

Medtronic

Targeted drug delivery, evolved

Simple, safe, and effective intrathecal therapy for **chronic pain and cancer pain** 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

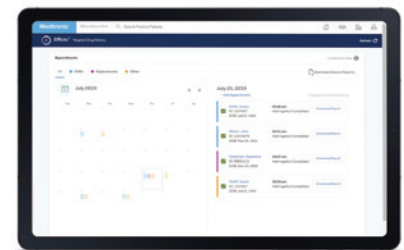
Refill Only workflow enables a shorter and more consistent update duration.



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



The myPTM™ **personal therapy manager** helps patients alleviate unpredictable chronic pain.‡



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, the myPTM™ personal therapy manager, and the Efficio™ management software are compatible with both the SynchroMed™ III and SynchroMed™ II pumps.

Redesigned for peace of mind

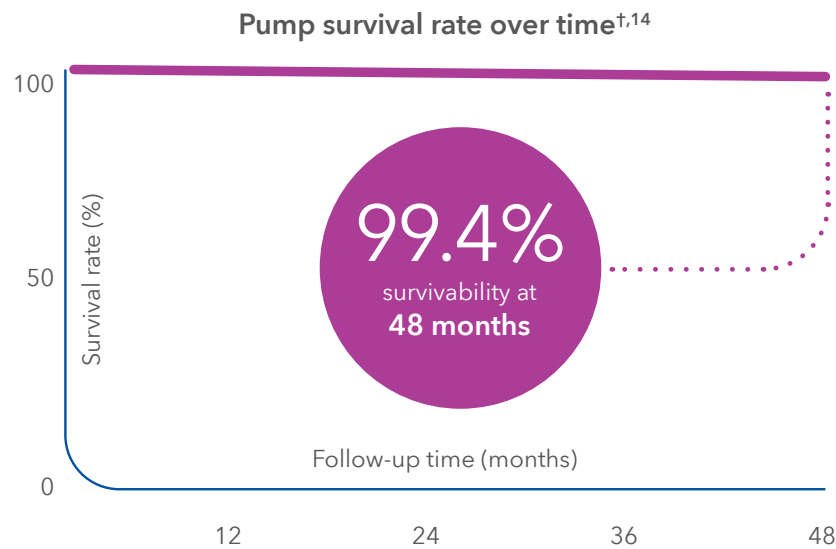
Equipped with durable design updates



Watch the videos to look inside the pump

Enhanced for reliability

Let the data do the talking



See the product performance report for details

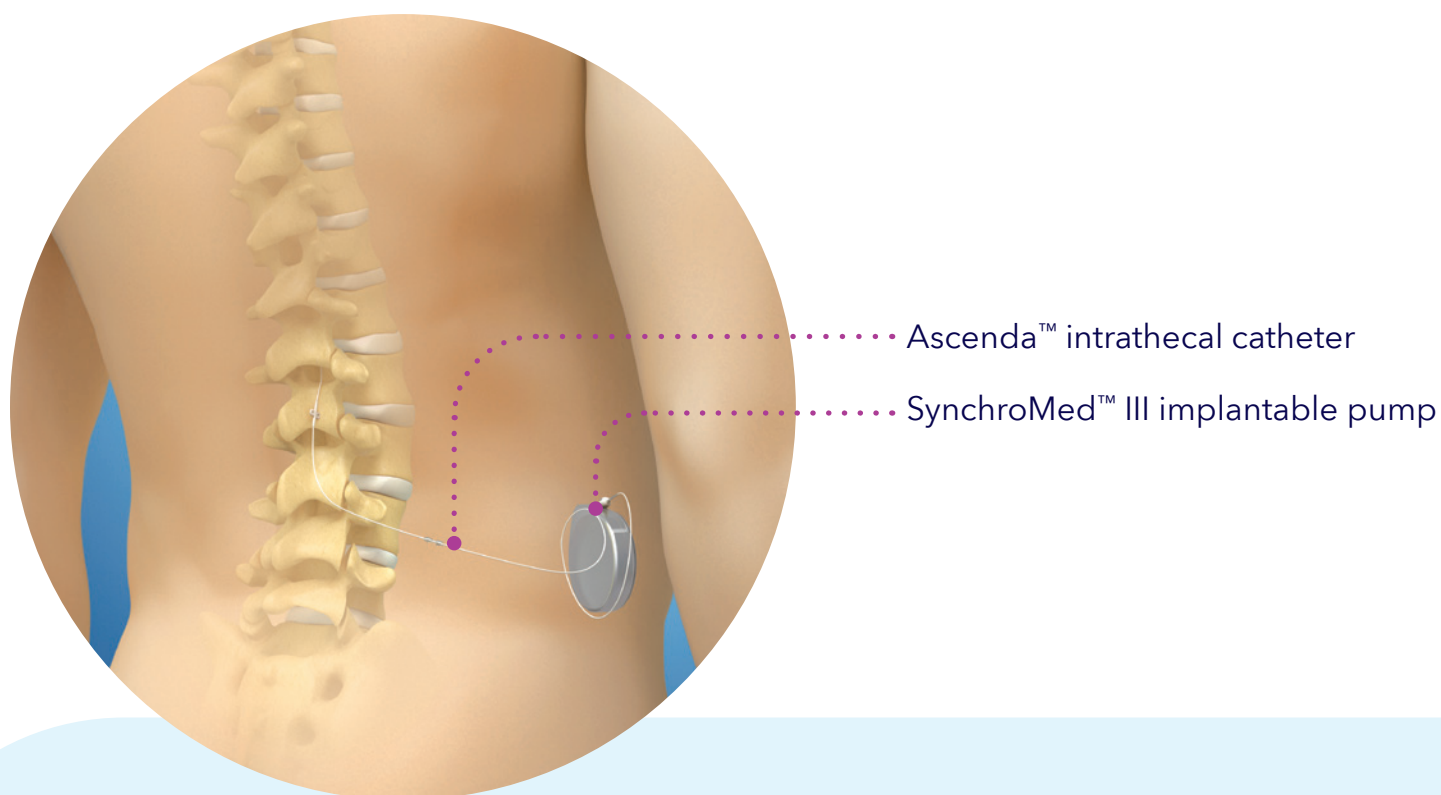
[†]This data represents pumps with four durable design changes (battery coating, gear wheel 3 material change, feedthrough encapsulation, diamond-like carbon coating). **The most recent design change was implemented in 2017. At 4 years, the survival probability (95% confidence intervals) was 97% pump survival rate pre-enhancements (n=3158 pumps); and 99.4% post-durable enhancements (n=203 pumps).**¹⁴

Why targeted drug delivery?

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

Millions are affected by pain and healthcare providers often prescribe systemic opioids (typically oral) as part of the treatment plan.¹ This is common, despite limited evidence on the benefits of long-term systemic opioid therapy and evidence that long-term systemic opioid therapy is associated with increased risk for opioid misuse or addiction.²

Giving clinicians control over medication administration is increasingly important given the widespread prevalence of medication abuse, misuse, overdose, diversion, and addiction. Targeted drug delivery is effective in reducing or eliminating the need for systemic opioids when used to treat both malignant and nonmalignant pain.^{3,4}



Learn more about patient selection and the Control Workflow™ on YouTube



How targeted drug delivery may benefit your patients

- **Achieve pain relief** with lower doses, more effectively^{5,6}
- **Fewer side effects** compared to oral medications^{6,7}


Chronic Pain

- **43-51% of patients completely eliminate systemic opioids** at 12 months^{3,8}
- **99% of chronic nonmalignant pain patients** choose to replace the pump⁹
- **90% of patients would recommend therapy** to a family member or friend¹⁰

Cancer Pain

- **94% reduction** in systemic opioid usage⁴
- **Sustained pain relief and improved quality of life**^{11,12}
- **Reduced cost burden compared with patients treated by conventional medical management (CMM)**¹³

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

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

More efficacy with less medication

Intrathecal drug delivery enables reduced drug dosages compared to other routes of administration.



Learn more about one physician's experience with patient satisfaction and targeted drug delivery

References

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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. USA Rx Only Rev 0823

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