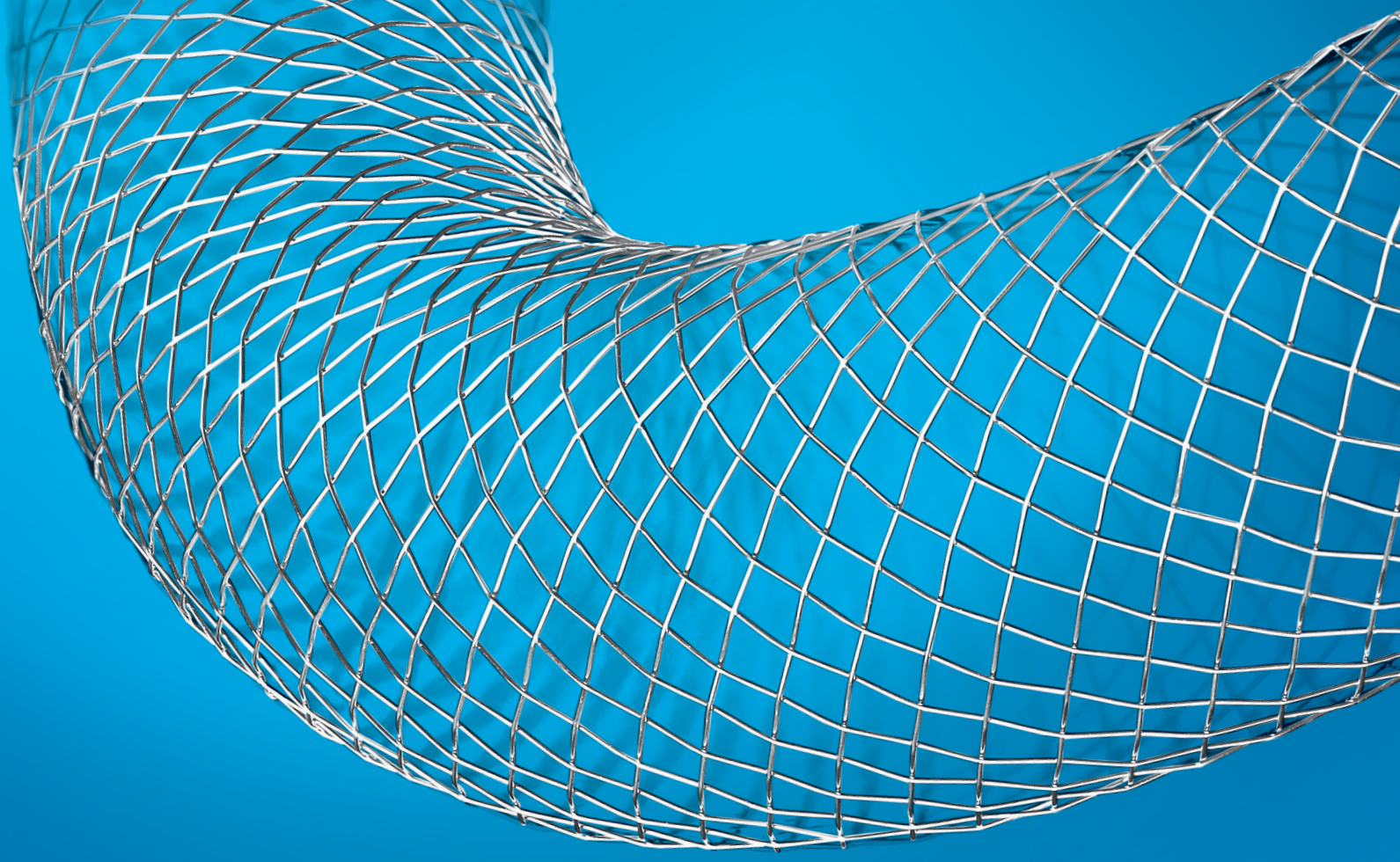
Boston Scientific
Advancing science for life™

VENOUS WALLSTENT™ SELF-EXPANDING STENT

Clinically Proven Case After Case



Backed by a decade of clinical data, Venous Wallstent Self-Expanding Stent delivers proven technology for the most challenging venous applications.

Unmatched Clincal Experience

The **safety and durability** of the Wallstent Self-Expanding Stent have been repeatedly validated.

This proven stent has demonstrated consistently low complication rates across all indicated uses.

It is indicated for improving luminal diameter in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

37

Publications reporting clinical results including Wallstent*

650K

Total stents sold

4,500

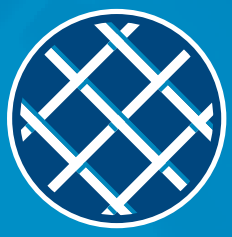
Patients with reported outcomes

*From 2000-2018

Dynamic, Innovative Design

HIGH DURABILITY

Venous Wallstent is specifically engineered to provide **fracture resistance.** It is designed to withstand the forces common in venous anatomy.



BRAIDED ARCHITECTURE

Braided design with Elgiloy® material provides **compression resistance** in venous anatomy. In addition, its reconstrainability eases placement.

UNIQUE CONFORMABILITY

The stent is designed for optimal **conformability** so it can be deployed effectively in curved and tapered vessels.

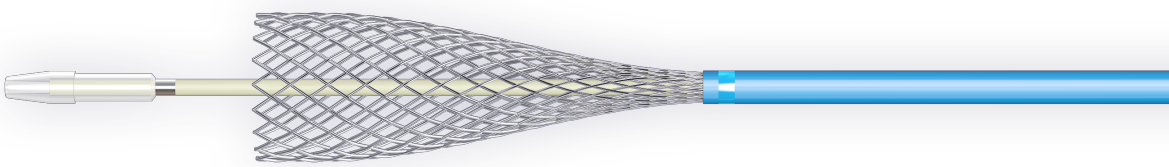
*Results for the WALLSTENT Endoprosthesis

Comprehensive Range of Sizes

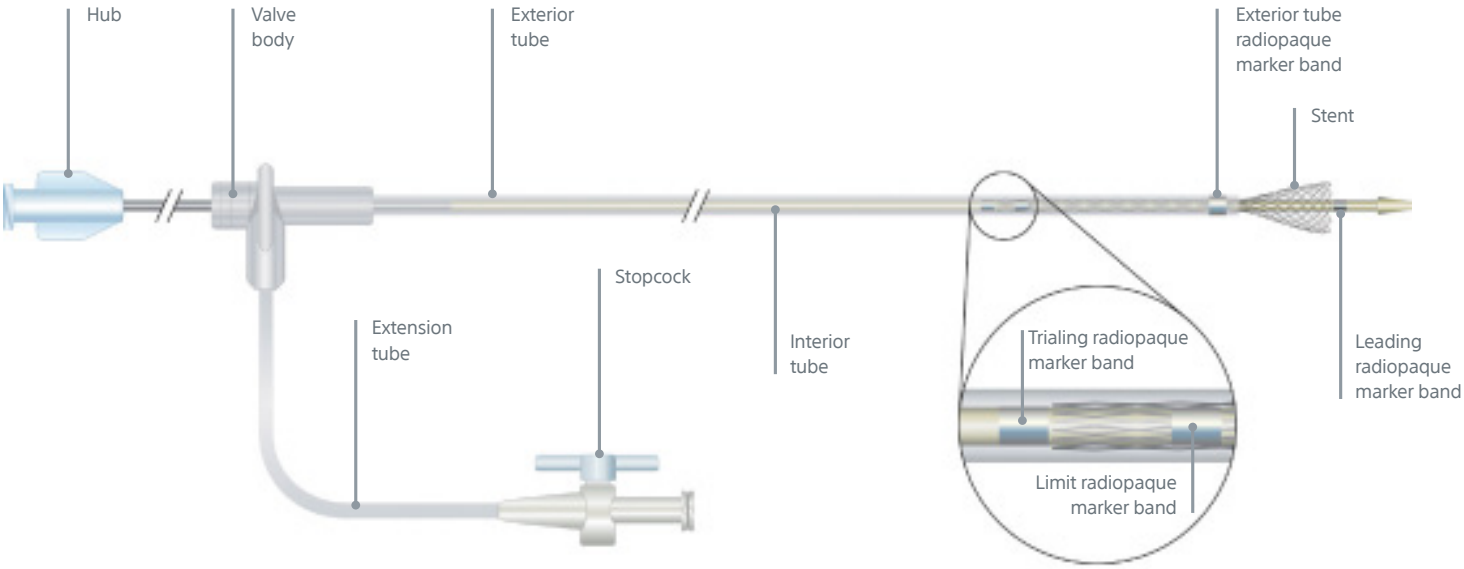
Diameters from 10 mm to 20 mm*

VENOUS WALLSTENT SELF-EXPANDING STENT | SKUs

Stent Diameter (cm)	SIZE / UPN	
10	10X20X75CM	H74912044102070
	10X42X75CM	H74912044104270
	10X68X75CM	H74912044106870
	10X94X75CM	H74912044109470
12	12X20X75CM	H74912044122070
	12X40X135CM	H74912044124010
	12X40X75CM	H74912044124070
	12X60X135CM	H74912044126010
	12X60X75CM	H74912044126070
	12X90X135CM	H74912044129010
	12X90X75CM	H74912044129070
14	14X20X75CM	H74912044142070
	14X40X75CM	H74912044144070
	14X60X75CM	H74912044146070
	14X90X75CM	H74912044149070
16	16X20X75CM	H74912044162070
	16X40X75CM	H74912044164070
	16X60X75CM	H74912044166070
	16X90X75CM	H74912044169070
18	18X40X75CM	H74912044184070
	18X90X75CM	H74912044189070
20	20X40X75CM	H74912044204070
	20X55X75CM	H74912044205570
	20X80X75CM	H74912044208070



VENOUS WALLSTENT SELF-EXPANDING STENT



VENOUS WALLSTENT™
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 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. **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. **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 (in the IFU) 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 individuals with nickel sensitivity. **PRECAUTIONS:** Do not advance a partially (≤50%) deployed stent. • 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). **MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION:** Non-clinical testing has demonstrated that 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. **RF Heating**: Under the scan conditions defined above, VENOUS WALLSTENT is expected to produce a maximum in-vivo temperature rise of 3.1° C after 15 minutes of continuous scanning. **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 lumen. **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. **ADVERSE EVENTS:** Adverse Events associated with 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 • Ischemia • Hypotension/hypertension • 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)
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