A Look at Focused Force in Calcified Lesions

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Disclosure

Speaker name:

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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
LINC 2016: Live Case (SFA Occlusion DEB with lesion Preparation with Scoring-Balloon VascuTrak)
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Proper Indications for Scoring Balloons

- Calcified Lesions
- Ostial Lesions (to reduce plaques shift)
- In-stent Restenosis
- Bypass Graft stenosis
- Lesion preparation prior to VMI or DEB
- Long Lesions
Challenges with Calcific Lesions in PAD

- Small BTK vessels / long diffuse disease
- No stent zones
- High pressure dilatations
  - Increase arterial trauma
  - May produce major dissections
ULTRASCORE™ Focused Force PTA Balloon

Scoring Balloon

24 x Force
Length up to 300mm
Focused Force Angioplasty

- Incorporates two external focal force wires to introduce high focal stresses longitudinally at low balloon inflation pressures.
- This focal force stress concentration can fracture the plaque at low pressure, allowing a slow gradual expansion of the vessel, which can reduce the risk of barotrauma that is associated with use of conventional angioplasty balloons\(^1\)

ULTRASCORE™ Focused Force PTA Balloon

• Mechanism of Action

May allow for a **more controlled plaque fracture** and **less vessel recoil**, even in **calcified lesions**
## ULTRASCORE™ Focused Force PTA Balloon

- **Product Offering**

<table>
<thead>
<tr>
<th>0.035”</th>
<th>0.014” – Hydrophilically Coated</th>
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<tbody>
<tr>
<td><strong>Shaft Lengths (cm)</strong></td>
<td>130</td>
</tr>
<tr>
<td><strong>Balloon Diameters (mm)</strong></td>
<td>4, 5, 6, 7, 8</td>
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<tr>
<td><strong>Balloon Lengths (mm)</strong></td>
<td>20, 40, 80, 100, 120, 150, 200, 300</td>
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<tr>
<td><strong>Sheath Compatibility (Fr)</strong></td>
<td>5F (up to 4X300, 5X150, 6X40), 6F</td>
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Testing Results: ULTRASCORE™ to AngioSculpt™

- UltraScore™ causes fracture at 8x lower inflation pressures*

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*Based on a simulated finite element analysis. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.
Scoring Mechanism: ULTRASCORE™ to AngioSculpt™

- ULTRASCORE’s™ longitudinal scoring wires are more effective at lower inflation pressure compared to AngioSculpt’s™ wire configuration.

ULTRASCORE™
breaks plaque at 1.10 atm
across entire length of lesion

AngioSculpt™
breaks plaque at 8.45 atm
at multiple single points along the lesion
Summary

- Focused force technology is designed for highly calcific PAD
- Focused force technology causes a controlled plaque fracture at lower inflation pressures
- BARD® will be launching ULTRASCORE™ Focused Force PTA Balloon, the next generation scoring balloon technology
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