

LIVE LIFE WITH LESS PAIN

Medtronic Pain Therapies



Medtronic

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Medtronic
Further. Together

Living with pain can be overwhelming. If you're experiencing chronic pain and aren't satisfied with oral pain medication, patches, injections, or therapy, it's time to look into something different.

TAKE CONTROL

Effective chronic pain relief is possible. Our goal at Medtronic is to help you get pain relief so you can live a fuller life. We offer two proven, long-term pain therapies:

- Spinal Cord Stimulation
- Targeted Drug Delivery

These pain therapies treat people with conditions like:

- Persistent pain following back surgery
- Radicular pain syndrome (pain that radiates into the leg)
- Slipped disk pain that isn't relieved with conservative treatments like medication or physical therapy
- Degenerative disk disease (DDD)
- Complex regional pain syndrome (CRPS), also called reflex sympathetic dystrophy (RSD) or causalgia

If you're suffering from chronic pain, read on.



SPINAL CORD STIMULATION

LEARN MORE

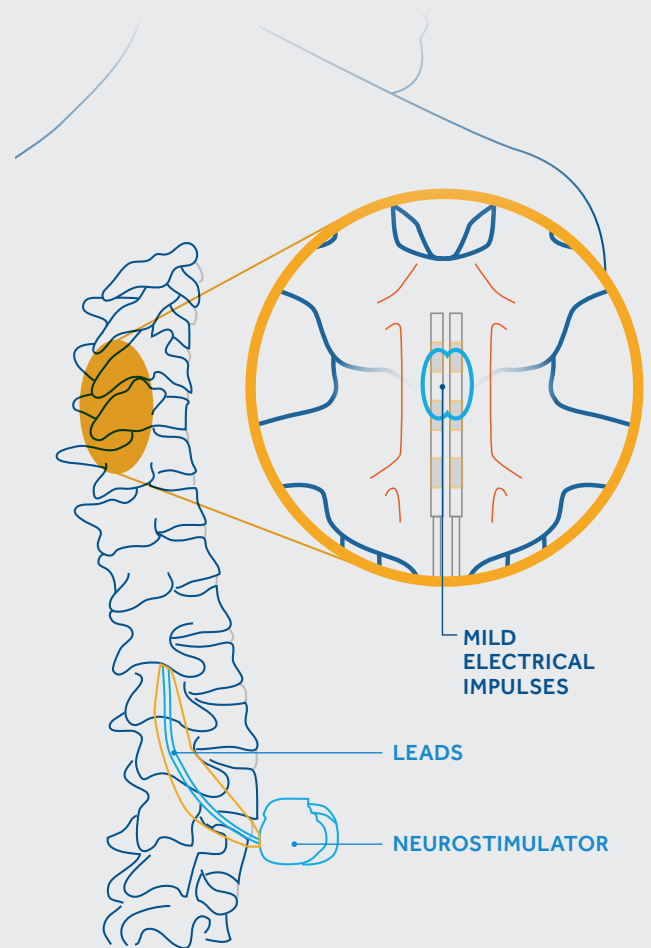
Spinal cord stimulation disrupts the pain signals traveling between the spinal cord and the brain, with the aim of giving you pain relief.

The stimulation is delivered by a neurostimulator, a device implanted under the skin that sends mild electrical impulses to an area near your spine.

A key benefit of spinal cord stimulation is that you can “test drive” the therapy first, to help you and your doctor decide if it’s right for you.

LEARN MORE ABOUT SPINAL CORD STIMULATION

tamethepain.com/relief



WATCH A VIDEO ABOUT HOW THE DEVICE WORKS

youtube.com/medtronicchronicpain

SPINAL CORD STIMULATION

EXPLORE THE BENEFITS

Spinal cord stimulation is a proven, long-term therapy for managing chronic pain.¹⁻³ People have experienced several benefits, including:

- Improved ability to participate in day-to-day activities¹
- Effective pain relief⁴
- More ability to function⁴
- Personalization — ability to manage your own pain therapy by adjusting your stimulation within pre-set limits

UNDERSTAND THE RISKS

Once the neurostimulation system is implanted, it's possible that device complications may occur. These include infection, pain at the implant site, jolting, lead breaking, and movement of the lead within the epidural space, which may require reprogramming, surgical replacement of the leads, or corrective surgery. These events may result in uncomfortable stimulation or loss of therapy.

Talk with your doctor to fully understand the risks and benefits of any therapy.



"The day I left the hospital with my temporary neurostimulator, my grandson was born. I rode 4 hours in the car to Abilene. I hadn't sat in a car that long for years! I couldn't believe it worked!"

— Marty

For a complete list of side effects that have been associated with the therapy, refer to the brief statements in the back of this brochure.

TARGETED DRUG DELIVERY

LEARN MORE

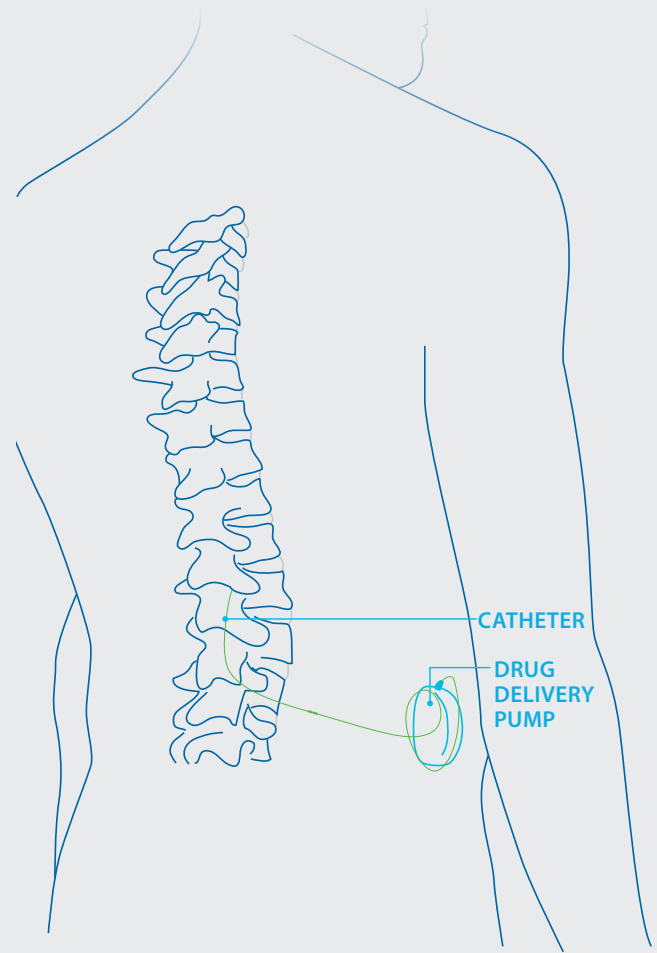
Targeted drug delivery is an alternate route of delivering pain medication at a fraction of a typical oral dose. It works *directly* at the source to stop nerves from sending pain messages. That means much less systemic opioid pain medicine and fewer side effects, like constipation and fatigue, compared to oral medication.⁵

An implantable pump is connected to a thin, flexible tube called a catheter. The pump delivers the pain medication directly into the fluid surrounding the spinal cord (called the intrathecal space).

Like Spinal Cord Stimulation, a key advantage of Targeted Drug Delivery is that you can try it first and experience how the therapy will work for you.

LEARN MORE ABOUT TARGETED DRUG DELIVERY

tamethepain.com/relief



WATCH A VIDEO ABOUT HOW THE DEVICE WORKS

youtube.com/medtronicchronicpain

TARGETED DRUG DELIVERY

EXPLORE THE BENEFITS

Targeted drug delivery is a proven, long-term therapy for managing chronic pain. People have experienced several benefits, including:

- More ability to function and participate in day-to-day activities⁶⁻⁸
- Less or no need for oral pain medication^{6,7,9,10}
- Fewer side effects compared to oral medication^{5,11}
- Effective pain relief^{5-7,9-13}
- Personalized — ability to manage your own pain therapy by delivering a dose of medication within your doctor's pre-set limits using myPTM™

UNDERSTAND THE RISKS

Some patients do experience problems. Surgical complications are possible and may include infection, spinal fluid leak, and headache.

- Do not have the implant surgery if you have an active infection at the time, or if your body size is too small to hold the drug pump.
- Once the device is implanted, device complications or adverse



"I can go out fishing with my son again."

— Jerry

drug events may occur, which could be life-threatening or require additional surgery to resolve.

- For more information, refer to the SynchroMed™ II Infusion System brief statement on the back of this brochure.

Talk with your doctor to fully understand the benefits and the risks of any therapy.

THE NEXT STEPS

Find the right doctor

- If your doctor is unable to offer you a Medtronic Pain Therapy, ask for a referral to a pain management specialist.
- Or visit tamethepain.com/relief and click on *Find a Specialist* to locate a pain specialist near you.

Talk with a pain management specialist

A pain management specialist is trained in the most advanced treatments for pain. Ask if you are a candidate for Medtronic Targeted Drug Delivery or Spinal Cord Stimulation. If you are, ask to try the therapy first to see if it's right for you.

Prepare for your visit

Access tamethepain.com/relief for resources and tips on talking with your doctor about your pain journey. The site includes:

- An interactive and downloadable *Doctor Discussion Guide*
- Conversation starters to use with your primary care doctor



"I have the energy to do the things that matter most to me — playing with the kids and going out with my husband."

—Nicole

- A downloadable pain journal to document the type, location, and severity of your pain
- Tips on making the most of your doctor visits

You can complete and print out your customized guide and bring it to your next appointment.

REFERENCES

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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 flouxidrine (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 overdose 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.**

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USA Rx Only Rev 0416

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