
# Surgical Procedures

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

# ABOUT THIS DOCUMENT

This document is a portion of the Instructions for Use (IFU) for the Barostim™ System. The full IFU consists of:

| | |
|---|---|
| System Overview | 900133-001 |
| Surgical Procedures | 900133-002 |
| Programming | 900133-003 |
| Magnetic Resonance Imaging (MRI) | 900133-004 |
| Patient Instructions | 900133-005 |

IFU documents are available at www.cvrx.com/ifu.

# Table of Contents

# 1
# Implant Preparation

# WARNINGS AND PRECAUTIONS

For a complete listing of Warnings and Precautions for the system including implant procedures please reference System Overview 900133-001 (available at www.cvrx.com/ifu).

# BEFORE IMPLANTATION

Formal preoperative duplex ultrasonography should.

- Confirm the absence of complex arterial anatomy, such as carotid kinks, loops and coils, which would compromise the implant procedure.
- Verify absence of any stenosis producing a greater than 50% reduction in diameter of the carotid arteries.
- Verify absence of any ulcerative plaques.
- Verify the level of the carotid bifurcation is easily accessible from standard cervical incisions.
- Determine if there are any anatomic variants present which might suggest that additional imaging would be helpful for treatment planning.
- Other variants or conditions that would eliminate the patient as a surgical candidate.

Ensure that a backup Implantable Pulse Generator (IPG) and Carotid Sinus Lead (CSL or Lead) are available in case the sterility of the first IPG is compromised, or the device is damaged during surgery.

Ensure that a backup Programmer System is available in case the primary system is damaged or becomes non-operational.

It is recommended that physicians verify compatibility with the implanted device(s) at the time of Barostim System implant. Ensure that proper instrumentation for monitoring the behavior of the currently implanted device is present.

# MATERIALS RECOMMENDED FOR IMPLANTATION

- A table or stand outside the sterile operating field to hold the Programmer System.
- Blood pressure monitoring equipment (such as an arterial line) for assessment of blood pressure changes during therapy testing.

# MATERIALS NEEDED

### IPG (Implantable Pulse Generator)


Supplied in a single use package as a kit with the following configuration:

- One sterile IPG Model 2104 with therapy OFF
- One sterile torque wrench

### CSL (Carotid Sinus Lead)

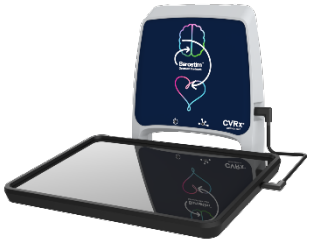
Supplied in a single use package as a kit with the following configuration:

- One sterile CSL – Model 1036
- One sterile Implant Tool

### Programmer

Supplied as a kit, in a case, with the following components:

- Programmer software
- Programmer Interface – Model 9020
- Tablet with power cord
- USB-C cable



Model 9020

# SURGICAL PREPARATION

### Skin Preparation

Follow your institution's surgical skin preparation practices. Consider applying an agent that is effective against typical skin flora.

Consider application of an impermeable skin barrier to minimize contact between the implanted components and the patient's skin.

## Antibiotic Coverage

Follow your institution's antibiotic coverage practices. Consider antibiotic coverage in the perioperative period if this is not the current practice. Consider a second dose of antibiotics during the implantation procedure.

## Sterile Packaging

The IPG, CSL, and Implant Tool are supplied STERILE (by ethylene oxide gas) and for SINGLE USE. Reuse of this product may result in malfunction, adverse event or death.

The components are supplied in a sterile package for direct introduction into the operating field. Carefully inspect the sterile packages before opening. Do not use if the package is opened, damaged or has evidence of damage or compromised sterility. Return the package and/or contents to CVRx.

Do not open the package if it has been exposed to extremes of temperature outside of the temperature range stated on the labeling, or if there is damage to the package or the package seal. Return the package, unopened, to CVRx.

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

Prior to opening the IPG package, use the Programmer System to check the IPG battery. If the reported battery voltage is less than 2.85V return the package, unopened, to CVRx.

To open the package, do the following:

1. Grasp the tab and peel back the outer cover.
2. Using sterile technique, lift out the inner tray.
3. Grasp the tab on the inner tray and peel off the inner cover to expose the contents.
4. Remove the product.

## Device Interaction Testing

If problematic interactions cannot be eliminated at implant, the Barostim System should be explanted. It is recommended that patients are monitored for interaction following implant and whenever changes are made to either device. If device interactions that develop after implant cannot be eliminated, the Barostim IPG should be programmed "OFF". Below are instructions to perform device interaction testing.

- If a patient has a CRM device (e.g., pacemaker, ICD or CRT-D), perform device interaction testing once the IPG is in the pocket and before the patient emerges from anesthesia.
- Ask CRM device rep or hospital device tech to:
    - Maximize CRM device sensitivity. For devices with auto-sensitivity (e.g., ICDs), program the device to pace faster than the intrinsic rate to assure device achieves highest sensitivity.

    - If applicable for CRM device, compare morphology discrimination criteria with Barostim off and on.
- Test the recommended Barostim settings:

| Pulse Width | Frequency | General Anesthesia | Local Anesthesia or Post-Operative |
|---|---|---|---|
| 30 µs | 40 pps | 20 mA (or highest within compliance) | Maximum before extraneous sensations |
| 170 µs | 40 pps | 12 mA | |
| 500 µs | 40 pps | 8 mA | |

If any interactions are observed record information in session summary report and mitigate by:

- Restoring CRM device sensitivity to programmed value.
- Lower Barostim amplitude until interaction no longer occurs.

# 2
# Implantation Procedure

Surgical approach and techniques for the implantation of the system will vary with the preference of the implanting surgeon. Requirements for proper and safe implantation of the system should include the items covered in this section.

# CLINICAL UPDATE

Based on the BeAT-HF PMA Amendment database from April 30, 2019, the implant position for the carotid sinus lead (A-D, picture below) was evaluated for chronic response by position. As shown in Table 1 , the results are consistent across lead location (A vs. B-D) supporting the elimination of the requirement to map during the implant. It is recommended that the implant location be prioritized at location “A”. In the instances where implanting at location “A” is anatomically undesirable, choose a location as close to “A” as the anatomy allows, based on the implanting physician experience. In the Intended Use Population of the BeAT-HF, 90% of the subjects had the lead implanted in position A on the carotid artery. Table 1 shows the percent of subjects that had a clinically relevant response at six months in 6MHW (≥25 meters), QoL (≥5 points) and/or NT-probing (≥10% relative reduction), as well as the percent of subjects who responded to at least one or two of these endpoints. The response rates across all endpoints were similar regardless of the final lead position.

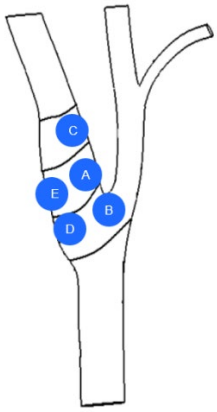



**Table 1: Response by Lead Location in Intended Use Subjects**

| Variable | Lead Location A | | | Lead Location B-D | | |
|---|---|---|---|---|---|---|
| | N | Mean ± SD or N (%) | Median (Range) | N | Mean ± SD or N (%) | Median (Range) |
| 6MHW Responder | 103 | 72 (69.9%) | N/A | 11 | 7 (63.6%) | N/A |
| QoL Response | 104 | 73 (70.2%) | N/A | 12 | 10 (83.3%) | N/A |
| NT-proBNP | 104 | 58 (55.8%) | N/A | 12 | 5 (41.7%) | N/A |
| Response >= 1 | 104 | 99 (95.2%) | N/A | 12 | 11 (91.7%) | N/A |
| Response >= 2 | 104 | 77 (74.0%) | N/A | 12 | 9 (75.0%) | N/A |

| Variable | Lead Location A | | | Lead Location B-D | | |
|---|---|---|---|---|---|---|
| | N | Mean ± SD or N (%) | Median (Range) | N | Mean ± SD or N (%) | Median (Range) |
| Mapping time (minutes) | 104 | 19 ± 12 | 16 (7 - 71) | 12 | 28 ± 17 | 26 (12 - 64) |
| Procedure time (minutes) | 103 | 74 ± 26 | 70 (34 - 205) | 12 | 87 ± 38 | 82 (47 - 184) |

CVRx is recommending placing the electrode at location “A” unless it is anatomically undesirable, then choose a location as close to “A” as the anatomy allows. If mapping is not performed go to Section ”Lead Placement” and then to Section “Final Positioning of the Lead and Fixation”.

Note: There may be instances where the implanting physician prefers to include mapping during the implant procedure. This may occur in instances of minimal implant experience or anatomy that the surgeon prefers to evaluate more fully during the implant. In these cases, please follow the following the next four sections in order.

# ANESTHESIA

Implants require anesthetic management that preserves the baroreflex during the electrode placement portion of the procedure. Consequently, special care must be used during the procedure with regard to administering anesthesia.

**The goal of the anesthesia is to ensure patient comfort during surgery while minimizing blunting of the baroreflex response during the mapping process for identifying the appropriate electrode implant location.**

The procedure is divided into the following two anesthesia phases:

Phase 1: Lead and IPG implant.

Phase 2: Create the strain relief loop on the common carotid artery and secure device in the pocket.

## Phase 1

Agents such as narcotics, benzodiazepines, barbiturates and local anesthetics that minimize blunting of the baroreflex may be used.

Anesthesia levels should be as stable as possible. Continued use of narcotics, benzodiazepines, and barbiturates that minimize blunting of the baroreflexes may be employed during this phase. The use of atropine or glycopyrrolate should be avoided unless patient safety requires as these may abolish some of the response to activation of the carotid baroreflex making mapping and the determination of the optimal location of the carotid sinus electrode more difficult.

NOTE: If the conscious sedation regimen is used, efforts should be made to avoid deep cervical blocks, which could impair mapping by abolishing the carotid baroreflex. Also, avoid directly injecting local anesthetic (e.g., lidocaine) into the carotid artery.

### Phase 2

Once the best electrode location has been determined, the electrode fully affixed to the vessel, and baroreflex testing completed (i.e., Phase 1 is complete), agents such as Isoflurane, Desflurane, Sevoflurane, propofol and dexmedetomidine may be used during pocket creation, tunneling and wound closure to achieve adequate levels of anesthesia.

# LEAD PLACEMENT

## Neck Incision

NOTE: Right side is preferred based on results from previous trials.

- Mark carotid bifurcation using portable ultrasound, i.e., Sonosite after head is positioned as required for surgery.
- Make a 2-3 cm incision centered on the carotid sinus bulb/bifurcation.

## Expose the Implant Site (Target) at the Carotid Bifurcation

- Use minimal dissection of periadventitial tissues, to preserve intrinsic innervation.
- Do not dissect between the internal and external carotid arteries, as it protects likely location of main carotid sinus nerve.
- Only the anterior (i.e., superficial) surface of carotid sinus bulb/bifurcation needs to be exposed.
- Dissect down to a level to allow for the identification of the carotid notch and sinus.
- Mobilizing the internal and external carotid arteries is not required.
- Minimize the manipulation of the carotid sinus.

# IPG PLACEMENT

## Create the Pocket

- It is recommended to locate the pocket on the same side as the lead/electrode implant.
- Incise the skin for the IPG pocket, in the infraclavicular location, and the dissection carried down to the level of the pectoralis major fascia.
- Make a horizontal incision below the clavicle.
- Fashion the pocket inferior to the incision, in the subfascial plane.
- Avoid lead body contact with the IPG by extending the IPG pocket to the medial aspect to hold excess lead body.

NOTE: Manage bleeding in the pocket to avoid pocket hematomas.

NOTE: Avoid electrocautery use while the IPG is in the pocket.

### Tunnel the Lead

- Initiate a tunnel from the medial aspect of the IPG pocket to the superficial aspect of the common carotid artery (tunnel from the pocket to the neck).
- Use a long Tonsil, Kelly, chest tube passer or other clamp to tunnel.
- Develop the tunnel to the level of the space between the sternal and clavicular heads of the sternocleidomastoid muscle (SCM).
- Attach a 14 Fr/ 16Fr Red Robinson Catheter (or similar tubing) to the terminal pin of the CSL.
- Grasp the free end of the 14 Fr/16Fr Red Robinson catheter (or similar tubing) with the clamp and bring through the tunnel (from the neck to the IPG pocket).
- Remove the tubing from the lead pin and clean the lead pin of any blood or material.

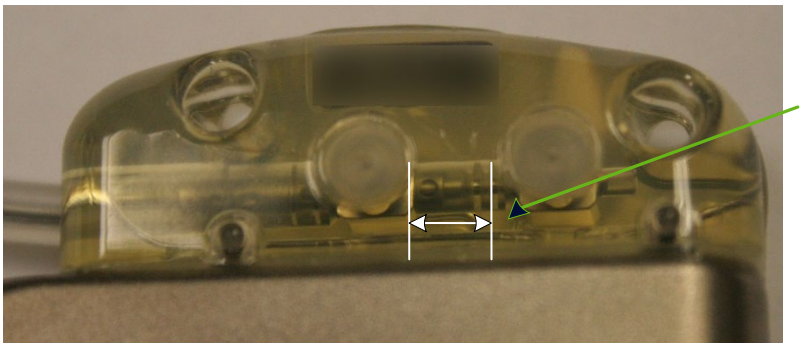
NOTE: Avoid grasping the lead body or connector with surgical instruments.

## CONNECT THE LEAD

### Connecting the Lead to the IPG

- Loosen both distal and proximal set screws at least four full counterclockwise turns.
- Insert the torque wrench into the pin (distal) setscrew. This releases trapped air from the header during insertion of the lead terminal into the header.
- Clean any blood or tissue from the lead terminal.
- Insert the lead terminal into the header port.
- Visually verify that the terminal pin is fully inserted into the header by viewing seals visible between setscrew blocks.
- Tighten the distal setscrew in a clockwise direction until the wrench begins clicking.
- Check that the lead terminal is tightened by gently pulling on the lead body.
- Insert the torque wrench into the ring (proximal) setscrew.
- Tighten the setscrew in a clockwise direction until the wrench begins clicking.

NOTE: Electrical connection to the IPG is not established until the setscrew(s) are completely tightened using the torque wrench. Do not attempt to deliver any therapy until the connections are secured using the torque wrench.

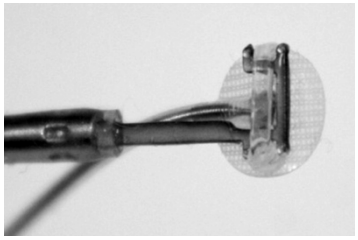



Model 2104 shown

## Preparing the electrode

- Place the Implant Tool into the buckle located on the inactive side of the electrode. Tool tip can be bent to accommodate mapping process.

NOTE: Do not grasp the lead body or active area of the electrode with metal clamps or forceps.



# MAPPING & FIXATING THE LEAD

NOTE: During carotid sinus mapping and testing, bradycardia may be induced. Bradycardia should resolve when therapy is stopped. Stopping therapy may be accomplished by:

- Pressing the Stop Test button during mapping;

or

- By removing the electrode from the carotid sinus.

### Systematic mapping of the exposed carotid sinus

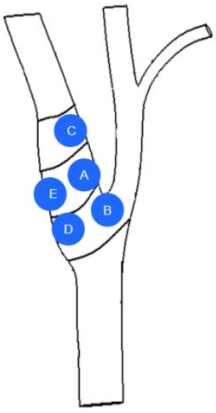
The goal of mapping is to achieve a drop of:

- 15-20% in blood pressure and/or 5-10% drop in heart rate for hypertensive patients.
- 5-10% drop of blood pressure and/or heart rate for heart failure patients.

Mapping is a team effort between the surgeon and anesthesiologist.

- Anesthesia plane and hemodynamics should be maintained as stable as possible.
  - The anesthesia should not blunt the baroreflex.
  - Preserve hemodynamic values for mapping:
    - Target SBP > 90% of conscious values
    - Target HR > 65 bpm
- Program the IPG to an amplitude of 8 mA and a pulse width of 125 µs and a frequency of 40pps.
- During carotid sinus mapping, the duration of each test activation should be sufficient to determine the hemodynamic response. This can typically be determined within 30 to 60 seconds.
- It is recommended that lower settings be used (Including turning therapy Off) if any of the following occur:
  - Concerning changes in hemodynamics occur.
  - Problematic tissue stimulation is noted.
  - Any other potentially hazardous patient responses are observed.

**Test different locations at implant site**




- Position A: Anterior aspect of exposed internal carotid artery adjacent to bifurcation.
  NOTE: This is the typical site for implant on most patients.
- Position B: Common carotid artery, just below bifurcation.
- Position C: Expose further above bifurcation (cephalad).
- Position D: Deeper around common carotid from C, down from B, diagonal from A.
- Position E: Base of internal carotid artery on free wall (opposite external carotid).

NOTE: If no optimal location is identified, fixate the lead to position A.
It may be helpful to mark optimal location with a sterile marker.

NOTE: During mapping, maintain full contact of the electrode and backer against the carotid sinus with gentle pressure (minimize vessel deformation with the electrode).

NOTE: Mapping to find the proper location of the electrode requires an assessment of the baroreflex response to stimulation. The most consistent response during implantation is derived from measures of heart rate and blood pressure.

# FINAL POSITIONING OF THE LEAD AND FIXATION

The goal is to ensure the electrode is securely fixed at target site with proper contact between the electrode and carotid.

After optimal location is identified, fixate the electrode to the tissue surrounding the target location, keeping in mind the following considerations:

- Six non-absorbable, 5-0- or 6-0 monofilament sutures (e.g., Prolene) should be placed.
- Sutures should incorporate the tissues surrounding the target and the electrode backer.
- The Implant Tool may be used to stabilize the lead for fixating (especially the first suture).
- The sutures (especially the first suture) may require a parachuting technique to enable placement through the small incision.
- After securing the electrode with initial sutures (2 or 3), the adequacy of the position may be confirmed by re-applying therapy only if it is believed the electrode moved from the location of best response.
- After confirming the proper position, the buckle on the inactive side of the electrode should be removed or at least cut to better facilitate electrode conformance to the artery.
- Complete electrode fixation with remaining sutures (6 total).
- Confirm proper lead impedance (300-3000 ohms) once the lead is fixated in position.

NOTE: After completing the mapping and lead fixating phase of the procedure, the anesthetic regimen may be changed to Phase II anesthesia.

### Create the Strain Relief

- Create a strain relief loop in the lead body between the electrode and suture tab to avoid traction when the patient moves his/her neck.
- The suture tab should be fixated to the adventitial layer of the common carotid artery or external carotid (inferior or medial/lateral location as driven by patient anatomy).
- Use 2 sutures of 5-0 or 6-0 Prolene to suture the wing caudal to the electrode.
- The preferred orientation of the lead body is parallel to the artery. Final orientation should consider the particular patient anatomy and the final electrode position.
- Create additional lead slack in the neck by pulling some lead body up from the chest pocket to ensure there is no tension on the lead between the neck and chest pocket before closure.

## Secure the IPG

NOTE: The IPG must be sutured using both suture holes in the header to avoid migration issues.

- Confirm pocket hemostasis.
- Consider irrigating the pocket with an antibiotic solution.
- Place two retention sutures into the fascia, spaced appropriately for the suture holes in the IPG. This should be a non-absorbable 0 or 1-0 Suture.
- Pass the sutures through the suture holes in the IPG header.
- Place the IPG into the pocket.
- Gently coil excess lead body and place medial to the IPG such that the excess lead body is not placed directly in front or behind the IPG. Ensure that lead body is not pulled taut and allow slack in the path between electrode and IPG pocket.


Correct lead body placement


Correct lead body placement


Incorrect Severe Lead Angle from Header


Incorrect Placement of Lead Behind IPG

- Tie the suture used to secure the IPG to the pectoral fascia.

Note: Verify lead impedance after inserting the IPG into the pocket to assure the adequacy of the electrical connections.

## Close the Incisions

- Consider infiltrating the incisions with local anesthetic.
- Close the incisions per the surgeon’s usual practice.

# 3
# IPG Replacement

# RECOMMENDATIONS

An IPG replacement procedure should be performed on, or before, the Recommended Replacement Time. Local anesthetics are typically used during this replacement procedure.

# MATERIALS NEEDED

Refer to Surgical Preparation section of this document for required inspections prior to the procedure.

- IPG
- Programmer
- RGA Kit

NOTE: Verify replacement IPG is compatible with the lead system currently implanted. The IPG Model 2104 is compatible with Lead models 103x and can be used to replace IPG model 2102 using a single lead for therapy.

# ANTIBIOTIC COVERAGE

Follow institutional guidelines. Consider administering antibiotic providing gram-positive coverage within 30 minutes of the skin incision and continuing postoperatively for 24 hours following the procedure.

# EXPLANTATION OF DEPLETED IPG

CAUTION: Palpate the site of the IPG and lead prior to first incision to verify the lead is not under the targeted incision site for IPG removal.

NOTE: Avoid damage to the implanted lead. Do not use scalpels on or near the CSL as damage could occur leading to failure of the lead. Electrocautery can be used at a low but effective power to minimize the potential of damaging the lead during dissection.

1. Initiate a telemetry session with the IPG and document previously programmed settings.
2. Complete skin incision over the implanted IPG.
3. Using electrocautery or blunt dissection, dissect down to the IPG. Portions of the lead(s) may need to be dissected in order to remove the IPG.
4. Cut the fixation sutures.

   NOTE: Prior to removing the IPG, to minimize strain on the lead, it is recommended to disconnect the lead from the connector port.

5. Using the torque wrench, turn the setscrews counterclockwise to loosen the setscrews for each CSL connector.

   NOTE: The setscrews are accessed on the side of the IPG opposite the device model and serial number.

6. Remove the CSL from the IPG connector port.
7. Remove the IPG from the pocket.
8. Remove the IPG from the sterile field.
9. Return the explanted IPG to CVRx for examination and proper disposal.

NOTE: Prior to returning the IPG, obtain a CVRx Returned Goods Authorization kit and follow the procedure contained within it.

# IPG PLACEMENT

IPG placement and connection should be performed using the steps contained in Connect the Lead section of this document.

# 4
# Explantation Procedures

## RECOMMENDATIONS

CVRx recommends leaving the lead implanted and capped. Full explantation of the lead should be done only if, in the opinion of the treating physician, it is medically necessary.

## MATERIALS RECOMMENDED

- Sterile Torque Wrench
- IS-1 compatible Lead Cap
- Return Goods Authorization Kit

## ANTIBIOTIC COVERAGE – NOT INFECTED

If the device is being removed for reasons other than infection, 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.

## ANTIBIOTIC COVERAGE – INFECTED

If the device is being removed due to an infection and cultures have identified the responsible bacteria, antibiotics that would be effective against identified bacteria should be initiated preoperatively and continued postoperatively until signs of infection have resolved (normal temperature, white blood cell count, and differential white blood cell count). Otherwise, it is recommended that broad spectrum antibiotics be initiated preoperatively, and antibiotics be narrowed when culture and sensitivity results are available from intraoperative cultures.

## IPG EXPLANTATION

NOTE: Electrocautery at a low but effective power can be used to minimize the potential of damaging the leads during dissection. Do not use scalpels on or near the CSL as damage could occur leading to failure of the lead.

1. Open the incision inferior to the clavicle over the implanted IPG.
2. Dissect down to the IPG. Portions of the lead may need to be dissected in order to remove the IPG.
3. Cut the fixation sutures.

   NOTE: Prior to removing the IPG, to minimize strain on the lead, it is recommended to disconnect the lead from the connector port.
4. Using the torque wrench, turn the setscrews counterclockwise to loosen the setscrews for the CSL connector.

   NOTE: The setscrews are accessed on the side of the IPG opposite the device model and serial number.

5. Remove the CSL from the IPG connector port.
6. Install a lead cap to cover the lead terminal pin.
7. Remove the IPG from the sterile field.
8. Return the explanted IPG to CVRx for examination and proper disposal.

NOTE: Prior to returning the IPG, obtain a CVRx Returned Goods Authorization kit and follow the procedure contained within it.

## CSL EXPLANTATION

1. Remove IPG if it is still implanted per instructions above.
2. Make an incision over the corresponding carotid bifurcation.
3. Dissect to fully uncover the CSL body in the caudal portion of the cervical incision. Free up the lead body extending cranially until reaching the caudal-most extent of the electrode.
4. Dissect to the points where the electrode is fixated to the carotid sinus adventitia.
5. Cut the sutures used to attach the electrode and suture wing.

   NOTE: It is recommended that the sutures be cut on the surface of the electrode to avoid injury to the surrounding tissue.
6. Apply gentle traction to the lead body and open the enveloping scar tissue in a caudal-to-cranial direction. This is continued until the caudal border of the carotid sinus electrode is encountered. Open the sleeve of enveloping scar tissue and cut the sutures holding the electrode. Apply gentle traction to remove the electrode from the carotid sinus.

   NOTE: If the electrode will not slide out of the enveloping fibrous tissue, further mobilization is required.
7. If required advance a small clamp along the CSL body to open the sheath of scar tissue enveloping the lead body.
8. From the cervical incision, apply gentle traction to remove the CSL.

   NOTE: If the lead cannot be extracted by this procedure, further manipulation, such as transection above the level of the IPG pocket or sequential dilation of the scar tissue sleeve, will be required.
9. Return the explanted CSL to CVRx for examination and proper disposal.
10. Follow the procedures in Implantation Procedure for implantation of any new components.

    NOTE: Prior to returning the CSL, obtain a CVRx Returned Goods Authorization kit and follow the procedure contained within it.

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For a list of applicable patents, see www.cvrx.com/patent-marking.

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



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# Barostim™

## Outsmart the heart

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