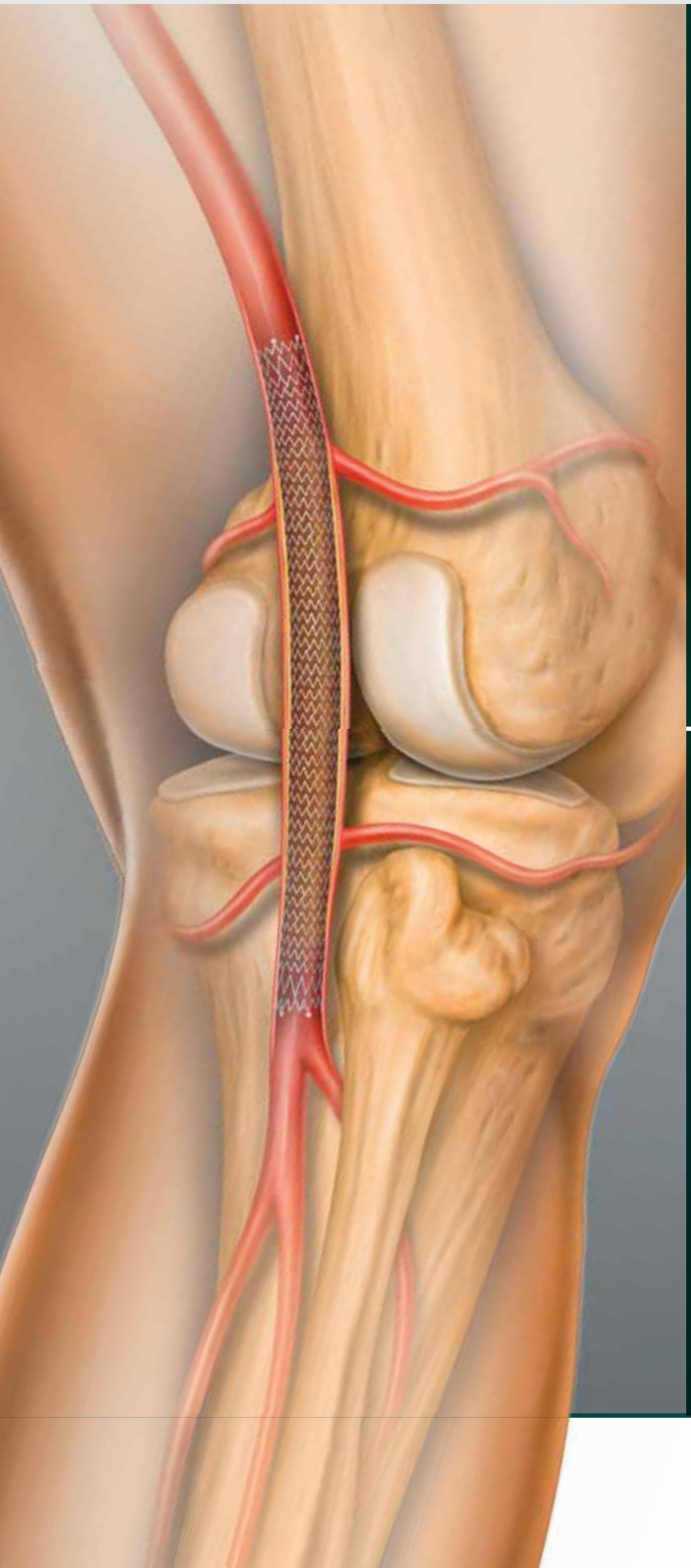


Low Profile Proven Design

LIFESTENT® | 5F

Vascular Stent System

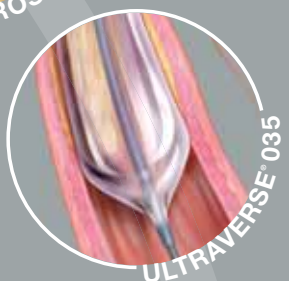
BD

BARD has joined BD

7F

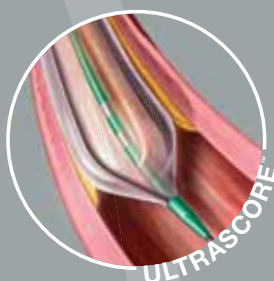
6F

5F ProSeries™



ProSeries™

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



The ProSeries™ Advantage

- Established technologies
- Low crossing profile
- Designed to reduce arteriotomy size*
- Enables alternative access sites†

* Versus comparable 6F devices.

† The LIFESTENT® 5F Vascular Stent System is designed to be used via a femoral access site.

The CROSSER® Recanalization System is indicated to facilitate the intraluminal placement of conventional guidewires beyond peripheral artery chronic total occlusions via atherectomy. The CROSSER® Recanalization System is contraindicated for use in carotid arteries.

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.

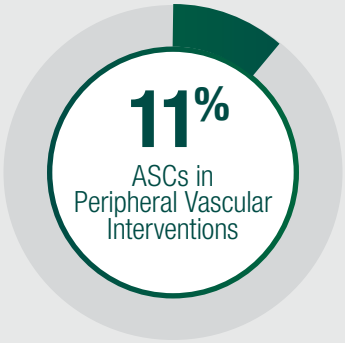
The ULTRASCORE™ Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation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

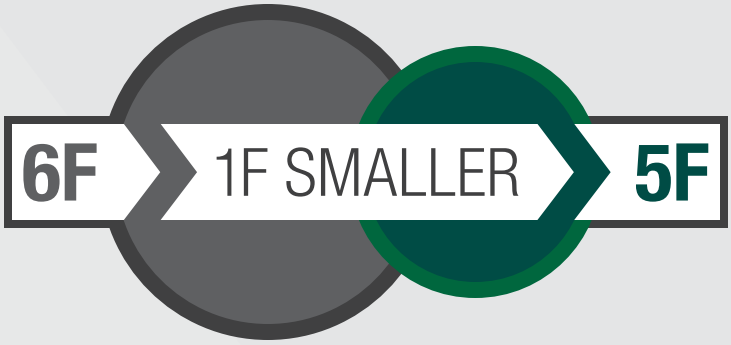
The ULTRAVERSE® 035 PTA Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native synthetic AV fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. This device is also recommended for post-dilatation of balloon expandable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

Innovative Design

Low Profile

Complete a 5F procedure with the low profile LIFESTENT® 5F Vascular Stent System



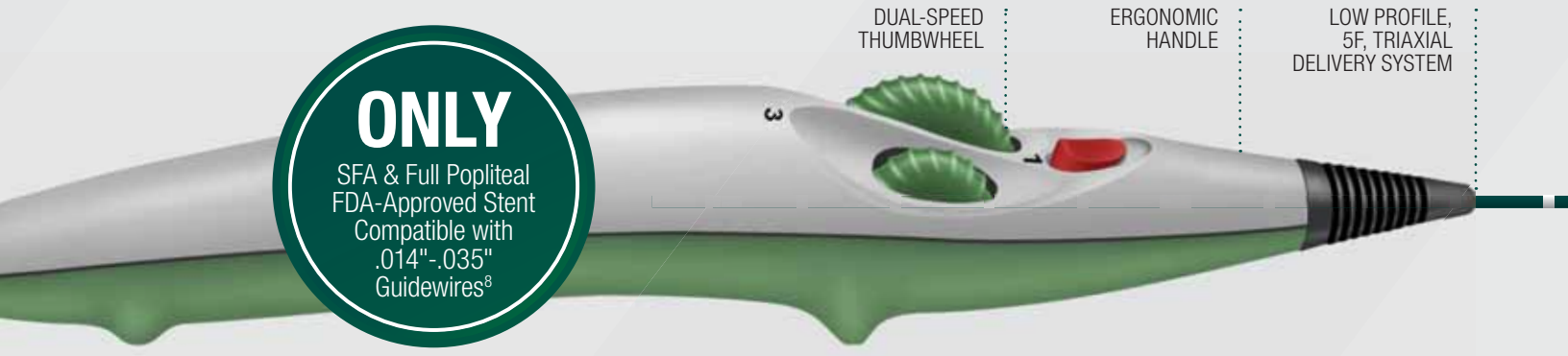


Access site complications (ASCs) have been reported to occur in up to 11% of peripheral vascular interventions[1-3]

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

Triaxial Delivery System

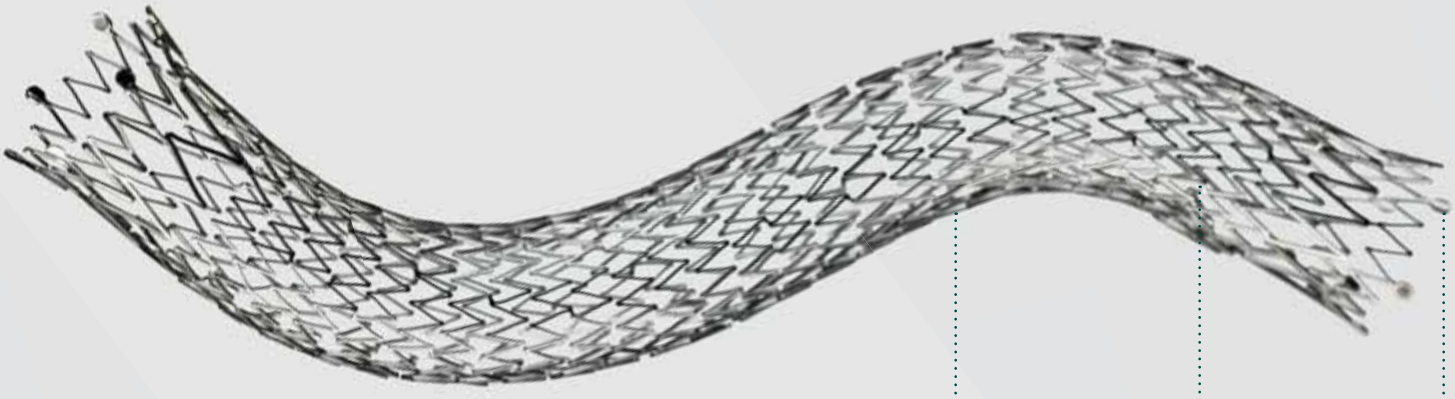
Designed for ease of use, deployment control, and precise placement accuracy[7]



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

Proven Stent Design

The only stent design that is FDA-approved for the SFA and full popliteal artery[8]



GeoAlign® Marking System

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

[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 LIFESTENT® 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.

LIFESTENT® 5F Vascular Stent System Product Codes

Diameter (mm)	Length (mm)	80 cm Catheter Length	135 cm Catheter Length
5	20	☐ 5F050201CS	☐ 5F050203CS
	30	☐ 5F050301CS	☐ 5F050303CS
	40	☐ 5F050401CS	☐ 5F050403CS
	60	☐ 5F050601CS	☐ 5F050603CS
	80	☐ 5F050801CS	☐ 5F050803CS
	100	☐ 5F051001CS	☐ 5F051003CS
	120	☐ 5F051201CS	☐ 5F051203CS
	150	☐ 5F051501CS	☐ 5F051503CS
	170	☐ 5F051701CS	☐ 5F051703CS
6	20	☐ 5F060201CS	☐ 5F060203CS
	30	☐ 5F060301CS	☐ 5F060303CS
	40	☐ 5F060401CS	☐ 5F060403CS
	60	☐ 5F060601CS	☐ 5F060603CS
	80	☐ 5F060801CS	☐ 5F060803CS
	100	☐ 5F061001CS	☐ 5F061003CS
	120	☐ 5F061201CS	☐ 5F061203CS
	150	☐ 5F061501CS	☐ 5F061503CS
7	20	☐ 5F070201CS	☐ 5F070203CS
	30	☐ 5F070301CS	☐ 5F070303CS
	40	☐ 5F070401CS	☐ 5F070403CS
	60	☐ 5F070601CS	☐ 5F070603CS
	80	☐ 5F070801CS	☐ 5F070803CS
	100	☐ 5F071001CS	☐ 5F071003CS
	120	☐ 5F071201CS	☐ 5F071203CS

I authorize the purchase of these products.

PHYSICIAN NAME

PHYSICIAN SIGNATURE

REPRESENTATIVE'S NAME

CONTACT PHONE NO.

LIFESTENT® 5F Vascular Stent System

Indications: The LIFESTENT® 5F Vascular Stent Systems are intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 - 6.5 mm.

Contraindications: The LIFESTENT® 5F Vascular Stent Systems are contraindicated for use in: patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum; patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy; or 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.

Warnings: The LIFESTENT® 5F Vascular Stent Systems are supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device. DO NOT use if pouch is opened or damaged. DO NOT use the device after the "Use By" date specified on the label. Persons with allergic reactions to nitinol (nickel-titanium) alloy 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). 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, potentially resulting in an elongated or foreshortened implant. The long-term outcomes following repeat dilatation of endothelialized stents are unknown. The safety and effectiveness of stent overlapping in the middle (P2) and distal popliteal artery (P3) has not been established. Operator deployment techniques other than those indicated by the Instructions For Use are advised against. Stent elongation or stent foreshortening are potential consequences as a result of not following the deployment Instructions for Use.

Precautions: The device is intended for use by physicians who have received appropriate training. 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. Store in a cool, dark, dry place. 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, 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. Guidewire compatibility and device performance have been evaluated clinically with 0.035 inch guidewires only. Compatibility with 0.014 inch guidewires is based on non-clinical testing only.

Potential Adverse Events: Potential adverse events that may occur include, but are not limited to, the following: allergic/anaphylactoid reaction; amputation; aneurysm; angina/coronary ischemia; arterial occlusion/thrombus, arterial occlusion/restenosis of the treated vessel; arteriovenous fistula; arrhythmia; bypass surgery; death related/unrelated to procedure; embolization; fever; hemorrhage/bleeding requiring a blood transfusion; hematoma bleed; hypotension/hypertension; incorrect positioning of the stent requiring further stenting or surgery; intimal injury/dissection; ischemia/infarction of tissue/organ; liver failure; local infection, malposition (failure to deliver the stent to the intended site); open surgical repair; pain; pancreatitis; pulmonary embolism/edema; pneumothorax; pseudoaneurysm; renal failure; respiratory arrest; restenosis; septicemia/bacteremia; stent fracture; stent migration; stroke; vasospasm; venous occlusion/thrombosis

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

 Bard Peripheral Vascular, Inc. | www.bardpv.com | 1 800 321 4254 | 1625 W. 3rd Street Tempe, AZ 85281 **BPV/STNT/0717/0061(3)**

BD BARD has joined BD