Medtronic

MRI experience matters

SureScan™ technology for InterStim™ systems

20+ years of MRI research

1.2 million scanning scenarios†,‡

10 million simulated patient scans‡

† Combination of body model, MRI manufacturer, implant location, lead length, and scan type.
‡ Medtronic data on file – result of animal studies combined with lab data, computational modeling, and statistical methods.

Leading innovations

Our proprietary SureScan™ lead technology for InterStim™ systems offers:

Safety

- Proprietary tantalum braiding allows radiofrequency energy to be safely distributed from the MRI – ensuring heat is shared across the entire lead, not solely on the electrodes

Quality

- Increased strength and durability of the lead body with a continuous braided diameter design§
- Single injection molding during manufacturing to remove bonded components

Control

The bent lead stylet and directional indicator are designed to:

- Improve steering of lead tip to target¶
- Expedite implant procedures¶
- Maximize points of stimulation with lead lying along the nerve's natural anatomy

Why SureScan™ technology matters

SureScan™ technology allows all eligible patients to receive a full-body 1.5T and 3T MRI, even with out-of-range impedance.◊

Why is 3T MRI labeling important?

3T MRI provides superior signal to noise ratio (SNR), which can result in improved image quality compared to 1.5T MRI imaging.[1,2]

If the MRI center has already upgraded to a 3T system, the patient will need an alternative if their device is not 3T eligible. By providing a 3T MRI eligibility to patients with out-of-range impedance, Medtronic ensures broad MRI access.

Hear from experts about the advantages of our MRI labeling

§ Medtronic data on file. Characterization Test Report.
◊ Under certain conditions; see approved labeling for details. Patients with InterStim™ SureScan™ MRI leads only.
¶ Medtronic data on file. System Design Document.

The Medtronic SureScan™ MRI difference

Know the difference

InterStim™ sacral neuromodulation systems offer broad MRI access.

	Medtronic InterStim™ systems†,[5]	Axonics™* all models[3]
Full-body MRI eligibility for low impedance	✓	✗
No impedance check required prior to full-body MRI	✓	✗
Digital display clearly confirms MRI mode activation	✓	✗
Full-body scans allowed within First Level Controlled Operating Mode	✓	✗
Same scan conditions for high impedance vs normal system	✓	✗

With Axonics™*, an MRI readiness check is required, and there are impedance disqualifiers.[3]

18.6%
of patients may have an impedance issue during the life of an implant[4]

What is impedance?

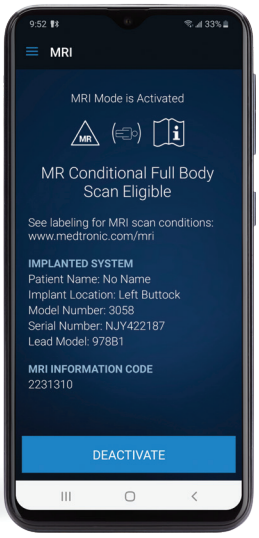
Impedance is a measurement of the effective resistance of an electrical circuit. An out-of-range impedance can indicate a source of electrical abnormality with the lead or connections. Low impedances can result from a short circuit (can occur from a crush injury or fluid leak). High impedance can indicate an open circuit (can occur from a lead fracture or loose connection).

See the difference

The InterStim™ smart programmer features a clearly visible and readable display of MRI mode and eligibility, providing confidence that the patient's device is MRI ready.

The Axonics™ remote displays MRI scan readiness using the same lights used to communicate other messages, such as stimulation amplitude, and the lights will only be seen for 15 seconds before the remote turns off.[6]

Axonics™ patient remote



InterStim™ smart programmer

† Under certain conditions; see approved labeling for details. Patients with InterStim™ SureScan™ MRI Leads only

1. Stankiewicz JM, Glanz BI, Healy BC, et al. Brain MRI lesion load at 1.5T and 3T versus clinical status in multiple sclerosis. *J Neuroimaging*. April 2011;21(2):e50-e56. 3)
2. Kamada K, Kakeda S, Ohnari N, Moriya J, Sato T, Korogi Y. Signal intensity of motor and sensory cortices on T2-weighted and FLAIR images: intraindividual comparison of 1.5T and 3T MRI. *Eur Radiol*. December 2008;18(12):2949-2955
3. Axonics MRI guidelines, US, 110-0092-001rAR
4. Fascelli M, Rueb J, Derisavifard S, et al. Mp31-06 Prevalence of Abnormal Impedance in Sacral Neuromodulation Device and Implication for Practice. *J Urol* 2020;203 (Supplement 4): e476-e477.
5. Medtronic MRI Guidelines for InterStim™ systems, M980291A032 Rev A.
6. Axonics Remote Control User Manual 110-0125-001 Rev N

Indications for Use:
Sacral Neuromodulation delivered by the InterStim™ system for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to Sacral Neuromodulation for Urinary Control:

> **Warning:** This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Sacral Neuromodulation delivered by the InterStim™ system for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.
Contraindications for Urinary Control and for Bowel Control: Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.
Warnings/Precautions/Adverse Events:
For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins.
For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.
For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

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