RNS® System MRI Pre-Scan Checklist

A physician managing the treatment of a patient with the RNS® System should use this checklist to ensure compliance with the conditions of safe use before an MRI scan. Refer to the entire MRI Guidelines for the RNS® System for complete safety information and guidelines for conducting an MRI scan.

Complete each section below to determine a patient's eligibility for an MRI scan and to prepare an eligible patient for an MRI scan. In order to facilitate communication with MR technicians who will perform the MR conditional scan, the physician should provide the completed form to the MRI radiology professional.

PATIENT INFORMATION

Patient Name	
Physician Name	
Physician Office Address	
Physician Phone	

MRI CENTER INFORMATION

MRI Center Name	
Checklist Delivered Via (select then enter below):	☐ MAIL ☐ EMAIL ☐ PHONE/FAX ☐ OTHER (specify):
Address/Number	

RNS® NEUROSTIMULATOR IMPLANTED IN THE PATIENT

Determine device system eligibility:

- *Use the Patient Data Management System (PDMS) to obtain a record of the RNS® System components implanted in this patient and to confirm the implanted RNS® Neurostimulator model number.*
- *Check the box corresponding to the implanted RNS® Neurostimulator model number.*

RNS® System Component*	Implanted Product (Model #)	MR Elibility
Neurostimulator	☐ RNS-300M	**MR Unsafe**
Neurostimulator	☐ RNS-320	MR Conditional
Neurostimulator	☐ No RNS Neurostimulator implanted (leads only)	MR Conditional

*All NeuroPace lead models are MR Conditional and can be attached or unattached to the neurostimulator. Unattached leads can be capped or uncapped. Leads that are cut or broken (at any point along the length of the lead) are eligible for MRI.

The following implantable RNS System components are MR Conditional: Connector Cover (CC-01), Connector Plug (CP-01), Ferrule (F-01), Ferrule Clamp (FC-01).The following implantable RNS System components are MR Safe: Lead Strain Relief (LSR-01), Lead Cap (LC-01), Suture Sleeve (SS-01). The following NeuroPace product is no longer distributed commercially and has not been evaluated for MRI safety: Cranial Prosthesis (P-01).

PATIENT ELIGIBILITY

Is the RNS® Neurostimulator implanted in the patient MR Conditional? **If NO, this patient is not eligible for MRI. Do not perform an MRI scan. If YES, the device system is eligible for MRI. Continue with the checklist.**	☐ Yes ☐ No

NEUROPACE

PATIENT PREPARATION

Check each box as the item is addressed. (All boxes should be checked.)

☐ Confirm that the patient has adequate time to recover from any invasive procedure related to the implantable components of the RNS® System prior to the MRI scan. Confirm that at least 10 days will have passed since any lead implant or repositioning before the MRI scan will occur.

☐ Confirm that the battery status is not at EOS (end of service).

☐ Identify if the patient has any non-NeuroPace implants. NeuroPace has not evaluated the safety or effect of implanted devices or implanted device components from other manufacturers in combination with or in proximity to the implanted RNS® System. Contact the appropriate device manufacturer with questions regarding other devices or device components.

☐ Confirm that the MRI facility performing the scan has an eligible MRI System. ***See Appendix B: Scan Checklist (Radiology).***

☐ Warn patient about the potential effects of MR exposure. Refer to ***Potential Effects of MR Exposure*** in the MRI Guidelines for the RNS® System for more information.

☐ Advise patient to take the NeuroPace Patient ID card to MRI appointment.

☐ Arrange to turn on MRI Mode as close to the date of the MRI scan as possible.

☐ Schedule follow-up appointment to satisfy post-scan requirements as soon after the date of the MRI scan as possible. **It is important to turn off MRI Mode soon after the scan to restore therapy and preserve battery longevity.** See *Appendix C: Post-Scan Checklist (Neurology).*

DEVICE PREPARATION

☐ **Turn on MRI Mode.** This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe.

CLINICIAN CONFIRMATION

☐ Check this Box to confirm that the information has been reviewed, is accurate as entered, and will be communicated to the MRI Center indicated above.

PERSON COMPLETING FORM (PRINT NAME)   **DATE COMPLETED**

RNS® System MRI Post-Scan Checklist

Appendix C in MRI Guidelines for the RNS® System

A physician managing the treatment of a patient with the RNS® System should use this checklist to ensure compliance with conditions of safe use after an MRI scan. Refer to the entire MRI Guidelines for the RNS® System for complete safety information and guidelines for conducting an MRI scan.

POST-SCAN CONDITIONS

☐ Confirm that MRI scan was performed or cancelled.

☐ **Turn off MRI Mode.** This step must be completed outside the MRI scanner room because the RNS® Tablet and Wand are MR Unsafe.

☐ Perform post-scan RNS® System checks. Confirm that the neurostimulator has been restored to its pre-MRI settings. If necessary, reprogram the neurostimulator. Immediately contact NeuroPace to report any suspected device anomalies after MR exposure.