Together, improving life

GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis MRI safety information

MR Conditional

A patient with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) may be safely scanned immediately after placement under the following conditions. Failure to follow these conditions may result in injury.

Static magnetic field strength (B_0)	1.5 T or 3.0 T
Maximum spatial field gradient	30 T/m (3,000-Gauss/cm)
RF excitation	There are no RF excitation restrictions
RF transmit coil type	There are no transmit coil restrictions
Operating mode	Normal operating mode
Maximum whole-body SAR	2 W/kg (Normal operating mode)
Scan duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (A sequence or back to back series/scan without breaks)
MR image artifact	The presence of this implant may produce an image artifact. With a gradient echo pulse sequence in a 3.0 T MR System, the artifact may extend up to 10 mm from the implant. The lumen of the central aortic and iliac components (i.e., Aortic Component, Distal Bifurcated Component, Contralateral Leg Components, and optional DBC Extender Component) could be visualized using gradient echo and spin echo pulse sequences, while the lumens of the GORE® VIABAHN® VBX Balloon Expandable Endoprostheses (i.e., Branch Components) could not be visualized using gradient echo and spin echo pulse sequences.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Consult Instructions for Use
eifu.goremedical.com

Indications for use in the U.S.: The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is indicated for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy as described below: Adequate iliac/femoral access and brachial/axillary access; Proximal (supraceliac) aortic neck treatment diameter range over 2 cm seal zone of 22-34 mm for aneurysms extending up to 6.5 cm or less above the origin of the most proximal branch vessel; Aortic neck angle ≤ 60° at the Aortic Component proximal seal zone; Iliac artery treatment diameter range of 8-25 mm and iliac artery seal zone length of at least 10 mm; Renal artery seal zone diameters between 4.0-10.0 mm; Celiac and superior mesenteric artery seal zone diameters between 5.0-12.0 mm; ≥ 15 mm seal zone length in renal arteries, superior mesenteric artery, and celiac artery; Visceral segment of aorta (3 cm proximal through 9.5 cm distal to the most proximal visceral artery) must be ≥ 20 mm in diameter. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the TAMBE Device materials including ePTFE, FEP, nickel titanium alloy (Nitinol), stainless steel, and gold. Patients who have a condition that threatens to infect the graft. Patients with known hypersensitivity to heparin, including patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II and cannot receive the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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