

The Minvasys Nile Paclitaxel-Eluting Sidebranch Access Stent: Results from the BiPAX Study

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On behalf of Co-investigators

Disclosure Statement of Financial Interest

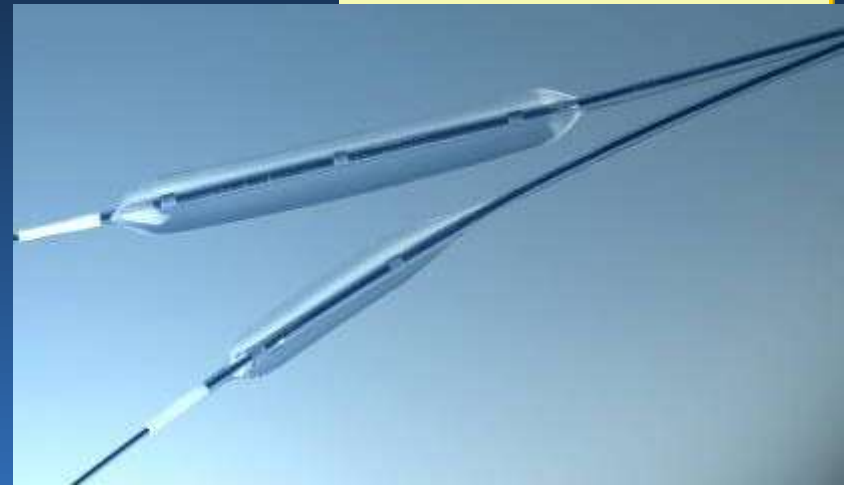
Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

<u><i>Affiliation/Financial Relationship</i></u>	<u><i>Company</i></u>
<i>Grant/ Research Support:</i>	<i>Minvasys</i>
<i>Consulting Fees/Honoraria:</i>	-
<i>Major Stock Shareholder/Equity Interest:</i>	-
<i>Royalty Income:</i>	-
<i>Ownership/Founder:</i>	-
<i>Salary:</i>	-
<i>Intellectual Property Rights:</i>	-
<i>Other Financial Benefit:</i>	-

NILE Design

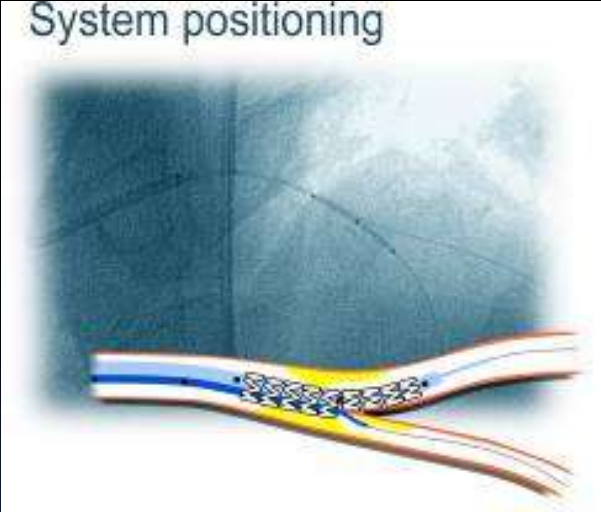
Dedicated Cobalt Chromium Stent

- Extra Thin (73μ thickness) Stent.
- Two Rx specific PTCA catheters, mounted on two wires, sequential balloons. All sizes 6 Fr compatible
- Design ensuring same ratio metal/artery all along the bifurcation without cell overstretching.
 - 7 or 9 cells on proximal part
 - 8 or 10 cells on the carina
 - 6 or 8 cells on the distal part.
- No angulation restriction
- CE marked since 2005 –
- Two registries validated the concept

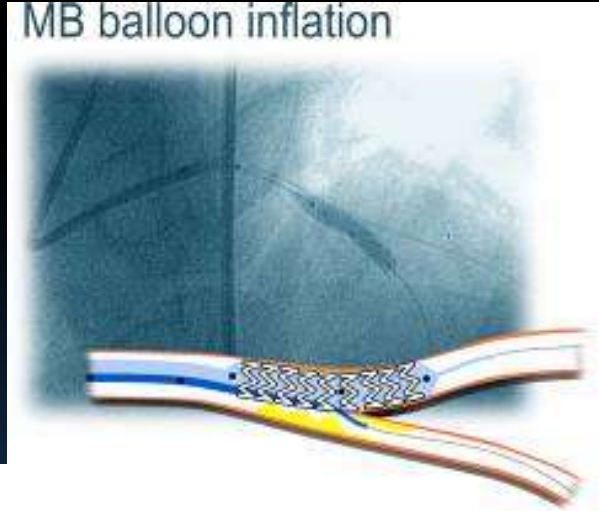


NILE Concept

System positioning



MB balloon inflation



SB balloon positioning



Balloon kissing



Nile Croco[®] Registry

Spanish French Experience ^(1, 2)



- Centers (n) 3
- Pts included (n) 93
- Male(%) 78
- Mean age (years) 65,6
- > 80 years (%) 11
- Diabetics (%) 22
- Angiographic success
 - complete (%) 99
 - complete + partial (SB>50%) 100
- Device success (%) 96



1 – B GARCIA, EBC 2008.
2 – F. DIGNE, SFC 2008

Nile Croco[®] Registry

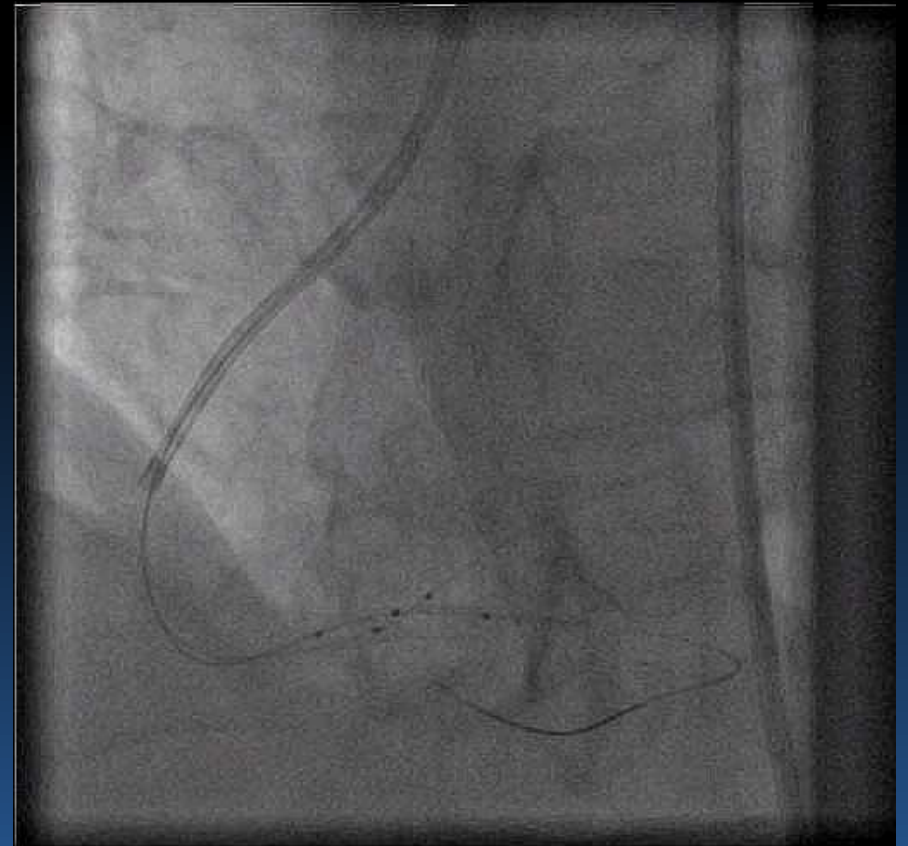
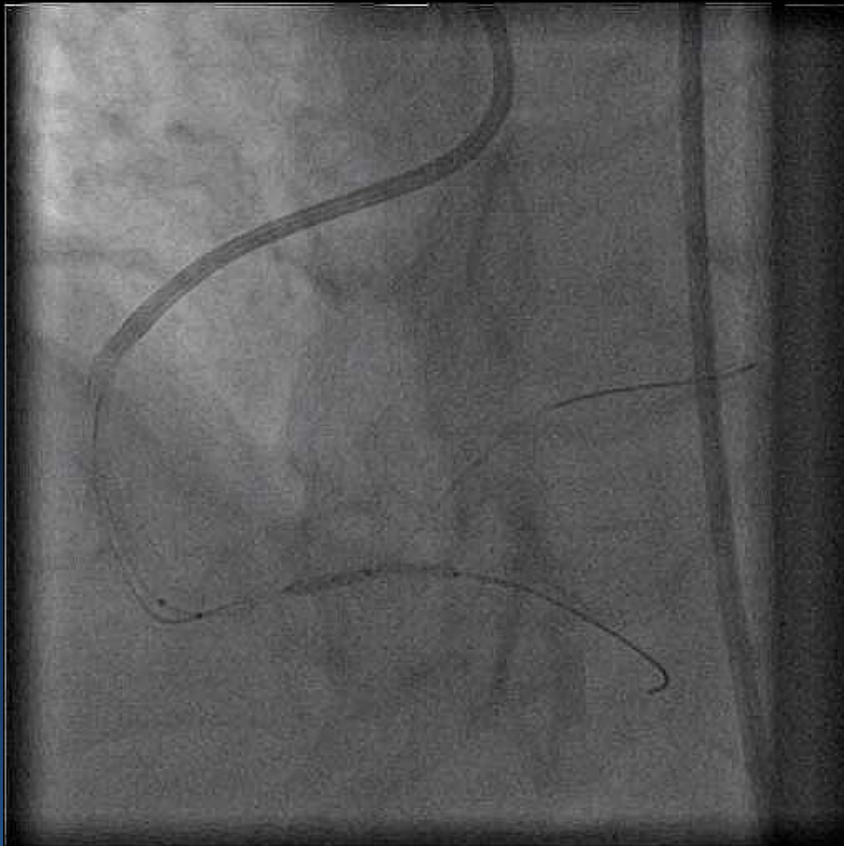
Spanish French Experience (1, 2)



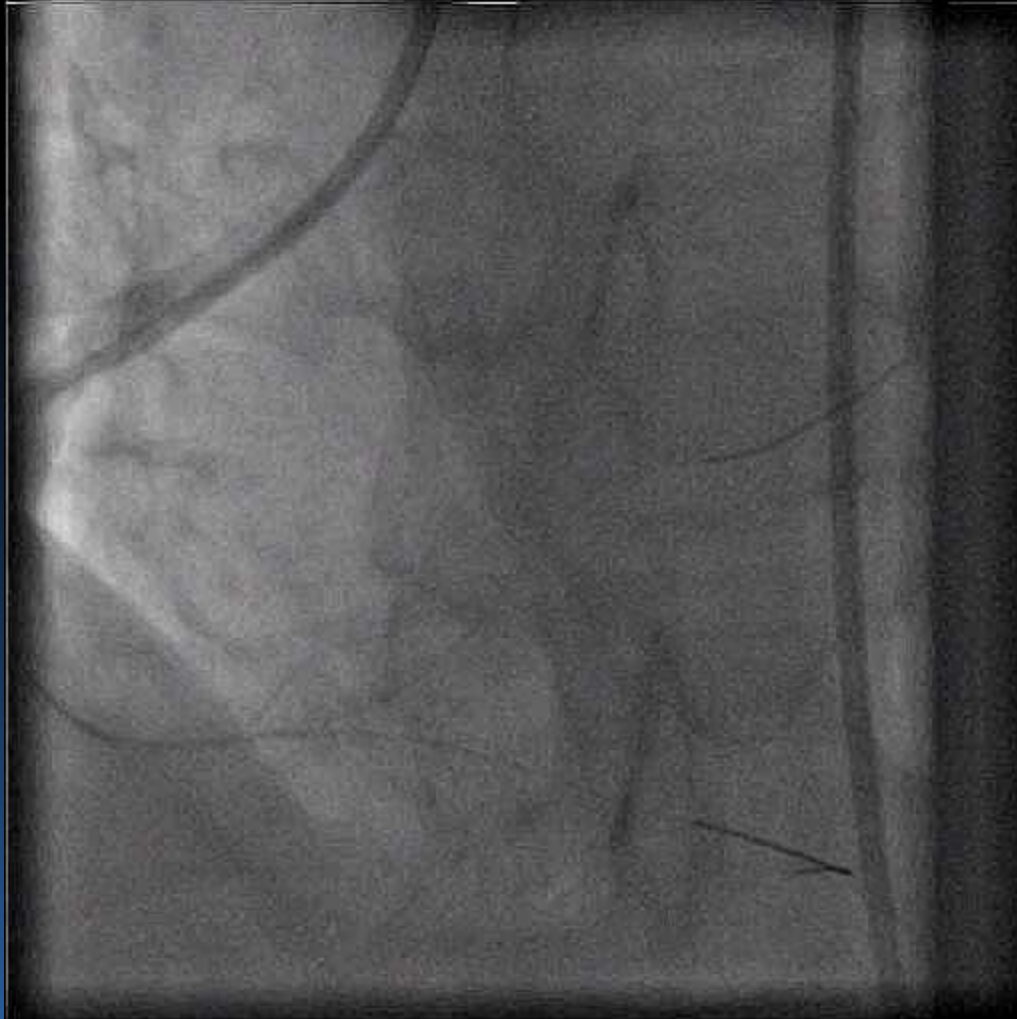
- 6-months clinical FU (n) 85
- MI 0 (0%)
- Re-PTCA 6 (7%)
- CABG 2 (2%)
- Death (1 in-hospital, 1 day 10) 2 (2%)
- MACE 10 (12%)
- TLR 8 (9.4%)



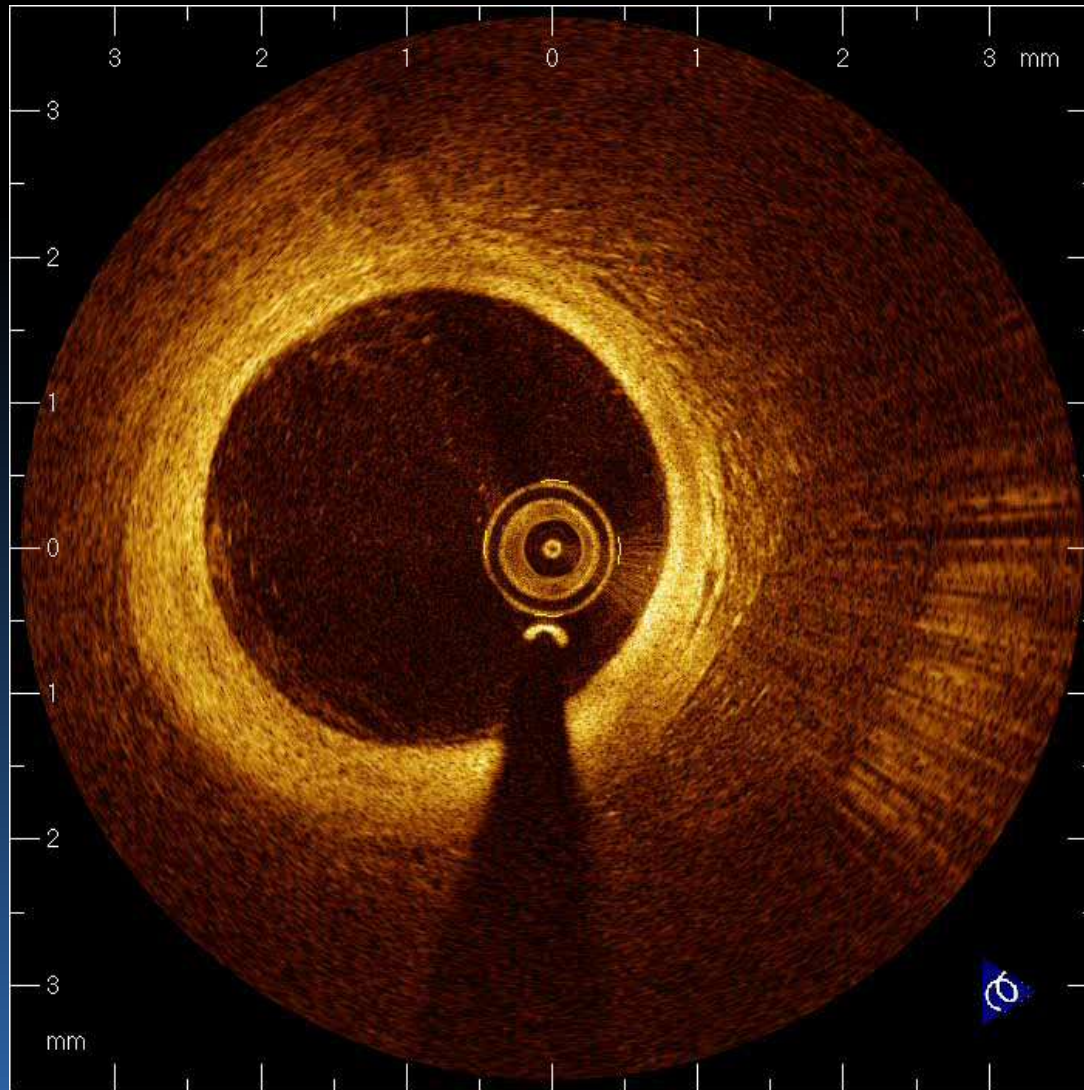
Nile Croco implantation



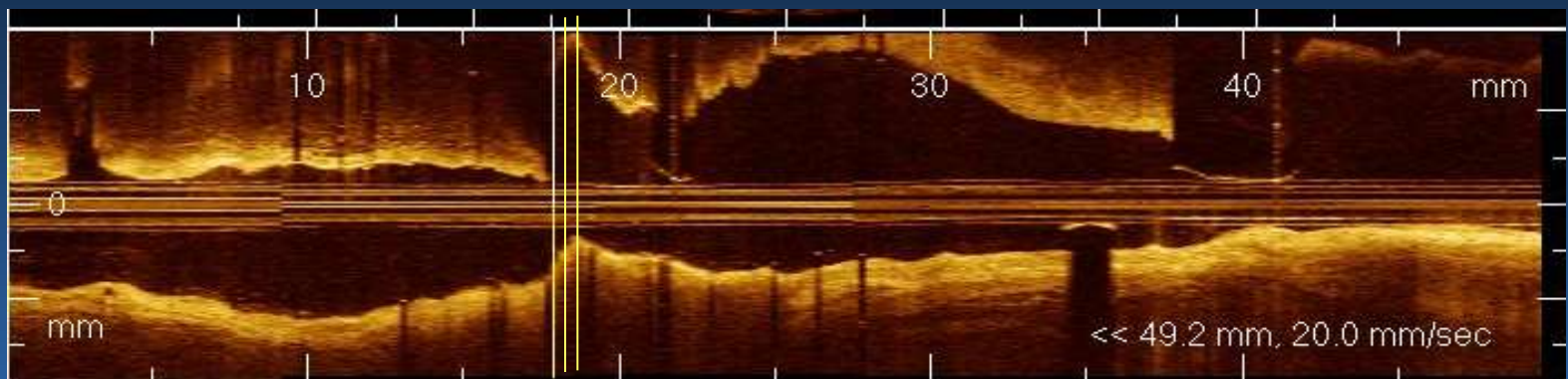
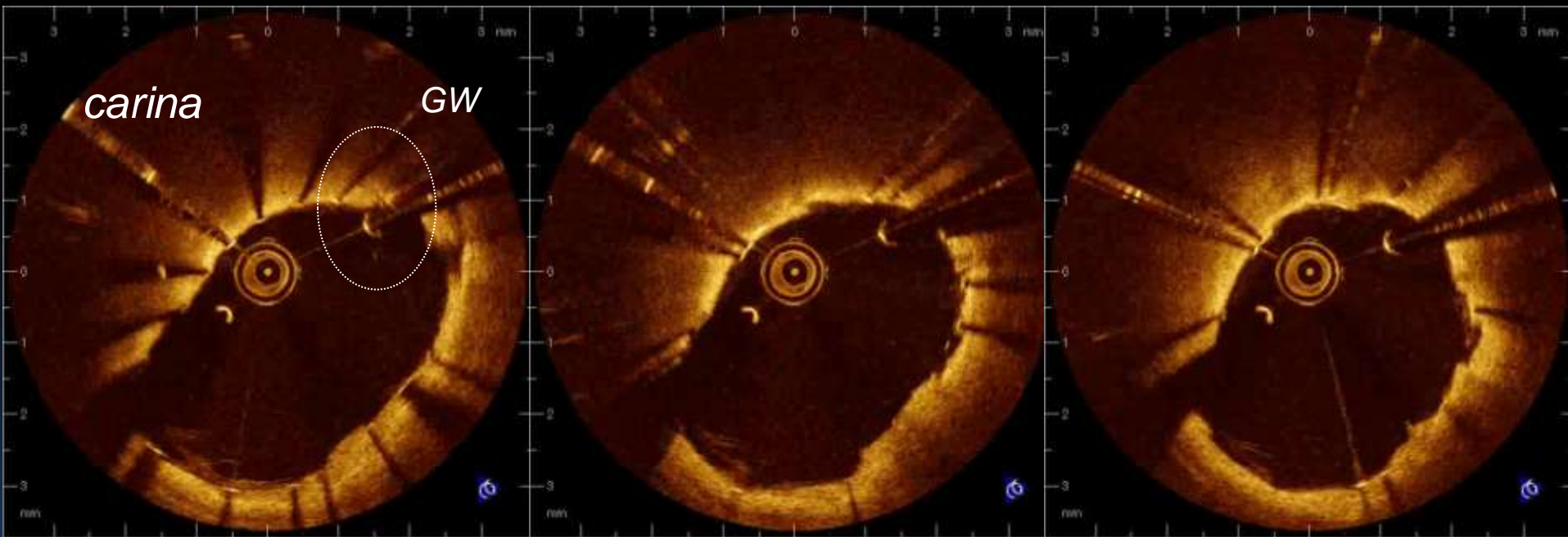
Nile Croco implantation



In vivo OCT with Nile Croco[®]



In vivo OCT with Nile Croco[®]

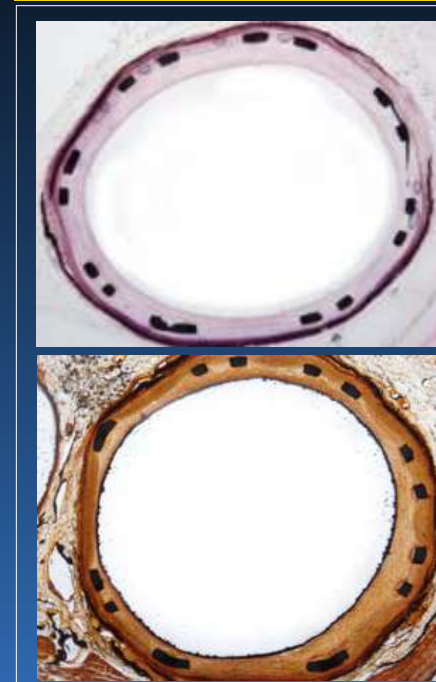
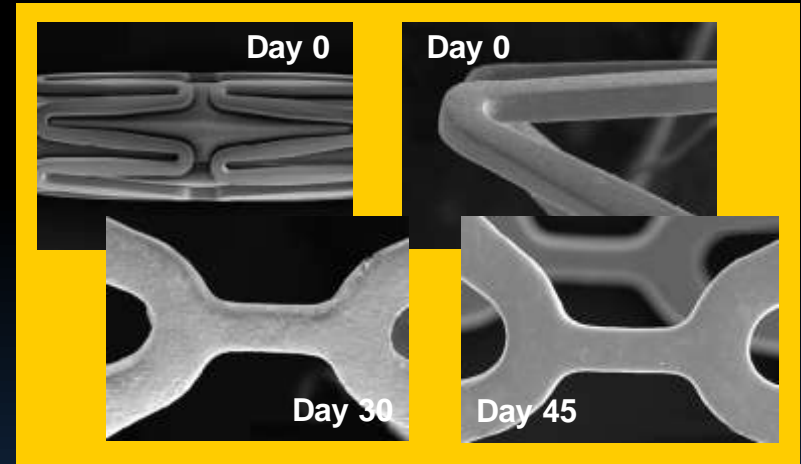


■ Abluminal Paclitaxel

- No coating on intra-luminal surface for a better reendothelization
- Specific action on Smooth Muscle Cell (SMC) main cause of restenosis.

■ Polymer-free

- 2.5 $\mu\text{g}/\text{mm}^2$ dose consistent coating ensuring 98% delivery.
- Release profile clearly establish in 30 days.
- Back to regular Cobalt Chromium stent after 45 days.



BiPAX study

PI: Dr Jean Fajadet,

Clinique Pasteur, unité de cardiologie interventionnelle, Toulouse, France

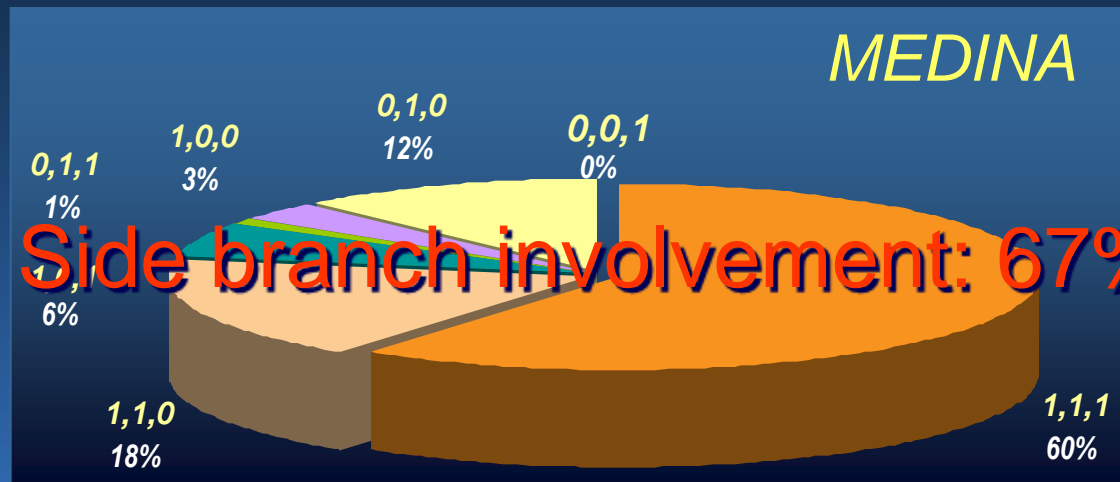
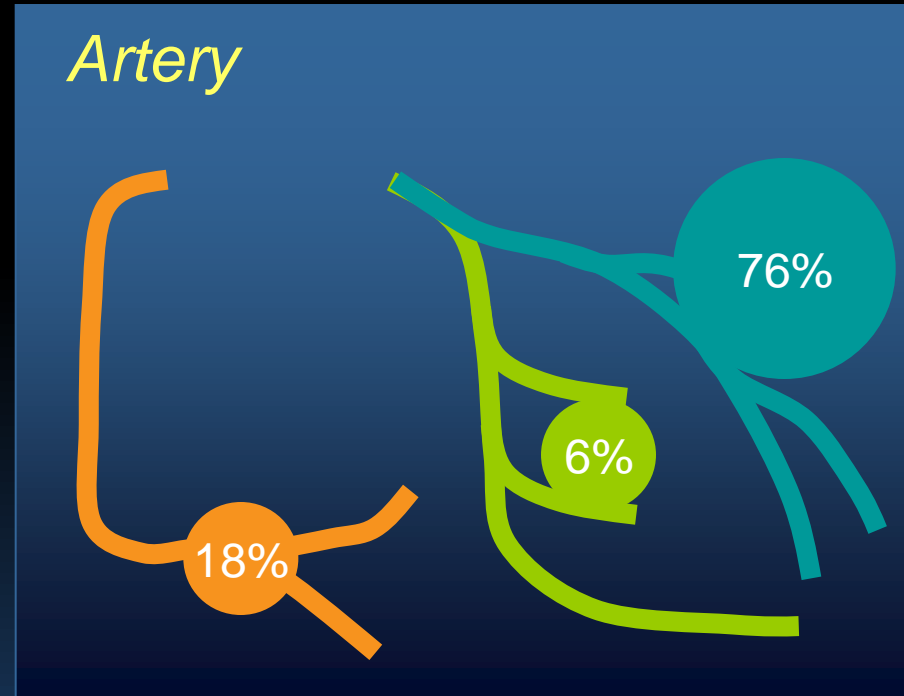
- Assess safety and efficacy of the NILE PAX® Bifurcation Drug Eluting Coronary Stent System.
- Treatment of single de novo bifurcation lesions in native coronary arteries.
- Prospective, non-randomized, multicenter study (N=100)
- Primary endpoints:
 - Restenosis of the main branch and side branch by QCA
 - Binary restenosis rate at 9 months post procedure.
- Secondary endpoints
 - In-stent late lumen loss at 9 months
 - Clinically driven MACE (TVF) at 9 months

Update September 2009

- First patient in: December 2008
- 63 patients enrolled
- Implant success: 59/60
- End of enrollment: December 2009
- Presentation of data: EuroPCR 2010

Bipax study population

<i>n=60</i>	<i>Nile Pax & Delta</i>
Mean age:	64 years
Female gender :	27%
Diabetes :	27%
Previous MI :	18.3%
Previous PCI :	40%
Stable angina :	41.7%
Silent ischemia :	18.3 %



Treatment technique

Predilatation

Principal Vessel	93.4%
Side Branch	45%

Stent implantation

Principal Vessel (study stent)	98.4%
Side	26.7%

Single postdilatation

Principal Vessel	20%
Side Branch	13.4%

Treatment technique

Kissing-balloon inflations	90%
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Additional stent(s) implanted

Principal Vessel	21.7%
Side Branch	0%

Visible wire "tangling"	33.4%
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Dissection during procedure

Principal Vessel	11.7%
Side Branch	3.4%

Preliminary QCA results



For the PV and SB (n=30).

Variable	PV		SB	
	Pre	Post	Pre	Post
Lesion length (mm)	11.57±4.91		3.43±0.38	
Reference diameter (mm)	2.82±0.39	2.89±0.34	2.19±0.50	2.24±0.35
MLD (mm)	1.06±0.44	2.59±0.31	1.31±0.50	1.81±0.36
% DS	62.7±13.8	11.9±6.4	38.9±22.6	18.9±9.8

CONCLUSIONS *BiPax trial*

- *Preliminary results on 60 patients confirm the clinical applicability of this specifically designed bifurcation stent in a population with challenging lesions closed to real life angioplasty.*
- *Despite high rate (67%)of ostial side branch lesions ,only 27% of patient received a SB stent confirming a satisfactory covering of the carina.*
- *At 30 days no device related MACE*
- *9 months clinical and angio data will be presented next year .*

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