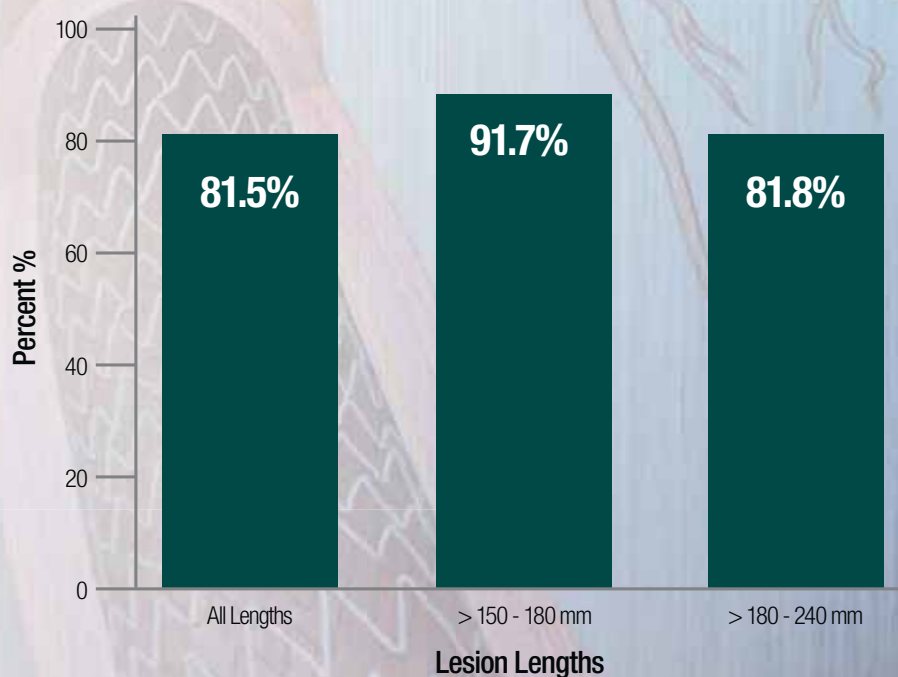


Proven Performance in Longer Lesions

The LIFESTENT® SOLO™ Vascular Stent has sustained effectiveness up to three years in longer lesions.

LIFESTENT® SOLO™ Vascular Stent Delivery System Study¹

Primary Patency at 1 Year (n=53)



LIFESTENT® | **LIFESTENT® SOLO™**
Vascular Stent System | Vascular Stent System

¹ LIFESTENT® SOLO™ Vascular Stent Delivery System Study. 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. The LIFESTENT® 5 mm diameter was not included in the LIFESTENT® Vascular Stent Delivery System Study.

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	LIFESTENT® Product Code
5	80	20	<input type="checkbox"/> EX050201CS
		30	<input type="checkbox"/> EX050301CS
		40	<input type="checkbox"/> EX050401CS
		60	<input type="checkbox"/> EX050601CS
		80	<input type="checkbox"/> EX050801CS
		100	<input type="checkbox"/> EX051001CS
		120	<input type="checkbox"/> EX051201CS
		150	<input type="checkbox"/> EX051501CS
		170	<input type="checkbox"/> EX051701CS
	130	20	<input type="checkbox"/> EX050203CS
		30	<input type="checkbox"/> EX050303CS
		40	<input type="checkbox"/> EX050403CS
		60	<input type="checkbox"/> EX050603CS
		80	<input type="checkbox"/> EX050803CS
		100	<input type="checkbox"/> EX051003CS
		120	<input type="checkbox"/> EX051203CS
		150	<input type="checkbox"/> EX051503CS
		170	<input type="checkbox"/> EX051703CS
6	80	20	<input type="checkbox"/> EX060201CS
		30	<input type="checkbox"/> EX060301CS
		40	<input type="checkbox"/> EX060401CS
		60	<input type="checkbox"/> EX060601CS
		80	<input type="checkbox"/> EX060801CS
		100	<input type="checkbox"/> EX061001CS
		120	<input type="checkbox"/> EX061201CS
		150	<input type="checkbox"/> EX061501CS
		170	<input type="checkbox"/> EX061701CS

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	LIFESTENT® Product Code
6	130	20	<input type="checkbox"/> EX060203CS
		30	<input type="checkbox"/> EX060303CS
		40	<input type="checkbox"/> EX060403CS
		60	<input type="checkbox"/> EX060603CS
		80	<input type="checkbox"/> EX060803CS
		100	<input type="checkbox"/> EX061003CS
		120	<input type="checkbox"/> EX061203CS
		150	<input type="checkbox"/> EX061503CS
7	80	20	<input type="checkbox"/> EX070201CS
		30	<input type="checkbox"/> EX070301CS
		40	<input type="checkbox"/> EX070401CS
		60	<input type="checkbox"/> EX070601CS
		80	<input type="checkbox"/> EX070801CS
		100	<input type="checkbox"/> EX071001CS
		120	<input type="checkbox"/> EX071201CS
		150	<input type="checkbox"/> EX071501CS
7	130	20	<input type="checkbox"/> EX070203CS
		30	<input type="checkbox"/> EX070303CS
		40	<input type="checkbox"/> EX070403CS
		60	<input type="checkbox"/> EX070603CS
		80	<input type="checkbox"/> EX070803CS
		100	<input type="checkbox"/> EX071003CS
		120	<input type="checkbox"/> EX071203CS
		150	<input type="checkbox"/> EX071503CS
		170	<input type="checkbox"/> EX071703CS

Stent Diameter (mm)	Catheter Length (cm)	Stent Length (mm)	LIFESTENT® SOLO™ Product Code
6	100	200	<input type="checkbox"/> EX062002CL
	135	200	<input type="checkbox"/> EX062003CL
7	100	200	<input type="checkbox"/> EX072002CL
	135	200	<input type="checkbox"/> EX072003CL

<div>REPRESENTATIVE NAME</div>
<div>CONTACT PHONE NO.</div>
<div>PHYSICIAN'S SIGNATURE</div>

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 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.

January 2017

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