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(54) **VACUUM MANDREL FOR USE IN FABRICATING AN IMPLANTABLE ELECTRODE**

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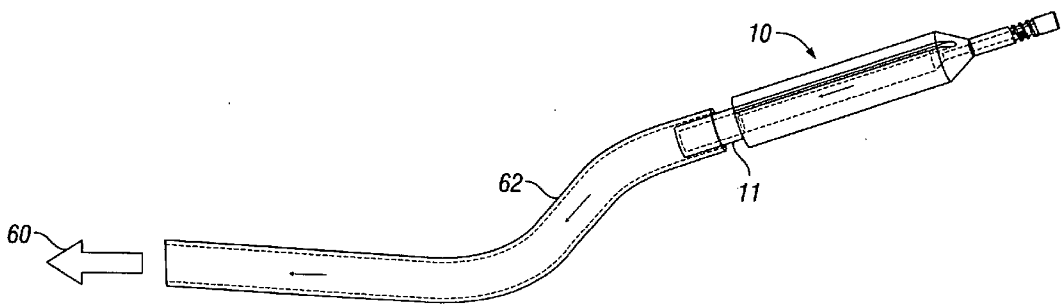
(57) **ABSTRACT**

A vacuum mandrel for use in fabricating an implantable electrode comprises a hollow body member and a first groove provided radially on an outer surface of the hollow body member. The first groove is adapted to receive an implantable electrode and retain the electrode in place with a vacuum pressure during an elastomeric encapsulation of the electrode. The vacuum mandrel further comprises a vacuum port provided in the first groove.



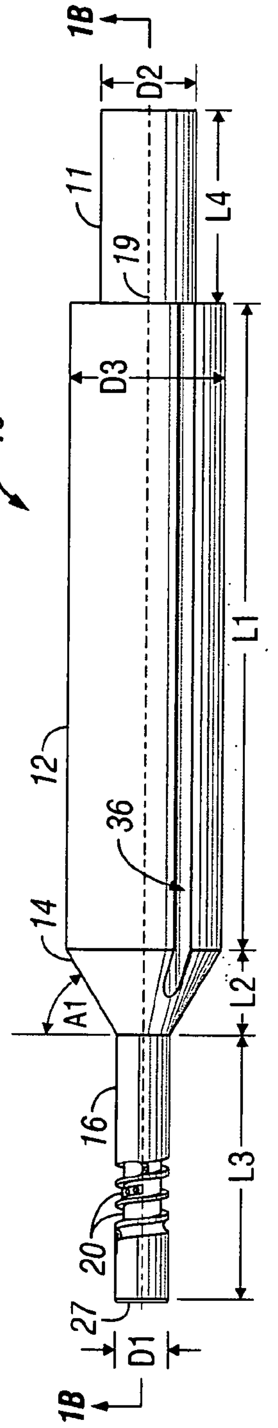


FIG. 1A

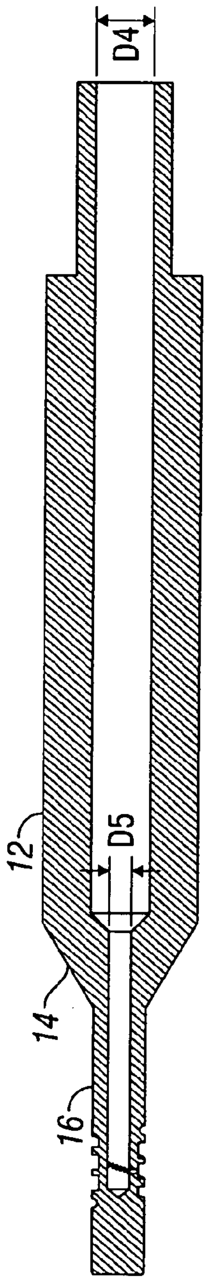


FIG. 1B

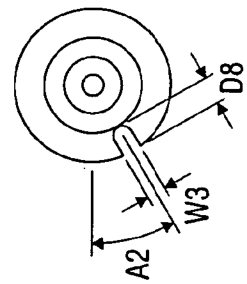


FIG. 1C

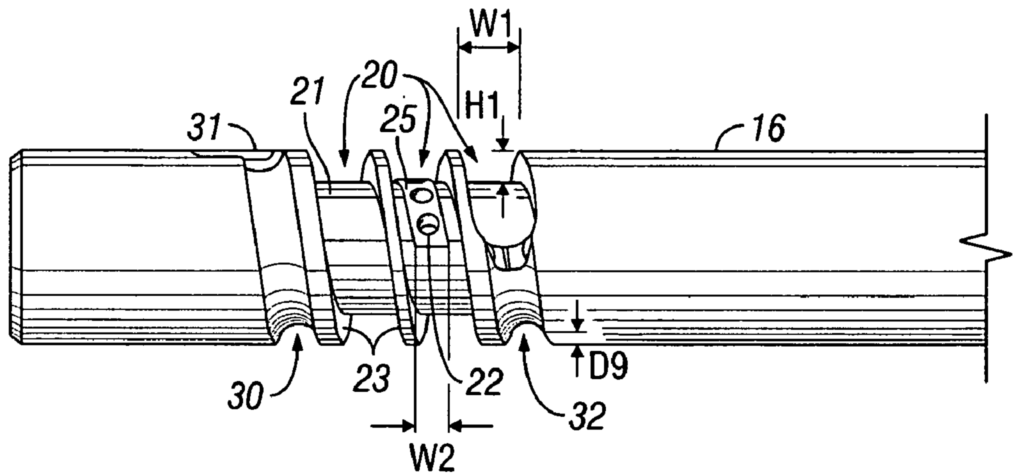


FIG. 2

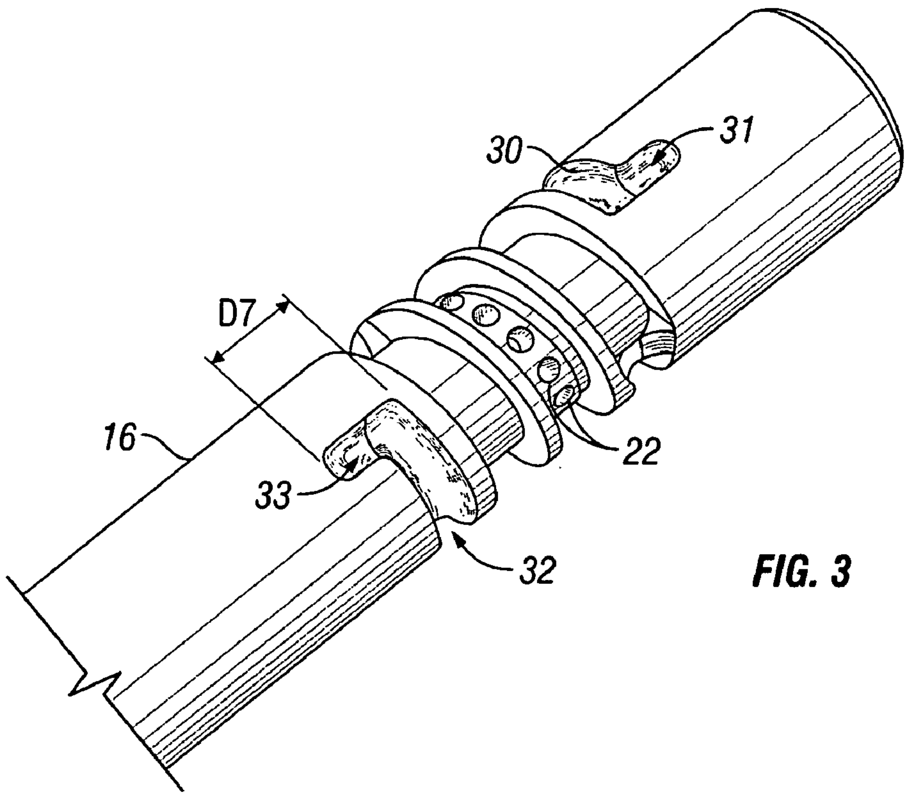


FIG. 3

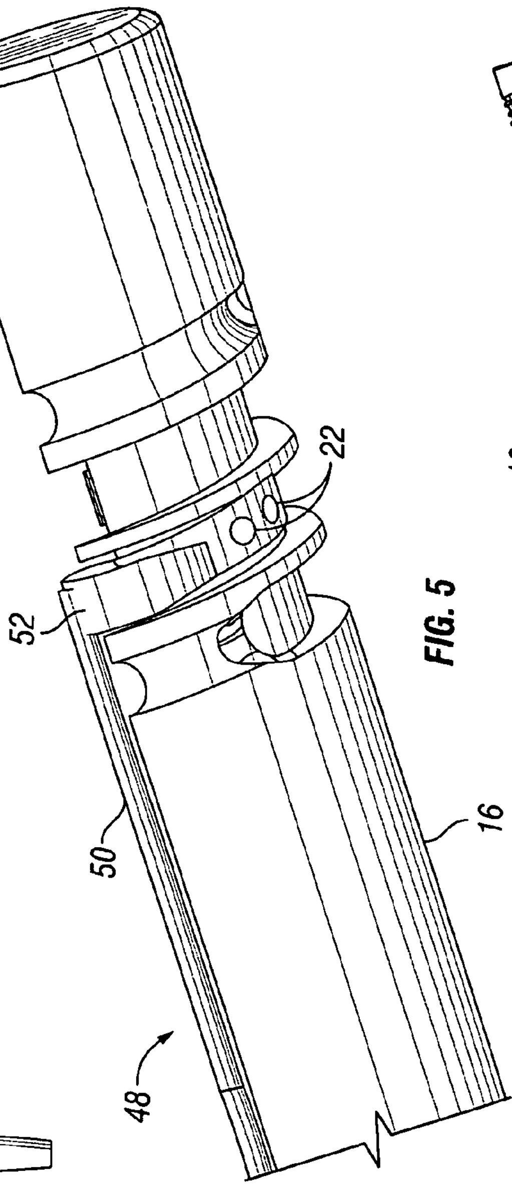


FIG. 5

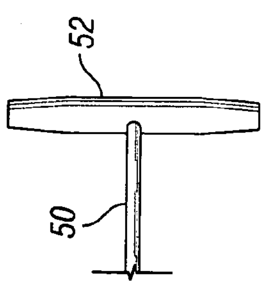


FIG. 4

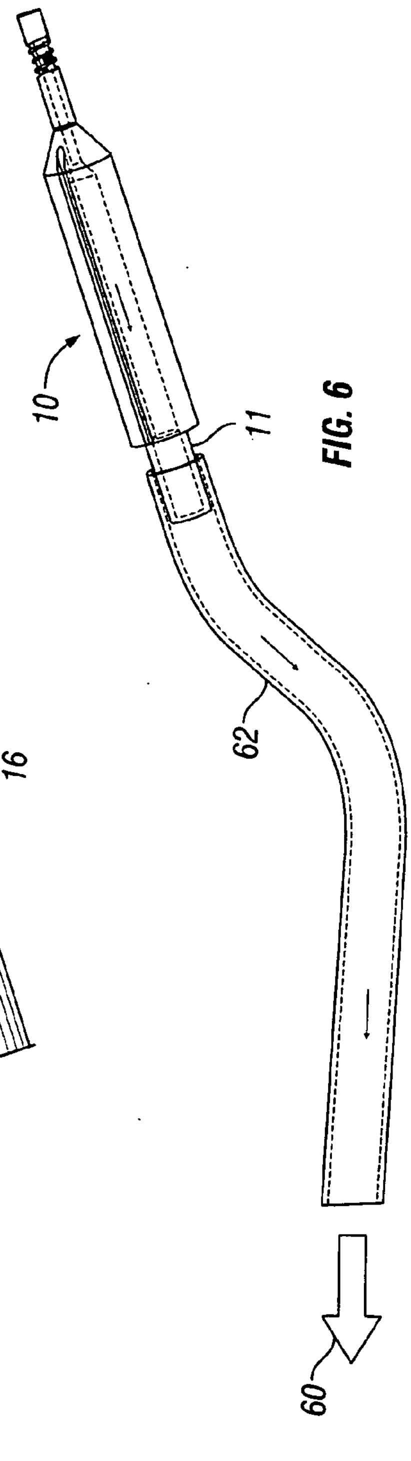


FIG. 6

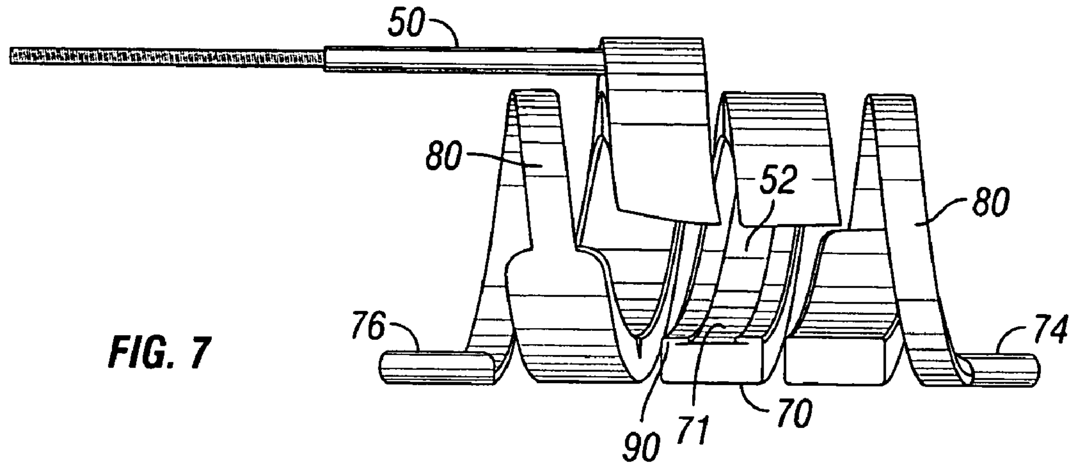


FIG. 7

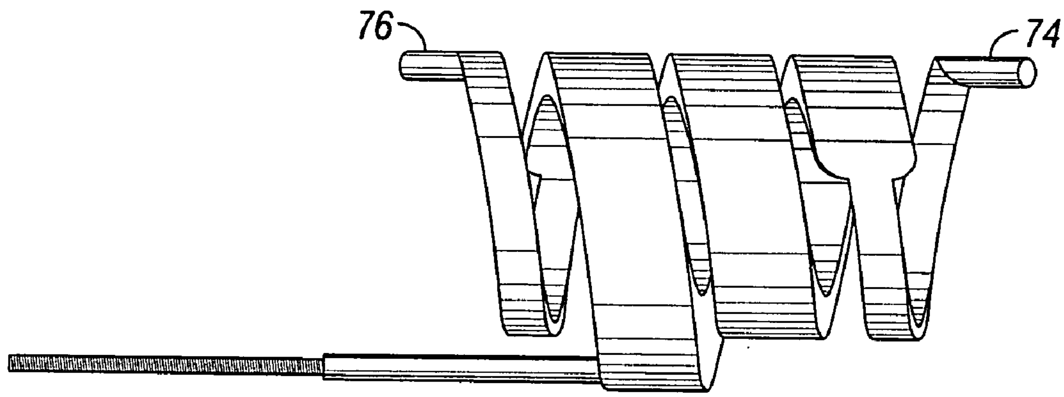


FIG. 8

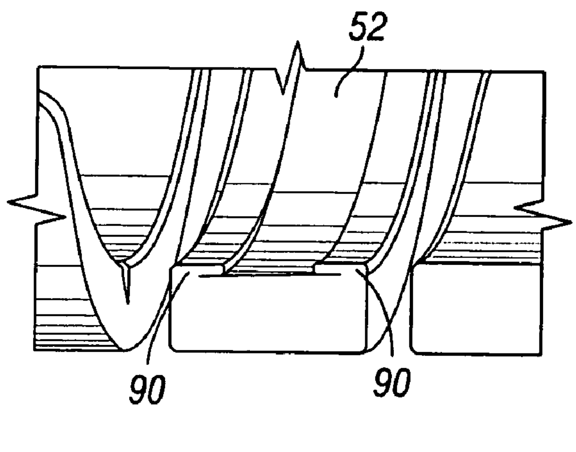


FIG. 9

VACUUM MANDREL FOR USE IN FABRICATING AN IMPLANTABLE ELECTRODE

BACKGROUND

[0001] Many types of implantable medical devices, such as pacemakers, defibrillators, and vagus nerve stimulators, have leads connected to an electronics unit. The distal end of the lead typically comprises or is coupled to one or more conductive electrodes. Such electrodes are typically fragile and thus should be handled carefully by the implanting surgeon when attaching the electrode to the relevant tissue to be stimulated. Fabrication of such electrodes is often a painstaking, time-consuming process.

BRIEF SUMMARY

[0002] A vacuum mandrel is disclosed that is used during the fabrication of an implantable conductive electrode. In accordance with at least one embodiment, the mandrel comprises a hollow body member having an axis, a first groove provided radially on an outer surface of the hollow body member, and a vacuum port provided in the groove. The first groove is adapted to receive the implantable electrode. In a particular embodiment, the first groove is a spiral groove around the outer periphery of the hollow body. By application of vacuum pressure through the hollow body member and the vacuum port, an electrode can be retained in place in the first groove while an elastomer, or another type of insulating material, is applied to the electrode. One or more second grooves, which are preferably longitudinal relative to the axis of the hollow body member, may be provided on opposing ends of the spiral groove to receive the elastomer and thereby form gripping members that an implantation surgeon can use when coupling the resulting electrode to a neural tissue such as a vagus nerve.

[0003] In accordance with another embodiment, a method comprises locating a conductive electrode formed on end of a lead adjacent a first, preferably spiral, groove in a vacuum mandrel, retaining the conductive electrode in the first groove through vacuum pressure applied through the at least one port, and applying an insulator over the conductive electrode while the electrode is retained in place in the first groove. The first groove contains at least one port through which the vacuum is applied to retain the conductive electrode in place.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] For a detailed description of exemplary embodiments of the invention, reference will now be made to the accompanying drawings in which:

[0005] FIGS. **1***a*-**1***c* show a vacuum mandrel in accordance with a preferred embodiment of the invention;

[0006] FIG. **2** shows an enlarged portion of the vacuum mandrel;

[0007] FIG. **3** shows a side of the vacuum mandrel opposite from that shown in FIGS. **1** and **2**;

[0008] FIG. **4** shows a ribbon electrode provided on a lead;

[0009] FIG. **5** shows a view of the vacuum mandrel with an electrode wrapped around a groove formed in the mandrel in accordance with a preferred embodiment of the invention;

[0010] FIG. **6** illustrates the connection between the vacuum mandrel and a vacuum source;

[0011] FIG. **7** shows a lead with coil electrode formed thereon and elastomer formed on a portion of the electrode in accordance with a preferred embodiment of the invention;

[0012] FIG. **8** shows a completed electrode assembly in accordance with embodiments of the invention; and

[0013] FIG. **9** shows an enlarged portion of FIG. **7**.

DETAILED DESCRIPTION

[0014] The following discussion is directed to various embodiments of the invention. Although one or more of these embodiments may be preferred, the embodiments disclosed should not be interpreted, or otherwise used, as limiting the scope of the disclosure, including the claims. In addition, one skilled in the art will understand that the following description has broad application, and the discussion of any embodiment is meant only to be exemplary of that embodiment, and not intended to intimate that the scope of the disclosure, including the claims, is limited to that embodiment. Any numerical dimensions provided herein are merely exemplary and do not limit the scope of this disclosure or the claims that follow.

[0015] FIG. **1***a* shows a plan view of a vacuum mandrel **10** in accordance with a preferred embodiment of the invention. The mandrel **10** comprises an elongate hollow body member formed from stainless steel or tool steel and has an exterior finish of nickel plating with Teflon®. As illustrated FIG. **1***b*, the mandrel **10** is generally circular in cross section, although other cross sectional shapes are possible as well. As shown, the vacuum mandrel **10** comprises a plurality of segments **12**, **14**, and **16**. Segment **12** has a diameter D**3** that, as is evident from FIG. **1***a*, is greater than the diameter D**1** of segment **16**. In accordance with at least one embodiment, D**1** is approximately 0.171 inches and D**3** is approximately 0.50 inches. The length L**1** of segment **12** preferably approximately is 2.094 inches and the length L**3** of segment **16** preferably is approximately 0.875 inches. Segment **12** includes a tip portion **11** provided at one end as shown in FIG. **1***a*. Tip portion **11** has a diameter D**2** of approximately 0.312 inches and a length L**4** of approximately 0.625 inches. Segment **14** has a generally frustoconical shape that transitions between segments **12** and **16**. The slope of segment **14** preferably is at an angle A**1** of approximately 60 degrees as shown in FIG. **1***a*, and the length L**2** of segment **14** is approximately 0.281 inches. Mandrel **10** may be formed as a unitary hollow body or in multiple pieces that are joined together in a suitable manner (e.g., by welding).

[0016] Segment **16** includes a first, preferably spiral (e.g., helical) groove **20** formed radially about the outer surface of segment **16** as shown in FIG. **1***a*. FIG. **2** shows an enlarged view of segment **16** of the vacuum mandrel. In the embodiments of FIGS. **1** and **2**, the first groove **20** comprises a spiral groove having about 2.5 revolutions around the outer surface of the mandrel. It will be appreciated by persons of skill in the art that non-spiral grooves can be used, and that where a spiral groove is employed the number of revolutions of the groove can be varied. The first groove **20** can have any dimensions that are suitable for the application described herein. In one embodiment, the groove **20** has a generally flat bottom surface **21** and flat side walls **23** formed generally perpendicular to the bottom surface **21**. In this embodiment, the groove has a rectangular cross-sectional shape, with a width W**1** of approximately 0.053 to 0.058 inches and a height H**1** of approximately 0.024 to 0.028 inches.

[**0017**] As best shown in FIG. **2**, a raised surface **25** is provided within groove **20**. The raised surface **25** preferably is formed integrally with the segment **12** although, in other embodiments, the raised surface can be a separately formed component that is then adhered in a suitable manner (e.g., welded, glued, etc.) to surface **21**. The raised surface **25** preferably has a height relative to the bottom surface **21** of approximately 0.002 to 0.003 inches and a width W**2** that is less than the width W**1** of the groove **20**. In one embodiment, the width W**2** of the raised surface **25** may range from approximately 0.028 to 0.032 inches. In such embodiments, therefore, the width W**2** of the raised surface is approximately 45% to 60% of the width W**1** of the first groove **20**. At least one vacuum port **22** is provided within the first groove **20**. In accordance with one embodiment, eight vacuum ports **22** are provided, although any number of ports sufficient to retain an electrode in place in the first groove may be employed. Preferably, the vacuum ports **22** comprise bore holes that extend through the raised surface **25** and into the hollow interior portion of segment **16**. In at least one embodiment, the eight radially extending vacuum ports **22** are spaced apart in increments of 30 degrees.

[**0018**] Referring to FIG. **1***a*, segment **12** of mandrel **10** comprises a lead groove **36** provided longitudinally along at least some or all of the length of segment **12**. Referring to FIGS. **1***a* and **1***c*, the lead groove **36** that is provided longitudinally along segment **12** relative to a plane that contains central axis **19** preferably is formed in the outer surface of the segment **12** at a location disposed on an angular measure A**2** from the plane. In one embodiment, the lead groove **36** preferably has a depth D**8** of approximately 0.089 inches and a width W**3** of approximately 0.063 inches. As will be explained above, an implantable lead resides in the lead groove **36** during fabrication of an electrode. Thus, the lead groove **36** has an engaging surface that engages the electrode during manufacturing.

[**0019**] The interior of the hollow body member is shown in FIG. **1***b*. In the embodiment depicted, the dimensions of the hollow interior of the body vary, although persons of skill in the art will appreciate that various hollow chamber designs may be employed. The hollow interior of segment **12** is shown with a diameter D**4** of approximately 0.19 inches. The hollow interior of segments **14** and **16** has a diameter D**5** of approximately 0.06 inches. The hollow interior of segment **16** extends to the end of, or just beyond the end of, the first groove **20**. The hollow interior may also extend throughout the hollow body and be sealed off via a plug fastened by various techniques such as welding, screw threads, or adhesive.

[**0020**] FIGS. **1***a* and **2** also show one or more second grooves **30**, **32** formed at, or near, opposing ends of first groove **20**. Second grooves **30** and **32** may advantageously have a different cross-sectional shape than groove **20**. Each second groove **30**, **32** preferably is curved and extends circumferentially preferably for less than one complete revolution around segment **16** and, in some embodiments, extends for three-fourths of one revolution. As better shown in FIG. **3**, each second groove **30** and **32** ends in a longitudinal groove portion **31** and **33**, respectively. Each second groove **30**, **32** may have a pitch of approximately from 0.65 to 0.70, a radius of curvature of approximately 0.020 inches and a depth D**9** (shown in FIG. **2**) of approximately 0.018 inches. Each of the longitudinal groove portions **31** and **33** may have a length D**7** (FIG. **3**) of approximately 0.074 inches. Further, each second groove **30**, **32** begins at or near an end of the first groove **20**. For example, second groove **32** begins at end **37** (FIG. **2**) of first groove **20**. The beginning of each second groove **30**, **32** preferably is centered within first groove **20** thereby forming a continuous groove within the body segment **16**. In one embodiment, each second groove **30** and **32** preferably comprises a spiral curved groove that extends for three-fourths of a revolution and the central flat-bottom groove **20** (having bottom surface **21**) extends for 2.5 revolutions. Thus, the combination of the two spiral curved second grooves **30** and **32** and the central flat first groove **20** form a groove that extends for, in a particular embodiment, four total revolutions around the body segment **16**.

[**0021**] The vacuum mandrel **10** may be used during a manufacturing process for an electrode. The electrode preferably comprises an electrode such as may be used in conjunction with an implantable medical device such as a vagus nerve stimulator. FIG. **4** shows an electrode **52** provided on an end of lead **50**. The electrode **52** preferably is an electrically conductive ribbon electrode that, when further processed as described below, can be attached to a nerve or nerve bundle such as a cranial nerve (e.g., a vagus nerve). The electrode **52** preferably comprises a conductive ribbon electrode formed from platinum, platinum-iridium, or other suitable material. In a particular embodiment, the electrode **52** is approximately 0.040 inches wide by approximately 0.500 inches long by approximately 0.0005 inches thick. The electrode **52** is coupled (e.g., welded) to the lead **50** at approximately the mid-point of the electrode. The lead **50** comprises an electrical conductor that is covered by an insulator and that electrically couples the implanted device (not shown) to electrode **52** provided on the end of the lead. When implanted, the electrode **52** is placed in contact with the tissue to be stimulated. Through the lead **50** and electrode **52**, the implanted device is able to deliver electrical current to the tissue to be stimulated.

[**0022**] FIG. **5** shows the body segment **16** of the vacuum mandrel **10** with the lead **50** and electrode **52** disposed thereon. The electrode **52** is placed on the mandrel and wrapped around and located within at least a portion of the first groove **20**. By residing in the first groove **20**, the ribbon electrode covers at least one or more, and preferably all, of the vacuum ports **22**. FIG. **5** also shows the lead **50** extending down the length of the segment **16**. The remaining length of the lead rests in the longitudinal lead groove **36** formed in segment **12** (FIG. **1***a*).

[**0023**] FIG. **6** illustrates the vacuum mandrel **10** coupled to a vacuum tube **62** that, in turn, connects to a vacuum source **60**. The vacuum tube **62** preferably comprises a flexible hose of rubber or other suitable material. The tip **11** of the vacuum mandrel is inserted into the vacuum tube **62**. Once the vacuum source **60** is turned on, the vacuum pressure thereby created through the mandrel **10** and vacuum ports **22** will cause the ribbon electrode to be retained in place during the next part of the manufacturing process. The raised surface **25** provides an engaging surface for the electrode in groove **20** and enables the electrode edges to be encapsulated by the elastomer/insulator. In one embodiment, the vacuum pressure is approximately 28 inches Hg, although the pressure can be varied as desired.

[**0024**] With the electrode held in place in first groove **20** by vacuum pressure, the next step in the manufacturing process is to apply an insulator such as an elastomer to all, or substantially all, of the lengths of first groove **20**, and second grooves **30** and **32**, thereby covering the ribbon electrode with the insulator. The ribbon electrode **52** preferably does not extend throughout the combined lengths of first groove **20** and second grooves **30** and **32**, and as such a portion of the insulator fills the grooves beyond the reach of the ribbon electrode. The insulator is applied by spraying or pouring by methods well known in the art. In a particular embodiment, the insulator comprises a silicone elastomer. However, persons of skill in the art will appreciate that other elastomers, and other insulators may be used.

[**0025**] The insulator is then permitted to cure. Once cured, vacuum source is turned off and the lead **50** and insulator-covered electrode **52** assembly can be removed from the vacuum mandrel. Examples of the completed electrodes **52** are shown in FIGS. **7** and **8**. FIG. **7** shows an electrode with a cut away portion to better illustrate the elastomer **70** covering the ribbon electrode **52**. Because the elastomer cured while the electrode **52** was still wrapped in the spiral first groove **20** of the vacuum mandrel, the resulting electrode generally retains the shape of the first groove **20**. Other shapes are, of course, possible depending upon the needs of the particular application in which the electrode will be used. Further, because the elastomer covered the exposed electrode **52** and was not able to penetrate between the electrode **52** and the raised surface **25** of the first groove **20**, one side of the electrode is not covered with elastomer, i.e., the interior surface **71** of the spirally formed electrode. This interior surface is the surface that will be in contact with the body tissue (e.g., a vagus nerve) being stimulated. The elastomer generally is an electrical insulator and thus the surface of the electrode opposite the body tissue is electrically insulated from other body tissues while the surface of the electrode touching the nerve is in electrical contact with the nerve.

[**0026**] The raised surface **25** on which the ribbon electrode rests while the elastomer is applied causes elastomer to fill the sides of the first groove **20** adjacent the electrode. As a result, some of the elastomer, such as that shown at reference numeral **90**, covers the side edges of the ribbon electrode and thereby covers any sharp edges that might otherwise cut into the nerve to which the electrode is attached. The relationship between the elastomer and the edges of the electrode are better shown in the enlarged view of FIG. **9**.

[**0027**] Reference numeral **80** in FIG. **7** shows the elastomer that was applied to the spiral second grooves **30** and **32**. The width of second grooves **30** and **32** preferably is less than the width of first groove **20** as measured in the direction parallel to axis **19**. As such, as shown in FIG. **7**, the two elastomer end portions **80** of the electrode assembly are narrower than the central portion that contains the ribbon electrode.

[**0028**] The longitudinal groove portions **31** and **33** (FIG. **3**) are also filled with elastomer. After the elastomer cures and the electrode is removed from the mandrel, the elastomer that filled the longitudinal groove portions **31** and **33** form gripping portions **74** and **76**, respectively. The gripping portions **74** and **76** are used during implantation to attach the electrode to the nerve. More specifically, the gripping portions **74** and **76** are pulled in opposite directions using, for example, forceps. Pulling the gripping surfaces **74** and **76** apart in this manner stretches the spiral electrode so that it can be wrapped around the nerve. Once wrapped around the nerve, the gripping portions **74** and **76** are released and the spring-like nature of the spiral electrode **52** causes the electrode naturally to attach itself to the nerve.

[**0029**] Another prior type of spiral electrode included a thread suture embedded in the elastomer. The ends of the suture protruded from the electrode and functioned as gripping mechanisms for the implantation surgeon. Unfortunately, embedding a thread suture in a spiral electrode adds complexity and time to the manufacturing process of such an electrode. Gripping portions **74** and **76** obviate the need for such a thread suture, although one could be included if desired. Without such a thread suture, the manufacturing of the disclosed electrode is made easier and less time consuming.

[**0030**] The above discussion is meant to be illustrative of the principles and various embodiments of the present invention. Numerous variations and modifications will become apparent to those skilled in the art once the above disclosure is fully appreciated. It is intended that the following claims be interpreted to embrace all such variations and modifications.

What is claimed is:

1. A vacuum mandrel for use in fabricating an implantable electrode, comprising:

a hollow body member having an outer surface;

a first groove on said outer surface, adapted to receive an electrode member; and

a vacuum port provided in said first groove.

2. The vacuum mandrel of claim 1 wherein said first groove is a spiral groove.

3. The vacuum mandrel of claim 2 further comprising a plurality of vacuum ports provided in said spiral groove.

4. The vacuum mandrel of claim 1 further comprising a longitudinal groove portion provided at an end of said first groove.

5. The vacuum mandrel of claim 1 further comprising a pair of second grooves provided at or near opposing ends of said first groove, each of said second grooves ending in a longitudinal groove portion.

6. The vacuum mandrel of claim 5 wherein each of said second grooves is provided on said hollow body member for less than one revolution.

7. The vacuum mandrel of claim 1 further comprising a raised surface in said first groove through which said vacuum port is provided.

8. The vacuum mandrel of claim 7 wherein the first groove comprises a first width and the raised surface comprises a second width that is less than the first width.

9. The vacuum mandrel of claim 7 wherein the raised surface has a height of approximately 0.002 to 0.003 inches.

10. The vacuum mandrel of claim 1 wherein said hollow body member comprises a distal segment and a proximal segment, and wherein said first groove is located in said distal segment.

11. An electrode fabrication system, comprising:

the vacuum mandrel of claim 10;

a lead;

an electrode coupled to an end of said lead, said electrode being positioned in said first groove of said vacuum mandrel;

a longitudinal groove provided along at least a portion of the distal segment of said hollow body member, in which at least a portion of the lead is positioned.

12. An electrode fabrication system comprising:

the vacuum mandrel of claim 1;

a vacuum source in communication with said vacuum port via said hollow body member;

an electrode positioned over said vacuum port in said first groove and retained in position through the application of vacuum pressure by said vacuum source, to thereby permit an elastomer to-be applied to said first groove to cover said electrode.

13. The vacuum mandrel of claim 1 wherein said first groove has a width of approximately 0.053 to 0.058 inches.

14. The vacuum mandrel of claim 1 wherein said vacuum port has a diameter of approximately 0.018 inches.

15. A method of making an electrode, comprising:

providing a mandrel comprising a first groove in an outer surface thereof, and a vacuum port in said first groove,

providing an electrode coupled to an end of a lead;

positioning said electrode in said first groove over said vacuum port; and

retaining said electrode in said first groove through vacuum pressure applied through said vacuum port; and

applying an elastomer over said conductive electrode while said electrode is retained in said first groove.

16. The method of claim 16 wherein said vacuum mandrel further comprises at least one longitudinal groove formed at one end of said spiral groove, and wherein applying said elastomer comprises applying said elastomer to said and least one longitudinal groove.

17. An electrode manufactured according to a method comprising:

locating a conductive ribbon electrode in a first groove of a hollow body member, said groove containing at least one vacuum port; and

retaining said conductive electrode in said spiral groove through vacuum pressure applied through said at least one vacuum port; and

applying an elastomer over said conductive electrode while said electrode is retained in place.

18. The electrode of claim 17 further manufactured by applying the elastomer in at least one longitudinal groove portion formed on the hollow body, the elastomer applied to said a least one longitudinal groove portion comprising a gripping surface to be used during implantation.

19. An apparatus for holding an implantable electrode in place during a manufacturing process, comprising:

an elongate body having an outer surface and a hollow interior portion;

a vacuum source in fluid communication with said hollow interior portion;

a channel formed in said outer surface and extending helically about said elongate body, said channel comprising an engaging surface for engaging the implantable electrode; and

at least one bore extending between said hollow interior portion and said engaging surface of said channel such that said bore and said hollow interior portion are in fluid communication.

20. The apparatus of claim 19 wherein the channel has a rectangular cross-sectional shape.

21. The apparatus of claim 19 wherein the engaging surface is raised from a bottom surface of said channel.

22. The apparatus of claim 19 wherein said channel extends for approximately 2.5 turns about said outer surface.

23. The apparatus of claim 19 wherein said elongate body has a longitudinal axis and said channel has opposing ends that extend in a direction generally parallel to the axis.

* * * * *