

Subject: MRI Safety Information for Roadsaver™ Carotid Stent System

Dear Customer,

We are writing to inform you that the Roadsaver™ Carotid Stent System is MR Conditional. This means that a patient implanted with the device may undergo MRI scans only under specific conditions. Scanning outside of these conditions may result in serious patient injury.

The Patient Implant Card you received includes a summary of these MRI conditions. For complete MRI safety information, please refer to the table below or consult the MRI Safety Information section of the Instructions for Use (IFU), available at www.terumoneuro.com.

MRI Safety Information

 MRI Safety Information A patient implanted with the Roadsaver Carotid Stent may safely be scanned under the following conditions. Failure to follow these conditions may result in injury.	
Parameter	Condition
Device Name	Roadsaver Carotid Stent System
Static Magnetic Field Strength (B0)	1.5T and 3T, Only
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Coil Type	Body Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2-W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	15 minutes of continuous scanning followed by 15 minutes of cooling
Image Artifacts	Extends approximately 5-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system

If you have questions regarding the Roadsaver™ device implant or MRI safety, please contact your physician or MicroVention at 1-800-990-8368.

Sincerely,
Terumo Neuro