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 150 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

### 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
- Embolization (air, plaque, thrombus, device, tissue, or other)
- Extremity ischemia/necrosis
- 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

### 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 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
- 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
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- A lesion that prevents proper placement or deployment of the stent

### COMPLETE SFA SIZE MATRIX

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<thead>
<tr>
<th>Stent diameter (mm)</th>
<th>Delivery system working length (cm)</th>
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**UPN**

**GTIN**