

Medtronic

# Targeted drug delivery, evolved

Simple, safe, and effective intrathecal therapy for **severe spasticity** made possible by the SynchroMed™ III implantable infusion system



SynchroMed™ III  
implantable infusion system

# The next generation SynchroMed™ implantable infusion system

## Updated electronics

New chipset and firmware allow end-to-end cybersecurity controls and an upgradeable platform.

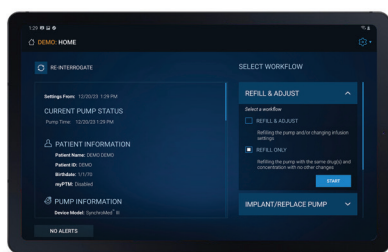


## Proven performance

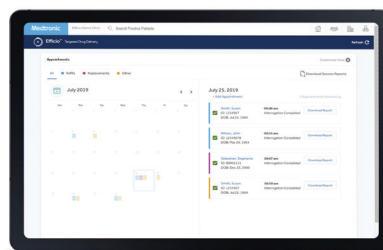
Reliability by design with proven durable design enhancements from the SynchroMed™ II infusion pump.

## Updated programming

Refill Only workflow enables a shorter and more consistent update duration.



The SynchroMed™ **clinician programmer** provides simple, guided “Refill & Adjust” and “Refill Only”† workflows for enhanced programming.‡



The Efficio™ **management software** is designed to simplify your pump practice by offering efficient schedule planning, simple drug tracking, historical dosing insights, and on-demand access to reports.‡

†The **Refill Only** workflow is compatible with only the SynchroMed™ III implantable infusion system.

‡The SynchroMed™ clinician programmer and the Efficio™ management software are compatible with both the SynchroMed™ III and SynchroMed™ II pumps.

# Redesigned for peace of mind

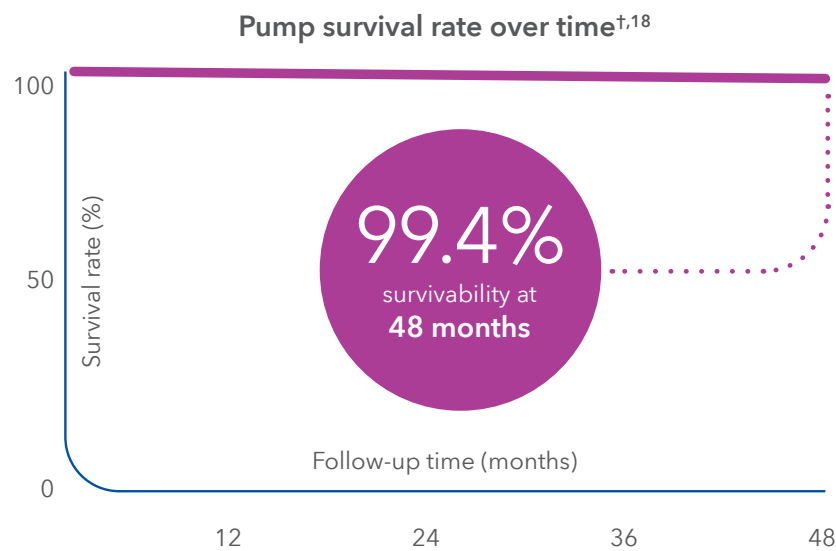
Equipped with durable design updates



Watch the videos to look inside the pump

# Enhanced for reliability

Let the data do the talking



See the product performance report for details

<sup>†</sup>This data represents pumps with four durable design changes (battery coating, gear wheel 3 material change, feedthrough encapsulation, diamond-like carbon coating). **The most recent design change was implemented in 2017. At 4 years, the survival probability (95% confidence intervals) was 97% pump survival rate pre-enhancements (n=3158 pumps); and 99.4% post-durable enhancements (n=203 pumps).**<sup>18</sup>

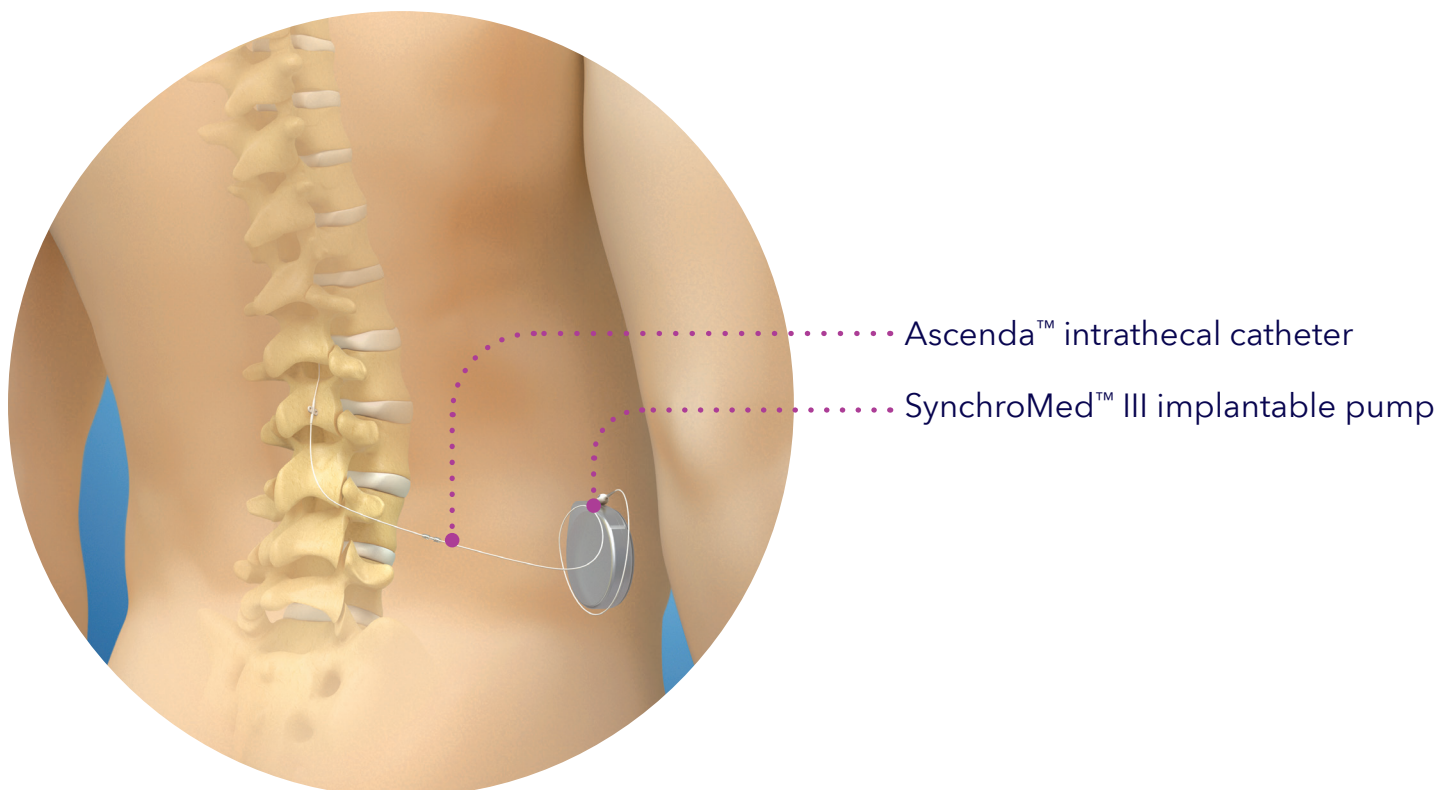
# Why targeted drug delivery?

## Greater efficacy, fewer side effects, and a high degree of clinician control

Severe spasticity can have a distressing effect on function, comfort, and caregiving. It may result in musculoskeletal complications, incoordination, loss of function, pain, and permanent muscle shortening or contracture. For patients with severe spasticity, enhancing their mobility, self-care abilities, and independence are significant achievements. To reach these milestones, effective therapy is necessary.

It can be difficult to effectively control severe spasticity. While physical rehabilitation, oral pharmacologic treatments, and injections work for many patients, some patients may not obtain sufficient relief with these treatments alone. In addition, some patients experience intolerable side effects from systemic medications.

**The SynchroMed™ III implantable infusion system delivers baclofen directly into the intrathecal space, thereby bypassing the blood-brain barrier. As a result, only a fraction of the oral dose is needed to produce efficacy while minimizing systemic side effects.<sup>5</sup>**



# How targeted drug delivery may benefit your patients

Targeted drug delivery for severe spasticity can significantly decrease severe spasticity<sup>1,2,4,6,12,13</sup> and spasms.<sup>1,13</sup>

- **Achieve relief** of severe spasticity symptoms with less baclofen<sup>1,2,3,4</sup>
- **Improve function and quality of life**<sup>4,8,9,10</sup>
- **Fewer side effects** compared to oral medications<sup>1,2,3,5,6</sup>
- **99.1% of severe spasticity patients** choose to replace the pump<sup>7</sup>
- **Reduce lifetime costs** when compared to conventional medical management (CMM)<sup>11</sup>

Allows  
**full-body  
1.5 and 3T  
MRI† scans**  
under specific  
conditions



†Under specific conditions. Refer to product labeling for full list of conditions.

## Benefits of the SynchroMed™ III implantable infusion system for severe spasticity

- **Control spasticity with flexible dosing patterns** – titrate the dose to provide graduated control of spasticity. Flexible dose schedules to customize the dose to match patient needs throughout the day, e.g., providing greater spasticity control at night than during the day.<sup>14</sup>
- **Effectively treat upper and lower extremity spasticity** – reduce upper and lower extremity spasticity.<sup>4,6,15</sup> Treatment may reduce spasticity and promote function among quadriplegic/tetraplegic as well as diplegic patients.<sup>2,16,17</sup>
- **Reversible treatment** – intrathecal baclofen therapy may be considered an alternative to destructive neurosurgical procedures.



Oral medication

Move toward control →



Intrathecal medication

## References

1. Meythaler JM, Guin-Renfroe S, Brunner RC, Hadley MN. Intrathecal baclofen for spastic hypertonia from stroke. *Stroke*. 2001;32(9):2099-2109
2. Gilmartin R, Bruce D, Storrs BB, et al. Intrathecal baclofen for management of spastic cerebral palsy: *Multicenter trial*. *J Child Neurol*. 2000;15:71-77.
3. Meythaler JM, DeVivo MJ, Hadley M. Prospective study on the use of bolus intrathecal baclofen for spastic hypertonia due to acquired brain injury. *Arch Phys Med Rehabil*. 1996;77(5): 461-466
4. Ivanhoe CB, Francisco GE, McGuire JR, Subramanian T, Grissom SP. Intrathecal baclofen management of poststroke spastic hypertonia: implications for function and quality of life. *Arch Phys Med Rehabil*. 2006;87(11):1509-1515
5. Penn RD, Savoy SM, Corcos D, et al. Intrathecal baclofen for severe spinal spasticity. *N Engl J Med*. 1989; 320: 1517-1521
6. Penn, RD. Intrathecal baclofen for spasticity of spinal origin: seven years of experience. *J Neurosurg*. 1992;77(2):236-40
7. Schiess et al, Intrathecal Baclofen for Severe Spasticity: Longitudinal Data From the Product Surveillance Registry. *Neuromodulation*. 2020; 23(7):996-1002
8. Dario A, Scamoni C, Bono G, et al. Functional improvement in patients with severe spinal spasticity treated with chronic intrathecal baclofen infusion. *Funct Neurol*. 2001;16:311-315
9. Azouvi P, Mane M, Thiebaut JB et al. Intrathecal baclofen administration for control of severe spinal spasticity: functional improvement and long-term follow-up. *Arch Phys Med Rehabil*. 1996;77(1):35-39.
10. Middel B, et al. Effect of intrathecal baclofen delivered by an implanted programmable pump on health related quality of life in patients with severe spasticity. *J Neurol Neurosurg Psychiatry*. 1997;63:204-209.
11. Venkatraman V, Spears CA, Futch BG, Yang LZ, Parente BA, Lee HJ, Lad SP. Assessment of Health Care Costs and Total Baclofen Use Associated With Targeted Drug Delivery for Spasticity. *Neuromodulation*. 2023 Aug;26(6):1247-1255.
12. Albright AL, Gilmartin R, Swift D, Krach LE, Ivanhoe CB, McLaughlin JF. Long-term intrathecal baclofen therapy for severe spasticity of cerebral origin. *J Neurosurg*. 2003;98(2):291-295.
13. Coffey RJ, Cahill D, Steers W. Intrathecal baclofen for intractable spasticity of spinal origin: results of a long-term multicenter study. *J Neurosurg*. 1993;78(6):226-232.
14. Natale M, Mirone G, Rotondo M, Moraci A. Intrathecal baclofen therapy for severe spasticity: Analysis on a series of 112 consecutive patients and future prospectives. *Clin Neurol Neurosurg*. 2012;114:321-325.)
15. Becker R, Alberti O, Bauer BL. Continuous intrathecal baclofen infusion in severe spasticity after traumatic or hypoxic brain injury. *J Neurol*. 1997; 224(3): 160-166
16. Hoving MA, van Raak EP, Spincemaille GH, Palmans LJ, Becher JG, Vles JS. Efficacy of intrathecal baclofen therapy in children with intractable spastic cerebral palsy: a randomised controlled trial. *Eur J Paediatr Neurol*. May 2009;13(3):240-246.
17. Shilt JS, Reeves S, Lai LP, et al. The outcome of intrathecal baclofen treatment on spastic diplegia: Preliminary results with a minimum of two year follow up. *J Ped Rehabil Med*. 2008;255-61.
18. 2022 TDD Product Performance Report; <https://www.medtronic.com/content/dam/medtronic-wide/public/united-states/products/neurological/product-performance-report-targeted-drug-delivery.pdf>

### 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](http://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. USA Rx Only Rev 0823

# Medtronic

710 Medtronic Parkway  
Minneapolis, MN 55432-5604  
USA  
Tel: 763-514-4000

[medtronic.com](http://medtronic.com)

©2024 Medtronic. All rights reserved. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic.™ Third-party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. UC202407863a EN