BIONESS STIMROUTER NEUROMODULATION SYSTEM — PATIENT ELIGIBILITY FORM AND PRE-MRI CHECKLIST

StimRouter®

Important Note: It is necessary to know the anatomical position of the implanted StimRouter prior to the MRI examination. The supervising clinician (e.g., the radiologist) must review the information provided by the implanting physician, the patient's Medical Device Identification Card, and/or obtain an x-ray to determine the anatomic location of the implanted StimRouter Lead in the patient's body.

Additionally, the patient must undergo a proper MRI screening procedure to determine the presence of a previously implanted (active or abandoned) medical device, including leads, lead extenders, lead adapters, and passive implants.

NEUROLOGY/REFERRING PHYSICIAN: Please complete this form and include information pertaining to the location of the StimRouter Lead. Provide this form to your patient to take to the MRI Center and make a copy to include in the patient's medical file.

MRI/RADIOLOGY: Patient safety will be ensured by using the information on this form and filling out the checklist to verify the use of the acceptable conditions, with special attention to the location of the StimRouter Lead and in consideration of the anatomic area of interest for the MRI examination. Additionally, specific conditions must be followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter Lead.

Important Note: In addition to utilizing this form and checklist, carefully review the latest Instructions for Use (IFU) in the StimRouter Clinician's Guide available online at stimrouter.com and follow all relevant information before proceeding with the MRI examination.

A MRI examination performed outside the guidelines may result in the MRI-related, electromagnetic fields adversely interacting with this implanted device, potentially injuring the patient and damaging the device.

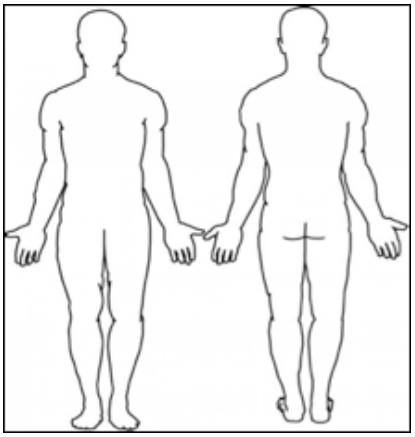
STIMROUTER TECHNICAL AND CLINICAL SUPPORT IS AVAILABLE MONDAY THROUGH FRIDAY, 8 AM – 5 PM PACIFIC STANDARD TIME PLEASE CALL US AT 800.211.9136, OPTION 3.

CONTACT INFORMATION

Patient Name:	
Referring Physician:	
Physician's Phone #:	

STIMROUTER NEUROMODULATION SYSTEM

Model Number:	
StimRouter Lead Position:	



Circle the position of the StimRouter Lead

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CHECKLIST: To be filled out by personnel from MRI/Radiology prior to MRI.

☐	The MRI examination will be performed on the patient with the implanted StimRouter Lead because there is a valid indication as determined by the supervising physician and all guidelines will be carefully followed to ensure patient safety.
☐	All external components of the StimRouter system are contraindicated for the MR system room. Therefore, the StimRouter Electrode, External Pulse Transmitter, and Patient Programmer will be removed before the patient is allowed into the MR system room.

StimRouter Electrode	☐ Removed ☐ N/A
External Pulse Transmitter	☐ Removed ☐ N/A
Patient Programmer	☐ Removed ☐ N/A

Each condition indicated below must be verified to ensure patient safety:

☐	Static magnetic field of 1.5 T or 3 T, only.
☐	Maximum spatial field gradient magnetic field of 2,500 gauss/cm (25 T/m).
☐	When the entire StimRouter Lead is at least 50 cm away from the center of the bore of the MR system and the center of the transmit RF body coil, the MR system reported, whole-body-averaged specific absorption rate (SAR) must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the Normal Operating Mode of operation for the MR system.
☐	If the above condition cannot be met, an appropriate level of SAR or a B_{1+RMS} value will be selected to ensure patient safety with consideration given to the position of the StimRouter Lead and the type of transmit RF coil that will be used for the MRI examination. (Please refer to the StimRouter Clinician's Guide for specific guidelines and information pertaining to this topic.) For this patient, indicate the selected whole body averaged SAR or B_{1+RMS} values used, *per pulse sequence:* (CHECK ONE) ☐ SAR or ☐ B_{1+RMS} Values _____ _____ _____ _____ _____ _____
☐	The MR system operator must maintain verbal and visual communication with the patient so that the MRI examination can be terminated in the event of painful nerve stimulation or other adverse or unusual event.
☐	The conscious patient must be instructed to notify the MR system operator of any pain, discomfort, or unusual sensation that may occur during the MRI examination.
☐	Specific conditions defined in the Clinician's Guide (IFU) have been followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter Lead.

"I attest that the information indicated on this form is true and correct." Date: _____

MRI Technologist's Name _____ _____
PRINT SIGN

Radiologist/Supervising Physician's Name _____ _____
PRINT SIGN

Patient's Signature _____

Bioness Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: 800.211.9136 or 661.362.4850
Website: www.bioness.com

EC REP **Bioness Europe B.V.**
Stationsweg 41
3331 LR Zwijndrecht, The Netherlands
Telephone: +31.78.625.6088
Email: international@nl.bioness.com
Website: www.bioness.com

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See Clinician's Guide

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