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Direct cardiac pressure monitoring

Abstract

A septal closure device includes a frame comprising one or more tissue anchor features, an occluding membrane, and a pressure sensor device attached to the occluding membrane.

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Background/Summary

RELATED APPLICATIONS (1) This application is a continuation application of International Patent Application Serial No. PCT/US2020/015319, filed Jan. 28, 2020, which claims priority to U.S. Provisional Application No. 62/803,182, filed on Feb. 8, 2019, both entitled DIRECT CARDIAC PRESSURE MONITORING, the disclosures of which are hereby incorporated by reference in their entireties.

BACKGROUND
Field
(1) The present disclosure generally relates to the field of medical implant devices.
Description of Related Art
(2) Various medical procedures involve the implantation of medical implant devices within the anatomy of the heart. Certain physiological parameters associated with such anatomy, such as fluid pressure, can have an impact on patient health.
SUMMARY
(3) Described herein are one or more methods and/or devices to facilitate pressure sensing in cardiac anatomy. In some implementations, the present disclosure relates to a septal closure device comprising a frame comprising one or more tissue anchor features, an occluding membrane, and a pressure sensor device attached to the occluding membrane.
(4) In some embodiments, the pressure sensor device comprises a first portion disposed on a first side of the occluding membrane and a second portion disposed on a second side of the occluding membrane. For example, the first portion of the pressure sensor device comprises a first pressure sensor element and the second portion of the pressure sensor device comprises a second pressure sensor element.
(5) The occluding membrane may comprise a cloth. The occluding membrane may comprise a bio-spun polymer. The pressure sensor device may comprise a rigid cylindrical body. For example, the body of the pressure sensor device may have one or more radial projection features associated therewith. In some embodiments, the occluding membrane comprises a cuff feature configured to hold the sensor device. For example, the septal closure device may further comprise a suture collar wrapped at least partially around the cuff feature of the occluding membrane.
(6) In some implementations, the present disclosure relates to an implant device comprising a leaflet spacer form, a first tether attached to a first end of the leaflet spacer form, a tissue anchor attached to the first tether, and a first pressure sensor device coupled to the leaflet spacer form. In some embodiments, the leaflet spacer form has a foam filler disposed therein. In some embodiments, the leaflet spacer form has an exterior recess and the first pressure sensor device is disposed at least partially within the recess. In some embodiments, the first pressure sensor device is disposed at least partially within the leaflet spacer form.
(7) The implant device may further comprise a second tether attached to a second end of the leaflet spacer form, a second pressure sensor device attached to the second tether, and an anchor attached to the second sensor device. The anchor is configured to secure the second sensor device at least partially within a blood vessel. The blood vessel may be the inferior vena cava, wherein the second tether is configured to couple the second pressure sensor device to the leaflet spacer form through the right atrium.
(8) In some implementations, the present disclosure relates to an edge-to-edge valve leaflet repair device comprising a first clasp member, a second clasp member, a spacer disposed between the first and second clasp members, the spacer having a ventricular base portion that is coupled to the first and second clasp members and an atrial end portion, and a pressure sensor device integrated with the spacer. In some embodiments, the pressure sensor device comprises a pressure sensor element

that protrudes from the end portion of the spacer. In some embodiments, the valve leaflet repair device further comprises a second pressure sensor element associated with the base portion of the spacer.

(9) In some implementations, the present disclosure relates to an implant device comprising a cylindrical elongate sensor device having a proximal end portion and a distal end portion, and a tissue anchor coupled to the sensor device, the tissue anchor comprising a plurality of curved distal arms, the plurality of distal arms being concave in a proximal direction with respect to the sensor device and having respective tissue-contact ends that point in the proximal direction in a deployment configuration and a plurality of at least partially straight proximal arms, the plurality of proximal arms being deflected away from the sensor device and projecting in a distal direction with respect to the sensor device.

(10) The implant device may further comprise one or more projection features associated with the sensor device. For example, the sensor device may comprise a glass cylinder body and the one or more projection features may be attached to the cylinder body by an adhesive. In some embodiments, the sensor device comprises a first sensor element associated with the distal end portion and a second sensor element associated with the proximal end portion.

(11) In some implementations, the present disclosure relates to an anchor comprising first and second coil portions having a first diameter and an intermediate coil portion disposed between the first and second coil portions and having a second diameter that is less than the first diameter. In some embodiments, the anchor comprises memory metal and the first and second coil portions are configured to be disposed in a delivery catheter in a compressed state and form a plurality of coils of the first diameter when deployed from the delivery catheter. The anchor may further comprise a cylinder form coupled to one or more coils of the intermediate coil portion by one or more projection features associated with the cylinder form. For example, the cylinder form may be a pressure sensor device.

(12) For purposes of summarizing the disclosure, certain aspects, advantages and novel features have been described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment. Thus, the disclosed embodiments may be carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Various embodiments are depicted in the accompanying drawings for illustrative purposes and should in no way be interpreted as limiting the scope of the inventions. In addition, various features of different disclosed embodiments can be combined to form additional embodiments, which are part of this disclosure. Throughout the drawings, reference numbers may be reused to indicate correspondence between reference elements. However, it should be understood that the use of similar reference numbers in connection with multiple drawings does not necessarily imply similarity between respective embodiments associated therewith. Furthermore, it should be understood that the features of the respective drawings are not necessarily drawn to scale, and the illustrated sizes thereof are presented for the purpose of illustration of inventive aspects thereof. Generally, certain of the illustrated features may be relatively smaller than as illustrated in some embodiments or configurations.

(2) FIG. **1** is a cross-sectional view of a human heart.

(3) FIG. **2** illustrates example pressure waveforms associated with various chambers and vessels of the heart according to one or more embodiments.

(4) FIG. **3** illustrates an implanted sensor implant device in accordance with one or more

embodiments.
(5) FIG. **4** is a block diagram of an implant device in accordance with one or more embodiments.
(6) FIG. **5** illustrates a perspective view of a sensor implant device in accordance with one or more embodiments.
(7) FIG. **6** shows a sensor implant device implanted in a tissue wall in accordance with one or more embodiments.
(8) FIG. **7** is a flow diagram illustrating a process for implanting a sensor implant device in accordance with one or more embodiments of the present disclosure.
(9) FIG. **8** illustrates states of components of a sensor implant device and/or an associated delivery system corresponding to the various steps of the process of FIG. **7** in accordance with one or more embodiments.
(10) FIG. **9** illustrates a system for removing a previously-implanted sensor implant device in accordance with one or more embodiments.
(11) FIG. **10** illustrates a sensor implant device in accordance with one or more embodiments.
(12) FIG. **11** shows a sensor implant device in accordance with one or more embodiments.
(13) FIG. **12** is a flow diagram illustrating a process for implanting a sensor implant device in accordance with one or more embodiments.
(14) FIG. **13** illustrates states of components of a sensor implant device and/or an associated delivery system corresponding to the various steps of the process of FIG. **12** in accordance with one or more embodiments.
(15) FIG. **14** illustrates a sensor anchor in accordance with one or more embodiments.
(16) FIG. **15** shows an anchor implanted in a septal wall in accordance with one or more embodiments.
(17) FIG. **16** illustrates a sensor anchor in accordance with one or more embodiments.
(18) FIG. **17** shows a pressure sensor device in accordance with embodiments of the present disclosure.
(19) FIG. **18** shows a front view of a sensor-integrated septal-closure device in accordance with one or more embodiments.
(20) FIG. **19** shows a perspective view of the sensor-integrated septal-closure device of FIG. **18** implanted in a tissue wall in accordance with one or more embodiments.
(21) FIG. **20** illustrates a sensor implant device comprising a sensor integrated with a septal closure device in accordance with one or more embodiments.
(22) FIG. **21** illustrates a process for removing a sensor implant device in accordance with embodiments.
(23) FIG. **22** illustrates a sensor implant device and associated removal system, as well as cardiac anatomy at various states corresponding to the process steps of FIG. **21**.
(24) FIG. **23** illustrates a sensor implant device comprising a sensor integrated with a heart valve spacer device in accordance with one or more embodiments.
(25) FIG. **24** illustrates a sensor assembly including a sensor-integrated spacer implant device and a tethered separate sensor device in accordance with one or more embodiments.
(26) FIG. **25** illustrates a sensor-integrated cardiac implant device comprising a sensor integrated with a left atrial appendage occluder implant device in accordance with one or more embodiments.
(27) FIGS. **26** and **27** show side and top views, respectively, of a sensor-integrated valve repair implant configured to provide edge-to-edge leaflet attachment for mitral valve repair in accordance with one or more embodiments.
(28) FIG. **28** shows another embodiment of a sensor integrated with a mitral valve repair implant to form a valve repair sensor assembly in accordance with one or more embodiments.
(29) FIG. **29** shows an embodiment of a sensor integrated with a mitral valve repair implant to form a valve repair sensor assembly in accordance with one or more embodiments.
(30) FIG. **30** illustrates a sensor-integrated annular reduction implant in accordance with one or

more embodiments.
(31) FIG. **31** illustrates a sensor coupled to a replacement mitral valve implant in accordance with one or more embodiments.
(32) FIG. **32** illustrates a valve repair and pressure sensor assembly in accordance with one or more embodiments.
(33) FIG. **33** illustrates a sensor device suspended in the left atrium using an anchor system in accordance with one or more embodiments.
(34) FIGS. **34**A and **34**B illustrate example embodiments of pressure sensors having associated or integrated tissue anchors in accordance with one or more embodiments.
(35) FIG. **35** illustrates a sensor-integrated implant device including a docking device integrated with a sensor in accordance with one or more embodiments.
(36) FIGS. **36**A and **36**B illustrate sensor-integrated cardiac implant devices in accordance with one or more embodiments.
(37) FIG. **37** illustrates various access paths through which access to a target cardiac anatomy may be achieved in accordance with one or more embodiments.

DETAILED DESCRIPTION

(38) The headings provided herein are for convenience only and do not necessarily affect the scope or meaning of the claimed invention.
(39) The present disclosure relates to systems, devices, and methods for telemetric pressure monitoring in connection with cardiac implants and/or other medical implant devices and/or procedures. Such pressure monitoring may be performed using cardiac implant devices having integrated pressure sensors and/or associated components.
(40) Although certain preferred embodiments and examples are disclosed below, inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses and to modifications and equivalents thereof. Thus, the scope of the claims that may arise herefrom is not limited by any of the particular embodiments described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain embodiments; however, the order of description should not be construed to imply that these operations are order dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components. For purposes of comparing various embodiments, certain aspects and advantages of these embodiments are described. Not necessarily all such aspects or advantages are achieved by any particular embodiment. Thus, for example, various embodiments may be carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.
(41) Certain standard anatomical terms of location are used herein to refer to the anatomy of animals, and namely humans, with respect to the preferred embodiments. Although certain spatially relative terms, such as “outer,” “inner,” “upper,” “lower,” “below,” “above,” “vertical,” “horizontal,” “top,” “bottom,” and similar terms, are used herein to describe a spatial relationship of one device/element or anatomical structure to another device/element or anatomical structure, it is understood that these terms are used herein for ease of description to describe the positional relationship between element(s)/structures(s), as illustrated in the drawings. It should be understood that spatially relative terms are intended to encompass different orientations of the element(s)/structures(s), in use or operation, in addition to the orientations depicted in the drawings. For example, an element/structure described as “above” another element/structure may represent a position that is below or beside such other element/structure with respect to alternate orientations of the subject patient or element/structure, and vice-versa.

(42) Embodiments of the present disclosure relate to cardiac pressure monitoring solutions including implant devices integrated with sensor functionality, such as pressure sensor functionality. For example, pressure monitoring solutions in accordance with embodiments of the present disclosure may be applicable for patients suffering from various forms of heart failure, such as acute congestive heart failure. Pressure monitoring solutions as disclosed herein may allow for improved diagnostics and/or notification relating to heart conditions. For example, embodiments of the present disclosure allow for cardiac pressure monitoring of a patient post-operatively, wherein the pressure monitoring may involve tracking and/or notification of pressure trends (or trends relating to one or more other physiological parameters monitored in accordance with the present disclosure) that may result in or be associated with adverse effects or events. The various embodiments disclosed herein involve sensor-integrated implant devices implanted in various vessels or chambers of the cardiac system. Furthermore, various embodiments disclosed herein relate to sensor-integrated implants of various types, including septal closure or occluder devices, leaflet repair spacers, leaflet clip devices, and the like.

(43) Certain embodiments are disclosed herein in the context of cardiac implant devices. However, although certain principles disclosed herein are particularly applicable to the anatomy of the heart, it should be understood that sensor implant devices in accordance with the present disclosure may be implanted in, or configured for implantation in, any suitable or desirable anatomy.

(44) The anatomy of the heart is described below to assist in the understanding of certain inventive concepts disclosed herein. In humans and other vertebrate animals, the heart generally comprises a muscular organ having four pumping chambers, wherein the flow thereof is at least partially controlled by various heart valves, namely, the aortic, mitral (or bicuspid), tricuspid, and pulmonary valves. The valves may be configured to open and close in response to a pressure gradient present during various stages of the cardiac cycle (e.g., relaxation and contraction) to at least partially control the flow of blood to a respective region of the heart and/or to blood vessels (e.g., pulmonary, aorta, etc.). The contraction of the various heart muscles may be prompted by signals generated by the electrical system of the heart, which is discussed in detail below. Certain embodiments disclosed herein relate to conditions of the heart, such as atrial fibrillation and/or complications or solutions associated therewith. However, embodiments of the present disclosure relate more generally to any health complications relating to fluid overload in a patient, such as may result post-operatively after any surgery involving fluid supplementation. That is, detection of atrial stretching as described herein may be implemented to detect/determine a fluid-overload condition, which may direct treatment or compensatory action relating to atrial fibrillation and/or any other condition caused at least in part by fluid overloading.

(45) FIG. **1** illustrates an example representation of a heart **1** having various features relevant to certain embodiments of the present inventive disclosure. The heart **1** includes four chambers, namely the left atrium **2**, the left ventricle **3**, the right ventricle **4**, and the right atrium **5**. In terms of blood flow, blood generally flows from the right ventricle **4** into the pulmonary artery via the pulmonary valve **9**, which separates the right ventricle **4** from the pulmonary artery **11** and is configured to open during systole so that blood may be pumped toward the lungs and close during diastole to prevent blood from leaking back into the heart from the pulmonary artery **11**. The pulmonary artery **11** carries deoxygenated blood from the right side of the heart to the lungs. The pulmonary artery **11** includes a pulmonary trunk and left **15** and right **13** pulmonary arteries that branch off of the pulmonary trunk, as shown. In addition to the pulmonary valve **9**, the heart **1** includes three additional valves for aiding the circulation of blood therein, including the tricuspid valve **8**, the aortic valve **7**, and the mitral valve **6**. The tricuspid valve **8** separates the right atrium **5** from the right ventricle **4**. The tricuspid valve **8** generally has three cusps or leaflets and may generally close during ventricular contraction (i.e., systole) and open during ventricular expansion (i.e., diastole). The mitral valve **6** generally has two cusps/leaflets and separates the left atrium **2** from the left ventricle **3**. The mitral valve **6** is configured to open during diastole so that blood in

the left atrium **2** can flow into the left ventricle **3**, and, when functioning properly, closes during diastole to prevent blood from leaking back into the left atrium **2**. The aortic valve **7** separates the left ventricle **3** from the aorta **12**. The aortic valve **7** is configured to open during systole to allow blood leaving the left ventricle **3** to enter the aorta **12**, and close during diastole to prevent blood from leaking back into the left ventricle **3**.

(46) The heart valves may generally comprise a relatively dense fibrous ring, referred to herein as the annulus, as well as a plurality of leaflets or cusps attached to the annulus. Generally, the size of the leaflets or cusps may be such that when the heart contracts the resulting increased blood pressure produced within the corresponding heart chamber forces the leaflets at least partially open to allow flow from the heart chamber. As the pressure in the heart chamber subsides, the pressure in the subsequent chamber or blood vessel may become dominant and press back against the leaflets. As a result, the leaflets/cusps come in apposition to each other, thereby closing the flow passage. Disfunction of a heart valve and/or associated leaflets (e.g., pulmonary valve disfunction) can result in valve leakage and/or other health complications.

(47) The atrioventricular (i.e., mitral and tricuspid) heart valves may further comprise a collection of chordae tendineae and papillary muscles (not shown) for securing the leaflets of the respective valves to promote and/or facilitate proper coaptation of the valve leaflets and prevent prolapse thereof. The papillary muscles, for example, may generally comprise finger-like projections from the ventricle wall. The valve leaflets are connected to the papillary muscles by the chordae tendineae. A wall of muscle **17**, referred to as the septum, separates the left **2** and right **5** atria and the left **3** and right **4** ventricles.

(48) As referenced above, certain physiological conditions or parameters associated with the cardiac anatomy can impact the health of a patient. For example, congestive heart failure is a condition associated with the relatively slow movement of blood through the heart and/or body, which can cause the fluid pressure in one or more chambers of the heart to increase. As a result, the heart does not pump sufficient oxygenated blood to meet the body's needs. The various chambers of the heart may respond to pressure increases by stretching to hold more blood to pump through the body or by becoming relatively stiff and/or thickened. The walls of the heart can eventually weaken and become unable to pump as efficiently. In some cases, the kidneys may respond to cardiac inefficiency by causing the body to retain fluid. Fluid build-up in arms, legs, ankles, feet, lungs, and/or other organs can cause the body to become congested, which is referred to as congestive heart failure. Acute decompensated congestive heart failure is a leading cause of morbidity and mortality, and therefore treatment and/or prevention of congestive heart failure is a significant concern in medical care.

(49) The treatment and/or prevention of heart failure (e.g., congestive heart failure) can advantageously involve the monitoring of pressure in one or more chambers or regions of the heart or other anatomy. As described above, pressure buildup in one or more chambers or areas of the heart can be associated with congestive heart failure. Without direct or indirect monitoring of cardiac pressure, it can be difficult to infer, determine, or predict the presence or occurrence of congestive heart failure. For example, treatments or approaches not involving direct or indirect pressure monitoring may involve measuring or observing other present physiological conditions of the patient, such as measuring body weight, thoracic impedance, right heart catheterization, or the like.

(50) Various methods for identifying and/or treating congestive heart failure involve the observation of worsening congestive heart failure symptoms and/or changes in body weight. However, such signs may appear relatively late and/or be relatively unreliable. For example, daily bodyweight measurements may vary significantly (e.g., up to 9% or more) and may be unreliable in signaling heart-related complications. Furthermore, treatments guided by monitoring signs, symptoms, weight, and/or other biomarkers have not been shown to substantially improve clinical outcomes. In addition, for patients that have been discharged, such treatments may necessitate

remote telemedicine systems. In some situations, congestive heart failure can result from fluid build-up over a period of time, such as a 2-3-week period. Therefore, detection and/or determination of fluid build-up within the initial days or week of fluid build-up can be useful in preventing development of congestive heart failure from fluid-build up over an extended period of time.

(51) The present disclosure provides systems, devices, and methods for guiding the administration of medication relating to the treatment of congestive heart failure at least in part by directly monitoring pressure in the left atrium, or other chamber or vessel for which pressure measurements are indicative of left atrial pressure, in order to reduce hospital readmissions, morbidity, and/or otherwise improve the health prospects of patients.

(52) Cardiac Pressure Monitoring

(53) Cardiac pressure monitoring in accordance with embodiments the present disclosure may provide a proactive intervention mechanism for preventing or treating congestive heart failure. Generally, increases in ventricular filling pressures associated with diastolic and/or systolic heart failure can occur prior to the occurrence of symptoms that lead to hospitalization. For example, cardiac pressure indicators may present weeks prior to hospitalization with respect to some patients. Therefore, pressure monitoring systems in accordance with embodiments the present disclosure may advantageously be implemented to reduce instances of hospitalization by guiding the appropriate or desired titration and/or administration of medications before the onset of heart failure.

(54) As referenced above, with respect to cardiac pressures, pressure elevation in the left atrium may be particularly correlated with heart failure. FIG. **2** illustrates example pressure waveforms associated with various chambers and vessels of the heart according to one or more embodiments. The various waveforms illustrated in FIG. **2** may represent waveforms obtained using right heart catheterization to advance one or more pressure sensors to the respective illustrated and labeled chambers or vessels of the heart. As illustrated in FIG. **2**, the waveform **225**, which represents left atrial pressure, may be considered to provide the best feedback for early detection of congestive heart failure. Furthermore, there may generally be a relatively strong correlation between increases and left atrial pressure and pulmonary congestion.

(55) Cardiac pressure monitoring, such as left atrial pressure monitoring, can provide a mechanism to guide administration of medication to treat and/or prevent congestive heart failure. Such treatments may advantageously reduce hospital readmissions and morbidity, as well as provide other benefits. An implanted pressure sensor in accordance with embodiments the present disclosure may be used to predict heart failure up two weeks or more before the manifestation of symptoms or markers of heart failure (e.g., dyspnea). When heart failure predictors are recognized using cardiac pressure sensor embodiments in accordance with the present disclosure, certain prophylactic measures may be implemented, including medication intervention, such as modification to a patient's medication regimen, which may help prevent or reduce the effects of cardiac dysfunction. Direct pressure measurement in the left atrium can advantageously provide an accurate indicator of pressure buildup that may lead to heart failure or other complications. For example, trends of atrial pressure elevation may be analyzed or used to determine or predict the onset of cardiac dysfunction, wherein drug or other therapy may be augmented to cause reduction in pressure and prevent or reduce further complications.

(56) The sensor-integrated implant devices of the present disclosure may be implemented in various locations of the human anatomy. For example, a variety of cardiac anatomy locations may be used for sensor-integrated implant device implantation for the purpose of hemodynamic pressure measurement within the cardiovascular system. The implant devices disclosed herein may include one or more sensors integrated with an implant structure that serves one or more additional purposes in addition to pressure monitoring, such as shunting, tissue closure/occluding, repairing, or otherwise treating certain heart anatomy and/or conditions. Implant devices in accordance with

the present disclosure may be implanted in any cardiac vessel or chamber, including the superior vena cava, inferior vena cava, right atrium, left atrium, right ventricle, left ventricle, pulmonary artery, pulmonary vein, coronary sinus, and/or the like.

(57) Sensor-Integrated Implant Devices

(58) Embodiments of the present disclosure may provide a mechanism for guiding administration of medication to a patient by monitoring left atrial pressure and/or other physiological conditions of the patient sensed by one or more sensor-integrated implant devices. With respect to congestive heart failure patients, such monitoring may help to reduce hospital readmissions and/or morbidity. In some implementations, a sensor-integrated implant device may be configured to detect physiological parameters or conditions indicative or predictive of heart failure or other condition(s) one or more weeks prior to manifestation of symptoms related therewith, such as dyspnea. Therefore, embodiments the present disclosure may advantageously facilitate modification of drug regimens or other treatments relatively early, potentially preventing more serious conditions or symptoms from developing. For example, early detection of pressure elevation in the left atrium may be used to determine trends in pressure elevation, wherein drug therapy may be augmented to drop left atrial pressure when detected or predicted to prevent further complications. With respect to heart failure related to fluid build-up in the lungs, such fluid build-up may typically gradually develop over one or more weeks, and therefore preliminary detection of increased pressure that may lead to such fluid build-up may allow for relatively early intervention and/or prevention.

(59) FIG. **3** shows a sensor implant device **310** implanted in an atrial septum **18** in accordance with one or more embodiments. The particular position in the interatrial septum wall may be selected or determined in order to provide a relatively secure anchor location for the implant **310**, as well as to provide a relatively low risk of thrombus. Furthermore, the sensor implant device **310** may be implanted at a position that is desirable in consideration of future re-crossing of the septal wall **18** for future interventions. Implantation of the sensor implant device **310** in the interatrial septum wall **18** may advantageously allow for communication between the left **2** and right **5** atria. With the device **310** in the atrial septum **18**, the sensor element(s) **311**, **312** of the sensor implant device **310** may advantageously be configured to measure pressure in the right atrium **5**, the left atrium **2**, or both atria. Although two sensor elements **311**, **312** are shown, in some embodiments, the sensor implant **310** comprise a single sensor element, or more than two sensor elements. With pressure sensor functionality for measuring pressure in both atria, the sensor implant device **310** may advantageously be configured to provide sensor signals that may be used to determine differential pressure between the atria. Differential pressure determination may be useful for monitoring fluid build-up in the lungs, which may be associated with congestive heart failure.

(60) With the sensor **310** implanted or disposed in the atrial septum **18**, as shown, pressure may be monitored in either or both the right atrium **5** and the left atrium **2**. For sensor embodiments comprising pressure sensor transducers disposed in both atria, the implant device **310** may provide the ability to measure differential pressure between the atria, which may be useful when monitoring fluid build-up in the lungs, which is associated with congestive heart failure as described above.

(61) Generally, the atrial septal wall **18** may provide a good anchoring location for a pressure sensor **310**. The sensor device **310** may advantageously be anchored in a secure location in the atrial wall **18**. Furthermore, it may be desirable for the sensor **310** to be configured and/or constructed such that it presents a relatively low risk of thrombus with respect to the portion of the sensor device **310** disposed in the left atrium **2**. In some embodiments, the present disclosure provides sensor-integrated implant devices that may be implanted in the interatrial septal wall **18**, such that the implant device provides a mechanism for access for re-crossing the septal wall **18** for future medical interventions.

(62) In some implementations, the present disclosure relates to pressure sensors associated or integrated with cardiac implant devices. Such sensor-integrated cardiac implant devices may be used to provide controlled and/or more effective therapies for treating and preventing heart failure.

FIG. **4** is a block diagram illustrating an implant device **400** comprising a cardiac implant structure **420**. In some embodiments, the cardiac implant structure **420** is physically integrated with and/or connected to a sensor device **410**. The sensor device **410** may be, for example, a pressure sensor, or other type of sensor. In some embodiments, the sensor **410** comprises a transducer **412**, such as a pressure transducer, as well as certain control circuitry **414**, which may be embodied in, for example, an application-specific integrated circuit (ASIC). The control circuitry **414** may be configured to process signals received from the transducer **412** and/or communicate signals associated therewith wirelessly through biological tissue using the antenna **418**. The antenna **418** may comprise one or more coils or loops of conductive material, such as copper wire or the like. In some embodiments, at least a portion of the transducer **412**, control circuitry **414**, and/or the antenna **418** are at least partially disposed or contained within a sensor housing **416**, which may comprise any type of material, and may advantageously be at least partially hermetically sealed. For example, the housing **416** may comprise glass or other rigid material in some embodiments, which may provide mechanical stability and/or protection for the components housed therein. In some embodiments, the housing **416** is at least partially flexible. For example, the housing may comprise polymer or other flexible structure/material, which may advantageously allow for folding, bending, or collapsing of the sensor **410** to allow for transportation thereof through a catheter or other introducing means.

(63) The transducer **412** may comprise any type of sensor means or mechanism. For example, the transducer **412** may be a force-collector-type pressure sensor. In some embodiments, the transducer **412** comprises a diaphragm, piston, bourdon tube, bellows, or other strain- or deflection-measuring component(s) to measure strain or deflection applied over an area/surface thereof. The transducer **412** may be associated with the housing **416**, such that at least a portion thereof is contained within or attached to the housing **316**. The term “associated with” is used herein according to its broad and ordinary meaning. With respect to sensor devices/components being “associated with” a stent or other implant structure, such terminology may refer to a sensor device or component being physically coupled, attached, or connected to, or integrated with, the implant structure.

(64) In some embodiments, the transducer **412** comprises or is a component of a piezoresistive strain gauge, which may be configured to use a bonded or formed strain gauge to detect strain due to applied pressure, wherein resistance increases as pressure deforms the component/material. The transducer **412** may incorporate any type of material, including but not limited to silicon (e.g., monocrystalline), polysilicon thin film, bonded metal foil, thick film, silicon-on-sapphire, sputtered thin film, and/or the like.

(65) In some embodiments, the transducer **412** comprises or is a component of a capacitive pressure sensor including a diaphragm and pressure cavity configured to form a variable capacitor to detect strain due to pressure applied to the diaphragm. The capacitance of the capacitive pressure sensor may generally decrease as pressure deforms the diaphragm. The diaphragm may comprise any material(s), including but not limited to metal, ceramic, silicon or other semiconductor, and the like. In some embodiments, the transducer **412** comprises or is a component of an electromagnetic pressure sensor, which may be configured to measure the displacement of a diaphragm by means of changes in inductance, linear variable displacement transducer (LVDT) functionality, Hall Effect, or eddy current sensing. In some embodiments, the transducer **412** comprises or is a component of a piezoelectric strain sensor. For example, such a sensor may determine strain (e.g., pressure) on a sensing mechanism based on the piezoelectric effect in certain materials, such as quartz. This technology is commonly employed for the measurement of highly dynamic pressures.

(66) In some embodiments, the transducer **412** comprises or is a component of a strain gauge. For example, a strain gauge embodiment may comprise a pressure sensitive element on or associated with an exposed surface of the transducer **412**. In some embodiments, a metal strain gauge is adhered to the sensor surface, or a thin-film gauge may be applied on the sensor by sputtering or other technique. The measuring element or mechanism may comprise a diaphragm or metal foil.

The transducer **412** may comprise any other type of sensor or pressure sensor, such as optical, potentiometric, resonant, thermal, ionization, or other types of strain or pressure sensors.
(67) In certain embodiments, the sensor **410** is configured to communicate with an external (e.g., non-implantable) device or system that includes an external reader (e.g., coil), which may include a wireless transceiver that is electrically and/or communicatively coupled to certain control circuitry. In certain embodiments, both the sensor **410** and the external subsystem include a corresponding coil antenna for wireless communication and/or power delivery through patient tissue disposed therebetween when the sensor **410** is implanted in a patient.
(68) The external reader/monitor (not shown) can receive the wireless signal transmissions and/or provide wireless power using an external antenna, such as a wand device or other handheld reader or device. The external transceiver can include radio-frequency (RF) front-end circuitry configured to receive and amplify the signals from the sensor **410**, wherein such circuitry can include one or more filters (e.g., band-pass filters), amplifiers (e.g., low-noise amplifiers), analog-to-digital converters (ADC) and/or digital control interface circuitry, phase-locked loop (PLL) circuitry, signal mixers, or the like. The external transceiver can further be configured to transmit signals over a network to a remote monitor subsystem or device. The RF circuitry of the external transceiver can further include one or more of digital-to-analog converter (DAC) circuitry, power amplifiers, low-pass filters, antenna switch modules, antennas or the like for treatment/processing of transmitted signals over a network and/or for receiving signals from the sensor **410**. In certain embodiments, the external monitor includes control circuitry for performing processing of the signals received from the sensor **410**. In certain embodiments, the external monitor is a smartphone, laptop computer, or other mobile computing device, or any other type of computing device.
(69) In certain embodiments, the sensor **410** includes some amount of volatile and/or non-volatile data storage. For example, such data storage can comprise solid-state memory utilizing an array of floating-gate transistors, or the like. The control circuitry **414** may utilize data storage for storing sensed data collected over a period of time, wherein the stored data can be transmitted periodically to an external monitor or other external subsystem. In certain embodiments, the sensor **410** does not include any data storage. The control circuitry **414** is configured to facilitate wireless transmission of data generated by the sensor transducer(s) **412**, or other data associated therewith. The control circuitry **414** may further be configured to receive input from one or more external subsystems, such as from an external reader (e.g., wand device), or from a remote monitor over, for example, a communications network (e.g., the Internet). For example, the sensor **410** may be configured to receive signals that at least partially control the operation of the sensor **410**, such as by activating/deactivating one or more components or sensors, or otherwise affecting operation or performance of the sensor **410**.
(70) The one or more components of the sensor **410** can be powered by one or more power sources (not shown). Due to size, cost and/or electrical complexity concerns, it may be desirable for such power source(s) to be relatively minimalistic in nature. For example, high-power driving voltages and/or currents in the sensor **410** may adversely affect or interfere with operation of the heart or other body part associated with the implant device **400**. In certain embodiments, the sensor **410** is configured to receive power from an external source wirelessly by passive circuitry of the sensor **410**, such as through the use of short-range, or near-field wireless power transmission, or other electromagnetic coupling mechanism. For example, an external device may be used as an initiator that actively generates an RF field that can provide power to the sensor **410**, thereby allowing the power circuitry of the implant device **400** to take a relatively simple form factor. In certain embodiments, the implant device **400** is configured to harvest energy from environmental sources, such as fluid flow, motion, or the like. Additionally or alternatively, the implant device **400** can comprise a battery, which can advantageously be configured to provide enough power as needed over the monitoring period (e.g., 1, 2, 3, 5, 10, 20, 30, 60, or 90 days, or other period of time).

(71) In some embodiments, the sensor **410** is configured to operate with a local reader/monitor that comprises a wearable communication device, or other device that can be readily disposed in proximity to the patient and sensor **410**. Such external reader/monitor device/system be configured to continuously, periodically, or sporadically interrogate the sensor **410** in order to extract or request sensor-based information therefrom. In certain embodiments, a user interface may be implemented that allows a user to utilize the interface to view sensor data, request sensor data, or otherwise interact with the sensor **410**.
(72) In certain embodiments, an external reader/monitor comprises a coil antenna that is matched and/or tuned to be inductively paired with the antenna **418** of the internal implant device **410**. In some embodiments, the sensor **410** is configured to receive wireless ultrasound power charging and/or data communication between from an external monitor system.
(73) FIG. **5** illustrates a perspective view of a sensor implant device **500** in accordance with one or more embodiments. The sensor implant device **500** comprises a sensor **510**, which may have a generally-cylindrical form with respect to one or more portions thereof. However, it should be understood that although certain embodiments are disclosed herein in the context of cylindrical sensor devices, the principles of the present disclosure relate to sensor implant devices comprising sensors having any suitable or desirable shape, form, or configuration.
(74) The sensor device **510** may comprise one or more sensors **511**, **512**, such as pressure transducers, which may be associated with one or more distal or proximal end portions of the sensor **510**. For example, the sensor **510** may comprise a first sensor element **512**, which may be considered a distal sensor element, as well as a second sensor element **511**, which may be considered a proximal sensor element in some embodiments. The sensor implant device **500** includes an anchor **520**, which may comprise one or more arms **521**, **522** for securing the sensor implant device **500** to a tissue wall, such as and atrial septal wall. The anchor **520** may comprise memory metal or other material and may be a fixed or attached in some manner to the sensor **510**. The anchor arms **521**, **522** of the anchor **520** may comprise one or more distal arms **521** and one or proximal arms **522**, which are described in further detail below. In some embodiments, the sensor **510** includes or is associated with one or more projection features **517**, which may comprise knobs, projections, extensions, teeth, grooves, posts, or the like, and may be used to secure the sensor **510** to one or more components of a delivery system (not shown) or to one or more features of the anchor **520**.
(75) The anchor **520** may allow for direct mounting or implantation of the sensor implant device **500** in a septal wall, or other tissue. FIG. **6** shows the sensor implant device **500** implanted in a tissue wall **18**, such as an interatrial septal wall. Although certain Figures and description herein are described in the context of the sensor implant device **500** implanted in an interatrial septal wall, it should be understood that the sensor implant device **500** may be implanted in any biological tissue or tissue wall in accordance with embodiments the present disclosure.
(76) In some embodiments, the sensor implant device **500** comprises a proximal sensor element **511** and a distal sensor element **512**, as shown. With the sensor implant device **500** implanted in the septal wall **18**, each of the proximal and distal sensor elements may be disposed in a respective atrium. For example, with respect to the orientation of the illustrated embodiment of FIG. **6**, the proximal sensor element **511** may be disposed in the right atrium, while the distal sensor element **512** may be disposed in the left atrium **2**.
(77) The anchor **520** may comprise any number of distal and/or proximal arms. The distal arms **521** may be curved such that end portions thereof point at least partially in a proximal direction in a deployed configuration. The proximal arms **522** may be at least partially straight and may be at least partially deflected away from a longitudinal axis of the sensor device and/or the sensor device itself and project at least partially in a distal direction. Furthermore, end portions of the proximal arms **522** may be at least partially curved, rounded, or otherwise configured to provide a blunt surface for contacting the tissue wall surface to reduce risk of tissue damage.

(78) The anchor **520** is illustrated as having three or more distal arms and three or more proximal arms. In some embodiments, the anchor **520** may comprise four or more proximal arms and four more distal arms in some embodiments. In some embodiments, the sensor implant device **500** has a size that is sufficiently small to not preclude future crossing of the septal wall for alternative interventions once implanted.
(79) In some embodiments, the sensor **510** comprises a rigid housing, which may be made of glass or other at least partially rigid material. The projection feature(s) **517** may be made of the same material as the housing **516** of the sensor **510**. For example, where the housing **516** comprises a cylindrical glass tube, the projection features **517** may be projections thereof that are a unitary form with the housing **516**. Alternatively, the projection feature(s) **517** may be attached or secured to the housing **516** in any suitable or desirable manner.
(80) Generally, where the sensor housing **516** comprises glass, the sensor **510** may have desirable biocompatibility and/or outgassing prevention characteristics. For example, with respect to certain materials as used for the sensor housing **516**, outgassing may occur at least in part through the housing **516**, such as from internally-disposed electronics of the sensor **510**, or the like. The housing **516** advantageously provides a sufficient hermetic barrier seal for the sensor **510** and/or internal circuitry or components thereof. In some embodiments, the anchor **520** comprises a memory metal frame, such as Nitinol or the like. The anchor **520** may be secured to the sensor **510** through a friction fit, or using any other suitable or desirable attachment mechanism, including biocompatible adhesive, welding, or other attachment mechanism.
(81) FIG. **7** is a flow diagram illustrating a process **700** for implanting a sensor implant device in accordance with one or more embodiments of the present disclosure. FIG. **8** illustrates states of components of a sensor implant device and/or an associated delivery system corresponding to the various steps of the process **700** of FIG. **7**. Although FIGS. **7** and **8** relate to implantation of a sensor implant device in a septal wall, it should be understood that initial puncture of the septal wall and/or dilation thereof (e.g., using a balloon or other mechanism) that may be used to create an aperture in the septal wall for insertion or implantation of a delivery catheter and/or sensor implant device is not shown or described in detail.
(82) In connection with the steps of the process **700**, access to the target implantation location may be achieved in any suitable or desirable way. For example, access to the right atrium may be made via the femoral vein in some implementations. At block **702**, the process **700** involves introducing a delivery catheter **730** into the left atrium through an aperture in the septal wall **18**. At block **704**, the process **700** involves advancing an internal pusher or ejector component (not shown) of the delivery catheter **730** to thereby deploy or eject a distal portion of a sensor implant device **700** out of a distal end of the delivery catheter **730**, as shown at state **802** of FIG. **8**. The sensor implant device **700** may comprise one or more distal anchor arms **721**, which may be similar to the distal arms **521** shown in FIGS. **5** and **6**. Further in connection with block **704**, the process **700** may involve ejecting the sensor device **700** from the delivery catheter **730** just enough to expose the distal arms **721**, but not enough to eject from the delivery catheter proximal arms associated with the sensor implant device.
(83) With the distal arms **721** ejected from the delivery catheter **730**, the process **700** involves, at block **706**, retracting the delivery system to set the distal arms **721** against the septal wall **18**, as shown at state **803** of FIG. **8**. For example, the distal end **731** of the delivery catheter **730** may be drawn back into the right atrium **5** to set the distal arms **721** against the left atrium side of the septal wall **18** in accordance with some implementations. Once the distal arms **721** have been set against the septal wall, the process **700** may involve, at block **708**, further retracting the delivery system **730** to deploy proximal arms **722** of the anchor **720** associated with the sensor implant device **700** against the right atrium side of the septal wall **18**. Retraction of the delivery catheter **730** to expose the proximal arms (e.g., Nitinol arms), which may thereafter engage the right side of the septal wall **18** with respect to the illustrated orientation of the septal wall. In some implementations, the distal

arms **721** and/or proximal arms **722** may be configured or formed to provide tension against the septal wall **18** when the sensor implant device is fully deployed as shown at state **804** of FIG. **8**. In some implementations, the distal arms **721** may have a curved form or shape, as shown herein, whereas the proximal arms **722** may comprise an at least partially straight form or shape.

(84) With the sensor implant device **700** implanted as shown at state **804** of FIG. **8**, the sensor element **712** may be deployed in the left atrium **2** and configured to provide pressure or other readings associated therewith. In some embodiments, an additional sensor element **711** associated with a proximal end or portion of the sensor **710** may be disposed in the right atrium **5** and may be used to provide pressure or other physiological parameter measurements associated with the right atrium **5**, which may be used for differential pressure measurements and/or other measurements.

(85) In some embodiments, sensor implant devices in accordance with the present disclosure may be configured, shaped, and/or designed to facilitate recapture or removal of the sensor implant device. FIG. **9** illustrates a system for removing a previously-implanted sensor implant device **900** in accordance with one or more embodiments. The system of FIG. **9** includes a delivery/extraction catheter **930**, which may be used to deliver and/or remove or extract the sensor implant device **900**. The system further includes a pusher or extraction device **935**, which may be movable within the delivery catheter **930** in some embodiments.

(86) As described in detail herein, a sensor device **910** may include one or more projections **917** or other engagement features to facilitate engagement of the sensor device **910** for implantation and/or extraction. In some embodiments, the pusher/extraction device **935** comprises a projection engagement feature **937**. For example, the pusher/extraction device **935** may have an at least partially hollow cylindrical form configured and dimensioned to fit at least partially around the sensor **910**, wherein a gap **939** of the engagement feature **937** of the pusher/extraction device **935** allows for the pusher/extraction device **935** to be passed longitudinally past the projection feature **917**, wherein rotation of the pusher/extraction device **35** allows for the engagement feature (e.g., extension member) **937** to circumferentially overlap the projection feature **917**. With the pusher/extraction device **935** rotated as shown in FIG. **9**, retraction of the pusher/extraction device **935** may cause the sensor implant device **900**, or the sensor **910** component thereof, to be drawn toward the direction of the right atrium. Therefore, the pusher/extraction device **935** may provide a bayonet-style engagement mechanism that may be selectively engaged with, and released from, the projection feature **917**. Although a single projection feature **917** is shown in FIG. **9**, it should be understood that the sensor implant device **900** may have any number of projection features, and further the pusher/extraction device **935** may have any number of respective projection engagement features.

(87) In some embodiments, the shape or form of the distal arms **921** of the anchor **920** may allow for the arms to be pulled into a more straightened configuration/form to allow for the anchor **920** to be pulled or drawn through the aperture in the septal wall **18**. Therefore, by further retracting the delivery catheter **930** and/or extraction device **935** in the illustrated direction, the sensor implant device **900** may be removed from its implanted location in the septal wall **18**. The shape of the distal **921** and proximal **922** arms of the anchor **920** may facilitate the recapture of the anchor **920**. Recapture/removal of the sensor implant device **900** may be performed interprocedurally, or at a later time, should the need or desire arise.

(88) Although the pusher/extraction device **935** is described in respect to removal of the sensor implant device **900** and/or sensor component **916**, the pusher/extraction device **935** may be utilized to implant the sensor implant device **900** and/or sensor component **916** in some embodiments. For example, the pusher **935** may be used to manipulate the implant device **900** as it is deployed. When used for deployment, the pusher device **935** may push the sensor projection feature **917** to engage the sensor implant device **900** and the septal wall as shown, after which the pusher device **935** may be rotated to disengage the engagement feature **937** from the projection feature **917** to allow for withdrawal of the pusher device **935** away from the sensor implant device **900**.

(89) FIGS. **5-9** illustrates a sensor implant device having an anchor with a particular configuration comprising distal and proximal arms, as described above. FIG. **10** illustrates a sensor implant device **1000** having an anchor **1020** having a different form and/or configuration than that described above. In particular, the anchor **1020** of the sensor implant device **1000** shown in FIG. **10** may allow for implantation of a sensor **1010** in a chamber or vessel associated with a heart or other anatomy, such as within the left atrium of the heart, wherein the entirety of the sensor device **1010** is disposed in a single vessel or chamber, whereas arms **1027** of the anchor **1020** are primarily maintained in a chamber or vessel opposite the tissue wall separating the sensor **1010** from the anchor arms **1027**.
(90) FIG. **11** shows the sensor implant device **1000** implanted in a septal wall **18**. In some embodiments, a cylindrical or other-shaped sensor **1010** is used as an anchoring member when implanting the sensor implant device **1000** in the desired tissue wall. As implanted, the anchor arms **1027** may serve to hold the sensor **1010** against a first side **119** of the septal wall **18** at least in part by applying pressure or force on an opposite side **117** of the septal wall **18**. As implanted, therefore, the sensor **1010** may be held relatively close to the septal wall **18**. With the sensor disposed and secured in the chamber **2** (e.g., left atrium), sensor elements thereof may be used to detect pressure or another physiological parameter in the chamber **2**. Although FIG. **11** shows the sensor **1010** disposed in the left atrium **2**, in some embodiments, the sensor may be disposed in the right atrium **5**, or other vessel or chamber, whereas the anchor arms **1027** may be primarily disposed within the left atrium **2**. In some embodiments, the implant device **1000** comprises an occluding membrane or cloth (e.g., polymer fiber cloth) attached to the frame of the anchor **1020** and covering at least a portion of the opening **115** in the septal wall **18**.
(91) With further reference to FIG. **10**, the anchor **1020** may comprise memory metal, such as Nitinol or the like, and/or other at least partially rigid material. In some embodiments, one or more arms or features of the anchor **1020** comprise tissue or suture attachment features **1025**, such as one or more eyelets, or the like. For example, once implanted, the eyelet(s) **1025** of the anchor frame **1020** may be stitched to the tissue wall to thereby secure the sensor implant device **1000** in the implanted position. Where the anchor **1020** comprises multiple eyelets or other attachment features, sutures may be run through each respective feature to provide desirable attachment. Alternatively, eyelets or other suture engagement features may be used for retrieval, movement, and/or retraction of the anchor frame **1020**. For example, prior to deployment thereof, with the anchor frame **1020** disposed within a delivery catheter in a collapsed state, sutures may be engaged with each of the eyelet features **1025** shown, wherein at least one eyelet or another suture engagement feature is associated with each respective anchor arm **1027**. If during placement of the sensor implant device **1000**, the position of the anchor frame and/or sensor **1010** is inadequate in some way, the sutures attached to the eyelet(s) or other suture-engagement feature(s) **1025** may be pulled through the delivery catheter to thereby bring the arms **1027** into an at least partially collapsed state, which may allow for repositioning of the sensor device **1000** and/or withdrawal of the sensor implant device **1000** and/or anchor **1020** back into the delivery catheter.
(92) The illustrated half-circle shape of the anchor arms **1027** may help secure the anchor arms **1027** with the tissue at the target location. For example, corner features **1029** of the anchor **1020** may provide desirable engagement with and/or embedding in the target tissue. Furthermore, the illustrated shape of the anchor arms **1027** may serve to allow for easy retraction and/or withdrawal of the anchor back into the delivery catheter.
(93) In the implanted configuration of FIG. **11**, tissue ingrowth may develop on one or both sides of the septal wall **18** on either or both the anchor frame arms **1027** and the sensor **1010**. In some embodiments, a coating or material may be added or used in connection with the sensor **1010** that serves to inhibit tissue ingrowth thereon. Such material or coating may advantageously be such as to not substantially affect the dynamics of the sensor element(s).
(94) FIG. **12** is a flow diagram illustrating a process **1200** for implanting a sensor implant device

similar in certain respects to the sensor implant device **1000** illustrated FIGS. **10** and **11** in accordance with one or more embodiments of the present disclosure. FIG. **13** illustrates the implant sensor device **600** and associated delivery system, as well as target implantation site anatomy, at various states of the process **1200**.

(95) At block **1202**, the process **1200** involves advancing/introducing a delivery catheter **630** into the left atrium **2**. For example, access to the left atrium **2** may be achieved through the inferior vena cava **29**, right atrium **5**, and through the septal wall **18** separating the right atrium **5** from the left atrium **2**. Access to the inferior vena cava **29** may be achieved through the femoral vein or other access port.

(96) With the distal end of the delivery catheter **630** disposed in the left atrium **2**, the process **1200** involves, at block **1204**, ejecting a sensor **610** of a sensor implant device **600** out of the delivery catheter **630**. The process **1200** may advantageously first involve ejecting only the sensor element **610**, while at least a portion of the associated anchor form **620** remains within the delivery catheter **630**, as shown in states **602** and **603** of FIG. **13**. In some embodiments, a pusher device **635** may be used to eject the sensor **610** from the delivery catheter **630**.

(97) At block **1206**, the process **1200** involves causing the sensor device **610**, which may be initially ejected from the delivery catheter in a longitudinally-aligned orientation with respect to the delivery catheter **630**, to turn or pivot to assume an orientation that is substantially perpendicular to a longitudinal axis of the distal end of the delivery catheter **630**, as shown in state **603** of FIG. **13**. Although a perpendicular orientation as shown and described for the sensor **610**, it should be understood that the step of causing the sensor **610** to turn or pivot may not bring the sensor into a perpendicular orientation but may merely cause the sensor **610** to assume an orientation that is more perpendicular than the coaxial orientation with the distal end of the delivery catheter. In some embodiments, the anchor frame **620** comprises memory metal (e.g., Nitinol), which may be pre-shaped to cause the sensor **610** to pivot/turn as shown. That is, the anchor frame **620** may be attached to a portion of the sensor **610**, wherein after ejection from the delivery catheter **630**, the shape memory characteristics of the frame cause the sensor **610** to pivot or turn as shown.

(98) At block **1208**, the process **1200** involves retracting the delivery catheter to position the sensor (e.g., pressure sensor) against the septal wall **18**. The sensor **610** may thereby serve to anchor itself in the desired position against septal wall on one side thereof.

(99) At block **1210**, the process **1200** involves further retracting the delivery catheter **630** to deploy the anchor arms **627** of the anchor frame **620** on the opposite side of the septal wall **18** with respect to the pressure sensor **610**. When the arms **627** have been deployed from the delivery catheter **630**, they may swing outward, as shown, to contact the septal wall **18** and provide tension force to secure the implant device **600** in the desired position. For example, the frame **620** may be pre-shaped such that the arms **627** flare outward when deployed from the delivery catheter **630**. In some embodiments, the anchor arms **627** have suture engagement features, such as eyelets or the like, for coupling suture(s) **640** thereto. Such suture(s) may advantageously allow for the frame arms **627** to be drawn back into a relatively straightened form for reentry into the delivery catheter **630** in the event that is desired to remove, retract, or reposition the sensor device **600**. When the desired implantation position is achieved, the suture(s) may be withdrawn through the suture engagement features of the anchor arms **627** to thereby release the anchor **620** from the delivery system. Although separate sutures are shown for each of the anchor arms in FIG. **13**, in some embodiments a single suture is coupled to both anchor arms.

(100) A sensor anchor in accordance with embodiments of the present disclosure may comprise a plurality of coil stacks at proximal and distal ends, with a smaller-diameter coil in between configured to engage protrusions or projections on a cylindrical sensor to secure the sensor to coil. FIG. **14** illustrates an embodiment of a sensor anchor **220** in accordance with one or more embodiments of the present disclosure. The anchor **220** comprises a wire form having a plurality of helical portions having different diameters. For example, in some embodiments, the anchor **220**

comprises two large-diameter helical portions, including a proximal large-diameter portion **222** and a distal large-diameter portion **224**, one or more of which may have a diameter d.sub.1, as shown. The anchor **220** may further comprise an intermediate smaller-diameter helical portion **223** having a diameter d.sub.2 that is less than the diameter d.sub.1. The anchor wire form **220** may advantageously comprise a single unitary wire formed into the illustrated complex helical coil. Alternatively, the wire form **220** may comprise a plurality of separate wire components that are coupled or integrated to form the anchor **220**.

(101) FIG. **15** shows the anchor **220** implanted in a septal wall **18**, wherein the anchor **220** is engaged with a sensor device **210**, such that the anchor **220** secures and anchors the sensor device **210** in the implanted position shown. For example, in some embodiments, the anchor **220** may be configured and/or dimensioned such that a cylindrical sensor device **210** may be held and secured within the smaller-diameter intermediate portion **223** of the anchor **220**, whereas the distal and proximal larger-diameter portions **222**, **224** may hold the implant device **200** against the septal wall **18**. For example, the smaller-diameter coil portion **223** may advantageously be dimensioned to fit within an aperture/opening in the septal wall **18**, whereas the larger-diameter portions **222**, **224** may have a diameter larger than the septal wall opening when in an expanded form.

(102) The anchor **220** may be delivered to the target implantation site in a delivery catheter in a compressed configuration. For example, the wire form **220** may be delivered in a substantially straightened configuration, or in a relatively-tightly wound configuration, wherein after deployment from the delivery catheter, the wire form anchor **220** is configured to assume the shape and configuration shown in FIGS. **14** and **15**. In some embodiments, the anchor **220** is delivered in the delivery catheter in a configuration as wound around or attached to the sensor **210**. Alternatively, the anchor may be delivered separately from the sensor. For example, the wire form anchor **220** may be implanted in the septal wall **18** as shown, after which the cylindrical sensor **210** may be pushed through the center of the one or more coils of the intermediate smaller-diameter helical portion **223** to achieve an interference fit with the smaller-diameter coil portion, such that the smaller-diameter coils are wrapped relatively tightly around the cylindrical sensor body (e.g., glass cylinder body).

(103) In some embodiments, the sensor **210** comprises one or more engagement features for engaging with and/or being secured to the smaller-diameter portion **223** of the anchor **220**. For example, as shown in FIG. **16**, the sensor **210** may comprise one or more projection features **217**, as described above. Such projection features **217** may be integrated with the body of the sensor **210** or may be attached thereto using adhesive or other attachment mechanism. The projection(s) **217** may be dimensioned and/or positions such that when the projections are intertwined or pass between the coils of the smaller-diameter coil portion **223**, contact between the projections and the wire coils serves to hold or maintain the sensor in a relative position with the anchor **220**. In some embodiments, the projection(s) **217** are configured such that the sensor **210** may be engaged with the anchor **220** by rotating or winding the sensor through the intermediate portion **223**. Therefore, removal of the sensor **210** may be achieved through unwinding the sensor **210** to disengage the projection features **217** from the smaller-diameter intermediate coils **223**. Such removal may allow for access to the left atrium through the opening between the smaller-diameter coils **223**. Furthermore, removal of the sensor **210** may be desirable if the sensor malfunctions or otherwise needs to be replaced or removed. In some embodiments, the wire form anchor **220** comprises memory metal wire preformed into the desired coil shape, as illustrated.

(104) Although various embodiments are illustrated in described herein in connection with sensor implant devices implanted in an interatrial septal wall, it should be understood that embodiments of the present disclosure are applicable to other implantation sites, including implantation of sensor implant devices in a ventricular septal wall. FIG. **17** illustrates an embodiment of a sensor implant device in accordance with aspects of the present disclosure. FIG. **17** shows a pressure sensor device **1710**, or other type of sensor device, in a ventricular septal wall **17**. The sensor implant device

1700 includes a sensor **1710** and one or more anchor features (not shown) configured to secure the sensor **1710** in the desired position in the septal wall **17**.

(105) The sensor implant device **1700** may be configured to provide sensor readings for monitoring pressure in the right ventricle **4** and/or left ventricle three. For example, the sensor **1710** may comprise one or more sensor elements **1711**, **1712**, each of which may be disposed in a respective ventricle of the heart **1** when implanted as shown in FIG. **17**. In some embodiments, the sensor **1710** comprises only a single sensor element, and is configured to provide pressure sensor readings for only one ventricle. Ventricular pressure monitoring may be useful for diagnosing and/or treating certain heart failure patients. As is true of other embodiments disclosed herein of sensor implant devices, the sensor implant device **1700** may advantageously comprise wireless transmission functionality for receiving and/or transmitting wireless data and/or power, as described in detail herein.

(106) Sensor-Integrated Tissue Closure Devices

(107) In certain embodiments, a sensor implant device in accordance with the present disclosure may comprise a sensor integrated with a septal closure device, or other tissue closure device. Although certain embodiments are disclosed below in the context of septal closure devices, it should be understood that such disclosure is applicable to sensor-integrated implant devices comprising one or more sensors integrated with other types of tissue closure devices. FIG. **18** shows a front view of a sensor-integrated septal-closure device in accordance with one or more embodiments of the present disclosure. FIG. **19** shows a perspective view of the sensor-integrated septal-closure device of FIG. **18** implanted in a tissue wall **18**. As shown in FIG. **18**, a sensor-integrated septal closure device **100** can include a frame **112** configured to support a blood-occluding membrane **138**. With respect to FIG. **19**, the septal closure device **100** may be implanted in the septal wall **18** to close off shunts across the septal wall, which may be congenital or created during an interventional procedure. In some embodiments, a septal occluder frame and occluding membrane **138** may be implanted in the septal wall **18** first, after which a sensor device **110** may be attached to the septal closure device, such as by puncturing the occluding membrane **138** and passing the sensor device **110** therethrough.

(108) The frame **112** in the illustrated configuration can comprise a generally planar body comprising a central portion **114** and a plurality of anchoring arms **116** extending radially outward from the central portion **114**. For example, at least four arms can extend from the central portion **114**, as shown in the illustrated embodiment, although the frame can have greater than four arms **116** or less than three arms **116** in other embodiments. Although arms **116** are shown and described, it should be understood that the septal closure device **100** and/or frame may include any type of tissue anchor feature(s).

(109) The four arms **116** may include a first set of opposing arms **118** and a second set of opposing arms **120**, extending from the central portion **114**. The closure device desirably (although not necessarily) has the same number of arms in the first and second sets so that the clamping force exerted by the arms is evenly distributed against the septum when the device is implanted. In the illustrated embodiment, for example, the first set of arms **118** includes exactly two arms extending from opposing sides of the central occluding membrane **138**, and the second set of arms **120** includes exactly two arms extending from opposing sides of the central occluding portion **138**. In other embodiments, the first or second set of arms can include just one arm or more than three arms.

(110) In a deployed or expanded configuration, the arms **116** can extend radially outwardly from the central occluding portion **138**. The arms **116** can extend perpendicularly or substantially perpendicularly to a central axis of the device **100** (the central axis extending through the center of a sensor device **110** integrated with the septal closure device and perpendicular to the plane of the page) such that an atrial septum **18** can be compressed or pinched between the first set of arms **118** and the second set of arms **120** when the device **100** is implanted in a septal wall **18**. In other

words, when the device **110** is implanted, the first set of arms **118** can be on one side of the septal wall **18**, the second set of arms **120** can be on the other side of the atrial septum, and the central portion **138** can be disposed within an opening or defect of the septum.

(111) The frame **112** in the illustrated embodiment has a relatively thin and flat profile to avoid or minimize thrombus. Thus, to such ends, the arms **116** can be attached to a central portion of the frame **114** that is associated with an outer circumference of the central occluding membrane **138** at angularly-spaced apart locations, with the attachment locations intersecting a common plane perpendicular to the central axis; in other words, all of the arms **116** in the illustrated embodiment can be attached to the central frame portion **114** along a circumferential path defined by the central frame portion **114**.

(112) In certain embodiments, the arms **116** and the central frame portion **114** can be coplanar with each other when the device **100** is in its fully-expanded, non-deflected shape; that is, the arms **116** do not have any portions that extend axially away from the central frame portion **114**. It should be understood that once implanted, the first set of arms **118** and the second set of arms **120** may be bent slightly axially away from each other by virtue of the thickness of the septum **18** and may no longer be coplanar. Nonetheless, the device **110** in certain embodiments can be said to have a flat profile with arms that are coplanar with each other and the central frame portion **114** when the device is in a non-deflected state. In other embodiments, however, the arms or portions thereof can be heat-set or otherwise shaped to extend axially away from each other or the central frame portion **114** in a non-deflected state.

(113) The frame **112** can be radially compressed or constricted to a delivery configuration for delivery to the heart in a delivery catheter/system. For example, in the delivery configuration, the frame **112** can be placed and retained in a generally compressed configuration in which the first set of arms **118** are folded towards each other along the central axis of the device **100** and the second set of arms **120** are folded towards each other along the central axis of the device **100**, such that the first and second sets of arms **118**, **120**, respectively, extend axially **120** and parallel to each other. When placed in the delivery configuration, the frame **112** can also be radially compressed relative to the deployed configuration.

(114) The frame **112** can include an eyelet **130** disposed at a distal end of one or more arms for coupling the closure device **100** to the delivery system via one or more attachment sutures, as further described below. An eyelet can project towards the central portion **114**, as shown in **18** and **19**, or it can project away from the central portion **114**.

(115) The frame **112** can be self-expandable and can be formed from a shape-memory material, such as Nitinol, so that the frame **112** self-expands from the delivery configuration to the deployed configuration when released or deployed from a delivery apparatus. In alternative embodiments, the frame **112** can be formed from a plastically-expandable material, such as stainless steel or cobalt-chromium alloy, and can be configured to be plastically expanded from the delivery configuration to the deployed configuration by an expansion device, such as an inflatable balloon. The frame **112** can be laser cut or otherwise formed from a flat sheet of metal, such as Nitinol. Alternatively, the frame **112** can be formed by bending one or more metal wires into the form shown.

(116) The occluding membrane **138** can be configured to block the flow of blood between the right and left atria. For an adult, the normal range of right atrial pressure is about 2-6 mmHg and the normal range of left atrial pressure is about 4-12 mmHg. Thus, throughout most of the cardiac cycle, the left atrial pressure is greater than the right atrial pressure. In some embodiments, the occluding membrane **138** can be configured to block at least the flow of blood from left atrium to the right atrium. In other embodiments, the occluding membrane **138** can be configured to block the flow of blood between the right and left atria in both directions throughout the cardiac cycle.

(117) In particular embodiments, the occluding membrane **138** can comprise one or more sheets or pieces of material that at least partially block or impede the flow of blood through the frame **112**.

For example, the occluding membrane **138** can comprise one or more pieces of bioresorbable material, film or cloth that are configured to encourage tissue ingrowth and can degrade over time, leaving just regrown tissue within the central frame portion **114**. For example, the occluding membrane **138** can comprise one or more pieces of bioresorbable electro-spun polymeric material, such as polylactide (PLA), polylactide glycolides (PLGA), polycaprolactone (PLC), polyacrylonitrile (PAN), poly(lactide-co-caprolactone) (PLCL), polyglyconate, and polypeptides. Compared to woven fabrics, electro-spun polymers promote faster tissue ingrowth, have faster biodegradation times, are potentially less thrombogenic, and can be created weaker and therefore can be easily punctured with a medical instrument during subsequent re-crossing of the closure device.

(118) In some embodiments, the occluding membrane **138** can comprise one or more sheets of pieces of non-bioresorbable material, such as any of various synthetic fabrics (e.g., polyethylene terephthalate (PET)) or natural tissue (e.g., pericardium). In some embodiments, the occluding membrane **138** can be completely or substantially impermeable to blood. In other embodiments, the occluding membrane **138** can be semi-porous to blood flow (e.g., a porous fabric). The porous material can be selected to remain porous or to close-up and become impermeable or non-porous to blood over time. In a specific implementation, the occluding membrane can be made of a bio-spun polyurethane having a fiber size between approximately 0.05-1.5 microns and a porosity of between approximately 50-80%. The thickness of the occluding membrane **138** can be between approximately 100-200 microns. In another implementation, the occluding membrane can be made of a bio-spun polymer blend comprising polyurethane and PET, such as a 70/30% blend of polyurethane/PET, having similar fiber sizes and porosity. In some embodiments, the occluding membrane **38** can be made of a biocompatible foam, such as polyurethane, PET, silicone, or polyethylene foam.

(119) The occluding membrane **138** can be configured to create a substantially fluid-tight seal with the adjacent tissue of the septum. In some embodiments, the occluding membrane **138** is configured, at least initially, to permit a small amount of blood flow between the atria to provide residual shunting. Over time, the occluding membrane **138** can promote tissue ingrowth and substantially completely close the opening in the septum and prevent residual shunting between the atria. The occluding membrane **138** can completely cover the central frame portion **114**, as shown in FIGS. **18** and **19**, or the occluding membrane **138** can cover a portion of the opening in the central frame portion **114**. The occluding membrane **38** can be configured such that opening in the septum **18** can be accessed for reentry through the defect either before or after degradation of the occluding membrane **138**.

(120) The occluding membrane **138** can be attached to the frame **112** via heat staking, sutures, molding, bonding, weaving and/or other means known to those skilled in the art with the benefit of the present disclosure. For example, the outer edges of the occluding membrane **138** can be folded over the central frame portion **114** and then welded to a more central area of the occluding membrane **138** to fix the occluding membrane **138** to the frame **112**. The occluding membrane **138** may extend beyond the periphery of the central frame portion **114**, for example up to 2 mm. In some embodiments, the occluding membrane **138** may have a generally circular shape prior to attachment to the frame **112**.

(121) The occluding membrane **138** may advantageously comprise relatively thin cloth, which may be penetrated to gain access to the left atrium should the need arise in connection with future interventions. Furthermore, the frame **112** may advantageously be configured to stretch open to accommodate relatively large-diameter catheters, such that access to the left atrium through the frame **112**, and particularly through the center frame portion **114**, may be made.

(122) As referenced above, the implant device **100** of FIGS. **18** and **19** includes a sensor device **110** attached to or otherwise integrated with the occluding membrane **138**. The sensor device **110** may be a pressure sensor including one or more sensor elements, as described herein. For example, the

sensor device **110** may have a generally cylindrical shape, and may penetrate through the occluding membrane **138**, such that distal and proximal end portions of the sensor **110** are exposed on opposite sides of the septal closure device **100**.

(123) Removal of the sensor device **110** after implantation may allow for access through the occluding membrane **138** to access the left atrium. For example, the frame **112** of the septal closure device **100** may comprise memory metal or other material that is relatively easily deformed to allow passage of interventional devices. In some implementations, interventional devices may be passed through the occluding membrane **138** with the sensor device **110** remaining disposed therein or integrated therewith. In some implementations, the sensor-integrated implant device **100** may be delivered with the sensor **110** already integrated with the septal closure device.

(124) FIG. **20** illustrates a sensor implant device **2000** comprising a sensor **2010** integrated with a septal closure device. The septal closure device comprises an occluding cloth or membrane **2038** connected to a frame **2012** comprising a plurality of arms, as described in detail herein. In order to maintain the intended function of the sensor-integrated implant device **2000**, embodiments disclosed herein utilize a means for affixing the sensor **2010** to the septal closure implant. In some embodiments, the occluding membrane **1038** may comprise a cloth (e.g. bio-spun polymer cloth) membrane that is formed into one or more sleeves/cuffs **2039** that are shaped to hold the sensor device **2010**. For example, with respect to a cylindrical sensor device **2010**, the sleeve/cuff **2039** may be at least partially cylindrical and may serve to affix the cylindrical sensor **2010** to the frame **2012**. The sleeve/cuff **2039** of the occluding membrane/cloth **2038** may be secured to the sensor device **2010** using a suture collar **2037**, which may be wrapped around the sleeve/cuff **2039** and sensor device **2010** to secure the sleeve/cuff **2039** to the sensor device **2010**

(125) As described above, the occluding membrane **2038** may comprise bio-spun polymer, which may be made in any suitable or desirable geometry, such as a fabric or scaffold geometry. In some embodiments, the occluding membrane **2038** is configured to gradually become integrated with biological tissue through tissue ingrowth over time. Such membrane may advantageously be of such a nature that forces required to penetrate the membrane are less than an amount of force required to dislodge the frame **2012** from the implantation position/site. In some embodiments, as described in detail herein, the sensor device **2010** comprises one or more projection features **2017**, which may be integrated forms with the body of the sensor **2010**, or may be attached or adhered using biocompatible adhesive, or other attachment means.

(126) In order to maintain the ability to gain access to the left atrium after implantation of a sensor-integrated septal closure device as described herein, a sensor implant device removal catheter may be utilized. FIG. **21** illustrates a process **2100** for removing a sensor implant device in accordance with embodiments of the present disclosure. FIG. **22** illustrates a sensor implant device and associated removal system, as well as cardiac anatomy at various states corresponding to the process steps of FIG. **21**. At block **2102**, the process **2100** involves introducing a removal catheter **2103** a right ventricle and advancing the removal catheter to the interatrial septal wall **18** in which a sensor implant device **2200** is implanted. The removal catheter **2230** may be used to safely remove the cylindrical sensor **2210** from the septal closure device with which it is integrated, or to remove the entire sensor-integrated septal closure device **2200**. The sensor **2210** may advantageously comprise one or more protrusions or other engagement features **2217**, which may be used to remove the sensor **2210**. The protrusion feature(s) **2217** may radially-project from the outer surface of the sensor body **2210**. Although protrusion features are described herein, it should be understood that other means of holding or grasping onto the sensor **2210** may be implemented in accordance with embodiments of the present disclosure.

(127) At block **2104**, the process **2100** involves advancing an extraction device **2235** within the retrieval catheter **2230**. In some embodiments, the pusher/extraction device **2235** comprises a projection engagement feature **2237**. For example, at block **2106**, the process **2100** involves engaging the engagement feature **2237** with the projection feature **2217** of the sensor **2210**, as

shown in state **2203** of FIG. **22**. The pusher/extraction device **2235** may have an at least partially hollow cylindrical tube form configured and dimensioned to fit at least partially around the sensor **2210**, wherein a gap **2239** of the engagement feature **2237** of the pusher/extraction device **2235** allows for the pusher/extraction device **2235** to be passed over the projection feature **2217** in a longitudinal direction, wherein rotation of the pusher/extraction device **2235** allows for the extension/engagement feature **2237** to circumferentially overlap the projection feature **2217** to provide engagement therewith.

(128) At block **2108**, the process **2100** involves withdrawing the retrieval catheter **2230** to thereby remove the sensor **2210** from the septal closure implant **2211**. For example, with the pusher/extraction device **2235** rotated as shown in state **2203** of FIG. **22**, retraction of the pusher/extraction device **2235** may cause the sensor **2010** and/or septal closure implant device **2200** to be drawn toward the direction of the right atrium. Therefore, the pusher/extraction device **2235** may provide a bayonet-style engagement mechanism that may be selectively engaged with or released from the projection feature **2217**. Although a single projection feature **2217** is shown in FIG. **22**, it should be understood that the sensor implant device **2200** may have any number of projection features, and further the pusher/extraction device **2235** may have any number of respective projection engagement features. In some embodiments, when the pusher/extraction device **2235** is engaged with the projection feature **2217**, the distal end **2231** of the of the removal catheter **2230** may be held against the septal closure device **2200** to prevent dislodgment of the septal closure device **2200** during extraction of the sensor **2210**.

(129) State **2204** of FIG. **22** shows the septal closure implant device **2200** with the sensor device **2210** removed therefrom. However, it should be understood that in certain embodiments the entire sensor-integrated septal closure device **2200** may be removed in connection with the process **2100**. Once the sensor **2210** is removed from the septal closure device **2200**, the relatively weak occluding membrane **2238** (e.g. bio-spun polymer) may be relatively easily crossed using standard device catheters.

(130) Although the pusher/extraction device **2235** is described with respect to removal of the sensor implant device **2200**, the pusher/extraction device **2235** may be utilized to implant the sensor implant device **2200** in some embodiments. For example, the pusher **2235** may be used to manipulate the implant device **2200** as it is deployed. When used for deployment, the pusher device **2235** may push the sensor projection feature **2217** to engage the sensor implant device **2200** and the septal wall as shown, after which the pusher device **2235** may be rotated to disengage the engagement feature **2237** from the projection feature **2217** to allow for withdrawal of the pusher device **2235** away from the sensor implant device **2200**.

(131) Additional Sensor-Integrated Cardiac Implant Devices

(132) In certain embodiments, a sensor implant device may comprise a sensor integrated with a heart valve spacer device. As shown in FIG. **23**, a valve spacer device **2300**, **2301** may be implanted in a heart **1** to improve competency of the tricuspid valve **8** or the mitral valve **6**. Although the description below focuses on the sensor-integrated spacer implant device **2300**, which is implanted in the right ventricle **4** and positioned to fit within the tricuspid valve **8** to improve competency thereof, it should be understood that the description below is applicable to sensor-integrated spacer implant devices implanted in any valve and/or in the left ventricle as well. This spacer implant device **2300** may be designed to reduce valve regurgitation by occupying a regurgitant orifice area between the native valve leaflets and providing a surface for leaflet coaptation. The sensor-integrated spacer implant device **2300** consists of a spacer form **2320** and a tether **2325** that is anchored in the right ventricle **4**, such as at or near the ventricular apex **26**. The spacer form **2320** may comprise an at least partially filled polymer (e.g., foam-filled) balloon that is configured to passively expand via one or more openings in the spacer chamber. The openings into the spacer form **2320** may be positioned at opposite longitudinal ends of the spacer form in some embodiments. The openings in the spacer form **2320** may allow for the spacer form **2320** to be

compressed for catheter-based deliverability. In some embodiments, the spacer implant **2300** includes one or more radiopaque markers to help in positioning the spacer using fluoroscopy. The spacer form **2320** may have any suitable or desirable size, such as approximately 12 mm or 15 mm in diameter, with a length of approximately 42 mm, or any other dimensional values.

(133) In some embodiments, the implant device **2300** is fixed at a distal end in the right (or left) ventricular myocardium using a tissue anchor **2327**. The tissue anchor **2327** may have any suitable or desirable form. For example, in some embodiments, the anchor **2327** comprises a pronged metal anchor that is designed to minimize the risk of penetration of the epicardial surface and/or prong exposure in the ventricle. In some embodiments, the implant device **2300** may comprise excess device length (not shown) that extends through the right atrium **5** and into a subcutaneous pocket (not shown). In some embodiments, one or more of an antenna and/or wireless communication chip and/or circuitry may be contained within the subcutaneous pocket. Such antenna and/or circuitry may be configured to wirelessly communicate and/or process data and/or power relating to sensor functionality of the implant device **2300**.

(134) The filling of the spacer form **2310** may comprise elastomeric foam in some embodiments, which may provide suitable or desirable compression and decompression characteristics. The implant device **2300** includes a sensor **2310**, which may be integrated with the spacer form **2320** in any suitable or desirable way. For example, in some implementations, the spacer form **2320** includes an exterior slot or recess in the exterior spacer form and/or the internal foam or chamber. The sensor **2310** may be configured and/or positioned within the implant device **2300** such that the sensor element is positioned to determine pressure readings in the ventricle **4** and/or the atrium **5**. In embodiments in which the sensor **2310** is disposed within the exterior balloon form of the spacer **2320**, a pressure sensor diaphragm of sensor **2010** may protrude at least partially from the spacer form **2320** such that the pressure sensor diaphragm may be used to determine fluid pressure external to the spacer form **2320**.

(135) In some embodiments, the spacer form **2320** is fluid-filled, such that fluid pressure external to the spacer form **2320** is at least partially transferred, or translates in some manner, to fluid pressure within the spacer form. In some embodiments, the internal pressure of the spacer form **2320** provides information indicating how hard the valve leaflets strike the spacer form during cardiac cycles. That is, in some embodiments, the sensor **2310** is configured to measure pressure in one or more chambers of the heart **1**, as well as leaflet contact force on the spacer form. Leaflet contact force may be measured to determine functional wear of the implant device **2300**. In some embodiments, the spacer form **2320** has one or more openings at one or more longitudinal ends thereof through which a sensor element may be exposed to external fluid pressure.

(136) In some embodiments, a battery or other power source is maintained within the **2320**. Furthermore, wireless transmission and/or control circuitry may be contained within the **2320** and/or sensor **2310**, including one or more antennas, chips, conductors, and/or the like. Such components and circuitry may be configured to wirelessly communicate and/or process data and/or power relating to sensor functionality associated with the sensor **2310**. In some embodiments, the sensor-integrated implant **2300** is configured to provide atrial pressure readings, as well as pressure readings relating to pulmonary artery pressure, which may provide information that describes both valve and ventricular performance.

(137) FIG. **24** illustrates a sensor assembly including a sensor-integrated spacer implant device **2400** and a tethered separate sensor device **2415**, which may be anchored in the inferior vena cava or other vessel or anatomy using an anchor **2417**. The sensor **2415** may be tethered to the spacer implant device **2400** via a tether **2419**, as illustrated. Although the spacer implant device **2400** is shown as being integrated with a sensor **2410**, in some embodiments, the spacer **2400** does not include a sensor. The spacer implant device **2400** may be anchored to the ventricular wall by a tether **2425** and/or tissue anchor **2427**.

(138) The tethered pressure sensor **2415** anchored in the inferior vena cava **29** may advantageously

provide central venous pressure measurements, which may provide a good measure of venous congestion, or other beneficial measurement(s). The anchor **2417** may advantageously be configured to center the pressure sensor **2415** in the vessel **29**, which may provide desirable pressure measurement position. Furthermore, the anchor **2417** and/or sensor **2415** may advantageously be configured to, and/or comprise material that serves to, limit tissue overgrowth onto the sensing element of the sensor **2415**. The anchor **2417** may further provide an additional anchoring feature for the valve spacer implant **2400**, which may further secure the valve spacer implant **2400** in its desired position.

(139) In some embodiments, the pressure sensor **2410** of the valve spacer implant device **2400** may measure right ventricular and/or right atrial pressure, whereas the sensor **2415** may provide measurements of inferior vena cava pressure, which in combination may provide a relatively complete picture of right-sided heart performance. Alternatively, sensors in spacer devices may be implanted in a similar fashion on the left side of the heart.

(140) In some embodiments, an implant device in accordance with the present disclosure may comprise a sensor integrated with a left atrial appendage implant device. FIG. **25** illustrates a sensor-integrated cardiac implant device **2500** comprising a sensor **2510** integrated with a left atrial appendage occluder implant device **2520**. The implant device **2500** may be implanted in a left atrial appendage **49** of a heart. The implant device **2500** can be positioned to measure pressure in the left atrial appendage **49** and/or left atrium **2**. Generally, measurement of left atrial pressure may be useful in monitoring fluid build-up the lungs associated with congestive heart failure, as described in detail above. The sensor implant device **2510** may be permanently affixed to the left atrial appendage closure implant device **2520** via or using any attachment or integration mechanism, including bonding, suture wrapping, or other attachment means for fixing the sensor **2510** to the implant **2520**. The sensor-integrated implant device **2500** may advantageously provide a secure location for anchoring the atrial pressure monitoring sensor **2510**. The sensor **2510** may advantageously be positioned and/or configured to present a relatively low risk of thrombus in the left atrium.

(141) In some embodiments, a sensor-integrated implant device in accordance with the present disclosure comprises a sensor integrated with valve repair clip or device configured to secure the valve leaflets to one another to reduce valve regurgitation. FIGS. **26** and **27** show side and top views, respectively, of a sensor-integrated valve repair implant **2600** configured to provide edge-to-edge leaflet attachment for mitral valve repair in accordance with one or more embodiments of the present disclosure.

(142) Edge-to-edge leaflet repair implemented using the implant device **2600** can advantageously at least partially restore valvular competence by anchoring the free edge of the anterior leaflet **62** of the mitral valve **6** to the corresponding free edge of the posterior leaflet **62**, thereby creating a double-orifice valve, as shown in FIG. **27**. The implant device **2600** may be deliverable using a transcatheter approach and may therefore be suitable in patients with increased risk for surgical valve-repair solutions.

(143) The implant device **2600** comprises a first clasp member **2621**, a second clasp member **2622**, and a spacer **2620**. The implant **2600** may be configured to capture the valve leaflets between the clasps **2621**, **2622** and the spacer **2620**, as shows, and may be particularly well for cases of relatively short posterior leaflets or relatively larger leaflet prolapse gaps. The spacer includes a base portion **2609** and an end portion **2607**. The base portion **2609** may be considered a ventricle or ventricular portion of the spacer, as the base portion **2609** may be disposed within the ventricle and/or exposed to the ventricle when the implant device **2600** is implanted. The end portion **2607** may be considered an atrium or atrial portion of the spacer, as the end portion **2607** may be disposed within the atrium and/or exposed to the atrium when the implant device **2600** is implanted.

(144) The implant **2600** further comprises a sensor **2610**, which may be disposed within and/or

integrated with the spacer **2620**, as shown. For example, in some embodiments, the sensor **2610** has an exposed sensor element that is positioned and/or configured to generate pressure readings indicative of left atrial pressure. Furthermore, in some embodiments, the implant device **2600** comprises one or more sensor elements positioned and/or configured to provide pressure sensor readings indicating left (or right for tricuspid valve repair) ventricular pressure. For example, such sensor elements may be disposed at or near the base **2609** ventricular portion of the spacer **2620** and/or implant device **2600**. In some embodiments, the sensor **2610** is embedded in the spacer **2620**.

(145) A sensor element **2601** (e.g., pressure sensor element as described herein) may be exposed and/or protrude from the end portion **2607** of the spacer **2620**, such that the sensor element can generate pressure readings associated with the atrial side of the valve **6**. In addition to measuring left atrial and/or left ventricular pressure, the sensor **2610** may be used to measure the long-term performance of the repaired valve **6**. For example, the sensor **2610** may comprise a dual-element sensor configured to measure the gradient across the valve **6** and/or regurgitation into the left atrium.

(146) FIG. **28** shows another embodiment of a sensor **2810** integrated with a mitral valve repair implant **2800** to form a valve repair sensor assembly **2801**. The assembly **2801** may provide a mechanism for measuring left atrial pressure by tethering a pressure sensor **2810** to the valve repair implant **2800**. The assembly **2801** may provide a simplified implant device for integrating pressure sensor functionality with a mitral leaflet repair implant compared to embodiments in which a pressure sensor is integrated with the spacer or other component of the repair clip implant. In some embodiments, the sensor-integrated assembly **2801** further comprises a support strut **2805**, which may be coupled or attached to the sensor **2810** in some manner and may serve to further secure the sensor **2810** in a desired position and/or range of positions. In some embodiments, the strut **2805** is at least partially rigid. A distal end **2806** of the strut **2805** may be embedded in tissue to anchor the strut and sensor **2810**.

(147) FIG. **29** shows yet another embodiment of a sensor **2910** integrated with a mitral valve repair implant **2900** to form a valve repair sensor assembly **2901**. In the embodiment of FIG. **29**, the sensor **2910** is anchored in the inferior vena cava **29** by an anchoring feature **2917**. The anchor **2917** may be any suitable or desirable anchor in accordance with embodiments of the present disclosure. In some embodiments, the anchor **2917** comprises a memory metal wire frame. The mitral valve repair device **2900** may be implanted using a transseptal access to the left atrium **2**. In connection with such procedure, the sensor **2910** may be anchored at least partially within the inferior vena cava or right atrium, wherein a tether **2905** coupling the sensor **2910** to the valve repair device **2900** extends through the interatrial septum wall **18**.

(148) In some embodiments, sensor-integrated implant devices in accordance with the present disclosure comprise an annular reduction implant device having integrated therewith a sensor, such as a pressure sensor, as described in detail herein. FIG. **30** illustrates a sensor-integrated annular reduction implant **3000** comprising an annular reduction tube **3020** mechanically coupled to a sensor **3010**, such as a pressure sensor. In some implementations, the implant device **3000** is configured to be implanted on or adjacent to a native mitral valve annulus.

(149) The annular reduction tube **3020** may comprise a textile tube configured to be sutured or otherwise secured to the native valve annulus and cinched in order to reduce an effective diameter thereof in order to repair the relevant valve. In some embodiments, the sensor-integrated implant device **3000** comprises an anchor wire **3005** that is coupled to the sensor **3010** and configured to further support the sensor **3010** when implanted. For example, the anchor **3005** may comprise a relatively large diameter wire (e.g., memory metal such as Nitinol) that provide support for the sensor **3010**. The anchor **3005** may be attached to the sensor **3010** in any way or using any attachment mechanism. For example, as illustrated, the anchor wire **3005** may be wrapped around at least a portion of the sensor **3010**. The anchor **35** may be configured to radially expand to

provide support within the left atrium or other chamber or blood vessel. In some embodiments, the anchor wire **3005** is configured to be embedded in tissue or is coupled to a tissue anchor element.
(150) In some embodiments, a distal end of the sensor **3005** is secured by the anchor **3005**, whereas the proximal end of the sensor **3010** is anchored or secured to a sleeve or other attachment feature of the tube **3020**. For example, the tube **3020** may comprise a reducing fitting feature **3001** or other attachment mechanism. The reducing fitting **3001** may be wrapped with suture or other tightening feature for tightening the reducing fitting **3001** around the sensor to thereby secure the sensor **3010** to the tube **3020**. Generally, by incorporating the sensor **3010** with an annular reduction implant, the impact on the procedural steps involved with affixing the annular reduction implant to the native valve annulus may be relatively minimal.
(151) FIG. **31** illustrates a sensor **3110** coupled to a replacement mitral valve implant **3120**. The combination of the sensor **3110**, replacement valve **3120**, and coupling structure **3105** may provide a sensor-integrated implant device that may be configured to provide atrial pressure readings as well as valve repair or functionality. In some embodiments, the replacement valve **3120** is a transcatheter heart valve.
(152) Generally, a relatively large delivery system may be required to deliver the transcatheter heart valve **3120** illustrated in FIG. **31**. For example, where access to the target implantation site is achieved through the interatrial septum wall **18**, such access opening or aperture in the septal wall may be between approximately 6-18 mm in diameter or larger. Therefore, it may be desirable to place a septal closure device in the septal wall to at least partially occlude flow through the septal opening. Described in detail herein are pressure sensor devices integrated with septal closure implants. The illustrated assembly **3101** may advantageously comprise a septal closure structure **3103** with which the sensor device **3110** is integrated, thereby providing septal closure functionality in addition to pressure monitoring and valve repair or functionality. Additionally or alternatively, the coupling structure **3105** may serve as a tether that is incorporated into the frame of the replacement valve **3120**, and may be used as an anchor to secure the pressure sensor **3110** in the atrial septum **18** or other position at least partially within the left atrium. Although the valve replacement **3120** is described as a mitral valve replacement, and the atrium **2** is described as the left atrium, it should be understood that the principles disclosed and shown in FIG. **31** apply to other replacement valves, including replacement tricuspid valves, aortic valves, and/or pulmonary valves.
(153) FIG. **32** illustrates a valve repair and pressure sensor assembly having an alternative anchoring mechanism for the sensor in the tissue wall **18** (e.g. septal wall). In some embodiments, the anchoring of the sensor **3210** may gain one anchoring point from the frame of the replacement valve **3220**, as well as another anchoring point from the septal wall, as illustrated. The tissue wall anchor **3217** may comprise a wire shaped into a coil at one end and a hook at another end. For example, the proximal end **3218** of the wire anchor **3217** may be coiled around the sensor **3210** to thereby at least partially secure the sensor **3210**. The distal end portion **3219** of the anchor **3217** may be embedded into tissue, and/or may form a larger-diameter coil, as shown, and may have a free end.
(154) The assembly **3201** of FIG. **32** may take advantage of a transseptal access needed to initially place the replacement valve **3220**. That is, procedurally, the access, septal crossing, and guide wire may be previously established in connection with placement of the replacement valve **3220**, such that introduction of a catheter for transporting the sensor **3210** and associated anchor **3217** may not add substantial complication to the procedure. Furthermore, in some embodiments, the anchor **3217** and sensor **3210** may serve as a septal defect closure device as well.
(155) In some embodiments, a sensor device, such as a pressure sensor device, may be implanted in an atrium or other chamber of the heart and secured at least in part using one or more radially-expanding anchor features or coils. FIG. **33** illustrates a sensor device **3310** suspended in the left atrium **2** of the heart. Although certain embodiments are disclosed herein in the context of the left

atrium, it should be understood that sensors in accordance with the present disclosure may be implanted in the right atrium or other chamber or blood vessel of the heart or body. The sensor **3310** is mounted or attached to a relatively large radially-expanding anchor system comprising a radially expanding wire **3305**. The wire **3305** may be configured to contact at least a portion of the inner wall of the atrium **2** when expanded. In some embodiments, the wire **3305** is configured to exert outward radial force against the walls of the atrium to thereby secure or even suspend the sensor device **3305** in a central or desired portion of the atrium. Furthermore, the wire **3305** may be at least partially flexible and/or elastic to allow for contracting and/or expanding in response to contraction and expansion of the atrium in connection with cardiac cycles.

(156) The sensor **3310** may be anchored or embedded in the atrial tissue in some embodiments. For example, the sensor **310** may have associated therewith a sensor anchor **3317** configured and dimensioned to be embedded in the tissue of the atrial wall at any suitable or desirable position and/or portion thereof. FIGS. **34**A and **34**B illustrate example embodiments of pressure sensors having associated or integrated tissue anchors. For example, as shown in FIG. **34**A, a pressure sensor **3410** can be associated or integrated with a multiple-prong tissue anchor, as illustrated. Furthermore, as shown in FIG. **34**B, a pressure sensor **3411** can be associated or integrated with a corkscrew-type anchor **3418**. The anchors of FIGS. **34**A and **34**B may be incorporated on a distal end of the respective sensors, wherein a shaped wire (e.g. memory metal wire) can be attached to the proximal end of the respective sensor to provide additional stability for the sensor, as illustrated in FIG. **33**.

(157) In some embodiments, a sensor-integrated cardiac implant device in accordance with the present disclosure comprises a pressure sensor integrated with a docking device, such as a docking device for docking a replacement heart valve, or other implant device. Various anchors and docking devices, such as coiled anchors or docking devices, can be used in conjunction with transcatheter heart valves at a native valve annulus (e.g., mitral or tricuspid valve annulus) in order to more securely implant and hold the prosthetic valve at the implantation site. FIG. **35** illustrates a sensor-integrated implant device **3500** including a docking device **3507** integrated with a sensor **3510**, such as a pressure sensor.

(158) The anchoring/docking device **3507** can provide a more circular and/or stable annulus at the implantation site, in which prosthetic valves having circular or cylindrically-shaped valve frames or stents can be expanded or otherwise implanted. In addition to providing an anchoring site for a prosthetic valve, the anchoring/docking device **3507** can be sized and shaped to cinch or draw the native valve (e.g., mitral, tricuspid, etc.) anatomy radially inwards. In this manner, one of the main causes of valve regurgitation (e.g., functional mitral regurgitation), specifically enlargement of the heart (e.g., left ventricle) and/or valve annulus, and consequent stretching out of the native valve (e.g., mitral) annulus, can be at least partially offset or counteracted. In some embodiments, the anchoring/docking device **3507** further includes features which, for example, are shaped and/or modified to better hold a position or shape of the docking device during and/or after expansion of a prosthetic valve therein.

(159) The docking device **3507** includes a coil with a plurality of turns extending along a central axis of the docking device. The coil can be continuous and can extend generally helically, with various differently sized and shaped sections. The docking device **3507** shown in FIG. **35** may be configured to best fit at the mitral position, but can be shaped similarly or differently in other embodiments for better accommodation at other native valve positions as well.

(160) The pressure sensor **3510** can be integrated with or attached to the proximal end **3503** of the docking device **3507**. In implanting the docking/sensor assembly **3500**, the sensor **3510** may be advanced to engage with the docking device **3507**. Additional anchoring features (not shown) may be added to secure the proximal end of the sensor **3510** to the septal wall or other wall of the atrium **2**. In some embodiments, the sensor **3510** is anchored to the septal wall and integrated with a septal closure device as described herein. In some embodiments, the docking device **3507** includes one or

more proximal coils or loops **3506**, which may be configured to assume a shape that can contact one or more portions of the inner wall of the atrium **2** to thereby at least partially secure the sensor **3510** in a desired position. Although a single proximal coil/loop **3506** is shown, the docking device **3507** may have any suitable or desirable number of coils/loops, or other shape and/or configuration features for securing or stabilizing the sensor **3510**.

(161) FIGS. **36**A and **36**B illustrate sensor-integrated cardiac implant devices **3600***a*, **3600***b* in accordance with one or more embodiments of the present disclosure. The cardiac implant devices **3600***a*, **3600***b* include cardiac implant structures **3620***a*, **3620***b*, which are implanted and/or secured within the pulmonary artery **11**. The cardiac implant structures may comprise a pulmonary valve replacement device **3620***b* and/or pulmonary stent device **3620***a*. For example, percutaneous pulmonary valve replacement **3620***b* can be an effective means by which to restore valve function for defective pulmonary valves. In some cases, the pulmonary artery may be at least partially dilated, and thus a reducer stent **3620***a* may desirably be placed in the pulmonary artery prior to percutaneous placement of a replacement valve. Therefore, the cardiac implant structure **3620***a* may comprise a reducer stent, which may include struts configured and designed to anchor and position the pressure sensor **3610***a* such that the sensing element of the pressure sensor **3610***a* is positioned at or near the center of the pulmonary artery **11**. To such end, the cardiac implant structures **3620***a*, **3620***b* may comprise an arm or strut **3605***a*, **3605***b*, which may have one or more attachment features **3601***a*, **3601***b* for attaching the sensor **3610***a*, **3610***b* thereto, such as one or more bands, straps, features, locking features, and/or other attachment means. In some embodiments, the strut or arm feature **3605** comprises memory metal shaped to receive and/or anchor the sensor **3610**. The stent structure **3620** may be sized to have placed therein a valve replacement device. Furthermore, although a stent is shown in FIG. **36**, it should be understood that in some embodiments the cardiac implant structure **3620** comprises a replacement pulmonary valve device.

(162) The various embodiments disclosed herein relate to sensor-integrated cardiac implant devices, which may be implanted in any heart chamber or blood vessel. With respect to embodiments relating to implant devices implanted in one or more of the left or right atria and/or one or more of the left right ventricles, or in one or more blood vessels accessed through one or more atria or ventricles, such access may be achieved in any suitable or desirable way. For example, FIG. **37** illustrates various access paths through which access to a target cardiac anatomy may be achieved, including transseptal access **3701**, which may be made through the inferior vena cava **29** or superior vena cava **19**, and from the right atrium **5**, through the septal wall (not shown) and into the left atrium **2**. For transaortic access **3702**, a delivery catheter may be passed through the descending aorta, aortic arch **12**, ascending aorta, and aortic valve **7**. For transapical access **3703**, access may be made directly through the apex of the heart and into the left ventricle **3** or right ventricle **4**.

ADDITIONAL EMBODIMENTS

(163) Depending on the embodiment, certain acts, events, or functions of any of the processes or algorithms described herein can be performed in a different sequence, may be added, merged, or left out altogether. Thus, in certain embodiments, not all described acts or events are necessary for the practice of the processes.

(164) Conditional language used herein, such as, among others, “can,” “could,” “might,” “may,” “e.g.,” and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is intended in its ordinary sense and is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular

embodiment. The terms “comprising,” “including,” “having,” and the like are synonymous, are used in their ordinary sense, and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term “or” is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term “or” means one, some, or all of the elements in the list. Conjunctive language such as the phrase “at least one of X, Y and Z,” unless specifically stated otherwise, is understood with the context as used in general to convey that an item, term, element, etc. may be either X, Y or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y and at least one of Z to each be present.

(165) It should be appreciated that in the above description of embodiments, various features are sometimes grouped together in a single embodiment, Figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that any claim require more features than are expressly recited in that claim. Moreover, any components, features, or steps illustrated and/or described in a particular embodiment herein can be applied to or used with any other embodiment(s). Further, no component, feature, step, or group of components, features, or steps are necessary or indispensable for each embodiment. Thus, it is intended that the scope of the inventions herein disclosed and claimed below should not be limited by the particular embodiments described above, but should be determined only by a fair reading of the claims that follow.

(166) It should be understood that certain ordinal terms (e.g., “first” or “second”) may be provided for ease of reference and do not necessarily imply physical characteristics or ordering. Therefore, as used herein, an ordinal term (e.g., “first,” “second,” “third,” etc.) used to modify an element, such as a structure, a component, an operation, etc., does not necessarily indicate priority or order of the element with respect to any other element, but rather may generally distinguish the element from another element having a similar or identical name (but for use of the ordinal term). In addition, as used herein, indefinite articles (“a” and “an”) may indicate “one or more” rather than “one.” Further, an operation performed “based on” a condition or event may also be performed based on one or more other conditions or events not explicitly recited.

(167) Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which example embodiments belong. It be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

(168) The spatially relative terms “outer,” “inner,” “upper,” “lower,” “below,” “above,” “vertical,” “horizontal,” and similar terms, may be used herein for ease of description to describe the relations between one element or component and another element or component as illustrated in the drawings. It be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation, in addition to the orientation depicted in the drawings. For example, in the case where a device shown in the drawing is turned over, the device positioned “below” or “beneath” another device may be placed “above” another device. Accordingly, the illustrative term “below” may include both the lower and upper positions. The device may also be oriented in the other direction, and thus the spatially relative terms may be interpreted differently depending on the orientations.

(169) Unless otherwise expressly stated, comparative and/or quantitative terms, such as “less,” “more,” “greater,” and the like, are intended to encompass the concepts of equality. For example, “less” can mean not only “less” in the strictest mathematical sense, but also, “less than or equal to.”

Claims

1. A septal closure device comprising: a wireform frame comprising: a central portion defining a circular shape; and a plurality of anchor loops that project radially outward from the central portion, each of the plurality of anchor loops forming a respective internal void; a planar occluding membrane formed as a sheet coupled to the central portion of the wireform frame and spanning a central void within the central portion of the wireform frame, the central void and occluding membrane lying in a plane that is perpendicular to an ax is of the circular shape of the central portion; and a pressure sensor device attached to the occluding membrane; wherein: the occluding membrane sheet covers an entirety of the central void within the central portion outside of a portion occupied by the pressure sensor device; the occluding membrane sheet does not cover the internal voids of the plurality of anchor loops; the pressure sensor device comprises a first portion disposed on a first side of the occluding membrane sheet and a second portion disposed on a second side of the occluding membrane sheet; and the pressure sensor device is supported solely by the occluding membrane sheet and not directly by the wireform frame.
2. The septal closure device of claim 1, wherein the first portion of the pressure sensor device comprises a first pressure sensor element, and the second portion of the pressure sensor device comprises a second pressure sensor element.
3. The septal closure device of claim 1, wherein the occluding membrane comprises a cloth, the cloth holding the pressure sensor device in suspension.
4. The septal closure device of claim 1, wherein the occluding membrane comprises woven polymer fibers.
5. The septal closure device of claim 1, wherein the pressure sensor device comprises a rigid cylindrical body.
6. The septal closure device of claim 1, wherein, in a non-deflected configuration, the plurality of anchor loops are coplanar with the central portion.
7. The septal closure device of claim 1, wherein each of the plurality of anchor loops has a radially inner neck that is open to the central void of the wireform frame.
8. The septal closure device of claim 1, wherein: the plurality of anchor loops comprises four angularly distributed diamond-shaped loop anchors emanating from the central portion of the wireform frame; the central portion of the wireform frame has a form of a segmented ring lying in the plane perpendicular to the axis of the central portion; and the pressure sensor device passes through the occluding membrane, the pressure sensor device being co-axial with the axis of the central portion of the wireform frame.
9. The septal closure device of claim 8, wherein each of the four angularly distributed loop anchors originates at a neck portion defined by and emanating from end portions of adjacent segments of the segmented ring and expands moving radially outward to form the diamond shape.
10. The septal closure device of claim 8, wherein: a first loop anchor and a second loop anchor of the four angularly distributed loop anchors each include an eyelet at a distal end of the respective loop anchor; and the first loop anchor and the second loop anchor are positioned opposite one another about the segmented ring.
11. The septal closure device of claim 1, wherein the wireform frame comprises a plurality of arc segments that define the circular shape of the central portion, the central portion having a form of a circular boundary with a plurality of angular breaks; the occluding membrane sheet comprises a cloth having a perimeter attached to the central portion.
12. The septal closure device of claim 11, wherein the plurality of anchor loops have neck regions defining the plurality of angular breaks of the circular boundary.
13. The septal closure device of claim 1, wherein the wireform frame is formed from a single, continuous wire.

14. The septal closure device of claim 1, wherein each of the plurality of anchor loops has a diamond shape with a width that is greater than a length of the anchor loop.