INTRODUCTION

Medtronic’s commitment to quality has long been stated as part of the Medtronic mission. We will strive without reserve for the greatest possible reliability and quality. The annual Medtronic Product Performance Report (PPR) reflects that commitment. Through this sharing of information, we can enable physicians to best leverage state-of-the-art therapy delivery and also understand the performance of our devices to best manage patients. Together, we can further patient safety and improve lives.


The registry is currently tracking more than 50,254 implanted devices and more than 16,557 patients in these therapies.

Access the 2017 full report at: Medtronic.com/SynchroMed
METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers participating in the Product Surveillance Registry (PSR).
- Medtronic also incorporates the findings of Returned Product Analysis (RPA) for devices followed in the registry that are returned to Medtronic.
- Patients at each center who provide informed consent are enrolled in the registry. Patients are followed prospectively for events related to the device, procedure, and/or therapy.
- Participating investigators provide event descriptions, patient symptoms, and patient outcomes. Any detection methods used to determine patient or device outcomes are also obtained.

EVENT CATEGORIZATION

Events collected through the registry are collapsed into two categories:

- **Product performance** — event possibly due to a device-related issue.
- **Non-product performance** — any undesirable patient symptom, illness, or other medical event that appears or worsens during the clinical study that possibly resulted from or was related to the implant procedure, therapy, or delivery of therapy, and cannot be classified as a product performance event.

DEVICE SURVIVAL ESTIMATES

Note that cumulative device survival — not patient survival — estimates are presented throughout this summary.

- Figures show the percentage of implanted devices that remain free from product performance-related events at various time points.
- Example: a device survival probability of 90% indicates that through the stated follow-up time period, the device had a 10% risk of incurring a product performance event since the time of implant.
- Estimates represent device survival where at least 20 total devices are still being followed for at least six months.

PATIENT ENROLLMENT

- 64 centers enrolled 7,975 total targeted drug delivery system patients in the registry through October 31, 2017.
- 57.6% of patients were implanted for the treatment of non-malignant pain (pain not related to cancer).
- 21.9% of patients were implanted for the treatment of spasticity.
- 18.2% of patients were implanted for the treatment of malignant pain (pain related to cancer).
- 2.4% of patients were implanted for the treatment of a combination of indications or for indications that were not specified in the database at the time of the data cut-off.
## MEDTRONIC TARGETED DRUG DELIVERY SYSTEMS DEVICE SURVIVAL SUMMARY TABLE

<table>
<thead>
<tr>
<th>Device Summary Information</th>
<th>Device Survival Probability (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model Number/Product Name</strong></td>
<td><strong>Device Events</strong></td>
</tr>
<tr>
<td><strong>Pumps</strong></td>
<td></td>
</tr>
<tr>
<td>SynchroMed™ EL 18 mL†</td>
<td>1,148</td>
</tr>
<tr>
<td>SynchroMed™ II 20 mL</td>
<td>3,350</td>
</tr>
<tr>
<td>SynchroMed™ II 40 mL</td>
<td>5,174</td>
</tr>
<tr>
<td><strong>Catheters</strong></td>
<td></td>
</tr>
<tr>
<td>Model 8709††</td>
<td>2,859</td>
</tr>
<tr>
<td>Model 8709SC</td>
<td>1,063</td>
</tr>
<tr>
<td>Model 8711</td>
<td>655</td>
</tr>
<tr>
<td>Model 8731</td>
<td>507</td>
</tr>
<tr>
<td>Model 8731SC</td>
<td>241</td>
</tr>
<tr>
<td>Model 8780</td>
<td>914</td>
</tr>
<tr>
<td>Model 8781</td>
<td>741</td>
</tr>
<tr>
<td><strong>Spliced Catheters</strong></td>
<td></td>
</tr>
<tr>
<td>Revised As Designed†</td>
<td>222</td>
</tr>
<tr>
<td>Ascenda †</td>
<td>188</td>
</tr>
<tr>
<td>Revised Not As Designed‡</td>
<td>683</td>
</tr>
<tr>
<td>Grafted Not As Designed‡</td>
<td>464</td>
</tr>
</tbody>
</table>

* This table shows the percentage of implanted devices that remain free from product performance-related events at various time points.

† There were a total of 416 pump-related product performance events reported to the registry, but only 327 events included in this summary table. The remaining events either occurred in pump models for which no device survival data are presented due to an insufficient number of enrolled devices (i.e., SynchroMed EL 10 mL[n=1]) or were subsequent events that did not affect the device survival estimates.

‡ As of August 2007, Medtronic voluntarily discontinued the SynchroMed EL pump in the United States.

§ There were a total of 1,238 catheter-related product performance events reported to the registry, but only 1,023 events included in this summary table. The remaining events either occurred in catheter models for which no device survival data are presented due to an insufficient number of enrolled devices (n=22), or in catheters for which no model information was provided (n=26), or were subsequent events that did not affect the device survival estimates.

¶ Catheters revised as designed are Model 8731 catheters that were repaired with an 8596 proximal or 8598 distal revision kit.

# Ascenda revised as designed catheters are Model 8780 or 8781 catheters repaired with the 8782 or 8784 revision kit.

** Catheters revised not as designed are Medtronic non-8731 catheters repaired with an 8596 proximal or 8598 distal revision kit.

†† Catheters grafted not as designed are catheters repaired or spliced using non-Medtronic components, or Medtronic components other than the Model 8596 or 8598 kits spliced together using existing or other industry sponsored products.
SynchroMed™ II Drug Infusion System Brief Statement:
Product technical manuals and the appropriate drug labeling must be reviewed prior to use for detailed disclosure.

**Indications:** US: 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 US: 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 or to administer ziconotide.

**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 II 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 of time to avoid system damage. EMI may interfere with programmer telemetry during pump programming sessions. EMI from the SynchroMed programmer may interfere with other active implanted devices (e.g., pacemaker, defibrillator, neurostimulator).

**Adverse Events:** In addition to procedure-related risks, the following may occur: pocket seroma; hematoma; erosion; infection; pump inversion; 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 Medtronic’s website at www.medtronic.com

Infumorph® is a registered trademark of West-Ward Pharmaceutical. Prialt® is a registered trademark of Jazz Pharmaceuticals plc or its subsidiaries. Lioresal® is a registered trademark of Saol.

USA Rx Only
Rev 0817