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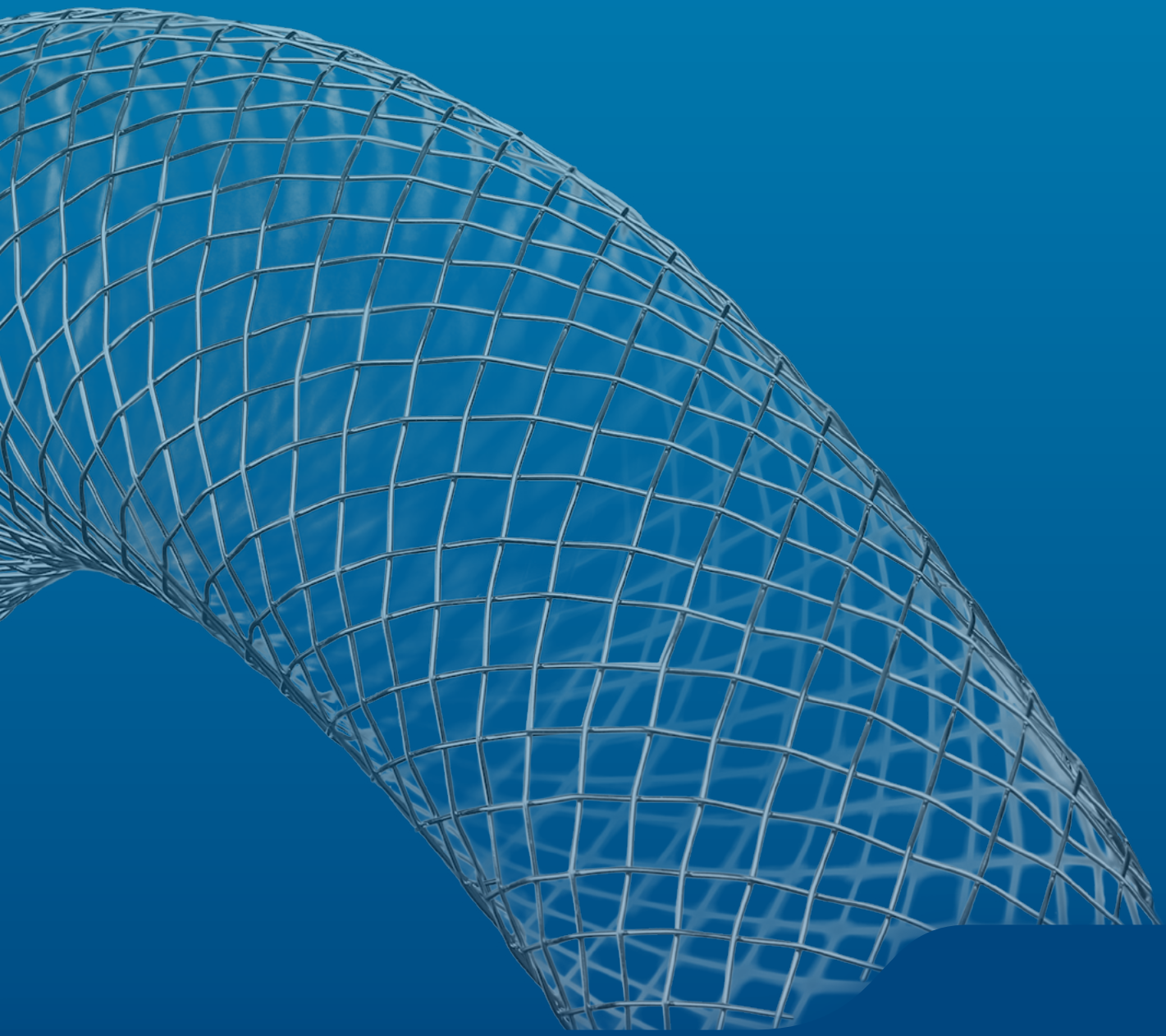
WALLSTENT™ Endoprosthesis

PROVEN SOLUTIONS, DEPENDABLE CHOICE



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

Compression Resistance

Braided construction and Elgiloy™ Material designed to provide excellent compressionresistance

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

*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.

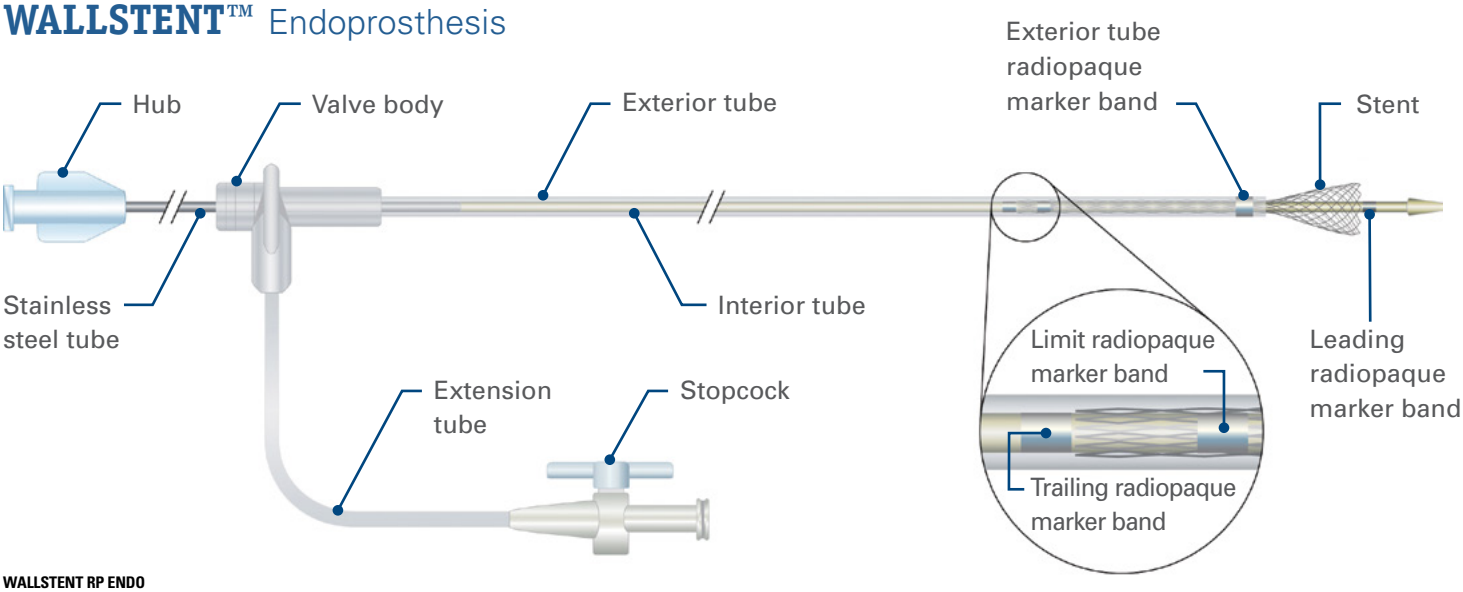
Product Information

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 RP ENDO

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

TRANSHEPATIC BILIARY INDICATIONS FOR USE/INTENDED USE: The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary are indicated for use in the treatment of biliary strictures produced by malignant neoplasms. **CONTRAINDICATIONS:** Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Transhepatic Biliary include: • Use of the device in very small intrahepatic ducts. • Stenting of a perforated duct, where leakage from the duct could be exacerbated by the prosthesis and leakage could occur across the mesh of the stent. • All of the customary contraindications associated with the percutaneous transhepatic manipulation of 6-9F (2.0-3.0 mm) caliber catheters (e.g.: bleeding disorders unresponsive to vitamin K or blood product therapy). **WARNINGS:** • The safety and effectiveness for use in the vascular system have not been established except for the following WALLSTENT product codes that are also indicated for improving central venous luminal diameter in the innominate and subclavian veins following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract: M001711320, M001711340, M001711360, M001711380, H965402110, H965402120, H965402130, H965402100. • 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 or misplacement of the entire stent into the duodenum may damage or obstruct the intestinal tract. **COMPLICATIONS:** Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic Biliary may include the usual complications reported for conventional biliary stents and transhepatic procedures such as infection, stent misplacement, stent migration, and stent obstruction secondary to tumor in-growth through the stent, tumor overgrowth at the stent ends, or sludge occlusion. **TRACHEOBRONCHIAL INDICATIONS FOR USE/INTENDED USE:** The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. With the exception of the following WALLSTENT Codes which are approved for Venous or TIPS indications, the safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death: H965402100, H965402110, H965402120, H965402130, H965403100, H965403110, H965403120, H965403130, H965403300, H965403310, H965403320, H965403330, M001711320, M001711340, M001711360, M001711380. **CONTRAINDICATIONS:** Contraindications associated with the use of the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial include: • 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. **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. **COMPLICATIONS:** Complications associated with the use of the WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial may include the usual complications reported for conventional tracheobronchial stents such as infection, stent misplacement, stent migration, 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. **TIPS INDICATIONS FOR USE/INTENDED USE:** The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are indicated for 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. **CONTRAINDICATIONS: T**he WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis TIPS are contraindicated for use in: • Patients with associated occlusion of the portal or hepatic vein. • Patients with gastric varices secondary to splenic vein thrombosis. **WARNING:** Treatment may exacerbate pulmonary hypertension or congestive heart failure in patients with severely compromised cardiovascular or pulmonary function. **PRECAUTIONS:** • 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. **ADVERSE EVENTS:** Adverse events recorded during the clinical trial of the WALLSTENTTIPS Endoprosthesis included: • Death – <30 days 15% & >30 days 15% • Intra-abdominal Hemorrhage secondary to: liver capsule/vessel puncture – 3% • Shock – 5% • Sepsis/Infection – 6% • Pulmonary hypertension/edema/Adult Respiratory Distress Syndrome – 1% • Hepatic Artery Thrombosis/Liver Failure – 1% • Shunt Stenosis or Occlusion – 17% • Hepatic or Portal Vein Occlusion or Stenosis – 1% • Encephalopathy – 30% increased • Puncture Site Hematoma – 1% • Recurrence of Esophageal Varices – 10% • Hyperbilirubinemia secondary to bile duct puncture – 1% • Hepatic Lobe Infarction – 1% Additional adverse events associated with TIPS, although not observed in the clinical study include: • Stent Misplacement • Stent Migration • Disseminated Intravascular Coagulation • Pulmonary Embolism • Vessel Rupture • Pneumonia The risks associated with the use of contrast media angiography (allergic type reactions, hypertension, shock, death) should also be considered, as fluoroscopy and angiography are recommended during the stent implant procedure. **VENOUS INDICATIONS FOR USE/INTENDED USE:** The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are indicated for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥30% for a vein ≤10 mm in diameter or ≥50% for a vein >10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site occlusion, or refractory spasm. The vessels that can be treated with the WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are the innominate and subclavian veins, ranging from 8.0 mm to 15 mm in diameter. **CONTRAINDICATIONS:** The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Venous are contraindicated for use in patients with bleeding disorders unresponsive to vitamin K or blood product therapy. **WARNINGS:** • 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 materials should be of similar composition. • Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Refer to Table 1 for sizing information. **PRECAUTIONS:** Stent Placement Precautions • 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 (e.g., surgery, further dilation, placement of additional stents, or other). **POTENTIAL ADVERSE EVENTS:** Potential adverse events associated with use of the WALLSTENT Venous Endoprosthesis may include the usual adverse events reported for conventional percutaneous transluminal angioplasty such as: hemorrhage, infection, contrast media reactions, dissection, distal emboli, graft rupture, graft/vein thrombosis or occlusion, perforation of the vein, suture disruption of the anastomosis, thromboembolism or transient spasm. Potential adverse events associated with the WALLSTENT Venous Endoprosthesis are stent misplacement, stent migration, or vein perforation.

WALLSTENT RP ENDOPROSTHESIS ILIAC

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. 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/INTENDED USE: The WALLSTENT RP 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. A suboptimal PTA is defined as a technically successful dilation, judged by the physician to be suboptimal due to the presence of unfavorable lesion morphology such as: • An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, lesion recoil, or intimal flaps. • Flow limiting dissections post PTA longer than the initial lesion length. • A 5 mm Hg or greater mean transtenotic pressure gradient post PTA.

CONTRAINDICATIONS: The WALLSTENT RP Endoprosthesis is contraindicated for use in: • 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. **WARNINGS:** • 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. **PRECAUTIONS:** • Stenting across a major bifurcation may result in stenosis or occlusion of the nonstented vascular limb, and prevent or hinder future access for angioplasty procedures. • The safety and effectiveness of the WALLSTENT™ RP Endoprosthesis has not been established for use: • at a lesion site within a vascular graft or at the anastomosis • in patients for whom antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy • in pediatric patients • in total non-thrombotic chronic iliac artery occlusions **ADVERSE EVENTS:** • Thrombosis • Stent Misplacement • Bleeding Requiring Transfusion • Hematoma Requiring Repair • Distal Emboli • Pseudoaneurysm • Minor Hematoma • Intraluminal Thrombus • Cerebrovascular Incident • Death Additional adverse events that have been reported to be associated with iliac stenting, although not observed in the clinical study include: • Vessel Rupture • Sepsis/Infection • AV Fistula Formation • Stent Migration • Need for Bypass or Amputation • Dissection

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