

Targeted Drug Delivery Systems

2025 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, 2025, the registry had 27,025 (14,424 pumps and 12,601 catheters) implanted devices and 11,146 patients in the Targeted Drug Delivery therapy.

Access the 2025 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

- 77 centers enrolled 11,146 total targeted drug delivery system patients in the registry through October 31, 2025.
- 59.8% of patients were implanted for the treatment of non-malignant pain (pain not related to cancer).
- 20.9% of patients were implanted for the treatment of spasticity.
- 16.9% 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 indication 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

* 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; 20 8709 Model catheter also had 47.9% survival out to 21 years

§ 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.

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	21 yrs	22 yrs
Pumps																									
SynchroMed™ II 20mL	4,675	130	199,270	99.60%	99.30%	98.90%	98.40%	97.40%	95.20%	92.00% (81M)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SynchroMed™ II 40mL	7,859	308	270,368	99.60%	99.20%	98.50%	97.50%	94.60%	89.70%	82.00% (81M)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SynchroMed™ III 40mL	496	0	2,145	100.0%																					
SynchroMed™ II 20mL and 40mL: Pre-enhancements	7,595	399	294,523	99.50%	99.00%	98.30%	97.00%	94.40%	89.70%	83.20% (81M)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SynchroMed™ II 20mL and 40mL: GW3/FT Enhancements	899	21	40,834	99.40%	99.40%	99.30%	99.30%	97.60%	95.70%	95.10% (81M)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
SynchroMed™ 20mL and 40mL: GW3/FT/DLC Enhancements	4,040	1,444	18	99.80%	99.70%	99.40%	99.40%	99.20%	99.20%	99.20% (81M)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Catheters																									
Model 8709†	2,928	369	103,870	91.80%	89.10%	85.50%	82.70%	80.10%	75.00%	70.30%	68.10%	66.30%	64.20%	62.00%	58.70%	55.50%	54.50%	54.10%	54.10%	53.10%	51.30%	49.90%	47.90%	47.90%	47.9% (255M)
Model 8709SC	1,111	157	52,141	93.80%	89.40%	87.20%	84.30%	82.30%	80.00%	75.10%	73.10%	71.60%	70.30%	69.30%	69.30%	65.80%	65.00%	65.00%	62.30%	62.3% (195M)	-	-	-	-	-
Model 8711	665	104	33,710	92.50%	90.10%	85.00%	82.60%	80.90%	77.40%	74.10%	72.30%	71.20%	68.80%	66.70%	62.30%	59.60%	55.90%	54.80%	54.80%	54.8%	54.80%	54.80% (219M)	-	-	-
Model 8731	538	67	25,649	93.70%	92.40%	91.40%	89.10%	87.50%	82.20%	78.90%	75.70%	73.90%	72.90%	71.70%	67.10%	63.40%	59.90%	59.90%	55.50%	55.50%	55.50%	53.10%	-	-	-
Model 8731SC	286	43	14,605	93.10%	89.10%	89.10%	87.20%	84.10%	83.00%	75.40%	75.40%	73.40%	71.10%	71.10%	71.10%	63.80%	58.9% (162M)	-	-	-	-	-	-	-	-
Model 8780	1,821	169	74,247	96.00%	93.20%	92.40%	91.00%	89.00%	87.10%	79.80%	78.80%	77.30%	76.10%	76.10%	73.9% (138M)	-	-	-	-	-	-	-	-	-	-
Model 8781	1,646	192	48,016	92.30%	89.90%	87.20%	85.60%	82.90%	78.40%	68.40%	65.20%	64.60%	63.60%	63.60%	63.6% (138M)	-	-	-	-	-	-	-	-	-	-
Spliced Catheters																									
Revised As Designed¶	924	127	32,614	91.40%	87.90%	85.20%	83.60%	81.70%	79.70%	76.60%	75.20%	71.80%	66.10%	66.10%	-	-	-	-	-	-	-	-	-	-	-
Ascenda™ Revised As Designed ¶	733	77	21,978	93.50%	90.30%	87.00%	84.50%	83.10%	82.10%	75.80%	74.10%	74.10%	74.1% (111M)	-	-	-	-	-	-	-	-	-	-	-	-
Revised Not As Designed #	749	163	39,260	91.40%	88.20%	84.20%	82.10%	79.80%	75.40%	67.40%	64.30%	61.50%	59.60%	58.10%	57.20%	53.10%	47.8% (165M)	-	-	-	-	-	-	-	-
Grafted Not As Designed**	532	116	27,832	90.50%	85.80%	82.90%	79.80%	77.60%	73.70%	69.90%	65.60%	63.60%	62.00%	59.50%	57.50%	53.80%	52.20%	52.20%	52.2% (186M)	-	-	-	-	-	-

If you have suggestions, inquiries, or specific problems related to our products or this information, contact:

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