Instructions for Use

CSL Repair Kit Model 5010

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

Table of Contents

1
Description

This kit is for a procedure to repair CVRx Carotid Sinus Lead(s) with damage to the insulation and/or conductor coils after chronic implantation. This repair kit is used in conjunction with the Barostim™ System. The electrode(s) on the implanted lead (that portion which is in contact with the patient's carotid artery(s)) and a section of lead body proximal to the electrodes must be intact. After cutting off the damaged section of lead (including the terminal connector), the lead repair kit will allow for the joining of a new lead body/terminal connector to the implanted lead body/electrode. The repair will require mechanical connection (crimp) of the conductor coils on the implanted lead to the conductor cables on the replacement lead. These connections will then be covered with silicone tubing filled with silicone medical adhesive.

CVRx LEAD REPAIR KIT

The Lead Repair Kit consists of the replacement lead, silicone tubings, crimping tool, and torque wrench.

Replacement Lead: A lead which includes the terminal connector on the proximal end and two exposed cable conductors on the distal end. These conductors will be crimped to the coil conductors of the implanted lead.

Inner and Outer Insulation Tubing: The silicone tubing of the lead under repair. There are two layers of tubing within the lead body.

Large Cover Tubing: A piece of large diameter silicone tubing that will be used to cover the entire repaired section of the lead.

Cathode (Small) Cover Tubing: A piece of small diameter silicone tubing that will be used to cover only the inner repaired (cathode) section of the lead. This is pre-assembled into the repair tool.

Crimping Tool: This tool is specifically designed to crimp the cuffs attached to each of the replacement lead cables to the inner and outer coil of the damaged lead.

Blue Torque Wrench: This tool is specifically designed to deliver the force required to collapse the cuffs of the replacement lead around the coils of the damaged lead.

MEDICAL ADHESIVE

Medical adhesive from a commercially available lead repair kit will need to be procured for use with the CVRx Lead Repair Kit. Obtain a 5 or 10 cc syringe to deliver the adhesive into the repair.

2
Contraindications

Patients are contraindicated if they have:

Infection at or near the implant pocket region.

3
Warnings and Precautions

Warnings

- The Carotid Sinus Lead (CSL) Repair Kit is a single-use-only device. Do not re-sterilize or reuse.
- The Carotid Sinus Lead (CSL) Repair Kit is for repair of lead damage near the connection to the IPG. The repair will require disconnecting the damaged lead from the IPG as the replacement lead has a new connector terminal.
- Do not implant product if expiration "Use Before" date has been reached.
- Do not implant a CSL Repair Kit lead if the storage package has been damaged, compromising the product sterility.
- Persons allergic to silicone may suffer an allergic reaction to lead placement.
- Only physicians who have appropriate experience should perform repair of the Carotid Sinus Lead.
- Patients who manipulate the CSL and/or the attached replacement lead through the skin may damage or disconnect the lead from the IPG and/or possibly cause damage to the carotid sinus.
- Lead malfunction could cause painful stimulation and/or stimulation of adjacent tissue.

Precautions

- Do not store the CSL Repair Kit outside the temperature range of -4°F (-20°C) to 122°F (50°C).
- Sterile seal integrity can be damaged by moisture. Do not expose to liquids.
- Prior to tightening the setscrews, make sure lead is fully inserted into the IPG connector module. Fully insert torque wrench in the setscrew; turn clockwise until the ratchet clicks.
- Electrocautery may damage the Carotid Sinus Leads and replacement leads if set to a high power. It is recommended to maintain a setting of 25% or less.
- Scalpels may damage the Carotid Sinus Leads and replacement leads. Avoid scalpel blade contact with the leads when using scalpels except when necessary during the repair process.
- Do not implant a CSL replacement lead if the device has been dropped.
- Exercise caution in utilizing line-powered equipment in conjunction with the Carotid Sinus Leads and replacement leads because leakage current could injure the patient.
- Do not use any other lead beside the Carotid Sinus Leads or attached replacement leads with the Barostim™ Legacy or Barostim System because such use may damage the IPG or injure the patient.
- Additional CSL replacement leads should be available in the event of compromised sterility or if damage is induced during surgery.

4
Pre-operative Preparation

To guide the explant procedure and avoid damage to system components, a radiograph should be obtained prior to the procedure to identify location and configuration of CSL and IPG positioning. This will also allow the surgeon to estimate the length of lead body that will be available after the damaged portion is removed. Sufficient lead body length must be available to prepare and attach to a replacement lead body. Repairs that require lead dissection above the clavicle are not recommended, as the length of lead body may not be sufficient for repair. Repair is not possible above the level of the suture wing.

5
Inspection Prior to Use

Carefully inspect the CSL Repair Kit sterile package before opening. If the package has been exposed to moisture or to extremes of temperature outside of the temperature range stated on the labeling, return the unopened package to CVRx.

The implantable components are supplied **STERILE** and for **SINGLE USE**. Do not use if the package is opened or damaged. Return the package and/or contents to CVRx. Reuse of this product may result in malfunction, adverse event or death.

Do not use on or after the "Use By" date. Return the unopened package to CVRx.

6
Surgical Procedure

A. Instructions for Use

Please refer to the Barostim System, Instructions for Use, Surgical Procedures (900133-002) for general instructions and recommendations for implant/explant of the components.

B. Anesthetics

Local anesthetics are typically used during this procedure.

C. Antibiotic Coverage

It is recommended that an antibiotic providing gram-positive coverage be administered within 30 minutes of the skin incision and continued postoperatively for 24 hours following the procedure.

D. Expose IPG and CSL

NOTE: During this procedure, take care to avoid damage to the implanted leads. Electrocautery can be used to minimize the potential of damaging the leads during dissection.

1. Turn off the IPG (recommended, not required).
2. Open the incision inferior to the clavicle over the implanted IPG unit and dissect down to the IPG.
3. Dissect out the portions of the leads near the IPG. Do not use scalpels or sharp instruments in close proximity to the leads. Electrocautery on low (25%) power is recommended. Dissect the lead(s) to expose the damaged area and then continue dissection at least 2 inches distal to the damaged site(s).
4. Prior to removing the IPG from the subcutaneous pocket, disconnect the damaged lead(s) from the IPG connector ports; using a CVRx IPG (white) torque wrench, turn the setscrews counterclockwise to loosen. Ensure that the left and right leads can be properly identified later during reconnection.
5. Cut the fixation sutures holding the IPG in the pocket and remove it from the sterile field. This IPG will be replaced with a new one after the repair is complete.

7
Prepare Damaged Lead

NOTE: If silicone insulation or coils are damaged at any point during this process, remove the damaged section and repeat the process from the beginning (Step 7A).

NOTE: It is highly recommended to use loupes or other personal magnification device during this procedure.

A. Remove Damaged Portion

Using surgical scissors carefully cut the lead body just distal to the damaged area. If the damage occurred on the lead terminal connector, cut the lead just distal to the serial number label tubing.

Remove the cut/damaged portion of CSL (this will include the lead connector). Return the damaged portion of the CSL to CVRx for examination and proper disposal per CVRx returned goods procedure.

B. Prepare Damaged Cut End for Crimping

The damaged CSL body consists of two coaxial coils with silicone tubing overlying each coil. The coils and their respective tubing must be cut to specific lengths to prepare the implanted lead for crimping to the replacement lead. This section provides step-by-step details for that preparation.

NOTE: The cut end of the implanted lead must be as free as possible from body fluids. Wipe away any body fluids as necessary.

1. Remove Outer Insulation Tubing

Estimate the length of outer tubing to be removed from the lead under repair by using the repair tool as a template. Remove sufficient outer tubing to allow the outer coil to be long enough to reach past the inner coil line of the tool. See Figure 1.

NOTE: Allow for extra tubing length for the outer insulation if in question. This extra tubing can be removed if desired prior to final adhesive backfill.

Using a scalpel blade, run the blade lengthwise down the tubing starting at the point identified with the repair tool to the cut end to split the tubing. Alternatively, using a very small scissors, the blade of the scissors may be run lengthwise up the coil from the cut end to the point identified with the repair tool, splitting the tubing along the way. Remove the outer tubing by cutting it free with the scalpel blade or scissors.

CAUTION: Use minimal pressure when cutting the tubing such that the blade does not penetrate the inner tubing.

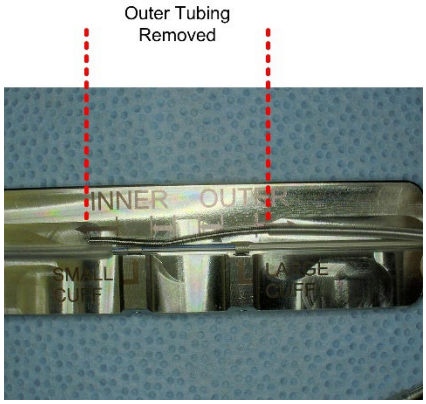

Figure 1 - Outer Insulation Tubing Cut to Length

2. Cut Outer Coil

Using the crimp tool as a guide, slightly separate the outer coil with your fingers at the place where the coil is to be cut. Using a small scissors, cut the exposed outer coil. The coil is made of two individual wires and both must be cut. Remove the cut portion of coil and discard. See Figure 2.

CAUTION: Do not nick, cut, or damage the underlying tubing.

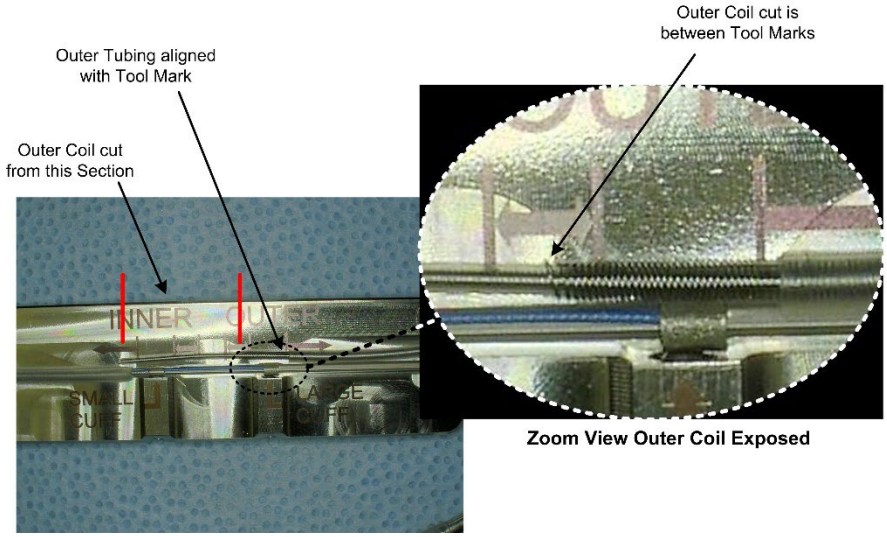

Figure 2 - Outer Coil Cut to Length

3. Remove Inner Insulation Tubing

Using the crimping tool as a guide, cut the exposed inner insulation tubing circumferentially at the point indicated. Remove the tubing with a gentle twisting motion, minimizing elongation of the underlying coil. Discard the removed tubing. See Figure 3.

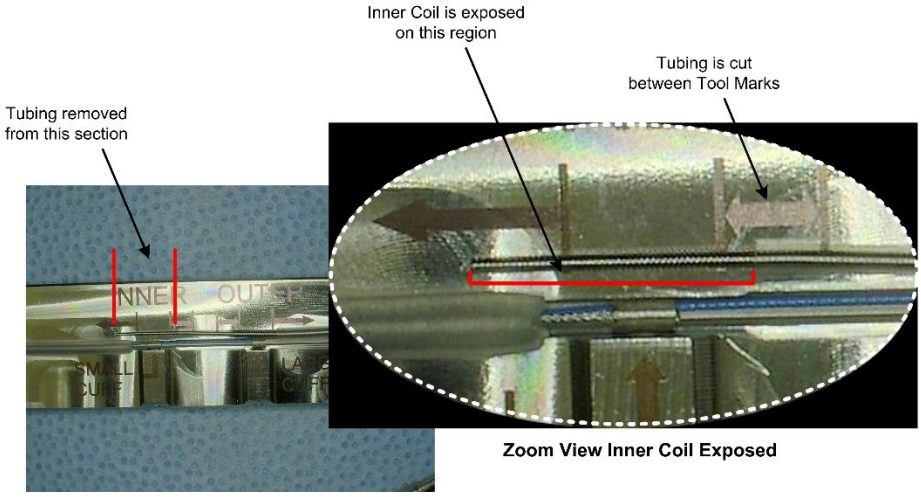

Figure 3 - Prepared Implanted Lead Body

NOTE: Hold the outer coil firmly to prevent the inner coil from retracting into the outer coil.

CAUTION: Do not nick, cut, or damage the underlying coil.

8
Attachment of Replacement Lead to Implanted Lead

A. Pre-Assemble Large Cover Tubing Over Lead Under Repair

Estimate the amount of large cover tubing required to fully insulate the repair section. Cut the cover tubing to this length. Slide the cover tubing onto the body of the lead under repair. Ensure the cover tubing is positioned so as to not interfere with crimp connections. This cover tubing will be slid back over the crimps in later steps to complete the insulating process. See Figure 4.

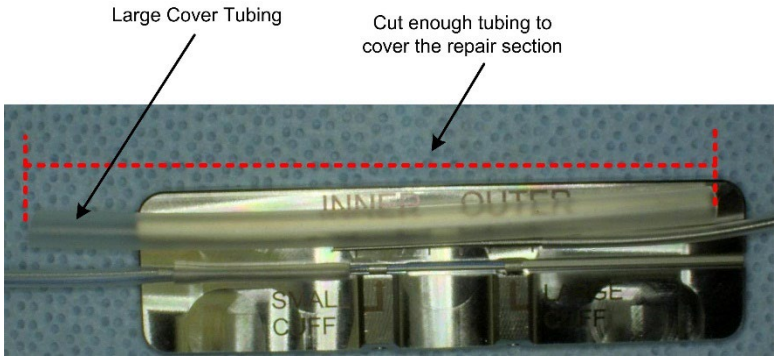

Figure 4 - Large Cover Tubing Length

B. Place Lead into Crimping Tool

The following steps will connect the inner coil and outer coil of the implanted lead to the replacement lead.

1. Align the outer coil in the crimping tool centered over the large cuff. The free end of the outer coil should not extend past the outer coil marks in the tool with the edge of the outer insulation aligned as closely to the outer insulation mark as possible. See Figure 5.
2. Align the inner coil in the crimping tool centered over the small cuff. The free end of the inner coil can extend past the inner coil mark in the tool as is will be trimmed in later steps. Verify the inner insulation is aligned within the inner insulation markings of the crimp tool. See Figure 5.

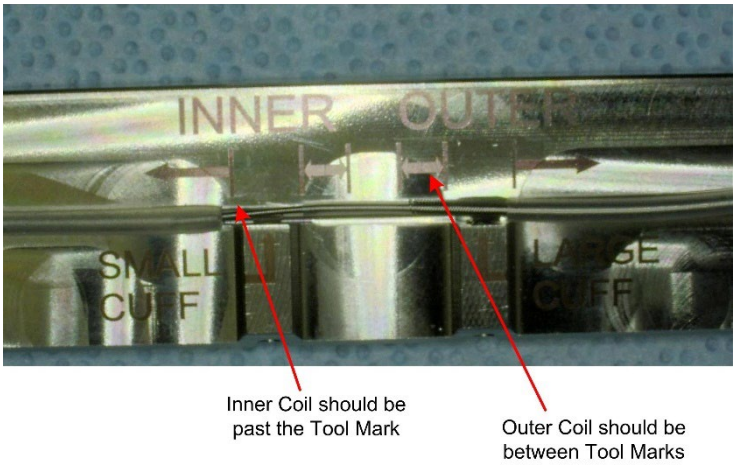

Figure 5 - Placing Lead into Crimping Tool

3. Press the coils into the cuffs such that they are seated into the cuffs completely.

C. Close Crimp Cuffs onto Coils

The following steps will close the cuffs around the coils completing the electrical connection.

1. Insert the blue torque wrench in the set screw hole opposite of the large cuff. The set screw is covered in a layer of adhesive, so light pressure will be required to insert the wrench end through the adhesive and seat it properly in the set screw.
2. Place a finger firmly over the top of the coil to hold it seated in the cuff. Tighten the set screw until the torques wrench activates. Back out the torque wrench and repeat. Remove the torque wrench from the set screw.
3. Visually verify the cuff has collapsed around the coil. See Figure 6.

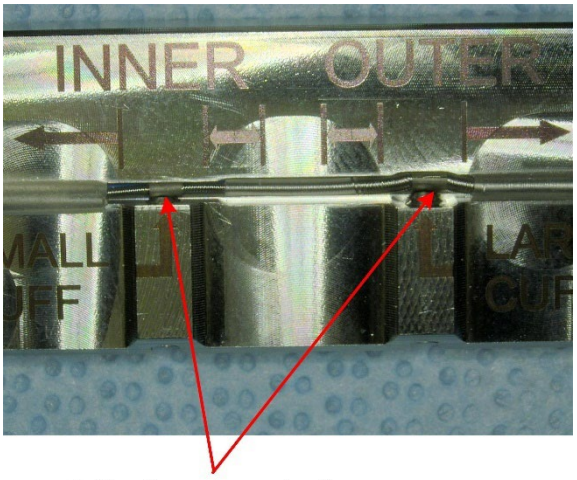

Figure 6 - Close Crimp Cuffs

4. Repeat steps 1 thru 3 for the small cuff. See Figure 6.

D. Remove Assembly from Crimping Tool

The following steps will allow removal of the crimped assembly from the tool and verify adequate crimps.

1. Insert the blue torque wrench in the set screw hole opposite of the large cuff. The set screw is covered in a layer of adhesive, so light pressure will be required to insert the wrench end through the adhesive and seat it properly in the set screw. Turn the wrench counter-clockwise, loosening the set screw. Continue turning wrench until the set screw is no longer visible in the tool trough next to the crimp cuff.
2. Repeat for the small cuff set screw.
3. CAREFULLY remove the assembly from the crimp tool.

   NOTE: The small cover tubing pre-placed for the cathode insulation will be compressed into the tool trough. Slowly and carefully peel the tubing out of the trough without straining the cathode crimp.

4. Inspect the cuff crimps. If the crimp did not collapse fully (edges almost touching), it is permissible to use a surgical tool such as a clamp to gently squeeze the cuff together further. A slight tug on the coil will verify if the crimp is sufficient (captured coil). See Figure 7.

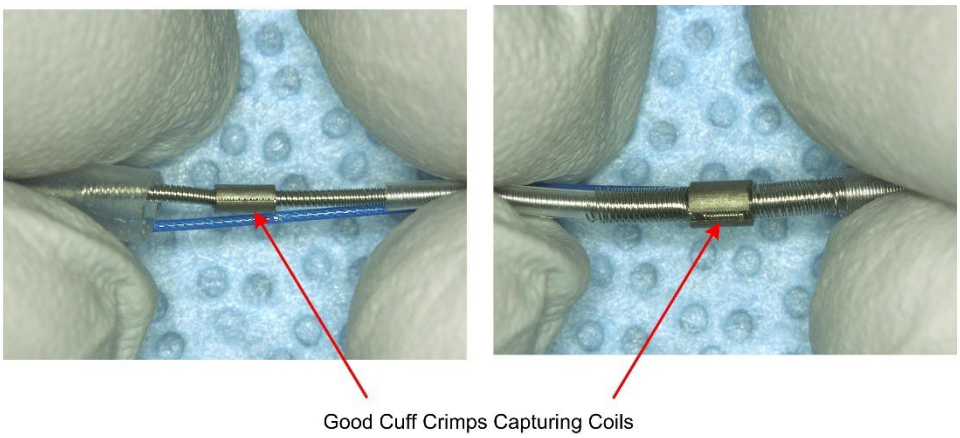

Figure 7 - Collapsed Cuffs

5. Trim the inner coil approximately 0.25 inches from the edge of the small cuff. See Figure 8.

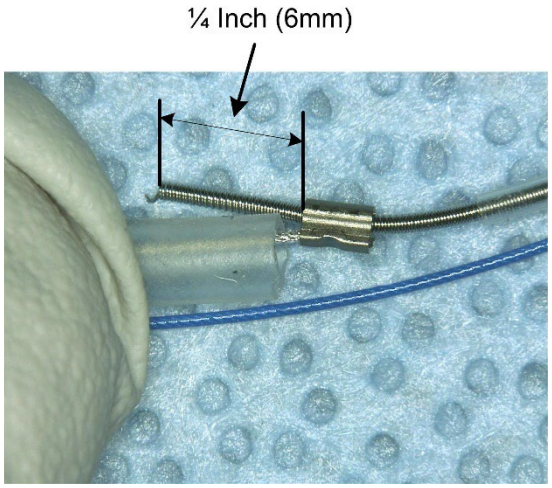

Figure 8 - Trim Inner Coil

9
Installing Final Lead Insulation

A. Place Cathode (Small) Cover Tubing

The cathode (small) cover tubing will electrically insulate the inner coil from the outer coil. This cover tubing was pre-placed onto the assembly in the crimp tool and will be loose upon removal of the crimped assembly from the tool. Slide the cathode cover tubing over the inner coil crimp area. Ensure that the cover tubing covers the exposed metal of the inner coil crimp, extending over the clear cable coating and silicone insulating tubing on either side of the crimp. Lightly tie a suture around the repair lead side to anchor the cathode cover tubing. Figure 9 shows the assembly with crimps complete and cathode cover tubing sutured in place.

NOTE: It is recommended to check the lead impedance at this point prior to adding adhesive into the cover tubing to verify lead electrical integrity.

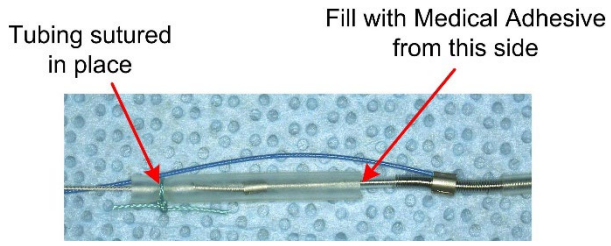

Figure 9 - Cathode Cover Tubing Placement

Fill a 5 or 10 cc syringe with medical adhesive. Place the syringe needle tip into the open end of the cathode tubing. Fill the tubing with medical adhesive. Attempt to minimize air entrapment and excess adhesive while filling. Using dry gauze, remove any excess adhesive.

B. Place Large Cover Tubing

The large cover tubing will electrically insulate the repaired section from the surrounding tissue. Slide the previously-placed large cover tubing over the repaired area, centering it to ensure that it overlaps the lead bodies on either side of the repair (over the outer insulating tubing). If necessary, trim the tubing to overlap each side by approximately 0.5 inch. Place the adhesive dispensing nozzle into the end of the large cover tubing that is over the replacement lead, pinching the tubing against the nozzle. (This will prevent backflow of adhesive and prevent the nozzle from slipping out of the tubing during dispensing. See Figure 10.) Fill the tubing with medical adhesive. Attempt to minimize air entrapment and excess adhesive while filling.

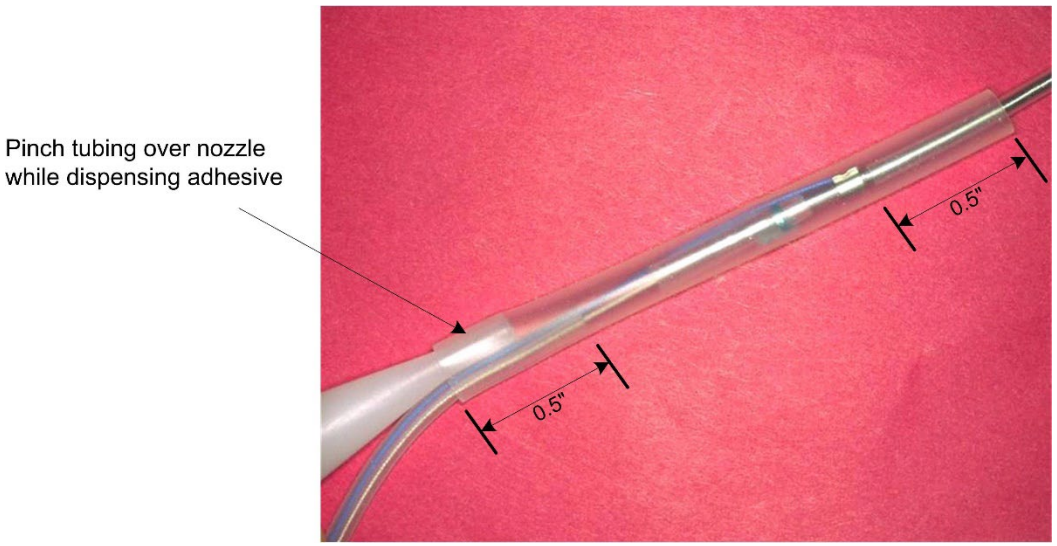

Figure 10 - Adhesive Fill Large Outer Cover Tubing

After it is filled with adhesive, secure the large cover tubing on each end by tying a suture around the tubing. Using dry gauze, remove any excess adhesive from the exterior of the repaired lead body. Figure 11 shows the completed repair section.

CAUTION: Do not to tie the suture so tight that it impinges on the underlying coils or cables.

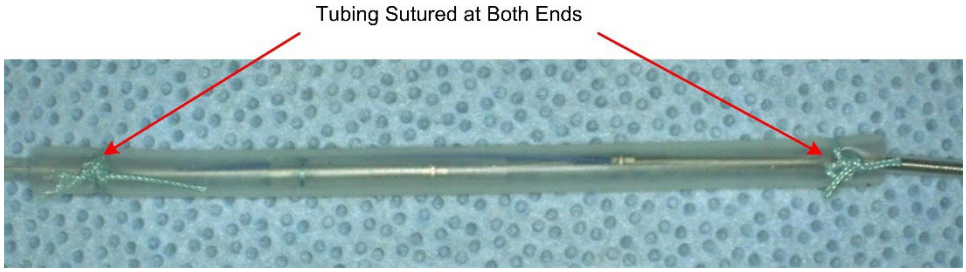

Figure 11 - Completed Repair

10
Testing the Lead

Attach the lead to the IPG and test lead impedance per the applicable System Reference Guide.

11
Implanting the Barostim NEO or Barostim NEO2 IPG

A. Implant Repaired Lead

Place the repaired lead subcutaneously following Instructions for Use, Surgical Procedures, 900133-002. Perform another impedance test after final placement of the lead.

CAUTION: *Use extreme caution to avoid pulling on the repaired section during implantation.*

WARNING: *Do NOT stimulate with (i.e., turn on) the system for a minimum of 72 hours following the lead repair. The silicone requires this time to cure. Applying voltage to the lead for extended periods during this curing cycle could damage the lead.*

B. Implant Barostim NEO™ or Barostim NEO2™ IPG

Barostim NEO or Barostim NEO2 IPG implantation should be performed following the Surgical Procedures, Instructions for Use (900133-002) implant procedure.

12
Specifications

Specification	Value (Nominal)
Length (as provided)	28 cm
Compatibility	Compatible with Barostim NEO & NEO2 System
Connector	
Connector Type	Bipolar, compatible with CVRx Barostim NEO & NEO2 IPG
Pin	Diameter = 1.41 mm, Active Length = 5.18 mm
Ring	Diameter = 2.67 mm, Active Length = 4.06 mm
Connector (Pin to Ring) Length	14.22 mm (including active ring length)
Pin/Ring Material	Stainless Steel
Seal/ Insulating Material	Silicone Rubber
Lead Body	
Conductor Material	Cobalt-Nickel-Chromium-Molybdenum Alloy with Silver Core
Lead Body Insulation Material	Silicone Rubber
Disposal of Product	Please contact CVRx representative to return product to CVRx. Product should not be disposed of in trash.

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Barostim™

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