

# Complex PCI Bifurcations

## **Bifurcation-Dedicated Stents: A Description of the Clinically Available Devices and their Performance**

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Thursday, August 9<sup>th</sup> 2012 - Room Chapultepec, 18:40 to 19:00  
XVIII SOLACI Congress - Mexico City, Mexico

# Why Dedicated-Bifurcation Devices?

- Bifurcation PCI is still complex with suboptimal outcomes especially in lesion with complex morphology
- Current standard techniques clearly do not work for all lesion subsets
- Straight stents are not design for bifurcation anatomy – conical shape; different diameters; wide variation in angulation, lesion distribution and location; distortions, deformations are common
- Facilitate PCI procedure (?)

# AVAILABLE SYSTEMS

DEDICATED-BIFURCATION DEVICE	PARENT VESSEL	PARENT VESSEL WITH SIDE BRANCH ACCESS PORT	SIDE BRANCH	PARENT VESSEL + SIDE BRANCH
<b>NO ALIGNMENT NEEDED</b>	<ul style="list-style-type: none"> <li>- AXCESS *</li> <li>- STENTYS *</li> <li>- BIOSS</li> </ul>		<ul style="list-style-type: none"> <li>- BIGUARD</li> <li>- SIDEGUARD</li> <li>- TRYTON</li> </ul>	- ADVANCED BIFURCATION SYSTEMS
<b>SELF-ALIGNMENT</b>		<ul style="list-style-type: none"> <li>- NILE PAX</li> <li>- PETAL</li> <li>- SBA</li> <li>- SIDEKICK</li> <li>- TWIN-RAIL</li> </ul>		- Y-STENT
<b>ACTIVE ALIGNMENT</b>		- TRIREME		

\* *Self-expanding devices*

*Collet C., Int J Cardiovasc Imaging 2011;27:181-8*

# DRUG-COATED SYSTEMS

DEDICATED-BIFURCATION DEVICE	PARENT VESSEL	PARENT VESSEL WITH SIDE BRANCH ACCESS PORT	SIDE BRANCH	PARENT VESSEL + SIDE BRANCH
NO ALIGNMENT NEEDED	- <b>AXXESS *</b> - <b>BIOSS</b> - <b>STENTYS *</b>		- BIGUARD - SIDEGUARD - <b>TRYTON</b>	- ADVANCED BIFURCATION SYSTEMS
SELF-ALIGNMENT		- <b>NILE PAX</b> - <b>PETAL</b> - SBA - SIDEKICK - TWIN-RAIL		- Y-STENT
ACTIVE ALIGNMENT		- TRIREME		

\* *Self-expanding devices*

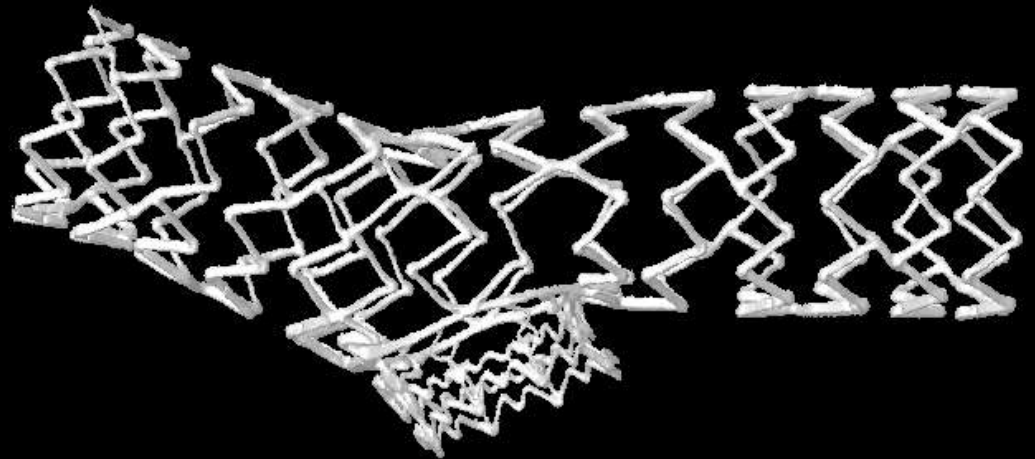
*Collet C., Int J Cardiovasc Imaging 2011;27:181-8*

**BALLOON-EXPANDABLE  
DEDICATED DEVICES**

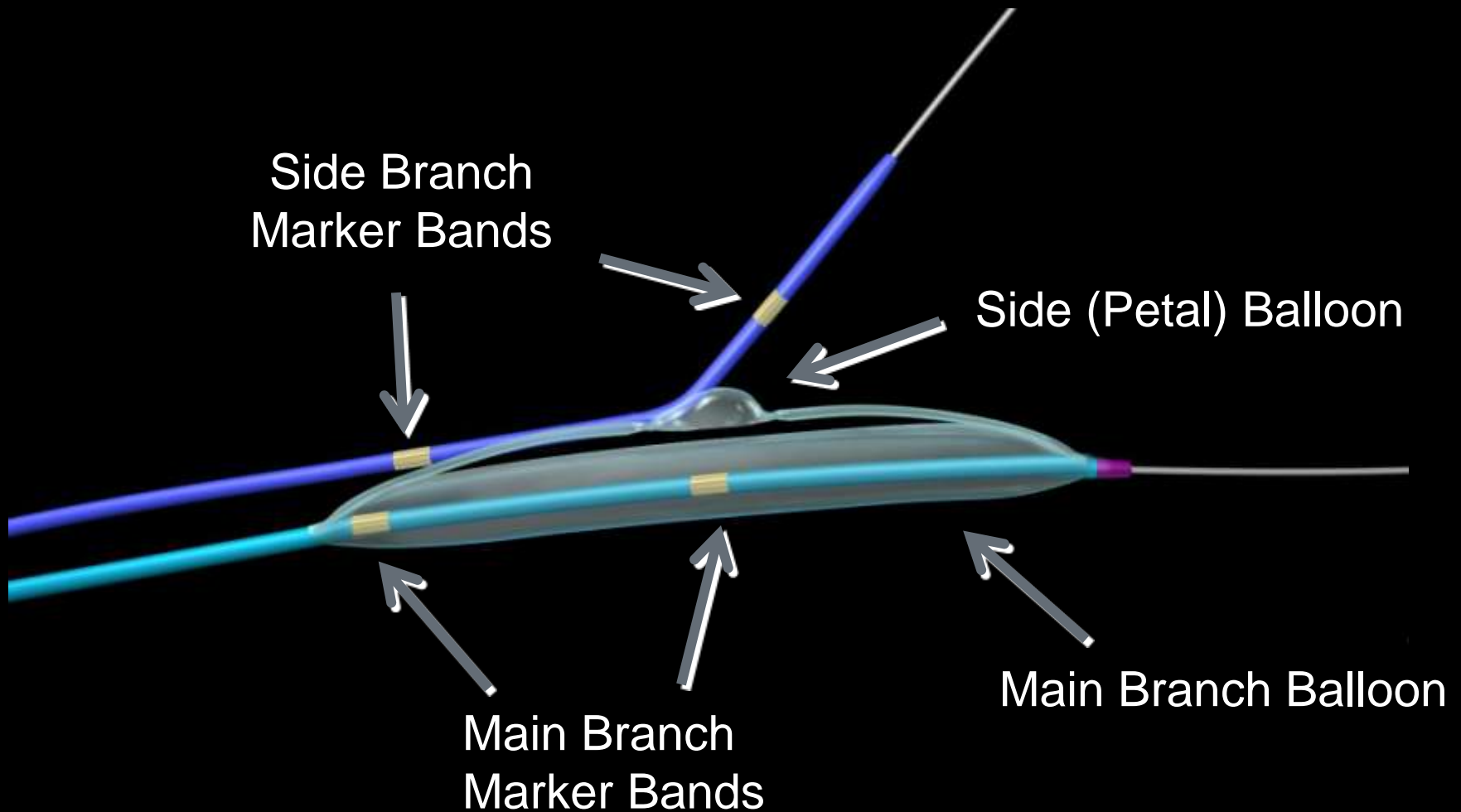
# **PETAL (Boston Scientific)**

# TAXUS Petal Bifurcation Stent

- Unique petal elements project into side branch ostium supporting and applying drug where restenosis is most common
- Constructed from platinum chromium
- 8F compatible

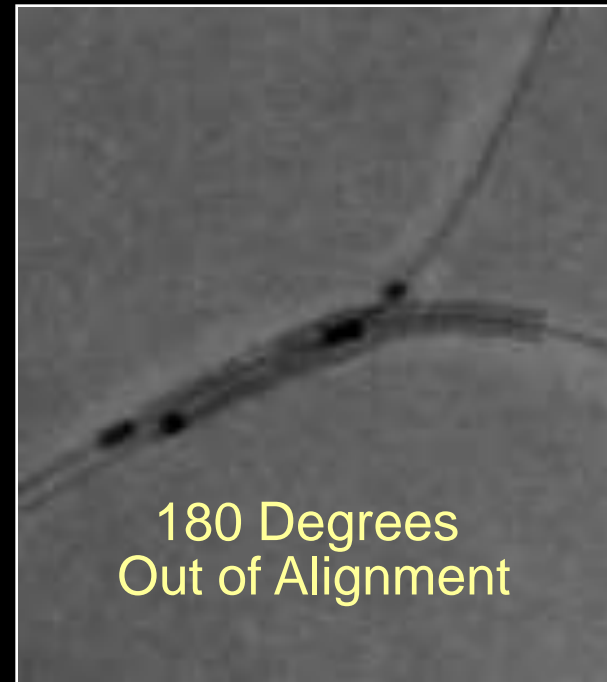


# TAXUS Petal Bifurcation Stent Delivery Balloons



# Petal Stent Alignment

- Delivers over 2 wires so protects the side branch
- Must rotate passively to align
- 4 marker bands to indicate correct alignment



# TAXUS Petal Trial Study Design

- Prospective, single-arm study; N=28
- 3 sites (New Zealand, France, Germany)
- Primary endpoint: 30-day death, MI, TVR

## *Key Lesion Criteria*

Lesion Type	De novo bifurcation lesion
Bifurcation Angle	$\geq 30^\circ$ and $\leq 90^\circ$
Main Branch (mm)	RVD $\geq 3.0$ – $\leq 3.5$ ; lesion length $\leq 20^a$
Side Branch (mm)	RVD $\geq 2.25$ – $\leq 3.5$ ; lesion length $\leq 14^b$

a: Covered by TAXUS<sup>®</sup> Petal<sup>™</sup> stent plus  $\leq 1$  TAXUS stent ( $\leq 12$  mm)

b: Treated by  $\leq 1$  TAXUS stent ( $\leq 16$  mm)

# Baseline Lesion Characteristics

<i>Variable<sup>a</sup></i>	<i>Main Branch</i>	<i>Side Branch</i>	
RVD (mm)	2.91±0.28	2.23±0.33	
MLD (mm)	1.18±0.38	1.31±0.55	
DS (%)	59.67±12.33	41.59±20.77	
Length (mm)	13.83±5.86	4.35±2.45 <sup>b</sup>	
<i>Baseline Medina Classification (N=28)</i>			
0.1.0	17.9% (5)	1.0.1	7.1% (2)
0.1.1	7.1% (2)	1.1.0	32.1% (9)
1.0.0	14.3% (4)	1.1.1	21.4% (6)

a: Determined by quantitative coronary angiography (QCA)

b: N=10 patients with side branch disease per Medina classification

DS=diameter stenosis; MLD=minimum lumen diameter

# Procedural Outcomes

Technical success <sup>a</sup>	96.4% (27/28)
Clinical procedural success <sup>b</sup>	92.9% (26/28)
TAXUS Petal Stent implanted	89.3% (25/28)
Non-Petal Stent implanted	MB: 35.7% (10); SB: 25.0% (7)
<b>Petal implant success per device</b>	<b>73.5% (25/34)</b>

a: Residual lesion percent diameter stenosis <30% (Main Branch) & <50% (Side Branch ostium) and TIMI flow 3 (MB & SB) attained with any device

b: No in-hospital death, MI, or target vessel revascularization associated with MB or SB

*Wire wrap & wire bias impaired delivery & rotational alignment in some cases*

# Angiographic Outcomes

<i>Analysis Segment</i>	<i>Main Branch Proximal</i>	<i>Main Branch Distal</i>	<i>Side Branch</i>
<u><i>Pre-Procedure (N=28)</i></u>			
RVD (mm)	3.32±0.39	2.51±0.30	2.23±0.33
Min Lumen Diam (mm)	1.28±0.59	1.08±0.55	1.31±0.55
% Diameter Stenosis	61.72±16.70	56.72±20.74	41.59±20.77
<u><i>Post Procedure (N=28)</i></u>			
RVD (mm)	3.31±0.37	2.48±0.33	2.22±0.34
Min Lumen Diam (mm)	2.83±0.41	2.25±0.37	1.70±0.38
% Diameter Stenosis	14.59±7.53	9.53±7.20	23.08±13.66
<u><i>6 Months (N=21)</i></u>			
RVD (mm)	3.13±0.34	2.43±0.29	2.11±0.29
Min Lumen Diam (mm)	2.31±0.55	1.89±0.56	1.61±0.47
Late Loss (mm)	0.47±0.45	0.41±0.57	0.18±0.39
% Diameter Stenosis	26.33±16.00	22.40±20.41	23.91±19.87
Restenosis (% , n)	9.5 (2)	9.5 (2)	9.5 (2)

Data are mean±SD

Presented by J. Ormiston at PCR 2010 – Ormiston J., EuroIntervention 2010;6:46-53

# Clinical Outcomes through 1 Year

	30D (N=27)	6M (N=27)	1Y (N=27)
<i>Primary endpoint = 3.7%</i>			
All death, MI, TVR (%)	3.7% (1)	14.8% (4)	14.8% (4)
All death (%)	0.0% (0)	0.0% (0)	0.0% (0)
Myocardial infarction (%)	3.7% (1)	3.7% (1)	3.7% (1)
Q-Wave MI (%)	0.0% (0)	0.0% (0)	0.0% (0)
Non-Q-Wave MI (%)	3.7% (1) <sup>a</sup>	3.7% (1) <sup>a</sup>	3.7% (1) <sup>a</sup>
TVR (Overall) (%)	0.0% (0)	11.1% (3)	11.1% (3)
TLR (Overall) (%)	0.0% (0)	7.4% (2) <sup>b</sup>	7.4% (2) <sup>b</sup>
TVR, non-TLR (%)	0.0% (0)	3.7% (1)	3.7% (1)
Stent thrombosis <sup>c</sup> (%)	0.0% (0)	0.0% (0)	0.0% (0)

Data are binary rates.

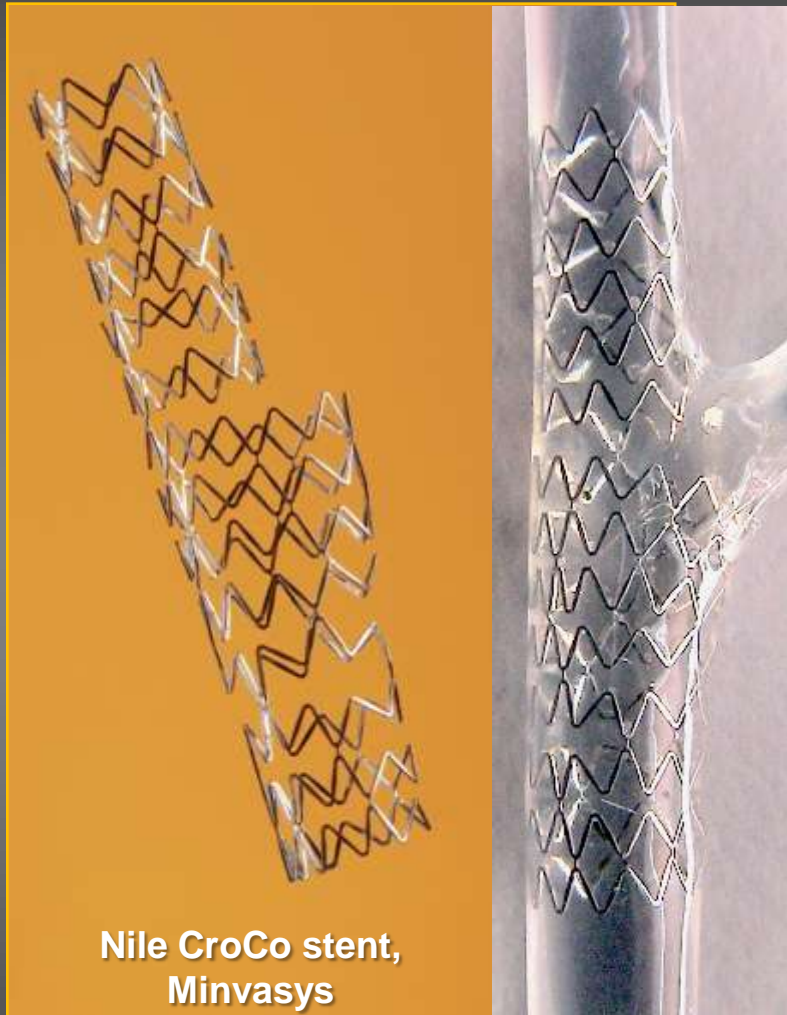
a: Thought to be secondary to stenting over a second side branch

b: One TLR at 183 days (non-Petal stent); one at 185 days; one TLR involved both main & side branches

c: Definite/probable (ARC definitions)

# **NILE PAX (Minvasys SAS)**

# Study Device – Nile CroCo<sup>®</sup> Stent

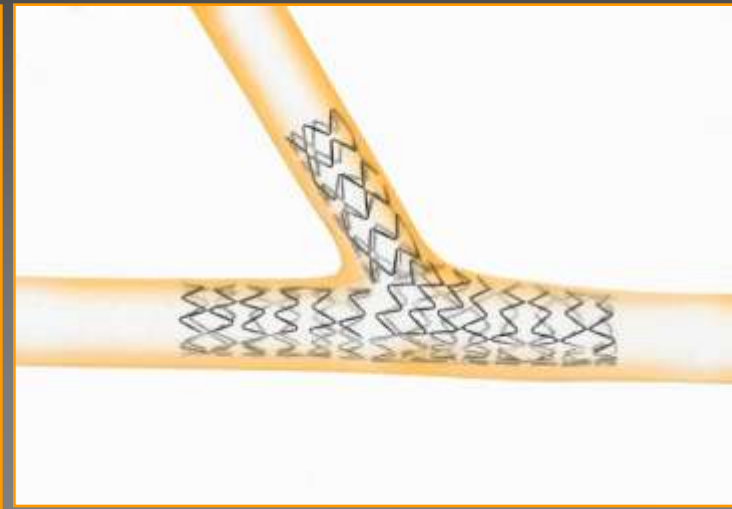


Nile CroCo stent,  
Minvasys

CE Marked since 2005, >4,500 pts treated to date



Delta stent, Minvasys



## Available measures:

MB diameter	SB diameter		
	2.5 mm	2.0 mm	-
3.0 mm	2.0 mm	2.5 mm	-
3.5 mm	2.5 mm	3.0 mm	3.5 mm

Length: **18 mm** for all diameters (now 24 mm)

Delta measures: 2.5 and 3.0 x 8 mm

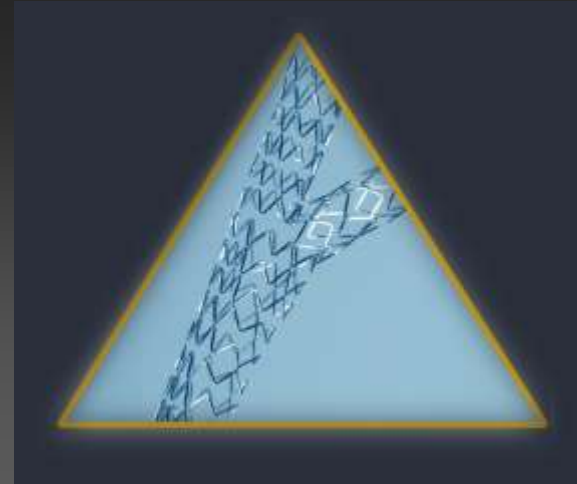
MB = main branch, SB = side branch



# Study Device Platform



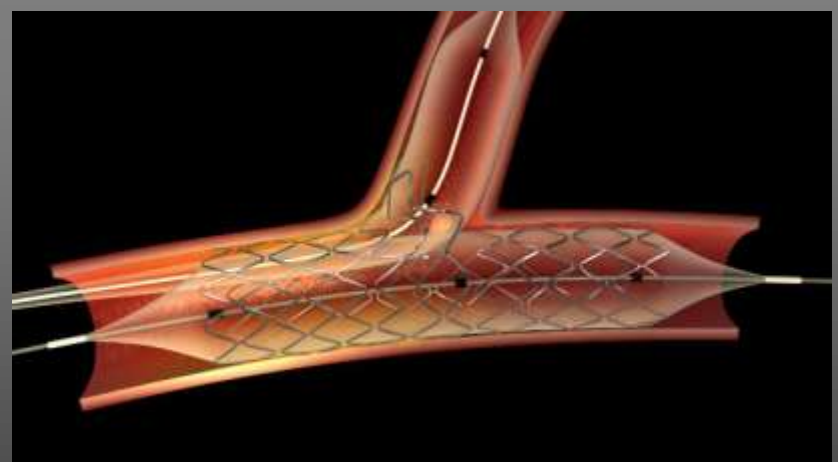
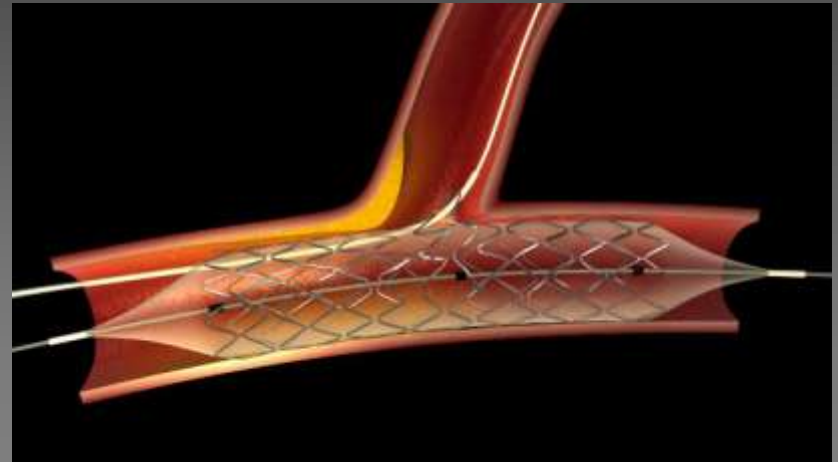
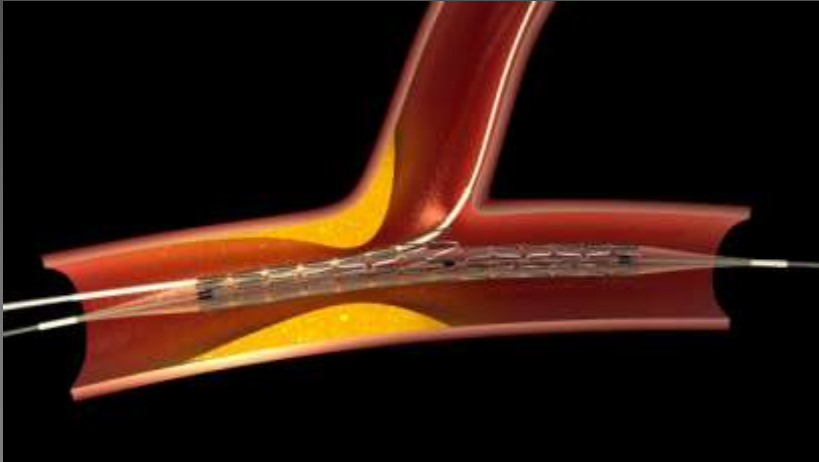
- Dedicated delivery system
- 2 independent Rx-PTCA catheters
- Ultra-low profile balloon combination
- Side branch balloon already engaged
- Conical side branch balloon shape
- 6-Fr. compatible



- Dedicated bifurcation stent
- Cobalt-Chromium alloy
- 73 $\mu$  stent thickness
- Modular stent design allowing carina coverage without cells overstretching
- No angulation restrictions

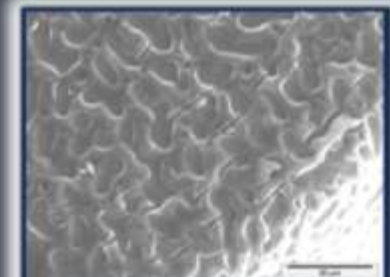
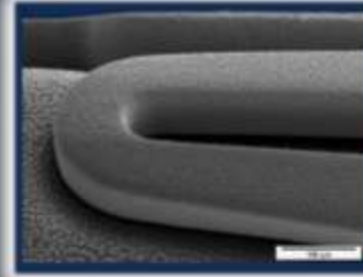
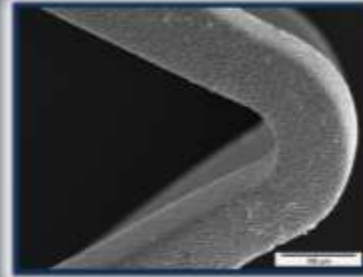


# Implant Steps



# PAX DES Technology

- Smooth stent surface
- Abluminal coating (5 $\mu$ m thickness) applied on crimped stent
- Consistent proprietary coating ensuring 98% of the drug delivered to the site
- Polymer-free DES system
- Potent antiproliferative agent Paclitaxel on dosage of 2.5 $\mu$ g/mm<sup>2</sup>
- Boost-release (60% in 2 days), profile release established in 30 days (98% of the drug) → Back to bare Cobalt-Chromium after 45 days



# BIPAX Trial Design

- Prospective, non-randomized, single-arm, multicenter clinical evaluation of the novel Nile PAX bifurcation dedicated drug-eluting stent system
- **Principal Investigator:** *Jean Fajadet, MD* – Clinique Pasteur, Toulouse, France
- **Enrollment:** 101 pts at 10 sites in Europe / South America
- **Clinical follow-up:** 1, 6, 9, and 12 months and yearly up to 5 yrs. Angiographic follow-up (mandatory): 9 months
- **Data Center/CEC:** Cardiovascular Research Center, São Paulo, Brazil – Director, *Andrea Abizaid, MD, PhD*
- **Angiographic Core Lab:** Cardiovascular Research Center, São Paulo, Brazil – Director, *Ricardo A. Costa, MD, PhD*
- **Sponsor:** Minvasys SAS, Gennevilliers, France



# Inclusion Criteria

- $\geq 18$  years of age
- Single *de novo* bifurcation lesion
- Vessel size:
  - 2.5-3.5 mm in the main branch (MB)
  - 2.0-3.0 mm in the side branch (SB)
- Lesion length:
  - $\leq 14$  mm in the MB
  - $\leq 5$  mm in the SB
- Acceptable candidate for CABG
- Comply with all schedule follow-ups including 9 months angiographic follow-up



# Angiographic Data

## VARIABLE

N=101 (102 lesions)

Target bifurcation lesion

LAD/Dg

80% (82)

LCx/OM

14% (14)

RCA (PDA/PLSA)

6% (6)

Lesion type (Medina classification)

1,1,1

29% (30)

1,0,1

16% (16)

0,1,1

17% (17)

1,1,0

10% (10)

1,0,0

13% (13)

0,1,0

16% (16)

Calcium (moderate/severe)

34% (35)

Normal LV function (EF >50%)

55% (55)

62%



# Procedural Outcomes

VARIABLE	N=101 (102 lesions)
Radial access (6-Fr.)	43% (43)
IIb/IIIa inhibitor use	4% (4)
Predilatation MB / SB	95% (97) / 35% (36)
Wire “tangling” / solved	41% (42) / 40 of 42
Study stent implanted	99% (101)
Stent implanted in SB (Delta PAX)	26% (26)
Single postdilatation MB / SB	27% (27) / 17% (17)
Final kissing-balloon inflation	93% (95)
Device success	98% (100)
Lesion success	98% (100)
Procedural success	97% (98)

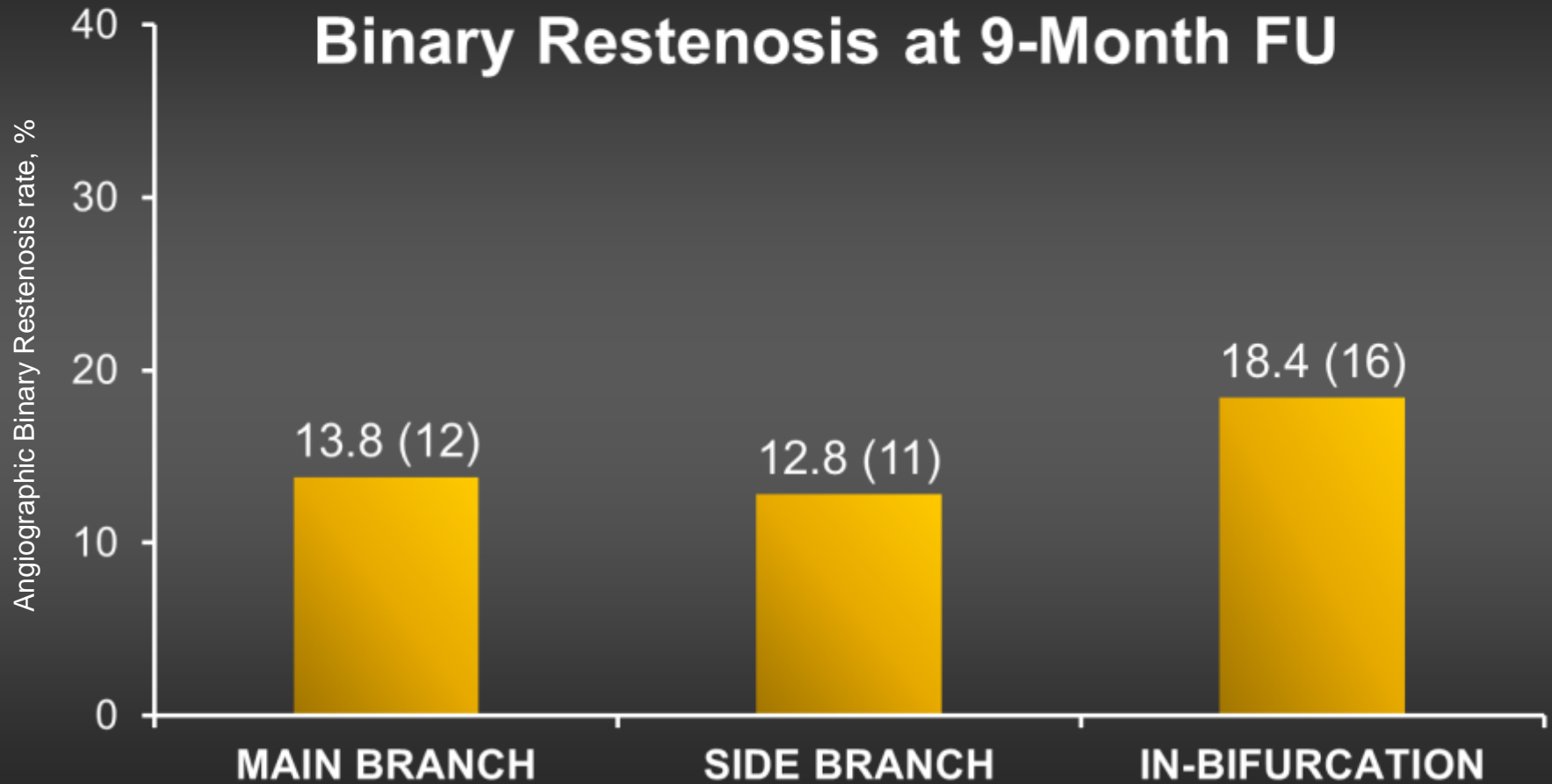


# 9-Month Angiographic FU

VARIABLE (N=92)	MB	SB
In-stent		
MLD, mm	1.63 ± 0.55	1.38 ± 0.43
% DS, mm	32.6 ± 17.5	36.4 ± 21.4
Late lumen loss, mm	0.93 ± 0.55	0.73 ± 0.41
In-segment		
MLD, mm	1.56 ± 0.51	1.47 ± 0.46
% DS	34.1 ± 18.3	34.9 ± 19.8
Late lumen loss, mm	0.70 ± 0.52	0.33 ± 0.48

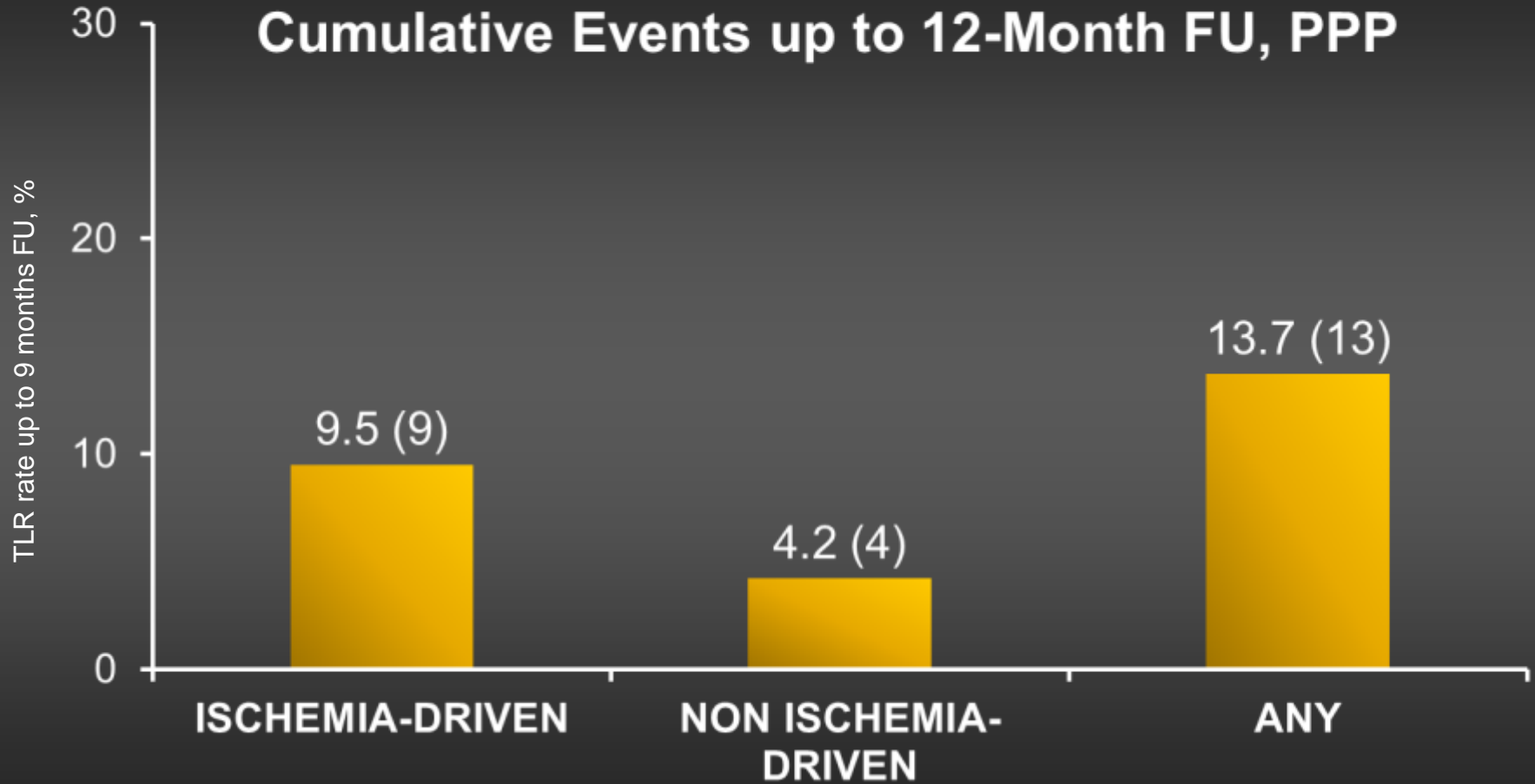
# Primary Endpoint – PPP

N=87



# Target Lesion Revascularization

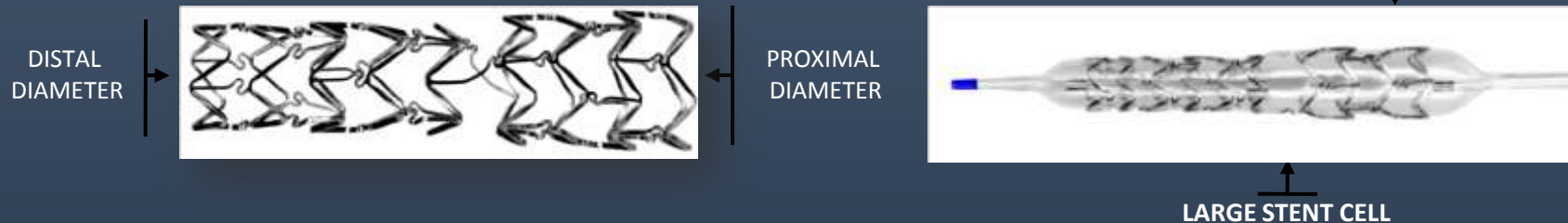
N=95

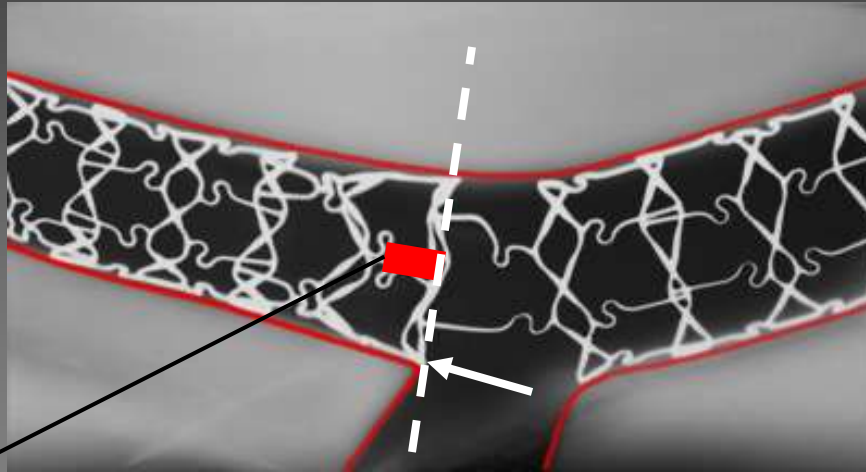


# **BIOSS (Balton)**

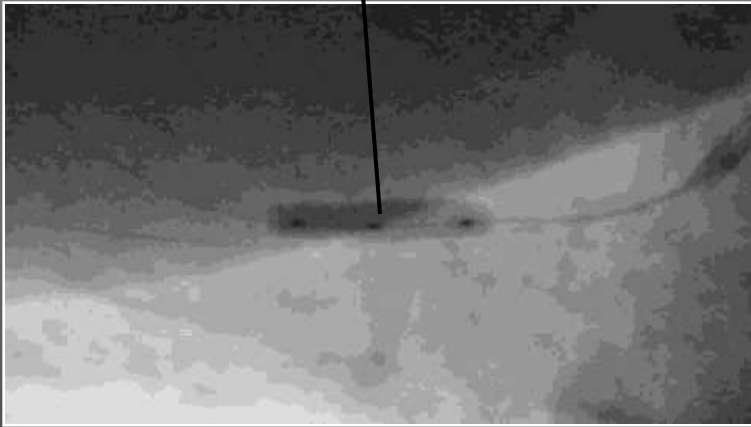
# Bifurcation Optimized Stent Systems - BIOSS®

- Unique configuration of the delivery system ensures safety and efficacy during the BioSS stent implantation procedure
- First dedicated for bifurcation delivery system guided on single guide wire
- One special balloon with two diameters corresponding to main vessel and main branch diameters





Mid –marker of the delivery system



**IMPORTANT: mid marker shall be placed in line with carina tip**

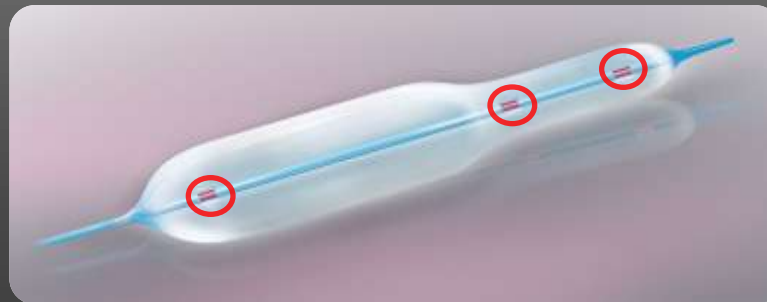
You will earn:

- Anatomically fitted stent which correspond with physiological vessel diameters
- Not disturbed SB blood flow
- Easy access to SB through large stent cell

# Delivery System – BOOTLE<sup>®</sup> ANGIOPLASTY BALLOON CATHETER FOR BIFURCATION



	Distal [mm]	Proximal [mm]
Balloon diameters	3.75	4.50
	3.50	4.25
	3.00	3.50
	3.00	3.75
	2.75	3.50
	2.50	3.25
	Balloon length	10, 15, 18, 23 mm
Use with guiding catheter	5F	
Guide wire compatibility	.014"	
Nominal pressure / RBP	10 atm. / 16 atm.	
Delivery system type	Rapid Exchange	



# AVAILABLE SIZES

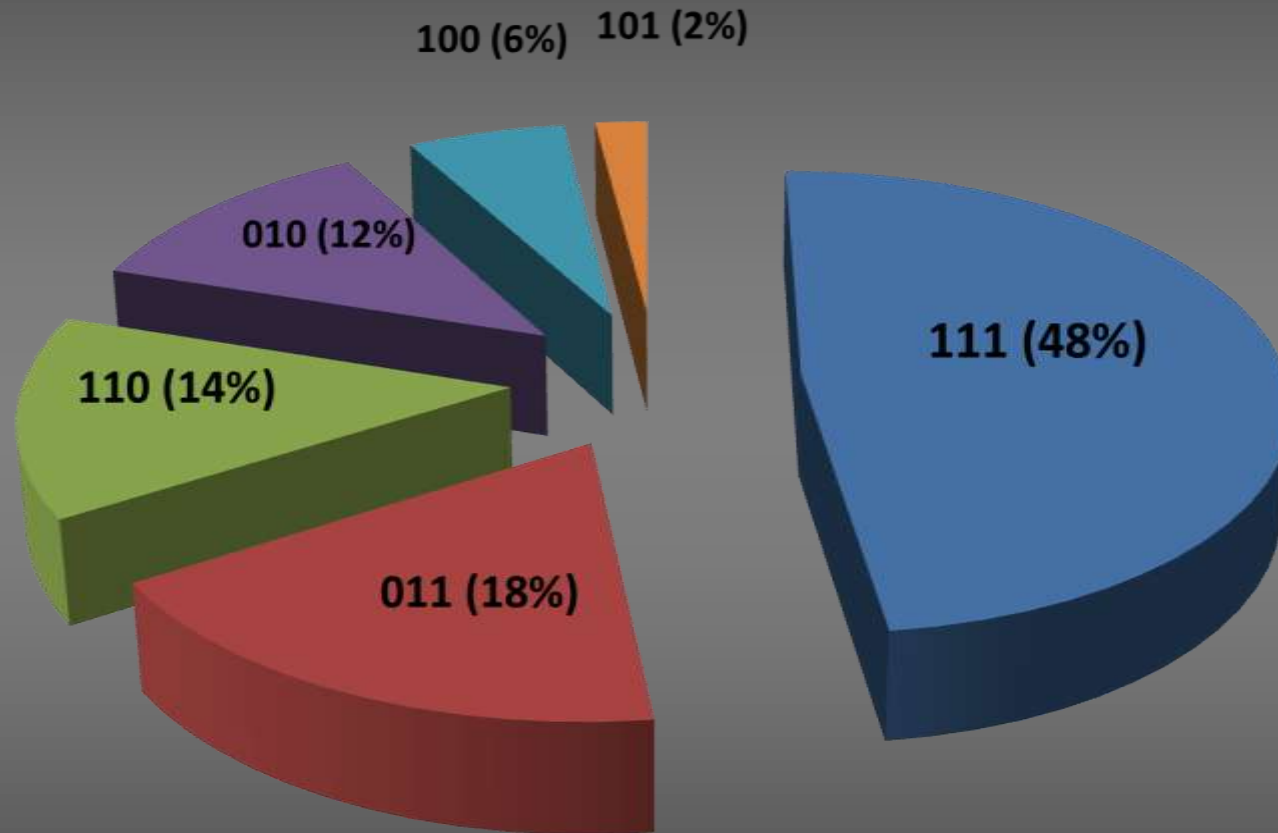
Stent total length [mm]	Proximal diameter [mm]	Distal diameter [mm]
15.00	4.50	3.75
	4.25	3.50
	3.75	3.00
	3.50	3.00
	3.50	2.75
	3.25	2.50
18.00	4.50	3.75
	4.25	3.50
	3.75	3.00
	3.50	3.00
	3.50	2.75
	3.25	2.50
23.00	4.50	3.75
	4.25	3.50
	3.75	3.00
	3.50	3.00
	3.50	2.75
	3.25	2.50

# BiOSS Registry (paclitaxel-coated system)

## FIM safety and feasibility study

- Primary end-point – MACE event rates at 12 months
- Secondary end-points
  - Device performance – implantation failure rates
  - Periprocedural safety – rate of periprocedural SB compromise (SB closure rates, elev. CK-MB)
  - Angiographic (after 9 months):
    - Late Lumen Loss (LL)
    - Percent Diameter Stenosis (%DS)
    - Binary restenosis rate

# MEDINA Types (n=63)



# ANGIOGRAPHIC CHARACTERISTICS

Angiographic characteristics	Before stent		After stent		p – value
Main vessel					
MV – RVD, mm	3.41	0.51	3.46	0.36	NS
MV - % DS	49%	15%	8%	13%	p < 0.001
Main branch					
Main branch – RVD, mm	2.72	0.49	2.79	0.37	NS
MB - %DS	51%	11%	2%	18%	p < 0.001
MB lesion length, mm	16	3			
Side branch					
SB – RVD, mm	2.39	0.45	2.34	0.41	NS
SB - %DS	55%	21%	63%	16%	NS
SB - %DS – final, mm			39%	21%	
SB lesion length, mm	4.1	1.46			
Angle alpha, degrees	40	15	39	16	NS
Angle A, degrees	58	18	53	17	P = 0.04

# Cumulative clinical results – 12 month (out of hospital)

- Death – 2/63 (3.2%): *1<sup>st</sup> - 3 months after index PCI - LAD/D*  
*2<sup>nd</sup> – 10 months after PCI – LM/LAD*
- Myocardial infarction – 0%
- Stroke – 0%
- ST – 0%
- TLR – 7/63 (11%): *3x CABG, 2x POBA, 2x Stent*
- TVR – 9/63 (14.3%)
- Overall MACE (death, MI, stroke, TVR) – 9/63 (14.3%)
- PCI in other vessel not related with BiOSS vessel – 15/63 (23.8%)

**TRYTON (Tryton Med.)**

# Tryton Side Branch Stent™

## Zone 2: Transition

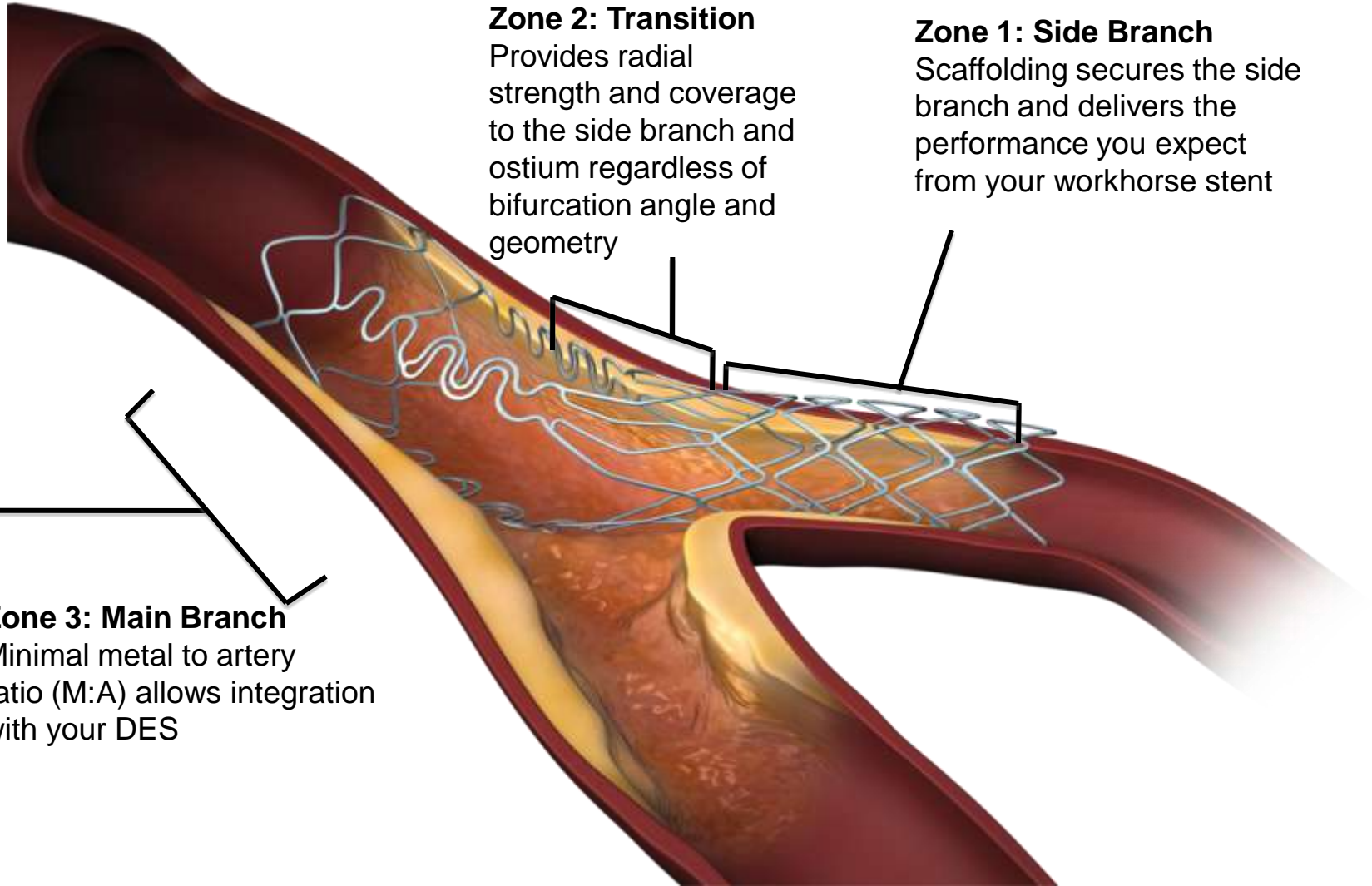
Provides radial strength and coverage to the side branch and ostium regardless of bifurcation angle and geometry

## Zone 1: Side Branch

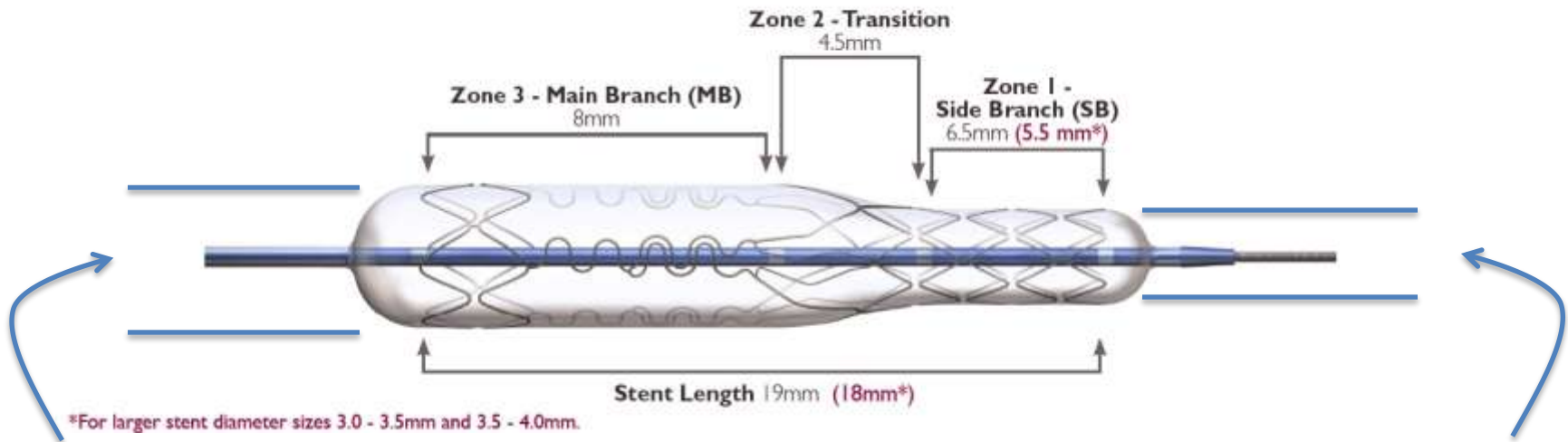
Scaffolding secures the side branch and delivers the performance you expect from your workhorse stent

## Zone 3: Main Branch

Minimal metal to artery ratio (M:A) allows integration with your DES



# Stent/Stent Delivery System Sizes

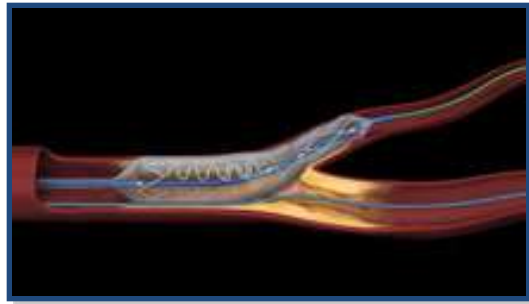


Main Branch Diameter (mm)	Side Branch Diameter (mm)
2.5	2.5
3.0	2.5
3.5	2.5
3.5	3.0
4.0	3.5

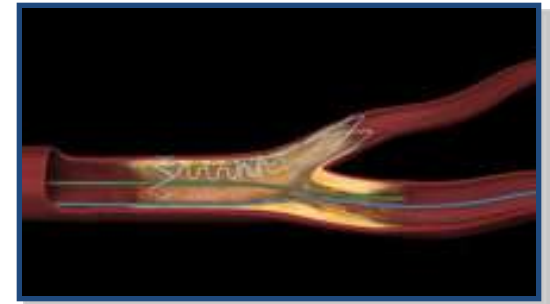
# Tryton Deployment Procedure



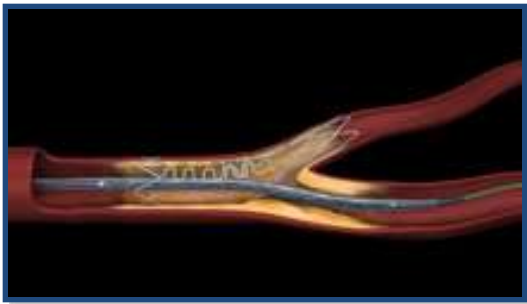
Position Side Branch Stent



Deploy Side Branch Stent



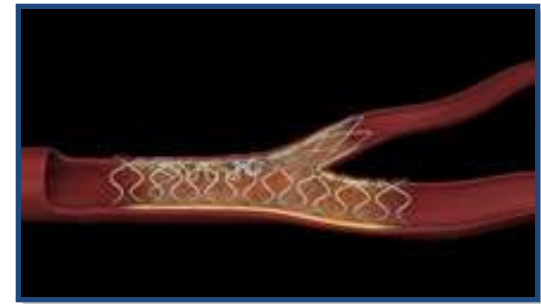
Advance Wire into Main Branch



Position Main Vessel Stent



Kissing Post-Dilatation of Bifurcation



Procedure Complete

# Tryton I – FIM Study Main Outcomes

Table 4. Angiographic parameters from the patient having angiographic follow-up (n=23).

	Pre	Post	Follow-up	P-value
<b>PMB</b>				
MLD (mm)	1.31±0.36	2.58±0.29	2.34±0.47	0.01
Reference diameter (mm)	2.46±1.20	3.15±0.29	2.98±0.24	0.11
%DS	42.0±42.3	17.3±17.3	20.8±21.0	0.67
<b>DMB</b>				
MLD (mm)	1.40±0.53	1.97±0.45	1.97±0.41	0.84
Reference diameter (mm)	2.01±0.63	2.50±0.36	2.41±0.35	0.33
%DS	33.9±19.7	22.1±13.3	20.5±10.2	0.36
<b>SB</b>				
MLD (mm)	1.22±0.36	1.72±0.36	1.55±0.28	0.08
Reference diameter (mm)	1.88±0.38	2.11±0.25	1.89±0.26	0.002
%DS	34.4±16.9	19.2±10.7	18.4±0.8	0.36
Bifurcation angles (between DMB and SB)	60.7±19.1	45.8±14.2	44.7±17.4	0.09
PMB LLL (mm)			0.25±0.43	
DMB LLL (mm)			0.00±0.31	
SB LLL (mm)			0.17±0.35	
In-stent binary restenosis*			0 (0)	
In-segment binary restenosis**			1 (4.3)	

Values are n(%) or mean±Standard deviation. MLD: minimal lumen diameter; LLL: late luminal loss; %DS: % diameter stenosis; PMB: proximal main branch; DMB: distal main branch; SB: side branch; P value is given in paired comparison between post and follow-up. \*including all stented segments in the bifurcation; \*\*including stented and peri-stent segments (segment 5mm proximal and 5mm distal to the stent in main and side branch)

# Registries included

Registry cohorts	Initiated by	Enrollment		Patients included	Follow-up	
		<u>start</u>	<u>end</u>		<u>Duration (M)</u>	<u>status</u>
First-In-Man	Sponsor	May, 2006	Jan, 2007	30	6	completed
eTryton 150/Benelux	Sponsor	May, 2009	Apr, 2010	216	6	completed
eTryton Spain	Sponsor	Aug, 2009	Mar, 2010	142	6	completed
IUVANT	Investigator	Mar, 2008	Jan, 2011	67	6	completed
Amsterdam	Investigator	Oct 2010	Dec, 2011	91	6	completed
Poznan	Investigator	Aug, 2009	ongoing	91	9	until Jan, 2012
Wolverhampton	Investigator	Nov 2008	ongoing	79	18	until Jan, 2012
Dublin	Investigator	Jul 2009	ongoing	189	16	until Jan, 2012

# Results

Lesion characteristics (visual estimate)		N=929
Bifurcation location	Left main	5%
	LAD / diagonal branch	67%
	Cx / obtuse marginal	16%
	Posterolateral / posterior descending	10%
True bifurcation	(Medina 1,1,1; 1,0,1; 0,1,1)	85%
Side branch angles	Narrow (<30°)	22%
	Large (>30°)	10%
Reference vessel diameter	Main branch	3.0 [3.0-3.5]
	Side branch	2.5 [2.5-2.7]
Lesion length	Main branch	20 [13-33]
	Side branch	7 [4-12]

# Results

Procedural characteristics		N=929
Side branch predilatation		89%
Successful Tryton placement		98%
Main branch stent type	DES	97%
	BMS	2.7%
	Other	0.3%
Length main branch stent		23 [18-28]
Diameter main branch stent		3.0 [3.0-3.5]
Final kissing performed		83%
Additional stenting	Main branch	32%
	Side branch	15%

# Results

Clinical outcomes	Six-month outcomes		One-year outcomes	
	Event rate	No.	Event rate	No.
Target vessel failure	6.5%	55	8.5%	62
Cardiac Death	1.6%	13	1.8%	14
Any MI	3.0%	26	4.3%	31
Clinically indicated TVR	3.3%	27	4.4%	31
Clinically indicated TLR	2.9%	24	4.0%	28
Stent thrombosis	0.5%	4	0.5%	4
Definite	0.2%	2	0.2%	2
Probable	0.2%	2	0.2%	2

# Tryton IDE Study: Schematic

Review Clinical Selection Criteria/Obtain Informed Consent



Base Line Angiography

Review Angiographic Selection Criteria

Randomize to Treatment, 75 sites in USA (PI: M. Leon)



N = 704

**Side Branch Stent/Tryton**

SB: Tryton

Main: Workhorse DES

**Side Branch PTCA/Provisional**

SB: PTCA

Main: Workhorse DES

Clinical F/U 30 day, 6 months

Clinical F/U 30 day, 6 months

Clinical F/U 9 months

Clinical F/U 9 months

Angiographic F/U  
9 month

Angiographic F/U  
9 month

IVUS F/U

IVUS F/U

Clinical F/U 1-5 year

Clinical F/U 1-5 year

Primary End point

Powered 2° End point  
n=374

IVUS Cohort  
Tryton = 64, Control =32

# Major Selection Criteria

*'Complex' bifurcation lesion requiring side branch treatment*

- Inclusion
  - Complex Bifurcation Lesion
    - Angiographic Disease in **BOTH** Main & Side Branch
    - Medina (1.1.1, 0.1.1, 1.0.1) by visual estimate
    - 'Significant' Side-Branch Disease >50% stenosis by visual estimate
- Exclusion
  - Main branch Dia: <2.5 or > 4.0 mm
  - Side branch Dia: <2.5 or > 3.5 mm
  - Diffuse Side branch Disease (>5 mm from origin)
  - Trifurcation Lesion
  - Lesion involving the Left Main Coronary Artery
  - Excessive lesion calcification
  - PCI-Stenting of up to 2 distinct lesions within non-study vessel permitted

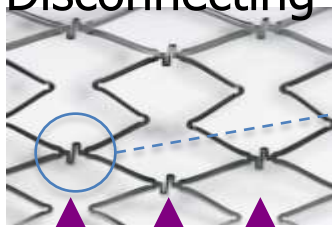
# **SELF-EXPANDING DEDICATED DEVICES**

**STENTYS (Stentys SA)**

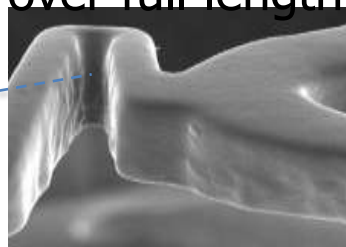
# STENTYS Self-Apposing® Stent



- Self-expanding nitinol stent deployed by retracting a sheath (no balloon)
- Bare or Paclitaxel-eluting with ProTeqtor biostable polymer
- 6 French, single-wire, rapid exchange, low profile (68  $\mu\text{m}$ )
- Disconnecting struts over full length\* for side-branch access



Disconnectors  
along the stent



Disconnectable  
interconnector



Disconnection

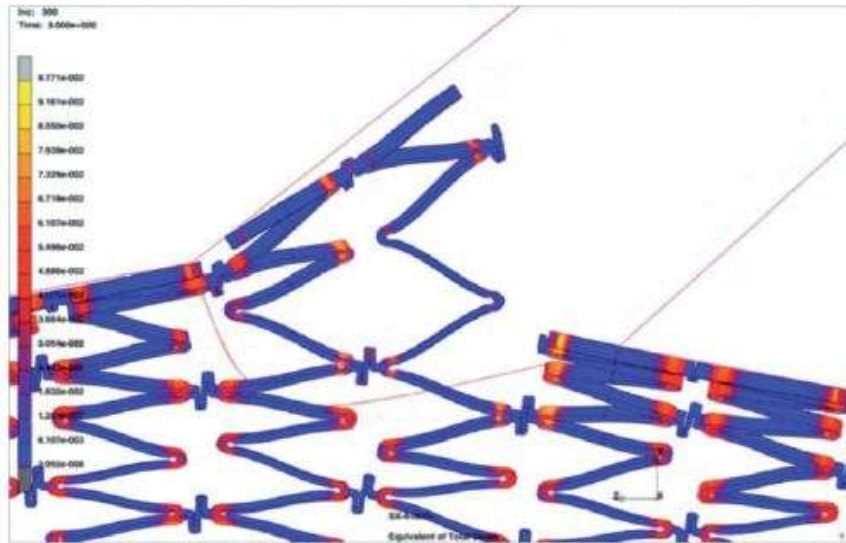


\* Except the first and last 2mm

# Technical Specifications

## Load-bearing Elements

This Finite Element Analysis (FEA) image shows the STENTYS™ stent deployed in a bifurcation model. The levels of strain placed on the stent when deployed confirm that disconnectors are not load-bearing elements of the stent.



# Easy selection of stent size

Size	Length in vessel (mm)	Vessel Diameter	Maximum Inner Diameter	Side-Branch Diameter (mm)
Small	22	<b>~2.5 to 3.0mm</b>	4.2mm	$\geq 2.20$
	27			
Medium	22	<b>~3.0 to 3.5mm</b>	5.3mm	$\geq 2.25$
	27			
Large	22	<b>~3.5 to 4.5mm</b>	6.6mm	$\geq 2.50$
	27			

\* At the vessel size boundaries, it is recommended to choose the smaller size.

# STENTYS Clinical Program

## OPEN (Bifurcation)

I	<b>Feasibility trial:</b> Single Arm – STENTYS BMS & DES <sup>(P)</sup> → 6 month QCA and IVUS
II	<b>“Real life” study:</b> Single arm – STENTYS DES → 6 and 12 month MACE, OCT in sub-group

60

200

## APPOSITION (STEMI)

I	<b>Feasibility trial:</b> Single Arm – STENTYS BMS → 3 day and 6 month QCA and IVUS
II	<b>Randomized trial:</b> STENTYS BMS vs VISION/Driver → 3 day QCA and OCT, 6 month clinical
III	<b>“Real life” study:</b> Single arm – STENTYS BMS & DES <sup>(P)</sup> → 30 day and 12 month MACE
IV	<b>Randomized trial:</b> STENTYS Sirolimus DES <sup>(S)</sup> vs Resolute → 4 and 9 month OCT

25

80

1000

150

# OPEN I

- **DESIGN:** Prospective, non-randomized, single-arm, multi-center trial
- **OBJECTIVE:** To evaluate the safety and feasibility of the STENTYS<sup>®</sup> DES and BMS in bifurcated lesions
- **ENDPOINTS:**
  - Procedural success
  - MACE @ 30 days and 6 months

*Events adjudicated by CEC*

*Independent monitoring: Medpass*

*Core lab: Cardialysis*

## DES Results (Number of MACE at 6 months)

Cardiac Death	0
Q-wave Myocardial Infarction	0
Non-Q-wave Myocardial Infarction	0
Clinically driven TLR	1
<b>Total MACE</b>	<b>1 (3.7%)</b>

- 0% restenosis in side branch when 2 stents used
- Late loss in main branch 0.39mm

63 patients enrolled between September 2007 and August 2009 in 9 European clinical sites

3 patients not stented

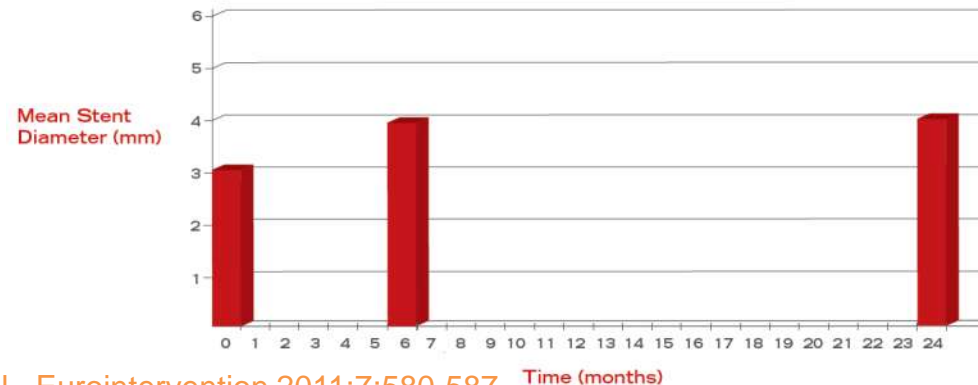
60 patients with STENTYS<sup>®</sup> stent:

- 33 patients with STENTYS<sup>®</sup> BMS
- 27 patients with STENTYS<sup>®</sup> DES

Clinical follow-up at 30 days

Clinical follow-up at 3 months

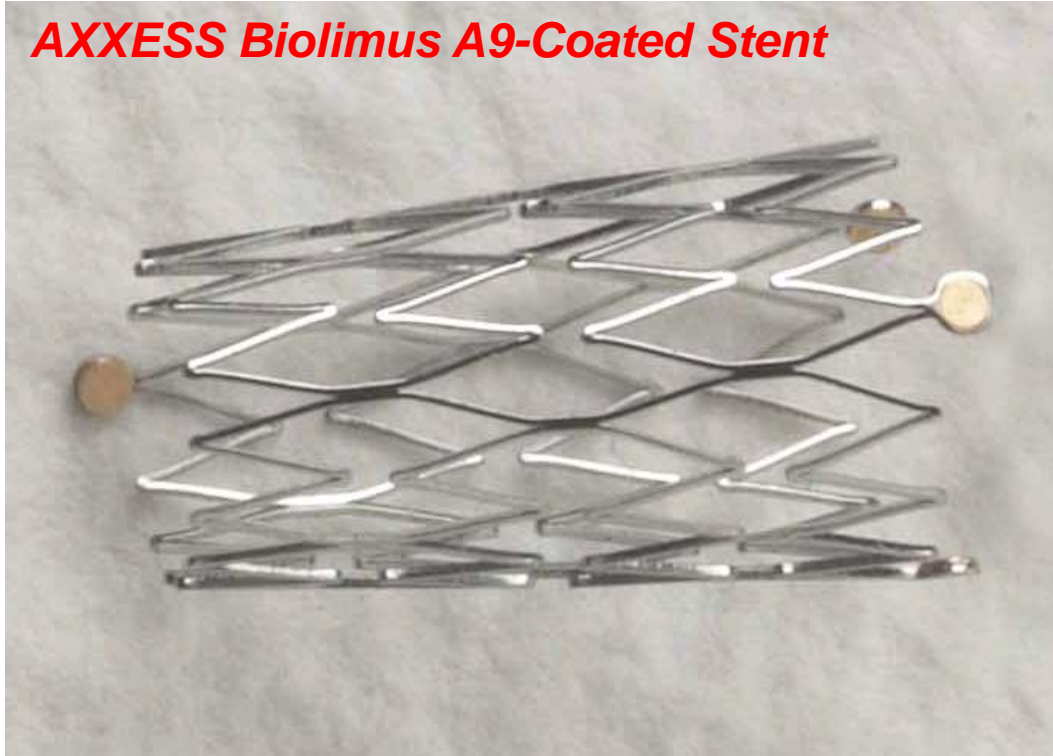
Angiographic & IVUS follow-up at 6 months



**AXXESS (Biosensors Int.)**

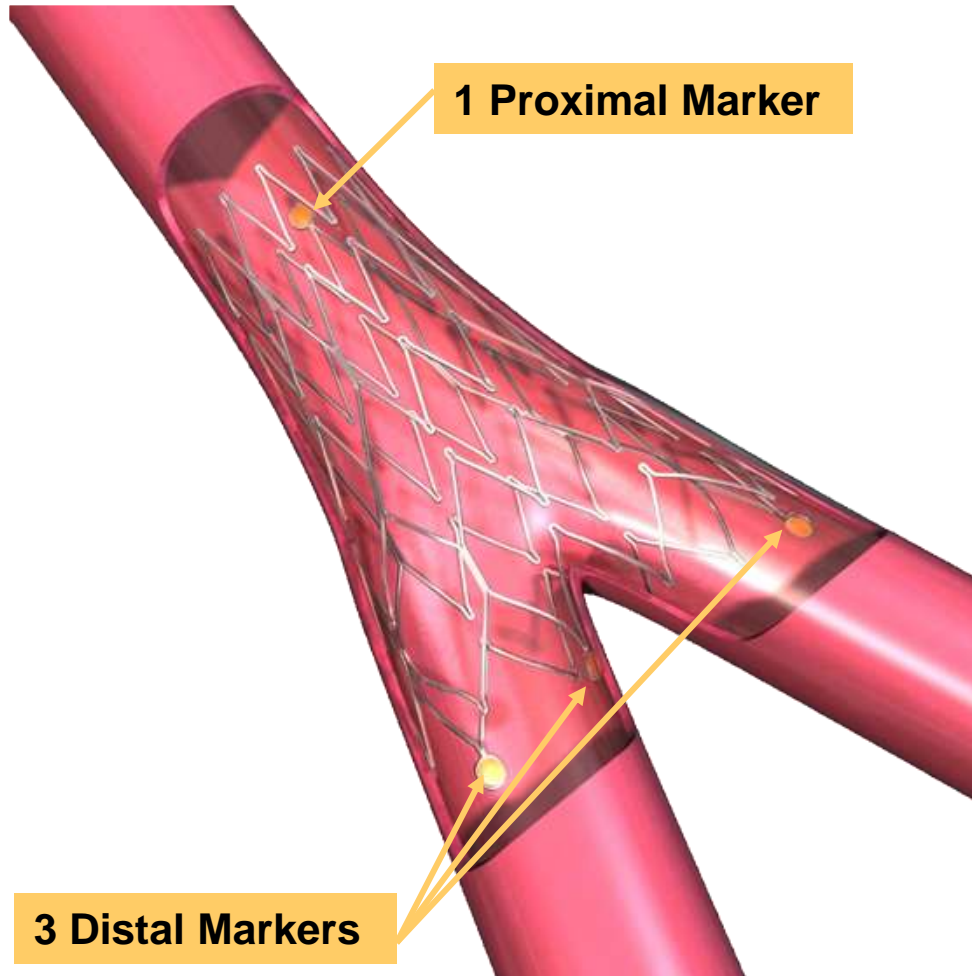
# DEVICE DESCRIPTION

**AXXESS Biolimus A9-Coated Stent**



- Self-expanding nickel-titanium (*Nitinol*) alloy
  - Conical shape
  - Proximal and distal gold markers to facilitate implantation
  - Coated with *Biolimus A9*<sup>™</sup> using a bioabsorbable polymer matrix (PLA) in a dose of 22  $\mu\text{g}/\text{mm}$  of stent length
- 
- First self-expanding coronary stent to incorporate a drug
  - First drug-eluting stent dedicated for the treatment of diseased coronary bifurcation lesions

# AXXESS STENT



*Nitinol* self-expanding stent platform

0.006 in. (0.15mm) strut thickness

Drug carrier: bioabsorbable polymer matrix (PLA)

Drug release rate: ~ 70% in 30 days, remaining ~ 30% released in < 6 months

Polymer absorption: ~ 6-9 months; then, only the metal strut remains

# SELF-EXPANDING STENT PLATFORM

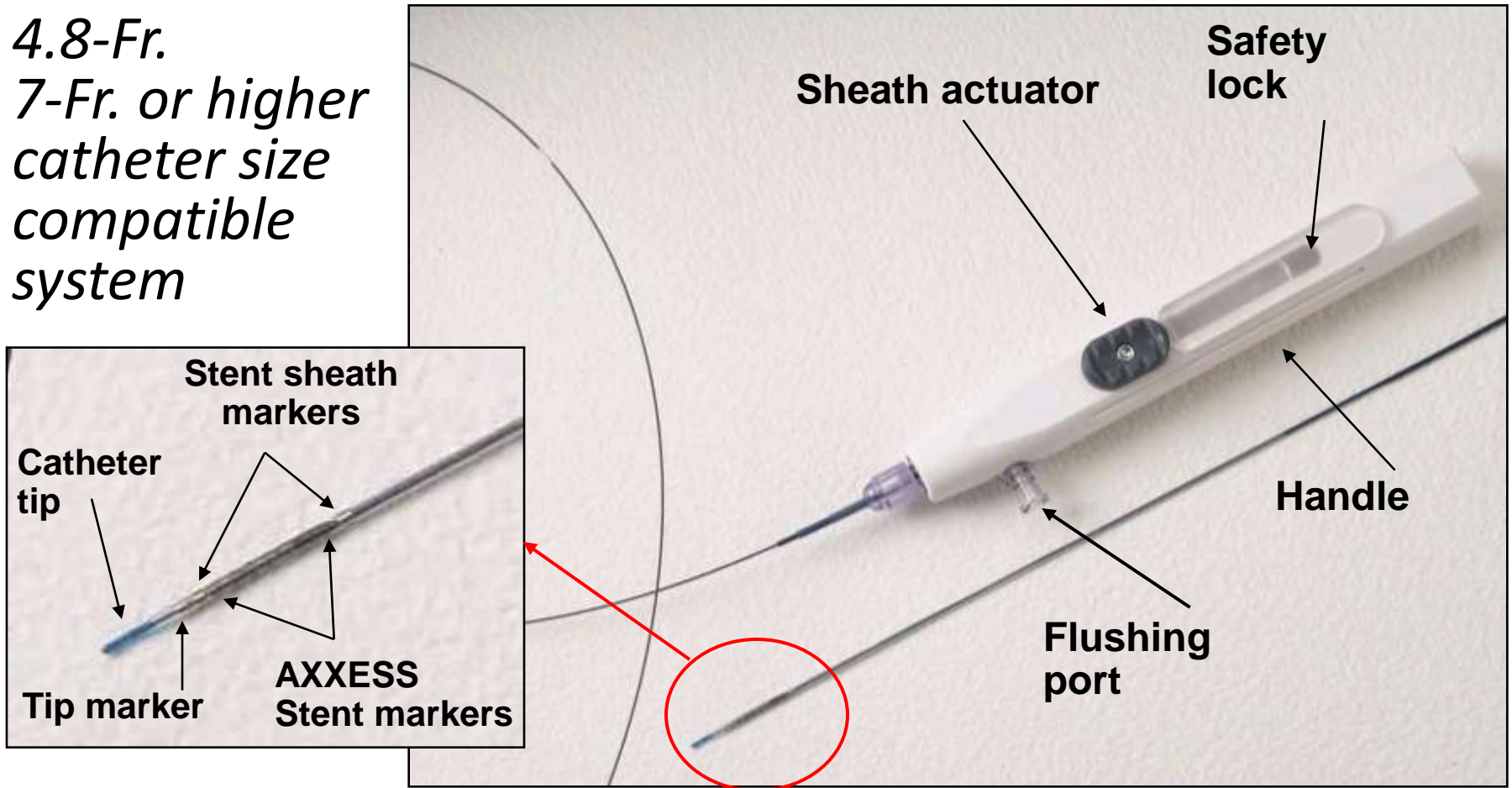


- Two models:
  - Reference diameter 3.0 mm
    - Max. proximal stent diameter = 3.75 mm
    - Max. distal stent diameter = 6.00 mm
  - Reference diameter 3.5 mm
    - Max. proximal stent diameter = 4.25 mm
    - Max. distal stent diameter = 6.50 mm

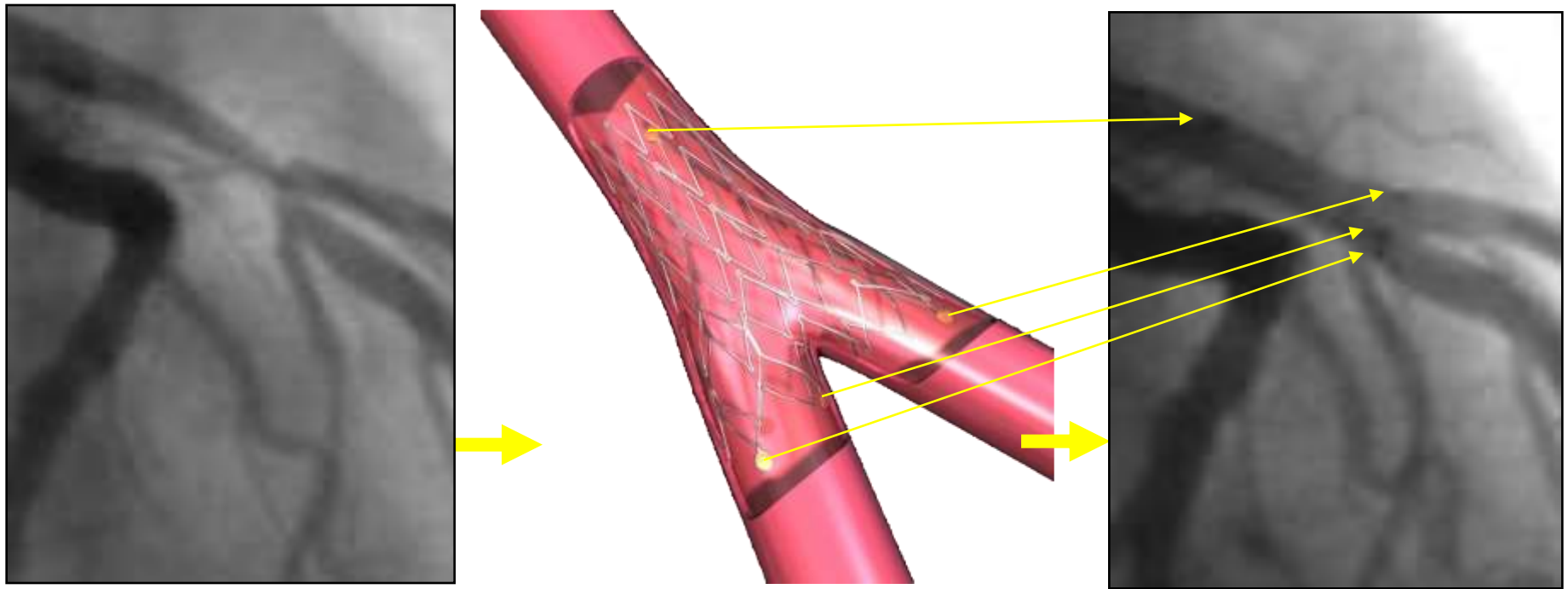
# DELIVERY SYSTEM

Covered sheath *Rapid Exchange* (RX) delivery catheter

4.8-Fr.  
7-Fr. or higher  
catheter size  
compatible  
system

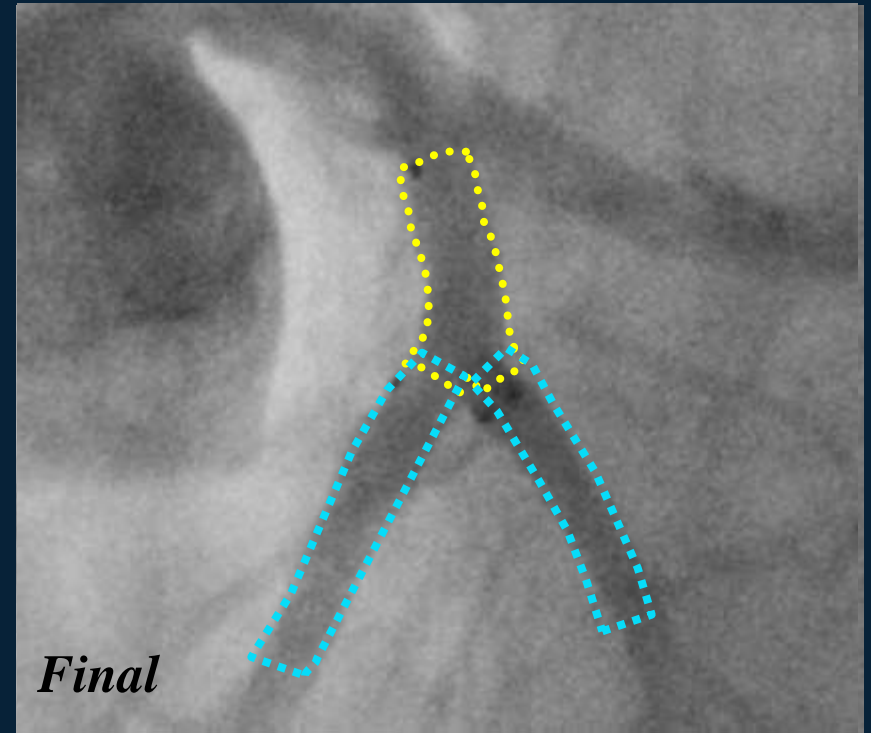


# GOAL: SPAN BOTH VESSELS



- Cover the proximal lesion segment
- Cover the ostium of the side branch and distal parent vessel without compromising access to the side branch
- This is accomplished if 2 markers are in 1 branch and 1 is in the other
- Provide a convenient placement marker for additional distal stents

# COMBINED TREATMENT WITH ADDITIONAL STENT FOR COMPLEX LESIONS



# AXXESS Clinical Studies

AXXESS  
N=43

- Bare metal version of AXXESS Stent
- Safety and effectiveness study
- 6 month follow-up completed

AXXESS  
PLUS  
N=139

- Evaluated drug-eluting AXXESS stent to BMS
- Safety and effectiveness study
- **Follow-up through 5 years completed**

DIVERGE  
N=302

- International safety and effectiveness study
- Evaluated best practices from AXXESS Plus
- **Follow-up through 3 years completed**

# DIVERGE Trial Design

Lesion type:

Any bifurcation with:

- Significant SB's  $\geq 2.25\text{mm}$
- PV-SB angulation  $< 70^\circ$

Prospective, single-arm,  
multi-center trial

**302 patients in 16 clinical sites in Europe, Australia and New Zealand**

Clinical FU

1 mo 6 mo 9 mo 12 mo 2 yrs 3 yrs 4 yrs 5 yrs

Angio/IVUS FU

**1° Endpoint:**

**MACE\* at 9 months**

**Key 2° Endpoints:**

MACE\* at 30 days, 6, 9 and 12 months and 2, 3, 4 and 5 yrs  
death, cardiac death, MI (Q-wave and non Q-Wave), id-TLR,  
id-TVR and stent thrombosis at 30 days, 6, 9 and 12 months  
and 2, 3, 4 and 5 yrs

Angiographic: In-stent restenosis and late loss at 9 months

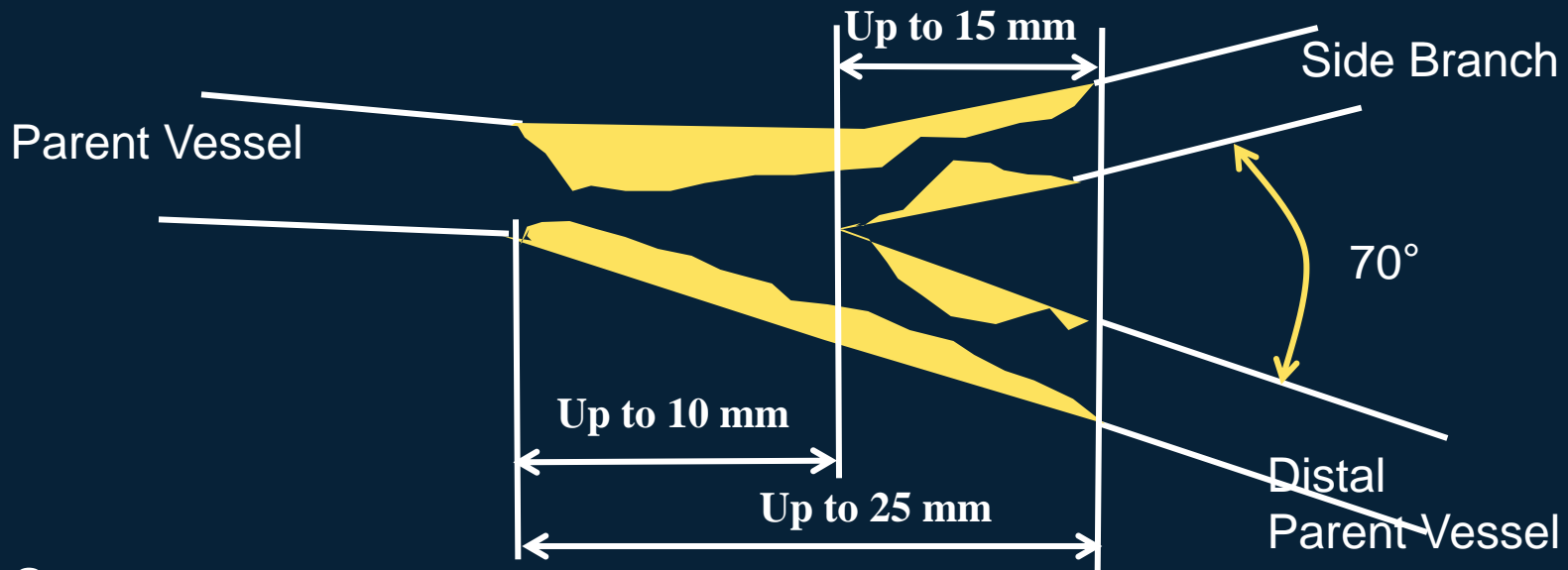
*\*MACE = Composite of Death, MI and ischemia driven TLR*

**DAPT recommended:**

**12 months**

# Lesion Inclusion Criteria

Any Type Bifurcation  
 $SB \geq 2.25$  mm



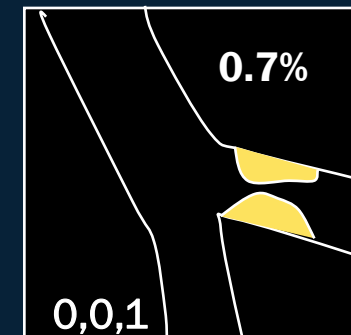
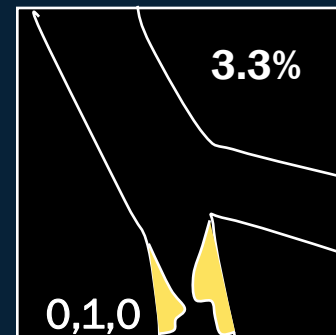
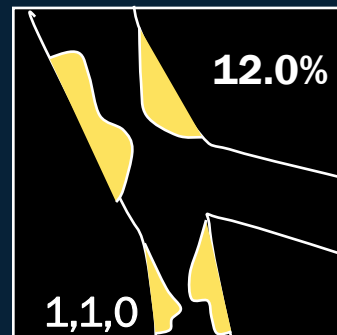
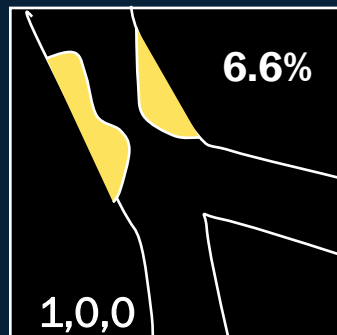
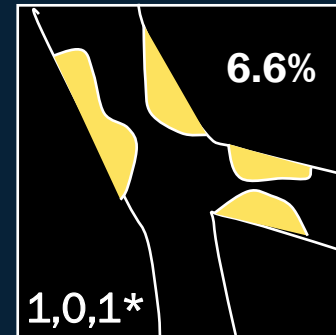
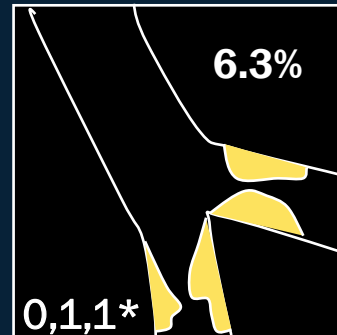
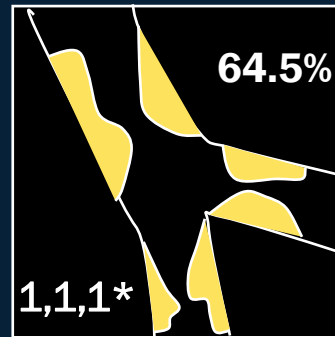
Stents:

Proximal = 10 or 14 mm Axxess

Distal PV or SB = add Cypher to fit

# Medina Class All Patients

**77.4%**  
**True Bifurcation \***



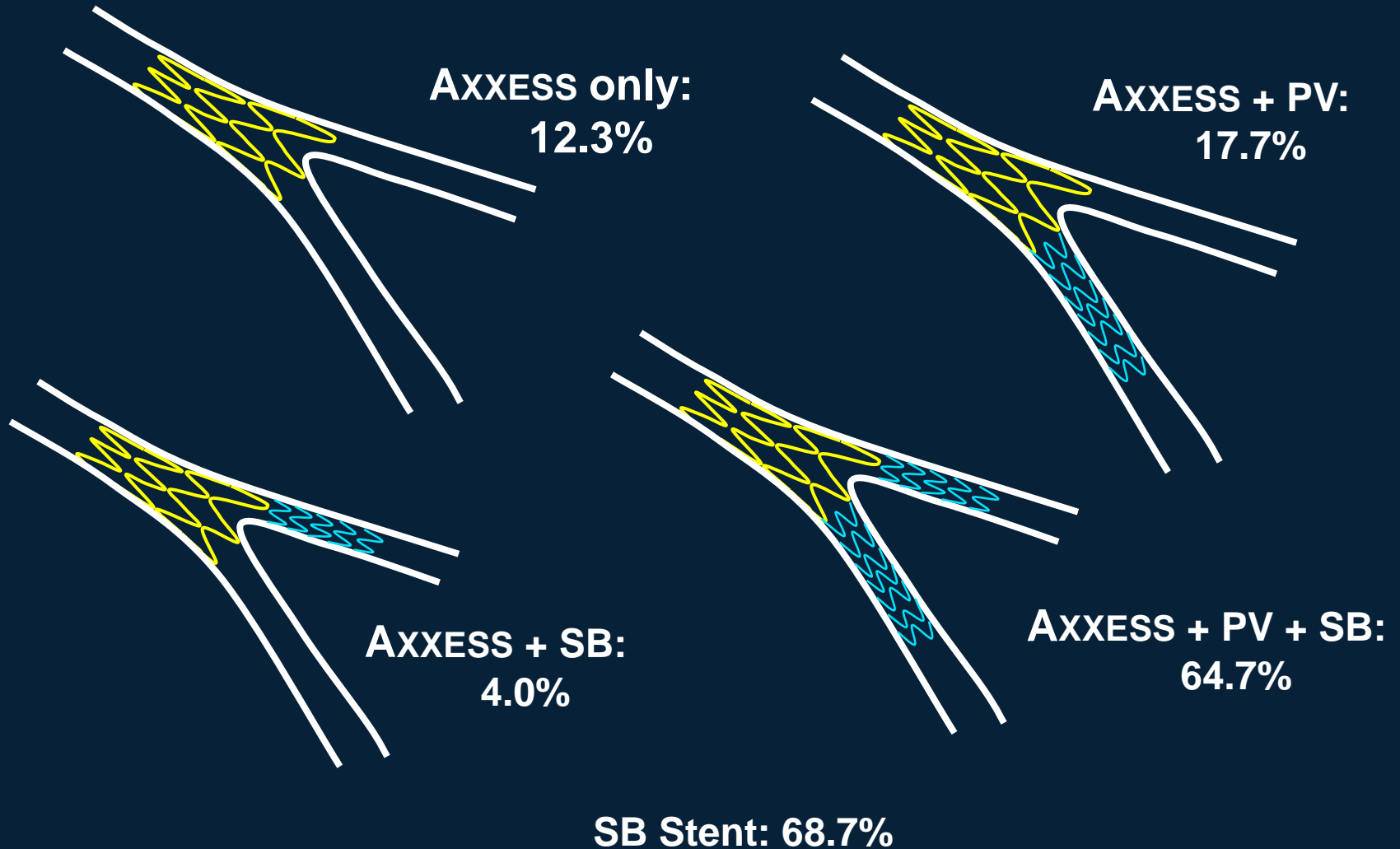
# Procedure Outcomes

	All Patients (N=302)
AXXESS stent placed <sup>1</sup>	99.0%
Optimal placement <sup>1</sup> (by core lab assessment)	93.0%
Branch vessel Cypher stents placed <sup>2</sup>	500 (210 in SB)
Angiographic success <sup>1</sup> (Final DS < 50% by QCA)	99.3%
Final mean diameter stenosis <sup>1</sup>	22.6% (PV) 18.8% (SB)
Procedure success <sup>1</sup> (Angio success without in-hospital MACE)	96.7%

<sup>1</sup> Verheye S. et al., J Am Coll Cardiol, 2009. 53(12): p. 1031-9

<sup>2</sup> Verheye S., oral presentation, TCT 2008

# Stent Distribution Patterns

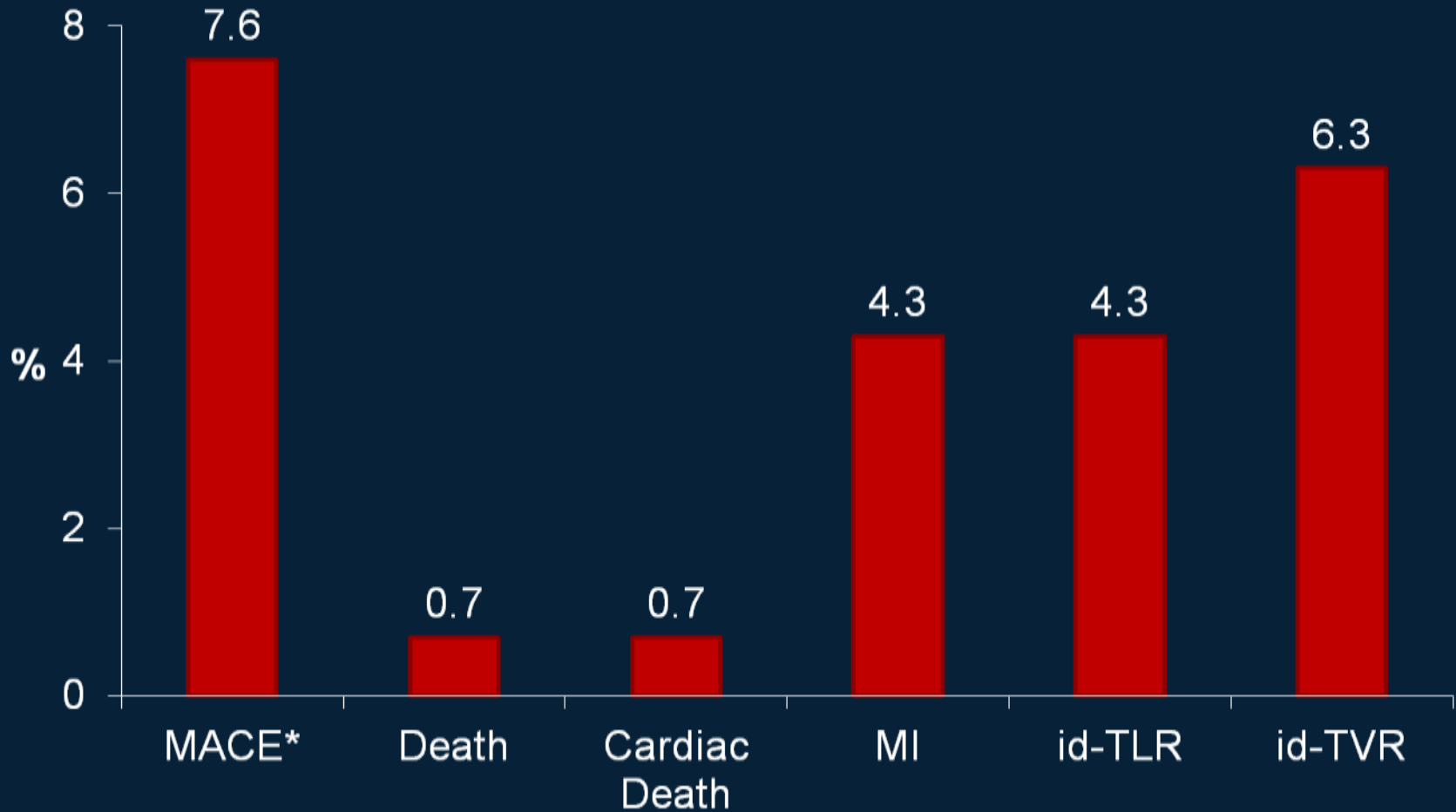


# 9-month QCA Results

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	In-stent - AXXESS Only	0.7%	-
Per Vessel	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)	

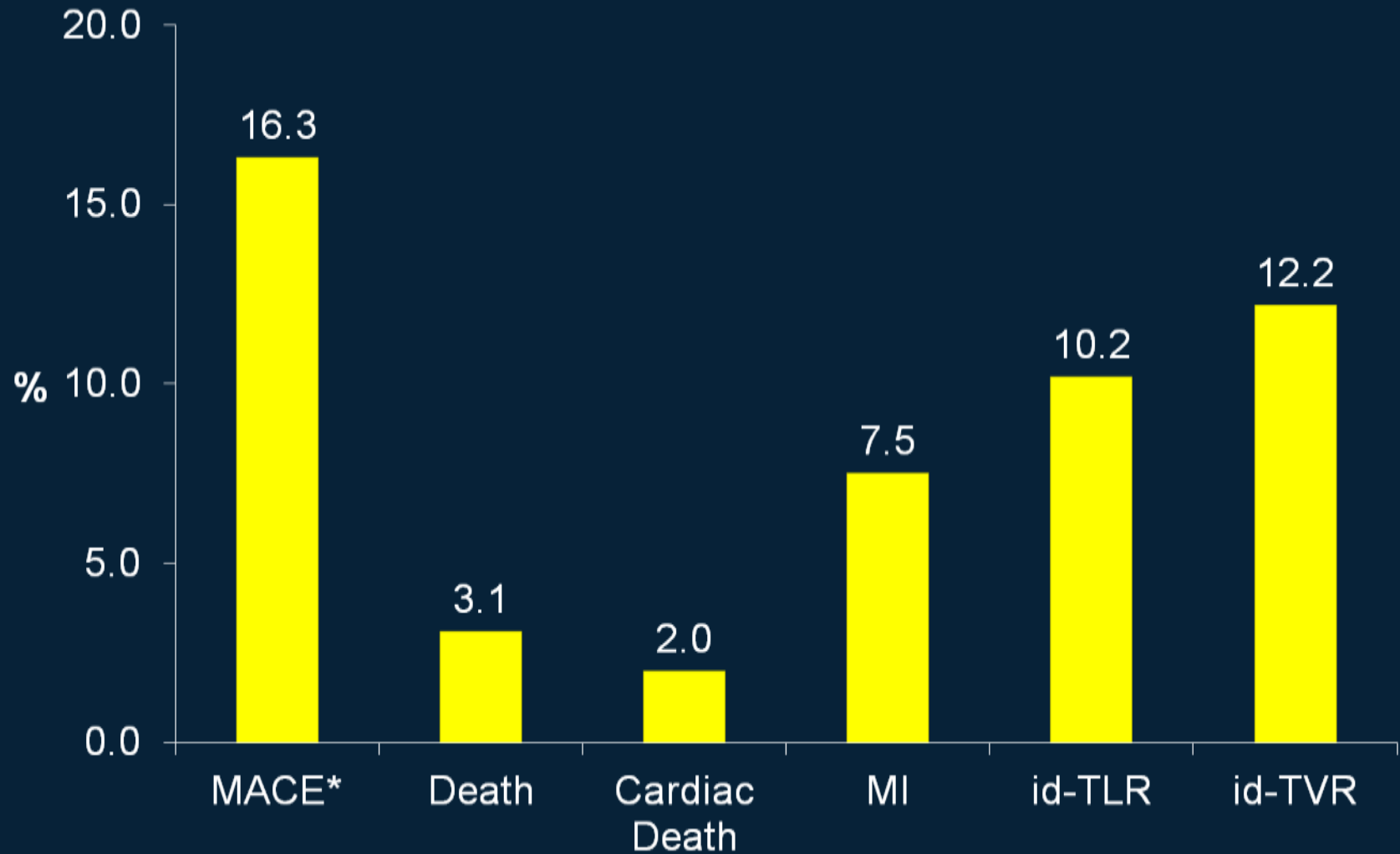
# 9-month Clinical Outcomes

## Primary Endpoint



\*MACE: a composite of Death, MI and id-TLR  
Verheye S. et al., J Am Coll Cardiol, 2009. 53(12): p. 1031-9

# 3-year Clinical Outcomes Cumulative Rates



\*MACE: a composite of Death, MI and id-TLR  
Agostoni P., oral presentation, EuroPCR 2011

# CONSIDERATIONS

- Dedicated bifurcation systems vary on design, material and profile; therefore, it is reasonable to believe that they will have different indications mainly due to anatomical and morphological factors
- Overall, all systems have shown positive clinical outcomes in selected cases; however, there is lack of comparative studies between each other and most importantly, against current standard technique (“provisional”)
- Still, they will probably be the ultimate solution for bifurcation PCI

*Thanks!*

