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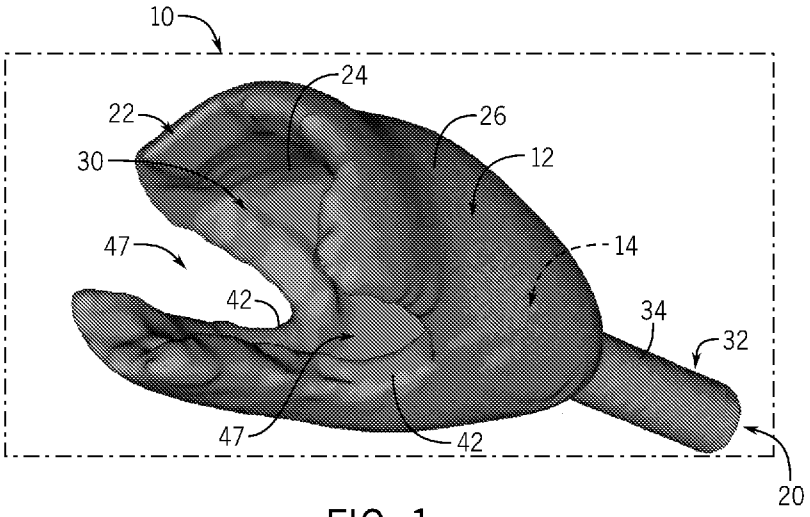

FIG. 1

(57) Abstract: A ventricular assist device configured to be positioned within a patient's ventricular cavity is provided. The ventricular assist device includes a sac and a self-expanding stent. The sac includes an intra-sac cavity, a port in fluid communication with the intra-sac cavity, a base, and an indentation extending from the base. The self-expanding stent is positioned within the intra-sac cavity.

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INTRA-CARDIAC PULSATILE VENTRICULAR ASSIST DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 U.S.C. § 119 to United States Provisional Patent Application No. 63/427,008 filed on November 21, 2022, the entire contents of which is incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] N/A

BACKGROUND

[0003] Ventricular assist devices (VADs) can be helpful for patients with failing hearts, used as a bridge to transplant or destination therapy. Currently used VADs are continuous flow VADs, which use pumps such as rotary turbines to generate continuous flow from the left ventricle to the aorta. However, continuous flow VADs have drawbacks, such as gastrointestinal (GI) bleeding, Von Willibrands syndrome (VWS), and hemolysis, and may not be tolerated on the long run.

[0004] Pulsatile flow VADs, on the other hand, can better mimic the pulsatile action of the heart and are less associated with hemolysis, VWS, and GI bleed, yet are generally not in use today. Such pulsatile flow VADs were originally made as an extracorporeal pumps, implanted outside the heart with inlet and outlet drive cables entering and exiting the body via skin incisions. However, such VADs had higher death rates compared to continuous flow VADs, often due damage to the drive cable and cannula detachments.

[0005] In view of the above, it can be appreciated that it would be desirable to provide a pulsatile flow VAD with less proclivity for the failures that precluded the success of earlier generations of pulsatile pumps.

SUMMARY

[0006] In some embodiments, a ventricular assist device configured to be positioned within a patient's ventricular cavity is provided. The ventricular assist device includes a sac and a self-expanding stent. The sac includes an intra-sac cavity, a port in fluid communication with the intra-sac cavity, a base, and an indentation extending from the base. The self-expanding stent

is positioned within the intra-sac cavity.

[0007] In some embodiments, a method of implanting a pulsatile ventricular assist device into patient's heart is provided. The method includes constraining the ventricular assist device within a constraining sheath to form a delivery system, placing the delivery system over a catheter with a hollow tube accommodating a delivery wire, and inserting the delivery wire through a ventricular apex of the patient's heart. The method further includes advancing the delivery system through the ventricular apex into a ventricular cavity of the patient's heart and retracting the constraining sheath to deploy ventricular assist device within the ventricular cavity so that an outer sac surface of the ventricular assist device lines walls of the ventricular cavity and indentations of the device extend around papillary muscles of the ventricular cavity. The method also includes removing the constraining sheath, the delivery wire, and the catheter from the patient's body.

[0008] The foregoing and other aspects and advantages of the present disclosure will appear from the following description. In the description, reference is made to the accompanying drawings that form a part hereof, and in which there is shown by way of illustration one or more exemplary versions. These versions do not necessarily represent the full scope of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The present disclosure may be better understood with reference to the following figures. Matching reference numerals designate corresponding parts throughout the figures, which are not necessarily drawn to scale.

[0010] FIG. 1 is a first perspective view of a computer rendering of a ventricular assist device according to some embodiments.

[0011] FIG. 2 is a second perspective view of the ventricular assist device of FIG. 1.

[0012] FIG. 3 is a third perspective view of the ventricular assist device of FIG. 1.

[0013] FIG. 4 illustrates medical imaging data of the ventricular assist device of FIG. 1 implanted into a patient's heart.

[0014] FIG. 5 is a schematic front view of the ventricular assist device implanted in a patient's heart.

[0015] FIG. 6 is a cutaway view of a heart.

[0016] FIG. 7 is a flowchart illustrating a method of implanting a ventricular assist device according to some embodiments.

[0017] FIG. 8 is a cross-sectional view of a ventricular assist device according to some embodiments.

[0018] FIG. 9 is a perspective view of a computer rendering of a ventricular assist device according to some embodiments, where FIG. 9A is a perspective view of the ventricular assist device including a stent embedded therein, FIG. 9B is a perspective view of the ventricular assist device relative to papillary muscles, and FIG. 9C is a perspective view of the ventricular assist device inside a ventricular cavity.

[0019] FIG. 10 is another perspective view of a computer rendering of the ventricular assist device of FIG. 9, where FIG. 10A is a perspective view of a self-expanding endoskeletal stent of the ventricular assist device, and FIG. 10B is a perspective view of a sac within which the stent is embedded.

[0020] FIG. 11 is yet another perspective view of a computer rendering of the ventricular assist device of FIG. 9, wherein FIG. 11A is a perspective view of a self-expanding endoskeletal stent of the ventricular assist device, FIG. 11B is a perspective view of a sac within which the stent is embedded, and FIG. 11C is a perspective view of the ventricular assist device inside a ventricular cavity.

[0021] FIG. 12 is yet another perspective view of a computer rendering of the ventricular assist device of FIG. 9.

[0022] FIG. 13 is a cross-sectional view of a ventricular assist device according to some embodiments.

DETAILED DESCRIPTION

[0023] Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms "mounted," "connected," "supported," and "coupled" and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, "connected" and "coupled" are not

restricted to physical or mechanical connections or couplings.

[0024] The following discussion is presented to enable a person skilled in the art to make and use embodiments of the invention. Various modifications to the illustrated embodiments will be readily apparent to those skilled in the art, and the generic principles herein can be applied to other embodiments and applications without departing from embodiments of the invention. Thus, embodiments of the invention are not intended to be limited to embodiments shown, but are to be accorded the widest scope consistent with the principles and features disclosed herein. The following detailed description is to be read with reference to the figures, in which like elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of embodiments of the invention. Skilled artisans will recognize the examples provided herein have many useful alternatives and fall within the scope of embodiments of the invention.

[0025] According to some embodiments, a pulsatile ventricular assist device is provided, for example, for use in patients with failing ventricles. The device is inserted via minimally invasive and established techniques directly into the failing ventricle and is coupled to a pump via a single port exiting the heart. The device, therefore, can provide pulsatile assistance within the ventricular cavity to directly mimic a pumping heart's actions. Furthermore, the device includes a "clamshell" configuration. This configuration includes indentations so as to not interfere with existing intracavity anatomical features, such as papillary muscles and cordal structures, thus enabling proper operation of the heart during assisted pumping action, such as properly enabling mitral valve closure.

[0026] For example, FIGS. 1-5and 8-13 illustrate ventricular assist devices (VADs) 10 according to some embodiments. Each device 10 includes a sac 12 with an internal stent 14. As further described below, the sac 12 may be generally shaped to fit an inner ventricular cavity of a heart 16, such as the left ventricular cavity 18 (shown in FIGS. 5, 9B, and 11C), and is configured to generate a contractile force that pumps blood out of the cavity 18 into the body. The sac 12 further includes a port 20 and a base 22 positioned generally opposite from the port 20.

[0027] As shown, for example, in FIGS. 1, 2, 4, and 8-11, the base 22 can be invaginated so to create an inner sac surface 24, an outer sac surface 26, and an intra-sac cavity 28 therebetween. When implanted, as shown in FIGS. 9C and 11C, the inner sac surface 24 can at least partially delineate a new blood chamber, e.g., a ventricular cavity 30, and is in contact with blood within the cavity 30, while the outer sac surface 26 conforms to and is in contact with the existing ventricular cavity 18. Additionally, in some embodiments, the sac 12 can

comprise a flexible material to enable sac 12 expansion and contraction, such as polytetrafluoroethylene (PTFE) or another or any other flexible, biocompatible material such as, but not limited to, polyurethane or silicone elastomers.

[0028] As shown in FIGS. 2, 4, 8, 11B, and 11C, the inner sac surface 24 can be a generally continuous surface, thus maintaining the general anatomy of a healthy ventricle, e.g., such that blood only moves through the new ventricular cavity 30 from the existing venous system to the existing arterial system. As shown in FIGS. 1, 3, 4, 8, and 12, the outer sac surface 26 can include a discontinuity forming the port 20, which opens into the intra-sac cavity 28. Furthermore, the port 20 can include a port extension 32 formed by port walls 34 sized to extend through the ventricular apex 36, as shown in FIG. 5. That is, the port 20 may be an apical extension of the outer sac 26, which exits the heart's apex 36.

[0029] Accordingly, as best shown in FIG. 8, the intra-sac cavity 28 is in fluid communication with the port 20, which can carry compression fluids (e.g., fluids or gases, not shown) into and out of the intra-sac cavity 28 to provide pulsatile forces. More specifically, as shown in FIG. 5, the port 20 can extend through the ventricular apex 36 to exit the heart 16 and can be connected to an intra- or extracorporeal pump 38 that cyclically fills and empties the intra-sac cavity 28 via compression fluids through the port 20. The flow of compression fluids or gases into and out of the intra-sac cavity 28 in a pulsatile manner, via the pump 38, causes the sac 12 and, more specifically, the new ventricular cavity 30, to expand and contract, mimicking the pulsatile action of a ventricular cavity of a healthy heart 16.

[0030] For example, FIG. 8 illustrates the device 10 in a contracted or systolic state (e.g., where the inner sac surface 24 is urged away from the outer sac surface 26) and an expanded or diastolic state (e.g., where the inner sac surface 24 is adjacent the outer sac surface 26, separated by the stent 14). That is, in the contracted state, expansion of the sac 12 can mimic the necessary contractile forces to pump blood out of the ventricular cavity 30. Pumping of fluid or gas into the intra-sac cavity 28 increases the pressure therein, causing the sac 12 to contract the new ventricular cavity 30, thus pumping blood out of the new ventricular cavity 30. In other words, given that the outer sac 26 is surrounded by stiffer ventricular walls, filling the intra-sac cavity 28 with compression fluids or gases results in compressive forces directed toward the inner sac 24 and, more specifically, into the new ventricular cavity 30. This results in an increase in intra-cavitary pressure (systole) that displaces the blood through the patient's aortic or pulmonic valves. FIG. 8 illustrates the inner sac in systole (indicated as 24A) and the larger volume of the intra-sac cavity (indicated as 28A) caused by in-flow of compression fluids.

[0031] Conversely, in the expanded state, pumping of fluid or gas out of the intra-sac cavity releases the pressure therein, causing the sac 12 to retract or expand so that new ventricular cavity 30 refills with blood. That is, removal of the gases or fluids (by the external pump 38) from that intra-sac cavity 28 results in a negative pressure that contracts the inter-saccular space 28 which, in turn, expands the blood chamber volume, inviting blood inflow from the mitral or tricuspid valve. During this phase "diastole", the inner sac 24 is pulled away from the blood chamber 30, driven by the suctioning force resulting from the removal of the gas or fluid. FIG. 8 illustrates the inner sac in diastole (indicated as 24B) and the smaller volume of the intra-sac cavity (indicated as 28B) caused by outflow of compression fluids. It should be noted that the term "compression fluids," as used herein, may refer to fluids or gases. In some embodiments, the compression gas may be, but not limited to, carbon dioxide.

[0032] As shown in FIG. 5, in some embodiments, a pneumatic or fluid-based compression pump 38 may be inserted and fixed in the thoracic or abdominal cavity 40 and fluidly connected to the port 20 via tubing 41. Accordingly, the device 10 is orthotopically inserted within the existing ventricular cavity and only includes a single port 20 exiting the heart 16, for example, as compared to many current continuous VADs, which include two ports through the heart 16 (e.g., an inflow port from the left ventricle and an outflow port into the aorta). Furthermore, the device 10 does not redirect blood flow outside of the normal, anatomical structures (e.g., like existing bypass devices) but, rather, acts to enhance the existing structures for proper anatomical function.

[0033] While the intra-sac cavity 28 of the deformable sac 12, in communication with the pump 38, provides the pulsatile functionality of the device 10, the internal stent 14 can further aid in this function as well as provide structure to the device 10 so that it lines the inner walls of the existing ventricular cavity 18. More specifically, as shown in FIGS. 4, 8, and 10-12, the stent 14 can be located within the intra-sac cavity 28 and can be a mesh self-expanding stent, for example, comprising perforated Nitinol (i.e., Nickel titanium) or another suitable material, such as another self-expanding metallic stent-like mesh. Generally, the mesh can comprise a structure including a plurality of cells. In some embodiments, the structure can be a closed-cell structure (such as, but not limited to, a honeycomb structure) or can be an open-cell structure, including periodic attachment points. For example, the structure of the mesh (either open-cell or closed-cell) can be selected to best fit specific cardiac anatomy of a particular patient.

[0034] The stent 14 can be shaped, in its expanded state, to mimic a ventricle as well as open port walls 34 of the port extension 32. As a result, the stent 14 can act as an "endoskeleton," supporting the intra-sac cavity 28. The stent 14 can cause the sac 12 to expand

into the shape of the existing ventricular cavity 18 so that it lines the existing ventricular walls and forms the new ventricular cavity 30.

[0035] Additionally, as shown in FIGS. 8-10 and 12, the stent 14 can extend partially or completely into the port 20 to provide structure and/or hold open the port walls 34 of the port extension 32. By including a portion of the stent 14 at the apex, the inner sac 24 is prevented from contacting the outer sac 26 during removal of compression fluid from the intra-sac cavity 28 (e.g., caused by negative pressure pulling the inner sac 24 toward the outer sac 26), which could potentially block the fluid pathway between the intra-sac cavity 28 and the port 20. In some embodiments, the stent 14 may comprise a single component through both the intra-sac cavity 28 and the port 20 while, in other embodiments, the stent 14 may comprise separate components in the intra-sac cavity 28 and the port 20 that are coupled together, such as a saccular stent component 14A and a tubular stent component 14B, as shown in FIGS. 8 and 10A.

[0036] For example, the saccular stent component 14A can be designed to fit within the intra-sac cavity 28 and may be custom-designed using patient-specific imaging data, such as CT or echocardiography imaging data in the diastolic phase of the cardiac cycle. The choice of diastolic phase is made to approximate the outer sac 26 against the inner ventricular wall when the device 10 is implanted, thus minimizing space that could harbor thrombi. Additionally, as described above, the saccular stent component 14A can include the "clam-shell" design to fit within the intra-sac cavity 28 and avoid the papillary muscles. As a further example, the tubular stent component 14B can be designed to be adjacent to an apical portion of the saccular stent component, acting as an endoskeleton of the port 20. Additionally, in some embodiments, the stent 14 can be sutured or otherwise coupled to the outer sac surface 26 and port 20 (and/or the inner sac surface 24) at various locations throughout the device 10.

[0037] Furthermore, in some embodiments, the device 10 can include one or more indentations. More specifically, as shown in FIGS. 1, 2, 4, and 9-12, the device 10 (e.g., both the sac 12 and the internal stent 14) can include medial and lateral indentations 42 extending from the base 22. The indentations 42 can extend through the entire device 10, that is, through both the inner sac surface 24 and the outer sac surface 26, thus forming a "clam-shell" configuration or look of the device 10. As noted above, the device 10 may be generally shaped to fit the inner ventricular cavity 18 of a heart 16, however, with the indentations 42 located around papillary muscles 44 (shown in FIGS. 6, 9, and 11) within the inner ventricular cavity 18.

[0038] For example, an intracavitary sac/stent that lines the entire ventricular cavity 18

would compress the papillary muscles 44 and cordal structures 46 (shown in FIG. 6). This impingement on the muscles 44 and structures 46 can interfere with proper movement of the mitral valve 48 or the tricuspid valve, potentially preventing full valve closure and inviting leakage (e.g., mitral or tricuspid regurgitation) during pumping action of the heart 16 assisted by such a device. Thus, according to some embodiments, the sac 12 and stent 14 geometry can be modified with the medial and lateral indentations 42, which can define spaces 47 (shown in FIGS. 1, 2, 4, and 9-12) that avoid interference with the papillary muscles 44 and cordal structures 46 during sac 12 compressions. Accordingly, FIGS. 9B, 9C, and 11C illustrate the device 10 conforming to the papillary muscle bases below the origin of cordae tendineae.

[0039] In some embodiments, the device 10 can be constructed to specifically mimic a patient's anatomy. For example, each individual patient can have minor differences in the shape, size, and/or structure of their ventricular cavity 18 (including the shape, size, structure and/or location of their papillary muscles 44 and cordal structures 46). Thus, the overall size of the device 10 as well as the size and/or location of the indentations 42 can be customized and patient-specific. Such individualized information can be determined using imaging data of the patient's heart, such as from commuted tomography (CT) imaging data, magnetic resonance (MR) imaging data, and/or echocardiography imaging data and three-dimensional (3D) reconstruction software. However, in other embodiments, the device 10 can be shaped to generally match ventricular anatomy of a general population or specific populations (e.g., males, females, patients within certain age ranges, etc.).

[0040] In light of the above, FIG. 7 illustrates a method 50 of implanting the device 10 in a patient, according to some embodiments. For implantation, as further described below, the device 10 can include a constraining sheath (not shown). Generally, the constraining sheath may be a plastic sheath to slenderize the deformable sac/endoskeletal stent assembly that gets pushed and constrained within its tubular lumen. Once the system reaches the ventricular cavity, retraction of the sheath will unrestrain the assembly and the self-expanding endoskeletal stent 14 will expand and, along with, it the deformable sac 12 to conform with the ventricular cavity. The sheath can be advanced over a previously placed trans-apical wire with the help of an introducer residing within it. The introducer can have a tapered tip through which a wire hole can be made spanning the length of the introducer. Once in place, the wire and introducer can be removed, leaving the hollow sheath in the ventricular cavity. Alternatively, the sheath can have within its wall a wire entry and exit port acting a "monorail" to advance the assembly over a guide wire previously inserted through the ventricular apical wall and into the aorta.

[0041] Accordingly, with reference to FIG. 7, at step 52, the device 10 is formed by

constraining the stent 14 within the sac 12. In some embodiments, step 52 may also include first acquiring imaging data of the patient's heart and defining device geometry specific to the patient's anatomy so that the device 10 is shaped to specifically conform to the patient's ventricular cavity. Alternatively, step 52 may include acquiring a generic, pre-assembled device.

[0042] Referring still to FIG. 7, at step 54, the patient's ventricular apex 36 is exposed and a delivery wire inserted into the ventricular cavity of a beating heart 16, e.g., via existing, minimally invasive trans-apical techniques. At step 56, a delivery sheath, including an introducer sheath, as described above, is advanced over the delivery wire into the ventricular cavity. At step 58, the introducer sheath and wire are removed from the delivery sheath. At step 60, the device 10 is constrained and slenderized within the delivery sheath. At step 62, the device 10 is advanced within the delivery sheath into the existing ventricular cavity 18. At step 64, the constraining sheath is retracted, which results in the expansion of the sac 12 as the self-expanding stent 14 deploys, and the device 10 is secured to the ventricle (e.g., via sutures). In some embodiments, step 64 further includes rotating or adjusting the device 10 to achieve proper orientation within the ventricular cavity 18, for example, so that the indentations 42 align with the patient's papillary muscles 44.

[0043] Once the device 10 is implanted, e.g., according to the method of FIG. 7 or another suitable method, a pump 38 may be coupled to the port 20 via tubing 41. As described above, in some embodiments, the pump 38 may be inserted and secured within the patient's thoracic or abdominal cavity 40. However, in other embodiments, the pump 38 may be an extracorporeal pump, such that the tubing 41 is routed to the port 20 through skin incisions and the pump is supported outside the body.

[0044] Once the device 10 is implanted and connected to the pump 38, the system (e.g., the device 10 and pump 38) can be operated through operation of the pump 38. In some embodiments, the system can synchronize movement of the device 10 with that of the native heart. More specifically, in order to synchronize the pulsatility of the deformable sac 12 with electrical activity of the native heart, the extracardiac pump 38 can be triggered by sensing electrodes embedded in the outer sac surface 26. For example, as shown in FIG. 13, the device 10 can include one or more sensing electrodes 70 embedded in or coupled to the outer sac surface 26 and interconnected with electrically conducting wires 72. The sensing electrodes 70 can be strategically placed along the outer sac surface 26 in order to sense electrical conduction of the ventricle walls. A circular coupling electrode 74 embedded on the inlet/outlet port 20 can receive input from the wires 72 and can transmit an electrical signal to the pump 38, e.g.,

via the tubing 41 connecting the device 10 to the pump 38. This signal can then be amplified and processed to trigger a mechanical pump contraction in synchrony with the native heart's contraction.

[0045] In light of the above, some embodiments provide a pulsatile ventricular assist device, for example, for use in patients with failing ventricles. The device is inserted via minimally invasive and established techniques directly into the failing ventricle and is coupled to a pump via a single port exiting the heart. The device, therefore, can provide pulsatile assistance within the ventricular cavity to directly mimic a pumping heart's actions as opposed to, e.g., heterotopic continuous flow devices that act as a bypass, delivering blood from the ventricular cavity to the aorta. Furthermore, the device includes minimal connections and less proclivity for the failures that precluded the success of earlier generations pulsatile pumps. That is, one reason for the failures of prior devices was damage to the drive cable or cannula detachments, as those pumps were implanted outside the heart and required both inlet and outlet drive cables exiting and entering the body via skin incisions. On the other hand, the device of some embodiments includes a single port fluidly connected to a pump that delivers fluid or gas for expanding and contracting an intra-sac cavity. Additionally, the device does not interfere with existing intracavity anatomical features, such as papillary muscles and cordal structures, thus enabling proper operation of those features, e.g., to properly enable mitral valve closure.

[0046] As used herein, unless otherwise defined or limited, the term "about" or "approximately" or "substantially" refers to variation in the numerical quantity that may occur, for example, through typical measuring and manufacturing procedures; through inadvertent error in these procedures; through differences in the manufacture, source, or purity of the ingredients used to make the compositions or mixtures or carry out the methods; and the like. Throughout the disclosure, the terms "about," "approximately," and "substantially" refer to a range of values ± 20% of the numeric value that the term precedes.

[0047] It will be appreciated by those skilled in the art that while the invention has been described above in connection with particular embodiments and examples, the invention is not necessarily so limited, and that numerous other embodiments, examples, uses, modifications and departures from the embodiments, examples and uses are intended to be encompassed by the claims attached hereto. The entire disclosure of each patent and publication cited herein is incorporated by reference, as if each such patent or publication were individually incorporated by reference herein. Various features and advantages of the invention are set forth in the following claims.

CLAIMS

1. A ventricular assist device configured to be positioned within a patient's ventricular cavity, the ventricular assist device comprising:

a sac comprising:

an intra-sac cavity,

a port in fluid communication with the intra-sac cavity,

a base, and

an indentation extending from the base; and

a self-expanding stent positioned within the intra-sac cavity.

2. The ventricular assist device of claim 1, wherein the sac expands and contracts via fluid pumped through the intra-sac cavity.

3. The ventricular assist device of claim 1, wherein the sac is invaginated at the base to form an inner sac surface, an outer sac surface, and the intra-sac cavity therebetween.

4. The ventricular assist device of claim 3, wherein the port extends from the outer sac surface.

5. The ventricular assist device of claim 3, wherein the stent is shaped, in its expanded state, to force the outer sac surface against walls of the ventricular cavity.

6. The ventricular assist device of claim 3, wherein the inner sac surface is a continuous surface.

7. The ventricular assist device of claim 1, wherein the port includes a port extension sized to extend through a ventricular apex of the patient's heart.

8. The ventricular assist device of claim 1, wherein the indentation includes a medial indentation and a lateral indentation, each sized to define a space for papillary muscle within the ventricular cavity.

9. The ventricular assist device of claim 1, wherein the sac comprises

polytetrafluoroethylene.

10. The ventricular assist device of claim 1, wherein the stent comprises Nickel titanium.

11. The ventricular assist device of claim 1, wherein the sac and the stent are constructed using imaging data of the patient's heart.

12. The ventricular assist device of claim 1, wherein the base is located opposite the port.

13. The ventricular assist device of claim 1 and further comprising a pump coupled to the port via tubing.

14. The ventricular assist device of claim 13 and further comprising a plurality of sensing electrodes coupled to an outer surface of the sac.

15. The ventricular assist device of claim 14, wherein the plurality of sensing electrodes are configured to provide a signal to the pump indicative of electrical activity of the patient's ventricular cavity.

16. A method of implanting a pulsatile ventricular assist device into patient's heart, the method comprising:

inserting a delivery wire through a ventricular apex and into a ventricular cavity of the patient's heart;

advancing a delivery sheath over the delivery wire, through the ventricular apex and into the ventricular cavity of the patient's heart;

constraining the ventricular assist device within the delivery sheath;

advancing the ventricular assist device within the delivery sheath into the ventricular cavity; and

retracting the delivery sheath to deploy ventricular assist device within the ventricular cavity so that an outer sac surface of the ventricular assist device lines walls of the ventricular cavity and indentations of the device extend around papillary muscles of the ventricular cavity.

17. The method of claim 16 and further comprising rotating the ventricular assist device within the ventricular cavity to align the indentations with the papillary muscles.

18. The method of claim 16 and further comprising securing a port of the ventricular assist device to a ventricle of the patient with sutures.

19. The method of claim 18 and further comprising coupling a pump to the port via tubing.

20. The method of claim 19 and further comprising securing the pump to one of an abdominal cavity or a thoracic cavity of the patient.

21. The method of claim 16 and further comprising forming the ventricular assist device by constraining a self-expanding stent within a sac.

22. The method of claim 21 and further comprising shaping the ventricular assist device using imaging data of the patient's heart.

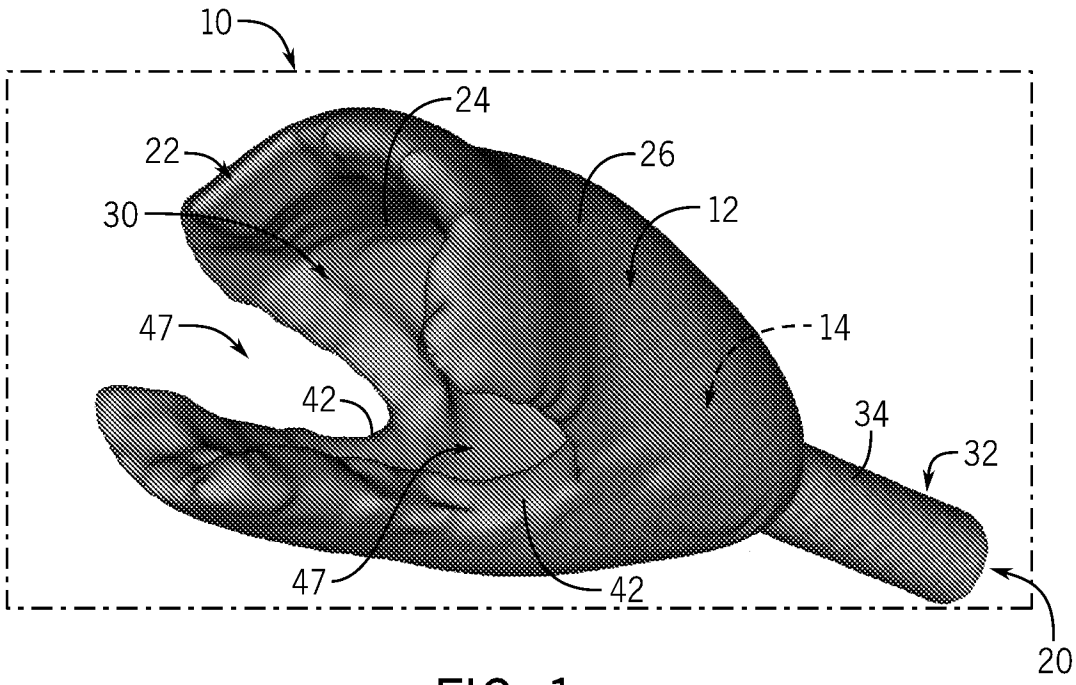

FIG. 1

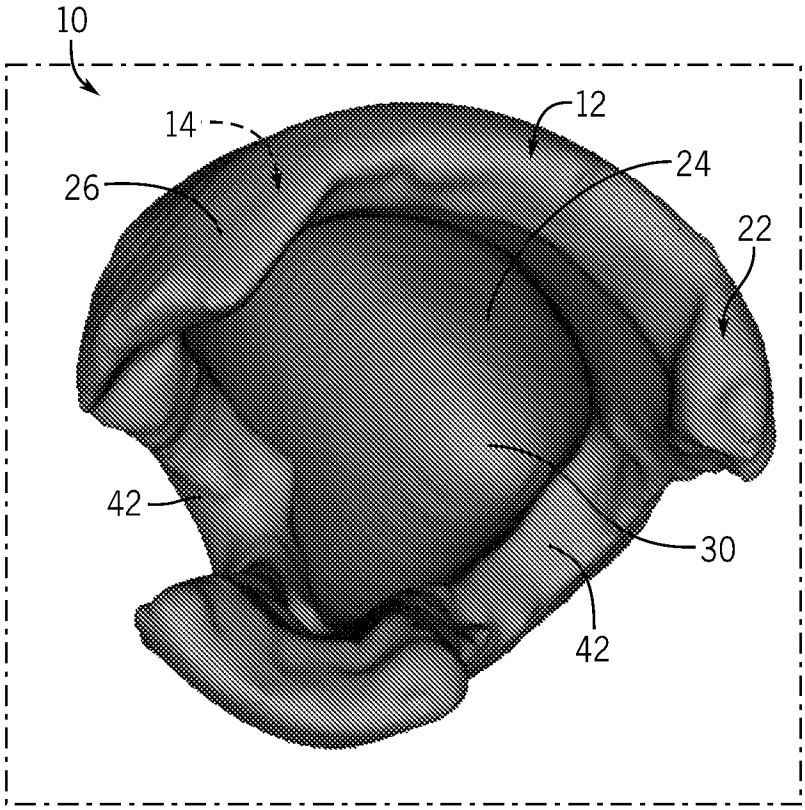

FIG. 2

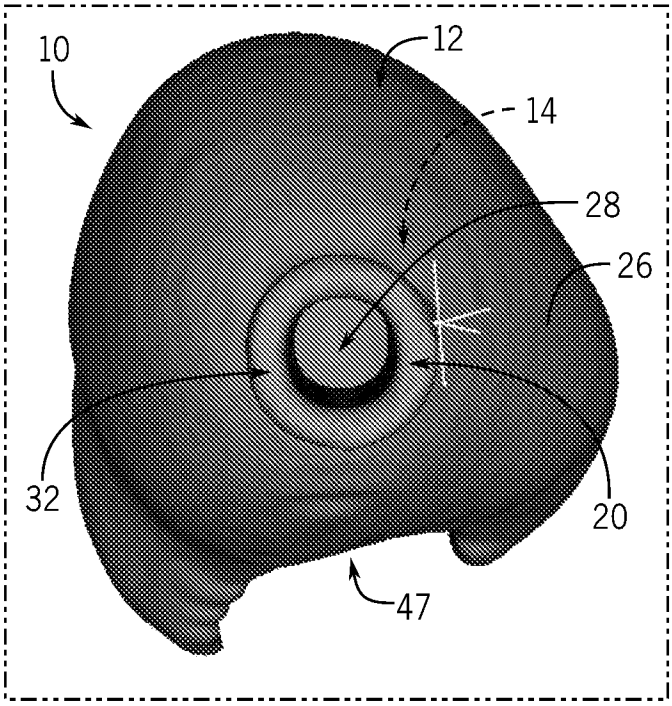

FIG. 3

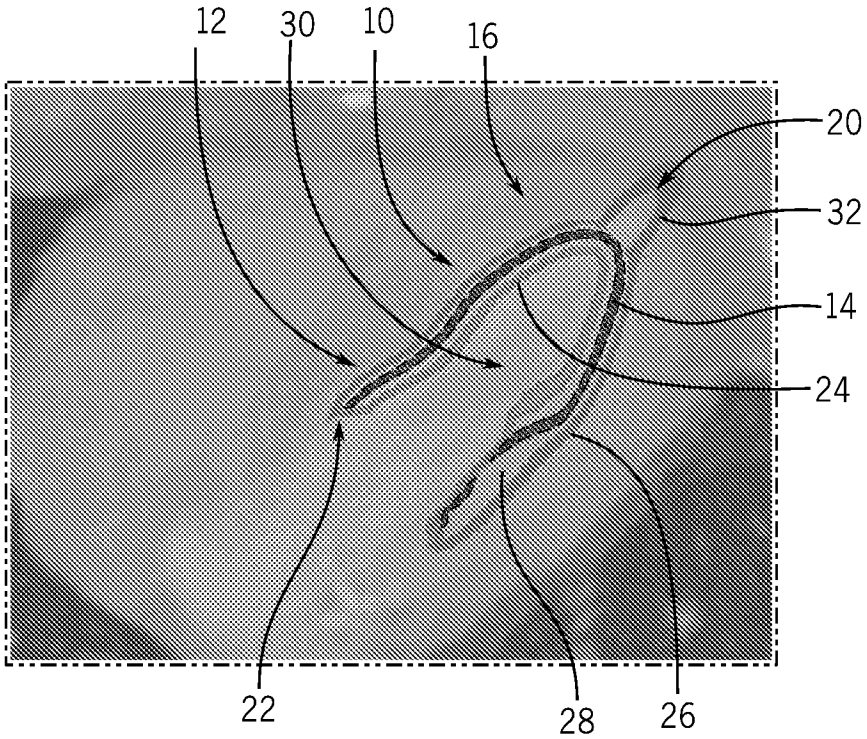

FIG. 4

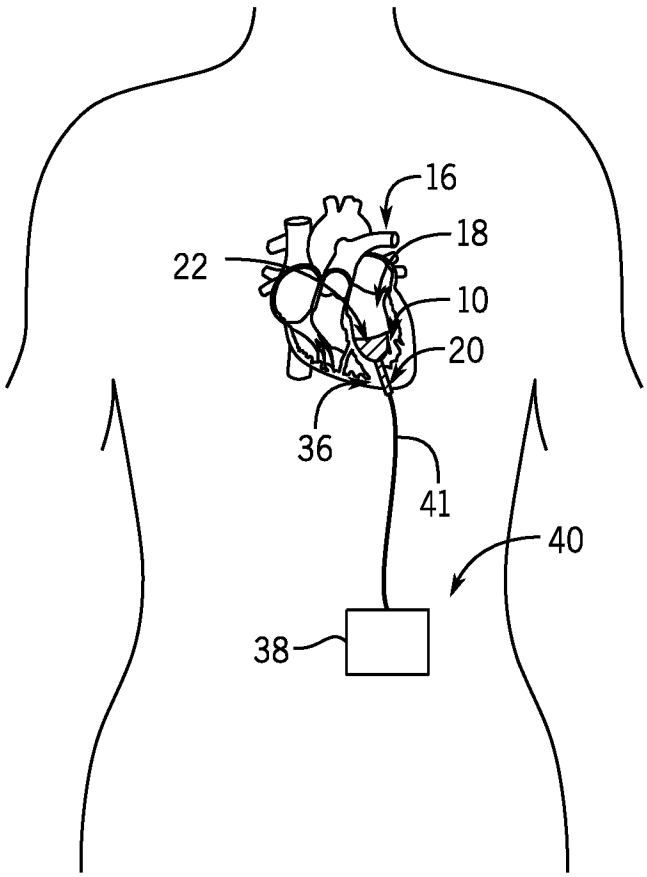

FIG. 5

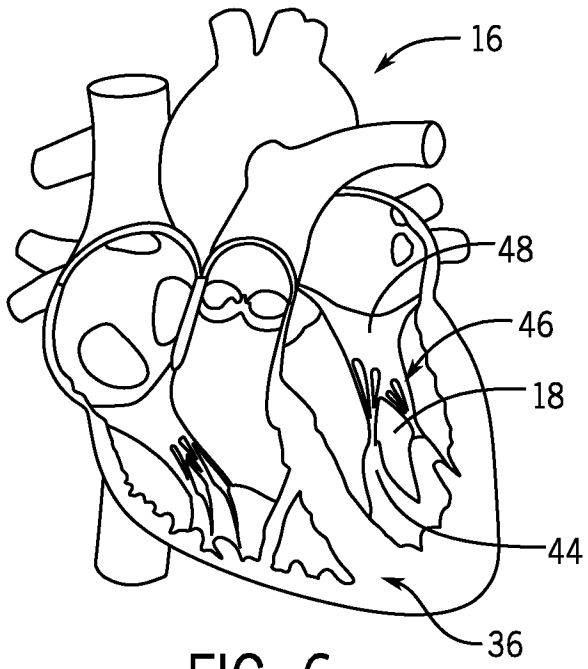

FIG. 6

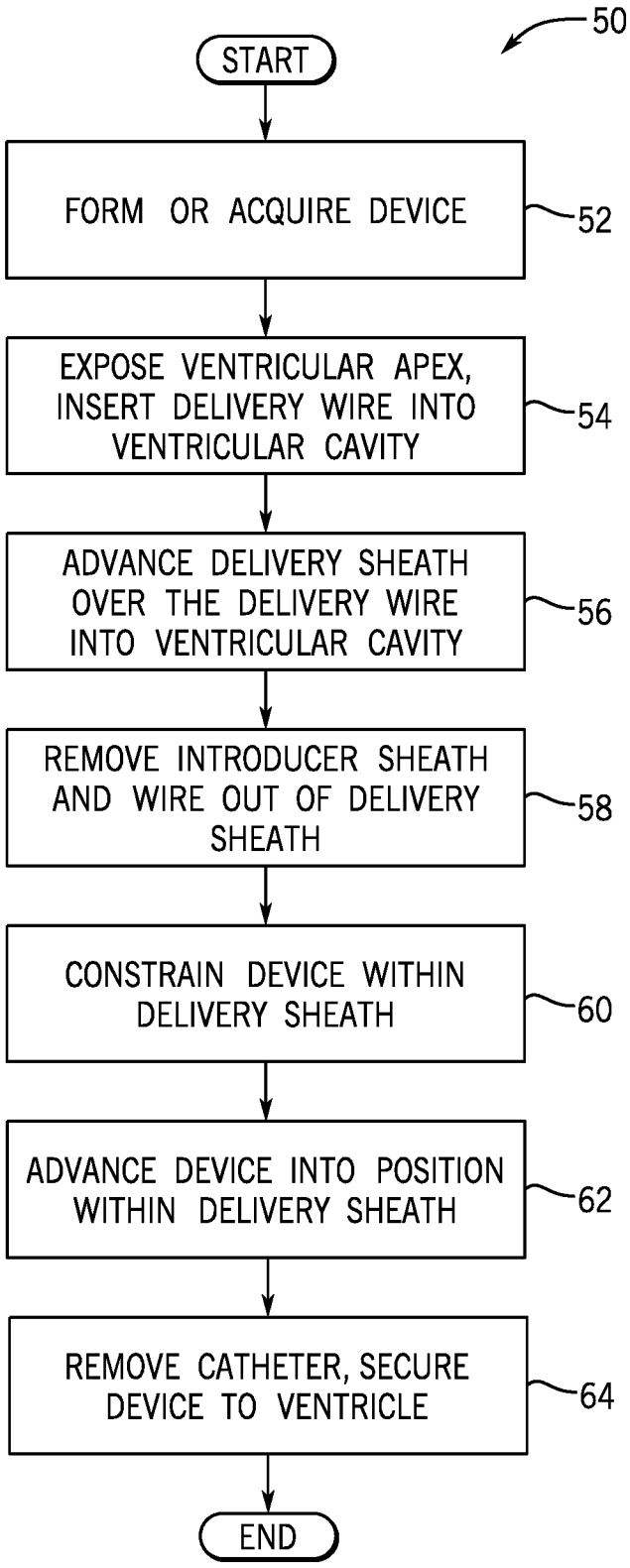
50
START
FORM OR ACQUIRE DEVICE
52
EXPOSE VENTRICULAR APEX, INSERT DELIVERY WIRE INTO VENTRICULAR CAVITY
54
ADVANCE DELIVERY SHEATH OVER THE DELIVERY WIRE INTO VENTRICULAR CAVITY
56
REMOVE INTRODUCER SHEATH AND WIRE OUT OF DELIVERY SHEATH
58
CONSTRAIN DEVICE WITHIN DELIVERY SHEATH
60
ADVANCE DEVICE INTO POSITION WITHIN DELIVERY SHEATH
62
REMOVE CATHETER, SECURE DEVICE TO VENTRICLE
64
END

FIG. 7

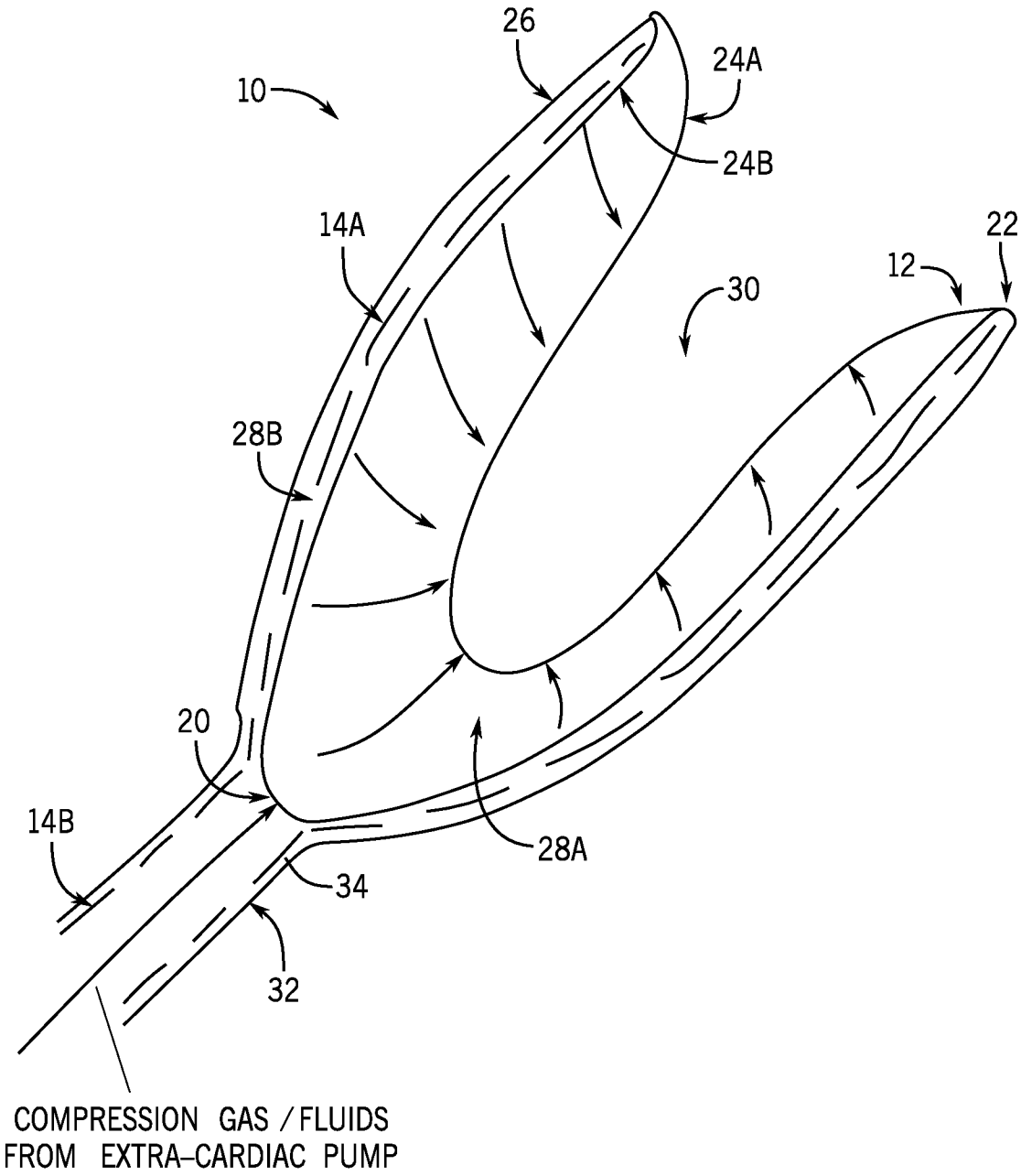
26
24A
10
24B
14A
22
12
30
28B
20
14B
28A
34
32
COMPRESSION GAS / FLUIDS
FROM EXTRA-CARDIAC PUMP

FIG. 8

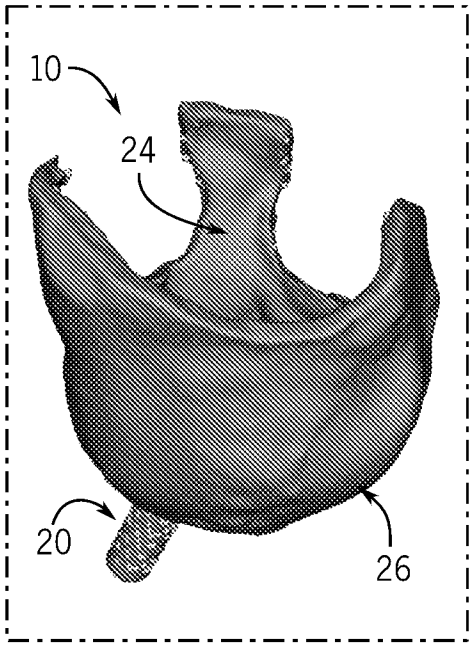

FIG. 9A

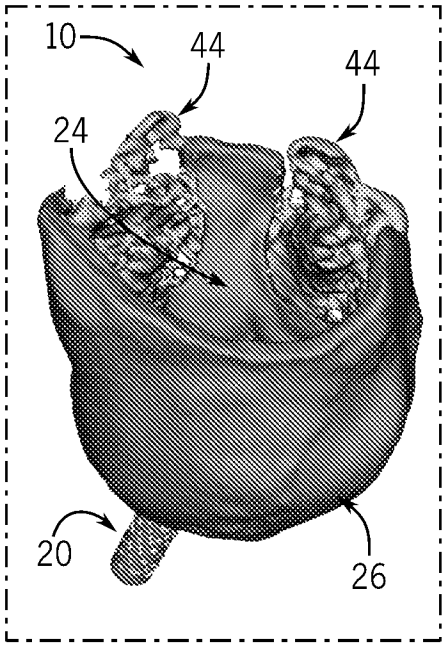

FIG. 9B

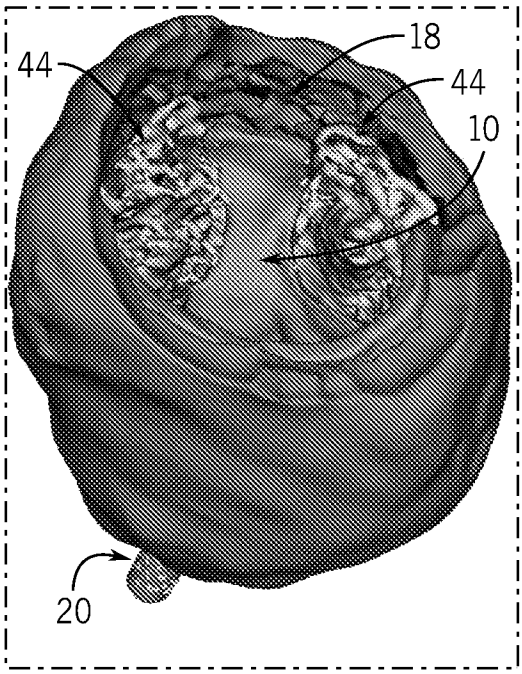

FIG. 9C

FIG. 9

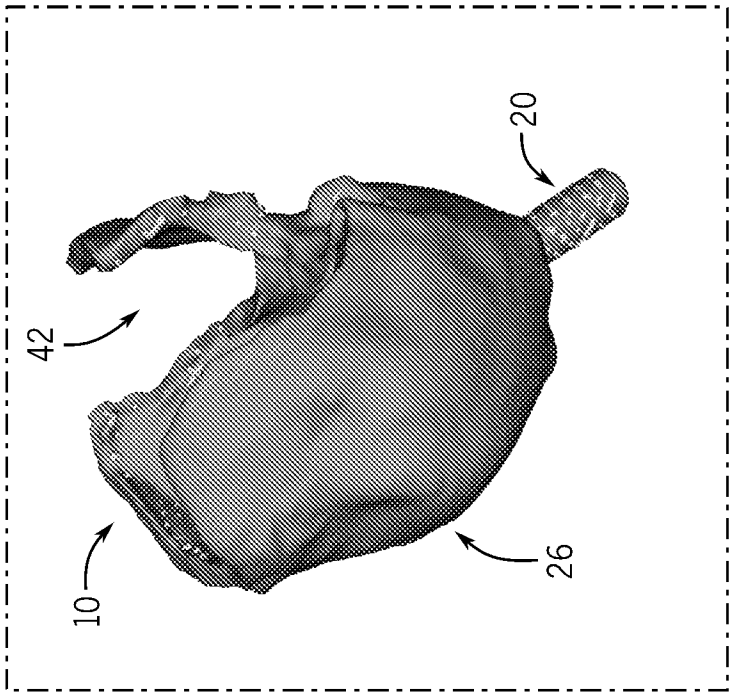

FIG. 10B

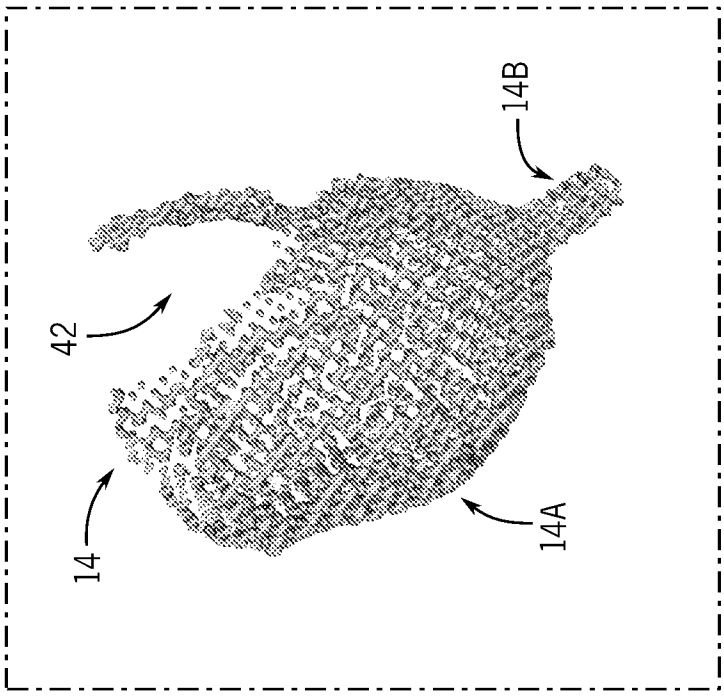

FIG. 10A

FIG. 10

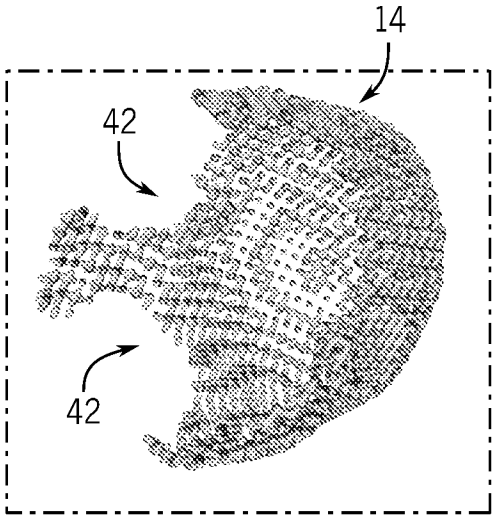

FIG. 11A

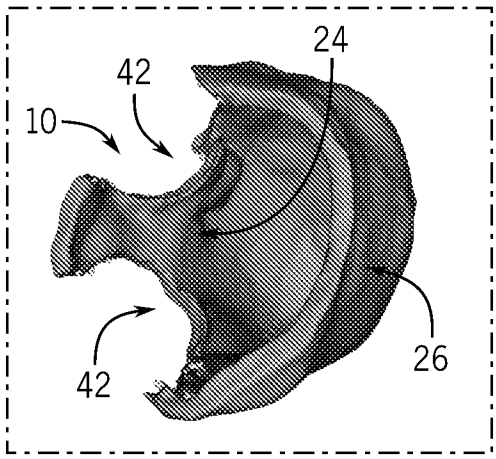

FIG. 11B

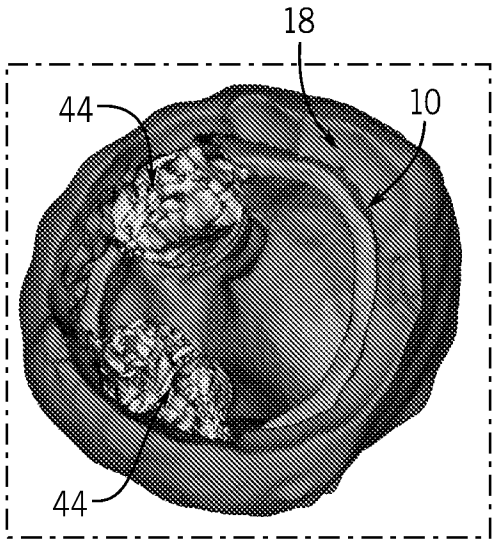

FIG. 11C

FIG. 11

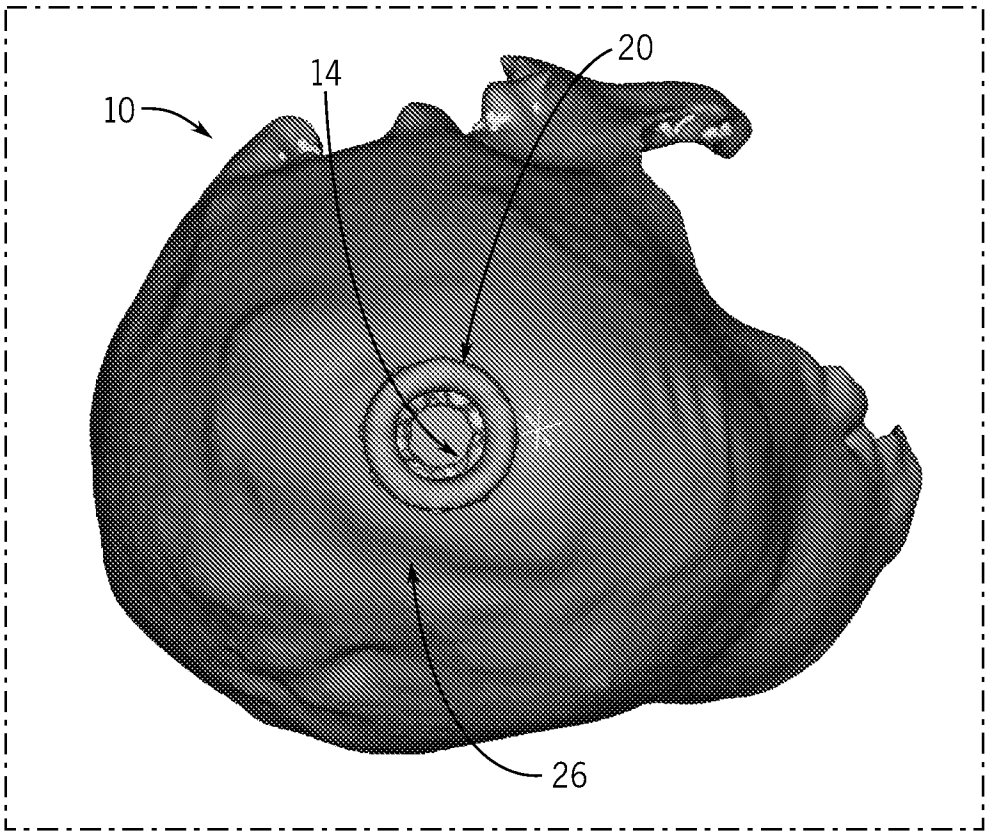

FIG. 12

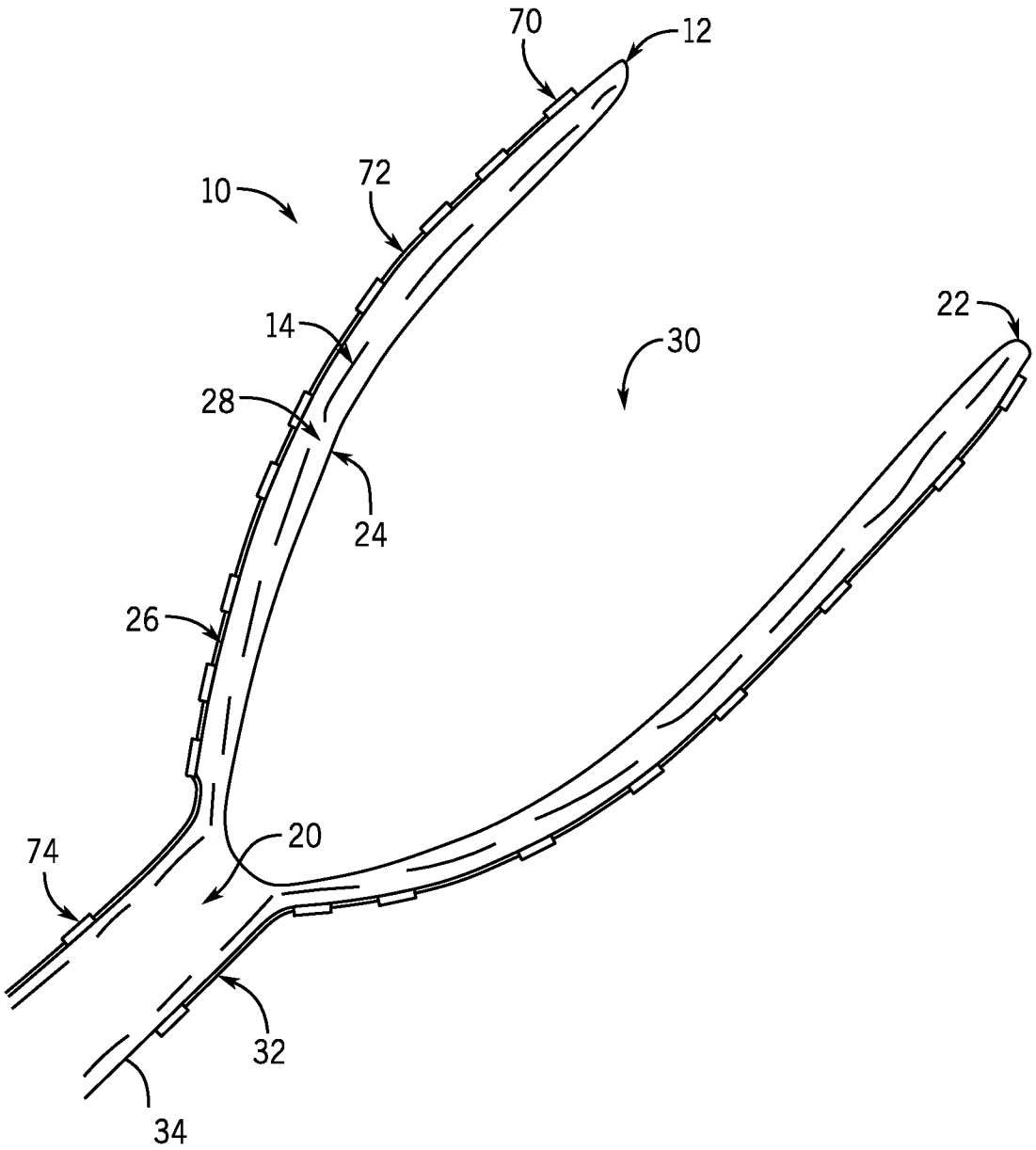

FIG. 13