



Universitair Medisch Centrum  
Utrecht

# ***3-day OCT follow-up of a STENTYS<sup>®</sup> stent in a STEMI patient with a bifurcation lesion***

*European Bifurcation Club*

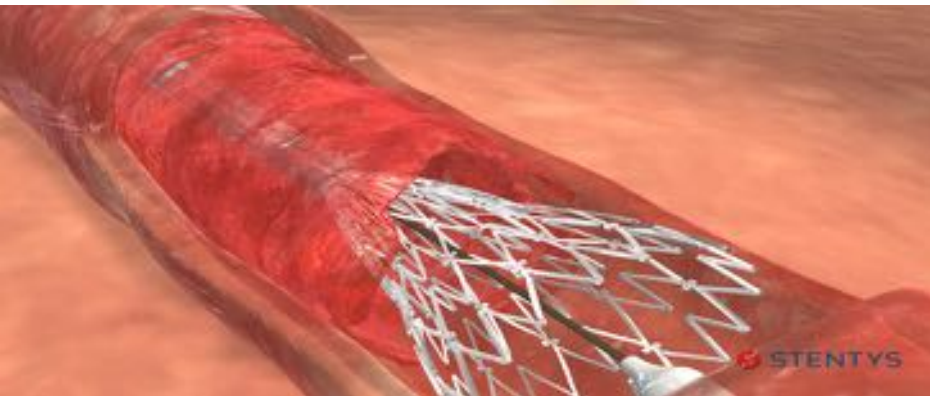


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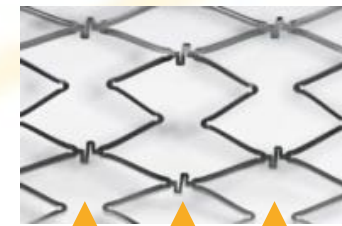


# STENTYS® Technology

- Nitinol, self-apposing stent (BMS and DES)
- 6F single-wire, rapid exchange
- Disconnectable struts over full length\* for easy access to side branches



Deployment of the STENTYS® stent

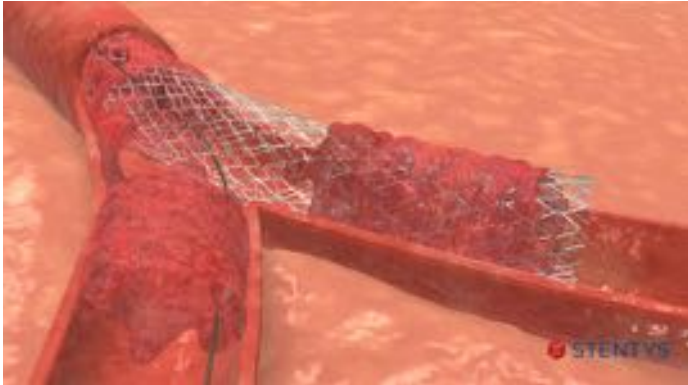


Disconnectors  
along the stent

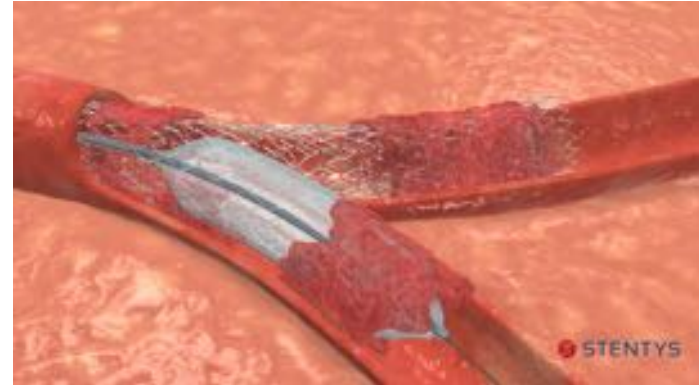
\* Except the first and last 2 rows of the stent



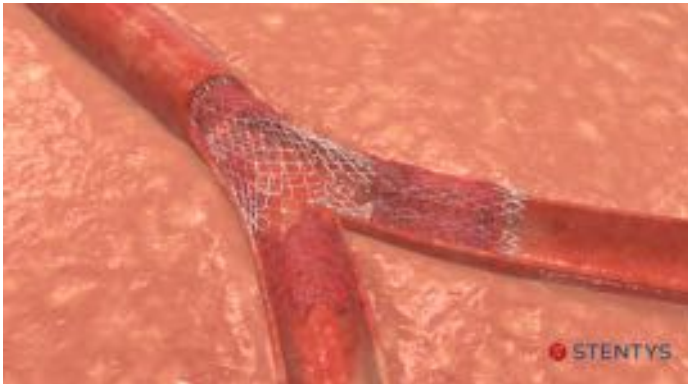
# Opening the STENTYS<sup>®</sup> Self-Apposing Stent at a Bifurcation



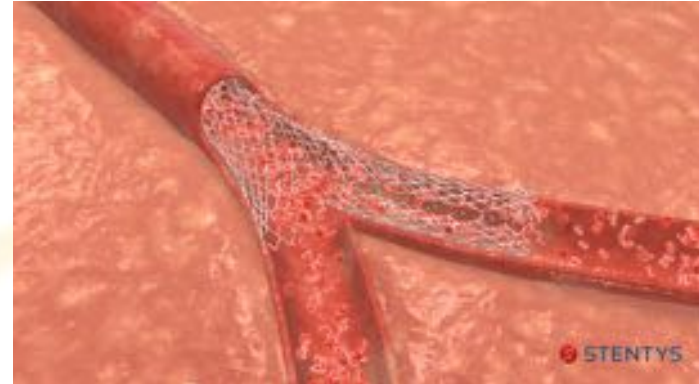
1. Position the guidewire into the side branch at the most distal point close to the carina.



2. Inflate a regular PTCA balloon at 8 atm at the side branch opening to disconnect the struts.



3. Deflate and withdraw the balloon allowing the stent to expand fully to create the opening to the side branch.



4. The STENTYS<sup>®</sup> stent expands with the vessel during vasodilation and as thrombus resolves ensuring perfect apposition.



# OPEN I Study Design

## Design

- **DESIGN:** Prospective, non-randomized, single-arm, multi-center study
- **OBJECTIVE:** To evaluate the safety and feasibility of the Stentys DES and BMS in bifurcated lesions
- **ENDPOINTS:**
  - Procedural success
  - MACE @ 30 days and 6 months
- Events adjudicated by CEC
- Independent monitoring: Medpass
- Core lab: Cardialysis

63 patients enrolled between September 2007 and August 2009 in 9 European clinical sites

3 patients not stented

60 patients with Stentys stent:  
• 33 patients with Stentys BMS  
• 27 patients with Stentys DES

Clinical follow-up  
at 30 days

Clinical follow-up  
at 3 months

Angiographic and IVUS  
follow-up at 6 months

# OPEN I: case



BASE

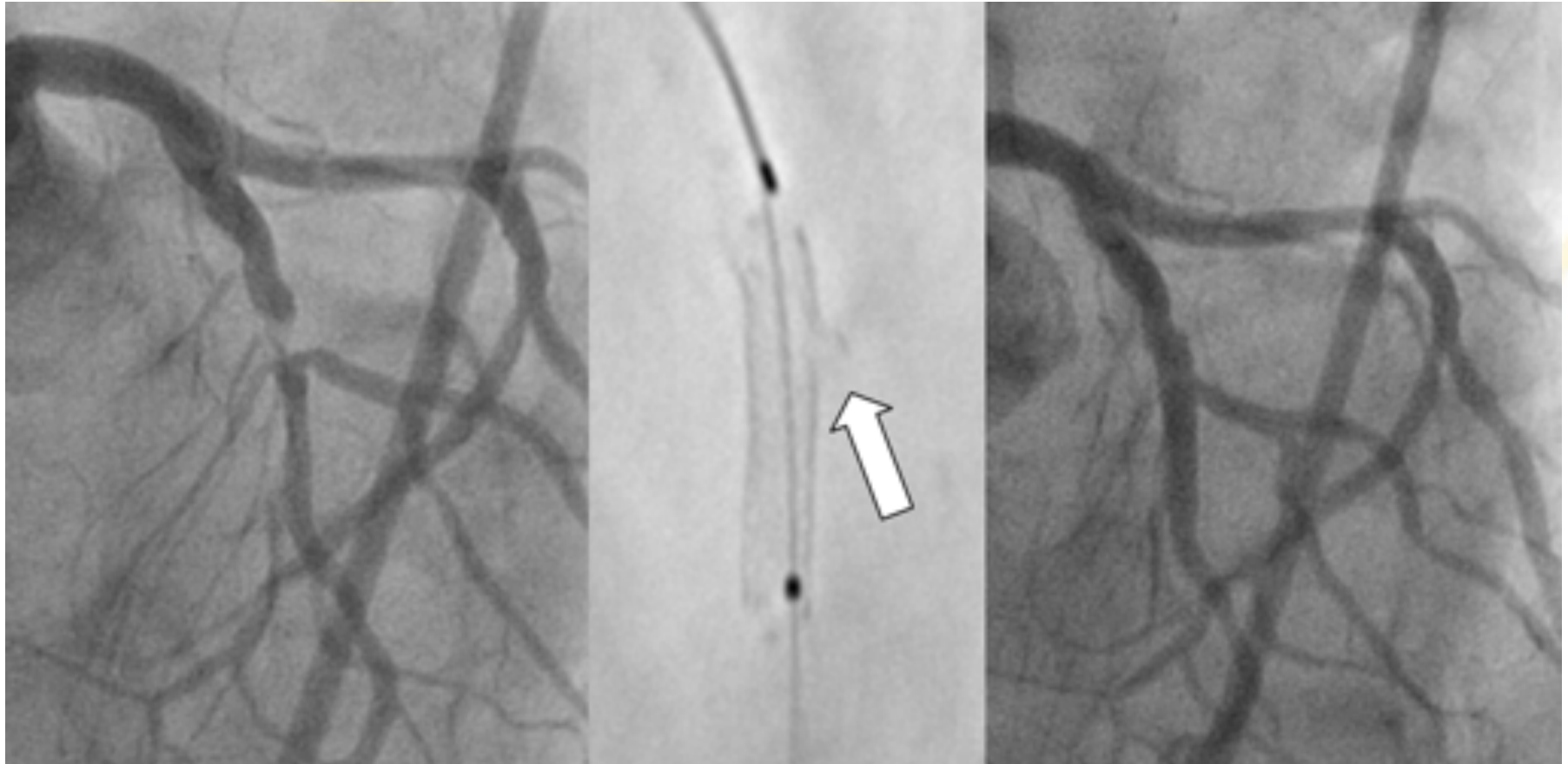


Post-procedure

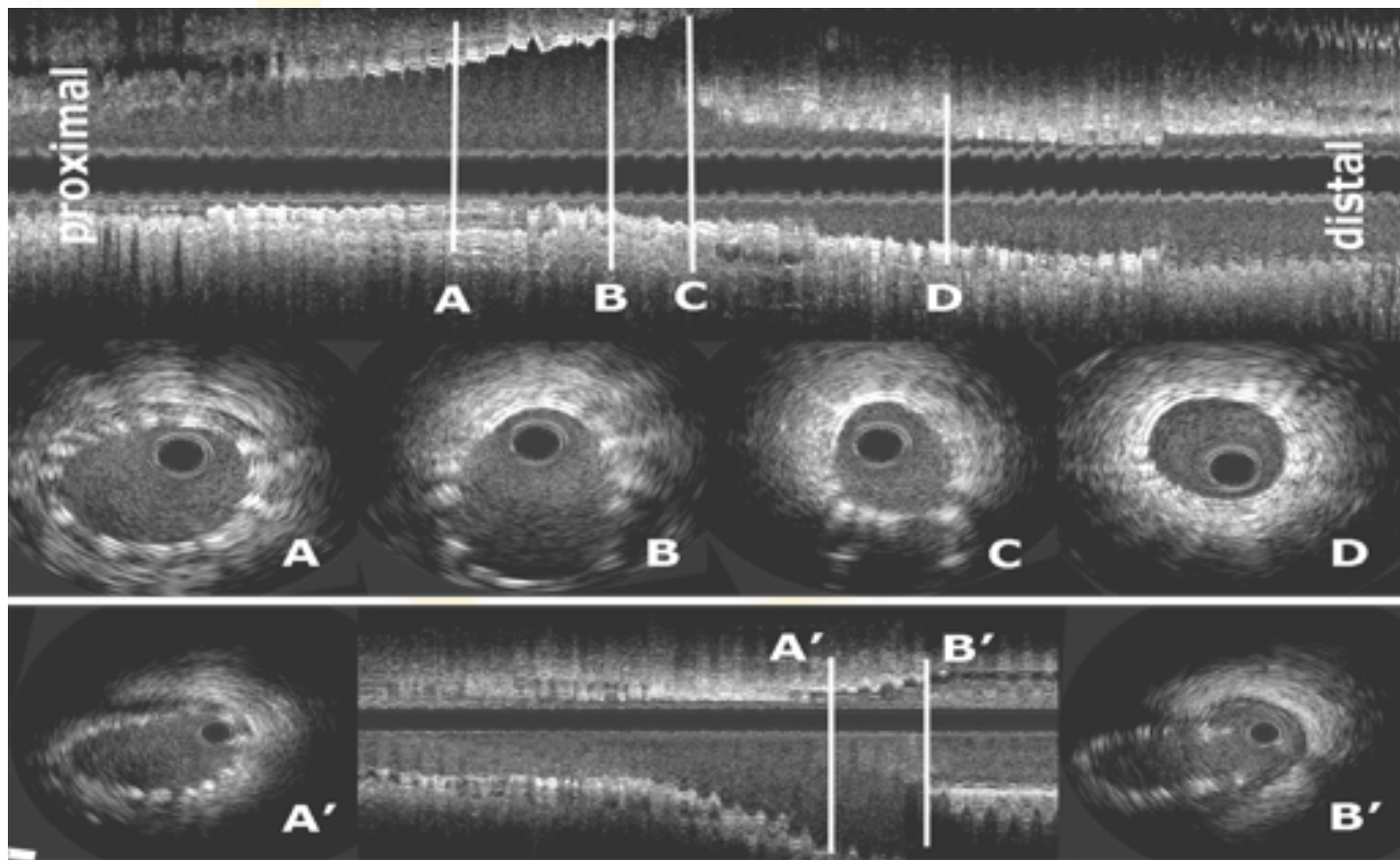


6 month FU

# Disconnection (StentBoost)



# IVUS





# STENTYS Clinical Program

## OPEN (Bifurcation)

I

**Feasibility trial:** Single Arm – STENTYS BMS & DES  
→ 6 month QCA and IVUS

60

## APPOSITION (STEMI)

I

**Feasibility trial:** Single Arm – STENTYS BMS  
→ 3 day and 6 month QCA and IVUS

25

II

**Randomized trial:** STENTYS BMS vs VISION/Driver  
→ 3 day QCA and OCT, 6 month clinical

80

III

**“Real life” study:** Single arm – STENTYS BMS & DES  
→ 30 day and 12 month MACE

500

IV

**Randomized trial:** STENTYS DES vs conventional DES  
→ 3, 6 and 9 month OCT

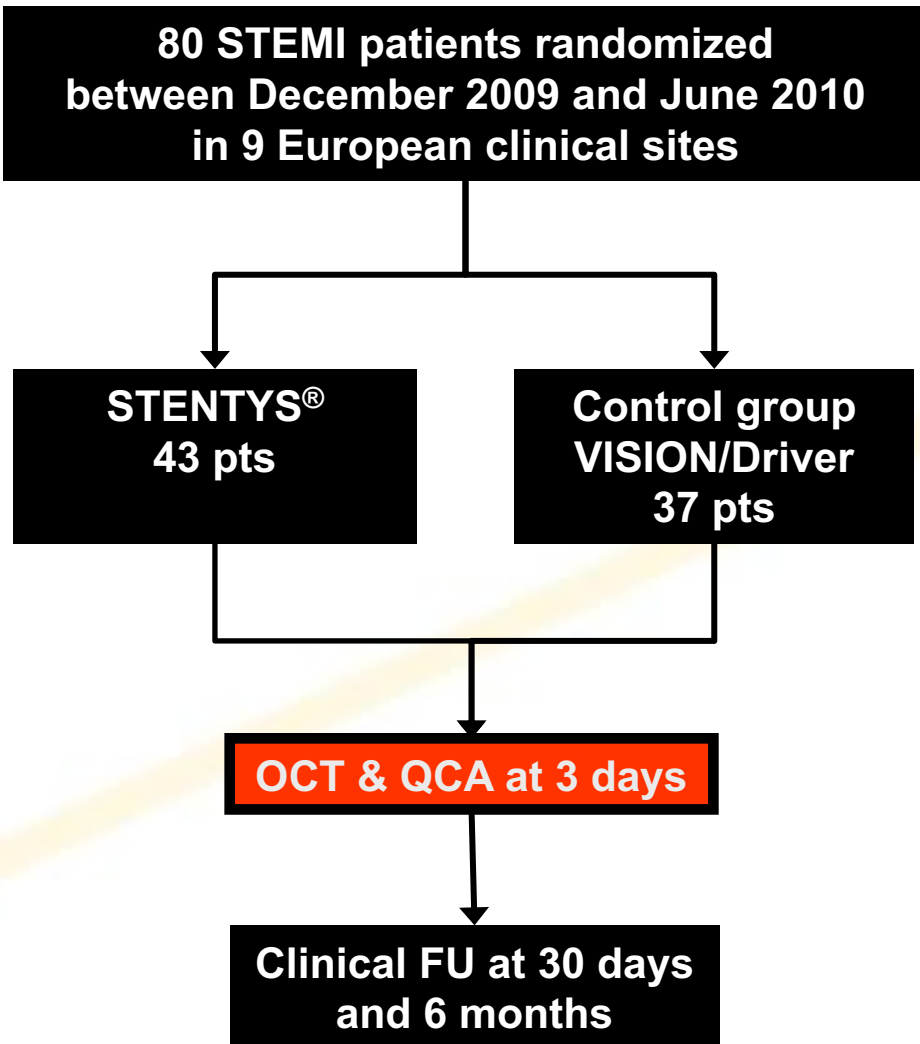
150

*Patients*



# APPOSITION II

- **DESIGN:** Prospective, randomized, two-arm multicenter study
- **OBJECTIVE:** To compare the STENTYS<sup>®</sup> Stent with a balloon-expandable stent in AMI
- **HYPOTHESIS:** Superior apposition with self-expanding stent compared to balloon-expandable stent
- **PRIMARY ENDPOINT:** Stent strut apposition at 3 days by OCT
- **STUDY ORGANIZATION:** CEC, DSMB, Core Lab, Independent monitoring



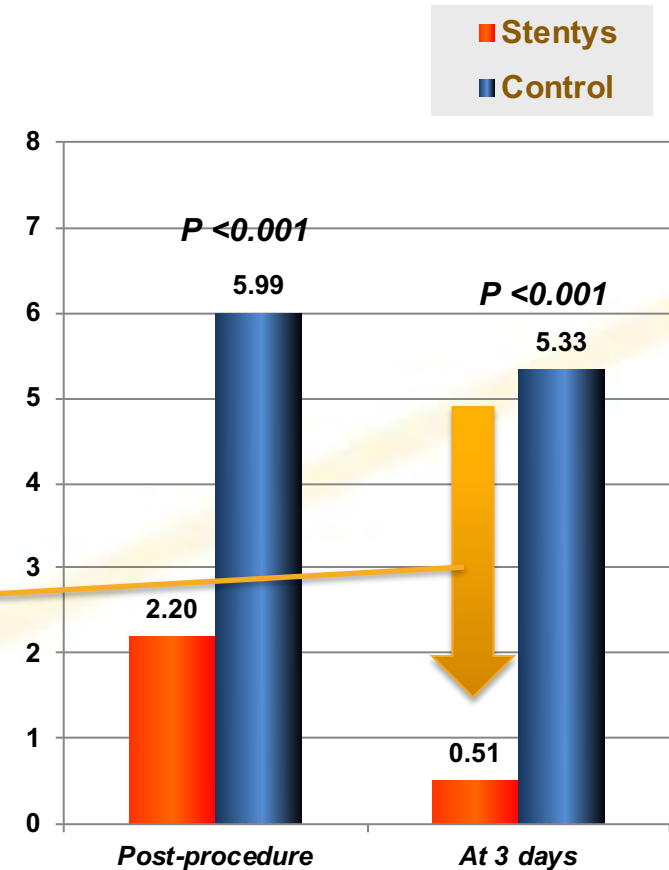


# Primary study endpoint

## Stent strut malapposition at 3 days

	<b>STENTYS n = 40</b>	<b>Control n = 36</b>	<b>P Value</b>
<b>Post PCI</b>	2.20%	5.99%	<b>&lt;0.05</b>
<b>3 days</b>	0.51%	5.33%	<b>&lt;0.001</b>

**10-fold reduction in malapposition with STENTYS self-apposing stent**





# STEMI Case - APPOSITION II Trial

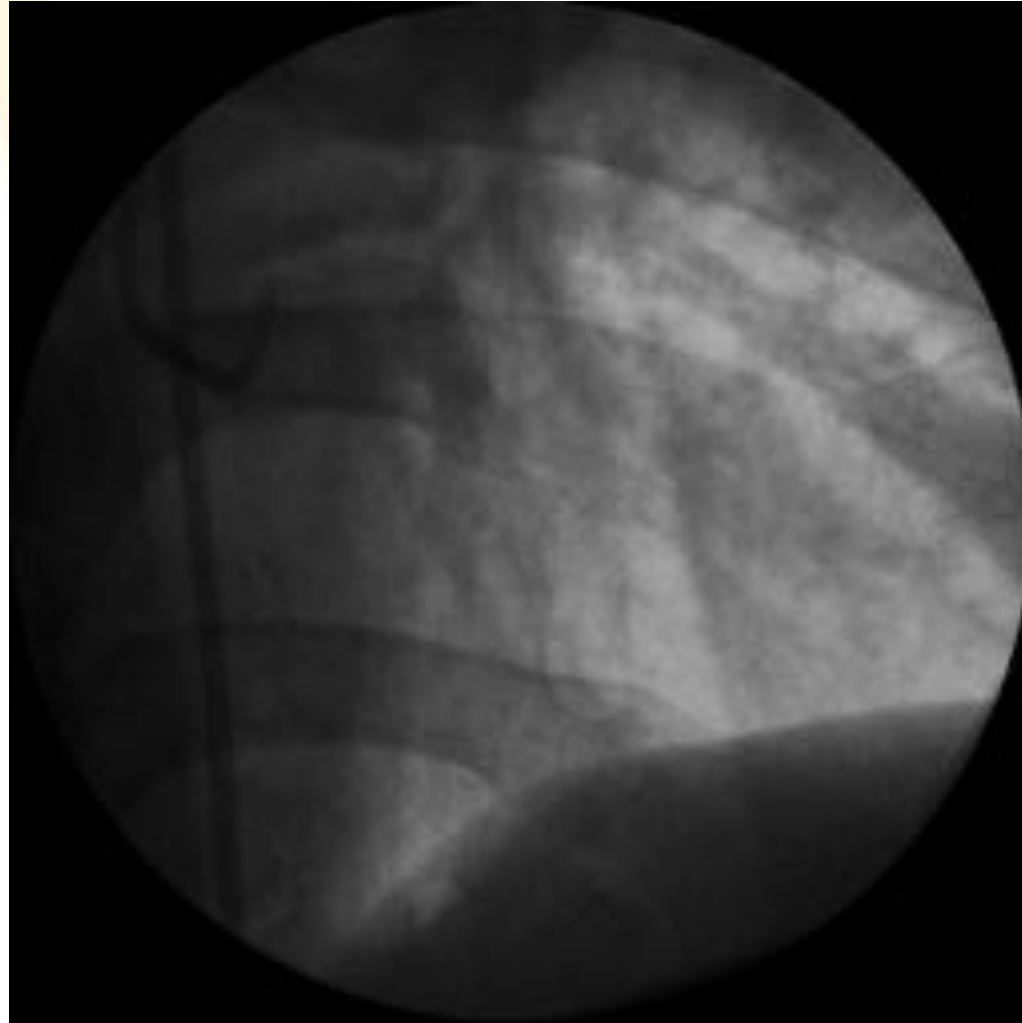
**42 years old, male**

- **Risk Factors:** Smoker
- **Clinical Presentation:** Anterior STEMI admitted for Primary PCI
- **Echocardiography:** Hypokinesia of the antero-septal wall with moderate ejection fraction reduction (LVEF 43%)

**Randomized to STENTYS**

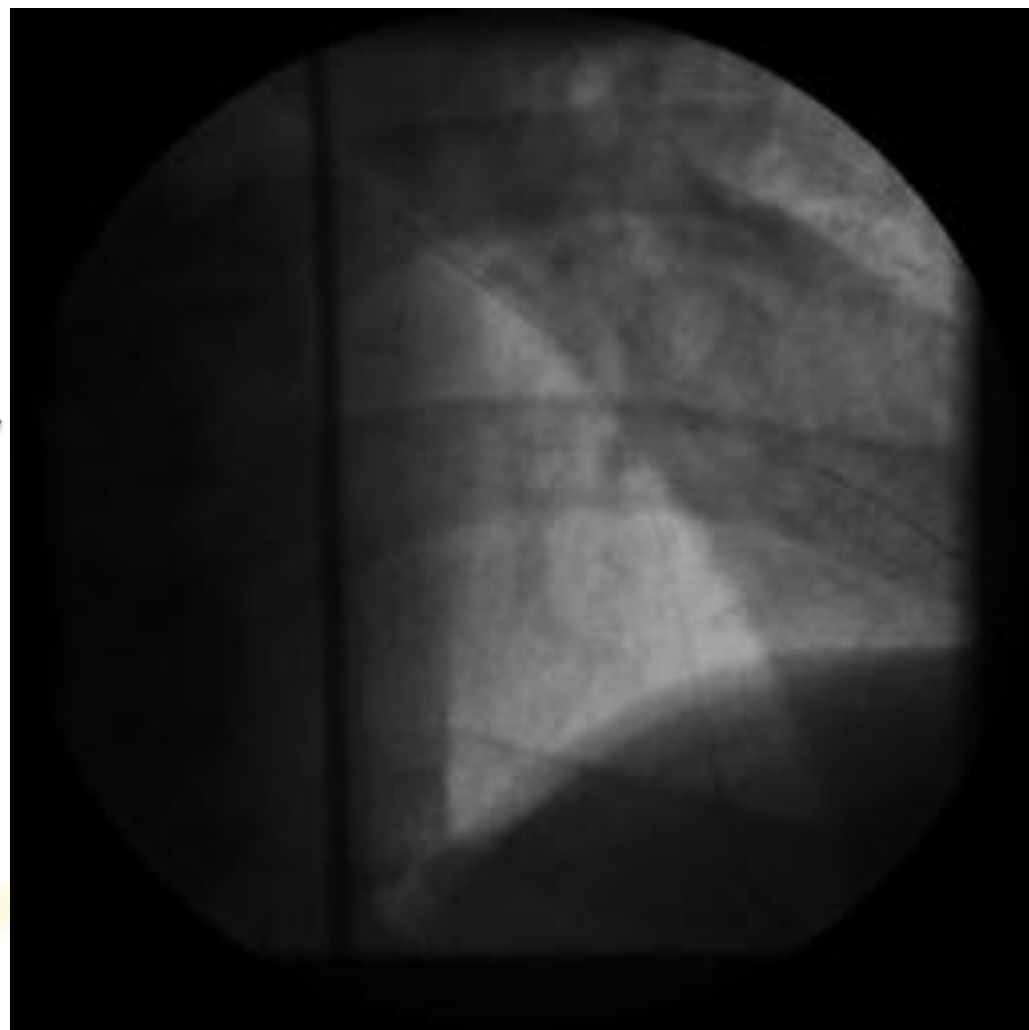
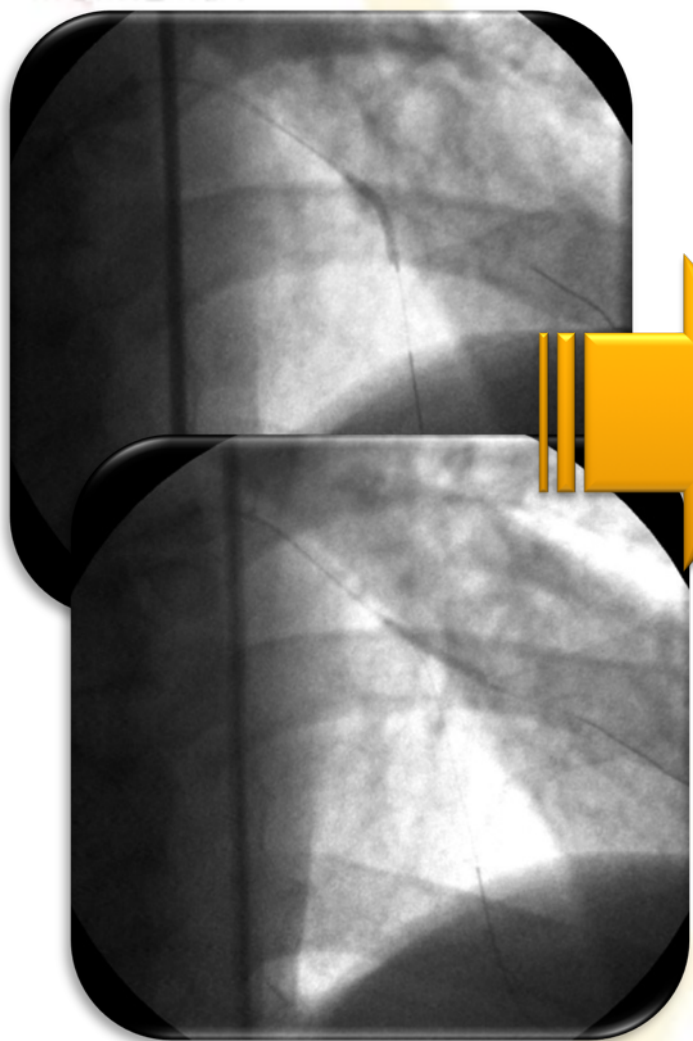


# Baseline Coronary Angiography

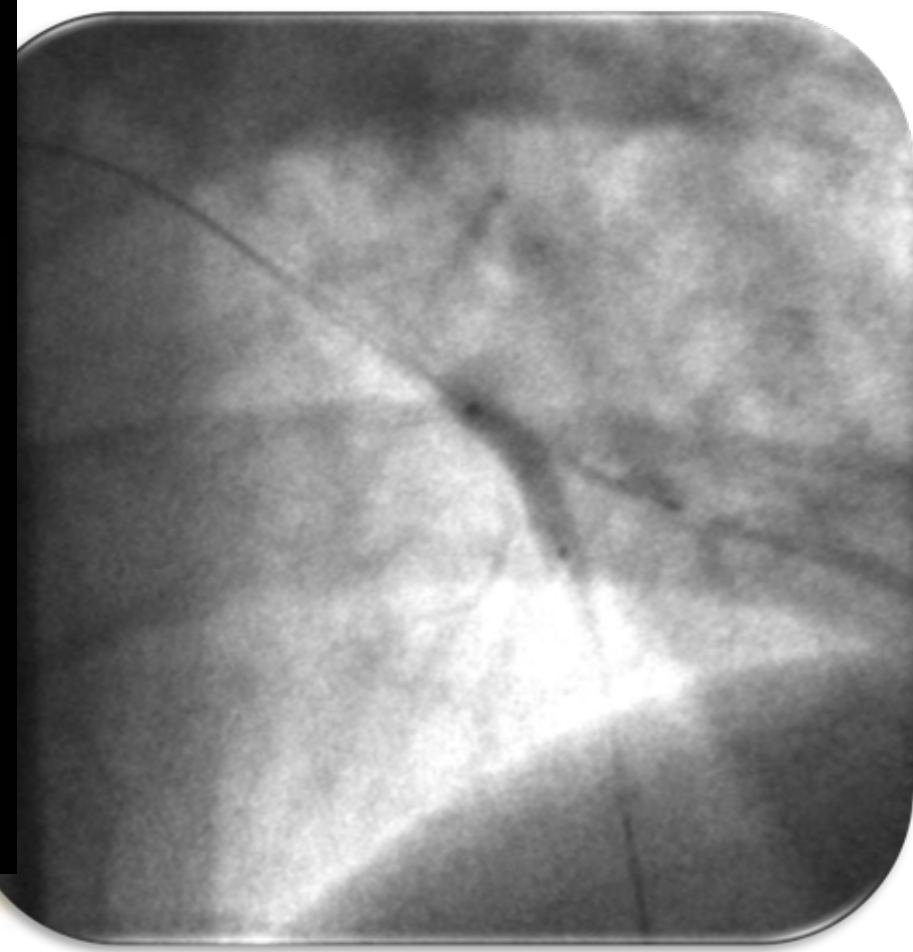
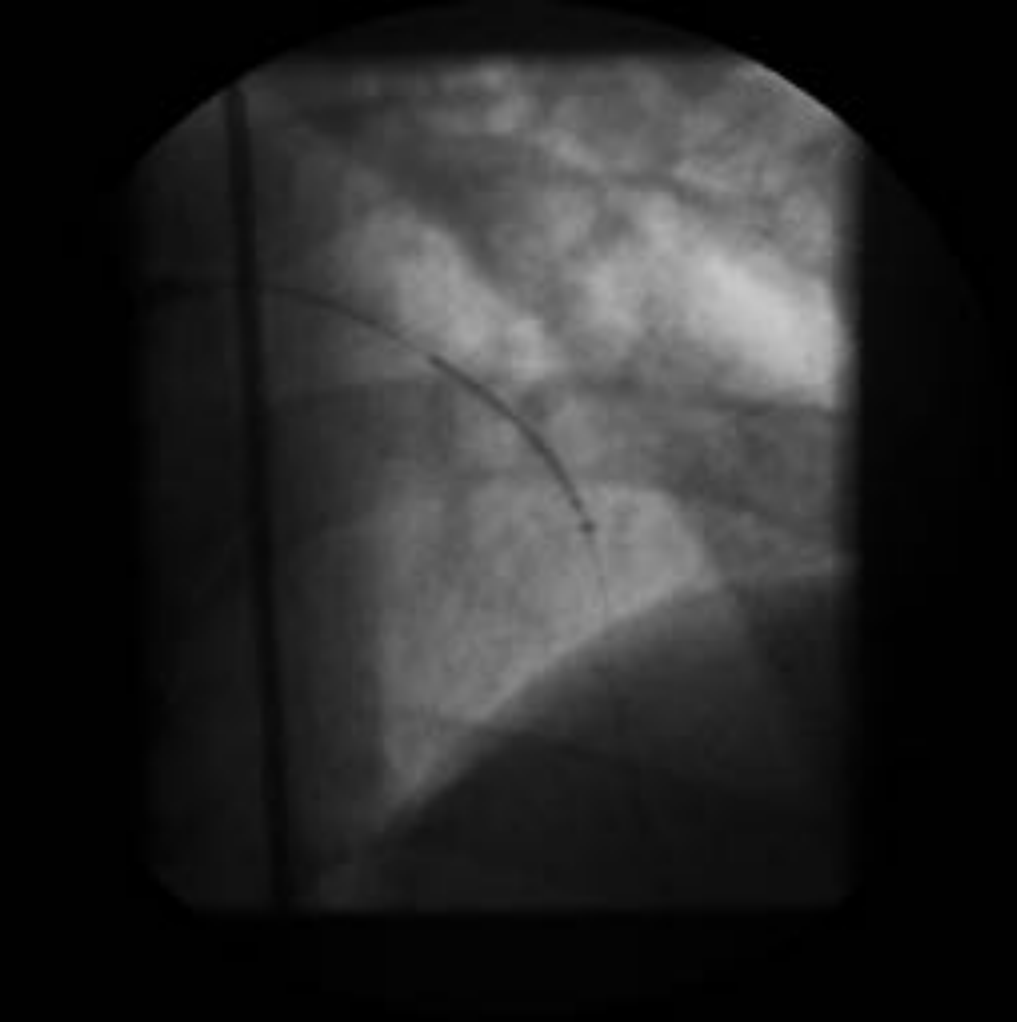


Courtesy of Dr La Manna, Ferrarotto University Hospital, Catania - Italy

# Predilatation



**2.0/20 mm balloon**



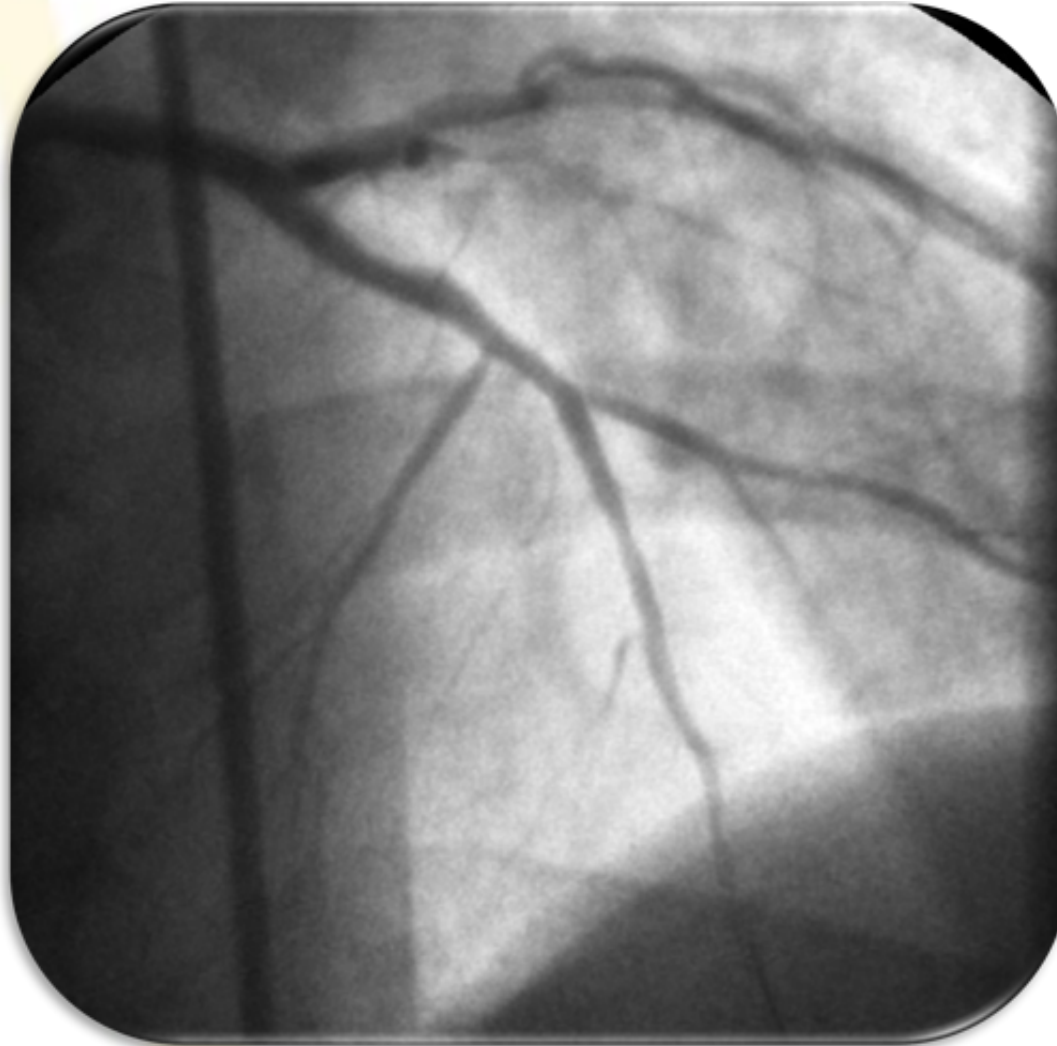
**STENTYS Stent**  
**3.0-3.5/27 mm**  
**release**



**Kissing balloon**

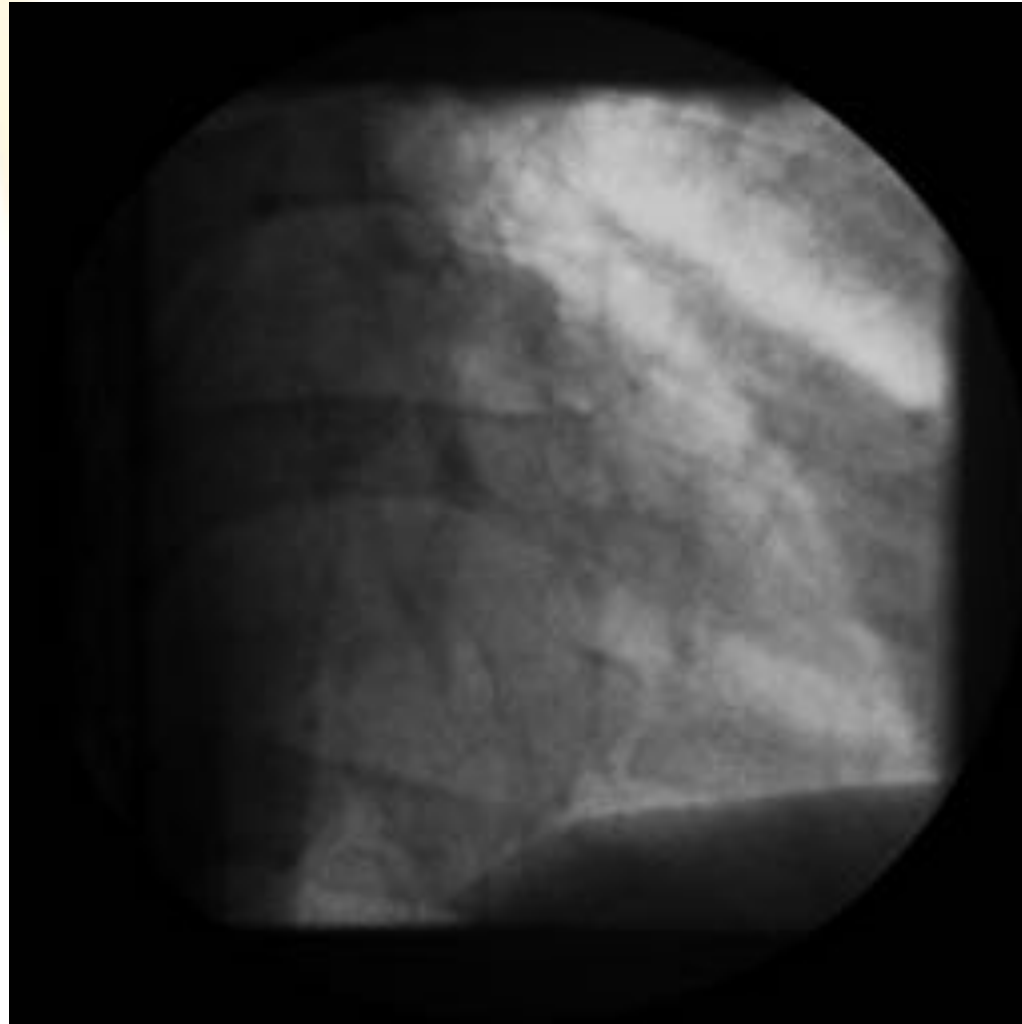


# Final Result

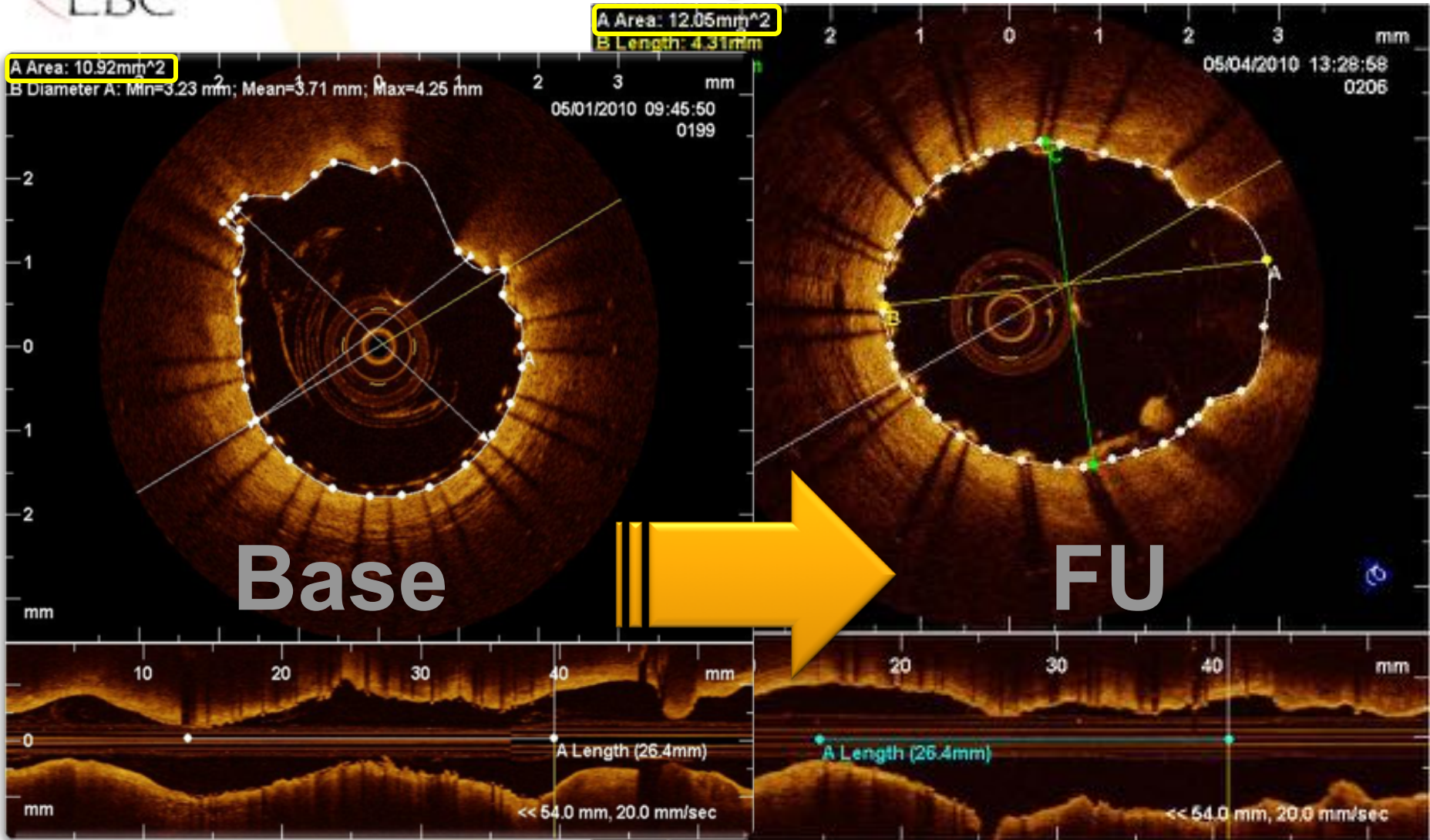


Courtesy of Dr La Manna, Ferrarotto University Hospital, Catania - Italy

# 3-Day FU

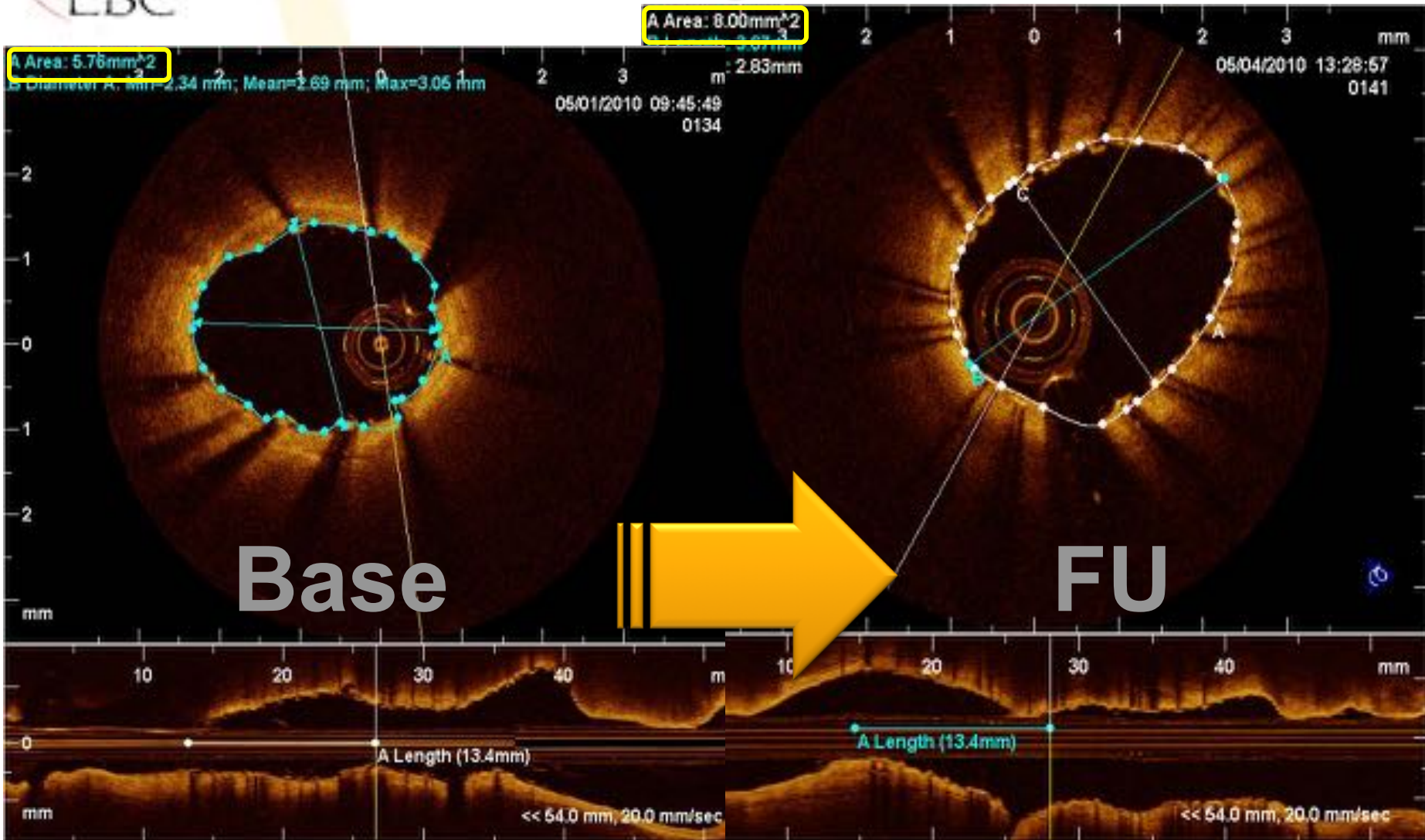


# 3-Day FU





# 3-Day FU

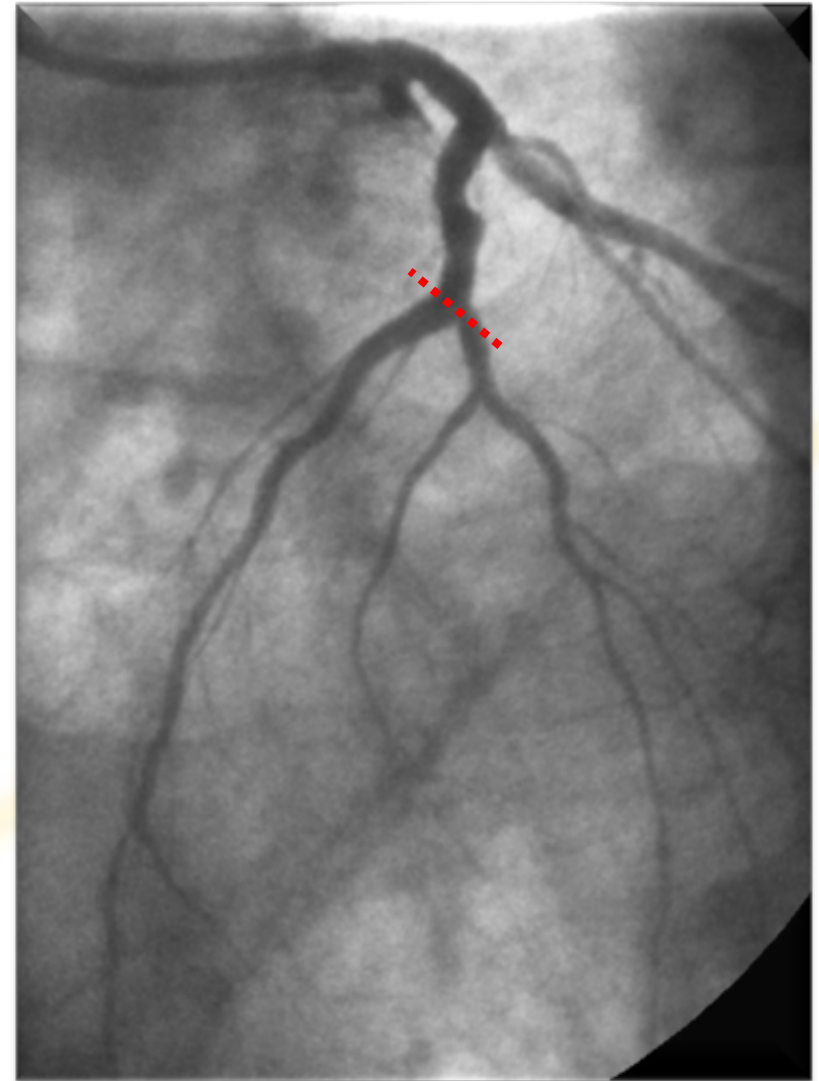
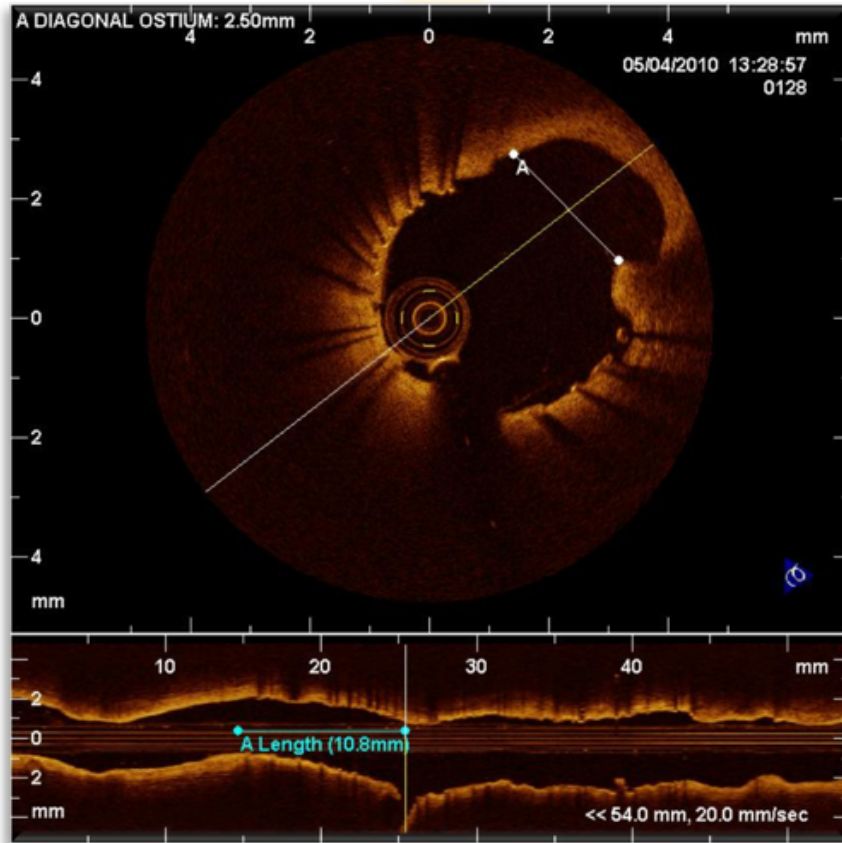


Courtesy of Dr La Manna, Ferrarotto University Hospital, Catania - Italy



# 3-Day FU

## Bifurcation stenting result



Courtesy of Dr La Manna, Ferrarotto University Hospital, Catania - Italy



# Conclusions

The Stentys platform:

- Is safe and feasible
- Provides side branch access and allows provisional treatment of branch vessels
- Can be successfully used in STEMI patients even more when significant side branches are involved



# EXTRA SLIDES



# OPEN I

## 6 month QCA Results: Main Branch

	DES	BMS
	n=25	n=31
In segment Restenosis*	1 (4%)	9 (29%)
Proximal MB	1 (4%)	4 (13%)
Distal MB	0 (0%)	7 (23%)
In stent Late Loss (mm)	n=25	n=30
Proximal MB	0.39 ± 0.62	0.83 ± 0.65
Distal MB	0.40 ± 0.50	0.85 ± 0.63

\* *Not mutually exclusive*



# OPEN I

## 6 month QCA Results: Side Branch

	<b>DES</b>	<b>BMS</b>
<b>Restenosis</b>	<b>4/25 (16%)</b>	<b>5/31 (16%)</b>
With SB Stent	0/4 (0%)	1/13 (8%)
Without SB stent	4 /21 (19%)	4/18 (22%)

*Excellent result when "cross-over" to 2 stents*



# Cumulative 6 month MACE<sup>1</sup>

	<b>DES (n=27)</b>	<b>BMS (n=33)</b>
Cardiac Death	0	0
AMI		
Q-wave MI	0	0
Non Q-wave MI <sup>2</sup>	0	1
Clinically driven TLR	1	8
<b>Total</b>	<b>1 (3.7%)</b>	<b>9 (27.3%)</b>

<sup>1</sup> CEC adjudicated

<sup>2</sup> CK>2ULN & CK-MB>ULN