Medtronic

Create better days

Targeted drug delivery for cancer-related pain

If you're living with cancer-related pain, you know how pain can interfere with your daily activities and your relationships.

And if you're taking oral medication for your pain, you may have experienced intolerable side effects like constipation, drowsiness, and clouded thinking.

You're not alone

Research shows that:

- A majority of adult patients with advanced cancer suffer from chronic pain[1]
- Cancer survivors may have chronic pain caused by past surgeries, chemotherapy, or radiation therapy[2]
- Poorly controlled cancer-related pain may interfere with your quality of life, function, and daily activities[3,4]

You don't have to live this way

It may be possible to have pain relief without intolerable side effects.

Medtronic Targeted Drug Delivery aims to[5,6,7]:

- Reduce your cancer-related pain
- Minimize undesirable side effects
- Improve your quality of life

This therapy is not for everyone. In addition to surgical risks such as infection and drug-related adverse events, pump or catheter problems can occur and may require corrective surgery. To understand the benefits and risks of this therapy, talk to your doctor. For additional safety information, refer to the Important Safety Information on the back of this brochure.

Contents

Better days with family

What is targeted drug delivery?

Millions are affected by pain and healthcare providers often prescribe systemic opioids (typically oral) as part of the treatment plan.[9]

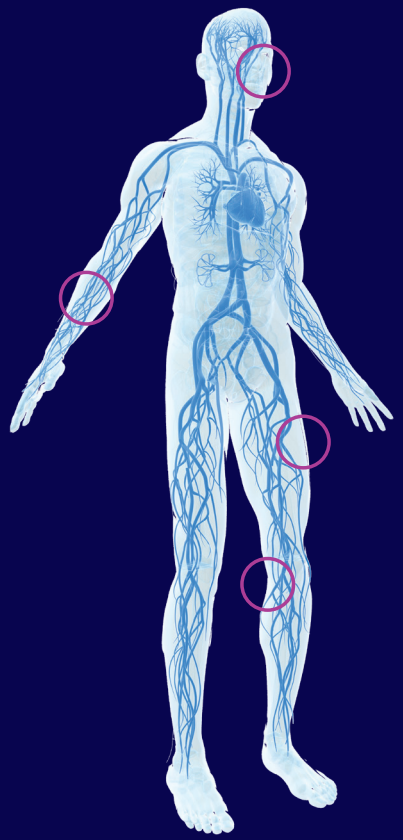
Despite limited evidence on the benefits of long-term systemic opioid therapy, systemic opioids are still routinely prescribed. Furthermore, there is evidence that long-term systemic opioid therapy is associated with increased risk for opioid misuse or addiction.[10]

Targeted drug delivery is an alternative to systemic opioid use for managing cancer-related pain.[6] With much less medication, this therapy may result in greater pain relief and fewer, or more tolerable, side effects.[6,8]

Targeted drug delivery has been demonstrated to be safe and effective for managing pain for patients with cancer.

Oral medication

- Circulates throughout the body to reach pain signals
- A higher dose of medication is required
- Higher drug levels circulate in your blood
- Non-invasive
- Requires you to watch the clock for the next dose
- Common side effects are nausea, constipation, and fatigue



Targeted drug delivery

- Requires minimally invasive surgery
- Delivers medication directly to the spinal cord to stop nerves from sending pain messages
- Lowers drug levels that circulate in your blood[8]
- Provides low dose of medication that is effective[6]
- Administers medication around the clock, as programmed by your clinician
- Reduces side effects like nausea, constipation, and fatigue[6]

The SynchroMed™ III implantable infusion system works to provide precise pain relief

SynchroMed™ III pump: A programmable infusion pump that accurately delivers medicine per the dosing instructions provided by your physician.

Catheter: A thin, flexible tube that connects to the pump and delivers medication.

myPTM™ Personal Therapy Manager: This handheld device prescribed by your physician at time of implant helps you manage unpredictable pain. The myPTM™ allows you to receive an extra dose of pain medication when needed and within physician set limits.

Better days walking

Benefits and risks

Explore the potential benefits with less pain and fewer side effects.

An important, high quality cancer pain study[6] followed two groups of patients, receiving either:

- Targeted drug delivery (TDD) plus conventional medical management (CMM), or
- CMM alone

Conventional medical management included oral medication, medication patches, and injectable drugs.

Among patients receiving TDD plus CMM:

85%
Achieved at least 20% pain relief ***or*** fewer side effects[6]

58%
Achieved at least 20% pain relief ***and*** fewer side effects[6]

Greater than
50%
pain relief[6]

Patients receiving TDD plus CMM also experienced less vomiting and confusion, fewer behavioral changes, and significantly less fatigue and sedation.[6]

Better days outside

Clinical studies show that targeted drug delivery for cancer-related pain effectively reduces or eliminates systemic opioid usage.

94%
reduction in systemic opioid[11]

83%
of patients **discontinued** systemic opioids[11]

Improved quality of life

After six months using targeted drug delivery to manage cancer-related pain, people reported significant improvements in pain and quality of life.[5]

Possible risks

- Surgical complications are possible and may include paralysis, 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 drug events may occur, which could be life threatening or require additional surgery to resolve

Better days with friends

Is this therapy right for you?

Medtronic targeted drug delivery is for people who have:

- Cancer-related pain that is not adequately controlled even though they are taking medication as directed, or
- Side effects from medication (such as feeling lethargic, vomiting, confusion, severe constipation, or changes in mood) that get in the way of their usual daily activities

Get help from a pain management specialist, if necessary

If your oncologist is unaware of targeted drug delivery from Medtronic, ask to see a pain management specialist. Your doctor can continue to treat your cancer while the pain management specialist treats your pain.

Pain management professionals may be oncologists, anesthesiologists, neurosurgeons, or other specialists. They typically receive specific training in relieving many types of pain with the most advanced treatments.

Talk with your doctor

No one knows your pain like you do. The first step to finding pain relief is talking to your doctor or nurse about how you're feeling.

Describe your pain – both where it is and how bad it is. Talk about your medication side effects too. Being specific about your symptoms will help clinicians better help you.

Tell your clinician about:

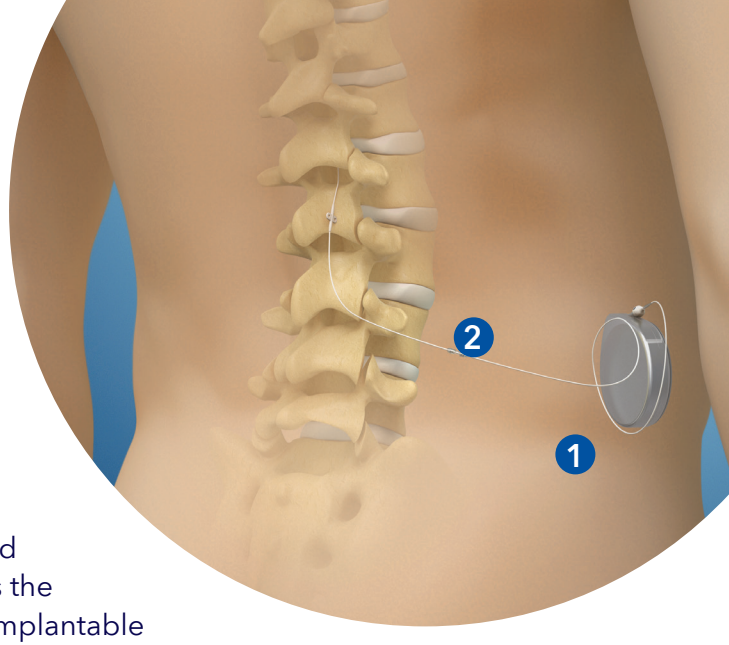
- Pain that isn't controlled even though you are taking medication as directed
- Side effects that get in the way of your usual daily activities

The implant procedure

If you and your doctor decide that targeted drug delivery is right for you, the system will be implanted with a surgical procedure.

Here are the general steps of the implant procedure. The steps and time will vary depending on your doctor.

1. Typically, the implant is performed under general anesthesia.
2. Your doctor makes an incision, about 6 inches long, in the abdomen.
3. He or she will form a pocket in the incision, large enough to hold the pump.
4. A smaller, second incision is made on the back. This incision is used to place one end of the catheter into the space surrounding the spine.
5. The other end of the catheter is placed under the skin and connected to the pump, resulting in a fully implanted system.
6. Once the pump and catheter are in place, the doctor closes the incisions and completes the surgery.
7. This is commonly an outpatient procedure and the length of your procedure and observation may vary.



Medtronic targeted drug delivery uses the SynchroMed™ III implantable infusion system, which includes:

1. **A programmable pump** – An implanted, battery-powered pump with a reservoir that stores and dispenses medicine.
2. **A catheter** – A thin, flexible tube that connects to the pump and delivers medication to the space surrounding the spine.

It's possible to have pain relief without intolerable side effects. Regardless of the state of your cancer, the right treatment for pain relief may improve daily life for you and your family.

Better days with hobbies

Ongoing care

Pump refills mean continuous pain relief therapy

- The pump needs to be refilled periodically with your medication
- During these appointments, your doctor may also adjust the dose so you receive the best pain relief possible

Be sure to make and keep your refill appointments! Missing a refill appointment could result in:

- Underdose (too little medication), which could lead to withdrawal symptoms
- Loss of pain relief therapy or a change in your therapy
- Pump damage, which could require pump replacement surgery

Be alert to your pump alarms

Your Medtronic SynchroMed™ III pump has two types of alarms – critical and noncritical. Below is a list of examples of alarms. Ask your doctor to sound the alarms so you can hear the difference.

Notify your doctor immediately if you hear a critical or a noncritical alarm.

Critical alarms: **Two tone alarm**	**A critical alarm sounds if:** • Pump runs out of medication • Battery power runs out (“end of service”) • Pump stops delivering medication • Pump has been stopped for more than 48 hours
Noncritical alarms: **Single tone alarm**	**A noncritical alarm sounds if:** • Pump medication is low and it’s time for a refill • Pump needs to be replaced (approximately 90 days before it reaches end of service)

***Important**: Don’t wait to hear an alarm before having your pump refilled! And note that it can be difficult to hear alarms in a loud environment.*

Product details

SynchroMed™ III programmable pump with catheter
(actual size)

Adjust Your Pain Therapy with myPTM™

If your doctor prescribes it, you may receive a handheld device to help control unpredictable pain. The myPTM™ Personal Therapy Manager works with your SynchroMed™ III drug pump. The myPTM™ device allows you to get an extra dose of pain medication when you need it, within limits set by your doctor. The myPTM™ device may help you better manage your own pain.

Your doctor will provide you with the Personal Therapy Manager Patient Manual.

myPTM™ not shown actual size.

Designed for MRI access with the most streamlined approach

It's important that your drug delivery system doesn't prevent your oncologist or other specialists from ordering an MRI when they think you need one.

Know that the Medtronic SynchroMed™ III system allows for safe access to MRI scans under certain conditions† on any part of your body.

Note that your doctor will need to make sure your pump has resumed its normal operation after an MRI procedure.

MR † Under specific conditions; refer to approved labeling for full list of conditions.

Better days relaxing

Bessie's Story

"I feel better than I have felt in years. It has given me a new lease on life. It has given me new hope. I am enjoying my children, my grandchildren – all of them!"

Every patient experience is unique. Not everyone who receives Medtronic Targeted Drug Delivery will experience the same results.

Targeted drug delivery — learn more

To learn more about how targeted drug delivery might help control your cancer-related pain and reduce side effects:

- Talk with your doctor
- Visit medtronic.com/cancerpain
- Call Medtronic Patient Services — (800) 510-6735 (Toll-free), Monday–Friday, 8 a.m. to 5 p.m. CT

Notes

1. _____

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2. _____

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3. _____

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4. _____

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5. _____

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References

1. Cleeland CS, Gonin R, Hatfield AK, et al. Pain and its treatment in out-patients with metastatic cancer. *N Engl J Med*. 1994;330:592-596.
2. Pachman DR, Barton DL, Swetz KM, et al. Troublesome symptoms in cancer survivors: fatigue, insomnia, neuropathy, and pain. *J Clin Oncol*. 2012;30:3687-3696.
3. Carr D, Goudas L, Lawrence D, et al. Management of cancer symptoms: pain, depression, and fatigue. Evidence report/technology assessment No. 61 (prepared by the New England Medical Center Evidence based Practice Center under contract No. 290-97-0019). AHRQ Publication No. 02-E032. Rockville, MD: Agency for Healthcare Research and Quality. July 2002.
4. Mystakidou K, Tsilika E, Parpa E, et al. Psychological distress of patients with advanced cancer: influence and contribution of pain severity and pain interference. *Cancer Nurs*. 2006;29(5):400-405.
5. Stearns LM, Abd-Elsayed A, Perruchoud C, et al. Intrathecal drug delivery systems for cancer pain: An analysis of a prospective, multicenter product surveillance registry. *Anesth Analg*. 2020;130(2):289-297.
6. Smith TJ, Staats PS, Deer T, et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. *J Clin Oncol*. 2002;20:4040-4049.
7. Perruchoud et al. Management of Cancer-Related Pain With Intrathecal Drug Delivery: A Systematic Review and Meta-Analysis of Clinical Studies. *Neuromodulation*. 2023;26(6):1142-1152.
8. Brogan SE, Sindt JE, Jackman CM, White J, Wilding V, Okifuji A. Prospective Association of Serum Opioid Levels and Clinical Outcomes in Patients With Cancer Pain Treated With Intrathecal Opioid Therapy. *Anesth Analg*. 2020 Apr;130(4):1035-1044.
9. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. (National Academies Press, 2011). doi:10.17226/13172.
10. Chou, R et al. The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain. Evidence report/technology assessment. 1 -219 (2014) doi:10.23970/ahrqepcerta218.
11. Sindt J.E., Odell D.W., Dalley A.P., Brogan S.E. 2020. Initiation of Intrathecal Drug Delivery Dramatically Reduces Systemic Opioid Use in Patients With AdvancedCancer. *Neuromodulation*. 2020; 23.

SynchroMed™ Drug Infusion System Brief Statement:
Review product technical manuals, including information about EMI, and the appropriate drug labeling prior to use for detailed disclosure.

Indications: U.S.: Chronic intrathecal infusion of Infumorph™* preservative-free morphine sulfate sterile solution in the treatment of chronic intractable pain, PRIALT™* 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. Outside of U.S.: Chronic infusion of drugs or fluids tested as compatible and listed in the product labeling.

Drug Information: Refer to appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration, screening procedures, and under-/overdose symptoms and methods of management. Patients should be informed of the signs and symptoms of drug under- or overdose, appropriate drug warnings and precautions, and signs and symptoms that require medical attention.

Contraindications: System implant is contraindicated in the presence of an infection; implant depth greater than 2.5 cm below skin; insufficient body size; and spinal anomalies. Use of the system with drugs with preservatives and drug formulations with pH ≤3. Use of CAP kit for refills or of refill kit for catheter access and use of PTM to administer opioid to opioid-naïve patients.

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. 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 carefully for any new neurological signs or symptoms, change in underlying symptoms, or need for rapid dose escalation. Monitor patients appropriately after refill if a pocket fill is suspected. Failure to recognize signs and symptoms of pocket fill and seek appropriate medical intervention can result in serious injury or death. Overinfusion may lead to underdose or overdose symptoms. Strong sources of electromagnetic interference (EMI) 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. The SynchroMed™ system is MR Conditional; consult the labeling for MRI information.

Precautions: Monitor patients after pump or catheter replacement for signs of underdose/overdose. Infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions.

Adverse Events: In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; pump migration; post-lumbar puncture risks (spinal headache); CSF leak and rare central nervous system pressure-related problems; radiculitis; arachnoiditis; spinal cord bleeding/damage; meningitis; neurological impairment (including paralysis) due to inflammatory mass; allergic response to implant materials; surgical replacement due to end of service life or component failure; loss of therapy, drug overdose, or inability to program the pump due to component failure; catheter complications resulting in tissue damage or loss of or change in therapy; potential serious adverse effects from catheter fragments in intrathecal space.

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

Infumorph™* is a registered trademark of Hikma Pharmaceuticals USA Inc. PRIALT™* is a registered trademark of TerSera Therapeutics LLC. Lioresal™* Intrathecal is a registered trademark of Amneal Pharmaceuticals.

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