March 2017

Dear Healthcare Professional:

This letter provides the recommendations for Magnetic Resonance Imaging (MRI) of the GORE® VIATORR® TIPS Endoprosthesis and GORE® VIATORR TIPS Endoprosthesis with Controlled Expansion.

MR Conditional

Non-clinical testing has demonstrated that the GORE® VIATORR® TIPS Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- **Static magnetic field of 1.5 or 3.0 Tesla**
- **Spatial gradient field of ≤ 720 Gauss / cm**
- **Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of scanning.**

3.0 Tesla Temperature Rise:
In non-clinical testing, the GORE® VIATORR® TIPS Endoprosthesis produced a temperature rise of 1.9ºC at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:
In non-clinical testing, the GORE® VIATORR® TIPS Endoprosthesis produced a temperature rise of 1.9ºC at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8 W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:
The image artifact extends approximately 1–2 mm from the device, both inside and outside the device lumen when scanned in non-clinical testing using sequence: T1– weighted, spin echo and gradient echo pulse sequences in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR system with a send-receive RF body coil.

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1– weighted, spin echo pulse sequence for the GORE® VIATORR® TIPS Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE® VIATORR® TIPS Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

Please contact me if you require further information. I can be reached at +1.623.234.5691 or at *amclark@wlgore.com*.

Regards,

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INDICATIONS FOR USE IN THE US: The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the *de novo* and revision treatment of portal hypertension and its complications such as variceal bleeding, gastropathy, refractory ascites, and / or hepatic hydrothorax. **INDICATIONS FOR USE UNDER CE MARK:** The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the treatment of portal hypertension and its complications such as: variceal bleeding refractory to, or intolerant of, conventional therapies, inaccessible varices, gastropathy, refractory ascites, and / or hepatic hydrothorax. Refer to *Instructions for Use* at goremedical.com for a complete description of all contraindications, warnings, precautions and adverse events. ℞ Only