Boston Scientific

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VENOUS WALLSTENT™

Self-Expanding Stent

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℞ ONLY

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

1. WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single 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.

2. DEVICE DESCRIPTION

The VENOUS WALLSTENT is comprised of two components: the implantable metallic stent and the delivery system (reference Figure A.). The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Stent sizes (10 mm – 12 mm) have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates an 0.035 in (0.89 mm) guidewire.

2.1. User Information

Only physicians experienced in percutaneous intravascular techniques and procedures should use the VENOUS WALLSTENT System.

2.2. Non-Pyrogenic

The VENOUS WALLSTENT is non-pyrogenic.

2.3. Contents

One (1) VENOUS WALLSTENT

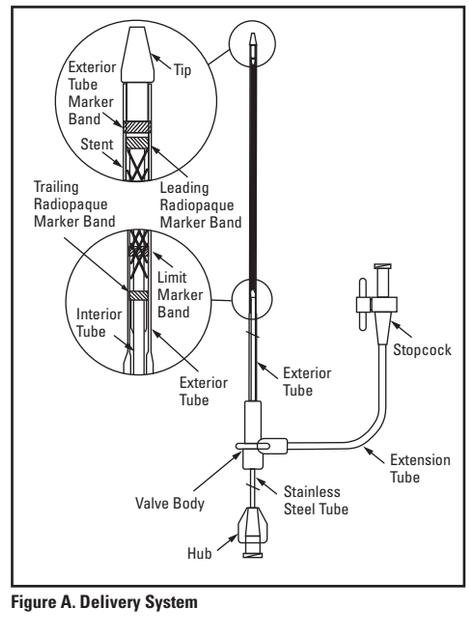

Figure A. Delivery System

3. INDICATIONS FOR USE /INTENDED USE

The VENOUS WALLSTENT is 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 VENOUS WALLSTENT are the innominate and subclavian veins, ranging from 8 mm to 15 mm in diameter.

The VENOUS WALLSTENT is also indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

4. CONTRAINDICATIONS

- Patients with uncorrected bleeding disorders.
- Patients who cannot receive anticoagulation or antiplatelet aggregation therapy.
- Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system.

5. 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.
- Proper stent sizing is critical to achieving adequate vessel apposition and avoiding possible stent migration. Refer to Tables 7.1. and 13.1. for sizing information.
- A stent cannot be repositioned or removed after the deployment threshold has been exceeded.
- The device contains nickel, which may cause allergic reaction in individuals with nickel sensitivity.

6. PRECAUTIONS

6.1. Stent Placement Precautions

- The target lesion should be predilated with a conventional balloon angioplasty catheter prior to stent placement.
- Do not release the stent if unusual force is required. If the stent does not deploy easily, use another device.
- Do not advance the delivery catheter without the guidewire extending from the tip.
- Do not fully deploy the stent if it is not properly positioned in the vessel.
- Do not advance a partially (≤50%) deployed stent. Reconstrain and then move distally. Partially deployed stents can be pulled proximally, if necessary.
- Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the device, see Step 10 of Section 14. VENOUS PROCEDURE.

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- 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).
- When treating multiple lesions, the distal lesion should be initially stented, followed by the stenting of the more proximal lesion(s). Stenting in this order obviates the need to cross the proximal stent in the placement of the distal stent and reduces the chance for dislodging the proximal stent.
- Stenting across a major side branch could obstruct the side branch and prevent or hinder percutaneous access or future interventions.
- Stent retrieval methods (use of additional wires, snares and/ or forceps) may result in additional trauma to the vascular site.

6.2. Stent/System Removal Precautions

- If Stent/System removal is required prior to full deployment, and when the stent is ≤50% deployed, first attempt to reconstrain the stent and remove as described in Step 8 of Section 14. VENOUS PROCEDURE. If the stent cannot be reconstrained, remove the entire Stent/System as follows:
  - Hold the Valve Body securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.
- Failure to follow these steps could potentially result in loss of, or damage to, the stent or delivery system.

6.3. Post Implant Precautions

- Care must be exercised when crossing a newly deployed stent with intravascular ultrasound (IVUS), or a guidewire, or a balloon catheter to avoid disrupting the stent geometry.
- Be aware of the location of stented venous lesions. Dislodging stents with catheters or other transluminal devices may produce unexpected stent migration.

7. VENOUS WALLSTENT™ Product Matrix

Table 7.1. Size and Indication Information

UPN	Stent Diameter	Stent Length	Recommended Introducer Sheath	Catheter Effective Length	Catheter Total Length	Indications for Use
	mm	mm	F (mm)	cm	cm	number
H74912044102070	10	20	6 (2.0)	75	100	1
H74912044104270	10	42	7 (2.3)	75	100	1
H74912044106870	10	68	7 (2.3)	75	100	1
H74912044109470	10	94	7 (2.3)	75	100	1
H74912044122070	12	20	9 (3.0)	75	100	1
H74912044124070	12	40	9 (3.0)	75	100	1,2
H74912044124010	12	40	9 (3.0)	135	160	2
H74912044126070	12	60	9 (3.0)	75	100	1,2
H74912044126010	12	60	9 (3.0)	135	160	2
H74912044129070	12	90	9 (3.0)	75	100	1,2
H74912044129010	12	90	9 (3.0)	135	160	2
H74912044142070	14	20	10 (3.3)	75	100	1
H74912044144070	14	40	10 (3.3)	75	100	1,2
H74912044146070	14	60	10 (3.3)	75	100	1,2
H74912044149070	14	90	10 (3.3)	75	100	1,2
H74912044162070	16	20	10 (3.3)	75	100	1
H74912044164070	16	40	10 (3.3)	75	100	1,2
H74912044166070	16	60	10 (3.3)	75	100	1,2
H74912044169070	16	90	10 (3.3)	75	100	1,2
H74912044184070	18	40	11 (3.7)	75	100	2
H74912044186070	18	60	11 (3.7)	75	100	2
H74912044189070	18	90	11 (3.7)	75	100	2
H74912044204070	20	40	11 (3.7)	75	100	2
H74912044205570	20	55	11 (3.7)	75	100	2
H74912044208070	20	80	11 (3.7)	75	100	2

Indication Key:
1. Central Venous
2. Iliofemoral

8. MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

Non-clinical testing has demonstrated the VENOUS WALLSTENT system is MR Conditional for single and overlapping lengths up to 120 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla
- Highest spatial gradient magnetic field of 19 Tesla/m (1900 Gauss/cm) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤1 W/kg for patient landmarks above the umbilicus (patient navel) and ≤2 W/kg (Normal Operating Mode) for patient landmarks below the umbilicus.

8.1. RF Heating

Under the scan conditions defined, VENOUS WALLSTENT is expected to produce a maximum in-vivo temperature rise of 3.1 °C after 15 minutes of continuous scanning.

8.2. Image Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 13 mm from the stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

8.3. Recommendations

It is recommended that patients register the conditions under which the implant can safely be scanned with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

9. ADVERSE EVENTS

Adverse Events associated with the use of stents for Vascular applications may include, but are not limited to, the following:

- Allergic reactions (drug, contrast, device or other)
- Angina
- Arteriovenous fistula
- Cerebrovascular accident/stroke/Transient Ischemic Attack
- Death
- Embolism (air, plaque, thrombus, device or other)
- Fever
- Hematoma
- Hemorrhage/bleeding
- Hypotension/hypertension
- Ischemia
- Myocardial infarction/ischemia
- Need for urgent intervention or surgery
- Pain
- Pulmonary embolism
- Renal insufficiency or failure
- Restenosis of stented vessel
- Sepsis/infection
- Stent fracture
- Stent migration
- Stent/vessel occlusion
- Thrombus/thrombosis
- Vasospasm
- Venous congestion
- Vessel injury (perforation, trauma, rupture, dissection, pseudoaneurysm or other)

10. CLINICAL STUDIES

10.1. Central Venous Clinical Trial

A total of 42 patients at 12 investigational sites within the United States were enrolled in a prospective, multi-center, non-randomized study with a historical percutaneous transluminal angioplasty (PTA) control cohort to investigate the safety and efficacy of the WALLSTENT Venous Endoprosthesis for improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis.

10.1.1. Primary Endpoint:

The primary endpoint for the WALLSTENT Venous Endoprosthesis trial was circuit secondary patency at 6 months. Circuit secondary patency is defined as the proportion of patients, over time, that have an occluded vessel that is successfully opened. Failure of circuit secondary patency occurs at the time the dialysis site is abandoned due to the inability to treat the stenosis, or occlusion of either the central lesion under consideration or any other peripheral or de novo central lesion.

10.1.2. Other endpoints evaluated include:

Stent Primary Patency, defined as the proportion of patients, over time, that have had uninterrupted (intervention-free) patency since the initial procedure. Primary patency ends at the first occurrence of one of the following: initial re-intervention for the purpose of treating patency of the central lesion; anatomical failure (50% or greater stenosis) of the central lesion; or when the dialysis site is abandoned due to the inability to treat the original central lesion. If percent stenosis of the central lesion is undetermined, the occurrence of arm/face edema indicates the end of primary patency.

Stent Secondary Patency, defined as the time to failure of the access site due to stenosis or occlusion of the stented central lesion. Anatomical failure (>50% stenosis) of the central lesion which is not successfully reopened is also considered failure of stent secondary patency. Patients failing circuit secondary patency due to other peripheral lesions, problems at the access site (e.g. pseudoaneurysm, infection), or a de novo central lesion that does not involve the stent margin, do not fail stent

secondary patency. These patients are censored from analysis at the date of the last follow-up documenting patency of the stent.

Patency rates were estimated by means of Kaplan-Meier Survival Analysis.

10.1.3. Patient Eligibility:

Patients were eligible for the study if they were on chronic hemodialysis and had a central venous stenosis which was treatable with PTA. If the PTA failed to reduce the stenosis to less than 50% in patients with a vein >10 mm in diameter, or 30% in a vein ≤10 mm in diameter, the patient received a WALLSTENT™ Venous Endoprosthesis. If the PTA was successful, but the stenosis recurred within 4 months, the patient received a WALLSTENT Venous Endoprosthesis.

10.1.4. Study Methods:

Clinical follow-up was obtained at 1 week, 2 months, 6 months, and every 6 months thereafter until study conclusion, or the graft site was abandoned. Baseline quantitative angiography was performed pre-procedure, following balloon angioplasty, following device deployment, and at the 2-month and 6-month visit. The stent primary patency, stent secondary patency, and circuit secondary patency were analyzed.

10.1.5. Results:

Among the 42 patients enrolled in the study, lesions involved the innominate vein in 14, subclavian vein in 23, and both subclavian and innominate veins in 5 patients. The mean lesion length was 25.8 mm (±18.8, range = 2.0-81.6 mm). Multiple stents were implanted in 5 patients (11.9%). A total of 28.6% of the patients (12/42) had occluded (100% stenosis) veins at the time of the study enrollment.

Initial intraoperative success, as measured by the reduction in stenosis to <30%, or angiographic demonstration of an increase in venous outflow, was achieved in 100% of patients. Analysis of the clinical data demonstrated a 74.3% circuit secondary patency rate at six months for the WALLSTENT Venous Endoprosthesis study group, compared to a 50% secondary patency rate for the historical control of percutaneous transluminal angioplasty (PTA), resulting in a highly significant statistical difference (p<0.0003). The WALLSTENT Venous Endoprosthesis was found to provide superior efficacy in the central venous patient cohort when compared to the historical control (PTA).

Baseline demographic and lesion characteristics were individually regressed on time to loss of circuit secondary patency to assess possible predictors of clinical outcome (univariate analysis). Presence of an occluded lesion pre-procedure was significantly associated with circuit secondary patency (p=0.022). The same variables were analyzed using stepwise selection to identify a multivariate predictor model. Presence of a totally occluded lesion pre-procedure was the only variable associated with time to loss of circuit secondary patency (p=0.0072). Implantation of multiple stents approached significance in the multivariate model (p=0.062).

Principal Efficacy and Safety results are summarized in Table 10.1.1.

Table 10.1.1. Principal Efficacy and Safety Results, BSC Patients (n=42)

Efficacy Measures	Result	95% C.I.
Device Success	100.0% (42/42)	[91.6%, 100.0%]
Initial Intraoperative Success: Criterion 1: 30% Residual Stenosis Criterion 2: Increased Venous Flow Met Either Criteria	 64.3% (27/42) 90.5% (38/42) 100.0% (42/42)	 [48.0%, 78.4%] [77.4%, 97.3%] [91.6%, 100.0%]
Acute Procedure Success	64.3% (27/42)	[48.0%, 78.4%]
Initial Clinical Success: Pre-PTA RVD (mm) Post-Stent MLD (mm) Post-Stent %DS 6-Month RVD (mm) 6-Month MLD (mm) 6-Month %DS	95.8% 12.6 }3.7 (42) (3.0, 20.1) 8.8 }2.8 (39) (3.7, 20.2) 24.1}18.4 (42) (0.0, 63.0) 10.4 }3.3 (25) (4.0, 18.3) 3.0 }2.7 (26) (0.0, 11.0) 67.9 29.1 (26) (9.0, 100.0)	[78.9%, 99.9%] [11.5, 13.7] [7.9, 9.7] [18.5, 29.6] [9.1, 11.7] [1.9, 4.0] [56.7, 79.1]
Patency 6-Month Stent Primary Patency (K-M) 24.4% 6-Month Stent Secondary Patency (K-M) 82.5% 6-Month Circuit Secondary Patency (K-M) 74.3% Stent Restenosis Arm-Face Edema	 76.2% (32/42) 40.5% (17/42)	 [9.8%, 39.0%] [69.7%, 95.2%] [60.6%, 88.1%] [60.5%, 87.9%] [25.6%, 56.7%]
Safety Measures Major In-Hospital Event	 0.0% (0/42)	 [0.0%, 8.4%]
Out-of-Hospital (Stent-Related) Event Stent Thrombosis Migration Death	 50.0% (21/42) 2.4% (1/42) 11.9% (5/42)	 [34.2%, 65.8%] [0.1%, 12.6%] [4.0%, 25.6%]

Results are mean ± SD (sample size) (min, max) for continuous variables, and percent (count/sample size) for binary variables.
Confidence intervals for binomial proportions are based on exact limits.
Patency rates are Kaplan-Meier estimates at 180 days; confidence intervals based on Greenwood standard errors.
RVD = Reference Vessel Diameter.
MLD = Minimum Lumen Diameter.
%DS = percent diameter stenosis which refers to "within lesion" measurement technique.
Device Success = Stent(s) deployed completely.
Initial Intraoperative Success, Criterion 2 = angiographic demonstration of an increase in venous outflow (visualization of less collateral flow, more rapid rate of contrast media clearing or less reflux flow post-procedure).
Acute Procedure Success = ≤30% residual stenosis and absence of major in-hospital event.
Initial Clinical Success = <20% recirculation fraction one week post-procedure. (Note: incomplete number of assessments (n=24) reflects a change in clinical practice during the course of the study in which many institutions stopped using recirculation fractions to monitor patients).
Stent Restenosis = within stent %DS of 50% or greater, or in the absence of angiography, the presence of arm-face edema.
Stent Thrombosis = total thrombotic stent occlusion documented by angiography. (Note: Stent Thrombosis is a subset of stent restenosis).

Additional clinical efficacy data was also retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. The enrollment criteria for this study were similar to the multi center WALLSTENT Venous Endoprosthesis central lesion study.

A Kaplan-Meier Survival analysis estimated the six-month circuit secondary patency, stent primary patency, and stent secondary patency rates at 68.6%, 33.8%, and 75%, respectively, for this patient cohort.

10.1.6. Central Venous - Observed Adverse Events:

A total of 42 patients were enrolled in the multi-center study of WALLSTENT Venous Endoprosthesis for central lesions. This study was conducted at 12 investigational sites.

Patients from the WALLSTENT Venous Endoprosthesis study form the basis of the observed events described in Table 10.1.2.

Five (5) patients enrolled in the WALLSTENT Venous Endoprosthesis Study died during the trial. None of these deaths occurred in the first 6 months following the WALLSTENT procedure and none were considered device related. The cause of death was reported as follows: (1) hyperkalemia 475 days post procedure; (2 and 3) cardiac arrest at 343 and 631 days post procedure; (4) septicemia with peripheral vascular disease and gangrene 902 days post procedure; (5) stomach cancer 276 days post procedure.

Table 10.1.2. Safety Results, WALLSTENT Venous Endoprosthesis Central Lesion Endoprosthesis Central Patients (n=42)

Adverse Event	Result	95% C.I.
General Events		
Death	11.9% (5/42)	[4.0%, 25.6%]
Surgical Revision	4.8% (2/42)	[0.6%, 16.2%]
Access abandoned from central lesion	40.5% (17/42)	[25.6%, 56.7%]
Access abandoned from peripheral graft	21.4% (9/42)	[10.3%, 36.8%]
Non-Stent-Related Events		
Graft Occlusion/Restenosis	45.2% (19/42)	[29.8%, 61.3%]
Pseudoaneurysm	16.7% (7/42)	[7.0%, 31.4%]
Infection	14.3% (6/42)	[5.4%, 28.5%]
Hematoma	4.8% (2/42)	[0.6%, 16.2%]
Stent-Related Events		
Stent Restenosis	76.2% (32/42)	[60.5%, 87.9%]
Stent Thrombosis	50.0% (21/42)	[34.2%, 65.8%]
Migration	2.4% (1/42)	[0.1%, 12.6%]
Edema	40.5% (17/42)	[25.6%, 56.7%]

Results are percent (count/sample size) of all patients experiencing the event, and reflect each patient's entire study experience regardless of length of follow-up.
Mean ± SD (sample size) (min, max) length of follow-up in days; 350.5±299.4 (42) (4.0, 1434). Confidence intervals are based on exact limits.

Note: Surgical revision refers to those events where the graft was revised, but not abandoned. Patients reporting edema are a subset of patients with stent restenosis/thrombosis.

Additional clinical safety data were retrospectively obtained on 12 patients enrolled in a physician's registry study of the WALLSTENT Venous Endoprosthesis for the treatment of stenotic or occluded subclavian veins of patients undergoing hemodialysis. Four deaths were reported among these 12 patients. The reported cause and time of occurrence of these deaths is: sepsis at 16 days post-procedure, aspiration pneumonia at 32 days post-procedure, myocardial infarction/subdural hematoma at 81 days post-procedure, and hypotension at 240 days post procedure.

Adverse events related to either the stent or the stent implant procedure included stent thrombosis (5), stent restenosis (8), stent migration (3), and an allergic reaction to contrast media (1). The three stent migrations in this physician single-center study and the one stent migration in the multi-center WALLSTENT Venous Endoprosthesis central lesion study were attributed to incorrect sizing of the stent and/or dislodgment with the guide catheter. All of the stent migration cases were treated with a percutaneous procedure and none resulted in abandonment of the access site.

10.1.7. 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.

10.1.8. Observed Device Malfunctions:

Two incidents of stent malfunction were reported in the central venous lesion study. In one incident, the delivery system failed to deploy. In the second incident, the stent did not fully expand.

10.2. Clinical Literature Summary and Analyses

Boston Scientific has compiled a comprehensive literature summary for iliac venous stenting. With studies and registries that represent thousands of patients, this provides supporting clinical evidence for the safe and effective use of VENOUS WALLSTENT to treat symptomatic iliofemoral venous outflow obstruction.

10.2.1. Literature Summary:

This literature review is focused on obtaining relevant clinical data, to provide a critical review of the published information relevant to safety and performance of the VENOUS WALLSTENT.

Table 10.2.1. Literature Summary

Biblio. Reference[a]	Publication
1	Neglen P, Berry MA, Raju S. Endovascular surgery in the treatment of chronic primary and post-thrombotic iliac vein obstruction. *Eur J Vasc Endovasc Surg. 2000;20(6):560-571.*
2	Neglen P, Raju S. Balloon dilation and stenting of chronic iliac vein obstruction: technical aspects and early clinical outcome. *J Endovasc Ther. 2000;7(2):79-91.*
3	Lamont JP, Pearl GJ, Patetsios P, *et al.* Prospective evaluation of endoluminal venous stents in the treatment of the May-Thurner syndrome. *Ann Vasc Surg. 2002;16(1):61-64.*
4	Raju S, McAllister S, Neglen P. Recanalization of totally occluded iliac and adjacent venous segments. *J Vasc Surg. 2002;36(5):903-911.*
5	Neglen P, Thrasher TL, Raju S. Venous outflow obstruction: An underestimated contributor to chronic venous disease. *J Vasc Surg. 2003;38(5):879-885.*
6	Kwak HS, Han YM, Lee YS, Jin GY, Chung GH. Stents in common iliac vein obstruction with acute ipsilateral deep venous thrombosis: early and late results. *J Vasc Interv Radiol. 2005;16(6):815-822.*
7	Raju S, Neglen P. High prevalence of nonthrombotic iliac vein lesions in chronic venous disease: a permissive role in pathogenicity. *J Vasc Surg. 2006;44(1):136-143; discussion 144.*
8	Neglen P, Hollis KC, Olivier J, Raju S. Stenting of the venous outflow in chronic venous disease: long-term stent-related outcome, clinical, and hemodynamic result. *J Vasc Surg. 2007;46(5):979-990.*
9	Husmann MJ, Heller G, Kalka C, *et al.* Stenting of common iliac vein obstructions combined with regional thrombolysis and thrombectomy in acute deep vein thrombosis. *Eur J Vasc Endovasc Surg. 2007;34(1):87-91.*
10	Oguzkurt L, Tercan F, Ozkan U, Gulcan O. Iliac vein compression syndrome: outcome of endovascular treatment with long-term follow-up. *Eur J Radiol. 2008;68(3):487-492.*
11	Raju S, Neglen P. Percutaneous recanalization of total occlusions of the iliac vein. *J Vasc Surg. 2009;50(2):360-368.*
12	Kolbel T, Lindh M, Akesson M, Wasselius J, Gottsater A, Ivancev K. Chronic iliac vein occlusion: midterm results of endovascular recanalization. *J Endovasc Ther. 2009;16(4):483-491.*
13	Hartung O, Loundou AD, Barthelemy P, Arnoux D, Boufi M, Alimi YS. Endovascular management of chronic disabling ilio-caval obstructive lesions: long-term results. *Eur J Vasc Endovasc Surg. 2009;38(1):118-124.*
14	Rosales A, Sandbaek G, Jorgensen JJ. Stenting for chronic post-thrombotic vena cava and iliofemoral venous occlusions: mid-term patency and clinical outcome. *Eur J Vasc Endovasc Surg. 2010;40(2):234-240.*
15	Alimi Y, Hartung O. Endovascular treatment of chronic ilio-caval occlusion. *Italian J Vasc Endovasc Surg. 2010;17:199-205.*
16	Raju S, Darcey R, Neglen P. Unexpected major role for venous stenting in deep reflux disease. *J Vasc Surg. 2010;51(2):401-408; discussion 408.*
17	Gutzeit A, Zollikofer Ch L, Dettling-Pizzolato M, Graf N, Largiader J, Binkert CA. Endovascular stent treatment for symptomatic benign iliofemoral venous occlusive disease: long-term results 1987-2009. *Cardiovasc Intervent Radiol. 2011;34(3):542-549.*
18	Kurklinsky AK, Bjarnason H, Friese JL, *et al.* Outcomes of venoplasty with stent placement for chronic thrombosis of the iliac and femoral veins: single-center experience. *J Vasc Interv Radiol. 2012;23(8):1009-1015.*
19	Ye K, Lu X, Li W, *et al.* Long-term outcomes of stent placement for symptomatic nonthrombotic iliac vein compression lesions in chronic venous disease. *J Vasc Interv Radiol. 2012;23(4):497-502.*
20	Nayak L, Hildebolt CF, Vedantham S. Postthrombotic syndrome: feasibility of a strategy of imaging-guided endovascular intervention. *J Vasc Interv Radiol. 2012;23(9):1165-1173.*
21	DeRubertis BG, Alktaifi A, Jimenez JC, Rigberg D, Gelabert H, Lawrence PF. Endovascular management of nonmalignant iliocaval venous lesions. *Ann Vasc Surg. 2013;27(5):577-586.*
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23	Liu Z, Gao N, Shen L, *et al.* Endovascular treatment for symptomatic iliac vein compression syndrome: a prospective consecutive series of 48 patients. *Ann Vasc Surg. 2014;28(3):695-704.*
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32	Daugherty SF, Gillespie DL. Venous angioplasty and stenting improve pelvic congestion syndrome caused by venous outflow obstruction. *J Vasc Surg Venous Lymphat Disord. 2015;3(3):283-289.*
33	Ganelin A, Hingorani A, Ascher E, *et al.* Complications with office-based venoplasties and stenting and their clinical correlation. *J Vasc Surg Venous Lymphat Disord. 2015;3(4):376-379.*
34	Ahmed O, Ng J, Patel M, *et al.* Endovascular Stent Placement for May-Thurner Syndrome in the Absence of Acute Deep Vein Thrombosis. *J Vasc Interv Radiol. 2016;27(2):167-173.*
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37	Gagne PJ, Gagne N, Kucher T, Thompson M, Bentley D. Long-term clinical outcomes and technical factors with the Wallstent for treatment of chronic iliofemoral venous obstruction. *J Vasc Surg Venous Lymphatic Disord. 2018; 7(1):44-55.*

[a] Shading indicates publications that use WALLSTENT exclusively.

10.2.2. Safety Outcomes:

Safety outcomes were evaluated differently by the various studies reported in the literature. For many articles, no prospective definition of Major Adverse Events (MAE) was specified. For the purposes of the literature analysis MAEs were collated as reported by the individual articles without reconciling the definitions. For the 21 Wallstent-exclusive studies, representing 2,268 patients, a total of 18 MAEs were reported. Furthermore, no device or procedure related deaths were reported.

A summary of adverse events observed literatures compiled by category are found in Table 10.2.2.

Table 10.2.2. Adverse events found in the published literature by category.

Adverse Event Category	Number of Events	Timings
Overall Event Rate	**307**	
Target vessel revascularization	204	To extent of follow-up
†Other	31	<30 days
Early occlusion of stented area	23	<30 days
Deep vein thrombosis involving the treated limb	17	<30 days
Embolization or migration of stent	11	To extent of follow-up
Deep vein thrombosis involving contra-lateral limb	7	<30 days
Vascular injury requiring surgical or endovascular intervention	7	<30 days
Major bleeding event (including access site complications and retroperitoneal hematoma)	6	<30 days
Stent fracture	1	To extent of follow-up
Pulmonary embolism	0	<30 days
Major amputation of target limb	0	To extent of follow-up
Device and/or procedure related death	0	To extent of follow-up

Studies including stents other than WALLSTENT are excluded. Note for the overall rate that some events are duplicative. For example, an early occlusion of the stented area may also result in a target vessel revascularization event.
†Other: Non-MAEs that do not fit any other category. These include: undefined non-thrombotic complications, minor access site bleeding, contrast extravasation, hematomas at access site, and peripheral sensory nerve lesion.

10.2.3. Effectiveness Outcomes:

Patency was calculated using a weighted average. A summary of the weighted average analyses is presented below in Table 10.2.3. In this table, an additional analysis of weighted averages for all studies, including non-Wallstent exclusive studies, is included for comparative purposes. In summary, the weighted mean 1-year patency rate for studies exclusively using Wallstent is 86.6%. The weighted mean 1-year patency rate for all studies, including non-Wallstent exclusive studies, is 86.8%.

Table 10.2.3. Weighted Mean 1-year primary patency for groups of interest.

	Weighted Mean 1 - Year Patency % [95% CI]	
Group Description	**For studies using Wallstent ONLY**	**All Studies**
All Studies	86.6 [77.0, 92.6]	86.8 [81.1, 91.0]
Studies with NIVL patients only	90.5 [80.3, 95.7]	88.4 [82.4, 92.5]
Studies with PTS patients only	67.9 [44.4, 84.8]	78.5 [62.5, 88.9]
Studies with mixed NIVL & PTS patient populations	88.4 [84.5, 91.3]	89.3 [87.5, 90.9]
Retrospective Studies	84.7 [72.9, 91.9]	85.0 [77.5, 90.3]
Prospective Studies	92.5 [85.7, 96.2]	90.2 [88.2, 91.9]
USA patient population	80.2 [54.5, 93.2]	84.4 [71.3, 92.2]
Non-US patient population	88.8 [84.9, 91.7]	88.4 [85.1, 91.0]
Mean baseline CEAP score ≥4	84.8 [49.8, 96.9]	---
Mean baseline CEAP score <4	85.5 [81.1, 89.0]	---

Studies that did not report a 1-year primary patency rate are excluded. Weighted for number of patients in each study. Weighted means were calculated using the Random Effects model.

10.2.4. Literature Summary Conclusion:

Boston Scientific has compiled an extensive literature summary comprised of 37 single data set peer-reviewed articles and one meta-analysis and of those, 21 used Wallstent exclusively. Analyses to demonstrate the effectiveness and safety of VENOUS WALLSTENT™ were provided; these analyses and discussions provide extensive evidence that VENOUS WALLSTENT is safe and effective for the treatment of iliofemoral venous outflow obstruction.

10.3. Iliofemoral Study

Supplementary to the literature summary detailed in Section 10.2. a single-site iliofemoral study was analysed to provide a greater level of detail regarding patient outcomes than was available within the literature summary. In this study a total of 67 patients (77 limbs) that presented with venous outflow obstruction and were treated with one or more WALLSTENT™ Endoprosthesis (WALLSTENT) were evaluated at a single centre. Charts were used to access physician evaluations of the patient chronic venous hypertension, venous duplex ultrasound study results, and CT venography results. This enabled access to pre-procedure and post-procedure evaluations and imaging studies. Intraoperative findings and complications were recorded from hospital operative reports. There were 126 WALLSTENTs implanted and evaluated in this study.

10.3.1. Primary Objective:

The study was an observational, retrospective, non-randomized study to evaluate the procedure, patency rates and clinical outcomes of endovascular therapy using the WALLSTENT for venous occlusions and compression syndromes in chronic venous outflow obstruction. The main objective of the trial was to test the hypothesis that large caliber WALLSTENTs used for treating chronic venous outflow obstruction in the iliac and common femoral veins are effective for resolving the symptoms of severe chronic venous hypertension and are associated with high patency and very low complication rates.

10.3.2. Patient Eligibility:

Patients were eligible for the study if they were at least 18 years of age and determined to have signs and symptoms consistent with chronic venous hypertension in the legs, not ascribed to superficial venous insufficiency, had a placement of an iliofemoral vein WALLSTENT and had a CEAP score of 3-6. Exclusion criteria included patients with acute or subacute deep vein thrombosis (DVT) less than eight weeks from the index procedure and patients who had stents placed for chronic outflow obstruction from chronic DVT and who terminated their anticoagulation independent of medical advice. Patients were also excluded if they had iliofemoral obstruction due to neoplasm.

10.3.3. Study Methods:

Intravascular ultrasound and venography were used to assess lesion type and extent. Baseline clinical severity was assessed with venous clinical severity score (VCSS) and CEAP classification. The subjects were followed in accordance with the standard of care schedule of 30-day, 6-, 12-, 24- and 36-month evaluations. Standard testing at each visit included a clinical assessment, ultrasound, VCSS and CEAP determination and adverse events collection. VCSS score change ≥4 points was considered significant improvement. Patency was assessed with duplex ultrasound per standard of care to determine if the stent was open or closed. Patients continued to be followed through 72 months and effectiveness data is also presented through the 72-month evaluation.

10.3.4. Results:

Enrollment included 67 patients and 77 limbs. Lesions were non-thrombotic (NT) in 42 limbs (55%) and left-sided in 48 limbs (62%). Ten patients were treated for bilateral venous disease. Patients were predominantly male (55%); median age was 63 years (range, 47-83 years). Median baseline VCSS was 9 (range, 3-23). IVUS and venography estimated equal vessel compromise length in 37 limbs (48%). IVUS estimated a longer lesion in 32 limbs (42%). Stenting correlated with venogram and IVUS in 37 limbs (48%), and more closely aligned with IVUS in 35 limbs (45%). Stents extended into the common femoral vein (CFV) in 17 limbs (22%) and into the inferior vena cava (IVC) in 6 limbs (8%). Sixty-five (97%) patients had available imaging follow-up (median, 50 months). At 72 months, primary patency in the overall cohort was 87%; assisted-primary and secondary patency were both 95%. In the NT subset, primary patency was 97%, assisted-primary and secondary patency were 100%. In the post-thrombotic (PT) subset, primary patency was 75%; assisted-primary and secondary patency were 88%. Three early failures (within 30 days of the index procedure) occurred. Eight patients required reintervention (range, 0.5-80 months); 5 interventions were to maintain patency. Cox multivariate regression identified CFV disease predicted later complications. At last VCSS follow-up per patient (median, 26 months), 52 patients (68%) showed ≥ 4-point VCSS improvement. No patient had a worsening of the VSCC score.

Baseline characteristics are provided in **Table 10.3.1.** and **Table 10.3.2.**

Table 10.3.1. Baseline Demographics and Clinical Characteristics

Parameter	Median (range) or no. (%) (N= 67 pts, 77 limbs)
Age, years	63 (47-83)
Female	30/67(45%)
DVT history	27/67(40%)
Thrombophilia	2/67 (3%)
Phlebitis	6/54 (11%)
Diabetes	16/65 (25%)
HTN	29/61 (48%)
Smoking (current or prior)	32/65 (49%)
Compression therapy	19/67 (28%)
No. receiving bilateral treatment	10/67 (15%)
Post-thrombotic	35/77 (45%)
Non-thrombotic	42/77 (55%)
No. treated left limbs	48/77 (62%)
No. treated right limbs	29/77 (38%)
CEAP classification	
3	25/77 (33%)
4	16/77 (21%)
5	8/77 (10%)
6	28/77 (36%)
VCSS Score	9 (3-23)
Vessels occluded as determined by IVUS and/or venography[a]	13/77 (17%)

CEAP, clinical-etiologic-anatomic-pathophysiologic; DVT, deep vein thrombosis; HTN, hypertension; IVUS, intravascular ultrasound; VCSS, venous clinical severity score. Continuous variables are reported as median (range) and categorical variables are reported as number (percentage).
[a] Because there was no protocol-driven definition for occlusion, multiple imaging modalities were used for determination (e.g., DUS, venography and IVUS)

Table 10.3.2. Procedural Characteristics of 77 Stented Limbs

	Median (range) or no. (%)
Access vessel[a]	
FV	40/78 (51%)
CFV	14/78 (18%)
PV	24/78 (31%)
No. stents	126
Left limb stents	80/126 (63%)
Right limb stents	46/126 (37%)
Number of patients with unilateral stents	57
Number of patients with bilateral stents	10
No. stents per patient (mean)	1.9
Stent location	
Isolated CIV	18/77 (23%)
Isolated EIV	11/77 (14%)
Isolated CFV	1/77 (1%)
CIV/EIV	28/77 (36%)
EIV/CFV	6/77 (8%)
IVC/CIV/EIV	3/77 (4%)
CIV/EIV/CFV	7/77 (9%)
IVC/CIV/EIV/CFV	3/77 (4%)
Lesion[b] traversing >1 segment	47/77 (61%)
Lesion extending into the CFV	17/77 (22%)
Lesion extending into the IVC	6/77 (8%)
Post-dilatation[c]	75/75 (100%)

CFV, common femoral vein; CIV, common iliac vein; EIV, external iliac vein; FV, femoral vein; IVC, inferior vena cava; PV, popliteal vein.
Continuous variables are reported as median (range) and categorical variables are reported as number (percentage).
[a]Seventy-eight (78) access vessels were required (10 bilateral patients and 1 patient requiring multiple access vessels).
[b]Lesion was subjectively determined by operator without specific criteria.
[c]Two patients are missing post-dilatation data; however, physician standard of care was to always balloon following stent placement.

Table 10.3.3. includes site-reported data on early failures, complications and re-interventions for the study.

Table 10.3.3. Summary of Complications

	Time from Index Procedure	Description
< 30 Days	7 days	82-year-old female with chronic post-thrombotic scar (popliteal vein to common iliac vein [CIV]), was implanted with two stents in the CIV and external iliac vein, which closed at 1 week. The patient refused reintervention and died of unknown causes remote to the intervention.
	14 days	50-year-old male with bilateral post-thrombotic occlusive scar (inferior vena cava [IVC] to CFVs bilaterally). The patient received four stents in each limb, with all eight stents closing at 2 weeks. Further revascularization was not attempted.
	20 days	59-year-old male with protein C deficiency and right leg post-thrombotic stenosis and scarring (popliteal vein-CIV), two stents were implanted from the CIV to the CFV. The stents were occluded 2 weeks later. The patient declined reintervention and was lost to follow-up after 4 weeks.
	0.5 Months	54-year-old male with acute DVT of contralateral (right) limb and subsequent jailing of right CIV. Right stent implantation, angioplasty.
<12 months	4 Months	69-year-old female developed an acute DVT in left limb; stents showed non-occlusive thrombus. Thrombolysis and additional left stent placed.
	5 Months	65-year-old female with an ipsilateral (left) leg ulcer never healed. Left fem-pop arterial bypass with ipsilateral GSV.
> 12 months	17 Months	62-year-old male with onset of new symptoms, morbid obesity; compression observed in EIV. Additional ipsilateral (left) stent placed.
	30 Months	76-year-old-male original stent stenosed and fractured, likely due to ending stent at inguinal ligament and tissue fibrosis from radiation treatment in pelvis for prostate cancer[a]. Two additional ipsilateral (left) stents placed.
	50 Months	60-year-old male original stent patent but exhibited narrowing and proximal scarring; compression noted proximal to the stent. Two additional ipsilateral (right) stents placed.
	72 Months	61-year-old male with right CIV jailed due to left stent implanted high in IVC. Contralateral (right) stent placed through ipsilateral (left) stent to return flow.
	92 Months	68-year-old male with left stents compressing right limb (also previously stented), jailing right CIV. Two additional right stents placed.

CIV, Common iliac vein; DVT, deep vein thrombosis; EIV, external iliac vein; fem-pop, femoral-popliteal; GSV, great saphenous vein; IVC, inferior vena cava.
All additional stents implanted were Wallstent.
[a]The fracture was at the caudal end of the stent under the inguinal ligament.

10.3.5. Major Adverse Events:

The safety outcome for this study was observed procedural and long-term complications related to WALLSTENT. Comparing the observed instances of 30-day MAEs in the table below, using definitions from approved venous stents in the literature, the rate of 30-day MAE events was 6% (4/67).

Table 10.3.4. Major Adverse Events at 30 Days

Major Adverse Event Criteria	Rate n/N (%)
Major Adverse Events within 30 days[a]	4/67 (6.0%)[1.7, 14.6]
Device or procedure-related death	0/67 (0.0 %)
Target vessel revascularization	1/67 (1.5%)
Major amputation of target limb	0/67 (0.0 %)
Stent thrombosis or Device- or procedure-related DVT	4/67 (6.0%)
Vascular reinjury requiring surgical/endovascular intervention[b]	0/67 (0.0 %)
Major bleeding event[c]	0/67 (0.0 %)
Pulmonary embolism[d]	0/67 (0.0 %)
Embolization within stent	0/67 (0.0 %)

DVT – Deep vein thrombosis; CI – Confidence Interval, two-sided Clopper-Pearson exact method
[a]Subjects with ≥ 1 event
[b]Device or procedure-related arterial or venous injury occurring in the target vessel segment and/or target lesion location or at the access site requiring surgical or endovascular intervention.
[c]Device or procedure-related bleeding at the target vessel and/or the target lesion or at the access site requiring surgical or endovascular intervention or blood transfusion ≥2 units.
[d]Clinically significant pulmonary embolism defined as being symptomatic with chest pain, hemoptysis, dyspnea, hypoxia etc. and documented on CT.

Table 10.3.5. includes the patency data for this study. Ninety-seven percent (65/67) of patients had available imaging follow-up (median, 50 months). At 12 months, primary, primary-assisted, and secondary patency were 93%, 95%, and 95%, respectively. Primary, primary-assisted, and secondary patency at 72 months were 87%, 95%, and 95%, respectively.

Table 10.3.5. Effectiveness Endpoints: Patency

	12 Months (all; NT[1]; PT[2])	24 Months (all; NT; PT)	36 Months (all; NT; PT)	72 Months (all; NT; PT)
Primary Patency	93.2%;100.0%; 84.8%	91.7%;100.0%; 84.8%	89.9%;97.4%; 81.2%	87.4%;97.4%; 74.9%
Primary Assisted Patency	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%
Secondary Patency	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%	94.6%;100.0%; 87.9%
[1]Non-thrombotic, [2]Post-thrombotic				

Clinical Improvement was also evaluated in this study. CEAP 3 (venous edema) patients had the least predictable response to iliofemoral venous stenting. There were 25 clinical CEAP 3 limbs; 15 (60%) had index leg pain and 15 (60%) wore compression garments pre-stent. Post stent, venous edema had resolved in 11/25 (44%) limbs, and pain remained in only 2/25 (8%) limbs. Venous edema had decreased (21/25, 84%) or stayed the same (4/25, 16%) in all patients. Of the 15/25 (60%) patients who did not wear compression therapy post stent, 8/15 (53%) had no venous edema or pain.

Table 10.3.6. presents clinical improvement by VCSS score. All patients underwent follow-up VCSS assessment within 36 months post index procedure, with 36 limbs (32 patients) undergoing multiple VCSS assessment. At each visit window, a majority exhibited significant clinical improvement of 4 points or more (75%, 62%, and 66%, respectively). Only 1 patient (1%) exhibited score worsening over follow-up, which resolved by a subsequent visit. The median VCSS score change at last available VCSS follow-up was 5 points improvement (range, 0-17 points improvement). At last follow-up, 52 patients (68%) were observed with VCSS score improvement ≥ 4 points. Seven patients (9%) exhibited no score change. No patient had a worsening of the VSCC score. VCSS scores at each follow-up window and at last available follow-up were significantly lower than baseline VCSS scores (P < .001) for all comparisons.

Table 10.3.6. Clinical Outcomes (VCSS)

Parameter	Baseline N=77	12 Months N=52[a]	24 Months N=29[b]	36 Months N=32[c]	Last Follow-up N=77[d]
VCSS score	9 (3-23)	3 (0-16)	4 (0-16)	4.5 (0-17)	4 (0-17)
VCSS score change		5 (0-14)	4 (1-12)	5 (0-13)	5 (0-14)

Continuous variables are reported as median (range). Categorical variables are reported as number (%).
[a] Median follow-up of the 52 limbs (46 patients) at this interval was 12 months (range, 0.25-20 months).
[b] Median follow-up of the 29 limbs (25 patients) in this window was 24 months (range, 18-29 months).
[c] Median follow-up of the 32 limbs (29 patients) in this window was 36 months (range, 32-42 months).
[d]The final follow-up assessment for each patient occurred at a median 26 months (range, 0.25-42 months). Thirty-six limbs in 32 patients had multiple VCSS assessments in follow-up.

10.3.6. Conclusion:

This retrospective, single-arm, non-randomized, study was designed to evaluate the procedure, patency rates, clinical outcomes of endovascular therapy using the WALLSTENT system for venous occlusions and compression syndromes in chronic venous insufficiency. The results of the study show that venous stenting with WALLSTENTs for iliofemoral post-thrombotic or compressive obstruction proved safe and effective through long-term follow-up with excellent patency rates. The majority of patients exhibited significant clinical improvement. Common femoral vein occlusive disease predicts increased complications.

11. PATIENT SELECTION AND TREATMENT

11.1. Individualization of Treatment

The risks and benefits of using the VENOUS WALLSTENT™ should be carefully considered for each patient before use. Stenting is generally avoided in those patients at heightened risk of bleeding (see CONTRAINDICATIONS).

Premorbid conditions that increase the risk of a poor initial result should also be considered. The relationship of baseline and procedural variables to failure of circuit secondary patency was examined. Presence of an occluded lesion pre-procedure was the only statistically significant predictor for failure of circuit secondary patency. Implantation of multiple stents approached significance in one analysis.

12. HOW SUPPLIED

The VENOUS WALLSTENT is supplied sterile and intended for single use only.

The VENOUS WALLSTENT is sterilized by ethylene oxide gas.

The VENOUS WALLSTENT System is non-pyrogenic.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

12.1. Handling & Storage

Do not expose delivery catheter to organic solvents, e.g., isopropyl alcohol. Such an exposure can cause delivery catheter to become brittle. Rotate inventory so that products are used prior to the "Use By" date on package label.

Store in a cool, dry, dark place.

13. PREPARATION AND OPERATIONAL INSTRUCTIONS

Table 13.1. Sizing Chart

Fully Open Dimensions (As labeled on box)	Approximate Implanted Stent Length At Various Inner Diameters						Delivery System
Outer Diameter (mm) x Length (mm)	Nominal Lumen Inner Diameter (mm)	Stent Length (mm)	Nominal Lumen Inner Diameter (mm)	Stent Length (mm)	Nominal Lumen Inner Diameter (mm)	Stent Length (mm)	Catheter Size F (mm)
10 x 20	9.0	27	8.0	33	7.0	38	6 (2.00)
10 x 42 10 x 68 10 x 94	9.0	48 69 103	8.0	54 77 115	7.0	58 83 124	7 (2.33)
12 x 20 12 x 40 12 x 60 12 x 90	11.0	26 47 66 100	10.0	31 51 73 110	9.0	36 55 79 119	8 (2.67)
14 x 20 14 x 40 14 x 60 14 x 90	13.0	27 46 65 98	12.0	33 50 72 107	11.0	38 54 77 115	9 (3.00)
16 x 20 16 x 40 16 x 60 16 x 90	15.0	23 45 64 97	14.0	28 49 70 105	13.0	32 52 75 112	9 (3.00)
18 x 40 18 x 60 18 x 90	17.0	45 64 95	16.0	48 69 103	15.0	51 73 110	10 (3.33)
20 x 40 20 x 55 20 x 80	19.0	40 57 86	18.0	44 63 94	17.0	47 68 102	10 (3.33)

Refer to Table 7.1. for sizes by approved indication.

13.1. Principle of Operation

The exterior tube is easily retracted by immobilizing the stainless steel tube in one hand, grasping the valve body with the other hand, and gently sliding the valve body along the stainless steel tube. Retraction of the exterior tube permits the open end of the exterior tube to release the constrained stent. A single operator can thus control deployment and implant the stent.

The deployment process can be reversed if repositioning is desired. The stent can be reconstrained by the exterior tube if the stent deployment threshold has not been exceeded. (The stent deployment threshold or point beyond which the stent cannot be reconstrained, is identified by the location of the limit marker band [Figure A.]). Once reconstrained, the stent can be repositioned either distally or proximally and the deployment process restarted. Reversing the deployment process can be completed twice, allowing a total of three deployment attempts.

13.2. Preparation of the Delivery System for Insertion

Table 13.2.1. Recommended Material for Implant:

Prepare the following material using sterile technique:

VENOUS WALLSTENT™ Delivery System	Recommended Hemostatic Introducer Sheath	
Outer Diameter (F)	Inner Diameter (F)/mm	Approx. Length (cm)
6	6F/2.0 mm	10 - 12
7	7F/2.3 mm	
8	9F/3.0 mm	
9	10F/3.3 mm	
10	11F/3.7 mm	
10 ml (cc) syringe filled with sterile saline		
0.035 in (0.89 mm) guidewire of appropriate length		

13.2.2. Device Selection:

Calculate the existing lesion length, allowing for possible lesion development. Also, allow for shortening of the stent due to continued stent expansion post-implant.

After considering the nominal implanted diameter of the stent, select a stent that is longer than the minimum length that would provide adequate lesion coverage (refer to Table 13.1.). Should two stents be required to cover the lesion, place the distal stent first, followed by the proximal stent, and allow for generous overlapping.

Deployed lengths reflect expansion to desired vessel diameter. Constricting the stent to a smaller diameter will cause a longer deployed length, depending on the degree of constriction. On average, a 0.5 mm change in diameter yields a 10% -15% change in length. Once the desired vessel diameter is reached, no additional reduction in stent length should occur.

13.2.3. Initial Preparation of the Device:

- Carefully remove the delivery system from its protective packaging.
- Visually inspect the entire device for damage or defects.
- Visually check that the leading end of the stent is covered by the exterior tube.
- Ensure that no stent wires have perforated the exterior tube.

13.2.4. Flushing the Delivery System:

- Attach a 10 ml (cc) syringe filled with sterile saline to the stopcock on the extension tube.
- Holding the device horizontally, open the stopcock and flush with saline to the tip of the delivery system.
- After priming the delivery system, close the stopcock and remove the syringe.
- Verify that the leading end of the stent is covered by the exterior tube. Do not use the device if the open end of the exterior tube has moved towards the proximal end, exposing stent wires. Proper device function cannot be assured during implant, and such use may cause vessel injury.

14. VENOUS PROCEDURE

1. Use radiopaque marker bands to identify the area to be dilated and stented.
2. Place an 0.035 in (0.89 mm) exchange guidewire percutaneously into the vessel to be treated.
3. Dilate the venous lesion with a balloon catheter measuring 10-20% less than the nominal stent diameter, using accepted technique and protocol.
4. Remove the balloon catheter, leaving the guidewire in place.
5. Having prepared the delivery system as previously described, insert the delivery system into the appropriate size introducer sheath and over the guidewire.

Note: Always use an introducer sheath for the implant procedure, to protect the puncture site, in the event a partially deployed stent were to be removed.

6. **Guidelines for Stent Positioning:**
   - Advance the stent across the site of the lesion, positioning the leading marker band a minimum of two (2) centimeters beyond the distal boundary of the dilated segment.
   - The radiopaque marker bands identify the constrained length of the stent. Since the stent shortens upon deployment, these markers should only be used as approximate markers of the final stent position. To assure precise stent placement, radioscopic visualization of the stent itself is necessary.
   - Maintain the delivery system as straight as possible during deployment of the stent.
7. To begin stent deployment, immobilize the stainless steel tube in one hand, grasp the valve body with the other hand, and gently slide the valve body along the stainless steel tube until the deployment threshold, identified by the location of the limit marker band, is reached.

Precaution: Do not push on the delivery system with the stent partially deployed. The stainless steel tube must be immobilized securely. Pushing on the delivery system will cause misalignment of the stent and possible tissue damage. The stent should deploy easily. Do not release the stent if unusual force is required, since this may indicate a failed device. To remove the instrument, see Step 10 of Section 14. VENOUS PROCEDURE.

8. Assess stent position and reposition if desired. To reposition, reconstrain the stent by holding the stainless steel tube stationary and gently sliding the valve body forward along the stainless steel tube. It may be necessary to guide the delivery system into the introducer sheath. Under fluoroscopy, the exterior tube marker band will be seen to move over the stent until even with the leading marker band. When fully constrained, the delivery system can be moved either proximally or distally and the deployment process restarted. Repositioning can be completed twice, allowing a total of three deployment attempts.

   As an alternative method for proximal repositioning only, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.

Note: To facilitate reconstrainment, the delivery system may be flushed with heparinized saline.

9. To complete stent deployment, immobilize the stainless steel tube with one hand, grasp the valve body with the other hand, and gently slide the valve body proximally along the stainless steel tube.

Precaution: A stent cannot be repositioned after the deployment threshold has been exceeded.

10. To remove a partially deployed stent, first reconstrain the stent (see Step 8 of Section 14. VENOUS PROCEDURE). If the stent cannot be reconstrained, remove the entire Stent/System as follows:

    Hold the Valve Body securely on the stainless steel tube and cautiously withdraw the Stent/System back toward and into the introducer sheath. The entire delivery system can be pulled into the introducer sheath. The delivery system and introducer sheath can then be removed, with the guidewire left in place.

    As an alternative method for stent removal, immobilize both the stainless steel tube and the valve body and pull the entire delivery system back.
11. After the stent is correctly positioned and fully deployed, the delivery system may be closed and removed. If desired, repeat balloon dilation inside the implanted stent may be performed to achieve nominal stent diameter. For this procedure, a new balloon dilatation catheter is recommended.
12. Using standard operative procedures, perform routine venography to demonstrate location and patency of the stent.
13. The implanted stent length should allow for adequate overlapping into the non-strictured vessel to compensate for further stent shortening. In the event the stent does not adequately cover the stricture, a second stent should be implanted providing adequate overlapping of the initially placed stent.

    If, prior to initial stent implantation, it is expected that a second stent will be necessary to cover the lesion, cover the distal end of the lesion with the first stent and use the second stent to cover the proximal portion of the lesion. This will minimize interference with placement of the second stent by the previously deployed stent.
14. When passing balloon catheters or additional (undeployed) stents within the lumen of an implanted stent, always use an introducer sheath to protect the balloon or delivery system.

15. PATIENT INFORMATION

The following patient materials are available for this product:

- A Patient Information Guide that includes information on Venous stenting (included in the package and available on-line at www.bostonscientific.com).
- A VENOUS WALLSTENT™ Patient Implant Card (attached to Patient Information Guide).

16. 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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