

PRODUCT PERFORMANCE REPORT

SUMMARY OF DATA
FROM THE MEDTRONIC
POST-MARKET
REGISTRY

2025

v.1.0 22Jun2026

Medtronic
Further, Together

Contents

5	Deep Brain Stimulation Systems.....	3
5.1	Study Participants	3
5.1.1	Centers.....	3
5.1.2	Patients	3
5.2	Event Summary	5
5.2.1	Product Performance Events	6
5.2.2	Clinical Events Not Related to Product Performance	9
5.2.3	Patient Deaths	11
5.3	Neurostimulators.....	11
5.3.1	Neurostimulator Events	13
5.3.2	Neurostimulator Models.....	14
5.3.2.1	Model Activa™ PC 37601	15
5.3.2.2	Model Activa™ SC 37602	17
5.3.2.3	Model Activa™ SC 37603	19
5.3.2.4	Model Activa™ RC 37612	21
5.3.2.5	Model Percept™ PC B35200	23
5.3.2.6	Model Percept™ RC B35300	25
5.3.3	Neurostimulator Summary	25
5.4	Leads	28
5.4.1	Lead Events	28
5.4.2	Lead Models	29
5.4.2.1	Model 3387.....	30
5.4.2.2	Model 3389.....	32
5.4.2.3	Model 3391.....	34
5.4.2.4	Model SenSight™ B33005.....	36
5.4.2.5	Model SenSight™ B33015.....	38
5.4.3	Lead Summary	40
5.5	Extensions.....	43
5.5.1	Extension Events.....	43
5.5.2	Extension Models.....	44
5.5.2.1	Model 37085/37086.....	45
5.5.2.2	Model B34000/B34000M.....	47
5.5.3	Extension Summary.....	48

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, 2025. Sixty-seven 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.

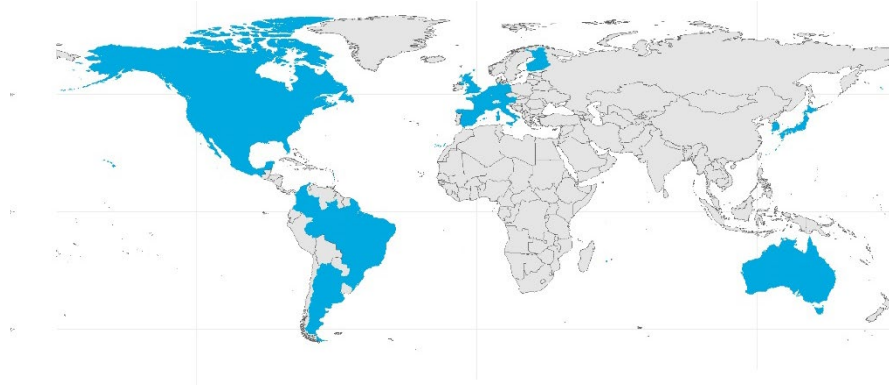


Figure 5.1: Countries with Deep Brain Stimulation Therapy Patients in Registry (Highlighted)

5.1.2 Patients

Of the 4,207 deep brain stimulation patients enrolled, the primary indications for implant were as follows: 64.11% were implanted for the treatment of Parkinson's Disease, 20.11% were implanted for the treatment of essential tremor, 9.29% were implanted for the treatment of dystonia, 1.90% were implanted for the treatment of epilepsy, 1.62% were implanted for the treatment of obsessive compulsive disorder (OCD), 2.47% were implanted for the treatment of other indications, and 0.50% 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](#)).

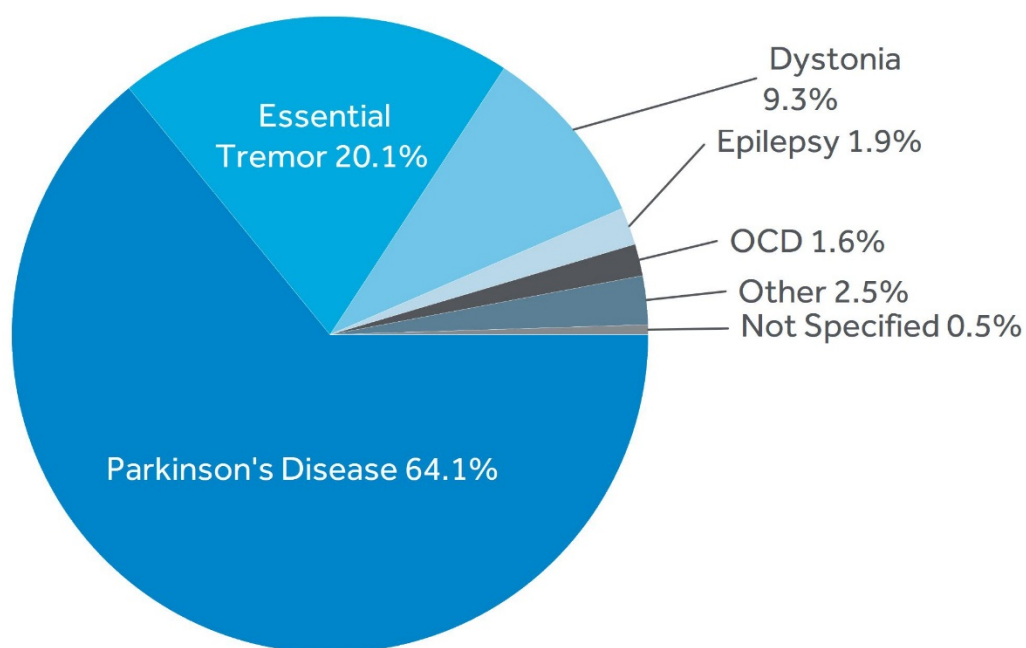


Figure 5.2: Deep Brain Stimulation Primary Treatment Indications

Table 5.1: Deep Brain Stimulation Primary Treatment Indications

Primary Treatment Indication ^a	Enrolled Patients (%)
Parkinson's Disease	2697 (64.11%)
Essential Tremor	846 (20.11%)
Dystonia	391 (9.29%)
Epilepsy	80 (1.90%)
OCD	68 (1.62%)
Other	104 (2.47%)
Not Specified	21 (0.50%)
Total Patients	4207 (100.0%)

^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 (www.medtronic.com/manuals).

5.2 Event Summary

Adverse and device events were reported by the investigational site, where the principal investigator determined the suspected etiology. For device-related events, etiology could be attributed to one or more system components (e.g., neurostimulator, lead, and/or extension). If multiple components were identified as contributing to a single event, a separate product performance event (PPE) was recorded for each implicated component. For example, an event attributed to both the neurostimulator and the lead would be counted as one PPE for the neurostimulator and an additional PPE for the lead. As a result, the total number of PPEs may exceed the number of unique PPEs.

For DBS, there were 636 PPEs (472 unique events) reported in 376 patients between July 2009 and October 31, 2025, in patients with deep brain stimulation systems ([Table 5.2](#)). These events represented 22.8% of the total reported events (636/2,792), occurred in 376 of the 4,207 (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 2,156 reported non-product performance related events, 368 were serious and 1,788 were non-serious. Serious non-product performance related events (n=368) are described in [Table 5.6](#). Non-serious non-product performance related (n=1,788) 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 602 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 (%) ^b N=4207
RPA Determination	3	<0.1	3 (0.07%)
Premature Battery Depletion	3	<0.1	3 (0.07%)
Physician's Determination	633	3.9	374 (8.89%)
High Impedance	310	1.9	185 (4.40%)
Lead Migration/Dislodgement	56	0.3	40 (0.95%)
Low Impedance	42	0.3	26 (0.62%)
Device Malfunction	33	0.2	29 (0.69%)
Lead Fracture	28	0.2	22 (0.52%)
Neurostimulator Unable To Recharge ^c	28	0.2	28 (0.67%)
Extension Migration	23	0.1	12 (0.29%)
Device Electrical Impedance Issue	16	0.1	7 (0.17%)
Extension Fracture	13	0.1	10 (0.24%)
Premature Battery Depletion	12	0.1	12 (0.29%)
Medical Device Complication	9	0.1	6 (0.14%)
Device Breakage	6	<0.1	6 (0.14%)
Unspecified	6	<0.1	6 (0.14%)
Device Charging Issue	4	<0.1	4 (0.10%)
Device Connection Issue	4	<0.1	4 (0.10%)
Device Electrical Finding ^d	4	<0.1	3 (0.07%)
Device End Of Life	4	<0.1	4 (0.10%)
Device Lead Issue	4	<0.1	4 (0.10%)
Device Protrusion	4	<0.1	2 (0.05%)
Neurostimulator Inversion	4	<0.1	4 (0.10%)
Device Damage	2	<0.1	1 (0.02%)

Product Performance Events ^a	Event Counts	Events Per 100 Patient Years	Patients with Events (%) ^b N=4207
Device Lead Damage	2	<0.1	1 (0.02%)
Device Material Corroded	2	<0.1	1 (0.02%)
Device Short Circuiting	2	<0.1	2 (0.05%)
Electromagnetic Interference	2	<0.1	2 (0.05%)
Neurostimulator Migration	2	<0.1	2 (0.05%)
Other ^e	11	0.1	11 (0.26%)
Total	636	3.9	376 (8.94%)

^a Medical Dictionary for Regulatory Activities (MedDRA) Lowest-Level Term (LLT) 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 983 patients that used rechargeable neurostimulators for DBS in the registry. A total of 2.85% (28/983) of patients with a rechargeable neurostimulator experienced a neurostimulator unable to recharge event.

^d Including open circuit contact and electric discharge.

^e Composed of event codes with 1 event each.

A total of 307 (48.3%) of the 636 product performance events were related to the lead, 119 (18.7%) were related to the extension, 111 (17.5%) were related to the neurostimulator, 15 (2.4%) were related to multiple etiologies, which includes events where at least one device and one non-device etiology was indicated, and 84 (13.2%) were related to other etiologies. Other etiologies included: 54 (8.5%) related to other components, 10 (1.6%) related to surgery/anesthesia, 7 (1.1%) related to incisional site/device tract, 6 (0.9%) related to recharging process, 4 (0.6%) related to programming/stimulation, and 3 (0.5%) related to other etiologies (see [Figure 5.4](#)). 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.

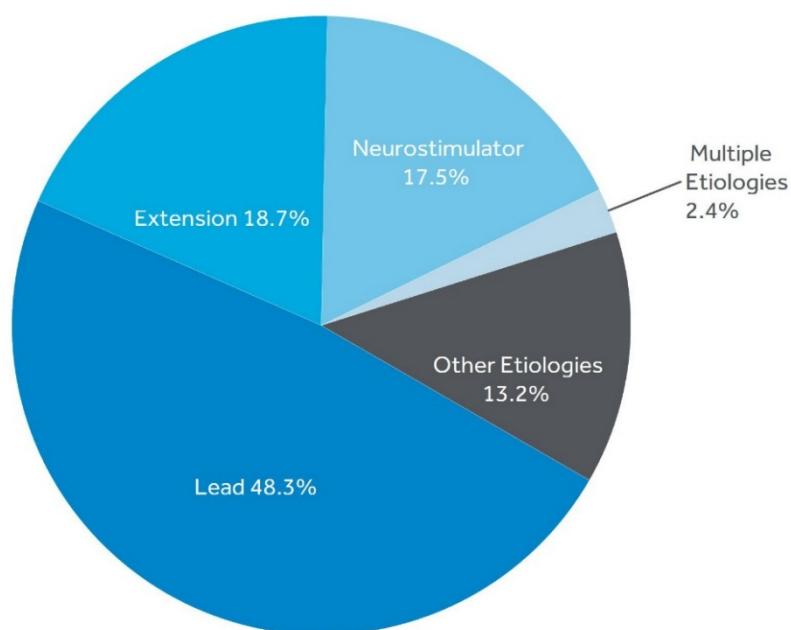


Figure 5.4: Deep Brain Stimulation System Product Performance Events by Relatedness

Table 5.3 and Table 5.4 describe the interventions taken for reported impedance events. In 35.81% and 30.95% of the high and low impedance events, respectively, 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 (58.71% for high impedance and 61.91% for low impedance).

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

Intervention	N (%) of High impedance Events
Device Surgical Intervention	95 (30.65%)
Reprogramming	69 (22.26%)
Other Surgical Intervention	16 (5.16%)
Other Intervention	8 (2.58%)
Medical or Non-Surgical Therapy	5 (1.61%)
Therapy Suspension	3 (0.97%)
Medication	1 (0.32%)
No Action Taken	113 (36.45%)
Total	310 (100.00%)

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

Intervention	N (%) of Low impedance Events
Device Surgical Intervention	13 (30.95%)
Reprogramming	10 (23.81%)
Medication	2 (4.76%)
Other Intervention	1 (2.38%)
No Action Taken	16 (38.10%)
Total	42 (100.00%)

Table 5.5 describes the interventions taken for reported lead migration/dislodgement events over the total of 4,207 patients enrolled. 76.78% of reported lead migration/dislodgement events resulted in a surgical intervention and 14.29% resulted in reprogramming.

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

Intervention	N (%) of Lead Migration/Dislodgement Events
Device Surgical Intervention	41 (73.21%)
Reprogramming	8 (14.29%)
Other Surgical Intervention	2 (3.57%)
Therapy Suspension	1 (1.79%)
No Action Taken	4 (7.14%)
Total	56 (100.00%)

* Considering "dislodgment" as an observation, not confirmed by imaging.

5.2.2 Clinical Events Not Related to Product Performance

The clinical events not related to product performance (see table 5.6) are summarized if:

- The patient was enrolled in the PSR since 2013, the year in which the clinical event collection was initiated (N=3,024).
- Categorized as serious adverse events (SAEs, N=368).
- 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 DBS therapy relevant events (e.g. Negative changes in behavior from baseline, new or worsening depression, attempted suicide, etc.) are collected to facilitate complete and

consistent related event reporting.

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

Event Type ^a	Number of SAE	Patients with SAE n (%) N=3,024	SAE Per 100 Patient Months	Patients with SAE Requiring Surgical Intervention n (%) N=3,024
Infections and infestations	135	112 (3.70%)	0.11	105 (3.47%)
Infections - pathogen unspecified	132	109 (3.60%)	0.10	103 (3.41%)
Other ^b	3	3 (0.10%)	<0.01	2 (0.07%)
Nervous system disorders	81	74 (2.45%)	0.06	20 (0.66%)
Central nervous system vascular disorders	24	24 (0.79%)	0.02	4 (0.13%)
Movement disorders (incl parkinsonism)	21	19 (0.63%)	0.02	5 (0.17%)
Neurological disorders NEC	16	16 (0.53%)	0.01	6 (0.20%)
Seizures (incl subtypes)	10	10 (0.33%)	0.01	2 (0.07%)
Increased intracranial pressure and hydrocephalus	5	5 (0.17%)	<0.01	1 (0.03%)
Other ^b	5	5 (0.17%)	<0.01	2 (0.07%)
General disorders and administration site conditions	72	68 (2.25%)	0.06	49 (1.62%)
Complications associated with device	54	52 (1.72%)	0.04	41 (1.36%)
General system disorders NEC	9	9 (0.30%)	0.01	2 (0.07%)
Other ^b	9	9 (0.30%)	0.01	7 (0.23%)
Other SOC Terms (<1.0% Threshold)	80	78 (2.58%)	0.06	36 (1.19%)
Total	368	296 (9.79%)	0.29	190 (6.28%)

^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 602 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, of the 4,207 enrolled patients, there have been 477 deaths reported in this patient registry study based upon patients receiving therapy for Parkinson's Disease, 89 for essential tremor, 18 for dystonia, 5 for epilepsy, 2 for OCD, and 11 for other indications (see [Table 5.7](#)).

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

Primary Indication ^a	N (%) of Deaths ^b	Mean Age of Death in Years
Parkinson's Disease	477 (79.2%)	74.1
Essential Tremor	89 (14.8%)	78.2
Dystonia	18 (3.0%)	61.3
Epilepsy	5 (0.8%)	23.1
OCD	2 (0.3%)	72.4
Other	11 (1.8%)	61.7
Total	602	74.3

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

^b The percentage is based upon the total patient death events per distribution group (indication) and not based upon the rate of occurrence among all enrolled patients

5.3 Neurostimulators

From July 2009 to the report cut-off date of October 31, 2025, there were 6,749 neurostimulators followed in the registry. The difference between the total number of patients (n=4,207) versus the number of neurostimulators (n=6,749) 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 209,393 months (17,449 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™ (model 37601)	2785 (41.3%)
Percept PC™ (model B35200)	1426 (21.1%)
Activa RC™ (model 37612)	1005 (14.9%)
Activa SC™ (model 37603)	708 (10.5%)
Activa SC™ (model 37602)	474 (7.0%)
Percept RC™ (model B35300)	231 (3.4%)
No longer manufactured	
Solettra™ (model 7426)	67 (1.0%)
Kinetra™ (model 7428)	13 (0.2%)
Other/Unspecified^a	40 (0.6%)
Total	6749

^a Other includes Activa™ PC+S and non-Activa™ systems used for DBS.

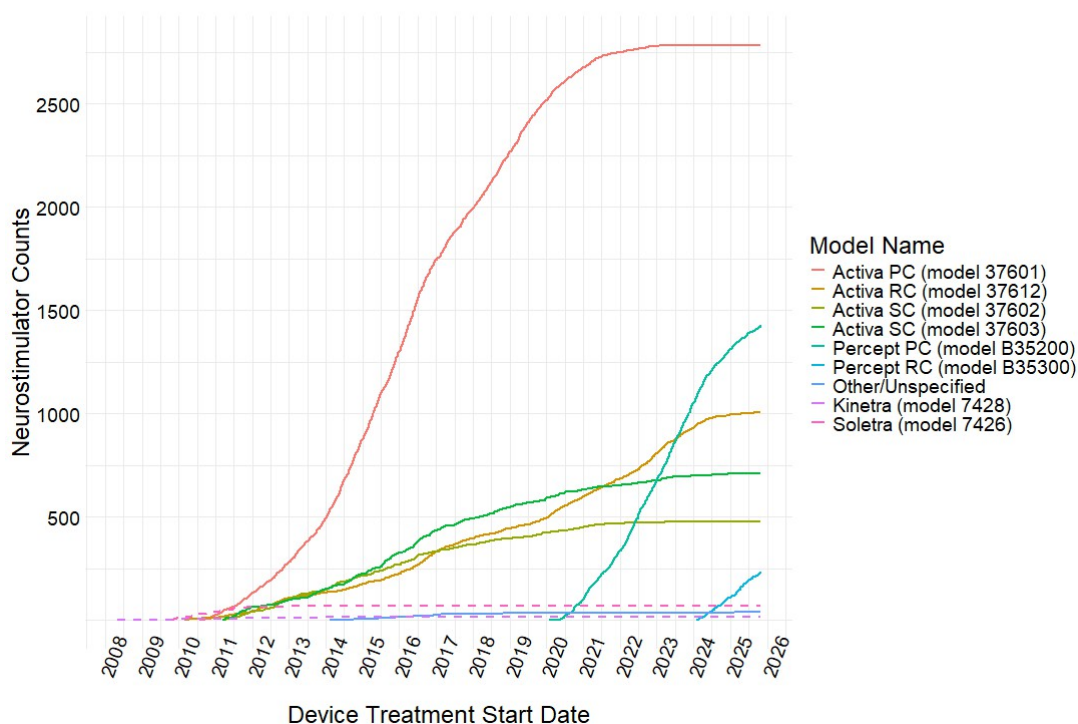


Figure 5.5: Cumulative Neurostimulator Counts by model over time

5.3.1 Neurostimulator Events

Of the total of 636 product performance-related events, there were 113 product performance-related events with an underlying reported etiology related to neurostimulator function. This includes 111 events with a neurostimulator etiology and 2 events with both a neurostimulator and other etiology (including device and non-device etiologies). Of these, 80 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 3.4% (106/3136). 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 113 neurostimulator events, 97.35% (110/113) 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 (2.7%)
Premature Battery Depletion	3 (2.7%)
Physician's Determination	110 (97.3%)
High Impedance	54 (47.8%)
Device Malfunction	14 (12.4%)
Premature Battery Depletion	12 (10.6%)
Low Impedance	8 (7.1%)
Device End Of Life ^a	4 (3.5%)
Device Electrical Impedance Issue	2 (1.8%)
Electromagnetic Interference	2 (1.8%)
Extension Migration	2 (1.8%)
Device Computer Software Issue	1 (0.9%)
Device Connection Issue	1 (0.9%)
Device Electrical Finding ^b	1 (0.9%)
Device Issue	1 (0.9%)
Device Protrusion	1 (0.9%)

Product Performance Events	N (%)
Device Short Circuiting	1 (0.9%)
Device Vibration	1 (0.9%)
Neurostimulator Inversion	1 (0.9%)
Neurostimulator Migration	1 (0.9%)
Neurostimulator Unable To Recharge	1 (0.9%)
No Adverse Event	1 (0.9%)
Unspecified	1 (0.9%)
Total	113 (100%)

^a Battery's life expectancy

^b 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:

- 80 had follow-up time cut-off due to product performance-related events.
- 4,827 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.
- 1,842 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.

Initial product performance events of other/unspecified models (n=1) are not summarized in the subsequent sections.

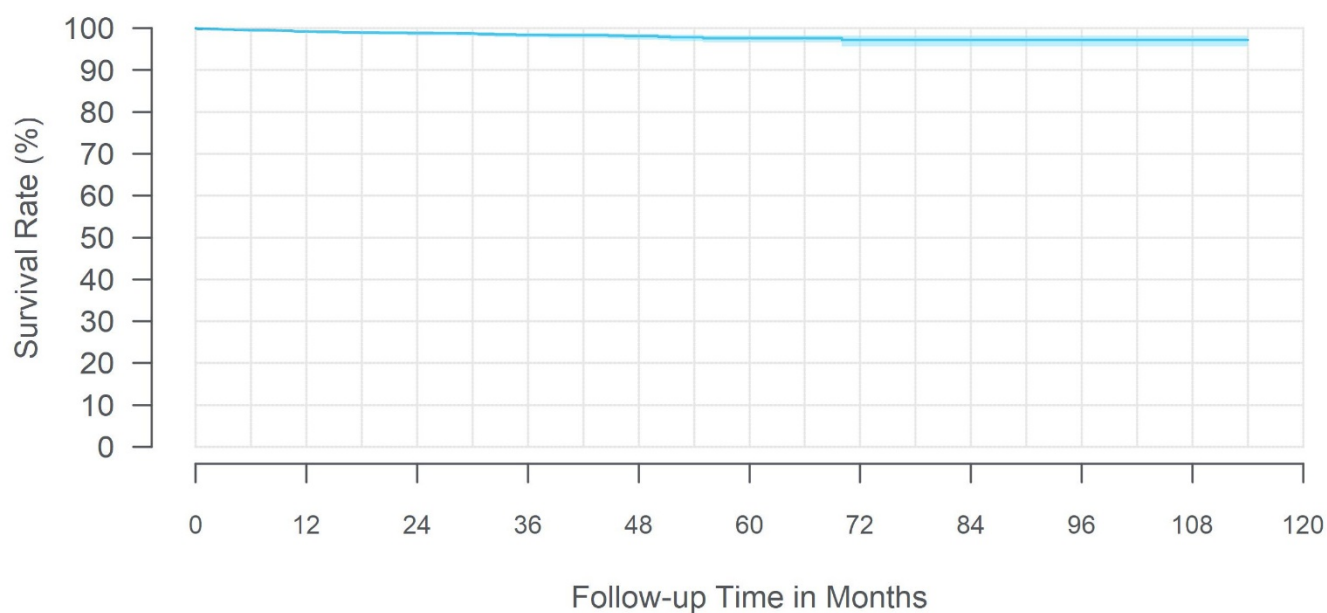
5.3.2 Neurostimulator Models

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 fact that there are no more active devices in PSR. For information on survival for those models, please refer to past reports.

5.3.2.1 Model Activa™ PC 37601

Model Name	Activa™ PC
FDA Approval Date	April 2009
Neurostimulators Enrolled	2,785
Neurostimulators Currently Active in Study	144
Initial Product Performance Events	46
Median Follow-up Time (Months)	33.6
Cumulative Follow-up Time (Months)	100,691



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (98.8%, 99.5%)	98.9% (98.4%, 99.2%)	98.4% (97.8%, 98.9%)	98.1% (97.4%, 98.7%)	97.7% (96.7%, 98.4%)
Sample Size	2321	1850	1272	775	417

Time Interval	6 Years	7 Years	8 Years	9 Years	At 114 Months
Survival (95% CI)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)	97.2% (95.7%, 98.2%)
Sample Size	192	98	53	28	22

Specification: Activa™ PC (model 37601)	
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
Number of Channels	2
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	16 (up to 4 per group)



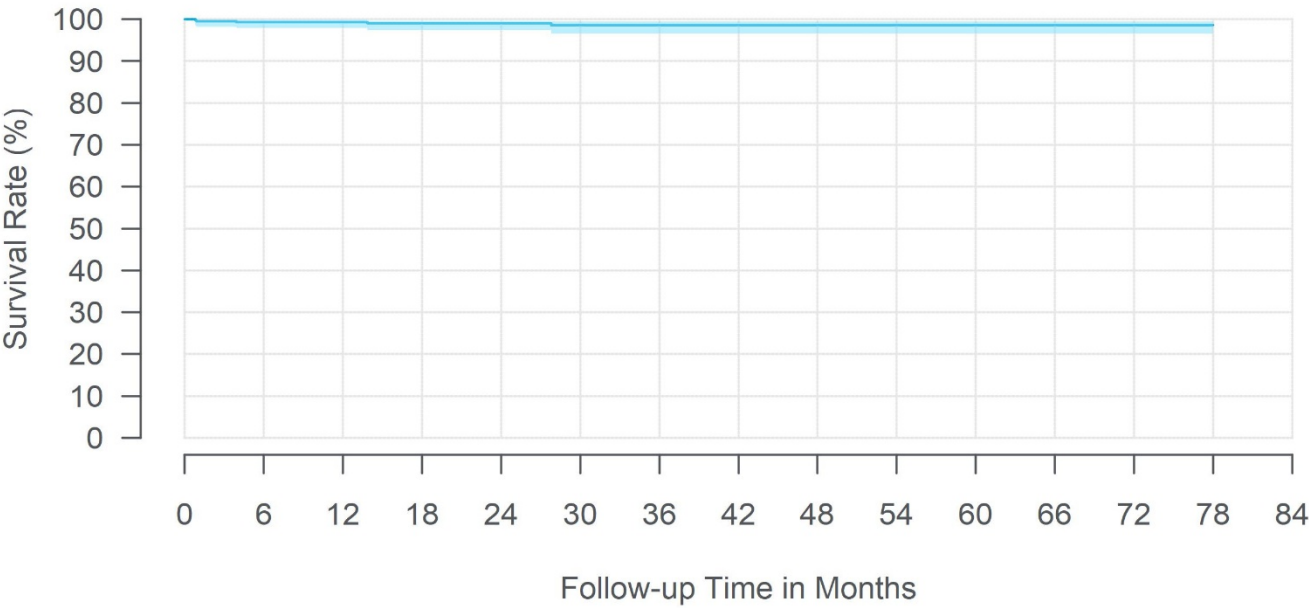
Neurostimulator Event Summary: Activa PC	N
High Impedance	19
Premature Battery Depletion	13
Device Malfunction	6
Device End Of Life	3
Device Electrical Finding ^a	1
Device Protrusion	1
Electromagnetic Interference	1
Low Impedance	1
No Adverse Event	1
Total	46

^a Open circuit contact

5.3.2.2 Model Activa™ SC 37602

Model Name	Activa™ SC (model 37602)
FDA Approval Date	January 2011
Neurostimulators Enrolled	474*
Neurostimulators Currently Active in Study	30
Initial Product Performance Events	5
Median Follow-up Time (Months)	27.2
Cumulative Follow-up Time (Months)	14,458

* Note: there is one less neurostimulator enrolled than reported in the 2024 Product Performance Report. This change is due to a single subject having two procedure forms entered. On October 21, 2025, the site deleted one of the procedure CRFs, citing it as a duplicate entry.



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.3% (97.9%, 99.8%)	99.0% (97.5%, 99.6%)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)
Sample Size	366	265	157	89	49

Time Interval	6 Years	At 78 Months
Survival (95% CI)	98.6% (96.6%, 99.4%)	98.6% (96.6%, 99.4%)
Sample Size	27	21

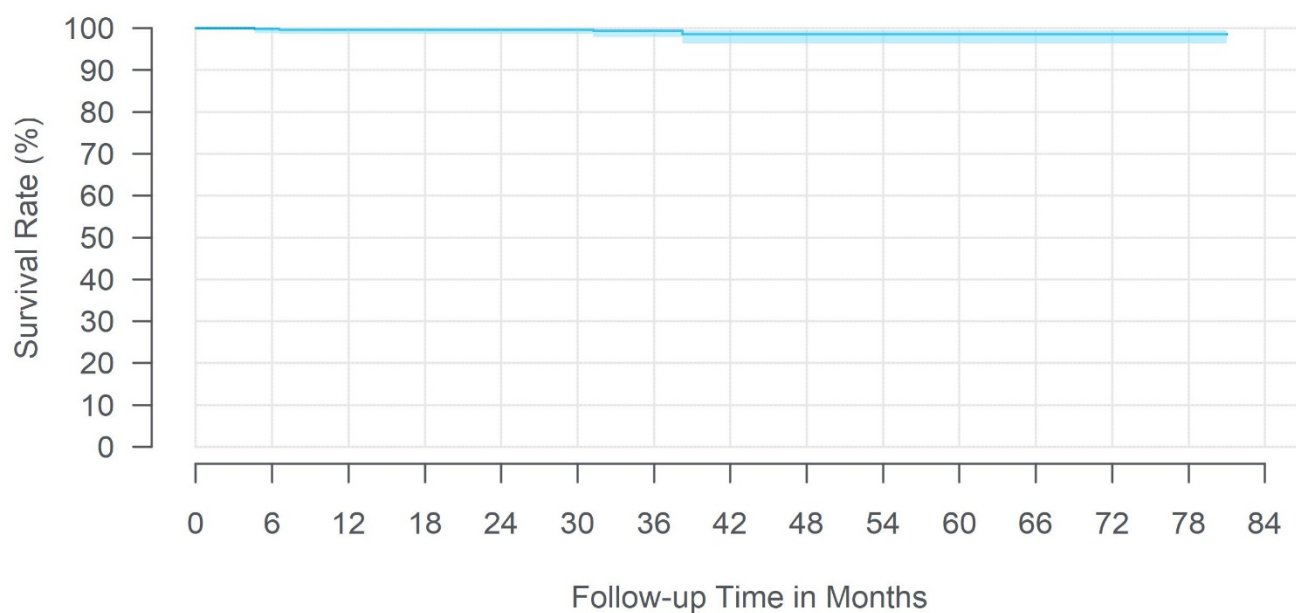
Specification: Activa™ SC (model 37602)	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	4
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	8 (up to 2 per group)



Neurostimulator Event Summary: Activa SC (model 37602)		N
High Impedance		2
Device Short Circuiting		1
Low Impedance		1
Premature Battery Depletion		1
Total		5

5.3.2.3 Model Activa™ SC 37603

Model Name	Activa™ SC (model 37603)
FDA Approval Date	January 2011
Neurostimulators Enrolled	708
Neurostimulators Currently Active in Study	57
Initial Product Performance Events	6
Median Follow-up Time (Months)	28.7
Cumulative Follow-up Time (Months)	22,485



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.7% (98.7%, 99.9%)	99.7% (98.7%, 99.9%)	99.4% (98.0%, 99.8%)	98.6% (96.4%, 99.4%)	98.6% (96.4%, 99.4%)
Sample Size	568	431	275	142	66

Time Interval	6 Years	At 81 Months
Survival (95% CI)	98.6% (96.4%, 99.4%)	98.6% (96.4%, 99.4%)
Sample Size	37	21

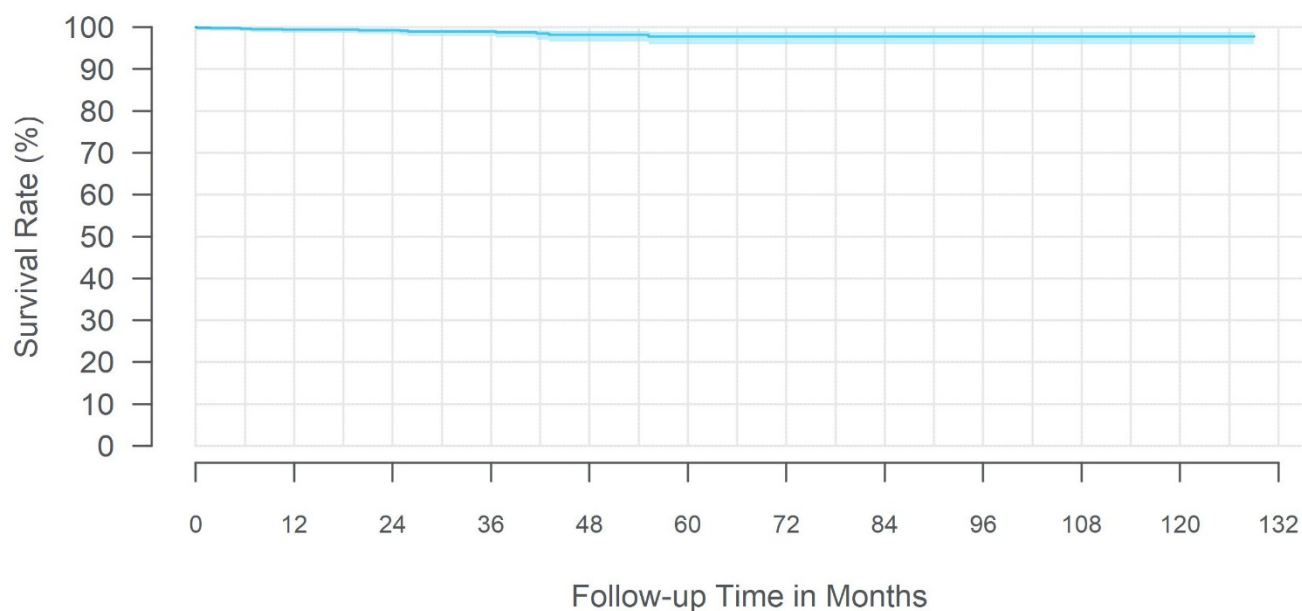
Specification: Activa™ SC (model 37603)	
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	27 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Number of Channels	2
Maximum Electrodes	4
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec
Groups	4
Programs	8 (up to 2 per group)



Neurostimulator Event Summary: Activa SC (model 37603)		N
High Impedance		5
Low Impedance		1
Total		6

5.3.2.4 Model Activa™ RC 37612

Model Name	Activa™ RC
FDA Approval Date	March 2009
Neurostimulators Enrolled	1005
Neurostimulators Currently Active in Study	486
Initial Product Performance Events	14
Median Follow-up Time (Months)	32.5
Cumulative Follow-up Time (Months)	41,924



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.5% (98.7%, 99.8%)	99.3% (98.5%, 99.7%)	99.0% (98.0%, 99.5%)	98.2% (96.6%, 99.0%)	97.8% (95.9%, 98.8%)
Sample Size	837	634	431	301	224

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)	97.8% (95.9%, 98.8%)
Sample Size	182	149	102	56	30

Time Interval	At 129 Months
Survival (95% CI)	97.8% (95.9%, 98.8%)
Sample Size	22

Specification: Activa™ RC

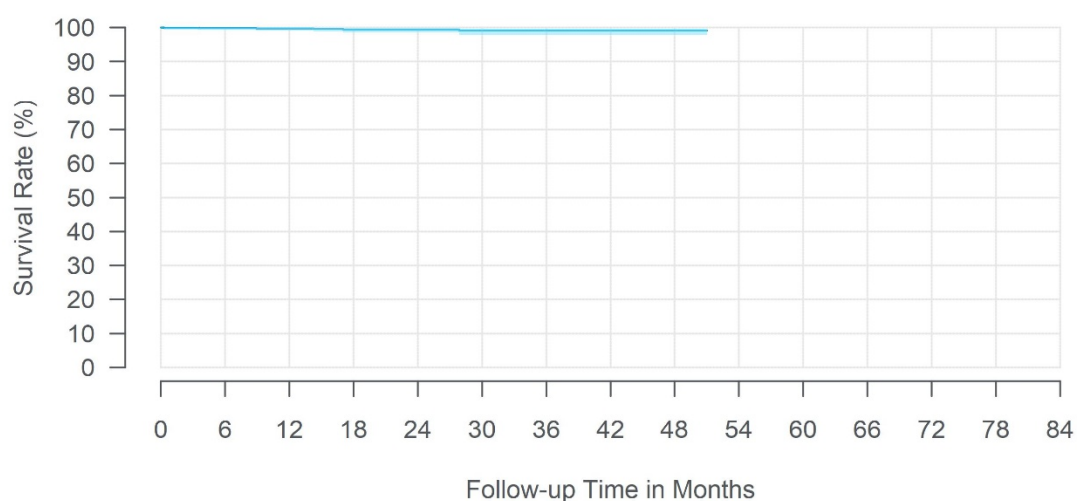
Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	8
Amplitude	0 - 10.5 V (voltage mode) 0 - 25.5 mA (current mode)
Rate	2 - 250 Hz (voltage mode) 30 - 250 Hz (current mode)
Pulse Width	60 - 450 µsec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



Neurostimulator Event Summary: Activa RC	N
High Impedance	4
Device Malfunction	2
Extension Migration	2
Device Computer Software Issue	1
Device Connection Issue	1
Low Impedance	1
Neurostimulator Inversion	1
Neurostimulator Migration	1
Neurostimulator Unable To Recharge	1
Total	14

5.3.2.5 Model Percept™ PC B35200

Model Name	Percept™ PC
FDA Approval Date	June 2020
Neurostimulators Enrolled	1,426
Neurostimulators Currently Active in Study	902
Initial Product Performance Events	8
Median Follow-up Time (Months)	14.8
Cumulative Follow-up Time (Months)	25,279



Time Interval	1 Year	2 Years	3 Years	4 Years	At 51 Months
Survival (95% CI)	99.7% (99.2%, 99.9%)	99.5% (98.6%, 99.8%)	99.1% (97.8%, 99.7%)	99.1% (97.8%, 99.7%)	99.1% (97.8%, 99.7%)
Sample Size	867	412	164	39	25

**Specification: Percept™ PC
(model B353200)**

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
Number of Channels	2
Maximum Electrodes	16 Electrodes (8 per channel)
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 Summary: Percept PC	N
High Impedance	4
Device Malfunction	2
Premature Battery Depletion	1
Unspecified	1
Total	8

5.3.2.6 Model Percept™ RC B35300

Model Name	Percept™ RC
FDA Approval Date	January 2024
Neurostimulators Enrolled	231
Neurostimulators Currently Active in Study	223
Initial Product Performance Events	0
Median Follow-up Time (Months)	1.2
Cumulative Follow-up Time (Months)	806

There is not sufficient data to report on Percept™ RC (model B35300) survival at 1 year or later and there have been no reported product performance events for this model as of the data cut-off date.

Specification: Percept™ RC (model B35300)	
Height	57 mm
Width	47 mm
Thickness	6 mm
Volume	13.77 cm ³
Battery type	Rechargeable
Expected Battery life	15 years before ERI*
Number of Channels	2
Maximum Electrodes	16 Electrodes (8 per channel)
Amplitude	0 to 25.5 mA
Rate	2 to 250 Hz
Pulse Width	20 to 450 µsec
Groups	4
Programs	16
Implant Depth	≤ 4cm

*ERI: Elective Replacement Indicator



5.3.3 Neurostimulator Summary

Table 5.10: Deep Brain Stimulation Neurostimulator Characteristics

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
Activa PC (model 37601)	April 2009	2,785	144	46	33.6	100,691
Activa SC (model	January	474	30	5	27.2	14,458

Model Name	FDA Approval Date	Neurostimulators Enrolled	Neurostimulators Active	Initial Product Performance Events	Median Follow-up Time (Months)	Cumulative Follow-up Time (Months)
37602)	2011					
Activa SC (model 37603)	January 2011	708	57	6	28.7	22,485
Activa RC (model 37612)	March 2009	1,005	486	14	32.5	41,924
Percept PC (model B35200)	June 2020	1,426	902	8	14.8	25,279
Percept RC (model B35300)	January 2024	231	223	0	1.2	806

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

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Activa PC (model 37601)	99.3%	98.9%	98.4%	98.1%	97.7%
	(98.8%, 99.5%)	(98.4%, 99.2%)	(97.8%, 98.9%)	(97.4%, 98.7%)	(96.7%, 98.4%)
Activa SC (model 37602)	99.3%	99.0%	98.6%	98.6%	98.6%
	(97.9%, 99.8%)	(97.5%, 99.6%)	(96.6%, 99.4%)	(96.6%, 99.4%)	(96.6%, 99.4%)
Activa SC (model 37603)	99.7%	99.7%	99.4%	98.6%	98.6%
	(98.7%, 99.9%)	(98.7%, 99.9%)	(98.0%, 99.8%)	(96.4%, 99.4%)	(96.4%, 99.4%)
Activa RC (model 37612)	99.5%	99.3%	99.0%	98.2%	97.8%
	(98.7%, 99.8%)	(98.5%, 99.7%)	(98.0%, 99.5%)	(96.6%, 99.0%)	(95.9%, 98.8%)
Percept PC (model	99.7%	99.5%	99.1%	99.1%	

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
B35200)					
	(99.2%, 99.9%)	(98.6%, 99.8%)	(97.8%, 99.7%)	(97.8%, 99.7%)	

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Activa PC (model 37601)	97.2%	97.2%	97.2%	97.2%	
	(95.7%, 98.2%)	(95.7%, 98.2%)	(95.7%, 98.2%)	(95.7%, 98.2%)	
Activa SC (model 37602)	98.6%				
	(96.6%, 99.4%)				
Activa SC (model 37603)	98.6%				
	(96.4%, 99.4%)				
Activa RC (model 37612)	97.8%	97.8%	97.8%	97.8%	97.8%
	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)	(95.9%, 98.8%)
Percept PC (model B35200)					

5.4 Leads

From July 2009 to the report cut-off date of October 31, 2025, there were 7,357 leads followed in the registry. The difference between the total number of leads (n= 7,357) versus neurostimulators (n= 6,749) 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 343,646 months (28,637 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 (%)
Currently manufactured	
3389 (compact electrode spacing)	3242 (44.1%)
3387 (standard electrode spacing)	2456 (33.4%)
SenSight B33005 (compact electrode spacing)	1184 (16.1%)
SenSight B33015 (standard electrode spacing)	381 (5.2%)
No longer manufactured	
3391 (large electrode and wide spacing)	73 (1.0%)
Other/Unspecified^a	21 (0.3%)
Total	7357

^a Includes leads used in other manufacturers' systems.

5.4.1 Lead Events

Of the total of 636 product performance-related events, there were 316 product performance-related events with an underlying reported etiology related to lead function. This includes 307 events with a lead etiology and 9 events with both a lead and other etiology (including device and non-device etiologies). Out of the 316 PPE's, 175 were the initial product performance event that affected lead survival estimates.

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:

- 175 had follow-up time cut-off due to product performance-related events.
- 3,983 were censored in the survival analysis for the following reasons: patient expired, leads explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.

- 3,199 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.

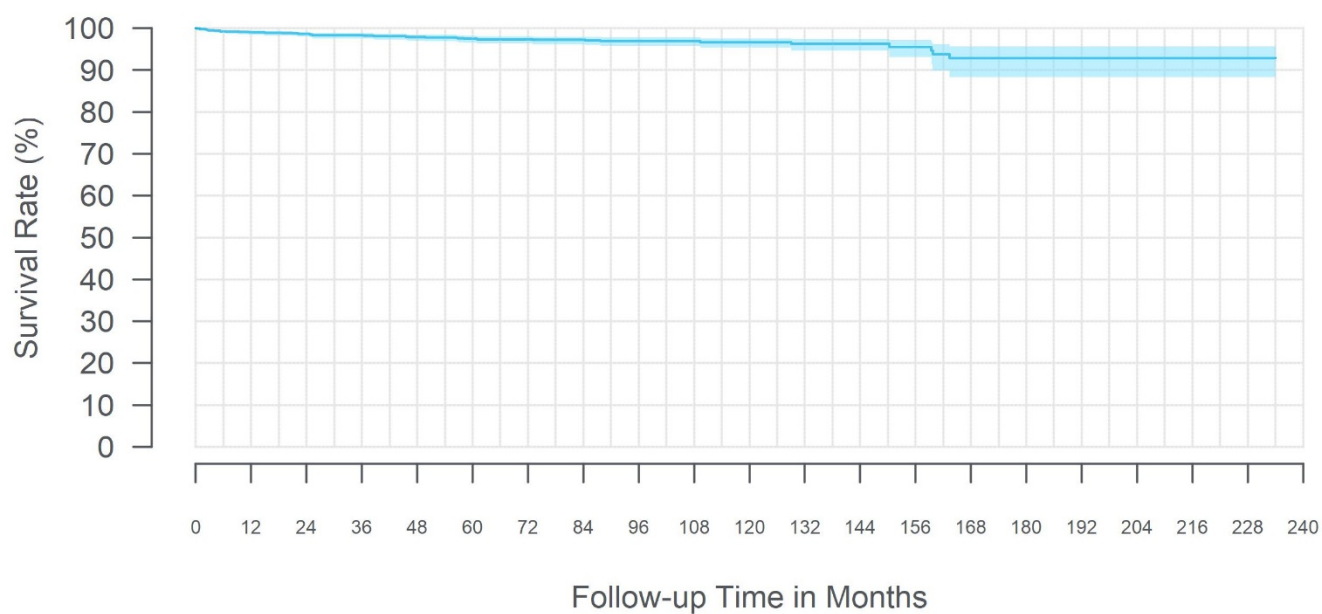
Initial product performance events of other/unspecified models (n=3) are not summarized in the subsequent sections.

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	2,456
Leads Currently Active in Study	780
Initial Product Performance Events	50
Median Follow-up Time (Months)	41.5
Cumulative Follow-up Time (Months)	130,846



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.1% (98.5%, 99.4%)	98.7% (98.0%, 99.1%)	98.3% (97.6%, 98.8%)	97.9% (97.1%, 98.5%)	97.5% (96.5%, 98.2%)
Sample Size	1767	1463	1202	1017	882

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	97.4% (96.4%, 98.1%)	97.2% (96.2%, 98.0%)	96.9% (95.8%, 97.8%)	96.9% (95.8%, 97.8%)	96.7% (95.4%, 97.6%)
Sample Size	763	647	533	372	295

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	96.3% (94.7%, 97.4%)	96.3% (94.7%, 97.4%)	95.5% (93.1%, 97.1%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)
Sample Size	224	160	112	84	65

Time Interval	16 Years	17 Years	18 Years	19 Years	At 234 Months
Survival (95% CI)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)	92.9% (88.4%, 95.7%)
Sample Size	48	35	23	23	20

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

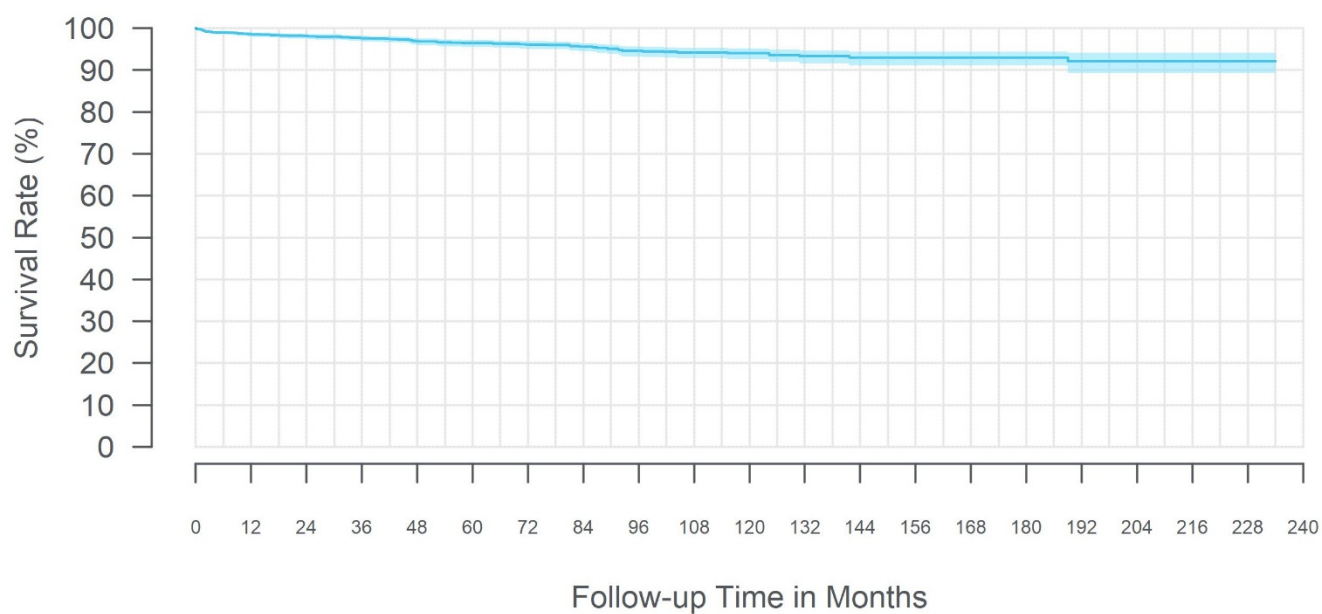


Lead Event Summary: 3387	N
High Impedance	21
Lead Migration/Dislodgement	16
Low Impedance	8
Lead Fracture	3
Device Electrical Finding ^a	1
Device Lead Issue	1
Total	50

^a Open circuit contact

5.4.2.2 Model 3389

Model Name	3389
FDA Approval Date	September 1999
Leads Enrolled	3,242
Leads Currently Active in Study	1,189
Initial Product Performance Events	99
Median Follow-up Time (Months)	48.6
Cumulative Follow-up Time (Months)	187,074



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	98.6% (98.0%, 99.0%)	98.2% (97.5%, 98.7%)	97.6% (96.9%, 98.2%)	96.9% (96.0%, 97.6%)	96.5% (95.5%, 97.2%)
Sample Size	2175	1870	1611	1464	1355

Time Interval	6 Years	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	96.1% (95.1%, 96.9%)	95.6% (94.5%, 96.5%)	94.6% (93.3%, 95.6%)	94.2% (92.9%, 95.3%)	94.0% (92.6%, 95.2%)
Sample Size	1222	1060	841	647	460

Time Interval	11 Years	12 Years	13 Years	14 Years	15 Years
Survival (95% CI)	93.3% (91.7%, 94.7%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)	93.0% (91.2%, 94.5%)
Sample Size	347	258	205	166	140

Time Interval	16 Years	17 Years	18 Years	19 Years	At 234 Months
Survival (95% CI)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)	92.1% (89.4%, 94.2%)
Sample Size	100	71	39	22	20

Specification: 3389

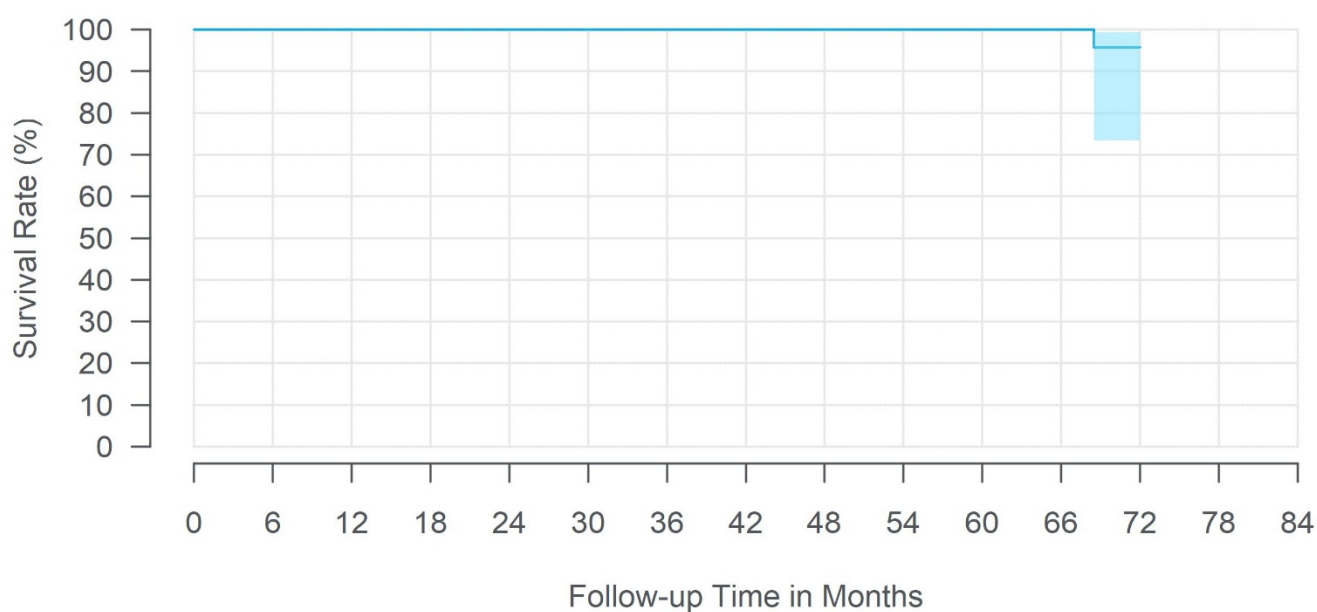
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (mm ²)	6.0
Inter-Electrode Spacing: Edge to Edge (mm)	0.5
Array Length (mm)	7.5



Lead Event Summary: 3389	N
High Impedance	52
Lead Migration/Dislodgement	21
Lead Fracture	13
Low Impedance	4
Device Electrical Impedance Issue	2
Device Material Corroded	2
Medical Device Complication	2
Device Lead Issue	1
Device Malfunction	1
Lead Insulation Failure	1
Total	99

5.4.2.3 Model 3391

Model Name	3391
FDA Approval Date	February 2009
Leads Enrolled	73
Leads Currently Active in Study	16
Initial Product Performance Events	2
Median Follow-up Time (Months)	42.1
Cumulative Follow-up Time (Months)	4,160



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI) ^a	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)	100.0% (NA)
Sample Size	51	47	34	30	27

Time Interval	6 Years
Survival (95% CI)	95.7% (73.4%, 99.4%)
Sample Size	20

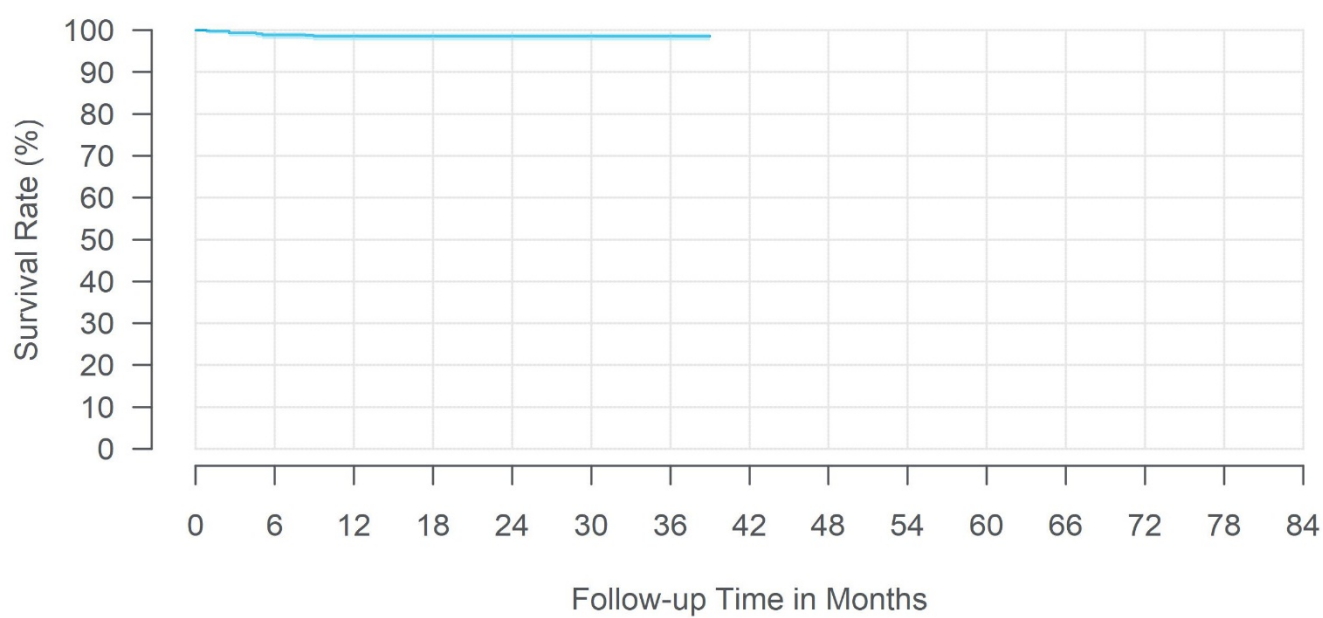
Specification: 3391	
Lead	
Length (cm)	40
Diameter (mm)	1.27
Electrode	
Number	4
Shape	Cylindrical
Length (mm)	3.0
Individual Surface Area (mm ²)	12
Inter-Electrode Spacing: Edge to Edge (mm)	4.0
Array Length (mm)	24



Lead Event Summary: 3391	N
High Impedance	1
Lead Fracture	1
Total	2

5.4.2.4 Model SenSight™ B33005

Model Name	B33005 (Compact electrode spacing)
FDA Approval Date	May 2021
Leads Enrolled	1,184
Leads Currently Active in Study	968
Initial Product Performance Events	12
Median Follow-up Time (Months)	10.8
Cumulative Follow-up Time (Months)	14,872



Time Interval	1 Year	2 Years	3 Years	At 39 Months
Survival (95% CI)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)	98.6% (97.6%, 99.2%)
Sample Size	529	178	34	29

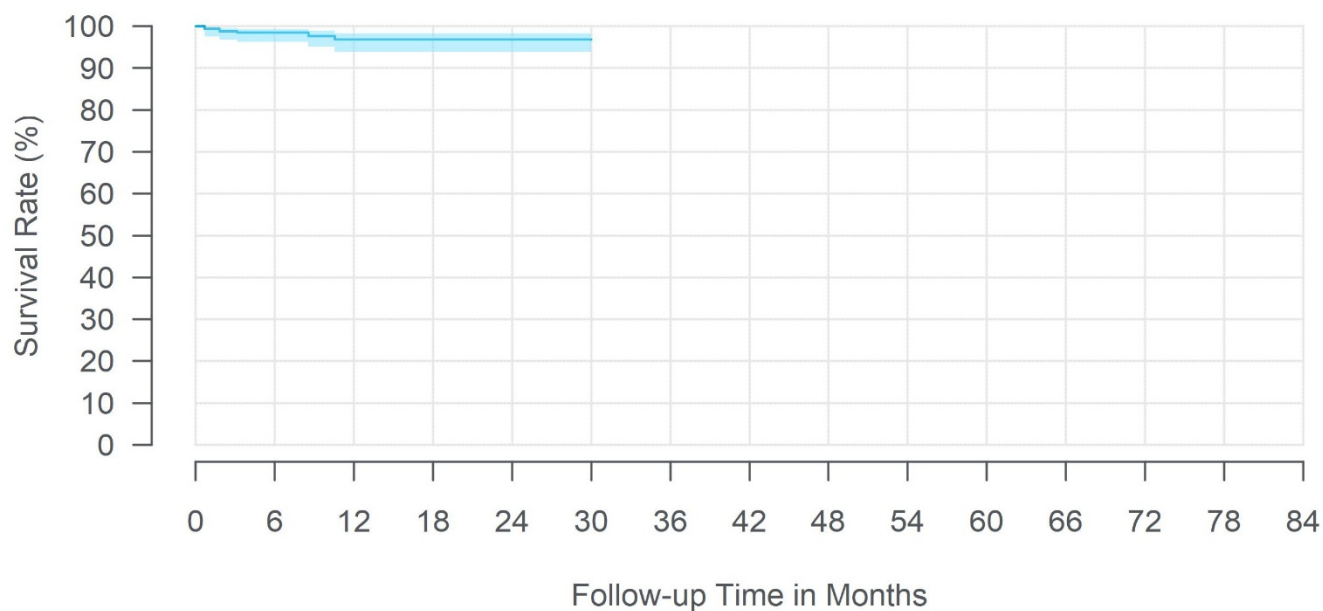
Specification: SenSight™ B33005	
Lead	
Length (cm)	33
Diameter (mm)	1.36
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	0.5
Individual Surface Area (cm ²)	33 cm: 13.55
Proximal end Lead contact spacing, Stylet handle length (mm)	8 contacts, in-line 2.2
Distal end Electrode shape Distal tip distance (mm)	8 electrodes Cylindrical 1.0



Lead Event Summary: B33005	N
High Impedance	8
Device Electrical Impedance Issue	2
Lead Migration/Dislodgement	2
Total	12

5.4.2.5 Model SenSight™ B33015

Model Name	B33015 (Standard electrode spacing)
FDA Approval Date	May 2021
Leads Enrolled	381
Leads Currently Active in Study	300
Initial Product Performance Events	9
Median Follow-up Time (Months)	12.9
Cumulative Follow-up Time (Months)	5,323



Time Interval	1 Year	2 Years	At 30 Months
Survival (95% CI)	96.8% (93.9%, 98.3%)	96.8% (93.9%, 98.3%)	96.8% (93.9%, 98.3%)
Sample Size	201	61	29

Specification: SenSight™ B33015	
Lead	
Length (cm)	42
Diameter (mm)	1.36
Electrode	
Number	8
Shape	Cylindrical
Length (mm)	1.5
Individual Surface Area (cm ²)	42 cm: 17.26
Proximal end Lead contact spacing, Stylet handle length (mm)	8 contacts, in-line 4.6
Distal end	8 electrodes
Electrode shape	Cylindrical
Distal tip distance (mm)	1.0



Lead Event Summary: B33015	N
High Impedance	7
Lead Fracture	2
Total	9

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)
Model 3387	July 1997	2,456	780	50	41.5	130,846
Model 3389	September 1999	3,242	1,189	99	48.6	187,074
Model 3391	February 2009	73	16	2	42.1	4,160
SenSight (model B33005)	May 2021	1,184	968	12	10.8	14,872
SenSight (model B33015)	May 2021	381	300	9	12.9	5,323

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

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
Model 3387	99.1%	98.7%	98.3%	97.9%	97.5%
	(98.5%, 99.4%)	(98.0%, 99.1%)	(97.6%, 98.8%)	(97.1%, 98.5%)	(96.5%, 98.2%)
Model 3389	98.6%	98.2%	97.6%	96.9%	96.5%
	(98.0%, 99.0%)	(97.5%, 98.7%)	(96.9%, 98.2%)	(96.0%, 97.6%)	(95.5%, 97.2%)
Model 3391	100.0%	100.0%	100.0%	100.0%	100.0%
	(NA)	(NA)	(NA)	(NA)	(NA)
SenSight (model B33005)	98.6%	98.6%	98.6%		
	(97.6%, 99.2%)	(97.6%, 99.2%)	(97.6%, 99.2%)		
SenSight (model B33015)	96.8%	96.8%			
	(93.9%, 98.3%)	(93.9%, 98.3%)			

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
Model 3387	97.4%	97.2%	96.9%	96.9%	96.7%

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
	(96.4%, 98.1%)	(96.2%, 98.0%)	(95.8%, 97.8%)	(95.8%, 97.8%)	(95.4%, 97.6%)
Model 3389	96.1%	95.6%	94.6%	94.2%	94.0%
	(95.1%, 96.9%)	(94.5%, 96.5%)	(93.3%, 95.6%)	(92.9%, 95.3%)	(92.6%, 95.2%)
Model 3391	95.7%				
	(73.4%, 99.4%)				
SenSight (model B33005)					
SenSight (model B33015)					

Model Name	11 Years	12 Years	13 Years	14 Years	15 Years
Model 3387	96.3%	96.3%	95.5%	92.9%	92.9%
	(94.7%, 97.4%)	(94.7%, 97.4%)	(93.1%, 97.1%)	(88.4%, 95.7%)	(88.4%, 95.7%)
Model 3389	93.3%	93.0%	93.0%	93.0%	93.0%
	(91.7%, 94.7%)	(91.2%, 94.5%)	(91.2%, 94.5%)	(91.2%, 94.5%)	(91.2%, 94.5%)
Model 3391					
SenSight (model B33005)					
SenSight (model B33015)					

Model Name	16 Years	17 Years	18 Years	19 Years
Model 3387	92.9%	92.9%	92.9%	92.9%
	(88.4%, 95.7%)	(88.4%, 95.7%)	(88.4%, 95.7%)	(88.4%, 95.7%)
Model 3389	92.1%	92.1%	92.1%	92.1%
	(89.4%, 94.2%)	(89.4%, 94.2%)	(89.4%, 94.2%)	(89.4%, 94.2%)
Model 3391				

Model Name	16 Years	17 Years	18 Years	19 Years
SenSight (model B33005)				
SenSight (model B33015)				

5.5 Extensions

From July 2009 to the report cut-off date of October 31, 2025, there were 7,407 extensions followed in the registry. The difference between the total number of extensions (n=7,407) versus neurostimulators (n=6,749) is due to some patients implanted with more than one extension or subsequently re-implanted with an extension. The aggregate prospective follow-up time for all extensions was 336,655 months (28,055 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)	5212 (70.4%)
SenSight B34000/B34000M	1555 (21.0%)
No longer manufactured	
7482 (quadripolar) ^a	510 (6.9%)
7483	1 (<0.1%)
Other/Unspecified^b	129 (1.7%)
Total	7407

^a Includes Models 7482 and 7482a.

^b Includes extensions for other legacy stimulation systems.

5.5.1 Extension Events

Of the total of 636 product performance-related events, there were 123 product performance-related events with an underlying reported etiology related to extension function. This includes 119 events with an extension etiology and 4 events with both an extension and other etiology (including device and non-device etiologies). Of these, 93 were the initial product performance event that affected extension survival estimates.

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:

- 93 had follow-up time cut-off due to product performance-related events.
- 4,131 were censored in the survival analysis for the following reasons: patient expired, extension explanted, patient discontinued, therapy suspended, or site discontinued participation in the registry.

- 3,183 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.

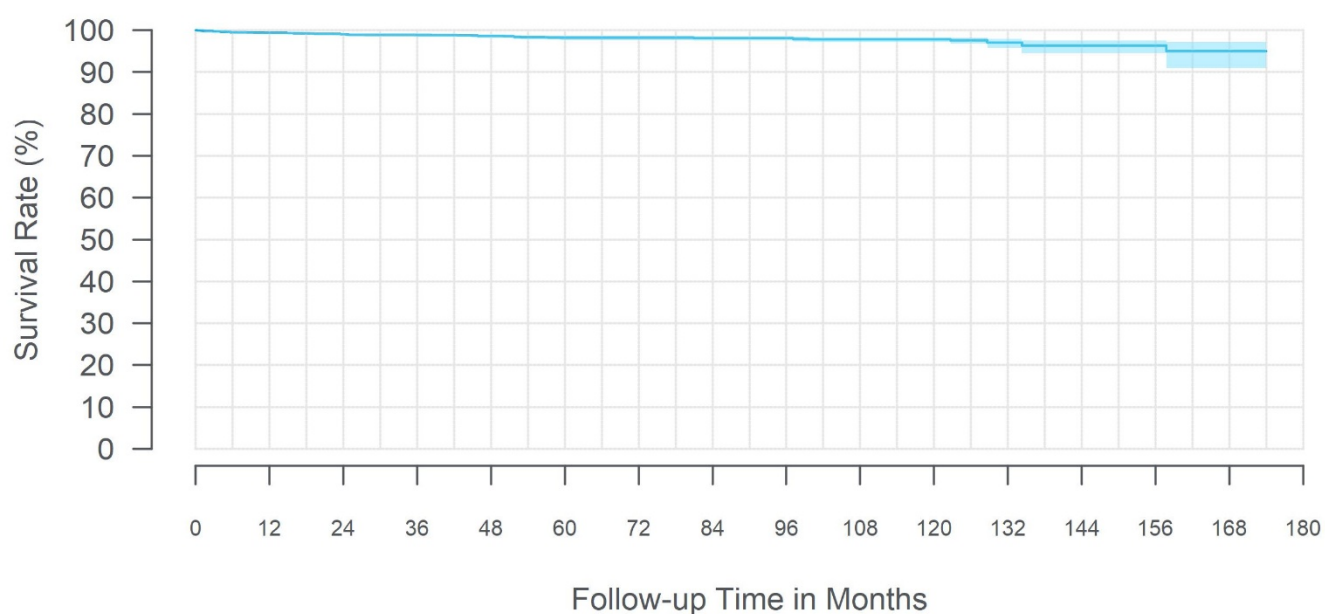
Initial product performance events of Model 7482 (n=7) and other/unspecified models (n=6) are not summarized in the subsequent sections as these models are not manufactured anymore.

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	5,212
Extensions Currently Active in Study	1,796
Initial Product Performance Events	74
Median Follow-up Time (Months)	42.1
Cumulative Follow-up Time (Months)	277,737



Time Interval	1 Year	2 Years	3 Years	4 Years	5 Years
Survival (95% CI)	99.4% (99.1%, 99.6%)	99.1% (98.7%, 99.3%)	98.9% (98.5%, 99.2%)	98.7% (98.2%, 99.0%)	98.2% (97.7%, 98.6%)
Sample Size	4005	3363	2805	2405	2059

Time Interval	6 Year	7 Years	8 Years	9 Years	10 Years
Survival (95% CI)	98.2% (97.7%, 98.6%)	98.1% (97.5%, 98.5%)	98.1% (97.5%, 98.5%)	97.8% (97.2%, 98.3%)	97.8% (97.2%, 98.3%)
Sample Size	1782	1460	1110	759	496

Time Interval	11 Years	12 Years	13 Years	14 Years	At 174 Months
Survival (95% CI)	97.1% (95.8%, 97.9%)	96.3% (94.6%, 97.5%)	96.3% (94.6%, 97.5%)	95.0% (91.0%, 97.2%)	95.0% (91.0%, 97.2%)
Sample Size	286	163	78	35	22

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, Percept™ PC, or Percept™ RC

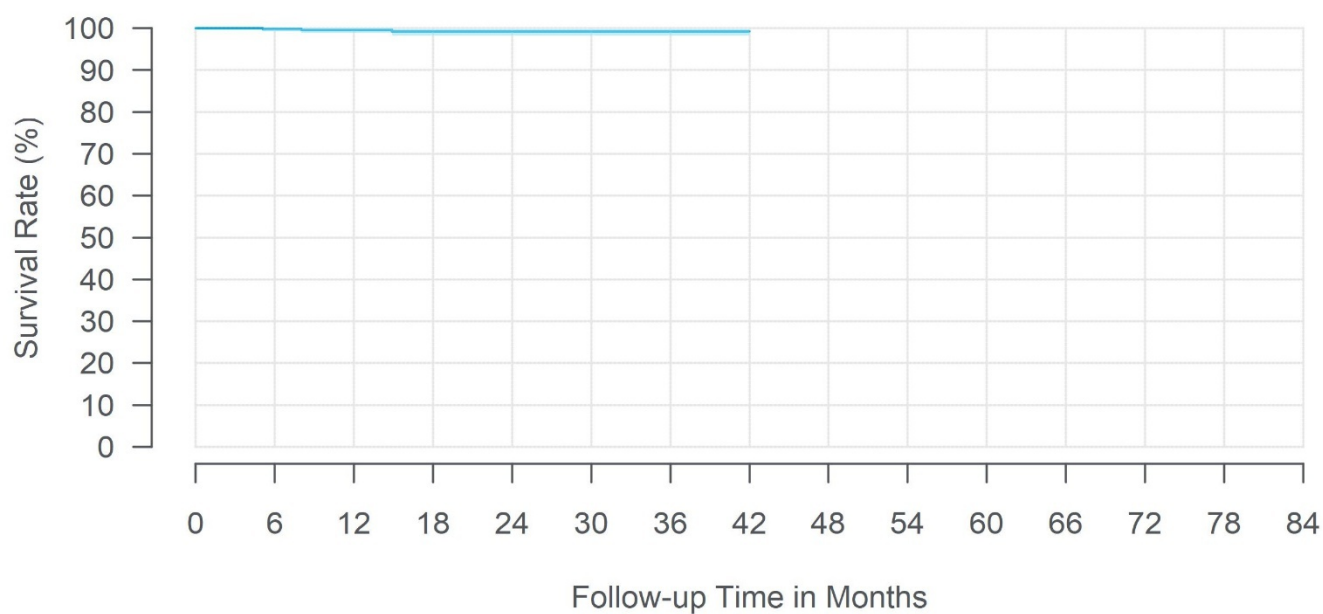


Extension Event Summary: 37085/37086	N
High Impedance	32
Extension Migration	15
Extension Fracture	8
Low Impedance	6
Medical Device Complication	4
Device Protrusion	3
Device Electrical Finding ^a	2
Device Extension Dislodgement	1
Device Malfunction	1
Lead Migration/Dislodgement	1
Unspecified	1
Total	74

^a Open circuit contact

5.5.2.2 Model B34000/B34000M

Model Name	B34000/B34000M
FDA Approval Date	May 2021
Extensions Enrolled	1,555
Extensions Currently Active in Study	1,248
Initial Product Performance Events	6
Median Follow-up Time (Months)	11.3
Cumulative Follow-up Time (Months)	19,605



Time Interval	1 Year	2 Years	3 Years	At 42 Months
Survival (95% CI)	99.6% (99.0%, 99.9%)	99.3% (98.3%, 99.7%)	99.3% (98.3%, 99.7%)	99.3% (98.3%, 99.7%)
Sample Size	727	229	46	29

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 Summary: B34000/B34000M	N
Extension Migration	4
Device Damage	2
Total	6

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	5,212	1,796	74	42.1	277,737
B34000/B34000M	May 2021	1,555	1,248	6	11.3	19,605

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

Model Name	1 Year	2 Years	3 Years	4 Years	5 Years
B34000/B34000M	99.6%	99.3%	99.3%		
	(99.0%, 99.9%)	(98.3%, 99.7%)	(98.3%, 99.7%)		
37085/37086	99.4%	99.1%	98.9%	98.7%	98.2%
	(99.1%, 99.6%)	(98.7%, 99.3%)	(98.5%, 99.2%)	(98.2%, 99.0%)	(97.7%, 98.6%)
Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
B34000/B34000M					

Model Name	6 Years	7 Years	8 Years	9 Years	10 Years
37085/37086	98.2%	98.1%	98.1%	97.8%	97.8%
	(97.7%, 98.6%)	(97.5%, 98.5%)	(97.5%, 98.5%)	(97.2%, 98.3%)	(97.2%, 98.3%)

Model Name	11 Years	12 Years	13 Years	14 Years
B34000/B34000M				
37085/37086	97.1%	96.3%	96.3%	95.0%
	(95.8%, 97.9%)	(94.6%, 97.5%)	(94.6%, 97.5%)	(91.0%, 97.2%)