Supera®
Peripheral Stent System
Instructions for Use

℞ ONLY

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10.0 PATENTS AND TRADEMARKS

1.0 DEVICE DESCRIPTION

The **Supera Peripheral Stent System (Supera**) includes:

Figure 1: Supera Peripheral Stent System

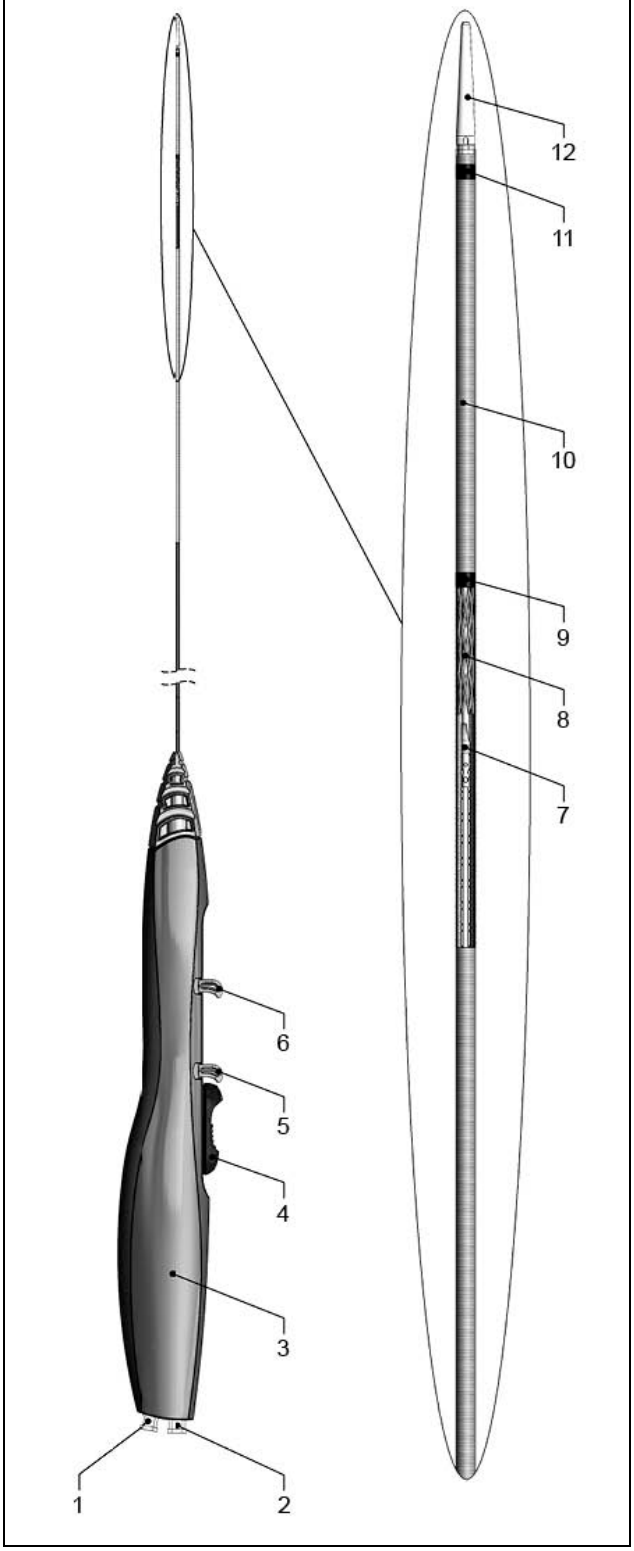
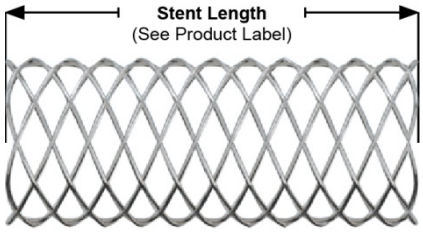


Table 1: Supera Peripheral Stent System Parts		
Part Number	**Part Name**	**Description/Function**
1	Outer Sheath Flush Port	• used to flush the outer sheath lumen of the device
2	Guidewire Flush Port	• used to flush the guidewire lumen
3	Handle	• used to control stent (8) deployment and delivery
4	Thumb Slide	• advances the stent (8) out of the outer sheath (10) while the outer sheath moves in the opposing direction in a de-coupled fashion • connected internally to the stent driver (7)
5	System Lock	• prevents premature stent (8) deployment
6	Deployment Lock	• prevents stent (8) detachment from the device when locked • allows final separation of the stent from the device when unlocked
7	Stent Driver	• pushes the stent out of the distal end of the outer sheath (10)
8	Stent	• made of six closed-end interwoven nitinol wires • constrained to three times its nominal length within the outer sheath (10)
9	Stent Length Marker	• together with the distal sheath marker (11), identifies nominal stent (8) length and adequate lesion coverage prior to stent deployment • embedded in the outer sheath (10) • radiopaque
10	Outer Sheath	• constrains the stent (8) until delivery • moves in the opposite direction of stent deployment
11	Distal Sheath Marker	• together with the stent length marker (9), identifies nominal stent (8) length and adequate lesion coverage prior to stent deployment • denotes the distal end of the outer sheath (10) • embedded in the outer sheath • radiopaque
12	Catheter Tip	• provides an atraumatic guide for catheter advancement along the guidewire • moves correspondingly with thumb slide (4) actuation • located at the distal end of the catheter shaft • attached directly to the stent driver (7) • radiopaque

The Supera Peripheral Stent System consists of a closed end, braided self-expanding stent made of Nitinol (nickel-titanium alloy) wire material that is premounted on a 6Fr or 7Fr delivery system. The stent does not include radiopaque markers.

The over-the-wire (OTW) stent delivery system is compatible with a 0.014” and a 0.018” guide wire and comes in lengths of 80cm and 120cm (6Fr) and 120cm (7Fr). The delivery system includes a reciprocating mechanism (Stent Driver) that incrementally moves the stent distally out of the outer sheath. This motion allows for the distal end of the stent to first come in contact with the targeted vessel, setting the distal reference point, and continues to feed the stent out of the sheath as the target wall is exposed by the proximal movement of the catheter. This stent deployment is achieved by the reciprocation of the Thumb Slide located on the Handle. On the final stroke, the Deployment Lock is toggled and the last deployment stroke is made.

Figure 2: Supera Stent (8)



Stent Diameter	Reference Vessel Diameter
4.5mm	4.0-4.5mm
5.5mm	4.6-5.5mm
6.5mm	5.6-6.5mm

The stent sizes are labeled based on the outer stent diameter. A stent should initially be chosen such that its labeled diameter matches the reference vessel diameter (RVD) proximal and distal to the lesion, as shown in Figure 2. Final stent selection should be confirmed after lesion pre-dilation: if possible, the stent diameter should match the prepared lesion diameter 1:1. Due to the mechanical behavior of the woven Supera stent, the stent should not be oversized by more than 1 mm relative to the RVD. This ensures optimum deployment of the Supera stent, maximizing radial strength and assisting in accurate stent length deployment. Choosing a labeled diameter to match the reference vessel diameter, then appropriately preparing the vessel to match that stent's diameter will result in a stent that is properly sized to the vessel. Refer to Section 9.2 under Lesion Treatment.

The Supera stent is provided in multiple lengths and diameters. **Table 2** lists the available stent diameters and lengths for the Supera Peripheral Stent System.

Table 2: Supera Peripheral Stent System Product Specifications

Labeled Stent Diameter (mm)	Nominal Stent Length (mm)	Catheter Outer Sheath Diameter	
		6F	7F
4.5	20, 30, 40, 60, 80, 100, 120	2.00mm, 0.079 inches	2.54mm, 0.100 inches
5.5	20, 30, 40, 60, 80, 100, 120, 150		
6.5	20, 30, 40, 60, 80, 100, 120, 150		

2.0 HOW SUPPLIED

Sterile: Sterilized with ethylene oxide gas. Non-pyrogenic.
Contents: One (1) **Supera Peripheral Stent System**
Storage: Store at room temperature only.

3.0 INDICATIONS

The **Supera Peripheral Stent System** is indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters of 4.0 to 6.5mm, and lesion lengths up to 140mm.

4.0 CONTRAINDICATIONS

The Supera Peripheral Stent System is contraindicated in:

- patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system
- patients who cannot receive antiplatelet or anticoagulation therapy. Based on in vivo thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation.

5.0 WARNINGS

- This device is intended for single-use only. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged.
- Use this device prior to the "Use By" date as specified on the device package label. Store in a dry, dark, cool place.
- DO NOT use if it is suspected that the sterility of the device has been compromised.
- Persons with known hypersensitivities to Nitinol and/or its components (e.g. nickel titanium) may suffer an allergic reaction to this implant.
- Administer appropriate antiplatelet therapy pre- and post- procedure.
- Careful attention should be paid when sizing and deploying the stent to prevent stent elongation. In the SUPERB clinical study, stent elongation was associated with a decrease in patency at 12 months.

6.0 PRECAUTIONS

The Supera Peripheral Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques and trained on the use of this device.

- The long-term safety and effectiveness of the Supera Peripheral Stent System has not been established beyond two years.
- The safety and effectiveness of the Supera Peripheral Stent System has not been established in patients who:
  - are less than 18 years old
  - are pregnant or lactating
  - have in-stent restenosis of the target lesion
  - have known hypersensitivity to any component of the stent system (e.g., nickel)
  - cannot tolerate contrast media and cannot be pre-treated
  - have uncontrolled hypercoaguability and/or other coagulopathy
- This device is not designed for use with contrast media injection systems or power injection systems.
- The flexible design of the Supera stent may result in variation in the deployed stent length.

6.1 Stent Delivery System Handling – Precautions

- Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.
- Do not use if device is damaged or kinked.
- Do not remove the stent from its delivery system, as removal may damage the stent and/or lead to stent embolization. Stent system is intended to perform as a system.
- A guidewire should not be loaded through the Guidewire Flush Port (2). The delivery system is not designed for guidewire exchanges. If a guidewire exchange is needed or desired, remove delivery system first.
- Never advance the device without the guidewire extending from the Catheter Tip (12).
- Avoid unnecessary handling or rotation that may damage the device.

6.2 Stent Placement – Precautions

- Failure to predilate the vessel according to **Table 15** may impair nominal/optimal stent delivery.
- **The stent should not be oversized > 1 mm.** The stents are labeled based on the outer stent diameter. Appropriate stent sizing is critical. Choosing a labeled diameter to match

the reference vessel diameter, then appropriately preparing the vessel to match that stent's diameter will result in a stent that is properly sized to the vessel. **Refer to Section 9.2 under Lesion Treatment.**

- Ensure the System Lock (5) is locked (in the path of the thumb slide) prior to insertion.
- Implantation of the Supera Stent should be performed only under fluoroscopic observation with radiographic equipment providing high resolution images.
- Ensure the Deployment Lock (6) remains locked during stent deployment until the end of the stent is ready to be released from the delivery system.
- Should unusual resistance be felt at any time during stent deployment the entire system should be removed together with the introducer sheath or guiding catheter as a single unit.
- The Outer Sheath (10) should not be restrained during stent deployment
- The Supera Peripheral Stent System is not designed for repositioning of the stent once deployment has been initiated and there is full vessel wall apposition.
- Once the stent is partially deployed, it cannot be recaptured using the stent delivery system.
- A single stent should be used to cover the entire target lesion. If an additional Supera Stent is used for treatment of a dissection or to ensure the target lesion is fully covered, overlap the stents by at least 1cm. Ensure that the stent(s) completely covers the target lesion, including >1cm of lesion-free vessel proximal and distal to the stent.
    - If the distal reference vessel diameter is >1mm smaller than the proximal RVD of the target lesion, the operator may choose to use two different diameter Supera Stents overlapping them by at least 1cm.
- Use caution when placing a stent near a bifurcation to avoid jailing the side branch.
- When placing multiple stents, the most distal stent should be placed first (if possible) followed by placement of the proximal stent. Stenting in this order eliminates the need to cross and reduces the chance of dislodging stents which have already been placed.
- To avoid the possibility of dissimilar metal corrosion, do not implant stents of different metals in tandem where overlap or contact is possible, with an exception of stents made of 316L stainless steel and cobalt chromium which are compatible with stents made of nickel titanium alloy.
- Insertion of the Supera Peripheral Stent System should always be performed under fluoroscopic guidance. If unusual resistance is met during catheter introduction, the system should be withdrawn and checked for damage.
  Reconfirm stent position and angiographic results to assess stented area. If post-dilatation is necessary, ensure that the final stent diameter matches the reference vessel diameter. Assure that the stent wall is in contact with the artery wall. **Do not leave stent under expanded.**

6.3 Stent/System Removal – Precautions

- Prior to removal of the delivery system, ensure the Supera Stent (8) is completely deployed, the Thumb Slide (4) is retracted, the System Lock (5) and Deployment Lock (6) are locked (in the path of the thumb slide),
- Should unusual resistance be felt at any time during stent system removal the entire system should be removed together with the introducer sheath or guiding catheter as a single unit.

6.4 Post Implant – Precautions

- Use caution when crossing a fully deployed stent with adjunct devices to avoid stent damage or migration.

Magnetic Resonance Imaging (MRI)

A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury.

Non-clinical testing has demonstrated the Supera Stents are MR Conditional for lengths up to 250mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 2,500 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of
  - 2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
  - 1 W/kg for landmarks below the umbilicus and above the mid-thigh
  - 0.5 W/kg for landmarks below the mid-thigh

  for 15 minutes of scanning (per pulse sequence), operating in the Normal Operating Mode (i.e., MR system mode of operation where there is no physiological stress to the patient).

RF Heating

In non-clinical testing and analysis of individual stents and overlapped stent pairs totaling up to 250mm in length, the Supera Stent(s) produced a temperature rise of less than 7.6°C (accounting for uncertainty and the cooling effects of blood flow) at the maximum MR system reported whole body averaged specific absorption rate (SAR) stated above as assessed by calorimetry, for 15 minutes of MR scanning (per pulse sequence) at both 1.5 Tesla and 3.0 Tesla in an MR scanner (GE Signa whole body coil, model #46- 258170G1 for 1.5T; and GE Signa HDx 3T whole body scanner, software version 15/LX/MR (15.0.M4.0910a) for 3.0T).

The effect of heating in the MRI environment for stents with fractures is unknown. High heating of the Supera Stent can occur for knee scans if the stent is implanted in the proximal popliteal anatomy. Particularly knee or leg scans of patients with Supera Stents implanted in the proximal popliteal anatomy with a stent length of about 180mm at 1.5 T (64 MHz) or about 100mm at 3 T (128 MHz) should be closely monitored during the MR scan and thoroughly examined after the scan. For these scans a reduction of the whole- body averaged SAR below the allowed 0.5 W/kg will further reduce the possible heating of the Supera Stent and should be considered for scanning of these patients.

Artifacts

The maximum artifact measured extended ~2cm from the stent, and the image of the stent lumen was obscured in the tests. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Supera Stent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. The shape of the expected artifact followed the approximate contour of the device and extended radially up to 2 cm from the implant in a gradient echo sequence (in tests performed in accordance with ASTM F2119-01).

It is recommended that patients register the conditions under which the implant can be scanned safely, listed above, with the MedicAlert Foundation or equivalent organization.

7.0 POTENTIAL ADVERSE EVENTS

Adverse events observed in the clinical study supporting approval of the device are provided in **Section 8.5**.

Potential adverse events include, but are not limited to:

- Abrupt stent closure
- Allergic reaction (contrast medium; drug; stent material)
- Amputation or limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina or coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Death
- Detachment of a system component or implantation in an unintended site
- Embolization, arterial or other (e.g. air, tissue, plaque, thrombotic material, or stent)
- Fever
- Hematoma or hemorrhagic event, with or without surgical repair
- Hypertension/Hypotension
- Infection**,** local or systemic, including bacteremia or septicemia
- Ischemia requiring intervention (bypass or amputation of toe, foot, or leg)
- Ischemia or infarction of tissue or organ (e.g., occlusion of SFA/PPA or distal vasculature)
- Myocardial Infarction
- Pain (leg, foot, and/or insertion site)
- Partial stent deployment
- Pulmonary embolism
- Renal failure insufficiency secondary to contrast medium (with or without treatment including dialysis)
- Restenosis of vessel in stented segment
- Shock
- Stent malapposition or migration, which may require emergency surgery to remove stent
- Stent strut fracture
- Stent thrombosis or occlusion
- Stroke
- Thrombosis/occlusion at the puncture site, treatment site or remote site
- Transient ischemic attack
- Venous Thromboembolism
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

8.0 SUMMARY OF CLINICAL INFORMATION

The clinical evidence supporting the safety and effectiveness of the Supera Peripheral Stent System for the treatment of de novo or restenotic lesions or occlusions (≤ 140mm) in the SFA or PPA in subjects with symptomatic peripheral artery disease (PAD) is from the SUPERB Study.

8.1 The SUPERB Study

A study titled "Comparison of the **SU**pera® **PER**ipheral System to a Performance Goal Derived from **B**alloon Angioplasty Clinical Trials in the Superficial Femoral Artery" (SUPERB) was conducted. SUPERB was a prospective, multi-center, non-randomized, un-blinded single-arm study comparing percutaneous transluminal angioplasty (PTA) and primary stenting with the Supera® Peripheral Stent Systems to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries. The safety performance goal was derived from literature and effectiveness performance goal was based on an aggregate of published trial data as described by VIVA Physicians Inc. (VPI). There were a total of 49 participating sites in the US; 46 of these sites enrolled 325 roll-in and intent-to-treat (ITT)subjects, with the ITT subjects defined as the subjects to be included in the statistical analyses of study endpoints. Of these 46 sites, 34 enrolled 264 intent-to-treat subjects into the study. Eligible subjects either had stenotic, restenotic (non-stented) or occluded lesions. The reference vessel diameter of the treated subjects was to be 4.0 - 6.0mm and the lesion length from 4-14cm. Subjects with Rutherford/Becker Clinical Categories of 2-4 were included in the study. Subject follow-up occurred at 30 days, 6 months, 12 months and 24 months, and will continue with annual follow-up for up to 3 years.

Patients were treated between July 30, 2009 and May 20, 2011. The database for this study reflected data collected through November 1, 2013, and included the 264 ITT patients. There were 46 investigational sites that enrolled subjects.

The primary study endpoints were as follows:

- The primary safety endpoint for the SUPERB SFA/PPA study was a composite of Major Adverse Events (MAEs) defined as all death, TLR or any amputation of the index limb to 30 days (± 7 days).
- The primary effectiveness endpoint for the SUPERB SFA/PPA study was primary stent patency rate at 12 months (360 ± 30 days). Primary patency was defined as Peak Systolic Velocity (PSV) ratio < 2.0 at the stented target lesion assessed by duplex ultrasound (DUS) with no clinically-driven reintervention within the stented segment.

Study success was declared only if both primary endpoints (safety and effectiveness) met their performance goals. For the primary safety endpoint, the null hypothesis was rejected if the lower limit on the one-sided 95% confidence limit calculated using the Wilson Score Method on the 30 day freedom from MAE rate exceeded the performance goal (PG) of 88.0%. For the primary effectiveness endpoint, the null hypothesis was rejected if the lower limit of the one-sided 95% confidence limit calculated using the Wilson Score Method on the 12 month patency rate exceeded the PG of 66%.

The SUPERB Study was monitored by independent contract monitors. Independent duplex ultrasound and angiographic core laboratories reviewed and analyzed key study variables. An independent Data Safety Monitoring Board (DSMB) was used to review study data on an ongoing basis and identify any potential safety trends. Adjudication of major adverse events was conducted by an independent Clinical Events Committee (CEC).

8.2 Patient Population

264 subjects were enrolled at 34 sites (United States) with a mean age of 69 years (range: 40 to 93), including 168 males (64%). Baseline subject demographics, risk factors and medical history are summarized in **Table 3**.

Table 3: Baseline Demographics and Medical History	
Patient Characteristics	**ITT Population (N=264 Patients)**
Age[1] (year)	
Mean±SD (N)	68.7±10.0 (264)
Median	70.0
Range (Min, Max)	(40.0,93.0)
Sex	
Male	63.6% (168/264)
Risk Factors	
Hypertension	93.9% (248/264)
Dyslipidemia	86.7% (229/264)
Diabetes Mellitus	43.5% (114/262)
Cigarette Smoking	
Former	48.1% (127/264)
Current	31.8% (84/264)
Renal Insufficiency	9.1% (24/264)
Medical History	
Coronary Artery Disease	66.9% (176/263)
Previous Peripheral Artery Revascularization or Surgery	38.0% (100/263)
Previous Percutaneous Coronary Revascularization	36.1% (95/263)
Coronary Artery Bypass Graft Surgery	27.3% (72/264)
Myocardial Infarction	20.3% (52/256)
Cerebrovascular Accident	9.8% (26/264)
Transient Ischemic Attack	6.1% (16/263)
Deep Vein Thrombosis	2.3% (6/264)
Amputation	1.1% (3/264)
Thrombophlebitis	0.4% (1/264)
Thrombocytopenia	0.4% (1/264)
Clinical Characteristics	
Rutherford Becker Scale	
(2) Moderate Claudication	37.5% (99/264)
(3) Severe Claudication	57.2% (151/264)
(4) Ischemic Rest Pain	5.3% (14/264)
Ankle Brachial Index	
Mean±SD (N)	0.73±0.18 (257)
Range (Min, Max)	(0.00,1.71)

[1] Age is calculated by rounding the value of procedure date-birth date.

8.3 Methods

The target lesion was to be predilated utilizing standard techniques and a balloon sized to the outside diameter of the stent. Subjects underwent SFA/PPA stent placement according to the Instructions for Use. During the stent procedure, use of supplemental anticoagulation was per the investigator's standard of care. Following the stenting procedure, the subject was prescribed daily aspirin (81 to 325 mg) and daily Plavix® (75 mg) (or Ticlid® (250mg) or Effient® (10mg), if required) for 1 month following the procedure.

Table 4 presents baseline lesion characteristics (assessed by the angiographic core laboratory except as otherwise noted), including lesion location, length and pre-procedure vessel diameter. Results for lesion length are consistent with the differences in methodology, with mean lesion length of 82.8 mm reported by the site investigators and 78.1 mm reported by the core laboratory. Per site assessment, normal-to-normal lesion was determined by measuring the length of the target lesion from healthy tissue to healthy tissue. In contrast, 20-to-20 lesion length was determined by the core laboratory, measuring

between the proximal and distal points at which the lesion exhibited 20% stenosis. The mean percent diameter stenosis was 78.0% and the lesion distribution included 24.6% completely occluded lesions and 44.7% severely calcified lesions.

Table 4: Baseline Target Lesion Characteristics	
Lesion Characteristics	**N of patients=264 N of segments=265**
Vessel Location[1]	
Proximal SFA	12.1% (32/265)
Middle SFA	54.3% (144/265)
Distal SFA	31.7% (84/265)
Distal SFA extending into Popliteal[1]	10.9% (29/265)
Popliteal, above knee	1.9% (5/265)
Lesion length, mm (normal-to-normal)[2]	
Mean±SD (N)	82.8±33.0 (273)
Range (Min,Max)	(20.0, 140.0)
Lesion Length, mm (20-to-20)[3]	
Mean±SD (N)	78.1±42.78 (264)
Range (Min, Max)	(8.51,236.40)
Pre-procedure Reference Vessel Diameter (mm)	
Mean±SD (N)	4.96±0.92 (265)
Range (Min, Max)	(2.71,7.52)
Pre-procedure Minimum Lumen Diameter (mm)	
Mean±SD (N)	1.1±0.88 (265)
Range (Min, Max)	(0.00, 3.52)
Pre-procedure Percent Stenosis (%)	
Mean±SD (N)	78.0±16.76 (265)
Range (Min, Max)	(42.84, 100.00)
Target Lesions treated with 1 study stent[4]	95.8% (251/262)
Target Lesions treated with 2 study stents[4]	3.8% (10/262)
Target Lesions treated with 3 study stents[4]	0.4% (1/262)
Total Occlusion (Per Patient)	24.6% (65/264)
Bend	
> 45-89 degrees	0.0% (0/265)
> 90 degrees	0.0% (0/265)
Thrombus	0.0% (0/265)
Eccentric	41.1% (109/265)
Calcification	
Mild	27.3% (72/264)
Moderate	28.0% (74/264)
Severe	44.7% (118/264)
Aneurysm Present	0.8% (2/265)
Ulceration Present	15.5% (41/265)
TASC II Lesion Type	
A	55.5% (147/265)
B	38.9% (103/265)
C	5.7% (15/265)

Note: Data Source: Angiographic Core Lab
[1*] Subset of SFA lesions based upon Core Lab's further analysis of the data.
[2**] *Normal-to-normal* lesion length assessed per site investigator
[3] Core Lab assessed.
[4] Site reported

8.4 Study Results

8.4.1 Primary Safety Endpoint

The primary analysis of safety was based on the 264 ITT subjects (**Table 5**).

The primary safety endpoint (the composite rate of freedom from all death, target lesion revascularization or any amputation of the index limb to 30 days (± 7 days) following stent implantation) was compared to a pre-determined safety goal of 88%. Of the enrolled ITT subjects with the 30-day (± 7 days) evaluable data (n=260), 99.2% (258/260) met the primary safety endpoint (one-sided lower 95% Wilson Score CL of 97.7%. demonstrating statistical significance (p<0.001) when comparing this rate to the 88% performance goal (**Table 5**).

Table 5: Primary Safety Endpoint (30 ± 7 Days)

Primary Endpoints	N=264 Lesions = 265				
	% (numerator/ denominator)	Performance Goal	Lower Bound of 95% one-sided Wilson CL	Lower Bound of 97.5% one-sided Wilson CL	Objective Met
Freedom from Death, Target Lesion Revascularization (TLR) or any amputation of the index limb	99.2% (258/260)	88.0%	97.7%*	97.2%	Yes
Freedom from All Cause Death	99.6% (259/260)				
Freedom from TLR	99.6% (259/260)				
Freedom from Amputation of the index limb	100.0% (260/260)				

Note:
Patients are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, were LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Specifically, events defined for the period of 30 days post-procedure follow up are reported for patients with at least 37 days of follow-up or had 30-day visit within window (30±7 days) or with event to 37 days.
*The p-value comparing the rate to the performance goal is < 0.001 using a one-sided binomial exact test.

8.4.2 Primary Effectiveness Endpoint

The analysis of primary effectiveness was based on 228 evaluable patients at the 12-month time point, as shown in **Table 6** below. The primary effectiveness endpoint was (primary patency of the stent at 12 months (360 ± 30 days), defined as freedom from restenosis [diameter stenosis >50% with a peak systolic velocity (PSV) ratio ≥ 2.0 as measured by duplex ultrasound] and TLR. Of the evaluable subjects, 78.9% (180/228) met the primary effectiveness endpoint (one-sided lower 95.0%% Wilson CL of 74.2%), demonstrating statistical significance (p<0.001) when comparing this patency rate to the 66% performance goal (**Table 6**).

Table 6: Primary Effectiveness Endpoint					
Primary Endpoint (PSVR < 2.0)	**ITT Population (N=264)**	**Performance Goal**	**Lower Bound of 95% one-sided Wilson CL**	**Lower Bound of 97.5% one-sided Wilson CI**	**Objective Met**
Patency rate at 12 months	78.9% (180/228)[1]	66.0%	74.2%*	73.2%	Yes
No Restenosis at 12 months**	86.7% (196/226)[2]				
Freedom from TLR at 12 months***	88.9% (209/235)[3]				

Note:
Patients in the ITT Population are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, were LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Specifically, events defined for the period of 12 months post-procedure follow up are reported for patients with at least 390 days of follow-up or had 12-month visit within window (360 ± 30 days) or with event to 390 days.

Patients are included in the denominator for the image (restenosis) endpoint time frame if:

1. They returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.
2. They came back for an earlier or later scheduled or unscheduled visit that is after the corresponding visit window and the patient's vessel is patent and an earlier imaging visit shows the vessel is patent OR the patient's vessel is not patent and an earlier imaging visit shows the vessel is not patent.

Patency is PSVR < 2.0; Restenosis is PSVR ≥ 2.0
*The p-value comparing the rate to the performance goal is < 0.001 using a one-sided binomial exact test.
**No stenosis ≥ 50% diameter stenosis.
***One (1) patient had a TVR, during which a balloon was inflated in the proximal segmental study stent. At that time the study stent was patent. Thus the TLR was non-clinically driven. This patient was censored from the primary patency analysis.
[1]234 subjects eligible – 2 missed visit – 7 other missing data + 1 patent at subsequent DUS + 2 revascularized prior to assessment.
[2]234 subjects eligible – 2 missed visit – 7 other missing data + 1 patent at subsequent DUS.
[3]235 subjects eligible for freedom from TLR (includes the patient mentioned above with the non-clinically driven TVR)

In further consideration of the overall device performance as well as to allow the application of a more modern study design, a secondary analysis of the data was also performed. This was not a pre-specified primary endpoint and was used for information purposes only. The secondary analysis applied a modified VIVA effectiveness criterion which uses a higher PSV ratio. Using these modified criteria of a PSV ratio < 2.4, the mean primary patency rate as a measure of primary effectiveness at 12 months was 80.3% with a one-sided lower 95% Wilson Score CL of 75.6% and one-sided lower 97.5% Wilson Score CL of 74.6%.

Table 7: Primary Patency with a PSVR ≤ 2.4

Endpoints	ITT Population (N=264)	Lower Bound of 95% one-sided Wilson CL	Lower Bound of 97.5% one-sided Wilson CL
Patency rate at 12 months	80.3% (183/228)	75.6%	74.6%
No Restenosis at 12 months*	88.1% (199/226)		
Freedom from TLR to 12 months**	88.9% (209/235)***		

Note:
Patients in the ITT Population are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, were LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Specifically, events defined for the period of 12 months post-procedure follow up are reported for patients with at least 390 days of follow-up or had 12-month visit within window (360 ± 30 days) or with event to 390 days.

Patients are included in the denominator for the image (restenosis) endpoint time frame if:

1. They returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.
2. They came back for an earlier or later scheduled or unscheduled visit that is after the corresponding visit window and the patient's vessel is patent and an earlier imaging visit shows the vessel is patent OR the patient's vessel is not patent and an earlier imaging visit shows the vessel is not patent.

Patency is PSVR ≤ 2.4; Restenosis is PSVR > 2.4
*No stenosis ≥ 50% diameter stenosis.
**One (1) patient had a TVR, during which a balloon was inflated in the proximal segmental study stent. At that time the study stent was patent. Thus the TLR was non-clinically driven. This patient was censored from the primary patency analysis.
***235 subjects eligible for freedom from TLR. For explanations of patency and restenosis denominators, see footnotes in Table 6.

As presented in **Figure 3** and **Table 8**, the freedom from loss of primary patency (PSVR < 2.0 and no clinically-driven reintervention within the stented segment) at 12 months (360 ± 30 days) was 86.3%.

Figure 3: Freedom from Loss of Patency – (Restenosis defined as PSV Ratio of ≥ 2.0) – ITT

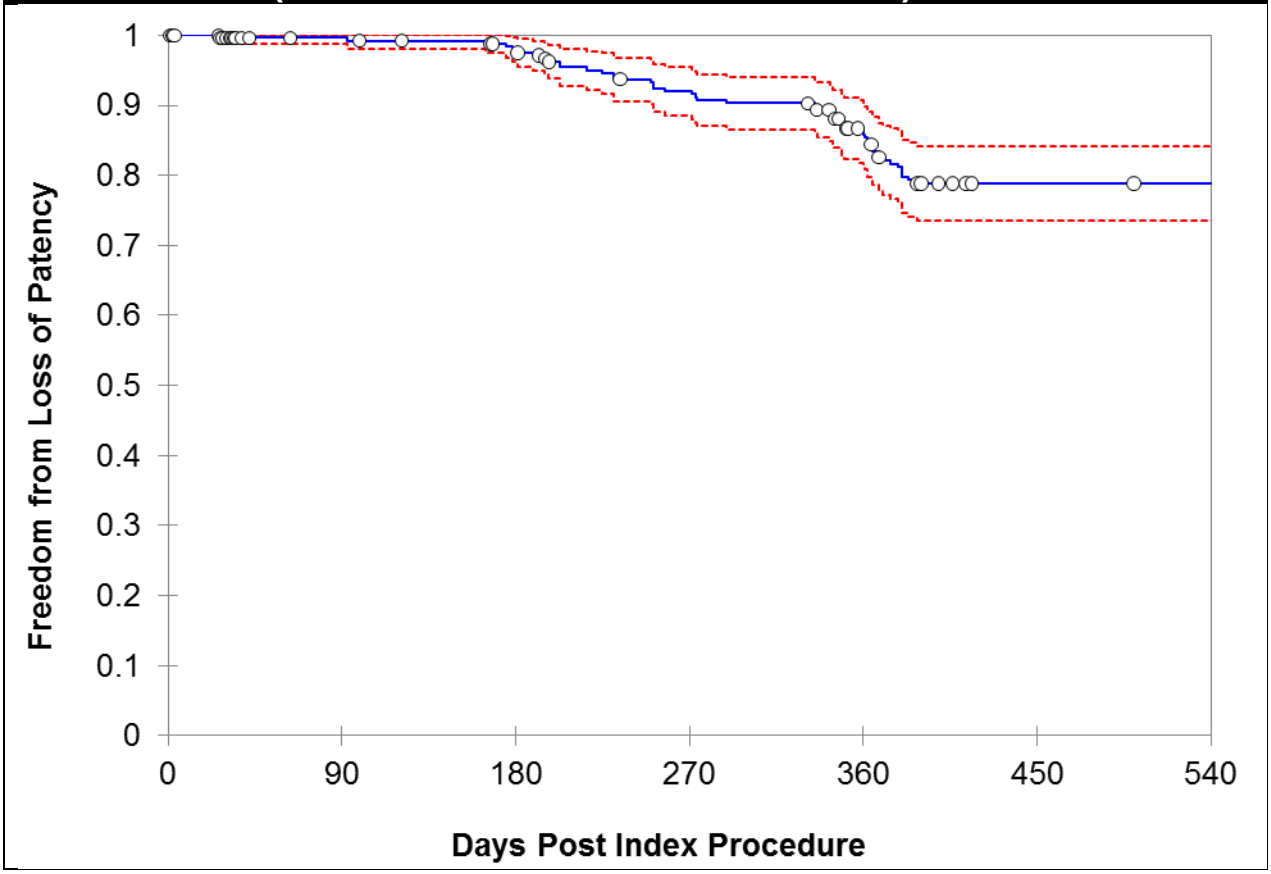


Table 8: Probability of Freedom from Loss of Patency (Restenosis defined as PSV Ratio of ≥ 2.0)

Interval	[0, 90)	[90, 180)	[180, 270)	[270, 360)	[360, 390)	≥391
# At Risk	264	242	234	215	188	169
# Events	1	4	14	13	16	0
# Censored	21	4	5	14**	3**	6
Survival Rate*	1.000	0.996	0.979	0.920	0.863	0.789
Standard Error	0.000	0.004	0.009	0.018	0.023	0.027

Note:
The following set of rules were employed for the Freedom from Loss of Patency analyses:
If a subject is free from TLR or restenosis and their last day of clinical follow-up is< 390 days, the subject is censored at the day after their last clinical follow-up
If a subject has restenosis and a TLR, the event is the day of whichever is earlier
If a subject has no TLR and no DUS at 12 months, they are censored at 331 days
If a subject had no TLR and no DUS at 6 and 12 months, they are censored at 166 days
If a subject had no TLR, restenosis after 390 days and restenosis at an earlier visit, the event is the day of the earlier restenosis
* Survival rate at beginning of time period
** Of the 17 censored patients (14 + 3), only 11 had sufficient follow-up to be included in the primary patency binary endpoint analysis.

Freedom from target lesion revascularization at 12 months was achieved in 89.4% (±2.0%) of the ITT population and in 84.0% (±2.5%) at 24 months (**Figure 4** and **Table 9**).

Figure 4: Survival Analysis of TLR to 24 Months

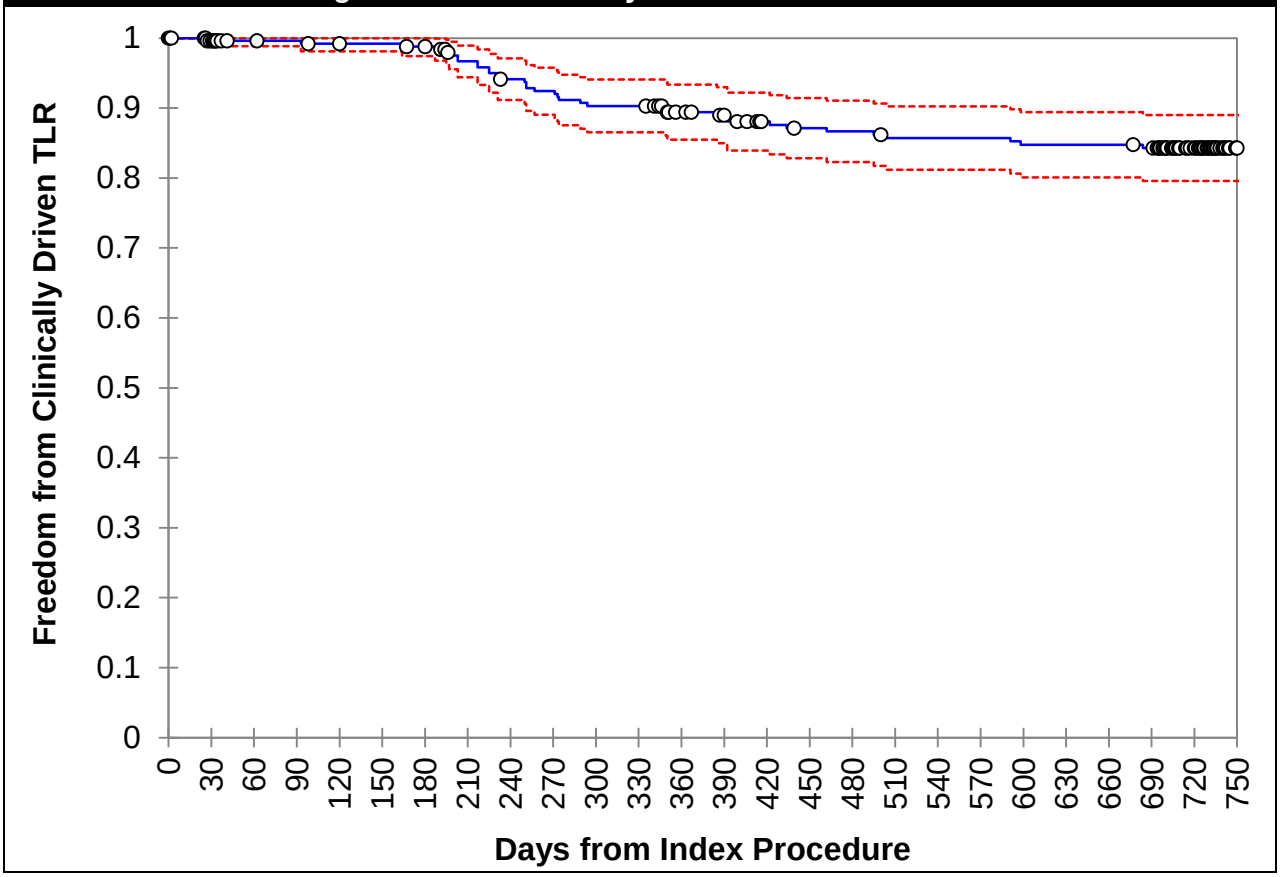


Table 9: Probability of Freedom TLR to 24 months (± 30 Days)

Interval	[0, 90)	[90, 180)	[180, 270)	[270, 360)	[360, 390)	[390, 720)	[720,750)
At risk	264	242	237	217	201	197	149
Failed	1	2	15	7	1	10	0
Censored	21	3	5	9**	3**	38	43
Survival Rate*	1.000	0.996	0.988	0.925	0.894	0.890	0.840
Standard Error	0.000	0.004	0.007	0.017	0.020	0.020	0.025

Note:
The following set of rules were employed for the Freedom from Clinically Driven TLR analyses:
If a subject is free from TLR and their last day of clinical follow-up is< 750 days, the subject is censored at the day after their last clinical follow-up
* Survival rate at beginning of time period
** The 12 censored patients (9 + 3) had sufficient follow-up to be included in the freedom from TLR binary endpoint analysis.

8.4.3 Secondary Endpoints

The secondary effectiveness endpoints are summarized in **Table 10** through **Table 12**, below.

Table 10: Acute Success	
Secondary Effectiveness Endpoints	**N=264 patients N=265 segments**
Device Success (Per Patient)	98.5% (257/261)
Technical Success (Per Segment)	100.0% (262/262)
Procedural Success (Per Patient)	100.0% (261/261)

Note:
Device success is the achievement of a final residual diameter stenosis of <50% (by QA), using the assigned treatment only.
Technical success is defined as <50% residual stenosis by Quantitative Angiography (QA) by any percutaneous method as determined by the Angiographic core laboratory.
Procedural success is defined as achievement of a final diameter stenosis of <50% (by QA) using any percutaneous method, without the occurrence of death, amputation or repeat revascularization of the target lesion during the hospital stay.

Table 11: Analysis of Secondary Endpoints	
Secondary Effectiveness Endpoints	**ITT Population (N=264 Patients, L=265 Segments)**
Patency At 6 Months (194 days) (PSVR <2.0)**	84.9% (191/225)
Patency At 6 Months (194 days) (PSVR ≤2.4)**	86.2% (194/225)
Patency At 12 Months (390 days) (PSVR ≤2.4)**	80.3% (183/228)
Target Lesion Revascularization - At 12 Months*	11.1% (26/235)
Target Lesion Revascularization – At 24 Months*	16.9% (36/213)
Target Vessel Revascularization - At 12 Months*	13.2% (31/235)
Target Vessel Revascularization - At 24 Months*	20.7% (44/213)
Improvement in the Rutherford-Becker Clinical Improvement Scale of ≥ one at 12 months	88.7% (204/230)
Improvement in the Rutherford-Becker Clinical Improvement Scale of ≥ one at 24 months	89.2% (181/203)

Note:

Patients in the ITT Population are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, was LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Patients are included in the denominator for the image (restenosis) endpoint time frame if:

1. They returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.
2. They came back for an earlier or later scheduled or unscheduled visit that is after the corresponding visit window and the patient's vessel is patent and an earlier imaging visit shows the vessel is patent OR the patient's vessel is not patent and an earlier imaging visit shows the vessel is not patent.

Events defined for the period of 12 months post-procedure follow up are reported for patients with at least 390 days of follow-up or had 12-month visit within window (360±30 days) or with event to 390 days.

Events defined for the period of 24 months post-procedure follow up are reported for patients with at least 750 days of follow-up or had 24-month visit within window (720±30 days) or with event to 750 days.

Patients are included in the denominator for the image (restenosis) endpoint time frame if they returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.

*One (1) subject had a TVR, during which a balloon was inflated in the proximal segmental study stent. At that time the study stent was patent. Thus the TLR was non-clinically driven. This patient was censored from the primary patency analysis.

**Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by DUS peak systolic velocity ratio ≥2.0 or > 2.4

Table 12: Analysis of Secondary Endpoints	
Secondary Safety Endpoints	**ITT Population (N=264 Patients, L=265 Segments)**
Stent Fracture - At 12 Months	0.0% (0/243)
Stent Fracture – At 24 Months*	0.5% (1/200)
Major Adverse Vascular Event (MAVE) - At 30 Days	1.2% (3/260)
Major Adverse Vascular Event (MAVE) - At 6 Months	2.5% (6/241)
Major Adverse Vascular Event (MAVE) - At 12 Months	3.8% (9/235)
Major Adverse Vascular Event (MAVE) - At 24 months)	5.3% (11/207)
Safety Composite Endpoint (Death At 30 days, TLR, Index Limb Amputation And Rutherford-Becker Classification Increase By 2 Classes At 12 Months)[1]	12.45% (29/233)
Death At 30 Days	0.4% (1/260)
TLR at 12 Months	11.1% (26/235)
Index Limb Amputation At 12 Months	0.4% (1/233)
Rutherford-Becker Classification Increase By 2 Classes As Compared To Pre-Procedure At 12 Months	1.3% (3/230)
Index Limb Amputations - At 6 Months	0.0% (0/240)
Index Limb Amputations - At 12 Months	0.4% (1/233)
Index Limb Amputations - At 24 Months	1.0% (2/205)

Note:

Events defined for the period of 30 days post-procedure follow-up are reported for patients with at least 23 days of follow-up or with events within 37 days. Events defined for the period of 12 months post-procedure follow-up are reported for patients with at least 330 days of follow-up or with events within 390 days.

* One patient experienced a Type III fracture at 24 months after three directional atherectomy procedures to treat in-stent restenosis. See Section 8.4.3.6.

8.4.3.1 Rutherford Becker (RB) Clinical Category

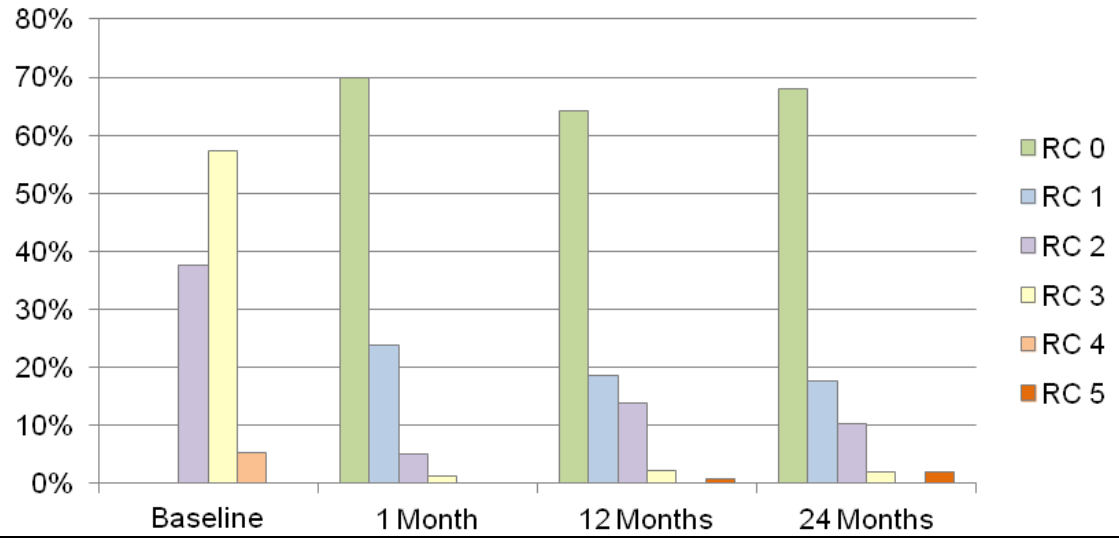
The majority of subjects had moderate-severe claudication (Rutherford Becker 2-3) at baseline. At 1, 12, and 24 months post procedure, a majority of subjects were asymptomatic (**Table 13** and **Figure 5**)**.**

Table 13: Analysis of Rutherford Becker Scale at Baseline, 1 Month, 12 and 24 Months of Follow-Up – ITT Population				
Rutherford Becker Scale	**Baseline**	**1 Month**	**12 Months**	**24 Months**
Clinical Category				
(0) Asymptomatic – No Hemodynamically Significant Occlusive Disease	0.0% (0/264)	69.9% (181/259)	64.3% (148/230)	68.0% (138/203)
(1) Mild Claudication	0.0% (0/264)	23.9% (62/259)	18.7% (43/230)	17.7% (36/203)
(2) Moderate Claudication	37.5% (99/264)	5.0% (13/259)	13.9% (32/230)	10.3% (21/203)
(3) Severe Claudication	57.2% (151/264)	1.2% (3/259)	2.2% (5/230)	2.0% (4/203)
(4) Ischemic Rest Pain	5.3% (14/264)	0.0% (0/259)	0.0% (0/230)	0.0% (0/203)
(5) Minor Tissue Loss, Focal Gangrene With Diffuse Pedal Ischemia	0.0% (0/264)	0.0% (0/259)	0.9% (2/230)	2.0% (4/203)
Limb Ischemia Improvement	NA	97.3% (252/259)	88.7% (204/230)	89.2% (181/203)

Note:

Limb ischemia improvement is defined as an improvement in the Rutherford-Becker Clinical Improvement Scale of greater than or equal to one.

Figure 5: Rutherford Becker Scale at Baseline, 1 Month, 12 and 24 Months of Follow-Up – ITT Population



8.4.3.2 Ankle-Brachial Index (ABI)

There was an overall improvement in ABI from a mean of 0.7 at baseline to 0.9 at 12 months. ABI data were not collected at 24 months (**Table 14**).

Table 14: ABI Through 12 Months

ABI on Target Limb	Baseline	1 Month	6 Months	12 Months
Mean±SD (N)	0.7±0.2 (257)	1.0±0.2 (251)	0.9±0.2 (226)	0.92±0.22 (227)
Median	0.7	1.0	0.9	0.9
Min, Max	0.0,1.7	0.4,2.2	0.0,2.5	0.0,2.1

8.4.3.3 Primary Patency at 12 Months as a Function of Lesion Length

Table 15 presents a lesion length tercile analysis based on SUPERB SFA/PPA Study outcomes and analyzed using a PSV ratio threshold of 2.0 and clinically-driven TLR as well as using modified VIVA criteria using a higher PSV ratio (2.4*)*.

Table 15: Primary Patency at 12 Months as a Function of Lesion Length

	Total N = 262 Total Lesions* = 262 Lesion Length Terciles		
	Lower (N = 87 Patients N = 87 Lesions)	**Mid (N = 88 Patients N = 88 Lesions)**	**Upper (N = 87 Patients N = 87 Lesions)**
Pre-Procedure Lesion Length (mm)			
n	87	88	87
Mean ± SD	35.4±12.3	73.5±10.8	126.1±33.4
Median	36.7	73.4	115.9
Min, Max	(8.5,55.0)	(55.5,91.5)	(91.6,236.4)
Primary Effectiveness Endpoint			
Primary Patency (PSVR < 2.0)** Rate at 12 Months	81.3% (61/75)	78.2% (61/78)	76.7% (56/73)
No Restenosis at 12 months***	87.7% (64/73)	84.6% (66/78)	87.7% (64/73)
Freedom from TLR to 12 months	92.2% (71/77)	90.2% (74/82)	83.8% (62/74)
Primary Patency (PSVR ≤ 2.4) Rate at 12 Months	85.3% (64/75)	78.2% (61/78)	76.7% (56/73)

Note:

Patients in the ITT Population are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, were LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Patients are included in the denominator for the image (restenosis) endpoint time frame if:

1. They returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint
2. They came back for an earlier or later scheduled or unscheduled visit that is after the corresponding visit window and the patient's vessel is patent and an earlier imaging visit shows the vessel is patent OR the patient's vessel is not patent and an earlier imaging visit shows the vessel is not patent

Events defined for the period of 12 months post-procedure follow up are reported for patients with at least 390 days of follow-up or had 12-month visit within window (360±30 days) or with event to 390 days.

Patients are included in the denominator for the image (restenosis) endpoint time frame if they returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.

One (1) subject had a TVR, during which a balloon was inflated in the proximal segmental study stent. At that time the study stent was patent. Thus the TLR was non-clinically driven. This patient was censored from the primary patency analysis.

*Lesions as reported by the Angiographic Core Laboratory. Terciles performed on single lesions: One patient is excluded because of missing lesion length data, and one patient is excluded due to multiple lesions.

**Defined as: uninterrupted patency with no procedures performed on or at the margins of the treated segment, with no restenosis ≥ 50% as documented by DUS peak systolic velocity ratio ≥2.0 or > 2.4

***No stenosis ≥ 50% diameter stenosis.

N = Intent-To-Treat Population

Note: Site, CEC, Duplex and Angiographic Core Laboratory Reported Data

Table 16: Primary Patency at 12 Months by Core Lab-Assessed Lesion Length		
Primary Endpoints	**Total N = 262 Total Lesions = 262**	
	Lesion length ≤ 140 mm (N=244 Subjects, L=244 Lesions)	**Lesion length > 140* mm (N=18 Subjects, L=18 Lesions)**
Patency rate at 12 months (PSVR < 2.0)*	80.6% (170/211)	53.3% (8/15)

Analysis based on the ITT population. Only 262 patients are included in this analysis. One patient is excluded because of missing lesion length data, and one patient is excluded due to multiple lesions.

Patients in the ITT Population are included in the clinical endpoint evaluation if:

1. They return for their corresponding visit within the window OR
2. They came back for a later scheduled or un-scheduled visit (i.e. a visit form is filled and the sponsor has documented information about their clinical status within the endpoint time frame) OR
3. The last contact date predated the endpoint time frame (they withdrew, was LTFU, died or exited the study for other reasons) BUT had an endpoint event within the endpoint time frame.

Patients are included in the denominator for the image (restenosis) endpoint time frame if:

1. They returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint
2. They came back for an earlier or later scheduled or unscheduled visit that is after the corresponding visit window and the patient's vessel is patent and an earlier imaging visit shows the vessel is patent OR the patient's vessel is not patent and an earlier imaging visit shows the vessel is not patent

Events defined for the period of 12 months post-procedure follow up are reported for patients with at least 390 days of follow-up or had 12-month visit within window (360±30 days) or with event to 390 days.

Patients are included in the denominator for the image (restenosis) endpoint time frame if they returned for corresponding visit within the pre-specified visit window, e.g. 360 ± 30 days for the 12 Month Restenosis endpoint.

One (1) subject had a TVR, during which a balloon was inflated in the proximal segmental study stent. At that time the study stent was patent. Thus the TLR was non-clinically driven. This patient was censored from the primary patency analysis.

* Lesion lengths greater than 140 mm were excluded from the trial and the longest available stent length was 150 mm.

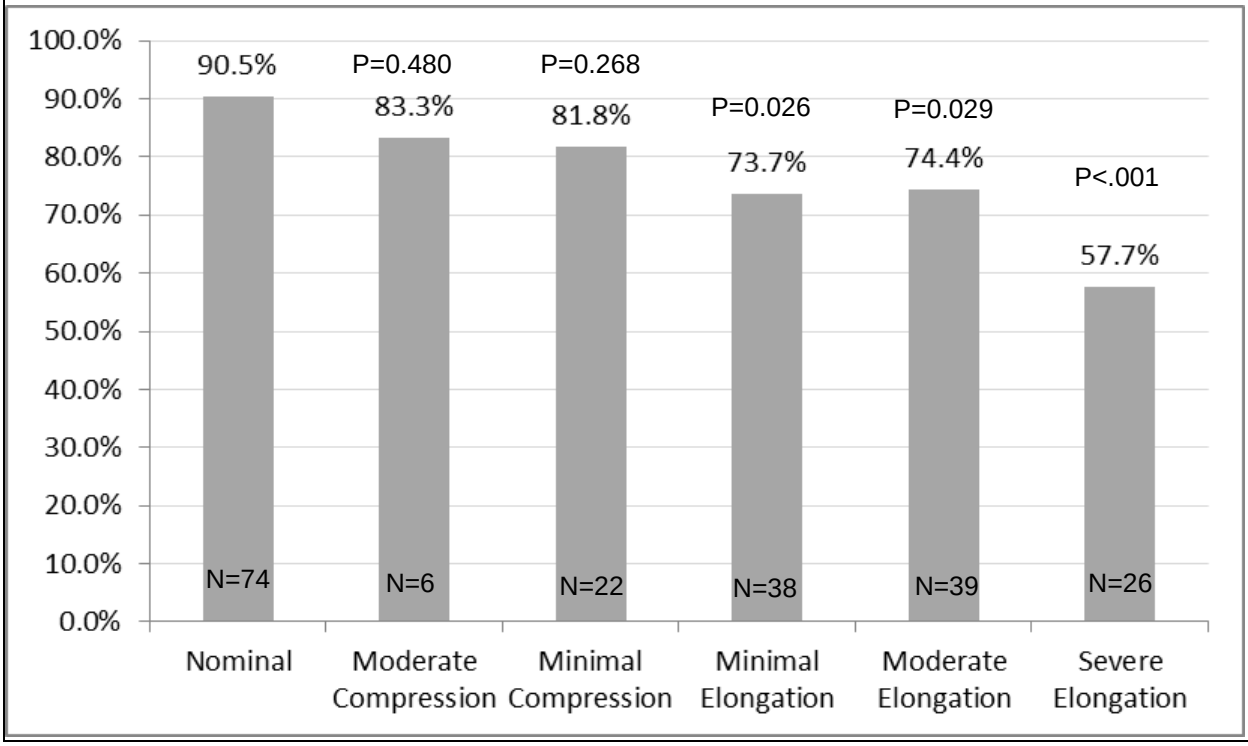
8.4.3.4 Post-Hoc Analysis of Deployed Stent Length

Compression (stacking) and elongation of the stent was detected in the SUPERB study. The impact of overall stent compression and elongation on the occurrence of primary patency in subjects undergoing SFA/PPA intervention with the Supera stent was evaluated by BIDMC Angiographic Core Laboratory. Procedural angiograms were analyzed at baseline after Supera stent implantation in 236 subjects who underwent single Supera stent implantation. There were 29/265 of ITT subjects' angiograms not included in the analysis due to a combination of multiple stent use, non-study stent use at the target lesion, or follow-up images that could not be assessed. Using an external calibration source, stent length was measured following implantation and compared to the labeled stent length.

- Nominal deployment is defined as the stent length upon deployment being within ±10% of labeled stent length
- Stent compression is defined as a percentage of measured deployed stent length shorter than labeled stent length
  - Minimal stent compression is defined as deployed length shorter than labeled stent length by 11 to 20%
  - Moderate stent compression is defined as deployed length shorter than labeled stent length by 21 to 40%
- Stent elongation is defined as a percentage of measured deployed stent length greater than labeled stent length
  - Minimal stent elongation is defined as deployed length longer than labeled stent length by 11 to 20%
  - Moderate stent elongation is defined as deployed length longer than labeled stent length by 21 to 40%

- Severe stent elongation is defined as deployed length longer than labeled stent length by greater than 41%

Figure 6: for Relationship of Stent Elongation to Primary Vessel Patency at 12 months – ITT, Single Stented Subjects



Note:
N represents the number of patients evaluable for the primary patency assessment. P-values indicate the statistical significance of the difference of the patency rates between each group and Nominal group.

As this figure demonstrates, a decrease in patency was observed when stents were deployed elongated. While this FDA-requested analysis was post-hoc and not powered to detect a difference, the greater amount of elongation correlated to a significant reduction in patency at 12 months. In addition, the demographics and lesion characteristics were similar across all groups. Physicians should pay careful attention to deploy the stent to the appropriate dimensions to achieve the best possible clinical results.

8.4.3.6 Stent Fracture Analysis

As indicated in **Table 17**, one patient (1/200, 0.5%) experienced a Type III fracture at 24 months. The patient had a revascularization with directional atherectomy for in-stent restenosis at 9 months post index procedure. At 12 month follow up there was no evidence of a stent fracture. Additional in-stent restenoses were treated twice more with directional atherectomy between the 12 and 24 month evaluations. At 24 months, a type III fracture was noted by x-ray in the region of the earlier restenoses. There was no report of a major adverse event at 24 months.

Table 17: Stent Fractures at 12- and 24-Months		
Stent Fractures*	**12-Months (N = 243)**	**24-Months (N=200)**
Type I – Single time fracture	0.0% (0/243)	0.0% (0/200)
Type II – Multiple time fractures	0.0% (0/243)	0.0% (0/200)
Type III – Stent fracture(s) with preserved alignment of the components	0.0% (0/243)	0.5% (1/200)
Type IV – Stent fracture(s) with mal-alignment of the components	0.0% (0/243)	0.0% (0/200)
Type V – Stent fracture(s) in a trans-axial spiral	0.0% (0/243)	0.0% (0/200)

*Evaluated by X-ray [anterior-posterior (AP) and lateral views in both straight and flexed knee positions] per an independent core lab.

8.5 Adverse Events

Table 18 provides a summary of the adverse events documented in the SUPERB study. The data are presented as a percentage of subjects experiencing an adverse event.

Table 18: Summary of Adverse Events – Cumulative to Time-Point – ITT			
System Organ Class/Preferred Term	**Events at ≤ 1 month**	**Events at ≤ 12 months**	**Events at ≤ 24 months**
Any AE	43.1% (110/255)	79.8% (198/248)	84.9% (203/239)
Blood and lymphatic system disorders	2.7% (7/255)	5.6% (14/248)	7.1% (17/239)
Cardiac disorders	3.5% (9/255)	20.6% (51/248)	24.7% (59/239)
Congenital, familial and genetic disorders	NA	0.4% (1/248)	0.8% (2/239)
Ear and labyrinth disorders	NA	0.4% (1/248)	0.4% (1/239)
Endocrine disorders	NA	0.4% (1/248)	0.8% (2/239)
Eye disorders	NA	0.8% (2/248)	0.8% (2/239)
Gastrointestinal disorders	3.1% (8/255)	11.3% (28/248)	14.6% (35/239)
General disorders and administration site conditions	16.5% (42/255)	27.0% (67/248)	31.0% (74/239)
Hepatobiliary disorders	NA	0.4% (1/248)	0.8% (2/239)
Immune system disorders	0.4% (1/255)	0.8% (2/248)	0.8% (2/239)
Infections and infestations	3.1% (8/255)	10.5% (26/248)	12.1% (29/239)
Injury, poisoning and procedural complications	2.4% (6/255)	15.7% (39/248)	19.2% (46/239)
Investigations	NA	2.0% (5/248)	2.1% (5/239)
Metabolism and nutrition disorders	0.8% (2/255)	3.6% (9/248)	5.0% (12/239)
Musculoskeletal and connective tissue disorders	10.6% (27/255)	24.2% (60/248)	27.2% (65/239)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.4% (1/255)	2.0% (5/248)	2.9% (7/239)
Nervous system disorders	2.7% (7/255)	10.9% (27/248)	12.1% (29/239)
Psychiatric disorders	0.4% (1/255)	2.0% (5/248)	2.5% (6/239)
Renal and urinary disorders	1.6% (4/255)	4.0% (10/248)	5.4% (13/239)
Reproductive system and breast disorders	0.4% (1/255)	0.8% (2/248)	0.8% (2/239)
Respiratory, thoracic and mediastinal disorders	1.2% (3/255)	9.3% (23/248)	13.0% (31/239)
Skin and subcutaneous tissue disorders	1.6% (4/255)	4.4% (11/248)	5.4% (13/239)
Surgical and medical procedures	NA	1.2% (3/248)	1.7% (4/239)
Vascular disorders	18.8% (48/255)	39.5% (98/248)	46.0% (110/239)

Note:

Patients included in each interval are as follows:

≤ 1 month: patients who had SAE occurring between 0 – 37 days post procedure or with follow up time for AE ≥ 37 days.

≤ 12 months: patients who had SAE occurring between 0 - 390 days post procedure or with follow up time for AE ≥ 390 days.

≤ 24 months: patients who had SAE occurring between 0 - 750 days post procedure or with follow up time for AE ≥ 750 days.

8.6 Conclusion

Among the 264 ITT subjects, 99.2% (258/260, 95% lower Wilson Score CL 97.7%) met the primary safety endpoint (i.e., freedom from a composite of all death, TLR, or any amputation of the index limb to 30 days). This rate was higher than the prespecified performance goal of 88% with statistical significance ($p<0.001$). Therefore, the primary safety endpoint was met.

The primary effectiveness endpoint, primary stent patency, was evaluated in all enrolled subjects with evaluable 1-year data, and was achieved in 78.9% (180/228) of the subjects (95% lower Wilson Score CL 74.2%. This rate is greater than the prespecified performance goal of 66%, with statistical significance ($p<0.001$). Therefore, the primary effectiveness endpoint was met.

In conclusion, the SUPERB study results support the safety and effectiveness of the Supera Peripheral Stent System for the treatment of de novo or restenotic lesions or occlusions (≤ 140mm) in the SFA or PPA in subjects with symptomatic peripheral artery disease (PAD).

9.0 DIRECTIONS FOR USE

9.1 Vessel Lesion Evaluation

1. Perform a percutaneous angiogram using standard technique.
2. Fluoroscopically evaluate and mark the lesion, observing the most distal location of the treatment area.
3. Select a stent size:
    a. Measure the length of the target lesion to determine the length of the stent required. Allow for an adequate margin of healthy tissue (at least 1cm) proximal and distal to the lesion to be covered with the stent.
    b. Measure the diameter of the reference vessel proximal and distal to the lesion.
    c. Select a stent corresponding to the reference vessel diameter of the target lesion.

Precaution: Refer to product labeling for stent diameter and length.

During deployment, the Supera stent foreshortens (decreases in length between catheter-loaded condition and deployed condition) by 60% ± 5%. Therefore the stent is approximately 3 times longer in the catheter than when deployed.

Table 19: Stent Foreshortening and Deployed Length

Stent length (mm)	Foreshortening* (ratio of catheter-loaded length : deployed length)	Length of stent in delivery system	Length of deployed stent **
20	60.2% (2.7 : 1)	53mm	18 – 22mm
30	60.6% (2.6 : 1)	79mm	27 - 33mm
40	62.2% (2.7 : 1)	108mm	36 – 44mm
60	61.3% (2.6 : 1)	157mm	54 – 66mm
80	60.2% (2.5 : 1)	203mm	72 – 88mm
100	60.2% (2.5 : 1)	251mm	90 – 110mm
120	59.5% (2.5 : 1)	298mm	108 – 132mm
150	59.5% (2.5 : 1)	373mm	135 – 165mm

*Foreshortening defined as percent change in length from constrained to deployed length
**Assuming proper vessel diameter and pre-dilatation diameter per IFU

9.2 Lesion Treatment

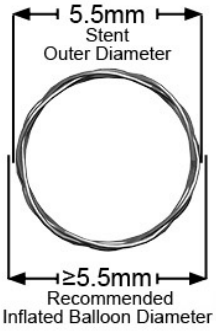
9.2.1 Lesion Pre-dilatation

1. Prepare the vessel utilizing standard angioplasty technique using a balloon size greater than or equal to the stent diameter. Refer to the balloon's instructions for use. (Refer to **Table 20** and **Figure 7**).

Table 20: Stent Diameter and Vessel Preparation

Reference Vessel Diameter	Stent Diameter	Recommended Inflated Balloon Diameter
4.0-4.5 mm	4.5mm	≥4.5mm
4.6-5.5 mm	5.5mm	≥5.5mm
5.6-6.5 mm	6.5mm	≥6.5mm

Figure 7: PTA Balloon Inflation Example for 5.5mm Stent



Precaution: The post-dilated vessel should be at least the size of the stent diameter. If recommended vessel diameter cannot be gained, optimal stent deployment may not be achieved and revised stent sizing should be considered.

2. Ensure vessel distal to the lesion is open in order to allow clearance for the Catheter Tip (12).
3. Remove the balloon from the patient while maintaining lesion access with the guidewire.

9.2.2 Inspection Prior to Use

Carefully remove the device from its protective packaging (i.e. Tyvek pouch and tray) using standard aseptic technique, and inspect for damage.

- Do not use if device is damaged or kinked.
- If it is suspected that the sterility of the device has been compromised, the device should not be used.

9.2.3 Materials Required

- Sterile isotonic saline
- 0.014“ or 0.018” guidewire of appropriate length
- 10-cc syringe for flushing
- Introducer sheath (Refer to **Table 21**)

Table 21: Sheath Selection

Catheter Size	Catheter Outer Sheath Diameter
6F	2.00mm, 0.079 inches
7F	2.54mm, 0.100 inches

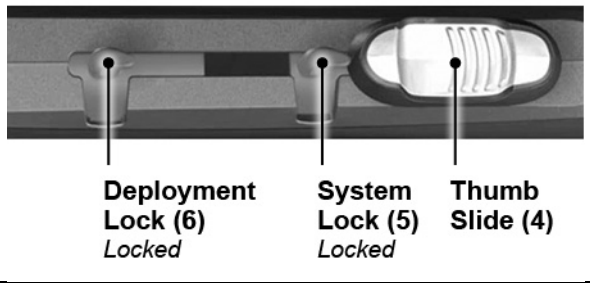
9.3 Lesion Access

1. Using standard technique, gain access at an appropriate anatomical site utilizing an appropriately-sized introducer sheath. (Refer to **Table 20**)
2. After establishing access, a guidewire should be inserted/exchanged and advanced until distal to the lesion.

9.4 Delivery System Preparation

1. Attach a 10-cc syringe filled with saline to the Sheath Flush Port (1) and Guidewire Flush Port (2) to flush lumens and purge air.
2. Wipe the distal portion of the Outer Sheath (10) of the catheter with saline soaked gauze to activate the hydrophilic coating.
3. Ensure the System Lock (5) and Deployment Lock (6) are in the locked position, in line with the Thumb Slide (4). (Refer to **Figure 8**)

Figure 8: System Lock and Deployment Lock in Locked Position



4. Load the distal end of the Catheter Tip (12) onto a 0.014” or 0.018” guidewire.
5. Advance the catheter over the guidewire and through the introducer while controlling the guidewire.

Precaution: Insertion of the Supera Peripheral Stent System should always be performed under fluoroscopic guidance. If unusual resistance is met during catheter introduction, the system should be withdrawn and checked for damage.

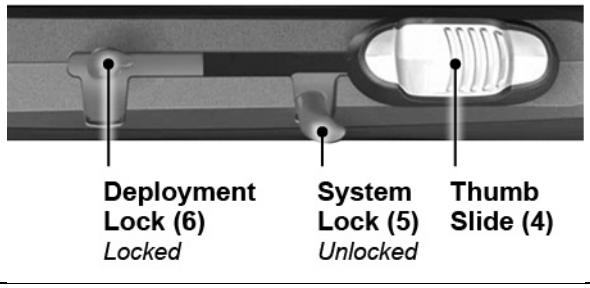
9.5 Stent Deployment

1. Advance the catheter until the Distal Sheath Marker (11) and Stent Length Marker (9) encompass the target lesion.

   Precaution: Should unusual resistance be felt at any time during stent system advancement or stent deployment the entire system should be removed together with the introducer sheath or guiding catheter as a single unit.

2. Rotate the System Lock (5) to the unlocked position. Do not unlock the Deployment Lock (6). (Refer to **Figure 9**)

Figure 9: System Lock in Unlocked Position



3. Increase magnification to better visualize stent deployment. Maintain increased magnification during the entire stent deployment procedure.
4. Under fluoroscopy, initiate stent deployment by advancing the Thumb Slide (4) while allowing the Outer Sheath (10) to retract proximally. Evaluate the initial location of the distal end of the Supera Stent. Minor repositioning can be done if full vessel wall apposition has not been achieved.
5. Under fluoroscopy, continuously and slowly retract and advance the Thumb Slide (4) multiple times. Each full advancement of the thumb slide will only deploy a short section of the stent. Shorter Thumb Slide (4) advancements may provide greater control versus full Thumb Slide (4) advancements.

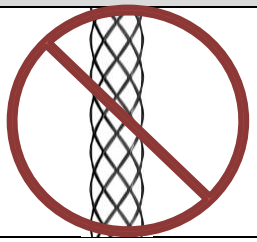
   Precaution: The flexible design of the Supera Stent may result in variation in the deployed stent length.

   Careful attention should be paid when sizing and deploying the stent to prevent stent elongation or compression. In the SUPERB clinical study, stent elongation was observed with a decrease in patency at 12 months.

   - Proper vessel sizing, preparation and attention to the pattern of the stent interwoven segments during deployment will help assure nominal stent length deployment. (Refer to **Figure 10**)

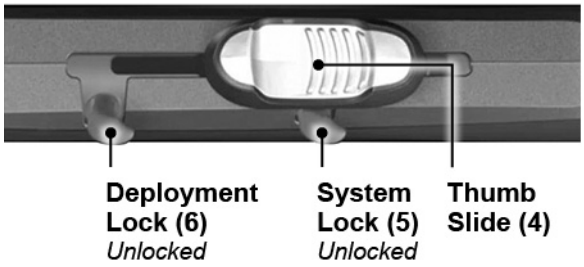
   Expansion to a size smaller than the nominal stent diameter will likely result in an overall stent length longer than the labeled length.

Figure 10: Stent Visualization Example

Nominal/Optimal Interwoven Segments ("Horizontal Diamonds")	**Compressed Delivery** Interwoven Segments ("Compressed Horizontal Diamonds")	**Elongated Delivery** Interwoven Segments ("Vertical Diamonds")
		
Ideal	***Not Optimal***	***Suboptimal Associated with Reduced Patency***

6. Repeat Step 5 until the Thumb Slide (4) advancement no longer deploys the stent.
7. While maintaining increased magnification from Step 3, rotate the Deployment Lock (6) to the unlocked position. (Refer to **Figure 11**)

Figure 11: Deployment Lock in Unlocked Position

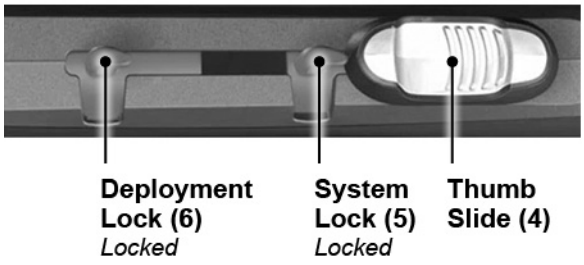


8. Under fluoroscopy, slowly advance the Thumb Slide (4) to the distal most position on the Handle (3).
9. Confirm under fluoroscopy that the entire Supera Stent has emerged from the Outer Sheath (10) and is released.

9.6 Removal Procedure

1. Following confirmed implantation of the Supera Stent, retract the Thumb Slide (4) in a single motion to the starting position on the Handle (3) and rotate the System Lock (5) and Deployment Lock (6) into the locked position, in line with the Thumb Slide (4). (Refer to **Figure 12**)

Figure 12: System Lock and Deployment Lock in Locked Position



2. Under fluoroscopy, remove the device from the guidewire and evaluate the improved luminal quality of the treated area.

Precaution: Should unusual resistance be felt at any time during stent deployment the entire system should be removed together with the introducer sheath or guiding catheter as a single unit.

3. Post deployment balloon dilatation is recommended using standard angioplasty technique with a balloon inflation diameter approximating the reference vessel diameter.
4. Complete the procedure using standard technique.
5. Discard all devices appropriately.

10.0 PATENTS AND TRADEMARKS

This product and/or its use are covered by one or more of the following United States Patents: 6,792,979; 7,018,401; 7,048,014 and 8,419,788. Other U.S. patents pending. Foreign patents issued and pending.

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

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Graphical Symbols for Medical Device Labeling

REF	Catalog Number
LOT	Lot Number
	Product Expiration (“Use Before”) Date
	Keep Away From Direct Sunlight
	Do Not Use if Package is Opened or Damaged
	MR Conditional
	Keep Dry
	Contents (Numeral Represents Quantity Inside)
	Do Not Reuse
STERILE EO	Sterilized with Ethylene Oxide Gas
	Non-Pyrogenic
	See Instructions for Use
R_x Only	For Prescription Only
	Consult Instructions for Use
	Manufacturer
	Telephone
FAX	Facsimile

Not made with natural rubber latex.

Supera®

Peripheral Stent System

Superficial Femoral and Popliteal Artery Stenting

A Guide for Patients and Their Families

This guide is provided to you by the makers of the Supera Peripheral Stent System. Your doctor has given you this guide because he or she thinks you may need treatment for superficial femoral and/or popliteal artery disease (narrowing of one or both of these arteries that carries blood through the thigh and knee to the lower legs).This guide will explain superficial femoral and/or popliteal artery disease and its treatment choices. One treatment choice is to place a stent in your superficial femoral and/or popliteal artery to keep it open.

The Supera Peripheral Stent System is authorized by Federal (U.S.) law for use in the treatment of patients with superficial femoral and/or proximal popliteal artery disease, a narrowing caused by a build-up of fatty materials inside the artery.

In this guide, you will learn what will happen before, during and after your stent procedure. As you read, you might think of more questions to talk about with your doctor or nurse. You will find a place in the back of this guide to write your questions and notes.

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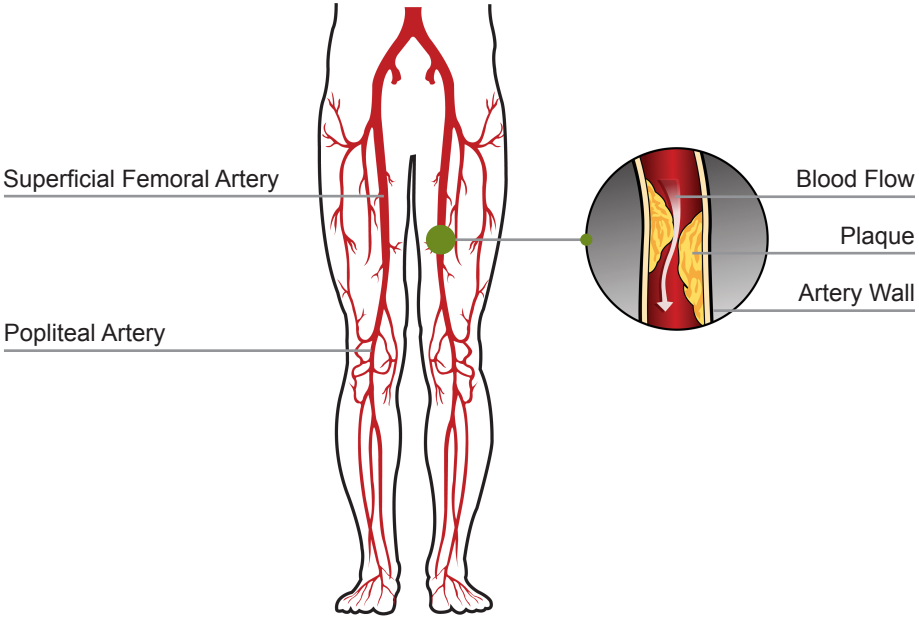
Superficial Femoral and Popliteal Artery Disease

Your Superficial Femoral and Popliteal Arteries

Figure 1 shows your superficial femoral and popliteal arteries. The superficial femoral artery (SFA) carries blood from the femoral artery through the thigh to the knee. The SFA becomes the popliteal artery just above the knee. The popliteal artery continues below the knee to supply blood to your lower leg. You have two superficial femoral arteries – one on the right side and one on the left. You have two popliteal arteries – one on the right side and one on the left.

Figure 1 – Your Superficial Femoral and Popliteal Arteries



What is Superficial Femoral or Popliteal Artery Stenosis?

Superficial femoral or popliteal artery stenosis (pronounced “steh-NO-sis”) is a narrowing in one or both of the arteries that carry blood to the legs (Figure 1).

This narrowing happens when fatty deposits, such as cholesterol, build up over time in the lining of the arteries. You may also hear this called “plaque” or a “lesion.” This build-up of plaque is Peripheral Artery Disease (PAD).

Two of the arteries commonly affected by PAD are the superficial femoral artery (SFA) and the popliteal artery. The narrowing in these arteries lowers or blocks blood flow to the legs. This lowered blood flow may cause pain in your legs or buttocks when you walk which gets better when you stop to rest. This pain is called “claudication”. In more severe cases, the decreased blood flow may cause pain in your legs or feet when you are at rest or cause open sores on your feet that do not get better.

What are the Risk Factors for Superficial Femoral or Popliteal Artery Stenosis?

Some people are more likely to get femoral or popliteal artery stenosis if they have certain risk factors. A risk factor is something that might increase your chance of getting femoral or popliteal artery disease. Some risk factors cannot be changed while others can.

You cannot change:

- your age, gender or race
- if you or a close relative have had a heart attack or stroke

You can change:

- high blood pressure, high cholesterol or diabetes
- if you are overweight
- if you smoke cigarettes or use tobacco

How Will My Doctor Know if I Have Superficial Femoral or Popliteal Artery Stenosis?

The most common symptom of femoral or popliteal artery stenosis is leg pain that happens when walking (claudication). Often, the pain goes away after a person stops and rests for a few minutes.

To find out if you have femoral or popliteal artery stenosis, your doctor will ask you questions about your medical and family history, perform a physical exam, and look at and touch your legs and feet. Your doctor may recommend tests to determine if you have femoral or popliteal artery stenosis. One common test is an ankle-brachial index (ABI). For this test, your blood pressure is measured in both arms and both ankles. These blood pressure numbers are used to calculate your ABI. Your doctor will use this to help decide if you might have femoral or popliteal artery stenosis.

One other possible test is an ultrasound. An ultrasound uses sound waves to get images of the inside of your femoral or popliteal artery. This test is done from outside the body.

Your doctor may also perform a special procedure called angiography to look inside your femoral or popliteal arteries. Angiography is an x-ray based picture that is performed in a catheterization laboratory (cath lab). A cath lab is a room with special monitors that the doctor will watch during your procedure. Your doctor will insert a long, thin, hollow tube (catheter) into an artery in your groin area. The catheter will be passed through your blood vessels to your superficial femoral or popliteal arteries. Your doctor will inject a special dye (contrast solution) through the catheter. This dye helps the doctor to see how much narrowing there is and where it is located in your artery.

Another possible test is called Magnetic Resonance Angiography (MRA), which uses a strong magnet to create images of your arteries. Using the information from one or more of these tests, your doctor will be better able to recommend the best treatment for you.

Your Treatment Choices

There are several ways to treat femoral or popliteal artery stenosis. The goal of treatment is to improve blood flow through your legs. Your doctor will suggest what is best for you.

Exercise: Although this may sound strange to you, exercise is actually good for someone with femoral or popliteal artery disease. Exercise, such as walking, helps keep blood flowing to the legs. Even if you have pain when you walk, you can stop and rest until the pain goes away. Exercise will not make your arteries less narrow but it may prevent them from becoming even narrower.

Medicine: Medicine can be used alone or with other treatments. Medicine does not make your arteries less narrow but can be used to improve blood flow to your legs. Your doctor may also tell you to take medicines to control other risk factors such as high cholesterol or high blood pressure.

Surgery: A surgeon can operate on your artery to clean out or bypass the narrowed part of your artery. Surgery is usually done under general anesthesia (you are asleep).

Angioplasty: A doctor threads a small deflated balloon through a catheter (tube) into the narrowed part of your femoral or popliteal artery. The balloon is inflated to open the narrowed part of the artery. The doctor will take the balloon and catheter out of your body when the procedure is done. Patients are usually awake during the procedure. Your doctor may give you some medicine to help you relax.

Superficial Femoral or Popliteal Artery Stenting: A stent is a small, metal mesh tube that holds open the narrowed part of your femoral or popliteal artery. It is packaged inside a catheter, which allows your doctor to move it through your arteries and place it to treat the narrowed portion of your artery. The stent stays in the artery permanently. Patients are usually awake during the stenting procedure. Your doctor may give you some medicine to help you relax.

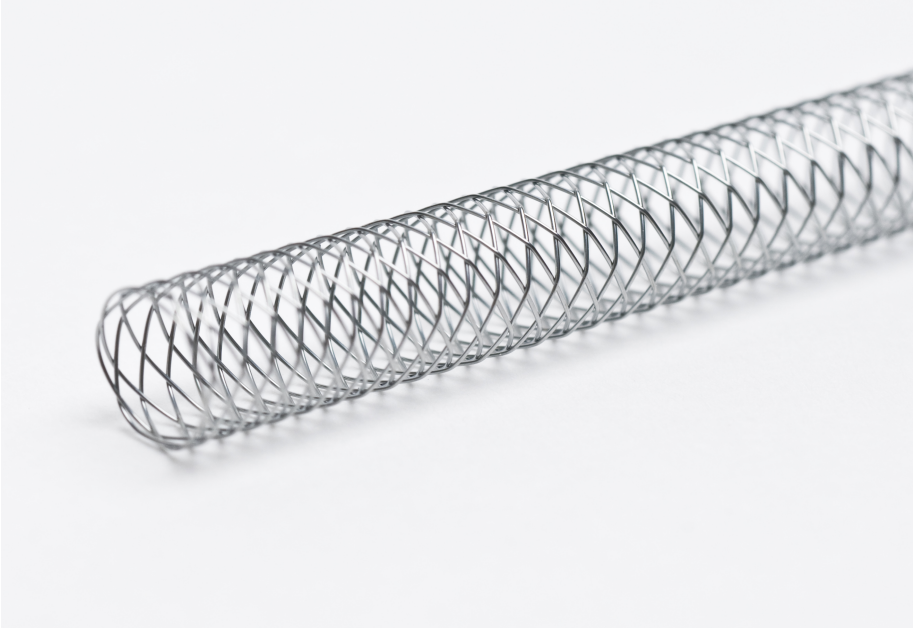
Your doctor may decide that stenting is the best way to treat your femoral or popliteal artery stenosis.

Superficial Femoral or Popliteal Artery Stent Procedure

Device Description

The Supera Peripheral Stent is a small woven tube made from metals (nickel and titanium) (Figure 2). When nickel and titanium are mixed together, they form something called nitinol. Nitinol stents can be gently collapsed into a smaller (unexpanded) shape. This is how the Supera stent is placed in the delivery system. To hold the stent in place, a sheath (outer tube) covers it. The Supera stent is pushed forward as the delivery system is pulled back to uncover it and allow it to expand on its own, back to its original shape and size.

Figure 2 – Supera Peripheral Stent



Discussions with Your Doctor

Before deciding to have a stent procedure, you should talk to your doctor:

- About all medicines you take, including non-prescription medicine.
- About allergies to contrast dye or iodine, metals (nickel, titanium), plastics or anything else, including medications.
- If you cannot take aspirin. Aspirin and other medicines are started before the procedure and may be used for several months after the procedure.
- About how long you will have to be in the hospital for the procedure.
- About the possible risks and benefits of the stenting procedure. Your doctor can answer any questions you or your family may have.

Once you and your doctor decide on a stent procedure:

- Be sure you understand the risks and benefits before you agree to treatment.
- Your doctor may tell you not to eat or drink anything for several hours before your procedure. This time will depend on when your procedure is scheduled.
- Follow all instructions given to you by your doctor, nurse or health care professional.

Prior to Your Procedure

- In the procedure room, you will lie on a special table. The staff will make you as comfortable as possible.
- You will be attached to monitors that will keep track of your heart rate and oxygen levels. The doctor and staff will watch these monitors throughout your procedure.
- You may be given medicine to help you relax. This medicine may make you sleepy.

During Your Procedure

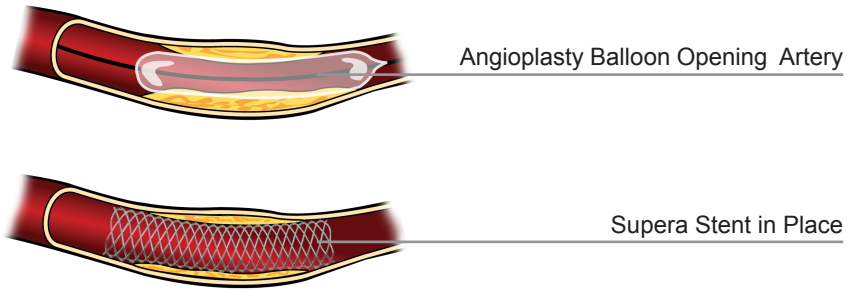
Your femoral or popliteal artery will be accessed through an artery in your leg (Figure 3). This place is called the access site.

- Your groin area (at the top of the leg) will be washed with an antiseptic solution and covered with a sterile sheet.
- You will receive medicine to numb the area around the access site. You may feel a sting from the needle and a brief warm feeling when the medicine is injected.
- Next, your doctor will put a needle into the artery in your groin. When the needle is first put into the artery, you may feel some pressure. A guide wire will be fed through your artery and the needle will be removed. Then a sheath (tube) will be fed over the guide wire through your artery. Contrast dye will be injected so the doctor can view your arteries.

If your doctor has chosen to use the Supera Peripheral Stent, it will be placed as follows:

- Your doctor will put a balloon catheter into the narrowed area and inflate the balloon to open up the artery more (Figure 3). Your doctor will remove the balloon catheter.
- The stent system will be positioned in the artery where it is narrowed.
- The doctor will push the stent forward and pull back the delivery system to allow the stent to open up on its own (Figure 3).

Figure 3 – Balloon Inflation to Widen the Stenosis and Positioning of Stent in Narrowed Superficial Femoral or Popliteal Artery



- Once the stent is placed, your doctor may use a balloon catheter to press the stent and plaque against the artery wall.
- The stent is permanent, but all catheters used in the procedure are removed.
- Once all catheters are removed from the access site, pressure will be applied to the access site until bleeding stops. A special closure device may be used to close the small incision in the artery.

After Your Procedure

- You may feel sleepy until the medicine you received wears off.
- You will be taken to a special area where nurses and doctors monitor your heart rate and blood pressure and the access site.
- You may need to stay in bed for several hours to allow the access site to heal.
- Do not try to sit up until your nurse or doctor tells you to do so. It is important to lie flat and keep still to prevent bleeding from the access site. If you see any bleeding, tell your doctor or nurse immediately.
- You should drink plenty of fluids to help your kidneys get rid of the dye that was injected into your arteries.
- Let the nurse or doctor know if you have any pain in your back, at the access site or anywhere else.
- You will be given a Stent Implant Card (explained at the end of the brochure).

Your Recovery

It is important to take all your medicines as your doctor told you. Ask your doctor about any side effects the medicines may cause and when you should call if you are having a side effect. Do not stop taking your medicines unless your doctor tells you to. Your doctor may be able to give you a different medicine.

Avoid lifting and activities that could tire you for as long as your doctor tells you. Your doctor may talk to you about making changes to your diet or lifestyle.

Make sure to keep all scheduled follow-up appointments. It is important for your doctor to check the condition of your superficial femoral or popliteal artery arteries after treatment. Most patients go home after the procedure and have no problems with the stent. In some patients, narrowing inside or around the superficial femoral or popliteal artery stent may occur (restenosis). Additional treatment may be needed. If you have any questions, ask your doctor.

Ask your doctor about when you should call if you are not feeling well. Tell your doctor if your address or telephone number changes so you can be contacted if any information about your stent is available in the future.

Safety Information

Benefits

Superficial femoral or popliteal artery stenting can improve blood flow to your legs. The stenting procedure does not require a large cut and stitches. The healing process after stenting is usually faster and may be less painful than surgery. The Supera Peripheral Stent System was studied in a clinical study in the United States. The results show that the use of the Supera Peripheral Stent System for femoral or popliteal artery stenting is safe and effective. Your doctor can help explain the risks and benefits that are specific to you.

When a Stent Might Not Be Appropriate

Your doctor may not choose stenting if:

- You cannot take medicines (anticoagulants) that make your blood take longer to form a clot
- You cannot take medicines (antiplatelets) that make it harder for cells in your blood to form a blood clot
- You are allergic to nickel or titanium, which are the metals used to make the stent
- You have a bleeding disorder
- You are allergic to contrast (dye), unless your doctor is able to pre-treat you

If you have any more questions, now is the time to discuss them with your doctor.

Warnings

Warning: People allergic to nickel or titanium may suffer an allergic reaction to these stents.

You can have a Magnetic Resonance Imaging (MRI) test, for any reason, at any time after your stent is implanted. ***IMPORTANT: You must tell the people conducting the MRI test that you have a stent.*** Show them your Stent Implant Card so that they will have the information needed about your stent to perform the testing correctly.

Potential Complications (Risks)

Complications can occur during any procedure performed through the blood vessels. The following lists some of the possible risks of the peripheral stent or the superficial femoral artery or popliteal artery stenting procedure. Ask your doctor to provide you more information on your risks for the procedure.

As with any stent procedure, there is a chance that complications may occur, including, but not limited to the following:

- Abnormal connection or passage between an artery and a vein
- Allergy or reaction to medicine, the stent material or contrast (dye)
- Bleeding
- Blood clots (including blood clot in the lung)
- Bruising, bleeding or blood clot at the puncture site
- Chest pain or heart attack
- Damage or injury to tissue or organs
- Damage or injury to your blood vessels
- Damage to the stent, movement of the stent while it is being placed in your artery or after it has been placed in your artery
- Damage to your legs and/or feet due to lack of blood flow to them
- Death
- Difficulty breathing
- Emergency surgery to remove the stent or to improve blood flow to the leg
- Fever
- High blood pressure
- Infection
- Kidney damage or failure
- Loss of limb
- Low blood pressure
- Nausea or vomiting
- Pain or discomfort
- Problems with the rhythm of your heart, such as slow heartbeat or uneven heartbeats
- Shock
- Stenosis (narrowing) or restenosis (re-narrowing) of the stented iliac artery
- Stroke
- Worsening discomfort or tiredness or resting pain in legs

Your doctor and nurses will watch you during and after the procedure for any complications. If any of these complications happen to you, your doctor will treat you as needed. Treatments will vary widely depending upon the type of complication and your medical history.

Summary of Clinical Information

The Supera Peripheral Stent System was evaluated in the SUPERB Clinical Study. The SUPERB Clinical Study enrolled 264 patients. The procedure was successful in most patients. Many patients had improved blood flow to their legs. Thirty days after the procedure, there was one patient that required re-treatment of their femoral artery. There were no amputations of the treated leg or foot within 30 days after the procedure. One death, possibly related to the procedure but not related to the device, was reported at 32 days.

At 12 months after the procedure, 26 out of 235 (11.1%) patients treated with the Supera stent needed to have their superficial femoral or popliteal arteries treated again because of re-narrowing.

At 24 months after the procedure, 36 out of 213 (16.9%) patients treated with the Supera stent needed to have their superficial femoral or popliteal arteries treated again because of re-narrowing.

The results of this study showed that the Supera Peripheral Stent System is safe and effective for treating superficial femoral or popliteal artery stenoses. Your doctor can explain the risks and benefits that are specific to you.

Lifestyle Changes

Superficial femoral artery or popliteal artery disease can be treated, but it has no cure. Keep all follow-up appointments and take all of the medicine your doctor has given to you. Your doctor may also recommend some of the following lifestyle changes.

Stop smoking: If you smoke, quitting is the single most important thing you can do to lower your risk of further femoral and popliteal artery disease. Chemicals in cigarette smoke may make it easier for plaque to build up on your artery walls. Smoking increases your heart rate and blood pressure, which also raises your risk of heart attack and stroke. If you are ready to quit, ask your doctor for advice – he or she can recommend ways to help you quit.

Increase your activity: Regular exercise can help lower your blood pressure and blood cholesterol. It can help you reach a healthy weight. Exercise can also help you deal more easily with daily stresses. Your doctor can recommend an activity program that meets your needs.

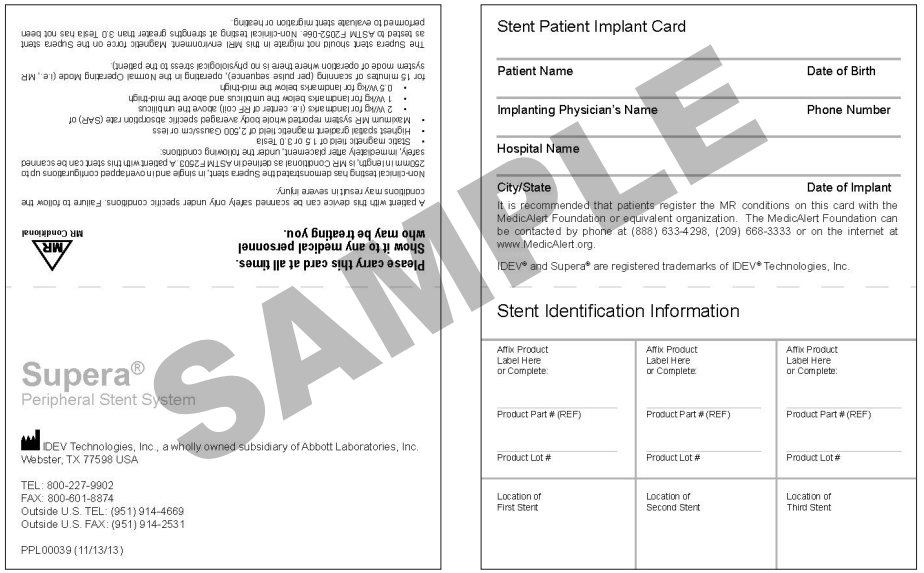
Eat a healthy diet: Choose a healthy diet that is low in saturated fats and cholesterol. This can help you reach a healthy weight, as well as help you control your blood pressure and cholesterol levels.

Your Stent Implant Card

Before you leave the hospital or surgery center, you will be given a card that includes important information about the procedure that was done, and the stent that was implanted.

Tell any medical person who treats you that you have a stent in your superficial femoral artery or popliteal artery. Keep your Stent Implant Card with you at all times. It has the name of the doctor who implanted your stent and how to reach him/her, the hospital where you received your stent, the date it was implanted and where it was placed in your superficial femoral artery or popliteal artery. It also identifies the size of your stent and the date the stent was made. The card has valuable information that is necessary if you need an MRI. There are also phone numbers on the card that your doctor can call if he/she has any questions.

Below is a sample of the Stent Implant Card you will receive:



Please carry this card at all times.
Show it to any medical personnel who may be treating you.

MR Conditional

A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury.

Non-clinical testing has demonstrated the Supera stent, in single and in overlapped configurations up to 250mm in length, is MR Conditional as defined in ASTM F2503. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 2,500 Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of
  - 2 W/kg for landmarks (i.e. center of RF coil) above the umbilicus
  - 1 W/kg for landmarks below the umbilicus and above the mid-thigh
  - 0.5 W/kg for landmarks below the mid-thigh

for 15 minutes of scanning (per pulse sequence), operating in the Normal Operating Mode (i.e., MR system mode of operation where there is no physiological stress to the patient).

The Supera stent should not migrate in this MRI environment. Magnetic force on the Supera stent as tested to ASTM F2052-06e. Non-clinical testing at strengths greater than 3.0 Tesla has not been performed to evaluate stent migration or heating.

Supera®
Peripheral Stent System

IDEV Technologies, Inc., a wholly owned subsidiary of Abbott Laboratories, Inc.
Webster, TX 77598 USA

TEL: 800-227-9902
FAX: 800-601-8874
Outside U.S. TEL: (951) 914-4669
Outside U.S. FAX: (951) 914-2531

PPL00039 (11/13/13)

Stent Patient Implant Card

Patient Name | Date of Birth

Implanting Physician's Name | Phone Number

Hospital Name

City/State | Date of Implant

It is recommended that patients register the MR conditions on this card with the MedicAlert Foundation or equivalent organization. The MedicAlert Foundation can be contacted by phone at (888) 633-4298, (209) 668-3333 or on the internet at www.MedicAlert.org.

IDEV® and Supera® are registered trademarks of IDEV® Technologies, Inc.

Stent Identification Information

Affix Product Label Here or Complete:	Affix Product Label Here or Complete:	Affix Product Label Here or Complete:
Product Part # (REF)	Product Part # (REF)	Product Part # (REF)
Product Lot #	Product Lot #	Product Lot #
Location of First Stent	Location of Second Stent	Location of Third Stent

SAMPLE

Notes

Notes

IDEV® Technologies, Inc., a wholly owned subsidiary of Abbott Laboratories, Inc.
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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, it is important to read the package insert thoroughly for Instructions for Use, Warnings and Potential Complications associated with the use of this device.

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