

INSTRUCTIONS FOR USE FOR:



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English

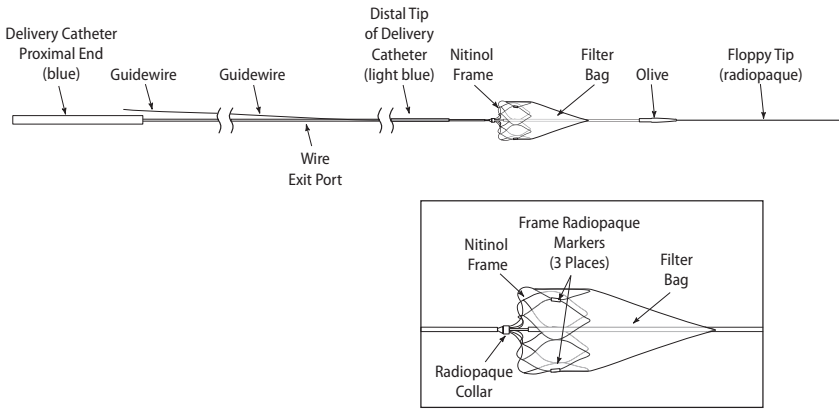
INSTRUCTIONS FOR USE FOR: GORE® Embolic Filter

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DEVICE DESCRIPTION

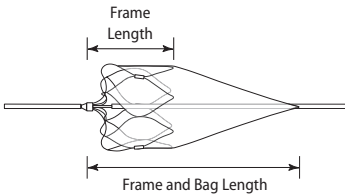
The GORE® Embolic Filter system consists of an embolic filter device, a delivery catheter, and a retrieval catheter, and is compatible with guide catheters and sheaths having a minimum inner diameter of 0.066". A wire torquing device and peel-away introducer sheath are packaged with the system. The embolic filter device is a nitinol frame with an attached expanded polytetrafluoroethylene (ePTFE) filter bag (Figure 1). The filter bag has a hydrophilic heparin coating and is perforated with pores (nominal pore size of 100 µm). The proximal end of the frame is attached to a 0.014" PTFE coated guidewire. The distal guidewire has a shapeable, radiopaque floppy tip. The guidewire passes through the distal end of the filter bag. There is rotational freedom between the guidewire and filter components so that when the device is loaded and deployed, the guidewire is free to rotate independent of the filter. There are four radiopaque markers on the filter: three markers on the frame and the radiopaque collar, joining the guidewire to the filter. The filter comes in two sizes to accommodate vessel diameters from 2.5 to 5.5 mm. The frame length and total frame and bag length are shown in Figure 2. The guidewire comes in 185 cm and 300 cm lengths. The delivery catheter and the retrieval catheter each have a working length of 150 cm and a guidewire exit port approximately 30 cm from the distal tip to facilitate single-operator use. The light blue tip of the delivery catheter has an outer diameter of less than or equal to 3.2 Fr (1.1 mm). The proximal end of the delivery catheter is colored blue. The gray tip of the retrieval catheter has an outer diameter of less than or equal to 4.8 Fr (1.6 mm) and contains a radiopaque marker. The proximal end of the retrieval catheter is colored black.

FIGURE 1: GORE® Embolic Filter



When deployed from the delivery catheter, the heparin-coated filter bag with perforated holes enables the capture of embolic debris that may be produced during the procedure while maintaining blood perfusion. The frame provides apposition to the vessel wall to enhance debris collection. At the completion of the procedure, the filter is recaptured and removed from the patient using the retrieval catheter. The GORE® Embolic Filter is supplied sterile and should not be resterilized.

FIGURE 2: GORE® Embolic Filter Frame Length / Frame and Bag Length



Filter Diameter Unconstrained	Frame Length *	Frame and Bag Length *
5 mm	8 mm	18 mm
7 mm	9 mm	20 mm

* When measured in the smallest indicated vessel diameter.

CONTENTS

One each: GORE® Embolic Filter, delivery catheter, retrieval catheter, wire torquing device, peel-away introducer.

INDICATIONS FOR USE

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.

CONTRAINDICATIONS

DO NOT USE IN:

- Patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of heparin induced thrombocytopenia (HIT) type II.
- Patients in whom anti-coagulant or anti-platelet therapy is contraindicated.
- Patients with tortuous anatomy or disease morphology which would prohibit the safe placement of guide catheters, sheaths, embolic protection systems, or stent systems within the access or target vessels.
- Patients with known hypersensitivity to nitinol.
- Patients with unresolved bleeding disorders.

WARNINGS

- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid artery interventional procedures should use this device.
- The safety and efficacy of the GORE® Embolic Filter has not been demonstrated with carotid stent systems other than ACCULINK Carotid Stent, XACT Carotid Stent, PRECISE Carotid Stent, PROTEGE Carotid Stent, and WALLSTENT Carotid Stent as listed in Table 5.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure at a dosage deemed appropriate by the physician.
- Ensure filter is sized properly for target vessel. Severe oversizing of the filter frame can lead to vessel spasm, vessel trauma or frame fracture. Severe undersizing can lead to inadequate vessel apposition and compromised filter efficiency.
- When introducing the delivery system, ensure that the floppy tip is free within the vessel lumen and is not directed against the vessel wall or advancing between the stent and vessel wall. Failure to do so may result in vessel trauma or the filter becoming trapped between the stent and vessel wall.
- Provide adequate distance between the radiopaque collar on the filter and the interventional device to avoid the potential for entanglement.
- Ensure the deployed filter is kept distal to the treatment site and the deployed stent. Do not attempt to pull a deployed filter through the stent or retrieve the filter within the stent. Pulling the filter into the stent area may lead to stent-filter entanglement and / or filter detachment.
- Avoid excessive movement of the GORE® Embolic Filter during catheter exchanges especially in a vessel with spasm as this may cause significant vessel damage.
- If blood flow is significantly reduced, aspirate blood proximal to filter prior to retrieving device.
- Complete withdrawal of the filter into the retrieval catheter may lead to filter bag tearing or rupture and release of embolic debris.
- During retrieval, withdraw the retrieval catheter and guidewire together. Pulling on only the retrieval catheter can lead to the filter redeploying from the retrieval catheter.
- The safety and effectiveness of this device as an embolic filter have not been established in vasculatures outside of the carotid arteries (coronary, cerebral, and peripheral).

PRECAUTIONS

- Confirm the compatibility of the GORE® Embolic Filter with the intended interventional devices prior to use.
- Do not use the GORE® Embolic Filter if the sterile package is compromised or the GORE® Embolic Filter is damaged.
- Follow the Directions for Use supplied with all accessories used in conjunction with the GORE® Embolic Filter.
- Exercise care in handling the GORE® Embolic Filter before and during the procedure to reduce the possibility of damaging the filter.
- The GORE® Embolic Filter is designed for single use only. Do not resterilize or reuse the GORE® Embolic Filter.
- Do not use the GORE® Embolic Filter after the labeled “use by” (expiration) date.
- Do not deliver the GORE® Embolic Filter with any interventional devices other than the GORE® Delivery Catheter.
- To ensure proper positioning and removal of the filter, the vessel distal to the treatment site should have adequate length and not be excessively tortuous.
- Do not continue to load device if filter bag is inverted (i.e., folded back on itself) or wrinkled. Stop and pull gently on the distal end of the bag to straighten it prior to completing device loading. Loading an inverted filter bag can lead to excessive loading and deployment forces.
- Always advance or withdraw the GORE® Embolic Filter slowly. Never push, withdraw or torque a wire that meets resistance. Resistance may be felt and / or observed under fluoroscopy by noting any buckling of the wire or tip. Determine the cause of the resistance under fluoroscopy and take any necessary remedial action.
- During delivery, advance the guidewire and the delivery catheter together. Advancing only the guidewire may result in premature filter deployment.
- Do not rotate the delivery or retrieval catheter excessively in either direction as this may cause the guidewire to wrap around the catheter.
- Maintain proper guide catheter / sheath support in the common carotid artery throughout the procedure. If guide catheter / sheath access cannot be maintained, the case should be discontinued. Failure to maintain proper support may lead to prolapse of the guide catheter / sheath in the aortic arch, resulting in any of the following:
 - Deployed filter pulled through an undilated lesion; or
 - Filter-stent entanglement; or
 - Filter fracture and / or detachment; or
 - Stent dislodgement
- Keep the wire position stable while the filter is deployed.
- Monitor the target vessel for signs of vasospasm. If evident, treat appropriately.
- Ensure there is adequate distance between the radiopaque collar on the filter and the distal end of the stent delivery system to achieve the desired stent position.
- Perform all catheter exchanges cautiously to prevent air embolism or damage to the artery.
- If excessive debris is collected in the filter and blood flow is obstructed, the filter may be removed and replaced or the procedure may be completed prior to device removal at the physician's discretion.
- Carefully retrieve the filter through newly deployed stents to ensure the stents are not disrupted.
- Do not attempt to retrieve filter with the delivery catheter.

ADVERSE EVENTS

Summary of Clinical Results (G080059):

The objective of the Gore EMBOLDEN Clinical Study was to assess the safety and effectiveness of the GORE® Embolic Filter for embolic protection during carotid artery angioplasty and stenting (CAS) procedures in high surgical risk patients. A comprehensive list of the major adverse events (MAEs) is provided in Table 1. In summary, outcomes in subcategories of the major adverse event end point included death (0.8%), death/major stroke (1.2%), death/any stroke (3.6%), myocardial infarction (MI) (0.4%), and death/stroke/MI (4.0%).

The device used in the EMBOLDEN study was improved upon based on feedback received as part of study use. Specifically, the delivery catheter was modified to improve filter deployment characteristics. This change was evaluated in bench testing and this data supported clearance of the improved device.

Table 1: Major Adverse Events

	GORE® Embolic Filter
Number of Subjects	250
Subjects With One or More Major Adverse Events	10 (4.0%)
Death	2 (0.8%)
Myocardial Infarction	1 (0.4%)
Q-Wave MI	0 (0.0%)
Non Q-Wave MI	1 (0.4%)
Stroke	7 (2.8%)
Major Stroke	1 (0.4%)
Ischemic Stroke	1 (0.4%)
Ipsilateral	1 (0.4%)
Non-Ipsilateral	0 (0.0%)
Hemorrhagic Stroke	0 (0.0%)
Ipsilateral	0 (0.0%)
Non-Ipsilateral	0 (0.0%)
Minor Stroke	6 (2.4%)
Ischemic Stroke	6 (2.4%)
Ipsilateral	5 (2.0%)
Non-Ipsilateral	1 (0.4%)
Hemorrhagic Stroke	0 (0.0%)
Ipsilateral	0 (0.0%)
Non-Ipsilateral	0 (0.0%)

The adverse events (serious and non-serious) that were reported during the Gore EMBOLDEN Clinical Study are summarized in Table 2. Adverse events (AEs) were defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of the GORE® Embolic Filter, whether or not considered related to the device.

Table 2: Summary of Adverse Events

GORE® Embolic Filter	Severity of Adverse Event		Overall
	Non-Serious	Serious	
Subjects with One or More Adverse Events	136 (54.4%)	56 (22.4%)	147 (58.8%)
Hypotension	38 (15.2%)	14 (5.6%)	51 (20.4%)
Anemia	14 (5.6%)	6 (2.4%)	19 (7.6%)
Hypertension	16 (6.4%)	2 (0.8%)	18 (7.2%)
Bradycardia	10 (4.0%)	5 (2.0%)	15 (6.0%)
Bleeding	11 (4.4%)	1 (0.4%)	12 (4.8%)
Headache	11 (4.4%)	2 (0.8%)	12 (4.8%)
Nausea	12 (4.8%)	-	12 (4.8%)
Access site pain	8 (3.2%)	-	8 (3.2%)
Angina/coronary ischemia	5 (2.0%)	3 (1.2%)	8 (3.2%)
Back pain	8 (3.2%)	-	8 (3.2%)
Cerebral ischemia/transient ischemic attack (TIA)	6 (2.4%)	2 (0.8%)	8 (3.2%)
Ecchymosis	8 (3.2%)	-	8 (3.2%)
Groin hematoma	6 (2.4%)	2 (0.8%)	8 (3.2%)
Hematoma	8 (3.2%)	-	8 (3.2%)
Vessel spasm	7 (2.8%)	1 (0.4%)	8 (3.2%)
Numbness	7 (2.8%)	-	7 (2.8%)
Renal failure/insufficiency	6 (2.4%)	1 (0.4%)	7 (2.8%)
Vomiting	7 (2.8%)	-	7 (2.8%)
Dyspnea	4 (1.6%)	2 (0.8%)	6 (2.4%)

GORE® Embolic Filter	Severity of Adverse Event		Overall
	Non-Serious	Serious	
Vascular access complication	3 (1.2%)	3 (1.2%)	6 (2.4%)
Abdominal pain	5 (2.0%)	-	5 (2.0%)
Asystole	3 (1.2%)	2 (0.8%)	5 (2.0%)
Dizziness	5 (2.0%)	-	5 (2.0%)
Urinary retention	5 (2.0%)	-	5 (2.0%)
Visual disturbance	4 (1.6%)	1 (0.4%)	5 (2.0%)
Fever	3 (1.2%)	1 (0.4%)	4 (1.6%)
Rash	3 (1.2%)	1 (0.4%)	4 (1.6%)
Stroke/cerebrovascular accident (CVA)	1 (0.4%)	3 (1.2%)	4 (1.6%)
Confusion	3 (1.2%)	-	3 (1.2%)
Congestive Heart Failure (CHF) - onset or worsening of	-	3 (1.2%)	3 (1.2%)
Edema	3 (1.2%)	-	3 (1.2%)
Hypokalemia	3 (1.2%)	-	3 (1.2%)
Infection at access site	2 (0.8%)	1 (0.4%)	3 (1.2%)
Itching	2 (0.8%)	1 (0.4%)	3 (1.2%)
Leg pain	3 (1.2%)	-	3 (1.2%)
Neck pain	3 (1.2%)	-	3 (1.2%)
Bronchitis	1 (0.4%)	1 (0.4%)	2 (0.8%)
COPD, worsening of	1 (0.4%)	1 (0.4%)	2 (0.8%)
Elevated WBC	2 (0.8%)	-	2 (0.8%)
Infection	1 (0.4%)	1 (0.4%)	2 (0.8%)
Ischemia/Infarction of tissue/organ	-	2 (0.8%)	2 (0.8%)
Pseudoaneurysm	1 (0.4%)	1 (0.4%)	2 (0.8%)
Retroperitoneal bleed	1 (0.4%)	1 (0.4%)	2 (0.8%)
Seizure	-	2 (0.8%)	2 (0.8%)
Slurred speech	2 (0.8%)	-	2 (0.8%)
Thrombocytopenia	2 (0.8%)	-	2 (0.8%)
Altered mental state	1 (0.4%)	-	1 (0.4%)
Atrial fibrillation	-	1 (0.4%)	1 (0.4%)
Bacteremia	1 (0.4%)	-	1 (0.4%)
Blurred vision	1 (0.4%)	-	1 (0.4%)
Head pain	1 (0.4%)	-	1 (0.4%)
Hematuria	1 (0.4%)	-	1 (0.4%)
Hyponatremia	1 (0.4%)	-	1 (0.4%)
Ischemic stroke	-	1 (0.4%)	1 (0.4%)
Myocardial infarction (MI)	-	1 (0.4%)	1 (0.4%)
Non-cardiac chest pain	1 (0.4%)	-	1 (0.4%)
Respiratory failure	-	1 (0.4%)	1 (0.4%)
Tachycardia	1 (0.4%)	-	1 (0.4%)
Thrombocytopenia, heparin-induced	1 (0.4%)	-	1 (0.4%)
Thrombosis/Occlusion - GEF	-	1 (0.4%)	1 (0.4%)
Thrombosis/Occlusion - stent	1 (0.4%)	-	1 (0.4%)
Vessel dissection, perforation or rupture	-	1 (0.4%)	1 (0.4%)
Nervous System - Other	14 (5.6%)	2 (0.8%)	15 (6.0%)
Respiratory, Thoracic & Mediastinal - Other	6 (2.4%)	4 (1.6%)	10 (4.0%)
Blood & Lymphatic System - Other	6 (2.4%)	1 (0.4%)	7 (2.8%)
Musculoskeletal and Connective Tissue - Other	6 (2.4%)	1 (0.4%)	7 (2.8%)
Renal & Urinary - Other	4 (1.6%)	2 (0.8%)	5 (2.0%)
Cardiac - Other	1 (0.4%)	3 (1.2%)	4 (1.6%)
Gastrointestinal - Other	3 (1.2%)	1 (0.4%)	4 (1.6%)
Infection & Infestations - Other	4 (1.6%)	-	4 (1.6%)

GORE® Embolic Filter	Severity of Adverse Event		Overall
	Non-Serious	Serious	
Metabolism & Nutrition - Other	3 (1.2%)	1 (0.4%)	4 (1.6%)
Vascular - Other	2 (0.8%)	2 (0.8%)	4 (1.6%)
Injury & Procedural - Other	3 (1.2%)	-	3 (1.2%)
Not Elsewhere Classified - Other	1 (0.4%)	2 (0.8%)	3 (1.2%)
Skin & Subcutaneous Tissue - Other	2 (0.8%)	-	2 (0.8%)

POTENTIAL PROCEDURE AND/OR DEVICE RELATED ADVERSE EVENTS:

Complications and adverse events can occur when using any embolic protection device in carotid artery stenting procedures. These complications include, but are not limited to:

- abrupt vessel closure
- allergic reactions
- aneurysm
- angina / coronary ischemia
- arteriovenous fistula
- bacteremia or septicemia
- balloon burst or rupture
- balloon-associated thrombosis
- bleeding from anticoagulant or Antiplatelet medications
- bradycardia / arrhythmia and other conduction disturbances
- cerebral edema
- cerebral hemorrhage
- component damage (e.g., kinked catheters)
- congestive heart failure
- death
- deployment and retrieval failure
- distal embolization
- drug reactions
- embolism (which includes thrombus, plaque, air, device and / or component)
- emergent / urgent endarterectomy
- fever
- fluid overload
- groin hematoma
- headache
- hemorrhage / hematoma
- hemorrhagic stroke
- hyperperfusion syndrome
- hypertension / hypotension
- infection / sepsis
- ischemia / infarction of tissue / organ
- ischemic stroke
- myocardial infarction
- pain and tenderness
- pseudoaneurysm
- reduced blood flow
- renal failure / insufficiency
- restenosis of the stented artery
- seizure
- stent deformation
- stroke or other neurological complications (e.g., paralysis, paraplegia or aphasia)
- surgery required due to device failure
- temporary or total occlusion of the artery
- thromboembolic episodes; thrombophlebitis
- transient ischemic attacks (TIAs)
- vascular access complications (e.g., bleeding, vessel damage, pseudoaneurysm and infection)
- ventricular fibrillation
- vessel spasm, dissection, rupture, or perforation
- vessel thrombosis (partial blockage)
- unstable angina pectoris

There were 5 documented cases where, a retrieval catheter other than the one supplied from Gore had to be used because the GORE® Retrieval Catheter could not cross the stent. The alternate retrieval catheters used were ANGIOGUARD Retrieval catheter, RX ACCUNET Recovery catheter, and 5Fr Multipurpose catheter. In one of these cases, a TIA was reported as the filter was retrieved.

SUMMARY OF CLINICAL RESULTS:

The results of this clinical study support the safety and efficacy of the GORE® Embolic Filter.

Objectives:

The objective of the study was to assess the safety and efficacy of the GORE® Embolic Filter when used to provide embolic protection during CAS procedures in conjunction with any FDA-approved carotid stent. This study compared the results of CAS with embolic protection using the GORE® Embolic Filter in high risk surgical subjects to a performance goal derived from carotid stent studies utilizing distal embolic protection.

Study Design:

Prospective, multicenter, non-randomized, single-arm study designed to compare 30-day safety and efficacy of GORE® Embolic Filter used with FDA-approved carotid stents to an objective performance criteria (OPC) determined from the major adverse event (MAE) rates from prior CAS studies where distal embolic protection devices were used (less than a 12.0% OPC). The primary endpoint for the Gore EMBOLDEN Clinical Study, major adverse events, was a composite of death, stroke, or myocardial infarction (MI) through the 30-day post procedure follow-up. The secondary endpoints for the study were GORE® Embolic Filter system (device) success, clinical success, access site complications, and neurological events.

Study Enrollment

Thirty-seven (37) US sites participated in the study and enrolled 250 pivotal subjects between January 2009 and July 2010. The data on these pivotal subjects is presented within this document.

Patients Studied

Eligible patients were diagnosed with carotid stenosis requiring revascularization with anatomic or co-morbid conditions placing them at high-risk for adverse events from CEA. Per NASCET criteria:

- Symptomatic subjects: >50% stenosis
- Asymptomatic subjects: >80% stenosis
- All subjects must have at least one anatomic or co-morbid risk factor placing them at high-risk for adverse events from CEA. The co-morbid and anatomic inclusion criteria for the study are summarized in Table 3:

Table 3: Co-morbid and Anatomic Study Inclusion Criteria

	GORE® Embolic Filter
Number of Subjects	250
Anatomic Risk	47.2% (118/250)
Surgically inaccessible lesions	6.0% (15/250)
Post radical head/neck surgery or RT	10.0% (25/250)
Spinal immobility of the neck	5.2% (13/250)
Presence of tracheostomy stoma	2.4% (6/250)
Laryngeal palsy or laryngectomy	2.0% (5/250)
Contralateral laryngeal nerve damage	0.4% (1/250)
Restenosis after prior CEA	26.8% (67/250)
	GORE® Embolic Filter
Co-Morbid Risk	64.8% (162/250)
Age ≥ 80 years	36.4% (91/250)
NYHA Class III or IV	3.6% (9/250)
COPD with FEV1 < 30%	3.2% (8/250)
LVEF < 30%	4.0% (10/250)
Uncontrolled diabetes	3.2% (8/250)
Unstable angina with EKG changes	0.8% (2/250)
MI within 30 days of procedure	0.8% (2/250)
Two or more diseased arteries	8.4% (21/250)
Planned CABG or valve replacement surgery	1.2% (3/250)
Contralateral total occlusion of the ICA	10.4% (26/250)

Table 4: Study Demographics

	GORE® Embolic Filter
Number of Subjects	250
Subject Age	
Mean (Min, Max)	74.7 (51.3, 92.6)
Gender	
Male	61.2% (153/250)
Female	38.8% (97/250)
Medical History	
Hypertension	94.4% (236/250)
Hyperlipidemia	94.0% (235/250)
Diabetes	34.8% (87/250)
Respiratory	30.8% (77/250)
Current Smoker	20.8% (52/250)
History of Stroke, TIA, MI	

Prior Stroke	18.8% (47/250)
Prior MI	25.6% (64/250)
Prior TIA	21.6% (54/250)
Previous Cardiovascular Interventions	
Previous CEA	31.6% (79/250)
Previous CABG	26.8% (67/250)
Previous PCI	31.6% (79/250)
Non-Carotid Vascular Disease	
Coronary	57.2% (143/250)
Peripheral	38.8% (97/250)
Cerebral	38.8% (97/250)
Symptom Status	
Symptomatic	14.8% (37/250)
Asymptomatic	85.2% (213/250)
Lesion and Vessel Characteristics	
Mean Lesion Length (min,max)	23.8 (6.0, 48.5)
Mean Minimum Lumen Diameter (MLD) (min, max)	1.6 (0.3, 3.2)
Mean % Diameter Stenosis (min, max)	72.6 (44.7, 93.2)

STUDY RESULTS

A summary of the distribution of the stents used in the study is provided in Table 5. Procedural outcomes for the study are summarized in Table 6. Serious adverse events, included hypotension in 5.6% of subjects, anemia in 2.4% of subjects, and bradycardia in 2.0% of subjects. A comprehensive summary of all adverse events is provided in Table 2. The GORE® Embolic Filter was successfully deployed in 96.4% of subjects and carotid stent deployment was successful in 98.0% of subjects. There were nine (9) technical failures of the GORE® Embolic Filter. In 6 of the cases an alternate distal filter was used. In the remaining 3 cases the procedure was terminated. The mean filter deployment time was 14 minutes in subjects with successful device deployment. A comprehensive list of the MAEs is provided in Table 1. In summary, outcomes in subcategories of the major adverse event endpoint included death (0.8%), death / major stroke (1.2%), death / any stroke (3.6%), MI (0.4%), and death / stroke / MI (4.0%). An overview of the primary and major adverse event endpoints for the study are summarized in Table 7 and 8.

Table 9 summarizes the secondary endpoints for the study. The primary endpoint for the Gore EMBOLDEN Clinical Study met the OPC hypothesis defined for the study (lower than the 12.0% OPC). Subgroup analysis for octogenarians and symptomatic subjects reports MAE rates of 5.4% for both populations.

Table 5: Distribution of Stents Implanted

	GORE® Embolic Filter
Stent Brand	
Acculink®	27.3% (70/256)
Precise®	35.9% (92/256)
Protege®	6.6% (17/256)
Xact®	25.0% (64/256)
WallStent®	5.1% (13/256)

Table 6: Procedural Outcomes

	GORE® Embolic Filter
Number of Subjects	250
Procedure Time (minutes)	N = 250
Mean (Std Dev)	50.9 (25.7)
Median	45.0
(Min, Max)	(16, 153)
Total Filter Time (minutes)	N = 249
Mean (Std Dev)	13.8 (8.6)
Median	11.0
(Min, Max)	(0, 63)

Total Fluoroscopy Time (minutes)	N = 247
Mean (Std Dev)	17.8 (9.3)
Median	16.1
(Min, Max)	(5.9, 64.5)
Hospital Stay (Days)	N = 250
Mean (Std Dev)	1.5 (1.5)
Median	1.0
(Min, Max)	(1, 17)

Table 7: Primary and Major Adverse Event Endpoints

	Intent-To-Treat Population ¹	
	% (n/N)	95% C.I.
Primary Endpoint		
Overall MAE	4.0% (10/250)	(1.9%, 7.2%)
Death	0.8% (2/250)	(0.1%, 2.9%)
Stroke	2.8% (7/250)	(1.1%, 5.7%)
Death/Any Stroke	3.6% (9/250)	(1.7%, 6.7%)
Myocardial Infarction (MI)	0.4% (1/250)	(0.0%, 2.2%)

¹ Intent-To-Treat Population defined as all enrolled subjects

Table 8: Primary and Major Adverse Event Endpoints

	Per Protocol Population ¹	
	% (n/N)	95% C.I.
Primary Endpoint		
Overall MAE	4.3% (10/234)	(2.1%, 7.7%)
Death	0.9% (2/234)	(0.1%, 3.1%)
Stroke	3.0% (7/234)	(1.2%, 6.1%)
Death/Any Stroke	3.8% (9/234)	(1.8%, 7.2%)
Myocardial Infarction (MI)	0.4% (1/234)	(0.0%, 2.4%)

¹ Per Protocol Population defined as enrolled subjects with Device Success and 30-Day follow-up

Table 9: Secondary Endpoints

	GORE® Embolic Filter	
	% (n/N)	95% C.I.
Secondary Endpoints		
Device Success	96.4% (241/250)	(93.3%, 98.3%)
Clinical Success	93.2% (233/250)	(89.3%, 96.0%)
Access Site Complications	2.4% (6/250)	(0.9%, 5.2%)
Neurological Events	6.4% (16/250)	(3.7%, 10.2%)

Device Success defined as successful delivery, deployment and retrieval of the filter.
Clinical Success defined as Device Success and the absence of death, emergency endarterectomy, repeat PTA / thrombolysis of target vessel and stroke/MI though hospital discharge.
Access Site Complications defined as large hematoma (>5cm or requiring treatment), fistula or pseudoaneurysm formation, retroperitoneal bleeding or need for surgical repair.
Neurological Events defined as stroke or TIA / cerebral ischemia through 30 day follow-up

HOW SUPPLIED

The GORE® Embolic Filter is supplied sterile in a single barrier protective sealed pouch.

STORAGE AND HANDLING

Handle the device with care, and avoid exposure to extreme temperatures and humidity. Store in a cool dry place.

MATERIALS REQUIRED




- A guide catheter or sheath (0.066" minimum I.D.) is required for the GORE® Embolic Filter
- An introducer sheath or appropriately sized guide catheter compatible with the vascular anatomy to accommodate the interventional device.
- Interventional device(s)
- Heparinized normal saline (sterile)
- Syringe (ex: 20 cc)

DIRECTIONS FOR USE

A. Preparation of Filter and Delivery Catheter

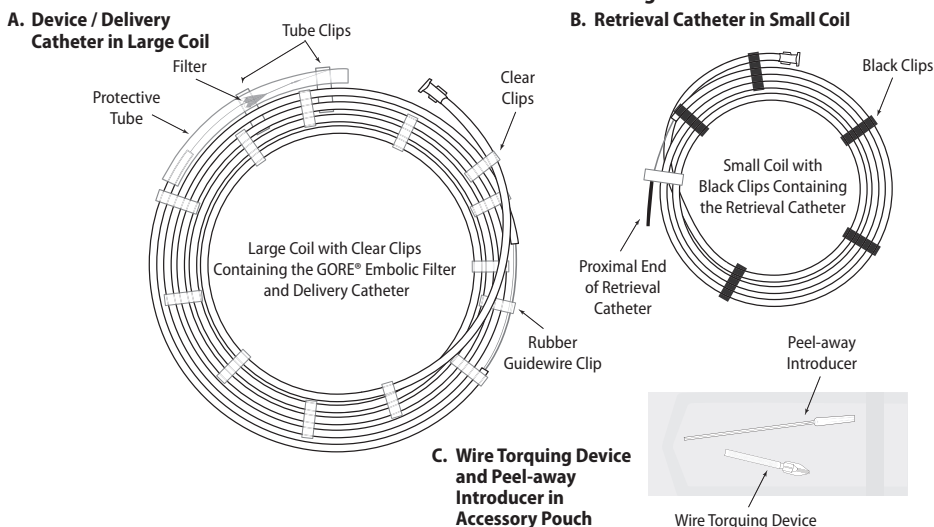
1. Prior to insertion of the GORE® Embolic Filter, the physician should read the Directions for Use.
2. Measure the target vessel diameter where the filter will be deployed using angiography. Refer to Device Sizing table (Table 10) for the appropriate sized filter for the measured reference vessel diameter.

TABLE 10: Device Sizing

 Filter Diameter Unconstrained	 Reference Vessel Diameter Range	 Guide Catheter / Sheath
5 mm	2.5 mm - 4 mm	min ID 0.066"
7 mm	4 mm - 5.5 mm	min ID 0.066"

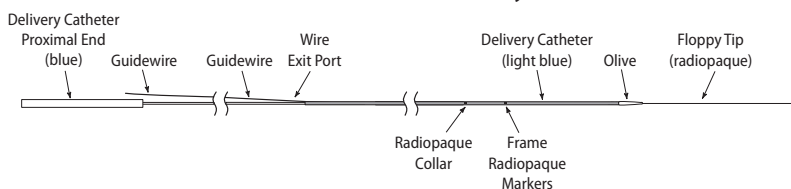
3. Prior to opening the sterile package, check that the diameter and guidewire length of the filter is correct.
4. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE® Embolic Filter after the "use by" (expiration) date or if the sterile package is compromised. Peel apart the sterile pouch and remove the components (Figure 3).

FIGURE 3: GORE® Embolic Filter as Packaged



5. Using a syringe with heparinized saline, flush the large coil with clear clips containing the GORE® Embolic Filter and delivery catheter (Figure 3A) to wet the components.
6. Remove the guidewire and delivery catheter from the rubber guidewire clip by rotating the clip 90° away from the guidewire and catheter. Simultaneously advance both until the distal end of the delivery catheter resides outside the coil.
7. Gently remove the protective tube from the tube clips and slide the tube off the filter.
8. Gently remove the filter and delivery catheter from the coil by grasping the distal end of the delivery catheter and withdrawing from the coil.
9. Inspect the system for damage. DO NOT use the GORE® Embolic Filter if any components are damaged.
10. Submerge the filter and delivery catheter to wire exit port in heparinized saline. Load device by pulling wire near where it exits the delivery catheter while supporting the distal end of the delivery catheter. Gentle manipulation can be used to remove air bubbles. Pull wire until olive abuts tip of delivery catheter (Figure 4). Do not force the olive into the delivery catheter. If filter bag inverts (i.e., folds back on itself) during loading, stop and pull gently on the distal end of the bag to straighten it prior to completing device loading.
11. For additional flushing, advance device so there is a 1-2 mm gap between the olive and tip of the delivery catheter. Gently insert loaded device (floppy tip first up to the tip of the delivery catheter) into a 20 cc syringe filled with heparinized saline. Providing a seal between the tip of the delivery catheter and wire with fingers, flush 10 cc until fluid emerges from the wire exit port. Ensure floppy tip is protected by not flushing entire contents of syringe.

FIGURE 4: Loaded Filter in Delivery Catheter

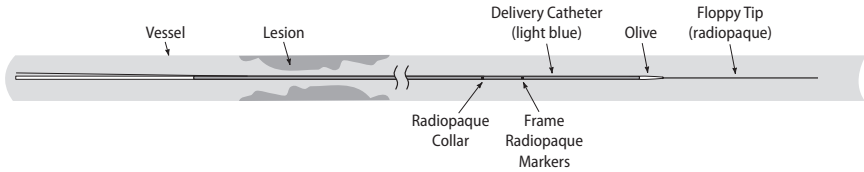


B. Insertion and Placement

1. Use standard percutaneous techniques. Shape the tip of the GORE® Embolic Filter guidewire, if desired.
2. Insert the GORE® Embolic Filter and peel-away introducer (Figure 3C) assembly through a rotating hemostasis valve into an appropriately sized guide catheter or introducer sheath. Once the system, including the wire exit port, is inserted into the guide catheter, remove the peel-away introducer.

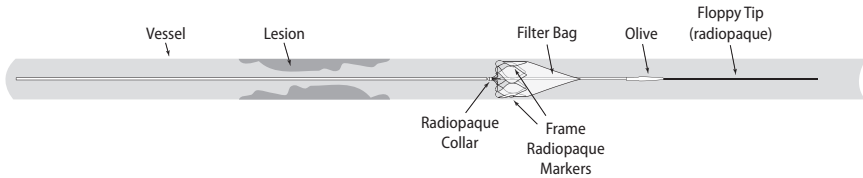
- Advance the delivery catheter and guidewire together through the guide catheter / sheath past the lesion using fluoroscopic guidance. Pushing the delivery catheter and wire together rather than just the wire will prevent premature filter deployment, especially in tortuous anatomy. DO NOT pull on the wire while advancing the system as this may lodge the olive within the delivery catheter. Advance the system cautiously, especially if resistance is encountered.
- To steer the system to the intended site, consider a two-handed approach, torquing the wire with one hand while advancing the delivery catheter with the other hand. The wire torquing device (Figure 3C) can be used to apply additional torque to the wire to improve steering. Appropriate position is verified when the radiopaque collar (proximal-most marker) of the frame is beyond the lesion (Figure 5).

FIGURE 5: Appropriate Position of Filter Prior to Deployment



- Once in position, deploy the filter by maintaining the position of the wire and pulling back on the delivery catheter.
- Device deployment is complete when the three radiopaque markers on the nitinol frame separate, indicating the frame is released from the delivery catheter and apposing the vessel wall (Figure 6). Note that depending on the fluoroscopy angle, overlap of radiopaque markers may occur. Therefore, it may appear that there are only two radiopaque markers.

FIGURE 6: Deployed Filter



- Inject contrast medium to verify the device is in the proper position and flow is present.
- Remove the delivery catheter and discard.

C. During Procedure

- Use the GORE® Embolic Filter as a standard guidewire to track the interventional treatment device and other 0.014" compatible guidewire-based interventional devices to the target lesion site. DO NOT attempt to advance catheters and delivery systems beyond the radiopaque collar on the frame. If resistance is felt and the filter is observed moving distally, it is likely that the non-radiopaque tip of the interventional device is in contact with the collar.
- Contrast media can be injected to visually assess the contents of the filter bag, and to verify that blood flow is not obstructed.
- Keep the wire position stable while the filter is deployed. DO NOT move the deployed filter, especially in the presence of vasospasm.
- If excessive debris is collected in the filter and blood flow is obstructed, the GORE® Embolic Filter may be removed and replaced or the procedure may be completed prior to device removal at the physician's discretion.
- Complete the procedure making sure the filter remains in the proper position distal to the lesion.

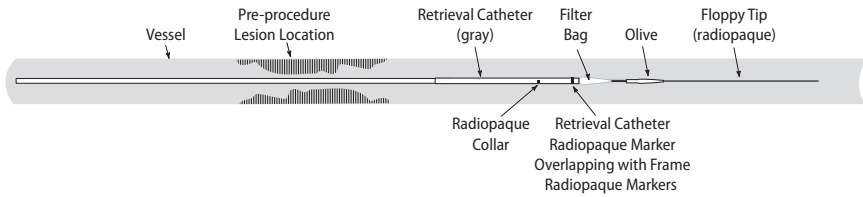
D. Retrieval

Note: If blood flow is significantly reduced, aspirate blood proximal to filter prior to retrieving filter.

- Remove all interventional devices from the guide wire.
- Using a syringe with heparinized saline, flush the small coil with black clips to wet the components.
- Unclip proximal end of retrieval catheter from rubber clip and remove the retrieval catheter from its coil (black clips) (Figure 3B).
- Inspect the retrieval catheter for damage. Do not use if any components are damaged.
- Flush the distal end of the retrieval catheter with heparinized saline. Observe fluid exiting the wire exit port.
- Route the proximal end of the guidewire through the distal end of the retrieval catheter and out the wire exit port. Handle the tip of the retrieval catheter with care to avoid kinking. Maintain the guidewire position and carefully advance the retrieval catheter over the wire to the radiopaque collar of the filter. Slowly advance the retrieval catheter until the frame is collapsed and within the catheter. This is confirmed when the radiopaque frame markers come together to form a single marker and subsequently overlap with the radiopaque marker on the tip of the retrieval catheter (Figure 7). DO NOT use excessive force to obtain marker overlap.

Note: If the retrieval catheter has difficulty passing through the stent, a variety of standard interventional techniques to aid in passage of the retrieval catheter may be used. Some options are:


- Rotate the patient's head to re-orient the anatomy.
- Change the position of the guiding catheter or sheath to better support the retrieval catheter and filter guidewire.
- If the stent struts are preventing advancement of the retrieval catheter, post-dilate the stent, or reposition the filter's guidewire.
- Insert an additional guidewire to straighten the stented area.
- Consider alternate retrieval catheter techniques.


FIGURE 7: Appropriate Position of Retrieved Device Prior to Removing From Patient


7. If resistance and / or entanglement is encountered with the portion of the filter bag protruding from the retrieval catheter, the filter may be retrieved further into the retrieval catheter at the discretion of the clinician. Additional imaging may be necessary to make the best clinical judgment. **DO NOT** use excessive force to retrieve the filter bag. Complete withdrawal of the filter into the retrieval catheter may lead to filter bag tearing or rupture and release of embolic debris.
8. Withdraw the entire system slowly through the guide catheter / sheath under fluoroscopic guidance. Withdrawing the retrieval catheter and guidewire together rather than just the retrieval catheter will prevent redeployment of the filter from the retrieval catheter. If there is any resistance when trying to withdraw the filter system into the guide catheter / sheath, pull back the guide catheter / sheath and the filter system together. If there is any resistance when trying to withdraw the filter system into the introducer sheath, withdraw the introducer sheath, guide catheter / sheath and filter system together.


DEFINITIONS


 Use By

 Caution


 Consult Instructions for Use

 Do Not Resterilize


 Do Not Reuse

 Catalogue Number

 Batch Code


 **CAUTION:** USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.


 Sterile

 Sterilized using Ethylene Oxide


 Do Not Use if Package is Damaged

 Keep Dry

 Store in a Cool Place

 Manufacturer

 Filter Diameter Unconstrained

 Guiding Catheter

 Length

 Reference Vessel Diameter Range



AP3440-ML1

 Manufacturer



W. L. GORE & ASSOCIATES, INC.


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Technical Information: Tel.: 928.779.2771 • Tel.: 800.437.8181

For international contact and additional product information,
visit **www.goremedical.com**

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