Medtronic

ASSURANT® COBALT ILIAC

Balloon-Expandable Stent System

Instructions for Use (IFU)

CAUTION: Federal law (USA) restricts this device for sale by or on order of a physician.

Assurant® is a registered trademark of Medtronic, Inc.

Instructions for Use

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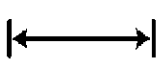
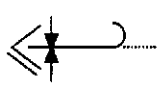
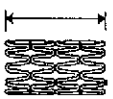
EXPLANATION OF SYMBOLS

Symbol	Definition
	Date of manufacture
	Do not use if package is damaged
	Do not reuse
	Lot number
	Manufacturer
	Catalogue number
	Sterilized using irradiation
	Use by
	MR Conditional
	Consult instructions for use at: www.medtronic.com/manuals
	Contents: One device
	Inflation pressure
	Effective Length
	Manufactured in
	Maximum guidewire diameter
	Minimum sheath inner diameter

	Nominal pressure
	Peel here
	Non-pyrogenic
	Rated burst pressure
	Do not exceed rated burst pressure
	Stent ID (inner diameter)
	Stent length

1.0 DEVICE DESCRIPTION

The Assurant Cobalt Iliac Balloon-Expandable Stent System consists of a balloon delivery system catheter and a premounted balloon-expandable stent.

The Assurant Cobalt stent is made from a cobalt-chromium alloy (MP35N). The stent delivery system has two radiopaque markers at the proximal and distal end of the balloon to aid in the placement of the stent. The stent is delivered to the intended lesion site, expanded by inflation, and remains as a permanent vessel scaffolding implant. An inflatable balloon on the stent delivery system allows for deployment of the stent. Upon deployment, the stent imparts an outward radial force on the arterial lumen to establish patency.

The Assurant Cobalt stent is available in 6 mm to 10 mm diameters and 20 mm to 60 mm lengths (Table 1). The Assurant Cobalt delivery system is available in 2 catheter lengths: 80 cm and 130 cm, and is compatible with a 6 F (0.086 in) sheath and a 0.035 in (0.89 mm) guidewire.

Table 1. Assurant Cobalt Iliac Balloon-Expandable Stent System Information

Stent Diameter (mm)	Stent Length (mm)	Nominal Deployment Pressure (atm)	Rated Burst Pressure (atm)	Minimum Required Sheath Size
6.0	20, 30, 40, 60	8	12	6 F (0.086 in)
7.0	20, 30, 40, 60	8	12	6 F (0.086 in)
8.0	20, 30, 40, 60	8	12	6 F (0.086 in)
9.0	30, 40, 60	8	10	6 F (0.086 in)
10.0	30, 40, 60	8	10	6 F (0.086 in)

2.0 INDICATIONS FOR USE

The Assurant Cobalt Iliac Balloon-Expandable Stent System is indicated for improving iliac luminal diameter in patients with de novo and restenotic lesions in the common and external iliac arteries with reference vessel diameters between 6 mm and 10 mm and lesion lengths up to 61 mm. The stent is intended as a permanent implant.

3.0 CONTRAINDICATIONS

There are no known contraindications.

4.0 WARNINGS

- The Assurant Cobalt Iliac Balloon-Expandable Stent System is provided sterile for single use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the mechanical/structural integrity of the device, compromise the essential material and design characteristics of the device, and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Do not modify the packaging or labeling as this may lead to the use of an incorrect or expired product, which could result in patient injury or death. Use prior to the Use By date noted on the package.
- Patients allergic to cobalt-chromium alloy may suffer an allergic reaction to this implant.
- Administration of appropriate anticoagulant therapy and/or antiplatelet therapy is critical to the success of the procedure.
- When multiple stents are required and placement may result in overlap or stent-to-stent contact, stent materials should be of similar composition to avoid the potential for dissimilar metal corrosion.
- Use only appropriate balloon-inflation media. Do not use air or gas to inflate the balloon as it may cause uneven expansion and stent deployment difficulties.
- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized iliac stents is unknown at present.

5.0 PRECAUTIONS

Caution: Read all the instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

- Use of the Assurant Cobalt Iliac Balloon-Expandable Stent System requires advanced iliac angioplasty technical skills. The following instructions will provide technical guidance but do not obviate the need for adequate training prior to use of the device.
- Stent placement should only be performed at hospitals where emergency surgery can be performed.
- Do not prepare or preinflate the stent delivery balloon prior to stent deployment other than as directed in these Instructions for Use.
- If the position of the stent is not optimal or appropriate for the vessel, it should not be deployed. **The stent cannot be repositioned once deployed**.
- Prior to stent deployment, utilize high resolution fluoroscopy to verify that the stent has not been damaged or dislodged during positioning.
- The Assurant Cobalt Iliac Balloon-Expandable Stent System is designed for use as a unit. The stent must not be removed from the delivery system.
- The Assurant Cobalt stent is not designed to be crimped onto another delivery system.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery system balloon. Removing the stent from its delivery system or excessively manipulating the stent (eg, rolling the mounted stent) may cause dislodgement, damage to the stent, and stent embolization.
- Once deployment is initiated, the stent can not be removed.
- Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the deployed stent. If the target lesion is not completely stented, use additional Assurant Cobalt Iliac stents as necessary to adequately treat the lesion.
- Use caution when crossing the stented area with ancillary equipment to avoid dislodgment of the stent.
- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications, and bleeding events.
- The Assurant Cobalt Iliac Balloon-Expandable Stent System does not provide for distal contrast injections or pressure measurements through the guidewire lumen.
- Stent retrieval methods (use of additional wires, snares, or forceps) may result in additional trauma to the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

5.1 Stent Delivery System Removal Precautions

If unusual resistance is felt at any time during lesion access or during the removal of the stent delivery system, do not force passage; resistance may indicate a problem. The stent delivery system and the sheath may need to be removed as a single unit. This must be done under direct visualization using fluoroscopy (see 10.4.1 Back-out Procedure).

6.0 POTENTIAL COMPLICATIONS

The following complications may be associated with the use of iliac stenting devices or iliac angioplasty:

- acute myocardial infarction
- allergic reaction (contrast medium, drug, or stent material)
- aneurysm, pseudoaneurysm, or arteriovenous fistula
- angina or coronary ischemia
- arrhythmias
- bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- death

- detachment and/or implantation of a component of the system
- embolization, arterial or other
- emergent or urgent surgery to perfuse limb or remove stent
- fever
- hematoma or hemorrhagic event
- hypotension or hypertension
- infection, local or systemic, including bacteremia or septicemia
- ischemia or infarction of tissue or organ
- pain at catheter insertion site
- pulmonary embolism
- renal failure or insufficiency secondary to contrast medium
- restenosis of vessel in stented segment
- stent malapposition or migration
- stent strut fracture
- stent thrombosis or occlusion
- stroke, cerebrovascular accident (CVA), or transient ischemic attack (TIA)
- target limb loss (amputation of toe, foot, and/or leg)
- vascular thrombosis or occlusion at puncture site, treatment site, or remote site
- vessel dissection, perforation, or rupture
- vessel spasm or recoil
- worsening claudication or rest pain

7.0 PATIENT INFORMATION

In addition to these Instructions for Use, the Assurant Cobalt Iliac Balloon-Expandable Stent System includes a Patient Implant Card that contains specific information about the Assurant Cobalt stent. All patients should be given this card and be instructed to keep the card in their possession at all times for procedure and stent identification.

8.0 HOW SUPPLIED

Contents: One sterile Assurant Cobalt Iliac Balloon-Expandable Stent System.
Sterile: This device is sterilized with electron beam radiation and is nonpyrogenic.
Storage: Store in a dry, dark, cool place.
CAUTION: Do not use if the package is damaged. Contact Medtronic US Customer Service/Product Inquiries at (888) 283-7868.

9.0 SELECTION OF STENT SIZE

The available stent diameters are 6 mm to 10 mm with stent lengths of 20 mm to 60 mm. Required stent diameter and length will be visually estimated by use of angiography or determined by intravascular ultrasound prior to stent selection. See Table 2 for guidance for stent diameter selection.

Table 2. Balloon Pressure Versus Stent Inner Diameter (Compliance Chart)

	Inflation Pressure		Stent Nominal Inner Diameter				
	(kPa)	(atm)	6.0 mm	7.0 mm	8.0 mm	9.0 mm	10.0 mm
	507	5	5.7	6.2	7.2	8.1	9.0
	608	6	5.9	6.5	7.5	8.5	9.4
	709	7	6.0	6.7	7.7	8.8	9.7
Nominal Pressure	811	8	6.2	6.9	7.9	9.1	10.0
	912	9	6.3	7.1	8.1	9.3	10.2
RBP for 9.0 mm-10.0 mm	1013	10	6.4	7.2	8.2	9.4	10.4
	1115	11	6.5	7.3	8.4		
RBP for 6.0 mm-8.0 mm	1216	12	6.6	7.4	8.5		

10.0 INSTRUCTIONS FOR USE

10.1 Inspection Prior to Use

Carefully inspect the inner sterile package before opening. Do not use if any defects are noted or the Use By date has elapsed. If the integrity of the sterile package is compromised, contact your local Medtronic representative for return information.

10.2 Recommended Materials

- appropriate size sheath, as identified on the device package label
- one 20 mL syringe/indeflator
- normal heparinized saline
- one 0.035 in (0.89 mm) guidewire
- contrast medium diluted 1:1 with heparinized normal saline
- one inflation device
- optional three-way stopcock
- sterile bowl filled with heparinized normal saline

10.3 Preparation

10.3.1 Guidewire Lumen Flush

1. Flush stent delivery system guidewire lumen with heparinized saline.

10.3.2 Balloon Preparation

1. Remove the protective sheath covering the stent/balloon. Care should be taken not to disrupt the stent.
2. Verify that the stent is positioned between the proximal and distal balloon markers.
3. Fill a 20 mL syringe/indeflator with 5 mL of contrast/saline mixture.
4. Attach the syringe/indeflator to the inflation lumen of the stent delivery system and apply negative pressure for 20 to 30 seconds.
5. Slowly release the negative pressure allowing the mixture to be drawn into the lumen.
6. Detach the syringe/indeflator and leave a meniscus of mixture on the hub of the inflation lumen.
7. Prepare the inflation device according to standard practice and purge to remove all air from the syringe and tubing.
8. Attach the inflation device directly to the stent delivery system inflation lumen, ensuring no air bubbles remain at the connection.
9. Maintain neutral pressure (ambient position).
   Caution: DO NOT put negative pressure on the inflation device after balloon preparation or prior to delivering the stent.
10. Submerge the stent into a sterile bowl containing heparinized normal saline solution.
    Caution: DO NOT use gauze sponges to wipe down the stent as gauze fibers may disrupt or damage the stent.
11. Visually inspect the stent to ensure it is placed between the proximal and distal balloon markers.

12. Check the integrity of the stent on the stent delivery system by gently running the stent segment through the thumb and finger. If not intact, do not use the stent system; utilize a new sterile system. Contact Medtronic US Customer Service and return the device to Medtronic.

10.4 Delivery Procedure

Caution: If resistance is encountered at any time during the procedure, do not force passage. The use of force may cause damage to the stent and/or to the vessel.

1. Prepare the vascular access site according to standard practice for percutaneous interventional procedures.
2. If predilation is performed, predilate the lesion/vessel with an appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel.
3. Maintain neutral (ambient) pressure on the inflation device. If used, open the rotating hemostatic valve to allow for easy passage of the stent.
4. Ensure guidewire and sheath stability before advancing the stent delivery system into the artery.
5. Carefully advance the stent delivery system over the guidewire and into the hub of the sheath.
   Caution: If resistance to the stent delivery system is encountered at any time, do not force passage. Maintain guidewire placement across the lesion, remove the stent delivery system and the sheath as a single unit, and examine (see 10.4.1 Back-out Procedure).
6. Advance the stent delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as reference points. If the position of the stent is not optimal, it should be carefully repositioned or removed prior to deployment (see 10.4.1 Back-out Procedure). Do not expand the stent if it is not properly positioned in the target lesion segment of the vessel.
   Note: Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
7. If a hemostatic valve is used, tighten the valve sufficiently to stabilize the guidewire and stent delivery system. Do not overtighten. The stent is now ready to be deployed.
8. When treating multiple lesions or when placing multiple stents, the distal lesion should be initially stented, followed by the proximal lesion. Stenting in this order removes the need to cross the proximal stent while placing the distal stent and reduces the chance of dislodging the proximal stent.

10.4.1 Back-out Procedure

If unusual resistance is felt at any time during lesion access or during the removal of the stent delivery system, do not force passage; resistance may indicate a problem. The stent delivery system and the sheath may need to be removed as a single unit. This must be done under direct visualization using fluoroscopy.

1. Pull back the stent delivery system until the proximal marker is aligned with the distal tip of the guide sheath.
2. Maintain guidewire position across the lesion and perform one of the following:
   a. If a guide sheath is used without the use of an introducer sheath, carefully remove the stent delivery system and guide sheath together as a single unit.
   b. If a guide sheath is used in conjunction with an introducer sheath;
      i. Pull back both the stent delivery system and guide sheath together as a single unit until the tip of the guide sheath is inside the arterial access introducer sheath. This will result in the tip of the guide sheath straightening, allowing the stent delivery system balloon to be in coaxial alignment with the arterial access introducer sheath lumen.
      ii. Carefully pull the stent delivery system into the guide sheath.

iii. Remove the stent delivery system and the guide sheath as a single unit from the introducer sheath.

Failure to follow these steps and/or applying excessive force to the stent delivery system may result in loss of or damage to the stent or stent delivery system.

10.5 Deployment Procedure

1. Deploy the stent by inflating the stent delivery system balloon to nominal pressure. **Note:** Refer to the device package label or Table 2 for the proper inflation pressure. DO NOT exceed rated burst pressure.
2. Maintain inflation pressure until full stent apposition is achieved. Use fluoroscopic visualization to determine the optimum expanded stent diameter as compared to the proximal and distal reference vessel diameter.
   Note: Underexpansion of the stent may result in stent migration. Care must be taken to properly expand the stent to ensure the stent is in full contact with the arterial wall upon deflation of the stent delivery system balloon.

10.6 Removal Procedure

1. Deflate the balloon by putting negative pressure on the inflation device.
   Note: Allow adequate time for full balloon deflation. Longer balloons and larger diameter balloons may require more time for deflation. Verify full deflation has been achieved under direct visualization using fluoroscopy.
2. Maintain the position of the guidewire. Fully open the hemostatic valve, if used.
3. Very slowly withdraw the balloon from the stent, maintaining negative pressure.
4. If any resistance is encountered when removing the balloon from the stent:
   a. Reinflate the balloon and ensure the stent is well apposed to the arterial wall.
   b. Deflate the balloon.
   c. Once the balloon is deflated, maintain negative pressure and gently remove the balloon from the stent.
5. Repeat angiography and visually assess the vessel and the stent for proper expansion.
6. If a more complete stent apposition is necessary, postdilation can be performed with an appropriately sized balloon having a diameter less than or equal to the reference diameter of the vessel.
   Note: The use of high balloon inflation pressures may overexpand the vessel and could result in vessel dissection. Do not inflate the balloon beyond rated burst pressure.
   Note: The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
7. Repeat angiography to evaluate and determine procedure status or termination.
8. Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intra-arterial infusions of a thrombolytic agent are recommended.
9. After use, dispose of the device according to the applicable hospital, administrative, or local government regulations.

10.7 Post Stent Placement Precautions

Care must be exercised when crossing a newly deployed stent with sheaths, guidewires and catheters to avoid disrupting the stent.

11.0 MRI INFORMATION

The Assurant Cobalt Iliac Stent was determined to be MR conditional according to the terminology specified in ASTM F2503-08[1].

[1] ASTM F2503-08: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. American Society for Testing and Materials (ASTM) International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, USA.

Nonclinical testing demonstrated that the Assurant Cobalt Iliac Stent is MR conditional. A patient with this implant can be scanned safely, immediately after placement under the following conditions:

Static Magnetic Field
- static magnetic field of 3 tesla or 1.5 tesla
- highest spatial gradient magnetic field of 720 gauss/cm or less

MRI-Related Heating
- Whole body averaged specific absorption rate (SAR) of 2 W/kg in the Normal Operating Mode (ie, the mode of operation of the MRI system in which none of the outputs have a value that cause physiological stress to patients) for 15 minutes (ie, per pulse sequence).

MRI-Related Heating – Single and Two Overlapped Stents
In nonclinical testing, the Assurant Cobalt Iliac Stent produced the following temperature rises during MRI performed for 15 min (ie, per pulse sequence) in 1.5-tesla (Magnetom[2], Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS) and 3-tesla (Excite[3], Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) MR systems, as described in Table 3:

Table 3. MRI Related Heating

	Highest Temperature Change	MRI Condition	MR System Reported, Whole Body Average SAR (W/kg)	Calorimetry Value (W/kg)
Single Stents	+1.1°C	1.5 T/64 MHz	3.7	1.54
	+0.9°C	3 T/128 MHz	3.0	2.8
Two Overlapped Stents	+2.4°C	1.5 T/ 64 MHz	2.7	2.1
	+2.9°C	3 T/128 MHz	2.4	1.9

Therefore, the MRI-related heating tests for the Assurant Cobalt Iliac Stent indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 1.1°C for single stents and equal to or less than 2.9°C for two overlapped stents.

Artifacts
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Assurant Cobalt Iliac Stent. The maximum artifact size (ie, as seen on the gradient echo pulse sequence) extends approximately 15 mm relative to the size and shape of this implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

Table 4. Dimensions: Assurant Cobalt Iliac Stent, 10-mm diameter; 60-mm length

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	819 mm^2	128 mm^2	1,550 mm^2	232 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

12.0 SUMMARY OF CLINICAL STUDY

12.1 The ACTIVE Study
The objective of the ACTIVE (Use of the Assurant Cobalt Stent System in the Treatment of Iliac VEssel Disease) Study was to evaluate the safety and efficacy of the Assurant Cobalt Iliac Balloon-Expandable Stent System in the treatment of de novo and restenotic lesions in iliac arteries of subjects with Peripheral Artery Disease (PAD). The primary endpoint for the

[2] Magnatom and syngo are trademarks of Siemens, AG.
[3] Excite is a trademark of General Electric Company.

123 subject data was safety at 9 months. This was measured by the occurrence of major adverse events (MAE) defined as device and/or procedure related death, target limb loss, and/or clinically driven target lesion or target vessel revascularization (TLR/TVR).
Note: Data collection for The ACTIVE Study is ongoing until the 3 year time point.

The data for the 123 subjects through 9 months of follow-up enrolled at 17 sites in the US are presented below.

12.2 Patient Population
Patients 18 years of age and older with symptomatic ischemic Peripheral Artery Disease (PAD) (Fontaine stage II or III), with stenotic lesions ≥50% and ≤100% in the common or external iliac arteries, with target vessel reference diameters ≥6.0 mm and ≤10.0 mm by visual estimate, and lesion lengths ≤100 mm which were amenable to percutaneous treatment by placement of a vascular stent, were eligible for this study. Multiple vessel disease, de novo target lesions, and restenotic lesions that have not undergone percutaneous interventional treatment using the same access site to any vessel within a minimum of 30 days prior to enrollment into the study, were included.

Table 5. Subject Demographic, Medical History, and Risk Factors[a]

	N=123
Age (n = 123)	**Years**
Mean ± SD	65.5 ± 10.6
Median	66.4
Min, Max	41, 86
Sex	**% (m/n)**
Male	56.1(69/123)
Female	43.9(54/123)
Medical History and Risk Factors	**% (m/n)**
Diabetes Mellitus	38.2 (47/123)
Type I	2.4 (3/123)
Type II	35.8 (44/123)
Dyslipidemia	74.8 (92/123)
Hypertension	82.9 (102/123)
Cigarette Smoking During the Past Year	50.4 (62/123)
Currently Smoking Cigarettes	42.3 (52/123)
History of Coronary Artery Disease	66.7 (82/123)
History of COPD	28.0 (33/118)
Previous MI	26.5 (31/117)
Previous Peripheral Vascular Disease (other than iliac)	63.4 (78/123)
Previous PTA/Stenting to Target Limb	8.1 (10/123)
Previous Aorta/Peripheral Bypass to Target Limb	2.4 (3/123)

[a] Based on number of subjects with available data
N = Intent-to-treat population
m = number of subjects in the category
n = number of subjects in the study group with sufficient data for analysis

Note: All subjects had known values for the tabulated variables, with the exception of history of COPD and Previous MI for which a value of unknown was entered by the Investigational Site.
Note: Site Reported Table

12.3 Methods

After a series of screening assessments and the administration of written informed consent, subjects underwent stent placement using standard procedures (according to the Instructions for Use) for percutaneous interventional procedures. After catheter introduction, supplemental anticoagulation was administered at the discretion of the investigator. Treatment in up to 2 target lesions and up to 2 nontarget lesions was permitted. Only 1 target lesion was allowed per limb. If bilateral treatment was planned with the investigational device no nontarget lesions were allowed. Up to 2 stents may have been used per target lesion.

After hospital discharge, patients were required to return to the study center for clinical assessments on Day 30 ± 5 days and 9 months ± 30 days. Ischemic testing, duplex scans, ABI, toe brachial index (TBI), Fontaine Scale Classification, and walking assessment were performed at the Day 30 and 9 month visits. Additionally, an angiogram was performed as needed to assess the safety and efficacy of the Assurant Cobalt Stent.

Table 6. Angiographic Quantitative Analysis

	Lesions[a]=159			
	n	Mean ± SD	Median	Min, Max
Reference Vessel Diameter (mm)	159	7.619±1.183	7.645	4.74, 10.80
Lesion Length (total) (mm)	154	29.430±14.659	26.400	1.00, 88.46
Lesion Preprocedure Percent Stenosis (most severe)	159	68.735±14.221	67.001	45.49, 100.00
Lesion Preprocedure Minimum Lumen Diameter (mm)	159	2.387±1.171	2.470	0.00, 5.70
Lesion Postprocedure Percent Stenosis (most severe)	159	14.615±6.989	13.944	1.30, 33.63
Lesion Postprocedure Minimum Lumen Diameter (mm)	159	6.584±1.157	6.560	3.81, 9.52
Acute gain (mm)	159	4.197±1.238	4.130	1.30, 8.82

[a] Lesions as reported by the Angiographic Core Laboratory
n = number of lesions in the study group with sufficient data for analysis

Table 7. Angiographic Morphology Data

Lesion Characteristic	Lesions[a] = 159 % (m/n)
Preprocedure Assessment	
Eccentric	24.5 (39/159)
Ulceration	5.7 (9/159)
Calcification	
None/mild	42.6 (66/155)
Moderate	36.1 (56/155)
Severe	21.3 (33/155)
Thrombus	0.0 (0/159)
Postprocedure Assessment	
Dissection Grade	
0 (no dissection)	100.0(159/159)
A	0.0(0/159)
B	0.0(0/159)
C	0.0(0/159)
D	0.0(0/159)
E	0.0(0/159)
F	0.0(0/159)

[a] Lesions as reported by the Angiographic Core Laboratory
m = number of lesions in the category
n = number of lesions in the study group with sufficient data for analysis

12.4 Results

The overall MAE rate at 9 months was 0.8% (1/121) (95% CI, 0.0%, 3.9%). The clinically driven TLR and TVR rates at 9 months were 0.8% (1/121) (95% CI, 0.0%, 3.9%).

Table 8. Primary Endpoint and Details of Major Adverse Events through 9 Months

	N = 123	
Primary Endpoint	**% (m/n)[a]**	**% Exact One-side Upper 95% CI**
MAE to 9 Months	0.8% (1/121)	(0.0%, 3.9%)
Death (Device and/or Procedure Related)	0.0% (0/121)	(0.0%, 2.4%)
Device Related	0.0% (0/121)	(0.0%, 2.4%)
Procedure Related	0.0% (0/121)	(0.0%, 2.4%)
Target Limb Loss	0.0% (0/121)	(0.0%, 2.4%)
TLR	0.8% (1/121)	(0.0%, 3.9%)
TL-PTA[b]	0.8% (1/121)	(0.0%, 3.9%)
TL-Iliac Bypass Graft	0.0% (0/121)	(0.0%, 2.4%)
TVR	0.8% (1/121)	(0.0%, 3.9%)
TV-PTA[c]	0.8% (1/121)	(0.0%, 3.9%)
TV-Iliac Bypass Graft	0.0% (0/121)	(0.0%, 2.4%)

[a] Percentage based on the number of subjects with sufficient follow-up for 9-month MAE assessment. Insufficient follow-up for 9-month MAE assessment is defined by a) withdrawn before 240 days without having MAE events, b) lost to follow-up before 240 days without having MAE events and had no contact thereafter, or c) any death unrelated to the device and/or procedure before 240 days without having MAE events.
[b] Target Lesion Percutaneous Transluminal Angioplasty
[c] Target Vessel Percutaneous Transluminal Angioplasty

Only one subject was deemed to have met the criteria defined in the protocol for a major adverse event. This subject had a target lesion/vessel revascularization 10 days postprocedure. This subject was reported as not taking aspirin or clopidogrel since being discharged from the hospital.

In addition, the results for secondary endpoints of primary patency rate of the target vessel at 9 months as determined by the duplex ultrasound core lab, acute success (device, lesion, and procedure), clinical success, hemodynamic success at 30 days, and 9 months and all cause mortality at 30 days and 9 months, are shown in table 9.

Table 9. Secondary Endpoints

Subjects[a] = 123 Lesions[b] = 141 Lesions[c] = 159 Limbs[d] = 159		
Secondary Endpoint	**% (m/n)[e]**	**% Exact Two-sided Upper 95% CI**
Primary Patency Rate at 9 Months	100.0% (141/141)	(97.4%, 100.0%)
Device Success[f]	97.5% (155/159)	(93.7%, 99.3%)
Lesion Success[g]	97.5% (155/159)	(93.7%, 99.3%)
Procedure Success[h]	96.7% (119/123)	(91.9%, 99.1%)
Clinical Success at 30 Days[i]	88.2% (134/152)	(81.9%, 92.8%)
Clinical Success at 9 Months[i]	90.4% (132/146)	(84.4%, 94.7%)
Hemodynamic Success at 30 Days[j]	64.1% (98/153)	(55.9%, 71.6%)
Hemodynamic Success at 9 Months[j]	55.2% (79/143)	(46.7%, 63.6%)
Hemodynamic Success at 30 Days[k]	75.8% (116/153)	(68.2%, 82.4%)
Hemodynamic Success at 9 Months[k]	80.1% (117/146)	(72.7%, 86.3%)
All Cause Mortality to 30 Days[l]	0.0% (0/123)	(0.0%, 3.0%)
All Cause Mortality to 9 Months[o]	0.0% (0/121)	(0.0%, 3.0%)

[a] Intent-to-treat population
[b] Lesions as reported by Duplex Core Laboratory
[c] Lesions as reported by Angiographic Core Laboratory
[d] Limbs as reported by site
[e] Percentage based on number of lesions with available data (clinical and hemodynamic success based on number of targeted limbs at related time point; procedure success and all cause mortality on subject level)
[f] Device Success defined as angiographic evidence of <30% final residual stenosis of the target lesion using only the assigned device
[g] Lesion Success defined as angiographic evidence of <30% final residual stenosis of the target lesion using any percutaneous method
[h] Procedure Success defined as angiographic evidence of <30% final residual stenosis of the target lesion after stent placement and no occurrence of a procedure related MAE prior to hospital discharge (for subjects with more than one lesion stented the worse case is counted)
[i] Clinical success defined as the improvement of Fontaine classification by at least one stage above the pretreated (preprocedure) clinical value
[j] Hemodynamic success (protocol defined): an improvement in ankle-brachial index (ABI) or toe brachial index (TBI) >0.10 over preprocedure level and not deteriorated by >0.15 from first postprocedure level
[k] Hemodynamic success (alternative definition[4]): 'sustained hemodynamic improvement' consists of persistent improvement of ABI/TBI values with ≥ 0.10 as compared to baseline values or to ABI/TBI ≥ 0.9 throughout follow-up without need for repeated TLR in surviving subjects
[l] Subjects are considered unevaluable for all cause mortality at 30 days if a) withdrawn before 25 days or b) lost to follow-up before 25 days and had no contact thereafter
[o] Subjects are considered unevaluable for all cause mortality at 9 months if a) withdrawn before 240 days or b) lost to follow-up before 240 days and had no contact thereafter
m = number of subjects in the category
n = number of subjects in the study group with sufficient data for analysis
Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Table

12.5 Summary of Adverse Events

An independent Clinical Events Committee (CEC) developed specific criteria for the categorization of clinical events and clinical endpoints in this study. The specific criteria related to device and/or procedure related death, target limb loss, and clinically driven target lesion/vessel revascularization. Sites also reported adverse events and serious adverse events. System organ class was assigned via MedDRA coding by the Medtronic Clinical Trial Safety Department.

[4] Diehm N, Pattynama PM, Jaff MR, Cremonesi A, et al. Clinical endpoints in peripheral endovascular revascularization trials: a case for standardized definitions. *Eur J Vasc Endovasc Surg.* 2008;36:409-419.

Table 10. Adverse Events through 9 Months

System Organ Class	N = 123 % (m/n)
Blood and Lymphatic System Disorders	6.5 (8/123)
Cardiac Disorders	16.3 (20/123)
Ear and Labyrinth Disorders	0.8 (1/123)
Endocrine Disorders	0.8 (1/123)
Eye Disorders	0.8 (1/123)
Gastrointestinal Disorders	11.4 (14/123)
General Disorders and Administration Site Conditions	13.8 (17/123)
Hepatobiliary Disorders	1.6 (2/123)
Infections and Infestations	13.8 (17/123)
Injury, Poisoning and Procedural Complications	11.4 (14/123)
Investigations	1.6 (2/123)
Metabolism and Nutrition Disorders	6.5 (8/123)
Musculoskeletal and Connective Tissue Disorders	17.9 (22/123)
Neoplasms; Benign, Malignant and Unspecified (Including Cysts and Polyps)	0.8 (1/123)
Nervous System Disorders	6.5 (8/123)
Psychiatric Disorders	0.8 (1/123)
Renal and Urinary Disorders	7.3 (9/123)
Reproductive System and Breast Disorders	0.8 (1/123)
Respiratory, Thoracic, and Mediastinal Disorders	8.9 (11/123)
Skin and Subcutaneous Tissue Disorders	7.3 (9/123)
Surgical and Medical Procedures	0.8 (1/123)
Vascular Disorders	26.0 (32/123)

N = Intent-to-treat population
m = number of subjects in the category
n = number of subjects in the study group with sufficient data for analysis
Note: Site Reported Table

12.6 Conclusion

Overall, the data demonstrated an acceptable safety and efficacy profile for the Assurant Cobalt Iliac Balloon-Expandable Stent System. A performance goal for this trial was determined based on published literature and the success of the Assurant Cobalt Iliac Balloon-Expandable Stent System was to be accepted if the 9-month MAE rate was less than 17%. For this subject population, 9-month MAE rate of 0.8% (1/121) (95% CI, 0.0%, 3.9%) met the prespecified performance goal with an associated p-value <0.001.
The study included lesions up to 88 mm, however the safety and effectiveness of lesion lengths longer than 61 mm has not been established.

Additionally, 100% (141/141) of the evaluable lesions were found to be exempt from restenosis of the target lesion during the 9-month follow-up achieving primary patency. Of the 123 subjects included in this report and the 159 lesions treated with 172 study stents, 99.4% of the Assurant Cobalt Iliac Stents were successfully delivered to the intended target lesion. Device and lesion success rates of 97.5% (155/159) (95% CI, 93.7%, 99.3%) and a procedure success rate of 96.7% (119/123) (95% CI, 91.9%, 99.1%) were reported. Clinical success was achieved in 90.4% (132/146) of limbs and hemodynamic success was achieved in 55.2% of limbs at 9 months.

A more recently developed definition[5] called 'sustained hemodynamic improvement' consists of persistent improvement of ABI/TBI values with ≥0.10 as compared to baseline values or to ABI/TBI ≥0.9 throughout follow-up without need for repeated TLR in surviving subjects. Applying this definition to ACTIVE subjects' ABI/TBI data, the sustained hemodynamic improvement rates were 75.8% (116/153) at 30 days and 80.1% (117/146) at 9 months. The all-cause mortality rate to 9 months was 0% (95% CI, 0.0%, 3.0%).

[5] Diehm N, Pattynama PM, Jaff MR, Cremonesi A, et al. Clinical endpoints in peripheral endovascular revascularization trials: a case for standardized definitions. *Eur J Vasc Endovasc Surg.* 2008;36:409-419.

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