FATEBENEFRATELLI
Ordine Ospedaliero San Giovanni di Dio
Provincia Lombardo Veneta

Hospitaller Order of St. John of God

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Dedicated bifurcation stents

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Background

Standard stents in Bifurcations

Optimal treatment

- Controversial

Variation in anatomy

- Vessel size
- Angulation
- Plaques distribution

Conventional stent

- Size mismatch
- SB compromise
- Stent deformation
- Double-layered struts

Over expansion

- Drug disruption
- Plaque prolapse

Compromise

- Vessel healing

Immediate risk

- Periprocedural MI
- Difficult wire access SB

Late risk

- Restenosis
- Thrombosis

Requirements

Dedicated stents in Bifurcations

Conformance

- Vessel contour
- No disruption
- Drug coating

Side branch

- Preservation

Procedure

- Simplify
- Shorten times
- Reduce contrast

Success

- Improve success rate
- Permanent SB access

Late risk

- Restenosis
- Thrombosis

Classification

Dedicated stents in Bifurcations

Y- stents

- MB&SB stent

Through DBS– stent on both MB & SB

- BARD, AVE, Guidant, Cordis, MDT

A type

- Parent → Main
- SB access

MB device with some scaffolding of SB

- Xience SBA, Minvasys Nile PAx, Antares, Invatec TwinRail, Multilink Frontier, Pathfinder, BSC Petal, Y-med SideKick, Trireme Medical (TMI), STENTYS, BIOSS

S type

- Side branch
- 2nd DES P→M

Side branch stents

- Tryton, Sideguard

M type

- Parent vessel
- SB access

Proximal bifurcation stent

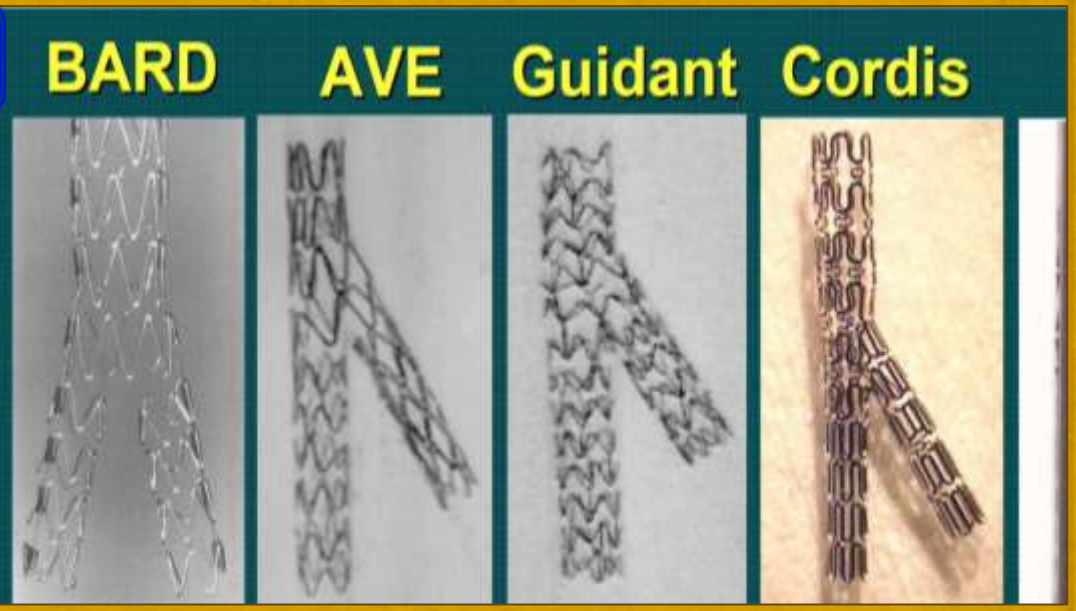
- Axxess

Classification

Through DBS– stent on MB & SB

Y- stents

- MB&SB stent



A type

- Parent ➔Main
- SB access

S type

- Side branch
- 2nd DES P➔M

M type

- Parent vessel
- SB access

Many problems have limited clinical progress: system complexity and profile, stent design, wire handling (and wrapping), delivery systems, variable lesion morphologies, ..

Classification	MB BDS scaffolding/access of SB	
Y- stents • MB&SB stent	Multilink Frontier	
A type • Parent ➔ Main • SB access	Invatec TwinRail	
	Minvasys Nile PAx	
S type • Side branch • 2nd DES P➔M	Xience SBA	
	BSC Taxus Petal	
M type • Parent vessel • SB access	Y-med SideKick	
	Trireme Antares	

Classification

MB BDS scaffolding/access of SB

Y- stents
- MB&SB stent

A type
- Parent ➔ Main
- SB access

S type
- Side branch
- 2nd DES P➔M

M type
- Parent vessel
- SB access

Two systems
- Delivers over 2 wires
- Wires my wrap

Technique
- Wire management
- System torqueing
- SB alignment
- Variable SB ostial coverage

Development in bifurcation PTCA
- EBC consensus documents
- New generation stents
- New generation wires

Classification

MB BDS scaffolding/access of SB

Y- stents

- MB&SB stent

A type

- Parent ➔ Main
- SB access

S type

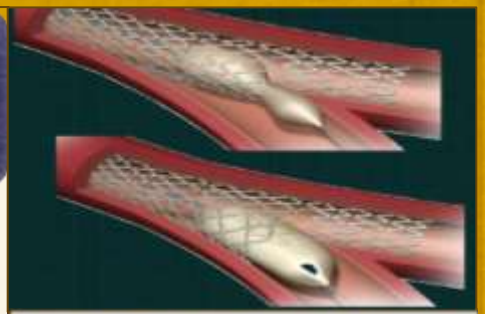
- Side branch
- 2nd DES P➔M

M type

- Parent vessel
- SB access

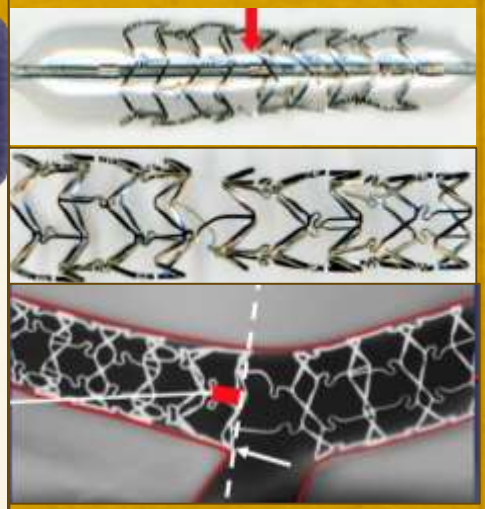
STENTYS Xposition S

- Nitinol + Sirolimus
- Self-expanding
- Balloon-delivery
- Interconnections



BIOSS

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable



Classification

Side branch BDS scaffolding

Y- stents

- MB&SB stent

A type

- Parent → Main
- SB access

S type

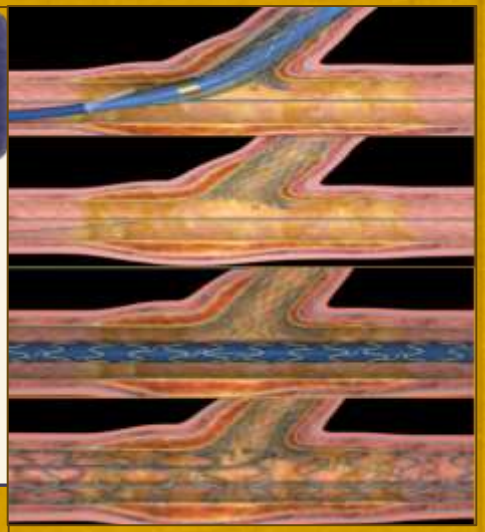
- Side branch
- 2nd DES P→M

M type

- Parent vessel
- SB access

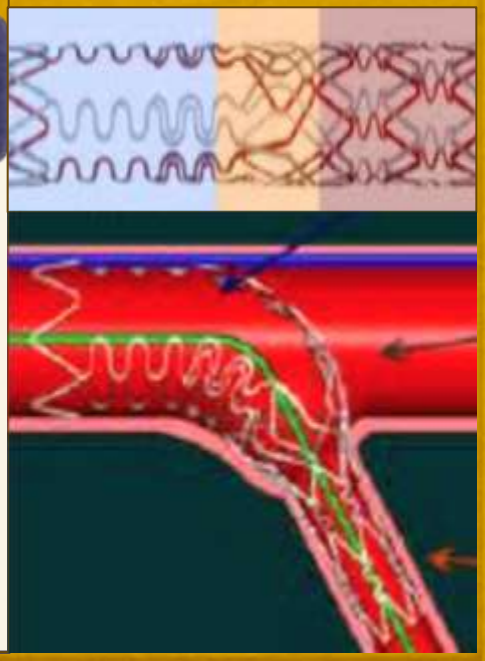
Capella Sideguard

- Nitinol
- Self-expanding
- Trumpet shape
- BMS



Tryton

- Chromo Cobalt
- Balloon expanding
- SB zone
- Transition zone
- Main vessel zone
- MBS



Classification

A type – special design

Y- stents

- MB&SB stent

A type

- Parent ➔ Main
- SB access

S type

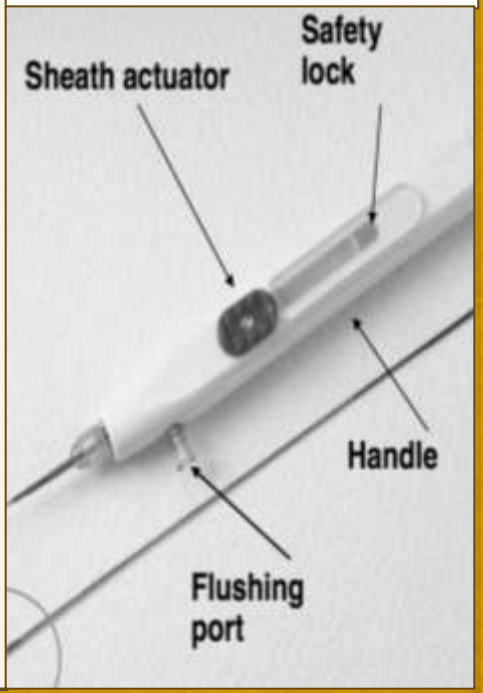
- Side branch
- 2nd DES P➔M

M type

- Parent vessel
- SB access

Axxess

- Nickel titanium
- Self-expanding
- Conical shape
- Biolimus A9
- Bioabsorbaple PLA
- Abluminal
- 1 proximal marker
- 3 distal markers
- No false carina
- Physiology
- Precise placement
- No rotation
- Span both vessels
- 7F GC
- 2nd or even 3rd DES



DBS Standard one/two technique

Y- stents

- MB&SB stent

A type

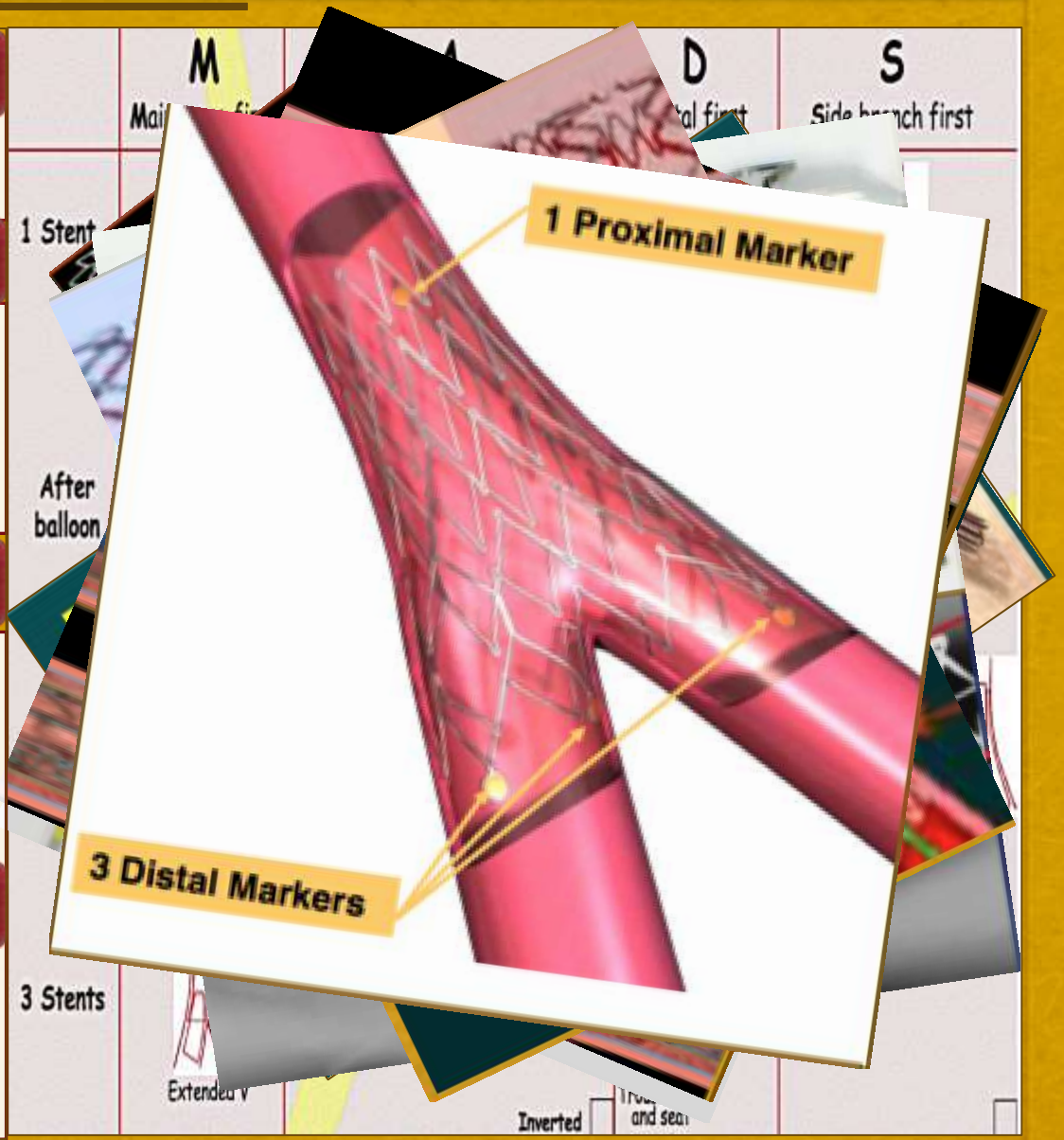
- Parent ➔Main
- SB access

S type

- Side branch
- 2nd DES P➔M

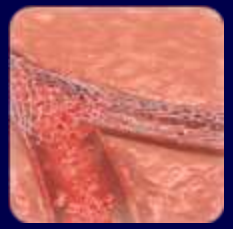
M type

- Parent vessel
- SB access



DBS	Standard one/two technique

Y- stents
- MB&SB stent



Stentys

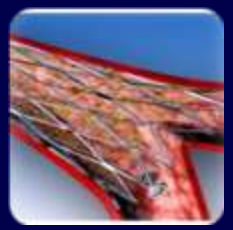
A type
- Parent ➔Main

BIOSS

S type
- Side branch

Tryton

M type
- Parent vessel

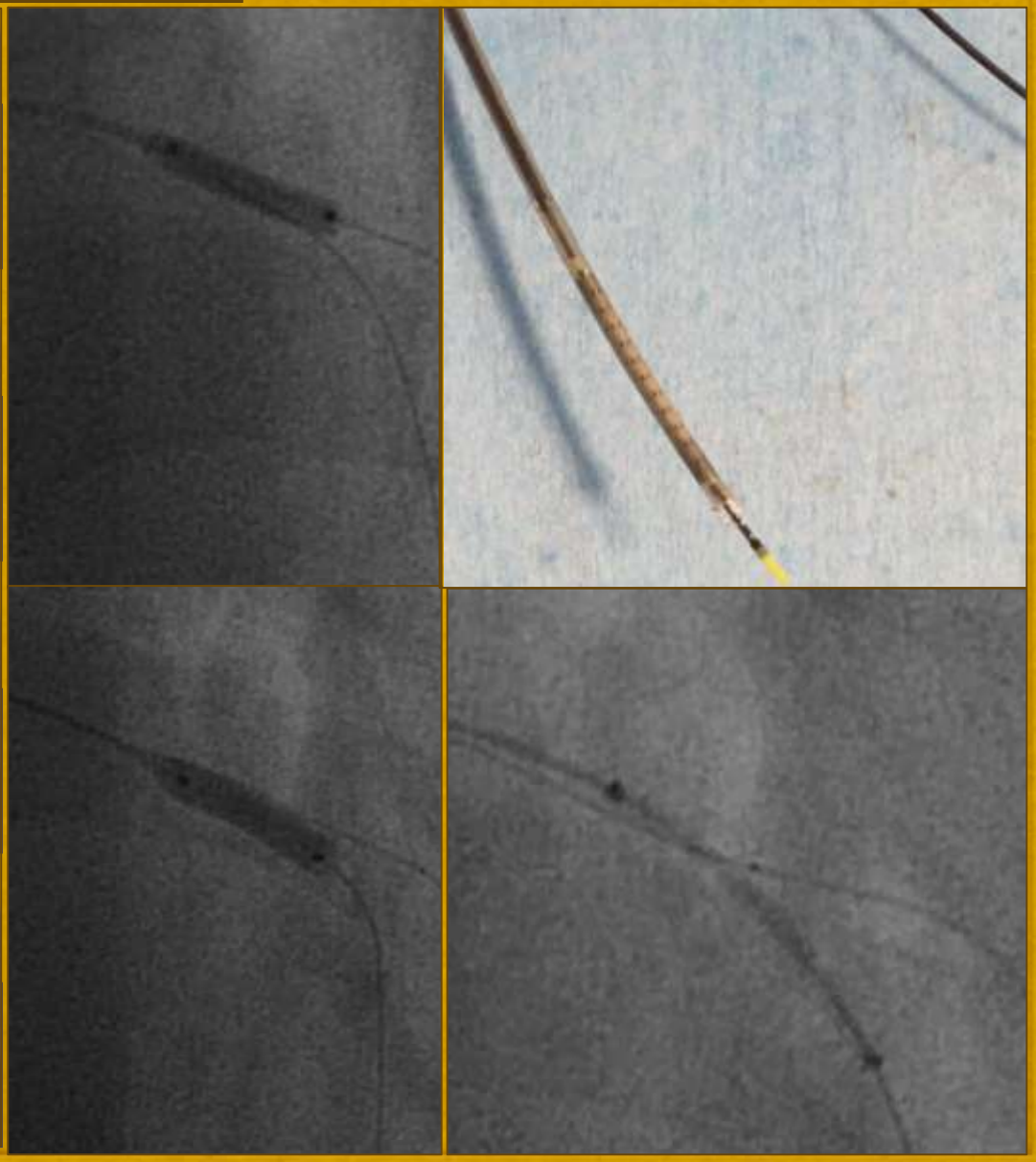


Axxess

M - type

STENTYS Xposition S

- Nitinol + Sirolimus
- Self-expanding
- Balloon-delivery
- Interconnections



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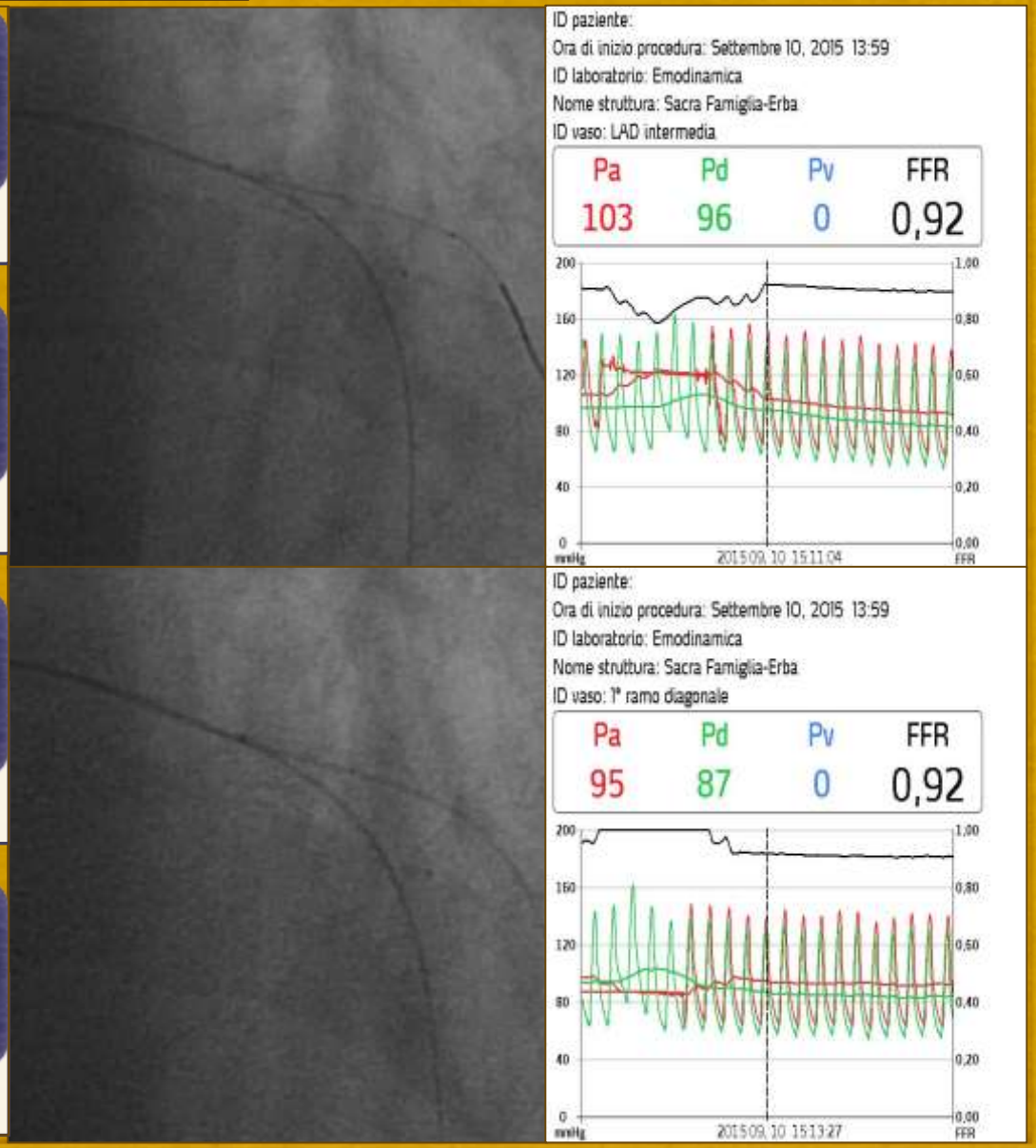


M - type

STENTYS Xposition S

- Nitinol + Sirolimus
- Self-expanding
- Balloon-delivery
- Interconnections

M - type

STENTYS Xposition S - Studies

- Nitinol + Sirolimus
- Self-expanding
- Balloon-delivery
- Interconnections

Six month outcome analysis of the OPEN I study

Table 3. Restenosis results in the side branch.

	DES (n=26)	BMS (n=33)
SB stent	5	13
Restenosis	0 (0%)	1 (8%)
Without SB stent	21	20
Restenosis	4 (19%)	4 (20%)

Table 1. Cumulative MACE at six months in both BMS and DES groups.

	DES=27 n (%)	BMS=33 n (%)
Cardiac death	0	0
Q- wave MI	0	0
Non-Q-wave MI	0	1
Clinically driven TLR	1 (3.7)	8 (24.2)
Total MACE	1 (3.7)	9 (27.3)

M – type

BIOSS LIM on LM

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable

M – type

BIOSS LIM on LM

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable

M – type

BIOSS LIM on LM

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable

M – type

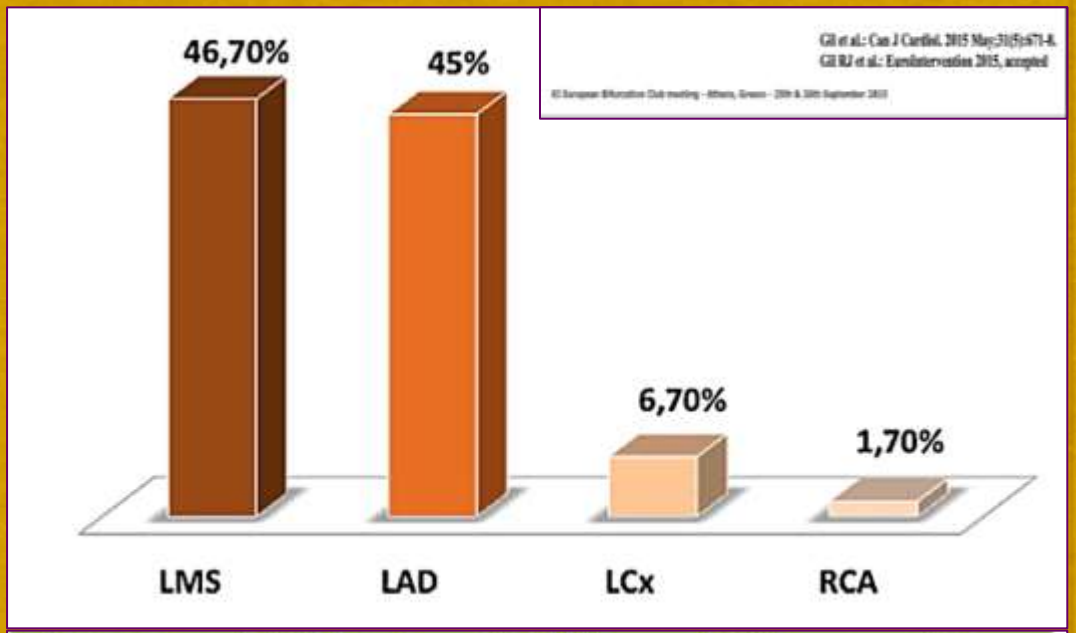
BIOSS LIM on LM final

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable

M – type

- Stainless steel
- Sirolimus
- Bottled balloon
- Two parts stent
- Biodegradable

BIOSS: POLBOS I+II Studies 12 m



Parameter	BiOSS Expert n = 120	BiOSS LIM n = 102	BiOSS n = 222	rDES n = 223
MACE	16 (13.3%)	12 (11.8%)	28 (12.6%)	30 (13.5%)
all-cause death	2 (1.7%)	1 (1%)	3 (1.4%)	6 (2.7%)
cardiac death	0	0	0	5 (2.2%)
MI	2 (1.6%)	2 (1.9%)	4 (1.8%)	7 (3.1%)
Definite ST	1 (0.8%)	1 (1%)	2 (0.9%)	1 (0.5%)
cumulative TLR	14 (11.5%)	10 (9.8%)	24 (10.8%)	18 (8.07%)*
clinically-driven TLR	7 (5.8%)	5 (4.9%)	12 (5.4%)	7 (3.2%)*
TVR	19 (15.8%)	14 (13.7%)	33 (14.9%)	24 (10.8%)

S – type

Tryton

- Chromo Cobalt
- Balloon expanding
- SB zone
- Transition zone
- Main vessel zone

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Tryton

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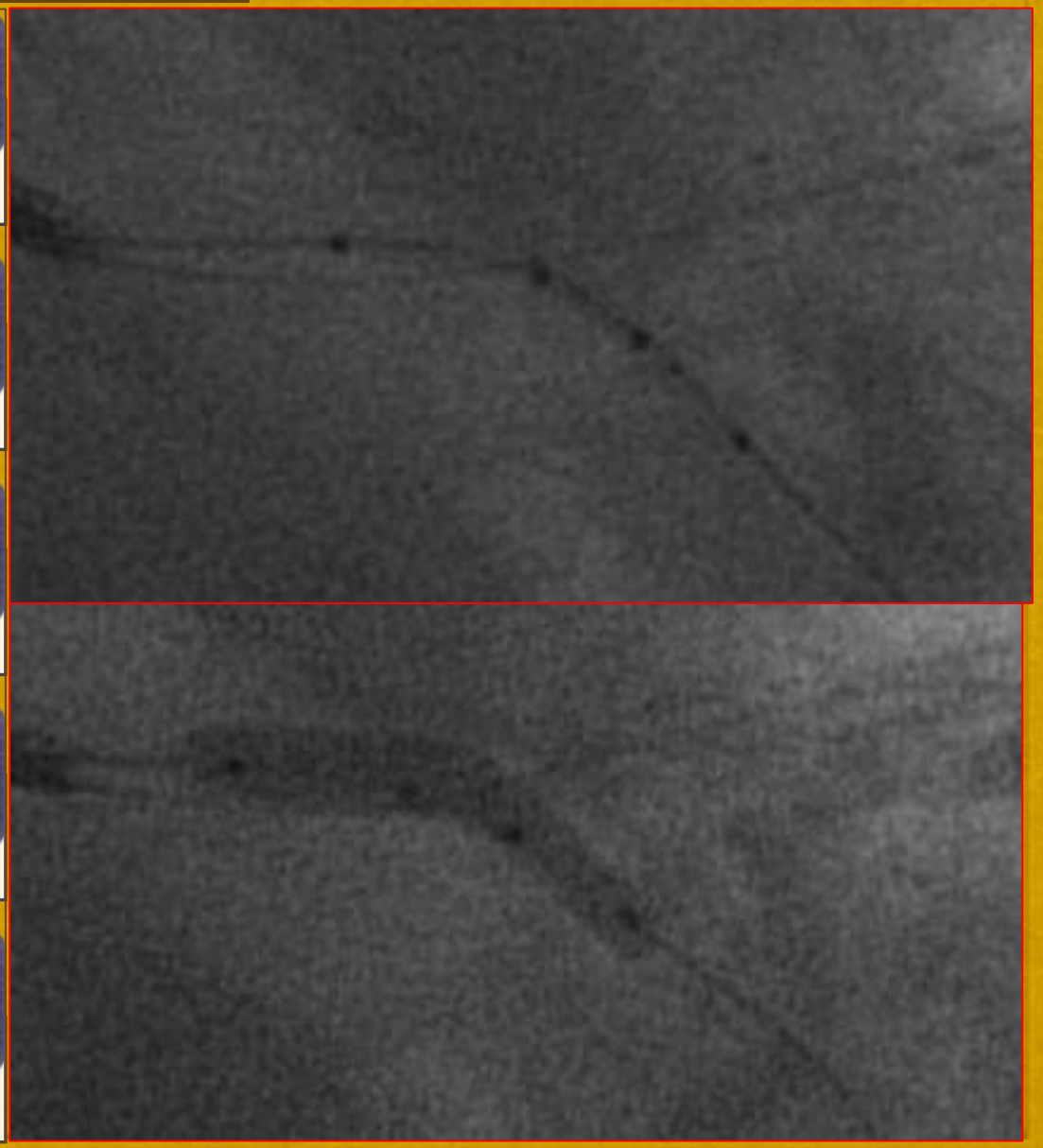

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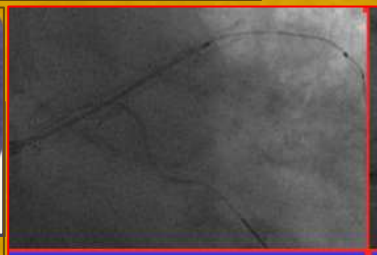
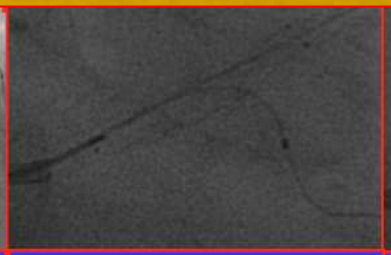
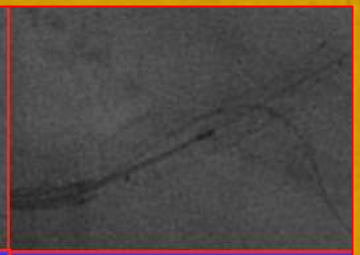


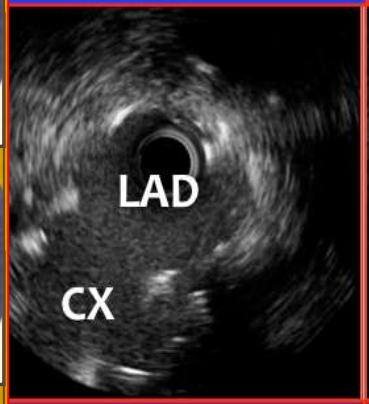
IVUS LAD



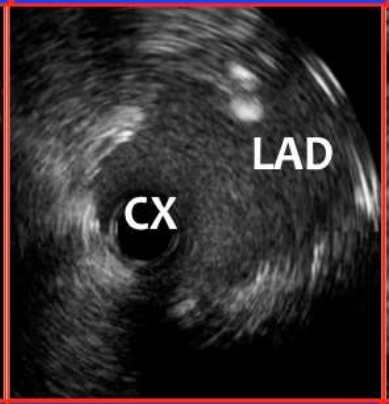
IVUS CX



IVUS LM



CARINA LAD/CX



CARINA CX/LAD

LEFT MAIN

S – type

Tryton

- Chromo Cobalt
- Balloon expanding
- SB zone
- Transition zone
- Main vessel zone

Study/Registry	Published	Patients	FU (M)	TLR	Thrombosis
Tryton Side-Branch Stent: First In Man	EuroInterv. 2008	30	6	3.3%	0%
IUVANT	CCI 2014	31	9	3.2%	0%
Rotterdam-Poznan Real World Registry	CCI 2011	96	6	4.0%	0%
E-Tryton Registry 150-Benelux	EuroInterv. 2012	296	6	3.0%	0.3%
Wolverhampton Experience	Abstract TCT 2011	66	15	1.5%	0%
Dublin Experience	Abstract TCT 2011	169	17.8	2.3%	0%
SAFE-TRY	Int.J. Card 2013	189	9	4.8%	0%
E-Tryton Spain	Poster - Abstract TCT 2011	132	6	3.8%	0%
AMC experience	Neth Heart J 2012	91	6	4.5%	1.1%
Patient Level Pooled Analysis (8 registries)	**EuroInterv. 2013**	**905**	**6**	**2.9%**	**0.5%**
			12	**4%**	**0.5%**
RCT	**JACC 2015 Full Population**	**355**	**9**	**4.7%**	**0.6%**
	CCI 2015 Intended Population	**141**	**9**	**3.5%**	**0.7%**
Confirmatory Study	**TCT 2015**	**133**		**August 2016**	

A – type

Axxess in acute occlusion STEMI

- Nickel titanium
- Self-expanding
- Conical shape
- Biolimus A9
- Bioabsorbaple PLA
- Abluminal
- 1 proximal marker
- 3 distal markers
- No false carina
- Physiology
- Precise placement
- No rotation
- Span both vessels
- 7F GC
- 2nd or even 3rd DES

A – type

Axxess – DIVERGE study 5y

- Nickel titanium
- Self-expanding
- Conical shape
- Biolimus A9
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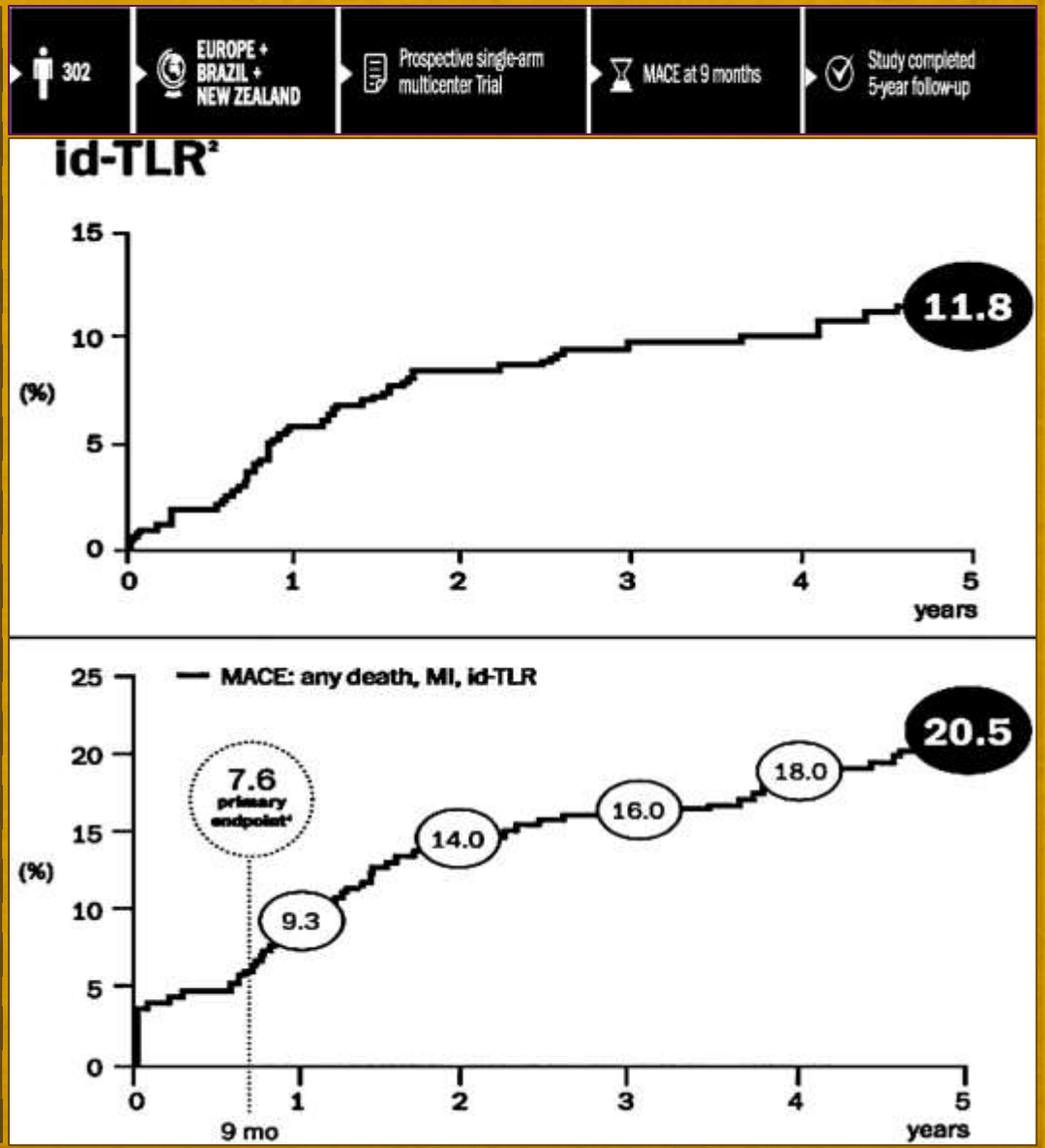

A – type

Axxess – COBRA study

- Nickel titanium
- Self-expanding
- Conical shape
- Biolimus A9
- Bioabsorbaple PLA
- Abluminal
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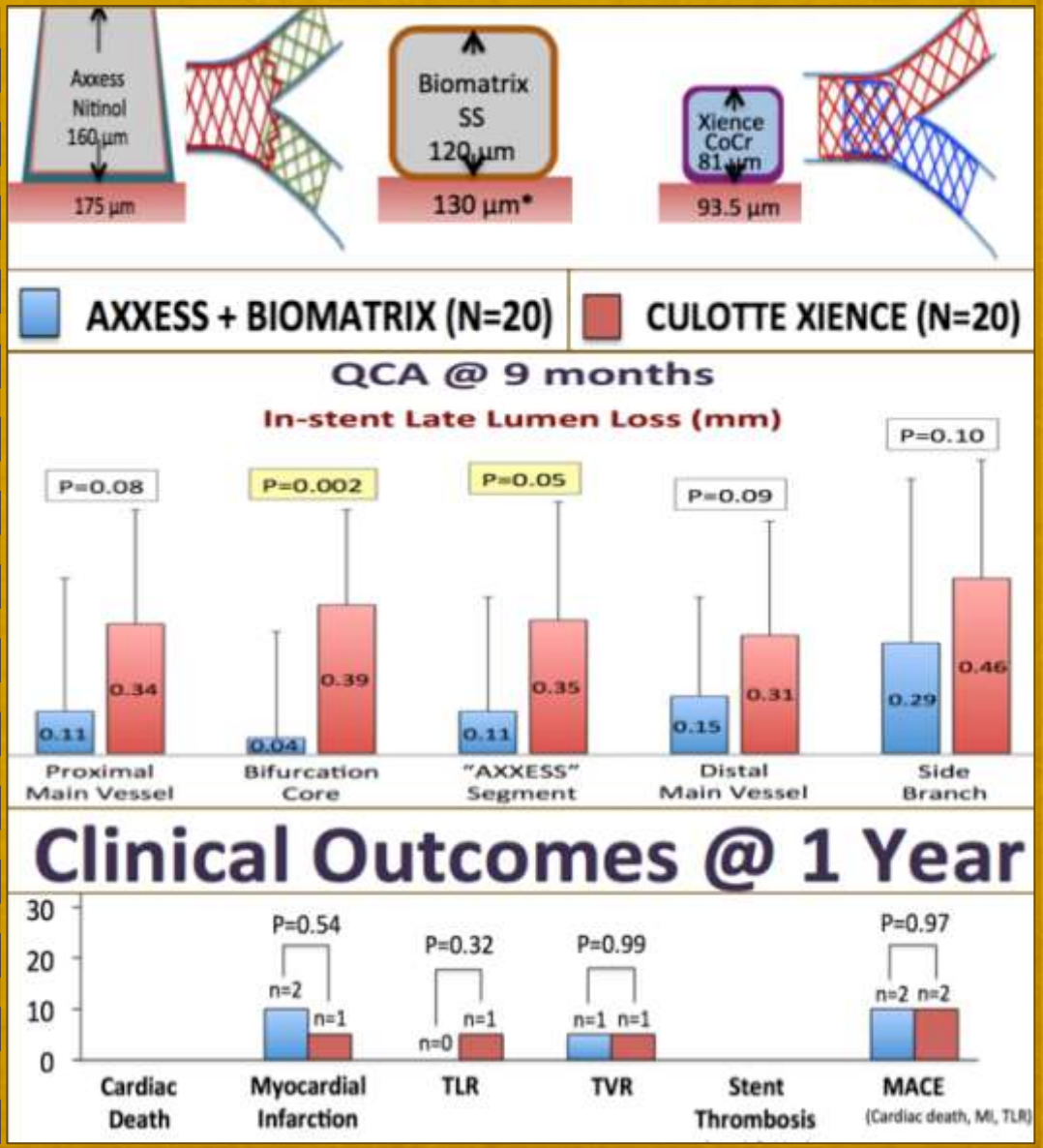

Conclusions Take home messages

Bifurcation anatomy is variable

- A family of DBS may be required
- BDS dedicate themselves to all patients?

Current BDS designs

- Still technically complex and unfriendly
- Require skilful expertise to handle them
- Different indications due to anatomical factors

All BDS regarding outcome

- Have shown positive clinical outcomes
- Lack of comparative studies between them
- Lack of studies against standard techniques

Conclusions Take home messages

Stentys

Provisional technique when intention is KB
Avoid 2nd DES as the struts thickness is high
Good for big vessels and LM
Needs good preparation

BIOSS

Provisional technique when intention is KB or not
Good if intention is 2nd DES on SB
Good for big vessels and LM
Needs good preparation

Tryton

When intention is 2 stent strategy
Good when SB has difficult access
Needs good preparation and good SB wire
Avoid in diabetics and SB < 2,0 mm

Axxess

Perfect BDS as preserves the carina and flow
Avoid 2nd/3rd DES as the struts thickness is high
Needs good preparation and 7F GC
Unpredictable!!

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