# LIFESTREAM™

Balloon Expandable Vascular Covered Stent

**ENGLISH**

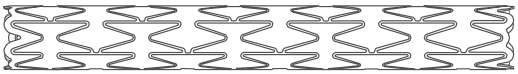
## INSTRUCTIONS FOR USE

## A Device Description

### 1. Implant

The LIFESTREAM™ Balloon Expandable Vascular Covered Stent is comprised of an electropolished balloon-expandable stent made from 316L stainless steel, encapsulated between two layers of ePTFE. (See Figure 1)

**Figure 1:**
**LIFESTREAM™ Balloon Expandable Vascular Covered Stent (Implant)**



### 2. Endovascular System

The covered stent is supplied pre-mounted on an over-the-wire delivery system with a non-compliant balloon. (See Figure 2)

Two radiopaque markers (A and B) on the balloon shaft indicate the length of the balloon and the ends of the covered stent and aid in accurate covered stent deployment. The proximal portion of the endovascular system includes an inflation female luer lock hub (C) and a guidewire female luer-lock hub (D).

**Figure 2:**
**LIFESTREAM™ Endovascular System**


The LIFESTREAM™ Balloon Expandable Vascular Covered Stent endovascular system is available in catheter lengths of 80 cm and 135 cm and it is compatible with 0.035" (0.89 mm) guidewires. The premounted covered stent is available in multiple diameters and lengths.

Refer to the product labels for the balloon compliance chart and for the covered stent dimensions (post nominal pressure and post rated burst pressure inflation).

## B Indication For Use

The LIFESTREAM™ Balloon Expandable Vascular Covered Stent is indicated for the treatment of atherosclerotic lesions in common and external iliac arteries with reference vessel diameters between 4.5 mm and 12.0 mm, and lesion lengths up to 100 mm.

## C Contraindications

The LIFESTREAM™ Balloon Expandable Vascular Covered Stent is contraindicated for use in:

- Patients with uncorrected bleeding disorders
- Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy
- Patients who are judged to have a lesion that prevents full expansion of the implant
- Lesions in which the lumen diameter post balloon angioplasty is insufficient for the passage of the endovascular system
- Lesion locations subject to external compression

## D Warnings

- **The LIFESTREAM™ Balloon Expandable Vascular Covered Stent is supplied sterile and is intended for single use only. Do not resterilize and/or reuse the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or injury, illness or death of the patient.**
- **Patients with allergies or hypersensitivity to stainless steel or ePTFE may suffer an allergic response to this implant.**
- **Do not use if packaging/pouch is damaged.**
- **Use the device prior to the USE BY date specified on the package.**
- **Stenting across a vessel side branch may impede blood flow and hinder or prevent future procedures.**
- **Stenting into a bifurcation may compromise future diagnostic or therapeutic procedures.**
- **Should excessive resistance be felt at any time during the insertion process, do not force passage.**
- **Attempts to retract the covered stent into the sheath/guiding catheter may result in dislodgement and embolization of the covered stent. Maintain guidewire placement across the lesion and withdraw the endovascular system only until the proximal end of the covered stent is aligned with the tip of the sheath/guiding catheter. Do not attempt to remove an unexpanded covered stent through the sheath/guiding catheter. Remove the sheath/guiding catheter and endovascular system as a single unit. Attempting to remove an unexpanded covered stent by pulling it back into the sheath/guiding catheter may result in stent dislodgement.**
- **Do not exceed the maximum rated burst pressure since this increases the potential for balloon rupture and vessel damage. The use of a pressure monitoring device is recommended to prevent over pressurization.**
- **Use only diluted contrast medium for balloon inflation. Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion and difficulty in deployment of the covered stent. For the contrast/saline solution, a ratio of 50/50 is recommended.**
- **The covered stent cannot be repositioned after it is deployed.**
- **Do not retract the balloon until the balloon is fully deflated under vacuum.**
- **Confirm optimal covered stent wall apposition using standard angiographic techniques. If the covered stent has not achieved full wall apposition, a post dilation with an appropriately sized balloon should be performed. 5-8 mm devices may be post-dilated with balloons up to 10 mm in diameter. 9-12 mm devices may be post-dilated with balloons up to 12 mm in diameter.**
- **Do not expose the covered stent to temperatures higher than 500 °F (260 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition products.**
- **Use of a laser on or around the surface of the covered stent may result in damage to the covered stent and could create toxic fumes, which may harm the patient or operator.**
- **After use, the delivery system is a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.**

## E Precautions

- The device should only be used by physicians who are trained in endovascular procedures and are familiar with the complications, side effects and hazards of peripheral vascular interventions.
- Anatomical variances may complicate the procedure; use caution when advancing the endovascular system through tortuous or difficult anatomy.
- Prior to device use, refer to the Covered Stent Sizing Table on the label and read the Instructions for Use.
- Do not use if the delivery system cannot be properly flushed.
- Crossing the implant with catheters or other adjunct devices can result in covered stent dislodgement or damage.
- This device has not been tested for use in overlapped conditions with stents or covered stents from other manufacturers.
- Store in a cool and dry place. Keep away from sunlight.

## F Potential Adverse Events

Potential patient/device adverse effects that may occur include, but are not limited to, the following:

- Abscess
- Allergic / anaphylactoid reaction
- Amputation
- Aneurysm / pseudoaneurysm
- 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
- Balloon rupture
- Blockage of major collateral artery or arterial branch
- Bypass surgery
- Covered stent dislodgement from balloon during tracking procedure
- Covered stent misplacement during placement procedure
- Covered stent migration post placement procedure
- Covered stent insufficient wall apposition
- Covered stent deformation / kink / fracture
- Death
- Distal embolization
- Drug reaction or allergic reaction to medication, substances or materials used for the procedure (e.g. anticoagulation or antiplatelet agent, contrast medium, stent or catheter materials)
- Edema
- Fever
- Hemorrhage/bleeding
- Hematoma and/or bleeding at puncture (access) site
- Hypotension / hypertension
- Inability to introduce/withdraw endovascular system
- Inability to track endovascular system to the target lesion
- Inability to inflate the balloon/deploy covered stent
- Infection at access site
- Infection at or around implant
- Inflammation
- Ischemia / infarction of tissue/organ
- Malposition / Malapposition
- Myocardial infarction
- Pain
- Radiation injuries
- Renal insufficiency / failure/toxicity
- Respiratory arrest
- Restenosis in the treatment area / covered stent edge
- Sepsis
- Shock
- Stroke/Transient Ischemic Attack (TIA)
- Thromboembolic event / thrombosis
- Vasospasm
- Vessel wall trauma, perforation / dissection / rupture

## G Magnetic Resonance Imaging (MRI) Information

The LIFESTREAM™ Balloon Expandable Vascular Covered Stent was determined to be MR Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2008.

Non-clinical testing demonstrated that the LIFESTREAM™ Balloon Expandable Vascular Covered Stent is MR Conditional for single lengths up to 58mm and overlapping lengths up to 106mm.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or 1.5-Tesla only.
- Spatial gradient magnetic field of 3000-Gauss/cm (30 T/m) or less.
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of <2 W/kg in the normal operating mode.

Under the scan conditions defined above, the LIFESTREAM™ Balloon Expandable Vascular Covered Stent is expected to produce a maximum temperature rise of 3.5°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 16mm from the LIFESTREAM™ Balloon Expandable Vascular Covered Stent when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system. The artifact does obscure the device lumen.

*It is recommended that patients with a covered stent register the MR conditions with the MedicAlert Foundation (www.medicalert.org).*

## H How Supplied

The LIFESTREAM™ Balloon Expandable Vascular Covered Stent is supplied sterile (by ethylene oxide gas) and intended for Single Use Only.

## I Contents

Contents of one (1) LIFESTREAM™ Balloon Expandable Vascular Covered Stent Box:

- One (1) LIFESTREAM™ Balloon Expandable Vascular Covered Stent Endovascular System
- One (1) Instructions for Use
- One (1) Patient Implant Card

## J Storage

Store in a cool, dry place. Keep away from sunlight. Use the device prior to the USE BY date specified on the package.

## K Disposal Instructions

After use, the delivery system is a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

## L Materials required for the LIFESTREAM™ Balloon Expandable Vascular Covered Stent Procedure

- Heparinized saline
- Sterile syringes
- 0.035" (0.89 mm) guidewire with a length at least twice as long as the endovascular system
- Introducer sheath or guiding catheter with appropriate inner diameter
- Balloon angioplasty catheter for pre and/or post dilation if required
- Inflation device with pressure monitoring capability
- Diagnostic catheters and accessories
- Contrast Medium

## M Directions For Use

### SITE ACCESS AND PREPARATION

1. Using standard techniques access the artery and place an introducer sheath or guiding catheter of appropriate inner diameter and a 0.035" (0.89 mm) guidewire across the target lesion.
2. Perform diagnostic angiography to confirm site of implantation and measure the reference vessel diameter and lesion length.

### COVERED STENT SIZE SELECTION

3. Select a covered stent diameter that is approximately 5%-20% larger than the largest reference vessel diameter at the proximal or distal target site.

Refer to the sizing table on the packaging label for appropriate selection of the covered stent diameter and length.

### ENDOVASCULAR SYSTEM PREPARATION

4. Carefully remove the selected device from the package. Remove the covered stent guard, being cautious not to grasp the covered stent with the guard.
5. Inspect the covered stent for adherence to the balloon and centered placement in relation to the balloon marker bands. If the covered stent is not centered and/or does not firmly adhere to the balloon, do not use.
6. Flush the delivery system guidewire lumen with sterile saline mixture until saline drops from the distal end of the endovascular system.

### AIR EVACUATION

7. A 20 cc or smaller luer-lock syringe with a minimum of 5 cc's sterile saline mixture is recommended for use for aspirating this device.
8. With the distal balloon tip pointing down and positioned below the level of the syringe, pull negative pressure until all air is expelled.
9. Induce a negative pressure to remove any air from the balloon and inflation lumen. Repeat until all air is expelled.
10. Carefully release to neutral. Allow the inflation lumen to fill with the diluted contrast medium and maintain a neutral pressure. **IMPORTANT:** Do not apply positive pressure to the balloon.
11. Attach the prefilled inflation device to the inflation lumen of the catheter hub, ensuring no air bubbles remain at the catheter connection.
12. Verify that the covered stent is still centered between the two radiopaque markers on the balloon catheter.

### INTRODUCTION OF THE ENDOVASCULAR SYSTEM AND PLACEMENT OF THE COVERED STENT

13. Advance the endovascular system over the guidewire into the introducer sheath.
14. Further advance the endovascular system to the target treatment site within the introducer sheath and position the covered stent across the lesion. Verify that the covered stent is still centered within the balloon marker bands. Slowly retract the introducer sheath / guiding catheter while maintaining the position of the covered stent. Ensure the introducer sheath is retracted far enough to not compromise the balloon expansion and covered stent release.
15. Slowly inflate the endovascular system balloon to nominal pressure, expanding the covered stent. Confirm complete expansion via fluoroscopic visualization. A 15 – 30 second inflation time is recommended. **IMPORTANT:** Do not exceed the Rated Burst Pressure of the delivery system.
16. After covered stent deployment, apply negative pressure to the balloon until it is fully deflated. Withdraw the delivery system while maintaining negative pressure with the guidewire remaining across the lesion.
17. Confirm optimal covered stent wall apposition using standard angiographic techniques. If the covered stent has not achieved full wall apposition, a post dilation with an appropriately sized balloon should be performed. 5-8 mm devices may be post-dilated with balloons up to 10 mm in diameter. 9-12 mm devices may be post-dilated with balloons up to 12 mm in diameter.

#### PLACEMENT OF TWO OVERLAPPED COVERED STENTS

18. In the event that two covered stents must be placed overlapped, place the distal covered stent first. Ensure approximately 10 mm overlap zone.

#### PLACEMENT OF KISSING COVERED STENTS

19. When placing bilateral LIFESTREAM™ Balloon Expandable Vascular Covered Stents, the proximal ends may be allowed to touch beyond the ostium consistent with a kissing stent technique.

## N Patient Implant Information Card

A Patient Implant Information Card is provided with this device. The Patient Data, Implant Data, and Hospital Data should be carefully recorded on the card and given to the patient.

Apply one of the peel-off stickers found on the product label on the pouch to the indicated area on the Patient Implant Information card. This peel-off sticker contains important information about the patient's covered stent implant. The patient should carry this card with them and provide to any medical personnel caring for the patient in the future.

**CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of the physician.**

## O Summary of Clinical Study

A total of 155 patients were treated at 17 investigational sites in the United States, Europe, and New Zealand in the prospective, multi-center, non-randomized, single-arm study of the BARD® LIFESTREAM™ Balloon Expandable Vascular Covered Stent in the treatment of iliac artery occlusive disease (BOLSTER). Overall, 228 subjects were enrolled, of which 155 were treated with the study device and included in the As Treated Population. The objective of this study was to assess the safety and effectiveness of the BARD® LIFESTREAM™ Balloon Expandable Vascular Covered Stent for the treatment of atherosclerotic lesions in common and external iliac arteries. A composite safety and effectiveness measure of subjects receiving the BARD® LIFESTREAM™ Balloon Expandable Vascular Covered Stent was compared to a Performance Goal (PG) derived from iliac stent published literature.

At the time of this analysis, 155 subjects passed their 9-month visit and were evaluated for the primary and secondary endpoints. Patients will be followed through 36 months.

**Study Endpoints**

The primary endpoint of the study is a composite safety and effectiveness measure defined as device and/or procedure-related death or myocardial infarction (MI) through 30 days, or any Target Lesion Revascularization (TLR), target limb(s) major amputation, or restenosis through 9-months post-index procedure.

Device and/or procedure-related death, MI, and target limb(s) major amputation is adjudicated by a Clinical Events Committee (CEC). TLR is defined as the first revascularization procedure (e.g., PTA, atherectomy, etc.) of the target lesion(s) following the index procedure as determined by an Independent Angiographic Core Lab (or CEC, as necessary). Restenosis is assessed by duplex ultrasonography (DUS), where the target lesion(s) is determined to have a peak systolic velocity ratio (PSVR) > 2.4 with post-stenotic turbulence, as determined by an Independent DUS Core Lab. In this study, a PSVR of > 2.4 suggests > 50% restenosis.

Secondary endpoints included the following which are evaluated at various timepoints throughout the study: (1) Rate of Major Adverse Events (MAEs), (2) Acute Lesion Success, (3) Acute Procedure Success, (4) Acute Technical Success, (5) Target Lesion Revascularization (TLR), (6) Target Vessel Revascularization (TVR), (7) Sustained Clinical Success, (8) Primary Patency, (9) Primary Assisted Patency, (10) Secondary Patency, and (11) Quality of Life.

**Patients Studied**

Eligible patients had intermittent claudication or ischemic rest pain and angiographic confirmation of either de novo or restenotic (non-stented) lesion(s) ≥ 50% (including total occlusions) in the common and/or external iliac arteries. To be included in the study, the reference vessel diameter(s) was between 4.5mm and 12.0mm in diameter and the target lesion(s) was ≤ 100 mm in combined length (per side.) The patients must have had angiographic evidence of a patent profunda and/or superficial femoral artery.

Patients were excluded from the study if they had a vascular graft previously placed in the native iliac vessel, or if the subject suffered a hemorrhagic stroke or transient ischemic attack (TIA) within 3 months prior to the index procedure.

**Methods**

Eligible subjects were considered enrolled once he / she has agreed to study participation and provided consent. Once treated with the LifeStream™ balloon expandable vascular covered stent, clinical follow-up occurred at discharge, 30-days, and 9-, 12-, 24-, and 36-months post index procedure. Follow-up visits included a comprehensive physical exam, duplex ultrasound, Rutherford classification assessment, ABI measurement, and quality of life assessment among other measures. A telephone screen for all treated subjects occurred at 6-months post-procedure.

An independent Clinical Events Committee (CEC) reviewed all adverse events and adjudicated all serious, unanticipated, and device-related adverse events. Additionally, an independent Data Safety Monitoring Board (DSMB) reviewed safety information including site reported events and summaries of CEC adjudication activities. The DSMB determined and made recommendations on whether the study should continue as described, or if changes should be made.

**Results**
**Patient Demographics**

Tables 1-4 summarize the patient demographics, medical history, baseline characteristics, and target lesions treated.

**Table 1: Patient Demographics**

| | Bolster (N=155) |
|---|---|
| Age(Years) | |
| N | 155 |
| Mean (SD) | 64.3 (9.75) |
| Min - Max | 42.0 – 86.0 |
| | |
| Gender | |
| Male | 107 (69.0%) |
| Female | 48 (31.0%) |
| | |
| Weight(kg) | |
| N | 151 |
| Mean (SD) | 79.6 (16.60) |
| | |

| | |
|---|---|
| Height(cm) | |
| N | 154 |
| Mean (SD) | 170.7 (8.80) |
| | |
| BMI(kg/m2) | |
| N | 151 |
| Mean (SD) | 27.2 (4.81) |

**Table 2: Patient Medical History**

| Category | Term | Bolster (N=155) |
|---|---|---|
| Cardiovascular Disease | Total | 142 (91.6%) |
| | AAA | 7 (4.5%) |
| | Angina | 11 (7.1%) |
| | Aortic Disease | 7 (4.5%) |
| | Atrial Fibrillation (A-FIB) | 12 (7.7%) |
| | Congestive Heart Failure(CHF) | 9 (5.8%) |
| | Coronary Artery Disease (CAD) | 49 (31.6%) |
| | Dyslipidemia | 101 (65.2%) |
| | Hypertension | 117 (75.5%) |
| | Myocardial Infarction (MI) | 21 (13.5%) |
| | Stroke | 8 (5.2%) |
| | Other | 54 (34.8%) |
| | | |
| Renal Disease | Total | 27 (17.4%) |
| | Hemodialysis | 1 (0.6%) |
| | Renal Failure | 3 (1.9%) |
| | Other | 27 (17.4%) |
| | | |
| Other Disease | Total | 152 (98.1%) |
| | Cancer | 13 (8.4%) |
| | Cigarette Smoking | 132 (85.2%) |
| | Diabetes | 50 (32.3%) |
| | Gastrointestinal Disorder | 17 (11.0%) |
| | Respiratory Disorder | 23 (14.8%) |
| | Other | 78 (50.3%) |

**Note:** One subject may take multiple medications

**Table 3: Summary of Baseline Characteristics by Subject**

| | Bolster (N=155) |
|---|---|
| Treated Limb | |
| Bilateral | 34 (21.9%) |
| Left Leg | 72 (46.5%) |
| Right Leg | 49 (31.6%) |
| | |
| Number of Target Lesions | |
| 1 | 117 (75.5%) |
| 2 | 34 (21.9%) |
| 3 | 4 (2.6%) |
| | |
| Target Lesion Location | |
| Common Iliac Artery | 103 (66.5%) |
| External Iliac Artery | 36 (23.2%) |
| Both Common and External Iliac Artery | 16 (10.3%) |
| | |
| Number of Treated Lesion Location | |
| 1 | 111 (71.6%) |
| 2 | 40 (25.8%) |
| 3 | 4 (2.6%) |
| | |
| Treated Lesion Location | |
| Left Common Iliac Artery | 83 (53.5%) |
| Right Common Iliac Artery | 65 (41.9%) |
| Left External Iliac Artery | 30 (19.4%) |
| Right External Iliac Artery | 25 (16.1%) |
| | |
| Baseline/Pre-Procedure Stenosis[1] | |
| Occlusion | 21 (13.5%) |
| Stenosis | 134 (86.5%) |
| | |
| Baseline TASC Score[2] | |
| A | 96 (61.9%) |
| B | 42 (27.1%) |
| C | 15 (9.7%) |
| D | 2 (1.3%) |

[1, 2] If a subject has more than one lesion, the worst type will be used as the category for Baseline/ Pre-procedure Stenosis and Baseline TASC Score.

At the time of this analysis, the 197 lesions were treated with the LIFESTREAM™ balloon expandable vascular covered stent. Table 4 shows the lesion characteristics that were treated.

**Table 4: Summary of Target Lesions**

| | Bolster (N=155) |
|---|---|
| Degree of Calcification | |
| None | 19 / 197 (9.6%) |
| Mild | 51 / 197 (25.9%) |
| Moderate | 89 / 197 (45.2%) |
| Severe | 38 / 197 (19.3%) |
| | |
| Target Lesion Length (mm) | |
| N | 197 |
| Mean (SD) | 30.7 (17.35) |
| Min – Max | 3.0 - 100.0 |
| | |
| Reference Vessel Diameter (mm) | |
| N | 197 |
| Mean (SD) | 8.0 (1.27) |
| Min – Max | 5.0 - 12.0 |
| | |
| Target Lesion Stenosis (pre-intervention) % | |
| N | 197 |
| Mean (SD) | 80.3 (13.60) |
| Min – Max | 30.0 - 100.0 |

As reported by the Investigational Site.

**Patient Accountability**

Investigators treated 155 patients at 17 sites. In a Pre-Specified analysis, 130 subjects were evaluable at the 9-month timepoint. A Post-Hoc analysis was performed based on 138 subjects.

**Primary Effectiveness Results**

The primary endpoint of the study is a composite safety and effectiveness measure defined as device and/or procedure-related death or myocardial infarction (MI) through 30 days, or any Target Lesion Revascularization (TLR), target limb(s) major amputation, or restenosis through 9-months post-index procedure. The primary composite endpoint was analyzed by subject. The proportion of subjects with these efficacy events was compared to the performance goal of 19.5%.

Restenosis was determined by the DUS Core Lab based on objective measures of DUS imaging and did not rely on other imaging modalities, the need for re-intervention, or other clinical factors in order to determine the patency of lesions treated with the LIFESTREAM™ device.

In a Pre-Specified analysis of the 155 subjects who were treated in the study, a total of 25 subjects were excluded from the 9-month analysis. 17 of these subjects were excluded for reasons such as unevaluable imaging, lost to follow-up before the 9-month assessment, or early termination. 8 subjects missed or did not have evaluable imaging at their 9-month visit and completed their 12-month visit at the time of this analysis.

**Table 5: Primary Composite Endpoint Results (Pre-Specified Analysis)**

| | Bolster (N=155) | 93.3% Confidence Interval |
|---|---|---|
| Subjects with the Composite Events | 21/130 (16.2%) | (10.6%, 23.2%) |
| Subjects fail due to | | |
| Device and/or procedure-related death (<=30 day) | 0 / 130 (0.0%) | |
| Device and/or procedure-related MI (<=30 day) | 0 / 130 (0.0%) | |
| Target limb(s) major amputation through 9 months* | 1/ 130 (0.8%) | |
| TLR through 9 months | 6 / 130 (4.6%) | |
| Restenosis through 9 months | 15 / 130 (11.5%) | |

* Not device and / or procedure related

As analyzed on a Pre-Specified basis, the primary composite endpoint result was 16.2% (p-value 0.1987) and did not meet the pre-defined statistical performance goal.

A Post-Hoc analysis was done. This analysis includes the 8 subjects who missed or did not have evaluable imaging at their 9-month visit but were evaluable at the 12-month visit. All 8 were subsequently judged patent by DUS Core Lab. Additionally, 5 subjects were deemed patent at the 9-month analysis by the CEC chair based on a review of DUS imaging and including evaluation of additional imaging where available, re-intervention status, improvements in Rutherford Category, and other clinical factors. Table 6 includes the results of this Post-Hoc analysis in which all of these 13 subjects were determined to be patent.

**Table 6: Primary Composite Endpoint Results (Post-Hoc Analysis)**

| | Bolster (N=155) | 93.3% Confidence Interval[1] |
|---|---|---|
| Subjects with the Composite Events | 16 / 138 (11.6%) | (7.0%, 17.8%) |
| Subjects fail due to | | |
| Device and/or procedure-related death (<=30 day) | 0 / 138 (0.0%) | |
| Device and/or procedure-related MI (<=30 day) | 0 / 138 (0.0%) | |
| Target limb(s) major amputation through 9 months[2] | 1/ 138 (0.7%) | |
| TLR through 9 months | 6 / 138 (4.3%) | |
| Restenosis through 9 months | 10 / 138 (7.2%) | |

[1] Confidence intervals have not been adjusted for multiplicity and are provided to illustrate the variability of the corresponding summary statistic. They should not be used to draw statistical inference.

[2] Not device and / or procedure related

The primary composite endpoint based on the Post-Hoc analysis utilizing 12-month assessments and additional clinical factors was 11.6%.

**Per-Limb Analysis**

On a Pre-Specified basis, the per-limb primary composite endpoint is evaluated to be 21/157 = 13.4%. As analyzed on a Post-Hoc per-limb basis, the primary composite endpoint is evaluated to be 16/168 = 9.5%.

**Secondary Effectiveness Results**

Table 7 and 8 below provide a summary of the secondary effectiveness endpoints at the time of this analysis.

**Table 7: Secondary Effectiveness Results (Pre-Specified Analysis)**

| | Result | N | 95% Confidence Interval[1] |
|---|---|---|---|
| Rate of Major Adverse Events (MAEs) | 4.7% | 150[2] | (1.9%, 9.4%) |
| Acute Lesion Success | 98.4% | 191[3] | (95.5%, 99.7%) |
| Acute Procedure Success | 97.4% | 152[3] | (93.4%, 99.3%) |
| Acute Technical Success | 98.3% | 230[3] | (95.6%, 99.5%) |
| Target Lesion Revascularization (TLR) | 4.0% | 150[2] | (1.5%, 8.5%) |
| Target Vessel Revascularization (TVR) | 4.0% | 150[2] | (1.5%, 8.5%) |
| Sustained Clinical Success | 90.5% | 137[4] | (84.3%, 94.9%) |
| Primary Patency | 84.5% | 129[5] | (77.1%, 90.3%) |
| Primary Assisted Patency | 85.3% | 129[5] | (78.0%, 90.9%) |
| Secondary Patency | 87.5% | 128[5] | (80.5%, 92.7%) |

**Table 8: Secondary Effectiveness Endpoints (Post-Hoc Analysis)**

| | Result | N | 95% Confidence Interval[1] |
|---|---|---|---|
| Primary Patency | 89.1% | 137[6] | (82.6%, 93.7%) |
| Primary Assisted Patency | 89.8% | 137[6] | (83.4%, 94.3%) |
| Secondary Patency | 91.9% | 136[6] | (86.0%, 95.9%) |

[1] Confidence intervals have not been adjusted for multiplicity and are provided to illustrate the variability of the corresponding summary statistic. They should not be used to draw statistical inference.

[2] All subjects followed through day 240

[3] All treated lesions / subjects / stents with evaluable angiographic imaging at implant

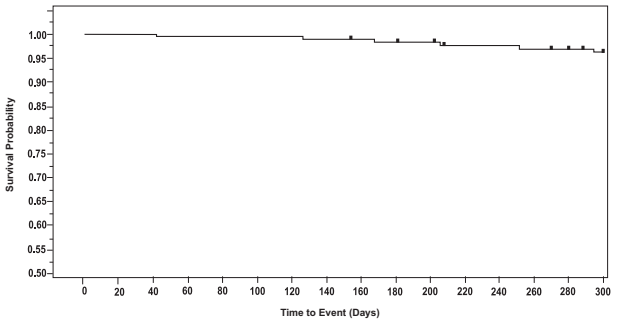
[4] All subjects completing the 9-month visit where Rutherford Category was assessed by the Investigator

[5] All subjects that completed the 9-month visit with evaluable duplex ultrasound imaging

[6] All subjects that completed the 9-month visit and/or 12-month visit with evaluable duplex imaging

The Kaplan-Meier analysis of TLR per subject was performed and results are provided in Figure 3. The Kaplan-Meier estimate of the incidence of TLR at 9 months (day 300) was 3.9% (95% CI 1.8%, 8.6%).

**Figure 3: Kaplan-Meier Analysis of TLR per Subject (As Treated Population)**




Quality of Life was assessed by the Walking Impairment Questionnaire (WIQ). The mean baseline total score was 32.0. At 9 months, the mean total score was 64.7, which represents an increase over baseline in total score of 32.7. Overall, improvements were seen in each domain of the WIQ.

**Summary of Safety**

Of the 155 subjects, 110 subjects (71.0%) reported 299 adverse events (AEs.) Sixty (60) subjects reported serious adverse events (60/110 = 54.5%.) The majority of the subjects had AEs that were not related to device (86/110; 78.2%) and/or related to the procedure (81/110; 73.6%). There were no unanticipated adverse device effects (UADEs) reported.

**Table 9: Summary of Safety**

| | Bolster (N=155) |
|---|---|
| | Site Reported |
| Total# of Events | 299 |
| Total# of Subjects with at Least One AE | 110 (71.0%) |
| Device Relatedness [1, 2] | |
| Definitely Related | 8 (7.3%) |
| Possibly Related | 16 (14.5%) |
| Not Related | 86 (78.2%) |
| | |
| Procedure Relatedness [1, 2] | |
| Definitely Related | 20 (18.2%) |
| Possibly Related | 9 (8.2%) |
| Not Related | 81 (73.6%) |
| | |
| Serious AE (SAE) [1] | 60 (54.5%) |
| Definitely or Possibly Device Related SAE | 9 (15.0%) |
| Not Device Related SAE | 51 (85.0%) |

[1] Subjects are only counted once with the highest level of relatedness.

[2] Percentages are based on denominator of 110, the total number of subjects with at least 1 AE

The types of safety events experienced in the study are expected for this patient population. All of the device and procedure related adverse events reported were consistent with those identified in section F Potential Adverse Events. Overall, the adverse event profiles appear comparable to standard of care for PTA and stenting of the iliac arteries.

**Patient Death Summary**

Five subjects died as of the date of this report. None of the deaths were considered to be related to the study device or procedure, as adjudicated by the CEC.

**Conclusions Drawn from the Study**

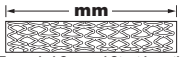
The prospective, multi-center, non-randomized, single-arm study of the BARD® LIFESTREAM™ Balloon Expandable Vascular Covered Stent in the treatment of iliac artery occlusive disease (BOLSTER) compared a composite safety and effectiveness measure to a Performance Goal (PG) derived from iliac stent published literature. At the time of this analysis, 155 subjects passed their 9-month visit and were evaluated for the primary and secondary endpoints.

The types of safety events experienced in the study are expected for this patient population. Overall, the adverse event profiles appear comparable to standard of care PTA and stenting of the iliac arteries.

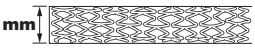
The clinical study results demonstrate the safety and effectiveness of the LifeStream Balloon Expandable Vascular Covered Stent for the treatment of atherosclerotic lesions of the common or external iliac artery.


Compressed Covered Stent Length


Working Length




Expanded Covered Stent Length




Expanded Covered Stent Diameter

Use By

Recommended Introducer

Recommended Guidewire


Contents: (1)


Catalogue Number


Lot Number


Non-Pyrogenic


Nominal Pressure


Rated Burst Pressure

Manufacturer

Consult Instructions for Use

Single Use


Do Not Resterilize

Do Not Use If Package Is Damaged

Keep Away From Sunlight

Keep Dry


Not Made With Natural Rubber Latex


Sterilized Using Ethylene Oxide


MR Conditional




**Distributed by:**
Bard Peripheral Vascular, Inc.
www.bardpv.com/globalcontact
TEL: 1-800-321-4254

**Manufacturer:**
Clearstream Technologies, Ltd.
Moyne Upper
Enniscorthy
Co. Wexford, Ireland

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