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 43,900 implanted devices and more than 14,600 patients in these therapies.

Access the 2016 full report at: professional.medtronic.com/performance
METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers. The registry is currently conducted utilizing two protocols titled the Implantable Systems Performance Registry (ISPR) and 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. They’re 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 being followed for at least 6 months.

PATIENT ENROLLMENT

- 36 centers enrolled 2,109 total deep brain stimulation patients in the registry through July 31, 2016.
- 67.1% of patients were implanted for the treatment of Parkinson’s disease.
- 21.3% of patients were implanted for the treatment of Essential Tremor.
- 7.1% of patients were implanted for the treatment of Dystonia.
- 2.0% of patients were implanted for the treatment of some other indication.
- 0.7% of patients were implanted for the treatment of Obsessive Compulsive Disorder.
- 0.2% of patients were implanted for the treatment of Epilepsy.
- 1.6% of patients were implanted for the treatment of indications that were not specified in the database at the time of the data cut-off.
### Medtronic Deep Brain Stimulation Systems Device Survival Summary Table

| Model Number/Product Name | Devices Enrolled | Device Events | Cumulative Months of Follow-up | 1 yr | 2 yrs | 3 yrs | 4 yrs | 5 yrs | 6 yrs | 7 yrs | 8 yrs | 9 yrs |
|---------------------------|------------------|---------------|-------------------------------|------|------|------|------|------|------|------|------|------|------|
| **Neurostimulators†**     |                  |               |                               |      |      |      |      |      |      |      |      |      |      |
| Activa™ PC                | 1,440            | 7             | 20,638                        | 99.6%| 99.3%| 99.3%| 99.3%|      |      |      |      |      |      |
| Activa™ SC                | 663              | 3             | 9,725                         | 99.4%| 99.4%| 99.4%|      |      |      |      |      |      |      |
| Activa™ RC                | 257              | 2             | 4,268                         | 99.5%| 98.6%| 98.6%|      |      |      |      |      |      |      |
| Soletra™                  | 68               | 0             | 1,427                         | 100.0%| 100.0%|      |      |      |      |      |      |      |      |
| **Leads‡**                |                  |               |                               |      |      |      |      |      |      |      |      |      |      |
| Model 3387                | 1,408            | 10            | 25,137                        | 99.3%| 99.1%| 99.1%| 99.1%| 97.8%| 97.8%| 97.8%| 97.8%| 97.8%|
| Model 3389                | 1,852            | 27            | 31,496                        | 99.0%| 98.1%| 97.5%| 96.3%| 95.6%| 93.0%| 93.0%| 93.0%| 93.0%|
| **Extensions§**           |                  |               |                               |      |      |      |      |      |      |      |      |      |      |
| Model 37086†              | 2,782            | 15            | 46,254                        | 99.5%| 99.3%| 99.3%| 99.3%| 98.3%|      |      |      |      |      |

* 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 12 neurostimulator-related product performance events reported to the registry.
‡ There were a total of 66 lead-related product performance events reported to the registry, but only 37 events included in this summary table. The remaining 29 events occurred in a lead model for which no device survival data are presented due to an insufficient number of enrolled devices (n=1) or were subsequent events that did not affect the device survival estimates.
§ There were a total of 23 extension-related product performance events reported to the registry, but only 15 events included in this summary table. The remaining 8 events were subsequent events that did not affect the device survival estimates.

*Includes Models 37085 and 37086.

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

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Medtronic DBS Therapy for Parkinson’s Disease, Tremor and Dystonia
Medtronic DBS Therapy for Parkinson’s Disease, Tremor, and Dystonia: Product technical manual must be used for device selection and programming.

Indications: Medtronic DBS Therapy for Parkinson’s Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson’s Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson’s disease of at least 4 years duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with either parkinsonian tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

Medtronic DBS Therapy for Dystonia: Unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Dystonia is indicated as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients seven years of age or above.

Contraindications: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator and, for Parkinson’s disease and Essential Tremor, patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulator implantation location other than pectoral and abdominal regions; unapproved MRI conditions (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device injury, including coma, paraplegia, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system systems ("abandoned systems"); misidentifcation of neurostimulator implantation location other than pectoral and abdominal regions; unapproved MRI connectors; device overheating, including lead fracture. Abrupt cessation of therapy has not been established. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. The safety and probable benefit of this therapy has not been established for patients: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulator implantation location other than pectoral and abdominal regions; unapproved MRI conditions (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device injury, including coma, paraplegia, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system systems ("abandoned systems"); misidentifcation of neurostimulator implantation location other than pectoral and abdominal regions; unapproved MRI connectors; device overheating, including lead fracture.