Stealth 360™ Peripheral Orbital Atherectomy System

System Overview

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Disclosure

Speaker name: Michael Lichtenberg

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- [ ] I do not have any potential conflict of interest
Change Compliance First

- **Vessel Preparation** with Orbital Atherectomy results in compliance change\(^1,2\)
- **Compliance Change** enables lower-pressure balloon inflation\(^1,2\)
- Compliance change and low pressure balloon inflation results in **Low Complication Rates, including Dissection**\(^1,2\)

Clinical Example: Two Similar Lesions
*(Results may vary.)*


Courtesy of Raymond Dattilo, MD
Stealth 360™
Orbital Atherectomy System (OAS)

- Stealth 360™ Orbital Atherectomy Device (OAD)
- OAS Pump
- ViperWire Advance™
- ViperSlide™ Lubricant
- Saline Line
Crown Options
- Micro Crown
- Classic Crown
- Solid Crown

Crowns shown are the 1.25 mm Micro Crown, 1.50 mm Classic Crown, and 2.00 mm Solid Crown. Photographs are not to scale and for illustrative purposes only.

Rotation Speed Controls
- Allows speed adjustment within the sterile field.

GlideAssist (1.25 Micro only)
- Enables the crown to spin at a low speed for easier device tracking and removal.¹

Crown Advancer Knob
- Starts/stops crown rotation
- 7.5 cm axial travel

Prime Button
- Allows quick flushing

Guidewire Brake
- Keeps the wire from rotating or moving axially. The OAD will not rotate the crown if the brake is up.

Electro-Powered Handle
- Allows 2-minute start-up and provides efficient torque transfer to the shaft and crown.

1. CSI data on file.
Peripheral Crown Types

Crown selection is a medical decision based upon actual patient condition. Sizing guide is only a general reference to indicate a commonly used starting point from which to analyze a patient’s needs. See the Instructions for Use for full information.

<table>
<thead>
<tr>
<th>Crown Size</th>
<th>1.25mm, 1.5mm, 2.0mm (6Fr)</th>
<th>1.25mm, 1.5mm (6Fr)</th>
<th>1.25mm (4Fr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlideAssist</td>
<td>NA</td>
<td>NA</td>
<td>5K RPM</td>
</tr>
<tr>
<td>Low</td>
<td>60K RPM</td>
<td>60K RPM</td>
<td>60K RPM</td>
</tr>
<tr>
<td>Medium</td>
<td>90K RPM</td>
<td>90K RPM</td>
<td>90K RPM</td>
</tr>
<tr>
<td>High</td>
<td>120K RPM</td>
<td>140K RPM</td>
<td>140K RPM</td>
</tr>
</tbody>
</table>

Solid Crown
For maximum calcium removal

Classic Crown
For vessel bends, ostial lesions, and distal BTK procedures

Micro Crown with GlideAssist
For tortuous vessels and tight bends BTK
Crown selection is a medical decision based upon actual patient condition. Sizing guide is only a general reference to indicate a commonly used starting point from which to analyze a patient's needs. See the Instructions for Use for full information.
ViperWire Advance™

ViperWire Advance®
PERIPHERAL GUIDE WIRES

Tip Load: 10 gram
Core: Stainless Steel
Support Coil: Stainless Steel

- Taper Length: 27 cm
- Radiopaque: 3 cm Coil
- 0.014" Diameter
- 335 cm long

Tip Load: 10 gram
Core: Stainless Steel
Support Coil: Stainless Steel

- Taper Length: 27 cm
- Radiopaque: 3 cm Coil
- 0.014/.017" Tip
- 475 cm long

ViperWire Advance®
PERIPHERAL GUIDE WIRE WITH FLEX TIP

Tip Load: 2.5 gram
Core: Stainless Steel
Support Coil: Nitinol

- Taper Length: 29 cm
- Radiopaque: 3 cm Coil
- 0.014" Diameter
- 335 cm long

- 0.014/.018" Tip
ViperSlide™ Library

- ViperSlide™ reduces friction within the OAD
- 20 ml ViperSlide™ per liter of saline

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soybean Oil</td>
<td>10%</td>
</tr>
<tr>
<td>Egg Yolk Phospholipids</td>
<td>1.2%</td>
</tr>
<tr>
<td>Glycerin</td>
<td>2.25%</td>
</tr>
<tr>
<td>Sodium Hydroxide (pH range is 6.0 to 8.9)</td>
<td>Quantity Sufficient</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Quantity Sufficient</td>
</tr>
</tbody>
</table>

ViperSlide™ is contraindicated in patients with known allergies to the components including eggs.

Warning: Never operate the OAD without normal saline and ViperSlide™ lubricant.
Flow Rates (ml/min)*

- Orbital Atherectomy Device (OAD) not spinning, prime button pressed: 16 - 36
- Not spinning: 12 - 19
- Spinning low: 11 - 34
- Spinning high: 7 - 29

*Flow rates are measured through the OAD.
Orbital Atherectomy
Dual Mechanism of Action

Atherectomy:
Bi-directional Differential Sanding
Reduces superficial calcium\textsuperscript{1,2}

Calcium Modification:
Pulsatile Forces
From eccentric-mounted mass
may contribute to compliance change\textsuperscript{2}


2. CSI Data on File: based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite block test models.

Atherectomy:
Bi-directional Differential Sanding
Reduces superficial calcium

- Superficial calcium is sanded by diamond surface.¹
- Differential Sanding reduces plaque while potentially minimizing damage to the medial layer of the vessel.¹
- Based on a carbon block model >93%² of particulate is smaller than a red blood cell (average particulate ~2 microns in size)

Diamond surface: 30 micron diamonds, 10 micron exposed.
TRUTH STUDY

Tissue removal assessment with ultrasound of the SFA and popliteal study (TRUTH): Orbital Atherectomy acute data and intravascular ultrasound analysis
TRUTH: Study Design & Demographics

Prospective, single-arm, single-center study using IVUS to assess OAS-related plaque modification of femoropopliteal lesions

- Prospective, Single-center
- Single Arm
- ATK Lesions
- IVUS Core Lab (CRF, NY)

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70.4 ± 7.8 years (N=25)</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>19/25 (76.0%)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1/25 (4.0%)</td>
</tr>
<tr>
<td>White</td>
<td>24/25 (96.0%)</td>
</tr>
<tr>
<td>BMI</td>
<td>31.2 ± 6.3 (N=25)</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>70.9 ± 25.0 (N=25)</td>
</tr>
<tr>
<td>History of diabetes (Type I or II)</td>
<td>18/25 (72.0%)</td>
</tr>
<tr>
<td>History of hyperlipidemia</td>
<td>25/25 (100.0%)</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>25/25 (100.0%)</td>
</tr>
<tr>
<td>History of angina</td>
<td>4/25 (16.0%)</td>
</tr>
<tr>
<td>Prior stroke/TIA</td>
<td>0/25 (0.0%)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>1/25 (4.0%)</td>
</tr>
<tr>
<td>Smoker (current or former)</td>
<td>21/25 (84.0%)</td>
</tr>
<tr>
<td>Rutherford classification</td>
<td>3.0 ± 0.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedural Information</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Lesion Location</td>
<td></td>
</tr>
<tr>
<td>Superficial femoral artery</td>
<td>23/29 (79.3%)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>4/29 (13.8%)</td>
</tr>
<tr>
<td>Tibioperoneal trunk</td>
<td>2/29 (6.9%)</td>
</tr>
<tr>
<td>Mean target lesions per patient</td>
<td>1.2 ± 0.4 (N=25)</td>
</tr>
<tr>
<td>Mean lesion length (mm)</td>
<td>65.4 ± 27.8 (n=29)</td>
</tr>
<tr>
<td>Proximal reference vessel diameter (mm)</td>
<td>5.2 ± 0.8 (n=29)</td>
</tr>
<tr>
<td>Distal reference diameter (mm)</td>
<td>5.4 ± 0.7 (n=29)</td>
</tr>
<tr>
<td>Minimum lumen diameter (mm)</td>
<td>0.9 ± 0.7 (n=29)</td>
</tr>
</tbody>
</table>
TRUTH: Study Results
Prospective, single-arm, single-center study using IVUS to assess OAS-related plaque modification of femoropopliteal lesions

**Procedural Results:**
- Average balloon inflation pressure post-OAS was 5.2 ± 1.2 atm
- 58.6% of lesions were stented (adjunctive) at physician preference
- Reduction in angiographic stenosis from 84.4% pre-OAS to 32.6% post-OAS+BA (p<0.001)
- No recoil, slow flow/no reflow, or Type D-F dissections noted

**1-year Follow Up:**
- No death or major amputation
- TLR was 8.2%
- Ankle-brachial index and Rutherford classification improved significantly from baseline through follow-up
- “The VH-IVUS analysis reveals that OAS modifies the calcified component of the plaque burden”

**IVUS Results:**
- Minimum lumen area increased from 4.0 mm\(^2\) pre-treatment to 9.1 mm\(^2\) post-OAS+BA (p<0.0001)
- Calcium reduction was responsible for 86% of the lumen area increase

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In a post-hoc assessment of OAS-mediated vessel wall injury, IVUS images from the TRUTH study were analyzed before and after OAS for signs of medial injury. Only 2 of the 23 post-OAS intervention images indicated medial injury (8.7%). This finding “suggests that OAS can treat calcific plaque while minimizing medial injury”.

Excellent Procedural Safety Profile with OAS
Consistently Low Acute Complication Rates

Excellent safety profile demonstrated by low angiographic complication rates.

1. CSI data on file.
6. CSI data on file (21-May-2018 data)
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