



Medtronic

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myPTM™

Drug Delivery Therapy

PERSONAL THERAPY MANAGER FOR CHRONIC PAIN



**MOVE
FORWARD**

Helping You Enjoy More of What Life Has to Offer

Congratulations on your decision to get a Medtronic drug pump. Drug delivery therapy can help you experience everyday life. We have developed this booklet to explain the myPTM™ Personal Therapy Manager, and how it can help you live with Medtronic drug delivery therapy.

As you rejoin your life, you may find that you experience increased pain when you do a particular activity or at certain times of the day. Or it may be unpredictable and have no pattern. This is a relatively common experience,¹ so Medtronic developed a way for you to respond when the symptoms first start.

The myPTM device allows you to get an extra dose of pain medication from your drug pump according to limits set by your physician. That way you may be able to do the things that are most important to you and enjoy more of what life has to offer.

What Is the myPTM Personal Therapy Manager?

The myPTM Personal Therapy Manager is a hand-held device that works with your SynchroMed® II drug pump allowing you to give yourself an extra dose of pain medication if you experience an increase in your pain. With the myPTM device, you can do something about your pain as soon as it occurs and take control of managing your symptoms.

The myPTM device has been designed with safety in mind and has features to protect you against delivering too much medication. Your physician will program the myPTM device so you stay within your dosing limits.

The myPTM device is easy to use and features one-button activation. It's also small (about the size of a cell phone), so it's convenient to carry and can be stored discreetly in a pocket or purse.

Benefits of the myPTM Device may include:

- **Ability to respond to your symptoms immediately.**
- **Safe and easy way to take a more active role in managing your pain.**
- **Reduced need for oral pain medication.²**

Note that amount of pain reduction varies from person to person and that your experience may vary.



myPTM™ Personal Therapy Manager
(Actual size)

Is the myPTM Device Right for Me?

The myPTM Personal Therapy Manager may be a good choice if:

- **You experience increased pain when you are involved in certain activities.**
- **You have increased pain at unpredictable times.**
- **You have intermittent pain that varies in intensity.**
- **You experience inadequate pain relief or intolerable side effects from oral pain medications.**
- **You are interested in taking a more active role in your pain management.**

Talk to your physician about whether the myPTM device is right for you.

“The Personal Therapy Manager gives me freedom to go out of the house, freedom to interact with family, because my pain is controlled. Furthermore, I no longer have to take a handful of pills every day.”

– Linda, drug delivery recipient

Frequently Asked Questions

How does the myPTM device communicate with my pump?

When you push a button to activate your myPTM device, it uses radio signals to tell your drug pump to deliver an extra dose of medication as prescribed by your physician.

How often will I need to replace the batteries?

In order to maintain the strongest communication link between the myPTM device and your drug pump, it is recommended that you change the batteries when the battery indicator displays one or two bars. The batteries may need to be replaced every couple of weeks.

How often will I need to use the myPTM Personal Therapy Manager?

Use will vary from patient to patient. It depends on a number of factors, including how often you experience increases in your pain; how well you can manage the increases without extra medication; and the prescription your physician has programmed into your device.

Is there a risk of overdose with this device?

Safety measures have been built into the device, including limits on the number of extra doses you can receive per day and how many hours you must wait between doses. However, an overdose is still possible. Be sure to talk with your physician about the symptoms of drug overdose. If you experience those symptoms, seek medical attention immediately.

When should I call my physician?

You should call your physician if you have difficulty breathing or have any of the following symptoms: dizziness, drowsiness, nervousness, seizures, or euphoria. Or if you experience anything unusual, such as new or unexplained symptoms; you notice that you begin to feel different or worse; your symptoms do not decrease with activation of a dose; you are not getting enough relief from your symptoms; or your symptoms change dramatically.

Medtronic Patient Resources

We understand how important it is for you to get the answers to your questions as you move forward with Medtronic drug delivery therapy. That's why we offer the following Medtronic patient resources:

Medtronic Patient Services

With over 35 years of experience working with therapies to help relieve pain, we are very knowledgeable and have staff who can speak directly with you about your myPTM device. Please call us with any questions or concerns. We can be reached at 1-800-510-6735.

Tame the Pain® Website

You can find a wealth of information about Medtronic drug delivery therapy by visiting our website at www.TameThePain.com.

We're here to support you every step of the way.

Our Goal Is to Help You Rejoin Your Life

At Medtronic, we're proud of our reputation as the worldwide leader in medical technology.

In fact, we have been working with physicians and patients around the world to develop pain therapies for longer than any other medical device company.

We were the first company to introduce a programmable implantable drug infusion system. With the most therapeutic options available, we can best meet your specific needs for pain relief.

Both physicians and patients count on Medtronic for the widest education and service network available. You will never be far from Medtronic support no matter where you are.

We never stop working on better therapies to help people lead fuller and healthier lives.

We would like to help improve yours.

REJOIN
your life.

SYNCHROMED® II 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 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:** 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; drugs with preservatives. Do not use the Personal Therapy Manager accessory to administer opioid to opioid-naïve patients or to administer ziconotide. **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 under- or overdose.** Refer to the appropriate drug labeling for specific under- or overdose symptoms and methods of management. Avoid using short-wave (SF) 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 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 under- 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 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. Explain 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. The magnetic field or telemetry signals produced by the programmer may cause sensing problems and inappropriate device responses with an implantable pacemaker and/or defibrillator. 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), 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 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 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, pump status should be confirmed. **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 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. **USA Rx Only** January 2008

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

References

1. Portenoy RK, Bennett DS, Rauck R, et al. Prevalence and characteristics of breakthrough pain in opioid-treated patients with chronic noncancer pain. *J Pain*. August 2006;7(8):583–591.
2. Ilias W, le Polain B, Demartini L; the oPTiMa study group. Patient-controlled analgesia in chronic pain patients: experience with a new device designed to be used with implanted programmable pumps. *Pain Pract*. 2008;8(3):164–170.

