Treating complex lesions with traditional balloon angioplasty can result in:

- Vessel dissection
- Poor luminal gain
- Lesion recoil
- Balloon slippage
- Poor stent apposition

The Excimer Laser Coronary Atherectomy Catheter and the AngioSculpt® PTCA Scoring Balloon Catheter can safely cross, prepare and treat a wide range of complex lesion types, modifying plaque to provide easier stent delivery, more predictable stent expansion and better stent apposition, while decreasing the risk of vessel dissection. 4-7

Clinical Success Rates

**ELCA®** Success Rates

<table>
<thead>
<tr>
<th>Study</th>
<th>Lesion Type</th>
<th>Technical Success</th>
<th>Procedural Success</th>
<th>MACE Rates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bilodeau</td>
<td>Calcified and Complex</td>
<td>10.4%</td>
<td>10.4%</td>
<td>8.0%</td>
</tr>
<tr>
<td></td>
<td>Coronary Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pratsos</td>
<td>Calcified, Unresistant</td>
<td>98.5%</td>
<td>95.5%</td>
<td>8.8%</td>
</tr>
<tr>
<td></td>
<td>Coronary Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*No perforations reported

**Angiosculpt®** Acute Gains

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Direct Stent</th>
<th>POBA</th>
<th>Angiosculpt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0.9 ± 0.4</td>
<td>1.2</td>
<td>1.2 ± 0.4</td>
</tr>
</tbody>
</table>

**ELCA®** Indications:

- Total occlusions traversable by a guidewire
- Occluded SVGs
- Ostial lesions
- Moderately calcified lesions
- Long lesions (>20 mm)
- Lesions that previously failed PTCA
- Restenosis in 316L stainless steel stents prior to brachytherapy

**Angiosculpt®** Indications:

- Treatment of hemodynamically significant coronary artery stenoses, including in-stent restenosis and complex type-C lesions, for the purpose of improving myocardial perfusion.

---

**Treatment Algorithm**

<table>
<thead>
<tr>
<th>Segment</th>
<th>CROSS</th>
<th>PREP</th>
<th>TREAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-Stent Restenosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrocalcific Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTOs Crossovable with a Wire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ostial Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long/Diffuse Lesions</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Fibrocalcific and ostial lesions**

- **The Angiosculpt® Scoring Balloon Catheter**
  - Applies 15 to 25 times the force of high-pressure balloons
  - Modifies plaque to improve luminal gain
  - Has a 2 to 3 lower dissection rate than standard balloons

**Chronic total occlusions**

- **The ELCA® Coronary Laser Atherectomy Catheter**
  - Crosses the lesion and modifies the plaque to allow for balloon delivery and definitive treatment with drug-eluting stents
  - Tissue the entire lesion
  - Modifies plaque to create a lumen that allows for delivery of other devices

**Long diffuse lesions**

- **The ELCA® Coronary Laser Atherectomy Catheter**
  - Vaporizes lesion material into particles smaller than a red blood cell
  - Increases luminal size for good stent apposition
  - Prepares the vessel for precise coronary stent delivery*

A complete portfolio for complex cases

The goal of all CAD treatment is a lasting, positive outcome for the patient. Only Spectranetics offers a complete portfolio of solutions for optimal vessel preparation in widely complex CAD cases. The ELCA® Coronary Laser Atherectomy Catheter and the AngioSculpt® PTCA Scoring Balloon Catheter modify plaque, providing easier stent delivery, more predictable stent expansion, incremental luminal gain and better stent apposition.

---

**In-stent restenosis**

- **The Angiosculpt® Scoring Balloon Catheter**
  - Resists slipping within the vessel
  - Provides improved luminal gain
  - Allows for increased focal pressure to reset stents, reducing the need for future additional stents

**In-stent restenosis**

- **The ELCA® Coronary Laser Atherectomy Catheter**
  - Modifies plaque, leading to better stent apposition
  - Vaporizes lesion material
  - Maximizes lumen for additional stent placement

---

**In-stent restenosis**

- **The Angiosculpt® Scoring Balloon Catheter**
  - Resists slipping within the vessel
  - Provides improved luminal gain
  - Allows for increased focal pressure to reset stents, reducing the need for future additional stents

**In-stent restenosis**

- **The ELCA® Coronary Laser Atherectomy Catheter**
  - Modifies plaque, leading to better stent apposition
  - Vaporizes lesion material
  - Maximizes lumen for additional stent placement
Important Safety Information
ELCA & ELCA X-80
The AngioSculpt Scoring Balloon Catheter (ELCA) is used in patients for coronary artery lesions and is intended for use in association with a variety of back-up devices in an effort to minimize a primary procedure failure rate. The AngioSculpt X-80 is used in patients for coronary artery lesions and is intended for use in association with a variety of back-up devices in an effort to minimize a primary procedure failure rate. The ELCA & ELCA X-80 catheters should never be used in association with atherectomy devices, including rotational atherectomy, unless specifically designed for such use. Additionally, the ELCA & ELCA X-80 catheters are intended for use in patients with a variety of blockages in single or multivessel coronary artery disease. The ELCA & ELCA X-80 catheters are not intended for use in patients with a variety of blockages in single or multivessel coronary artery disease. The ELCA & ELCA X-80 catheters should not be used as a primary device in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt X-80 catheter is indicated for use in the treatment of hemodynamically significant coronary artery lesions, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Do not resterilize and/or reuse, as this can potentially result in compromised performance analysis. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Use of air or any gaseous medium to inflate the balloon can result in damage to the balloon. Use only the recommended balloon inflation medium. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Use only the recommended balloon inflation medium. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Use only the recommended balloon inflation medium. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion. Use only the recommended balloon inflation medium. The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis (ISR) lesions, the inflated diameter of the balloon should approximate the vessel diameter size just distal to the treated lesion.

References


Acute- and 6-Month Follow-up Results. The Journal of Invasive Cardiology, Vol. 18, No. 1, 9-14.


Vascular Intervention
FOR CAD TREATMENT
PLAQUE MODIFICATION
SAFE AND EFFECTIVE
PREPARE TO SUCCEED:
PREPARE TO SUCCEED: