Medtronic
Alleviating Pain · Restoring Health · Extending Life

INTRATHECAL DRUG DELIVERY THERAPY FOR CHRONIC PAIN

Preparing For Your Screening Test

Nurturing seeds. Growing gardens. Prepare yourself for all the special moments to come by addressing chronic pain today.

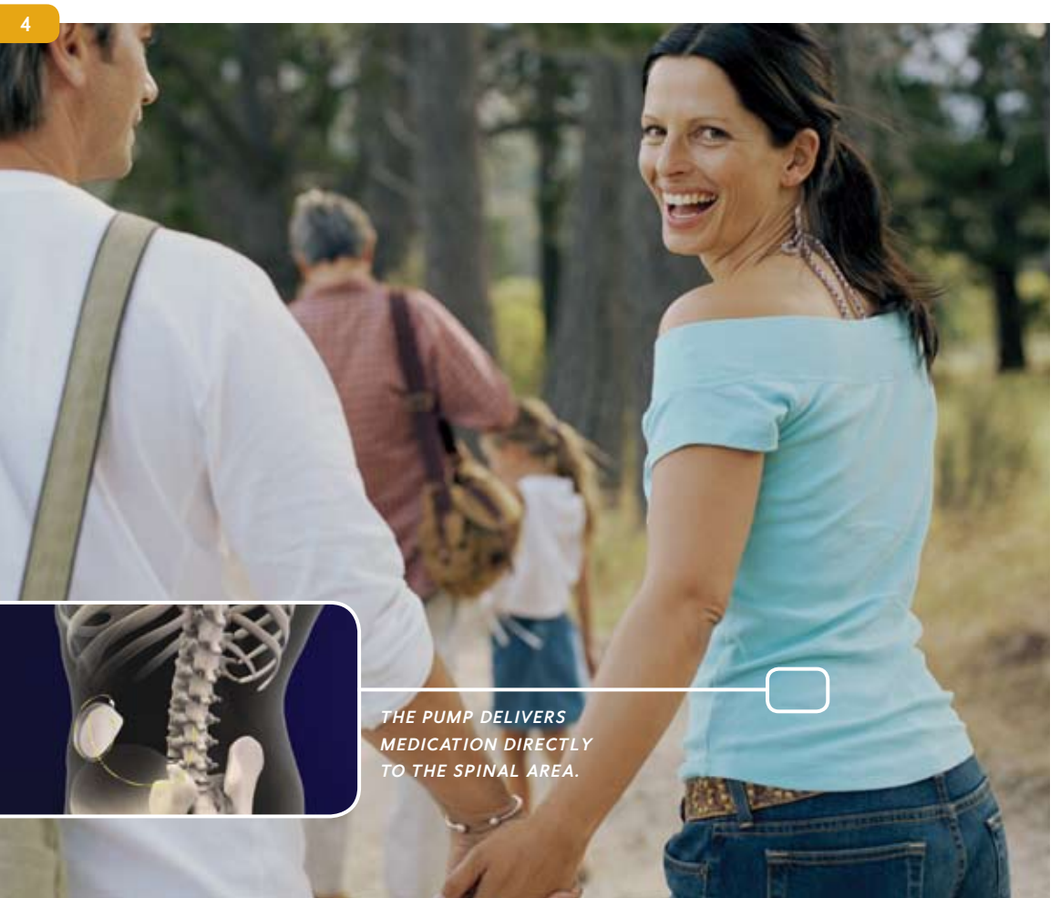
Your screening test will help you and your doctor objectively explore the option of intrathecal drug delivery therapy. During the test, your doctor will deliver medication, assess your response, and help you decide if intrathecal drug delivery therapy can aid in significantly reducing your chronic pain.

One test, one step closer to a vibrant future.
Medtronic Pain Therapies.
Relieving Pain. Restoring Life.

DELIVERING RELIEF

What is intrathecal drug delivery?

Intrathecal drug delivery is a pain management therapy that delivers medication directly to the intrathecal space (the fluid-filled area surrounding the spinal cord). After a successful screening test, a round pump (approximately 3" x 1") is surgically placed under the abdominal skin to deliver medication directly into the intrathecal space surrounding the spinal cord. Then the medication is delivered through a thin, flexible, surgically-placed tube called a catheter.



Benefits

The spinal cord is like a highway for pain signals traveling to the brain, where pain sensation is experienced by the body. Because the pain medication is delivered directly to the "site of action" (the area surrounding the spinal cord) instead of circulating throughout the body, intrathecal drug delivery offers significant pain control using a small fraction of the dose that oral medication requires. This drug delivery method has been shown to increase pain relief and comfort for people with severe pain. It may also cause fewer side effects than oral medications.[1-5] Clinical studies show that for people who did not experience enough pain relief with high doses of oral medication, most achieved significant pain control with intrathecal drug delivery and were able to improve their activities of daily living.[1,3]

Drug delivery system options

There are two types of fully implantable systems that treat chronic pain through continuous delivery of medication into the intrathecal space.

The SynchroMed® System consists of an implantable pump and catheter, and an external programmer used by physicians. Programmability allows for different doses of medication to be given throughout the day, and your doctor can make dose changes using the external programmer. Some patients may also have the option of a Personal Therapy Manager (PTM). The PTM allows you to deliver medication when you need it, within physician prescribed limits.

The IsoMed® System consists of an implantable pump and catheter. The system dispenses medication at a constant flow rate (meaning it gives one dose all the time at the same rate). The IsoMed pump is used for someone who does not need a variable-dosing pump.

PROGRESSING WITH CONFIDENCE

Why take a screening test?

A screening test is a way for your doctor to evaluate how well long-term drug delivery therapy may work for you. The test helps determine your response to medication delivered into your spinal region. During the screening test, your doctor will administer small doses of medication into the fluid surrounding your spinal cord and assess your level of functional improvement and pain relief. If your pain is measurably reduced, it means that long-term intrathecal drug delivery may work effectively for you.

A successful screening test generally results in meaningful pain reduction, a reduction in medication side effects and improvement in your function. However, success should be determined by you and your doctor. Your doctor will closely monitor your response to the medication given in the screening. He or she will work with you to determine if you are a candidate for long-term therapy with an implantable infusion system.

Setting your goal

Realistic goals are key to satisfaction with intrathecal drug delivery. Depending on your physical ability, you may be able to accomplish certain goals with the help of intrathecal drug delivery. It is important to understand that this therapy will not eliminate the primary source of your pain and will not cure any underlying disease. However, it may help you manage your pain and improve your ability to do daily activities.[6] Talk with your doctor about activities that may be easier for you with intrathecal drug delivery.

Things to do

- Inform your doctor of any allergic reactions to medications or materials before a screening is scheduled.
- Arrive at the hospital or surgery center on time for your screening.
- Ask questions about anything you do not understand.
- Wear loose, comfortable clothing if you will be going home with an external pump.
- After the procedure, notify your doctor immediately if you experience any swelling, redness, or pain near your incision or needle stick.

GATHERING KNOWLEDGE

What to expect

You will check into the hospital or surgery center either the night before or the day of the test. The morning of your screening test, your doctor will review the screening test procedure with you in detail. Be sure to talk to him or her about any questions or concerns you may have.

The Intrathecal Drug Delivery screening test is usually conducted using local anesthesia. Your doctor may use a local anesthetic to numb a small area of your back and follow with an injection or continuous infusion procedure. In both of these procedures, the medication is injected in the region surrounding the spinal cord. Some people have reported that the procedure stings a little.

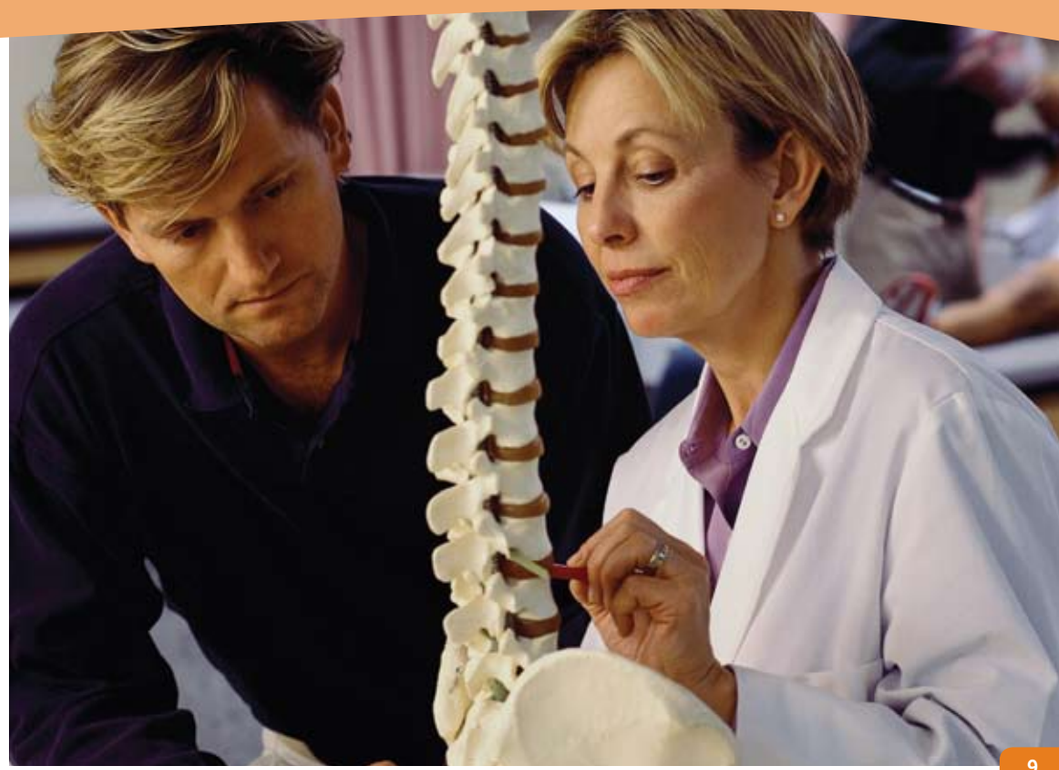
Your two test options

INJECTION

This procedure consists of a single injection or multiple injections of a small amount of medication into your spinal area. The injection is delivered with a needle and syringe. A medication injection will be followed by several hours of hospital monitoring. You will then be allowed to return home.

CONTINUOUS INFUSION

This screening test takes place over a few days and closely resembles the therapy delivered by the fully implantable infusion system. With this procedure, a continuous flow of medication is delivered to the spinal area through a temporary catheter (a soft, flexible tube). One end of the catheter is placed in your back and the other end is attached to an external pump. There are two types of external pumps that could be used, depending on the placement of the catheter. One is for epidural infusion, the other is for intrathecal infusion. Either pump makes it possible for you to resume normal activities of daily living (within your doctor's guidelines) during this test period that usually lasts up to four days.



During the screening test, and the monitoring to follow, your doctor will regularly observe your vital signs (pulse, respiration, blood pressure) as well as your response to the pain medication and the reduction of side effects. Be sure to tell your doctor about any pain. By measuring and comparing your pain before and during the screening, he or she will be able to evaluate the medication's effects.

Response to medication

In general, only a small amount of medication injected into the space around the spine is needed to affect most people. If you receive a single injection, the medication may take 30 minutes to one hour before the pain begins to decrease. You will probably begin to feel the medication's greatest effect about four hours after the injection, and the effect usually lasts six to eight hours more. After the effect of the medication wears off, you will return to the same pain level that you experienced before the trial.

People commonly respond differently to the medication they receive during the screening test. The medication may decrease your pain or reduce the need for your other pain medication. Be sure to inform your doctor if you are allergic to any medications before the screening test.

The screening test is done simply to see if the medication works for you. The screening is like a light switch that is either "on" or "off." It shows whether your pain can be turned "off" with intrathecal drug delivery. When you turn on a light switch, the room floods with light. The screening is sometimes like "flooding" the spinal fluid with medication. Just as a dimmer switch allows you to adjust the amount of light in a room, receiving the medication with a pump enables your doctor to adjust your medication dose to meet your pain management needs.

POSSIBLE SIDE EFFECTS

During the screening test, these temporary effects are possible:

- Sleepiness
- Nausea/vomiting
- Headache
- Dizziness

Be sure to tell your doctor if you experience any of these side effects. If you go on to receive long-term intrathecal drug delivery therapy, you and your doctor will work together to adjust the pump (like a dimmer switch) to manage your pain by delivering the dose of medication that's right for you. Remember that pain management with intrathecal drug delivery is a process. You and your doctor must work together to find the dose of medication that is most comfortable for you. This may take some time.

"I WOULD ENCOURAGE OTHERS TO LEARN EVERYTHING POSSIBLE ABOUT THEIR INJURY, DISEASE, OR ILLNESS. PAIN MAY BE UNAVOIDABLE, BUT SUFFERING CAN BE OPTIONAL. THE PUMP HAS WORKED GREAT FOR ME FOR EIGHT YEARS, AND I AM SO GRATEFUL."

-HELEN, BACK PAIN PATIENT

Common questions about screening tests

HOW LONG DOES THE SCREENING TEST TAKE?

If you receive a single injection for the test, you will be in the procedure room up to one hour and then monitored in another room for up to eight hours. If you receive a temporary catheter and pump, you will be in the procedure room for up to two hours and then monitored in another room for eight hours. You will then be allowed to return home or to your hospital room. Depending on your doctor's preference, you may spend the test period at home or in the hospital. Usually, the test period will last three to four days.

WILL IT HURT?

Before you are given the injection or the catheter is placed, your doctor may numb a small region of your lower back with a local anesthetic. Some people have reported that the procedure stings a little.

CAN I HAVE OTHER PAIN MEDICATION DURING THE SCREENING TEST?

This will depend on your doctor and your pain level. Your doctor may withdraw your oral medication one to two weeks prior to the test. During the screening, systemic medication (oral medication) may be given for breakthrough pain. Never stop taking your prescribed pain medication without first consulting your doctor.

SETTING YOUR COURSE

If your screening test is successful, you may be a candidate for an intrathecal drug delivery system.

After your screening test is complete, you and your doctor will discuss your results and the next steps of the intrathecal drug delivery process. If your pain goals are not met during the screening, you and your doctor may pursue other ways to help manage your pain. If your pain lessens or your function improves during the screening, you may go on to receive long-term intrathecal drug delivery therapy.

Starting intrathecal drug delivery

A round pump is placed just beneath your abdominal skin. A thin, flexible catheter is inserted into the intrathecal space (where spinal fluid flows around the spinal cord) and connected to the pump. Local or general anesthesia is used during this surgery, which usually takes one to three hours. Length of hospital stay will vary depending on your doctor's preference and hospital procedures.

"DAY-TO-DAY LIFE IS REALLY GOOD FOR ME NOW. I KNOW I AM IN CONTROL. THE PUMP LETS ME CONTROL MY PAIN. I HAVE BEEN ABLE TO DO WHAT I ENJOY AND CONTINUE WITH MY CAREER."

-HELEN, BACK PAIN PATIENT

Therapy maintenance

The pump periodically needs to be refilled with medication. To ensure that you receive the maximum benefit from intrathecal drug delivery therapy, it is very important that you schedule and keep all refill appointments. Your doctor may also adjust your dose of medication to ensure that you are receiving the dose that's best for you. Prior to travel, we recommend that your doctor make referral arrangements before your trip begins.

Common questions about intrathecal drug delivery

IF THE SCREENING TEST IS SUCCESSFUL FOR ME, WILL THE IMPLANTED PUMP GIVE ME THE SAME RELIEF?

After the screening test has been successful and you go on to receive the implanted pump, your pain relief may differ slightly. This is because the dose may be different than your screening test dose. The placement of the catheter also may be at a slightly different location than during the screening test. Your doctor may adjust the dose so that you obtain optimal relief. Be sure to talk with him or her about the way you feel. Your doctor wants you to be as comfortable as possible.

HOW LONG AFTER THE SCREENING TEST IS THE INTRATHECAL DRUG DELIVERY SYSTEM IMPLANTED?

If the screening test is successful, you and your doctor will discuss when the system should be implanted. Some doctors prefer to wait just a few days, while others prefer to wait longer.

IS THE PUMP A NEW DEVICE?

The pump has been tested and approved by the FDA, and it has been used successfully by more than 80,000 people worldwide.

continued on next page

WILL INTRATHECAL DRUG DELIVERY ELIMINATE OTHER SOURCES OF PAIN?

Your intrathecal drug delivery will not provide relief from other types of acute pain, such as headaches, stomach-aches, fractures, etc.

IF THE IMPLANTED PUMP DOESN'T WORK, CAN IT BE REMOVED?

The screening test is designed to determine whether or not the pump will help to manage your pain. If the screening test is not successful, you will not go on to receive the implanted infusion system. If you do receive a drug delivery system, it is removable if you no longer require it for pain relief or if you change your mind after it has been implanted.

It's important to talk with your doctor

As with any treatment, side effects can occur. Talk with your doctor about the possible side effects of intrathecal drug delivery (including underdose and overdose), as well as the benefits, risks and responsibilities involved. For example, because the pump and catheter are surgically placed, surgical complications such as infections, are possible. Other potential complications include fluid accumulation around the pump, spinal fluid leaks resulting in headaches or other problems, and damage to the spinal cord. The catheter could become dislodged or blocked, or, in rare cases, the pump could stop working. These complications could cause a reduction in or loss of pain relief and may require surgery to correct.

POTENTIAL ADVERSE EVENTS WITH THE PAIN MEDICATION INCLUDE:

- Itching
- Urinary retention
- Constipation
- Reduced urine flow
- Swelling in your legs
- Anxiety
- Depression of cough reflex
- Convulsions/seizures
- Psychosis
- Respiratory depression

References

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3. Paice JA, Penn RD, Shott S. Intraspinal Morphine for Chronic Pain: A Retrospective, Multicenter Study. J Pain Symptom Manage 1996; 11(2): 71-80.

4. Lamer TJ. Treatment of Cancer-Related Pain: When Orally Administered Medications Fail. Mayo Clin Proc 1994; 69:473-480.

5. Portenoy RK. Management of Common Opiod Side Effects During Long-Term Therapy of Cancer Pain. Ann Acad Med 1994; 23:160-170.

6. Kanoff R. Intraspinal Delivery of Opiates by an Implantable, Programmable Pump in Patients with Chronic, Intractable Pain of Nonmalignant Origin. JAOA 1996; 94: 487-493.

Important safety information

SYNCHROMED® II AND ISOMED® DRUG INFUSION SYSTEM

BRIEF SUMMARY: Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure.

INDICATIONS: US: 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 intrathecal infusion of preservative-free ziconotide sterile solution for the management of severe chronic pain, and chronic intravascular infusion of 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: When infection is present; when the pump cannot be implanted 2.5 cm or less from the surface of the skin; when body size is not sufficient to accept pump bulk and weight; when contraindications exist relating to the drug. Do not use the Personal Therapy Manager accessory to administer opioid to opioid-naïve patients or to administer ziconotide. Blood sampling through the catheter access port is contraindicated.

WARNINGS: Comply with all product instructions for initial preparation and filling, implantation, programming, refilling, and injecting into the catheter access port (CAP) of the pump. Failure to comply with all instructions can lead to technical errors or improper use of implanted infusion pumps and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant or fatal drug underdose or overdose. Refer to the appropriate drug labeling for specific underdose or overdose symptoms and methods of management. Avoid using short wave (RF) diathermy within 30 cm of the pump or catheter. Diathermy may produce significant temperature rises in the area of the pump and continue to heat the tissue in a localized area. If overheated, the pump may over infuse the drug, potentially causing a drug overdose. Effects of other types of diathermy (microwave, ultrasonic, etc.) on the pump are unknown. 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 opioid therapy carefully for any new neurological signs or symptoms. For intraspinal therapy, use only preservative-free sterile solution indicated for intraspinal use. Use only Medtronic components indicated for use with this system. Failure to firmly secure connections can allow drug or cerebrospinal fluid (CSF) leakage into tissue and result in tissue damage or inadequate therapy. A postoperative priming bolus should not be programmed if the pump is a replacement and the catheter has not been aspirated.

Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures. Physicians must be familiar with the drug stability information in the technical manual 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.

Inform patients of the signs and symptoms of drug underdose or overdose, appropriate drug warnings and precautions regarding drug interactions, potential side effects, and signs and symptoms that require medical attention. Instruct patients to notify their clinician of travel plans, to return for refills at prescribed times, avoid activities such as strenuous exercise or contact sports that jar, impact, twist, or stretch the body, to always carry their Medtronic device identification card, to avoid manipulating the pump through the skin, and to notify healthcare professionals of the implanted pump before medical tests/procedures. Patients must consult their physician before engaging in activities involving pressure or temperature changes (e.g., scuba diving, saunas, hot tubs, hyperbaric chambers, flights, skydiving, etc.) Inform patients that the SynchroMed pump has an Elective Replacement Indicator (ERI) that sounds when the pump is nearing its end of service. When the alarm sounds, patients must contact their doctor to schedule pump replacement.

PRECAUTIONS: The pump is ethylene oxide sterilized. Do not use if the product or package is damaged, the sterile seal is broken, or the "Use By" date has expired. Do not reuse or resterilize the pump; it is intended for "single use only." Do not expose the pump to temperatures above 43°C or below 5°C. Consider use of peri- and post-operative antibiotics for pump implantation, for any subsequent surgical procedure, or if infection is present. For patients prone to CSF leaks, clinicians should consider special procedures, such as a blood patch. Follow instructions for emptying and filling the pump during a replacement or revisions that require removal of the pump from the pocket. Explant the pump postmortem if incineration is planned (to avoid explosion), or if local environmental regulations mandate removal. Return explanted devices to Medtronic for analysis and safe disposal. Do not implant a pump dropped onto a hard surface or showing signs of damage. Implant the pump less than 2.5 cm from the surface of the skin. Ensure pump ports will be easy to access after implant, that the catheter is not kinked and secured well away from pump ports before suturing. Keep the implant site clean, dry, and protected from pressure or irritation. If therapy is discontinued for an extended period of time, fill the reservoir with preservative-free saline in intraspinal applications or appropriate heparinized solution (if not contraindicated) in vascular applications.

Electromagnetic interference (EMI) is an energy field generated by equipment found in the home, work, medical, or public environments. Most EMI normally encountered will not affect the operation of the pump. Exceptions include: injury resulting from heating of the pump which can damage surrounding tissue (diathermy, MRI), SynchroMed system damage which can require surgical replacement or result in loss/change in symptom control (defibrillation, electrocautery, high-output ultrasonics, radiation therapy), and operational changes to the SynchroMed pump causing the motor to stop, loss of therapy, return of underlying symptoms, and require confirmation of pump function (diathermy, high magnetic field devices, hyperbaric/hypobaric conditions, magnetic resonance imaging (MRI)). MRI will temporarily stop the SynchroMed pump motor's rotor due to the magnetic field of the MRI scanner and suspend drug infusion during MRI exposure which will cause the pump alarm to sound. The pump should resume normal operation upon termination of MRI exposure. Prior to MRI, the physician should determine if the patient can safely be deprived of drug delivery. If not, alternative delivery methods for the drug can be utilized during the MRI scan. Prior to scheduling an MRI scan and upon its completion, SynchroMed pump status should be confirmed. The magnetic field or telemetry signals produced by the SynchroMed programmer may cause sensing problems and inappropriate device responses with an implantable pacemaker and/or defibrillator.

ADVERSE EVENTS: Include, but are not limited to, cessation of therapy due to end of device service life or component failure, change in flow performance due to component failure, inability to program the SynchroMed device due to programmer failure, CAP component failure; inaccessible refill port due to inverted pump, pocket seroma, hematoma, erosion, infection, post-lumbar puncture (spinal headache), CSF leak, radiculitis, arachnoiditis, bleeding, spinal cord damage, meningitis (intrathecal applications), anesthesia complications, damage to the pump, catheter and catheter access system due to improper handling and filling before, during, or after implantation; change in catheter performance due to catheter kinking, disconnection, leakage, breakage, occlusion, dislodgement, migration, or catheter fibrosis; body rejection phenomena, surgical replacement of pump or catheter due to complications; local and systemic drug toxicity and related side effects, complications due to use of unapproved drugs and/or not using drugs in accordance with drug labeling, or inflammatory mass at the tip of the catheter in patients receiving intraspinal morphine or other opioid drugs. USA Rx Only

NOTES

< Use these questions as a guide when talking with your doctor.

Watch this video for more information on your screening test and intrathecal drug delivery from Medtronic.

Every 6 seconds—somewhere in the world—another person's life is improved by a Medtronic product.

At Medtronic, with over 30 years of collaboratively working with physicians and patients in neurostimulation and drug delivery technologies and more than 250,000 patients implanted—we set the standard for quality, safety and reliability in pain management technologies.

Advancing the field of pain management is a primary focus for Medtronic. Through clinical studies and extensive research efforts, we continue to explore new solutions. In turn, we provide the most knowledgeable education and support network in the industry. With the most comprehensive resources available, Medtronic's dedicated teams work closely with each physician and their staff.

For more information, please call Medtronic toll-free at 1-800-510-6735 or consult Medtronic's web site at www.medtronic.com.

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Alleviating Pain · Restoring Health · Extending Life