StimRouter®
Neuromodulation System

Clinician's Guide

Bioness®

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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.

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Table of Contents

List of Symbols

	Caution
	Warning
	Class II Equipment (Double Insulated)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Not Reading Instructions Can Cause Hazard
	Consult Instructions for Use
REF	Re-Order Number
LOT	Lot Number
SN	Serial Number
	Complies with United States and Canadian Product Safety Standards
	Single Patient Use
	Single Use
	Storage Temperature
EC REP	European Authorized Representative
	Humidity Limitation
	Atmospheric Pressure Limitation
IPX3	Protection Against Ingress of Water
	Keep Dry
	Use By
	Quantity
Rx Only	Prescription Only

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Introduction

The Bioness StimRouter Neuromodulation System is intended to help relieve chronic pain of peripheral origin. The Bioness StimRouter Neuromodulation System consists of the following:

- An implantable multi-electrode lead with integrated receiver in loader.
- Surgical tools for implantation of the StimRouter Lead.
- A clinician programming system with a Clinician's Programmer and charger, a Programmer Connector Cable, a Tester and accessories.
- A patient-operated system with a rechargeable External Pulse Transmitter (EPT), an external Patient Programmer, a system charger and accessories.
- Disposable StimRouter Electrodes.

This guide describes the clinician programming system components of the StimRouter Neuromodulation System, which are provided in the StimRouter Clinician Kit. The clinician programming components are used to program the patient's External Pulse Transmitter (EPT) and Patient Programmer.

Refer to the StimRouter Procedure Manual for a description of the StimRouter Implantable Lead and Lead Introducer Kit, package contents, device specifications and the StimRouter implant procedure.

Refer to the StimRouter User's Guide for a full description of the StimRouter User Kit, StimRouter Electrode, External Pulse Transmitter (EPT), Patient Programmer, external accessories, package contents, device specifications and instructions for use.

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Warnings and Precautions

Physicians and patients should know the limitations, warnings, and precautions associated with the Bioness StimRouter Neuromodulation System. Physicians should review the warnings and precautions and the instructions for use with the patient. If at any time the physician or patient is concerned about the safety or effectiveness of the StimRouter System, they should call Bioness at 800.211.9136 or their local distributor.

The StimRouter Clinician Programmer and the patient-operated system consisting of the StimRouter Patient Programmer, StimRouter External Pulse Transmitter (EPT), and the StimRouter Electrode, should only be used under proper medical guidance and as described in the StimRouter Clinician's Guide and in the StimRouter User's Guide.

Indications

The StimRouter 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 StimRouter is not intended to treat pain in the craniofacial region.

Contraindications

The Bioness StimRouter Neuromodulation System is contraindicated for:

- Patients who have any active implanted devices such as an implanted demand cardiac pacemaker, implantable cardioverter defibrillator (ICD), other implanted, active devices, or any metallic implant in the immediate area intended for implant.

Note: Maintain a minimum safe separation distance of 15 cm (6 in.) between the StimRouter Electrode with External Pulse Transmitter (EPT) 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 a 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 who are poor surgical candidates in general.
- Patients who have a cancerous lesion near the target stimulation point or near where the StimRouter 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.
- Do not use the transmit/receive RF head coil if the StimRouter Lead is implanted above the shoulder.

Implantation Setting

The StimRouter Lead should be implanted in an appropriately outfitted physician's office, outpatient surgical center, or hospital surgical center. Fluoroscopy and/or ultrasound should be available if deemed necessary and be used at the implanting physician's discretion.

Patient Screening

Candidates for the StimRouter Neuromodulation System should be appropriately screened for selection and fully informed about the therapy risks and benefits, the surgical procedure, system operation, and self-treatment responsibilities.

Select patients carefully to ensure that:

- Their symptoms are of an anatomical and/or physiological origin.
- They are appropriate candidates for surgery.
- They can properly operate the StimRouter system.

Bioness recommends the following optional screening procedure prior to StimRouter Lead implantation:

- Transcutaneous electrical nerve stimulation (TENS) to determine the patient's tolerance of stimulation near the anticipated site for the StimRouter Electrode. Please note that some individuals are very sensitive to the sensation of electrical stimulation applied to the skin.

⚠ Warnings

Magnetic Resonance Imaging (MRI) Warnings and Precautions

- Do not scan patients with a specific absorption rate (SAR) level exceeding
  2 W/kg. A scan above 2 W/kg may increase the risk of MRI-related heating.
- Do not place a local RF transmit coil directly over the implanted StimRouter Lead.
- The entire StimRouter Lead must always be outside the MR coil and must not be exposed to any radio frequency field.

StimRouter External Component Restrictions

All external components of the StimRouter system are contraindicated for the MRI environment. Therefore, the StimRouter Electrode, External Pulse Transmitter, and Patient Programmer must be removed before the patient is allowed into the MR system room.

MRI Information

Non-clinical testing demonstrated that the StimRouter Lead is MR Conditional. Patients with an implanted StimRouter Lead can be scanned safely, immediately after implantation, on MRI cylindrical bore systems that meet the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 T.
- Highest spatial magnetic gradient of 2500 gauss/cm or less.
- MR system reported, whole-body-averaged SAR does not exceed 2 W/kg at 1.5 T and 2 W/kg at 3 T.
- Do not scan patients with a SAR level exceeding 2 W/kg. A scan above 2W/kg may increase the risk of MR-related heating.

- The entire StimRouter Lead must be at least 50 cm (19.7 in.) from the center of the MR system's bore (the iso-center of the bore) and at least 16 cm (6.3 in.) outside of the MR coil measured from the edge of the MR coil, to ensure patients safety relative to MRI-related heating. See Figure 2-1.

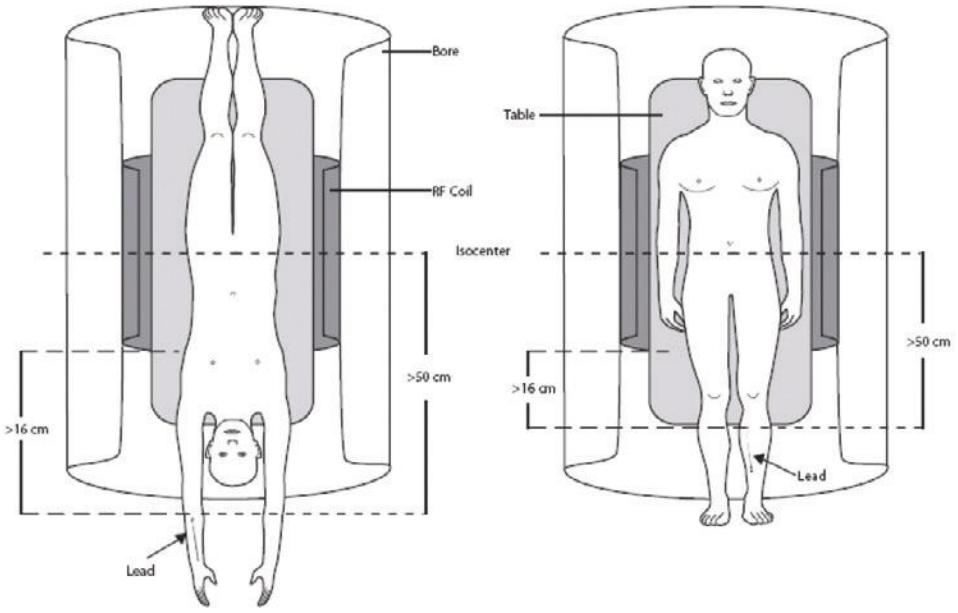

Figure 2-1: Left: Lead implanted in the forearm. Right: Lead implanted in the lower leg.

- Communication is maintained with the patient so that the scan can be promptly terminated in the event of painful nerve stimulation or other adverse event.

Information regarding the position of the lead is necessary for routine MRI procedures. Review of the patient's Medical Device Identification Card, direct communication with the implanting physician or obtaining an x-ray is recommended to determine the location of the implanted lead.

Patients must be screened for previously implanted (active or abandoned) medical devices, leads, lead extenders or lead adapters.

MRI-Related Heating: Supplemental Information

1.5 T/64 MHz

Temperature changes of the electrodes of the StimRouter Lead were measured at 1.5 T/64 MHz according to ASTM F2182 (GE Signa, 46-258170G1, whole body transmit radio frequency (RF) coil.). With the lead in

an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a background local SAR of 1 W/kg was 3.9°C after six minutes of RF power application. This temperature change was with the lead in an elongated, “straight” configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or looped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR of 2 W/kg predicts a worst case in the patient during an MRI of less than 2°C provided that the entire StimRouter Lead is at least 50 cm from the center of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

3 T/128 MHz

Temperature changes of the electrodes of the StimRouter Lead were measured at 3 T/128 MHz according to ASTM F2182 (GE Signa, 3T HDx, Software Version 15/LX/MR, 15.0.M4.0910a). With the lead in an orientation and a position in the phantom to produce worst-case heating, the greatest measured temperature rise scaled to a local background SAR of 2 W/kg was 2.9°C after six minutes of RF power application. The temperature change occurred with the lead in an elongated, “straight” configuration (i.e., no curves), which produced the highest temperature change. With the lead in curved or looped configurations, temperature changes were less.

A computer simulation that incorporated the worst-case measured rise and a whole-body-averaged SAR od 2 W/kg predicts a worst case in the patient during MRI of less than 1°C provided that the entire StimRouter Lead is at least 50 cm from the center of the bore of the MR system and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

Image Artifacts

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the StimRouter Lead. Therefore, optimization of MR imaging parameters to compensate for the presence of the StimRouter Lead may be necessary.

Induced Currents

The electric fields induced in a patient with the StimRouter Lead by the pulsed gradient fields were calculated. The induced current will be less than the stimulation threshold if the StimRouter Lead is at least 50 cm from the center of the bore and at least 16 cm outside of the MR coil measured from the edge of the MR coil.

⚠ **CAUTION:** Electrical current induced in the StimRouter Lead during MR procedure may cause stimulation of the nerves proximal to the lead causing sensation, motor response, or nerve blocking.

Potential Adverse Events

The utilization of MRI could result in excessive heating of the StimRouter Lead if all MRI parameters and conditions of use are not carefully followed.

Induced voltages in the StimRouter Lead may occur due to the time-varying, gradient magnetic fields of the MR system, possibly causing uncomfortable levels of neurostimulation.

Note: Since the StimRouter Lead is not a life-sustaining device, it could be explanted from the patient prior to an MRI exam and re-implanted after the MRI exam.

Pregnancy

The effects of electrical stimulation on pregnancy are unknown. Do not use electrical stimulation on a pregnant patient.

Long-Term Effectiveness of Neurostimulation

The long-term effectiveness of neurostimulation is not known.

Programming

The StimRouter components should only be programmed by the treating physician and/or under proper medical guidance.

Device Components

The use of non-Bioness components with the StimRouter system may result in damage to the system and increased risk to the patient.

No modification of this equipment is allowed.

The Patient Programmer and External Pulse Transmitter (EPT) can heat up to 43°C during operation in extremely hot areas/rooms. If this occurs turn off stimulation, remove EPT and Patient Programmer, and set aside until temperature is within operational conditions.

Flammable Fuel, Chemicals or Environment

The StimRouter is not intended to be used in oxygen-rich environments.

Advise patients to turn off the StimRouter system (Patient Programmer and stimulation) 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.