How does the RNS System work?
The RNS System consists of a small, battery-powered neurostimulator that is placed in the skull and is connected to leads (thin wires with electrodes) that are placed in the area of the brain where your seizures start. The neurostimulator monitors the electrical activity of the brain and detects abnormal activity that could lead to a seizure. When abnormal activity is detected, the neurostimulator delivers brief, usually imperceptible pulses of stimulation through the leads. These pulses are intended to disrupt the abnormal activity and reduce seizure frequency.

How many patients have been treated with the RNS System?
As of March 2015, over 400 patients have been treated with the RNS System. Two hundred and fifty-six patients were treated during the NeuroPace clinical trials that led to FDA approval of the RNS System in November 2013. The rest have been treated after FDA approval.

How effective is the RNS System? Should I expect to be seizure free? (Bergey, et al., Neurology, 2015)
In clinical trials, more than half of the patients experienced a minimum of a 50% seizure frequency reduction over time compared to their pre-implant baseline. The median percent decrease in seizures after implant was:
- 44% at 1 year
- 53% at 2 years
- 60% or more in years 3 through 6 post-implant

Although you should not expect seizure freedom, recent data from the RNS System trials showed that 36% of patients had at least one 3 month period of seizure freedom, 23% had at least one 6 month period of seizure freedom and 13% had a period of a year or longer with no seizures. For comparative purposes, patients in the trials had an average at 3 or more seizures per month before they were treated with the RNS System.

Does the effect of the RNS System wear off?
No. Although it can take as long as a year to see the full effect of treatment with the RNS System, experience over many years shows that seizure reductions appear to continue over the long-term.

SURGICAL EXPECTATIONS

What are the biggest risks with the surgery to implant the RNS neurostimulator and the NeuroPace leads?
Your surgeon will review the risks related to surgery with you. In clinical trials, 2.6% of patients had an infection where the neurostimulator was placed, 1% had a hematoma (bleeding) inside the brain, 1% had temporary excess fluid in the brain, and 1% had a headache related to the implant procedure. No one had any permanent neurological problems related to the surgery.

Does the device go into my brain?
The neurostimulator itself does not come in contact with any part of the brain. It is placed under the scalp and sits within the skull in a small tray. The leads are placed at your seizure focus and are placed either within the brain or on the surface of your brain.

How long will I have to stay in the hospital after the implant surgery?
Your surgeon will decide what is best for you and it is typically 1-2 nights post-implant.

Will people be able to see that I have a device implanted in my head?
No one should be able to tell that you have anything implanted.

Will stimulation be turned on right away?
Usually stimulation is turned on several weeks after the neurostimulator is implanted. The RNS System will be programmed initially to gather data on your seizure patterns.

Once the RNS System has been personalized to pick up your patterns, stimulation will be turned on and will automatically respond to abnormal activity.

Can the RNS System be removed if I change my mind?
You can have the RNS neurostimulator and leads removed if you change your mind but you don't have to have them removed. The neurostimulator and leads are designed so that they can be left in place.

LIFE WITH THE RNS® SYSTEM

Will I feel stimulation?
Stimulation will be tested during office visits to ensure the RNS System is programmed to settings that can't be felt and won't cause you pain or discomfort.

How often will I have to be seen in my doctor's office to have the device programmed?
Patients usually have their first programming appointment 2 to 4 weeks after the implantation procedure. Patient appointments are about 15-30 minutes longer than regular appointments. Your doctor will talk to you about the visit frequency but it is often every 3 to 4 months.

When can I expect a response?
Many people find that they experience a reduction in seizures when stimulation is started but generally you will find that it could take up to a year to know how well you will respond.
What is the Remote Monitor and why do I need it?
The remote monitor is a laptop with special software and a handheld wand that you take home with you. It is used to collect data from your neurostimulator and send it to a database called the Patient Data Management System (PDMS) for your medical team to review.

Do I need to bring my remote monitor every time I have an appointment?
No. The remote monitor is for your use at home.

I am not very good with computers, will I understand how to use the remote monitor?
You will be trained how to use your remote monitor prior to your discharge from the hospital. You will also receive written instructions to take home.

How long does it take to transfer data from my neurostimulator?
It usually takes about 3-5 minutes each time you complete the data transfer from your neurostimulator using the remote monitor.

How often will I have to transfer my data?
Initially you will transfer your data daily as well as after a seizure. Over time, you will continue to need to transfer data from your neurostimulator to the remote monitor but you and your doctor will decide how often that should be.

How often does the neurostimulator have to be replaced and what does that involve?
With medium stimulation and detection settings the battery will last about 3.9 years. The replacement requires a small skin incision to replace the neurostimulator and is usually done as an outpatient procedure.

DAILY ROUTINES
Are there household devices that will interfere with the device?
Common household devices will not interfere with the RNS System. This includes, but is not limited to: cell phones, most headsets and earphones, electric toothbrushes, electric razors, hairdryers, microwave ovens, stereo systems, televisions or computers.

Will I be able to go through airport security?
Yes, the airport security screening process will not harm your neurostimulator. You should let the TSA personnel know that you have an implanted medical device.

Will I be able to go back to my normal daily activities?
Your medical team will advise you on the recovery from surgery but aside from that, the device is very durable and should not stop you from participating in any sport or activity.

What happens if I fall or get hit in the head near the device?
The device is designed to be very sturdy. Once the neurostimulator is implanted in your skull, there is no “soft spot” over your brain. If you injure your head you should contact your medical team.

I use a cell phone, work with computers and other electronics; will they interfere with the device?
Cell phones, computers and similar electronics should not interfere with the device.

Will this have any negative effect on my memory or thinking?
In clinical trials, the RNS System had no negative effects on memory or thinking.

Will I be able to stop taking my anti-seizure medications?
The RNS System has been approved as an adjunctive treatment which means it is an additional treatment along with your medications.

Can I have an MRI or other tests or procedures?
Procedures such as MRI; Electroconvulsive Therapy (ECT); Transcranial Magnetic Stimulation (TMS) or Diathermy are not allowed if you have the RNS System.

Are there patients that I can talk to who already have the RNS System?
Yes, we can put you in touch with someone through our Patient Connections program. You can call 650-793-5377 or email medicalaffairs@neuropace.com

Where can I get more information on the RNS System?
You can learn more about the RNS System by going to www.NeuroPace.com and clicking on “Learn more about the RNS System”. You can also call 650-793-5377 or email medicalaffairs@neuropace.com.

RxOnly
See important prescribing and safety information in the RNS System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com.