NeuroPace RNS® System and Post-Approval Study (PAS)
Frequently Asked Questions

About Drug-Resistant Focal Epilepsy

What is drug-resistant epilepsy?

Drug-resistant epilepsy (DRE) is defined as the persistence of seizures despite the use of two or more anti-seizure medications. Focal epilepsy is the most common form of DRE and often results in a lifetime of debilitating seizures.

DRE remains a significant unmet medical need, accounting for up to 30-40% of all epilepsy diagnoses and affecting approximately 1.2 million people in the U.S. alone[1]. The inability to control the occurrence of seizures can have a profound impact on a patient's quality of life, such as poor cognitive outcomes, depression, decreased social interaction, increased seizure frequency, and sudden unexplained death in epilepsy (SUDEP); therefore, seizure control and reduction is essential.

Individuals with focal DRE may be candidates for advanced treatment options, including the RNS® System.

What type of treatment options are available for drug-resistant focal epilepsy?

Among the most common treatment options for drug-resistant focal epilepsy are neuromodulation and surgery. Surgical options, which include resection or laser ablation, target the source of the seizures and remove brain tissue. Neuromodulation devices, which preserve brain tissue, may offer an alternative to surgery for some patients. The RNS System is the only neuromodulation device that recognizes and responds to brain activity in real-time and delivers stimulation only when needed.

About The NeuroPace RNS® System

What is the NeuroPace RNS® System?

The NeuroPace RNS® System is the first and only responsive neuromodulation platform that delivers personalized, real-time seizure treatment through targeted stimulation to alter brain activity. The system, built on cutting-edge technology, provides direct, brain-responsive stimulation and monitoring in a closed-loop system that detects abnormal brain activity, responds to a patient's unique seizure fingerprint, and effectively reduces seizures before they happen.

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[1] Chen, Z., et al., JAMA Neurology, 2018

Is the RNS System approved by the Food and Drug Administration (FDA)?

The NeuroPace RNS System is FDA approved for drug-resistant focal epilepsy (DRE) as a supplemental therapy to be used alongside standard epilepsy care in individuals 18 years of age or older.

How is NeuroPace's RNS System different than other neuromodulation therapies?

The RNS System has been shown to deliver greater seizure reduction than other neuromodulation therapies[2,3,4,5] and is the first and only neuromodulation platform that delivers personalized, real-time seizure treatment through targeted stimulation to alter brain activity.

Does the RNS System work the same as vagus nerve stimulation (VNS) and deep brain stimulation (DBS)?

They do not. Though the RNS System, VNS and DBS send electrical pulses, the RNS System is the only device to detect seizure activity and respond immediately. The RNS System provides therapy when it's needed, lets doctors view data online, and has no serious stimulation-related side effects. With 82% median seizure reduction at 3 years, the RNS System delivers greater seizure reduction than VNS and DBS.[3-5]

How many people are currently using the RNS System for DRE?

Over 6,500 individuals in the United States have experience with the RNS System.

Is it possible to achieve seizure freedom with the RNS System?

Data from the prespecified three-year effectiveness analysis of NeuroPace's Post-Approval Study (PAS) presented at the 2025 AAN Annual Meeting showed seizure freedom is possible, with 42% of patients remaining seizure free for 6+ months[2,6].

About NeuroPace's Post-Approval Study (PAS)

What data is NeuroPace announcing at the American Academy of Neurology (AAN) Annual Meeting?

At the 2025 AAN Annual Meeting, NeuroPace is presenting three-year effectiveness data from the Post-Approval Study (PAS) of the RNS System, which showed an 82% median reduction at 3 years in seizures in adults treated with direct brain responsive stimulation for drug-resistant focal epilepsy[2].

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[2] RNS System Post-approval Study Oral Presentation, American Academy of Neurology, April 2025. All outcomes are ITT, median seizure reduction is observed case data, seizure freedom at last follow-up is LOCF.
[3] Morris et al, Neurology, 1999
[4] Kaufmann et al., Epilepsia, 2024
[5]Therapies were studied using different study designs. Caution must be exercised when comparing results.
[6] At some point during the study

What is the PAS and what are the key findings from the study?

The PAS of the RNS System is a rigorously designed five-year study with a primary effectiveness endpoint at three years and primary safety endpoint at five years.

Data from the prespecified three-year effectiveness analysis presented at the 2025 AAN Annual Meeting showed continued evidence of substantial seizure reductions with the RNS System for drug-resistant focal epilepsy. Most notably, the data showed[3]:

- Long-term seizure reduction with a median reduction of 82% at 3 years.
- Rapid seizure reduction with a median reduction of 62% at 6 months.
- Extended periods of seizure freedom were possible, with 42% of patients remaining seizure free for 6+ months[6].
- 1 in 3 patients did not require intracranial monitoring.

The results presented at AAN add to the growing body of evidence demonstrating consistency in the power of combining neurostimulation and monitoring to provide seizure control for people who live with DRE.

What is the significance of the PAS?

The PAS enrolled 324 patients from 32 centers making it the largest-ever, U.S. FDA-reviewed, prospectively enrolled trial in the field of neuromodulation for drug-resistant focal epilepsy.

Results from this study are important to provide additional and long-term clinical evidence of the safety and effectiveness of the RNS System.

What is the purpose of the PAS and why were these three-year data submitted to the FDA?

The Post-Approval Study (PAS) of the RNS System is a five-year prospective study designed to collect additional data on the safety and effectiveness of the RNS System.

These data have been submitted to the FDA to demonstrate the effectiveness of the RNS System at 3 years. The study will continue to a five-year follow-up as a condition of initial FDA approval.