Complex coronary bifurcation lesions treated with the novel polymer-free dedicated bifurcation paclitaxel-eluting stent (Nile pax): clinical and angiographic results of the prospective, multicenter bipax clinical trial

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On behalf of Dr. Jean Fajadet
and Co-investigators

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Potential conflicts of interest

Speaker's name: **Dr. Robert J. van Geuns**

❑ **I have the following** potential conflicts of interest to report:

- ❑ Research contracts
- ❑ Consulting
- ❑ Employment in industry
- ❑ Stockholder of a healthcare company
- ❑ Owner of a healthcare company
- ❑ Other(s)

✓ ❑ **I do not have any potential conflict of interest**

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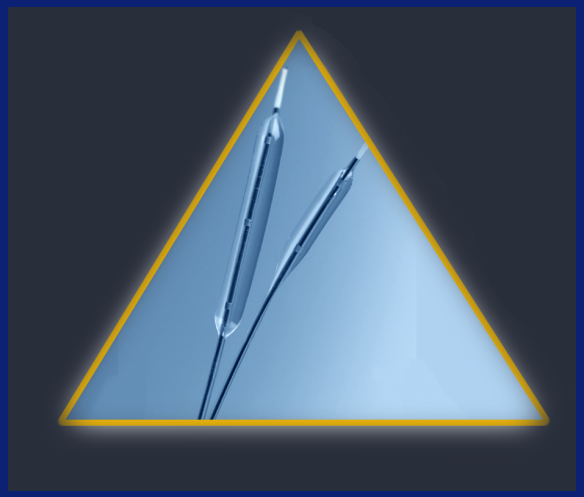
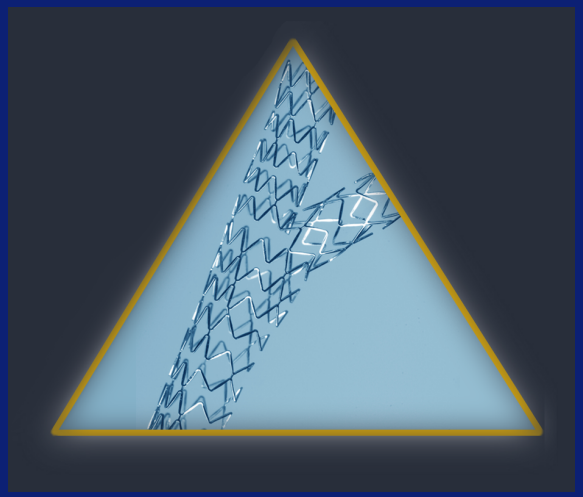
Study Device Platform



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



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

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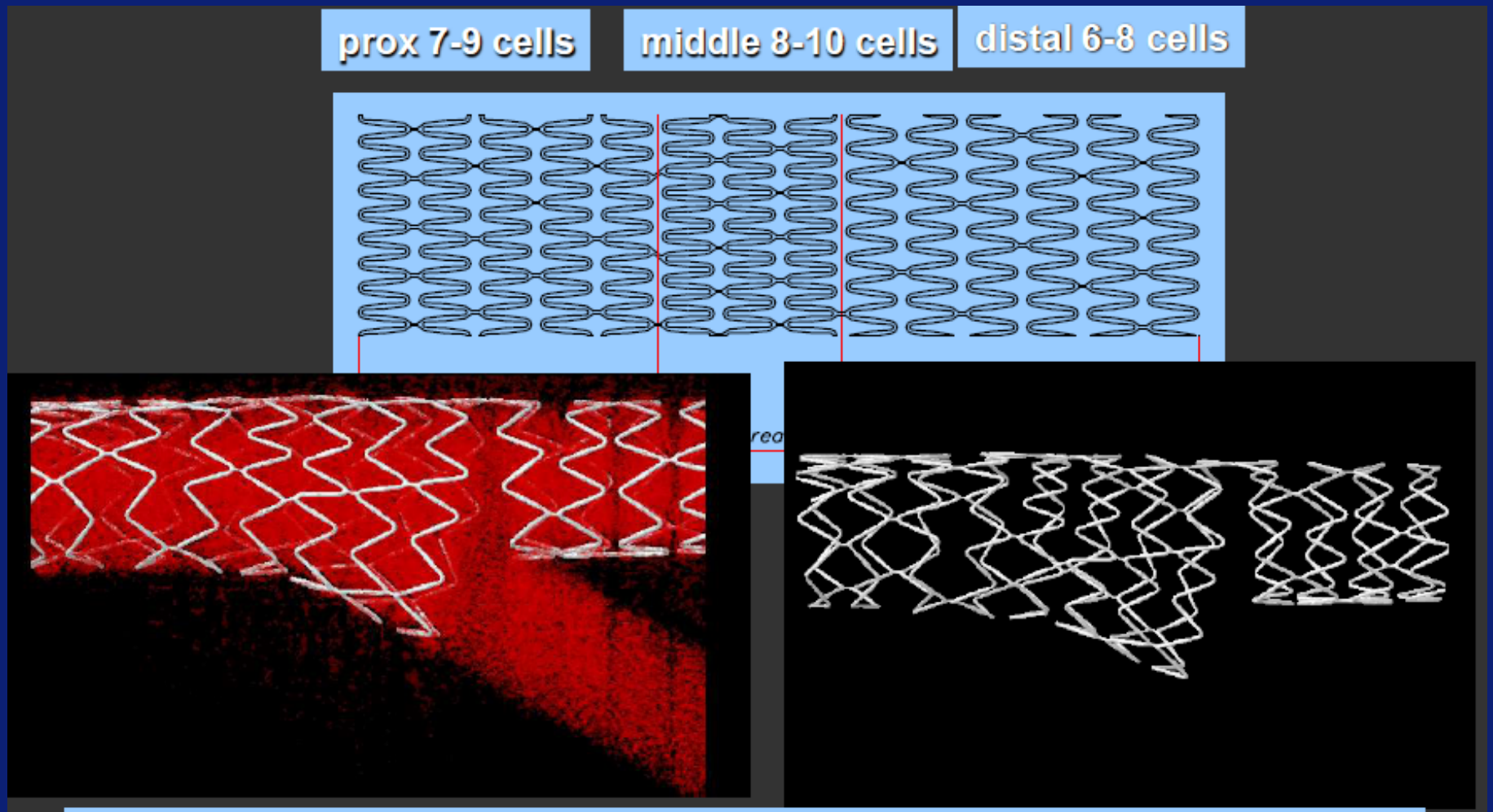
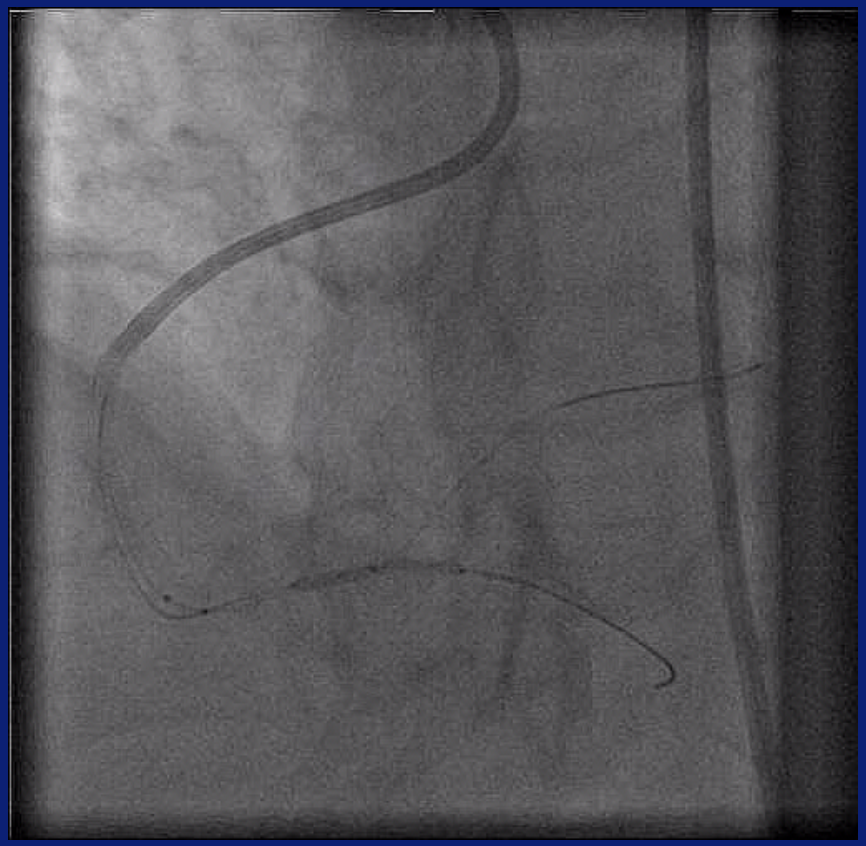
Study Device Platform

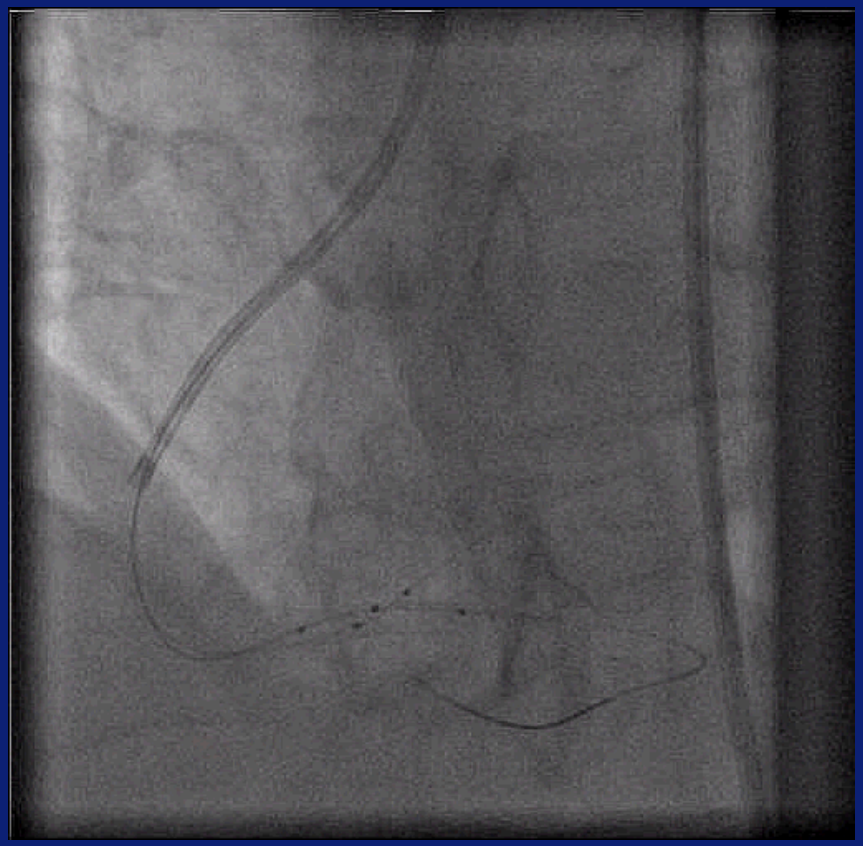


18 mm length, range of MB and SB diameters

Images by John Orminston

Nile Croco implantation





Wire both braches, predilatation of MB
Marker at mid-stent balloon **locating SB opening**
SB balloon proximal to MB balloon

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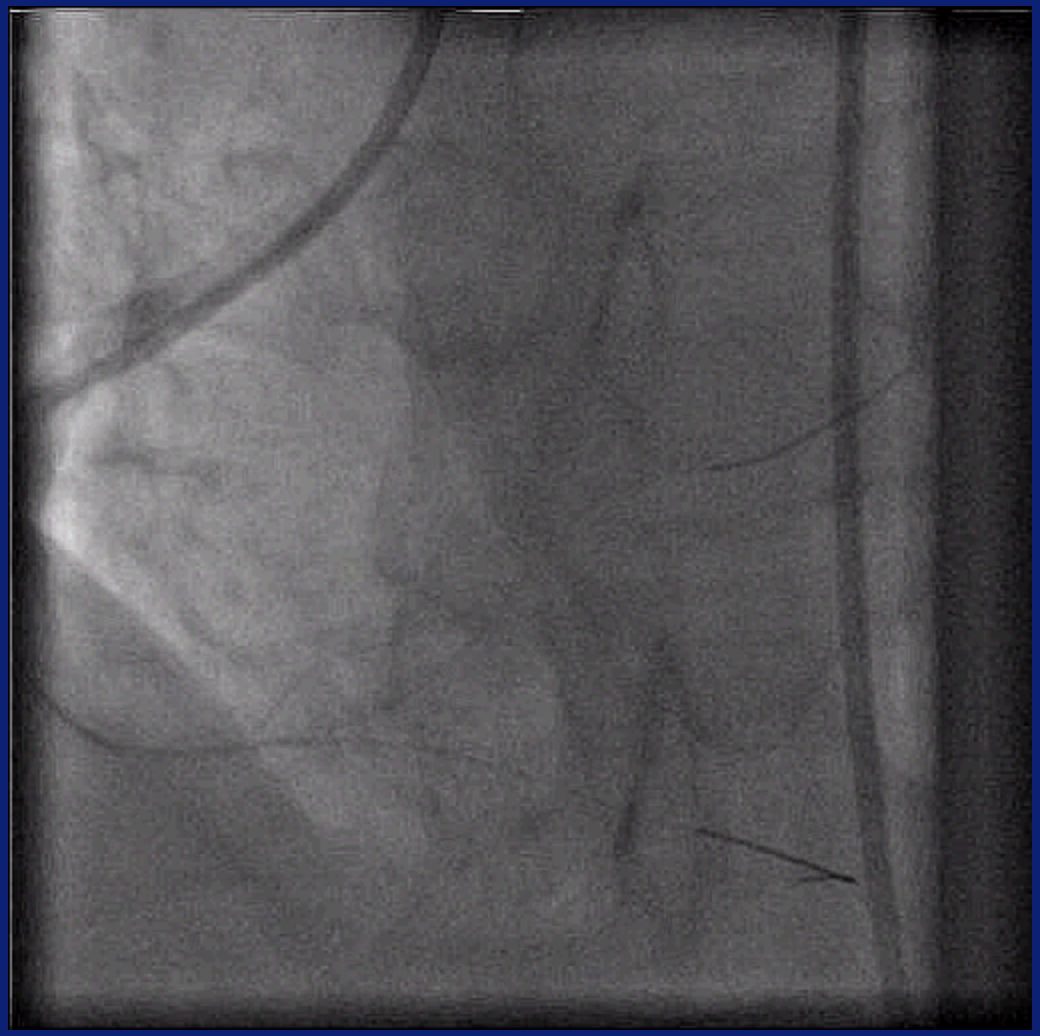
Nile Croco implantation



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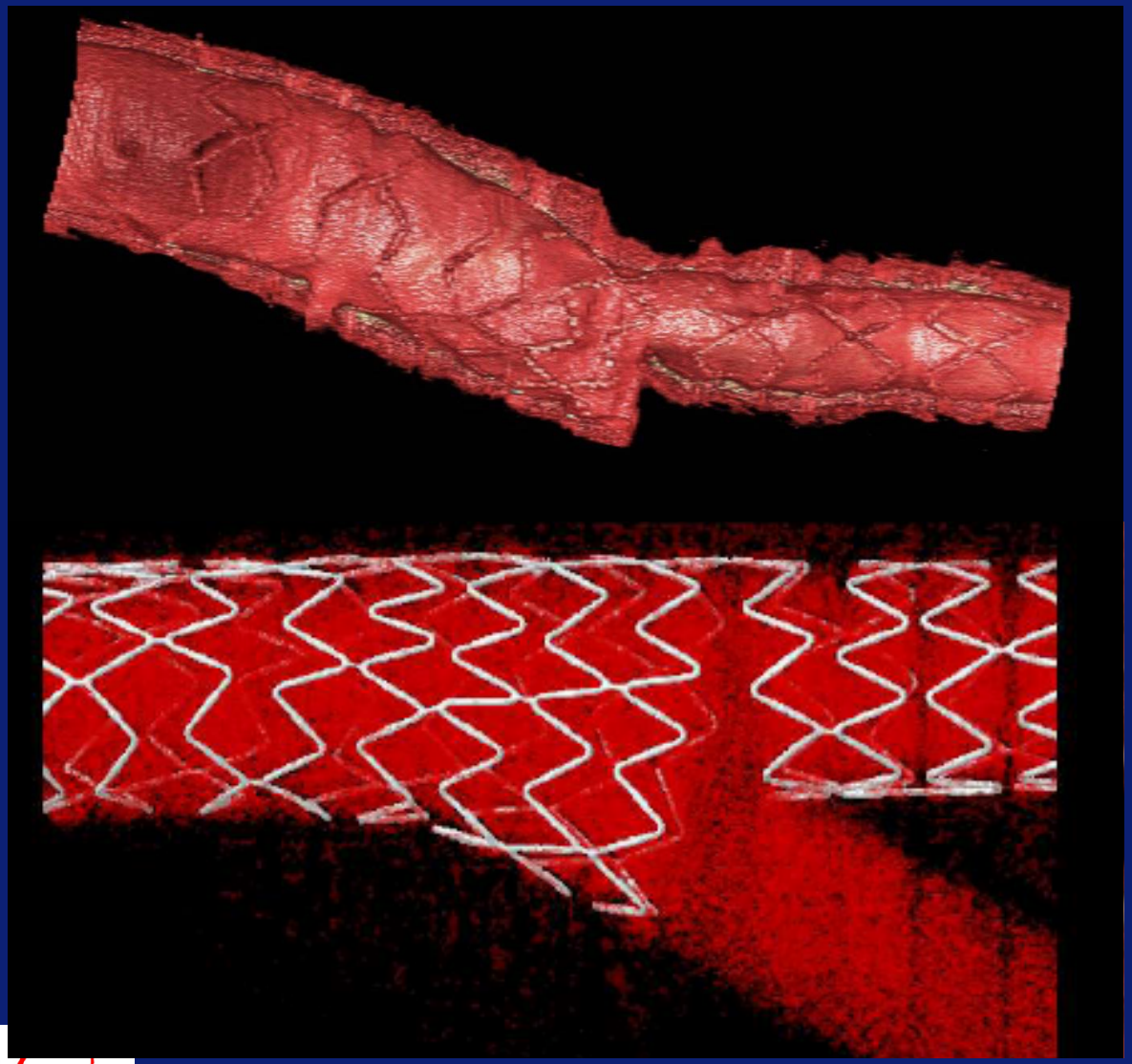
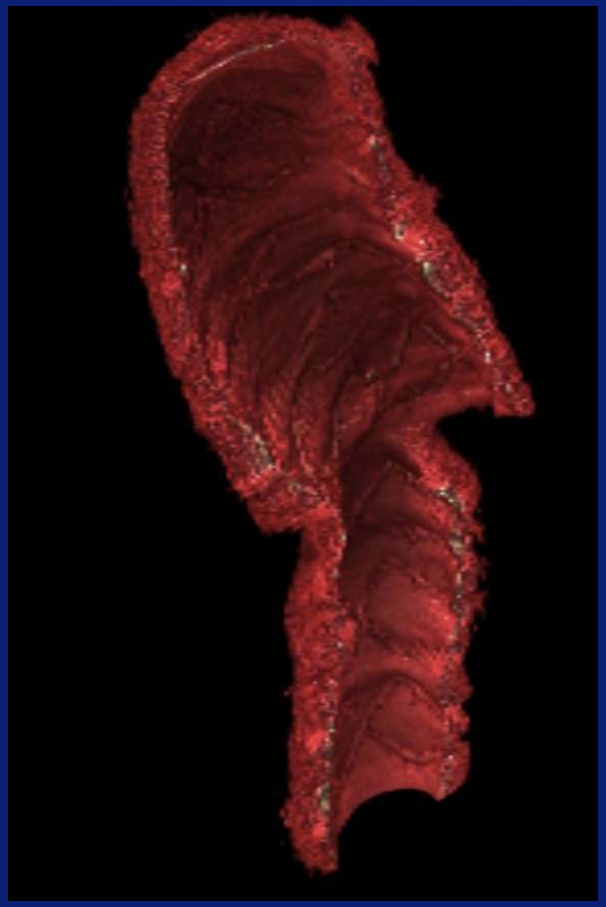
Intravascular imaging





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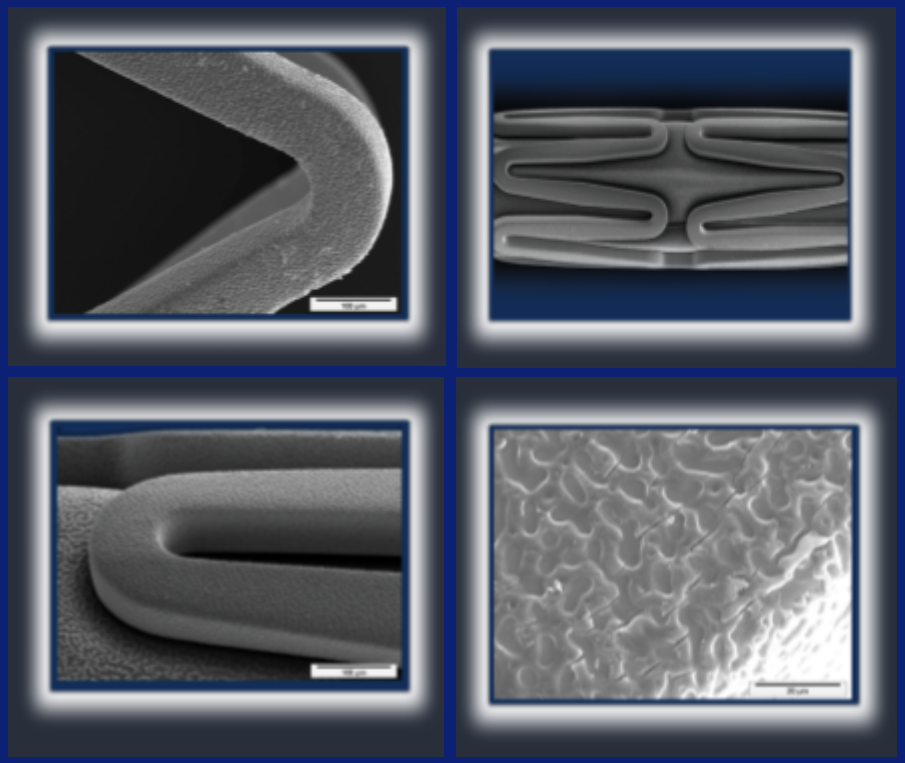
PAX DES Technology

- Smooth stent surface
- Abluminal coating – 5µ 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 2.5µg/mm²
- Boost-release (60% in 2 days), profile release established in 30 days (98% of the drug) → Back to regular Cobalt Chromium after 45 days

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Nile Pax
Bipax Clinical study

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Objective

To assess the safety and efficacy of the novel Nile PAX polymer-free drug-eluting coronary stent system for the treatment of single de novo bifurcation lesions in native coronary arteries

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BIPAX Trial Design

- Prospective, 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: **102** pts at 9 sites in Europe / South America
- Clinical follow-up: 1, 6, 9, and 12 months and yearly up to 5 years. Angiographic follow-up: 9 months (mandatory)
- Data Center/CEC: Cardiovascular Research Center, São Paulo, Brazil – Director, Andrea Abizaid, MD, PhD
- Angiographic Core Laboratory: Cardiovascular Research Center
- Sponsor: Minvasys SAS, Gennevilliers, France

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Clinical Sites and Investigators

1. Hosp. Universitari Vall D'Hebron
   Barcelona, Spain – 23 patients

   Bruno Garcia, MD

2. Clinique Saint Hilaire
   Rouen, France – 17 patients
   Jacques Berland, MD

3. Tokuda Hospital
   Sofia, Bulgaria – 15 patients
   Ivo Petrov, MD

4. Clinique Pasteur
   Toulose, France – 13 patients
   Jean Fajadet, MD

5. Centre Cardiologique
   Evecquemont, France – 11 patients
   Philippe Brenot, MD

6. Thorax Center
   Rotterdam, Netherlands – 7 patients
   Patrick Serruys, MD, PhD

7. Centre Cardiologique du Nord
   Saint Denis, France – 6 patients
   Thierry Royer, MD

8. Instituto Dante Pazzanese
   São Paulo, Brazil – 4 patients
   Alexandre Abizaid, MD, PhD

9. Casa di Cura Montevergine
   Mercogliano, Italy – 4 patients
   Paolo Rubino, MD

10. Hospital K. P. Panskiego
    Panskiego, Poland – 2 patients
    Maciej Lasiak, MD

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Inclusion Criteria

- ≥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:
  - ≤14 mm in the MB
  - ≤ 5 mm in the SB
- Acceptable candidate for CABG
- Comply with all schedule follow-ups including 9 months angiographic follow-up

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Endpoints

- *Primary endpoint:*
  - Angiographic binary restenosis in the treated lesion (MB and SB), as assessed by independent QCA analysis, at 9 months angiographic follow-up

- *Secondary endpoints:*
  - TVF, TLR, and TVR at 9 months follow-up
  - Acute success
  - Late lumen loss at 9 months follow-up
  - MACE at 30 days and 9 months follow-up

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Baseline Demographics

VARIABLE	N=101
Mean age, years	63.4±11.3
Female gender	22% (22)
Diabetes mellitus	26% (26)
Insulin dependent	8% (8)
Hypertension	74% (77)
Dyslipidemia	72% (73)
Smoking history / current	38% (38) / 17% (17)
Family history of CAD	26% (26)
Previous MI	20% (20)
Previous PCI	33% (33)
Renal insufficiency (serum creatinine ≥ 1.5mg/dL)	3% (3)

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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)

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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)

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QCA at 9 months FU

	Baseline		
	RD	MLD	%DS
PV	2.75 ± 0.37	1.05 ± 0.43	61.3 ± 15.7
SB	2.44 ± 0.54	1.36 ± 0.56	43.6 ± 21.4

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Restenosis at AT 9-MO. FU (primary endpoint)

Binary Restenosis	**N=86**
Parent vessel	13.9% (12)
Side branch	12.8% (11)

*per bifurcation lesion

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Clinical Outcomes (N=95)

Event (cumulative)	IH	30-Day	6-Mo.	9-Mo.
Death				
Cardiac	0% (0)	0% (0)	0% (0)	0% (0)
Non-cardiac	1% (1)	1% (1)	1% (1)	1% (1)
MI	0% (0)	0% (0)	1% (1)	1% (1)
TLR (any)	0% (0)	0% (0)	4.2% (4)	12.6% (12)
TVR (any)	0% (0)	0% (0)	4.2% (4)	12.6% (12)
ST	0% (0)	0% (0)	0% (0)	0% (0)

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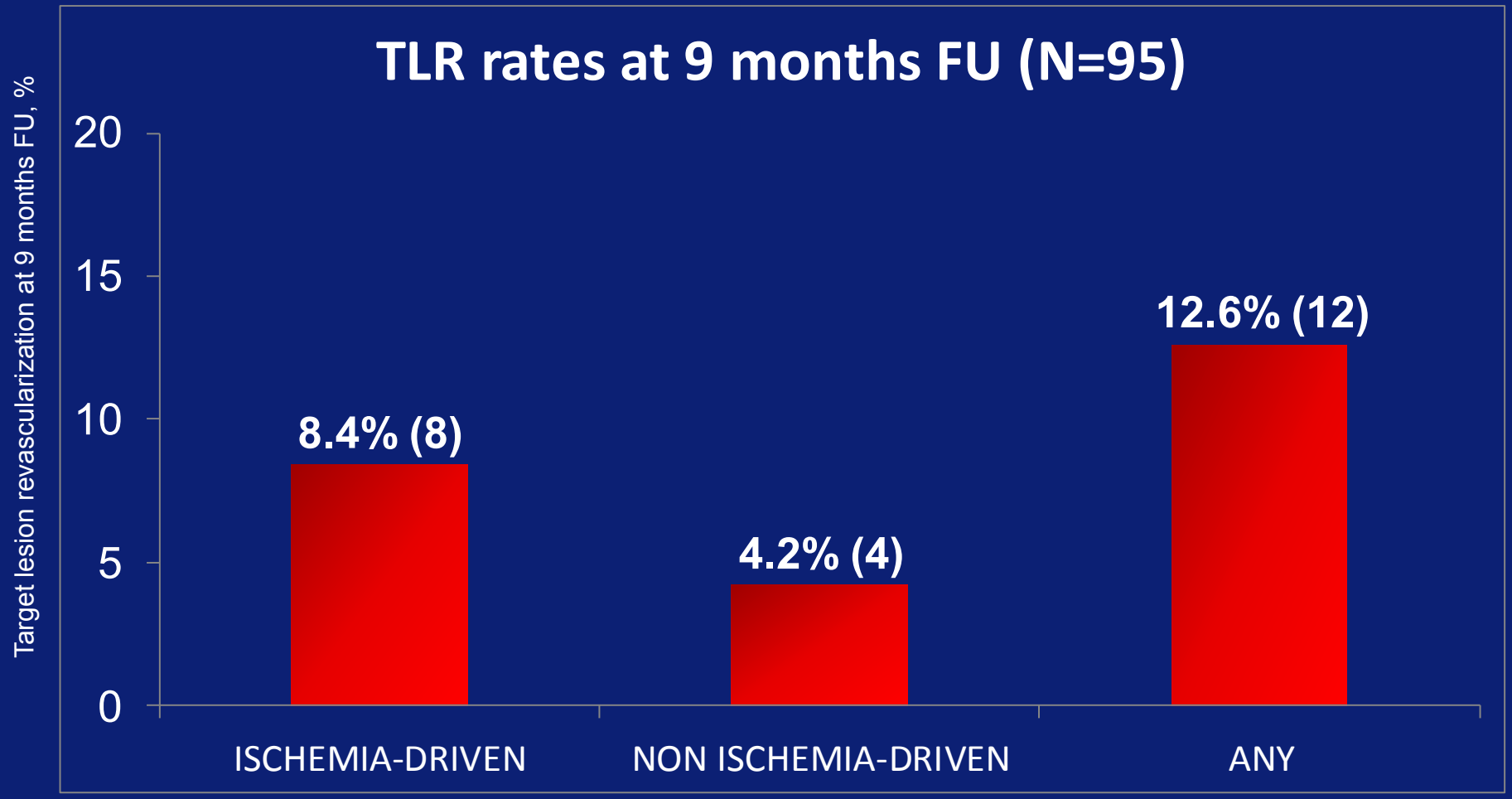
Target Lesion Revascularization



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Conclusions

In patients following the protocol criteria (n=95):

- Angiographic FU at 9 months demonstrated binary restenosis rates in the PV and SB of 13.9% and 12.8%, respectively (primary endpoint), with overall in-bifurcation lesion restenosis of 18.6%
- At 9 months clinical FU, cumulative ischemia-driven TLR rate was 8.4%, and overall TLR rate was 12.6%
- Overall, there were no safety concerns, including absence of cardiac death and stent thrombosis throughout the study, and only 1 case of non-Q wave MI related to a new revascularization procedure

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