Innova™ Vascular
OVER-THE-WIRE
Self-Expanding Stent System

Directions for Use

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OVER-THE-WIRE
Self-Expanding Stent System

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions.

Failure to do so may result in complications.

DEVICE DESCRIPTION
The Innova Vascular Self-Expanding Stent System is comprised of two components: the implantable endoprosthesis and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (Nitinol). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The stent is constrained within a 6F (2.1 mm maximum OD) delivery system. The delivery system is a triaxial design with an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system is compatible with 0.035 in (0.89 mm) guidewires. See **Figure 3** for a device diagram and **Table 12** for a device size matrix.

Prior to use, please refer to the OPERATIONAL INSTRUCTIONS.

Contents
One (1) Innova™ Vascular Self-Expanding Stent System

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 use after the "Use By" date specified on the package. Ensure that the device has been properly stored in a cool, dark, dry place not to exceed 51°C (124°F).
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing.
- 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.
- Do not use a kinked delivery system.
- 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.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Magnetic Resonance Conditional

A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury. Non-clinical testing has demonstrated the Innova™ Stents are MR Conditional for single and overlapping lengths up to 200mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 40 Tesla/m (4,000 Gauss/cm) or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of
    - ≤2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
    - ≤1 W/kg for landmarks below the umbilicus

RF Heating
Under the scan conditions defined above, the Innova Stent is expected to produce a maximum in-vivo temperature rise of 4.3°C after 15 minutes of continuous scanning.

Image Artifact
In non-clinical testing, the image artifact caused by the device extends approximately 12 mm from the Innova™ stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact does obscure the device lumen.

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

CLINICAL STUDIES

The clinical evidence supporting the safety and effectiveness of the Innova Self-Expanding Stent System for 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 is from the SuperNOVA study.

The SuperNOVA Study

A study titled "SuperNOVA: Stenting of the Superficial Femoral and Proximal Popliteal Arteries with the Boston Scientific Innova™ Self-Expanding Bare Metal Stent System" (SuperNOVA) was conducted. The SuperNOVA study is a prospective, single arm, controlled, multicenter, global clinical trial designed to treat stenosed superficial femoral and proximal popliteal arteries by implanting the Innova™ Self-Expanding Stent. Its objective was to prospectively evaluate the safety and effectiveness of the Innova™ Self-Expanding Stent System in SFA/PPA by comparing to Performance Goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries. The performance goals were based on an aggregate of published trial data as described by VIVA Physicians Inc. (VPI)[1]. A total of 299 subjects requiring treatment of symptomatic de-novo or restenotic lesions in the native SFA and/or PPA with reference vessel diameters ranging from 4.0 mm -7.0 mm were enrolled and treated with the Innova™ Self-Expanding Stent System. Thirty-nine (39) of the stented segments were treated with the long stents (180 mm or 200 mm). The remaining 260 stented segments were treated with the core stent matrix (20 mm to 150 mm). Subjects were enrolled by 49 centers located in the United States, Europe, Canada and Japan. The follow-up period after the index procedure is ongoing and set for 3 years (or 5 years in Japan only) in subjects successfully implanted with the Innova stent(s).

Eligible subjects were 18 years or older who consented to participate. These subjects had documented peripheral artery disease defined as Rutherford categories 2, 3, or 4 and evidence of a stenotic, restenotic (from angioplasty only) or occlusive lesion(s) located in the native superficial femoral artery or proximal popliteal artery with degree of stenosis ≥70% by visual angiographic assessment. The vessel diameter was ≥ 4 mm and ≤ 7mm and total lesion length was ≥ 30mm and ≤ 190mm located at least 3 cm above the inferior edge of the femur. Subject follow-up occurred at 30 days, 6 months, 12 months, 2 years and 3 years (4 and 5 years for subjects at Japan sites only). The first subject was enrolled April 1, 2011. Enrollment completed June 28, 2013. The database for this study reflects data collected through August 14, 2014.

The primary study endpoints were as follows:

- The primary safety endpoint was a composite of Major Adverse Events (MAE) defined as all causes of death through 1 month post-index procedure, target limb major amputation through 12 months post-index procedure and/or Target Lesion Revascularization (TLR) through 12 months post-index procedure. The primary safety endpoint assessed the composite MAE rate in order to demonstrate a 12 month MAE-free rate exceeds the performance goal (PG) of 59.6%.
- The co-primary effectiveness endpoints assessed primary stent patency rate at 12 months. Primary patency was defined as the percentage of lesions (target stented segments) that reach endpoint without a hemodynamically significant stenosis on DUS (Systolic Velocity (PSV) ratio <2.4), and without TLR or bypass of the target lesion.
    - The co-primary effectiveness endpoint (1) assessed stented segments intended to be treated with the core stent matrix (stent lengths from 20 mm to 150 mm) in order to demonstrate that the 12 month vessel primary patency rate exceeds the PG of 66%.
    - The co-primary effectiveness endpoint (2) assessed stented segments intended to be treated with the entire stent matrix (stent lengths from 20 mm to 200 mm) in order to demonstrate that the 12 month vessel primary patency rate exceeds the PG of 63%. In addition to rejecting the null hypothesis, a non-statistically driven goal needed to be observed, such that the rate of vessel primary patency at 12 months observed with the long stents must be ≥ 50%.

[1]Rocha-Singh KJ, et.al.. "Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients with Symptomatic Peripheral Arterial Disease." Catheterization and Cardiovascular Interventions 2007;69: 910-19.

The SuperNOVA Study employed independent duplex ultrasound, x-ray and angiographic core laboratories to review and analyze key study variables. An independent data reviewer was used to review study data on an ongoing basis and identify any potential safety trends. Adjudication of any potential major adverse events was conducted by an independent Clinical Events Committee (CEC).

Patient Population

Table 1 provides a review of baseline demographics and clinical characteristics of the 299 subjects enrolled into the SuperNOVA study.

Table 1: Baseline Demographics and Clinical Characteristics

	Overall (**N=299**)
Age (Year)	67.4±9.7 (299) (45.0, 93.0)[1]
Male Gender	74.2% (222/299)
Race/Ethnicity	
Hispanic or Latino	1.3% (4/299)
Caucasian	79.6% (238/299)
Asian	14.0% (42/299)
Black, or African heritage	4.3% (13/299)
Native Hawaiian or other Pacific Islander	0.3% (1/299)
American Indian or Alaska Native	0.3% (1/299)
Other	0.0% (0/299)
Not Disclosed	0.0% (0/299)
General Medical History	
History of Smoking	83.9% (251/299)
Current Diabetes Mellitus	40.5% (121/299)
Type 1	2.3% (7/299)
Type 2	36.8% (110/299)
Unknown	1.3% (4/299)
Medically-Treated Diabetes	35.1% (105/299)
History of Hyperlipidemia requiring medication	74.9% (224/299)
History of Hypertension requiring medication	79.9% (239/299)
History of Chronic Obstructive Pulmonary Disease	8.4% (25/299)
Cardiac History	
History of Coronary Artery Disease	43.5% (130/299)
History of Myocardial Infarction (MI)	24.7% (74/299)
History of Congestive Heart Failure	8.4% (25/299)
New York Heart Assoc. (NYHA) Classification	
I	1.3% (4/299)
II	2.7% (8/299)
III	1.3% (4/299)
IV	0.3% (1/299)
Unknown	2.7% (8/299)
History of Percutaneous Coronary Intervention (PCI)	28.4% (85/299)
History of Coronary Artery Bypass Graft (CABG) Surgery	18.1% (54/299)
Current Angina Status	
Stable Angina	14.7% (44/299)
Unstable Angina	0.3% (1/299)
None	81.9% (245/299)
Neurologic/Renal History	
History of Transient Ischemic Attacks (TIA)	7.0% (21/299)

History of Cerebrovascular Accident (CVA)	8.0% (24/299)
History of Renal Insufficiency	10.4% (31/299)
History of Renal Percutaneous Intervention	1.3% (4/299)
Peripheral Vascular History	
History of Peripheral Vascular Surgery	9.0% (27/299)
History of Other Peripheral Endovascular	41.8% (125/299)
History of Claudication	94.0% (281/299)

[1]Values include the mean plus/minus standard deviation and range.

Lesion Characteristics:

Table 2 and **Table 3** present the site-reported and angiographic core lab assessed lesion characteristics, respectively.

Table 2: Baseline Site-Reported Lesion Characteristics
(N=299 Lesions)

	Overall
Treated Limb	
Right leg	46.2% (138/299)
Left leg	53.8% (161/299)
Arterial Segments[2]	
Proximal	11.0% (33/299)
Mid	58.2% (174/299)
Distal	58.2% (174/299)
Ostial	0.3% (1/299)
Proximal Popliteal Artery	15.7% (47/299)
Target Lesion Reference Vessel Diameter (RVD, mm)	5.6±0.7 (299) (4.0, 7.0) [1]
Target Lesion % Diameter Stenosis	91.7±9.2 (299) (70.0, 100.0) [1]
Target Lesion Length (mm)	90.8±44.4 (299) (30.0, 190.0) [1]
Thrombus Seen	2.3% (7/299)
TASC II Lesion Classification	
A	40.5% (121/299)
B	42.1% (126/299)
C	13.7% (41/299)
D	3.7% (11/299)
Predilation	
Predilation Performed	81.9% (245/299)
If Yes, Number of Predilation Balloons Used	1.1±0.4 (245) (1.0, 5.0) [1]
Post-Deployment Dilation	
Post-Deployment dilation Performed	96.7% (289/299)
If Yes, Number of post-deployment Balloons Used	1.1±0.4 (289) (1.0, 3.0) [1]
Target Lesion Final Outcome	
Final % Stenosis	4.2±8.2 (299) (0.0, 50.0) [1]
Thrombus seen in treated vessel at the end of the procedure	0.7% (2/299)

[1]Values include the mean plus/minus standard deviation and range.
[2]Subjects under “Arterial Segments” may have checked more than one location present.

Table 3: Angiographic Core Lab Baseline Measurements
(N=299 Lesions)

Treated Limb[2]	
Right leg	45.6% (136/298)
Left leg	54.4% (162/298)
Arterial segments[3]	
Proximal	10.4% (31/298)
Mid	57.0% (170/298)
Distal	67.4% (201/298)
Ostial	1.7% (5/298)
Proximal Popliteal Artery	15.1% (45/298)
mm from Ostium (mm)	100.1±54.2 (75) (0.0, 233.1)[1]
Length (mm)	93.2±49.1 (293) (10.2, 284.7) [1]
Reference Vessel Diameter (RVD, mm)	5.0±0.9 (295) [1](2.9, 7.6)
Lesion Type	
Eccentric Lesion	46.6% (139/298)
Concentric Lesion	52.3% (156/298)
Bend (degrees)	
>45 degrees	0.0% (0/298)
>90 degrees	0.0% (0/298)
Thrombus[4]	
Grade 0	97.7% (291/298)
Grade 1	0.7% (2/298)
Grade 2	0.3% (1/298)
Grade 3	0.3% (1/298)
Grade 4	0.0% (0/298)
Grade 5	0.0% (0/298)
Calcification	
None/Mild	29.5% (88/298)
Moderate	34.6% (103/298)
Severe	35.6% (106/298)
Ulceration (Present)	13.4% (40/298)
Aneurysm (Present)	3.4% (10/298)
Patency to Foot	
No Infrapopliteal Vessel Patent	9.2% (23/250)
1 Infrapopliteal Vessel Patent	30.0% (75/250)
2 Infrapopliteal Vessels Patent	37.6% (94/250)
3 Infrapopliteal Vessels Patent	23.2% (58/250)
Anterior Tibial Artery (Patent)	37.6% (112/298)
Posterior Tibial Artery	54.0% (161/298)
Peroneal Artery	56.7% (169/298)
Profunda Femoris Artery	66.1% (197/298)

[1]Values include the mean plus/minus standard deviation and range.
[2]Core lab reported "Treated Limb" may differ from the site reported "Treated Limb".
[3]Subjects under "Arterial Segments" may have checked more than one location present
[4]Thrombus could have subjects with "N/A" response as allowed by CRF so percentages may not add up to 100%.

Study Results

Primary Safety Endpoint Results

Table 4 summarizes the primary safety endpoint results for the SuperNOVA study. The 12 month MAE free rate was 85.8% with the lower 95% Confidence interval exceeding the established PG of 59.6%.

Table 4: Primary Safety Endpoint and Components
(N=299 Subjects)

Primary Safety Endpoint	Overall	95% CI	Lower 1-Sided[2] 97.5% CI	PG
12-Month Freedom from MAE[1]	85.8% (230/268)	[81.1%, 89.8%]	81.1%	59.6% (Met)
12-Month MAE[1](Composite Endpoint)	14.2% (38/268)			
All Causes of Deaths at 1 Month	0.0% (0/268)			
Target Limb Major Amputation	0.4% (1/268)			
Target Lesion Revascularization (TLR)	14.2% (38/ 268)			

[1]Twelve-Month Major Adverse Events (MAEs) defined as all causes of death through 1 month, target limb major amputation through 12 months and/or target lesion revascularization through 12 months.
[2]Binomial Exact Method
Abbreviation: PG, Performance Goal

Secondary Safety Endpoint Results

Table 5 summarizes the secondary safety endpoint results for the SuperNOVA study. The 1 month MAE free rate was 99.7%

Table 5: Secondary Safety Endpoint and Components
(N=299 Subjects)

Secondary Safety Endpoint	Overall	95% CI	Lower 1-Sided[2] 97.5% CI	PG
1-Month Freedom from MAE[1]-Free	99.7% (296/297)	[98.1%, 100.0%]	98.1%	88.0% (Met)
1-Month MAE[1] (Composite Endpoint)	0.3% (1/297)			
All Causes of Deaths	0.0% (0/297)			
Target Limb Major Amputation	0.0% (0/297)			
Target Lesion Revascularization (TLR)	0.3% (1/297)			

[1]One-month Major Adverse Events (MAEs) defined as all causes of death, target limb major amputation and/or target lesion revascularization through 1 month.
[2]Binomial Exact Method
Abbreviation: PG, Performance Goal

Evaluation of Safety

Table 6 displays the rates of all Serious Adverse Events (SAEs) reported by MedDRA System/Organ Class (SOC). The sub-categories are Preferred Terms (PTs), and include only those SAEs that were reported by the treating physician as related to the device and/or the procedure.

Table 6: Serious Adverse Events by MedDRA System/Organ Class

Serious Adverse Event by SOC and PT[1]	**Events**	**Rate of Subjects With Event**
Any serious adverse event	309	49.2% (147/299)
Not Coded	4	0.7% (2/299)
Cardiac disorders	36	8.4% (25/299)
Congenital, familial and genetic disorders	1	0.3% (1/299)
Gastrointestinal disorders	18	4.3% (13/299)
Retroperitoneal hematoma	2	0.7% (2/299)
General disorders and administration site conditions	14	4.3% (13/299)
Catheter site hemorrhage	2	0.7% (2/299)
Impaired healing	1	0.3% (1/299)
Immune system disorders	2	0.7% (2/299)
Infections and infestations	18	5.7% (17/299)
Catheter site infection	1	0.3% (1/299)
Localized infection	1	0.3% (1/299)
Injury, poisoning and procedural complications	21	5.7% (17/299)
Arterial injury	1	0.3% (1/299)
Metabolism and nutrition disorders	3	1.0% (3/299)
Musculoskeletal and connective tissue disorders	14	4.0% (12/299)
Pain in extremity	2	0.7% (2/299)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9	2.7% (8/299)
Nervous system disorders	9	2.3% (7/299)
Renal and urinary disorders	5	1.7% (5/299)
Reproductive system and breast disorders	1	0.3% (1/299)
Respiratory, thoracic and mediastinal disorders	3	1.0% (3/299)
Skin and subcutaneous tissue disorders	2	0.7% (2/299)
Surgical and medical procedures	1	0.3% (1/299)
Vascular disorders	148	28.1% (84/299)
Arterial thrombosis limb	5	1.3% (4/299)
Femoral arterial stenosis	38	10.7% (32/299)
Femoral artery dissection	1	0.3% (1/299)
Femoral artery occlusion	8	1.7% (5/299)
Intermittent claudication	7	2.0% (6/299)
Peripheral arterial occlusive disease	1	0.3% (1/299)

[1] All PTs that were experienced are not listed. The PTs that are listed are physician-reported to be either device and/or procedure-related.

Primary Effectiveness Endpoint Results

Table 7 presents primary patency results for the co-primary effectiveness endpoints incorporated into the SuperNOVA study. The performance goal of 66% was not met.

Table 7: Co-Primary Effectiveness Endpoints
(N=299)

	Overall	**95% CI**	Lower 1-Sided[5] 97.5% CI	PG
12-Month Primary Patency in Core Matrix Stents[1]	69.5% (157/226)	[63.0%, 75.4%]	63.0%	66.0% (Not Met)
12-Month Primary Patency in Entire Stent Matrix[2]	66.4% (174/262)			
12-Month Primary Patency in Long Stents[3,4]	47.2% (17/36)			

[1]Core Matrix Stents (20-150 mm)
[2]Entire Stent Matrix (20-200 mm)
[3]Long Stents (180-200 mm)
[4]The observed rate must be ≥ 50.0%
[5]Binomial Exact Method
Abbreviation: PG, Performance Goal

As presented in **Figure 1** and **Table 8**, the freedom from loss of primary patency at 12 months for the core stent matrix was 76.7%.

Figure 1: Primary Patency in Core Stents through 12 Months

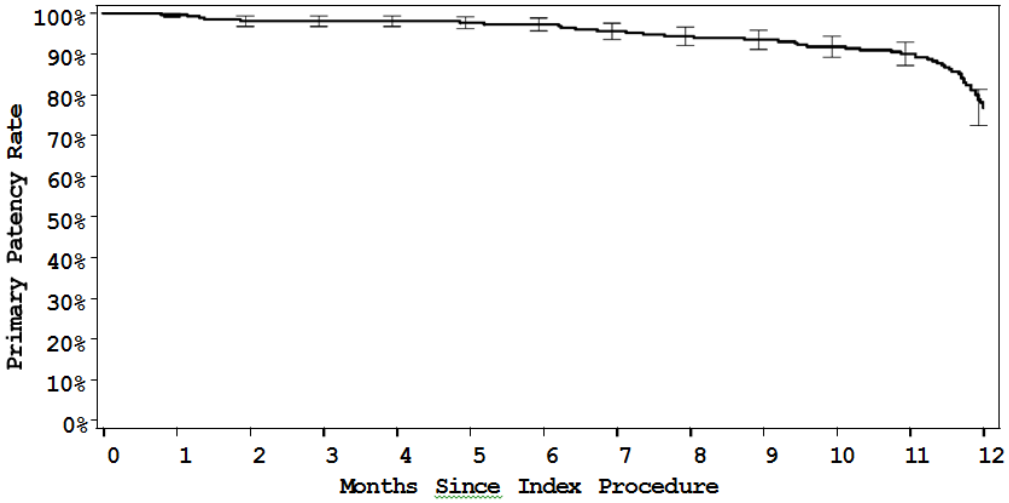

Table 8: Primary Patency in Core Stents Subjects through 12 Months

	Time from Index Procedure (months)							
Number of Subjects	**0**	**1**	**2**	**3**	**4**	**6**	**9**	**12**
Entered	260	259	254	244	243	243	236	220
Censored	1	4	6	1	0	5	7	78
At Risk[1]	259.5	257	251	243.5	243	240.5	232.5	181
Events	0	1	4	0	0	2	9	32
Events/Month	0.0	1.0	4.0	0.0	0.0	1.0	3.1	10.1
Event Rate	0%	0.4%	2.0%	2.0%	2.0%	2.8%	6.6%	23.3%
Event Free	100%	99.6%	98.0%	98.0%	98.0%	97.2%	93.4%	76.7%
Std Error	0%	0.4%	0.9%	0.9%	0.9%	1.0%	1.6%	3.0%
SVS SE	0%	0.4%	0.9%	0.9%	0.9%	1%	1.6%	2.8%

[1]$\text{At risk} = \text{Entered} - 0.5 \times \text{Censored}$
Subjects event-free at 12 months or later are censored at greater than 12 months. Intervals are end inclusive, e.g. interval 6 is defined as 4-6 months, inclusive.
Event rate and standard error estimates are for interval end. Standard errors by Greenwood formula

As presented in **Figure 2** and **Table 9**, the freedom from loss of primary patency at 12 months for the entire stent matrix was 73.7%.

Figure 2: Primary Patency in All Stents through 12 Months

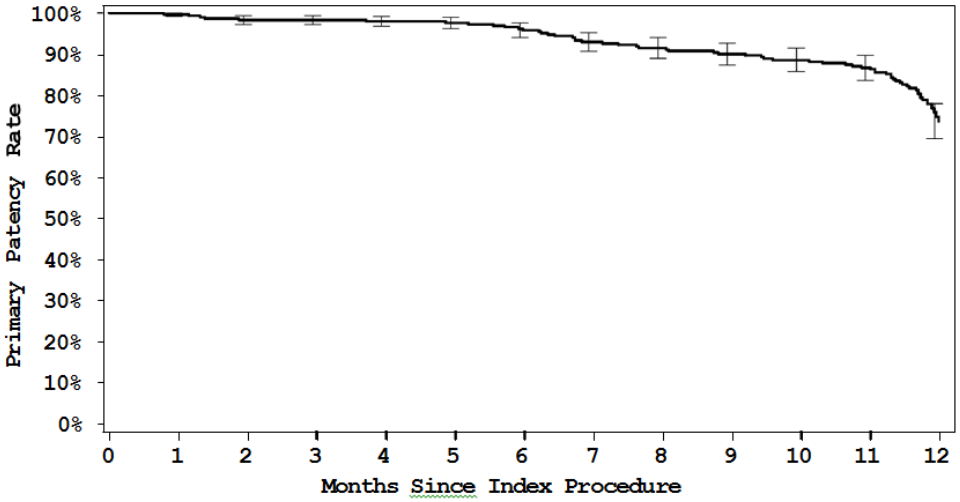

Table 9: Primary Patency in All Stents through 12 Months

	Time from Index Procedure (months)							
Number of Subjects	**0**	**1**	**2**	**3**	**4**	**6**	**9**	**12**
Entered	299	298	293	283	282	280	269	246
Censored	1	4	6	1	1	5	7	82
At Risk[1]	298.5	296	290	282.5	281.5	277.5	265.5	205
Events	0	1	4	0	1	6	16	37
Events/Month	0.0	1.0	4.0	0.0	1.0	2.9	5.5	11.7
Event Rate	0%	0.3%	1.7%	1.7%	2.1%	4.2%	10.0%	26.3%
Event Free	100%	99.7%	98.3%	98.3%	97.9%	95.8%	90.0%	73.7%
Std Error	0%	0.3%	0.8%	0.8%	0.8%	1.2%	1.8%	2.9%
SVS SE	0%	0.3%	0.8%	0.8%	0.8%	1.2%	1.7%	2.6%

[1] $\text{At risk} = \text{Entered} - 0.5 \times \text{Censored}$

Subjects event-free at 12 months or later are censored at greater than 12 months. Intervals are end inclusive, e.g. interval 6 is defined as 4-6 months, inclusive.

Event rate and standard error estimates are for interval end. Standard errors by Greenwood formula

Secondary Effectiveness Endpoint Results

The secondary effectiveness endpoints are summarized in **Table 10** and **Table 11** below.

Table 10: Technical and Procedural Success
(N=299)

	Overall
Technical Success[1]	99.0% (296/299)
Procedure Success[2]	99.0% (296/299)

[1] Technical success was defined as the ability to cross and dilate the lesion to achieve residual angiographic stenosis no greater than 30%.

[2] Procedural success is defined as technical success with no MAEs within 24 hours of the index procedure.

Table 11: Analysis of Secondary Effectiveness Endpoints
(N= 299)

Primary Patency at 12 Months	66.4% (174/262)
Primary Patency for Core Stent Matrix at 12 Months	69.5% (157/226)
Assisted Primary Patency at 12 Months	83.8% (207/247)
Assisted Primary Patency for Core Stent Matrix at 12 Months	85.5% (183/214)
Target Vessel Revascularization (TVR) Rate at 12 Months	13.8% (38/275)
Target Lesion Revascularization (TLR) Rate at 12 Months	13.8% (38/275)
Improvement in the Rutherford Clinical Improvement Scale of ≥ one at 12 months without the need for repeat TLR	79.5% (209/263)
Improvement in the Rutherford Clinical Improvement Scale of ≥ one at 12 months including subjects with repeat TLR	90.1% (237/263)
Increase in ABI of ≥ 0.10 or to an ABI ≥ 0.90 as compared to pre-procedure without the need for repeat TLR	59.0% (164/278)
Walking Improvement – Change in Walking Impairment Questionnaire Score from Baseline to 12 Months	34.03±37.22 (263) (-50.00,100.00)[1]
Walking Improvement – Change in Total Distance Walked over 6 Minutes from Baseline to 12 Months	69.3±130.1 (235) (-294.0,1033.0) [1]
Stent Fracture Rate at 12 Months	1.9% (6/318)

[1] Values include the mean plus/minus standard deviation and range.

Subgroup Analyses

Gender: The female population had a higher overall TLR rate (22.4% vs. 11.4%) and a lower 12 month primary patency rate in the core stents matrix (55.6% vs 73.8%) than the male population. The female subgroup was slightly older with a greater prevalence of Rutherford classification 3 and 4 as well as hypertension compared to the male subgroup. The male subgroup had a higher prevalence of diabetes and coronary artery disease than the female subgroup. Despite these differences and the differences observed for patency in the core stent matrix, both female and male subgroups behaved similarly with respect to patency in the long stent matrix (44.4% and 48.1%, respectively). This subgroup analysis was not statistically powered.

Diabetic Patients: There was a slight trend towards higher patency in the non-diabetic population for shorter lesions (<150mm) and no differences seen in the MAE rate, but the findings were not statistically significant as the analysis was not sufficiently powered.

Rutherford Classification: The subgroup analysis based on Rutherford classification (claudication vs. critical limb ischemia [CLI]) was not conclusive given the very small proportion of subjects with CLI (n=14). This analysis was not statistically powered.

Stent Matrix: The last subgroup analysis was based on stent matrix (core vs. long vs. entire matrix) and was not statistically powered either. The findings showed very similar patency rates between the entire matrix and the core matrix, both showing an advantage over the long matrix as it should be expected.

HOW SUPPLIED

The Innova™ Vascular Self-Expanding Stent System is supplied sterile inside a pouch. The device is sterilized via Ethylene Oxide. The device is non-pyrogenic.

Handling and Storage

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.
The packaged device should be stored in a cool, dark place, and temperatures should not exceed 51°C (124°F).

RECOMMENDED MATERIALS

- 0.035 in (0.89 mm) stiff guidewire of appropriate length (300 cm length recommended for 130 cm length stent delivery systems)
- Introducer or guide sheath of appropriate size and length and equipped hemostatic valve
- Luer lock syringe 10 ml (10 cc) for flushing the stent delivery system

OPERATIONAL INSTRUCTIONS

Patient Preparation

The percutaneous placement of a self-expanding stent in a stenotic or obstructed artery should be done in an angiography procedure room with the appropriate imaging equipment. Patient preparation and sterile precautions should be the same as for any angioplasty procedure. Appropriate antiplatelet and anticoagulation therapy must be administered pre- and post-procedure in accordance with standard practices. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. Access vessels must be sufficiently patent to proceed with further intervention. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice.

Inject Contrast Media

Perform angiogram using standard technique.

Evaluate and Mark the Stenosis

Observe fluoroscopically the most distal view of the stenotic or obstructed artery. Obtain a road map image of the lesion area if necessary.

Select Proper Stent System

1. Measure the diameter of the reference vessel (proximal and distal to the lesion or obstruction). Select a stent based on the table below to ensure a secure placement. **Table 12** summarizes the total intended Innova™ Vascular Self-Expanding Stent sizes.

Table 12: Innova™ Vascular Self-Expanding Stent System Models and Sizes

Stent Nominal Diameter (mm)	Unconstrained Length (mm)	Reference Vessel Diameter (mm)
5	20	4
	40	
	60	
	80	
	100	
	120	
	150	
	180	
	200	
6	20	4.0 - 5.0
	40	
	60	
	80	
	100	
	120	
	150	
	180	
	200	
7	20	5.0. - 6.0
	40	
	60	
	80	
	100	
	120	
	150	
	180	
	200	
8	20	6.0 - 7.0
	40	
	60	
	80	
	100	
	120	
	150	
	180	
	200	

*All sizes may not be available in all regions. The Innova stent deployed length change from the delivery system is less than 2mm on average for stent lengths </= 40mm and approximately 4.0% on average or less for all other stent lengths.

2. Measure the entire length of the actual lesion and select the proper length of the stent(s) to be deployed. To help ensure adequate apposition, it is recommended that the length of the stent be chosen so that the ends of the stent extend at least 5 mm beyond both ends of the lesion into healthy tissue.

   Should more than one stent be required to cover the lesion, allow for at least 5 mm of stent overlap. It is generally recommended that the distal stent be placed first.

   When multiple stents are required, if placement results in metal to metal contact, stent materials should be of similar composition.

3. Estimate the distance between the lesion and the entry site to select the proper stent delivery system length.

Preparation of Stent Delivery System

1. Open the outer box to reveal the pouch containing the stent delivery system.

2. Check the temperature exposure indicator on the pouch label to confirm that the product has not been compromised. See Warnings section.

3. After careful inspection of the pouch looking for damage to the sterile barrier, carefully peel open the pouch and extract the stent delivery system tray.

4. Carefully withdraw the stent delivery system from the tray by grasping the handle of the delivery system.

5. Examine the stent delivery system for any damage. If it is suspected that the sterility or integrity of the device has been compromised (i.e. kinking or missing component), the device should not be used. The device should not be used if the device is kinked, or if the thumbwheel lock is not attached.

6. Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.

7. Attach a 10 ml (10 cc) syringe filled with saline to the flushing luer ⑥ on the handle. Apply positive pressure. Continue to flush until saline appears at the distal end of the guidewire lumen. Remove the flushing luer ⑥ by pulling the syringe or by pulling flushing luer ⑥ (Reference **Figure 3**).

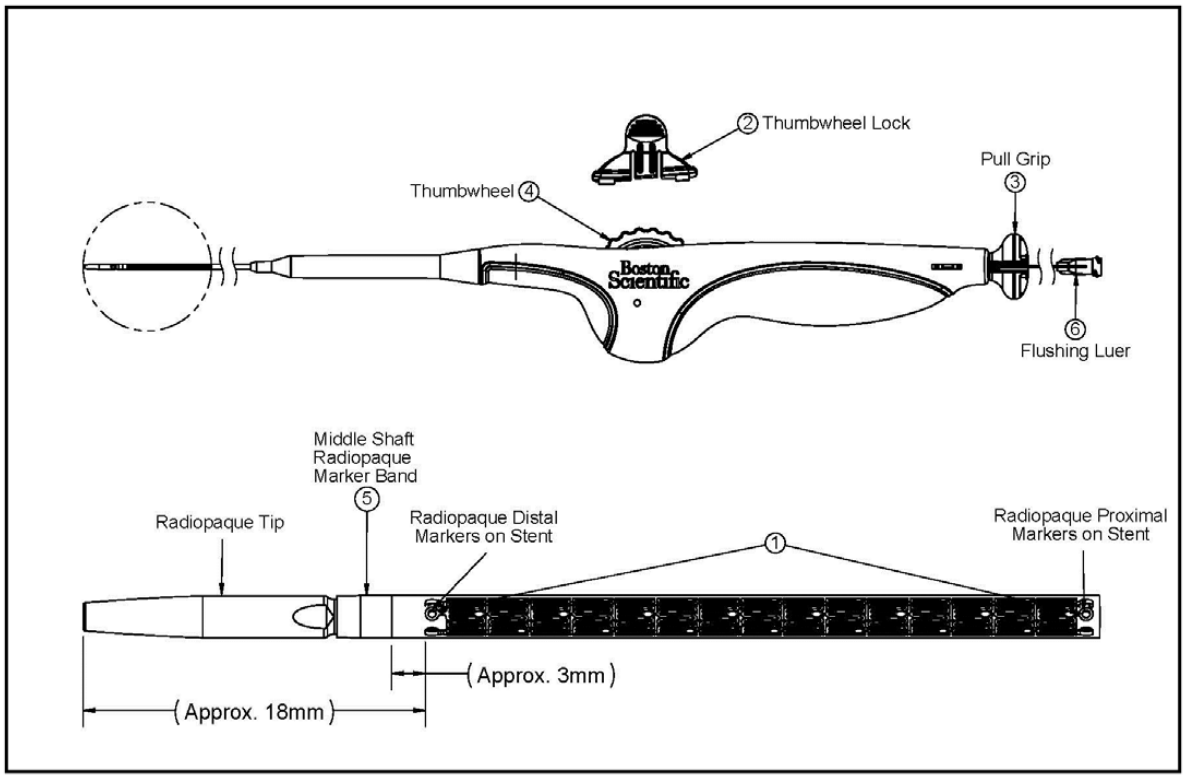

Figure 3.

Delivery Procedures

1. Gain arterial access utilizing a 6F (2.1 mm) or larger sheath with a hemostatic valve.

Precautions:

- Always use an introducer or guide sheath for the implant procedure, to protect the access site and prevent system damage.

- Do not use a kinked delivery system. Kinking of the introducer/guide sheath at the access site can restrict the movement of the delivery system during deployment.

2. Pass an 0.035 in (0.89 mm) guidewire of appropriate length (300 cm length recommended for 130 cm stent delivery system length systems) across the target lesion or obstruction.

Notes:

- A **stiff** 0.035 in guidewire is strongly recommended for deployment of the stent, especially for tortuous anatomy and contralateral approaches. Use of undersized guidewires may lead to insufficient support of the device which can compromise stent delivery.

- If using a hydrophilic guidewire, ensure that it is hydrated at all times.

3. Pre-dilate the lesion with a balloon dilatation catheter using conventional technique. After the lesion has been properly dilated, remove the dilatation catheter, leaving the guidewire with the tip distal to the lesion for stent system advancement.

4. Place the Innova™ Vascular Stent Delivery System over the guidewire. Advance the delivery system as a unit through the hemostatic valve of the introducer or guide sheath.

Notes:

- Do not tighten Tuohy-Borst such that it restricts the movement of the delivery system.

- Do not remove the thumbwheel lock prior to deployment. Premature removal of the thumbwheel lock may result in an unintended deployment of the stent.

Stent Deployment Procedure (Reference Figure 3)

1. Remove slack from the system by advancing the system just beyond the target lesion, then, pulling the system back until stent radiopaque markers ① are centered over the target lesion.

Note:

- Prior to deployment, ensure adequate distance between the proximal end of the stent and the introducer/guide sheath to prevent deployment within the introducer/guide sheath.

2. Remove the thumbwheel lock ② by compressing the tabs and pulling. Confirm that the radiopaque markers are still properly positioned across the target lesion.

Precaution:

- 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.

Notes:

- For optimal performance, keep the entire length of the delivery system that is outside the body as straight and stable as possible. To do so, remove slack from the system, maintain slight backward tension on the delivery system, and anchor the handle on the patient or operating table during deployment. Alternatively, the operator may straighten and stabilize the distal end of the blue outer shaft during deployment.

- Failure to eliminate slack (Reference **Figure 4**) and/or curvature of the delivery system catheter between the introducer/guide sheath and the delivery system handle during deployment may adversely affect deployment accuracy, especially in ipsilateral cases.

- If repositioning of the stent delivery system is required, reinserting the thumbwheel lock will prevent inadvertent deployment.

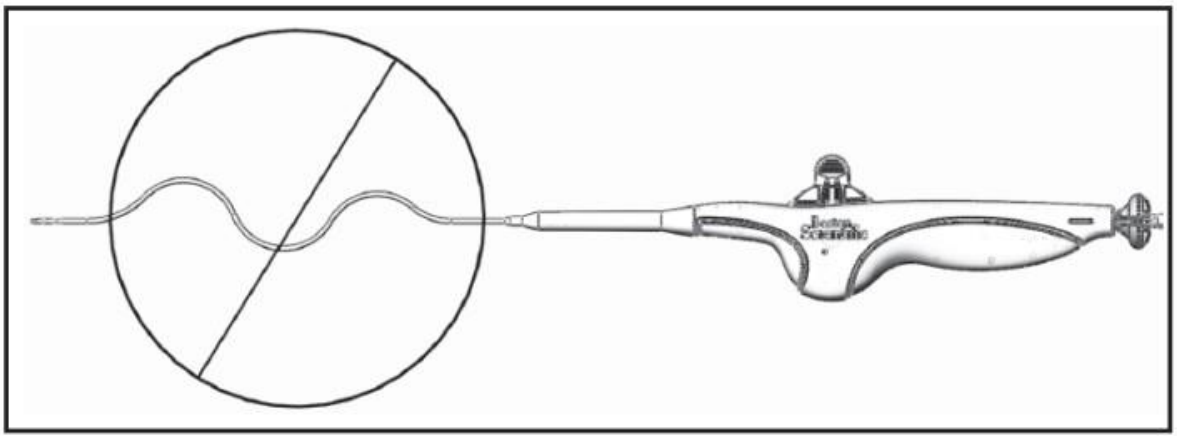

Figure 4

Recommended Method of Deployment

1. While using fluoroscopy maintain position of the distal and proximal stent radiopaque markers ① relative to the targeted site. Roll the thumbwheel ④ of the deployment handle in the direction of the arrow indicated on the handle. Continue to roll thumbwheel until the middle shaft radiopaque marker band ⑤ passes the distal stent radiopaque markers. Watch for the distal stent radiopaque markers to begin separating: separation of the distal stent radiopaque markers signals that the stent is deploying.

2. Continue to roll thumbwheel until the middle shaft radiopaque marker band ⑤ passes the proximal radiopaque markers of the stent resulting in full deployment, or until the white activation arrow is visible on pull grip extension rod (for 150 mm to 200 mm length stents), which indicates that pull grip activation is required to complete stent deployment (Reference **Figure 5**). Long stents (150 mm to 200 mm length) will not be fully deployed by the thumbwheel alone.

Notes:

- When activating the pull grip, avoid rapid deployment.

- Do not restrict movement of the thumbwheel ④ otherwise deployment difficulties could be encountered.

- Do not attempt to pull a partially expanded stent back into introducer / guide sheath as dislodgement may occur.

- Do not push or pull the delivery system during deployment as this may compromise stent length.

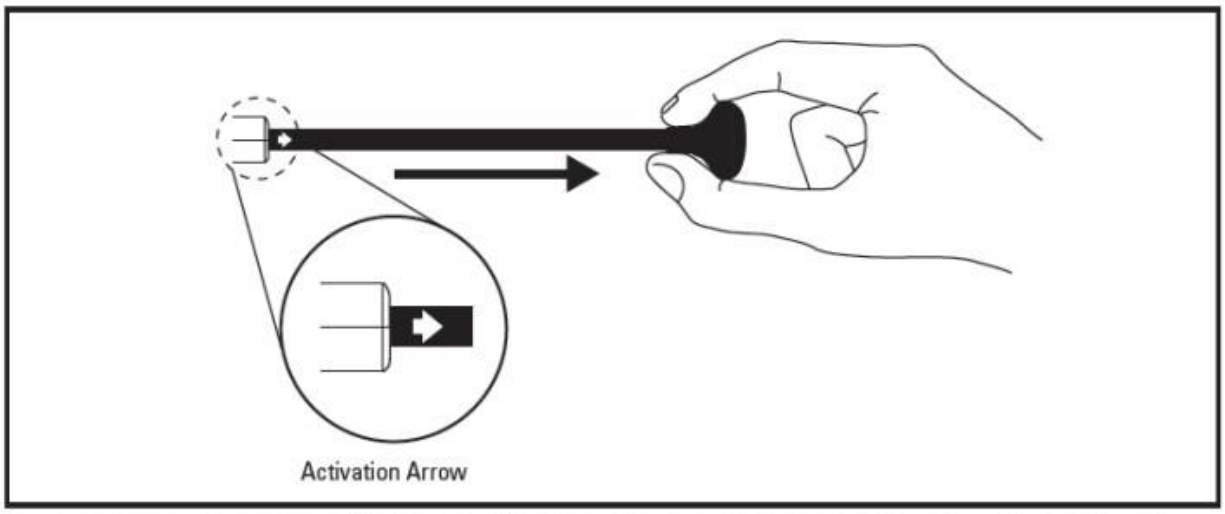

Figure 5: Long stents (150 mm to 200mm length) require the pull grip to be retracted only after the white activation arrow is visible to complete deployment.

3. Long stents (150 mm to 200 mm length) require pull grip deployment after the white activation arrow becomes visible on the pull grip extension rod. Grasp the manual pull grip ③ and gently pull away from the handle in the direction of the arrow. Slowly pull back until the middle shaft radiopaque marker band ⑤ passes the proximal radiopaque markers of the stent resulting in full deployment.

4. View the delivery system under fluoroscopy, ensuring that the middle shaft radiopaque marker band ⑤ has crossed the proximal stent markers. The delivery system can now be withdrawn.

5. Grasp the guidewire a short distance from handle and repeatedly retract the system over the wire until fully removed. Use caution when withdrawing the stent delivery system and always manipulate under fluoroscopy. If unusual resistance is felt, carefully readvance and rotate the delivery system in an attempt to center the delivery system within the vessel, then carefully attempt to repeat withdrawal.

Note:
- Avoid bending the guidewire excessively near handle when retracting device to aid removal and prevent guidewire kinking.

6. If incomplete expansion exists within the stent at any point along the lesion, balloon dilatation can be performed utilizing standard PTA technique.

Precaution:
- Never pre-dilate the stent using a balloon that is larger in diameter than the nominal (labeled) diameter of the stent.

7. Withdraw guidewire and sheath from patient and establish hemostasis per conventional technique.

Post Procedure
Assess patient for hematoma and/or other signs of bleeding at the puncture site.

REFERENCES
The physician should consult recent literature on current medical practice on stent implantation.

WARRANTY

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