Bard Life Stent®
& The RESILIENT Trial:
Two-Year Update of Outcomes

Sanjoy Kundu MD, FRCPC, RPVI, FCIRSE, FSIR
LifeStent® Vascular Stent System

- The LifeStent® Vascular Stent is intended for primary stenting of de-novo or restenotic lesions of the peripheral arteries.
- Up to 170 mm length
<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>
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<td>170</td>
<td>EX091701C</td>
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</tbody>
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For All Product Codes: 0.035" Guidewire.
LifeStent® offers Multi-Dimensional Helical Architecture
How Does Multi-Dimensional Helical Architecture Address SFA Forces?

- **Extension and Compression**
  Dynamically adapts to extension and compression of the SFA through its unique combination of helical elements.

- **Torsion**
  Lumen patency maintained during twisting of the SFA through helical strut and bridge orientation.

- **Bending**
  Avoids creating discontinuities in arterial pathways by conforming closely to new anatomical positions.

**Compressive Resistance and Radial Expansion Force**
Treatment of highly stenosed SFAs and resistance to external compression is facilitated by optimized stent design parameters.
A Randomized Study Comparing the Edwards Self-Expanding LifeStent vs. Angioplasty-Alone In Lesions Involving The SFA and/or Proximal Popliteal Artery

(An FDA approval protocol)
RESILIENT: Study Device

LifeStent® NT Self-Expanding Stent
Helically-Designed, Nitinol Self-Expanding Stent

Sizes Used in the Study

<table>
<thead>
<tr>
<th>Diameters</th>
<th>Lengths</th>
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<tbody>
<tr>
<td>6 mm</td>
<td>40, 60, 80 mm</td>
</tr>
<tr>
<td>7 mm</td>
<td>40, 60, 80 mm</td>
</tr>
</tbody>
</table>

Delivery System Used in the Study

1st Generation Coaxial System

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RESILIENT: Trial Overview

- Lesions: SFA and/or Proximal Popliteal Artery
- Lifestyle-Limiting Claudication: Rutherford Category 1 – 3
- Lesion Length: <15 cm
- Test Device: LifeStent® NT Stent & Delivery System

206 Randomized Patients - 24 Sites (U.S. & Europe)

PTA Control
- n = 72
  - 43 PTA Only
  - 29 Bailout Stents*

LifeStent®
- n = 134

*Intention-to-Treat Analysis: Bailout stents analyzed as randomized
### RESILIENT: Baseline Demographics

<table>
<thead>
<tr>
<th></th>
<th>Control Group (Pts. =72)</th>
<th>Test Group (Pts. =134)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male / Female</strong></td>
<td>66.7% / 33.3%</td>
<td>70.9% / 29.1%</td>
<td>0.53 ^</td>
</tr>
<tr>
<td><strong>Age, (years) μ ± S.D.</strong></td>
<td>66.1 ± 9.2</td>
<td>68.4 ± 9.9</td>
<td>0.11 +</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>91.7%</td>
<td>83.6%</td>
<td>0.14 #</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia</strong></td>
<td>73.6%</td>
<td>78.4%</td>
<td>0.49 #</td>
</tr>
<tr>
<td><strong>Smoker</strong></td>
<td>83.3%</td>
<td>71.6%</td>
<td>0.09 #</td>
</tr>
<tr>
<td><strong>Coronary Artery Disease</strong></td>
<td>54.2%</td>
<td>56.0%</td>
<td>0.88 #</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>38.9%</td>
<td>38.1%</td>
<td>1.00 #</td>
</tr>
</tbody>
</table>

**Rutherford Category:**

- **Control**:
  - Rutherford 1: 6.9%
  - Rutherford 2: 41.7%
  - Rutherford 3: 50.0%

- **Test**:
  - Rutherford 1: 3.0%
  - Rutherford 2: 35.8%
  - Rutherford 3: 61.2%

^ = Chi Square Test  
+ = t-test for Equality of Means  
# = Fisher´s Exact Test
## RESILIENT: Lesion Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control Group (Lesions=81)</th>
<th>Test Group (Lesions=153)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Lesion Length</strong> (per pt.)</td>
<td>6.4 cm ± 4.0</td>
<td>7.1 cm ± 4.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.33</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Target Vessel RVD</strong></td>
<td>5.1 mm ± 0.7</td>
<td>5.2 mm ± 0.8</td>
<td>0.64</td>
</tr>
<tr>
<td><strong>Lesion % Diameter Stenosis</strong></td>
<td>74.5% ± 18.2</td>
<td>72.7% ± 17.6</td>
<td>0.49</td>
</tr>
</tbody>
</table>

### Lesion Calcification†

- **PTA Group**: 8% none/mild, 32% moderate/severe, 60% no data
- **LifeStent® Group**: 2% none/mild, 35% moderate/severe, 63% no data

† = Core Lab Analysis
+ = t-test for Equality of Means
# = Fisher’s Exact Test
• Data from the bailout stenting cases were included in the Control Arm (as randomized)

• Bailout stenting was considered a target lesion revascularization (TLR) & patency failure:
  – Immediate need for additional intervention, and
  – Loss of flow \( (\text{residual stenosis} > 30\% \text{ after repeated inflations}) \)

• The need for bailout stenting was confirmed by:
  – Angiographic core lab and clinical events committee (93%), or
  – Study site documentation in two patients (7%)
Bailout Lesion Characteristics*

Mean Lesion Length (mm)

- PTA only (n=47): 47.7 ± 32.6
- PTA-Bailout-Stent (n=34): 70.3 ± 38.8
- LifeStent (n=153): 61.8 ± 42.5

Mean Lesion Length / Patient (mm)

- PTA only (n=43): 52.0 ± 38.2
- PTA-Bailout-Stent (n=29): 82.8 ± 37.8
- LifeStent (n=134): 70.5 ± 44.3

Bailout lesions were significantly longer than the PTA-only lesions

* = Site Reported
+ = Statistically Significant
Bailout Lesion Characteristics

Lesion Calcification

PTA Only

- none/mild: 23%
- moderate/severe: 68%
- no data: 9%

Bailout Stent

- none/mild: 7%
- moderate/severe: 48%
- no data: 45%

Bailout lesions tended to be more heavily calcified than the PTA-only lesions.
Bailout stenting patients tended to have more severe claudication than the PTA-only patients.
## RESILIENT: Peri-Procedural Results

<table>
<thead>
<tr>
<th>Measure (per lesion)</th>
<th>PTA Group</th>
<th>LifeStent® Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Success</strong> †(%) residual stenosis &lt; 30%</td>
<td>85.5% (59/69)</td>
<td>96.3% (131/136)</td>
<td>.0087#</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure (per patient)</th>
<th>PTA Group</th>
<th>LifeStent® Group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure Success</strong> †(%) residual stenosis &lt; 30% and no peri-procedural complications</td>
<td>83.9% (52/62)</td>
<td>95.8% (114/119)</td>
<td>.0092#</td>
</tr>
</tbody>
</table>

**Mean Stented Length:** 9.9 cm (± 5.0)

†Core Lab Analysis: 119 test and 62 control patients had angiograms that could be evaluated by the core lab

# Fisher’s Exact Test; p-values based on two-sided test
Target Lesion Revascularization (TLR):
- “Clinically-driven” repeat intervention of the target lesion

Major Adverse Clinical Event (MACE):
- Death, stroke, MI, significant distal embolization, emergent surgical revascularization of the limb, thrombosis, and Rutherford category worsening post-procedure.

Patency:
- DUS Peak Systolic Velocity (PSV) ratio < 2.5. Failure of primary patency is a TLR or restenosis greater than 50% (PSV > 2.5).

Clinical Success:
- An improvement of baseline symptoms by at least one Rutherford category and sustained through follow-up (with no additional intervention).
RESILIENT: Freedom from TLR 24m

Kaplan-Meier Survival Analysis; p-value from log rank test

PTA
LifeStent

12 Month 24 Month

PTA
LifeStent

45%
87%
42%
78%

12 Month 24 Month

p<.0001
p<.0001

24 Months

RESILIENT:
Freedom from TLR 24m

p<.0001

Kaplan-Meier Survival Analysis; p-value from log rank test
RESILIENT: Freedom from MACE 24m

Kaplan-Meier Survival Analysis; p-value from log rank test

12 Month 24 Month
PTA
LifeStent

86% 86%
p=.91
82% 79%
p=.60

24 Months

PTA
LifeStent
RESILIENT: Primary Patency*

#Primary patency: Continuous blood flow through the treated area assessed by duplex ultrasound (DUS):

- **6 Month**
  - PTA: 47%
  - LifeStent: 94%
  - *p<.0001*

- **12 Month**
  - PTA: 37%
  - LifeStent: 81%
  - *p<.0001*

Kaplan-Meier Survival Analysis; p-value from log rank test
### Stent Fractures: 18-Month Analysis*

<table>
<thead>
<tr>
<th>Fracture Type</th>
<th>Total 0-18 months</th>
<th>2 or more overlapping stents</th>
<th>Stent Elongation at deployment</th>
<th>Locations^</th>
<th>Lesion Moderate - Severe Calcification</th>
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</thead>
<tbody>
<tr>
<td>Type I</td>
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<td>1 of 5</td>
<td>1 of 5</td>
<td>MMMMMD</td>
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<td>Type II</td>
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<td>Type III</td>
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<tr>
<td>Type IV</td>
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<td>4 of 6</td>
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<td>MMMMMMP</td>
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</table>

### 0-12 months vs 0-18 months

<table>
<thead>
<tr>
<th></th>
<th>0-12 months</th>
<th>0-18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fractured Stents</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>Fracture Rate^#</td>
<td>3.1%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

^fractures / 287 stents evaluated by the angiographic core lab

* Per Core Lab Analysis at 6, 12, & 18 Months

^M=Mid SFA; D=Distal SFA; P=Popliteal
RESILIENT: Clinical Success

*Clinical Success: Sustained improvement of at least one Rutherford category above the pre-treatment value. Also, a repeat intervention was considered a loss of clinical success.

Fisher’s Exact Test; p-values based on two-sided test
“Longer” and/or “more calcified” lesions did not respond sufficiently to a PTA-only strategy:
- The bailout stenting rate in the Control Group was 40.2%

A low fracture rate: 3.8% at 18 months
- Observed fractures may be partially explained by elongation of the stent at deployment.
- A “One Stent” strategy is recommended when possible.
In claudicants with SFA/proximal popliteal lesions ≤ 15 cm, primary stenting with the LifeStent® Self-Expanding Stent was superior to a PTA-only strategy:

- At One Year: evidenced by primary patency & freedom from TLR
- At Two Years: evidenced by freedom from TLR & sustained clinical success
- The LifeStent® Self-Expanding Stent did not lead to a higher rate of Major Adverse Clinical Events than PTA alone

A PTA-only strategy has a role in patients with less complex lesions (e.g., shorter, less severely calcified).