



### GORE® EXCLUDER® Device family MRI information

Through non-clinical testing, the GORE® EXCLUDER® AAA Endoprosthesis, GORE® EXCLUDER® Conformable AAA Endoprosthesis, and GORE® EXCLUDER® Iliac Branch Endoprosthesis have been shown to be MR Conditional. A patient with these devices can be scanned safely, immediately after placement under the following conditions for each device listed in Table 1.

If the GORE® EXCLUDER® Iliac Branch Endoprosthesis is used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable AAA Endoprosthesis, it is recommended to use the GORE® EXCLUDER® Iliac Branch Endoprosthesis MRI recommendations. The GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® Conformable AAA Endoprosthesis are not currently indicated for use together.

Device specific heating and image artifact data is also provided below.

**Table 1**

	GORE® EXCLUDER® AAA Endoprosthesis	GORE® EXCLUDER® Conformable AAA Endoprosthesis	GORE® EXCLUDER® Iliac Branch Endoprosthesis
Static magnetic field	1.5 T or 3.0 T	1.5 T or 3.0 T	1.5 T or 3.0 T
Highest / maximum spatial field gradient	3,000-Gauss / cm	3,000-Gauss / cm	3,000-Gauss / cm
Whole body-averaged Specific Absorption Rate (SAR)	2.0-W / kg in normal operating mode	2.0-W / kg in normal operating mode	2.0-W / kg in normal operating mode

#### GORE® EXCLUDER® AAA Endoprosthesis

Under the scan conditions defined above, the GORE® EXCLUDER® AAA Endoprosthesis produced a temperature rise of less than or equal to 2.7° C at a maximum whole body averaged Specific Absorption Rate (SAR) of 2.9 W / kg for 15 minutes of MRI on a 3-Tesla / 128-MHz MR system.

MRI quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® EXCLUDER® AAA Endoprosthesis.

#### GORE® EXCLUDER® Conformable AAA Endoprosthesis

Under the scan conditions defined above, the GORE® EXCLUDER® Conformable AAA Endoprosthesis is expected to produce a maximum temperature rise of 2.0° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the GORE® EXCLUDER® Conformable AAA Endoprosthesis when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does not obscure the device lumen.

#### GORE® EXCLUDER® Iliac Branch Endoprosthesis

Under the scan conditions defined above, the GORE® EXCLUDER® Iliac Branch Endoprosthesis produced a temperature rise of less than or equal to 3.2° C at a maximum whole body averaged Specific Absorption Rate (SAR) of 2.9-W / kg for 15 minutes of MRI on a 3-Tesla / 128-MHz MR system.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the GORE® EXCLUDER® Iliac Branch Endoprosthesis when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. This artifact does not obscure the device lumen.

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Products listed may not be available in all markets.