Supera®
Peripheral Stent System
Instructions for Use

Table of Contents

Rx ONLY

Abbott

1.0 DEVICE DESCRIPTION

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

Figure 1: Supera Peripheral Stent System

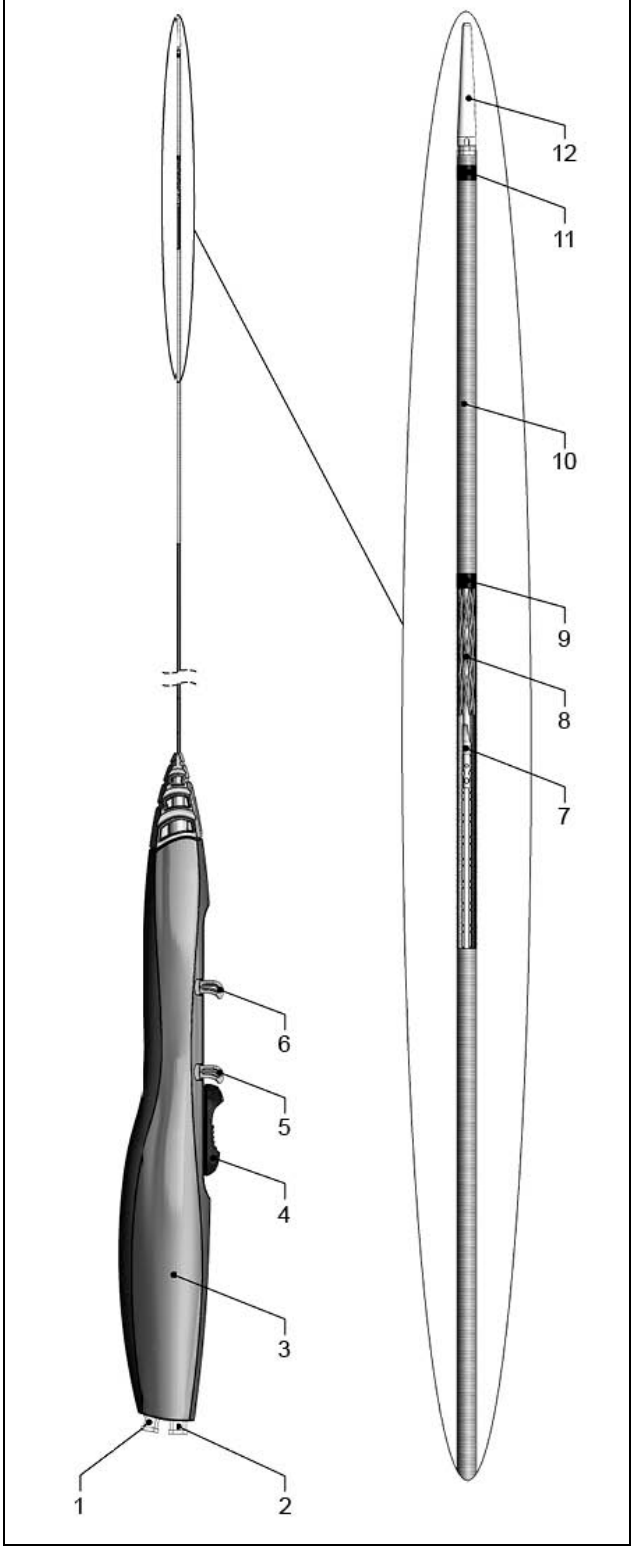
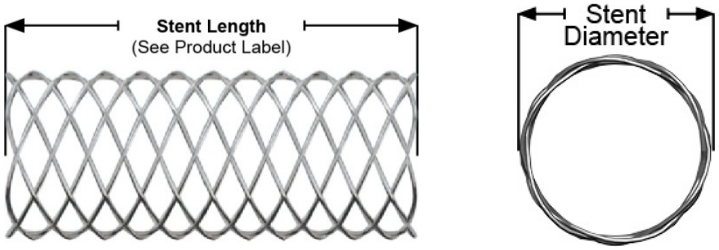


Table 1: Supera Peripheral Stent System Parts		
Part Number	**Part Name**	**Description / Function**
1	Outer Sheath Flush Port	• used to flush the outer sheath lumen of the device
2	Guide Wire Flush Port	• used to flush the guide wire lumen
3	Handle	• used to control stent (8) deployment and delivery
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 guide wire • 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 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 80 cm and 120 cm (6Fr). 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
4.5 mm	**4.0 – 4.5 mm**
5.0 mm	**4.5 – 5.0 mm**
5.5 mm	**5.0 – 5.5 mm**
6.0 mm	**5.5 – 6.0 mm**
6.5 mm	**6.0 – 6.5 mm**

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
4.5	20, 30, 40, 60, 80, 100, 120	2.06 mm, 0.081 inches
5.0	20, 30, 40, 60, 80, 100, 120	
5.5	20, 30, 40, 60, 80, 100, 120, 150	
6.0	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 6.5 mm, and lesion lengths up to 140 mm.

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 three 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 guide wire should not be loaded through the Guide Wire Flush Port (2). The delivery system is not designed for guide wire exchanges. If a guide wire exchange is needed or desired, remove delivery system first.
- Never advance the device without the guide wire 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 1 cm. Ensure that the stent(s) completely covers the target lesion, including > 1 cm of lesion-free vessel proximal and distal to the stent.
  0 If the distal reference vessel diameter is > 1 mm 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 1 cm**.**
- 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.

MR Conditional

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 250 mm. 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 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 legs of the patient should not be touching during the procedure.

RF Heating
In non-clinical testing and analysis of individual stents and overlapped stent pairs totaling up to 250 mm 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 1.5 T; 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 180 mm at 1.5T (64 MHz) or about 100 mm at 3T (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 ~ 2 cm 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 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 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)
- Emergent surgery
- Fever

- Hematoma or hemorrhagic event, with or without surgical repair
- Hyperperfusion syndrome
- Hypertension / Hypotension
- Infection
- Myocardial infarction
- Pain (leg, foot, and / or insertion site)
- Partial stent deployment
- Peripheral nerve injury
- Pulmonary embolism
- Renal failure or insufficiency
- Restenosis of vessel in stented segment
- Shock
- Stent malapposition or migration, which may require emergency surgery to remove stent
- Stent strut fracture
- Thrombosis or occlusion
- Stroke
- 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 (≤ 140 mm) 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 – 6.0 mm and the lesion length from 4 – 14 cm. 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, 24 months, and 36 months.

Patients were treated between July 30, 2009 and May 20, 2011. The database for this study reflected data collected through May 12, 2014, 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

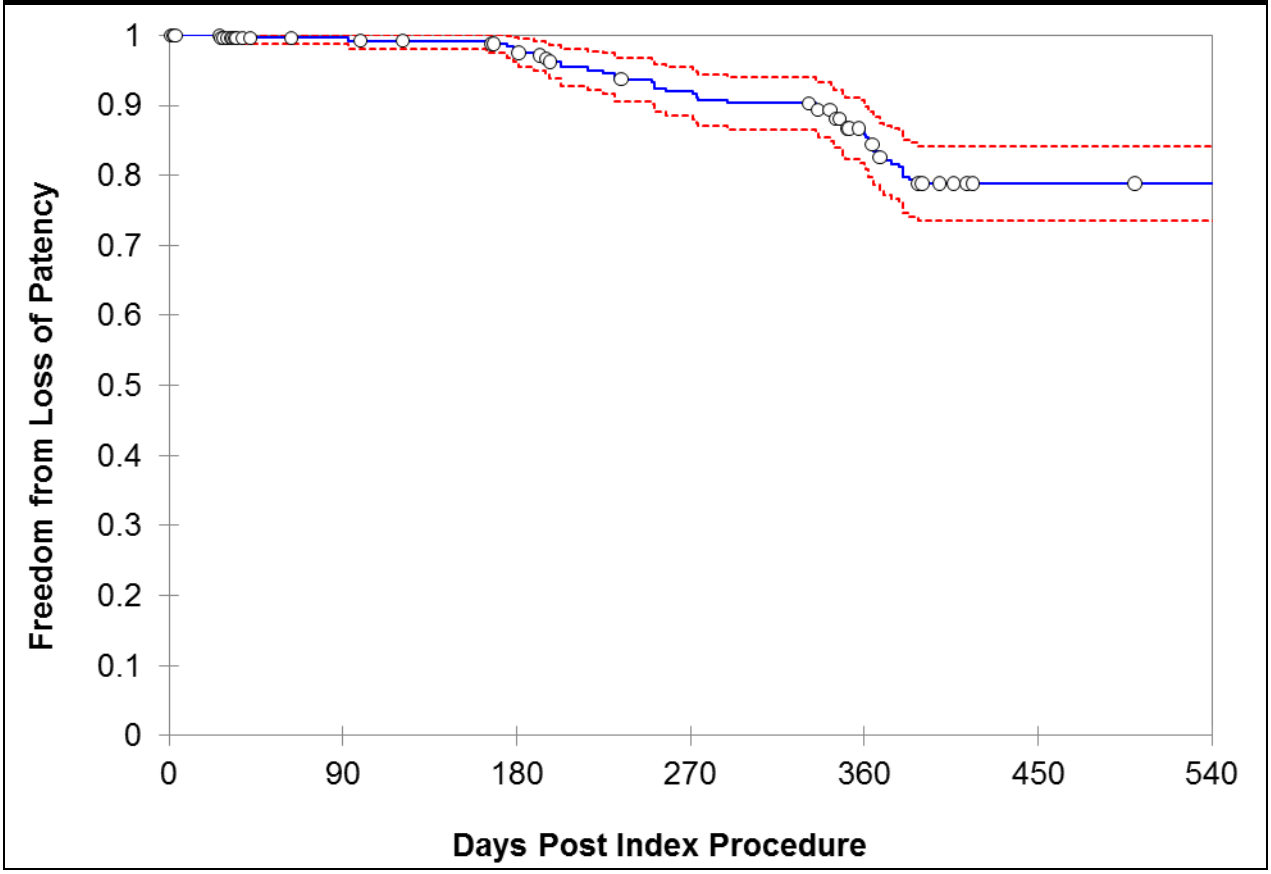


Table 8: Probability of Freedom from Loss of Patency (Restenosis defined as PSV Ratio of ≥ 2.0)

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 84.3% (± 2.4%) at 24 months and 83.2% (± 2.5%) at 36 months (**Figure 4** and **Table 9**).

Figure 4: Survival Analysis of TLR to 36 Months

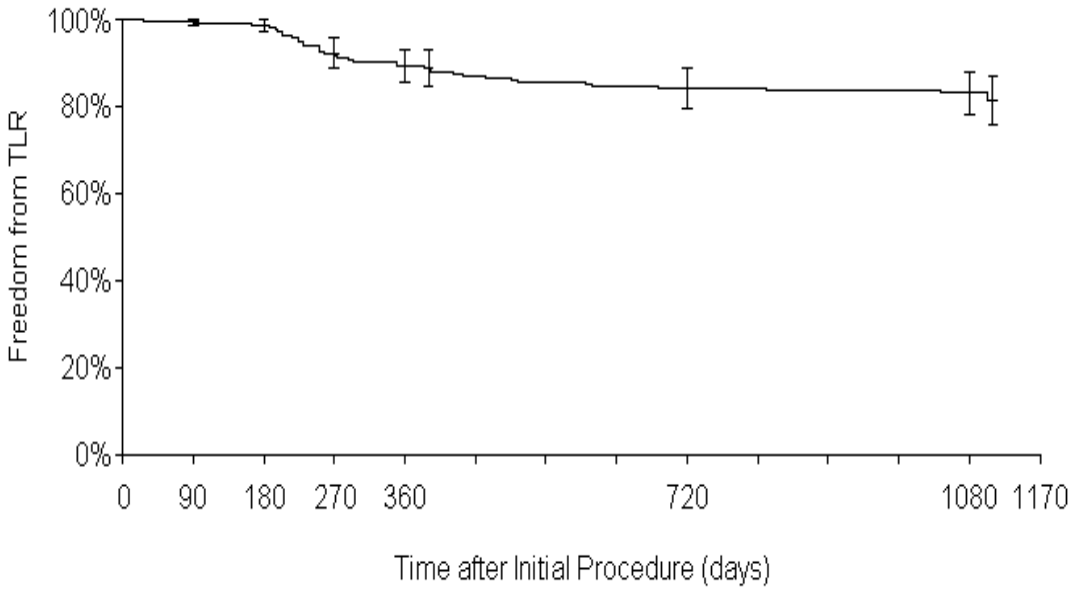


Table 9: Probability of Freedom TLR to 36 months (± 30 Days)

TLR	0	90	180	270	360	390	720	1080	1110
# Entered	264	263	242	236	217	201	196	172	84
# Censored	1	20	4	4	9**	4**	14	86	48
# Events	0	1	2	15	7	1	10	2	1
% Survived*	100.00%	99.61%	98.78%	92.42%	89.42%	88.97%	84.31%	83.20%	81.63%
SE	0.00%	0.39%	0.70%	1.72%	2.00%	2.04%	2.41%	2.50%	2.91%

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 < 1170 days, the subject is censored at the day after their last clinical follow-up
* Survival rate at end of time period
** The 13 censored patients (9 + 4) 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. The long-term safety endpoints are summarized in **Table 13.**

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 Effectiveness 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. 7% (36/215)
Target Lesion Revascularization – At 36 Months*	21.3% (39/183)
Target Vessel Revascularization - At 12 Months*	13.2% (31/235)
Target Vessel Revascularization - At 24 Months*	20.5% (44/215)
Target Vessel Revascularization - At 36 Months*	25.8% (48/186)
Improvement in the Rutherford-Becker Clinical Improvement Scale of ≥ one at 12 months	89.1% (205/230)
Improvement in the Rutherford-Becker Clinical Improvement Scale of ≥ one at 24 months	89.2% (181/203)
Improvement in the Rutherford-Becker Clinical Improvement Scale of ≥ one at 36 months	92.2% (154/167)

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.
Events defined for the period of 36 months post-procedure follow-up are reported for patients with at least 1110 days of follow-up or had 36-month visit within window (1080 ± 30 days) or with event to 1110 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 Safety Endpoints	
Secondary Safety Endpoints	**ITT Population (N = 264 Patients, L = 265 Segments)**
Stent Fracture - At 12 Months	0.0% (0/244)
Stent Fracture – At 24 Months*	0.5% (1/202)
Stent Fracture – At 36 Months*	0.6% (1/162)
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% (11/209)
Major Adverse Vascular Event (MAVE) - At 36 months	6.3% (11/175)
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% (2/207)
Index Limb Amputations - At 36 Months	1.2% (2/173)

Note:

[1]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.

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.

Events defined for the period of 36 months post-procedure follow-up are reported for patients with at least 1110 days of follow-up or had 36-month visit within window (1080 ± 30 days) or with event to 1110 days.

* One patient experienced a Type III fracture at 24 months after three directional atherectomy procedures to treat in-stent restenosis. See section 8.4.3.5.

Table 13: Analysis of Long-Term Safety Endpoints		
Secondary Safety Endpoints	**SUPERA device (264 Patients) (265 Segments)**	**[95% CI]**
Long-Term Safety Endpoint (Clinically Driven TLR, Index Limb Amputation) at 1 year	11.5% (27/235)	[7.7%, 16.3%]
Clinically Driven TLR	11.1% (26/235)	[7.4%, 15.8%]
Index Limb Amputation	0.4% (1/233)	[0.0%, 2.4%]
Long-Term Safety Endpoint (Clinically Driven TLR, Index Limb Amputation) at 2 year	17.7% (38/215)	[12.8%, 23.4%]
Clinically Driven TLR	16.7% (36/215)	[12.0%, 22.4%]
Index Limb Amputation	1.0% (2/207)	[0.1%, 3.4%]
Long-Term Safety Endpoint (Clinically Driven TLR, Index Limb Amputation) at 3 year	22.3% (41/184)	[16.5%, 29.0%]
Clinically Driven TLR	21.3% (39/183)	[15.6%, 28.0%]
Index Limb Amputation	1.2% (2/173)	[0.1%, 4.1%]

Note: Events defined for the period of 1-month post-procedure follow up are reported for patients with at least 37 days of follow-up or had 1-month visit within window (30 ± 7 days) or with event to 37 days .

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.

Events defined for the period of 36 months post-procedure follow up are reported for patients with at least 1110 days of follow-up or had 36-month visit within window (1080 ± 30 days) or with event to 1110 days

8.4.3.1 Rutherford Becker (RB) Clinical Category

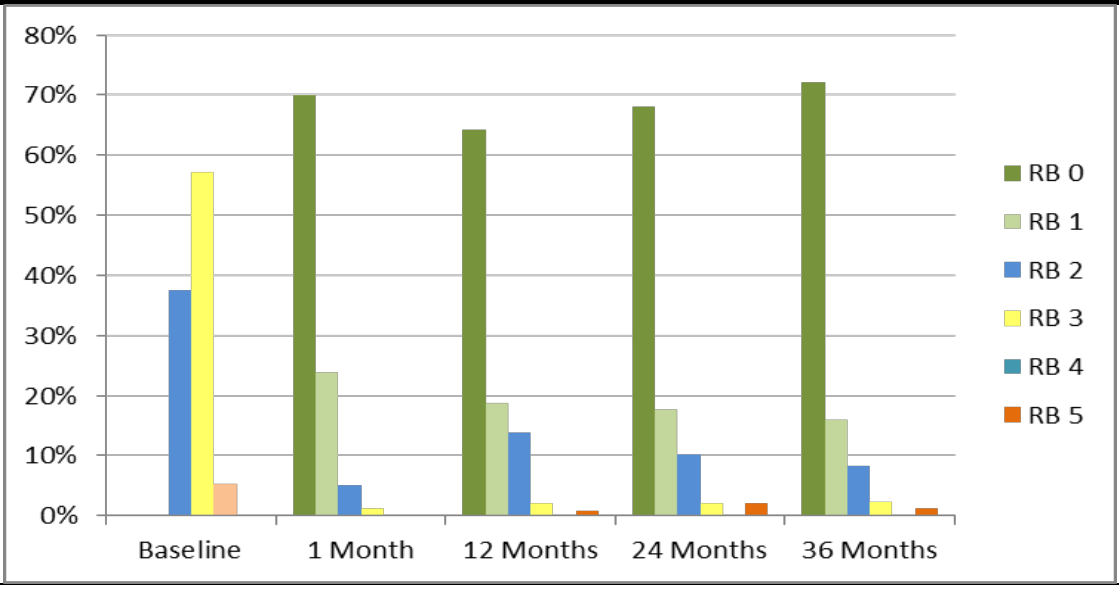
The majority of subjects had moderate-severe claudication (Rutherford Becker 2-3) at baseline. At 1, 12, 24 and 36 months post procedure, a majority of subjects were asymptomatic (**Table 14** and **Figure 5**)**.**

Table 14: Analysis of Rutherford Becker Scale at Baseline, 1 Month, 12, 24 and 36 Months of Follow-up – ITT Population

Rutherford Becker Scale	Baseline	1 Month	12 Months	24 Months	36 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)	72.2% (122/169)
(1) Mild Claudication	0.0% (0/264)	23.9% (62/259)	18.7% (43/230)	17.7% (36/203)	16.0% (27/169)
(2) Moderate Claudication	37.5% (99/264)	5.0% (13/259)	13.9% (32/230)	10.3% (21/203)	8.3% (14/169)
(3) Severe Claudication	57.2% (151/264)	1.2% (3/259)	2.2% (5/230)	2.0% (4/203)	2.4% (4/169)
(4) Ischemic Rest Pain	5.3% (14/264)	0.0% (0/259)	0.0% (0/230)	0.0% (0/203)	0.0% (0/169)
(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)	1.2% (2/169)
Limb Ischemia Improvement	NA	97.3% (252/259)	89.1% (205/230)	89.2% (181/203)	92.2% (154/167)

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, 24 and 36 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 or 36 months (**Table 15**).

Table 15: 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 16 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 16: 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 17: 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.

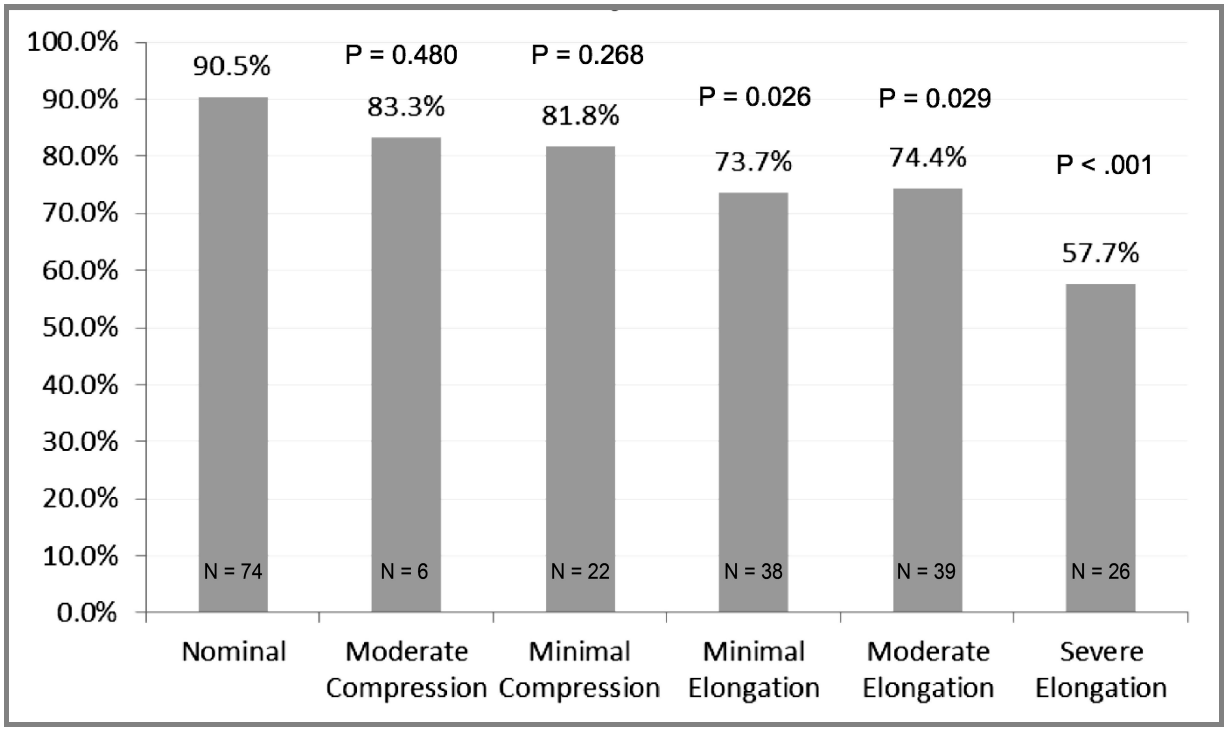
8.4.3.4 Post-Hoc Analysis of Deployed Stent Length

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%

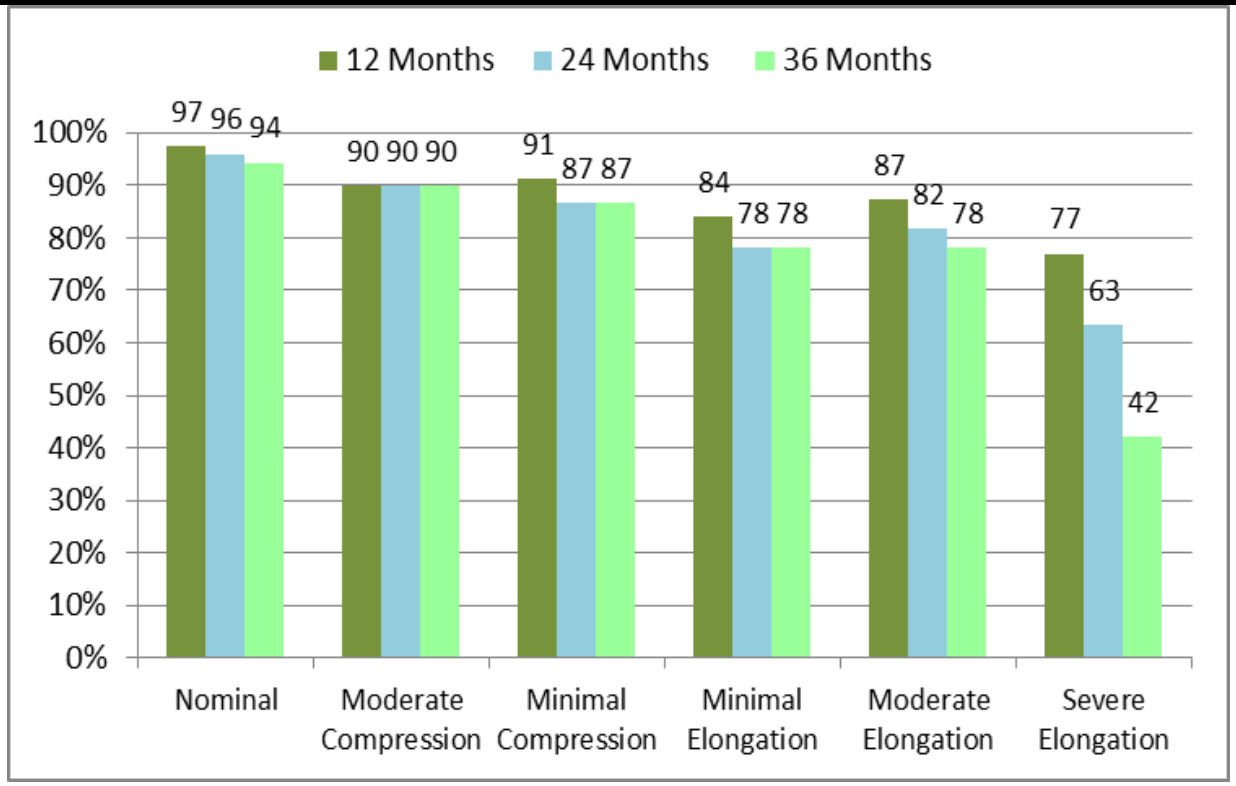
Figure 6: For Relationship of Stent Elongation to Primary Vessel Patency at 12 Months – ITT, Single Stented Subjects



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. A decrease in Freedom from TLR was also observed when stents were deployed elongated. 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.

Figure 7: For Relationship of Stent Elongation to Freedom from Target Lesion Revascularization through 36 Months – ITT, Single Stented Subjects



8.4.3.5 Stent Fracture Analysis

As indicated in **Table 18**, one patient (1/202, 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. There were no additional stent fractures between 24 and 36 months.

Table 18: Stent Fractures at 12, 24 and 36 Months

Stent Fractures*	12-Months (N = 243)	24-Months (N = 200)	36 Months (N = 162)
Type I – Single time fracture	0.0% (0/244)	0.0% (0/202)	0.0% (0/162)
Type II – Multiple time fractures	0.0% (0/244)	0.0% (0/202)	0.0% (0/162)
Type III – Stent fracture(s) with preserved alignment of the components	0.0% (0/244)	0.5% (1/202)	0.6% (1/162)
Type IV – Stent fracture(s) with mal-alignment of the components	0.0% (0/244)	0.0% (0/202)	0.0% (0/162)
Type V – Stent fracture(s) in a trans-axial spiral	0.0% (0/244)	0.0% (0/202)	0.0% (0/162)

*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 19 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 19: 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	Events at ≤ 36 months
Any AE	43.1% (110/255)	79.8% (198/248)	82.9% (203/245)	97.2% (211/217)
Blood and lymphatic system disorders	2.7% (7/255)	5.6% (14/248)	6.9% (17/245)	8.8% (19/217)
Cardiac disorders	3.5% (9/255)	20.6% (51/248)	24.1% (59/245)	31.8% (69/217)
Congenital, familial and genetic disorders	NA	0.4% (1/248)	0.8% (2/245)	0.9% (2/217)
Ear and labyrinth disorders	NA	0.4% (1/248)	0.4% (1/245)	0.5% (1/217)
Endocrine disorders	NA	0.4% (1/248)	0.8% (2/245)	0.9% (2/217)
Eye disorders	NA	0.8% (2/248)	0.8% (2/245)	0.9% (2/217)
Gastrointestinal disorders	3.1% (8/255)	11.3% (28/248)	14.3% (35/245)	18.9% (41/217)
General disorders and administration site conditions	16.5% (42/255)	27.0% (67/248)	30.2% (74/245)	36.9% (80/217)
Hepatobiliary disorders	NA	0.4% (1/248)	0.8% (2/245)	0.9% (2/217)
Immune system disorders	0.4% (1/255)	0.8% (2/248)	0.8% (2/245)	0.9% (2/217)
Infections and infestations	3.1% (8/255)	10.5% (26/248)	12.2% (30/245)	18.0% (39/217)
Injury, poisoning and procedural complications	2.4% (6/255)	15.7% (39/248)	18.8% (46/245)	21.7% (47/217)
Investigations	NA	2.0% (5/248)	2.0% (5/245)	2.3% (5/217)
Metabolism and nutrition disorders	0.8% (2/255)	3.6% (9/248)	4.9% (12/245)	6.5% (14/217)
Musculoskeletal and connective tissue disorders	10.6% (27/255)	23.8% (59/248)	26.1% (64/245)	30.4% (66/217)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.4% (1/255)	2.0% (5/248)	3.3% (8/245)	6.5% (14/217)
Nervous system disorders	2.7% (7/255)	10.9% (27/248)	11.8% (29/245)	15.2% (33/217)
Psychiatric disorders	0.4% (1/255)	2.0% (5/248)	2.4% (6/245)	3.2% (7/217)
Renal and urinary disorders	1.6% (4/255)	4.0% (10/248)	5.7% (14/245)	6.9% (15/217)
Reproductive system and breast disorders	0.4% (1/255)	0.8% (2/248)	0.8% (2/245)	0.9% (2/217)
Respiratory, thoracic and mediastinal disorders	1.2% (3/255)	9.3% (23/248)	12.7% (31/245)	15.7% (34/217)
Skin and subcutaneous tissue disorders	1.6% (4/255)	4.4% (11/248)	4.9% (12/245)	5.5% (12/217)
Surgical and medical procedures	NA	0.8% (2/248)	0.8% (2/245)	0.9% (2/217)
Vascular disorders	18.8% (48/255)	39.5% (98/248)	44.5% (109/245)	51.2% (111/217)

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.

≤ 36 months: patients who had SAE occurring between 0 - 1110 days post procedure or with follow up time for AE ≥ 1110 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).

Study Strengths and Weaknesses

The study met the primary safety and effectiveness endpoints. Of the enrolled IT subjects with 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 ($p < 0.001$) compared to the 88% performance goal. The primary effectiveness endpoint, primary stent patency, was evaluated in all enrolled subjects with evaluable 1-year (360 ± 30 days) data. Of the evaluable subjects, 78.9% (180/228) met the primary effectiveness endpoint (one-sided lower 95% Wilson Score CL of 74.2%), demonstrating statistical significance ($p < 0.001$) when compared to the 66% performance goal.

Good long-term outcomes were observed for the SUPERB patients. The long-term safety endpoint, defined as clinically driven TLR and index limb amputation, occurred in 11.5% (27/235), 17.7% (36/215) and 22.3% (41/184) subjects at 12, 24 and 36 months post index procedure.

There was a low stent fracture rate. There were no stent fractures through 12 months, and only 1 confirmed stent fracture through 36 months that occurred after the use of directional atherectomy to treat in-stent restenosis.

Subjects had limb ischemia improvement using Rutherford-Becker Scale reduction of ≥ 1 in 89.1% (205/230) of the ITT population at 12 months, and 89.2% (181/203) and 92.2% (154/167) at 24 and 36 months, respectively.

At 12, 24 and 36 months, 99%, 98% and 98.8%, respectively, of the eligible population completed the visit. Only 5.3% of the subjects were lost-to-follow-up at 36 months.

At 36 months, 68% of the original population (n = 264) were eligible for follow-up due to deaths, study withdrawals, insufficient information, lost-to-follow-ups, adverse events, or other.

The Exercise Tolerance Test was completed in a small number of subjects, so application of results to a broader population is limited.

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 20: 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)	53 mm	18 – 22 mm
30	60.6% (2.6 : 1)	79 mm	27 – 33 mm
40	62.2% (2.7 : 1)	108 mm	36 – 44 mm
60	61.3% (2.6 : 1)	157 mm	54 – 66 mm
80	60.2% (2.5 : 1)	203 mm	72 – 88 mm
100	60.2% (2.5 : 1)	251 mm	90 – 110 mm
120	59.5% (2.5 : 1)	298 mm	108 – 132 mm
150	59.5% (2.5 : 1)	373 mm	135 – 165 mm

*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

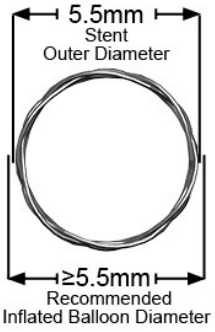
9.2.1 Lesion Pre-dilatation

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 21** and **Figure 8**).

Table 21: Stent Diameter and Vessel Preparation

Reference Vessel Diameter	Stent Diameter	Recommended Inflated Balloon Diameter
4.0 – 4.5 mm	4.5 mm	≥ 4.5 mm
4.5 – 5.0 mm	5.0 mm	≥ 5.0 mm
5.0 – 5.5 mm	5.5 mm	≥ 5.5 mm
5.5 – 6.0 mm	6.0 mm	≥ 6.0 mm
6.0 – 6.5 mm	6.5 mm	≥ 6.5 mm

Figure 8: 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 guide wire.

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" guide wire of appropriate length
- 10-cc syringe for flushing
- Introducer sheath (Refer to **Table 22**)

Table 22: Sheath Selection

Catheter Size	Catheter Outer Sheath Diameter
6F	2.06 mm, 0.081 inches

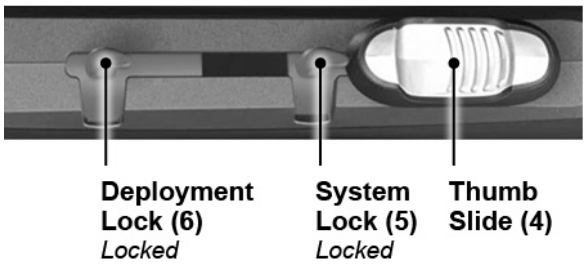
9.3 Lesion Access

1. Using standard technique, gain access at an appropriate anatomical site utilizing an appropriately sized introducer sheath. (Refer to **Table 22**)
2. After establishing access, a guide wire 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 Guide Wire 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 9**)

Figure 9: System Lock and Deployment Lock in Locked Position

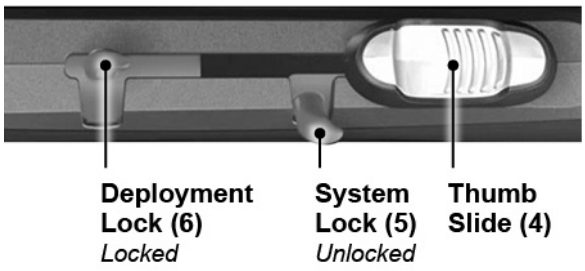


4. Load the distal end of the Catheter Tip (12) onto a 0.014" or 0.018" guide wire.
5. Advance the catheter over the guide wire and through the introducer while controlling the guide wire.
   Precaution: Insertion of the Supera Peripheral Stent System should always be performed under fluoroscopic guidance. 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 10**)

Figure 10: System Lock in Unlocked Position

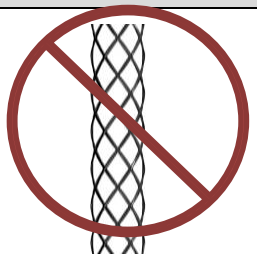


3. Increase magnification to better visualize stent deployment. Maintain increased magnification during the entire stent deployment procedure.
4. Under fluoroscopy, initiate stent deployment by advancing the Thumb Slide (4) while allowing the Outer Sheath (10) to retract proximally. Evaluate the initial 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 11**)

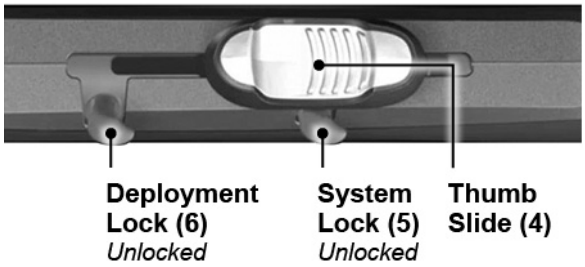
   Expansion to a size smaller than the nominal stent diameter will likely result in an overall stent length longer than the labeled length.

Figure 11: 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 12**)

Figure 12: Deployment Lock in Unlocked Position

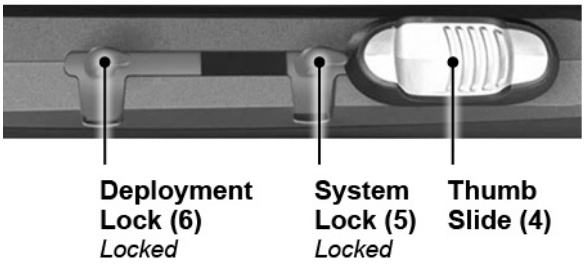


8. Under fluoroscopy, slowly advance the Thumb Slide (4) to the distal most position on the Handle (3).
9. Confirm under fluoroscopy that the entire Supera Stent has emerged from the Outer Sheath (10) and is released.

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 13**)

Figure 13: System Lock and Deployment Lock in Locked Position



2. Under fluoroscopy, remove the device from the guide wire 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 may be covered by one or more of the following United States Patents: 6,792,979; 7,018,401; 7,048,014; 8,414,635; 8,419,788; 8,739,382; 8,966,733; 9,023,095; and 9,149,374. Other U.S. patents pending. Foreign patents issued and pending.

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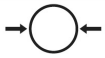
Graphical Symbols for Medical Device Labeling

	Manufacturer		Catalogue number
	Date of manufacture		CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Batch code		Sterilized using ethylene oxide
	Use by		Non-pyrogenic
	Consult instructions for use		MR Conditional
	Contents (numeral represents quantity of units inside)		
	Do not use if package is damaged	F	French size
	CAUTION: Consult instructions for use for warnings and precautions	REC SHEATH	Recommended sheath
	Do not reuse		Stent length
	Do not resterilize		Outer diameter
	Keep dry		Inner diameter
	Keep away from sunlight	OTW	Over-the-wire