

Medtronic

SynchroMed® II System

INTRATHECAL DRUG DELIVERY FOR THE TREATMENT
OF SEVERE SPASTICITY AND CHRONIC PAIN.

- Programmable pump
- Compatible with MRI up to 3 Tesla
- Up to 7 years of battery life



Innovating for life.

The SynchroMed® II programmable pump is the world standard for the delivery of medication directly in the intrathecal space of the spinal cord.



Spasticity

ITB Therapy® treats patients suffering from non-focal, severe spasticity.

Improves the quality of life of patients

Quality of life improves in 88% of patients¹

Facilitates the achievement of therapeutic goals

94% of carer-set treatment goals are achieved or almost achieved²

Reduces pain associated with spasticity

Pain is significantly reduced in 89% of patients with spasticity³

The pump is approved for the infusion of baclofen.

Chronic Pain

Intrathecal drug delivery with Medtronic pumps has helped more than 100,000 patients obtain relief for their refractory chronic pain.*

Provides efficacious pain relief

Provides pain relief in patients refractory to more conventional therapies^{4,5}

Reduces the need for oral pain opioid medication

36% of patients required complementary oral opioid medication when treated with a pump and PTM, compared to 85% before⁶

The pump is approved for the infusion of morphine or ziconotide.

The advantages of programmability

FASTER DOSE ADJUSTMENTS:

the programmer is used for adjusting the rate without refilling the pump. Bridge bolus can be easily programmed.

SAVES TIME AND MEDICATION

THERAPY ADAPTED TO INDIVIDUAL DAILY ACTIVITIES:

flexible drug delivery can be programmed to deliver more drug in certain periods of the day.

ADAPTS TO DAILY LIFE

PATIENT ACTIVATED THERAPY:

Patients can use external programmer myPTM™ to request additional boluses of medication.

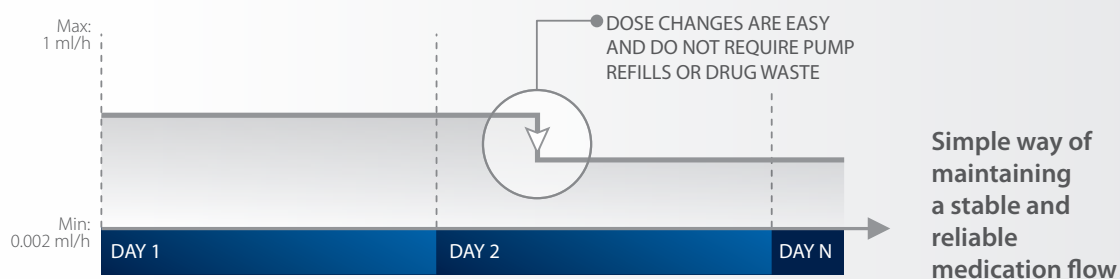
RELIEF WHEN NEEDED



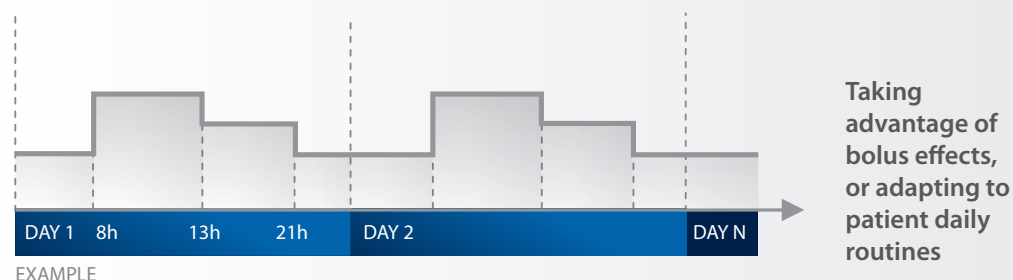
Programmability

What are the options and benefits?

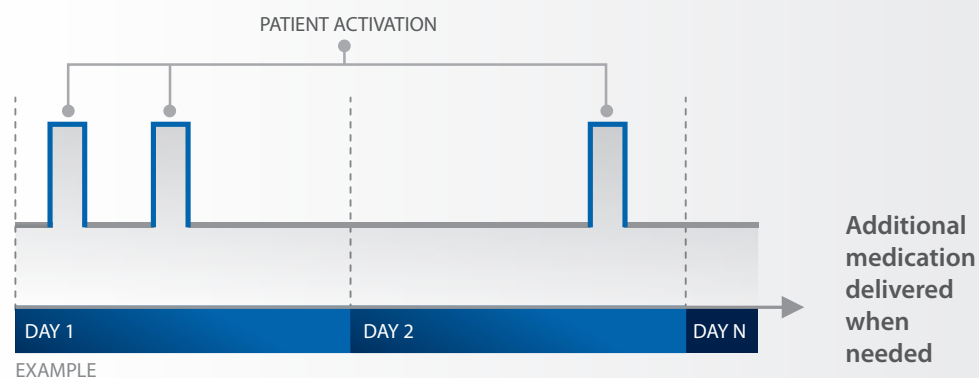
Continuous infusion



Flexdose



Patient-Activated boluses combined with continuous infusion



No other implantable pump provides these therapy options

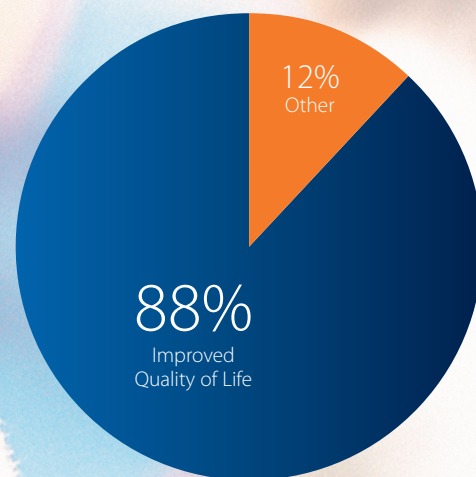
Patient satisfaction

Patients confirm the benefits of intrathecal drug infusion

SPASTICITY

Change in Quality of Life¹

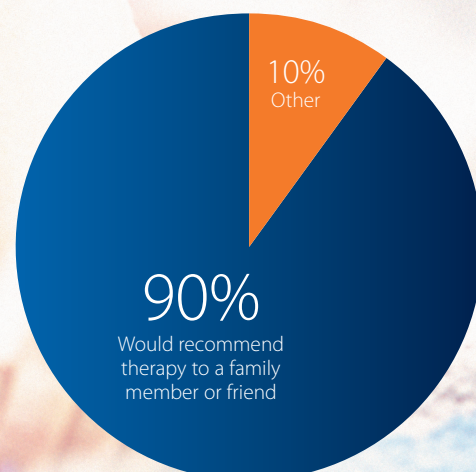
(n=67, spasticity patients)



CHRONIC PAIN

Patient Satisfaction at 12 month⁴

(n=72, chronic pain patients)



A comprehensive solution

Combining Medtronic technology with continuous service and support

SynchroMed II
Programmable
pump



From the implant...

SynchroMed® II Programmable pump

- 20ml reservoir
- 40ml reservoir

Ascenda™ intrathecal catheter:

- Unique four layer catheter construction for integrity such as compression resistance and tensile strength
- Simplified Implant Process

N'Vision
Clinician
Programmer



...to programming...

N'Vision® Clinician programmer:
One device for all the Medtronic
Neuromodulation programming
sessions

Medtronic provides a complete system that helps medical teams maximize the benefits of intrathecal drug delivery and supports medical teams with unparalleled technical and education support worldwide.

ON-SITE SUPPORT

- Pre-surgery system preparation
- Programming advice and support
- Troubleshooting

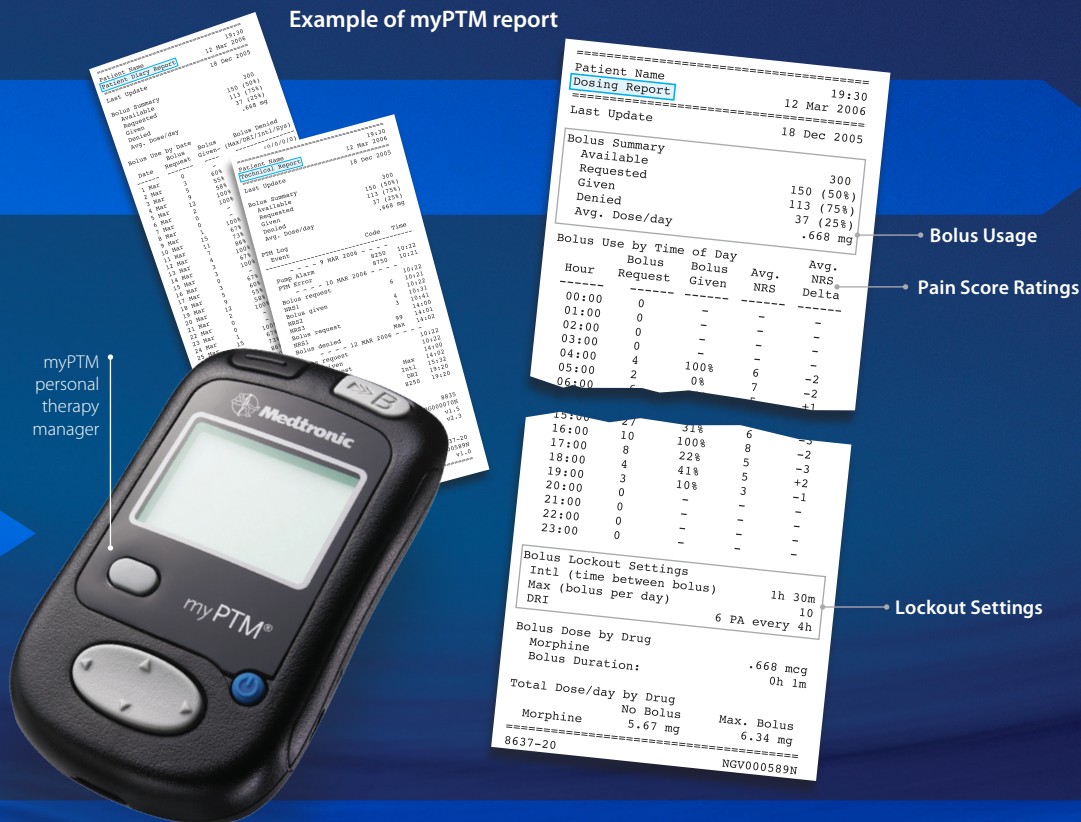
EDUCATION

- Staff training
- Medical Education

VIGILANCE AND EVENT REPORTING

CLINICAL EXPERTISE AND SUPPORT

Example of myPTM report



...to therapy maintenance

- myPTM™: personal therapy manager, giving patients the flexibility, maintaining physician control.
- SynchroMed® II refill kit: safely renewing the medication.

Technical Information

SynchroMed® II Pump Models

Model number	8637-20	8637-40
External properties		
Thickness	19.5 mm	26 mm
Weight (empty/full)	165/185 g	175/215 g
Displacement volume	91 ml	121 ml
Diameter *	87.5 mm	87.5 mm
Material	Titanium and silicone rubber	Titanium and silicone rubber
Drug reservoir		
Capacity	20.0 ml	40.0 ml
Residual volume	1.4 ml max	1.4 ml max
Fill volume at shipping	17.5 ml	37.5 ml
Pump internal fluid path volume	0.25 ml	0.25 ml
Silicone septum puncture life	500 punctures	500 punctures
Catheter access port (CAP)		
Prime volume	0.14 ml max	0.14 ml max
Silicone septum puncture life	500 punctures	500 punctures

* Largest diameter including the Catheter Access Port.

Ascenda™ Intrathecal catheter

Model number	8780	8781
Description	Ascenda™ Intrathecal Catheter with a 86cm spinal segment	Ascenda™ Intrathecal Catheter with a 66cm spinal segment
Length		
Total catheter	114.3 cm	139.7 cm
Spinal segment	86.4 cm	66.0 cm
Pump segment	27.9 cm	73.7 cm
Interval marker	1 cm interval	1 cm interval
Catheter tip	Closed with 6 side holes	Closed with 6 side holes
Trimable segments	Catheter connector end of the spinal segment	Catheter connector end of the spinal and pump segments
Connector pin	Sutureless	Sutureless
Pump segment to spinal segment separation force	> 10.0 N	> 10.0 N
Sutureless pump connector to pump separation force	> 10.0 N	> 10.0 N
Introducer needle	16 T-gauge	16 T-gauge
Needle length	11.4 cm	11.4 cm
Anchor with anchor dispenser	Yes	Yes

Patient and Clinician Programmers

Model number	8835	8840
Description	myPTM™ Personal Therapy Manager	N'Vision® - Clinician Programmer

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References

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2. Campbell WM, Ferrel A, McLaughlin JF, et al. Long-term safety and efficacy of continuous intrathecal baclofen. *Dev Med Child Neurol* 2002;44:660–5.
3. Sampson FC, Hayward A, Evans G, et al. Functional benefits and cost/benefit analysis of continuous intrathecal baclofen infusion for the management of severe spasticity. *J Neurosurg* 2002;96:1052–7.
4. 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.
5. Turner, Sears and Loeser, Programmable Intrathecal Opioid Delivery Systems for Chronic Noncancer Pain: A Systematic Review of Effectiveness and Complications, *Clin J Pain* 2007;23:180–195.
6. Ilias W, le Polain, Buchser E, et al. Intrathecal pain management with patient-controlled analgesia: 12-month study with the personal therapy manager. Presented at the 4th World Congress of the World Institute of Pain (WIP), Budapest, Hungary, September 25–28 2007.

*. Reference: Medtronic Data on file.

Please refer to the product technical manuals and the appropriate drug labeling for a listing of the indications, contraindications, warnings, precautions and adverse events.

تهران - خیابان ولیعصر - مقابل باشگاه خبرنگاران جوان - کوچه رامین - پلاک ۶، کدپستی ۱۹۶۶۸۴۳۳۵۹

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