LIFEStent®
The Only SFA & Full Popliteal Stent on the U.S. Market

LIFEStent® LIFEStent® Solo™
Vascular Stent System Vascular Stent System
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.¹

Available in diameters from 5 to 7 mm and lengths from 20 to 200 mm, the LIFESTENT® Vascular Stent is indicated to treat stenoses and occlusions in the SFA and entire popliteal artery.

### 2009
Only FDA-approved SFA/PPA stent on the market

### 2010
Longest lesion length indicated SFA/PPA stent (up to 240 mm)

### 2011
First 200 mm SFA/PPA stent

### 2014
5 mm stent diameter

### 2016
Only FDA-approved stent with SFA and full popliteal indication on the market
**Popliteal Artery Study (ETAP)**

**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**

<table>
<thead>
<tr>
<th></th>
<th>12 month</th>
<th>24 month</th>
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<tbody>
<tr>
<td>PTA</td>
<td>67.4%</td>
<td>64.2%</td>
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<tr>
<td>LIFE®STENT® Vascular Stent</td>
<td>44.9%</td>
<td>31.3%</td>
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</table>

**Freedom from TLR**

<table>
<thead>
<tr>
<th></th>
<th>12 month</th>
<th>24 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA</td>
<td>85.3%</td>
<td>77.6%</td>
</tr>
<tr>
<td>LIFE®STENT® Vascular Stent</td>
<td>55.9%</td>
<td>n=99</td>
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</tbody>
</table>

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 LIFE®STENT™ 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 LIFE®STENT® 5 mm and LIFE®STENT® SOLO™ were not included in the ETAP Trial.
**LIFESTENT® Vascular Stent System**

<table>
<thead>
<tr>
<th>Stent Diameter (mm)</th>
<th>Catheter Length (cm)</th>
<th>Stent Length (mm)</th>
<th>Product Code</th>
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<tr>
<td>7</td>
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<td>130</td>
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<td>200</td>
<td>EX050201CS</td>
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**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 nickel (nitrile, 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 appropriately sized 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 reinitialize 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 (i.e., 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 deployment of endothermalized 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 forestalled 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 System. 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. The 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 insuffigent amount of saline 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; anemia; angina; angina/pneumonia; arterial occlusion/thrombosis; arterial occlusion/restenosis of the treated vessel; arteriovenous fistula; arterial rupture; arterial thrombosis; arterial ulceration; arterial wall injury; asphyxia; by-pass surgery; death related/unrelated to procedure; embolization; fever; hemorrhage/bleeding; requiring a blood transfusion; hemorrhage/bleeding; 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; pneumonia; prothesis/electrocardiomyogram; renal failure; respiratory arrest; restenosis; sepsis/sepsis/bacteremia; stent fracture; stent migration; stroke; vasoconstrictor; vescicourethral/urethral/thrombus.

Please consult package insert for more detailed safety information and instructions for use.

January 2017


BP/NSTN/0616/003371

**PHYSICIAN'S SIGNATURE**

**REPRESENTATIVE NAME**

**CONTACT PHONE NO.**