LIFESTENT® SOLO™

Vascular Stent System

Instructions for Use

BARD | PERIPHERAL VASCULAR

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LIFESTENT® SOLO™ Vascular Stent System

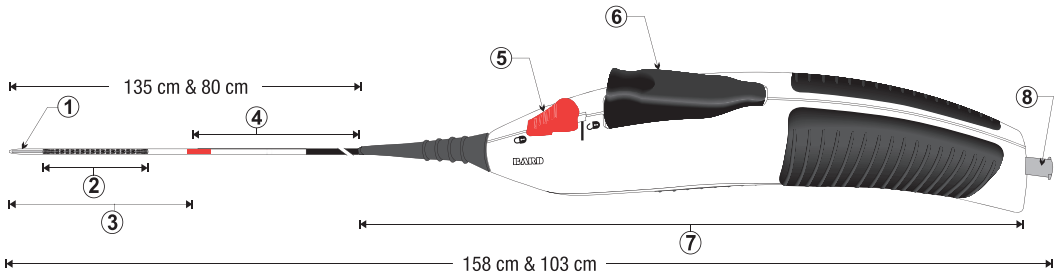


Figure 1

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

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.

Instructions for Use

Please use the product illustration at the beginning of this booklet to guide you through the device description.

A. Device Description

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

An implantable self-expanding nickel-titanium alloy (nitinol) stent (2), 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).

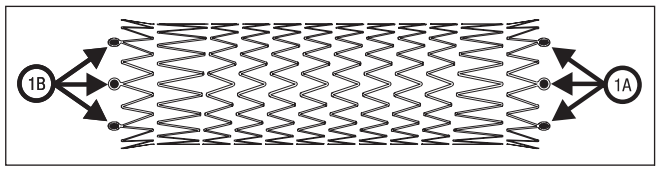


Figure 2. LifeStent® Solo™ Vascular Stent

A delivery system, as shown in Figure 1, is comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath (3) and a system stability sheath (4), which are linked together by means of a handle (7). The guidewire lumen terminates distally in an atraumatic catheter tip (1) and originates proximally in a luer hub (8) designed to accept a compatible guidewire. The self-expanding stent (2) 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. Prior to deployment, the safety lock slider (5) must be unlocked.

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

B. Indication for Use

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

- Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum.
- Patients who cannot receive recommended antiplatelet 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® Solo™ 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** 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.
- During system flushing, observe that saline exits at the catheter tip.

  Note: An insignificant amount may also exit at the junction between the stent delivery sheath and the system stability sheath.
- 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® Solo™ 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® Solo™ 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 2500 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 60 mm length LifeStent® Solo™ Stent was determined to produce a potential worst-case temperature rise of 5.5°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 2.7 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 2.4°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 100 mm length LifeStent® Solo™ Stent was determined to produce a potential worst-case temperature rise of 6.0°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 2.3 W/kg. When the stent was placed in a worst-case location within the phantom, the maximal temperature rise was 3.2°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® Solo™ 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 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® Solo™ 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 are being followed for a total of three years following the index procedure.

The BARD® LIFESTENT® Vascular Delivery System Study supporting trial was single-arm, non-randomized, prospective, multi-center study. Subjects were treated in 8 European centers. The primary safety endpoint was freedom from occurrence of death, amputation and TLR and/or TVR at day 30 and the primary effectiveness endpoint was successful delivery of the stent and assessment of stent length following deployment. 30-day mortality data is available for 98.7% (75/76) of the treated subjects and deployed stent length data is available for 64 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).

RESILIENT Trial Adverse Event Summary			
Event	**RESILIENT Randomized**		**RESILIENT Feasibility**
	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]
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 BARD® LIFESTENT® Vascular Delivery System Study (N=76).

BARD® LIFESTENT® Vascular Delivery System Study - Adverse Event Summary	
Event	**30 Day**
Major Adverse Event	1.3% (1/75)
Death	0% (0/75)
Myocardial Infarction	0% (0/75)
Target Limb Loss	0% (0/75)
Target Lesion Revascularization (TLR)	1.3% (1/75)
Stent Thrombosis	1.3% (1/75)
Distal Embolization	0% (0/75)
Access Site Bleeding	1.3% (1/75)
Non-Access Site Bleeding	0% (0/75)
Vessel Perforation	0% (0/75)
Vessel Aneurysm	0% (0/75)
Vessel Pseudo-Aneurysm	0% (0/75)
Vessel Dissection	0% (0/75)

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
- 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 two 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:

- 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 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 lower intervention rate (TLR/TVR combined rate) 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. BARD® LIFESTENT® Vascular Delivery System Study

Design

The BARD® LIFESTENT® Vascular Delivery System Study was a single-arm, non-randomized, prospective, multi-center study to evaluate the safety and effectiveness of the enhanced BARD® LIFESTENT® SOLO™ Vascular Stent System in the treatment of symptomatic vascular disease of the SFA and proximal popliteal artery. A total of 76 subjects were treated at 8 European investigative sites.

Subjects eligible to be enrolled in this study had to be Rutherford Category 2 - 4. 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 240 mm. Subjects underwent angiographic analysis of the lesion prior to and immediately following treatment. Subjects were followed at 30 days with an office visit including DUS.

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.

Subject Demographics		
Variable	**Category**	**Total**
Age at procedure (Yrs)	Mean +/- SD	71.0
		Range 50.0 - 87.0
Gender, % (n/N)	Female	32.9 (25/76)
	Male	67.1 (51/76)
Race	Caucasian	100% (76/76)
Hypertension, % (n/N)		84.2% (64/76)
Hypercholesterolemia, % (n/N)		38.2% (64/76)

Subject Demographics		
Variable	**Category**	**Total**
Coronary Artery Disease, % (n/N)		50.0% (38/76)
Diabetes, % (n/N)		38.2% (29/76)
Myocardial Infarction, % (n/N)		15.8% (12/76)
Target Limb Rutherford Category, % (n/N)	Class 0	1.3% (1/76)
	Class 2	17.1% (13/76)
	Class 3	72.4% (55/76)
	Class 4	6.6% (5/76)
Target Limb ABI (mm Hg)	Mean +/- SD (N)	0.6 +/- 0.2 (72)
Contralateral Limb ABI (mm HG)	Mean +/- SD (N)	0.8 +/- 0.2 (73)

Lesion Characteristics		
Variable	**Category**	**Total**
Number of Lesions, % (n/N)	1	96.2% (76/79)
	2	3.8% (3/79)
Target Side, % (n/N)	Left	43.4% (33/76)
	Right	56.6% (43/76)
Lesion Location, % (n/N)	Popliteal	2.6% (2/76)
	SFA	84.3% (64/76)
	SFA & Popliteal	11.9 (9/76)
Lesion Classification, % (n/N)	Occlusion	35.5% (27/76)
	Reoccluded	1.3% (1/76)
	Restenosed	2.6% (2/76)
	Stenosed	60.5% (46/76)
Lesion Severity/TASC Grade, % (n/N)	TASC A	32.9% (25/76)
	TASC B	32.9% (25/76)
	TASC C	31.6% (24/76)
	TASC D	2.6% (2/76)
Target Vessel RVD (mm)	N, Mean +/- SD	76, 5.6 +/-0.5
Lesion % Diameter Stenosis	N, Mean +/- SD	76, 91% +/- 9.7
Lesion Length (mm)	N, Mean +/- SD	75, 90.7 +/- 60.0

Methods

Subjects underwent PTA plus LIFESTENT® SOLO™ 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. Independent core laboratories were utilized to analyze angiographic data.

Results

As shown in the principal Safety and Effectiveness table (Section J) the LIFESTENT® SOLO™ Vascular Stents 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
Hypercholest-erolemia (%)	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

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

Characteristic	RESILIENT	ELODIE I	US Series	EU Series	TOTAL
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® 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 $\leq$ 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 $\geq$ 0.10 and not deteriorated by $>$ 0.15.

Procedure Success*: Attainment of $\leq$ 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.

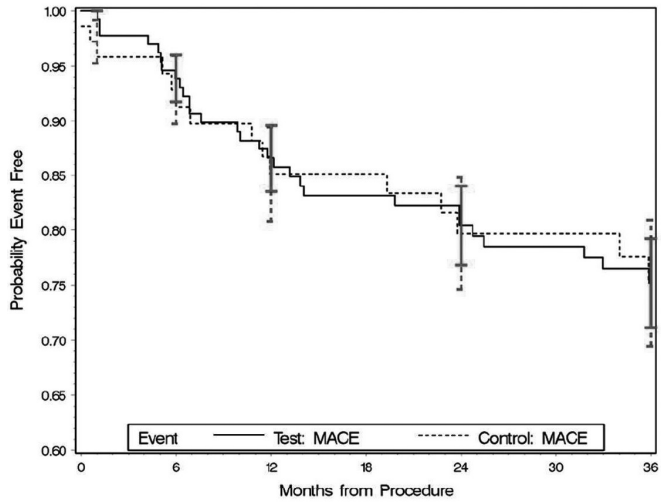
Primary Patency*: The continued flow through the target lesion as evidenced by DUS or angiogram without further/repeat intervention over time.

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

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)

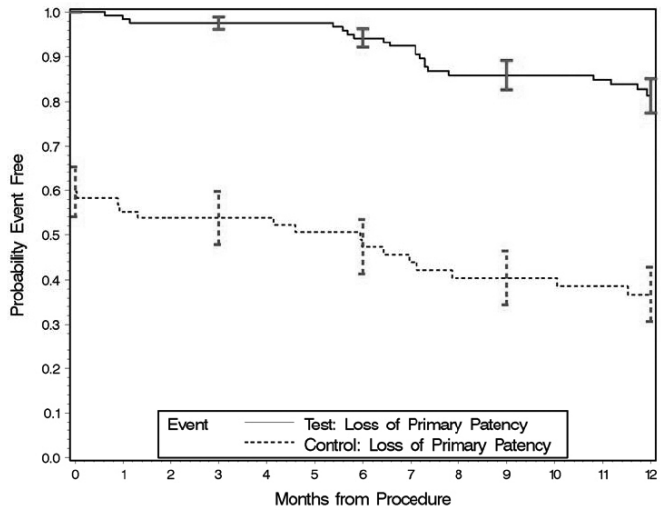
Time Until MACE



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.			

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.			

Apply “Patient/Inv. chart” sticker here

Bard Peripheral Vascular, Inc.
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Non-clinical testing has demonstrated that the LIFESTENT® SOLO™ Vascular stent is MR Conditional. It can be scanned safely under the following conditions:

MR Conditional

- Static magnetic field of 1.5 or 3-Tesla.
- Spatial gradient field of 2500 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.

The LIFESTENT® SOLO™ Vascular Stent has not been evaluated in MRI systems other than 1.5 or 3.0 Tesla.

Patient's Name: _____

Date of Implant(s): _____

Site of Implant(s): _____

Implanting Physician: _____

Hospital: _____

Address: _____

_____

Telephone: _____

LIFESTENT® SOLO™ Vascular Stent System

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 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. Bard® LifeStent® Vascular Delivery System Study

Bard® LifeStent® Vascular Delivery System Study Principal Safety and Effectiveness Table	
Variable	**Test % (n/N)**
Acute effectiveness	100 (64/64)
Placement accuracy	97.7 (84/86)
MACE at 30 days	1.3 (1/75)
Freedom from TLR and TVR at day 30	98.7 (74/75)
Acute lesion success	96.1 (73/76)
Acute procedure success	94.7 (72/76)
Sustained hemodynamic success	71.0 (49/69)
Acute clinical success	89.8 (44/49)
Sustained clinical success	94.1 (64/68)
Sustained primary TLP at day 30	100 (73/73)

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

Acute effectiveness: Defined as successful delivery of the stent with the post-deployment stent length being within 10% of the pre-deployment length (with hypothesis testing)

Placement accuracy: Determination of placement accuracy based on a rating scale completed by the Investigators

MACE: Freedom from occurrence of death, amputation and TLR and/or TVR at Day 30 (with hypothesis testing)

Freedom from TLR and TVR at day 30*: TLR is defined as the first revascularization procedure of the target lesion. TVR is defined as the first revascularization procedure to the target vessel

Acute lesion success*: Attainment of ≤ 30% residual stenosis of the target lesion using any percutaneous method and/or non-investigational device (i.e. post-dilatation)

Acute procedure success*: Lesion success and no peri-procedural complications (death, stroke, myocardial infarction [MI], emergent surgical revascularization, significant distal embolization in target limb, or thrombosis of target vessel)

Sustained hemodynamic success*: Sustained improvement of Ankle-Brachial Index (ABI) from Baseline to Day 30 of ≥ 0.15

Acute clinical success*: Cumulative improvement from Baseline of ≥ 1 Category according to Rutherford following index procedure (at discharge)

Sustained clinical success*: Sustained cumulative improvement from Baseline of ≥ 1 Category according to Rutherford at Day 30, Month 12, 24 and 36

Sustained TLP at Day 30*: Corresponding to PSR ≤ 2.5 (PSR is determined by comparing velocities within the treated segment to the proximal normal arterial segment. A PSR of > 2.5 suggests > 50% stenosis)

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 BARD® LIFESTENT® Vascular Delivery System Study investigations. Demographics for the two investigations are provided in Section I – Clinical Studies of this "Instructions for Use" document. Additionally, treatment of the patients should follow the treatment practices used by the RESILIENT and BARD® LIFESTENT® Vascular Delivery System Study investigators. These methods have been reiterated below in Section L – Patient Counseling Information and Section N – Directions 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.
- Discuss the risks of early discontinuation antiplatelet therapy.
- Recommendation to register the stent implant under MedicAlert Foundation (www.medicalert.org) or equivalent organization.

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

- A Patient Guide which includes information on the LIFESTENT® SOLO™ Vascular Stent System, peripheral artery occlusive disease, the implantation procedure and patient care following the implant.
- A Patient implant Card at the end of the IFU, that is used to record and disseminate information about the patient and the stent.

M. How Supplied

STERILE: FOR SINGLE USE ONLY. The LIFESTENT® SOLO™ 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® SOLO™ Vascular Stent System:

- One (1) LIFESTENT® SOLO™ Vascular Stent System
- One (1) Instructions for Use including one (1) Patient Implant Card
- 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. Directions 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:	
Reference Vessel Diameter	Unconstrained Stent Inner Diameter
4.0 – 5.5 mm	6 mm
5.5 – 6.5 mm	7 mm

Refer to product labeling for stent length

4. Materials Required

In addition to the LIFESTENT® SOLO™ Vascular Stent System, the following standard materials may also be required to facilitate delivery and deployment of the LIFESTENT® SOLO™ Vascular Stent System: heparinized normal saline, 6F (2.0 mm) or larger introducer sheath, 0.035 inch 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.
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 sealed tray containing the stent system.

d) Carefully inspect the sealed seam of the tray for damage to the sterile barrier. Peel open the sealed tray. The lid covers the proximal part of the grip. Remove the lid and extract the stent system from the tray.

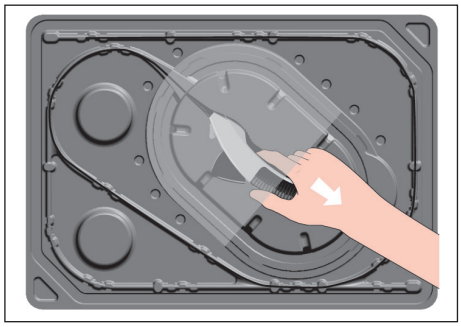


Figure 3. Removal of the Grip

Note: **DO NOT** rotate the grip while extracting the stent system from the tray.

e) Check the following:

i) Verify that the safety lock slider is still in the locked position.

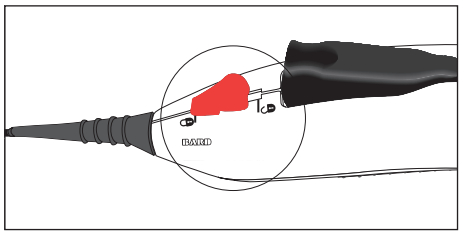


Figure 4. Handle with locked safety lock slider

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 must not be used.

f) 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.

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

h) 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 femoral access utilizing 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
135 cm	300 cm
80 cm	200 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. Always use for contralateral access the stent system in conjunction with a long introducer sheath which covers the aortic bifurcation.

Note: If resistance is met during stent system introduction, the stent system should be withdrawn 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.

Note: The device was tested for a puncture radius of ≥ 15 mm which typically correlates with a very steep entry angle.

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

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

b) Unlock the safety lock slider by pulling it back towards the trigger from the locked position into the unlocked position. Ensure that the red safety lock slider is completely pulled back and the proximal end of the red lock lines up with the printed line on the handgrip.

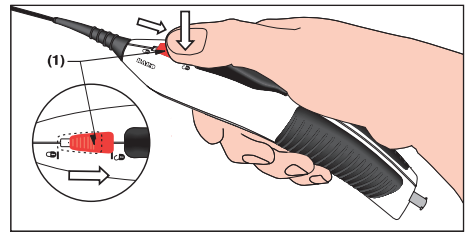


Figure 5. Handle with unlocked safety lock slider

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) The second hand should be used to support the stent delivery system. Gently hold the stability sheath at or proximal to the orange marking and maintain it straight and under tension throughout the procedure.

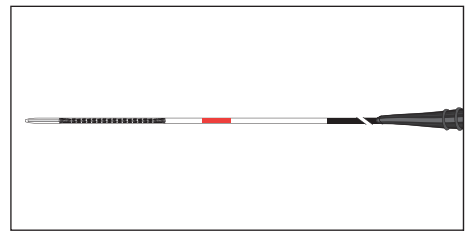


Figure 6. System Stability Sheath with orange marking

Note: **DO NOT** constrict the delivery system during stent deployment. If excessive force is felt during stent deployment, do not force the stent system. Remove the stent system and replace with a new unit.

e) Initiate stent deployment by pushing the trigger. Six micro-triggers result in one full trigger.

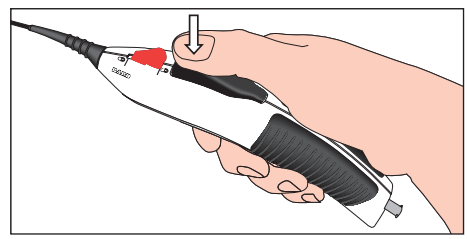


Figure 7. Stent Release

f) While using fluoroscopy, maintain position of the distal and proximal stent radiopaque markers relative to the targeted site. Continue pushing the trigger until the distal end of the stent obtains complete wall apposition.

g) With the distal end of the stent apposing the vessel wall, final deployment can be continued with full triggers.

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

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

5. Post stent placement

a) Remove the delivery 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.

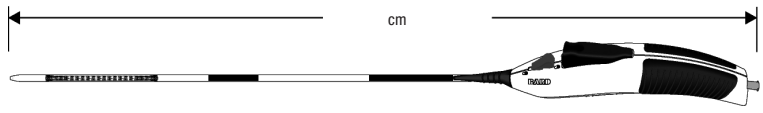
e) Discard the delivery system, guidewire and introducer sheath.

Note: Physician experience and discretion will determine the appropriate drug regimen for each patient.

Symbols used on labelling

Consult Instructions For Use		Catalogue Number	
Keep Away From Sunlight		Lot Number	
Keep Dry		Sterilized Using Ethylene Oxide	
Do Not Use If Package Is Damaged		Use By	
Single Use		Manufacturer	
Do Not Resterilize		Minimum Introducer Size	
Contents: (1)		Guidewire Compatibility	
MR Conditional		Stent Length	
Does Not Contain Natural Rubber Latex		Stent Diameter	
Non Pyrogenic		DO NOT rotate the grip while extracting the stent system from the tray.	

Working Length



System Length

Labeling Issue Date:
2011-09

LIFESTENT® SOLO™

Vascular Stent System

Distributed in the USA by:

Bard Peripheral Vascular, Inc.
Subsidiary of C. R. Bard, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA
TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-966-7062
1-800-440-5376
www.bardpv.com

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

BARD | PERIPHERAL VASCULAR

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