

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Peripheral Stent System

Device Trade Name: Bard® LifeStent® Vascular Stent System

Device Procode: NIP

Applicant's Name and Address: Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281-1740
USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P070014/S037

Date of FDA Notice of Approval: May 31, 2016

The original PMA (P070014) was approved on February 13, 2009 and is indicated to improve luminal diameter in the treatment of symptomatic *de novo* or restenotic lesions up to 160 mm in length in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. The SSED to support the indication is available on the CDRH website

(http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070014b.pdf) and is incorporated by reference here. These indications for use were expanded on December 23, 2010 (P070014/S010) to include lesions up to 240 mm in length. The SSED to support the indication is available on the CDRH website

(http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070014S010B.pdf).

The current supplement was submitted to expand the indication for the device to include treatment of lesions in the mid and distal popliteal artery.

II. INDICATIONS FOR USE

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

III. CONTRAINDICATIONS

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

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

therapy.

- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

IV. **WARNINGS AND PRECAUTIONS**

See WARNINGS AND PRECAUTIONS in the LifeStent® Vascular Stent System labeling (Instructions for Use).

V. **DEVICE DESCRIPTION**

The Bard® LifeStent® Vascular Stent System (P070014) is comprised of the LifeStent® Vascular Stent (stents 20 – 80 mm) and the LifeStent® XL Vascular Stent (stents 100 – 170 mm), as well as the Bard® LifeStent® Solo™ Vascular Stent System (stents 20-200 mm; approved via P070014/S022). All devices contain self-expanding, flexible, nitinol stents that expand to a preset diameter upon exposure to body temperature. The stents are equivalent to one another in design with only one difference located at the crown section; the LifeStent® and LifeStent® Solo™ stents contain 6 tantalum radiopaque markers on both the distal and proximal ends of the stent, while the LifeStent® XL stent does not have markers (Figures 1 and 2, respectively). Please see Table 1 for the delivery system summary as well as respective size matrix for the implant.

Figure 1: LifeStent® and LifeStent® Solo™ Stent

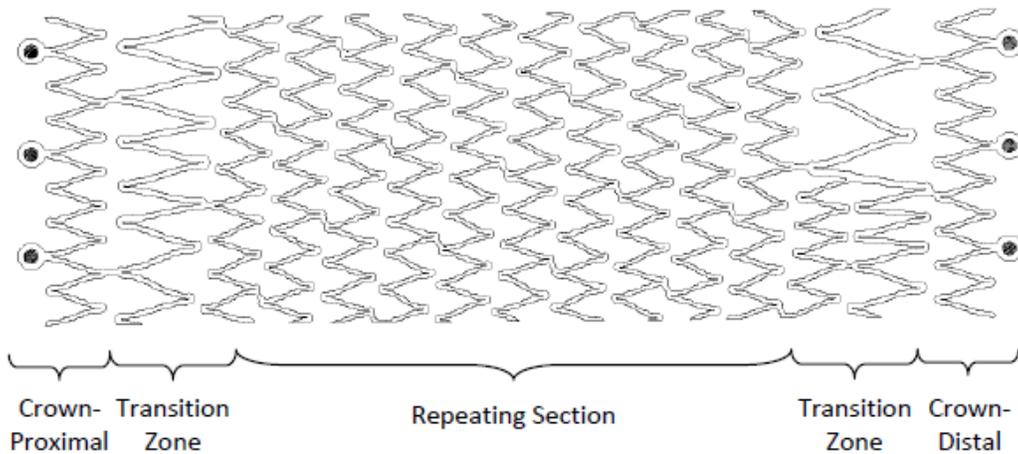


Figure 2. LifeStent® XL Stent

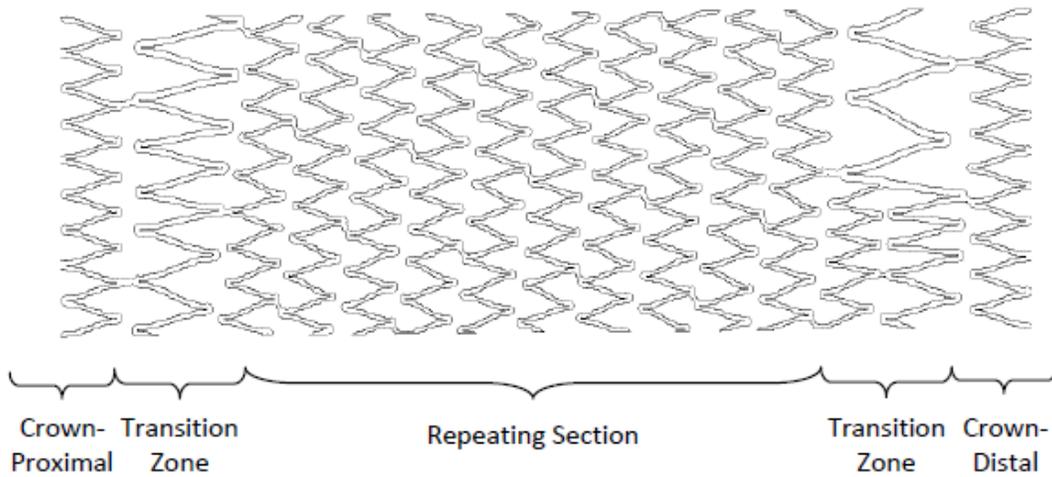


Table 1: LifeStent® Delivery Systems Summary

	System	Stent	Deployment Mechanisms
LifeStent®	<p>LifeStent®</p>  <p>Available system lengths: 80 and 130 cm</p>	<p>Ø6mm X 20-80mm Ø7mm X 20-80mm</p> <p>Contains 6 radiopaque tantalum markers on each end</p>	<p>1.2 Thumbwheel 2.2 Rapid Deployment Lever 3.2 Rapid Deployment Ring</p>
LifeStent® XL	<p>LifeStent® XL</p>  <p>Available system lengths: 80 and 130 cm</p>	<p>Ø6mm X 100-170mm Ø7mm X 100-170mm</p> <p>No radiopaque markers</p>	<p>1. Thumbwheel 2. Rapid Deployment Lever</p>
LifeStent® Solo™	<p>LifeStent® Solo™</p>  <p>Available system lengths: 100 and 135 cm</p>	<p>Ø6mm X 20-200mm Ø7mm X 20-200mm</p> <p>All stents contain 6 radiopaque tantalum markers on each end</p>	<p>1. Trigger for slow (micro clicks) and rapid stent deployment (full pumps of the trigger)</p>

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of peripheral arterial disease. Some of these alternatives include: non-invasive lifestyle changes, drug therapy, drug-coated balloons, and angioplasty. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The LifeStent and LifeStent XL Vascular Stent Systems have been approved in the US since February 13, 2009 with the indication to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 160 mm in length in the native SFA and proximal popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. These indications for use were expanded on December 23, 2010 (P070014/S010) to include lesions up to 240 mm in length.

The LifeStent and LifeStent XL Vascular Stent Systems have been approved for the primary stenting of de-novo or restenotic lesions of the peripheral arteries including the full popliteal artery in the following countries: European Union, Canada, Russia, Ukraine, China, Korea, Taiwan, Thailand, Vietnam, Singapore, Australia, Brazil, Mexico, Columbia, and Uruguay.

The LifeStent® Solo™ Vascular Stent System was approved in the US (P070014/S022) on September 16, 2011 with the indication to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 240 mm in length in the native SFA and proximal popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm. LifeStent® Solo™ Vascular Stent System has been available in the following countries: European Union, Canada, Uruguay, Colombia, Brazil, Argentina, Turkey.

The LifeStent Vascular Stent Systems are currently being marketed in the locations listed above and have not been withdrawn from marketing for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse effects (e.g., complications) 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

For the specific adverse events that occurred in the clinical studies conducted to support the original indication, please see Section X of the original SSED.

IX. SUMMARY OF PRECLINICAL STUDIES

The designs of the Bard[®] LifeStent[®] Vascular Stent Systems are not changed from the currently-marketed devices. Therefore, the potential effects of the new intended anatomy formed the basis for the preclinical test strategy.

The pre-clinical data reviewed under P070014 were found to be adequate to support the enhanced indication of treatment in the SFA and full popliteal artery in the current PMA Supplement in the following technical areas:

- Pre-clinical animal studies
- Biocompatibility
- Sterilization
- Packaging

A. Laboratory Studies

Because the device design has not changed, appropriate non-clinical data were leveraged from P070014 and its supplements to support this supplement. Testing relevant to the new intended anatomy in the distal popliteal artery was performed, as described in Table 2 below.

Table 2: Supporting Non-clinical Tests

Test	Purpose/Objective	Acceptance Criteria	Results
Material Composition	To verify the chemical composition of the nitinol (nickel-titanium) and tantalum of the implant.	Characterization study	Leveraged*
Shape Memory and Superelasticity	To ensure incoming tubing used in the manufacture of the implant complies with visual, dimensional, and performance specifications.	Characterization Study; At temperature between 16° - 25°	Leveraged*
Mechanical Properties	To characterize the implant’s raw material mechanical properties (for uniaxial tensile strength and fatigue strength) to support stress/strain and fatigue analyses.	Characterization study	Leveraged*
Pitting and Crevice Corrosion	To verify the implant’s ability to resist corrosion via in vitro testing and ensure that the implant maintains corrosion resistance following implantation.	Breakdown Potential (Eb) > 300mV	Leveraged*
Fretting Corrosion		Eb>300mV	Leveraged*
Galvanic Corrosion.		Material loss less than 2µm / year	Leveraged*
Dimensional Verification - Implant	To verify that critical implant dimensions (outer diameter and length) are met post-deployment under simulated physiological conditions.	6mm size: 6.08 – 6.68mm 7mm size: 7.08 – 7.68mm	Pass
Percent Surface Area	To characterize the implant’s percent free surface area.	7-20%	Leveraged*
Foreshortening	To quantify the relationship between length and diameter for the implant from its crimped to deployed form as well as in the freely expanded state.	< =5%	Pass

Test	Purpose/Objective	Acceptance Criteria	Results
Integrity (post-deployment)	To evaluate the integrity of the implant post deployment. To verify that the implant shows no defects that would render it unsuitable for the intended use.	No cracks, bends, kinks or fractures at 20x magnification	Pass
Radial Stiffness and Radial Strength	To verify that the implant has sufficient Radial stiffness and radial strength to resist collapse under short-term or long-term external loads.	Radial Resistive Force (RRF) \geq 0.07N/mm	Leveraged*
Radial Outward Force	To characterize force exerted by the implant as a function of implant diameter.	Chronic Outward Force (COF) \leq 0.12N/mm	Leveraged*
Stress / Strain Analysis	To characterize the stress / strain behaviors of the implant when subjected to worst-case physiological loads and ensure structural integrity of the stent for the intended use.	Characterization study to determine worst case loading condition and stent configuration (size and oversizing) for use in accelerated durability tests	Pass
Fatigue Analysis		Stent durability needs to be suitable for the intended use	Pass
Accelerated Durability / Non Radial Fatigue	To evaluate the durability (maintenance of structural integrity) of the implant under worst case non radial fatigue conditions simulating 10 years of use.	Stent integrity must be maintained after 10.6 Mill. cycles	Pass
MRI Safety and Compatibility	To evaluate MRI safety and compatibility.	The presence of the stent must not pose an additional unacceptable risk to patients when subjected to 1.5T and 3.0T magnetic fields	Leveraged*
Radiopacity	To evaluate the radiopacity of the implant with radiographic and angiographic imaging.	Stent visualization needs to be rated clinical acceptable	Leveraged*
Crush Resistance	To evaluate the ability of the implant to resist permanent deformation and demonstrate the stent's resistance to localized compressive loads.	Mean stent diameter not decrease more than 5%	Leveraged*
Kink Resistance	To evaluate the implant's flexibility in its deployed configuration.	No luminal compromise	Leveraged*

Test	Purpose/Objective	Acceptance Criteria	Results
Dimensional Verification – Delivery System	To verify that the delivery system meets its dimensional pre- and post-deployment.	Max outer diameter LifeStent DS: 0.0795” Max outer diameter LifeStent XL DS: 0.0825”	Leveraged*
Delivery, Deployment and Retraction	To characterize the system with respect to flushability / leakproofness and luer lock compatibility; trackability, pushability, torqueability, premature deployment; deployment force and accuracy; stent conformability and ability to withdraw.	Various acceptance criteria for delivery, deployment and retraction, Placement accuracy <= 2.5mm	Pass
Bond Joint Strength	To determine the bond strength of the joints and/or fixed connections of the delivery system and verify that the strength of the bond joints are adequate for the intended use.	Various acceptance criteria for different bonding joints	Leveraged*
Tip Pull Test	To determine the bond strength of the tip joint of the delivery system and verify that the strength of the bond joint is adequate for the intended use.	Tensile strength of tip to inner catheter joint > 1.12lbf	Leveraged*
Flexibility / Kinkability	To ensure that the system does not kink during delivery, deployment or withdrawal to and from the target deployment site under anticipated use conditions.	Delivery systems do not show any relevant kinks during visual inspection post deployment	Leveraged*
Torque Strength	To determine the torsional bond strength between relevant components of the delivery system and to verify the strength of the bond joints are adequate for the intended use.	No breaks or failures	Leveraged*
Stability of Product for Labeled Shelf Life	To ensure that the product performance characteristics are maintained for the stated shelf life of the product.		Leveraged*
Biocompatibility	To ensure that product materials are biologically safe and biocompatible		Leveraged*

*Results indicated were performed as part of the original PMA and results support the popliteal indication.

B. Animal Studies

No new animal testing was conducted to support the new indication. Information from animal study data from the previously-approved systems was appropriately leveraged based on the device and anatomical similarities.

C. Additional Studies

The Bard® LifeStent® Vascular Stent System has a labeled shelf-life of 2 years. Device packaging materials and the sterilization method are the same. Therefore, sterilization

and packaging testing are leveraged from the previously approved systems. No new testing was performed for this supplement.

X. SUMMARY OF PRIMARY CLINICAL STUDY

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 artery¹. In total, 246 subjects were randomized between the two study arms at nine European centers, with 119 subjects 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.

A. 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 System in patients with stenosis and occlusion of the SFA and popliteal artery (including the P2 and P3 segments) in comparison to PTA alone.

A total of 246 patients were recruited and randomized into the two treatment groups, PTA or stent, with 119 patients in the stent group and 127 patients in the PTA group. Eligible patients had de novo occlusion of the popliteal artery or de novo stenosis of the popliteal artery with >70% diameter reduction. At least one artery of the lower leg had to be open (stenosis grade \leq 60%) along its entire length with no significant inflow stenosis. Patients also had to have a clinical Fontaine stage IIa-IV or Rutherford category 2 to 6.

For patients randomized to the PTA group, a balloon angioplasty was performed, representing standard clinical care of these lesions. For patients randomized to the stent group, nitinol stent placement was performed after successful crossing of the guidewire with the goal of not pre-dilating the lesion before stent placement. For the PTA group, if there was a persistent stenosis of >30% after repeated and prolonged PTA or a flow-limiting dissection, a study stent was to be placed at the target lesion.

All patients were given 100 mg of aspirin daily through the duration of the study. If the patient was not taking aspirin before the procedure, a 500-mg loading dose was administered before the intervention. In addition, a loading dose of clopidogrel (1 \times 300 mg PO) was administered on the day of the intervention, followed by a daily dose of 75 mg for a minimum of 4 weeks. Patients were followed for 24 months with scheduled visits after 6, 12, and 24 months.

Of the 246 patients recruited in the study, 152 patients received a LifeStent® Vascular Stent System while 93 patients received PTA alone. The difference between assigned and treated patients is related to those PTA patients who crossed over into the stent group.

The primary study endpoint was 1-year primary patency, defined as freedom from target-lesion restenosis (luminal narrowing of $\geq 50\%$) as detected by duplex ultrasound. Secondary end points included target-lesion revascularization (TLR) rate and changes in Rutherford-Becker class. The study was conducted to evaluate stenting versus PTA in the SFA and popliteal segments. Because the Lifesent® Vascular System was previously FDA-approved for treatment of the SFA and proximal popliteal segment (P1), an additional post-hoc analysis was conducted to compare outcomes for the P1 segment and P2/P3 segments.

B. Accountability of PMA Cohort

Subject accountability is described below in Table 3. At the 12-month interval, the overall compliance rate was greater than 91% for all groups. For patients treated with stents in the P1 segment, the overall compliance rate was 100% of available subjects completing the visit. For the P2/P3 group, the overall compliance rate was 99% of available subjects at the 12-month follow-up visit. The available 24-month data for both groups are provided below. However, German informed consent laws did not allow identification of specific patients and compliance rates were not available.

Table 3: Patient Accountability P1 & P2/P3 Subsets ITT Populations

Study Status	P1		P2/P3	
	PTA	Stent	PTA	Stent
Randomized Enrollment	37	35	90	84
LTF all follow-ups*	4	4	17	13
12 Month – Available/Completed Visit	30/33 (91%)	31/31 (100%)	68/73 (93%)	70/71 (99%)
Lost to Follow-Up/Missing	1	10	6	10
24 Month – Available **	32	28	67	52
Death (total)	2	4	4	4

* Documented LTF, deaths and withdrawn consent.

** 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.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are shown in Table 4, and the lesion characteristics are shown in Table 5. Note that these data are for the entire study cohort, including treatment of SFA and P1 segment lesions.

Table 4. Study Demographics

Characteristic (ITT population)	PTA (N=127)	Stent (N=119)	Total (N=246)

Characteristic (ITT population)	PTA (N=127)	Stent (N=119)	Total (N=246)
Age (years) Median	73	72	72
Gender N (%)			
Female	45 (35.4)	43 (36.1)	88 (35.8)
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)

Table 5. 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)

D. Safety and Effectiveness Results

In order to highlight the results specific to the popliteal segments behind the knee (i.e., P2/P3 segments) which represent the most clinically challenging anatomy treated in the study and the popliteal segments previously not included in the approved indications for use for this device, results for a post-hoc sub-analysis were primarily considered in order to support the marketing application.

1. Effectiveness Results

As shown in Table 6, 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.

Table 6. Restenosis 12 and 24 Months – PVR > 2.4

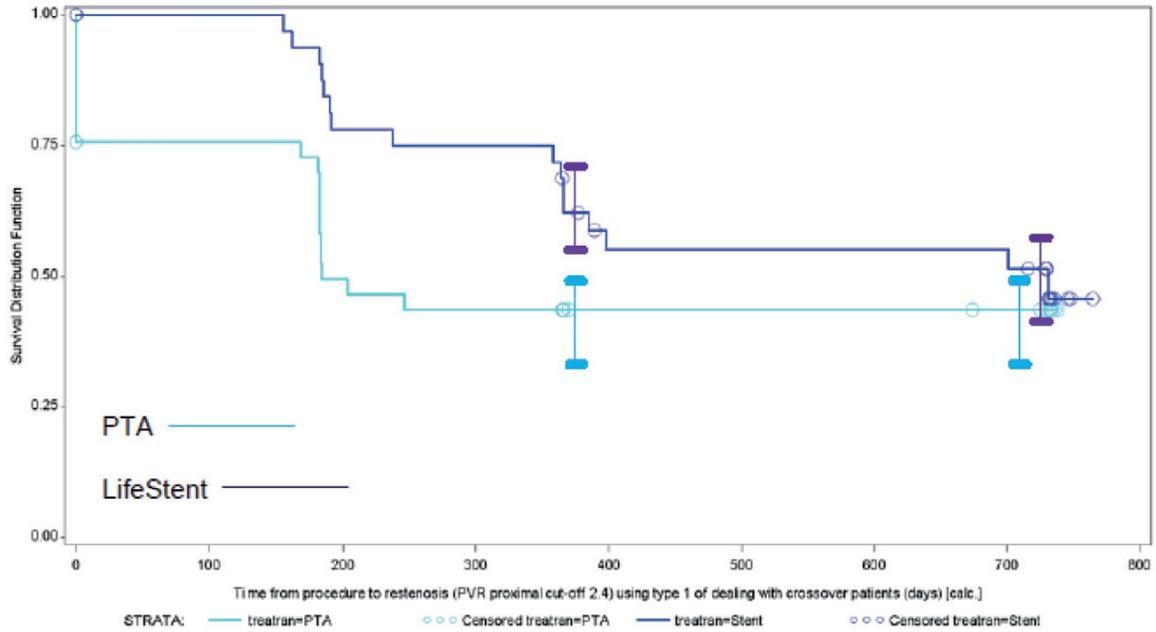
	P1		P2/P3	
	Number (%) pts		Number (%) pts	
	PTA (N=37)	Stent (N=35)	PTA (N=90)	Stent (N=84)
12 months	17 (53.1%)	12 (40.0%)	42 (56.0%)	19 (29.2%)
Evaluable*	32	30	75	65
24 months	15 (57.7%)	10 (43.5%)	42 (72.4%)	16 (32.0%)
Evaluable *	26	23	58	50

This data collection was using ultrasound PVR>2.4

*evaluable accounts for missing data

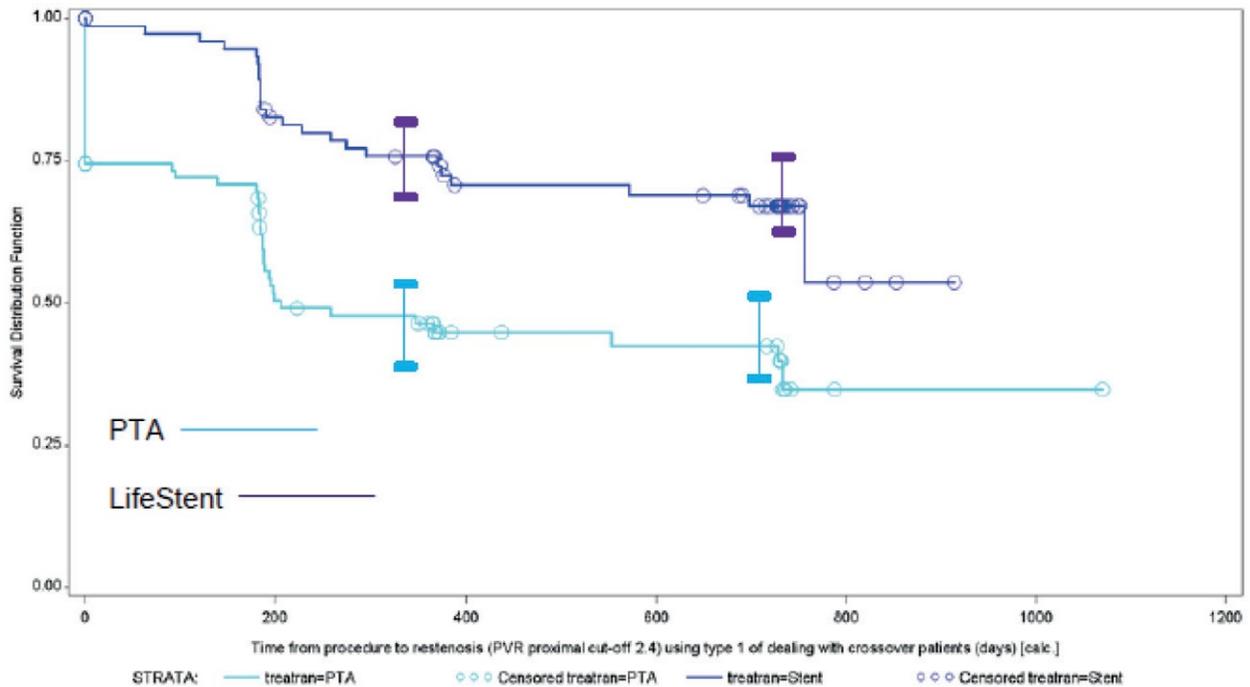
Figures 3 and 4 demonstrate the Kaplan-Meier restenosis results for the P1 and P2/3 segments, respectively. Provisional stent placement with a LifeStent® Vascular Stent System was observed during this study in 27% of the randomized PTA population.

Figure 3. Freedom from Restenosis for Popliteal Segment 1



Time	Control PTA				Test Stent			
	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

Figure 4. Freedom from Restenosis for Popliteal P2/P3



Time	Control PTA				Test Stent			
	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

Analysis of secondary endpoints suggest a beneficial clinical trend in favor of stent placement. Preoperative Rutherford scores in the high risk population (Rutherford category 3 or higher) for both the PTA group and stent group improved post-operatively at both the 12- and 24-month intervals. One- and two-year freedom from TLR trended higher in the stented group than the PTA group for treatment in the P2/P3 segment. However, conclusions regarding significance of these individual endpoints may not be made.

2. Safety Results

A separate prospective safety hypothesis was not included in the study. Death, major amputation and minor amputation, TLR (including need for surgical revascularization), and myocardial infarction were defined as major adverse events and they were cumulatively collected for 370 days after index procedure. All clinical

endpoints and major adverse events were adjudicated by an independent clinical events committee. As described in Table 7, 13 patients had died by Month 24, 4 patients who were treated with PTA and 9 patients who received a stent. The Clinical Events Committee determined that none of the adverse events causing death were related to LifeStent® Stent or procedure. No concerning trends were noted regarding overall safety when the LifeStent® Vascular Stent System was compared to PTA for multiple safety endpoints.

Table 7. Safety Events

	P1		P2/P3	
	Number (%) pts		Number (%) pts	
	PTA (n=37)	Stent (n=35)	PTA (n=90)	Stent (n=84)
Severe Cardiovascular Events*				
12 month Evaluable Subjects^	8 (23.5%) n=34	8 (23.5%) n=34	22 (28.2%) n=78	19 (26.0%) n=73
24 month Evaluable Subjects^	9 (33.3%) n=27	9 (31.0%) n=29	24 (41.4%) n=58	22 (35.5%) n=62
Adverse Events**				
12 month Evaluable Subjects^	25 (69.4%) n=36	18 (52.9%) n=34	46 (56.8%) n=81	41 (54.7%) n=75
24 month Evaluable Subjects^	27 (81.8%) n=33	23 (76.7%) n=30	53 (75.7%) n=70	43 (64.2%) n=67
Death***				
12 month Evaluable Subjects^	1 (2.9%) 34	1 (3.1%) 32	1 (1.4%) 74	2 (2.7%) 74
24 month Evaluable Subjects^	2 (7.4%) 27	3 (11.5%) 26	4 (8.0%) 50	4 (7.1%) 56

3. Stent Fracture Analysis

The stent fracture rate was assessed for patients who 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). Stent fracture was identified in four patients. Of the seven patients with two stents, none had a stent fracture in both stents. One patient had occlusions in the treated limb following a stent fracture.

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 8 below). 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.

Table 8. X-ray Reported Stent Fractures

	X-ray(s) Reviewed		Stent Fractures	
	P1 (N=43)	P2/P3	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.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. 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 System in patients with stenosis and occlusion of the popliteal artery in comparison to PTA alone. There are no disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Please refer to the previous Summaries of Safety and Effectiveness Data (P070014 and P070014/S010) for the clinical data that supported the originally and subsequently approved indications for the LifeStent® Vascular Stent System (P070014).

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

Non-clinical and clinical testing support the expansion of the indications to the entire popliteal artery. The in vitro engineering testing conducted on the stent demonstrated that the performance characteristics continue to meet product specifications. Results from the post-hoc analysis from the ETAP physician-sponsor study demonstrate that the device is acceptable for clinical use. The primary study endpoint was 1-year primary patency, defined as freedom from target-lesion restenosis (luminal narrowing of $\geq 50\%$) as detected by duplex ultrasound. Specifically in the P2/P3 segment of the popliteal artery, stenting resulted in a lower restenosis rate than PTA (29.2% compared to 56.0%), when the crossover procedure was considered to be a TLR and by definition a restenosis. Although a separate prospective safety hypothesis was not

included, major adverse events defined as death, major amputation and minor amputation, TLR (including need for surgical revascularization), and myocardial infarction were similar between the two groups with no major adverse events attributed to the device or procedure. The reported stent fracture rate was 5.4% at 12-months and 11.1% at 24-months for P2/P3.

B. Benefit-Risk Conclusion

The probable benefits of the LifeStent® Vascular Stent System are based on the data collected in the clinical study conducted to support PMA approval, as described above. The results of the ETAP study show positive clinical outcomes in terms of the primary and secondary endpoints and outweigh risks when used as intended according to the Instructions for Use. The clinical study results demonstrate that the LifeStent® Vascular Stent System can be safely implanted in the treatment of the P2/P3 segment of the popliteal artery and can provide an effective treatment with acceptable freedom from reintervention rates and fracture.

1. Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

C. Overall Conclusions

Based on the provided evidence, the data supports the conclusion that the probable benefits of implanting the LifeStent® Vascular Stent System in the distal popliteal artery outweigh the probable risks when used as indicated in accordance with the labeling and Instructions for Use (IFU).

XIII. CDRH DECISION

CDRH issued an approval order on May 31, 2016. The final conditions of approval cited in the approval order are described below.

The applicant has agreed to actively participate in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative (VQI) Peripheral Vascular Intervention (PVI) Registry and undertake such activities to ensure that surveillance occurs for the Bard LifeStent Vascular Stent System. All patients in the PVI Registry that receive the device to treat symptomatic de novo or restenotic lesions in the popliteal artery (i.e. P2/P3 segments), as specified in the indications for use, should be included in this surveillance effort, with at least 74 patients being from the United States.

The surveillance should monitor through two years freedom from major adverse events, freedom from target lesion revascularization (TLR), target vessel revascularization (TVR), acute lesion success, acute procedure success, primary patency, primary assisted patency, secondary patency, sustained clinical success, sustained hemodynamic success, limb ischemia assessed by Rutherford classification, ankle brachial index and stent fracture assessed at revascularization.

The applicant's manufacturing facilities has/have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XV. REFERENCES

1. 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