

# BOLSTER Clinical Study

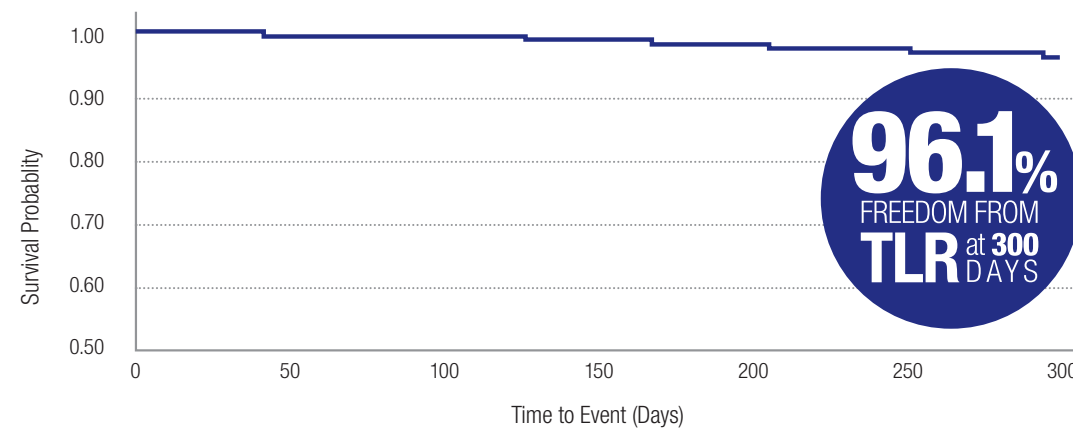
Balloon Expandable Vascular Covered Stent in the Treatment of Iliac Artery Occlusive Disease

## Study Design

<b>Design</b>	Prospective, Multi-Center, Non-Randomized, Single-Arm Study
<b>Objective</b>	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
<b>As Treated Population</b>	155 patients at 17 investigational sites (US, Europe, and New Zealand)
<b>National Principal Investigator</b>	John Laird, MD
<b>Primary Endpoint</b>	Composite safety and effectiveness measure defined as: <ul style="list-style-type: none"> <li>Device- and/or procedure-related death or MI through 30 days; or</li> <li>Any TLR, major limb amputation, or restenosis (DUS) through 9 months.</li> </ul> The primary endpoint is evaluated against a performance goal (PG) of 19.5%, which was derived from iliac stent published literature
<b>Secondary Endpoints Included</b>	<ul style="list-style-type: none"> <li>Technical Success</li> <li>Procedure Success</li> <li>TLR/TVR</li> <li>Primary Patency</li> </ul>

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). 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.

# LIFESTREAM®

Balloon Expandable Vascular Covered Stent

80 cm Catheter Length			135 cm Catheter Length		
Stent Diameter (mm)	Stent Length (mm)	Product Code	Stent Diameter (mm)	Stent Length (mm)	Product Code
5	26	<input type="checkbox"/> LSMU0800526	5	26	<input type="checkbox"/> LSMU1350526
	37	<input type="checkbox"/> LSMU0800537		37	<input type="checkbox"/> LSMU1350537
6	16	<input type="checkbox"/> LSMU0800616	6	16	<input type="checkbox"/> LSMU1350616
	26	<input type="checkbox"/> LSMU0800626		26	<input type="checkbox"/> LSMU1350626
	37	<input type="checkbox"/> LSMU0800637		37	<input type="checkbox"/> LSMU1350637
7	58	<input type="checkbox"/> LSMU0800658	7	58	<input type="checkbox"/> LSMU1350658
	16	<input type="checkbox"/> LSMU0800716		16	<input type="checkbox"/> LSMU1350716
	26	<input type="checkbox"/> LSMU0800726		26	<input type="checkbox"/> LSMU1350726
8	37	<input type="checkbox"/> LSMU0800737	8	37	<input type="checkbox"/> LSMU1350737
	58	<input type="checkbox"/> LSMU0800758		58	<input type="checkbox"/> LSMU1350758
	16	<input type="checkbox"/> LSMU0800816		16	<input type="checkbox"/> LSMU1350816
9	26	<input type="checkbox"/> LSMU0800826	9	26	<input type="checkbox"/> LSMU1350826
	37	<input type="checkbox"/> LSMU0800837		37	<input type="checkbox"/> LSMU1350837
	58	<input type="checkbox"/> LSMU0800858		58	<input type="checkbox"/> LSMU1350858
10	38	<input type="checkbox"/> LSMU0800938	10	38	<input type="checkbox"/> LSMU1350938
	58	<input type="checkbox"/> LSMU0800958		58	<input type="checkbox"/> LSMU1350958
12	38	<input type="checkbox"/> LSMU0801038	12	38	<input type="checkbox"/> LSMU1351038
	58	<input type="checkbox"/> LSMU0801058		58	<input type="checkbox"/> LSMU1351058
12	38	<input type="checkbox"/> LSMU0801238	12	38	<input type="checkbox"/> LSMU1351238
	58	<input type="checkbox"/> LSMU0801258		58	<input type="checkbox"/> LSMU1351258

REPRESENTATIVE NAME	PHYSICIAN'S SIGNATURE
CONTACT PHONE NO.	

### LIFESTREAM® Balloon Expandable Vascular Covered Stent

**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.

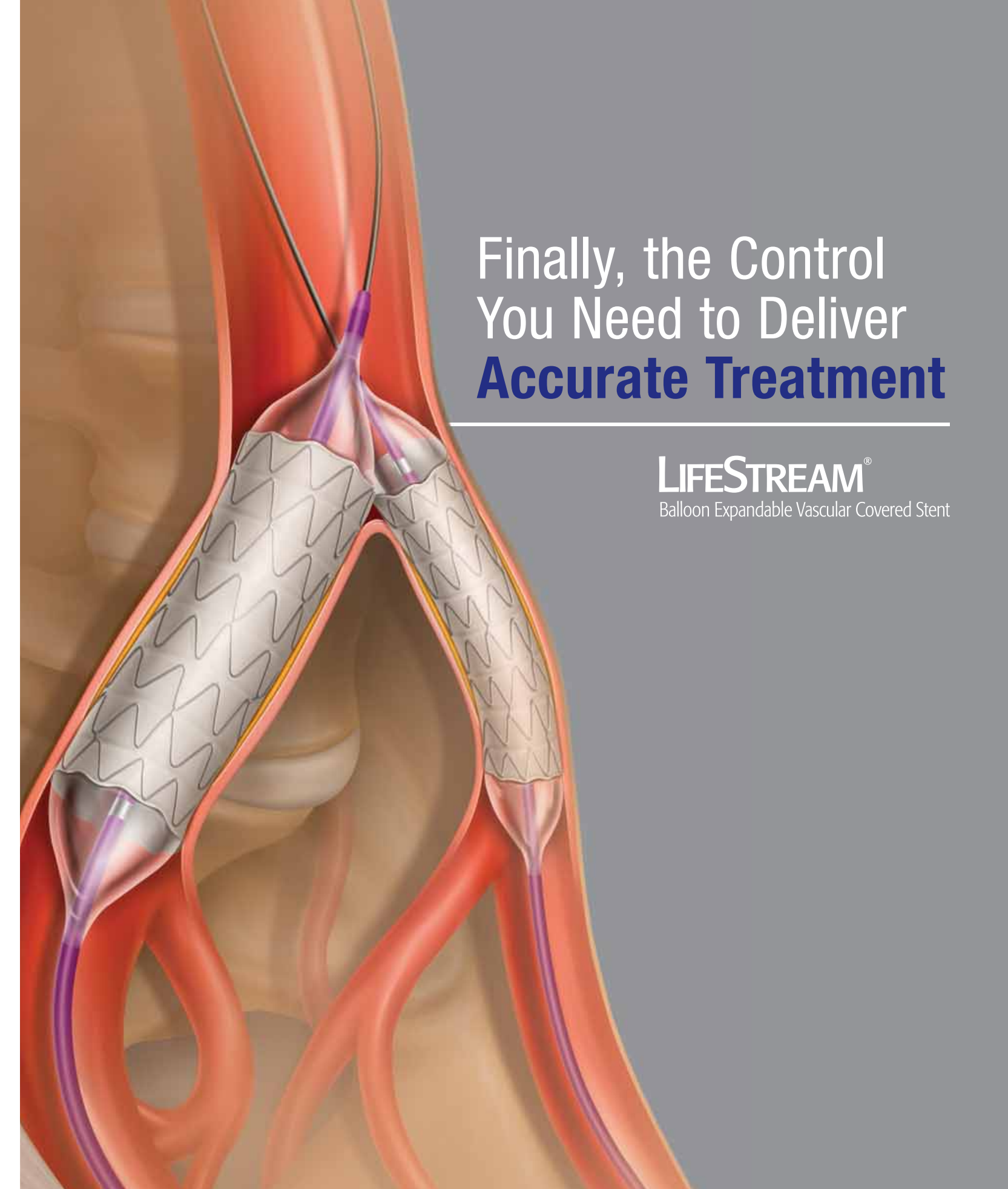
**Warnings:** Stenting across a vessel side branch may impede blood flow and hinder or prevent future procedures. Should excessive resistance be felt at any time during the insertion process, do not force passage. Do not attempt to remove an unexpanded covered stent through the sheath/guiding catheter. 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.**

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# Finally, the Control You Need to Deliver Accurate Treatment

LIFESTREAM®  
Balloon Expandable Vascular Covered Stent

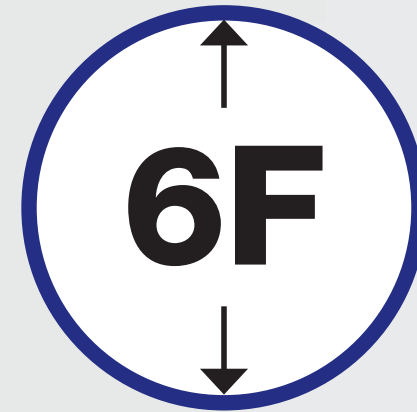
When you reach for a balloon expandable stent, you require accuracy. The LIFESTREAM® Balloon Expandable Covered Stent was developed using Bard's vast experience in PTA and covered stents to create a device designed for the challenging anatomy of iliac arteries and engineered to facilitate accurate placement. 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 performance.

**LIFESTREAM®**  
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.<sup>1</sup>

6F platform  
for balloon  
expandable  
covered stent



## Broad size matrix

Diameter (mm)	LIFESTREAM® Crimped Covered Stent Length (mm)			
	16	26	37/38 <sup>2</sup>	58
5				
6		6F		
7				
8			7F	
9				
10				
12			8F	

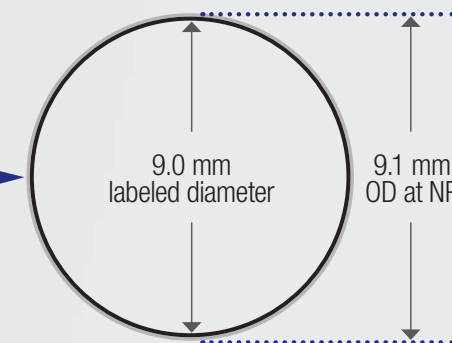
## Ease of Delivery

The LIFESTREAM® Covered Stent is designed to provide trackability to reach lesions through complex and tortuous anatomy—providing ease of delivery to the target lesion.

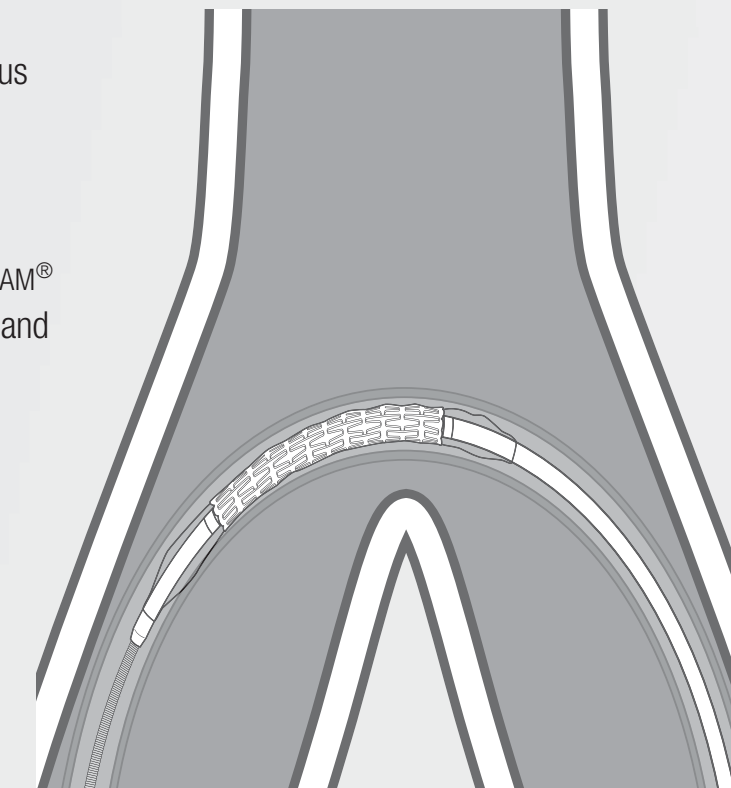
## Non-compliant balloon technology

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<sup>3</sup>



Diameter Variance as labeled for  
9 mm LIFESTREAM® PTA Catheter  
Not drawn to scale

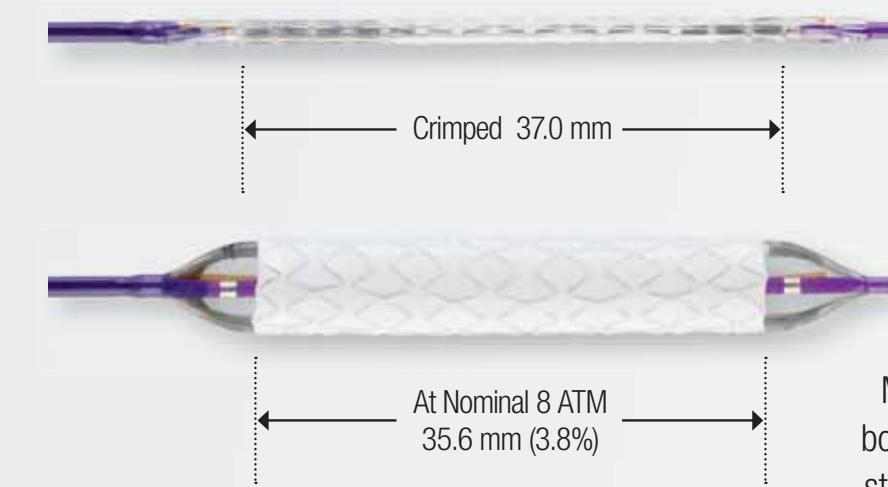


Designed for trackability

## 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<sup>4</sup>, achieved a high Acute Technical Success Rate of 98.3% in the BOLSTER Study<sup>5</sup>.

## Minimal foreshortening (7 x 37 mm example)



Stent-specific marker bands  
Maximum distance between inner  
border of marker band and covered  
stent end on each side = 0.80 mm

9-12 mm  
Diameters



## 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.

1. As of April 2019.  
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% to 2.4%, with a mean of 1.1% at nominal pressure. Please consult package insert for the LIFESTREAM® Covered Stent compliance chart.

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.