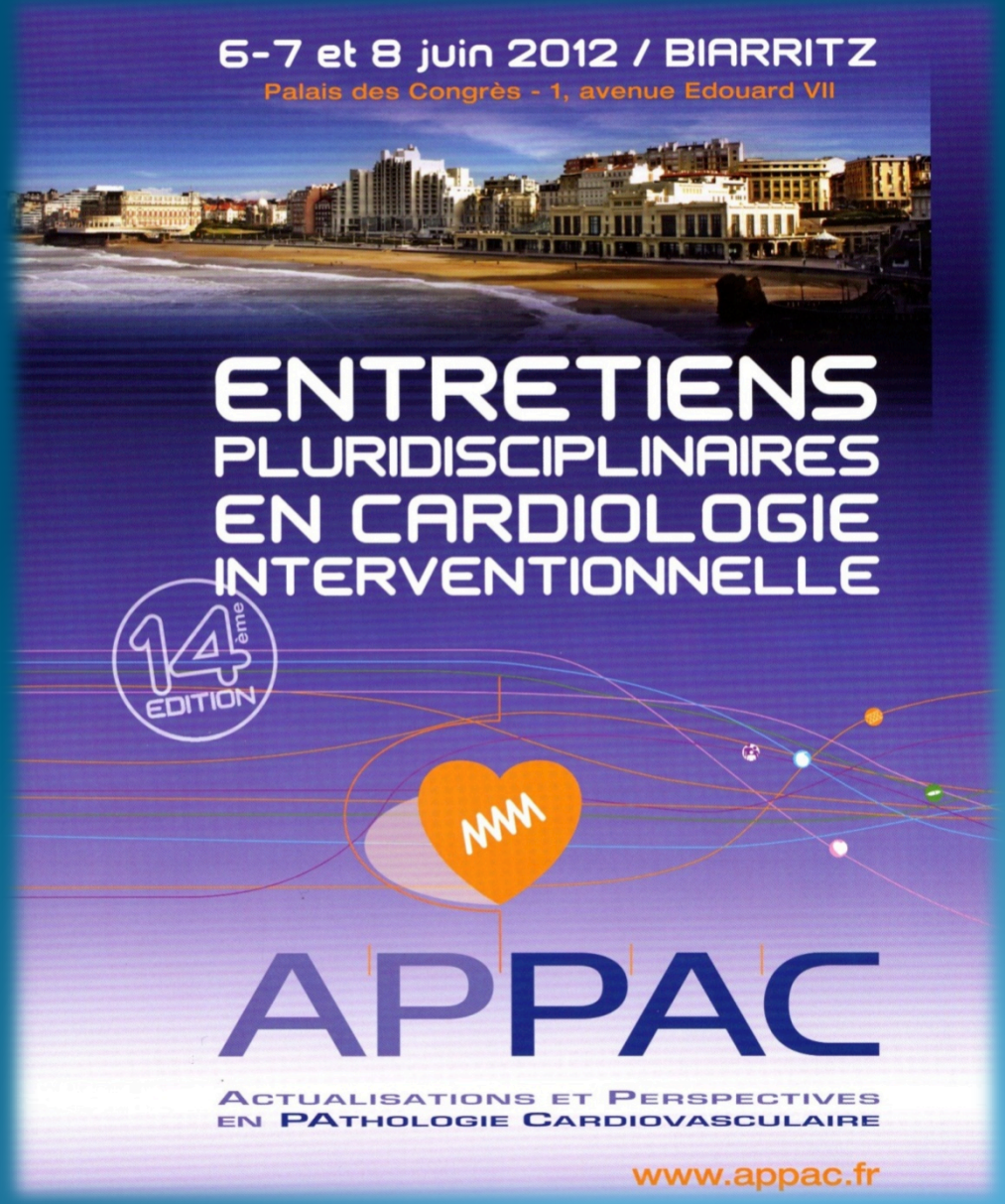


U.C.V.

Docteur B. VALEIX
Clinique Casamance
Aubagne

17H50-18H50

ATELIERS

MINVASYS

COMMENT TRAITER AUJOURD'HUI LES LESIONS CORONAIRES DE BIFURCATION ?

Modérateur : B. VALEIX *(Marseille)*

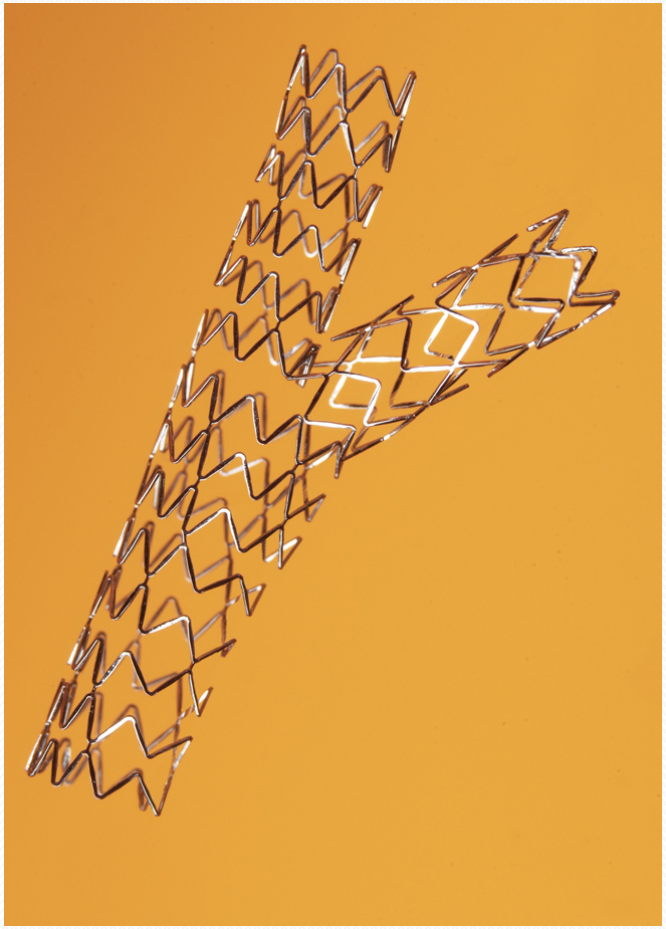
- Le concept NILE, les enjeux et les réponses — ***B. VALEIX*** *(Marseille)*
- Une lésion de bifurcation 1.1.0. — ***P. DUPOUY*** *(Paris)*
- Une lésion de bifurcation 1.1.1. — ***R. BOURKAÏB*** *(Plessis-Robinson)*

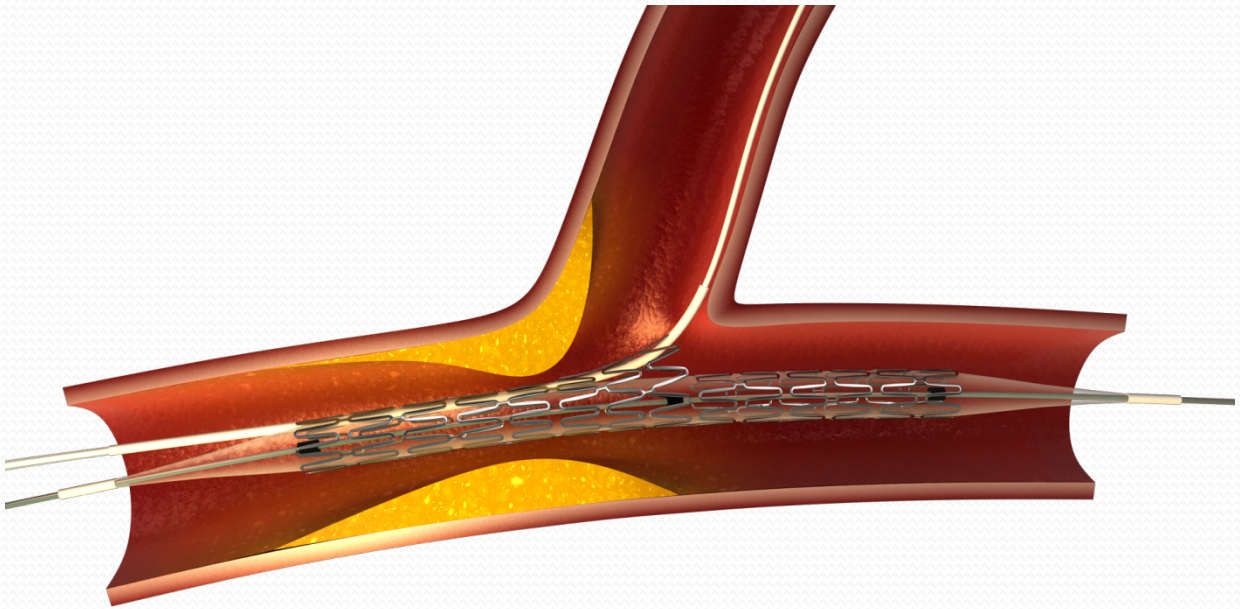
CONFLIT D'INTERÊTS

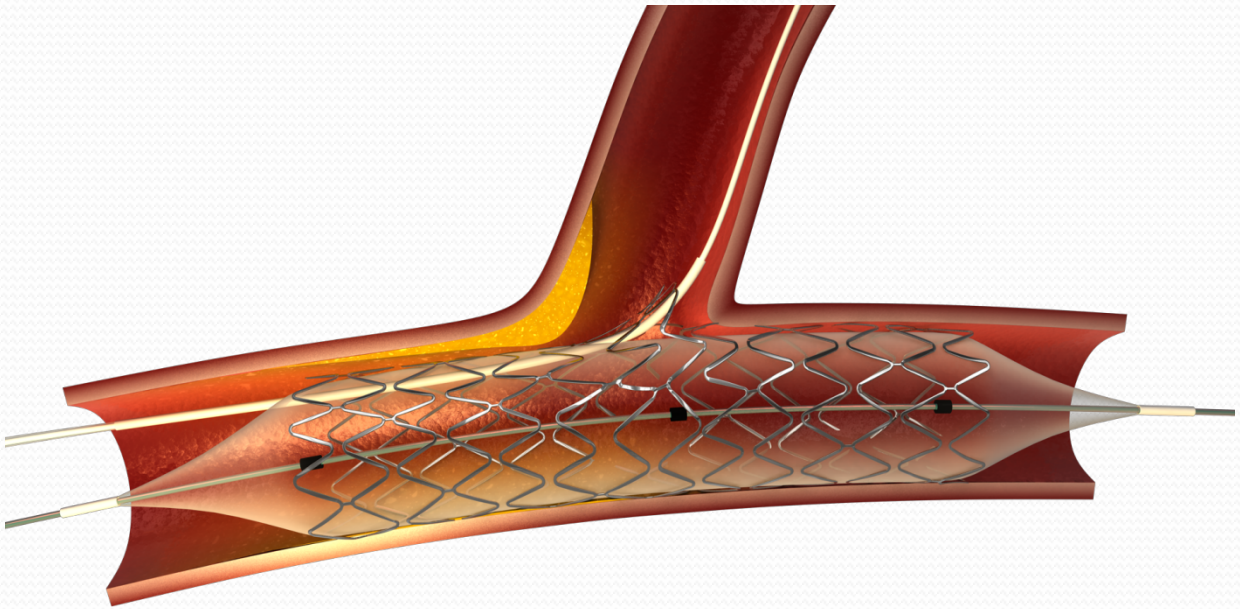
- **Absence de conflit d'intérêts**
  - avec le laboratoire MINVASYS.

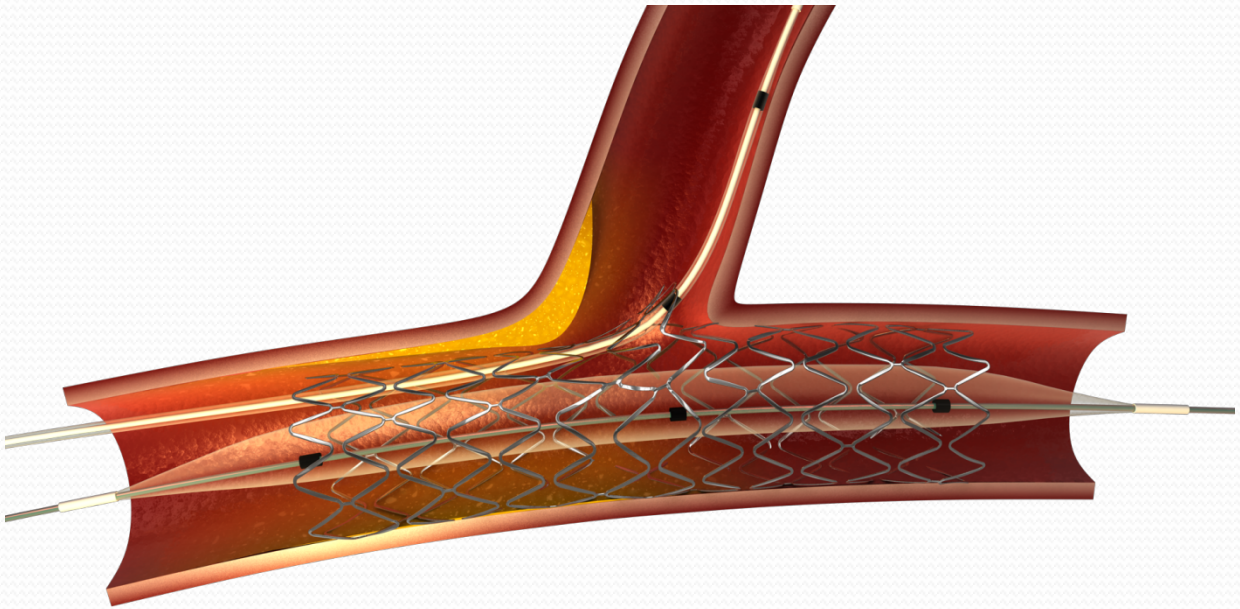
LE CONCEPT NILE

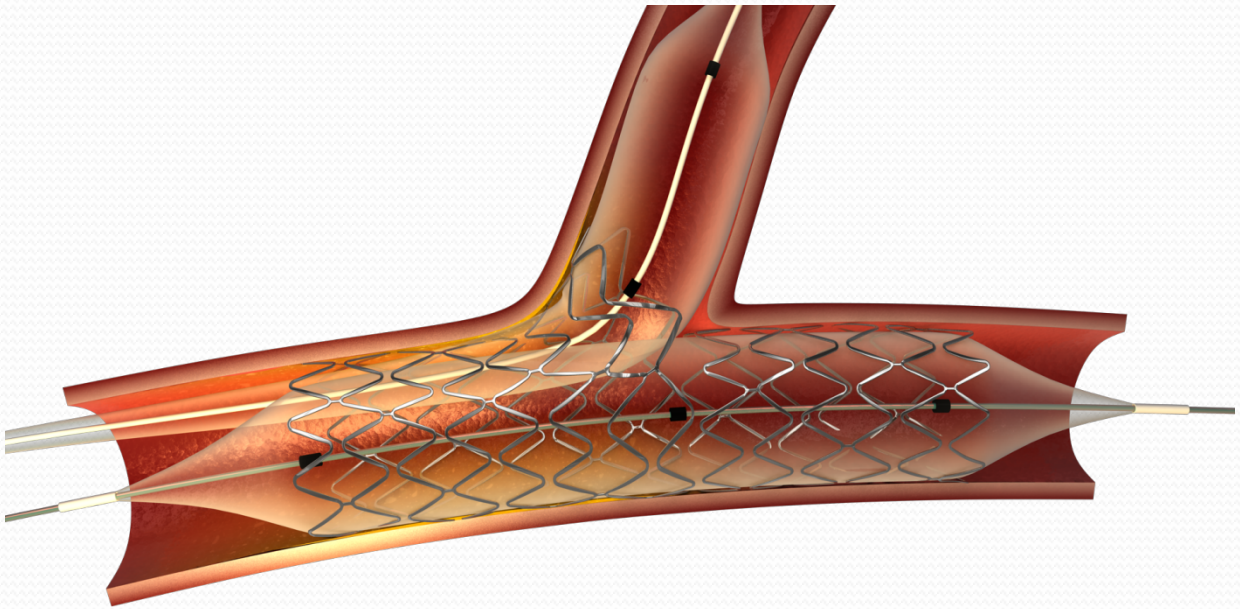
- Enjeux
- Réponses

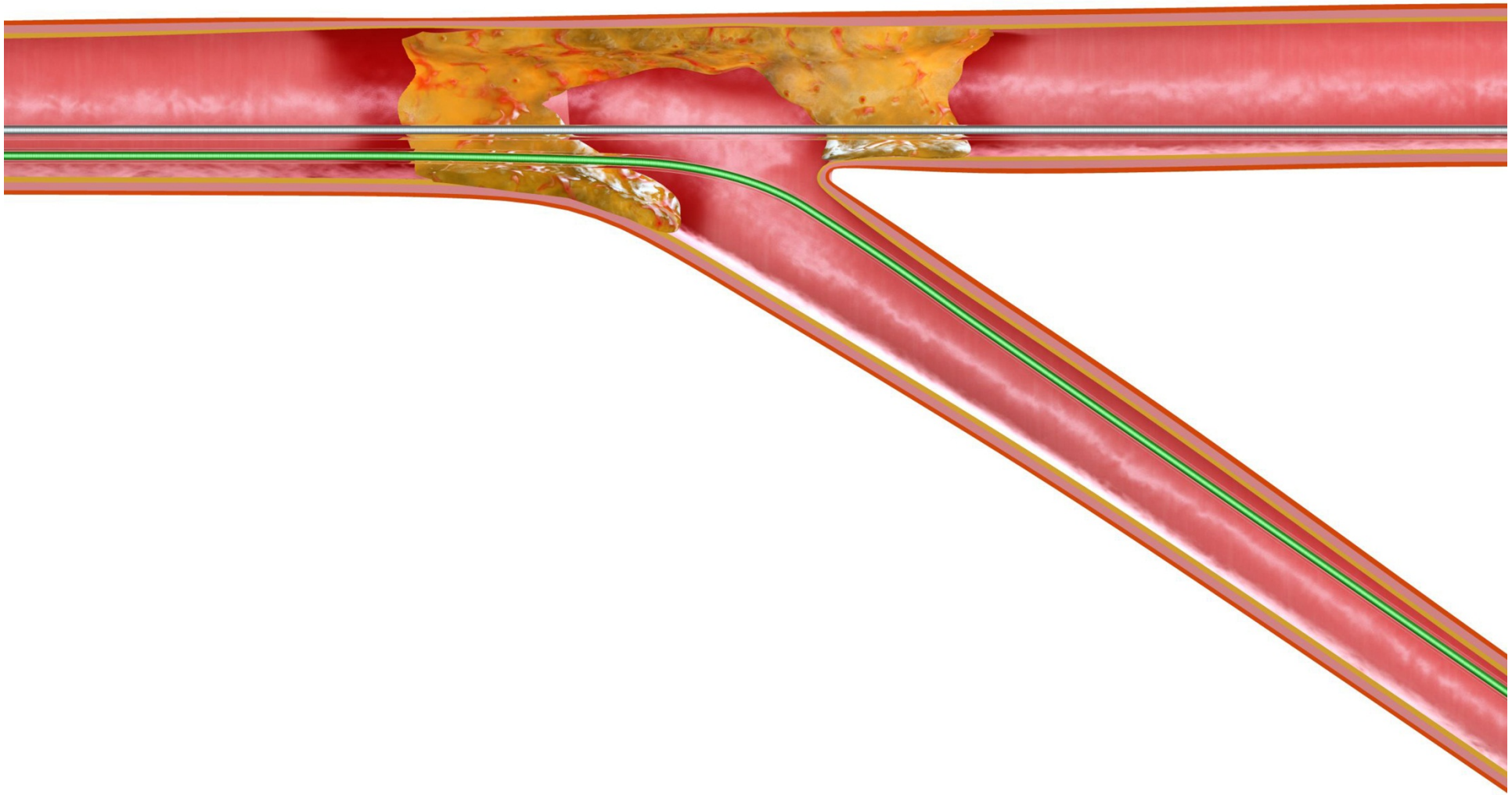


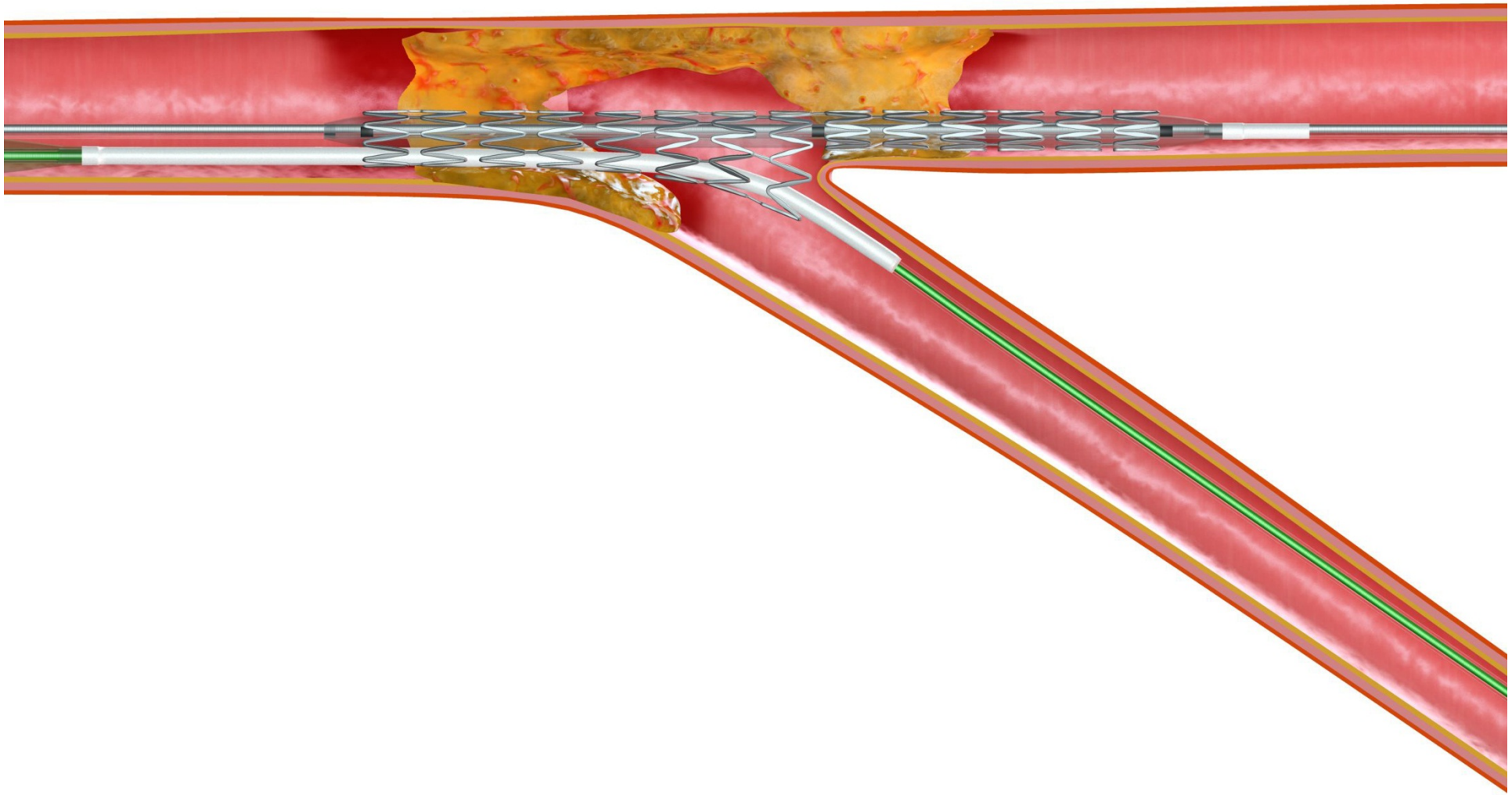


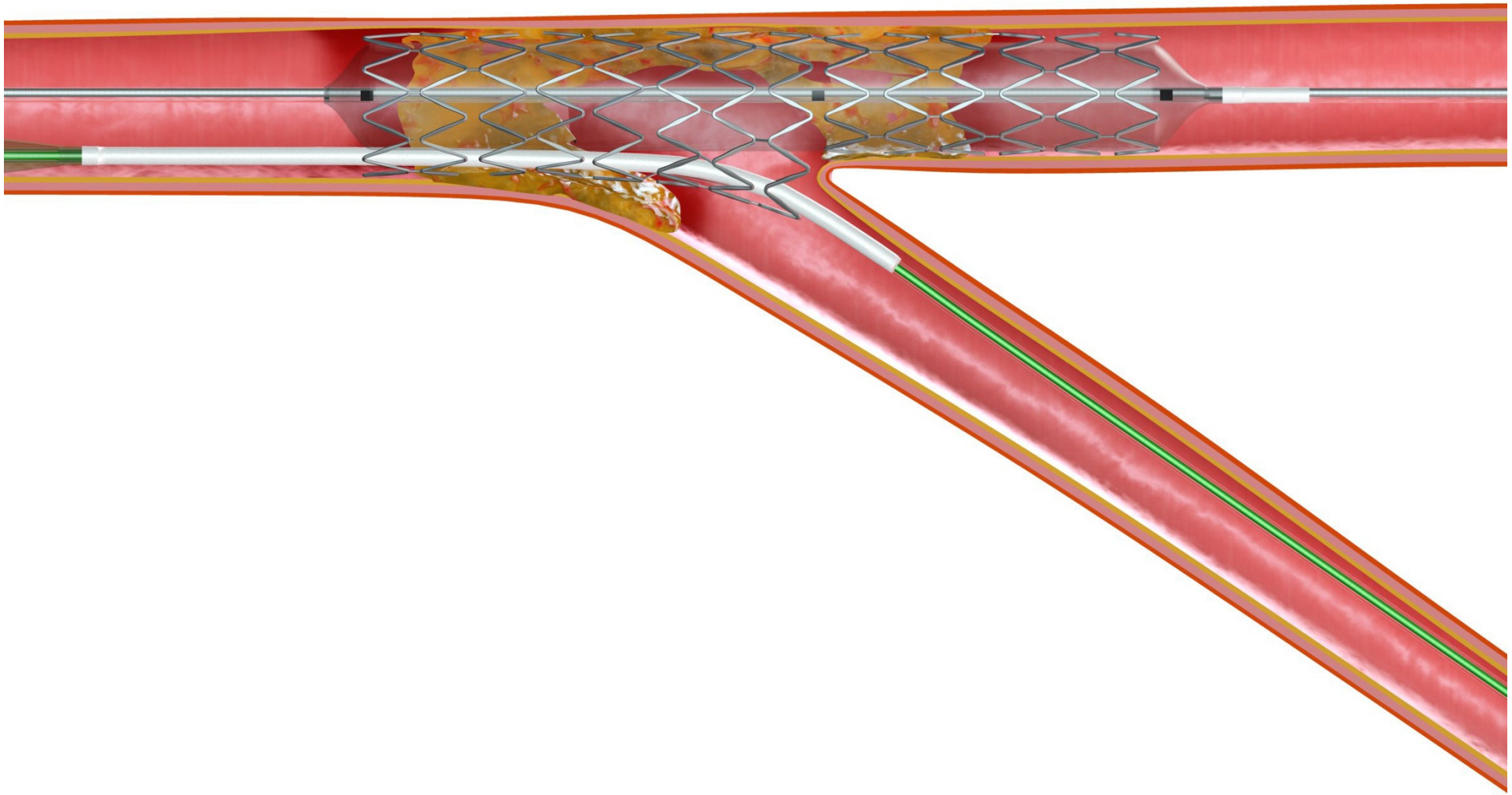


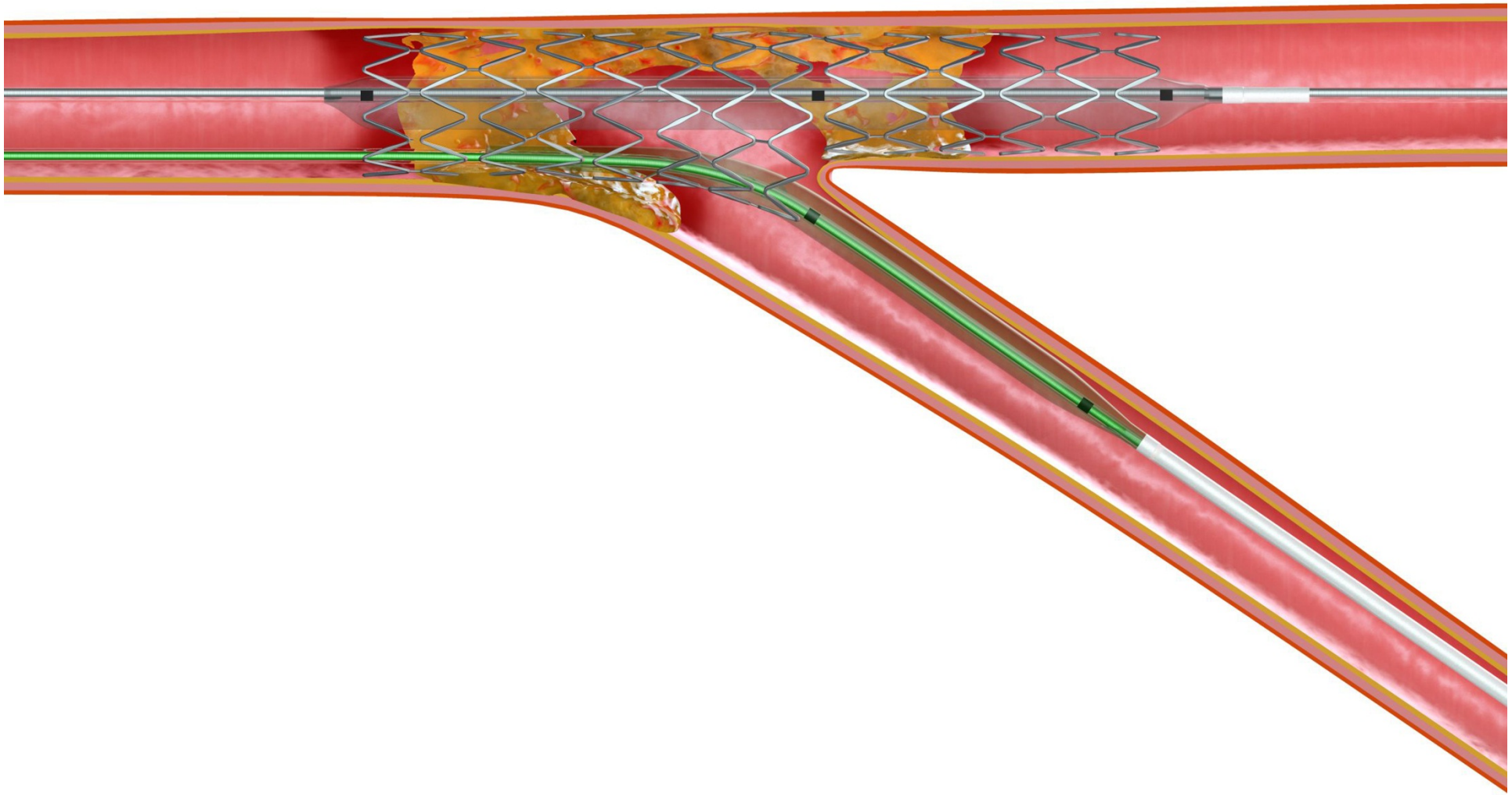


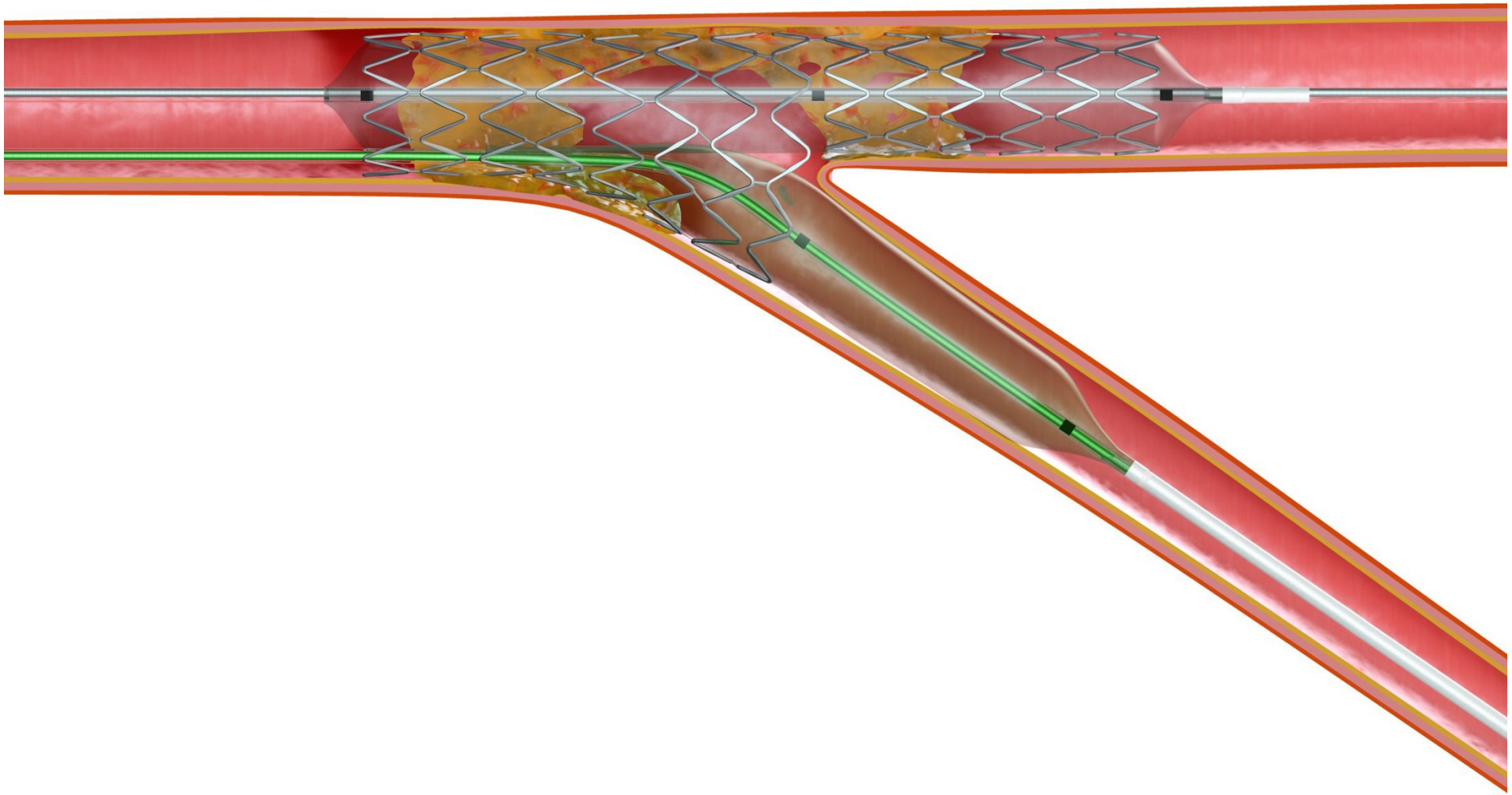


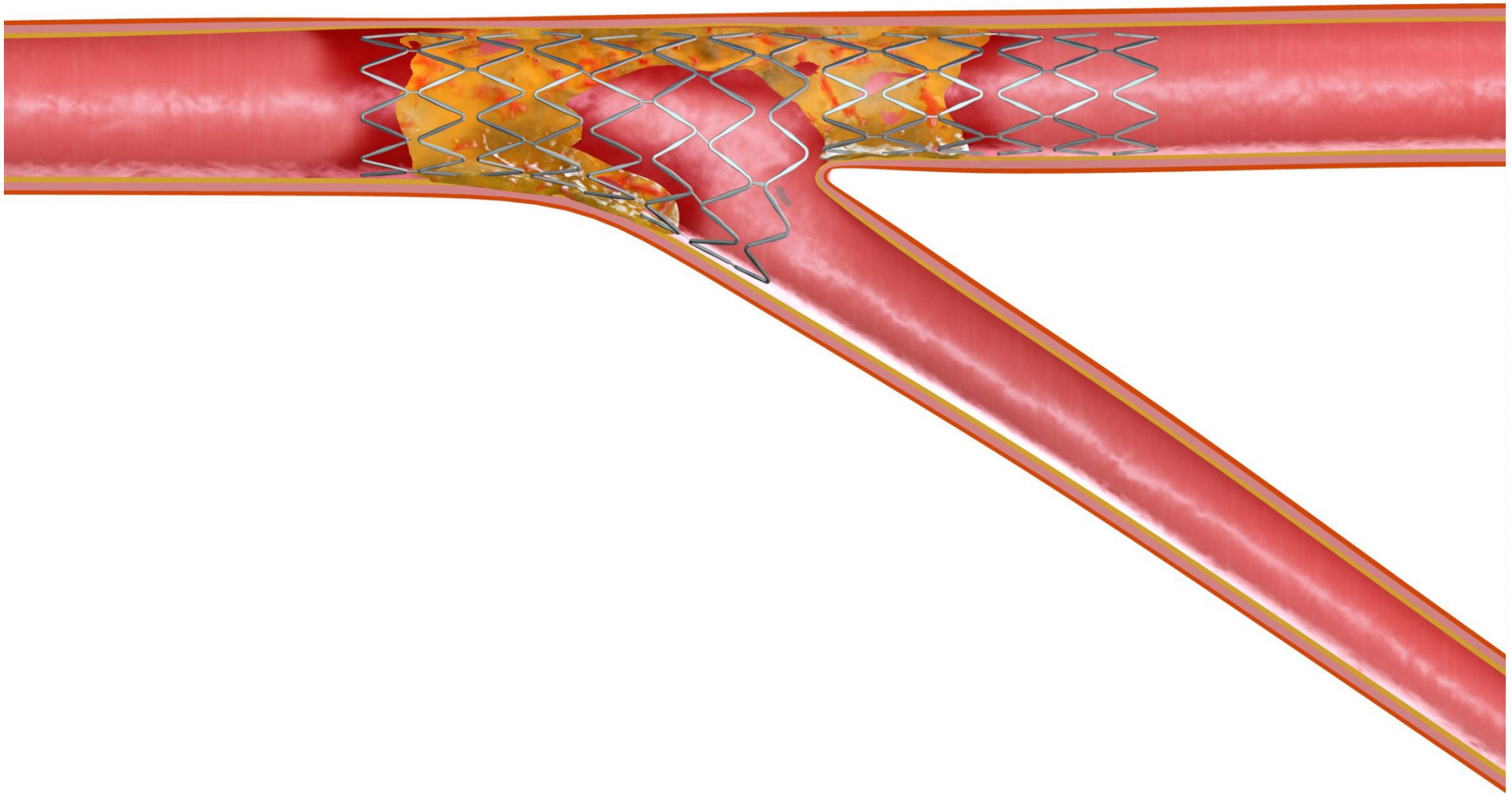


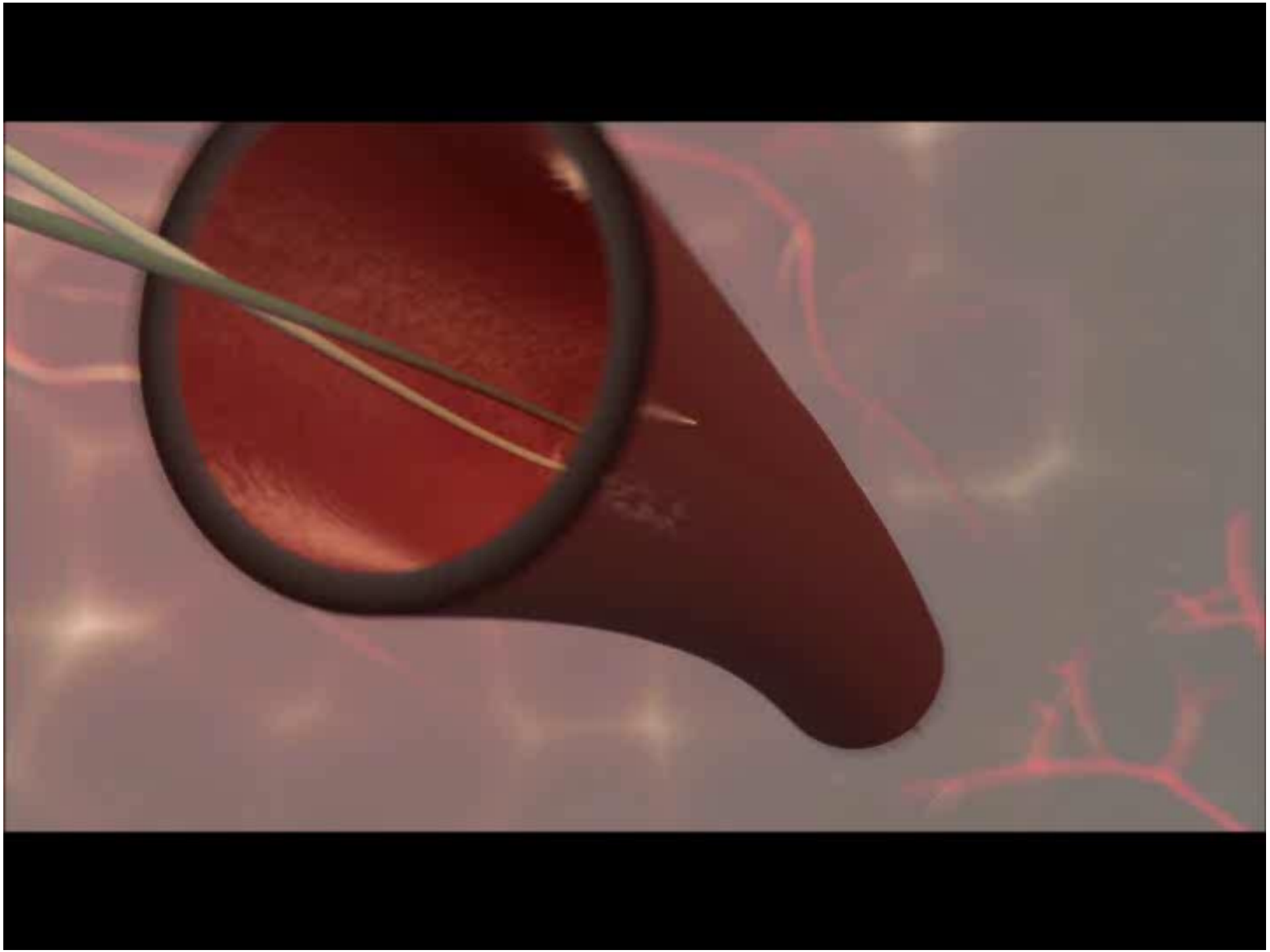












NILE STENT : Major advantages

- Dedicated stent for provisional treatment of bifurcation lesions.
- Excellent coverage of the side branch ostium.
- Low stent profile.
- A low profile delivery system.
- 6F compatibility.
- If double stenting is needed, additional stent deployment at the ostium of the side branch is easy to perform (T or TAP technique).

NILE STENT : Technique

- Predilatation of the main branch lesion is mandatory.
- Repositioning of wires (main or side branch) is easy to perform.
- Good positioning of the mid-marker on the carena is essential.
- The position must be maintained during stent deployment.
- Final kissing balloon inflation is mandatory and easy to perform.
- If needed, additional stent placement in the side branch will be performed with a deflated balloon left in the main branch followed by a final kissing balloon.

Nile®

Pax

Paclitaxel Elution

The Ultimate Paclitaxel Bifurcation System

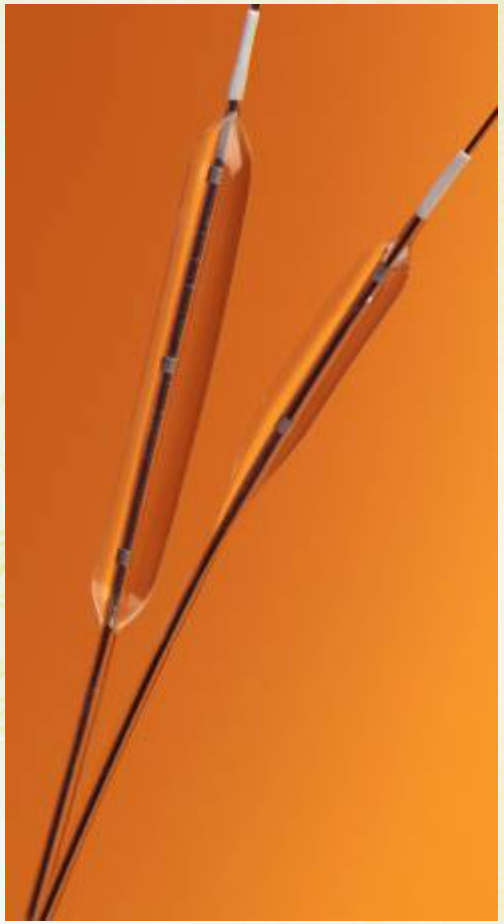
MINVASYS

NILE PAX

- 1er Stent à élution médicamenteuse dédié aux TRT des bifurcations coronariennes.

Dedicated Delivery Device

- 2 independent Rx PTCA catheters
- Ultra-low profile balloon combination.
- Side branch balloon already engaged.
- Specific side branch balloon shape.
- Peel-away onto catheter shaft.
- 6F compatible even on 3.5/3.0 sizes.

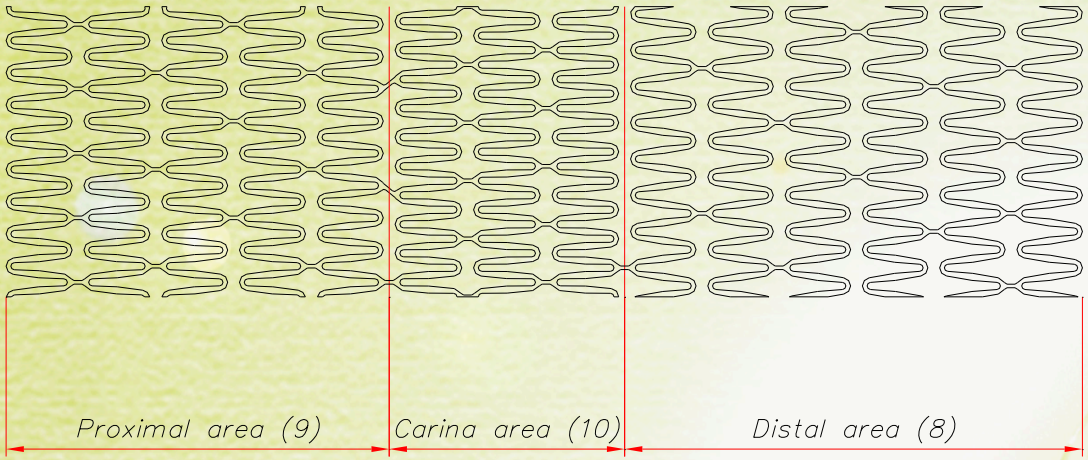


Dedicated Bifurcation Stent

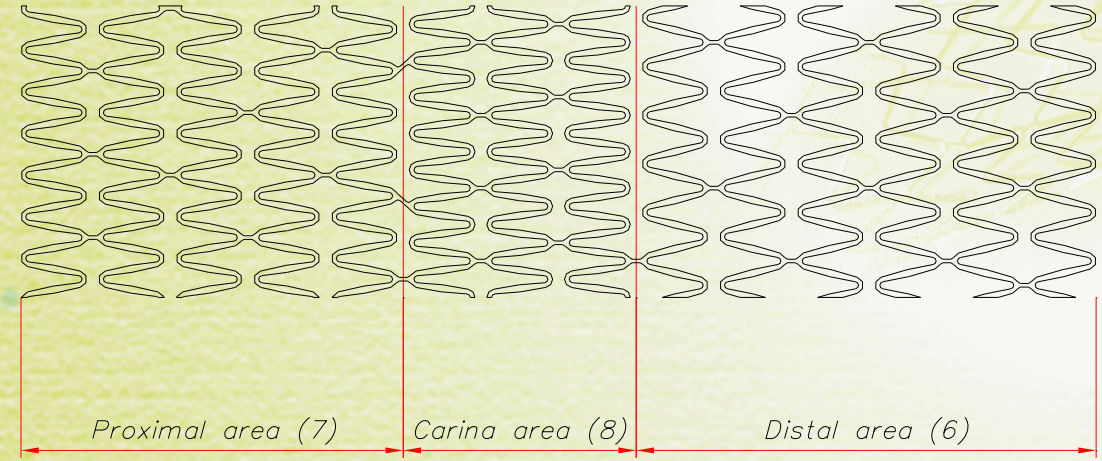
- Chromium Cobalt stent.
- 73µ stent thickness.
- Modular stent design for allowing carina coverage without cell’s overstretching.
- No angulations' restriction

Dedicated Bifurcation Stent

- **Design 1 : 8 cells distal, 10 carina, 9 proximal for vessels of 3.0 & 3.5mm**



- **Design 2 : 6 cells distal, 8 carina, 7 proximal for vessels of 2.5mm**



NILE PAX

- Absence de polymère.
- Elution de Paclitaxel
  - revêtement abluminal.
- 8ème jour : 60 % de la dose délivrée.
- 45ème jour : 100 % de la dose délivrée
  - retour à un Stent Cobalt -Chrome nu.

NILE / TAKE HOME MESSAGES

- **Dispositif compatible 6F.**
- **Pré dilatation impérative du vaisseau mère.**

Complex Coronary Bifurcation Lesions Treated with the Novel Polymer-Free Dedicated Bifurcation Paclitaxel-Eluting Stent (Nile Pax): 9-Month Clinical and Angiographic Results of the Prospective, Multicenter BIPAX Clinical Trial

Ricardo A. Costa, Alexandre Abizaid, Andrea Abizaid, Bruno Garcia, Jacques Berland, Ivo Petrov, Philippe Brenot, Patrick Serruys, Paolo Rubino, Thierry Royer, Maciej Lasiak, Jean Fajadet, for the BIPAX Investigators

Oral Abstracts: Left Main and Bifurcation PCI – Room 121
Tuesday, November 8th , 2011 – From 12:12 to 12:22 pm

TCT 2011 – San Francisco, CA

INSTITUTO DANTE PAZZANESE
de Cardiologia

CARDIOVASCULAR
RESEARCH CENTER

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, Toulose, 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

Key Exclusion Criteria

- Bifurcation lesion type with single involvement of the SB ostium (Medina 0,0,1)
- LM location
- Heavy calcification
- Severe tortuosity
- LVEF <30%
- Baseline serum creatinive level ≥ 2.0 mg/dL
- AMI <72 hours
- PCI in non-target vessel <30 days
- Known hypersensitivity or contraindication to aspirin or thienopyridine

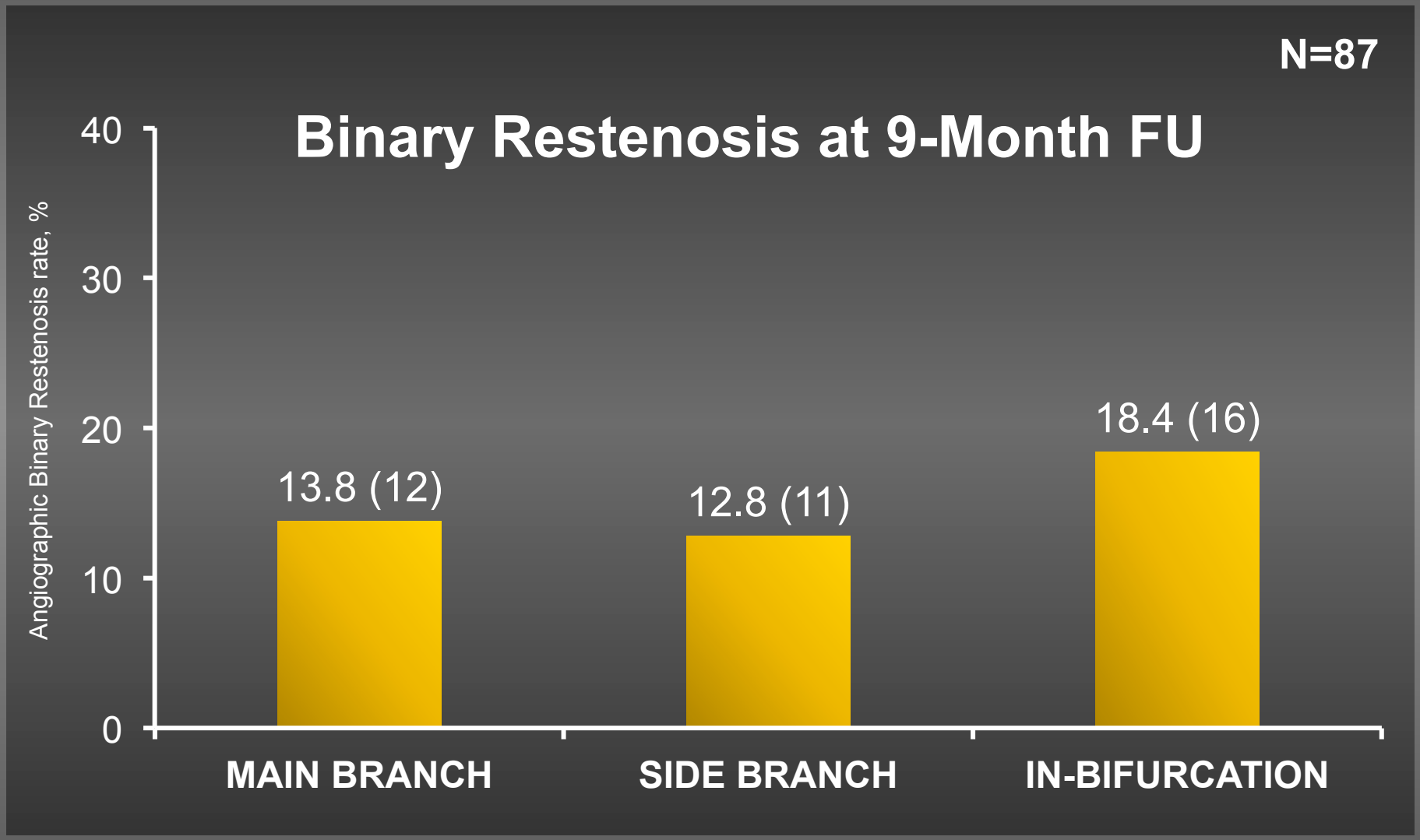
Endpoints

- **Primary endpoint**:
  - Angiographic binary restenosis in the treated lesion (MB and SB) at 9 months angiographic follow-up, as assessed by independent QCA analysis
- **Secondary endpoints**:
  - Acute success
  - Late lumen loss at 9 months follow-up
  - MACE, TVR and TVF at all study timepoints
  - Ischemia-driven TLR (secondary endpoint)

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)

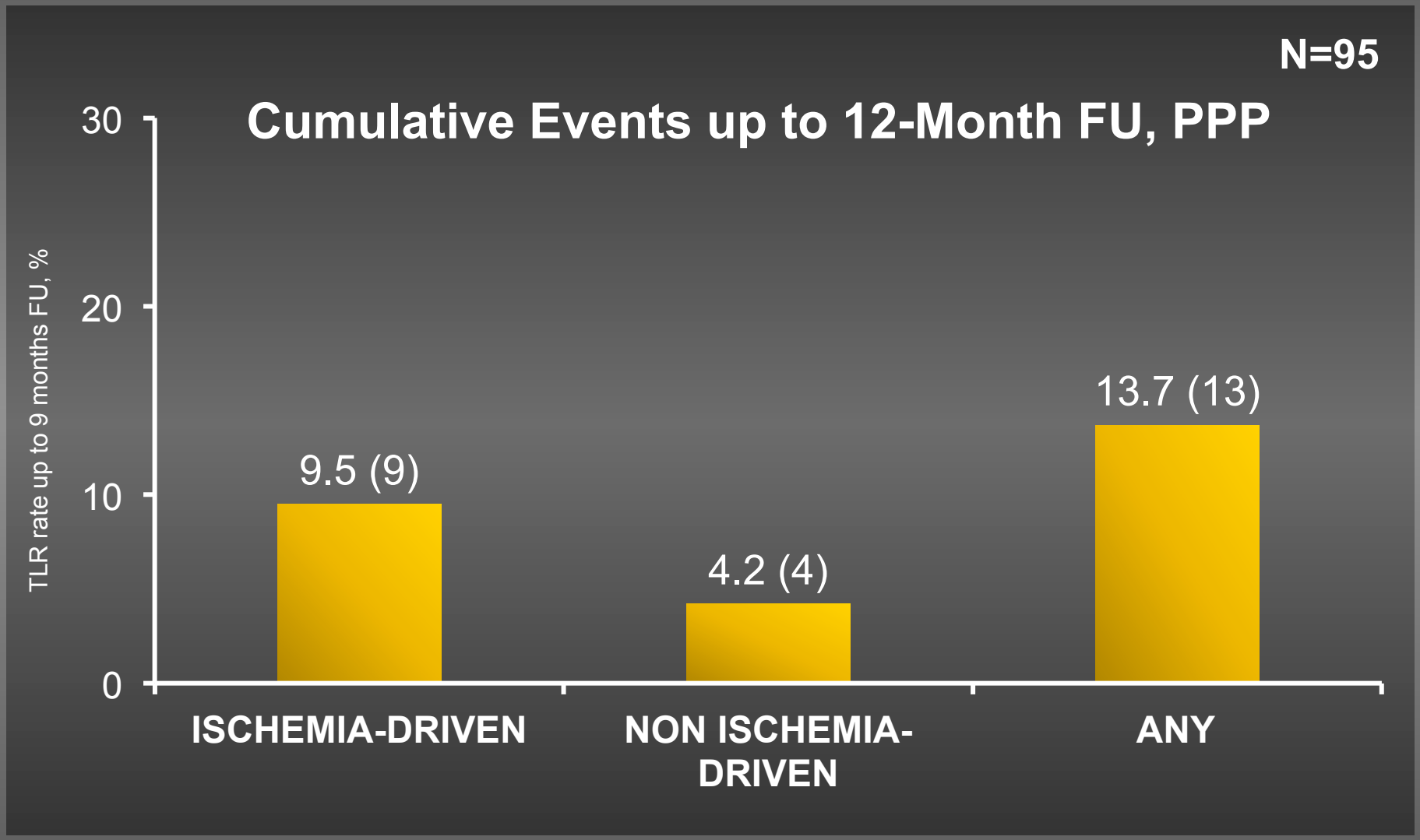
Primary Endpoint – PPP



12-Month Clinical Outcomes, PPP

EVENT, N=95	IH	30-Day*	6-Mo.*	9-Mo.*	12-Mo.*
Death					
Cardiac	0% (0)	0% (0)	0% (0)	1.1% (1)	1.1% (1)
Non-cardiac	1.1% (1)	0% (0)	0% (0)	0% (0)	0% (0)
MI					
Q wave	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Non-Q wave	0% (0)	0% (0)	1% (1)	1% (1)	1% (1)
TLR	0% (0)	0% (0)	4.2% (4)	12.6% (12)	13.7% (13)
TVR	0% (0)	0% (0)	4.2% (4)	12.6% (12)	13.7% (13)
ST	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)

Target Lesion Revascularization



Conclusions

- The Nile PAX dedicated DES demonstrated excellent acute results for bifurcation PCI with a provisional approach, including high device, lesion and procedural success despite significant involvement of both branches in the majority of lesions (>60%)
- Overall, there were no safety concerns including low rates of death and MI (<2%) and absence of stent thrombosis up to 12 months follow-up
- In those meeting inclusion criteria (94%), binary restenosis rates at 9 months in the MB and SB were 13.8% and 12.8%, respectively (primary endpoint), with overall in-bifurcation restenosis of 18.4%. Furthermore, cumulative ischemia-driven TLR rate was 9.5% (secondary endpoint)