INSTRUCTIONS FOR USE FOR:

GORE CARDIOVASCULAR STENT

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English

INSTRUCTIONS FOR USE

GORE® CAROTID STENT

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® Carotid Stent is comprised of a closed-cell 500 micron pore size ePTFE lattice on the exterior of an open-cell self-expanding nitinol metal frame. The CBAS® Heparin Surface on the GORE® Carotid Stent consists of stable, covalent, end-point attached heparin of porcine origin. It covers all surfaces of both the nitinol and fluoropolymer elements of the stent (**Figure 1 and 1a**).
- The device is preloaded on a rapid exchange catheter which is either 5 Fr (for 5-8 mm stents) or 6 Fr (for 9-10 mm stents) guide sheath compatible. For ease of catheter size distinction, the 5 Fr system has a white distal tip whereas the 6 Fr tip is gray.
- The GORE® Carotid Stent delivery system (**Figure 2**) is comprised of a retractable ePTFE sheath restraining the stent, a .014" guidewire compatible rapid exchange guidewire lumen, and a flexible low profile proximal catheter (2.4 Fr). The overall working length of the catheter is 135 cm. This catheter system is attached to a deployment handle, with stent deployment achieved via removal of the red safety pin and actuation of the unidirectional deployment wheel (**Figure 3**).
- Radiopaque markers aid visualization in the delivery and deployment of the stent and are incorporated into the delivery system. A marker is embedded within the tip of the retractable sheath. Upon actuation of the deployment wheel, this marker aids in visualization of sheath retraction during stent deployment. Additional markers are incorporated into the catheter at the distal and proximal ends of the crimped stent, and the atraumatic tip incorporates a radiopaque polymer (**Figure 2**).
- The GORE® Carotid Stent is available in a variety of straight and tapered sizes (**Table 1**).

FIGURE 1: ENGINEERING DRAWING OF STRAIGHT STENT

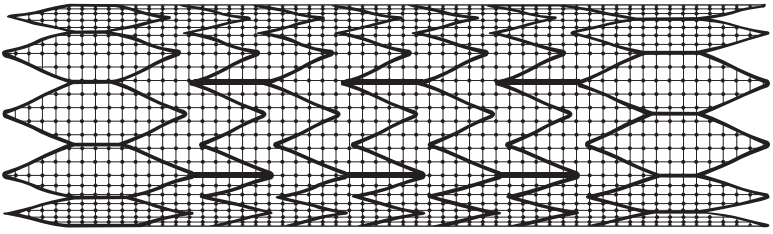

FIGURE 1A: ENGINEERING DRAWING OF TAPERED STENT

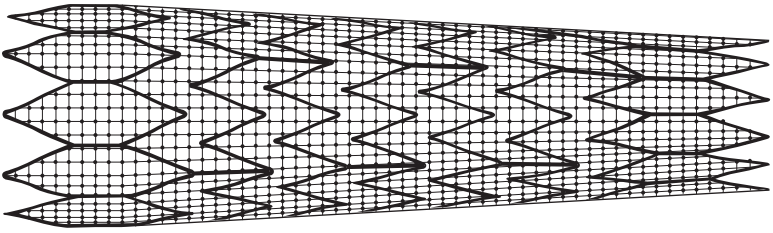

FIGURE 2: SCHEMATIC OF THE GORE® CAROTID STENT DELIVERY SYSTEM

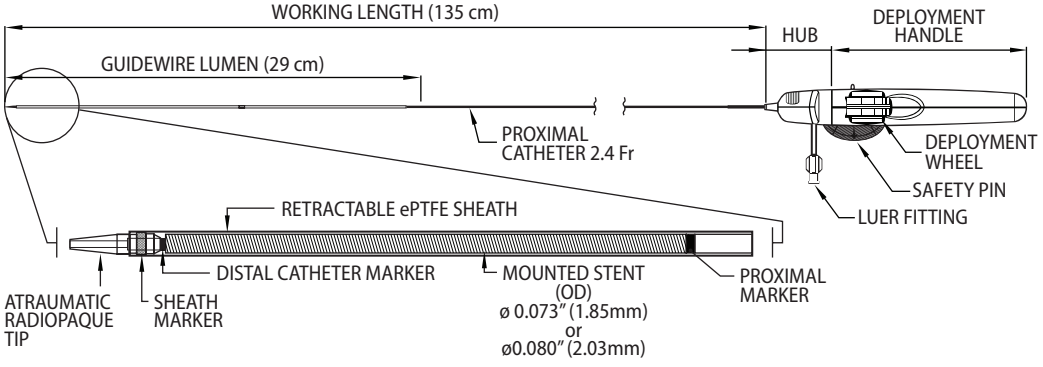

FIGURE 3: SINGLE HANDED DEPLOYMENT HANDLE

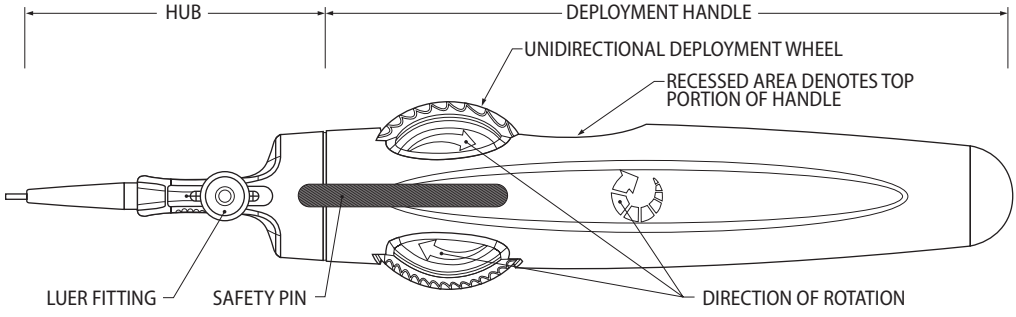

TABLE 1 – GORE® CAROTID STENT SYSTEM SIZING SUMMARY

	Unconstrained Stent Dimensions	Percent Length Foreshortening (%)	Reference Vessel Diameter	Minimum Introducer or Guiding Sheath Catheter I.D.
		Mean (Range)		
5 Fr	5[1] x 30 mm	1.3 (0.9-1.6)	3.7-4.5 mm	.073″ (1.85 mm) White Tip
	5[1] x 40 mm	2.5 (1.9-3.1)		
	6 x 30 mm	1.9 (1.3-2.2)	4.5-5.4 mm	
	6 x 40 mm	3.3 (1.9-5.1)		
	7 x 30 mm	2.8 (1.9-3.4)	5.4-6.3 mm	
	7 x 40 mm	4.5 (2.9-6.0)		
	8 x 30 mm	8.1 (7.9-8.2)	6.3-7.2 mm	
	8 x 40 mm	7.7 (6.6-8.7)		
	6-8 x 30 mm taper	3.1 (2.5-3.7)	4.5-5.4 mm x 6.3-7.2 mm	
	6-8 x 40 mm taper	4.8 (3.2-5.9)		
6 Fr	9 x 30 mm	6.1 (5.0-8.0)	7.2-8.1 mm	.080″ (2.03 mm) Gray Tip
	9 x 40 mm	5.4 (5.1-5.8)		
	10 x 30 mm	7.5 (6.8-8.4)	8.1-9.0 mm	
	10 x 40 mm	7.4 (4.9-8.8)		
	7-9 x 30 mm taper	3.3 (2.5-4.1)	5.4-6.3 mm x 7.2-8.1 mm	
	7-9 x 40 mm taper	3.6 (3.1-4.0)		
	8-10 x 30 mm taper	4.5 (3.8-5.0)	6.3-7.2 mm x 8.1-9.0 mm	
	8-10 x 40 mm taper	3.7 (3.5-4.0)		

1 Although 5 mm diameter stents were available during the SCAFFOLD clinical study, they were not implanted in any of the subjects; therefore, evaluation of the 5 mm size is limited to pre-clinical performance bench testing and animal testing.

INDICATIONS FOR USE

The GORE® Carotid Stent, used with the GORE® Embolic Filter, is indicated for the treatment of carotid artery stenosis in patients deemed at high surgical risk for carotid endarterectomy (CEA) and who meet the criteria below.

- Patients with symptomatic carotid artery stenosis, ≥50%, as confirmed by ultrasound or angiography.
- Patients with asymptomatic carotid artery stenosis, ≥80%, as confirmed by ultrasound or angiography.
- Patients must have a Reference Vessel Diameter of 3.7 mm – 9.0 mm.

CONTRAINDICATIONS

The GORE® Carotid Stent is contraindicated for use in:

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of the delivery catheter or embolic protection device.
- Patients with a known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Lesions in the ostium of the common carotid artery.
- Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II.

WARNINGS

GENERAL

- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with carotid interventional procedures should use this device.
- Preparation of patients receiving the GORE® Carotid Stent should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period as deemed appropriate by the treating physician. The presence of heparin on the GORE® Carotid Stent is not intended to serve as an alternative to the surgeon's chosen intraoperative or postoperative anticoagulation regimens.
- Manufacturer's instructions for use should be consulted for all interventional devices used in conjunction with the GORE® Carotid Stent for their contraindications, warnings, and precautions.
- Placement of the stent across a bifurcation may preclude future diagnostic or therapeutic procedures to the restricted vessel.
- When multiple stents are required, stent materials should be of similar composition.

SPECIFIC

- Do not use in patients who have severe lesion calcification that may restrict the full deployment of the carotid stent.
- Do not use if there is presence of filling defect or thrombus in the target vessel.
- Do not use the GORE® Carotid Stent in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of HIT type II. With any vascular procedure, the possibility of HIT may exist. The incidence of HIT type II is extremely low in vascular patients receiving heparin over a period of several days. If HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed.[1,2] If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures, including ligation or removal of the device, may be considered at the discretion of the attending physician.
- Do not use the GORE® Carotid Stent in patients in whom anti-coagulant or anti-platelet therapy is contraindicated.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- Maintain a snug seal between the device and the hemostasis Tuohy/Borst valve. Device insertion should be performed slowly to minimize the risk of air entrapment.
- Perform all exchanges slowly to prevent air embolism or trauma to the artery.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stent and may cause acute closure of the vessel requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.
- In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.
- Allow for and maintain adequate distance between the radiopaque collar on the GORE® Embolic Filter and the stent delivery system or other compatible interventional devices to avoid potential entanglement.
- Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured.
- Ensure proper sizing per Table 1. Over- or under-sizing may result in partial or complete stent occlusion, embolization, branch vessel occlusion, artery perforation/rupture, or inadequate lesion coverage that may require additional endovascular or surgical intervention.
- Excessive force on the catheter may cause device damage resulting in vessel perforation/rupture or additional required surgical intervention/conversion.
- Use of a stent that is not fully constrained in the delivery system or use of improperly sized introducer sheath may result in unintended device deployment leading to arterial perforation/rupture or additional endovascular or surgical intervention.
- If the delivery system fails prior to or during device deployment, consult the alternate deployment section of the IFU to initiate/complete deployment.
- Failure to follow the IFU procedure for catheter and rapid exchange port flush may result in air embolization to the brain during device delivery or deployment.
- Ensure the Tuohy/Borst valve of the introducer sheath is fully open prior to device introduction to avoid unintended device deployment leading to arterial perforation/rupture or additional required endovascular or surgical intervention.
- Failure to inspect the device for damage prior to use may result in improper device function leading to arterial perforation/rupture or additional required surgical or endovascular intervention.

PRECAUTIONS

- The device is intended for single use only. DO NOT re-sterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate re-sterilization and cross contamination.
- Do not use the product after the USE BY DATE specified on the label.
- Do not expose to organic solvents or ionizing radiation.
- The clinician should be familiar with and experienced in standard techniques of rapid exchange percutaneous transluminal angioplasty and stenting and be knowledgeable of the current medical literature concerning the complications of such procedures.
- Confirm the compatibility of the GORE® Carotid Stent with the interventional devices before actual use.
- Precautions to prevent or reduce clotting should be taken when any interventional device is used. Flush or rinse all devices entering the vascular system with sterile isotonic heparinized saline prior to use.
- Do not remove the stent from its delivery system as removal may damage the stent. The stent and delivery system are intended to be used in tandem. Once deployment of the stent is initiated, the stent cannot be recaptured on to the delivery system.
- During stent placement, an adequate distance should be left between the distal margin of the stent and the GORE® Embolic Filter. The stent delivery system should not contact the embolic protection device.
- The outside diameter of the loaded stent for the 5 Fr system is .073" (1.85 mm) and .080" (2.03 mm) for the 6 Fr system. An appropriate sized sheath/guiding catheter should be selected based on this diameter.
- The GORE® Carotid Stent system is not recommended for use with bleed back control hemostatic valves.
- Use of a sheath/guiding catheter which has an internal diameter slightly larger than the outside diameter of the GORE® Carotid Stent system may limit the amount and force of any contrast injections. Proper selection of the sheath/guiding catheter should allow for a larger internal diameter to allow for contrast injections.
- Do not use a prepared GORE® Carotid Stent system if the stent is not fully constrained within the delivery system.
- Advancement and deployment of the GORE® Carotid Stent should only be performed under fluoroscopic observation.
- Do not attempt to reposition the delivery system once the stent has made contact with the vessel wall.
- Do not torque the GORE® Carotid Stent delivery system greater than one revolution.
- If more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion.
- If overlap of the sequential stents is necessary, the amount of overlap should be between 5-10 mm.
- Antiplatelet medication should be initiated prior to placement of the GORE® Carotid Stent. Effective anticoagulation therapy should be maintained at a dosage deemed appropriate by the physician. The presence of heparin on the GORE® Carotid Stent is not intended to serve as an alternative to the surgeons's chosen intraoperative or postoperative anticoagulation regimens.
- Do not inject contrast or pharmaceutical agents through the GORE® Carotid Stent system. The luer fitting on the handle is for flushing of the system only.
- The presence of heparin on the GORE® Carotid Stent is not intended to serve as an alternative to the surgeon's chosen intraoperative or postoperative anticoagulation regimens.

MRI SAFETY INFORMATION MR Conditional

Non-clinical testing demonstrated that the GORE® Carotid Stent (single and two-overlapped versions) is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the GORE® Carotid Stent (single and two-overlapped versions) is expected to produce a maximum temperature rise of 2.7°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the GORE® Carotid Stent extends approximately 5 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

POSSIBLE ADVERSE EVENTS REPORTED WITH CAROTID ARTERY STENTING

Possible adverse events and complications that may occur with the use of any carotid stent or in any carotid artery stenting procedure and require intervention include, but are not limited to (shown in alphabetical order):

- Abrupt vessel closure
- Allergic reactions to anti-platelet agents/contrast medium
- Aneurysm
- Angina/coronary ischemia
- Arrhythmia
- Arterial occlusion/thrombosis at puncture site or remote site
- Arteriovenous fistula
- Bacteremia or septicemia
- Bleeding from anticoagulant or antiplatelet medications
- Bradycardia/arrhythmia and other conduction disturbances
- Cerebral edema
- Cerebral hemorrhage
- Cerebral ischemia / transient ischemic attack (TIA)
- Congestive heart failure (CHF)
- Death
- Detachment and/or implantation of a component of the system
- Drug reactions
- Emboli, distal (air, device, tissue or thrombotic emboli)
- Emergent or urgent endarterectomy or access vessel surgical or endovascular procedure
- Fever
- Filter thrombosis/occlusion
- Groin hematoma, with or without surgical repair
- Hemorrhage, with or without transfusion
- Heparin induced thrombocytopenia (HIT)
- Hyperperfusion syndrome
- Hypotension/hypertension
- Infection and pain at insertion site
- Ischemia/infarction of tissue/organ
- Myocardial infarction (MI)
- Pain (head, neck)
- Pseudoaneurysm, femoral
- Renal failure/insufficiency
- Restenosis of stented segment
- Seizure
- Severe unilateral headache
- Stent/filter entanglement / damage
- Stent embolization
- Stent fracture
- Stent malposition
- Stent migration
- Stent thrombosis / occlusion
- Stroke/cerebrovascular accident (CVA) or other neurological complications (e.g. paralysis, paraplegia or aphasia)
- Temporary or total occlusion of carotid artery or branch vessels
- Tissue necrosis
- Vascular access complications (e.g. bleeding, vessel damage, pseudoaneurysm and infection)
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil
- Vessel thrombosis
- Unstable angina pectoris

CLINICAL AND DEVICE ADVERSE EVENT REPORTING

Any adverse event involving the GORE® Carotid Stent should be reported to the manufacturer and the country specific regulatory authorities immediately.

To report an event to W. L. Gore & Associates, call: +18005281866 Ext. 44922 or email: medcomplaints@wlgore.com.

SUMMARY OF CLINICAL INFORMATION

Study Summary

The primary objective of this study was to evaluate the safety and efficacy of the GORE® Carotid Stent for the treatment of carotid artery stenosis in patients at increased risk for adverse events from carotid endarterectomy in symptomatic or asymptomatic patients meeting the following key criteria:

- Symptomatic with carotid stenosis ≥ 50% as determined by angiography using NASCET methodology.
  - Symptomatic is defined as amaurosis fugax ipsilateral to the carotid lesion; TIA or non-disabling stroke within 180 days of the procedure within the hemisphere supplied by the target vessel.
- Asymptomatic with carotid stenosis ≥ 80% as determined by angiography using NASCET methodology.

The study was a prospective, multicenter, single-arm clinical study with a performance goal based on historical carotid stenting literature. The study enrolled 312 total subjects at 30 investigational sites in the U.S. 265 of these subjects were determined to meet the eligibility requirements and constitute the Per Protocol analysis population.

The primary endpoints were as follows:

- Composite of Major Adverse Events (MAE): Death, any stroke, or myocardial infarction (MI) through 30 days post-index procedure
- Ipsilateral stroke between 31 days and 1 year

All primary endpoint events were adjudicated and determined by the study Clinical Events Committee.

Duration of Follow-Up

Subjects with a successful GORE® Carotid Stent implant returned for follow-up at 30 days, 6 months, and 1, 2 and 3 years.

The following assessments were required for each follow-up visit:

- Exam and vital signs
- NIHSS
- Modified Rankin Scale
- Carotid Duplex Ultrasound of target vessel

- Concomitant medications (antiplatelet or anticoagulant therapy) assessment
- Adverse events assessment

Demographics and Procedure Results

The Per Protocol population consisted of 176 men and 89 women, with a median age of 74 years (range 45 to 92). Subject demographics are summarized in **Table 2**.

TABLE 2: SUBJECT DEMOGRAPHICS

All Per-Protocol Subjects	
Number of Subjects	265
Sex at Birth	N = 265
Male	176 (66.4%)
Female	89 (33.6%)
Ethnicity	N = 263
Hispanic or Latino	5 (1.9%)
Not Hispanic or Latino	258 (98.1%)
Race	N = 265
American Indian or Alaska Native	1 (0.4%)
Asian	2 (0.8%)
Black	7 (2.6%)
White	253 (95.5%)
Hawaiian	0 (0.0%)
Other Race	3 (1.1%)
Age at Procedure (years)	N = 265
Mean (Std Dev)	73.1 (8.8)
Median	74.4
(Min, Max)	(45.8, 92.8)

A summary of subject medical history is provided in **Table 3**. A total of 33 subjects (12.5%) were reported to be symptomatic, 249 (94%) were reported as having hypertension, and 107 (40%) were reported as having a history of diabetes.

TABLE 3: SUBJECT MEDICAL HISTORY

All Per-Protocol Subjects (N = 265)	
Carotid Disease and Symptoms	
Previous carotid disease	47.2% (125/265)
Etiology of current carotid disease	N = 265
Atherosclerosis	207 (78.1%)
Radiation	9 (3.4%)
Restenosis	43 (16.2%)
Other	1 (0.4%)
Unknown	5 (1.9%)
Symptomatic	12.5% (33/265)
Evidence of non-carotid morphology	6.1% (2/33)
History of ischemic stroke	18.1% (48/265)
Location of most recent ischemic stroke	N = 43
Ipsilateral	27 (62.8%)
Contralateral	16 (37.2%)
History of TIA	15.1% (40/265)
Location of most recent TIA	N = 33
Ipsilateral	25 (75.8%)
Contralateral	8 (24.2%)
Ipsilateral Amaurosis Fugax or TMB	3.4% (9/265)
Endarterectomy	29.8% (79/265)
Location of most recent endarterectomy	N = 79
Ipsilateral	53 (67.1%)
Contralateral	26 (32.9%)
Vascular and Cardiovascular History	

All Per-Protocol Subjects (N = 265)	
Coronary artery disease	62.6% (166/265)
Peripheral vascular disease	37.0% (98/265)
Myocardial infarction	26.8% (71/265)
Previous Cardiovascular Intervention	
PCI	38.1% (101/265)
Aortic / mitral valve surgery	3.8% (10/265)
CABG	27.2% (72/265)
Radiotherapy in cerebral circulation	3.8% (10/265)
General Medical History	
Diabetes Mellitus	40.4% (107/265)
Hypertension	94.0% (249/265)
Cigarette Smoking	N = 265
Current or stopped < 12 Months ago	67 (25.3%)
Previous (stopped > 12 Months ago)	139 (52.5%)
Never	59 (22.3%)

Procedure characteristics are summarized in **Table 4** below. The mean lesion length was 20 mm. The mean target lesion percent stenosis was 84.9%.

TABLE 4: PROCEDURE CHARACTERISTICS

All Per-Protocol Subjects (N = 265)	
Angiography performed	100.0% (265/265)
Bovine Arch	15.8% (42/265)
Pre-procedure ECA < 50% stenosis	51.7% (137/265)
Pre-dilation required before EPD deploy	5.7% (15/265)
Pre-dilation required before stent deploy	79.6% (211/265)
Post-dilation performed after stent deploy	92.5% (245/265)
Target Lesion Side	N = 265
Right	144 (54.3%)
Left	121 (45.7%)
Arch Type	N = 265
Type I	133 (50.2%)
Type II	120 (45.3%)
Type III	12 (4.5%)
Arterial Access Site	N = 265
Left femoral	15 (5.7%)
Right femoral	244 (92.1%)
Other	6 (2.3%)
Target Lesion Location	N = 265
ICA	235 (88.7%)
Bifurcation	30 (11.3%)
Target vessel reference diameter (mm)	N = 265
Mean (Std Dev)	5.6 (1.0)
Median	5.5
(Min, Max)	(3.7, 9.0)
Target lesion length (mm)	N = 265
Mean (Std Dev)	20.0 (9.0)
Median	20.0
(Min, Max)	(1.0, 40.0)
Target lesion % stenosis	N = 265
Mean (Std Dev)	84.9 (6.3)
Median	85.0
(Min, Max)	(50.0, 99.0)

A summary of procedure outcomes is provided in **Table 5**. All study devices (100%) were successfully delivered to the target lesion with a mean residual stenosis of 11.8% at the completion of the study procedure.

TABLE 5: PROCEDURE OUTCOMES

All Per-Protocol Subjects (N = 265)	
GORE® Carotid Stent attempted	100.0% (265/265)
GORE® Embolic Filter successfully used	94.7% (251/265)
Additional EPD used	4.5% (12/265)
GORE® Carotid Stent successfully implanted	100.0% (265/265)
Other stent implanted	0.8% (2/265)
More than one stent implanted	3.0% (8/265)

PRIMARY ENDPOINT RESULTS

Eight (8) subjects (3.0%) had one or more MAEs through 30 days post-index procedure. Of those MAEs, four (1.5%) were due to myocardial infarction, three (1.1%) were due to major stroke, and one (0.4%) was due to death resulting from pulseless electrical activity at day 15.

Three subjects (1.2%) had ipsilateral stroke between 31 days and 1-year post-index procedure. All three of the strokes reported were ischemic and minor with one occurring at day 50, one at day 249 and one at day 276 post-index procedure.

Table 6 lists the MAEs through 30 days post-index procedure and ipsilateral stroke between 31 days and 1 year.

TABLE 6: MAJOR ADVERSE EVENTS THROUGH 30 DAYS AND 1 YEAR

Subjects Evaluable for 30-Day MAE[1]	264 (99.6%)
Subjects With One or More 30-Day MAE	8 (3.0%)
Death	1 (0.4%)
Myocardial Infarction	4 (1.5%)
Stroke	3 (1.1%)
Major Stroke	3 (1.1%)
Ischemic Stroke	2 (0.8%)
Ipsilateral	2 (0.8%)
Non-ipsilateral	0 (0.0%)
Hemorrhagic Stroke	1 (0.4%)
Ipsilateral	1 (0.4%)
Non-ipsilateral	0 (0.0%)
Minor Stroke	0 (0.0%)
Ischemic Stroke	0 (0.0%)
Ipsilateral	0 (0.0%)
Non-ipsilateral	0 (0.0%)
Hemorrhagic Stroke	0 (0.0%)
Ipsilateral	0 (0.0%)
Non-ipsilateral	0 (0.0%)
Subjects Evaluable for 1-year MAE[2]	244 (92.1%)
Subjects With One or More 1-year MAE	11 (4.5%)
30-Day MAE	8 (3.3%)
Ipsilateral Stroke (31-365 Days)	3 (1.2%)

1 Experienced MAE within 30 days or MAE-free with at least 23 days clinical follow-up.
2 Experienced 30-Day MAE or 31-365-day ipsilateral stroke, or MAE-free with at least 335 days clinical follow-up.

PRIMARY ENDPOINT STATISTICAL TESTING

The overall weighted MAE proportion was 4.5%. The 95.1% 1-sided upper confidence limit (UCL) for the weighted MAE proportion was 8.5%, which is substantially lower than the pre-specified weighted performance goal of 16.9%, leading to the conclusion of acceptable performance of the test device on the basis of 1-year MAE. The corresponding binomial test versus the 16.9% performance goal produced a highly significant 1-sided $p < 0.00001$.

SECONDARY ENDPOINT RESULTS (PERFORMANCE ANALYSIS)

TABLE 7: SECONDARY ENDPOINTS

All Per-Protocol Subjects (N=265)	
Stent Technical Success[1]	100.0% (265/265)
Stent Technical Failure	0.0% (0/265)
EPD Technical Success[2]	94.7% (251/265)
EPD Technical Failure	5.3% (14/265)
Procedure Success[3]	94.3% (250/265)
Procedure Failure	5.7% (15/265)
Stent Technical Failure	0.0% (0/265)
≥30% Residual Stenosis	4.2% (11/265)
In-hospital MAE	1.5% (4/265)

1 Successful deployment of a GORE® Carotid Stent
2 GORE® Embolic Filter delivered, placed, and retrieved without requiring assisting interventional methods
3 Stent Technical Success, < 30% residual stenosis and no in-hospital MAE

TABLE 8: KAPLAN-MEIER ESTIMATES OF PROBABILITY OF RESTENOSIS

Time from Procedure (Months)	At Risk at Start of Interval	Events During Interval (Cumulative)	Censored During Interval (Cumulative)	Probability of Restenosis	95% C.I.
All Per-Protocol Subjects (N=265)					
0	265	0 (0)	0 (0)	0.0%	(0.0%, 0.0%)
1	265	0 (0)	5 (5)	0.0%	(0.0%, 0.0%)
6	260	0 (0)	11 (16)	0.0%	(0.0%, 0.0%)
12	249	4 (4)	104 (120)	1.8%	(0.7%, 4.7%)

Time defined as time from index procedure to restenosis, or last follow-up, if censored.
Event defined as restenosis (≥80% diameter stenosis by core lab angiographic analysis).

TABLE 9: FREEDOM FROM CLINICALLY DRIVEN TARGET LESION REVASCULARIZATION (TLR)

Kaplan-Meier Estimates of Probability of Freedom from Clinically Driven TLR

Time from Procedure (Months)	At Risk at Start of Interval	Events During Interval (Cumulative)	Censored During Interval (Cumulative)	Probability of Freedom from Clinically Driven TLR	95% C.I.
All Per-Protocol Subjects (N=265)					
0	265	0 (0)	0 (0)	100.0%	(100.0%, 100.0%)
1	265	0 (0)	5 (5)	100.0%	(100.0%, 100.0%)
6	260	0 (0)	11 (16)	100.0%	(100.0%, 100.0%)
12	249	5 (5)	103 (119)	97.8%	(94.8%, 99.1%)

Time defined as time from index procedure to first clinically driven TLR, or last follow-up, if censored.
Event defined as any clinically driven target lesion revascularization.
Clinically driven defined as core lab angiographic diameter stenosis ≥80%, or diameter stenosis ≥50% with clinical symptoms.

DISCUSSION AND CONCLUSIONS

The study was designed to assess the safety and efficacy of the GORE® Carotid Stent for the treatment of carotid artery stenosis in patients at increased risk for adverse events from carotid endarterectomy.

The primary study endpoint is a composite of MAEs defined as death, any stroke, or myocardial infarction (MI) through 30 days post-index procedure, and ipsilateral stroke between 31 days and 1 year.

The proportion of subjects with 1-year MAE (weighted by the prespecified expected design weights for subjects with anatomic and comorbid high risks) was 4.5% with a 1-sided 95.1% upper confidence limit of 8.5%, which is substantially less than the prespecified performance goal of 16.9%. Therefore, the study met its primary endpoint and leads to a conclusion of acceptable performance of the test device on the basis of 1-year MAE.

The results of this study support the safety and efficacy of the GORE® Carotid Stent for the treatment of carotid artery disease.

DIRECTIONS FOR USE

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.
WARNING: The GORE® Carotid Stent system is intended for single use only. DO NOT re-sterilize and/or reuse it, as this can potentially result in compromised device performance and risk of cross contamination.
WARNING: Do not use the product after the Use by Date specified on the package.

MATERIALS REQUIRED

- Confirm the compatibility of the GORE® Carotid Stent system with the interventional devices to be used prior to actual use.
- Select the appropriate guiding catheter or introducer sheath compatible with the vascular anatomy and device size. Minimum guiding catheter/sheath size inner diameter (I.D.) of .074"/1.88 mm for the 5 Fr compatible system and .080"/2.03 mm for the 6 Fr compatible system.
- > 0.096 (2.44 mm) Rotating Hemostatic Valve (RHV) (optional). **WARNING:** The GORE® Carotid Stent system is not recommended for use with bleed back control hemostatic valves because of possible damage to the sheath constraining the stent and difficulty/inability to properly deploy.
- 0.014" guidewire of at least 190 cm is recommended.
- GORE® Embolic Filter
- Balloon dilatation catheter (optional)
- Heparinized normal saline (sterile)

PERIPROCEDURAL CARE

Preparation of patients receiving the GORE® Carotid Stent should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period as deemed appropriate by the treating physician. The presence of covalently bound heparin on the GORE® Carotid Stent is not intended to serve as an alternative to the surgeon's chosen intraoperative or postoperative anticoagulation regimens.

PRE-PROCEDURE

The placement of the stent in a stenotic or obstructed carotid artery should be performed in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is visualized, do not proceed with stent deployment. Access vessels must be sufficiently patent or sufficiently recanalized to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

Using Contrast Media

- During the insertion of rapid exchange catheters through guide catheters or sheaths, careful handling is required to ensure that air is not drawn into the access device. It is therefore recommended that flushing of contrast media (or other fluids) is performed before or after insertion of the catheter, but not while the catheter is within the access device.
- In the case where contrast media injection must be performed with the catheter in place it is essential to ensure that no air is present within the access device prior to injection. This risk will be minimized by the following instructions of slow catheter insertion and good hemostasis valve control.
- If aspiration is to be performed prior to contrast media injection, it should be performed slowly and steadily at a rate of not more than 0.5 ml (0.5 cc) per second until it can be visually confirmed that no further air is entering the aspiration syringe.

STENT-SIZE DETERMINATION

- Measure the length of the target lesion to determine the length of the stent(s) required to sufficiently cover the lesion.
- Measure the diameter of the vessel proximal and distal to the target lesion to determine stent diameter. See **Table 1** for stent sizes and recommended reference vessel diameters for straight and tapered stents.
- Should a second stent be required, the second stent should have the same internal diameter as the first stent deployed. Overlap regions should be kept to between 5-10 mm.
- The GORE® Carotid Stent is provided in a range of lengths, diameters, and configurations. Care should be taken to select the most appropriately sized stent. The GORE® Carotid Stent foreshortens approximately 1-2 mm, regardless of length, during deployment.

DELIVERY SYSTEM PREPARATION

Preparation

1. Select the appropriate system for the target lesion according to **Table 1**.
2. Remove the backer card from the foil package and visually inspect for shipping damage. If damage is present, do not use system.
   a. If it is suspected that the sterile barrier has been compromised, do not use the device and return it to the manufacturer.
3. Ensure the red safety pin is in place and remove the device from its protective hoop by pulling the device out by the deployment handle.
4. Visually inspect the system. Check for bends, kinks, and other damage. Do not use if defects are noted.
5. Examine the distal end of the device to ensure that no part of the stent is exposed. Do not use the device if any portion of the stent is exposed, and return to the manufacturer.
6. Attach a 2.5 ml syringe filled with normal heparinized saline to the hub's luer connection and flush until fluid flows from the distal end of the sheath. It is recommended to flush the full 2.5 ml of saline. Remove syringe.
7. Carefully remove the guidewire lumen mandrel.
8. Attach the white flushing adapter to syringe and flush the guidewire lumen from the distal tip of the system. Do not force tip of system into flushing adapter.
9. Do not remove the red safety pin until the stent is ready to deploy.

CAUTION: Do not use the luer connection for contrast injection or delivery of pharmaceutical agents.

Introduction of the Stent Delivery System

1. Access the target lesion and establish embolic protection using the GORE® Embolic Filter as per the instructions for use.
2. The outside diameter of the sheath constraining the stent is **.073" (1.85 mm) for the 5 Fr system and .080" (2.03 mm) for the 6 Fr system**.
3. Following pre-dilation of the lesion (if required), back-load the GORE® Carotid Stent delivery system over the 0.014" guidewire/embolic filter wire while maintaining wire position. The guidewire will emerge approximately 30 cm from the distal tip of the GORE® Carotid Stent delivery catheter.
4. After securing the guiding catheter/sheath and guidewire/embolic filter wire position, advance the GORE® Carotid Stent delivery system through the sufficiently open Tuohy/Borst valve and through the sheath to the lesion location, taking care to maintain positive control of the deployment handle. Once the rapid exchange portion of the delivery system has passed the Tuohy/Borst valve, tighten the hemostatic valve to a snug fit around the black proximal catheter. Failure to maintain a snug fit of the Tuohy/Borst valve may result in air being drawn into the access device.

CAUTION: Ensure the Tuohy/Borst valve is fully open for the initial insertion of the GORE® Carotid Stent delivery system. Failure to do so may cause the sheath restraining the stent to be retracted and expose the device.
CAUTION: If resistance is encountered, withdraw the system as resistance may indicate damage to the stent or stent delivery system. Maintain guidewire/embolic filter wire placement across the lesion and remove the delivery system as a single unit. The cause of any resistance should be determined via fluoroscopy and remedial action taken.

STENT DEPLOYMENT

1. Advance the system distal of the lesion and then retract to align stent with the lesion thus removing any slack in the deployment system.
2. Ensure optimal positioning of the stent across the lesion utilizing the radiopaque markers and confirm fluoroscopically. The farthest distal marker denotes the position of the sheath restraining the stent and will aid the operator in visualizing stent deployment. The second and third markers on the catheter indicate the distal and proximal ends of the stent (**Figure 2**).
   NOTE: Ensure an adequate stand-off between the distal end of the delivery catheter and the GORE® Embolic Filter to avoid potential entanglement.
3. If the position of the stent is not optimal, it should be repositioned or removed. Do not deploy the stent until it is properly positioned across the target lesion.
4. Ensure that the Tuohy/Borst valve is tightened to fix the position of GORE® Carotid Stent delivery system and guidewire. As the deployment line of the delivery system is located within the catheter, the deployment of the stent will not be impacted by a completely closed Tuohy/Borst valve.
5. Once stent positioning is confirmed, verify that the deployment handle is in the proper orientation. The proper orientation for the deployment handle is with the recessed area at the base of the unidirectional deployment wheel facing upward and the red safety pin facing to the left.
6. Obtain a comfortable grip on the deployment handle to allow for proper rotation of the deployment wheel and remove the red safety pin by pulling it away from the handle.
7. The direction of rotation, which will initiate stent deployment, is limited to one direction only and is indicated by arrows on either side of the deployment wheel.
8. Begin to rotate the deployment wheel in the indicated direction. An audible "click" of the deployment wheel indicates tensioning of the deployment line. Approximately "8 - 10 clicks" are required to tension the deployment line to initiate stent release. As the distal marker on the sheath begins movement, each "click" thereafter indicates approximately 2-mm of sheath retraction. Observe the sheath marker retraction and subsequent stent deployment fluoroscopically.
9. Do not attempt to reposition the delivery system once the stent has made contact with the vessel wall.
10. Continue to rotate the deployment wheel until full deployment of the device is visualized. Full deployment is achieved when the sheath marker passes proximal to the proximal catheter marker.
11. Alternative Deployment Options:
    A. Manual deployment of the stent can be accomplished by removal of the hub from the deployment handle, which allows direct visualization of the deployment line, followed by manually retracting the handle from the hub.
       1. Removal of the hub is accomplished by grasping the hub with one hand and rotating the deployment handle body counter clockwise for a 1/8 turn. This will release the hub from the handle body.
       2. While maintaining a firm grip on the hub, slowly retract the handle body in a linear fashion which will result in stent deployment.

CAUTION: When more than one stent is required to cover the lesion, or if there are multiple lesions, the distal lesion should be stented first, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent for placement of the distal stent, and reduces the chance of dislodging stents that have already been placed.

CAUTION: If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum (approximately 5 - 10 mm).

CAUTION: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.

WARNING: Overstretching of the artery may result in rupture and life-threatening bleeding.

DELIVERY SYSTEM REMOVAL AND POST DILATATION

1. Under fluoroscopic observation, carefully retract the stent delivery system while maintaining accessory position. If significant resistance is felt, remove the stent delivery system together with the sheath or guide catheter while maintaining filter/guidewire position.
2. Assess the deployed stent under fluoroscopic observation.
3. If desired, the stent may be dilated with a balloon dilatation catheter. The diameter of the balloon shall not be larger than the unconstrained stent diameter or the vessel's reference diameter.
4. If the device is oversized outside the recommended vessel diameter as stated in the GORE® Carotid Stent Sizing Summary, use of IVUS is recommended to help visualize the position of the lattice. If lattice material appears to protrude within the lumen, a low pressure balloon inflation is recommended to reposition the lattice against the stent frame.

POST-STENT PLACEMENT

1. Once the desired result is achieved, the GORE® Embolic Filter should be retrieved as per the manufacturer's instructions for use.
2. All other ancillary devices should be removed and, if required, the puncture site closed.

HOW SUPPLIED

- The GORE® Carotid Stent is provided preloaded on a delivery system, with a 2.5 cc flushing syringe and a guidewire lumen flush adapter.
- The GORE® Carotid Stent is provided STERILE and non-pyrogenic, and is sterilized by Ethylene Oxide. Do not resterilize.
- Do not use after the "Use By" (expiration) date printed on the label.
- The GORE® Carotid Stent is designed for single use only; do not reuse device. Gore does not have data regarding reuse of this device. Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination which may lead to patient harm.

STORAGE & HANDLING

- Store in a dry place. Avoid exposing the package or device to extreme hot or cold temperatures.
- Do not use the GORE® Carotid Stent if the foil packaging is compromised or if the device is damaged.
- Handle and dispose of the device and packaging in accordance with acceptable medical practice and with applicable local, state, and federal laws and regulations.
- See WARNINGS AND PRECAUTIONS for additional considerations specific to storage and handling.
- For additional Storage and Handling information, see HOW SUPPLIED.

REFERENCES

1. Linkins LA, Dans AL, Moores LK, Bona R, Davidson BL, Schulman S, Crowther M; American College of Chest Physicians. Treatment and prevention of heparin-induced thrombocytopenia: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2)Supplement:e495S-e530S.
2. Warkentin TE. Heparin-coated intravascular devices and heparin-induced thrombocytopenia. In: Warkentin TE, Greinacher A, eds. *Heparin-Induced Thrombocytopenia*. 5th ed. New York, NY: Informa Healthcare USA; 2012;(20):573-590.

DEFINITIONS

EC REP Authorised Representative in the European Community

REF Catalogue Number

Caution

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

Consult Instructions for Use

Date of Manufacture

Do Not Expose to Extreme Hot or Cold Temperature

Do Not Resterilize

Do Not Reuse

Do Not Use if Package is Damaged

Keep Dry

Manufacturer

MR Conditional

SN Serial Number

STERILE Sterile

STERILE EO Sterilized using Ethylene Oxide

Use By

Catheter Working Length

Delivery Profile

Diameter

Guidewire Compatibility

Guiding Catheter

Introducer Sheath

Vessel Diameter

20053859

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