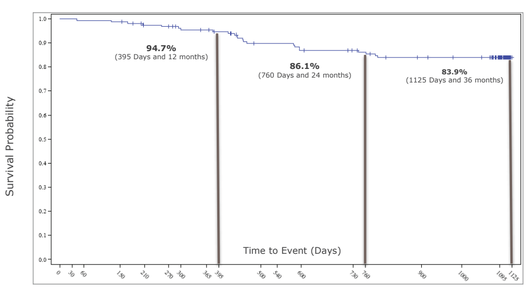
Bolster Clinical Study

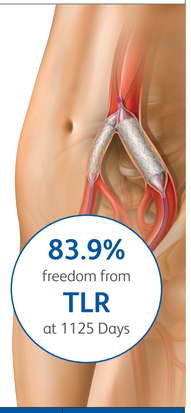
Balloon Expandable Vascular Covered Stent in the treatment of Iliac Artery Occlusive Disease

Bolster clinical trial design[1]

Design	Prospective, multi-center, non-randomised, 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 limb amputation, 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 • TLR/TVR • Procedure success • Primary patency

Freedom from TLR (Kaplan-Meier analysis)[2]





Time to event (days)	Number of subjects censored	Number of subjects event	Number of subjects left	K-M estimates of subjects with event	95% Confidence Interval
Day 365	9	7	139	4.6%	(2.2% , 9.5%)
Day 395	11	8	136	5.3%	(2.7% , 10.4%)
Day 730	18	18	119	12.4%	(8.0% , 19.0%)
Day 760	19	20	116	13.9%	(9.2%, 20.7%)
Day 1095	66	23	66	16.1%	(11.0%, 23.3%)
Day 1125	132	23	0	16.1%	(11.0%, 23.3%)

The control you need to deliver long term efficiency LifeStream™ Balloon Expandable Vascular Covered Stent

Ordering Information

LifeStream™
Balloon Expandable Vascular Covered Stent

80 cm Catheter Length				
Order code	Expanded Covered Stent Diameter (mm)	Compressed Covered Stent Length (mm)	Rated Burst Pressure (atm)	Recommended Introducer
LSM0800526	5	26	12	6F
LSM0800537		37	12	6F
LSM0800616	6	16	12	6F
LSM0800626		26	12	6F
LSM0800637		37	12	6F
LSM0800658		58	12	7F
LSM0800716	7	16	12	6F
LSM0800726		26	12	6F
LSM0800737		37	12	7F
LSM0800758		58	12	7F
LSM0800816	8	16	12	7F
LSM0800826		26	12	7F
LSM0800837		37	12	7F
LSM0800858		58	12	7F
LSM0800938	9	38	12	7F
LSM0800958		58	12	7F
LSM0801038	10	38	12	8F
LSM0801058		58	12	8F
LSM0801238	12	38	12	8F
LSM0801258		58	12	8F

135 cm Catheter Length				
Order code	Expanded Covered Stent Diameter (mm)	Compressed Covered Stent Length (mm)	Rated Burst Pressure (atm)	Recommended Introducer
LSM1350526	5	26	12	6F
LSM1350537		37	12	6F
LSM1350616	6	16	12	6F
LSM1350626		26	12	6F
LSM1350637		37	12	6F
LSM1350658		58	12	7F
LSM1350716	7	16	12	6F
LSM1350726		26	12	6F
LSM1350737		37	12	7F
LSM1350758		58	12	7F
LSM1350816	8	16	12	7F
LSM1350826		26	12	7F
LSM1350837		37	12	7F
LSM1350858		58	12	7F
LSM1350938	9	38	12	7F
LSM1350958		58	12	7F
LSM1351038	10	38	12	8F
LSM1351058		58	12	8F
LSM1351238	12	38	12	8F
LSM1351258		58	12	8F

Units per case: 1

LIFESTREAM™Balloon Expandable Vascular Covered Stent

Indications for Use: The LifeStream™ Balloon Expandable Vascular Covered Stent is indicated for the treatment of atherosclerotic lesions in common and external iliac arteries.

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.

For direct advertising to healthcare professionals that is exemption for permission. Registered under Act 737. GD16910500817

1. Balloon-Expandable Vascular Covered Stent in the Treatment of Iliac Artery Occlusive Disease: 9-Month Results from the BOLSTER Multicenter Study . John RLaird MD. J VascIntervRadiology 2019. 30:836–844. June 2019
2. BOLSTER Clinical Study The BOLSTER Study with LifeStream™ covered stent in iliac lesions: 3 Year Outcomes; John R Laird, MD, LINC 2019
3. 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.
4. 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.

BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.

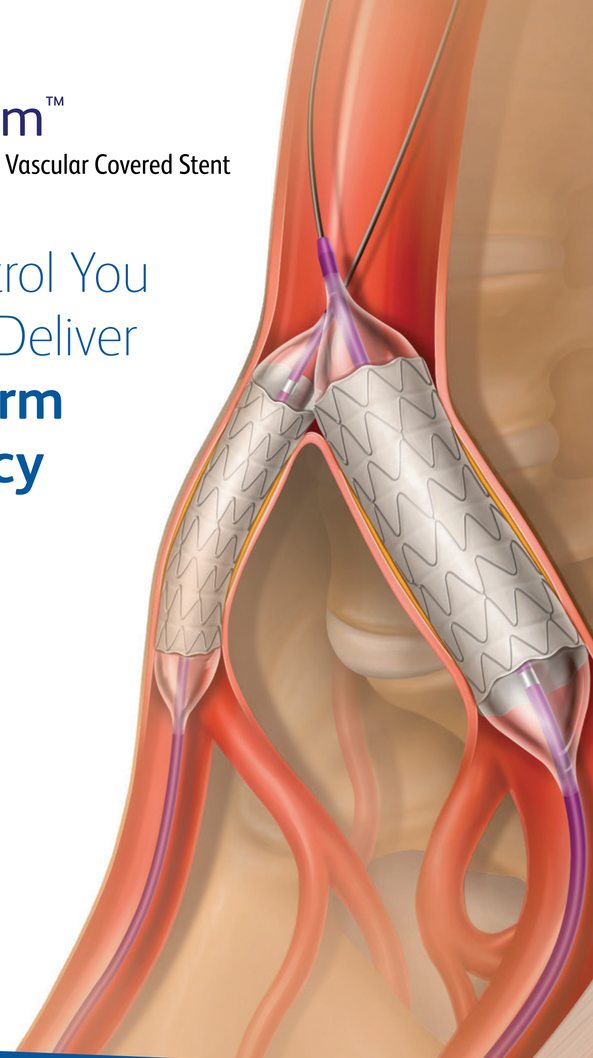
CE 0344

bd.com

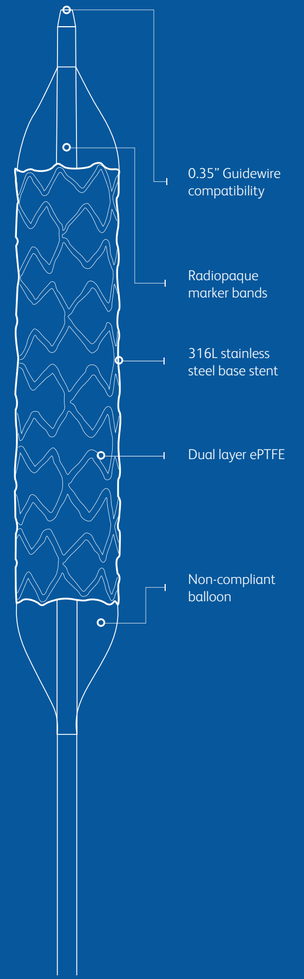
LifeStream™

Balloon Expandable Vascular Covered Stent

The Control You Need to Deliver **Long Term Efficiency**



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

The control you need to deliver long term efficiency
LifeStream™ Balloon Expandable Vascular Covered Stent

TLR rate through 36 months (proportional analysis)[2]

Follow Up, % (n/N)	ITT Group	95% CI^
6 months	2.6% (4/155)	[0.7%, 6.5%]
6 months	4.0% (6/150)	[1.5%, 8.5%]
12 months	5.4% (8/147)	[2.4%, 10.4%]
24 months	14.2% (20/139)	[9.0%, 21.3%]
36 months+	17.6% (23/131)	[11.5%, 25.2%]

First revascularisation procedure of the target lesion(s) following covered stent placement, determined by the angiographic core lab

^95% CI is estimated by the exact binomial method +Proportional analysis through 36 months (denominator: number of evaluable patients at a given follow-up time point)

Patency through 36 months (proportional analysis)[2]

Primary Patency, % (n/N)	ITT Group	95% CI^
12 months	92.4% (122/132)	[86.5%, 96.3%]
24 months	83.2% (99/119)	[75.2%, 89.4%]
36 months+	77.2% (78/101)	[67.8%, 85.0%]

Freedom from occlusion by DUS or angiography and/or TLR

Secondary Patency, % (n/N)	ITT Group 95% CI^	95% CI^
12 months	95.4% (124/130)	[90.2%, 98.3%]
24 months	95.6% (108/113)	[90.0%, 98.5%]
36 months+	93.4% (85/91)	[86.2%, 97.5%]

Patency re-established via an endovascular procedure following restenosis

^95% CI is estimated by the exact binomial method +Proportional analysis through 36 months (denominator: number of evaluable patients at a given follow-up time point)

Sustained Clinical Success[2]

Follow Up, % (n/N)	ITT Group	95% CI^
9 months	90.5% (124/137)	[84.3%, 94.9%]
12 months	93.9% (124/132)	[88.4%, 97.3%]
24 months	90.6% (106/117)	[83.8%, 95.2%]
36 months	92.5% (98/106)	[85.7%, 96.7%]

Cumulative improvement ≥ 1 category from baseline Rutherford values – Improvement sustained through 36 months

+Proportional analysis (denominator: number of evaluable patients at a given follow-up time point) ^95% CI is estimated by the exact binomial method

Quality of Life: WIQ[2]

	Baseline	9 months	12 months	24 months	36 months
WIQ Total Score					
N	153	135	132	117	104
Mean (SD)	32.0 (18.03)	64.7 (28.1)	65.7 (28.2)	64.8 (28.6)	67.4 (27.0)
Median	28.4	72.4	75.0	68.3	71.8
Min - Max	0.0 - 96.9	0.1 - 100.0	0.1 - 100.0	0.2 - 100.0	6.3 - 100.0
Change from baseline					
N		134	130	116	103
Mean (SD)		32.1 (26.8)	32.8 (26.8)	31.3 (26.8)	32.5 (27.3)
Median		34.0	34.9	30.9	35.9
Min - Max		-45.3 - 94.8	-34.6 - 82.3	-28.8 - 78.2 -	-46.9 - 89.1

Patient Quality of Life, assessed by the Walking Impairment Questionnaire (WIQ), average improvement from baseline to 9 months just over 32 points – improvement sustained through 3 years (32.5 + 27.3)

The control you need to deliver long term efficiency
LifeStream™ Balloon Expandable Vascular Covered Stent

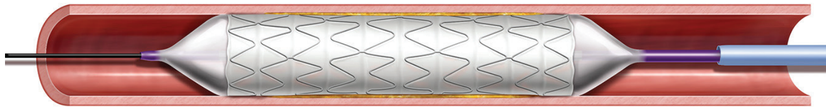
LifeStream™ Balloon Expandable Vascular Covered Stent

Accurate placement optimised for iliac interventions

Ease of delivery

Low sheath profile

36 months clinical results



The LifeStream™ Balloon Expandable Vascular Covered Stent provided good clinical outcomes through 3 years for the treatment of stenotic and occlusive lesions of the iliac arteries.[2]

Outcomes through 36 months:

83.9%	77.2%	93.4%	92.5%	32.5	> 0.10: 70.4%
Freedom from TLR (Kaplan-Meier)	Primary patency	Secondary patency	Sustained clinical success	Sustained improvement in average score for Quality of Life (WIQ)	Improvement in ABI