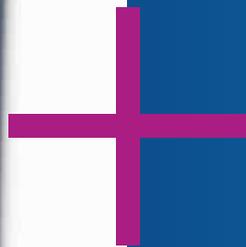


TAKE CONTROL OF YOUR PAIN

INTRATHECAL DRUG DELIVERY FOR MANAGING
CHRONIC CANCER REFRACTORY PAIN



SynchroMed™ II
Programmable Drug Infusion System

This brochure is intended for medical doctors willing to present SynchroMed™ II Therapy for refractory cancer pain as a treatment option to patients that have been identified as candidates.

Medtronic
Further, Together

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- 4 What is intrathecal drug delivery?
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YOU AND YOUR PAIN SPECIALIST HAVE DECIDED TO **GAIN CONTROL OVER YOUR CANCER PAIN** OR TO DECREASE THE SIDE EFFECTS FROM ORAL MEDICATION **WITH INTRATHECAL DRUG DELIVERY**¹⁻³

This patient guide will take you through the next steps of your treatment.

UNDERSTANDING THE TYPE OF CANCER PAIN

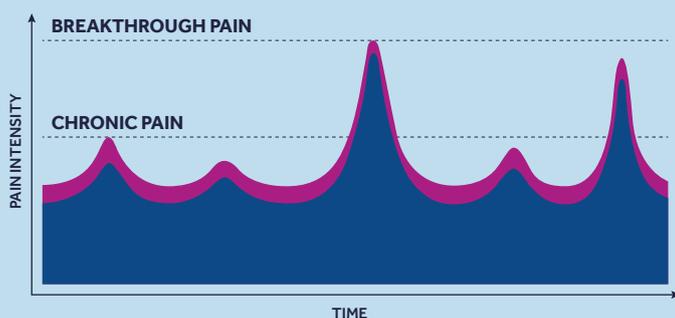
Chronic cancer pain is due to changes to the nerves. Nerve changes may be caused by cancer pressing on nerves, chemicals produced by a tumour or due to cancer treatment.

Chronic cancer pain continues long after the injury or treatment is over, and can range from mild to severe. Chronic cancer pain is also called persistent pain and can be experienced at all times.

The term refractory cancer pain is used when your pain cannot be controlled by medication anymore or you cannot take the medication due to the side effects.

In addition to persistent pain, you may be experiencing excruciating pain, otherwise known as breakthrough cancer pain because it 'breaks through' the control of your ongoing pain medicine.

Chronic cancer pain and breakthrough pain



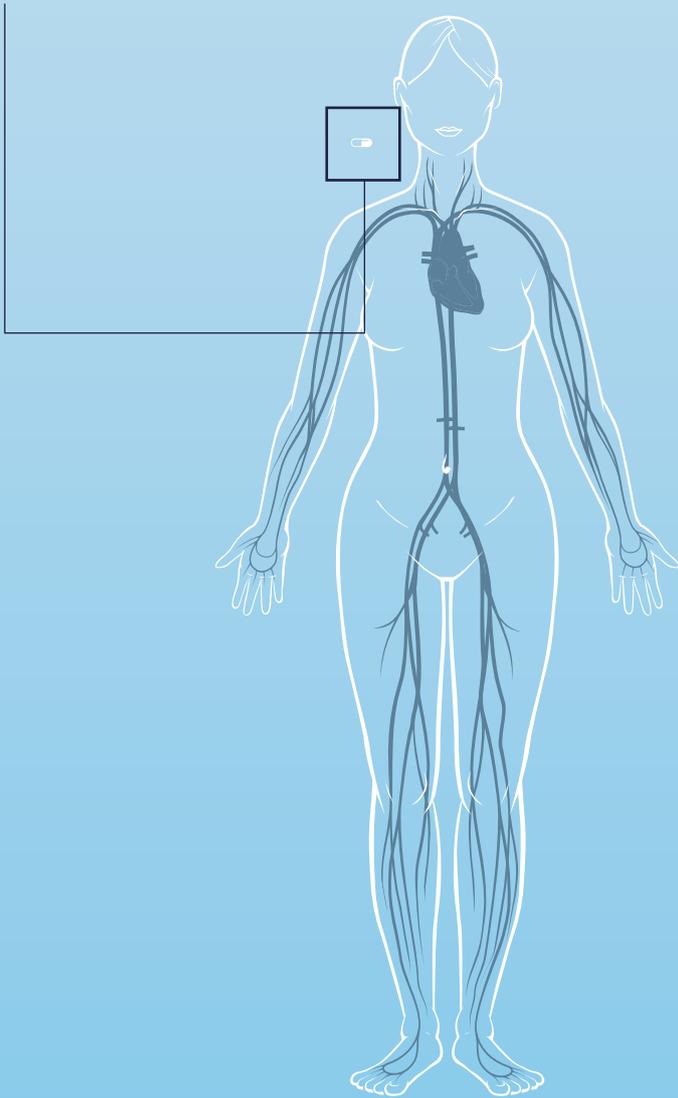
Breakthrough cancer pain⁴

- The onset is sudden and reaches a maximum intensity within 1 second to 30 minutes (median of about 3 minutes).
- Averages 4 to 6 episodes per day.
- The median duration of each episode is about 15 to 30 minutes.
- Episodes of breakthrough pain may or may not be associated with a precipitating factor and therefore may or may not be predictable. Precipitating factors can be identified in 55% to 80% of all episodes.

WHAT IS INTRATHECAL DRUG DELIVERY?

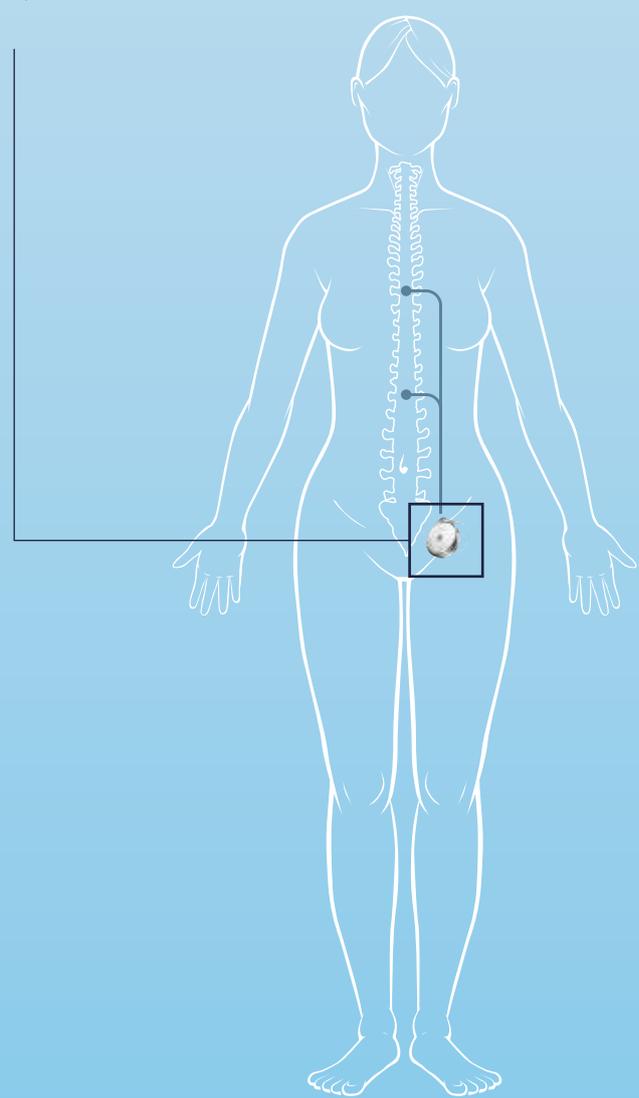
ORAL:

Systemic delivery through the circulatory system



INTRATHECAL:

Targeted delivery of the drug directly to the cerebral spinal fluid



Intrathecal drug delivery therapy has been developed to be effective directly where it needs to be without having the full dose of the drug circulating your blood stream.

INTRATHECAL DRUG DELIVERY THERAPY DELIVERS PAIN MEDICATION DIRECTLY TO THE FLUID AROUND THE SPINAL CORD, CALLED THE INTRATHECAL SPACE, VIA A PROGRAMMABLE DRUG INFUSION SYSTEM.

Your programmable drug infusion system will be continuously working in order to deliver very small amounts of medication to ensure round-the-clock control of your pain.

The pump is implanted, so you can move freely and return home with your loved ones after the procedure.

The pump will need to be refilled with medication on a regular basis. Your physician will also assess your pain level and adjust the medication you are receiving if needed.

In the event of breakthrough pain, you will be able to use an external remote control called myPTM™ to deliver an extra dose of medication to relieve your pain when you need it the most.



Delivers a liquid form of medicine directly to fluid around spinal cord.

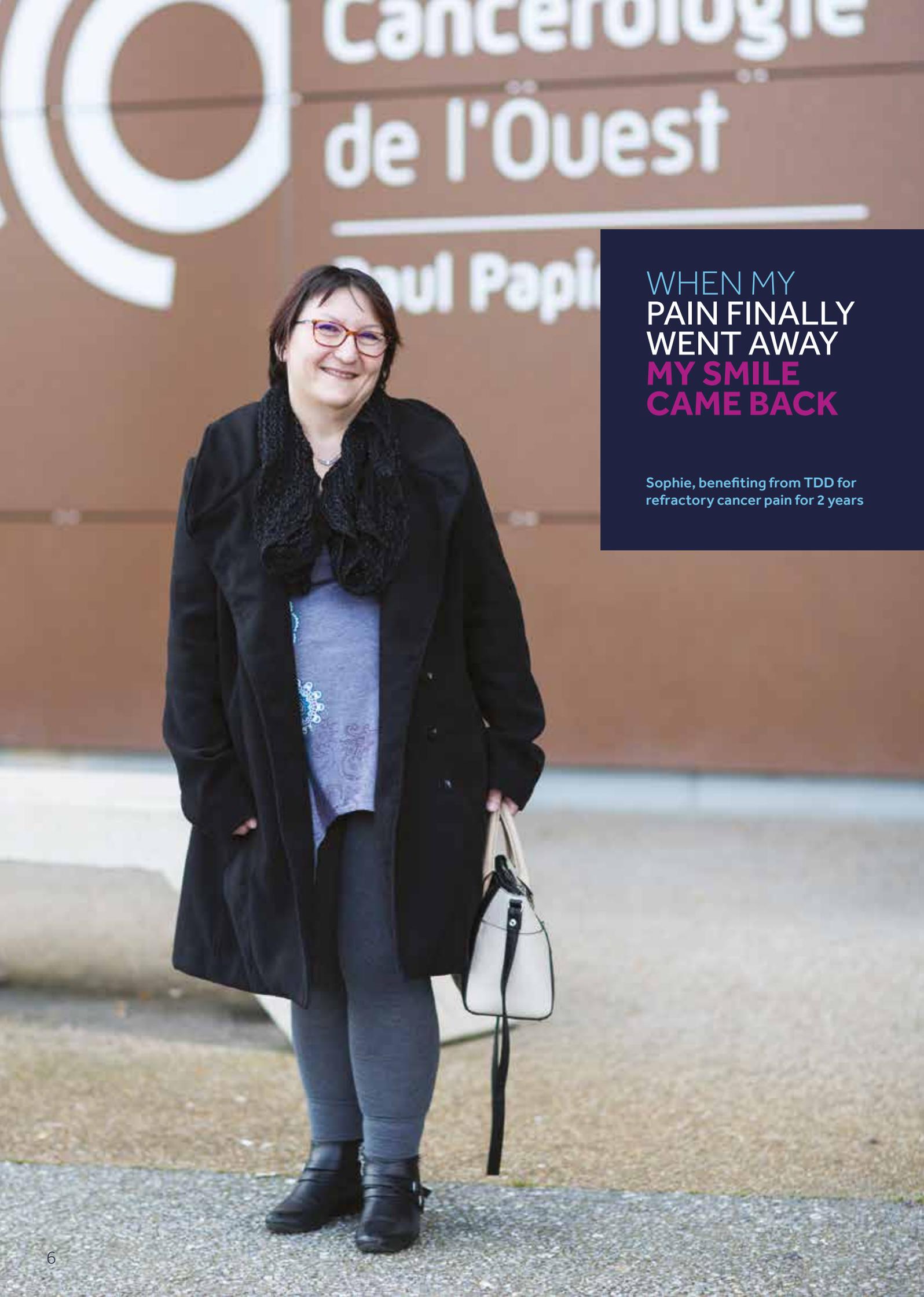


Requires 300x lower morphine equivalent dose than oral morphine to be effective.¹



Expected to produce fewer side effects as compared to oral administration of morphine.^{2,3}





WHEN MY
PAIN FINALLY
WENT AWAY
**MY SMILE
CAME BACK**

Sophie, benefiting from TDD for
refractory cancer pain for 2 years

THE SYNCHROMED™ II PROGRAMMABLE DRUG INFUSION SYSTEM

CONSISTING OF:



A battery-operated pump surgically placed under the skin of the abdomen.



A soft tube called a catheter surgically placed under the skin, that carries the medication from the pump to the intrathecal space of the spine.



A handheld patient programmer called myPTM™ that allows you to give yourself an extra dose of medication (within physician-set parameters) in response to intermittent pain.



It is important to note that the system can be surgically removed if you decide to discontinue the therapy.



myPTM™



SynchroMed™ II
Programmable Drug Infusion System

YOUR PROGRAMMABLE DRUG INFUSION SYSTEM **STEP BY STEP**

STEP 1: THE SCREENING TEST

If you have agreed with your physician to receive a programmable drug infusion system, it is more likely that you will first undergo a screening test phase.

A screening test helps assess whether the programmable drug infusion system might be right for you, and gives you a chance to try the medication before committing to implantation and long-term therapy.

If you achieve satisfactory pain relief or experience reduced side effects during the test period compared to oral medication, you may be a candidate.

There are two screening test methods: injection or continuous infusion. Your physician will decide which is most appropriate for you.



TRY THE THERAPY – TWO DIFFERENT METHODS

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

1. **Injection**
2. **Continuous infusion**



INJECTION METHOD

A single dose or multiple doses of a small amount of medication is injected into the intrathecal space. Here are the general steps of the procedure. They'll vary depending on your doctor:

1. A medication is given to help you relax.
2. You'll be placed on your stomach or side on a procedure table.
3. Your back will be cleaned with a solution.
4. Your heart rate and breathing will be monitored.
5. Pain medication will be injected into the intrathecal space around your spinal cord.
6. You'll be monitored in a fully equipped and staffed environment.



CONTINUOUS INFUSION METHOD

This method takes place over a few days and closely resembles the therapy delivered by the implanted drug pump.

Here are the general steps of the trial procedure. They'll vary depending on you doctor.

1. A medication is given to help you relax.
2. You'll be placed on your stomach or side on a procedure table.
3. Your back will be cleaned with a solution.
4. Your heart rate and breathing will be monitored.
5. A small incision will be made in your back.
6. A thin, flexible tube, called a catheter, is placed in the incision and attached to an external pain medication pump.
7. A continuous flow of medication will be delivered directly to the intrathecal space.
8. You'll be monitored in a fully equipped and staffed environment.
9. During the next few days, you'll be able to experience what targeted drug delivery feels like, either at home or in the hospital, depending on your doctor's preference.

YOUR PROGRAMMABLE DRUG INFUSION SYSTEM **STEP BY STEP**

STEP 2: THE IMPLANTATION PROCEDURE

If the screening test is successful, you and your doctor will choose a date for the procedure.

During the procedure:

- A SynchroMed™II Programmable Drug Infusion System is surgically placed just under the skin of your abdomen. The Programmable Drug Infusion System is securely tightened to avoid potential rotation of the infusion system.
- A thin, flexible catheter is inserted in the intrathecal space (the fluid around the spinal cord) and connected to the infusion system beneath the skin.



The procedure generally takes 1 to 3 hours.

The length of your hospital stay will be determined by your doctor and the hospital. It is more likely that you will stay in the hospital for a couple of days in order for your physician to adjust the medication dosage you need to reduce your pain.



STEP 3: TAKING CARE OF YOUR THERAPY

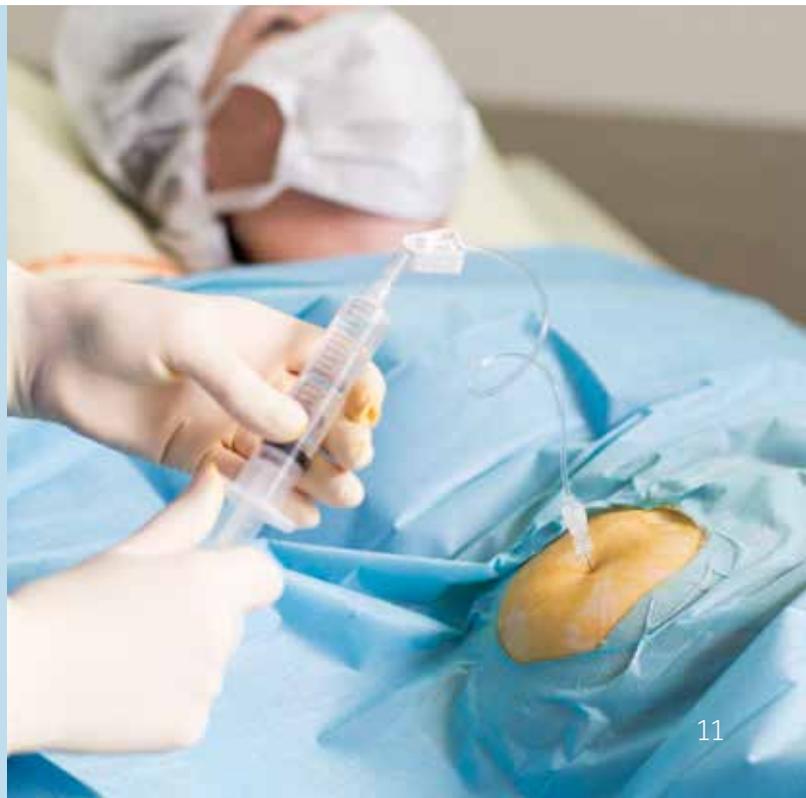
Programmable drug infusion system refill

The medication injected into your infusion system needs to be refilled every few weeks, depending on your needs.

It is important that you return to your clinic at the appropriate time so you can receive refills and your dosage can be adjusted, if necessary.

The infusion system is refilled by a needle injection through the skin in an outpatient setting (usually in your doctor's office) and takes less than 30 minutes.

**A MEDICATION
REFILL INTO YOUR
INFUSION SYSTEM**
PERFORMED BY
YOUR PHYSICIAN OR
QUALIFIED NURSE



YOUR PROGRAMMABLE DRUG INFUSION SYSTEM STEP BY STEP

STEP 3: TAKING CARE OF YOUR THERAPY

Programmable drug infusion system assessment

During these appointments, your doctor can adjust your medication dose to address your pain relief needs.

Your doctor may ask you to note the number of times you have used your remote control to get extra pain control so they can decide whether a change in dose is necessary.

Your physician will use the clinician programmer to adjust the quantity of medication you receive and the number of boluses you are allowed to trigger.



PROGRAMMABLE
DRUG INFUSION
SYSTEM
REPROGRAMMING
USING THE
CLINICIAN
PROGRAMMER

Using myPTM™ for breakthrough pain

Your myPTM™ remote control allows you to access an additional drug release shot to get through intermittent and unpredictable pain (e.g. breakthrough pain).

It is important to understand when situations of breakthrough pain are happening so you can use your remote control at the very beginning of the crisis and decrease its magnitude and duration.

Your doctor will be able to control the quantity of extra shot you are able to administer to yourself each day.

Note: Not all patients will benefit from myPTM™ use. Your physician will decide if myPTM™ may be beneficial for you.



EXAMPLE
OF myPTM™
USES FOR
BREAKTHROUGH
PAIN

myPTM™ OVERVIEW

COMMUNICATION LIGHT

- Blinks while the myPTM™ personal therapy manager searches for your pump.
- Maintains a steady light when the myPTM™ device communicates with your pump.

SELECTOR KEY

- Allows you to select screens and functions when the selector key icon  appears in the lower left corner.

NAVIGATOR KEY

- Allows you to select screens and settings by pressing the up , down , left  and right  arrows on the navigator key.



BOLUS KEY

- Sends a request for bolus dose to your pump.

SCREEN

- Displays information about your pump, myPTM™ device and therapy.

POWER/BACKLIGHT KEY

- Turns the myPTM™ device ON and OFF.
- Turns the screen backlight ON and OFF. Hold for about 2 seconds to illuminate the screen.

TO ACTIVATE A BOLUS DOSE

1. Press the BOLUS KEY .
2. If your doctor has programmed the patient diary, the patient diary screen appears.
3. You have the option to make a patient diary entry.
4. Press the SELECTOR KEY .
5. Place the myPTM™ device over your pump. While the myPTM™ device searches for your pump, the search screen appears, the COMMUNICATION LIGHT blinks, and a tone repeats.
6. When the myPTM™ device finds your pump, the pump communication screen appears, the COMMUNICATION LIGHT remains on, and the tone stops sounding.
7. Confirm the status of your activation request.



PATIENT TESTIMONY

SOPHIE RECEIVED AN INTRATHECAL DRUG DELIVERY SYSTEM TWO YEARS AGO

When did you discover your cancer?

Six years ago, I was diagnosed with a rare type of cancer called pseudomyxoma peritonei. It is an aggressive cancer that causes abdominal and pelvic pain.

I have been through several rounds of chemotherapy to control the disease's progression. My medical oncologist prescribed oral and patch morphine to control my pain.

In a sense I was lucky, as I didn't have many of the side effects that others have had with those medications, but two years ago, my pain couldn't be controlled with medication any more even though I had a high dose.

How was the intrathecal drug delivery programme brought to your attention?

My medical oncologist referred me to a pain specialist. The specialist proposed a programmable drug infusion system to reduce my pain.

What was your first impression?

I was impressed by the size of the pump and the fact that a catheter would be inserted directly into my spine. Thinking about it, I've already

been through several surgeries to remove part of my intestine and to implant a port catheter for the chemotherapy. So if I got through those interventions, I could certainly support the implantation of a drug infusion system to relieve the refractory pain I was suffering.

The medical team explained the whole implantation process step by step. After talking it through, I was reassured about the intervention and receiving a programmable drug infusion system.

Was your family involved in this choice?

I discussed it with my husband and kids, and decided that it was for the best. Anyway my quality of life was seriously impacted by the pain, so I had nothing to lose!

How were your first days after receiving the pump?

I had to stay in the hospital for a few days for the doctor to adjust my medication dosage. Unfortunately, I had some side effects due to leakage of fluids around the spine that caused headaches. It was temporary and disappeared after a couple of days.

How do you feel now with the pump?

It took me a few days to adjust to the pump and feeling comfortable with it. But what a change! I could barely enjoy being out of the house before the infusion system placement. Now the pain is very well controlled and I can walk again, drive my car and go to places I like with my family and friends – it's like living again. I can even go on holiday.

I have been trained to use my remote control to get additional bolus when needed. Now, I can better anticipate when pain is coming and use the remote control right away when I feel pain resurging. I don't take any additional painkillers – my infusion system has it under control.

Now the infusion system is a part of my life. Every month I have to go back to the hospital so it can be refilled. I've even taken my family with me so they can understand what I am going through.



**NOW, I ONLY
HAVE BENEFITS.
I HAVE GAINED
MY LIFE BACK.**



SynchroMed™ II
Programmable Drug Infusion System

USEFUL RESOURCES

KEEP TRACK OF YOUR BOLUSES

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total boluses
Week 1								
Week 2								
Week 3								
Week 4								
Week 5								
Week 6								
Week 7								
Week 8								
Week 9								
Week 10								
Week 11								
Week 12								
Week 13								
Week 14								
Week 15								
Week 16								
Week 17								
Week 18								
Week 19								
Week 20								
Week 21								
Week 22								
Week 23								
Week 24								
Week 25								
Week 26								

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total boluses
Week 27								
Week 28								
Week 29								
Week 30								
Week 31								
Week 32								
Week 33								
Week 34								
Week 35								
Week 36								
Week 37								
Week 38								
Week 39								
Week 40								
Week 41								
Week 42								
Week 43								
Week 44								
Week 45								
Week 46								
Week 47								
Week 48								
Week 49								
Week 50								
Week 51								
Week 52								

YOUR HEALTHCARE TEAM

	Name	Office phone number	Out of hours phone number
Refill nurse			
Palliative care			
Social worker			
Dietician			
Home care			
Spiritual care			
Physical therapy			
Occupational therapy			
Psychologist or psychiatrist			
Pain specialist			

APPENDICES

Disclaimer

This information is designed to help you learn more about Intrathecal Therapy. 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. For more information please speak to your healthcare professional.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Brief statement

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions and potential adverse events.

Credit

We would like to extend our gratitude to Sophie to share her story and life experience with the SynchroMed™II pump. Photography: RouleMarcel.

References

1. Bhatia G, Lau ME, Koury KM and Gulur P. Intrathecal Drug Delivery (ITDD) systems for cancer pain. F1000Research 2014, 2:96 (doi: 10.12688/f1000research.2-96.v4)
2. Smith TJ, Staats PS, Deer T, Stearns LJ, et al. Randomized clinical trial of an implantable drug delivery (IDDS) system compared with comprehensive medical management (CMM) for refractory cancer pain: impact on pain, drug-related toxicity, and survival. J Clin Oncol. 2002;20(19):4040-4049.
3. Smith TJ, Coyne PJ. Implantable drug delivery systems (IDDS) after failure of comprehensive medical management (CMM) can palliate symptoms in the most refractory cancer pain patients. J Pall Med. 2005;8(4):736-742.
4. S Mishra, S Bhatnagar, P Chaudhary, S Pratap Singh Rana. Breakthrough Cancer Pain: Review of Prevalence, Characteristics and Management. Indian J Palliat Care. 2009 Jan-Jun; 15(1): 14-18.

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