TALISMANN™

Pulse Generator and Receiver

Procedure Manual

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Innovations For Active Healing

Procedure Manual

This manual provides basic information needed for the implantation and testing of the TalisMann Pulse Generator and Receiver included in the TalisMann Pulse Generator and Receiver Implant Kit (TM-1000).

Note: This Procedure Manual describes an implant procedure that takes place after implantation of the stimulating (distal) electrode array of the StimRouter Lead. This procedure manual replaces instructions in the StimRouter procedure manual for implanting the Receiver (proximal) end of the StimRouter Lead.

This procedure shares some of the tools and accessories supplied with and used during implantation of the StimRouter Lead:

- Yellow cable (sterile)
- Black cable
- Gel electrode cable (Black)
- Intraoperative peripheral nerve stimulator (IPNS)

Device Description

The TalisMann Pulse Generator and Receiver and Implant Kit consists of the following components and accessories:

- An implantable Pulse Generator and Receiver to be attached to an implanted StimRouter Lead
- Tools for testing and attaching the Pulse Generator and Receiver to an implanted StimRouter Lead
- Surgical tools for implanting/pocketing of the Pulse Generator and Receiver

Contents

The TalisMann Pulse Generator and Receiver and Implant Kit consist of sterile and non-sterile components:

Note: Pulse Generator and Receiver is supplied preloaded in the Pulse Generator and Receiver Attachment Tool

Sterile Components

- Pulse Generator and Receiver (preloaded in tool)
- Pulse Generator and Receiver Attachment Tool
- Silicone Sleeve Deployment Tool
- Pocketing Tools

Non-Sterile Components

- Procedure Manual

Component Description

Pulse Generator and Receiver

The Pulse Generator and Receiver is packaged in a sterile tray for direct entry into the sterile field. Specifications for the TalisMann Pulse Generator and Receiver are supplied in Table 1.

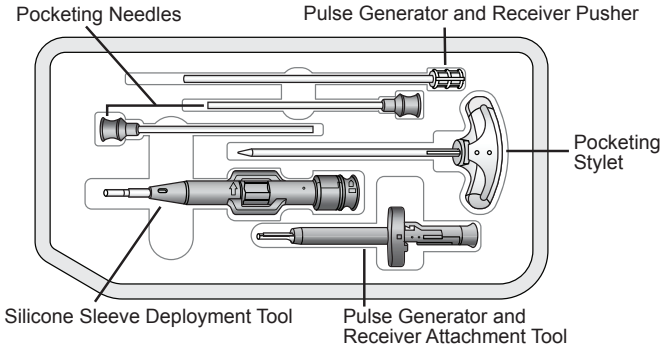

Figure 1: Sterile Kit Contents

The TalisMann Pulse Generator and Receiver, attached to the receiver end of the StimRouter Lead, captures a portion of the energy generated by the External Electric Field Conductor (E-EFC) and emitted by the surface gel pad on the Gel Electrode. The TalisMann Pulse Generator and Receiver has one Receiver Electrode, which is comprised of a hermetically sealed Titanium housing. The conductive surface of the TalisMann Pulse Generator and Receiver is in contact with the surrounding tissue. The TalisMann Pulse Generator and Receiver converts the captured energy into a stimulating signal delivered to the Stimulating Electrode array of the StimRouter Lead.

Figure 2: TalisMann Pulse Generator and Receiver and the StimRouter Lead

The stimulating electrode array of the StimRouter Lead deliver the current received from the TalisMann Pulse Generator and Receiver attached to the StimRouter Lead to the target peripheral nerve. The conductive surface of the stimulating electrode array 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 Stimulating Electrodes, ensures proper Lead release from the insertion tools and is designed to reduce Lead migration after implantation (see Figure 3).

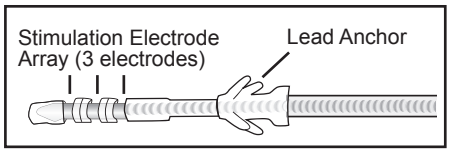

Figure 3: StimRouter Lead Stimulation End (close-up)

Pulse Generator and Receiver length	22.9 mm
Pulse Generator and Receiver body diameter	4.2 mm
Pulse Generator and Receiver (proximal) electrode count	1
Pulse Generator and Receiver electrode material	Titanium
Pulse Generator and Receiver insulation material	PEEK (Polyether Ether Ketone and Silicone)

Table 1: TalisMann Pulse Generator and Receiver Specification

⚠ **CAUTION:** Do not substitute components included in the TalisMann Pulse Generator and Receiver and Implant Kit.

The TalisMann Pulse Generator and Receiver Implant Kit also contains the surgical tools used for implantation of the TalisMann Pulse Generator and Receiver. Implanting physicians should read the product literature included in this kit before performing the TalisMann implant procedure.

Pulse Generator and Receiver Attachment Tool

The Pulse Generator and Receiver is supplied preloaded in the Pulse Generator and Receiver Attachment Tool. The tool allows for the correct connection of the TalisMann Pulse Generator and Receiver to the proximal end of the StimRouter Lead. Prior to permanently attaching the Pulse Generator and Receiver to the StimRouter Lead, when the StimRouter Lead is placed in the Pulse Generator and Receiver Attachment Tool, it is possible to test stimulation with the Stimulation Cable (yellow) by connecting the Stimulation Cable to the connector pin on the Pulse Generator and Receiver Attachment Tool.

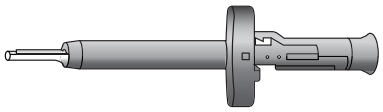

Figure 4: Pulse Generator and Receiver Attachment Tool

Note: The sterile Stimulation Cable is part of StimRouter Lead and Introducer Kit.

Silicone Sleeve Deployment Tool

The Silicone Sleeve Deployment Tool is used to apply the Silicone Sleeve for electrical insulation over the junction between the StimRouter Lead and attached TalisMann Pulse Generator and Receiver. The clear Silicone Sleeve is preloaded onto the Silicone Sleeve Deployment.

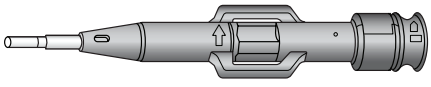

Figure 5: Silicone Sleeve Deployment Tool

Pocketing Needles

The Pocketing Needles are used to provide a channel for the Pocketing Stylet and the TalisMann Receiver when deploying the TalisMann Receiver into the subcutaneous pocket created by either Pocketing Needle.

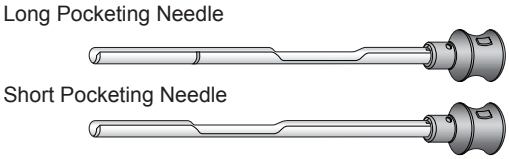

Figure 6: Pocketing Needles

Pocketing Stylet

The Pocketing Stylet is used in combination with either Pocketing Needle to create a subcutaneous pocket for the TalisMann Receiver.

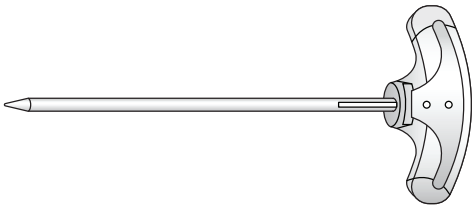

Figure 7: Pocketing Stylet

Pulse Generator and Receiver Pusher

The Pulse Generator and Receiver Pusher is used deploy the connected TalisMann Pulse Generator and Receiver into the subcutaneous pocket created by the Pocketing Stylet below the skin.

Figure 8: Pulse Generator and Receiver Pusher

⚠ **CAUTION:** Do not resterilize or reuse any items in the TalisMann Pulse Generator and Receiver and Implant Kit. Components are for use in a single procedure only. Once the kit is opened, discard unused contents.

Indications for Use:

The TalisMann Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The TalisMann Neuromodulation System is not intended to treat pain in the craniofacial region.

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 TalisMann System and all other active implanted devices and metallic implants.
- A risk/benefit determination should be performed before using the TalisMann System for:

- Patients exposed to diathermy, shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on patients who have a TalisMann Neuromodulation System. The energy generated by diathermy can be transferred through the TalisMann System components, causing tissue damage at the lead site and potentially resulting in severe injury. Diathermy may also damage the TalisMann 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 healthcare professionals that they should not be exposed to diathermy.
- Patients exposed to therapeutic ultrasound.
- Patients who are unable to operate the TalisMann 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 Gel Electrode will adhere.
- Patients with bleeding disorders or active anticoagulation that cannot be stopped for a few days prior to the time of the surgical procedure.

Warnings

- The long-term effectiveness of neurostimulation is unknown.
- Simultaneous connection of a patient to the TalisMann components and high-frequency surgical equipment may result in skin burns where the gel pads on the back of the Gel Electrode adhere to the skin and may damage the External Electric Field Conductor (E-EFC). Advise patients to remove the Gel 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 TalisMann components should only be programmed by the treating clinician and/or under proper medical guidance.
- The use of non-Bioventus components with the TalisMann System may result in damage to the system and increased risk to the patient.
- Advise patients to turn the TalisMann System off when near a refueling station, flammable fuel, fumes or chemicals. The operation of the TalisMann 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 TalisMann Neuromodulation System 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 TalisMann 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 TalisMann 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 radio-frequency (RF) communication used in the TalisMann Neuromodulation System. Stimulation control may be delayed, in which case visual alerts will be emitted by the External Electric Field Conductor (E-EFC). To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the TalisMann System and all other electronic devices. Refer to the Troubleshooting section and Appendix of the TalisMann User's Guide for more information.
- The TalisMann 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.
- E-EFC Electrode placement and stimulation settings should be determined by the implanting physician and/or treating clinician.
- Do not apply any part of the E-EFC Electrode over any obstruction (e.g., dressing or bandage) that would reduce the designated electrode surface area. A smaller electrode surface area could result in serious injury to the patient.
- Do not apply an E-EFC Electrode close to (<2 cm) primary incision site. Placing and removing the electrode could interfere with the wound closure and healing.
- Same day placement of the E-EFC Electrode over pocketed TalisMann Receiver/IPG may lead to skin irritation and delay pocket healing or lead to adverse events.
- Do not apply the E-EFC Electrode over skin folds, scarred tissue, irritated skin, bruised or swollen skin, uneven skin surfaces or broken skin.
- 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 TalisMann User's Guide for more information.) If they must pass through such a device, 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 TalisMann 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 TalisMann Pulse Generator and Receiver implantation procedure. Bioventus requires that physicians be formally trained in the TalisMann Pulse Generator and Receiver and StimRouter implantation procedures by Bioventus 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 Pulse Generator and Receiver.
- Revision of the TalisMann Pulse Generator and Receiver is not supported.
- If the TalisMann Pulse Generator and Receiver is moved from the target subcutaneous pocket, it may not function correctly or effectively. In some instances, an implanted Pulse Generator and Receiver can move from its original location, causing a loss of stimulation at the target stimulation point. If the Pulse Generator and Receiver moves, the Pulse Generator and Receiver 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 Gel Electrode.
- Gel Electrode placement and stimulation settings should be determined by the implanting physician and/or treating clinician.
- Do not apply the Gel 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 Gel Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces, or broken skin.
- Always inspect the gel pads on the back of the Gel Electrode before use. Do not apply Gel Electrode if the Gel Pads appear dried out, worn, dirty, or irregular.
- Make sure the Gel Electrode liner is removed before applying the Gel Electrode.
- Do not handle Gel Electrode with both hands while stimulation is on; serious injury can result from current passing through the cardiac tissues.
- A Gel Electrode should 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 Gel Electrode to any other person or to any other part of the body.
- Do not adhere Gel Electrode to sites that are swollen, infected or inflamed, or that have skin eruptions such as phlebitis, thrombophlebitis, and varicose veins. Do not adhere Gel Electrode to skin that is broken.
- It is normal for the skin under the Gel Electrode to become red. The redness should disappear in approximately one hour after the Gel 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 TalisMann components should be temporarily halted until the irritation is resolved. In some cases, irritation can be avoided by removing the Gel 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 TalisMann Pulse Generator and Receiver components should be kept out of the reach of children.
- Do not use a Gel Electrode with a “Use by” date that has expired.
- All TalisMann Pulse Generator and Receiver 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, may permanently damage the components.
- Verify that the TalisMann Pulse Generator and Receiver and Implant Kit expiration (“Use By”) date has not expired. If it has expired, do not use any of the components.
- Open the TalisMann Pulse Generator and Receiver and Implant Kit using sterile technique.
- The TalisMann Pulse Generator and Receiver and Implant Kit is for use in a single procedure only. Never resterilize or reuse components in the TalisMann Pulse Generator and Receiver and Implant Kit. Once the kit is opened, discard all unused components.

- TalisMann Pulse Generator and Receiver and Implant Kit Storage Temperature Range: 0°C to 40°C (32°F to 104°F).

Same Day Programming Precautions

- Anesthesia may restrict what a patient can feel when attempting to establish paresthesia through programming the E-EFC on the same day of the procedure. Please be aware that the E-EFC programing parameters may need to be revised based on what patients may feel after anesthesia effects wear off.
- Placing the E-EFC electrode patch near the incision(s) may impact/slow healing and cause bruising, swelling or pain at the incision site.
- Please make sure all foreign material (eg: skin prep materials) are properly cleaned from the skin before placing the E-EFC electrode patch.
- The E-EFC electrode patch should not be in contact with any skin dressing or bandages. Overlap of the electrode patch with any materials over the skin will increase current density and could lead to skin irritation as well as inconsistent therapeutic response.
- The skin over the surgical pocket for the TalisMann IPG/ Receiver should be inspected before placement of the E-EFC patch. Excessive bruising and swelling could be aggravated, and pocket pain could result by same day placement of the E-EFC electrode patch in this area.

⚠ **CAUTION:** Do not use the contents of the TalisMann Pulse Generator and Receiver and Implant 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 TalisMann Pulse Generator and Receiver include those listed below.

- Suboptimal Pulse Generator and Receiver placement may necessitate therapeutic adjustment and/or Pulse Generator/ Receiver 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 TalisMann Pulse Generator and Receiver 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 Gel 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 Gel Electrode, and notify their physician.
- Migration of the TalisMann Pulse Generator and Receiver may cause changes in stimulation effectiveness.

While unlikely, a tissue reaction to the implanted materials may occur.

- External EMI may cause the TalisMann Pulse Generator and Receiver to malfunction and may affect stimulation.
- Patients may experience persistent pain at the implant site of the implantable Pulse Generator and Receiver.
- Although rare, the skin overlying the TalisMann Pulse Generator and Receiver may erode.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The External Electric Field Conductor (E-EFC) could overheat if the components fail, which could cause burning.

⚠ **CAUTION:** If patients experience any pain or discomfort during stimulation, or notice any skin abnormalities, they should stop stimulation immediately, cease contact with the TalisMann Neuromodulation System components, and notify their physician.

Sterilization

Items in the TalisMann Pulse Generator and Receiver and Implant 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 a TalisMann Pulse Generator and Receiver and Implant 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 TalisMann Pulse Generator and Receiver and Implant 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.

Procedure

For implant of the StimRouter Lead, please see the StimRouter Neuromodulation System Procedure Manual packaged with that product.

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 TalisMann Pulse Generator and Receiver and the overlying Gel Electrode on the skin surface. See Figure 9.

Effectiveness of stimulation is sensitive to alignment and rotation of the Gel Electrode with the External Electric Field Conductor (E-EFC) attached in relation to the implanted TalisMann Pulse Generator and Receiver. If the alignment or rotation of the Gel 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), etc.

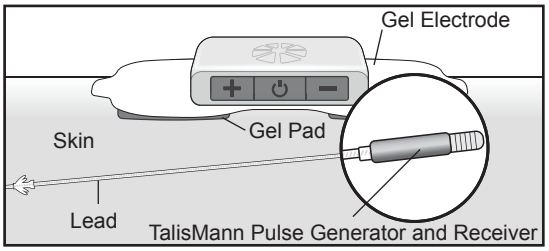

Figure 9: Optimal Position of the TalisMann Pulse Generator and Receiver under the Gel Electrode

Equipment Preparation

⚠ **CAUTION:** Inspect the TalisMann Pulse Generator and Receiver and Implant 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 TalisMann Pulse Generator and Receiver and Implant Kit.

⚠ **CAUTION:** Do not use a sterile package if the “Use by” date has expired. Open using sterile technique. Do not resterilize.

1. The distal end of the StimRouter Lead should be placed with the electrode array of the Lead on/near the target peripheral nerve. Reference the StimRouter Procedure Guide for instructions for placing the StimRouter Lead. The proximal end of the StimRouter Lead with the integral Receiver portion should be outside the patient.
2. Have a non-sterile assistant open the TalisMann Pulse Generator and Receiver and Implant Kit and place the non-sterile components and product literature outside the sterile field. The non-sterile assistant should peel back the outer cover of the outer tray with and present to sterile practitioner without touching the inner tray. The sterile nurse can remove
3. the the inner sterile tray from the outer tray and place it 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 sterile components from the inner sterile tray and place on the sterile field.

Pulse Generator and Receiver Attachment to Lead

1. Insert proximal end of the StimRouter Lead (StimRouter Receiver) into the Reed Sleeve of the Pulse Generator and Receiver Attachment Tool. See Figure 10. Take care not to put tension on the portion of the exposed lead at the incision site. The StimRouter Lead should be firmly seated inside the Reed Sleeve with only 1-2mm of StimRouter Lead outside the Reed Sleeve.

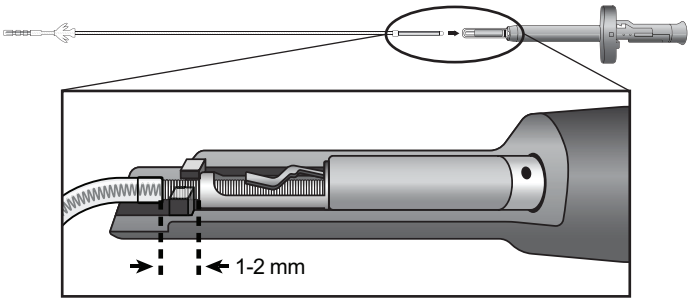

Figure 10: Insert Proximal End of the StimRouter Lead into the Pulse Generator and Receiver Attachment Tool.

2. Attach the white end of the Stimulation Cable to the testing pin of the Pulse Generator and Receiver Attachment Tool and the yellow end of the cable to the non-sterile IPNS being operated by a non-sterile team member. Yellow cable should already be in place from StimRouter procedure. Confirm that the output amplitude of the IPNS is set to zero. See Figure 11.

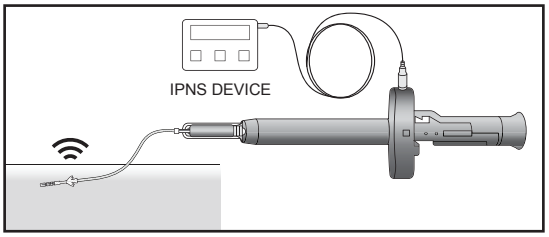

Figure 11: Attach the Stimulation Cable to the Pulse Generator/Receiver Attachment Tool.

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

⚠ **CAUTION:** An output setting on the IPNS that is too high can result in tissue damage. Always consult the IPNS product literature for the manufacturer’s instructions before operating.

3. Have the non-sterile assistant activate the IPNS output at stimulation frequency of 100Hz and slowly increase the output amplitude until the desired paresthesia is achieved. Please limit the maximum output amplitude to 8.0mA or until the patient is uncomfortable, whichever comes first.

Note: If the amplitude 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 this screen is still not displaying amplitude output, do not proceed. Consult the IPNS product literature.

Note: There may be two failure modes:

- No electrical connection (as indicated by the intraoperative stimulator (IPNS).
- There is an electrical connection, but stimulation does not cause paresthesia or motor response.

4. To find the minimal stimulation amplitude, slowly decrease the amplitude level of the stimulation output until paresthesia response is lost.
5. Once paresthesia is lost, slowly increase the stimulation amplitude until paresthesia is restored. Optimally, the stimulation amplitude level should be below 5.0 and no greater than 8.0 mA. If paresthesia cannot be achieved at a target stimulation amplitude level of 8.0 mA or less, remove the StimRouter Lead from the Reed Sleeve and confirm correct placement of the StimRouter Lead.

Note: The stimulation parameters used intraoperatively with the IPNS should be recorded for future programming of the TalisMann Neuromodulation System. See the TalisMann Programming section.

6. Disconnect the white connector of the yellow Stimulation Cable from the Receiver Connection and Testing Tool once paresthesia is restored.
7. Rotate the plunger of the Pulse Generator and Receiver Attachment tool 90 degrees counter clockwise to align the keyway and enable deployment.
8. Taking care not to apply tension on the Lead, fully depress the handle to attach the Pulse Generator and Receiver to the Lead and remove the Pulse Generator and Receiver from the tool, taking care not to put tension on any portion of the lead.

Note: Ejection of the Pulse Generator and Receiver may occur.

9. Apply slight pull force between Lead and Receiver junction to verify that the Lead does not move out of the Pulse Generator and Receiver.

Deployment of the Silicone Sleeve

1. The Silicone Sleeve Deployment Tool is used to apply the Silicone Sleeve over the junction between the StimRouter Lead and attached TalisMann Pulse Generator and Receiver. The clear Silicone Sleeve is preloaded into the Silicone Sleeve Deployment Tool.
2. Wipe the StimRouter Lead and attached TalisMann Pulse Generator and Receiver clean of any blood or other fluids, if necessary.
3. Insert the titanium can of the TalisMann Pulse Generator and Receiver all the way into the inner tubing of the tool. See Figure 12.
4. Retract the tool handle to pull the TalisMann Pulse Generator and Receiver completely inside the tool. Rotate the tool handle 90 degrees to lock the handle. See Figure 12.
5. Visually ensure that the TalisMann Pulse Generator and Receiver is completely inside the tool before proceeding. See Figure 12.

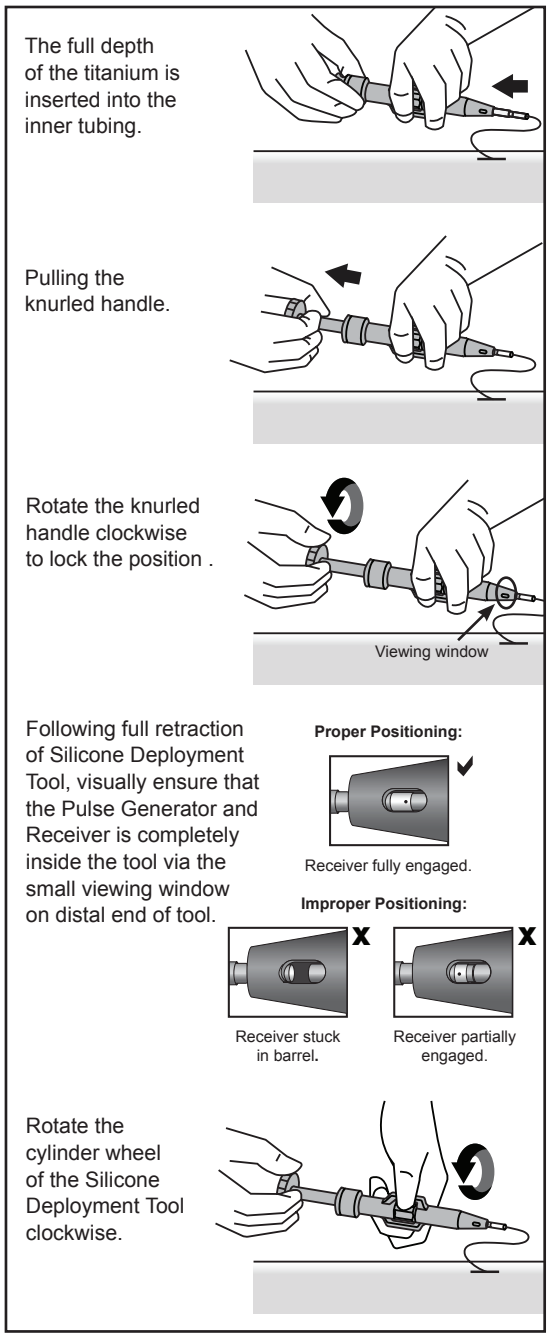

Figure 12: Deploying the Silicone Sleeve.

6. Rotate the cylinder wheel of the Silicone Sleeve Deployment Tool clockwise to “push” sleeve off tool over the StimRouter Lead and TalisMann Pulse Generator and Receiver junction. Rotate until sleeve is deployed and rotation resistance is felt. See Figure 12.

7. Rotate the tool handle counter-clockwise 90 degrees back to its original orientation and gently push. As illustrated in Figure 13, remove the StimRouter Lead and attached TalisMann Pulse Generator and Receiver with the deployed Silicone Sleeve, paying careful attention that the sleeve is deployed correctly over the Receiver/Pulse Generator and Lead. See Figure 14.

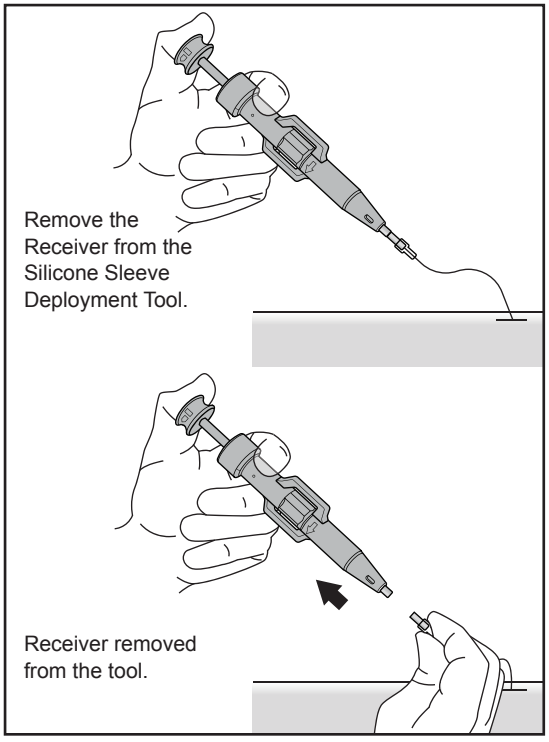

Figure 13: Removal of the Pulse Generator and Receiver from the Silicone Sleeve Deployment tool.

8. Visually ensure that the Silicone Sleeve is deployed approximately equidistant across both TalisMann Pulse Generator and Receiver and StimRouter Lead and snugly fits both components. See Figure 14. Gently roll and compress the Silicone Sleeve over the lead body to gain contact between sleeve and Lead. See Figure 15.

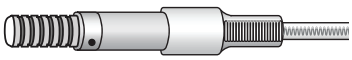

Figure 14: Final Layout of the silicon sleeve over the IPG and Lead Receiver

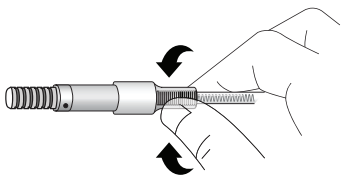

Figure 15: Gently roll fingers and compress the silicon sleeve over the lead body.

9. The intent of this suturing step is to close any potential gap between the silicone sleeve and the StimRouter lead. Use the 2-0 suture packet that is included along with the TalisMann Pulse Generator and Receiver Implant Kit. Take one of the suture strands from this packet and tie a knot over the silicone sleeve. Locate this knot approximately in the middle portion of the silicone sleeve that is over the StimRouter lead (see image below). You may want to start with a loose knot so you can adjust the location of this knot on the silicone sleeve.

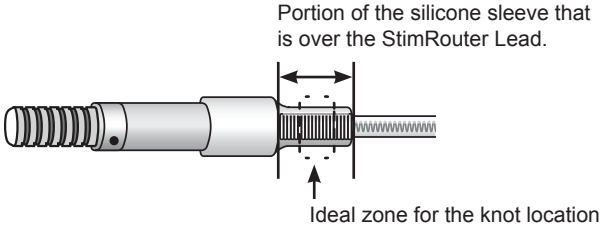

Figure 16: IPG and Lead Receiver Assembly

Once you are satisfied with the location of the knot, tighten the knot with a reasonable force. Do not over-tighten this knot, as this may create a risk of the suture cutting through the silicon sleeve. Please cut any additional suture such that the length of the remaining suture strands does not exceed the portion of the silicone sleeve that is over the StimRouter lead. The following image provides a reference for the suture knot in its final configuration:

Figure 17: IPG and Lead Receiver Assembly with suture

Note:

1. Use caution during this step to not apply undue tension on the StimRouter lead, as this may impact the location of the distal end of the StimRouter Lead next to the target nerve.

2. Please use the sutures provided with this product. Alternative suture options is not recommended and may cause loss of functionality of the TalisMann Pulse Generator and Receiver.

3. Avoid locating the knot at the distal end of the silicone sleeve

Pocket creation and insertion of the Pulse Generator and Receiver

1. Measure the length of StimRouter Lead attached to the TalisMann Pulse Generator and Receiver protruding from the skin. See Figure 18.

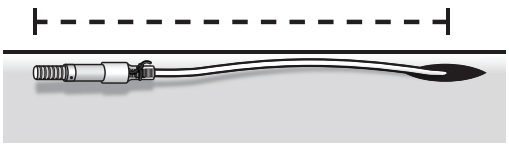

Figure 18: Measurement of the StimRouter Lead attached to the Pulse Generator and Receiver.

2. Use the primary incision to insert the TalisMann Pulse Generator and Receiver.
3. Inject local anesthetic subcutaneously along the pocketing tract.
4. Use the most appropriate Pocketing Needle length from the two options supplied in the implant kit. If the length of the StimRouter Lead attached to the TalisMann Pulse Generator is more than 3cm, use a Long Pocketing Needle. Otherwise use a Short Pocketing Needle. See Figure 6. In most cases the long pocketing needle will be used.
5. Assemble the Pocketing Stylet and Pocketing Needle. See Figure 19. Insert the combined Pocketing Needle assembled with the Pocketing Stylet subcutaneously into the hypodermis through the same incision that was made to implant the StimRouter Lead. The Pocketing Needle and Stylet Assembly should be at an angle approximately parallel to the skin surface in the direction of the desired location for the TalisMann Pulse Generator and Receiver connected to the StimRouter Lead. The Pocketing Needle and Pocketing Stylet Assembly should be along a subcutaneous path, until the tip at the desired subcutaneous location. See Figure 20.

⚠ Warning: During pocketing in the hypodermis, do not advance the open channel of the pocketing needle/ stylet past the incision, to allow for insertion of the Pulse generator and Receiver in to the needle and prevent skin damage at incision site. Do not contact the Lead.

⚠ Warning: Insert the Pocketing Needle deep enough such that the receiver can be fully seated in the slot of the Pocketing Needle.

⚠ Warning: If a non-linear pocket is desired (angle to the implanted lead), the TMPGR must be at least 7cm distance form position of electrode array.

In most cases the long pocketing needle will be used.

6. When the desired depth of the Pocketing Needle is reached, remove the Pocketing Stylet. Take care not to rotate the Pocketing Needle as this may cause tissue damage.

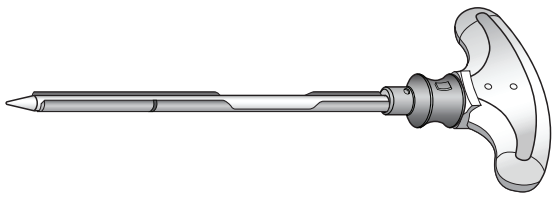

Figure 19: Assembled Pocketing Needle and Stylet.

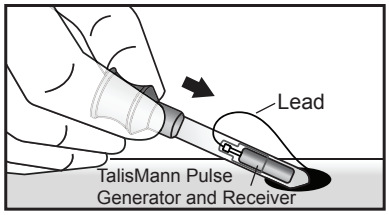

Figure 20: Insert the TalisMann Pulse Generator and Receiver into the Pocketing Needle.

7. Place the TalisMann Pulse Generator and Receiver into the open channel of Pocketing Needle taking care that the Lead does not cross the edge of the Pocketing Needle channel.

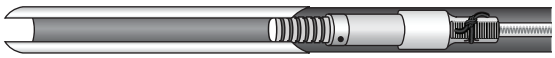

Figure 21: IPG Orientation in Pocketing Needle.

⚠ Warning: If the StimRouter Lead silicone insulation is cut, it may result in loss of stimulation current to the StimRouter electrode array.

8. Insert the Pulse Generator and Receiver Pusher into the proximal end of the Pocketing Needle and advance the Pusher to move the TalisMann Pulse Generator and Receiver into the desired tissue pocket created by the Pocketing Needle. Take care not to place undue tension on the StimRouter Lead during this process. Insert the Pusher until the mark on the pusher lines up with the handle on the Pocketing Needle. This ensures the Pulse Generator and Receiver Assembly is positioned at the distal end of the Pocketing Needle. See Figure 22.

Figure 22: Pusher position just before IPG final placement.

9. While maintaining the position for the pusher, retract the Pocketing Needle towards the Pusher to ensure the Pulse Generator and Receiver Assembly is deployed into the tissue pocket. See Figure 23.

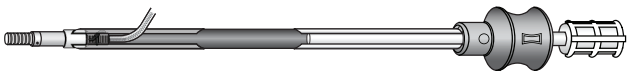

Figure 23: Pusher position at IPG final placement.

10. Place light pressure on the skin over the implanted Receiver and gently remove the Pocketing Needle and Pusher through the primary incision.
11. If the TalisMann Pulse Generator/Receiver is in the desired location and excess StimRouter Lead is visible, a strain relief loop can be created with the excess Lead and pocketed in a space adjacent to the incision, with care not to move position of electrode array. If forceps are used, take care not to pinch or damage the lead or move the position of the electrode array. Non-toothed forceps are recommended.

Wound Closure

1. The implant physician may choose to use fluoroscopic imaging to document the anatomical placement of the Pulse Generator and Receiver end of the Lead.
2. 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

Physicians should adequately observe the incision sites and monitor for infection, possible device rejection, or other possible adverse effects, per standard surgical procedure. It is recommended that when the incision sites are healed, the skin surface over the Pulse Generator and Receiver be marked to assist with accurate Gel Electrode placement.

TalisMann Programming

The time between TalisMann Pulse Generator and Receiver implant and programming is at the discretion of the implanting doctor based on multiple variables, including level of sedation or local anesthetic used and wound location with respect to the location of the implanted Receiver, among others. The physician should assess the area around and including the surgical incision site and Receiver/IPG pocket for skin integrity, swelling, bruising, and post-surgical trauma to determine programming timing and E-EFC Electrode placement. Additionally, if the decision is made to program the day of the implant, the area for E-EFC Electrode placement should be cleaned of skin preparations agents.

Note: Same day programming may increase the risk of skin irritation to the E-EFC electrode.

The continued action of local anesthesia could also blunt the stimulation response and may require reprogramming after full recovery. 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. Please refer to the Warnings section for specifics of placement of the E-EFC Electrode and programming the E-EFC.

The stimulation parameters used intraoperatively with the IPNS to evaluate proper placement of the TalisMann Pulse Generator and Receiver may provide an efficient starting point for setting therapeutic stimulation parameters at initial programming. 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 IPNS 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 StimRouter Plus E-EFC.

Explant Procedure

Tissue encapsulation of the TalisMann Pulse Generator and Receiver and StimRouter Lead is expected by approximately 14 days post-implant. If the TalisMann Pulse Generator and Receiver must be explanted prior to encapsulation, then the following procedures may be used. Beyond 14 days, the specific technique used to explant the TalisMann Pulse Generator and Receiver 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 explant site with a local anesthetic.
4. Use the cut down technique to expose the silicone sleeve. Attempt to extract the TalisMann Pulse Generator and Receiver with forceps grasping onto the silicone sleeve. Additional cut-down may be required if encapsulation has occurred.
5. Use a finger-over-finger technique to remove the remainder of the StimRouter Lead. A finger-over-finger technique or grasping and regrasping the lead with forceps within the incision as it is explanted.
6. Close the explant site using standard techniques and apply wound dressing as appropriate.

Please refer to StimRouter Procedure manual for more details about the explant procedure

Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to the manufacturer 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
STERILE EO	Sterilized Using Ethylene Oxide
	Manufacturer
	Refer to Instruction Manual/Booklet
REF	Reorder Number
LOT	Lot Number
Rx Only	Prescription Only
SN	Serial Number
	Single Use
	Single Patient Use - To Prevent Cross Contamination
	Do Not Resterilize
	Do Not Use if Sterile Packaging is Breached or Damaged
	Date of Manufacture
	Storage Temperature
	Double Barrier Sterile Packaging
	Use by Date
	MR Conditional

Environmental Policy
Service personnel are advised that when changing any part of the TalisMann 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 TalisMann 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 Bioventus. Bioventus is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

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Rx Only