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(54) **HEART IMPLANT WITH SEPTUM GRIPPER**

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A61B 17/00	(2006.01)

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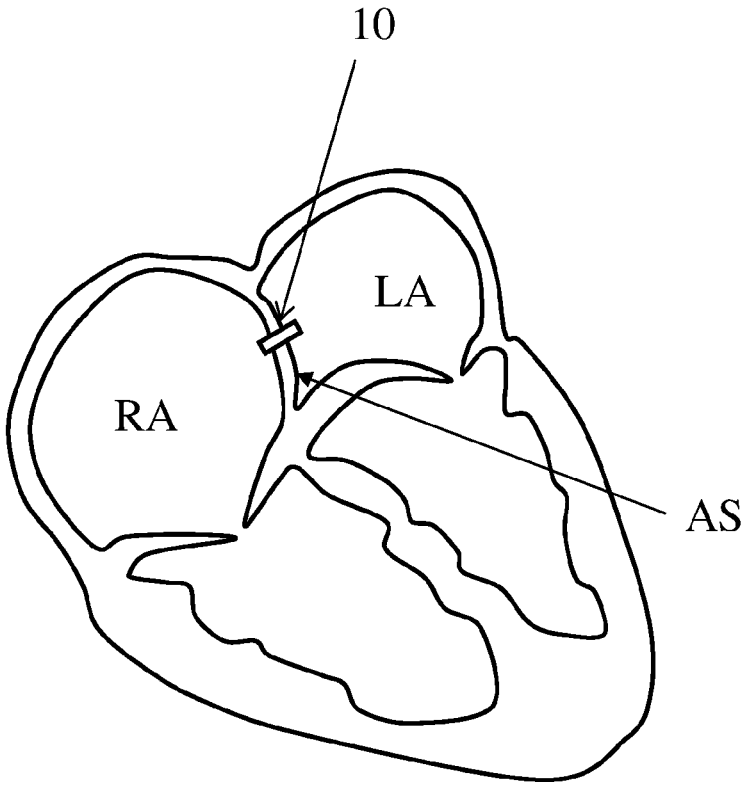
(57) **ABSTRACT**

Implant (e.g., sensory implant) positionable within subject's left heart atrium, for facilitating functional activity thereof, such as sensing or/and measuring physiological conditions or/and parameters. Implant includes: implant body housing physiological parameter sensing or/and measuring means; coupling means for coupling with an implant deployment device; and septum gripper having a flexible gripping sleeve fixedly connected to implant body wall, and selectively shapeable to pass through organ wall septum opening, and for gripping onto organ wall, such that implant body is fixatable or/and stabilizable across organ wall and through septum opening, to facilitate sensing or/and measuring in subject's body organ. Also disclosed are: a system including the implant, a process control unit, and a transcatheter implant deployment device; and an implant for implantation in subject's body organ separated by an organ wall, and configured for inductive coupling with electronic unit located outside subject's body and for interactively communicating with electronic unit.



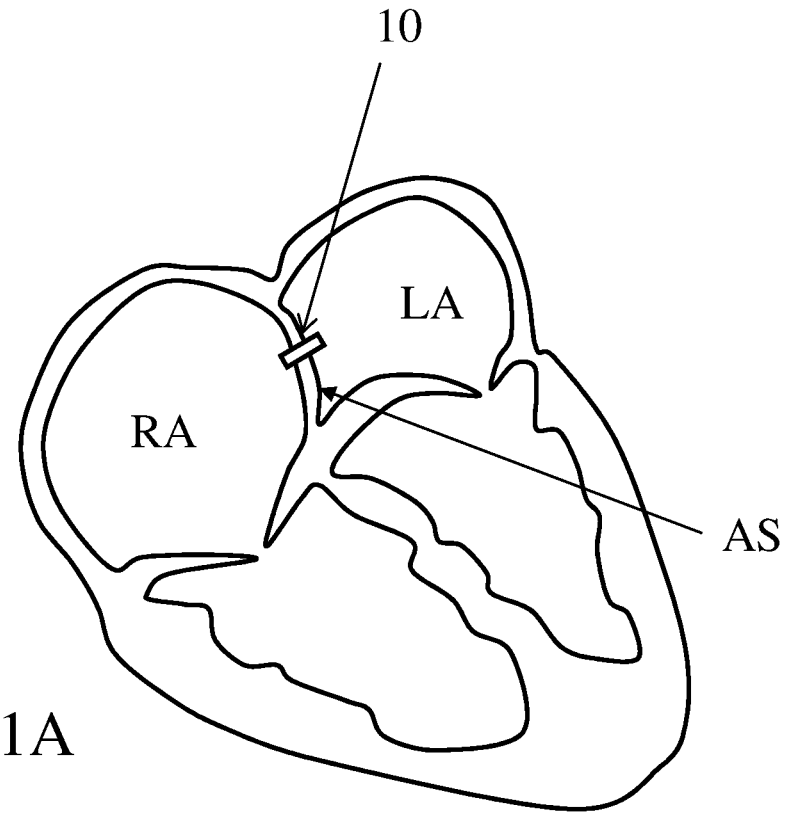


FIG. 1A

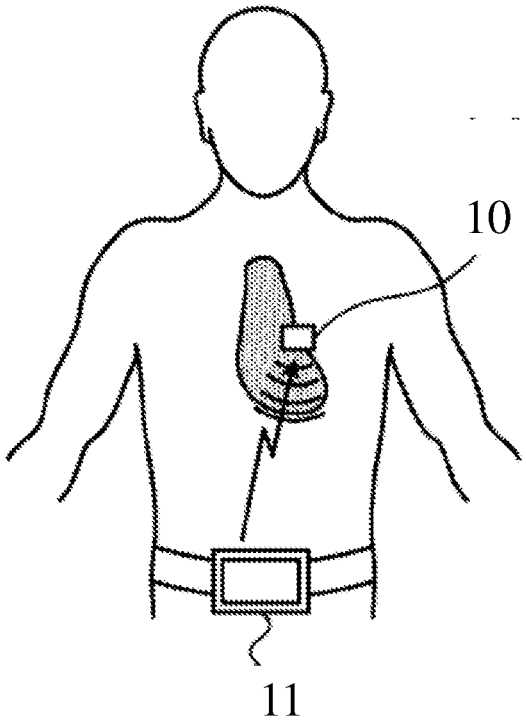


FIG. 1B

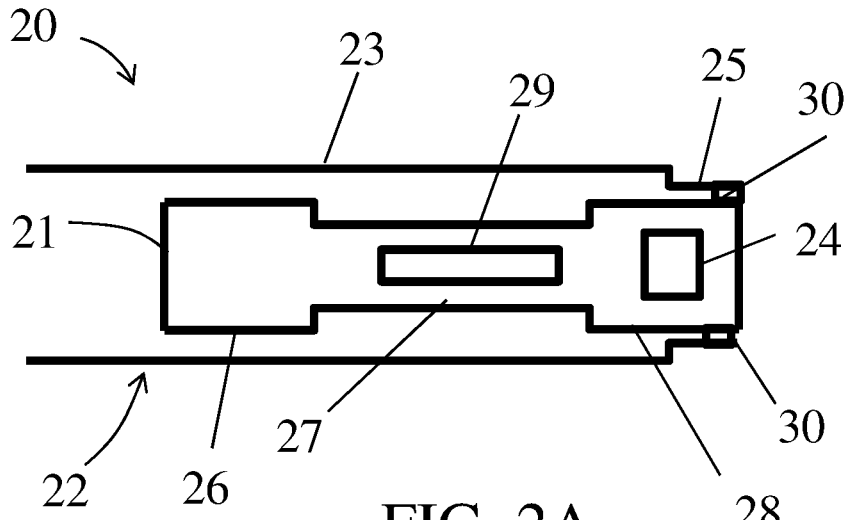

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FIG. 2A

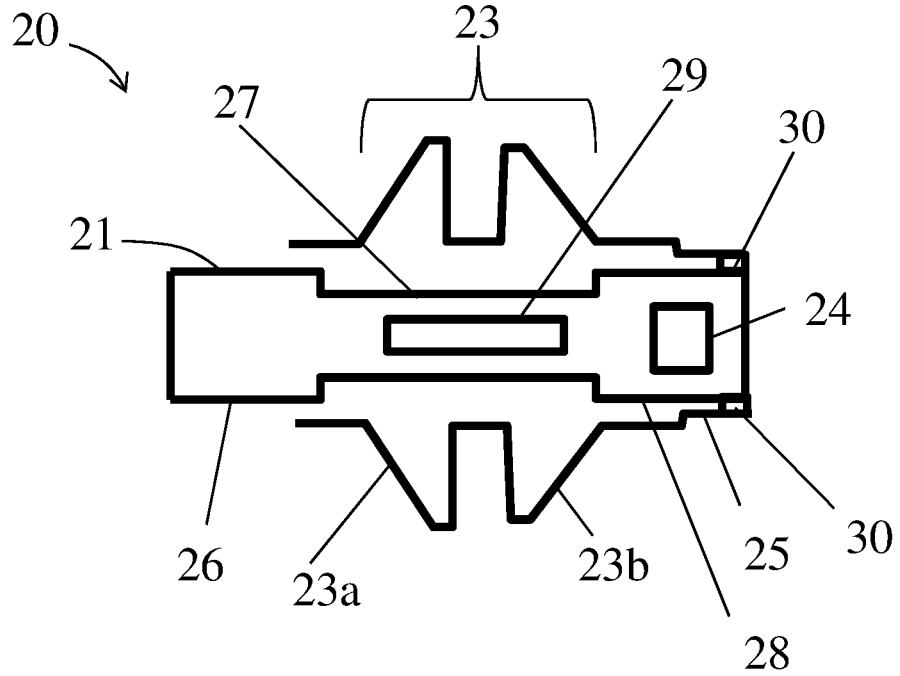
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FIG. 2B

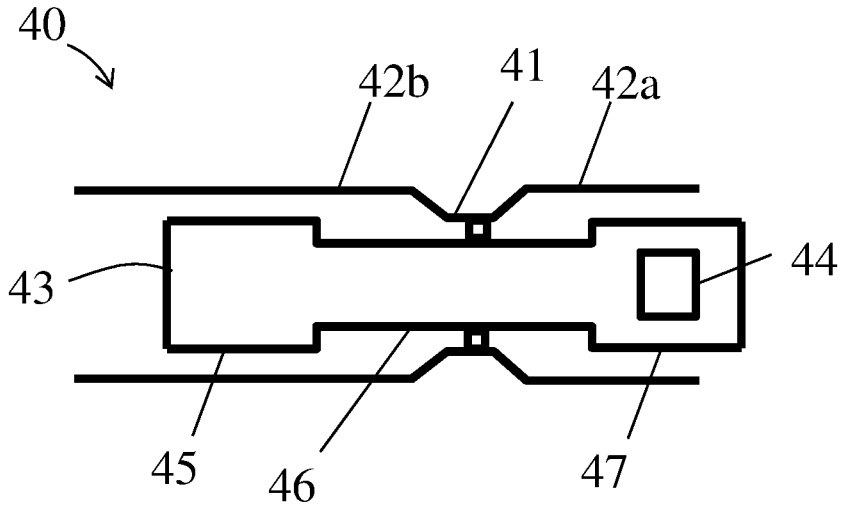

FIG. 3A

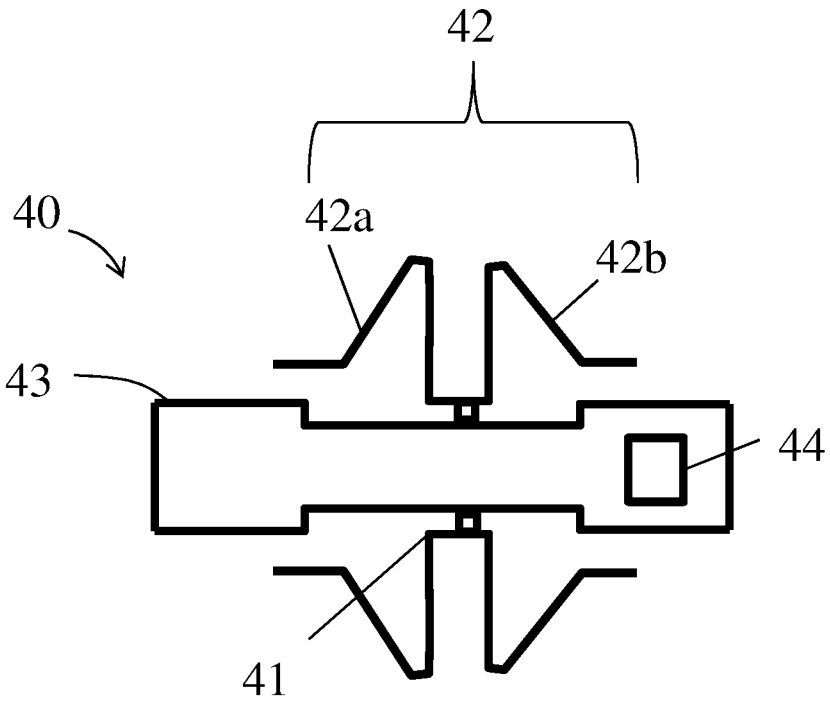

FIG. 3B

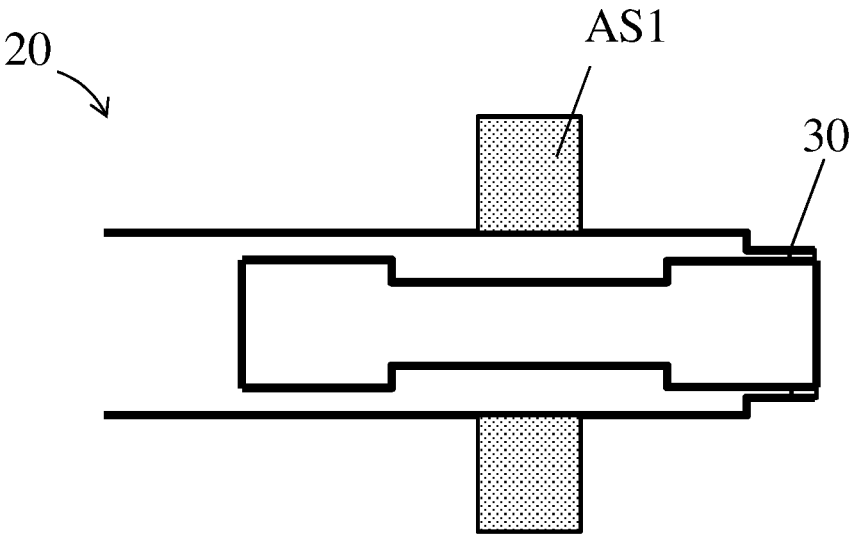

FIG.4A

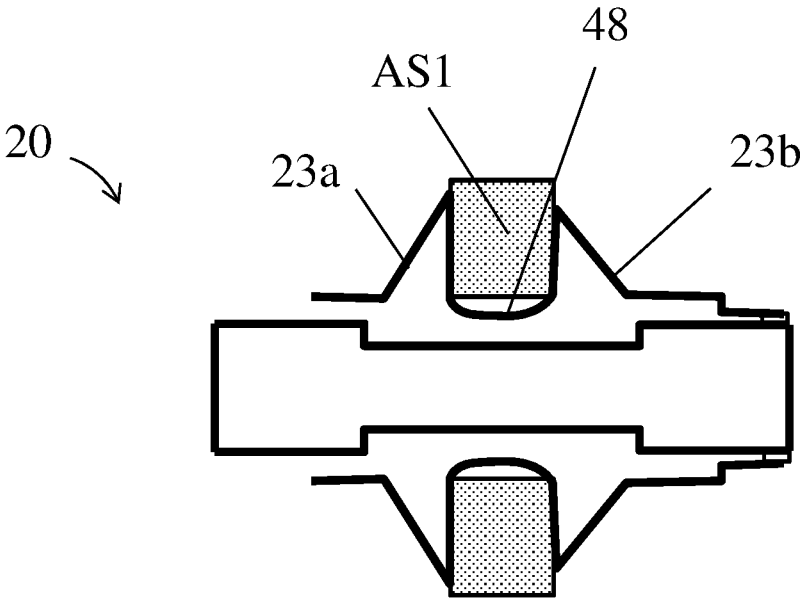

FIG. 4B

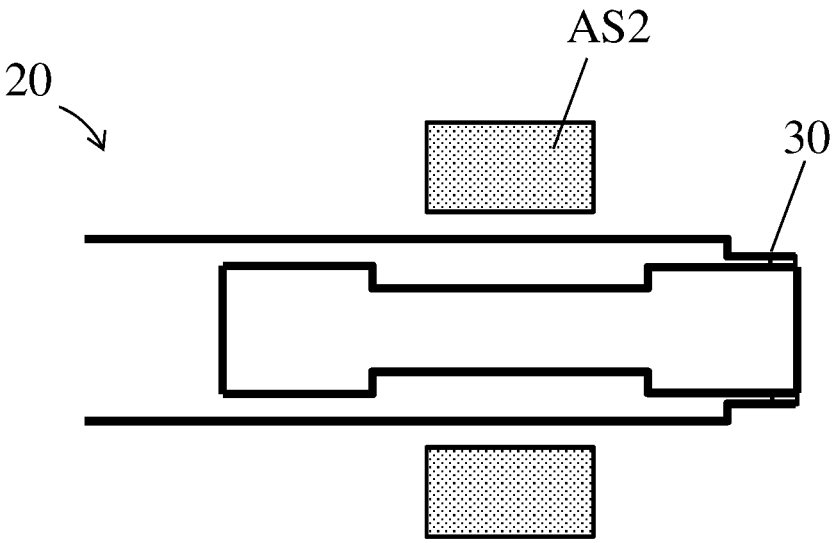

FIG. 5A

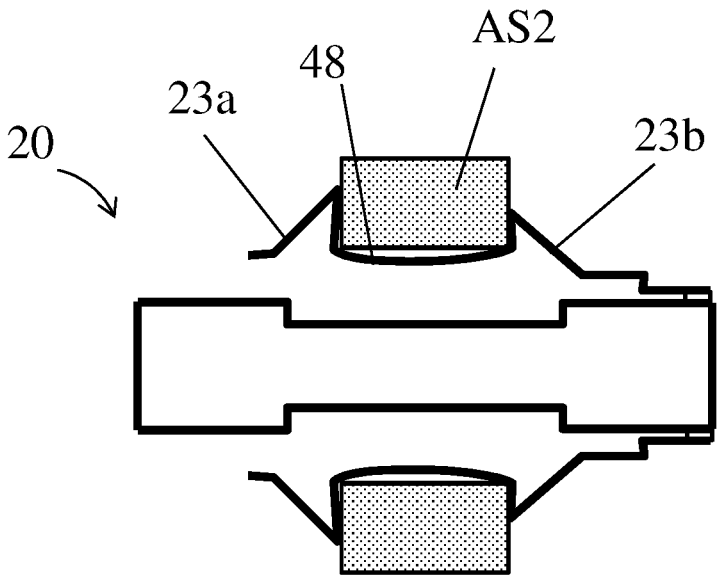

FIG. 5B

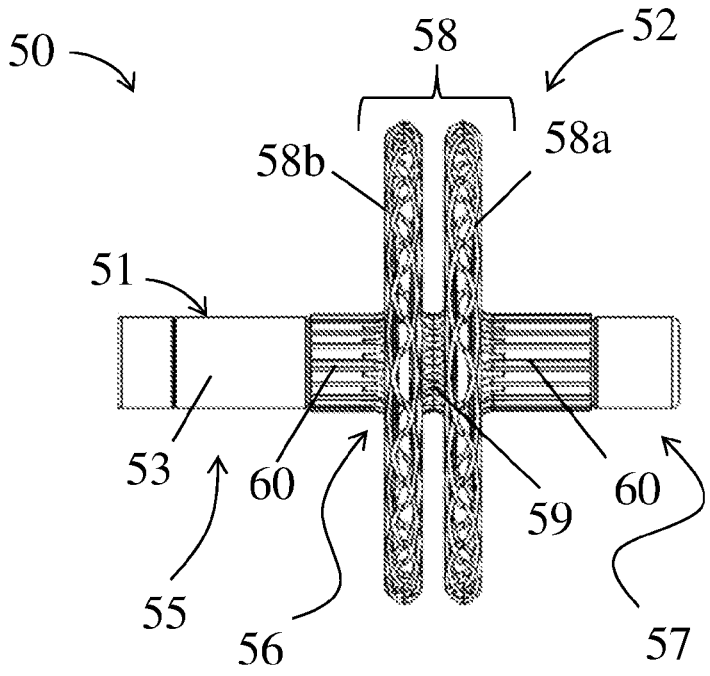

FIG. 6A

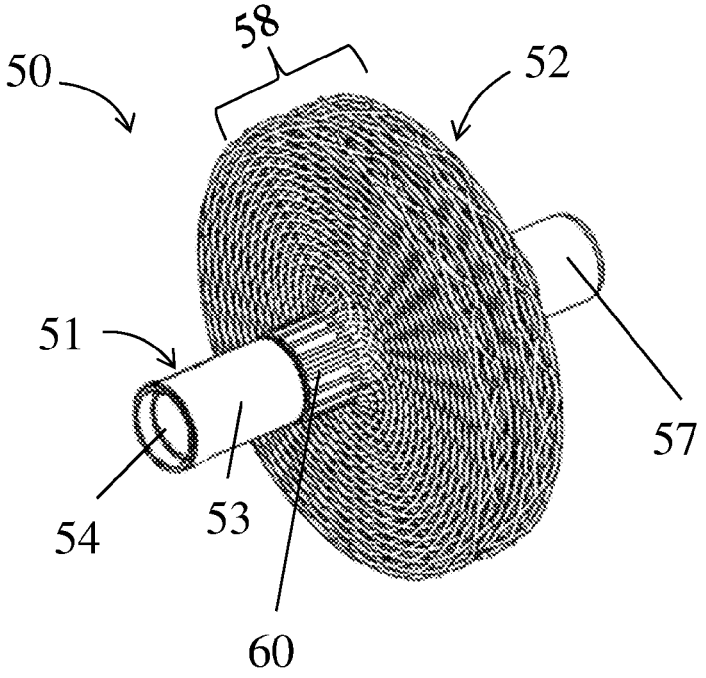

FIG. 6B

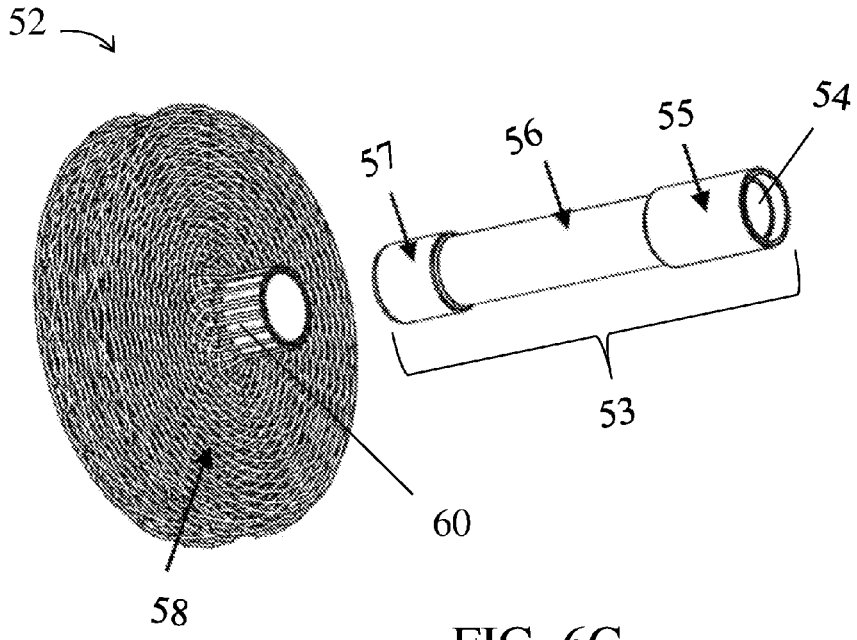

FIG. 6C

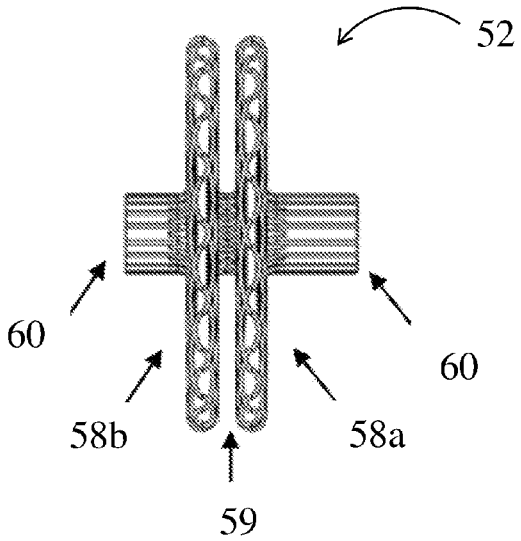

FIG. 6D

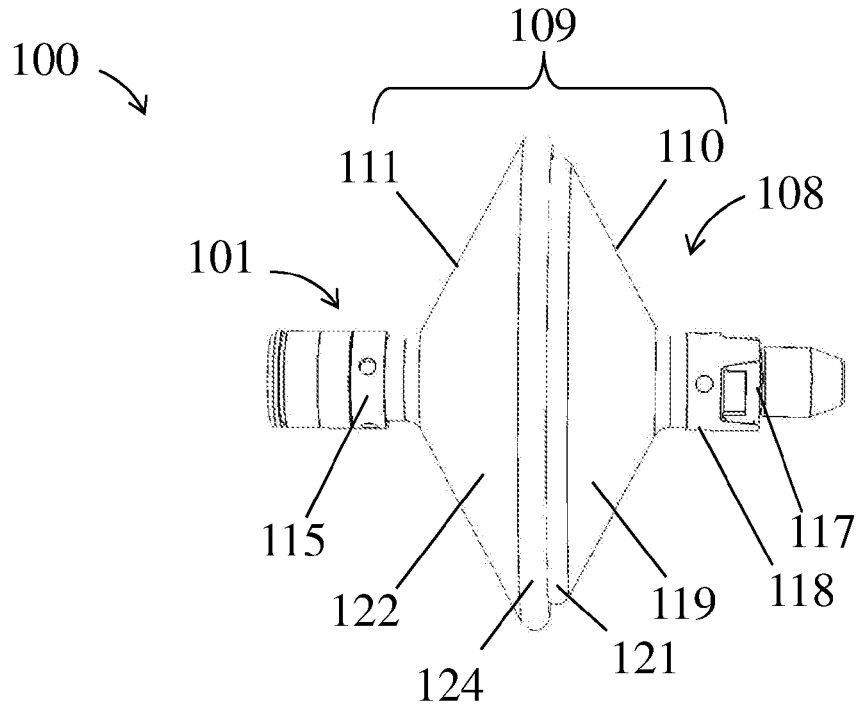
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FIG. 7A

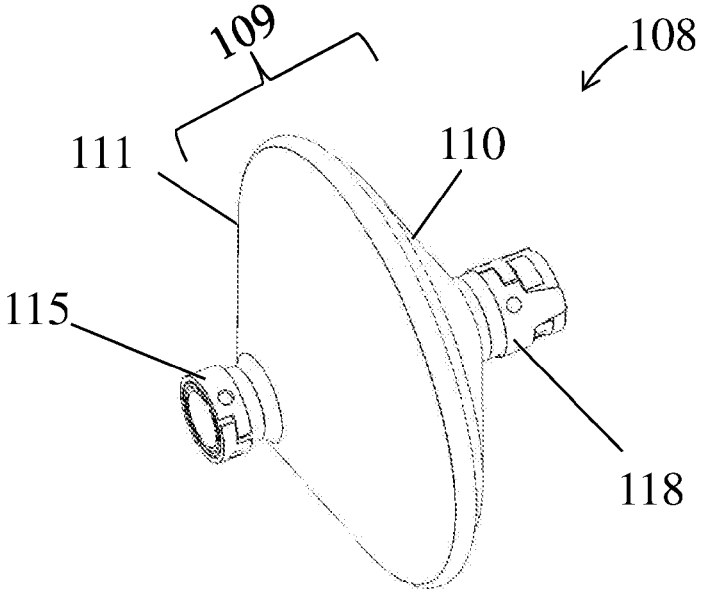
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FIG. 7B

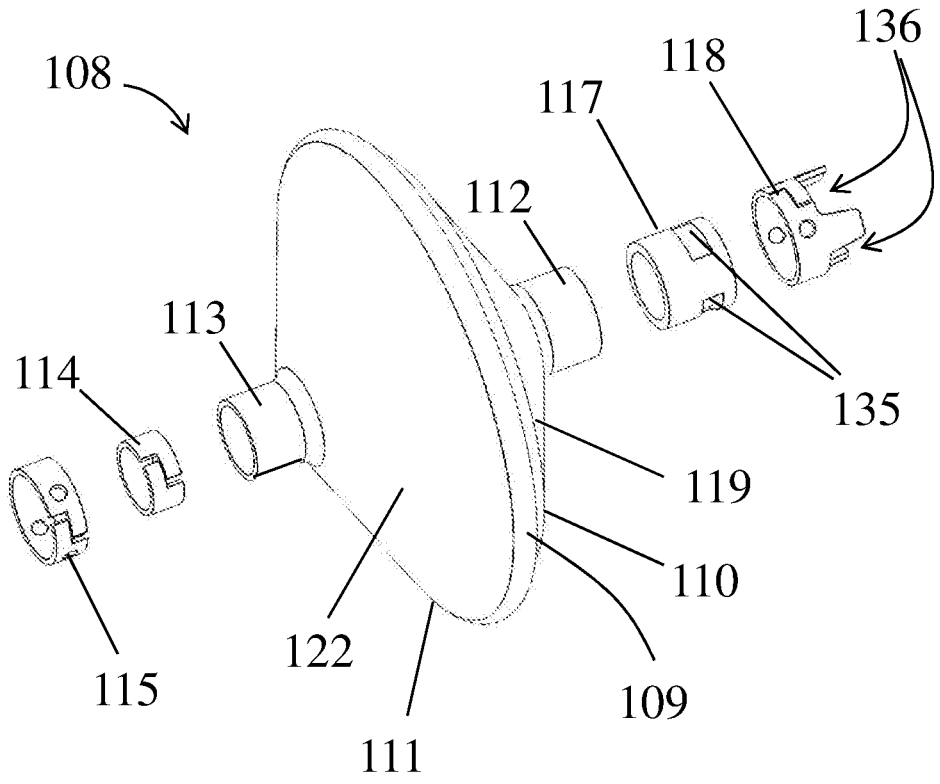

FIG. 7C

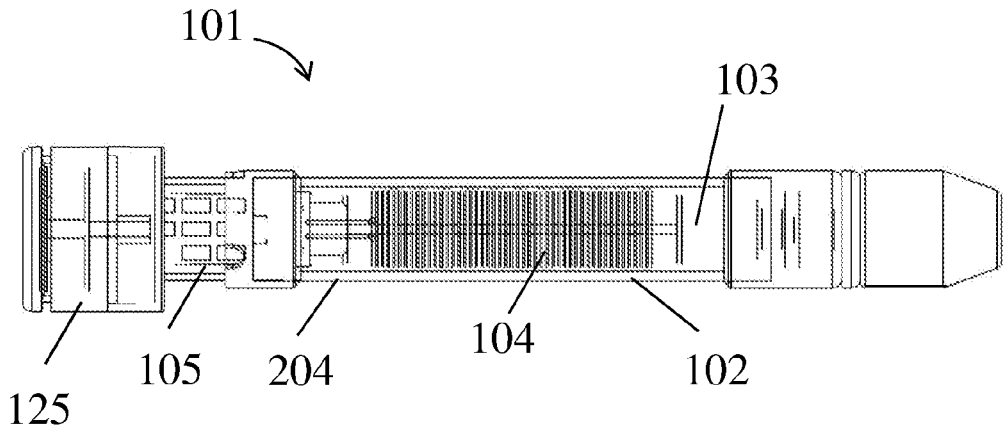
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FIG. 7D

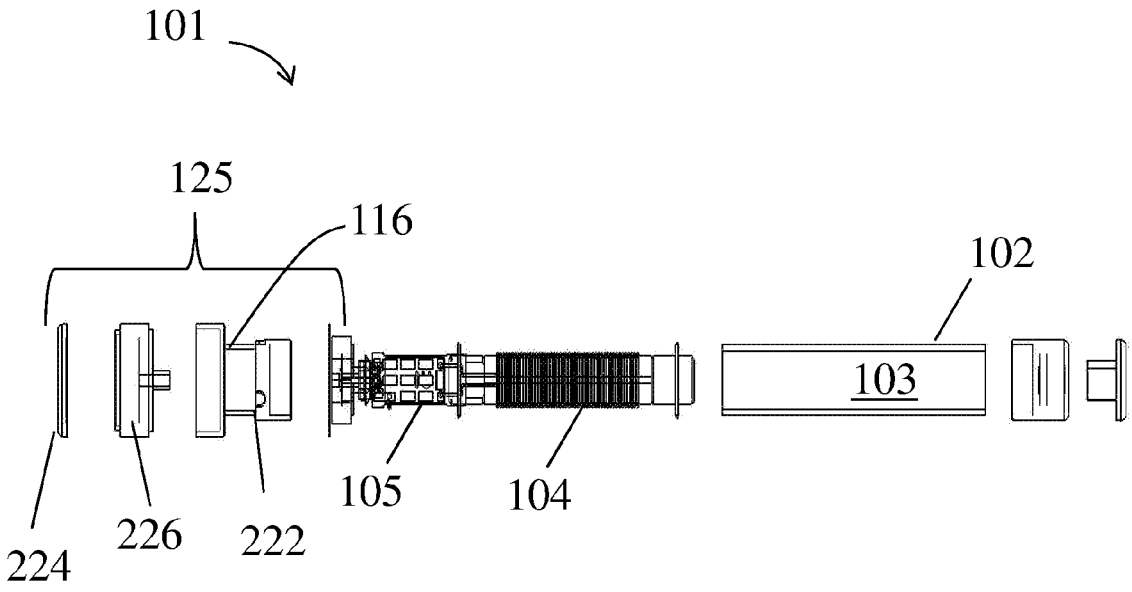
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FIG. 7E

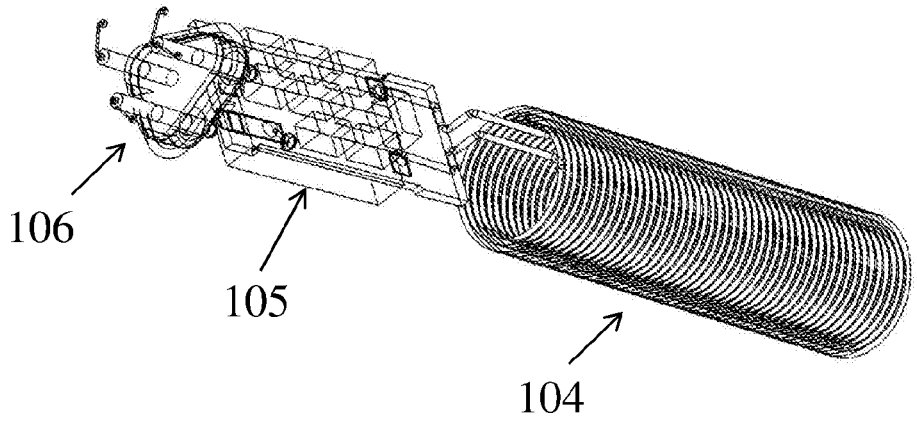

FIG. 7F

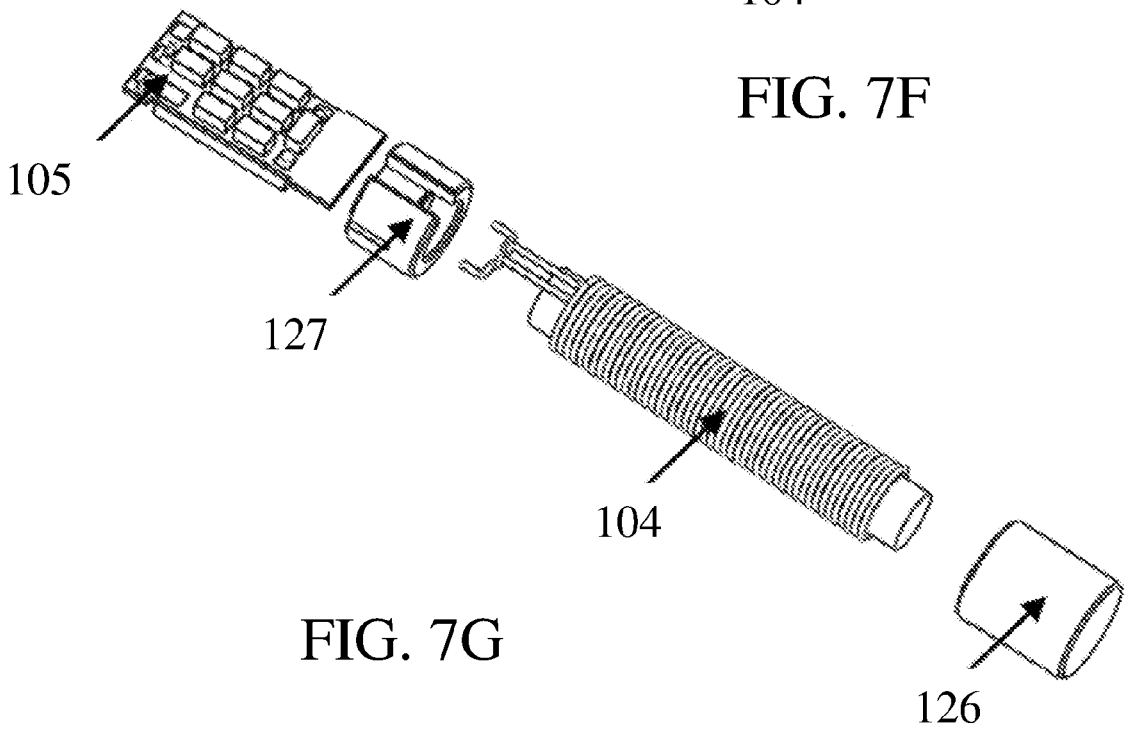

FIG. 7G

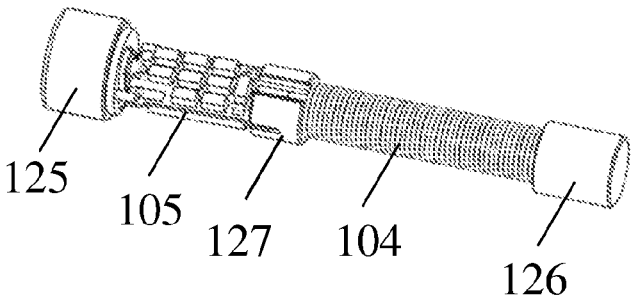

FIG. 7H

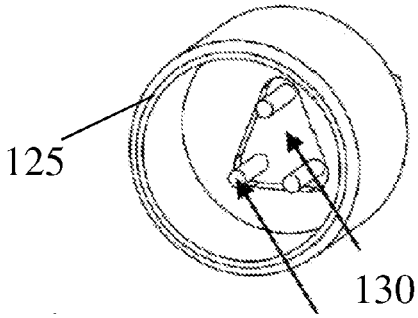

FIG. 7J

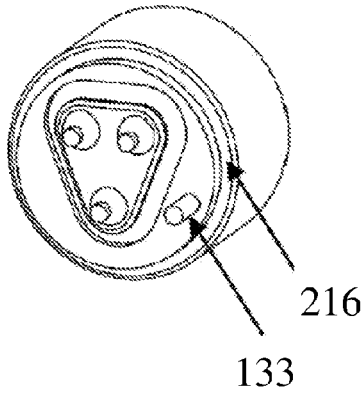

FIG. 7I

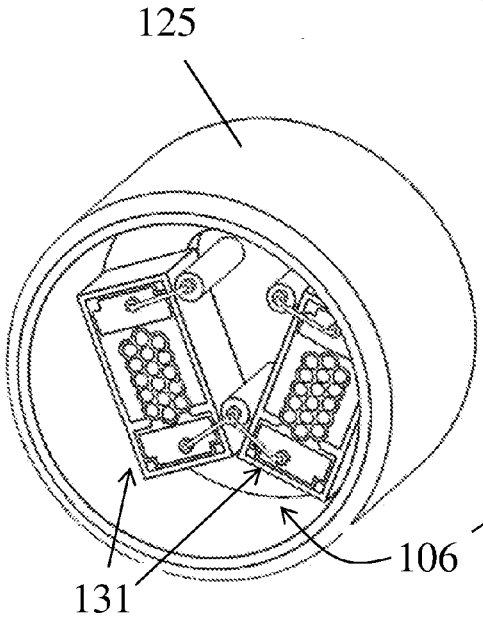

FIG. 7K

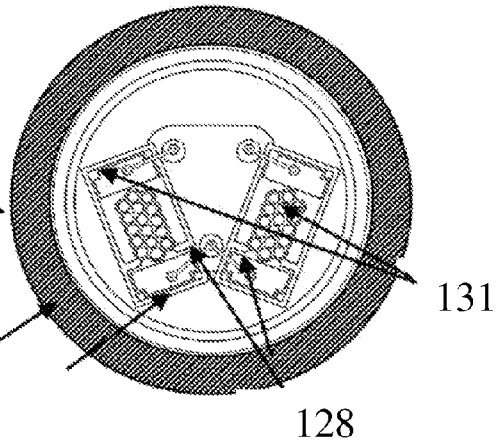

FIG. 7L

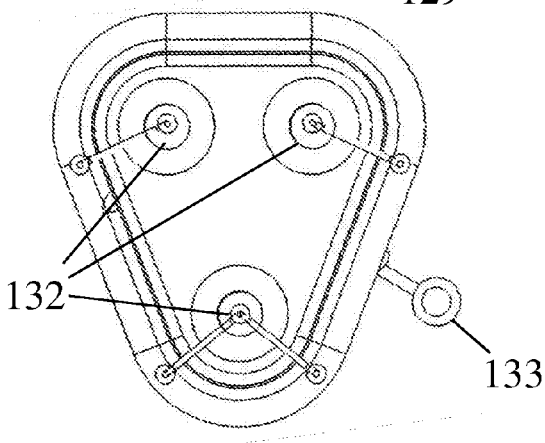

FIG. 7M

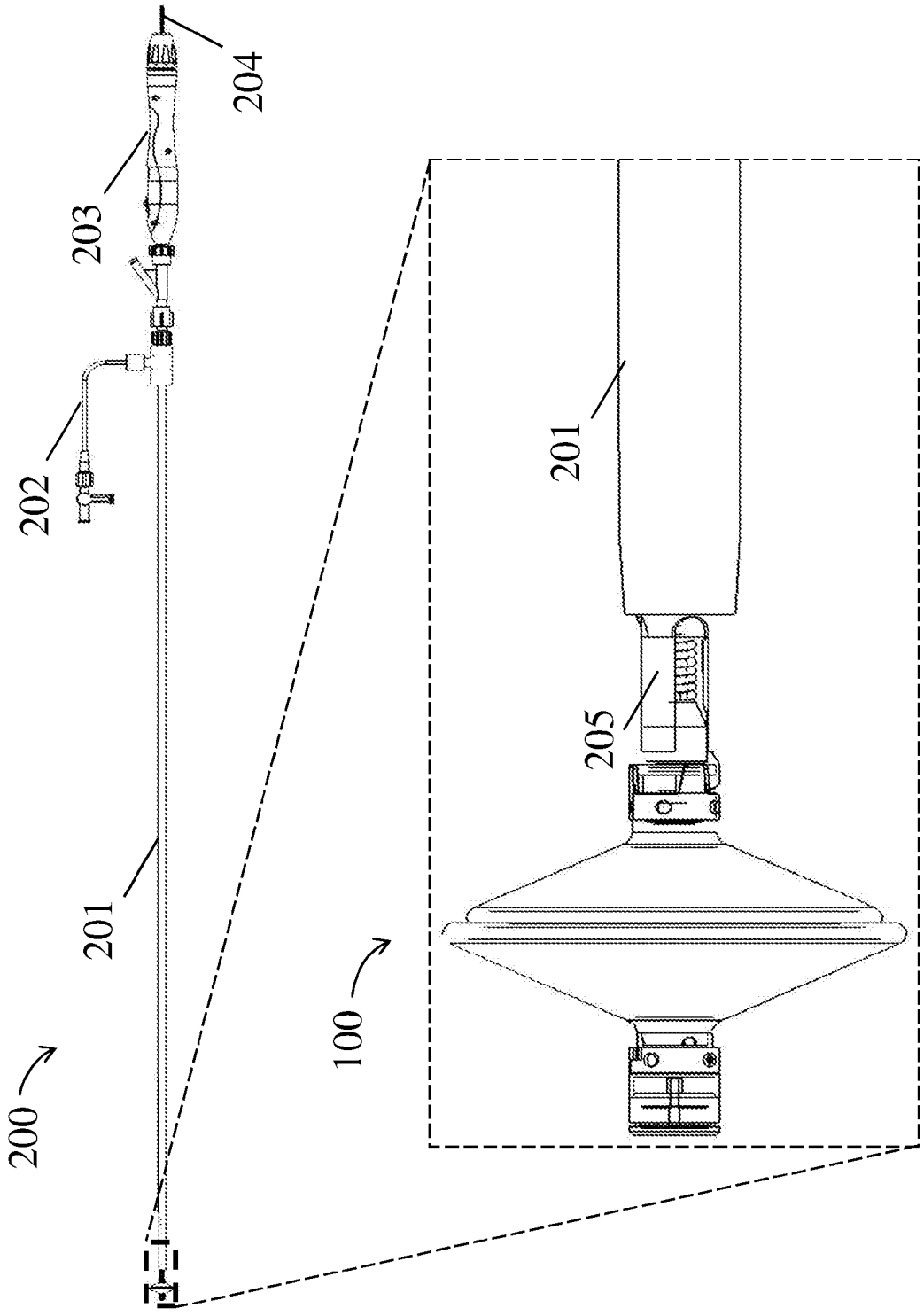

FIG. 8A FIG. 8B

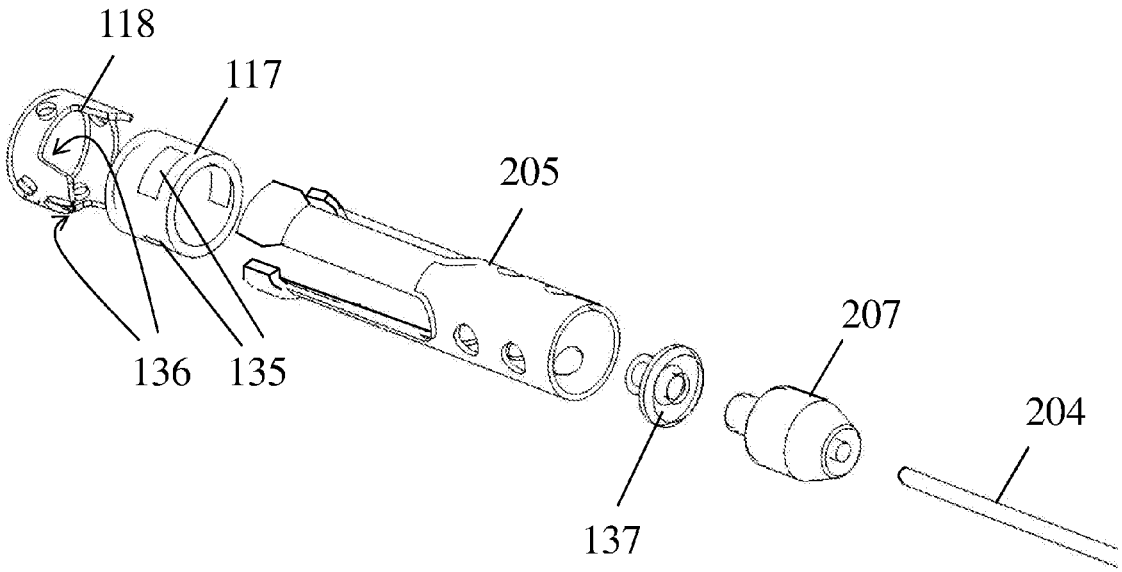

FIG. 8C

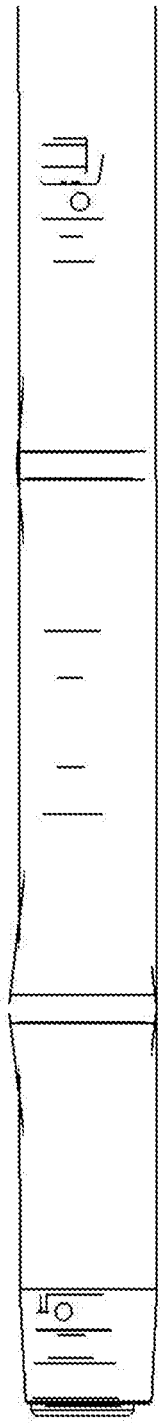

FIG. 8D

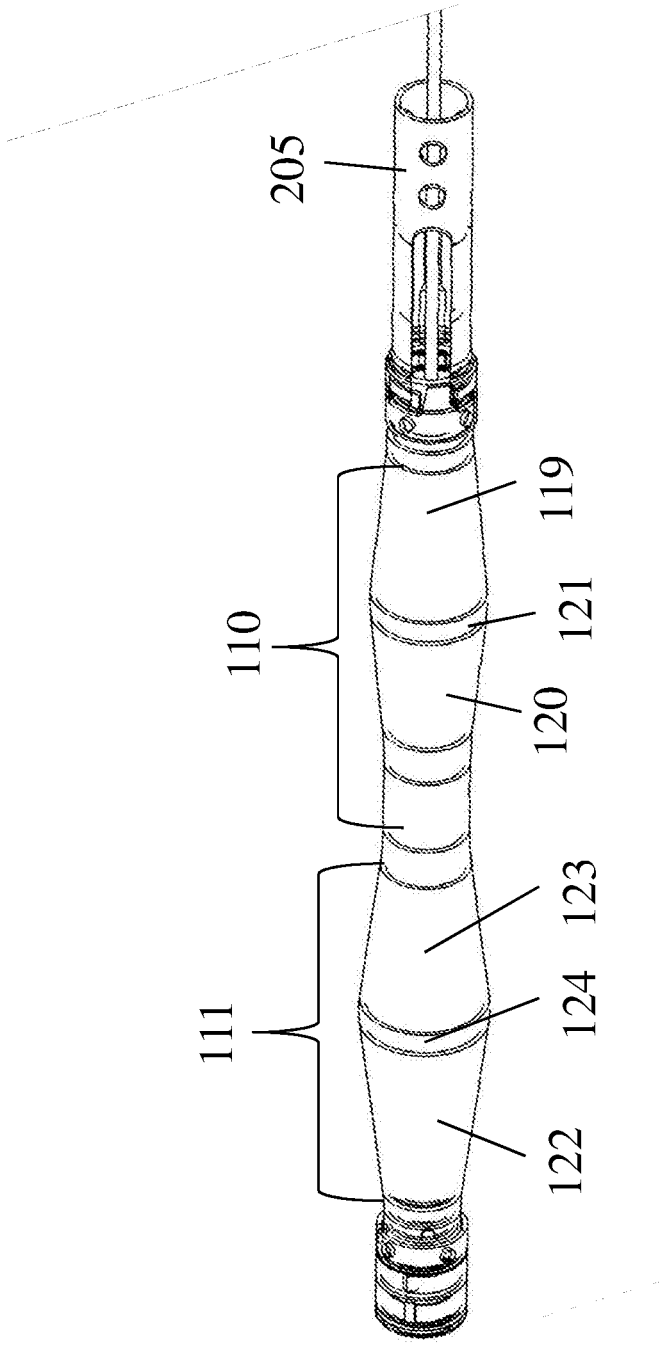

FIG. 8E

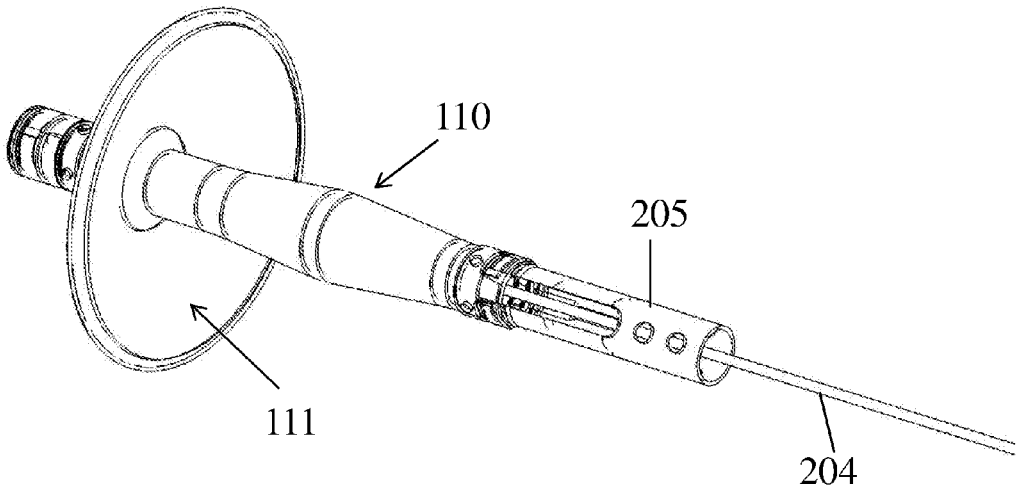

FIG. 8F

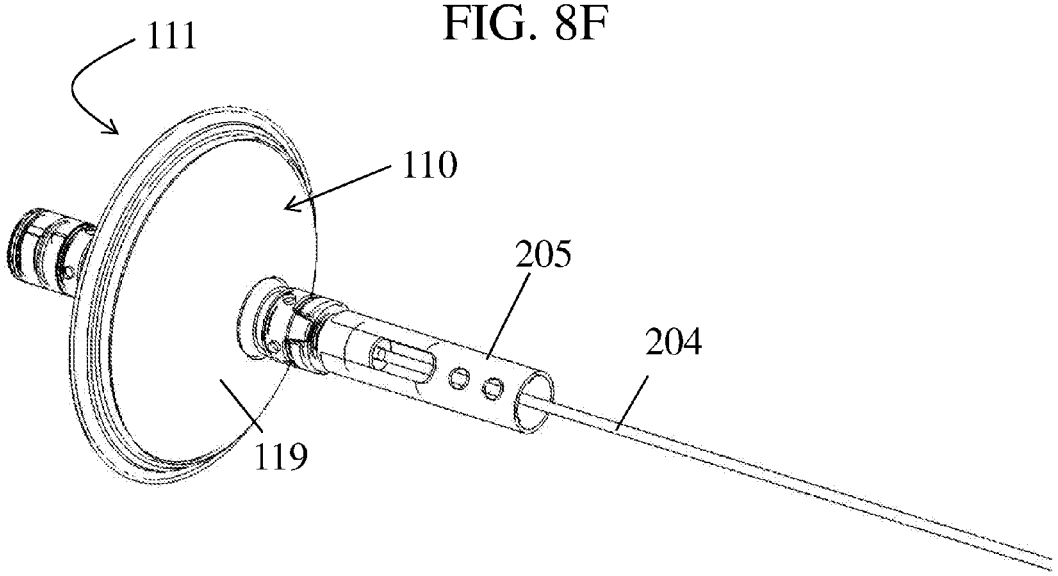

FIG. 8G

HEART IMPLANT WITH SEPTUM GRIPPER

RELATED APPLICATIONS

[0001] This application claims the benefit of priority under 35 USC 119(e) of U.S. Provisional Patent Application No. 62/157,991, filed May 7, 2015, entitled "MECHANICAL DESIGN, PACKAGING AND DELIVERY FOR A SENSORY IMPLANT", and of U.S. Provisional Patent Application No. 62/306,134, filed Mar. 10, 2016, entitled "HEART IMPLANT WITH SEPTUM GRIPPER", the contents of the above documents are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0002] The present invention, in some embodiments thereof, relates to implants, and more particularly, but not exclusively, to an implant, such as a sensory implant positionable within a left atrium in subject's heart, being configured and suitable for facilitating functional activity thereof. Such functional activity may include, for example, sensing, measuring, and, optionally, monitoring, physiological conditions or/and parameters in a subject's body organ.

BACKGROUND OF THE INVENTION

[0003] Pressure measurements in one or more chambers of the heart may be used as an indicator for several cardiac conditions. By sensing and measuring cardiac pressure, abnormal events can be detected and appropriate treatment methodology may be applied to avoid otherwise deleterious cardiac conditions. For example, monitoring left atrial pressure of congestive heart failure (CHF) patients is commonly done as part of effectively diagnosing an abnormal change in left atrial pressure.

[0004] Prior art teaches about implants capable of sensing and measuring pressure in a heart atrium, and which can be fixed to the atrial wall (such as the atrial septum). Means are required for deploying and fixating such implants to the atrial wall. Typically, there is need to prevent, or at least diminish, potentially undesirable or problematic short-term or/and long-term effects that local or/and surrounding disturbances may impose upon the sensing and measuring, or/and other capabilities, of such heart atrial implants. There is also need for such sensory implants to be safely and effectively implanted within the heart, and usable for long-term, real time, and reliable cardiac pressure measurements in the right atrium or/and the left atrium.

SUMMARY OF THE INVENTION

[0005] The present invention, in some embodiments thereof, relates to implants, and more particularly, but not exclusively, to an implant, such as a sensory implant positionable within a left atrium in subject's heart, being configured and suitable for fixation or/and stabilization by gripping on to both sides of a septal wall to thereby facilitating functional activity thereof. Such functional activity may include, for example, sensing or/and measuring, and, optionally, monitoring, physiological conditions or/and parameters in a subject's body organ.

[0006] In exemplary embodiments, the implant includes an implant body having a body wall and enclosing an inner lumen sized and configured for housing physiological condition or/and parameter sensing or/and measuring means. In exemplary embodiments, such sensing or/and measuring means are miniature in size (so as to fit into, and be positionable inside of, a heart atrium), and include wireless communication means. In exemplary embodiments, the implant further includes a septum gripper having a flexible gripping sleeve selectively shapeable from a delivery mode narrowed form sized to pass through a septum opening in an atrial septum, to a deployment mode (expanded) septum gripping form.

[0007] Also disclosed are exemplary embodiments of a system for sensing or/and measuring a physiological parameter in a subject's body organ separated by an organ wall, the system including: the herein disclosed implant, a process control/data-information processing unit located outside of the subject's body and configured for interactively communicating with a physiological parameter sensing or/and measuring means of the implant; and a transcatheter implant deployment device configured for implanting or/and retrieving the implant.

[0008] Also disclosed are exemplary embodiments of an implant suitable for implantation in a subject's body organ separated by an organ wall, and configured for inductive coupling with an electronic unit located outside the subject's body and for interactively communicating with the electronic unit.

[0009] According to an aspect of some embodiments of the present invention, there is provided an implant for sensing or/and measuring a physiological parameter in a subject's body organ separated by an organ wall, the implant comprising: an implant body comprising a rigid body wall enclosing an inner lumen sized and configured for housing physiological parameter sensing or/and measuring means, said body wall includes coupling means at a proximal end thereof and configured for coupling with a distal end of an implant deployment device; and a septum gripper comprising a flexible gripping sleeve fixedly connected to periphery of said rigid body wall at a sleeve fixation area between center point and distal end of said body wall, said gripping sleeve is configured and selectively shapeable from a narrowed or/and stretched form, sized to pass through a septum opening in the organ wall, to a radially expanded form, suitable for gripping onto the organ wall from opposite sides thereof and around said septum opening, such that said implant body is fixatable or/and stabilizable across the organ wall and through said septum opening, so as to facilitate the sensing or/and measuring in the subject's body organ.

[0010] According to some embodiments of the invention, the subject's body organ is a left atrium in the subject's heart, and the organ wall is an interatrial septum.

[0011] According to some embodiments of the invention, the gripping sleeve is fixedly extendable or/and compressible to a chosen length or/and shape in between more than two distinct forms, including said narrowed form and said expanded form, when said coupling means are coupled with said distal end of said implant deployment device.

[0012] According to some embodiments of the invention, the septum gripper includes a mesh. According to some embodiments of the invention, the mesh is formed by braiding of at least one wire. According to some embodiments of the invention, the wire is made from metal alloy.

[0013] According to some embodiments of the invention, the gripping sleeve includes a bellows-like structure comprising a plurality of foldable units, including a proximal foldable unit and a distal foldable unit. According to some embodiments of the invention, when said gripping sleeve is

in said expanded form, said proximal foldable unit forms a proximal wing extending outwardly-radially relative to said implant body, so as to form a first proximal surface and a second proximal surface interconnected with a proximal edge, and said distal foldable unit forms a distal wing extending outwardly-radially relative to said implant body, so as to form a first distal surface and a second distal surface interconnected with a distal edge.

[0014] According to some embodiments of the invention, the bellows-like structure is configured for gripping the organ wall, by pressing said second proximal surface or/and said proximal edge against a proximal side of the organ wall and pressing said second distal surface or/and said distal edge against a distal side of the organ wall, under a continuous compression force greater than a predetermined minimal force value. According to some embodiments of the invention, the bellows-like structure is configured with a coefficient of static friction chosen so as to prevent relative motion of said septum gripper relative to the organ wall under normal stresses applied thereto in the subject's body organ.

[0015] According to some embodiments of the invention, the proximal foldable unit and said distal foldable unit are spaced or/and interconnected with, and foldable relative to, a spacing unit. According to some embodiments of the invention, the spacing unit has a length equal to or smaller than a maximal thickness of the organ wall.

[0016] According to some embodiments of the invention, when said gripping sleeve is in said expanded form, said first proximal surface and said second proximal surface are formed as nested conic structures extending proximally away from said proximal edge, or formed as parallel flat structures, separated by said proximal edge; or/and said first distal surface and said second distal surface are formed as nested conic structures extending distally away from said distal edge, or formed as parallel flat structures, separated by said distal edge. According to some embodiments of the invention, the septum gripper, when gripping onto the organ wall, is configured to have a chosen tridimensional orientation relative to a center point of said septum opening. According to some embodiments of the invention, the chosen orientation includes said implant body extending through said septum opening such that an operational member of said implant body is positionable inside of the subject's body organ. According to some embodiments of the invention, the operational member includes a pressure sensor configured for the sensing or/and measuring when positioned within the body organ remotely from the organ wall.

[0017] According to some embodiments of the invention, the septum gripper comprises a non-foldable sleeve portion, wherein said septum gripper sleeve is connected to said body wall only via said non-foldable sleeve portion. According to some embodiments of the invention, the non-foldable sleeve portion is sandwiched between interconnecting sleeve fixation inner ring and sleeve fixation outer ring affixed to said sleeve fixation area. According to some embodiments of the invention, the sleeve fixation inner ring is sized and shaped to mate or/and lock in a recess forming said sleeve fixation area, to thereby prevent axial and rotation movement therebetween. According to some embodiments of the invention, the non-foldable sleeve portion has an inner dimension of about 2.5 mm or less. According to some embodiments of the invention, the non-foldable sleeve portion is provided between said proximal foldable unit and said distal foldable unit. According to some embodiments of the invention, the non-foldable sleeve portion is provided proximally to said proximal foldable unit. According to some embodiments of the invention, the non-foldable sleeve portion is provided distally to said distal foldable unit.

[0018] According to some embodiments of the invention, at least one of said proximal edge and said distal edge has an outer dimension of about 2.5 mm or more. According to some embodiments of the invention, the gripping sleeve has super elastic properties, or/and shape memory properties. According to some embodiments of the invention, the gripping sleeve is formed by pressing over a rigid mandrel shaped and dimensioned with inner dimensions of said gripping sleeve in said expanded form. According to some embodiments of the invention, the gripping sleeve is encapsulated with an electrically non-conductive layer. According to some embodiments of the invention, the electrically non-conductive layer separates or/and spaces between said gripping sleeve and electrically conductive portions of, or connected to, said body wall.

[0019] According to some embodiments of the invention, the septum gripper includes or is connected to a sliding element configured for unhindered sliding along said body wall during shifting between said narrowed form and said expanded form.

[0020] According to some embodiments of the invention, wherein a free end of said gripping sleeve is sandwiched between interconnecting sleeve deploying inner ring and sleeve deploying outer ring, wherein said sleeve deploying inner ring comprises said sliding element and said sleeve deploying outer ring is configured for coupling with a sleeve deploying arm provided with said implant deployment device.

[0021] According to some embodiments of the invention, the body wall includes a first elongated wall segment of a first outer dimension and a second elongated wall segment of a second outer dimension smaller than said first outer dimension, wherein said gripping sleeve is configured to cover said first and second wall segments when in said narrowed form and to expose said first wall segment when in said expanded form. According to some embodiments of the invention, the second wall segment houses a metal coil or/and an antenna configured for transmitting or/and receiving radio-frequency electromagnetic waves. According to some embodiments of the invention, the first wall segment is formed of metal alloy, and said second wall segment is formed of ceramic material. According to some embodiments of the invention, the implant further comprises a third wall segment distally to said second wall segment, configured for housing electronic or/and electro-mechanical components. According to some embodiments of the invention, the third wall segment is formed of metal alloy.

[0022] According to an aspect of some embodiments of the present invention, there is provided a system for sensing or/and measuring a physiological parameter in a subject's body organ separated by an organ wall, the system comprising: an implant comprised of: an implant body comprising a rigid body wall enclosing an inner lumen sized and configured for housing physiological parameter sensing or/and measuring means, said rigid body wall includes coupling means at a proximal end thereof and configured for coupling with a distal end of an implant deployment device;

and a septum gripper comprising a flexible gripping sleeve fixedly connected to periphery of said rigid body wall at a sleeve fixation area between center point and distal end of said body wall, said gripping sleeve is configured and selectively shapeable from a narrowed or/and stretched form, sized to pass through a septum opening in the organ wall, to a radially expanded form, suitable for gripping onto the organ wall from opposite sides thereof and around said septum opening, such that said implant body is fixatable or/and stabilizable across the organ wall through said septum opening, so as to facilitate the sensing or/and measuring in the subject's body organ; a process control/data-information processing unit, located outside of the subject's body, and configured for interactively communicating with said physiological parameter sensing or/and measuring means of said implant; and a transcatheter implant deployment device configured for implanting or/and retrieving said implant.

[0023] According to an aspect of some embodiments of the present invention, there is provided an implant suitable for implantation in a subject's body organ separated by an organ wall, and configured for inductive coupling with an electronic unit located outside the subject's body and for interactively communicating with the electronic unit, the implant comprising: an implant body comprising a rigid body wall having an electrically non-conductive wall section, housing an RF antenna configured for facilitating the inductive coupling or/and the interactive communication with the electronic unit; and a septum gripper comprising: an electrically conductive flexible gripping sleeve provided between said non-conductive wall section and the electronic unit, and encompassing said non-conductive wall section; an electrically non-conductive distal inner ring fixedly connecting distal portion of said gripping sleeve to said implant body; and an electrically non-conductive proximal inner ring connecting proximal portion of said gripping sleeve to said implant body and allowing sliding thereof lengthwise about outer periphery of said rigid body wall between a proximal-most location and a distal-most location; wherein said gripping sleeve is configured and selectively shapeable from a narrowed or/and stretched form when said proximal inner ring is positioned at said proximal-most location, to an expanded form when said proximal inner ring is positioned at said distal-most location.

[0024] According to some embodiments of the invention, the flexible gripping sleeve includes an electrically conductive mesh. According to some embodiments of the invention, the gripping sleeve includes a bellows-like structure comprising a proximal foldable unit and a distal foldable unit, wherein, when said gripping sleeve is in said expanded form, said proximal foldable unit forms a proximal wing extending outwardly-radially relative to said implant body, so as to form a first proximal surface and a second proximal surface interconnected with a proximal edge, and said distal foldable unit forms a distal wing extending outwardly-radially relative to said implant body, so as to form a first distal surface and a second distal surface interconnected with a distal edge. According to some embodiments of the invention, the distal inner ring is fixated to said rigid body wall at a sleeve fixation area between center point and distal end of said body wall.

[0025] According to some embodiments of the invention, the gripping sleeve, when in said narrowed or/and stretched form, is sized to pass through a septum opening in the organ wall. According to some embodiments of the invention, the gripping sleeve, when in said radially expanded form, is configured for gripping onto the organ wall from opposite sides thereof and around said septum opening, such that said implant body is fixatable or/and stabilizable across the organ wall through said septum opening, so as to facilitate the inductive coupling or/and the interactive communication with the electronic unit.

[0026] According to some embodiments of the invention, the septum gripper further comprises a distal outer ring sandwiching said distal portion of said gripping sleeve with and around said distal inner ring, and a proximal outer ring sandwiching said proximal portion of said gripping sleeve with and around said proximal inner ring. According to some embodiments of the invention, the septum gripper includes a layer of electrically non-conductive covering material configured for separating or/and spacing between electrically conductive parts thereof and said body wall. According to some embodiments of the invention, the gripping sleeve is encapsulated with said electrically non-conductive covering material. According to some embodiments of the invention, the distal outer ring or/and said proximal outer ring is electrically conductive.

[0027] According to some embodiments of the invention, the rigid implant body has a total length in a range of between about 5 mm and about 50 mm, optionally, between about 10 mm and about 30 mm, optionally, between about 15 mm and about 20 mm, optionally, about 18 mm, and has a maximal outer diameter being about 5 mm or less, optionally, about 3.5 mm or less, or optionally, about 2 mm or less.

[0028] According to some embodiments of the invention, the tubular skirt in its extended and narrowed form has a length in a range of between about 25 mm and about 100 mm, optionally, about 50 mm in length, and is sized for unhindered passage when constricted to a diameter in a range from about 2 mm to about 4 mm, such as through a 12 French outer sheath/catheter (i.e., about 4 mm outer diameter) or/and is about 6 mm or less in diameter if not constricted. The septum opening is optionally substantially smaller than the outer sheath outer diameter but is elastically stretched wide when passing therethrough, optionally, about 1 mm to about 3 mm (slit or puncture), optionally using a 5 to 8 French (1.25 mm to 2.67 mm) trans-septal puncture kit. Tubular skirt may be loaded into the outer sheath via a gradually constricting passage, such as from about 7-10 mm down to about 3.8-4.2 mm in diameter.

[0029] When in the (radially expanded) gripping form, the tubular skirt may be less than about 25 mm, optionally, about 15 mm or less in length, and about 10 mm or more, optionally, about 15 mm or about 18 mm or more, in diameter. The tubular skirt may be formed of a mesh having intertwined members (e.g., fibers, cords, or the like), optionally, made of metal (e.g., Ni—Ti alloy). In exemplary embodiments, the mesh includes 42 intertwined (one over one) Ni—Ti 100 micron fibers/cords fiber diameter, optionally, with light oxide surface finish, and 90-degree intersection angle.

[0030] According to an aspect of some embodiments of the present invention, there is provided a wireless pressure sensor implant, provided in a miniature packaging, with a dedicated delivery system. According to some embodiments of the invention, the implant is a part of a sensory system (also comprising a remote device applicable from outside subject's body and configured for monitoring physiological

data from within the human body, for example, direct pressure measurement from within the heart's left atrium.

[0031] According to some embodiments of the invention, the implant includes anchoring means designed for being fixated on to a wall of an internal body organ, for example, the interatrial septal wall, and implantable via a minimal invasive procedure.

[0032] According to some embodiments of the invention, the implant includes sensing or/and measuring elements integrated into a tube (tubular) shaped (rigid) implant body which houses electronic circuitry.

[0033] According to some embodiments of the invention, the implant includes several sub-assemblies, for example: (i) a sensory element cup assembly that includes electrical feedthrough, which can house, for example, one or more pressure sensing or/and measuring transducers positionable on one or both ends of the implant, (ii) a brazed tube assembly including a tube applied with a braided (mesh) fixation means, and (iii) an inner electronic assembly that includes electronic circuitry for interfacing with the sensing or/and measuring element and communicating the data to the external unit.

[0034] According to some embodiments of the invention, the inner electronic assembly may include one or more of the followings: (i) a dedicated application-specific integrated circuit (ASIC) that is mounted on a miniature printed circuit board (PCB) that is applied with other discreet elements, (ii) an RF antenna, which is electrically connected to the PCB and includes a metallic core wrapped with a conductive coil.

[0035] The implant body (tube) may be about 1 mm, 2 mm, 2.5 mm, 3.5 mm, or up to about 5 mm, in outer diameter, and about 8 mm, 10 mm, or up to about 22 mm, in length. The fixation means (e.g., a septum gripper, optionally, including a mesh or a braided pattern) may be from about 10 mm to about 24 mm wide/diameter, when fully deployed (radially expanded). These fixation means, when crimped (e.g., stretched or/and narrowed) are optionally deliverable through the lumen of an 8-French (Fr), 10-Fr, 11-Fr, 12-Fr, or a larger diameter, or a smaller diameter, sheath.

[0036] According to some embodiments of the invention, the implant body is made of a metal with possible combination with ceramic, for example, in the form of a metal-ceramic composite or composite type material. The implant body is optionally configured particularly to endure internal body environment providing biocompatibility and structural strength, and to allow sufficient radio frequency (RF) interactive communication between the implant and its external unit for transmitting/receiving power and digital information, and, to process and transmit/receive physiological parameters and information from the sensor. Optionally, implant body segment which houses the antenna may be an RF compatible tube, and may be either non-metallic/electrical non-conductive (optionally, made from zirconia or titania) or metallic with grooves. An exemplary non-metallic tube is ceramic.

[0037] According to some embodiments of the invention, the implant fixation means (septum gripper) is made of either a metallic and/or polymeric material or with any other material combination that is either electrical conductive or electrical non-conductive in nature. Optionally, the fixation means include a mesh (e.g., braid) made from Ni—Ti alloy ('Nitinol'), which is thermally shaped to preformed double-sided wall gripping form shape, and is configured for mechanical stabilization in human body temperature, yet deformable for allowing forming from a crimped (narrowed or/and stretched) form to its expanded form.

[0038] According to some embodiments of the invention, the implant fixation means (septum gripper) is connected to the rigid implant body using several designated fixtures. Optionally, at least one of the fixtures includes inner and outer rings configuration, sandwiching a portion of the septum gripper (sleeve/mesh) therebetween. Fixtures may optionally be made from electrically non-conductive materials for isolating the septum gripper (sleeve) from electrically conductive parts of the implant body, as well as for sealing and mechanically protecting outer edges of the sleeve (mesh/braid). Two fixtures may exist for both the proximal end and the distal braid end.

[0039] According to some embodiments of the invention, the implant is deliverable, deployable, or/and fixatable, using a delivery kit or system which may include a trans-septal outer sheath and dilator kit, an implant loader (into outer sheath), and an implant delivery/deployment device which may include a rod-like element or a cable connectable to the implant and applicable for pushing the implant through the outer sheath until reaching the target deployment location, and be released after the implant has been positioned properly. Prior to implantation with the dedicated delivery system, the septal wall may be punctured using a standard trans-septal puncturing kit in accordance to known practice.

[0040] According to some embodiments of the invention, the implant is positioned across the interatrial septum. Optionally, implantation is carried out following standard trans-septal puncture and passage typically using a femoral venous approach. Following sheath and wire positioning in the left atrium, or alternatively, in a pulmonary vein, the implant may be introduced through the sheath to a chosen position or/and orientation in the left atrium. The implant is optionally inserted either preloaded within a dedicated catheter or pushed directly through the outer sheath prior to deployment and fixation across the interatrial septum.

[0041] According to some embodiments of the invention, the implant is first introduced partially within the left atrium followed by deployment (radial expansion) of gripping sleeve distal end only, and it is slowly and safely exposed within the left atrium by gradual retraction of the outer sheath. The septum gripper is shaped and configured for recollapsing into the outer sheath and allows for adjustment of the space between its gripping surfaces in conformity to wall anatomy (such as the interatrial septum thickness. Deployment of the proximal part of the septum gripper is optionally performed after fully exposing the septum gripper from the outer sheath, optionally under vision using fluoroscopy or/and echocardiography. Following confirmation of device position across the interatrial septum and its stability, the implant can be detached from the implant deployment device. Complete retrieval of the implant is possible during the deployment at least until complete detachment of the deployment device from the implant.

[0042] According to some embodiments of the invention, the implant deployment procedure may include at least one of the following steps (not necessarily in same order):

[0043] holding the outer sheath in place and slowly advancing the implant forward using the implant deployment device until the implant is aligned with the distal tip of the outer sheath.

[0044] under echocardiographic guidance or/and fluoroscopy, repositioning the outer sheath so that its distal tip is approximately 2-3 cm distal to the Fossa Ovalis inside the left atrium.

[0045] retracting the outer sheath while keeping the implant in-place using the implant deployment device, until a chosen distal portion of the septum gripper (gripping sleeve) is exposed in the left atrium and radially expands.

[0046] verifying that the expanded distal portion of the sleeve correctly opposes the interatrial septum.

[0047] further retracting the outer sheath until exposing the rest of the septum gripper.

[0048] expanding the proximal side of the septum gripper.

[0049] following confirmation of stability, disengaging the implant deployment device from the implant.

[0050] removing the outer sheath and the implant deployment device.

[0051] All technical or/and scientific words, terms, or/and phrases, used herein have the same or similar meaning as commonly understood by one of ordinary skill in the art to which the invention pertains, unless otherwise specifically defined or stated herein. Exemplary embodiments of methods (steps, procedures), apparatuses (devices, systems, components thereof), equipment, and materials, illustratively described herein are exemplary and illustrative only and are not intended to be necessarily limiting. Although methods, apparatuses, equipment, and materials, equivalent or similar to those described herein can be used in practicing or/and testing embodiments of the invention, exemplary methods, apparatuses, equipment, and materials, are illustratively described below. In case of conflict, the patent specification, including definitions, will control.

[0052] Implementation of some embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the invention, several selected tasks could be implemented by hardware, by software, by firmware, or a combination thereof, using an operating system.

[0053] For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip, as a circuit, or a combination thereof. As software, selected tasks of some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks of exemplary embodiments of the method or/and system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions or/and data. Alternatively or additionally, optionally, the data processor includes a non-volatile storage, for example, a magnetic hard-disk or/and removable media, for storing instructions or/and data. Optionally, a network connection is provided as well. Optionally, a display or/and a user input device such as a keyboard or mouse is provided as well.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0054] Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

[0055] In the drawings:

[0056] FIGS. **1**A-**1**B are a schematic views of a human heart (FIG. **1**A), showing an exemplary implant configured for implantation in the atrial septum (AS) and to extend from the right atria (RA) to the left atria (LA), and communication capabilities between the implant and an external (electronic) unit (FIG. **1**B), in accordance with some embodiments of the invention;

[0057] FIGS. **2**A-**2**B are schematic side cut views of an exemplary implant, having an implant body, and a septum gripper that includes a proximal foldable unit and a distal foldable unit, the septum gripper is connected and fixated to the implant body at a sleeve fixation area located distally to the distal foldable unit, in accordance with some embodiments of the present invention;

[0058] FIGS. **3**A-**3**B are schematic side cut views of an exemplary implant, having an implant body, and a septum gripper that includes a proximal foldable unit and a distal foldable unit, the septum gripper is connected and fixated to the implant body through sleeve fixation area being positioned in between the proximal and the distal foldable units, in accordance with some embodiments of the present invention;

[0059] FIGS. **4**A-**4**B are schematic side cut views of an exemplary implant, when in the (delivery) narrowed or/and stretched form (FIG. **4**A) configured to cross an atrial septum AS**1** having a first wall thickness, and the (gripping) radially expanded form (FIG. **4**B) that grips the atrial septum AS**1** having a first wall thickness, in accordance with some embodiments of the present invention;

[0060] FIGS. **5**A-**5**B are schematic side cut views of an exemplary implant, when in the (delivery) narrowed or/and stretched form (FIG. **5**A) configured to cross an atrial septum having a second wall thickness AS**2**, and the (gripping) radially expanded form (FIG. **5**B) that grips the atrial septum AS**2** having a second wall thickness, in accordance with some embodiments of the present invention;

[0061] FIGS. **6**A-**6**D are side or isometric views of an exemplary implant in a (gripping) radially expanded form, the implant is having an implant body and a griping sleeve including a mesh and suitable for continuous gripping an atrial septum, in accordance with some embodiments of the invention;

[0062] FIGS. **7**A-**7**M are side or isometric views of an exemplary implant, the implant is having an implant body and a griping sleeve that forms a bellows-like structure when in the gripping form (FIGS. **7**A-**7**C), the implant body is further having internal electronic components (FIGS. **7**D-**7**M), in accordance with some embodiments of the invention; and

[0063] FIGS. **8**A-**8**G are schematic side or isometric views of an exemplary implant deployment device configured for

implantation and deployment of the herein disclosed exemplary implants, in accordance with some embodiments of the invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

[0064] The present invention, in some embodiments thereof, relates to implants, and more particularly, but not exclusively, to an implant, such as a sensory implant positionable within a left atrium in subject's heart, being configured and suitable for fixation or/and stabilization by gripping on to both sides of a septal wall to thereby facilitating functional activity thereof. Such functional activity may include, for example, sensing or/and measuring, and, optionally, monitoring, physiological conditions or/and parameters in a subject's body organ.

[0065] In the field and art of the invention, there is a requirement to provide wall mounting/fixating means for implants, particularly implants which are deliverable (e.g., transcatheter delivery) into a body organ that is separated by an organ wall, where the implant is to reside across this organ wall. Usually, such an implant is provided across a naturally occurring opening (e.g., a normal opening or an abnormal/defect opening) or a premade opening (e.g., hole, cut, or puncture) and is fixated by pressing against the two sides of the organ wall around the wall opening. The inventors of the present invention observed that there is still an on-going need for such fixating/mounting means in view of the following conditions or/and requirements, singly, or in combination:

[0066] such means should be stored and delivered in a very small diameter constrictive channels, for example, diameters of 4 mm, or even 3 mm and less, without deteriorating their structure and function when expanded for fixating the implant to the organ wall.

[0067] such means should be able to inherently compensate for different dimensions of the wall, for example wall thickness which may be substantially variable, without compensating for their structure and function when expanded for fixating the implant to the organ wall.

[0068] such means should be able to deform into final fixation (e.g., gripping) form without relying on anatomy, as in current practice whereby deployment of trans-septal implants (e.g., septal occluders) is done by extracting the implant (thereby allowing its fixation means to self-expand) out of an outer sheath against the organ wall margins surrounding the wall opening, yet the opening size may not allow that practically or efficiently.

[0069] such means should be able to recollapse and retrieve for optional discarding or redeployment (e.g., in a different target location), since that, especially with respect to sensory implants, implant's functionality can be determined only after deployment.

[0070] In exemplary embodiments of the present invention, the implant includes an implant body having a body wall and enclosing an inner lumen sized and configured for housing physiological condition or/and parameter sensing or/and measuring means. In exemplary embodiments, such sensing or/and measuring means are miniature in size (so as to fit into, and be positionable inside of, a heart atrium), and include wireless communication means. In exemplary embodiments, the implant further includes a septum gripper having a flexible gripping sleeve selectively shapeable from a delivery mode narrowed form sized to pass through a septum opening in an atrial septum, to a deployment mode (expanded) septum gripping form.

[0071] Also disclosed are exemplary embodiments of a system for sensing or/and measuring a physiological parameter in a subject's body organ separated by an organ wall, the system including: the herein disclosed implant, a process control/data-information processing unit located outside of the subject's body and configured for interactively communicating with a physiological parameter sensing or/and measuring means of the implant; and a transcatheter implant deployment device configured for implanting or/and retrieving the implant.

[0072] Also disclosed are exemplary embodiments of an implant suitable for implantation in a subject's body organ separated by an organ wall, and configured for inductive coupling with an electronic unit located outside the subject's body and for interactively communicating with the electronic unit.

[0073] Sensing or/and measuring, and optionally, monitoring, physiological conditions or/and parameters (such as pressure) within the left atrium or/and right atrium of the heart may be associated with several challenges and limitations. For example, access to the left or right heart atrium needs to be done in a safe manner. In addition, the one or more physiological sensors (sensing or/and measuring means) need to be implanted in a manner that ensures accurate sensing or/and measuring, and optionally, monitoring, of the physiological conditions or/and parameters (such as pressure) for a prolonged period of time (e.g., 3 years or more, optionally, particularly 5 years or more, or, optionally, particularly 10 years or more). At least some exemplary embodiments of the implant of the present invention may successfully address and overcome such potential challenges and limitations, and may provide for safe, reliable, and accurate sensing or/and measuring, and optionally, monitoring, of one or more physiological conditions or/and parameters (such as pressure), within the left or/and right heart atrium.

[0074] In exemplary embodiments, the herein disclosed implant is implanted through the septum using minimal procedure (minimally invasive) means. In exemplary embodiments, the herein disclosed implant may be easily retrieved, and either replaced or completely removed, from within the heart, when and if necessary, at least so long as the implant is connectable to dedicated delivery/retrieval means. Such exemplary embodiments of the herein disclosed heart atrial septum implant may have structural and functional features that are advantageous compared to those of known heart atrial implants and methods used for employing them.

[0075] The implant of the invention affords measuring pressure within at least one of the left and right atrium, optionally particularly in the left atrium. Such measurements are of particular importance especially when referring to heart failure patients (e.g., CHF patients). In such modalities, continuous heart pressure monitoring may be effective for assessing and managing disease progression. Timely interventions including medication taken as immediately as possible after an increase in pressure would be considered more effective for applying timely treatment to a CHF patient or/and for reducing unnecessary hospitalization.

[0076] The implant of the invention thus fulfills a long felt need in providing heart pressure monitoring for long periods (e.g., about 5 years or more, optionally about 10 years or more).

[0077] Thus, the present invention provides an implant that includes sensing or/and measuring means extendable within a left atrium in a patient's heart, and fixatable (e.g., by gripping) to the heart atrial septum. Referring now to the drawings, FIG. **1**A is a schematic frontal cut view of a human heart showing the atrial septum (AS). Atrial septum is the wall that separates the right atrium (RA) from the left atrium (LA) of the heart. This term is interchangeable with the term "interatrial septum". As shown in FIG. **1**A and will be explained in more details below, the implant of the invention, is configured to be placed through or reside within the atrial septum. In FIG. **1**A, a simplified illustration of implant **10**, in accordance with some embodiments of the invention is shown.

[0078] The implant may include sensing or/and measuring means. The term "sensing or/and measuring means", as used herein, refers to component(s) or/and electronics that enable and facilitate sensing or/and measuring and transmitting data associated with one or more physiological conditions or/and parameters of the heart/cardiac system that may be processed to provide information regarding condition of a patient's heart. According to some embodiments, the mean (s) include at least a pressure sensor or transducer capable of specifically sensing or/and measuring, or measurably reacting to, pressure (or change thereof, or difference thereof with ambient pressure, for example) within the heart (e.g., particularly in the left atrium).

[0079] The term "sensing or/and measuring means", as used herein, is interchangeable with the term "operational member" or may be considered a component or a part thereof. The data transmitted from the sensing or/and measuring means may include, without limitation, at least one of the following physiological conditions or/and parameters: pressure, stress, heart rate, anatomical abnormalities (e.g., valve malfunction), temperature, blood flow rate, and gas (e.g., oxygen) concentration or/and volume. The data transmitted from the sensing or/and measuring means is transmitted wirelessly to an external unit **11** located outside patient's body (As shown in FIG. **1**B), and configured for communicating (i.e., reading, processing and providing an input) with the sensing or/and measuring means, which includes for example reading, analyzing or/and processing a data (picked-up by the sensing or/and measuring means or/and combined with stored data or/and newly introduced data) to provide a readout by the external unit. According to some embodiments, the external unit may also provide power to the sensing or/and measuring means or/and to other components thereinside.

[0080] The implant includes a (selectively deployable) septum gripper configured to grip on to the septum, such as from both sides thereof. The septum gripper includes a first and a second foldable units. In exemplary embodiments, the first and the second foldable units are configured to shift from a delivery mode extended form to a post-delivery mode gripping form, such that, in the delivery mode form, the foldable units are extended and the implant is capable of passing through an opening of the septum, and in the post-delivery mode gripping form, the foldable units are deployed and the septum is gripped or clamped in-between the two foldable units.

[0081] The implant further includes at least one sensing or/and measuring means confined within the implant body and adapted to monitor physiological condition(s) or/and parameter(s) within a heart cavity.

[0082] The description that follows illustrates possible example embodiments of the implant and its delivery and anchoring (e.g., fixating, such as by gripping). The embodiments described herein are depicted purely by way of example, and various other suitable implementations can be used in alternative embodiments.

[0083] Reference is now made to FIGS. **2**A-**2**B, which schematically illustrate side, cut views of an implant **20**, in accordance with some embodiments of the invention. Implant **20** includes implant body **21** which houses sensing or/and measuring means **24** capable of sensing (detecting) or/and measuring, and optionally, monitoring, one or more physiological conditions or/and parameters in a chamber of the heart. Implant **20** further includes septum gripper **22** including gripping sleeve **23** shapeable from a narrowed (delivery) form (FIG. **2**A) sized to pass through a septum opening in an atrial septum, to an expanded (gripping) form configured for gripping onto atrial septum (FIG. **2**B). Gripping sleeve **23** includes proximal foldable unit **23***a* and distal foldable unit **23***b* (shown in FIG. **2**B). Gripping sleeve **23** further includes a non-foldable sleeve portion **25** whose dimensions are constant during sleeve change in shape when the gripping sleeve **23** transforms from the narrowed form to the expanded form.

[0084] Implant body **21** of implant **20** includes a first elongated wall segment **26** of a first outer dimension and a second elongated wall segment **27** of a second outer dimension. Implant body **21** of implant **20** may further include a third elongated wall segment **28**. According to some embodiments, the outer dimension of the second elongated wall segment **27** is smaller than the outer dimension of the first elongated wall segment **26**.

[0085] According to some embodiments, first wall segment **26** and optionally, second elongated wall segment **27** is formed of metal alloy. Suitable metal alloys include, but are not limited to alloys including titanium (Ti). The Alloys may have a certain purity. For example, the Ti alloy may be of grade II. According to some embodiments, the second wall segment **27** is formed from a ceramic material such as zirconia or alumina. According to some embodiments, the second wall segment **27** houses a metal coil or/and an antenna **29** configured for transmitting or/and receiving radio-frequency electromagnetic waves. According to some embodiments, gripping sleeve **23** is connected to implant body **21** only through non-foldable sleeve portion **25**. According to some embodiments, non-foldable sleeve portion **25** is connected to implant body **21** through sleeve fixation area **30**. According to some embodiments and as shown in the FIG. sleeve fixation area **30** may be disposed distally to the distal foldable unit **23***a*. The sleeve fixation area **30** may include an inner and an outer ring, wherein the outer ring clamps the inner ring which in turn clamps the distal non-foldable sleeve portion, thereby fixating distal non-foldable sleeve portion to implant body **21**.

Reference is now made to FIGS. **3**A-**3**B, which show a schematic side, cut views of implant **40**; in accordance with some embodiments of the invention. Implant **40** includes a gripping sleeve **42** shapeable from a narrowed or/and stretched (delivery) form (FIG. **3**A) sized to pass through a septum opening in an atrial septum, to a radially expanded

(gripping) form configured for gripping onto atrial septum (FIG. **3**B). Implant **40** is similar to implant **20**, except for its sleeve fixation area **41** (which includes a non-foldable sleeve portion) being positioned in between proximal foldable unit **42***a* and distal foldable unit **42***b* of gripping sleeve **42**. Similar to implant **20**, implant **40** includes an implant body **43** which houses sensing or/and measuring means **44** capable of sensing (detecting) or/and measuring, and optionally, monitoring, one or more physiological conditions or/and parameters in a chamber of the heart. Implant body **43** of implant **40** includes a first elongated wall segment **45** of a first outer dimension a second elongated wall segment **46** of a second outer dimension and optionally a third elongated wall segment **47**.

[0086] Reference is now made to FIGS. **4**A-**4**B, which show implant **20** of the invention when extending across a pre-made opening in a first atrial septum AS**1**, when in the delivery form (FIG. **4**A), and in a gripping form (FIG. **4**B), where it grips the atrial septum AS**1**. In this example the atrial septum (wall) is relatively thin.

[0087] FIGS. **5**A-**5**B show implant **20** first extending across a pre-made opening in a second, relatively thick, atrial septum (wall) AS**2**, when in the delivery form (FIG. **5**A), and then in a gripping form (FIG. **5**B), where it grips the atrial septum AS**2**. Atrial septum wall thickness may vary substantially between patients. Typically, atrial septum wall-thickness ranges between about 1 mm to about 20 mm. Implant **20** is configured to accommodate various atrial septum wall thicknesses and is therefore adjustable to all atrial septum wall sizes. Specifically, at least one of: proximal foldable unit **23***a*, spacing unit **48**, and distal foldable unit **23***b* are elastically stretchable and at the same time maintain septum gripping functionality.

[0088] Reference is now made to FIGS. **6**A-**6**D which show implant **50** in accordance with some embodiments of the invention. Implant **50** includes an implant body **51** configured for housing means capable of sensing (detecting) or/and measuring, and optionally, monitoring, one or more physiological conditions or/and parameters in a chamber of the heart (hereinafter "sensing or/and measuring means", shown for example in FIGS. **7**D-**7**M) and a septum gripper **52** configured for coupling implant **50** by gripping the atrial septum from both its sides (one side facing the right atrium and opposite side facing the left atrium). Implant body **51** has a body wall **53** enclosing an inner lumen **54** (shown in FIGS. **6**B-**6**C) sized for housing the sensing or/and measuring means, and may have a tubular structure, or any other structure suitable for housing the sensing or/and measuring mean(s).

[0089] Implant body **51** of implant **50** includes a first elongated wall segment **55** and a second elongated wall segment **56** (shown in FIG. **6**C). Optionally, Implant body **51** includes a third elongated wall segment **57**. According to some embodiments, third elongated wall segment **57** is configured for housing sensing or/and measuring means, although either or both first and third elongated wall segments, **55** and **57**, may be used to house sensors/transducers.

[0090] The implant body **51** has an outer diameter within the range of about 1 mm to about 5 mm, optionally about 2 mm to about 5 mm, optionally about 2.5 mm to about 5 mm, or optionally about 3.5 mm to about 5 mm. Each possibility represents a separate embodiment of the invention. According to some embodiments, the implant has a length within the range of about 8 mm and about 51 mm, optionally about 10 mm and about 51 mm.

[0091] Implant body **51** may be made or fabricated from a metal and may optionally include ceramic materials. Suitable materials from which implant body **50** is made of are those that provide biocompatibility and structural strength and allow effective radio frequency (RF) communication between the implant and an external unit to thereby facilitate harmonization of the data transmittal and processing. The metals suitable for manufacturing implant body **51** include, without limitation, metal alloys that include, for example titanium (hereinafter "Ti alloy"). The alloy may include, for example, Ti "grade II" or Titanium Grade I. Non-metallic materials suitable for manufacturing implant body **51** may include, without limitation, ceramics. Exemplary suitable ceramics may include zirconia, titania, or alumina.

[0092] According to some embodiments, first wall segment **55** or/and third wall segment **57** is formed of metal alloy. According to some embodiments, the second wall segment **56** is formed of a ceramic material such as zirconia or alumina. According to some embodiments, the second wall segment **56** houses an antenna, optionally in a form of a metal coil (as shown in FIG. **7**F, for example), which is configured for transmitting or/and receiving radio-frequency electromagnetic waves.

[0093] Septum gripper **52** includes a flexible gripping sleeve **58** shapeable from an extended (slim) delivery form sized to pass through a septum opening in an atrial septum, to a non-bounded gripping form configured for gripping onto the atrial septum (shown in FIGS. **6**A-**6**D). The gripping sleeve **58**, when in the gripping form may have a structure that resembles double parallel flat plates that are facing each other.

[0094] According to some embodiments, the gripping sleeve **58** includes a proximal foldable unit **58***a* and a distal foldable unit **58***b*. Proximal foldable unit **58***a* and distal foldable unit **58***b* may each have a different shape or may both be structurally similar. Optionally, additionally or alternatively, proximal foldable unit **58***a* and distal foldable unit **58***b* may each have different dimensions (e.g. diameter or/and thickness) or may have similar or identical dimensions. Proximal foldable unit **58***a* and distal foldable unit **58***b* are each interconnected with and foldable relative to a spacing unit **59** that spaces apart proximal foldable unit **58***a* from distal foldable unit **58***b*

[0095] As will be explained in more details below, spacing unit **59** is configured to accommodate the atrial septum and to allow gripping thereof by the foldable units **58***a* and **58***b*. Spacing unit **59**, optionally together with at least portions of foldable units **58***a* and **58***b* closest thereto, are therefore adjustable or/and conformable and accommodative relative to a particular thickness (variable or relatively constant) of the atrial septum, which may vary between patients. Spacing unit **59** itself, when in a relaxed non-stresses form, may have a length equal to or smaller than a maximal thickness of the atrial septum in order to maintain a continuous compression force upon gripping an atrial septum.

[0096] According to some embodiments, the gripping sleeve **58** includes at least one of a non-foldable sleeve portion **60**. The non-foldable sleeve portion may be non-shapeable. As used herein the term "non-shapeable" relates to a portion that is not changing in dimensions during sleeve

change in shape when the septum gripper **52** transforms from a narrowed or/and stretched (delivery) form to a radially expanded (gripping) form. Non-foldable sleeve portion **60** may be disposed proximally to the proximal foldable unit **58***a*, distally to the distal foldable unit **58***b*, or both.

[0097] According to some embodiments, non-foldable sleeve portion **60** is about 2.5 mm or less, 2.2 mm or less, 2 mm or less, 1.8 mm or less, or 1.5 mm or less in inner dimension. Each possibility represents a separate embodiment of the invention. According to some embodiments, inner dimensions may be inner diameter.

[0098] Gripping sleeve **58** may be made or fabricated from an elastic material capable of deforming from one configuration to another configuration. For example, gripping sleeve **58** may be made from a material having super elastic properties. Further, gripping sleeve **58** may be made from or may have shape memory properties (metal or polymer), or include locking mechanism for locking it in the second, deployed (gripping), configuration. According to some embodiments, gripping sleeve is made from a metal alloy. Suitable metal alloys include, but are not limited to nitinol (Ni—Ti).

[0099] In accordance with those embodiments, gripping sleeve **58** may be formed by pressing griping sleeve **58** over a rigid mandrel shaped and dimensioned substantially similarly with the in inner dimensions of gripping sleeve **58** when in the gripping form.

[0100] According to some embodiments, gripping sleeve **58** is made from a material that does not produce an adverse effect or that is compatible with human body (such as biocompatible). According to one embodiment, the gripping sleeve **58** is made or fabricated from a mesh. According to some embodiments, the mesh is formed by braiding of at least one wire. According to some embodiments, the number of wires that form the mesh is in between the range of 56 wires to 60 wires, or in between 35 wires to 45 wires. Each possibility represents a separate embodiment of the invention. According to some embodiments, at least one wire has a wire thickness of at least 80 μm, at least 100 μm or at least 150 μm. Each possibility represents a separate embodiment of the invention. The wires may be round shaped in order to minimize damage to tissue, the implant or the delivery system. The wires may be braided at a ratio of 1:1 clock wise to counter clockwise.

[0101] According to some embodiments, at least a portion of septum gripper **52** (such as gripping sleeve **58**, or the mesh or wire forming the sleeve **58**) or/and the non-foldable portion(s) **60**, or/and any connection means thereof, is encapsulated with electrically non-conductive layer. Optionally and alternatively, septum gripper **52** is only partially encapsulated. Encapsulation with a non-conductive layer(s) is utilized to electrically isolate the septum gripper **52** from the metal portions of implant body **51** and to thereby prevent data transmittal disturbances or interference. Suitable materials for encapsulations include polymers (such as Parylene C), and ceramics, glass, and oxides. According to some embodiments, the electrically non-conductive layer separates or/and spaces between body wall **53** or/and adjacent bodily tissue and blood and the gripping sleeve **58**. Encapsulation results with a layer coating a material and may vary in thickness. The encapsulation layer thickness may range from several nanometers to several micrometers. An exemplary encapsulation thickness may be within the range of about 50 nm about 50 μm.

[0102] Optionally, additionally or alternatively, the electrically non-conductive layer may include an oxidative layer covering the material (e.g., natively oxidized nitinol).

[0103] As shown in FIG. **6**C, implant body **51** of implant **50** includes a first elongated wall segment **55** of a first outer dimension and a second elongated wall segment **56** of a second outer dimension. Optionally, implant body **51** includes a third elongated wall segment **57** that may have an outer diameter greater than outer diameter of second elongated wall segment **56** or/and equals to the outer diameter of the first elongated wall segment **55**. According to some embodiments, the outer dimension of the second elongated wall segment **56** is smaller than the outer dimension of the first elongated wall segment **55**. In accordance with those embodiments, second elongated wall segment **56** allows to accommodate in a fixator and continuous manner, that prevents axial movement, non-foldable sleeve portion **60** including spacing unit **59**.

[0104] Reference is now made to FIGS. **7**A-**7**M, which show different views of implant **100** and of sub-systems and components thereof. Implant **100** includes an implant body **101** having a tubular body wall **102** (shown in FIG. **7**D, for example) and connected body segments.

[0105] In some embodiments, implant **100** is configured for coupling onto a chamber wall in a subject body, and configured for inductive coupling with an external unit (such as external unit **11** of FIG. **1**B) positionable outside the subject body, and for transmitting digital signals to the external unit. In some embodiments, body wall **102** includes an electrically non-conductive wall section housing an RF antenna configured for facilitating the inductive coupling or/and the transmitting of the digital signals. Optionally, this non-conductive wall section is made from an electrically non-conductive material, and is optionally connected to a distal section or/and to a proximal section made from an electrically conductive material.

[0106] Body wall **102** encloses an inner lumen **103** (shown in FIG. **7**E, for example) and configured for housing an RF antenna **104**, an electronic circuit unit **105** or/and sensing or/and measuring means **106** (shown in FIG. **7**F, for example), which are configured for sensing (detecting) or/and measuring, and optionally, monitoring, at least one physiological condition or/and parameter in a chamber of the heart.

[0107] Implant **100** further includes a septum gripper **108** (shown, separately, in FIGS. **7**B and **7**C) including a flexible gripping sleeve **109**. Flexible gripping sleeve **109** is optionally fixedly connected to implant body **101** with a distal inner ring and slidably connected to the implant body with an axially slidable proximal inner ring. Flexible gripping sleeve **109** is selectively shapeable from a narrowed and stretched (delivery) form, when the proximal inner ring is withdrawn proximally away from the distal inner ring, to a radially expanded (gripping) form encompassing the non-conductive wall section, configured for gripping onto the chamber wall, when the proximal inner ring is advanced distally towards the distal inner ring. Flexible gripping sleeve **109** may include an electrically conductive mesh covered with an electrically insulating layer, and each of the proximal and distal inner rings is made from an electrically non-conductive material.

[0108] Gripping sleeve **109** includes a bellows-like structure, with a plurality of the foldable units, namely, a proximal foldable unit **110** and distal foldable unit **111**. Septum

gripper **108** further includes a proximal non-foldable sleeve portion **112** disposed proximally to the proximal foldable unit **110**, and a distal non-foldable sleeve portion **113** disposed distally to the distal foldable unit **111** (shown in FIG. **7**C, for example).

[0109] Distal non-foldable sleeve portion **113** is sandwiched between a sleeve fixation inner ring **114** and a sleeve fixation outer ring **115**. According to some embodiments, sleeve fixation inner ring **114** is sized and shaped to mate or/and lock in a recess **116** (shown in FIG. **7**E) in implant body **101**, which forms a sleeve fixation area and prevents axial and rotation movement of distal non-foldable sleeve portion **113** during transformation (reshaping or/and motion) of septum gripper **108**.

[0110] Proximal non-foldable sleeve portion **112** is sandwiched between a sleeve deploying inner ring **117** and a sleeve deploying outer ring **118**. As will be explained in more details below, sleeve deploying inner ring **117** and sleeve deploying outer ring **118**, and proximal non-foldable sleeve portion **112** sandwiched therebetween, are configured to selectively slide axially along implant body wall **102**, as part of implantation of implant **100**.

[0111] According to some embodiments, septum gripper **108** or at least a portion or a part thereof (e.g., sleeve fixation inner ring **114**, sleeve fixation outer ring **115**, sleeve deploying inner ring **117**, sleeve deploying outer ring **118**, or/and flexible gripping sleeve **109**) is made from a non-conductive material (e.g., plastic), or encapsulated with an electrically non-conductive layer, in order to minimize RF transmittal disturbances or interferences, between RF antenna **104** and a remote receiver/transmitter (such of external unit **11** of FIG. **1**B, for example). Encapsulation with a non-conductive layer(s) can be utilized to electrically isolate the septum gripper **108** from direct contact with metal portions of implant body **101** and to thereby prevent data transmittal disturbances. Suitable materials for encapsulations may include polymers (e.g., Parylene C), and ceramics. Encapsulation may include an oxide layer. According to some embodiments, the electrically non-conductive layer or/and possible non-conductive spacers, separates or/and spaces between the body wall **102**, or/and adjacent bodily tissue and blood, and the gripping sleeve **109**.

[0112] Gripping sleeve **109** is configured such that in the gripping form, the proximal foldable unit **110** forms a proximal wing extending outwardly-radially relative to implant body **101** so as to form a first proximal surface **119** and a second proximal surface **120** (as shown in FIG. **8**E) interconnected with a proximal edge **121**. Similarly, gripping sleeve **109** is configured such that in the gripping form, distal foldable unit **111** forms a distal wing extending outwardly-radially relative to implant body **101** so as to form a first distal surface **122** and a second distal surface **123** (as shown in FIG. **8**E) interconnected with a distal edge **124**.

[0113] Gripping sleeve **109** is further configured such that the plurality of foldable units **110** and **111** are configured for gripping by pressing the second proximal surface **120** or/and the proximal edge **121** against a proximal side of an atrial septum and pressing the second distal surface **123** or/and the distal edge **124** against a distal side of the atrial septum, under a continuous compression force greater than a predetermined minimal force value. As used herein the term "continuous compression force" relates to a continuous compression force applied by the foldable units **110** and **111** of the gripping sleeve **109** on the atrial septum. According to some embodiments, the gripping sleeve **109** is configured such to continuously for long periods, for example a year or so compress the atrial septum. The continuous compression force is greater than a predetermined minimal force taken, for example, from between about 0.1 gr and about 100 gr, optionally particularly between about 0.5 gr and about 50 gr, optionally particularly from about 1 gr and about 10 gr.

[0114] According to some embodiments, the bellows-like structure of foldable units **110** and **111** is configured with a coefficient of static friction chosen so as to prevent relative motion of the septum gripper **108** relative to the atrial septum under normal stresses (i.e., physiological stresses) applied thereto in the chamber of the heart.

[0115] According to some embodiments, when gripping sleeve **109** is in the gripping form, the first proximal surface **119** and the second proximal surface **120** are formed as nested conic structures extending proximally away from the proximal edge **121** separated by the proximal edge **121**. According to some embodiments, when gripping sleeve **109** is in the gripping form, the first distal surface **122** and the second distal surface **123** are formed as nested conic structures extending distally away from the distal edge **124** separated by the distal edge **124**.

[0116] Sensing or/and measuring means **106** is encapsulated in a sensory cup **125**, and is electrically connected to electronic circuit unit **105** and to RF antenna **104**.

[0117] Sensing or/and measuring means **106** and sensory cup **125** are provided in this exemplary embodiment at distal end of implant **100** (and configured for positioning in the left atrium) when gripped to the atrial septum, but may be positioned on the proximal and distal end of the implant or that the implant will include two such units (or more), provided at both ends thereof, for example. The electronic circuit unit **105** includes dedicated application-specific integrated circuit (ASIC) mounted on a miniature printed circuit board (PCB) applied with further discreet elements. The RF antenna **104** is electrically connected to the PCB. The RF antenna **104** may, for example, include a core (e.g., metallic) wrapped with a conductive coil. The PCB and the antenna **104** may be electrically connected via soldering or via any other relevant method. The sensing or/and measuring means **106** may further include two non-(electrically) conductive spacers **126** and **127** (shown in FIGS. **7**G-**7**H). The spacers **126** and **127** may be made of either a polymer or/and an inorganic compound and are configured for fixating the means in a specific plan within the implant body **101**. According to some embodiments, the sensing or/and measuring means **106** are confined within and may be integrated into implant body **101**.

[0118] Sensing or/and measuring means **106**, within sensory cup **125**, may include a membrane **128**, a ring **129** and a ceramic assembly **130**, which may, for example, connect to or/and store pressure traducers **131**. Sensory cup **125** may be formed by metal or non-metal material, or/and be encapsulated, covered or have lining with a polymer. For example, a thin polymeric layer may be added to inner surfaces of the sensory cup **125**, as well as, possibly, an outside coating, generating an outer thin encapsulation that surrounds the entire cup perimeter. Coating may use medical grade silicone rubber, e.g. MED4-4420

[0119] Sensory cup **125** includes a plurality (e.g., three) of feed through pins **132** which may be brazed within preshaped ceramic assembly **130**. According to some embodiments, a single feed through pin **132** is connected to two

pressure traducers **131** at a first pole while two other feed through pins **132** are each connected to one of these two pressure transducers **131** at their second pole. A fourth feed through pin **133** may be non-connected to a pressure transducer and applied for ground. Each feed through pin **132** and **133** may have a diameter within the range of about 0.1 mm and bout 0.5 mm, for example 0.3 mm. Sensory cup **125** may be made of a metallic material, including, without limitation Titanium II. Sensory cup **125** may be from about 1.5 mm and about 5 mm in diameter, for example about 2.5 mm.

[0120] Reference is now made to FIGS. **8**A-**8**G which show use of an implant deployment device **200** for the delivery and deployment of implant **100**, releasably connected thereto. Implant deployment device **200** optionally includes at least one of a sheath **201**, a fluid inlet **202** communicating with interior of sheath **201**, an implant delivery loader **203**, and a rod or a tether **204**. Implant deployment device **200** may further include clip-deploying arm **205**, configured for releasably coupling with septum gripper **108** and thereby applicable for shifting septum gripper **108** between the delivery form and the gripping form by unhindered sliding along a segment of body wall **102** of implant **100** or/and of outer periphery of sheath **201**. Optionally the clip-deploying arm **205** has a smooth surface. Implant deployment device **200**, via tether **204**, is attached to the proximal end of implant body **201**, and can be used for maintaining the implant body **201** in place when clip-deploying arm **205** is put to motion in order to achieve relative motion between the septum gripper **108** and implant body **101**.

[0121] Rod **204** is connectable to implant body **101** optionally with a threading component **207** which is threadable into a mating threading part **137** connected to or is part of proximal end of implant body **101**. When connected to implant **100** with both rod/tether **204** and clip-deploying arm **205**, the implant deployment device **200** can be used for deploying and fixating implant **100** within the heart septum. Clip-deploying arm **205** may then be applied for grasping the septum wall using septum gripper **108**. The clip-deploying arm **205** may then be released from septum gripper **108**, prior to, followed by or in parallel to disconnecting tether **204** from proximal end of implant body **101**, once the implant has been positioned.

[0122] Clip-deploying arm **205** is releasably coupled to implant **100** at recesses **135** provided on sleeve deploying inner ring **117** of septum gripper **108**. In some embodiments, sleeve deploying inner ring **117**, when coupled with clip-deploying arm **205** and during deployment of septum gripper **108**, is configured as a sliding element, optionally having a smooth surface in contact with implant body **101**. In some embodiments, sleeve deploying inner ring **117** is also made from a non-conductive material.

[0123] As detailed above, a free end of gripping sleeve **109** is sandwiched with interconnecting sleeve deploying inner ring **117** and sleeve deploying outer ring **118**, wherein the sleeve deploying outer ring **118** is crown-like shaped with proximally pointing concavities **136** for uncovering recesses **135** (when connected thereto above) for facilitating coupling of clip-deploying arm **205**.

[0124] According to some embodiments, and as will be explained below, gripping sleeve **109** is fixedly extendable or/and compressible to a chosen length or/and shape in between more than two distinct forms, including a delivery form and a gripping form, when coupled with a distal end of the implant deployment device **200**. According to some embodiments, septum gripper **108** coupling to the delivery system **200** enables full control on the deployment of the gripper **108**. Such control affords selective positioning of the foldable units **110** and **111**, separately, while their design optionally allows some degree of conformity in response to local anatomy or/and external stresses (e.g., applied by anatomy of the heart).

[0125] The procedure of implanting implant **100** within the atrial septum includes puncture and forming of a septum opening using any standard trans septal puncturing kit and in according to the normal procedure. The puncturing is associated with routing and inserting, for example, a lead including a punctuator through the septum for effecting opening within the septum. Implant deployment device **200** connected to implant **100** is then routed through the septum opening. When in the delivery configuration, gripping sleeve **109** of septum gripper **108** is extended to be sized for passing through the septum opening. Gripping sleeve **109** is thus forced to stretch or/and confined with an outer boundary having an outer boundary inner diameter. As the implant is inserted to protrude into the left atrium, when in the delivery configuration, the distal foldable unit **111** is first to be deployed (FIG. **8**F). Following stabilization of the distal foldable unit **111** against the left atrial septum wall, the deployment device is stabilized to facilitate deployment of the proximal foldable unit **110** against the right atrial septum wall. Consequently, shifting from the delivery configuration to the gripping configuration (i.e., a non-bounded preformed gripping form) includes gripping of the griping sleeve **109** onto the atrial septum.

[0126] The implant body **101** is further fixated to or/and stabilized within the septal walls in a chosen orientation. As used herein the term "chosen orientation" refers to the orientation of implant **100** that the physician chooses for gripping the atrial septum by the gripping sleeve **109**. Chosen orientation is a tridimensional orientation relative to a center point of the septum opening and includes implant body extending through the septum opening such that an operational member thereof (i.e., sensing or/and measuring means) is provided in the target chamber of the heart.

[0127] The implant **100** may be retrieved, if and when necessary in a manner similar to the deployment of the implant with the exception that the foldable units **110** and **111** are unfolded. Specifically, the proximal foldable unit **110** is firstly unfolded and thereafter the distal foldable unit **111** is unfolded to thereby afford retrieval and removal of the implant from the body.

[0128] Each of the following terms written in singular grammatical form: 'a', 'an', and 'the', as used herein, means 'at least one', or 'one or more'. Use of the phrase 'one or more' herein does not alter this intended meaning of 'a', 'an', or 'the'. Accordingly, the terms 'a', 'an', and 'the', as used herein, may also refer to, and encompass, a plurality of the stated entity or object, unless otherwise specifically defined or stated herein, or, unless the context clearly dictates otherwise. For example, the phrases: 'a unit', 'a device', 'an assembly', 'a mechanism', 'a component', 'an element', and 'a step or procedure', as used herein, may also refer to, and encompass, a plurality of units, a plurality of devices, a plurality of assemblies, a plurality of mechanisms, a plurality of components, a plurality of elements, and, a plurality of steps or procedures, respectively.

[0129] Each of the following terms: 'includes', 'including', 'has', 'having', 'comprises', and 'comprising', and, their linguistic/grammatical variants, derivatives, or/and conjugates, as used herein, means 'including, but not limited to', and is to be taken as specifying the stated component(s), feature(s), characteristic(s), parameter(s), integer(s), or step (s), and does not preclude addition of one or more additional component(s), feature(s), characteristic(s), parameter(s), integer(s), step(s), or groups thereof. Each of these terms is considered equivalent in meaning to the phrase 'consisting essentially of'.

[0130] Each of the phrases 'consisting of' and 'consists of', as used herein, means 'including and limited to'.

[0131] The phrase 'consisting essentially of', as used herein, means that the stated entity or item (system, system unit, system sub-unit, device, assembly, sub-assembly, mechanism, structure, component, element, or, peripheral equipment, utility, accessory, or material, method or process, step or procedure, sub-step or sub-procedure), which is an entirety or part of an exemplary embodiment of the disclosed invention, or/and which is used for implementing an exemplary embodiment of the disclosed invention, may include at least one additional 'feature or characteristic' being a system unit, system sub-unit, device, assembly, sub-assembly, mechanism, structure, component, or element, or, peripheral equipment, utility, accessory, or material, step or procedure, sub-step or sub-procedure), but only if each such additional 'feature or characteristic' does not materially alter the basic novel and inventive characteristics or special technical features, of the claimed entity or item.

[0132] The term 'method', as used herein, refers to steps, procedures, manners, means, or/and techniques, for accomplishing a given task including, but not limited to, those steps, procedures, manners, means, or/and techniques, either known to, or readily developed from known steps, procedures, manners, means, or/and techniques, by practitioners in the relevant field(s) of the disclosed invention.

[0133] Throughout this disclosure, a numerical value of a parameter, feature, characteristic, object, or dimension, may be stated or described in terms of a numerical range format. Such a numerical range format, as used herein, illustrates implementation of some exemplary embodiments of the invention, and does not inflexibly limit the scope of the exemplary embodiments of the invention. Accordingly, a stated or described numerical range also refers to, and encompasses, all possible sub-ranges and individual numerical values (where a numerical value may be expressed as a whole, integral, or fractional number) within that stated or described numerical range. For example, a stated or described numerical range 'from 1 to 6' also refers to, and encompasses, all possible sub-ranges, such as 'from 1 to 3', 'from 1 to 4', 'from 1 to 5', 'from 2 to 4', 'from 2 to 6', 'from 3 to 6', etc., and individual numerical values, such as '1', '1.3', '2', '2.8', '3', '3.5', '4', '4.6', '5', '5.2', and '6', within the stated or described numerical range of 'from 1 to 6'. This applies regardless of the numerical breadth, extent, or size, of the stated or described numerical range.

[0134] Moreover, for stating or describing a numerical range, the phrase 'in a range of between about a first numerical value and about a second numerical value', is considered equivalent to, and meaning the same as, the phrase 'in a range of from about a first numerical value to about a second numerical value', and, thus, the two equivalently meaning phrases may be used interchangeably. For example, for stating or describing the numerical range of room temperature, the phrase 'room temperature' refers to a temperature in a range of between about 20° C. and about 25° C.', is considered equivalent to, and meaning the same as, the phrase 'room temperature refers to a temperature in a range of from about 20° C. to about 25° C.'.

[0135] The term 'about', as used herein, refers to ±10% of the stated numerical value.

[0136] It is to be fully understood that certain aspects, characteristics, and features, of the invention, which are, for clarity, illustratively described and presented in the context or format of a plurality of separate embodiments, may also be illustratively described and presented in any suitable combination or sub-combination in the context or format of a single embodiment. Conversely, various aspects, characteristics, and features, of the invention which are illustratively described and presented in combination or sub combination in the context or format of a single embodiment, may also be illustratively described and presented in the context or format of a plurality of separate embodiments.

[0137] Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications, and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications, and variations that fall within the spirit and broad scope of the appended claims.

[0138] All publications, patents, and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

1. An implant for sensing or/and measuring a physiological parameter in a subject's body organ separated by an organ wall, the implant comprising:

an implant body comprising a rigid body wall enclosing an inner lumen sized and configured for housing physiological parameter sensing or/and measuring unit, said body wall configured for coupling proximal end thereof with a distal end of an implant deployment device; and

a septum gripper comprising a flexible gripping sleeve fixedly connected to periphery of said rigid body wall at a sleeve fixation area between center point and distal end of said body wall, said gripping sleeve is configured and selectively shapeable from a narrowed or/and stretched form, sized to pass through a septum opening in the organ wall, to a radially expanded form, suitable for gripping onto the organ wall from opposite sides thereof and around said septum opening, such that said implant body is fixatable or/and stabilizable across the organ wall and through said septum opening, so as to facilitate the sensing or/and measuring in the subject's body organ.

2. The implant according to claim **1**, wherein the subject's body organ is a left atrium in the subject's heart, and the organ wall is an interatrial septum.

3. (canceled)

4. The implant according to claim **1**, wherein said gripping sleeve includes a bellows-like structure comprising a plurality of foldable units, including a proximal foldable unit and a distal foldable unit, wherein, when said gripping sleeve is in said expanded form,

said proximal foldable unit forms a proximal wing extending outwardly-radially relative to said implant body, so as to form a first proximal surface and a second proximal surface interconnected with a proximal edge, and

said distal foldable unit forms a distal wing extending outwardly-radially relative to said implant body, so as to form a first distal surface and a second distal surface interconnected with a distal edge.

5. (canceled)

6. The implant according to claim **4**, wherein said bellows-like structure is configured for gripping the organ wall, by pressing said second proximal surface or/and said proximal edge against a proximal side of the organ wall and pressing said second distal surface or/and said distal edge against a distal side of the organ wall, under a continuous compression force greater than a predetermined minimal force value.

7. The implant according to claim **4**, wherein said bellows-like structure is configured with a coefficient of static friction chosen so as to prevent relative motion of said septum gripper relative to the organ wall under normal stresses applied thereto in the subject's body organ.

8. The implant according to claim **4**, wherein said proximal foldable unit and said distal foldable unit are spaced or/and interconnected with, and foldable relative to, a spacing unit having a length equal to or smaller than a maximal thickness of the organ wall.

9. (canceled)

10. The implant according to claim **4**, wherein, when said gripping sleeve is in said expanded form,

said first proximal surface and said second proximal surface are formed as nested conic structures extending proximally away from said proximal edge, or formed as parallel flat structures, separated by said proximal edge; or/and

said first distal surface and said second distal surface are formed as nested conic structures extending distally away from said distal edge, or formed as parallel flat structures, separated by said distal edge.

11. The implant according to claim **4**, wherein said septum gripper comprises a non-foldable sleeve portion provided distally to said distal foldable unit, wherein said septum gripper sleeve is connected to said body wall only via said non-foldable sleeve portion.

12.-**13**. (canceled)

15. The implant according to claim **1**, wherein said septum gripper includes or is connected to a sliding element configured for unhindered sliding along said body wall during shifting between said narrowed form and said expanded form.

16. The implant according to claim **15**, wherein a free end of said gripping sleeve is sandwiched between interconnecting sleeve deploying inner ring and sleeve deploying outer ring, wherein said sleeve deploying inner ring comprises said sliding element and said sleeve deploying outer ring is configured for coupling with a sleeve deploying arm provided with said implant deployment device.

17. The implant according to claim **1**, wherein said body wall includes a first elongated wall segment of a first outer dimension and a second elongated wall segment of a second outer dimension smaller than said first outer dimension, wherein said gripping sleeve is configured to cover said first and second wall segments when in said narrowed form and to expose said first wall segment when in said expanded form.

18. The implant according to claim **17**, wherein said second wall segment houses a metal coil or/and an antenna configured for transmitting or/and receiving radio-frequency electromagnetic waves.

19. The implant according to claim **17**, wherein said first wall segment is formed of metal alloy, and said second wall segment is formed of ceramic material.

20. The implant according to claim **17**, comprising a third wall segment distally to said second wall segment, configured for housing said physiological parameter sensing or/and measuring unit.

21. (canceled)

22. The implant according to claim **1**, configured for facilitating interaction with an electronic unit located outside the subject's body;

wherein said rigid body wall having an electrically non-conductive wall section, for housing an RF antenna configured for facilitating the interaction with said electronic unit;

wherein said gripping sleeve is formed of an electrically conductive material and configured, when deployed in the subject's body, for positioning between said non-conductive wall section and said electronic unit, and for encompassing said non-conductive wall section; and

wherein said septum gripper further comprising:

an electrically non-conductive distal inner ring fixedly connecting distal portion of said gripping sleeve to said implant body; and

an electrically non-conductive proximal inner ring connecting proximal portion of said gripping sleeve to said implant body and allowing sliding thereof lengthwise about outer periphery of said rigid body wall between a proximal-most location and a distal-most location.

23.-**28**. (canceled)

29. An implant according to claim **22**, wherein said septum gripper includes a layer of electrically non-conductive covering material configured for separating or/and spacing between electrically conductive parts thereof and said body wall.

30. An implant according to claim **29**, wherein said gripping sleeve is encapsulated with said electrically non-conductive covering material.

31. An implant according to claim **22**, wherein said distal outer ring or/and said proximal outer ring is electrically conductive.

32. The implant according to claim **1**, wherein said gripping sleeve is formed of a mesh.

33. The implant according to claim **1**, wherein said septum gripper, when gripping onto the organ wall, is configured to have a chosen tridimensional orientation relative to a center point of said septum opening in which said implant body extends through said septum opening such that said physiological parameter sensing or/and measuring unit is positionable inside of the subject's body organ remotely from the organ wall.

34. The implant according to claim **1**, wherein said gripping sleeve has super elastic or/and shape memory properties.

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