Carotid WALLSTENT®

Monorail® Endoprosthesis

Product Information

Catalog Number	Stent						Delivery Catheter		Compatibility	
	Unconstrained Diameter* (mm)	Unconstrained Length* (mm)	Representative Length Adjustments				Outer Diameter (F/mm)	Working Length (cm)	Guiding Sheath Minimum I.D. (F/inches)	Guiding Catheter Minimum I.D. (F/inches)
			Vessel Diameter (mm)	Implanted Length (mm)	Vessel Diameter (mm)	Implanted Length (mm)				
71-900	6	22	5	30	4	36	5.0/1.67	135	5.0/0.073	7.0/0.073
71-901	8	21	7	30	6	36				
71-902	8	29	7	40	6	48				
71-903	8	36	7	50	6	62				
71-904	10	24	9	30	8	36	5.9/1.97	135	6.0/0.086	8.0/0.086
71-905	10	31	9	40	8	49				
71-906	10	37	9	50	8	59				

*Unconstrained stent diameter selected should be 1mm-2mm larger than the largest vessel to be stented.

The C-code used for this product is C1876, Stent, non-coated/non-covered with delivery system. C-codes are used for hospital outpatient device reporting for Medicare and some private payers.

Note: Boston Scientific is not responsible for the correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

BEACH TRIAL

Trial Design: Multi-center, prospective, single-arm study. N=747, Roll-In Group N=189, Bilateral Group N=78, Pivotal Group N=480 (symptomatic ≥50% stenosis N=112; asymptomatic ≥80% stenosis N=368). 47 U.S. clinical sites participated in the study.

Trial Objective: To evaluate the outcomes of patients with carotid artery stenosis at high risk for carotid endarterectomy (CEA) using the Carotid WALLSTENT Monorail Endoprosthesis and the FilterWire EX® and FilterWire EZ™ Embolic Protection Systems.

One-Year Morbidity and Mortality:

- Non-Q-wave myocardial infarction within the 24 hours following carotid stenting
- Peri-procedural (≤30 days) death, stroke, Q-wave myocardial infarction
- Late ipsilateral stroke or death due to neurologic events from 31 days up to and including 12-month follow-up

Peri-Procedural Morbidity and Mortality:

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

CAROTID WALLSTENT® MONORAIL® ENDOPROSTHESIS

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 following criteria: • 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 4.0mm and 9.0mm at the target lesion.

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.

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 long-term performance of the Carotid WALLSTENT Endoprosthesis has not been established. • 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. • The implantation of the Carotid WALLSTENT Endoprosthesis should be performed only under fluoroscopic observation with radiographic equipment providing high-resolution images. • 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 1mm to 2mm 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. • 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. • Balloon angioplasty of the carotid bifurcation may initiate transient hemodynamic instability consisting of bradycardia or hypotension. Appropriate pharmacologic therapy must be immediately available.

PRECAUTIONS: 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. 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.

ADVERSE EVENTS: 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.

POTENTIAL ADVERSE EVENTS: 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.

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

FILTERWIRE EZ™ EMBOLIC PROTECTION SYSTEM

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

INDICATIONS FOR USE: The FilterWire EZ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts and carotid arteries. The diameter of the vessel at the site of filter loop placement should be between 3.5mm and 5.5mm. • The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature, peripheral vessels other than carotid arteries, or in treating native coronaries, including acute myocardial infarction.

CONTRAINDICATIONS: Patients with severe allergy to heparin. • Patients with bleeding diathesis or other disorders which limit the use of anticoagulant therapy.

WARNINGS: Only physicians thoroughly trained in percutaneous, intravascular techniques and procedures should use the FilterWire EZ System. • The safety and effectiveness of coronary drug-eluting stents (DES) when used with embolic protection devices has not been established. • The safety and effectiveness of the FilterWire EZ System has not been demonstrated with carotid stents other than the Carotid WALLSTENT® Monorail® Endoprosthesis System. • Avoid using power injection in the cerebral circulation. Filter safety and effectiveness has not been tested with power injection. • Failure to follow recommended device preparation and delivery instructions may result in air embolism. • Introduce and advance devices slowly to prevent air embolism or trauma to the vasculature. • Do not attempt to move the protection wire without observing the resultant tip response. • All distal wire tips have the potential to cause vessel injury. Confirm that the wire tip is free within the vessel. • Do not use excessive force when attempting to cross the lesion with the FilterWire EZ System. • Observe all protection wire movement in the vessel under fluoroscopic imaging. • Always keep the open filter loop distal to a deployed stent. Pulling the filter loop into the stent area may lead to entanglement with the stent and possible filter loop detachment. • Ensure that the protection wire is stabilized throughout the procedure. Failure to stabilize the protection wire could lead to inadvertent movement of the filter resulting in protection wire entanglement and/or delay in the procedure. • Do not pull excessively on the protection wire or the EZ Retrieval Sheath to avoid filter membrane tears, filter loop detachment or other protection wire damage.

ADVERSE EVENTS: Possible adverse effects include, but are not limited to, the following: • Angina • Bleeding complications • Bradycardia or arrhythmias, including ventricular fibrillation or tachycardia • Congestive heart failure • Damage to or dislocation of the implanted stent(s) • Death • Detachment and/or implantation of a component of the system • Drug reaction, allergic reaction to contrast media, medications or device materials • Emergent surgery • Embolization of air, tissue, thrombus or other embolic debris • End organ ischemia, vessel thrombosis or spasm • Hypotension/hypertension • Infection (local or systemic) • Myocardial infarction • No-reflow resulting from reduced blood flow through the FilterWire EZ™ System filter • Puncture site complications (i.e., vessel occlusion, hemorrhage, hematoma, pseudoaneurysm or arteriovenous fistula) • Renal insufficiency, kidney failure, hematuria • Stroke/cerebrovascular accident (CVA), transient ischemic attack (TIA) or seizure • Vessel damage, dissection, occlusion, aneurysm, perforation, rupture or injury.

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

Boston Scientific

Delivering what's next.™

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