Neurostimulation

**Medtronic Itrel®, Synergy®, and Mattrix® Neurostimulation Systems**
Product technical manual must be reviewed prior to use for detailed disclosure.

**Indications**
The Medtronic Itrel®, Synergy®, and Mattrix® Neurostimulation systems are indicated as an aid in the management of chronic, intractable pain of the trunk or limbs. The Mattrix Receiver Model 3272 system is also indicated for peripheral nerve stimulation. Peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain.

**Contraindications**
Unsuccessful pain relief during trial stimulation of the spinal cord or peripheral nerve, or inability of patients to properly operate the system. The Mattrix systems also are contraindicated for patients with an implantable cardiac pacemaker or cardioverter/defibrillator, or for those patients who will be exposed to magnetic resonance imaging (MRI). 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.

**Warnings/Precautions/Adverse Events**
Safety has not been established for pregnancy or pediatric use. Patients should not drive or use dangerous equipment during stimulation. Systems may be affected by or adversely affect cardiac pacemakers, cardioverter/defibrillators, external defibrillators, MRI, ultrasonic equipment, electrocautery, radiation therapy, theft detectors, security systems, and aircraft communications systems. Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks. Patient selection criteria include physiological origin for the pain, appropriate surgical candidate, detoxification from narcotics, and availability of long-term post-surgical management.

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

**Rx only**
Site-Specific Drug Delivery

**Medtronic SynchroMed® and IsoMed® Infusion Systems**
Product technical manual must be reviewed prior to use for complete prescribing information.

**Indications**
Chronic intrathecal infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain and chronic intravascular infusion of floxuridine (FUDR) for the treatment of primary or metastatic cancer. SynchroMed is also indicated for chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for severe spasticity, chronic epidural infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intravascular infusion of doxorubicin, cisplatin, or methotrexate for the treatment of primary or metastatic cancer, and chronic intravenous infusion of clindamycin for the treatment of osteomyelitis.

**Contraindications**
When infection is present (except when SynchroMed is indicated for the treatment of osteomyelitis); when the pump cannot be implanted within 2.5 cm (1 inch) from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist related to the drug. Blood sampling through the side catheter access port is contraindicated.

**Warnings**
Use only with approved drugs. Improper use, calculation errors, or component failure may result in loss of therapeutic effect, or clinically significant or fatal drug withdrawal or overdose symptoms. Clinically significant or fatal drug overdose may result from overpressurization of the pump reservoir, improper injection of drug through the catheter access port or into the pump pocket, or failure to account for significant amounts of drug residing in the reservoir, pump tubing, catheter access port, or catheter. The effects of mixing drugs are unknown. Flow rate of the IsoMed pump may decrease or stop if drug precipitation occurs. The effects of implanting the SynchroMed pump in patients with other implanted programmable devices are unknown.

**Precautions**
Only qualified personnel should implant, fill and refill the pumps, access the catheter access ports, or program the SynchroMed pump. Maintain strict aseptic techniques during all procedures to prevent infection. Consider use of peri- and postoperative antibiotics for pump implantation and any subsequent surgical procedures. Use caution in selecting an anatomical pump site appropriate to the size and mass of the patient. Initial fill and refill volumes must not exceed levels specified in the technical manuals. Do not expose pumps to temperatures above 43 degrees C (110 degrees F) or below 5 degrees C (40 degrees F). Do not implant a pump that has been dropped onto a hard surface or shows signs of damage. Do not attempt to resterilize the pump. Follow manufacturer’s instructions regarding drug preparation, dosage, and administration. FUDR should be used with added caution in patients with impaired hepatic or renal function. Systemic therapy should be considered for patients with known disease extending beyond an area capable of infusion. IsoMed pump flow rate will vary depending on factors such as body temperature, altitude, arterial pressure at the catheter tip, and solution viscosity. In rare instances, an inflammatory mass may develop at the tip of an implanted spinal catheter, which can result in progressive neurological effects.
Magnetic Resonance Imaging (MRI): MRI will temporarily stop the SynchroMed pump motor and suspend drug infusion for the duration of MRI exposure. The SynchroMed pump should resume normal operation upon termination of MRI exposure. Exposure of IsoMed pumps to Magnetic Resonance Imaging (MRI) fields of 1.5 T (Tesla) has demonstrated no impact to pump performance and a limited effect on the quality of the diagnostic information. During an MRI scan, the patient may experience heating or peripheral nerve stimulation at or near the pump implant site. In the unlikely event that this happens, the MRI scan parameters should be adjusted to reduce Specific Absorption Rate (SAR) for heating or dB/dt for nerve stimulation or both. Upon completion of an MRI scan, the SynchroMed pump parameters should be confirmed using a SynchroMed® Programmer. SynchroMed pump performance has not been established in >2.0 T (Tesla) MR scanners nor has IsoMed pump performance been established in >1.5 T (Tesla) MR scanners — it is not recommended that patients have MRI scans using these scanners.

Adverse Events
Include, but not limited to, cessation or change in therapy, a return of underlying symptoms or drug withdrawal symptoms due to an empty reservoir, component failure or SynchroMed battery depletion; seroma/hematoma, infection, inflammation, tissue erosion, or pain at implant site; complete or partial catheter occlusion, kinking, breakage, leakage or disconnection; catheter dislodgment or migration; CSF leak/accumulation, internal/GI bleeding; arachnoiditis; meningitis; spinal headache; perforation of internal organs; drug toxicity and related side effects; and procedural complications.

Rx only