Welcome to the 4th European Bifurcation Club 26-27 September 2008 - PRAGUE

A novel side branch solution to bifurcation disease

European Bifurcation Club

EBC

TargetSE
Delivery System for Self-Expanding Devices

Sideguard
Ostium Protection Device

Cappella
Cardiovascular Innovations

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European Bifurcation Club

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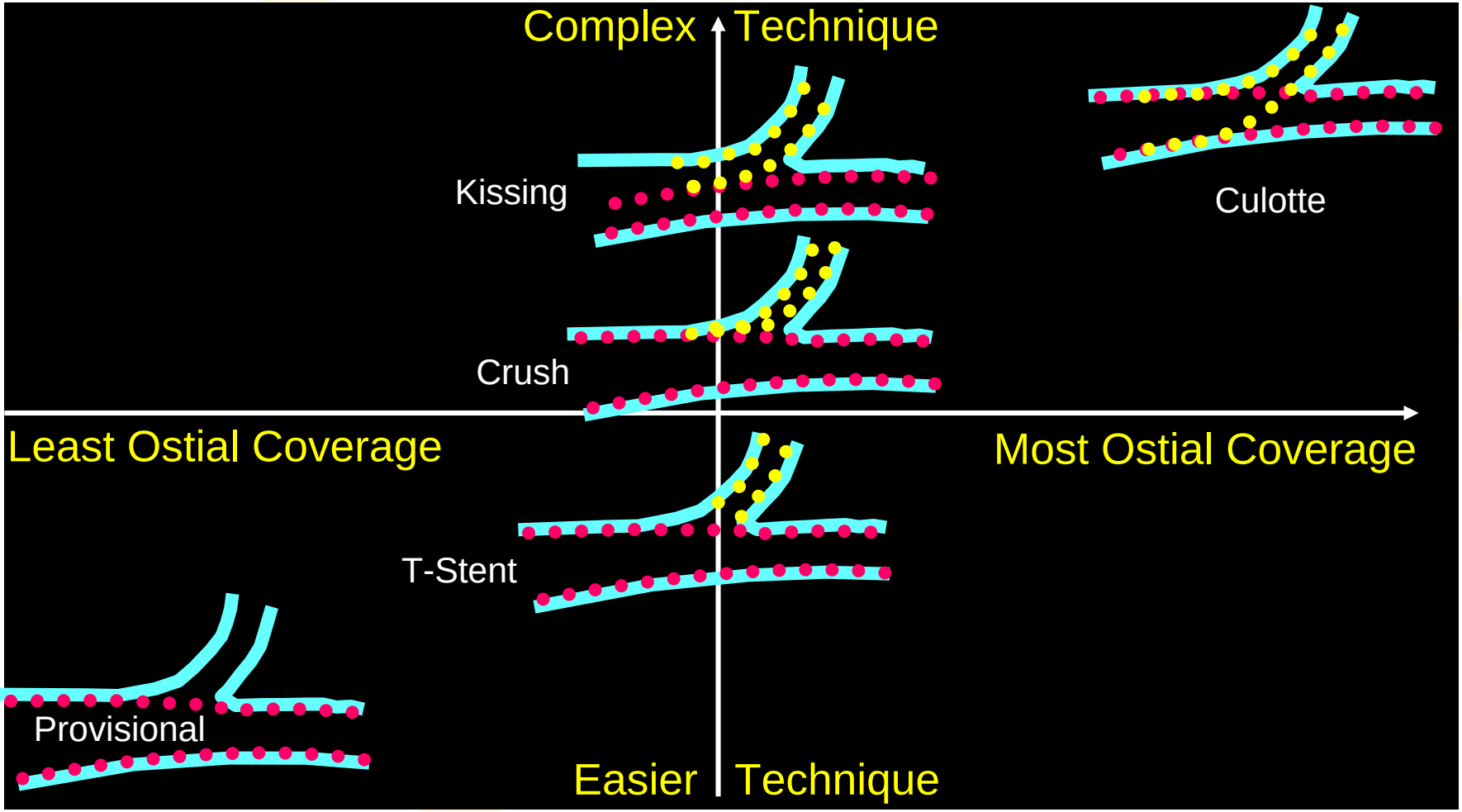
Bifurcation Stent Techniques Matrix



The Next Generation of Bifurcation Stenting

European Bifurcation Club

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The Cappella Sideguard™
Side Branch Stenting System

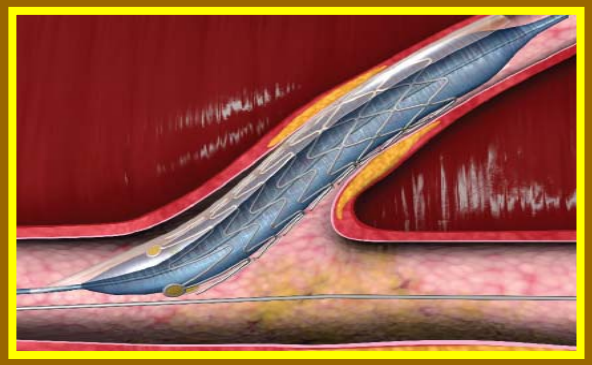
About Cappella

- Co-founded by Drs. Antonio Colombo & Ascher Shmulewitz in 2004
- Developed a non-DES solution for the treatment of coronary bifurcations -- the Sideguard™ self-expanding side branch stent
- Completed CE pivotal safety trial:
  - 75 patients treated
  - Investigational device
  - Preparing to file for CE Mark approval in Europe in Q4-08
- European product launch scheduled for Q1-09

The Cappella Products

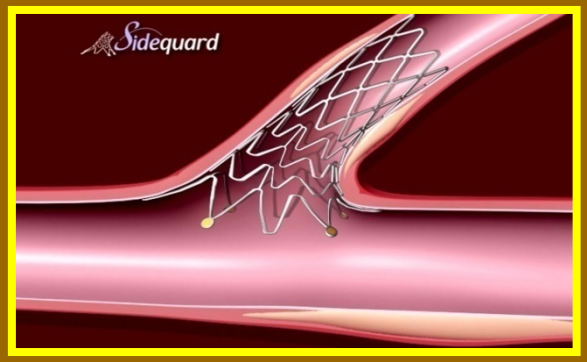
Cappella products uniquely address the complexities associated with ostial and bifurcated lesions

Target SE Delivery System



Splittable Sheath, Balloon Catheter System

Bare Metal Sideguard OPD



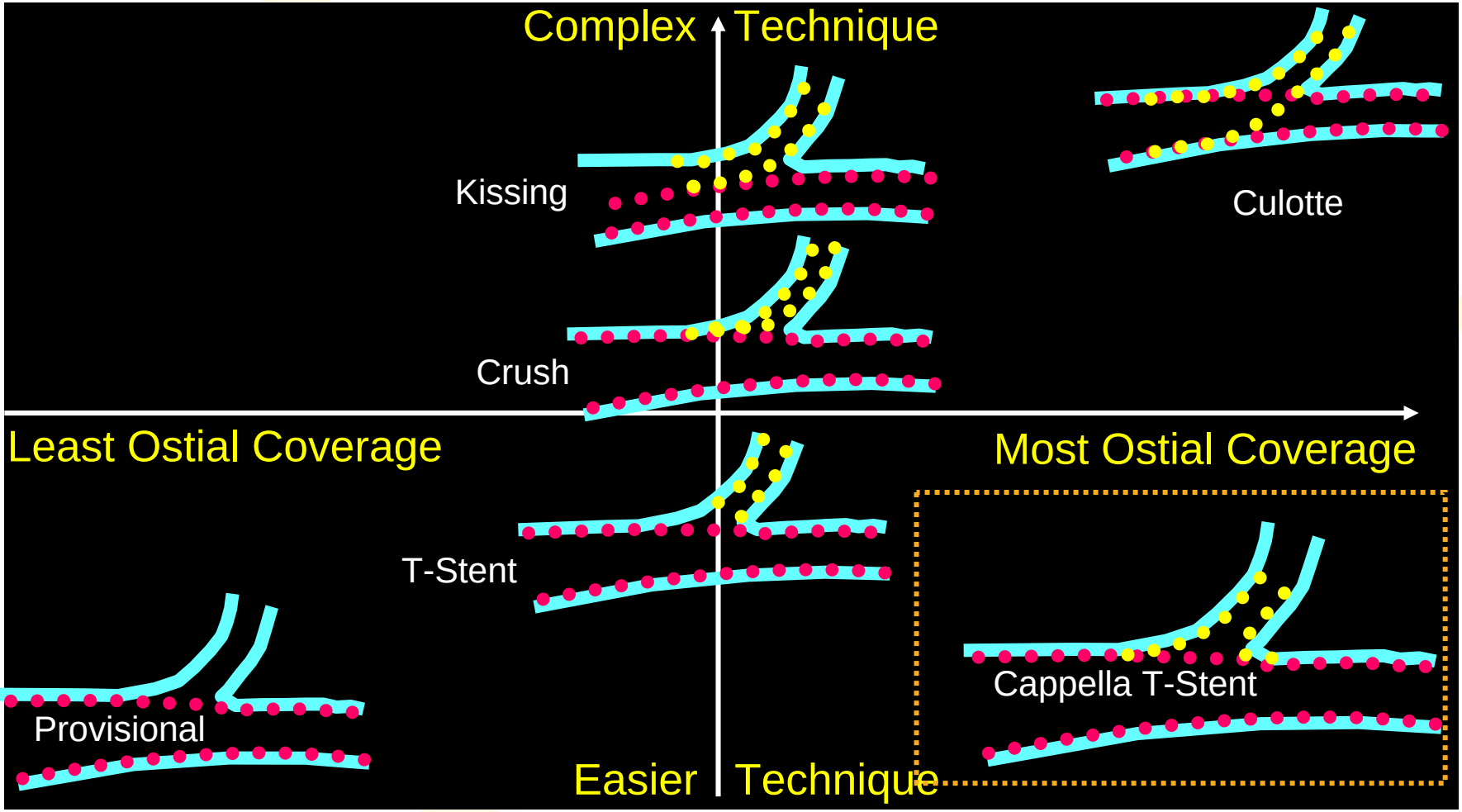
Self-Expanding (SE) Stent

- Sideguard is a self-expanding, anatomically-shaped stent
- Target is a balloon-release delivery system for SE stents

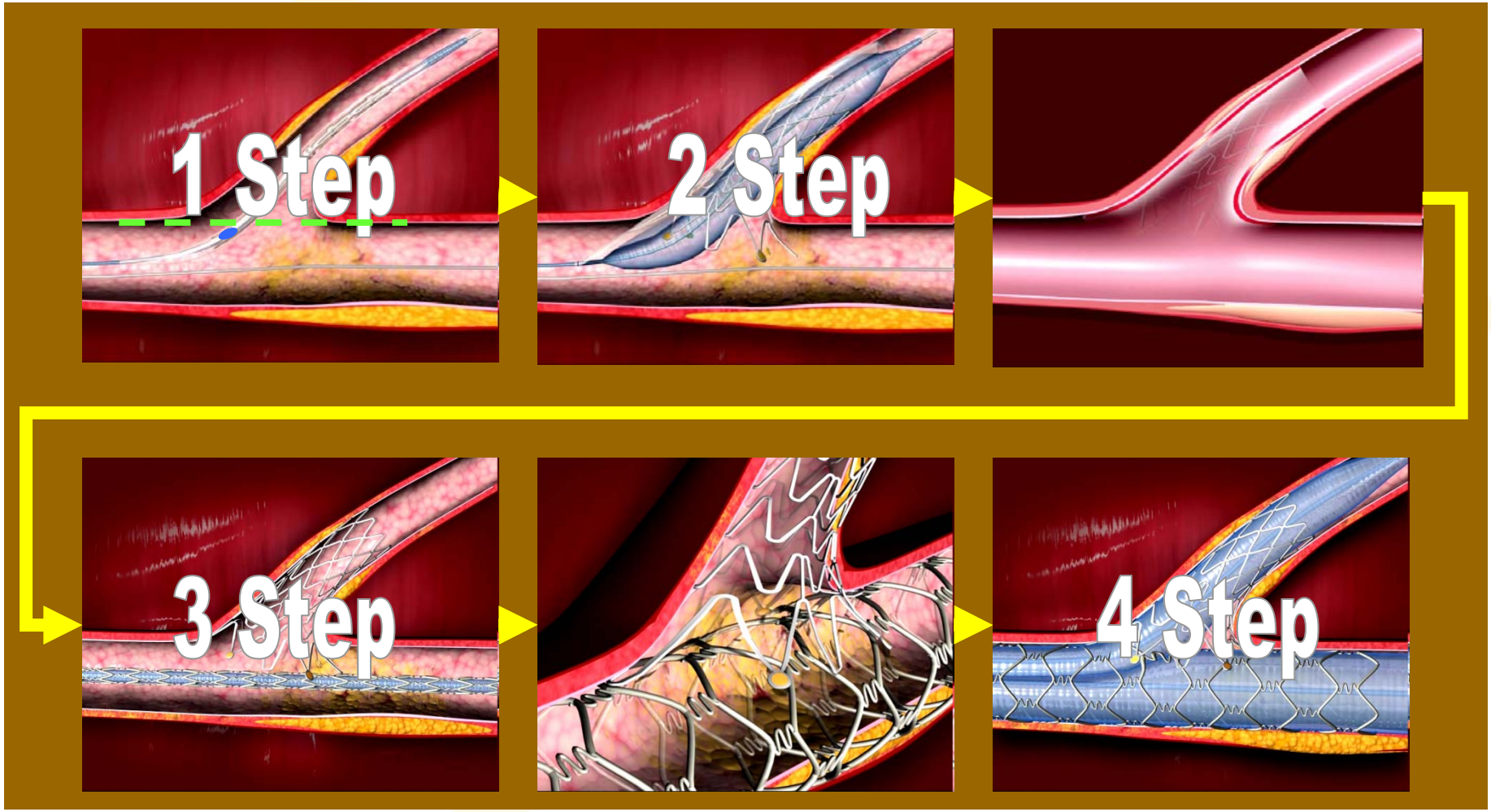
The Cappella Technology

Sideguard Side Branch Stent & Target SE Delivery System	
Device description	Self-Expanding, Bare-Metal Nitinol, Full Ostial-Supporting Side Branch stent
Mechanism of operation	Splittable-sheath, balloon release catheter system
Device size (Fr)	3.1
Length	Treats lesions up to 7 mm in SB
3 sizes – SB vessel size up to	2.5 mm | 2.75 mm | 3.25 mm
Product Approval and Indication	*Investigational device;* *CE Mark expected Q1-2009*

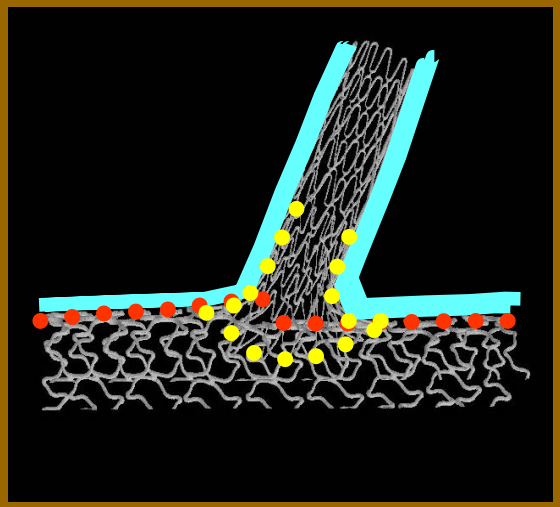
Bifurcation Stent Techniques Matrix

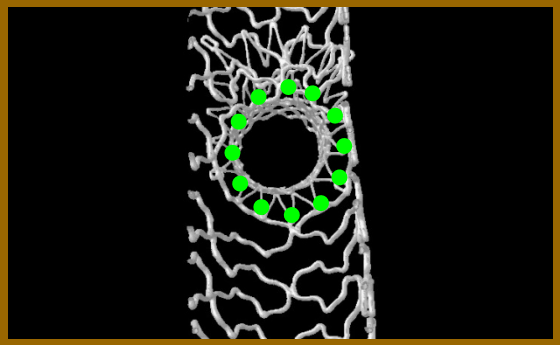


Cappella T-Stenting Approach



Cappella "T" seamless bifurcation stenting



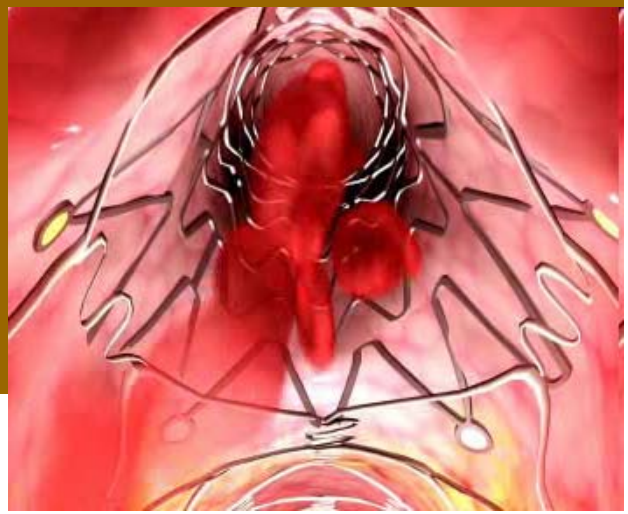


- Seamless transition
- No crushing of metal
- No excess metal in MV
- No crossing of struts
- Improves flow dynamics
- Fewer thrombotic events
- Easier SB re-access

The Sideguard Advantage

For ostial and side branch lesions:

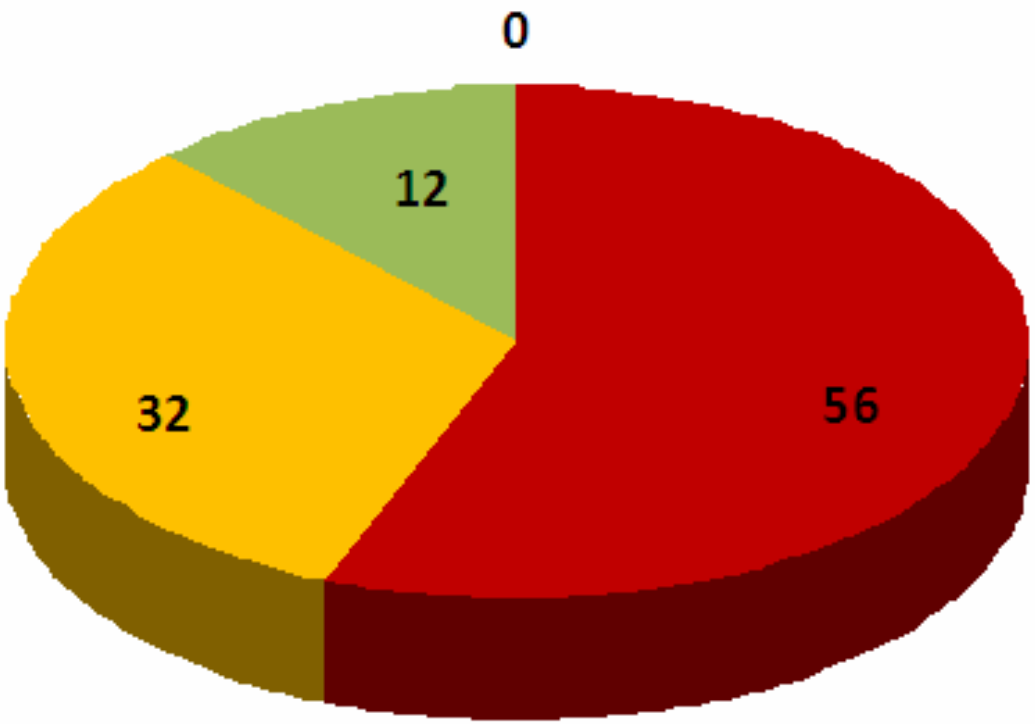
- Protects and opens the side branch ostium
- Facilitates side branch rewiring
- Eliminates jailed side branches
- Provides maximum coverage of ostium
- Minimizes stent overlap at transition zone
- No crushing of metal



Sideguard FIM Experience

Objective	FIM Feasibility study of SG stent & catheter to establish: • safety to proceed to pivotal trial • baseline efficacy of Bare Metal FIM design • procedural best practices
Design	Single Arm, multi-centers
Endpoints	• Major Adverse Cardiac Events (MACE) @ 1 & 6 months • Technical Success (Procedural) • MV and SB MLD @ 6 months • MV and SB Binary Restenosis @ 6 months
Patients	**25 enrolled**
Investigators	W. Wijns, MD — Belgium (Aalst) — P.I. E. Grube, MD — Germany (Siegburg) R. Mueller,MD — Germany (Siegburg) J. Schofer, MD — Germany (Hamburg)

Sideguard FIM Lesion Summary



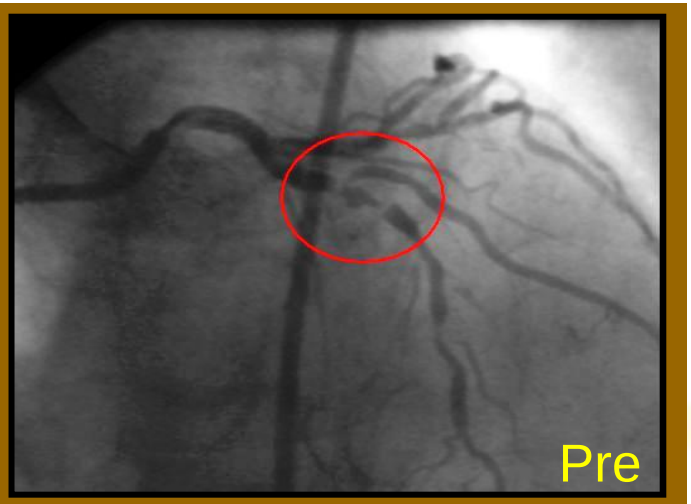
- Disease in all 3 segments (1,1,1)
- Disease in 2 of 3 segments including SB (1,0,1) (0,1,1)
- Disease in MB only (1,1,0) (1,0,0) (0,1,0)
- Disease in SB only (0,0,1)

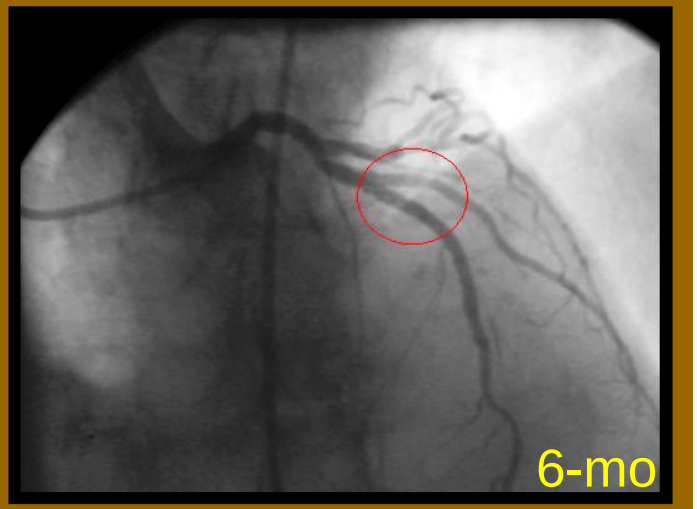
Sideguard FIM Lesion Characteristics

Baseline Lesion Characteristic Averages (N=25)

Pre-Procedure	Side Branch	Main Vessel
MLD (mm)	5.8	13.6
RVD (mm)	0.69	0.90
Stenosis	70%	71.5%

High degree of vessel narrowing = challenging cases

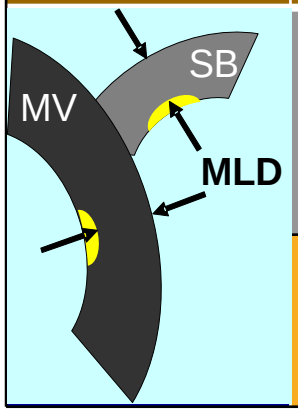




Sideguard FIM Clinical Outcomes

	N=25
Procedural Success	84%
Cardiac Death	0%
CABG	0%
MI	4%
TLR	8%
MACE	12%

Sideguard FIM Efficacy Data

2 Segment Analysis	N=21	Pre-Proc. (Ave)	Post/ Acute (Ave)	6 Mo F/Up (Ave)	Late Gain (Ave)	Late Loss (Ave)
	Sideguard MLD	0.69 mm	2.19 mm	1.81 mm	1.12mm	0.38 mm
	Cypher MLD	0.90 mm	2.81 mm	2.60 mm	1.70mm	0.21 mm

Summary of Sideguard FIM Clinical Data

- Low restenosis rate:
  - 2/25 patients
- Acceptable safety profile:
  - MACE rate of 3/25 patients
- Late loss of < 0.4 in the SB

Full CE dataset to be presented at TCT 2008 TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

Conclusion

- Very promising 6-month angiographic data and more will be available and presented at TCT
- FIM safety data is very acceptable
- Cappella T is similar to a reverse T-stent technique and due to the stent's trumpet design provides better coverage
- The Cappella stent makes T-stenting approach easier