sideKicK

Stent System for the Treatment of Coronary Bifurcation and Ostial Lesions

European Bifurcation Club

EBC

European Bifurcation Club
Valencia, 2007
Ronald J. Solar Ph.D.

Bifurcation Treatment
Alternatives

- **Specialized techniques w/ standard devices**
  - *Kissing stents: Y, T, V*
  - *Culotte stenting*
  - *Crush*
- **Dedicated, specialized systems**
  - *Frontier™ stent (Abbott)*
  - *Avion™ Bifurcation RX2 (Invatec)*
  - *AXXESS™ stent (Devax)*
  - *PETAL™ stent (Boston Scientific)*
  - *Nile™ SDS (Minvasys)*
  - *Tryton, Cappella, Stentys*

Unmet Needs

- *Low profile, sleek device*
- *Easy to use (single wire, single operator)*
- *Torquable*
  - *For optimal stent positioning*
- *Accurate device orientation for optimal stent deployment*
- *Means to assess position and orientation*
- *Side branch access post-stent deployment*
- *Versatile platform for various bifurcation anatomies*

Clinical Issues

Variety of Anatomical Subsets

- **Plaque morphology**
- **Plaque location**
- **Side Branch diseased**
- **Side branch take-off angle**
- **Side Branch Ref. Diameter**

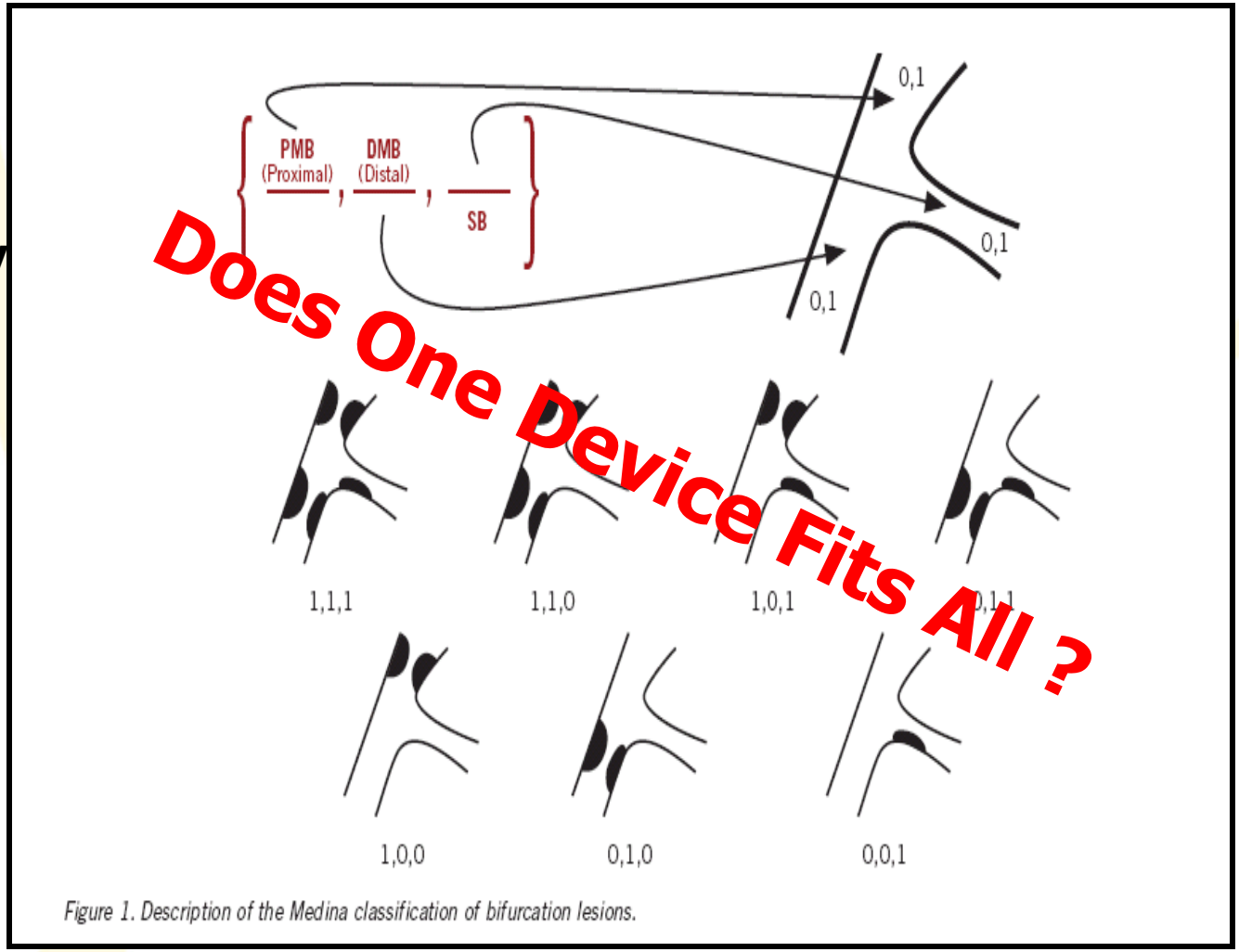


Figure 1. Description of the Medina classification of bifurcation lesions.

2006 European Bifurcation Club Recommendations

Percutaneous coronary intervention of bifurcation lesions: state-
Europ

Victor Leg
FESC; Nic
MD; Olivi
Lassen[12],

1. Centre H
3. Klinika k
5. Intervent
7. Sussex Su
Bordeaux, F
Reina Sofia,
of Aarhus

None of the a

WHAT WE ALL AGREE:

- The MEDINA classification of coronary bifurcation lesion and the MADS classification for treatment techniques should be adopted.
- QCA software needs to be standardised, with appropriate algorithms allowing multiple segment of interest analysis.
- With BMS, as well as with DES, a stepwise provisional T-stenting strategy is the best.
- Deliberate double stenting is an inferior technique.
- SB predilatation is recommended if calcified lesion or long lesion.
- Jailed wire is strongly recommended in complex lesions.
- After complex stenting (for complex lesions), kissing balloon inflations should be routinely performed.

Introduct
Percutaneous
remains com
to the variety
which are rela
op a consens
lesions, the E
The first EBC
emerged[1].
Briefly, the p
should be ad
T-stent strate
deliberate double-stenting may be an inferior technique, d) with drug-eluting stents, the optimal strategy is under development and ongoing trials (Nordic and BBC1) will help to define it, e) after complex stenting, kissing balloon inflations should be routinely performed.

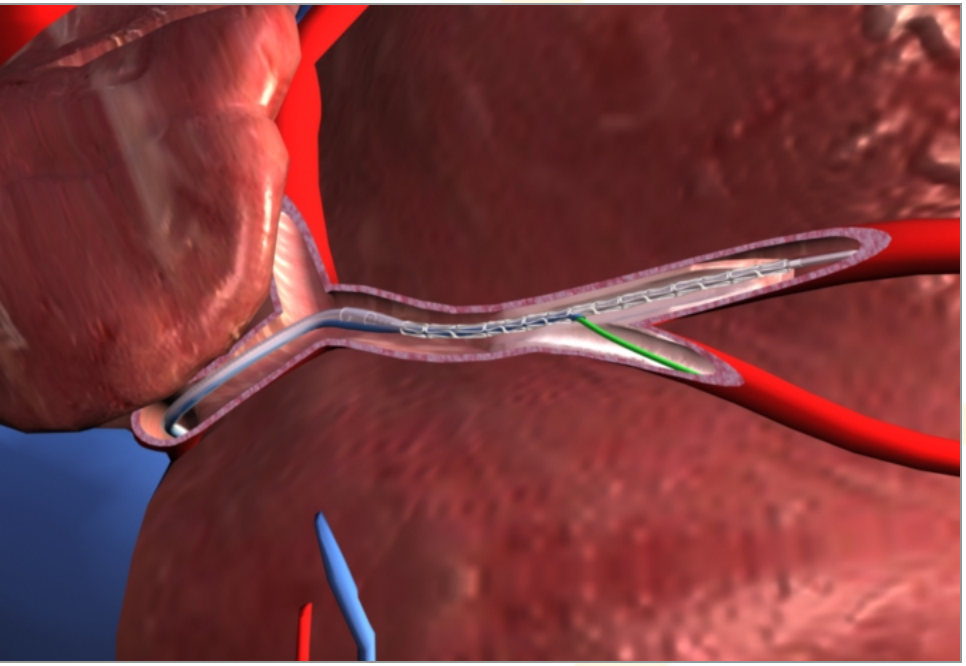
accepted by the EBC. These classifications may need some refinements, however, and take into consideration the angle between the two branches, the lesion length, the observed/expected diameter, the TIMI flow, presence of calcification, plaque situation or eccen-

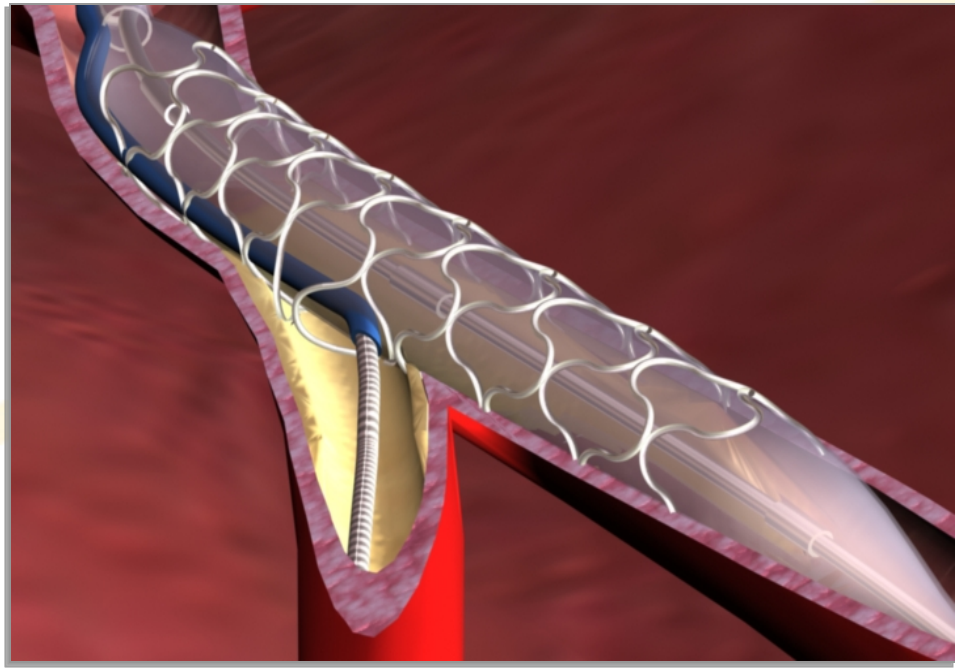
sideKicK Stent System

Innovative & Simple: *Precise stent placement with side branch protection*

Low profile; Operator friendly; Torquable system

Optimal Provisional Stenting

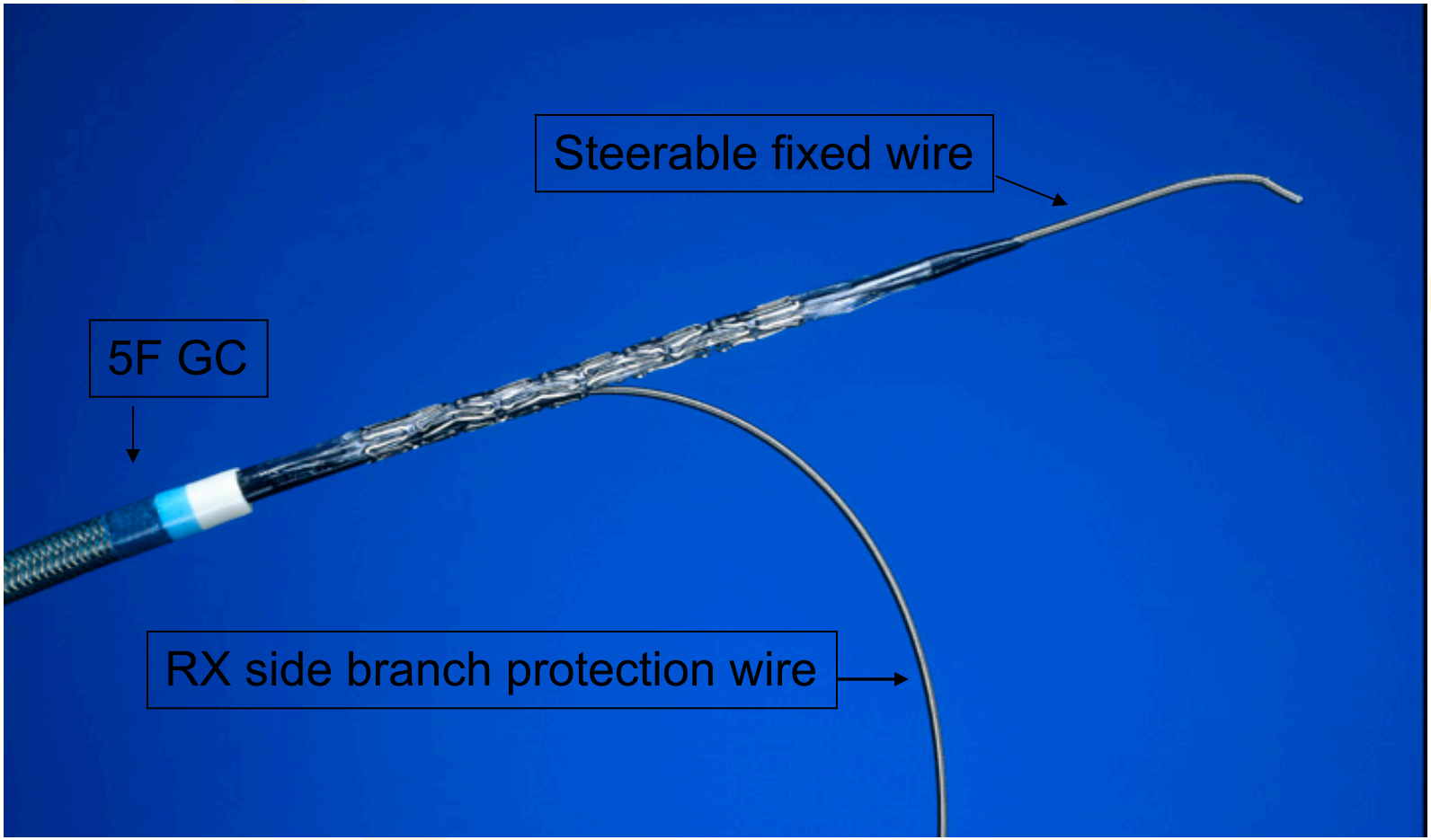




sideKick™

Stent Delivery System

Mid Exit Port Model

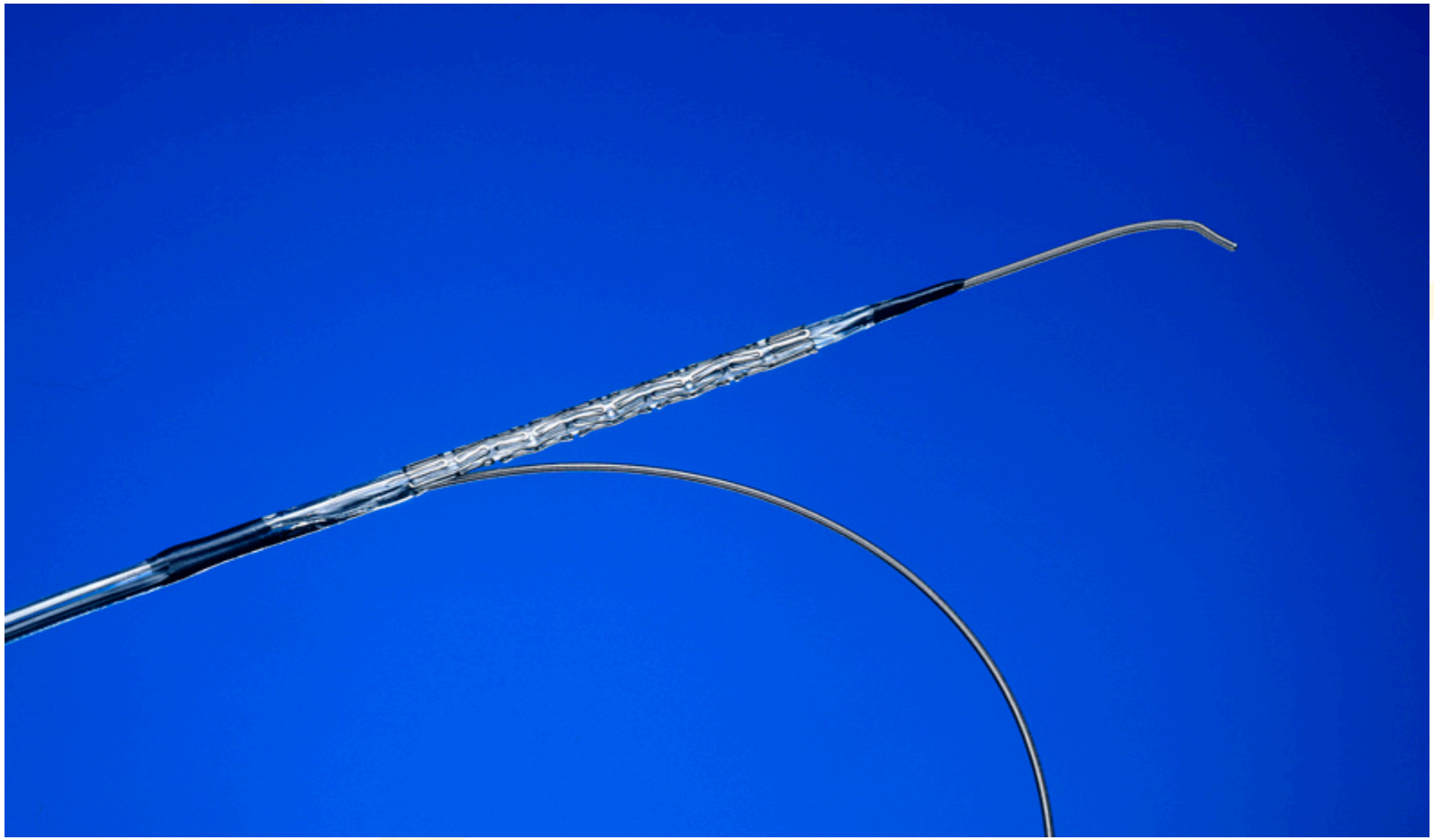


EBC

sideKick™

Stent Delivery System

Proximal Exit Port Model



EBC

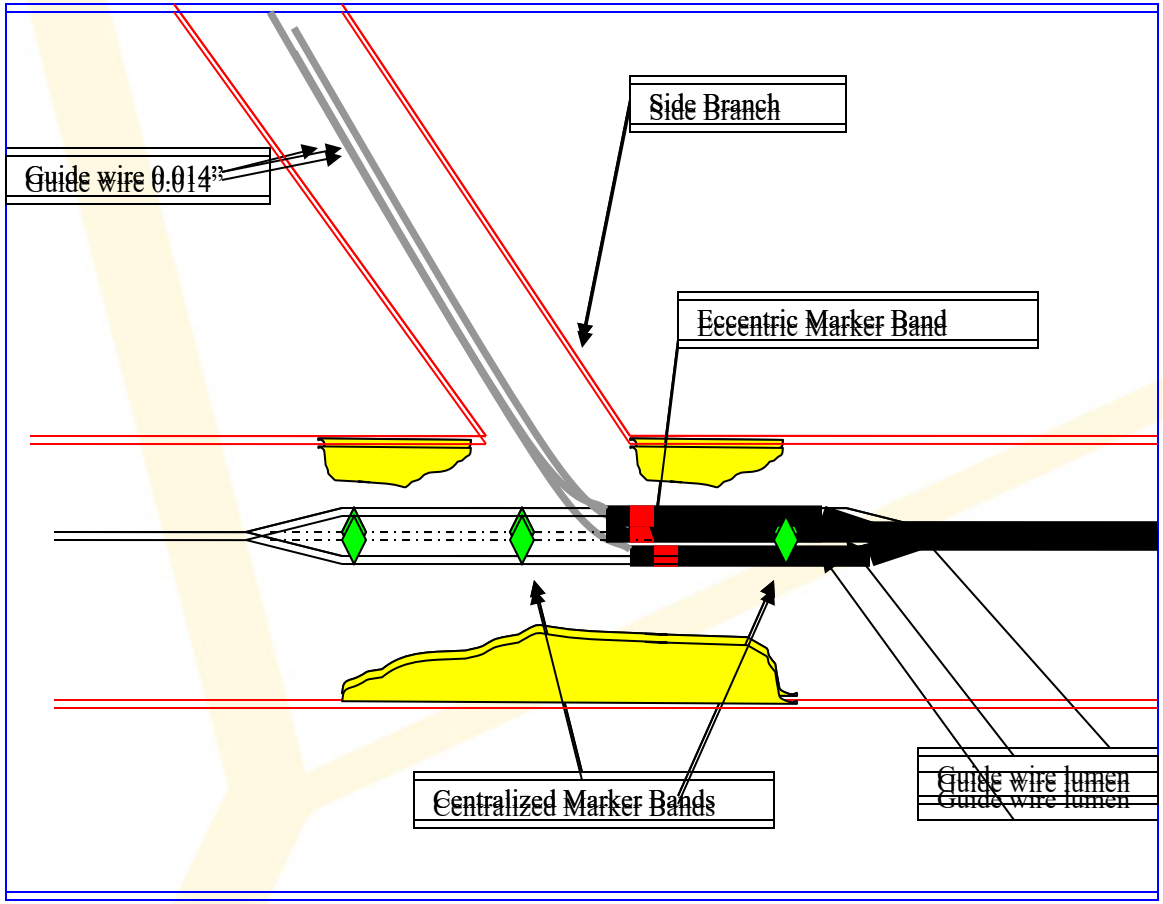
sideKick™

Stent Delivery System

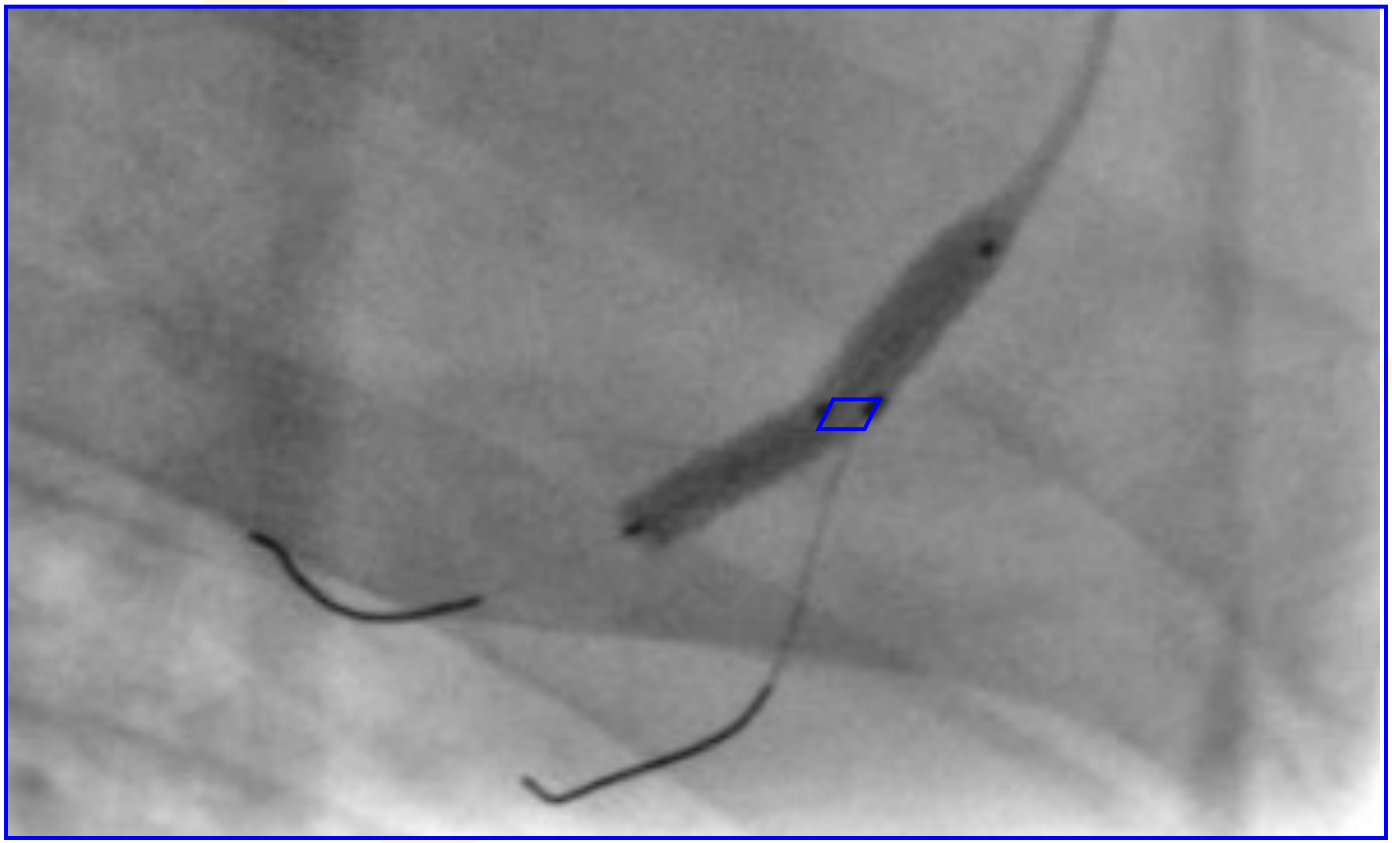
Distal Exit Port Model

Unique Marker Configuration

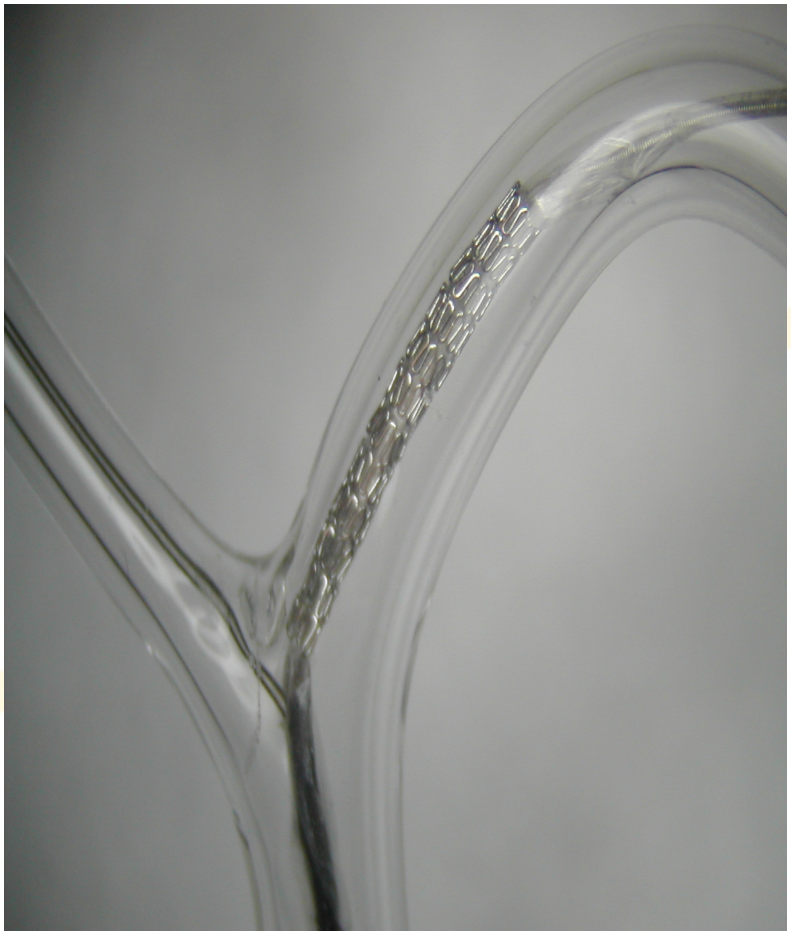
Torque 90° counter clock



Unique marker band configuration and torquability allow precise positioning of stent cell to side branch



Ostial Application



First-In-Man Clinical Study

- CE Marked 3.0 x 17 mm SS BMS
- All 3 sideKicK models
  - Proximal, Mid, Distal
- 1° endpoint: Technical success & 30-day MACE

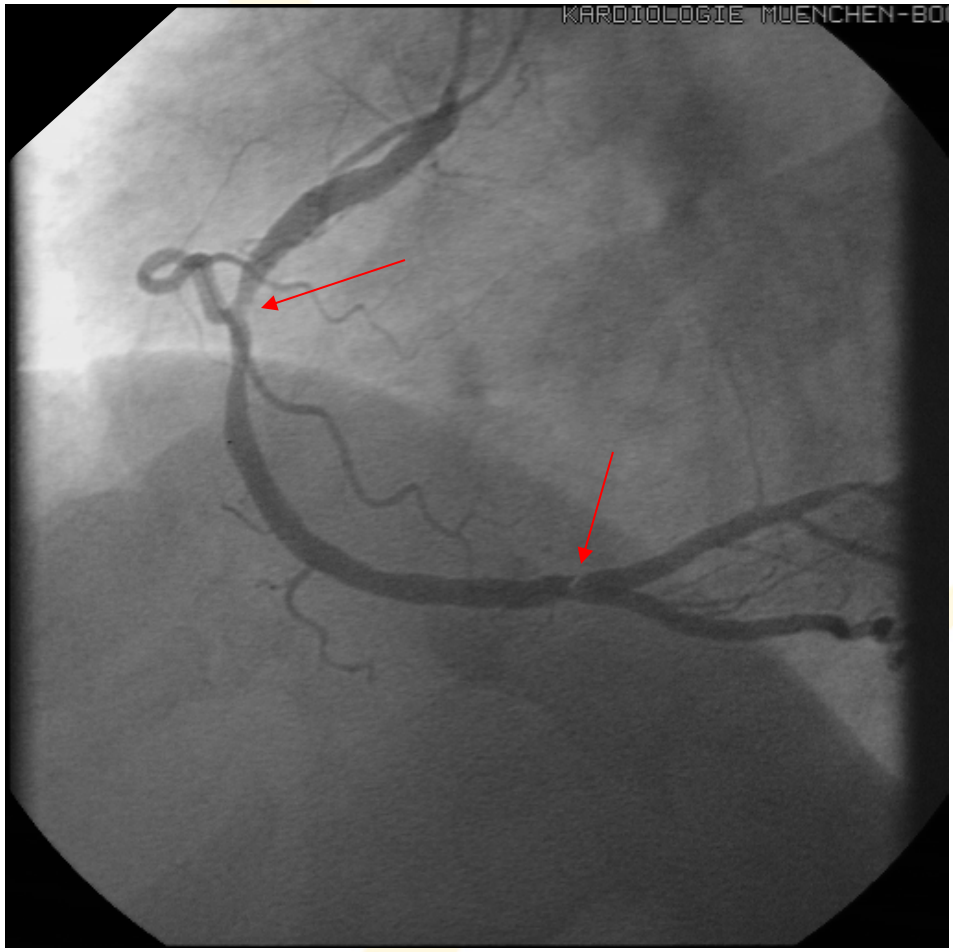
First-In-Man Clinical Study

- **Study Objectives: To evaluate safety and effectiveness of the sideKicK mid, proximal and distal models**
- **Study Design: Any patient with lesion involving side branch**
- **17 patients, 20 Lesions**
- **Participating sites:**
  - **Bogenhausen Hospital, Munich (Prof. T. Ischinger)**
  - **Heart Center, Siegburg (Prof. E. Grube)**

Lesions (n=20)

Location		Bifurcation Class	
LAD	6 (30%)	1,1,0	5 (25%)
CX	3 (15%)	1,0,0	5 (25%)
RCA	11 (55%)	0,1,1	2 (10%)
		0,0,1	2 (10%)
		0,1,0	6 (30%)

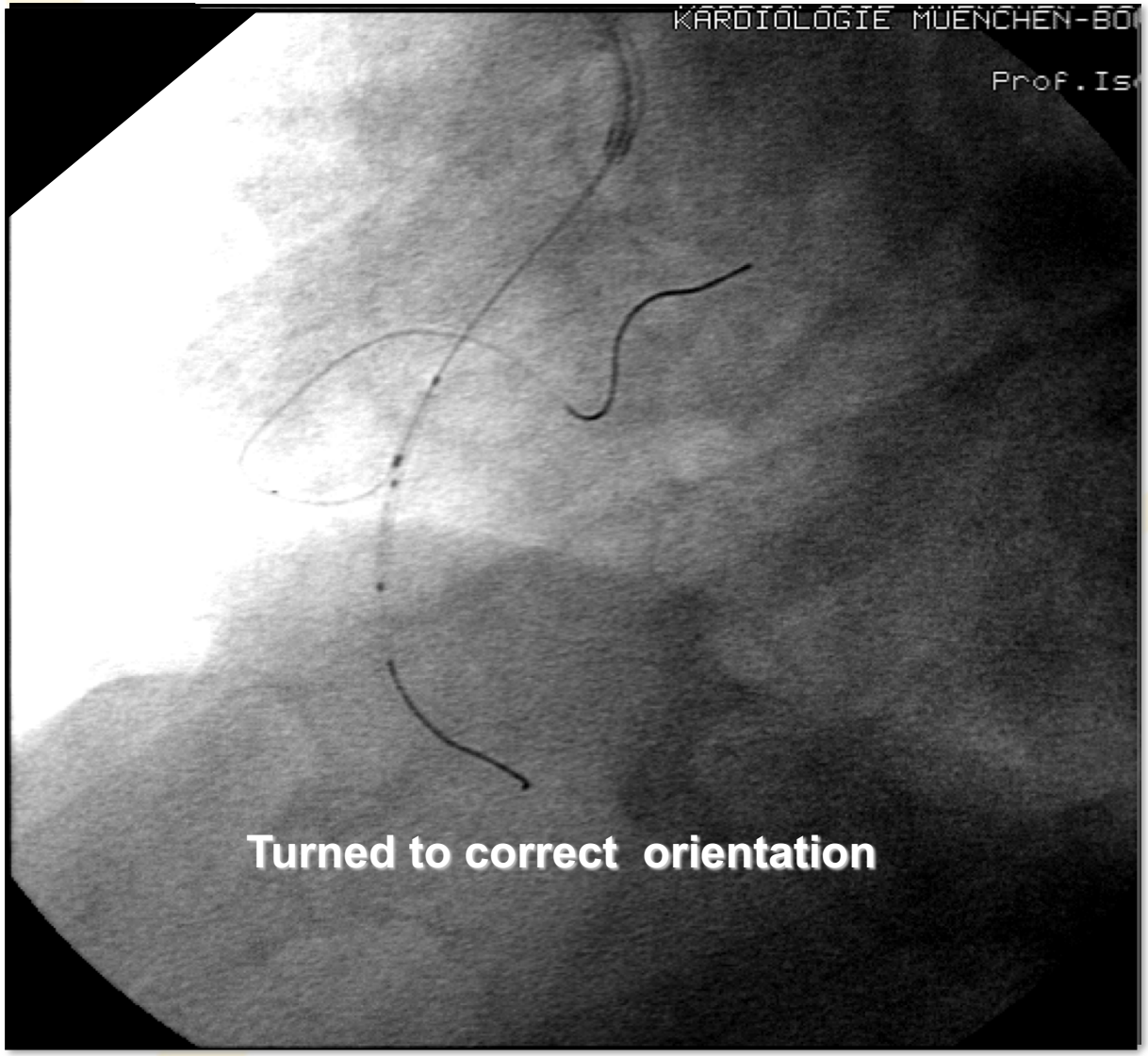
Case # 1-8: 68 YOM



- Proximal RCA; Type 1,1,0 bifurcation
- Distal RCA; Type 1,0,0 bifurcation

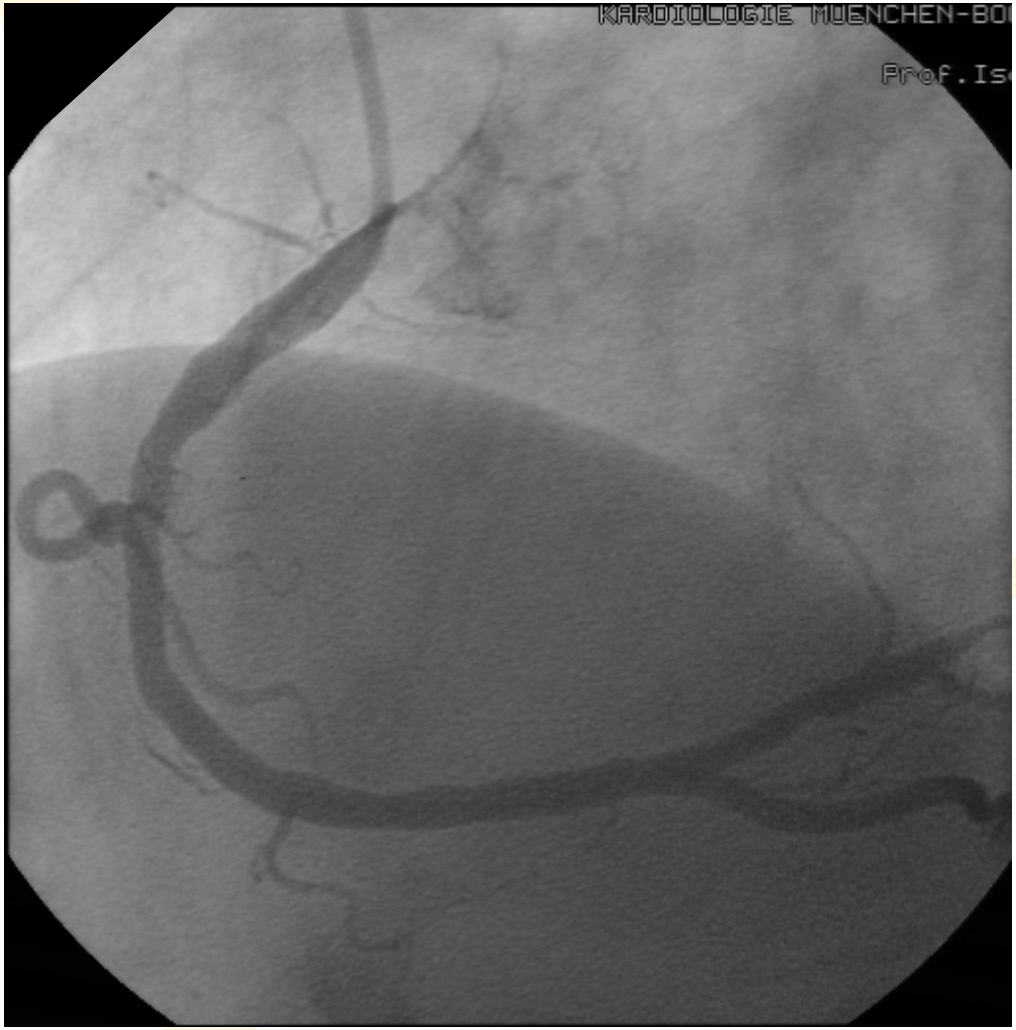
Distal RCA treated with sideKicK™ distal exit port model

Proximal RCA treated with sideKicK™ mid exit port model

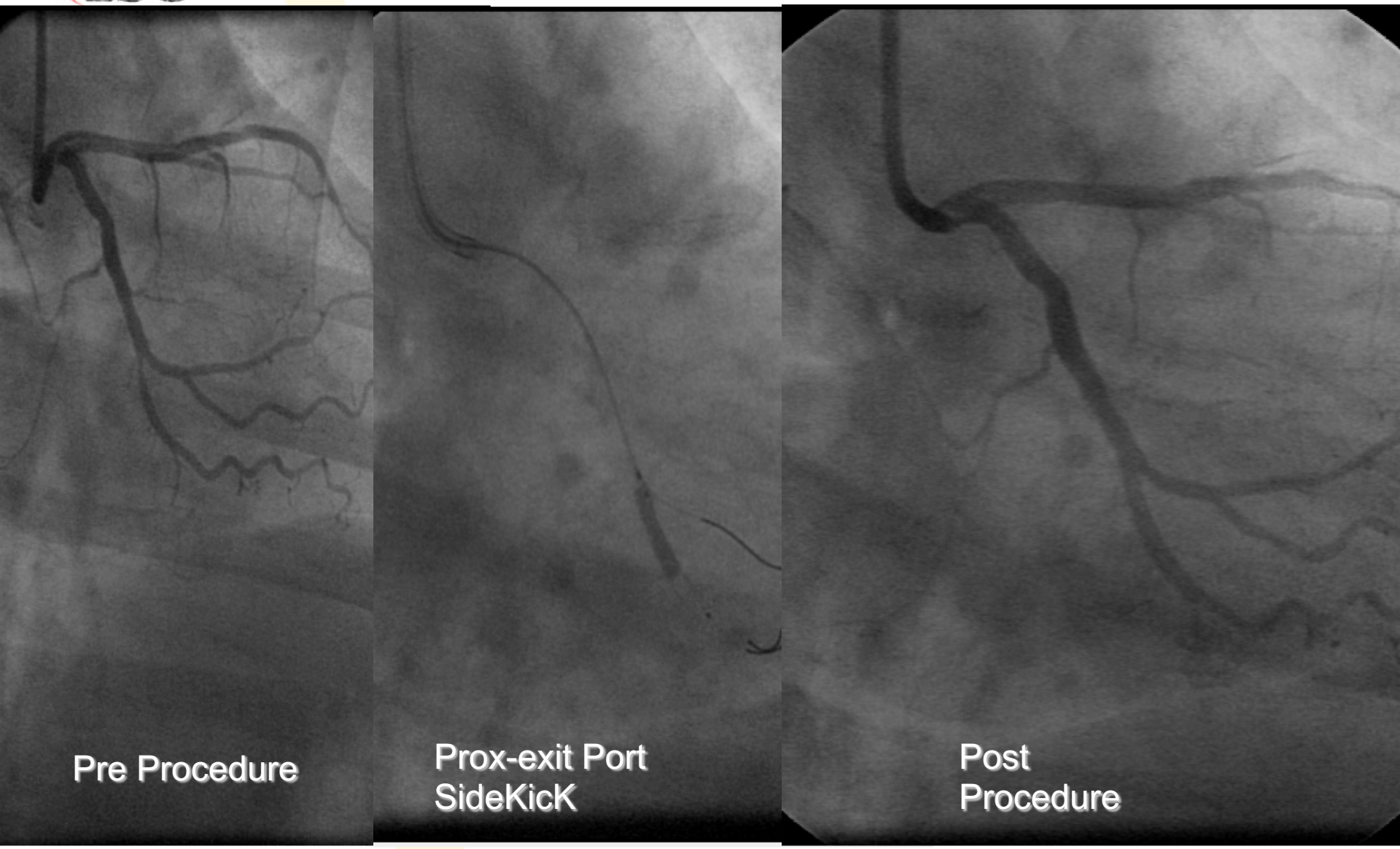


Investigational use only

Post Procedure



Case # 2-3: 58 : Mid Crx Type 0,0,1 bifurcation; Proximal exit port sidekick model



Investigational use only

Results

	In Hospital	FU 68±32 Days
Death	0	0
Q Wave MI	0	1 (5.8%)
Non Q Wave MI	0	0
SAT	0	1 (5.8%)
TLR (PCI/CABG)	0	0
Death, Q-MI, TLR	0	1 (5.8%)

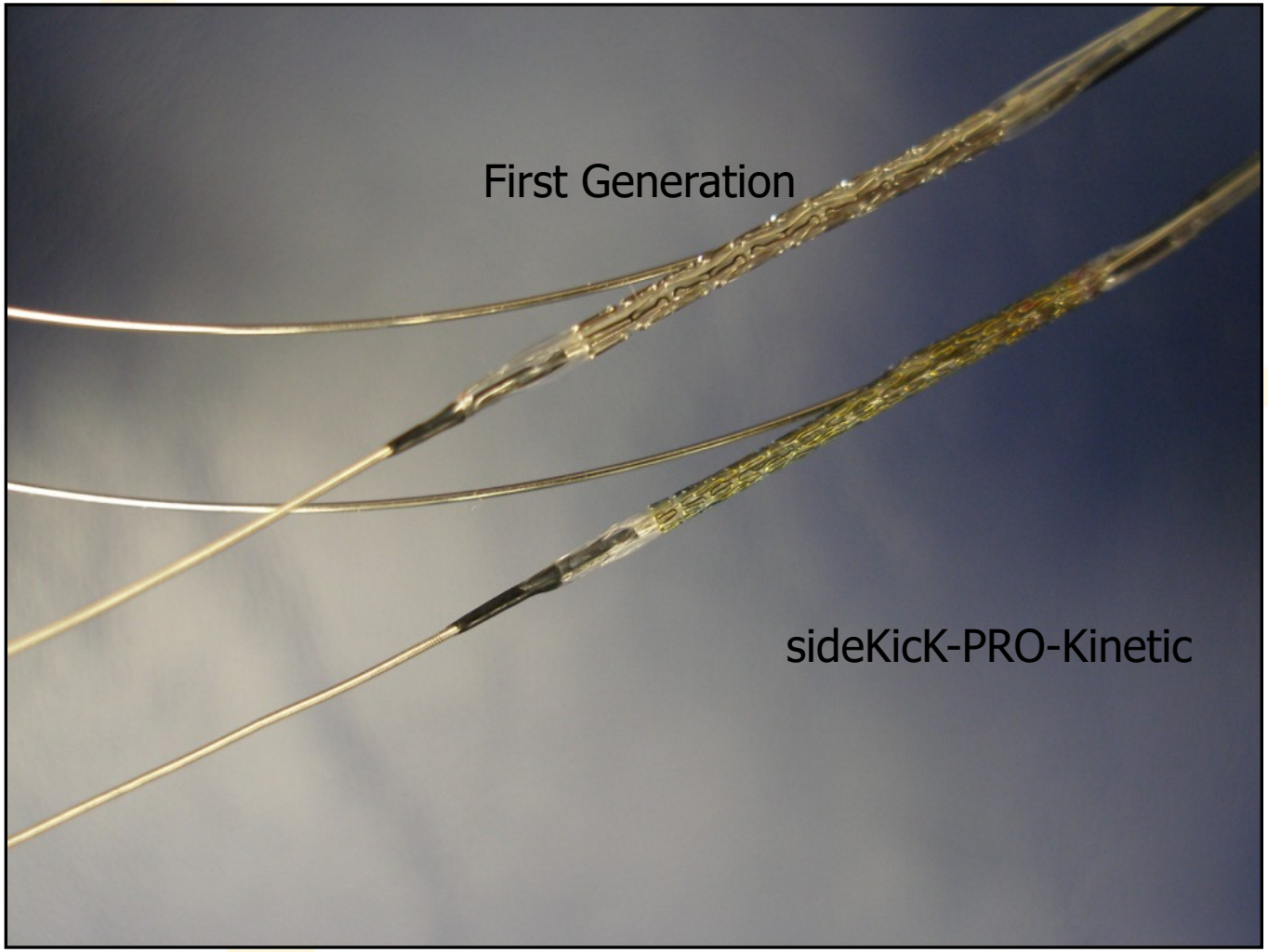
Results

Device Success	*16 (80%)*	*Post-dil*	*6 (30%)*
Procedure Success	*20 (100%)*	*Additional Stent*	*8 (40%)*
Final MLD, mm	*2.91 ± 0.46*	*Side Branch PTCA*	*4 (20%)*
Final %DS	*9.1 ± 11.9*		

Next Generation sideKicK

YMed and Biotronik will bring to market an optimal provisional stenting system for the treatment of coronary bifurcation lesions

Next Generation sideKicK - PRO-Kinetic

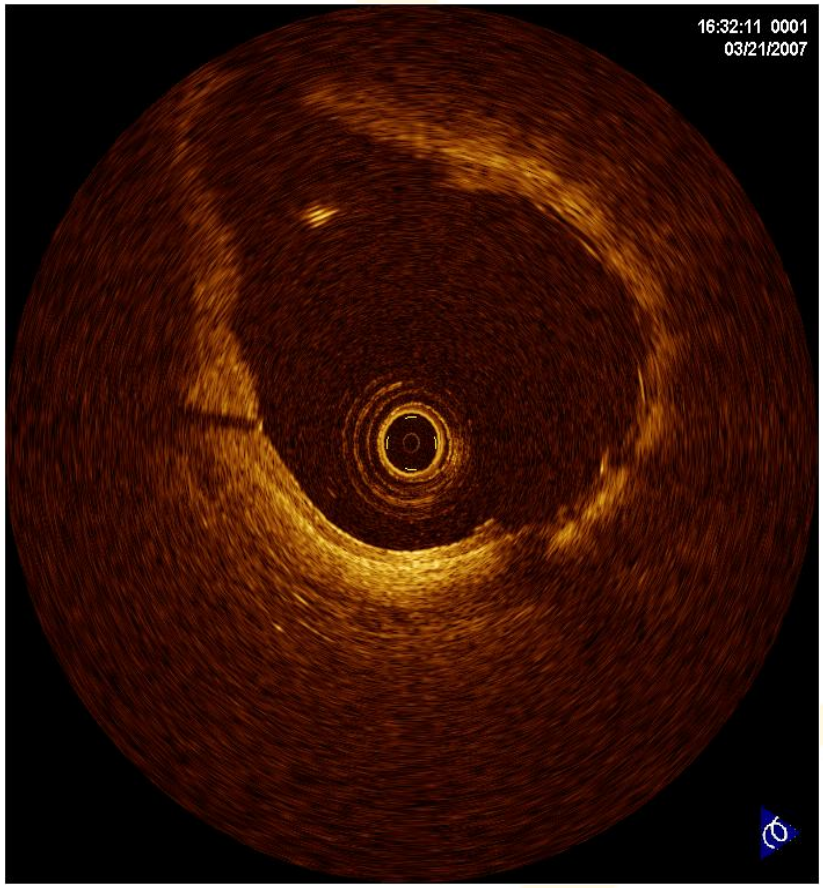


Investigational use only

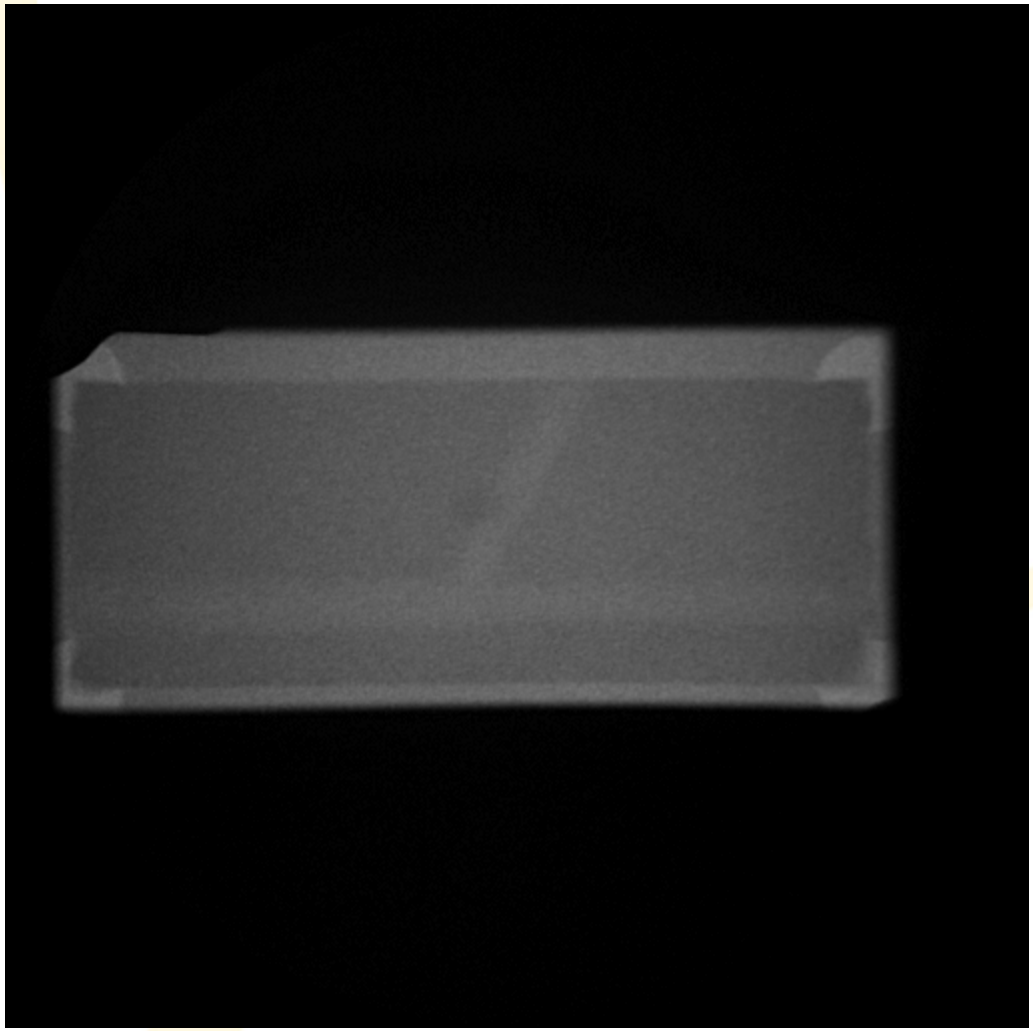
Next Generation Sidekick

- Confirmation of deliverability, stent cell alignment, and minimum stent distortion effect via:
  - Animal Work
  - OCT
  - 3D Analysis with micro-CT imaging

Sidekick-PRO-Kinetic Deployment Validation by OCT & Visual Inspection

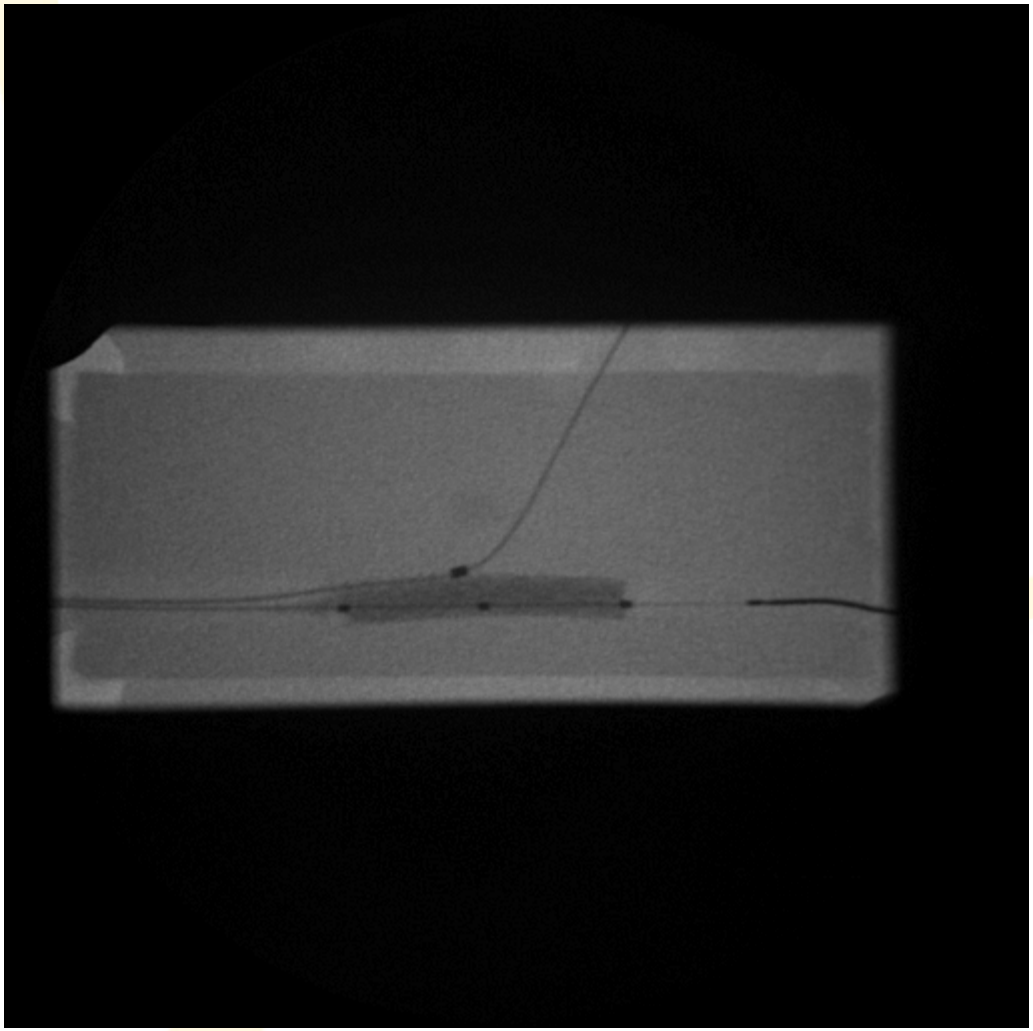


Silicon Phantom – Bifurcation Model



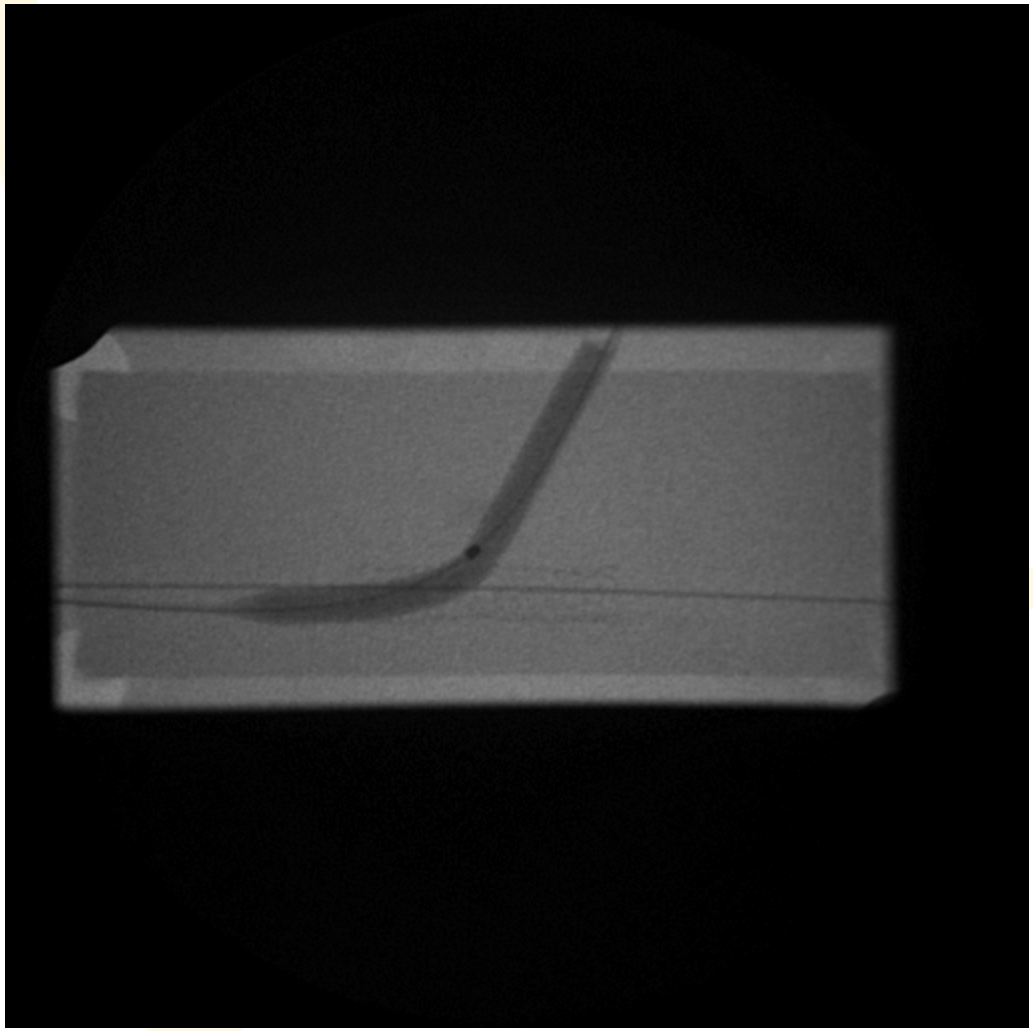
Courtesy of Dr. David Meerkin and Dr. John Orminston

sideKicK-PRO-Kinetic Deployment



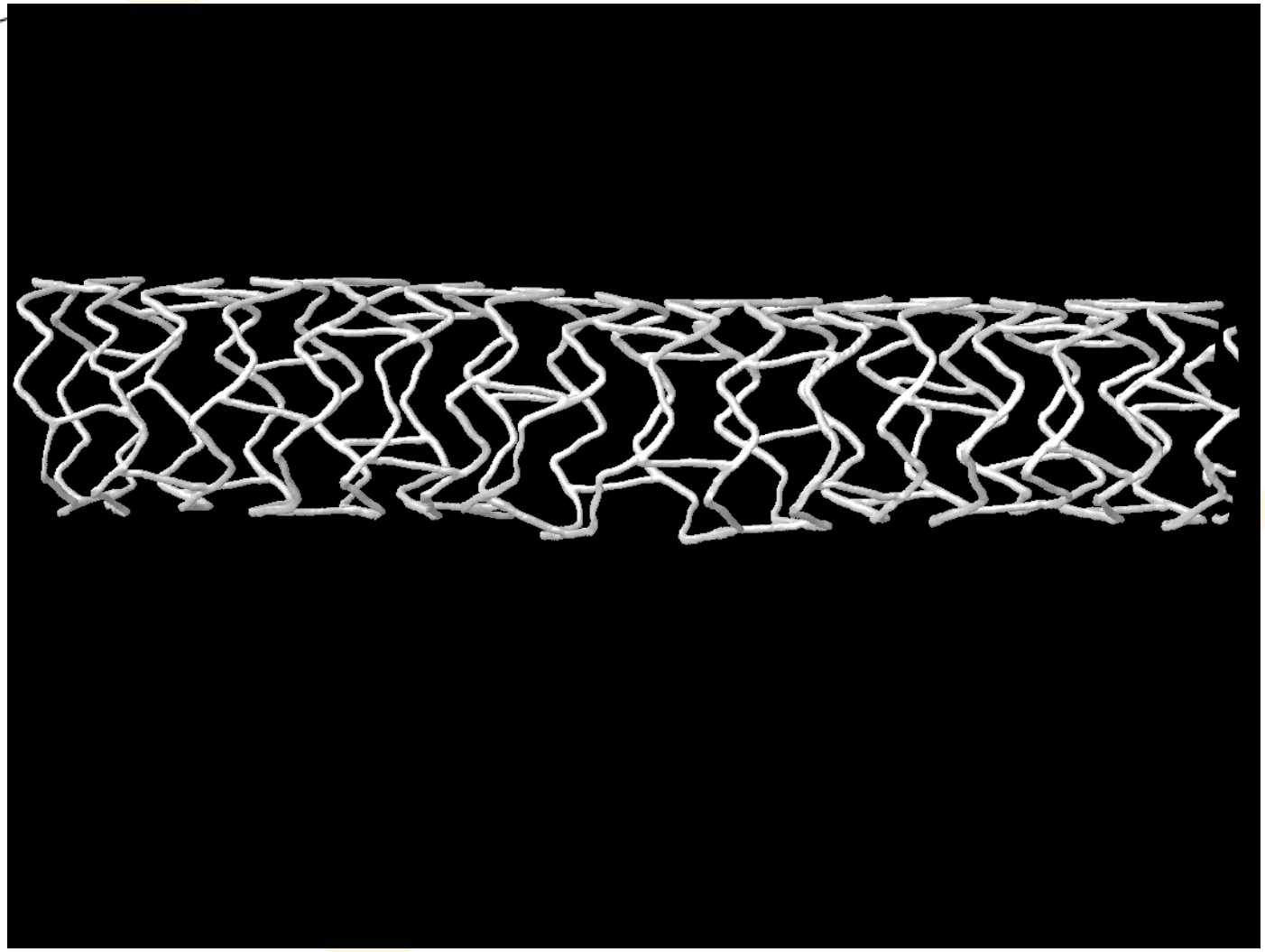
Courtesy of Dr. David Meerkin and Dr. John Orminston

Side Branch Ballooning (2.5mm) – No Kiss



Courtesy of Dr. David Meerkin and Dr. John Orminston

3D micro-CT Analysis



Courtesy of Dr. David Meerkin and Dr. John Orminston

Summary

Features of the YMed sideKicK System:

- Highly torquable
- Low crossing profile
- Single operator
- Accurate positioning and deployment
- Preserves access to the side branch
- Family of models addressing a variety of bifurcations and ostial locations

Optimizes Provisional Stenting