Magnetic Resonance Imaging (MRI) for the Revi™ System

For use of MRI when the Revi is implanted refer to “MRI Conditional Labeling” below.

- Do not conduct an MRI examination on a patient implanted with the Revi until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can potentially result in heating of the Implant, resulting in damage to surrounding tissue, damage to the Implant and unexpected changes in stimulation.
- A responsible individual with expert knowledge about MRI, such as an MR trained radiologist or MRI physicist, must assure all procedures in this guideline are followed and that the MRI scan parameters comply with the recommended settings during the MRI examination. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this section.
- Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations/uncomfortable stimulation, or unusual sensations.
- The Revi System should not be activated during the MRI procedure.
- All external components and accessories of the Revi System are MR Unsafe and are contraindicated for the MRI environment and not allowed into the MRI suite. Therefore, the External Control Unit and Clinician Programmer must be removed before the patient is allowed into the MRI environment.
- The Revi Implant has not been tested in simultaneous combination with other devices in the MRI environment.

MRI Conditional Labeling

The Revi Implant is MR conditional as defined in ASTM F2503-13.

A patient implanted with the Revi Implant may be safely scanned anywhere in the body, under the following conditions:

Parameter	Condition
MR system with static field	1.5T or 3.0T May also be performed at field strengths >1.5T
Maximum spatial gradient in the static field	30 T/m
Maximum scanner gradient slew rate	200T/m/s

Static Magnetic Field Strength	Landmark	RF Condition
1.5 MR Scanner	Above the waist	Normal or first level controlled operating mode with maximum whole-body SAR of 4 W/kg. No restrictions on scan time due to implanted device.*
	Below the waist	Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan duration of 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks).*
3T MR Scanner	Above the waist	Normal or first level controlled operating mode with maximum whole-body SAR of 4 W/kg. No restrictions on scan time due to implanted device.*
	Between waist and knee (not including the knee)	Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan duration of 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks).*
	Knee and below	Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan duration of 30 minutes of continuous RF (a sequence or back-to-back series/scan without breaks). Wait 30 minutes before the next imaging session.*

**Actual scan time according to MRI scanner guidelines*.

The health state of the patient or the presence of other implants may require reduction of the MRI limits.

Information from non-clinical tests of MRI interactions on Revi Implant

RF heating was measured at 1.5 T and 3 T in phantom tests performed according to ASTM F 2182-11a. Under the conditions of the IFU, the maximum temperature rise during MRI of tissues near the Revi Implant is acceptable and is not expected to cause thermal damage to the surrounding tissue.

Magnetic force was measured according to ASTM F2052-15. Fixation of the device to the tissue will prevent device movement in the MRI static field.

Image artifact was measured according to ASTM 2119-13 in a 3T clinical MR system. Maximum artifact beyond the implant was 1.2 in (3 cm) for the spin echo sequence and 1.6 in (4 cm) for the gradient echo sequence. It may be possible to reduce artifact by use of suitable scan sequences.

Following ISO/IEC 10974 (2018) multiple exposures of Revi Implant to MRI electromagnetic fields were made at 1.5 T and 3 T. These exposures did not damage the device. RF and gradient fields during MRI are not expected to elicit unintended stimulation.