The ENABLER-P
A Novel CTO Crossing System
Report of First Human Experience

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Disclosure

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Current Limitations of CTO Treatments

- Despite the advent of new devices and improved operator technique, success rates remain limited (60-80%)
- Unsuccessful attempts are primarily due to inability to cross lesions with a guidewire
- Typically CTO procedures are associated with extended procedural time, radiation exposure and increased contrast load.
- Treatment of CTO lesions remains highly dependent on operator skill and experience.
ENABLER-P System

Includes 2 components:

Support balloon Catheter

- Catheter lumen 0.35 compatible
- Catheter length 135cm
- Balloon length 20mm
- Balloon Diameter 6mm

* The ENABLER-P Support Catheter is pending FDA 510(k) approval
ENABLER-P System

- Pressure Control Unit (PCU)
  - Disposable, battery operated sterile unit
  - Allows additional
  - Cyclical inflations
  - and deflation of the balloon
ENABLER-P System

• Reciprocating inflations facilitate guidewire advancement along the longitudinal axis while increasing axial force at the tip of the guidewire.

• These reciprocating inflations result in guidewire gripping, balloon elongation which in turn leads to forward movement of the guidewire.

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First Human Use Experience

- Designed to demonstrate **Safety** and **Effectiveness** of the ENABLER-P in crossing Chronic Total Occlusions located in the Superficial Femoral Artery
Clinical Experience to date

- Patients enrolled: 6 (3 female)
- Mean Age: 63
- Vessel location: SFA
- Occlusion length: 50-120mm
- Calcification: 4 heavy, 1 non-calcified
- Vessel diameter: 4-6 mm
Why Degradable Stents?

Clinical Results  n=6

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<tr>
<td>Successful cross</td>
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<td>Serious adverse events</td>
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<td>Device related adverse events</td>
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<td>Procedure related adverse events</td>
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<td>Successful revascularization</td>
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* Proximal dissection from initial vessel access resulting in sheath placement into false lumen
* CTO crossing time equals the time from anchoring to termination of the procedure.

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Conclusion:

• ENABLER-P is a promising novel device for treatment of Chronic Total Occlusions

• In this very early experience the device appears to be safe and effective in crossing long calcified lesions in SFA

• Ongoing evaluation continues to be extremely favorable.