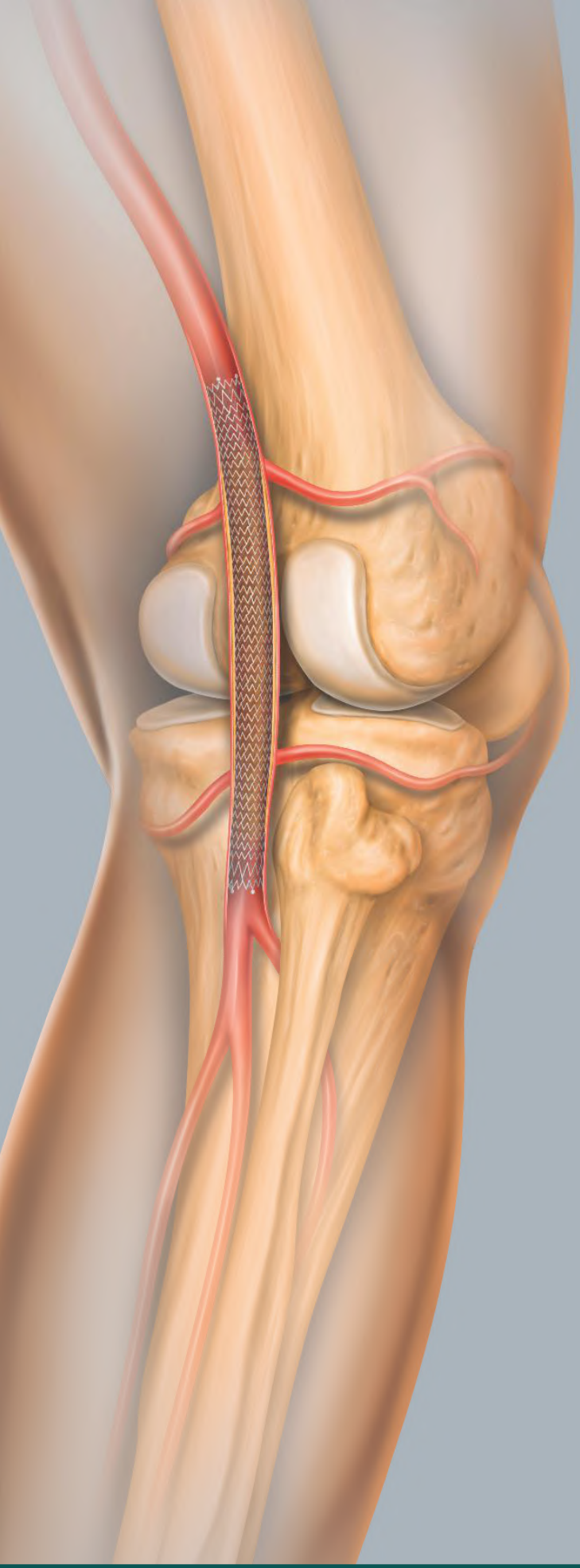

LIFESTENT®

The Only SFA & Full Popliteal, Longest Length Stent on the U.S. Market

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LIFESTENT® Vascular Stent System

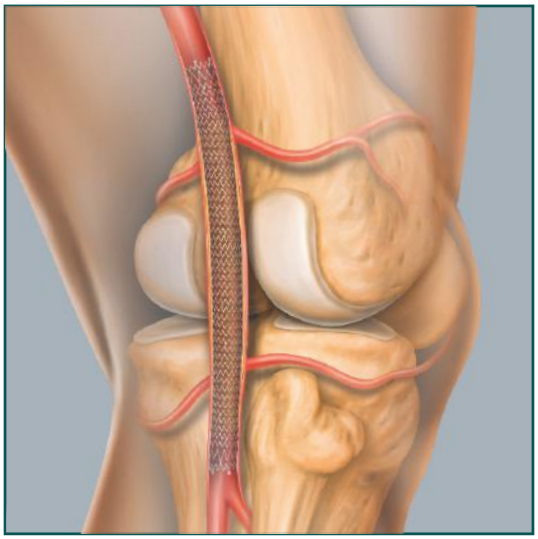
LIFESTENT® SOLO™ Vascular Stent System

Advancing Lives and the Delivery of Heath Care

BARD

LIFESTENT®
Vascular Stent System

SFA and Full Popliteal

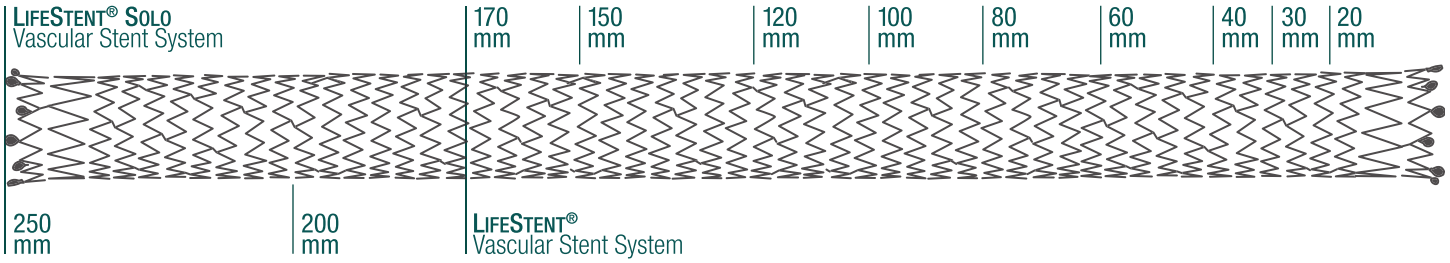


The LIFESTENT® and LIFESTENT® SOLO Vascular Stents are the only stents **FDA indicated for the SFA and the entire popliteal artery** on the U.S. market. The unique helical design of the LIFESTENT® Vascular Stent is engineered to perform in challenging anatomies and is the only FDA-approved stent proven to be safe and effective in the SFA and full popliteal artery.

LIFESTENT®
Vascular Stent System

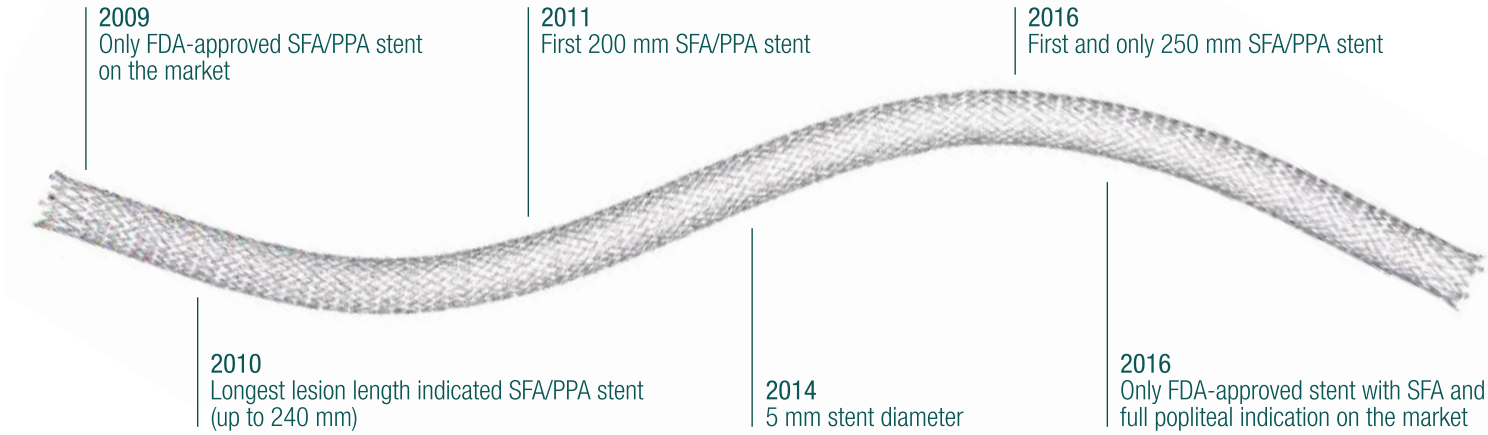
Longest

Available in diameters from 5 to 7 mm and lengths from 20 to 250 mm, the longest stent on the market, the LIFESTENT® Vascular Stent is indicated to treat stenoses and occlusions in the SFA and entire popliteal artery.



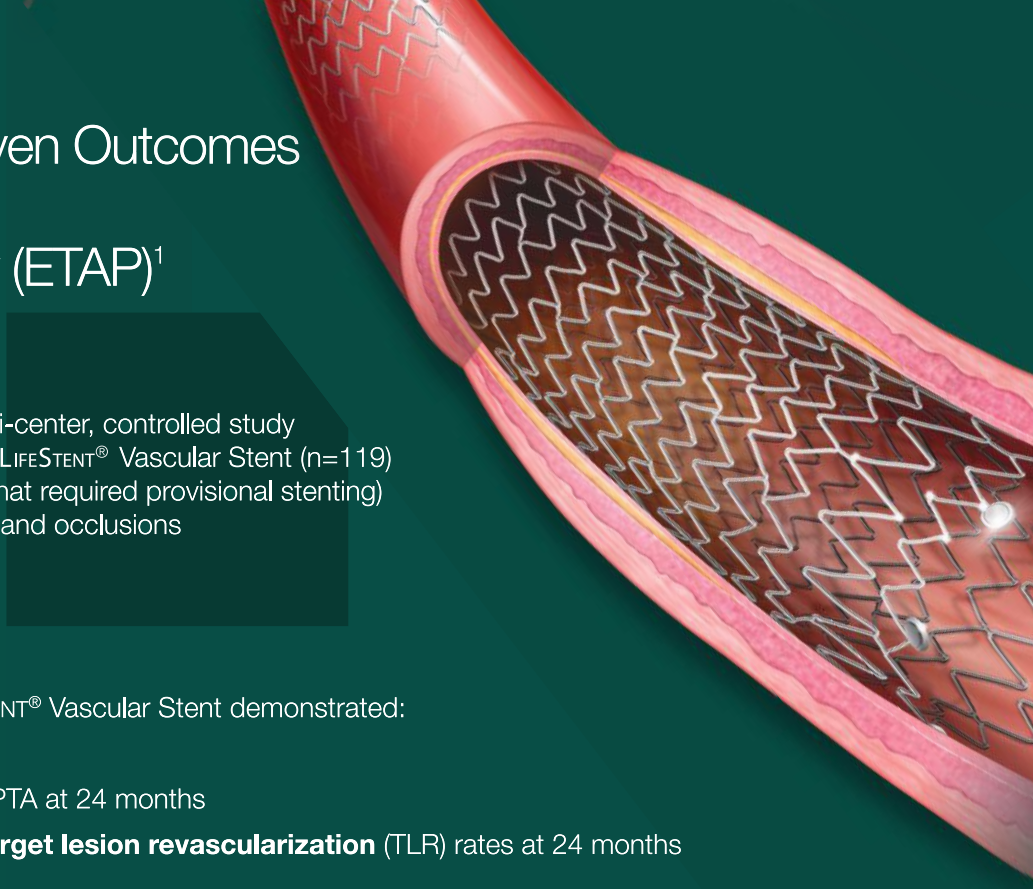
LIFESTENT®
Vascular Stent System

Innovative



LIFESTENT®
Vascular Stent System

Proven Outcomes



Popliteal Artery Study (ETAP)[1]

Study Description

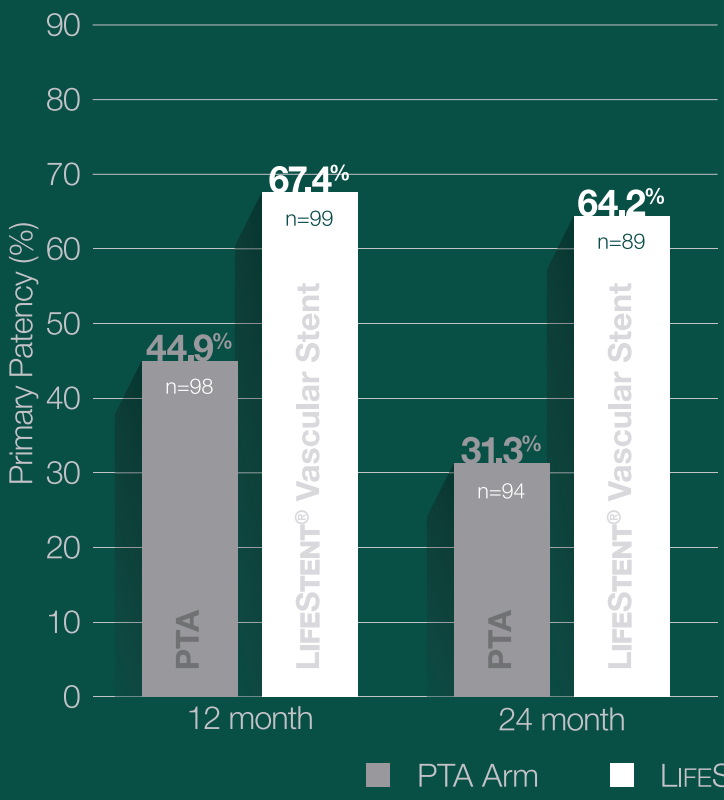
An investigator-initiated, prospective, multi-center, controlled study involving 246 patients that compared the LIFESTENT® Vascular Stent (n=119) to PTA (n=127, with 32 patients [25.2%] that required provisional stenting) in the treatment of patients with stenoses and occlusions of the popliteal artery.

Study Results

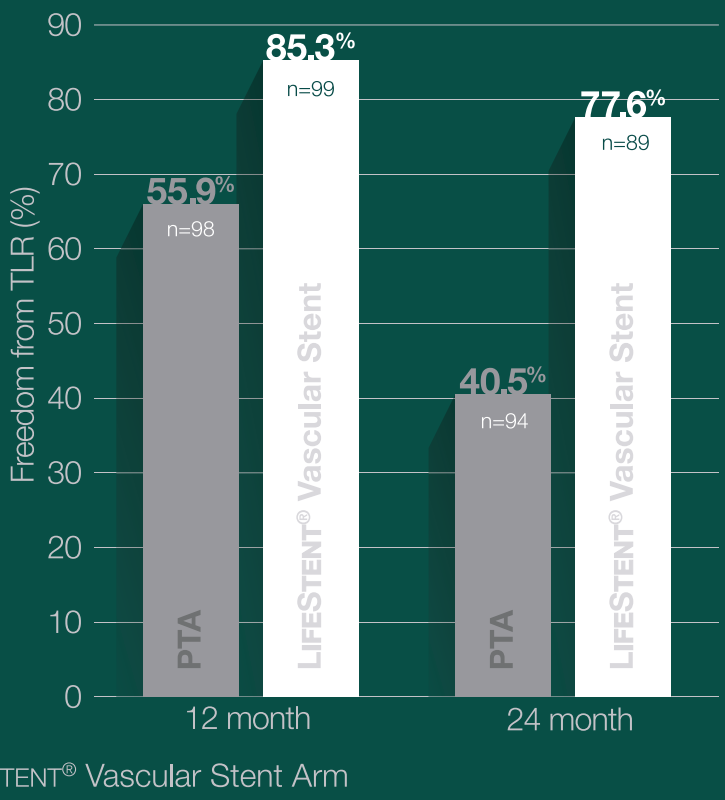
Compared to balloon angioplasty, LIFESTENT® Vascular Stent demonstrated:

- **Superior patency** rates at 12 months
- **Double the primary patency rate** of PTA at 24 months
- **Significantly higher freedom from target lesion revascularization** (TLR) rates at 24 months

Primary Patency



Freedom from TLR



PTA Arm LIFESTENT® Vascular Stent Arm

[1] Rastan A, et al. Angioplasty for the Treatment of Obstructive Lesions of the Popliteal Artery: A Prospective, Multicenter, Randomized Trial. Circulation2013 Jun 25;127(25):2535-2541.
Rastan A, et al. Stent placement vs. balloon angioplasty for popliteal artery treatment: two-year results of a prospective, multicenter, randomized trial. J Endovasc Ther2015 Feb;22(1):22-27.
Patency and TLR rates calculated when provisional stenting is considered TLR. Event-free survival; a composite of freedom from death, TLR, myocardial infarction, and major or minor amputation of the target limb; was as good as or better for the LIFESTENT® group compared to PTA through 24 months. Event-free survival was significantly longer in the stent group (605 days) than the PTA group (455 days; p<0.001) when provisional stent placement was considered a TLR. Kaplan-Meier analysis with Mantel-Cox log-rank test. The LIFESTENT® 5 mm and LIFESTENT® SOLO™ were not included in the ETAP Trial.

LIFESTENT® SOLO Vascular Stent System

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	Product Code
6	100	200	EX062002CL
		250	EX062502CL
	135	200	EX062003CL
		250	EX062503CL
7	100	200	EX072002CL
		250	EX072502CL
	135	200	EX072003CL
		250	EX072503CL

LIFESTENT® Vascular Stent System

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	Product Code
5	80	20	EX050201CS
		30	EX050301CS
		40	EX050401CS
		60	EX050601CS
		80	EX050801CS
		100	EX051001CS
		120	EX051201CS
		150	EX051501CS
		170	EX051701CS
	130	20	EX050203CS
		30	EX050303CS
		40	EX050403CS
		60	EX050603CS
		80	EX050803CS
		100	EX051003CS
		120	EX051203CS
		150	EX051503CS
		170	EX051703CS
6	80	20	EX060201CS
		30	EX060301CS
		40	EX060401CS
		60	EX060601CS
		80	EX060801CS
		100	EX061001CS
		120	EX061201CS
		150	EX061501CS
		170	EX061701CS
	130	20	EX060203CS
		30	EX060303CS
		40	EX060403CS
		60	EX060603CS
		80	EX060803CS
		100	EX061003CS
		120	EX061203CS
		150	EX061503CS
		170	EX061703CS
7	80	20	EX070201CS
		30	EX070301CS
		40	EX070401CS
		60	EX070601CS
		80	EX070801CS
		100	EX071001CS
		120	EX071201CS
		150	EX071501CS
		170	EX071701CS
	130	20	EX070203CS
		30	EX070303CS
		40	EX070403CS
		60	EX070603CS
		80	EX070803CS
		100	EX071003CS
		120	EX071203CS
		150	EX071503CS
		170	EX071703CS

LIFESTENT® and LIFESTENT® SOLO Vascular Stent Systems

Indication for Use

The LIFESTENT® and LIFESTENT® SOLO 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 for Use

The LIFESTENT® and LIFESTENT® SOLO 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; and 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.

LIFESTENT® and LIFESTENT® SOLO Vascular Stent Systems Warnings

DO NOT use if the temperature exposure indicator (i.e., square label found on the pouch) is black, as the unconstrained stent diameter may have been compromised. DO NOT resterilize and/or reuse the device. DO NOT use if pouch is opened or damaged. DO NOT use the device are the Use By date specified on the label. Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant. DO NOT use with ETHIODOL or Lipiodol contrast media. 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). The safety and effectiveness of stent overlapping in the middle (P2) and distal popliteal artery (P3) has not been established. The long-term outcomes following repeat dilatation of endothelialized stents are unkown.

LIFESTENT® SOLO Vascular Stent System Only Warnings

It is recommended to use the 100 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. DO NOT continue triggering the device following complete deployment. Operator deployment techniques other than those indicated by the IFU are advised against. Stent elongation or stent foreshortening are potential consequences as result of not following the IFU.

LIFESTENT® and LIFESTENT® SOLO Vascular Stent Systems 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. Note: An insignificant amount may also exit at the junction between the stent delivery sheath and the system stability sheath. 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. Prior to stent deployment, remove slack from the delivery system catheter outside the patient. 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® and LIFESTENT® SOLO Vascular Stent Systems. 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. Stent fractures were noted to be an uncommon event in the RESILIENT trial and appeared to not impact the safety and performance of the LIFESTENT® implant. Stent fractures may occur with the use of overlapping stents; however, there was no correlation between stent fractures and the number of stents implanted in the RESILIENT trial. Fractures may occur in SFA or popliteal segments that undergo significant motion, particularly in areas with severe angulation and tortuosity. Care should be taken when deploying the stent, as manipulation of the delivery system may, in rare instances, lead to stent elongation and subsequent fracture. The long-term clinical implications of these stent fractures have not yet been established.

LIFESTENT® SOLO Vascular Stent System Only Precautions

Keep the device as straight as possible following removal from the packaging as while inserted in the patient. Failure to do so may impede the optimal deployment.

LIFESTENT® Vascular Stent System Only Precautions

The safety and effectiveness of this device for use in treatment of instent restenosis has not been established.

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, arterial; embolization, stent; 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.

As of June 2016.

 Bard Peripheral Vascular, Inc. | 1 800 321 4254 | www.bardpv.com | 1625 W. 3rd Street Tempe, AZ 85281 **BPV/STNT/0616/0037**

BARD

Bard India Healthcare Pvt. Ltd.

501, Hub Town Solaris, N. S. Phadke Marg, Andheri (E), Mumbai - 400 069.

Phone: +91 2261361111

Email: bard.india@crbard.com, www.bardpv.com