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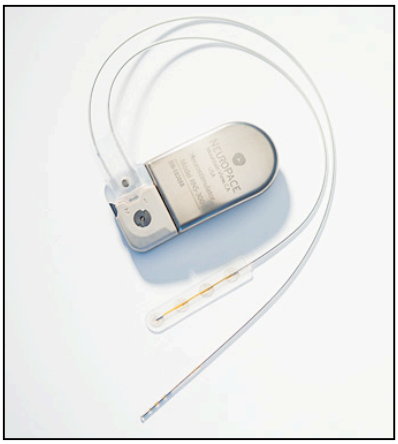
RNS® System Technology Backgrounder

Recently, the U.S. Food and Drug Administration granted premarket approval for the NeuroPace® RNS® System, the first closed-loop responsive brain stimulation system. The RNS System provides an adjunctive therapy in reducing the frequency of seizures in adults 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than two epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and/or secondarily generalized seizures). The RNS System has demonstrated safety and effectiveness in patients who average three or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures.

The RNS System is a novel, implantable therapeutic device that delivers responsive neurostimulation, an advanced technology designed to continuously monitor brain electrical activity, detect abnormal electrical activity, and respond by delivering imperceptible levels of electrical stimulation to normalize that activity before an individual experiences seizures.

The RNS System includes implantable and external components:



- The implantable components are the RNS Neurostimulator and leads (tiny wires containing electrodes). The neurostimulator is a battery-powered, microprocessor-controlled device that is placed within the skull and beneath the scalp by a surgeon. It is connected to one or two leads that are placed within the brain or rest on the brain surface in the area of the seizure focus. The neurostimulator and leads are implanted by a neurosurgeon during a procedure that typically takes two to five hours.
- External components include a NeuroPace® Programmer and a NeuroPace® Remote Monitor. Both devices use proprietary software that enable communication with an implanted RNS Neurostimulator.

Physicians use the programmer to non-invasively program the detection and stimulation settings of an implanted RNS Neurostimulator to customize therapy for each individual. Physicians also use the programmer to retrieve data stored in the neurostimulator and transmit it to the NeuroPace® Patient Data Management System (PDMS), an interactive web-based database used for storage and clinician remote access. Patients use the remote monitor at home to transmit recordings of their brain electrical activity and other information stored in the neurostimulator to the PDMS. Physicians can review and analyze this information over the internet between the patient's office appointments to help with patient management.