Spinal Cord Stimulation 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 21,858 implanted devices and 6,328 patients in the Spinal Cord Stimulation 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. All clinical events not related to a product performance and reported as a serious adverse event were summarized by MedDRA System Organ Class (SOC) if the event met a patient threshold and are included in the full Product Performance Report.

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 6 months.

PATIENT ENROLLMENT

- 85 centers enrolled 6,328 total Spinal Cord Stimulation patients in the registry through October 31, 2022.
- 45.5% of patients were implanted for the treatment of chronic back and leg pain.
- 25.8% of patients were implanted for the treatment of other primary indications.
- 18.1% of patients were implanted for the treatment of trunk and limb pain
- 10.0% of patients were implanted for the treatment of complex regional pain syndrome.
- 0.6% of patients were implanted for the treatment of 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 Spinal Cord Stimulation 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
Rechargeable Neurostimulators																					
Intellis with Adaptive Stim	1,281	13	24,254		99.5%	98.7%	98.1%	97.6%	-	-	-	-	-	-	-	-	-	-	-	-	-
RestoreAdvanced	357	1	11,327		99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	99.7%	-	-	-	-	-	-	-	-	-
RestoreAdvanced™ SureScan™MRI	116	2	4,239		99.0%	99.0%	99.0%	99.0%	99.0%	-	-	-	-	-	-	-	-	-	-	-	-
RestoreUltra™ SureScan™ MRI	93	4	2,917		97.4%	94.2%	94.2%	94.2%	-	-	-	-	-	-	-	-	-	-	-	-	-
RestoreSensor™	377	5	12,047		99.7%	99.2%	98.5%	98.5%	98.5%	96.8%	96.8%	96.8%	-	-	-	-	-	-	-	-	-
RestoreSensor™ SureScan™ MRI	1,382	36	48,075		98.5%	97.8%	97.3%	96.4%	95.8%	95.8%	94.7%	-	-	-	-	-	-	-	-	-	-
Non-Rechargeable Neurostimulators																					
Itrel™ 4	135	1	4,596		100%	99.1%	99.1%	99.1%	-	-	-	-	-	-	-	-	-	-	-	-	-
PrimeAdvanced™	668	6	15,767		99.6%	99.3%	99.3%	96.8%	96.8%	96.8%	96.8%	-	-	-	-	-	-	-	-	-	-
PrimeAdvanced™ SureScan™MRI	785	10	24,884		99.6%	99.4%	98%	97.7%	97.7%	97.7%	97.7%	-	-	-	-	-	-	-	-	-	-
Lead Models																					
3776 1 x 8	188	17	5,565		91.8%	91.8%	91.8%	89.8%	86.7%	83.5%	77.6%	77.6%	-	-	-	-	-	-	-	-	-
3777 1 x 8	838	71	24,810		92.8%	89.3%	89.3%	88.1%	87.4%	85.6%	83.6%	80.8%	78.1%	78.1%	78.1%	76.8%	76.8%	76.8%	-	-	-
3778 1 x 8	2,168	265	68,373		90.4%	87.0%	84.7%	84.2%	81.8%	80.6%	77.4%	75.9%	75.4%	73.2%	72.5%	72.5%	69.1%	-	-	-	-
3487A Pisces-Standard Quad™	992	166	42,088		91.8%	89.3%	84.8%	80.8%	76.5%	73.3%	71.4%	71.4%	66.7%	63.5%	61.2%	58.2%	58.2%	58.2%	55.6%	54.1%	50.4%
3887 Pisces- Compact Quad™	200	25	7,666		92.5%	83.1%	76.8%	75.3%	71.6%	69.4%	67.1%	67.1%	61.9%	59.3%	59.3%	-	-	-	-	-	-
3888 Pisces-Plus Quad™	455	44	12,490		92.5%	88.3%	85.1%	81.2%	79.2%	74.3%	71.7%	71.7%	71.7%	71.7%	71.7%	71.7%	-	-	-	-	-
977A1 Vectris™ SureScan®	144	11	4,153		94.3%	90.0%	90.0%	90.0%	-	-	-	-	-	-	-	-	-	-	-	-	-
977A2 Vectris™ SureScan™	4,602	342	130,139		94.4%	91.8%	90.6%	89.5%	88.4%	87.7%	86.6%	86.6%	-	-	-	-	-	-	-	-	-
AnkerStim Lead (Approved in Europe): 09100	201	13	3,165		94.3%	91.2%	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39565 Surgical	294	11	8,507		96.3%	95.7%	95.7%	94.0%	94.0%	94.0%	94.0%	89.8%	-	-	-	-	-	-	-	-	-
977C2 Specify SureScan MRI 2x8	43	2	902		97.4%	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
977C1 Specify SureScan MRI 5-6-5	77	2	1,297		100%	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Extensions																					
37081	1,533	15	52,830		99.7%	99.1%	98.8%	98.5%	98.5%	98.5%	98.1%	98.1%	97.1%	97.1%	97.1%	97.1%	95.4%	-	-	-	-
37082	647	4	23,353		99.8%	99.6%	99.6%	99.6%	99.6%	99.6%	97.6%	97.6%	97.6%	97.6%	-	-	-	-	-	-	-
37083	391	16	10,796		97.0%	96.0%	95.3%	95.3%	95.3%	91.2%	91.2%	91.2%	87.7%	87.7%	87.7%	-	-	-	-	-	-

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

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

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