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.

USA Rx Only. Rev 0517

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PATIENT MANAGEMENT GUIDE

InterStim™ system for Sacral Neuromodulation
**INITIAL TROUBLESHOOTING QUESTIONS**

1. Have your symptoms returned? ▶ No
   - Refer to other sections in this guide for additional troubleshooting information.
   - Yes

2. Is the neurostimulator on? ▶ No
   - Instruct patient to turn device on with the smart programmer.
   - Yes

Instruct patient to follow their provider’s recommendations for assessment and treatment.

3. Do you have signs or symptoms of an infection? ▶ Yes

   1. Have you had a change in bladder or bowel function (constipation or diarrhea)?
   2. Have there been changes with other known medical conditions (e.g., neurological disorder, IC flare, glucose change)?
   3. Have there been any changes in your diet?

   Some foods and fluids can cause changes in your bladder and bowel function.

   No

   Yes
Medications (e.g., antibiotics, diuretics, blood pressure, hormones) may cause changes in urinary and bowel symptoms, such as urgency-frequency or diarrhea.

Have there been any changes to your medications or have you started any antibiotics?

- Yes: Consider scheduling an office visit for the patient. You may decide to check impedance using the smart programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic sales representative, if necessary.

1. Have you recently fallen or had trauma to your body?
2. Have you recently had any procedures or surgeries?

- Yes: Refer to other sections in this guide for additional troubleshooting information.

- No: No action required.
Record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review the patient’s usage report on the smart programmer, review program settings, change to a different program, check impedance, and review battery life using the smart programmer. Contact your Medtronic representative, if necessary.
Can’t Feel Stimulation

Ask Initial Troubleshooting Questions

Symptom Return

Record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review the patient’s usage report on the smart programmer, review program settings, change to a different program, check impedance, and review battery life using the smart programmer. Contact your Medtronic representative, if necessary.

No Symptom Return

You may need to re-educate the patient on stimulation sensation. Patients do not need to feel stimulation for the InterStim™ system to be working.
Intermittent Stimulation

Ask Initial Troubleshooting Questions

Is the stimulation positional?

Yes

Stimulation may fluctuate slightly due to positions or activities. Patients do not need to feel stimulation for the InterStim™ system to be working. If the intermittent stimulation is bothersome, instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to palpate for loose connections and check for positional sensitivity or check impedance using the smart programmer. Contact your Medtronic representative, if necessary.

No

Stimulation may fluctuate slightly due to positions or activities. Patients do not need to feel stimulation for the InterStim™ system to be working. If the intermittent stimulation is bothersome, instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review program settings (SoftStart/Stop™, cycling, etc.) and check impedance using the smart programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic representative, if necessary.
I feel the stimulation in my ________________

Ask Initial Troubleshooting Questions

Symptom Return

Instruct patient to change to a different program and record symptoms using the Patient Management Worksheet. Patient may need to schedule an office visit. You may decide to review usage report, review program settings (rate, pulse width, etc.), change to a different program, check impedance, and review battery life using the smart programmer. Contact your Medtronic representative, if necessary.

No Symptom Return

You may need to re-educate the patient on stimulation location. Patients do not need to feel stimulation in a certain area for the InterStim™ system to be working. Focus on symptom relief. If the stimulation location is bothersome, patient may need to schedule an office visit. You may decide to review and adjust program settings (rate, pulse width, etc.).
**UNCOMFORTABLE STIMULATION**

**Ask Initial Troubleshooting Questions**

Instruct patient to adjust the stimulation to a comfortable level or change to a different program with the smart programmer.

**Do you still feel uncomfortable stimulation?**

- **Yes**
  - Consider scheduling an office visit for the patient. You may decide to adjust the rate or pulse width to a comfortable level using the smart programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic representative, if necessary.

- **No**
  - Re-educate the patient on use of the smart programmer.
**Ask Initial Troubleshooting Questions**

Instruct patient to turn device off with the smart programmer.

**Do you still feel pain?**

- **Yes**
  - The pain is not likely related to stimulation. Rule out sources of non-stimulation pain (e.g., incision healing/pulling, seroma, skin staples, infection, falls/trauma). Instruct patient to follow their provider’s recommendations for assessment and treatment.

- **No**
  - Consider scheduling an office visit for the patient. You may decide to change program settings using the smart programmer. If the electrode configuration is unipolar, program a bipolar configuration using the standard programs. Record symptoms using the Patient Management Worksheet. Contact your Medtronic representative, if necessary.
**SHOCKING/JOLTING SENSATION**

Ask
*Initial Troubleshooting Questions*

Instruct patient to turn stimulation off with the smart programmer.

Do you still feel the shocking/jolting stimulation?

**Yes**

The sensation is not likely related to stimulation. Instruct patient to follow their provider’s recommendations for assessment and treatment.

**No**

Consider scheduling an office visit for the patient. You may decide to adjust the rate or pulse width to a comfortable level using the smart programmer. Record symptoms using the Patient Management Worksheet. Contact your Medtronic representative, if necessary.
Review the Initial Troubleshooting Questions (pages 1-2), then instruct patient to:

1. Record symptoms using a diary for a minimum of three days and call back with results.
   a. If >50% improvement from baseline: Review patient expectations. Reassure patient that stimulation is on and working.
   b. If <50% improvement from baseline: Instruct patient to try the next program (if available) in their smart programmer.

2. If necessary, repeat Step 1 to evaluate other programs in the smart programmer. Advise patient to evaluate each program for a minimum of three days and record symptoms using a diary.

3. If all seven standard programs (if available) in the smart programmer have been tried, schedule an office visit.

At appointment:

1. Review diary information and fill out Patient Management Worksheet.

2. Run impedance check and review usage report using the smart programmer.

3. If greater than or equal to 50% efficacy is NOT ACHIEVED with the 7 standard programs, the physician may:
   - Realize this is the best possible efficacy for the patient with this lead placement
   - Revise the lead
   - Remove the interstim™ components
   - Reprogram beyond the 7 standard programs*

   *Likelihood of success with custom programs is low
**Patients without a Patient Management Worksheet**

**Review the Initial Troubleshooting Questions (pages 1-2), then instruct patient to:**

1. Complete a three-day diary on current program.
2. Turn the device off for one week and then complete a three-day diary.
3. Schedule an office visit.

**At appointment:**

1. Collect the two diaries, record on the Patient Management Worksheet, and compare results.
2. Run impedance check and review usage report using the smart programmer.
3. Make the 7 standard programs visible in the smart programmer.
4. Advise patient to evaluate each program for a minimum of 3 days and record symptoms using a diary.

**Post-appointment, instruct patient to:**

1. Review diary information and fill out Patient Management Worksheet.
2. Run impedance check and review usage report using the smart programmer.
3. If greater than or equal to 50% efficacy is NOT ACHIEVED with the 7 standard programs, the physician may:
   - Realize this is the best possible efficacy for the patient with this lead placement
   - Revise the lead
   - Remove the interstim™ components
   - Reprogram beyond the 7 standard programs*

*Likelihood of success with custom programs is low