Introducing the RNS® System

The RNS System is a proven treatment option for adults who have disabling seizures that are not controlled by medication.

Most epilepsy treatments deliver therapy continuously, whether or not you are having a seizure. The RNS System is different. It is a smart device that responds to what's happening in your brain to stop seizures at their source.

Where you need it

Your doctor positions the RNS System so that it can monitor and respond to brain activity directly at the seizure source.

When you need it

The RNS System is programmed to deliver treatment as soon as unusual brain activity is detected—often before a seizure can start.

Without you noticing it

Once the RNS System is implanted and properly programmed, you don't see the device or feel it working.

> "I've had epilepsy for a long time. I've suffered through countless anitepileptic drugs and their side effects. When I heard about the RNS® System, I felt fortunate to have something else to try. Well, I did try it, and now I'm planning on getting a job and restarting my life."
>
> —Carolyn, RNS® System Patient

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Please see important safety information in pocket.

Indication for Use: The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than 2 epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures.

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THE RNS® SYSTEM

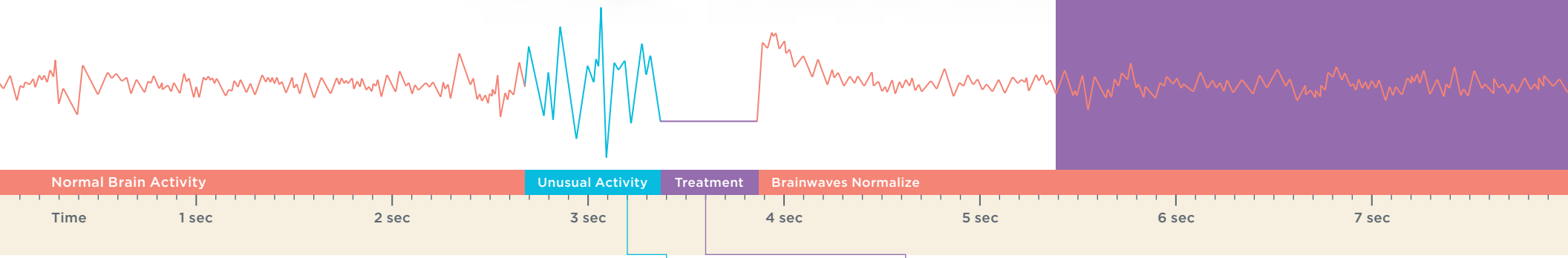
Epilepsy treatment just got a lot smarter

Designed to prevent seizures at their source

A window to your brain

Seizures result from abnormal electrical discharges in your brain. This activity is difficult to see, like looking into a black box.

With the RNS® System, for the first time your doctor can see what's happening in your brain during your normal daily activities. The device collects ongoing information that helps your doctor better control your seizures.



How it Works

Monitors

The RNS® System constantly monitors your brainwaves, looking for unusual activity that may lead to a seizure. It works all the time, even while you are sleeping.

Detects

The device is personalized to recognize the electrical patterns specific to your brain, rapidly identifying unusual activity that can lead to a seizure.

Responds

Within milliseconds of detecting unusual activity, the device sends brief pulses to instantly disrupt this activity and normalize your brainwaves, often before you can feel seizure symptoms.

You don't even have to think about it—once your doctor programs the RNS® System to detect and respond to your brain activity, it automatically provides treatment when you need it.

Proven seizure control that is safe & effective

In clinical studies, the RNS System was shown to significantly reduce seizures with continued improvement over time. Patients also reported better cognitive function, quality of life, and mood.

Talk with your doctor to find out if the RNS System is right for you.

Patient Education

NeuroPace® RNS®
System Brief Statement

Indication for Use
The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than 2 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 3 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.

Contraindications
The RNS® System is contraindicated for patients at high risk for surgical complications, with medical devices implanted that deliver electrical energy to the brain, and those who are unable (or do not have the necessary assistance) to properly operate the NeuroPace® Remote Monitor or Magnet. For patients with an implanted RNS® System the following medical procedures are contraindicated:

- Magnetic Resonance Imaging (MRI) -- The RNS® System is MR Unsafe
- Electroconvulsive Therapy (ECT)
- Transcranial Magnetic Stimulation (TMS)
- Diathermy procedures (any treatment that uses high-frequency electromagnetic radiation, electric currents or ultrasonic waves to produce heat in body tissues)

Warnings and Precautions
The RNS® System is not compatible with non-NeuroPace leads and/or pulse generators. Electrical shock may occur with incorrect use of the Programmer or Remote Monitor. Do Not Resterilize and Do Not Reuse the implantable products.

Clinical Use
The RNS® System should only be implanted at Comprehensive Epilepsy Centers by neurosurgeons with adequate experience in the implantation of subdural and stereotactic implantation of intraparenchymal electrodes and in the surgical treatment of intractable epilepsy. The RNS® System should only be used by neurologists and neurosurgeons with adequate experience in the management of intractable epilepsy and in the localization of epileptic foci. They must complete a NeuroPace® RNS® System training program and demonstrate specific expertise related to epilepsy, video-EEG monitoring, interpretation of electrocorticograms (ECoGs), the pharmacology of antiepileptic medications and selection of patients for epilepsy surgery. In some instances Neurologists who meet the experience and certification requirements but do not practice at Comprehensive Epilepsy Centers could be qualified by NeuroPace to provide post-implant programming.

Surgical
Implantation of the RNS® System and associated surgical procedure risks may cause, but are not limited to, infection, intracranial hemorrhage, tissue damage, temporary pain at the implant site, CSF leakage, seroma, and paralysis.

RNS® System and Therapy
The safety and effectiveness has not been studied in pregnant women. The effects of long-term brain stimulation are not completely known. Strong electromagnetic interferences (EMI) can result in serious patient injury or death, damaged brain tissue, loss or change in symptom control, reoperation, stimulation to turn on or off, a return of symptoms, or a momentary increase in stimulation felt by the patient. In addition EMI, such as security screening devices and radio frequency identification, can result in delivering the programmed stimulation to the patient and appear as sensing artifacts on the ECoG recordings. The RNS® System could interact with implanted cardiac devices and result in inappropriate device response or device damage.

Additional surgical procedures can result from battery malfunction, electrical short, open circuit, lead fracture, lead insulation failure, damage as a result of head trauma, or lead migration. Severe brain tissue damage can result from exposure to battery chemicals if the Neurostimulator is ruptured or pierced due to outside forces. The patient must collect data from the Neurostimulator once a day and send data to the PDMS once a week.

Medical Environment
Electrolysis on the head and neck should be avoided. Prior to the administration of Extracorporeal Shock Wave Lithotripsy or high radiation sources the administering physician should consult with the physician prescribing the RNS® System. Read the user manual to understand the steps to be taken before, during and after computerized tomography (CT) scans.

Potential Adverse Events
Serious adverse events occurring in ≥ 2.5% of patients and those of particular relevance reported during the RNS® System clinical studies include EEG monitoring, infection, change in seizures, medical device removal, death, device lead damage or revision, antiepileptic drug toxicity, hemorrhage, psychiatric events, status epilepticus and seizure-related injury. Refer to the product labeling for a detailed disclosure of other reported adverse events.

Rx Only. Refer to the product labeling for a detailed disclosure of specific indications, contraindications, warnings, precautions and adverse events.

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