MEDTRONIC DEEP BRAIN STIMULATION (DBS) FOR EPILEPSY
SUMMARY OF CLASS I EVIDENCE FOR NEUROMODULATION THERAPIES

Therapies	MEDTRONIC DEEP BRAIN STIMULATION (DBS) Implanted brain stimulation system for epilepsy, Parkinson's disease, essential tremor, dystonia	LIVANOVA VAGUS NERVE STIMULATION (VNS) Implanted autonomic nerve stimulator for epilepsy and Treatment-Resistant Depression

Results are from different studies and are shown for illustrative purposes only. Results may differ in a head-to-head study. Refer to product labeling for specific information regarding indications, contraindications, warnings, precautions and safety.

	DBS	VNS	
Regulatory Status for Epilepsy	CE Mark (2010) FDA Approval (2018)	CE Mark (1994) FDA Approval (1997)	
Indication	Bilateral stimulation of the anterior nucleus of the thalamus (ANT) as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.[1]	An adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications.[2]	
Published Clinical Studies	SANTE Pivotal Study - RCT ■ Blinded Phase Results[3] ■ Long-term Results[4,5]	E03 / E05 Studies - RCTs ■ Blinded Phase Results[6,7] ■ Long-term Results[9]	
Stimulation / Target Procedure	Stereotactic placement of bilateral leads in the Anterior Nucleus of Thalamus (ANT)	Electrodes wrapped around cranial nerve accessed via the neck	
MRI	Conditional; full-body 1.5T Scan[9]	Conditional: device set to 0mA; transmit RF body coil would require system explant[2]	
Implant Location of the Neurostimulator	Pectoral or Abdominal	Pectoral	
Clinical Programming / Therapy Maintenance	Programming for optimal therapy benefit	Programming for optimal therapy benefit	
Blinded Phase Results - Median % Change	Active: -35.0% Control: -21.1%[10]	**E03**[2] High: -23% Low: -6%	**E05**[2] High: -23% Low: -21%
Blinded Phase Results - Responder Rate (% of subjects with ≥50% reduction in seizures)	Active: 29.6% Control: 25.9%[10]	**E03**[2] High: 30% Low: 14%	**E05**[2] High: 23% Low: 16%
Seizure Reduction 3 Years-Median % Change	57% Last Observation Carried Forward[10]	44% Last Value Carried Forward[8]	
Seizure Reduction 6 Years - Median % Change	70% Last Observation Carried Forward[10]	Data Not Available	
Quality of Life Results Blinded Phase - Responder Rate (5 point or greater improvement on the QOLIE Assessment)	Active: 48.1% Control: 32.1%[10]	Not Assessesd in E03/E05	
Quality of Life Results: Long Term - Responder Rate (5 point or greater improvement on the QOLIE Assessment)	1 Year: 46.1% 2 Year: 38.8% 5 Year: 47.5% 7 Year: 43.3%[10]	Improvement on various QOL metrics subjectively rated by physicians Provider Survey Data[11]	
Epilepsy Related Injuries : Blinded Phase	Active Group exhibited significantly fewer epilepsy related injuries (Active: 7.4% vs Control: 25.5%)[10]	NA	

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Further, Together

	DBS	VNS
Healthcare Resource Utilization (Epilepsy and Device Related Visits Normalized to 1 Year)	Active Group had fewer hospital visits but difference not statistically significant (Active: 4.2 vs Control: 20.2) Blinded Phase Results[10]	Reduction in seizure-related hospitalizations. RTI Health Solutions[12]
Mood and Memory Outcomes	Subjective reports of depression and memory impairment during the blinded phase. Neuropsych scores are stable or improved over the long term (7 years).[5]	No clear cognitive changes during the blinded phase (E05). Long-term results not reported.[13]
Most Common Serious Device Related Adverse Event	Implant Site Infection (10.9%) 713 Device Years[10]	Surgically Related (4.1%)* 591 Device Years in E03/E05[2]
Sudden Unexplained Death in Epilepsy (SUDEP) Rate (95% Confidence Interval)	2.5 deaths / 1000 Years (0.31–9.16)[10]	4.1 deaths / 1000 Years (CI not available)[14]

*** Included infection, nerve paralysis, hypesthesia, facial paresis, left vocal cord paralysis, left facial paralysis, left hemidiaphragm paralysis, left recurrent laryngeal nerve injury, urinary retention, and low-grade fever.**

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Brief Statement:
See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.