BARD® LIFESTENT® Stent and Delivery System
Vascular Application

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

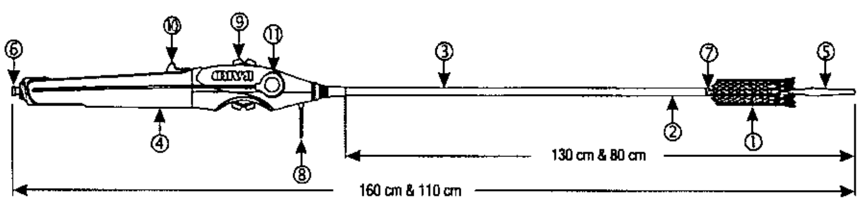

Figure 1. LIFESTENT® Vascular Stent System

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent, as shown in Figure 1, as well as the tray and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.

A. Device Description

The LIFESTENT® Vascular Stent System is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery system. The LIFESTENT® Vascular Stent System is comprised of the following:

An implantable self-expanding nickel-titanium alloy (nitinol) stent (1), as shown in Figure 1 and Figure 2. The stent is a flexible, fine tubular mesh prosthesis, with a helical design, which achieves its unconstrained diameter upon deployment into the target vessel. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency. The stent has a total of 12 tantalum radiopaque markers (Figure 2, items 1A & 1B) located on the ends of the stent (i.e., 6 at each end).

A delivery system, as shown in Figure 1, is comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath (2) and a system stability sheath (3), which are linked together by means of a handle (4). The guidewire lumen terminates distally in an atraumatic catheter tip (5) and originates proximally in a luer hub (6) designed to accept a compatible guidewire. The self-expanding stent (1) is constrained in the space between the guidewire lumen and stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery system. The stent delivery sheath has a radiopaque zone (7) at its distal end. Prior to deployment, the shipping lock (8) must be removed and discarded.

Refer to "Stent Deployment Procedure, Section 4. Deploy Stent" for directions on deploying the stent with the:

- Thumbwheel (9)
- Fast Track Deployment Lever (10)
- Rapid Deployment Ring (11)

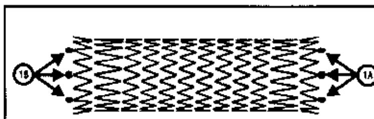

Figure 2. LIFESTENT® Vascular Stent

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B. Indication for Use

The LifeStent® Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic *de-novo* or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5 mm.

C. Contraindications

The LifeStent® Vascular Stent System is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.
- Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy.
- 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.

D. Warnings

- DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch.
- The LifeStent® Vascular Stent System is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device.
- DO NOT use if pouch is opened or damaged.
- DO NOT use the stent after the end of the month indicated by the "Use By" date specified on the package.
- Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant.
- DO NOT use with Ethiodol™ or Lipiodol contrast media.
- DO NOT expose the delivery system to organic solvents (e.g., alcohol).
- The stent is not designed for repositioning or recapturing.
- Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.
- If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol).
- The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

E. Precautions

- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- Prior to stent deployment, remove slack from the delivery system catheter outside the patient.
- If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit.
- Store in a cool, dark, dry place.
- Do not attempt to break, damage, or disrupt the stent after placement.
- Cases of fracture have been reported in clinical use of the LifeStent® Vascular Stent. Cases of stent fracture occurred in lesions that were moderate to severely calcified, proximal or distal to an area of stent overlap and in cases where stents experienced >10% elongation at deployment. Therefore, care should be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established (see section J).

F. MRI Conditions

Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent® Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 1000 Gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning. For landmarks superior of the umbilicus, a whole body SAR up to 2 W/kg may be applied.
- In a configuration where the patients legs are not in contact with each other.

3.0 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 80 mm length LifeStent® Stent was determined to produce a potential worst-case temperature rise of 3.2°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.8 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 1.9°C when the local SAR was scaled to 2 W/kg.

1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 170 mm length LifeStent® XL Stent was determined to produce a potential worst-case temperature rise of 3.9°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.2 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.5°C when the local SAR was scaled to 2 W/kg.

Additional Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. The LifeStent® Vascular stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for overlapped or fractured stents is not known.

G. Overview of Clinical Studies

Two independent clinical studies and a retrospective analysis support the safety and effectiveness of the LifeStent® Vascular Stent Systems.

The RESILIENT pivotal trial was a prospective, randomized, multi-center study designed to compare the safety and effectiveness of the LifeStent® Vascular Stent System to PTA in the treatment of symptomatic vascular disease of the superficial femoral artery (SFA) and proximal popliteal artery. 206 subjects were randomized in a 2:1 fashion between the test and control arm at 22 U.S. and 2 European centers. In total, 134 subjects were randomized to the test arm (treatment with the LifeStent® Vascular Stent System) and 72 subjects were randomized to the control arm (treatment with stand alone balloon angioplasty). The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the 6-month re-intervention rate. 30-day data is available for 96.1% (198/206) of the randomized subjects and 6-month effectiveness data is available for 89.8% (184/205) of the randomized subjects. All subjects were followed for a total of three years following the index procedure.

The E-TAGIUSS supporting trial was a prospective, non-randomized, multi-center study designed to assess the acute deliverability of the LifeStent® and LifeStent® XL Vascular Stent Systems. 37 subjects were treated in 7 European centers. The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the assessment of stent length following deployment. 30-day mortality data is available for 91.9% (34/37) of the treated subjects and deployed stent length data is available for 46 deployed stents. All subjects were followed for 30 days following the index procedure.

Furthermore, a retrospective analysis of the performance of the LifeStent® Vascular Stent Systems for long segment lesions was also undertaken. 285 subjects were included in the analysis in which 46 lesions had lengths ≥ 160 mm. The primary endpoints of this analysis were acute safety (freedom from death, amputation or TVR) at 30-days, long-term safety (freedom from death or amputation) at 12 months in patients with total lesion lengths ≥ 160 mm and effectiveness (freedom from TVR) at 12 months in lesions of length 50 mm, 100 mm, 160 mm, 200 mm and 240 mm..

H. Adverse Events

a. Observed Adverse Events

The following adverse events were documented during the course of the RESILIENT trial (N=226).

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RESILIENT Trial Adverse Event Summary			
	RESILIENT Randomized		RESILIENT Feasibility
Event	LifeStent® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® (N=20) % (N pts) [N events]
In-Hospital Events			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0 (0/134) [0]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0 (0/134) [0]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	0 (0/72) [0]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	1.4 (1/72) [1]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Events at 30-Days			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0.7 (1/134) [2]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0.7 (1/134) [1]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	1.4 (1/72) [1]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	2.8 (2/72) [2]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis (24 Hrs - 30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Events at 12-Months			
Major Adverse Events	8.2 (11/134) [13]	6.9 (5/72) [6]	5.0 (1/20) [1]
Death	3.7 (5/134) [5]	2.8 (2/72) [2]	0 (0/20) [0]
Myocardial Infarction	4.5 (6/134) [8]	1.4 (1/72) [1]	5.0 (1/20) [1]
Target Limb Loss / Amputation	0 (0/134) [0]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	16.4 (22/134) [28]	54.2 (39/72) [54]	15.0 (3/20) [3]
TLR	11.9 (16/134) [16]	54.2 (39/72) [46]	10.0 (2/20) [2]
Non-TLR	8.2 (11/134) [12]	8.3 (6/72) [8]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

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RESILIENT Trial Adverse Event Summary			
	RESILIENT Randomized		RESILIENT Feasibility
Event	LifeStent® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® (N=20) % (N pts) [N events]
Events at 24-Months			
Major Adverse Events	13.4 (18/134) [23]	11.1 (8/72) [11]	5.0 (1/20) [1]
Death	7.5 (10/134) [10]	5.6 (4/72) [4]	0 (0/20) [0]
Myocardial Infarction	6.0 (8/134) [11]	5.6 (4/72) [4]	5.0 (1/20) [1]
Target Limb Loss / Amputation	1.5 (2/134) [2]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	25.4 (34/134) [48]	58.3 (42/72) [69]	15.0 (3/20) [4]
TLR	20.1 (27/134) [30]	56.9 (41/72) [53]	10.0 (2/20) [3]
Non-TLR	12.7 (17/134) [18]	15.3 (11/72) [16]	5.0 (1/20) [1]
Stroke/CVA	0.7 (1/134) [1]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Latest Data Available	**36-Months**	**36-Months**	**36-Months**
Major Adverse Events	15.7 (21/134) [27]	11.1 (8/72) [12]	10.0 (2/20) [2]
Death	9.0 (12/134) [12]	6.9 (5/72) [5]	0 (0/20) [0]
Myocardial Infarction	7.5 (10/134) [13]	5.6 (4/72) [4]	10.0 (2/20) [2]
Target Limb Loss / Amputation	1.5 (2/134) [2]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	28.4 (38/134) [57]	58.3 (42/72) [71]	15.0 (3/20) [4]
TLR	21.6 (29/134) [35]	56.9 (41/72) [54]	10.0 (2/20) [3]
Non-TLR	15.7 (21/134) [22]	16.7 (12/72) [17]	5.0 (1/20) [1]
Stroke/CVA	1.5 (2/134) [2]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

The following adverse events were documented during the course of the E-TAGIUSS trial (N=37).

E-TAGIUSS Trial Adverse Event Summary		
Event	In-Hospital	30 Day
Major Adverse Event	0% (0/37)	0% (0//37)
Death	0% (0/37)	0% (0//37)
Myocardial Infarction	0% (0/37)	0% (0//37)
Target Limb Loss	2.7% (1/37)	2.7% (1//37)
Target Lesion Revascularization (TLR)	0% (0/37)	0% (0//37)
Stent Thrombosis	0% (0/37)	0% (0//37)
Distal Embolization	2.7% (1/37)	2.7% (1/37)
Access Site Bleeding	2.7% (1/37)	2.7% (1/37)
Non-Access Site Bleeding	0% (0/37)	0% (0//37)
Vessel Perforation	0% (0/37)	0% (0//37)
Vessel Aneurysm	0% (0/37)	0% (0//37)
Vessel Pseudo-Aneurysm	0% (0/37)	0% (0//37)
Vessel Dissection	0% (0/37)	0% (0//37)

b. Potential Adverse Events

Potential adverse events that may occur include, but are not limited to, the following:

- Allergic/anaphylactoid reaction
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arterial occlusion/thrombus, near the puncture site

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- Arterial occlusion/thrombus, remote from puncture site
- Arterial occlusion/restenosis of the treated vessel
- Arteriovenous fistula
- Arrhythmia
- By-pass Surgery
- Death related to procedure
- Death unrelated to procedure
- Embolization, arterial
- Embolization, stent
- Fever
- Hemorrhage/bleeding requiring a blood transfusion
- Hematoma bleed, remote site
- Hematoma bleed at needle, device path: nonvascular procedure
- Hematoma bleed, puncture site: vascular procedure
- Hypotension/hypertension
- Incorrect positioning of the stent requiring further stenting or surgery
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Liver failure
- Local infection
- Malposition (failure to deliver the stent to the intended site)
- Open surgical repair
- Pain
- Pancreatitis
- Pulmonary embolism/edema
- Pneumothorax
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Restenosis
- Septicemia/bacteremia
- Stent Fracture
- Stent Migration
- Stroke
- Vasospasm
- Venous occlusion/thrombosis, remote from puncture site
- Venous occlusion/thrombosis, near the puncture site

I. Clinical Studies

a. RESILIENT FEASIBILITY STUDY

The RESILIENT study included a feasibility study to assess the safety of the LifeStent® Vascular Stent System. This feasibility study enrolled 20 subjects at six US investigative sites. Results from this study provided justification for initiation of a pivotal study to assess the safety and effectiveness of the LifeStent® Vascular Stent System.

b. RESILIENT RANDOMIZED STUDY

Design

The RESILIENT trial was a prospective, multi-center, randomized clinical investigation to evaluate the superiority of the LifeStent® Vascular Stent System compared to PTA in the treatment of symptomatic vascular disease of the SFA and/or proximal popliteal artery. A total of 206 subjects were treated at 22 US and 2 European investigative sites. Each site not participating in the feasibility study was required to perform one roll-in case. A total of 20 roll-in cases were performed and 206 randomized cases were performed. Seventy-two (72) subjects were randomized to the PTA arm and 134 subjects were randomized to treatment with the LifeStent® Vascular Stent System.

Subjects eligible to be enrolled in this study had stenotic or occluded lesions of the SFA and/or proximal popliteal artery and suffered from lifestyle limiting claudication (Rutherford Category 1 – 3). Lesions could be either de novo or restenotic. Subjects with previously stented lesions or target limb vascular by-pass were excluded. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm in diameter and the collective length of the treated segment was to be less than 150 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days, 6 months and annually thereafter with follow-up planned out to 36-months. Office visits were coupled with duplex ultrasound assessments of the treated segments. X-ray evaluation of the stented lesions was also performed. The RESILIENT trial utilized a Frequentist approach with its statistical plan. The primary objectives were to show the following:

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- that the probability of the occurrence of Target Lesion Revascularization (TLR) or Target Vessel Revascularization (TVR) at 6-months post-procedure for the subjects treated with LIFESTENT® NT (test arm) was significantly lower than (and therefore superior to) that for the subjects treated with PTA-alone (control arm); and,
- that the death rates at 30-days post-procedure were not significantly different between the test arm and the control arm.

Continuous variables were compared using an independent samples t-test. Dichotomous variables were compared using Fisher's exact test. Ordinal variables were compared using a Chi-square test. Time to event was compared using a log-rank test. Interval censored data were analyzed using the Kaplan-Meier method as the primary analysis. A sensitivity analysis for interval censored data was performed using the Weibull distribution. Effectiveness endpoints were analyzed as one-sided tests. Safety endpoints were analyzed as two-sided tests.

The results were evaluated using an Intent-to-Treat (ITT) analysis. In particular, control subjects requiring stent placement to salvage a failed angioplasty remained in the cohort to which they were randomized.

Demographics

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

RESILIENT Trial Subject Demographics			
Variable	**Category**	**Test**	**Control**
Age at Procedure (Yrs)	N, Mean ± SD	134, 68.4 ± 9.9	72, 66.1 ± 9.2
Gender, % (n/N)	Female	29.1 (39/134)	33.3 (24/72)
	Male	70.9 (95/134)	66.7 (48/72)
Race, % (n/N)	African American	9.0 (12/134)	9.7 (7/72)
	Caucasian	89.6 (120/134)	84.7 (61/72)
	Other	1.5 (2/134)	5.6 (4/72)
Hypertension, % (n/N)		83.6 (112/134)	94.4 (68/72)
Hypercholesterolemia, % (n/N)		79.9 (107/134)	76.4 (55/72)
Diabetes, % (n/N)		38.1 (51/134)	38.9 (28/72)
Smoking, % (n/N)		72.4 (97/134)	83.3 (60/72)
Coronary Artery Disease, % (n/N)		56.0 (75/134)	54.2 (39/72)
Myocardial Infarction, % (n/N)		20.1 (27/134)	26.4 (19/72)
Target Limb Rutherford Category, % (n/N)	Class 1	3.0 (4/134)	6.9 (5/72)
	Class 2	35.8 (48/134)	41.7 (30/72)
	Class 3	61.2 (82/134)	50.0 (36/72)
	Class 5		1.4 (1/72)
Target Limb ABI (mm Hg)	N, Mean ± SD	124, 0.71 ± 0.19	67, 0.72 ± 0.19
Contralateral Limb ABI (mm Hg)	N, Mean ± SD	120, 0.88 ± 0.21	64, 0.84 ± 0.21

RESILIENT Trial Lesion Characteristics			
Variable	**Category**	**Test**	**Control**
Number of Lesions, % (n/N)	1 Lesion(s)	85.8 (115/134)	87.5 (63/72)
	2 Lesion(s)	14.2 (19/134)	12.5 (9/72)
Target Side, % (n/N)	Left	47.7 (73/153)	54.3 (44/81)
	Right	52.3 (80/153)	45.7 (37/81)
Lesion Location, % (n/N)	Proximal 1/3 of SFA	13.1 (20/153)	14.8 (12/81)
	Middle 1/3 of SFA	32.0 (49/153)	38.3 (31/81)
	Distal 1/3 of SFA	50.3 (77/153)	45.7 (37/81)
	Proximal Popliteal	4.6 (7/153)	1.2 (1/81)
Lesion Classification, % (n/N)	De Novo/Stenosed	80.4 (123/153)	79.0 (64/81)
	Occlusion	17.0 (26/153)	18.5 (15/81)
	Restenosed	2.6 (4/153)	2.5 (2/81)
Target Vessel RVD (mm)	N, Mean ± SD	153, 5.2 ± 0.8	81, 5.2 ± 0.9
Lesion % Diameter Stenosis	N, Mean ± SD	153, 86.3 ± 12.5	80, 87.9 ± 11.6
Lesion Length (mm)	N, Mean ± SD	153, 61.3 ± 42.4	81, 57.0 ± 37.0

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Methods

Subjects underwent either PTA or PTA plus LifeStent® Vascular Stent System placement in the target lesion(s). In cases where the PTA only result was sub-optimal, stent placement was performed. This occurred in 40% (29/72) of the subjects that were randomized to the PTA-only treatment arm. Post procedure medication was suggested as aspirin for 6 months and clopidogrel for 12 weeks.

All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board routinely reviewed the study outcomes to ensure that the benefits of continuing the study outweighed any potential risks. Independent core laboratories were utilized to analyze angiographic, x-ray and duplex imaging.

Results

As shown in the principal Safety and Effectiveness table (Section J) the LifeStent® Vascular Stent System demonstrated a significantly higher freedom from intervention rate (freedom from TVR/TLR) at 6 months (LifeStent® 94.6%; control 52.6%), 12 months (LifeStent® 82.7%; control 45.2%), 24 months (LifeStent® 70.5%; control 40.1%), and 36 months (LifeStent® 68.1%; control 40.1%) than the PTA control group ($p < 0.0001$). Additionally, as expected, there was no difference in the 30-day mortality rate between the two study arms.

c. E-TAGIUSS CONFIRMATORY STUDY

Design

The E-TAGIUSS trial was a prospective, multi-center, confirmatory clinical investigation to evaluate the LifeStent® and LifeStent® XL Vascular Stent Systems in the treatment of symptomatic vascular disease of the SFA and proximal popliteal artery. A total of 37 subjects were treated at 7 European investigative sites.

Subjects eligible to be enrolled in this study had to demonstrate Trans-Atlantic Inter-Society Consensus (TASC) A, B or C lesions. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm in diameter and the collective length of the treated segment was to be less than 200 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days with an office visit.

Demographics

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

E-TAGIUSS Trial Subject Demographics		
Variable	**Category**	**Total**
Age at Procedure (Yrs)	Mean ± SD (N)	37, 71.1 ± 7.8
Gender, % (n/N)	Female	29.7 (11/37)
	Male	70.3 (26/37)
Race, % (n/N)	Caucasian	97.3 (36/37)
	Other	2.7 (1/37)
Hypertension, % (n/N)		83.8 (31/37)
Hypercholesterolemia, % (n/N)		56.8 (21/37)
Smoking, % (n/N)		48.6 (18/37)
Coronary Artery Disease, % (n/N)		32.4 (12/37)
Diabetes, % (n/N)		24.3 (9/37)
Myocardial Infarction, % (n/N)		13.5 (5/37)
Target Limb Rutherford Category, % (n/N)	Class 1	5.4 (2/37)
	Class 2	35.1 (13/37)
	Class 3	45.9 (17/37)
	Class 4	5.4 (2/37)
	Class 5	8.1 (3/37)
Target Limb ABI (mm Hg)	Mean ± SD (N)	35, 0.6 ± 0.2
Contralateral Limb ABI (mm Hg)	Mean ± SD (N)	31, 0.9 ± 0.2

E-TAGIUSS Trial Lesion Characteristics		
Variable	**Category**	**Total**
Number of Lesions, % (n/N)	1	86.5 (32/37)
	2	13.5 (5/37)
Target Side, % (n/N)	Left	47.6 (20/42)
	Right	52.4 (22/42)
Lesion Location, % (n/N)	Popliteal	2.4 (1/42)
	SFA	95.2 (40/42)
	SFA & Popliteal	2.4 (1/42)
Lesion Classification, % (n/N)	Occlusion	42.9 (18/42)
	Reoccluded	7.1 (3/42)
	Restenosed	2.4 (1/42)
	Stenosed	47.6 (20/42)
Lesion Severity/TASC Grade, % (n/N)	TASC A	45.9 (17/37)
	TASC B	24.3 (9/37)
	TASC C	29.7 (11/37)
Target Vessel RVD (mm)	N, Mean ± SD	42, 5.3 ± 0.6
Lesion % Diameter Stenosis	N, Mean ± SD	42, 89.3 ± 15.1
Lesion Length (mm)	N, Mean ± SD	42, 89.2 ± 69.8

Methods

Subjects underwent PTA plus LifeStent® and/or LifeStent® XL Vascular Stent placement in the target lesion(s). Post procedure medication was suggested as aspirin and clopidogrel for a minimum of 30 days.

All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board reviewed the study outcomes. Independent core laboratories were utilized to analyze angiographic data.

Results

As shown in the principal Safety and Effectiveness table (Section J) the LifeStent® and LifeStent® XL Vascular Stent Systems were able to accurately deploy the stent and demonstrated minimal length change (deployment success 100.0%). Additionally, the acute safety and effectiveness measures demonstrated positive results.

d. Retrospective Analysis of LifeStent® Vascular Stent Systems in the Treatment of Long Segment Lesions

Design

This study consisted of a post-hoc analysis of four sources of data: (1) a pivotal IDE clinical trial (RESILIENT: IDE G040023; "RESILIENT"), (2) a multi-center, non-randomized, observational study conducted in Europe ("ELODIE I"), (3) the routine clinical practice of a United States (U.S.) physician ("US Series"), and (4) the routine clinical practice of a European Union (EU) physician ("EU Series"). In total, two-hundred-eighty-five (285) patients with one or more implanted LifeStent® devices were identified and included in the analysis. There were a total of 46 lesion segments in this analysis with lesion lengths beyond 160 mm.

Demographics

Characteristics of the subjects and lesions analyzed are provided in the tables below.

Demographics: Retrospective Analysis of LifeStent® Vascular Stent Systems in the Treatment of Long-Segment Lesions

Characteristic	RESILIENT	ELODIE I	US Series	EU Series	TOTAL
Age at Procedure (years)					
N reported	198	11	66	10	285
Mean	68.4	71.8	72.6	73.9	69.7
St Dev	10.2	8.63	10.9	5.53	10.3
Range	20.7 – 88.2	53.9 - 85.6	36.3 - 96.8	63.9 - 83.1	20.7 – 96.8
Gender (% male)	69.2	45.5	60.6	44.4	65.5
N reported*	198	11	66	9	284
Race (% Caucasian)	88.9	100	77.3	100	86.6
N reported	198	3	66	10	277
Hypertension (%)	85.4	72.7	84.9	100	85.3
N reported	198	11	66	10	285
Hypercholesterolemia (%)	80.3	54.6	75.8	80.0	78.3
N reported	198	11	66	10	285
Smoking (%)	25.8	36.4	60.6	0.0	33.3
N reported	198	11	66	10	285
CAD (%)	56.6	27.3	57.6	30.0	54.7
N reported	198	11	66	10	285
DM (%)	38.9	0.00	50.0	30.0	39.7
N reported	198	11	66	10	285
Rutherford Category of Target Limb					
N reported	198	11	NR	10	219
Class 1 (%)	3.5	0		0	3.2
Class 2 (%)	40.4	45.5		10.0	39.3
Class 3 (%)	56.1	36.4		60.0	55.3
Class 4 (%)	0.0	0		0	0
Class 5 (%)	0.0	18.2		30.0	2.3
Indication of Target Limb					
N reported	198	11	71	10	290
Claudication (%)	100	90.9	49.3	70.0	86.6
Critical Limb Ischemia (%)	0	9.1	50.7	30.0	13.4
ABI of Target Limb					
N reported	183	NR	51	10	244
Mean	0.72		0.61	0.41	0.69
St Dev	0.20		0.22	0.18	0.22
Range	0.24 - 1.45		0 - 1.34	0.1 - 0.67	0 – 1.45

* One patient did not report gender
NR- Not Reported

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Lesion and Stent Characteristics

Characteristic	RESILIENT	ELODIE I	US Series	EU Series	TOTAL
N Patients	198	11	66	10	285
N Treated Limbs	198	11	72	10	291
N Treated Lesions	212	16	72	10	310
Individual Lesion Length					
N reported	212	16	72	10	310
Mean (mm)	66.0	108.8	152.6	214.0	93.1
St Dev Length	35.7	44.7	104.5	109.6	75.1
Mean N per Limb	1.1	1.5	1.1	1.0	1.1
Percent Stenosis (max per limb):					
N reported	198	11	0	10	219
Mean	87.8	92.7		96.0	88.5
St Dev	11.3	9.05		6.99	11.2
Range	50 - 100	80 - 100		80 - 100	50 - 100
N Total Lesion Lengths:					
< 50 mm	62	1	9	0	72
50 – <100 mm	93	0	19	0	112
100 – <160 mm	37	6	15	3	61
160 – <200 mm	5	1	3	4	13
200 – 240 mm	1	2	8	0	11
≥ 240 mm	0	1	18	3	22
Total Lesion Lengths:					
*N	198	11	72	10	291
Mean	70.6	158.2	152.6	214	99.15
St Dev	37.7	57.8	104.5	109.6	77.3
Range	10 - 202	30 - 240	16 - 360	140 - 500	10 - 500
N Total Stented Lengths:					
< 60 mm	40	0	NR	0	40
60 – < 110 mm	71	0	NR	0	71
110 – < 170 mm	73	1	NR	1	75
170 – < 210 mm	7	7	NR	5	19
210 – < 250 mm	5	0	NR	1	6
≥ 250 mm	2	3	NR	3	8
Total Stent Lengths:					
N	198	11	NR	10	219
Mean	104.5	204.5		244.4	115.9
St Dev	55.4	53.2		125.1	69.4
Range	30 - 340	160 - 290		160 - 574	30- 574
TASC Classification					
N Grade A (%)	NR	1 (9.1%)	23 (39.0%)	NR	24 (34.3%)
N Grade B (%)		3 (27.3%)	11(18.6 %)		14 (20.0%)
N Grade C (%)		7 (63.6%)	6 (10.2%)		13 (18.6%)
N Grade D (%)		0 (0%)	19 (32.2%)		19 (27.1%)
Total		11	59		70

* For lesion characteristics, core lab data were used when available; the site reported data were used otherwise. Five (5) patients did not have lesion characteristics reported by the core lab

NR- Not Reported

Methods

Subjects received at least one commercially available LifeStent® stent - in the case of those subjects enrolled in the RESILIENT study (IDE - G040023), they received the device as described in G040023, which were identical to the current commercially available LifeStent® device. Specifically, the following analyses were undertaken:

- Estimating the patency (defined in this analysis as freedom from TVR) at 12-months post-procedure of lesions of length: 50 mm, 100 mm, 160 mm, and 240 mm (long-term effectiveness)
- Comparing the acute safety performance of the LifeStent® device at 30-days post-procedure to the ViVa OPC, and,
- Estimating the freedom from death and amputation at 12-months post-procedure in patients with long lesions treated with the LifeStent®

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device by calculating the observed rates in this study (long-term safety).

Data for this retrospective analysis were compiled 'as received' from their respective sources.

Results
The rate of freedom from death, amputation, and TVR, at 30 days post-procedure was 99.6% for the combined performance of the LifeStent and LifeStent XL Vascular Stent Systems, and 88% for the VIVA OPC. Furthermore, long-term safety was shown to have a clinically acceptable freedom from death and amputation rate through 12-months (84.5%). Moreover, effectiveness was evaluated through estimation of patency at 12 months post-procedure for lesion lengths of 50 mm, 100 mm, 160 mm, 200 mm and 240 mm via the lesion-length model. The patency at 12 months for lesions greater than 160 mm in length is 67%.

J. Principal Safety and Effectiveness Tables

a. RESILIENT RANDOMIZED STUDY

RESILIENT Principal Safety and Effectiveness Table			
Variable	Test	Control	p-value
MACE at 30 Days, % (n/N)	0.0 (0/134)	1.4 (1/72)	ns*
Freedom from MACE at 6 Months, %	93.9	92.8	ns*
Freedom from MACE at 12 Months, %	86.6	85.1	ns*
Freedom from MACE at 24 Months, %	80.5	79.7	ns*
Freedom from MACE at 36 Months, %	75.2	75.2	ns*
Lesion Success, % (n/N)	95.8 (114/119)	83.9 (52/62)	0.009
Hemodynamic Success, % (n/N)	71.2 (79/111)	59.6 (31/52)	ns*
Procedure Success, % (n/N)	95.8 (114/119)	83.9 (52/62)	0.009
Clinical Success at 6 Months, % (n/N)	82.2 (97/118)	30.9 (21/68)	<0.0001
Primary Patency at 6 Months, %	94.2	47.4	<0.0001
Secondary Patency at 6 Months, %	100.0	98.3	ns*
Freedom From TVR/TLR at 6 Months, %	94.6	52.6	<0.0001
Clinical Success at 12Months, % (n/N)	72.3 (81/112)	31.8 (21/66)	<0.0001
Primary Patency at 12 Months, %	81.5	36.7	<0.0001
Secondary Patency at 12 Months, %	100.0	98.3	ns*
Freedom From TVR/TLR at 12 Months, %	82.7	45.2	<0.0001
Clinical Success at 24 months, % (n/N)	68.6 (70/102)	25.4 (16/63)	<0.0001
Freedom From TVR/TLR at 24 months, %	70.5	40.1	<0.0001
Clinical Success at 36 months, % (n/N)	63.2 (60/95)	17.9 (10/56)	<0.0001
Freedom From TVR/TLR at 36 months, %	68.1	40.1	0.0002

ns* - not significant

Definitions (secondary endpoints denoted with an asterisk (*)):

Major adverse clinical events* (MACE): Any event of death (through 30-days), stroke, myocardial infarction, significant distal embolization, emergent surgical revascularization of target limb, thrombosis, and/or worsening Rutherford category post procedure at the indicated time point.

Lesion Success*: Attainment of ≤ 30% residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

Hemodynamic Success*: Angiographic evidence of improved flow across the treated area immediately post-procedure. ABI improved from baseline by ≥ 0.10 and not deteriorated by > 0.15.

Procedure Success*: Attainment of ≤ 30% residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

Clinical Success*: Relief or improvement of baseline symptoms by Rutherford categories/grades for acute or chronic limb ischemia and the "definition of improvement". Improvement must be sustained by one clinical category above the pre-treatment clinical value.

Primary Patency*: The continued flow through the target lesion as evidenced by DUS or angiogram without further/repeat intervention over time.

Secondary Patency*: The patency history for the target lesion that is sustained or restored (with repeated intervention) over time.

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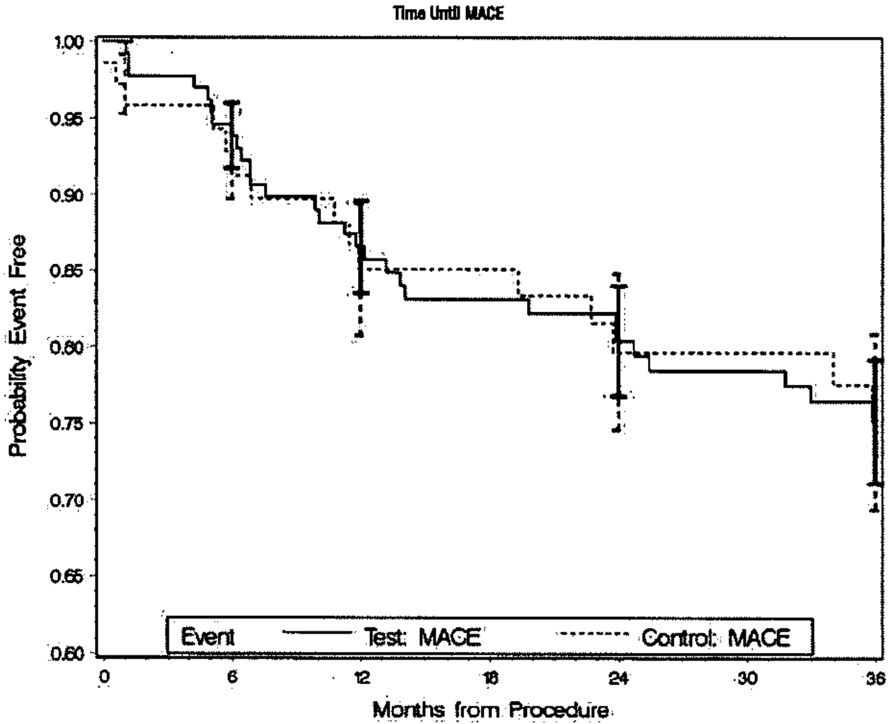
Target Vessel Revascularization (TVR) / Target Lesion Revascularization (TLR): Any "clinically-driven" repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel. If a control subject requires a stent peri-procedurally due to a bailout procedure, it will be considered a TLR/TVR for the control group.

Survival Analysis – Freedom from MACE (at 36 months)



MACE	Event Free	Event Rate	P-Value*
Test (LIFESTENT®)	75.2%	24.8%	0.98
Control (balloon angioplasty)	75.2%	24.8%	
*p-value is from Log-rank test on all available data.			

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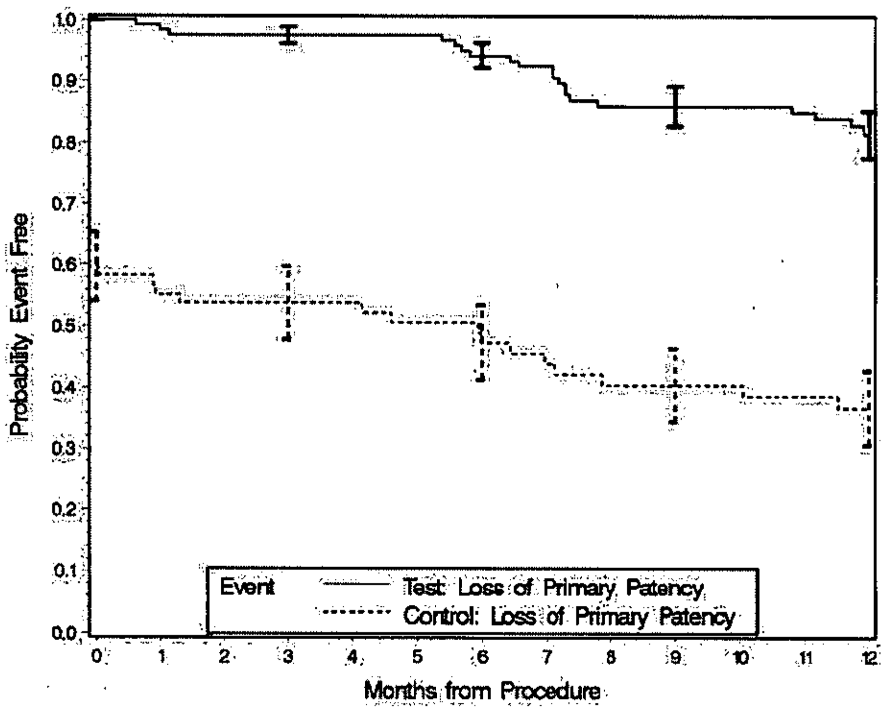
Survival Analysis – Freedom from Loss of Primary Patency (at 12 months)

Time Until Loss of Primary Patency



Loss of Primary Patency	Event Free	Event Rate	P-Value*
Test (LifeStent®)	81.5%	18.5%	<0.0001
Control (balloon angioplasty)	36.7%	63.3%	
*p-value is from Log-rank test on all available data.			

Stent Fracture Analysis

Independent Analysis

As pre-specified in the RESILIENT protocol, A-P and lateral x-rays were taken at 6-, 12-, and 18-months post-procedure and analyzed by an independent core lab. X-rays on 291 stents were available for analysis from all phases of the RESILIENT trial. Fractures were classified as follows:

Classification Type	
1	Single-strut fracture only
2	Multiple single-stent fractures occuring at different sites
3	Multiple stent fractures resulting in complete transverse linear fracture but without stent displacement
4	Complete transverse linear fracture with stent displacement
Based on Allie, et. al. Endovascular Today 2004; July/August: 22-34.*	

** Please note that the fracture analysis in the RESILIENT Study was conducted by an independent core laboratory using the classification system described by Allie et al., 2004 in accordance with the protocol approved in the IDE prior to study initiation (G040023, 3/19/2004). This system classifies fractures into four distinct types. Since study initiation, other stent classification systems have been proposed (Scheinert et al, 2005; Roca-Singh et al., 2007; Popma et al., 2009). The classification system published by Rocha-Singh et al., is currently used by many core labs in the U.S., and splits the Type 4 fractures as defined by Allie et al. into "stent fracture(s) with mal-alignment of*

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components"(Type 4) and "stent fracture(s) in a trans-axial spiral configuration" (Type 5). The Type 4 fractures in the RESILIENT Study were not sub-categorized according to the system proposed by Rocha-Singh and colleagues.

One (1) fracture was noted at the time of the six-month analysis, eight (8) additional fractures were noted at the twelve-month analysis (i.e., between 6 and 12 months), and three (3) more fractures were noted at the final eighteen-month analysis (i.e., between 12 and 18 months). 67% (8/12) of the fractures were identified within 7 months of implantation. At the eighteen month analysis, six fractures were noted as Type I (single-strut fracture) and six fractures were classified as Type IV (complete transverse fracture). Since the overall number of stent fractures was low throughout the course of the RESILIENT trial, statistical analysis as to cause was not possible.
It was observed however, that of the six Type IV fractures, all six were elongated at deployment, four of six occurred in lesions that were moderate to severely calcified, and four of six occurred proximal or distal to an area of stent overlap. 38% of patients with >10% elongation went on to develop Type 4 fractures in less than 1 year and 36% of the fractures occurred in patients where multiple (≥ 2) stents were deployed in an overlapping fashion. No patients with stent fractures developed restenosis as evaluated at the 12-month follow-up, and no fractures were associated with MACE. Overall, fractures in RESILIENT had no apparent effect on device safety or effectiveness. The following table summarizes the fractures categorized according to Allie, et. al.

RESILIENT Fracture Analysis (18 Months)	
Type	**Count (stents/subjects)**
Type 1	6/6
Type 4	5/4
Type 1 & 4	1/1
Total	12/11

Review of Medical Device Reporting
Since February 13, 2009, in the global commercial experience, Bard Peripheral Vascular received complaints of suspected LifeStent® fractures in 38 patients. Of these reports, nine (9) patients with 10 fractures were confirmed from evaluation of baseline or follow-up angiograms. A review of the confirmed fractures showed that seven (7) of the stents had single strut fractures and three (3) of the stents had multiple strut fractures. These were associated with one case of stent twisting, one case of stent elongation, and three cases of stent compression that may have contributed to the occurrence of fracture. Classification of fracture type was not completed due to the limitations of the data received from the user and a systematic review of all stents by an angiographic core lab was not performed. Because of the difficulty in identifying stent fracture and the lack of comprehensive angiographic follow-up, it is not possible to determine the true fracture rate of the LifeStent® in commercial use.

Conclusion
Stent fractures were noted to be an uncommon event in the RESILIENT trial and appeared to not impact the safety and performance of the LifeStent® implant. Stent fractures may occur with the use of overlapping stents; however there was no correlation between stent fractures and the number of stents implanted in the RESILIENT trial. Fractures may occur in SFA or popliteal segments that undergo significant motion, particularly in areas with severe angulation and tortuosity. The RESILIENT trial was not designed to show a correlation between stent fractures and the location, although six (6) fractured stents were observed in areas with severe calcification, and one (1) stent placed across the point of flexion in the mid-popliteal region resulted in a fracture.

Patency vs. Lesion Length
In order to assess the impact of lesion length on patency outcomes, a Cox regression analysis, with the total lesion length as a risk factor was performed which demonstrated that for the LifeStent® group, lesion length is not a significant predictor of primary patency outcomes (p-value = 0.46). Additionally, the calculated hazard ratio of 1.003 indicates that there is only a remote relationship between lesion length and patency outcomes in the LifeStent® group. It should be noted that based on the analysis, the lesion length is a significant predictor of patency outcomes for the control group (p-value = 0.0025).

b. E-TAGIUSS CONFIRMATORY STUDY

E-TAGIUSS Principal Safety and Effectiveness Table	
Variable	**Test % (n/N)**
Death at 30 Days	0% (0/37)
MACE at 30 Days	2.7% (1/37)
Deployment Success	100.0 (46/46)
Lesion Success	90.9 (30/33)
Procedure Success	90.9 (30/33)

Definitions (secondary endpoints denoted with an asterisk (*)):

Major adverse clinical events* (MACE): Any event of death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, amputation of the target limb and thrombosis of the target vessel at the indicated time point.

Deployment Success: Ability to deliver the stent to the intended site with the post deployment stent length being within 10% of the pre-deployment length.

Lesion Success*: Attainment of ≤ 30% residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

Procedure Success*: Attainment of ≤ 30% residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

c. Retrospective Analysis of LifeStent® Vascular Stent Systems in the Treatment of Long-Segment Lesions

The results for the primary effectiveness endpoint as defined by freedom from TVR/TLR are shown in table below.

Freedom from TLR/TVR* by Time and Lesion Length

Variable	12 months Weibull* / Kaplan-Meier (n/N**at 12 months)	24 months Weibull* / Kaplan-Meier (n/N**at 24 months)
Average of all (total) lesion lengths (= 101.1 mm)	82.4% / 79.2% (54/291)	63.3% / 62.5% (29/170)
(n=72) < 50 mm lesions (Weibull: 50 mm)	85.4% / 83.4 (11/72)	69.0% / 68.1% (7/48)
(n=112) 50 - < 100 mm lesions (Weibull: 100 mm)	81.9% / 87.9% (12/112)	62.5% / 74.3% (9/73)
(n=61) 100 - < 160 mm lesions (Weibull: 160 mm)	76.7% / 76.5% (13/61)	53.6% / 55.2% (9/35)
(n=13) 160 - < 200 mm lesions (Weibull: 200 mm)	72.6% / 38.9% (7/13)	47.0% / 38.9% (0/2)
(n=11) 200 - < 240 mm lesions (Weibull: 240 mm)	67.9% / 67.5% (3/11)	40.2% / NA (1/5)
(n=22) > 240 mm lesions	NA / 55.9% (8/22)	NA / 23.9% (3/7)

* From the Weibull covariate-adjusted analysis
** Number starting the year

The primary acute safety endpoint of the LifeStent® and LifeStent® XL Vascular Stent Systems at 30 days post-procedure showed the freedom from rates were higher than the VIVa OPC (88%). The 30-day freedom-from-death, amputation and TVR rate was 99.6% with a standard error of 0.34% (95% CI: 97.59% - 99.95%).

The primary long-term safety endpoint was freedom from death/amputation. The Kaplan-Meier analysis showed that the freedom-from-death/amputation rate at 12 months was 100% (lesions < 50 mm), 94.5% (lesions 50 - 100mm), 91.4% (lesions 100 - 160 mm), 63.6% (lesions 160 - 200 mm), 90.9% (lesions 200 - 240 mm) and 94.1% (lesions >240 mm).

Freedom from Death/Amputation*

	12 months (n/N**)
All Lesions	93.8 (17/291)
Lesions < 50 mm	100% (0/72)
Lesions 50 - 100 mm	94.5% (6/112)
Lesions 100 - 160 mm	91.4% (5/61)
Lesions 160 - 200 mm	63.6% (4/13)
Lesions 200 - 240 mm	90.9% (1/11)
Lesions > 240 mm	94.1% (1/22)

* From the Kaplan-Meier analysis
** Number starting the year

K. Patient Selection and Treatment

Patient selections should be based on the populations treated in the RESILIENT and E-TAGIUSS investigations. Demographics for the two investigations are provided in Section I – Clinical Investigations of this "Instructions for Use" document. Additionally, treatment of the patients should follow the treatment practices used by the RESILIENT and E-TAGIUSS investigators. These methods have been reiterated below in Section L – Patient Counseling Information and Section N – Instructions for Use.

L. Patient Counseling Information

Physicians should consider the following in counseling the patient about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with a LifeStent® implant.
- Discuss the risks/benefits issues for this particular patient.
- Discuss alterations to current lifestyle immediately following the procedure and over the long term.

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- Discuss the risks of early discontinuation antiplatelet therapy.

The following information is provided in the packaging for the physician to provide their patients:

- A Patient Guide which includes information on the LifeStent® Vascular Stent System, peripheral artery occlusive disease, the implantation procedure and patient care following the implant.
- A Patient Implant Card that is used to record and disseminate information about the patient and the stent.

M. How Supplied

STERILE: FOR SINGLE USE ONLY. The LifeStent® Vascular Stent System is supplied sterile (by ethylene oxide gas) and is nonpyrogenic. Do not resterilize and/or reuse the device. Do not use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch. Do not use if pouch is opened or damaged. Do not use the stent after the end of the month indicated by the "Use By" date specified on the package. For returned product or product issues, please contact Bard Peripheral Vascular at the address below:

Bard Peripheral Vascular, Inc.
Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281 USA

CONTENTS for one (1) LifeStent® Vascular Stent System:

- One (1) LifeStent® Vascular Stent System
- One (1) Patient Implant Card
- One (1) Instructions for Use
- One (1) Patient Guide

STORAGE: Store in a cool, dark, dry place. Storage temperature should not exceed 60°C. Use by the end of the month indicated by the "Use By" date specified on the package.

DISPOSAL INSTRUCTIONS: After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

N. Instructions for Use

Pre-Deployment Procedure

1. **Inject Contrast Media**
   Perform an angiogram using standard technique.
2. **Evaluate and Mark Target Site**
   Fluoroscopically evaluate and mark the target site, observing the most distal diseased or obstructed segment.
3. **Select Stent Size**
   Measure the length of the target lesion to identify the appropriate length of stent(s) required. Ensure that the stent is long enough to permit the area proximal and distal of the lesion to be covered by the stent.

   Identify the diameter of the reference vessel (proximal and distal to the lesion). To ensure secure placement, refer to the stent size selection table for proper sizing scheme.

Stent Size Selection Table: LifeStent® Vascular Stent System	
Reference Vessel Diameter	Unconstrained Stent Inner Diameter
4.0 – 5.5 mm	6.0 mm
5.6 – 6.5 mm	7.0 mm

   Refer to product labeling for stent length

4. **Materials Required**
   In addition to the LifeStent® Vascular Stent System, the following standard materials may also be required to facilitate delivery and deployment of the LifeStent® Vascular Stent System: heparinized normal saline, 6F (2.0 mm) or larger introducer sheath, 0.035" diameter guidewire, standard balloon angioplasty (PTA) catheter, contrast medium diluted 1:1 with heparinized normal saline, inflation device and appropriate anticoagulation and antiplatelet drugs.
5. **Prepare Stent System**

a) Open the box and remove the pouch containing the stent system.

b) Check the temperature exposure indicator label on the pouch to confirm that the grey background is clearly visible. See "Warnings" section.

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c) Carefully inspect the pouch for damage to the sterile barrier. Do not use after the expiration date. Peel open the pouch and remove the tray containing the stent system. Extract the stent system from the tray and check the following:
   i) Verify that the shipping lock is still secure in the stent system handle.
   ii) Examine the stent system for any damage. If it is suspected that the sterility or performance of the stent system has been compromised, the device should not be used.

d) Visually inspect the distal end of the stent system to ensure that the stent is contained within the sheath. Do not use if the stent is partially deployed.

e) Visually inspect the distal end of the delivery system catheter to ensure there is no gap between the delivery system catheter tip (grey colored) and the primary sheath (braided catheter with light blue colored end) such that the guidewire lumen (orange colored) is visible. Do not use the device if the orange colored guidewire lumen is visible.

f) Flush the inner lumen of the stent system with heparinized normal saline prior to use.

g) Wipe the usable length portion of the stent system with gauze soaked with heparinized normal saline.

Stent Deployment Procedure

1. Insert Introducer Sheath and Guidewire

a) Gain access at the appropriate site using a 6F (2.0 mm) or larger introducer sheath.

b) Insert a guidewire of appropriate length (see table) and diameter across the lesion to be stented via the introducer sheath.

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

2. Dilate Lesion

Predilation of the lesion should be performed using standard techniques. While maintaining site access with a guidewire, remove the balloon catheter from the patient.

Caution: During dilation, do not expand the balloon such that dissection complication or perforation could occur.

3. Introduce stent system

a) Advance the stent system over the guidewire through the sheath introducer.

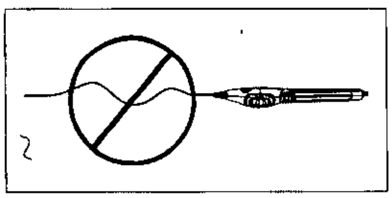
Note: If resistance is met during stent system introduction, the stent system should be removed and another stent system should be used.

Caution: Always use an introducer sheath for the implant procedure to protect the vasculature and the puncture site. A 6F (2.0 mm) or larger introducer sheath is recommended.

b) Position the tip of the stent system past the target site.

c) Pull back the stent system until the distal and proximal stent radiopaque markers are in position so that they are distal and proximal to the target site.

d) Remove slack from the stent system held outside the patient



Caution: Any slack in the stent system (outside the patient) could result in deploying the stent beyond the target site.

4. Deploy stent

a) Verify that the distal and proximal stent radiopaque markers are distal and proximal to the target lesion.

b) Confirm that the introducer sheath is secure and will not move during deployment.

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c) Remove the shipping lock.

d) To ensure the most accurate placement, firmly hold the black system stability sheath throughout deployment
Note: Do NOT hold the silver stent delivery sheath at any time during deployment. DO NOT constrict the stent delivery sheath during stent deployment.

e) Initiate stent deployment by rotating the thumbwheel in the direction of the arrows while holding the handle in a fixed position.
Note: If excessive force is felt during stent deployment, do not force the stent system. Remove the stent system as possible, and replace with a new unit.

f) While using fluoroscopy, maintain position of the distal and proximal stent radiopaque markers relative to the targeted site. Watch for the distal stent radiopaque markers to begin separating; separation of the distal stent radiopaque markers signals that the stent is deploying. Continue turning the thumbwheel until the distal end of the stent obtains complete wall apposition.

g) With distal end of the stent apposing the vessel wall, final deployment can be continued with the following methods (Fig. 3, 4, 5).

Continue to rotate the thumbwheel to achieve complete stent deployment.

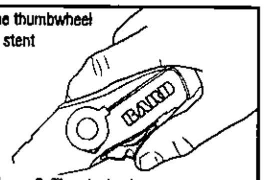

Figure 3. Thumbwheel

While maintaining a fixed handle position, place your finger in front of the deployment slide and slide it from the distal to proximal end.

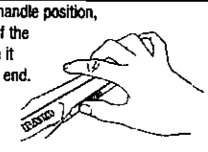

Figure 4. Fast Track Deployment Lever

While maintaining a fixed handle position, peel the circular ring from the handle. Pull the rapid deployment ring towards the proximal end of the handle to achieve complete stent deployment.

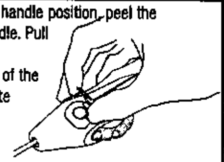

Figure 5. Rapid Deployment Ring

h) Deployment of the stent is complete when the proximal stent radiopaque markers appose the vessel wall and the sheath radiopaque zone is proximal to the proximal stent radiopaque markers.

i) **DO NOT** attempt to re-sheath stent system prior to removal.

5. Post stent placement

a) Remove the stent system from the body.
Note: If resistance is met while retracting the delivery system over a guidewire, remove the delivery system and guidewire together.

b) Post stent expansion with a PTA catheter is recommended. If performed, select a balloon catheter that matches the size of the reference vessel, but that is not larger than the stent diameter itself.

c) Remove the guidewire and introducer sheath from the body.

d) Close entry wound as appropriate.

e) Discard the stent system, guidewire, and introducer sheath.
Note: Physician experience and discretion will determine the appropriate drug regimen for each patient.

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Symbols used on labeling

Keep away from sunlight

The Green Dot

Keep dry

Recyclable

LifeStent® Vascular Stent Systems

This product is manufactured and sold under one or more of the following patents: U.S. Patent No. 6,878,162. Other international and U.S. patents pending.

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

Distributed in the USA by:

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BARD® LIFESTENT® XL Stent and Delivery System Vascular Application

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

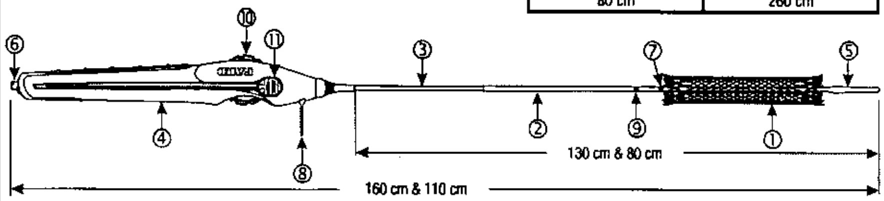

Figure 1. LIFESTENT® XL Vascular Stent System

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent, as shown in Figure 1, as well as the tray and pouch liner) are sterile. The external surface of the sterile barrier pouch, as well as the product carton, should not be considered sterile.

A. Device Description

The LIFESTENT® XL Vascular Stent System is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery system. The LIFESTENT® XL Vascular Stent System is comprised of the following:

An implantable self-expanding nickel-titanium alloy (nitinol) stent (1), as shown in Figure 1 and Figure 2. The stent is a flexible, fine tubular mesh prosthesis, with a helical design, which achieves its unconstrained diameter upon deployment into the target vessel. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.

A delivery system, as shown in Figure 1, comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath (2) and a system stability sheath (3), which are linked together by means of a handle (4). The guidewire lumen terminates distally in an atraumatic catheter tip (5) and originates proximally in a luer hub (6) designed to accept a compatible guidewire. The self-expanding stent (1) is constrained in the space between the guidewire lumen and stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery system. The stent delivery sheath has a radiopaque zone (9) at its distal end. The stent delivery system has a second radiopaque zone (7) proximal to the stent. Prior to deployment the shipping lock (8) must be removed and discarded.

Refer to "Stent Deployment Procedure, Section 4. Deploy Stent" for directions on deploying the stent with the:

- Thumbwheel (10)
- Fast Track Deployment Lever (11)

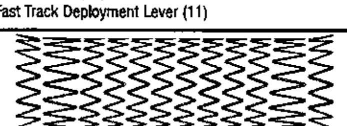

Figure 2. LIFESTENT® XL Vascular Stent

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B. Indication for Use

The LifeStent® XL Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic *de-novo* or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5 mm.

C. Contraindications

The LifeStent® XL Vascular Stent System is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.
- Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy.
- 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.

D. Warnings

- DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch.
- The LifeStent® XL Vascular Stent System is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device.
- DO NOT use if pouch is opened or damaged.
- DO NOT use the stent after the end of the month indicated by the "Use By" date specified on the package.
- Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant.
- DO NOT use with Ethiodol™ or Lipiodol contrast media.
- DO NOT expose the delivery system to organic solvents (e.g., alcohol).
- The stent is not designed for repositioning or recapturing.
- Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.
- If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol).
- The long-term outcomes following repeat dilatation of endothelialized stents are unknown.

E. Precautions

- The device is intended for use by physicians who have received appropriate training.
- The delivery system is not designed for use with power injection systems.
- Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
- Prior to stent deployment, remove slack from the delivery system catheter outside the patient.
- If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit.
- Store in a cool, dark, dry place.
- Do not attempt to break, damage, or disrupt the stent after placement.
- Cases of fracture have been reported in clinical use of the LifeStent® Vascular Stent. Cases of stent fracture occurred in lesions that were moderate to severely calcified, proximal or distal to an area of stent overlap and in cases where stents experienced >10% elongation at deployment. Therefore, care should be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established (see section J).

F. MRI Conditions

Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent® Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 1000 Gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning. For landmarks superior of the umbilicus, a whole body SAR up to 2 W/kg may be applied.
- In a configuration where the patients legs are not in contact with each other.

3.0 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 80 mm length LifeStent® Stent was determined to produce a potential worst-case temperature rise of 3.2°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.8 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 1.9°C when the local SAR was scaled to 2 W/kg.

1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 170 mm length LifeStent® XL Stent was determined to produce a potential worst-case temperature rise of 3.9°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.2 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.5°C when the local SAR was scaled to 2 W/kg.

Additional Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. The LifeStent® Vascular stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for overlapped or fractured stents is not known.

G. Overview of Clinical Studies

Two independent clinical studies and a retrospective analysis support the safety and effectiveness of the LifeStent® Vascular Stent Systems.

The RESILIENT pivotal trial was a prospective, randomized, multi-center study designed to compare the safety and effectiveness of the LifeStent® Vascular Stent System to PTA in the treatment of symptomatic vascular disease of the superficial femoral artery (SFA) and proximal popliteal artery. 206 subjects were randomized in a 2:1 fashion between the test and control arm at 22 U.S. and 2 European centers. In total, 134 subjects were randomized to the test arm (treatment with the LifeStent® Vascular Stent System) and 72 subjects were randomized to the control arm (treatment with stand alone balloon angioplasty). The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the 6-month re-intervention rate. 30-day data is available for 96.1% (198/206) of the randomized subjects and 6-month effectiveness data is available for 89.8% (184/205) of the randomized subjects. All subjects were followed for a total of three years following the index procedure.

The E-TAGIUSS supporting trial was a prospective, non-randomized, multi-center study designed to assess the acute deliverability of the LifeStent® and LifeStent® XL Vascular Stent Systems. 37 subjects were treated in 7 European centers. The primary safety endpoint was 30-day mortality and the primary effectiveness endpoint was the assessment of stent length following deployment. 30-day mortality data is available for 91.9% (34/37) of the treated subjects and deployed stent length data is available for 46 deployed stents. All subjects were followed for 30 days following the index procedure.

Furthermore, a retrospective analysis of the performance of the LifeStent® Vascular Stent Systems for long segment lesions was also undertaken. 285 subjects were included in the analysis in which 46 lesions had lengths ≥ 160 mm. The primary endpoints of this analysis were acute safety (freedom from death, amputation or TVR) at 30-days, long-term safety (freedom from death or amputation) at 12 months in patients with total lesion lengths ≥ 160 mm and effectiveness (freedom from TVR) at 12 months in lesions of length 50 mm, 100 mm, 160 mm, 200 mm and 240 mm.

H. Adverse Events

a. Observed Adverse Events

The following adverse events were documented during the course of the RESILIENT trial (N=226).

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RESILIENT Trial Adverse Event Summary			
	RESILIENT Randomized		RESILIENT Feasibility
Event	LIFESTENT® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LIFESTENT® (N=20) % (N pts) [N events]
In-Hospital Events			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0 (0/134) [0]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0 (0/134) [0]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	0 (0/72) [0]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	1.4 (1/72) [1]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Events at 30-Days			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0.7 (1/134) [2]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0.7 (1/134) [1]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	1.4 (1/72) [1]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	2.8 (2/72) [2]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis (24 Hrs - 30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Events at 12-Months			
Major Adverse Events	8.2 (11/134) [13]	6.9 (5/72) [6]	5.0 (1/20) [1]
Death	3.7 (5/134) [5]	2.8 (2/72) [2]	0 (0/20) [0]
Myocardial Infarction	4.5 (6/134) [8]	1.4 (1/72) [1]	5.0 (1/20) [1]
Target Limb Loss / Amputation	0 (0/134) [0]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	16.4 (22/134) [28]	54.2 (39/72) [54]	15.0 (3/20) [3]
TLR	11.9 (16/134) [16]	54.2 (39/72) [46]	10.0 (2/20) [2]
Non-TLR	8.2 (11/134) [12]	8.3 (6/72) [8]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

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RESILIENT Trial Adverse Event Summary			
	RESILIENT Randomized		RESILIENT Feasibility
Event	LifeStent® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® (N=20) % (N pts) [N events]
Events at 24-Months			
Major Adverse Events	13.4 (18/134) [23]	11.1 (8/72) [11]	5.0 (1/20) [1]
Death	7.5 (10/134) [10]	5.6 (4/72) [4]	0 (0/20) [0]
Myocardial Infarction	6.0 (8/134) [11]	5.6 (4/72) [4]	5.0 (1/20) [1]
Target Limb Loss / Amputation	1.5 (2/134) [2]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	25.4 (34/134) [48]	58.3 (42/72) [69]	15.0 (3/20) [4]
TLR	20.1 (27/134) [30]	56.9 (41/72) [53]	10.0 (2/20) [3]
Non-TLR	12.7 (17/134) [18]	15.3 (11/72) [16]	5.0 (1/20) [1]
Stroke/CVA	0.7 (1/134) [1]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Latest Data Available	**36-Months**	**36-Months**	**36-Months**
Major Adverse Events	15.7 (21/134) [27]	11.1 (8/72) [12]	10.0 (2/20) [2]
Death	9.0 (12/134) [12]	6.9 (5/72) [5]	0 (0/20) [0]
Myocardial Infarction	7.5 (10/134) [13]	5.6 (4/72) [4]	10.0 (2/20) [2]
Target Limb Loss / Amputation	1.5 (2/134) [2]	4.2 (3/72) [3]	0 (0/20) [0]
TVR	28.4 (38/134) [57]	58.3 (42/72) [71]	15.0 (3/20) [4]
TLR	21.6 (29/134) [35]	56.9 (41/72) [54]	10.0 (2/20) [3]
Non-TLR	15.7 (21/134) [22]	16.7 (12/72) [17]	5.0 (1/20) [1]
Stroke/CVA	1.5 (2/134) [2]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Late Thrombosis (>30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

The following adverse events were documented during the course of the E-TAGIUSS trial (N=37).

E-TAGIUSS Trial Adverse Event Summary		
Event	In-Hospital	30 Day
Major Adverse Event	0% (0/37)	0% (0//37)
Death	0% (0/37)	0% (0//37)
Myocardial Infarction	0% (0/37)	0% (0/37)
Target Limb Loss	2.7% (1/37)	2.7% (1//37)
Target Lesion Revascularization (TLR)	0% (0/37)	0% (0//37)
Stent Thrombosis	0% (0/37)	0% (0//37)
Distal Embolization	2.7% (1/37)	2.7% (1/37)
Access Site Bleeding	2.7% (1/37)	2.7% (1/37)
Non-Access Site Bleeding	0% (0/37)	0% (0//37)
Vessel Perforation	0% (0/37)	0% (0//37)
Vessel Aneurysm	0% (0/37)	0% (0/37)
Vessel Pseudo-Aneurysm	0% (0/37)	0% (0//37)
Vessel Dissection	0% (0/37)	0% (0//37)

b. Potential Adverse Events

Potential adverse events that may occur include, but are not limited to, the following:

- Allergic/anaphylactoid reaction
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arterial occlusion/thrombus, near the puncture site

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- Arterial occlusion/thrombus, remote from puncture site
- Arterial occlusion/restenosis of the treated vessel
- Arteriovenous fistula
- Arrhythmia
- By-pass Surgery
- Death related to procedure
- Death unrelated to procedure
- Embolization, arterial
- Embolization, stent
- Fever
- Hemorrhage/bleeding requiring a blood transfusion
- Hematoma bleed, remote site
- Hematoma bleed at needle, device path: nonvascular procedure
- Hematoma bleed, puncture site: vascular procedure
- Hypotension/hypertension
- Incorrect positioning of the stent requiring further stenting or surgery
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Liver failure
- Local infection
- Malposition (failure to deliver the stent to the intended site)
- Open surgical repair
- Pain
- Pancreatitis
- Pulmonary embolism/edema
- Pneumothorax
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Restenosis
- Septicemia/bacteremia
- Stent Fracture
- Stent Migration
- Stroke
- Vasospasm
- Venous occlusion/thrombosis, remote from puncture site
- Venous occlusion/thrombosis, near the puncture site

I. Clinical Studies

a. RESILIENT FEASIBILITY STUDY

The RESILIENT study included a feasibility study to assess the safety of the LIFESTENT® Vascular Stent System. This feasibility study enrolled 20 subjects at six US investigative sites. Results from this study provided justification for initiation of a pivotal study to assess the safety and effectiveness of the LIFESTENT® Vascular Stent System.

b. RESILIENT RANDOMIZED STUDY

Design

The RESILIENT trial was a prospective, multi-center, randomized clinical investigation to evaluate the superiority of the LIFESTENT® Vascular Stent System compared to PTA in the treatment of symptomatic vascular disease of the SFA and/or proximal popliteal artery. A total of 206 subjects were treated at 22 US and 2 European investigative sites. Each site not participating in the feasibility study was required to perform one roll-in case. A total of 20 roll-in cases were performed and 206 randomized cases were performed. Seventy-two (72) subjects were randomized to the PTA arm and 134 subjects were randomized to treatment with the LIFESTENT® Vascular Stent System.

Subjects eligible to be enrolled in this study had stenotic or occluded lesions of the SFA and/or proximal popliteal artery and suffered from lifestyle limiting claudication (Rutherford Category 1 – 3). Lesions could be either de novo or restenotic. Subjects with previously stented lesions or target limb vascular by-pass were excluded. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm in diameter and the collective length of the treated segment was to be less than 150 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days, 6 months and annually thereafter with follow-up planned out to 36-months. Office visits were coupled with duplex ultrasound assessments of the treated segments. X-ray evaluation of the stented lesions was also performed. The RESILIENT trial utilized a Frequentist approach with its statistical plan. The primary objectives were to show the following:

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- that the probability of the occurrence of Target Lesion Revascularization (TLR) or Target Vessel Revascularization (TVR) at 6-months post-procedure for the subjects treated with LifeStent NT (test arm) was significantly lower than (and therefore superior to) that for the subjects treated with PTA-alone (control arm); and,
- that the death rates at 30-days post-procedure were not significantly different between the test arm and the control arm.

Continuous variables were compared using an independent samples t-test. Dichotomous variables were compared using Fisher's exact test. Ordinal variables were compared using a Chi-square test. Time to event was compared using a log-rank test. Interval censored data were analyzed using the Kaplan-Meier method as the primary analysis. A sensitivity analysis for interval censored data was performed using the Weibull distribution. Effectiveness endpoints were analyzed as one-sided tests. Safety endpoints were analyzed as two-sided tests.

The results were evaluated using an Intent-to-Treat (ITT) analysis. In particular, control subjects requiring stent placement to salvage a failed angioplasty remained in the cohort to which they were randomized.

Demographics

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

RESILIENT Trial Subject Demographics			
Variable	**Category**	**Test**	**Control**
Age at Procedure (Yrs)	N, Mean ± SD	134, 68.4 ± 9.9	72, 66.1 ± 9.2
Gender, % (n/N)	Female	29.1 (39/134)	33.3 (24/72)
	Male	70.9 (95/134)	66.7 (48/72)
Race, % (n/N)	African American	9.0 (12/134)	9.7 (7/72)
	Caucasian	89.6 (120/134)	84.7 (61/72)
	Other	1.5 (2/134)	5.6 (4/72)
Hypertension, % (n/N)		83.6 (112/134)	94.4 (68/72)
Hypercholesterolemia, % (n/N)		79.9 (107/134)	76.4 (55/72)
Diabetes, % (n/N)		38.1 (51/134)	38.9 (28/72)
Smoking, % (n/N)		72.4 (97/134)	83.3 (60/72)
Coronary Artery Disease, % (n/N)		56.0 (75/134)	54.2 (39/72)
Myocardial Infarction, % (n/N)		20.1 (27/134)	26.4 (19/72)
Target Limb Rutherford Category, % (n/N)	Class 1	3.0 (4/134)	6.9 (5/72)
	Class 2	35.8 (48/134)	41.7 (30/72)
	Class 3	61.2 (82/134)	50.0 (36/72)
	Class 5		1.4 (1/72)
Target Limb ABI (mm Hg)	N, Mean ± SD	124, 0.71 ± 0.19	67, 0.72 ± 0.19
Contralateral Limb ABI (mm Hg)	N, Mean ± SD	120, 0.88 ± 0.21	64, 0.84 ± 0.21

RESILIENT Trial Lesion Characteristics			
Variable	**Category**	**Test**	**Control**
Number of Lesions, % (n/N)	1 Lesion(s)	85.8 (115/134)	87.5 (63/72)
	2 Lesion(s)	14.2 (19/134)	12.5 (9/72)
Target Side, % (n/N)	Left	47.7 (73/153)	54.3 (44/81)
	Right	52.3 (80/153)	45.7 (37/81)
Lesion Location, % (n/N)	Proximal 1/3 of SFA	13.1 (20/153)	14.8 (12/81)
	Middle 1/3 of SFA	32.0 (49/153)	38.3 (31/81)
	Distal 1/3 of SFA	50.3 (77/153)	45.7 (37/81)
	Proximal Popliteal	4.6 (7/153)	1.2 (1/81)
Lesion Classification, % (n/N)	De Novo/Stenosed	80.4 (123/153)	79.0 (64/81)
	Occlusion	17.0 (26/153)	18.5 (15/81)
	Restenosed	2.6 (4/153)	2.5 (2/81)
Target Vessel RVD (mm)	N, Mean ± SD	153, 5.2 ± 0.8	81, 5.2 ± 0.9
Lesion % Diameter Stenosis	N, Mean ± SD	153, 86.3 ± 12.5	80, 87.9 ± 11.6
Lesion Length (mm)	N, Mean ± SD	153, 61.3 ± 42.4	81, 57.0 ± 37.0

Methods

Subjects underwent either PTA or PTA plus LifeStent® Vascular Stent System placement in the target lesion(s). In cases where the PTA only result was sub-optimal, stent placement was performed. This occurred in 40% (29/72) of the subjects that were randomized to the PTA-only treatment arm. Post procedure medication was suggested as aspirin for 6 months and clopidogrel for 12 weeks.
All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board routinely reviewed the study outcomes to ensure that the benefits of continuing the study outweighed any potential risks. Independent core laboratories were utilized to analyze angiographic, x-ray and duplex imaging.

Results

As shown in the principal Safety and Effectiveness table (Section J) the LifeStent® Vascular Stent System demonstrated a significantly higher freedom from intervention rate (freedom from TVR/TLR) at 6 months (LifeStent® 94.6%; control 52.6%), 12 months (LifeStent® 82.7%; control 45.2%), 24 months (LifeStent® 70.5%; control 40.1%), and 36 months (LifeStent® 68.1%; control 40.1%) than the PTA control group ($p < 0.0001$). Additionally, as expected, there was no difference in the 30-day mortality rate between the two study arms.

c. E-TAGIUSS CONFIRMATORY STUDY

Design

The E-TAGIUSS trial was a prospective, multi-center, confirmatory clinical investigation to evaluate the LifeStent® and LifeStent® XL Vascular Stent Systems in the treatment of symptomatic vascular disease of the SFA and proximal popliteal artery. A total of 37 subjects were treated at 7 European investigative sites.

Subjects eligible to be enrolled in this study had to demonstrate Trans-Atlantic Inter-Society Consensus (TASC) A, B or C lesions. Reference vessel diameter (RVD) of the treated subjects was to be 4.0 – 6.5 mm in diameter and the collective length of the treated segment was to be less than 200 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days with an office visit.

Demographics

Characteristics of the subjects enrolled in the study including age, gender, medical history as well as lesion characteristics are provided in the tables below.

E-TAGIUSS Trial Subject Demographics		
Variable	**Category**	**Total**
Age at Procedure (Yrs)	Mean ± SD (N)	37, 71.1 ± 7.8
Gender, % (n/N)	Female	29.7 (11/37)
	Male	70.3 (26/37)
Race, % (n/N)	Caucasian	97.3 (36/37)
	Other	2.7 (1/37)
Hypertension, % (n/N)		83.8 (31/37)
Hypercholesterolemia, % (n/N)		56.8 (21/37)
Smoking, % (n/N)		48.6 (18/37)
Coronary Artery Disease, % (n/N)		32.4 (12/37)
Diabetes, % (n/N)		24.3 (9/37)
Myocardial Infarction, % (n/N)		13.5 (5/37)
Target Limb Rutherford Category, % (n/N)	Class 1	5.4 (2/37)
	Class 2	35.1 (13/37)
	Class 3	45.9 (17/37)
	Class 4	5.4 (2/37)
	Class 5	8.1 (3/37)
Target Limb ABI (mm Hg)	Mean ± SD (N)	35, 0.6 ± 0.2
Contralateral Limb ABI (mm Hg)	Mean ± SD (N)	31, 0.9 ± 0.2

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E-TAGIUSS Trial Lesion Characteristics		
Variable	**Category**	**Total**
Number of Lesions, % (n/N)	1	86.5 (32/37)
	2	13.5 (5/37)
Target Side, % (n/N)	Left	47.6 (20/42)
	Right	52.4 (22/42)
Lesion Location, % (n/N)	Popliteal	2.4 (1/42)
	SFA	95.2 (40/42)
	SFA & Popliteal	2.4 (1/42)
Lesion Classification, % (n/N)	Occlusion	42.9 (18/42)
	Reoccluded	7.1 (3/42)
	Restenosed	2.4 (1/42)
	Stenosed	47.6 (20/42)
Lesion Severity/TASC Grade, % (n/N)	TASC A	45.9 (17/37)
	TASC B	24.3 (9/37)
	TASC C	29.7 (11/37)
Target Vessel RVD (mm)	N, Mean ± SD	42, 5.3 ± 0.6
Lesion % Diameter Stenosis	N, Mean ± SD	42, 89.3 ± 15.1
Lesion Length (mm)	N, Mean ± SD	42, 89.2 ± 69.8

Methods

Subjects underwent PTA plus LIFESTENT® and/or LIFESTENT® XL Vascular Stent placement in the target lesion(s). Post procedure medication was suggested as aspirin and clopidogrel for a minimum of 30 days.

All data were collected on case report forms at investigative sites. Adverse events were adjudicated by the clinical events committee and the data safety monitoring board reviewed the study outcomes. Independent core laboratories were utilized to analyze angiographic data.

Results

As shown in the principal Safety and Effectiveness table (Section J) the LIFESTENT® and LIFESTENT® XL Vascular Stent Systems were able to accurately deploy the stent and demonstrated minimal length change (deployment success 100.0%). Additionally, the acute safety and effectiveness measures demonstrated positive results.

d. Retrospective Analysis of LIFESTENT® Vascular Stent Systems in the Treatment of Long Segment Lesions

Design

This study consisted of a post-hoc analysis of four sources of data: (1) a pivotal IDE clinical trial (RESILIENT: IDE G040023; "RESILIENT"), (2) a multi-center, non-randomized, observational study conducted in Europe ("ELODIE I"), (3) the routine clinical practice of a United States (U.S.) physician ("US Series"), and (4) the routine clinical practice of a European Union (EU) physician ("EU Series"). In total, two-hundred-eighty-five (285) patients with one or more implanted LIFESTENT® devices were identified and included in the analysis. There were a total of 46 lesion segments in this analysis with lesion lengths beyond 160 mm.

Demographics

Characteristics of the subjects and lesions analyzed are provided in the tables below.

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Demographics: Retrospective Analysis of LifeStent® Vascular Stent Systems in the Treatment of Long-Segment Lesions

Characteristic	RESILIENT	ELODIE I	US Series	EU Series	TOTAL
Age at Procedure (years)					
N reported	198	11	66	10	285
Mean	68.4	71.8	72.6	73.9	69.7
St Dev	10.2	8.63	10.9	5.53	10.3
Range	20.7 – 88.2	53.9 - 85.6	36.3 - 96.8	63.9 - 83.1	20.7 – 96.8
Gender (% male)	69.2	45.5	60.6	44.4	65.5
N reported*	198	11	66	9	284
Race (% Caucasian)	88.9	100	77.3	100	86.6
N reported	198	3	66	10	277
Hypertension (%)	85.4	72.7	84.9	100	85.3
N reported	198	11	66	10	285
Hypercholesterolemia (%)	80.3	54.6	75.8	80.0	78.3
N reported	198	11	66	10	285
Smoking (%)	25.8	36.4	60.6	0.0	33.3
N reported	198	11	66	10	285
CAD (%)	56.6	27.3	57.6	30.0	54.7
N reported	198	11	66	10	285
DM (%)	38.9	0.00	50.0	30.0	39.7
N reported	198	11	66	10	285
Rutherford Category of Target Limb					
N reported	198	11	NR	10	219
Class 1 (%)	3.5	0		0	3.2
Class 2 (%)	40.4	45.5		10.0	39.3
Class 3 (%)	56.1	36.4		60.0	55.3
Class 4 (%)	0.0	0		0	0
Class 5 (%)	0.0	18.2		30.0	2.3
Indication of Target Limb					
N reported	198	11	71	10	290
Claudication (%)	100	90.9	49.3	70.0	86.6
Critical Limb Ischemia (%)	0	9.1	50.7	30.0	13.4
ABI of Target Limb					
N reported	183	NR	51	10	244
Mean	0.72		0.61	0.41	0.69
St Dev	0.20		0.22	0.18	0.22
Range	0.24 - 1.45		0 - 1.34	0.1 - 0.67	0 – 1.45

* One patient did not report gender
NR- Not Reported

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Lesion and Stent Characteristics

Characteristic	RESILIENT	ELODIE I	US Series	EU Series	TOTAL
N Patients	198	11	66	10	285
N Treated Limbs	198	11	72	10	291
N Treated Lesions	212	16	72	10	310
Individual Lesion Length					
N reported	212	16	72	10	310
Mean (mm)	66.0	108.8	152.6	214.0	93.1
St Dev Length	35.7	44.7	104.5	109.6	75.1
Mean N per Limb	1.1	1.5	1.1	1.0	1.1
Percent Stenosis (max per limb):					
N reported	198	11	0	10	219
Mean	87.8	92.7		96.0	88.5
St Dev	11.3	9.05		6.99	11.2
Range	50 - 100	80 - 100		80 - 100	50 - 100
N Total Lesion Lengths:					
< 50 mm	62	1	9	0	72
50 – <100 mm	93	0	19	0	112
100 – <160 mm	37	6	15	3	61
160 – <200 mm	5	1	3	4	13
200 – 240 mm	1	2	8	0	11
≥ 240 mm	0	1	18	3	22
Total Lesion Lengths:					
N	198	11	72	10	291
Mean	70.6	158.2	152.6	214	99.15
St Dev	37.7	57.8	104.5	109.6	77.3
Range	10 - 202	30 - 240	16 - 360	140 - 500	10 - 500
N Total Stented Lengths:					
< 60 mm	40	0	NR	0	40
60 – < 110 mm	71	0	NR	0	71
110 – < 170 mm	73	1	NR	1	75
170 – < 210 mm	7	7	NR	5	19
210 – < 250 mm	5	0	NR	1	6
≥ 250 mm	2	3	NR	3	8
Total Stent Lengths:					
N	198	11	NR	10	219
Mean	104.5	204.5		244.4	115.9
St Dev	55.4	53.2		125.1	69.4
Range	30 - 340	160 - 290		160 - 574	30- 574
TASC Classification					
N Grade A (%)	NR	1 (9.1%)	23 (39.0%)	NR	24 (34.3%)
N Grade B (%)		3 (27.3%)	11(18.6 %)		14 (20.0%)
N Grade C (%)		7 (63.6%)	6 (10.2%)		13 (18.6%)
N Grade D (%)		0 (0%)	19 (32.2%)		19 (27.1%)
Total		11	59		70

* For lesion characteristics, core lab data were used when available; the site reported data were used otherwise. Five (5) patients did not have lesion characteristics reported by the core lab

NR- Not Reported

<u>Methods</u>

Subjects received at least one commercially available LifeStent® stent - in the case of those subjects enrolled in the RESILIENT study (IDE - G040023), they received the device as described in G040023, which were identical to the current commercially available LifeStent® device. Specifically, the following analyses were undertaken:

- Estimating the patency (defined in this analysis as freedom from TVR) at 12-months post-procedure of lesions of length: 50 mm, 100 mm, 160 mm, and 240 mm (long-term effectiveness)
- Comparing the acute safety performance of the LifeStent® device at 30-days post-procedure to the ViVa OPC, and,
- Estimating the freedom from death and amputation at 12-months post-procedure in patients with long lesions treated with the LifeStent®

device by calculating the observed rates in this study (long-term safety).

Data for this retrospective analysis were compiled 'as received' from their respective sources.

Results

The rate of freedom from death, amputation, and TVR, at 30 days post-procedure was 99.6% for the combined performance of the LifeStent and LifeStent XL Vascular Stent Systems, and 88% for the VIVA OPC. Furthermore, long-term safety was shown to have a clinically acceptable freedom from death and amputation rate through 12-months (84.5%). Moreover, effectiveness was evaluated through estimation of patency at 12 months post-procedure for lesion lengths of 50 mm, 100 mm, 160 mm, 200 mm and 240 mm via the lesion-length model. The patency at 12 months for lesions greater than 160 mm in length is 67%.

J. Principal Safety and Effectiveness Tables

a. RESILIENT RANDOMIZED STUDY

RESILIENT Principal Safety and Effectiveness Table			
Variable	Test	Control	p-value
MACE at 30 Days, % (n/N)	0.0 (0/134)	1.4 (1/72)	ns*
Freedom from MACE at 6 Months, %	93.9	92.8	ns*
Freedom from MACE at 12 Months, %	86.6	85.1	ns*
Freedom from MACE at 24 Months, %	80.5	79.7	ns*
Freedom from MACE at 36 Months, %	75.2	75.2	ns*
Lesion Success, % (n/N)	95.8 (114/119)	83.9 (52/62)	**0.009**
Hemodynamic Success, % (n/N)	71.2 (79/111)	59.6 (31/52)	ns*
Procedure Success, % (n/N)	95.8 (114/119)	83.9 (52/62)	**0.009**
Clinical Success at 6 Months, % (n/N)	82.2 (97/118)	30.9 (21/68)	<0.0001
Primary Patency at 6 Months, %	94.2	47.4	<0.0001
Secondary Patency at 6 Months, %	100.0	98.3	ns*
Freedom From TVR/TLR at 6 Months, %	94.6	52.6	<0.0001
Clinical Success at 12Months, % (n/N)	72.3 (81/112)	31.8 (21/66)	<0.0001
Primary Patency at 12 Months, %	81.5	36.7	<0.0001
Secondary Patency at 12 Months, %	100.0	98.3	ns*
Freedom From TVR/TLR at 12 Months, %	82.7	45.2	<0.0001
Clinical Success at 24 months, % (n/N)	68.6 (70/102)	25.4 (16/63)	<0.0001
Freedom From TVR/TLR at 24 months, %	70.5	40.1	<0.0001
Clinical Success at 36 months, % (n/N)	63.2 (60/95)	17.9 (10/56)	<0.0001
Freedom From TVR/TLR at 36 months, %	68.1	40.1	0.0002

ns* - not significant

Definitions (secondary endpoints denoted with an asterisk (*)):

Major adverse clinical events* (MACE): Any event of death (through 30-days), stroke, myocardial infarction, significant distal embolization, emergent surgical revascularization of target limb, thrombosis, and/or worsening Rutherford category post procedure at the indicated time point.

Lesion Success*: Attainment of ≤ 30% residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

Hemodynamic Success*: Angiographic evidence of improved flow across the treated area immediately post-procedure. ABI improved from baseline by ≥ 0.10 and not deteriorated by > 0.15.

Procedure Success*: Attainment of ≤ 30% residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

Clinical Success*: Relief or improvement of baseline symptoms by Rutherford categories/grades for acute or chronic limb ischemia and the "definition of improvement". Improvement must be sustained by one clinical category above the pre-treatment clinical value.

Primary Patency*: The continued flow through the target lesion as evidenced by DUS or angiogram without further/repeat intervention over time.

Secondary Patency*: The patency history for the target lesion that is sustained or restored (with repeated intervention) over time.

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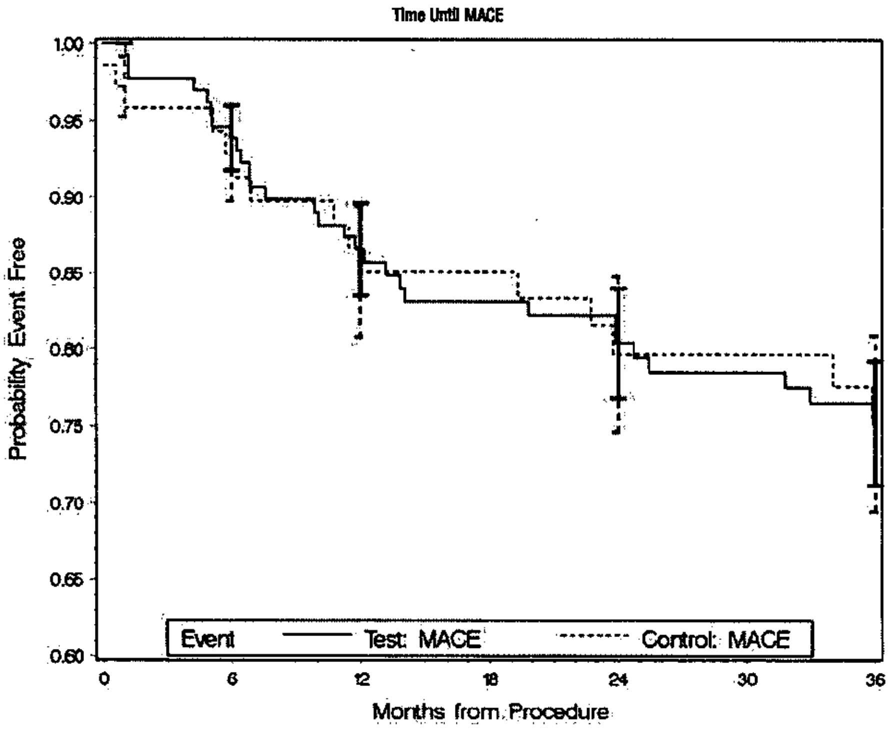
Target Vessel Revascularization (TVR) / Target Lesion Revascularization (TLR): Any "clinically-driven" repeat percutaneous intervention of the target lesion or bypass surgery of the target vessel. If a control subject requires a stent peri-procedurally due to a ballout procedure, it will be considered a TLR/TVR for the control group.

Survival Analysis – Freedom from MACE (at 36 months)



MACE	Event Free	Event Rate	P-Value*
Test (LIFESTENT®)	75.2%	24.8%	0.98
Control (balloon angioplasty)	75.2%	24.8%	
*p-value is from Log-rank test on all available data.			

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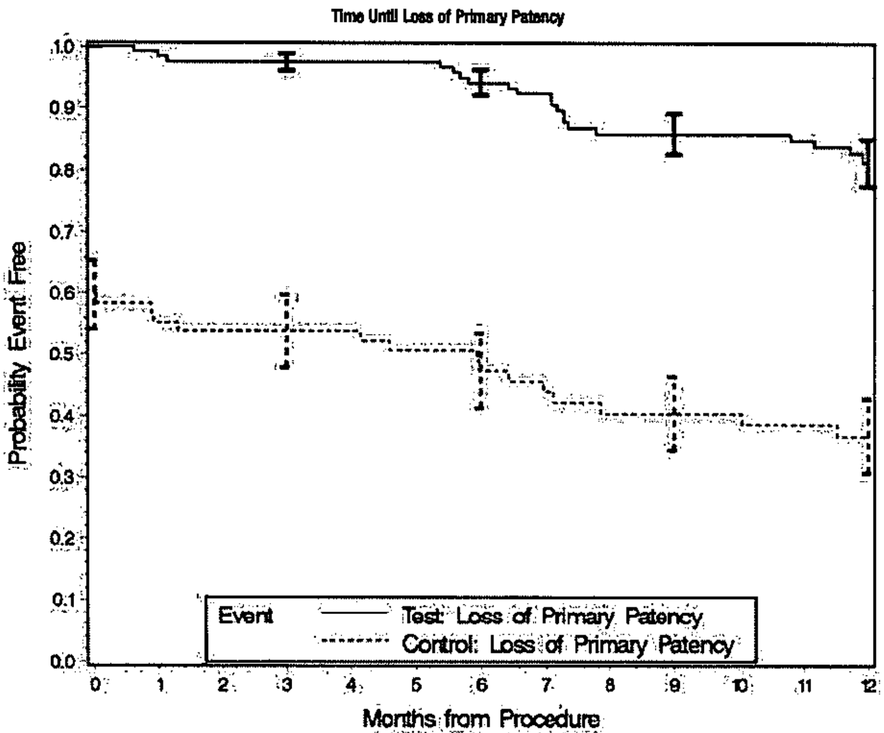
Survival Analysis – Freedom from Loss of Primary Patency (at 12 months)



Loss of Primary Patency	Event Free	Event Rate	P-Value*
Test (LIFESTENT®)	81.5%	18.5%	<0.0001
Control (balloon angioplasty)	36.7%	63.3%	
*p-value is from Log-rank test on all available data.			

Stent Fracture Analysis

Independent Analysis

As pre-specified in the RESILIENT protocol, A-P and lateral x-rays were taken at 6-, 12-, and 18-months post-procedure and analyzed by an independent core lab. X-rays on 291 stents were available for analysis from all phases of the RESILIENT trial. Fractures were classified as follows:

Classification Type	
1	Single-strut fracture only
2	Multiple single-stent fractures occuring at different sites
3	Multiple stent fractures resulting in complete transverse linear fracture but without stent displacement
4	Complete transverse linear fracture with stent displacement
Based on Allie, et. al. Endovascular Today 2004; July/August: 22-34.*	

** Please note that the fracture analysis in the RESILIENT Study was conducted by an independent core laboratory using the classification system described by Allie et al., 2004 in accordance with the protocol approved in the IDE prior to study initiation (G040023, 3/19/2004). This system classifies fractures into four distinct types. Since study initiation, other stent classification systems have been proposed (Scheinert et al, 2005; Roca-Singh et al., 2007; Popma et al., 2009). The classification system published by Rocha-Singh et al., is currently used by many core labs in the U.S., and splits the Type 4 fractures as defined by Allie et al. into "stent fracture(s) with mal-alignment of*

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components" (Type 4) and "stent fracture(s) in a trans-axial spiral configuration" (Type 5). The Type 4 fractures in the RESILIENT Study were not sub-categorized according to the system proposed by Rocha-Singh and colleagues.

One (1) fracture was noted at the time of the six-month analysis, eight (8) additional fractures were noted at the twelve-month analysis (i.e., between 6 and 12 months), and three (3) more fractures were noted at the final eighteen-month analysis (i.e., between 12 and 18 months). 67% (8/12) of the fractures were identified within 7 months of implantation. At the eighteen month analysis, six fractures were noted as Type I (single-strut fracture) and six fractures were classified as Type IV (complete transverse fracture). Since the overall number of stent fractures was low throughout the course of the RESILIENT trial, statistical analysis as to cause was not possible.

It was observed however, that of the six Type IV fractures, all six were elongated at deployment, four of six occurred in lesions that were moderate to severely calcified, and four of six occurred proximal or distal to an area of stent overlap. 38% of patients with >10% elongation went on to develop Type 4 fractures in less than 1 year and 36% of the fractures occurred in patients where multiple (≥ 2) stents were deployed in an overlapping fashion. No patients with stent fractures developed restenosis as evaluated at the 12-month follow-up, and no fractures were associated with MACE. Overall, fractures in RESILIENT had no apparent effect on device safety or effectiveness. The following table summarizes the fractures categorized according to Allie, et. al.

RESILIENT Fracture Analysis (18 Months)	
Type	**Count (stents/subjects)**
Type 1	6/6
Type 4	5/4
Type 1 & 4	1/1
Total	12/11

Review of Medical Device Reporting

Since February 13, 2009, in the global commercial experience, Bard Peripheral Vascular received complaints of suspected LifeStent® fractures in 38 patients. Of these reports, nine (9) patients with 10 fractures were confirmed from evaluation of baseline or follow-up angiograms. A review of the confirmed fractures showed that seven (7) of the stents had single strut fractures and three (3) of the stents had multiple strut fractures. These were associated with one case of stent twisting, one case of stent elongation, and three cases of stent compression that may have contributed to the occurrence of fracture. Classification of fracture type was not completed due to the limitations of the data received from the user and a systematic review of all stents by an angiographic core lab was not performed. Because of the difficulty in identifying stent fracture and the lack of comprehensive angiographic follow-up, it is not possible to determine the true fracture rate of the LifeStent® in commercial use.

Conclusion

Stent fractures were noted to be an uncommon event in the RESILIENT trial and appeared to not impact the safety and performance of the LifeStent® implant. Stent fractures may occur with the use of overlapping stents; however there was no correlation between stent fractures and the number of stents implanted in the RESILIENT trial. Fractures may occur in SFA or popliteal segments that undergo significant motion, particularly in areas with severe angulation and tortuosity. The RESILIENT trial was not designed to show a correlation between stent fractures and the location, although six (6) fractured stents were observed in areas with severe calcification, and one (1) stent placed across the point of flexion in the mid-popliteal region resulted in a fracture.

Patency vs. Lesion Length

In order to assess the impact of lesion length on patency outcomes, a Cox regression analysis, with the total lesion length as a risk factor was performed which demonstrated that for the LifeStent® group, lesion length is not a significant predictor of primary patency outcomes (p-value = 0.46). Additionally, the calculated hazard ratio of 1.003 indicates that there is only a remote relationship between lesion length and patency outcomes in the LifeStent® group. It should be noted that based on the analysis, the lesion length is a significant predictor of patency outcomes for the control group (p-value = 0.0025).

b. E-TAGIUSS CONFIRMATORY STUDY

E-TAGIUSS Principal Safety and Effectiveness Table	
Variable	**Test % (n/N)**
Death at 30 Days	0% (0/37)
MACE at 30 Days	2.7% (1/37)
Deployment Success	100.0 (46/46)
Lesion Success	90.9 (30/33)
Procedure Success	90.9 (30/33)

Definitions (secondary endpoints denoted with an asterisk (*)):

Major adverse clinical events* (MACE): Any event of death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, amputation of the target limb and thrombosis of the target vessel at the indicated time point.

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Deployment Success: Ability to deliver the stent to the intended site with the post deployment stent length being within 10% of the pre-deployment length.

Lesion Success*: Attainment of ≤ 30% residual stenosis of the target lesion using any percutaneous method and/or non-investigational device.

Procedure Success*: Attainment of ≤ 30% residual stenosis of the target lesion and no in-hospital serious adverse events defined as: death, stroke, myocardial infarction, emergent surgical revascularization, significant distal embolization in the target limb, and thrombosis of the target vessel.

c. Retrospective Analysis of LifeStent® Vascular Stent Systems in the Treatment of Long-Segment Lesions

The results for the primary effectiveness endpoint as defined by freedom from TVR/TLR are shown in table below.

Freedom from TLR/TVR* by Time and Lesion Length

Variable	12 months Weibull* / Kaplan-Meier (n/N**at 12 months)	24 months Weibull* / Kaplan-Meier (n/N**at 24 months)
Average of all (total) lesion lengths (= 101.1 mm)	82.4% / 79.2% (54/291)	63.3% / 62.5% (29/170)
(n=72) < 50 mm lesions (Weibull: 50 mm)	85.4% / 83.4 (11/72)	69.0% / 68.1% (7/48)
(n=112) 50 - < 100 mm lesions (Weibull: 100 mm)	81.9% / 87.9% (12/112)	62.5% / 74.3% (9/73)
(n=61) 100 - < 160 mm lesions (Weibull: 160 mm)	76.7% / 76.5% (13/61)	53.6% / 55.2% (9/35)
(n=13) 160 - < 200 mm lesions (Weibull: 200 mm)	72.6% / 38.9% (7/13)	47.0% / 38.9% (0/2)
(n=11) 200 - < 240 mm lesions (Weibull: 240 mm)	67.9% / 67.5% (3/11)	40.2% / NA (1/5)
(n=22) > 240 mm lesions	NA / 55.9% (8/22)	NA / 23.9% (3/7)

* From the Weibull covariate-adjusted analysis
** Number starting the year

The primary acute safety endpoint of the LifeStent® and LifeStent® XL Vascular Stent Systems at 30 days post-procedure showed the freedom from rates were higher than the ViVa OPC (88%). The 30-day freedom-from-death, amputation and TVR rate was 99.6% with a standard error of 0.34% (95% CI: 97.59% - 99.95%).

The primary long-term safety endpoint was freedom from death/amputation. The Kaplan-Meier analysis showed that the freedom-from-death/amputation rate at 12 months was 100% (lesions < 50 mm), 94.5% (lesions 50 - 100mm), 91.4% (lesions 100 - 160 mm), 63.6% (lesions 160 - 200 mm), 90.9% (lesions 200 - 240 mm) and 94.1% (lesions >240 mm).

Freedom from Death/Amputation*

	12 months (n/N**)
All Lesions	93.8 (17/291)
Lesions < 50 mm	100% (0/72)
Lesions 50 - 100 mm	94.5% (6/112)
Lesions 100 - 160 mm	91.4% (5/61)
Lesions 160 - 200 mm	63.6% (4/13)
Lesions 200 - 240 mm	90.9% (1/11)
Lesions > 240 mm	94.1% (1/22)

* From the Kaplan-Meier analysis
** Number starting the year

K. Patient Selection and Treatment

Patient selections should be based on the populations treated in the RESILIENT and E-TAGIUSS investigations. Demographics for the two investigations are provided in Section I – Clinical Investigations of this "Instructions for Use" document. Additionally, treatment of the patients should follow the treatment practices used by the RESILIENT and E-TAGIUSS investigators. These methods have been reiterated below in Section L – Patient Counseling Information and Section N – Instructions for Use.

L. Patient Counseling Information

Physicians should consider the following in counseling the patient about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with a LifeStent® implant.
- Discuss the risks/benefits issues for this particular patient.
- Discuss alterations to current lifestyle immediately following the procedure and over the long term.

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- Discuss the risks of early discontinuation antiplatelet therapy.

The following information is provided in the packaging for the physician to provide their patients:
- A Patient Guide which includes information on the LifeStent® XL Vascular Stent System, peripheral artery occlusive disease, the implantation procedure and patient care following the implant.
- A Patient Implant Card that is used to record and disseminate information about the patient and the stent.

M. How Supplied

STERILE: FOR SINGLE USE ONLY. The LifeStent® XL Vascular Stent System is supplied sterile (by ethylene oxide gas) and is nonpyrogenic. Do not resterilize and/or reuse the device. Do not use if the temperature exposure indicator (i.e., square label found on the pouch) is black as the unconstrained stent diameter may have been compromised. The temperature exposure indicator label should be grey and must be clearly visible on the pouch. Do not use if pouch is opened or damaged. Do not use the stent after the end of the month indicated by the "Use By" date specified on the package. For returned product or product issues, please contact Bard Peripheral Vascular at the address below:

Bard Peripheral Vascular, Inc.
Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281 USA

CONTENTS for one (1) LifeStent® XL Vascular Stent System:
- One (1) LifeStent® XL Vascular Stent System
- One (1) Patient Implant Card
- One (1) Instructions for Use
- One (1) Patient Guide

STORAGE: Store in a cool, dark, dry place. Storage temperature should not exceed 60°C. Use by the end of the month indicated by the "Use By" date specified on the package.

DISPOSAL INSTRUCTIONS: After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

N. Instructions for Use

Pre-Deployment Procedure

1. **Inject Contrast Media**
   Perform an angiogram using standard technique.

2. **Evaluate and Mark Target Site**
   Fluoroscopically evaluate and mark the target site, observing the most distal diseased or obstructed segment.

3. **Select Stent Size**
   Measure the length of the target lesion to identify the appropriate length of stent(s) required. Ensure that the stent is long enough to permit the area proximal and distal of the lesion to be covered by the stent.

   Identify the diameter of the reference vessel (proximal and distal to the lesion). To ensure secure placement, refer to the stent size selection table for proper sizing scheme.

Stent Size Selection Table: LifeStent® Vascular Stent System	
Reference Vessel Diameter	Unconstrained Stent Inner Diameter
4.0 – 5.5 mm	6.0 mm
5.6 – 6.5 mm	7.0 mm

   Refer to product labeling for stent length

4. **Materials Required**
   In addition to the LifeStent® XL Vascular Stent System, the following standard materials may also be required to facilitate delivery and deployment of the LifeStent® XL Vascular Stent System: heparinized normal saline, 6F (2.0 mm) or larger introducer sheath, 0.035" diameter guidewire, standard balloon angioplasty (PTA) catheter, contrast medium diluted 1:1 with heparinized normal saline, inflation device and appropriate anticoagulation and antiplatelet drugs.

5. **Prepare Stent System**

a) Open the box and remove the pouch containing the stent system.

b) Check the temperature exposure indicator label on the pouch to confirm that the grey background is clearly visible. See "Warnings" section.

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c) Carefully inspect the pouch for damage to the sterile barrier. Do not use after the expiration date. Peel open the pouch and remove the tray containing the stent system. Extract the stent system from the tray and check the following:
   i) Verify that the shipping lock is still secure in the stent system handle.
   ii) Examine the stent system for any damage. If it is suspected that the sterility or performance of the device has been compromised, the stent system should not be used.

d) Visually inspect the distal end of the stent system to ensure that the stent is contained within the sheath. Do not use if the stent is partially deployed.

e) Flush the inner lumen of the stent system with heparinized normal saline prior to use.

f) Wipe the usable length portion of the stent system with a gauze soaked with heparinized normal saline.

Stent Deployment Procedure

1. Insert Introducer Sheath and Guidewire

a) Gain access at the appropriate site using a 6F (2.0 mm) or larger introducer sheath.

b) Insert a guidewire of appropriate length (see table) and diameter across the lesion to be stented via the introducer sheath.

Recommended Guidewire Length Table	
Catheter Working Length	Recommended Guidewire Length
130 cm	300 cm
80 cm	260 cm

2. Dilate Lesion

Predilation of the lesion should be performed using standard techniques. While maintaining site access with a guidewire, remove the balloon catheter from the patient.

Caution: During dilation, do not expand the balloon such that dissection complication or perforation could occur.

3. Introduce stent system

a) Advance the stent system over the guidewire through the sheath introducer.

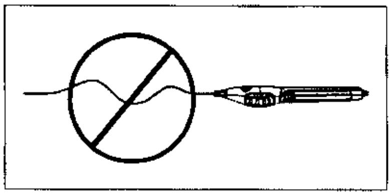
Note: If resistance is met during stent system introduction, the stent system should be removed and another stent system should be used.

Caution: Always use an introducer sheath for the implant procedure to protect the vasculature and the puncture site. A 6F (2.0 mm) or larger introducer sheath is recommended.

b) Position the tip of the stent system past the target site.

c) Pull back the stent system until the distal and proximal ends of the stent are in position so that they are distal and proximal to the target site.

d) Remove slack from the stent system held outside the patient.



Caution: Any slack in the stent system (outside the patient) could result in deploying the stent beyond the target site.

4. Deploy stent

a) Verify that the distal and proximal stent ends are distal and proximal to the target lesion.

b) Confirm that the introducer sheath is secure and will not move during deployment.

c) Remove the shipping lock.

d) To ensure the most accurate placement, firmly hold the black system stability sheath throughout deployment

Note: Do NOT hold the silver stent delivery sheath at any time during deployment. DO NOT constrict the stent delivery sheath during stent deployment.

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e) Initiate stent deployment by rotating the thumbwheel in the direction of the arrows while holding the handle in a fixed position.
Note: If excessive force is felt during stent deployment, do not force the stent system. Remove the stent system as possible, and replace with a new unit.

f) While using fluoroscopy, maintain position of the distal and proximal stent ends relative to the targeted site. Watch for the distal stent end to begin expanding; separation of the distal stent end signals that the stent is deploying. Continue turning the thumbwheel until the distal end of the stent obtains complete wall apposition.

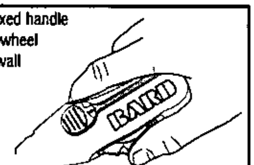

Figure 3. Initial Thumbwheel Deployment

Note: The thumbwheel is designed to initially deploy the stent distal end a minimum of 1 cm. Final stent deployment is achieved by using the deployment lever.

g) With distal end of the stent apposing the vessel wall, deployment continues with the following method (Fig. 4).

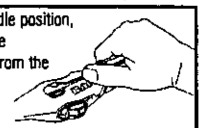

Figure 4. Fast Track Deployment Lever

Note: To ensure correctly deployed stent length, fluoroscopically monitor the distal stent end initially until wall apposition then monitor the delivery system proximal radiopaque marker relative to the proximal edge of the target site.

h) Deployment of the stent is complete when the proximal stent end apposes the vessel wall and the sheath radiopaque zone is proximal to the proximal end of the stent.

i) **DO NOT** attempt to re-sheath stent system prior to removal.

5. Post stent placement

a) Remove the stent system from the body.
Note: If resistance is met while retracting the delivery system over a guidewire, remove the delivery system and guidewire together.

b) Post stent expansion with a PTA catheter is recommended. If performed, select a balloon catheter that matches the size of the reference vessel, but that is not larger than the stent diameter itself.

c) Remove the guidewire and introducer sheath from the body.

d) Close entry wound as appropriate.

e) Discard the stent system, guidewire, and introducer sheath.
Note: Physician experience and discretion will determine the appropriate drug regimen for each patient.

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Symbols used on labeling

Keep away from sunlight

The Green Dot

Keep dry

Recyclable

LifeStent® XL Vascular Stent Systems

This product is manufactured and sold under one or more of the following patents: U.S. Patent No. 6,878,162. Other international and U.S. patents pending.

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

Distributed in the USA by:

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BARD® LIFESTENT® and LIFESTENT® XL Vascular Stent

Patient Information

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1-800-321-4254

B05925 Vers.5/12-10

If you or a member of your family has been diagnosed with **peripheral arterial occlusive disease (PAOD)*** or **claudication***, you may have questions about the disease and its treatment, especially if your doctor has treated you using the LifeStent® or LifeStent® **XL Vascular Stent***.

This guidebook is designed to help you and your family understand PAOD and the treatment with a vascular stent.

While this guidebook answers some of the questions patients with PAOD often ask, if you have any questions as you read this guidebook, please write them down and discuss them with your doctor or nurse.

** See glossary for definition*

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TABLE OF CONTENTS

** See glossary for definition*

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GLOSSARY

Term	Definition
Angiogram	An x-ray procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.
Ankle-Brachial Index (ABI)	A non–invasive test used to determine the degree of peripheral arterial occlusive disease within a patient's legs.
Artery	A blood vessel that carries blood from the heart and lungs through the body. Blood in arteries is full of oxygen.
Atherosclerosis	The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.
Balloon Angioplasty	A procedure whereby a small tube containing a balloon is passed through to the blocked area of an artery. Once the balloon is inflated, the catheter opens the blocked area in the artery. Also called Percutaneous Transluminal Angioplasty (PTA).
Blood Clot	A clump of blood cells that blocks or prevents normal blood flow.
Blood Vessel	An artery or vein
Catheter	A hollow tube used for gaining access to a blood vessel.
Catheterization	A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
Cholesterol	A substance that moves through the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.
Claudication	Pain in the leg that occurs with work or exercise, but may also occur when resting.
Contraindications	A condition that makes a specific treatment or procedure improper or undesirable.
Contrast	X-ray dye used to view the arteries during an angiogram.
Coronary artery disease	A condition where the arteries that supply blood to the heart muscles narrow.
***De-Novo* Lesion**	A lesion identified within your own artery that has not been previously treated via percutaneous intervention or surgical means.
Diabetes	A disease affecting one's metabolism of glucose (sugar) which causes changes in the blood vessels. These changes may aid in the development of peripheral artery disease.
Dilation	The widening or stretching of an opening or a hollow structure in the body
Dilation Catheter	A catheter (or tube) with a balloon on the end that can be inflated.
Fluoroscopy	An x-ray procedure in which contrast dye is injected into the arteries to find narrowing or blockage of the artery.
Graft	A portion of one of your veins or a man-made synthetic tube that your surgeon connects above and below a blockage to allow blood to pass through it and around the blockage.
Guiding Catheter	A hollow-tube through which fluids or objects can be introduced or removed from the body.

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Term	Definition
High Blood Pressure	Called hypertension. A condition where there is too much pressure inside your blood vessels. Blood is pushed too hard by the heart against the blood vessel walls.
High Cholesterol	A medical condition where there is too much cholesterol circulating in the blood stream.
Indication for Use	When a device or procedure can be used
Lesion	A blockage in a blood vessel. Also known as a plaque or stenosis.
LifeStent® Vascular Stent	A thin, flexible metal mesh tube that can be implanted in the arteries that supply blood to the thigh and knee.
Local Anesthetic	A substance used to numb the area to which it is applied.
Lumen	The inner channel or cavity of a vessel or tube.
MRI (Magnetic Resonance Imaging)	A diagnostic test that uses magnetic waves to obtain images of the inside of your body.
Nitinol	A special metal made of nickel and titanium that remembers its shape. Nitinol can be compressed when cold and expands back to its original shape and size when heated.
Percutaneous	Performed through a small opening in the skin.
Peripheral Artery Occlusive Disease	Vascular disease, which affects the blood vessels, especially those of the extremities.
Plaque	An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the lumen.
Platelet Inhibitors	Medications to prevent blood cells called platelets from sticking together and blocking the artery.
Popliteal Arteries	The arteries that pass through your knee.
Restenosis	The recurrence of a narrowing or blockage in an artery after treatment.
Stenosis	A narrowing of any canal, especially one of the superficial femoral vessels.
Stent	An expandable, metallic, tubular shaped device that provides structural support for a vessel.
Superficial Femoral Arteries	The arteries that extend from your pelvic region down to your knee.
Thrombus	A blood clot.
Transluminal	Through the inside opening of an artery.
Triglycerides	Substances in the blood that are a component of the "bad" type of cholesterol.
Ultrasound	A test, outside the body, using sound waves to determine the presence of arterial narrowing.
Vein	A blood vessel that carries blood from the organs of the body back to your heart.

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UNDERSTANDING PAOD AND YOUR TREATMENT

What Are The Superficial Femoral and Proximal Popliteal Arteries*?

Arteries* are **blood vessels*** (or pipes) that carry blood away from the heart. The superficial femoral and popliteal arteries extend from the arteries in the hip region down to your knee. The superficial femoral arteries carry blood containing oxygen through the legs down to the foot. Figure 1 shows a picture of arteries and veins (pipes) as they connect in the body system.

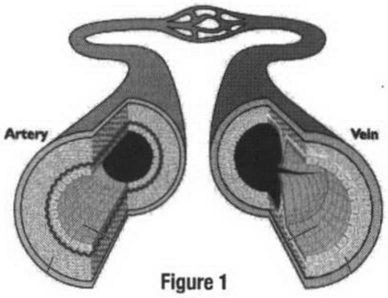

Figure 1

What Is Peripheral Arterial Occlusive Disease (PAOD)?

PAOD is caused by the build-up of fatty substances within the arteries, in a process known as **atherosclerosis***. This causes a narrowing or blockage called a **stenosis*** that limits blood flow. Some of the more commonly affected arteries by PAOD are located in the legs, arms, neck and abdomen. Figure 2 shows a picture of a stenosis (or blockage) in an artery due to atherosclerosis. Some of the symptoms you may experience due to blockages located in the arteries of the leg are:

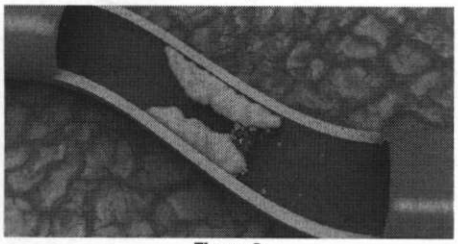
Figure 2

- Pain in the hips, thighs, buttock or calf muscles (**Claudication***);
- Numbness/tingling in the leg, foot, or toes;
- Changes in skin color such as paleness or bluish color in leg, foot, or toe;
- Changes in skin temperature of leg, foot, or toes.

What Are The PAOD Risk Factors?

Based on clinical studies, it has been determined that you are at the greatest risk for PAOD if you have a history of:

- **Diabetes***
- **Coronary artery disease***
- **High blood pressure***, also known as heart disease
- **High cholesterol***
- Smoking, or are a current smoker

You may also be at risk for PAOD if you are overweight, do not exercise, or people in your family have had PAOD.

** See glossary for definition*

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How is PAOD Diagnosed?

You should be screened for superficial femoral artery blockages if you have:

- Pain in your legs when you are moving around or walking that stops when you are resting.

Figure 3 shows a picture of an open artery compared to one that is narrow. The following diagnostic tests may be performed if superficial femoral artery disease is suspected. These tests can be used to diagnose where blockages might be and how narrow your arteries are in areas of your leg.

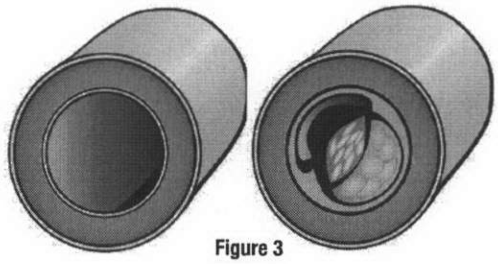

Figure 3

Ankle-Brachial Index*: The Ankle-Brachial Index (ABI) is a test done by measuring blood pressure at the ankle and the arm while a person is sitting or laying still. Blood pressures are then taken again at the ankle and the arm after 5 minutes of walking on a treadmill. A slight drop in your ABI score with exercise means that you probably have PAOD. Knowing if you have PAOD is important. Often, people with PAOD are also at risk of other blood flow problems like heart attack and stroke.

Superficial femoral artery ultrasound*: A sound-wave test that shows an image of the superficial femoral arteries on a screen. This test allows the size of the vessel to be measured and looks at how the blood is moving through your legs. This can help to show areas of the artery that may be narrow. This test is painless and does not require the use of needles, dye, or x-rays.

Fluoroscopy*/Angiogram*: An x-ray based image obtained by putting dye through a small tube (**catheter***) inserted into an artery in the groin or arm. This test will determine exactly where the artery may be more narrow and will provide important information to the doctor or medical team.

Superficial Femoral Artery Balloon Angioplasty and Stenting

When your doctor performs this procedure, he/she will start with needle entry in your **Femoral Artery*** (see Figure 4). Your doctor will then use a small tube (catheter) with a small balloon on the end that inflates to widen the narrow sections of the artery. As the balloon inflates it squeezes the "plaque" against the inside wall of the artery. This process is designed to reduce the narrowing until it doesn't slow the blood flow anymore. The balloon is deflated and removed from the artery.

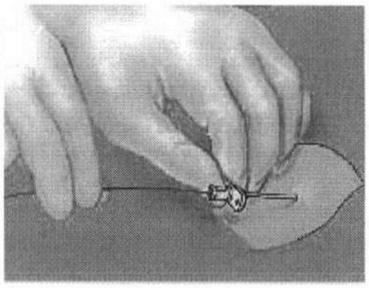

Figure 4

** See glossary for definition*

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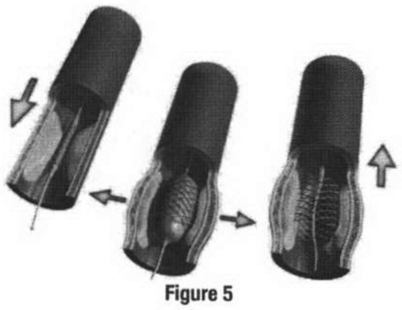

Figure 5

A **stent***, which is a wire-mesh tube made of special metal, is then placed into your artery. The metal stent is then expanded and continually pushes against the inside of the artery wall to keep the artery open. The stent is used to help blood flow through your legs easier. Over time, the artery wall will heal around the stent as it continues to support the vessel. Figure 5 shows a picture of a balloon opening up the blocked artery and a stent being put into place to help keep the artery open.

WHAT IS THE LIFESTENT® & LIFESTENT® XL VASCULAR STENT (DEVICE DESCRIPTION)?

The LIFESTENT® & LIFESTENT® XL Vascular Stent is a flexible mesh tube made from **Nitinol***. Nitinol is a metal designed to expand to a given size once it is warmed by the heat of your body. The stent comes inside a delivery system which allows your physician to move it through the body to the specific narrow place in the artery. The expanded stent is shown in Figure 6.

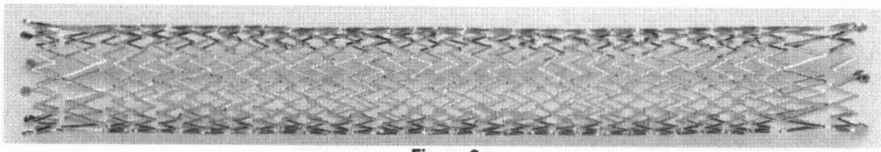

Figure 6

When Can The Device Be Used (Indication for Use*)?

The LIFESTENT® & LIFESTENT® XL Vascular Stent is indicated to improve luminal diameter in the treatment of symptomatic **de-novo*** or **restenotic*** lesion up to 240 mm in length in native superficial femoral artery (SFA) and proximal popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. In other words, the device has been proven safe and effective by the FDA to help open a blocked area of the artery in your leg. The major arteries in the leg can be seen in Figure 7.

** See glossary for definition*

Leg Anatomy

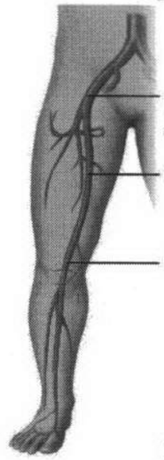

Figure 7

When Should The Device Not Be Used (Contraindications*)?

- If you have an allergy to Nitinol (nickel, titanium), and/or tantalum. If you have had a skin reaction to metal jewelry or belt buckles you may be allergic to the metal used to make this stent and it is important to discuss with your doctor whether the potential benefits of implanting a stent outweigh the risks.
- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent.

Warnings Associated With Stent Implantation

- It is important to tell your physician about all allergies you know about.
- Tell your physician about any reasons why you cannot take blood thinning medications (also called anticoagulants or antiplatelets).
- Be sure to show the stent implant card on all future physician visits or medical tests you may be receiving, even if it seems unrelated to that particular visit.

** See glossary for definition*

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YOUR PROCEDURE

What Are The Risks Of The Procedure?

Your doctor should have discussed the procedure in detail with you and explained the possible risks and potential benefits of the device. Please make sure that your doctor has answered all of your questions.

Specific risks associated with vascular stents like the LifeStent® & LifeStent® XL Vascular Stents include:

- Placement of the device in the wrong spot;
- Movement of the device once it is placed in your body causing reduced blood flow;
- Allergic reaction to the metal of the stent, which includes nickel, titanium, and tantalum;
- Breakage of the flexible mesh tube (i.e., fracture), occurred at a rate of 3.1% at 12 months in the RESILIENT Trial on LifeStent® and LifeStent® XL Vascular Stent.

The above device related events might result in additional procedures and/or the placement of additional vascular stents.

The procedure used to place the LifeStent® & LifeStent® XL Vascular Stent may involve certain risks. These risks are uncommon, but are important to be aware of:

- Abnormal blood-filled **dilation*** (or pocket) of a weakened artery wall (aneurysm)
- Air, pieces of devices, or fragments of clot blocking the artery, which could cause your toe to turn blue.
- Allergic reaction to the dye (**contrast***) which could include kidney failure
- Bleeding at the access (puncture) site in your groin or arm
- Bruising, swelling at the puncture site
- Creation of an abnormal pathway between two areas of the body (fistulization)
- Damage to the superficial femoral artery
- Death
- Decrease or increase in blood pressure
- Excessive bleeding (hemorrhage)
- Expansion of one or more layers of the vessel wall (pseudoaneurysm)
- Heart attack (myocardial ischemia/infarction)
- Infection/fever
- Irregular heartbeats, which could be life threatening
- Nerve damage (peripheral neuropathy)
- Persistent vessel spasm
- Plaque that was previously stuck in one place could be allowed to move freely, which could lead to a new clot
- Recurrence of the blockage (restenosis*)
- Re-narrowing of the artery
- Rupture of the superficial femoral artery (dissection)
- Stroke
- Unexpected limb loss (amputation)

** See glossary for definition*

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RESILIENT Trial Adverse Event Summary			
	RESILIENT Randomized		RESILIENT Feasibility
Event	LifeStent® (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® (N=20) % (N pts) [N events]
In-Hospital Events			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0 (0/134) [0]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0 (0/134) [0]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	0 (0/72) [0]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	1.4 (1/72) [1]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Events at 30-Days			
Major Adverse Events	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Death	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Myocardial Infarction	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Target Limb Loss / Amputation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
TVR	0.7 (1/134) [2]	41.7 (30/72) [31]	5.0 (1/20) [1]
TLR	0.7 (1/134) [1]	41.7 (30/72) [30]	0 (0/20) [0]
Non-TLR	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Stroke/CVA	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Distal Embolization	0 (0/134) [0]	1.4 (1/72) [1]	0 (0/20) [0]
Access Site Bleeding / Hematoma	0.7 (1/134) [1]	1.4 (1/72) [1]	5.0 (1/20) [1]
Blood Loss requiring Transfusion	1.5 (2/134) [2]	2.8 (2/72) [2]	0 (0/20) [0]
Vessel Perforation	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Aneurysm	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]
Vessel Pseudo-Aneurysm	0 (0/134) [0]	1.4 (1/72) [1]	5.0 (1/20) [1]
Vessel Dissection	4.5 (6/134) [6]	20.8 (15/72) [16]	5.0 (1/20) [1]
Thrombosis (24 Hrs - 30 Days Only)	0 (0/134) [0]	0 (0/72) [0]	0 (0/20) [0]

The table above shows the adverse events (complaints) that were reported during the time of the stent procedure and 30 days after the stent procedure. These events were part of the RESILIENT stent trial with the LifeStent® Vascular Stent.

- The first column shows the type of complaint observed or reported.

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- The second and fourth columns show you how many people treated with the LifeStent® Vascular Stent had that type of complaint. The first number is the percentage or frequency of the complaint. The numbers in the "( )" show the actual number of patients in the group of 134 (second column) or group of 20 (fourth column) who actually had an adverse event.

- The third column called "PTA" shows the complaints that happened with the patients who did not get treated with the LifeStent® Vascular Stent , and only with a balloon.

You will see that the frequency of adverse events at the time of the procedure was very low.

What Is The Potential Benefit Of Using The LifeStent® & LifeStent® XL Vascular Stent?

The safety and effectiveness of the LifeStent® Vascular Stent was compared to balloon inflation alone in the RESILIENT trial that included 206 patients. The study results showed that patients who received a LifeStent® Vascular Stent had a significantly higher patency rate (normal blood flow) at one year, when compared to balloon inflation alone, (81.5% for LifeStent® Vascular Stent, 36.7% for balloon angioplasty). When looking at the two groups at three years, Major Adverse Clinical Events, which includes death within 30 days, stroke, heart attacks, clot blocking the artery, emergency surgery, and/or worse leg pain, was 24.8% for LifeStent® Vascular Stent patients and 24.8% for balloon angioplasty patients. This means that the study showed the risks associated with the LifeStent® Vascular Stent are similar to the risks associated with balloon inflation alone.

Additionally, the safety and effectiveness of the LifeStent® and LifeStent® XL Vascular Stent Systems were confirmed in the E-TAGIUSS trial that included 37 patients. All patients in the trial were followed for 30 days. The study results showed that the LifeStent® and LifeStent® XL Vascular Stents were able to be accurately put in patient's legs and had very little change in stent length when being implanted (deployment success 100.0%).

Also, an analysis of four sources of existing data: (1) the RESILIENT trial (2) the ELODIE trial which was conducted in Europe, (3) information reported by a United States (U.S.) physician, and (4) information reported by a European Union (EU) physician was included. In total, two-hundred-eighty-five (285) patients with one or more implanted LifeStent® Vascular Stent devices were identified and included in the analysis. In total, there were 46 lesions in this analysis with lesion lengths beyond 160 mm.

The results show that LifeStent® Vascular Stent can be safely implanted in patients and can provide an effective solution to the treatment of long segment lesions.

Long term risks and benefits (i.e., greater than three years) associated with the LifeStent® Vascular Stent are currently unknown.

** See glossary for definition*

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AFTER YOUR LifeStent® or LifeStent® XL VASCULAR STENTING PROCEDURE

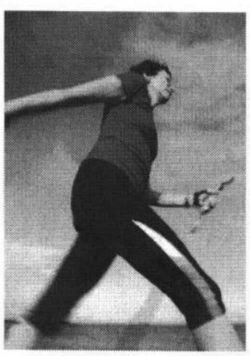
What To Expect During Your Recovery

Before you leave the hospital, your doctor will speak to you about what kind of movement you can do, what you should eat, and what medicine you will need to take. You will be told when you can start to return to normal activities and return to work. Your doctor will prescribe medications for you to take to prevent **blood clots*** from forming in your newly opened blood vessel. It is very important you tell your doctor if these medicines make you feel bad or you have any kind of allergic reaction. Do not stop taking them unless your doctor advises you to do so. Your doctor may be able to provide you other medications that you may be able to take more easily. Also, medications that help to lower your cholesterol and fats may be provided. If you have diabetes, your physician may recommend modifications to medications to help reduce your blood sugar levels.

The artery that has been treated with the stent will begin to slowly grow around the stent and it will become permanent. You will not feel the stent and your daily activities will not be affected. Since you now have a vascular stent implanted in your leg, you should tell this to any doctor who treats you in the future.

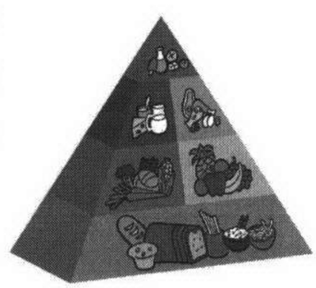
To help yourself stay healthy in the future, it is recommended you change your diet, continually exercise, and live an active life. Those patients who are able to reduce the fats and cholesterol in their diets are less likely to redevelop blockages in the stent. A low-fat, low-cholesterol diet can lower the levels of fat in your blood and reduce your risk. Eating healthy foods in the right size meals will also help you to achieve and maintain a healthy weight.

Necessary Life Style Changes



Decreasing the amount of fat and **cholesterol*** in your diet together with walking exercises are important ways of treating superficial femoral artery stenosis. Your doctor will make specific dietary and exercise suggestions for you. The American Heart Association suggests the following nutrition and lifestyle changes. Complete guidance can be found at the American Heart Association website: www.heart.org.

- Use up at least as many calories as you eat each day
- Eat a variety of nutritious foods from all the food groups.
- Choose vegetables, fruits, and whole-grained products.
- Select low fat or fat free dairy products.
- Include fish in your diet, high with Omega-3 oils, if possible.
- Eat less nutrient-poor foods, high in fat and high in sugars.
- Do not smoke



** See glossary for definition*

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In addition to a healthy diet, it is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

Follow-Up Examinations

You will need to see the doctor who put in your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the status of your disease, and how the stent is working for you.

Keep your Implant Card Handy

Show your implant card if you report to an emergency room. The implant card will let your doctor or health care providers know that you have a stent in your leg.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant and direct them to follow the instructions written on the implant card or included in this booklet.

Safety During Magnetic Resonance Imaging (MRI*)

After placement of your LifeStent® or LifeStent® XL Vascular Stent, your doctor may request a special test that uses electrical waves from a magnet to obtain images of the inside of your body, called an MRI. Your LifeStent® or LifeStent® XL Vascular Stent has been classified as MR-Conditional. This means that an MRI can be done safely if specific testing conditions are followed. These conditions are outlined on the implant card that was provided to you as part of your procedure. Please provide this information to anyone assisting you with a MRI. A copy of the information located on the card is also provided below.

Conditions for All Stents

Non-clinical testing has demonstrated that the LifeStent® Vascular Stent is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Spatial gradient field of 1000 Gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning. For landmarks superior of the umbilicus, a whole body SAR up to 2 W/kg may be applied.
- In a configuration where the patients legs are not in contact with each other.

3.0 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 80 mm length LifeStent® Vascular Stent as determined to produce a potential worst-case temperature rise of 3.2°C for a whole body averaged specific bsorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 3.0 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa HDX Whole Body active shield MR scanner using software version 14/LX/MR and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.8 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 1.9°C when the local SAR was scaled to 2 W/kg.

1.5 Tesla Temperature Rise

In an analysis based on non-clinical testing and computer modeling of a patient, the 170 mm length LifeStent® Vascular Stent was determined to produce a potential worst-case temperature rise of 3.9°C for a whole body averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of MR scanning in a 1.5 Tesla, whole body MR system for a landmark in the legs. Temperature rises can be twice as high at a whole body averaged SAR of 2 W/kg for landmarks below the umbilicus. Temperature rises were reduced for landmarks above the umbilicus. Temperature rises of stents were measured in a non-clinical configuration using a GE Signa whole body coil and a phantom designed to simulate human tissue. The phantom average SAR calculated using calorimetry was 2.2 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.5°C when the local SAR was scaled to 2 W/kg

Additional Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. The LifeStent® Vascular Stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla. The heating effect in the MRI environment for overlapped or fractured stents is not known.

CONTACT INFORMATION

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.

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