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.

METHODS

- Medtronic uses a prospective, long-term, multi-center registry to monitor the performance of certain products at selected centers titled 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 6 months.

PATIENT ENROLLMENT

- 38 centers enrolled 2,459 total deep brain stimulation patients in the registry through October 31, 2017.
- 66.1% of patients were implanted for the treatment of Parkinson’s disease.
- 21.6% of patients were implanted for the treatment of Essential Tremor.
- 8.2% of patients were implanted for the treatment of Dystonia.
- 2.4% of patients were implanted for the treatment of some other indication.
- 0.8% of patients were implanted for the treatment of Obsessive Compulsive Disorder.
- 0.5% of patients were implanted for the treatment of Epilepsy.
- 0.5% 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

## Device Summary Information

| 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 | 10 yrs | 11 yrs |
|---------------------------|------------------|---------------|--------------------------------|------|------|------|------|------|------|------|------|------|------|------|-------|
| **Neurostimulators†**     |                  |               |                                |      |      |      |      |      |      |      |      |      |      |      |       |
| Activa® PC                | 1,865            | 21            | 37,204                         | 99.2%| 98.8%| 98.8%| 98.4%| 98.4%| -    | -    | -    | -    | -    | -    |       |
| Activa® SC                | 814              | 6             | 15,817                         | 99.3%| 99.0%| 99.0%| 99.0%| -    | -    | -    | -    | -    | -    | -    |       |
| Activa® RC                | 364              | 5             | 7,249                          | 99.1%| 98.4%| 97.5%| 97.5%| -    | -    | -    | -    | -    | -    | -    |       |
| **Leads‡**                |                  |               |                                |      |      |      |      |      |      |      |      |      |      |      |       |
| Model 3387                | 1,693            | 17            | 40,644                         | 99.3%| 99.1%| 99.1%| 99.1%| 97.4%| 97.4%| 97.4%| 96.0%| 96.0%| 94.1%| 94.1% |       |
| Model 3389                | 2,310            | 52            | 55,327                         | 98.8%| 98.1%| 97.3%| 96.1%| 95.0%| 92.4%| 91.8%| 91.1%| 91.1%| 89.8%| 89.8% |       |
| **Extensions§**           |                  |               |                                |      |      |      |      |      |      |      |      |      |      |      |       |
| Model 37086              | 3,503            | 32            | 80,005                         | 99.5%| 99.1%| 98.9%| 98.8%| 97.8%| 97.8%| 97.8%| -    | -    | -    | -    |       |

*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 34 neurostimulator-related events reported to the registry, but only 32 events are included in this summary table. The remaining 2 events were attributable to other non-Activa models not included on this table.

‡ There were a total of 98 lead-related product performance events reported to the registry, but only 69 events included in this summary table. The remaining lead-related events occurred in a lead model for which no device survival data are presented due to an insufficient number of enrolled devices (n=3) or were subsequent events that did not affect the device survival estimates.

§ There were a total of 42 extension-related product performance events reported to the registry, but only 32 events included in this summary table. The remaining events occurred in an extension model for which no device data are presented due to an insufficient number of enrolled devices (n=7) or were subsequent events that did not affect the device survival estimates or attributable to other models not included on this table.

‖ Includes Models 37085 and 37086.

The Soletra model was removed from the table due to the limited number of active devices. Please refer to the 2016 Product Performance Report for information on survival for that model.

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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:

- Indications: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson’s Disease may be used for adjunctive treatment 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 0 to 7 years’ duration), in patients 70 years of age or older. The effectiveness of the device for treating these conditions has not been demonstrated.

- 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 neuromuscular stimulation or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if they have an implanted Solotera™ Model 7426 Neurostimulator, Kineta™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

- Warnings: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. Theft detectors and security screening devices may cause stimulation to switch ON or OFF and may cause some patients to experience a momentary increase in perceived stimulation. The DBS System may be affected by or adversely affect medical equipment such as pacemakers or defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., TMS, ECT) has not been established. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious injury, including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location too superficially or too deeply may result in nerve or vascular injury, or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant (“rebound” effect). Onset of status dystonicus, which may be life-threatening, may occur in dystonia patients during ongoing or loss of DBS Therapy. Patients using a rechargeable neurostimulator for Parkinson’s disease or Essential Tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist. Loss of coordination in activities such as swimming may occur. Depression, suicidal ideations and suicide have been reported in patients receiving DBS Therapy for Movement Disorders, although no direct cause-and-effect relationship has been established.

- Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (lightening or bowstringing), new or exacerbation of neurologic symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shaking or jerking sensation, ineffective therapy, and weight gain or loss.

- Humanitarian Device (Dystonia): Authorized by Federal Law as an aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (fortisitum), in patients 7 years of age and older. The effectiveness of the devices for treating these conditions has not been demonstrated.

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Medtronic Reclaim™ DBS Therapy for OCD:

- Indication: The Medtronic Reclaim™ DBS Therapy is indicated for bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adults who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

- Contraindications: Medtronic Reclaim DBS Therapy for OCD is contraindicated for patients who are unable to properly operate the neurostimulator. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation damage or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if they have an implanted Solotera™ Model 7426 Neurostimulator, Kineta™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

- Warnings: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. The DBS System may be affected by or adversely affect medical equipment such as pacemakers or defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (e.g., TMS, ECT) has not been established. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious injury, including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location too superficially or too deeply may result in nerve or vascular injury, or tunneling through unintended anatomy. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant (“rebound” effect).

- Patients should be monitored for at least 30 minutes after a programming session for side effects, including: autonomic effects (e.g., facial flushing, facial muscle contractions, or increased heart rate), hypomania, increased disease symptoms, and sensations such as tingling, smell, or taste. During treatment, patients should be monitored closely for increased depression, anxiety, suicidality, and worsening of obsessive-compulsive symptoms. Loss of coordination in activities such as swimming may occur.

- Adverse Events: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, surgeries, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (lightening or bowstringing), new or exacerbation of neurologic symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shaking or jerking sensation, ineffective therapy, and weight gain or loss.

- The safety and probable benefit of this therapy has not been established for patients with: Tourette's syndrome, OCD with a subclassification of hoarding, previous surgical ablation (e.g., capsulotomy), dementia, coagulopathies or who are on anticoagulant therapy, neurological disorders, and other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus. In addition, the safety and probable benefit has not been established for these patients: those whose diagnosis of OCD is documented to be less than 5 years duration or whose YBOCS score is less than 30, who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation, who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT), who are pregnant, who are under the age of 18 years, and who do not have comorbid depression and anxiety. Physicians should carefully consider the potential risks of implanting the Medtronic Reclaim™ DBS System in patients with comorbid psychiatric disorders (e.g., bipolar, body dysmorphic, psychotic) as the Reclaim DBS System may aggravate the symptoms.

- Humanitarian Device: Authorized by Federal (U.S.A) law as use as an adjunct to medications and as alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adults who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of this device for this use has not been demonstrated.

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