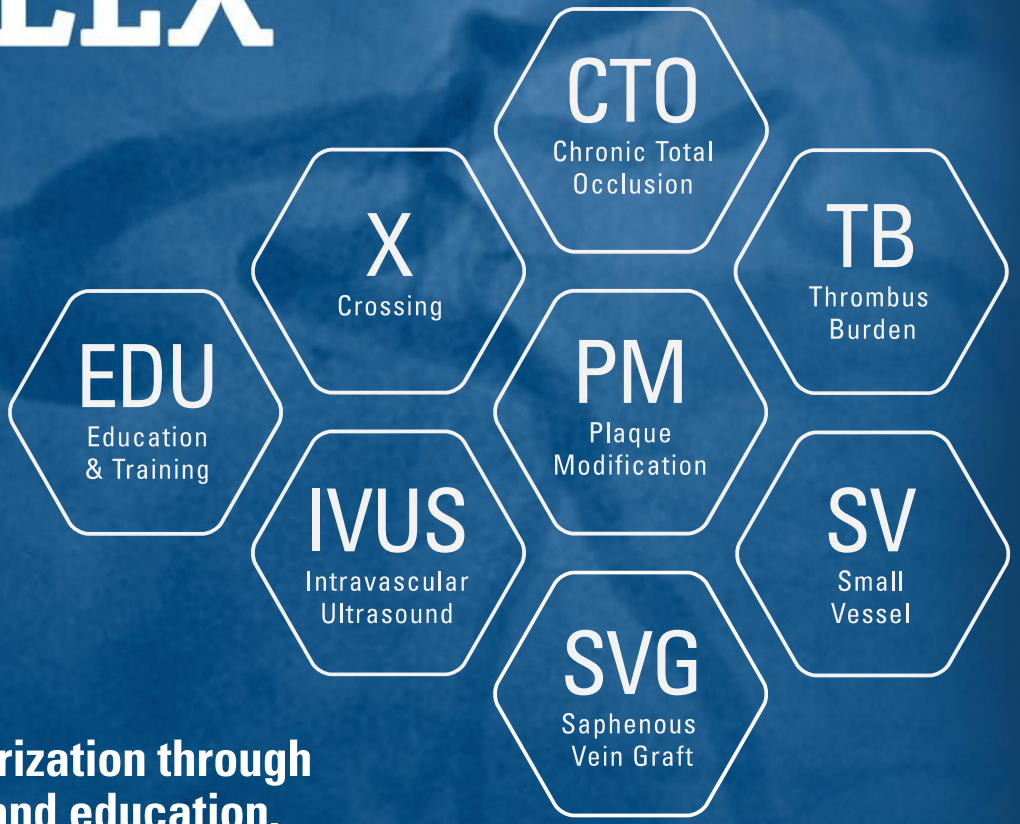
Rotablator®
Rotational Atherectomy System

Boston Scientific
Advancing science for life™

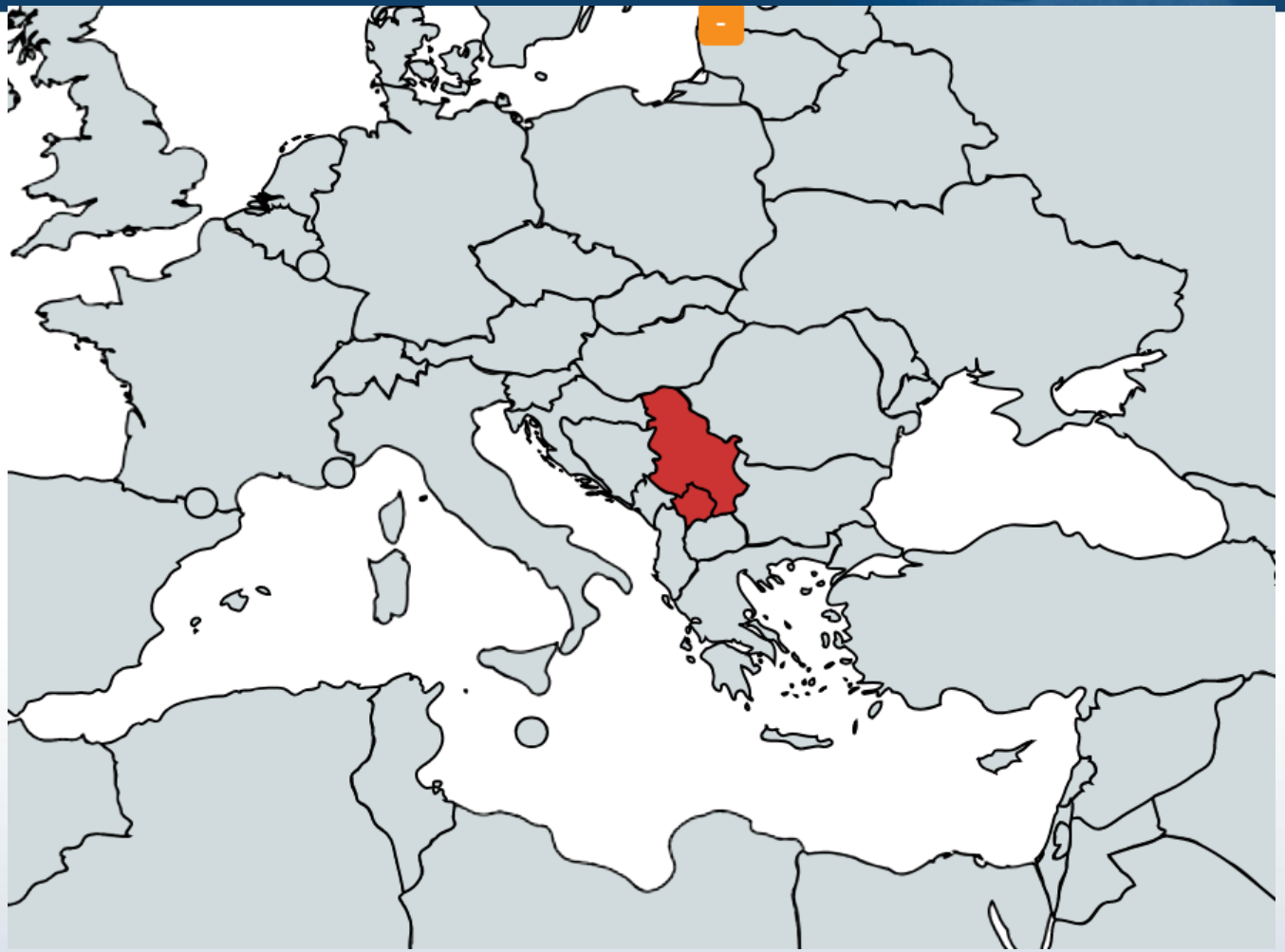
MASTER THE COMPLEX

In-Service Presentation

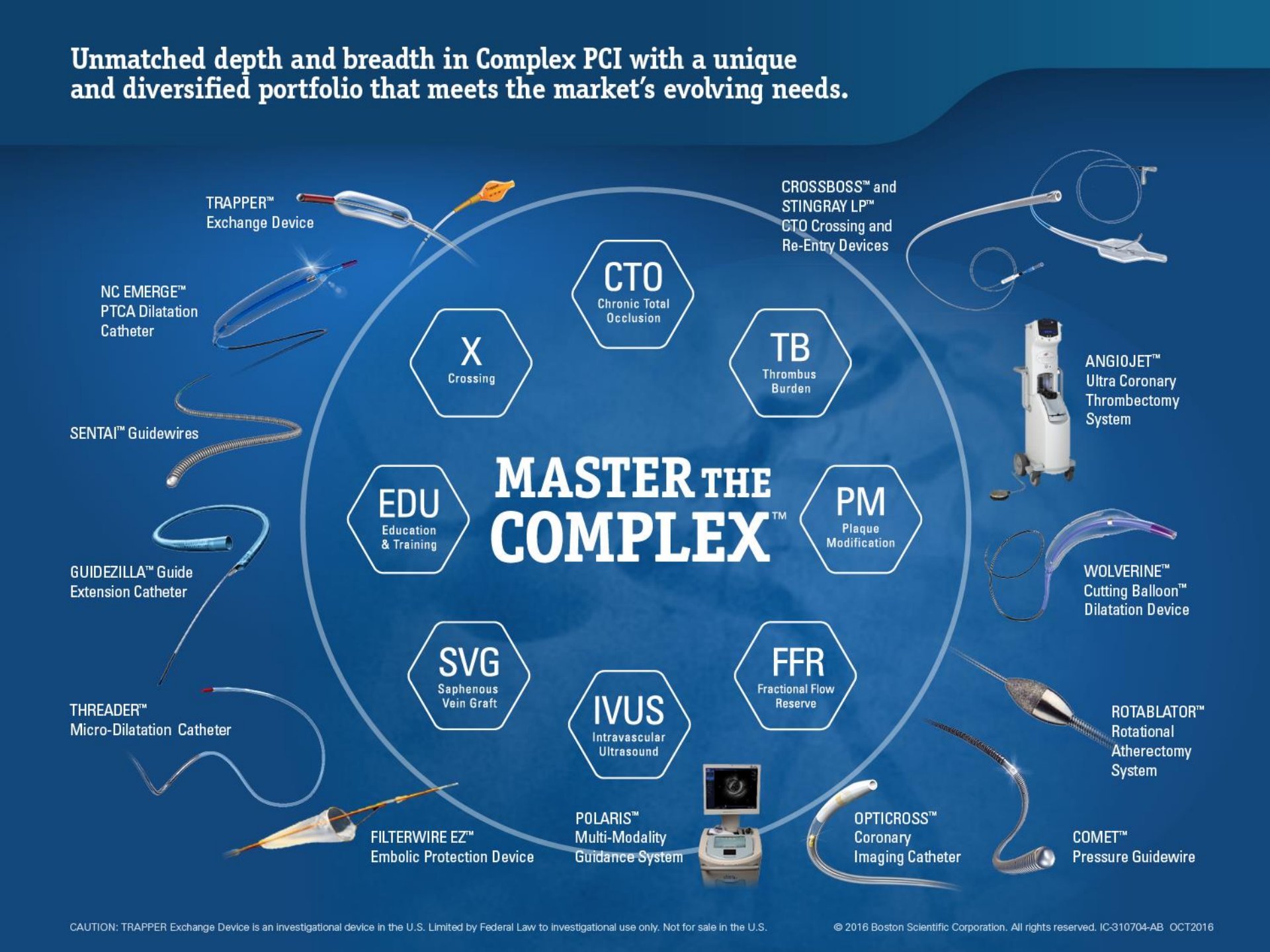


Optimizing revascularization through innovation, training, and education.

Nikola Pesic, Therapy representative for Eastern Europe and EURASIA
Boston Scientific



Unmatched depth and breadth in Complex PCI with a unique and diversified portfolio that meets the market's evolving needs.



CAUTION: TRAPPER Exchange Device is an investigational device in the U.S. Limited by Federal Law to investigational use only. Not for sale in the U.S.

Rotablator®
Rotational Atherectomy System

MASTER THE COMPLEX

What is the Rotablator System?

Rotational Atherectomy System

- Diamond-tipped burr designed to preferentially ablate calcium and fibrous plaque

System includes both capital equipment and disposable components

Capital Equipment

- Console
- Foot Pedal
- Air Tank

Disposables

- Wires
- Advancer
- Burr
- Rotaglide® Lubricant

Why use Rotational Atherectomy?

Calcium is out there.

- The prevalence of severe calcium, defined as superficial in nature with greater than 180° arc, is estimated to present itself in 12% of cases using angiographic imaging. When IVUS guidance is used, it's seen in approximately 26% of cases.[1]

Calcium can preclude optimal stenting.

- Asymmetrical stent expansion occurs in up to 50% of cases where calcium is not treated before stent deployment.[2]

With DES, rotational atherectomy is an important tool for calcified lesions.

- Lesion preparation with compliance change for a calcified lesion can substantially facilitate stent delivery and symmetrical stent expansion for more homogeneous drug delivery.[3]

1. Mintz et al. Patterns of Calcification in Coronary Artery Disease. *Circulation* April 1995, Volume 91, No 7
2. Moussa, Moses, Columbo et al. Coronary Stenting After Rotational Atherectomy in Calcified and Complex Lesions. *Circulation* 1997; 96:128-136
3. Iakovou, I. et. al. J Am Coll Cardiol 2005;46:1446-55

Clinical Application

MASTER THE COMPLEX

SPORT[1] (Stent Implantation Post Rotational Atherectomy Trial)

- While moderate de-bulking did not significantly improve clinical outcomes (TVR and TLR), it did result in higher acute procedural success and larger final lumen diameters.
- The study limitations included a lesion subset of mostly lesions with minimal calcification where de-bulking with RA is known to be of limited value.

	ROTA + Stent (n=360)	PTCA + Stent (n=375)	P-value
Post Procedure MLD	2.81 ± 0.44	2.74 ± 0.40	p = 0.032
Acute Gain	1.94 ± 0.50	1.86 ± 0.48	p = 0.041
Technical Success	93.1%	87.7%	p = 0.0146
Procedure Success	93.6%	88.1%	p = 0.0114
Clinical Success	91.6%	87.0%	p = 0.0495

1 Buchbinder, M., et al, presentations at TCT 2001 & ACT 2001

Clinical Application

MASTER THE COMPLEX

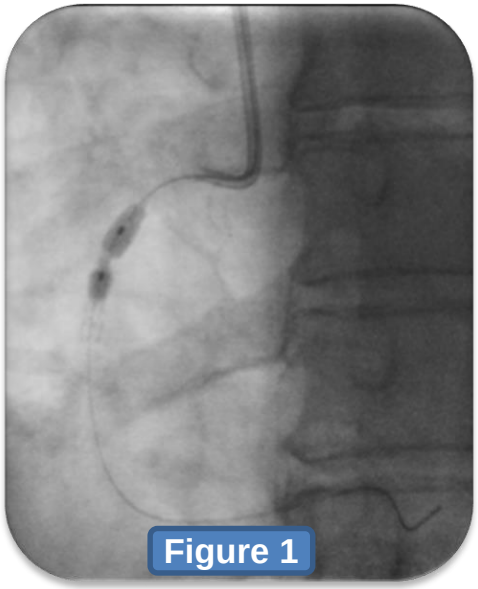


Figure 1


Figure 2

- Single 2.75 mm stent placed
- Post Dilatation: 3.5x9 mm non-compliant balloon for 30 seconds at 22 ATM followed by 4.0x9 mm non- compliant balloon for 30 seconds at 16 ATM. (figure 1)
- Results sub-optimal. (figure 2)

- **Lesions which initially appear as either treatable with PTCA or by stenting may benefit from pre-treatment with the Rotablator® Rotational Atherectomy System.**
- **Using Rotablator System may favorably impact complications, acute angiographic results, TLR and angiographic restenosis in calcified and complex lesions.[1]**
- **Asymmetrical stent expansion occurs in up to 50% of cases where calcium is not treated before stent deployment.[2]**

1.Hoffman R, et al. Comparative Early and Nine-Month Results of Rotational Atherectomy, Stents and the Combination of Both for Calcified Lesions in Large Coronary Arteries. *Am J. Cardiology*; March 1, 1998: vol. 81, :552-557
2.Moussa, Moses, Columbo et al. Coronary Stenting After Rotational Atherectomy in Calcified and Complex Lesions. *Circulation* 1997; 96:128-136
Results from case studies are not predictive of results in other cases. Results in other cases may vary.
Case images courtesy of Dr. Arthur Lee, Santa Clara Valley Medical Center, Kaiser Permanente, San Jose, CA

Mechanism of Action

MASTER THE COMPLEX

Porcine Model*

Angioplasty result with vessel injury

Rotablator® System result with minimal vessel injury

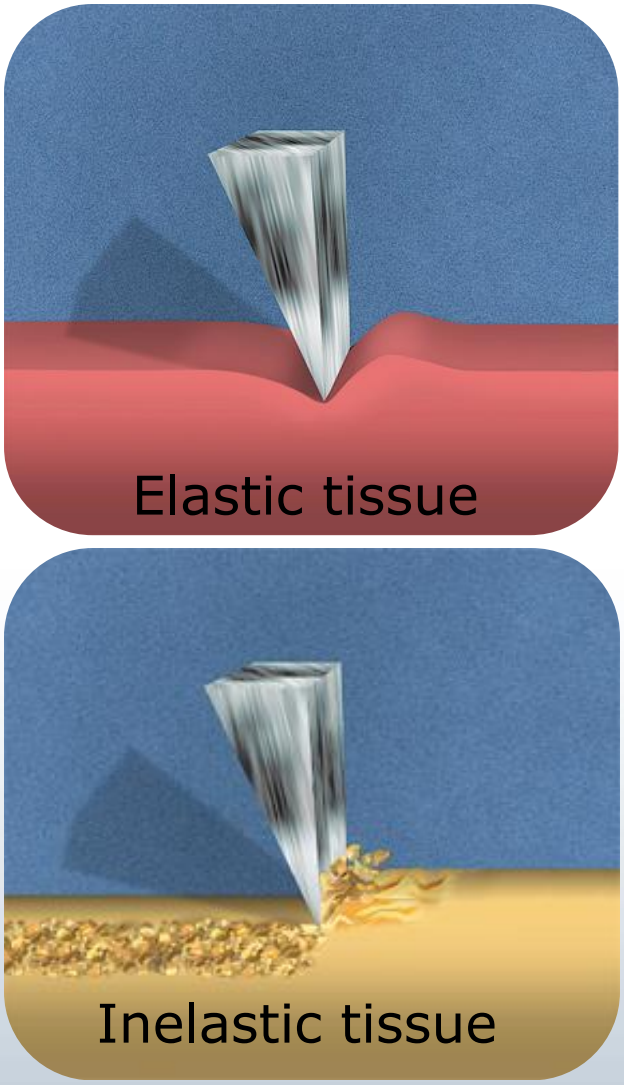
Intended PTCRA benefits

- Minimizes vessel wall stretch and elastic recoil
- Eliminates vessel barotrauma
- Produces a smooth lumen/channel
- Facilitates stent delivery and expansion

*Porcine model results may not necessarily be indicative of clinical performance.

Rotational Atherectomy

MASTER THE COMPLEX



Differential Cutting

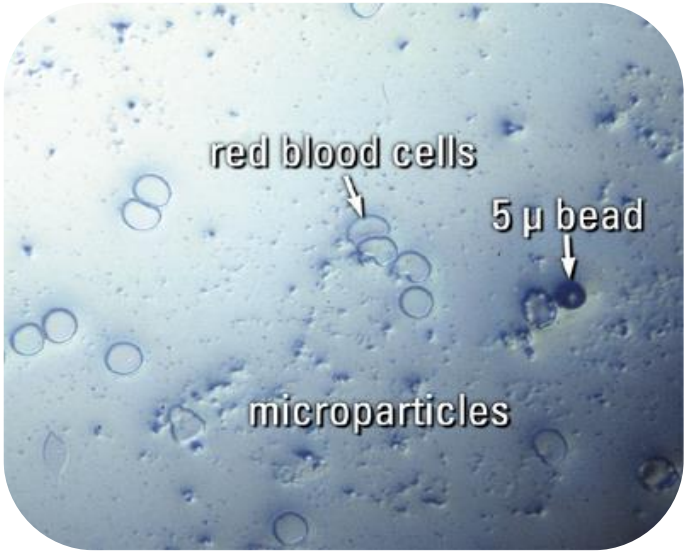
- The Rotablator® Atherectomy System is designed to ablate the inelastic, calcified, atherosclerotic tissue making up plaque in coronary arteries
- All plaque is inelastic
- Helpful analogies:
  - Shaving
  - A nail file

Rotational Atherectomy

MASTER THE COMPLEX

Plaque is ablated into small particles called microparticles:

- The size of the microparticles is less than 5 microns (smaller than a red blood cell)
- The microparticles are picked up by the RES (Reticuloendothelial System)
- Embolic protection filters designed for 100+ microns



Hardware

MASTER THE COMPLEX

Console

DynaGlide™ foot pedal

Tank, regulators, attachments

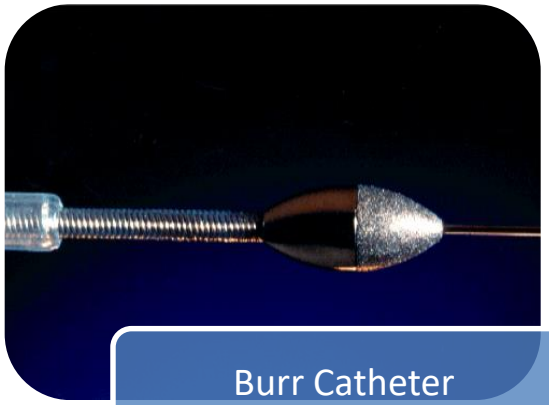
Compressed air or nitrogen

Disposables

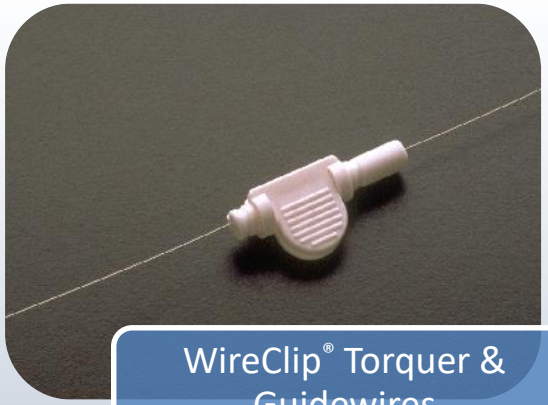
MASTER THE COMPLEX

Components

Advancer



Burr Catheter



WireClip® Torquer & Guidewires

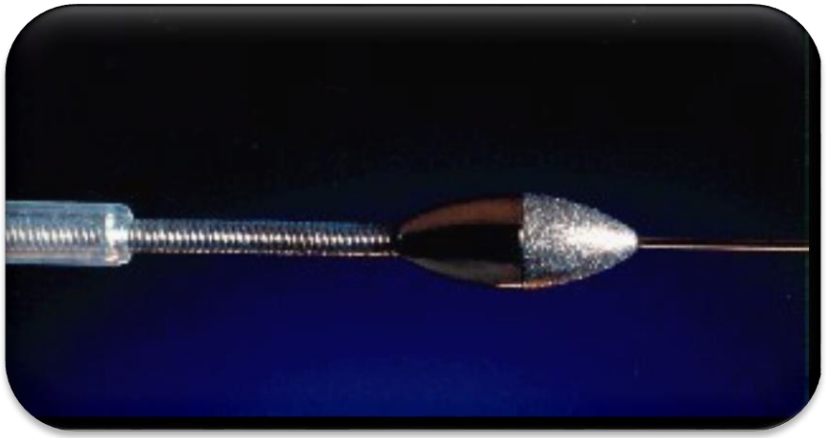
RotaGlide® Lubricant

Rotalink® Exchangeable Catheter

MASTER THE COMPLEX

Catheter

- 135 cm in length
- Sheath is .058”



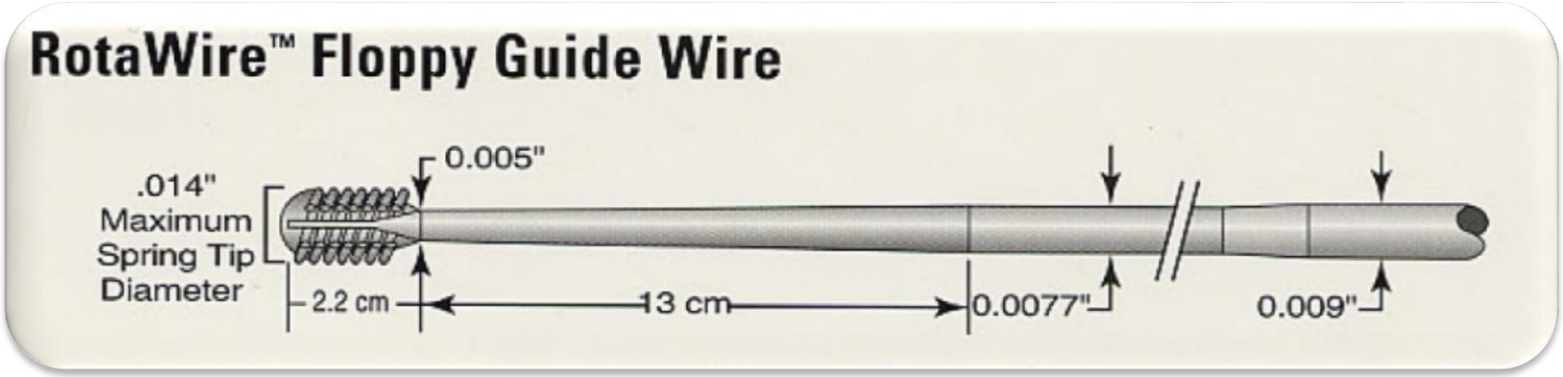
Burr

- Elliptical shaped with 2,000 to 3,000 microscopic diamond crystals on the distal edge. The proximal surface of the burr is smooth
- The brass burr is nickel coated
- The diamond crystals are 20 microns in size, with only 5 microns extruding from the nickel coating

Rotawire™ Floppy Guide Wire

MASTER THE COMPLEX

330 cm total length

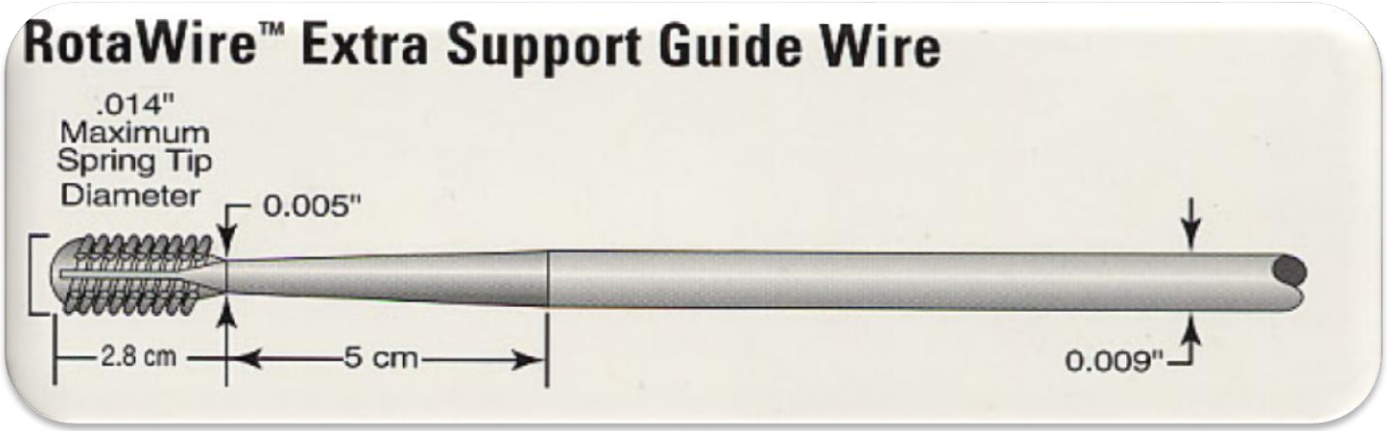


- **Flexible and torqueable to enhance navigation**
- **Significantly reduced guidewire bias**
- **Short Spring Tip (2.2 cm)**
- **Light rail support**

Rotawire™ Extra Support Guide Wire

MASTER THE COMPLEX

330 cm total length



- **Spring Tip (2.6 cm)**
- **Lead wire for those physicians requiring a “stiffer” wire**

Burr Size and Guide Selection

MASTER THE COMPLEX

Physician Considerations

- Guide catheter with side holes
- Guide catheter that provides coaxial engagement will reduce unfavorable guidewire bias
- Guide catheter to accommodate the final burr size to be utilized

Recommended Curves

Left	Right
Q Curve®	FR4
CLS™	Multi-purpose

Quick Reference Burr Guide

Burr Diameter		Recommended Guide Catheter	Minimum ID Required
mm	Inches	(French)*	(Inches)
1.25	0.049	6.0	0.060**
1.50	0.059	6.0	0.063
1.75	0.069	7.0	0.073
2.00	0.079	8.0	0.083
2.15	0.085	8.0	0.089
2.25	0.089	9.0	0.093
2.38	0.094	9.0	0.098
2.50	0.098	9.0	0.102

* Avoid abrupt primary and secondary curves.

Boston Scientific
Advancing science for life™

MAIN OBJECTIVE OF CONTEMPORARY ROTATIONAL ATHERECTOMY:

PLAQUE MODIFICATION

Boston Scientific
Advancing science for life™

MAIN OBJECTIVE OF CONTEMPORARY ROTATIONAL ATHERECTOMY:

PLAQUE MODIFICATION

Single, small burr
(1.25mm to 1.50mm)

- To smoothen the lumen and disconnect the calcified coronary ring

- To facilitate balloon dilatation and stent implantation

Boston Scientific
Advancing science for life™

PRE-PROCEDURAL RECOMMENDATIONS

GUIDE CATHETER SELECTION

- Single curve with strong support
- Most procedures can be performed with a 6 FR guiding catheter

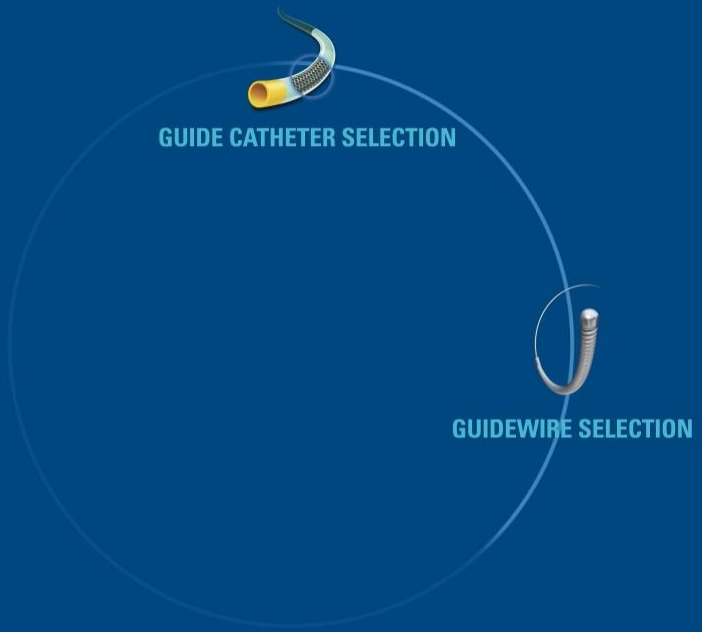
PRE-PROCEDURAL RECOMMENDATIONS

GUIDE CATHETER SELECTION

GUIDEWIRE SELECTION

- Most procedures can be performed with the ROTAWIRE Floppy
- **It is important to shape the ROTAWIRE tip smoothly**

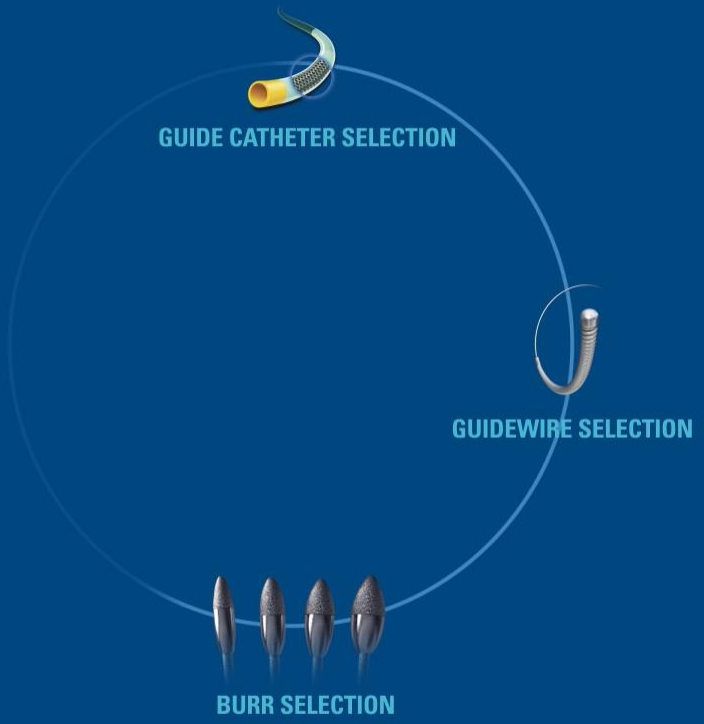
PRE-PROCEDURAL RECOMMENDATIONS



BURR SELECTION

- Single, small burr (1.25 or 1.5mm) works for the majority of lesions
- Consider a **burr-to-artery ratio of 0.6**

PRE-PROCEDURAL RECOMMENDATIONS



PACING CONSIDERATIONS

- Positioning a temporary pacemaker should be considered when treating the right coronary artery or dominant left circumflex

PRE-PROCEDURAL RECOMMENDATIONS

PRE-PROCEDURAL RECOMMENDATIONS

Boston Scientific
Advancing science for life™

PROCEDURAL RECOMMENDATIONS

Boston Scientific
Advancing science for life™

PROCEDURAL RECOMMENDATIONS

180,000

ABLATION SPEED

Between **135,000** and **180,000** rpm

RUN TIME

Short duration: individual runs **< 30 secs**

Boston Scientific
Advancing science for life™

PROCEDURAL RECOMMENDATIONS

ABLATION SPEED

Pecking motion should be used to minimize deceleration

DECELERATION

Should be < **5,000 RPM**

Boston Scientific
Advancing science for life™

PROCEDURAL RECOMMENDATIONS

DOWNSIZING BURR

If the lesion cannot be crossed after several passes

ROTABLATION FLUSH

Cocktail with verapamil, nitrates and heparin in saline

recommended (5 mg/5 mg/5,000 U in 500 ml of saline)

WHEN TO STOP?

Sufficient plaque modification to achieve
optimal balloon dilatation and stent implantation

Boston Scientific
Advancing science for life™

TECHNIQUES TO AVOID COMPLICATIONS

Boston Scientific
Advancing science for life™

TECHNIQUES TO AVOID COMPLICATIONS

SLOW FLOW

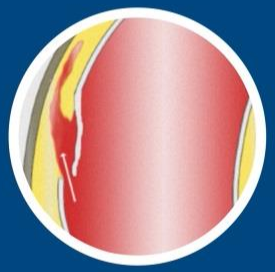
Technique to avoid
- Small burrs and lower speeds
- Be patient between ablation runs

Strategy for resolution
- Optimise BP if low
- Use of flush cocktail

Boston Scientific
Advancing science for life™

TECHNIQUES TO AVOID COMPLICATIONS

DISSECTION



Technique to avoid

- Careful case selection to avoid excessive tortuosity

Strategy for resolution

- Avoid further rotablation if dissection identified
- Dissection management as for any PCI

Boston Scientific
Advancing science for life™

TECHNIQUES TO AVOID COMPLICATIONS

BURR ENTRAPMENT

Technique to avoid

- Rare complication usually avoided with careful case selection and good technique

Strategy for resolution

- Controlled push and pull of rota shaft
- Position 2nd wire to allow balloon placement
- Cautious deep intubation with mother-in-child catheter for more support
- Cardiothoracic surgical resolution occasionally required

Boston Scientific
Advancing science for life™

TECHNIQUES TO AVOID COMPLICATIONS

PERFORATION

Technique to avoid

- Commonly related to poor technique (oversizing of burr, too angulated, inappropriate speed)

Strategy for resolution

- Standard techniques to resolve any perforation including emergency pericardiocentesis and use of covered stents

Boston Scientific
Advancing science for life™

CONCLUSIONS

CONTEMPORARY ROTATIONAL ATHERECTOMY

- Rotablation for **plaque modification** instead of plaque debulking

- The technique of a smaller burr-to-artery ratio and speed between **135,000 & 180,000 rpm** has been improving outcomes and reducing complications