Peripheral CTO Crossing with the SoundBite™ Active Wire

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Disclosure

Speaker name:

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
SoundBite™ Crossing System

SoundBite™ Console (re-usable)

Active Wire Technology

SoundBite™ Active Wire (single use)

Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Value</th>
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<tbody>
<tr>
<td>A: Total Length</td>
<td>300 cm</td>
</tr>
<tr>
<td>B: Ground section length</td>
<td>16 cm</td>
</tr>
<tr>
<td>C: Distal tip diameter</td>
<td>0.0115&quot;</td>
</tr>
<tr>
<td>D: Wire diameter</td>
<td>0.018&quot;</td>
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Mechanism of Action

Active Wire micro-jackhammer effect

Effective on hard material

Safe on soft tissue
PRIMARY ENDPOINT

• **30-day device success**: Ability to facilitate treatment of the target lesion by allowing additional crossing and/or treatment devices to cross the CTO + Freedom from MAEs

STUDY POPULATION

• **52 Subjects** (56 CTOs)
• **Canada** (Montreal, Sherbrooke, Ottawa) & **Europe** (Graz)
• **CTO length = 1 cm to 32 cm** (mean 10 cm +/- 8 cm)
PROSPECTOR Peripheral Clinical Trial

**TRIAL RESULTS**

- 30-day Device Success 92.3%
  - 0% MAEs
- Mean **Active Wire Activation Time** = 3.58 min ± 3.16 min
- Median **CTO Crossing Time** = 10 min ($\bar{x}=20$ min.)
- The Active Wire crossed the full CTO length in 86.5% of subjects.

- Over 60% subjects with moderate to severe CTO calcification

![Pie chart showing the distribution of CTO calcification severity]

- 32.1% Mild
- 39.3% Moderate
- 28.6% Severe
Trial Results: Rutherford Category and ABI Improvements

Rutherford Category

ABI Ratio
Case Presentation 2

- 77 y.o. male
- Rutherford III
- R. 14 mm popliteal CTO
- Severe Ca++
- Activation time: 26 sec.
Conclusion

• Efficient device: **92.3%** Device Success
• Good safety record: **no MAEs**
  • AW action on **hard tissues**, innocuous on soft tissues
  • 0.018: **perforation less likely** to be problematic
• **Easy** and **fast** to operate
  • Compatible with standard 0.018” platform tools
  • No saline solution, cooling or specialized catheter
  • No need to push hard on the wire
• Coronary Trial presently ongoing with 0.014” wire
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