# PRODUCT PERFORMANCE REPORT

## SUMMARY OF DATA FROM THE MEDTRONIC POST-MARKET REGISTRY

# 2022

v.1.0 23Mar2023

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# Contents

# 5 Deep Brain Stimulation Systems

## 5.1 Study Participants

### 5.1.1 Centers

In this section, the deep brain stimulation tables and graphs were generated based on data collected between July 2009 and the report cut-off date of October 31, 2022. Sixty-four centers in North America, Europe, South America, Asia, and Australia have enrolled and contributed patients to the deep brain stimulation systems section of this report. Figure 5.1 shows a World Map, in which the countries that enrolled DBS patients are highlighted.

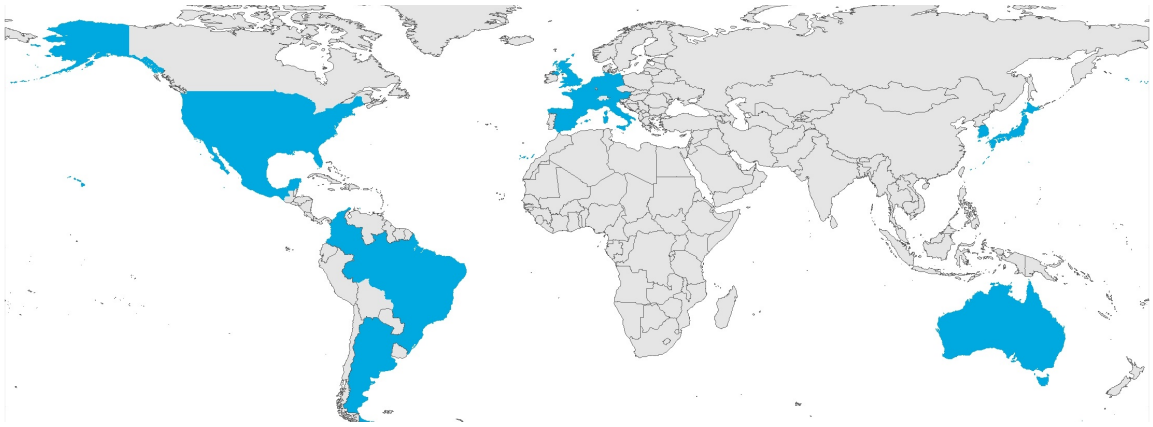


**Figure 5.1:** Countries with Deep Brain Stimulation Therapy Patients in Registry (Highlighted)

### 5.1.2 Patients

Of the 3,295 deep brain stimulation patients enrolled, the primary indications for implant were as follows: 61.1% were implanted for the treatment of Parkinson's Disease, 22.6% were implanted for the treatment of essential tremor, 9.9% were implanted for the treatment of dystonia, 1.5% were implanted for the treatment of epilepsy, 1.5% were implanted for the treatment of obsessive compulsive disorder, 2.3% were implanted for the treatment of other indications, and 1.0% were implanted for indications that were not specified in the database at the time of data cut-off (see Figure 5.2 and Table 5.1).

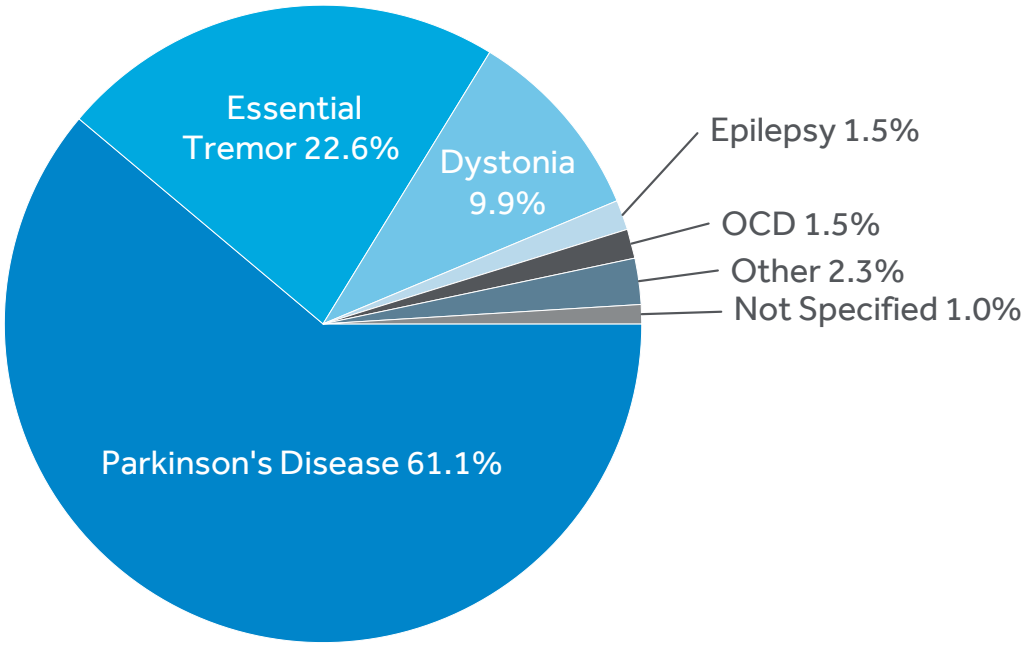



**Figure 5.2:** Deep Brain Stimulation Primary Treatment Indications

**Table 5.1:** Deep Brain Stimulation Primary Treatment Indications

| Primary Treatment Indication[a] | Enrolled Patients (%) |
|---|---|
| Parkinson's Disease | 2,014 (61.1%) |
| Essential Tremor | 746 (22.6%) |
| Dystonia | 327 (9.9%) |
| Epilepsy | 50 (1.5%) |
| OCD | 49 (1.5%) |
| Other | 77 (2.3%) |
| Not Specified | 32 (1.0%) |
| **Total Patients** | **3,295(100%)** |

[a] For approved indications refer to product labeling for your geography.

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 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).

## 5.2 Event Summary

There were 479 product performance events reported between July 2009 and October 31, 2022, in patients with deep brain stimulation systems. These events represent 22.6% of the total reported events (479/2,124), occurred in 294 of the 3,295 (8.9%) total patients enrolled, and are presented graphically within this report (e.g. events per patient years as well as survival curves). Of the remaining 1,645 reported events 269 were serious (not product performance related) and 1,376 were non-serious (not product performance related). Serious non-product performance related events (n=269) are described in Table 5.6. Non serious non-product performance related (n=1,376) events are not listed in this report.

Any registry devices that are returned to Medtronic are analyzed via a Returned Product Analysis (RPA) process. If available, RPA findings overwrite in the classification of the events. Within this report, Table 5.2 differentiates the events by those determined by the RPA process versus those determined by the physician. Please refer to the Methodology section for more information.

There were 385 deaths reported for patients followed in the PSR with deep brain stimulation systems (see Table 5.7), none of which were reported as a direct result of a product performance event. Early versions of the protocol required events to be reported only when the event required a surgical intervention, resulted in therapy abandonment, or resulted in death. The required event reporting definition was expanded in April 2010 to include all adverse events related to the device, implant procedure, and/or therapy.

### 5.2.1 Product Performance Events

**Table 5.2:** Deep Brain Stimulation System Product Performance Events

| Product Performance Events[a] | Event Counts | Events Per 100 Patient Years | Patients with Events (%) N=3,295[b] |
|---|---|---|---|
| **RPA Determination** | **3** | **0.03** | **3 (0.09%)** |
| Premature Battery Depletion | 3 | 0.03 | 3 (0.09%) |
| **Physician's Determination** | **476** | **4.08** | **292 (8.86%)** |
| High Impedance | 215 | 1.84 | 131 (3.98%) |
| Lead Migration/Dislodgement | 46 | 0.39 | 33 (1.00%) |
| Low Impedance | 32 | 0.27 | 21 (0.64%) |
| Device Malfunction | 24 | 0.21 | 20 (0.61%) |
| Lead Fracture | 22 | 0.19 | 18 (0.55%) |
| Extension Migration | 21 | 0.18 | 11 (0.33%) |
| Neurostimulator Unable To Recharge[c] | 18 | 0.15 | 18 (0.55%) |
| Extension Fracture | 12 | 0.1 | 9 (0.27%) |
| Premature Battery Depletion | 10 | 0.09 | 10 (0.30%) |
| Medical Device Complication | 9 | 0.08 | 6 (0.18%) |
| Device Breakage | 5 | 0.04 | 5 (0.15%) |
| Device Electrical Finding[d] | 5 | 0.04 | 4 (0.12%) |

...continued

| Product Performance Events[a] | Event Counts | Events Per 100 Patient Years | Patients with Events (%) N=3,295[b] |
|---|---|---|---|
| Medical Device Site Infection | 5 | 0.04 | 4 (0.12%) |
| Device Lead Issue | 4 | 0.03 | 4 (0.12%) |
| Device Protrusion | 4 | 0.03 | 2 (0.06%) |
| Device Connection Issue | 3 | 0.03 | 3 (0.09%) |
| Device Electrical Impedance Issue | 3 | 0.03 | 2 (0.06%) |
| Device End Of Life | 3 | 0.03 | 3 (0.09%) |
| Electric Shock Sensation | 3 | 0.03 | 2 (0.06%) |
| Neurostimulator Inversion | 3 | 0.03 | 3 (0.09%) |
| Device Charging Issue | 2 | 0.02 | 2 (0.06%) |
| Device Material Corroded | 2 | 0.02 | 1 (0.03%) |
| Device Short Circuiting | 2 | 0.02 | 2 (0.06%) |
| Electromagnetic Interference | 2 | 0.02 | 2 (0.06%) |
| Medical Device Site Erosion | 2 | 0.02 | 2 (0.06%) |
| Other[e] | 19 | 0.16 | 17 (0.52%) |
| **Total** | **479** | **4.11** | **294 (8.92%)** |

[a] Medical Dictionary for Regulatory Activities (MedDRA) Lower-Level Term or Medtronic's coding system term for events that do not exist in the MedDRA dictionary.

[b] The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.

[c] There were 721 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.5% (18/721) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

[d] Including open circuit contact, electric discharge.

[e] Composed of event codes with 1 event each.

A total of 221 (46.1%) of the 479 product performance events were related to the lead, 92 (19.2%) were related to the extension, 84 (17.5%) were related to the neurostimulator, 15 (3.1%) were related to multiple etiologies, which includes events where at least one device and one non-device etiology was indicated, and 67 (14.0%) were related to other etiologies, including: 36 (7.5%) were related to other component, 10 (2.1%) were related to incisional site/device tract, 9 (1.9%) were related to surgery/anesthesia, 6 (1.3%) were related to recharging process, 5 (1.0%) were related to programming/stimulation, and 1 (0.2%) was related to other etiology (see Figure 5.3). Events could have more than one etiology.

Relatedness is reported by the physician. In cases where the Clinical Events Committee (CEC) has adjudicated relatedness differently from the site, the CEC adjudication is used in this report for analysis purposes. However, both the site's reporting and the CEC's adjudication remain in the database.

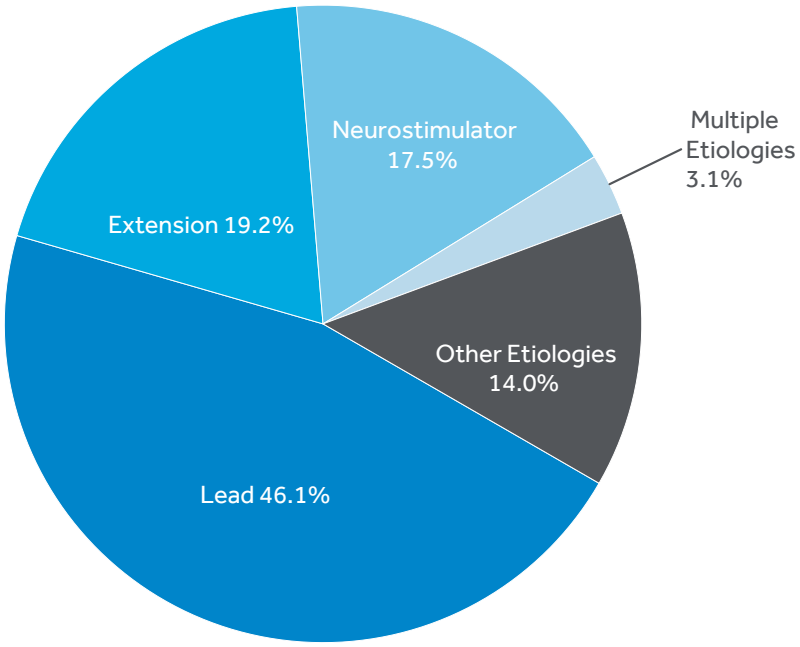



**Figure 5.3:** Deep Brain Stimulation System Product Performance Events by Relatedness

Table 5.3 and Table 5.4 describe the interventions taken for reported impedance events. In 39.1% and 31.2% of the high and low impedance events, the action taken was a surgical intervention. However, impedance could be used as a diagnostic measurement and may not result in any intervention or clinical impact. The majority of events required no intervention, or device reprogramming only (54.9% for high impedance and 68.8% for low impedance).

**Table 5.3:** Deep Brain Stimulation System High Impedance Events by Intervention

| Intervention | N (%) of High Impedance Events |
|---|---|
| Device Surgical Intervention | 72 (33.5%) |
| Reprogramming | 52 (24.2%) |
| Other Surgical Intervention | 12 (5.6%) |
| Other Intervention | 7 (3.3%) |
| Medical or Non-Surgical Therapy | 5 (2.3%) |
| Therapy Suspension | 1 (0.5%) |
| No Action Taken | 66 (30.7%) |
| **Total** | **215 (100%)** |

**Table 5.4:** Deep Brain Stimulation System Low Impedance Events by Intervention

| Intervention | N (%) of Low Impedance Events |
|---|---|
| Device Surgical Intervention | 10 (31.2%) |
| Reprogramming | 10 (31.2%) |
| No Action Taken | 12 (37.5%) |
| **Total** | **32 (100%)** |

Table 5.5 describes the interventions taken for reported lead migration/dislodgement events; 78.3% of them led to a surgical intervention, and 13.0% were reprogramming.

**Table 5.5:** Deep Brain Stimulation System Lead Migration/Dislodgement Events by Intervention

| Intervention | N (%) of Lead Migration/Dislodgement Events |
|---|---|
| Device Surgical Intervention | 34 (73.9%) |
| Reprogramming | 6 (13.0%) |
| Other Surgical Intervention | 2 (4.3%) |
| Medication | 1 (2.2%) |
| No Action Taken | 3 (6.5%) |
| **Total** | **46 (100%)** |

### 5.2.2 Clinical Events Not Related To Product Performance

The clinical events not related to product performance are summarized if:

- The patient was enrolled in the PSR at the time in which the clinical event collection was initiated (N=2,112)
- Categorized as serious adverse events (SAEs, N=269)
- Occurred with a System Organ Class (SOC) threshold $\geq$1% of patients
- Other Considerations
  - Some events are described in high level group terms (HLGT) to provide more specificity, if needed
  - Some therapies will provide therapy relevant events

**Table 5.6:** Deep Brain Stimulation System Clinical Events Not Related To Product Performance

| Event Type | Number of SAE | Patients with SAE n (%)[a] N=2,112 | SAE Per 100 Patient Months | Patient with SAE Requiring Surgical Intervention n (%) N=2,112 |
|---|---|---|---|---|
| **Infections and infestations** | **107** | **87 (4.12%)** | **0.13** | **81 (3.84%)** |
| Infections - pathogen unspecified | 104 | 84 (3.98%) | 0.13 | 78 (3.69%) |
| Other[b] | 3 | 3 (0.14%) | 0.00 | 3 (0.14%) |
| **Nervous system disorders** | **59** | **52 (2.46%)** | **0.07** | **11 (0.52%)** |
| Central nervous system vascular disorders | 19 | 19 (0.90%) | 0.02 | 3 (0.14%) |
| Movement disorders (incl parkinsonism) | 18 | 18 (0.85%) | 0.02 | 3 (0.14%) |
| Neurological disorders NEC | 11 | 10 (0.47%) | 0.01 | 3 (0.14%) |
| Other[b] | 11 | 11 (0.52%) | 0.01 | 2 (0.09%) |
| **General disorders and administration site conditions** | **49** | **46 (2.18%)** | **0.06** | **29 (1.37%)** |
| Complications associated with device | 36 | 34 (1.61%) | 0.05 | 25 (1.18%) |
| General system disorders NEC | 7 | 7 (0.33%) | 0.01 | 1 (0.05%) |
| Other[b] | 6 | 6 (0.28%) | 0.01 | 3 (0.14%) |
| **Other SOC Terms (<1.0% Threshold)** | **54** | **52 (2.46%)** | **0.07** | **19 (0.90%)** |
| **Total** | **269** | **212 (10.04%)** | **0.34** | **130 (6.16%)** |

[a] The total number of patients with events may not represent the sum of all rows, as a patient may have experienced more than one type of event.
[b] Composed of high level group term event codes with fewer than 5 events each.

### 5.2.3 Patient Deaths

There were 385 deaths reported for patients with deep brain stimulation systems, none of which were reported as a direct result of a product performance event. Since July 2009, a total of 310 (80.5%) deaths have been reported in this patient registry study based upon patients receiving therapy for Parkinson's Disease, 51 (13.2%) for essential tremor, 15 (3.9%) for dystonia, 3 (0.8%) for epilepsy, 1 (0.3%) for OCD, and 5 (1.3%) for other indications (see Table 5.7). The percentage is based upon the total patient death events and not based upon the rate of occurrence.

**Table 5.7:** Deep Brain Stimulation System Patient Deaths by Primary Indication

| Number of Reports of Death by Primary Indication[a] | N (%) of Deaths | Mean Age of Death in Years |
|---|---|---|
| Parkinson's Disease | 310 (80.5%) | 74.06 |
| Essential Tremor | 51 (13.2%) | 79.8 |
| Dystonia | 15 (3.9%) | 56.1 |
| Epilepsy | 3 (0.8%) | 37.6 |
| OCD | 1 (0.3%) | 70.4 |
| Other | 5 (1.3%) | 75.3 |
| **Total** | **385 (100%)** | **74.1** |

[a] For approved indications refer to product labeling for your geography.

## 5.3 Neurostimulators

From July 2009 to the report cut-off date of October 31, 2022, there were 5,212 neurostimulators followed in the registry. The difference between the total number of patients (n=3,295) versus the number of neurostimulators (n=5,212) is due to the fact that some patients were implanted with more than one neurostimulator or were subsequently re-implanted. The aggregate prospective follow-up time for all neurostimulators was 150,157 months (12,513 years). Table 5.8 provides the number and percentage of neurostimulators by model.

**Table 5.8:** Deep Brain Stimulation Neurostimulator Counts by Model

| Model Name | N (%) |
|---|---|
| **Currently manufactured** | |
| Activa PC | 2,730 (52.4%) |
| Activa SC | 1,106 (21.2%) |
| Activa RC | 738 (14.2%) |
| Percept PC | 526 (10.1%) |
| **No longer manufactured** | |
| Soletra | 67 (1.3%) |
| Other/Unspecified[a] | 33 (0.6%) |
| **Total** | **5,212 (100%)** |

[a] Other includes Activa PC+S and non-Activa systems used for DBS.

### 5.3.1 Neurostimulator Events

Of the total of 479 product performance-related events, there were 86 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 84 events with a neurostimulator etiology and 2 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 66 were the initial product performance events that affected neurostimulator survival estimates. For neurostimulators in the registry, the current return rate to Medtronic Returned Product Analysis (RPA) was 4.1% (94/2,311). The proportion was based upon the number of registry neurostimulators received by RPA, divided by the sum of the total number of explanted devices and the total number of neurostimulators in patients who have expired. In the 86 neurostimulator events, 96.5 % (83/86) were assigned as device related by the physician, not returned to Medtronic RPA (see Table 5.9).

**Table 5.9:** Deep Brain Stimulation Neurostimulator Product Performance Events by Determination

| Product Performance Events | N (%) |
|---|---|
| **RPA Determination** | **3 (3.5%)** |
| Premature Battery Depletion | 3 (3.5%) |
| **Physician's Determination** | **83 (96.5%)** |
| High Impedance | 37 (43.0%) |
| Device Malfunction | 10 (11.6%) |
| Premature Battery Depletion | 10 (11.6%) |
| Low Impedance | 6 (7.0%) |
| Device End Of Life | 3 (3.5%) |
| Device Electrical Finding[a] | 2 (2.3%) |
| Electromagnetic Interference | 2 (2.3%) |
| Extension Migration | 2 (2.3%) |
| Device Computer Software Issue | 1 (1.2%) |
| Device Protrusion | 1 (1.2%) |
| Device Short Circuiting | 1 (1.2%) |
| Device Vibration | 1 (1.2%) |
| Electric Shock Sensation | 1 (1.2%) |
| Medical Device Site Discomfort | 1 (1.2%) |
| Medical Device Site Erosion | 1 (1.2%) |
| Medical Device Site Infection | 1 (1.2%) |
| Neurostimulator Inversion | 1 (1.2%) |
| Neurostimulator Unable To Recharge | 1 (1.2%) |
| Wound Infection | 1 (1.2%) |
| **Total** | **86 (100%)** |

[a] Open circuit contact.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For neurostimulators:

- 66 had follow-up time cut-off due to product performance-related events.
- 3,390 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 1,756 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

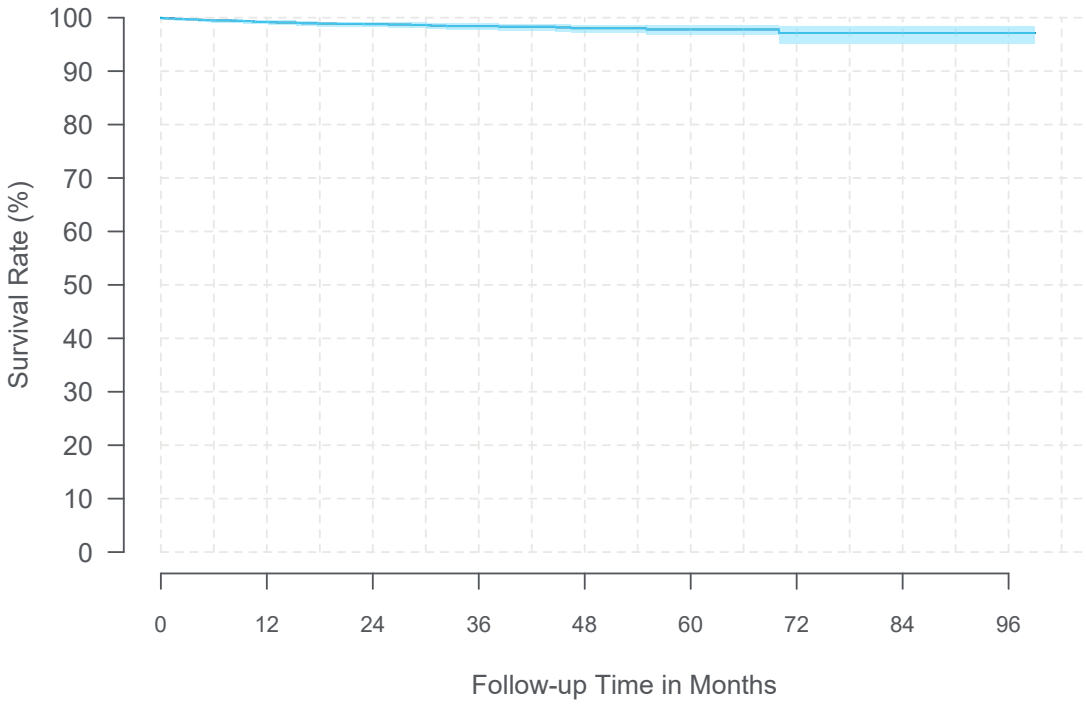
### 5.3.2 Neurostimulator Models

The following figures and tables represent neurostimulator survival and 95% confidence intervals where at least 20 neurostimulators contributed to each 3-month interval.

The Soletra and Kinetra models were removed from the table due to the limited number of active devices in PSR. For information on survival for those models, please refer to past reports.

### 5.3.2.1 Model Activa PC

| | |
|---|---|
| **Model Name** | Activa PC |
| **FDA Approval Date** | April 2009 |
| **Neurostimulators Enrolled** | 2,730 |
| **Neurostimulators Currently Active in Study** | 584 |
| **Initial Product Performance Events** | 42 |
| **Median Follow-up Time (Months)** | 29.2 |
| **Cumulative Follow-up Time (Months)** | 87,874 |




| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 99.2% (98.7%, 99.5%) | 98.8% (98.2%, 99.2%) | 98.4% (97.8%, 98.9%) | 98.0% (97.2%, 98.6%) | 97.8% (96.8%, 98.5%) |
| Sample Size | 2,193 | 1,640 | 1,042 | 600 | 323 |

| Time Interval | 6 Years | 7 Years | 8 Years | At 99 Months | |
|---|---|---|---|---|---|
| Survival (95% CI) | 97.1% (95.1%, 98.3%) | 97.1% (95.1%, 98.3%) | 97.1% (95.1%, 98.3%) | 97.1% (95.1%, 98.3%) | — |
| Sample Size | 125 | 60 | 23 | 21 | |

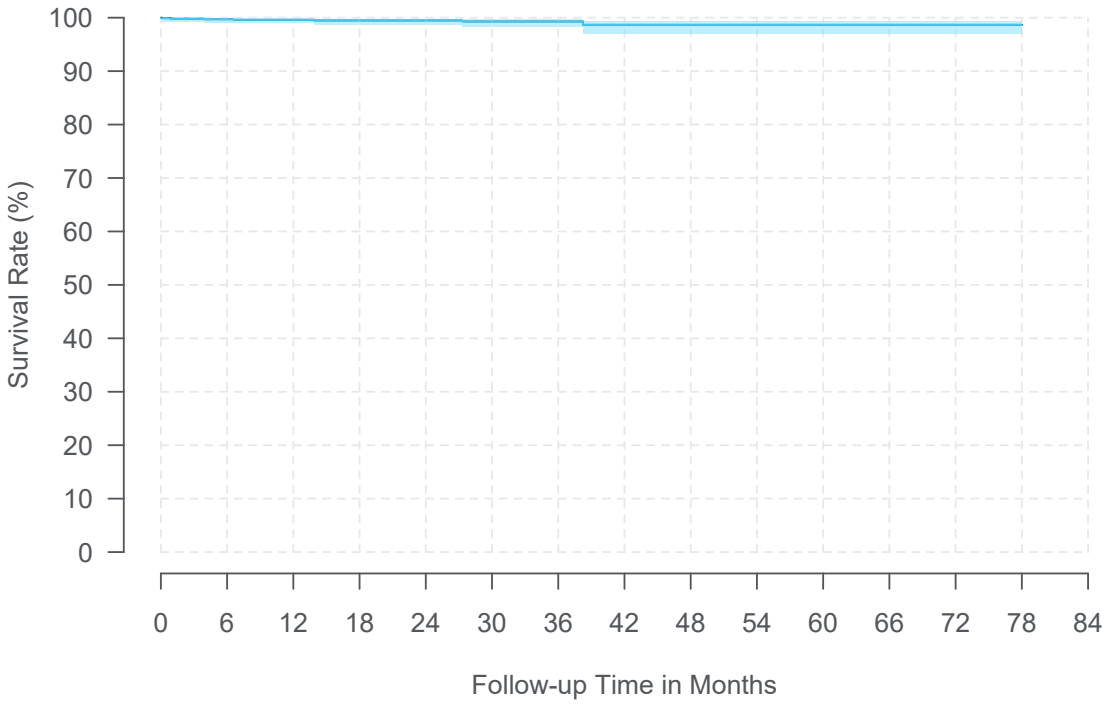
| Specification: Activa PC | |
|---|---|
| **Height** | 2.6 in (65 mm) |
| **Width** | 1.9 in (49 mm) |
| **Thickness** | 0.6 in (15 mm) |
| **Volume** | 39 cc |
| **Battery type** | Non-Rechargeable |
| **Expected Battery life** | Depends on settings and use |
| **Maximum Electrodes** | 8 |
| **Amplitude** | 0 - 10.5 V (voltage mode)<br>0 - 25.5 mA (current mode) |
| **Rate** | 2 - 250 Hz (voltage mode)<br>30 - 250 Hz (current mode) |
| **Pulse Width** | 60 - 450 µsec |
| **Groups** | 4 |
| **Programs** | 16 (up to 4 per group) |
| **Implant Depth** | $\leq$ 4 cm |


| Neurostimulator Event: Activa PC | N |
|---|---|
| High impedance | 17 |
| Premature battery depletion | 12 |
| Device malfunction | 5 |
| Device end of life | 3 |
| Device electrical finding[a] | 1 |
| Device protrusion | 1 |
| Electromagnetic interference | 1 |
| Low impedance | 1 |
| Medical device site infection | 1 |
| **Total** | **42** |

[a] Open circuit contact.

### 5.3.2.2 Model Activa SC

| | |
|---|---|
| **Model Name** | Activa SC |
| **FDA Approval Date** | January 2011 |
| **Neurostimulators Enrolled** | 1,106 |
| **Neurostimulators Currently Active in Study** | 206 |
| **Initial Product Performance Events** | 9 |
| **Median Follow-up Time (Months)** | 26.5 |
| **Cumulative Follow-up Time (Months)** | 31,524 |




| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 99.6% (98.9%, 99.8%) | 99.5% (98.7%, 99.8%) | 99.3% (98.4%, 99.7%) | 98.7% (97.1%, 99.4%) | 98.7% (97.1%, 99.4%) |
| Sample Size | 846 | 613 | 359 | 183 | 77 |

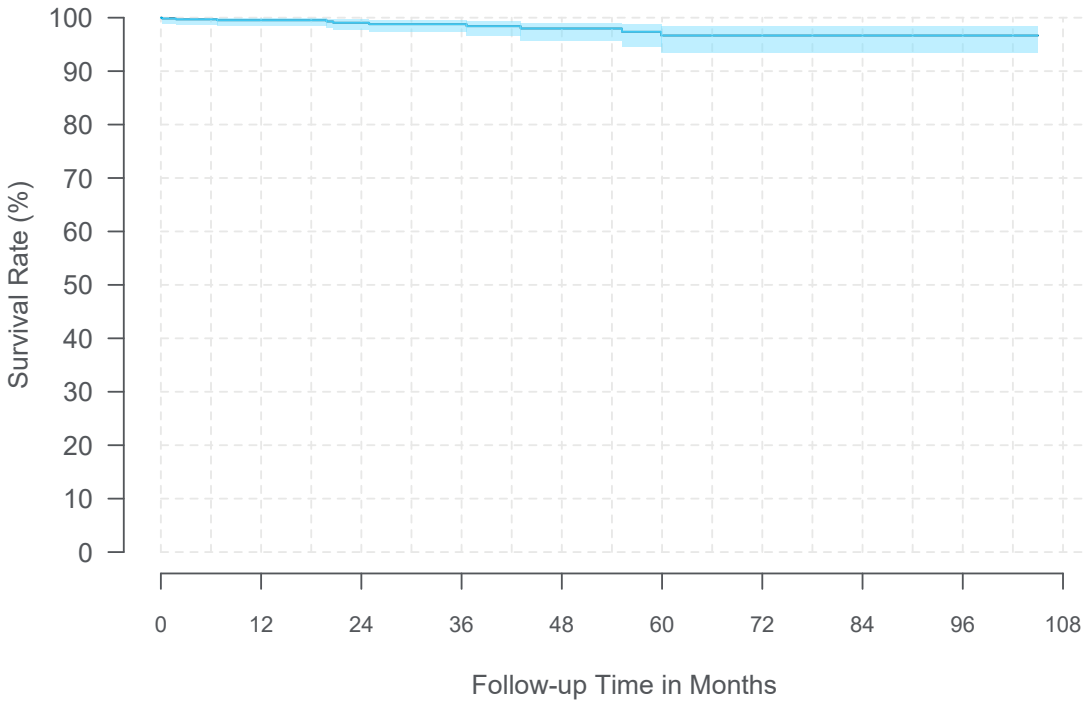
| Time Interval | 6 Years | At 78 Months | | | |
|---|---|---|---|---|---|
| Survival (95% CI) | 98.7% (97.1%, 99.4%) | 98.7% (97.1%, 99.4%) | — | — | — |
| Sample Size | 38 | 27 | | | |

| Specification: Activa SC | |
|---|---|
| **Height** | 2.2 in (55 mm) |
| **Width** | 2.4 in (60 mm) |
| **Thickness** | 0.4 in (11 mm) |
| **Volume** | 28 cc (Model 37602)<br>27 cc (Model 37603) |
| **Battery type** | Non-Rechargeable |
| **Expected Battery life** | Depends on settings and use |
| **Maximum Electrodes** | 4 |
| **Amplitude** | 0 - 10.5 V (voltage mode)<br>0 - 25.5 mA (current mode) |
| **Rate** | 2 - 250 Hz (voltage mode)<br>30 - 250 Hz (current mode) |
| **Pulse Width** | 60 - 450 µsec |
| **Groups** | 4 |
| **Programs** | 8 (up to 2 per group) |
| **Implant Depth** | ≤ 4 cm |


| Neurostimulator Event: Activa SC | N |
|---|---|
| High impedance | 4 |
| Device short circuiting | 1 |
| Low impedance | 1 |
| Medical device site discomfort | 1 |
| Premature battery depletion | 1 |
| Wound infection | 1 |
| **Total** | **9** |

### 5.3.2.3 Model Activa RC

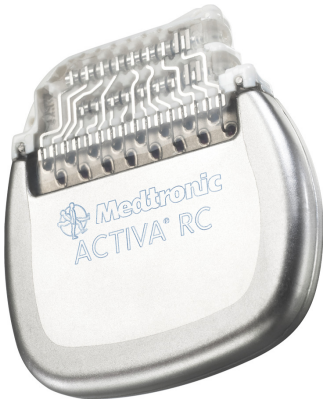
| | |
|---|---|
| **Model Name** | Activa RC |
| **FDA Approval Date** | March 2009 |
| **Neurostimulators Enrolled** | 738 |
| **Neurostimulators Currently Active in Study** | 489 |
| **Initial Product Performance Events** | 12 |
| **Median Follow-up Time (Months)** | 24.8 |
| **Cumulative Follow-up Time (Months)** | 24,295 |




| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 99.5% (98.5%, 99.8%) | 99.1% (97.7%, 99.6%) | 98.8% (97.3%, 99.5%) | 98.0% (95.8%, 99.0%) | 96.7% (93.3%, 98.3%) |
| Sample Size | 523 | 378 | 269 | 196 | 138 |

| Time Interval | 6 Years | 7 Years | 8 Years | At 105 Months | |
|---|---|---|---|---|---|
| Survival (95% CI) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) | — |
| Sample Size | 86 | 52 | 29 | 21 | |

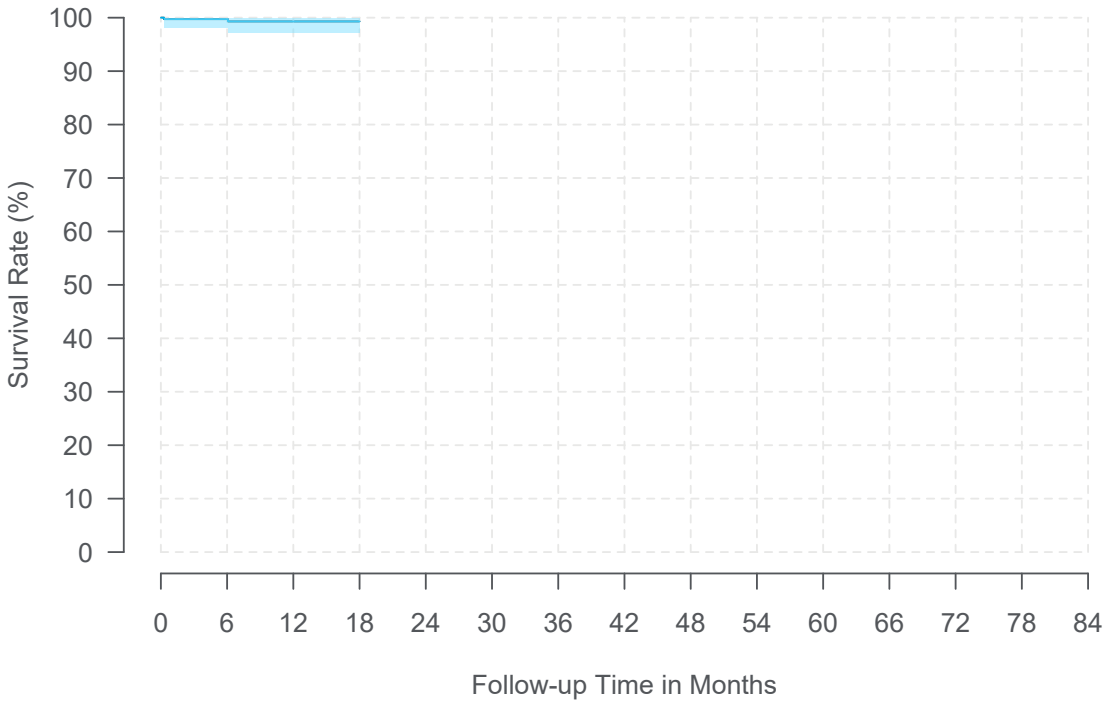
| Specification: Activa RC | |
|---|---|
| **Height** | 2.1 in (54 mm) |
| **Width** | 2.1 in (54 mm) |
| **Thickness** | 0.4 in (9 mm) |
| **Volume** | 22 cc |
| **Battery type** | Rechargeable |
| **Expected Battery life** | 9 years |
| **Maximum Electrodes** | 8 |
| **Amplitude** | 0 - 10.5 V (voltage mode)<br>0 - 25.5 mA (current mode) |
| **Rate** | 2 - 250 Hz (voltage mode)<br>30 - 250 Hz (current mode) |
| **Pulse Width** | 60 - 450 µsec |
| **Groups** | 4 |
| **Programs** | 16 (up to 4 per group) |
| **Implant Depth** | $\leq$ 1 cm |




| Neurostimulator Event: Activa RC | N |
|---|---|
| Device malfunction | 2 |
| Extension migration | 2 |
| High impedance | 2 |
| Device computer software issue | 1 |
| Electric shock sensation | 1 |
| Low impedance | 1 |
| Medical device site erosion | 1 |
| Neurostimulator inversion | 1 |
| Neurostimulator unable to recharge | 1 |
| **Total** | **12** |

### 5.3.2.4 Model Percept PC

| | |
|---|---|
| **Model Name** | Percept PC |
| **FDA Approval Date** | June 2020 |
| **Neurostimulators Enrolled** | 526 |
| **Neurostimulators Currently Active in Study** | 477 |
| **Initial Product Performance Events** | 2 |
| **Median Follow-up Time (Months)** | 4.9 |
| **Cumulative Follow-up Time (Months)** | 3,306 |




| Time Interval | 1 Year | At 18 Months |
|---|---|---|
| Survival | 99.3% | 99.3% |
| (95% CI) | (97.1%, 99.8%) | (97.1%, 99.8%) |
| Sample Size | 110 | 36 |

| Specification: Percept PC | |
|---|---|
| **Height** | 68 mm |
| **Width** | 2 in (51 mm) |
| **Thickness** | 0.43 in (11 mm) |
| **Volume** | 33 cc |
| **Battery type** | Non-Rechargeable |
| **Expected Battery life** | Depends on settings and use |
| **Maximum Electrodes** | 16 Electrodes (8 per lead) |
| **Amplitude** | 0 to 25.5 mA |
| **Rate** | 2 to 250 Hz |
| **Pulse Width** | 20 to 450 µsec |
| **Groups** | 4 |
| **Programs** | 16 |
| **Implant Depth** | ≤ 4cm |


| Neurostimulator Event: Percept PC | N |
|---|---|
| Device electrical finding[a] | 1 |
| High impedance | 1 |
| **Total** | **2** |

[a] Open circuit contact.

## 5.3.3 Neurostimulator Summary

**Table 5.10:** Deep Brain Stimulation Neurostimulator Characteristics

| Model Name | FDA Approval Date | Neurostimulators Enrolled | Neurostimulators Active | Initial Product Performace Events | Median Follow-up Time (Months) | Cumulative Follow-up Time (Months) |
|---|---|---|---|---|---|---|
| Activa PC | April 2009 | 2,730 | 584 | 42 | 29.2 | 87,874 |
| Activa SC | January 2011 | 1,106 | 206 | 9 | 26.5 | 31,524 |
| Activa RC | March 2009 | 738 | 489 | 12 | 24.8 | 24,295 |

**Table 5.11:** Deep Brain Stimulation Neurostimulator Survival Probability (95% Confidence Intervals)

| Model Name | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years | 6 Years | 7 Years | 8 Years |
|---|---|---|---|---|---|---|---|---|
| Activa PC | 99.2% (98.7%, 99.5%) | 98.8% (98.2%, 99.2%) | 98.4% (97.8%, 98.9%) | 98.0% (97.2%, 98.6%) | 97.8% (96.8%, 98.5%) | 97.1% (95.1%, 98.3%) | 97.1% (95.1%, 98.3%) | 97.1% (95.1%, 98.3%) |
| Activa SC | 99.6% (98.9%, 99.8%) | 99.5% (98.7%, 99.8%) | 99.3% (98.4%, 99.7%) | 98.7% (97.1%, 99.4%) | 98.7% (97.1%, 99.4%) | 98.7% (97.1%, 99.4%) | — | — |
| Activa RC | 99.5% (98.5%, 99.8%) | 99.1% (97.7%, 99.6%) | 98.8% (97.3%, 99.5%) | 98.0% (95.8%, 99.0%) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) | 96.7% (93.3%, 98.3%) |

## 5.4 Leads

From July 2009 to the report cut-off date of October 31, 2022, there were 5,602 leads followed in the registry. The difference between the total number of leads (n=5,602) versus neurostimulators (n=5,212) is due to the fact that some patients were subsequently re-implanted with a lead or were implanted with more than one lead. The aggregate prospective follow-up time for all leads was 241,313 months (20,109 years). Table 5.12 provides the number and percentage of leads by model.

**Table 5.12:** Deep Brain Stimulation Lead Counts by Model

| Model Name | N (%) |
|---|---|
| 3389 (compact electrode spacing) | 2,935 (52.4%) |
| 3387 (standard electrode spacing) | 2,269 (40.5%) |
| SenSight B33005 (compact electrode spacing) | 237 (4.2%) |
| SenSight B33015 (standard electrode spacing) | 73 (1.3%) |
| 3391 (large electrodes and wide spacing) | 68 (1.2%) |
| Other/Unspecified[a] | 20 (0.4%) |
| **Total** | **5,602 (100%)** |

[a] Includes leads used in non-Activa systems.

### 5.4.1 Lead Events

Of the total of 479 product performance-related events, there were 230 product performance-related events with an underlying reported etiology related to lead function. This includes 221 events with a lead etiology and 9 events with both a lead and other etiology (including device and non-device etiologies). Of these, 134 were the initial product performance event that affected lead survival estimates.

Events of other/unspecified models are not shown. Model 3391 did not have any product performance-related events.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For leads:

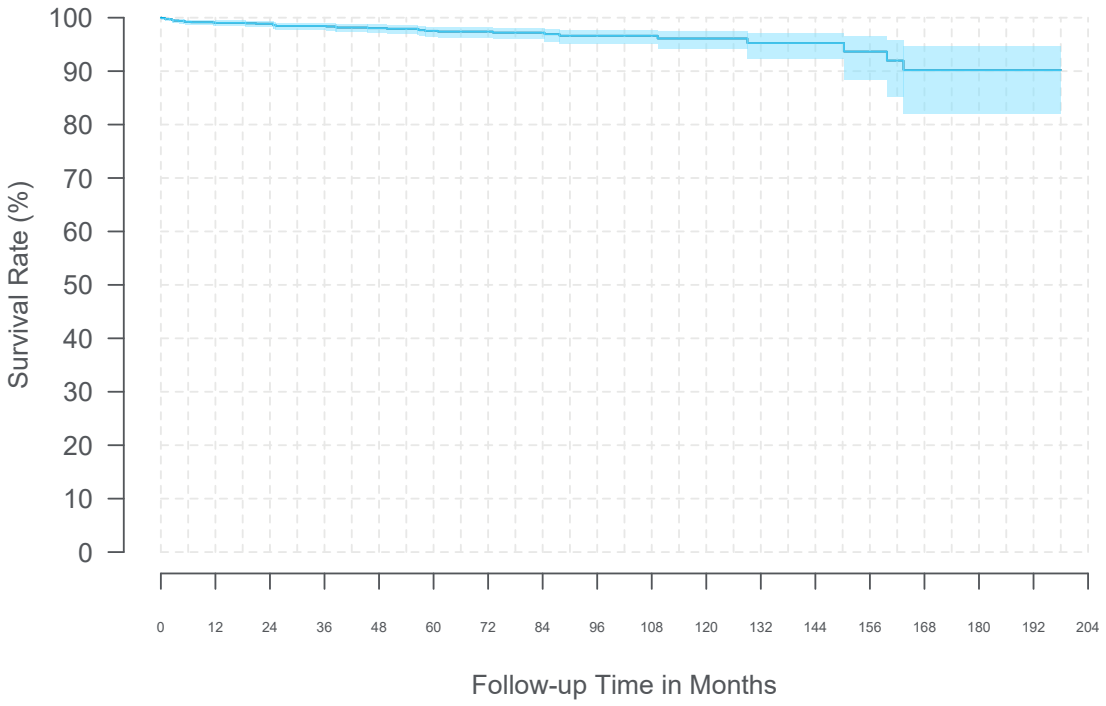
- 134 had follow-up time cut-off due to product performance-related events.
- 2,547 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,921 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

### 5.4.2 Lead Models

The following figures and tables represent lead survival and 95% confidence intervals where at least 20 leads contributed to each 3-month interval. Due to enrollment of replacement patients with previously implanted leads, sample size may increase at later timepoints.

### 5.4.2.1 Model 3387

| | |
|---|---|
| **Model Name** | 3387 |
| **FDA Approval Date** | July 1997 |
| **Leads Enrolled** | 2,269 |
| **Leads Currently Active in Study** | 1,144 |
| **Initial Product Performance Events** | 43 |
| **Median Follow-up Time (Months)** | 36.3 |
| **Cumulative Follow-up Time (Months)** | 97,797 |



| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 99.0% (98.4%, 99.4%) | 98.9% (98.2%, 99.3%) | 98.5% (97.7%, 99.0%) | 98.0% (97.1%, 98.7%) | 97.5% (96.5%, 98.3%) |
| Sample Size | 1,532 | 1,189 | 1,000 | 851 | 714 |

| Time Interval | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 97.4% (96.3%, 98.2%) | 97.2% (96.0%, 98.0%) | 96.6% (95.1%, 97.7%) | 96.6% (95.1%, 97.7%) | 96.1% (94.1%, 97.4%) |
| Sample Size | 512 | 354 | 253 | 187 | 140 |

| Time Interval | 11 Years | 12 Years | 13 Years | 14 Years | 15 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 95.3% (92.3%, 97.1%) | 95.3% (92.3%, 97.1%) | 93.7% (88.5%, 96.6%) | 90.2% (82.1%, 94.7%) | 90.2% (82.1%, 94.7%) |
| Sample Size | 108 | 62 | 56 | 53 | 35 |

| Time Interval | 16 Years | At 198 Months | | | |
|---|---|---|---|---|---|
| Survival (95% CI) | 90.2% (82.1%, 94.7%) | 90.2% (82.1%, 94.7%) | — | — | — |
| Sample Size | 24 | 22 | | | |

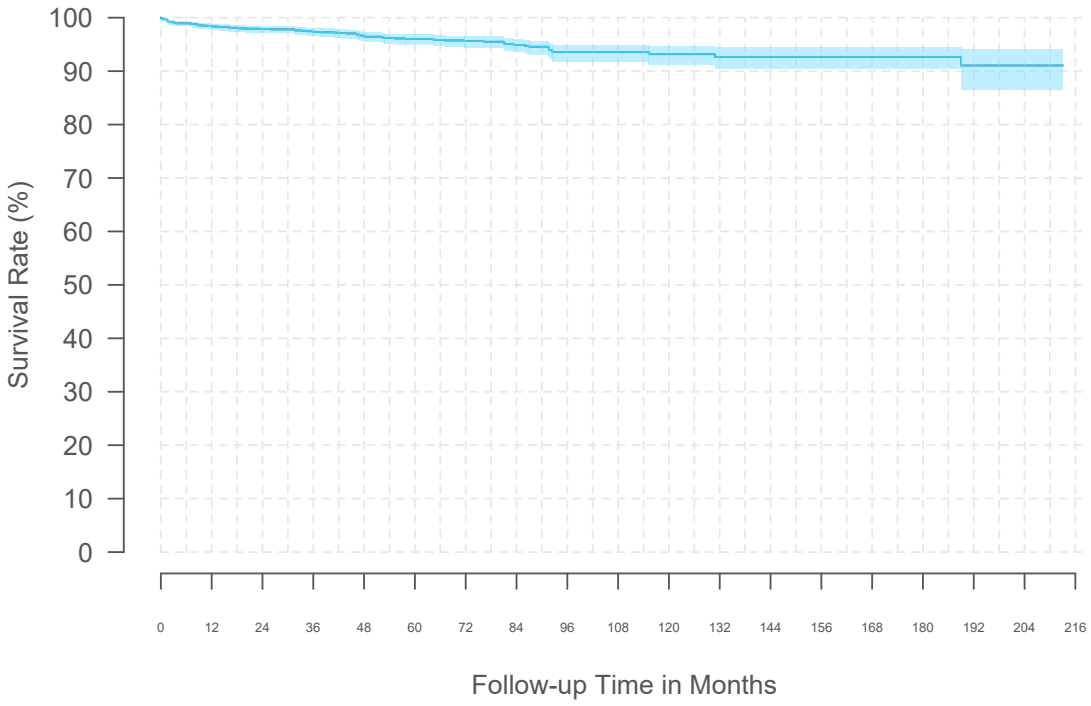
| Specification: 3387 | |
|---|---|
| **Lead** | |
| Length (cm) | 40 |
| Diameter (mm) | 1.27 |
| **Electrode** | |
| Number | 4 |
| Shape | Cylindrical |
| Length (mm) | 1.5 |
| Individual Surface Area ($mm^2$) | 6.0 |
| Inter-Electrode Spacing: Edge to Edge (mm) | 1.5 |
| Array Length (mm) | 10.5 |

| Lead Event: 3387 | N |
|---|---|
| High impedance | 20 |
| Lead migration/dislodgement | 10 |
| Low impedance | 7 |
| Lead fracture | 3 |
| Device electrical finding[a] | 1 |
| Device lead issue | 1 |
| Medical device site pain | 1 |
| **Total** | **43** |

[a] Open circuit contact.

### 5.4.2.2 Model 3389

| | |
|---|---|
| **Model Name** | 3389 |
| **FDA Approval Date** | September 1999 |
| **Leads Enrolled** | 2,935 |
| **Leads Currently Active in Study** | 1,483 |
| **Initial Product Performance Events** | 87 |
| **Median Follow-up Time (Months)** | 44.7 |
| **Cumulative Follow-up Time (Months)** | 138,874 |



| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 98.3% (97.7%, 98.8%) | 97.9% (97.1%, 98.4%) | 97.3% (96.5%, 98.0%) | 96.5% (95.5%, 97.3%) | 96.0% (95.0%, 96.9%) |
| Sample Size | 1,879 | 1,565 | 1,405 | 1,257 | 1,091 |

| Time Interval | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 95.6% (94.5%, 96.5%) | 94.9% (93.6%, 96.0%) | 93.6% (91.8%, 94.9%) | 93.6% (91.8%, 94.9%) | 93.2% (91.2%, 94.7%) |
| Sample Size | 818 | 600 | 414 | 295 | 218 |

| Time Interval | 11 Years | 12 Years | 13 Years | 14 Years | 15 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) |
| Sample Size | 183 | 152 | 131 | 97 | 74 |

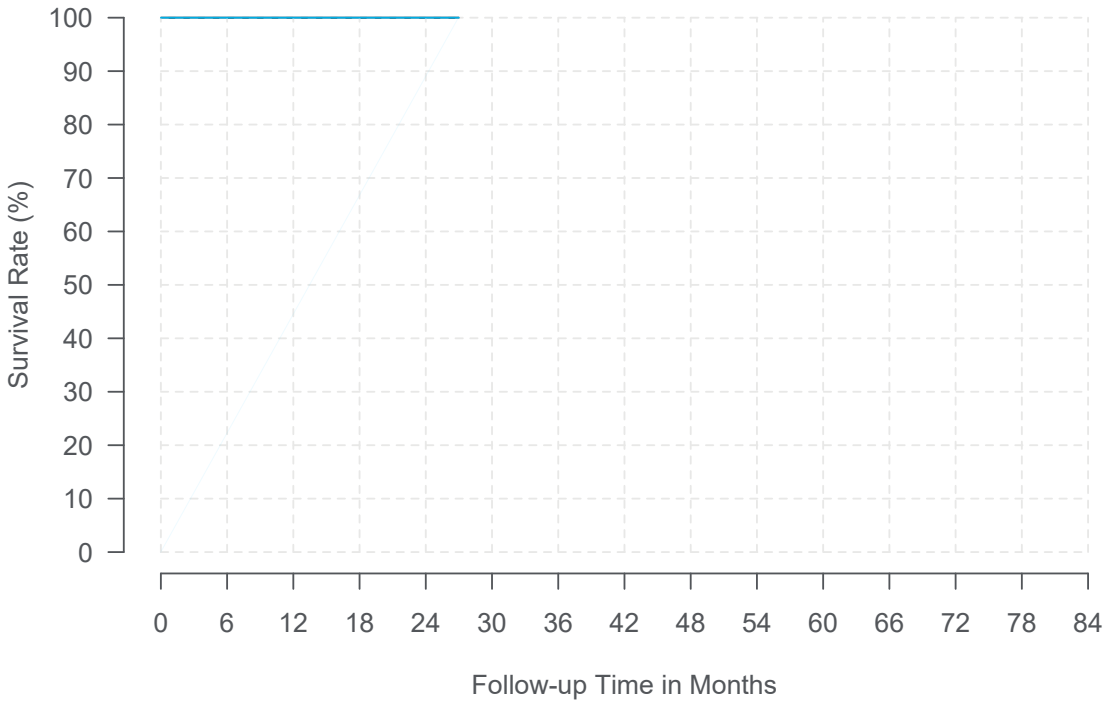
| Time Interval | 16 Years | 17 Years | At 213 Months | | |
|---|---|---|---|---|---|
| Survival (95% CI) | 91.1% (86.6%, 94.1%) | 91.1% (86.6%, 94.1%) | 91.1% (86.6%, 94.1%) | — | — |
| Sample Size | 54 | 36 | 21 | | |

| Specification: 3389 | |
|---|---|
| **Lead** | |
| Length (cm) | 40 |
| Diameter (mm) | 1.27 |
| **Electrode** | |
| Number | 4 |
| Shape | Cylindrical |
| Length (mm) | 1.5 |
| Individual Surface Area ($mm^2$) | 6.0 |
| Inter-Electrode Spacing: Edge to Edge (mm) | 0.5 |
| Array Length (mm) | 7.5 |

| Lead Event: 3389 | N |
|---|---|
| High impedance | 43 |
| Lead migration/dislodgement | 20 |
| Lead fracture | 12 |
| Low impedance | 4 |
| Device material corroded | 2 |
| Medical device complication | 2 |
| Medical device site infection | 2 |
| Device lead issue | 1 |
| Lead insulation failure | 1 |
| **Total** | **87** |

### 5.4.2.3 Model 3391

| | |
|---|---|
| **Model Name** | 3391 |
| **FDA Approval Date** | February 2009 |
| **Leads Enrolled** | 68 |
| **Leads Currently Active in Study** | 48 |
| **Initial Product Performance Events** | 0 |
| **Median Follow-up Time (Months)** | 29.0 |
| **Cumulative Follow-up Time (Months)** | 2,607 |




| Time Interval | 1 Year | 2 Years | At 27 Months |
|---|---|---|---|
| Survival (95% CI) | 100.0% (NA) | 100.0% (NA) | 100.0% (NA) |
| Sample Size | 38 | 26 | 26 |

| Specification: 3391 | |
|---|---|
| **Lead** | |
| Length (cm) | 40 |
| Diameter (mm) | 1.27 |
| **Electrode** | |
| Number | 4 |
| Shape | Cylindrical |
| Length (mm) | 3.0 |
| Individual Surface Area ($mm^2$) | 12 |
| Inter-Electrode Spacing: Edge to Edge (mm) | 4.0 |
| Array Length (mm) | 24 |

### 5.4.3 Lead Summary

**Table 5.13:** Deep Brain Stimulation Lead Characteristics

| Model Name | FDA Approval Date | Leads Enrolled | Leads Active | Initial Product Performance Events | Median Follow-up Time (Months) | Cumulative Follow-up Time (Months) |
|---|---|---|---|---|---|---|
| 3387 | July 1997 | 2,269 | 1,144 | 43 | 36.3 | 97,797 |
| 3389 | September 1999 | 2,935 | 1,483 | 87 | 44.7 | 138,874 |
| 3391 | February 2009 | 68 | 48 | 0 | 29.0 | 2,607 |

**Table 5.14:** Deep Brain Stimulation Lead Survival Probability (95% Confidence Intervals)

| Model Name | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| 3387 | 99.0% (98.4%, 99.4%) | 98.9% (98.2%, 99.3%) | 98.5% (97.7%, 99.0%) | 98.0% (97.1%, 98.7%) | 97.5% (96.5%, 98.3%) |
| 3389 | 98.3% (97.7%, 98.8%) | 97.9% (97.1%, 98.4%) | 97.3% (96.5%, 98.0%) | 96.5% (95.5%, 97.3%) | 96.0% (95.0%, 96.9%) |
| 3391 | 100.0% (NA) | 100.0% (NA) | — | — | — |

| Model Name | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|
| 3387 | 97.4% (96.3%, 98.2%) | 97.2% (96.0%, 98.0%) | 96.6% (95.1%, 97.7%) | 96.6% (95.1%, 97.7%) | 96.1% (94.1%, 97.4%) |
| 3389 | 95.6% (94.5%, 96.5%) | 94.9% (93.6%, 96.0%) | 93.6% (91.8%, 94.9%) | 93.6% (91.8%, 94.9%) | 93.2% (91.2%, 94.7%) |
| 3391 | — | — | — | — | — |

| Model Name | 11 Years | 12 Years | 13 Years | 14 Years | 15 Years |
|---|---|---|---|---|---|
| 3387 | 95.3% (92.3%, 97.1%) | 95.3% (92.3%, 97.1%) | 93.7% (88.5%, 96.6%) | 90.2% (82.1%, 94.7%) | 90.2% (82.1%, 94.7%) |
| 3389 | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) | 92.7% (90.4%, 94.4%) |
| 3391 | — | — | — | — | — |

| Model Name | 16 Years | 17 Years | | | |
|---|---|---|---|---|---|
| 3387 | 90.2% (82.1%, 94.7%) | — | — | — | — |
| 3389 | 91.1% (86.6%, 94.1%) | 91.1% (86.6%, 94.1%) | — | — | — |
| 3391 | — | — | — | — | — |

## 5.5 Extensions

From July 2009 to the report cut-off date of October 31, 2022, there were 5,657 extensions followed in the registry. The difference between the total number of extensions (n=5,657) versus neurostimulators (n=5,212) is due to some patients implanted with more than 1 extension or subsequently re-implanted with an extension. The aggregate prospective follow-up time for all extensions was 236,127 months (19,677 years). Table 5.15 provides the number and percentage of extensions by model.

**Table 5.15:** Deep Brain Stimulation Extension Counts by Model

| Model Name | N (%) |
|---|---|
| **Currently manufactured** | |
| 37085/37086 (quadripolar stretch) | 4,735 (83.7%) |
| SenSight B34000/B34000M | 309 (5.5%) |
| **No longer manufactured** | |
| 7482[b] (quadripolar) | 491 (8.7%) |
| Other/Unspecified[a] | 122 (2.2%) |
| **Total** | **5,657 (100%)** |

[a] Includes extensions for other legacy stimulation systems.
[b] Includes Models 7482 and 7482a.

### 5.5.1 Extension Events

Of the total of 479 product performance-related events, there were 96 product performance-related events with an underlying reported etiology related to extension function. This includes 92 events with an extension etiology and 4 events with both an extension and other etiology (including device and non-device etiologies). Of these, 82 were the initial product performance event that affected extension survival estimates.

Events of other/unspecified models and discontinued models are not shown.

For the purposes of survival analysis, a device's follow-up time is cut-off for one of three reasons: 1) the occurrence of a product performance-related event; 2) the occurrence of a censoring event; or 3) the device is event-free and censored at the patient's last follow-up prior to the data cut-off. For extensions:

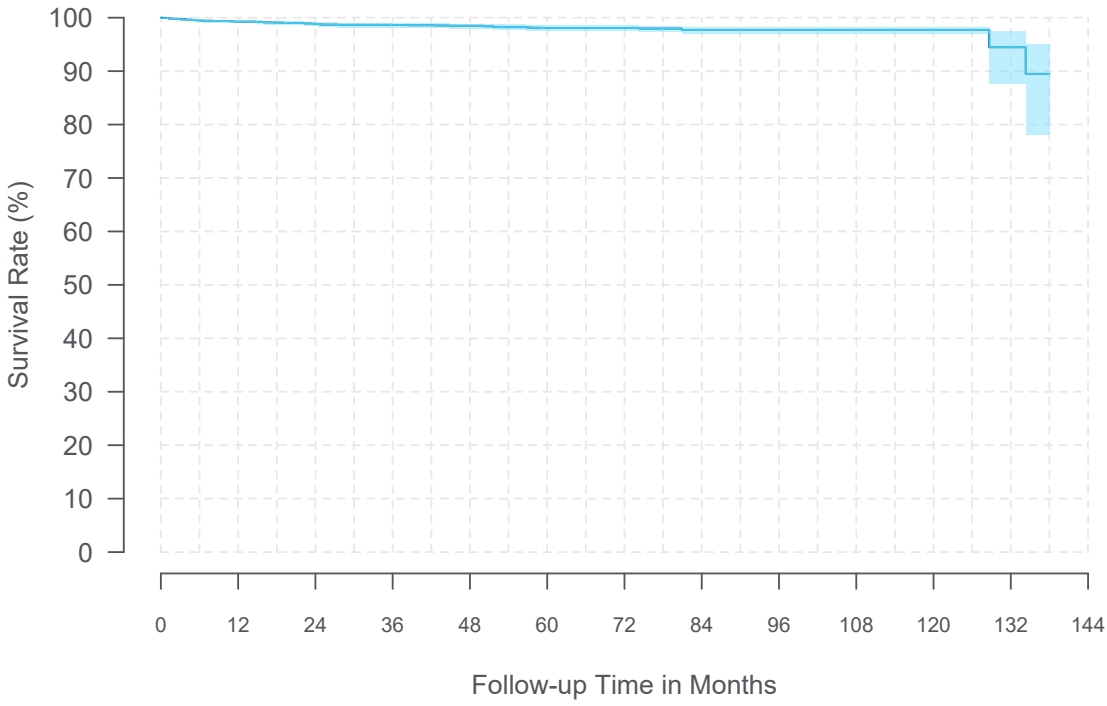
- 82 had follow-up time cut-off due to product performance-related events.
- 2,620 were censored in the survival analysis for the following reasons: patient expired, neurostimulator explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.
- 2,955 were free from product performance-related events and censoring events, and were censored at the last follow-up visit prior to the report cut-off.

### 5.5.2 Extension Models

The following figures and tables represent extension survival and 95% confidence intervals where at least 20 extensions contributed to each 3-month interval.

### 5.5.2.1 Model 37085/37086

| | |
|---|---|
| **Model Name** | 37085/37086 |
| **FDA Approval Date** | March 2009/February 2012 |
| **Extensions Enrolled** | 4,735 |
| **Extensions Currently Active in Study** | 2,471 |
| **Initial Product Performance Events** | 68 |
| **Median Follow-up Time (Months)** | 37.6 |
| **Cumulative Follow-up Time (Months)** | 203,009 |

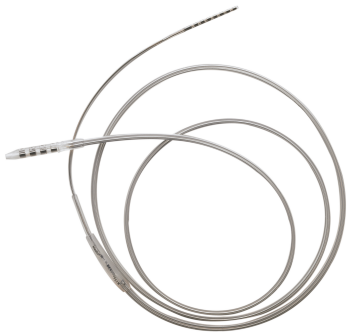


| Time Interval | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 99.2% (98.9%, 99.5%) | 98.9% (98.4%, 99.2%) | 98.6% (98.2%, 99.0%) | 98.5% (98.0%, 98.9%) | 98.1% (97.5%, 98.5%) |
| Sample Size | 3,418 | 2,741 | 2,362 | 2,005 | 1,619 |

| Time Interval | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|
| Survival (95% CI) | 98.1% (97.5%, 98.5%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) |
| Sample Size | 1,143 | 722 | 418 | 241 | 113 |

| Time Interval | 11 Years | At 138 Months | | | |
|---|---|---|---|---|---|
| Survival (95% CI) | 94.5% (87.7%, 97.6%) | 89.5% (78.1%, 95.1%) | — | — | — |
| Sample Size | 44 | 24 | | | |

| Specification: 37085/37086 | |
|---|---|
| **Device Name** | Stretch-Coil Extension |
| **Length (cm)** | 40, 60, 95 |
| **Distal End Compatibility** | 3387, 3389, or 3391 lead |
| **Distal End Set Screws** | 4 |
| **Proximal End INS Compatibility** | Activa RC, Activa PC, Activa SC, or Percept PC |



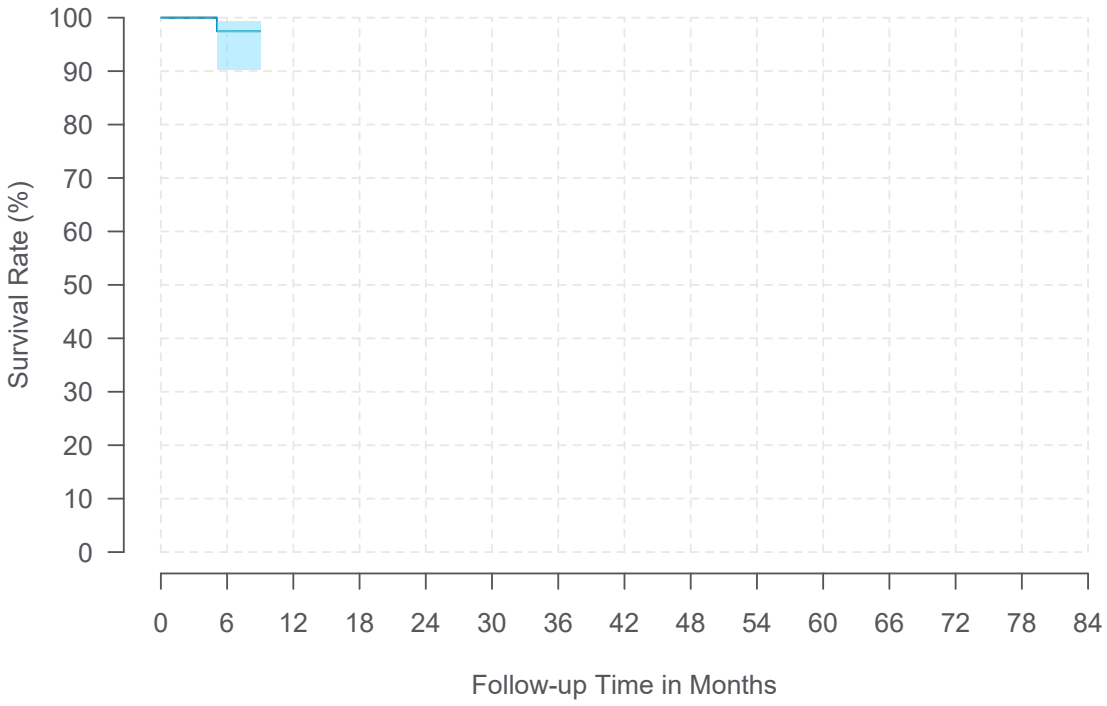
| Extension Event: 37085/37086 | Total |
|---|---|
| High impedance | 27 |
| Extension migration | 15 |
| Extension fracture | 8 |
| Low impedance | 4 |
| Medical device complication | 4 |
| Device protrusion | 3 |
| Device electrical finding[a] | 2 |
| Electric shock sensation | 2 |
| Device malfunction | 1 |
| Dystonia[b] | 1 |
| Lead migration/dislodgement | 1 |
| **Total Extension Events** | **68** |

[a] Open circuit contact.

[b] Device recharging process issue.

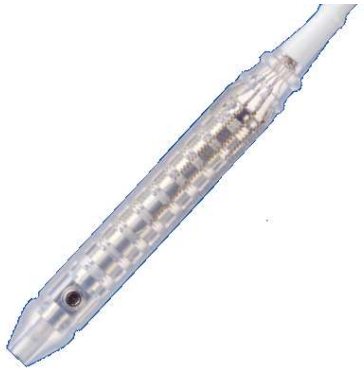
### 5.5.2.2 Model B34000/B34000M

| | |
|---|---|
| **Model Name** | B34000/B34000M |
| **FDA Approval Date** | May 2021 |
| **Extensions Enrolled** | 309 |
| **Extensions Currently Active in Study** | 290 |
| **Initial Product Performance Events** | 2 |
| **Median Follow-up Time (Months)** | 1.2 |
| **Cumulative Follow-up Time (Months)** | 922 |




| Time Interval | 6 Months | 9 Months |
|---|---|---|
| Survival (95% CI) | 97.5% (90.3%, 99.4%) | 97.5% (90.3%, 99.4%) |
| Sample Size | 62 | 33 |

| Specification: B34000/B34000M | |
|---|---|
| **Device Name** | SenSight Extension Kit |
| **Length (cm)** | 40, 60, 95 |
| **Distal End Compatibility** | B33005, or B33015 Lead |
| **Distal End Set Screws** | 1 |
| **Proximal End INS Compatibility** | Activa RC, Percept PC , or Percept RC |



| Extension Event: B34000/B34000M | Total |
|---|---|
| Extension migration | 2 |
| **Total Extension Events** | **2** |

### 5.5.3 Extension Summary

**Table 5.16:** Deep Brain Stimulation Extension Characteristics

| Model/Name | FDA Approval Date | Extensions Enrolled | Extensions Active | Initial Product Performance Events | Median Follow-up Time (Months) | Cumulative Follow-up Time (Months) |
|---|---|---|---|---|---|---|
| 37085/37086 | March 2009 | 4,735 | 2,471 | 68 | 37.6 | 203,009 |
| B34000/B34000M | May 2021 | 309 | 290 | 2 | 1.2 | 922 |

**Table 5.17:** Deep Brain Stimulation Extension Survival Probability (95% Confidence Intervals)

| Model Name | 1 Year | 2 Years | 3 Years | 4 Years | 5 Years |
|---|---|---|---|---|---|
| 37085/37086 | 99.2% (98.9%, 99.5%) | 98.9% (98.4%, 99.2%) | 98.6% (98.2%, 99.0%) | 98.5% (98.0%, 98.9%) | 98.1% (97.5%, 98.5%) |
| B34000/B34000M | — | — | — | — | — |

| Model Name | 6 Years | 7 Years | 8 Years | 9 Years | 10 Years |
|---|---|---|---|---|---|
| 37085/37086 | 98.1% (97.5%, 98.5%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) | 97.7% (97.0%, 98.3%) |
| B34000/B34000M | — | — | — | — | — |

| Model Name | 11 Years | | | | |
|---|---|---|---|---|---|
| 37085/37086 | 94.5% (87.7%, 97.6%) | — | — | — | — |
| B34000/B34000M | — | — | — | — | — |