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.

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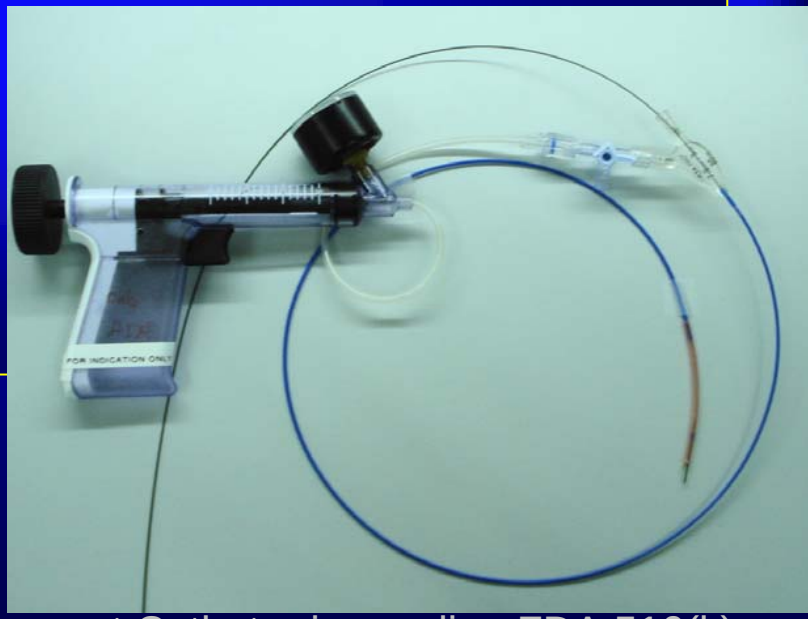
ENABLER-P System

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

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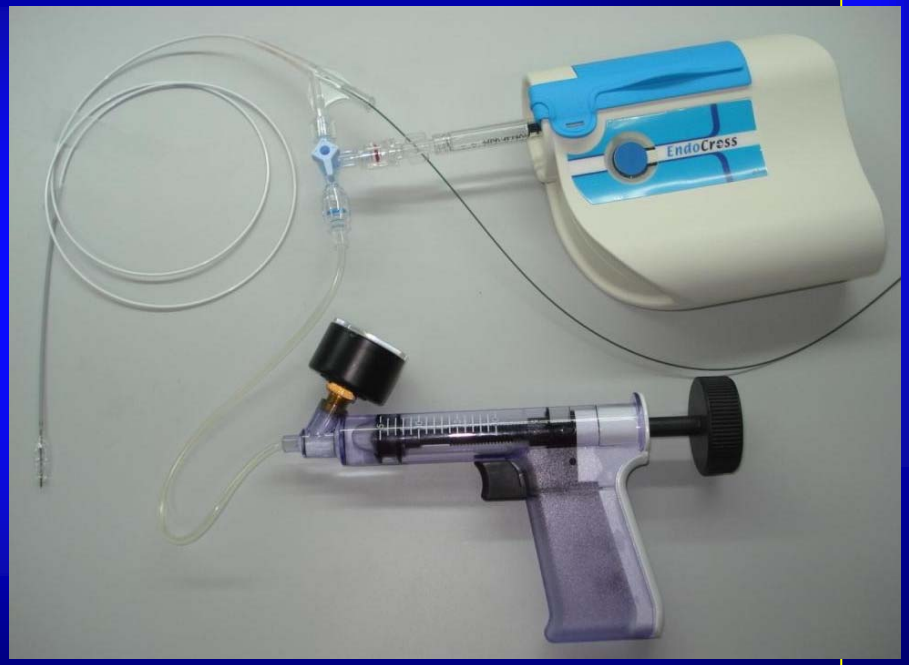
ENABLER-P System

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



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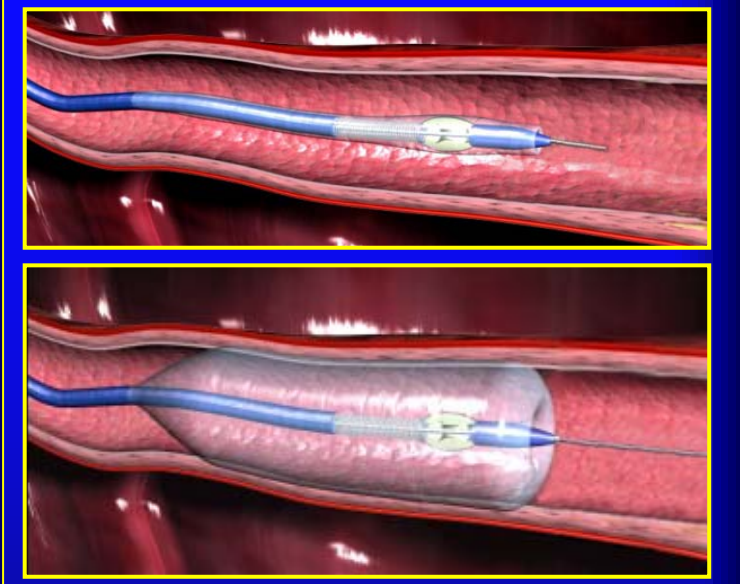
ENABLER-P System

- 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

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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

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Clinical Results n=6

Successful cross	5
Serious adverse events	0
Device related adverse events	0
Procedure related adverse events	1*
Successful revascularization	5

* Proximal dissection from initial vessel access resulting in sheath placement into false lumen

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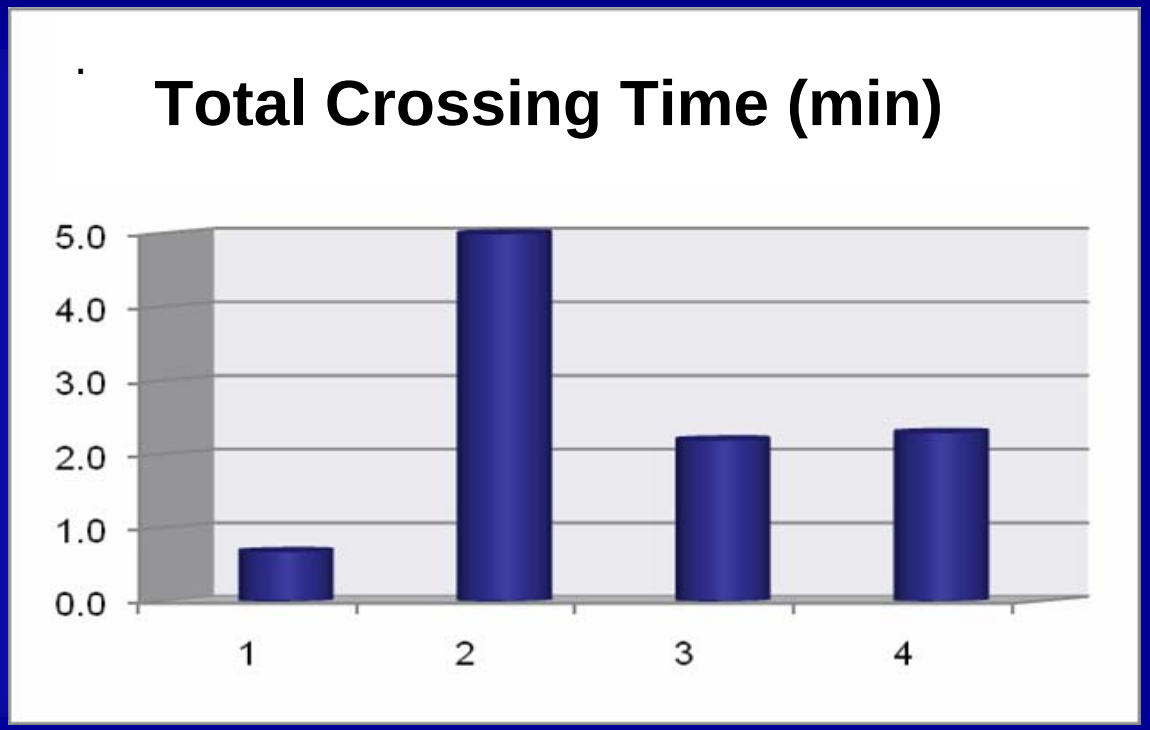
ENABLER-P Crossing Results



* 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.