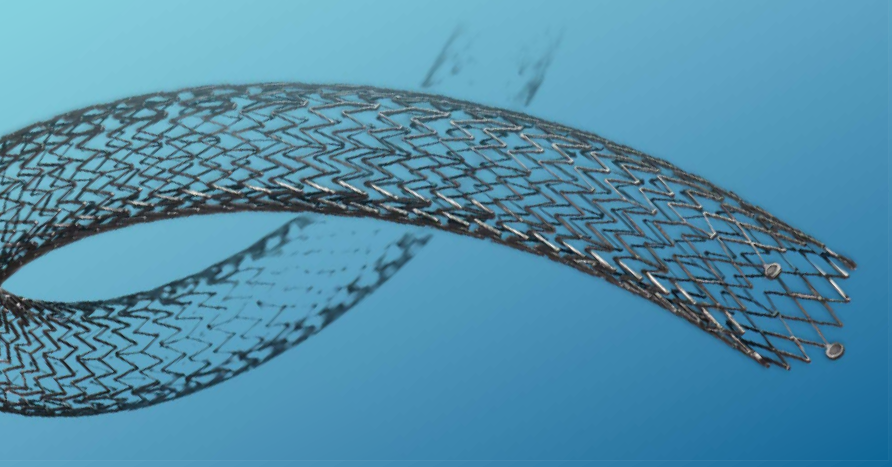


Boston Scientific
Advancing science for life™

INNOVA™ Vascular Self-Expanding Stent System

Intuitive by Design

The Innova Stent System is designed to provide a precise, predictable experience for vascular interventionalists. It is purpose-built for the treatment of SFA lesions and expertly engineered for smooth deployment and accurate placement.

88%

FREEDOM FROM TLR IN **SEVERELY CALCIFIED** LESIONS AT 2 YEARS*

Hybrid cell architecture

- Closed-cell ends for deployment stability and uniformity
- Open-cell center for flexibility and fracture resistance

Complete SFA size matrix

- Diameters 5 to 8 mm
- Lengths up to 200 mm

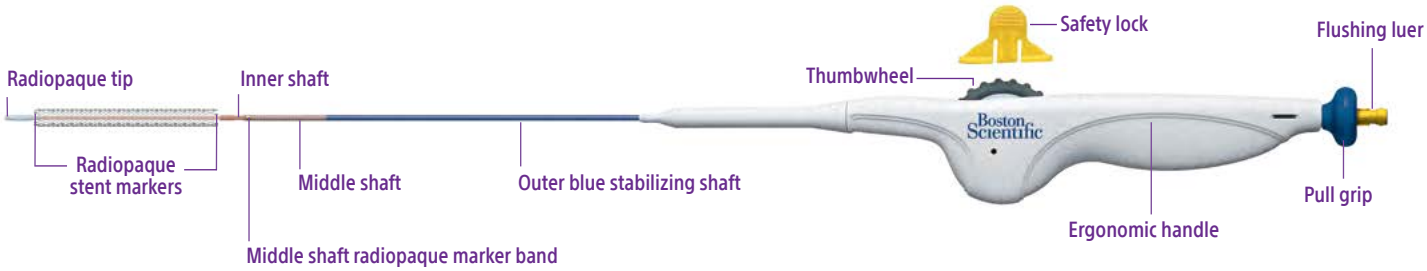
Triaxial delivery system

- Blue outer stabilizing shaft designed to control deployment forces and facilitate precise placement
- Middle shaft retracts to deploy stent

Learn more:
www.bostonscientific.com/Innovastent

*Powell RJ, et al. Stent placement in the superficial femoral and proximal popliteal arteries with the Innova self-expanding bare metal stent system. Catheter Cardiovasc Interv. 2017 May;89(6):1069-1077.

INNOVA™ Vascular Self-Expanding Stent System



Complete SFA Size Matrix

Stent Length (mm)	Stent diameter (mm)							
	5		6		7		8	
	Delivery system working length (cm)							
	75	130	75	130	75	130	75	130
20	H74939293050270 08714729873532	H74939293050230 08714729873891	H74939293060270 08714729873624	H74939293060230 08714729873983	H74939293070270 08714729873716	H74939293070230 08714729874072	H74939293080270 08714729873808	H74939293080230 08714729874164
40	H74939293054070 08714729873549	H74939293054030 08714729873907	H74939293064070 08714729873631	H74939293064030 08714729873990	H74939293074070 08714729873723	H74939293074030 08714729874089	H74939293084070 08714729873815	H74939293084030 08714729874171
60	H74939293056070 08714729873556	H74939293056030 08714729873914	H74939293066070 08714729873648	H74939293066030 08714729874003	H74939293076070 08714729873730	H74939293076030 08714729874096	H74939293086070 08714729873822	H74939293086030 08714729874188
80	H74939293058070 08714729873563	H74939293058030 08714729873921	H74939293068070 08714729873655	H74939293068030 08714729874010	H74939293078070 08714729873747	H74939293078030 08714729874102	H74939293088070 08714729873839	H74939293088030 08714729874195
100	H74939293051070 08714729873570	H74939293051030 08714729873938	H74939293061070 08714729873662	H74939293061030 08714729874027	H74939293071070 08714729873754	H74939293071030 08714729874119	H74939293081070 08714729873846	H74939293081030 08714729874201
120	H74939293051270 08714729873587	H74939293051230 08714729873945	H74939293061270 08714729873679	H74939293061230 08714729874034	H74939293071270 08714729873761	H74939293071230 08714729874126	H74939293081270 08714729873853	H74939293081230 08714729874218
150	H74939293051570 08714729873594	H74939293051530 08714729873952	H74939293061570 08714729873686	H74939293061530 08714729874041	H74939293071570 08714729873778	H74939293071530 08714729874133	H74939293081570 08714729873860	H74939293081530 08714729874225
200	H74939293052070 08714729873617	H74939293052030 08714729873976	H74939293062070 08714729873709	H74939293062030 08714729874065	H74939293072070 08714729873792	H74939293072030 08714729874157	H74939293082070 08714729873884	H74939293082030 08714729874249

■ UPN ■ GTIN

INNOVA™ VASCULAR OTW STENT SYSTEM

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.

INTENDED USE / INDICATIONS FOR USE: The Innova™ Vascular Self-Expanding Stent System is indicated to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA) with reference vessel diameters from 4.0 mm to 7.0 mm and lesion lengths up to 190 mm. **CONTRAINDICATIONS:** Patients with contraindication to antiplatelet and/or anticoagulation therapy • Patients who are judged to have a lesion that prevents proper placement or deployment of the stent • A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion • Patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure • A lesion through which a guide wire cannot pass. **WARNINGS:** Do not expose to organic solvents (e.g. alcohol); Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures; The stent is not designed for repositioning; once the stent is partially deployed, it cannot be "recaptured" or "reconstrained" using the stent delivery system. **PRECAUTIONS:** The delivery system is not designed for use with power injection systems. Only advance the stent delivery system over a stiff 0.035 in guidewire. Always use an introducer or guide sheath for the implant procedure, to protect the access site. If strong resistance is met with the introduction of the delivery system or if unable to initiate release of the stent, remove the entire system from the patient and introduce a new system. Never post-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent. When catheters are in the body, they should be manipulated only under fluoroscopy. Radiographic equipment that provides high quality images is needed. The stent delivery system is not intended for arterial blood monitoring. The minimally acceptable introducer or guide sheath size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than indicated on the label. Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent. Prior to deployment, ensure adequate distance between the proximal end of stent and the introducer/guide sheath to prevent deployment within introducer/guide sheath. This device has not been tested in patients who are pregnant or patients who may be pregnant. Take caution when considering whether to use this device in patients with known allergy to nickel-titanium alloy or contrast media. Take caution when considering whether to use this device in vessel in which there may be a residual stenosis of 50% diameter or larger in the target vessel after the planned intervention. In patients with poor kidney function, contrast agents may precipitate kidney failure. **POTENTIAL ADVERSE EVENTS:** Based on the literature and on clinical and commercial experience with self-expanding stents, the following list includes some possible adverse events associated with the use of the device or the stenting procedure: Allergic reaction (to drug, contrast, device or other) • Angina Aneurysm; Arrhythmia • Arteriovenous fistula • Bleeding/Hemorrhage • Bradycardia • Death • Drug reactions Embolization (air, plaque, thrombus, device, tissue, or other) • Extremity ischemia/amputation • Fever • Hematoma • Leg pain/claudication; Myocardial Infarction • Nausea or vomiting • Need for urgent intervention or surgery • Pseudoaneurysm formation • Renal insufficiency or failure • Restenosis of stented artery • Sepsis/infection • Stent fracture • Stent migration • Stent misplacement/jumping • Stroke • Target Lesion Revascularization • Thrombosis/thrombus; Tissue ischemia/necrosis • Transient hemodynamic instability (hypotensive/hypertensive episodes); Vasospasm • Vessel injury, including perforation, trauma, rupture and dissection • Vessel occlusion. **91075222 Rev/Ver. AA**

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