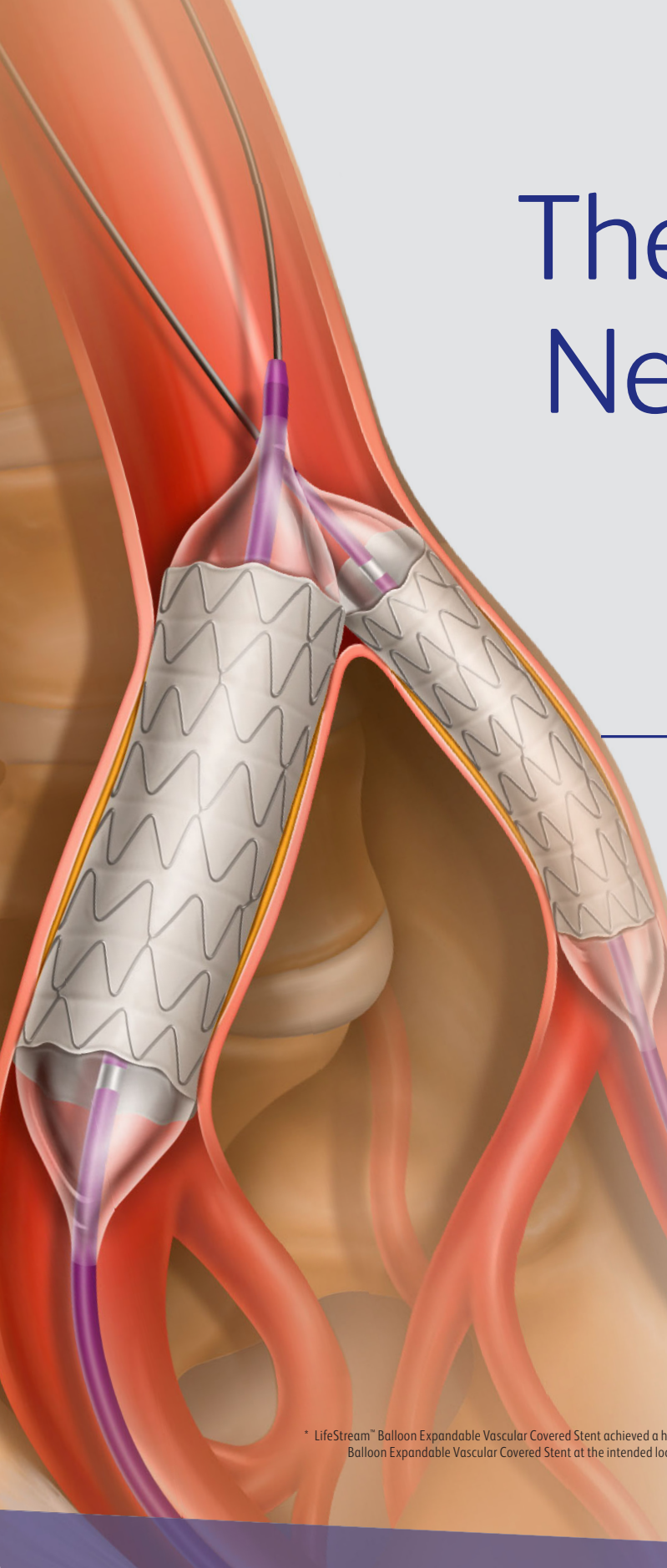

The Control You Need to Deliver Accurate Treatment*

LifeStream™

Balloon Expandable Vascular Covered Stent

* LifeStream™ Balloon Expandable Vascular Covered Stent achieved a high acute technical success rate of 98.3%. Acute Technical Success is defined as successful deployment of the LifeStream™ Balloon Expandable Vascular Covered Stent at the intended location, as determined by the investigator. BOLSTER Clinical Study. Data on File. Bard Peripheral Vascular, Inc., Tempe, AZ.

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BOLSTER Clinical Study

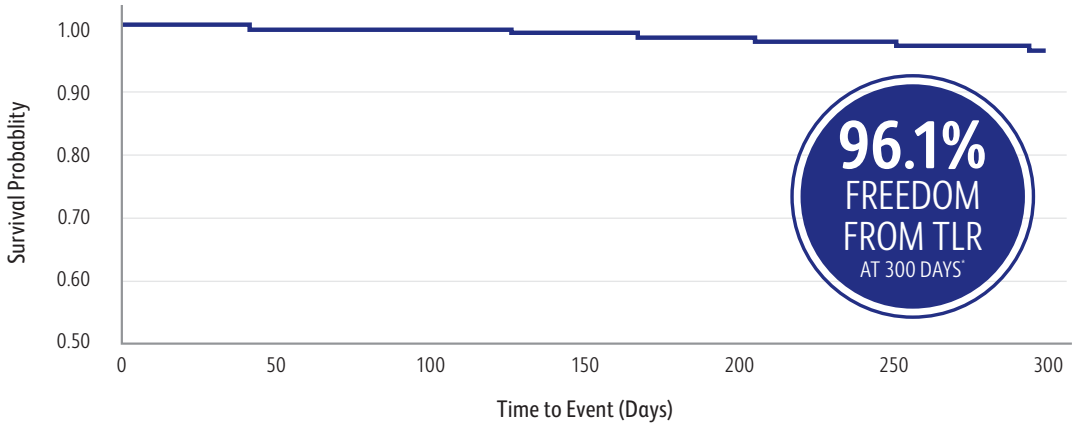
Balloon Expandable Vascular Covered Stent in the Treatment of Iliac Artery Occlusive Disease

Study Design

Design	Prospective, Multi-Center, Non-Randomized, Single-Arm Study
Objective	Assess the safety and effectiveness of the LifeStream™ Balloon Expandable Vascular Covered Stent for the treatment of stenoses and occlusions in the common and/or external iliac arteries
As Treated Population	155 patients at 17 investigational sites (US, Europe, and New Zealand)
National Principal Investigator	John Laird, MD
Primary Endpoint	Composite safety and effectiveness measure defined as: • Device- and/or procedure-related death or MI through 30 days; or • Any TLR, major amputation to the target limb, or restenosis (DUS) through 9 months. The primary endpoint is evaluated against a performance goal (PG) of 19.5%, which was derived from iliac stent published literature
Secondary Endpoints Included	• Technical Success • Procedure Success • TLR/TVR • Primary Patency

The clinical study results demonstrate the safety and effectiveness of the LifeStream™ Balloon Expandable Vascular Covered Stent for its intended use. 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. As analyzed on a Post-Hoc basis utilizing 12-month assessments and additional clinical factors, the primary composite endpoint result was 11.6%.

Freedom from TLR



* Based on Kaplan-Meier analysis of Freedom from TLR per subject (As Treated Population). BOLSTER Clinical Study. Data on File. Bard Peripheral Vascular, Inc, Tempe, AZ.

When you reach for a balloon expandable stent, you require accuracy. The LifeStream™ Balloon Expandable Covered Stent was developed using BD's vast experience in PTA and covered stents to create a device designed for the challenging anatomy of iliac arteries and engineered to facilitate accurate placement. With a design that facilitates ease of trackability, low sheath profile, stent-specific marker bands, and minimal foreshortening, the LifeStream™ Covered Stent helps you deliver accurate placement.

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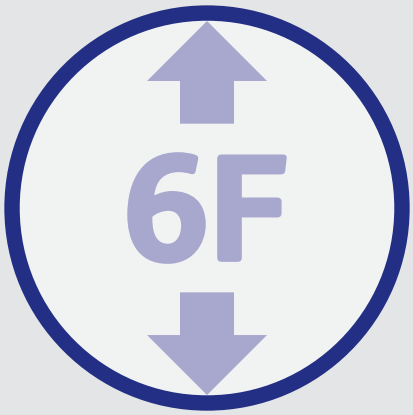
Balloon Expandable Vascular Covered Stent

Low Sheath Profile

LifeStream™ Covered Stent offers sizes on a 6F platform, which is the lowest sheath profile among balloon expandable covered stents on the U.S. market with an iliac indication.[1]

6F platform for balloon expandable covered stent



Broad size matrix

LifeStream™ Crimped Covered Stent Length (mm)

Diameter (mm)	16	26	37/38[2]	58
5				
6		6F		
7				
8			7F	
9				
10				8F
12				

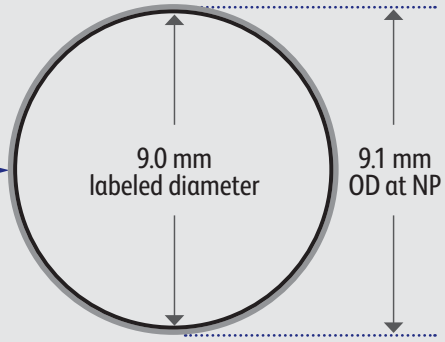
Ease of Delivery

The LifeStream™ Covered Stent is designed to provide trackability to reach lesions through complex and tortuous anatomy–helping to provide ease of delivery to the target lesion.

Non-compliant balloon technology

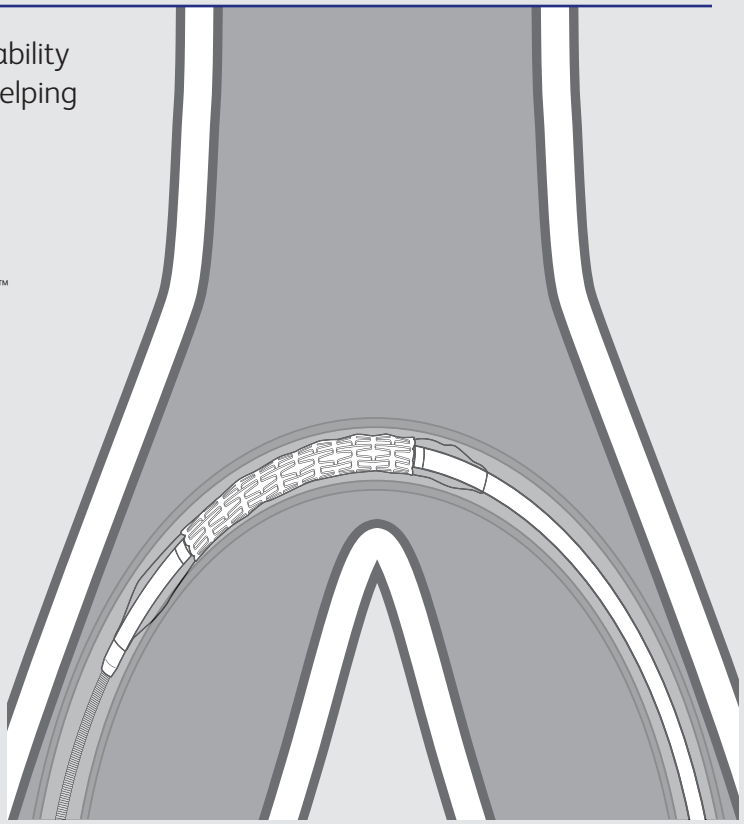
Utilizing non-compliant balloon technology, the LifeStream™ Covered Stent is designed to provide precise diameters and efface heavily-calcified iliac lesions.

AVERAGE COMPLIANCE 1.1% AT NP ACROSS ALL SIZES[3]



Diameter Variance as labeled for 9 mm LifeStream™ PTA Catheter

Not drawn to scale



Designed for trackability

[1] As of March 2022.

[2] 5 mm - 8 mm diameters utilize a 37 mm base stent platform. 9 mm - 12 mm diameters utilize a 38 mm base stent platform.

[3] Calculated as the percentage difference between the labeled balloon outer diameter and the actual balloon outer diameter at nominal pressure (NP). Across all balloon sizes, compliance ranged from -0.4% to 2.6%, with a mean of 1.1% at nominal pressure. Please consult package insert for the LifeStream™ Covered Stent compliance chart.

Accurate Placement

The radiopaque marker bands of the LifeStream™ Covered Stent have been specifically positioned on the balloon catheter at the ends of the crimped covered stent to facilitate accurate stent placement. And when millimeters count, the LifeStream™ Covered Stent, with an average of 3.5% foreshortening across all balloon sizes at nominal inflation pressure[4], achieved a high Acute Technical Success Rate of 98.3% in the BOLSTER Study[5].

Minimal foreshortening (7 x 37 mm example)

Optimized for iliac interventions

An optimized balloon design with short balloon shoulders and cones helps minimize dilatation of healthy tissue and reduce the risk of catheter entanglement during kissing stent procedures.

Stent-specific marker bands

Maximum distance between inner border of marker band and covered stent end on each side = 0.80 mm.

[4] Foreshortening is calculated as the difference, represented as a percentage, between the labeled covered stent length in crimped condition and the actual stent length measured at both nominal and at rated burst pressure. Across all balloon sizes, foreshortening ranged from -1.5%% to 11.6% at nominal pressure, with a mean of 3.5%, and from -0.8% to 11.8% at rated burst pressure, with a mean of 4.6%. Please consult package insert for the LifeStream™ Covered Stent foreshortening chart.

[5] Acute Technical Success defined as successful deployment of the LifeStream™ Covered Stent at the intended location, as determined by the investigator. BOLSTER Clinical Study. Data on File. Bard Peripheral Vascular, Inc., Tempe, AZ.

LifeStream™

Balloon Expandable Vascular Covered Stent

80 cm Catheter Length		
Stent Diameter (mm)	**Stent Length (mm)**	**Product Code**
5	26	☐ LSMU0800526
	37	☐ LSMU0800537
6	16	☐ LSMU0800616
	26	☐ LSMU0800626
	37	☐ LSMU0800637
	58	☐ LSMU0800658
7	16	☐ LSMU0800716
	26	☐ LSMU0800726
	37	☐ LSMU0800737
	58	☐ LSMU0800758
8	16	☐ LSMU0800816
	26	☐ LSMU0800826
	37	☐ LSMU0800837
	58	☐ LSMU0800858
9	38	☐ LSMU0800938
	58	☐ LSMU0800958
10	38	☐ LSMU0801038
	58	☐ LSMU0801058
12	38	☐ LSMU0801238
	58	☐ LSMU0801258

135 cm Catheter Length		
Stent Diameter (mm)	**Stent Length (mm)**	**Product Code**
5	26	☐ LSMU1350526
	37	☐ LSMU1350537
6	16	☐ LSMU1350616
	26	☐ LSMU1350626
	37	☐ LSMU1350637
	58	☐ LSMU1350658
7	16	☐ LSMU1350716
	26	☐ LSMU1350726
	37	☐ LSMU1350737
	58	☐ LSMU1350758
8	16	☐ LSMU1350816
	26	☐ LSMU1350826
	37	☐ LSMU1350837
	58	☐ LSMU1350858
9	38	☐ LSMU1350938
	58	☐ LSMU1350958
10	38	☐ LSMU1351038
	58	☐ LSMU1351058
12	38	☐ LSMU1351238
	58	☐ LSMU1351258

PHYSICIAN SIGNATURE

REPRESENTATIVE NAME

CONTACT PHONE NO.

LifeStream™ Balloon Expandable Vascular Covered Stent

Prescriptive Information: Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions. " above the indication

Indications: 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.

Contraindications: 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.

Warnings: Stenting across a vessel side branch may impede blood flow and hinder or prevent future procedures. Should excessive resistance be felt at any time during the insertion process, do not force passage. 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.

Precautions: Use caution when advancing the endovascular system through tortuous or difficult anatomy. This device has not been tested for use in overlapped conditions with stents or covered stents from other manufacturers.

Please consult package insert for more detailed safety information and instructions for use.

bd.com BD, Tempe, AZ, USA, 1 800 321 4254

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