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](http://www.bostonscientific.com/Innovastent)
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 at an unacceptable risk for intervention
- Patients with a lesion length of >10 cm
- Patients with a lesion located in a vascular graft
- Patients with an abnormal anatomy that prohibits delivery of the device
- Patients with a lesion in which the stent is not expected to be repositionable
- Patients with a lesion that is not amenable to stenting
- Patients who are unable to receive stenting
- Patients who cannot tolerate stenting
- Patients who are not expected to tolerate stenting
- Patients who are not expected to benefit from stenting

**POTENTIAL ADVERSE EVENTS:**
- 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/necrosis
- Transient hemodynamic instability
- Hematoma
- Leg pain/claudication
- Myocardial Infarction
- Nausea or vomiting
- Need for urgent intervention or surgery
- Pseudoaneurysm
- Renal insufficiency or failure
- Restenosis of stented artery
- Sepsis/infection
- Stent fracture
- Stent migration
- Stent misplacement
- Stroke
- Target Lesion Revascularization
- Thrombosis/thrombus
- Tissue ischemia/necrosis
- Tumor
- Vascular occlusion
- Venous occlusion

**INDICATIONS FOR USE:**
- To improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions in the native SFA and/or proximal PPA with reference vessel diameters from 4.0 mm to 7.0 mm and lesion lengths up to 190 mm.

**ADVERSE EVENTS:**
- In patients with poor kidney function, contrast agents may precipitate kidney failure.

**OPERATOR'S INSTRUCTIONS:**
- Do not expose to organic solvents (e.g. alcohol); Stenting across a bifurcation or side branch could compromise future access to side branches in the higher runoff territories.
- Do not stent lesions that are thrombosed.
- Do not stent lesions that exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty (PTA) procedure.
- A lesion located in a vascular graft may not be amenable to stenting.

**ADVANCEMENT OF STENT:**
- Practice proper pre-dilation of the lesion with a balloon catheter prior to stent placement. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent. Prior to deployment, ensure adequate advancement of the stent delivery system.
- Do not attempt to pass the stent delivery system through a smaller size introducer or guide sheath than is 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.
- Do not deploy 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:**
- Embolization (air, plaque, thrombus, device, tissue, or other)
- Extremity ischemia/necrosis
- Transient hemodynamic instability
- Hematoma
- Leg pain/claudication
- Myocardial Infarction
- Nausea or vomiting
- Need for urgent intervention or surgery
- Pseudoaneurysm
- Renal insufficiency or failure
- Restenosis of stented artery
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- Stent migration
- Stent misplacement
- Stroke
- Target Lesion Revascularization
- Thrombosis/thrombus
- Tissue ischemia/necrosis
- Vascular occlusion
- Venous occlusion

**CONTRAINDICATIONS:**
- 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. This device is not recommended for use in patients who are allergic to nickel-titanium alloy.