



TARGETED DRUG
DELIVERY FOR
CHRONIC PAIN

OUT
OF PAIN
**INTO
RELIEF**

Medtronic

Further, Together

CONTENTS

OUT OF PAIN INTO SHOPPING

OVERVIEW	2
TRY THE THERAPY FIRST	4
HOW DOES TARGETED DRUG DELIVERY WORK?	10
ONGOING CARE	14
ANSWERS TO COMMON QUESTIONS	16

"Besides pain killers, I tried shots, nerve burnings, triggers, and multiple injections, but I was still in agony. I couldn't vacuum or walk. I just sat in a chair. Now, I can finally go shopping again and do the things I want to do."

Tami

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



OVERVIEW

OUR NUMBER ONE GOAL IS TO HELP YOU GET THE PAIN RELIEF YOU NEED.

Targeted drug delivery is an effective way to manage chronic pain, with fewer side effects and lower doses than oral medication.^{1,3}

An implantable pump is connected to a thin, flexible tube that releases the pain medication directly into the fluid surrounding the spinal cord, in an area called the intrathecal space. Because targeted drug delivery releases small amounts of medication, pain can be controlled with a fraction of the oral medication dose.³ Most people experience fewer or more tolerable side effects versus oral dosing.³ Targeted drug delivery may provide relief when other treatments — like oral medications or injections — have not.

A key advantage of targeted drug delivery is that you can try it first and experience how the therapy may work for you. You'll learn about this trial in the next few pages.

POTENTIAL BENEFITS OF TARGETED DRUG DELIVERY

- Improved ability to function and participate in day-to-day activities⁴
- Effective pain relief¹⁻²
- Less or no need for oral pain medication^{1,2,3,5}
- Fewer side effects compared to oral medication³
- Patient satisfaction⁴



- **Personalized** — the optional my PTM™ personal Therapy Manager allows you to activate delivery of physician-programmed supplemental doses of medication, this helps you manage unpredictable pain.
- **Surgically reversible**
If you don't want the pump anymore, the pump and the catheter can be explanted and you are going back to your initial state.

POSSIBLE RISKS AND CONTRAINDICATIONS

- Surgical complications are possible. Some of these complications may include infection, headache, spinal fluid leak, wound dehiscence, pump pocket hematoma or pain.⁷
- The infusion system should not be implanted if: you have an infection, meningitis, ventriculitis, skin infection, bacteremia, or septicemia. The pump cannot be implanted 2.5 cm (1 inch) or less from the surface of the skin. You do not have sufficient body size to accept the pump bulk and weight. You have spinal anomalies that complicate placement of the catheter for spinal applications.
- Once the device is implanted, device complications or adverse drug events may occur, which could be life threatening or require additional surgery to resolve.

For more information, please talk with your doctor to fully understand the benefits and the risks of any therapy.

TRY THE THERAPY FIRST

OUT OF PAIN INTO WALKING

Like test driving a car, the trial allows you to “test drive” targeted drug delivery before committing to long-term therapy.

The trial allows you to:

- Assess how targeted drug delivery may relieve your pain during daily activities
- Experience how it feels to receive pain medication targeted to the intrathecal space
- Decide if you want to go ahead with an implant

WHAT TO EXPECT

Targeted drug delivery doesn't cure the underlying disease, but it may help you better manage your chronic pain. Here's what to expect:

- Before the trial, you may have a psychological evaluation to help determine if you are a candidate.
- Your physician may ask you to reduce or stop taking oral pain medications before the trial.
- Your physician will recommend the trial method that makes the most sense for your situation and discuss the risks of the procedure with you.
- After the trial, you and your physician will discuss your experience and decide if an implantable targeted drug delivery system is right for you.

“Pain took my life away. The pump gave it back to me. I’m back to enjoying things I want to do. I’m getting out with my dogs and playing with them. Life is good again.”

Sherry

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



TRY THE THERAPY FIRST

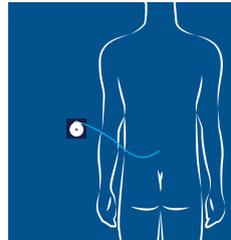
TRY THE THERAPY — TWO DIFFERENT METHODS.

Your doctor will choose the method that's right for you.



INJECTION METHOD

This method uses a special needle filled with pain medication. A single dose or multiple doses of a small amount of medication is injected into the intrathecal space.



CONTINUOUS INFUSION METHOD

This method takes place over a few days using a temporary system that closely resembles the therapy delivered by the implanted drug pump.

POTENTIAL RISKS DURING THE TRIAL

Complications can occur with the trial, including bleeding, infection, spinal headaches, damage to the spinal cord, and drug side effects.⁸



OUT OF PAIN INTO FAMILY TIME

"Since getting drug delivery therapy, I can attend family events and not have to leave shortly after arriving because of pain. I can have meaningful conversations with people and not be clouded by medication."

Hank

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



HOW DOES TARGETED DRUG DELIVERY WORK?

Targeted drug delivery is an effective way to manage chronic pain, with fewer side effects and lower doses than oral medication.^{1,3}

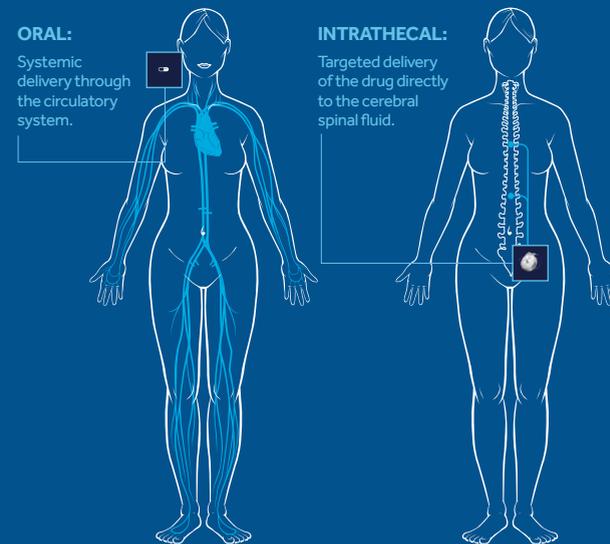
If you and your physician decide that targeted drug delivery is right for you, the system will be implanted during a surgical procedure. After surgery, the implanted pump will be filled with pain medication. The pump is connected to a thin, flexible tube called a catheter. The system continuously delivers the drug directly into the fluid surrounding the spinal cord, in an area called the intrathecal space.

The SynchroMed™ II pump may be prescribed with the optional myPTM™ Personal Therapy Manager as a way to help alleviate unpredictable pain and to help eliminate the need for oral opioids.⁶

You might be able to control your breakthrough pain 3 times faster with myPTM™ compared to conventional medication, which has been shown to increase therapy satisfaction.^{9,10}

After receiving targeted drug delivery, patients report a reduction in pain scores. 87% of patients rated their quality of life as fair to excellent.²

90% of patients would recommend the therapy to a family member or friend.²



TARGETED DRUG DELIVERY PRODUCTS WORK TOGETHER TO PROVIDE PRECISE PAIN RELIEF

SynchroMed™ II Pump

A programmable, battery driven pump that delivers medicine at a controlled rate per the dosing instructions provided by your physician.

Catheter

A thin, flexible tube that connects to your pump. The pump delivers medication through the catheter to the fluid surrounding the spinal cord, in an area called the intrathecal space where it can have a better effect.

myPTM™ Personal Therapy Manager

This optional handheld device may be prescribed by your physician at time of implant or in the follow up visits to help you manage unpredictable pain.



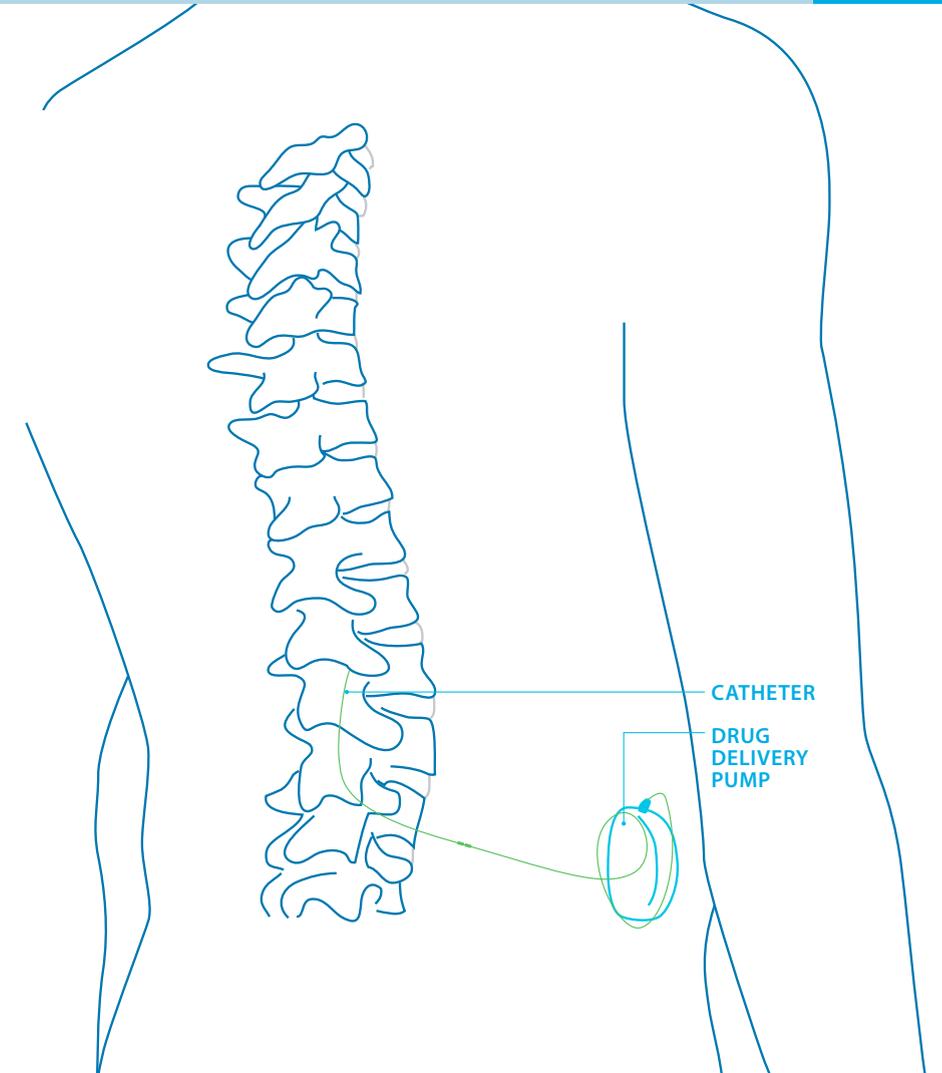
HOW DOES TARGETED DRUG DELIVERY WORK?

If the test is successful, and a decision was made to go ahead with IDD, the pump is implanted in an operation that may require a short hospital stay.

- Before the operation, the patient and his surgeon will decide the most comfortable and suitable place for the pump. Usually this position is below the belt-line to one side of the lower abdomen.
- On average, the surgery takes about 1 to 2 hours and is performed under anesthesia.
- The surgeon will place the pump just below the skin in the area defined above.
- A small skin incision in the back is needed to stabilize the catheter in its position. The catheter is then passed below the skin to the pump and securely connected to it.
- Once the pump and catheter are in place, the incisions are closed and the operation is concluded.

POST-SURGERY CARE

After the surgery, there will be some discomfort and tenderness where the pump and catheter have been implanted. Often antibiotics are prescribed to avoid infections. If any excessive redness, swelling or soreness is noted around any of the wounds the medical team must be notified. The patients should be advised to restrict their activities for a few weeks after surgery to allow the implanted pump system to "settle". Once the wounds have healed the pump site requires no special care.



ONGOING CARE

PUMP REFILLS MEAN CONTINUOUS PAIN THERAPY

You will need to return to your physician's office periodically for checkups and to have your pump refilled with medication. Refills are important for providing you with continuous pain therapy.

Missing a refill appointment could result in:

- Loss of, or change in, your therapy
- Underdose (too little of the drug) that could lead to a return of pain symptoms or, possibly, symptoms of withdrawal
- Damage to the pump that could require replacement surgery

DOSING ADJUSTMENTS

You will work with your physician to find the dose of medication that is most comfortable for you. Dosing can be customized to accommodate your needs at different times of the day, night, or week.

PERSONALIZE YOUR PAIN THERAPY

If your physician prescribes it at time of implant, you may receive a handheld device, called myPTM™, to help alleviate unpredictable pain. The myPTM™ Personal Therapy Manager works with your SynchroMed™ II pump and allows you to activate delivery of physician-programmed supplemental doses of medication when needed and within limits set by your physician.

OUT OF PAIN INTO LIFE

"The only thing I would do is watch the clock for when I could take that next pill. Now the clock is nothing. I'm outside, I'm busy, I'm constantly on the go. I'm with my neighbors, I'm doing things, I'm helping them move. I just bought my own home and moved in."

Elaine

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



ANSWERS TO COMMON QUESTIONS

Will targeted drug delivery completely eliminate my pain?

Many people experience improvement in pain symptoms and their quality of life after receiving targeted drug delivery. However, it's important to have realistic expectations. Remember that drug delivery therapy can't eliminate the source of your pain or cure underlying disease, but it may help you better manage your pain.

Will targeted drug delivery eliminate other sources of pain?

No. It won't relieve other types of pain such as headaches, stomach aches, fractures, etc.

Will my insurance company cover the costs?

Many insurance companies will pay for targeted drug delivery, like for many other pain treatments. Check with your doctor or insurance carrier for specific information about coverage.

How often does the pump need to be replaced?

About every four to seven years, depending on usage.

If my trial is successful, will the implanted system provide the same pain relief?

Your pain relief may differ slightly because the medication dose may be different than the dose used during the trial. During the recovery period, your doctor will slowly adjust the dose so you receive the best pain relief possible. Be sure to tell your doctor how you feel, so changes can be made to optimize your therapy. It may take some time to find just the right dose to manage your pain — this is called "titrating" the dose.

How often will the drug pump need to be refilled?

The frequency of your refill appointments will depend on the concentration and amount of medication you receive each day. Refills generally happen between 4 weeks to 6 month. Medication is injected into the pump with a needle inserted through the skin. Your doctor will fill the pump and make sure the entire system is working properly. Your doctor also can adjust your dosage during these appointments.

Will people see that I have a pump?

The pump is placed near the surface of your skin for refill access. Someone might notice a slight bump if you are wearing fitted clothes. However, depending on your size and shape, location of the pump, and the size of your pump, it may not show under your clothes at all.

Can I get an MRI or diagnostic tests with a pump?

The Medtronic SynchroMed™ II pump was designed to be safe under certain conditions for patients who may require an MRI scan.* The pump is also compatible with many other diagnostic tests.



* Under specific conditions. Talk to your doctor and refer to product labeling for full list of conditions.

REFERENCES

1. Hamza M, Doleys D, Wells M, et al. Prospective study of 3-year follow-up of low dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain Med.* 2012;13:1304-1313.
2. Deer T, Chapple I, Classen A, et al. Intrathecal drug delivery for treatment of chronic low back pain: report from the National Outcomes Registry for Low Back Pain. *Pain Med.* 2004;5:6-13.
3. 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.
4. Roberts LJ, Finch PM, Goucke CR, Price LM. Outcome of intrathecal opioids in chronic non-cancer pain. *Eur J Pain.* 2001;5:353-361.
5. Grider JS, Harned ME, Etscheidt MA. Patient selection and outcomes using a low-dose intrathecal opioid trialing method for chronic nonmalignant pain. *Pain Physician.* 2011;14:343-351.
6. Bolash RB, Niazi T, Kumari M, Azer G, Mekhail N. Efficacy of a targeted drug delivery on-demand bolus option for chronic pain. *Pain Pract.* 2018;18(3):305-313.
7. Product Performance Report "<http://professional.medtronic.com/ppr/intrathecal-drug-delivery-systems/index.htm> Accessed 18Feb2019"
8. Johnson KS, et Daniel JS. Lumbar puncture: Technique, indications, contraindications, and complications in adults. <https://www.uptodate.com/contents/search>. Accessed Feb. 18, 2019.
9. Ilias W, le Polain B, Buchser E, Demartini L. 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.
10. Brogan E, Winter NB, Okifuji A. Prospective Observational Study of Patient-Controlled Intrathecal Analgesia: Impact on Cancer-Associated Symptoms, Breakthrough Pain Control, and Patient Satisfaction. *Reg Anesth Pain Med.* 2015;40(4):369-75.

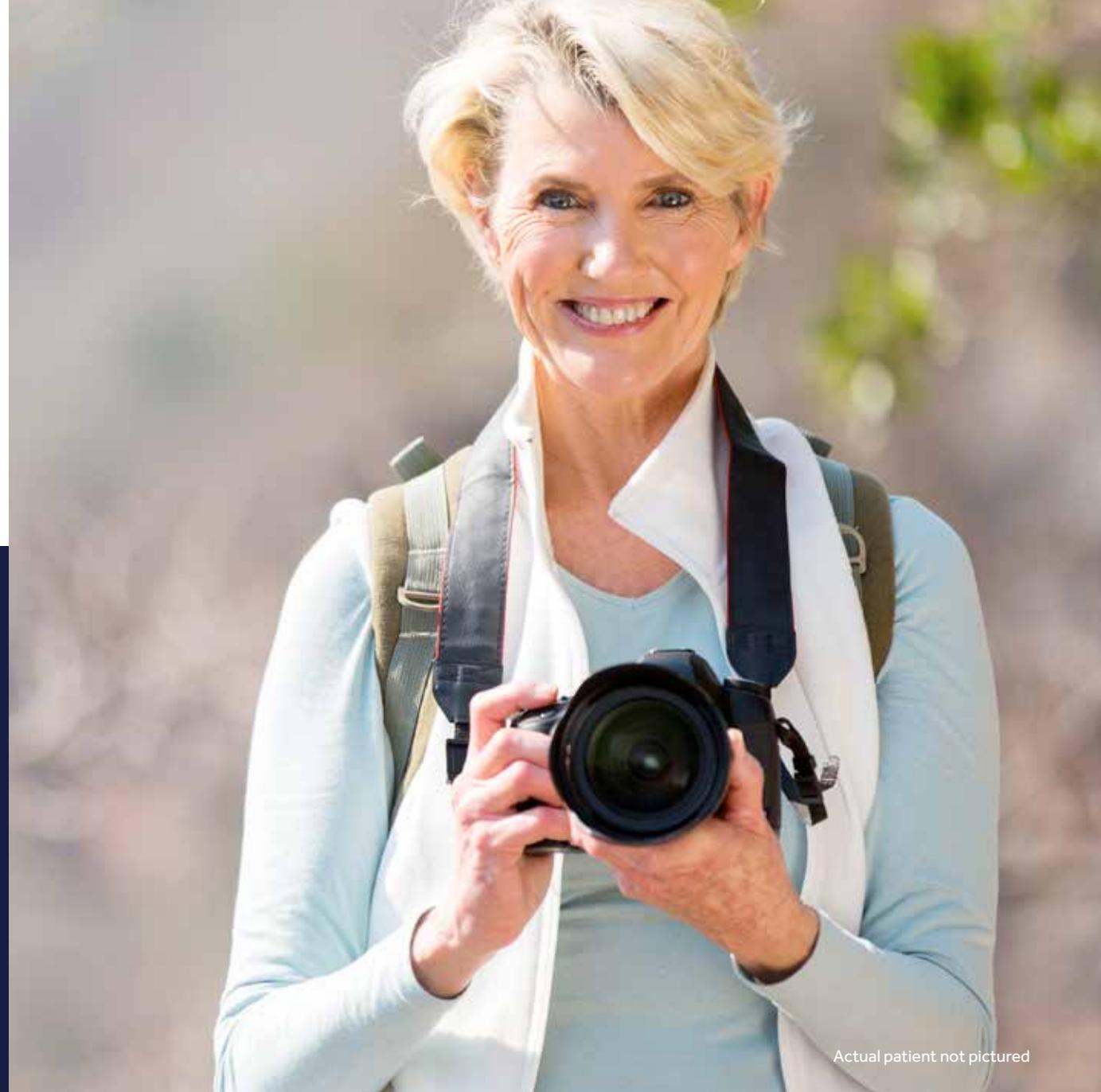
This therapy is not for everyone. In addition to surgical risks, such as infection and drug-related adverse events, pump or catheter problems can occur and may be life threatening, result in spinal cord injury, or require corrective surgery. To understand the benefits and risks of this therapy, please talk to your doctor. For additional safety information, please refer to the labeling provided with the device.



"It's been transforming with me in the activities that I'm able to do, in my relationships with people, and it gives me a sense of hope and completeness now. I thought that my life was going to be pain, pain, pain — but it's not anymore."

John

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



Actual patient not pictured

This information is designed to help you learn more about Targeted Drug Delivery for chronic pain. It is intended to provide you with helpful information but is for information purposes only, is not medical advice and should not be used as an alternative to speaking with your doctor. Be sure to discuss questions specific to your health and treatments with a healthcare professional.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. Information contained here does not replace the recommendations of your healthcare professional. For further information, contact your Health Care Professional.

Medtronic

Europe

Medtronic International
Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Tel. +41 (0)21 802 70 00
Fax +41 (0)21 802 79 00

medtronic.eu

United Kingdom/Ireland

Medtronic Limited
Building 9
Croxley Park
Hatters Lane
Watford Herts
WD18 8WW
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

UC201500977gEE - © Medtronic 2019.
All rights reserved. Printed in Europe.