WALLSTENT® Endoprostheses

CAUTION: Federal law restricts these devices to sale by or on the order of a physician.
INDICATIONS: Biliary WALLSTENT Endoprosthesis is indicated for: The treatment of biliary strictures produced by malignant neoplasms. **WALLSTENT Iliac Endoprosthesis is indicated for:** Use following suboptimal percutaneous transluminal angioplasty (PTA) of common and/or external iliac artery stenotic lesions, which are ≤ 10 cm in length. **WALLSTENT TIPS Endoprosthesis is indicated for:** The creation of intrahepatic shunt connections between the portal venous system and the hepatic vein for prophylaxis of variceal bleeding in the treatment of portal hypertension and its complications in patients who have previously failed conventional treatment techniques. **WALLSTENT Tracheobronchial Endoprosthesis is indicated for:** Use in the treatment of tracheobronchial strictures produced by malignant neoplasms. **WALLSTENT Venous Endoprosthesis is indicated for:** Improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. The vessels that can be treated with the WALLSTENT Venous Endoprosthesis are the innominate and subclavian veins, ranging from 8.0 mm to 15 mm in diameter. **CONTRAINDICATIONS: Biliary WALLSTENT Endoprosthesis:** Use of the device in very small intrahepatic ducts: Stenting of a perforated duct, where leakage from the duct could be exacerbated by prosthesis and leakage could occur across the mesh of the stent; All of the customary contraindications associated with the percutaneous transhepatic manipulation of 6-9 F caliber catheters (e.g. bleeding disorders unresponsive to vitamin K or blood product therapy). **WALLSTENT Iliac Endoprosthesis:** Patients who exhibit persistent acute intraluminal thrombus at the proposed landing site, post thrombolytic therapy. Patients who experience the complication of arterial perforation during the angioplasty procedure preceding possible stent implantation. Patients who demonstrate evidence of a fusiform or saccular aneurysm of the vessel. **WALLSTENT TIPS Endoprosthesis:** Patients with associated occlusion of the portal or hepatic vein. Patients with gastric varices secondary to splenic vein thrombosis. **WALLSTENT Tracheobronchial Endoprosthesis:** Use of the device in very small bronchials which could impede catheter removal. All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system. **WALLSTENT Venous Endoprosthesis:** Patients with bleeding disorders unresponsive to vitamin K or blood product therapy. **WARNINGS/PRECAUTIONS Biliary WALLSTENT Endoprosthesis:** The safety and effectiveness for use in the vascular system have not been established for all WALLSTENT product codes. Reference product code listing for the specific indications of each product code. Stenting across a major bifurcation may prevent or hinder future endoscopic access or other procedures. Stents cannot be repositioned after the deployment threshold has been exceeded. Final stent placement resulting in an excessive length of stent protruding into the duodenum may damage or obstruct the intestinal tract. **WALLSTENT Iliac Endoprosthesis:** Care should be taken during stent deployment to avoid stent placement beyond the iliac ostium into the aorta as this may result in thrombus formation. A stent cannot be repositioned or removed after the deployment threshold has been exceeded. Stenting across a major bifurcation may result in stenosis or occlusion of the non-stented vascular limb, and prevent or hinder future access for angioplasty procedures. Safety and effectiveness for use in total nonthrombotic iliac artery occlusions has not been established. Safety and effectiveness in patients for whom antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy has not been established. Safety and effectiveness for use in pediatric patients has not been established. Safety and effectiveness for use at a lesion site within a vascular graft or at the anastomosis has not been established. **WALLSTENT TIPS Endoprosthesis:** Treatment may exacerbate pulmonary hypertension or congestive heart failure in patients with severely compromised cardiovascular or pulmonary function. A stent cannot be repositioned or removed after the deployment threshold has been exceeded. Ultrasonographic or angiographic follow-up is recommended for post-TIPS monitoring of shunt status. **WALLSTENT Tracheobronchial Endoprosthesis:** The safety and effectiveness for use in the vascular system have not been established for all WALLSTENT product codes. Reference product code listing for the specific indications of each product code. Stenting across a major bifurcation may prevent or hinder future access or other procedures. Use of this device across bifurcations or side branches could impede airflow to the affected portion of the lung. Stents cannot be repositioned after the deployment threshold has been exceeded. Stents should not be placed near or across the cricopharyngeus. Use of laser on or around the surface of the stent may result in damage to the stent.**WALLSTENT Venous Endoprosthesis:** Subsequent restenosis may require repeat dilation of the vessel segment containing the stent. The long-term outcome following repeat dilation of venous stents is unknown at present. When multiple stents are required, stent material should be of similar composition. Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Do not advance a partially (≤ 50%) deployed stent. A stent cannot be repositioned after the deployment threshold has been exceeded. Implanting a stent may lead to dissection of the vessel distally, and/or proximally, to the stented portion, and may cause acute closure of the vessel requiring additional intervention. **POTENTIAL ADVERSE EFFECTS*** Include (but are not limited to): Infection, Sepsis, Stent Misplacement, Stent Migration, Stent Obstruction, Intraluminal Thrombosis, Thrombosis, Bleeding, Hematoma, Emboli, Pseudoaneurysm, Cerebrovascular incident, Vessel Rupture, AV fistula formation, Intra-abdominal hemorrhage secondary to liver capsule/vessel puncture, Shock, Pulmonary hypertension/edema/adult respiratory distress syndrome (ARD), Hepatic artery thrombosis/liver failure, shunt stenosis or occlusion, hepatic or portal vein occlusion or stenosis, encephalopathy, recurrence of esophageal varices, hyperbilirubinemia secondary to bile duct puncture, hepatic lobe infarction, disseminated intravascular coagulation (DIC), pulmonary embolism, pneumonia, and stent obstruction secondary to tumor or granuloma ingrowth through the stent, tumor or granuloma overgrowth at the stent ends, or mucous occlusion or perforation.

***NOTE:** Please refer to the device Directions for Use for a description of the known potential adverse effects associated with a particular use of these devices.

Carotid WALLSTENT® Monorail® Endoprosthesis

CAUTION: Federal law restricts hese devices to sale by or on the order of a physician.
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 4.0 mm and 9.0 mm 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. **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 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. 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.

WALLGRAFT® Endoprosthesis

CAUTION: Federal law restricts this device to sale by or on the order of a physician.
INDICATIONS: The WALLGRAFT Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. The safety and effectiveness of this device for use in the vascular system has not been established. **CONTRAINDICATIONS:** Contraindications associated with the use of the WALLGRAFT Tracheobronchial Endoprosthesis include: Use of the device in very small bronchioles which could impede catheter removal. All of the customary contraindications associated with the manipulation of catheters within the tracheobronchial system **WARNINGS:** Stenting across a major bifurcation may prevent or hinder future access or other procedures. Use of the device across bifurcations or side branches could impede airflow to the affected portion of the lung. Stents cannot be repositioned after the deployment threshold has been exceeded. Stents should not be placed near or across the cricopharyngeus. Use of a laser on or around the surface of the stent may result in damage to the stent.

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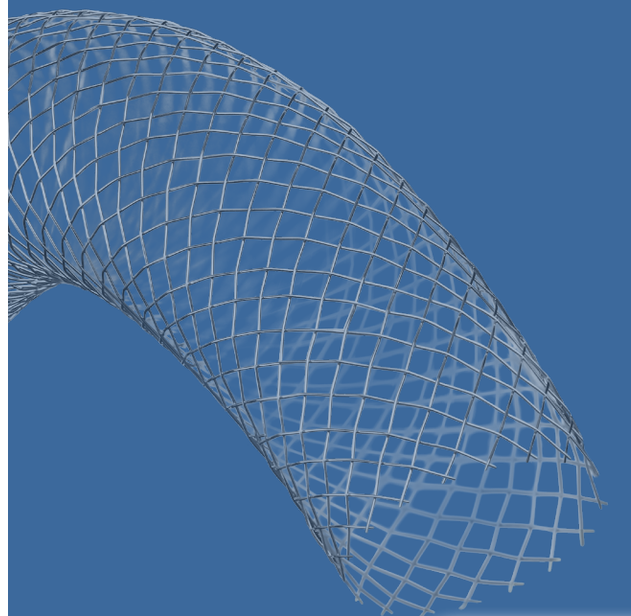
WALLSTENT®, Carotid WALLSTENT® & WALLGRAFT®

Endoprostheses



Sizing Guide

WALLSTENT® Endoprosthesis

Fully Open Dimensions (as labeled on box)	Approximate Implanted Stent Length				Sheath Compatability
Diameter* x Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Minimum I.D. (F)
5 x 20 5 x 40 5 x 55 5 x 80	4.0	26 54 78 116	3.0	30 63 89 134	6
6 x 20 6 x 45 6 x 60 6 x 90	5.0	25 52 74 111	4.0	29 60 85 128	6
7 x 20 7 x 40 7 x 60 7 x 90	6.0	25 50 72 108	5.0	28 57 82 123	6
8 x 20 8 x 40 8 x 60 8 x 80	7.0	29 49 70 105	6.0	36 56 79 119	6
10 x 20	9.0	27	8.0	33	6
10 x 42 10 x 68 10 x 94	9.0	48 69 103	8.0	54 77 115	7
12 x 20 12 x 40 12 x 60 12 x 90	11.0	26 47 66 100	10.0	31 51 73 110	9
14 x 20 14 x 40 14 x 60 14 x 90	13.0	27 46 65 98	12.0	33 50 72 107	10
16 x 20 16 x 40 16 x 60 16 x 90	15.0	23 45 64 97	14.0	28 49 70 105	10
18 x 40 18 x 60 18 x 90	17.0	45 64 95	16.0	48 69 103	11
20 x 40 20 x 55 20 x 80	19.0	40 57 86	18.0	44 63 94	11
22 x 35 22 x 45 22 x 70	21.0	35 50 75	20.0	40 57 85	11
24 x 35 24 x 45 24 x 70	23.0	35 50 75	22.0	39 56 84	12

INDICATIONS: Tracheobronchial: 5–24 mm stents;
Transhepatic Biliary: 8–12 mm stents;
TIPS: 10–12 mm stents; Venous: 10–6 mm stents

WALLSTENT® Iliac Endoprosthesis

Fully Open Dimensions (as labeled on box)	Approximate Implanted Stent Length				Sheath Compatability
Diameter* x Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Minimum I.D. (F)
6 x 24 6 x 36 6 x 46 6 x 59	5.0	33 50 67 83	4.0	41 61 81 101	6
7 x 23 7 x 34 7 x 55 7 x 67	6.0	31 46 77 93	4.0	38 57 95 114	6
8 x 20 8 x 38 8 x 47 8 x 66	7.0	29 57 72 100	6.0	36 72 89 124	6
9 x 18 9 x 35 9 x 52 9 x 61	8.0	27 53 80 93	7.0	34 67 101 117	6
10 x 20 10 x 39 10 x 49 10 x 69	9.0	27 54 67 93	8.0	33 66 83 115	6

Carotid WALLSTENT® Monorail® Endoprosthesis

Fully Open Dimensions (as labeled on box)	Approximate Implanted Stent Length				Sheath Compatability
Diameter* x Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Minimum I.D. (F)
6 x 22	5.0	30	4.0	36	5
8 x 21 8 x 29 8 x 36	7.0	30 40 50	6.0	36 48 62	5
10 x 24 10 x 31 10 x 37	9.0	30 40 50	8.0	36 49 59	6

WALLGRAFT® Endoprosthesis

Fully Open Dimensions (as labeled on box)	Approximate Implanted Stent Length				Sheath Compatability**
Diameter* x Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Lumen Diameter (mm)	Stent Length (mm)	Minimum I.D. (F)
6 x 20 6 x 30 6 x 50 6 x 70	5.0	28 41 69 97	—	— — — —	10
7 x 20 7 x 30 7 x 50 7 x 70	6.0	27 40 67 94	5.0	30 44 74 104	10
8 x 20 8 x 30 8 x 50 8 x 70	7.0	26 39 66 92	6.0	29 43 72 101	10
9 x 20 9 x 30 9 x 50 9 x 70	8.0	26 39 65 91	7.0	28 43 71 100	11
10 x 20 10 x 30 10 x 50 10 x 70	9.0	25 38 63 88	8.0	27 41 68 96	11
12 x 30 12 x 50 12 x 70	10.0	40 67 94	9.0	43 72 100	12
14 x 50 14 x 70	12.0	66 92	11.0	70 98	12

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

**The use of a sheath in conjunction with WALLGRAFT is at the discretion of the physician