Targeted Drug Delivery Systems
2022 Medtronic Product Performance Report
Executive Summary

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 understand the performance of our devices to best manage patients.

Medtronic published the industry's first Neuromodulation PPR in 2008. The report uses data gathered from a prospective, long-term, multi-center registry. It allows for active surveillance of our Spinal Cord Stimulation, Targeted Drug Delivery, Deep Brain Stimulation, and Sacral Nerve Stimulation devices.

As of October 31, 2022, the registry had 24,117 implanted devices and 10,053 patients in the Targeted Drug Delivery therapy.

Access the 2022 full report at: https://www.medtronic.com/us-en/healthcare-professionals/products/product-performance/neuromodulation-product-performance.html

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** (or a clinical event not related to 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 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 6 months.

PATIENT ENROLLMENT

- 76 centers enrolled 10,053 total targeted drug delivery system patients in the registry through October 31, 2022.
- 58.8% of patients were implanted for the treatment of non-malignant pain (pain not related to cancer).
- 21.7% of patients were implanted for the treatment of spasticity.
- 17.3% of patients were implanted for the treatment of malignant pain (pain related to cancer).
- 2.2% 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.

It is recognized that healthcare providers prescribe therapies to meet specific patient needs; however, Medtronic only directs the use of its products based on approved regulatory labeling, which varies by geography. Please contact your local Medtronic representative for region-specific product labeling (http://www.medtronic.com/us-en/about/locations.html).

Medtronic Targeted Drug Delivery Systems Device Survival Summary Table

Device Summary Information				Device Survival Probability (%)*																		
Model Number/ Product Name	Devices Enrolled	Initial Product Performance Events	Cumulative Months of Follow-up	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs	18 yrs	19 yrs	20 yrs
Pumps																							
SynchroMed™ II 20mL	4,376	128	173,127	99.6%	99.3%	98.9%	98.3%	97.0%	94.3%	88.3%	-	-	-	-	-	-	-	-	-	-	-	-	-
SynchroMed™ II 40mL	7,179	297	219,981	99.6%	99.1%	98.4%	97.0%	93.3%	87.0%	76.8% (81 M)	-	-	-	-	-	-	-	-	-	-	-	-	-
Catheters																							
Model 8709†	2,918	362	100,121	91.9%	89.1%	85.6%	82.8%	80.1%	74.9%	70.2%	68.0%	66.2%	64.2%	61.9%	59.5%	56.1%	55.0%	54.6%	54.6%	53.1%	50.3%	49.0%	47.4% (237 M)
Model 8709SC	1,104	151	48,161	94.0%	89.6%	87.3%	84.4%	82.4%	80.0%	75.1%	73.1%	71.5%	70.1%	68.8%	68.8%	66.6%	64.4% (165M)	-	-	-	-	-	-
Model 8711	661	100	32,077	92.5%	90.0%	84.9%	82.5%	80.8%	77.3%	74.0%	72.2%	71.1%	68.7%	66.5%	62.7%	59.8%	56.5%	56.5%	56.5%	56.5%	56.5% (207M)	-	-
Model 8731	534	64	24,448	93.6%	92.3%	91.4%	89.4%	87.9%	82.6%	79.2%	75.9%	74.0%	73.0%	71.8%	67.1%	63.4%	59.8%	59.8%	54.5%	54.5% (198 M)	-	-	-
Model 8731SC	282	38	12,658	93.1%	89.1%	89.1%	87.1%	83.9%	82.8%	75.9%	75.9%	73.8%	71.0%	71.0%	71.0%	-	-	-	-	-	-	-	-
Model 8780	1,498	139	55,106	95.7%	92.7%	92.1%	90.3%	88.1%	86.2%	76.5%	75.1%	75.1%	71.8% (111M)	-	-	-	-	-	-	-	-	-	-
Model 8781	1,256	149	33,238	91.6%	89.8%	86.8%	85.1%	82.3%	77.1%	63.7%	62.2%	60.7% (102M)	-	-	-	-	-	-	-	-	-	-	-
Spliced Catheters																							
Revised As Designed§	759	104	20,675	90.3%	86.3%	82.7%	79.7%	78.1%	76.1%	72.6%	71.3%	67.6%	62.8% (114M)	-	-	-	-	-	-	-	-	-	-
Ascenda™ Revised As Designed ¶	528	59	12,781	92.1%	87.5%	83.9%	83.3%	80.6%	78.4%	70.0%	70.0% (87 M)	-	-	-	-	-	-	-	-	-	-	-	-
Revised Not As Designed #	733	151	35,750	91.5%	88.2%	84.2%	82.0%	79.6%	74.9%	67.4%	64.3%	62.3%	59.7%	58.6%	58.6%	58.6% (147 M)	-	-	-	-	-	-	-
Grafted Not As Designed**	504	108	24,939	90.7%	85.8%	83.0%	79.8%	77.4%	73.8%	69.6%	65.2%	62.9%	61.2%	58.9%	55.8%	50.6%	48.7%	-	-	-	-	-	-

* This table shows the percentage of implanted devices that remain free from product performance-related events at various time points.
† Includes 8709 and 8709AA Models.
§ 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 that involve the ad-hoc assembly of components other than a Medtronic revision kit or brand-new catheter.

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