Advanced Helical Design
Proven Performance

LifeSTENT®
Vascular Stent System

LifeSTENT® SOLO™
Vascular Stent System
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

SUSTAINED LONG-TERM OUTCOMES

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® 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

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### PRIMARY STENT PATENCY AT 12 MONTHS

<table>
<thead>
<tr>
<th>Lesion Lengths</th>
<th>Mean Lesion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Lengths</td>
<td>81.5%</td>
</tr>
<tr>
<td>&gt; 150-180 mm</td>
<td>91.7%</td>
</tr>
<tr>
<td>&gt; 180-240 mm</td>
<td>81.8%</td>
</tr>
</tbody>
</table>

n=53 of 65 available subjects

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**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

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<table>
<thead>
<tr>
<th>Mean Lesion Length</th>
<th>LIFESTENT® RESILIENT TRIAL</th>
<th>LIFESTENT® 200 MM TRIAL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stents per Patient</td>
<td>71 mm</td>
<td>91 mm</td>
</tr>
<tr>
<td>Primary Patency at 12 months</td>
<td>81.5%</td>
<td>81.5%</td>
</tr>
<tr>
<td>Freedom from TLR at 12 months</td>
<td>87%</td>
<td>91.2%</td>
</tr>
</tbody>
</table>

*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® SOLO™ Vascular Stent System

## 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

- **Allergic/anaphylactoid reaction**
- **Amputation**
- **Arrhythmia**
- **By-pass surgery**
- **Death related/unrelated to procedure**
- **Embolic event**
- **Embolic event**
- **Fistula**
- **Hemorrhage/bleeding requiring a transfusion**
- **Hepatic failure**
- **Hypertension/hypertension**
- **Intimal injury/dissection**
- **Ischemia/infarction of tissue/organ**
- **Ischemia/infarction of tissue/organ**
- **Local infection**
- **Malposition (failure to deliver the stent to the intended site)**
- **Myocardial infarction**
- **Pneumothorax**
- **Pseudoaneurysm**
- **Renal failure**
- **Resection**
- **Restenosis**
- **Sepsis**
- **Stent fracture**
- **Stent migration**
- **Stroke**
- **Vasospasm**
- **Venous occlusion/thrombosis**

## Warnings

- DO NOT use if the temperature exposure indicator (i.e., square label peeling) is visible or if the device has been exposed to conditions that may affect its integrity.
- Stents may have sharp edges that may cause injury. Pouch is opened or damaged. DO NOT use the device after the “Use By” date specified on the label. Persons who are judged to have a lesion that prevents complete repositioning or recapturing. Stenting across a major branch could lead to 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.

## 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.
- DO NOT use if the temperature exposure indicator (i.e., square label peeling) is visible or if the device has been exposed to conditions that may affect its integrity.

## Potential adverse events

- Allergic/anaphylactoid reaction
- Amputation
- Arrhythmia
- By-pass surgery
- Death related/unrelated to procedure
- Embolic event
- Fistula
- Hemorrhage/bleeding requiring a transfusion
- Hypertension/hypertension
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Myocardial infarction
- Pneumothorax
- Pseudoaneurysm
- Renal failure
- Respiratory arrest
- Restenosis
- Septicemia/bacteraemia
- Stent fracture
- Stent migration
- Stroke
- Venous occlusion/thrombosis

## Instructions for Use

- DO NOT use in-stent restenosis has not been established.
- DO NOT use if the temperature exposure indicator (i.e., square label peeling) is visible or if the device has been exposed to conditions that may affect its integrity.
- Stents may have sharp edges that may cause injury. Pouch is opened or damaged. DO NOT use the device after the “Use By” date specified on the label. Persons who are judged to have a lesion that prevents complete repositioning or recapturing. Stenting across a major branch could lead to 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.

## 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.

## Instructions for Use

- DO NOT use if the temperature exposure indicator (i.e., square label peeling) is visible or if the device has been exposed to conditions that may affect its integrity.
- Stents may have sharp edges that may cause injury. Pouch is opened or damaged. DO NOT use the device after the “Use By” date specified on the label. Persons who are judged to have a lesion that prevents complete repositioning or recapturing. Stenting across a major branch could lead to 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.

## LifeStent® and LifeStent® SOLO™ Vascular Stent Systems

- **Physician’s Signature**

## Representative Name

- **Contact Phone No.**