Boston Scientific

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Epic™ Vascular

Self-Expanding Stent System

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℞ 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 Epic Vascular Self-Expanding Stent System (Epic 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 outside diameter) delivery system. The delivery system is a coaxial design with an exterior shaft to protect and constrain the stent prior to deployment. The delivery system is an Over-The-Wire system compatible with 0.035 in (0.89 mm) guidewires.

When ready to be implanted, the stent is deployed by retracting the exterior shaft of the delivery system. A radiopaque marker at the distal end of the delivery system aids in visibility during deployment. As the stent is exposed to body temperature, it expands to appose the vessel wall.

The Epic Vascular Self-Expanding Stent System is available in a variety of stent diameters and lengths. The delivery system is also offered in two shaft lengths (75 cm and 120 cm).

Please see the product label for the specific delivery system length, stent diameter, and stent length.

Contents

One (1) Epic Vascular Self-Expanding Stent System

INTENDED USE

The Epic Vascular Self-Expanding Stent System is intended for the treatment of iliac artery atherosclerotic lesions and obstructions.

INDICATIONS FOR USE

The Epic Vascular Self-Expanding Stent System is indicated for the improvement of luminal diameter in patients with de novo or restenotic symptomatic atherosclerotic lesions up to 120 mm in length in the common and/or external iliac arteries, with a reference vessel diameter between 5 and 11 mm.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

- Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with interventional procedures should use this device.
- 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 prior to use.
- Do not use if the temperature exposure indicator dot is red.
- Do not use if the temperature exposure indicator dot is missing.
- Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.
- Persons allergic to nickel-titanium may suffer an allergic response to this implant.
- Improper stent size selection may lead to stent migration or stent jumping.
- Remove all slack from the catheter prior to stent deployment, as excessive slack may result in stent jumping or the stent length being reduced.
- If unable to initiate release of the stent or if strong resistance is met with the introduction of the delivery system, remove the entire system from the patient and introduce a new system.
- Once the stent is partially deployed, it cannot be "recaptured" or "resheathed" using the stent delivery system.
- As with any type of intravascular implant, infection secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm, or rupture into a neighboring organ or into the retroperitoneum.
- The stent may cause thrombus or distal emboli to migrate from the site of the implant down the arterial lumen.
- Do not expose to organic solvents (e.g. alcohol).
- The long-term outcome following repeat dilatation of endothelialized stents is unknown at present.
- In patients with poor kidney function, contrast agents may precipitate kidney failure.

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PRECAUTIONS

- Safety and effectiveness has not been demonstrated in patients with the following characteristics:
  - Highly calcified lesions resistant to PTA.
  - Persistent, intraluminal thrombus at the target lesion.
  - Uncorrected bleeding disorders or patients who cannot receive anticoagulation or anti-platelet aggregation therapy.
  - Perforated vessels evidenced by extravasation of contrast media.
  - Lesions that are within or adjacent to an aneurysm.
  - Vessels with excessive tortuosity.
- The delivery system is not designed for use with power injection systems.
- Do not use a kinked delivery system.
- Always use an introducer or guide sheath for the implant procedure, to protect the access site.
- Only advance the stent delivery system over a guidewire.
- Never dilate the stent using a balloon that is larger in diameter than the 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.
- Two stents can be placed to cover a lesion. Should more than one stent be required, allow for at least 5 mm of stent overlap. It is generally recommended that the distal stent be placed first. If stent overlapping is needed, stent materials should be of similar composition.
- The stent delivery system is not intended for arterial blood monitoring.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the stent. If the target lesion is not fully covered, use additional stents as necessary to adequately treat the lesion.
- The minimally acceptable sheath French size is printed on the package label. Do not attempt to pass the stent delivery system through a smaller size sheath introducer than indicated on the label.
- In the event of thrombosis of the expanded stent, thrombolysis and/or PTA should be considered.
- In the event of complications such as infection, pseudoaneurysms or fistula formation, surgical removal of the stent may be required.
- Recrossing a stent with adjunct devices must be performed with caution.
- Premature removal of the safety lock may result in an unintended deployment of the stent.
- Limited data exists on the use of two overlapping stents from the ORION clinical trial.

MAGNETIC RESONANCE IMAGING (MRI)

Non-clinical testing has demonstrated the Epic™ Stent System is MR Conditional. It can be scanned safely up to a total length of 155 mm and overlapping stents up to 155 mm under the following conditions:

- Static magnetic field of 3 Tesla and 1.5 Tesla.
- Spatial gradient field of 2500 Gauss/cm.
- Normal operating mode only with a maximum whole body (WB) averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of active scanning for patient landmarks above the umbilicus (patient navel).
- Maximum WB-SAR of 1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.
- Use whole body transmit/receive coils only. Do not use local transmit coils. Local receive coils can be used.

MRI at 3T or 1.5T may be performed immediately following the implantation of the Epic Stent. The Epic Stent should not migrate in this MRI environment. This stent has not been evaluated to determine if it is MR Conditional beyond these conditions.

Magnetic Resonance Conditional

3.0 Tesla Temperature Information

In non-clinical testing, the Epic Stent at single lengths of 120 mm and overlapped lengths of 155 mm produced a maximum temperature rise of 4.4°C at a maximum whole body averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 3 Tesla Siemens Magnetom Trio®, software version Numaris/4, Syngo® MR A30, COEM VD20F, Syngo VE31G, N4 VA30A Latest MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks **above** the umbilicus the calculated temperature rise was 4.4°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks **below** the umbilicus the calculated temperature rise was 2.8°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

1.5 Tesla Temperature Information

In non-clinical testing, the Epic Stent at single lengths of 120 mm and overlapped lengths of 155 mm produced a maximum temperature rise of 3.2°C at a maximum whole body averaged of 2 W/kg, that was determined by validated calculation for 15 minutes of MR scanning in a 1.5 Tesla Philips Intera®, software version Release 10.6.2.4, 2006-03-10 MR scanner. In this model, the reported temperatures are conservative as they do not take into account the cooling effects of perfusion and blood flow.

- For landmarks **above** the umbilicus the calculated temperature rise was 3.2°C for a whole body average SAR value of 2.0 W/kg and a continuous scan time of 15 minutes.
- For landmarks **below** the umbilicus the calculated temperature rise was 2.7°C for a whole body average SAR value of 1.0 W/kg and a continuous scan time of 15 minutes.

Image Artifact

The image artifact extends approximately 1.25 mm from the perimeter of the device diameter and 2 mm beyond each end of the length of the stent when scanned in non-clinical testing using the sequence, Spin Echo. With a Gradient Echo sequence the image artifact extends 1.25 mm beyond the perimeter of the device diameter and 3 mm beyond each end of the length of the stent with both sequences partially shielding the lumen in a 3.0 Tesla Siemens Medical Solutions, software version Numaris/4, Syngo MR 2004A 4VA25A MR system with a transmit/receive CP head coil. Image artifacts in a body birdcage coil are similar to the image artifacts in the transmit/receive CP head coil.

Recommendations

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

ADVERSE EVENTS

Potential adverse events that may occur following intravascular stent implantation include, but are not limited to:

- Abscess
- Allergic reaction (to drug, contrast, device or other)
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arrhythmia
- Arteriovenous fistula
- Death
- Drug reactions
- Embolization (air, plaque, thrombus, device, or other)
- Entanglement of delivery system in deployed stent
- Fever
- GI bleeding
- Hemorrhage/hematoma
- Hypotension/hypertension
- Myocardial Infarction (MI)
- Need for urgent intervention or surgery
- Pseudoaneurysm
- Renal insufficiency or failure
- Restenosis of stented artery
- Sepsis/infection
- Stent fracture
- Stent migration
- Stent misplacement/jumping
- Stent thrombosis with possible neurological injury
- Stroke
- Thrombosis/thrombus
- Tissue ischemia/necrosis
- Vasospasm
- Vessel injury, examples include perforation, dissection, intimal tear, rupture
- Vessel occlusion

ORION CLINICAL TRIAL

A total of 125 subjects were treated at 28 centers in this prospective, single arm, non-randomized, multicenter trial. **Table 1** presents the principal effectiveness and safety results for the ORION trial through 9-months post-index procedure. **Figure 1** displays the Kaplan-Meier curve for Major Adverse Events (MAEs) through the 270 days. Four subjects (3.4%) had an MAE as adjudicated by an independent Clinical Events Committee (CEC). There were four subjects with Target Vessel Revascularization (TVR) through 9 months, no deaths through 30 days, no index hospitalization myocardial infarctions (MI), and no amputations through 9 months.

Table 1. Primary Effectiveness and Safety Results, All Subjects (N=125)

	(N=125 Subjects)	[95% CI]
9-Month MAE (per subject)	3.4% (4/117)	[0.9%, 8.5%]
Device- or index procedure-related Death within 30 days	0.0% (0/117)	[0.0%, 3.1%]
Myocardial Infarction (MI) during index hospitalization	0.0% (0/117)	[0.0%, 3.1%]
Target Vessel Revascularization (TVR) through 9 months	3.4% (4/117)	[0.9%, 8.5%]
Amputation of index limb through 9 months	0.0% (0/117)	[0.0%, 3.1%]

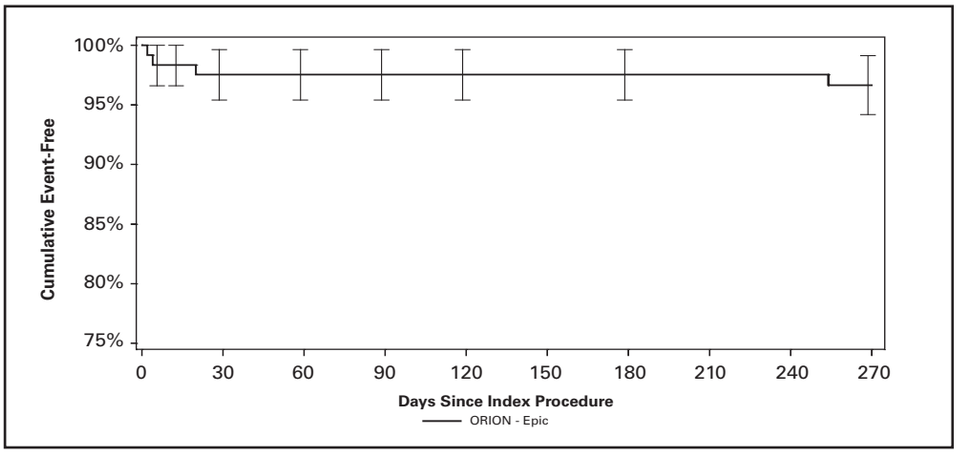

Figure 1. Freedom from 9 month MAE, Event-Free Survival ± 1.96 SE, All Subjects (N=125)

Objective: To determine whether the Epic™ Stent for primary stenting of iliac atherosclerotic lesions showed acceptable performance at 9 months.

Design: The ORION Trial was a prospective, single-arm, non-randomized clinical trial conducted at 28 centers in the US. A total of 125 subjects were enrolled.

Subjects considered for enrollment had documented chronic, symptomatic iliac artery atherosclerotic disease (Rutherford/Becker category 1, 2, 3 or 4) with lifestyle-limiting claudication or rest pain. Target lesions were de novo or restenotic from prior PTA and located in the common and/or external iliac artery. Lesion length was ≤13cm with reference vessel diameter (RVD) ≥5 mm to ≤11 mm and baseline lesion stenosis ≥50% (all visually assessed). A subject could receive a maximum of 2 study stents for up to 2 target lesions. Two target lesions in the same target vessel could be treated if there was a 20 mm non-treated segment between the 2 implanted study stents. Subjects with bilateral disease could have only 1 target lesion treated per side. Subjects with uncorrected bleeding disorders; intolerance to anticoagulation, antithrombolytic or antiplatelet medications; intraluminal thrombus of the proposed treated lesion(s) post thrombolytic therapy or known allergy to nitinol were excluded from the study.

Before the stenting procedure, subjects were administered anticoagulation and antiplatelet therapy consistent with current clinical practice. After the procedure antiplatelet therapy was to be prescribed throughout the subject's participation in the study.

Enrolled subjects were evaluated in the office at baseline, index procedure, pre-discharge, 1 month, and 9 months post-index procedure. Additional follow-up evaluations are ongoing and will occur in the office at 12 months and by phone contact at 2 and 3 years post-index procedure. ABI, Rutherford Classification and Duplex ultrasound follow-up are performed at 1, 9 and 12 months. The Walking Impairment Questionnaire is administered at baseline, 9 and 12 months.

Endpoints: The Primary Endpoint was the 9-month device- and/or procedure-related major adverse event (MAE) rate (subject-based), adjudicated by an independent CEC. MAE was defined as death within 30 days, myocardial infarction (MI) that occurs during index hospitalization, target vessel revascularization (TVR) through nine months, and/or amputation of index limb through nine months.

Secondary Endpoints through 30 days included:

- Technical success (residual stenosis ≤30% based on visual assessment immediately post-procedure)
- Procedural success (technical success and no in-hospital major adverse events)
- Early clinical success at hospital discharge and 30 days post-procedure: improvement in Rutherford classification by ≥1 class as compared to baseline
- Early hemodynamic success at hospital discharge and 30 days post-procedure: improvement in Ankle-Brachial Index (ABI) by ≥0.1 as compared to baseline
- Frequency distribution of Rutherford classification preprocedure and at 30 days postprocedure
- Target vessel revascularization (TVR)
- Target lesion revascularization (TLR)
- Amputation of index limb
- Myocardial infarction (MI) that occurs during index hospitalization
- Death
- Stent thrombosis

Secondary Endpoints through 9 months included:

- Late clinical success at 9 months post-procedure: improvement in Rutherford classification by ≥1 class as compared to baseline
- Frequency distribution of Rutherford classification at 9 months
- Primary, primary-assisted, and secondary patencies at 9 months as assessed by duplex ultrasound
- Restenosis at 9 months as assessed by duplex ultrasound
- Late hemodynamic success at 9 months postprocedure: improvement in ABI by ≥0.1 as compared to baseline
- Change in Walking Impairment Questionnaire scores at 9 months postprocedure
- Target vessel revascularization (TVR)
- Target lesion revascularization (TLR)
- Amputation of index limb
- Death
- Stent thrombosis
- Incidence of unanticipated adverse device effects
- Incidence of all serious adverse events (SAE) reported within the trial
- Incidence of all non-serious adverse events reported within the trial

For the primary endpoint of 9-month MAE, an exact, one-sided 95% upper confidence bound was calculated and compared to the prespecified performance goal. The performance goal of 17% included an expected 9 month MAE rate of 8.0% for Epic and for iliac artery stenting with self-expanding stents based on published literature plus a margin of 9.0%. The upper confidence bound was less than the performance goal; therefore, the primary endpoint was met and the Epic Stent System demonstrated acceptable performance.

Demographics: Baseline characteristics of the ORION clinical trial showed 64.8% were males. The average age was 61.1 (range 39 to 83 years), 96.0% were current or previous smokers, 36.8% had current diabetes mellitus, 78.4% had a history of hyperlipidemia and 76.0% had history of hypertension. Baseline lesion characteristics included mean reference vessel diameter (RVD) of 7.69 mm, mean luminal diameter (MLD) of 2.20 mm, mean percent diameter stenosis (%DS) of 71.51% and mean lesion length of 31.04 mm.

Table 2 presents baseline demographic and clinical characteristics. **Table 3** summarizes baseline lesion characteristics.

Table 2. Baseline Demographics and Clinical Characteristics, All Subjects (N=125)

Variable	(N=125 Subjects)
Demographics	
Age, Mean±SD (N), (min,max)	61.09±9.25 (125) (39.00, 83.00)
Male Gender	64.8% (81/125)
Race/Ethnicity	
Hispanic or Latino	2.4% (3/125)
Caucasian	89.6% (112/125)
Asian	0.0% (0/125)
Black, or African heritage	6.4% (8/125)
Native Hawaiian or other Pacific Islander	0.0% (0/125)
American Indian or Alaska Native	0.8% (1/125)
Other	0.8% (1/125)
General Medical History	
History of Smoking	96.0% (120/125)
Current Diabetes Mellitus	36.8% (46/125)
History of Hyperlipidemia	78.4% (98/125)
History of Hypertension	76.0% (95/125)
History of COPD	24.8% (31/125)
Cardiac History	
History of CAD	58.4% (73/125)
History of MI	28.0% (35/125)
History of PCI	36.8% (46/125)
History of CABG	17.6% (22/125)
Neurologic/Renal History	
History of Transient Ischemic Attacks	4.0% (5/125)
History of Cerebrovascular Accident	5.6% (7/125)
History of Renal Insufficiency	7.2% (9/125)
Peripheral Vascular History	
History of Peripheral Vascular Surgery	8.0% (10/125)
History of Other Peripheral Endovascular Interventions	20.0% (25/125)
History of Claudication	92.8% (116/125)

Table 3. Baseline Lesion Characteristics – Core Lab, All Lesions (N=166)

Lesion Characteristic	(N=166 Lesions)
Iliac Artery Segment	
Left Common Iliac Artery	36.3% (58/160)
Left External Iliac Artery	10.0% (16/160)
Right Common Iliac Artery	36.3% (58/160)
Right External Iliac Artery	17.5% (28/160)
Reference Vessel Diameter (RVD, mm)	7.69±1.79 (160) (4.61, 12.79)
Stent Size to RVD Ratio	1.19±0.25 (160) (0.68, 1.87)
Minimum Lumen Diameter (MLD, mm)	2.20±1.34 (160) (0.00, 5.44)
Percent Diameter Stenosis (% DS)	71.51±16.27 (160) (39.78, 100.00)
Lesion Length (mm)	31.04±22.13 (160) (4.08, 130.10)

Methods: Clinical follow-up was conducted in the office at baseline, index procedure, pre-discharge, 30 days, and 9 months.

Results: **Table 4** presents the 9-month MAE rate (primary endpoint) of 3.4% (4/117) with a one-sided upper confidence bound of 7.7%, significantly less than the performance goal of 17.0% (P<0.0001). The ORION study met its primary endpoint, supporting safety and efficacy of the Epic™ Stent System. Four subjects (3.4%) had an MAE as adjudicated by an independent CEC. There were 4 subjects with TVR through 9 months, no deaths through 30 days, no index hospitalization MI, and no amputations through 9 months.

Table 4. Primary Endpoint- Performance Goal Assessment, All Subjects (N=125)

Measure	(N=125 Subjects)	One-sided 95% Upper Confidence Bound	Performance Goal	p-Value*
9-Month MAE	3.4% (4/117)	7.7%	17.0	<0.0001

*p-Value is from the one-sided exact-test

All subjects enrolled in the ORION trial received an Epic™ Stent. Technical success was achieved in 100% of the lesions treated and procedural success was achieved in 99.2% of the subjects in the study. One subject had an MAE prior to hospital discharge.

Late clinical success was achieved in 89.9% of the subjects and late hemodynamic success was achieved in 66.7% of the treated limbs. Lesion based rates for primary patency and restenosis were 95.9% and 4.1% respectively.

Principal effectiveness and safety results are summarized in **Tables 5** and **6**.

Table 5. Principal Effectiveness and Safety Results, (N=125 Subjects; N=162 Limbs; N=166 Vessels; N=166 Lesions)

Parameter	Epic[a]
9-Month Clinical Outcomes	
Subject based	
Major adverse events (MAE) through 9 months[b]	3.4% (4/117)
Device- or index procedure-related death within 30 days	0.0% (0/117)
Myocardial infarction (MI) during index hospitalization	0.0% (0/117)
Target vessel revascularization (TVR) through 9 months	3.4% (4/117)
Amputation of index limb through 9 months	0.0% (0/117)
Late clinical success[c]	89.9% (98/109)
Death	0.9% (1/117)
Stent thrombosis	2.6% (3/117)
Stent thrombosis within 30 days	2.5% (3/121)
Acute (≤24 hours post index procedure)	0.0% (0/121)
Subacute (>24 hours to ≤30 days post index procedure)	2.5% (3/121)
Lesion based	
Primary patency	95.9% (117/122)
Primary-assisted patency	98.4% (120/122)
Secondary patency	100% (120/120)
Restenosis	2.5% (3/122)
Target lesion revascularization (TLR)	3.2% (5/156)
Limb based	
Early hemodynamic success[d]	
Hospital discharge	61.2% (93/152)
30 days	66.2% (100/151)
Late hemodynamic success[e]	66.7% (94/141)
Vessel based	
TVR	3.2% (5/156)
Peri-procedural Endpoints	
Technical success (per lesion)[f]	100% (166/166)
Procedure success (per subject)[g]	99.2% (124/125)

Numbers are % (counts/sample size) or mean±SD (n); outcomes are based on protocol definitions.

a: Two subjects did not complete a 9-month follow-up visit but did return for a 1 year visit. Data for these 2 subjects are included in primary endpoint calculations for MAE n=117.

b: Includes death within 30 days, MI that occurs during index hospitalization, TVR through 9 months, and/or amputation of index limb through 9 months

c: Improvement in Rutherford classification at 9 months by ≥1 class as compared to baseline

d: Improvement in ankle-brachial index at hospital discharge and 30 days by ≥0.1 as compared to baseline

e: Improvement in ankle-brachial index at 9 months by ≥0.1 as compared to baseline

f: Residual stenosis ≤30% based on visual assessment immediately post-procedure

g: Residual stenosis ≤30% based on visual assessment immediately post-procedure and no in-hospital MAE

Table 6. Summary of Patency and Restenosis Results at 9 Months due to Alternate Analysis, (All Lesions (N=166) in all Subjects (N=125)

	Epic*
Lesion Based	
Primary-assisted patency	96.7% (118/122)
Secondary patency	98.3% (118/120)
Restenosis	4.1% (5/122)

*Two cases of restenosis and TLR occurred in one subject (Left Common and Right Common Iliac Arteries) at the most proximal part of the stents (located at the ostium of both iliac arteries). In this case, the conventional method of deriving Systolic Velocity Ratio is invalid and the Proximal Peak Systolic Velocity was analyzed to assess restenosis at 9 months. These are the results after the alternate analysis has been applied.

The rates of center-reported serious adverse events (SAEs) are summarized by MedDRA System / Organ Class and MedDRA Preferred Term in **Table 7**. The rates include all reported serious events, regardless of study device or procedure relatedness.

Table 7. Rates of Center-Reported Serious Adverse Events to 300 Days Intent-to-Treat, All Subjects (N=125)

Serious Adverse Event			(N= 125 Subjects)
MedDRA System/Organ Class	**MedDRA Preferred Term**	**Events**	**Rate of Subjects with Event**
Total	Total	88	32.0% (40/125)
Not Coded	Not Coded	1	0.8% (1/125)
Blood And Lymphatic System Disorders	Total	4	1.6% (2/125)
	Anaemia	2	0.8% (1/125)
	Febrile Neutropenia	1	0.8% (1/125)
	Haemorrhagic Anaemia	1	0.8% (1/125)
Cardiac Disorders	Total	23	12.8% (16/125)
	Acute Coronary Syndrome	1	0.8% (1/125)
	Angina Pectoris	3	2.4% (3/125)
	Angina Unstable	1	0.8% (1/125)
	Atrial Fibrillation	7	3.2% (4/125)
	Cardiac Arrest	1	0.8% (1/125)
	Coronary Artery Disease	4	2.4% (3/125)
	Coronary Artery Stenosis	1	0.8% (1/125)
	Ischaemic Cardiomyopathy	2	1.6% (2/125)
	Mitral Valve Stenosis	1	0.8% (1/125)
	Myocardial Infarction	2	1.6% (2/125)
Eye Disorders	Total	1	0.8% (1/125)
	Blindness	1	0.8% (1/125)
Gastrointestinal Disorders	Total	6	2.4% (3/125)
	Abdominal Pain	2	0.8% (1/125)
	Constipation	1	0.8% (1/125)
	Gastrointestinal Haemorrhage	1	0.8% (1/125)
	Ileus	1	0.8% (1/125)
	Upper Gastrointestinal Haemorrhage	1	0.8% (1/125)
General Disorders And Administration Site Conditions	Total	5	4.0% (5/125)
	Catheter Site Haematoma	1	0.8% (1/125)
	Catheter Site Haemorrhage	1	0.8% (1/125)
	Chest Discomfort	1	0.8% (1/125)
	Non-cardiac Chest Pain	1	0.8% (1/125)
	Oedema Peripheral	1	0.8% (1/125)
Hepatobiliary Disorders	Total	3	1.6% (2/125)
	Bile Duct Stenosis	1	0.8% (1/125)
	Cholecystitis Acute	1	0.8% (1/125)
	Cholecystitis Chronic	1	0.8% (1/125)
Infections And Infestations	Total	8	4.0% (5/125)
	Abdominal Abscess	1	0.8% (1/125)
	Clostridial Infection	1	0.8% (1/125)
	Diverticulitis	2	0.8% (1/125)
	Pneumonia	3	2.4% (3/125)
	Wound Infection	1	0.8% (1/125)
Injury, Poisoning And Procedural Complications	Total	6	4.0% (5/125)
	Drug Toxicity	1	0.8% (1/125)
	Stent-graft Malfunction	2	1.6% (2/125)
	Vascular Pseudoaneurysm	2	1.6% (2/125)
	Wound Dehiscence	1	0.8% (1/125)
Investigations	Total	1	0.8% (1/125)
	Blood Creatinine Increased	1	0.8% (1/125)
Musculoskeletal And Connective Tissue Disorders	Total	2	1.6% (2/125)
	Lumbar Spinal Stenosis	1	0.8% (1/125)
	Pain In Extremity	1	0.8% (1/125)

Serious Adverse Event			(N= 125 Subjects)
MedDRA System/Organ Class	**MedDRA Preferred Term**	**Events**	**Rate of Subjects with Event**
Neoplasms Benign, Malignant And Unspecified (incl Cysts And Polyps)	Total	3	2.4% (3/125)
	Breast Cancer	1	0.8% (1/125)
	Lung Neoplasm Malignant	1	0.8% (1/125)
	Recurrent Cancer	1	0.8% (1/125)
Nervous System Disorders	Total	4	3.2% (4/125)
	Carotid Artery Stenosis	1	0.8% (1/125)
	Diplegia	1	0.8% (1/125)
	Headache	1	0.8% (1/125)
	Hypoaesthesia	1	0.8% (1/125)
Psychiatric Disorders	Total	1	0.8% (1/125)
	Mental Status Changes	1	0.8% (1/125)
Respiratory, Thoracic And Mediastinal Disorders	Total	7	3.2% (4/125)
	Acute Pulmonary Oedema	1	0.8% (1/125)
	Acute Respiratory Failure	1	0.8% (1/125)
	Chronic Obstructive Pulmonary Disease	4	1.6% (2/125)
	Pneumonia Aspiration	1	0.8% (1/125)
Vascular Disorders	Total	13	8.8% (11/125)
	Angiodysplasia	1	0.8% (1/125)
	Arterial Stenosis	1	0.8% (1/125)
	Iliac Artery Thrombosis	1	0.8% (1/125)
	Intermittent Claudication	2	1.6% (2/125)
	Peripheral Artery Dissection	3	2.4% (3/125)
	Peripheral Ischaemia	1	0.8% (1/125)
	Peripheral Vascular Disorder	1	0.8% (1/125)
	Thrombosis	1	0.8% (1/125)
	Vascular Occlusion	1	0.8% (1/125)
	Vessel Perforation	1	0.8% (1/125)

Conclusions: The ORION trial demonstrated the Epic™ Stent System to be safe and effective in the treatment of atherosclerotic iliac artery disease.

HOW SUPPLIED

Handling and Storage

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Upper Temperature Limit: 55°C

Store in a cool, dry, dark place.

RECOMMENDED MATERIALS

- 0.035 in (0.89 mm) guidewire of appropriate length
- Introducer sheath of appropriate size and length and equipped with a hemostatic valve
- Syringe (10 ml (cc) for prepping the stent delivery system)

OPERATIONAL INSTRUCTIONS

Patient Preparation

The percutaneous placement of an iliac self-expanding nitinol stent in a stenotic or obstructed artery should be done in an angiography procedure room equipped 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.

Select Proper Stent System

1. Measure the diameter of the reference vessel (proximal and distal to the lesion or obstruction) and use the largest reference diameter as your basis for choosing the appropriate stent size. Select a stent per **Table 8** below to achieve a secure placement:

Warning: Improper stent size selection may lead to stent migration or stent jumping.

Table 8

Reference Vessel Diameter (mm)	Labeled Stent Diameter (mm)
5	6
5-6	7
6-7	8
7-8	9
8-9	10
9-11	12

2. Measure the entire length of the actual lesion and select the proper length of the stent(s) to be deployed. In-vitro testing has predicted the Epic Stent foreshortens 4.2% (for 6-7 mm diameters), 5.2% (for 8-10 mm diameters) and 8.1% (for 12 mm diameter) when used in the recommended vessel diameters. 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.
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. Open the door on the tray that contains the handle.
5. Carefully withdraw the stent delivery system from the tray by grasping the handle of the delivery system.
6. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
7. If the safety lock (3) (Reference **Figure 2**) is not attached to the device, verify that the stent is fully constrained in the delivery system and place safety lock in position as shown in **Figure 2**.
8. Attach a 10 ml (cc) syringe filled with saline to the luer (7) (Reference **Figure 2**) on the handle. Apply positive pressure. Continue to flush until saline appears at the distal end of both the guidewire lumen and the sheath – tip junction.
9. Remove the flushing luer (7) (Reference **Figure 2**).

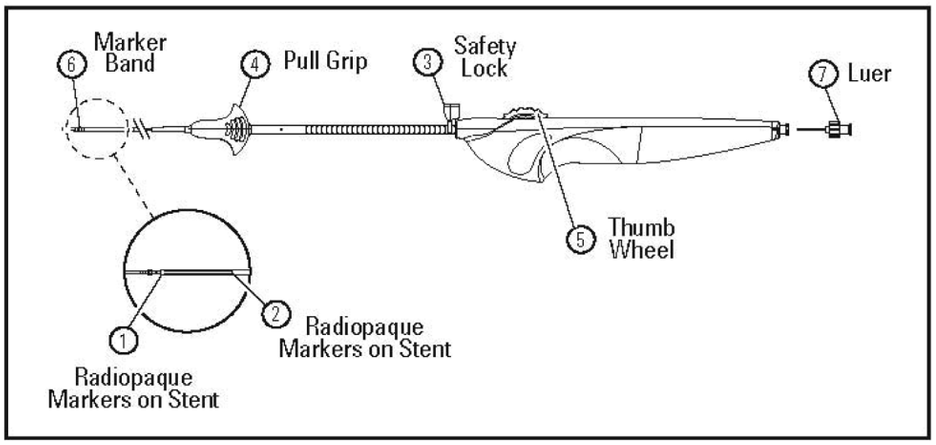

Figure 2.

Delivery Procedures

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

   Precaution: Always use an introducer or guide sheath for the implant procedure, to protect the access site.

2. Pass a 0.035 in (0.89 mm) guidewire of appropriate length across the target lesion or obstruction.
3. Pre-dilate the lesion as necessary 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.

   Precaution: Physicians should use judgment based on experience in dilating arterial lesions and/or obstructions. Never force a balloon catheter to inflate to the point of risking dissection of the arterial wall.

4. Place the Epic™ Stent System over the guidewire. Advance the delivery system as a unit through the hemostatic valve of the introducer sheath.

Stent Deployment Procedure (Reference Figure 2)

1. Advance the delivery system until the stent radiopaque markers (1) and (2) are centered over the target lesion.

   Warning: If unable to initiate release of the stent or if strong resistance is met with the introduction of the delivery system, remove the entire system from the patient and introduce a new system.

   Warning: Remove all slack from the catheter prior to stent deployment, as excessive slack may result in stent jumping or the stent length being reduced.

   Precaution: Do not use a power injector through the delivery system for angiography.

2. Remove the safety lock positioned on the rack (3) by pulling vertically. Confirm that the radiopaque markers are still properly positioned across the target lesion. Keep the entire length of the delivery system as straight as possible and maintain slight backward tension on the delivery system during deployment.

   Note: If repositioning of the delivery system is required prior to stent deployment, reinsert the safety lock to prevent inadvertent deployment.

3. Prior to initiating stent deployment, make sure to keep the stent delivery catheter stationary. Do not hold the outer sheath of the delivery catheter during deployment as it must be free to move.
4. Start deploying the stent by slowly rotating the thumb wheel (5). Allow the stent to contact and anchor to the vessel wall and then proceed with one of the following methods:
   - Roll the thumb wheel (5) of the deployment handle in a proximal direction. Continue to roll thumb wheel until the radiopaque marker of the exterior shaft (6) passes the proximal radiopaque markers of the stent resulting in full deployment. Do not continue to roll the thumb wheel after the stent is fully deployed.

     Note: Do not restrict movement of the thumb wheel (5) otherwise deployment difficulties could be encountered.

   - Grasp the manual pull grip (4) and pull toward the deployment handle. Continue to pull back until the radiopaque marker of the exterior shaft (6) passes the proximal radiopaque markers of the stent resulting in full deployment. Do not continue to pull back the manual grip after the stent is fully deployed.
   - Any combination of the methods above can be used to achieve full deployment.
5. When released from the delivery system, the stent will immediately expand into position. View the delivery system under fluoroscopy, ensuring that the exterior shaft marker band (6) has crossed the proximal stent markers. The delivery system can now be withdrawn. Use caution when withdrawing the stent delivery system and always manipulate under fluoroscopy. If unusual resistance is felt, re-advance and rotate the delivery system in an attempt to center the delivery system within the vessel, and then carefully attempt repeat withdrawal.
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 dilate the stent using a balloon that is larger in diameter than the 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

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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