LIFESTENT® | 5F

Vascular Stent System

INSTRUCTIONS FOR USE

BARD | PERIPHERAL VASCULAR

B05881 Rev.2/04-20

INSTRUCTIONS FOR USE

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

This device is supplied in sterile condition. All materials inside the sterile barrier pouch (the delivery system and stent (Figure 2), 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® 5F Vascular Stent System is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery system. The LifeStent® 5F Vascular Stent System is comprised of the following:

An implantable self-expanding nitinol (nickel-titanium) alloy stent, as shown in Figure 1. 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 markers located on the ends of the stent, six at each end. Three at each end are radiopaque tantalum markers (1A) and three are made out of nitinol (nickel-titanium) (1B).

Figure 1: LifeStent® Vascular Stent

A triaxial, over-the-wire delivery system (Figure 2) comprised of an inner tubing assembly that contains the guidewire lumen, a stent delivery sheath (D + E) and a system stability sheath (C), which are linked together by a handle. The guidewire lumen originates proximally with a Luer hub (B) and terminates distally with an atraumatic catheter tip (A). The 0.035 inch guidewire lumen is designed to accept guidewires of 0.014 inch (0.36mm) - 0.035 inch (0.89mm) diameter.

Figure 2: LifeStent® 5F Vascular Stent System

The self-expanding stent is constrained in the space between the guidewire lumen and the stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery system. Prior to deployment, the safety lock slider (F) must be unlocked. Deployment of the stent is initiated by rotating the large thumbwheel (G) on the handle. The distal catheter will retract using either the large thumbwheel for slow deployment of the stent or the small thumbwheel (H) for faster deployment of the stent.

The GeoAlign® Marking System is a non-radiopaque ruler on the catheter shaft measured from the distal tip. The GeoAlign® markings are designated on the catheter shaft by 1 cm increment bands. The distance from the distal catheter tip is labeled in 10 cm increments. Thicker bands denote the midway point (5 cm) between the labeled distances (Figure 3). The GeoAlign® Marking System can provide an intravascular reference regarding the location of the distal tip of the catheter. The GeoAlign® Marking System may also facilitate geographic alignment of an adjunctive therapy that includes the same GeoAlign® Marking System.

Note: The GeoAlign® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy. The GeoAlign® Marking System includes non-radiopaque white markings that are designed to be utilized outside the sheath.

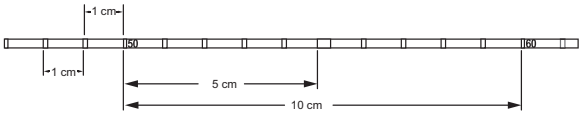


Figure 3: GeoAlign® Marking System on LifeStent® 5F Vascular Stent System Catheter Shaft

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

B. INDICATION FOR USE

The LifeStent® 5F Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenostic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 - 6.5 mm.

C. CONTRAINDICATIONS

The LifeStent® 5F 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

- The LifeStent® 5F 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 device after the "Use By" date specified on the label.
- Persons with allergic reactions to nitinol (nickel-titanium) 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 safety and effectiveness of stent overlapping in the middle (P2) and distal popliteal artery (P3) has not been established.
- The long-term outcomes following repeat dilatation of endothelialized stents are unknown.
- It is recommended to use the 80cm working length device for ipsilateral procedures. The longer working length of the 135 cm device may potentially be challenging for the user to keep straight for ipsilateral procedures. Failure to keep the device straight may impede optimal deployment of the implant, potentially resulting in an elongated or foreshortened implant.
- Operator deployment techniques other than those indicated by the Instructions For Use are advised against. Stent elongation or stent foreshortening are potential consequences as a result of not following the deployment Instructions For Use.

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.
- 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.
- Keep the device as straight as possible following removal from the packaging and while inserted in the patient. Failure to do so may impede the optimal deployment of the implant.
- Prior to and during stent deployment, remove slack from the delivery system catheter outside the patient by gently holding the stability sheath and keeping it straight and under tension.
- 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).
- The safety and effectiveness of this device for use in treatment of in-stent restenosis has not been established.
- The GeoAlign® Marking System is designed to be used as an additional reference tool to accompany the interventionalist's standard operation procedure. The use of fluoroscopic imaging is recommended following positioning of the catheter to the target lesion and prior to stent deployment or balloon inflation.
- If the GeoAlign® location reference is on the brown moving sheath (Figure 9), the location reference will move relative to the introducer hub and stability sheath as soon as stent deployment has been initiated. **DO NOT** try to re-align the location reference after stent deployment has been initiated. The green stability sheath should remain stationary relative to the introducer and under tension throughout deployment.
- Guidewire compatibility and device performance have been evaluated clinically with 0.035 inch guidewires only. Compatibility with 0.014 inch guidewires is based on non-clinical testing only.

F. MRI CONDITIONS

Non-clinical testing has demonstrated that the LifeStent® Vascular Stent is MR Conditional. The LifeStent® Vascular Stent can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 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

Under the scan conditions defined above, the LifeStent® Vascular Stent is expected to produce a maximum temperature rise in the patient of 2.7 °C after 15 minutes of continuous scanning.

1.5 Tesla Temperature Rise

Under the scan conditions defined above, the LifeStent® Vascular Stent is expected to produce a maximum temperature rise in the patient of 3.0 °C after 15 minutes of continuous scanning.

Image Artifact

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. Artifact tests were performed according to ASTM F2119-07. In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the LifeStent® Vascular Stent when imaged with a spin echo sequence and 8 mm when imaged with a gradient echo sequence in a 3.0 Tesla MRI system. The lumen was obscured.

Additional Information

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 fractured stents is not known.

G. OVERVIEW OF CLINICAL STUDIES

Six separate 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 percutaneous transluminal angioplasty (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 US 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.

The Bard® LifeStent® Vascular Delivery System Study supporting trial was a 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.

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.

The REALITY study, a single-arm, non-randomized, prospective, single-center study was conducted to demonstrate the safety and effectiveness of the Bard® LifeStent® Vascular stent systems with a 5mm diameter size offering. The primary objective of this study was to assess the acute effectiveness of the Bard® LifeStent® Vascular Stent Systems. Primary effectiveness was defined as successful deployment and placement accuracy based upon a rating scale completed by the investigators at the time of the index procedure. Primary safety was defined as freedom from occurrence of death, amputation and TVR/TLR at 30 days post-index procedure.

A physician sponsored study, the ETAP trial, was a prospective, randomized, multi-center study designed to compare the LifeStent® Vascular Stent Systems to percutaneous transluminal angioplasty (PTA) in the treatment of patients with stenosis and occlusion of the popliteal artery. 246 subjects were randomized between the two study arms at 9 European centers. In total, 119 subjects were treated with the LifeStent® Vascular Stent and 127 with PTA. The primary endpoint was the restenosis rate at 12 months. Subjects were followed for 24 months.

The REALITY III study, a single-arm, non-randomized, prospective, multi-center study was conducted to assess the deliverability, clinical utility and effectiveness of the LifeStent® 5F Vascular Stent System in the treatment of de novo or restenotic lesions of the SFA and/or popliteal artery. Primary safety was defined as freedom from occurrence of death, amputation and TLR/TVR at 30 days post-index procedure. Primary effectiveness (technical success) was defined as successful deployment and placement accuracy based upon a rating scale completed by the investigators at time of the index procedure.

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® Vascular Stent (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® Vascular Stent (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]

TABLE CONT. NEXT COL.

RESILIENT Trial Adverse Event Summary			
Event	RESILIENT Randomized		RESILIENT Feasibility
	LifeStent® Vascular Stent (N=134) % (N pts) [N events]	PTA (N=72) % (N pts) [N events]	LifeStent® Vascular Stent (N=20)% (N pts) [N events]
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)

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)

The following adverse events were documented during the course of the ETAP Trial.

ETAP Trial Safety Events						
	P1			P2/P3		
	Number (%) pts		p-value	Number (%) pts		p-value
	PTA/Stent (n=9)	Stent (n=36)		PTA/Stent (n=22)	Stent (n=85)	
Severe Cardiovascular Events*						
12 month	3 (37.5%)	8 (22.9%)	0.4010	6 (31.6%)	19 (25.7%)	0.5770
Evaluable Subjects^	n=8	n=35		n=19	n=74	
24 month	4 (50.0%)	9 (31.0%)	0.4132	6 (40.0%)	22 (34.9%)	0.7689
Evaluable Subjects^	n=8	n=29		n=15	n=63	
Adverse Events**						
12 month	7 (77.8%)	18 (51.4%)	0.2600	13 (61.9%)	43 (56.6%)	0.8510
Evaluable Subjects^	n=9	n=35		n=21	n=76	
24 month	7 (77.8%)	23 (76.7%)	1.0000	16 (80.0%)	45 (65.2%)	0.3270
Evaluable Subjects^	n=9	n=30		n=20	n=69	
Death***						
12 month	0 (0.0%)	1 (3.0%)	1.0000	1 (5.3%)	2 (2.7%)	0.4962
Evaluable subjects^	8	33		19	75	
24 month	0 (0.0%)	3 (11.5%)	1.0000	2 (12.5%)	4 (7.0%)	0.6065
Evaluable subjects^	8	26		16	57	

**defined within the report as injury, poisoning, procedural complications.*

***At least one occurrence of an AE*

**** P1 and P2/P3 subset compliance was not stratified at the 24 month interval due to the fact that the deaths verified from Protocol Version 1.0 could not be confirmed to specific patient ID numbers.*

^ Evaluable accounts for missing data

REALITY III Study

Freedom from the occurrence of death, amputation, and TLR and/or TVR at Day 30 post index procedure was present in all 30 subjects. There were 10 adverse events, including two serious adverse events (SAE), noted in eight subjects. No adverse events were related to the device.

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
- Bypass 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 bypass 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 Stent System (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 ± 0.21
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. 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 segments was to be less than 200 mm. Subjects underwent angiographic analysis of the lesions 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)	N, Mean ± SD	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 (31/87)
Hypercholesterolemia, % (n/N)		56.8 (21/37)
Smoking, % (n/N)		48.6 (18/37)

TABLE CONT. NEXT PAGE

E-TAGIUSS Trial Subject Demographics		
Variable	**Category**	**Total**
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)	N, Mean ± SD	35, 0.6 ± 0.2
Contralateral Limb ABI (mm Hg)	N, Mean ± SD	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 Stenoses	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 tables (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 measure demonstrated positive results.

d. Bard® LifeStent® Vascular Stent 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)
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.

e. 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 (US) 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	100.0	77.3	100.0	86.6
N reported	198	3	66	10	277
Hypertension (%)	85.4	72.7	84.9	100.0	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	30	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		0.0	3.2
Class 2 (%)	40.4	45.5		10	39.3
Class 3 (%)	56.1	36.4		60	55.3
Class 4 (%)	0.0	0.0		0.0	0.0
Class 5 (%)	0.0	18.2		30	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	13.4
ABI of Target Limb					
N reported	183	NR	51	10	244
Mean	0.72		0.61	0.41	0.69
Std 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	108.8	152.6	214	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	1.1
Percent Stenosis (max per limb):					
N reported	198	11	0	10	219
Mean	87.8	92.7		96	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 (%)		1 (9.1%)	23 (39.0%)		24 (34.3%)
N Grade B (%)		3 (27.3%)	11 (18.6 %)		14 (20.0%)
N Grade C (%)	NR	7 (63.6%)	6 (10.2%)	NR	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® Vascular 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® Vascular Stent. 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® Vascular Stent at 30-days post-procedure to the VIVA OPC
- Estimating the freedom from death and amputation at 12-months post-procedure in patients with long lesions treated with the LifeStent® Vascular Stent 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%.

f. REALITY Study

Design

The REALITY study was a single-arm, non-randomized, prospective, single center study to assess the deliverability, clinical utility, and effectiveness of the 5 mm diameter size offering of the LifeStent® Vascular Stent System in subjects with lifestyle-limiting claudication or minor tissue loss (Rutherford Category 2-5) who were candidates for PTA and stenting with lesion(s) in the infra-inguinal segment (SFA and/or popliteal artery). A total of 30 subjects were treated at 1 European investigative site.

Subjects eligible to be enrolled in this study had to be Rutherford Category 2 – 4. The target vessel reference diameter was (by visual estimate) appropriate for treatment with an available stent diameter of 5.0 mm. The reference vessel diameter (RVD) of the treated subjects was 4.0 – 4.5 mm in diameter. Subjects were followed out to 30 days.

Demographics

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

REALITY Study Subject Demographics		
Variable	**Category**	**Total**
Age at Procedure (yrs)	Mean	69
	Standard Deviation	10.5
Gender, % (n/N)	Female	60.0 (18/30)
	Male	40.0 (12/30)
Race, % (n/N)	Caucasian	96.7 (29/30)
	Asian	3.3 (1/30)
Hyperlipidemia		~57%
Hypercholesteremia		~87%
Diabetes		~37%

REALITY Study Lesion Characteristics		
Variable	**Category**	**Total**
Number of Lesions	1	30/32
	2	2/32
Target Side	Left	62.5 %
	Right	37.5%
Lesion Length (mm)	Mean, Standard Deviation	64.8, 50.0
Target Vessel (RVD)	Mean, Standard Deviation	4.5, 0.2
Lesion Classification	Stenosed	68.8%
	Occluded	28.1%
	Reoccluded	3.1%
Lesion Severity/TASC Grade	TASC A	43.8%
	TASC B	34.4%
	TASC C	15.6%
	TASC D	6.3%
Lesion Calcification	No Calcification	34.4%
	Mild Calcification	21.9%
	Moderate Calcification	18.8%
	Severe Calcification	25.0%

Methods

Subjects underwent PTA plus LifeStent® Vascular Stent placement in the target lesion(s). All data were collected on case report forms at the investigative site.

Results

The LifeStent® Vascular Stent System is effective, as technical success was shown, i.e. deployment accuracy was good or excellent and placement accuracy was successful at the target site. Additionally, freedom from TLR and/or TVR was achieved. The LifeStent® Vascular Stent is safe in the acute period (index procedure through the 30-day follow-up period) as demonstrated through freedom from occurrence of death, amputation, and TLR and/or TVR. No ADEs were reported during this period.

g. ETAP Randomized Physician-Sponsored Study

Design

The ETAP* physician-sponsored study was conducted at nine European centers as a prospective, randomized, controlled study to investigate the use of LifeStent® Vascular Stent Systems in patients with stenosis and occlusion of the popliteal artery in comparison to percutaneous transluminal angioplasty (PTA) alone.

A total of 246 patients were recruited and randomized into the two treatment groups, PTA or stent. 119 patients were randomized to the stent group and 127 patients were randomized to the PTA group. For patients randomized to the PTA group, a balloon angioplasty was performed, representing standard clinical care of these lesions. If a lesion had a residual stenosis of > 50% after repeated and persistent (5 minutes) inflations or a flow-limiting dissection, a provisional stent was used to treat the lesion. Of the 246 patients recruited in the study, 152 patients received a LifeStent® Vascular Stent while 93 patients received PTA alone. Results are provided to individually show the results for the P1 segment and P2/P3 segments in order to compare the outcomes.

*Rastan A, Krankenberg H, Baumgartner I, et al. Stent placement vs. balloon angioplasty for popliteal artery treatment: Two-year results of a prospective, multicenter, randomized trial. J Endovasc Ther. 2015; 22:22-27.

ETAP Trial Demographics			
Characteristic (ITT population)	**PTA (N=127)**	**Stent (N=119)**	**Total (N=246)**
Age (years) Median	73	72	72
Range	41 - 89	42 - 89	41 - 89
Gender N (%)			
Female	45 (35.4)	43 (36.1)	88 (35.8)
Male	82 (64.6)	76 (63.9)	158 (64.2)
Rutherford Category N (%)			
Category 1	3 (2.4)	4 (3.4)	7 (2.8)
Category 2	12 (9.4)	24 (20.2)	36 (14.8)
Category 3	76 (59.8)	68 (57.1)	144 (58.5)
Category 4	8 (6.3)	4 (3.4)	12 (4.9)
Category 5	22 (17.3)	16 (13.4)	38 (15.4)
Category 6	-	1 (0.8)	1 (0.4)
Missing	6 (4.7)	2 (1.7)	8 (3.3)
Hypertension (%)	112 (88.2)	98 (82.4)	210 (85.4)
Hypercholesterolemia (%)	104 (81.9)	90 (75.6)	194 (78.9)
Smoking (%)	29 (23)	26 (21.8)	55 (22.4)

ETAP Trial Lesion Characteristics		
Variable (ITT Population)	**PTA (N=127)**	**Stent (N=119)**
Mean Lesion Length (mm)	43.2	41.3
(STD)	(28.1)	(31.3)
Stenosis (%)	92.5	92.9
(STD)	(7.9)	(7.2)
Lesion Location, (% patients)		
Popliteal I	37 (29.1)	35 (29.4)
Popliteal II	54 (42.5)	48 (40.3)
Popliteal III	6 (4.7)	7 (5.9)
Popliteal I + II	23 (18.1)	20 (16.8)
Popliteal II + III	6 (4.7)	7 (5.9)
Popliteal I + II + III	1 (0.8)	2 (1.7)
Lesion Calcification, (%, patients)		
Missing	35 (27.6)	32 (26.9)
Unable to Determine	1 (0.8)	-
None	14 (11.0)	8 (6.7)
Little	21 (16.5)	33 (27.7)
Moderate	11 (8.7)	14 (11.8)
Severe	45 (35.4)	32 (26.9)

Methods

Patients underwent PTA or stenting and received acetylsalicylic acid (ASS; if not already on long-term treatment) and additionally received clopidogrel before the intervention and for a minimum of 4 weeks after the intervention as long-term medication. Patients were followed for 24 months with scheduled visits after 6, 12, and 24 months.

Results

Patients in the stent group had a lower restenosis rate than patients in the PTA group, when the crossover procedure was considered to be a TLR and by definition a restenosis. Also, analysis of secondary endpoints suggested a beneficial clinical trend in favor of stent placement; however, conclusions regarding significance of individual endpoints may not be made. Provisional stent placement with a LifeStent® Vascular Stent was observed during this study in 27% of the randomized PTA population. No concerning trends were noted regarding overall safety when the LifeStent® Vascular Stent was compared to PTA for multiple safety endpoints.

h. REALITY III Study

Design

The REALITY III study was a single-arm, prospective, multi-center study of the LifeStent® 5F Vascular Stent System in the treatment of symptomatic de novo or restenotic lesions in the SFA and/or popliteal artery. A total of 30 subjects were treated at 4 European investigative sites.

The study population was comprised of subjects who presented with moderate lifestyle-limiting claudication to mild tissue loss (Rutherford Category 2-5) that were candidates for PTA and stenting. Subjects with lesion(s) in the infra-inguinal segment (SFA and/or popliteal artery) were considered for enrollment. The reference vessel diameter had to be appropriate for treatment with available stent diameters (5, 6, and 7mm) (by visual estimate).

Demographics

Characteristics of the subjects enrolled in the REALITY III Study including age, gender, medical history, as well as lesions characteristics are provided in the tables below.

REALITY III Study Subject Demographics		
Variable	**Category**	**Total**
Age at procedure (Yrs)	Median (range)	69.5 (50.0-85.0)
Gender, % (n/N)	Female	30 (9/30)
	Male	70 (21/30)
Race, % (n/N)	Caucasian	96.7 (29/30)
	Asian	3.3 (1/30)
Hypertension, % (n/N)		70.0 (21/30)
Hyperlipidemia, % (n/N)		93.3 (28/30)
Smoking, % (n/N)		80.0 (24/30)
Cardiac disease, % (n/N)		63.3 (19/30)
Respiratory illness, % (n/N)		20.0 (6/30)
Renal disease, % (n/N)		33.3 (10/30)
Vascular disease, % (n/N)		63.3 (19/30)
Diabetes, % (n/N)		33.3 (10/30)
Other disease % (n/N)		80.0 (24/30)
Target Limb Rutherford Category, % (n/N)	Class 0	0.0 (0/30)
	Class 1	0.0 (0/30)
	Class 2	10.0 (3/30)
	Class 3	76.7 (23/30)
	Class 4	6.7 (2/30)
	Class 5	3.3 (1/30)

REALITY III Study Lesion Characteristics		
Variable	**Category**	**Total**
Target Side, % (n/N)	Left	60.0 (18/30)
	Right	40.0 (12/30)
Target Vessel RVD (mm)	N, Mean (SD)	30, 5.67 (0.62)
Lesion % Diameter Stenosis	N, Mean	30, 94.4
Lesion Length (mm)	N, Mean (SD)	30, 126.8 (101.9)
Lesion Location % (n/N)	SFA only	73.3 (22/30)
	Popliteal I Only	3.3 (1/30)
	SFA + Popliteal I	16.7 (5/30)
	SFA + Popliteal I + Popliteal II	6.7 (2/30)

TABLE CONT. NEXT COL.

REALITY III Study Lesion Characteristics		
Variable	**Category**	**Total**
Lesion Classification, % (n/N)	Stenosed	46.7 (14/30)
	Restenosed	3.3 (1/30)
	Occluded	46.7 (14/30)
	Reoccluded	3.3 (1/30)
Lesion Calcification, % (n/N)	None	6.7 (2/30)
	Mild	30.0 (9/30)
	Moderate	50.0 (15/30)
	Severe	13.3 (4/30)
TASC Classification, % (n/N)	TASC A	36.7 (11/30)
	TASC B	33.3 (10/30)
	TASC C	16.7 (5/30)
	TASC D	13.3 (4/30)

Results

Technical success was present for 33 of 37 LifeStent® 5F Vascular Stent System deployments, (i.e. the investigator rated the deployment accuracy as 'good' or 'excellent' and the placement accuracy as 'successfully at target site'). The technical success rate was 89.2%. In a post-hoc analysis, technical success was re-defined to include 'fair' deployment accuracy to achieve technical success. Per this definition, all 37 stents (100%) demonstrated the required deployment accuracy and the post-hoc technical success rate therefore increased to 94.6% of stent placements (35 of 37 stents).

Freedom from the occurrence of death, amputation, and TLR and/or TVR at Day 30 post index procedure was present in all 30 subjects.

The LifeStent® 5F Vascular Stent System is effective, as was shown by technical success. Additionally, freedom from TLR and/or TVR was achieved. The LifeStent® 5F Vascular Stent System is safe in the acute period (index procedure through the 30-day follow-up period) as demonstrated by freedom from occurrence of death, amputation, and TLR and/or TVR. No ADEs were reported during this period.

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 12 Months, % (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.

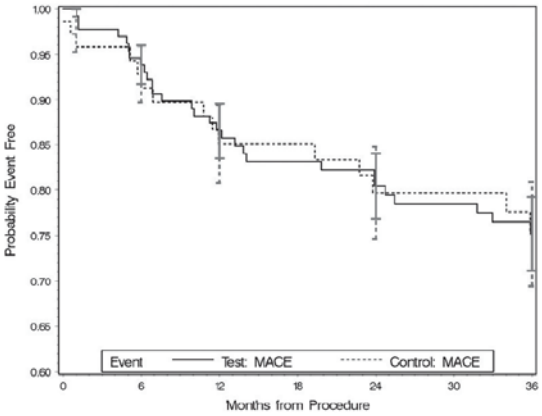
Primary Patency*: The continued flow through the target lesion as evidenced by DUS or angiogram without further/repeat intervention over time.

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

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)

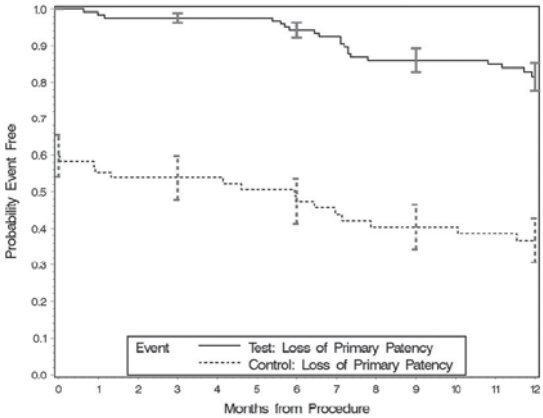
Time Until MACE



RESILIENT MACE Event Rate			
MACE	**Event Free**	**Event Rate**	**P-Value***
Test (LifeStent® Vascular Stent System)	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



RESILIENT Loss of Primary Patency Event Rate			
Loss of Primary Patency	**Event Free**	**Event Rate**	**P-Value***
Test (LifeStent® Vascular Stent)	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 occurring 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 US, 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® Vascular Stent 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® Vascular Stent in commercial use.

Conclusions

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® Vascular Stent. 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® Vascular Stent 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® Vascular Stent 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 lengths being within 10% of the pre-deployment lengths.

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. 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)

d. 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 50-100 mm), 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*

e. REALITY Study

Technical Success: All 36 stents deployed in the study were successfully deployed.

Placement Accuracy: The deployment accuracy was evaluated and found to be acceptable in all cases.

Freedom from Death through 30 days post index procedure: All subjects showed freedom from occurrence of death.

Freedom from Amputation through 30 days post index procedure: All subjects showed freedom from occurrence of amputation.

Freedom from TLR/TVR through 30 days post index procedure: All subjects showed freedom from TLR and/or TVR.

Primary Effectiveness Endpoint: Technical success, defined as successful deployment and placement accuracy based upon a rating scale completed by the investigators at the time of the index procedure. Bookend sizes were evaluated for clinical utility of the size range. All stents had good or excellent deployment accuracy with successful placement at the target site. In none of the patients, TLR and/or TVR was conducted until day 30 from the index procedure.

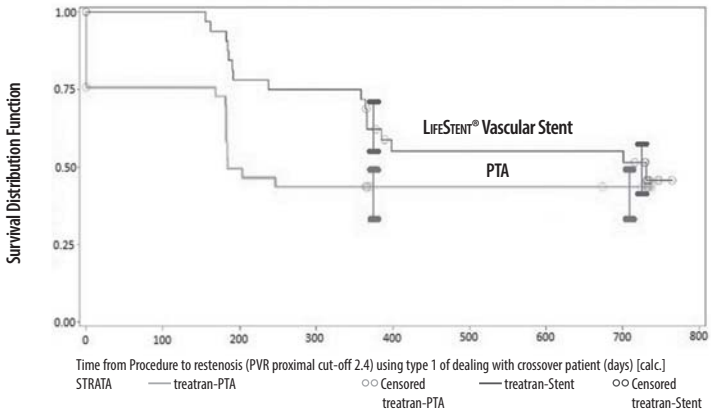
Primary Safety Endpoint: Freedom from occurrence of death, amputation and TVR and/or TLR at 30 days post index procedure. All 30 subjects showed freedom from occurrence of death, amputation, and TVR and/or TLR at 30 days post index procedure. Overall, this study demonstrated the safety of the LifeStent® Vascular Stent Systems deploying stents of 5 mm in diameter.

f. ETAP Randomized Physician-Sponsored Study

Restenosis 12 and 24 Months – PVR > 2.4				
	P1		P2/P3	
	Number (%) pts		Number (%) pts	
	PTA (n=37)	Stent (n=35)	PTA (n=90)	Stent (n=84)
12 mon	17 (53.1%)	12 (40.0%)	42 (56.0%)	19 (29.2%)
Evaluable Subjects*	32	30	75	65
24 mon	15 (57.7%)	10 (43.5%)	42 (72.4%)	16 (32.0%)
Evaluable Subjects*	26	23	58	50

This data collection was using ultrasound PVR>2.4
**evaluable accounts for missing data*

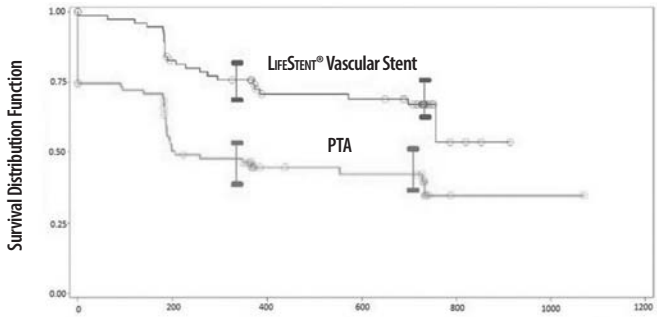
Freedom from Restenosis for Popliteal Segment 1



Time from Procedure to restenosis (PVR proximal cut-off 2.4) using type 1 of dealing with crossover patient (days) [calc.]
STRATA — treatran-PTA ○○ Censored treatran-PTA — treatran-Stent ○○ Censored treatran-Stent

	Control PTA				Test Stent			
Time	**Survival %[95% CI]**	**Subjects with Event**	**Censored Subjects**	**Subjects at Risk**	**Survival %[95% CI]**	**Subjects with Event**	**Censored Subjects**	**Subjects at Risk**
180 days	72.8% [65.4, 80.1]	10	2	25	93.8% [89.5, 98.0]	2	3	30
365 days	43.7% [35.3, 52.1]	20	4	13	68.8% [60.6, 76.9]	10	4	21
730 days	43.7% [45.3, 61.3]	20	11	6	51.4% [42.3, 60.5]	15	11	9

Freedom from Restenosis for Popliteal P2/P3



Time from Procedure to restenosis (PVR proximal cut-off 2.4) using type 1 of dealing with crossover patient (days) [calc.]
STRATA — treatran-PTA ○○ Censored treatran-PTA — treatran-Stent ○○ Censored treatran-Stent

	Control PTA				Test Stent			
Time	**Survival %[95% CI]**	**Subjects with Event**	**Censored Subjects**	**Subjects at Risk**	**Survival %[95% CI]**	**Subjects with Event**	**Censored Subjects**	**Subjects at Risk**
180 days	70.8% [66.0, 75.6]	26	6	58	94.7% [92.1, 97.3]	4	9	71
365 days	46.5% [40.9, 52.0]	45	17	28	75.8% [70.8, 80.7]	18	19	47
730 days	39.8% [33.8, 45.8]	48	33	9	67.0% [61.3, 72.8]	23	39	22

Safety

Thirteen (13) patients had died by Month 24, 4 patients who were treated with PTA and 9 patients who received a stent. None of the adverse events causing death were related to the LifeStent® Vascular Stent or procedure.

Stent Fracture Analysis

The stent fracture rate was assessed for patients who actually received stent treatment (TR set, N=152). At Month 12, valid x-ray data were available for 60 patients with 67 stents (53 patients with one stent and 7 patients with two stents). Four patients had a stent fracture. Of the seven patients with two stents, none had a stent fracture in both stents.

The reported fracture rate was 5.4% at 12-months and 11.1% at 24-months for P2/P3 segment treatment. The number of available x-rays was 37 and 45 x-rays at the 12-month and 24-month time-point respectively (see Table "X-ray Reported Stent Fractures"). Fractures are counted once, at the first time the fracture was reported.

During the ETAP study, patients in the P2/P3 group experienced three Type I, one Type II, one Type III and two Type IV fractures, while, the P1 group had one Type III and one Type II fracture. No correlation could be found between the incidence of stent fractures and either restenosis or TLR.

X-Ray Reported Stent Fractures				
	X-Ray(s) Reviewed		**Stent Fractures* (%)**	
	P1 (n=43)	P2/P3 (n=109)	P1	P2/P3
12-month	23	37	2 (8.6%)	2 (5.4%)
24-month	25	45	0	5 (11.1%)

**Fractures were recorded the first time they were reported.*

g. REALITY III Study

REALITY III Study Principal Safety and Effectiveness Table	
Variable	**Test % (n/N)**
Technical Success Effectiveness	89.2 (33/37 devices)
Post-hoc Analysis Technical Success Effectiveness	94.6 (35/37 devices)
Freedom from death, amputation, TLR/TVR at day 30	100.0 (30/30)
Freedom from TLR/TVR at day 30	100.0 (30/30)

Technical Success: successful deployment and placement accuracy based upon a rating scale completed by the investigators at the time of the index procedure. Includes investigator rated deployment accuracy as 'good' or 'excellent' and placement accuracy as 'successfully at target site'.

Post-hoc Analysis Technical Success: successful deployment and placement accuracy based upon a rating scale completed by the investigators at the time of the index procedure. Includes investigator rated deployment accuracy as 'good', 'excellent', or 'fair' and placement accuracy as 'successfully at target site'.

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.

K. PATIENT SELECTION AND TREATMENT

Patient selections should be based on the populations treated in the RESILIENT, E-TAGIUSS, Bard® LifeStent® Vascular Delivery System Study, REALITY, ETAP, and REALITY III investigations. Demographics for these 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 investigators of these studies. 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® Vascular Stent.
- 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 an equivalent organization.

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

- 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® 5F Vascular Stent System is supplied sterile (by ethylene oxide gas) and is non-pyrogenic. Do not resterilize and/or reuse the device. Do not use if pouch is opened or damaged. Do not use the device after the "Use by" date specified on the label.
For returned product or product issues, please contact Bard Peripheral Vascular at the address below:

Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281 USA

CONTENTS

- One (1) LifeStent® 5F Vascular Stent System
- One (1) Patient Implant Card

STORAGE: Store in a cool, dark, dry place. Storage temperature should not exceed 60° C. Keep away from sunlight. Use the device prior to the "Use By" date specified on the label.

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

N. DIRECTIONS FOR USE

1. Pre-Deployment Procedure

a. Inject Contrast Media
Perform an angiogram using standard technique.

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

2. 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 (Table 1).

Stent Size Selection Table			
Reference Vessel Diameter	**Unconstrained Stent Inner Diameter**	**Stent Length Change [%]***	
		Min	**Max**
4.0 – 4.5 mm	5.0 mm	-2	1
4.5 – 5.5 mm	6.0 mm	-2	0
5.5 – 6.5 mm	7.0 mm	-3	0

Table 1: Stent Size Selection Table

* *Change in length between the undeployed mounted stent inside the delivery system and the expanded labeled-diameter condition.*

Note: The percent stent length change is based upon mathematical calculation.

Refer to product labeling for stent length.

3. Utilizing the GeoAlign® Marking System (Optional)

When used as a location reference tool, utilize the GeoAlign® Marking System to determine how far the LifeStent® 5F Vascular Stent System has advanced (Figure 4).

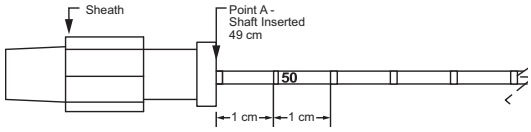


Figure 4: Using the GeoAlign® Marking System as a location reference tool.

To facilitate repeat catheter alignment with an additional device with the GeoAlign® Marking System, ensure the GeoAlign® Markings are at the same location outside the sheath as the initial device. The GeoAlign® Marking System provides an approximation that may not be an exact representation of the actual distance traveled intravascularly and should be confirmed under fluoroscopy.

Note: Ensure the sheath does not move during the withdrawal of the initial device or the advancement of subsequent devices.

4. Materials Required

In addition to the LifeStent® 5F Vascular Stent System, the following standard materials may also be required to facilitate delivery and deployment of the LifeStent® 5F Vascular Stent System:

- Heparinized normal saline
- 5F (1.67 mm) or larger introducer sheath
- 0.014 inch (0.36 mm) - 0.035 inch (0.89 mm) diameter guidewire
- standard balloon angioplasty (PTA) catheter
- contrast medium diluted 1:1 with heparinized normal saline
- inflation device
- appropriate anticoagulation and antiplatelet drugs

5. Prepare Stent System

- Open the box and remove the pouch containing the stent system.
- Carefully inspect the pouch for damage to the sterile barrier. **DO NOT** use the device after the "Use By" date specified on the label. Peel open the pouch and remove the tray containing the stent system. Carefully extract the stent system from the tray.
- **Check the following:**
  - › Verify that the safety lock slider is still in the locked position (Figure 5).

Safety Lock Slider in Locked Position **Safety Lock Slider in Unlocked Position**

Figure 5: Handle top view

  - › 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.
  - › 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.
- Prior to use flush the guidewire lumen of the stent system with heparinized normal saline until saline exits the tip of the system (Figure 6).

Figure 6: System flushing

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

6. Stent Deployment Procedure

a. Insert Introducer Sheath and Guidewire

- Gain ipsilateral or contralateral femoral access utilizing an appropriate introducer sheath – 5F (1.67 mm) or larger introducer sheath. See "Materials Required" Section.
- Insert a guidewire of appropriate length (Table 2) and 0.014 inch (0.36 mm) - 0.035 inch (0.89 mm) 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	260 cm

Table 2: Recommended Guidewire Length Table

- It is recommended to use the 80 cm working length device for ipsilateral procedures. The longer working length of the 135 cm device may potentially be challenging for the user to keep straight for ipsilateral procedures. Failure to keep the device straight may impede the optimal deployment of the implant, potentially resulting in an elongated or foreshortened implant.

b. Dilate Lesion

- Pre-dilatation of the lesion with a balloon dilatation catheter is recommended. If performed, select a balloon catheter that matches the size of the reference vessel.

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

- While maintaining site access with a guidewire, remove the balloon catheter from the patient.

c. Introduce Stent System

- Advance the stent system over the guidewire through the introducer sheath. For contralateral access, always use a long introducer sheath that 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.

- Position the tip of the stent system past the target site.

d. Deploy Stent

- Confirm that the introducer sheath is secure and will not move during deployment.
- Pull back the stent system until the distal stent radiopaque marker is placed distally to the target site to ensure full coverage of the lesion.
- The second hand should be used to support the stent delivery system. Gently hold the stability sheath close to the introducer sheath and keep it stationary and under tension throughout deployment (Figure 7).

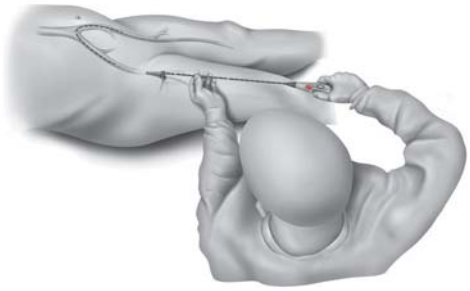


Figure 7: Hold system straight and under tension.

- 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.

- Unlock the safety lock slider by pulling it back towards the wheels from the locked position into the unlocked position. Ensure that the red safety lock slider is completely pulled back (Figure 8).

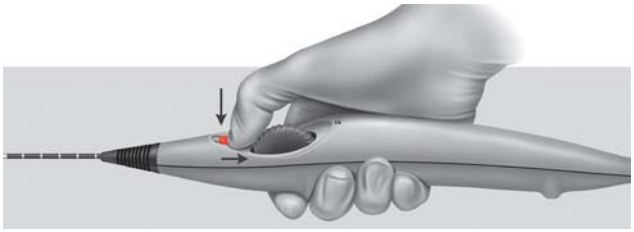


Figure 8: Unlock safety lock slider.

Figure 9: Hold the green stability sheath. DO NOT hold or touch the brown moving sheath.

- **DO NOT** hold or touch the brown moving sheath during stent release (Figure 9).

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.

- Initiate stent deployment by rotating the large thumbwheel (labeled 2 on the system grip) in the direction of the arrows, while holding the handle in a fixed position (Figure 10).

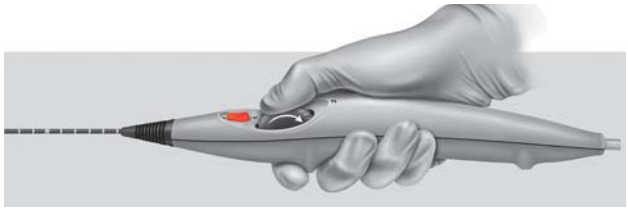


Figure 10: Initiate stent deployment by rotating the large thumbwheel (labeled 2 on the system grip).

- 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 large thumbwheel until the distal end of the stent obtains complete wall apposition (Figure 11).

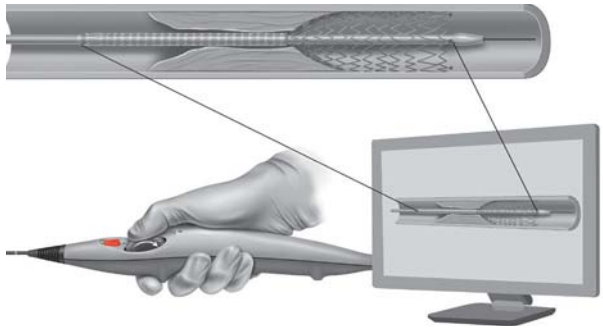


Figure 11: Stent Release

- With the distal end of the stent apposing the vessel wall, final deployment can be continued, depending on user preference, with rotating the small (labeled 3 on the system grip) or the large thumbwheel (Figure 12).

Figure 12: Overview of large and small thumbwheels

- Deployment of the stent is complete when the proximal stent radiopaque markers appose the vessel wall. **DO NOT** attempt to recapture the stent.

7. Post Stent Placement

- 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.

- Post stent expansion with a balloon dilatation 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.
- Remove the guidewire and introducer sheath from the body.
- Close entry wound as appropriate.
- Discard the delivery system, guidewire and introducer sheath following institutional procedures.

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

DISCLAIMER OF WARRANTY

BARD PERIPHERAL VASCULAR, INC. WARRANTS TO THE FIRST PURCHASER OF THIS PRODUCT, THAT THIS PRODUCT WILL BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP FOR A PERIOD OF ONE YEAR FROM THE DATE OF FIRST PURCHASE AND LIABILITY UNDER THIS LIMITED PRODUCT WARRANTY WILL BE LIMITED, TO REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT, IN BARD'S SOLE DISCRETION, OR REFUNDING YOUR NET PRICE PAID. WEAR AND TEAR FROM NORMAL USE OR DEFECTS RESULTING FROM MISUSE OF THIS PRODUCT IS NOT COVERED BY THIS LIMITED WARRANTY.

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Symbols used on Labeling

Consult Instructions For Use

Keep Away From Sunlight

Keep Dry

Do Not Use If Package Is Damaged

Single Use

Do Not Resterilize

Contents: (1)

MR Conditional

Not Made With Natural Rubber Latex

Non-Pyrogenic

Catalogue Number

Lot Number

Sterilized Using Ethylene Oxide

Use By

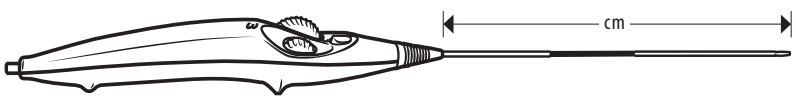
Manufacturer

Minimum Introducer Size

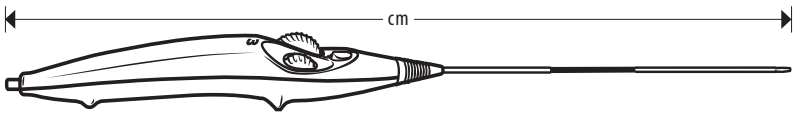
Guidewire Compatibility

Stent Length

Stent Diameter



Working Length



System Length

Labeling issue date 2020-04

LIFESTENT® | 5F

Vascular Stent System

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www.bardpv.com

Manufacturer:
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Wachhausstrasse 6
76227 Karlsruhe
Germany

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B05881 Rev.2/04-20