We are pleased to inform you that InterStim® systems are now FDA-approved to allow implanted patients to undergo an MRI head scan under specific conditions. Medtronic recently completed non-clinical testing which demonstrated that your patients previously implanted with the InterStim II system and specific InterStim I systems, as well as your prospective InterStim patients, can now safely undergo an MRI head scan under specific conditions.*

View MRI guidelines for InterStim systems
Note that the new MR conditional status is an FDA-approved labeling update – no changes have been made in the product design. Exposing a patient to MRI conditions other than those listed in the labeling may result in severe patient injury or device malfunction.

This expanded labeling ensures access to an important diagnostic tool. Let your patients know that the InterStim System is a proven treatment option for bladder control and bowel control and conditionally compatible with MRI head scan imaging.

Important Safety Information

InterStim Therapy 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 InterStim Therapy for Urinary Control:

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

InterStim Therapy 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.

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 such as multiple sclerosis.

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. 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. USA Rx Only. Rev 0409