

# INSTRUCTIONS FOR USE FOR:

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**INSTRUCTIONS FOR USE FOR:****GORE Flow Reversal System**

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

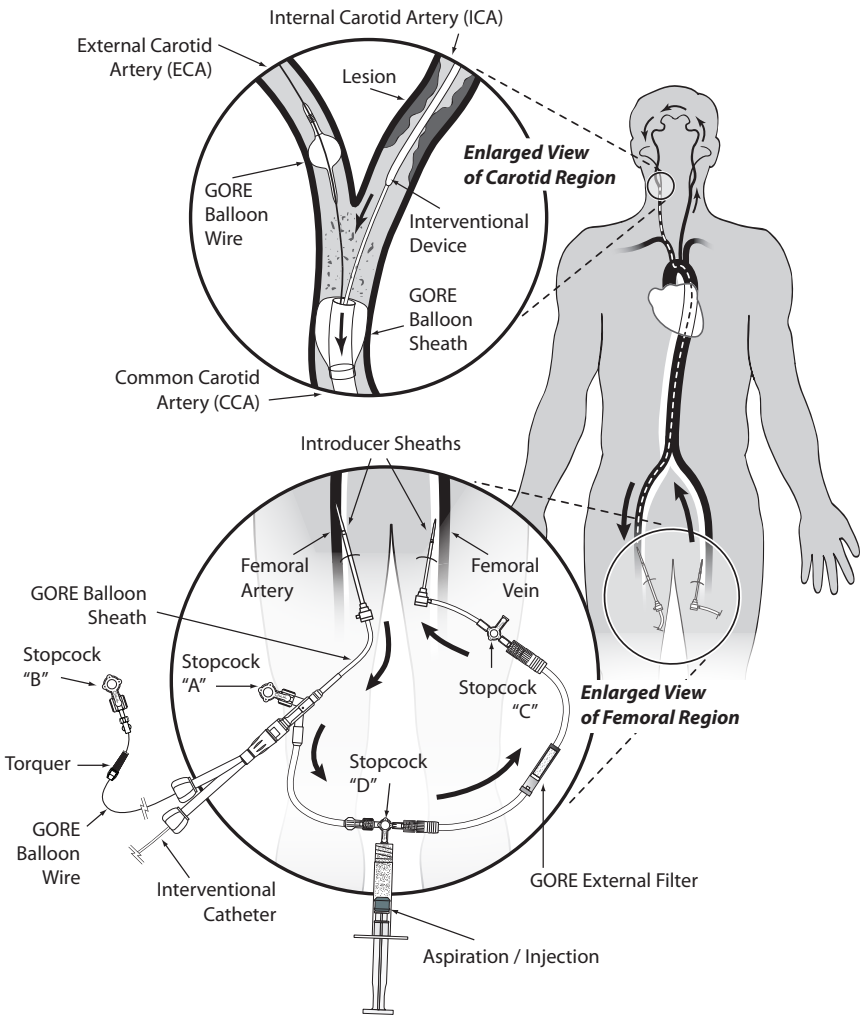
**DEVICE DESCRIPTION**

The GORE Flow Reversal System consists of three primary components:

- GORE Balloon Sheath (with Dilator)
- GORE Balloon Wire (with Removable Hub), and
- GORE External Filter

When assembled (Figure 1) the GORE Flow Reversal System creates an arteriovenous shunt that has the ability to reverse the flow of blood at the treatment site of the internal carotid artery (ICA), directing embolic particles away from the neurovascular circulation.

**Figure 1: GORE Flow Reversal System**



Each component of the GORE Flow Reversal System is described in the subsequent sections.

**GORE Balloon Sheath (with Dilator)**

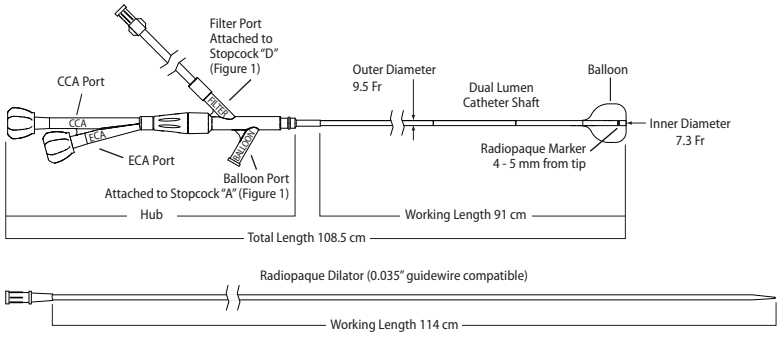
The GORE Balloon Sheath consists of a dual-lumen catheter shaft with a compliant balloon mounted at the distal-most tip of the shaft (Figure 2). The first lumen acts as the inflation lumen while the second lumen provides passage for blood flow and embolic particles and acts as the working channel to accommodate diagnostic and therapeutic interventional devices. The GORE Balloon Sheath is provided with a compatible dilator which facilitates a gradual transition from the guidewire diameter to the sheath internal diameter.

The hub of the GORE Balloon Sheath consists of four ports (Figure 2).

- The Balloon port has a female luer connector, allowing assembly of a syringe and stopcock for balloon inflation.
- The Filter port has a flexible tubing extension permitting access to the working channel to allow blood and embolic particles to exit the channel. This port connects to the GORE External Filter which then connects to a venous introducer sheath.
- The ECA port allows side access to the working channel to introduce the GORE Balloon Wire.
- The CCA port provides linear access to the working channel, functioning primarily as the delivery port for diagnostic and therapeutic devices such as an angioplasty balloon catheter, stent delivery system, etc.

*In vivo*, the GORE Balloon Sheath is positioned within the common carotid artery, and the balloon is inflated to occlude antegrade blood flow.

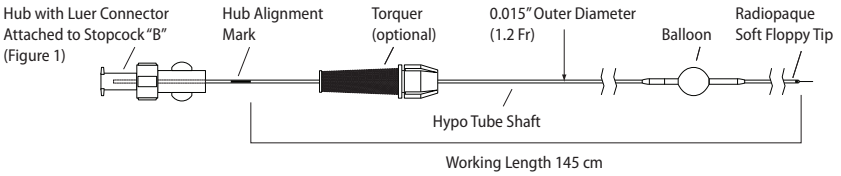
**Figure 2: GORE Balloon Sheath and Dilator**



**GORE Balloon Wire (with Removable Hub)**

The GORE Balloon Wire consists of a compliant balloon mounted on a variable stiffness hypotube shaft with a polymer jacket. The distal end of the hypotube transitions to an atraumatic radiopaque floppy tip (Figure 3). The removable hub has a female luer connector, allowing assembly of a syringe and stopcock for balloon inflation, after manually tightening on the hub alignment mark. The GORE Balloon Wire is supplied with a torquer (use optional) to aid in positioning the device. *In vivo*, the GORE Balloon Wire occludes blood flow when positioned and inflated within the external carotid artery.

**Figure 3: GORE Balloon Wire**



**GORE External Filter**

The GORE External Filter consists of a blood transfusion filter in transparent housing with flexible tubing at both ends terminated by luer connectors (Figure 4). The flexible tubing allows blood to flow into and out of the unit. The inlet port is connected to the flexible tubing Filter port of the GORE Balloon Sheath, and the outlet port is connected to the venous introducer sheath, completing an arteriovenous shunt via the GORE External Filter.

**Figure 4: GORE External Filter**



**Accessories**

The GORE Flow Reversal System includes a 5.5 Fr tear away sheath and a wire torquing device. The tear away sheath assists in the introduction of the GORE Balloon Wire into the GORE Balloon Sheath ECA port. The wire torquing device (torquer) is used to apply torque to the GORE Balloon Wire to improve steering to the intended location in the ECA. No other accessories are included in the system.

The dimensional details for the GORE Flow Reversal System and components are provided in the following table:

**Table 1: System dimensions**

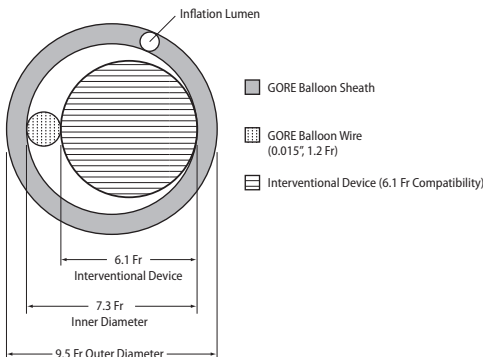
ATTRIBUTE	BALLOON SHEATH <sup>1</sup>	BALLOON WIRE	SYSTEM <sup>2</sup>
Working Length	91 cm	145 cm	91 cm
Inner Diameter	7.3 Fr	N / A	6.1 Fr <sup>3</sup>
Outer Diameter	9.5 Fr	0.015" (1.2 Fr)	9.5 Fr

<sup>1</sup> GORE Balloon Sheath Dilator is compatible with 0.035" guidewire.

<sup>2</sup> The "System" is defined as the assembly of the three primary components (Figure 5).

<sup>3</sup> 6.1 Fr effective luminal diameter when the GORE Balloon Wire resides within the GORE Balloon Sheath lumen (Figure 5).

**FIGURE 5: CATHETER SYSTEM CROSS SECTION**



## CONTENTS

One each: GORE Balloon Sheath (with Dilator), GORE Balloon Wire (with Removable Hub), GORE External Filter, Torquer, 5.5 Fr tear away sheath (not shown in Figure 1).

## 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 below:

- Adequate iliac / femoral access
- Common carotid artery reference vessel diameters between 6 and 12 mm
- External carotid artery reference vessel diameters less than 6 mm

## CONTRAINDICATIONS

The GORE Flow Reversal System is contraindicated for use on patients exhibiting the following conditions:

- Arterial anatomy, vessel tortuosity, or disease involvement that will not allow correct and safe positioning and retrieval of the GORE Flow Reversal System components or procedural components.
- Uncontrollable intolerance to flow reversal (i.e., pre-conditioning does not result in tolerance to vessel occlusion / flow reversal).
- Severe peripheral vascular disease preventing femoral access or existing coagulopathy or inability to obtain hemostasis at the femoral puncture site.
- Patients in whom anticoagulant or antiplatelet therapy is contraindicated.
- 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 Flow Reversal System has not been demonstrated with carotid stent systems other than ACCULINK® Carotid Stent, XACT® Carotid Stent, PRECISE® Carotid Stent, NEXSTENT Carotid Stent, and PROTÉGÉ® Carotid Stent, as listed in Table 6.
- Consideration should be given to the carotid anatomy (angulation at bifurcation of carotid vessels), morphology of bifurcation lesions, and subsequent stent selection relative to GORE Balloon Wire and GORE Balloon Sheath placement and retrieval.
- Consider the effect of total occlusion of the target vessel or severe intracranial stenosis distal to the target lesion on flow reversal.
- Consider severe disease of the contralateral arteries and ipsilateral posterior arteries which may affect adequate cerebral blood flow during flow reversal.
- The GORE Flow Reversal System is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative imaging or who have chronic renal insufficiency.
- Antiplatelet and anticoagulation therapy should be administered pre- and post-procedure at a dosage deemed appropriate by the physician.
- Do not over-inflate the GORE Balloon Sheath or GORE Balloon Wire balloons during device preparation (GORE Balloon Sheath: ≤ 12 mm in diameter; GORE Balloon Wire: < 6 mm in diameter). Excess inflation volume may result in balloon damage and / or balloon rupture.
- Proper placement of the GORE Balloon Sheath and GORE Balloon Wire should be monitored and confirmed using fluoroscopy.
- When positioning the GORE Balloon Sheath in the CCA, consider the following criteria:
  - The GORE Balloon Sheath position should minimize the risk of any interaction with possible disease in the carotid artery vasculature.
  - Ensure the stability of the GORE Balloon Sheath landing zone to minimize the risk of a loss of position during the procedure.
  - Ensure visibility of the GORE Balloon Sheath in the working field throughout the procedure.
  - Allow sufficient distance between the anticipated location of the proximal edge of the deployed stent and the distal end of the GORE Balloon Sheath to minimize the risk of an interaction with the stent during and after deployment, or an interaction with the GORE Balloon Wire during retrieval.
- When positioning the GORE Balloon Wire across a tight common carotid artery and / or external carotid artery lesion, the GORE Balloon Sheath should be inflated and aspiration performed via the Filter port to create localized flow reversal.
- Ensure that there is minimal residual slack in the distal portion of the GORE Balloon Wire catheter when tightening the ECA hemostasis valve.
- Where anatomically feasible, ensure that the GORE Balloon Wire is excluding the vessels (e.g., superior thyroid artery, ascending pharyngeal artery, etc.), originating at or near the carotid bifurcation. Inability to exclude the origins of these vessels may affect flow reversal performance, leading to embolic events.
- The GORE Balloon Sheath should not be deployed in a vessel smaller than 6 mm or larger than 12 mm diameter.
- The GORE Balloon Wire should not be deployed in a vessel larger than or equal to 6 mm diameter.
- Prior to any injections through the lumen of the GORE Balloon Sheath, ensure that air and embolic particles are removed from the GORE Balloon Sheath lumen.
- During retrieval of the GORE Balloon Wire, ensure that there is sufficient distance between the distal edge of the GORE Balloon Sheath and the proximal edge of the deployed stent to minimize the potential for interaction and damage to the GORE Balloon Wire.
- Should the GORE Balloon Wire become ensnared on the stent, do not exert undue force to remove it. Stent dislodgement, embolism or related complications may occur. Interventional or surgical techniques may be required to address the situation.

## PRECAUTIONS

- Refer to Instructions For Use supplied with other interventional devices to be used in conjunction with the GORE Flow Reversal System for their intended uses, contraindications and potential complications.
- Ilio-femoral access size and morphology should be compatible with vascular access techniques and accessories for the delivery profile of the recommended introducer sheath.
- Monitoring of patient's neurological status during carotid artery stenting procedure is recommended. Consideration of patient's ability to respond to commands should be given (i.e., ability to hear the commands and physically able to squeeze with the hand contralateral to the target lesion).
- Continuous monitoring of blood pressure should be performed to avoid hypotension and hypertension
- Use only the recommended introducer sheath. Insert the GORE Balloon Sheath only once.
- Do not continue advancing any component of the GORE Flow Reversal System if resistance is felt. Stop and assess cause of resistance. Vessel or product component damage may occur.
- Where anatomically feasible, ensure that the GORE Balloon Wire is fully inserted into the ECA to permit clear passage of the therapeutic or diagnostic device into the internal carotid artery (ICA).
- The balloons of the GORE Balloon Sheath and GORE Balloon Wire should not be over-inflated. Infuse no more contrast media than is necessary to achieve occlusion by fluoroscopically observing balloon apposition to the vessel wall.
- Balloon contact with calcified vessels or existing interventional devices (e.g., stents, filters) may result in balloon leakage.
- Do not move the GORE Balloon Sheath or GORE Balloon Wire when the balloons are inflated. This may cause complications such as detachment of the blood vessel intima or damage to the balloon.
- Consider discontinuing flow reversal if there is any significant change in the patient's neurologic status or level of consciousness.
- During stent deployment ensure the stability (e.g., appropriate position, inflation, etc.) of the GORE Balloon Wire in the ECA to prevent loss of embolic protection.
- Inflation of the GORE Balloon Sheath or the GORE Balloon Wire within a diseased artery has not been tested.

- To prevent air entrapment in the GORE Balloon Sheath hub, prior to aspiration ensure that the hemostatic valves on the hub are fully closed (see Directions for Use).
- The GORE External Filter should be closed (flow reversal stopped) during episodes of coughing or emesis.

## ADVERSE EVENTS

### SUMMARY OF CLINICAL RESULTS (G060054)

The objective of the Gore EMPIRE Clinical Trial was to assess the safety and effectiveness of the GORE Flow Reversal System for embolic protection during carotid artery angioplasty and stenting (CAS) procedures in high surgical risk patients. A comprehensive list of the MAEs is provided in Table 2. In summary, outcomes in subcategories of the Major Adverse Event endpoint included death (0.8%), death / major stroke (0.8%), death / any stroke (2.9%), MI (0.8%), and death / stroke / MI (3.7%).

**Table 2: Major Adverse Events**

	EMPIRE
<b>Number of Subjects</b>	245
<b>Subjects With One or More Major Adverse Events</b>	11 (4.5%)
<b>Death</b>	2 (0.8%)
Cardiac	0
Neurological	2 (0.8%)
Non-Cardiac, Non-Neurological	0
<b>Myocardial Infarction (MI)</b>	2 (0.8%)
Q-Wave MI	0
Non Q-Wave MI	2 (0.8%)
<b>Stroke</b>	7 (2.9%)
CVA - Ischemic, Major Ipsilateral	0
CVA - Ischemic, Major Non-Ipsilateral	0
CVA - Hemorrhagic, Major Ipsilateral	1 (0.4%)
CVA - Hemorrhagic, Major Non-Ipsilateral	1 (0.4%)
CVA - Ischemic, Minor Ipsilateral	5 (2.0%)
CVA - Ischemic, Minor Non-Ipsilateral	0
CVA - Hemorrhagic, Minor Ipsilateral	0
CVA - Hemorrhagic, Minor Non-Ipsilateral	0
CVA - Non-Disabling	0
<b>Transient Ischemic Attack (TIA)</b>	2 (0.8%)
TIA - Ipsilateral	2 (0.8%)
TIA - Non-Ipsilateral	1 (0.4%)
Amaurosis Fugax	0

The adverse events (serious and non-serious) that were reported during the Gore EMPIRE Clinical Trial are summarized in Table 3. Adverse events were defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of the GORE Flow Reversal System, whether or not considered related to the device.

**Table 3: Summary of EMPIRE Adverse Events**

EMPIRE (N=245)	SEVERITY OF ADVERSE EVENT	
	NON-SERIOUS	SERIOUS
Subjects With One or More Adverse Events	82 (33.5%)	34 (13.9%)
Hypotension	28 (11.4%)	14 (5.7%)
Arrhythmia	8 (3.3%)	4 (1.6%)
Hypertension	12 (4.9%)	—
Pain (Head, Neck)	11 (4.5%)	1 (0.4%)
Anemia	6 (2.4%)	4 (1.6%)
Groin Hematoma (with / without Surgical Repair)	7 (2.9%)	2 (0.8%)
Flow Reversal Intolerance	6 (2.4%)	—
Pseudoaneurysm (Femoral)	1 (0.4%)	1 (0.4%)
Renal Failure / Insufficiency	1 (0.4%)	1 (0.4%)
Restenosis of Stented Segment	2 (0.8%)	—
Angina / Coronary Ischemia	—	1 (0.4%)
Congestive Heart Failure (CHF)	—	1 (0.4%)
Fever	1 (0.4%)	—
Hemorrhage (with / without Transfusion)	1 (0.4%)	—
Hyperperfusion Syndrome	—	1 (0.4%)
Severe Unilateral Headache	1 (0.4%)	—
Stent Migration	1 (0.4%)	—
Stent Thrombosis / Occlusion	1 (0.4%)	—
Vessel Dissection, Perforation, or Rupture	1 (0.4%)	—
<i>Other (Neurologic) - Non-serious: 9 (3.7%) and Serious: 2 (0.8%); Other (Bleeding) - Non-serious: 7 (2.9%) and Serious: 3 (1.2%); Other (Cardiac) - Non-serious: 6 (2.4%) and Serious: 4 (1.6%); Other (Infectious/Inflammatory) - Non-serious: 3 (1.2%) and Serious: 3 (1.2%); Other (Wound) - Non-serious: 2 (0.8%) and Serious: 1 (0.4%); Other (Surgical Procedure) - Non-serious: 0% and Serious: 1 (0.4%); Other (Other) - Non-serious: 18 (7.3%) and Serious: 5 (2.0%)</i>		

## 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; intolerance to vessel occlusion and / or flow reversal; myocardial infarction; pain and tenderness; pseudoaneurysm; reduced blood flow; renal failure / insufficiency; restenosis of the stented artery; seizure; stent deformation; stent / GORE Balloon Wire or GORE Balloon Sheath entanglement / damage / dislodgement; 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.

## SUMMARY OF CLINICAL RESULTS

The results of this clinical study support the safety and efficacy of the GORE Flow Reversal System.

### Investigational Device Exemption (G060054): Gore EMPIRE Clinical Trial

The following acronyms are used in the Summary of Clinical Results: Carotid Artery Stenting (CAS); Carotid Endarterectomy (CEA); Cerebral Vascular Accident (CVA); Chronic Obstructive Pulmonary Disease (COPD); Coronary Artery Bypass Graft (CABG); Electrocardiogram (ECG); Internal Carotid Artery (ICA); Left Ventricular Ejection Fraction (LVEF); Myocardial Infarction (MI); New York Heart Association (NYHA); Percutaneous Coronary Intervention (PCI); Radiotherapy (RT); Transient Ischemic Attack (TIA).

### Objectives

The objective of the Gore EMPIRE Clinical Trial was to assess the safety and effectiveness of the GORE Flow Reversal System for embolic protection during carotid artery angioplasty and stenting (CAS) procedures in high surgical risk patients. This study compared the results of CAS with embolic protection using the GORE Flow Reversal System in high risk surgical subjects to an objective performance criteria developed from prior CAS studies where distal embolic protection devices were used.

### Study Design

Prospective, multicenter, non-randomized, single-arm study designed to compare 30-day safety and efficacy of GORE Flow Reversal System 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 an 11.83% OPC). The primary endpoint for the Gore EMPIRE Clinical Trial, Major Adverse Events, was a composite of death, stroke, transient ischemic attack (TIA), or myocardial infarction (MI) through the 30-day post procedure follow-up. The secondary endpoints for the study were Flow Reversal system success, stent success, clinical success, and stent patency at 30 days.

### Study Enrollment

Twenty-nine (29) US sites participated in the study and enrolled 245 pivotal subjects between July 2006, and July 2008. The data on these pivotal subjects are presented within this document. Fifty-six (56) additional subjects (the first two subjects enrolled at each site) were training cases and were excluded from the primary analyses.

### 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 4:

**Table 4: Co-morbid and anatomic study Inclusion Criteria**

	<b>EMPIRE</b>
<b>Number of Subjects Enrolled</b>	245
<b>Anatomic Risk</b>	68.6% (168/245)
Surgically inaccessible lesions	13.9% (34/245)
Post radical head/neck surgery or RT	21.2% (52/245)
Spinal immobility of the neck	4.5% (11/245)
Presence of tracheostomy stoma	3.3% (8/245)
Laryngeal palsy or laryngectomy	2.9% (7/245)
Contralateral laryngeal nerve damage	0.4% (1/245)
Restenosis after prior CEA	36.3% (89/245)
<b>Co-Morbid Risk</b>	49.4% (121/245)
Age ≥ 80 years	15.5% (38/245)
NYHA Class III or IV	11.8% (29/245)
COPD with FEV1 < 50%	6.5% (16/245)
LVEF < 35%	4.9% (12/245)
Uncontrolled diabetes	4.9% (12/245)
Unstable angina with ECG changes	2.9% (7/245)
MI within 30 days of procedure	0.4% (1/245)
Two or more diseased arteries	6.9% (17/245)
CABG or valve replacement surgery	2.9% (7/245)
Contralateral total occlusion of the ICA	10.6% (26/245)

The pre-procedure demographics for the pivotal subjects are summarized in Table 5:

**Table 5: Subject Demographics**

	EMPIRE
<b>Number of Subjects</b>	245
<b>Subject Age</b>	
Mean (Min, Max)	70.2 (46.0, 89.8)
<b>Gender</b>	
Male	67.3% (165/245)
Female	32.7% (80/245)
<b>Medical History</b>	
Hypertension	86.5% (212/245)
Hyperlipidemia	82.4% (202/245)
Diabetes	35.1% (86/245)
Respiratory	38.4% (94/245)
Current Smoker	31.4% (77/245)
<b>History of Stroke, TIA, MI</b>	
Prior Stroke	21.6% (53/245)
Prior MI	22.9% (55/240)
Prior TIA	32.0% (77/241)
<b>Previous Cardiovascular Interventions</b>	
Previous CEA	41.6% (102/245)
Previous CABG	21.6% (53/245)
Previous PCI	26.1% (64/245)
<b>Non-Carotid Vascular Disease</b>	
Coronary	43.8% (106/242)
Peripheral	36.4% (88/242)
Cerebral	17.8% (43/242)
<b>Symptom Status</b>	
Symptomatic	31.8% (78/245)
Asymptomatic	68.2% (167/245)
<b>Lesion and Vessel Characteristics</b>	
Mean Lesion Length (min,max)	13.76 (3.00, 43.04)
Mean MLD (min, max)	1.15 (0.11, 5.47)
Mean % Diameter Stenosis (min, max)	73.37 (44.75, 95.91)

### Study Results

A summary of the distribution of the stents used in the study is provided in Table 6. Procedural outcomes for the study are summarized in Table 7. Serious adverse events, included hypotension in 5.7% of subjects, arrhythmia in 1.6% of subjects, groin hematoma in 0.8% of subjects, and hyperperfusion syndrome in 0.4% of subjects. A comprehensive summary of all adverse events is provided in Table 3. Flow reversal intolerance (non-serious adverse event) was reported in 2.4%. Intolerance to flow reversal was defined as unfavorable change in the patient's level of awareness (consciousness and motor function) from baseline. No permanent neurological deficits were associated with flow reversal intolerance when antegrade blood flow was re-established. The GORE Flow Reversal System was successfully deployed in 96.3% of subjects and carotid stent deployment was successful in 99.2% of subjects. The nine (9) technical failures were due to: flow reversal intolerance (3 subjects), tortuous anatomy (2 subjects), and technical issues with the device (4 subjects). Mean occlusion time (flow reversal time) was 15 minutes in subjects with successful device deployment.

A comprehensive list of the MAEs is provided in Table 2. In summary, outcomes in subcategories of the Major Adverse Event endpoint included death (0.8%), death / major stroke (0.8%), death / any stroke (2.9%), MI (0.8%), and death / stroke / MI (3.7%). An overview of the primary and secondary endpoints for the study is summarized in Tables 8A and 8B. The primary endpoint for the Gore EMPIRE Clinical Trial (4.5%) met the OPC hypothesis defined for the study (lower than the 11.83% OPC). Subgroup analysis for octogenarians and symptomatic subjects reports MAE rates of 2.6% and 3.8%, respectively.

Additionally, analysis of the death / stroke rates for symptomatic subjects (2.6%) and asymptomatic subjects (3.0%) found that subjects undergoing CAS with the GORE Flow Reversal System meet the American Heart Association Guidelines for Carotid Endarterectomy\* (Symptomatics: 6%; Asymptomatics: 3%)

\*Circulation 1995; 91:566-579

**Table 6: Distribution of stents used in empire**

Stent Brand	EMPIRE
ACCULINK® Carotid Stent	19.9% (51/256)
XACT® Carotid Stent	39.8% (102/256)
PRECISE® Carotid Stent	27.0% (69/256)
NEXSTENT Carotid Stent	9.0% (23/256)
PROTÉGÉ® Carotid Stent	4.3% (11/256)

Table 7: Procedural Outcomes for Empire

	EMPIRE
<b>Number of Subjects</b>	245
<b>Procedure Time (minutes)</b>	N = 245
Mean (Std Dev)	80 (38)
Median	72
Range	(25, 345)
<b>Total Occlusion Time (minutes)</b>	N = 239
Mean (Std Dev)	15 (9)
Median	12
Range	(0, 56)
<b>Total Fluoroscopy Time (minutes)</b>	N = 240
Mean (Std Dev)	20.3 (13.8)
Median	17.0
Range	(6.2, 164.0)
<b>Hospital Stay (days)</b>	N = 245
Mean (Std Dev)	2.0 (2.6)
Median	1.0
Range	(0.0, 24.0)

Table 8A: Empire Primary Endpoints

Primary Endpoint	EMPIRE	
	% (n/N)	95% C.I.
Overall MAE	4.5% (11/245)	(2.3%, 7.9%)
Death	0.8% (2/245)	(0.1%, 2.9%)
Stroke	2.9% (7/245)	(1.2%, 5.8%)
Death/Any Stroke	2.9% (7/245)	(1.2%, 5.8%)
Myocardial Infarction (MI)	0.8% (2/245)	(0.1%, 2.9%)
Death/Stroke/MI	3.7% (9/245)	(1.7%, 6.9%)
Transient Ischemic Attack (TIA)	0.8% (2/245)	(0.1%, 2.9%)

Table 8B: Empire SECONDARY Endpoints

Secondary Endpoints <sup>1</sup>	EMPIRE
	% (n/N)
Flow Reversal System Success	95.1% (233/245)
Stent Success	99.1% (228/230)
Clinical Success	91.7% (211/230)
Patency at 30 Days	97.8% (182/186)

<sup>1</sup> Definitions: Flow Reversal System Success: GORE Flow Reversal System was delivered, placed, reverse flow was established, and the balloon sheath and wire retrieved as outlined in the Instructions for Use without causing any adverse events during the procedure.; Stent Success: FDA-approved stent was successfully delivered, deployed, and delivery system removed with an attainment of < 50% residual stenosis following stent placement, as assessed by the angiographic core laboratory.; Clinical Success: Flow Reversal System and Stent Success in the absence of death, emergency carotid endarterectomy, repeat angioplasty/thrombolysis of the target vessel, stroke, or MI, as determined by the Clinical Events Committee (CEC). Clinical Success evaluated at 24-48 hours post procedure.; Patency at 30 Days: Less than 50% restenosis as determined by carotid duplex ultrasound core laboratory at 30 days post-procedure.

#### HOW SUPPLIED

The GORE Flow Reversal System components are packaged as a system and supplied sterile.

#### STORAGE AND HANDLING

- Do not resterilize; single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the "use by" (expiration) date printed on the label.
- Store in a cool dry place.

table 9: RECOMMENDED MATERIALS

Quantity	MATERIAL
1	9 Fr x 10 cm TERUMO® PINNACLE® Introducer Sheath or 9 Fr x 10 cm TERUMO® RADIFOCUS® Introducer Sheath for arterial access. Introducer Sheaths ≥ 10 Fr may be used if recommended TERUMO® Devices are unavailable.
1	6 Fr Introducer sheath for venous access
1	20 cc syringe
2	3 cc syringe
Up to 5	Stopcocks: At least one stopcock must be a three-way stopcock (for Stopcock 'D', Figure 1); all other stopcocks may be three-way stopcocks / one way stopcocks / flow switches / flow control valves (for GORE Balloon Sheath / GORE Balloon Wire balloon inflation and GORE External Filter preparation)

**DIRECTIONS FOR USE**

Inspect the GORE Flow Reversal System components for integrity prior to and during device preparation and use.

**A. Access Femoral Artery and Femoral Vein**

1. Access the femoral artery and complete the aortic and cerebral angiograms. This complete diagnostic study may provide insight into the patient's ability to tolerate flow reversal. The angiographic field should include the tip of the catheter and the carotid bifurcation.
2. Access the femoral vein using a 6 Fr introducer sheath.

**B. Prepare the GORE Flow Reversal System Components For Use**

1. The GORE Balloon Sheath (with Dilator):
  - a. Prepare the GORE Balloon Sheath balloon using standard balloon catheter techniques, for example:
    - i. Fill a 3 cc syringe with diluted contrast (25% contrast, 75% sterile saline) and flush a stopcock and the Balloon port of the GORE Balloon Sheath hub to remove residual air from the connections.
    - ii. Connect the stopcock (Stopcock "A" in Figure 1) to the Balloon port.
    - iii. Fill the 3 cc syringe with 1 cc diluted contrast and attach syringe to opened Stopcock "A" on Balloon lumen.
    - iv. Aspirate to remove air from the balloon.
    - v. Inject sufficient diluted contrast to partially inflate the balloon.
    - vi. Draw back on the syringe to deflate the balloon.
    - vii. Repeat steps v and vi to remove as much air as possible from the balloon.
    - viii. With the balloon fully deflated, close Stopcock "A" and remove syringe.
  - b. Connect stopcock (Stopcock "D" in Figure 1) to the Filter port of the hub.
  - c. Flush the working channel and hub of the GORE Balloon Sheath with heparinized saline solution through the Stopcock "D" connected to the Filter port of the hub.
  - d. Flush the guidewire lumen of the Dilator with heparinized saline solution.

**Note:** Ensure the balloon is not over-inflated during preparation ( $\leq 12$  mm in diameter).

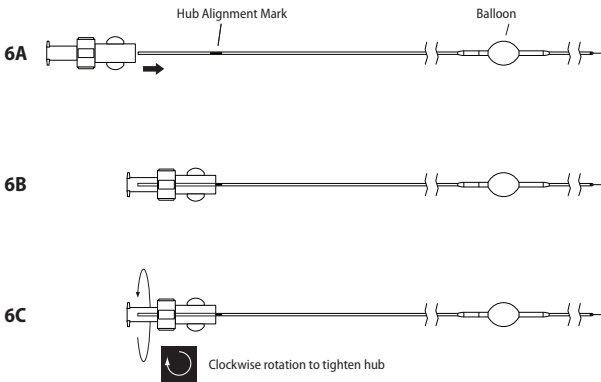
2. The GORE Balloon Wire (with Removable Hub):

Assemble the GORE Balloon Wire:

- a. If use of the Torquer is desired, position it over the proximal end of the GORE Balloon Wire shaft (white end first) distal of the Hub Alignment Mark and tighten into position.
  - b. Advance the Removable Hub onto the GORE Balloon Wire (green end first) until the distal end of the hub is within the Hub Alignment Mark marked on the wire (Figure 6B).
  - c. Tighten the hub by holding the distal green portion of the hub and the GORE Balloon Wire catheter stable while twisting the proximal white portion clockwise (Figure 6C). Ensure that the Removable Hub position is maintained within the Hub Alignment Mark of the wire.
  - d. Confirm attachment by gently pulling on GORE Balloon Wire while holding the Removable Hub.
3. Prepare the GORE Balloon Wire balloon using standard balloon catheter techniques, for example:
    - a. Fill a 3 cc syringe with diluted contrast (25% contrast, 75% sterile saline) and flush a stopcock and the hub of the GORE Balloon Wire to remove residual air from the connections.
    - b. Connect the stopcock (Stopcock "B" in Figure 1) to the GORE Balloon Wire hub.
    - c. Fill a 3 cc syringe with 0.5 cc diluted contrast and attach syringe to opened Stopcock "B" on the GORE Balloon Wire hub.
    - d. Aspirate to remove the air from the balloon.
    - e. Inject sufficient diluted contrast to partially inflate the balloon.
    - f. Draw back on the syringe to deflate the balloon.
    - g. Repeat steps e and f to remove as much air as possible from the balloon.
    - h. With the balloon fully deflated, close Stopcock "B" and remove syringe.

**Note:** Ensure the balloon is not over-inflated during preparation ( $< 6$  mm in diameter).

**Figure 6: GORE Balloon wire assembly**

**C. Position the GORE Balloon Sheath**

1. Placement of the GORE Balloon Sheath along with the Dilator into the common carotid artery (CCA) should be performed using a support guidewire previously positioned in the external carotid artery (ECA).
2. Using the recommended introducer sheath, advance the GORE Balloon Sheath along with the Dilator into the ipsilateral CCA over the guidewire. The GORE Balloon Sheath should track into the carotid artery without difficulty. If significant resistance to forward progress is noted, a stiffer wire may be necessary or the anatomy may not be appropriate for the GORE Flow Reversal System. Avoid aggressive force to overcome resistance. This may result in embolization or vessel trauma.
3. When positioning the GORE Balloon Sheath in the CCA, consider the following criteria:
  - The GORE Balloon Sheath position should minimize the risk of any interaction with possible disease in the carotid artery vasculature.
  - Ensure the stability of the GORE Balloon Sheath landing zone to minimize the risk of a loss of position during the procedure.
  - Ensure visibility of the GORE Balloon Sheath in the working field throughout the procedure.
  - Allow sufficient distance between the anticipated location of the proximal edge of the deployed stent and the distal end of the GORE Balloon Sheath to minimize the risk of an interaction with the stent during and after deployment, or an interaction with the GORE Balloon Wire during retrieval.
4. Withdraw the Dilator.

## D. Preparation and Assembly of the GORE External Filter

Two suggested techniques for removing air from the GORE External Filter are provided:

Preparation *in situ*:

1. Attach the arterial end of the GORE External Filter (cap-end) to the GORE Balloon Sheath Filter port via the stopcock (Stopcock "D" in Figure 1).
2. Elevate the venous end of the GORE External Filter and open Stopcock "D", allowing the body of the filter to fill with the patient's blood.
3. Once the GORE External Filter has filled with blood, close Stopcock "D" and attach the GORE External Filter to the 6 Fr venous introducer sheath side port.
4. Turn Stopcock "C" and Stopcock "D" to allow the blood to flow from the GORE Balloon Sheath Filter port to the GORE External Filter (as shown in Figure 1).
5. Connect a 20 cc syringe to the unused port of Stopcock "D".

Bench preparation of the GORE External Filter (alternative technique):

1. Attach stopcocks to the arterial and venous ends of the GORE External Filter and fill the body of the filter with sterile, heparinized saline, removing as much air as possible. Close the stopcocks and remove the syringe.
2. Remove the stopcock at the arterial end of the GORE External Filter (cap-end) and attach the GORE External Filter to the GORE Balloon Sheath Filter port via Stopcock "D" (Figure 1).
3. Remove the stopcock at the venous end of the GORE External Filter and elevate the venous end of the GORE External Filter. Open Stopcock "D", allowing the body of the filter to fill with the patient's blood, removing any residual air present in the filter. Attach the GORE External Filter to the 6 Fr venous introducer sheath side port.
4. Turn Stopcock "C" and Stopcock "D" to allow the blood to flow from the GORE Balloon Sheath Filter port to the GORE External Filter (as shown in Figure 1).
5. Connect a 20 cc syringe to the unused port of Stopcock "D".

## E. Position the GORE Balloon Wire

**Note:** GORE Balloon Sheath inflation along with aspiration at the Filter port should be performed while crossing tight common carotid artery and / or external carotid artery lesions.

1. Remove the guidewire previously positioned within the GORE Balloon Sheath.
2. Position the GORE Balloon Wire into the 5.5 Fr tear away sheath and fully introduce, as a single unit, into the ECA side port of the GORE Balloon Sheath.
3. Introduce the GORE Balloon Wire into the lumen of the GORE Balloon Sheath and retract the tear away sheath from the GORE Balloon Sheath hub. Do not remove the tear away sheath from the GORE Balloon Wire shaft.
4. Position the GORE Balloon Wire in the ECA.
5. Ensure that the GORE Balloon Wire is fully inserted into the ECA to permit clear passage of the therapeutic or diagnostic device into the internal carotid artery (ICA).
6. Tighten the hemostatic valve at the proximal end of the GORE Balloon Sheath hub to prevent the GORE Balloon Wire from being pulled out of position. Ensure that there is minimal slack in the GORE Balloon Wire shaft, particularly the distal portion of the catheter.

The system is now ready for flow reversal.

## F. Image the Carotid Artery Before Balloon Occlusion

1. Perform an arteriogram of the carotid artery by injecting sufficient contrast to produce a well-defined image of the vasculature.

## G. Occlude the External Carotid Artery

**Note:** To minimize flow reversal time, consider preparing all additional interventional components for the procedure prior to vessel occlusion or establishing flow reversal.

1. Using a 3 cc syringe with less than 0.5 cc of a diluted contrast (25% contrast, 75% saline), inflate the GORE Balloon Wire. Complete occlusion of the external carotid artery is confirmed fluoroscopically by observing balloon apposition to the ECA vessel wall. Additionally, angiography can be used to confirm occlusion. The balloon of the GORE Balloon Wire should not be over-inflated. Infuse no more contrast than is necessary to achieve occlusion by fluoroscopically observing balloon apposition to the vessel wall.
2. Where anatomically feasible, ensure that the GORE Balloon Wire is excluding the vessels originating at or near the carotid bifurcation (e.g., superior thyroid artery, ascending pharyngeal artery, etc.). Inability to exclude the origins of these vessels may affect flow reversal performance, leading to embolic events. If it is not feasible to exclude all the branching vessels, consider active flow reversal at the critical steps of the procedure (see NOTE REGARDING ACTIVE FLOW REVERSAL).

**Note:** Inability to inflate the balloon may indicate balloon damage and may result in an air emboli.

**Note:** During stent deployment ensure the stability (e.g., appropriate position, inflation, etc.) of the GORE Balloon Wire in the ECA to prevent loss of embolic protection.

## H. Occlude the Common Carotid Artery

1. Using a 3 cc syringe with diluted contrast (25% contrast, 75% saline), inflate the GORE Balloon Sheath balloon. Complete occlusion of the artery can be confirmed fluoroscopically by observing balloon apposition to the vessel wall. Additionally, angiography can be used to confirm occlusion. Do not position the GORE Balloon Sheath such that the balloon will impinge on diseased vasculature when inflated.
2. The balloons of the GORE Balloon Sheath should not be over-inflated. Infuse no more contrast than is necessary to achieve occlusion by fluoroscopically observing balloon apposition to the vessel wall.

**Note:** Inability to inflate the balloon may indicate balloon damage and may result in an air emboli.

## I. Monitor Patient Response to Vessel Occlusion and / or Flow Reversal

1. With both the GORE Balloon Sheath and the GORE Balloon Wire balloons inflated, observe the tolerance of the patient to occlusion.
2. With the GORE External Filter open to venous return (flow reversal), observe the tolerance of the patient to flow reversal.
3. Check mental and motor statuses of the patient.
4. If the patient exhibits symptoms of intolerance when the CCA vessel is occluded or during flow reversal, use active flow reversal to remove any embolic particles residing within the GORE Balloon Sheath and at the treatment location and deflate the occlusion balloon in the CCA.
5. When patient symptoms resolve, consider reinflating the GORE Balloon Sheath and re-assessing the patient's tolerance to vessel occlusion and / or flow reversal. The patient may be pre-conditioned to achieve tolerance to vessel occlusion and / or flow reversal. In some instances, where pre-conditioning does not result in tolerance, the procedure may need to be terminated.

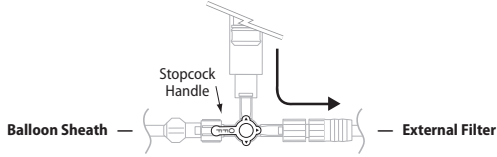
## J. System Completion

Establish cerebral protection by confirming blood flow reversal in the ICA. Perform aspiration (see NOTE REGARDING ASPIRATION) and then angiography to confirm flow reversal by injecting contrast through Stopcock "D". Turn Stopcock "D" to open the system to venous return and observe contrast return through the GORE Balloon Sheath.

The Stopcock "D" handle (connected between GORE Balloon Sheath Filter port and the GORE External Filter) is operable in the three positions outlined below, altering flow as follows:

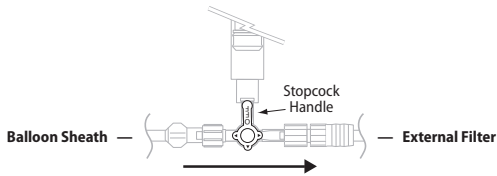
1. With the Stopcock "D" handle directed toward the GORE Balloon Sheath, the 20 cc syringe is positioned for flushing the GORE External Filter and returning aspirated material / blood to the patient via the filter. Flow reversal is stopped (Figure 7).

**Figure 7: Stopcock "D" in position preventing blood flow reversal**



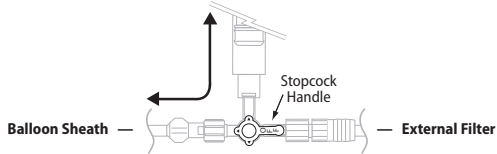
2. The Stopcock "D" handle directed toward the 20 cc syringe port of the stopcock (injection port to stopcock closed) directs blood in the GORE Balloon Sheath to flow into the GORE External Filter connected to the venous introducer sheath. Flow reversal is established (Figure 8).

**Figure 8: Stopcock "D" in position allowing blood flow reversal**



3. The Stopcock "D" handle directed toward the GORE External Filter, allows antegrade injections into the GORE Balloon Sheath and / or aspiration of material or blood (active flow reversal) (Figure 9). Prior to aspiration ensure that the hemostatic valves on the hub are fully closed (a minimum of an additional half a rotation of the valve in the closed direction past hemostasis) to prevent air entrainment in the GORE Balloon Sheath hub. To perform aspiration via the 20 cc syringe, gently withdraw the syringe plunger. After aspiration of material or blood, inject blood from the syringe into the femoral vein through the GORE External Filter using the Stopcock "D" with the handle positioned toward the GORE Balloon Sheath (Figure 7).

**Figure 9: Stopcock "D" in position for the injection of a bolus of contrast media or aspiration**



### Note Regarding Verification of Flow Reversal

Flow reversal can be verified during the procedure using angiography. Perform aspiration (see NOTE REGARDING ASPIRATION) and then angiography to confirm flow reversal by injecting contrast through Stopcock "D". Turn Stopcock "D" to open the system to venous return and observe contrast return through the GORE Balloon Sheath.

### Note Regarding Active Flow Reversal

Active flow reversal via aspiration is strongly recommended under the following circumstances:

1. Prior to any injection through the lumen of the GORE Balloon Sheath.
2. During positioning of the GORE Balloon Wire while crossing tight common carotid and / or external carotid artery lesions.
3. If the GORE Balloon Wire is not positioned to exclude all vessels originating at or near the carotid bifurcation (e.g., superior thyroid artery, ascending pharyngeal artery, etc.), and there is residual antegrade flow, consider active flow reversal during critical interactions with the lesion (e.g., pre- and post-dilation, stent deployment, etc.)
4. During retrieval of the GORE Balloon Wire past a stent deployed across the carotid bifurcation.
5. At the discretion of the physician, during any portion of the carotid artery stenting procedure where aspiration may assist in the removal of a high embolic load.

### Note Regarding Aspiration

To prevent air entrainment in the GORE Balloon Sheath hub, prior to aspiration ensure that the hemostatic valves on the hub are fully closed (a minimum of an additional half a rotation of the valve in the closed direction past hemostasis). To perform aspiration via the 20 cc syringe, gently withdraw the syringe plunger.

If air does enter the hub assembly:

- Stop aspiration.
- Turn Stopcock "D" off to the GORE Balloon Sheath (Figure 7).
- Alternately open the CCA and ECA hemostatic valve on the hub and allow blood flow to flush the air out of the hub assembly.
- Gently aspirate any air remaining in the Filter port connection tubing.
- Ensure entire hub assembly and Filter port connection tubing are free of all air prior to opening Stopcock "D" and injecting through the GORE Balloon Sheath or restoring flow reversal.

### Note Regarding Manifolds

Note that the compatibility of manifolds with the GORE Flow Reversal System has not been determined. If the use of a manifold is desired for the procedure, verify flow reversal as described in NOTE REGARDING VERIFICATION OF FLOW REVERSAL.

**L. Upon Completion of the Intervention**

1. Consider leaving the ICA guidewire in place to allow further intervention if needed.
2. Remove interventional devices (e.g., stent delivery system).
3. To remove the GORE Balloon Wire:
  - a. Perform active flow reversal as previously described in NOTE REGARDING ASPIRATION.
  - b. Deflate the GORE Balloon Wire.
  - c. If the stent is deployed across the ostium of the ECA, remove the GORE Balloon Wire by fully deflating the balloon and then gently pulling the device out from behind the stent. Active flow reversal should be utilized while removing the GORE Balloon Wire.
4. Deflate the GORE Balloon Sheath. At this stage all active and passive flow reversal has been completed.

**CAUTION!**

- During retrieval of the GORE Balloon Wire, ensure that there is sufficient distance between the distal edge of the GORE Balloon Sheath and the proximal edge of the deployed stent to minimize the potential for interaction and damage to the GORE Balloon Wire.
- Should the GORE Balloon Wire become ensnared on the stent, do not exert undue force to remove it. Stent dislodgement, embolism or related complications may occur. Interventional or surgical techniques may be required to address the situation.

**M. Image Arteries Post-Procedure**

1. Perform a completion arteriogram, including intracranial views.

**N. Remove GORE Balloon Sheath**

1. Flush the GORE External Filter with sterile heparinized saline until clear. Disconnect GORE External Filter from the GORE Balloon Sheath and the venous introducer sheath.
2. Remove the guidewire.
3. The GORE Balloon Sheath may be removed at the discretion of the clinician.

**Note:** Alternatively, the GORE Balloon Sheath may be removed over the ICA guidewire (or a stiff guidewire positioned at the distal end of the GORE Balloon Sheath specifically for this step) to aid in a smooth retrieval. The guidewire may then be removed.

**DEFINITIONS**

Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.



Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.



Do Not Re-Sterilize



Inner Diameter



Outer Diameter



Guidewire Compatibility



Store in a cool dry place



Working Length



AM0163-ML2



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