

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

Affiliation/Financial Relationship

Company

Grant/ Research Support:

Minvasys

Consulting Fees/Honoraria:

-

Major Stock Shareholder/Equity Interest:

-

Royalty Income:

-

Ownership/Founder:

-

Salary:

-

Intellectual Property Rights:

-

Other Financial Benefit:

-

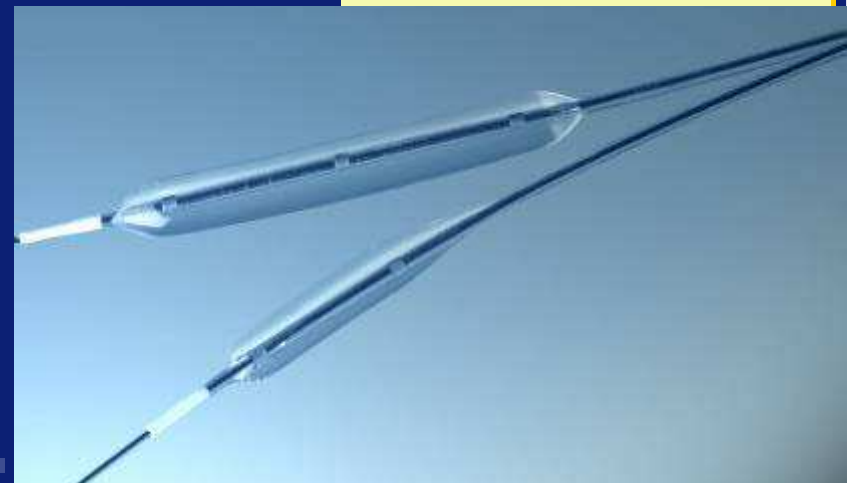


Erasmus MC
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NILE Design

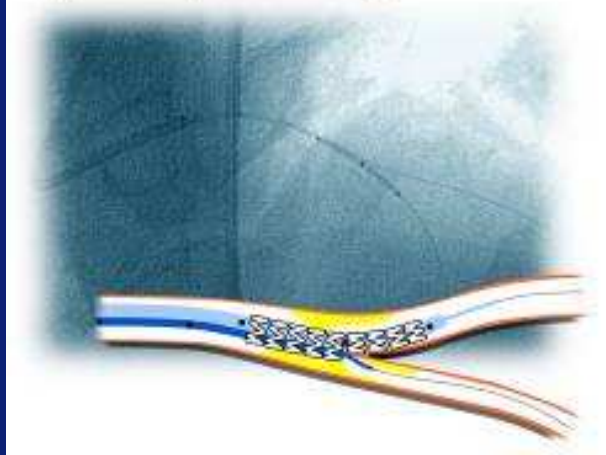
Dedicated Cobalt Chromium Stent

- Extra Thin (73 μ 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

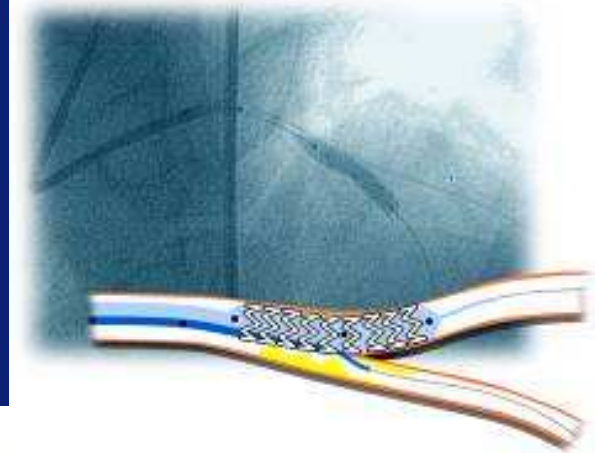


NILE Concept

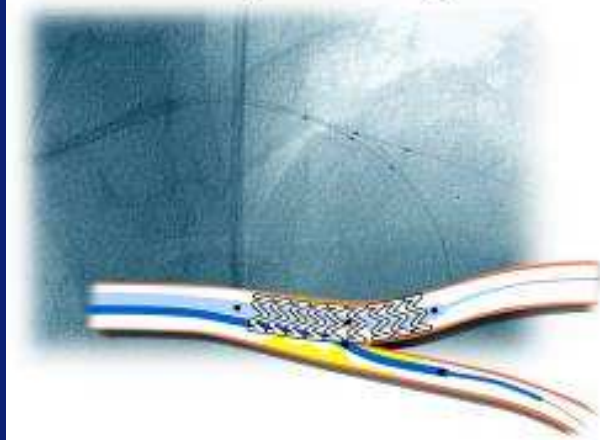
System positioning



MB balloon inflation



SB balloon positioning



Balloon kissing



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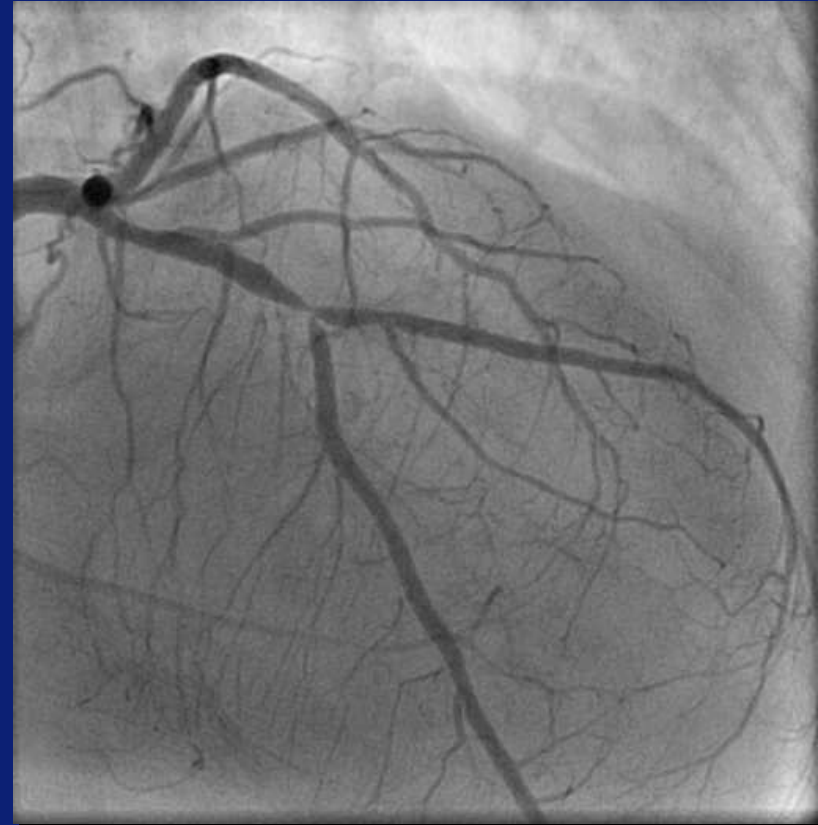
The Erasmus MC logo, featuring a stylized signature of the name 'Erasmus' in a cursive font.



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



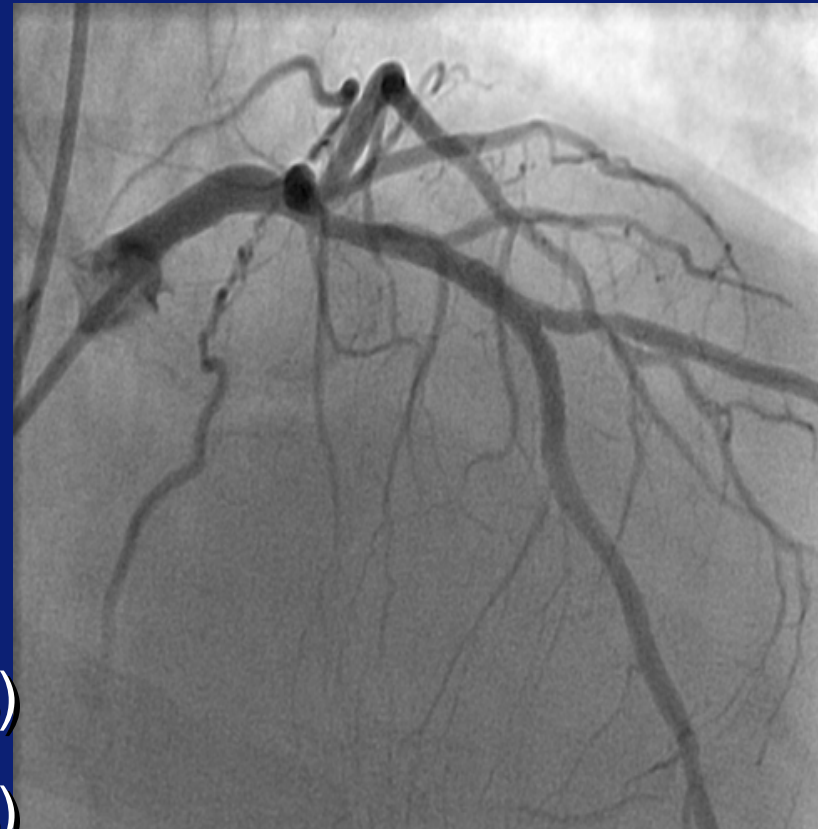
1 – B GARCIA, EBC 2008.
2 – F. DIGNE, SFC 2008

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Nile Croco[®] Registry

Spanish French Experience ^(1, 2)

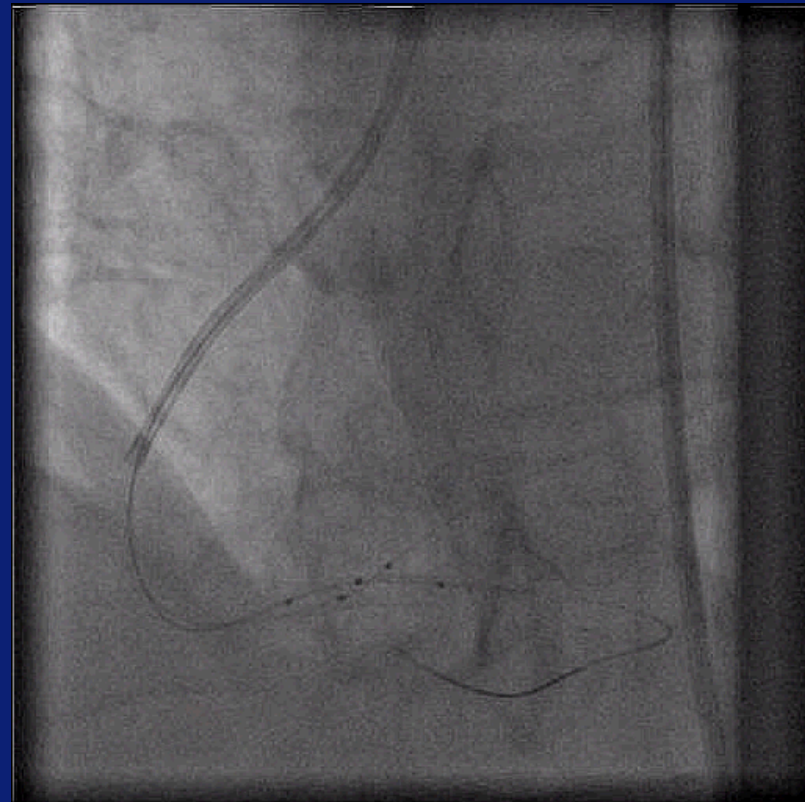
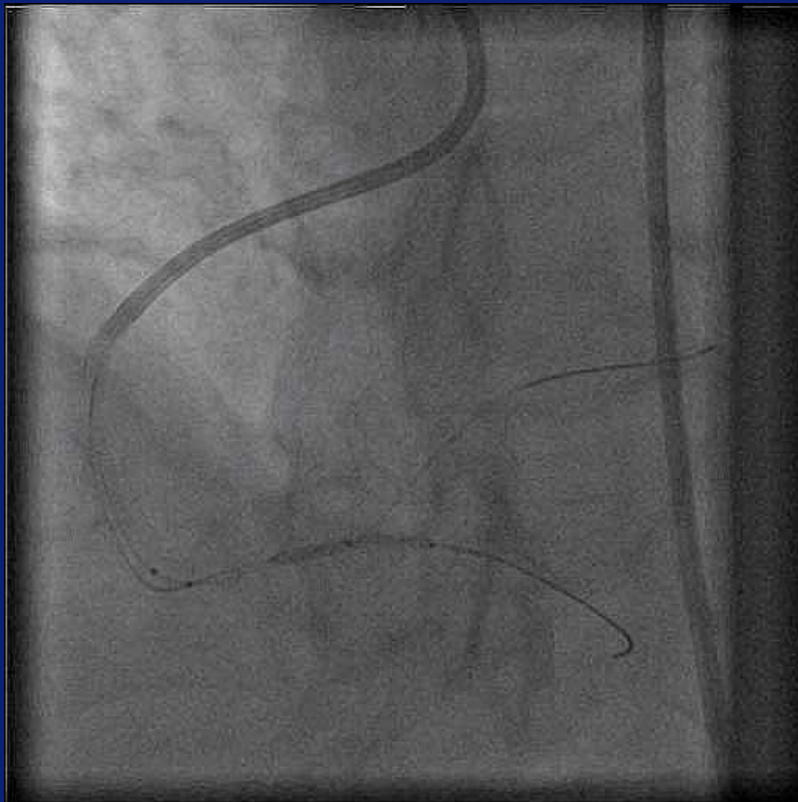
- 6-months clinical FU (n) 85
- MI 0 (0%)
- Re-PTCA 6 (7%)
- CABG 2 (2%)
- Death (1 in-hospital, 1 day 10) 2 (2%)
- MACE 10 (12%)
- TLR 8 (9.4%)



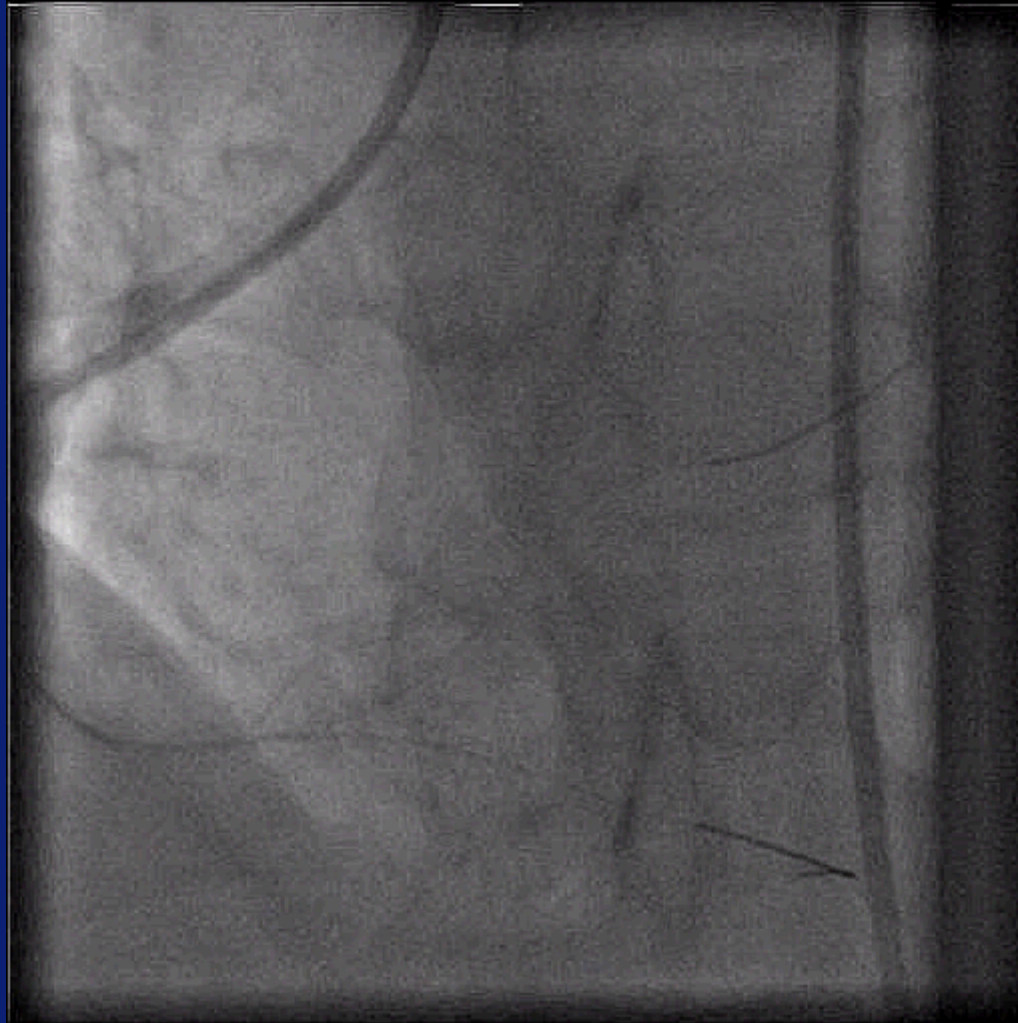
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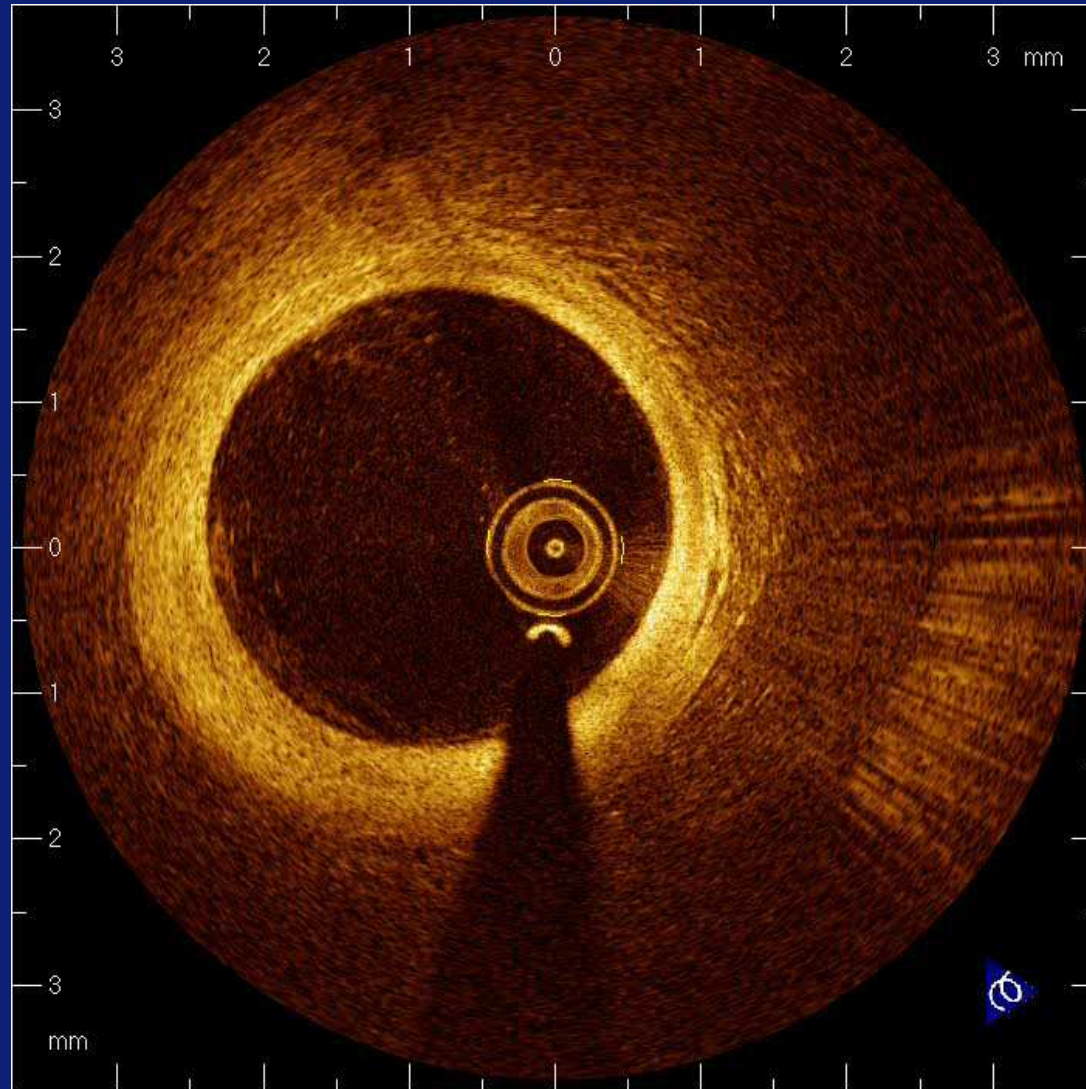
Nile Croco implantation



Nile Croco implantation



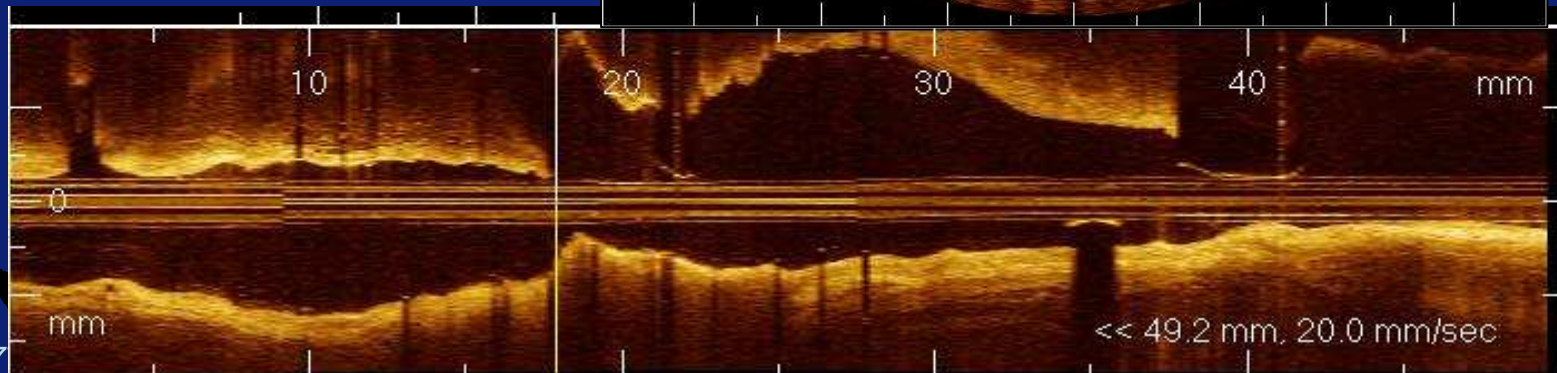
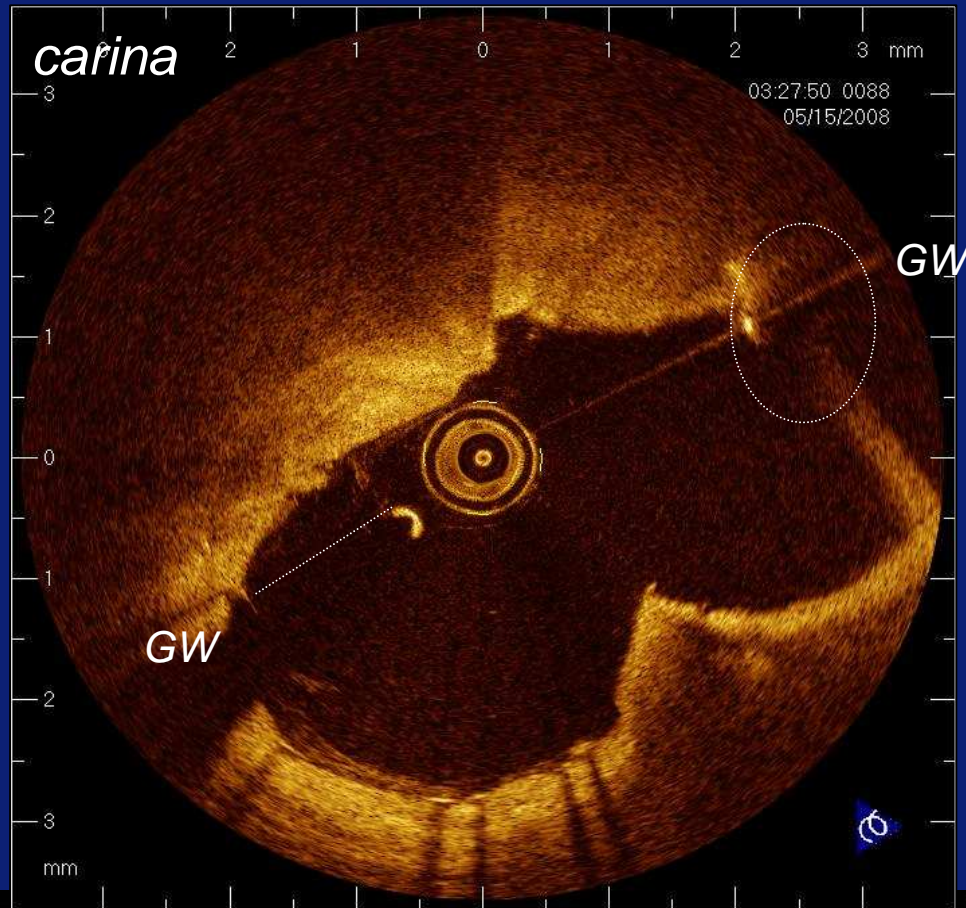
In vivo OCT with Nile Croco[®]



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In vivo OCT with Nile Croco[®]



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Ezafus

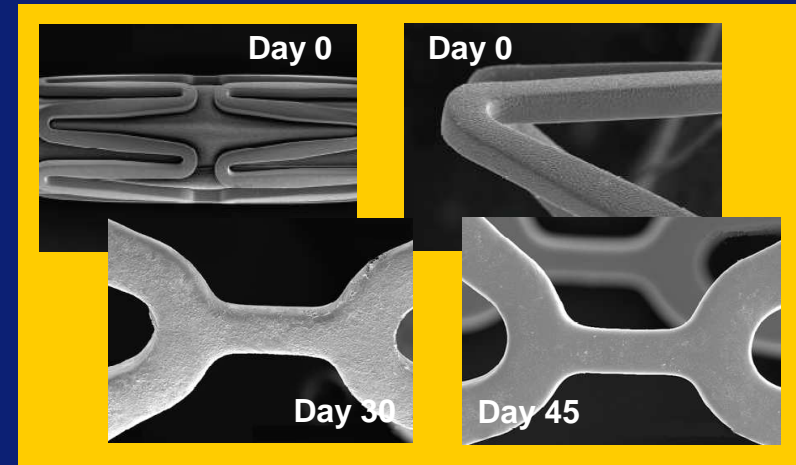


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Pax Technology

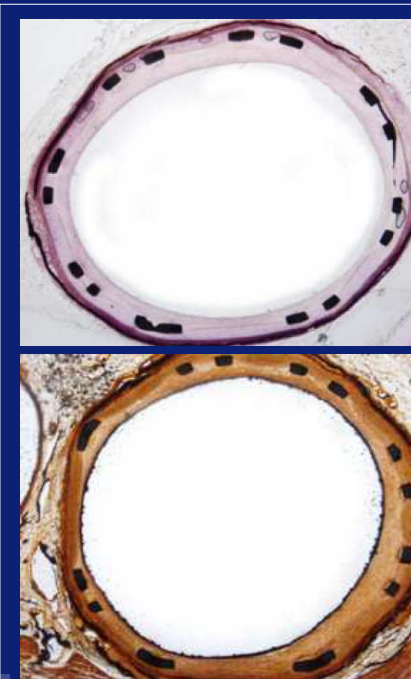
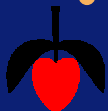
■ Abluminal Paclitaxel

- 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 June 2009

- First patient in: December 2008
- 43 patients enrolled
- Inplant succes: 42/43
- End of enrollement: December 2009
- Presentation of data: EuroPCR 2010



BIPAX STUDY POPULATION

n=30	
Mean age:	•63 years
Female gender :	•30%
Diabetes :	•23%
Previous MI :	27%
Previous PCI :	43%
Stable angina :	73%
Silent ischemia :	27 %

ARTERY	% (n/30)
LAD/Dg	87% (26/30)
LCx/OM	7% (2/30)
RCA-PDA/PLSA	7% (2/30)

LESION TYPE (MEDINA)	% (n/30)
1,1,1	23% (7/30)
1,1,0	7% (2/30)
1,0,1	17% (5/30)
0,1,1	13% (4/30)
1,0,0	17% (5/30)
0,1,0	23% (7/30)
0,0,1	0% (0/30)

Side branch involvement: 53%



PROCEDURAL DATA

TREATMENT TECHNIQUE	% (n/30)
Predilatation	
Principal Vessel	90% (27/30)
Side Branch	30% (9/30)
Stent implantation	
Principal Vessel (study stent)	97% (29/30)
Side	20% (6/30)
Single postdilatation	
Principal Vessel	17% (5/29)
Side Branch	10% (4/29)

TREATMENT TECHNIQUE	% (n/30)
Kissing-balloon inflations	93% (27/29)
Additional stent(s) implanted	
Principal Vessel	27% (8/30)
Side Branch	20% (6/30)
Visible wire “tangling”	36% (10/28)
Dissection during procedure	
Principal Vessel	17% (5/29)
Side Branch	10% (4/29)



PRELIMINARY QCA RESULTS

FOR THE PV AND SB (N=29).

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	2.18±0.47	1.31±0.50	1.81±0.36
% DS	62.7±13.8	21.9±10.8	38.9±22.6	18.9±9.8



CONCLUSIONS *BiPax trial*

- *Preliminary results on 30 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 (53%)of ostial side branch lesions ,only 20% 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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- Doctor Robert Jan van Geuns

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