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FACT SHEET

Medtronic InterStim® Therapy for Urinary Control

Overview
InterStim Therapy helps control urinary problems through an implanted device that sends mild electrical impulses via a lead (a thin wire) to the sacral nerves that control the bladder, sphincter and pelvic floor muscles. Physicians have referred to the InterStim system as a pacemaker for the bladder.

Indication
InterStim Therapy is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urge incontinence and significant symptoms of urgency-frequency, alone or in combination, in patients who have failed or could not tolerate more conservative treatments. InterStim Therapy is not intended for patients with mechanical obstruction.

Benefits
- InterStim Therapy may eliminate or greatly reduce urinary symptoms for many people who suffer from urinary retention or the symptoms of overactive bladder including 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 treatment is reversible and can be discontinued at any time.
- In clinical studies, InterStim Therapy has been shown to successfully treat certain bladder control problems in many patients who had failed or could not tolerate other treatments.
- Physicians and patients can assess the effectiveness of the therapy through a test stimulation before committing to implantation of the entire system.

InterStim System
- The InterStim system consists of a neurostimulator, an extension, a lead, accessories and a patient programmer.
- InterStim Therapy works by electrically stimulating the sacral nerve, which influences the bladder and surrounding muscles that manage urinary function. The electrical stimulation may eliminate or reduce certain bladder control symptoms in some people.
The sacral nerves are stimulated via a lead that is implanted adjacent to a sacral nerve. Sacral nerves are peripheral nerves located below the base of the spinal cord. An extension connects the lead to a neurostimulator (about the size of a stopwatch), which is typically implanted under the skin of the upper buttocks, below the beltline or in the abdomen.

**Procedure and Follow-up**
- Treatment with InterStim Therapy involves three steps: test stimulation, surgical implant and post-implant follow-up.

  ⇒ *Test Stimulation*. The test stimulation can occur in a simple outpatient procedure in a urologist or urogynecologist’s office. During the trial, the patient wears an external stimulator that sends mild electrical pulses to the sacral nerve via a temporary lead. The temporary lead is implanted under the skin in the upper buttock.

  ⇒ *Surgical Implant Procedure*

  - *Using Tined Lead Models 3093 and 3889*: Following a successful trial, the temporary lead is removed and replaced with a tined lead and extension. The tined lead can be placed near the sacral nerve through an introducer. The other end of the lead is passed under the skin and connected to the neurostimulator. This minimally invasive procedure is often performed while the patient is under local anesthesia. The tined lead was designed to reduce surgical time as a result of a sutureless anchoring procedure and reduced number of surgical steps.

  - *Using Lead Models 3080, 3092, 3886, 3966*: Following a successful trial, the temporary lead is removed and replaced with a chronic lead and extension. The neurostimulator is implanted under the skin in the upper buttock. A small surgical opening is made over the sacrum and the chronic lead is placed near the sacral nerve. The other end of the lead is passed under the skin and connected to the neurostimulator. Often performed while the patient is under general anesthesia, the procedure typically takes about two hours. Hospitalization is typically one day.

  ⇒ *Post-Implant*. Following implant, the neurostimulator is activated. The neurostimulator sends mild electrical pulses via the lead to the sacral nerve. The patient typically experiences a gentle tingling sensation that is not intrusive. Physicians can adjust the stimulation to optimize the therapy for each patient. Follow-up examinations usually occur every six to 12 months to monitor the therapy’s effectiveness. The patient programmer allows patients to adjust the intensity of the stimulation.

**Safety Profile**
- InterStim Therapy is reversible and does not preclude the use of complementary or future therapeutic options.
- As with any surgical procedure, there are risks with InterStim Therapy. They include, but are not limited to, pain at the implant site, risks associated with the procedure itself and possible infection.
- Patients are able to test the system before committing to the implant of the entire system.
- In addition to the risk related to a medical procedure, complications from this therapy can include pain, infection, transient electrical shock, lead migration, and adverse change in bowel function, among others. These complications were generally resolvable in the clinical study.

History
- Before the introduction of InterStim Therapy in the 1990s, patients’ options were mainly limited to irreversible bladder surgery or a lifetime of absorbent pads or self-catheterization.
- Multi-center clinical studies of InterStim Therapy began in the United States in December 1993.
- InterStim Therapy was commercially released in Europe, Canada and Australia in April 1994.
- In September 1997, the FDA approved InterStim Therapy for the treatment of urinary urge incontinence.
- In April 1999, the FDA approved InterStim Therapy for the treatment of urinary retention and significant symptoms of urgency-frequency.
- In February 2002, the FDA approved the revised InterStim Therapy indication to include the term “overactive bladder.”
- In September 2002, the FDA approved a minimally invasive lead implant technique, using the InterStim Tined lead (Models 3093/3889).

Cost and Coverage
- Most private insurance companies have a written policy providing coverage for InterStim Therapy. Medicare has a national policy providing coverage for all approved indications.
Disclosure

InterStim® Therapy for Urinary Control: Product technical manual must be reviewed prior to use for detailed disclosure.

Indications:
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.

Contraindications:
Patients are contraindicated for implant of the InterStim System if they have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator. Also, diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy’s energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system.

Precautions/Adverse Events:

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

Safety and effectiveness have not been established for: bilateral stimulation, patients with neurological disease origins such as multiple sclerosis, pregnancy and delivery, or for pediatric use under the age of 16. System may be affected by or adversely affect cardiac pacemakers or therapies, cardioverter defibrillators, electrocautery, external defibrillators, ultrasonic equipment, radiation therapy, magnetic resonance imaging (MRI), theft detectors and screening devices. Adverse events related to the therapy, device, or procedure can include: pain at the implant sites, lead migration, infection or skin irritation, technical or device problems, transient electric shock, adverse change in bowel or voiding function, numbness, nerve injury, seroma at the neurostimulator site, change in menstrual cycle, and undesirable stimulation or sensations.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.