

Update of Dedicated Bifurcation Stents

Martin B. Leon, MD

*Columbia University Medical Center
New York Presbyterian Hospital
New York City*



Disclosure Statement of Financial Interest

Martin B. Leon, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity

Company

- Abbott, Boston Scientific, Edwards Lifesciences, Medtronic
- Meril Lifescience, Angioscore, Micell
- Sadra, Claret, Coherex, Medinol, Valve Medical

Dedicated Bifurcation/LM Stents

Background

Bifurcation Lesions are a “Pain in the Butt”



- more time, anxiety, skill and equipment required
- increased complications
 - early - MIs and ST
 - late - restenosis
- suboptimal angiographic outcomes
- no dedicated devices with validated benefit

Leaders Trial/Bifurcation Lesions: Patients 29.1%/Lesions 21.6%

Variables, n(%)	True bifurcations		Partial bifurcation		P value
	BES (n=131)	SES (n=102)	BES (n=151)	SES (n=150)	
Number of wires					
One	32(24.4)	27(26.5)	30(19.8)	42(28.0)	
Two	99(75.6)	75(73.5)	121(80.2)	108(72.0)	
Stenting technique					
One stent	94(71.8)	75(73.5)	129(85.4)	135(90.0)	
1 wire	32(24.4)	27(26.5)	30(19.9)	42(28.0)	
2 wires (Provisional T-stent)	55(42.0)	41(40.2)	57(37.7)	59(39.3)	
2 wires (2nd wire post MB stenting)	7(5.3)	7(6.9)	42(27.8)	34(22.7)	
Two stents	37(28.2)	27(26.5)	22(14.6)	15(10.0)	
Cross-over from 1-stent technique	7(5.3)	8(7.8)	6(4.0)	3(2.0)	
Classic T	7(5.3)	8(7.8)	9(6.0)	7(4.7)	
Crush	16(12.2)	7(6.9)	3(2.0)	4(2.7)	
Culotte	7(5.3)	0(0.0)	1(0.7)	0(0.0)	
Modified T	0(0.0)	1(1.0)	2(1.3)	0(0.0)	
V stenting	0(0.0)	3(2.9)	1(0.7)	1(0.7)	
Post dilatation	73(55.7)	49(48.0)	58(38.4)	52(34.7)	
MB only	5(3.8)	3(2.9)	8(5.3)	14(9.3)	
MB-SB ostium	16(12.2)	14(13.7)	19(12.6)	16(10.7)	
Kissing balloon	52(39.7)	32(31.4)	31(20.5)	22(14.7)	

**True Bif
43.6%**

**2 wires
75.3%**

**2 Stents
Total = 18.9%
True Bif = 27.5%**

**Kissing
Total = 25.7%
True Bif = 36.1%**

BES: biolimus-eluting stent; SES: sirolimus-eluting stent; MB: main branch; SB: side branch; No significant difference in technique between BES and SES for

EuroIntervention 2011;6:928-935

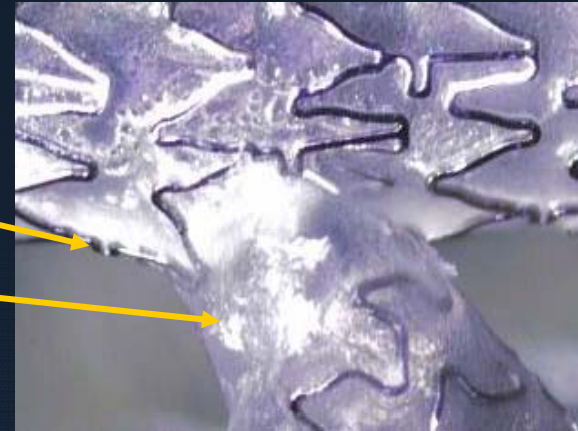
Dedicated Bifurcation/LM Stents

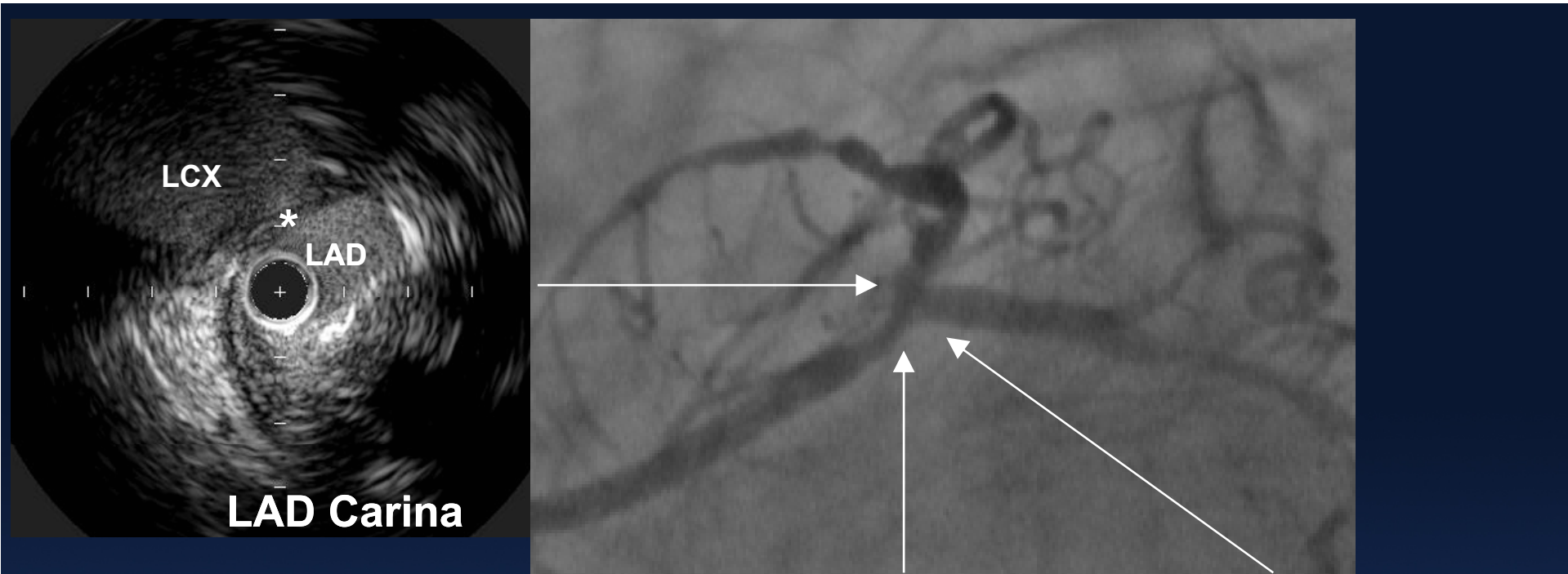
Special Considerations

- There is marked variability in the morphology of coronary bifurcation and left main lesions.
- This includes varying vessel size (MB and SB), lesion location, lesion length, lesion severity, morphology, and SB takeoff angle.
- *Therefore, multiple stent designs and operator techniques may be required to optimally treat highly variable bifurcation/LM lesions.*

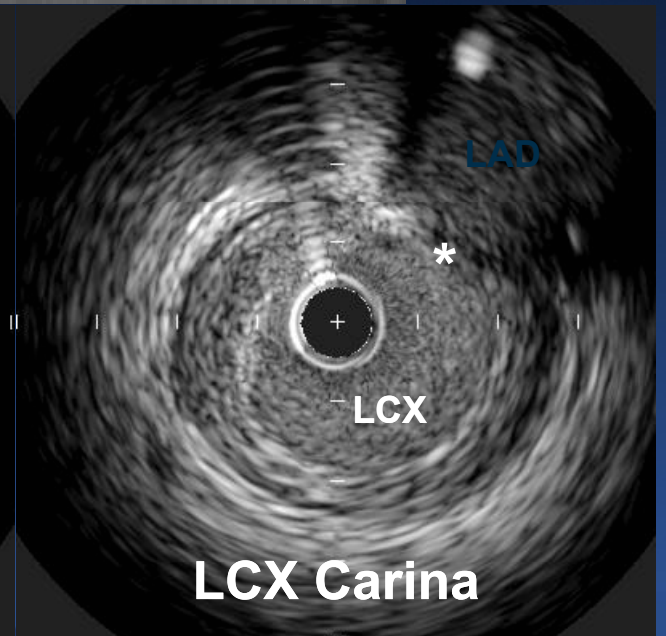
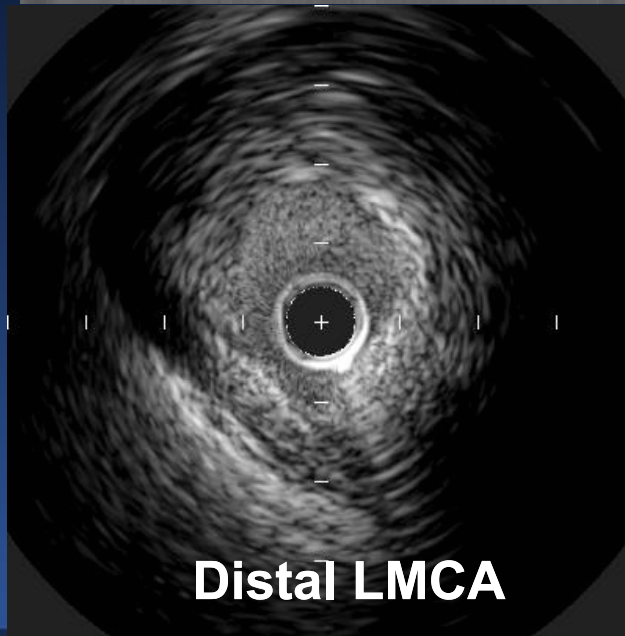
The Ostial Junction of Coronary Arteries (bifurcations)

- **Complex transition zone** from main vessel to side branch with many asymmetric features (**incl. oval shape and rapid taper**)
- **Anatomic distortion** likely with symmetric (cylindrical) designs
 - **Strut protrusion/injury**
 - **Coverage gaps**
 - **Incomplete wall apposition**
- **Matching design to asymmetric ostial geometry may minimize implant injury, enhance scaffolding and improve outcomes**

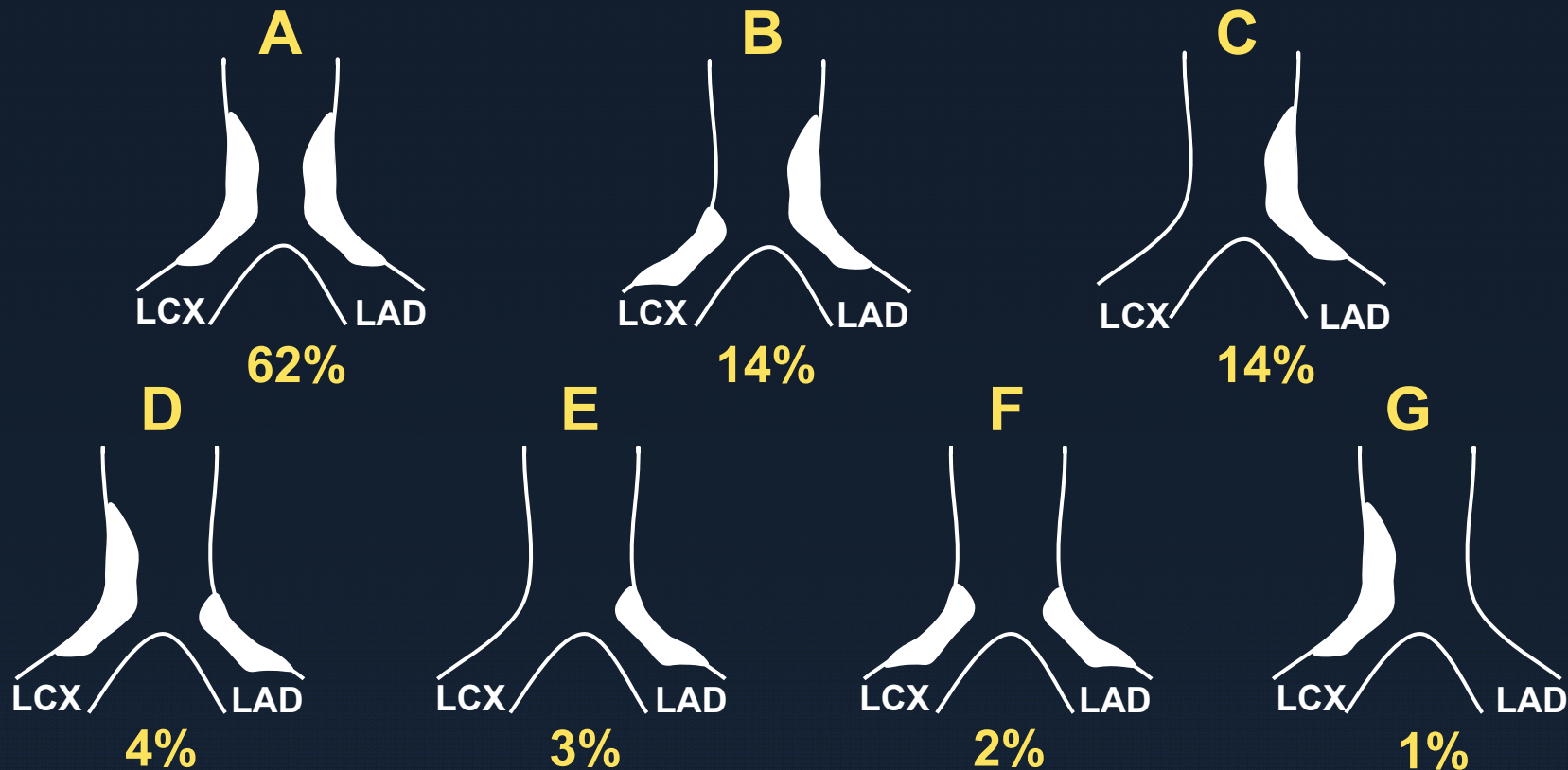




IVUS Findings in Left Main Lesions (140 pts)



IVUS Findings in Left Main Lesions



- 140 pts; 93% with IVUS LM lesions
- Usually diffuse; no flow divider disease
- Eccentric lesions w neg remodeling

- LM → LAD 90%, LM → LCX 66%,
→ LAD + LCX 62%, only LAD 9%,
and only LCX 17%

Recent Bifurcation Stent Studies (*Nordic 1, BBC 1, CACTUS*)

**Randomized Study on Simple Versus Complex Stenting
of Coronary Artery Bifurcation Lesions**

Interventional Cardiology

**Randomized Trial of Simple Versus Complex Drug-Eluting
Stenting for Bifurcation Lesions**

The British Bifurcation Coronary Study: Old, New, and

**Randomized Study of the Crush Technique Versus
Provisional Side-Branch Stenting in True
Coronary Bifurcations**

**The CACTUS (Coronary Bifurcations: Application of the Crushing
Technique Using Sirolimus-Eluting Stents) Study**

Antonio Colombo, MD; Ezio Bramucci, MD; Salvatore Saccà, MD; Roberto Violini, MD;
Corrado Lettieri, MD; Roberto Zanini, MD; Imad Sheiban, MD; Leonardo Paloscia, MD;
Eberhard Grube, MD; Joachim Schofer, MD; Leonardo Bolognese, MD; Mario Orlandi, MD;
Giampaolo Niccoli, MD; Azeem Latib, MD; Flavio Airolidi, MD

Dedicated Bifurcation/LM Stents

Worth Noting...

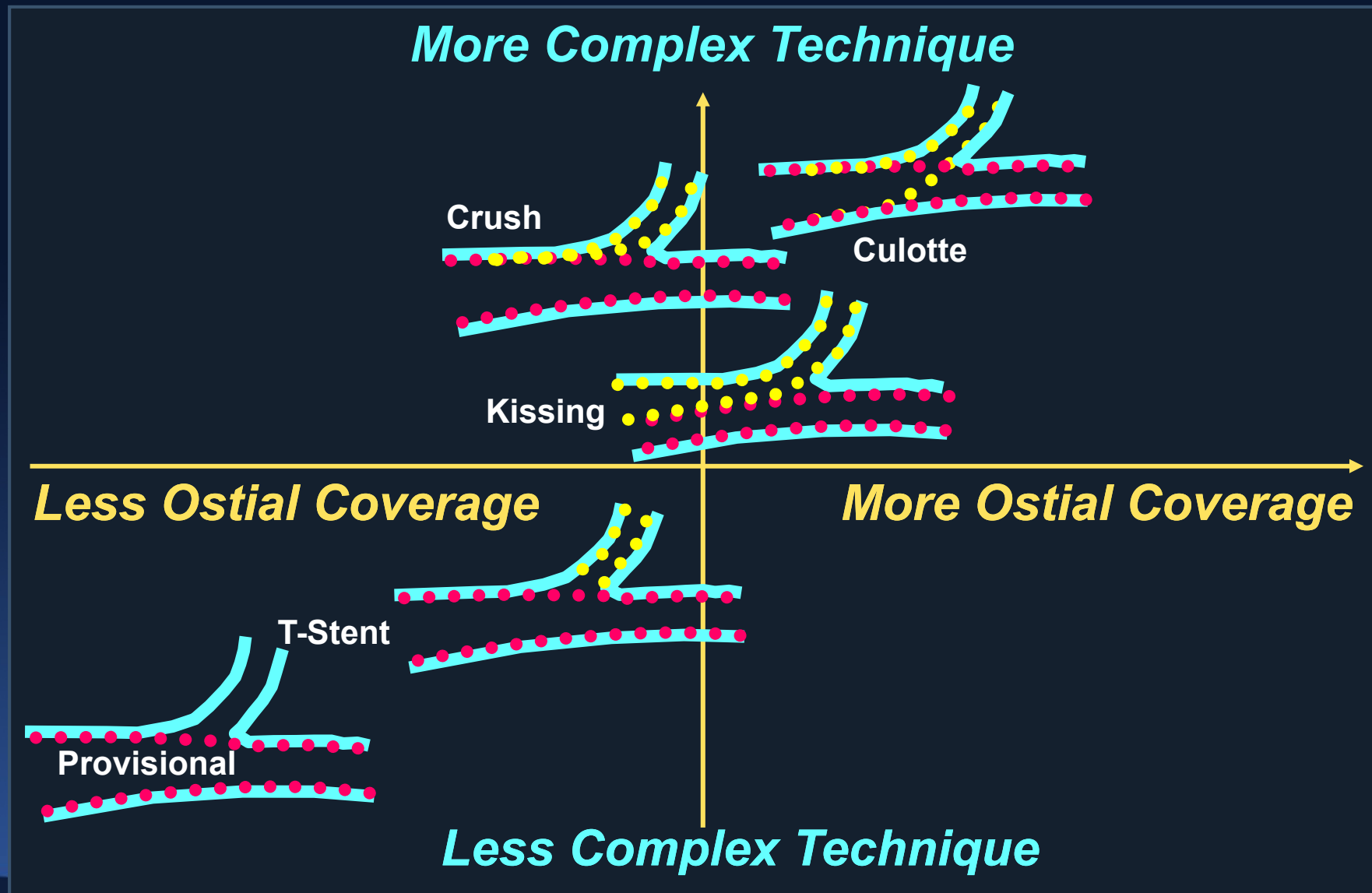
The reliance on a provisional bifurcation stent strategy may have been exaggerated by...

- (1) less rigorous application of essential operator techniques to optimize two-stent results (e.g. HP two-step final kiss),
- (2) negative experiences associated with the more challenging current two-stent strategies (crush, T, culotte, and kissing stents), and
- (3) the lack of dedicated user-friendly bifurcation stent designs

Dedicated Bifurcation/LM Stents

Stent Designs

Bifurcation Stent Techniques



Dedicated Bifurcation/LM Stents

General Categories

- Sidebranch access MB stents
- Sidebranch only stents
- Specialty designs (e.g. carina or for LM disease)

Dedicated Bifurcation/LM Stents

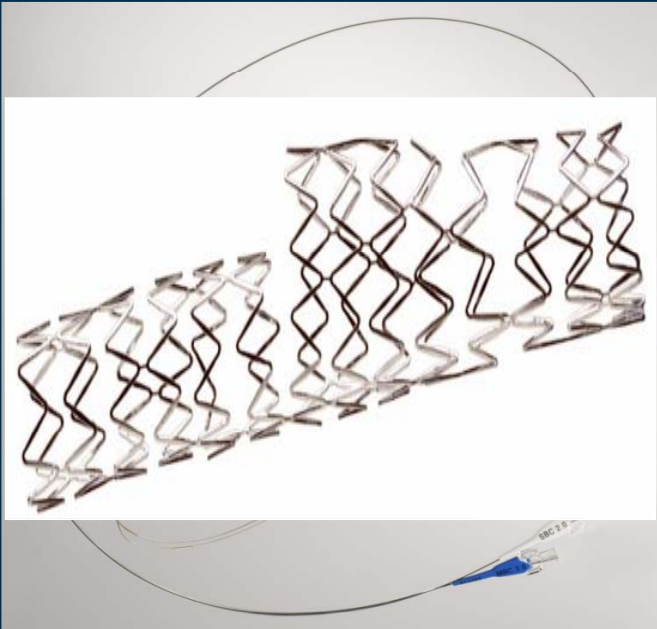
General Categories

- *Sidebranch access MB stents*
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Minvasys Nile Pax

Design Summary

One System
Two independent catheters

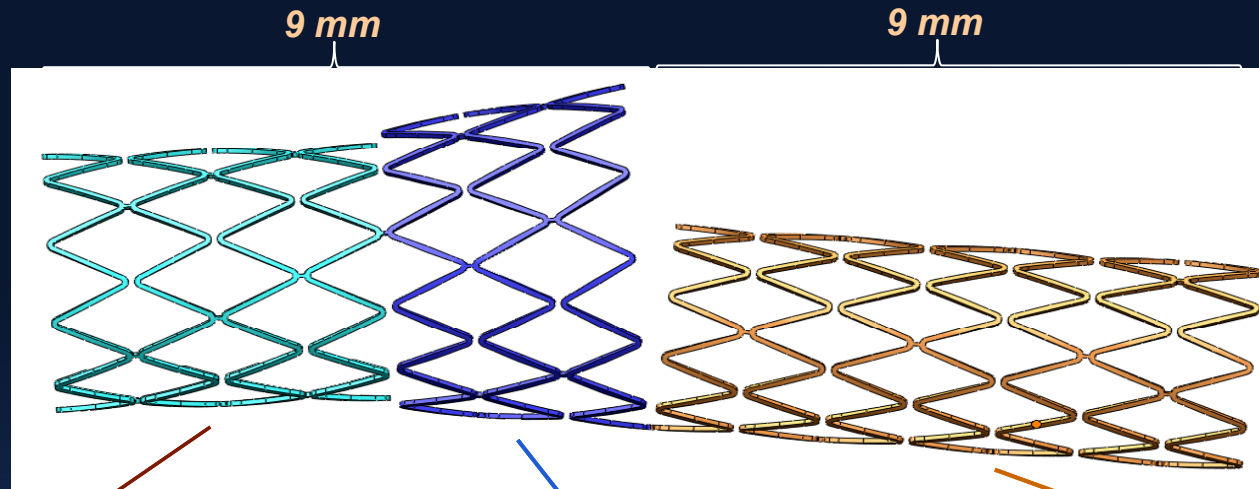


Side branch
balloon

Main branch
Balloon + stent + tip



Minvasys Nile LM



Proximal part

- Links for longitudinal compression resistance
- 10 strut peeks segment
- To fit up to 5 mm

Carina part

- 12 strut peeks segment
- A single link to distal segment for wide sb opening
- Fits all angulations

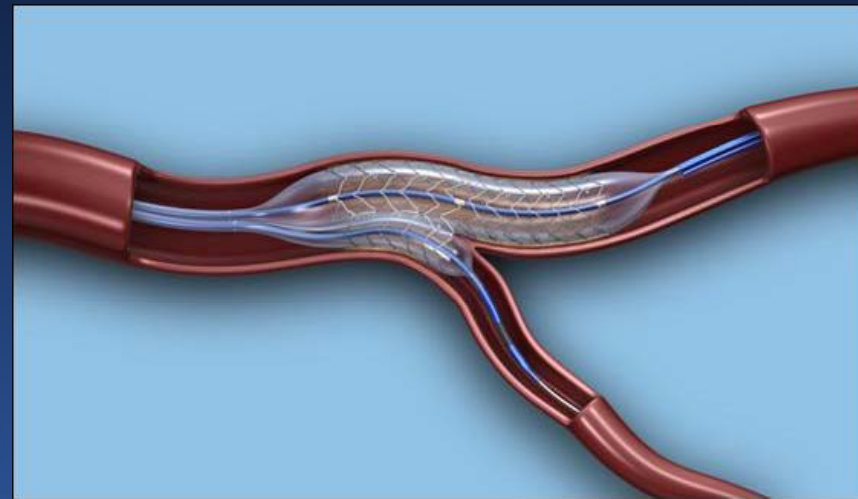
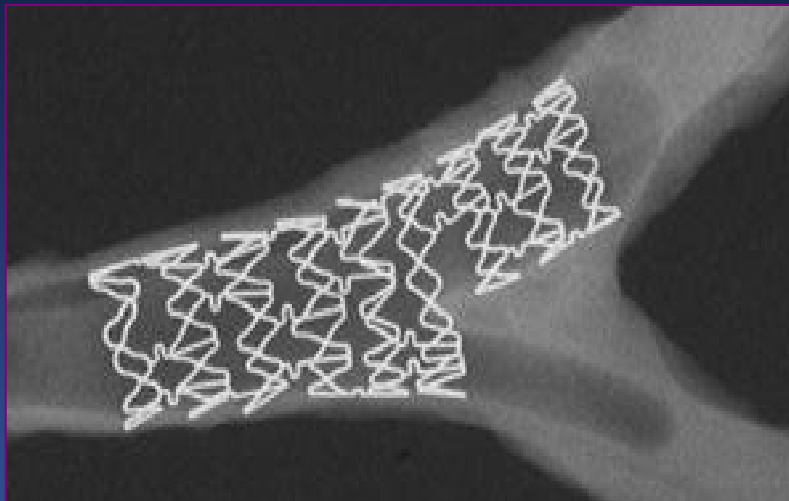
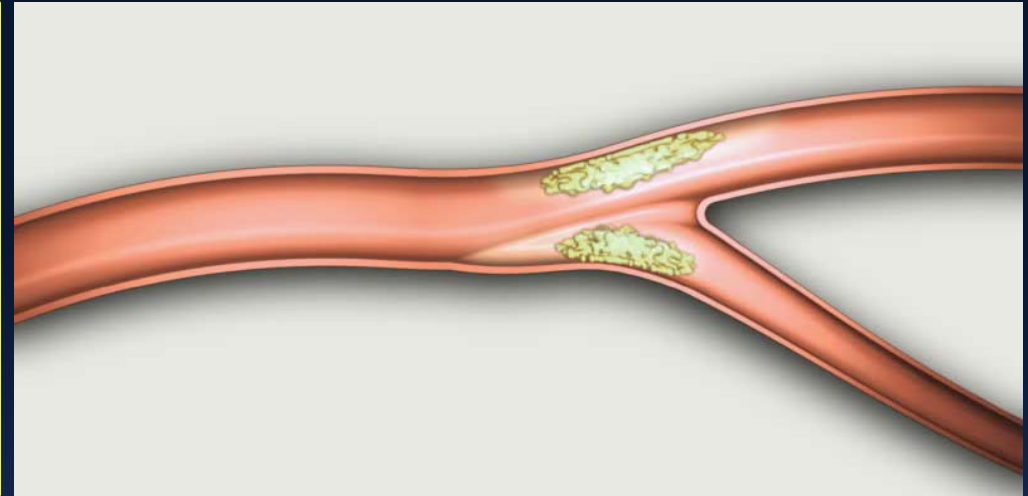
Distal part

- 10 strut peeks segment
- Flexibility with open cell design

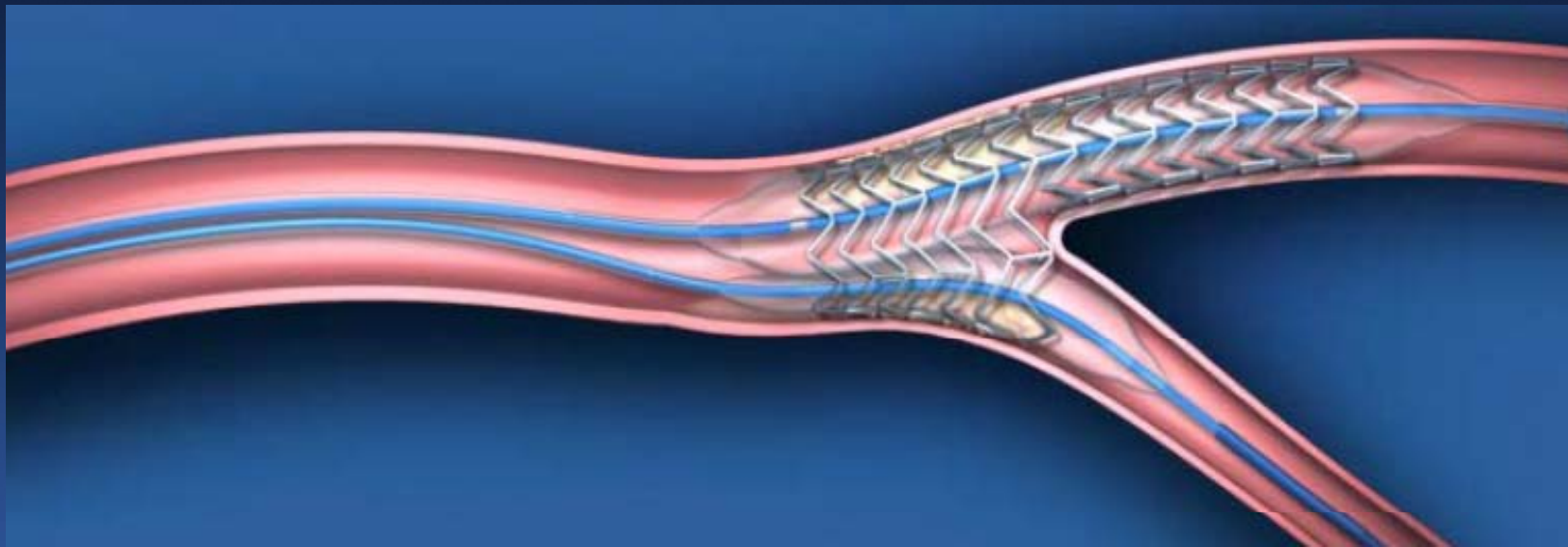
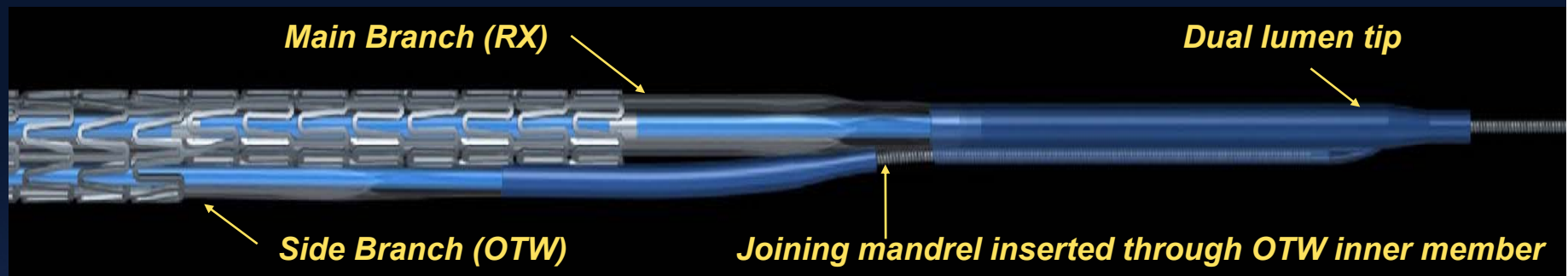
Xience SBA Stent Program

**** The device formerly known as Frontier & Pathfinder**

**** Design & profile issues and therefore the practical conversion of the Frontier Catheter to the Xience V platform**



Xience SBA is identical to Xience V with respect to metal, polymer, drug, elution kinetics and delivery characteristics



StentYs Bifurcation Stent

Design Characteristics

Self-expanding
nitinol

Anatomical reconstruction of
the bifurcation shape

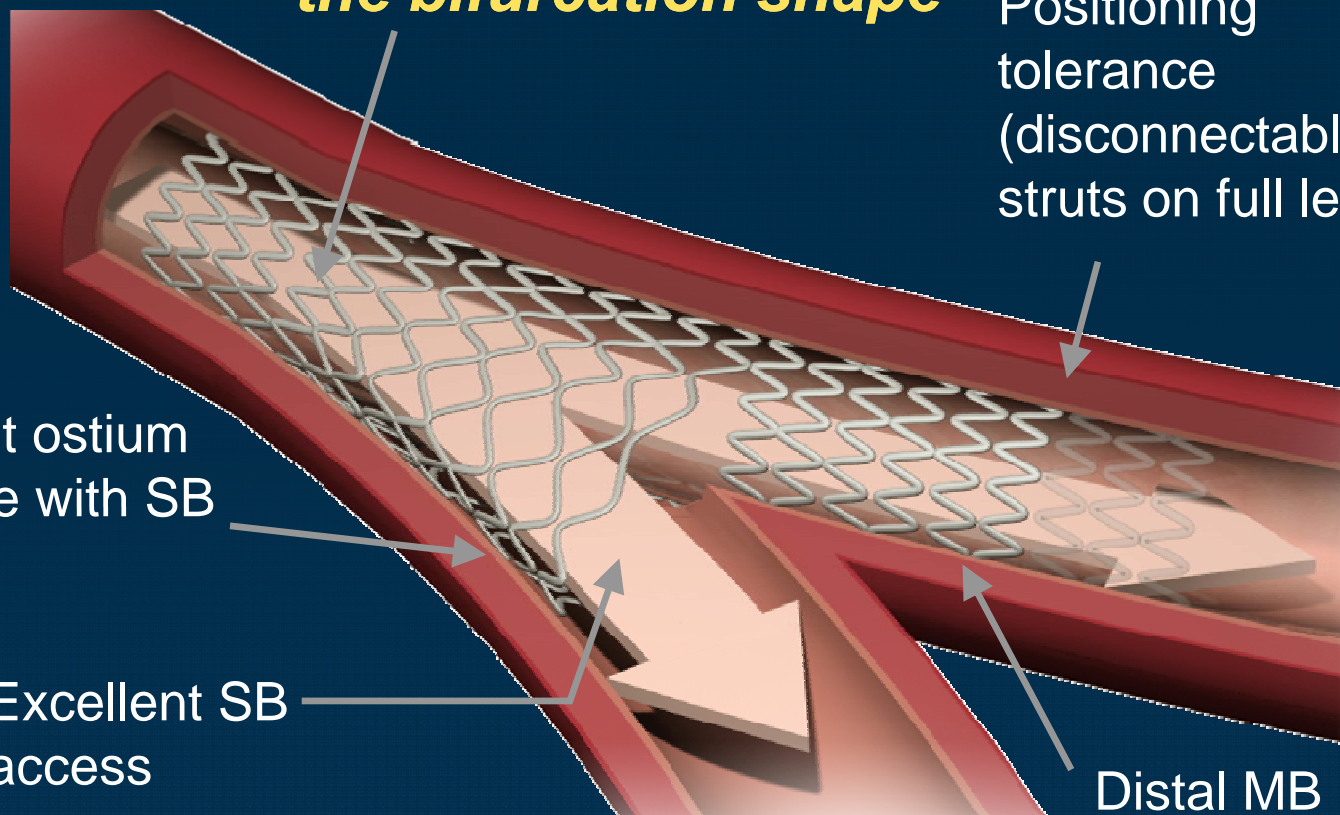
Positioning
tolerance
(disconnectable
struts on full length)

Excellent ostium
coverage with SB
stent

Excellent SB
access

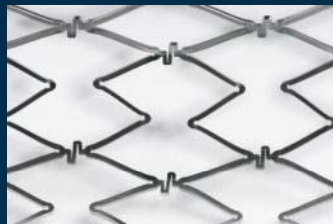
Distal MB
stented

Single wire 5F delivery system

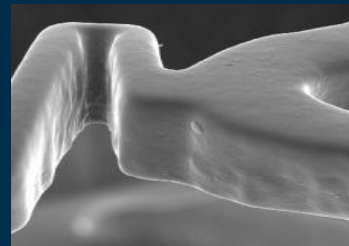


STENTYS self-apposing stent

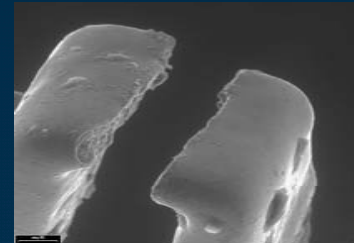
- ***Nitinol, self-apposing stent***
- ***6F Single-wire, Rapid Exchange***
- ***Disconnectable struts over full length***



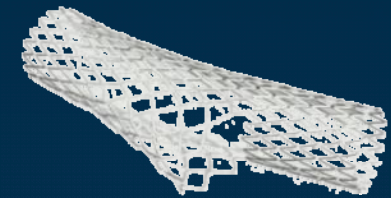
↑ ↑ ↑
***Disconnectors
along the stent***



***Disconnectable
interconnector***



Disconnection

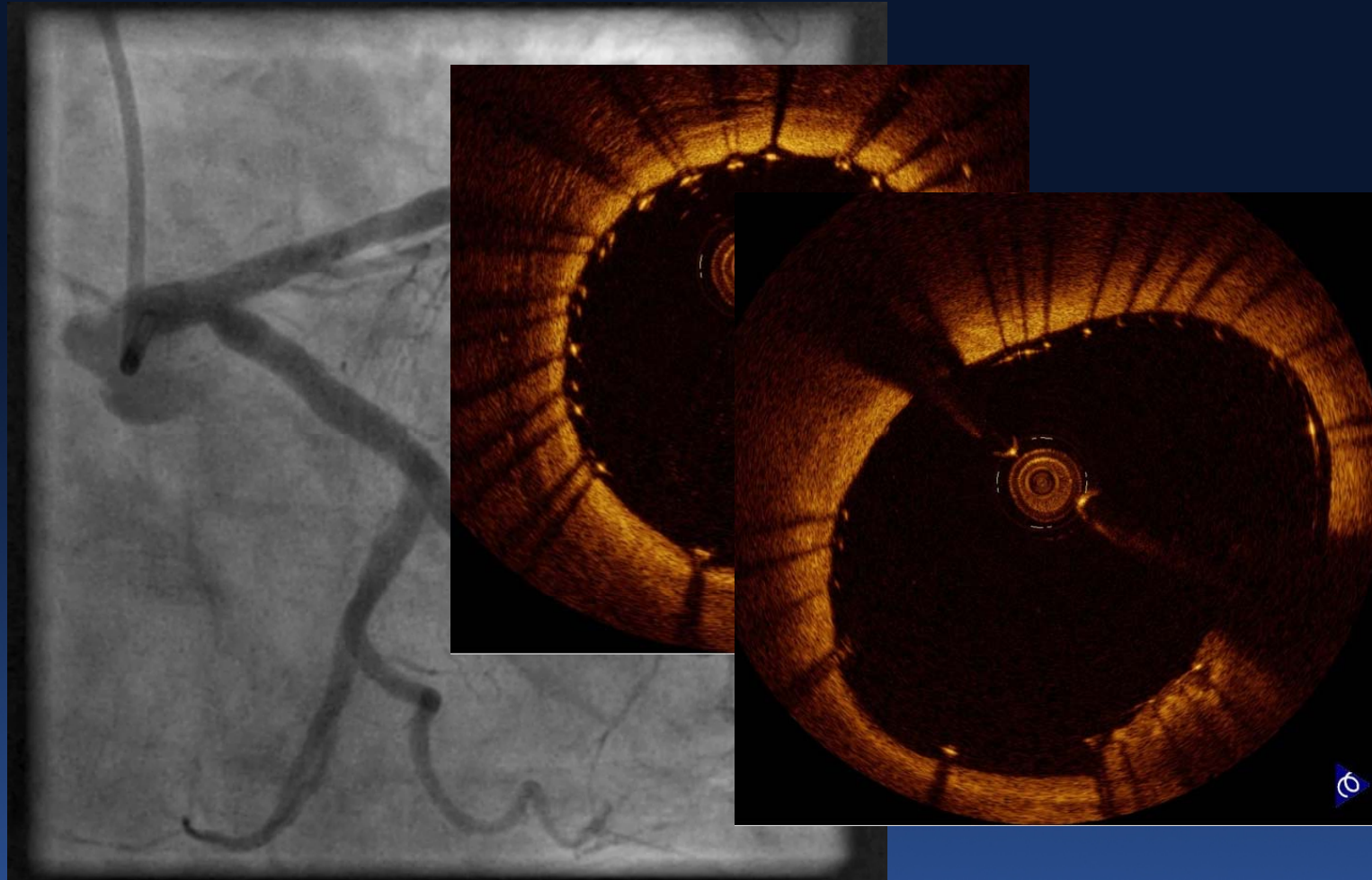


StentYs LM Case



- *57 yo male with acute AWWMI*
- *Thrombus aspiration*
- *Stentys in LM (crossover to LAD)*
- *4.5mm balloon in LM/LAD; 3.5 NC balloon in LCx*

StentYs LM Case

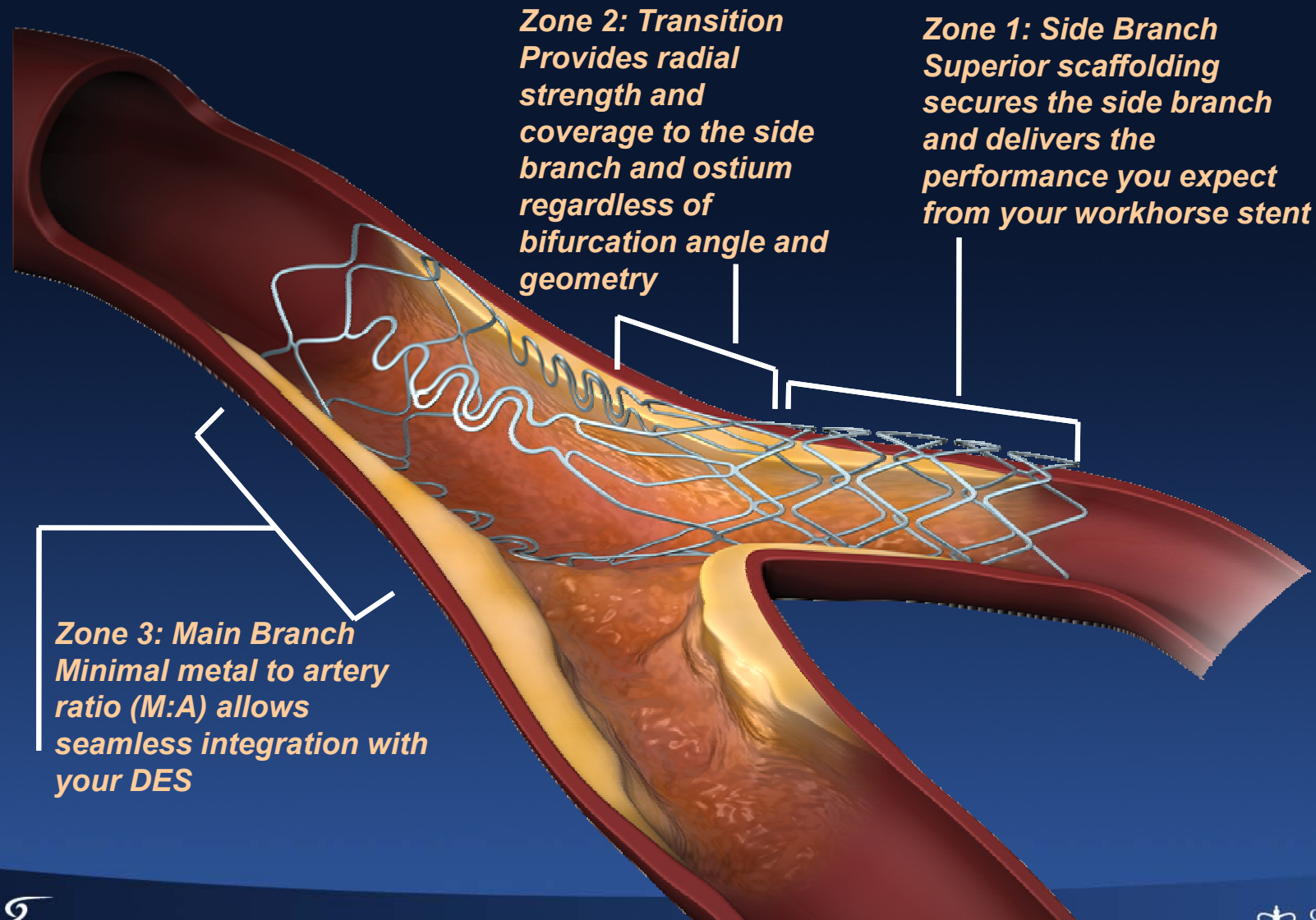


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Tryton Sidebranch Stent



Zone 2: Transition
Provides radial strength and coverage to the side branch and ostium regardless of bifurcation angle and geometry

Zone 1: Side Branch
Superior scaffolding secures the side branch and delivers the performance you expect from your workhorse stent

Zone 3: Main Branch
Minimal metal to artery ratio (M:A) allows seamless integration with your DES

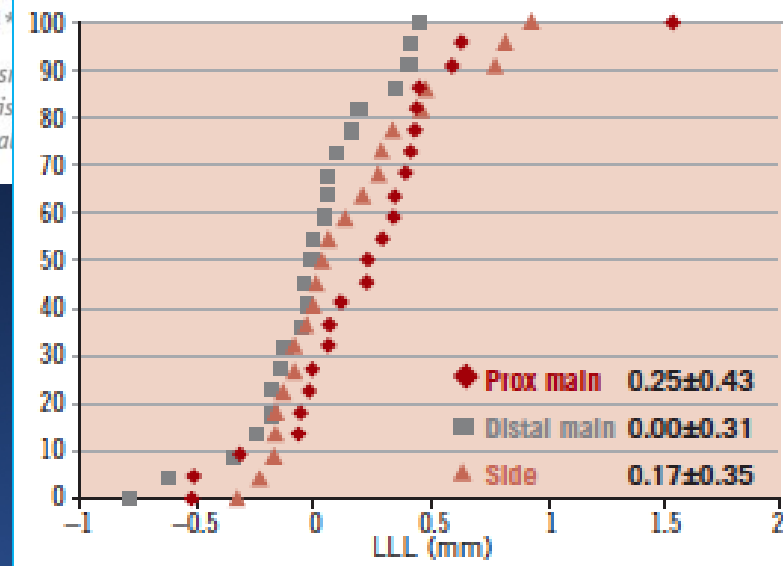
Tryton Clinical Experiences (*First-in-Man Angio FU*)

Tryton I, First-In-Man (FIM) study: six month clinical and angiographic outcome, analysis with new quantitative coronary angiography dedicated for bifurcation lesions

Yoshinobu Onuma¹, MD; Ralf Müller², MD; Steve Ramcharitar¹, MRCP DPhil; Robert-Jan M. van Geuns¹, MD, PhD; Yves Louvard³, MD; Marie-Angèle Morel⁴, BSc; Marie-Claude Morice³, MD; Richard Davis⁵, MSc; Aaron V. Kanlan⁶, MD; Thierry Lefèvre³, MD; Fherhard Grube², MD; Patrick Serruys^{1*}

1. Thoraxcenter, Erasmus
Cardiovasculaire Paris
6. Dartmouth Medical

y; 3. Institut
c. Newton, MA, USA;



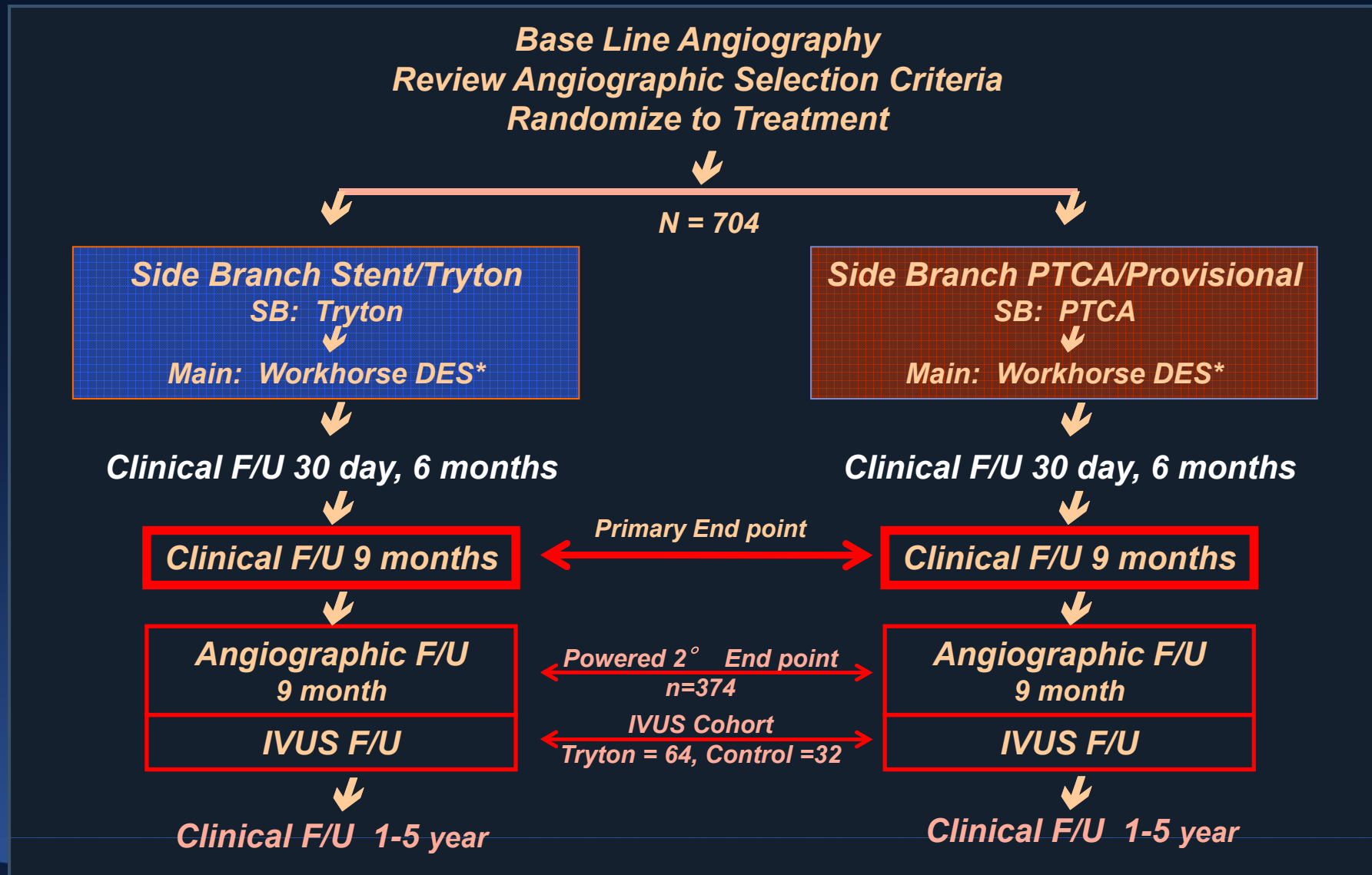
Sidebranch late loss = 0.17mm

TRYTON Clinical Experiences

(> 900 patients; TLR ≤ 4%)

Study/Registry	Published - Presented	Patients (FU)	FU (M)	TLR	Thrombosis Rate
Tryton Side-Branch Stent: First In Man	EuroInterv. 2008;3:546-552	30	6	3.3%	0%
IUVANT	Presented TCT 2010	31	9	3.2%	0%
Rotterdam-Poznan Real World Registry	CCI 77:798-806 (2011)	96	6	4.0%	0%
E-Tryton Registry I50-Benelux	Presented EuroPCR 2011 (submitted for publication)	296	6	3.0%	0.3%
Wolverhampton Experience	Poster Abstract TCT 2011	66	15 ^{††}	1.5%	0%
Dublin Experience	Poster Abstract TCT 2011	169	17.8 ^{††}	2.3%	0%
SAFE-TRY	Presented at JIM 2012	189	9	4.8%	0%
E-Tryton Spain	Poster Abstract TCT 2011	132	6	3.8%	0%
Total		> 900	—	≤ 4%	—

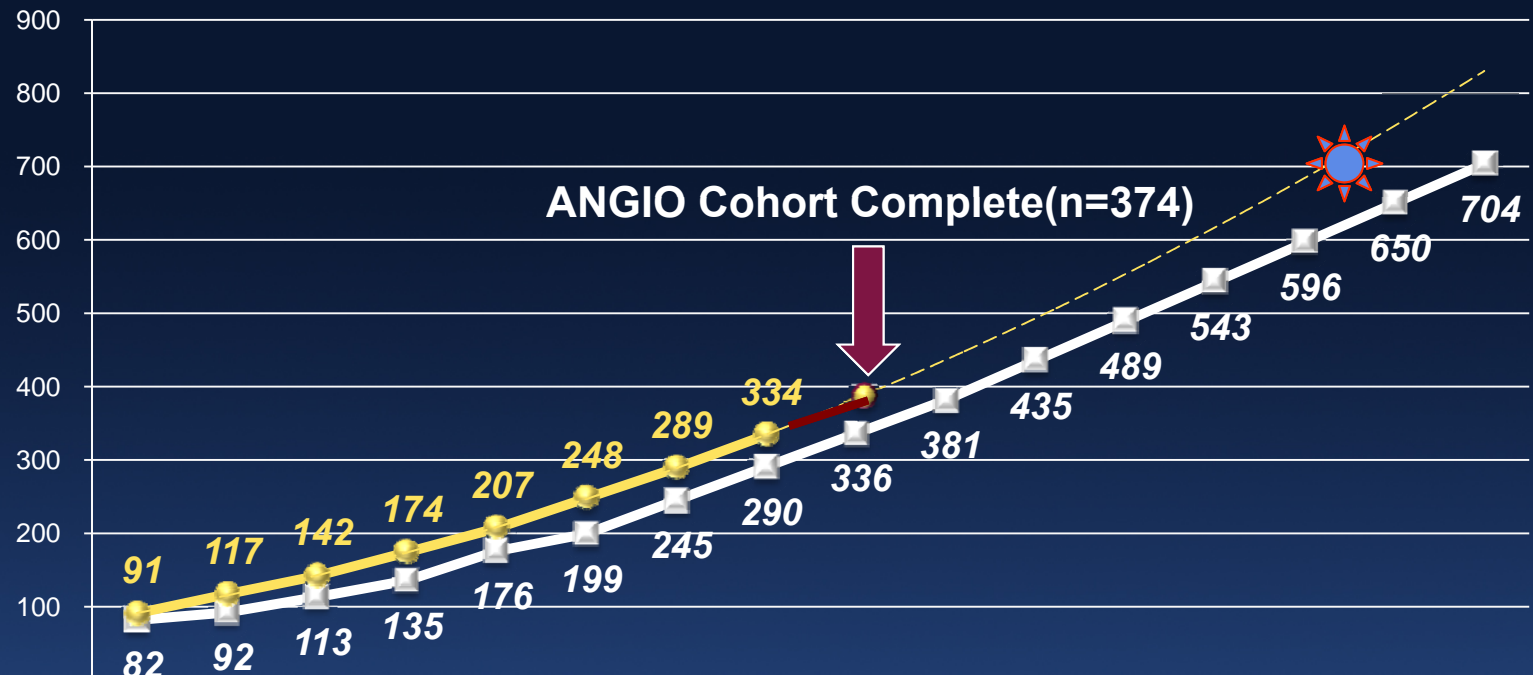
Tryton IDE Bifurcation Study



* Workhorse DES = Xience (V or Prime),
Promus (V or Element), or Resolute

Trial Status

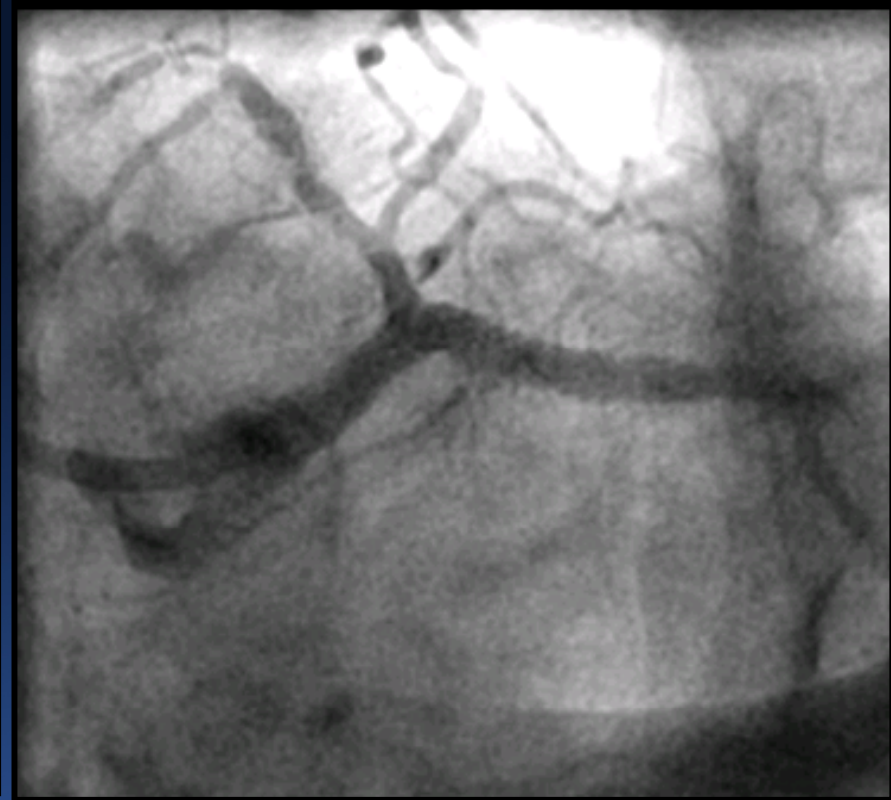
On-Track for Completion Early Fall



Cumulative	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT 12
Forecast	82	92	113	135	176	199	245	290	336	381	435	489	543	596	650	704
Actual	91	117	142	174	207	248	289	334	381							

Complex LM Bifurcation

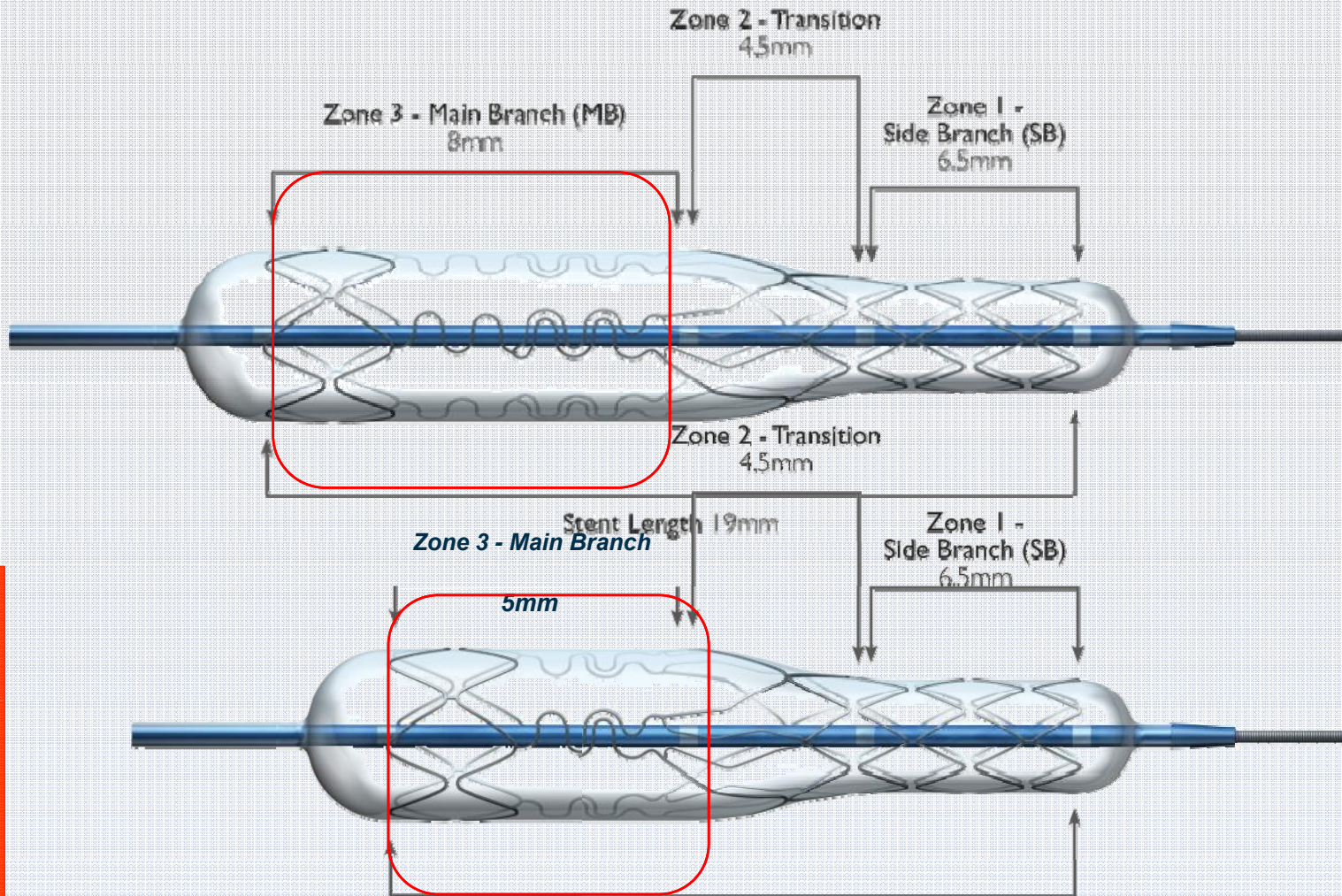
Treated with Tryton



Tryton Sidebranch Stent (Large Diameter Design)

CE-Marked

Under
Development



Tryton Sidebranch Stent (LM)



Tryton LM Registry: Acute procedural and 30 day outcome

Technical success	96% (22/23) *
Angiographic success	100% (22/22)
Dissection	
Main Vessel	0
Side Branch	2 (9%)
PCI related MI	2/22 (9%) [¶]
Procedural success	91% (20/22)
30-day outcome	
Cardiac death	0 (0%)
Myocardial infarction (MI)	2 (9%)
PCI-related MI	2 (9%)
TVR/TLR	0 (0%)
Stent Thrombosis	0 (0%)

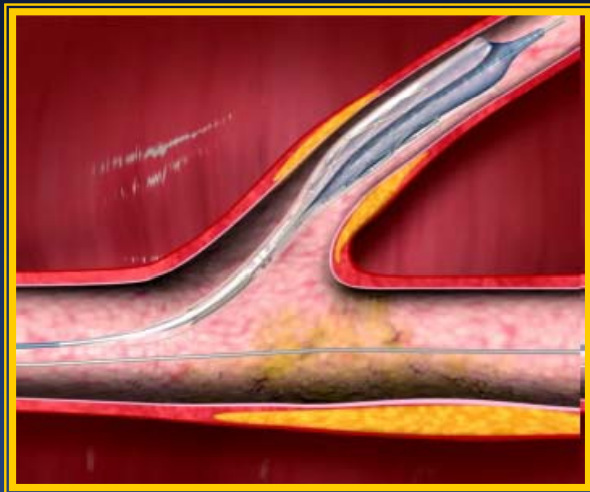
1 failure of delivery of the Tryton stent despite repeated predilatation

[¶] Both NSTEMI



Cappella Sideguard *Sidebranch Stent*

*Self-Expanding, Balloon-Actuated,
Anatomically-Shaped Coronary Side Branch Stent*



**Balloon-Actuated
Catheter System (3.1 Fr)**

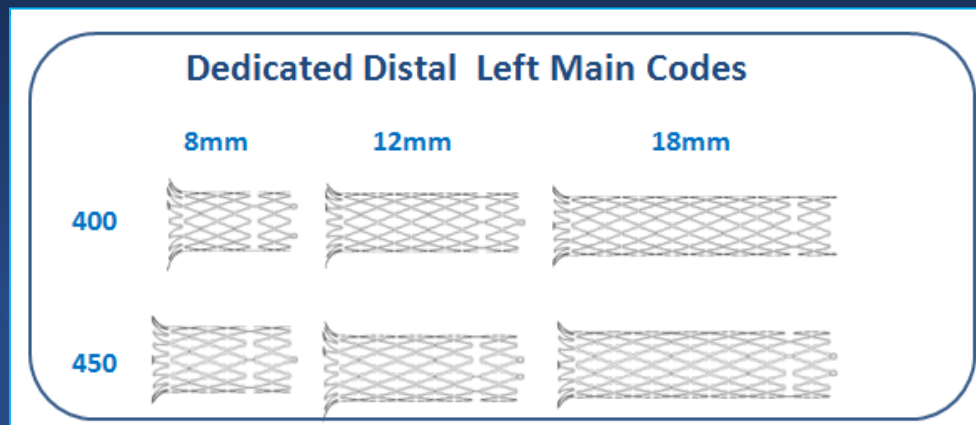
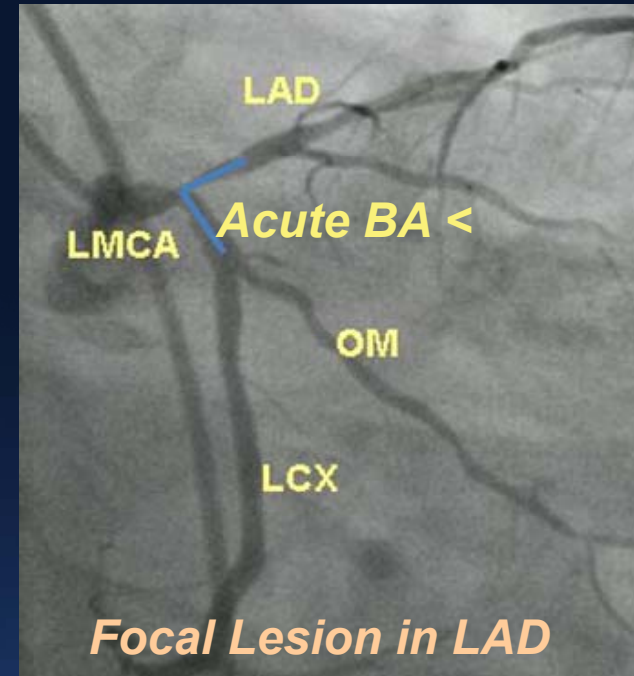
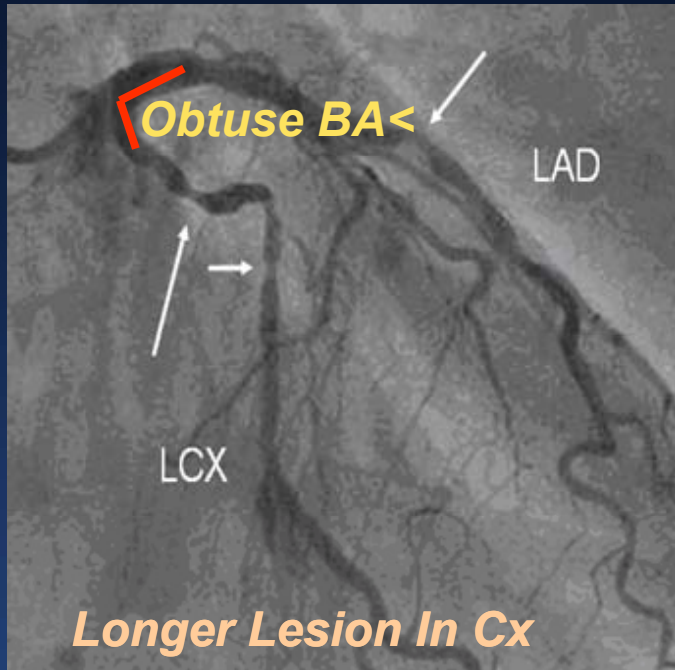


**Self-Expanding
Nitinol SB Stent**



**Anatomically-Shaped
Design**

Cappella Sideguard in Left Main

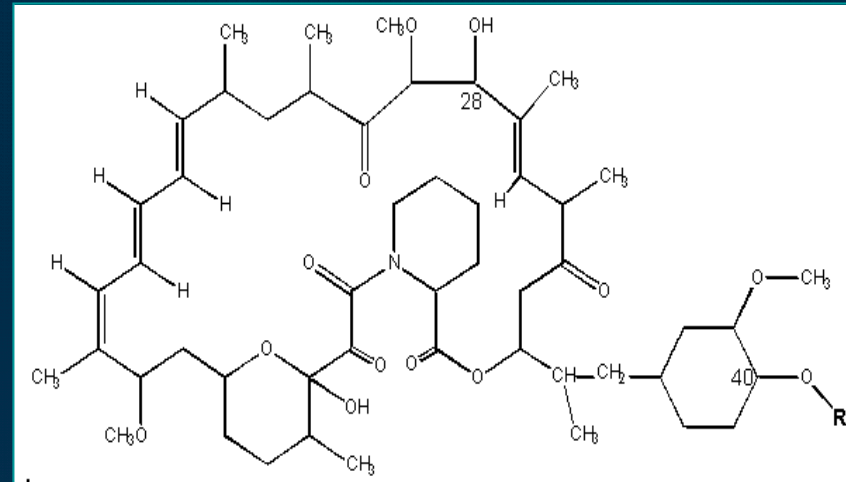
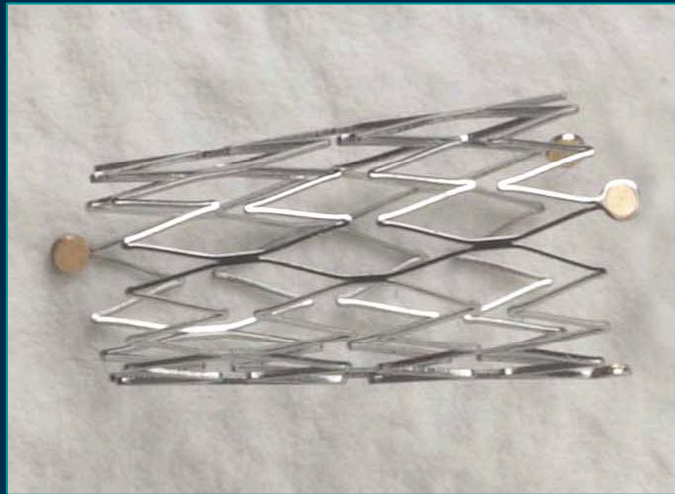


Dedicated Bifurcation/LM Stents

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Devax **AXXESS PLUS** *Carina Expansion for Bifurcations*



**AXXESS
Stent**

PLUS

**Biolimus-A9
Anti-proliferative &
Bioerodable Polymer**

DIVERGE: Drug Stent Intervention for Treating Side Branches Effectively

Prospective, Single-arm, Multicenter Registry

Patients with de novo bifurcated lesions in
native coronary arteries N=300

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

DIVERGE - Clinical Results

Cumulative 9 Month MACE

N completing follow up (%)	99.3% (300)
All-cause MACE	7.7%
<i>Any death</i>	0.7%
<i>Q wave MI</i>	1.0%
<i>Non-Q wave MI</i>	3.3%
<i>Ischemia-driven TLR - ALL BIFURCATION</i>	4.3%
<i>Exclusively side branch driven</i>	1.3%

DIVERGE - Stent Thrombosis

	Protocol		ARC		
	Definite*	Probable	Definite*	Probable	Possible
Acute (In-hospital)	0	0	0	0	0
Subacute (to 30 days)	0.7%	0	0.7%	0	0
Late (30 days - 9 months)	0.7%	0	0.3% [§]	0	0

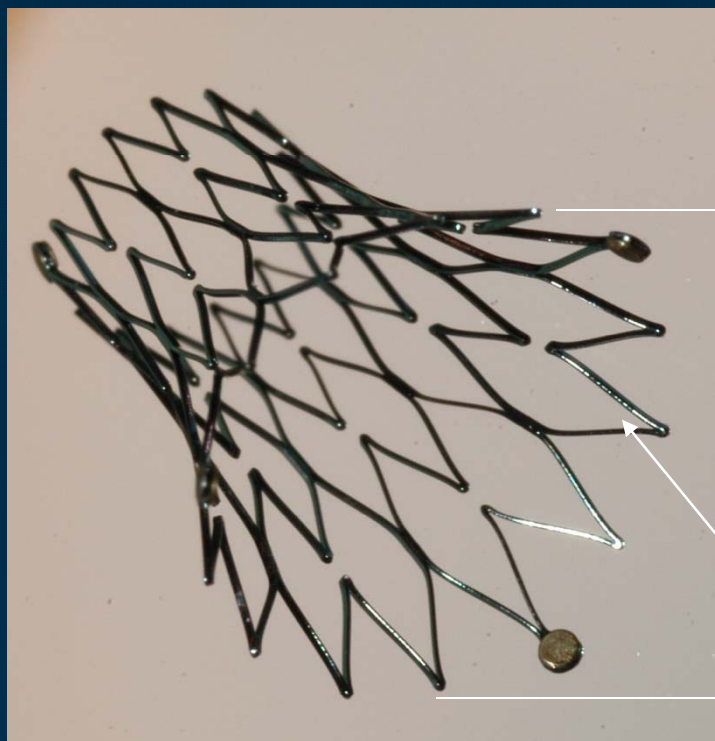
**All stent thrombosis in DIVERGE were confirmed with angiography.*

§ One case of asymptomatic chronic total occlusion is omitted in ARC classification but included in protocol definition.

DIVERGE - 9 Month QCA Results

At Follow Up		Parent Vessel (N=140)	Side Branch (N=140)
Late Loss (mm)	In-stent LL (AXXESS only)	0.18 ± 0.49	-
	In-stent LL (all stents)	0.29 ± 0.50	0.29 ± 0.45
	In-lesion LL	0.20 ± 0.41	0.17 ± 0.34
Restenosis <i>Per Vessel</i>	In-stent - AXXESS Only	0.7%	--
	In-stent - Cypher	2.3%	4.8%
	In-lesion restenosis (all stents + edges)	3.6%	4.3%
Overall Bifurcation Restenosis	In-stent - PV + SB	5.0% (7/140)	
	In-stent or edges, within PV + SB	6.4% (9/140)	

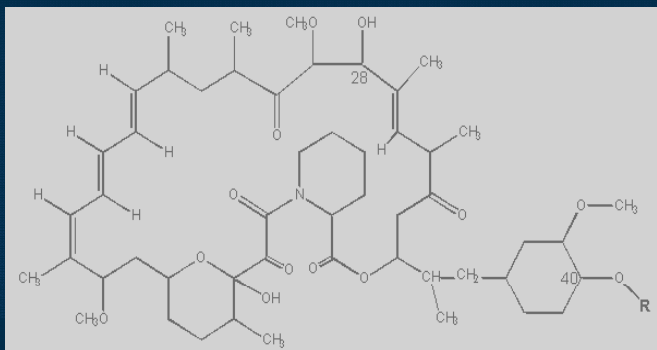
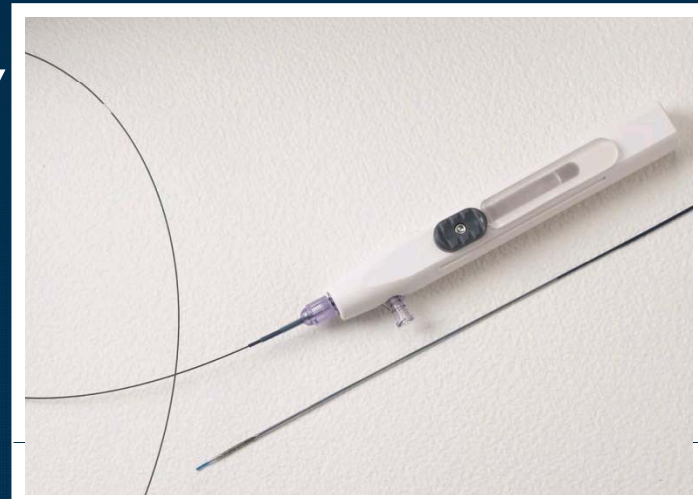
AXXESS PLUS LM System



Flared Distal-End Stent Design
Self Expanding Nitinol Material

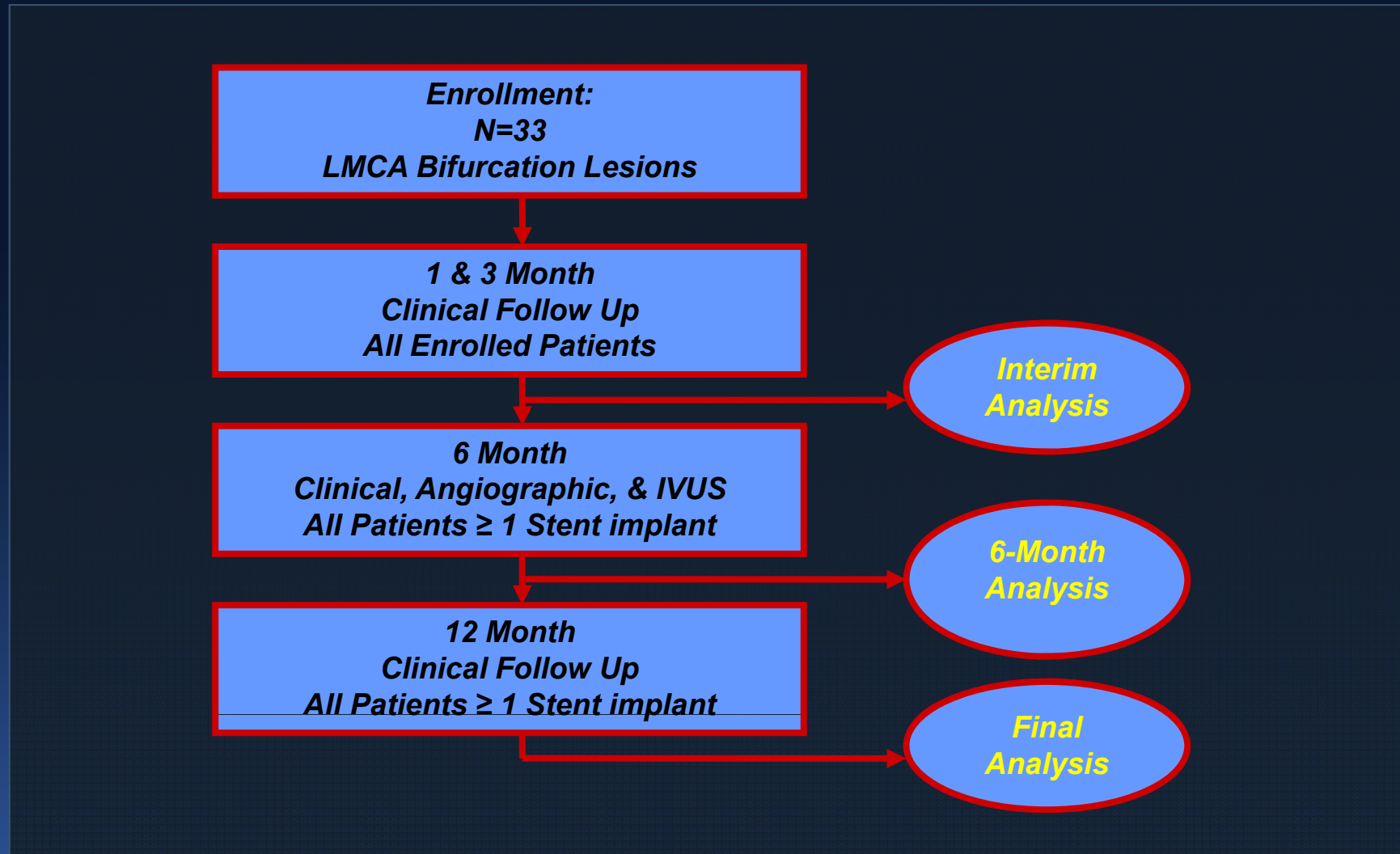
8, 10, or 12 mm
 flare diameter

4.8F Rx Delivery System



Biolimus A9
 antiproliferative
 strut coating

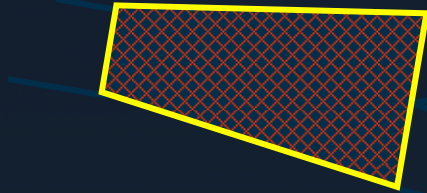
AXXENT FIM Study (Left Main)



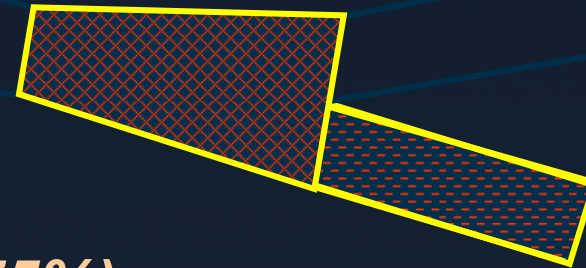
AXXENT LM FIM

Stent Implant Distribution

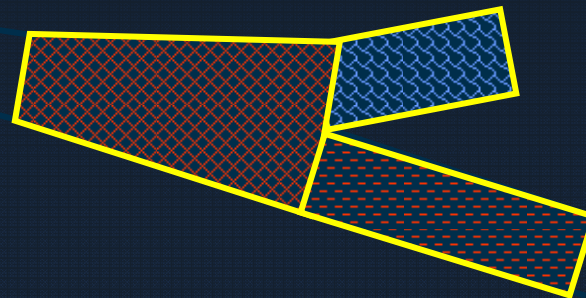
1 Stent: 2 (6%)



2 Stents: 6 (18%)



3 Stents: 23 (75%)



AXXENT LM FIM - Clinical Outcomes

<i>Follow Up Period</i>	<i>In-Hospital</i>	<i>Discharge-30 Days</i>	<i>Discharge-180 Days</i>
Death	0	0	0
MI			
QW	0	0	1 (3.0%) §
NQW	2 (6.1%)	0	0
TLR			
PCI	0	0	3 (9.1%) *
CABG	1 (3%)	0	0
Any MACE	2 (6.1%)	0	4 (12.1%)
Stent Thrombosis	0	0	0

**All TLR was in LCX § 180 day QWMI; RCA occl*

AXXENT LM FIM - Follow Up QCA

**N=31 Patients
with FU (94%)**

Left Main

**Left Anterior
Descending**

**Left
Circumflex**

Post Procedure

MLD- mm	3.63 ± 0.37	2.65 ± 0.41	2.47 ± 0.41
%DS	9.6 ± 5.3	13.7 ± 6.7	14.6 ± 6.6
Acute Gain- mm	1.80 ± 0.84	0.82 ± 0.71	0.96 ± 0.58

6 Month Follow Up

MLD- mm	3.59 ± 0.46	2.41 ± 0.62	2.03 ± 0.64
%DS	9.66 ± 8.5	20.6 ± 18.1	28.4 ± 21.5
Late Loss- mm	0.043 ± 0.32	0.24 ± 0.26	0.46 ± 0.69

Binary Restenosis

0%

2 (6.9%)

5 (16.1%)

Dedicated Bifurcation/LM Stents

Final Thoughts

Dedicated Bifurcation/LM Stents

Final Thoughts...

- Provisional bifurcation SB stenting is the consensus default strategy for many (? most) distal bifurcation/LM lesions.
- Current “off-the-shelf” two-stent approaches are controversial, non-uniform, and there are many technical issues which must be optimized.
- A “family” of dedicated bifurcation stents may be helpful to achieve improved outcomes in bifurcation/LM lesions; ease-of-use issues, design preferences and DES integration/need (esp. SB stents) still requires further clarification and clinical trial validation.