



# Astron

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Peripheral self-expanding nitinol stent system

English

**STERILE** **EO**  

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

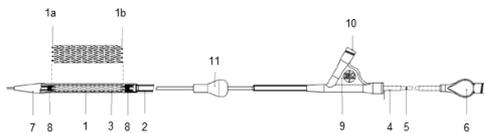
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## Device Description

The Astron stent system (Figure 1) is a self-expanding stent loaded on an over-the-wire delivery system. The stent (1) is laser-cut from a nitinol tube. It carries four radiopaque extensions at each end (1a, 1b) and is completely coated with amorphous silicon carbide (a-SiC:H). The delivery system consists of two coaxially arranged elements: the inner shaft (2) and the outer sheath (3). The inner shaft is made of a thermoplastic polymer. At the proximal end, it is covered with a stainless steel tube. The safety tab (4) that covers the stainless steel tube prevents accidental stent release. The stainless steel tube incorporates a black release marker (5) that indicates the completion of stent deployment and ends with a Luer port (6) at the proximal guide wire exit.

The central guide wire lumen within the inner shaft continues to the radiopaque tip (7). The stent is mounted between the inner shaft and the outer sheath proximal to the tip, between two radiopaque markers (8), which facilitate fluoroscopic visualization, and positioning of the delivery system towards and across the lesion. The outer sheath begins within the T-connector (9) and extends towards the tip. It covers the stent and keeps it constrained within its distal end. A hydrophobic coating is applied to the inside and the outside of the entire outer sheath. The annular space between the inner shaft and the outer sheath can be flushed through the Luer port (10) at the T-connector. The guide wire lumen of the inner shaft is flushed through the Luer port at the proximal guide wire exit. The guide wire lumen permits the use of 0.035" guide wires to facilitate advancement of the delivery system through the lesion to be treated. The stent system is shipped with an "Easy Release"-tube (11) inserted over the proximal outer sheath. The "Easy Release"-tube is intended to be inserted into the hemostatic valve of the introducer to reduce friction between the delivery system and the hemostatic valve during stent release.

Figure 1: Astron stent system



The stent system and the "Easy Release"-tube are compatible with an appropriately sized introducer sheath according to the indications on the label.

The stent is advanced to the intended implantation location by means of the over-the-wire delivery system and is deployed by pulling back the outer sheath at the T-Connector while immobilizing the inner shaft. The stent remains in the vessel as a permanent implant.

## How Supplied

STERILE. Non-pyrogenic. Device is sterilized with ethylene oxide.

## Contents

- One (1) Astron self-expanding stent system in a sealed, peel-open pouch
- One (1) Patient Implant Card

## Storage

Store in a dark, dry location between 10°C (50°F) and 30°C (86°F).

## Indications

The Astron stent system is indicated for improving luminal diameter in patients with iliac atherosclerotic lesions in vessel reference diameters between 4.3mm and 9.5mm and lesion lengths up to 105 mm.

## Contraindications

There are no known contraindications.

## Warnings

- In patients with poor kidney function, contrast agents may precipitate kidney failure.
- Persons with known hypersensitivities to the following substances may suffer an allergic reaction to this implant:
  - nitinol and / or its components (e.g. nickel, titanium)
  - amorphous silicon carbide
- DO NOT use after the "use by" date specified on the label.
- Device is supplied STERILE and for single use only. DO NOT re-sterilize and/or reuse. Reuse of single use devices creates potential risks including infections. Contamination of the device may lead to serious injury or patient harm.
- Appropriate anticoagulation and antiplatelet therapy should be administered pre- and post-procedure in accordance with standard practices.
- If using to treat a previously stented lesion, long-term outcomes following repeat dilatation of endothelialized stents have not been studied.
- DO NOT use in patients after failed guide wire or balloon catheter access.
- DO NOT use in highly-calcified lesions resistant to Percutaneous Transluminal Angioplasty (PTA) or in lesions that prevent complete inflation of an appropriately sized angioplasty balloon.
- DO NOT use if the sterile package is opened or damaged or any information provided is obscured. DO NOT use if the device is damaged or if the stent is partially deployed.
- Advancement of the stent system without the guide wire extended beyond the tip may lead to vessel damage.
- DO NOT push the stainless steel tube. The stent will not be deployed at the target site if the tube is pushed.
- DO NOT advance a partially deployed stent proximally or distally. Dragging or repositioning the stent may cause injury to the patient.
- Once the stent is partially deployed it cannot be recaptured using the stent system.
- It is only recommended to place overlapping stents using two Astron stents. The risk of corrosion increases when stents of differing metals contact one another.
- If unusual resistance is experienced during the introduction of the delivery system or deployment, or if stent cannot be deployed, remove the entire stent system (a partially deployed stent may require surgical removal).

## Precautions

- Only physicians thoroughly trained and educated in the performance of PTA and stent implantation should use this device.
- Stenting across a bifurcation or side branch could compromise future diagnostic or therapeutic procedures.
- The minimum introducer sheath size is indicated on the label. If the device is used in conjunction with long and/or braided introducer sheaths, a larger French size than indicated on the label may be necessary to reduce friction.
- Exercise care during handling to reduce the possibility of releasing the stent prematurely, accidental breakage, bending or kinking of the delivery system.
- Exposure of the stent system to organic solvents, e.g. alcohol, may cause damage to the stent system.
- The stent system is not designed for use with power injection systems.
- Always keep the device filled with sterile heparinized isotonic saline while it is in the vascular system.
- Verify that the distal end of the outer sheath is flush with the radiopaque tip. If a gap exists between the outer sheath and the tip,

carefully advance the outer sheath over the inner catheter tubing until the outer sheath is flush with the proximal edge of the tip.

- To avoid premature stent release, secure the sliding T-connector to the safety tab and underlying stainless steel tube while manipulating the stent system.
- Limited data exists on use of two overlapping Astron stents. If multiple stents are required to treat a lesion, it is recommended to use the same type of stent and a maximum of two stents. Overlapping of more than two stents has not been investigated.
- If multiple stents are required to treat the lesion, it is recommended that the more distal stent should be placed first. Allow for sufficient overlap between the stents.
- Recrossing a stent with adjunct devices must be performed with caution.
- The use of mechanical atherectomy devices or laser catheter is not recommended within the stented area.

### Potential Adverse Events/Complications

Possible complications include, but are not limited to:

- Allergic reactions to contrast media, antiplatelet aggregation or anticoagulant medications, amorphous silicon carbide and nitinol and/or its components (e.g. nickel, titanium)
- Bleeding events: Access site bleeding or hemorrhage, hemorrhage requiring transfusion or other treatment
- Death
- Embolization of air, thrombotic or atherosclerotic material
- Emergency surgery to correct vascular complications
- Infection and sepsis
- Stent system events: Failure to deliver stent to intended site, stent misplacement, stent deformation, stent embolization, stent thrombosis or occlusion, stent fracture, stent migration, inadequate apposition or compression of stent/s, withdrawal difficulties, embolization of catheter material
- Tissue necrosis and limb loss due to distal embolization
- Vascular events: Access site hematoma, hypotension/ hypertension, pseudoaneurysm, arteriovenous fistula formation, retroperitoneal hematoma, vessel dissection or perforation, restenosis, thrombosis or occlusion, vasospasm, peripheral ischemia, dissection, distal embolization (air, tissue debris, thrombus)

### Directions for use

#### Patient preparation and stent system selection

PTA and placement of an iliac self-expanding nitinol stent should be performed in an angiography equipped room. Patient preparations are the same as for any angioplasty procedure.

It is recommended to pre-dilate the lesion using standard PTA techniques before stenting. Maintain lesion access with the guide wire when removing the PTA balloon catheter from the patient.

01. Select the appropriate stent size based on the diameter of the artery adjacent to the lesion and the length of the segment to be stented. The (unconstrained) stent diameter in relation to the target artery reference diameter can be seen in Table 1. The length of the stent should overlap the lesion by at least 5 mm on either side.

Table 1: Astron Stent Size Selection

Vessel Diameter [mm]	Unconstrained Stent Diameter [mm]
4.3 - 6.0	7
6.0 - 7.0	8
7.0 - 8.0	9
8.0 - 9.5	10

Table 2: Astron Stent Foreshortening Table

Unconstrained Stent Diameter [mm]	Vessel Diameter [mm]	Foreshortening [%]			Percent Stent Free Area % at max. to min. oversizing
		Min.	Mean	Max.	
7	4.3 - 6.0	-1	0	2	78 - 85
8	6.0 - 7.0	-1	1	1	85 - 87
9	7.0 - 8.0	0	1	2	87 - 88
10	8.0 - 9.5	-1	1	7	88 - 90

### Stent system preparation

02. Open the outer packaging and remove the sterile pouch.
03. After careful inspection for damage to the sterile barrier, peel open the pouch, and remove the tray. Carefully peel open the lid, remove the stent system and place it onto the sterile field.
04. Examine the device for damage. Ensure that the stent is contained within the outer sheath.

### Flushing of the stent system

05. Attach a 10 ml syringe filled with sterile heparinized saline to the Luer port at the proximal guide wire exit and inject the saline into the guide wire lumen until the fluid exits the catheter tip.
06. Attach a 10 ml syringe filled with sterile heparinized saline to the Luer port of the sliding T-connector and vigorously inject the saline until the fluid exits distally between the outer sheath and the tip. Fluid may also be visualized at the Luer port at the proximal guide wire exit.
07. Remove the syringes.

### Introduction of the stent system

08. Thread the distal tip of the stent system over the proximal end of the guide wire and advance the system until the wire exits the Luer port at the proximal end of the delivery system. Take care to keep the delivery system as straight as possible.
09. Carefully insert the stent system through the introducer while immobilizing the guide wire.
10. Carefully advance the stent system over the guide wire toward the lesion to be treated.
11. Advance the stent system across the stenosis, positioning the markers on either side of the lesion.

**Note:** Whenever the stent system is in the body it should be manipulated while under sufficient high quality fluoroscopy.

### Stent deployment

- Note:** If necessary, the "Easy Release"-tube can be inserted into the introducer to reduce friction between the hemostatic valve and the outer sheath of the delivery system during stent deployment. The blood loss may increase when the "Easy Release"-tube is used.
12. Maintain the instrument as straight as possible outside the body.
  13. Gently remove the safety tab while checking the position of the device under fluoroscopy.
  14. Immobilize the stainless steel tube and guide wire.
  15. Under fluoroscopic guidance, begin stent deployment by sliding the T-connector gently towards the black release marker on the stainless steel tube.
  16. During deployment, ensure that the position of distal and proximal stent ends relative to the lesion is maintained.
  17. Once the distal end of the stent has been deployed, observe and maintain the 2-3 mm gap between the distal stent markers and the distal delivery system marker until the stent has been completely deployed.
  18. Deployment is completed when the T-connector covers the black release marker.
- Note:** Appropriately deployed stent length (not compressed or stretched) can be checked by matching the delivery system markers with the respective stent markers following deployment.
19. Obtain angiographic visualization of the stented vessel segment.

## Delivery system removal

20. After full stent deployment, carefully remove the delivery system under fluoroscopic guidance while observing the radiopaque tip, leaving the guide wire in place.

**Note:** If the tip encounters any resistance during withdrawal, free the tip by carefully moving the delivery system in the distal direction. If the tip is still blocked after this maneuver, immobilize the stainless steel tube and gently advance the sliding T-connector under fluoroscopic guidance until the distal end of the outer sheath contacts the tip.

21. After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

## Overlapping stents

For placing a second stent, repeat steps 02 to 21 with a new device. The stent overlap area must be at least 10mm and not more than 20mm. To position the second stent, use the radiopaque markers of the already implanted stent and delivery system.

## Post-procedural

22. If the stent is incompletely expanded along the lesion, post deployment balloon dilatation can be performed. Select a PTA balloon whose inflated diameter matches the reference diameter of the target vessel.

23. Obtain angiographic visualization of the stented vessel segment.

## Magnetic Resonance Imaging (MRI)



MR conditional

### MRI Safety Information

Non-clinical testing has demonstrated that the BIOTRONIK Astron stent is MR Conditional for single and overlapping lengths up to 200 mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 3000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole-body averaged specific absorption rate [SAR] of 1 W/kg for landmarks below the umbilicus and 2 W/kg [Normal Operating Mode] for landmarks above the umbilicus.

Under the scan conditions defined above, the Astron stent is expected to produce a maximum temperature rise of 4.6°C after 15 minutes of continuous scanning.

In non-clinical testing of the BIOTRONIK Astron stent, the image artifact caused by the device extends approximately 5 mm when imaged with a gradient echo sequence or 4 mm when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system. The artifact may obscure the device lumen.

### Summary of Clinical Studies

BIOTRONIK collected clinical data through the BIOFLEX-I clinical trial to establish a reasonable assurance of safety and effectiveness of iliac stenting with the Astron Stent System for the treatment of atherosclerotic lesions found in iliac arteries. A summary of the clinical trial is presented below.

### Study Design

BIOFLEX-I was a prospective, non-randomized, multi-center study focusing separately on lesion treatment in the superficial femoral artery and iliac artery. Only the iliac lesion treatment cohort is applicable to the Astron stent. Overall, the BIOFLEX-I study provisionally enrolled 474 subjects in order to achieve 161 evaluable Astron stent group subjects at 30 sites located in the United States, Canada, and Austria.

The Astron stent was used for the treatment of common or external iliac artery lesions in 161 subjects in all 30 study sites. The primary endpoint for the Astron stent was a composite safety and effectiveness endpoint of the procedure- or stent-related Major Adverse Events (MAE) rate at 12 months post-index procedure. The MAE rate includes 30-day mortality, along with 12-month rates of target lesion revascularization (TLR) and index limb amputation. The primary endpoint evaluated whether the observed rate of MAEs at 12 months met a performance goal of 15%, given a 7.5% expected 12-month MAE rate, with an assumed delta value of 7.5%, which was based on data from long-term, multi-center clinical trials for stenting of the iliac arteries. The study included several additional secondary endpoints, but no formal hypotheses were associated with the evaluation of the secondary endpoints.

Subjects were considered eligible for Astron stent implantation if they had de novo or restenotic, atherosclerotic ( $\leq 140$  mm long) or occlusive ( $\leq 100$  mm long) lesions in either the common or external iliac arteries, with reference vessel diameters ranging from 6 to 9 mm. Subjects were allowed to receive treatment for one lesion per limb, however, if multiple limbs were treated they could not be for the same indication; the lesions had to represent different indications (i.e. one iliac lesion and one femoro-popliteal lesion on contralateral limbs). Evaluable subjects are subjects that underwent an investigational stent implant procedure where the stent system entered the introducer sheath.

Following enrollment/baseline and the index procedure, all evaluable subjects were to be assessed at 1, 6 and 12 months post-index procedure.

## 1. Clinical Endpoints

### a. Primary Endpoint

The primary endpoint for the Astron stent is a composite of the rate of procedure- or stent-related MAEs at 12 months post-index procedure. The MAE rate includes 30-day mortality, along with 12-month rates of clinically-driven TLR and index limb amputation. A clinically-indicated TLR is defined as any repeat, percutaneous intervention or bypass surgery of the target lesion driven by clinical findings (ischemic symptoms). Index limb amputation includes the loss of any part of the limb receiving intervention. All site-reported MAEs or possible MAEs, including deaths, were adjudicated as to their relationship to the procedure or stent by an independent Clinical Events Committee (CEC) composed of physicians knowledgeable in the treatment of Peripheral Artery Disease (PAD).

An expected MAE rate of 7.5% at 12 months for the iliac indication was derived based on prior clinical trial results. As such, the study evaluated whether the observed MAE rate at 12 months could statistically meet a performance goal of < 15%, given a 7.5% expected 12-month MAE rate, with an assumed delta value of 7.5%.

### b. Secondary Endpoints

Secondary endpoints for the Astron stent were as follows:

- Determination of the contribution of each individual MAE to the primary, composite endpoint
- Primary patency at 12 months
- Primary assisted patency
- Secondary patency
- Acute procedural success
- 30-day clinical success
- Ankle-brachial indices (ABI) at pre-treatment and 12 months
- Walking Impairment Questionnaire (WIQ) scores at pre-treatment and 12 months
- Six-minute walk distance at pre-treatment and 12 months
- Rates of all adverse events not included in the evaluation of the primary endpoints
- Comparison of all primary and secondary endpoints between occlusive lesions (100% stenosis) and non-occlusive lesions (70% - 99% stenosis)

## 2. Demographics and Clinical Characteristics

Table 3 provides a summary of the subject demographics and clinical characteristics at the enrollment/baseline visit for all evaluable subjects in the Astron stent group.

**Table 3: Astron Stent Group Baseline Demographics and Clinical Characteristics**

Parameter	Astron Evaluable n=161	
<b>Age in years at enrollment</b>		
Mean $\pm$ SD	63.6 $\pm$	10.1
Range (Min/Max)	40.9 to	91.9
<b>Gender (n, %)</b>		
Male	105	65.2%
Female	56	34.8%
<b>Race (n, %)</b>		
White	152	94.4%
Black or African American	4	2.5%
Asian	4	2.5%
American Indian or Alaska Native	1	0.6%
Native Hawaiian or other Pacific Islander	0	0.0%
<b>Hispanic Ethnicity (n, %)</b>		
Hispanic	18	11.2%
Non-Hispanic	143	88.8%
<b>General Medical History (n, %)*</b>		
Diabetes	32	19.9%
Hypertension	117	72.7%
Hyperlipidemia	125	77.6%
Smoking status		
Current	78	48.4%
Within last 5 years	36	22.4%
Never/not within last 5 years	47	29.2%
Cerebrovascular disease	22	13.7%
History of congestive heart failure	11	6.8%
History of ischemic heart disease	69	42.9%
History of coronary revascularization	54	33.5%
Renal insufficiency	11	6.8%

\*Definitions: Hypertension and Hyperlipidemia: requiring treatment with a prescription medication; cerebrovascular disease: carotid artery disease and history of stroke or Transient Ischemic Attack (TIA); congestive heart failure: ejection fraction < 40% or heart failure diagnosis; ischemic heart disease: myocardial infarction, angina pectoris, percutaneous or surgical coronary revascularization, positive exercise test or anti-anginal therapy; renal insufficiency: creatinine  $\geq$  1.5 mg/dL (last measurement prior to baseline).

### 3. Methods

Clinical follow-up was conducted before discharge and at 1-month, 6-months and 12-months after the index procedure. Subjects were to be prescribed dual antiplatelet therapy at the index procedure and upon discharge, for a minimum of three months and then in accordance with clinical guidelines based on physician discretion. The subjects were to continue aspirin therapy for the duration of study participation. Upon completion of the study, subjects returned to standard of care follow-up with their physician.

Table 4 summarizes the baseline lesion characteristics for all evaluable subjects obtained from the baseline angiogram at the index procedure

**Table 4: Astron Stent Group Baseline Lesion Characteristics**

Variable (site reported)	Category	Astron n = 161	
Target side (n, %)	Right	87	54.0%
	Left	74	46.0%
Lesion type (n, %)	De novo	147	91.3%
	Occlusion	13	8.1%
	Restenosis	1	0.6%
<b>Variable (core lab)</b>	<b>Category</b>	<b>Astron n = 161</b>	
Lesion location (n, %)	Common iliac	107	66.5%
	External iliac	54	33.5%
Lesion calcification (n, %)	None	47	29.2%
	Moderate	68	42.2%
	Severe	46	28.6%
Lesion length (mm)	mean $\pm$ SD	35.9 $\pm$	21.3
	range	8.6 to	105.1
<b>Variable (site reported)</b>	<b>Category</b>	<b>Astron n = 161</b>	
Pre-deployment lesion stenosis (%)	mean $\pm$ SD	83.1 $\pm$	9.6
	range	70 to	100
Post-deployment lesion stenosis (%)	mean $\pm$ SD	4.6 $\pm$	8.1
	range	0 to	50
<b>Variable (core lab)</b>	<b>Category</b>	<b>Astron n = 161</b>	
Pre-deployment minimum lumen diameter (mm)	mean $\pm$ SD	2.1 $\pm$	1.3
	range	0 to	5.68
Post-deployment minimum lumen diameter (mm)	mean $\pm$ SD	6.0 $\pm$	1.2
	range	2.9 to	9.1
<b>Variable (core lab)</b>	<b>Category</b>	<b>Astron n = 161</b>	
Reference vessel diameter (mm)	mean $\pm$ SD	7.6 $\pm$	1.5
	range	4.3 to	12.2
Distal vessel runoff (n, %)	Not Available	35	21.7%
	0 vessel	9	5.6%
	1 vessel	32	19.9%
	2 vessel	48	29.8%
	3 vessel	37	23.0%
TASC II Type (n, %)	Type A	99	61.5%
	Type B	56	34.8%
	Type C	6	3.7%
	Type D	0	0.0%

## 4. Safety and Effectiveness Results

### a. Primary Endpoint

The performance goal assessment (primary endpoint) for the Astron stent was a composite of the rate of procedure- or stent-related MAEs at 12 months post-index procedure. The MAE rate included 30-day mortality, along with 12-month rates of TLR and index limb amputation. All MAEs have been adjudicated as to their relationship to the procedure or Astron stent by an independent CEC composed of physicians knowledgeable in the treatment of PAD.

In the 146 Intention-to-Treat (ITT) subjects with 12-month evaluations, the overall MAE rate was 2.1% [3 events in 146 subjects], with a 95% confidence interval of 0.4% - 5.9%, which was lower than the expected rate of 7.5% and therefore met the performance goal of a rate < 15% ( $p < 0.001$ ). The distribution of individual MAEs (30-day mortality, TLR and index limb amputation) is reported in Table 5.

Three Astron subjects experienced a MAE prior to 12 months, including one death on the day of the index procedure due to a rupture of the contralateral iliac, and two TLRs. One target lesion revascularization was adjudicated by the angiographic core laboratory as a target vessel revascularization, as the region of restenosis was outside the stented segment. However, the CEC adjudicated this event as a TLR, as the balloon and stent used for vessel revascularization overlapped the Astron study stent. The second TLR was prompted by a 40% restenosis with clinical symptoms.

### b. Secondary Endpoints

Secondary endpoints were assessed at the specified time points. Key secondary endpoint safety and efficacy results for the ITT population are summarized in Table 5.

Table 5: Key Secondary Endpoint Effectiveness Results

Effectiveness Measure	Secondary Endpoint
Distribution of procedure or stent-related MAE at 12-months	
30-Day mortality	0.7% (1/146)
TLR	1.4% (2/146)
Index limb amputation	0.0% (0/146)
Primary patency rate at 12 months <sup>a</sup>	89.8% (115/128)
Primary assisted patency rate at 12 months <sup>b, c</sup>	97.9% (143/146)
Subjects with repeat endovascular procedure on study limb outside of study lesion	n=2
Subjects with repeat surgical procedure on study limb outside of study lesion	n=0
Secondary patency rate at 12 months <sup>c, d</sup>	99.3% (145/146)
Subjects requiring bypass on study limb	n=0
Subjects requiring amputation of study limb	n=0
Acute procedural success <sup>c, e</sup>	95.0% (153/161)
30-day clinical success <sup>c, f</sup>	95.0% (153/161)
ABI Change from Baseline to 12-month Paired Data (Mean ± SD), n=141	0.23 ± 0.19
Six Minute Walk Test Change from Baseline to 12 months Paired Data (Mean feet ± SD), n=131	157.5 ± 420.6
WIQ Score Changes from Baseline to 12 months Paired Data	
WIQ PAD Specific Score (Mean ± SD), n=143	43.9 ± 36.8
WIQ Walking Distance Score (Mean ± SD), n=144	40.7 ± 38.0
WIQ Walking Speed Score (Mean ± SD), n=143	21.5 ± 27.5
WIQ Stair Climbing Score (Mean ± SD), n=142	26.1 ± 35.6

a) Freedom from more than 50% restenosis based on the duplex ultrasound peak systolic velocity ratio, comparing data within the treated segment to the proximal normal segment. A peak systolic velocity ratio greater than 2.4 was used to diagnose a stenosis greater than 50% in diameter.

b) Freedom from a repeat procedure [endovascular or surgical] outside of the initially treated lesion to maintain patency of the target vessel. The treated lesion includes the stented segment plus 5 mm proximal and distal to the stent.

c) One subject death within 30-days was included in this count.

d) Freedom from treated lesion abandonment (bypass) or amputation of the target limb.

e) Completion of the procedure and the stented lesion having less than 30% residual stenosis determined by angiography immediately after stent placement and no MAEs before hospital discharge.

f) Completion of the procedure and the stented lesion having less than 30% residual stenosis determined by angiography immediately after stent placement and no MAEs within 30 days of the index procedure.

### c. Secondary Safety Endpoint - Summary of Serious Adverse Events Observed

The rates of all individual adverse event types that were not included in the primary endpoint analyses for the Astron stent group were evaluated as a secondary endpoint. All reported adverse events from evaluable subjects through the 12-month primary endpoint follow-up period are reported here and events are categorized as serious and classified as to whether the event is related to the stent and/or index procedure.

A serious adverse event is any untoward medical occurrence during the course of the study that:

1. Resulted in death
2. Lead to a serious deterioration in health in the subject that:
  - Resulted in a life-threatening illness or injury
  - Resulted in permanent impairment of a body structure or function
  - Required in-subject hospitalization or prolongation of an existing hospitalization
  - Resulted in medical or surgical intervention to prevent life threatening illness or injury or a permanent impairment of body structure or function
3. Lead to congenital anomaly/birth defect

An adverse event is considered to be device- and/or procedure-related if the site classified the event as being related to the device or procedure, possibly related to the device or procedure, or having an unknown relationship to the device or procedure.

Of the 365 adverse events reported, 335 were reported for evaluable subjects. There have been 115 serious adverse events in 67 evaluable subjects, and 41 adverse events were reported as device- and/or procedure-related in 34 evaluable subjects. The percentage of evaluable subjects with a serious adverse event is 41.6%.

Table 6 summarizes the adverse events for the ITT population, which a site reported as meeting the above criteria for serious in nature. Note that the total for each category of adverse events is not necessarily a sum of individual events, as it is a count of unique subjects with the adverse event.

Table 6: Summary of Serious Adverse Events through 12 months

Category	Number of Evaluable Subjects with Event	Rate of Subjects with Event (n = 161 Subjects)
<b>Vascular</b>		
Angioplasty on left external iliac and SFA	1	0.62% (1/161)
Occlusion of bypass graft left iliofemoral bypass conduit	1	0.62% (1/161)
Peripheral ischemia	3	1.86% (3/161)
Pseudoaneurysm	3	1.86% (3/161)
Stenosis or occlusion in contralateral extremity/target lesion within stent segment in the SFA	14	8.70% (14/161)
Stenosis or occlusion in target extremity outside of stent segment	8	4.97% (8/161)
Vessel dissection or perforation during PTA	1	0.62% (1/161)
Worsening of claudication	1	0.62% (1/161)
<b>Total Vascular Events</b>	<b>29</b>	<b>18.01% (29/161)</b>
<b>Stent</b>		
Failure to deliver stent to intended site	1	0.62% (1/161)
Stenosis or occlusion of target lesion within stent segment	2	1.24% (2/161)
Vessel dissection or perforation during stenting procedure	1	0.62% (1/161)
<b>Total Stent Events</b>	<b>4</b>	<b>2.48% (4/161)</b>
<b>Procedure-Related</b>		
Bleeding requiring treatment	2	1.24% (2/161)
Right femoral occlusion	2	1.24% (2/161)
<b>Total Procedure-Related Events</b>	<b>4</b>	<b>2.48% (4/161)</b>
<b>Neurological</b>		
Stroke	1	0.62% (1/161)
Transient ischemic attack	2	1.24% (2/161)
<b>Total Neurological Events</b>	<b>3</b>	<b>1.86% (3/161)</b>

Category	Number of Evaluable Subjects with Event	Rate of Subjects with Event (n = 161 Subjects)
<b>Cardiovascular</b>		
Angina	1	0.62% (1/161)
Atrial arrhythmia	2	1.24% (2/161)
Cardiac arrest	1	0.62% (1/161)
Cardiac catheterization	2	1.24% (2/161)
Chest pain	1	0.62% (1/161)
Coronary artery disease	4	2.48% (4/161)
Dizziness	1	0.62% (1/161)
ICD Device replacement	1	0.62% (1/161)
Myocardial infarction	1	0.62% (1/161)
Pericarditis	1	0.62% (1/161)
Superior mesenteric artery stenosis	1	0.62% (1/161)
Ventricular arrhythmia	1	0.62% (1/161)
Worsening heart failure	2	1.24% (2/161)
<b>Total Cardiovascular Events</b>	<b>12</b>	<b>7.45% (12/161)</b>
<b>Infection</b>		
E. coli infection	1	0.62% (1/161)
Erysipel	1	0.62% (1/161)
Pneumonia	2	1.24% (2/161)
Positive E. faecalis	1	0.62% (1/161)
Purulent drainage from wound	1	0.62% (1/161)
Urinary tract infection	1	0.62% (1/161)
<b>Total Infection Events</b>	<b>5</b>	<b>3.11% (5/161)</b>
<b>Musculoskeletal</b>		
Fracture	1	0.62% (1/161)
Lumbar laminectomy and fusion	1	0.62% (1/161)
Musculoskeletal injury	1	0.62% (1/161)
Musculoskeletal pain	2	1.24% (2/161)
<b>Total Musculoskeletal Events</b>	<b>5</b>	<b>3.11% (5/161)</b>

Category	Number of Evaluable Subjects with Event	Rate of Subjects with Event (n = 161 Subjects)
<b>Gastrointestinal</b>		
Abdominal Pain	3	1.86% [3/161]
Bleeding	5	3.11% [5/161]
Diarrhea	1	0.62% [1/161]
Nausea and/or vomiting	1	0.62% [1/161]
<b>Total Gastrointestinal Events</b>	<b>9</b>	<b>5.59% [9/161]</b>
<b>Renal</b>		
Acute pyelonephritis	1	0.62% [1/161]
Renal failure	1	0.62% [1/161]
<b>Total Renal Events</b>	<b>2</b>	<b>1.24% [2/161]</b>
<b>Respiratory</b>		
Asthma	1	0.62% [1/161]
COPD	2	1.24% [2/161]
Dyspnea	1	0.62% [1/161]
Hemoptysis	1	0.62% [1/161]
<b>Total Respiratory Events</b>	<b>5</b>	<b>3.11% [5/161]</b>
<b>Nervous System</b>		
Axonal sensible polyneuropathy	1	0.62% [1/161]
<b>Total Nervous System Events</b>	<b>1</b>	<b>0.62% [1/161]</b>
<b>Endocrine</b>		
Hyperglycemia	1	0.62% [1/161]
<b>Total Endocrine Events</b>	<b>1</b>	<b>0.62% [1/161]</b>
<b>Other Medical Event</b>		
Allergic reaction	1	0.62% [1/161]
Altered mental status	1	0.62% [1/161]
Anemia	1	0.62% [1/161]
Bleeding left eye	1	0.62% [1/161]
Cancer	6	3.73% [6/161]
Cataract	1	0.62% [1/161]
Electrolyte imbalance	2	1.24% [2/161]
Leucocytosis	1	0.62% [1/161]
Traumatic Injury	1	0.62% [1/161]
<b>Other Adverse Event Total</b>	<b>14</b>	<b>8.70% [14/161]</b>
<b>Overall Serious Adverse Events Totals</b>	<b>67</b>	<b>41.61% [67/161]</b>

**d. BIOFLEX-I Study Astron Group Results by Gender**

No statistically significant differences in primary or secondary endpoint event rates were observed based on gender.

**e. Summary of Results**

The study demonstrated an overall device-related and procedure-related MAE rate of 2.1% at 12 months. Iliac stenting with the Astron stent system is safe as shown by the low MAE rate and one procedure-related MAE through 30 days. Mean paired ABI values, walking scores (as measured by WIQ) and distance, based on the six minute walk test showed improvement from baseline. In conclusion, the BIOFLEX-I Astron group study results support the safety and effectiveness of the Astron stent system in subjects with de novo, restenotic or occluded atherosclerotic lesions.

**f. Applicability to Pediatric Population**

PAD is not typically found in pediatric populations excepting rare lipid disorders. Accordingly, the safety and effectiveness of the Astron stent system in pediatric populations were not studied in the BIOFLEX-I study.

**Other**

Patients are advised to register the presence of an implanted stent and the conditions under which it can be scanned safely with the MedAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or equivalent organization.

**Warranty / Liability**

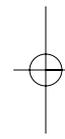
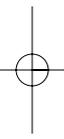
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Table 7: Available Astron Stent Sizes

Stent Length (mm)	30		40		60		80	
Usable Length (cm)	72	130	72	130	72	130	72	130
Nominal Stent ø [mm]	7	x	x	x	x	x	x	x
	8	x	x	x	x	x	x	x
	9	x	x	x	x	x	x	x
	10			x		x		x

## Symbol legend

	Sterilized using ethylene oxide		Do not use if package is damaged
	Do not reuse		Batch code
	Caution		Catalogue number
	Keep dry		Use by
	Keep away from sunlight		Consult instruction for use
	Temperature limitation		MR conditional
	Do not resterilize		Date of manufacture



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