Boston Scientific

90451284-01

Carotid WALLSTENT®

MONORAIL® ENDOPROSTHESIS

TABLE OF CONTENTS

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using irradiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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

1. DEVICE DESCRIPTION

This product contains no detectable latex.

The Carotid WALLSTENT Monorail Endoprosthesis (Carotid WALLSTENT Endoprosthesis) is a closed cell design self-expanding stent composed of biomedical DFT (Drawn Filled Tubing) alloy monofilament wires braided in a tubular mesh configuration. The wires are manufactured from a biomedical grade cobalt-chromium-iron-nickel-molybdenum alloy (commonly known as Elgiloy® or Conichrome) containing an enhanced radiopaque tantalum core. The device has two components: the stent and the stent delivery system (see Figure 1).

The Monorail delivery system consists of two coaxially arranged shafts: an inner shaft (8) made of stainless steel proximally and thermoplast distally and an outer sheath (5) made of thermoplast. The central lumen (1) within the inner shaft continues to the tip (2) and accepts a 0.014 in (0.36 mm) guide wire, which exits the inner lumen through two guide wire holes (13, 14). To ensure that the inner guide wire lumen remains patent during the shelf life of the product, a packaging stylus (not pictured) is inserted through the tip (2) and out through the inner and outer shaft guide wire holes (13, 14).

The Carotid WALLSTENT Endoprosthesis (6) is pre-loaded on the stent carrier located on the distal segment of the inner shaft. Two radiopaque markers (3a,b) on the inner shaft and one radiopaque marker (4) on the retractable outer sheath are used to facilitate stent placement. The distal end of the outer sheath covers the Carotid WALLSTENT Endoprosthesis and is used to deploy the stent during the interventional procedure. The annular space between the coaxial inner shaft (8) and outer sheath (5) is accessed through the T-connector (9). The proximal end of the Carotid WALLSTENT Endoprosthesis is firmly held on the inner shaft with a holding mechanism (7), which enables a partially deployed Carotid WALLSTENT Endoprosthesis (up to 50%) to be reconstrained and repositioned. However, reconstrainment and repositioning of the Carotid WALLSTENT Endoprosthesis should only be done if absolutely necessary and should be strictly avoided when the partially deployed Carotid WALLSTENT Endoprosthesis is already in contact with the plaque of the stenosis. A black limit marker (11) on the proximal stainless steel tube (10) shows the maximum deployment still allowing reconstrainment of the Carotid WALLSTENT Endoprosthesis. A heart shaped hub (12) located at the end of the stainless steel tube (10) provides product identification.

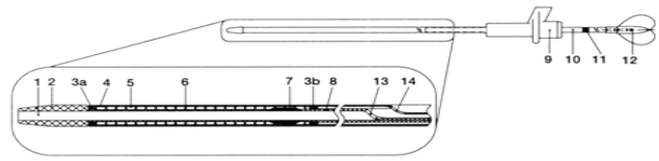

Figure 1. - Carotid WALLSTENT Monorail Endoprosthesis

The stent is available in three unconstrained diameters (6 mm, 8 mm, and 10 mm; see Table 1). There is one length for the 6 mm stent (22 mm, unconstrained), and three lengths each for the 8 mm stent (21, 29, and 36 mm, unconstrained) and 10 mm stent (24, 31, and 37 mm, unconstrained).

Table 1 - Carotid WALLSTENT Endoprosthesis (0.014 in Guide Wire Lumen) Stent Sizes and Sizing

Catalog Number	Stent						Delivery Catheter		Compatibility	
	* Fully Open Diameter	* Fully Open Length	Representative Length Adjustments				Outer Diameter	Working Length	Guiding Sheath Minimum ID	Guiding Catheter Minimum ID
			Vessel Diameter	Implanted Length	Vessel Diameter	Implanted Length				
	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	(F / mm)	(cm)	(F / inches)	(F / inches)
71-900	6	22	5	30	4	36	5.0 / 1.67	135	5 / 0.073	7 / 0.073
71-901	8	21	7	30	6	36	5.0 / 1.67	135	5 / 0.073	7 / 0.073
71-902	8	29	7	40	6	48	5.0 / 1.67	135	5 / 0.073	7 / 0.073
71-903	8	36	7	50	6	62	5.0 / 1.67	135	5 / 0.073	7 / 0.073
71-904	10	24	9	30	8	36	5.9 / 1.97	135	6 / 0.086	8 / 0.086
71-905	10	31	9	40	8	49	5.9 / 1.97	135	6 / 0.086	8 / 0.086
71-906	10	37	9	50	8	59	5.9 / 1.97	135	6 / 0.086	8 / 0.086

* Fully opened stent diameter selected should be 1 mm to 2 mm larger than nominal vessel diameter.

Guiding Catheter Compatibility:

7F (min. internal diameter 0.073 in [1.85 mm]): use with 71-900 to 71-903

8F (min. internal diameter 0.086 in [2.18 mm]): use with 71-904 to 71-906

Guiding Sheath Compatibility:

5F (min. internal diameter 0.073 in [1.85 mm]): use with 71-900 to 71-903

6F (min. internal diameter 0.086 in [2.18 mm]): use with 71-904 to 71-906

2. INDICATIONS

The Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis), used in conjunction with the Boston Scientific embolic protection system, is indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy due to either anatomic or comorbid conditions who require carotid revascularization in the treatment of ipsilateral or bilateral carotid artery disease and meet the criteria outlined below:

- Patients with neurological symptoms and ≥50% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram OR patients without neurological symptoms and ≥80% stenosis of the common, internal carotid artery and/or the bifurcation by ultrasound or angiogram, AND
- Patients with a reference vessel diameter within the range of 4.0 mm and 9.0 mm at the target lesion.

3. CONTRAINDICATIONS

The Carotid WALLSTENT Endoprosthesis 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 a guide catheter, sheath, embolic protection system or stent system
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery

4. 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 stent placement should use the device.

4.1 General Warnings

- Refer to the Directions for Use supplied with any interventional devices to be used in conjunction with the Carotid WALLSTENT Endoprosthesis for their intended uses, contraindications, and potential complications.
- The safety and efficacy of the Carotid WALLSTENT Endoprosthesis have not been demonstrated with embolic protection devices other than the FilterWire EZ™ System.
- Risk of distal embolization may be higher if the Carotid WALLSTENT Endoprosthesis cannot be used in conjunction with an embolic protection system during the carotid stenting procedure.
- The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the embolic protection device filter membrane to tear at the hemostasis valve upon removal.
- During and after the procedure, appropriate antiplatelet and anticoagulation therapy must be provided to the patient, according to the current medical practice.
- The long-term performance of the Carotid WALLSTENT Endoprosthesis has not been established.
- As with any type of vascular implant, infection secondary to contamination of the stent may lead to thrombosis, pseudoaneurysm, or rupture.
- Stenting across a major bifurcation may hinder or prevent future diagnostic or therapeutic procedures.
- In patients requiring the use of antacids and/or H2-antagonists before or immediately after stent placement, oral absorption of antiplatelet agents such as aspirin may be adversely affected.
- Prior to use, the packaging and product should be inspected for signs of damage and expiration. Never use damaged or expired product or product from a damaged package.
- Flush all instruments entering the vascular system with sterile heparinized isotonic saline or a similar solution prior to use.
- The implantation of the Carotid WALLSTENT Endoprosthesis should be performed only under fluoroscopic observation with radiographic equipment providing high-resolution images.
- If pre-dilatation of the stenosis is necessary to allow crossing of the Carotid WALLSTENT Endoprosthesis, it is recommended to employ the smallest diameter balloon that allows safe passage of the stent system. A 2 mm to 3 mm balloon is typically sufficient.
- Always keep the Carotid WALLSTENT Endoprosthesis filled with sterile heparinized isotonic saline while it is in the vascular system.
- Never advance the Carotid WALLSTENT Endoprosthesis without the guide wire extending from the tip.
- Do not advance the Carotid WALLSTENT Endoprosthesis against significant resistance.
- The Carotid WALLSTENT Endoprosthesis should be oversized in relation to the artery diameter by 1 mm to 2 mm to prevent migration.
- Do not release the Carotid WALLSTENT Endoprosthesis if unusual force is required; in such a situation use another device.
- Never advance a partially deployed Carotid WALLSTENT Endoprosthesis distally.
- Reconstrainment and repositioning of the Carotid WALLSTENT Endoprosthesis should be strictly avoided when the partially deployed Carotid WALLSTENT Endoprosthesis is already in contact with the plaque of the stenosis.
- Use of this device in patients with hypersensitivity to cobalt, chromium, iron, nickel, or molybdenum may provoke an allergic reaction.
- Avoid using power injection in the cerebral circulation.

4.2 Patient Selection

The safety and efficacy of the Carotid WALLSTENT Endoprosthesis have NOT yet been established in patients with the characteristics noted below.

4.2.1 Patient Characteristics

- Low to moderate risk for adverse events from carotid endarterectomy
- Experiencing acute ischemic neurologic stroke or having experienced a stroke within 21 days of the procedure
- Intracranial mass lesion (i.e., abscess, tumor, or infection) or aneurysm >5 mm
- Arteriovenous malformations of the territory of the target carotid artery
- Coagulopathies
- Presence of fresh unlysed, unorganized thrombus
- Patients undergoing laser debulking or electrocoagulation within the stent
- Poor renal function or life threatening allergy which, in the physician's opinion, may constitute high risk for a reaction to contrast medium
- Carotid string sign
- Aneurysmal dilation immediately proximal or distal to the lesion
- Active infection
- Severe dementia
- Pregnancy
- Under the age of 18

4.2.2 Lesion Characteristics

- Evidence of intraluminal thrombus thought to increase the risk of plaque fragmentation and distal embolization
- Previously placed stent in the target artery
- Requirement of more than two stents
- Total occlusion of the target vessel
- Presence of carotid artery dissection prior to initiation of the procedure
- Highly calcified lesions

4.2.3 Access Characteristics

- Known peripheral vascular, supra-aortic, or internal carotid artery tortuosity that would preclude the use of catheter-based techniques
- Femoral access not possible
- Inadequate local hemostasis at the access site
- Failed guide wire or balloon catheter access

4.3 Device Use

- This device is intended for single-use only. Do not reuse. Do not resterilize as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.
- Do not use the product after the "Use By" date specified on the package.
- Heparinize the patient to achieve and maintain an Activated Clotting Time (ACT) of ≥ 275 seconds (≥200 seconds if using GP IIb/IIIa inhibitors) to prevent thrombus formation on the devices.
- To minimize the possible introduction of air into the delivery system, it is important to maintain tight catheter connections and to thoroughly flush the delivery system.
- Maintain continuous flush while removing and reinserting devices on the guide wire. 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).
- The stent may cause a thrombus, distal embolization or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. 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.
- Overstretching of the artery may result in rupture and life-threatening bleeding.
- If a filter-based embolic protection system is used, allow for and maintain adequate distance between the filter and the stent delivery system or deployed stent to avoid potential entanglement. If filter basket entanglement or basket detachment occurs, surgical conversion or collapsing the basket with a second stent should be considered.
- Balloon angioplasty of the carotid bifurcation may initiate transient hemodynamic instability consisting of bradycardia or hypotension. Appropriate pharmacologic therapy must be immediately available.

5. PRECAUTIONS

5.1 Stent Handling

- Carefully inspect the Carotid WALLSTENT Endoprosthesis to verify that the device has not been damaged in shipment. Do not use damaged equipment.
- The delivery system has an internal hypotube. Take care to avoid unnecessary handling, which may kink or damage the delivery system. Do not use if the device is kinked.
- Do not expose the delivery system to organic solvents like alcohol as structural integrity and/or function of the device may be impaired.
- Do not remove the stent from its delivery system as removal may damage the stent. The stent on the delivery system is intended to perform as a system. If removed, the stent cannot be put back on the delivery system.
- Special care must be taken not to handle or in any way disrupt the stent on the delivery system during catheter removal from packaging, stylus removal, placement over the guide wire and advancement through hemostatic valve adapter and guiding catheter or guiding sheath hub.
- Do not hold the sheath or stent during stylus removal.

5.2 Stent Placement

- The Carotid WALLSTENT Endoprosthesis is not compatible with any guide wire larger than 0.014 in (0.36 mm).
- The Carotid WALLSTENT Endoprosthesis must be used with a guiding catheter or guiding sheath to maintain adequate support of the 0.014 in (0.36 mm) guide wire throughout the procedure.

Boston Scientific (Master Brand eDFU Template 8.2677in x 11.6929in A4, 90105918 Rev/Ver. AG), eDFU, Carotid WALLSTENT, EN, 90451284-01A

- For best device performance, the guide wire exit notch should remain within the guiding catheter or guiding sheath.
- Ensure the stent system is fully flushed with heparinized saline prior to use. Do not use the delivery system if flush is not observed exiting at the distal end of the sheath.
- Venous access should be available during carotid stenting to manage bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.
- When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.
- The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.
- If resistance is met during delivery system introduction, the system should be withdrawn and another system used.
- Prior to stent deployment, remove all slack from the delivery system.
- 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.
- If overlap of sequential stents is necessary, the amount of overlap should be 5 mm. In no instance should more than 2 stents overlap.

5.3 Post Implant

- Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting stent placement.
- In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

5.4 Magnetic Resonance Imaging (MRI) Compatibility

Through non-clinical testing, the Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis), has been shown to be MRI safe at field strengths of 3.0 Tesla or less, and a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MRI exposure. In this testing, a single stent produced a temperature rise of ≤1.03 °C at a maximum calculated whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. For an overlapped pair of stents, the temperature rise was ≤1.72 °C at a maximum calculated whole body averaged SAR of 2.0 W/kg for 15 minutes of MRI. The effect of heating for stents with fractured struts is not known. The Carotid WALLSTENT Endoprosthesis should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3.0 Tesla.

MRI at 3.0 Tesla or less may be performed immediately following the implantation of the Carotid WALLSTENT Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. MR image artifact has been evaluated at 1.5 Tesla only.

6. ADVERSE EVENTS

6.1 Observed Adverse Events

BEACH (Boston Scientific EPI: A Carotid Stenting Trial for High-Risk Surgical Patients) was a prospective, single-arm, multi-center trial to evaluate the safety and efficacy of the Carotid WALLSTENT Endoprosthesis in conjunction with the FilterWire EX®/FilterWire EZ™ Embolic Protection System to treat surgical high risk, symptomatic (≥50% stenosis) and asymptomatic (≥80% stenosis) patients with disease in the carotid artery. The primary objective of the trial was to show non-inferiority between carotid stenting and a historical control representative of outcomes with carotid endarterectomy, based upon the 1-year morbidity and mortality rate including non Q-wave MI to 24 hours; death, stroke, and Q-wave MI through 30 days; and ipsilateral stroke and neurologic death from 31 to 360 days. A total of 747 patients were enrolled in the trial: 189 roll-in patients, 480 pivotal patients and 78 bilateral registry patients.

Table 2 and Table 3 present Major Adverse Events (MAE) and Serious Adverse Events (SAE) respectively, as reported in the BEACH pivotal trial patients. A serious adverse event (SAE) may or may not be considered related to the device and was defined as follows:

- Death due to any cause
- Life-threatening condition (e.g., stroke)
- Persistent or significant disability/incapacity
- Any event resulting in an unscheduled in-patient hospitalization or prolongation of existing hospitalization >72 hours post index procedure
- Any event requiring intervention, except for comorbid scheduled events, which are scheduled and planned during the follow-up period
- Congenital abnormality or birth defect

Serious adverse events have been coded using the Medical Dictionary for Regulatory Activities (MedDRA™) version 5.0 and are presented by System Organ Class and Preferred Term as follows:

- BLOOD AND LYMPHATIC SYSTEM DISORDERS include events such as anemia.
- CARDIAC DISORDERS include events such as angina, arrhythmias, cardiac failure congestive and myocardial infarction.
- EYE DISORDERS include events such as retinal infarction.
- GASTROINTESTINAL DISORDERS include events such as gastrointestinal hemorrhage and retroperitoneal hemorrhage.
- GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS include events such as death, multi-organ failure, and pyrexia.
- HEPATOBILIARY DISORDERS include events such as cholelithiasis.
- INFECTIONS AND INFESTATIONS include events such as pneumonia, sepsis and urinary tract infection.
- INJURY, POISONING AND PROCEDURAL COMPLICATIONS include events such as hip fracture and stent occlusion.
- INVESTIGATIONS include events such as blood creatinine increased and neurological examination abnormal.
- METABOLISM AND NUTRITION DISORDERS include events such as dehydration and hyperglycemia.
- MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS include events such as arthritis and pain.
- NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCLUDING CYSTS AND POLYPS) include events such as carcinomas, lung cancer, and neoplasms.
- NERVOUS SYSTEM DISORDERS include events such as cerebral hemorrhage, cerebrovascular accident, convulsions, dizziness, syncope and transient ischemic attack.
- PSYCHIATRIC DISORDERS include events such as confusion, depression and mental status changes.
- RENAL AND URINARY DISORDERS include events such as renal failure and impairment.
- REPRODUCTIVE SYSTEM AND BREAST DISORDERS include events such as vaginal hemorrhage.
- RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS include events such as chronic obstructive airway disease, dyspnea, pulmonary fibrosis, and respiratory failure.
- SKIN AND SUBCUTANEOUS TISSUE DISORDERS include events such as skin ulcer.
- SURGICAL AND MEDICAL PROCEDURES include events such as aortic valve replacement, arterial stent insertion, carotid endarterectomy, coronary artery surgery and revascularization, and hip arthroplasty.
- VASCULAR DISORDERS include events such as hematoma, hemorrhage, hypertension, hypotension, peripheral revascularization and vascular pseudoaneurysm.

Table 2: BEACH Trial Major Adverse Events

Adverse Events	≤ 30 Days			31-360 Days			0-360 Days		
Primary Endpoint	**# of Events**	**# of Patients**	**% Patients**	**# of Events**	**# of Patients**	**% Patients**	**# of Events**	**# of Patients**	**% Patients (N=448)**
1-Year Morbidity and Mortality[1]	NA	NA	NA	NA	NA	NA	50	40	8.9%
Major Adverse Events[2]	**# of Events**	**# of Patients**	**% Patients (N=478)**	**# of Events**	**# of Patients**	**% Patients (N=462)**	**# of Events**	**# of Patients**	**% Patients (N=469)**
Death	7	7	1.5%	29	29	6.3%	36	36	7.7%
Neurologic	2	2	0.4%	7	7	1.5%	9	9	1.9%
Non-neurologic	5	5	1.0%	22	22	4.8%	27	27	5.8%
Stroke	20	20	4.2%	19	19	4.1%	39	39	8.3%
Ipsilateral Stroke	15	15	3.1%	11	11	2.4%	26	26	5.5%
Major	5	5	1.0%	6	6	1.3%	11	11	2.3%
Minor	9	9	1.9%	2	2	0.4%	11	11	2.3%
Contralateral	5	5	1.0%	8	8	1.7%	13	13	2.8%
Major	0	0	0.0%	3	3	0.6%	3	3	0.6%
Minor	3	3	0.6%	4	4	0.9%	7	7	1.5%
Myocardial Infarction (MI)	5	5	1.0%	8	7	1.5%	13	12	2.6%
Non Q-wave MI	4	4	0.8%	7	6	1.3%	11	10	2.1%
Q-wave MI	1	1	0.2%	1	1	0.2%	2	2	0.4%

[1]The 1-year morbidity and mortality rate is defined as the cumulative incidence of any non Q-wave myocardial infarction within 24 hours, peri-procedural (≤30 days) death, stroke, and Q-wave myocardial infarction, and late ipsilateral stroke or death due to neurologic events from 31 days up to and including 12-month follow-up.

[2]Major adverse events are defined as any death, stroke, or myocardial infarction.

Table 3. BEACH Trial Serious Adverse Events

MedDRA System Organ Class/ Preferred Term	≤ 30 Days (N=480)			31-360 Days (N=470)			0-360 Days (N=480)		
	# of Events	# of Patients	% Patients	# of Events	# of Patients	% Patients	# of Events	# of Patients	% Patients
Any SAE	**196**	**115**	**24.0%**	**428**	**182**	**38.7%**	**624**	**251**	**52.3%**
Blood And Lymphatic System Disorders	**9**	**9**	**1.9%**	**14**	**12**	**2.6%**	**23**	**18**	**3.8%**
Anemia Not Otherwise Specified	9	9	1.9%	14	12	2.6%	23	18	3.8%
Cardiac Disorders	**26**	**21**	**4.4%**	**84**	**54**	**11.5%**	**110**	**69**	**14.4%**
Angina Pectoris	2	2	0.4%	17	12	2.6%	19	13	2.7%
Angina Unstable	0	0	0.0%	4	4	0.9%	4	4	0.8%
Bradycardia Not Otherwise Specified	3	3	0.6%	3	3	0.6%	6	6	1.3%
Cardiac Arrest	2	2	0.4%	3	3	0.6%	5	5	1.0%
Cardiac Failure Congestive	2	2	0.4%	19	15	3.2%	21	16	3.3%
Coronary Artery Disease Not Otherwise Specified	1	1	0.2%	2	2	0.4%	3	3	0.6%
Myocardial Infarction	6	6	1.3%	15	14	3.0%	21	20	4.2%
Other Cardiac Disorders	10	8	1.7%	21	19	4.0%	31	25	5.2%
Eye Disorders	**1**	**1**	**0.2%**	**0**	**0**	**0.0%**	**1**	**1**	**0.2%**
Gastrointestinal Disorders	**15**	**12**	**2.5%**	**30**	**23**	**4.9%**	**45**	**33**	**6.9%**
General Disorders And Administration Site Conditions	**6**	**5**	**1.0%**	**8**	**7**	**1.5%**	**14**	**11**	**2.3%**
Death Not Otherwise Specified	0	0	0.0%	2	2	0.4%	2	2	0.4%
Other General Disorders and Administration Site Conditions	6	5	1.0%	6	5	1.1%	12	9	1.9%
Hepatobiliary Disorders	**0**	**0**	**0.0%**	**2**	**2**	**0.4%**	**2**	**2**	**0.4%**
Infections And Infestations	**6**	**6**	**1.3%**	**37**	**29**	**6.2%**	**43**	**35**	**7.3%**
Injury, Poisoning And Procedural Complications	**1**	**1**	**0.2%**	**17**	**16**	**3.4%**	**18**	**17**	**3.5%**
Stent Occlusion	0	0	0.0%	5	5	1.1%	5	5	1.0%
Other Injury, Poisoning and Procedural Complications	1	1	0.2%	12	11	2.3%	13	12	2.5%
Investigations	**5**	**4**	**0.8%**	**5**	**4**	**0.9%**	**10**	**8**	**1.7%**
Metabolism And Nutrition Disorders	**2**	**2**	**0.4%**	**4**	**4**	**0.9%**	**6**	**5**	**1.0%**
Musculoskeletal And Connective Tissue Disorders	**1**	**1**	**0.2%**	**4**	**4**	**0.9%**	**5**	**4**	**0.8%**
Neoplasms Benign, Malignant And Unspecified (Including Cysts and Polyps)	**0**	**0**	**0.0%**	**10**	**10**	**2.1%**	**10**	**10**	**2.1%**
Nervous System Disorders	**53**	**43**	**9.0%**	**48**	**36**	**7.7%**	**101**	**75**	**15.6%**
Carotid Artery Dissection	3	3	0.6%	0	0	0.0%	3	3	0.6%
Carotid Artery Occlusion	3	3	0.6%	0	0	0.0%	3	3	0.6%
Carotid Artery Stenosis	0	0	0.0%	2	1	0.2%	2	1	0.2%
Cerebral Hemorrhage	2	2	0.4%	2	2	0.4%	4	4	0.8%
Cerebrovascular Accident	14	14	2.9%	19	19	4.0%	33	33	6.9%
Transient Ischemic Attack	17	17	3.5%	8	8	1.7%	25	24	5.0%
Vasovagal Attack	1	1	0.2%	1	1	0.2%	2	2	0.4%
Other Nervous System Disorders	13	11	2.3%	16	12	2.6%	29	22	4.6%
Psychiatric Disorders	**2**	**1**	**0.2%**	**7**	**7**	**1.5%**	**9**	**8**	**1.7%**
Renal And Urinary Disorders	**10**	**10**	**2.1%**	**8**	**8**	**1.7%**	**18**	**18**	**3.8%**
Reproductive System And Breast Disorders	**1**	**1**	**0.2%**	**0**	**0**	**0.0%**	**1**	**1**	**0.2%**
Respiratory, Thoracic And Mediastinal Disorders	**8**	**7**	**1.5%**	**27**	**24**	**5.1%**	**35**	**30**	**6.3%**
Skin And Subcutaneous Tissue Disorders	**0**	**0**	**0.0%**	**2**	**2**	**0.4%**	**2**	**2**	**0.4%**
Surgical And Medical Procedures	**16**	**15**	**3.1%**	**62**	**50**	**10.6%**	**78**	**60**	**12.5%**
Carotid Endarterectomy	0	0	0.0%	2	2	0.4%	2	2	0.4%
Other Surgical and Medical Procedures	16	15	3.1%	60	48	10.2%	76	58	12.1%
Vascular Disorders	**34**	**28**	**5.8%**	**59**	**46**	**9.8%**	**93**	**73**	**15.2%**
Hematoma Not Otherwise Specified	8	8	1.7%	2	2	0.4%	10	10	2.1%
Hemorrhage Not Otherwise Specified	2	2	0.4%	2	2	0.4%	4	4	0.8%
Hypotension Aggravated	1	1	0.2%	0	0	0.0%	1	1	0.2%
Hypotension Not Otherwise Specified	10	10	2.1%	0	0	0.0%	10	10	2.1%
Vascular Pseudoaneurysm	3	3	0.6%	1	1	0.2%	4	4	0.8%
Other Vascular Disorders	10	10	2.1%	54	43	9.1%	64	53	11.0%

Table 4 presents all deaths, regardless of device or procedure relatedness.

Table 4. Causes of Death

Death (by type)	0-30 Days		31-360 Days	
	(N=480)		(N=470)	
	n	%	n	%
Neurologic	2	0.4	7	1.5
Cardiac	3	0.6	8	1.7
General	2	0.4	7	1.5
Respiratory/Pulmonary	0	0.0	5	1.1
Infectious/Inflammatory	0	0.0	2	0.4

6.2 Potential Adverse Events

Based on the literature, and on clinical and commercial experience with carotid stents and embolic protection systems, potential adverse events include, but are not limited to the following:

- Abrupt vessel closure
- Additional interventional or surgical treatment (e.g., stenting or carotid endarterectomy)
- Allergic reactions (including to antiplatelet agents, contrast medium or stent materials)
- Aneurysm
- Angina / coronary ischemia
- Arrhythmia
- Arteriovenous fistula
- Bacteremia or septicemia
- Bleeding
- Bradycardia
- Cerebral vascular event such as edema
- Cerebral ischemia / transient ischemic attack
- Congestive heart failure (CHF)
- Death
- Detachment and/or implantation of a component
- Emboli (air, tissue, plaque, thrombus, device or other)
- Fever
- Filter thrombosis / occlusion
- Hematoma
- Hemorrhage
- Hyperperfusion syndrome
- Hypotension / hypertension
- Hypotonia
- Infection
- Ischemia / infarction of tissue or organ
- Myocardial Infarction (MI)
- Pain
- Pseudoaneurysm
- Renal failure / insufficiency
- Restenosis of stented segment
- Seizure
- Severe unilateral headache
- Stent embolization
- Stent / filter entanglement or damage
- Stent migration
- Stent malposition
- Stent thrombosis / occlusion
- Stroke / cerebrovascular accident (CVA)
- Vessel injury / dissection / perforation / rupture / trauma
- Vessel occlusion or thrombosis
- Vessel spasm or recoil

Any device related adverse event involving the Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis) should be reported immediately to Boston Scientific, Customer Service, at (888) 272-1001.

7. CLINICAL STUDIES

BEACH, (Boston Scientific EPI: A Carotid Stenting Trial for High-Risk Surgical Patients), was a prospective, single-arm, multi-center trial to evaluate the safety and efficacy of the Carotid WALLSTENT Endoprosthesis in conjunction with the FilterWire EX®/FilterWire EZ™ Embolic Protection System to treat high-surgical-risk, symptomatic (≥50% stenosis) and asymptomatic (≥80% stenosis) patients with disease in the carotid artery. A trial design utilizing a roll-in phase for initial clinical experience was employed in the study. In addition, a bilateral registry was included for patients presenting with bilateral carotid artery disease requiring treatment. A total of 747 patients were enrolled at 47 centers in the United States, including 189 roll-in patients, 480 pivotal patients and 78 bilateral registry patients. This trial is summarized in Table 5.

Table 5. Overview of BEACH Trial Study Design

Product Evaluated: Carotid WALLSTENT Endoprosthesis and FilterWire EX / FilterWire EZ System

Sample Size for Pivotal Patients: 480

Number of Centers: 47

Primary Endpoint: 1-Year Morbidity and Mortality:

- Non Q-wave MI through 24 hours
- Death, Stroke, Q-wave MI through 30 days
- Neurologic Death, Ipsilateral Stroke from 31-360 days

Secondary Endpoints:

- FilterWire EX / FilterWire EZ System Technical Success[1]
- Carotid WALLSTENT Endoprosthesis Technical Success[2]
- System Technical Success[3]
- Angiographic Success[4]
- Procedure Success[5]
- 30-Day Clinical Success[6]
- Peri-Procedural Morbidity and Mortality[7]
- Peri-Procedural Overall Morbidity[8]
- 1-Year Clinical Success[9]
- Late Stroke, TIA and Death[10]

Study Hypothesis: Non-inferiority to historical control

Patient Follow-up:

- Neurological assessment by independent neurologist
- CK/CKMB to 24 hours
- ECG: discharge and 30 days
- Carotid ultrasound: discharge, 30 days, 6 months and 1 year to 3 years
- AEs: discharge, 30 days, 6 months, 1 year to 3 years

[1] FilterWire EX/FilterWire EZ System successfully delivered and deployed beyond the target lesion and successfully retrieved after completion of the stent placement. Calculated based on the number of FilterWire® System uses attempted.

[2] Deployment of the Carotid WALLSTENT Endoprosthesis at the intended location and successful retrieval of the delivery catheter after stent placement. Calculated based on the number of stent implantations attempted.

[3] Includes FilterWire System Technical Success combined with Carotid WALLSTENT Endoprosthesis Technical Success. Calculated based on the number of system placement attempts.

[4] System Technical Success with a residual diameter stenosis ≤30% immediately after post-dilatation as determined by angiographic core lab. Based on number of patients on whom a procedure is attempted.

[5] Includes System Technical Success and Angiographic Success without death, stroke and MI (Q-wave and non Q-wave) immediately following the index procedure. Based on number of patients attempted to be treated.

[6] Procedure Success without any death, stroke or MI (Q-wave) up to and including 30 days post procedure. Based on number of patients on whom a procedure is attempted.

[7] Non Q-wave MI through 24 hours post procedure and death, stroke and Q-wave MI through 30 days post procedure.

[8] Morbidity occurring up to and including 30 days after the index procedure, including complications associated with routine catheterization, e.g., infection, hematoma, etc.

[9] Defined as a patent vessel by Duplex Ultrasound (as assessed by core laboratory to be <50% stenosis and confirmed by angiogram in patients that develop symptoms post procedurally) combined with freedom from stroke and death through 30 days, ipsilateral stroke and neurologic death 31-360 days and interim target vessel revascularization through 360 days. One-year clinical success was based on the number of patients treated.

[10] Defined as the incidence of any stroke (major or minor), TIA or death occurring after 30 days and up to and including 1 year post procedure. Major stroke: a new focal ischemic neurological deficit of abrupt onset, which is present after 7 days and increases the NIH Stroke Scale by ≥4. Minor stroke: a new focal ischemic neurological deficit of abrupt onset, lasting >24 hours and increases the NIH Stroke Scale by ≤3. TIA: a focal ischemic neurological deficit of abrupt onset and of presumed vascular etiology that resolves completely within 24 hours of onset.

The BEACH trial was designed to show non-inferiority between carotid stenting and a historical control, based on standard of care. The historical control was established based on a review of the current literature on carotid endarterectomy and was defined as a weighted Objective Performance Criterion (OPC). A criterion of 15% for patients who had comorbidity risk factors and a criterion of 11% for patients who had anatomic risk factors were selected. A spread of 4% for the "delta" definition of equivalency was selected.

Weighted OPC = (% Comorbid x 15%) + (% Anatomic x 11%)

Enrollment percentages in each category were 41.2% (197/478) in the comorbid group and 58.8% (281/478) in the anatomic group; therefore, the weighted OPC for BEACH was 12.6%. Note that 59 patients included in the comorbid group presented with both comorbid and anatomic risk factors.

12.6 % = (41.2% x 15%) + (58.8% x 11%)

Based on the weighted OPC of 12.6% and the pre-specified delta of 4%, the threshold for claiming non-inferiority to CEA is 16.6%, i.e., the one-sided upper 95% confidence limit of the primary endpoint must be <16.6% to conclude non-inferiority.

The protocol required regular patient follow-up by the treating physician and follow-up neurological assessments by an independent neurologist. Core laboratories provided independent assessments for angiographic, ultrasound, ECG and CT/MRI testing. Monitors reviewed all safety data to ensure appropriate reporting of adverse events. A Clinical Events Committee adjudicated suspected primary endpoint events. A Data Safety Monitoring Board reviewed adverse events to ensure patient safety.

Eligibility Criteria Summary

The study population consisted of male and female patients, at least 18 years of age, with discrete lesions in the common carotid artery (CCA), internal carotid artery (ICA) or carotid bifurcation. Patients had to be at high-risk for surgical intervention; both symptomatic (≥50% stenosis) and asymptomatic (≥80% stenosis) patients were eligible.

The key inclusion criteria included the following:

- Symptomatic: Carotid stenosis of ≥50% via angiography with cerebral or retinal TIA or ischemic stroke symptoms determined to have occurred ipsilateral to the target lesion and to be reasonably attributable to the lesion within 180 days of the stenting procedure
- Asymptomatic: Carotid stenosis of ≥80% via angiography without cerebral or retinal TIA or ischemic stroke symptoms within 180 days of the stenting procedure
- Patient had to have an anatomic or comorbid high-risk condition as follows:

Anatomic High-Risk Conditions

ONE (1) criterion qualifies

1. Surgically inaccessible lesions at or above C2 or below the clavicle
2. Previous neck or head radiation therapy or surgery that included the area of stenosis/repair or ipsilateral radical neck dissection for cancer
3. Spinal immobility of the neck due to cervical arthritis or other cervical disorders
4. Restenosis after a previous or unsuccessful attempt of CEA (≥50% symptomatic, ≥80% asymptomatic) at least 31 days prior to enrollment if arteriotomy was performed
5. Presence of laryngeal palsy or laryngectomy
6. Presence of a tracheostoma
7. Contralateral total occlusion with a qualifying lesion on the ipsilateral side (Note: Applied to roll-in and pivotal groups only)
8. Bilateral carotid artery disease (Note: Patients with bilateral disease were placed in the Bilateral Registry provided that both ipsilateral and contralateral arteries required treatment at the time of enrollment.)

Comorbid High-Risk Conditions

CLASS I [ONE (1) criterion qualifies]

1. Congestive heart failure (NYHA Class III/IV)
2. Unstable angina (CCS Class III/IV)
3. Requirement for staged and scheduled Coronary Artery Bypass Graft (CABG) or valve replacement post carotid index procedure (Note: The staged procedure had to occur >30 days post index procedure.)

4. Chronic Obstructive Pulmonary Disease (COPD) manifested with a forced expired volume (FEV) ≤30%
5. Known severe left ventricular ejection fraction (LVEF) ≤30%

CLASS II [TWO (2) criteria qualify]

1. Age ≥75 years
2. Recent MI (Q-wave and/or non Q-wave) >72 hours and ≤30 days, with any elevation in CK-MB greater than the local laboratory upper limit of normal values
3. Two or more major diseased coronary arteries with ≥70% stenosis at the time of index procedure in patients with a history of angina
4. Requirement for staged and scheduled peripheral vascular surgery or other major surgeries [e.g., abdominal aortic aneurysm (AAA)] post carotid index procedure

Specific Inclusion Criteria for the Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis) and FilterWire EZ™ System

1. Target lesion in the common carotid artery (CCA), internal carotid artery (ICA) or carotid bifurcation
2. Diameter of the target arterial segment to be stented ≥4.0 mm and ≤9.0 mm
3. Vessel diameter distal to the target lesion ≥3.5 mm and ≤5.5 mm as an optimal "landing zone" for placement of the FilterWire EZ System with visual angiographic recommendations

Description of Patients Evaluated

Table 6 summarizes patient follow-up at the endpoint evaluation time points of 30 days, 6 months, and 12 months. Patients were considered to have been evaluated if they had physician contact as evidenced by at least one of the following at the given time point: office visit, neurologic evaluation, AE log, stroke scales, event forms such as Repeat Carotid Angiography Form, SAE Notification Form, Subsequent Hospitalization Form, Vascular Event Form, Neurological Event Form, etc.

Table 6. BEACH Patient Follow-up

	Pivotal (N=480)
Primary Analysis Sample (ITT[1])	480
30-day Follow-up Evaluation Completed	466
6-month Follow-up Evaluation Completed	435
12-month Follow-up Evaluation Completed	418
12-month Follow-up Evaluation not Completed	62
Death	36
Lost to Follow-up	10
Missed Visit	16
Patients with Ultrasound Data Pre-Procedure	455
Patients with Ultrasound Data at 30 Days	446
Patients with Ultrasound Data at 6 Months	418
Patients with Ultrasound Data at 12 Months	377

[1]ITT is Intent to Treat

Baseline demographics and lesion characteristics for the study are presented in Table 7. All reported angiographic data on the treated lesions are based on measurements obtained by the centralized angiographic core laboratory.

Table 7. Baseline Patient Demographics

Demographic and Medical History	Value	95% CI
Age (years)		
Mean ± SD (N)	70.9±9.3 (480)	[70.0, 71.7]
Range (min, max)	(41.0, 92.0)	
Gender %		
Male	65.2% (313/480)	[60.8%, 69.5%]
History %		
Diabetes mellitus	33.8% (162/480)	[29.5%, 38.2%]
Hypertension	89.4% (429/480)	[86.3%, 92.0%]
Hyperlipidemia	86.5% (415/480)	[83.1%, 89.4%]
Current or history of smoking	74.6% (358/480)	[70.4%, 78.4%]
Number of Symptomatic Patients	23.3% (112/480)	[19.6%, 27.4%]
Baseline Lesion Characteristics %		
Calcification	48.8% (234/480)	[44.2%, 53.3%]
Lesion Length (mm)		
Mean ± SD (N)	15.13±7.25 (480)	[14.48, 15.78]
Range (min, max)	(2.46, 57.60)	
Minimal Lumen Diameter (mm)		
Mean ± SD (N)	1.33±0.58 (480)	[1.27, 1.38]
Range (min, max)	(0.12, 3.51)	
Percent Diameter Stenosis (%DS)		
Mean ± SD (N)	71.61%±10.71% (480)	[70.65%, 72.58%]
Range (min, max)	(36.75%, 96.52%)	
High-Risk Inclusion Criteria		**Value**
Anatomic High-Risk Conditions (One Criterion Qualifies)		
Surgically inaccessible lesions		9.2% (44/480)
Previous head/neck radiation therapy or radical neck surgery		10.8% (52/480)
Spinal immobility		7.3% (35/480)
Restenosis after previous, or unsuccessful attempt, of CEA		34.2% (164/480)
Presence of laryngeal palsy or laryngectomy		1.0% (5/480)
Presence of tracheostoma		2.1% (10/480)
Contralateral total occlusion		18.1% (87/480)
Comorbid High-Risk Conditions- Class I (One Criterion Qualifies)		
Congestive heart failure (NYHA Class III/IV)		11.7% (56/480)
Unstable angina (CCS Class III/IV)		12.5% (60/480)
Requirement for CABG or valve replacement		6.5% (31/480)
COPD manifested with a forced expired volume (FEV) ≤30%		2.3% (11/480)
Known severe left ventricular ejection fraction (LVEF) ≤30%		12.1% (58/480)
Comorbid High-Risk Conditions - Class II (Two Criteria Qualify)		
Age ≥75 years old		39.0% (187/480)
Recent MI (Q-wave and/or non Q-wave) >72 hours and ≤30 days		1.3% (6/480)
Two or more major diseased coronary arteries with ≥70% stenosis		21.7% (104/480)
Requirement for peripheral vascular or other major surgery		2.9% (14/480)

Results

The primary endpoint for the BEACH trial was 1-year morbidity and mortality defined as the cumulative incidence of any non Q-wave myocardial infarction within the 24 hours following carotid stenting, peri-procedural (≤30 days) death, stroke, Q-wave myocardial infarction, and late ipsilateral stroke or death due to neurologic events from 31 to 360 days. The 1-year morbidity and mortality rate was 8.9%. Rates for each contributor to the composite primary endpoint rate are presented along with the secondary endpoints in Table 8.

The trial utilized the FilterWire EX® and the FilterWire EZ embolic protection devices. A total of 195 patients were enrolled using the FilterWire EX System and 285 patients were enrolled using the FilterWire EZ System. Poolability analysis was conducted to determine baseline homogeneity. No significant differences between the groups were found. In addition, a group difference on peri-procedural outcome analysis was performed. There was no evidence found against pooling the FilterWire EX System and FilterWire EZ System groups for purposes of estimating the treatment effect on 1-year morbidity and mortality.

The primary objective of the BEACH trial was met. The observed 1-year morbidity and mortality rate of 8.9% with an upper confidence limit of 11.5% fell well below the predefined weighted OPC + delta of 16.6%, demonstrating that carotid stenting with the Carotid WALLSTENT Endoprosthesis and the FilterWire® Embolic Protection System is non-inferior to surgical treatment for carotid artery disease in patients who were at high risk for CEA.

Table 8. Clinical Results Through 360 Days Follow-up

Primary Endpoint Measures	Pivotal (N=480)	95% CI[1]
1-Year Morbidity and Mortality	8.9% (40/448)	[11.5%]
Non Q-wave MI (Through 24 hours)	0.9% (4/448)	[0.2%, 2.3%]
Death, Stroke, Q-wave MI (Through 30 days)	5.4% (24/448)	[3.5%, 7.9%]
Death	1.6% (7/448)	[0.6%, 3.2%]
Neurologic	0.4% (2/448)	[0.1%, 1.6%]
Cardiac	0.7% (3/448)	[0.1%, 1.9%]
General	0.4% (2/448)	[0.1%, 1.6%]
Stroke	4.5% (20/448)	[2.8%, 6.8%]
Ipsilateral[2]	3.3% (15/448)	[1.9%, 5.5%]
Major Ischemic	1.1% (5/448)	[0.4%, 2.6%]
Minor Ischemic	2.0% (9/448)	[0.9%, 3.8%]
Hemorrhagic (excludes Subarachnoid Hemorrhages)	0.2% (1/448)	[0.0%, 1.2%]
Contralateral	1.1% (5/448)	[0.4%, 2.6%]
Major Ischemic	0.0% (0/448)	[0.0%, 0.8%]
Minor Ischemic	0.7% (3/448)	[0.1%, 1.9%]
Hemorrhagic (excludes Subarachnoid Hemorrhages)	0.4% (2/448)	[0.1%, 1.6%]
Subarachnoid Hemorrhagic	0.0% (0/448)	[0.0%, 0.8%]
Q-wave MI	0.2% (1/448)	[0.0%, 1.2%]
Neurologic Death, Ipsilateral Stroke (31 days through 360 days)	3.1% (14/448)	[1.7%, 5.2%]
Neurologic Death	1.6% (7/448)	[0.6%, 3.2%]
Ipsilateral Stroke	2.5% (11/448)	[1.2%, 4.4%]
Major Ischemic	1.3% (6/448)	[0.5%, 2.9%]
Minor Ischemic	0.4% (2/448)	[0.1%, 1.6%]
Hemorrhagic (excludes Subarachnoid Hemorrhages)	0.7% (3/448)	[0.1%, 1.9%]
Freedom from 1-Year Morbidity and Mortality – KM Estimate	91.6%	[89.0%, 94.2%]
Secondary Endpoint Measures	**Pivotal (N=480)**	**95% CI**
FilterWire EX and FilterWire EZ™ System Technical Success[3]	97.1% (475/489)	[95.2%,98.4%]
Carotid WALLSTENT Endoprosthesis Technical Success[4]	94.1% (475/505)	[91.6%,96.0%]
System Technical Success[5]	98.3% (469/477)	[96.7%,99.3%]
Angiographic Success[6]	90.8% (433/477)	[87.8%,93.2%]
Procedure Success[7]	87.6% (418/477)	[84.3%,90.5%]
30-Day Clinical Success[8]	85.3% (405/475)	[81.8%,88.3%]
Peri-Procedural Morbidity and Mortality[9]	5.6% (27/478)	[3.8%,8.1%]
Peri-Procedural Overall Morbidity[10]	68.5% (328/479)	[64.1%,72.6%]
1-Year Clinical Success[11]	69.9% (297/425)	[65.3%,74.2%]
Late Stroke, TIA and Death (31 days through 360 days)[12]	10.6% (49/462)	[7.9%,13.8%]
Post-procedure In-lesion Minimal Lumen Diameter (mm):		
Mean ± SD (N)	4.2±0.8 (478)	[4.1, 4.2]
Range (min, max)	(2.3, 7.9)	
Post-procedure In-lesion Percent Diameter Stenosis:		
Mean ± SD (N)	10.6%±14.4% (478)	[9.4%, 11.9%]
Range (min, max)	(-73.3%,51.9%)	
Target Vessel Revascularization (TVR) Rate (≤ 360 days)[13]	4.7% (20/425)	[2.9%, 7.2%]
1-Year Restenosis Rate (≥ 50% Stenosis via Duplex U/S)	18.7% (72/385)	[14.9%, 23.0%]
Carotid Duplex Ultrasound ICA/CCA Ratio:		
Pre-Procedure	5.3±3.1 (420)	[5.0, 5.6]
Post-Procedure	1.4±0.5 (438)	[1.4, 1.5]
At 1 month	1.4±0.5 (434)	[1.4, 1.5]
At 6 months	1.9±1.2 (399)	[1.8, 2.1]
At 12 months	1.9±1.1 (362)	[1.8, 2.0]

Numbers are % (count/sample size) or %.

[1] 1-sided 95% upper confidence limit is presented for 1-year morbidity and mortality.

[2] Patient 42-014 was originally denoted to have suffered a minor ipsilateral stroke 27 days post-procedure. This event was sent back to the CEC for additional review after the CT/MRI core lab provided a review of films made available to them. Based upon the core lab report, the CEC adjudicated the event as a TIA.

[3] FilterWire EX/ FilterWire EZ System successfully delivered and deployed beyond the target lesion and successfully retrieved after completion of the stent placement. Calculated based on the number of FilterWire® uses attempted.

[4] Deployment of the Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis) at the intended location and successful retrieval of the delivery catheter after stent placement. Calculated based on the number of stent implantations attempted. Three patients did not have a Carotid WALLSTENT Endoprosthesis implantation attempted.

[5] Includes FilterWire System Technical Success combined with Carotid WALLSTENT Endoprosthesis Technical Success. Calculated based on the number of system placement attempts.

[6] System Technical Success with a residual diameter stenosis ≤30% immediately after post-dilatation as determined by angiographic core lab. Based on number of patients on whom a procedure is attempted.

[7] Includes System Technical Success and Angiographic Success without death, stroke and MI (Q-wave and non Q-wave) immediately following the index procedure. Based on number of patients attempted to be treated.

[8] Procedure Success without any death, stroke or MI (Q-wave) up to and including 30 days post procedure. Based on number of patients on whom a procedure is attempted.

[9] Non Q-wave MI through 24 hours post procedure and death, stroke and Q-wave MI through 30 days post procedure.

[10] Morbidity occurring up to and including 30 days after the index procedure, including complications associated with routine catheterization, e.g., infection, hematoma, etc.

[11] Defined as a patent vessel by Duplex Ultrasound (as assessed by core laboratory to be <50% stenosis and confirmed by angiogram in patients that develop symptoms post procedurally) combined with freedom from stroke and death through 30 days, ipsilateral stroke and neurologic death 31-360 days and interim target vessel revascularization through 360 days. One-year clinical success was based on the number of patients treated.

[12] Defined as the incidence of any stroke (major or minor), TIA or death occurring after 30 days and up to and including 1-year post procedure. Major stroke: a new focal ischemic neurological deficit of abrupt onset, which is present after 7 days and increases the NIH Stroke Scale by ≥4. Minor stroke: a new focal ischemic neurological deficit of abrupt onset, lasting >24 hours and increases the NIH Stroke Scale by ≤3. TIA: a focal ischemic neurological deficit of abrupt onset and of presumed vascular etiology that resolves completely within 24 hours of onset.

[13] Defined as any surgical or percutaneous attempt to revascularize the target lesion after the initial treatment. The target lesion is defined as the stented segment including 0.5 cm at the proximal and distal margins of the stented segment.

The Kaplan-Meier curve through 360 days for all pivotal patients is presented in Figure 2. As can be seen, most major adverse events occur within 30 days with acceptable adverse event rates within 1 year.

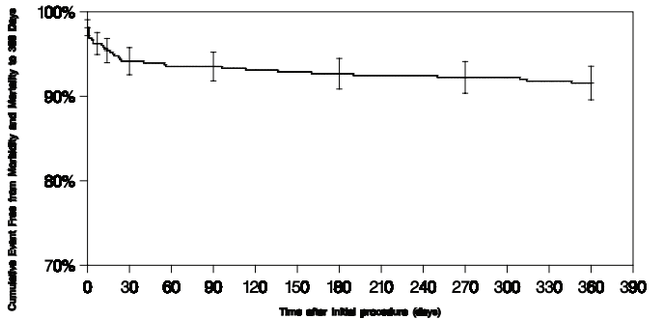

Figure 2. All Pivotal Patients, Freedom from Morbidity and Mortality through 360 Days

Time After Initial Procedure	0	7	14	30	90	180	270	360
PIVOTAL								
# Entered	480	471	460	456	450	441	432	422
# Censored	0	2	0	0	6	5	8	17
# At Risk	480	470	460	456	447	439	428	414
# Patients with Events	9	9	4	6	3	4	2	3
% Event-Free	98.1%	96.2%	95.4%	94.2%	93.5%	92.7%	92.2%	91.6%
SE	0.6%	0.9%	1.0%	1.1%	1.1%	1.2%	1.3%	1.3%

Figures 3 and 4 present the Kaplan-Meier curves through 360 days for symptomatic and asymptomatic patients, respectively.

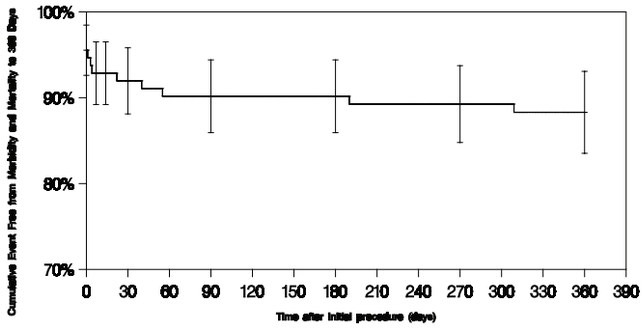

Figure 3. Symptomatic Patients, Freedom from Morbidity and Mortality through 360 Days

Time After Initial Procedure	0	7	14	30	90	180	270	360
PIVOTAL								
# Entered	112	107	104	104	103	100	100	96
# Censored	0	0	0	0	1	0	3	5
# At Risk	112	107	104	104	103	100	99	94
# Patients with Events	5	3	0	1	2	0	1	1
% Event-Free	95.5%	92.9%	92.9%	92.0%	90.2%	90.2%	89.3%	88.3%
SE	2.0%	2.4%	2.4%	2.6%	2.8%	2.8%	3.0%	3.2%

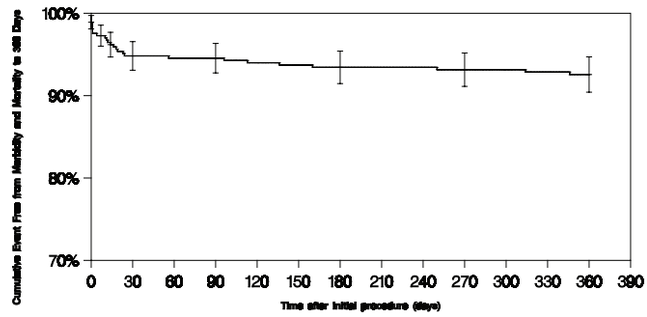

Figure 4. Asymptomatic Patients, Freedom from Morbidity and Mortality through 360 Days

Time After Initial Procedure	0	7	14	30	90	180	270	360
PIVOTAL								
# Entered	368	364	356	352	347	341	332	326
# Censored	0	2	0	0	5	5	5	12
# At Risk	368	363	356	352	345	339	330	320
# Patients with Events	4	6	4	5	1	4	1	2
% Event-Free	98.9%	97.3%	96.2%	94.8%	94.5%	93.4%	93.1%	92.6%
SE	0.5%	0.9%	1.0%	1.2%	1.2%	1.3%	1.4%	1.4%

8. CLINICAL USE INFORMATION

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid stent placement should use the device.

Warning: Do not use after the "Use By" date specified on the package. Assure that the device has been properly stored in a cool, dark, dry place prior to use.

Warning: The Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis) is supplied STERILE and intended for single use only. Do not use if the package is open or damaged. Do not reuse. Do not resterilize as this can compromise device performance and increase the risk of cross-contamination due to inappropriate reprocessing.

Refer to Section 1 for a description and diagram (Figure 1) of device components and a chart (Table 1) with available stent sizes and sizing information.

8.1 Materials Recommended

1. Guiding Catheter or Guiding Sheath
   - Guiding Catheter Compatibility:
     - 7F (min. internal diameter 0.073 in [1.85 mm]): use with 71-900 to 71-903
     - 8F (min. internal diameter 0.086 in [2.18 mm]): use with 71-904 to 71-906
   - Guiding Sheath Compatibility:
     - 5F (min. internal diameter 0.073 in [1.85 mm]): use with 71-900 to 71-903
     - 6F (min. internal diameter 0.086 in [2.18 mm]): use with 71-904 to 71-906
2. 5-ml sterile syringe for flushing
3. Small basin containing heparinized sterile isotonic saline
4. Guiding sheath or guiding catheter equipped with a rotating hemostatic valve (RHV) Touhy-Borst Tip (The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the embolic protection device filter membrane to tear at the hemostasis valve upon removal.)
5. Boston Scientific embolic protection device with a 0.014 in (0.36 mm) guide wire
6. 0.014 in (0.36 mm) balloon dilatation catheter

8.2 Periprocedural Care

In the BEACH trial, it was recommended that patients receive aspirin and a total of at least 450mg of clopidogrel prior to the procedure. After the procedure, it was recommended that patients receive clopidogrel 75mg qd for 30 days and aspirin 325mg qd indefinitely, if possible. If clopidogrel was contra-indicated, ticlopidine was recommended as an alternative to clopidogrel.

WARNING: The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions. Special consideration should be given to those patients with recently active gastritis or peptic ulcer disease.

8.3 Pre-procedure

Placement of the Carotid WALLSTENT Endoprosthesis in a stenotic or obstructed carotid artery should be done 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 present, 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.

8.4 Stent Size Determination

Select the proper size Carotid WALLSTENT Endoprosthesis (see Table 1) based on the largest diameter of the artery adjacent to the stenosis and the length of the segment to be stented. The unconstrained diameter of the Carotid WALLSTENT Endoprosthesis should be at least 1 mm to 2 mm larger than the diameter of the largest vessel to be stented. The Carotid WALLSTENT Endoprosthesis should overlap healthy tissue by at least 5 mm on each side of the lesion.

Note: For carotid bifurcation stenting, select the Carotid WALLSTENT Endoprosthesis size based on the diameter of the largest vessel (normally the CCA). The unconstrained diameter of the Carotid WALLSTENT Endoprosthesis should be at least 1 mm to 2 mm larger than the largest artery diameter. The Carotid WALLSTENT Endoprosthesis should overlap healthy tissue by at least 5 mm into the CCA and 5 mm into the ICA.

Warning: Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration.

8.5 Inspection Prior to Use

1. Carefully remove the Carotid WALLSTENT Endoprosthesis from its packaging. Do not remove the packaging stylus from the inner lumen.

   Caution: The delivery system has an internal hypotube. Take care to avoid unnecessary handling, which may kink or damage the delivery system. Do not use if the device is kinked.

2. Visually inspect the entire Carotid WALLSTENT Endoprosthesis for damage and check that the stent and the distal radiopaque marker (3a in Figure 1) are fully covered by the distal end of the outer sheath.

   Caution: Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during catheter removal from packaging, stylus removal, placement over the guide wire and advancement through a hemostatic valve and guiding catheter or guiding sheath hub.

   Caution: Do not remove the stent from its delivery system as removal may damage the stent. The stent on the delivery system is intended to perform as a system. If removed, the stent cannot be put back on the delivery system.

8.6 Preparation

8.6.1 Carotid WALLSTENT Endoprosthesis Preparation

Caution: Do not expose the delivery system to organic solvents (e.g., alcohol) as structural integrity and/or function of the device may be impaired.

1. Carefully remove the Carotid WALLSTENT Endoprosthesis from its protective hoop and place it uncoiled on the sterile field.
2. Keep the packaging stylus in the guide wire lumen and check that the stent and the distal radiopaque marker (3a in Figure 1) are fully covered by the distal end of the outer sheath.
3. Attach a 5-ml syringe filled with sterile heparinized saline to the T-connector (9 in Figure 1) and vigorously inject the saline into the annular space between the coaxial inner shaft and outer sheath until the fluid comes out of the guide wire hole (14 in Figure 1).
4. Clamp the device between the fingers covering the guide wire hole (14 in Figure 1) and continue flushing until the saline solution comes out of the catheter tip and the outer sheath at the marker. If necessary, refill the syringe.

   Caution: Ensure the stent delivery system is fully flushed with heparinized saline prior to use. Do not use if saline is not observed exiting the distal end of the outer sheath.

5. Hold the distal tip of the delivery system and gently remove the packaging stylus. If the packaging stylus does not remove easily, do not use the device.

   Caution: Do not hold the outer sheath where the stent is present during stylus removal.

6. Flush again after removal of packaging stylus and observe saline exiting distal tip.

8.6.2 Embolic Protection System Preparation and Delivery

The Carotid WALLSTENT Endoprosthesis is indicated for use in conjunction with a Boston Scientific carotid embolic protection system. Please refer to the Directions for Use included with the embolic protection system for information on device preparation and placement.

Warning: If a filter-based embolic protection system is used, allow for and maintain adequate distance between the filter and the stent delivery system or deployed stent to avoid potential entanglement. If filter basket entanglement or basket detachment occurs, surgical conversion or collapsing the basket with a second stent should be considered.

8.6.3 Lesion Preparation

Warning: Maintain an Activated Clotting Time (ACT) of ≥ 275 seconds (≥ 200 seconds if using GP IIb/IIIa inhibitors) to prevent thrombus formation on the devices.

Caution: Venous access should be available during carotid stenting to manage bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.

Warning: The use of a guiding sheath or guiding catheter with a fixed hemostasis valve may cause the embolic protection device filter membrane to tear at the hemostasis valve upon removal.

Caution: When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed.

Warning: To minimize the possible introduction of air into the delivery system, it is important to maintain tight catheter connections and to thoroughly flush the delivery system.

Warning: Maintain continuous flush while removing and reinserting devices on the guide wire. Perform all exchanges slowly to prevent air embolism or trauma to the artery.

1. Define the largest artery diameter and the proximal and distal limits of the stenosis.
2. Use the selected guiding catheter or guiding sheath.
3. If needed, pre-dilate the lesion with an appropriate size balloon dilatation catheter.

   Note: If no pre-dilatation is performed, there must be an adequate luminal opening to enable passage of the stent delivery system.

4. Maintain the embolic protection system wire position across the stenosis and withdraw the balloon dilatation catheter. Do not remove the guiding catheter or guiding sheath.

8.7 Delivery Procedure

1. After the pre-dilatation catheter has been removed, backload the Carotid WALLSTENT Endoprosthesis over the 0.014 in (0.36 mm) embolic protection system wire.

   Caution: For best device performance, the guide wire exit notch should remain within the guiding catheter or sheath.

   Caution: The delivery system is not designed for use with power injection. Use of power injection may adversely affect device performance.

   Caution: If the shaft kinks during preparation of the Carotid WALLSTENT Endoprosthesis or its insertion over the guide wire, remove the device and use another one.

2. When advancing (or retracting when necessary) the Carotid WALLSTENT Endoprosthesis and during deployment, loosen the hemostatic valve of the introducer to allow easy movement.
3. Maintain the stent delivery system as straight as possible outside the body removing all slack. As the Carotid WALLSTENT Endoprosthesis deploys, it shortens from both ends towards the middle. Therefore, place the proximal and distal radiopaque markers of the inner shaft overlapping both edges of the stenosis.
4. Immobilize the stainless steel tube and confirm stent position angiographically.

8.8 Stent Deployment

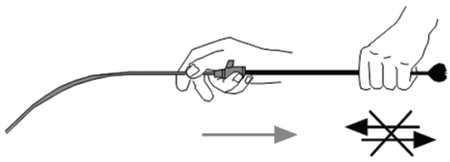

Figure 5. - Stent Deployment

Caution: Do not push the stainless steel tube!

1. Deploy the Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT Endoprosthesis) stepwise a few millimeters at a time (see Figure 5) by sliding the T-connector gently towards, but not past, the black limit marker (11 in Figure 1) until the Carotid WALLSTENT Endoprosthesis is approximately 50% deployed.
2. During deployment, the radiopaque marker on the outer sheath (4 in Figure 1) is retracted from the distal marker (3a in Figure 1), which allows fluoroscopic control of the Carotid WALLSTENT Endoprosthesis release.
3. Check position of the partially deployed Carotid WALLSTENT Endoprosthesis within the stenosis.
4. Contrast medium can be injected through the guiding catheter or guiding sheath, if desired.
5. If the Carotid WALLSTENT Endoprosthesis does not need to be repositioned, continue with final deployment (see Section 8.9 for Repositioning instructions).
6. Immobilize the stainless steel tube once again.
7. When the Carotid WALLSTENT Endoprosthesis is in its final position, gently slide the T-connector on the immobilized stainless steel tube towards the heart shaped hub (12 in Figure 1), until complete deployment of the Carotid WALLSTENT Endoprosthesis (see Figure 6).

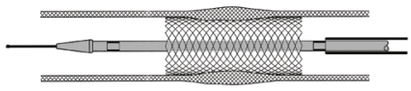

Figure 6. - Final Stent Deployment

8. After full Carotid WALLSTENT Endoprosthesis deployment, carefully remove the stent delivery system under fluoroscopic guidance, leaving the embolic protection system in place.

Caution: If the tip catches on the distal stent filaments upon removal of the stent delivery system, free the tip with gentle movements!

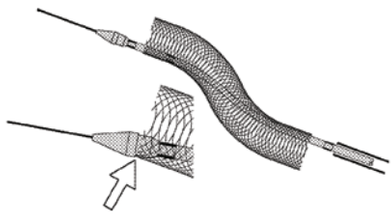

Figure 7. - Removal of Stent Delivery System

Note: Balloon dilatation with an undersized balloon inside the Carotid WALLSTENT Endoprosthesis is recommended.

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 allowing a minimal overlap of at least 5 mm.

Caution: Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting stent placement.

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

8.9 Stent Repositioning (Only when absolutely necessary!)

As previously noted, reconstrainment and repositioning of the Carotid WALLSTENT Endoprosthesis should be strictly avoided when the partially deployed Carotid WALLSTENT Endoprosthesis is already in contact with the plaque of the stenosis.

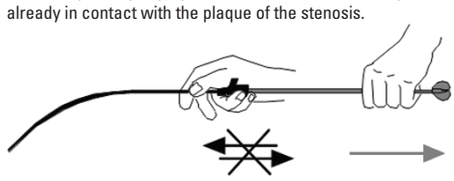

Figure 8. - Stent Repositioning

Caution: Do not reconstrain the Carotid WALLSTENT Endoprosthesis more than twice!

1. Repositioning of a partially deployed Carotid WALLSTENT Endoprosthesis is possible if the stent has not been deployed past the limit marker (11 in Figure 1).
2. Immobilize the T-connector and carefully pull back the stainless steel tube (see Figure 8), reconstraining the Carotid WALLSTENT Endoprosthesis into the outer sheath.
3. Position the Carotid WALLSTENT Endoprosthesis appropriately across the lesion and commence deployment steps outlined earlier (Section 8.8).

Caution: When reconstraining, do not pull the inner shaft with excessive force to avoid damage to the tip.

8.10 Post Stent Placement

1. Following stent placement, perform a final angiogram to confirm optimal angiographic appearance of the deployed stent and vessel patency.

Warning: The stent may cause a thrombus, distal embolization, or may migrate from the site of implant down the arterial lumen. Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration. In the event of thrombosis of the expanded stent, thrombolysis and PTA should be attempted.

2. Upon completion of the angiogram, the embolic protection system should be removed according to the Directions for Use supplied with the device.
3. Patients should be put on an appropriate regimen of anticoagulants and/or antiplatelets.

Warning: In the event of complications such as infection, pseudoaneurysm, or fistulization, surgical removal of the stent may be required.

Warning: The long-term performance of the Carotid WALLSTENT Endoprosthesis has not been established.

9. PATIENT INFORMATION

The Carotid WALLSTENT Endoprosthesis is packaged with a Patient Implant Card for the patient that contains specific information about the Carotid WALLSTENT Endoprosthesis. All patients should keep this card in their possession at all times for procedure and stent identification.

A Patient Guide, which includes information on carotid artery disease and the carotid stent implant procedure using embolic protection, can be obtained from Boston Scientific by visiting the online Web site at www.bostonscientific.com/carotidwallstent and www.carotid.com or by contacting Customer Service at (888) 272-1001.

10. HOW SUPPLIED

STERILE: This device is sterilized and non-pyrogenic.

CONTENTS: One (1) Carotid WALLSTENT Monorail Endoprosthesis.

STORAGE: Store in a cool, dark, dry area.

11. WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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