



- (51) International Patent Classification:
A61N 1/375 (2006.01)
- (21) International Application Number:
PCT/US2015/028051
- (22) International Filing Date:
28 April 2015 (28.04.2015)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/985,788 29 April 2014 (29.04.2014) US
- (71) Applicant: CARDIAC PACEMAKERS, INC. [US/US];
4100 Hamline Avenue North, St. Paul, MN 55112 (US).
- (72) Inventors: SCHMIDT, Brian, L.; 12727 Homestead Drive, White Bear Lake, MN 55110 (US). HAASL, Benjamin, J.; 9420 207th Street, Forest Lake, MN 55025 (US). EDGELL, John, M.; 3180 Sycamore Lane North, Plymouth, MN 55441 (US). SACHS, Dana; 19600 County Highway 61, Pine City, MN 55063 (US).
- (74) Agent: BURGMAIER, Jason, W.; Seager, Tufte & Wickhem, LLC, 1221 Nicollet Avenue, Suite 800, Minneapolis, MN 55403-2420 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,

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(54) Title: LEADLESS CARDIAC PACEMAKER WITH RETRIEVAL FEATURES

(57) Abstract: An implantable leadless cardiac pacing device and associated retrieval features. The implantable device includes a docking member extending from the proximal end of the housing of the implantable device including a covering surrounding at least a portion of the docking member configured to facilitate retrieval of the implantable leadless cardiac pacing device.

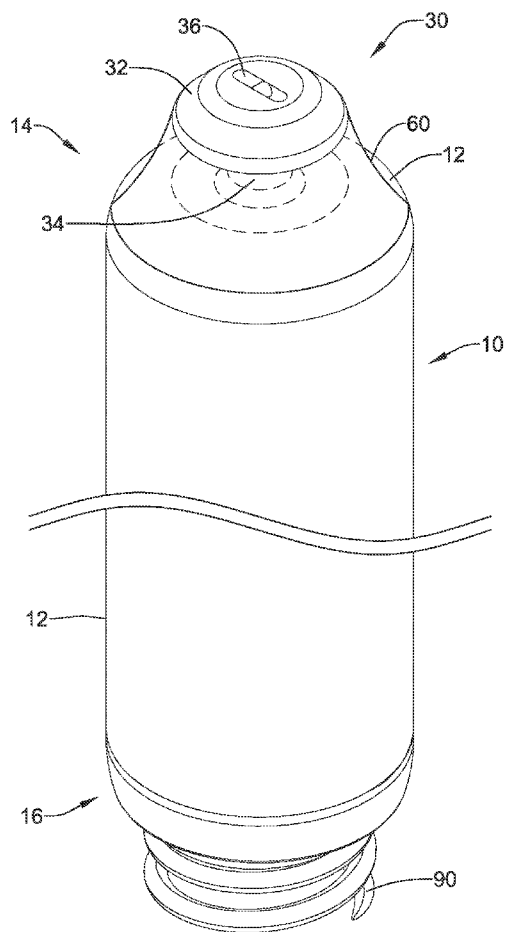


FIG. 4



HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,

— *with international search report (Art. 21(3))*

LEADLESS CARDIAC PACEMAKER WITH RETRIEVAL FEATURES

5 CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Serial No. 61/985,788, filed April 29, 2014, the disclosure of which is incorporated herein in its entirety.

10 TECHNICAL FIELD

The disclosure is directed to implantable cardiac devices. More particularly, the disclosure is directed to leadless cardiac stimulators or pacemakers including retrieval features, such as a collar or covering associated with a proximal docking member.

15 BACKGROUND

Cardiac pacemakers provide electrical stimulation to heart tissue to cause the heart to contract and thus pump blood through the vascular system. Conventional pacemakers typically include an electrical lead that extends from a pulse generator implanted subcutaneously or sub-muscularly to an electrode positioned adjacent the
20 inside or outside wall of the cardiac chamber. As an alternative to conventional pacemakers, self-contained or leadless cardiac pacemakers have been proposed. Leadless cardiac pacemakers are small capsules typically fixed to an intracardiac implant site in a cardiac chamber with a fixation mechanism engaging the intracardiac tissue. The small capsule typically includes bipolar pacing/sensing electrodes, a power
25 source (e.g. a battery), and associated electrical circuitry for controlling the pacing/sensing electrodes, and thus provide electrical stimulation to heart tissue and/or sense a physiological condition.

Accordingly, it is desirable to provide alternative structures to facilitate retrieving leadless cardiac pacemakers from an implantation site in a heart chamber.

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SUMMARY

The disclosure is directed to several alternative designs, materials and methods of manufacturing medical device structures and assemblies, and uses thereof.

Accordingly one illustrative embodiment includes an implantable leadless cardiac pacing device including a housing having a proximal end and a distal end, an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue, and a docking member extending from the proximal end of the housing along a longitudinal axis of the housing. The docking member is configured to facilitate retrieval of the implantable leadless cardiac pacing device. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion has a radial dimension from the longitudinal axis and the neck portion has a radial dimension from the longitudinal axis less than the radial dimension of the head portion. A covering surrounds at least a portion of the neck portion of the docking member.

Another illustrative embodiment includes an implantable leadless cardiac pacing device including a housing having a proximal end and a distal end, an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue, and a docking member extending from the proximal end of the housing along a longitudinal axis of the housing. The docking member is configured to facilitate retrieval of the implantable leadless cardiac pacing device. The docking member includes a head portion and a neck portion extending between the housing and the head portion. The head portion has a radial dimension from the longitudinal axis and the neck portion has a radial dimension from the longitudinal axis less than the radial dimension of the head portion. A collapsible covering is located between the head portion of the docking member and the proximal end of the housing. The collapsible covering has a peripheral surface collapsible toward the neck portion when engaged with a retrieval device.

Yet another illustrative embodiment includes a method of retrieving an implantable cardiac pacing device. The implantable cardiac pacing device has a housing having a longitudinal axis, an electrode positioned proximate a distal end of the housing, and a docking member extending from a proximal end of the housing opposite the distal end. The docking member includes a head portion, a neck portion extending between the housing and the head portion, and a covering surrounding at least a portion of the neck portion. The method includes advancing a snare toward the docking member and encircling the docking member with a loop of the snare. The loop is then cinched around the neck portion of the docking member such that the covering

collapses toward the longitudinal axis as the loop presses against the covering. In some instances, the covering collapses to a radial extent from the longitudinal axis less than an outermost radial extent of the head portion of the docking member from the longitudinal axis.

- 5 The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the aspects of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

- 10 The aspects of the disclosure may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

FIG. 1 illustrates an exemplary implantable device implanted in a chamber of a heart;

- 15 FIG. 2 illustrates an exemplary retrieval device capturing an implantable device during a retrieval procedure;

FIG. 3 illustrates another exemplary retrieval device capturing an implantable device during a retrieval procedure;

FIG. 4 illustrates an exemplary docking member of an implantable device including a covering surrounding at least a portion of the docking member;

- 20 FIGS. 5A-5C are top views illustrating some exemplary configurations of a covering surrounding at least a portion of a docking member of an implantable device;

FIGS. 6A-6B illustrate an exemplary covering for a docking member of an implantable device;

- 25 FIGS. 7A-7B illustrate another exemplary covering for a docking member of an implantable device;

FIGS. 8A-8B illustrate another exemplary covering for a docking member of an implantable device; and

FIGS. 9A-9E illustrate another exemplary covering for a docking member of an implantable device.

- 30 While the aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the

contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

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

All numeric values are herein assumed to be modified by the term “about”, whether or not explicitly indicated. The term “about” generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e.,
10 having the same function or result). In many instances, the term “about” may be indicative as including numbers that are rounded to the nearest significant figure.

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

Although some suitable dimensions, ranges and/or values pertaining to various
15 components, features and/or specifications are disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges and/or values may deviate from those expressly disclosed.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise.
20 As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The detailed description and the drawings, which are not necessarily to scale, depict illustrative
25 embodiments and are not intended to limit the scope of the disclosure. The illustrative embodiments depicted are intended only as exemplary. Selected features of any illustrative embodiment may be incorporated into an additional embodiment unless clearly stated to the contrary.

Referring to FIG. 1, an exemplary implantable leadless cardiac pacing device
30 10 (e.g., a leadless pacemaker) is illustrated implanted in a chamber of a heart H, such as the apex of the right ventricle RV. The implantable device 10 may include a shell or housing 12 having a proximal end 14 and a distal end 16. The implantable device 10 may include a first electrode 20 positioned proximate the distal end 16 of the housing

12 and a second electrode 22 positioned proximate the proximal end 14 of the housing 12. The electrodes 20, 22 may be sensing and/or pacing electrodes to provide electro-therapy and/or sensing capabilities. The first electrode 20 may be configured to be positioned against or otherwise contact the cardiac tissue of the heart H while the second
5 electrode 22 may be spaced away from the first electrode 20, and thus spaced away from the cardiac tissue.

The implantable device 10 may include a pulse generator (e.g., electrical circuitry) and a power source (e.g., a battery) within the housing 12 to provide electrical signals to the electrodes 20, 22 and thus control the pacing/sensing electrodes 20, 22.
10 Electrical communication between pulse generator and the electrodes 20, 22 may provide electrical stimulation to heart tissue and/or sense a physiological condition.

The implantable device 10 may include a fixation mechanism 24 proximate the distal end 16 of the housing 12 configured to attach the implantable device 10 to a tissue wall of the heart H, or otherwise anchor the implantable device 10 to the anatomy of
15 the patient. As shown in FIG. 1, in some instances, the fixation mechanism 24 may include one or more, or a plurality of hooks 26 anchored into the cardiac tissue of the heart H to attach the implantable device 10 to a tissue wall. In other instances, the fixation mechanism 24 may include one or more, or a plurality of passive tines, configured to entangle with trabeculae within the chamber of the heart H and/or a
20 helical fixation anchor configured to be screwed into a tissue wall to anchor the implantable device 10 to the heart H.

The implantable device 10 may include a docking member 30 proximate the proximal end 14 of the housing 12 configured to facilitate delivery and/or retrieval of the implantable device 10. For example, the docking member 30 may extend from the
25 proximal end 14 of the housing 12 along a longitudinal axis of the housing 12. The docking member 30 may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may be an enlarged portion relative to the neck portion 34. For example, the head portion 32 may have a radial dimension from the longitudinal axis of the implantable device 10 which
30 is greater than a radial dimension of the neck portion from the longitudinal axis of the implantable device 10. The docking member 30 may be configured to facilitate delivery of the implantable device 10 to the intracardiac site and/or retrieval of the implantable

device 10 from the intracardiac site. Some exemplary embodiments of the docking member 30 are described in further detail herein.

The implantable device 10 may also include a covering 60 surrounding at least a portion of the neck portion 34 of the docking member 30. For example, the covering 60 may extend from the head portion 34 of the docking member 30 to the proximal end of the housing 12, in some instances. The covering 60 may be collapsible radially inward toward the longitudinal axis, and thus toward the neck portion 34. In some instances, the covering 60 may be provided to preclude blood coagulation or embolization around the neck portion 34 while implanted in a patient, yet resilient to permit a snare or other retrieval device to cinch around the neck portion 34 during a retrieval procedure.

If it is desired to retrieve the implantable device 10 from the heart H, a retrieval device 50 may be advanced into the chamber of the heart H to capture the implantable device 10 and remove the implantable device 10 from the heart H. One exemplary retrieval device 50 is illustrated in FIG. 2. The retrieval device 50 may include a snare 52 advanceable from a lumen 58 of a retrieval catheter 54. The snare 52 may include one or more, or a plurality of loops 56 extending from a distal end of the snare 52 configured to engage the docking member 30 of the implantable device 10. The snare 52 shown in FIG. 2 includes three loops 56 formed by elongate filaments extending from the shaft of the snare 52. Once the loop(s) 56 of the snare 52 has captured the docking member 30, the snare 52 may be actuated proximally relative to the retrieval catheter 54 to pull the implantable device 10 into the lumen 58 of the retrieval catheter 54. The enlarged size of the head portion 32 relative to the neck portion 34 may permit the loop 56 of the snare 52 to encircle the neck portion 34 below (i.e., distal of) the head portion 32 and retain the loop 56 around the docking member 30 as the snare 52 is pulled proximally.

The loop of the snare 56 may collapse the covering 60 radially inward toward the neck portion 34 as the loop of the snare is cinched around the neck portion 34. The resiliency of the covering 60 may permit the loop of the snare 56 or other retrieval device to cinch around the neck portion 34 distal of the head portion 32 to secure the snare 56 with the docking member 30 to apply a retrieval force to pull the implantable device 10 into the retrieval catheter 54.

As the implantable device 10 is pulled into the retrieval catheter 54, the fixation mechanism 24 may disengage from the heart tissue to detach the implantable device 10 from the heart wall. For example, the hooks 26 may elongate as the implantable device 10 is drawn proximally into the lumen 58 of the retrieval catheter 54. Thereafter, the retrieval device 50, with the implantable device 10 captured in the lumen of the retrieval catheter 54 with the snare 52, may be withdrawn from the heart H.

Another exemplary retrieval device 50 is illustrated in FIG. 3. Similar to FIG. 2, the retrieval device 50 may include a snare 52 advanceable from a lumen 58 of a retrieval catheter 54. The snare 52 may include one or more, or a plurality of loops 56 extending from a distal end of the snare 52 configured to engage the docking member 30 of the implantable device 10. The snare 52 shown in FIG. 3 includes a single loop 56 formed by an elongate filament extending from the shaft of the snare 52. Once the loop 56 of the snare 52 has captured the docking member 30, the snare 52 may be actuated proximally relative to the retrieval catheter 54 to pull the implantable device 10 into the lumen 58 of the retrieval catheter 54. The enlarged size of the head portion 32 relative to the neck portion 34 may permit the loop 56 of the snare 52 to encircle the neck portion 34 below (i.e., distal of) the head portion 32 and retain the loop 56 around the docking member 30 as the snare 52 is pulled proximally.

The loop of the snare 56 may collapse the covering 60 radially inward toward the neck portion 34 as the loop of the snare is cinched around the neck portion 34. The resiliency of the covering 60 may permit the loop of the snare 56 or other retrieval device to cinch around the neck portion 34 distal of the head portion 32 to secure the snare 56 with the docking member 30 to apply a retrieval force to pull the implantable device 10 into the retrieval catheter 54.

As the implantable device 10 is pulled into the retrieval catheter 54, the fixation mechanism 30 may disengage from the heart tissue to detach the implantable device 10 from the heart wall. For example, the hooks 26 may elongate as the implantable device 10 is drawn proximally into the lumen 58 of the retrieval catheter 54. Thereafter, the retrieval device 50, with the implantable device 10 captured in the lumen of the retrieval catheter 54 with the snare 52, may be withdrawn from the heart H.

FIG. 4 illustrates one exemplary docking member 30 with an associated covering 60 located at the proximal end 14 of the implantable device 10. The docking member 30 shown in FIG. 4 may include a head portion 32 and a neck portion 34

extending between the housing 12 and the head portion 32. The head portion 32 may be a generally disc shaped ball, having a radial dimension (e.g., diameter) greater than the radial dimension (e.g., diameter) of the neck portion 34. The docking member 30 may also include a passage 36 extending through a portion of the docking member 30 to receive a tether (not shown) which may be used in delivery and/or retrieval of the implantable device 10. For example, the passage 36 may extend through the head portion 32 from a first side to a second side of the head portion 32.

The covering 60 may be provided with the docking member 30. For example, the covering 60 may surround at least a portion of the neck portion 34 of the docking member 30 between the head portion 32 and the housing 12. The covering 60 may be configured to inhibit tissue growth or entanglement around the docking member 30 and/or preclude blood coagulation or embolization around the neck portion 34 while implanted in a patient, yet resilient to permit a snare or other retrieval device to cinch around the neck portion 34 during a retrieval procedure. For example, the covering 60 may deflect, compress, or otherwise collapse toward the longitudinal axis of the implantable device 10 by an applied force from the snare 56.

FIGS. 5A-5C are top views illustrating some exemplary configurations of the covering 60 surrounding at least a portion of the docking member 30 of the implantable device 10. These configurations are illustrative of some possible configurations, however, other configurations of the covering 60 are contemplated. As shown in FIG. 5A, in some embodiments, the covering 60 may be an annular member fully surrounding the entire perimeter of the neck portion 34 of the docking member 30. In other embodiments, such as in FIGS. 5B and 5C, the covering 60 may extend around less than the entire perimeter of the neck portion 34 of the docking member 30. For example, FIG. 5B illustrates a configuration of the covering 60 having a pair of regions extending in opposite directions from the docking member 30. FIG. 5C illustrates another configuration in which the covering 60 includes four regions equally arranged around the perimeter (e.g., circumference) of the neck portion 34 of the docking member 30. In embodiments in which the covering 60 includes one or more, or a plurality of segments, the segments may be arranged symmetrically or asymmetrically around the perimeter (e.g., circumference) of the neck portion 34, as desired.

The covering 60, which in some instances may be a shroud, collar, sheath, casing, or other structure covering or extending over at least portion of the neck portion

34 of the docking member 30, may be formed of any desired biocompatible material. For example, in some instances the covering 60 may include a fibrous material, such as an electro-spun fibrous material, formed of one or more, or a plurality of nano-fibers. In some instances, the fibrous material may be a fabric or mesh material, formed of a plurality of non-woven, interwoven, entangled, or otherwise arranged fibers or filaments. In some instances, the covering 60 may include porous material having desired porosity. For example, the covering 60 may include a sponge material, such as synthetic sponge material, having an open cell or a closed cell structure which may be compressed with the application of force. In some instances, the covering 60 may include a foam material, such as an open-cell or closed-cell foam material having a desired porosity. For example, in some instances the foam material may be a reticulated foam material. In some instances, the covering 60 may include a gel.

The covering 60, which may be formed of one or more of the above configurations, or other desired configurations, may be formed of a biostable material and/or a bioabsorbable material. Some suitable biostable polymeric materials include, but are not necessarily limited to, polyamide, polyether block amide, polyethylene, polyethylene terephthalate, polypropylene, polyvinylchloride, polyurethane, polytetrafluoroethylene, polysulfone, and copolymers, blends, mixtures or combinations thereof. Examples of suitable bioabsorbable materials may include polymers, such as polylactide, poly-L-lactide (PLLA), polyglycolide (PGA), polylactide (PLA), poly-D-lactide (PDLA), polycaprolactone, polydioxanone, polygluconate, polylactic acid-polyethylene oxide copolymers, modified cellulose, collagen, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), and combinations thereof.

In some instances the covering 60 may include a therapeutic agent, if desired. The therapeutic agent may be a drug, a non-genetic agent, a genetic agent, etc. Some examples of suitable non-genetic therapeutic agents include but are not limited to: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopentin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miogenic agents such

as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

FIGS. 6A-6B illustrate a first exemplary covering 60 for the docking member 30 of the implantable device 10. The covering 60 may extend from the docking member 30, for example the head portion 32 of the docking member 30, to the proximal end of the housing 12 of the implantable device 10, or otherwise be positioned between the head portion 32 and the housing 12. The covering 60 may extend across a recessed area 70 or hollow defined between the enlarged head portion 32 of the docking member 30 and a proximal end of the housing 12 of the implantable device 10. For example, the covering 60 may be a thin polymeric film extending across the recessed area 70. In the embodiment of FIGS. 6A-6B, a cavity 62 may be located between the covering 60 and an outer surface of the neck portion 34 of the docking member 30. In some instances, the covering 60 may extend entirely around the perimeter (e.g., circumference) of the docking member 30, or the covering 60 may be located around a portion of the perimeter of the docking member 30.

In the equilibrium state, shown in FIG. 6A, the covering 60 may have a radial dimension from the longitudinal axis X greater than the radial dimension of the neck portion 34. For example, the covering 60 may have a radial dimension from the longitudinal axis X greater than or equal to the radial dimension of the head portion 32.

In embodiments in which the covering 60 annularly surrounds the neck portion 34, the collapsible covering 60 may have a first diameter in the equilibrium state.

The covering 60 may be collapsible toward the longitudinal axis, and thus toward the neck portion 34, to a collapsed state through the application of force, such as the cinching force of a snare 56 of a retrieval device, shown in FIG. 6B. In the collapsed state, shown in FIG. 6B, the radial dimension of the covering 60 in a plane perpendicular to the longitudinal axis X may be reduced from the radial dimension at the equilibrium state to a smaller radial dimension at the collapsed state. For example, in the collapsed state, shown in FIG. 6B, the diameter of the covering 60 in a plane perpendicular to the longitudinal axis X may be reduced from the first diameter at the equilibrium state to a second diameter smaller than the first diameter at the collapsed state.

Thus, the covering 60 may permit a loop of a snare 56 or other retrieval device, to engage the docking member 30 distal of the head portion 32 during a retrieval procedure and sufficiently tighten around the neck portion 34 such that the loop of the snare 56 will enter the recessed area 70 or hollow, and thus not slip off the docking member 30. For instance, the snare 56 may be sufficiently tightened around the neck portion 34 such that the head portion 32 is prevented from passing through the loop of the snare 56. For example, the snare 56 may be tightened in the recessed area 70 to a radial dimension less than the radial dimension of the head portion 32 in at least one radial direction from the longitudinal axis X, preventing the head portion 32 from passing through the loop of the snare 56. The collapsible covering 60 may inhibit tissue growth or entanglement around the docking member 30, such as in the recessed area 70, and/or preclude blood coagulation or embolization around the neck portion 34, such as in the recessed area 70, while implanted in a patient which may otherwise obstruct the recessed area 70 and thus inhibit the loop of the snare 56 from being sufficiently tightened around the docking member 30.

FIGS. 7A-7B illustrate a second exemplary covering 160 for the docking member 30 of the implantable device 10. The covering 160 may extend from the docking member 30, for example the head portion 32 of the docking member 30, to the proximal end of the housing 12 of the implantable device 10, or otherwise be positioned between the head portion 32 and the housing 12. The covering 160 may substantially fill a recessed area 70 or hollow defined between the enlarged head portion 32 of the

docking member 30 and a proximal end of the housing 12 of the implantable device 10. In some instances, the covering 160 may be an annular member extending entirely around the perimeter (e.g., circumference) of the docking member 30 in the recessed area 70, or the covering 160 may be located around a portion of the perimeter of the
5 docking member 30.

In the equilibrium state, shown in FIG. 7A, the covering 160 may have a radial dimension from the longitudinal axis X greater than the radial dimension of the neck portion 34. For example, the covering 160 may have a radial dimension from the longitudinal axis X greater than or equal to the radial dimension of the head portion 32.
10 In embodiments in which the covering 160 annularly surrounds the neck portion 34, the collapsible covering 160 may have a first diameter in the equilibrium state.

The covering 160 may be collapsible toward the longitudinal axis, and thus toward the neck portion 34, to a collapsed state through the application of force, such as the cinching force of a snare 56 of a retrieval device, shown in FIG. 7B. In the
15 collapsed state, shown in FIG. 7B, the radial dimension of the covering 160 in a plane perpendicular to the longitudinal axis X may be reduced from the radial dimension at the equilibrium state to a smaller radial dimension at the collapsed state. For example, in the collapsed state, shown in FIG. 7B, the diameter of the covering 160 in a plane perpendicular to the longitudinal axis X may be reduced from the first diameter at the
20 equilibrium state to a second diameter smaller than the first diameter at the collapsed state.

Thus, the covering 160 may permit a loop of a snare 56 or other retrieval device, to engage the docking member 30 distal of the head portion 32 during a retrieval procedure and sufficiently tighten around the neck portion 34 such that the loop of the
25 snare 56 will enter the recessed area 70 or hollow, and thus not slip off the docking member 30. For instance, the snare 56 may be sufficiently tightened around the neck portion 34 such that the head portion 32 is prevented from passing through the loop of the snare 56. For example, the snare 56 may be tightened in the recessed area 70 to a radial dimension less than the radial dimension of the head portion 32 in at least one
30 radial direction from the longitudinal axis X, preventing the head portion 32 from passing through the loop of the snare 56. The collapsible covering 160 may inhibit tissue growth or entanglement around the docking member 30, such as in the recessed area 70, and/or preclude blood coagulation or embolization around the neck portion 34,

such as in the recessed area 70, while implanted in a patient which may otherwise obstruct the recessed area 70 and thus inhibit the loop of the snare 56 from being sufficiently tightened around the docking member 30.

FIGS. 8A-8B illustrate a third exemplary covering 260 for the docking member 30 of the implantable device 10. The covering 260 may extend from the docking member 30, for example the head portion 32 of the docking member 30, to the proximal end of the housing 12 of the implantable device 10, or otherwise be positioned between the head portion 32 and the housing 12. The covering 260 may include an outer layer of material 264 and a core layer of material 262 radially interior of the outer layer 264. The covering 260 may substantially fill a recessed area 70 or hollow defined between the enlarged head portion 32 of the docking member 30 and a proximal end of the housing 12 of the implantable device 10. In some instances, the covering 260 may be an annular member extending entirely around the perimeter (e.g., circumference) of the docking member 30 in the recessed area 70, or the covering 260 may be located around a portion of the perimeter of the docking member 30. For example, the outer layer 264 may be an annular sleeve, with the inner layer 262 filling the space between the outer layer 264 and the neck portion 34 in the recessed area 70.

In the equilibrium state, shown in FIG. 8A, the covering 260 may have a radial dimension from the longitudinal axis X greater than the radial dimension of the neck portion 34. For example, the covering 260 may have a radial dimension from the longitudinal axis X greater than or equal to the radial dimension of the head portion 32. In embodiments in which the covering 260 annularly surrounds the neck portion 34, the collapsible covering 260 may have a first diameter in the equilibrium state.

The covering 260 may be collapsible toward the longitudinal axis, and thus toward the neck portion 34, to a collapsed state through the application of force, such as the cinching force of a snare 56 of a retrieval device, shown in FIG. 8B. In the collapsed state, shown in FIG. 8B, the radial dimension of the covering 260 in a plane perpendicular to the longitudinal axis X may be reduced from the radial dimension at the equilibrium state to a smaller radial dimension at the collapsed state. For example, in the collapsed state, shown in FIG. 8B, the diameter of the covering 260 in a plane perpendicular to the longitudinal axis X may be reduced from the first diameter at the equilibrium state to a second diameter smaller than the first diameter at the collapsed state.

Thus, the covering 260 may permit a loop of a snare 56 or other retrieval device, to engage the docking member 30 distal of the head portion 32 during a retrieval procedure and sufficiently tighten around the neck portion 34 such that the loop of the snare 56 will enter the recessed area 70 or hollow, and thus not slip off the docking member 30. For instance, the snare 56 may be sufficiently tightened around the neck portion 34 such that the head portion 32 is prevented from passing through the loop of the snare 56. For example, the snare 56 may be tightened in the recessed area 70 to a radial dimension less than the radial dimension of the head portion 32 in at least one radial direction from the longitudinal axis X, preventing the head portion 32 from passing through the loop of the snare 56. The collapsible covering 260 may inhibit tissue growth or entanglement around the docking member 30, such as in the recessed area 70, and/or preclude blood coagulation or embolization around the neck portion 34, such as in the recessed area 70, while implanted in a patient which may otherwise obstruct the recessed area 70 and thus inhibit the loop of the snare 56 from being sufficiently tightened around the docking member 30.

FIGS. 9A-9E illustrate another exemplary covering 360 for a docking member 30 of an implantable device 10. The covering 360 may extend from the docking member 30, for example the head portion 32 of the docking member 30, to the proximal end of the housing 12 of the implantable device 10, or otherwise be positioned between the head portion 32 and the housing 12. The covering 360 may substantially fill a recessed area 70 or hollow defined between the enlarged head portion 32 of the docking member 30 and a proximal end of the housing 12 of the implantable device 10. In some instances, the covering 360 may be an annular member extending entirely around the perimeter (e.g., circumference) of the docking member 30 in the recessed area 70, or the covering 360 may be located around a portion of the perimeter of the docking member 30.

In the equilibrium state, shown in FIG. 9A, the covering 360 may have a radial dimension from the longitudinal axis X greater than the radial dimension of the neck portion 34. For example, the covering 360 may have a radial dimension from the longitudinal axis X greater than or equal to the radial dimension of the head portion 32. In embodiments in which the covering 360 annularly surrounds the neck portion 34, the collapsible covering 360 may have a first diameter in the equilibrium state.

The covering 360 may be collapsible toward the longitudinal axis, and thus toward the neck portion 34, to a collapsed state through the application of force, such as the cinching force of a snare 56 of a retrieval device, shown in FIG. 9E. In the collapsed state, shown in FIG. 9E, the radial dimension of the covering 360 in a plane perpendicular to the longitudinal axis X may be reduced from the radial dimension at the equilibrium state to a smaller radial dimension at the collapsed state. For example, in the collapsed state, shown in FIG. 9E, the diameter of the covering 360 in a plane perpendicular to the longitudinal axis X may be reduced from the first diameter at the equilibrium state to a second diameter smaller than the first diameter at the collapsed state.

Thus, the covering 360 may permit a loop of a snare 56 or other retrieval device, to engage the docking member 30 distal of the head portion 32 during a retrieval procedure and sufficiently tighten around the neck portion 34 such that the loop of the snare 56 will enter the recessed area 70 or hollow, and thus not slip off the docking member 30. For instance, the snare 56 may be sufficiently tightened around the neck portion 34 such that the head portion 32 is prevented from passing through the loop of the snare 56. For example, the snare 56 may be tightened in the recessed area 70 to a radial dimension less than the radial dimension of the head portion 32 in at least one radial direction from the longitudinal axis X, preventing the head portion 32 from passing through the loop of the snare 56. The collapsible covering 360 may inhibit tissue growth or entanglement around the docking member 30, such as in the recessed area 70, and/or preclude blood coagulation or embolization around the neck portion 34, such as in the recessed area 70, while implanted in a patient which may otherwise obstruct the recessed area 70 and thus inhibit the loop of the snare 56 from being sufficiently tightened around the docking member 30.

The covering 360 may also include one or more retrieval features configured to direct a retrieval device into the recessed area 70 and into engagement with the docking member 30. For example, the covering 360 may include a retrieval member 380 including one or more, or a plurality of radially extending protrusions 382. As shown in FIG. 9A, the radially extending protrusion(s) may extend a radial distance D2 greater than the radial distance D1 of the housing 12 in an equilibrium or deployed state. The protrusion(s) 382 may include an engagement surface 384, such as an angled engagement surface 384. The engagement surface 384 may be oriented at an oblique

angle to the longitudinal axis X to facilitate guiding a snare 56 of a retrieval device into the recessed area 70.

In a delivery state, such as shown in FIG. 9B, the protrusion(s) may deflect within a delivery sheath 90, and expand outward to the equilibrium position shown in
5 FIG. 9A when deployed.

During retrieval of the implantable device 10 with a snare 56 of a retrieval device, the snare 56 may be manipulated to surround the housing 12 of the implantable device 10, shown in FIG. 9C. Once the snare 56 has encircled the housing 12, the snare 56 may be cinched down around the housing 12 and drawn proximally toward the
10 docking member 30, as shown in FIG. 9C. Turning the FIG. 9D, as the snare 56 reaches the protrusion(s) 382, the snare 56 may engage the engagement surface 384 of the protrusion(s) 382 to guide the snare 56 into the recessed area 70. The retrieval member 380 may prevent the snare 56 from slipping off of the docking member 30.

With the snare 56 guided into the recessed area 70, the loop of the snare 56 may
15 be cinched down around the neck portion 34, thus collapsing the covering 360 radially inward toward the neck portion 34.

Those skilled in the art will recognize that aspects of the present disclosure may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departure in form and detail may be made without
20 departing from the scope and spirit of the present disclosure as described in the appended claims.

Additional Examples

One additional example is an implantable leadless cardiac pacing device
25 including a housing having a proximal end and a distal end, an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue, and a docking member extending from the proximal end of the housing along a longitudinal axis of the housing. The docking member is configured to facilitate retrieval of the implantable leadless cardiac pacing device. The docking member
30 includes a head portion and a neck portion extending between the housing and the head portion. The head portion has a radial dimension from the longitudinal axis and the neck portion has a radial dimension from the longitudinal axis less than the radial

dimension of the head portion. A covering surrounds at least a portion of the neck portion of the docking member.

Additionally or alternatively, in a second embodiment, the covering precludes blood coagulation or embolization around the neck portion while implanted in a patient.

5 Additionally or alternatively, in a third embodiment, the covering is collapsible toward the neck portion.

Additionally or alternatively, in a fourth embodiment, the covering extends from the head portion of the docking member to the proximal end of the housing.

10 Additionally or alternatively, in a fifth embodiment, the covering has a radial dimension from the longitudinal axis greater than the radial dimension of the neck portion.

Additionally or alternatively, in a sixth embodiment, the covering has a radial dimension from the longitudinal axis greater than or equal to the radial dimension of the head portion.

15 Additionally or alternatively, in a seventh embodiment, the covering comprises an electro-spun fibrous material.

Additionally or alternatively, in an eighth embodiment, the covering comprises a synthetic sponge material.

20 Additionally or alternatively, in a ninth embodiment, the covering comprises a foam material.

Additionally or alternatively, in a tenth embodiment, the covering comprises a gel.

Additionally or alternatively, in an eleventh embodiment, the covering comprises a fabric material.

25 Additionally or alternatively, in a twelfth embodiment, the covering comprises a bioabsorbable material.

Additionally or alternatively, in a thirteenth embodiment, the covering comprises a drug.

30 Additionally or alternatively, in a fourteenth embodiment, the covering includes one or more retrieval features configured to direct a retrieval device into engagement with the docking member.

Additionally or alternatively, in a fifteenth embodiment, the one or more retrieval features include one or more radially extending protrusions.

What is claimed is:

1. An implantable leadless cardiac pacing device comprising:
 - a housing having a proximal end and a distal end;
 - an electrode positioned proximate the distal end of the housing configured to be positioned adjacent cardiac tissue; and
 - a docking member extending from the proximal end of the housing along a longitudinal axis of the housing, the docking member configured to facilitate retrieval of the implantable leadless cardiac pacing device;
 - the docking member including a head portion and a neck portion extending between the housing and the head portion;
 - the head portion having a radial dimension from the longitudinal axis and the neck portion having a radial dimension from the longitudinal axis less than the radial dimension of the head portion; and
 - a covering surrounding at least a portion of the neck portion of the docking member.
2. The implantable leadless cardiac pacing device of claim 1, wherein the covering is collapsible toward the neck portion.
3. The implantable leadless cardiac pacing device of claim 1 or 2, wherein the covering extends from the head portion of the docking member to the proximal end of the housing.
4. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering has a radial dimension from the longitudinal axis greater than the radial dimension of the neck portion.
5. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering has a radial dimension from the longitudinal axis greater than or equal to the radial dimension of the head portion.
6. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises an electro-spun fibrous material.

7. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a synthetic sponge material.
8. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a foam material.
9. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a gel.
10. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a fabric material.
11. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a bioabsorbable material.
12. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering comprises a drug.
13. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering includes one or more retrieval features configured to direct a retrieval device into engagement with the docking member.
14. The implantable leadless cardiac pacing device of claim 13, wherein the one or more retrieval features include one or more radially extending protrusions.
15. The implantable leadless cardiac pacing device of any one of the preceding claims, wherein the covering precludes blood coagulation or embolization around the neck portion while implanted in a patient.

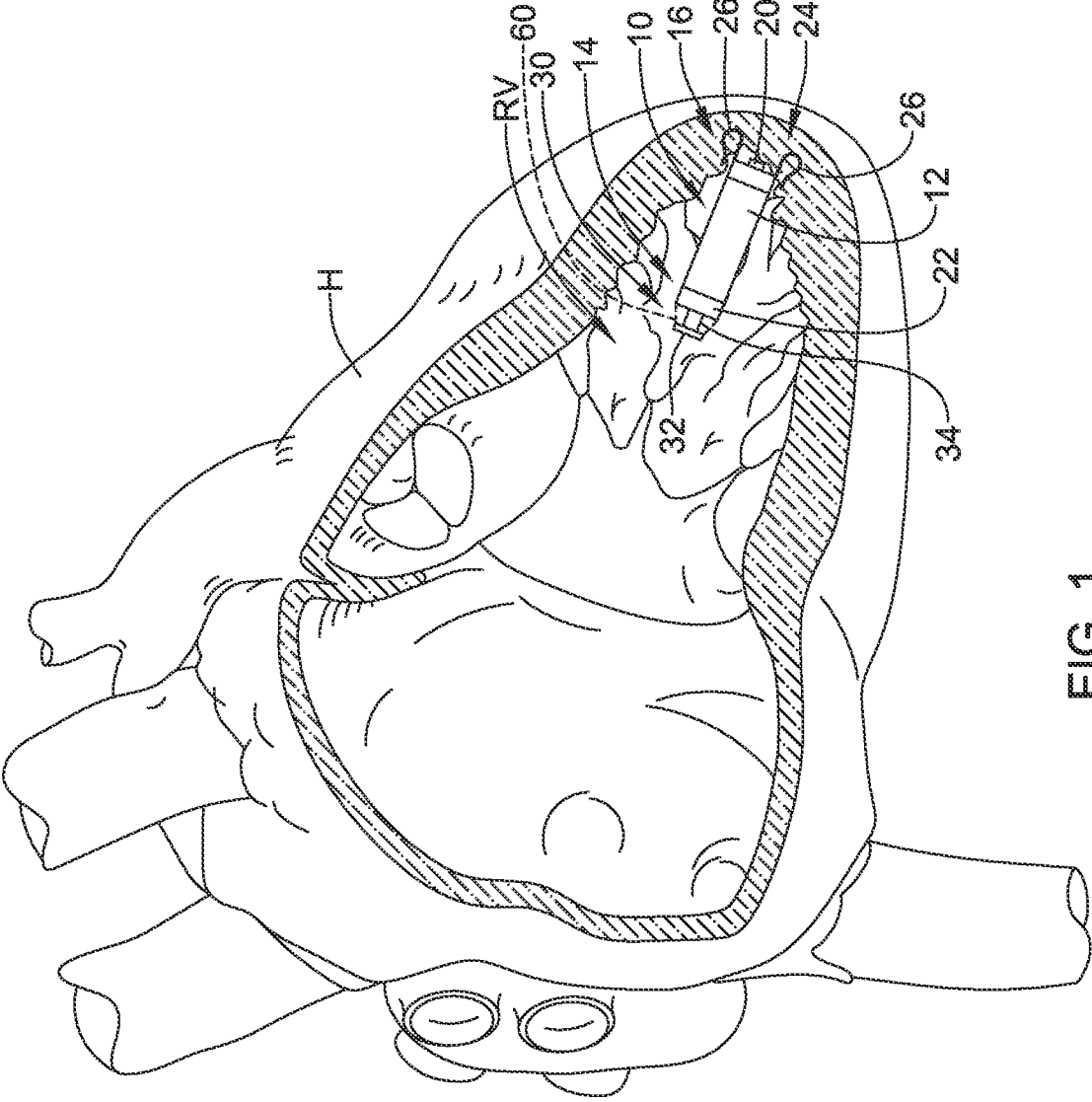


FIG. 1

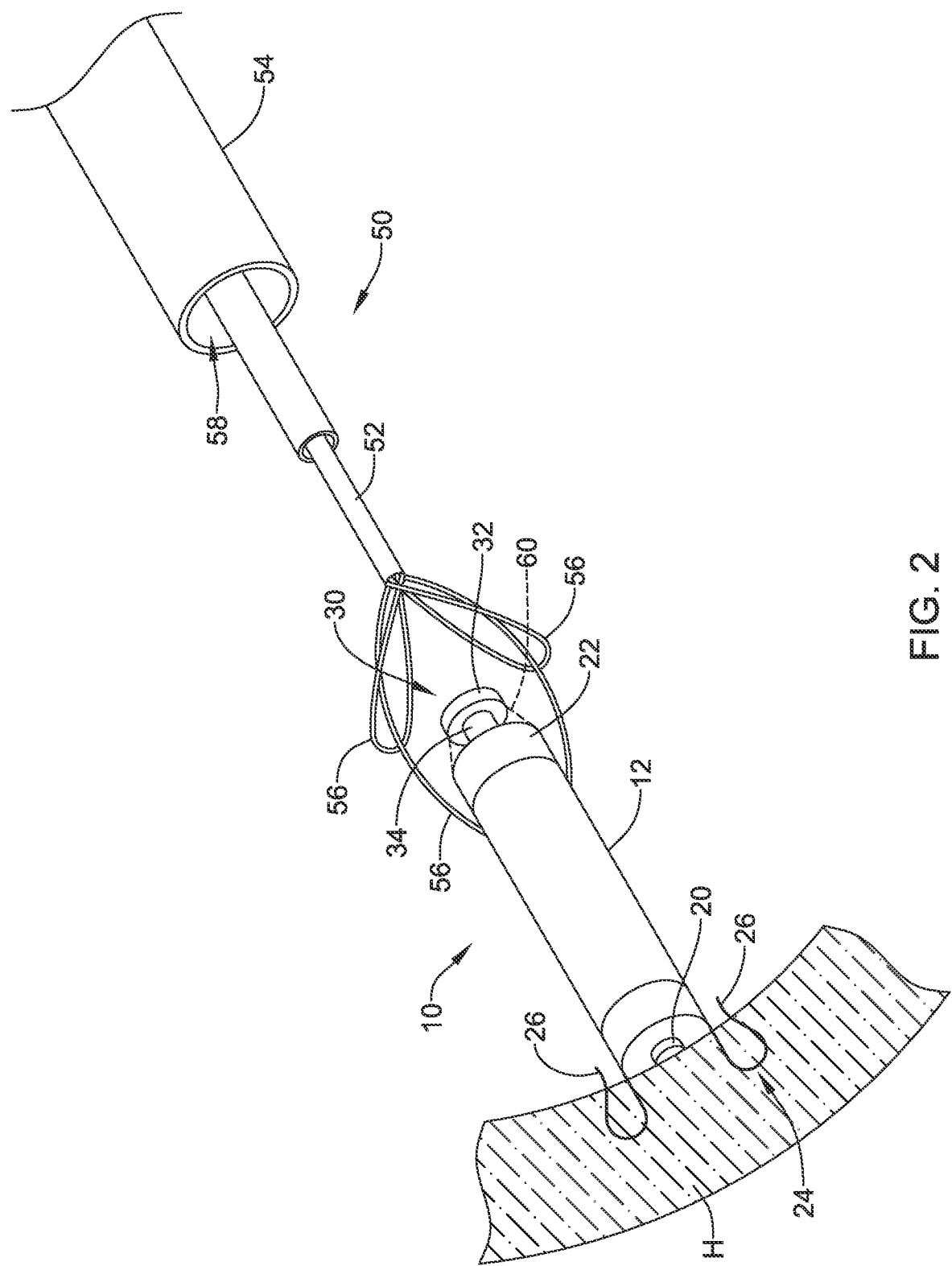
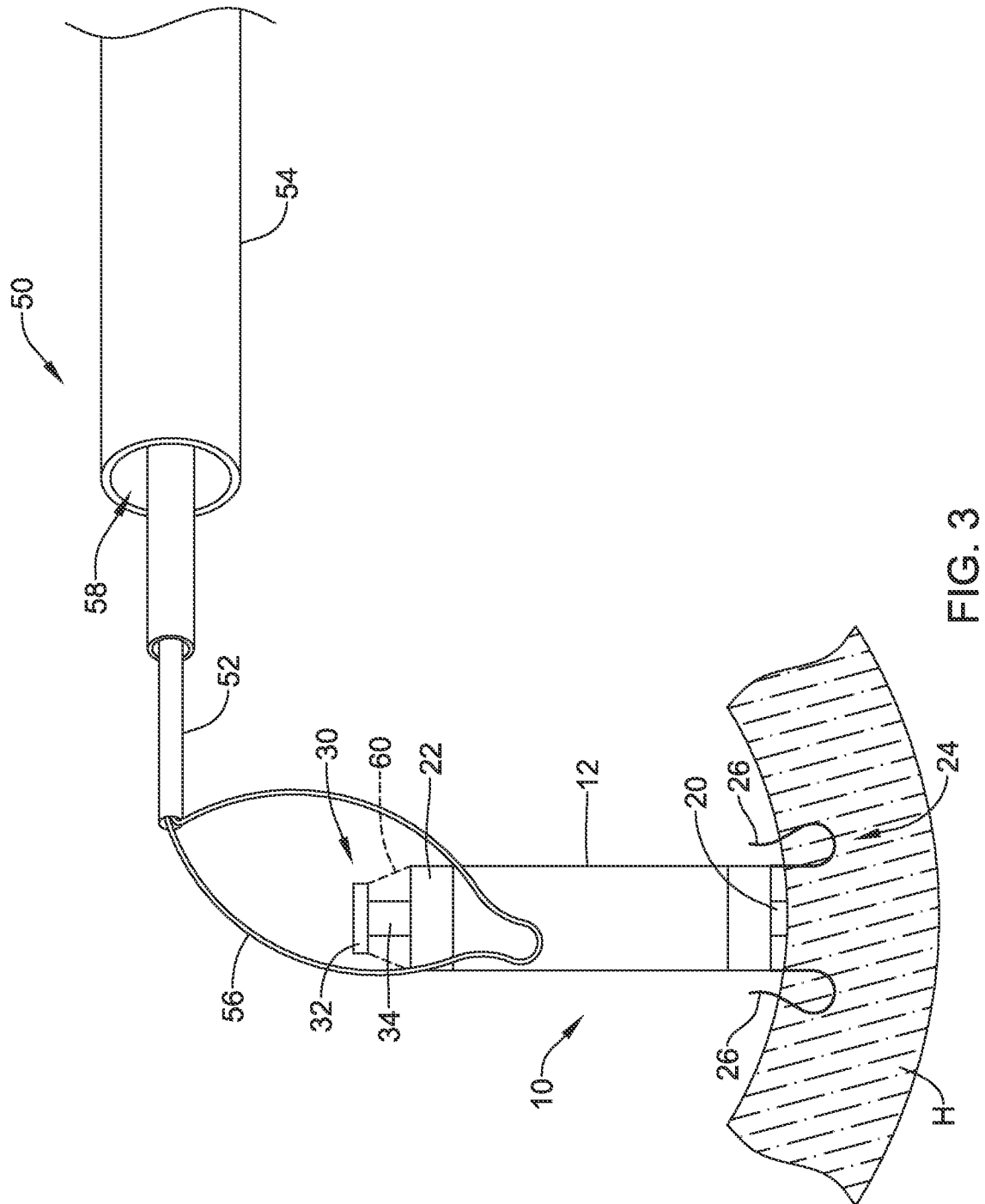


FIG. 2



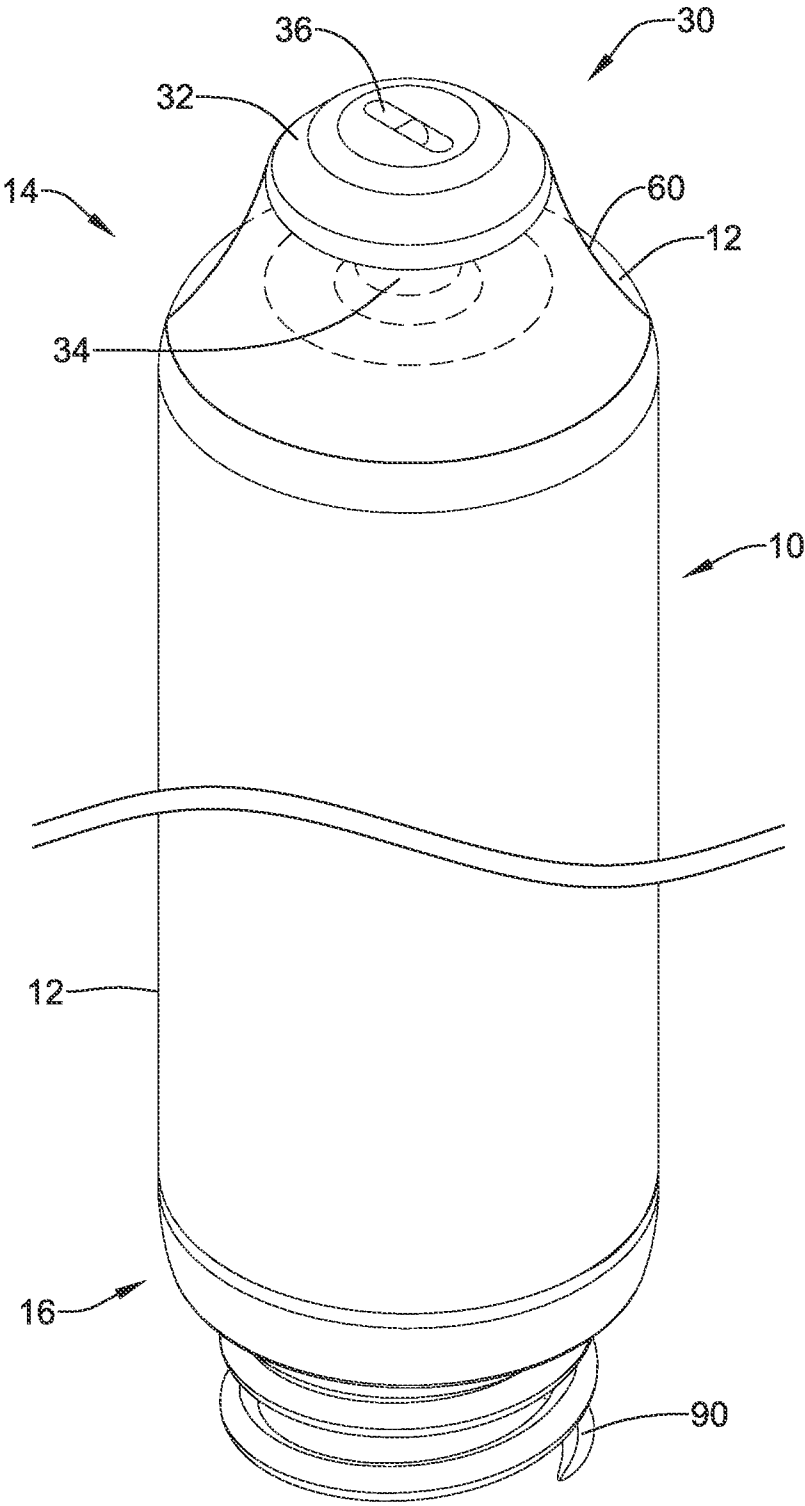


FIG. 4

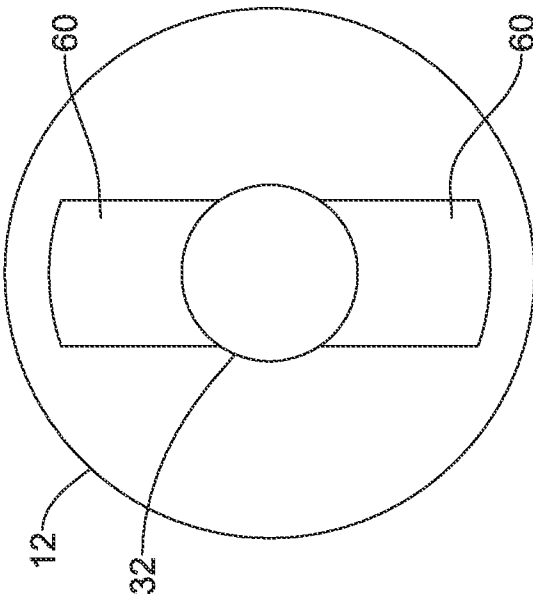


FIG. 5B

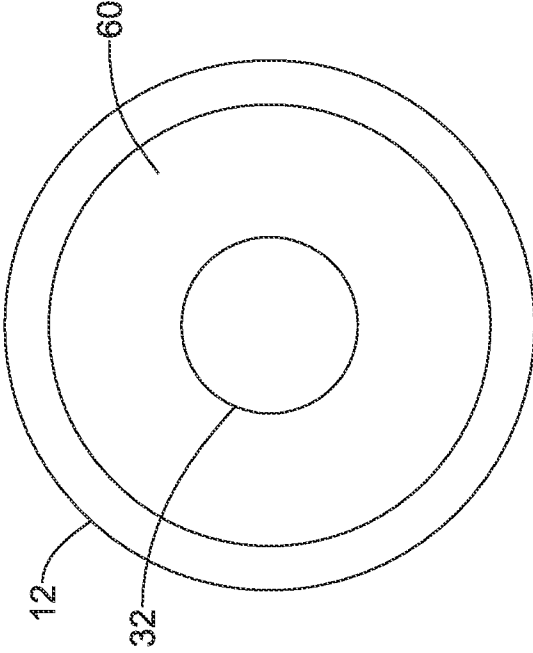


FIG. 5A

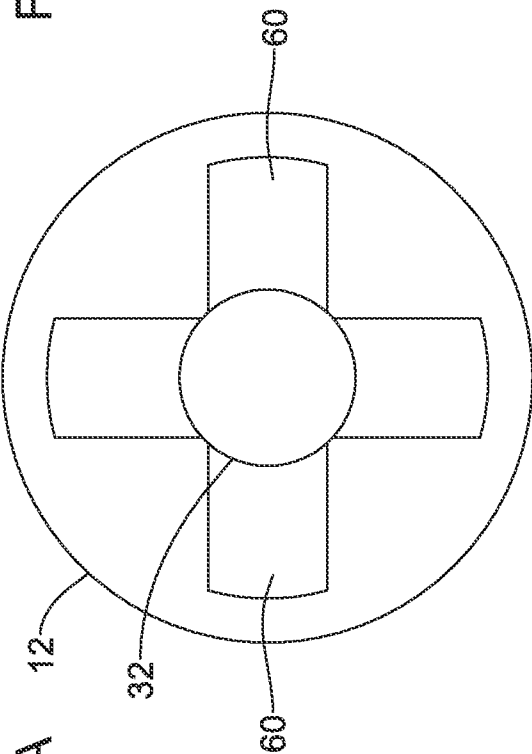


FIG. 5C

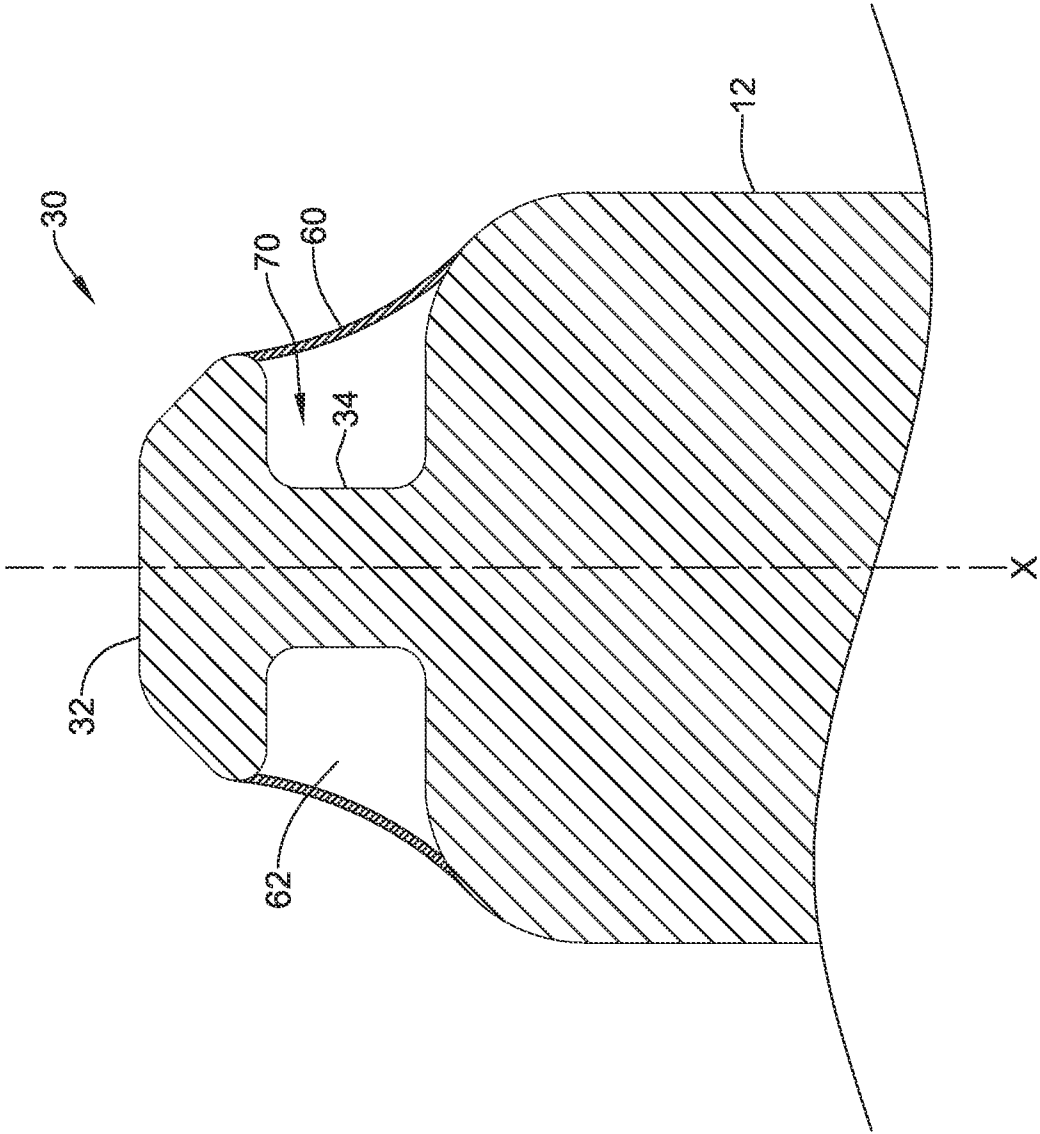


FIG. 6A

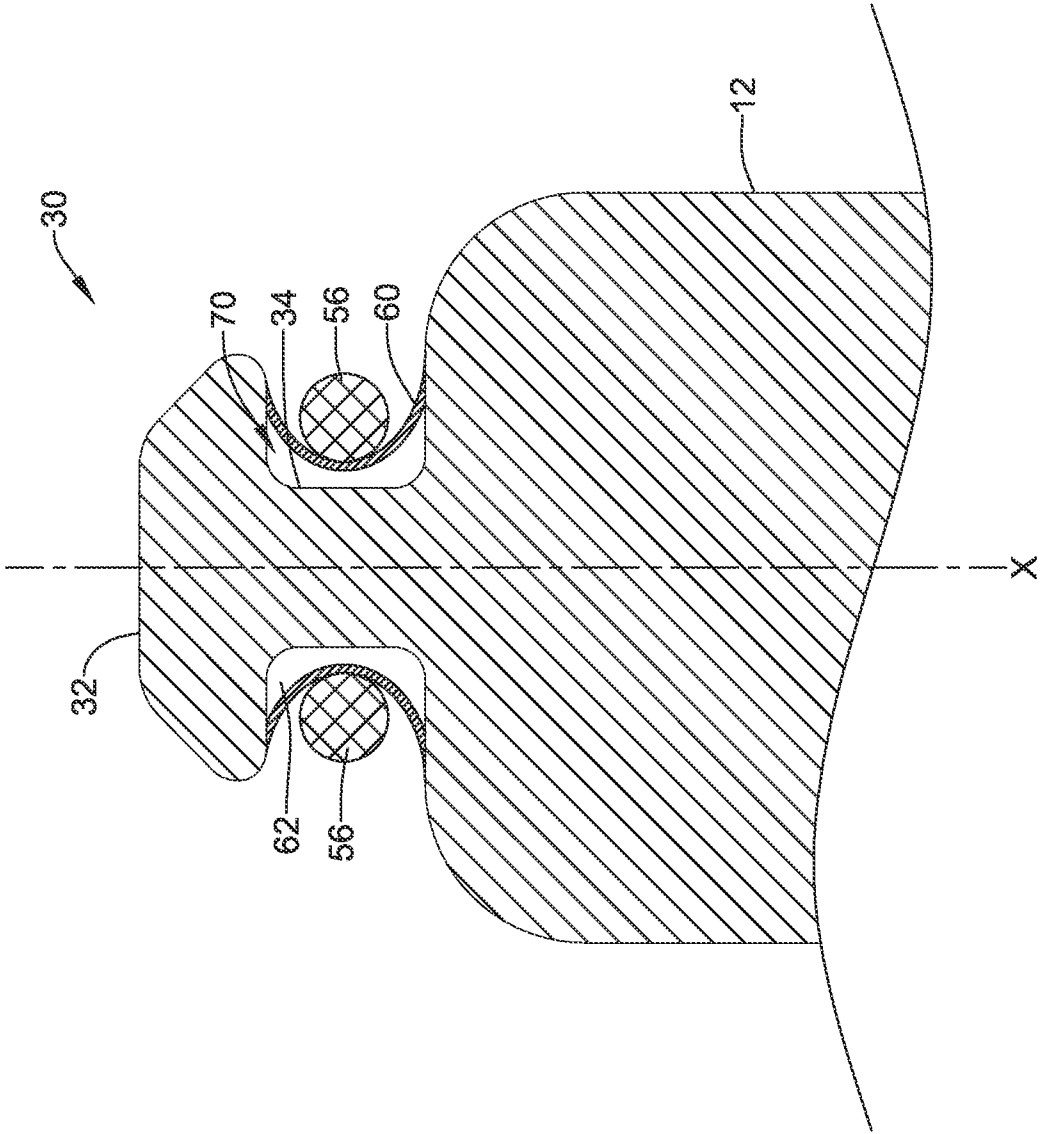


FIG. 6B

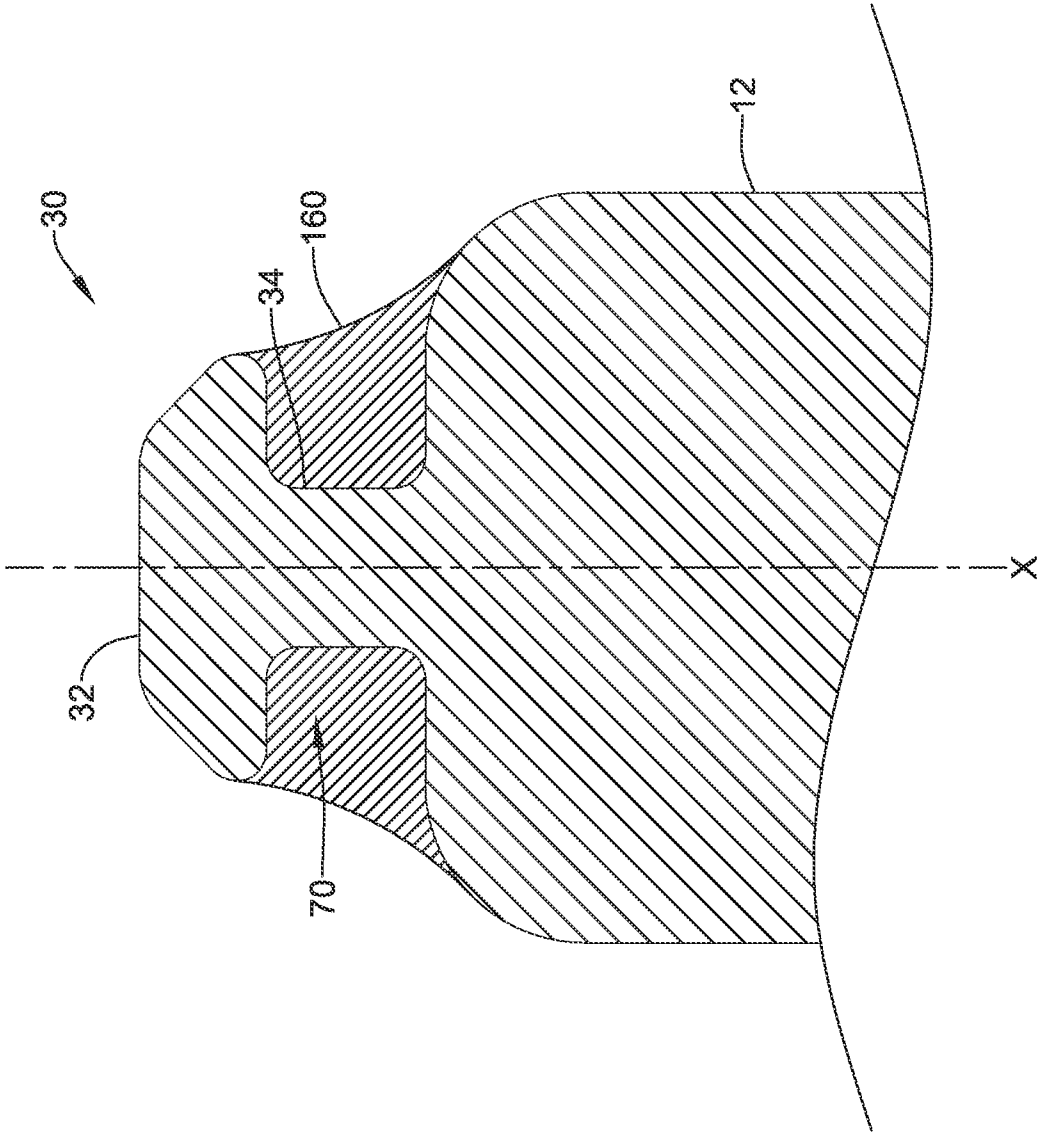


FIG. 7A

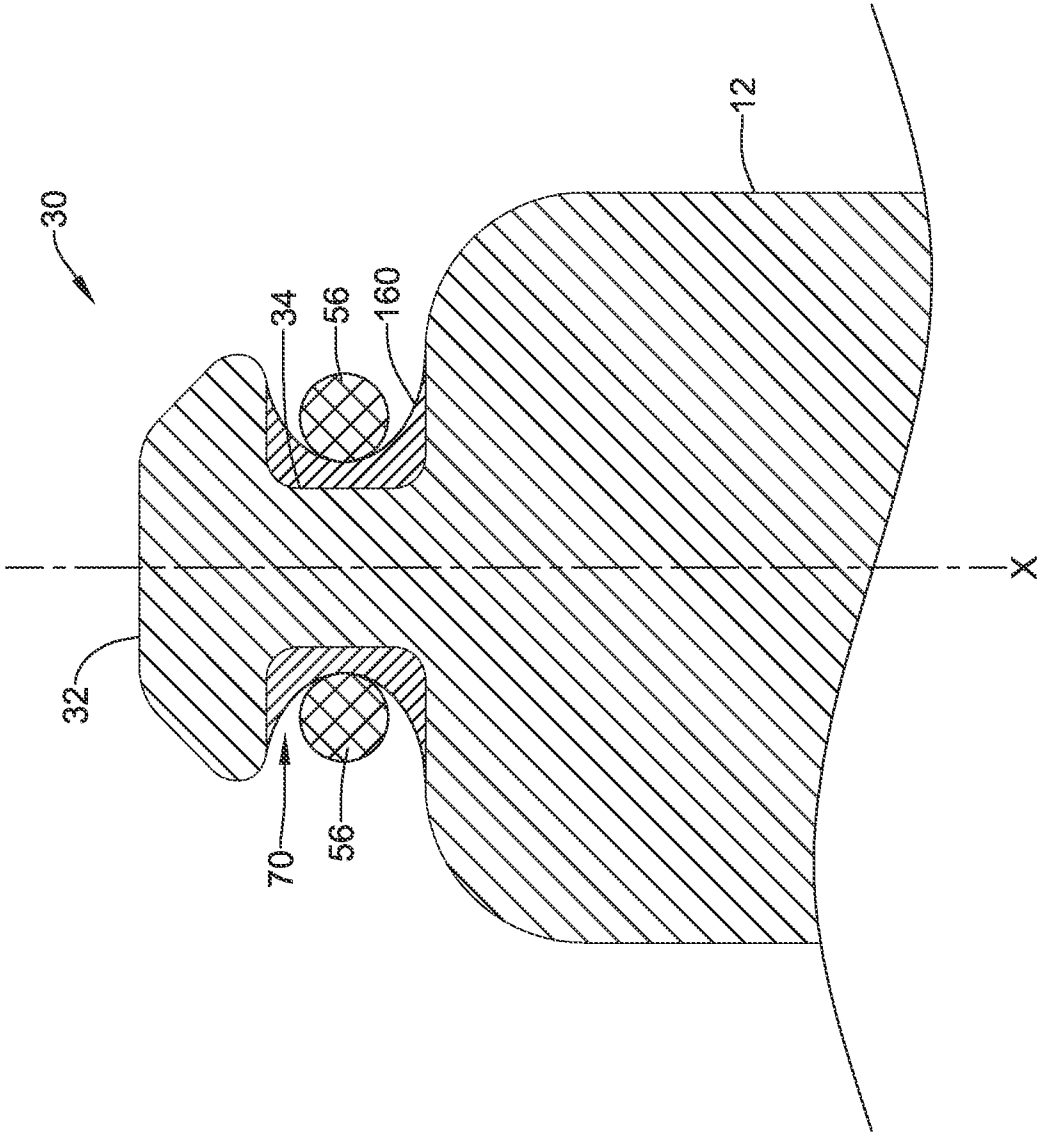


FIG. 7B

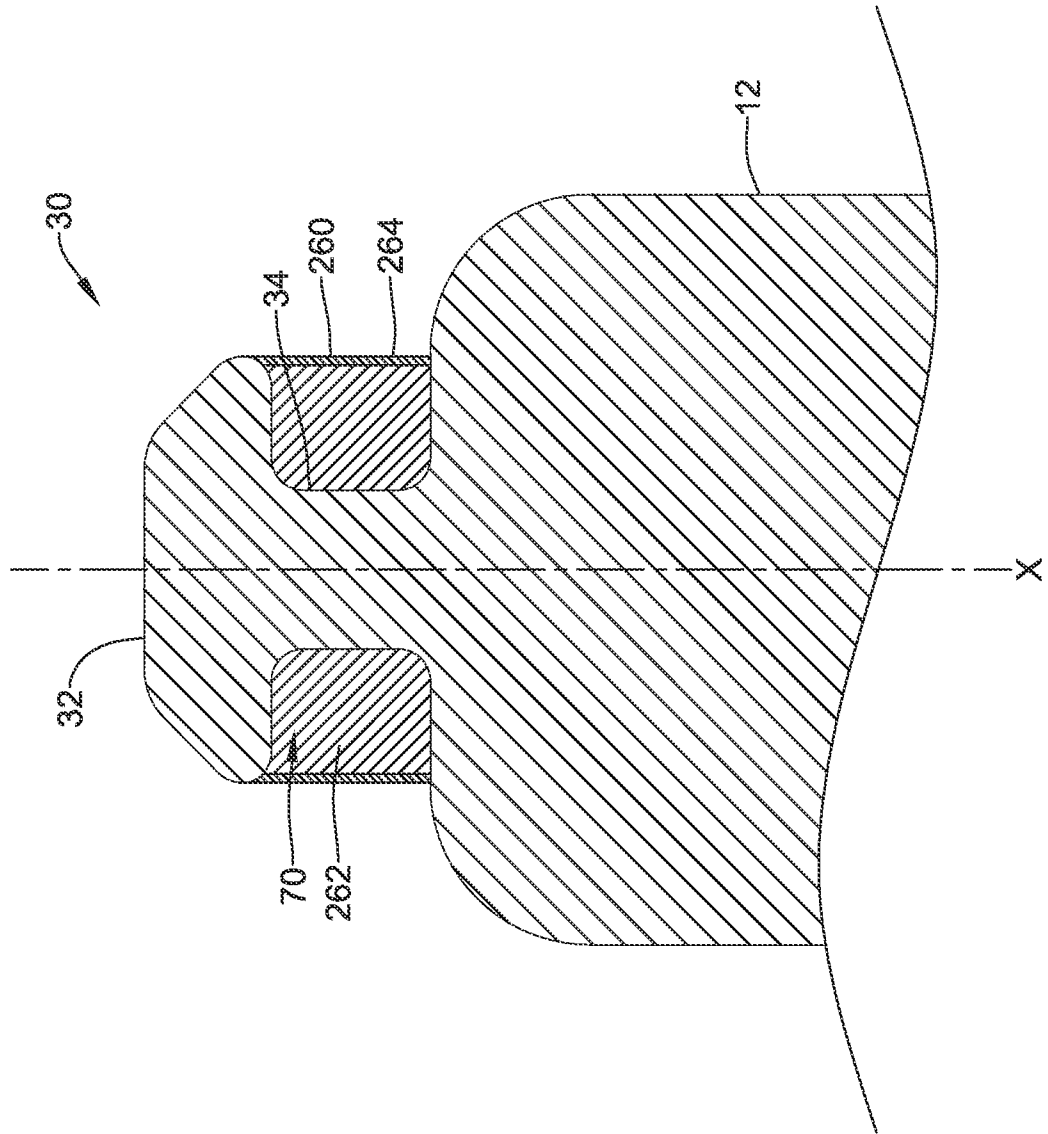


FIG. 8A

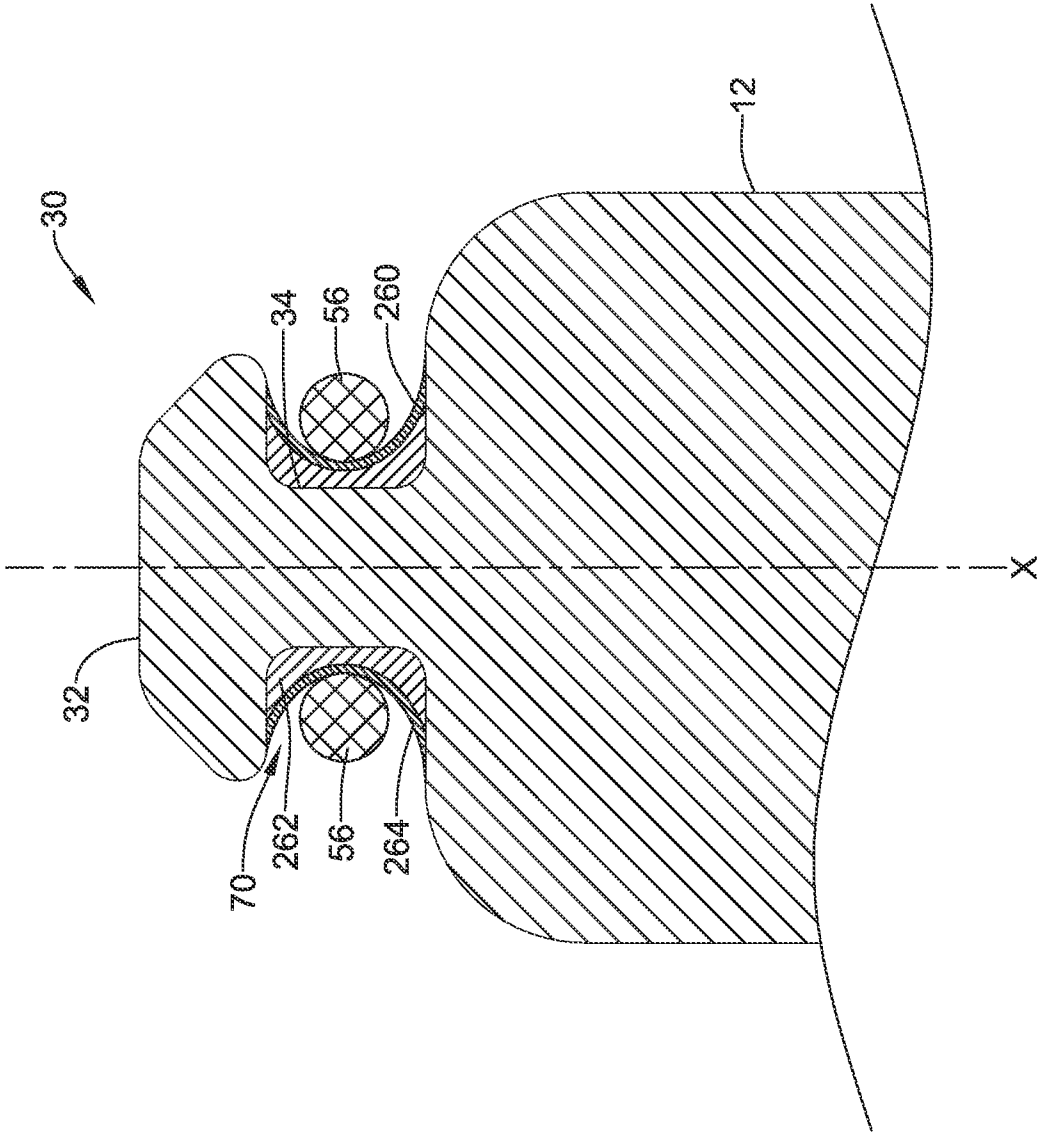


FIG. 8B

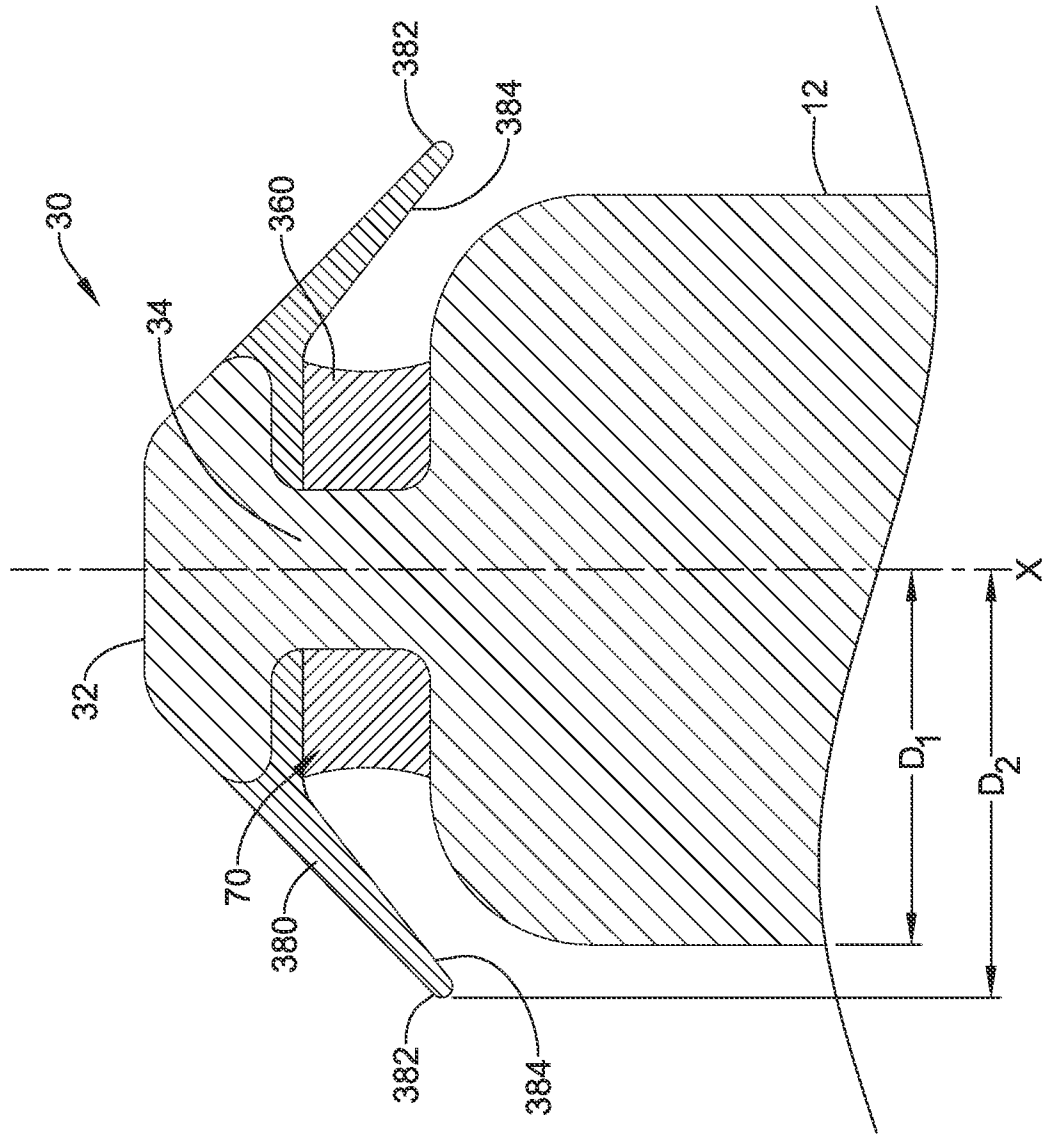


FIG. 9A

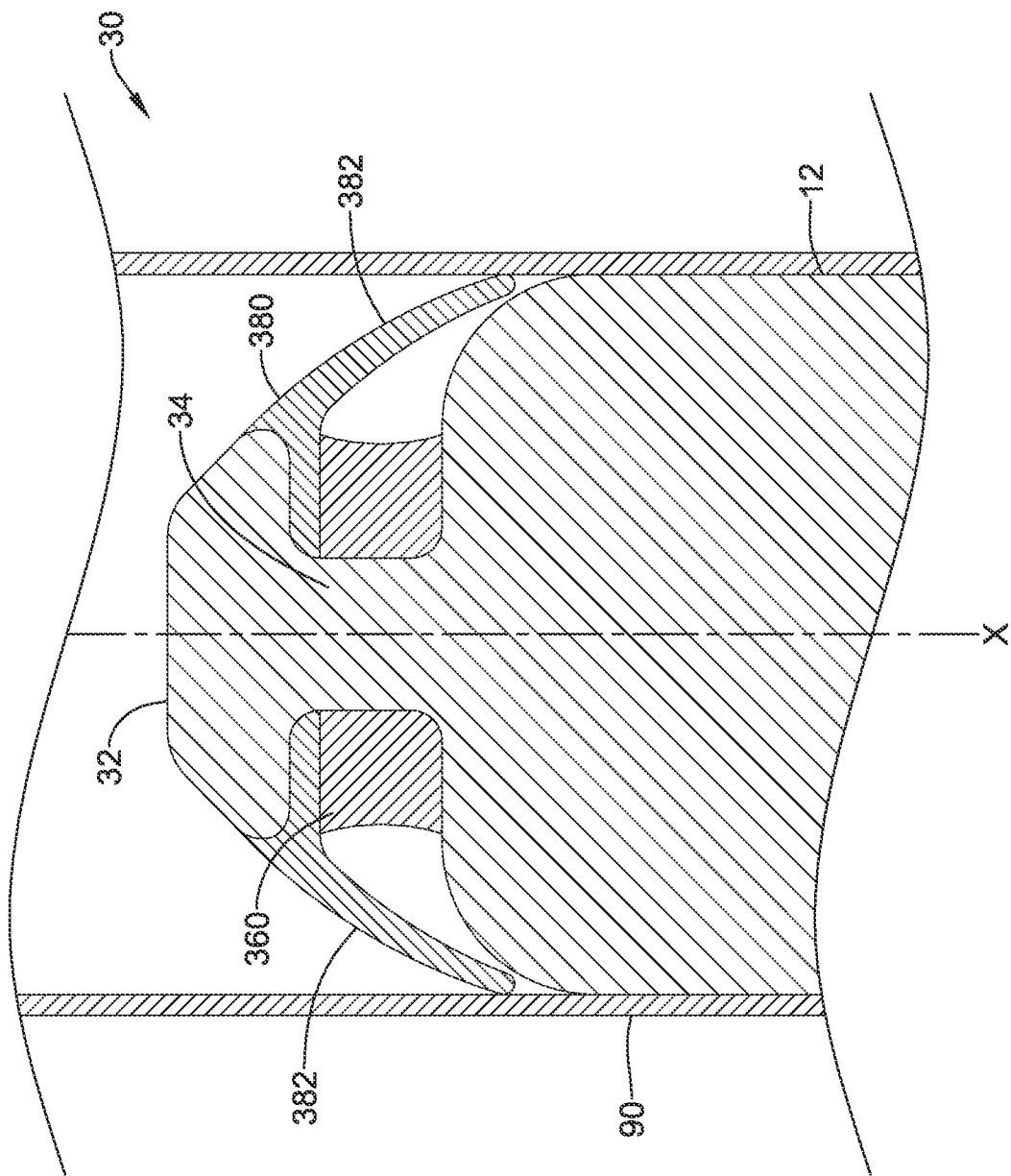


FIG. 9B

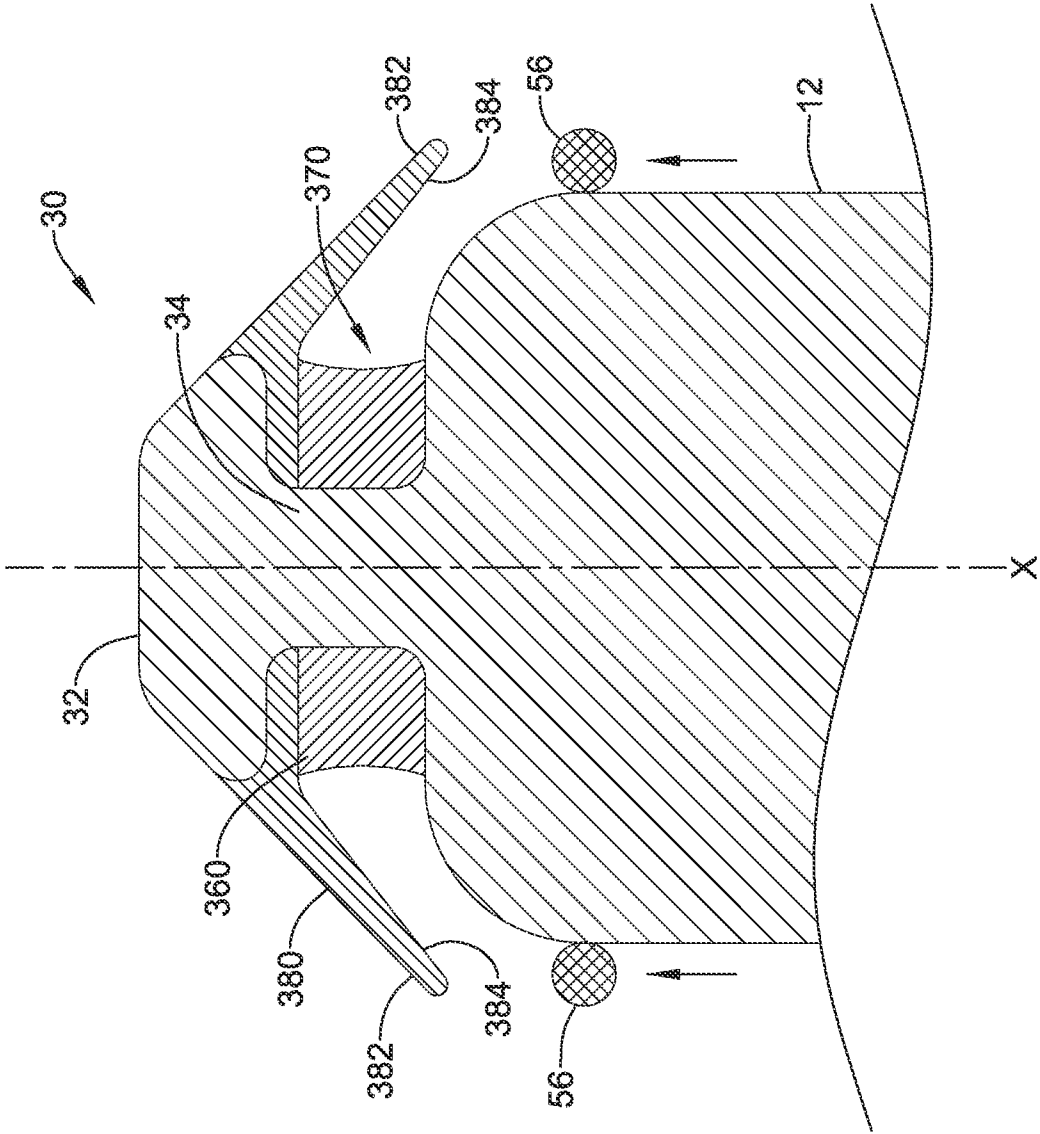


FIG. 9C

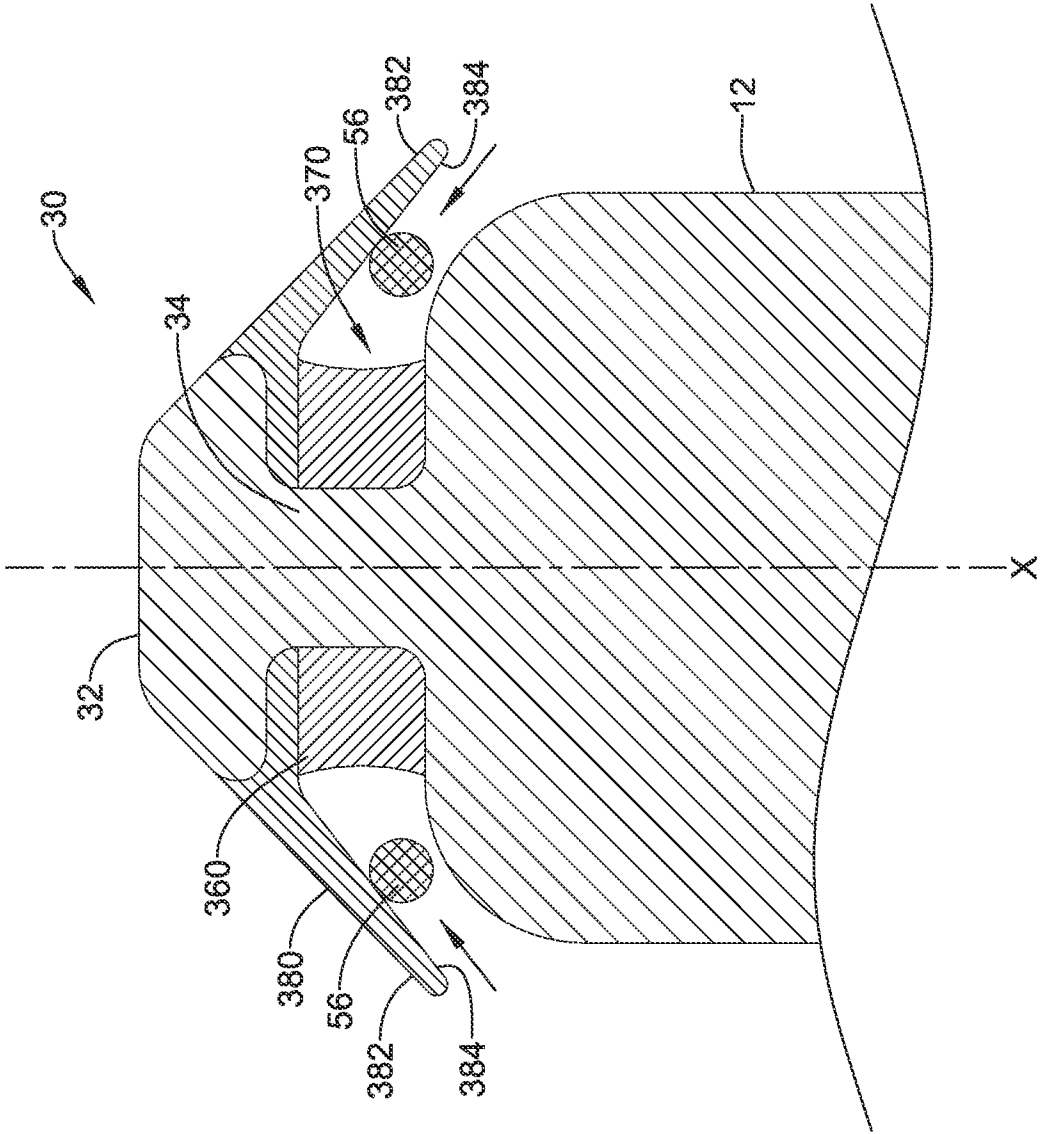


FIG. 9D

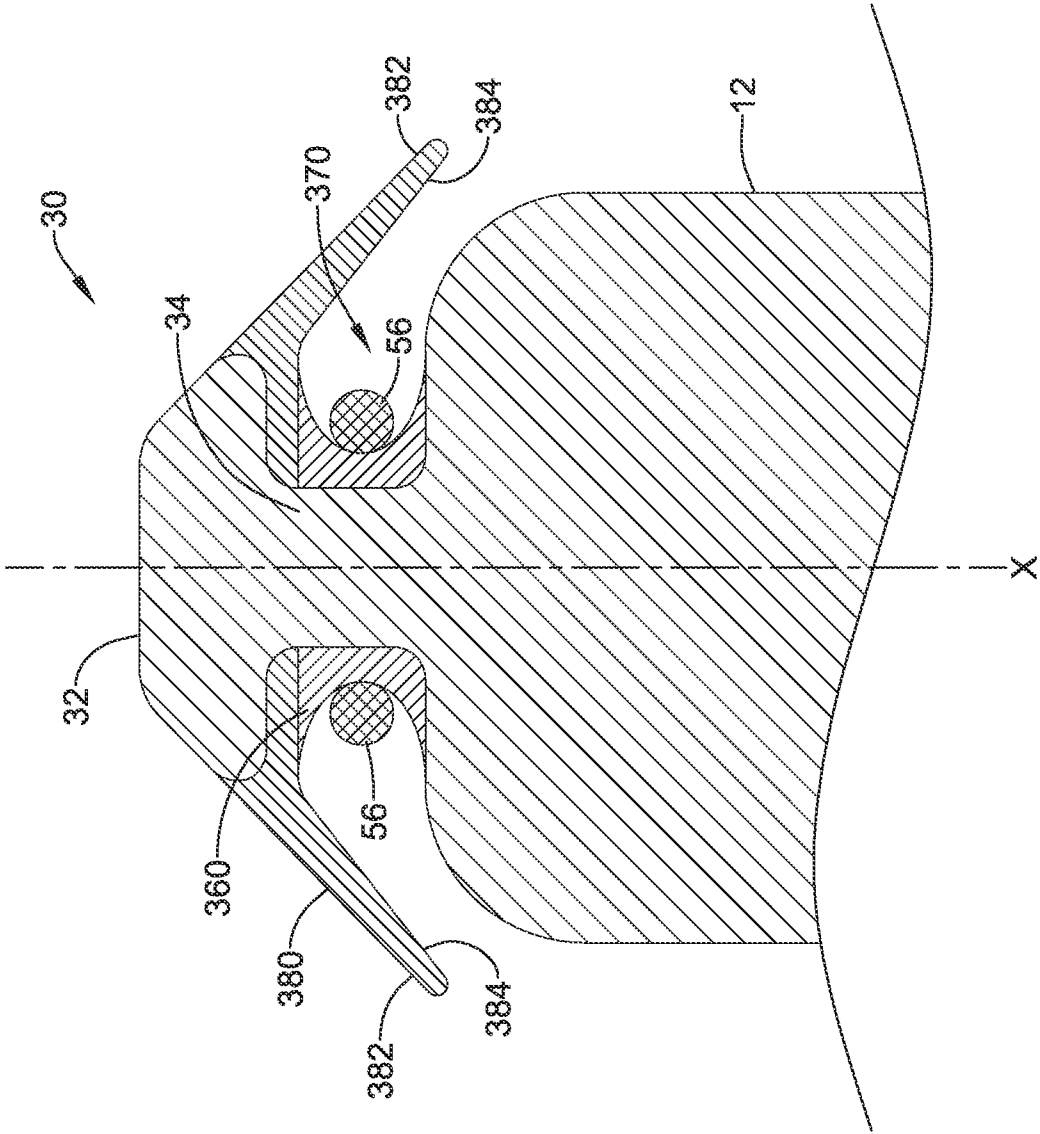


FIG. 9E

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2015/028051

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/375
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, BIOSIS, COMPENDEX, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013/053921 A1 (BONNER MATTHEW D [US] ET AL) 28 February 2013 (2013-02-28) paragraphs [0019] - [0027]; figures 3A-D, 4A-B, 6A-B -----	1-15
A	US 2012/158111 A1 (KHAIRKHAHAN ALEXANDER [US] ET AL) 21 June 2012 (2012-06-21) paragraphs [0030] - [0035]; figure 1A -----	1-15
A,P	WO 2015/023473 A1 (CARDIAC PACEMAKERS INC) 19 February 2015 (2015-02-19) page 9, lines 3-13 -----	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 June 2015

Date of mailing of the international search report

02/07/2015

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Aronsson, Fredrik

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2015/028051

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