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.

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

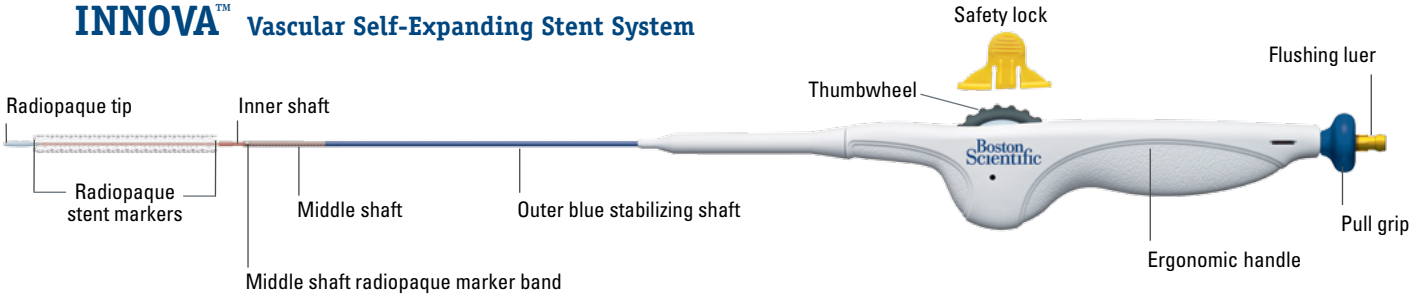
- Blue outer stabilizing shaft designed to control deployment forces and facilitate precise placement
- Middle shaft retracts to deploy stent

INTUITIVE DELIVERY

- Thumbwheel for one-handed deployment
- Pull-grip to complete deployment of 150 mm and 200 mm stents

Learn more:
www.bostonscientific.com/Innovastent

INNOVA™ Vascular Self-Expanding Stent System



COMPLETE SFA SIZE MATRIX

Stent Length (mm)	Stent diameter (mm) 5 — Delivery system working length (cm) 75	5 — 130	6 — 75	6 — 130	7 — 75	7 — 130	8 — 75	8 — 130
20	H749**39293050270** 08714729873532	H749**39293050230** 08714729873891	H749**39293060270** 08714729873624	H749**39293060230** 08714729873983	H749**39293070270** 08714729873716	H749**39293070230** 08714729874072	H749**39293080270** 08714729873808	H749**39293080230** 08714729874164
40	H7493**9293054070** 08714729873549	H749**39293054030** 08714729873907	H749**39293064070** 08714729873631	H749**39293064030** 08714729873990	H749**39293074070** 08714729873723	H749**39293074030** 08714729874089	H749**39293084070** 08714729873815	H749**39293084030** 08714729874171
60	H749**39293056070** 08714729873556	H749**39293056030** 08714729873914	H749**39293066070** 08714729873648	H749**39293066030** 08714729874003	H749**39293076070** 08714729873730	H749**39293076030** 08714729874096	H749**39293086070** 08714729873822	H749**39293086030** 08714729874188
80	H749**39293058070** 08714729873563	H749**39293058030** 08714729873921	H749**39293068070** 08714729873655	H749**39293068030** 08714729874010	H749**39293078070** 08714729873747	H749**39293078030** 08714729874102	H749**39293088070** 08714729873839	H749**39293088030** 08714729874195
100	H749**39293051070** 08714729873570	H749**39293051030** 08714729873938	H749**39293061070** 08714729873662	H749**39293061030** 08714729874027	H749**39293071070** 08714729873754	H749**39293071030** 08714729874119	H749**39293081070** 08714729873846	H749**39293081030** 08714729874201
120	H749**39293051270** 08714729873587	H749**39293051230** 08714729873945	H749**39293061270** 08714729873679	H749**39293061230** 08714729874034	H749**39293071270** 08714729873761	H749**39293071230** 08714729874126	H749**39293081270** 08714729873853	H749**39293081230** 08714729874218
150	H749**39293051570** 08714729873594	H749**39293051530** 08714729873952	H749**39293061570** 08714729873686	H749**39293061530** 08714729874041	H749**39293071570** 08714729873778	H749**39293071530** 08714729874133	H749**39293081570** 08714729873860	H749**39293081530** 08714729874225
200	H749**39293052070** 08714729873617	H749**39293052030** 08714729873976	H749**39293062070** 08714729873709	H749**39293062030** 08714729874065	H749**39293072070** 08714729873792	H749**39293072030** 08714729874157	H749**39293082070** 08714729873884	H749**39293082030** 08714729874249

■ **UPN** ■ GTIN

INNOVA™ VASCULAR SELF-EXPANDING 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.

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