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Medical system for treating a left atrial appendage

Abstract

A medical system for monitoring a left atrial pressure in a heart of a patient may include an implantable device including an expandable framework and a first sensor secured to the expandable framework and an external component configured to communicate wirelessly with the implantable device. The first sensor may be configured to detect a first measurement. The first sensor may be a pressure sensor and the first measurement may be the left atrial pressure. The implantable device or the external component may include a processor configured to create a first trend for the first measurement. The processor may be configured to use the first trend to modify the first measurement prior to outputting a corrected result.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application claims the benefit of priority of U.S. Provisional Application No. 63/145,144 filed Feb. 3, 2021, the entire disclosure of which is hereby incorporated by reference.

TECHNICAL FIELD
(1) The disclosure relates generally to medical devices and more particularly to medical devices that are adapted for use in percutaneous medical procedures including implantation into the left atrial appendage (LAA) of a heart.
BACKGROUND
(2) The left atrial appendage is a small organ attached to the left atrium of the heart. During normal

heart function, as the left atrium constricts and forces blood into the left ventricle, the left atrial appendage constricts and forces blood into the left atrium. The ability of the left atrial appendage to contract assists with improved filling of the left ventricle, thereby playing a role in maintaining cardiac output. However, in patients suffering from atrial fibrillation, the left atrial appendage may not properly contract or empty, causing stagnant blood to pool within its interior, which can lead to the undesirable formation of thrombi within the left atrial appendage.

(3) Thrombi forming in the left atrial appendage may break loose from this area and enter the blood stream. Emboli that migrate through the blood vessels may eventually plug a smaller vessel downstream and thereby contribute to stroke or heart attack. Clinical studies have shown that the majority of blood clots in patients with atrial fibrillation originate in the left atrial appendage. As a treatment, medical devices have been developed which are deployed to close off the left atrial appendage. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices and introducers as well as alternative methods for manufacturing and using medical devices and introducers.

SUMMARY

(4) In one example, a medical system for monitoring a left atrial pressure in a heart of a patient may comprise: an implantable device including an expandable framework and a first sensor secured to the expandable framework; and an external component configured to communicate wirelessly with the implantable device. The first sensor may be configured to detect a first measurement. The first sensor may be a pressure sensor and the first measurement may be the left atrial pressure. The implantable device or the external component may include a processor configured to create a first trend for the first measurement. The processor may be configured to use the first trend to modify the first measurement prior to outputting a corrected result.

(5) In addition or alternatively to any example described herein, the processor is configured to use the first trend to remove drift from the first measurement prior to outputting the corrected result.

(6) In addition or alternatively to any example described herein, the medical system may further comprise a second sensor secured to the expandable framework. The second sensor may be configured to detect a second measurement that is a surrogate for the left atrial pressure.

(7) In addition or alternatively to any example described herein, the processor is configured to create a second trend for the second measurement.

(8) In addition or alternatively to any example described herein, the processor is configured to use the first trend and the second trend to modify the first measurement prior to outputting the corrected result.

(9) In addition or alternatively to any example described herein, the processor uses the second trend to correct the first measurement for drift.

(10) In addition or alternatively to any example described herein, the second measurement is a third heart sound (S3).

(11) In addition or alternatively to any example described herein, the second sensor has a different sensing modality than the first sensor.

(12) In addition or alternatively to any example described herein, the second sensor is an accelerometer.

(13) In addition or alternatively to any example described herein, the second sensor is an acoustic sensor.

(14) In addition or alternatively to any example described herein, the medical system may further comprise a second sensor disposed in a second medical device configured to be in contact with a body of the patient. The second sensor may be configured to detect a second measurement that is a surrogate for the left atrial pressure when the second medical device is in contact with the body of the patient and send the second measurement to the external component.

(15) In addition or alternatively to any example described herein, a method of autonomous recalibration of a pressure sensor used to detect a left atrial pressure within a heart of a patient may

comprise: detecting signals of the left atrial pressure using a first sensor coupled to an expandable framework, the expandable framework being implantable within a left atrial appendage of the heart of the patient; detecting signals of a third heart sound (S3) from the heart of the patient using a second sensor coupled to the expandable framework; using the signals of the left atrial pressure to establish a trend of the left atrial pressure with a processor; using the signals of the third heart sound to establish a trend of the third heart sound with the processor; comparing the trend of the left atrial pressure to the trend of the third heart sound with the processor to determine if the first sensor is experiencing drift; and using the trend of the third heart sound to correct the trend of the left atrial pressure to remove the drift with the processor; outputting a corrected trend of the left atrial pressure devoid of the drift.

(16) In addition or alternatively to any example described herein, comparing the trend of the left atrial pressure to the trend of the third heart sound includes comparing a slope of the trend of the left atrial pressure to a slope of the trend of the third heart sound.

(17) In addition or alternatively to any example described herein, using the trend of the third heart sound to correct the trend of the left atrial pressure to remove the drift includes subtracting a difference between the slope of the trend of the third heart sound and the slope of the trend of the left atrial pressure from the trend of the left atrial pressure.

(18) In addition or alternatively to any example described herein, when the drift exceeds a predetermined limit, the method further includes issuing a warning to manually recalibrate the first sensor.

(19) In addition or alternatively to any example described herein, the first sensor has a first sensing modality and responds to a first set of daily physiological changes, and the second sensor has a second sensing modality different from the first sensing modality and responds to the first set of daily physiological changes.

(20) In addition or alternatively to any example described herein, a medical system for monitoring a left atrial pressure in a heart of a patient may comprise: an implantable device including an expandable framework and a first sensor secured to the expandable framework; and an external component configured to communicate wirelessly with the implantable device. The first sensor may be configured to detect a first measurement. The first sensor may be a pressure sensor and the first measurement may be the left atrial pressure. The system may further include a processor and a signal filter. The signal filter may be used by the processor to modify the first measurement prior to outputting a corrected result.

(21) In addition or alternatively to any example described herein, the signal filter is a low pass filter configured to create a signal representative of drift in the first measurement.

(22) In addition or alternatively to any example described herein, the processor subtracts the signal representative of drift from the first measurement to produce the corrected result.

(23) In addition or alternatively to any example described herein, the low pass filter has a frequency cutoff at about 10.sup.−7 Hertz.

(24) In addition or alternatively to any example described herein, the signal filter is a high pass filter configured to remove a portion of the first measurement corresponding to drift in the first sensor to produce the corrected result.

(25) In addition or alternatively to any example described herein, the high pass filter has a frequency cutoff at about 10.sup.−7 Hertz.

(26) The above summary of some embodiments, aspects, and/or examples is not intended to describe each embodiment or every implementation of the present disclosure. The figures and the detailed description which follows more particularly exemplify these embodiments.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

(2) FIGS. **1**-**2** illustrate aspects of a left atrial appendage closure device;

(3) FIG. **3** illustrates the left atrial appendage closure device disposed within the ostium of a left atrial appendage of a heart of a patient;

(4) FIG. **4** illustrates aspects of a medical system for monitoring left atrial pressure in the heart of the patient;

(5) FIG. **5** illustrates example profiles of drift of a pressure sensor;

(6) FIG. **6** illustrates an example left atrial pressure measurement using a pressure sensor;

(7) FIGS. **7**A-**7**B illustrate example left atrial pressure measurements affected by drift;

(8) FIG. **8** illustrates example frequency ranges of a pressure signal;

(9) FIG. **9** illustrates an example left atrial pressure measurement using an accelerometer to monitor a third heart sound (S3);

(10) FIG. **10** illustrates the example left atrial pressure measurements of FIGS. **7**A-**7**B corrected to remove drift;

(11) FIG. **11** illustrates example signal processing related to left atrial pressure;

(12) FIG. **12** illustrates example frequency ranges of a pressure signal and a filter;

(13) FIG. **13** illustrates example signal processing related to left atrial pressure using a low pass filter; and

(14) FIG. **14** illustrates example signal processing related to left atrial pressure using a high pass filter.

(15) While aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

(16) The following description should be read with reference to the drawings, which are not necessarily to scale, wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings are intended to illustrate but not limit the current disclosure. Those skilled in the art will recognize that the various elements described and/or shown may be arranged in various combinations and configurations without departing from the scope of the disclosure. The detailed description and drawings illustrate example embodiments of the current disclosure. However, in the interest of clarity and ease of understanding, while every feature and/or element may not be shown in each drawing, the feature(s) and/or element(s) may be understood to be present regardless, unless otherwise specified.

(17) For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

(18) All numeric values are herein assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about”, in the context of numeric values, generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the term “about” may include numbers that are rounded to the nearest significant figure. Other uses of the term “about” (e.g., in a context other than numeric values) may be assumed to have their ordinary and customary definition(s), as understood from and consistent with the context of the specification, unless otherwise specified.

(19) The recitation of numerical ranges by endpoints includes all numbers within that range, including the endpoints (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

(20) Although some suitable dimensions, ranges, and/or values pertaining to various components,

features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges, and/or values may deviate from those expressly disclosed.

(21) As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed example(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For simplicity and clarity purposes, not all elements of the current disclosure are necessarily shown in each figure or discussed in detail below. However, it will be understood that the following discussion may apply equally to any and/or all of the components for which there are more than one, unless explicitly stated to the contrary. Additionally, not all instances of some elements or features may be shown in each figure for clarity.

(22) Relative terms such as “proximal”, “distal”, “advance”, “retract”, variants thereof, and the like, may be generally considered with respect to the positioning, direction, and/or operation of various elements relative to a user/operator/manipulator of the device, wherein “proximal” and “retract” indicate or refer to closer to or toward the user and “distal” and “advance” indicate or refer to farther from or away from the user. In some instances, the terms “proximal” and “distal” may be arbitrarily assigned in an effort to facilitate understanding of the disclosure, and such instances will be readily apparent to the skilled artisan. Other relative terms, such as “upstream”, “downstream”, “inflow”, and “outflow” refer to a direction of fluid flow within a lumen, such as a body lumen, a blood vessel, or within a device. Still other relative terms, such as “axial”, “circumferential”, “longitudinal”, “lateral”, “radial”, etc. and/or variants thereof generally refer to direction and/or orientation relative to a central longitudinal axis of the disclosed structure or device.

(23) The term “extent” may be understood to mean a greatest measurement of a stated or identified dimension, unless the extent or dimension in question is preceded by or identified as a “minimum”, which may be understood to mean a smallest measurement of the stated or identified dimension. For example, “outer extent” may be understood to mean an outer dimension, “radial extent” may be understood to mean a radial dimension, “longitudinal extent” may be understood to mean a longitudinal dimension, etc. Each instance of an “extent” may be different (e.g., axial, longitudinal, lateral, radial, circumferential, etc.) and will be apparent to the skilled person from the context of the individual usage. Generally, an “extent” may be considered a greatest possible dimension measured according to the intended usage, while a “minimum extent” may be considered a smallest possible dimension measured according to the intended usage. In some instances, an “extent” may generally be measured orthogonally within a plane and/or cross-section, but may be, as will be apparent from the particular context, measured differently—such as, but not limited to, angularly, radially, circumferentially (e.g., along an arc), etc.

(24) The terms “monolithic” and “unitary” shall generally refer to an element or elements made from or consisting of a single structure or base unit/element. A monolithic and/or unitary element shall exclude structure and/or features made by assembling or otherwise joining multiple discrete structures or elements together.

(25) It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment(s) described may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it would be within the knowledge of one skilled in the art to

implement the particular feature, structure, or characteristic in connection with other embodiments, whether or not explicitly described, unless clearly stated to the contrary. That is, the various individual elements described below, even if not explicitly shown in a particular combination, are nevertheless contemplated as being combinable or arrangeable with each other to form other additional embodiments or to complement and/or enrich the described embodiment(s), as would be understood by one of ordinary skill in the art.

(26) For the purpose of clarity, certain identifying numerical nomenclature (e.g., first, second, third, fourth, etc.) may be used throughout the description and/or claims to name and/or differentiate between various described and/or claimed features. It is to be understood that the numerical nomenclature is not intended to be limiting and is exemplary only. In some embodiments, alterations of and deviations from previously used numerical nomenclature may be made in the interest of brevity and clarity. That is, a feature identified as a "first" element may later be referred to as a "second" element, a "third" element, etc. or may be omitted entirely, and/or a different feature may be referred to as the "first" element. The meaning and/or designation in each instance will be apparent to the skilled practitioner.

(27) The following figures illustrate selected components and/or arrangements of an implant for occluding the left atrial appendage, a medical system for occluding the left atrial appendage, and/or methods of using the implant and/or the medical system. It should be noted that in any given figure, some features may not be shown, or may be shown schematically, for simplicity. Additional details regarding some of the components of the implant and/or the system may be illustrated in other figures in greater detail. While discussed in the context of occluding the left atrial appendage, the implant and/or the system may also be used for other interventions and/or percutaneous medical procedures within a patient. Similarly, the devices and methods described herein with respect to percutaneous deployment may be used in other types of surgical procedures, as appropriate. For example, in some examples, the devices may be used in a non-percutaneous procedure. Devices and methods in accordance with the disclosure may also be adapted and configured for other uses within the anatomy.

(28) FIGS. **1-2** illustrate an example configuration of an implantable device **100** (e.g., a left atrial appendage closure device) comprising an expandable framework **110** configured to shift between a collapsed delivery configuration and an expanded deployed configuration. Hereinafter, the terms implantable device and left atrial appendage closure device may be considered to be interchangeable and may be used interchangeably throughout the disclosure. The implantable device **100** and/or the expandable framework **110** may be configured to shift between the collapsed delivery configuration and the expanded deployed configuration when the implantable device **100** is unconstrained. In the figures, the implantable device **100** is shown in the expanded deployed configuration. Some suitable, but non-limiting, examples of materials for the implantable device **100** and/or the expandable framework **110**, etc. are discussed below.

(29) In some embodiments, the implantable device **100** may include a proximal hub **130** centered on a central longitudinal axis of the expandable framework **110**. For example, the proximal hub **130** may be coaxial with the central longitudinal axis of the expandable framework **110**. In some embodiments, the proximal hub **130** may be configured to releasably attached the implantable device **100** and/or the expandable framework **110** to a delivery device (not shown) configured to deliver the implantable device **100** and/or the expandable framework **110** to the left atrial appendage of the patient. In some embodiments, the expandable framework **110** may include a plurality of interconnected struts joined together at the proximal hub **130**. In some embodiments, the proximal hub **130** may be integrally formed with and/or may be monolithically formed with the expandable framework **110** and/or the plurality of interconnected struts. In some embodiments, the implantable device **100** may include, and/or the expandable framework **110** may be, a self-expanding framework.

(30) In some embodiments, the implantable device **100** may optionally include an occlusive

element **120** (e.g., a mesh, a fabric, a membrane, and/or other surface treatment) disposed on, disposed over, disposed about, or covering at least a portion of the expandable framework **110**, as seen in FIG. **1**. In some embodiments, the occlusive element **120** may be disposed on, disposed over, disposed about or cover at least a portion of an outer (or outwardly facing) surface of the expandable framework **110**. In some embodiments, the occlusive element **120** may be secured to and/or may extend radially outward from the proximal hub **130**. For reference, the occlusive element **120** has been removed from FIG. **2** to show selected aspects of the implantable device **100** otherwise hidden from view by the occlusive element **120**.

(31) In some embodiments, the expandable framework **110** may include a plurality of anchor members **112** disposed about a periphery of the expandable framework **110** in the expanded deployed configuration. The plurality of anchor members **112** may extend radially outward from the expandable framework **110**. In some embodiments, the plurality of anchor members **112** may provide an anchoring mechanism to aid in retaining the implantable device **100** at a target site within a patient's anatomy (i.e., the left atrial appendage, for example) in the expanded deployed configuration. In some embodiments, the barb(s) may be configured, positioned, and/or arranged such that engagement of the barb(s) with surrounding tissue at the target site is minimized or avoided. In some embodiments, the barb(s) may not puncture, pierce, and/or extend into the surrounding tissue in the expanded deployed configuration.

(32) In some embodiments, at least a portion of the occlusive element **120** may be secured to the expandable framework **110** by at least some of the plurality of anchor members **112**. In at least some embodiments, at least a distal portion of the occlusive element **120** may be attached to the expandable framework **110**. In some embodiments, at least some of the plurality of anchor members **112** extend and/or project through the occlusive element **120**. In some embodiments, the occlusive element **120** may be attached to the expandable framework **110** at some and/or each of the plurality of anchor members **112**, for example, by passing some and/or each of the plurality of anchor members **112** through the occlusive element **120**.

(33) In some embodiments, the barb and/or the tip portion on some and/or each of the at least some of the plurality of anchor members **112** may be disposed radially outward of the occlusive element **120** of the occlusive element **120** while the base of its respective anchor member is disposed radially inward of the occlusive element **120**. The barb may serve to retain the occlusive element **120** on the expandable framework **110**, thereby preventing the occlusive element **120** from working loose and/or releasing from the expandable framework **110** as the expandable framework **110** is shifted between the collapsed delivery configuration and the expanded deployed configuration. In some embodiments, attachment of the distal portion of the occlusive element **120** to the expandable framework **110** is devoid of sutures and/or adhesives.

(34) In some embodiments, the occlusive element **120** may be permeable, semi-permeable, or impermeable to blood and/or other fluids, such as water. In some embodiments, the occlusive element **120** may include a polymeric membrane, a metallic or polymeric mesh, a porous filter-like material, or other suitable construction. In some embodiments, the occlusive element **120** may be configured to prevent thrombi (i.e. blood clots, etc.) from passing through the occlusive element **120** and/or exiting the left atrial appendage into the blood stream and/or the patient's circulatory system when the implantable device **100** and/or the expandable framework **110** is disposed within an ostium of the left atrial appendage in the expanded deployed configuration. In some embodiments, the occlusive element **120** may be configured to promote endothelization across the ostium of the left atrial appendage after implantation of the implantable device **100**, thereby effectively removing the left atrial appendage from the patient's circulatory system. Some suitable, but non-limiting, examples of materials for the occlusive element **120** are discussed below.

(35) In some embodiments, the implantable device **100** may include a first sensor **150** at least partially disposed within an interior of the expandable framework **110**. The first sensor **150** may be secured to the expandable framework **110** and/or the proximal hub **130**. The first sensor **150** may

be configured to detect a first measurement. In some embodiments, the implantable device **100** may include a second sensor **160** at least partially disposed within an interior of the expandable framework **110**. The second sensor **160** may be secured to the expandable framework **110** and/or the proximal hub **130**. The second sensor may be configured to detect a second measurement. In some embodiments, the first sensor **150** and/or the second sensor **160** may be disposed within and/or may be contained within a sensor module **140**. In some embodiments, each of the first sensor **150** and the second sensor **160** may be disposed and/or contained within its own sensor module.

(36) In at least some embodiments, the sensor module **140**, the first sensor **150**, and/or the second sensor **160** may be at least partially disposed within the proximal hub **130**, as seen in FIGS. **1** and **2**. The first sensor **150** and/or the second sensor **160** may be in communication with a proximal end **142** of the sensor module **140**. In some embodiments, the proximal end **142** of the sensor module **140** may be disposed substantially flush with a proximalmost extent of the proximal hub **130** in the released configuration. In some embodiments, the proximal end **142** of the sensor module **140** may extend proximal of the proximalmost extent of the proximal hub **130** in the released configuration. For example, in some embodiments, the proximal end **142** of the sensor module **140** may extend about 1 millimeter (mm), about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, or about 10 mm proximal of the proximalmost extent of the proximal hub **130** in the released configuration. In one example, the proximal end **142** of the sensor module **140** may extend about 4 mm to about 5 mm proximal of the proximalmost extent of the proximal hub **130** in the released configuration. Other ranges and/or dimensions are also contemplated. In some embodiments, the proximal end **142** of the sensor module **140** may have a convex shape extending in the proximal direction. In some embodiments having the proximal end **142** of the sensor module **140** with a convex shape, a proximalmost extent of the sensor module **140** may be substantially flush with the proximalmost extent of the proximal hub **130** in the released configuration. In some embodiments having the proximal end **142** of the sensor module **140** with a convex shape, the proximalmost extent of the sensor module **140** may extend proximal of the proximalmost extent of the proximal hub **130** in the released configuration.

(37) In some embodiments, having the proximal end **142** of the sensor module **140** extend proximal of the proximalmost extent of the proximal hub **130** in the released configuration may permit endothelial growth over the occlusive element **120** and/or the ostium of the left atrial appendage without obstructing and/or obscuring the proximal end **142** of the sensor module **140**. In some embodiments, the proximal end **142** of the sensor module **140** may be disposed distal of the proximalmost extent of the proximal hub **130** and proximal of a distal end of the proximal hub **130** in the released configuration such that the proximal end **142** of the sensor module **140** is recessed within the proximal hub **130** to permit and/or promote endothelial growth thereover. The skilled artisan will recognize that the type, construction, and capabilities of the sensor module **140** may be used to determine whether or not endothelial overgrowth should be permitted and/or promoted.

(38) As shown in FIG. **2**, the sensor module **140** may extend distally into the interior of the implantable device **100** and/or the expandable framework **110**. In some embodiments, the sensor module **140** may have a substantially cylindrical outer surface. In some embodiments, the sensor module **140** may be hollow and/or may include an interior space configured to house components of the sensor module **140**. An overall length of the sensor module **140** may vary depending on the construction of the sensor module **140** and/or components disposed within the interior space of the sensor module **140**.

(39) In one example configuration, the sensor module **140** may include one or more internal components disposed within the interior space. For example, the sensor module **140** may include the first sensor **150** and/or the second sensor **160** disposed therein. In some embodiments, any of the internal components may be considered optional in any particular example. In some embodiments, the first sensor **150** may be a pressure sensor. The first sensor **150** may be configured

to sense a fluid pressure within a space facing the proximal end **142** of the sensor module **140** (e.g., a left atrium) and/or adjacent the proximal end **142** of the sensor module **140** when the expandable framework **110** and/or the implantable device **100** is disposed within an ostium of the left atrial appendage in the released configuration. Accordingly, the first measurement may be a left atrial pressure. In some embodiments, the second measurement may be a surrogate for the left atrial pressure. For example, the second measurement may be a third heart sound (S3). Additional details relating the third heart sound to the left atrial pressure are provided herein. In patients with physiological conditions where monitoring left atrial pressure may be beneficial, the same physiological conditions that may cause abnormal left atrial pressure may also cause and/or result in the third heart sound (S3). The third heart sound (S3) may be detected using the second sensor **160**, which may have a different sensing modality than the first sensor **150**. For example, the second sensor **160** may be an accelerometer, an acoustic sensor, or a pressure sensor sensitive to a particular frequency corresponding to the third heart sound (S3). Other sensor types are also contemplated. In some embodiments, the first sensor **150** may have a first sensing modality and may respond to a first set of daily physiological changes. The second sensor may have a second sensing modality and may respond to the same first set of daily physiological changes.

(40) In some embodiments, the first sensor **150** and/or the second sensor **160** may be configured to sense and/or detect (and/or the sensor module **140** may include a sensor configured to sense and/or detect) temperature, flow rate, heart rate, electrical signals in the heart, heart rhythm, or other characteristics.

(41) In some embodiments, the sensor module **140** may include an integrated circuit board for controlling the first sensor **150**, the second sensor **160**, and/or other internal components of the sensor module **140**. In some embodiments, the sensor module **140** may include a communication coil disposed within the interior space of the sensor module **140**. In some embodiments, the communication coil may be configured for bi-directional wireless communication and/or energy transfer. In some embodiments, the sensor module **140** may optionally include at least one battery. In some embodiments, the sensor module **140** may be powered “on-demand” via an inductive link. In some embodiments, the communication coil may be and/or may form a part of the inductive link. In some embodiments, the sensor module **140** may include at least one capacitor disposed within the interior space configured to act as a temporary power source for the sensor module **140**, the first sensor **150**, the second sensor **160**, and/or other internal components of the sensor module **140** (during “on-demand” energy transfer to the sensor module **140** and/or the implantable device **100**, for example). In some embodiments, the communication coil may be wrapped around the at least one battery. In some embodiments, the communication coil may be wrapped around the at least one capacitor. In some embodiments, the communication coil may be wrapped around a component containing a high permeability material (e.g. ferrite). In some embodiments, the communication coil may be a stand-alone feature and/or may be wrapped around an inert and/or non-functional structure to maintain shape and/or form. Other configurations are also contemplated.

(42) In some embodiments utilizing the at least one battery, the at least one battery may be rechargeable. While a direct connection may be used to recharge the at least one battery, such a configuration may be rather invasive to the patient. Accordingly, a wireless (e.g., inductive) recharging capability may be more desirable and far less invasive to the patient. In some embodiments, utilizing the at least one battery, the at least one battery may not be rechargeable. When the at least one battery is non-rechargeable, it may be desirable to use at least one battery having a lifetime at least as long as the expected remaining lifetime of the patient to avoid needing to replace the at least one battery during a patient's later years when surgical procedures may be more challenging.

(43) FIG. **3** is a partial cross-sectional view of an example left atrial appendage **50**, which may be attached to and in fluid communication with a left atrium **60** of a heart of a patient. In some

patients, the left atrial appendage **50** may have a complex geometry and/or irregular surface area. Skilled artisans will recognize that the illustrated left atrial appendage is merely one of many possible shapes and sizes for the left atrial appendage **50**, which may vary from patient to patient. Skilled artisans will also recognize that the medical devices, systems, and methods disclosed herein may be adapted for various sizes and shapes of the left atrial appendage **50**, as necessary. The left atrial appendage **50** may include a generally longitudinal axis arranged along a depth of a main body **52** of the left atrial appendage **50**. The main body **52** may include a wall **54** and an ostium **56** forming a proximal mouth **58**. In some embodiments, a lateral extent of the ostium **56** and/or the wall **54** may be smaller or less than a depth of the main body **52** along the longitudinal axis, or a depth of the main body **52** may be greater than a lateral extent of the ostium **56** and/or the wall **54**. In some embodiments, the left atrial appendage **50** may include a tail-like element associated with a distal portion of the main body **52**, which element may protrude radially or laterally away from the main body **52**.

(44) As shown in FIG. **3**, the implantable device **100** may be implanted within the ostium **56** of the left atrial appendage **50** to close off the proximal mouth **58** and substantially and/or completely sealing off the left atrial appendage **50** from the left atrium **60** and/or the patient's circulatory system. As noted herein, the sensor module **140** may face toward the left atrium **60** when implanted within the ostium **56** of the left atrial appendage **50**. In at least some embodiments, the sensor module **140** may include a pressure sensor configured to sense fluid pressure within the left atrium **60** (e.g., left atrial pressure) when the implantable device **100** is disposed within the ostium **56** of the left atrial appendage **50** in the released configuration.

(45) The expandable framework **110** may be compliant and substantially conform to and/or be in sealing engagement with the shape and/or geometry of the wall **54** and/or the ostium **56** of the left atrial appendage **50** in the expanded deployed configuration. In some embodiments, the implantable device **100** may expand to a size, extent, or shape less than or different from a maximum unconstrained extent, as determined by the surrounding tissue, the wall **54**, and/or the ostium **56** of the left atrial appendage **50**. In some embodiments, reducing a thickness of various elements of the expandable framework **110** may increase the flexibility and compliance of the expandable framework **110** and/or the implantable device **100**, thereby permitting the expandable framework **110** and/or the implantable device **100** to conform to the tissue around it, rather than forcing the tissue to conform to the expandable framework **110** and/or the implantable device **100**.

(46) FIG. **4** illustrates aspects of a medical system for monitoring a left atrial pressure within a heart of a patient. The medical system may include the implantable device **100**, which may be implanted within the left atrial appendage **50** of the heart of the patient **10**, and an external component **200** configured to communicate wirelessly with the implantable device **100**. In some embodiments, the external component **200** may be a handheld device. In some embodiments, the external component **200** may be a portable device. In some embodiments, the external component **200** may be a user-worn device. In some embodiments, the external component **200** may be a fixed device (e.g., attached to a table, chair, or other fixture). In some embodiments, the external component **200** may be configured to communicate with a computer, a network, and/or a data storage unit. In some embodiments, the external component **200** may be configured to communicate with the computer, the network, and/or the data storage unit via a wired connection (e.g., ethernet, etc.). In some embodiments, the external component **200** may be configured to communicate with the computer, the network, and/or the data storage unit via a wireless connection (e.g., Wi-Fi, Bluetooth, near-field communication (NFC), etc.). In some embodiments, the external component **200** may include display capabilities including but not limited to built-in display screens, LEDs or indicator lights, analog dials, and/or meters or gauges. In some embodiments, the external component **200** may be connectable to an external display unit.

(47) In some embodiments, the external component **200** may be configured to connect to an external power source (e.g., a wall outlet, a battery, etc.). In some embodiments, the external

component **200** may include an internal power source (e.g., a battery, a capacitor, etc.). In some embodiments, the external component **200** may be configured to send and/or transmit power wirelessly to the implantable device **100** (e.g., via induction, etc.).

(48) In some embodiments, at least one of the implantable device **100** and/or the external component **200** may include a processor configured to create a first trend for the first measurement, as discussed herein. The processor may be configured to use the first trend to modify the first measurement prior to outputting a corrected result. In some embodiments, the processor may be configured to create a second trend for the second measurement. In some embodiments, the processor may be configured to use the first trend and the second trend to modify the first measurement prior to outputting the corrected result. In some embodiments, the processor may be configured to use the first trend to remove drift from the first measurement prior to outputting the corrected result. In some embodiments, the processor may be configured to use the second trend to correct the first measurement for drift.

(49) In an alternative configuration, the medical system may include a second medical device **190** configured to be in contact with a body of the patient **10**. In some embodiments, the second medical device **190** may be a second implantable device. In some embodiments, the second medical device **190** may be disposed on and/or mounted to the skin of the patient. In some embodiments, the second medical device **190** may be a second external component. In some embodiments, the second medical device **190** may be a portable device and/or a handheld device. The second medical device **190** may be configured to communicate wirelessly with the implantable device **100** and/or the external component **200**. In some embodiments, the second medical device **190** may include the second sensor **160**. As such, the second medical device **190** may be configured and/or used to detect the second measurement when the second medical device **190** is in contact with the body of the patient **10**.

(50) Pressure sensors can lose calibration over time due to one or more reasons. For example, sensor element aging and/or advancing physiological effects (such as tissue growth) may affect the calibration of the pressure sensor causing the pressure measurement to be less accurate. In some cases, sensor drift may be a slowly occurring phenomenon over the course of several months to years. As a result of this, the need for recalibration may not be apparent. Clinical action and/or treatments based on inaccurate pressure measurements may be a hazard to the patient. However, calibration drift generally occurs along a predictable profile, and the prediction may be made using and/or based on both pre-implant and post-implant data. FIG. **5** illustrates several different drift profiles that may identified and/or predicted. Generally speaking, the drift trend profile may be a linear trend **302**, an exponential trend **304**, a logarithmic trend **306**, or a combination trend **308** combining two or more of these trends.

(51) Left atrial pressure changes due to most physiological events (e.g., heart failure, etc.) are irregular, which is related to nonpredictable events. As shown in FIG. **6**, stable heart function may follow along a generally steady trend and/or within a reasonable and/or stable range illustrated at reference number **312**. Even if the heart and/or the heart function is not necessarily healthy, the left atrial pressure will typically remain within the reasonable and/or stable range. However, left atrial pressure will be particularly elevated many days before a heart failure event. Thus, acute heart failure exacerbations or events, as shown at reference number **314**, may be identifiable or predicted by measurements that are outside of the stable range indicated at reference number **312**. It is noted that other physiological events (e.g., atrial fibrillation, valvular disease, etc.) may also affect left atrial pressure, and may in at least some instances be shown or manifested as a left atrial pressure exacerbation or event (e.g., reference number **314**).

(52) FIGS. **7**A and **7**B illustrate examples of the first measurement (e.g., left atrial pressure) charted over time to illustrate drift in the first sensor. The figures show the first measurement **320** and an associated drift trend profile. As shown in FIG. **7**A, the first measurement **320** is slowly increasing over time, wherein the first measurement **320** is increasing along the linear trend **302**. Using the

actual data for the first measurement **320** and the linear trend **302**, a predicted first measurement **322** may be identified along the expected and/or predicted linear trend **303** by extrapolating past sensor measurements and/or using pre-implant sensor characterization. Similarly, the first measurement **320** in FIG. **7**B is increasing along the exponential trend **304**. Again, using the actual data for the first measurement **320** and the exponential trend **304**, a predicted first measurement **322** may be identified along the expected and/or predicted exponential trend **305** by extrapolating past sensor measurements and/or using pre-implant sensor characterization.

(53) FIG. **8** illustrates aspects or elements of the first measurement. As shown in FIG. **8**, the first sensor **150** may detect a pressure signal **400** within a pressure sensor frequency range. As such, the pressure signal **400** may be used interchangeably with the first measurement. The pressure signal **400** and/or the pressure sensor frequency range may generally extend from a constant signal (DC) over a time scale of months or years to a frequency of about 10.sup.2 Hertz (Hz) over a time scale of milliseconds (msec). In some embodiments, the pressure signal **400** and/or the pressure sensor frequency range may extend to a frequency over 10.sup.2 Hz. Within the pressure signal **400** and/or the pressure sensor frequency range, there are two frequency bands of interest with respect to the left atrial pressure. The low frequency signal of interest **402** relates and/or corresponds to average filling pressure of the left ventricle and extends from about 10.sup.−7 Hz to about 10.sup.−4 Hz. The low frequency signal of interest **402** is slow and occurs over a relatively long period of time (e.g., days, weeks, months, years, etc.) and represented by for example the mean left atrial pressure per day. The high frequency signal of interest **406** relates and/or corresponds to cardiac and respiration morphology and extends from about 10.sup.−1 Hz to about 10.sup.2 Hz. The high frequency signal of interest **406** is faster and occurs over a relatively short period of time (e.g., seconds, fractions of second, within a single heartbeat, within a single respiratory cycle, etc.) and represented by the left atrial pressure real-time morphology. Between the low frequency signal of interest **402** and the high frequency signal of interest **406** is signal **404**, extending from about 10.sup.−4 Hz to about 10.sup.−1 Hz. Signal **404** may be filtered out if there is substantial energy within it. Alternatively signal **404** may be ignored if its energy is low enough such that it does not interfere with measurement of the low frequency signal of interest **402** and the high frequency signal of interest **406**.

(54) The pressure signal **400** and/or the pressure sensor frequency range of the first sensor **150** may also include a drift value **408**. The drift value **408** has very low frequency content extending from about 10.sup.−7 Hz down to DC. However, the lower edge F**1** of the low frequency signal of interest **402** is not precisely known because it may vary due to characteristics of individual patients (no two patients are exactly the same). Additionally, the upper edge F**2** of the drift value **408** are not precisely known because it is sensor dependent. In some embodiments, the lower edge F**1** and the upper edge F**2** may overlap (e.g., the low frequency signal of interest **402** may overlap the drift value **408**), as shown in FIG. **8**, the lower edge F**1** and the upper edge F**2** may abut at and/or share a common frequency (e.g., the low frequency signal of interest **402** may abut the drift value **408**), or the lower edge F**1** and the upper edge F**2** may underlap or be spaced apart (e.g., there could be a frequency gap between the low frequency signal of interest **402** and the drift value **408**).

(55) As discussed herein, the second sensor **160** may be an accelerometer configured to detect a raw signal of the third heart sound (S3). The raw signal of the third heart sound (S3) may be used to produce, create, and/or determine an S3 signal **410**, which may be measured periodically (e.g., weekly, daily, hourly, etc.) using the second sensor **160**. The raw signal of the third heart sound (S3) may be comprised of frequencies between about 10 Hz and 50 Hz. An average amplitude of the above frequency contents of the raw signal of the third heart sound (S3) corresponds to how "loud" the raw signal of the third heart sound (S3) is and may be used to determine the S3 signal **410**. The average amplitude of the S3 signal **410** has a frequency of about 10.sup.−4 Hz or less. The S3 signal **410** may generally extend from a constant signal (DC) over a time scale of months or years to a frequency of about 10.sup.−4 Hertz (Hz) over a time scale of hours. In some

embodiments, the S3 signal **410** may extend to a frequency over 10.sup.−4 Hz. The S3 signal **410** is correlated to the low frequency signal of interest **402** from the first sensor **150**, especially when left atrial pressure is elevated. As discussed herein, the same physiological conditions that cause elevated left atrial pressure also cause the third heart sound (S3). Therefore, as heart illnesses advance, the third heart sound (S3), which is generally not present or is undetectable in healthy patients, gets louder.

(56) However, the second sensor **160** and/or the accelerometer may be less accurate when used as a surrogate for left atrial pressure, because the second sensor **160** and/or the accelerometer may register larger spikes and/or valleys in the raw signal of the third heart sound (S3) than the first sensor **150** registers for the left atrial pressure, and/or the second sensor **160** and/or the accelerometer may register spikes when the left atrial pressure does not spike and the second sensor **160** and/or the accelerometer may fail to register spikes when the left atrial pressure does spike, as shown in FIG. **9**. As such, the S3 signal **410** may exhibit greater variation in amplitude than the pressure signal from the first sensor **150**. Comparing the graph of FIG. **9** to the graph of FIGS. **7**A and **7**B may further illustrate the less accurate nature of the S3 signal **410**. One benefit of using the S3 signal **410** is that the S3 signal **410** may be inherently immune to the same type of drift experienced by the first sensor **150** (e.g., the pressure sensor). The second sensor **160** and/or the accelerometer may be used to detect the second measurement (e.g., the third heart sound (S3)) by detecting vibration and/or sound, and the value of the second measurement (e.g., the third heart sound (S3)) may be proportional to the intensity of the vibration and/or sound (e.g., the average amplitude).

(57) The second measurement and/or the S3 signal **410** may be used to create a second trend **412**, which may be and/or reflect a mean value for the S3 signal **410**. The S3 signal **410** may correlate to the first measurement, the pressure signal **400**, and/or the second trend **412** may correlate to the first trend (e.g., linear trend **302**, exponential trend **304**, etc.). Therefore, the second measurement and/or the S3 signal **410** may serve as a surrogate for the first measurement (e.g., the pressure signal **400**). Additionally, using the actual data for the S3 signal **410** and the second trend **412**, a predicted second trend **413** may be identified by extrapolating past sensor measurements and/or using pre-implant sensor characterization.

(58) In some embodiments, the second trend **412** may be generally flat and/or constant, as shown in FIG. **9** for example, thus indicating that the second measurement and/or the S3 signal **410** contains no drift. The lack of drift in the second measurement makes the second measurement and/or the S3 signal **410** a good choice for verifying and/or correcting the first measurement for drift. However, the S3 signal **410** cannot capture the high frequency signal of interest **406** (e.g., FIG. **8**) and may provide poorer prediction of heart function and/or possible heart failure. As such, the second measurement and/or the S3 signal **410** may not be a good standalone choice for detecting, measuring, and/or deriving left atrial pressure as a means to monitor heart function and/or to predict heart failure.

(59) In some embodiments, the second trend **412** may be angled or sloped (e.g., may not be flat or may not have a slope of zero). This does not indicate drift in the second measurement and/or the second sensor **160**. Instead, as some physiological conditions advance and/or deteriorate, the first measurement and the second measurement may both trend in a similar direction (e.g., upward, downward, etc.). As such, in order to remove drift from the first measurement, a slope of the first trend may be compared to a slope of the second trend **412**. Differences in slope between the first trend and the second trend **412** may illustrate and/or may equate to drift in the first measurement. Accordingly, the first trend and/or the second trend **412** may be used to modify the first measurement affected by drift (e.g., FIGS. **7**A, **7**B) to output a corrected result, shown in FIG. **10**. For example, if the first trend is known, calculated, and/or predicted from past and/or current values/measurements, the first measurement may be modified using the first trend to produce the corrected result. In another example, if the second trend **412** is flat, the first trend may be simply

removed from the first measurement to produce the corrected result. In still another example, if the first trend and the second trend **412** both slope in the same direction at the same value, physiological changes and/or deterioration can be assumed to be present, and no drift has occurred. In yet another example, if the first trend and the second trend **412** both slope in the same direction at different values, drift has occurred in the first measurement and/or the first sensor **150**. In this example, the difference between the slope of the first trend and the slope of the second trend indicates and/or corresponds to drift. As such, the first measurement may be modified to remove the drift profile and/or to follow the slope of the second trend **412**, thereby removing drift to produce and/or output the corrected result shown in FIG. **10**, which more accurately reflects the true left atrial pressure.

(60) FIG. **11** illustrates aspects of a method of autonomous recalibration of a pressure sensor used to detect the left atrial pressure within the heart of the patient. As discussed herein, the S3 signal **410** may be used to remove the drift value **408** (e.g., FIG. **8**) and/or the first trend from the first measurement and/or the pressure signal **400**. In some embodiments, the method may include detecting signals of the left atrial pressure (e.g., the first measurement and/or the pressure signal **400**) using the first sensor **150** coupled to the expandable framework **110**, the expandable framework **110** being implantable within the left atrial appendage **50** (e.g., FIG. **3**) of the heart of the patient. During initial implantation of the implantable device **100**, the first sensor **150** and/or the second sensor **160** may be calibrated and/or a calibration value may be saved within the relative sensor and/or the within the processor (or a data storage unit associated therewith). The calibration value of the first sensor **150** and/or the second sensor **160** may be used to establish the drift value and/or to determine a need for recalibration of the first sensor **150**. The method may include using the signals of the left atrial pressure (e.g., the first measurement and/or the pressure signal **400**) to establish a first trend of the left atrial pressure with the processor.

(61) The method may include detecting signals of the third heart sound (S3) from the heart of the patient using the second sensor **160** coupled to the expandable framework **110**. The method may include using the signals of the third heart sound (S3) to establish a second trend of the third heart sound (S3) with the processor. The method may further include comparing the first trend of the left atrial pressure to the second trend of the third heart sound (S3) with the processor to determine if the first sensor **150** is experiencing drift. The method may then use the second trend of the third heart sound (S3) to correct and/or modify the first trend of the left atrial pressure to remove the drift with the processor. The method may subsequently output a corrected trend and/or a correct first measurement of the left atrial pressure devoid of the drift.

(62) In some embodiments, comparing the first trend of the left atrial pressure to the second trend of the third heart sound (S3) may include comparing the slope of the first trend of the left atrial pressure to the slope of the second trend of the third heart sound (S3). In some embodiments, using the second trend of the third heart sound (S3) to correct and/or modify the first trend of the left atrial pressure to remove the drift includes subtracting a difference between the slope of the second trend of the third heart sound (S3) and the slope of the first trend of the left atrial pressure from the first trend of the left atrial pressure. In some embodiments, when the drift exceeds a predetermined limit and/or when the slope of the first trend of the left atrial pressure exceeds the slope of the second trend of the third heart sound (S3) by a predetermined value, the method may further include issuing a warning (to and/or via the external component **200**, for example) to manually recalibrate the first sensor **150**.

(63) In some embodiments, determining if the first sensor **150** is experiencing drift, and/or what the amount of drift is, takes place via signal processing within the processor. The first measurement and/or the pressure signal **400** may be separated into a low frequency pressure signal **426** (e.g., the low frequency signal of interest **402** plus the drift value **408**) by a low pass filter **424** and the high frequency signal of interest **406** by a high pass filter **420**. The second measurement and/or the S3 signal **410** may be compared to a stored S3 calibration value **432** for the second sensor **160** to

determine the slope of the second trend **412** of the S3 signal **410**. A stored pressure calibration value **430** for the first sensor **150** may then be modified by the slope of the second trend **412** of the S3 signal **410** to determine an expected low frequency pressure signal **450** (e.g., the low frequency signal of interest **402**). The expected low frequency pressure signal **450** may then be used by the processor to determine a corrected left atrial pressure **460** and/or an actual drift value **470**. In some embodiments, the actual drift value **470** may correspond to and/or may be the drift value **408** in the first measurement. The corrected left atrial pressure **460** may be determined by adding the high frequency signal of interest **406** and the expected low frequency pressure signal **450**, as shown in FIG. **11**. The actual drift value **470** may be determined by subtracting the expected low frequency pressure signal **450** from the low frequency pressure signal **426**. In some embodiments, the actual drift value **470** may then be compared to the predetermined limit by the processor to determine if a warning should be issued to manually recalibrate the first sensor **150**. As may be seen from the signal processing shown in FIG. **11**, the high frequency signal of interest **406** does not drift. Drift is a gradual signal degradation that only presents itself within the low frequency signal of interest **402**.

(64) In an alternative configuration, a method and medical system for monitoring the left atrial pressure in the heart of the patient may include using a signal filter having a signal cutoff frequency **428** of about 10.sup.−7 Hz, as shown in FIG. **12**. In such a configuration, the medical system may include the implantable device **100** including the expandable framework **110** and the first sensor **150** secured to the expandable framework **110**, and the external component **200** configured to communicate wirelessly with the implantable device **100**. The first sensor **150** may be configured to detect the first measurement (e.g., the pressure signal **400**). In at least some embodiments, the first sensor **150** may be a pressure sensor and the first measurement may be the left atrial pressure. The medical system may further include a processor and the signal filter. The signal filter may be used by the processor to modify the first measurement (e.g., the pressure signal **400**) prior to outputting a corrected result (e.g., the corrected left atrial pressure **460**).

(65) In some embodiments, the signal filter may be a low pass filter configured to create a signal representative of drift in the first measurement. The low pass filter only permits the drift value **408** of the pressure signal **400** (e.g., a portion of the pressure signal **400** below the cutoff frequency **428**) to pass through. As such, the portion of the pressure signal **400** below the cutoff frequency **428** may be considered to be the signal representative of drift (e.g., the drift value **408**) in the first measurement. The processor may be configured to subtract the signal representative of drift (e.g., the drift value **408**) in the first measurement from the first measurement (e.g., the pressure signal **400**) to produce the corrected result (e.g., the corrected left atrial pressure **460**) devoid of drift, as shown in FIG. **13**.

(66) In some embodiments, the signal filter may be a high pass filter configured to remove a portion of the first measurement corresponding to drift (e.g., a portion of the pressure signal **400** below the cutoff frequency **428**) in the first sensor **150** to produce the corrected result (e.g., the corrected left atrial pressure **460**). The high pass filter only permits the portion of the pressure signal **400** above the cutoff frequency **428** to pass through. As such, the portion of the pressure signal **400** below the cutoff frequency **428**, which consists primarily or entirely of drift, may be removed from the first measurement (e.g., the pressure signal **400**) to produce the corrected result (e.g., the corrected left atrial pressure **460**) devoid of drift, as shown in FIG. **14**.

(67) The materials that can be used for the various components of the medical system and the various elements thereof disclosed herein may include those commonly associated with medical devices. For simplicity purposes, the following discussion refers to the medical system. However, this is not intended to limit the devices and methods described herein, as the discussion may be applied to other elements, members, components, or devices disclosed herein, such as, but not limited to, the external component **200**, the second medical device **190**, the delivery device, the implantable device **100**, the expandable framework **110**, the occlusive element **120**, the proximal

hub **130**, the sensor module **140**, the first sensor **150**, the second sensor **160**, the signal filter, and/or elements or components thereof.

(68) In some embodiments, the medical system and/or components thereof may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material.

(69) Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), MARLEX® high-density polyethylene, MARLEX® low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly praraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-b-isobutylene-b-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, polyurethane silicone copolymers (for example, ElastEon® from Aortech Biomaterials or ChronoSil® from AdvanSource Biomaterials), biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

(70) Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; platinum; palladium; gold; combinations thereof; or any other suitable material.

(71) In some embodiments, a linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

(72) In at least some embodiments, portions or all of the medical system and/or components

thereof, may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of the medical system in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of the medical system to achieve the same result.

(73) In some embodiments, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the medical system and/or other elements disclosed herein. For example, the medical system and/or components or portions thereof may be made of a material that does not substantially distort the image and create substantial artifacts (i.e., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The medical system or portions thereof may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nitinol, and the like, and others.

(74) In some embodiments, the medical system and/or other elements disclosed herein may include a fabric material disposed over or within the structure. The fabric material may be composed of a biocompatible material, such a polymeric material or biomaterial, adapted to promote tissue ingrowth. In some embodiments, the fabric material may include a bioabsorbable material. Some examples of suitable fabric materials include, but are not limited to, polyethylene glycol (PEG), nylon, polytetrafluoroethylene (PTFE, ePTFE), a polyolefinic material such as a polyethylene, a polypropylene, polyester, polyurethane, and/or blends or combinations thereof.

(75) In some embodiments, the medical system and/or other elements disclosed herein may include and/or be formed from a textile material. Some examples of suitable textile materials may include synthetic yarns that may be flat, shaped, twisted, textured, pre-shrunk or un-shrunk. Synthetic biocompatible yarns suitable for use in the present disclosure include, but are not limited to, polyesters, including polyethylene terephthalate (PET) polyesters, polypropylenes, polyethylenes, polyurethanes, polyolefins, polyvinyls, polymethylacetates, polyamides, naphthalene dicarboxylene derivatives, natural silk, and polytetrafluoroethylenes. Moreover, at least one of the synthetic yarns may be a metallic yarn or a glass or ceramic yarn or fiber. Useful metallic yarns include those yarns made from or containing stainless steel, platinum, gold, titanium, tantalum or a Ni—Co—Cr-based alloy. The yarns may further include carbon, glass or ceramic fibers. Desirably, the yarns are made from thermoplastic materials including, but not limited to, polyesters, polypropylenes, polyethylenes, polyurethanes, polynaphthalenes, polytetrafluoroethylenes, and the like. The yarns may be of the multifilament, monofilament, or spun types. The type and denier of the yarn chosen may be selected in a manner which forms a biocompatible and implantable prosthesis and, more particularly, a vascular structure having desirable properties.

(76) In some embodiments, the medical system and/or other elements disclosed herein may include and/or be treated with a suitable therapeutic agent. Some examples of suitable therapeutic agents may include anti-thrombogenic agents (such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone)); anti-proliferative agents (such as enoxaparin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid); anti-inflammatory agents (such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine); antineoplastic/antiproliferative/anti-mitotic agents (such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors); anesthetic agents (such as lidocaine, bupivacaine, and ropivacaine); anti-coagulants (such as D-

Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, anti-thrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, and tick antiplatelet peptides); vascular cell growth promoters (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters); vascular cell growth inhibitors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin); cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms.

(77) It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The disclosure's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

1. A method of autonomous recalibration of a pressure sensor used to detect a left atrial pressure within a heart of a patient, comprising: detecting signals of the left atrial pressure using a first sensor coupled to an expandable framework, the expandable framework being implantable within a left atrial appendage of the heart of the patient; detecting signals of a third heart sound (S3) from the heart of the patient using a second sensor coupled to the expandable framework; using the signals of the left atrial pressure to establish a trend of the left atrial pressure with a processor; using the signals of the third heart sound to establish a trend of the third heart sound with the processor; comparing the trend of the left atrial pressure to the trend of the third heart sound with the processor to determine if the first sensor is experiencing drift, including comparing a slope of the trend of the left atrial pressure to a slope of the trend of the third heart sound; and using the trend of the third heart sound to correct the trend of the left atrial pressure to remove the drift with the processor; outputting a corrected trend of the left atrial pressure devoid of the drift.

2. The method of claim 1, wherein using the trend of the third heart sound to correct the trend of the left atrial pressure to remove the drift includes subtracting a difference between the slope of the trend of the third heart sound and the slope of the trend of the left atrial pressure from the trend of the left atrial pressure.

3. The method of claim 1, wherein when the drift exceeds a predetermined limit, the method further includes issuing a warning to manually recalibrate the first sensor.

4. The method of claim 1, wherein the first sensor has a first sensing modality and responds to a first set of daily physiological changes of the heart, and the second sensor has a second sensing modality different from the first sensing modality and responds to the first set of daily physiological changes of the heart.