

## Procedure Manual

This manual provides basic information needed for the implantation and testing of the Bioness StimRouter Lead included in the StimRouter Implantable Lead and Lead Introducer Kit. Two methods of implantation are described. The first describes how to implant the Lead using a stab incision and tools included in the Kit. The second, alternative method, describes how to implant the Lead using an open procedure where the nerve location has been surgically exposed. Information on Lead testing is provided after these sections.

## Device Description

The StimRouter System consists of the following components and accessories:

- An implantable multi-electrode lead with integrated receiver in loader.
- Surgical tools for implantation of the implantable lead.
- An external programming system with a clinician programmer and charger, an external pulse transmitter tester and accessories.
- A patient-operated system with an external pulse transmitter (StimRouter EPT), disposable StimRouter Electrodes, an external patient programmer and charger, and accessories.

## Contents

The StimRouter Implantable Lead and Lead Introducer Kit consists of both sterile and non sterile components.

### Sterile Tray Components

- (1) Implantable Multi-Electrode Lead with Integrated Receiver (StimRouter Lead) in Loader
- (2) Stimulation Probes
- (2) Stimulation Cables (yellow)
- (1) Introducer Set 9 Fr
- (1) Lead Adapter
- (1) Tunneling Needle
- (1) Tunneling Needle Stylet

### Non Sterile Components

- (1) Pack of 4 Gel Electrodes
- (1) Gel Electrode Cable (black)
- Procedure Manual

## Component Description

### StimRouter Lead and Loader

The StimRouter Lead is supplied in a loader (see Figure 3) and packaged in a sterile tray for direct entry into the sterile field. Specifications for the StimRouter Lead are provided in Table 1.

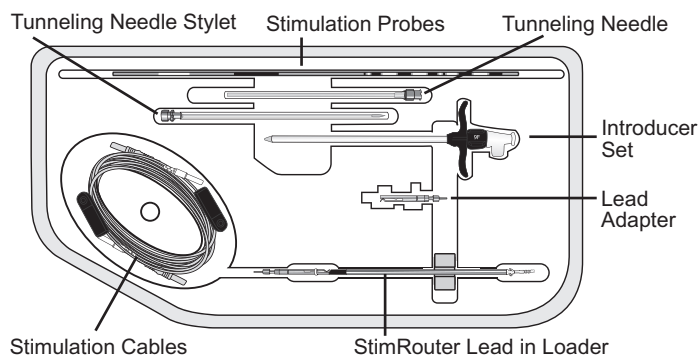


Figure 1: Sterile Kit Contents

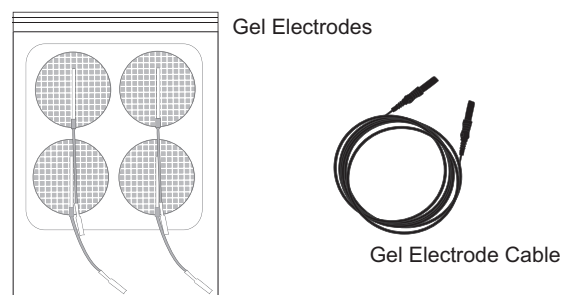


Figure 2: Non Sterile Contents

The receiver end of the StimRouter Lead captures a portion of the signal generated by the StimRouter EPT and emitted by the surface gel pads on the StimRouter Electrode. The receiver end of the StimRouter Lead has one receiver electrode, which is manufactured by coiling the wire on the outside of the silicone tubing at the end of the lead. The conductive surface of the receiver end is in contact with the surrounding tissue.

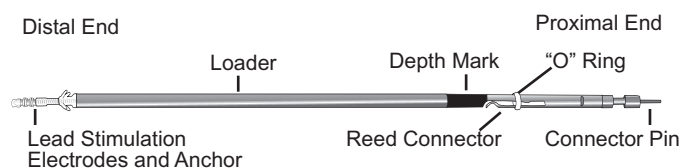


Figure 3: StimRouter Lead

The stimulation end of the StimRouter Lead delivers the current received from the receiver end of the lead to the target stimulation point. The stimulation end of the lead has three electrodes, which are manufactured by coiling the wire on the outside of the silicone tubing at the end of the lead. The conductive surface of the stimulation end is in contact with the surrounding tissue. Each electrode measures 1 mm in length and is spaced 1 mm from the adjacent electrode. The silicone anchor of the StimRouter Lead secures the lead in the tissue. This four-pronged anchor placed toward the distal end of the lead, just proximal to the stimulation electrodes, ensures proper lead release from the insertion tools and is designed to reduce lead migration after implantation (see Figure 4).

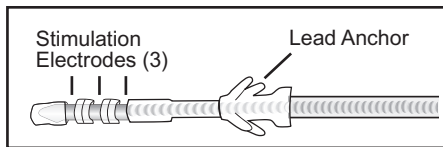


Figure 4: StimRouter Lead Stimulation End (close-up)

The lead body of the StimRouter Lead connects the receiver end of the lead with the stimulation end of the lead. The lead body consists of a coiled wire conductor within silicone tubing. The conductor is insulated from the tissue by the silicone tubing and by the silicone backfill that closes the tubing at each end.

The StimRouter Loader consists of a stainless steel tube with a reed connector designed to ensure a galvanic connection with the StimRouter Lead. (Do not squeeze the reed connector. Pressure on the reed connector can damage the lead.) The distal end of the loader exposes the three stimulation electrodes of the lead and the lead anchor. The proximal end of the loader has a connector pin, used to connect the loader to the yellow Stimulation Cable when testing the StimRouter Lead.

Lead length	15 cm
Lead body diameter	1.2 mm
Lead anchor diameter	1.5 mm
Receiver/Proximal electrodes (count)	1
Stimulation electrodes (count)	3
Electrode length	1 mm
Electrode spacing	1 mm
Electrode material	Platinum-Iridium wire
Insulation material	Silicone
Conductor material	Platinum-Iridium wire
Conductor resistance	< 25 ohms

Table 1: StimRouter Lead Specifications

**CAUTION:** Do not substitute non-Bioness components for components included in the StimRouter Implantable Lead and Lead Introducer Kit.

The StimRouter Implantable Lead and Lead Introducer Kit also contains the surgical tools used for implantation of the StimRouter Lead. Implanting physicians should read the product literature included in this kit before performing the StimRouter implant procedure.

### Stimulation Probe

The Stimulation Probe is used to locate the target stimulation point for the stimulation end of the StimRouter Lead. Two Stimulation Probes are provided. Only one Stimulation Probe is used in the implant procedure. The second Stimulation Probe is supplied for backup.

The Stimulation Probe is a stainless steel wire coated with titanium nitride and insulated in a PET shrink tube. It is cylindrical in shape and is approximately 27 cm long. The stimulation end of the Stimulation Probe is distinguished by 1 cm graduated black and white pad-printed markings (see Figure 5). The proximal end of the Stimulation Probe is distinguished by one larger white band and one larger black band. The proximal end of the Stimulation Probe will attach to the white connector on the yellow Stimulation Cable during the implant procedure.

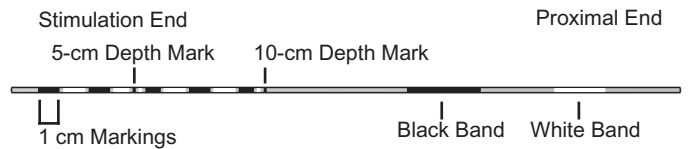


Figure 5: Stimulation Probe

### Stimulation Cable (Yellow)

The yellow Stimulation Cable is used during the implant procedure to connect the Stimulation Probe, Loader and Lead Adapter to a Peripheral Nerve Stimulator (PNS). Two yellow Stimulation Cables are provided. Only one yellow Stimulation Cable is used in the implant procedure. The second one is provided for backup.

The Stimulation Cable is approximately 2 meters in length. It has a yellow connector for attachment to a PNS yellow connector, and a white connector for attachment to the proximal end of the Stimulation Probe, Loader and Lead Adapter (see Figure 6). The Stimulation Cable also includes a black clip for securing the Stimulation Cable to the sterile drape during the implant procedure. The PNS is used for intraoperative testing of the implantable lead.

**Warning:** Only yellow and black connectors of the PNS are used in this procedure. Any other PNS connectors must NEVER BE USED.

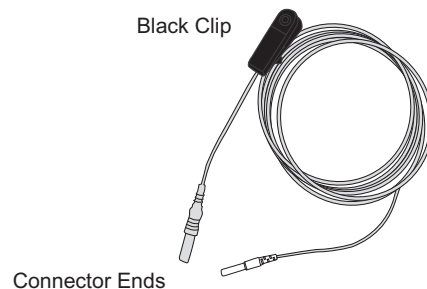


Figure 6: Stimulation Cable (Yellow)

### Introducer Set

The Introducer Set is used to aid in routing, or directing, the stimulation end of the StimRouter Lead from the incision to the target stimulation point. The Introducer Set consists of a blue dilator inserted in a white sheath. The components are locked together by a luer lock (see Figure 7). The Introducer Set insertable length is approximately 11 cm.

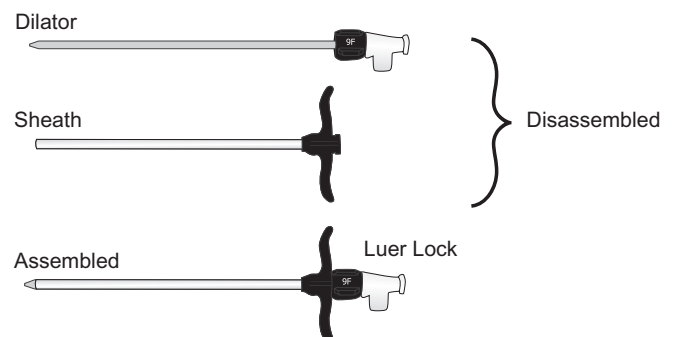


Figure 7: Introducer Set

### Lead Adapter

The Lead Adapter is used to connect the yellow Stimulation Cable to the StimRouter Lead during intra-operative testing of

the StimRouter Lead. The Lead Adaptor is cylindrical in shape, made of stainless steel and is 5.5 cm in length. (see Figure 8).

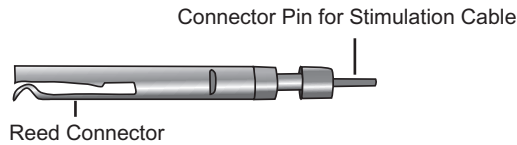


Figure 8: Lead Adapter

### Tunneling Needle and Tunneling Needle Stylet

The Tunneling Needle and Tunneling Needle Stylet are used to implant the receiver end of the StimRouter Lead. The 12-gauge stainless steel hollow Tunneling Needle has an insertable length of approximately 11 cm. The solid stainless steel Tunneling Needle Stylet has an insertable length of approximately 12 cm.

The components are supplied separately, in protective sheaths. The Tunneling Needle Stylet is sharp. Take care during assembly not to puncture the skin. To assemble, remove the protective sheath over the Tunneling Needle Stylet, insert the stylet into the Tunneling Needle and twist the handles to align. (The handles do not lock together.)

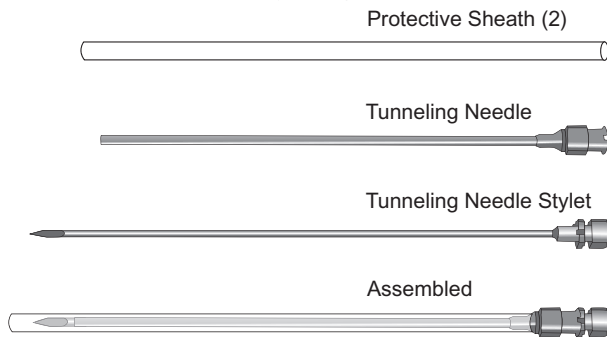


Figure 9: Tunneling Needle and Tunneling Needle Stylet Components and Assembly

### Gel Electrodes and Gel Electrode Cable

The nonsterile components of the StimRouter Implantable Lead and Lead Introducer Kit are packaged separately on top of the sterile tray. The nonsterile components are: one pack of four gel electrodes and one black gel electrode cable. One gel electrode is used during the StimRouter implant procedure as a grounding pad when stimulation is applied through the Stimulation Probe and StimRouter Lead. The other gel electrodes are provided for backup. Electrode diameter is 5 cm.

The black gel electrode cable is 1.5 meters in length. The gel electrode cable is used to connect the PNS to the gel electrode during the StimRouter implant procedure.

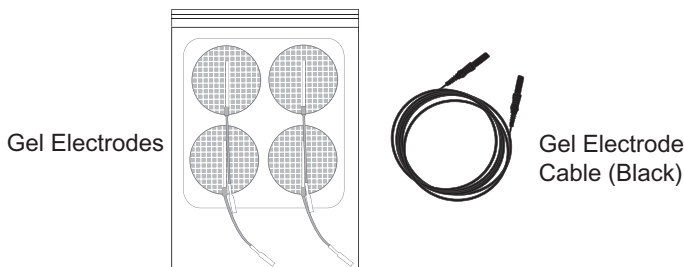


Figure 10: Gel Electrodes (Pack of 4) and Gel Electrode Cable (Black)

StimRouter Implantable Lead and Lead Introducer Kit.

Components are for use in a single procedure only. Once the kit is opened, discard unused contents.

### Contraindications

Patients who have any active implanted medical device such as an implanted demand cardiac pacemaker or defibrillator, or any metallic implant in the immediate area intended for implant. Maintain a minimum safe separation distance of 15 cm (6 in.) between the StimRouter System and all other active implanted devices and metallic implants.

A risk/benefit determination should be performed before using the StimRouter System for:

- Patients exposed to diathermy, shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients who have Bioness StimRouter Neuromodulation System. The energy generated by diathermy can be transferred through the StimRouter System components, causing tissue damage at the lead site and potentially resulting in severe injury. Diathermy may also damage the StimRouter System components, resulting in loss of therapy. Injury or damage can occur during diathermy treatment whether neurostimulation is turned on or off. All patients are advised to inform their health-care professionals that they should not be exposed to diathermy.
- Patients exposed to therapeutic ultrasound.
- Patients who are unable to operate the StimRouter Neuromodulation System.
- Patients who are high surgical risks or poor surgical candidates in general.
- Patients who have a cancerous lesion present near the target stimulation point or near to where the StimRouter Electrode will adhere.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days close to the time of the surgical procedure.

### ⚠ Warnings

- The long-term effectiveness of neurostimulation is unknown.
- Simultaneous connection of a patient to the StimRouter components and high-frequency surgical equipment may result in skin burns where the gel pads on the back of the StimRouter Electrode adhere to the skin and may damage the StimRouter external pulse transmitter (EPT). Advise patients to remove the StimRouter Electrode before medical treatment.
- Electrosurgery devices should not be used in close proximity to the implantable lead. Contact between an active electrode of the electrosurgery device and the implanted lead can cause direct stimulation of the target stimulation point and severe injury to the patient.
- The effects of electrical stimulation on pregnancy are unknown. Patients should avoid exposure to electrical stimulation for the entire duration of pregnancy.
- The StimRouter components should only be programmed by the treating clinician and/or under proper medical guidance.
- The use of non-Bioness components with the StimRouter System may result in damage to the system and increased risk to the patient.

**⚠ Caution:** Do not resterilize or reuse any items in the

- Advise patients to turn the StimRouter System (patient programmer and stimulation) off when near a refueling station, flammable fuel, fumes or chemicals. The operation of the StimRouter could cause the chemicals or fumes to ignite, causing severe burns, injury or death.
- Advise patients to turn off stimulation while driving and operating machinery.
- The following medical therapies or procedures may turn stimulation off, may cause permanent damage to the StimRouter external components and may injure the patient, particularly if used in close proximity to the system components: lithotripsy, electrocautery, external defibrillation, ultrasonic scanning, and high-output ultrasound.
- Electromagnetic interference (EMI) from the following medical procedures is unlikely to affect the Bioness StimRouter Neuromodulation System: computerized axial tomography (CT or CAT) scans, diagnostic ultrasound (e.g., carotid scan, Doppler studies), and diagnostic x-rays or fluoroscopy. Advise patients to remove the StimRouter Electrode before undergoing medical therapies or procedures.
- Although unlikely, body-worn medical devices, such as an insulin pump or a monitoring device, may interfere with the RF communication used in the Bioness StimRouter Neuromodulation System. Stimulation control may be delayed, in which case visual alerts will be emitted by the StimRouter Patient Programmer. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the StimRouter System and all other electronic devices. Refer to the Troubleshooting section and Appendix of the StimRouter User's Guide for more information.
- The StimRouter System wireless technology may cause EMI to other body-worn medical devices. Refer to the instructions for use for those devices regarding information on recommended minimum separation distances.
- Certain types of security devices, such as those used at the entrances and exits of public buildings such as libraries, airports and retail stores, may affect stimulation. Patients should use caution when approaching a security screening device. They should ask for assistance to bypass the device by showing their Medical Device Identification Card. (Refer to the StimRouter User's Guide for more information.) If they must pass through such a device, then patients should turn stimulation off and pass through the device quickly and stay as far from the emitter as possible; for example, in the center of a pass-through security gate.
- There is potential for interference between electronic devices, including cell phones. Stimulation control may be delayed. To minimize interference, maintain a minimum safe distance of 15 cm (6 in.) between the StimRouter System and all other electronic devices. If interference is suspected or anticipated, distance yourself from the source of interference.

## Precautions

- Only a licensed physician should perform the StimRouter implantation procedure. Bioness requires that physicians be formally trained in the StimRouter implantation procedure by Bioness and/or a physician with experience in performing the procedure.
- Physicians should adequately observe the incision site and

monitor for infection, possible device rejection or other possible adverse effects. If the patient notices excessive redness or discharge around the incision site, then the physician should be contacted immediately to check for infection and administer proper treatment following standard medical procedures.

- Advise patients to never manipulate the implantable lead. If the StimRouter Lead is moved from the target stimulation point, then it may not function correctly or effectively. In some instances a lead can move from its original location, thus causing a loss of stimulation at the target stimulation point. If the lead moves, then the lead may need to be replaced.
- Use caution when treating patients with suspected or diagnosed heart problems.
- Electrical stimulation should not be applied trans-thoracically or at the heart such that current may travel into or through the cardiac tissue, as such introduction of electrical current may cause heart rhythm disturbances.
- Turn off stimulation before adhering, removing or handling the StimRouter Electrode.
- StimRouter Electrode placement and stimulation settings should be determined by the implanting physician and/or treating clinician.
- Do not apply the StimRouter Electrode over any obstruction that would reduce the designated electrode surface area (for example, an adhesive bandage). A smaller electrode surface area could result in serious injury to the patient.
- Do not apply the StimRouter Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.
- Always inspect the gel pads on the back of the StimRouter Electrode before use. Do not apply the StimRouter Electrode if the gel pads appear dried out, worn, dirty or irregular.
- Make sure the StimRouter Electrode liner is removed before applying the StimRouter Electrode.
- Do not handle the StimRouter Electrode with both hands while stimulation is on; serious injury can result from current passing through the cardiac tissues.
- The StimRouter Electrode is meant to be worn only by the patient for whom it is prescribed and in the location for which it is prescribed. Patients and physicians should not adhere the StimRouter Electrode to any other person or to any other part of the body.
- Do not adhere the StimRouter Electrode to sites that are swollen, infected or inflamed, or that have skin eruptions such as phlebitis, thrombophlebitis and varicose veins. Do not adhere the StimRouter Electrode to skin that is broken.
- It is normal for the skin under the StimRouter Electrode to become red. The redness should disappear in approximately one hour once the StimRouter Electrode is removed. However, some patients may experience skin irritation, an allergic reaction, or hypersensitivity to the electrical stimulation or the gel electrodes. Persistent redness, lesions or blisters are signs of irritation. Use of the StimRouter components should be temporarily halted until the irritation is resolved. In some cases, irritation can be avoided by removing the StimRouter Electrode periodically to allow the skin to breathe and changing the stimulation parameters. Patients should consult their physician if irritation persists.



- Changes in posture or abrupt movements may decrease or increase the perceived level of stimulation. Advise patients to turn off stimulation before making extreme posture changes or abrupt movements such as stretching, lifting of arms overhead or exercising.
- The StimRouter components should be kept out of the reach of children.
- Do not use a StimRouter Electrode with a “Use by” date that has expired.
- All StimRouter components and accessories should be handled with care. Components and accessories should not be dropped. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the components on hard surfaces, or other rough handling, can permanently damage the components.
- Verify that the StimRouter Implantable Lead and Lead Introducer Kit expiration (“Use By”) date has not expired. If it has expired, do not use any of the components.
- Open the StimRouter Implantable Lead and Lead Introducer Kit using sterile technique.
- The StimRouter Implantable Lead and Lead Introducer Kit is for use in a single procedure only. Never resterilize or reuse components in the StimRouter Implantable Lead and Lead Introducer Kit. Once the kit is opened, discard all unused components.
- StimRouter Implantable Lead and Lead Introducer Kit Storage Temperature Range: 0°C to 40°C (32°F to 104°F).

**CAUTION:** Do not use the contents of the StimRouter Implantable Lead and Lead Introducer Kit if a defective sterile package seal is suspected.

## Adverse Effects

Potential risks are involved with any surgery. In addition to those typically associated with surgery, the possible risks associated with lead implantation and use of the Bioness StimRouter Neuromodulation System includes those listed below.

- Suboptimal lead placement may necessitate therapeutic adjustment and/or lead explant. Nerve injury is possible, although unlikely. Possible surgical complications include infection, cellulitis, abscess, fever, sepsis, bleeding and temporary pain at the implant site.
- Operation of the StimRouter components may cause increased pain in an area other than the lead site. This pain may be caused by stimulation of the tissue surrounding the stimulation electrodes (skin, fascia and muscle).
- Patients may experience an undesirable motor response during stimulation. If patients experience any pain or discomfort during stimulation, or notice any skin abnormalities, they should stop stimulation immediately, remove the StimRouter Electrode and notify their physician.
- Migration of the StimRouter Lead may cause changes in stimulation effectiveness.
- While unlikely, a tissue reaction to the implanted materials may occur.
- External electromagnetic interference may cause the StimRouter components to malfunction and may affect stimulation.

- Patients may experience persistent pain at the implant site of the implantable lead.
- Although rare, the skin overlying the lead may erode.
- Portable and mobile radio frequency communications equipment can affect medical electrical equipment.
- The StimRouter external components could overheat if the components fail, which could cause burning.
- If patients experience any pain or discomfort during stimulation, or notice any skin abnormalities, they should stop stimulation immediately, cease contact with the StimRouter System components and notify their physician.

## Sterilization

Items in the StimRouter Implantable Lead and Lead Introducer Kit have been sterilized using ethylene oxide gas and are supplied in a sterile package to permit direct introduction into the sterile field.

- Never resterilize or reuse the components in the StimRouter Implantable Lead and Lead Introducer Kit for a separate procedure. Components are for use in a single procedure only.
- Reuse in a single procedure could damage the components. Examine the components before reuse in a single procedure.
- Once a kit is opened, discard all unused components.
- Verify that the expiration (“Use by”) date on the StimRouter Implantable Lead and Lead Introducer Kit has not expired. If a date has expired on a kit, do not use any of the components in the kit.

**CAUTION:** Always open sterile trays using sterile technique.

**CAUTION:** Do not use contents if a defective sterile package seal is suspected.

**CAUTION:** Due to the risk of infection and loss of product optimal performance, do not re-sterilize and re-use any components of the StimRouter Implantable Lead and Lead Introducer Kit.

## Procedure

At some time before the implant procedure it is recommended that the implant physician evaluate and determine the best anatomic position for both the implanted subcutaneous receiver end of the implantable lead and the overlying StimRouter Electrode on the skin surface. See Figure 11.

Effectiveness of stimulation is sensitive to alignment and rotation of the StimRouter Electrode (with EPT attached) in relation to the receiver end of the StimRouter Lead. If the alignment or rotation of the StimRouter Electrode changes, the stimulation intensity may need to be adjusted. Issues to consider may include variation in cosmetics, skin folds, hair, anatomy (including placement issues that may arise with typical movement or changes in position, such as going from supine or prone to sitting or standing), motor response, etc.

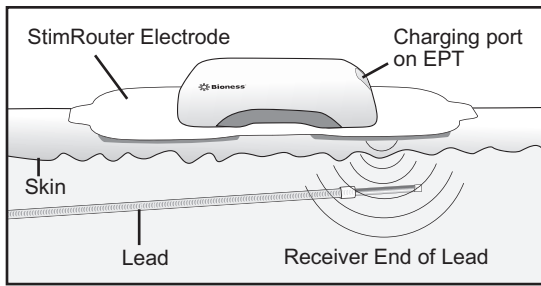


Figure 11: Depiction of StimRouter for Evaluation of the Best Anatomic Position

## Equipment Preparation

1. Have a nonsterile assistant position the patient. Hair removal is not required.
2. Set up the PNS by following the manufacturer's instructions for use. Remove the PNS from the package, and place it outside the sterile field. Check the battery charge level. If required, install new battery(ies) according to the manufacturer's instructions for use. Set the output amplitude to zero level.

Note: The output level reading of the PNS may not be accurate until the grounding electrode is attached to the patient and the Stimulation Probe is inserted.

**Caution:** Inspect the StimRouter Implantable Lead and Lead Introducer Kit sterile package for sterile integrity before opening. If the sterile package has been opened, damaged or altered, do not use any of the items in the StimRouter Implantable Lead and Lead Introducer Kit.

**Caution:** Do not use a sterile package if the "Use by" date has expired. Open using sterile technique. Do not resterilize.

3. Have a nonsterile assistant open the StimRouter Implantable Lead and Lead Introducer Kit and place the nonsterile components and product literature outside the sterile field. Sterile nurse to peel back the outer cover of the outer tray. Place the inner sterile tray onto the sterile field without compromising the sterility of the sterile field.
4. Using sterile technique, grasp the sterile tray's tab and then peel off the inner cover to expose the contents without dropping them.
5. Remove the lead in loader from the tray and carefully separate the silicone holder from the loader. See Figure 12.

**Caution:** Do not squeeze the reed connector. Pressure on the reed connector can damage the lead.

**Caution:** Do not slide the silicone holder along the shaft of the loader. Sliding the holder could cause the holder to catch on the anchor and prematurely deploy the lead.

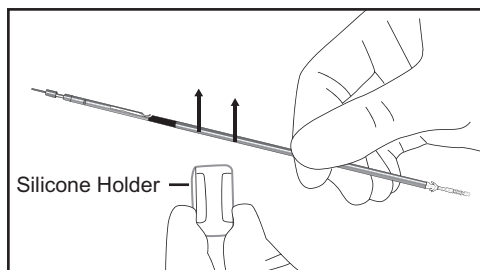


Figure 12: Separating the Lead in Loader from the Silicone Holder

6. Gently slide the protective "O" ring on the loader into the notch on the proximal end of the loader (see Figure 13).

**Caution:** Do not squeeze the reed connector. Pressure on the reed connector can damage the lead.

**Caution:** Do not move the "O" ring into the reed connector.

**Caution:** Do not remove the "O" ring. The "O" ring is used to protect the lead during shipping only.

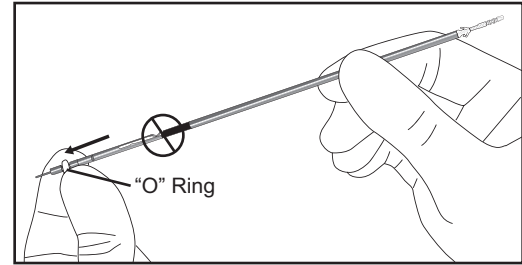


Figure 13: Correct Direction to Slide the "O" Ring

7. Place the prepared StimRouter Lead in Loader on a sterile, lint-free surface.
8. Remove the remaining sterile components from the inner sterile tray and place on the sterile field.
9. Assemble the Tunneling Needle; remove the protective sheath over the Tunneling Needle Stylet, insert the stylet into the Tunneling Needle and twist the handles to align (see Figure 9). The handles do not lock together.
10. Have the nonsterile assistant remove one gel electrode and the black gel electrode cable from their packaging. Remove the gel electrode from the plastic backing. Place the gel electrode on the patient's skin outside the sterile field and near to the implant site, where current cannot cross the patient's chest cavity. Connect the gel electrode to the connector on the black gel electrode cable. Connect the black gel electrode cable to the black connector of the PNS.

**Caution:** Do not allow current to pass across or through the patient's chest cavity such that current may pass through the cardiac tissues.

**Warning:** Only yellow and black connectors of the PNS are used in this procedure. Any other PNS connectors must NEVER BE USED.

11. Identify the implant site for the StimRouter Lead. Sterile prep and drape the skin using institutional guidelines. Identify the skin area overlying the target stimulation point. Using a sterile marker, mark the skin superficial to the target stimulation point. Determine the approximate depth of the target stimulation point. Using a sterile marker, make a second mark to indicate the intended incision point for inserting the stimulation end of the lead, approximately 6 - 9 cm from the target stimulation point (see Figure 14). Placement of the incision mark will depend on the depth of the target stimulation point. As the depth of the target stimulation point increases, the two skin markings will be closer to each other.

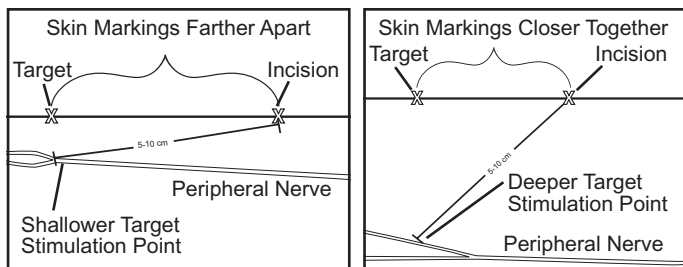


Figure 14: Establish Skin Markings

12. Attach the black clip on the yellow Stimulation Cable to the sterile drape to prevent accidental contamination of the sterile white connector of the Stimulation Cable.

**Caution:** Keep the white connector of the stimulation cable sterile.

13. Hand the yellow connector of the Stimulation Cable to the nonsterile assistant to attach to the PNS yellow connector. Confirm that the output amplitude of the PNS is set to zero.

## Target Point Identification

1. Per standard surgical procedure, inject local anesthesia at the intended incision point, taking care not to anesthetize the target stimulation site, including the target stimulation point (both in terms of injection location and injected anesthetic drug volume).
2. Make a single 10–15 mm incision (#11 blade suggested) through the cutaneous and subcutaneous layers at the incision mark. It is recommended that the incision line be transverse to the trajectory intended for the lead insertion.
3. Attach the proximal end of the Stimulation Probe to the white connector of the yellow stimulation cable (see Figure 15).

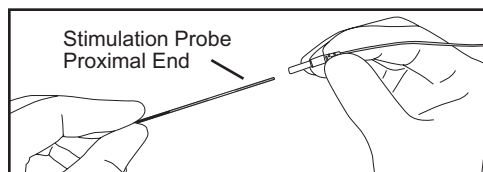


Figure 15: Connecting the Stimulation Probe to the White Connector

4. Insert the stimulation end of the Stimulation Probe through the incision, moving subcutaneously just past the target stimulation point (see Figure 16).

**Caution:** Take care not to perforate an artery or vein with the Stimulation Probe.

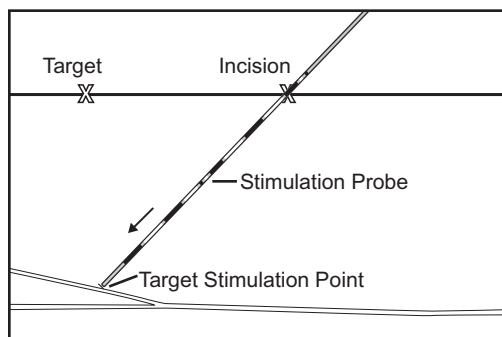


Figure 16: Insertion of the Stimulation Probe

5. Verify that the output amplitude of the PNS is set to zero.

**Caution:** An output setting on the PNS that is too high

can result in tissue damage. Always consult the PNS product literature for the manufacturer's instructions before operating.

6. Have the nonsterile assistant activate the PNS output at stimulation frequency of 50Hz, and slowly increase the output amplitude until the display reads a maximum of 3.0 mA or until the patient is uncomfortable, whichever comes first.

**Note:** If the amplitude output is not displayed, check all cable connections, make sure the gel electrode is adhered to the patient's skin and then try again. Recheck the screen display. If the screen is still not displaying amplitude output, do not proceed. Consult the PNS product literature included in the PNS package or contact your local distributor.

**Warning:** Only yellow and black connectors of the PNS are used in this procedure. Any other PNS connectors must NEVER BE USED.

7. While applying the 50Hz stimulation, establish a location for the stimulation end of the probe that produces paresthesia in the sensory distribution of the target nerve.

**Note:** The stimulation parameters used intraoperatively with the PNS should be recorded for future programming of the StimRouter implant system. See "StimRouter Programming" section.

8. If paresthesia is not achieved, withdraw the stimulation end of the probe and reinsert it in the corrected direction. Repeat as necessary until paresthesia is achieved.

**Caution:** Do not bend the Stimulation Probe while it is inserted in the tissue, nor manipulate the tissue to elicit paresthesia. Doing so could result in damage to the Introducer Set and lead when they are inserted.

9. To find the minimal stimulation amplitude, slowly decrease the amplitude level of the stimulation output until paresthesia response is lost.
10. Once paresthesia is lost, slowly increase the stimulation amplitude until paresthesia is restored. Optimally, the stimulation amplitude level should be no greater than 1.5 mA. If paresthesia cannot be achieved at a target stimulation amplitude level of 1.5 mA or less, then repeat Steps 7-10.
11. Disconnect the white connector of the yellow Stimulation Cable from the Stimulation Probe once paresthesia is restored at a stimulation amplitude level of less than 1.5 mA. Take care to maintain the depth and orientation of the Stimulation Probe. Small changes in the location of the stimulation end of the probe may compromise achieved results.

**Note:** If desired, use fluoroscopic imaging to document anatomical placement of the probe and for reference when implanting the lead.

**Caution:** Use care when inserting into tissue that venous or arterial vessel damage does not occur.

12. Have the sterile assistant hold the Stimulation Probe in place, to make sure the stimulation end does not move from the target stimulation point. Using the pad-printed marks, take note of the depth of the Stimulation Probe for reference should the probe move.

- Slide the pointed tip of the Introducer Set dilator over the proximal end of the Stimulation Probe (see Figure 17).

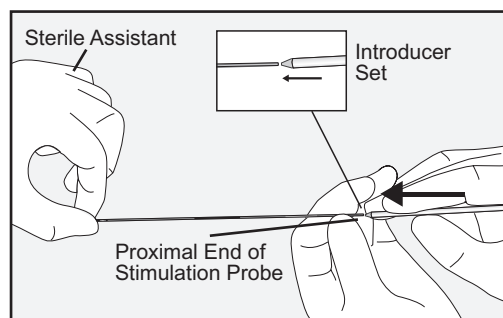


Figure 17: Slide Introducer Set Over Stimulation Probe

Note: Make sure at all times that the position of the Stimulation Probe relative to the tissue remains constant. Displacement of the tip will necessitate readjustments to attain optimal placement.

- Advance the Introducer Set toward the stimulation end of the Stimulation Probe until the entire black band on the probe is visible. Align the distal edge of the black band on the Stimulation Probe with the proximal end of the Introducer Set (see Figure 18). In this position, only the tip of the stimulation end of the probe is protruding from the dilator at the target stimulation point (see Figure 19).

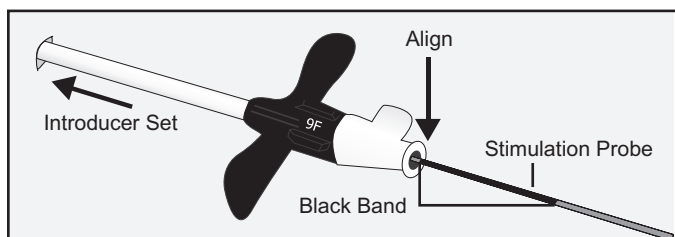


Figure 18: Distal Edge of the Black Band on Stimulation Probe Aligns with Proximal End of Introducer Set

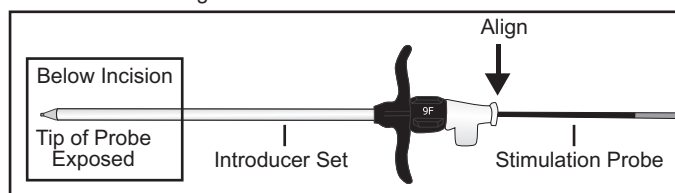


Figure 19: Position of Tip of Stimulation Probe

- Once the Stimulation Probe and the Introducer Set are aligned, reattach the white connector of the yellow stimulation cable to the proximal end of the Stimulation Probe.
- Retest the probe using the PNS. A patient response similar to that achieved initially with the Stimulation Probe confirms correct placement of the Stimulation Probe and the Introducer Set.

Note: If the patient reports a diminished response, first check that the distal edge of the black band on the Stimulation Probe is still aligned with the proximal end of the Introducer Set. Then, if necessary, slightly adjust the amplitude on the PNS. If neither of these adjustments achieves paresthesia, move the Stimulation Probe and the Introducer Set slightly forward or backward along the path of insertion. If no acceptable result can be attained, then remove the Introducer Set and the Stimulation Probe. Inspect the components for mechanical damage. If the components are not bent or otherwise damaged, then repeat

the Stimulation Probe insertion procedure.

- Slowly withdraw the Stimulation Probe from the Introducer Set.

**Caution:** Avoid withdrawing the Introducer Set while removing the Stimulation Probe. Movement of the Introducer Set may interfere with proper lead placement.

- Detach the white connector of the yellow stimulation cable from the Stimulation Probe. Make certain both the white connector and the Stimulation Probe stay within the sterile field.

- Unlock the Introducer Set dilator from the sheath by twisting the luer lock counterclockwise (see Figure 20).

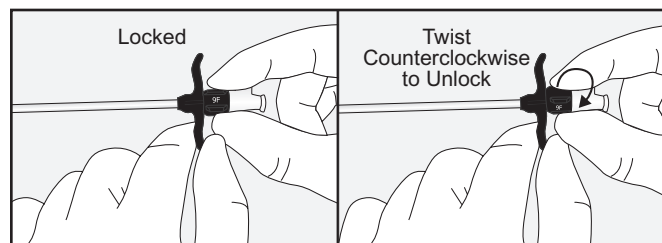


Figure 20: Unlock the Luer Lock

- Slowly pull the dilator from the sheath without moving the sheath. (See Figure 21). Keep the dilator in the sterile field.

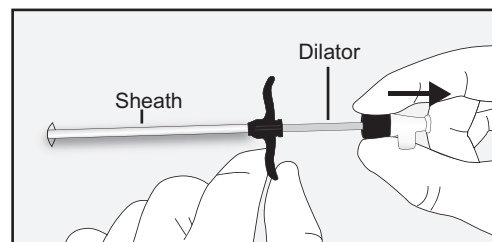


Figure 21: Slowly Pull the Dilator from the Sheath

## Lead Insertion: Stimulation End

- Attach the white connector of the yellow Stimulation Cable to the connector pin of the Loader. Do not squeeze the reed connector.
- With the sheath still in place, insert the StimRouter Lead in Loader (anchor end first) into the sheath until the distal end of the depth mark on the loader aligns with the proximal end of the sheath. In this position, the lead is not yet exposed (see Figure 22).

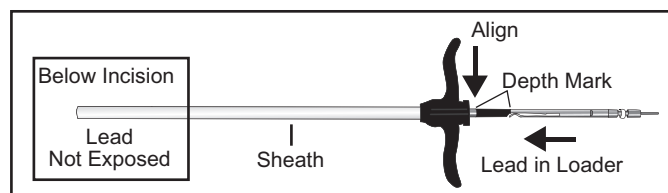


Figure 22: Insert the StimRouter Lead in Loader into the Sheath

- Firmly hold the StimRouter Lead in Loader in its fixed position relative to the tissue.

Note: Do not advance the lead any farther at this point. Doing so can damage the lead.

- Slowly withdraw the sheath until the proximal end of the



sheath aligns with the proximal end of the mark on the loader (see Figure 23). In this position, the stimulation end of the lead is exposed.

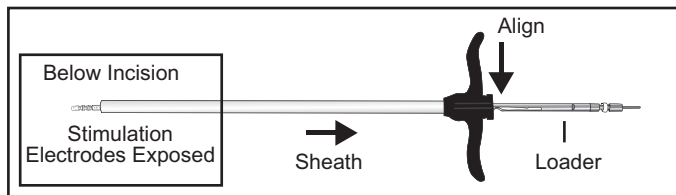


Figure 23: Slowly Withdraw the Sheath to the Mark on the Loader

5. Test the positioning of the stimulation end of the lead with the PNS by adjusting the stimulation amplitude as needed to achieve paresthesia. Slightly higher amplitude may be required to achieve paresthesia.

Note: The stimulation parameters used intraoperatively with the PNS should be recorded for future programming of the StimRouter implant System. See “StimRouter Programming” section.

6. If the patient reports a diminished response, then adjust placement to improve the response. If an acceptable response cannot be achieved, withdraw the StimRouter Lead in Loader together with the sheath. Inspect the components for mechanical damage. If the components are not bent or otherwise damaged, then retry the Stimulation Probe insertion procedure.
7. If the patient's response signals correct lead placement at acceptable stimulation intensity, then hold the lead in loader firmly. Slowly withdraw the sheath approximately 2 cm, until the proximal end of the sheath aligns with the proximal end of the reed connector on the loader. This step deploys the lead anchor. See Figures 24 and 25.

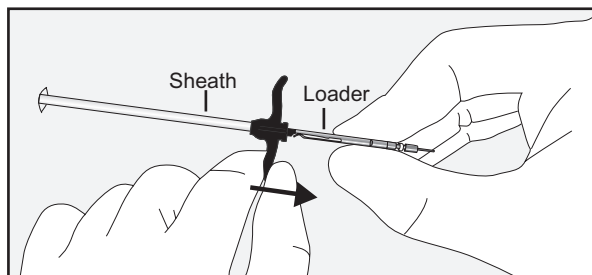


Figure 24: Pull the Sheath until the Proximal End is Aligned with the Proximal End of the Reed Connector

Note: Once the anchor is deployed, do not stimulate the lead again until after the loader and sheath are withdrawn. Doing so may result in an unrepresentative physiological response.

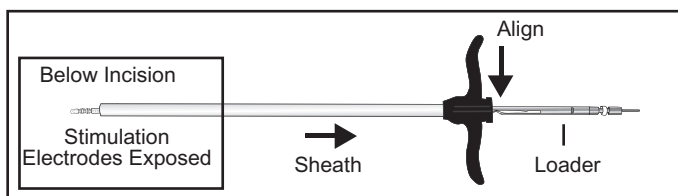


Figure 25: In This Position Lead Anchor is Deployed.

## Lead Testing

1. If desired, use fluoroscopic imaging to document the anatomical placement of the StimRouter Lead in Loader for future reference.
2. With one hand, gently apply pressure to the tissue

surrounding the stimulation end of the lead. With the other hand, gently withdraw the loader from the sheath. Do not squeeze the reed connector. Pressure on the reed connector can damage the lead (see Figure 26).

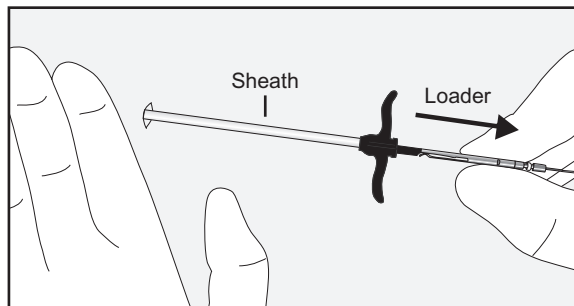


Figure 26: Withdraw the Loader From the Sheath

3. While maintaining pressure on the tissue, withdraw the sheath from the tissue, leaving the receiver end of the StimRouter Lead protruding through the skin.
4. Have the sterile assistant disconnect the yellow Stimulation Cable from the connector pin of the loader.
5. Connect the receiver end of the StimRouter Lead to the Lead Adapter (See Figure 27). Visually confirm that the receiver end of the lead is in contact with the reed connector.

**Warning:** Do not squeeze the reed connector. Pressure on the reed connector can damage the lead.

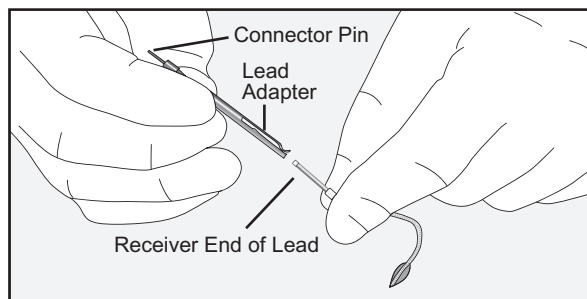


Figure 27: Connect the StimRouter Lead to the Lead Adapter

6. Attach the white connector of the yellow Stimulation Cable to the connector pin of the Lead Adapter.
7. Test for correct placement of the StimRouter Lead using the PNS.

Note: The stimulation parameters used intraoperatively with the PNS should be recorded for future programming of the StimRouter implant system. See “StimRouter Programming” section.

8. A patient response similar to that achieved on prior tests confirms correct placement of the lead. Continue to Lead Insertion: Receiver End” Section.
9. If the patient reports a diminished response, then detach the Lead Adapter from the StimRouter Lead, and keep the Lead Adapter in the sterile field. Explant the lead by grasping the lead body as close to the skin as possible. Then, keeping slight but constant pressure on the skin surface, slowly withdraw the lead from the skin along the path of insertion (see Figure 28). Take care not to stretch the lead; stretching could cause the lead to fracture. Repeat the implant procedure using a new StimRouter Lead in Loader. If the lead fractures, then see “Alternative Explant Procedure” section.

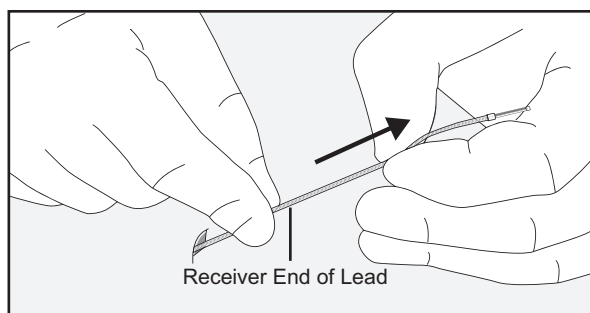


Figure 28: Explant StimRouter Lead

## Lead Insertion: Receiver End

1. Measure the length of lead protruding from the skin.
2. Select a termination site for the receiver end of the lead. The receiver end should not cross a joint and must terminate in an area where the patient can tolerate surface stimulation and where the StimRouter Electrode can adhere to the skin.
3. Identify an insertion point for the Tunneling Needle. To reduce the risk of the receiver becoming exposed, the insertion point must be farther from the intended termination site for the receiver, preferably  $\geq 2$  cm but no more than 11.5 cm from the first incision site (see Figure 29).

**Warning:** The Tunneling Needle is sharp. Take care to not injure any arteries, veins or nerves during the tunneling procedure. Do not damage the StimRouter Lead.

4. Inject local anesthesia subcutaneously along the tunneling tract.
5. For optimal insertion, make a small (e.g., stab) incision through the cutaneous and subcutaneous layers at the Tunneling Needle insertion point.
6. Insert the Tunneling Needle assembly subcutaneously into the hypodermis at an angle approximately parallel to the skin surface. Tunnel along a path as shallow as possible, until the tip of the needle exits at the incision point.

**Warning:** During tunneling in the hypodermis, avoid entering the dermis with the Tunneling Needle, to ensure that the lead is placed in the hypodermis. Do not hit the lead.

7. Withdraw the Tunneling Needle Stylet, leaving the needle in place (see Figure 29).

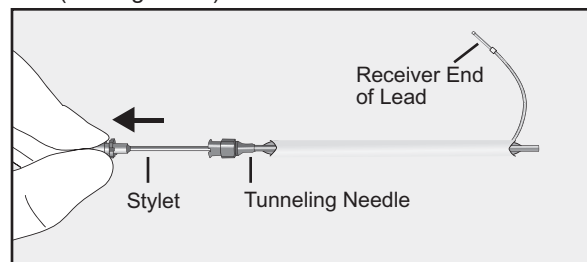


Figure 29: Withdraw the Tunneling Needle Stylet

8. Insert the receiver end of the StimRouter Lead into the distal end of the Tunneling Needle, and push the lead loop until there is no slack in the lead (see Figure 30). If forceps are used, take care not to pinch or damage the lead. Non-toothed forceps are recommended.

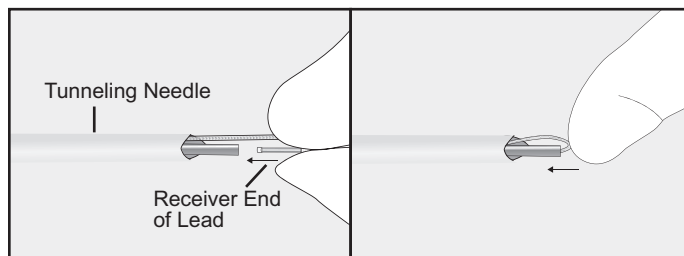


Figure 30: Inserting Receiver End of the StimRouter Lead

9. Slowly withdraw the Tunneling Needle while applying gentle pressure on the incision site to prevent lead migration. No excess lead should be visible at this point. Please proceed to the Wound Closure section.

## Alternative Implant Procedure

### Introduction:

In situations where open implantation of the StimRouter Lead is indicated, surgical exposure of the target StimRouter Lead location may be performed using proper surgical dissection technique, similar to nerve decompression, open nerve neurolysis, peripheral nerve neurolysis, nerve repair, denervation or nerve transfer.

The StimRouter Lead should be placed parallel to the surgically identified nerve with the stimulation electrodes approximately 1-2mm from the nerve. A small portion of soft tissue (e.g. septal fascia) should be interposed between the nerve and stimulation electrodes to avoid direct contact with the nerve.

The StimRouter Lead should be properly fixated with dissolvable sutures and/or dissolvable tissue glue after proper placement. Fixation will help prevent post-operative migration and reduce the possibility of neural irritation. Sutures should be placed so that they will not contact the nerve during normal bodily movement. Care must be taken not to damage the StimRouter Lead during fixation.

After completion of StimRouter Lead placement and fixation, the extremity or body should be moved to stimulate normal human biomechanical motion. Inspection of the site during this passive movement will allow the surgeon to confirm proper StimRouter Lead placement and confirm that fixation should adequately prevent post-operative StimRouter Lead migration.

The remainder of the StimRouter Lead should be pocketed into adjacent soft tissue so that the receiver end is approximately 5-7cm from the stimulation electrodes. The receiver end should be pocketed more superficially and closer to the dermis than the stimulation electrodes. Pocketing may be accomplished via a percutaneous method but should be completed before closure of the surgical incision.

Take care to place the StimRouter Lead to allow patients optimal use of the external StimRouter EPT and StimRouter Electrode. Be sure to place the StimRouter Lead so that the external components will not interfere with normal biomechanics or with anything worn by the patient (i.e. ankle foot orthosis, shoes, clothing, etc.).

Alternative Implant Procedure Instructions: The following instructions represent an alternative StimRouter Lead Insertion technique where "open" implantation of the target peripheral

nerve and StimRouter lead is indicated. They are meant as a general set of guidelines considering the implanters best clinical judgement and standard surgical practice.

1. Mark the intended incision location and inject local anesthesia. If patient feedback is required and the patient is awake, take care not to anesthetize the target stimulation site or target peripheral nerve (account for both injection location and injected anesthetic drug volume).
2. Make a single incision of the appropriate length through the cutaneous and subcutaneous layers at the incision mark to expose the target location of the StimRouter Lead Electrodes.
3. If the patient is under local anesthetic only and patient feedback is required to verify the desired lead placement, or if motor response is required to verify lead location, please refer to the "Target Point Identification on page 7. If patient feedback is not required or possible, proceed to Step 4.
4. Expose the target lead location using proper surgical dissection technique.
5. Remove StimRouter Lead from Lead Loader taking care not to strain or damage the lead. The "O" Ring can be rolled back to allow relaxation of the Reed Connector holding the Lead in place. The Reed Connector on the Lead Loader may need to be lifted slightly to allow the Lead to be removed freely.

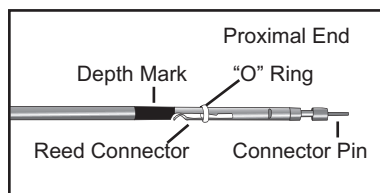


Figure 31: Reed Connector of Lead Loader

6. Place the StimRouter Lead Electrodes in the wound in the desired location. Place Receiver portion of the lead on top of the skin in the general location outside the wound over the subcutaneous location where the receiver will reside. Mark that site with a sterile marker for reference when pocketing the distal portion of the Lead.

**Caution:** Take care to interpose a small portion of soft tissue between the nerve and stimulation electrodes to avoid direct contact with the nerve

**Caution:** Take care to properly fixate the lead using dissolvable tissue glue and/or dissolvable sutures to avoid post-operative lead migration.

7. The StimRouter Lead has an integrated anchor made of silicone tines proximal to the Lead Electrodes that are designed to reduce migration after the wound is healed, approximately 2-4 weeks after implant. If additional anchoring is required, care must be taken not to damage/modify the lead with suture or tissue glue. Damage/ modification to the lead may cause lead malfunction or render the lead inoperable.
8. After the Lead Electrodes are verified and secured, use the Tunneling Needle Stylet to create a tunnel from the wound,

subcutaneously, past the marked area where the Lead Receiver will reside in the subcutaneous tissue. Take care to ensure enough tunnel length to accommodate the Lead Receiver.

9. Pass the Tunneling Needle over the Stylet starting from remote incision location toward the wound until it can be seen in the wound. Remove the Tunneling Needle Stylet leaving the Tunneling Needle in place. See Figure 32.

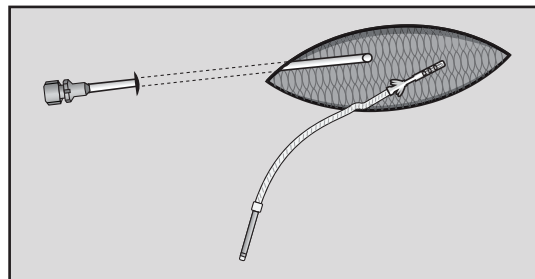


Figure 32: Tunneling Needle Ready for StimRouter Lead Insertion

10. Carefully place receiver portion of StimRouter Lead into the Tunneling Needle. If an instrument is used, take care not to damage the Lead. When the portion of the lead that will be tunneled from the wound is loaded into the Tunneling Needle, gently pull the Tunneling Needle out from the remote incision location taking care not to dislodge the lead electrodes. When the Tunneling Needle is removed, the Lead Receiver should be in the subcutaneous space proximal to the Tunneling Needle exit site. If the Lead Receiver is visible outside the skin pull the Receiver back from the Lead in the wound and create a loop so both the lead's electrodes and Receiver are in the proper/desired locations.
11. Close the incision site using standard techniques such as suture, and apply wound dressing as appropriate.

## Wound Closure

1. The implant physician may choose to use fluoroscopic imaging to document the anatomical placement of the receiver end of the lead.
2. Make certain the "O" ring on the loader is accounted for.
3. Use standard wound closure techniques, such as suture, to close the wounds.

**Caution:** Take care not to loop a suture under the StimRouter Lead.

## Post-Operative Care

Per standard surgical procedure, physicians should adequately observe the incision sites and monitor for infection, possible device rejection or other possible adverse effects. It is recommended that when the incision sites are healed, the skin surface over the receiver end of the StimRouter Lead be marked to assist with accurate StimRouter Electrode placement.

After completing wound closure, ensure that the UDI Serial Number, and Lot of the StimRouter Implantable Lead and Lead Introducer Kit are recorded to be entered on the patient's Medical Device Card.

## StimRouter Programming

The physician should allow 14 days for recovery after implantation before applying the StimRouter Electrode and programming the EPT. However, if a patient is immunocompromised, such as a smoker, diabetic or chronic prednisone user, then the physician should check the patient weekly until the wound appears to be healed.

For initial programming, the stimulation parameters used intraoperatively with the PNS to evaluate proper placement of the StimRouter Lead may provide an efficient starting point for setting therapeutic stimulation parameters. However, such extrapolation of the intraoperative stimulation parameters must account for the energy dispersion likely associated with transdermal stimulation (versus direct electrical connection of the lead to the PNS during the implant procedure). Therefore, the optimal amplitude determined intraoperatively will require multiplication by a factor of 10 to approximate the most effective initial stimulation amplitude for the EPT.

## Explant Procedure

Tissue encapsulation of the StimRouter Lead is expected by approximately 14 days post-implant. If the StimRouter Lead must be explanted prior to encapsulation, then the following procedures may be used. Beyond 14 days, the specific technique used to explant the StimRouter Lead is at the discretion of the explanting physician, but these steps are still applicable.

1. Examine the incision site for signs of infection.
2. Using sterile technique, prepare and drape the explant site in typical fashion.
3. Inject the original incision for the stimulation end of the lead with local anesthesia.
4. Remove the sutures from the skin, and then make an incision over or near to the original incision, taking care not to cut the StimRouter Lead. Using forceps, hook the lead and gently draw it above the skin first pulling out the receiver end of the lead, and then proceeding with the stimulation end of the lead.
5. To minimize risk of lead fracture, grasp the protruding lead as close to the incision site as possible and gently pull the receiver end of the lead out of the body in the direction opposite of how it was implanted. The lead will elongate when pulled. As the lead elongates, regrasp the lead closer to where it exits the incision site, and continue pulling until the receiver end is explanted. A finger-over-finger technique should be used, or grasping and regripping the lead with forceps within the incision as it is explanted. Under normal conditions, minimum to moderate tension will stretch the StimRouter Lead to twice its length (including the subcutaneous part of the lead).
6. Once the receiver end is explanted, explant the stimulation end following the steps above. The stimulation end will elongate until the anchor dislodges from the tissue or the lead fractures.
7. Examine the StimRouter Lead to ensure that it is intact. If the StimRouter Lead is fractured, then further surgical exploration may be required to remove any remaining parts.
8. Close the incision site using standard techniques such as suture, and apply wound dressing as appropriate.

## Alternative Explant Procedure

In rare cases, the anchor or stimulation end of the StimRouter Lead may not dislodge from the tissue when pulled with moderate tension. If the StimRouter Lead elongates more than 7–10 cm without dislodging from the tissue, then a second incision may be needed to explant the lead.





















1. Make a second incision through the skin directly above the stimulation end of the lead, and dissect down to the stimulation electrode and anchor. The stimulation end can be located by referencing the fluoroscopic images taken during the implant procedure.
2. Cut the StimRouter Lead proximal to the anchor.
3. Extract the stimulation end and anchor.
4. Extract the remaining lead body through the original incision.
5. Close both incision sites using standard techniques such as suture, and apply wound dressing as appropriate.
6. Monitor the incision sites for infection or other possible adverse effects.

## Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacture and the competent authority of the Member State in which the user and/or patient is established if within the European Union.



## List of Symbols

	Caution
	Warning
	Sterilized Using Ethylene Oxide
	Manufacturer
	Refer to Instruction Manual/ Booklet
	Re-Order Number
	Lot Number
<b>Rx Only</b>	Prescription Only
	Serial Number
	Single Use
	Single Patient Use
	Do Not Resterilize
	Do Not Use if Sterile Packaging is Breached or Damaged
	Date of Manufacture
	Storage Temperature
	Use by Date
	Complies with United States and Canadian Product Safety Standards
	Complies with the European Union Medical Device Directive
	European Authorized Representative
	MRI Conditional
	Medical Device





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**Environmental Policy**

Service personnel are advised that when changing any part of the StimRouter system, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled. When the life cycle of a StimRouter component has been completed, the product should be discarded according to the laws and regulations of the local authority.

For more information regarding these recommended procedures, please contact Bioness Inc. Bioness is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

**Conformity Certification**

2797

**Rx Only**

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