Magnetic Resonance Imaging (MRI) Safety Information for Devices Labeled as MR Conditional

The tables show the Gore devices that are labeled as MR conditional. This means that the devices have demonstrated safety in a specified MRI environment with the defined conditions of use listed.

The information on this page provides only a summary of MR conditions for each device and is intended as a reference for the U.S. only. For a full version of conditions, please see product *Instructions for Use* (IFU).

The information on this page is current as of November 2022. For the most current and complete MR safety information on any product, always refer to the IFU at eifu.goremedical.com.

GORE® VIABIL® Biliary Endoprosthesis/GORE® VIABIL® Short Wire Biliary Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 and 3.0 Tesla
Maximum spatial gradient	3000 Gauss/cm (30 T/m)
Max whole-body-averaged specific absorption rate (SAR)	4 W/kg (first level controlled mode)
Scan duration	15 minutes of continuous scanning
Image artifact (3 tesla, gradient echo pulse sequence)	5 mm from the device The artifact does obscure the device lumen
Time (post-implant) to safely scan	No restrictions listed in IFU

GORE® CARDIOFORM Septal Occluder

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	4000 Gauss/cm (40 T/m)
Max whole-body-averaged SAR	4 W/kg (first level controlled operating mode)
Scan duration	15 minutes of scanning (i.e., per pulse sequence)
Image artifact (3 tesla, gradient echo pulse sequence)	In non-clinical testing, the image artifact caused by the GORE® CARDIOFORM Septal Occluder extends approximately 10 mm from this implant
Time (post-implant) to safely scan	No restrictions listed in IFU

GORE® CARDIOFORM ASD Occluder

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	4000 Gauss/cm (40 T/m) or less
Max whole-body-averaged SAR	<2 W/kg (normal operating mode)
Scan duration	15 minutes of continuous scanning
Image artifact (3 tesla, gradient echo pulse sequence)	In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the GORE® CARDIOFORM ASD Occluder
Time (post-implant) to safely scan	Immediately after placement if conditions are met

GORE® TAG® Conformable Thoracic Stent Graft

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	3000 Gauss/cm (30 T/m)
Max whole-body-averaged SAR	2.0 W/kg (normal operating mode) Testing to a maximum MR system reported whole-body-averaged SAR of 3 W/kg for 15 minutes of scanning has also been found to be safe
Scan duration	15 minutes of continuous scanning
Image artifact (3 tesla, gradient echo pulse sequence)	10 mm relative to the size and shape of the vascular device
Time (post-implant) to safely scan	Immediately after placement

GORE® TAG® Thoracic Branch Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	3000 Gauss/cm (30 T/m)
Max whole-body-averaged SAR	2.0 W/kg (normal operating mode)
Scan duration	60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
Image artifact (3 tesla, gradient echo pulse sequence)	The artifact may extend up to 10 mm from the implant. Under these conditions, the central portion of the lumen of the aortic component was visible.
Time (post-implant) to safely scan	Immediately after placement

GORE® EXCLUDER® AAA Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	3000 Gauss/cm or less
Max whole-body-averaged SAR	2.0 W/kg (normal operating mode)
Scan duration	15 minutes of scanning (i.e. per pulse sequence)
Image artifact (3 tesla, gradient echo pulse sequence)	10 mm
Time (post-implant) to safely scan	Immediately after placement

GORE® EXCLUDER® Conformable AAA Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	3000 Gauss/cm (30 T/m) or less
Max whole-body-averaged SAR	2 W/kg (normal operating mode)
Scan duration	15 minutes of continuous scanning
Image artifact (3 tesla, gradient echo pulse sequence)	8 mm from the device The artifact does not obscure the device lumen
Time (post-implant) to safely scan	Immediately after placement

GORE® EXCLUDER® Iliac Branch Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	3000 Gauss/cm (30 T/m) or less
Max whole-body-averaged SAR	4 W/kg (normal operating mode)
Scan duration	15 minutes of continuous scanning
Image artifact (3 tesla, gradient echo pulse sequence)	5 mm from the device The artifact does not obscure the device lumen
Time (post-implant) to safely scan	Immediately after placement

GORE® VIABAHN® Endoprosthesis/GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla
Maximum spatial gradient	30 T/m (3000 Gauss/cm)
Max whole-body-averaged SAR	2 W/kg (normal operating mode) For a GORE® VIABAHN® Endoprosthesis/GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface placed within a bare nitinol stent, the lesser of the maximum whole-body averaged SAR reported in the bare nitinol stent's IFU, or the maximum whole-body averaged SAR of 2.0 W/kg should be used.
Scan duration	60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
Image artifact (3 tesla, gradient echo pulse sequence)	The presence of this implant may produce an image artifact. With a gradient echo pulse sequence, the artifact may extend up to 5 mm from the implant and may obscure the lumen. When the GORE® VIABAHN® Endoprosthesis/GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface was placed within a bare nitinol stent the image artifact extended up to 20 mm from the devices. Artifacts extended both inside and outside the device lumen.
Time (post-implant) to safely scan	Immediately after placement

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	1000 Gauss/cm or less
Max whole-body-averaged SAR	2 W/kg (normal operating mode)
Scan duration	15 minutes of scanning (i.e. per pulse sequence)
Image artifact (3 tesla, gradient echo pulse sequence)	15 mm from the device
Time (post-implant) to safely scan	No restrictions listed in IFU

GORE® VIATORR® TIPS Endoprosthesis/GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion

MR status	MR conditional
Static magnetic field strengths	1.5 Tesla or 3.0 Tesla only
Maximum spatial gradient	720 Gauss/cm
Max whole-body-averaged SAR	3.0 W/kg
Scan duration	15 minutes of scanning
Image artifact (3 tesla, gradient echo pulse sequence)	The image artifact extends approximately 2 mm from the device, both inside and outside the device lumen
Time (post-implant) to safely scan	No restrictions listed in IFU

GORE® CARDIOFORM Septal Occluder

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS/INTENDED USE: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs); patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin, or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. 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

GORE® CARDIOFORM ASD Occluder

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS/INTENDED USE: The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM ASD Occluder is contraindicated for use in patients: unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin; with anatomy where the GORE® CARDIOFORM ASD Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. 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

GORE® TAG® Conformable Thoracic Stent Graft

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Conformable Thoracic Stent Graft is intended for endovascular repair of all lesions of the descending thoracic aorta, including: Isolated lesions in patients who have appropriate anatomy, including: adequate iliac/femoral access, aortic inner diameter in the range of 16–42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac/femoral access, ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16–42 mm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. 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

GORE® TAG® Thoracic Branch Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who are at high risk for debranching subclavian procedures and have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the left subclavian artery and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16–42 mm; Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0–4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with a surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Left Subclavian Landing Zone:** Not aneurysmal, dissected, heavily calcified, or heavily thrombosed and without severe tortuosity (180 degree turn within the treated length); Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Left subclavian artery minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16–42 mm; Non aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (Fluoroethylpropylene), Nitinol (Nickel, Titanium), Gold, SB Component only - Heparin (CBAS® Heparin surface]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

GORE® EXCLUDER® AAA Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: Trunk–Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac/femoral access; Infrarenal aortic neck treatment diameter range of 19–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in: patients with known sensitivities or allergies to the device materials; patients with a systemic infection who may be at increased risk of endovascular graft infection. 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

GORE® EXCLUDER® Conformable AAA Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: Trunk–Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® Conformable AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac/femoral access; Infrarenal aortic neck treatment diameter range of 16–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Conformable AAA Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials; Patients with a systemic infection who may be at increased risk of endovascular graft infection. 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

GORE® EXCLUDER® Iliac Branch Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to be used with the GORE® EXCLUDER® AAA Endoprosthesis or the GORE® EXCLUDER® Conformable AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: adequate iliac/ femoral access; minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; external Iliac artery treatment diameter range of 6.5–25 mm and seal zone length of at least 10 mm; internal iliac artery treatment diameter range of 6.5–13.5 mm and seal zone length of at least 10 mm; adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **GORE® EXCLUDER® AAA Endoprosthesis Components used in conjunction with GORE® EXCLUDER® Iliac Branch Endoprosthesis. Trunk–Ipsilateral Leg Component.** The Trunk-Ipsilateral Leg is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions For Use*. **Contralateral Leg Endoprosthesis Component.** The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Device Trunk-Ipsilateral Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions For Use*. **Aortic Extender and Iliac Extender Components**. The Aortic and Iliac Extender Components can be used after deployment of the GORE® EXCLUDER® Iliac Branch and GORE® EXCLUDER® AAA Endoprostheses. These extensions are used when additional length and/or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions For Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy) and gold; patients with a systemic infection who may be at increased risk of endovascular graft infection. 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

GORE® VIABAHN® Endoprosthesis/GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface

Consult Instructions for Use
eifu.goremedical.com

INTENDED USE / INDICATIONS: The GORE® VIABAHN® Endoprosthesis and the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface are indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–7.5 mm. The GORE® VIABAHN® Endoprosthesis and the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface are indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–6.5 mm. The GORE® VIABAHN® Endoprosthesis and the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface are indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0–12 mm. The GORE® VIABAHN® Endoprosthesis and the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface are indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis and the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface are contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. ℞ Only

GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

INTENDED USE/INDICATIONS: The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm–13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation. **CONTRAINDICATIONS:** Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. 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

GORE® VIABIL® Biliary Endoprosthesis/GORE® VIABIL® Short Wire Biliary Endoprosthesis

Consult Instructions for Use
eifu.goremedical.com

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

GORE® VIATORR® TIPS Endoprosthesis with Controlled Expansion

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: 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. **CONTRAINDICATIONS:** There are no known contraindications for this device. 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

Products listed may not be available in all markets.

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W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 67332882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771