SEE IT. PLACE IT.

Diagnostic Ultrasound for Basic Evaluation
Lead Placement

Sacral Neuromodulation for Bladder Control or Bowel Control Delivered by the InterStim™ System
Medtronic now offers the convenience of diagnostic ultrasound to help visually guide needle insertion in real time as part of a basic evaluation of Medtronic bladder or bowel control therapy delivered by the InterStim system, also known as sacral neuromodulation (SNM).

If you have access to ultrasound equipment, diagnostic ultrasound is an easy, convenient, and FDA-approved option for lead placement. It offers another reliable option for locating and visualizing the sacral foramina, so you can make the best choice for your patient.

**EXPECT EASIER LEAD PLACEMENT**
- Real-time visual guidance
- Convenient procedure
- Visual clarity for challenging anatomy
- Alternative to fluoroscopy or boney landmarks
- Radiation-free operation

**ULTRASOUND EQUIPMENT**
- Standard diagnostic ultrasound system
- Linear array 7-8 MHz probe (preferred) or convex (curvilinear) probe
- Sterile ultrasound gel
- Sterile disposable cover for the ultrasound probe

**ANATOMIC LANDMARKS**
- 3rd SACRAL SPINOUS PROCESS
- 3rd SACRAL FORAMEN
- SACRAL CORNUA
- COCCYGEAL CORNUA
- COCCYX
- MEDIAN SACRAL CREST
- LATERAL SACRAL CREST
- SACRAL HATUS
- SACRAL CORNUA
- COCCYGEAL CORNUA
- COCCYX
Place the probe over the coccyx to begin.
This is the first landmark.
Move the probe cephalad approximately 2 cm from Landmark 1 to find Landmark 2. This is the coccygeal cornua.
From Landmark 2, move the probe cephalad approximately 2 cm to find Landmark 3, the sacral cornua and hiatus.
Slightly lateral to Landmark 3 is Landmark 4, the S4 foramen.
Center the probe over Landmark 4 and then move the probe cephalad approximately 2 cm to find the S3 foramen.

Tip: Adjusting focal length(s) to the depth of the sacrum may improve image quality.
Use this view for guiding foramen needle insertion.
Indications for Use:
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.

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 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. 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.

USA Rx Only. Rev 0815