

# BioMatrix™ : Next generation biodegradable polymer stent

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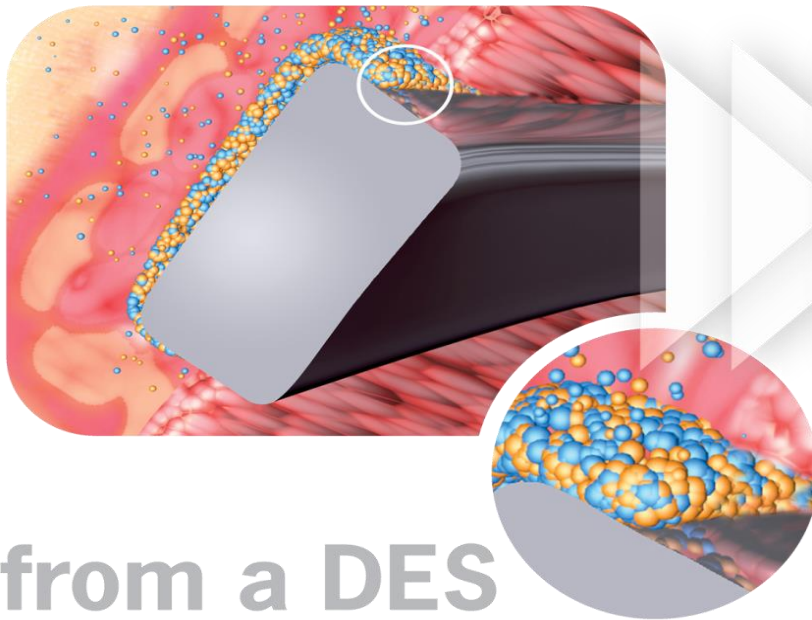
***Seoul National University Hospital, Seoul, Korea***



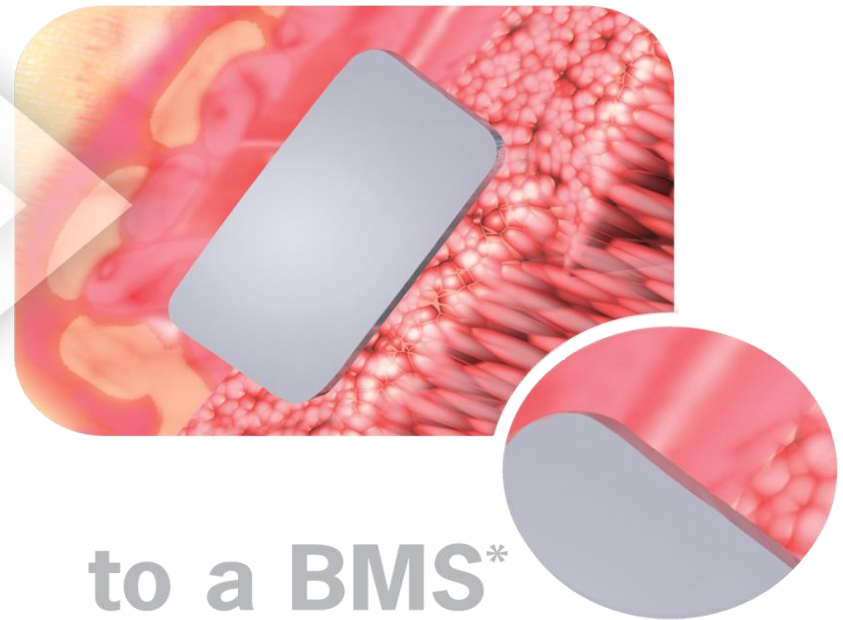


# The Abluminal Biodegradable Polymer DES

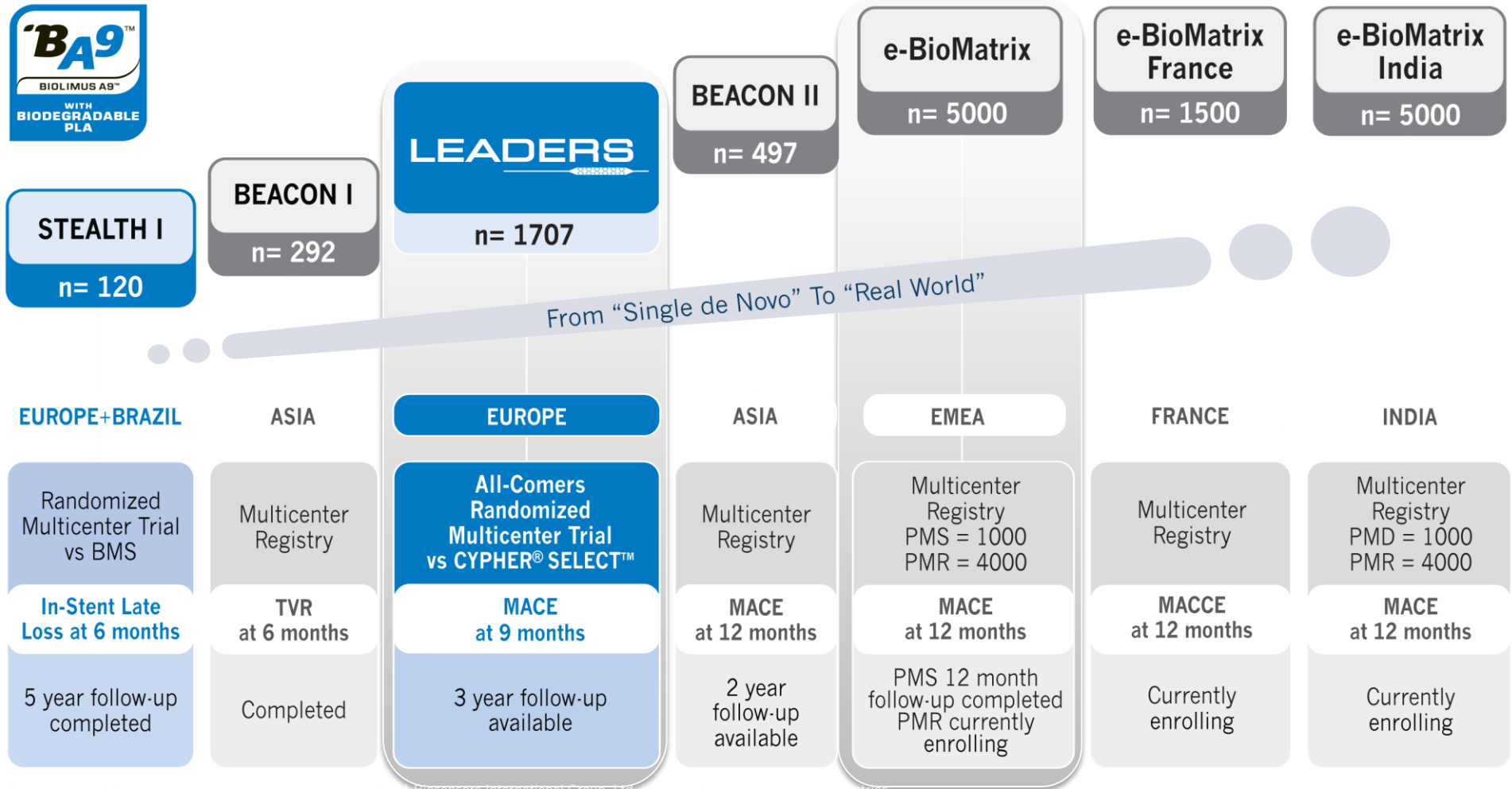
PLA biodegradation  
and BA9™ elution



Abluminal biodegradable coating  
absorbed after 6-9 months\*

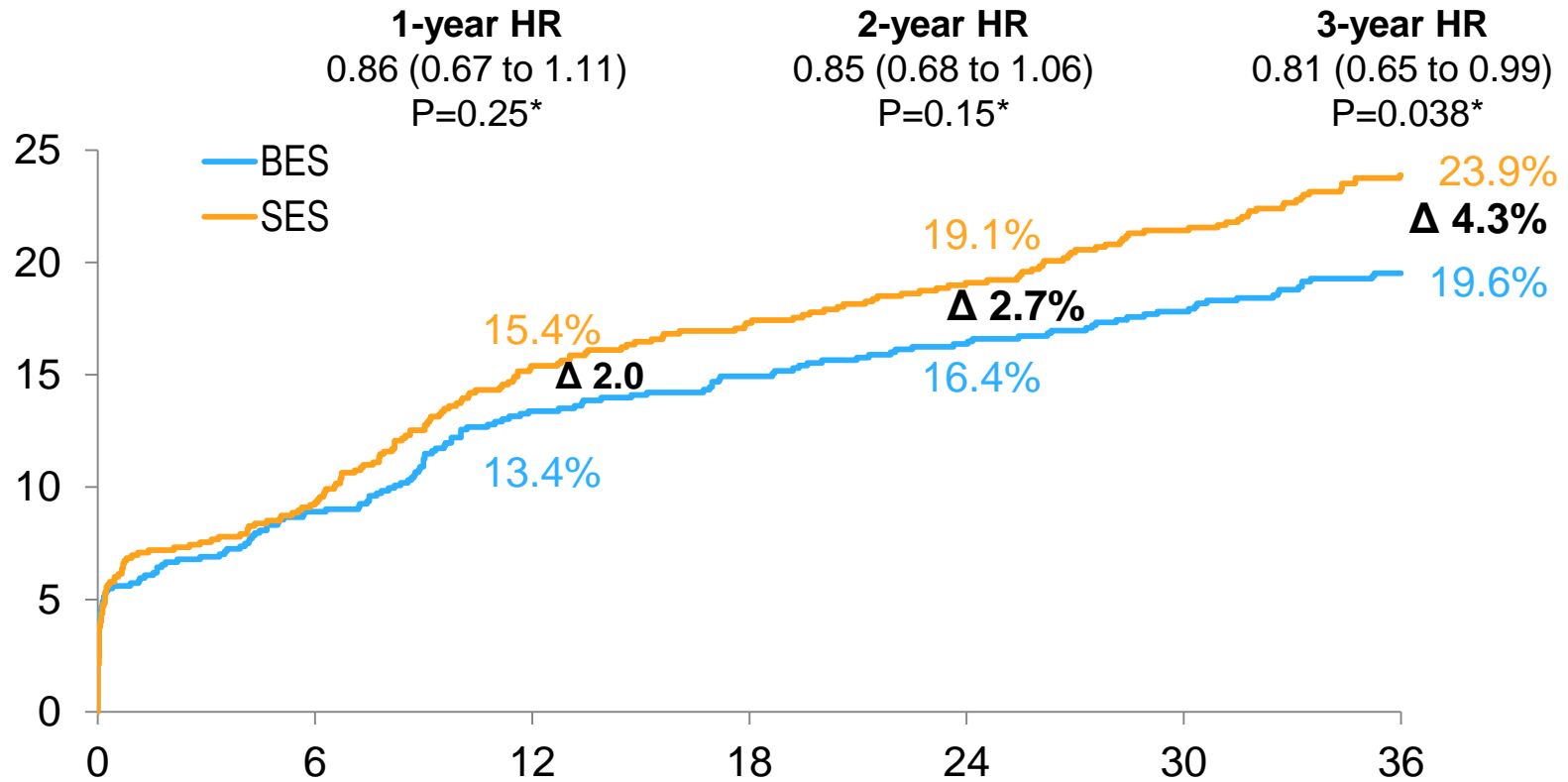


# Biolimus A9™ / Abluminal Biodegradable Polymer DES Clinical Trial Program



# LEADERS-Patient-oriented Outcomes

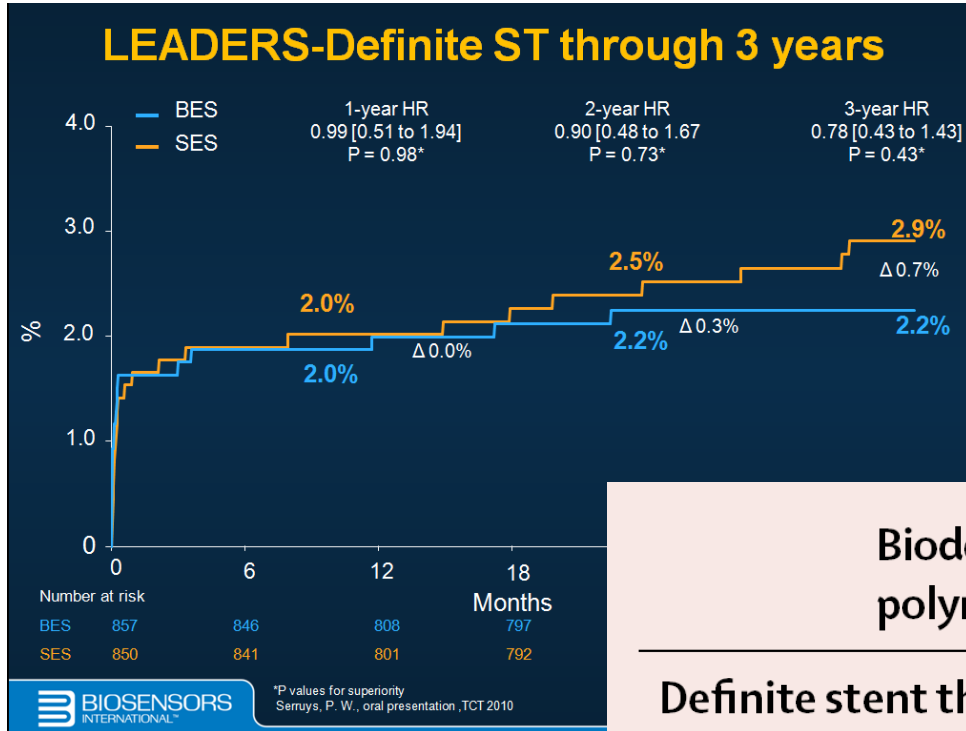
## Death/ MI/ Any Revascularisation



Numbers  
at risk

BES	857	774	731	713	701	676	615
SES	850	766	711	691	675	640	578

# LEADERS-Definite ST through 3 and 4 years



	Biodegradable polymer BES	Durable polymer SES	Risk ratio (95% CI)	p value
<b>Definite stent thrombosis</b>				
Early	14/857 (2%)	14/850 (2%)	0.99 (0.47–2.08)	0.98
Late	3/857 (<1%)	4/850 (1%)	0.74 (0.17–3.33)	0.70
Very late	3/857 (<1%)	15/850 (2%)	0.20 (0.06–0.67)	0.004
Overall	20/857 (2%)	32/850 (4%)*	0.62 (0.35–1.08)	0.09

# HOST-Biolimus Registry

**H**armonizing **O**ptimal **S**trategy for **T**reatment  
of CAD using **Biolimus**-eluting stents Registry

# Trial Design

1. Prospective, open label, multi-center, real world, observational registry
2. Single arm registry : **Biomatrix®** / **Nobori®**



# Objectives

1. To evaluate the **safety and long-term effectiveness** of coronary stenting with the **biolimus-eluting stent** in a cohort of “real world” Korean patients and lesion subsets.
2. To determine clinical device and procedural success during commercial use of **biolimus-eluting stent**.

# Total number of patients

**: 3000 patients**

All comers undergoing PCI with coronary stents for significant coronary artery disease

# Endpoints

1) **Primary endpoint:** Major Adverse Cardiac Events (cardiac death, non-fatal MI and target lesion revascularization) at 12 months

2) **Secondary endpoint:**

In-stent & In-segment Late Loss at 9 months

ST at 24 hrs (acute), 30 days (subacute), 1 yr (late), yearly up to 3 years (very late)

Target Vessel Failure at 12 months (composite of cardiac death, MI, and TVR)

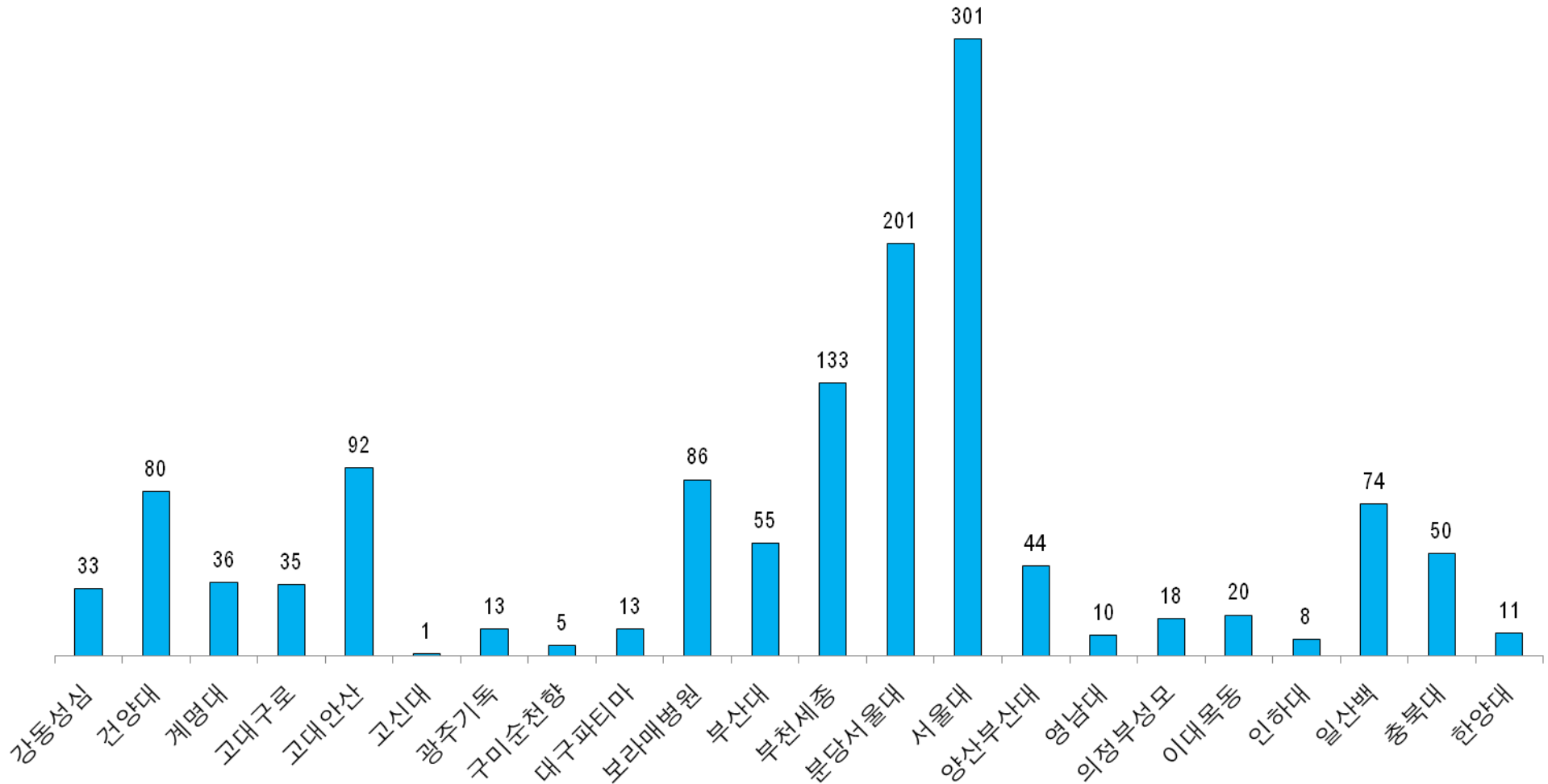
MACE at 30 days, 9 months, 1 year, 2 years and 3 years

Clinical device and procedural success

# Enrollment Status

- Up to Nov, 2011: 1319 patients
- Biomatrix®/Nobori® = 803 (61%) / 516 (39%)

# HOST-Biolimus Registry: Total N=1319



# Baseline Characteristics

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<b>Age, y</b>	64 ± 11
<b>Male</b>	69%
<b>Initial diagnosis</b>	
Stable angina	36%
Unstable angina	29%
NSTEMI	14%
STEMI	15%
Silent ischemia	7%
<b>Previous CABG</b>	1%
<b>Hypertension</b>	54%
<b>Diabetes Mellitus</b>	28%

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# Baseline Characteristics

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<b>Multi-vessel disease</b>	59%
<b>Complex lesion (type B2, C)</b>	72%
<b>In-stent restenosis</b>	3.8%
<b>LAD lesion</b>	53%
<b>Left Main lesion</b>	3.5%
<b>Bifurcation lesion</b>	24.8%
Bifurcation PCI	- 29.4%
2 stenting	- 7.7%

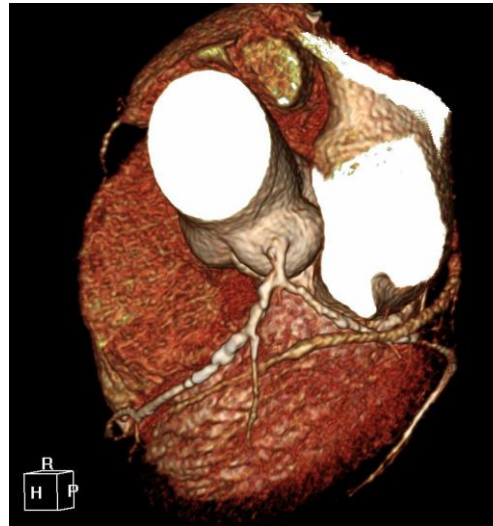
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# M/50 Silent ischemia

DM, Hypercholesterolemia

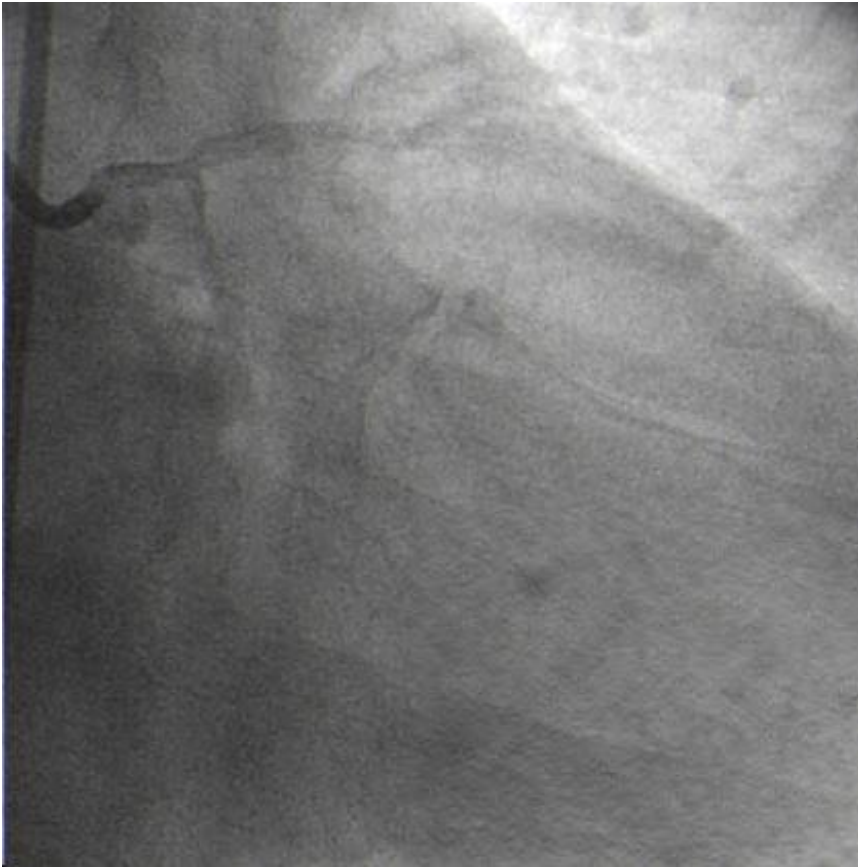
## Routine screening for ischemic heart disease

- EKG: normal
- Echocardiography: normal
- CT coronary angiography: LAD os: 50-70% stenosis
- Exercise EKG: + at 6min

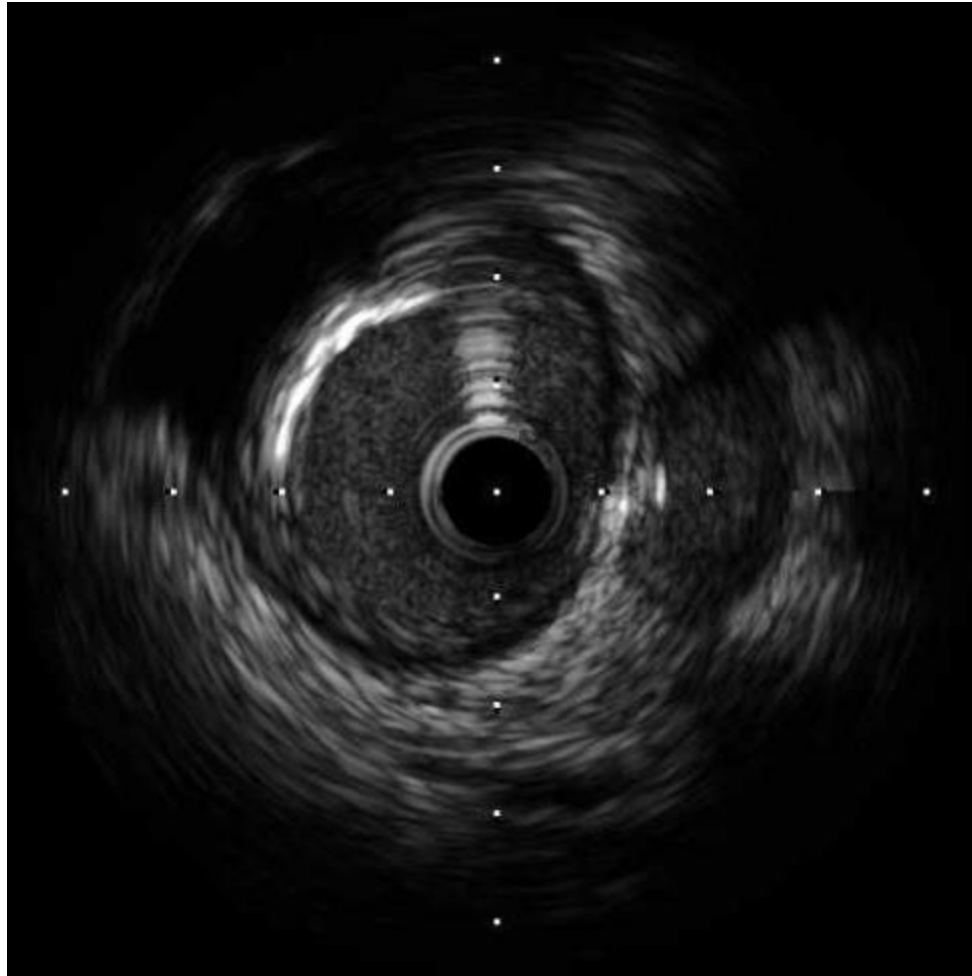
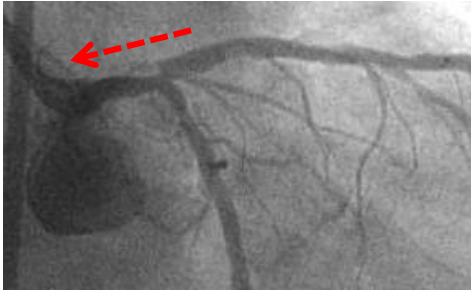




# M/50 Silent ischemia with Unstable plaques

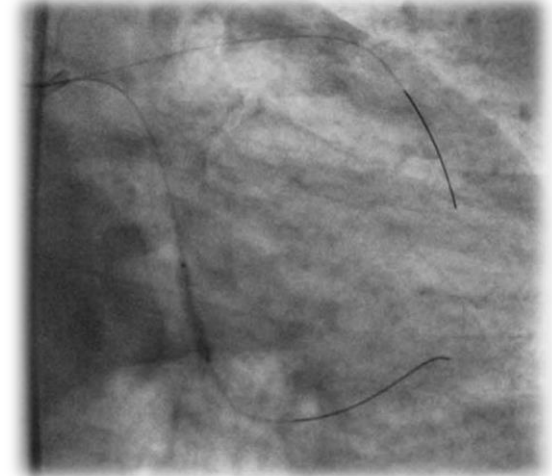
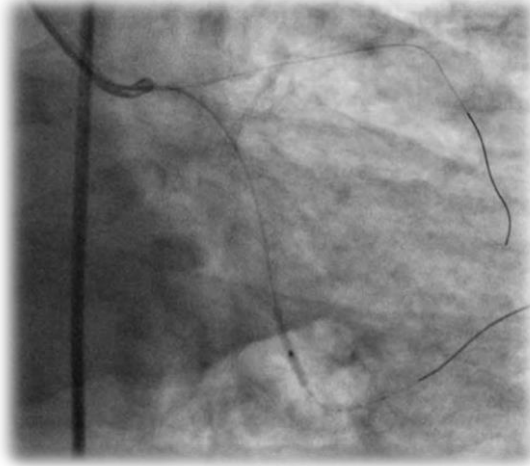


# M/50 Silent ischemia with Unstable plaque

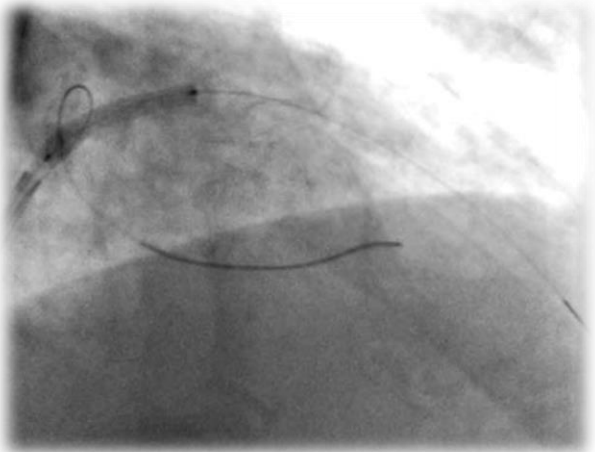


# M/50 Silent ischemia with Unstable plaques

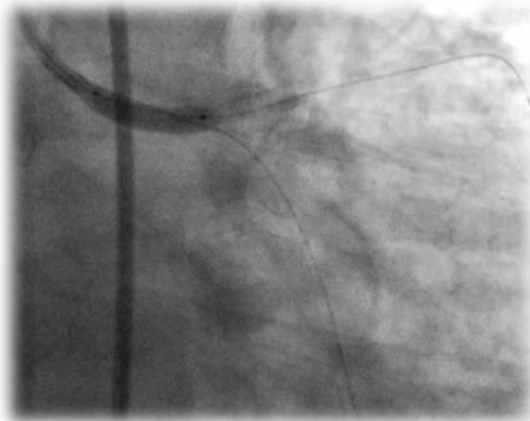
Distal LCX stenting → Intentional modified-T stenting



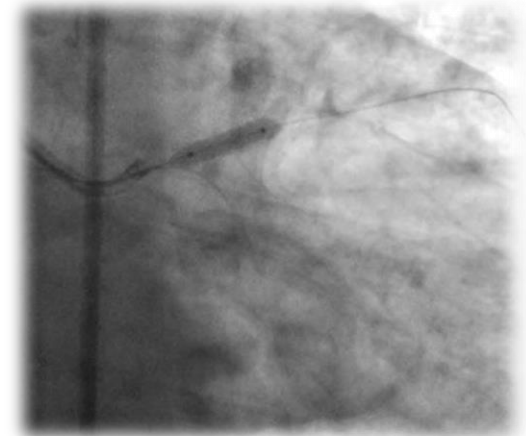
**BioMatrix 2.75x14mm**



**BioMatrix 3.5x18mm**

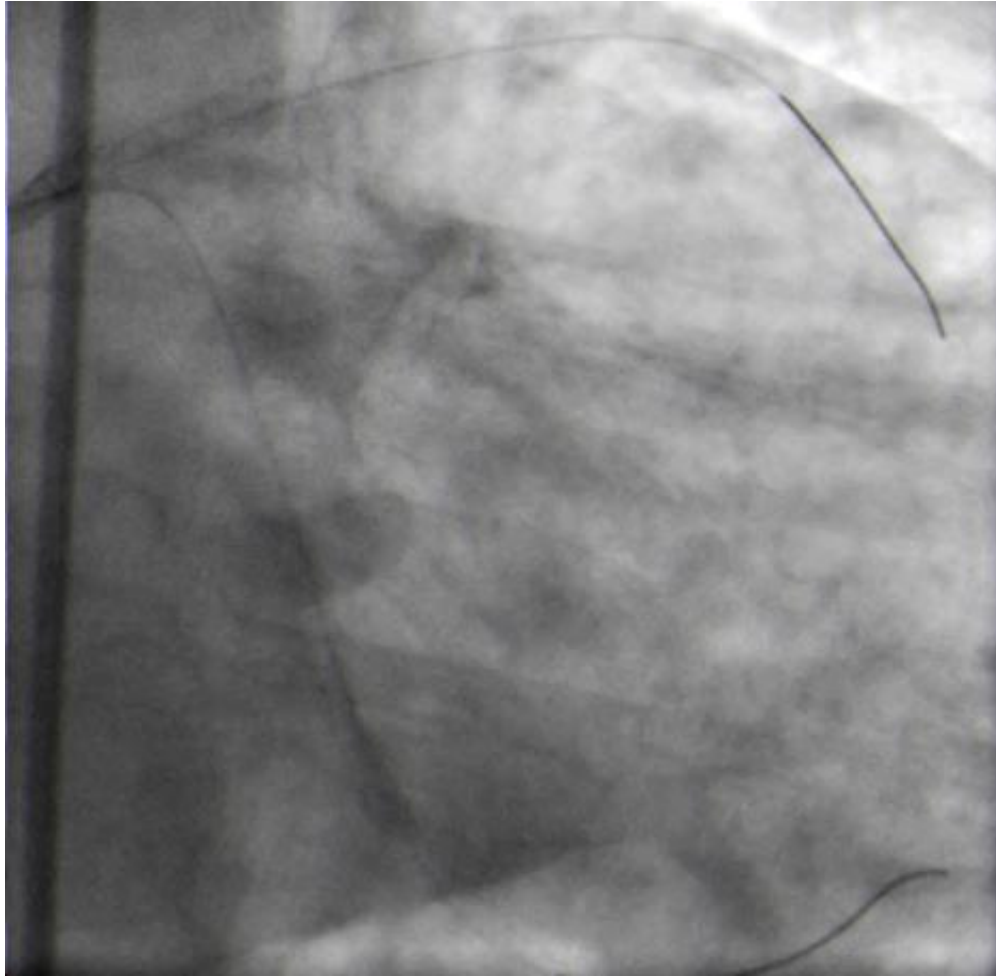


**LM balloon at 16atm**

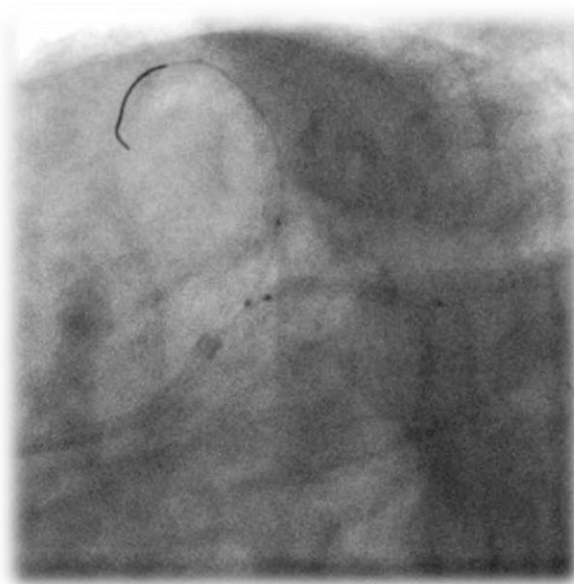
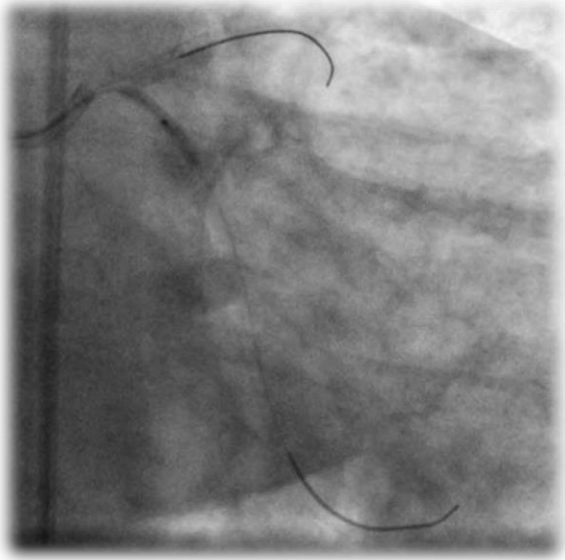


**LAD balloon at 14atm**

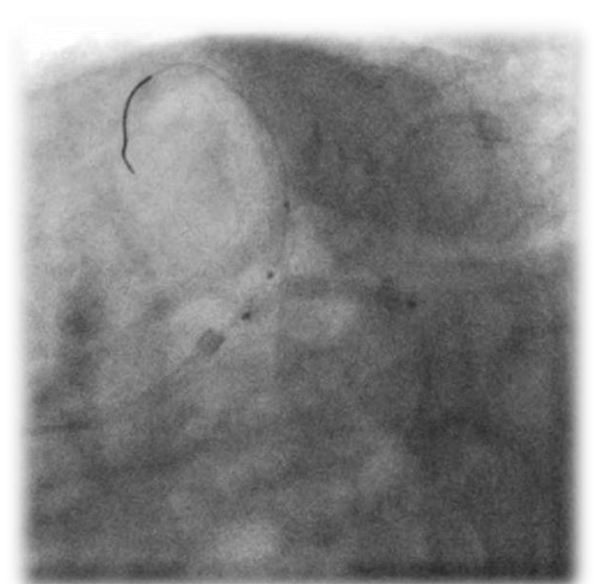
# M/50 Silent ischemia with Unstable plaques



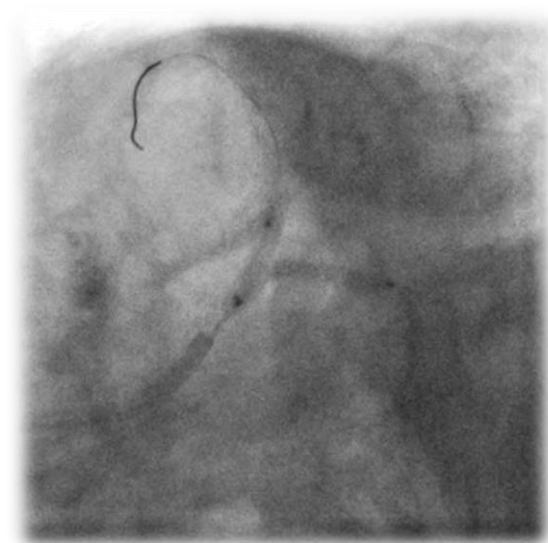
# M/50 Silent ischemia with Unstable plaques



**BioMatrix 2.75x18mm**



**2.75x18, 14atm**

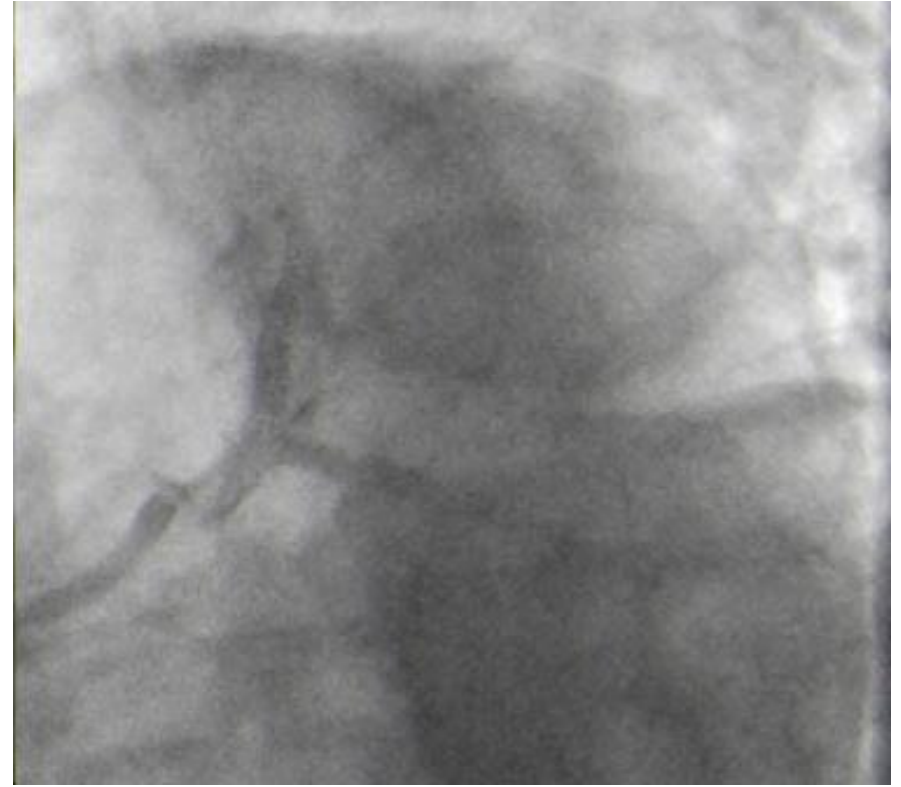
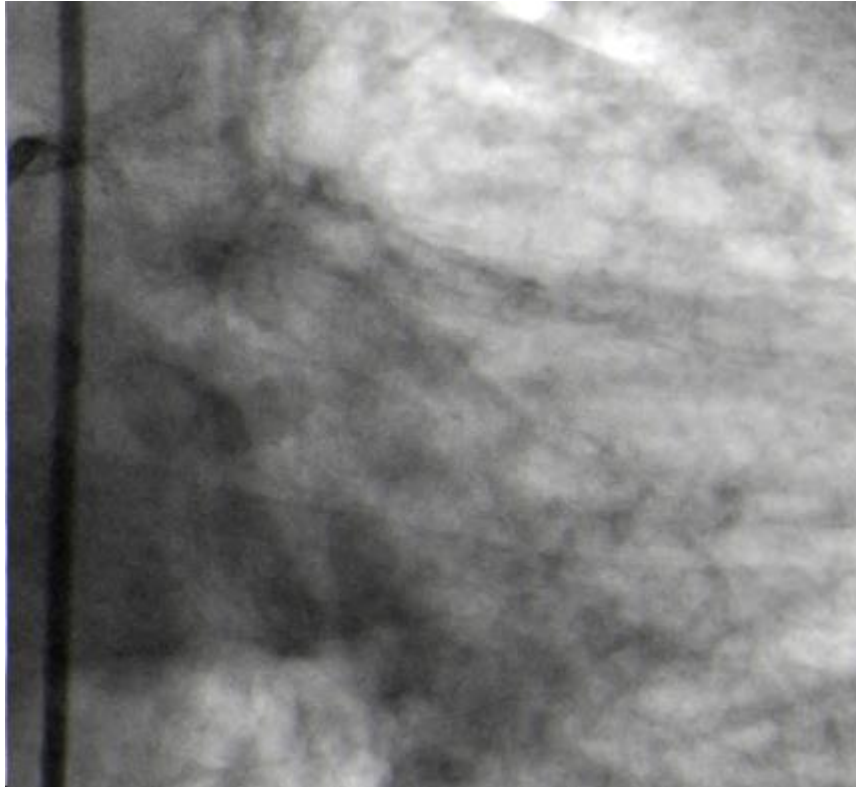


**KBI 3x12, 2.75x18mm**



**3.5x12, 18atm**

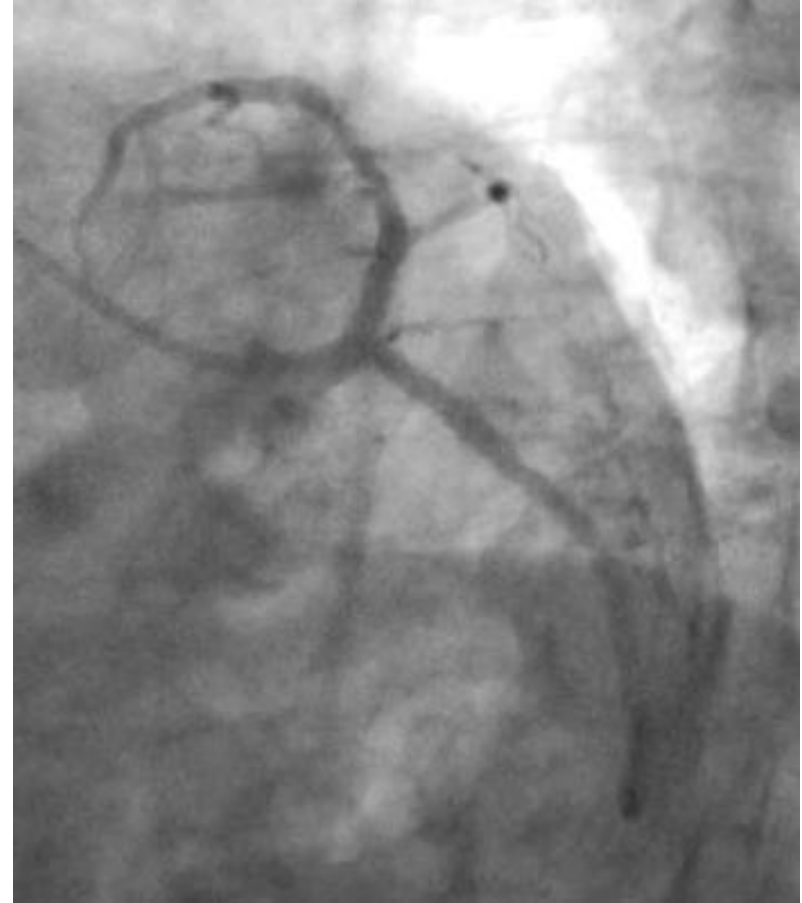
# M/50 Silent ischemia with Unstable plaques



BioMatrix 3.5x18mm  
BioMatrix 2.75x18mm  
BioMatrix 2.75x14mm

# M/50 Silent ischemia with Multiple unstable plaques

## Nine-months follow-up



**BioMatrix 3.5x18mm**

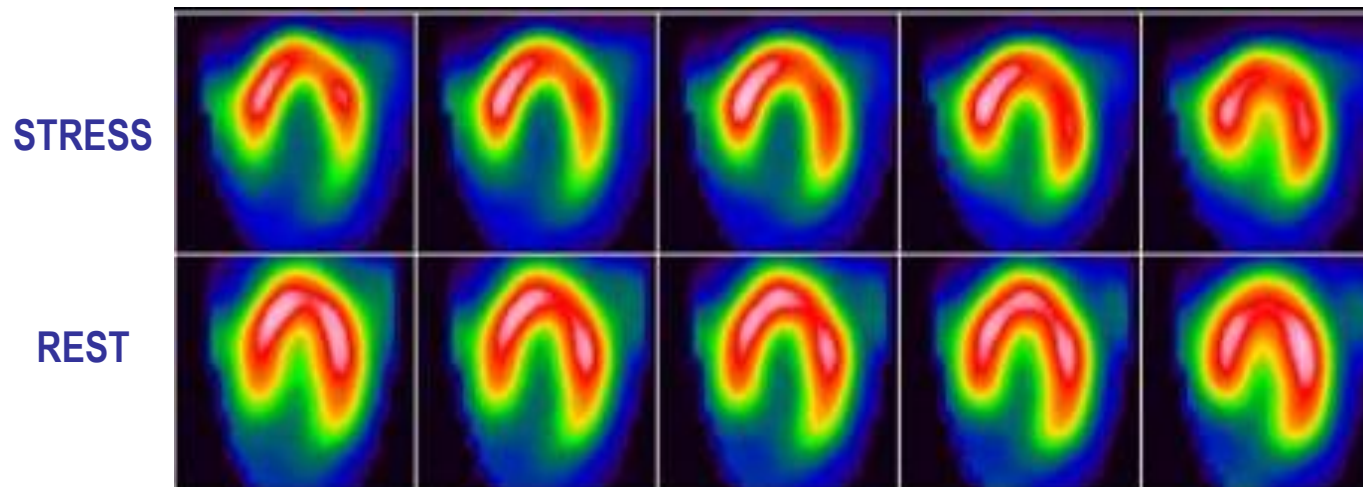
**BioMatrix 2.75x18mm**

**BioMatrix 2.75x14mm**

# M/55 Silent ischemia

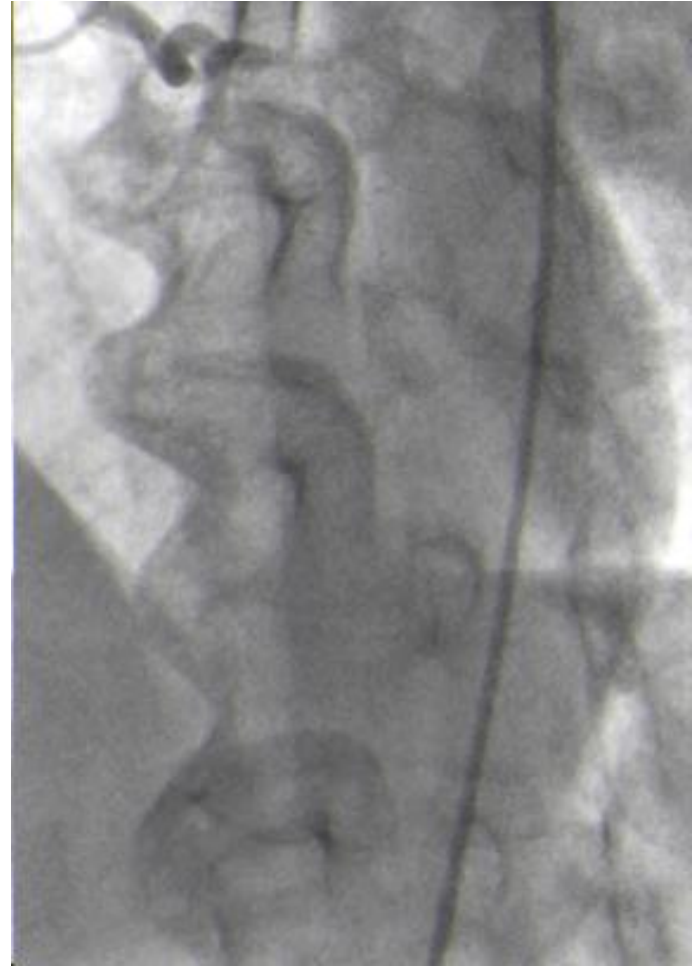
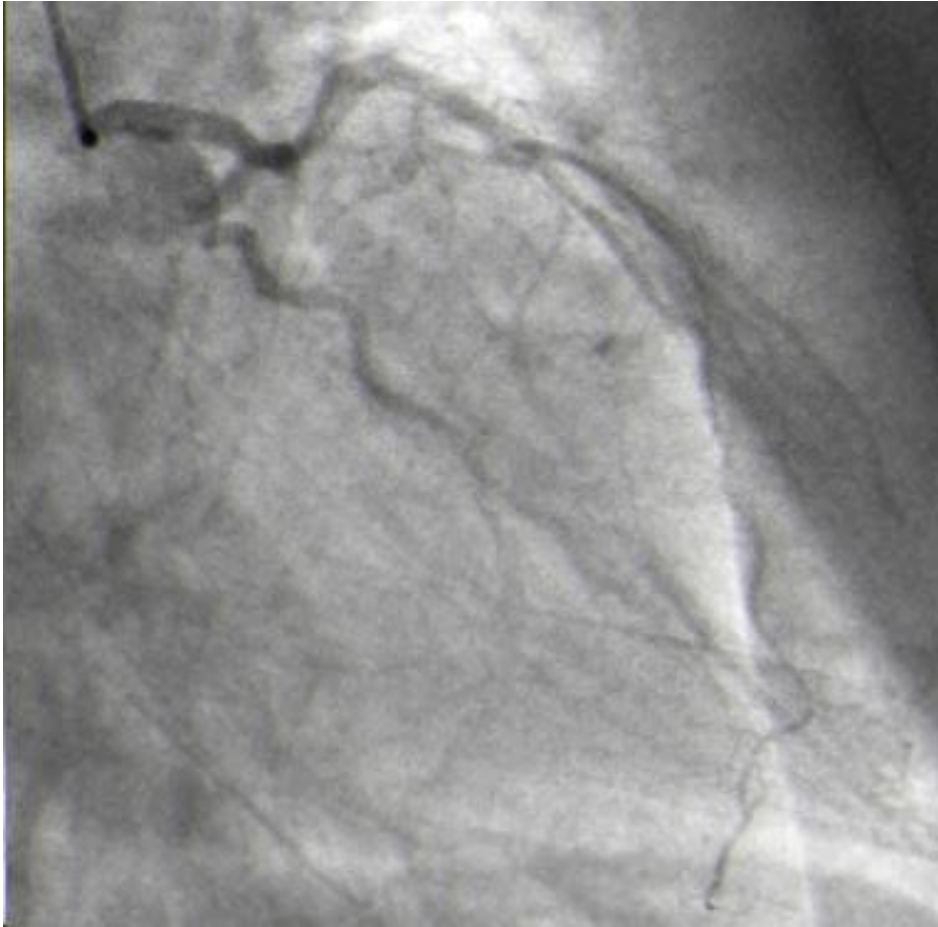
DM, Hypertension, Chronic renal failure

- EKG: LVH
- Echocardiography: Concentric LVH with normal LV function
- Myocardial SPECT: reversible perfusion defect in lateral wall

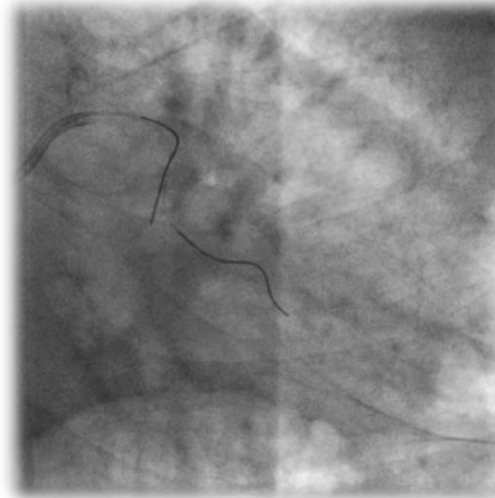




# M/55 Silent ischemia with calcified total occlusion



# M/55 Silent ischemia with calcified total occlusion



**Runthrough: failed**



**Fielder XT: failed**

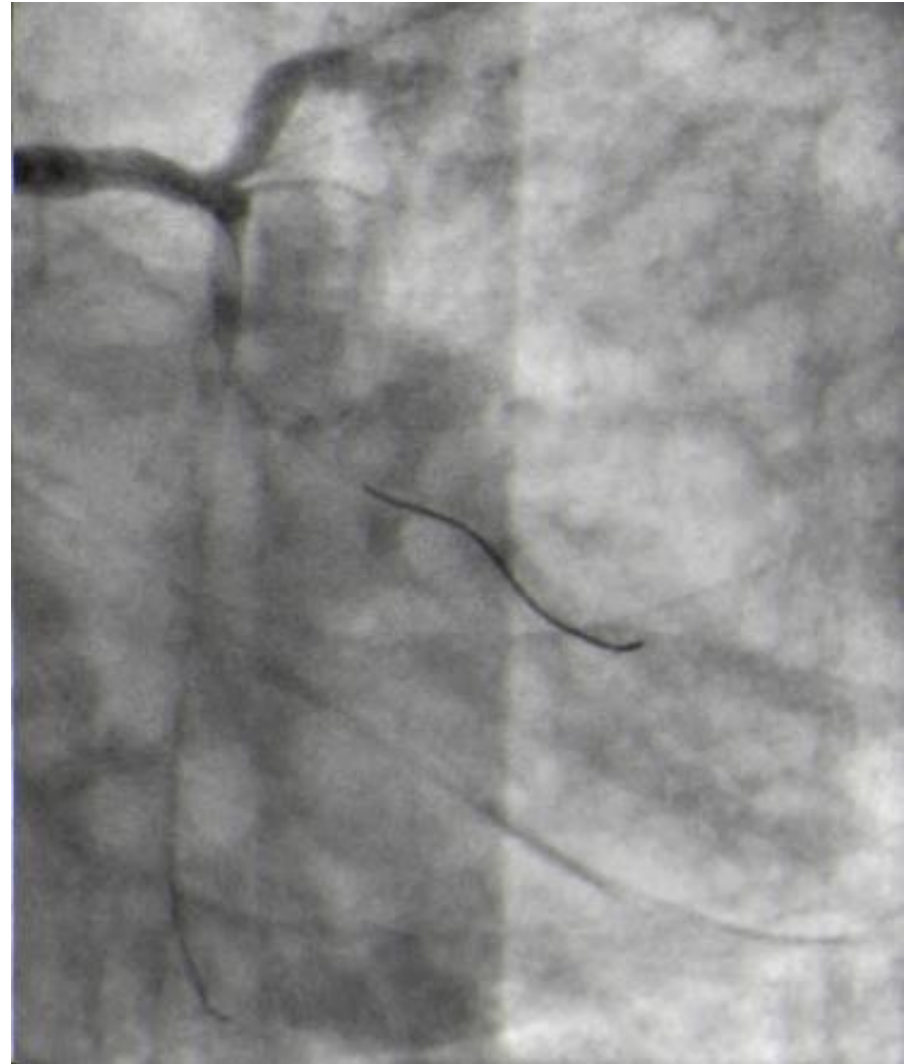
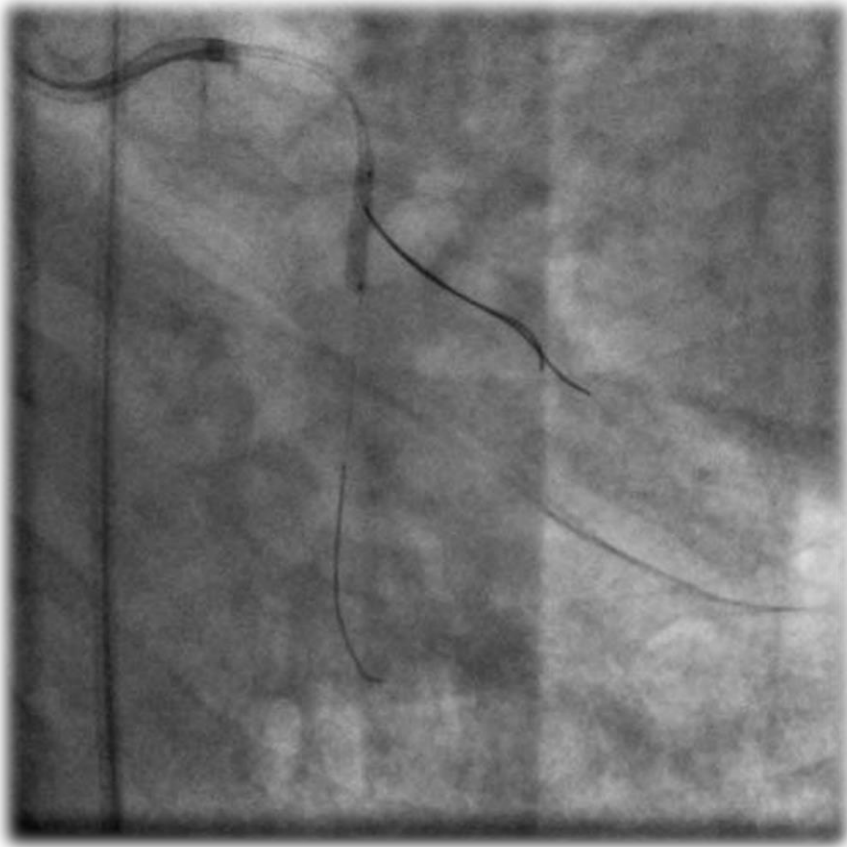


**Runthrough interm: failed**

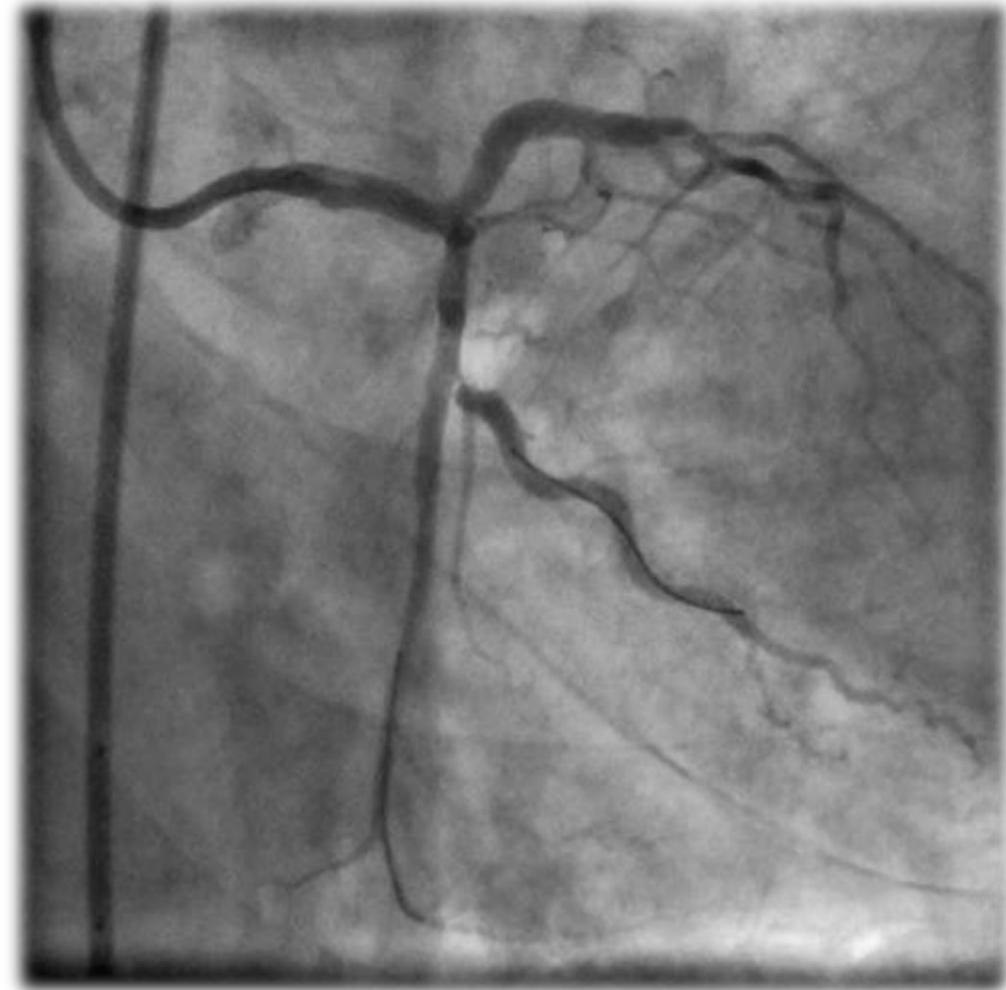


**Crossit 200**

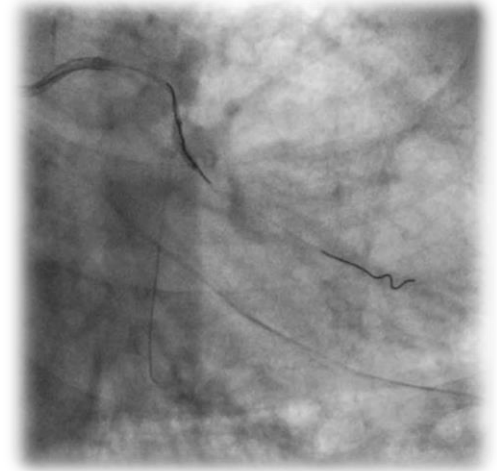
# M/55 Silent ischemia with calcified total occlusion



# M/55 Silent ischemia with calcified total occlusion

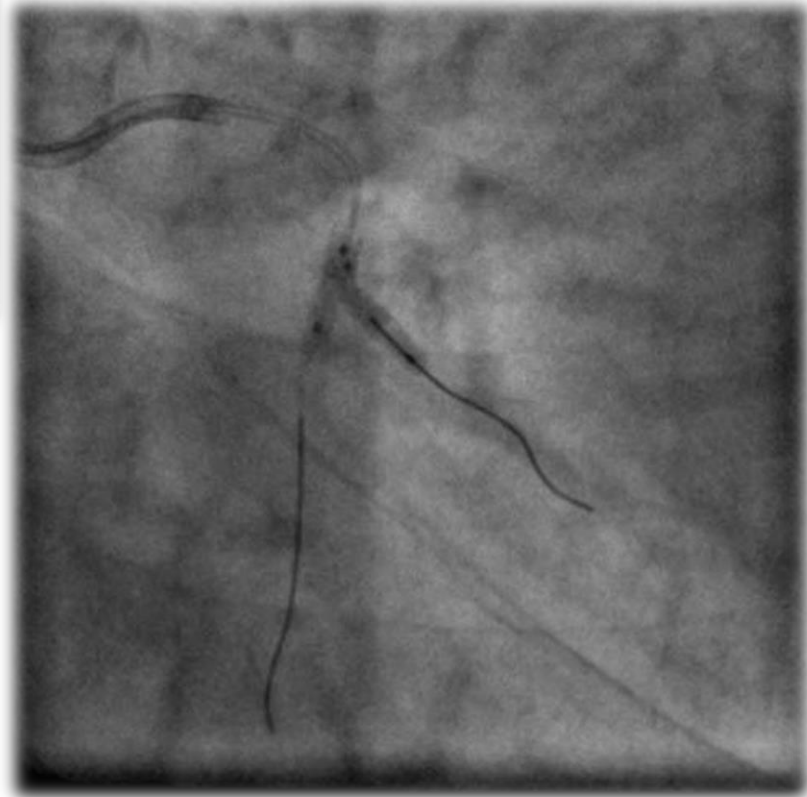
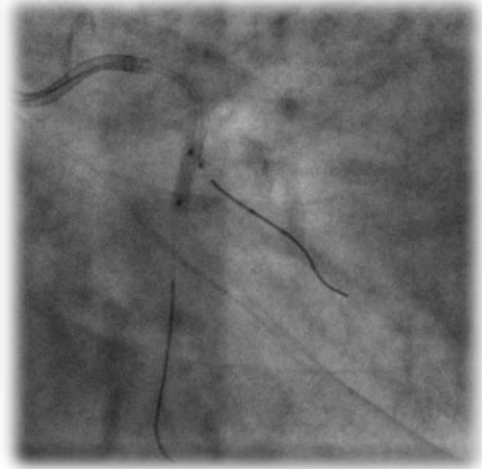
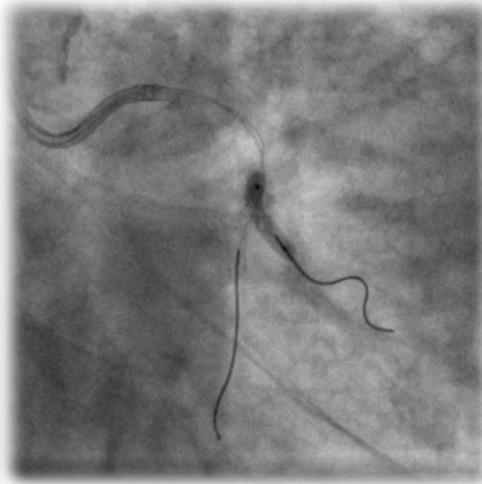
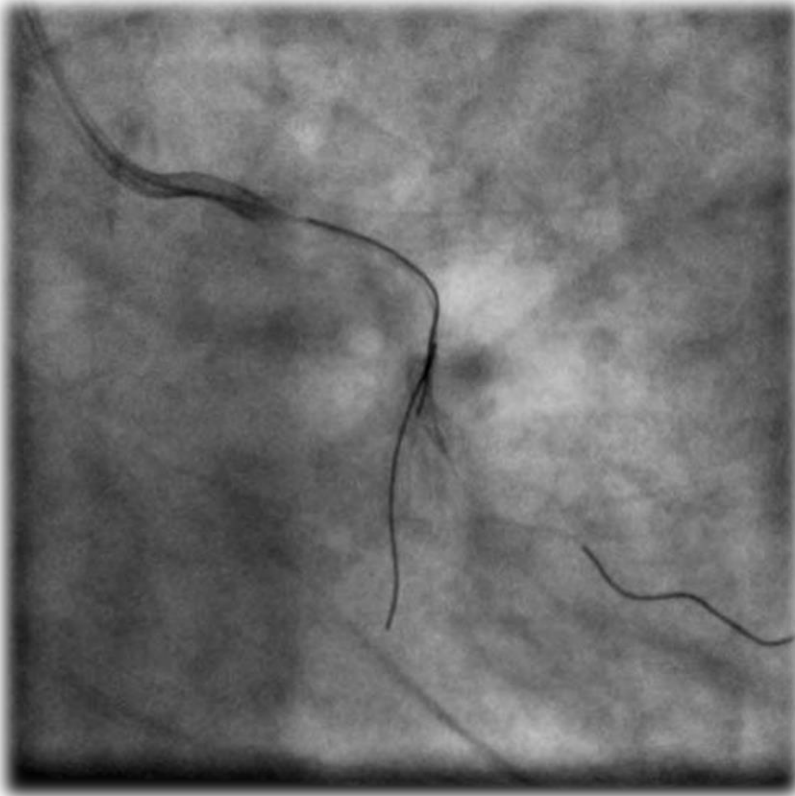


**BioMatrix 2.75x14mm**

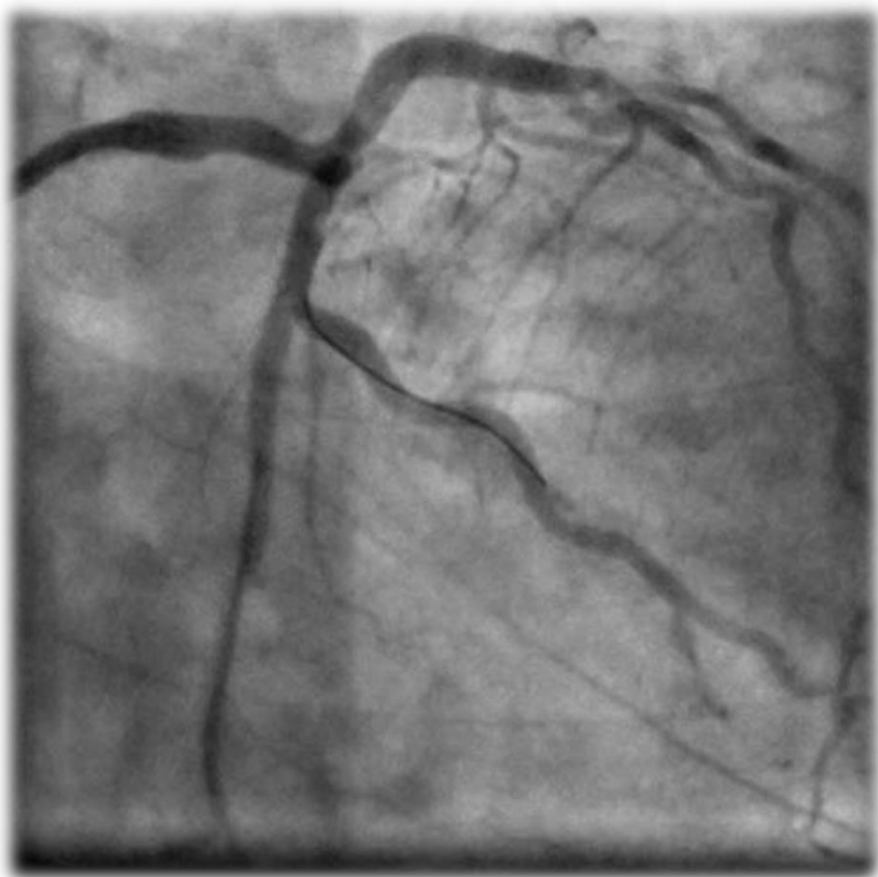


**BioMatrix 2.75x14mm**

# M/55 Silent ischemia with calcified total occlusion



# M/55 Silent ischemia with calcified total occlusion



# M/55 Silent ischemia with calcified total occlusion

## **Progress note**

- 17 mo after PCI
- No event, patient is doing good.

# One-year Clinical outcomes

	n=151
<b>MACE</b>	2(1.3%)
<b>Cardiac death</b>	0
<b>Myocardial infarction</b>	0
<b>TLR</b>	2(1.3%)
<b>Stent thrombosis</b>	0(0%)



# Take home message

- 1. Biomatrix® stent showed great acute and long-term performance in complex lesion subsets.**
- 2. The HOST-Biolimus registry is expected to show the performance of the next generation bioabsorbable polymer technology based BES in a 'real-world' cohort of Asian (Korean) patients.**