Our goal is to help you make the right decision for you.

Talk to your doctor now to see if spinal cord stimulation or targeted drug delivery may be right for you.

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY
Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure. Indication for Use: Chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines and precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, and other activities may cause shocking/jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging. **Adverse Events:** Undesirable change in stimulation; 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. For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. USA Rx Only Rev 0313

SynchroMed® II Drug Infusion System Brief Statement: Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure.
Indications: US: Chronic intraspinal (epidural and intrathecal) infusion of preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, chronic intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intrathecal infusion of Lioresal® Intrathecal (baclofen injection) for the management of severe spasticity; chronic intravascular infusion of floxuridine (FUDR) or methotrexate for the treatment of primary or metastatic cancer. Outside of US: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling. **Contraindications:** Infection; implant depth greater than 2.5 cm below skin; insufficient body size; spinal anomalies; drugs with preservatives, drug contraindications, drug formulations with pH ≤3, use of catheter access port (CAP) kit for refills or of refill kit for catheter access, blood sampling through CAP in vascular applications, use of Personal Therapy Manager to administer opioid to opioid-naïve patients or to administer ziconotide. **Warnings: Non-indicated formulations may contain neurotoxic preservatives, antimicrobials, or antioxidants, or may be incompatible with and damage the system. Failure to comply with all product instructions, including use of drugs or fluids not indicated for use with system, or of questionable sterility or quality, or use of non-Medtronic components or inappropriate kits, can result in improper use, technical errors, increased risks to patient, tissue damage, damage to the system requiring revision or replacement, and/or change in therapy, and may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug under- or overdose.** Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures and underdose and overdose symptoms and methods of management. Physicians must be familiar with the drug stability information in the product technical manuals and must understand the dose relationship to drug concentration and pump flow rate before prescribing pump infusion. Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the infusion system. An inflammatory mass that can result in serious neurological impairment, including paralysis, may occur at the tip of the implanted catheter. Clinicians should monitor patients on intraspinal therapy carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Inform patients of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention, including prodromal signs and symptoms of inflammatory mass. If it is suspected or known that all or part of the drug was injected into the pocket during the refill procedure, monitor the patient closely for signs and symptoms of overdose in an appropriate facility for a sufficient amount of time or until the symptoms have resolved. Failure to recognize signs and symptoms and seek appropriate medical intervention can result in serious injury or death. Instruct patients to notify their healthcare professionals of the implanted pump before medical tests/procedures, to return for refills at prescribed times, to carry their Medtronic device identification card, to avoid manipulating the pump through the skin, to consult with their clinician if the pump alarms and before traveling or engaging in activities that can stress the infusion system or involve pressure or temperature changes. Strong sources of electromagnetic interference (EMI), such as short wave (RF) diathermy and MRI, can negatively interact with the pump and cause heating of the implanted pump, system damage, or changes in pump operation or flow rate, that can result in patient injury from tissue heating, additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose. Avoid using shortwave (RF) diathermy within 30 cm of the pump or catheter. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. Drug infusion is suspended during MRI; for patients who can not safely tolerate suspension, use alternative drug delivery method during MRI. Patients receiving intrathecal baclofen therapy are at higher risk for adverse events, as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively. Confirm pump status before and after MRI. Reference product labeling for information on sources of EMI, effects on patient and system, and steps to reduce risks from EMI. **Precautions:** Monitor patients after device or catheter replacement for signs of underdose/overdose. Infuse preservative-free (intraspinal) saline or, for vascular applications, infuse heparinized solutions therapy at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator). **Adverse Events:** Include, but are not limited to, spinal/vascular procedure risks; infection; bleeding; tissue damage, damage to the system or loss of, or change in, therapy that may result in additional surgical procedures, a return of underlying symptoms, and/or a clinically significant or fatal drug underdose or overdose, due to end of device service life, failure of the catheter, pump or other system component, pump inversion, technical/programming errors, injection into the pocket or subcutaneous tissue or improper use, including use of non-indicated formulations and/or not using drugs or system in accordance with labeling; pocket seroma, hematoma, erosion, infection; post-lumbar puncture (spinal headache); CSF leak and rare central nervous system pressure-related problems; hygroma; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; potential serious adverse effects from catheter fragments in intrathecal space, including potential to compromise antibiotic effectiveness for CSF infection; anesthesia complications; body rejection phenomena; local and systemic drug toxicity and related side effects; potential serious adverse effects from catheter placement in intravascular applications.

Lioresal® is a registered trademark of Saol.

USA Rx Only Rev 0416

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CONSIDERING CHRONIC PAIN THERAPIES?

Get some first-hand information:

- Talk to someone living with a chronic pain therapy.
- Ask a nurse your questions.

WE'LL CONNECT YOU!

Medtronic
Further, Together

TALK WITH SOMEONE WHO UNDERSTANDS

Choosing the right treatment takes solid information and a chance to ask your own questions. We're here to help you make the right decision for you.

TALK WITH A PAIN AMBASSADOR

They're not medical experts or employees. They're pain patients who live with spinal cord stimulation or targeted drug delivery. They've volunteered to personally answer questions such as:

- **What was the procedure like?**
- **How did you know spinal cord stimulation or targeted drug delivery was the right option for you?**
- **How has your life been impacted?**

At Medtronic, we understand you may have questions that can only be answered by someone who has had a similar experience. We want to help you make that connection.

ASK A NURSE

You may also choose to speak with a registered nurse who is experienced in Medtronic chronic pain therapies. They've helped others through the process and can coach you on what to expect before, during, and after receiving spinal cord stimulation or targeted drug delivery. Unlike the Pain Ambassadors who are volunteers, our registered nurses are paid consultants of Medtronic.

While the nurse is available to provide general educational information about Medtronic devices and therapies, you should always talk to your doctor about your unique medical condition and therapy management.

IT'S EASY TO CONNECT

Calls with a Pain Ambassador or nurse typically last about 20 minutes and are free of charge.

To set up a phone call:

Sign up online

Talk with a Pain Ambassador
www.tamethepain.com/painambassador

Ask a Nurse
www.tamethepain.com/nurse

OR

Sign up by calling
888-430-PAIN (7246)

When you sign up to talk to an ambassador or nurse, we'll ask you a few questions. Then, we'll schedule a convenient time for you to have an ambassador or nurse call.