

LIFEStENT[®] SOLO[™]

Vascular Stent System

LIFEStENT[®] SOLO[™] Vascular Stent Systems Ordering Information

| Stent Diameter (mm) | Catheter Length (cm) | Stent Length (mm) | Product Code | |
|---------------------|----------------------|-------------------|--------------|--------------------------|
| 6 | 80 | 200 | EX062001CL | <input type="checkbox"/> |
| 7 | | 200 | EX072001CL | <input type="checkbox"/> |
| 6 | 135 | 200 | EX062003CL | <input type="checkbox"/> |
| 7 | | 200 | EX072003CL | <input type="checkbox"/> |

| |
|-----------------------|
| REPRESENTATIVE NAME |
| CONTACT PHONE NO. |
| PHYSICIAN'S SIGNATURE |

LIFEStENT[®] SOLO[™]

Vascular Stent System

Advanced Design. Proven Performance.

200 MM
NOW AVAILABLE

BARD[®] LIFEStENT[®] SOLO[™] Vascular Stent System

Prescriptive Information: Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator's Instructions.

Indications:

The LIFEStENT[®] SOLO[™] Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 240 mm in length in native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4.0-6.5 mm.

Contraindications:

The LIFEStENT[®] SOLO[™] Vascular Stent System is contraindicated for use in patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum. Patients who cannot receive recommended antiplatelet and/or anti-coagulation therapy. 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 use of this device carries the risks associated with peripheral vascular stenting, including vessel dissection and/or bleeding events.

Precautions:

Stent fractures were noted to be an uncommon event in the RESILIENT trial. 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 also 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.

Potential Adverse Events:

Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: • Allergic/anaphylactoid reaction • Amputation • Aneurysm • Arterial occlusion/thrombus • Bypass Surgery • Embolization • Hemorrhage/bleeding • Pseudoaneurysm • Renal failure • Restenosis • Stent Fracture • Stent Migration

Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.

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S120084 Rev 0

BARD | PERIPHERAL VASCULAR

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BARD | PERIPHERAL VASCULAR



ENHANCED
accuracy

- Designed for Enhanced Distal and Proximal Stent Placement Accuracy
- Engineered to Reduce Deployment Force
- Radiopaque Markers Now On All Lengths to Aid Deployment Accuracy



enabling
**A SINGLE
STENT STRATEGY**

Treat Longer Lesions with
one stent

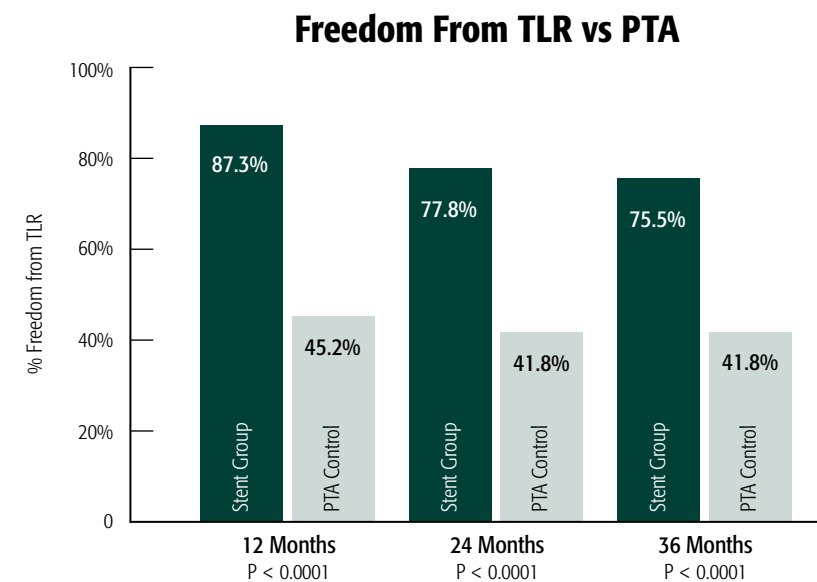
**200
MM**

LIFESTENT[®] VASCULAR STENT THREE YEAR **outcomes**

- Sustained Effectiveness up to 3 Years
- Maintained Primary Stent Treatment Superiority Over PTA

These rates are estimated by Kaplan-Meier analysis. The p-values are based on the comparison control vs. test of the randomized patients (stent group, n=134 and PTA 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).



Data based on the Bard RESILIENT Trial