

OCCLUSION DEVICES

Company Name	Occlusion/Embolic Protection Devices			US FDA Indicated Use
	Name	Type	Position	
Concentric Medical (acquired by Stryker Neurovascular)	Concentric and Merci Balloon Guide Catheters	Occlusion balloon	Proximal	Not provided
LeMaitre Vascular, Inc.	Pruitt Aortic Occlusion Catheter	Occlusion balloon	Distal	Designed for the purpose of obtaining rapid control of in-flow blood in the abdominal aorta in cases of ruptured aortic aneurysm or in other conditions when dissection of the neck of the aneurysm for different reasons may be especially difficult; this application of direct internal balloon occlusion is in lieu of external, proximal cross-clamping of the abdominal aorta and may prevent technical complications from special physiological situations. Intraluminal balloon occlusion may be accomplished by direct insertion through the wall of the aneurysm
	Pruitt Occlusion Catheter			The occlusion of vessels both arterial and venous for the control of bleeding
	Pruitt Irrigation Occlusion Catheter			To temporarily occlude vessels for the control of bleeding and to access the vessel lumen distal to the point of occlusion
Medrad Interventional	GuardDog Guidewire Occlusion System	Occlusion balloon	Distal	Indicated for use in the peripheral vasculature to facilitate the localized infusion of therapeutic or diagnostic fluids, with or without vessel occlusion
Medtronic, Inc.	GuardWire	Occlusion balloon	Distal	Not provided

GORE® Flow Reversal System

INDICATIONS FOR USE: The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have appropriate anatomy as described in the *Instructions for Use*. Refer to the *Instructions for Use* at goremedical.com for contraindications, warnings and precautions. ® & ©

GORE® Embolic Filter

INDICATIONS FOR USE IN THE US: The GORE® Embolic Filter is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during angioplasty and stenting procedures in carotid arteries with diameters between 2.5 and 5.5 mm. **INDICATIONS FOR USE UNDER CE MARK:** The GORE® Embolic Filter is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus / debris) during angioplasty and stenting procedures in coronary arteries, saphenous vein grafts, carotid arteries and peripheral arteries with reference diameters of 2.5 to 5.5 mm. Refer to *Instructions for Use* at goremedical.com for a complete list of contraindications, warnings and precautions, and adverse events. ® & ©



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