Advanced Helical Design
Proven Performance

LIFESTENT®
Vascular Stent System

LIFESTENT® SOLO™
Vascular Stent System

Advancing Lives and the Delivery of Health Care™

BARD

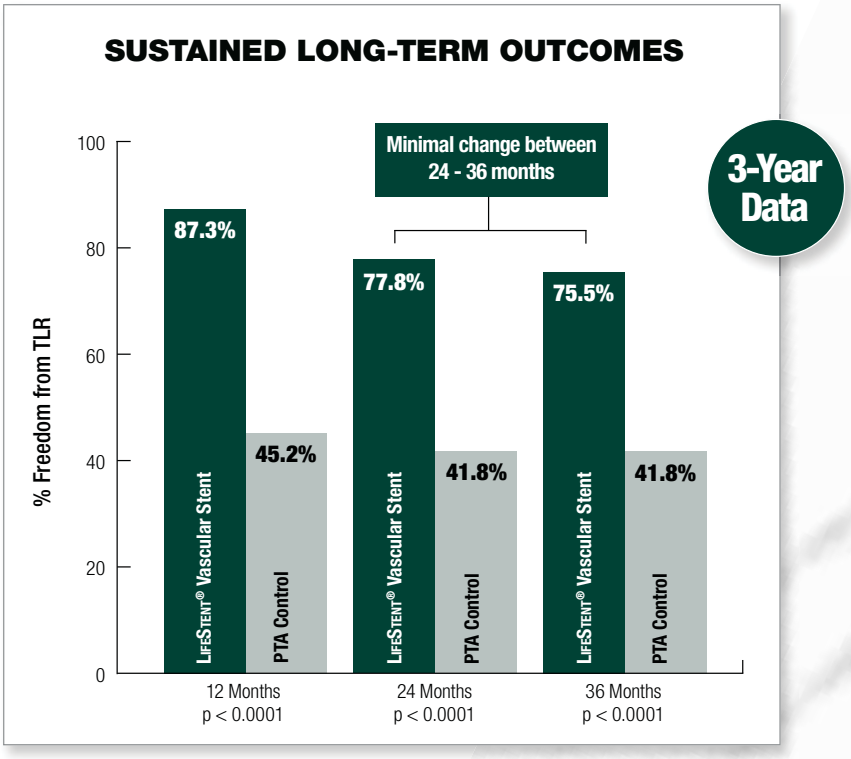
LIFESTENT® Vascular Stent Systems & THE RESILIENT TRIAL

lasting RESULTS LONG-TERM

Sustained **effectiveness up to 3 years**

Maintained primary stent treatment **superiority over PTA**

Only **FDA-approved** stent on the market for the **SFA and full popliteal artery**



Data based on The RESILIENT Trial

These rates are estimated by Kaplan-Meier analysis. The p-values are based on the comparison of control vs. test of the randomized patients (stent group, n=134 and PTA control group, n=72). Target Lesion Revascularization (TLR) occurred in subjects who underwent revascularization (surgical or endovascular) of the segment treated by the stent (test) or PTA (control). The LIFESTENT® 5 mm diameter was not included in the RESILIENT Trial

RESILIENT TRIAL

A prospective, randomized, controlled, multi-center study comparing LIFESTENT® Vascular Stent vs. angioplasty alone in lesions of the SFA and/or proximal popliteal artery.

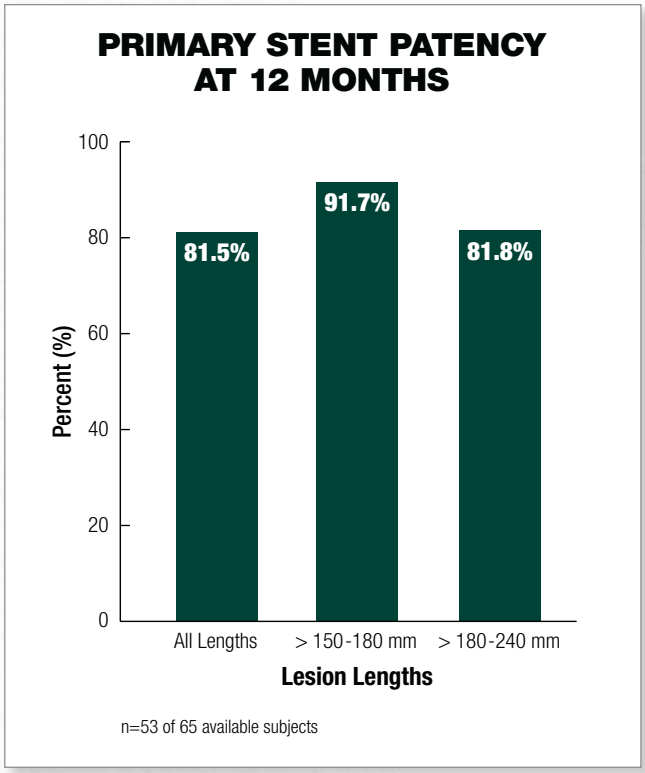
TRIAL OVERVIEW

- 206 patients enrolled: 72 in PTA group, 134 in PTA and LIFESTENT® Vascular Stent group
- 24 study sites in the United States and Europe
- Symptomatic de-novo or restenosed lesions
- Average lesion length of 71 mm

LIFESTENT® SOLO™ & LIFESTENT® 200 MM TRIAL+

Vascular Stent System

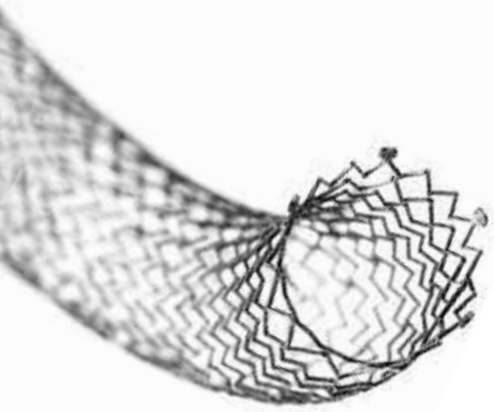
LIFESTENT® SOLO™ Delivery System Study



STENT LENGTHS UP TO 200 mm

Designed to allow for treatment of **longer lesions with one stent***

Patency rates remained high at 12 months for all lesion lengths



LIFESTENT® 200 MM TRIAL+

A single-arm, prospective, non-randomized, multi-center study evaluating the safety and effectiveness of the LIFESTENT® SOLO™ in the treatment of symptomatic vascular disease of the SFA and/or proximal popliteal artery. Subjects were treated with conventional PTA followed by implantation of the Bard LIFESTENT® Vascular Stent.

TRIAL OVERVIEW

- 76 patients
- 7 study sites in Germany
- Symptomatic de-novo or restenosed lesions
- Average lesion length of 91 mm

	LIFESTENT® RESILIENT TRIAL	LIFESTENT® 200 MM TRIAL+
Mean Lesion Length	71 mm	91 mm
Stents per Patient	1.6	1.1
Primary Patency at 12 months	81.5%	81.5%
Freedom from TLR at 12 months	87%	91.2%

*The LIFESTENT® Vascular Stent System and the LIFESTENT® SOLO™ Vascular Stent System 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.
†The LIFESTENT® 5 mm diameter was not included in the LIFESTENT® 200 mm Trial.

LIFESTENT®
Vascular Stent System

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	LIFESTENT® 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
6	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® SOLO™
Vascular Stent System

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	LIFESTENT® SOLO™ Product Code
6	100	200	☐ EX062002CL
	135	200	☐ EX062003CL
7	100	200	☐ EX072002CL
	135	200	☐ EX072003CL

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

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.

LIFESTENT® and LIFESTENT® SOLO™ Vascular Stent Systems Contraindications

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 after 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 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 unknown.

LIFESTENT® Vascular Stent System Only Warnings

DO NOT use with ETHIODOL™ or Lipiodol contrast media.

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. 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 stent fracture. The long-term clinical implications of these stent fractures have not yet been established.

LIFESTENT® SOLO™ Vascular Stent System Only Precautions

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. 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.

LIFESTENT® Vascular Stent System Only Precautions

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

LIFESTENT® and LIFESTENT® SOLO™ Vascular Stent Systems 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; by-pass 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.

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