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(54) **MEDICAL LEAD AND METHOD FOR MEDICAL LEAD MANUFACTURE**

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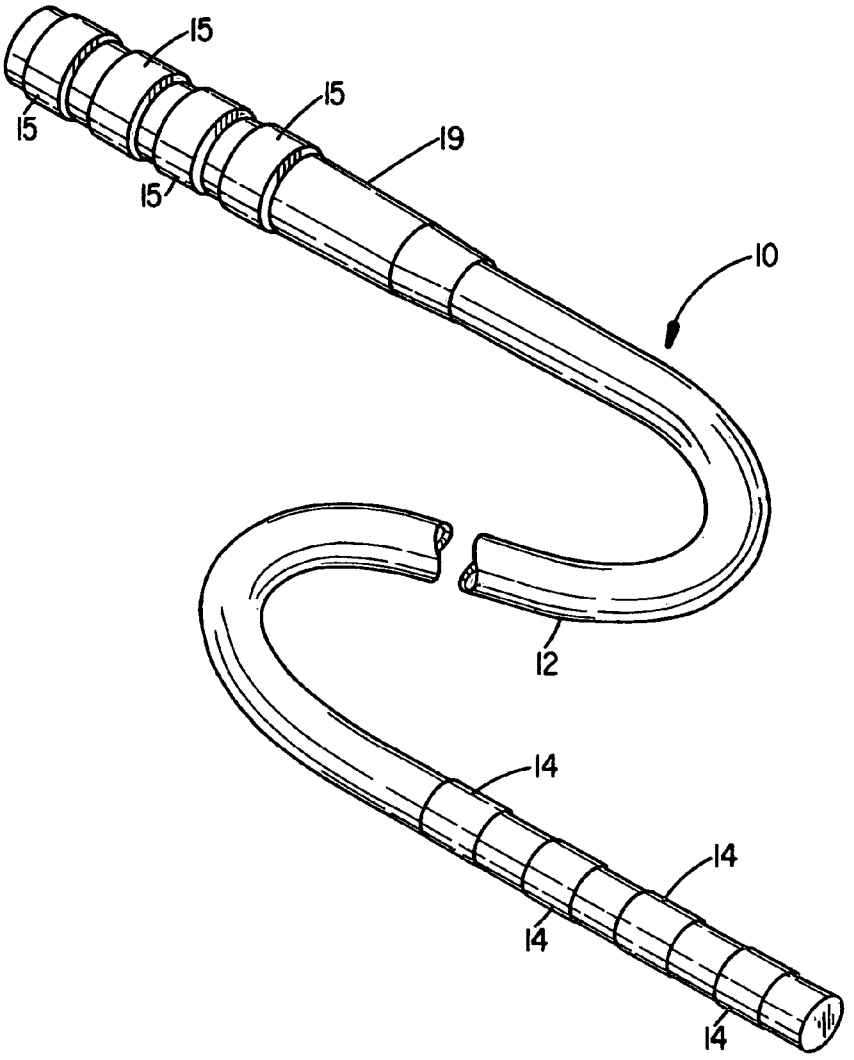
(57) **ABSTRACT**

A lead employing a connection between a conductor and an electric element is provided. The connection includes a conductive pad electrically connected to at least one conductor and the electric element electrically connected to the conductive pad. The conductive pad can further include an elongated element to connect the pad to the electric element. The method for connecting a conductor to an electric element is also provided. The method includes forming a groove in the insulator of a lead body to expose the conductor. Placing a conductive pad within the groove and electrically connecting a conductive pad to the conductor. An electric element is then placed over the conductive pad and the electric element is electrically connected to the conductive pad.



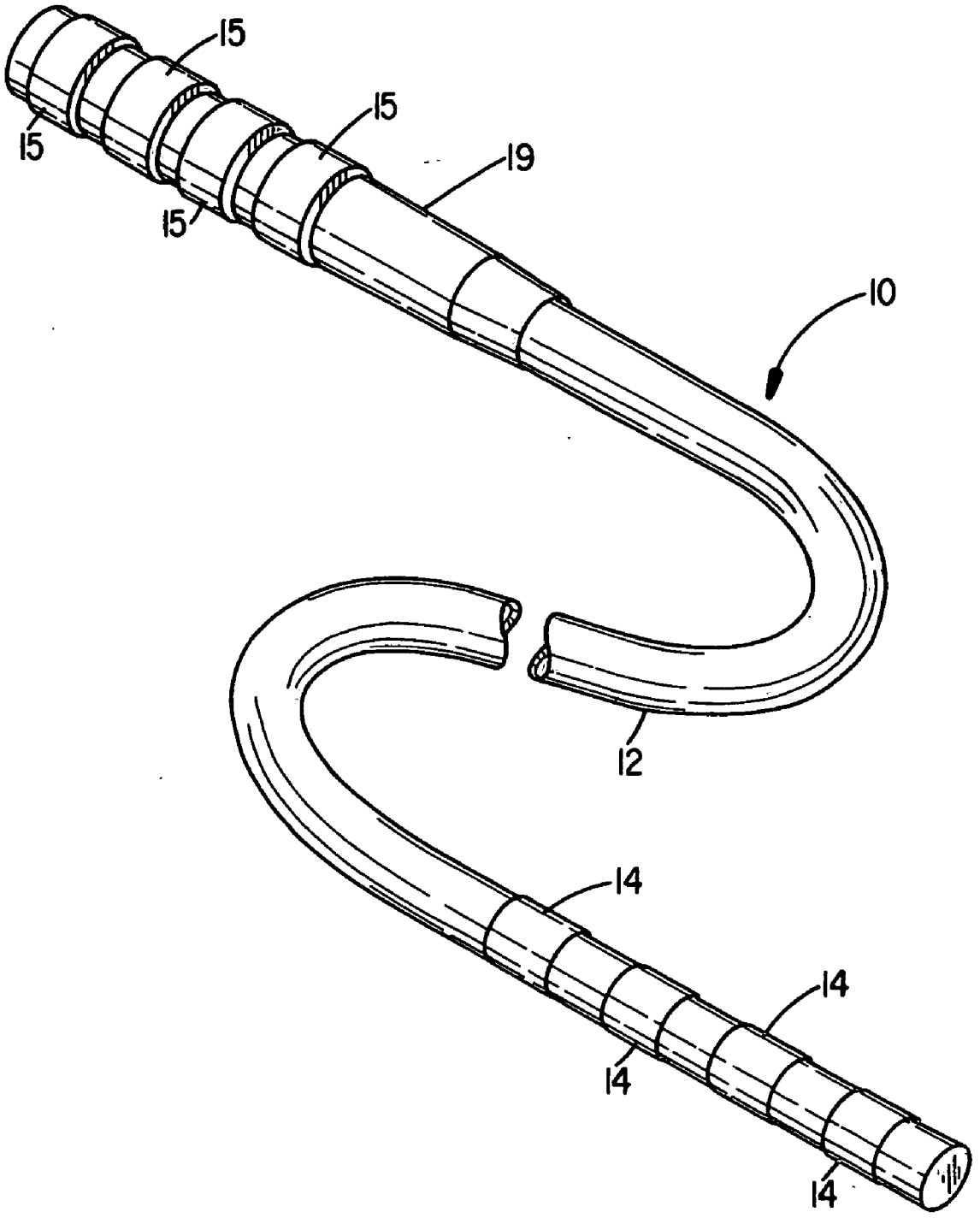


FIG. 1

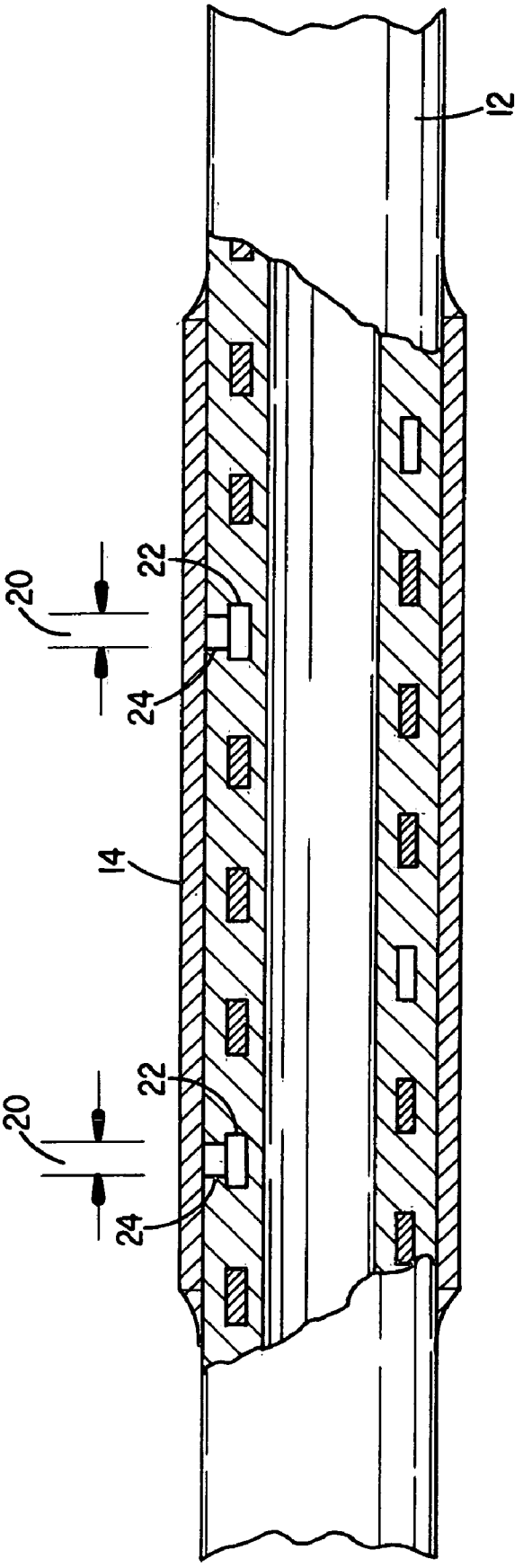


FIG. 2

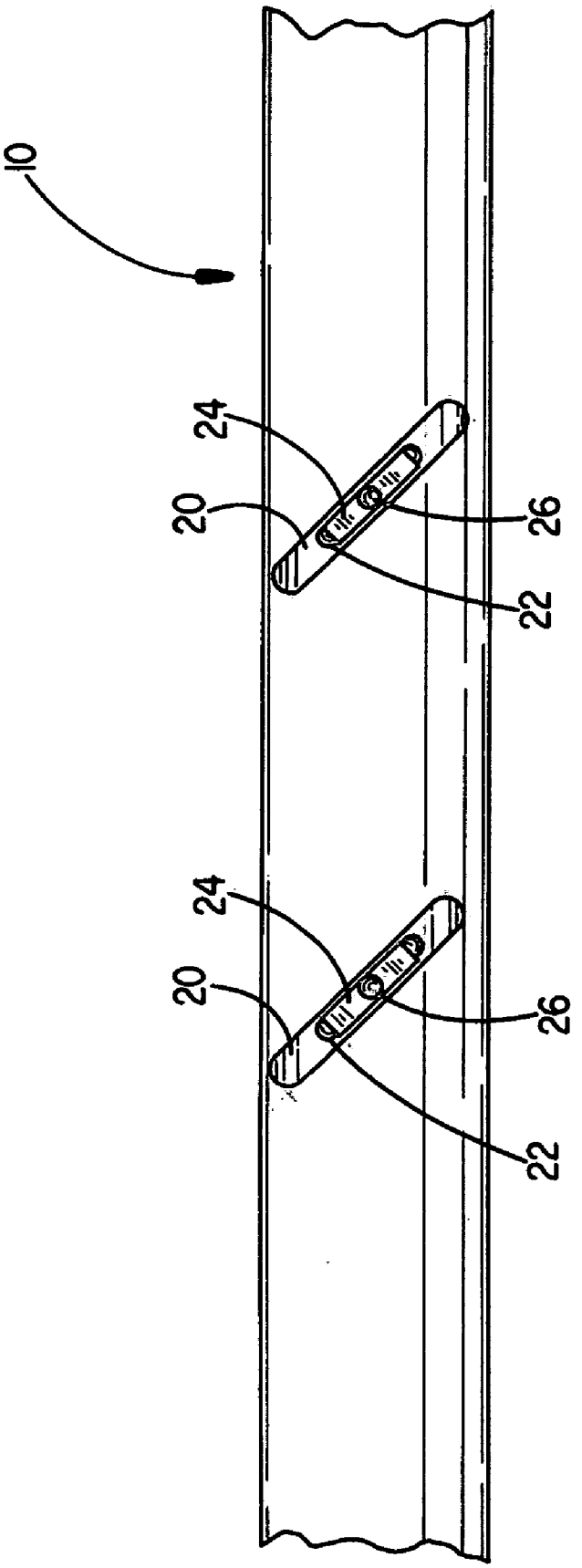


FIG. 3

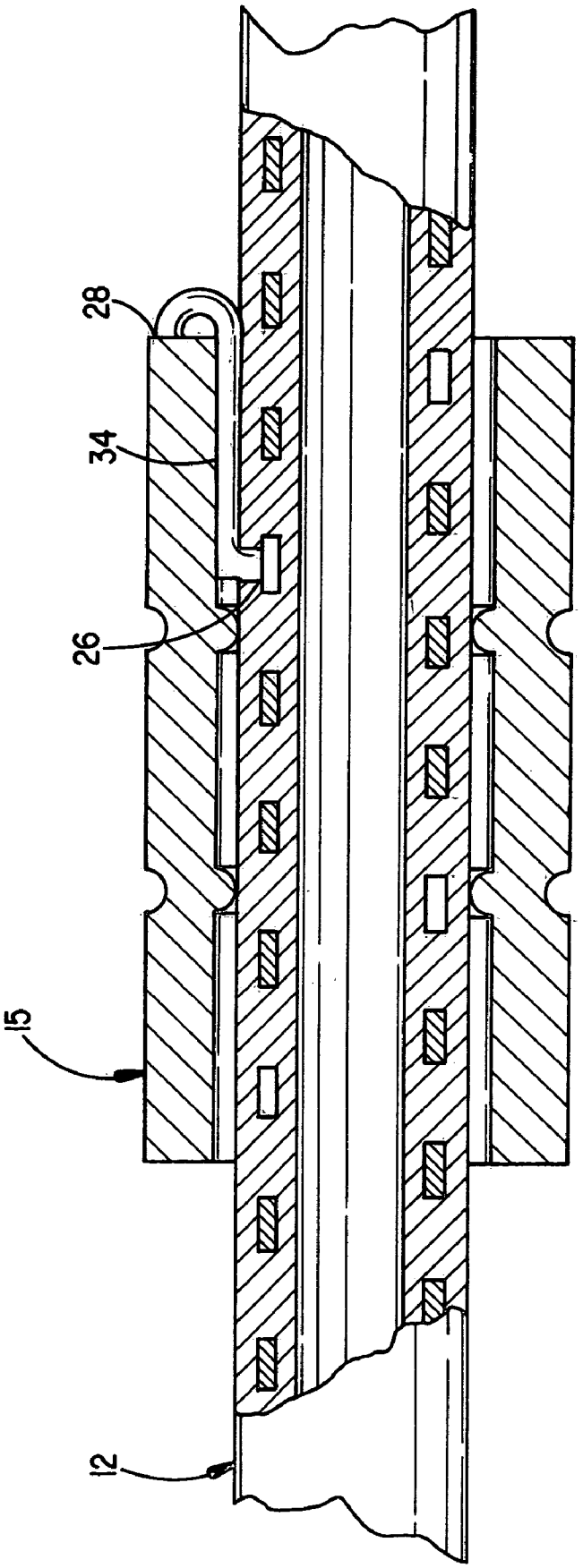


FIG. 4

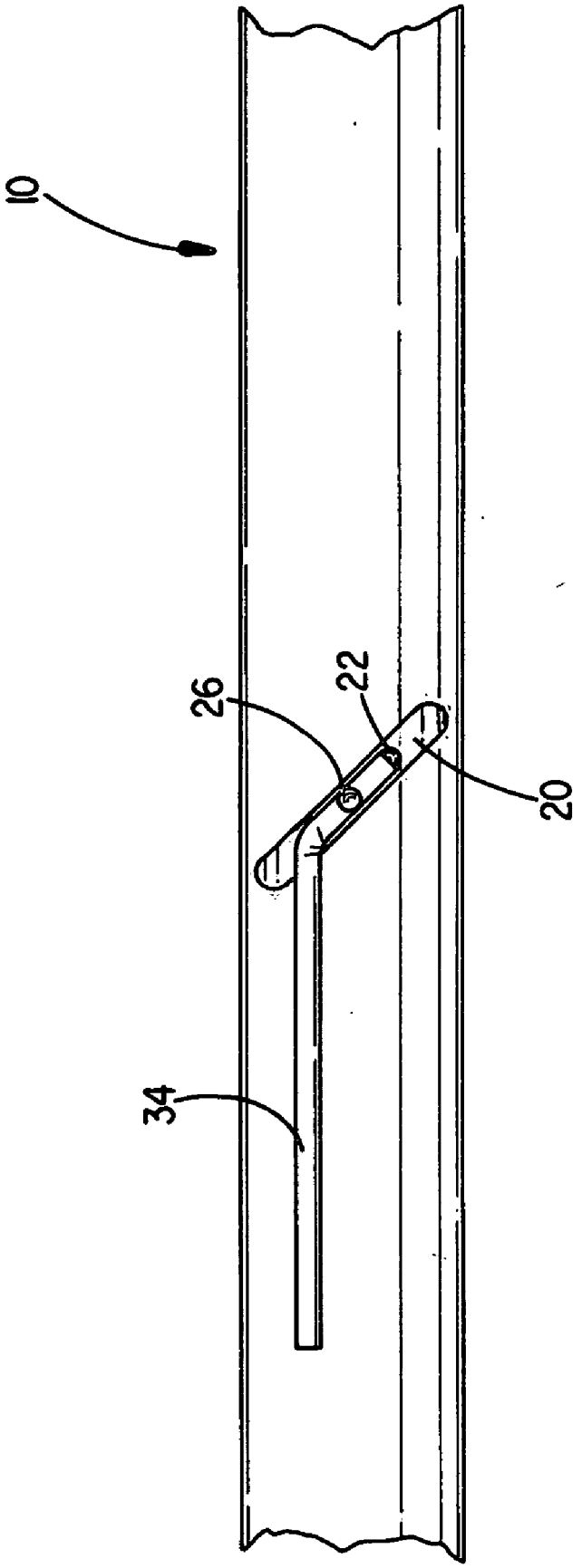


FIG. 5

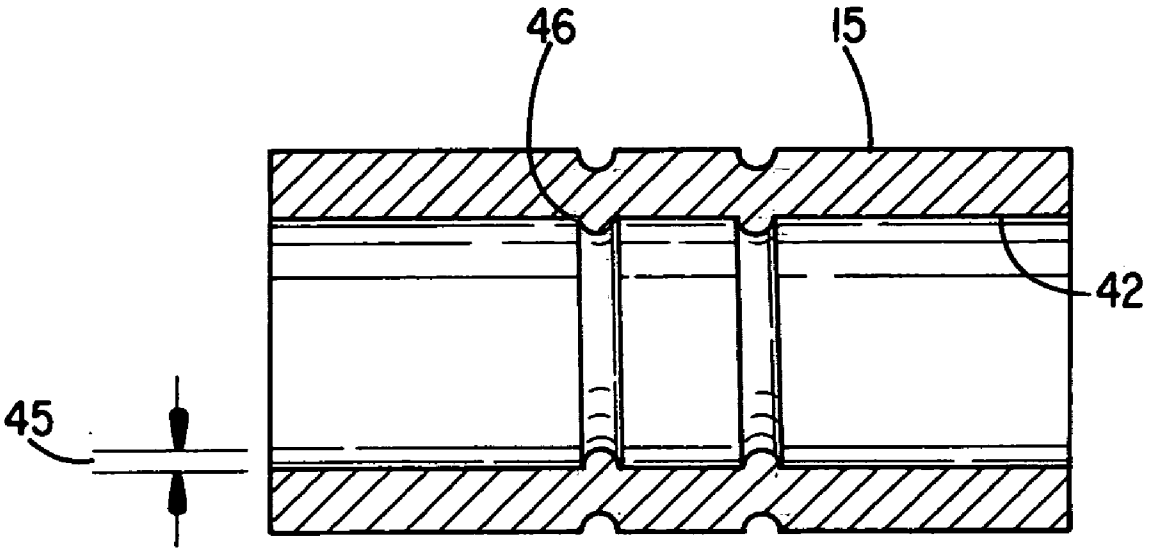


FIG. 6A

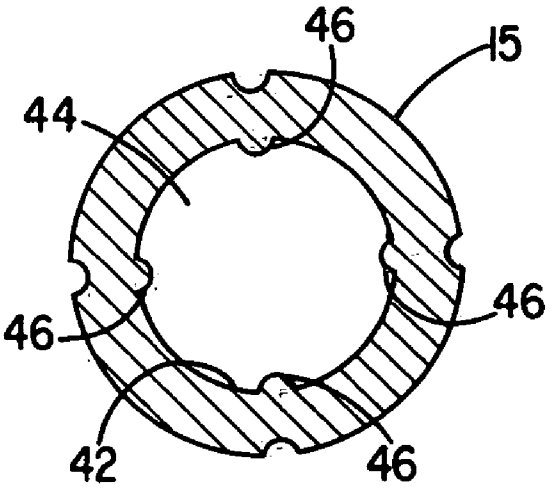


FIG. 6B

MEDICAL LEAD AND METHOD FOR MEDICAL LEAD MANUFACTURE

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to a medical leads and particularly to a method of medical lead manufacture and medical leads having a conductive pad connecting a band electrode to a conductor.

[0003] 2. Description of the Related Art

[0004] Implantable leads form an electrical connection between a pulse generator or other electronic device and a tissue or structure in the body. For example, leads transmit electric signals used to stimulate cardiac or nerve tissue in one direction and signals generated by sensors placed in proximity to particular organs or tissues in the opposite direction. Leads typically include one or more electrodes at the lead's distal end. The electrodes are designed to form an electrical connection with a tissue or organ. Most leads also include a lead connector at the lead's proximal end. Lead connectors are adapted to electrically and mechanically connect leads to the pulse generators or other electronic medical devices. A conductor connects the electrode to the lead connector. Commonly, the conductor takes the form of a single or multifilar wire coil. Although, there is an increasing interest in using stranded cables as conductors. Regardless of the conductor's form, an insulating material typically surrounds the conductors. Spinal chord stimulation leads are typically formed with individually insulated conductors surrounded by a separate lead body tube. Together, the conductor and the insulating material form the lead body. The lead body couples the lead connector at the proximal end with the electrode at the distal end.

[0005] Manufacturing leads is costly. A significant portion of the cost is allocated to electrically connecting the conductors to the various electrodes, sensors and connectors used in the industry. Forming a secure electrical junction has proven difficult and time consuming. Laser welds are commonly used to connect the conductors to the electrodes. The conductors are typically helically wound into a coil for increased reliability and flexibility. Band electrodes are typically connected to conductors by welding in an operation separate from the application of the lead body tube. Once the band electrodes are connected to the conductors, an extruded tube is placed over the conductor coil and welded band electrodes are connected to the lead body tube by insert molding or RF welding. Band electrodes may also be connected to a conductor by etching away a region of insulator, applying a coating of electrically conductive adhesive, and then placing the band electrode around the conductor. This etching method is complex, not amenable to automation and expensive. Therefore, a need exists for a method that reduces complexity and is easily automated to reduce production costs.

[0006] In another method of attachment, band electrodes are electrically connected to coiled conductors by placing a soft metal in a hole cut into an insulating sleeve. An electrode is placed over the metal and crimped or swaged to bring the electrode, soft metal and coiled conductors into electrical contact and to secure the electrode to the lead body. The crimping or swaging method of connection results in electrical connections between the conductor and the band electrode that may fail. Further, swaging to electrically connect an electrode to a conductor is time consuming and difficult to implement with the modern reduced diameter leads. Hence, a need exists for an improved manufacturing technique to secure band electrodes to conductors that reduces the time, complexity and cost while increasing reliability.

[0007] In addition, current manufacturing techniques frequently require adding elements, such as collars, when connecting a band electrode to a coil. The added elements increase the lead's diameter near the weld. In application, a uniform diameter weld would result in a smaller lead. A smaller diameter lead is desired to allow placement in restricted spaces such as the epidural space or cardiac veins to reduce the effects of implanted lead on the patient. Further, a smaller lead allows for a smaller introducer that reduces the trauma associated with implantation and similarly a smaller removal sheath when explanting the lead. Hence, there exists a need to reduce the diameter of the welds used to secure electrodes to conductors in implantable medical leads.

[0008] The present invention meets these needs and provides other advantages and improvements that will be evident to those skilled in the art.

SUMMARY OF THE INVENTION

[0009] The present invention provides a lead and method for lead construction that reduces the time, complexity and costs of producing implantable electrical leads by providing a novel connection between the conductors and an electrode, connector or sensor.

[0010] The medical lead includes a lead body, a conductive pad and a band. The lead body is comprised of an insulator and at least one conductor. The insulator includes at least one welding region exposing at least one conductor. The welding region may be in the form of a groove cut in the insulator. When in the form of a groove, the welding region typically is cut parallel to the orientation of the conductor. The conductive pad is secured within the welding region to electrically connected to the conductor to the pad. The conductive pad may be composed of stainless steel, MP35N, platinum, gold, silver, copper, vanadium or other metal. The conductive pad may be electrically connected to the conductor by welding, conductive adhesives, crimping or other methods. Alternative to the conductive pad, an elongated conductive element may be used to electrically connected to the conductor to the pad. The elongated conductive element can be a wire, a ribbon wire, a cable, or other elongated form. The elongated conductive element may be composed of stainless steel, MP35N, platinum, gold, silver, copper, vanadium or other metal. The elongated conductive element may be electrically connected to the conductor by welding, conductive adhesives, crimping or other methods. The band is welded to the conductive pad to electrically connect the band to the conductor. The band may be a band electrode, a band connector, a sensor, or other element electrically secured to medical leads. The band may include a plurality of projections on an inner wall of a lumen. The projections space the inner wall from an outer surface of the lead body. Three or more projections may be positioned around the inner wall to center the lead body within the lumen during assembly.

[0011] The method for manufacturing a medical lead includes forming a welding region, securing a conductive pad within the welding region, and securing a band to the conductive pad. The welding region is typically formed by cutting through the insulator to expose the conductor. The welding region can cut with a laser, typically an excimer laser, or can be mechanically cut. The conductive pad is secured within the welding region adjacent the conductor. The conductive pad can be secured within the welding region using a weld, crimping conductive adhesives or other method. The band is secured to the conductive pad to electrically connect the band to the conductor. To secure the band, a weld is formed between the conductive pad and the band. A yttrium-arsenic-garnet laser may be used to form the weld.

[0012] Alternatively to the use of a conductive band, an elongated conductive element may be substituted. The proximal end of the elongated conductive element is secured conductor within the welding region. The band is then positioned around the lead body and over the welding region. The distal end of the elongated conductive element is then electrically connected to the band. The elongated conductive element may be electrically connected to the band by welding.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] **FIG. 1** illustrates a perspective view of a lead in accordance with the present invention;

[0014] **FIG. 2** illustrates a longitudinal cross-sectional view of a of a lead showing an embodiment of the connection between a coiled conductor and a band with a conductive pad;

[0015] **FIG. 3** illustrates a top view of a lead, as shown in **FIG. 2**, without the band;

[0016] **FIG. 4** illustrates a longitudinal cross-sectional view of a of a lead showing the connection between a coiled conductor and a band with an elongated conductive element;

[0017] **FIG. 5** illustrates a top view of a lead, as shown in **FIG. 4**, without the band;

[0018] **FIG. 6A** illustrates a cross-sectional longitudinal view of a band electrode, as shown in **FIGS. 4 and 5**; and

[0019] **FIG. 6B** illustrates and end view of the band electrode, as in **FIG. 6A**.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The present invention provides a medical lead and a method for lead manufacture. The invention is described generally in the context of an electrode for a neurostimulating lead and a method for manufacturing a neurostimulating lead as a specific example for illustrative purposes only. The appended claims are not intended to be limited to any specific example or embodiment described in this patent. It will be understood by those skilled in the art that leads in accordance with the present invention may be used for a wide variety of applications including, but not limited to, leads and catheters for use with cardiac monitoring devices, cardiac rhythm management devices, ablation devices, mapping devices, neurostimulating devices, neuromonitoring devices or other medical devices using leads or catheters. Further, in the drawings described below, the reference numerals are generally repeated where identical elements appear in more than one figure.

[0021] **FIG. 1** illustrates an embodiment of a lead **10** made in accordance with the present invention. Leads designed for neurostimulation typically have two or more longitudinally spaced band electrodes at the lead's distal end. Lead **10**, as shown, includes a lead body **12** and four band electrodes **14**. Lead **10** is generally configured to transmit an electric signal from a pulse generator (not shown) to a spinal nerve or peripheral nerve. Thus, electrodes **14** are typically located at the distal end of lead **10**. Lead body **12** includes a flexible lead insulator surrounding one or more conductors. The conductors are electrically coupled to the band electrodes. In addition, a lead connector **15** is typically located at the proximal end of lead body **12** to electrically couple the conductors to the pulse generator.

[0022] Typically, lead body **12** is a flexible, elastomeric structure having a round cross-section. Alternatively, lead body's cross-section could be any number of shapes appropriate for the specific application. The figures and the following description generally refer to round cross-sectional shape for lead bodies for exemplary purposes. The lead insulator is generally configured to insulate the conductors and to present a smooth biocompatible external surface to body tissues. Thus, the lead insulator is typically coextensive with the conductor or conductors. When a plurality of conductors form a multipolar lead, individual conductors are typically electrically isolated from one another. The insulator material is typically selected based on biocompatibility, biostability and durability for the particular application. The insulator material may be silicone, polyurethane, polyethylene, polyimide, polyvinylchloride, PTFE, ETFE, or other materials known to those skilled in the art. Moreover, alloys and blends of these materials may also be formulated to control the relative flexibility, torqueability, and pushability of the lead. Depending on the particular application, the diameter of the lead body may be as small as 2 French or smaller for neurological and myocardial mapping/ablation leads and can be sizes larger than 12 French for other applications.

[0023] The conductors may take the form of solid wires, drawn-filled-tube (DFT), drawn-brazed-strand (DBS), stranded cables or other forms that will be recognized by those skilled in the art. The conductors may be composed of stainless steel, MP35N, or other conductive materials known to those skilled in the art. The number, size, and composition of the conductors will depend on particular application for the lead.

[0024] At least one band electrode **14** is positioned at the distal end of lead body **12** for electrically engaging a target tissue or organ. In addition, at least one band connector **15** is positioned at the proximal end of the lead body for electrically connecting the conductors to the neurostimulator. For purposes of the present invention, band electrodes **14** and band connectors **15** are collectively referred to as bands. The bands are typically made of a conductive material such as platinum, gold, silver, platinum-iridium, stainless steel, MP35N or other conductive metals or alloys thereof known to those skilled in the art. The bands are typically composed of a material thin enough to allow for welding of the elements to the underlying conductive pad, as

discussed below. For neurostimulation, band electrodes **14** are typically between 1 and 10 millimeters long and have a diameter between about 2 and about 8 French but are more typically between 4 and 6 French. Typically, band connectors **15** have a size and configuration appropriate to connect the lead to a particular neurostimulator.

[**0025**] **FIG. 2** illustrates the details of an embodiment of the connection between a conductor **22** and band electrode **14** in accordance with the present invention. Band electrodes are the point of electrical contact between the conductors and the patient. Although discussed in the context of a band electrode, one skilled in the art will recognize that the following description is also applicable to a band connector, a sensor or other electrical element. For exemplary purposes, band electrode **14** and lead body **12** is configured for two welds at a welding region **20**. At least one weld is typically utilized. In the particular embodiment, the same conductor is connected to band electrode **14** twice. **FIG. 2** illustrates a longitudinal cross-section of a lead body having four spirally wound conductors for exemplary purposes. The lead body is shown with four conductors. The conductors may be visible through the insulating material when the insulating material is translucent.

[**0026**] **FIG. 3** illustrates a top view of a lead body having the insulating material removed to form welding region **20** by exposing conductor **22**. Welding region **20** provides access to conductor(s) **22** for electrically connecting the band electrode to conductor **22**. Welding region **20** is typically formed by removing the insulating material from lead body **10**. The insulating material is removed to expose small sections of the individual conductors **22** without breaching an inner lumen, if present. Typically, an excimer laser is used to remove the insulating material. When the insulator is removed by laser, welding region **20** may be in the form of a groove in the insulator. Although, welding region **20** may take a variety of forms and orientations that expose a sufficient surface area of conductor **22** to form an electrical connection with a conductive pad, discussed below. When in the form of a groove, welding region **20** is typically formed such that the groove runs parallel to conductor **22**. Regardless of the form of welding region **20**, enough insulating material is removed to expose sufficient surface area of conductor **22** for securing a conductive pad or elongated conductive element to the conductor.

[**0027**] Referring to **FIGS. 2 and 3**, a conductive pad **24** is positioned within welding region **20** during manufacture to facilitate the electrical connection of band electrode **14** and conductor **22**. A weld **26** is typically used to secure the conductive pad **24** in electrical contact with conductor **22**. Alternatively, conductive pad **24** may be secured using an adhesive. Conductive pad **22** may be composed of any of a variety of conductive materials that can be welded or secured with adhesives. The metal may be stainless steel, MP35N, Pt—Ir, platinum, silver, gold, copper, vanadium or other metal that will be recognized by one skilled in the art upon review of this disclosure. Conductive pad **24** is positioned within welding region **20** so that conductive pad **24** is in electrical contact with conductor **22**. Typically, conductive pad **24** is welded to the conductor prior to placing band electrode **14** over the welding regions and conductive pads **24**. A pulsed Neodymium:yttrium-arsenic-garnet (YAG) laser may be used to weld conductive pad **24** to conductor **22**. **FIG. 2** shows a side view of a cross-section of two grooves **20** that expose two regions of the same conductor **22**. Conductive pads **24** are welded to conductor **22** within grooves **20**. Band electrode **14** is placed over lead body **12** of lead **10** and welded to conductive pads **24**, thereby securing band electrode **14** to lead body **12** and electrically connecting conductor **22** and band electrode **14**. Band electrode **14** may be further secured to lead body **12** by swaging, crimping and/or adhesives. Alternatively, the band electrode may be secured to the lead body by heating the lead body. Heating the lead body stress-relieves the plastic increasing the outside diameter and securing the band electrode over the lead body. In addition, heating the lead body may be used to create a lead having a uniform diameter band and lead body.

[**0028**] **FIGS. 4 and 5** illustrate the details of another embodiment of a connection between conductor **22** and a band connector **15** in accordance with the present invention. Band connectors are the point of electrical contact between the medical device using the lead and the conductors within the lead. Although discussed in the context of a band connector, one skilled in the art will recognize that the following description is also applicable to band electrodes, sensors or other electrical elements. An elongated conductive element **34** is used to electrically connect the band to conductor **22**. The elongated conductive element may be in the form of a wire, a ribbon wire, or a cable. The metal may be stainless steel, MP35N, Pt—Ir, platinum, silver, gold, copper, vanadium or other metal that will be recognized by one skilled in the art upon review of this disclosure. A distal end of elongated conductive element **34** is electrically connected to band connector **15**. Typically, the electrical connection employs a weld **28**, although a conductive adhesive or other method of conductively attaching may be used. **FIG. 4** shows a longitudinal cross-section of a lead body having four spirally wound conductors. One or more welding regions **20** are formed through the insulating material by removing the insulating material from lead body **10**. Typically, the insulating material is removed with a laser. The proximal end of elongated conductive element **34** is positioned within welding region **20** so that the proximal end is in electrical contact with conductor **22**. Typically, the proximal end is secured to conductor **22** prior to placing band connector **15** over lead body **12**. Again, the proximal end is typically welded although a conductive adhesive or other method of conductively attaching the proximal end may be used. The elongated conductive element **34** and attached proximal end are typically configured to allow band connector **15** to pass over elongated conductive element **34** during assembly. The distal ends of elongated conductive elements **34** may then be electrically connected to band connector **15**.

[**0029**] **FIGS. 4 and 5** illustrate a single exemplary connection between conductor **22** and band connector **15** by welds **26** and **28**. Thus, **FIG. 4** shows only one groove **20** exposing conductor **22**. The proximal end of elongated conductive element **24** is positioned within groove **20** is welded to conductor **22**. Band connector **15** is placed over lead body **12** and welded to elongated conductive element **34**, thereby electrically connecting conductor **22** and band connector **15**. Band connector **15** may be further secured to lead body **12** by swaging, crimping, adhesives and/or insert molding. In addition, swaging may reduce the outside diameter of lead connector **15** to permit the manufacture of a lead

of uniform diameter. Further, lead body **12** may be expanded by heating to create a uniform diameter for lead connector **15**.

[0030] **FIGS. 6A and 6B** illustrate an embodiment of a band which may be used in conjunction with the present invention. Although discussed in the context of a band connector, one skilled in the art will recognize that the following description is also applicable to band electrodes, sensors or other electrical elements. Band connector **15** includes an inner wall **42** defining a lumen **44**. At least one projection **46** is formed on the inner wall **42**. Projections **46** define a space between inner wall **42** and an outer surface of the lead body during assembly. Projections **46** may be molded on the inner surface; formed by crimping the exterior surface of the band; or added as separate elements secured to the inner surface of the band. Projections **46** have a height **45** which defines the amount of space between the outer surface of the lead body and inner wall **42**. Height **45** is generally selected to allow conductive pads **24** and/or conductive elements **34** to pass beneath the inner wall during assembly. Typically, three projections are provided at positions around the circumference of band connector **15** to center band connector **15** over lead body **12** during assembly. Centering band connector **15** so that height **45** is substantially the same around the circumference of the lead body assures clearance of the conductive element during assembly.

1.-**29**. (canceled)

30. A method for manufacturing a medical lead, the method comprising:

cutting a welding region in a lead body to expose a conductor;

securing a conductive pad within the welding region adjacent the conductor; and

securing a band to the conductive pad to electrically connected the band to the conductor.

31. A method in accordance with claim 30 wherein the conductive pad is secured within the welding region by a method selected from the group consisting of welding, crimping and adhesives.

32. A method in accordance with claim 30 wherein the welding region is in the shape of a groove.

33. A method in accordance with claim 32 wherein the groove is formed obliquely across the lead body and parallel to the conductor.

34. A method in accordance with claim 32 wherein the welding region is formed using a laser.

35. A method in accordance with claim 34 wherein securing the band further comprises welding the band to the conductive pad using a laser.

36. A method of forming a medical lead, the method comprising:

forming using a laser a first welding region within insulating material in a lead body to expose a first conductor;

forming using a laser a second welding region within the insulating material in the lead body expose the first conductor;

forming a first conductive pad within the first welding region and electrically connecting the first conductive pad to the first conductor;

forming a second conductive pad within the second welding region and electrically connecting the first conductive pad to the first conductor;

electrically connecting a first electrode to the first conductive pad; and

electrically connecting the first electrode to the second conductive pad.

37. A method in accordance with claim 36 wherein the first welding region and the second welding region are in the shape of a groove.

38. A method in accordance with claim 37 wherein the grooves are formed obliquely across the lead body and parallel to the first conductor.

39. A method in accordance with claim 34 wherein electrically connecting the first electrode to the first conductive pad further comprises welding the electrode to the first conductive pad, and electrically connecting the first electrode to the second conductive pad further comprises welding the electrode to the second conductive pad.

40. A method in accordance with claim 36 wherein the first and second conductive material each comprise a conductive metal selected from the group consisting of stainless steel, MB35N, Pt—Ir, platinum, silver, gold, copper and vanadium.

41. A method of forming a medical lead, the method comprising:

forming a welding region within insulating material in a lead body of the medical lead to expose a conductor, the welding region having a shape of a groove and formed obliquely across the lead body and parallel to the conductor;

placing a conductive pad within the welding region and securing the conductive pad to the conductor using a laser; and

electrically connecting an electrode to the conductive pad.

42. A method in accordance with claim 41 wherein the welding region is formed using a laser.

43. A method in accordance with claim 42 wherein the conductive material comprises a conductive metal selected from the group consisting of stainless steel, MB35N, Pt—Ir, platinum, silver, gold, copper and vanadium.

44. A method in accordance with claim 41 further comprising:

forming a second welding region within the insulating material to expose the conductor, the second welding region having a shape of a groove and formed obliquely across the lead body and parallel to the conductor;

placing a second conductive pad within the second welding region and securing the second conductive pad to the conductor using a laser; and

electrically connecting the electrode to the second conductive pad.

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