitudinal height can be the maximum dimension as measured along the longitudinal axis of attachment ring **22**. The longitudinal height of an exemplary attachment ring is indicated by arrow **348** in FIG. **46***d*. In use, slitting tool **300** can be inserted by a surgeon or other user into attachment ring **22** secured to the heart, with no valvular structure **12** attached to attachment ring **22**. When stop feature **304** abuts interface lip **25** of attachment ring **22**, the user will know that tip **344** of slitting tool **300** is located at the proper position just above the heart. The user can twist slitting tool **300** about its central axis **301** until protrusions **346** become seated within indentations **230** (FIG. **4***a*) formed into interface lip **25**. When protrusions **346** engage indentations **230**, the user will know from tactile feed back that slitting tool **300** is in proper rotational alignment. Thereafter, the user can extend flat blade **326** to make a slit through the heart, and then use coring knife **140** under the same rotational alignment as slitting tool **300** to form a circular hole around the slit.

[0280] In some embodiments, predetermined distance **342** is equivalent to or a few millimeters less than the longitudinal stack height of valvular structure **12** and attachment ring **22**.

The longitudinal stack height of an exemplary assembly of valvular structure **12** and attachment ring **22** is indicated by arrow **350** in FIG. **2***b*. In use, slitting tool **300** can be inserted by a surgeon or other user into valvular structure **12** and attachment ring **22** which has been attached to the heart. When stop feature **304** abuts the proximal end of valvular structure **12**, the user will know that tip **344** of slitting tool **300** is located at the proper position just above the heart. The user can twist slitting tool **300** about its central axis **301** until protrusions **346** become seated within alignment features (for example, coupling grooves **71** (FIG. **11***a*), alignment groove **497** (FIG. **56***a*) and alignment groove (FIG. **57***a*)) formed into the proximal end of valvular structure **12**. When protrusions **346** engage the alignment features, the user will know from tactile feed back that slitting tool **300** is in proper rotational alignment. Thereafter, the user can extend flat blade **326** to make a slit through the heart, and then use coring knife **140** under the same rotational alignment as slitting tool **300** to form a circular hole around the slit.

[0281] Stop feature **340** can be an annular flange, as illustrated, which can be an integral part of or permanently affixed to housing **320**. Protrusions **346** can be spaced 180 degrees apart from each other on the circumference of stop feature **340**. Alternatively, stop feature **304** can be movable along housing **302** to allow predetermined distance **342** to be adjusted if desired.

[0282] In FIGS. **53***a*-**53***f*, another embodiment of coring knife **140** is shown having pistol-type grip **360**, release trigger **362**, and abutment control lever **364**. FIG. **53***a* shows coring knife **140** in its starting configuration, in which the plane of coring abutment **145** is in line with longitudinal axis **366** of coring knife **140**, and coring blade **137** is completely contained within coring knife case **141**. The plane of the coring abutment **145** is defined by a plurality of points on the outer perimeter of coring abutment **145**. Coring abutment **145** is held in position by two support rods **368**. Control arm **146** is disposed between support rods **368**. Support rods **368** and control arm **146** extend into the forward end of slide assembly **370** and into central shaft **372** (FIG. **53***d*) which is fixedly attached to grip **360**. The forward ends of support rods **368** and control arm **146** are pivotally connected to different points on coring abutment **145**. Control arm **146** is operatively coupled to abutment control lever **364**.

[0283] As shown in FIG. **53***b*, the forward ends of support rods **368** are attached to coring abutment **145** at points **372** that form pivot line **374** that is substantially perpendicular to longitudinal axis **366**. The forward ends of support rods **368** can be attached to coring abutment **145** by a slender pin that extends within coring abutment **145**. Control arm **146** is attached to coring abutment **145** at point **376** which is longitudinally offset by offset distance **377** from points **372** so as to be closer to forward most tip **378** of coring abutment **145**. The forward end of control arm **146** can be attached to coring abutment **145** by another slender pin that extends within coring abutment **145**. Due to offset distance **377**, movement of control arm **146** rearward in the direction of arrow **380**, while support rods **368** remain stationary, causes coring abutment **145** to rotate about pivot line **374**. As shown in FIG. **53***c*, when point **376** has moved rearward by a distance equivalent to offset distance **377**, the plane of coring abutment **145** is substantially perpendicular to longitudinal axis **366**. Control arm **146** is operatively coupled to control lever **366** which is pivotally attached to grip **360**. As shown in FIG. **53***d*, pivoting control lever **366** upward in a direction along arrow **382** causes control arm **146** to move rearward along arrow **380** until the plane of abutment surface **145** is substantially perpendicular to longitudinal axis **366**. Control lever **364** includes safety latch **384**. When control lever **366** is in a lowered position (FIG. **53***a*), safety latch **384** is in front of knob **385** of slide assembly **370** where it prevents slide assembly **370** from inadvertently sliding toward coring abutment **145**. When control lever **366** is in a raised position (FIG. **53***d*), safety latch **384** has moved away from knob **385** and slide assembly **370** can slide toward coring abutment **145** when release trigger **362** is pressed by the user.

[0284] Slide assembly **370** comprises coring blade **137**, coring knife case **141**, and internal sleeve **386**. Internal sleeve **386** (FIG. **53***f*) is disposed around and slides longitudinally over central shaft **372**. Coring knife case **141** is fixedly attached to internal sleeve **386**. Internal sleeve **386** includes a pair of linear slots **388** (FIG. **53***f*) which extend substantially parallel to longitudinal axis **366**. Pin **390** (FIG. **53***e*) protrudes from central shaft **372** into linear slots **388** and thereby prevents internal sleeve **386** from rotating relative to central shaft **372** and grip **360**. Pin **390** prevents internal sleeve **386** from rotating relative to central shaft **372**. Internal sleeve **386** also includes a series of holes **392** arranged along one or more lines substantially parallel to longitudinal axis **366**. A ball detent mechanism within central shaft **372** engages one or more of the holes **392** to prevent slide assembly **370** from sliding freely on central shaft **372**. Ball detent mechanism is operatively coupled to release trigger **362**. Release trigger **362** is spring loaded in such a way that ball detent mechanism prevents slide assembly **370** from sliding when no force is applied to release trigger **362**.

[0285] When a force is applied by a user to depress release trigger **362**, ball detent mechanism disengages holes **392**. The user may then grasp slide assembly **370** and slide it forward toward coring abutment **145**, as shown in FIG. **53***e*. In use, slide assembly **370** is preferably moved forward to a point where forward edge **396** of coring knife case **141** touches or is just above the heart tissue **398**. It is understood that coring knife case **141** is now located within the ring channel **14** of attachment ring **22** or valvular structure **12** combined with attachment ring **22**. It is also understood that the coring abutment **145** is located within the heart cavity and abuts the heart tissue from the side opposite coring knife case **141**. When forward edge **396** of coring knife case **141** is at the desired position, the user may let go of release trigger **362** so that ball detent mechanism engages holes **392** and locks in the longitudinal position of coring knife case **141**.

[0286] At this stage, coring blade **137** remains completely retracted within coring knife case **141**. Coring blade **137** is a hollow cylinder the forward end of which forms sharp circular tip **400**. The rear end of coring blade **137** is fixedly attached to the front end of rotatable control sleeve **402**. Helical coring guide or slot **147** is formed into the rear segment of rotatable control sleeve **402**. Knob **385** is fixedly attached to the rear end of control sleeve **402**. Manual rotation of knob **385** by the user causes control sleeve **402** and coring blade **137** to rotate relative to coring knife case **141** and internal sleeve **386** which are held stationary by ball detent mechanism and pin **390**. Guide peg **148** protrudes from coring knife case **141** into helical slot **147** of control sleeve **402**. Thus, rotation of knob **385** simultaneously causes control sleeve **402** and coring blade **137** to translate longitudinally toward coring abutment **145**. Rotation in the reverse direction causes control sleeve **402** and coring blade **137** to translate

longitudinally away from coring abutment **145**. It is understood that knob **385** allows the user to have complete control of the force applied by coring blade and complete control of coring blade advancement by each turn of knob **385**. In this embodiment, there is no spring loading on coring blade **137** that might otherwise remove complete control of applied force from the user.

[0287] In FIG. **53***f*, knob **385** has been rotated until circular tip **400** of coring blade **137** has pressed against coring abutment **145**. In use, coring blade **137** would have made a circular cut entirely through the myocardium. A round piece of polymer foam, absorbent material, or resilient material, can be disposed within the rear end of the coring blade **137** to seal access holes for support rods **368** and control arm **146**, and thereby stop or soak up blood and prevent blood from rushing into the rear portions of coring knife **140**. A cylindrical portion of the myocardium would be completely detached from the remainder of the heart and contained within coring blade **137**. The user may then pull coring knife **140** rearward, in a direction substantially parallel to longitudinal axis **366**, thereby extracting the cylindrical portion of the myocardium out from beneath attachment ring **22** or the combination of valvular structure **12** and attachment ring **22**. If the procedure is performed while the heart is beating, either ring valve **230** (FIG. **48***b*) of attachment ring **22** or valve **16** (FIG. **2***a*) of valvular structure **12** autonomously close after coring knife **140** is pulled out and thereby prevents significant loss of blood.

[0288] Use of coring knife **140** can begin by inserting coring abutment **145** oriented as shown in FIG. **53***a* into the slit previously formed by slitting tool **300**. To facilitate insertion into the slit, the plane of the coring abutment **145** should be aligned in the same direction as the slit. Establishing the proper alignment can be difficult because the visual line of sight to the slit could be obstructed by the coring knife itself, by ring valve **230** (FIG. **48***b*) of attachment ring **22**, or by valve **16** (FIG. **2***a*) of valvular structure **12**. An alignment feature on the proximal end of attachment ring **22** or valvular structure **12** can be used by the user to align coring abutment **145** to the slit in the heart. The alignment feature can be in the form of indentations **230** (FIG. **4***a*) formed into interface lip **25** at the proximal end of attachment ring **22** and/or indelible markings **232** (FIG. **46***c*) in a contrasting color applied on interface lip **25**. The alignment feature can be in the form of coupling grooves **71** (FIG. **11***a*) or alignment groove **497** (FIGS. **56***a* and **57***a*) formed into the proximal end of valvular structure **12** or be in the form of indelible markings applied to the proximal end of valvular structure **12**. A corresponding feature on coring knife case **141**, such as a protrusion and/or indelible markings, can be visually aligned or physically engaged with the alignment feature on attachment ring **22** or valvular structure **12**.

[0289] As previously discussed, while the user depresses release trigger **362**, slide assembly **370** can be moved forward to a point where forward edge **396** of coring knife case **141** touches or is just above the heart tissue **398**. Positioning forward edge **396** to the desired position relative to the surface of the heart may be difficult to perform visually if the line of sight to the heart surface is obstructed by coring knife **140**, valvular structure **12**, and/or attachment ring **22**.

[0290] As shown in FIG. **54**, stop feature **410** can be located on coring knife casing **141** at a predetermined distance **412** from forward edge **396** of coring knife case **141**. Stop feature **410** prevents forward edge **396** from pushing into the heart when slide assembly **370** is being positioned within attachment ring **22**. Stop feature **410** can include protrusions **411** sized and shape to fit within the alignment feature on attachment ring **22** or valvular structure **12**, and/or can include indelible markings for aligning coring abutment **145** with the slit in the heart.

[0291] In some embodiments, predetermined distance **412** is equivalent to or a few millimeters less than the longitudinal height of attachment ring **22**. The longitudinal height of an exemplary attachment ring is indicated by arrow **348** in FIG. **46***d*. In use, coring knife **140** can be inserted by a surgeon or other user into attachment ring **22** secured to the heart, with no valvular structure **12** attached to attachment ring **22**. When stop feature **410** abuts interface lip **25** of attachment ring **22**, the user will know that forward edge **396** of coring knife case **141** is located at the proper position. Thereafter, the user can let go of release trigger **362** to lock coring knife case **141** in place, then rotate knob **385** to extend coring blade **137** out of coring knife case **141** and into the heart.

[0292] In some embodiments, predetermined distance **412** is equivalent to or a few millimeters less than the longitudinal stack height of valvular structure **12** and attachment ring **22**. The longitudinal stack height of an exemplary assembly of valvular structure **12** and attachment ring **22** is indicated by arrow **350** in FIG. **2***b*. In use, coring knife **140** can be inserted by a user into valvular structure **12** and attachment ring **22** which has been attached to the heart. When stop feature **410** abuts the proximal end of valvular structure **12**, the user will know that forward edge **396** of coring knife case **141** is located at the proper position. Thereafter, the user can let go of release trigger **362** to lock coring knife case **141** in place, then rotate knob **385** to extend coring blade **137** out of coring knife case **141** and into the heart.

[0293] Stop feature **410** can be an annular flange which can be an integral part of or permanently affixed to coring knife casing **141**. Alternatively, stop feature **410** can be movable along coring knife casing **141** to allow predetermined distance **412** to be adjusted if desired.

[0294] Referring again to FIG. **54**, coring abutment **145** has abutment surface **414** that is substantially flat or planar. Abutment surface **414** faces coring knife case **141** after control lever **364** has been pivoted upward. In use, abutment surface **414** supports the interior surface of the heart as coring blade **137** rotates, extends out of coring knife case **141**, and cuts from the exterior surface of the heart. Coring blade **137** ultimately presses against abutment surface **414** when cutting is complete.

[0295] In other embodiments, such as shown in FIG. **55**, abutment surface **414** has a raised central portion **416** and tapered edges **418** at the outer circumference of coring abutment **145**. As coring blade **137** rotates and moves closer to abutment surface **414**, raised central portion **416** enters into coring blade **137** and tapered edges **418** abut forward edge **396** of coring blade. Raised central portion **416** and tapered edges **418** align the center of abutment surface **414** with the center of forward edge **396** of coring blade **137**. Raised central portion **416** and tapered edges **418** prevent misalignment in which a portion of forward edge **396** extends beyond the outer circumference of coring abutment **145** and fails to press against abutment surface **414**. Abutment surface **414** can be convex, spherical, conical or other shape having raised central portion and tapered edges.

[0296] In FIGS. **56***a*-**56***d*, another embodiment of valvular structure **12** is shown having a spring-loaded hinge. Valvular

structure **12** is shown with attachment ring **22** in FIGS. **56***a* and **56***b*. Valvular structure **12** is shown without attachment ring **22** in FIGS. **56***c* and **56***d*. Valvular structure is divided into two halves which are hinged together at one end and have locking features at the other end. The hinge facilitates installation onto and removal from attachment ring **22**, as shown in FIG. **56***b*. Each half of valvular structure **12** includes half of housing **18** and half of valve **16**. Housing **18** encases valve **16** which has a quadcupsid configuration. Valve **16** can be as described in connection with FIGS. **10***a*-**10***e*, **12***a*-**15***f* or any of the previously described embodiments. In use, housing **18** encases interface lip **25** of attachment ring **22**. Attachment ring **22** can be as described in connection with FIGS. **4***a*, **4***b*, **7***a*, **7***b* or **46***a*-**46***c*.

[0297] As shown in FIG. **56***b*, housing first portion **46** and housing second portion **54** form two longitudinal halves of housing **18**. The longitudinal halves are formed by a "cut" that runs along longitudinal axis **187**. Housing first portion **46** and housing second portion **54** are separated by an imaginary plane coincident with longitudinal axis **187**. Housing first portion **46** and housing second portion **54** each have, at one end thereof, first and second hinge members **450***a,b* that mate with each other and are pivotally connected to each other by hinge pin **452**. Housing first portion **46** and housing second portion **54** each have, at the opposite end thereof, first and second lock members **454***a,b* which are locked together by slide member **456**. Slide member **456** is slidably coupled first lock member **454***a*. Slide member **456** has groove **460** sized and shaped to receive rib **462** on second lock member **454***b*. When housing **18** is closed, as shown in FIG. **56***a*, slide member **456** is at a distal position in which rib **462** is retained within slide member **456**, thereby keeping housing first portion **46** and housing second portion **54** closed and sealed together. To open housing **18**, a user moves slide member proximally in the direction of arrow **464** (FIG. **56***a*), which disengages slide member **456** from rib **462** and allows housing first portion **46** and housing second portion **54** to pivot on hinge pin **452** and open as shown in FIG. **56***b*. Slide member **456** includes longitudinal rib **457** which a user can grasp with his/her fingers or a tool in order to move slide member **456**.

[0298] Housing channel **58** runs through the center of housing **18**, through valve **16** and communicates with ring channel **14** of attachment ring **22**. Housing first portion **46** includes de-airing port **62** which includes a through-hole that extends from the exterior of housing **18** to the portion of housing channel **58** between valve **16** and attachment ring **22**.

[0299] The interior of housing first portion **46** and housing second portion **54** can be mirror images of each other, with the exception of the de-airing port through hole. Thus features shown add/or described for housing first portion **46** is present in housing second portion **54**, and vice versa. The interior of housing first portion **46** and housing second portion **54**, in combination, can be rotationally symmetric about longitudinal axis **187**. Thus, features within housing channel **58** extend for about 180 degrees on housing first portion **46** and about 180 degrees on housing second portion **54**.

[0300] When housing **18** is closed, interface lip **25** of attachment ring **22** is retained within interface groove **466**. Interface groove **466** is formed between distal flange **468** and guide flange **470**. Proximal facing surface **472** of guide flange **470** can be sloped so as to guide slitting tool **300** or coring knife **140** into attachment ring **22**. A pair of proximal flanges **474** form valve groove **61** which retains valve shoulder **59** of valve **16**.

[0301] When housing **18** is closed, first gasket **476** and second gasket **478** are compressed and form a fluid-tight seal between housing first portion **46** and housing second portion **54**. First gasket **476** is located adjacent first and second hinge members **450***a,b*. Second gasket **478** is located adjacent first and second lock members **454***a,b*. First gasket **476** and second gasket **478** can be made of a flat piece of silicone rubber foam or other resilient polymer material having edges which match the interior edges of housing **18**, including edges of distal flange **468**, guide flange **470**, and proximal flanges **474**. A first pair of handles **480**, each in the form of a longitudinal rib, are located adjacent to lock members **454***a*, **454***b* and protrude from housing first portion **46** and housing second portion **54**. A user can pinch handles **480** together, using his/her fingers or a tool, when closing housing **18** in order to compress first gasket **476** and second gasket **478** sufficiently to allow slide member **456** to be slid onto rib **462**.

[0302] FIGS. **56***c* and **56***d* are views of the proximal end of housing **18**. A second pair of handles **482** are located adjacent to hinge members **450***a*, **450***b* and hinge pin **452**. As shown in FIG. **56***a*, each handle **482** has a base **484** adjacent the distal end of housing **18** and longitudinal wing member **486** that extends proximally from base **484**. Base **484** and wing member **486** are attached to housing **18**. Through hole **488** is formed into base **484**. Groove **490** extends from through hole **488** and onto wing member **486**. Torsion spring **492** (FIG. **56***c*) is disposed between handles **482**. Straight ends **496** of torsion spring **492** are retained within grooves formed in wing members **486**. Torsion spring **492** is under compression such that straight ends **496** constantly push wing members **486** apart, thereby biasing housing **18** closed. Hinge pin **452** extends through helical segment **494** of torsion spring **492**, thereby preventing torsion spring **492** from detaching from wing members **486**. After moving slide member **456** to a proximal position in which rib **462** is released, a user may squeeze handles **462** together to overcome torsion spring **492** and thereby open housing **18** as shown in FIG. **56***d*. The user may engage a tool on grooves **490** and/or through holes **488** in order to squeeze handles **462** together.

[0303] Alignment groove **497** is formed into proximal edge **498** of each of housing first portion **46** and housing second portion **54**. Alignment groove **497** can be sized and shape to receive protrusions **346** on the exterior surface of the slitting tool **300** (FIG. **52***a*) and protrusions **411** on the exterior surface of coring knife **140** (FIG. **54**). Engaging slitting tool **300** and coring knife **140** into grooves **497** can ensure that coring abutment **145** of coring knife **140** is aligned with the slit previously formed by flat blade **326** of slitting tool **300**. Alignment marking **498** is embossed on the side of each of housing first portion **46** and housing second portion **54** to facilitate alignment of slitting tool **300** and coring knife **140**.

[0304] In FIGS. **57***a*-**57***d*, there is shown an embodiment of valvular structure **12** which can be installed with C-clamp tool **600** (FIG. **58***a*). Valvular structure is divided into two identical halves which can be locked together and separated, as desired, to facilitate installation onto and removal from attachment ring **22** (not shown in FIGS. **57***a*-**57***b*). Housing **18** encases valve **16** which has a quadcupsid configuration. Valve **16** can be as described in connection with FIGS. **10***a*-**10***e*, **12***a*-**15***f* or any of the previously described embodiments. In use, the proximal end of attachment ring **22** can abut the distal end of housing **18**, instead of being encased within housing **18**. Housing **18** is rotationally symmetric about lon-

gitudinal axis **187** such that for each feature on housing **18** there is an identical feature located 180 degrees away.

[0305] Housing first portion **46** and housing second portion **54** are identical to each other so for any feature shown and/or described for one of them, there is a corresponding feature present on the other. As shown in FIG. **57***b*, opposite ends of housing first portion **46** have hinge members **510** which interlock with that of housing second portion **54**. Each hinge member **510** has a through hole **511**. Interlocking hinge members **510** are held together by slidable hinge pin **520** having a first straight leg **522** and a second straight leg **524**. First straight leg is slideable within through holes **511** of hinge members **510**. Second straight leg **524** is slideable within through hole **526** formed in wing **528** at the proximal end of housing **18**.

[0306] When housing **18** is closed, as shown in FIG. **57***a*, each hinge pin **520** is in a distal position, and first straight leg **524** holds hinge members **510** together. To open housing **18**, a surgeon or other user may move hinge pin **520** proximally from the distal position, in the direction of arrow **530**, which causes first straight leg **522** to move and allow hinge members **510** to pull apart from each other, as shown in FIG. **57***b*. Foot member **532** on second straight leg **524** abuts wing **528**, which prevents hinge pin **520** completely pulling out and detaching from housing **18**. When one of the hinge pins **520** is moved proximally and the other hinge pin **520** is in the distal position, housing first portion **46** and housing second portion **54** can pivot apart from each other so that housing **18** opens. When both hinge pins **520** are moved proximally, housing first portion **46** and housing second portion **54** can completely detached from each other. When housing first portion **46** and housing second portion **54** are detached or pivoted apart from each other, valve **16** can be pulled out from between proximal flanges **534** within housing channel **58** and be completely removed.

[0307] Housing first portion **46** and housing second portion **54** each have de-airing port **62** which includes a through-hole the extends from the exterior of housing **18** to the portion of housing channel **58** between valve **16** and the distal end of housing **18**. Housing first portion **46** and housing second portion **54** each have gasket **536**, alignment pins **538**, and alignment holes **540**. Alignment pins **538**, and alignment holes **540** are located on opposite ends of housing first portion **46** and housing second portion **54**, so that alignment pins **538** of one of housing portion is received into alignment holes **540** of the other housing portion. When housing **18** is closed, gasket **536** is compressed and forms a fluid-tight seal between housing first portion **46** and housing second portion **54**. Gasket **536** can be bonded to the housing portion and can be made of a flat piece of silicone rubber foam or other resilient polymer material having edges which match the interior edges of housing **18**, including the contours of proximal flanges **534** and base flange **552**.

[0308] Alignment groove **542** is formed into proximal edge **544** of each of housing first portion **46** and housing second portion **54**. Alignment groove **542** can be sized and shape to receive protrusions **346** on the exterior surface of the slitting tool **300** (FIG. **52***a*) and protrusions **411** on the exterior surface of coring knife **140** (FIG. **54**). Engaging slitting tool **300** and coring knife **140** into grooves **496** can ensure that coring abutment **145** of coring knife **140** is aligned with the slit previously formed by flat blade **326** slitting tool **300**.

[0309] Referring to FIG. **57***b*, alignment groove **542** can be configured in such a way that a cylindrical protrusion can be pushed distally into proximal opening **544** and snapped into and retained within channel **546**. Retention is provided by proximal opening **544** which has width **548** that is slightly smaller than width **550** of channel **546**. In some embodiments, valvular structure **12** can be carried at the end of an installation tool having cylindrical protrusions engaged with alignment grooves **542**. The installation tool can be used to position valvular structure **12** at a desired position adjacent attachment ring **22** during a surgical procedure. For example and without limitation, the installation tool can be slitting tool **300**.

[0310] FIGS. **57***c* and **57***d* show views of the distal end of housing **18** when closed. Housing first portion **46** and housing second portion **54** each have base flange **552**. Base flange **552** is rigid and can be made of the same material used to form the remainder of housing **18**. Base gasket **554** is adhered to base flange **552**. Base gasket **554** can be made of a flat piece of silicone rubber foam or other resilient polymer material having edges which substantially match the edges of base flange **552**.

[0311] Base flange **552** is sized and shaped to fit within rotatable within C-clamp **600** (FIG. **58***c*), which will be described below Inner surface **556** of each base flange **552** has the shape of a half circle sized to allow slitting tool **300**, coring knife **140**, and inflow conduit **10** to pass through. The Outer surface of base flange **552** includes an outer curved surface **558** between two outer straight surfaces **560**. Outer straight surfaces **560** are substantially parallel to each other and are offset from each other by distance **562** (FIG. **57***d*). The curvature of outer curved surface **558** is defined by diameter **564**. When the housing **12** is closed, diameter **564** corresponds to the distance, as measured through the geometric center **566** of housing, between outer curved surface **558** on housing first portion **46** and outer curved surface **558** on housing second portion **54**. Diameter **564** is greater than distance **562**.

[0312] Outer curved surface **558** and outer straight surface **560** define the edge of compression surface **561** of base flange **552**. Compression surface **561** (FIGS. **57***a* and **57***b*) faces in the proximal direction and, as explained below, can be pushed by C-clamp **600** to compress base gasket **554** onto attachment ring **22**. Side groove **568** is formed into a portion of the outer surface of base flange **552** and is disposed distal to compression surface **561**. Stop wall **570** at one end of side groove **568** is formed into curved surface **558**. Side groove **568** extends from stop wall **570** along the circumference of curved surface **558** until side groove **568** opens onto and intersects one of the outer straight surfaces **560** at groove entrance point **572**.

[0313] FIGS. **58***a*-**58***e*, **59***a* and **59***b* show C-clamp **600** used for stabilizing attachment ring **22** after attachment ring **22** has been secured the heart, and for aligning and clamping valvular structure **12** onto attachment ring **22**. C-clamp **600** facilitates alignment and control during use of slitting tool **300** and coring knife **140** and during insertion of inflow conduit **10** into attachment ring **22**.

[0314] C-clamp **600** can be attached to a handle **602** for inserting C-clamp **600** into the body of a patient. Handle **602** can be of sufficient length to reach the apex of the heart with a portion of the handle extending out of the patient's chest no more than about 5 to 6 inches from the chest surface. In some embodiments, handle **602** is rigid and has a fixed curvature. In some embodiments, the curvature of the handle **602** can be adjusted and locked by the user. In some embodiments, as shown in FIG. **58***b*, handle **602** can be articulated and have a

plurality of segments **604** connected to each other by joints **606** which can be selectively loosened and locked by knob **608** to allow the curvature of handle **602** to be adjusted. Knob **608** can be configured to tighten joints **606** and/or adjust tension in one or more cables that run through the center of segments **604**, wherein movement of joints depend on the amount of tension in the cables. After the curvature of handle **602** is locked and C-clamp **600** is in the desired position within the patient, handle **602** can be secured to a chest retractor attached to the patient.

[0315] Referring to FIGS. **58***c* and **58***d*, shoulder segment **610** of C-clamp **600** is attached to handle **602**. Two arm segments **612** extend from shoulder segment. Free end **614** of arm segments **612** are spaced apart from each other and define side opening **616** of C-clamp **600**. Two finger members **618** form the tips of free end **614** of each arm segment **612**. Side slot **620** is formed between finger members **618**. Distal offset distance **622** separates the tips of finger members **618** of one arm segment from the tips of finger members **618** of the other arm segment. Distal offset distance **622** corresponds to the width of distal opening **624** at the base of C-clamp **600**. Edges of distal opening **624** form a U-shape, as shown in FIG. **58***d*, which includes distal linear edges **625** that are parallel to each other and are offset from each other by distal offset distance **622**. Distal groove diameter **648***a* (FIG. **58***e*) is greater than distal offset distance **622**. Side opening width **623** separates the base surface of side slot **620** of one arm segment from the base surface of side slot **620** of the other arm segment. In use, interface lip **25** of the attachment ring **22** passes through side opening width **623**, and distal opening **624** receives attaching ring wall **29**.

[0316] The shoulder segment **610** and the arm segments **612** form clamp body **601**. Distal groove **632** and proximal groove **644** in clamp body **601** form cylindrical surfaces **628***a*, **628***b* and ledge surfaces **626***a*, **626***b* that intersect each other. In illustrated embodiment, ledge surfaces **626***a*, **626***b* are planar. Cylindrical surfaces run substantially parallel to clamp longitudinal axis **630** and interface with circumferential surfaces of attachment ring **22** and valvular structure **12** when in use. Distal cylindrical surface **626***a* of distal groove **632** has a curvature which can be concentric with the curvature of proximal cylindrical surface **626***b* of proximal groove **644**. Ledge surfaces **626***a*, **626***b* are substantially planar and perpendicular to clamp longitudinal axis **630** and interface with distal or proximal facing surfaces of attachment ring **22** and valvular structure **12** when in use. In other embodiments, ledge surfaces **626***a*, **626***b* may include curves or indentations.

[0317] FIGS. **59***a* and **59***b* show C-clamp **600** with various devices. In use, C-clamp **600** is advanced toward attachment ring **22** which has already been secured to the heart. C-clamp **600** is advanced so that attachment ring **22** passes through side opening **616**. Interface lip **25** of attachment ring **22** passes between fingers **618** and into side slot **620**, and ring wall **29** of attachment ring **22** passes through distal opening **624** of C-clamp. Side opening width **623** between side grooves **620** is about the same as or slightly larger than the outer diameter of interface lip **25** of attachment ring **22**. Distance **622** between the tips of fingers **618** is about the same as or slightly larger than the outer diameter of ring wall **29** of attachment ring **22**. C-clamp **600** is positioned so that interface lip **25** is seated within distal groove **632** of C-clamp **600**. Distal ledge surface **626***a* of distal groove **632** supports interface lip **25**.

[0318] Proximal opening **634** (FIG. **59***a*) of C-clamp **600** is shaped and sized to receive base flange **552** and base gasket **554** of valvular structure **12** of FIGS. **57***a*-**57***d*. Exterior surface **626***c* of arm segments **612** of C-clamp **600** include linear edges **636** and curved edge **638** which correspond in shape to outer curved surface **558** and outer straight surfaces **560** of base flange **552**. Linear edges **636** are parallel to each other. Curved edge **638** intersects proximal cylindrical surface **628***b*. To allow base flange **552** to pass through proximal opening **634**, linear edges **636** and curved edge **638** have dimensions which about the same as or slightly larger than outer curved surface **558** and outer straight surfaces **560** of base flange **552**. Proximal offset distance **642** separates linear edges **636** and is about the same as or slightly larger than distance **562** (FIG. **57***d*) between straight surfaces **560** of base flange **552**. Proximal offset distance **642** is less than proximal groove diameter **648***a*.

[0319] As shown in FIG. **58***d*, the curvature of the distal cylindrical surface **628***a* extends between 180 degrees and 300 degrees. In the illustrated embodiment, distal cylindrical surface **628***a* extends about 270 degrees. The curvature of the proximal cylindrical surface **628***b* extends between 180 degrees and 300 degrees. In the illustrated embodiment, proximal cylindrical surface **628***b* extends about 270 degrees.

[0320] In use, valvular structure **12** is moved distally toward C-clamp **600** in the direction of arrow **640** (FIG. **59***a*), which base flange **552** facing C-clamp **600**. Valvular structure **12** is rotated about its longitudinal axis until outer straight surfaces **560** of base flange **552** are substantially parallel with linear edges **636** of C-clamp **600**, thereby allowing base flange **552** and base gasket **554** to pass through proximal opening **634**. Base gasket **554** contacts interface lip **25** of attachment ring **22**. Base flange **552** is seated within proximal groove **644** defined by proximal ledge surface **626***b*, proximal cylindrical surface **628***b*, and proximal compression surface **650** which intersect each other. Proximal cylindrical surface **628***b* extends from side slot **620** on one arm segment to side slot **620** on the other arm segment, and forms a circular shape having proximal groove diameter **648***b* (FIG. **58***d*) that is about the same as or slightly larger than diameter **564** (FIG. **57***d*) of outer curved surface **558** of base flange **552**. As shown in FIG. **58***d*, proximal groove diameter **648***b* is greater than proximal offset distance **642** which separates linear edges **636**. A portion of proximal cylindrical surface **628***b* is located below (distal to) linear edges **636** and intersects proximal compression surface **650**, as shown in FIG. **58***e* (side view of C-clamp). A pair of stop pins **652** (FIGS. **58***d* and **59***a*) protrude radially inward from the portion of proximal cylindrical surface **628***b* below linear edges **636**.

[0321] Referring to FIG. **58***e*, distal cylindrical surface **628***a* of distal groove **632** has a curvature having a distal groove diameter **648***a* which is about the same as or slightly greater than the outer diameter of attaching ring wall **29** of attachment ring **22**. The proximal groove diameter **628***b* is greater than the distal groove diameter **628***a*. Proximal compression surface **650** faces proximal ledge surface **626***b*. Distal opening **624** extends through distal ledge surface **626***a*. Proximal opening **634** extends through compression surface **650**.

[0322] After valvular structure **12** is seated within distal groove **644**, valvular structure **12** can be rotated relative to C-clamp **600** about clamp longitudinal axis **630** in the direction of arrow **654** (FIG. **59***b*). To allow for rotation, valvular structure **12** can be pushed distally in the direction of arrow

640 to compress base gasket 554 of valvular structure 12 against interface lip 25 and cause compression surface 561 of base flange 552 to be longitudinally aligned with or move slightly below proximal compression surface 650 of C-clamp 600. Thereafter, valvular structure 12 can be rotated in the direction of arrow 654. Each Stop pin 652 of C-clamp 600 prevents rotation in the opposite direction. During rotation, stop pin 652 is received within side groove 568 in base flange 552. Stop pin 652 enters groove entrance point 572. As valvular structure 12 is rotated, stop wall 570 at the end of side groove 568 moves toward stop pin 652 until they abut each other, which prevents any further rotation. Rotation stops when valvular structure 12 has rotated one quarter turn (or 90 degrees). After rotation has stopped, as shown in FIG. 59*b*, outer curved surface 558 of base flange 552 is located below (distal to) linear edges 636 of C-clamp 600. Compression surface 561 of base flange 552 engages proximal compression surface 650 of C-clamp 600, which keeps base gasket 554 of valvular structure 12 compressed and sealed against interface lip 25 of attachment ring 22.

[0323] As shown in FIG. 59*b*, alignment assembly 660 is disposed within proximal edge 544 of valvular structure 12. Protrusions 662 (one visible in FIG. 59*a*) of alignment assembly 660 extend radially outward and are engaged within alignment groove 542 is formed into proximal edge 544. Alignment assembly 660 can be part of a tool having a tip that extends into valvular structure 12 and attaching ring 22. Alignment assembly 660 can be attached to coring knife casing 141.

[0324] FIGS. 60*a*-60*c* show other embodiments of aortic punch 126. Aortic punch 126 includes punch casing 680, handle 682, guide cylinder 684, cylinder stem 686, and punch head 688. Longitudinal axis 681 runs through the center of guide cylinder 684. Cylinder stem 686 connects punch head 688 to guide cylinder 684. Guide cylinder 684 slides within internal channel 690 within punch casing 680. Guide cylinder 684 maintains the travel direction of punch head 688 parallel to longitudinal axis 681. Handle 682 passes through and is secured to guide cylinder 684. Handle 682 extends out of slots 692 formed through punch casing 680. A surgeon or other use can slide guide cylinder 684 within punch casing 680 by manipulating handle 682. Hollow blade 694 is disposed at the forward end of punch casing 680. Internal channel 690 extends through blade 694 where it forms blade opening 696.

[0325] As shown in FIG. 60*b*, internal channel 690 has an oblong cross-sectional shape as viewed from longitudinal axis 691. The cross-sectional shape is defined by two parallel sides 700 connected to each other by semi-circle ends 702. Semi-circle ends 702 are equal in diameter. Each semi-circle ends 702 has diameter 698 less than the length of the sides 700. The shape of blade opening 696 is defined by blade cutting edge 704. When viewed from longitudinal axis 681, blade cutting edge 704 has substantially the same oblong shape (with parallel sides and semi-circle ends) and same dimensions as the cross-sectional shape of internal channel 690. Punch head 688 is shaped and sized to pass through blade opening 696. The contours of outer perimeter 706 of punch head 688 includes parallel sides and semi-circle ends which form the same oblong shape as blade cutting edge 704. Thus, when viewed from longitudinal axis 681, punch head 688 has the same oblong shape as the cross-sectional shape of the internal channel 690.

[0326] In use, punch head 688 can be inserted within a small incision through the aorta or other anatomical vessel, such that punch head 688 is located within the lumen of the vessel, cylinder stem 686 passes through the incision, and blade 694 remains outside the vessel. Thus, the wall of the vessel is disposed between punch head 688 and blade 694. The user may then pull handle 682 rearward in the direction of arrow 708 which moves punch head 688 toward blade cutting edge 704. The wall of the vessel is cut or sheared as punch head 688 travels past blade cutting edge 704. Depending on the shape of blade cutting edge 704 and punch head 688, cutting or shearing of the vessel wall may not occur at the same time and may occur progressively as different parts of the blade cutting edge 704 and punch head 688 move past each other. A hole is made through the vessel wall when punch head 688 has moved completely within blade 694.

[0327] FIGS. 60*c*-60*e* show variations in the side profile shape of blade cutting edge 704 and punch head 688. The side profiles correspond to views of greatest dimension 705 of blade cutting edge 704 in a direction perpendicular to longitudinal 681. In FIG. 60*c*, punch head outer perimeter 706 lies on a plane substantially perpendicular to longitudinal axis 681, and blade cutting edge 704 has a convex side profile. The convex side profile of blade cutting edge 704 includes side segments 712 and central segment 714 that extends in front of side segments 712. Thus, when punch head 688 moves toward blade 694, cutting or shearing occurs first at the central portion of the vessel wall adjacent central segment 714 and cylinder stem 686, then at the portion of the vessel wall adjacent side segments 712.

[0328] In FIG. 60*d*, punch head outer perimeter 706 has a convex side profile and blade cutting edge 704 lies on a plane substantially perpendicular to longitudinal axis 681. The convex side profile of punch head outer perimeter 706 includes side segments 716 and central segment 718 that extends in front of side segments 716. Thus, when punch head 688 moves toward blade 694, cutting or shearing occurs first at the central portion of the vessel wall adjacent central segment 718 and cylinder stem 686, then at the portion of the vessel wall adjacent side segments 712.

[0329] For the side profile shapes in FIGS. 60*c* and 60*d*, the central portion of the vessel wall, closest the cylinder stem 686, is cut first. However, side profile shapes in FIGS. 60*c* and 60*d* produce holes in the vessel wall which are different in shape. As shown in FIG. 61*a*, the side profile shapes in FIG. 60*c* result in a substantially oblong shaped hole 720 through a vessel wall 722. Hole 720 has substantially parallel sides and semi-circle ends. The oblong shaped hole 720 can be the preferred shape for attaching outflow conduit 2 to an aorta. As shown in FIG. 61*b*, the side profile shapes in FIG. 60*d* result in a substantially "dog-bone" shaped hole 724 through vessel wall 726. Hole 724 has curved sides that make middle area of hole 724 narrower than the ends of hole 724.

[0330] In FIG. 60*e*, punch head outer perimeter 706 lies on a plane substantially perpendicular to longitudinal axis 681, and blade cutting edge 704 has a concave side profile. The concave side profile of blade cutting edge 704 includes central segment 714 and side segments 712 that extend in front of central segment 714. Thus, when punch head 688 moves toward blade 694, cutting or shearing occurs first at the portions of the vessel wall adjacent side segments 712, then at the portion of the vessel wall adjacent central segment 714 and cylinder stem 686. The side profile shapes in FIG. 60*e* result in a substantially "dog-bone" shaped hole through a vessel wall, such as shown in FIG. 61*b*.

[0331] FIGS. **62***a*-**65***d* show various embodiments of coring knife **140** having structural elements that function in the same manner as corresponding elements described in connection with FIGS. **53***a*-**53***f*. Each embodiment is shown in a sequence of four figures (with letters a through d) which correspond to the operational steps described in connection with FIGS. **53***a* and **53***d*-**53***f*.

[0332] In FIGS. **62***a*-**62***d*, an embodiment of coring knife **140** is shown having a pistol-type grip configuration. In the starting configuration shown in FIG. **62***a*, release trigger **362** is covered by abutment control lever **364** which prevents inadvertent actuation of release trigger **362** while coring abutment **145** is being inserted through a slit formed in the heart.

[0333] In FIGS. **63***a*-**63***d* and **64***a*-**64***d*, other embodiments of coring knife **140** is shown having an in-line grip configuration. Grip **360** is substantially parallel to longitudinal axis **366**. In the starting configuration shown in FIGS. **63***a* and **64***a* release trigger **362** is covered by abutment control lever **364** which prevents inadvertent actuation of release trigger **362** while coring abutment **145** is being inserted through a slit formed in the heart.

[0334] In FIGS. **65***a*-**65***d*, an embodiment of coring knife **140** is shown having a pistol-type grip configuration. Release trigger is located on central shaft **372** and is in the form of knob **362**. Standoff **365** (FIG. **65***b*) protrudes from abutment control lever **364**. In the starting configuration shown in FIG. **65***a*, standoff **365** abuts the rear of knob **362**, which prevents knob **362** for inadvertently being pressed while coring abutment **145** is being inserted through a slit formed in the heart.

[0335] Any elements described herein as singular can be pluralized (i.e., anything described as "one" can be more than one). Attaching, coupling, and joining can be used interchangeably within this description. Any species element of a genus element can have the characteristics or elements of any other species element of that genus. The above-described configurations, elements or complete assemblies and methods and their elements for carrying out the invention, and variations of aspects of the invention can be combined and modified with each other in any combination.

What is claimed is:

1. A method of preparing a heart for connection with a ventricular assist device, the method comprising:
- attaching an attachment ring to a ventricular apex of the heart, the attachment ring including a seal or a valve and configured to receive an inflow conduit;
- removing tissue, through the attachment ring, from the heart to form a hole in the ventricular apex; and
- closing a clamp around the attachment ring to secure an inflow conduit, inserted through the attachment ring, against the attachment ring, wherein the inflow conduit is configured to attach to or form a part of the ventricular assist device.

2. The method of claim **1**, further comprising, before the closing of the clamp, inserting the inflow conduit through the attachment ring and the hole in the ventricular apex.

3. The method of claim **1**, wherein the removing of the tissue from the heart includes inserting a coring knife into the attachment ring.

4. The method of claim **1**, further comprising, before the removing of the tissue, making a slit through the ventricular apex, wherein the making of the slit includes inserting a slitting tool into the attachment ring.

5. The method of claim **4**, wherein the slitting tool is aligned relative to the attachment ring by twisting the slitting tool until a feature on the slitting tool aligns with or is received within an alignment feature, the alignment feature being part of the attachment ring or a valvular structure connected to the attachment ring.

6. The method of claim **1**, wherein a valvular structure is either an integral part of or is removably attached to the attachment ring.

7. A method of preparing a heart for connection with a ventricular assist device, the method comprising:
- attaching an attachment ring to a ventricular apex of the heart, the attachment ring including a valve or a seal;
- forming a slit in the ventricular apex, the forming of the slit performed with use of a slitting tool aligned relative to and passed through the attachment ring; and
- removing tissue around the slit to form a hole in the ventricular apex, the removing of the tissue performed through the attachment ring.

8. The method of claim **7**, wherein the slitting tool is aligned relative to the attachment ring by twisting the slitting tool until a feature on the slitting tool aligns with or is received within an alignment feature, the alignment feature being part of the attachment ring or a valvular structure connected to the attachment ring.

9. The method of claim **8**, wherein the feature on the slitting tool is a protrusion on a housing of the slitting tool, and the alignment feature is an indentation configured to receive the protrusion.

10. The method of claim **7**, further comprising:
- inserting an inflow conduit through the attachment ring and the hole in the ventricular apex; and
- closing a clamp around the attachment ring to secure the inflow conduit to the attachment ring, wherein the inflow conduit is attached to or forms a part of the ventricular assist device.

11. The method of claim **7**, wherein the removing of the tissue from the heart includes inserting a coring knife into the attachment ring.

12. The method of claim **11**, wherein the inserting of the coring knife includes forming a substantially fluid-tight seal between the attachment ring and an exterior surface of the coring knife.

13. The method of claim **11**, wherein the removing of the tissue from the heart includes aligning a feature on an external surface of the coring knife with an alignment feature, the alignment feature being part of the attachment ring or a valvular structure connected to the attachment ring.

14. The method of claim **13**, wherein the feature on the external surface of the corning knife is a protrusion, and the alignment feature is an indentation configured to receive the protrusion.

15. A method of preparing a heart for connection with a ventricular assist device, the method comprising:
- attaching an attachment ring to a left ventricular apex of the heart; and
- attaching a valvular structure to the attachment ring using a clamp device, wherein a valvular structure has a closed position, and when in the closed position blood from an aperture in the left ventricular apex is substantially prevented from flowing out of the valvular structure.

16. The method of claim **15**, further comprising closing a ring clamp around the attachment ring to secure an inflow conduit to the attachment ring, wherein the inflow conduit is attached to or forms a part of the ventricular assist device.

17. The method of claim **15**, further comprising removing tissue from the heart to form a hole in the left ventricular apex, wherein the removing of the tissue includes:

inserting a coring knife into the valvular structure and the attachment ring; and

pulling the coring knife, with the removed tissue, out of the valvular structure and the attachment ring, wherein the valvular structure moves to the closed position after the coring knife is pulled out.

18. The method of claim **17**, wherein the removing of the tissue includes aligning a feature on an external surface of the coring knife with an alignment feature, the alignment feature being part of the attachment ring or the valvular structure.

19. The method of claim **17**, further comprising, before the removing of the tissue, making a slit through the left ventricular apex, wherein the making of the slit includes:

inserting a slitting tool into the valvular structure and the attachment ring to make the slit; and

pulling the slitting tool out of the valvular structure and the attachment ring after the slit is made, wherein the valvular structure moves to the closed position after the slitting tool is pulled out.

20. The method of claim **19**, wherein the making of the slit includes twisting the slitting tool until a feature on the slitting tool aligns with or is received within an alignment feature, the alignment feature being part of the attachment ring or the valvular structure.

21. The method of claim **15**, wherein the valvular structure includes a housing first portion and a housing second portion that are configured to be selectively locked together and moved apart from each other, the first housing portion connected to the second housing portion by a slide member configured to lock the housing first portion and the housing second portion together.

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