New Technologies for Bifurcation: Main Vessel Centric vs Side Branch Centric

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Conflict of Interest

Scientific Advisory Board to

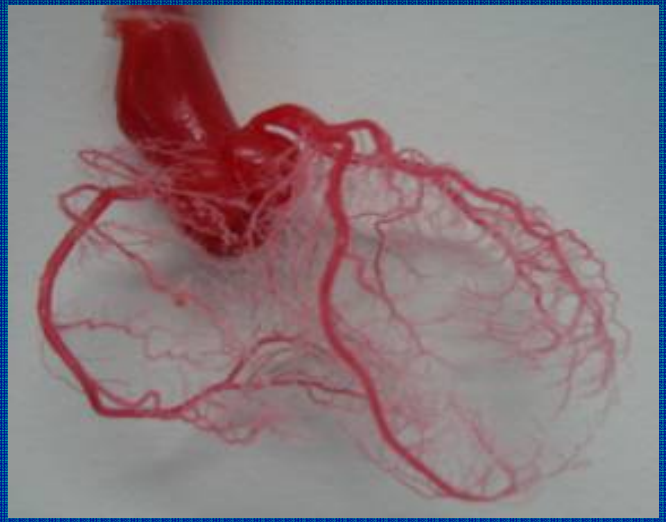
- **Abbott Vascular**
- **Boston Scientific Corpoaration**
- **Cordis**
- **Medtronic**

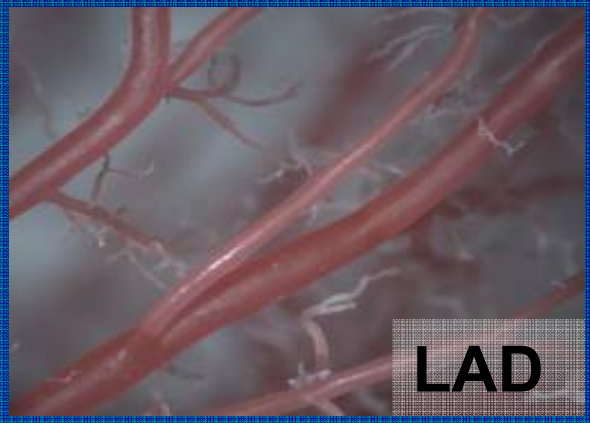
Stents are not designed for bifurcations

Does this damage pre-dispose to stent thrombosis?

3 Dimensional Casts of Coronary Tree (Aorta to terminal branches (<1mm)

- Angle
- Branching
- Curvature
- Tortuosity
- Lesions Ecc.
- Intersections





Summary

Bifurcation diameters ~ to previous findings

MV: Wide Range (1.7 to 4.2),

proximal mean= 2.86

distal mean= 2.39

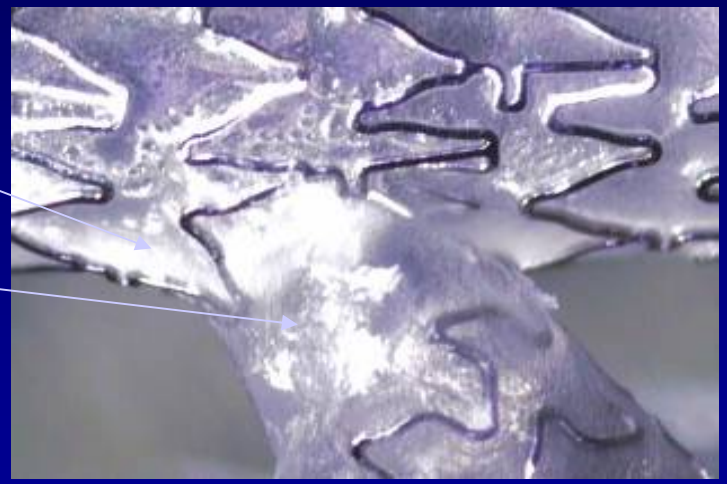
SB: Wide Range (1.6 to 2.6), mean 2.28

Four types of Asymmetric Ostial Geometry:

- **Multifaceted transition (high magnification detail)**
- **Oval rather than round ostium**
- **SB Taper 3-fold greater than MB**
- **Side branch take off angles**
  - **Proximal (obtuse)**
  - **Distal (acute)**

Conclusions
Distorted stent or Distorted anatomy

- Complex transition zone from the main vessel to the side branch with many asymmetric features
- Anatomic distortion likely with symmetric (cylindrical) designs
  - Strut protrusion/injury
  - Gaps
  - Incomplete wall apposition



- Matching design to asymmetric ostial geometry may minimize implant injury, enhance scaffolding and improve outcomes

Bifurcated Stent Approaches

Twin-Rail (by Invatec)

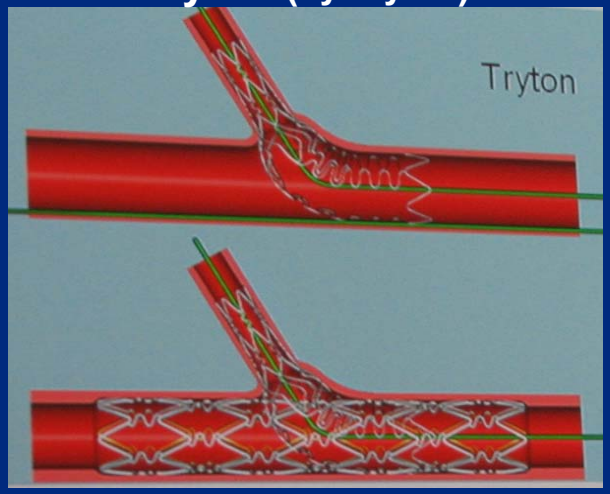
Stentys (by Stentys)

Petal (by Boston)

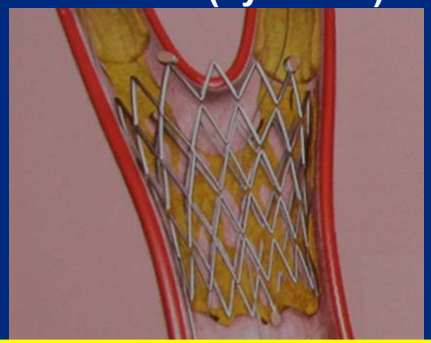
Frontier (by Abbott)

Sideguard (by Cappella)

Tryton (by Tryton)

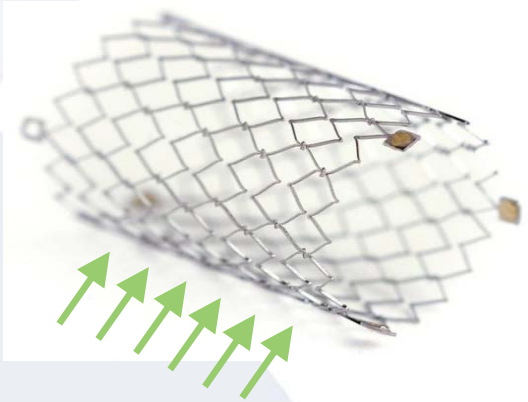


Axxess (by Devax)

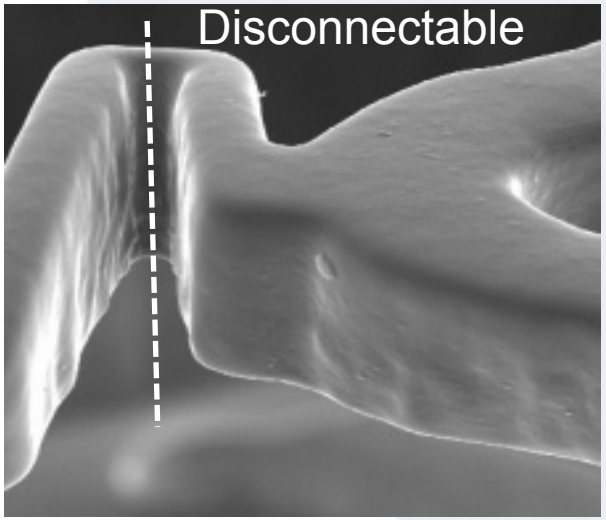


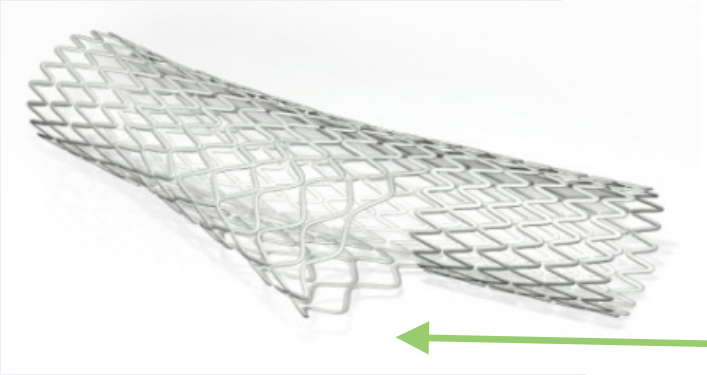
Antares™ (by TriReme)

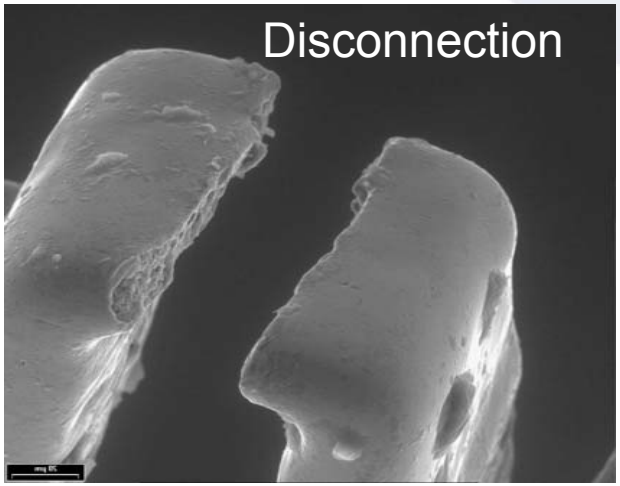
Technology



Opening possible at any level : initial positioning irrelevant to procedure success.

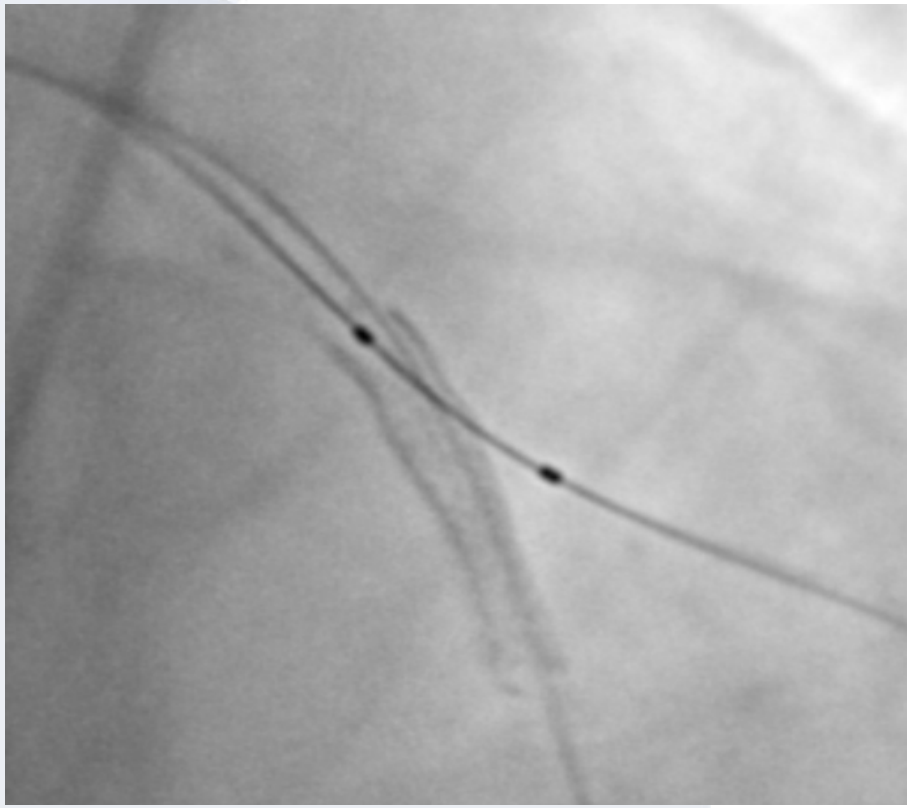


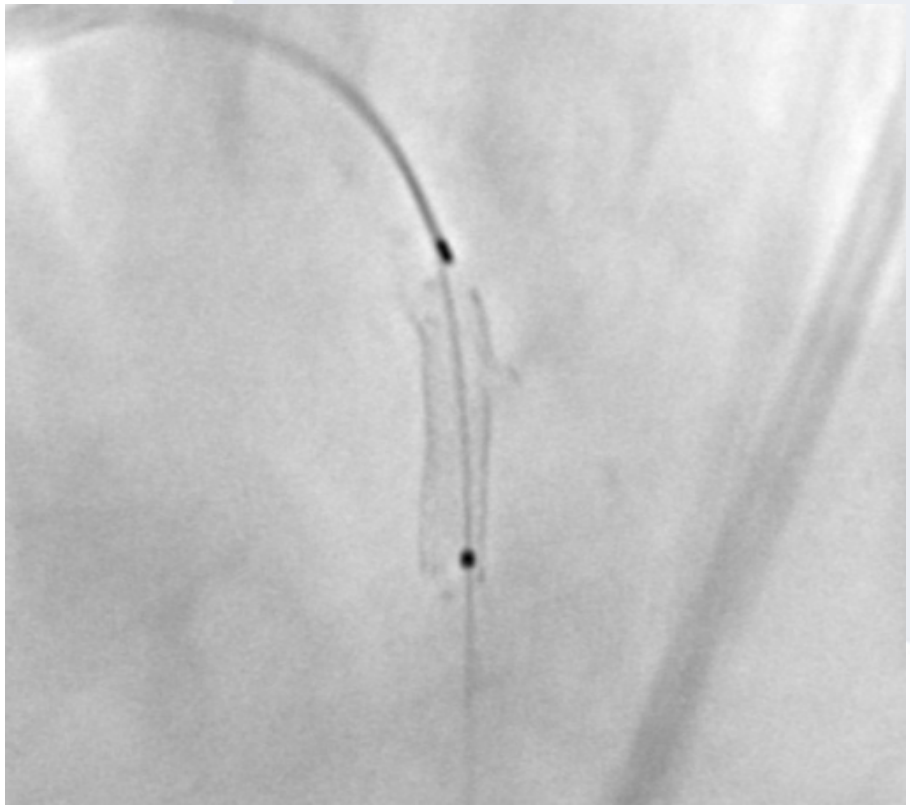




stentys
Simple Stent Solutions

Stent Boost





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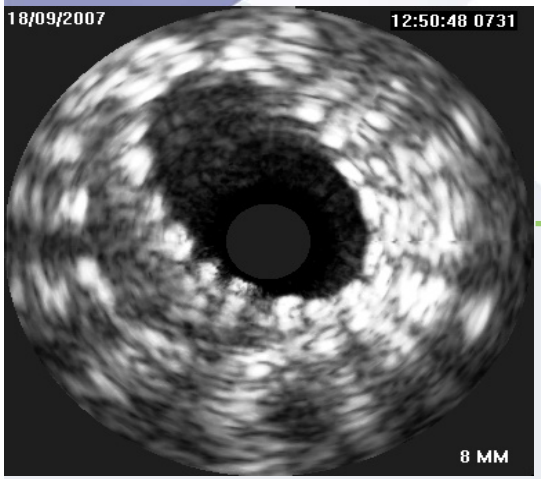
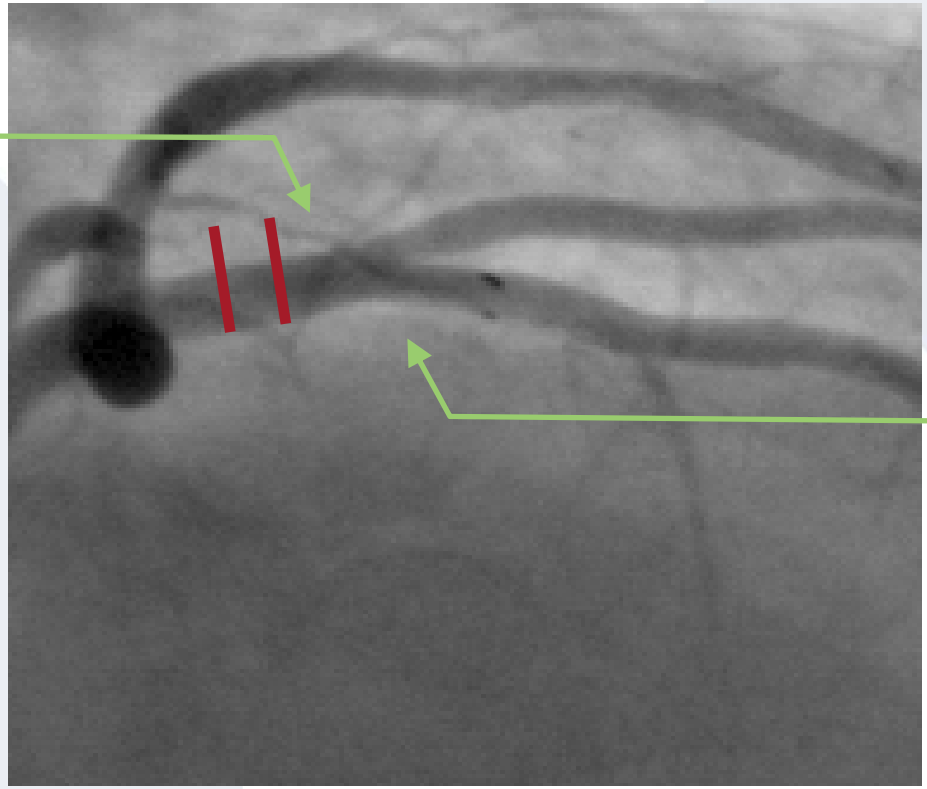
IVUS





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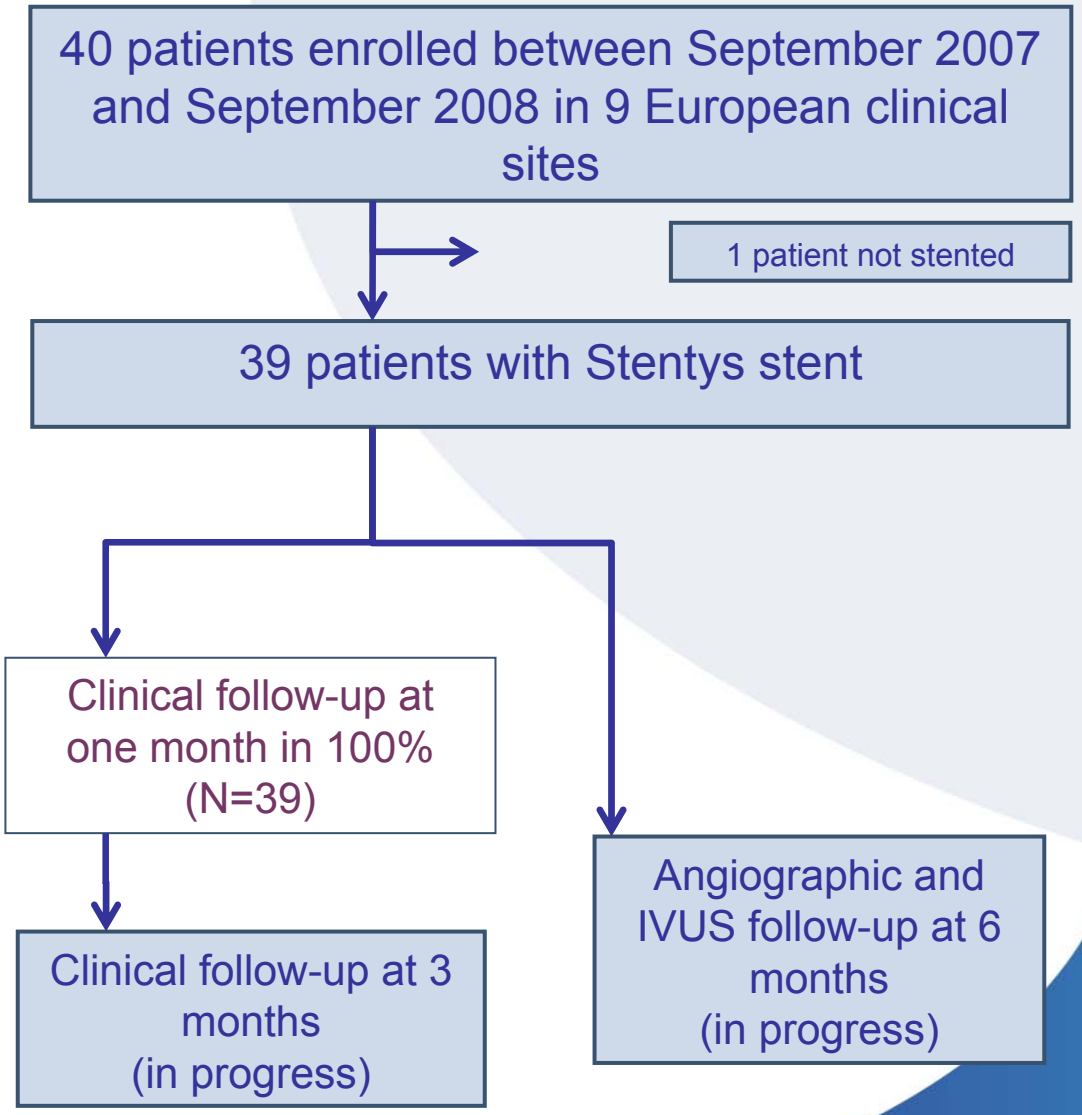
Simple Stent Solutions

OPEN I Study Design

Design

- DESIGN: Prospective, non-randomized, single-arm, multi-center study
- OBJECTIVE: To evaluate the safety and feasibility in bifurcated coronary lesions
- Endpoints:
  - Procedural success
  - MACE @ discharge & 30 days
- Events adjudicated by CEC
- Independent monitoring: MedPass
- Core Lab: Cardialysis



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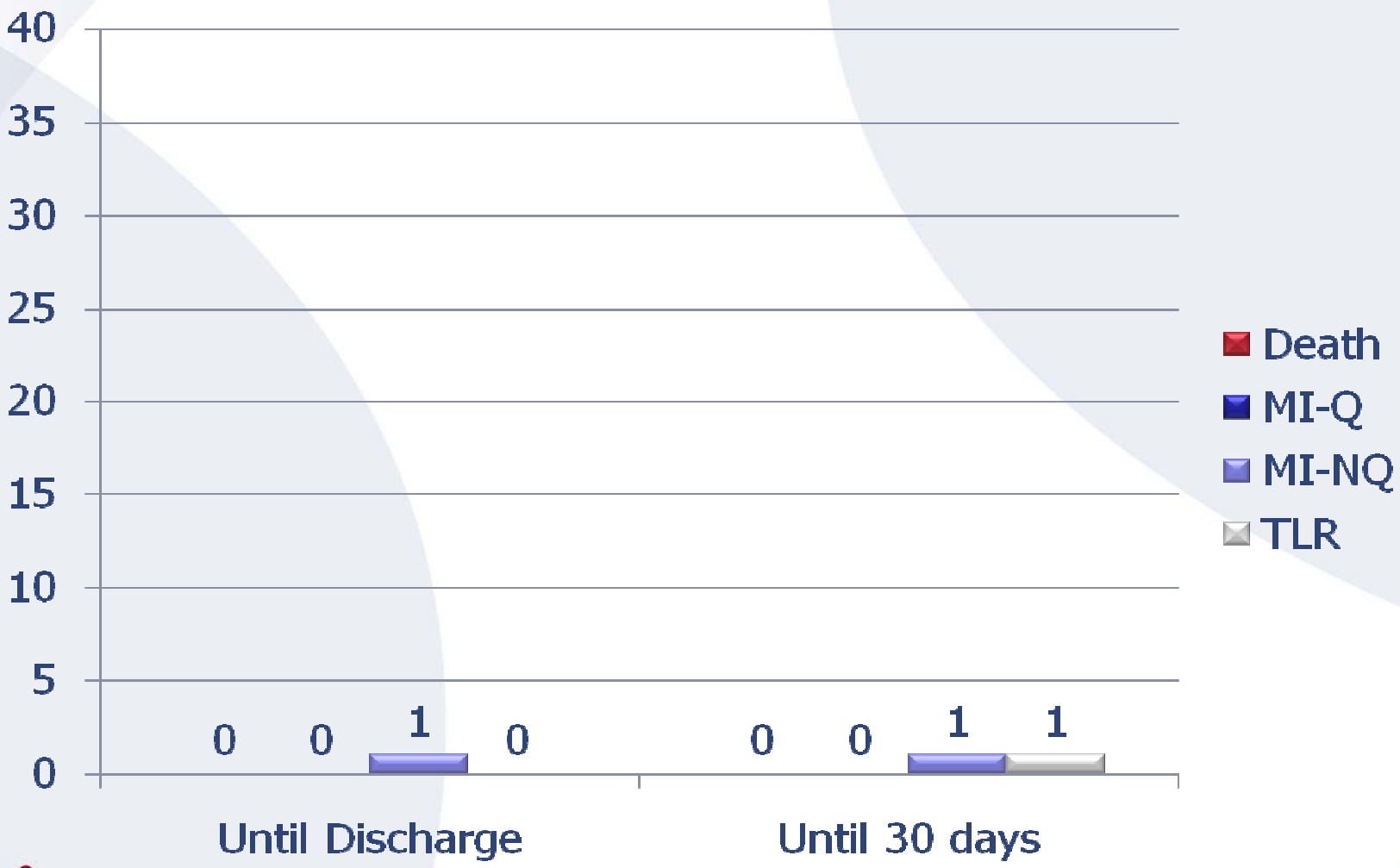
Cumulative adverse events



stentys
Simple Stent Solutions

Main Vessel Centric-Stentys

Advantages

- Single wire delivery
- Self expanding
- Open to SB at any level
- Preserve elliptical geometry to MB and SB

Disadvantages

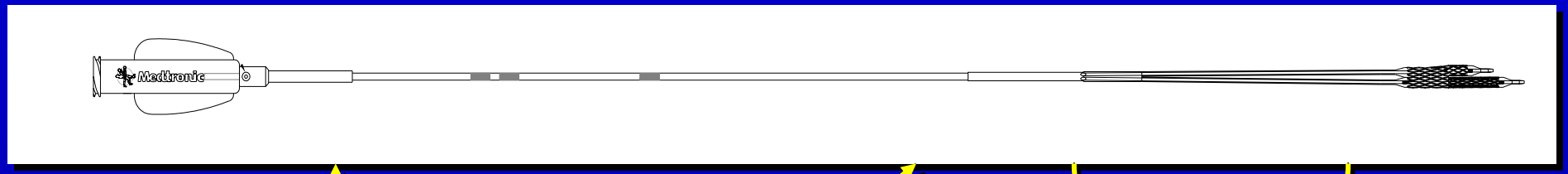
- Self expanding
- Only cover SB on one side of carina

MDT BRANCH Bifurcation Stent
Main Features

- **Stent - Driver platform**
  - Three stents optimally welded to accommodate multiple bifurcation angles
- **Delivery System - Endeavor Sprint technology**
  - Dual Rapid Exchange
  - Simultaneous inflation / deflation
  - Tapered side-branch balloon
  - Carina marker band to aids placement of side branch stent

SB (mm)	DMB (mm)	PMV (mm)	Nom. (atm)	RBP (atm)
2.5	3.5	4.3	9	16
2.5	3.0	3.8	9	16

MDT Branch Bifurcation Stent Design

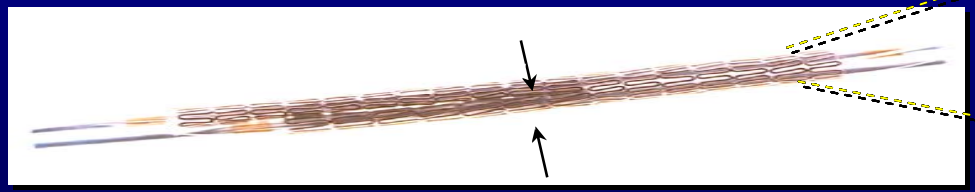


Single inflation/deflation lumen

Dual guidewire exit ports

Independent lumens ~ 20cm

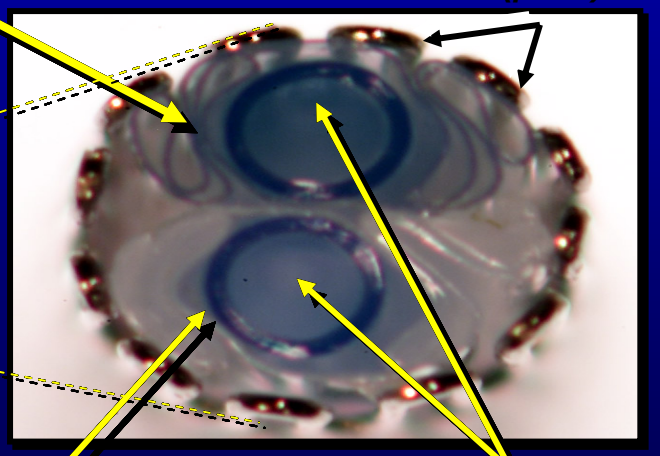
Stent & 2 balloons



7F Guiding Catheter Compatible

Side branch balloon folds

Stent (prox.)



Main branch balloon folds

Guidewire Lumens

BRANCH Study Design

Single *De Novo* Bifurcation Lesions in Native Coronary Arteries with RVDs of
- Proximal Main Vessel: 3.8-4.3 mm
- Distal Main Branch: 3.0-3.5 mm
- Side Branch up to 2.5 mm

Pre-dilatation required; Plavix ≥ 30 Days

Bifurcation Stent System

60 patients ~7 sites

Primary Endpoint: A composite of cardiac death, target vessel myocardial infarction (MI) and clinically driven target vessel revascularization (TVR)

Secondary Endpoints:

1. Acute success (device, lesion, procedure)
2. Total fluoroscopy time
3. Total volume of contrast used
4. Total index PCI procedure time
5. Composite of cardiac death, target vessel MI and clinically driven TVR @ 6, 9 and 12 mo
6. TLR rate at 9 months

Main Vessel Centric-MDT

Advantages

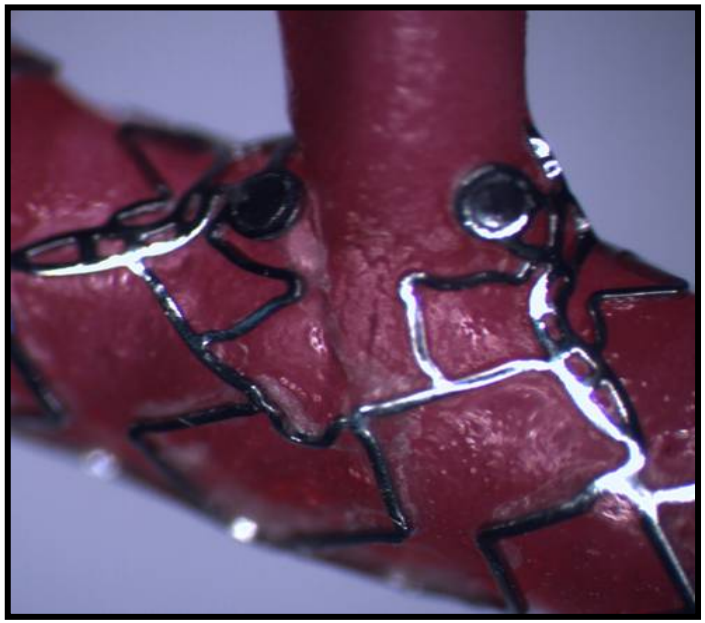
- Good and complete coverage of MB and SB
- No overlapping struts
- All angles of take-off
- Easy to re-cross to add lengths

Disadvantages

- Profile, turning and wire wrap
- Size metric limited
- Alignment issues
- Not-DES

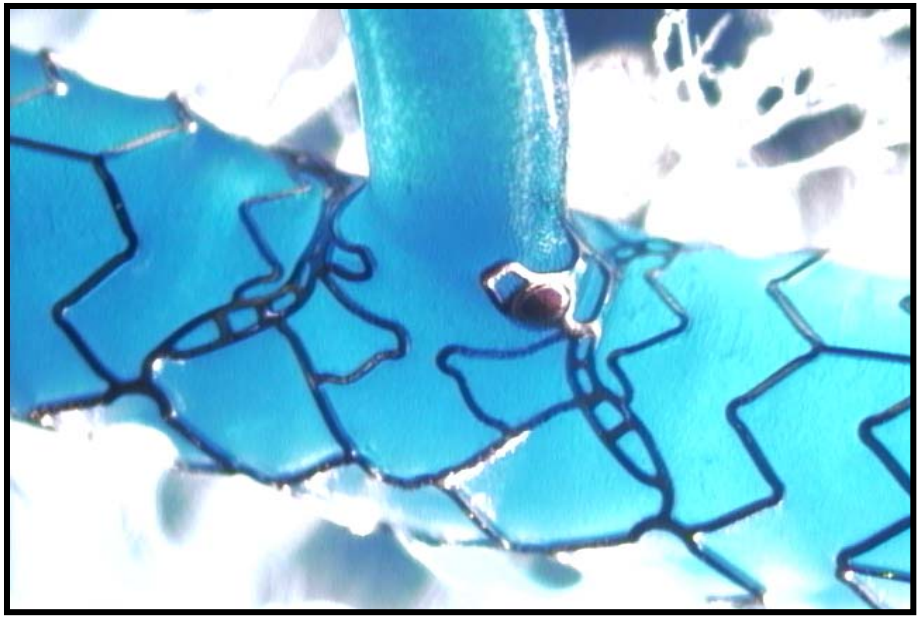
Antares™ – Polymer Model

Automatic deployment of ostial crown upon expansion of main stent body – single balloon is use



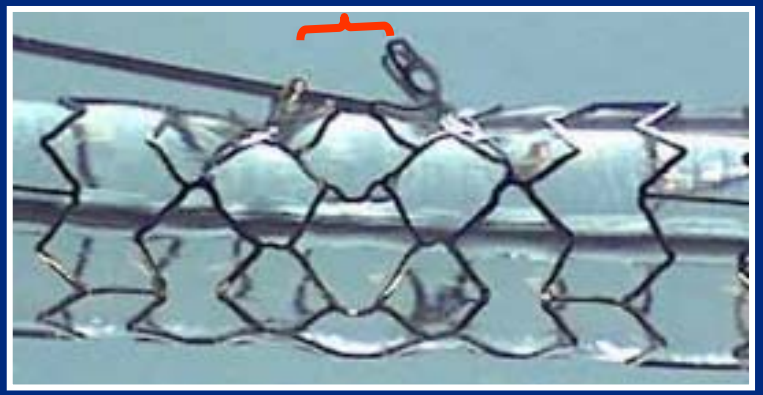
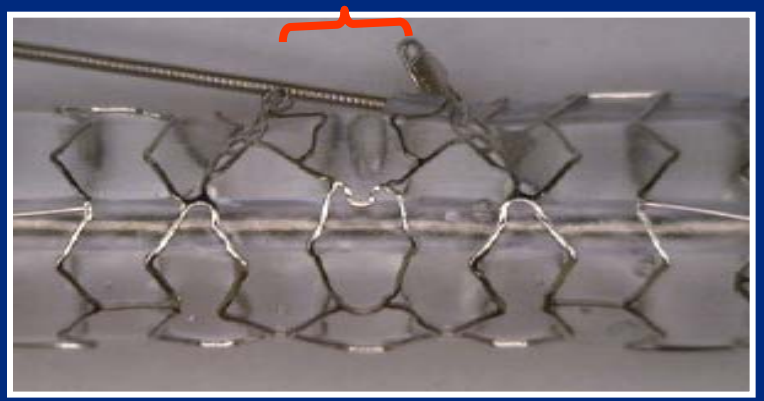
Ostial Locators:

- improves alignment
- provide structural support
- improves apposition
- minimize injury



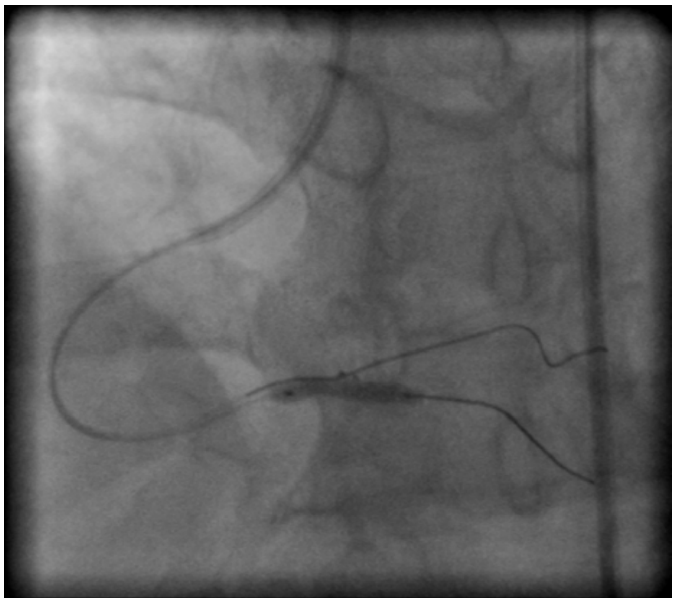
2/12/08 Stanford, A. Yeung
Antares™ II, Cx

From Antares™ II to Antares™ SX

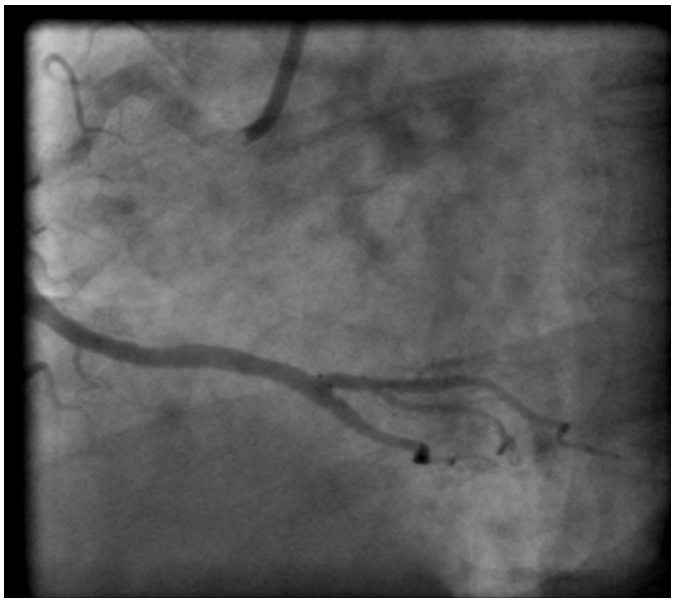
	Prior Generation: Antares™ II	Current Generation: Antares™ SX (CE mark approved)
Stent	 Ostial opening for access Connectors	 Expanded ostial opening for bigger branches Connectors removed for flexibility & crossing
Delivery System	Single balloon to decrease profile	More predictable torque
Markers	2 radiopaque proximal markers	Thicker markers improved radio-opacity
Side Wire	0.012”	0.014” supports positioning & re-crossing Longer coil on wire for smoother tracking

FIM Experience

Pre-procedure



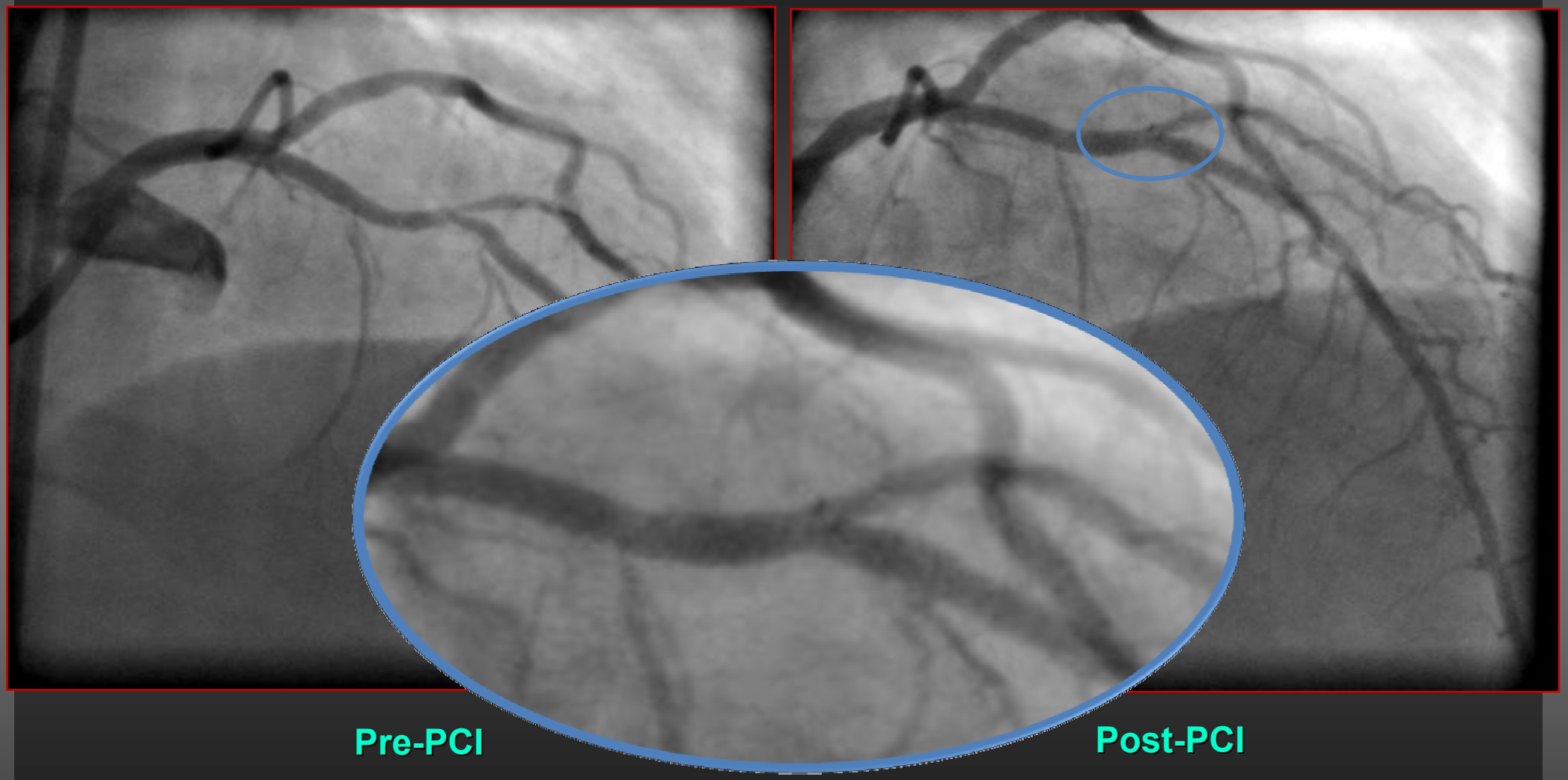
Deployment



Final result

Successful deployment of Antares™ stent in RCA case, Sao Paulo, Brazil

Antares stenting, SB PTCA



Pre-PCI

Post-PCI

TOP Study (TMI Ostial Preservation)

- **Goal:** Acute performance & device optimization
- **Multi-center, single arm study**
- **Up to 100 patients**
  - **45 enrolled/ 7 centers as of Oct.1, 2008**
- **Primary Endpoint: Acute procedural success**
- **Side branch treatment operator discretion**
  - **If stent, protocol mandated TAXUS liberte**

Enrollment on going – status update

Main Vessel Centric-TMI

Advantages

- Self lifting SB struts
- No wire wrap issues
- Markers to align the SB struts

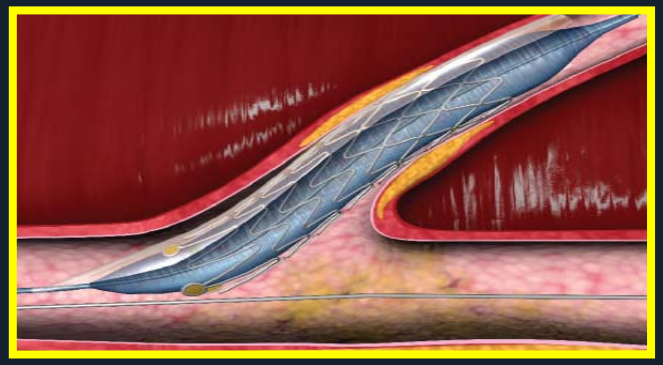
Disadvantages

- Minimal SB coverage
- Need to wire the SB using a wire under the stent
- Need to torque the system

Sideguard Ostium Protection Device

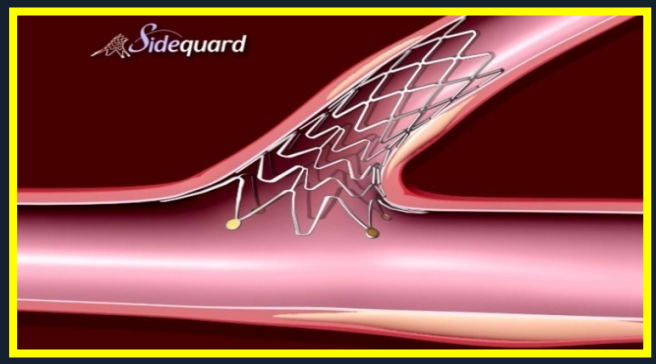
Sideguard address the complexities associated with ostial and bifurcated lesions

Precise BE Delivery System



Peel-away Split Sheath, Balloon Expandable Delivery

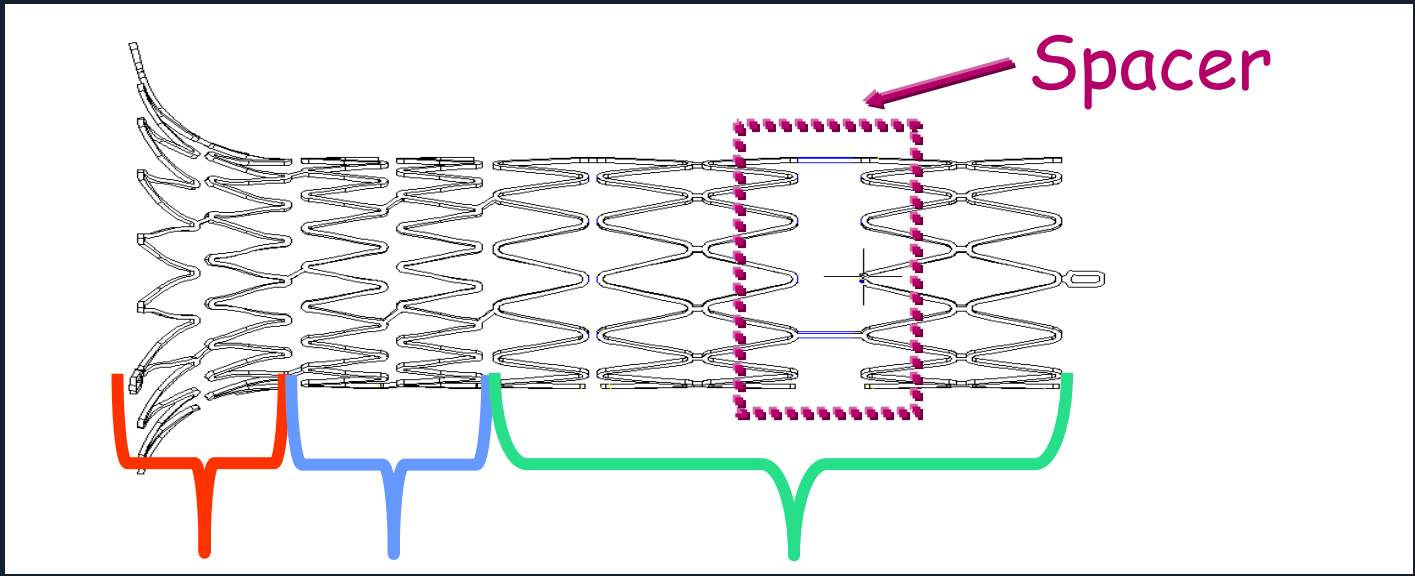
Bare Metal Sideguard OPD



Anatomically-shaped, Self-Expanding (SE) Stent

- **Sideguard is a self-expanding, anatomically-shaped stent**
- **Target™ Catheter is a balloon-release delivery system for SE stents**

Cappella Sideguard OPD



Cup

- Flared end, conforms to ostium of side branch
- Excellent ostial coverage & Protection

Gimbal

- Provides expanding force to open the side branch
- Transition zone between cup and anchor

Anchor

- “Spacer” region to improve anchoring keeping stent from migrating
- Enhances crossing flexibility

Sideguard I and II

QCA @ 6 mos

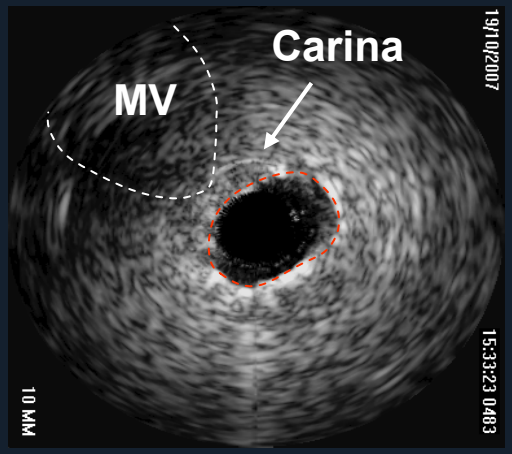
	MV (50 pts)	SB (47 pts)
MLD (mm)		
In-stent	2.59 ± 0.50	1.83 ± 0.53
In-segment	2.20 ± 0.46	1.69 ± 0.49
% DS		
In-stent	14.00 ± 14.34	18.60 ± 21.06
In-segment	27.44 ± 14.75	26.93 ± 18.06
Late Loss (mm)		
In-stent	0.28 ± 0.50	0.38 ± 0.50
In-segment	0.23 ± 0.60	0.38 ± 0.50
Binary Restenosis		
In-stent	4.0% (2/50)	6.4% (3/47)
In-segment	8.0% (4/50)	8.5% (4/47)

Sideguard I and II

IVUS Substudy (11 pts)

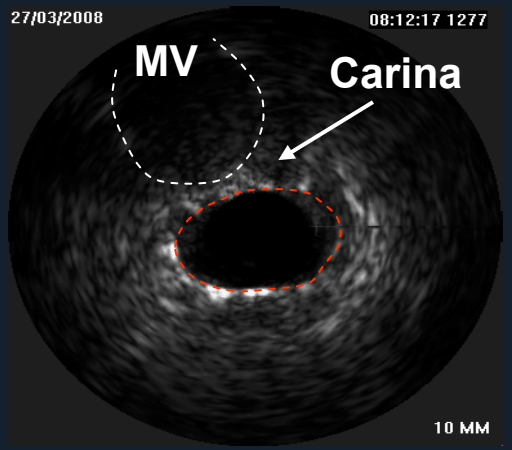
Case in Group A

Post-intervention



Stent area=4.4 mm²
Lumen area=4.4 mm²

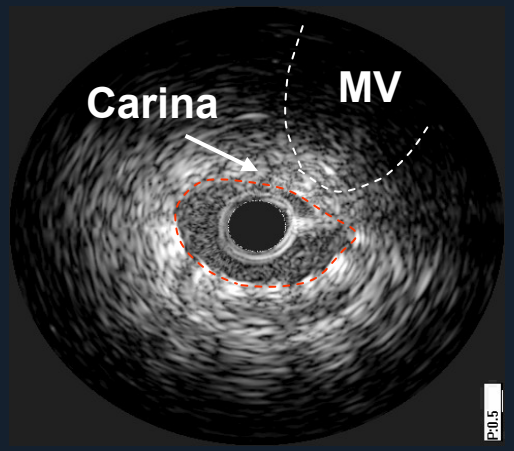
Follow-up



Stent area=5.7 mm²
Lumen area=5.7 mm²
IH area=0.0 mm²
ΔStent area=1.3 mm²
ΔLumen area=1.3 mm²

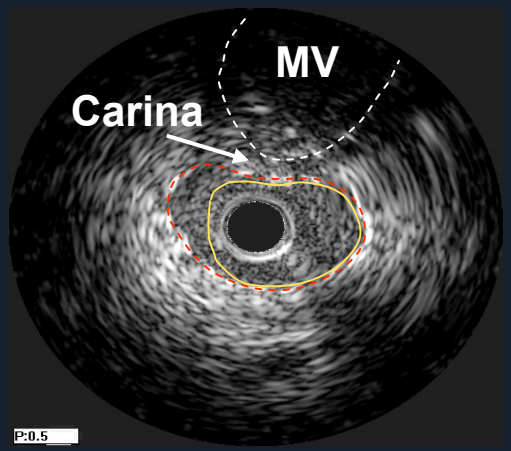
Case in Group B

Post-intervention



Stent area=3.9 mm²
Lumen area=3.9 mm²

Follow-up



Stent area=5.1 mm²
Lumen area=3.9 mm²
IH area=1.2 mm²
ΔStent area=1.2 mm²
ΔLumen area=0.0 mm²

CARDIOVASCULAR RESEARCH FOUNDATION

Hiroshi Doi, Akiko Maehara, Gary S. Mintz

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian
The University Hospital of Columbia and Cornell

Side Branch Centric-Cappella

Advantages

- Treat side branch first
- Similar to T-stenting
- Self expanding
- Preserve elliptical anatomy

Disadvantages

- Overlapping struts in the MV near ostium
- Self expanding
- May need to re-open MV stent struts

Tryton Side Branch Stent

Side Branch Region

Standard Design

Transition Zone

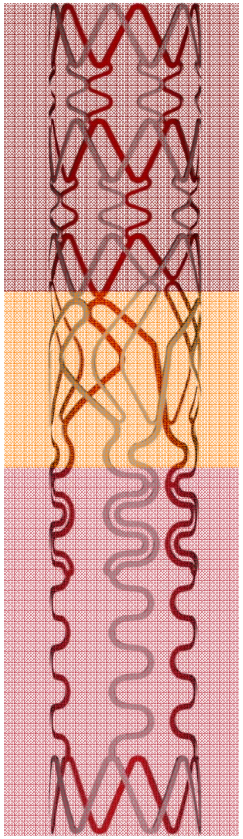
Coverage

Hoop Strength

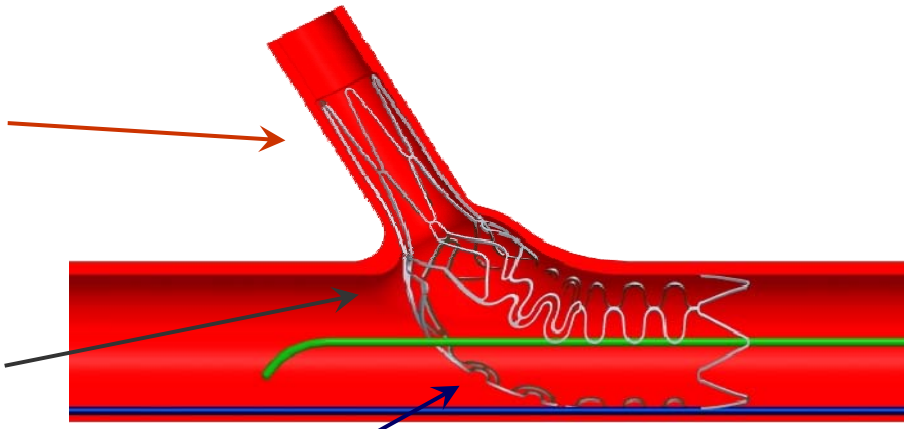
Main Vessel Region

3 Fronds - Minimal Coverage

Wedding Band



Side Branch



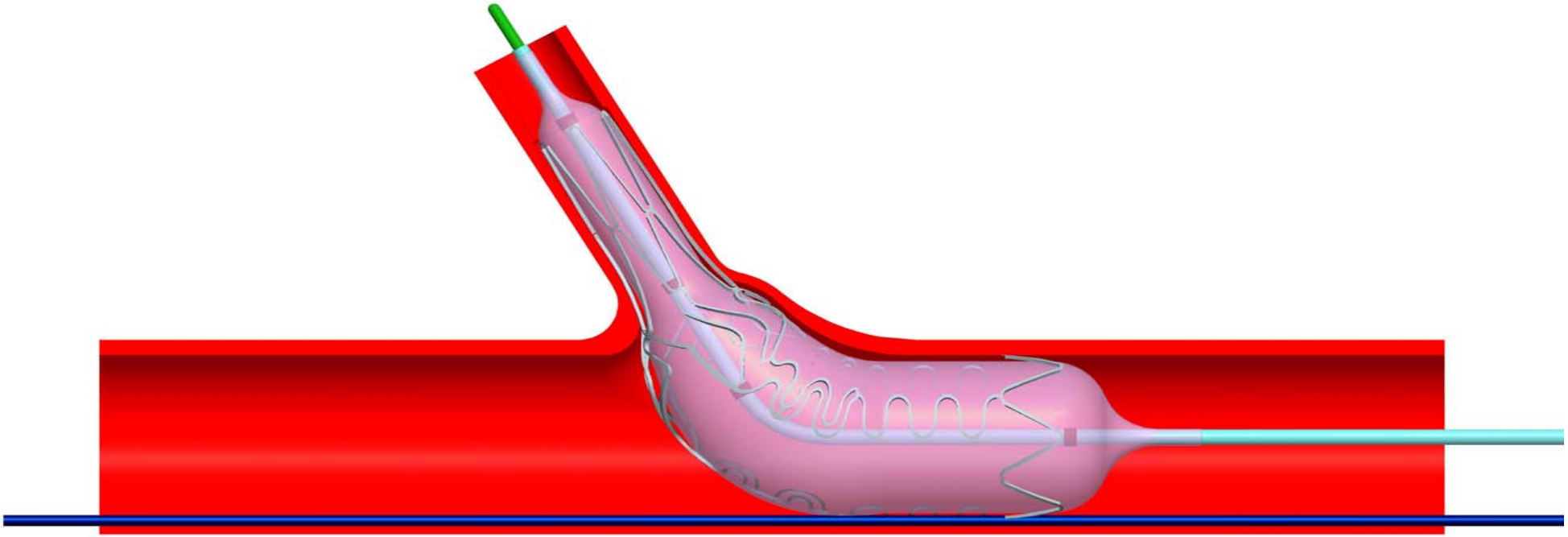
Main Vessel

Cobalt Chromium

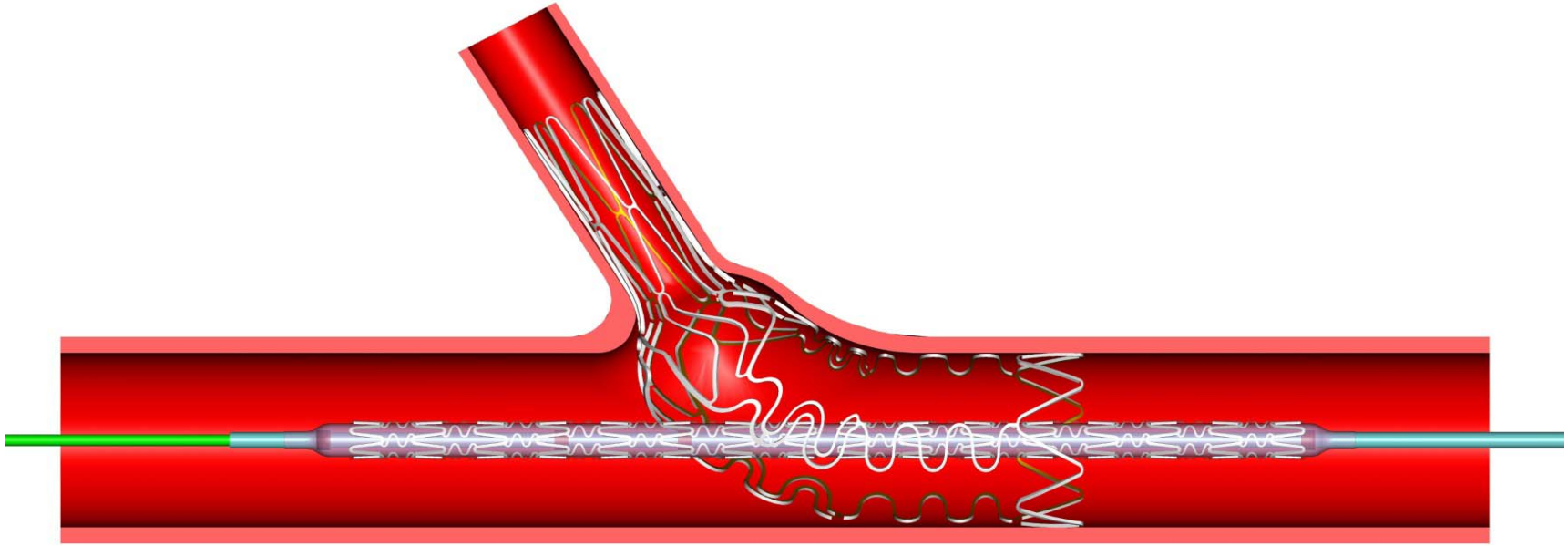
Strut Thickness: 0.003”

Diameter: 2.5 mm

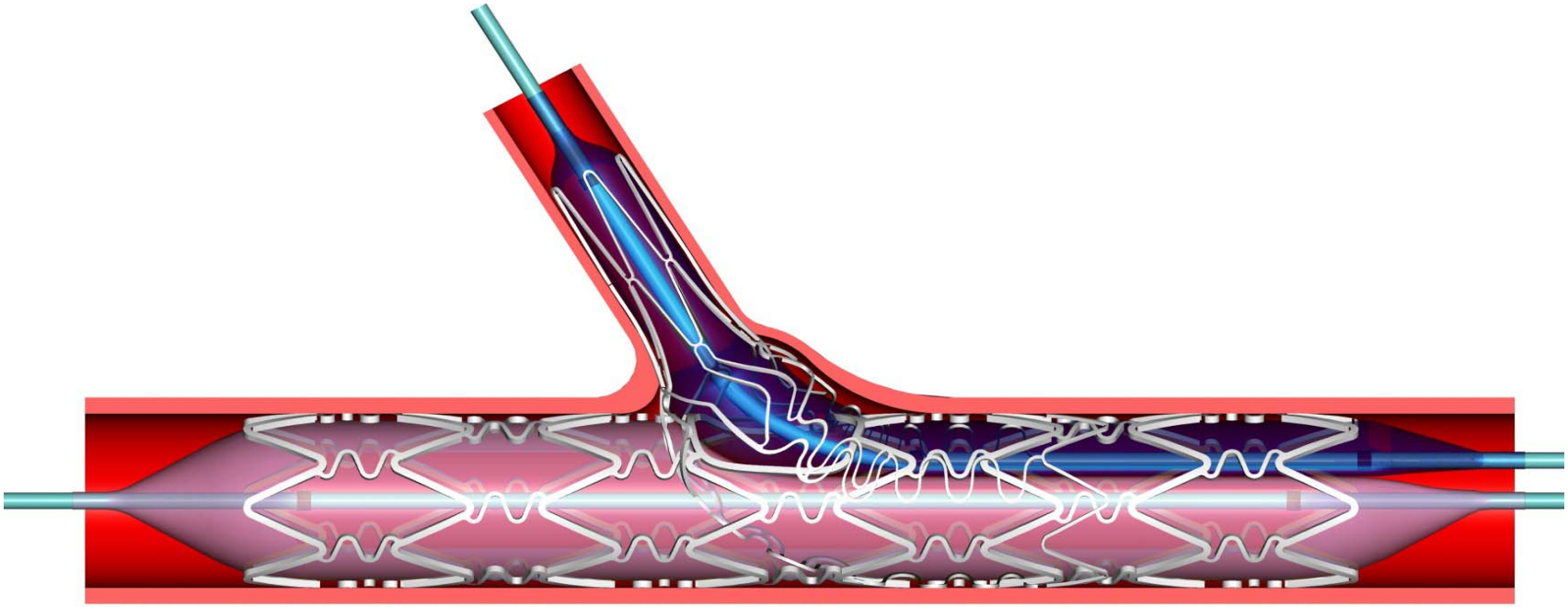
2. Deploy Side Branch Stent



4. Position Main Vessel Stent

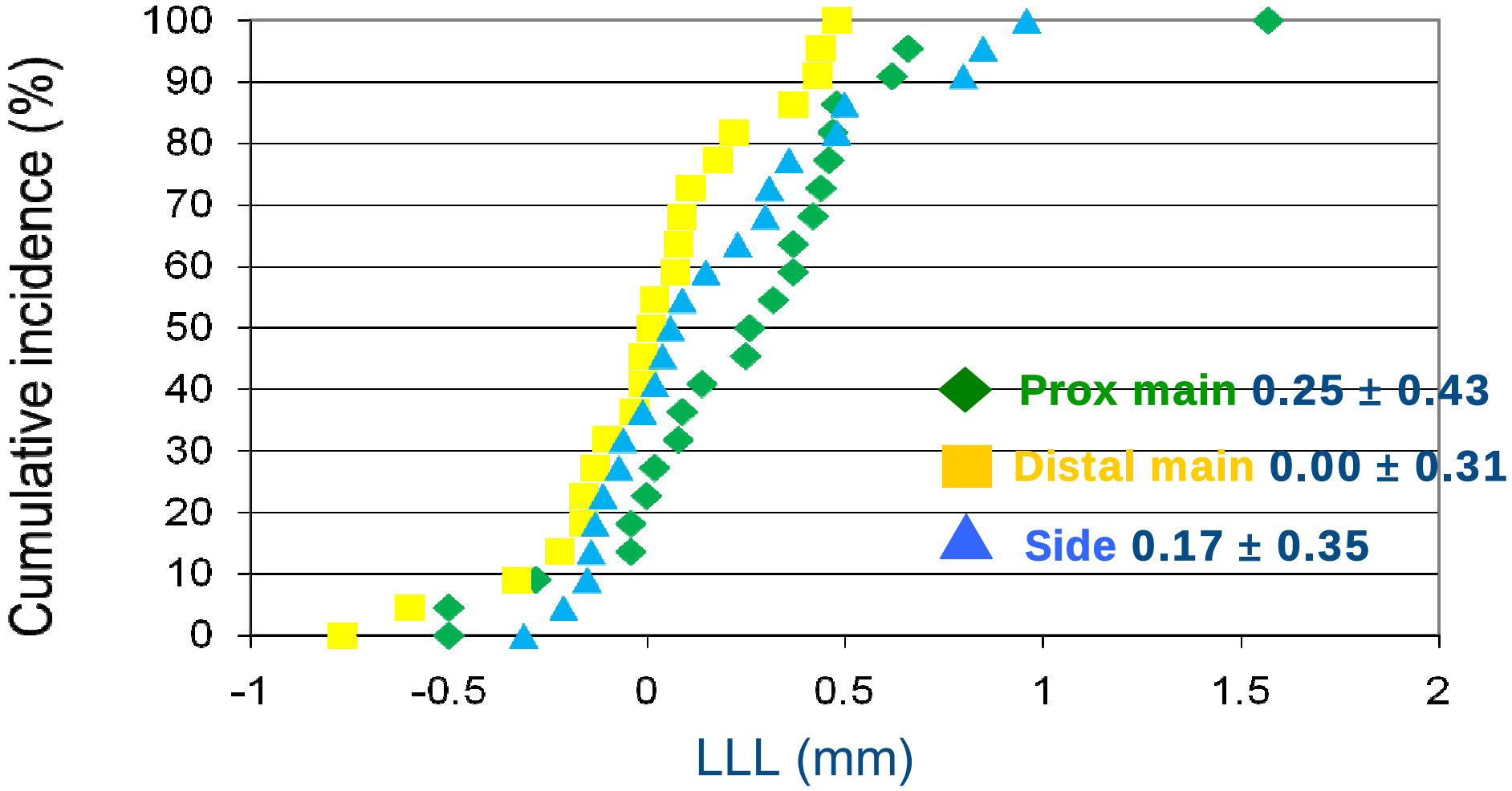


6. Post-Dilate Side Branch



Tryton Side Branch Stent

FIM - Cumulative Late Loss



Eurointerv 2008;3:546-552

Side Branch Centric-Tryton

Advantages

- Treat side branch first
- Coverage of all zones
- Similar to T-stenting

Disadvantages

- Overlapping struts in the MV
- Need to re-open MV stent struts

Dedicated Bifurcation Stents

	Main Vessel Centric	Side-Branch Centric
DES Program	Not yet	Mainly No
Side Branch Angle	Yes	No
Wire Wrap/Device to turn	Yes	No
Overlap Struts (M/S)	Side (if new stent is needed)	Main (100%)
New Carina	Y (Devax)	N
Predetermined Ostial Geometry	Y	N
Accuracy	Fair	Excellent