2

Warnings and Cautions

Be sure to follow your physician's guidance. Use your StimRouter system only as instructed in the User's Guide.

Indications for Use

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 of craniofacial nerve origin.

Contraindications

The Bioness StimRouter Neuromodulation System is contraindicated for:

- Patients who have any active implanted 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 Electrode with External Pulse Transmitter 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 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.
- Do not use the transmit/receive RF head coil if the StimRouter Lead is implanted above the shoulder.

⚠ Warnings

Magnetic Resonance Imaging (MRI) Warnings and Precautions

- An MRI examination performed on a patient with an implanted StimRouter Neuromodulation System Lead (i.e., StimRouter Lead) should only be done if there is a valid indication as determined by the supervising physician, and then only if all guidelines are carefully followed.
- All external components of the StimRouter system are contraindicated for the MR system room. Therefore, the StimRouter Electrode, External Pulse Transmitter, and Patient Programmer must be removed **before** the patient is allowed into the MR system room.
- Do not conduct an MRI examination on a patient with an implanted StimRouter Neuromodulation System Lead (i.e., StimRouter Lead) until you read and fully understand the information in the Clinician's Guide. Failure to follow all warnings and guidelines related to MRI can result in **SERIOUS INJURY** to the patient.
- The implanted StimRouter Lead should not be within transmit RF body coil unless the specific restrictions are followed for reduced radiofrequency (RF) power deposition (i.e., WBA SAR or B_{1+RMS} values) as presented in the Tables 2-1 and 2-2.
- Do not scan patients using a whole-body-averaged, specific absorption rate (SAR) level that exceeds 2 W/kg (i.e., with the MR system operating in the Normal Operating Mode). An MRI examination performed using a whole-body-averaged SAR above 2 W/kg may increase the risk of MRI-related heating, resulting in injury to the patient.

StimRouter External Component Restrictions

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

MRI Safety Information

MRI Conditional

Non-clinical testing demonstrated that the StimRouter Lead is **MR Conditional**. A patient with an implanted StimRouter Lead can be scanned safely, immediately after implantation, under the following conditions:

- 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)
- Specific conditions (see below) must be followed to ensure patient safety relative to the prevention of excessive heating of the StimRouter Lead
- If 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 reported, whole-body-averaged 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
- Limit B1 and or SAR to values in Table 2.1 if the entire StimRouter is not at least 50 cm from the center of the MRI bore. (This is the Reduced RF Zone.)
- The patient must be conscious. Maintain 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
- Skin above StimRouter must not be in direct contact with the wall of the MRI bore. Use insulating padding of at least 1 cm thickness between the skin above StimRouter and the wall of the bore.
- Legs of patient do not touch each other.
- Arms of patient are not in contact with each other or the side of the body.
- MR system is in Normal Operating Mode for gradient magnetic fields.

Note: The precise anatomical position of the implanted StimRouter Lead is necessary to know prior to the MRI exam. Therefore, before initiating an MRI exam, the supervising clinician (e.g., the radiologist) should review the patient's Medical Device Identification Card, communicate directly with the implanting physician, and/or obtain an x-ray to determine the precise 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.

Position	WBA SAR 1.5 T	WB SAR 3 T	B1 +rms 1.5 T	B1 +rms 3 T
Upper Arm	0.4	0.6	1.2	0.7
Intercostal	0.4	0.6	1.2	0.7
Lower Leg	0.2	0.6	1.2	0.7
Upper Leg	0.4	0.6	1.2	0.7

Table 2.1. Whole body SAR and B1+rms limits for StimRouter inside the Reduced RF Zone, i.e. within 50 cm of center of the RF body coil. If B1+rms is not displayed on the MR system console, the whole bodySAR limit is to be used.

WARNING: If the StimRouter Lead is at least 50 cm from the center of the bore of the MR system and the center of the transmit/receive RF body coil, DO NOT perform an MRI exam on the patient above a whole-body-averaged SAR of 2 W/kg in the Normal Operating Mode for a 1.5 T/64 MHz or a 3 T/128 MHz MR system. For a StimRouter Lead implant located inside the Reduced RF Zone (see Figures and Tables in this Guide) a reduced value of the whole-body-averaged SAR or, alternatively, the value of the B_{1+RMS} must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam.

The **"Reduced RF Zone"** is defined as the anatomic area of the patient that will receive the RF power deposition during an MRI exam. When all or part of the StimRouter Lead is within a 50 cm distance from the center of the bore of the MR system and the center of the transmit RF body coil, this is referred to as the "Reduced RF Zone." A reduced value of the whole-body-averaged SAR or, alternatively, the value of the B_{1+RMS} must be utilized in order to ensure acceptable tissue temperature increases based on the MRI conditions that are used for the MRI exam. See Tables 2-1 and 2-2 for the acceptable whole-body-averaged SAR and B_{1+RMS} values.

To ensure safety for a patient with an implanted StimRouter Lead, MRI healthcare professionals must adhere to the following conditions:

Using the Transmit Body RF Coil

When the entire StimRouter Lead is outside of the Reduced RF Zone and a receive-only RF coil is being used (note, any type of receive-only RF coil is permitted for use under these circumstances), the reported whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz and 2 W/kg at 3 T/128 MHz (Figure 2-1). Do not perform MRI in patients using a whole-body-averaged SAR level that exceeds 2 W/kg. An MRI exam scan performed using a whole-body-averaged SAR level above 2 W/kg may increase the risk of unacceptable MRI-related heating of the implanted StimRouter Lead.

When all or part of the StimRouter Lead is inside the Reduced RF Zone (Figure 2-1), reduced values of the whole-body-averaged (WBA) SAR or the B_{1+RMS} value must be used to result in acceptable tissue temperature increases. See Tables 2-1 and 2-2 for the WBA SAR or the B_{1+RMS} recommended for use when all or part of the StimRouter Lead is within the Reduced RF Zone during the MRI exam.

Using the Transmit RF Body Coil and the Receive-Only RF Head Coil

When all or part of the StimRouter Lead is inside of the Reduced RF Zone and a receive-only RF head coil is being used (Figure 2-2), reduced values of the whole-body-averaged (WBA) SAR or the B_{1+RMS} value must be used to result in acceptable tissue temperature increases. See Tables 2-1 and 2-2 for the WBA SAR or the B_{1+RMS} recommended for use when all or part of the StimRouter Lead is within the Reduced RF Zone during the MRI exam. Do not use the transmit RF Body Coil if the StimRouter Lead is implanted above the shoulder.

Using the Transmit/Receive RF Head Coil

Limit the head SAR to 3.2 W/kg using the Normal Operating Mode of operation for the MR system if the StimRouter Lead is located in the patient's shoulder or a lower anatomic position (Figure 2-3).

As previously mentioned in the contraindication section, do not use the transmit/receive RF head coil if the StimRouter Lead is implanted above the shoulder. Please refer to Chapter 2 for a complete list of contraindications.

Using the Transmit/Receive RF Knee Coil

MRI scans with the Transmit/Receive RF Knee Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive RF Hand/Wrist Coil

MRI scans with the Transmit/Receive RF hand/wrist Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Using the Transmit/Receive RF Foot/Ankle Coil

MRI scans with the Transmit/Receive RF foot/ankle Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

Note: The StimRouter Lead is considered to be outside of the “Reduced RF Zone” if the entire lead is located outside of the transmit RF body coil as shown in Figures 2-1 and 2-2, StimRouter Lead (A).

Note: The bore dimensions of clinical MR systems and associated transmit/receive RF coils will vary according to the type of MR system used on the patient with the StimRouter Lead.

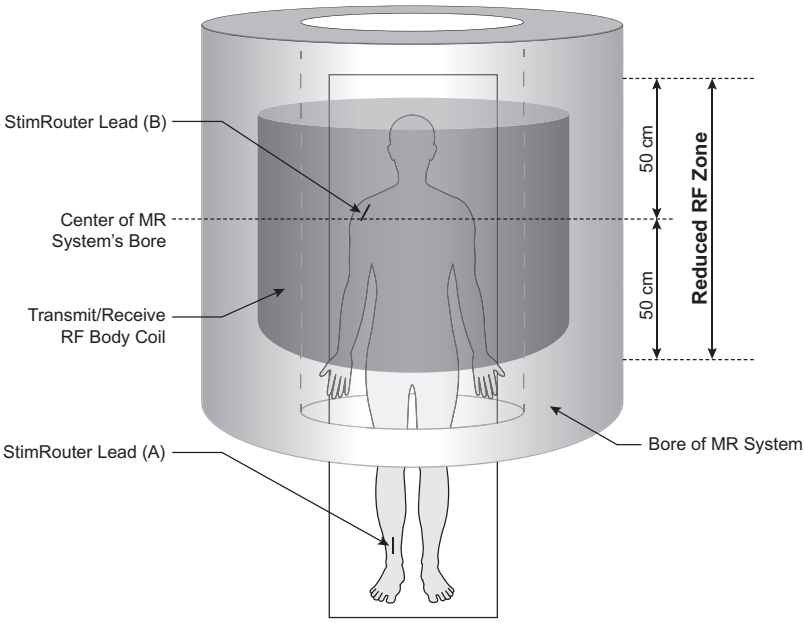

Figure 2-1: The StimRouter Lead (A) is located outside of the Reduced RF Zone and is more than 50 cm away from the center of the MR system's bore and the transmit/receive RF body coil. In this case, a whole-body-averaged SAR must not exceed 2 W/kg at 1.5 T/64 MHz or a whole-body-averaged SAR of 2 W/kg at 3 T/128 MHz in the Normal Operating Mode of operation for the MR system. The StimRouter Lead (B) is located inside of the Reduced RF Zone. The use of reduced WBA SAR or B_{1+RMS} values are required.

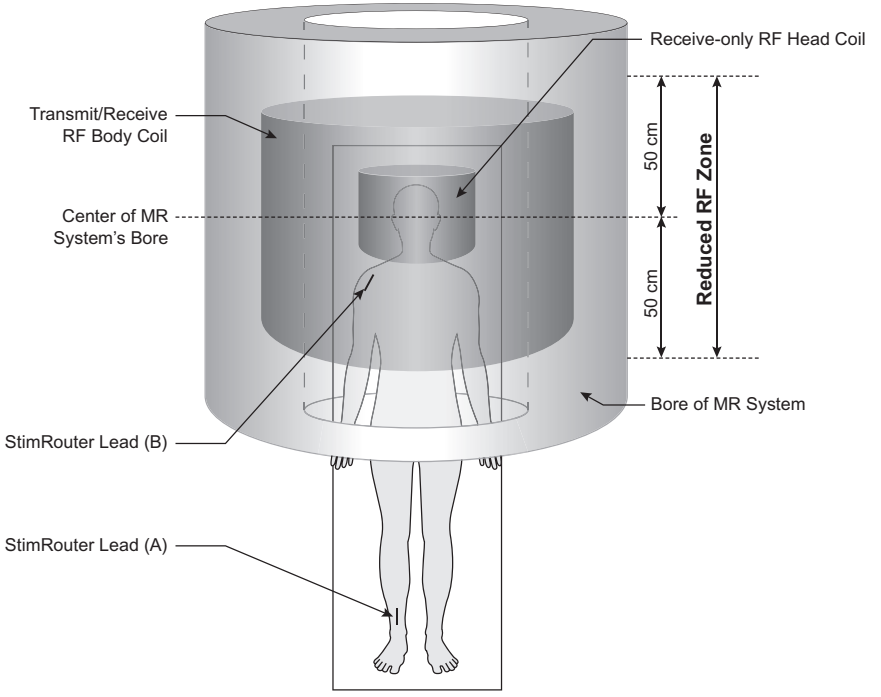

Figure 2-2: The transmit RF body coil and the receive-only RF head coil are being used with the StimRouter Lead (B) inside of the Reduced RF Zone. The use of reduced WBA SAR or B_{1+RMS} values are required.

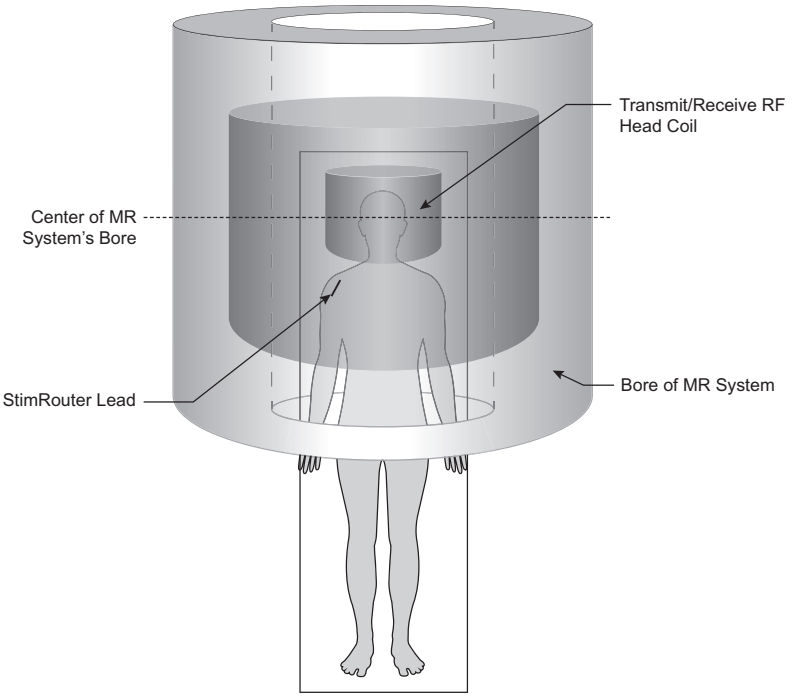

Figure 2-3: The transmit/receive RF head coil is being used.

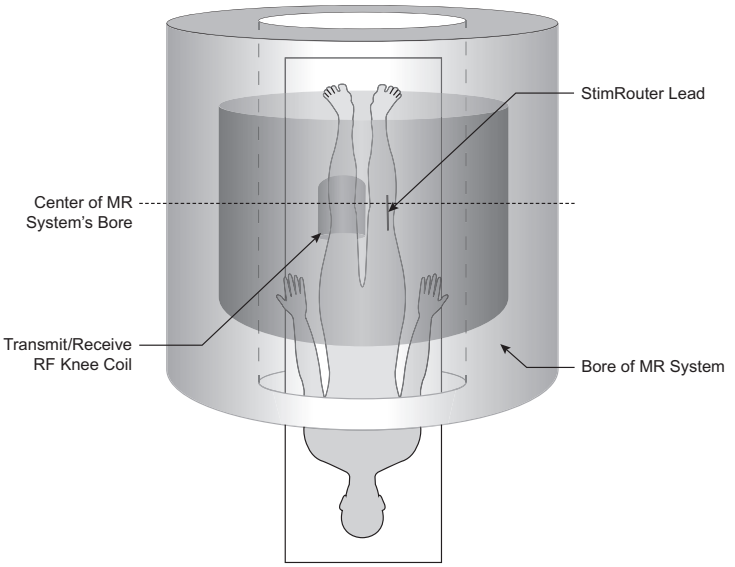

Figure 2-4: MRI scans with the Transmit/Receive RF Knee Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

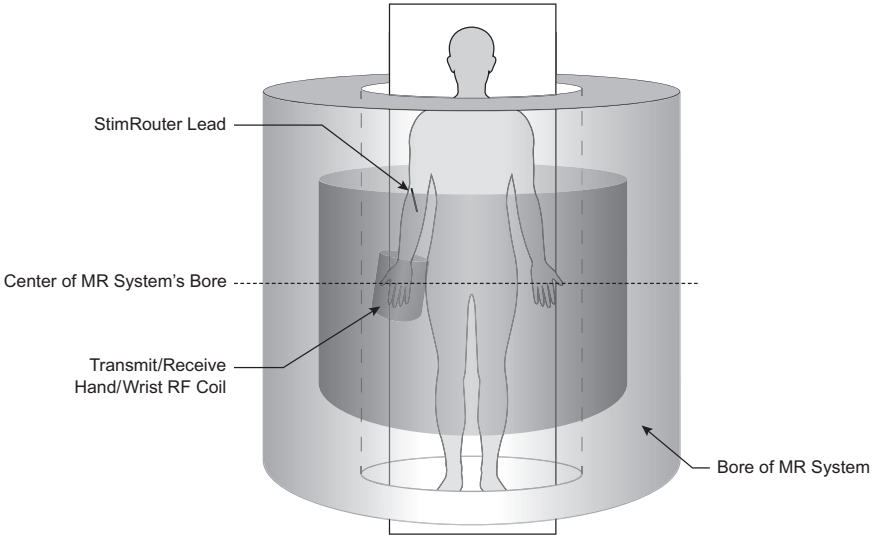

Figure 2-5: MRI scans with the Transmit/Receive RF hand/wrist Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

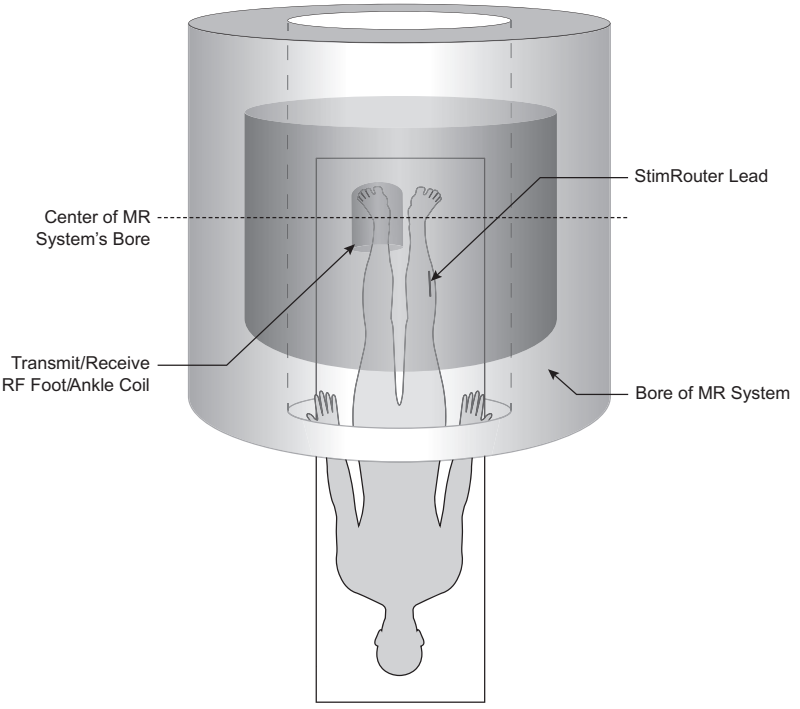

Figure 2-6: MRI scans with the Transmit/Receive RF foot/ankle Coil may be performed provided that StimRouter Lead is outside the coil and at least one coil radius away from the edge of the coil.

Do not scan if StimRouter is inside the coil or less than a coil radius away from the edge.

MRI-Related Heating of the StimRouter Lead: Supplemental Information

1.5 T/64 MHz

For situations where the entire StimRouter Lead is located **outside** of the Reduced RF Zone:

Temperature changes of the electrodes of the StimRouter Lead were measured at 1.5 T/64 MHz according to American Society for Testing and Materials (ASTM) International F2182 (i.e., using a 64-MHz transmit RF body coil). With the StimRouter Lead in an orientation and a position in the phantom[1] 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 the application of RF power. This temperature change was with the StimRouter Lead in an elongated, "straight" configuration (i.e., no

[1]A "phantom" is a container filled with gelled saline that allows for the testing of MRI-related heating for implants.

curves), which produced the highest temperature rise. With the StimRouter Lead in curved or looped configurations, temperature rises were less.

A computer simulation that incorporated the worst-case measured temperature rise at several anatomic locations and at a whole-body averaged SAR of 2 W/kg predicts a worst-case heating of an implanted StimRouter Lead in the patient during an MRI exam of less than 2°C after 15 minutes of continuous scanning (i.e., per pulse sequence) provided that the entire StimRouter Lead implant is outside of the Reduced RF Zone (see Figures 2-1 to 2-6).

For a StimRouter Lead implant located inside of the Reduced RF Zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+RMS in Table 2.1.

3 T/128 MHz

For situations where the entire StimRouter Lead is located **outside** of the Reduced RF Zone:

Temperature changes of the StimRouter Lead electrodes were measured at 3 T/128 MHz according to ASTM International F2182 (i.e., using a 128-MHz transmit RF body coil). With the StimRouter Lead in an orientation and a position in the phantom[1] 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 application of RF power. The highest temperature rise occurred with the StimRouter Lead in an elongated, “straight” configuration (i.e., no curves). Temperature rises were less when the StimRouter Lead was in curved or looped configurations.

A computer simulation showed that there would be less than a 1°C heating of an implanted StimRouter Lead in the patient during an MRI exam, provided the entire StimRouter Lead implant was outside of the Reduced RF Zone (see Figures). The computer simulation incorporated the worst-case measured temperature rise at several anatomic locations and a whole-body-averaged (WAR) SAR of 2 W/kg.

For a StimRouter Lead implant located inside of the Reduced RF Zone, the worst-case heating was calculated to be less than 6°C for the values of whole-body-averaged (WBA) SAR and B1+RMS in Table 2.1.

Image Artifacts

MR imaging 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 MRI 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 time-varying, gradient magnetic fields used during MRI were calculated.

If the StimRouter Lead is at least 50 cm from the center of the bore of the MR system and outside the gradient coils of the MR system, the induced current will be less than the stimulation threshold. However, the induced current may reach the stimulation threshold if the StimRouter Lead is located less than 50 cm from the center of the bore of the MR system and the center of the transmit RF body coil (i.e., the approximate area inside the "Reduced RF Zone").

⚠ **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 not known. Do not use electrical stimulation during pregnancy.

Long-Term Effectiveness of Neurostimulation

The long-term effectiveness of neurostimulation is not known.

Programming

Only your physician should program the StimRouter system.

Device Components

Use only Bioness components with your StimRouter system. Use of non-Bioness components may damage the system and cause injury.

No modification of this equipment is allowed.

The Patient Programmer and 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.

Turn off the Patient Programmer and stimulation when you are near a refueling station, flammable fuel, fumes or chemicals. If your system is on, it could ignite the chemicals or fumes, causing severe burns, injury or death.

Driving and Operating Machinery

Turn off stimulation while driving or operating machinery.

Electromagnetic Compatibility Warnings

Medical Devices/Therapies

Operation of the StimRouter system in close proximity (e.g., 1 meter) to shortwave or microwave therapy equipment may produce instability in the EPT output.

The following medical therapies or procedures may turn stimulation off. They may also permanently damage the StimRouter external components and may cause injury, particularly if used close to the system components.

- Lithotripsy
- Electrocautery
- External defibrillation
- Ultrasonic scanning
- High-output ultrasound

Electromagnetic interference (EMI) from the following medical procedures is unlikely to affect the StimRouter system:

- Computerized Axial Tomography (CT or CAT) scans
- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy

Note: Turn off stimulation and remove the StimRouter Electrode before undergoing a medical procedure.

Electrosurgery Devices

If you require electrosurgery, tell your physician you have an implanted lead. Electrosurgery devices should not be used close to an implanted StimRouter lead. Contact between an active electrode of the electrosurgery device and the implanted lead can stimulate the lead and cause severe injury.

High-Frequency Surgical Equipment

Remove the StimRouter electrode before medical treatment. If you are connected to the StimRouter system and high-frequency surgical equipment, you may experience a skin burn where the gel electrodes adhere. Also, the StimRouter EPT may become damaged.

Body-Worn Devices

Although unlikely, body-worn medical devices may interfere with the RF communication used in the StimRouter system. Stimulation control may be delayed. Examples of a body-worn device are a pain pump or an insulin pump and a monitoring device. The patient programmer will emit visual alerts if interference occurs. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the StimRouter system and all other electronic devices. See the “Troubleshooting” section for help. See the “Appendix” for more information.

The StimRouter system’s wireless technology may cause EMI to other body-worn medical devices. Refer to the instructions for use for those devices for information on recommended minimum separation distances.

Security Screening Devices

Certain types of security devices may affect stimulation. Examples include those used at the entrances and exits of public buildings such as libraries, airports and retail stores. Ask for help to bypass the device. Show your Medical Device Identification Card if you must pass through the device:

- Turn off your StimRouter system.
- Pass through the security screening device quickly.
- Stay as far from the emitter as possible. Walk, for example, in the center of a pass-through security gate.

Cell Phones

There is potential for interference between electronic devices, including cell phones. Stimulation control may be delayed. If interference is suspected or anticipated, distance yourself from the source of interference. To minimize interference, maintain a minimum safe separation distance of 15 cm (6 in.) between the StimRouter system and all other electronic devices.

Precautions

Post-Operative Care

After the implant procedure, check the incision site for infection, possible device rejection or other possible adverse effects.

Contact your physician immediately if you have:

- Excessive redness or discharge around the incision site.
- Prolonged pain at the incision site.
- Warmth and swelling of the incision site.
- Fever
- Dizziness
- Bleeding

Known or Suspected Heart Problems

Consult your physician if you have or suspect you have a heart condition. Physicians should use caution when treating patients with suspected or diagnosed heart problems.

Implant Failure

Leads may fail at any time. If a lead fails or breaks, then the lead may need to be removed or replaced. It is possible that small fragments of the lead could remain at the implantation site after removal, which will indefinitely prevent you from being eligible for certain procedures, such as diathermy, therapeutic ultrasound, or MRI in the affected area. Immediately contact your physician, if implant failure is suspected.

Postural Changes

Changes in posture or abrupt movements may change the stimulation you feel. Turn off stimulation before stretching or exercising.

For Single Patient Use Only

Do not adhere the StimRouter Electrode to any other person or any other part of your body.

Keep Out of Reach of Children

Keep all StimRouter components out of the reach of children.

Skin Abnormalities

Do not adhere the StimRouter Electrode to skin that is swollen, infected or inflamed or to skin that is broken. Do not adhere the StimRouter Electrode over veins that are swollen or inflamed.

Skin Irritation

It is normal for the skin under the StimRouter Electrode to become red. The redness should disappear about one hour after you remove the StimRouter Electrode.

Some people may be allergic or hypersensitive to the electrical stimulation or the gel on the StimRouter Electrode. Persistent redness, lesions or blisters are signs of irritation. Stop using the StimRouter system until the irritation is gone. To avoid irritation, remove the StimRouter Electrode every three to four hours for 15 minutes. Talk to your physician if irritation persists.

Sensations Caused by Stimulation

As with other nerve stimulation devices, the StimRouter achieves pain relief by causing different sensations to be felt in the area of treatment. These sensations (also referred to as “paresthesia”) include tingling and numbness. While these sensations are normal during StimRouter use, stimulation should not proceed to the point of being painful.

StimRouter Electrode Expiration Date

Do not use a StimRouter Electrode with a “Use by” date that has expired.

StimRouter Electrode Placement and Stimulation

- Use only StimRouter Electrodes manufactured by Bioness Inc.
- Only your physician should decide where to place the StimRouter Electrode.
- Only your physician should program your StimRouter system.
- Turn off stimulation before adhering, removing or handling the StimRouter Electrode.
- Do not adhere the StimRouter Electrode across your chest or near your heart. Electrical stimulation of the heart may disturb heart rhythm.
- Apply user patch only to the areas recommended by your physician. Avoid placing the user patch across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus).
- Do not adhere the StimRouter Electrode over anything other than skin. Do not adhere it over an adhesive bandage, for example. The StimRouter Electrode must be in full contact with the skin or the stimulation could cause serious injury.
- Do not place the StimRouter Electrode over skin folds, scarred tissue, irritated skin, uneven skin surfaces or broken skin.
- Always check the StimRouter Electrode gel pads before use. Do not use the StimRouter Electrode if the gel appears dry, worn, dirty or irregular.
- Remove the clear protective cover from the StimRouter Electrode before using.
- Do not handle the StimRouter Electrode with both hands while stimulation is on. Serious injury can occur if electrical current passes through your heart.
- Do not apply the StimRouter Electrode to anyone else or any other part of the body than that determined by your physician.

Storage and Handling

Handle all StimRouter components with care. Dropping components on hard surfaces, or other rough handling, can damage them. Avoid exposing them to extreme temperatures or moisture.

Protect all StimRouter components from contact with water, such as from sinks, bathtubs, shower stalls, rain and snow.

StimRouter Electrode Storage Temperature Range: 5°C to 27°C (41.0°F to 80.6°F)

External Pulse Transmitter (EPT) Storage Temperature Range: -20°C to +60°C (-4°F to +140°F)

Patient Programmer Storage Temperature Range: -20°C to +60°C (-4°F to +140°F)

Adverse Effects

In the unlikely event that any of the following occurs, stop using your StimRouter system, remove the StimRouter Electrode and immediately contact your physician.

Risks Related to the Implant Procedure

If the lead is not placed properly, it may need to be removed or your therapy may need to be adjusted. Nerve injury is possible, although unlikely. Possible surgical complications include infection and device rejection. Contact your physician immediately if you experience fever, swelling, bleeding or prolonged pain at the implant site.

Risks Related to Stimulation

- Stimulation of skin and muscles surrounding the lead may cause increased pain.
- You may have undesirable movements during stimulation. If this occurs please contact your physician.

If you experience any discomfort during stimulation, or notice any skin abnormalities:

- Stop stimulation immediately.
- Remove the StimRouter Electrode.
- Notify your physician.

Additional Risks Related to the StimRouter System

- If the lead moves, it may change the stimulation effectiveness.
- While very unlikely, the tissue around the lead may react to the implanted materials.
- External electromagnetic interference (EMI) may cause the StimRouter components to malfunction. EMI may also affect stimulation.
- You may have persistent pain at the implant site.
- 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. Overheating could cause burning.

If you experience any discomfort during stimulation, or notice any skin abnormalities:

- Stop stimulation immediately.
- Stop contact with the StimRouter components.
- Notify your physician.