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APPARATUS FOR REMOVING AN ELASTOMERIC TERMINAL PORTION ON A MEDICAL LEAD

Abstract

An apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead includes a first arm and a second arm. The first arm and the second arm are connected to each other and move in opposition between an open position and a closed position. Opposed mating portions on the first and second arms are configured to retain the proximal end of the lead when the apparatus is in the closed position. An elongate cutting implement enclosed within the second arm includes a cutting blade oriented at an angle such that, when the apparatus is in the closed position, the cutting blade forms a slit in at least a portion of the elastic terminal component.

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Background/Summary

BACKGROUND

[0001] Implantable medical systems commonly include one or more implantable medical leads coupled to an implantable or external medical device to provide a therapy to the patient. As an example, cardiac systems, such as implantable pacemakers, cardioverter-defibrillators, cardiac resynchronization therapy devices and the like, commonly include an implantable medical device (IMD) such as an implantable pulse generator electrically connected to the heart by at least one transvenous endocardial lead. An endocardial lead provides an electrical pathway between the pacemaker, connected to the proximal end of the lead, and endocardial tissue, which is in contact with the distal end of the lead. Endocardial tissue refers to a specific layer of tissue in the interior of the heart's chambers. Electrical stimulation pulses emitted by the IMD travel through the endocardial lead and stimulate the heart to deliver a prescribed therapy. Other implantable medical systems, such as neuromodulation stimulators, may have leads implanted in other locations of the patient, e.g., brain, spine and the like.

[0002] In some patients, it may become necessary to extract and replace an implanted lead. For example, a lead may need to be acutely replaced when unacceptable stimulation thresholds are measured during an implant procedure. A lead may also need to be replaced when the lead fails, or when the endocardial tissue around the lead implantation site becomes infected.

[0003] In some examples, if the lead has been implanted for an extended period of time, scar tissue formed around the lead along the intravascular course and at the implantation site in the endocardial tissue can make the extraction procedure more difficult. In such cases, a tubular extraction sheath may be used to track over the length of the lead. The extraction sheath, which may be monitored with fluoroscopy and/or transesophageal echocardiography, is guided within the vasculature of the patient to dissect the fibrotic scar adhesions that prevent lead extraction. In some examples, a distal tip of the tubular extraction sheath may include a rotating cutting element, a laser, a plasma generator, or an electrocautery system to assist in dissecting the adhesions. Once the tubular extraction sheath has been advanced to the implantation site, the lead may be extracted through the sheath and removed from the body of the patient.

[0004] In some examples, an inside diameter of an extraction sheath is about 7 French (Fr) (2.3 mm) to as large as 13 Fr (4.3 mm), and smaller extraction sheaths are desirable to prevent injury to the vasculature of the patient. However, the proximal end of pacemaker leads typically have a relatively bulky connector assembly that plugs into, and makes an electrical connection with, the pacemaker. Standard connectors used to connect leads to pacemakers, such as IS-1, IS-4 and DF-4, have an outside diameter of about 14 Fr to 15 Fr (4.6 mm to 5.0 mm). In some procedures, when extracting a lead, the relatively large diameter of the connector can require that the lead be cut near the connector to allow insertion of the lead into the extraction sheath. Once cut, the lead requires additional preparation steps to bind the conductors to a suitable locking stylet or compression coil so that traction may be applied to the lead. Incorrect preparation of the severed conductors can decrease lead tensile strength and increase the chance of lead breakage. Some lead designs can lose substantial lead strength when cut, and cutting the lead to remove the bulky connector may require lead insulation and other protective layers overlying the lead conductor be immobilized by, for example, a ligation suture.

[0005] To avoid cutting the lead, some practitioners have adopted a lead removal method that retains the bulky lead connectors, but this method can require use of an extraction sheath with a larger internal diameter to allow passage of the bulky connector. While retaining the connector maintains the structural strength of the lead, the large disparity between the inner diameter of the extraction sheath and the outside diameter of the lead can cause higher complication rates for vascular damage. For example, in some cases the larger gap between the lead outside diameter and the lead inside diameter can pull the vascular wall into the sheath, which can increase the likelihood of a large vascular tear.

SUMMARY

[0006] To maintain lead integrity and strength during a procedure to extract a chronic lead such as, for example a cardiac lead, in some cases it is desirable to leave the lead connectors intact. However, leaving the lead connectors in place on the proximal end of the lead requires an extraction sheath with a larger internal diameter to translate over the relatively large lead connector. To further reduce the diameter of the lead connector, in some cases practitioners employ a scalpel to manually shave off the elastomeric terminal components such as, for example, grip sleeves and seals, on the proximal end of the connector. Removing the elastomeric terminal components reduces the overall diameter of the connectors and the proximal end of the lead, which can make the prepared lead assembly more compatible with an extraction sheath having a preferred size for translation through the vasculature of a particular patient. However, manually shaving away the elastomeric terminal components may potentially leave foreign material at the implant site, which increases patient risk resulting from pocket infections, and the somewhat haphazard shaving procedure may increase risk to the patient, the practitioner, or other operating room personnel.

[0007] In general, the present disclosure is directed to a handheld tool that can be used by a practitioner to safely and reproducibly remove one or more elastomeric terminal components from a proximal end of a medical lead, such as, for example, an implanted cardiac lead. In one example, the tool includes opposed arms that may be closed over an elastomeric terminal component on an outer surface of the lead body such as, for example, a silicone grip sleeve, at proximal end of the lead. When the opposed arms of the tool move from an open position to a closed position, an elongate blade housed in the tool is configured to score the elastic terminal component such as, for example, a silicone grip sleeve. The tool may then be translated with respect to the lead to form a slit in the elastic terminal component that extends substantially along a longitudinal axis of the lead. Once longitudinally slit, the elastic terminal component may be peeled away from the lead body in a single piece, or in large multiple pieces, forming fewer shards or shavings. Housing the blade within the body of the tool prevents accidental injury to the practitioner, operating room staff, and patient, and the reduction in small shavings at the implant site can reduce the risk to the patient caused by pocket contamination.

[0008] In another example, a portion of the tool includes a port with an optional hypotube having a recessed annular cutting edge. When an elastic terminal component on a proximal end of a medical lead such as, for example, an implanted cardiac lead, is inserted into the hypotube, the annular cutting edge slices the elastomeric terminal component at a diameter slightly greater than the diameter of the lead structure adjacent to the elastic terminal component. The cutting edge engages the elastomeric terminal component, and the tool may then be translated with respect to the lead to strip and peel away the elastomeric terminal component, which remains within a body of the tool to prevent loss in the operating field.

[0009] By easily and reproducibly removing the elastomeric terminal components on the proximal end of the lead, the tool of the present disclosure further reduces the overall outside diameter of the lead. For example, reducing the diameter of a cardiac lead can allow use of a smaller extraction

sheath during lead extraction procedures. In some cases, removing elastic terminal components such as the grip sleeve and the seal from a cardiac lead can reduce the outside diameter of the connector region on the proximal end of the lead from about 12 French (Fr) (4 mm) to less than about 10 Fr (3.33 mm), or less than about 8 Fr (2.67 mm). This smaller diameter in turn allows the use of a smaller extraction sheath when removing the cardiac lead, which can reduce the likelihood of patient vascular damage.

[0010] In one aspect, the present disclosure is directed to an apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead. The apparatus includes: a first arm and a second arm, wherein the first arm and the second arm each include a first end and a second end, and wherein the first arm and the second arm are connected to each other and move in opposition to each other between an open position and a closed position; wherein the first arm and the second arm include opposed first mating portions and second mating portions configured to retain the proximal end of the lead when the first end of the first arm and the first end of the second arm are in the closed position; and an elongate cutting implement enclosed within the second arm, wherein the cutting implement includes a cutting blade oriented at an angle such that, when the first end of the first arm and the first end of the second arm are moved from the open position to the closed position, the cutting blade is configured to form a slit in at least a portion of the elastic terminal component, and wherein the slit extends along a longitudinal axis of the lead.

[0011] In another aspect, the present disclosure is directed to a handheld tool including opposed first and second arms movable about a hinge from an open position to a closed position, wherein the second arm includes an elongate cutting blade within a body thereof, the cutting blade being configured to cut a first elastomeric terminal component on a proximal end of a medical lead and form a slit on the elastic terminal component when the first arm and the second arm are in the closed position, wherein the slit extends along a longitudinal axis of the lead, and wherein the body of the second arm further includes a hypotube with an annular cutting edge configured to form a cut on a second elastomeric terminal component on a proximal end of the lead, wherein the cut formed by the annular cutting edge extends along a direction generally normal to the longitudinal axis of the lead.

[0012] In another aspect, the present disclosure is directed to a method for removing a grip sleeve from a proximal end of a medical lead, the method including: retaining the proximal end of the lead between a first arm and a second arm of a tool, wherein the first arm and the second arm are moveable from an open position to a closed position, and wherein at least one of the first arm and the second arm of the tool includes an elongate linear cutting blade; moving the first arm and the second arm into a closed position to engage the linear cutting blade with the grip sleeve on the lead; and translating the lead with respect to the tool such that the linear cutting blade forms a slit in the grip sleeve, the slit extending along a longitudinal axis of the lead.

[0013] In another aspect, the present disclosure is directed to a method for removing a seal from a proximal end of a medical lead, the method including: inserting the seal into a hypotube in a tool, wherein the hypotube includes an annular cutting edge; urging the seal against the annular cutting edge such that the seal forms a cut in the seal along a direction normal to a longitudinal axis of the lead; and translating the lead with respect to the tool to strip the seal from the medical lead.

[0014] In another aspect, the present disclosure is directed to an apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead, the apparatus including a first arm and a second arm connected to each other and configured to move in opposition to each other between an open position and a closed position, wherein the first and the second arms include opposed mating surfaces configured to retain the proximal end of the lead when the apparatus is in the closed position, and wherein an elongate cutting implement enclosed within the second arm includes a cutting blade oriented at an angle such that, when the apparatus is in the closed position, the cutting blade slits at least a portion of the elastic terminal component.

[0015] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

Description

BRIEF DESCRIPTION OF DRAWINGS

[0016] FIG. **1** is a conceptual drawing illustrating an example system that includes a temporary or permanent implantable medical device (IMD) coupled to implantable medical leads.

[0017] FIG. **2** is a perspective view of an example of a tool of the present disclosure suitable for removing at least one elastomeric terminal component from a proximal end of a medical lead.

[0018] FIG. **3** is an cross-sectional view along line A-A of FIG. **2**, which illustrates the hypotube configured to remove a elastomeric terminal component from the proximal end of a medical lead.

[0019] FIG. **4** is a perspective view of the tool of FIG. **2** in an open position and retaining a proximal end of a medical lead.

[0020] FIG. **5** is a side view of the tool of FIG. **2** in a closed position and retaining a proximal end of a medical lead.

[0021] FIG. **6** is a flow chart of a method for removing an elastomeric terminal component such as a grip sleeve from a proximal end of a medical lead using the tool of any of FIGS. **2-5**.

[0022] FIG. **7** is a flow chart of a method for removing an elastic terminal component such as a seal from a proximal end of a medical lead using the tool of any of FIGS. **2-5**. Like symbols in the drawings indicate like elements.

DETAILED DESCRIPTION

[0023] FIG. **1** is a conceptual diagram illustrating a portion of an example implantable medical device system **100**. Implantable medical device system **100** may function as a single chamber, e.g., ventricular, pacemaker, as illustrated by the example of FIG. **1** that delivers pacing to a heart **122** of patient **116**. Implantable medical device system **100** may be a temporary or permanent pacemaker. In alternative embodiments, however, implantable medical device system **100** may include one or more leads and function a multi-chamber pacemaker, such as a dual-chamber pacemaker or triple-chamber pacemaker that delivers pacing to a heart **122** of patient **116**. In some examples, the devices and methods of the present disclosure may be implemented in IMDs other than pacemakers, such as implantable cardioverter-defibrillators (ICDs), implantable cardiac resynchronization (CRT) devices, implantable neurostimulators, or other implantable medical systems that couple to implanted medical leads.

[0024] In the example of FIG. **1**, implantable medical device system **100** includes one or more implantable medical leads **112** electrically connected to the IMD **126**. The implantable medical lead **112** includes an elongated lead body **118** with a distal portion **120** positioned at a target implantation site **114** within the heart **122** such as, for example, a wall within one or more ventricles or atria. The lead **112** may be a unipolar, a bipolar, or a multipolar lead.

[0025] A clinician may maneuver the distal portion **120** of the lead **112** through the vasculature of patient **116** to position the distal portion **120** at or near the target site **114**. For example, the clinician may guide distal portion **120** through the superior vena cava (SVC) to target site **114** on or in a ventricular wall of heart **122**, e.g., at the apex of the right ventricle as illustrated in FIG. **1**. Implantable medical device system **100** may include a delivery catheter and/or outer member (not shown), and implantable medical lead **112** may be guided and/or maneuvered within a lumen of the delivery catheter in order to approach target site **114**.

[0026] The implantable medical lead **112** includes one or a plurality of electrodes. In the example of FIG. **1**, the lead **112** includes electrodes **124**A and **124**B (collectively, “electrodes **124**”) configured to be positioned on, within, or near cardiac tissue at or near target site **114**. In some examples, electrodes **124** provide pacing to heart **122**. The electrodes **124** may be electrically connected to conductors (not shown in FIG. **1**) extending through the lead body **118**. In some examples, the conductors are electrically connected to therapy delivery circuitry of IMD **126**, with the therapy delivery circuitry configured to provide electrical signals through the conductor to electrodes **124**. Electrodes **124** may conduct the electrical signals to the target tissue of heart **122**, causing the cardiac muscle, e.g., of the ventricles, to depolarize and, in turn, contract at a regular interval. Electrodes **124** may also be connected to sensing circuitry of IMD **126** via the conductors, and the sensing circuitry may sense activity of heart **122** via electrodes **124**.

[0027] The electrodes **124** may have various shapes such as tines, helices, screws, rings, coils and so on. Again, although a bipolar configuration of lead **112** including two electrodes **124** is illustrated in FIG. **1**, in other examples lead **112** may include different numbers of electrodes, such as one electrode, three electrodes, or four electrodes. In configurations in which the lead is a defibrillation lead, the lead may include one or more defibrillation coil electrodes and respective conductors extending through the lead body. In other examples (not shown in FIG. **1**), the IMD **126** can be connected to two leads (atrium and right ventricle) or three leads (A, RV, LV), or other electrode or lead configurations.

[0028] The configuration of the therapy system **100** illustrated in FIG. **1** is merely one example. In other examples, a therapy system may include epicardial leads, subcutaneous, substernal, and/or patch electrodes instead of or in addition to the transvenous lead **112** illustrated in FIG. **1**. Further, the IMD **126** need not be implanted within the patient **116**. In examples in which the IMD **126** is not implanted in the patient **116**, the IMD **126** may deliver therapies to the heart **122** via percutaneous leads that extend through the skin of patient **116** to a variety of positions within or outside of heart **122**.

[0029] In one or more examples, IMD **126** includes electronic circuitry contained within an enclosure where the circuitry may be configured to deliver cardiac pacing. In the example of FIG. **1**, the electronic circuitry within IMD **126** may include therapy delivery circuitry electrically coupled to electrodes **124**. The electronic circuitry within IMD **126** may also include sensing circuitry configured to sense electrical activity of heart **122** via electrodes **124**. The therapy delivery circuitry may be configured to administer cardiac pacing via electrodes **124**, e.g., by delivering pacing pulses in response to expiration of a timer and/or in response to detection of the activity (or absence thereof) of the heart.

[0030] In some examples, the system **100** includes an optional external device **130** such as a programmer. For example, optional external device **130** can be a handheld computing device such as a tablet or a phone, a computer workstation, or a networked computing device. The optional external device **130** can include a user interface that receives input from a clinician, which can include a keypad and a suitable display such as, for example, a touch screen display, or a peripheral pointing device, such as a mouse, via which a user may interact with the user interface. The clinician may also interact with the external device **130** remotely via a networked computing device.

[0031] After the implantable medical lead **112** and the electrodes **124** have been temporarily or more permanently implanted in the heart of a patient, the lead **112** and electrodes **124** may need to be removed due to structural defects, infections, or the need to upgrade a pre-existing system. After implantation for extended periods of time (for example, greater than about 1 year), chronic leads may develop a dense fibrotic and sometimes calcific process within the thin-walled venous structures or the endocardial surface of the heart or tricuspid valve, which can make the lead **112** and electrodes **124** difficult to extract. Complex lead extraction is associated with the risk of vascular injury by traction or perforation, causing tamponade, hemothorax, arteriovenous fistula, tricuspid valve disruption, or possibly pulmonary embolism, so simplifying or otherwise improving lead extraction techniques can have significant value for patient safety.

[0032] Extraction of medical leads can be performed by a variety of techniques, and in many cases simple traction or traction devices can be used to remove the lead from the body of the patient.

However, for chronic leads, various types of extraction sheaths, including mechanical, laser, electrosurgical, rotating threaded tip, and telescoping sheaths may be advanced over the lead and into the vein of the patient to remove the fibrotic scar tissue retaining the lead.

[0033] For various types of IMDs **126** (FIG. **1**), standard male connector pins of lead **112**, such as IS-1, IS-4, DF-4, SQ-1, and the like, have one or more structural features configured to engage a female receptacle in the IMD **126**. These standard connector pins have a relatively large diameter compared to the body of the lead **112**, and if left intact can require an extraction sheath with a larger diameter to be used. In addition, the standard leads include at least one elastomeric terminal component including, but not limited to, a seal between the connector pin and the body of the lead, and a silicone grip sleeve overlying a portion of the outer surface of the lead body near the proximal end thereof. The elastomeric terminal components further increase the outer diameter of the lead, which requires an even larger extraction sheath be used to move over the connector assembly on the proximal end of the lead. However, as noted above, larger diameter extraction sheaths increase the likelihood of vascular injury, so smaller diameter extraction sheaths are preferred for most patients.

[0034] Referring now to FIG. **2**, in one aspect, the present disclosure is directed to a handheld tool **10** that can be used by a practitioner to remove the elastomeric terminal components on a proximal end of a medical lead including, but not limited to, an implanted cardiac lead. The tool **10** includes a first arm **12** with a first end **11** and a second end **13**. The first arm **12** is connected to a second arm **14**, which includes a first end **15** and a second end **17**. The first arm **12** and the second arm **14** are configured to move in opposition to each other to retain an end of the medical lead including an elastomeric terminal component.

[0035] In the example of FIG. **2**, the first arm **12** and the second arm **14** are connected by a hinge **16**. In the example of FIG. **2**, the hinge **16** is retained within a vertical member **18** extending in a direction generally normal to a longitudinal axis **20** of the tool **10**, and includes a pin **22**. The first arm **12** and the second arm **14** articulate about the pin **22** such that the first arm **12** and the second arm **14** move in opposition to each other. The first arm **12** and the second arm **14** move about the hinge **16** such that the second end **13** of the first arm **12** and the second end **15** of the second arm **14** move between an open position and a closed position.

[0036] In another example (not shown in FIG. **2**), the hinge **16** may include members articulating about opposed adjacent edges **19**, **21** of the respective first and second arms **12**, **14**, or may include a continuous flexible hinge portion extending between the edges **19**, **21**.

[0037] In some examples (not shown in FIG. **2**), the first arm and the second arm may include one or more interlocking members that form a snap-fit joint. For example, the interlocking members may include one or more annular joints in which a more elastic member on one arm is inserted into a more rigid member in an opposed arm, an arrangement of cantilevered members in one or both of the first and the second arms **12**, **14** that insert into corresponding apertures, or may include an arrangement of torsional members on one or both arms that can be deflected to allow insertion of a corresponding member on the opposed arm.

[0038] In some examples, the tool **10** further includes an optional biasing member (not shown in FIG. **2**) between the first arm **12** and the second arm **14**. The biasing member can assist in maintaining the first arm **12** and the second arm **14** in an open position such that the tool **10** can more easily be moved over an elastomeric terminal component on the proximal end of the medical lead, or can be utilized to more forcefully urge a cutting implement (shown in more detail below) into contact with an elastomeric terminal component. The biasing member can vary widely, and in some examples can include a spring, an elastomer, or other biasing member, or a combination thereof.

[0039] The first arm **12** includes a substantially planar first mating surface **30**, and the second arm **14** includes an opposed substantially planar second mating surface **32**. As the first arm **12** and the second arm **14** move from an open position to a closed position, the first mating surface **30** and the second mating surface **32** move in opposition to each other and come together to grip between them an elastomeric terminal component overlying a medical lead. In some examples, the first mating surface **30**, the second mating surface **32**, or both, may optionally include opposed recessed regions (not shown in FIG. **2**, shown in more detail below) shaped to accept and house the proximal end of the medical lead. For example, each of the recessed regions can include a substantially hemispherical cross-sectional shape. When the first arm **12** and the second arm **14** are in a closed position, the opposed recessed regions can move together to more securely grip the elastomeric terminal component on the proximal end of the medical lead.

[0040] The second arm **14** further includes a housing **40** that retains therein a cutting implement **42** such that the cutting implement **42** is fully enclosed within the second arm **14**. In the example of FIG. **2**, which is not intended to be limiting, the cutting implement **42** is an elongate substantially linear blade that is directed toward the first end **11** of the first arm **12**, and is oriented at an acute angle θ with respect to the longitudinal axis **20** of the tool **10**. As shown in more detail below, as the first arm **12** and the second arm **14** of the tool **10** move into a closed position, the proximal end of the lead is clamped between the opposed mating surfaces **30**, **32**, and the blade of the cutting implement **42** moves into contact with the elastic terminal component on the lead.

[0041] Referring now to FIGS. **2-3**, in some examples the housing **40** of the second arm **14** further includes an optional port **54**. The port **54** includes a hypotube **35** concentric with the port **54** and recessed within a chamber **36**. In the example shown in FIGS. **2-3**, the port **54** has a generally conical shape having a wall **50** with a gradually tapering diameter configured to allow insertion of a proximal end of a medical lead. The hypotube **35** terminates in a precision sharpened recessed annular cutting edge **52** sized to the diameter of a connector pin **152** to create an annular cut into an elastic terminal component such as, for example, a seal **154** on the connector **152** as the connector **152** is inserted and pressed into the port **50**. A wiper edge **53** strips the cut seal **154** when the lead is pulled out of the port **54**, and the annular cutting edge **52** skives off the seal **154** at a diameter slightly larger than the adjacent connector pin **152**, which allows the seal **154** to be easily stripped from the lead **150** and retained inside the housing **40**.

[0042] The first arm **12** and the second arm **14** may be made from a wide variety of materials including, but not limited to, polymeric materials, metals such as stainless steel, titanium, and combinations thereof. In some examples, the first arm **12** and the second arm **14** may be made of a polymeric material, and at least one of the hypotube **35** and the annular cutting edge **52** may be formed from a metal or other material suitable for skiving an elastomeric material such as, for example, a silicone.

[0043] In the example of FIG. **2**, the first arm **12** and the second arm **14** include optional ergonomic features such that the practitioner can obtain a more secure grip on the tool **10** during procedures for removing an elastic terminal component from a medical lead.

[0044] In FIG. **2**, the first arm **12** includes an external surface **60** with a first grip portion **62**. The first grip portion **62** can have a wide variety of shapes, but in the example of FIG. **2** has a generally arcuate shape configured to engage an index finger of a human hand. In some examples, the first grip portion **62** can be made of soft elastomeric polymeric materials, or may include a textured surface to provide a more secure engagement between the grip surface **62** and the fingers of the practitioner.

[0045] The second arm **14** also includes an external surface **64** with a second grip portion **66**. The second grip portion **66** can also have a wide variety of shapes, but in the example of FIG. **2** includes a shape configured to engage a thumb of a human hand. The second grip portion includes a substantially planar region **68**, and an acutely angled shelf **70** extending upward therefrom and away from the longitudinal axis **20** of the tool **20**. In operation, the practitioner may apply force to the shelf **70** to rotate the first arm **12** and the second arm **14** about the hinge **16** from the open position to the closed position. In some examples, the second grip portion **66** can be made of soft elastomeric polymeric materials, or may include a textured surface to provide a more secure engagement between the grip surfaces **66**, **68** and the fingers of the practitioner.

[0046] FIG. **3** is a cross-sectional view of the body **40** of the second arm **14** that shows a detail of the port **54** and the hypotube **35** therein. The hypotube **35** includes an opening **41** that extends into the body **40** in a direction generally normal to the longitudinal axis **20** of the tool **10**. The port opening **41** has a generally conical shape with a wall **50** have a tapering diameter configured to accept a proximal end **153** of a medical lead assembly **150**. The proximal end **153** of the lead assembly **150** includes a connector **152**, and an elastomeric seal **154** separates the connector **152** from a lead body **151**.

[0047] In the example of FIG. **3**, the hypotube **35** in the tool **10** includes an annular cutting edge **52** configured to grip and cut a seal member on a proximal end of a cardiac lead. The annular cutting edge **52** is supported by a flange **39**, which is configured such that the seal **154** inserted into the hypotube **50** is securely urged against the cutting edge **52**, which allows the cutting edge **52** to score the seal **154**. It should be understood that the shape and size of the flange **39** are merely provided as an example, and the configuration of the flange **39** and the cutting edge **52** can be selected to grip and remove any type of elastomeric terminal component from a medical lead assembly **150**.

[0048] The body **40** further includes a recessed, well-like region **36** shaped to accept and house a portion of a proximal end of a medical lead. For example, the region **36** may be configured to house the generally cylindrical lead connector **152** adjacent to the seal **154**. The region **36** may be shaped and sized to provide a guide for secure insertion of a particular configuration of a connector **152** so that the medical lead assembly **150** can be inserted into the port **54** and the seal **154** can be urged against the annular cutting edge **52**.

[0049] Referring now to FIG. **4**, the tool **10** is shown with the first arm **12** and the second arm **14** in an open position. The hinge **16** joins the first end **11** of the first arm **12** to the first end **15** of the second arm **14**. The first arm **12** includes a first mating surface **30** with a first recessed region **31**, and the second arm **14** includes a second mating surface **32** with a second recessed region **33**. The second arm **14** houses a cutting implement **42**, which is an elongate substantially linear blade that is directed toward the first end **11** of the first arm **12**. The connector **152** protrudes from the second end **17** of the second arm **14**. The opposed recessed regions **31**, **33** are shaped to retain the lead **150** such that the cutting edge **43** of the cutting implement **43** contacts all or a portion of the length of the silicone grip sleeve **156**.

[0050] The linear blade is directed toward the first end **15** of the second arm **14** and is oriented at an acute angle θ with respect to the longitudinal axis **20** of the tool **10**. In some examples, the angle θ is selected such that substantially all of a cutting edge **43** of the cutting implement contacts the grip sleeve **156** of the medical lead assembly **150** when the first arm **12** and the second arm **14** are closed about the hinge **16** and the medical lead assembly is retained between the first mating surface **30** and the second mating surface **32**. The cutting edge **43** is then urged into contact all or a portion of the full length of the grip sleeve **156**, and forms a substantially continuous slit in all or a portion of the full length of the grip sleeve. The slit extends along a direction parallel to the longitudinal axis **20** of the tool **10** and the lead assembly **150**. In some examples, which are not intended to be limiting, and can depend on the shape and size of the grip sleeve **156**, the angle θ is about 10° to about 50°, or about 30°. In some examples, the biasing member (not shown in FIG. **4**) between the first arm **12** and the second arm **14**, or the body **40** of the second arm **14**, may optionally include an adjustment mechanism such as a screw, to allow the cutting edge **43** to penetrate a predetermined distance into the grip sleeve **156**.

[0051] With further reference to FIG. **5**, as the first arm **12** and the second arm **14** rotate about the hinge **16** from the open position shown in FIG. **4** to a closed position, the cutting edge **43** is urged into contact with the grip sleeve **156**, and scores the grip sleeve **156**. With the first arm **12** and the second arm **14** of the tool **10** in the closed position, and the cutting edge **43** remaining in intimate contact with the grip sleeve **156**, if the lead body **151** of the lead **150** is pulled in a direction A and the tool **10** remains substantially stationary, the cutting edge **43** forms a longitudinal slit in the grip sleeve **156**. Or, if the tool **10** is pulled in a direction B and the lead **150** remains substantially stationary, the cutting edge **43** forms a longitudinal slit in the grip sleeve **156**. In other words, as the lead **150** and the tool **10** are translated with respect to each other, the cutting edge **43** forms a substantially continuous slit along a direction parallel to the longitudinal axis **20** of the tool **10**.

[0052] Referring again to FIGS. **4-5**, when the first arm **12** and the second arm **14** are in either an open or a closed position, the proximal seal **154** on the lead may be inserted into the port **54**. As the annular cutting edge **52** of the hypotube **35** is urged into contact with the seal **154**, the annular cutting edge **52** scores the seal **154**, forming a cut that extends in a direction substantially normal to the longitudinal axis **20** of the tool **10** and the lead assembly **150**. When the lead **150** assembly is pulled away from the port **54** with the seal **154** contacting the annular cutting edge **52**, the scored seal **154** is stripped away from the connector **152**. The seal **154** peels cleanly away from the lead assembly **150**, and is retained within the body **40** of the second arm **12** to prevent contamination of the surgical field.

[0053] Referring now to FIG. **6**, in another aspect, the present disclosure is directed to a method **200** for removing an elastic terminal component such as, for example, a grip sleeve **156**, from a proximal end **151** of a medical lead using the tool **10** described above in FIGS. **2-5**.

[0054] The method **200** includes retaining the proximal end **151** of a lead between a first arm **12** and a second arm **14** of a tool **10** wherein at least one of the first arm and the second arm of the tool includes an elongate linear cutting blade **43** (**202**).

[0055] The method **200** further includes moving the first arm **12** and the second arm **14** into a closed position to engage the linear cutting blade **43** with the grip sleeve **156** on the lead (**204**).

[0056] The method **200** also includes translating the implanted lead with respect to the tool such that the linear cutting blade **43** forms a slit in the grip sleeve **156**, wherein the slit extends along a longitudinal axis of the lead (**206**).

[0057] As shown in FIG. **7**, in another aspect the present disclosure is directed to a method **300** for removing an elastic terminal component such as, for example, a seal, from a proximal end of a lead using the tool **10** described above in FIGS. **2-5**.

[0058] The method **300** includes inserting the seal **154** into the port **54** in the body **40** of the second arm **14** such that the seal **154** is urged against the annular cutting edge **52** of the hypotube **35** (**302**).

[0059] The method **300** further includes pulling the endocardial lead from the port **54** with the annular cutting edge **52** contacting the seal **154** such that the cutting edge **52** scores the seal along a direction normal to a longitudinal axis of the lead (**304**).

[0060] The method **300** also includes stripping the seal **154** from the connector on the proximal end of the lead (**306**).

[0061] Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims.

[0062] The following examples are a non-limiting list of clauses in accordance with one or more techniques of this disclosure.

[0063] Example 1. An apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead, the apparatus comprising: a first arm and a second arm, wherein the first arm and the second arm each comprise a first end and a second end, and wherein the first arm and the second arm are connected to each other and move in opposition to each other between an open position and a closed position; wherein the first arm and the second arm comprise opposed first mating portions and second mating portions configured to retain the proximal end of the lead when the first end of the first arm and the first end of the second arm are in the closed position; and an elongate cutting implement enclosed within the second arm, wherein the cutting implement comprises a cutting blade oriented at an angle such that, when the first end of the first arm and the first end of the second arm are moved from the open position to the closed position, the cutting blade is configured to form a slit in at least a portion of the elastic terminal component, and

wherein the slit extends along a longitudinal axis of the lead.
[0064] Example 2. The apparatus of example 1, wherein the second end of the first arm is connected to the second end of the second arm to form a hinge, and wherein the first arm and the second arm move about the hinge such that the first arm and the second arm pivot in opposition to each other to move the first end of the first arm and the first end of the second arm between an open position and a closed position.
[0065] Example 3. The apparatus of any one of example 1 or 2, wherein the medical lead is a cardiac lead.
[0066] Example 4. The apparatus of any one of examples 1 to 3, wherein the body of the second arm further comprises a port, wherein the port comprises a hypotube with an annular cutting edge configured to form a cut in at least a portion of the elastomeric terminal component, and wherein the cut formed by the annular cutting edge extends in a direction normal to the longitudinal axis of the lead.
[0067] Example 5. The apparatus of any one of examples 1 to 4, further comprising a biasing member between the first arm and the second arm.
[0068] Example 6. The apparatus of any one of examples 1 to 5, wherein the first mating portion and the second mating portion comprise opposed first recessed portions and second recessed portions, wherein the first recessed portion and the second recessed portion are shaped to retain the proximal end of the lead when the first end of the first arm and the first end of the second arm are in the closed position.
[0069] Example 7. The apparatus of any one of examples 1 to 6, wherein an opening to the hypotube has a substantially conical shape.
[0070] Example 8. The apparatus of any one of examples 1 to 7, wherein the first arm comprises a first external surface comprising a first grip portion configured to engage an index finger of a human hand.
[0071] Example 9. The apparatus of example 8, wherein the first grip portion has a substantially arcuate shape.
[0072] Example 10. The apparatus of any one of examples 8 or 9, wherein the first grip portion comprises a polymeric material.
[0073] Example 11. The apparatus of any one of examples 8 to 10, wherein the first grip portion has a surface texture.
[0074] Example 12. The apparatus of any one of examples 1 to 11, wherein the second arm comprises a second external surface comprising a second grip portion configured to engage a thumb of a human hand.
[0075] Example 13. The apparatus of example 12, wherein the second grip portion comprises a wall with a first portion and a second portion, and wherein the second portion of the wall is angled is configured to engage the thumb.
[0076] Example 14. The apparatus of any one of examples 12 or 13, wherein the first portion and the second portion of the wall are each substantially planar.
[0077] Example 15. The apparatus of any one of examples 12 to 14, wherein at least a part of the second grip portion comprises a polymeric material.
[0078] Example 16. The apparatus of any one of examples 12 to 15, wherein at least a part of the second grip portion has a surface texture.
[0079] Example 17. The apparatus of example 5, wherein the biasing member is chosen from a spring, an elastomeric member, or a combination thereof.
[0080] Example 18. The apparatus of any one of examples 1 to 17, wherein the first arm and the second arm comprise a material chosen from metals, polymers, and combinations thereof.
[0081] Example 19. A handheld tool comprising opposed first and second arms movable about a hinge from an open position to a closed position, wherein the second arm comprises an elongate cutting blade within a body thereof, the cutting blade being configured to cut a first elastomeric

terminal component on the proximal end of a medical lead and form a slit in the elastic terminal component when the first arm and the second arm are in the closed position, wherein the slit extends along a longitudinal axis of the lead, and wherein the body of the second arm further comprises a hypotube with an annular cutting edge configured to form a cut on a second elastomeric terminal component on the proximal end of the lead, wherein the cut formed by the annular cutting edge extends along a direction generally normal to the longitudinal axis of the lead.

[0082] Example 20. The tool of example 19, further comprising a biasing member between the first arm and the second arm, wherein the biasing member is configured to maintain the tool in the open position.

[0083] Example 21. The tool of any one of examples 19 to 20, wherein the hypotube has a substantially conical shape.

[0084] Example 22. The tool of any one of examples 19 to 21, wherein the mating surfaces of the first arm and the second arm each comprise a recessed portion shaped to retain the lead.

[0085] Example 23. The tool of any one of examples 19 to 22, wherein the first arm comprises a first grip feature configured to engage an index finger of a human hand, and wherein the second arm comprises a second grip feature configured to engage a thumb of a human hand.

[0086] Example 24. The tool of example 23, wherein the first grip feature on the first arm has an arcuate shape.

[0087] Example 25. The tool of any one of example 23 to 24, wherein the second grip feature on the second arm comprises at least one ledge, and wherein the ledge comprises a substantially planar gripping surface.

[0088] Example 26. A method for removing a grip sleeve from a proximal end of a medical lead, the method comprising: retaining the proximal end of the lead between a first arm and a second arm of a tool, wherein the first arm and the second arm are moveable from an open position to a closed position, and wherein at least one of the first arm and the second arm of the tool comprises an elongate linear cutting blade; moving the first arm and the second arm into a closed position to engage the linear cutting blade with the grip sleeve on the lead; and translating the implanted lead with respect to the tool such that the linear cutting blade forms a slit in the grip sleeve, the slit extending along a longitudinal axis of the lead.

[0089] Example 27. The method of example 26, wherein the first arm of the tool comprises a grip surface configured to engage an index finger of a human hand, and the second arm of the tool comprises a grip surface configured to engage a thumb of a human hand, wherein the first grip surface and the second grip surface are opposed to each other, and wherein the retaining comprises applying pressure on the opposed first and the second grip surfaces to urge the tool from an open position to a closed position.

[0090] Example 28. The method of any one of examples 26 to 27, wherein the first grip surface has an arcuate shape, and the second grip surface comprises an angled ledge.

[0091] Example 29. A method for removing a seal from a proximal end of a medical lead, the method comprising: inserting the seal into a hypotube in a tool, wherein the hypotube comprises an annular cutting edge; urging the seal against the annular cutting edge such that the seal forms a cut in the seal along a direction normal to a longitudinal axis of the lead; and translating the implanted lead with respect to the tool to strip the seal from the lead.

[0092] Example 30. The method of example 29, wherein the seal, when stripped from the medical lead, remains in a body of the tool.

[0093] Example 31. The method of any one of examples 29 to 30, wherein a first arm of the tool comprises a grip surface configured to engage an index finger of a human hand, and a second arm of the tool comprises a grip surface configured to engage a thumb of a human hand, wherein the first grip surface and the second grip surface are opposed to each other, and wherein the method further comprises applying pressure on the opposed first and the second grip surfaces to urge the tool from an open position to a closed position.

[0094] Example 32. The method of any one of examples 29 to 31, wherein the first grip surface has an arcuate shape, and the second grip surface comprises an angled ledge.
[0095] Example 33. An apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead, the apparatus comprising a first arm and a second arm connected to each other and configured to move in opposition to each other between an open position and a closed position, wherein the first and the second arms comprise opposed mating surfaces configured to retain the proximal end of the lead when the apparatus is in the closed position, and wherein an elongate cutting implement enclosed within the second arm comprises a cutting blade oriented at an angle such that, when the apparatus is in the closed position, the cutting blade forms a slit in at least a portion of the elastic terminal component.

Claims

1. An apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead, the apparatus comprising: a first arm and a second arm, wherein the first arm and the second arm each comprise a first end and a second end, and wherein the first arm and the second arm are connected to each other and move in opposition to each other between an open position and a closed position; wherein the first arm and the second arm comprise opposed first mating portions and second mating portions configured to retain the proximal end of the lead when the first end of the first arm and the first end of the second arm are in the closed position; and an elongate cutting implement enclosed within the second arm, wherein the cutting implement comprises a cutting blade oriented at an angle such that, when the first end of the first arm and the first end of the second arm are moved from the open position to the closed position, the cutting blade is configured to form a slit in at least a portion of the elastic terminal component, and wherein the slit extends along a longitudinal axis of the lead.
2. The apparatus of claim 1, wherein the second end of the first arm is connected to the second end of the second arm to form a hinge, and wherein the first arm and the second arm move about the hinge such that the first arm and the second arm pivot in opposition to each other to move the first end of the first arm and the first end of the second arm between an open position and a closed position.
3. The apparatus of claim 1, wherein the body of the second arm further comprises a port, wherein the port comprises a hypotube with an annular cutting edge configured to form a cut in at least a portion of the elastomeric terminal component, and wherein the cut formed by the annular cutting edge extends in a direction normal to the longitudinal axis of the lead.
4. The apparatus of claim 1, further comprising a biasing member between the first arm and the second arm.
5. The apparatus of claim 4, wherein the biasing member comprises one of a spring, an elastomeric member, or a combination thereof.
6. The apparatus of claim 1, wherein the first mating portion and the second mating portion comprise opposed first recessed portions and second recessed portions, wherein the first recessed portion and the second recessed portion are shaped to retain the proximal end of the lead when the first end of the first arm and the first end of the second arm are in the closed position.
7. The apparatus of claim 3, wherein an opening to the hypotube has a substantially conical shape.
8. The apparatus of claim 1, wherein the first arm comprises a first external surface comprising a first grip portion configured to engage an index finger of a human hand.
9. The apparatus of claim 8, wherein the first grip portion has a substantially arcuate shape.
10. The apparatus of claim 8, wherein the second arm comprises a second external surface comprising a second grip portion configured to engage a thumb of a human hand.
11. The apparatus of claim 10, wherein the second grip portion comprises a wall with a first portion and a second portion, and wherein the second portion of the wall is angled is configured to engage

the thumb.

12. The apparatus of claim 11, wherein the first portion and the second portion of the wall are each substantially planar.

13. The apparatus of claim 10, wherein at least one of the first grip portion or the second grip portion or both has a surface texture.

14. A handheld tool comprising opposed first and second arms movable about a hinge from an open position to a closed position, wherein the second arm comprises an elongate cutting blade within a body thereof, the cutting blade being configured to cut a first elastomeric terminal component on the proximal end of a medical lead and form a slit in the elastic terminal component when the first arm and the second arm are in the closed position, wherein the slit extends along a longitudinal axis of the lead, and wherein the body of the second arm further comprises a hypotube with an annular cutting edge configured to form a cut on a second elastomeric terminal component on the proximal end of the lead, wherein the cut formed by the annular cutting edge extends along a direction generally normal to the longitudinal axis of the lead.

15. An apparatus for removing at least one elastomeric terminal component on a proximal end of a medical lead, the apparatus comprising a first arm and a second arm connected to each other and configured to move in opposition to each other between an open position and a closed position, wherein the first and the second arms comprise opposed mating surfaces configured to retain the proximal end of the lead when the apparatus is in the closed position, and wherein an elongate cutting implement enclosed within the second arm comprises a cutting blade oriented at an angle such that, when the apparatus is in the closed position, the cutting blade forms a slit in at least a portion of the elastic terminal component.

16. The tool of claim 14, further comprising a biasing member between the first arm and the second arm, wherein the biasing member is configured to maintain the tool in the open position.

17. The tool of claim 14, wherein the mating surfaces of the first arm and the second arm each comprise a recessed portion shaped to retain the lead.

18. The tool of claim 14, wherein the first arm comprises a first grip feature configured to engage an index finger of a human hand, and wherein the second arm comprises a second grip feature configured to engage a thumb of a human hand.

19. The tool of claim **19**, wherein the first grip feature on the first arm has an arcuate shape.

20. The tool of claim 19, wherein the second grip feature on the second arm comprises at least one ledge, and wherein the ledge comprises a substantially planar gripping surface.
