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(54) **LEAD REMOVAL SLEEVE**

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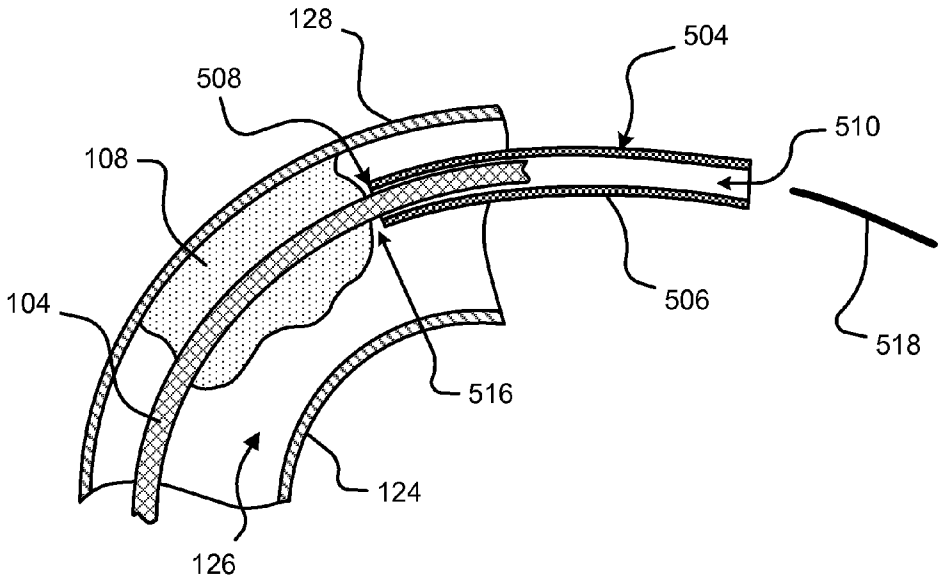
(57) **ABSTRACT**

Methods and systems for removing an object, such as a lead, from formed tissue are provided. Specifically, a lead removal sleeve is configured to engage patient formed tissue at a dilation engagement point. The lead removal sleeve is configured to dilate the formed tissue around a lead, while providing an inner lumen with clearance for the lead to move within the sleeve. It is an object of the lead removal sleeve to support the formed tissue, and even forces of the formed tissue, with a structure of the sleeve as the lead is removed from a patient. The methods and systems are well suited for use in cardiac pacing or defibrillator lead explant procedures.



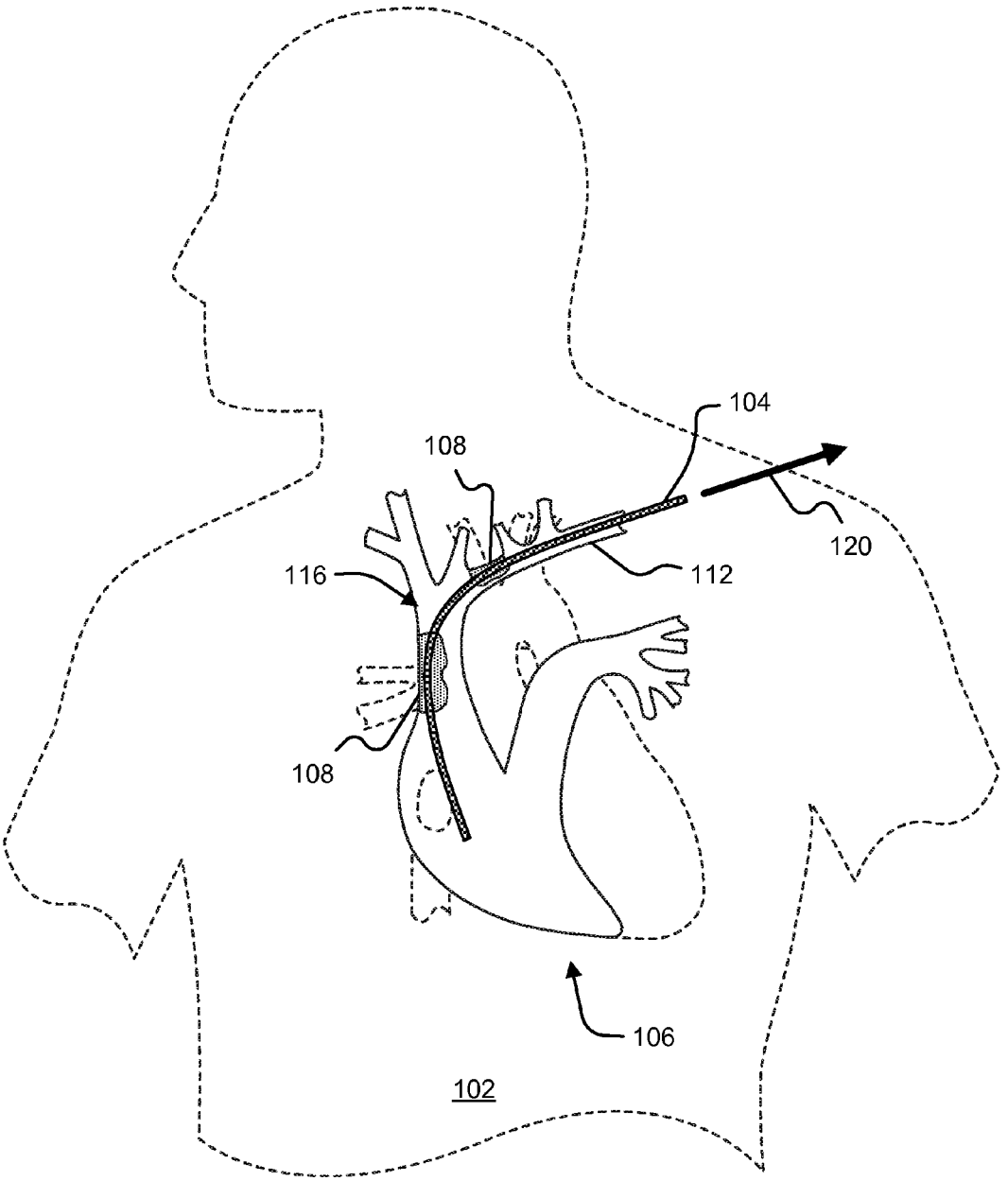


Fig. 1

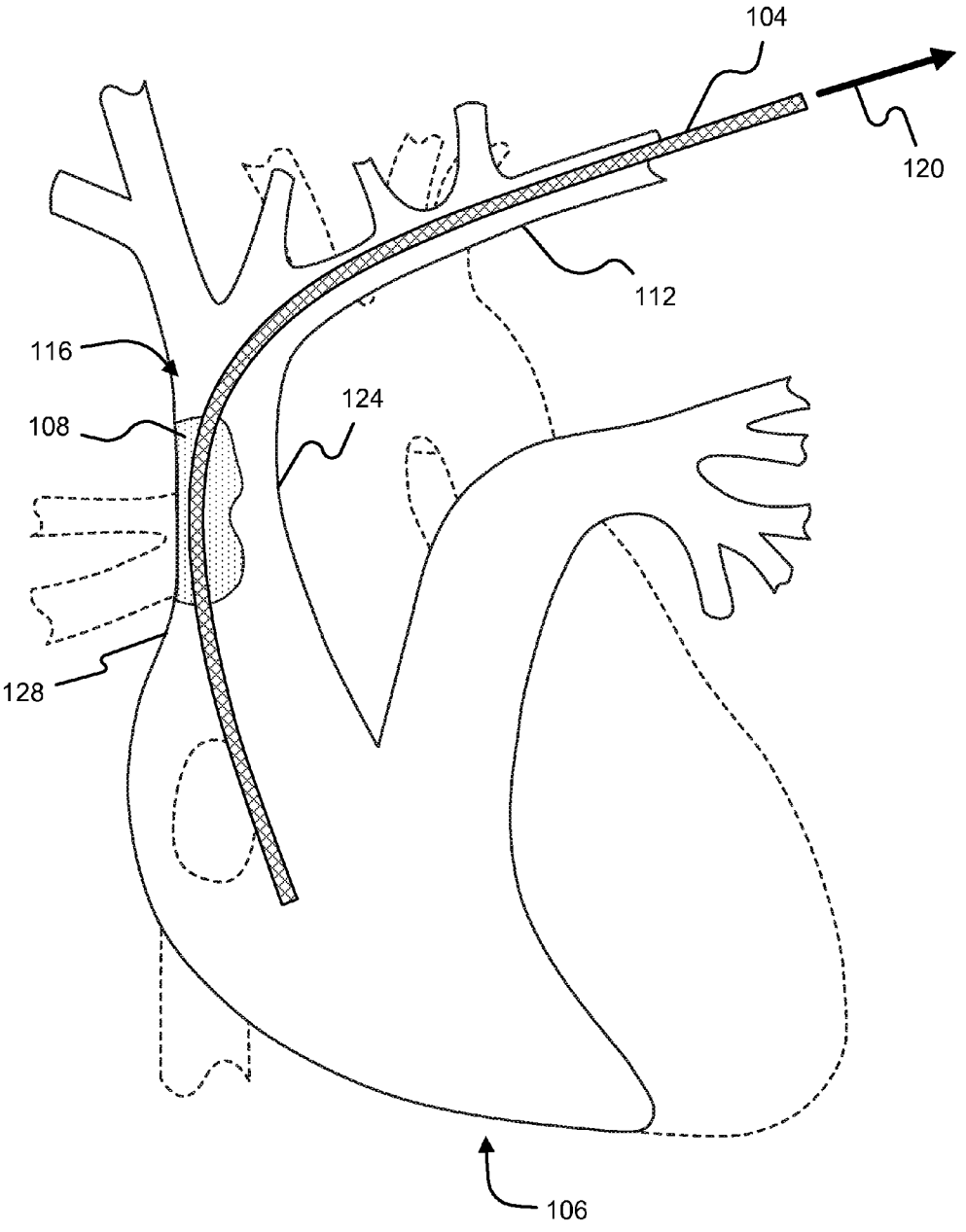


Fig. 2A

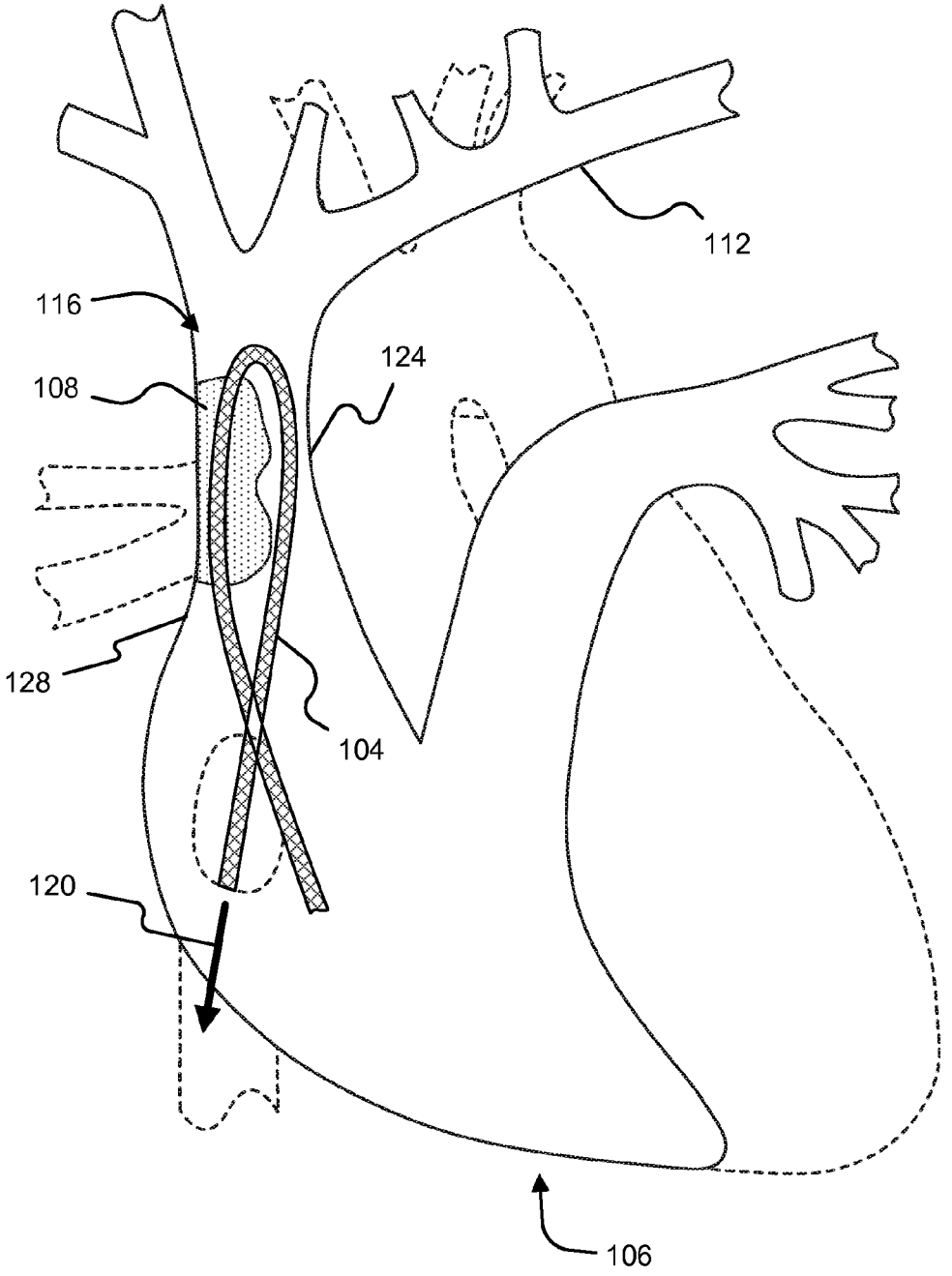


Fig. 2B

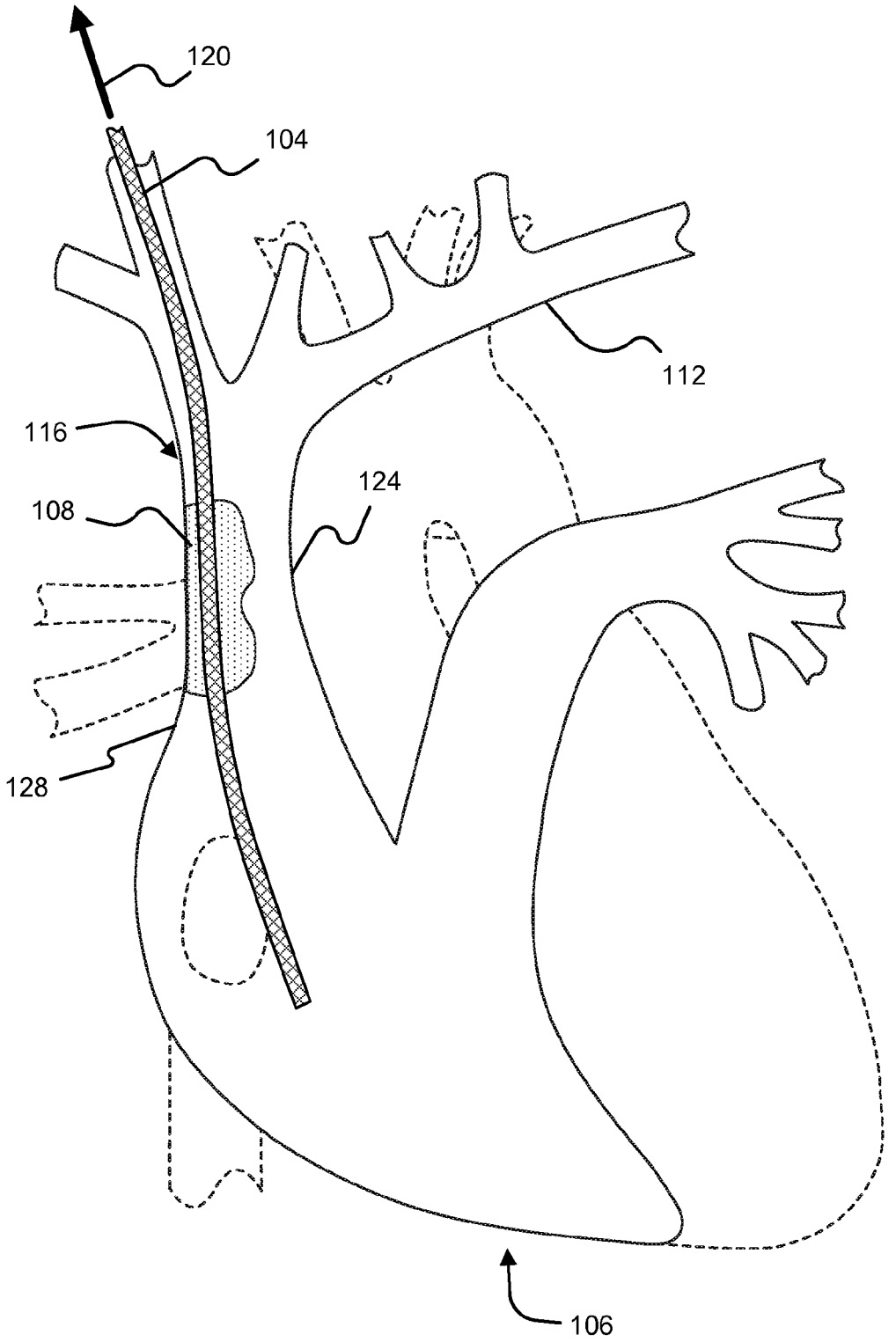


Fig. 2C

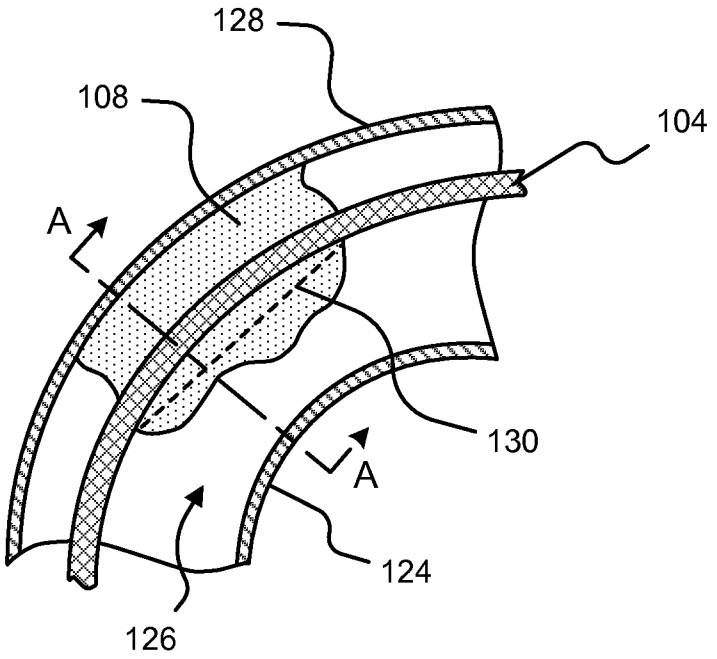


Fig. 3

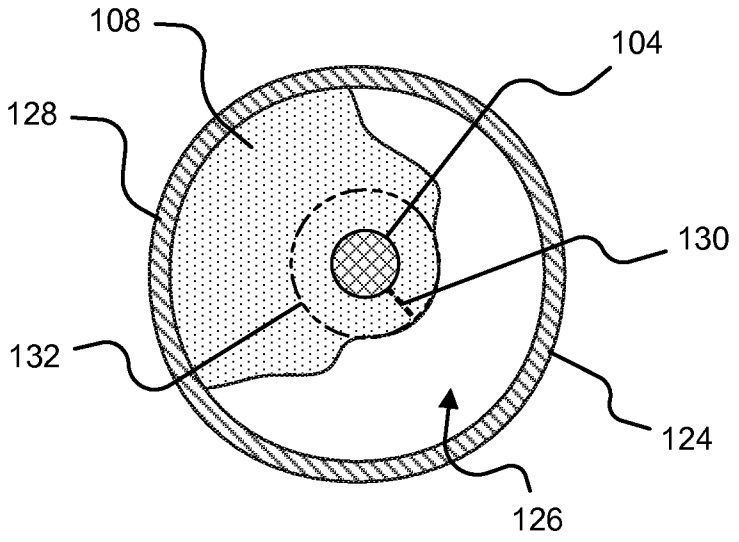


Fig. 4

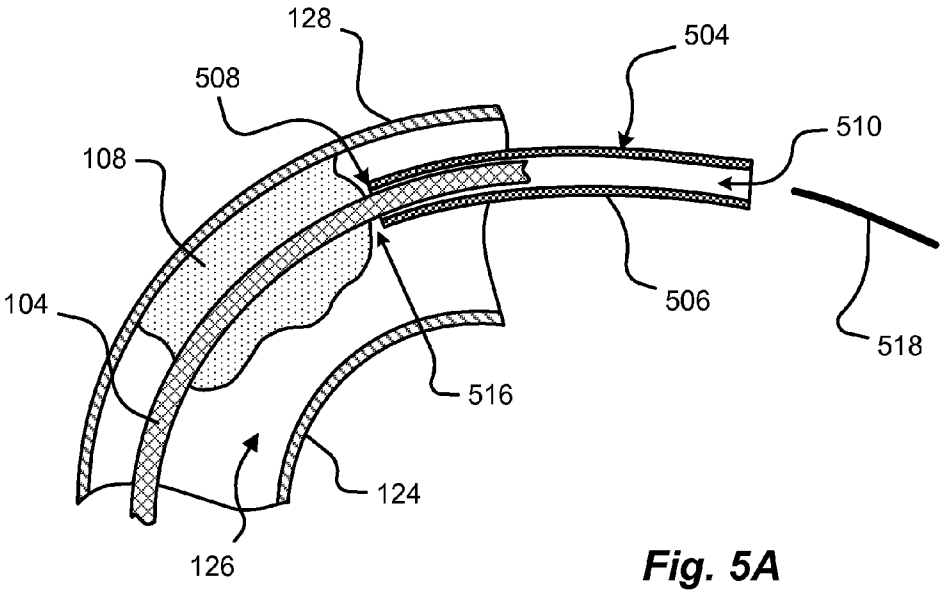

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Fig. 5A

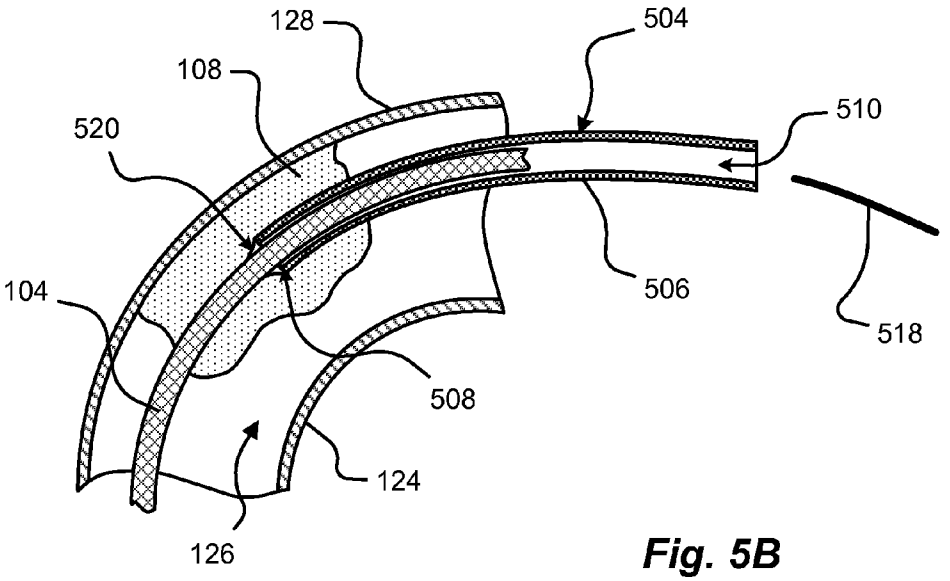
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Fig. 5B

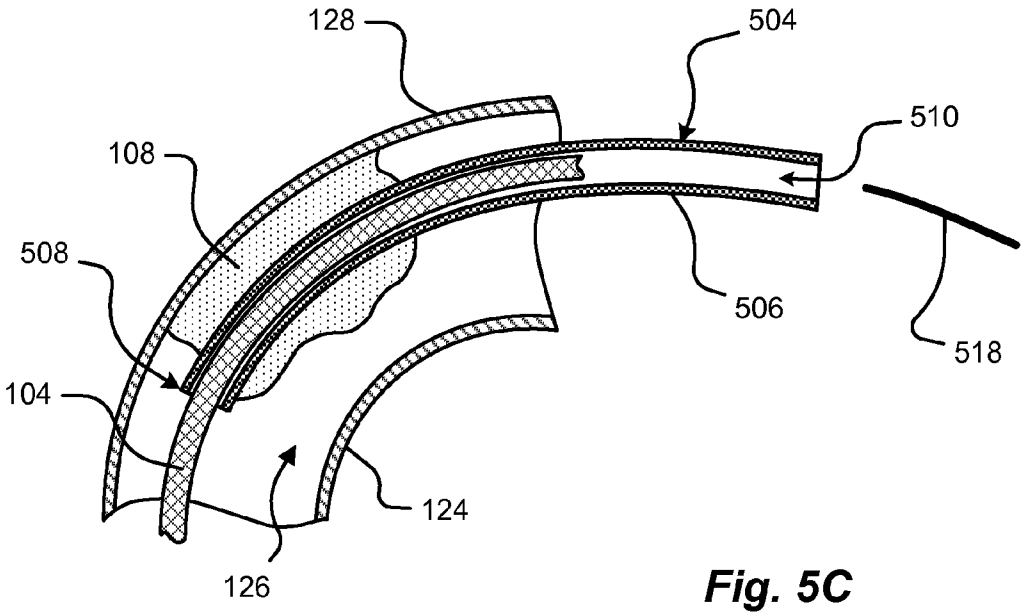
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Fig. 5C

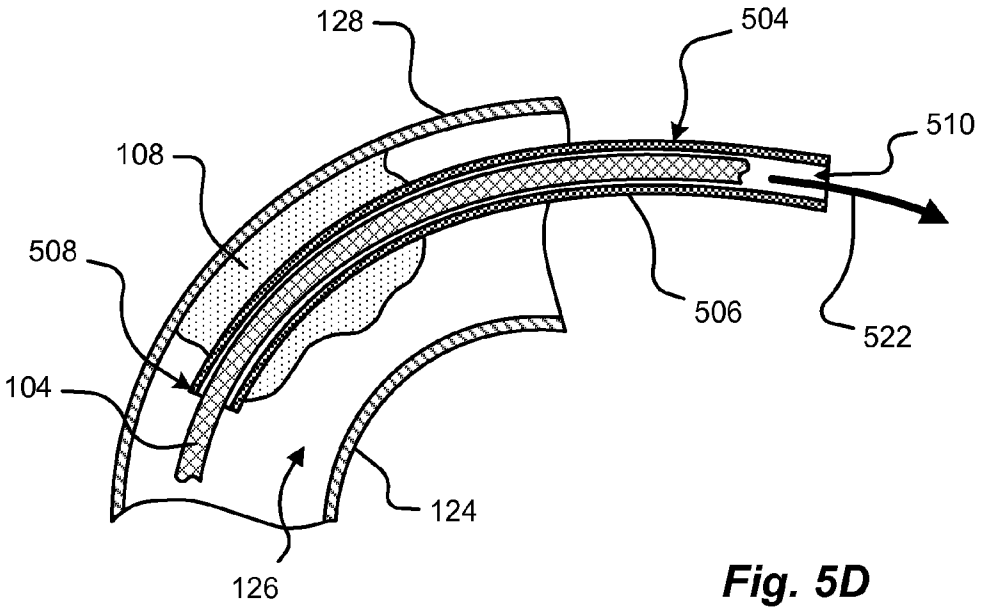
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Fig. 5D

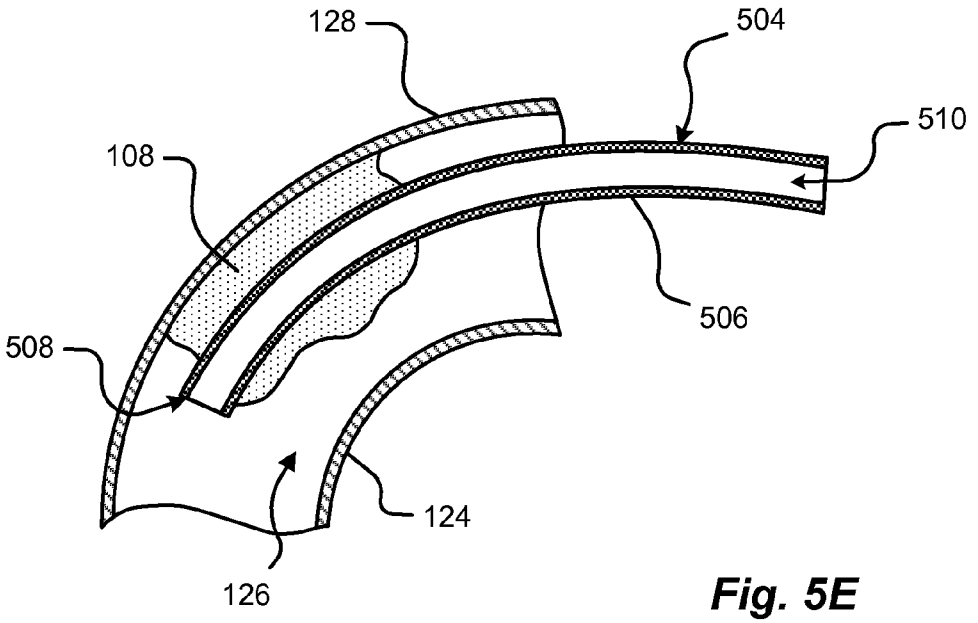
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Fig. 5E

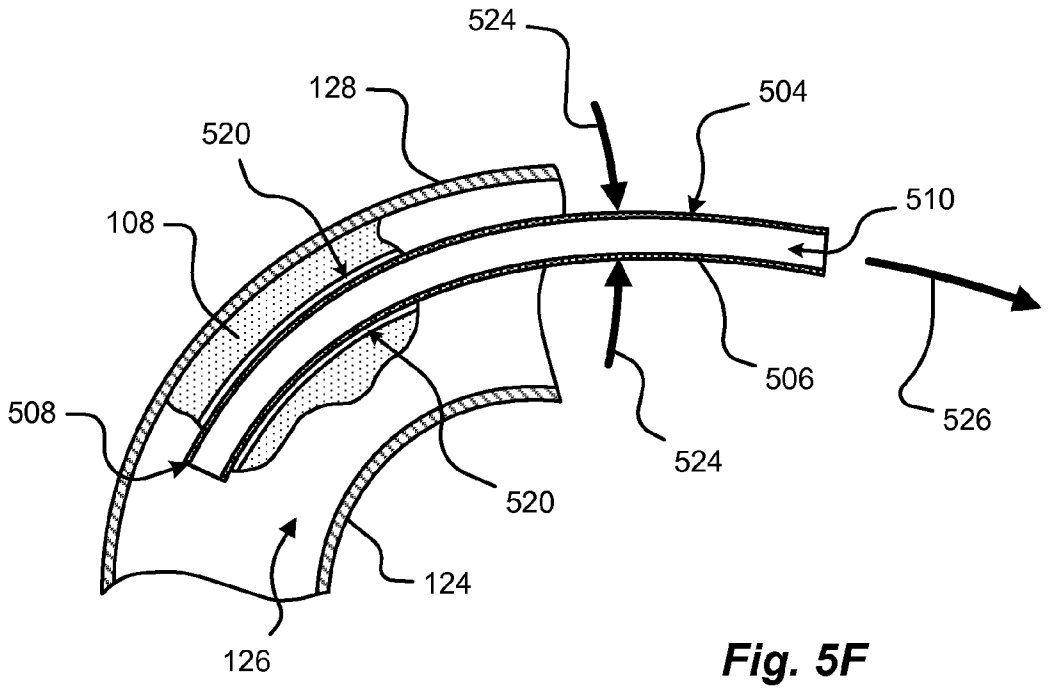
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Fig. 5F

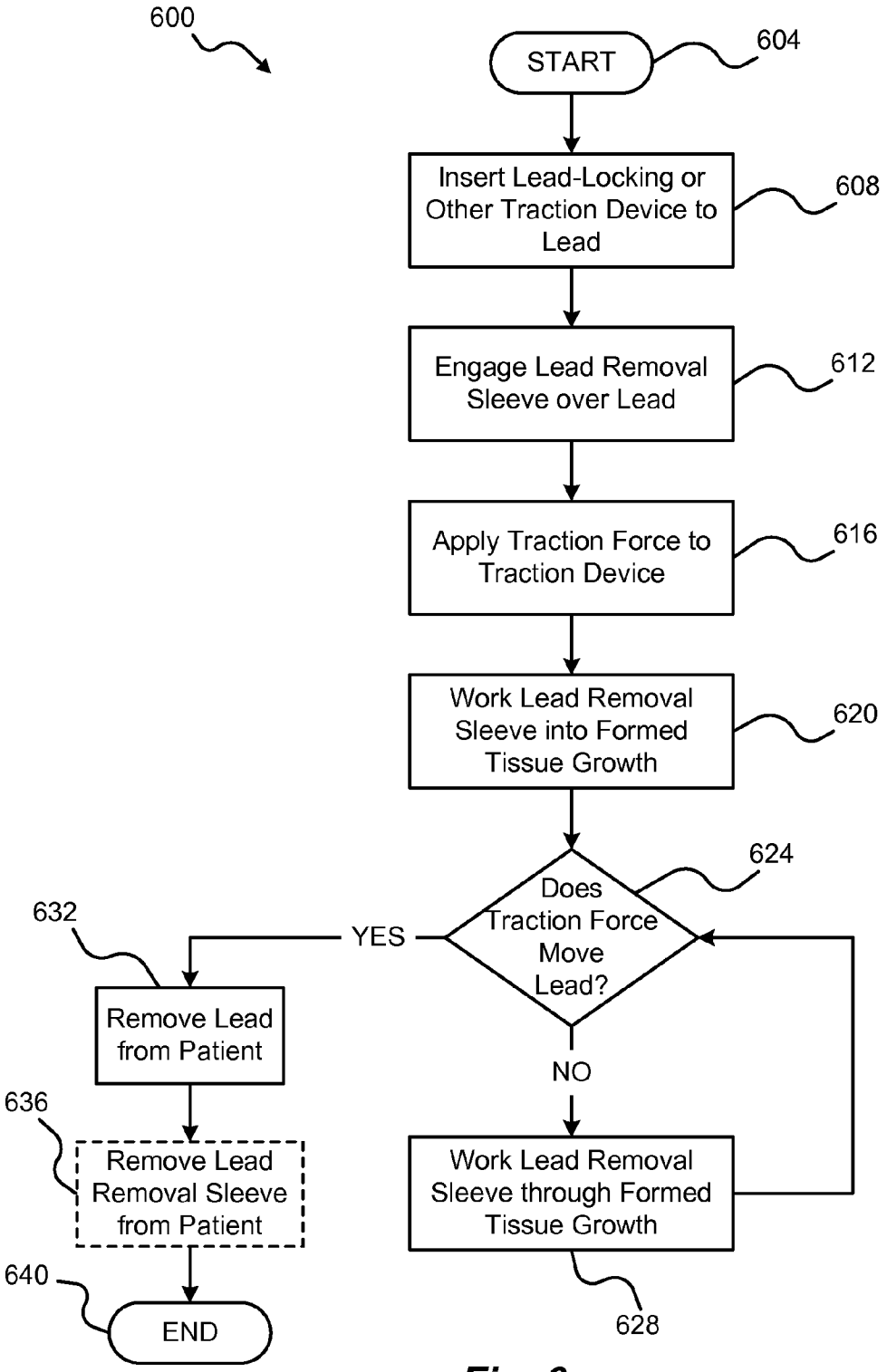
600
START
604
Insert Lead-Locking or Other Traction Device to Lead
608
Engage Lead Removal Sleeve over Lead
612
Apply Traction Force to Traction Device
616
Work Lead Removal Sleeve into Formed Tissue Growth
620
Does Traction Force Move Lead?
624
YES
632
Remove Lead from Patient
636
Remove Lead Removal Sleeve from Patient
640
END
NO
Work Lead Removal Sleeve through Formed Tissue Growth
628

Fig. 6

LEAD REMOVAL SLEEVE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of and priority, under 35 U.S.C. §119(e), to U.S. Provisional Application Ser. No. 61/701,520, filed Sep. 14, 2012, entitled "TISSUE SEPARATING METHODS AND SYSTEMS," which is hereby incorporated herein by reference in its entirety for all that it teaches and for all purposes.

[0002] This application is also related to U.S. patent application Ser. Nos. _____/_____,_____, filed on Mar. 14, 2013, entitled, "Tissue Slitting Methods and Systems" (Attorney Docket No. 6593-208); _____/_____,_____, filed on Mar. 14, 2013, entitled, "Tissue Slitting Methods and Systems" (Attorney Docket No. 6593-251); _____/_____,_____, filed on Mar. 14, 2013, entitled, "Tissue Slitting Methods and Systems" (Attorney Docket No. 6593-252); _____/_____,_____, filed on Mar. 14, 2013, entitled, "Tissue Slitting Methods and Systems" (Attorney Docket No. 6593-253); and _____/_____,_____, filed on Mar. 14, 2013, entitled, "Expandable Lead Jacket" (Attorney Docket No. 6593-246). The entire disclosures of the applications listed above are hereby incorporated herein by reference, in their entirety, for all that they teach and for all purposes.

FIELD OF THE DISCLOSURE

[0003] The present disclosure relates generally to devices, methods and systems for removing an implanted object from a patient, and more specifically, to techniques for removing an electrical lead from tissue attached to a patient.

BACKGROUND

[0004] Cardiac pacing systems typically include a pacemaker and one or more leads, which are placed inside the body of a patient. The pacemaker includes a power source and circuitry configured to send timed electrical pulses to the lead. The lead carries the electrical pulse to the heart to initiate a heartbeat, and transmits information about the heart's electrical activity to the pacemaker. The lead can include a fixation mechanism that holds the lead to the cardiac tissue. In some cases, a lead is inserted through a vein or artery (collectively vasculature) and guided to the heart where it is attached. In other instances, a lead is attached to the outside of the heart. During its time in the body, tissue can attach to the lead in the form of lesions, adhesions or scar tissue, or tissue can encase a lead. In addition, the lead and/or tissue can become attached to the vasculature wall. At times, leads may be removed from patients for numerous reasons, including but not limited to, infections, lead age, and lead malfunction. Accordingly, removal or extraction of the lead may present associated complications.

[0005] Current lead extraction techniques include mechanical traction, mechanical devices, and laser devices. Mechanical traction can be accomplished by inserting a locking stylet into the hollow portion of the lead and then pulling the lead to remove it. An example of such a lead locking device is described and illustrated in U.S. Pat. No. 6,167,315 to Coe et al., which is hereby incorporated herein by reference in its entirety for all that it teaches and for all purposes. In some cases, dilating telescopic sheaths may also be used to strip away the scar tissue adhering the lead to the body. Examples of a such devices and methods used to extract leads is described and illustrated in United States Patent Publication No. 2008/0154293 to Taylor, which is hereby incorporated herein by reference in its entirety for all that it teaches and for all purposes.

[0006] Dilation techniques typically involve pushing tissue away from the lead when the sheath is pushed longitudinally along the lead. However, this pushing technique may be difficult to implement, particularly when the lead has a tortuous path or curvature because the requisite longitudinal forces to extract the tissue from the lead in under these circumstances increase. The longitudinal forces also may require heavy counter forces on the lead, which may result in lead breakage.

[0007] Some mechanical sheaths have proposed trigger mechanisms for extending a blade from a sheath. At least some of these devices, however, involve complicated activation mechanisms and may not be well suited for negotiating the tortuous paths that exist in certain vascular or physiological environments.

[0008] Laser devices typically employ laser energy to cut the scar tissue away from the lead thus allowing for removal. Examples of such laser devices and systems are described and illustrated in U.S. Pat. Nos. 5,383,199 and 5,824,026 and 5,916,210 and 6,228,076 and 6,290,668 all of which are hereby incorporated herein by reference in their entirety for all that they teach and for all purposes.

[0009] Further complicating lead removal is the fact that in some cases, the leads may be located in, and/or attached to, the body of a patient in a structurally-weak portion of the vasculature. For instance, typical leads in a human may pass through the innominate vein, past the superior vena cava ("SVC"), and into the right atrium of the heart. A majority of tissue growth can occur along the SVC and other locations along the innominate vein where the leads make contact with the vein walls. However, tissue growth can also occur at locations within a patient where the leads make contact with arterials or other areas of the vasculature. Certain veins and arteries, and certain areas of vein and arterial walls, can be thin which can make lead removal a complicated and delicate process.

SUMMARY

[0010] A traditional approach to removing tissue from implanted leads is based on the presumption that the tissue growths are adhered directly to the surfaces of the implanted leads. As such, methods and systems have been designed to dislocate the connection between the tissue attached to the implanted device and the body of a patient. Although some tissue may remain on the lead, current methods focus on removing most of the tissue surrounding a circumference of the lead. In other words, while tissue may remain attached around the lead, current systems essentially core around this tissue surrounding the circumference of a lead to free the lead along with a section of the cored tissue to create slack for removing the lead from a patient.

[0011] Surprisingly and unexpectedly, it has been discovered that tissue growth may not adhere directly to the implanted lead but actually form a substantially cylindrical "tube" around the implanted substantially cylindrical lead at a given contact area. Contrary to conventional wisdom, the tissue growth typically does not physically adhere to the lead. For example, this tissue growth, once formed completely around a lead, forms a tubular-shaped member that essentially holds the lead and resists lead removal. The tubular-

shaped section of formed tissue around an implanted device may impart a combination of connection forces/modes that prevent the removal of the device from a patient. For example, the tubular-shaped section of formed tissue, or tissue growth, may constrict, capture, and/or surround implanted leads. In some cases, the tissue growth may constrict a lead, especially if a force is applied to one end of the lead during a removal operation. In other cases, the tissue growth may capture the lead and prevent removal, by, among other things, being attached to the patient and the lead simultaneously. Additionally or alternatively, the tissue growth, during attempted lead removal, may at least partially adhere to the lead in one or more sections while completely forming around the lead.

[0012] Based upon the surprising and unexpected discovery that tissue growth may not be directly adhered to the implanted lead, alternative devices and methods may be used to extract an object from such tissue. In other words, methods and devices are disclosed herein, that are capable of exploiting the growth nature of the tissue around a lead to efficiently extract the lead from tissue that acts to hold the lead with some type of force. The tissue growth may form around the lead such that the lead is contained from free movement within a patient. For instance, the tissue growth may impart a clamping, or constrictive, force around the circumference of the lead that can prevent movement of the lead within this constrictive tissue growth. Due to the taught and constrictive nature of the tissue around the lead, the lead may be able to be removed without mechanically removing or laser ablating the entire tissue region surrounding the lead in a 360 degree, or circumferential, fashion. Rather, at least a portion of the tissue surrounding the lead may be dilated to reduce and/or eliminate forces preventing movement of the lead within a patient. In some cases, a lead removal sleeve, or structure, may be introduced over a lead and worked into an area between the tissue growth and the lead. The structure may be configured to dilate at least a portion of the tissue surrounding the lead. Additionally, the structure may be configured to provide support and/or clearance around a section of the lead. As can be appreciated, the support may maintain the tissue growth in a dilated state around a section of the lead, while the clearance may facilitate at least partially unrestricted movement and even subsequent removal of the lead from the patient. It is anticipated that the structure may include one or more features to control the support provided and/or the structure clearance for lead movement (e.g., ribs, various thicknesses, collapsing sections/points, coatings, films, jackets, and the like).

[0013] Once the tissue growth is dilated by, inter alia, a lead removal sleeve, subsequent movement of the lead relative to the section of tissue growth can be achieved using various lead removal techniques, including but not limited to, the use of traction applied to the lead, lead locking devices, snares, additional sheath and/or structure insertion, moving the lead within a lead removal sleeve, and the like.

[0014] Accordingly, there is a need for a device, method and/or system such as a device that includes a sleeve having an outer surface, a distal end, a proximal end, and an inner lumen running from the proximal to the distal end, wherein the sleeve facilitates the dilation of formed tissue surrounding a lead, and optionally a method and system capable of removing the lead from the formed tissue and/or sleeve that captures at least a portion of an implanted lead.

[0015] In an embodiment, a lead removal apparatus is provided comprising: a shaft, wherein the shaft is flexible, the shaft having at least one outer surface, a proximal and a distal end, and wherein the shaft includes an inner lumen running from the proximal to the distal end to receive at least one of an implanted object and a mechanical traction device; and a tissue dilating tip disposed adjacent to the distal end of the shaft, wherein the tissue dilating tip is configured to passively wedge into an area between a tissue growth and the implanted object, and wherein the at least one outer surface of the lead removal apparatus is configured to dilate the tissue growth about an area of the implanted object.

[0016] In another embodiment, a lead removal method is provided, the method comprising: engaging a lead removal apparatus over an implanted object in a patient; passively dilating a length of tissue growth surrounding the implanted object; and thereafter removing the implanted object from the tissue growth. In one embodiment, the passively dilating and thereafter removing steps may comprise the sub-steps: attaching a mechanical traction device to the implanted object; inserting the mechanical traction device into the lead removal apparatus, the lead removal apparatus further comprising: a flexible shaft, wherein the flexible shaft has a proximal and a distal end; an internal lumen, wherein the internal lumen is configured to allow at least one of an implanted object and mechanical traction device to pass therethrough; and a tissue dilating tip operatively connected to the distal end of the flexible shaft; applying a mechanical traction force to the mechanical fraction device; indexing the lead removal apparatus to an engagement area of the tissue growth in contact with the implanted object; and moving the tissue dilating tip into the tissue growth, such that the tissue growth is dilated around the flexible shaft and dislocated from the implanted object at least at the engagement area with the tissue dilating tip.

[0017] In yet another embodiment, a system to remove a lead from a vascular lumen is provided, the system comprising: a lead locking device for locking onto a lead within the vascular lumen; a flexible shaft comprising: a proximal end; a distal end comprising a tip capable of passively dilating and directing tissue about a lead; and an internal lumen configured to allow at least one lead to pass therethrough, wherein the lead locking device holds the lead while the tip dilates tissue surrounding at least a portion of the lead.

[0018] The method can include the steps of inserting a lead removal sleeve in an area between an implanted object and at least a portion of a tissue growth at least substantially surrounding the implanted object in a patient and thereafter removing the implanted object. The lead removal sleeve can be inserted along an entire length of a tissue growth in an area between an implanted object and the tissue growth. In some cases, the lead removal sleeve may be inserted along only a partial length, not an entire length, of a tissue growth in an area between the implanted object and the tissue growth.

[0019] The lead removal sleeve may be manufactured as an extruded shape of substantially uniform cross-sectional area. Additionally or alternatively, the distal and or proximal end of the lead removal sleeve may be shaped to include a surface and/or geometry other than the substantially uniform cross-sectional area. For example, the lead removal sleeve may include a tissue dislocation, or dilation, tip disposed at or adjacent to the distal end of the sleeve. In some cases, the tissue dislocation tip may be configured to contact and direct at least a portion of tissue growth away from contacting a surface of an implanted lead. For instance, the tissue dislocation tip may be configured to wedge into an area between the

tissue growth and an implanted lead. In one case, as the wedge is inserted into an area between the tissue growth and the implanted lead, the tissue may be caused to dilate about an outer surface of the lead removal sleeve. In other words, the tissue dislocation tip may be configured to "passively" wedge into the area between the tissue growth and the implanted lead, that is, without substantially cutting or disrupting the formation of the tissue growth. As can be appreciated, the tissue dislocation tip may include one or more of various shapes, thicknesses, hardnesses, materials, and the like.

[0020] Removal of the implanted lead from the formed tissue, or tissue growth, may be effected by creating clearance between the lead and the tissue growth. By dilating the formed tissue along an axial portion, or length, of the tissue in contact with the surgically implanted device or surgical implant, it is anticipated that the tissue may stretch around at least a portion of the outer surface of the lead removal sleeve. The outer surface of the lead removal sleeve acts to support the tissue growth in a dilated state. As such, the lead may move within the inner lumen of the lead removal sleeve without being subjected to any constriction forces subjected by the tissue growth. These and other needs are addressed by the various aspects, embodiments, and/or configurations of the present disclosure. Also, while the disclosure is presented in terms of exemplary embodiments, it should be appreciated that individual aspects of the disclosure can be separately claimed.

[0021] The lead removal sleeve includes a flexible shaft having a proximal end, a distal end, and an internal lumen having an internal diameter configured to allow a lead, lead locking device, and/or other implanted device to pass through it. The sleeve may also include a tissue dislocation tip operatively coupled with the distal end of the flexible shaft. As can be appreciated, the dislocation and/or dilation of formed tissue can be performed by at least one of moving, directing, displacing, dilating, expanding, wedging, and combinations thereof. It is anticipated that the lead removal sleeve may be oriented within a patient via use of the flexible shaft and monitor, or a catheter-based system. In some cases, the lead removal sleeve may be positioned over an implanted lead, such that the tissue dislocation tip is caused to contact tissue growth in contact with the lead.

[0022] Among other things, the lead removal sleeve may be constructed such that the sleeve may wedge into an area between the tissue growth surrounding an implanted lead via a force transmitted along the flexible shaft. Additionally or alternatively, the flexible portion may be configured to allow the lead removal sleeve to move as directed within a patient.

[0023] The phrases "at least one", "one or more", and "and/or" are open-ended expressions that are both conjunctive and disjunctive in operation. For example, each of the expressions "at least one of A, B and C", "at least one of A, B, or C", "one or more of A, B, and C", "one or more of A, B, or C" and "A, B, and/or C" means A alone, B alone, C alone, A and B together, A and C together, B and C together, or A, B and C together. When each one of A, B, and C in the above expressions refers to an element, such as X, Y, and Z, or class of elements, such as X_1-X_n, Y_1-Y_m, and Z_1-Z_o, the phrase is intended to refer to a single element selected from X, Y, and Z, a combination of elements selected from the same class (e.g., X_1 and X_2) as well as a combination of elements selected from two or more classes (e.g., Y_1 and Z_o).

[0024] The term "a" or "an" entity refers to one or more of that entity. As such, the terms "a" (or "an"), "one or more" and "at least one" can be used interchangeably herein. It is also to be noted that the terms "comprising", "including", and "having" can be used interchangeably.

[0025] The term "bioresorbable" may be used herein to refer to the property of a material manufactured to degrade, biodegrade, bioabsorb, dissolve, and/or be absorbed by a body. Bioresorbable materials may include, but are in no way limited to, iron, magnesium, metals, alloys thereof, polymers, amino-acid based polymers, polyester amides, silica composites, coatings, and combinations thereof. Bioresorbable materials may be controlled to degrade over a period of time by incorporating layers of materials and/or coatings in specific combinations. Such combinations may include constructing various material layers, including coatings, with known degradation rates in an order that may facilitate degradation over a designed time period.

[0026] A "lead" is a conductive structure, typically an electrically insulated coiled wire. The electrically conductive material can be any conductive material, with metals and intermetallic alloys common. The outer sheath of insulative material is biocompatible and biostable (e.g., non-dissolving in the body) and generally includes organic materials such as ultra high weight polyethylene, polyurethane, and polyimide. Lead types include, by way of non-limiting example, epicardial and endocardial leads. Leads are commonly implanted into a body percutaneously or surgically.

[0027] A "surgical implant" is a medical device manufactured to replace a missing biological structure, support, stimulate, or treat a damaged biological structure, or enhance, stimulate, or treat an existing biological structure. Medical implants are man-made devices, in contrast to a transplant, which is a transplanted biomedical tissue. In some cases implants contain electronics, including, without limitation, artificial pacemaker, defibrillator, electrodes, and cochlear implants. Some implants are bioactive, including, without limitation, subcutaneous drug delivery devices in the form of implantable pills or drug-eluting stents.

[0028] The term "means" as used herein shall be given its broadest possible interpretation in accordance with 35 U.S. C., Section 112, Paragraph 6. Accordingly, a claim incorporating the term "means" shall cover all structures, materials, or acts set forth herein, and all of the equivalents thereof. Further, the structures, materials or acts and the equivalents thereof shall include all those described in the summary of the invention, brief description of the drawings, detailed description, abstract, and claims themselves.

[0029] It should be understood that every maximum numerical limitation given throughout this disclosure is deemed to include each and every lower numerical limitation as an alternative, as if such lower numerical limitations were expressly written herein. Every minimum numerical limitation given throughout this disclosure is deemed to include each and every higher numerical limitation as an alternative, as if such higher numerical limitations were expressly written herein. Every numerical range given throughout this disclosure is deemed to include each and every narrower numerical range that falls within such broader numerical range, as if such narrower numerical ranges were all expressly written herein.

[0030] The preceding is a simplified summary of the disclosure to provide an understanding of some aspects of the disclosure. This summary is neither an extensive nor exhaustive overview of the disclosure and its various aspects, embodiments, and configurations. It is intended neither to

identify key or critical elements of the disclosure nor to delineate the scope of the disclosure but to present selected concepts of the disclosure in a simplified form as an introduction to the more detailed description presented below. As will be appreciated, other aspects, embodiments, and configurations of the disclosure are possible utilizing, alone or in combination, one or more of the features set forth above or described in detail below

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] The accompanying drawings are incorporated into and form a part of the specification to illustrate several examples of the present disclosure. These drawings, together with the description, explain the principles of the disclosure. The drawings simply illustrate preferred and alternative examples of how the disclosure can be made and used and are not to be construed as limiting the disclosure to only the illustrated and described examples. Further features and advantages will become apparent from the following, more detailed, description of the various aspects, embodiments, and configurations of the disclosure, as illustrated by the drawings referenced below.

[0032] FIG. **1** shows an exemplary patient vasculature in section with implanted lead and multiple locations of tissue growth in accordance with some embodiments of the present disclosure;

[0033] FIG. **2**A shows a detail section view of a patient vasculature and implanted lead subjected to a traction force in a first path in accordance with some embodiments of the present disclosure;

[0034] FIG. **2**B shows a detail section view of a patient vasculature and implanted lead subjected to a traction force in second path in accordance with some embodiments of the present disclosure;

[0035] FIG. **2**C shows a detail section view of a patient vasculature and implanted lead subjected to a traction force in third path in accordance with some embodiments of the present disclosure;

[0036] FIG. **3** shows a section view of a curved area of vasculature with tissue growth formed around an implanted lead in accordance with embodiments of the present disclosure;

[0037] FIG. **4** shows a cross-sectional view of the curved area of vasculature of FIG. **3** taken along line A-A;

[0038] FIG. **5**A shows a cross-sectional view of an area of vasculature with a lead removal sleeve introduced along an implanted lead in accordance with embodiments of the present disclosure;

[0039] FIG. **5**B shows a cross-sectional view of an area of vasculature with a lead removal sleeve engaging and dilating formed tissue surrounding an implanted lead in accordance with embodiments of the present disclosure;

[0040] FIG. **5**C shows a cross-sectional view of an area of vasculature with a lead removal sleeve dilating formed tissue along an entire length of the formed tissue surrounding an implanted lead in accordance with embodiments of the present disclosure;

[0041] FIG. **5**D shows a cross-sectional view of an area of vasculature with an implanted lead subjected to a removal force within an area of a lead removal sleeve dilating formed tissue along an entire length of the formed tissue in accordance with embodiments of the present disclosure;

[0042] FIG. **5**E shows a cross-sectional view of an area of vasculature with a lead removal sleeve in a tissue growth after a lead has been removed from the area in accordance with embodiments of the present disclosure;

[0043] FIG. **5**F shows a cross-sectional view of an area of vasculature with a lead removal sleeve within an area of a tissue growth where the sleeve is subjected to removal forces in accordance with embodiments of the present disclosure; and

[0044] FIG. **6** is a flow diagram depicting a lead removal method in accordance with embodiments of the present disclosure.

[0045] It should be understood that the drawings are not necessarily to scale. In certain instances, details that are not necessary for an understanding of the disclosure or that render other details difficult to perceive may have been omitted. It should be understood, of course, that the disclosure is not necessarily limited to the particular embodiments illustrated herein.

DETAILED DESCRIPTION

[0046] Before any embodiments of the disclosure are explained in detail, it is to be understood that the disclosure is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The disclosure is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0047] Embodiments of the present disclosure are directed to lead removal sleeves and methods of using lead removal sleeves to remove an implanted lead from within the vascular system of a patient. Among other things, the method of removing an implanted lead from formed tissue may include causing at least a partial dilation of tissue along an axial length of the implanted lead. In some embodiments, the tissue may be "passively" dilated and displaced (e.g., without cutting or otherwise disrupting the continuity of the tissue growth) by a lead removal sleeve along an entire length of the tissue growth to enable removal of the implanted lead. In other embodiments, the tissue may be dilated and displaced about a lead removal sleeve, where the lead removal sleeve provides support to maintain the tissue in a dilated state. Additionally or alternatively, the lead removal sleeve may provide clearance between the inner lumen of the sleeve and the lead to allow an implanted lead to be removed from a patient.

[0048] While the phrases "tissue displacing tip" or "tissue dilating tip" are used in this disclosure, it is not limited to an extruded shape of uniform cross-section. These phrases are further intended to encompass any modality for dilating or displacing tissue, including the various modalities discussed herein. Nonlimiting examples include not only a tapered area, point, or shaped end disposed at or near the distal end of the sleeve, but also a machined tip, formed tip, welded and/or tip otherwise connected to the flexible shaft of the lead removal sleeve.

[0049] FIG. **1** depicts an exemplary patient **102** with an implanted lead **104** running along the left innonimate vein **112** past the superior vena cava ("SVC") **116** and connected into, or about, the right ventricle of the heart **106**. Along the

length of the lead **104** at least one formed tissue growth **108** is shown where the tissue **108** may completely surround a section of the lead **104**. In a typical lead **104** explant procedure, the one or more of the tissue growths **108** may act to contain the lead **104**. For example, the tissue **108** may impart one or more forces (e.g., constrictive, shear, compression, and the like) on the lead **104** that may act to prevent successful removal of the lead **104** when subjected to a traction force **120**.

[0050] FIGS. **2**A-C show examples of an implanted lead **104** subjected to a traction force via different paths in a patient **102** vasculature. Accordingly, the methods and/or devices disclosed in conjunction with any of the FIGS. **2**A-C may equally apply to all instances disclosed.

[0051] FIG. **2**A shows a detail view of a heart **106** having an implanted lead **104** subjected to a traction force **120** in a first path in accordance with embodiments of the present disclosure. In some embodiments, a lead **104** explant procedure may involve removing the lead from a patient **102** via one or more paths. For example, a lead-locking, or other traction, device may be engaged with the lead **104** and then used to pull the lead **104** from a patient. However, in some cases the lead **104** may be contained by a formed tissue growth **108** that resists the traction force **120** applied to the lead **104**. As can be appreciated, subjecting the lead **104** to excessive traction forces **120** may cause a tear inside the patient **102** where the tissue is attached to the vasculature. In one example, a tissue growth **108** may form along a critical area of the vasculature, such as the SVC curve **116**, of a patient. If this critical area is torn during a lead **104** explant procedure, the result can be fatal to the patient **102**.

[0052] Complicating the lead **104** removal process is the fact that the tissue growth **108** surrounding a lead **104** may attach to a vessel in a curved portion of the vasculature. Removal of the lead **104** from such a curved portion of vasculature can present a challenge when introducing tissue removal devices alone or in conjunction with traction devices. In some cases, the tissue removal devices include sharp edges, aggressive tips, or imprecise actuation mechanisms that can puncture the thin walls of a patient **102** vasculature. It is an aspect of the present disclosure to orient any sharp edge of a tissue dislocation tip associated with a lead removal sleeve adjacent to the unconnected, or tissue free, side **124** of a vessel wall. This orientation can prevent puncture and/or damage occurring to the vasculature at the tissue connected side **128** of the vessel wall.

[0053] Referring now to FIG. **2**B a detail section view of a patient vasculature and implanted lead **104** subjected to a traction force **120** in second path in accordance with some embodiments of the present disclosure is shown. In some instances, at least one end of the lead **104** may be directed inside a patient **102** for removal via a path within the vasculature. Direction of the lead **104** may be effected via a snaring tool, lead-locking device, traction device, combinations thereof, and the like. As shown in FIG. **2**B, the lead **104** is directed toward the general direction of a patient's femoral artery via the inferior vena cava. The lead **104** may be directed in the manner shown to provide additional tearing forces on the tissue growth **108** by the lead **104** being subjected to a traction force **120**. In one embodiment, a lead removal sleeve may be run along the lead **104** to the tissue growth **108** via the femoral artery.

[0054] In some embodiments, the lead **104** may be captured and pulled such that the pull force causes the lead **104** to turn inside a patient **102**. This mode of capture and pulling may cause a bending at a first connection point between the tissue growth **108** and the lead **104**. When the lead removal sleeve is engaged with the tissue growth **108**, the assistive bending force provided by the traction force **120** can aid in dilating the tissue growth **108**. For instance, the bending force may cause a stretching of the tissue growth **108** where the lead engages with the tissue growth **108**. This stretching of tissue may assist in the dilating operation by causing tension on the fibers of the tissue growth **108** that provide a greater area for introduction of a lead removal sleeve. As can be expected, the dilating operation may be performed in any area within a patient that is capable of receiving a lead removal sleeve.

[0055] FIG. **2**C shows a detail section view of a patient vasculature and implanted lead **104** subjected to a traction force **120** in third path in accordance with some embodiments of the present disclosure. Similar to FIGS. **2**A and **2**B, the lead **104** may be directed along a path in the patient vasculature. In this case, the lead **104** may be directed toward the general direction of a patient's jugular vein.

[0056] As can be appreciated, the path chosen for removal of a lead **104** from a patient **102** may depend on one or more of the orientation of the lead **104** within a patient **102**, the state of the at least one tissue growth **108** and the lead removal device used. In some cases, the lead **104** (e.g., pacing, defibrillator, etc.), or other object, may have moved after implantation. In these scenarios, the lead **104** may have to be captured via some other method. In some embodiments, a capturing tool equipped with a lasso, snare, or other lead grasping element may need to be inserted into the patient **102**. As can be expected, the capturing tool may be inserted into the patient **102** via any number of the veins and/or arteries that are interconnected to the lead **104** location in the vasculature. For example, the lead **104** may be grasped via a capturing tool that has been inserted through a patient's femoral artery and led to the point of the vasculature where the lead's **104** free end may be located.

[0057] In some embodiments, rather than attach a separate mechanical traction device, the capturing tool may be used to provide traction force **120** during the tissue dilation operation. In accordance with embodiments of the present disclosure, the lead may be grasped via a capturing tool, or lead-locking device, and/or removed via some other pathway in the vasculature. In other words, the lead may be accessed via one or more veins, arteries, chambers, biological channels, and/or other sections of the vasculature of a patient **102**.

[0058] FIG. **3** shows a section view of a curved area of vasculature with tissue growth **108** formed around an implanted lead **104** in accordance with embodiments of the present disclosure. The tissue growth **108** may completely surround a section of the lead **104** and even be attached to a vessel wall at a tissue connected side **128** of the vasculature. In some cases, the tissue growth **108** may not be adhered to at least one free side **124** of a vessel, such that a vessel opening **126** exists where bodily fluid may pass through the vessel unobstructed. Surprisingly and unexpectedly, it has been discovered that the tissue growth **108**, before attempted lead extraction, is commonly at least substantially free of and even more commonly completely free of attachment to the lead **104**.

[0059] FIG. **4** shows a cross-sectional view of the curved area of vasculature of FIG. **3** taken along line A-A. In some embodiments, reference may be made to the tissue growth **108** forming a tube **132** (or cylindrical or sock-like structure)

around the implanted lead **104**. Previous methods have been disclosed that are directed to separating the tissue around the lead **104** in the area defined by the tube **132**.

[0060] FIGS. **5**A-F show a cross-section of a vessel where a lead removal sleeve **504** is progressively engaged with a tissue growth **108** for lead **104** removal. As shown, the lead removal sleeve **504** causes a section of the tissue growth **108** to dilate around at least a portion of the lead **104** allowing the forces containing the lead **104** to be directed to a structure **506** of the lead removal sleeve **504**. An implanted lead **104** may be removed from the vasculature through the lead removal sleeve **504**. Additionally or alternatively, the lead removal sleeve **504** may be removed from the vasculature.

[0061] Referring to FIG. **5**A a cross-sectional view of an area of vasculature with a lead removal sleeve **504** introduced therein in accordance with embodiments of the present disclosure is shown. The lead removal sleeve **504** includes a flexible shaft having a proximal and a distal end, an inner lumen **510** running from the proximal to the distal end, and a tissue dislocation tip **508** disposed at or near the distal end of the shaft that is configured to dilate at least a portion of tissue growth **108** formed around an area of an implanted lead **104**. As can be appreciated, the tissue dislocation tip **508** may be the distal end of the shaft and/or operatively attached adjacent to the distal end of the shaft. In some embodiments, the inner lumen **510** may include an internal diameter configured to allow a lead, lead locking device, and/or other implanted device to pass through it.

[0062] In another embodiment, a lead removal sleeve **504** may be configured to work into an area between a tissue growth **108** and a lead **104**. It is anticipated that the geometry of the lead removal sleeve **504** and/or the tissue dislocation tip **508** may allow the lead removal sleeve **504** to be worked into this area. For instance, the lead removal sleeve **504** may be constructed with a thin wall between the inner lumen **510** and an outer surface of the structure **506** of the lead removal sleeve **504**. An example of this thin wall may include a thickness range from 0.005" to 0.1875." In some embodiments, the thickness may vary at the tissue dislocation tip **508**, such that a thickness at the tip **508** is less than a thickness along another portion of the lead removal sleeve **504** proximal to the tissue dislocation tip **508**. This variation in thickness may act to wedge the tissue dislocation tip **508** into the area between the tissue growth **108** and the lead **104**. Depending on the tissue growth **108**, various thicknesses may be required to work into an area between the tissue growth **108** and the lead **104**. Tougher tissue growths **108** may require a thinner wall thickness of the lead removal sleeve **504**, while softer tissue growths **108** may allow for a greater wall thickness of the lead removal sleeve **504**. The lead removal sleeve **504**, and/or its constituent parts, may be manufactured from any plastic, metal, resin, composite material, and/or combinations thereof disclosed herein. For example, the lead removal sleeve **504** may be manufactured from the same material as the inner lumen **510** and vice versa. In some embodiments, the lead removal sleeve **504** may be manufactured as a single extruded piece, as a tri-coil assembly, and even as a combination of various components.

[0063] In one embodiment, the tissue dislocation tip **508** may be oriented such that a leading edge may be presented to a section of tissue growth **108** between the lead **104** and the open area **126** of a vessel. Orientation of the lead removal sleeve **504** may be achieved in operation via a fluoroscopy and/or other monitoring devices and the use of one or more radiopaque markers on the lead removal sleeve **504**. Additionally or alternatively, an orientation of the lead removal sleeve **504** may be achieved via a monitoring device operatively attached to the lead removal sleeve **504**. In some embodiments, the monitoring device may be operatively attached to the distal end of the lead removal sleeve **504**. Once the lead removal sleeve **504** is oriented, the lead removal sleeve **504** may contact the tissue growth **108** at an engagement area **516**.

[0064] FIG. **5**B shows a cross-sectional view of an area of vasculature with a lead removal sleeve **504** engaging formed tissue **108** in accordance with embodiments of the present disclosure. The lead removal sleeve **504** may be pushed, indexed, and/or gradually rotated into the formed tissue **108**. The directional force **518** may be applied to the lead removal sleeve **504** via one or more mechanical actuators, electrical actuators, manual positioning, and combinations thereof. As the lead removal sleeve **504** engages the tissue growth **108** the tissue dislocation tip **506**, may dilate the tissue growth **108** by dislocating, expanding, stretching, parting, and/or otherwise causing a separation of tissue **520** at the engagement area **516**. In some embodiments, as the lead removal sleeve **504** is engaged with the tissue growth **108**, the separation of tissue **520** redirects forces (e.g., clamping, constricting, compression, etc.) subjected to the lead **104** by the tissue growth **108** to be directed to an outer surface associated with the flexible shaft **506**.

[0065] FIG. **5**C shows a cross-sectional view of an area of vasculature with a lead removal sleeve **504** dilating a complete length of a tissue growth **108** in accordance with embodiments of the present disclosure. As shown in FIG. **5**C, the tissue growth **108** is dilated by the lead removal sleeve **504** along a section of the lead **104**. In some embodiments, a structure **506** of a lead removal sleeve **504** may provide support to maintain the tissue growth **108** in a dilated state. Additionally or alternatively, the inner lumen **510** of the lead removal sleeve **504** may provide clearance for the lead **104** to move relative to the tissue growth **108** and the lead removal sleeve **504**.

[0066] FIG. **5**D shows a cross-sectional view of an area of vasculature with an implanted lead **104** subjected to a removal force **522**. As can be appreciated, the lead **104** may create a tunnel, through which, the lead **104** may be moved (e.g., removed from a patient and/or tissue growth **108**). The tunnel provided by the lead removal sleeve **504** may prevent forces from the tissue growth **108** from acting on the lead **104**. In some embodiments, the inner lumen **510** of the lead removal sleeve **504** may be configured with a low-friction surface for an implanted lead **104**, lead-locking device, and/or other object to move along. It is anticipated that the low-friction surface may prevent the lead from adhering to the inner lumen **510**. Examples of low-friction surfaces of the inner lumen **510** may include, but are not limited to, a manufactured shape (e.g., smooth, uninterrupted, sinusoidal, undulated, etc.), a material with a low coefficient of friction (e.g., polytetrafluroethylene ("PTFE"), fluropolymer, polymers, plastics, resins, metal alloy, steel alloy, etc.), a lining, a deposited film, rollers, liquid bearing, polished material, and the like. In one embodiment, the low-friction surface may include a surface with a coefficient of friction ("μ") less than 1. In other words, a force required to slide an object along a low-friction surface having a $\mu<1$, is less than the normal force of the object acting against the low-friction surface.

[0067] FIG. **5**E shows a cross-sectional view of an area of vasculature with a lead removal sleeve **504** in a tissue growth **108** after a lead **104** has been removed in accordance with embodiments of the present disclosure. In some embodiments, the lead removal sleeve **504** may continue to dilate the tissue growth **108** even after a lead **104** has been removed. The lead removal sleeve **504** may be configured and/or allowed to remain inside the vasculature of a patient **102**. In one instance, the lead removal sleeve **504** may be manufactured from or include at least one bioresorbable material. As such, the lead removal sleeve **504** may be left inside of a patient **102** to degrade and/or be absorbed by the patient **102** over time. In an alternative embodiment, the lead removal sleeve **504** may be manufactured from a non-bioresorbable material, where the sleeve **504** is left inside a patient without appreciably degrading over time. It is anticipated that the non-bioresorbable material of the lead removal sleeve may be manufactured from a biocompatible material configured to remain inside a patient **102** indefinitely. Alternatively, the lead removal sleeve **504** may be subsequently removed from the vasculature of the patient **102**.

[0068] FIG. **5**F shows a cross-sectional view of an area of vasculature with a lead removal sleeve **504** within an area of a tissue growth **108** where the sleeve **504** is subjected to removal forces in accordance with embodiments of the present disclosure. The lead removal sleeve **504** may be pulled from a tissue growth **108** in a removal direction **526**. In some embodiments, as the lead removal sleeve **504** is pulled (e.g., via a removal force) from a tissue growth **108**, one or more forces subjected to an outer diameter of the sleeve **504** may cause the sleeve **504** to radially collapse. In another embodiment, the lead removal sleeve **504** may be subjected to a twisting removal force to collapse the sleeve **504**. It is anticipated that the twisting removal force may be in a rotational direction about an axis running along the lead removal sleeve. For example, the twisting force may cause the lead removal sleeve **504** to reduce an inner and outer overall diameter of the sleeve **504** such that forces subjected to the lead via a tissue growth **108** are reduced and/or eliminated. Additionally or alternatively, the lead removal sleeve **504** may include one or more stress concentration areas, and/or collapsible sections, that may be configured to collapse along a given section, area, point, and/or line. As can be appreciated, the one or more stress concentration areas and/or collapsible sections may collapse when subjected to a specific force or combination of forces.

[0069] In one embodiment, the lead removal sleeve **504** may be collapsed along its length in a direction **524** toward an axis running along the length of the sleeve **504**. Additionally or alternatively, the lead removal sleeve **504** may be configured to collapse along a section of the sleeve structure **506**. In an embodiment, it is anticipated that the lead removal sleeve **504** may include at least one weakened, or reduced thickness, area along a length of the structure **506**.

[0070] In any of the collapsing embodiments disclosed herein, it is anticipated that the collapsing of a section of the lead removal sleeve **504** will allow a dilated section **520** of the tissue growth **108** to remain dilated about the lead removal sleeve **504**. As such, any forces subjected to the structure **506** of the uncollapsed sleeve **504** will be at least temporarily reduced on the collapsed sleeve. This temporary reduction in forces may allow the lead removal sleeve **504** to be removed from the tissue growth **108** by subjecting the sleeve **504** to a removal force.

[0071] Referring to FIG. **6**, a lead removal method **600** will be described in accordance with at least some embodiments of the present disclosure. The method **600** starts at **604** and begins by connecting a lead-locking device or other traction device to the lead **104** (step **608**). In some embodiments, the lead-locking device may be inserted into the core of an implanted lead **104**. In other embodiments, a traction device may be connected to the lead **104** to provide traction on the lead **104**. For instance, mechanical traction can be achieved in leads **104** by inserting a locking stylet into the lead **104** and applying a pull force onto the lead **104** via the locking stylet. In some embodiments, it may be beneficial to support the lead removal sleeve **504** and/or lead locking device with another structure. For instance, the lead removal sleeve **504** may be inserted into a support catheter. The support catheter may be inserted adjacent to the tissue growth **108** and may be configured to at least partially contain and/or restrain movement associated with the lead removal sleeve **504**. In one embodiment, the support catheter may include a vacuum system that may be configured to direct a vacuum force to an outer diameter of the lead removal sleeve **504**. The vacuum system may be selectively operated to allow free movement and/or restrict movement based on an unapplied vacuum and an applied vacuum, respectively. In some embodiments, the vacuum may be contained adjacent to an inner diameter of the support catheter.

[0072] Once a traction device is attached to the lead **104**, the traction device can be threaded through the internal, or inner, lumen **510** of a lead removal sleeve **504** (step **612**). For example, the lead-locking device may be inserted through the lumen in an implanted lead **104** and attached to the internal portions of the implanted lead **104**, which can be at the distal portion or proximal to the distal portion of the lead **104**. The lead removal sleeve **504** may ride over an external portion of the lead **104** and lead-locking device and may be configured to dilate tissue growths **108** along an axial length of the tissue **108** in contact with the lead **104**.

[0073] As the lead removal sleeve **504** is engaged with the lead **104**, a slight traction force may be applied to the lead **104** to allow the lead removal sleeve **504** to guide along the lead **104** (step **616**). The lead removal sleeve **504** can be moved toward a first formed tissue growth **108** while applying a mechanical traction force to the lead **104** itself or through a locking stylet, or other traction device. Mechanical traction force should be applied with appropriate force to prevent tearing a vein or artery wall by moving the lead **104** and tissue **108** before they are dislocated. In some embodiments, the lead removal sleeve may be observed moving inside a patient **102** via a fluoroscope or other monitor. It is anticipated that the tissue dislocation tip **508**, or some other area, of the lead removal sleeve may include a fluorescing material or marker (e.g., radiopaque band, and the like). This fluorescing material or marker may be used to aid in monitoring the movement of the lead removal sleeve when it is inside a patient **102**. Additionally or alternatively, the lead removal sleeve **504** may include a monitoring system disposed at or adjacent to the distal end of the sleeve **504** to determine a location of the sleeve and/or the tissue dislocation tip inside a patient **102**.

[0074] Next, the sleeve **504** is moved into contact with the formed tissue growth **108** (step **620**). In some embodiments, a sharp, tapered, or leading edge of the tissue dislocation tip **508** of the lead removal sleeve **504** may be oriented toward the center of the vein, or away from the vein wall connecting the lead **104** to the vein. In addition to preventing accidental

puncture, trauma, or other damage to the delicate surfaces of the vasculature this orientation of the tissue dislocation tip **508** may aid in safely actuating the sleeve **504** and dilating the tissue **108** about the implanted lead **104**. For example, a lead removal sleeve **504** may include a tissue dislocation tip **508** with a wedge and/or tapered portion adjacent to the distal end of the sleeve **504**. It is anticipated that this tissue dislocation tip **508** may be configured to wedge into an area between the tissue growth **108** and a lead. As the lead removal sleeve **504** traverses along the lead **104**, the tissue dislocation tip **508** continues to dilate the tissue growth **108**. Additionally the leading portion, which may include a wedge and/or tapered portion, can act to cause a stretching of the formed tissue growth **108** at the point where it engages with the tissue dislocation tip **508**. This stretching of tissue may assist in the actuating the lead removal sleeve further into the tissue growth **108**. In addition, the stretching of tissue may aid in redirecting forces created by the tissue growth **108** from contacting the lead **104** to contacting the structure of the sleeve **504**.

[0075] Once the tissue dislocation tip is engaged with, and/or dilating, the formed tissue **108**, the lead removal sleeve **504** may be actuated and moved along the lead **104** to further engage with the tissue growth **108**. In some embodiments, the lead removal sleeve **504** may be indexed forward (into the tissue formation **108**) continuously or periodically. In other embodiments, the lead removal sleeve **504** may be repeatedly indexed into and removed from the engagement area of the formed tissue growth **108**. It is anticipated that each time the lead removal sleeve **504** is indexed into the engagement area the sleeve **504** can dilate a successively longer section of the formed tissue **108**. Indexing the sleeve **504** along the lead **104** and into a tissue growth **108** may require a rotational movement of the sleeve **504** about an axis running from the proximal to the distal end of the sleeve **504**. In some cases, the lead removal sleeve **504** may be worked into an area between the tissue growth **108** and the lead **104** by rotating and translating the sleeve **504**.

[0076] The method **600** may be continued by determining whether a traction force applied to the lead **104** moves the lead **104** relative to the tissue growth **108** and/or the lead removal sleeve **504** (step **624**). In the event that the lead **104** is determined to move such that it may be removed from the patient, the method may continue at step **632**. If it is determined, however, that the lead **104** does not move sufficiently relative to the tissue growth **108** and/or the lead removal sleeve **504**, the method may continue at step **628**.

[0077] In some cases, the lead removal sleeve **504** may need to be worked through an entire length of a tissue growth **108** and/or worked through more than one tissue growth **108** such that the lead **104** may be removed from a patient **102** (step **628**). Accordingly, the lead removal sleeve **504** may be indexed through one or more tissue growths **108** until it is determined (at step **624**) that the lead **104** can be moved/removed.

[0078] Once the lead is determined to move relative to the tissue growth **108** and/or lead removal sleeve **504**, the method may continue at step **632** by removing the lead **104** from the patient **102** (step **632**). Additionally or alternatively, once the tissue growth(s) have been dilated, the lead **104** may be removed by applying a pull force to the lead-locking device in the same direction as the mechanical traction force previously applied to the lead **104**. It is anticipated that any movement of the lead removal sleeve **504** may be accompanied by an applied mechanical traction force to the lead **104**/lead-locking device.

[0079] In some embodiments, the method **600** may continue by removing the lead removal sleeve **504** from the patient **102** (step **636**). Otherwise, the method **600** ends at step **640**. As disclosed herein, a lead removal sleeve **504** may be removed from a patient **102** via collapsing an area of the structure **506** of the lead removal sleeve **504**. In one embodiment, the lead removal sleeve **504** may be twisted about an axis running along the sleeve **504**. As the sleeve **504** is twisted, an inner and/or outer diameter associated with the sleeve **504** may be caused to reduced in diameter. This reduction in diameter may reduce forces subjected to the sleeve **504** via the tissue growth **108**. In one embodiment, it is anticipated that the tissue growth **108** surrounding a twisted sleeve **504** may remain in a temporarily dilated state after the sleeve **504** is collapsed. This temporarily dilated state of the tissue growth **108** may allow for removal of the lead removal sleeve **504** by subjecting the lead removal sleeve **504** to a directional removal force configured to dislocate a position of the sleeve **504** (e.g., pulling the sleeve **504** from the patient **102**).

[0080] Embodiments of the present disclosure anticipate using a mechanical collapse structure to remove the sleeve **504** from a patient **102**. For instance, the lead removal sleeve **504** may incorporate one or more mechanical elements, such as, cams, wires, coils, removable strips, combinations thereof, and the like to facilitate a mechanical collapse of the structure **506** of the sleeve **504**. Once the sleeve structure **506** is collapsed it may be removed from a patient **102** in a similar manner as disclosed above. The method **600** ends at step **640**.

[0081] In the appended figures, similar components and/or features may have the same reference label. Further, various components of the same type may be distinguished by following the reference label by a letter that distinguishes among the similar components. If only the first reference label is used in the specification, the description is applicable to any one of the similar components having the same first reference label irrespective of the second reference label.

[0082] Presented herein are embodiments of a lead removal sleeve, system, and method. As described herein, the device(s) may be electrical, mechanical, electro-mechanical, and/or combinations thereof.

[0083] Also, while the flowcharts have been discussed and illustrated in relation to a particular sequence of events, it should be appreciated that changes, additions, and omissions to this sequence can occur without materially affecting the operation of the disclosed embodiments, configuration, and aspects.

[0084] A number of variations and modifications of the disclosure can be used. It would be possible to provide for some features of the disclosure without providing others. By way of illustration, any methodology or modality of dislocating and/or dilating tissue may be employed as described herein to effect lead removal from an encased tissue growth.

[0085] The present disclosure, in various aspects, embodiments, and/or configurations, includes components, methods, processes, systems and/or apparatus substantially as depicted and described herein, including various aspects, embodiments, configurations embodiments, subcombinations, and/or subsets thereof. Those of skill in the art will understand how to make and use the disclosed aspects, embodiments, and/or configurations after understanding the present disclosure. The present disclosure, in various aspects, embodi-

ments, and/or configurations, includes providing devices and processes in the absence of items not depicted and/or described herein or in various aspects, embodiments, and/or configurations hereof, including in the absence of such items as may have been used in previous devices or processes, e.g., for improving performance, achieving ease and/or reducing cost of implementation.

[0086] The foregoing discussion has been presented for purposes of illustration and description. The foregoing is not intended to limit the disclosure to the form or forms disclosed herein. In the foregoing Summary for example, various features of the disclosure are grouped together in one or more aspects, embodiments, and/or configurations for the purpose of streamlining the disclosure. The features of the aspects, embodiments, and/or configurations of the disclosure may be combined in alternate aspects, embodiments, and/or configurations other than those discussed above. This method of disclosure is not to be interpreted as reflecting an intention that the claims require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed aspect, embodiment, and/or configuration. Thus, the following claims are hereby incorporated into this Summary, with each claim standing on its own as a separate preferred embodiment of the disclosure.

[0087] Moreover, though the description has included description of one or more aspects, embodiments, and/or configurations and certain variations and modifications, other variations, combinations, and modifications are within the scope of the disclosure, e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure. It is intended to obtain rights which include alternative aspects, embodiments, and/or configurations to the extent permitted, including alternate, interchangeable and/or equivalent structures, functions, ranges or steps to those claimed, whether or not such alternate, interchangeable and/or equivalent structures, functions, ranges or steps are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

1. A lead removal apparatus comprising:

a shaft, wherein the shaft is flexible, the shaft having at least one outer surface, a proximal and a distal end, and wherein the shaft includes an inner lumen running from the proximal to the distal end to receive at least one of an implanted object and a mechanical traction device; and

a tissue dilating tip disposed adjacent to the distal end of the shaft, wherein the tissue dilating tip is configured to passively wedge into an area between a tissue growth and the implanted object, and wherein the at least one outer surface of the lead removal apparatus is configured to dilate the tissue growth about an area of the implanted object.

2-29. (canceled)

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