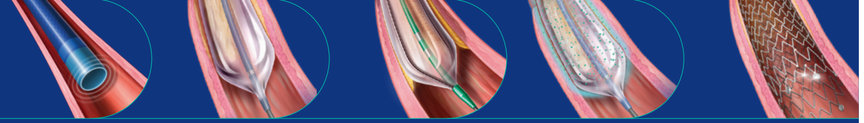

Halo One™ | Ultraverse™ 035 | UltraScore™ | Lutonix™ 035 I 5F | LifeStent™ I 5F

7F

6F

5F

LifeStent™ I5F

Vascular Stent System

The Halo Effect™

Low profile solutions to enable a 5F procedure from various access sites

- The Halo Effect™ Advantage
- Established technologies
- Low crossing profile
- Designed to reduce arteriotomy size*
- Enables alternative access sites**
- 4F Arteriotomy size***

* Versus comparable 6F devices.

** The LifeStent™ 5F Vascular Stent System is designed to be used via a femoral access site.

*** The Halo Effect™ Versus regular 5F guiding sheath

The Lutonix™ 035 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

The Ultrascore™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

The Ultraverse™ 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native synthetic AV fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. This device is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. This catheter is not for use in the coronary arteries.

Ordering information

80 cm Catheter Length

Order code	Stent Diameter (mm)	Stent Length (mm)	Sheath Size (F)
5F050201C		20	5
5F050301C		30	5
5F050401C		40	5
5F050601C		60	5
5F050801C	5	80	5
5F051001C		100	5
5F051201C		120	5
5F051501C		150	5
5F051701C		170	5
5F060201C		20	5
5F060301C		30	5
5F060401C		40	5
5F060601C		60	5
5F060801C	6	80	5
5F061001C		100	5
5F061201C		120	5
5F061501C		150	5
5F070201C		20	5
5F070301C		30	5
5F070401C		40	5
5F070601C	7	60	5
5F070801C		80	5
5F071001C		100	5
5F071201C		120	5

135 cm Catheter Length

Order code	Stent Diameter (mm)	Stent Length (mm)	Sheath Size (F)
5F050203C		20	5
5F050303C		30	5
5F050403C		40	5
5F050603C		60	5
5F050803C	5	80	5
5F051003C		100	5
5F051203C		120	5
5F051503C		150	5
5F051703C		170	5
5F060203C		20	5
5F060303C		30	5
5F060403C		40	5
5F060603C		60	5
5F060803C	6	80	5
5F061003C		100	5
5F061203C		120	5
5F061503C		150	5
5F070203C		20	5
5F070303C		30	5
5F070403C		40	5
5F070603C	7	60	5
5F070803C		80	5
5F071003C		100	5
5F071203C		120	5

Unit per case: 1

LifeStent™ 5F Vascular Stent System

Indications: The LifeStent™ 5F Vascular Stent System is indicated for the treatment of atherosclerotic lesions in the superficial femoral artery (SFA) and popliteal artery.

Contraindications: The LifeStent™ 5F Vascular Stent System is contraindicated for use in: • Patients with a known hypersensitivity to nitinol (nickel, titanium) or tantalum.

Warnings: • The LifeStent™ 5F Vascular Stent System is supplied STERILE (by ethylene oxide) 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 to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with uncorrectable coagulation disorders. • DO NOT use in patients that cannot be adequately pre-medicated. • DO NOT use in patients with a target lesion with a large amount of adjacent acute or subacute thrombus. • DO NOT use in 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. • DO NOT use the device if the sterile packaging has been damaged or unintentionally opened prior to use. • DO NOT use the device after the „Use By" date specified on the label. • Persons with allergic reactions to nitinol (nickel, titanium) and/or tantalum may suffer an allergic response to this implant. • DO NOT expose the delivery system to organic solvents (e.g., alcohol). • The stent is not designed for repositioning or recapturing. • Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. • If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol (nickel-titanium alloy)). • The safety and effectiveness of stent overlapping in the middle (P2) and distal popliteal artery (P3) has not yet been established. • It is recommended to use the 80 cm working length device for ipsilateral procedures. The longer working length of the 135 cm device may potentially be challenging for the user to keep straight for ipsilateral procedures. Failure to keep the device straight may impede the optimal deployment of the implant. • The long-term outcomes following repeat dilatation of endothelialized stents are unknown

Precautions: • During system flushing, observe that saline exits at the catheter tip. • The delivery system is not designed for use with power injection systems. • Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. • Keep the device as straight as possible following removal from the packaging and while inserted in the patient. Failure to do so may impede the optimal deployment of the implant. • Prior to and during stent deployment, remove slack from the delivery system catheter outside the patient by gently holding the stability sheath and keeping it straight and under tension. • If excessive force is felt during stent deployment, DO NOT force the delivery system. Remove the delivery system and replace with a new unit. • DO NOT attempt to break, damage, or disrupt the stent after placement. • Cases of fracture have been reported in clinical use of the LifeStent™ Vascular Stent. Cases of stent fracture occurred in lesions that were moderate to severely calcified, proximal or distal to an area of stent overlap and in cases where stents experienced > 10% elongation at deployment. Therefore, care should be taken when deploying the stent as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent stent fracture. The long-term clinical implications of these stent fractures have not yet been established. • The safety and effectiveness of this device for use in treatment of in-stent restenosis has not been established. • The GeoAlign™ Marking System is designed to be used as an additional reference tool to accompany the interventionalist's standard operation procedure. The use of fluoroscopic imaging is recommended following positioning of the catheter to the target lesion and prior to stent deployment or balloon inflation. • If the GeoAlign™ location reference is on the brown moving sheath (Figure 9), the location reference will move relative to the introducer hub and stability sheath as soon as stent deployment has been initiated. DO NOT try to re-align the location reference after stent deployment has been initiated. The green stability sheath should remain stationary relative to the introducer and under tension throughout deployment. • One or more components of this device contain the following substance defined as CMR 1B (reproduction toxic) in a concentration above 0,1% weight by weight: N-Methyl-2-pyrrolidinone (NMP; CAS 872-50-4) N-Methyl-2-pyrrolidinone (NMP) is a solvent used in the manufacturing process of certain components of the LifeStent™ 5F Delivery System. NMP has been shown to have adverse effects in experimental animals, including reproductive and developmental effects. BD has not assessed any related adverse effects in relation to the exposure to NMP when this device is used with neonates, infants, pregnant or breast-feeding women. It is the responsibility of the physician to assess risks associated with the use of a device containing NMP..

Potential complications and adverse events: Complications and Adverse Events which may occur include, but are not limited to the following: • Allergic reaction • Amputation • Arteriovenous fistula • Distal embolization • Hematoma • Hemorrhage • Ischemia complications • Infection • Open surgical intervention • Pseudoaneurysm • Renal impairment • Restenosis • Surgical intervention • Stent fracture • Stent kinking / collapse • Stent migration • Stent misplacement • Thromboembolic event • Thrombosis • Vasospasm • Vessel occlusion • Vessel wall trauma Note: Users and/or patients should report any serious incident that has occurred in relation to the device to the manufacturer and to either the European Union National Competent Authority or to the regulatory authority of the country in which the user and/or patient is established. **Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions**

BD Switzerland

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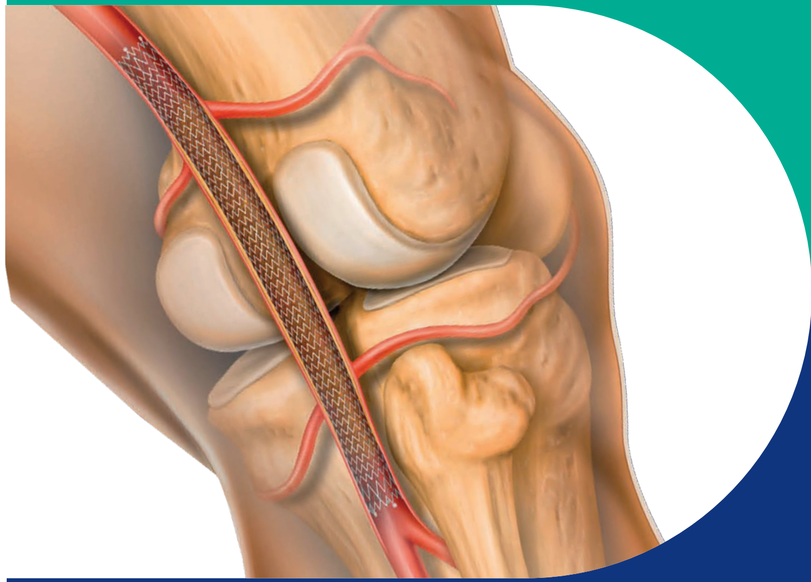


Low profile proven preformance

Halo One™ Thin-Walled Guiding Sheath | Ultraverse™ 035 PTA Dilatation Catheter | UltraScore™ Focused Force PTA Balloon | Lutonix™ 035 Drug Coated Balloon PTA Catheter

The Halo Effect™

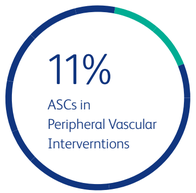
LifeStent™ I 5F

Vascular Stent System

Innovative design

Low profile

Complete a 5F procedure with the low profile LifeStent™ 5F Vascular Stent System

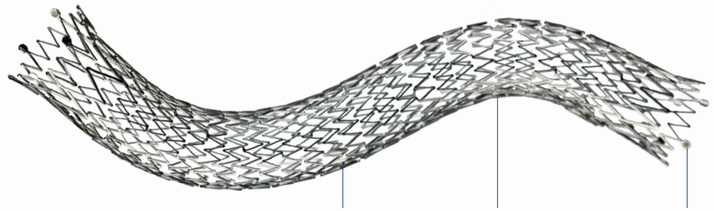


Access site complications (ASCs) have been reported to occur in up to 11% of peripheral vascular interventions[1-3]

Literature suggests that access site complications may be minimised by reducing sheath profile[3-6]

Proven stent design

The only bare-metal stent with Level 1 data in the full popliteal artery[8]



Triaxial delivery system

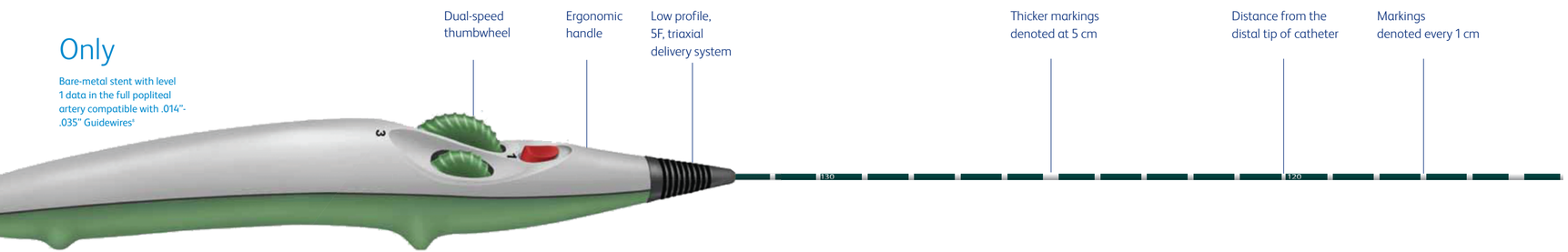
Designed for ease of use, deployment control, and precise placement accuracy[7]

GeoAlign marking system

Designed to reduce radiation exposure by minimising fluoroscopy time[9]

Only

Bare-metal stent with level 1 data in the full popliteal artery compatible with .014"-.035" Guidewires[4]



1 Hackl G, et al. Vasc Endovascular Surg. 2015 Oct;49(7), 160-165.
2 Das R, Ahmed et al. Cardiovasc Intervent Radiol. 2011 Aug;34(4):723-738.
3 Bhatty S, et al. Interv Cardiol. 2011;3(4): 503–514.
4 Doyle BJ, et al. JACC Cardiovasc Interv. 2008 Apr;1(2):202-209.
5 Metz D, et al. Am Heart J. 1997 Jul;134(1):131-7.
6 Büchler JR, et al. J Interv Cardiol. 2008 Feb;21(1):50-55
7 Based on physician ratings during animal testing. May not be indicative of clinical performance. Data on file at Bard Peripheral Vascular, Inc., Tempe, AZ
8 Commercially available as of February 2019.
9 The GEOALIGN® Marking System provides an approximation that may not be an exact representation of the distance traveled intravascularly and should be confirmed under fluoroscopy.

Proven clinical results

The LifeStent™ Vascular Stent System, in varying sizes, have been studied in more than ten clinical trials globally.

Resilient trial

Level 1, sustained effectiveness over PTA out to 3 years[10]

Popliteal Artery Study (ETAP)

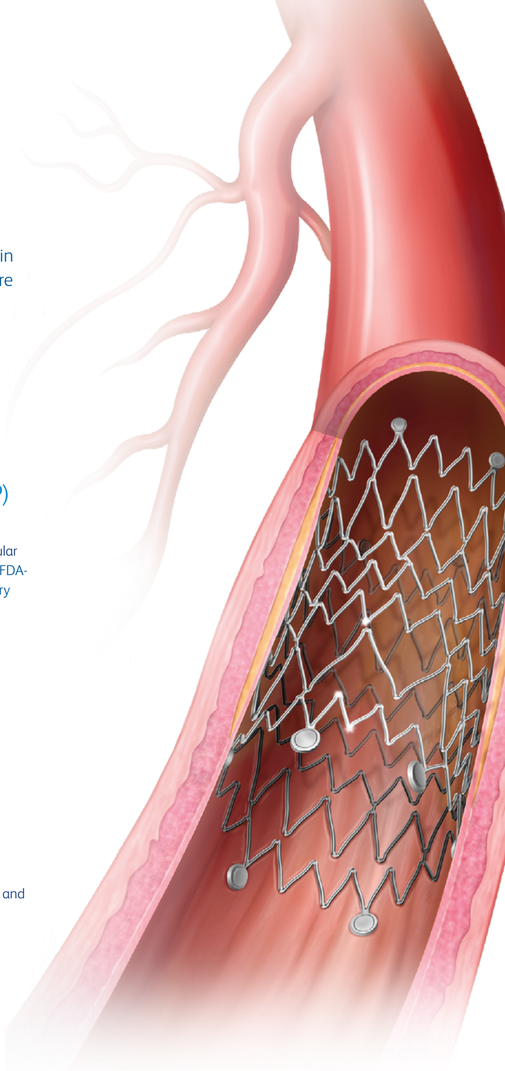
Level 1, investigator-initiated double the primary patency of PTA out to 2 years[11] LifeStent™ 5F Vascular Stent System is the ONLY commercially available, FDA-approved stent indicated for the full popliteal artery

Long Lesion Data

High primary patency at 12 months in lesions up to 240mm[12]

Additional trials

RESILIENT II Trial, E-TAGIUSS Trial, STELLA Trial, Retrospective Analysis of LifeStent™ Vascular Stent Systems in the treatment of long-segment lesions, CONTINUUM Trial, REALITY I/II/III Trials, and RELIABLE Trial



10 Freedom from TLR at 3 years: 75.5% LifeStent™ Vascular Stent arm (n=134), 41.8% PTA arm (n=72), p<0.0001. TLR occurred in subjects who underwent revascularization (surgical or endovascular) of the segment treated by the stent (test) or PTA (control). This study included LifeStent™ Vascular Stent in 6 mm and 7 mm diameters and lengths of 40-80 mm.
11 Primary Patency at 2 years: 64.2% LifeStent™ Vascular Stent arm (n=89), 31.3% PTA arm (n=94), p=0.0001. Patency rates calculated when provisional stenting is considered TLR. Kaplan-Meier analysis with Mantel-Cox log-rank test. The study included LifeStentTM Vascular Stent in 6 mm, 7 mm and 8 mm diameters and lengths of 20-170 mm.
12 Primary Patency at 12 months: 81.5% all lesion lengths (n=53). This study included LifeStent™ Vascular Stent in 6 mm and 7 mm diameters and lengths of 20-200 mm. The LifeStent™ 5 mm stent diameter and LifeStent™ 5F delivery system were not included in these clinical studies. Data on file at Bard Peripheral Vascular, Inc., Tempe, AZ.