SoundBite™ Active Wire Technology
Crossing Peripheral CTO

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Active Wire Technology

Mechanism of Action
Shock Waves create a 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)

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 (x=20 min.)
• In 85.7% of cases the Active Wire alone crossed the full CTO length

Prospector Peripheral Clinical Trial

Disclosures
Consulting/Honoraria
• Medtronic
• BARD
• Spectranetics
• Intact Vascular
• Soundbite Medical
• Biotronik
• Bayer
• Daiichi
• Böhringer Ingelheim
• Astra Zeneca
Case Presentation 1
- 6 cm CTO distal SFA
- Antegrade access
- Severely calcified
- Energy helped crossed calcified proximal cap
- Crossing time: 4 min

Case Presentation 2
- 14 cm right SFA CTO
- Proximal cap with flush collateral
- Moderate calcification
- R. Antegrade access
- Activation time: 50 sec.
- Crossing time: 7 min

PROSPECTOR Study: What we learned
- No need to push hard
  - Let the device bore into the lesion
- AW has good steerability
  - Easy to change point of attack
- Shaping the AW’s tip
  - Help to steer the wire through CTO
  - Can help re-entry into true lumen if subintimal

PROSPECTOR Study: What we learned
- Shaft stiffness: catheter support
- Tip stiffness: effective for CTO with flush collateral
  - Power optional to cross whole CTO
  - Apply power as needed
  - 5 min. maximum activation time: 1 AW enough in majority of cases, but operator can use as many as needed
- Stiff wire + shock wave
  - Effective to cross calcified CTO

Conclusion
- Efficient device: 92.3% Device Success
- Good safety record: no MAE / device-related SAE
  - 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