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(71) Applicant: **UNIVERSITY OF FLORIADA RESEARCH FOUNDATION, INC.** [US/US]; 223 Grinter Hall, Gainesville, FL 32611 (US).

(72) Inventor: **CATANZARO, John, N.**; C/o University of Florida Research Foundation, Inc., 223 Grinter Hall, Gainesville, FL 32611 (US).

(74) Agent: **BIANCO, Paul, D.**; Fleit Gibbons Gutman Bongini & Bianco PL, 21355 East Dixie Highway, Suite 115, Miami, FL 33180 (US).

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(54) **Title**: REMOVING ELECTRICAL LEADS ATTACHED TO THE BODY BY NATURAL TISSUE GROWTH

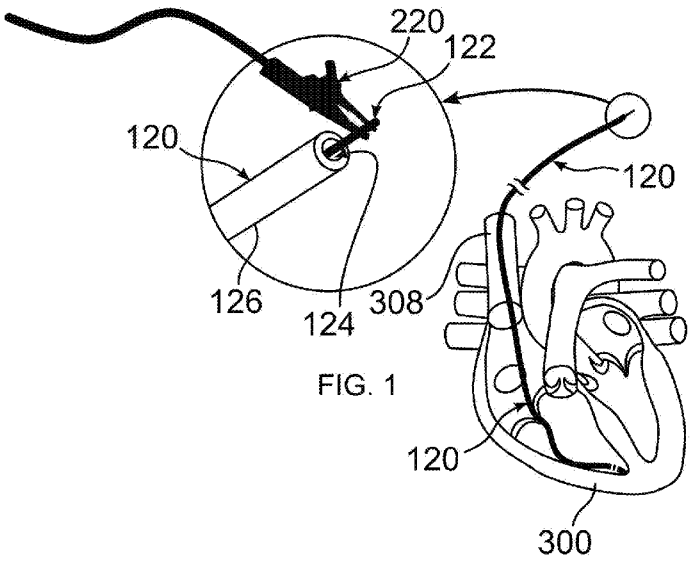

FIG. 1

(57) **Abstract**: Therapeutic cardiac leads can become attached to body tissue by tissue growth, causing them to be difficult to remove without injury to the patient or breaking of the lead, which can result in portions of the lead remaining within the patient. A mesh sheath is inserted into a lumen of the lead. The mesh is contractable or expandable to either compress to grip an outer surface of a wire of the lead, or to expand to contact a peripheral inner surface of the lumen. In this way, the sheath engages the lead and provides stability to keep the lead intact during removal. A source of electrical energy can be applied to the sheath to loosen the tissue attachment, further facilitating removal of the lead without harm.

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REMOVING ELECTRICAL LEADS ATTACHED TO THE BODY BY NATURAL TISSUE GROWTH

FIELD OF THE DISCLOSURE

The disclosure relates to a system and method for extracting cardiac electrical leads, and in particular, applying electrical wave energy to loosen natural tissue growth to facilitate removal of leads.

BACKGROUND OF THE DISCLOSURE

A permanent pacemaker (PPM) is an electronic device that provides an electrical signal to cause the heart to beat regularly when the internal signal of the heart is not functioning properly. The PPM includes a power source, an electronic programmable pacemaking circuit, and one or more pacing leads which make contact with an internal or external surface of the heart.

For a typical unipolar pacing wire, a conductor at a tip of the wire forms the negative pole, and a coil in the wire casing forms the positive pole. In a typical bipolar pacing wire, an inner coil forms the positive pole or cathode which extends beyond the casing to contact body tissue, and the negative pole is another coil surrounding the cathode and stopping near the end of the wire, but at a distance, for example 12 mm from the end of the cathode.

An implantable cardioverter-defibrillator (ICD) is similar to a PPM, but it can also perform cardioversion and defibrillation, and is therefore able to correct life-threatening cardiac arrhythmias. As with PPMs, ICDs can be implanted subcutaneously.

A lead is typically placed at the apex or septum of the right ventricle, and another lead can be also be placed in the right atrium. The atrium lead typically forms a J-shape, so that electrical contact is made near an upper surface of the atrium. In some cases, a third lead is placed on the outer wall of the left ventricle. Sensors are additionally provided on the leads for sensing electrical signals from the heart, which are used to determine timing or to generate other events.

PPM and ICD leads may become non-functional and need to be replaced. Problems can include inefficiency at delivering a required energy to the heart; too weak of a signal coming back from the heart, lead fracture, insulation failure, or infection. A lead must be removed when it becomes infected or is not working well enough.

SUMMARY OF THE DISCLOSURE

In an embodiment of the disclosure, a device for extracting a lead attached to body tissue by tissue growth comprises a sheath insertable into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface of the lumen, to engage the lead; and a connector for connecting a source of electrosurgical energy to the sheath.

In variations thereof, the electrosurgical energy is radiofrequency energy; the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz; the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz; the sheath is electrically conductivethe device further includes a tip connected to a distal end of the sheath, the tip electrically connected to the connector, the tip operative to produce heat when the electrosurgical energy is applied to the connector; the device further includes a tip connected to a distal end of the sheath, the tip electrically connected to the connector, the tip operative to radiate electrosurgical energy when electrosurgical energy is applied to the connector; and/or the sheath is configured to radiate electrosurgical energy along its length when electrosurgical energy is applied to the connector.

In another embodiment of the disclosure, a method of extracting a lead attached to body tissue by tissue growth comprises inserting a sheath into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface of the lumen, to engage the lead; connecting a source of electrosurgical energy to the sheath; applying electrosurgical energy to the sheath through the connection to weaken the attachment between the tissue growth and the lead; and extracting the lead after weakening the connection.

In variations thereof, the electrosurgical energy is radiofrequency energy the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz; the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz; and/or the attachment is weakened by at least one of heat and ablation.

In another embodiment of the disclosure, a method for extracting a lead attached to body tissue by tissue growth comprises inserting a sheath into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface

of the lumen, to engage the lead; connecting a source of electrosurgical energy to a wire within the lead; applying electrosurgical energy to the wire through the connection to weaken the attachment between the tissue growth and the lead; and extracting the lead after weakening the connection by applying traction to the sheath engaged with the lead.

In variations thereof, the electrosurgical energy is radiofrequency energy; the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz; the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz; the attachment is weakened by at least one of heat and ablation; the sheath is electrically conductive; and/or a tip is attached to a distal end of the sheath, the tip electrically connected to source of electrosurgical energy, the tip operative to produce heat when the electrosurgical energy is applied to the connector.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present disclosure, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 depicts a PPM or ICD lead within the heart, and a method for attaching a source of electrosurgical energy to a wire of the lead while the lead is inside the heart, in accordance with the disclosure;

FIG. 2 depicts a lead locking stylet connected to a source of electrosurgical energy;

FIG. 3 depicts a heat generating region of a sheath of the stylet of FIG. 2;

FIG. 4A depicts a stylet of the disclosure inserted within a blood vessel, surrounding a central wire, the stylet not fully engaged with the lead;

FIG. 4B depicts the stylet of FIG. 4A, expanded to be engaged with the lead and a coil of the lead, and with electrosurgical energy applied to the sheath of the stylus to generate heat in the coil;

FIG. 5 depicts a unipolar stylet sheath and tip of the disclosure;

FIG. 6 depicts a bipolar stylet sheath and tip of the disclosure;

FIG. 7 depicts a cross-section of a stylet of the disclosure inserted into a lead lumen, and a source of electrosurgical energy applied to a wire of the lead to cause electrosurgical energy to produce heat in a tip of the lead in accordance with the disclosure;

FIG. 8 depicts electrosurgical energy applied to an inner coil and exposed distal helix in a cross-section of a lead, and a stylet lumen inserted within a lumen of the lead, in accordance with the disclosure;

FIG. 9 depicts leads attached by tissue growth to the body within the heart and vasculature;

FIG. 10A depicts two leads attached by tissue growth to myocardium of the right ventricle;

FIG. 10B depicts separation of the two leads by application of electrosurgical energy in accordance with the disclosure;

FIGS. 11A-11D depict PRIOR ART leads; and

FIGS. 12A-12C depict expansion and contraction of a sheath of the disclosure.

DETAILED DESCRIPTION OF THE DISCLOSURE

As required, detailed embodiments are disclosed herein; however, it is to be understood that the disclosed embodiments are merely examples and that the systems and methods described below can be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present subject matter in virtually any appropriately detailed structure and function. Further, the terms and phrases used herein are not intended to be limiting, but rather, to provide an understandable description of the concepts.

The terms “a” or “an”, as used herein, are defined as one or more than one. The term plurality, as used herein, is defined as two or more than two. The term another, as used herein, is defined as at least a second or more. The terms “including” and “having,” as used herein, are defined as comprising (i.e., open language). The term “coupled,” as used herein, is defined as “connected”, although not necessarily directly, and not necessarily mechanically.

Lead removal is often complicated by the development of a fibrous material around the leads over time. The longer the indwelling lead has been implanted, the more difficult the process of extraction tends to be. In-depth analyses of extracted leads have shown that fibrous adhesions do not occur uniformly over the length of the lead. In fact, there appears to be a greater predilection for fibrous tissue development at the defibrillator coils and the tip of the implanted lead, and also at the vasculature. Defibrillator coil-associated adhesions have often required the application of more advanced methodologies beyond simple traction such as dilating sheaths, snares, and excimer laser sheaths. But when only the tip of the lead remains fibrosed to the myocardial wall, safe removal is difficult or impossible. The current standard of care for this scenario is the application of increasing degrees of manual traction. This can

either result in hemodynamically significant right ventricular eversion or potentially fatal vascular or myocardial avulsions.

Lead extraction can be performed using either the subclavian vein, or if access is difficult through that route, then a femoral vein can be used. First, an incision is made where the pacemaker or ICD device has been implanted. The device can be removed, or alternatively the battery can be removed if the device is to remain. Leads are then disconnected, and any visible scar tissue or adhesions are removed, with particular attention to adhesions associated with the subclavian vein near the implantation site of the device.

A hollow tube or sheath, typically of plastic, is inserted over the lead, passed into the vein, and is guided along the lead to the lead tip which is attached to the myocardium by scar tissue or fibrous growth. A laser or cutting sheath can be used to separate the lead from attachment to the vasculature or heart other than at the tip, along these techniques bring additional risk to the patient. The sheath can contact body tissue at the tip, to hold the heart muscle in place while traction is applied to the lead. In accordance with the disclosure, the amount of traction is reduced due to the application of EE to the lead tip, to ablate or weaken with heat the tissue attaching the lead tip to the body.

In accordance with the disclosure, radio frequency energy is directed to locations contacted by the lead, in order to disintegrate tissue or otherwise loosen the attachment between the lead and body tissue or vegetations, scar tissue, or fibrous material which is adhered to the lead. The disclosure is applicable to PPM or ICD leads, and leads for any other electrical device used anywhere within the body, where the leads are in contact with body tissue for a period of time sufficient to form natural growths which attach the leads to the body.

With reference to FIG. 1, in accordance with the disclosure, a device and method are provided for lead extraction from the heart 300 and vasculature 308, particularly where lead explant would appear to require excess or potentially injurious force. Once it is determined that explant is not to be pursued, the lead 120 is prepared to have electrosurgical energy (EE) applied to it, in order to heat body tissue in contact with it. In one embodiment, a mating connector end (not shown) is connected to the lead end, and a generator 200 of EE, for example radio frequency (RF) energy, is connected to the mating connector. An example generator is the COVIDIEN FORCE FX, although numerous other types can be used, which are generally designed for cutting or coagulating body tissue using electrical energy, as is well understood within the art.

RF energy in the range of 100 kHz and 1 MHz, and advantageously between 350–500 kHz can be effectively used, but any frequency range which can cause ablation or sufficient heating of body tissue, and particularly scar tissue or fibrous material, can be used. Power levels are selected to be just sufficient to cause weakening of the fibrous connection to the lead, to avoid damage to adjacent tissues. Sensors can be used to monitor heat at the localized region of application of EE energy in accordance with the disclosure, whereby power levels can be reduced if heating becomes excessive. While lower frequency AC or pulses of DC can be used as EE, these have been found to have the disadvantage of stimulating nerves which can cause pain, while RF frequencies have been found to largely avoid this problem. Additionally, RF can be controlled to have a local effect, penetrating body tissue to a limited depth, thereby reducing damage to nearby tissue.

Alternatively, where the lead will no longer be used, it may be more expedient to simply strip the cut lead end, particularly as a mating connector end may not be readily available. Accordingly, the lead is disconnected from the PPM or ICD (not shown), and any connectors are removed. The lead end is then stripped of insulation, exposing a sufficient amount of the central wire 122, typically a cathode, to enable an electrical connection to be made to wire 122. In the embodiment shown, an alligator clip 220 is used, although any other suitable form of electrical connection can be made.

If an outer coil 130 exists, that can be stripped back as well, although in an embodiment, EE can be applied to the coil in addition to, or alternatively to, central wire 122. More particularly, adhesions can be connected to the coil, and while an Excimer laser may be able to remove such adhesions, not all facilities are equipped with such a device. Moreover, if the device of the disclosure is to be used, it can address vascular adhesions and other adhesions along the wire as well as adhesions on the distal tip of lead 120 at the myocardium, thereby requiring less equipment in the operating theatre, and reducing costs.

A grounding electrode is placed on the patient, and is connected to generator 200. As EE is applied to wire 122, heating occurs at the wire tip, for example at an embedded wire helix, where a conductive path has been formed to the grounding electrode through the adhesion. This weakens the connection of the adhesion to the wire, enabling a reduced force to be applied to the wire in order to extract the lead. Additional details can be found in <www.researchgate.net/publication/262879922> which is incorporated by reference herein.

It can be a difficult or impossible, however, to introduce EE to the distal end of the wire and to the fibrosis, where wire 122 cannot conduct sufficient EE along its entire length, or where wire 122 is broken. Accordingly, further in accordance with the disclosure, and with

reference to FIG. 2, a locking stylet 170 is inserted into a lumen 124 of the wire, for example interior to conduction coil 130, or within an outer sheath 126 of lead 120. More particularly, an expandable braided stylet sheath 172 is inserted within lead 120 to extend as close as possible to a distal end of lead 120. Sheath 172 is formed of electrically conductive metal, for example NITINOL or other shape memory metal, stainless steel, or other conductive metal or material, and accordingly, EE can be applied to sheath 172 to cause the release of EE near to the distal end of lead 120, where it may act upon the fibrosis to weaken the connection between lead 120 and body tissue.

In an embodiment, sheath 172 is passed within an outer sheath 126 or other lumen 124 of lead 120, over wire 122, as shown in FIG. 12A. Sheath 172 can be contracted, for example by being stretched, to thereby compress and grip wire 122 within the lumen. In this manner, sheath 126 provides stability to wire 122 to prevent the wire 122 from breaking during extraction, particularly during extraction using tension. Alternatively, sheath 172 can be expanded to grip an inner wall of sheath 126, whereby sheath 172 can be pulled to remove lead 120 while simultaneously providing stability to lead 120.

For either expansion or contraction, sheath 126 can include a tensioning rod 184 which passes from a distal end of the sheath to the proximal end. Pulling on sheath 172 (arrow "A" of FIG. 12B) causes contraction of sheath 172, while pushing on sheath 126 (arrow "B" of FIG. 12C) relative to the tensioning wire produces expansion of sheath 172. Alternatively, pushing or maintaining an orientation of the tensioning rod 184 while. The use of tensioning rod 184 can avoid stressing parts of the lead 120 during expansion or contraction, thereby avoiding break lead 120, which could lead to complications. It should be understood that tensioning rod 184 can have the form of a sleeve or coil, for example, or other elongate structure which has a limited deformability in the axial direction relative to sheath 172.

As shown in FIG. 2, sheath 172 may not extend outside the body when style 170 is deployed, and accordingly, one or two wires can be routed through stylet 170 to electrically connect to sheath 172. FIG. 2 illustrates, by a dashed line, an electrical connection to a grounding electrode 174, which is used for a unipolar configuration of the disclosure. In this event, a single wire is routed through stylet 170 to connect to sheath 172. A bipolar configuration of the disclosure is described in greater detail elsewhere herein.

There are a variety of types of stylets 170, and the illustrations are representative. For example, the illustrations generally correspond to a COOK MEDICAL LIBERATOR, or a SPECTRANETICS LLD (Lead Locking Device) type stylet, which expand within a lumen 124 of lead 120, passing over or alongside an innermost wire. Alternatively, a COOK

MEDICAL BULLDOG type device can be used, in which a loop and mesh is passed over the outside of lead 120, and which compresses against the outside of lead 120, for instances in which lead 120 is damaged or does not include an inner lumen of sufficient width. The Bulldog device would tend to produce heat along its length as it makes contact with body tissue; however, portions can be insulated from contact with the body, thereby releasing EE at the uninsulated regions.

FIG. 3 illustrates an enlarged view of a stylet mesh sheath 172, illustrating a zone of heating occurring most proximate contact with body tissue at a distal end 176. FIGS. 3 and 4 illustrate the functioning of the stylet sheath 172 which has been passed over the inner wire in FIG. 4A, and which has been expanded against an inner coil 130 in FIG. 4B. If inner coil 130 is not insulated and contacts an inner wall 306 of the vasculature 308, as illustrated in FIGS. 4A-B, heating will occur along the length of the inner coil 130, as illustrated, including the area of fibrotic adhesion 310.

FIGS. 5-8 illustrate various possible forms of lead extractors 170 of the disclosure which can be used to apply EE to loosen or release a wire 120 which has been attached to the body by overgrowth. In FIG. 5, in a unipolar configuration, a single insulated EE conducting lead 178 is passed through the interior of sheath 172, to an insulating connector 180. Lead 178 can pass through connector 182, or can be connected to a conductor passing through insulating connector 182. At an opposite side of connector 180 is attached a heater tip 182, which is heated by forming a connection between the EE signal delivered by lead 178 and a ground applied to an exterior of the body. In an embodiment, a ground is applied within the body, for example by piercing the body to place a conductive electrode tip close to or at an area of adhesion.

In FIG. 6, a bipolar configuration of stylet 170 includes two wires 178 and 186, wherein each pass a signal through insulating connector 180, and is connected to tip 182 to cause local heating or release of EE energy, only near the tip of lead 120. Tip 182 can be configured as a heater or a transmitter of EE.

In FIG. 7, a stylet 170 of the disclosure is inserted within a lumen 124 of wire 120, and EE is applied to wire 122, which is connected to tip 182′. A ground path can be formed through an electrode placed on the patient. In an alternative embodiment, coil 130 is connected to tip 182′ during manufacturing to form a lead of the disclosure, and is insulated from wire 122, whereby a ground signal can be applied to coil 130 to cause heating or transmission of EE at tip 182′ by forming a path within tip 182′ to wire 122. In accordance with the disclosure, a separate electrical pathway is manufactured together with the lead of

any configuration, to conduct EE as described herein, thereby forming a lead of the disclosure that is readily adapted for the application of EE to aid in releasing adhered leads.

In FIG. 8, stylet sheath 172 surrounds an inner coil 128, and secures against in inner wall of lumen 124. Traction can be applied to sheath 172 as EE energy is transmitted through inner coil 128, which forms a helix at a distal end that is implanted into body tissue. A ground signal applied to the body causes application of EE at the region of implantation to loosen an attachment between body tissue and helix 132.

FIG. 9 illustrates a typical application of a stylet or lead of the disclosure, wherein the superior vena cava 314 includes fibrous material 312 attaching two leads 120 to an inner wall of the venous lumen. Fibrous material 316 adheres an end of a J-shape 320 formed in wire 120A, which forms a contact near an A-V node of the right atrium 318. In the right ventricle 330, a fibrosis attaches a distal end of lead 120 near Purkinje fibers. While not illustrated, there can be additional leads, particularly for an ICD, and there can be leads within the left side of the heart, as well. There may also be leads that were previously abandoned in the heart or vasculature, and which may be interfering with an atrioventricular valve, or causing an infection. The disclosure can be used with abandoned leads, additional leads, and leads in the left side of the heart in the same manner as shown and described for leads 120. For J-shaped lead 320, the disclosure can be particularly advantageous, as Excimer or cutting sheaths may not be able to safely negotiate the tortuous path formed by the lead 120A, whereas the disclosure can apply EE to the end of any shaped lead, reducing or eliminating the required traction for extraction. FIGS. 10 and 10A illustrate a fibrosis that has formed in the ventricle at two locations 324, 326. In FIG. 10A, EE has been applied to separate the wire from the fibrous material, whereby the lead may be extracted.

FIGS. 11A-11D depict various prior art forms of ICD or PPM leads each having one or more lumens 114 into which a stylet sheath 172 can be inserted. As can be seen in FIG. 11A, sheath 172 can be passed into an interior space formed by a tip electrode coil 132. As described with respect to FIGS. 5-8, either inner pacing coil/helix 132 or inserted sheath 172 can conduct EE. In FIG. 11A, outer coil 130, which may be a shocking coil, can conduct EE and can form an EE radiator, to cause heating along the length of lead 110. Alternatively, only sheath 172, which is inserted through central lumen 114, delivers EE, either by radiation along its length, or by release proximate a distal end thereof. In FIG. 11B, the tip electrode coil 132 and shocking electrode coil 130 are wound adjacent to each other around central lumen 114. As before, EE can be applied to either or both of coil 130, 132. FIG. 11C illustrates a lead design having sensing and pacing conductors 140, 110, and a non-

concentrically disposed high voltage defibrillation coil 142, which forms a lumen 114 into which sheath 172 can be inserted. Either or both of coil 142 or sheath 172 can apply EE as described herein. FIG. 11D depicts a lead 110 design in which several lumens 114 are available for sheath 172 insertion, and several conducts are available for introduction of EE. Herein, a conductor can be selected based upon the conductor having an electrically exposed are which is proximate a fibrous connection, to thereby direct EE to adhesions or connections to body tissue which prevent extraction of lead 110.

In an embodiment, a fluid having a predetermined conductivity can be directed to a location where EE is applied to control impedance to either increase or decrease conductivity at the site, or to cool adjacent tissue which it is desired to protect. One or more sensors can be used to monitor heat at the location where EE is directed, to determine if the total heat generated is within a predetermined range of efficacy regarding releasing lead 120, and safety for surrounding tissue.

All references cited herein are expressly incorporated by reference in their entirety. It will be appreciated by persons skilled in the art that the present disclosure is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. There are many different features to the present disclosure and it is contemplated that these features may be used together or separately. Thus, the disclosure should not be limited to any particular combination of features or to a particular application of the disclosure. Further, it should be understood that variations and modifications within the spirit and scope of the disclosure might occur to those skilled in the art to which the disclosure pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present disclosure are to be included as further embodiments of the present disclosure.

THE CLAIMS

What is claimed is:

1. A device for extracting a lead attached to body tissue by tissue growth, comprising:

a sheath insertable into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface of the lumen, to engage the lead; and

a connector for connecting a source of electrosurgical energy to the sheath.

2. The device of claim 1, wherein the electrosurgical energy is radiofrequency energy.

3. The device of claim 1, wherein the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz.

4. The device of claim 1, wherein the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz.

5. The device of claim 1, wherein the sheath is electrically conductive.

6. The device of claim 1, further including a tip connected to a distal end of the sheath, the tip electrically connected to the connector, the tip operative to produce heat when the electrosurgical energy is applied to the connector.

7. The device of claim 1, further including a tip connected to a distal end of the sheath, the tip electrically connected to the connector, the tip operative to radiate electrosurgical energy when electrosurgical energy is applied to the connector.

8. The device of claim 1, wherein the sheath is configured to radiate electrosurgical energy along its length when electrosurgical energy is applied to the connector.

9. A method of extracting a lead attached to body tissue by tissue growth, comprising:

inserting a sheath into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface of the lumen, to engage the lead;

connecting a source of electrosurgical energy to the sheath;

applying electrosurgical energy to the sheath through the connection to weaken the attachment between the tissue growth and the lead; and

extracting the lead after weakening the connection.

10. The method of claim 9, wherein the electrosurgical energy is radiofrequency energy.

11. The method of claim 9, wherein the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz.

12. The method of claim 9, wherein the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz.

13. The method of claim 9, wherein the attachment is weakened by at least one of heat and ablation.

14. A method for extracting a lead attached to body tissue by tissue growth, comprising:

inserting a sheath into a lumen of the lead, the sheath forming a mesh that is at least one of expandable and contractable to at least one of compress to grip an outer surface of a wire of the lead and expand to contact a peripheral inner surface of the lumen, to engage the lead;

connecting a source of electrosurgical energy to a wire within the lead;

applying electrosurgical energy to the wire through the connection to weaken the attachment between the tissue growth and the lead; and

extracting the lead after weakening the connection by applying traction to the sheath engaged with the lead.

15. The method of claim 14, wherein the electrosurgical energy is radiofrequency energy.

16. The method of claim 14, wherein the electrosurgical energy is radiofrequency energy between 100 kHz and 1 MHz.

17. The method of claim 14, wherein the electrosurgical energy is radiofrequency energy between 300 kHz and 500 kHz.

18. The method of claim 14, wherein the attachment is weakened by at least one of heat and ablation.

19. The method of claim 14, wherein the sheath is electrically conductive.

20. The method of claim 14, wherein a tip is attached to a distal end of the sheath, the tip electrically connected to source of electrosurgical energy, the tip operative to produce heat when the electrosurgical energy is applied to the connector.

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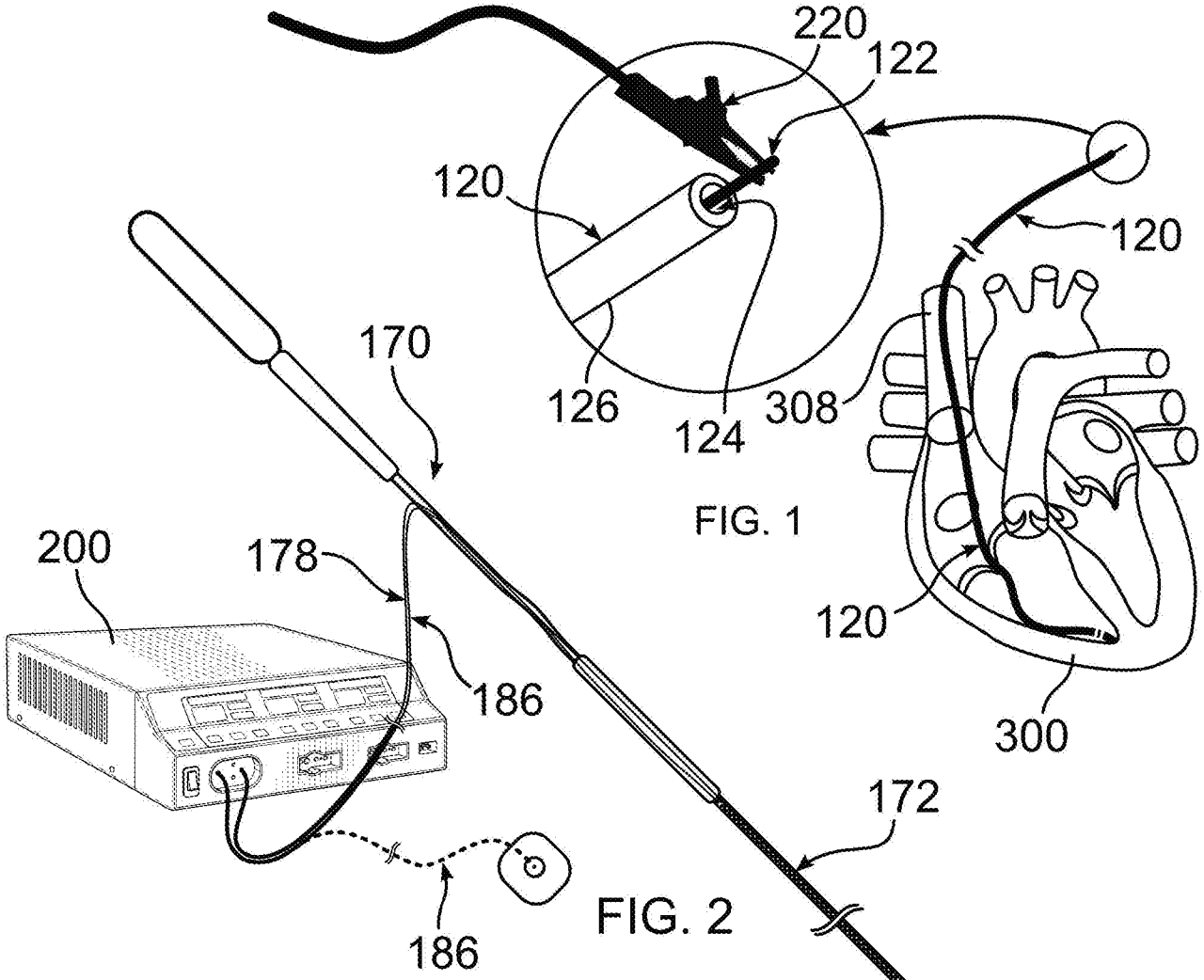


FIG. 1

FIG. 2

FIG. 3

FIG. 4A

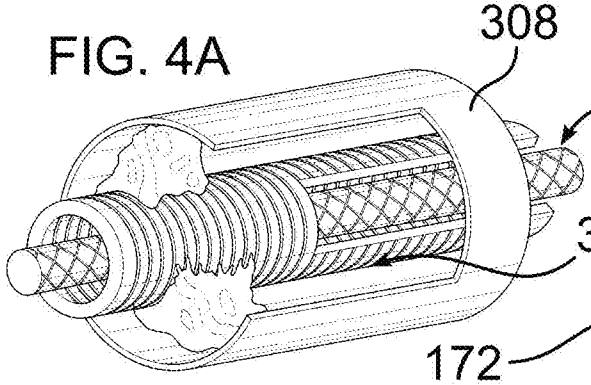
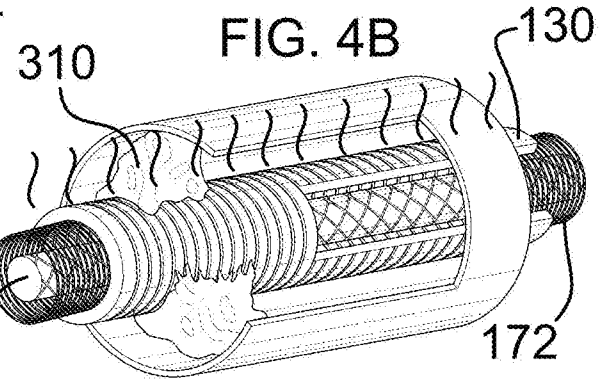


FIG. 4B



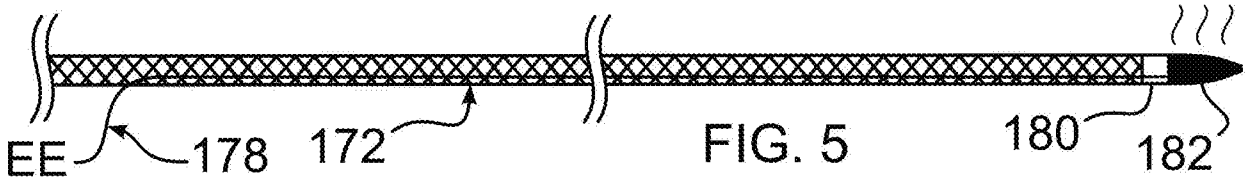


FIG. 5

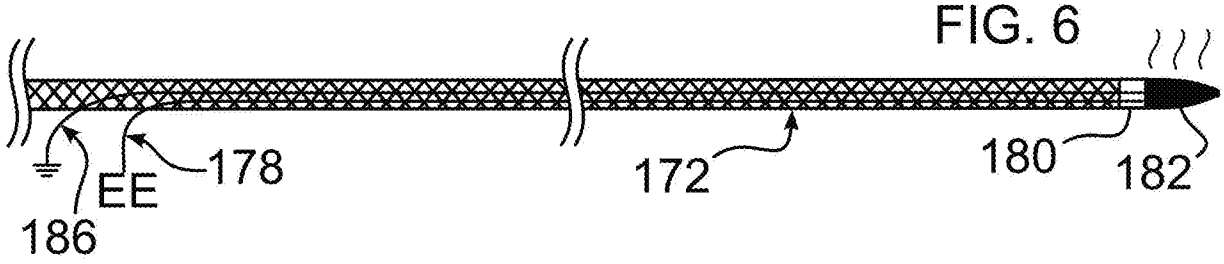


FIG. 6

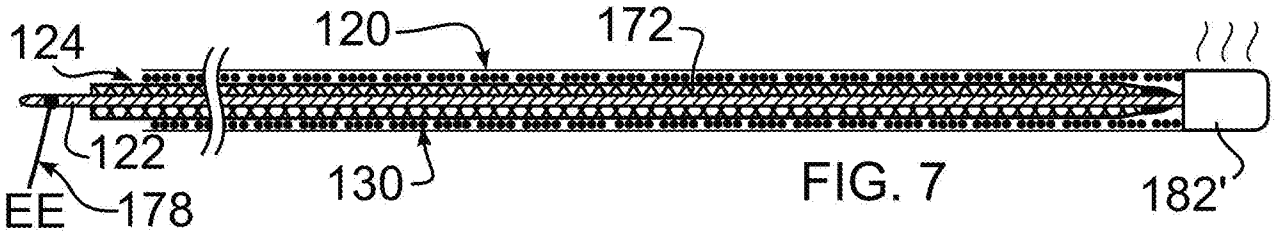


FIG. 7

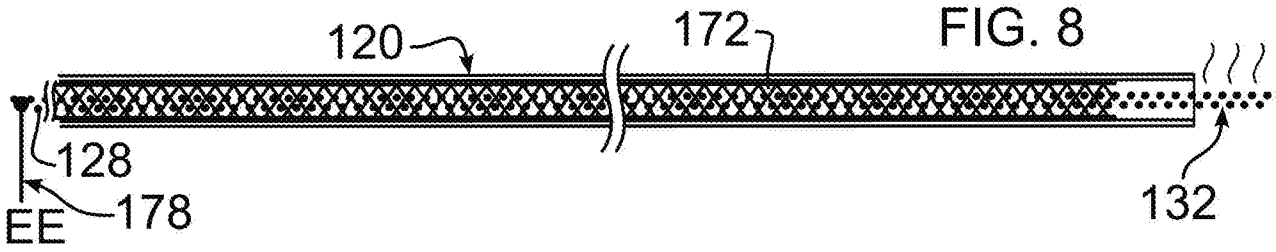


FIG. 8

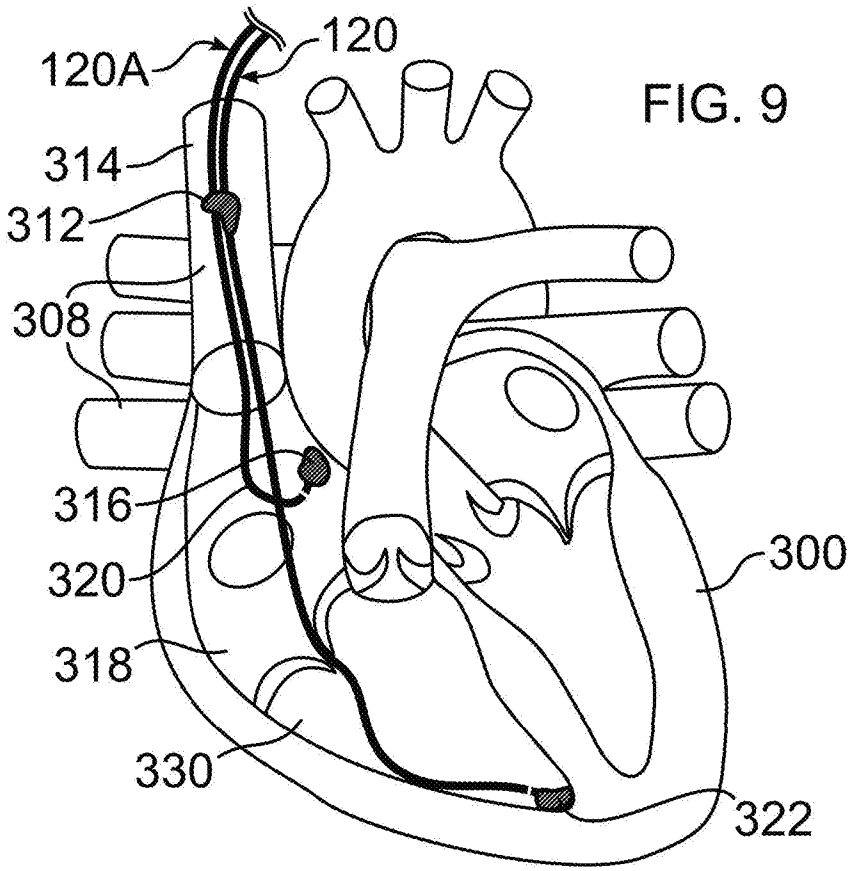


FIG. 9

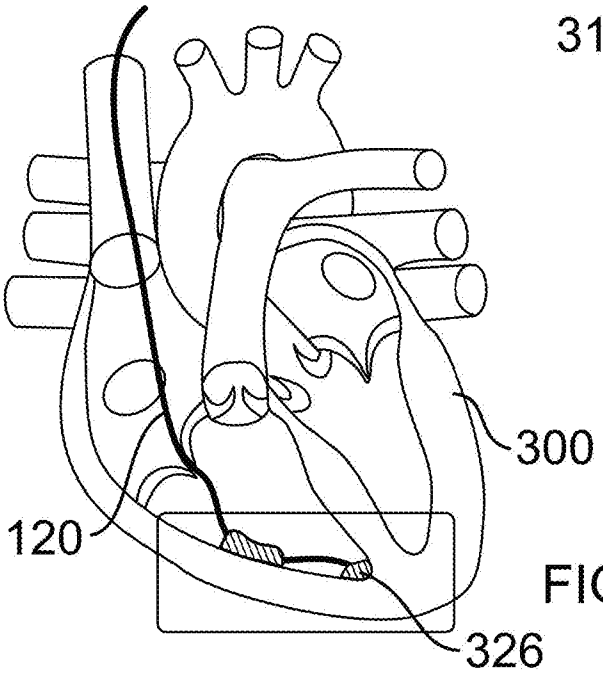


FIG. 10A

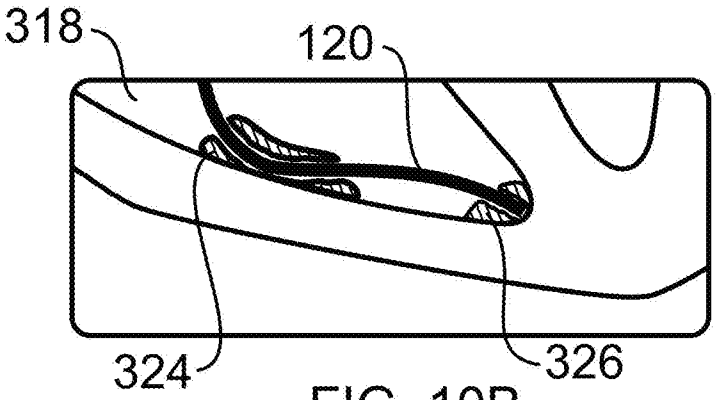


FIG. 10B

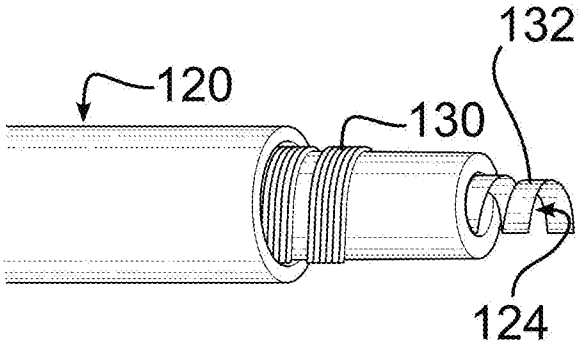


FIG. 11A

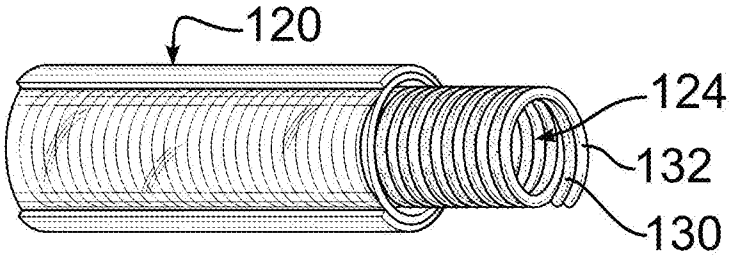


FIG. 11B

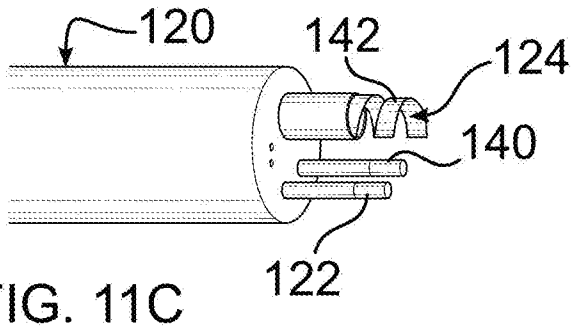


FIG. 11C

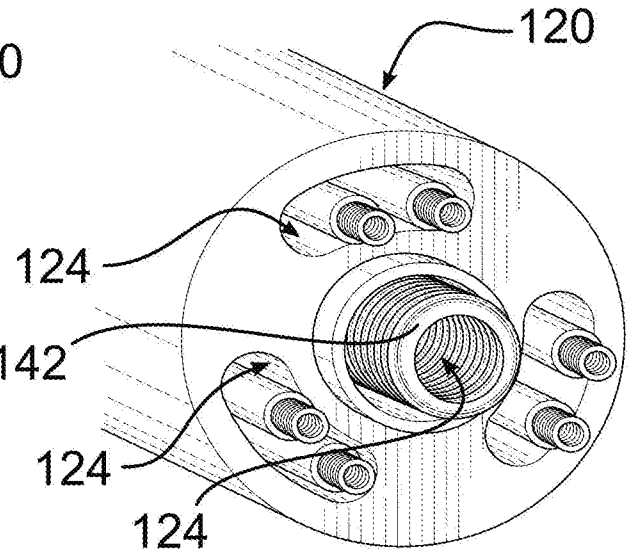


FIG. 11D

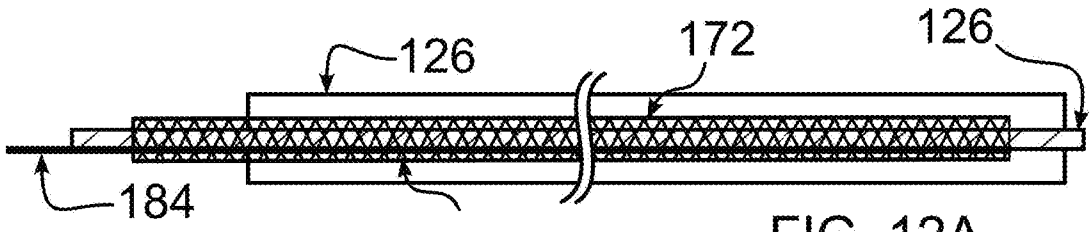


FIG. 12A

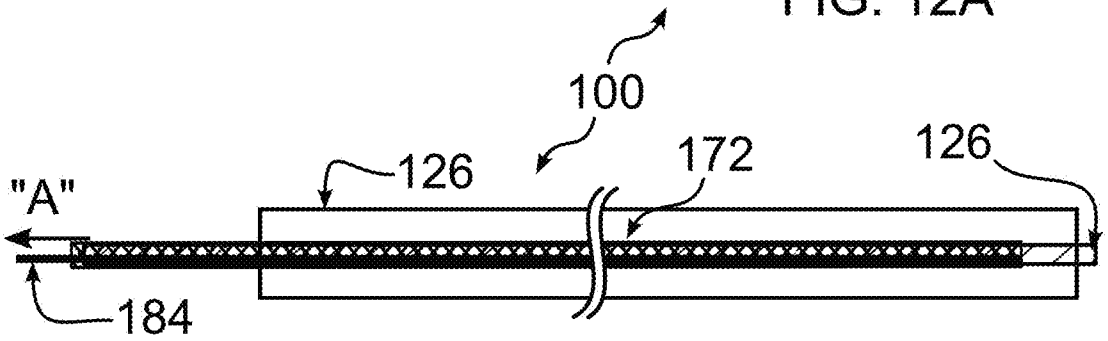


FIG. 12B

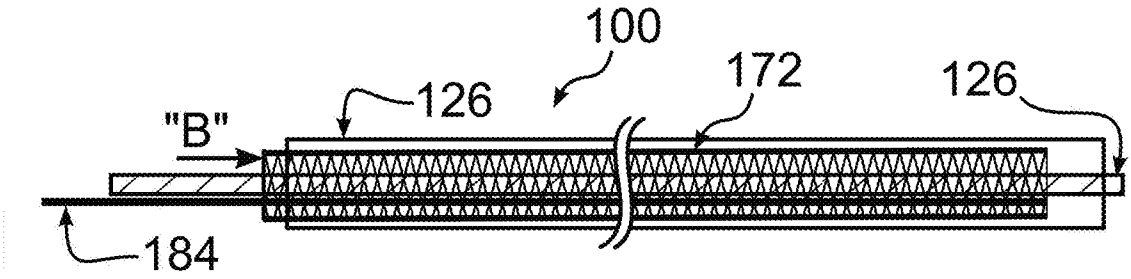


FIG. 12C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/026566

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00; A61B 17/22; A61B 17/221; A61B 18/00; A61B 18/04; A61B 18/12 (2017.01)

CPC - A61B 17/3468; A61B 17/32053; A61B 18/1492; A61B 18/1815; A61B 2017/22035; A61B 2018/00196; A61B 2018/00577; A61N 2001/0578 (2017.02)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 606/108; 606/1; 606/32; 606/33; 606/41; 606/45; 607/122; 607/126 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,207,683 A (GOODE et al) 04 May 1993 (04.05.1993) entire document	1-13
Y	US 6,033,402 A (TU et al) 07 March 2000 (07.03.2000) entire document	1-13
Y	US 2013/0178841 A1 (REID JR) 11 July 2013 (11.07.2013) entire document	5, 7
Y	US 8,808,281 B2 (EMMONS et al) 19 August 2014 (19.08.2014) entire document	8
A	US 8,668,687 B2 (JOHNSON) 11 March 2014 (11.03.2014) entire document	1-20
A	US 9,301,773 B2 (OLOMUTZKI et al) 05 April 2016 (05.04.2016) entire document	1-20
A	US 6,183,469 B1 (THAPLIYAL et al) 06 February 2001 (06.02.2001) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2017	15 JUN 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774