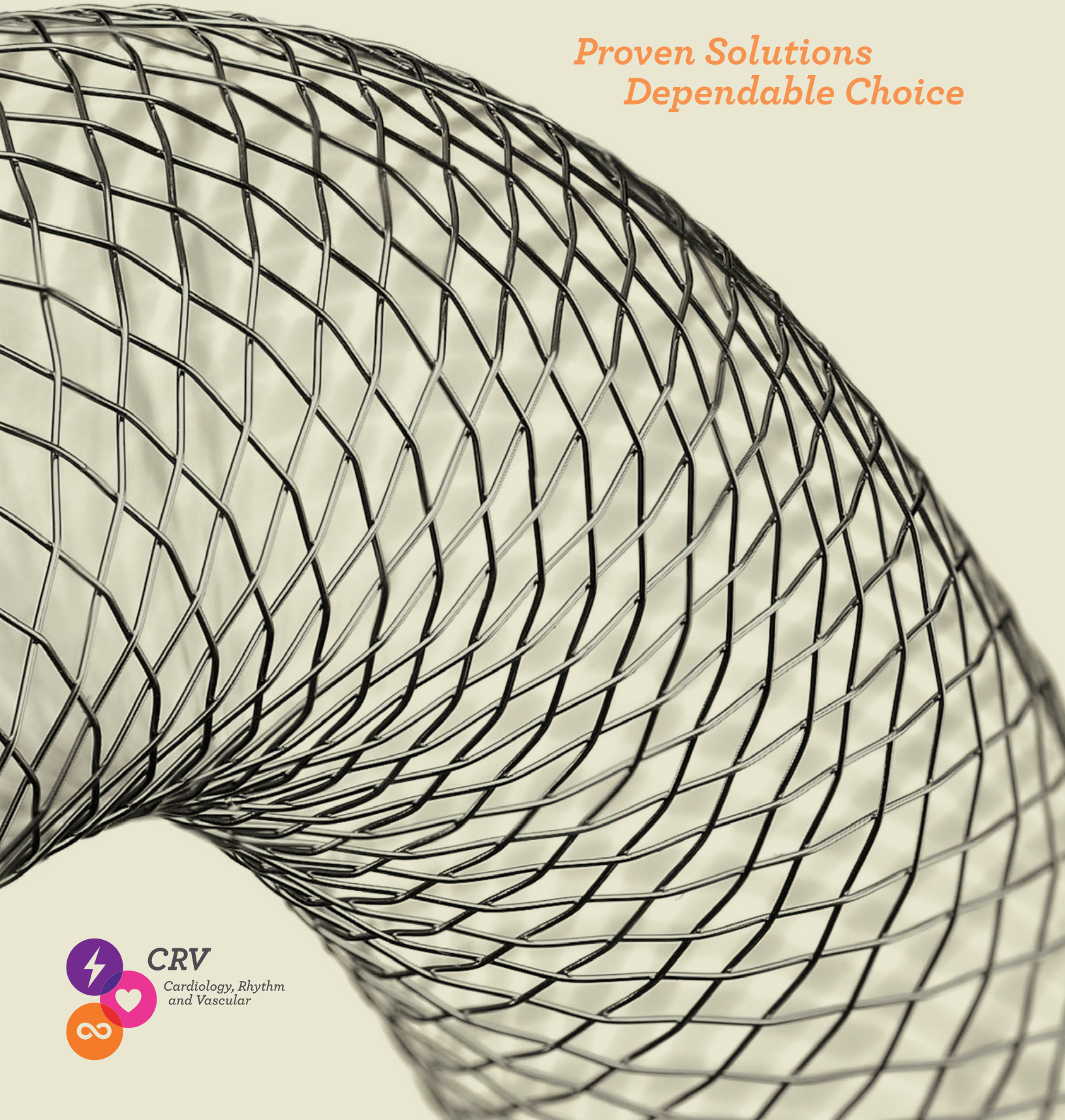
WALLSTENT® Endoprosthesis

Boston Scientific

Proven Solutions
Dependable Choice

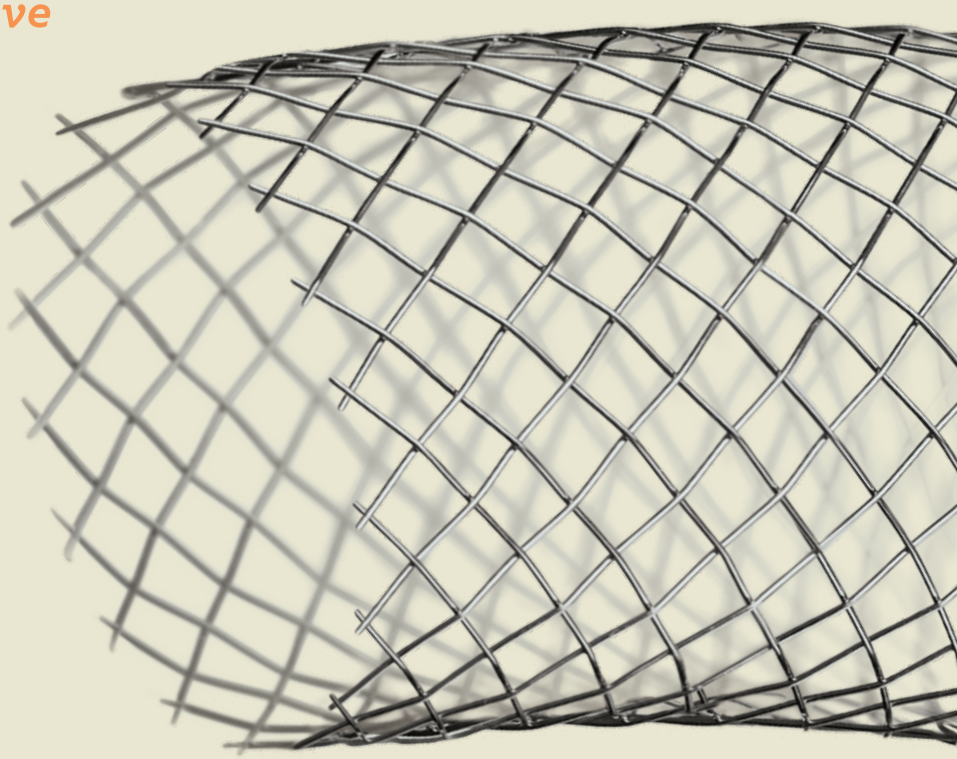


CRV
Cardiology, Rhythm and Vascular

WALLSTENT® Endoprosthesis

The Most Comprehensive Range of Sizes

Diameters from 5 mm to 24 mm* and deployed lengths from 23 mm to 145 mm**



Reconstrainability

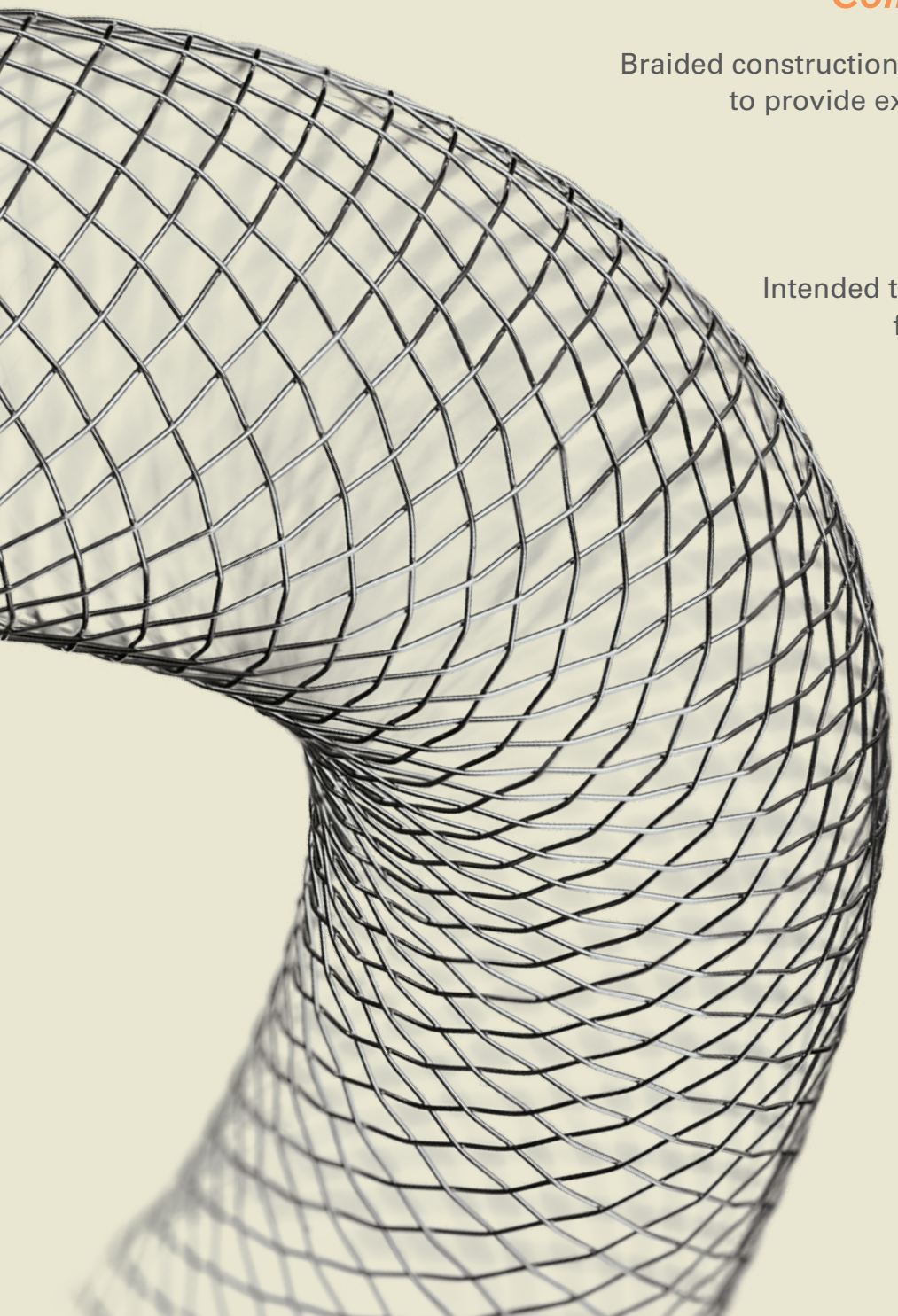
Designed for ease of placement, the WALLSTENT Endoprosthesis allows reconstrainability with the stent deployed up to the limit marker band

Visibility

Exclusive HALO™ Technology and platinum core provides excellent fluoroscopic visibility intended to facilitate precise positioning

*Available sizes vary per indication. See product information table for specific size availability.

**Approximate implanted stent length. Refer to DFU sizing chart for more information.



Compression Resistance

Braided construction and Elgiloy® Material designed to provide excellent compression resistance

Closed-Cell Design

Intended to provide increased scaffolding for optimal lesion coverage and a smooth inner lumen

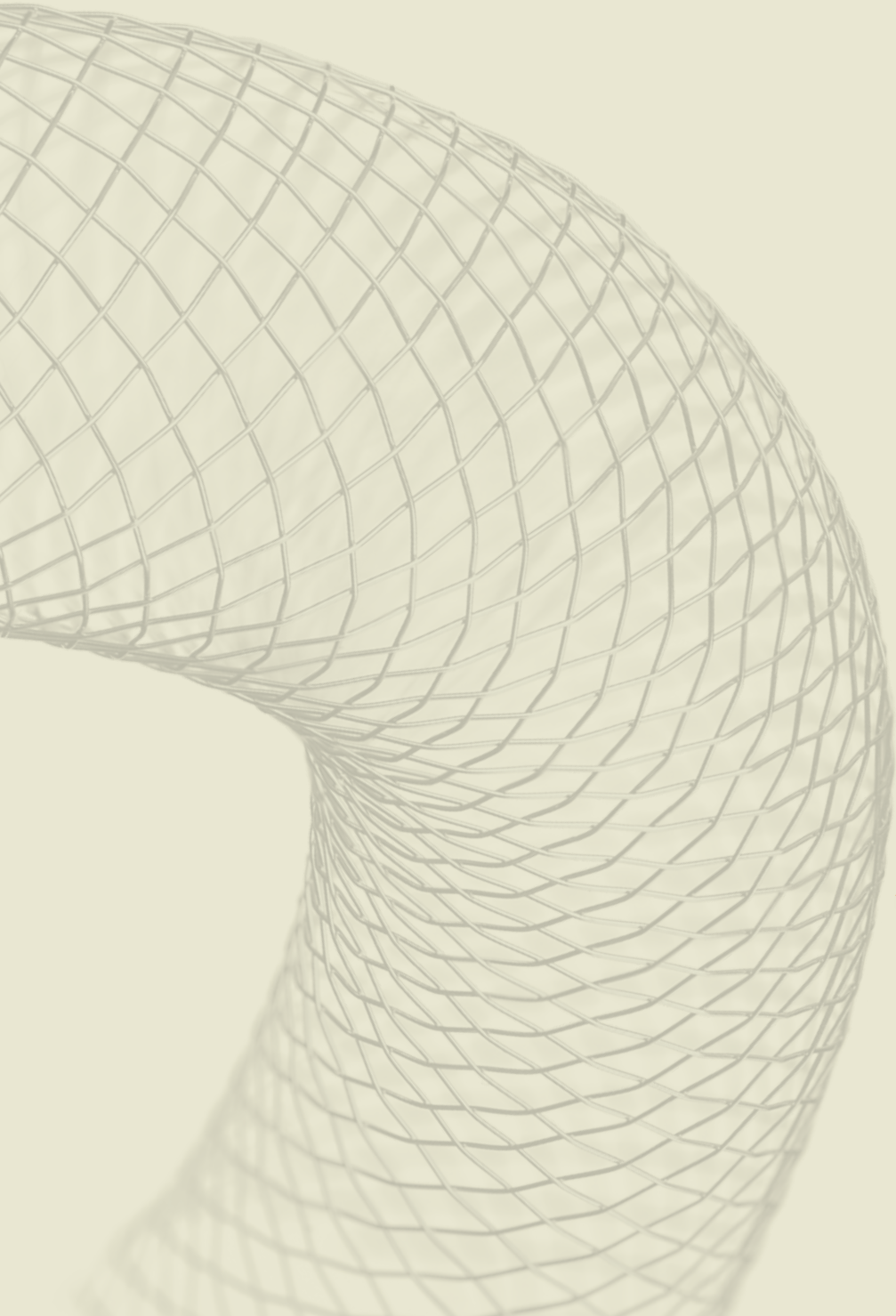
Conformability

Excellent adaption to anatomical contours designed to provide exceptional stent-to-wall apposition

Flexibility

Highly flexible stent designed to smoothly cross lesions

WALLSTENT®
Endoprosthesis offers five indications to meet your stenting needs



Iliac Artery
Central Venous
Transhepatic Biliary
Tracheobronchial
TIPS

Product Information

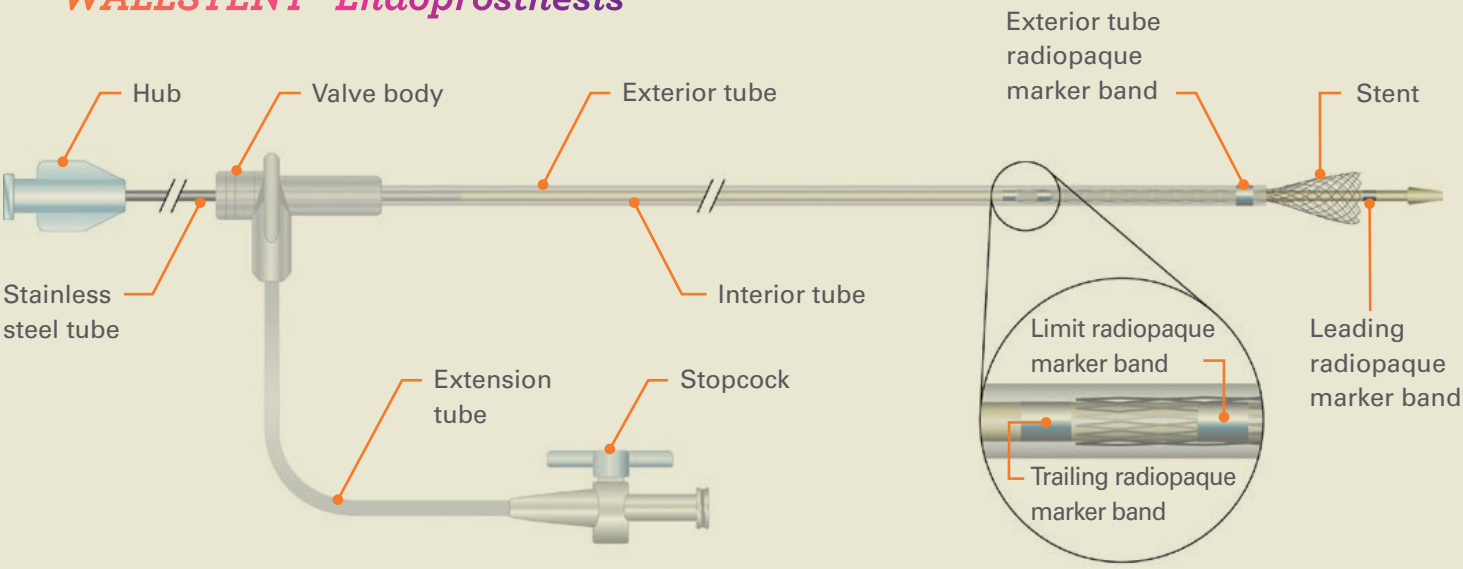
Product Information for WALLSTENT® Endoprosthesis with the UNISTEP® Plus Delivery System

UPN	Order Number	Stent Diameter (mm)	Stent Length (mm)	Sheath Compatibility (F)	Catheter Working Length (cm)	Total Length (cm)	Indications
M001711000	71-100	5	20	6	75	100	❶
M001711010	71-101	5	20	6	135	160	❶
M001711020	71-102	5	40	6	75	100	❶
M001711030	71-103	5	40	6	135	160	❶
M001711040	71-104	5	55	6	75	100	❶
M001711050	71-105	5	55	6	135	160	❶
M001711060	71-106	5	80	6	75	100	❶
M001711070	71-107	5	80	6	135	160	❶
M001711080	71-108	6	20	6	75	100	❶
M001711090	71-109	6	20	6	135	160	❶
M001711100	71-110	6	45	6	75	100	❶
M001711110	71-111	6	45	6	135	160	❶
M001711120	71-112	6	60	6	75	100	❶
M001711130	71-113	6	60	6	135	160	❶
M001711140	71-114	6	90	6	75	100	❶
M001711150	71-115	6	90	6	135	160	❶
M001711160	71-116	7	20	6	75	100	❶
M001711170	71-117	7	20	6	135	160	❶
M001711180	71-118	7	40	6	75	100	❶
M001711190	71-119	7	40	6	135	160	❶
M001711200	71-120	7	60	6	75	100	❶
M001711210	71-121	7	60	6	135	160	❶
M001711220	71-122	7	90	6	75	100	❶
M001711230	71-123	7	90	6	135	160	❶
M001711240	71-124	8	20	6	75	100	❶ ❸
M001711250	71-125	8	20	6	135	160	❶
M001711260	71-126	8	40	6	75	100	❶ ❸
M001711270	71-127	8	40	6	135	160	❶
M001711280	71-128	8	60	6	75	100	❶ ❸
M001711290	71-129	8	60	6	135	160	❶
M001711300	71-130	8	80	6	75	100	❶ ❸
M001711310	71-131	8	80	6	135	160	❶
M001711320	71-132	10	20	6	75	100	❶ ❸ ❺
M001711330	71-133	10	20	6	135	160	❶
M001711340	71-134	10	42	7	75	100	❶ ❷ ❸ ❺
M001711350	71-135	10	42	7	135	160	❶
M001711360	71-136	10	68	7	75	100	❶ ❷ ❸ ❺
M001711370	71-137	10	68	7	135	160	❶
M001711380	71-138	10	94	7	75	100	❶ ❷ ❸ ❺
M001711390	71-139	10	94	7	135	160	❶
H965402100	40210	12	20	9	75	100	❶ ❸ ❺
H965412000	41200	12	20	9	135	160	❶
H965402110	40211	12	40	9	75	100	❶ ❷ ❸ ❺
H965412010	41201	12	40	9	135	160	❶
H965402120	40212	12	60	9	75	100	❶ ❷ ❸ ❺
H965412020	41202	12	60	9	135	160	❶
H965402130	40213	12	90	9	75	100	❶ ❷ ❸ ❺
H965412030	41203	12	90	9	135	160	❶
H965403100	40310	14	20	10	75	100	❶ ❺
H965403110	40311	14	40	10	75	100	❶ ❺
H965403120	40312	14	60	10	75	100	❶ ❺
H965403130	40313	14	90	10	75	100	❶ ❺
H965403300	40330	16	20	10	75	100	❶ ❺
H965403310	40331	16	40	10	75	100	❶ ❺
H965403320	40332	16	60	10	75	100	❶ ❺
H965403330	40333	16	90	10	75	100	❶ ❺
H965404110	40411	18	40	11	75	100	❶
H965404120	40412	18	60	11	75	100	❶
H965404130	40413	18	90	11	75	100	❶
H965404300	40430	20	40	11	75	100	❶
H965404310	40431	20	55	11	75	100	❶
H965404320	40432	20	80	11	75	100	❶
H965404500	40450	22	35	11	75	100	❶
H965404510	40451	22	45	11	75	100	❶
H965404520	40452	22	70	11	75	100	❶
H965405100	40510	24	35	12	75	100	❶
H965405110	40511	24	45	12	75	100	❶
H965405120	40512	24	70	12	75	100	❶
M001712000	71-200	6	24	6	75	100	❹
M001712010	71-201	6	24	6	135	60	❹
M001712020	71-202	6	36	6	75	100	❹
M001712030	71-203	6	36	6	135	160	❹
M001712040	71-204	6	46	6	75	100	❹
M001712050	71-205	6	46	6	135	160	❹
M001712060	71-206	6	59	6	75	100	❹
M001712070	71-207	6	59	6	135	160	❹
M001712080	71-208	7	23	6	75	100	❹
M001712090	71-209	7	23	6	135	160	❹
M001712100	71-210	7	34	6	75	100	❹
M001712110	71-211	7	34	6	135	160	❹
M001712120	71-212	7	55	6	75	100	❹
M001712130	71-213	7	55	6	135	160	❹
M001712140	71-214	7	67	6	75	100	❹
M001712150	71-215	7	67	6	135	160	❹
M001712160	71-216	8	20	6	75	100	❹
M001712170	71-217	8	20	6	135	160	❹
M001712180	71-218	8	38	6	75	100	❹
M001712190	71-219	8	38	6	135	160	❹
M001712200	71-220	8	47	6	75	100	❹
M001712210	71-221	8	47	6	135	160	❹
M001712220	71-222	8	66	6	75	100	❹
M001712230	71-223	8	66	6	135	160	❹
M001712240	71-224	9	18	6	75	100	❹
M001712250	71-225	9	18	6	135	160	❹
M001712260	71-226	9	35	6	75	100	❹
M001712270	71-227	9	35	6	135	160	❹
M001712280	71-228	9	52	6	75	100	❹
M001712290	71-229	9	52	6	135	160	❹
M001712300	71-230	9	61	6	75	100	❹
M001712310	71-231	9	61	6	135	160	❹
M001712320	71-232	10	20	6	75	100	❹
M001712330	71-233	10	20	6	135	160	❹
M001712340	71-234	10	39	6	75	100	❹
M001712350	71-235	10	39	6	135	160	❹
M001712360	71-236	10	49	6	75	100	❹
M001712370	71-237	10	49	6	135	160	❹
M001712380	71-238	10	69	6	75	100	❹
M001712390	71-239	10	69	6	135	160	❹

Key

❶ Tracheobronchial
❷ Transjugular Intrahepatic Portosystemic Shunt (TIPS)
❸ Transhepatic Biliary
❹ Iliac
❺ Venous

WALLSTENT® Endoprosthesis



WALLSTENT ENDOPROSTHESIS

INDICATIONS:
WALLSTENT Biliary 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 <10cm 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 or fistulas 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 8mm to 15mm in diameter.

CONTRAINDICATIONS:
WALLSTENT Biliary 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 8-9F 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 standing site, post thrombolytic therapy.
- Patients who experience the complication of arterial perforation or a fusiform of sacciform aneurysm during the procedure preceding possible stent implantation.

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:
WALLSTENT Biliary 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 non-thrombotic iliac artery occlusions have not been established.
- Safety and effectiveness in patients for whom antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy have not been established.
- Safety and effectiveness for use in pediatric patients have not been established.
- Safety and effectiveness for use at a lesion site within a vascular graft or at the anastomosis have 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 bifurcation 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 caudal aspect of the cricoid cartilage.
- 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, intraabdominal 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.

CAUTION: Federal law restricts these devices to sale by or on the order of a physician. *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. Elgiloy is a trademark of Combined Metals of Chicago, L.L.C.

Boston Scientific

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