The Spectrum of Dedicated Stents for Bifurcation Lesions: Current Status and Future Projections

Martin B. Leon, MD

Columbia University Medical Center
Cardiovascular Research Foundation
New York City

Angioplasty Summit TCT Asia-Pacific 2007
April 25-27, 2007; Seoul, Korea

Presenter Disclosure Information for Angioplasty Summit 2007

Martin B. Leon, M.D.

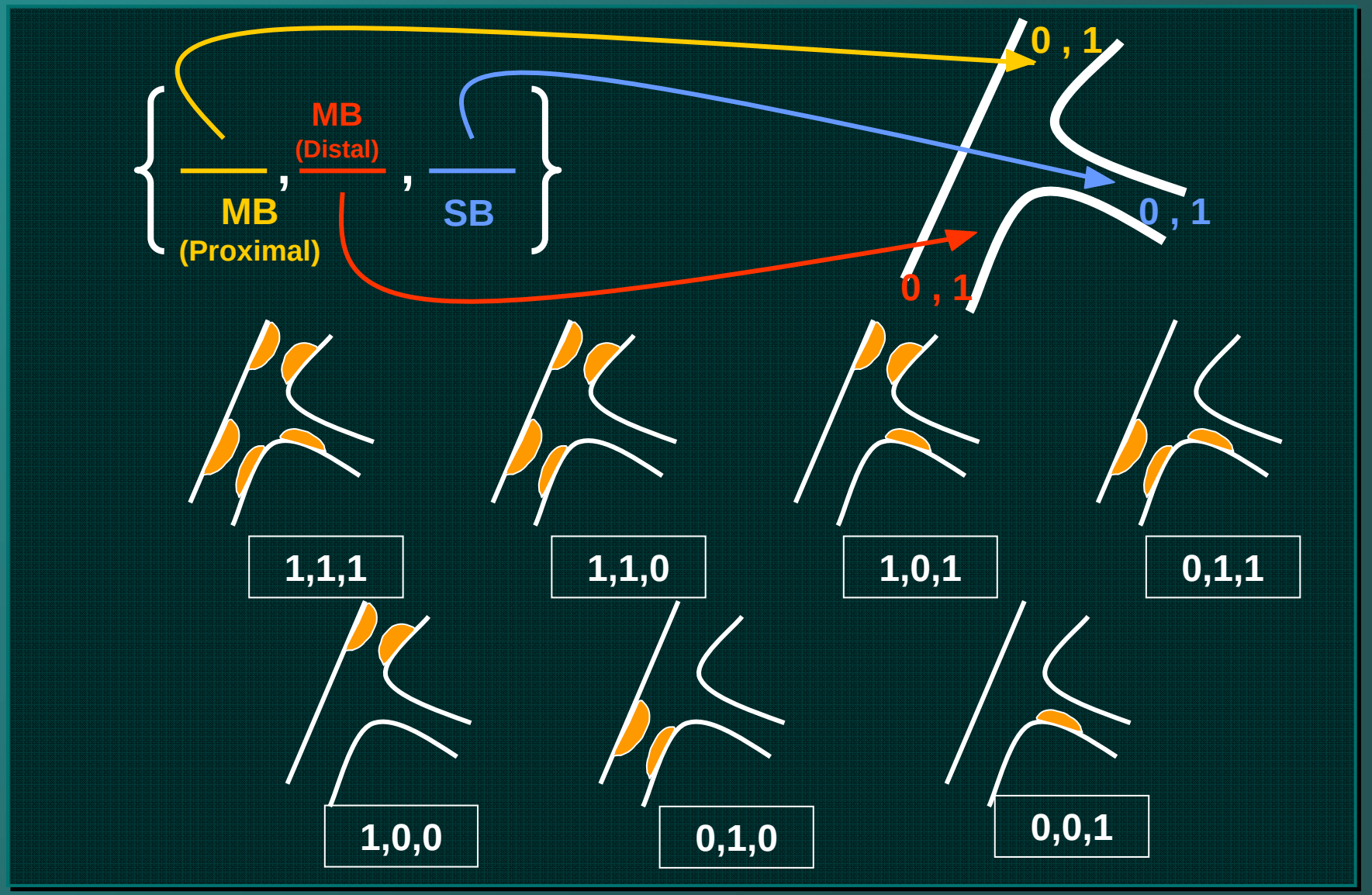
Consultant or Advisory Board:
BSC, Cordis-JNJ, Medtronic, Abbott, Cappella, Tryton, TMI

Stockholder or other Equity:
Cappella, TMI

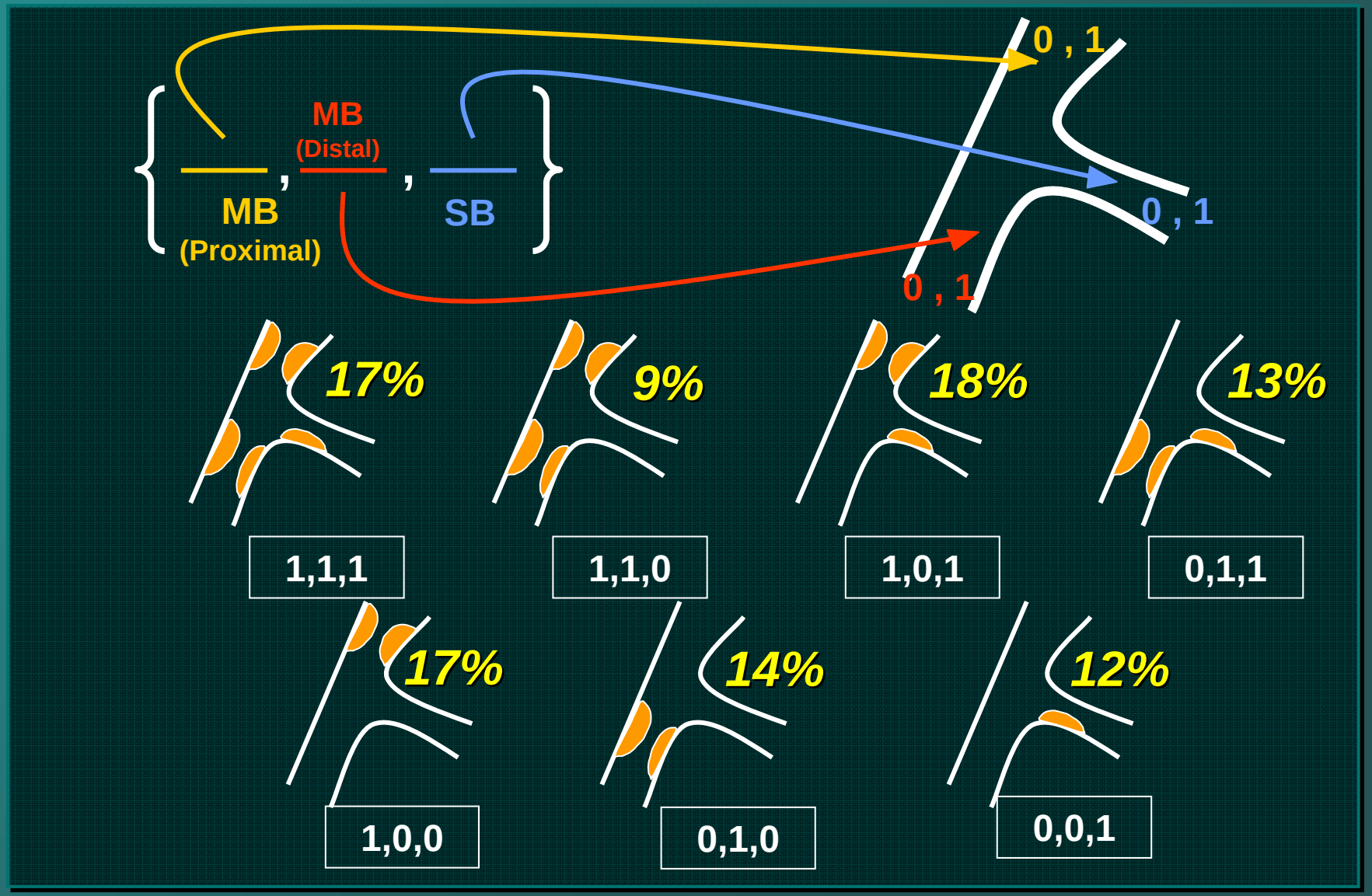
Dedicated Bifurcation Stents

Classification and Clinical Trends

Medina Bifurcation Classification



Medina Bifurcation Classification



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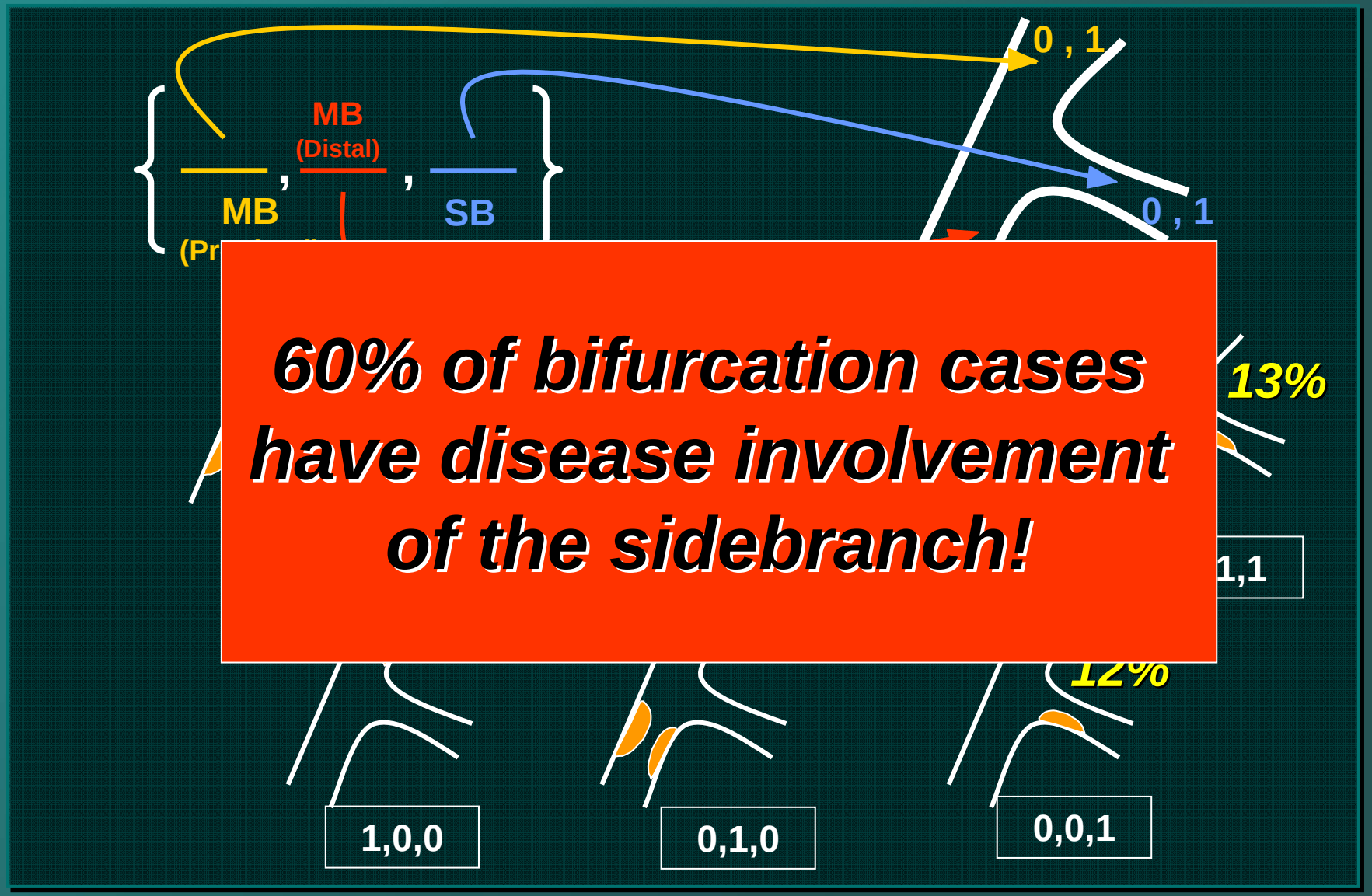
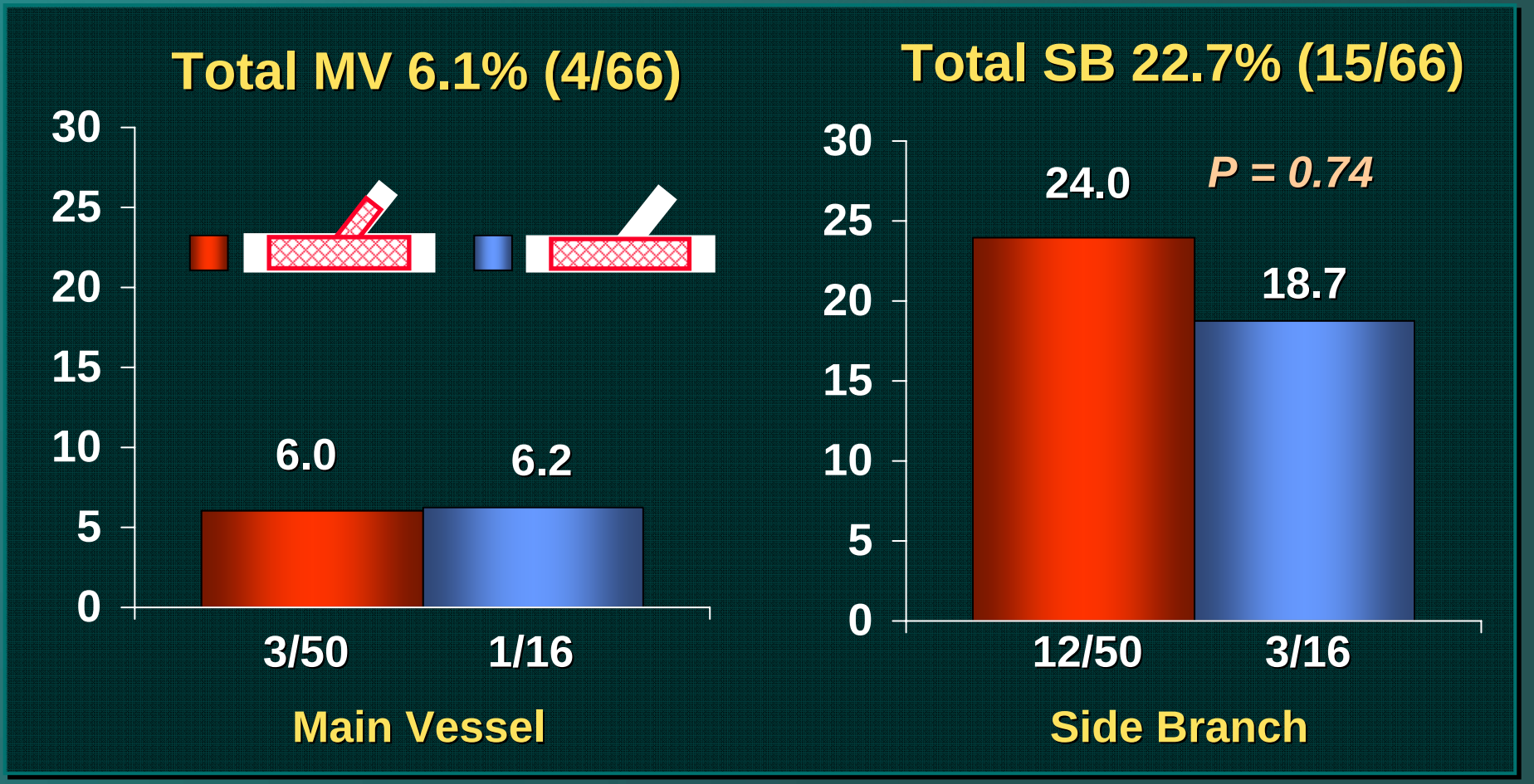


60% of bifurcation cases have disease involvement of the sidebranch!

SIRIUS Bifurcation Study

In-lesion Restenosis (treatment received); 78% FU

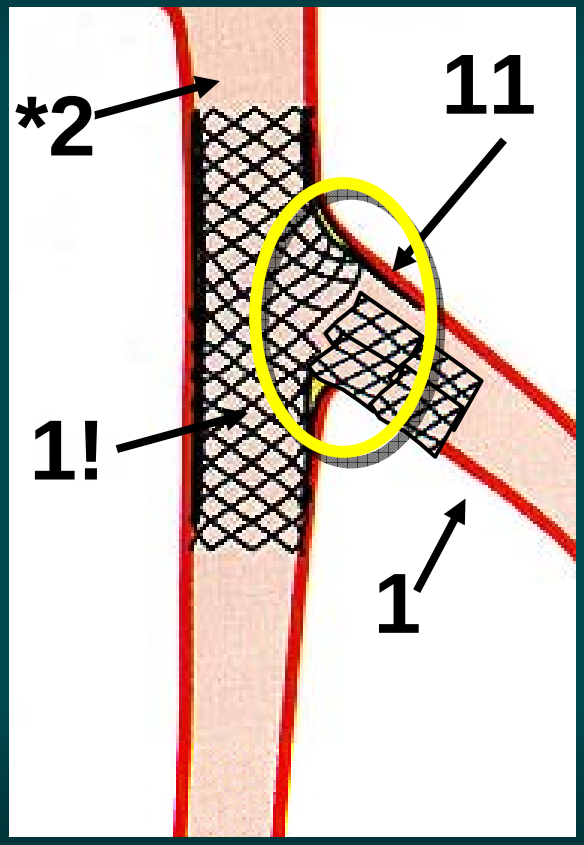
Total Restenosis (MV and/or SB) 25.7% (17/66)



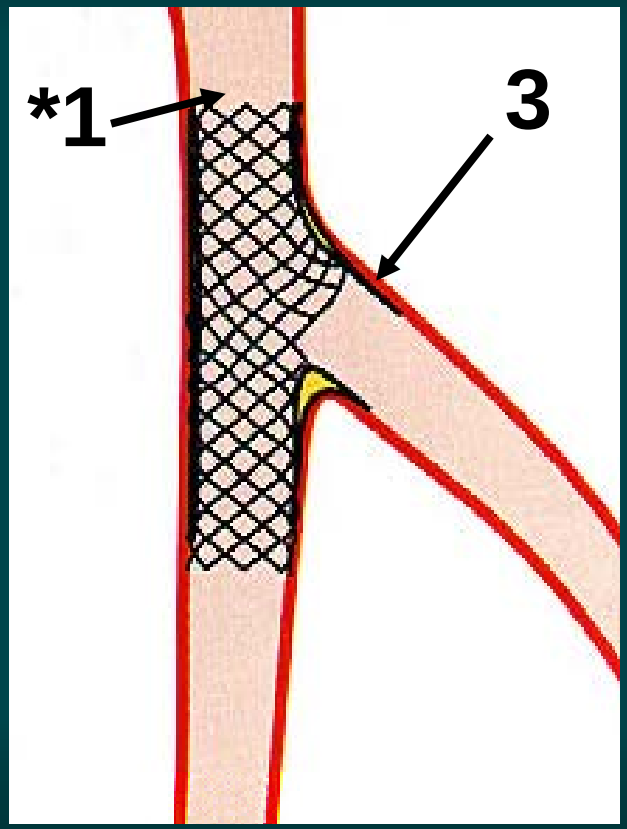
SIRIUS Bifurcation Study

Restenosis Site (17 cases)

Stent + Stent



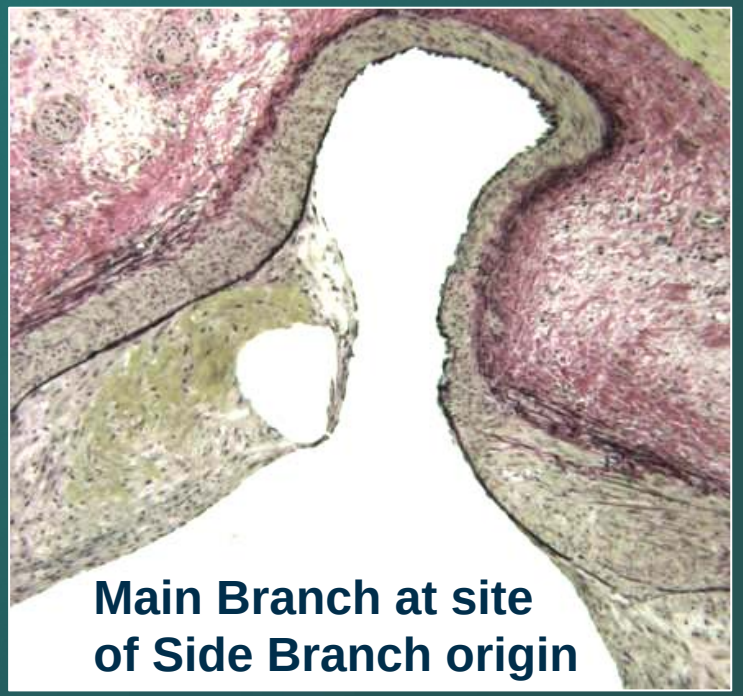
Stent + PTCA

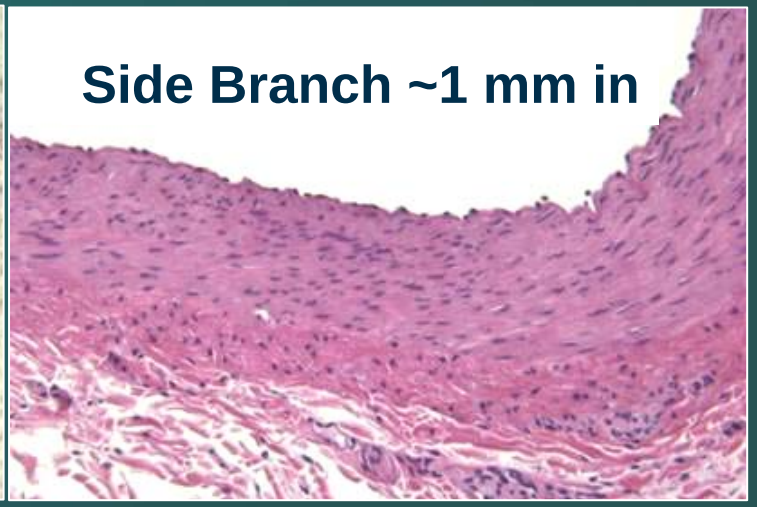


DES (Cypher) drug effects in side branches 30 days after implant (porcine coronaries)

Courtesy of:
AR Groothuis, ER Edelman, P Seifert, J Dooley, and C Rogers

CBSET and Cordis Corporation





NORDIC Bifurcation Trial (SES)

Study Design

413 patients with bifurcation lesions
(LMCA, LAD. LCx, or RCA)

Stenting of both the main vessel and side branch (MV+SB) n=206 pts	Stenting of the main vessel and optional stenting of the side branch (MV only) n=207 pts
(95.1% SB stent)	*(4.3% SB stent)*

- **Primary Endpoint: Major adverse cardiac event (MACE) at 6 months, defined as cardiac death, myocardial infarction (MI), target lesion revascularization (TLR) or stent thrombosis of the index lesion**

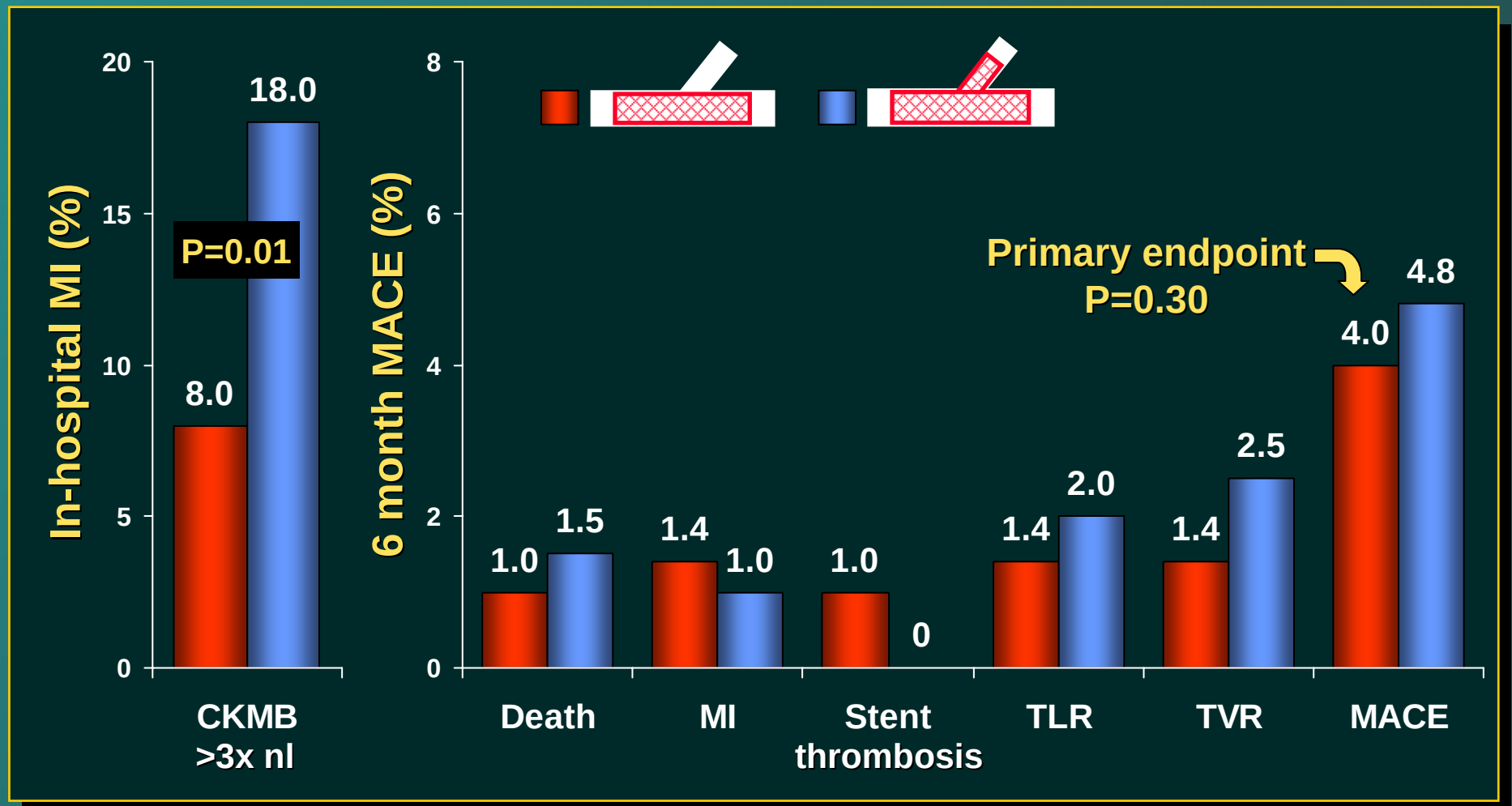
Nordic Bifurcation RCT

413 pts at 28 centers in 5 countries with true bifurcation received Cypher in main vessels and randomized to PTCA vs. Cypher (crush", "culotte", "Y" or other techniques) of side branch with final kiss. Clinical FU at 6 months.

			
	N=206	N=207	
MV stented (%)	100	98.5	NS
SB stented (%)	4.3	95.1	<0.001
Kissing balloon (%)	32	74	<0.001
Tx successful (%)*	97	95	NS

Nordic Bifurcation Study (n=413)

Major Endpoints (clinically driven)



Dedicated Bifurcation Stents

Classification and Clinical Trends

- There is marked variability in the morphology of coronary bifurcation lesions.
- The variability includes vessel size (MB and SB), lesion location, eccentricity, length, morphology, and SB takeoff angle.
- Therefore, multiple strategies may be required to optimally treat highly variable bifurcation lesions.

Dedicated Bifurcation Stents

Classification and Clinical Trends

- Main branch DES do not elicit anti-restenosis responses in covered side branches (requires SB ostial DES coverage).
- Current clinical trends favor a minimalist single stent approach, but restenosis at the sidebranch ostium remains problematic.

Dedicated Bifurcation Stents

Categories of Bifurcation Stents

Dedicated Bifurcation Stents

General Categories

- Complete bifurcation “Y” stents
- Sidebranch access MB stents
- Sidebranch stents
- Specialty designs (e.g. for LM disease)

Dedicated Bifurcation Stents

General Categories

- ***Complete bifurcation "Y" stents***
- **Sidebranch access MB stents**
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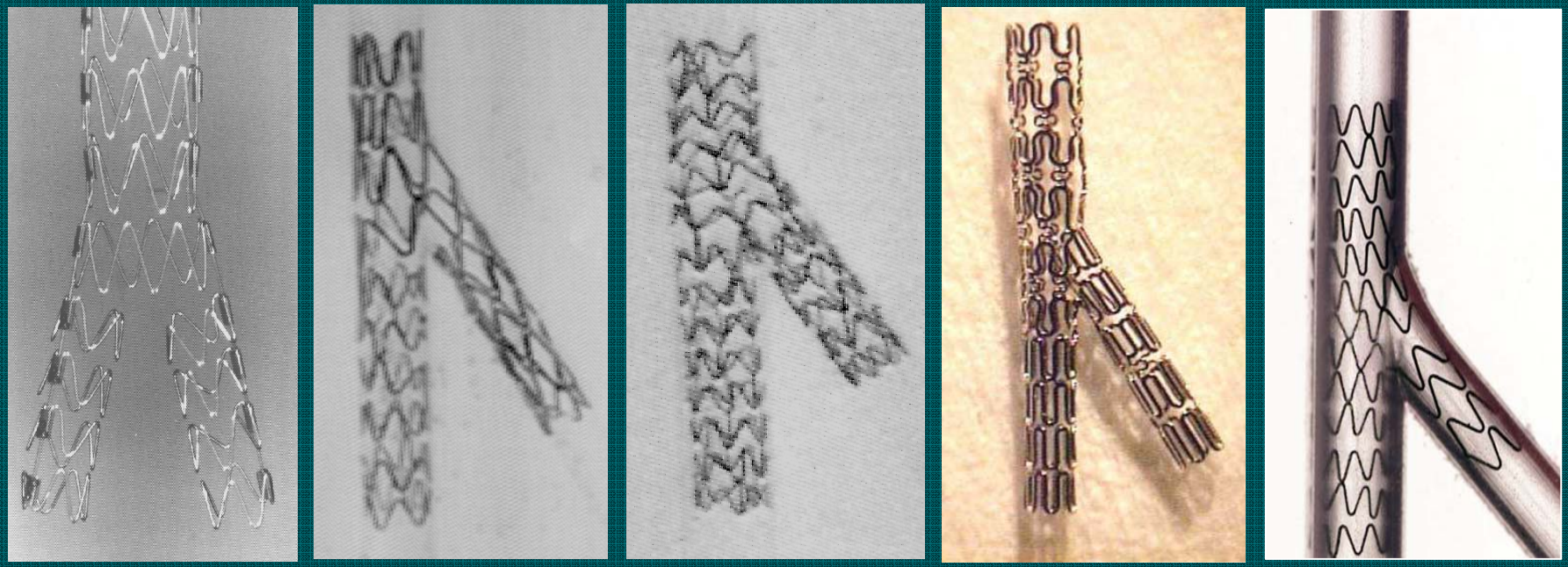
Dedicated Bifurcation Stents

Complete Bifurcation "Y" Stents (1997-present)

BARD **AVE** **Guidant** **Cordis** **MDT**



Dedicated Bifurcation Stents

Complete Bifurcation "Y" Stents

- The "holy grail" has been the development of a complete bifurcation "Y" stent.
- Thusfar, many problems have limited clinical progress: system complexity and profile, stent design, wire handling (and wrapping), delivery systems, variable lesion morphologies, AND perceived need.
- Main use in the future may focus on "large" vessel bifurcations (LM disease).

Dedicated Bifurcation Stents

General Categories

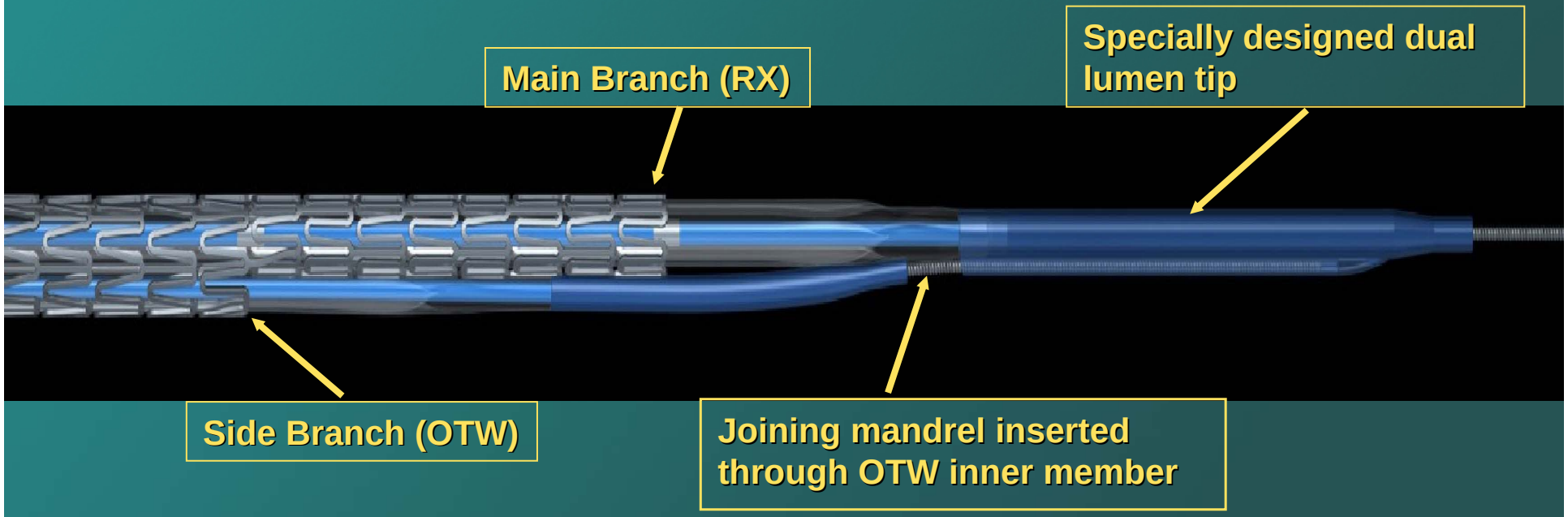
- Complete bifurcation “Y” stents
- ***Sidebranch access MB stents***
- Sidebranch stents
- Specialty designs (e.g. for LM disease)

Dedicated Bifurcation Stents

Sidebranch Access
MB Stents

- ABT Frontier
- Invatec Twinrail
- Minvasys Nile
- BSC Petal
- Ymed Sidekick
- Trireme Medical (TMI)
- StentYs

ABT Frontier
Design Characterisitics



- ***Single-Tip Delivery*** **to avoid wire wrap**
- ***Two Wires*** **maintain access across both branches**
- ***Kissing Balloon Deployment*** **to minimize plaque shift**
- ***Provisional T-Stent*** **approach maintains options for additional treatment**

ABT Frontier
Next Generation DES

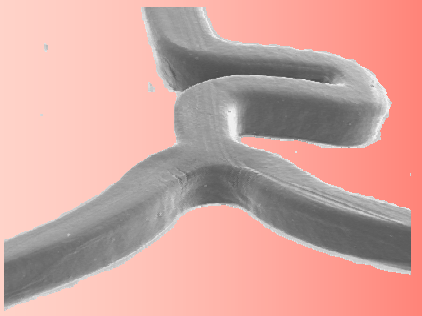
Main Branch Balloon

Side Branch Balloon

MULTI-LINK FRONTIER™

Side Branch Access

DES for Bifurcation

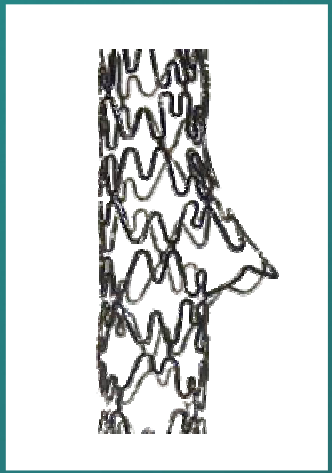


XIENCE™ V Everolimus Coating

MULTI-LINK VISION® CoCr Design

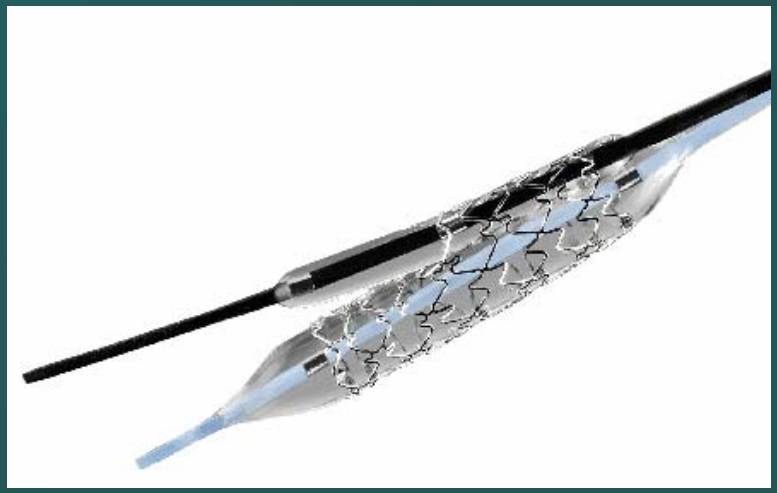
ML VISION™ Catheter

Invatec Twin-Rail
Design Summary



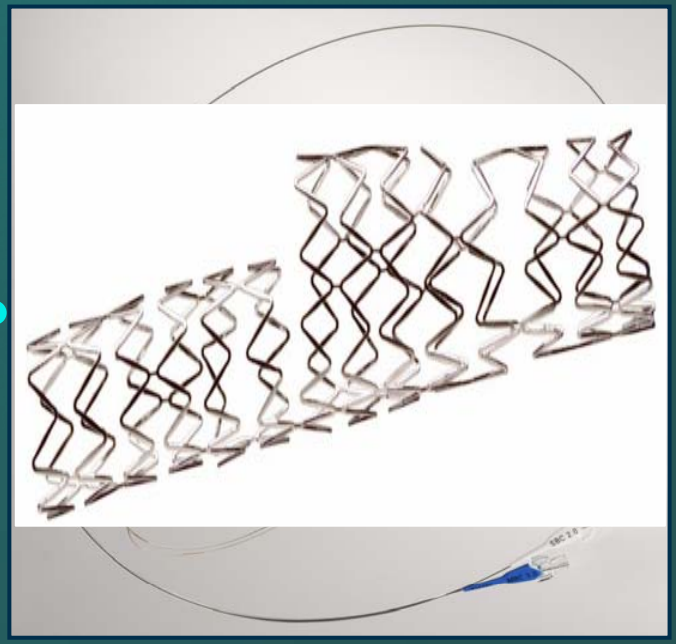
- ***Stent Platform***
  - Closed Cell design
  - Variable Stent Geometry
  - Adequate scaffolding of main vessel and side branch ostium

- ***Stent Delivery System***
  - Double balloon design SDS
    - Main vessel balloon ∅ 3.0mm and 3.5mm
    - Side branch balloon ∅ 1.5mm
  - Double RX design
  - 6 F Guiding catheter compatible



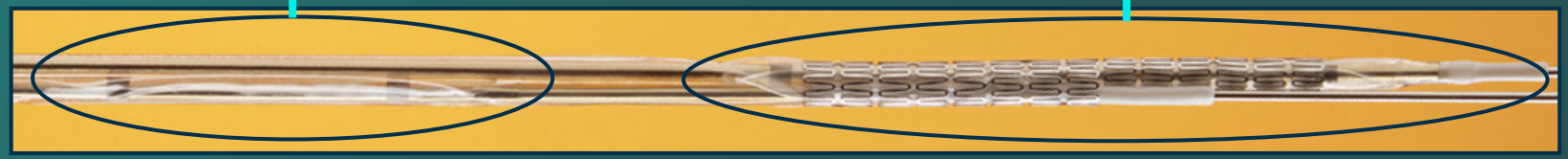
Minvasys Nile
Design Summary

One System
Two independent catheters

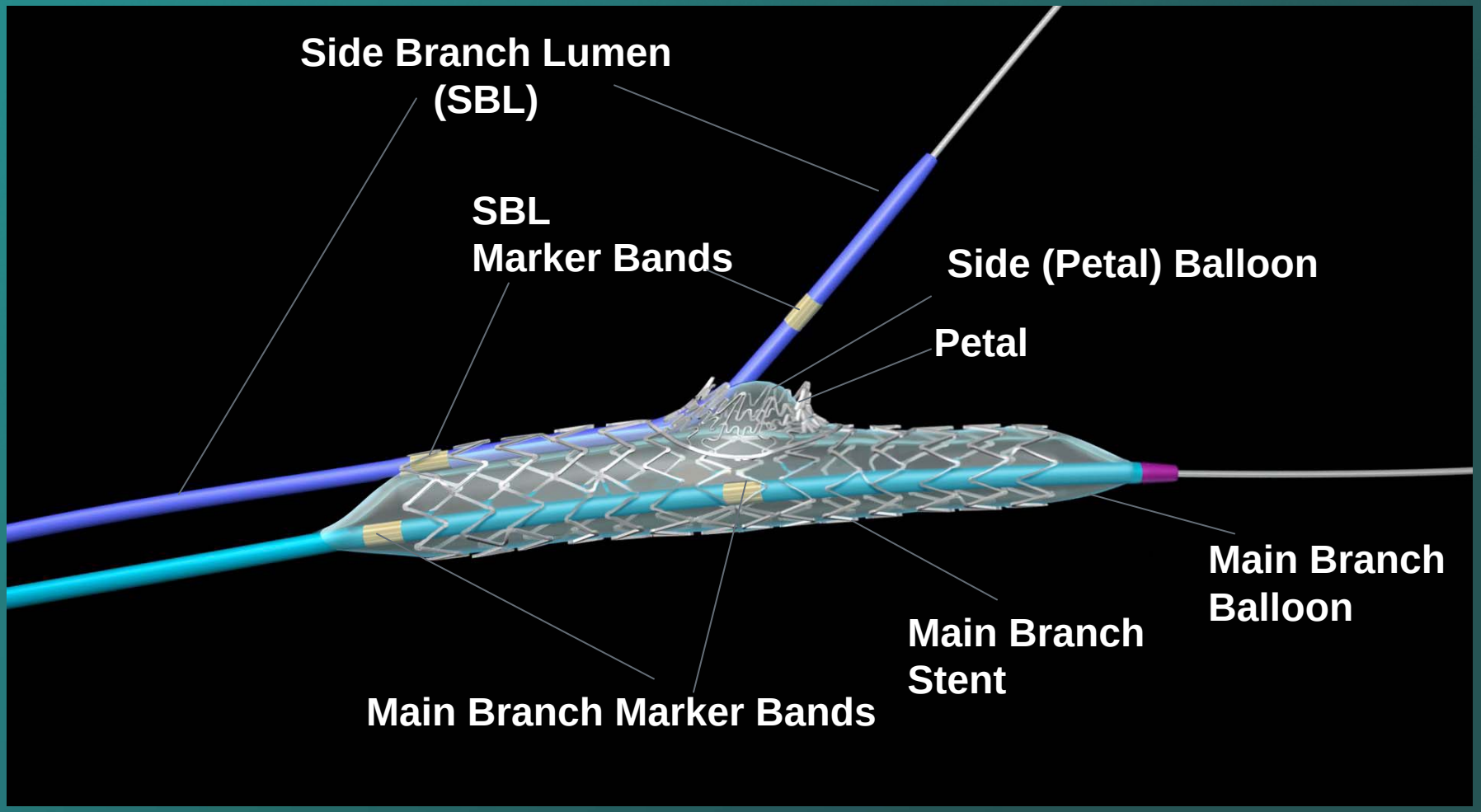


Side branch balloon

Main branch
Balloon + stent + tip



TAXUS® Petal™ Bifurcation Stent



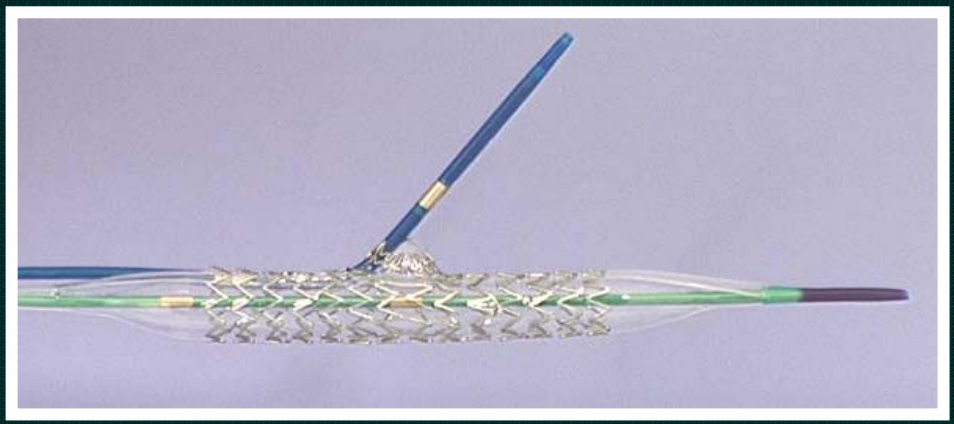
First Human Use Q2 2007

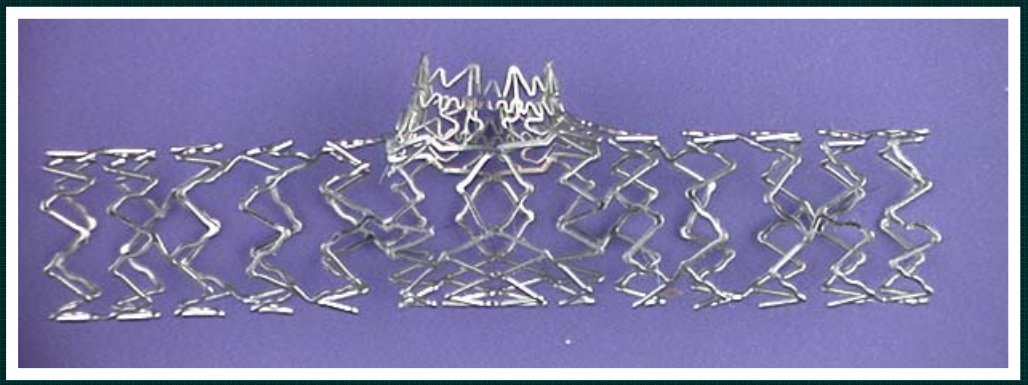
BSC TAXUS Petal

Design Characteristics

Delivery System Advantages

- Side Branch wire lumen aids in alignment at ostium
- Side branch “pre-wired”, no need to re-access through stent
- Final Petal size determined by post dilatation balloon



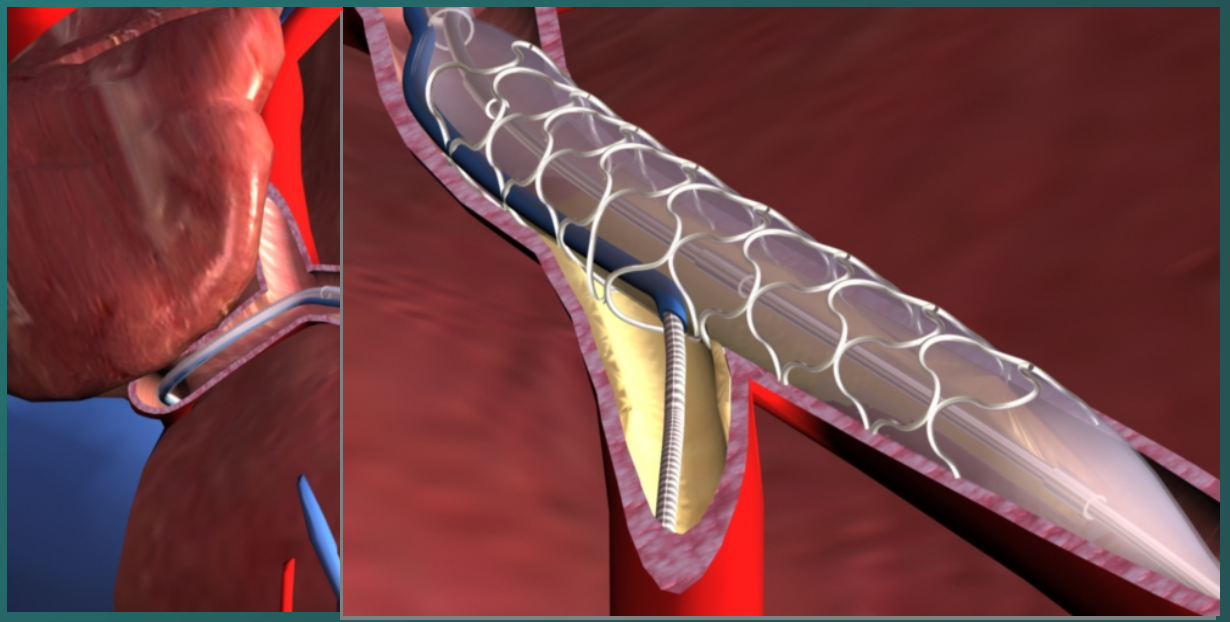


Stent Advantages

- Special stent feature to cover ostium of side branch (~2mm)
- Reduces / eliminates side branch “gap” and reduce need for 2nd stent
- Placing 2nd stent, when necessary, is technically straight forward

Y-Med Side-kick
Design Characteristics

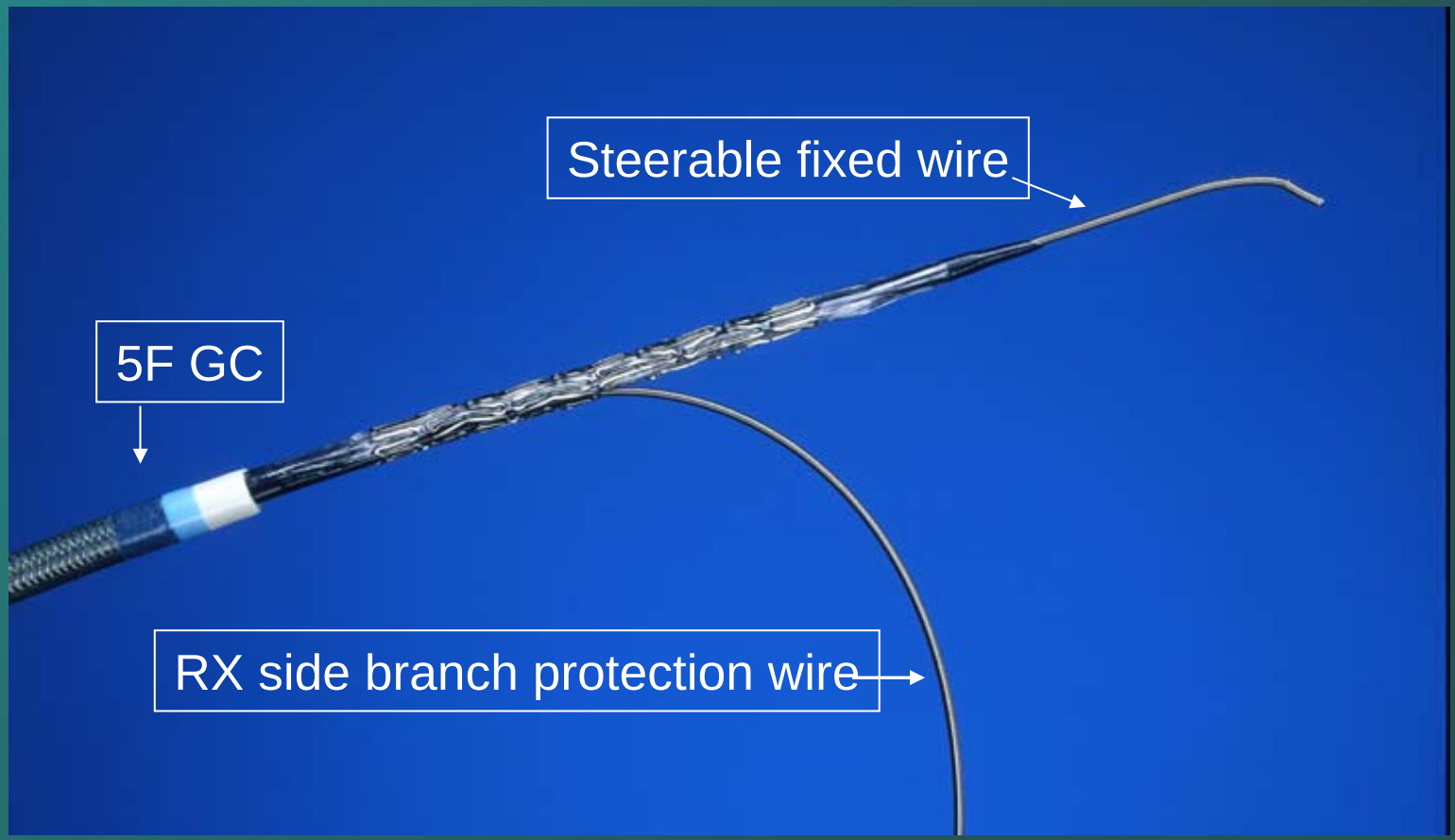
- *Low profile system (5 Fr guide compatible)*
- *Steerable fixed wire for main branch*
- *Rx movable wire for sidebranch access*
- *Easily torquable for accurate positioning*



Y-Med Side-kick

Design Characteristics

Mid exit port



TriReme Bifurcation Stent

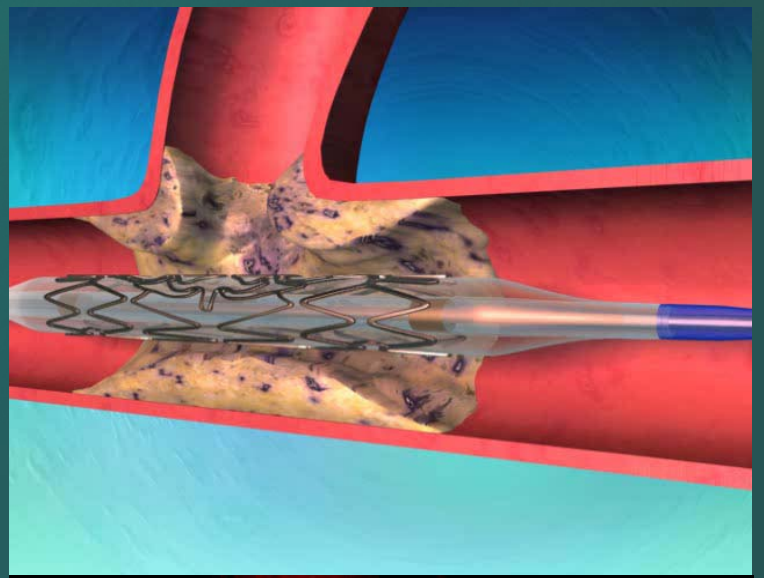
Design Characteristics

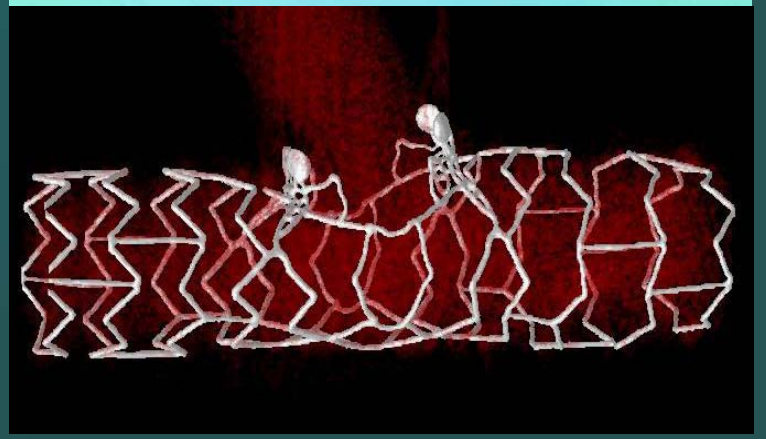
Stent Design

- Central “custom” cell with crowns extending into sidebranch ostium upon balloon expansion (ostial coverage and support)
- Low profile (6-7Fr guide compatible)

Delivery System

- Rx main branch wire
- Custom “nested” side branch wire advanced thru central cell when proximal to side branch
- Crown markers to assist with axial and rotational alignment

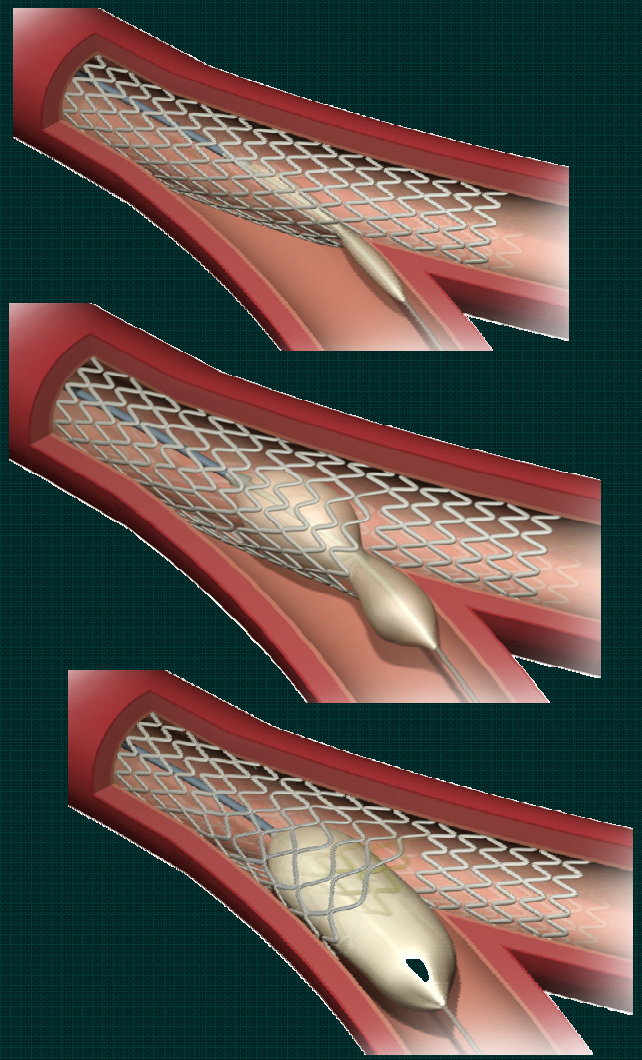




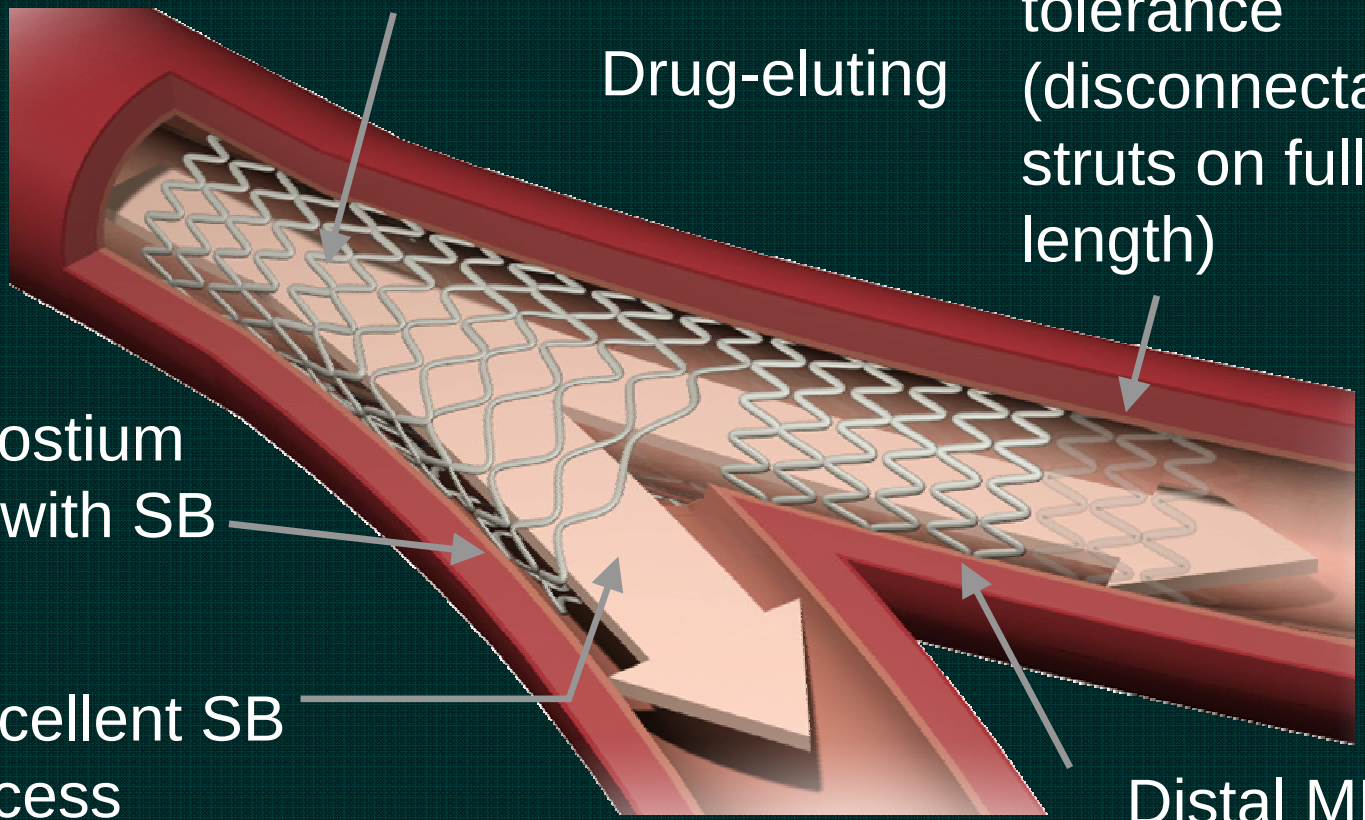
StentYs Bifurcation Stent

Design Characteristics

1. Optimal strut selection
2. Disconnection
3. Self-expansion



StentYs - Features



Dedicated Bifurcation Stents

Sidebranch Access
MB Stents

- With "provisional" SB stenting being the "fashionable" technique presently, these SB access designs offer special advantages.
- Delivery systems and technique remain the major concerns, including wire management, system torquing and consistent alignment (both axial and rotational) with the SB ostium.
- Ostial coverage is variable and DES versions are in development.

Dedicated Bifurcation Stents

General Categories

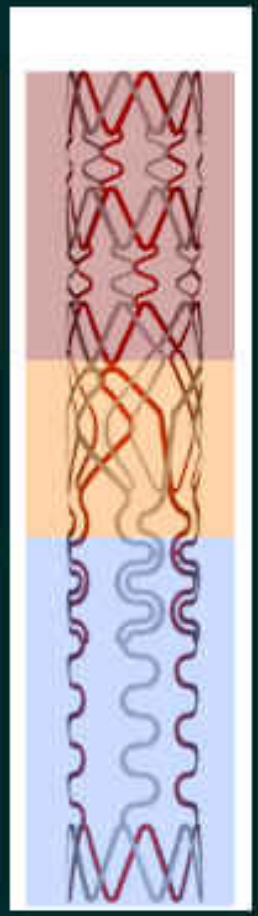
- Complete bifurcation "Y" stents
- Sidebranch access MB stents
- ***Sidebranch stents***
- Specialty designs (e.g. for LM disease)

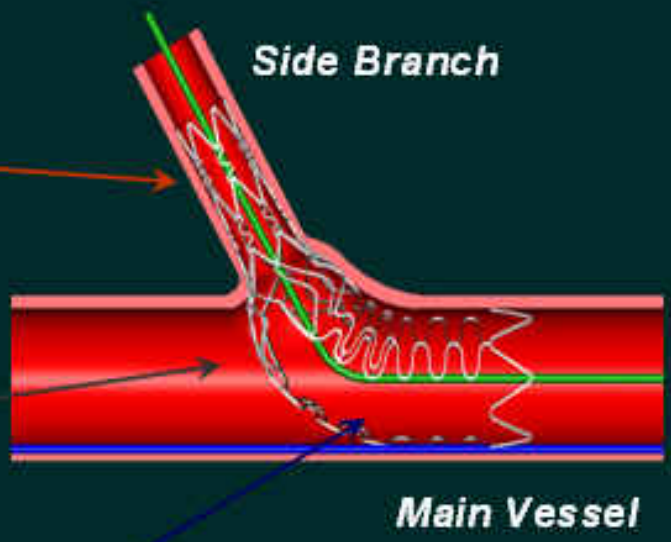
Tryton Side-Branch Stent

Side Branch Region
Standard Design

Transition Zone
Coverage
Hoop Strength

Main Vessel Region
3 Fronds - Minimal Coverage
Wedding Band





Cobalt Chromium
Strut Thickness: 0.003”
Diameter: 2.5 mm

Tryton Stent Delivery Systems

Stent Border Markers (19 mm)

Step Balloon

Single Wire Tracking

Rotational Independence

Easy Landing Zone

4mm Transition Zone

Stent Delivery System

- Rapid Exchange
- Low Profile
  - 5Fr. Guide compatible
- Tracking = Zeta
- Balloon
  - Semi-compliant
  - Rated Burst = 16 ATM
- Stent Length = 18 mm

Transition Zone Markers (4 mm)

Standard Balloon

Cappella Sideguard Ostium Protection Device

Cappella Sideguard Ostium Protection Device

Side branch @ carina

Main branch @ carina

- First **anatomically-shaped side branch** stent for complete ostial coverage
- First **balloon-mounted** delivery system for self-expanding stents
- First **vertically-flexible** stent

Dedicated Bifurcation Stents

Sidebranch Stents

- Designed specifically for patients with significant sidebranch lesions requiring a second stent (not provisional – planned).
- "Sidebranch first" strategy, followed by main branch stenting, simplifies procedure and reduces technical difficulties.
- Issues of precise ostial placement, "metal-on-metal" (crush-like) and DES platforms require further development.

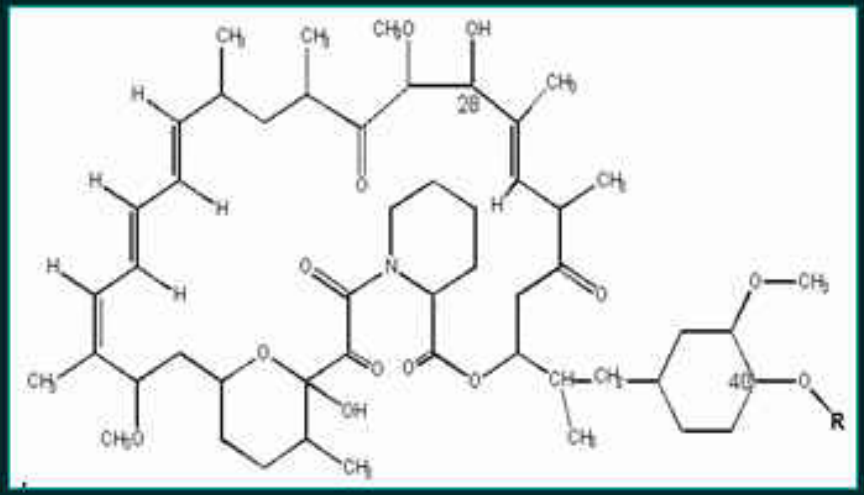
Dedicated Bifurcation Stents

General Categories

- Complete bifurcation "Y" stents
- Sidebranch access MB stents
- Sidebranch stents
- ***Specialty designs (e.g. for LM disease)***

Devax AXXESS PLUS System for Bifurcations

+



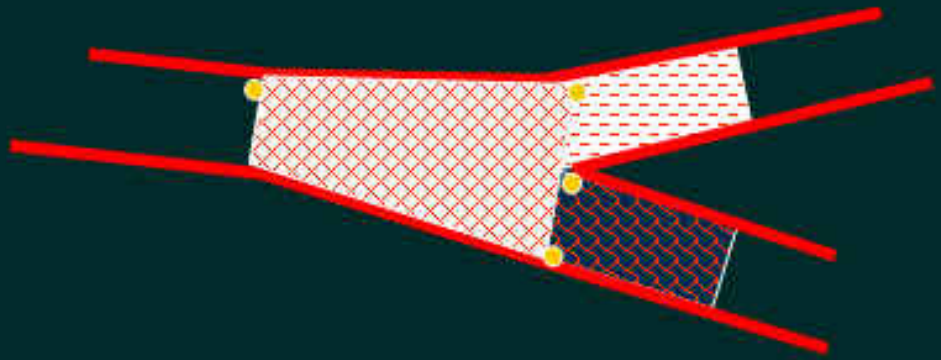
AXXESS Stent

PLUS

Biolimus-A9 Anti-proliferative & Bioerodable Polymer

AXXESS PLUS Concept

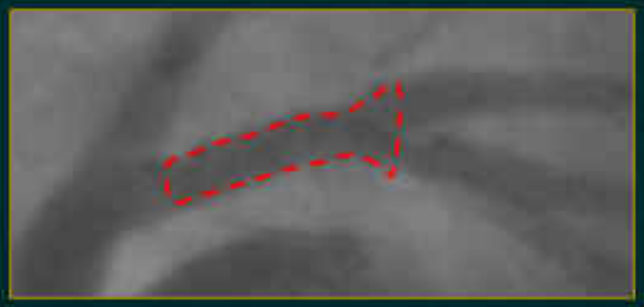
- The Axxess Plus stent is implanted at the level of the carina
- A successful implant will span the ostia of both branching vessels, indicated by the presence of one marker in each branch vessel



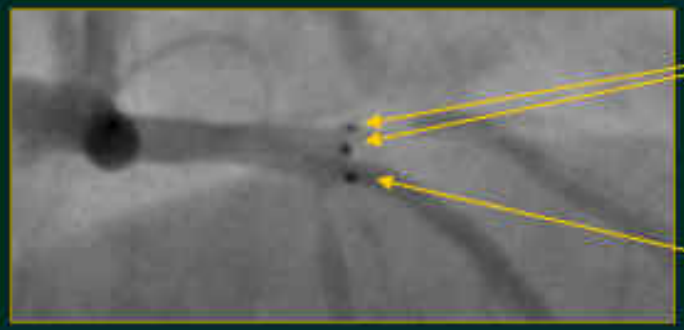
- Stents for the branch vessels are selected to match the length and diameter of the LAD and LCX

The AXXESS PLUS Concept

The flared shape of the AXXESS PLUS stent matches the flared geometry of a bifurcation



The Axxess Plus stent expands into both the MB and SB, providing complete vessel coverage at the carina



The AXXESS PLUS Concept

- ***With the Axxess Stent covering the ostia, branch vessel stents are placed just distal to the bifurcation***

Distal stents are implanted in their natural shape, and do not need to be "remodeled" by PTCA to fit the anatomy of the bifurcation

AXXESS PLUS FIM (outside US)

Angiographic FU	124/136 (91.2%)
Acute Gain	
Axxess Plus stent only	2.05 ± 0.48
All stents in PV	1.85 ± 0.49
Late Loss	
Axxess Plus	0.09 ± 0.56
All stents in PV	0.21 ± 0.44
In segment	0.26 ± 0.53
Binary Restenosis	
Axxess Plus only	4.0%
All stents (Axxess + distal DES)	5.6%
In segment	10.5%

DIVERGE: a Prospective, Single-arm, Multi-center Registry Drug Stent Intervention for Treating Side Branches Effectively

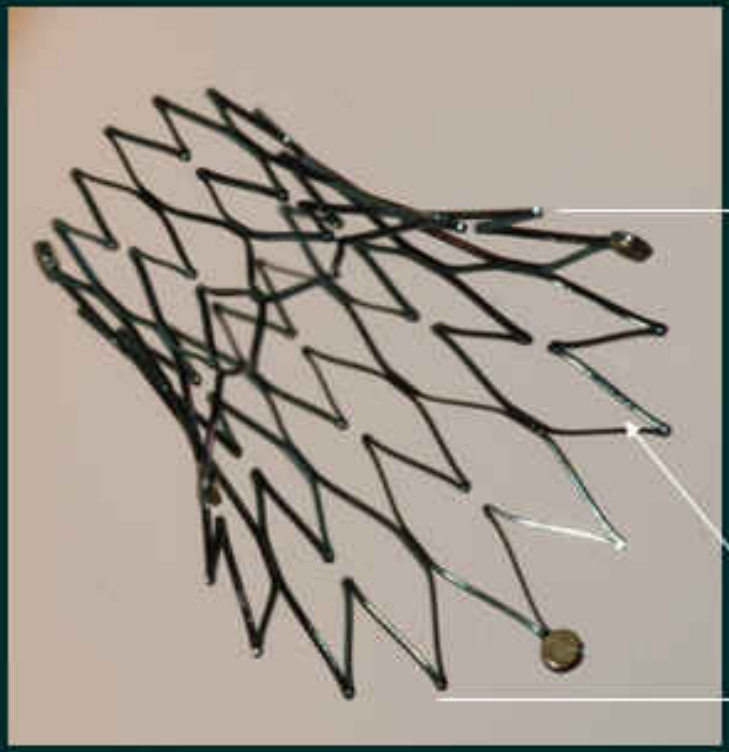
Patients with de novo **bifurcated lesions in native coronary arteries** N=600

PCI using Axxess™ stent System

Angio F/U at 9 mo in 300 pts
Annual clinical F/U for 5 years

PRIMARY Endpoint: 9-mo MACE: death, MI, iTLR
SECONDARY Endpoints: device success, binary restenosis, late loss

AXXESS PLUS LM System

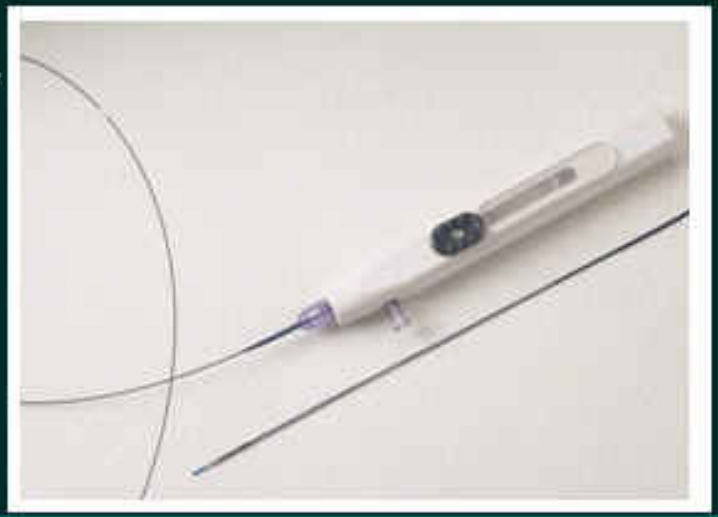


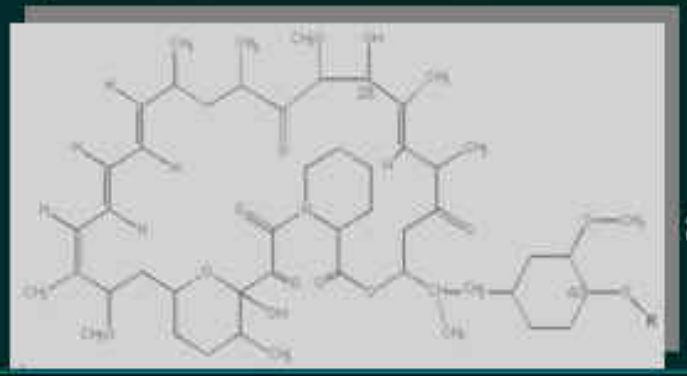
Flared Distal-End Stent Design

Self Expanding Nitinol Material

8, 10, or 12 mm flare diameter

4.8F Rx Delivery System





Biolimus A9 antiproliferative strut coating

Dedicated Bifurcation Stents

Final Thoughts

- Bifurcation disease is markedly variable and poorly understood!
- A "family" of dedicated bifurcation stents may be required to manage all lesions.
- Current bifurcation stent designs are still technically complex and operator unfriendly!
- DES integration will pose further challenges.
- Must prove superiority cw simplified non-dedicated bifurcation stent strategies…