Cyberonics®

Implantation Procedure

VNS Therapy® System

For Healthcare Professionals

October 2010

Worldwide Version

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

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2011

***Note*:** This is one part of a multi-part physician's manual. The information contained herein is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the physician's manual sections for the VNS Therapy System and its component parts, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes.

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1. PHYSICIAN TRAINING / INFORMATION

All VNS Therapy® System programming should be by or under the supervision of a physician familiar with the use and operation of the Programming Software.

1.1. Training Materials

Physicians implanting the VNS Therapy System should be thoroughly familiar with all associated training materials, including:

- Product labeling for the Pulse Generator, Lead, and accessories, including physician and patient manuals and directions for use
- *"Implant Guide for the VNS Therapy System"* training manual and other brochures
- Video on the proper implantation technique: "Implantation of the VNS Therapy System"
- Electrode practice fixture—a device used to practice placing the helices around the left vagus nerve

2. VNS Therapy Devices

2.1. Generator Package Contents

The Generator package contains the following:

- 1 Cyberonics® VNS Therapy Pulse Generator (single receptacle or dual receptacle)
- 1 hex screwdriver
- 1 resistor assembly
- Documentation

Note: Ensure that at least one back-up Pulse Generator is available before starting the procedure.

2.2. Lead Package Contents

The Lead package contains the following:

- 1 VNS Therapy Lead
- 4 (or more) silicone tie-downs
- Documentation

Note: Ensure that at least one back-up Lead is available before starting the procedure.

2.3. Other Cyberonics Products

- 1 VNS Therapy Tunneler (sterile)
- 1 VNS Therapy Accessory Pack (sterile)
- 1 VNS Therapy Programming System (non-sterile)

Note: Remember to use proper technique for introducing non-sterile items into a sterile field.

2.4. Surgical Materials

The following is a list of additional materials typically used during the VNS Therapy implantation procedure:

- Sterile Laser Arm Bag or equivalent (required)
- Vessel loops and/or silicone sheet for manipulation of the vagus nerve (suggested but optional)

Note: These items are not provided by Cyberonics.

Caution: The sterile Lead package should only be opened after exposing the vagus nerve and selecting the Cyberonics Lead helical that best fits.

Caution: Do not open the package if it has been exposed to extreme temperatures or if there is any indication of external damage or damage to the package seal. Instead, return it unopened to Cyberonics.

2.5. To Open the Sterile Package

Before the package is opened, it should be examined carefully for evidence of damage or compromised sterility. If the outer or inner package has been opened or damaged, Cyberonics cannot guarantee sterility of the Pulse Generator or Lead, and it should not be used. An opened or damaged product should be returned to Cyberonics.

To open the package, do the following:

1. Grasp the tab, and peel back the outer cover.
2. Observing sterile technique, lift out the sterile inner tray.
3. Grasp the inner tray's tab, and carefully peel off the inner cover to expose the contents without dropping them.

3. Recommendations for Implantation

In general, implantation of the VNS Therapy System is similar to accepted practice for implantation of a cardiac pacemaker, with the exception of the placement of the helices and the subcutaneous routing of the Lead body. Although the surgical approach and techniques will vary with the preference of the implanting physician, to ensure correct Lead placement, this part of the multi-part physician's manual provides recommendations for implantation, along with a detailed description of the order of placement of the helical electrodes and the anchor tether and other essential steps.

Caution: To maximize system performance and minimize possible mechanical damage to the nerve or Lead, **pay careful attention to helical placement and Lead routing.**

Critical to the long-term success of the implant are proper techniques both for the attachment of the electrodes and the anchor tether to the left vagus nerve, and for the provision of adequate strain relief below and above the sternocleidomastoid muscle.

Note: See Figure 1 on page 11 for general placement of the Pulse Generator and Lead.

It is recommended that the Lead body be coiled and placed in the chest pocket to the side of the Pulse Generator.

Adequate exposure of the vagus nerve (>3 cm) facilitates placement of the helices on the nerve. Stretching the nerve or allowing it to dry during implantation may result in temporary swelling of the nerve. Constriction of the nerve or other nerve damage may result in vocal cord dysfunction.

Cyberonics recommends that output of the Pulse Generator and performance of the implanted system be tested at the time of implantation. Although an oscilloscope can be used for measurements, Cyberonics recommends use of the appropriate version of the Programming Software and Programming Wand (placed in a sterile drape) for routine system verification.

Note: See "Test the VNS Therapy System" on page 27.

After the electrode is placed on the nerve, the electrode-nerve interface impedance is tested by connecting the Lead directly to the Pulse Generator and performing a System Diagnostics (Lead Test). The Pulse Generator is packaged with a separate resistor assembly to be used while performing the optional Generator Diagnostics (Pre-Implant Test).

3.1. Before Surgery and Outside of the Sterile Field

Caution: (For 103 and subsequent models only) If interrogating a Pulse Generator that has been exposed to low temperatures within the last 24 hours, low battery status indicator(s) may be displayed. See the "Troubleshooting" section in the *Technical Information* part of this multi-part physician's manual.

3.1.1. Interrogate the device

To ensure proper device communication, interrogate the device while still in the sterile package. [See the Programming Software physician's manual for a detailed explanation or the Programming Software instruction card (handheld) for a quick reference.]

3.1.2. Program patient data

Program the patient identification and implant date into the Pulse Generator. [See the Programming Software physician's manual for a detailed explanation or the Programming Software instruction card (handheld) for a quick reference.]

3.2. Procedure Overview

Caution: This procedural overview is not a substitute for the complete implantation procedure.

The following overview summarizes the recommended sequence for implanting the Lead:

1. Expose the left carotid sheath and left vagus nerve.
2. Create a pocket in the chest for the Pulse Generator.
3. Choose the correct size Lead.
4. Tunnel the Lead subcutaneously from the neck to the Pulse Generator pocket in the chest.
5. Attach the electrodes and anchor tether to the left vagus nerve.
6. Secure the Lead parallel to the nerve.
7. Form the strain relief bend and strain relief loop.
8. Connect the Lead to the Pulse Generator.
9. Verify that the connector pin is fully inserted, and tighten the setscrew.
10. Perform the System Diagnostics (Lead Test).
11. Place the Pulse Generator in the chest pocket, with the extra coiled Lead to the side of the Pulse Generator, not behind it.
12. Secure the Pulse Generator to fascia; do not place sutures directly around or on the Lead.
13. Perform the second System Diagnostics (Lead Test).
14. Interrogate the Pulse Generator to verify current is 0.0 mA.
15. Irrigate the incision site with bacitracin or other solution.
16. Close the incisions.

3.3. Prepare for Surgery

The surgeon should ensure that the Pulse Generator, Lead, and Tunneler are compatible.

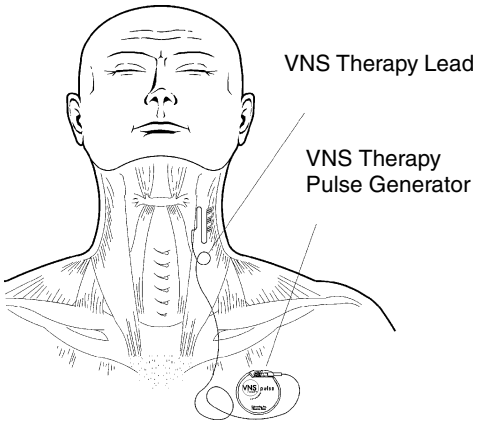
Cyberonics recommends that the patient be given antibiotics preoperatively and that both incision sites be irrigated frequently with generous amounts of bacitracin or equivalent solution prior to closure. (These incisions should be closed with cosmetic closure techniques to minimize scarring.) Also, antibiotics should be administered postoperatively at the discretion of the physician.

Caution: **Infections related to any implanted device are difficult to treat,** and explantation of the VNS Therapy System may be required.

4. LEAD AND POCKET LOCATION

The Pulse Generator is usually implanted just below the clavicle in a subcutaneous pocket in the left upper chest. Suggested placement for the Lead is the area of the left vagus nerve half-way between the clavicle and the mastoid process, with the Lead subcutaneously tunneled between the incision site in the neck and the pocket formed in the upper chest (see Figure 1). It is recommended that both the Lead body and the Pulse Generator be positioned on the left side of the body. The Cyberonics VNS Therapy Tunneler is recommended for subcutaneous routing of the Lead.

Figure 1. Placement of Pulse Generator and Lead



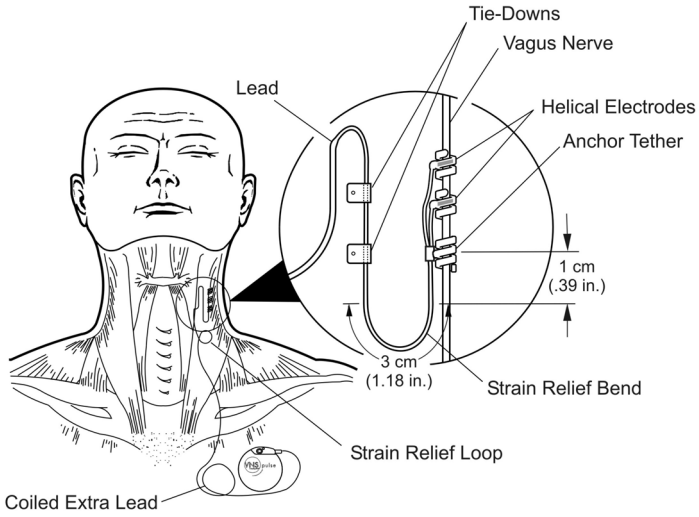
5. BEGIN THE PROCEDURE

While the specific surgical approach and techniques for implanting the Lead will vary with the physician performing the implant, the following detailed instructions are provided for guidance:

1. After administering appropriate anesthesia to the patient, expose the left carotid sheath as it extends along the anterior border of the sternocleidomastoid muscle.
2. Locate and expose *at least 3 centimeters (1.18 inches)* of the left vagus nerve. The recommended stimulation site is a 3-cm section of the vagus nerve, approximately half-way up between the clavicle and the mastoid process, where it is clear of branches (below where the superior and inferior cervical cardiac branches separate from the vagus nerve—see Figure 2 and Figure 4). The nerve usually lies in a posterior groove between the carotid artery and internal jugular vein.

Caution: Avoid letting the vagus nerve become dry during surgery, because dehydration of the nerve can result in nerve damage and swelling.

Figure 2. Electrode Placement



3. Create a subcutaneous pocket in the chest below the clavicle for the Pulse Generator.

Note: It is preferable to place the subcutaneous pocket along the axillary border.

6. IMPLANT THE LEAD

To implant the Lead, follow these steps:

6.1. Choose a Lead

1. Choose the appropriately sized Lead (2.0 or 3.0 mm electrode inner diameter) carefully. It should fit snugly without constricting the nerve. The Lead (2.0 mm/.08 in) should accommodate most nerves.

Note: For Lead size availability, see the "Product Specifications" section in the *Technical Information* parts of the Lead physician's manuals.

Caution: The Lead is available in multiple sizes. Since it is not possible to predict in patients what size Lead will be needed, **Cyberonics recommends that at least one alternate Lead size be available in the operating room.** In addition, backups for Leads should be available in the event of compromised sterility or damage induced during surgery.

Caution: Do not expose the Lead to dust or other similar particulates, because its silicone insulation can attract particulate matter.

Caution: Do not soak the Lead in saline or similar solution before implanting it, because this may cause the insulated portions of the connector pin to swell and become difficult to insert into the Pulse Generator.

6.2. Pass the Tunneler and Lead

Note: A detailed description of the tunneling tool can be found in the *Cyberonics Tunneler Directions for Use.*

The Cyberonics Tunneler is used to tunnel the Lead connector and Lead body subcutaneously from the neck incision site to the Pulse Generator in the chest pocket. As an alternative, the Lead connector and Lead body can be tunneled subcutaneously from the neck incision site to the Pulse Generator in the chest pocket *after placement of the electrodes and anchor tether on the nerve, and placement of strain relief with the tie-downs.* (See "Place the Electrodes" on page 15 and "Provide Strain Relief" on page 20, respectively.)

Caution: To maximize system performance and minimize possible mechanical damage to the nerve or Lead, pay careful attention to Lead routing, Lead stabilization, and electrode placement.

Caution: Never route the Lead through muscle.

Caution: Never suture the Lead or Lead body to muscle tissue.

Caution: Always use the tie-downs.

Caution: Do not place sutures directly on the Lead body. Doing so may result in insulation damage or wire failure, causing premature failure of the Lead.

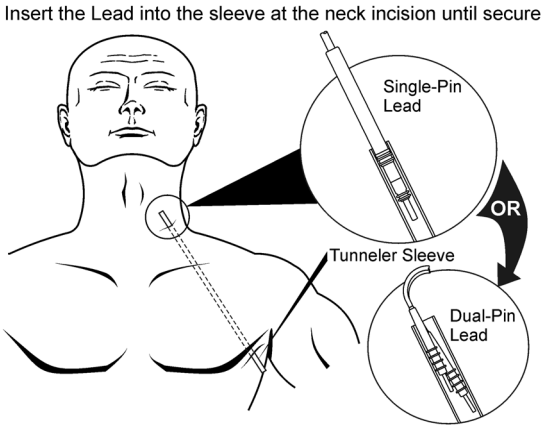
If necessary, the Tunneler can be manually shaped to help direct it through the body.

Do not manually shape the Tunneler **more than 25 degrees** because doing so may cause the sleeve to bend or kink.

To pass the Tunneler, do the following:

1. Place the bullet-tip end of the Tunneler through the neck incision and tunnel subcutaneously toward the chest incision, exerting force on the handle end and directing the Tunneler as necessary.
2. After the bullet tip has passed from one incision site to the other, unscrew the bullet and withdraw the shaft from the sleeve, leaving the sleeve extended through both incisions (see Figure 3).

Figure 3. Position of Sleeve and Lead Connector(s)



3. With the sleeve in place between the two incisions, carefully insert the Lead connector(s) inside the end of the sleeve at the neck incision. For a dual-pin Lead, the second connector will form a slight compression fit between the first Lead connector tubing and the inside of the sleeve (see Figure 3).
4. Carefully pull the sleeve, along with the Lead connector(s), from the chest incision end until the lead connector(s) completely exit(s) the chest incision.
5. Remove the Lead connector(s) from the sleeve, leaving the electrode array at the neck incision site.
6. Discard the Tunneler after use.

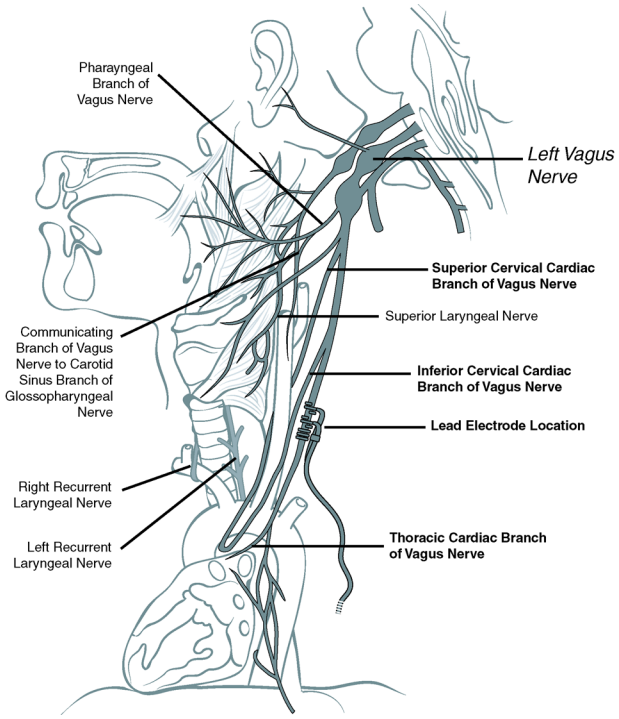
6.3. Place the Electrodes

Caution: Attachment of Lead electrodes must not involve the superior cervical cardiac branch or the inferior cervical cardiac branch of the vagus nerve. Place the electrodes *below* where these two branches separate from the vagus nerve.

Caution: Excessive manipulation of the vagus nerve during placement of the Lead can result in noticeable post-operative hoarseness. Under most circumstances, this condition will resolve without additional medical intervention within three to four weeks, depending on the degree of stress applied to the nerve during surgery. Cyberonics does not recommend that stimulation treatment be initiated until this condition has resolved, since it could aggravate the condition.

It is very important that the surgeon implanting the VNS Therapy System be familiar with vagus nerve anatomy, particularly the cardiac branches. The Lead electrodes must not be placed on either the superior or the inferior cervical cardiac branches. **Place the Lead below where the superior and inferior cardiac branches separate from the vagus nerve.** Stimulation of either of these two branches during the System Diagnostics (Lead Test) may cause **bradycardia and/or asystole.** Careful dissection laterally on the vagus nerve should aid the physician in determining proper electrode placement. In most but not all patients, the main vagus nerve is the largest of the three nerves. Figure 4 shows the correct anatomical placement of the helices.

Figure 4. Vagus Nerve Anatomy and Placement of the Lead

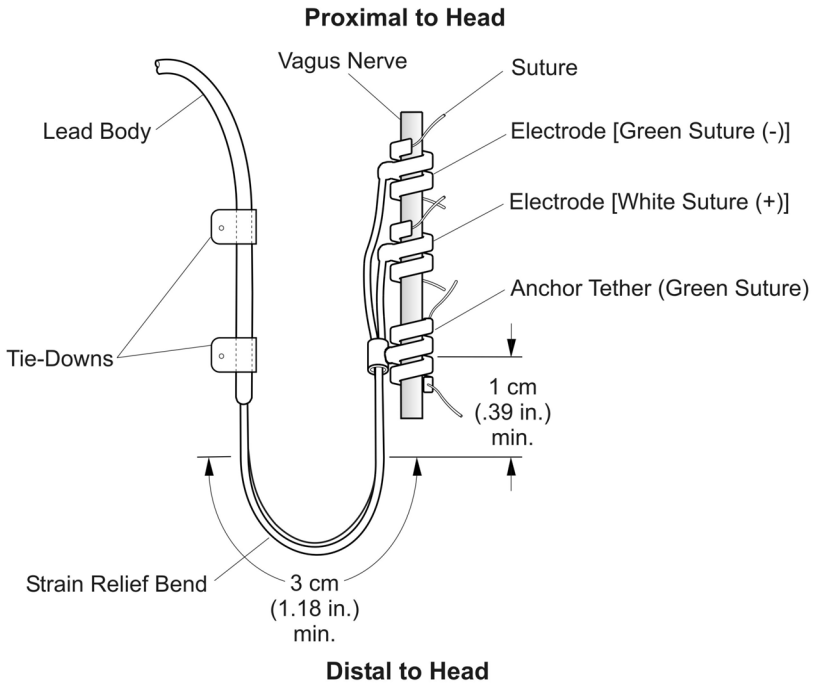


The helical electrodes and anchor tether are coiled around the nerve, beginning with the electrode that is farthest from the Lead bifurcation (with a green suture embedded in the helical material). This electrode should be nearest (proximal to) the patient's head.

Depending on the surgeon's preference, the helices can alternately be placed by putting the anchor tether on first (distal to head), next placing the electrode closest to the Lead bifurcation (with white suture), and then placing the electrode farthest from the Lead bifurcation (with green suture). The polarity of stimulation does not change (see Figure 5).

Caution: The Lead and helical electrodes are very delicate; be careful not to stretch, pinch, or crush them when using forceps, and not to over-straighten or stretch the helices when coiling them around the nerve, because doing so may damage the electrode or tether. Use soft rubber vessel loops to raise, or lift, the nerve, if necessary.

Figure 5. Electrode Polarity

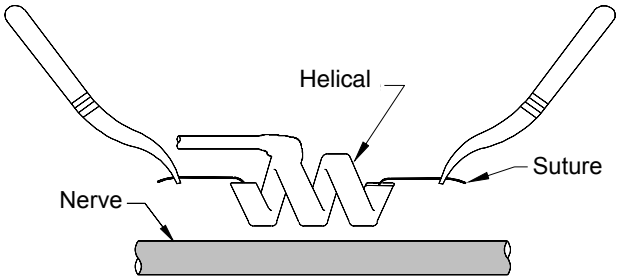


The helicals can be placed on the nerve as described below. As an alternative, each helical can be placed underneath the nerve before it is spread. A silicone sheet may be useful to separate the nerve from tissue during the procedure.

1. Coil the first helical (with green suture) in the following manner:
   a. With forceps, gently pull each end of the helical, using the attached sutures to spread the helical (see Figure 6).

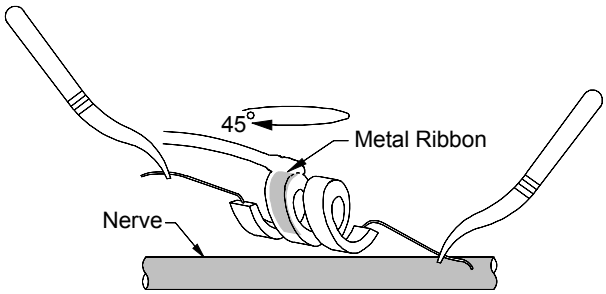
Caution: The suture may become dislodged from the helical if product labeling is not followed, i.e., grasping the elastomer and suture to manipulate the helical onto the nerve.

Figure 6. Spread the Helical



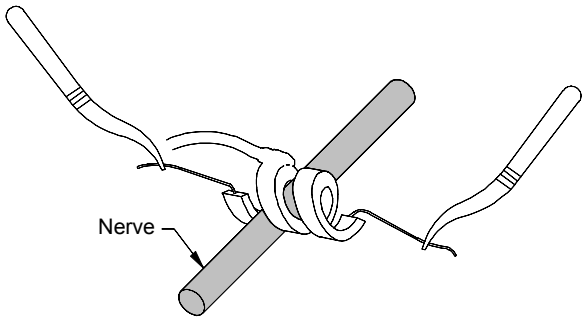
b. Starting with the opened helical spread directly above and parallel to the exposed nerve, turn the helical clockwise at a 45 degree angle to the nerve (see Figure 7).

Figure 7. Turn the Helical



c. Place the turn of the helical where the Lead wire connects to the helical (the section with the metal ribbon) onto the nerve (see Figure 8).

Figure 8. Placement of the Turn



d. Pass the *distal* suture portion of the helical under the nerve and back around so that it encircles the nerve (see Figure 9 and Figure 10).

Figure 9. Initial Placement of the Distal Portion of the Helical

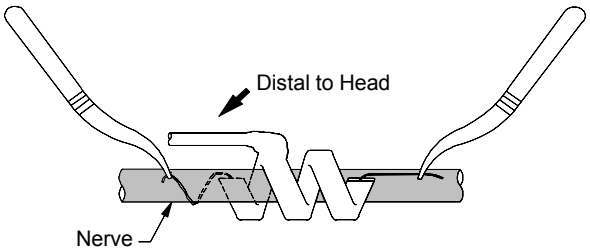
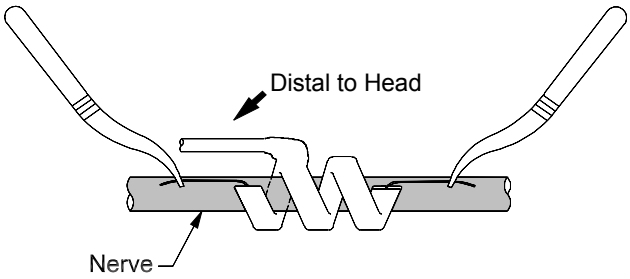
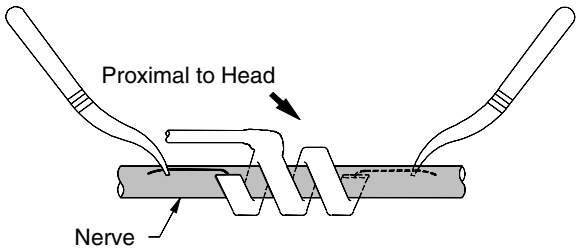


Figure 10. Helical Placement After Distal Portion Encircles the Nerve



e. Pass the *proximal* suture portion of the helical under the nerve and back around so that it encircles the nerve (see Figure 11).

Figure 11. Placement of the Proximal Portion of the Helical



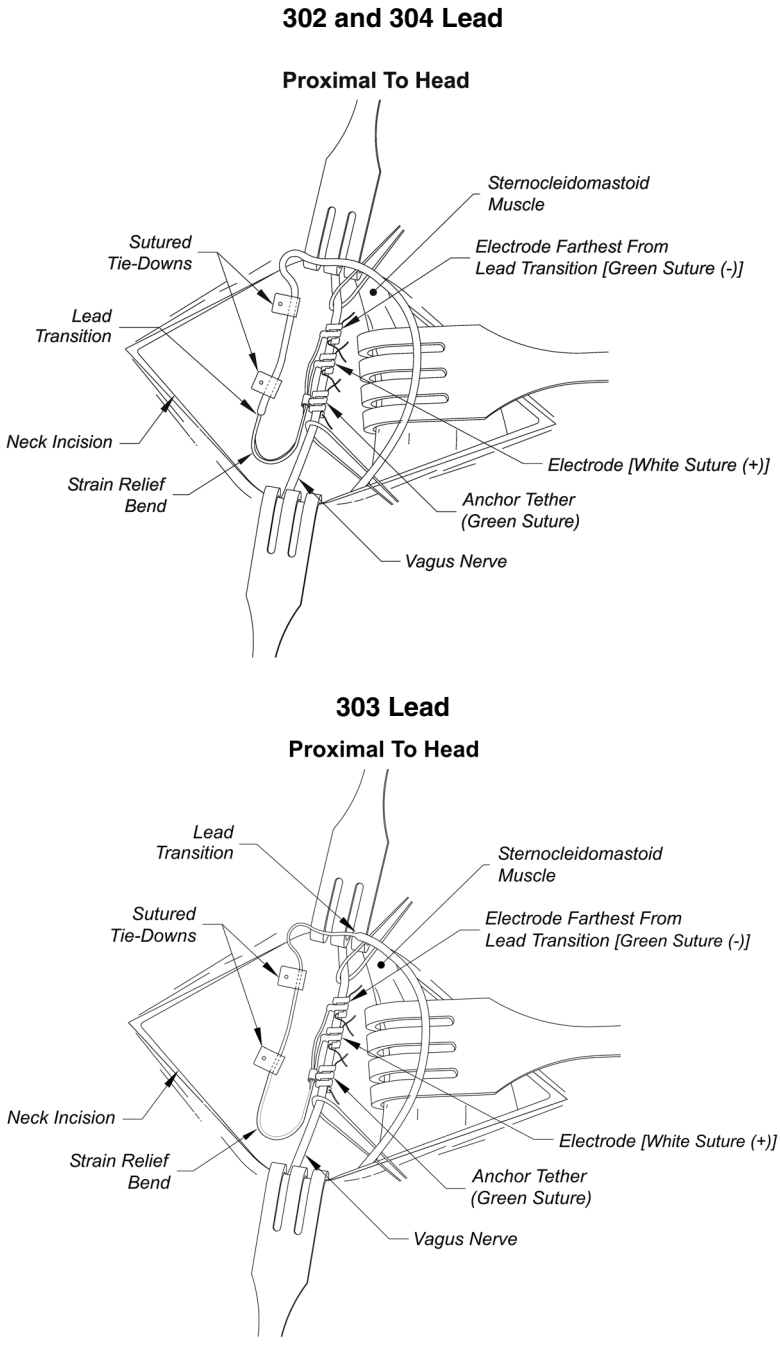
2. Repeat steps 1a through 1e for the middle helical (with white suture).
3. Next, place the third helical (with green suture) around the nerve, following the same general steps as for the other two helices.

Caution: Sutures that are part of the Lead (embedded in the helices of the electrodes and anchor tether) are meant to assist in helical placement around the vagus nerve. These sutures should not be tied to each other or around the nerve, since this may cause nerve damage.

Caution: Proper techniques for attaching the electrodes and the anchor tether to the left vagus nerve are critical to the long-term success of the implant.

4. After all three helices have been coiled around the nerve, verify that the Lead body exits each helical in the same direction and that the two Lead bodies are aligned parallel to each other and to the nerve. The correct placement of the two helical electrodes and anchor tether is shown in Figure 12.

Figure 12. Placement of Electrodes and Anchor Tether



6.4. Provide Strain Relief

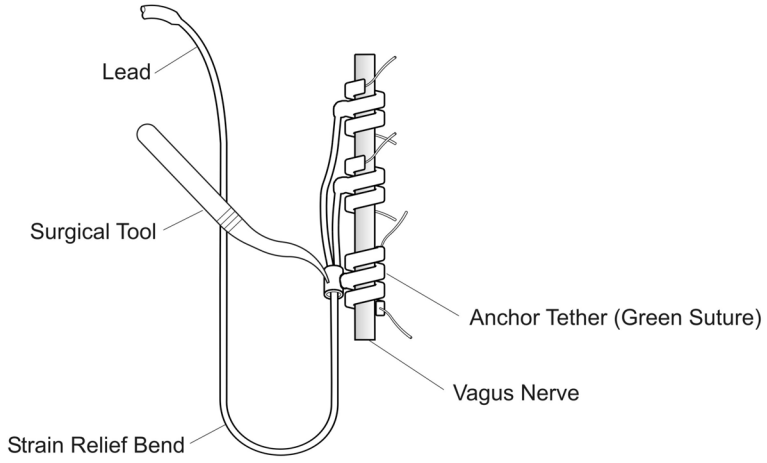
After attaching the two electrodes and the anchor tether, form a strain relief bend and a strain relief loop in the Lead to provide adequate slack and allow for neck movement.

1. To form the *strain relief bend* [see Figure 2 on page 12, Figure 13 (303 only), and Figure 14], do the following:
   a. Form the Lead body into a 3-cm (1.18 in) strain relief bend with at least 1 cm (.39 in) of Lead routed parallel to the nerve. [303 Lead only—Pay careful attention to the previously placed anchor tether and electrodes so they do not come unattached. Slight pressure may be placed against the anchor tether with a surgical instrument to ensure support to the anchor tether while the strain relief bend is being formed (see Figure 13).] The parallel portion can be placed in a pocket formed adjacent to the anchor tether.

Caution: Proper techniques for providing adequate strain relief below and above the sternocleidomastoid muscle are critical to the long-term success of the implant.

Caution: The Lead wire has a potential for fracture if the recommended strain relief is not provided as described.

Figure 13. (*303 Lead only*) Use of Surgical Tool (e.g., forceps) to Support Anchor Tether During Strain Relief Formation

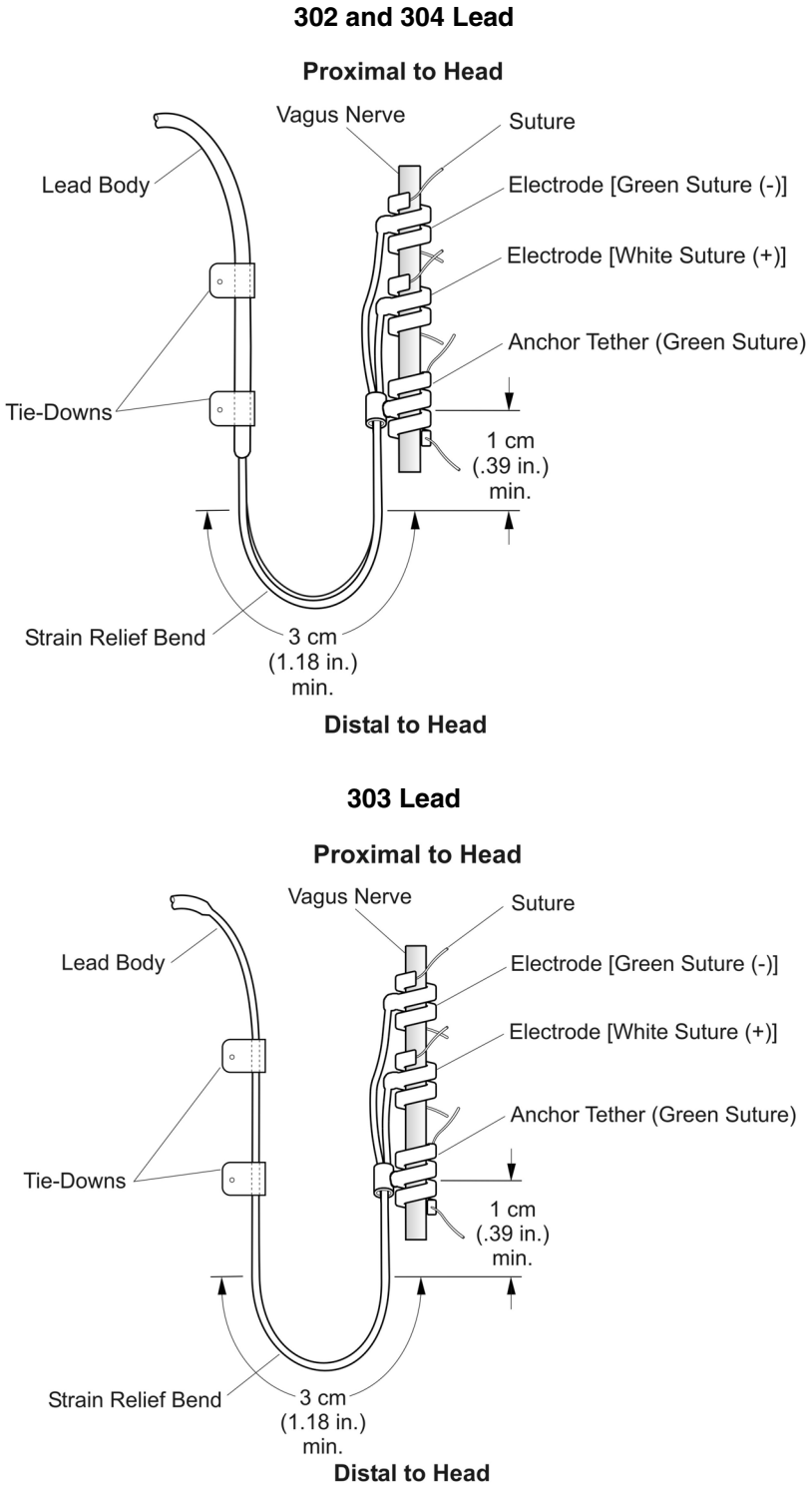


   b. Loosely attach the 3-cm strain relief bend to the adjacent fascia with tie-downs before routing the Lead over the muscle. The first tie-down should be positioned laterally to the anchor tether (see Figure 14). Four (or more) tie-downs are provided in the Lead package.

Caution: Sutures that are part of the Lead coil are meant to assist in electrode placement around the left vagus nerve. These sutures should *not* be tied to each other since this may cause nerve damage (see Figure 14).

Caution: The Lead and its electrodes are very delicate, and care should be taken not to over stretch or crush the helices.

Figure 14. Use of Tie-downs in Electrode Placement

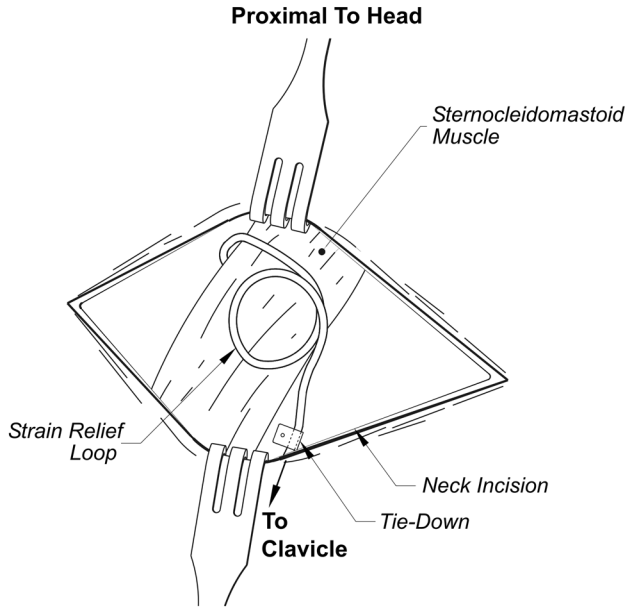


2. To form the *strain relief loop* (see Figure 15), do the following above the sternocleidomastoid muscle:
   a. In the neck, form the Lead into a large subcutaneous loop.
   b. Loosely attach it to fascia with a tie-down before routing the Lead over the clavicle. This strain relief loop should be large enough to provide several inches/centimeters of Lead extension when the neck is turned to its maximum stretched positions.

Caution: Leave enough extra Lead on both sides of the clavicle to prevent the tension over the clavicle from damaging the Lead.

Caution: Placing the sutures directly on the Lead body may result in insulation damage or wire failure, causing premature failure of the Lead. Use only supplied tie-downs to secure the Lead.

Figure 15. Strain Relief Loop



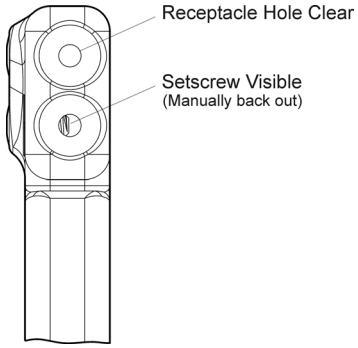
7. Connect the Lead to the Pulse Generator

To connect the Lead directly to the Pulse Generator:

Caution: Do not use electrosurgical equipment after the Pulse Generator has been introduced to the sterile field. Exposure to this equipment may damage the Pulse Generator.

1. Look inside the Pulse Generator Lead receptacle(s) to verify that no obstruction exists and that the setscrew(s) has been backed out adequately to allow full insertion of the connector pin(s). Avoid backing the setscrew(s) out further than needed for Lead insertion (see Figure 16). The figure is intended to show the contrast between a blocked and a clear receptacle, and applies to single or dual pin headers.

Figure 16. Pulse Generator Receptacle and Setscrew

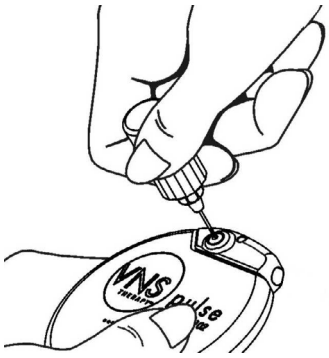


2. Keep the hex screwdriver perpendicular to the Pulse Generator. Insert the hex screwdriver through the center of the setscrew plug(s) to vent back pressure accumulated during Lead insertion.

Caution: In the steps below, **always push down on the hex screwdriver while turning it clockwise until it clicks** (begins ratcheting) while ensuring that it is fully inserted in the setscrew. Also, the hex screwdriver must be inserted into the center of the silicone rubber setscrew plug and kept perpendicular to the Pulse Generator to avoid stripping the setscrew and/or dislodging the setscrew plug.

Caution: When using the hex screwdriver, grasp it by the handle only, as shown in Figure 17. Do not grasp any other portion of the hex screwdriver during use, as this may affect its proper function. Touching the metal shaft while the hex screwdriver is engaged with the setscrew can conduct an electrostatic discharge into the device circuitry and may damage the Pulse Generator.

Figure 17. Hex Screwdriver Position



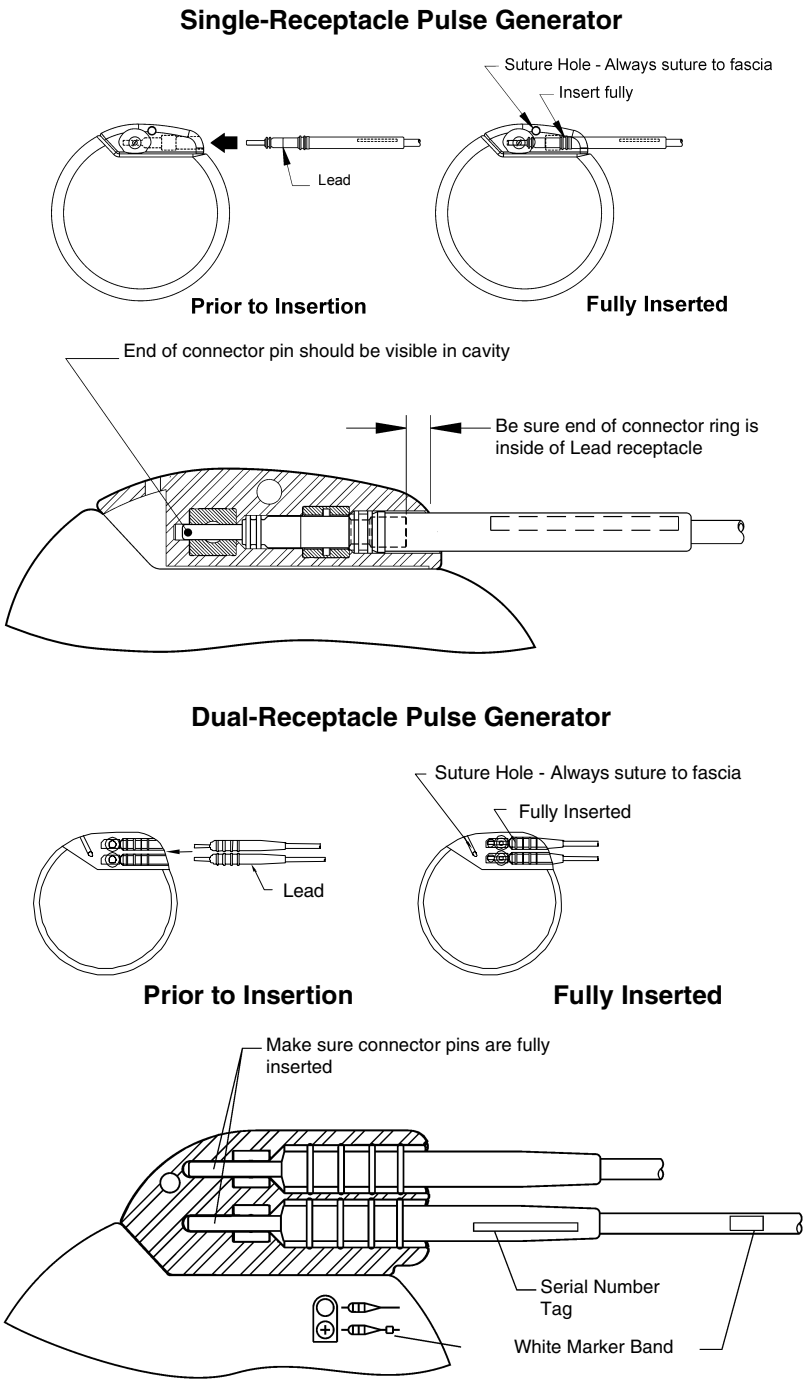
3. When using a **single-receptacle** Pulse Generator and Cyberonics single-pin Lead, insert the Lead connector pin fully into the Pulse Generator header. To allow escape of the back pressure created by insertion, leave the tip of the hex screwdriver in the slit in the setscrew plug.

   When using a **dual-receptacle** Pulse Generator and Cyberonics dual-pin Lead, insert the Lead connector pins fully into the appropriate Lead receptacles in the Pulse Generator header. To allow escape of the back pressure created by insertion, leave the tip of the hex screwdriver in the slit in the setscrew plug of the connector being inserted. Insert the Lead connector with the white marker band and with the embedded model number and serial number tag into the Lead receptacle labeled "+" [see the Dual-Receptacle Pulse Generator portion of Figure 18]. The remaining Lead connector is inserted into the remaining Lead receptacle.

Caution: To avoid backing the setscrew out completely when loosening, during surgery, use no more than two counterclockwise turns.

Caution: Reversal of Lead polarity has been associated with an increased chance of bradycardia in animal studies. It is important to make sure that the Lead connector pins in the Cyberonics dual-pin Lead are correctly inserted (white marker band to + connection) into the Pulse Generator dual receptacles.

Figure 18. Lead Connector(s) Prior to Insertion and Fully Inserted



4. With the hex screwdriver still inserted through the setscrew plug, verify that the connector pin is fully inserted. The pin should be visible in the area at the back end of the setscrew connector block. If it is not, remove the pin. To loosen the setscrew, engage the hex screwdriver into the setscrew, and turn it counterclockwise until the connector pin can be fully inserted. Avoid backing the setscrew out further than

needed for Lead insertion. If using the dual-receptacle Pulse Generator, repeat this procedure for each setscrew.

5. After verifying that the connector pin(s) has been fully inserted, tighten each setscrew by engaging the setscrew with the hex screwdriver and turning the hex screwdriver clockwise until it begins to click. Always push in on the hex screwdriver while turning it to ensure that the hex screwdriver is fully inserted in the setscrew.

Caution: It is important to do the following:

- Ensure that the Lead receptacle(s) is clean and free of obstruction.
- Carefully insert the Lead connector pin(s) into the Lead receptacle(s) without bending the Lead connector(s).
- Visually inspect that the connector pin(s) is clean and completely inserted.
- **Electrical connection to the Pulse Generator is not established until the setscrew(s) is completely tightened with the hex screwdriver.** Failure to make a good connection can result in HIGH impedance during a System Diagnostics (Lead Test) or erratic stimulation at varying intensity due to rapid, unpredictable changes in Lead impedance, which is expected to adversely affect device effectiveness and may have serious safety consequences.
- Gently grasp and pull on Lead connector boot(s) (the thick section of the Lead) to verify the Lead is properly secured inside the Lead receptacle(s). Do not pull on Lead body (thin section) or use excessive pull force, because doing so may cause Lead damage.

8. TEST THE VNS THERAPY SYSTEM _____

Note: The Programming Wand should be placed into a sterile laser arm bag or equivalent (not provided by Cyberonics) in order to introduce the Programming Wand into the sterile field. See the Programming Wand physician's manual for more information.

The System Diagnostics (Lead Test), which should be conducted first, is performed with the Lead and the Pulse Generator connected. Thus, if the System Diagnostics (Lead Test) is successful, both components are working properly. However, if the System Diagnostics (Lead Test) fails, either of the two components could be defective, or there may not be a good electrical connection between the Pulse Generator and the Lead connector pin(s). If a defective component is suspected, disconnect the Lead and perform the optional Generator Diagnostics (Pre-Implant Test), using the resistor assembly supplied with the Pulse Generator.

Caution: During the intraoperative System Diagnostics (Lead Test), infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate <40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics (Lead Test) or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS).

Additionally, postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. If a patient has experienced asystole, severe bradycardia (heart rate <40 bpm), or a clinically significant change in heart rate during a System Diagnostics (Lead Test) at the time of initial device implantation, the patient should be placed on a cardiac monitor during initiation of stimulation.

The safety of this therapy has not been systematically established for patients experiencing bradycardia or asystole during VNS Therapy System implantation.

Note: See "Model 103/104 and 105 System Diagnostics" for the 103/104 and 105 System Diagnostics procedure.

8.1. Model 102/102R System Diagnostics (Lead Test)

The System Diagnostics is performed when the Lead and the Pulse Generator are connected. During intraoperative System Diagnostics, the Pulse Generator will deliver stimulation at 1.0 mA, 500 µsec for approximately 14 seconds.

Note: See the Programming Software physician's manual for Lead impedance details.

To ensure proper system connection (impedance of the electrode-nerve interface), do the following:

1. Verify that the Lead impedance status is "OK."
2. If Lead impedance status is not "OK," see the "Troubleshooting" section of the 102/102R Pulse Generator *Technical Information* part of this multi-part physician's manual.

Caution: Electrical connection between the Pulse Generator and the Lead connector pin(s) may be at fault.

8.2. Model 103/104 and 105 System Diagnostics

The System Diagnostics is performed when the Lead and the Pulse Generator are connected. During intraoperative System Diagnostics, when the output current is set to 0.0 mA, the Pulse Generator will administer one brief pulse at 0.25 mA, 130 µsec and then deliver stimulation at 1.0 mA, 500 µsec for approximately 14 seconds. If the output current is programmed to any value >0.0 mA, the System Diagnostics will administer one brief pulse at 0.25 mA, 130 µsec and then deliver the programmed output for the duration of the programmed ON time. The System Diagnostics is used intraoperatively to check the connection between the Lead, the Pulse Generator, and the nerve.

- If the System Diagnostics is successful (output current "OK" and Lead impedance "OK"), both components are working properly.
- If the System Diagnostics fails (output current "LOW" or Lead impedance "HIGH" or "LOW"), see the "Troubleshooting" section of the Pulse Generator *Technical Information* part of this multi-part physician's manual.

Caution: Electrical connection between the Pulse Generator and the Lead connector pin(s) may be at fault.

8.3. Generator Diagnostics (Pre-Implant Test)

The optional Generator Diagnostics is performed when the test resistor is attached to the Pulse Generator. When the System Diagnostics fails (Lead impedance "HIGH" or "LOW"), the Generator Diagnostics can be used to determine whether the Lead or the Pulse Generator is causing the problem. The Generator Diagnostics is performed with the test resistor that is included in the Pulse Generator packaging. This test will verify that the Pulse Generator is functioning properly, independent of the Lead.

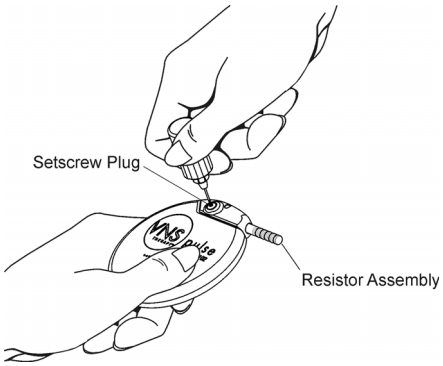
To connect the test resistor to the Pulse Generator, perform these steps:

1. Remove the Lead connector pin(s) from the Lead receptacles by inserting the hex screwdriver through the center of the setscrew plug(s) and loosening the setscrew(s). Avoid backing out the setscrew(s) more than necessary to remove the Lead. No more than a half-turn should be required to remove the Lead.
2. Insert the connector pin(s) of the resistor assembly into the Lead receptacle(s). Be careful while inserting the test resistor pin(s) into the Lead receptacle(s). If binding or significant resistance is felt, remove the test resistor, inspect it, and clean it if necessary. Without the use of excessive force, reinsert the test resistor.
3. When the resistor assembly is in place, tighten the setscrew(s) until the hex screwdriver begins to click (see Figure 19). Again, always push in on the hex screwdriver while turning it to ensure that the hex screwdriver is fully inserted in the setscrew.

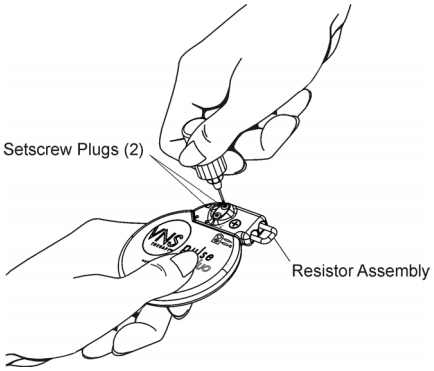
Note: Fully insert the hex screwdriver into the setscrew and push in on the hex screwdriver whenever the setscrew(s) is being tightened or loosened.

Figure 19. Connect the Resistor Assembly

Single-Receptacle Pulse Generator



Dual-Receptacle Pulse Generator



Note: See the Programming Software physician's manual for details.

4. Perform the Generator Diagnostics (Pre-Implant Test).
   - If the Generator Diagnostics (Pre-Implant Test) is successful (Lead impedance "OK"), the Pulse Generator is working properly.
   - If the Generator Diagnostics fails (Lead impedance "HIGH" or "LOW"), see the "Troubleshooting" section of the Pulse Generator *Technical Information* part of this multi-part physician's manual.
   - If the component is damaged, contact Cyberonics and return the item (following the disinfection procedure described in the "Precautions" section of the *Introduction to the VNS Therapy System* part of this multi-part physician's manual), along with a completed Returned Product Form.

8.4. Optional Monitoring

Optional physiologic monitoring of VNS Therapy System operation may be done if surgery is performed under local anesthesia. Monitor the patient's voice for signs of hoarseness while gradually increasing the Pulse Generator output current. After performing the System Diagnostics and obtaining successful results, reset the current to 0.0 mA.

9. Complete the Implantation Procedure

After the testing has been completed, finish the implantation procedure:

1. Place the Pulse Generator in the chest pocket, coiling the remaining slack of the Lead and placing it to the side of the Pulse Generator. The Pulse Generator can be placed with either side facing outward.
2. Secure the Pulse Generator by placing a suture through the suture hole and attaching it to fascia (not to muscle).
3. Perform the second System Diagnostics and verify Lead impedance status remains "OK."
4. Interrogate the Pulse Generator to verify that Normal Mode and Magnet Mode output is 0.0 mA.
   - Output current (mA): 0.0
   - Magnet current (mA): 0.0

   Caution: Do not program the Pulse Generator to an ON or periodic stimulation treatment for at least 14 days after the initial or replacement implantation. Failure to observe this precaution may result in patient discomfort or adverse events.
5. Cyberonics recommends irrigation of both incision sites with generous amounts of bacitracin or equivalent solution before closure.
6. Close the surgical incisions. Use cosmetic closure techniques to minimize scarring.
7. Administer antibiotics postoperatively (at the discretion of the physician).

A neck brace can be used by the patient for the first week to help ensure proper Lead stabilization.

Caution: Do not place the Lead slack under the Pulse Generator, because doing so could result in insulation failure and system malfunction.

Caution: This suturing is important to stabilize the Pulse Generator and to prevent manipulation by the patient, which could damage the Lead wires.

Caution: Do not place the sutures directly around the body of the Lead; this could result in insulation failure and system malfunction, and possible Lead breakage.

9.1. Patient Identification

Included with the Pulse Generator is an Implant Warranty and Registration Card that *must* be completed and the top, white copy returned to Cyberonics. This information, as required by government agencies, becomes part of the Cyberonics' registry of implantees and is used as a permanent record of implant recipient information. Additionally, the patient should be given a Patient Essentials kit, which contains Magnets, patient's manuals, and wallet-sized Patient Emergency Information Cards that contain information about the VNS Therapy System. The patient should be instructed to carry this card at all times.