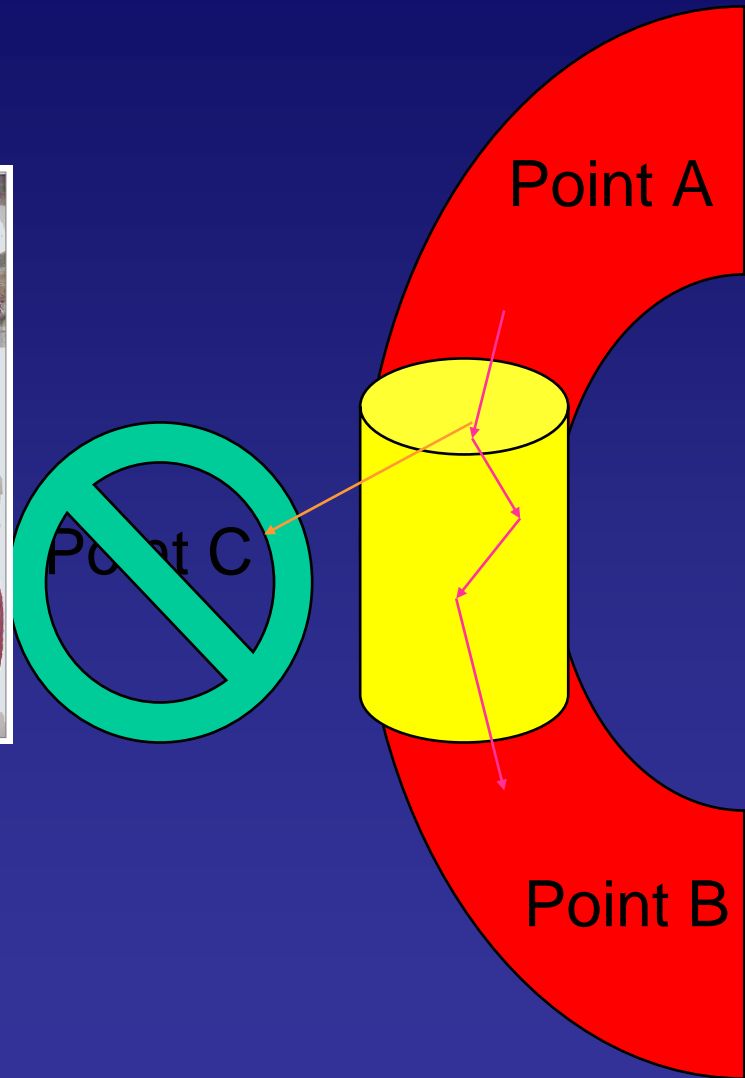
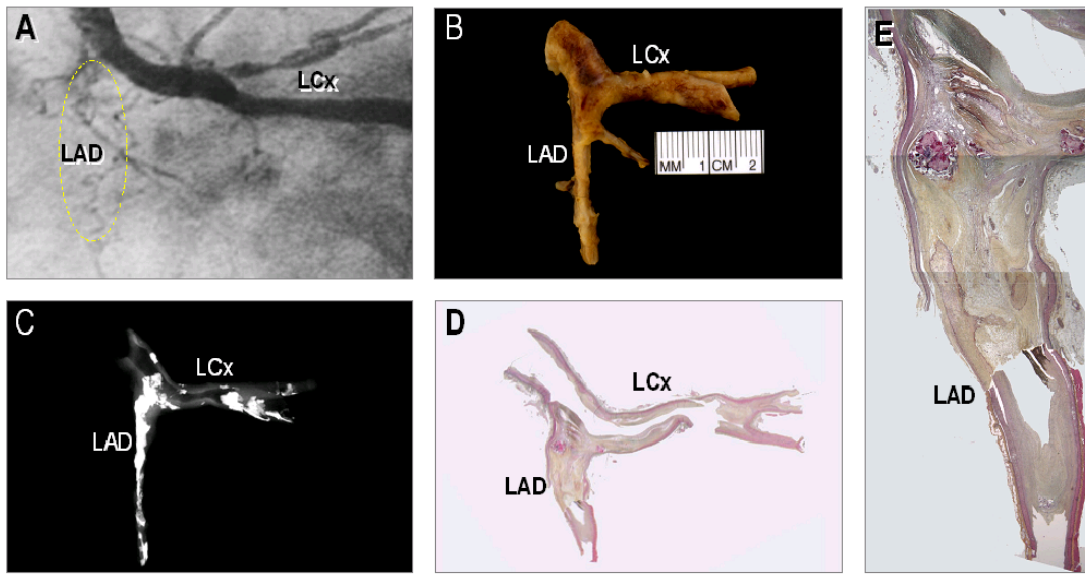


Chronic Total Occlusions: When and How to Use the Safe-Cross System

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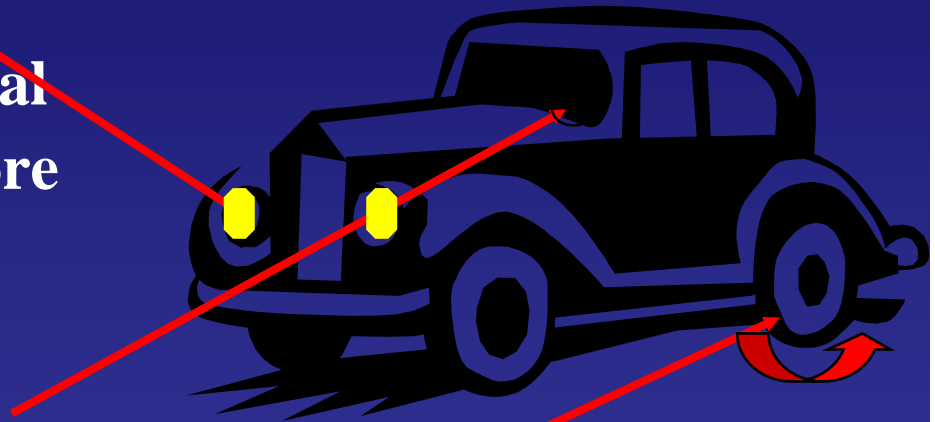
The challenge



The challenge of chronic totals

Like trying to drive on a dark road...

- We need devices that are
 - **Smart enough** to tell the difference between potential lumen and vessel wall before perforation or dissection occurs
 - **Steerable enough** to choose the best path
 - **Strong enough** in force or energy to make headway in these fibrotic/calcific lesions



IntraLuminal



Safe-CrossTM

Total Occlusion Radio Frequency Crossing System

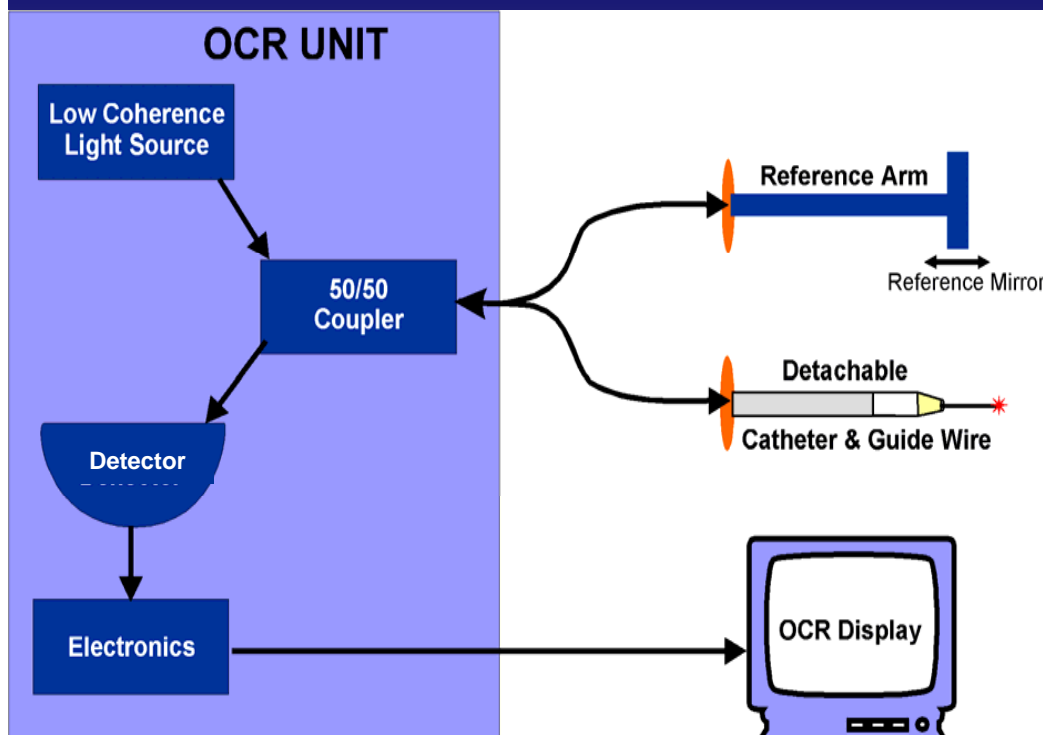
The Safe-Cross Technological Principle

- Forward-Looking Guidance System
- High Resolution (10-15 microns)
- Precise Control of RF Energy

Radio Frequency

- Controlled RF Energy to effectively cross total occlusions
- Ease of use with simple pedal used to deliver RF energy
- Precise RF energy release at distal tip of wire

Optical Coherence Reflectometry (OCR)

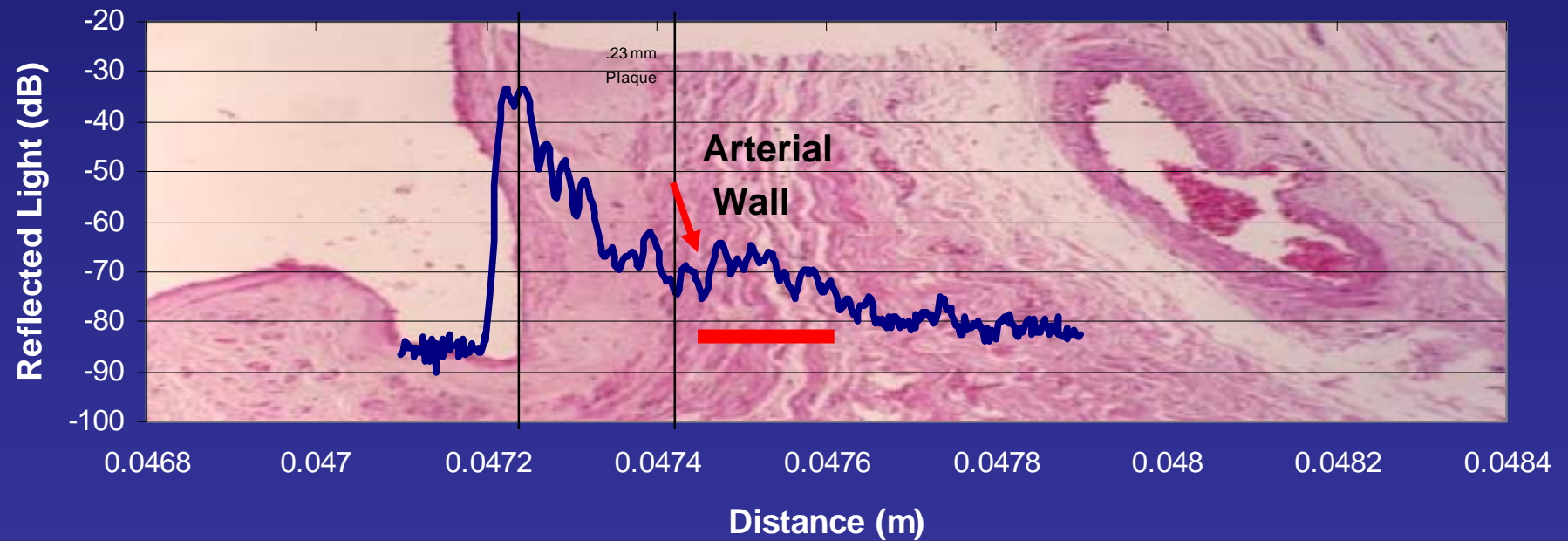


Similar to Ultrasound, but

- Uses near-infrared light instead of sound to create 10X better resolution
- Forward looking to offer guidance capability

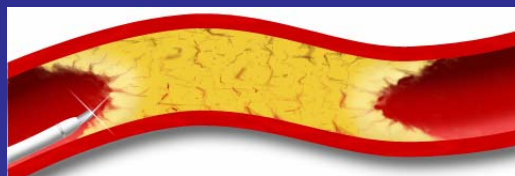
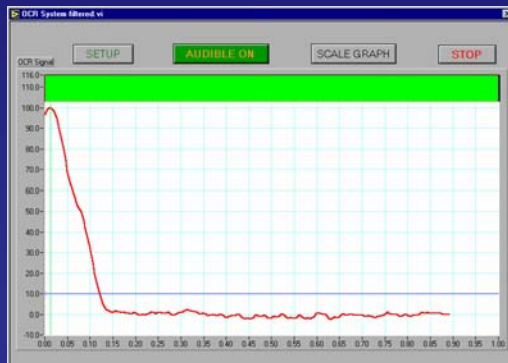
OCR Signal Correlation with Histology

In Vitro Measurement of Plaque in an Artery
(1300 nm, $n=1.34$, 14 sweeps)

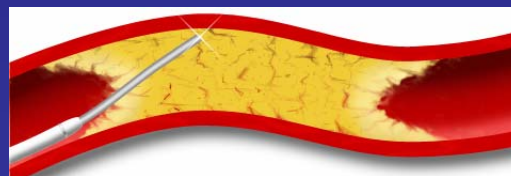
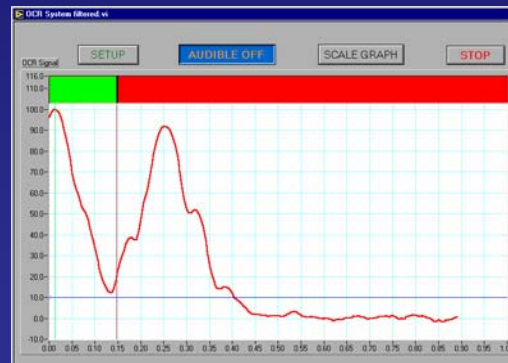


OCR Waveform Displays

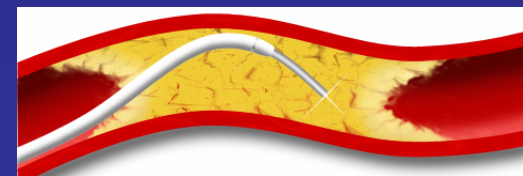
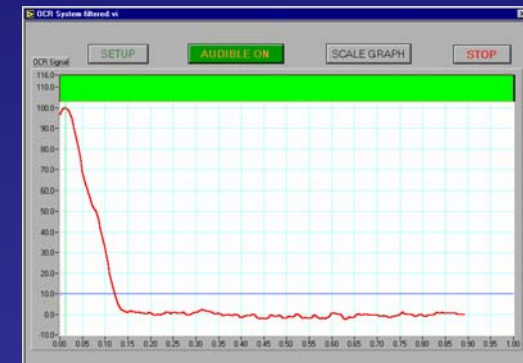
No artery wall detected



Artery wall detected



No artery wall detected



Safe-Cross Console and Display

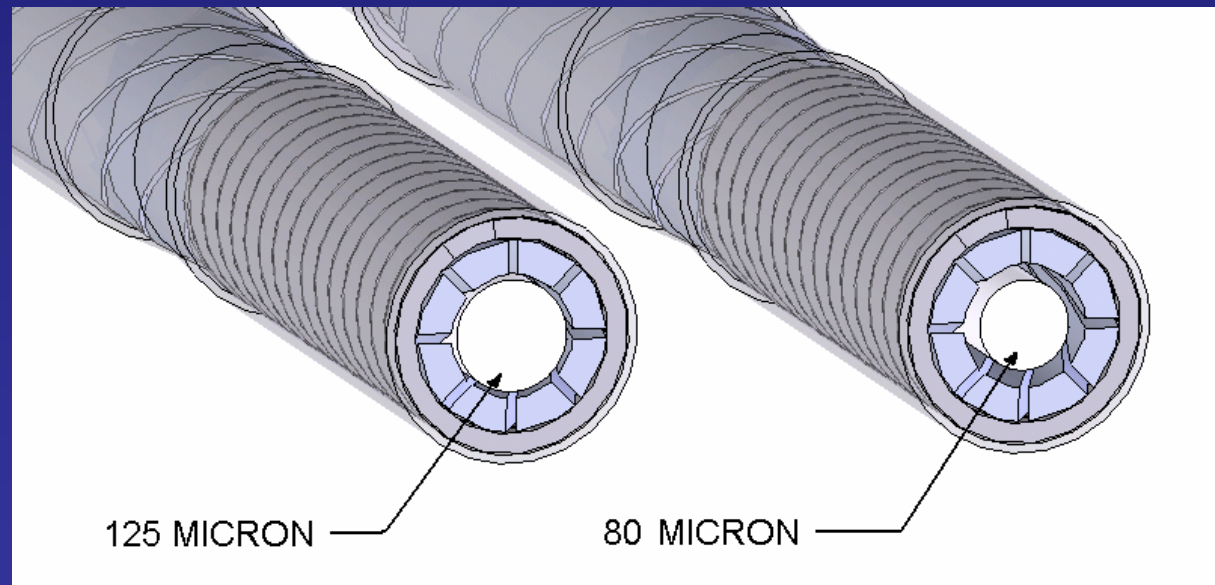


Safe-Cross[®] Family of Guide Wires

- **Safe-Cross[®] AP Guide Wire**
 - Launched August, 2005
 - .014” compatibility
 - working lengths 175 & 275
 - angle tip straight & angled
- **Safe-Cross[®] Crossing Wire**
 - .018” and .035” compatibility
 - Working length 275
 - Angle tip straight & angled

Safe-Cross[®] AP Wire

- August 1, 2005, IntraLuminal launched New Safe-Cross[®] AP Guide Wire
 - Reduced the optical fiber from 125 μ to 80 μ

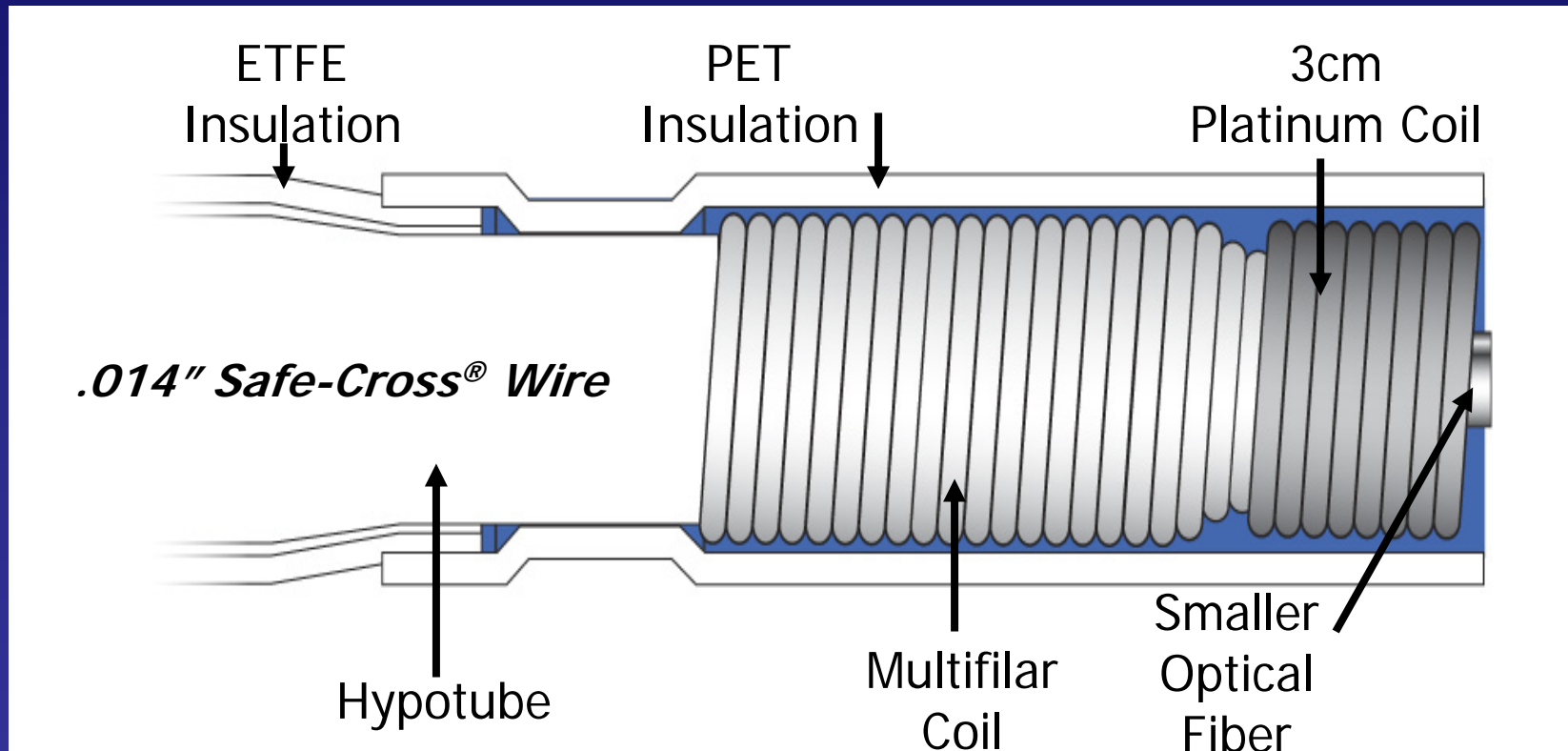


Safe-Cross[®] AP Guide Wire

Features and Benefits:

- Greatly Improved Steerability
- Enhanced Angle Tip Retention
- Superior Shapeability in straight wires
- Better Tip Flexibility

Safe-Cross[®] AP Wire



Safe-Cross Crossing Wire



Multiple tip configurations

- Straight
- Angled

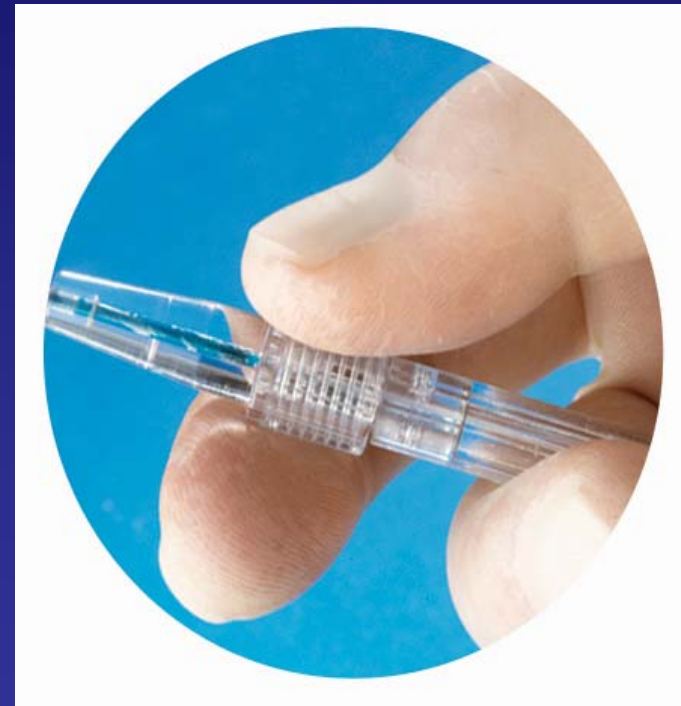
Multiple sizes

- For coronary and peripheral applications

Deflectable Tip



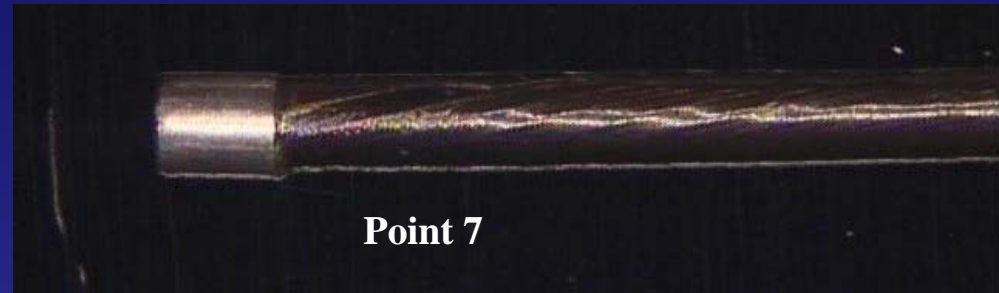
Tip can be deflected from straight to 90 degrees



Tip deflection is mechanically activated by turning knob on proximal handle

Point 7mm Catheter

- OTW design
- 80/80 capability
- Radiopaque tip marker for easy visualization
- Lubricious coating to minimize drag



Specifications

Max. Tip OD	0.031 in
Min. Tip ID	0.015 in
Max. Shaft OD	0.043 in
Min. Working Length	130 cm
27, 50 micron fibers	
4.0 mJ output at 80 fluence	

Tips on Using the Safe-Cross System

1. Lesion Selection:

- a. True, well-developed CTO lesions with presumed firm proximal and distal caps
- b. Lesion lengths < 30mm preferable
- c. Minimal vessel tortuosity and calcium
- d. Well-visualized distal vessel via collaterals

2. Technique Tips:

- a. **Use 8F guide** : Better support for crossing and ? bifurcations
- b. Load new **AP wire** into either a low-profile balloon catheter, transit catheter, or tip-deflecting catheter
- c. Can usually **steer new AP wire to lesion** without having to start with more floppy wire and change
- d. **GO SLOW** at proximal cap and be sure “green” light is steady; when hit resistance, fire RF for 4-5 pulses
- e. Once into the CTO segment, continue with AP wire if can steer through bends, but don’t force the wire and **change out for more steerable wire as needed (Pilot 50 my favorite)**
- f. If other wires will not pierce distal cap, change back out for AP wire and **give RF pulses**, or if angulated use a stiffer wire with acute bend at tip (Confianza Pro my favorite)