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:

- 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.

MRI Safety Information
RNS® Neurostimulator model RNS-320: An MRI scan may be safely performed on patients with the RNS® System (with RNS Neurostimulator model RNS-320) only under the specific conditions of safe use detailed in the MRI Guidelines for the RNS® System. Scanning under different conditions may result in device damage or malfunction and serious patient risks including permanent brain damage which may cause severe injury, coma, or death.

RNS® Neurostimulator model RNS-300M of the RNS® System is MR Unsafe. Having an MRI scan with a model RNS-300M Neurostimulator implanted may result in serious injury or possible death.

RNS® System External Components: All external components and accessories of the RNS® System such as the Magnet, RNS® Tablet, NeuroPace® Programmer, NeuroPace® Remote Monitor, and Wand are MR Unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the MRI scanner room.

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 at www.NeuroPace.com for a detailed disclosure of specific indications, contraindications, warnings, precautions and adverse events.

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