



MY RNS[®] SYSTEM

Starting your journey.





Join the growing RNS community!

Visit [NeuroPace.com/connect](https://www.neuropace.com/connect) to get connected today.

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WELCOME

Congratulations on taking an important step in the treatment of your epilepsy. The RNS System is a therapy that has helped many individuals achieve a better quality of life with more seizure control. We hope that this therapy will benefit you too. This Welcome Guide provides information on how your RNS System works, how to transfer information to your doctor, and what to expect in your daily life. We also have included fun and practical advice from patient ambassadors who have seen their lives change with the RNS System.

This guide is intended as a convenient reference. For a more in-depth explanation about the RNS System, risks, contraindications, warnings, cautions, and other important safety information, please refer to the patient manual that can be found on our website at [NeuroPace.com](https://www.neuropace.com).



AMBASSADOR INSIGHTS

Inside Your Welcome Kit

In your welcome kit, we've provided a model (actual size) of the neurostimulator that is currently monitoring your brain's electrical activity. Many RNS System patients find it useful to have this model so that they can explain the device to others.

"I carry mine with me all the time to show people I work with." —Don

Mine is my good luck charm and I carry it all the time.

—Janie

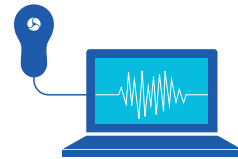
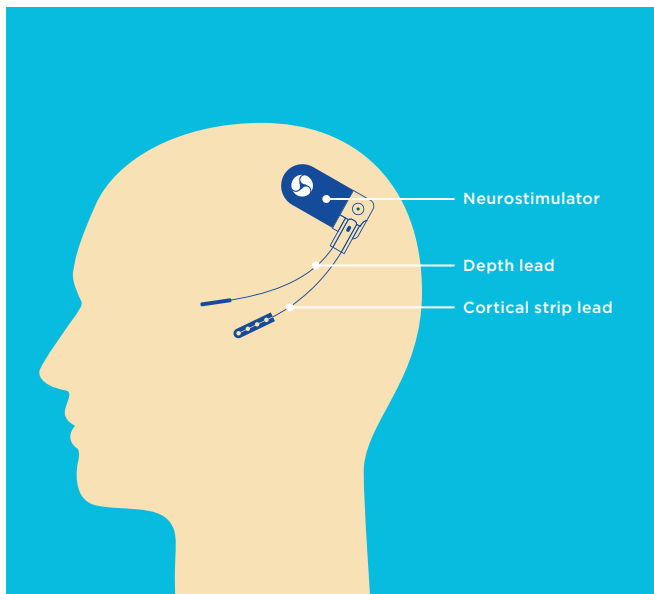
Your RNS® System

It's time to get to know your RNS System! You are now the proud owner of a medical device that is constantly monitoring your brain's electrical activity. Over time, this information will help your doctor identify your unique seizure fingerprint and personalize the therapy for you.

Neurostimulator and Leads

The neurostimulator sits inside a titanium tray that has been placed so that it is flush with your skull and does not touch your brain. The device is hidden under your scalp—unnoticeable to you and others. The

leads are tiny wires that are implanted at the seizure focus or foci. You may have up to 4 leads in place, but only 2 are connected to the neurostimulator at a time. The neurostimulator is already set up to monitor and record your brain's electrical activity.



Wand & Remote Monitor

The wand and remote monitor allow you to collect information from the neurostimulator and send the information to your doctor. This important feature of

the RNS® System provides your doctor with objective, ongoing information about your brain's electrical activity that can help inform your treatment.



Magnet

The magnet enables you to record brain activity during a seizure. See Section 3 for more information on how to use the magnet.



Medical Implant Identification Card

This wallet-sized card lets others know you are using the RNS System. It will also make them aware of procedures that are not allowed (such as any MRI if you have a model RNS-300M Neurostimulator), your physician's name and phone number, and which NeuroPace product you have.

Your Personalized Treatment

The RNS® System is a truly personalized therapy that is programmed to your unique seizure fingerprint. It will take some time for your doctor to fine-tune the RNS System to detect your specific patterns.

Step 1: Identifying your unique seizure patterns.

In the beginning—usually for the first month after the procedure—the RNS® System will simply be observing your brain patterns. It constantly monitors your brainwaves, even while you are sleeping.

In the coming days and weeks, you will use the wand and remote monitor

at home to send information from your neurostimulator to your doctor. The information will be used to program the device to distinguish between normal brain patterns and the unusual brain patterns that can lead to a seizure.

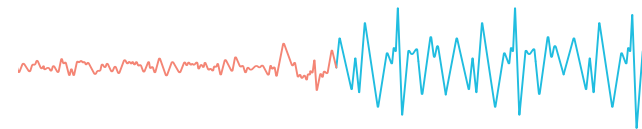
Find more information on how to use the wand and remote monitor in Section 3.

Step 2: Optimizing stimulation to help prevent seizures.

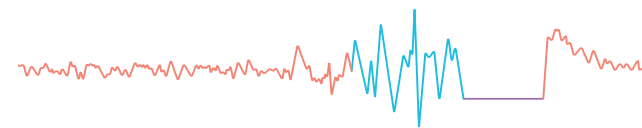
Once your doctor is satisfied that the neurostimulator is detecting the specific brain patterns that can develop into seizures, the next step is to turn on therapy (therapeutic stimulation). This usually happens at the first or second office visit, about a month after the procedure. When therapy is turned on, the neurostimulator responds within milliseconds of detecting unusual brain activity. It sends small,

brief pulses of electrical stimulation to disrupt this activity and normalize your brainwaves—often before you feel seizure symptoms. The total stimulation delivered is usually less than 6 minutes a day and should not be felt.

Some people find that they experience a reduction in seizures when stimulation is started, but the time frame for optimizing your neurostimulator settings may vary.



Step 1: In the beginning, the neurostimulator will simply be observing your brain patterns. A recording from the RNS® System shows unusual brain patterns (in blue) that could lead to a seizure.



Step 2: When therapeutic stimulation is turned on in response to detecting unusual brain activity, small electric pulses are delivered to normalize brainwaves with the goal of preventing a seizure from developing.

GETTING STARTED

Follow-up Visits


Initially, you may visit your doctor about once a month. Over time, your visits are likely to occur less often, usually every three months.

The follow-up visits allow your medical team to:

- Review your personal seizure diary and your seizure activity.
- Make any necessary adjustments to your neurostimulator.
- Discuss any questions or concerns you have.

Note: you do not need to bring your remote monitor to follow up visits.

Post-procedure	Initial follow-up at about 1 month	Subsequent visits about every 3 months
<ul style="list-style-type: none">• Your neurostimulator is programmed to monitor and detect brain activity.• You learn to use the remote monitor.• You typically return home after 1-2 days.	<ul style="list-style-type: none">• Your doctor reviews your seizure diary.• Your doctor reviews the data recorded by the RNS System.• Your doctor typically turns on stimulation at the first or second office visit.	<ul style="list-style-type: none">• Your doctor reviews your seizure diary.• Your doctor reviews the data recorded by the RNS System.• Your doctor adjusts device settings as needed.



“Don’t get discouraged if you don’t see immediate improvement. Stay positive & ask for support. Keep journaling in your seizure diary! —Michael

AMBASSADOR INSIGHTS

Have patience with the process

“The RNS System gets better with time. Have patience while data is collected and treatment is adjusted to one’s seizure activity.” —Paula

SHARING INFORMATION WITH YOUR DOCTOR

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, your doctor can see for the first time what's happening in your brain during your normal daily activities. The device collects ongoing information that helps your doctor learn more about your seizures and improve your care.

You play an important role in the management of your care. By collecting and sending information from your neurostimulator to a secure database, called the Patient Data Management System (PDMS), you can help your doctor see your brain activity and ensure the device is working properly.

AMBASSADOR INSIGHTS

A unique window to your brain

“Before the RNS System, when a doctor would ask if I had any seizures, I would say yes, but most of the time I could only relay what someone else witnessed. Now, when I say I had a bad seizure, there is recorded data and my doctor can see what was happening in my brain at that time.” —Michael

If we do our part in regularly sending the data and keeping our seizure diary, then our care team is better able to help us.

—Ouida

Using Your Wand and Remote Monitor

Sharing data with your doctor usually takes about 5 minutes and involves two steps. You will be trained on how to use the remote monitor (laptop, wand, accessories) prior to your discharge from the hospital. You will also receive written instructions to take home. For complete instructions on how to use your remote monitor, please see the Remote Monitor Manual, available at [NeuroPace.com/resources](https://www.neuropace.com/resources).



Scan for an instructional video.



Daily

Download data from your neurostimulator to your remote monitor.

We recommend that you collect data from the neurostimulator:

- At least once a day (morning or evening)
- After any significant seizures or auras
- Prior to any follow-up appointments

How to download data from the neurostimulator to the remote monitor:

- Press **Control-Alt-Delete** to start
- Type "NPUser" as the User Name (no password)
- Hold the wand over the neurostimulator and click on **Interrogate**. Hold the wand where the signal bars are high until the remote monitor says you're done.

Weekly

Upload data to the secure PDMS database using the internet.

NeuroPace recommends that you send the data to the PDMS database (via the internet) at least once a week. This makes it available for your doctor to view in a secure database called PDMS (Patient Data Management System). Please note that when you transfer your data, it is made

available to your doctor, but does not necessarily mean that they have reviewed the data immediately.

How to transfer data from the remote monitor to the PDMS:

- Click on **Transfer Data** on the Main Menu.
- Click on **Synchronize**

SHARING INFORMATION WITH YOUR DOCTOR

Using Your Magnet

The magnet instructs the neurostimulator to record brain activity, so that your doctor is able to identify the event during data review and make adjustments to the neurostimulator settings as needed. To learn more about using the magnet, please refer to the patient manual, available at [NeuroPace.com/resources](https://www.neuropace.com/resources).

Note: The magnet pictured is not actual size.



Scan for an instructional video.

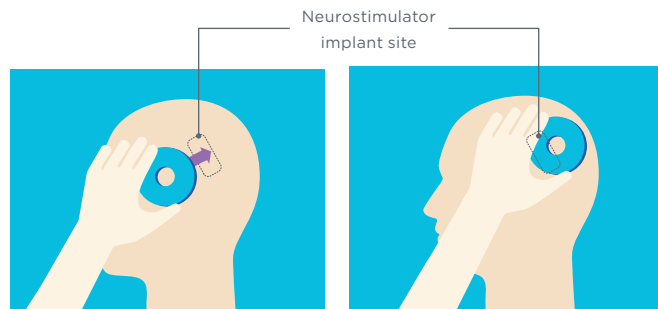


Figure 1

Figure 2

How to use the Magnet (as seen in Figures 1 and 2).

Swipe the magnet in line with your neurostimulator, while you say “counting 1, counting 2, counting 3.” This instructs the neurostimulator to record brain activity, so that your doctor is able to identify the event during data review and make adjustments to the neurostimulator settings as needed.

Talk to your doctor to find out when you should use the magnet to record your brain activity (such as when a seizure is starting). The recording will be included with the other data stored in the neurostimulator that you will send to the PDMS database. At your next office visit, your doctor can identify the event as a magnet swipe and make adjustments to the neurostimulator settings as needed.

AMBASSADOR INSIGHTS

Making the RNS[®] System work for your life

“Every night I take time to download my data, which only takes a few minutes. It is kind of like brushing your teeth; you just get into a routine.”

—Carlo

Using the magnet has really improved my follow-up visits because it’s helped my doctor see what’s going on in that moment.

—Heather



Continue Your Normal Activities

In general, you should be able to continue your normal activities, such as:

- Traveling
- Participating in sports and water activities like swimming.
- Using common household devices, including cell phones, computers, electronic tablets, most headsets and earphones, etc.
- Undergoing standard dental procedures such as X-rays, teeth cleaning and fillings (although you should not have procedures that involve electrocautery).

Travel with the RNS System

You will not have any travel restrictions with the RNS System. But here are some things to keep in mind or consider.

- Airport scanners will not damage the system but could cause or temporarily disrupt stimulation.
- You may want to inform the airport or security personnel that you have the RNS System by showing your Medical Implant Identification Card.
- You might want to bypass a body scan and opt for a pat-down security inspection.
- If you are unable to travel with your remote monitor, you won't be able to transfer your neurostimulator data until you return from your trip. Talk with your doctor about your options.
- If you travel internationally, connecting to the internet might be different and you might be unable to send data. Talk with your doctor in advance to find out what you should do.

Restricted Activities

Once you have the RNS System, you should not undergo any of the following procedures. Consult your doctor with questions you may have.

Diathermy

You should not be treated with any type of shortwave, microwave, or therapeutic ultrasound diathermy device, whether or not it is used to produce heat.

Transcranial Magnetic Stimulation (TMS)

You should not have any procedures that use electromagnetic currents to treat psychiatric disorders.

Electroconvulsive Therapy (ECT)

You should not undergo any electrically-induced seizures to treat psychiatric disorders.

Replacement Procedure

At medium stimulation and detection settings, the battery in the RNS-320 Neurostimulator is estimated to last nearly eleven years*, on average. Your doctor will let you know when the neurostimulator needs to be replaced.

During a replacement procedure, the surgeon will remove the old neurostimulator and replace it with a new one. The leads usually do not need to be replaced.

Replacement procedures are typically outpatient procedures that last about an hour or less. Your doctor will program your replacement device during the procedure.

Risks and Side Effects

The primary risks associated with the RNS System are those that are related to most surgical procedures, such as risk of infection or bleeding. These risks are comparable to other surgical procedures to treat epilepsy.

The RNS System does not cause the chronic side effects associated with many anti-seizure medications such as dizziness, drowsiness, depression, or confusion. Your doctor will test the stimulation in

the office to ensure you do not perceive or feel it.

For more information about the risks and cautions of the RNS System, see the safety information on pages 23-24.

*The median battery longevity is 10.8 years for the RNS Neurostimulator (model RNS-320). Estimates for longevity were derived from medium stimulation and detection utilization (mAh/day).



Now with the RNS System, I can plan to celebrate and spend time with family.

—Tracey

AMBASSADOR INSIGHTS

Embrace your new life.

“I started coaching high school girls fastpitch at my husband and son’s alma mater, and will help with the bowling team in the fall.” —Paula

“It has changed my life in so many ways. I have the freedom and security that I thought I would never feel again. I am now working on restarting my bucket list!” —Tammey

Every person’s seizures are different and individual results will vary.

Getting an MRI

Patients who have the model RNS-320 Neurostimulator are eligible for MRIs under certain conditions. Patients with the model RNS-300M Neurostimulator still CANNOT receive an MRI.

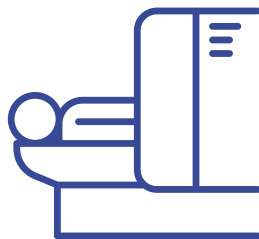
Full Body MRI Conditional

You can receive an MRI anywhere on your body under certain conditions.



Scan for more information about getting your MRI.

MRI ✓
RNS-320



MRI X
RNS-300M



Steps to Follow Before, During and After Your MRI

#1 Contact Your Epilepsy Specialist about Your MRI Needs

If your doctor has recommended you receive an MRI, contact your epilepsy specialist to confirm that you have an RNS® Neurostimulator model RNS-320 and discuss next steps.

#2 Schedule Your MRI

When you make an appointment for your MRI, tell them that you have an RNS® Neurostimulator (model RNS-320) and Leads implanted in your head.

#3 Schedule Two (2) Appointments with Your Epilepsy Specialist

Schedule the first appointment with your epilepsy specialist just before your MRI scan, so they can turn MRI Mode ON.

Schedule the second appointment to take place right after your MRI scan, so they can turn MRI Mode OFF.

#4 Getting Your MRI

Visit your epilepsy specialist just prior to your MRI scan to have MRI Mode turned ON. The specialist will give you an RNS® System MRI checklist to bring to your scan.

Tell the Radiologist or MR Technician that you have an RNS® Neurostimulator and Leads implanted in your head and give them the RNS® System MRI checklist from your epilepsy specialist.

Do: Bring your RNS® Neurostimulator patient identification card with you to the MRI Scan.

Do Not: Bring your magnet or Remote Monitor laptop to the MRI scan. The magnet and Remote Monitor laptop are MRI Unsafe and are not needed during your scan.

#5 After Your MRI

As soon as possible after your MRI, visit your epilepsy specialist so they can turn MRI mode OFF. Bring the RNS® System MRI checklists with you.

We're Here to Support You

When you chose the RNS System, you joined a community of people with shared hopes for a better quality of life. Why not stay connected? If you are interested in staying in touch, visit [Facebook.com/NeuroPaceRNSSystem](https://www.facebook.com/NeuroPaceRNSSystem) and [Twitter.com/NeuroPace](https://twitter.com/NeuroPace).

RNS Ambassadors

You've heard from many of our volunteer RNS Ambassadors in this book, as they share their journey with you. If you'd like to ask an ambassador a question or hear about their experience with a particular matter, you can visit [NeuroPace.com/stories](https://www.neuropace.com/stories) to schedule a call.

Patient Educator

Even after you have the RNS System, our NeuroPace® Patient Educator is here to answer your basic questions and help you get the information you need. Our Patient Educator can be reached at connect@NeuroPace.com or at 1-888-646-8483.

Technical Assistance

Contact NeuroPace Customer Support (available 24 hours a day) at 1-866-726-3876 if you:

- Need help setting up or using the remote monitor and wand.
- Need more information about what to do when traveling.
- Experience technical difficulties sending data. If possible, please write down the issue(s) or error message(s).

Medical Assistance

Medical Emergencies: Contact 911

Please call 911 if you have any medical emergencies. Inform the personnel that you have an RNS System medical implant and share your Medical Implant Identification Card.

Medical Concerns: Contact Your Physician

Please contact your physician if you:

- Have infections at the site after surgery.
- Have any medical issues following your RNS System implant surgery.

- Experience seizures with greater frequency or severity.
- Experience any pain or discomfort from the stimulation.
- Want to verify if it's safe to undergo a medical procedure or treatment.
- Want to verify if it's safe to participate in a specific activity.
- Cannot collect data from the neurostimulator and send it to the PDMS.

IMPORTANT SAFETY INFORMATION

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 $\geq 2.5\%$ 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.

DN 1014760 Rev 4
Rev. Date: 2020-03

NOTES

NOTES

Thank you for choosing the RNS System to start your new journey. We can't wait to see what you do next.

For more information, visit [NeuroPace.com](https://www.NeuroPace.com).



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NP160076 Rev 6/ Rev. Date: 2022-03