

Discovering New Frontier With Polymer Free Stenting in Complex PCI

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I receive a speaker's fee for B. Braun

59 yr old lady
UA and CCS II on treatment
DM, HT, Dyslipidaemia

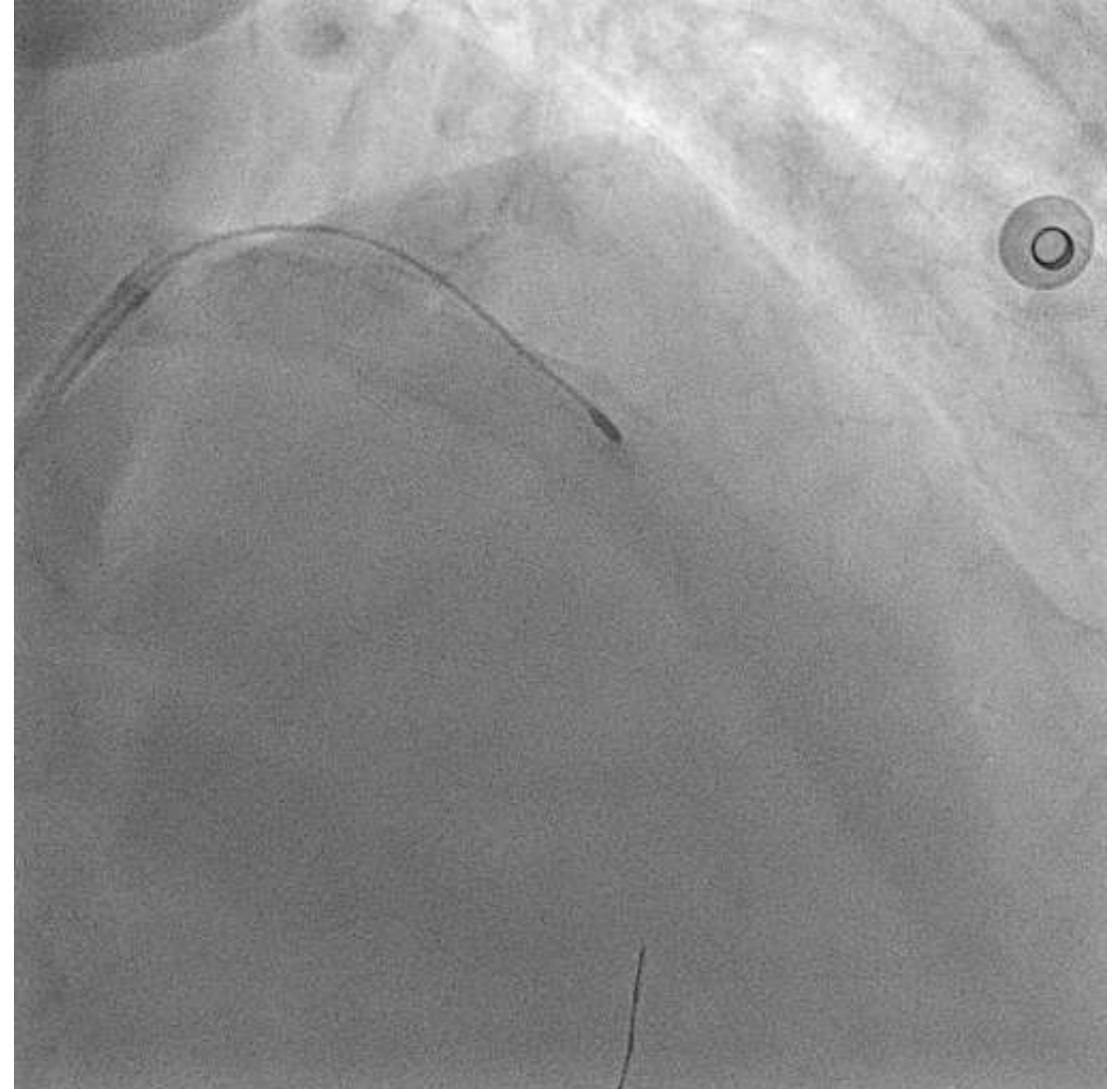
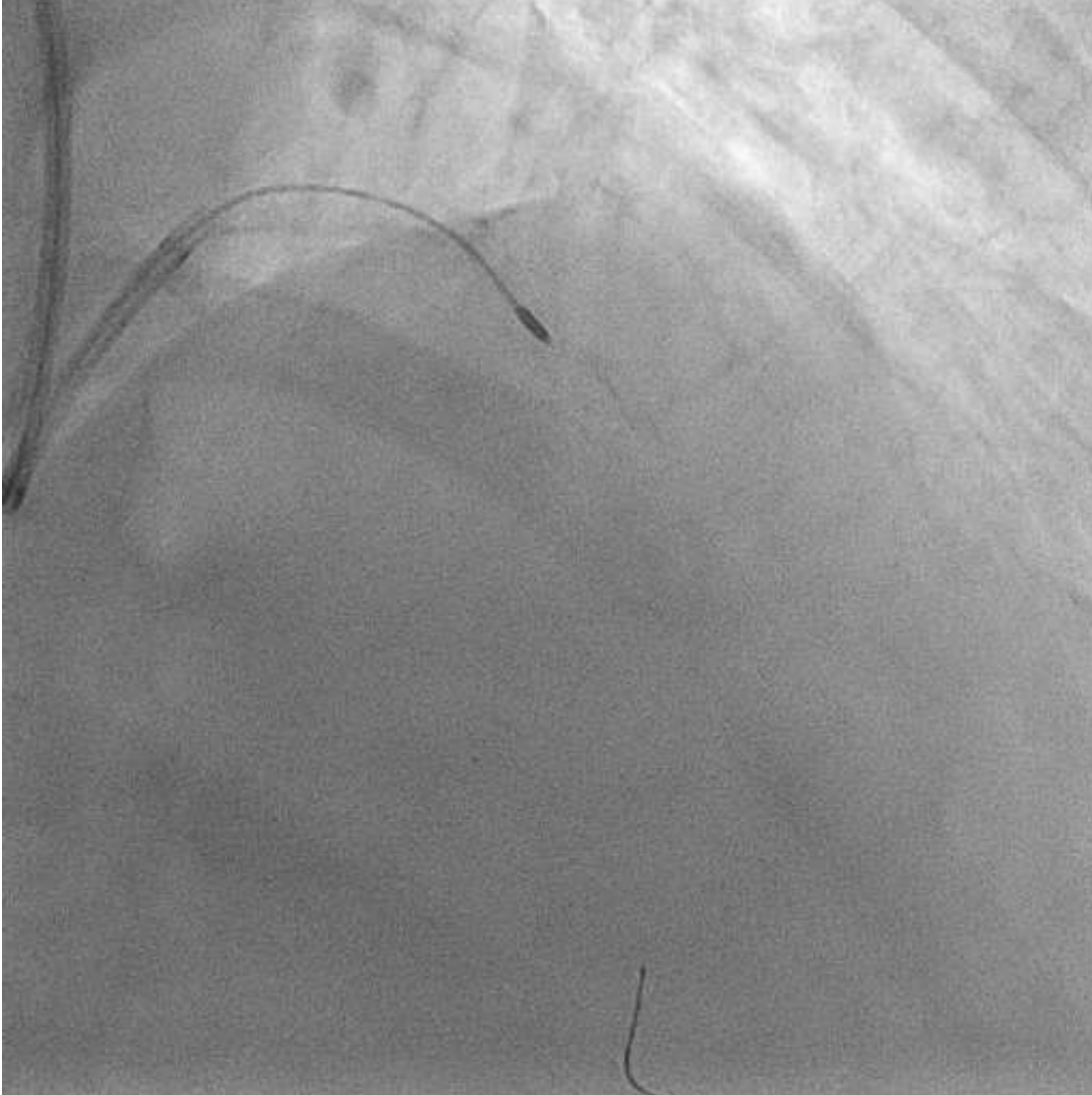


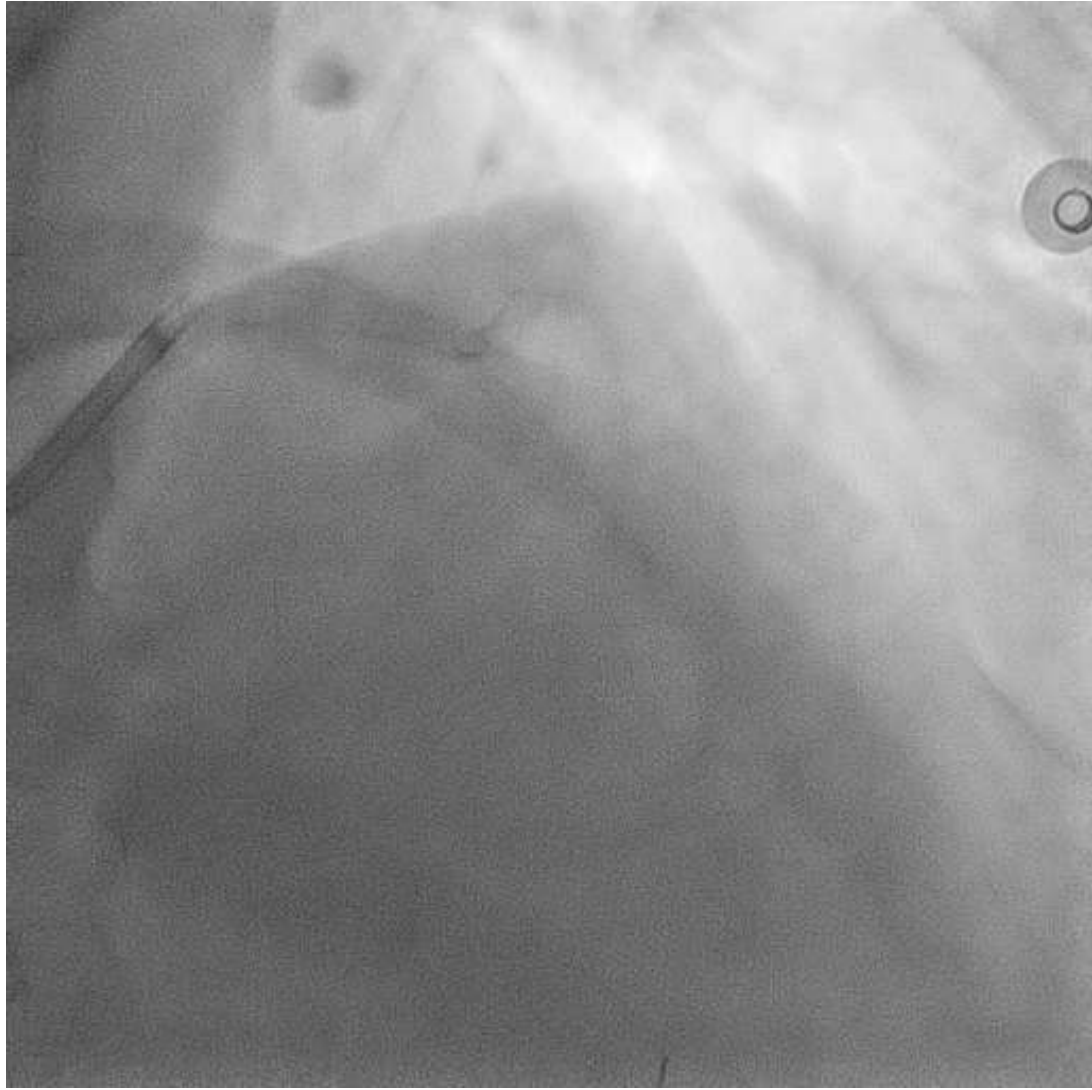
TRI
Calcified, tortuous LAD

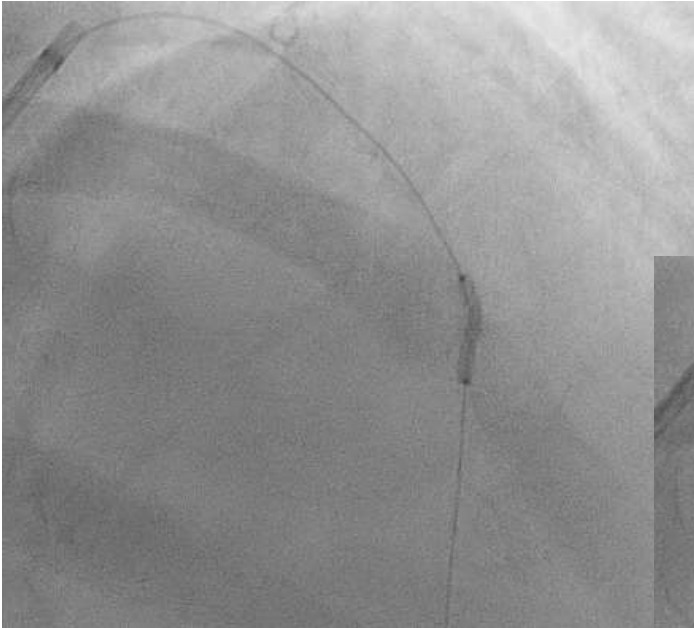


EBU 3.5 6 Fr
1.25 mm Burr
Rotafloppy wire

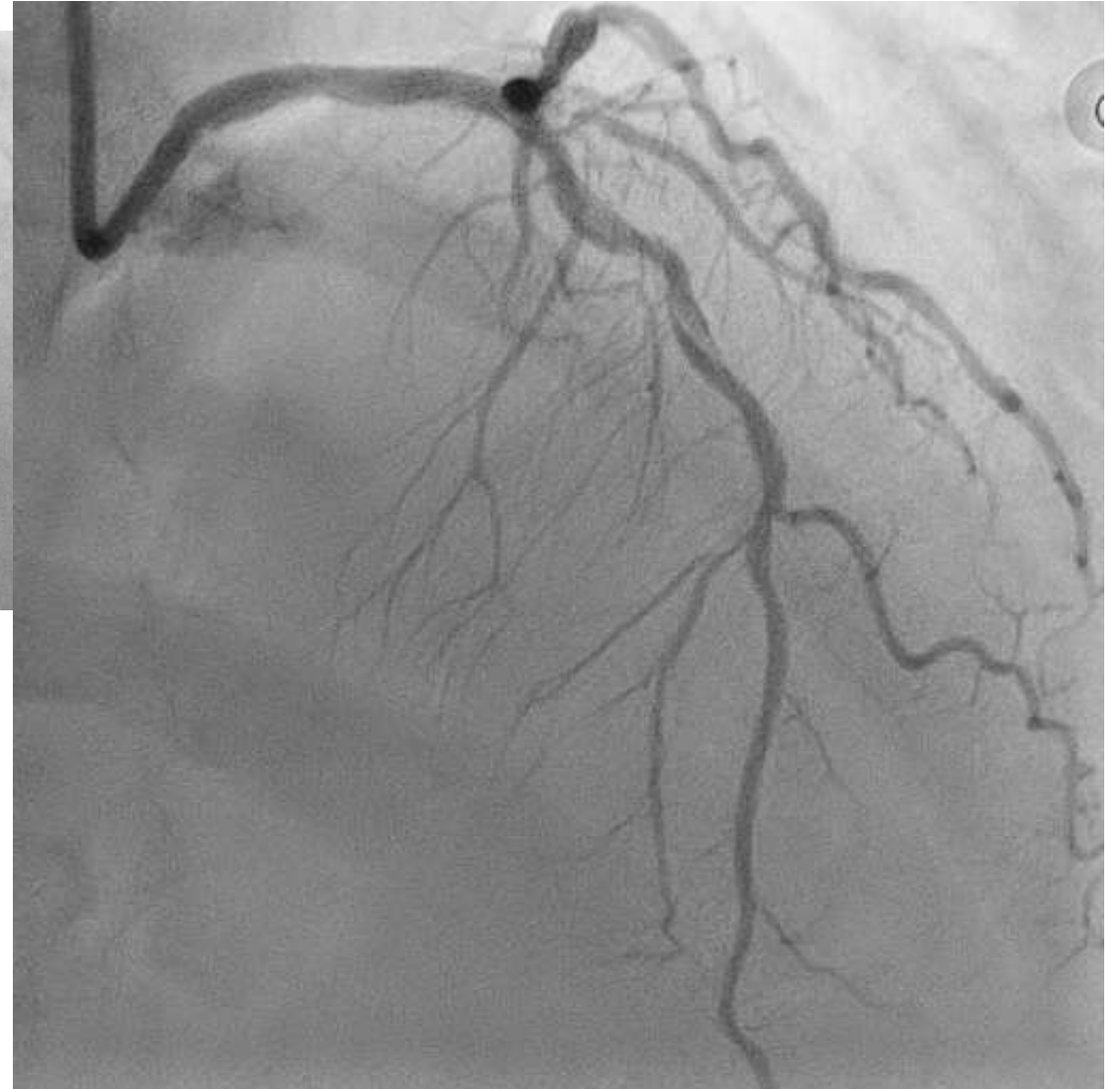
5 runs at 180,000 rpm



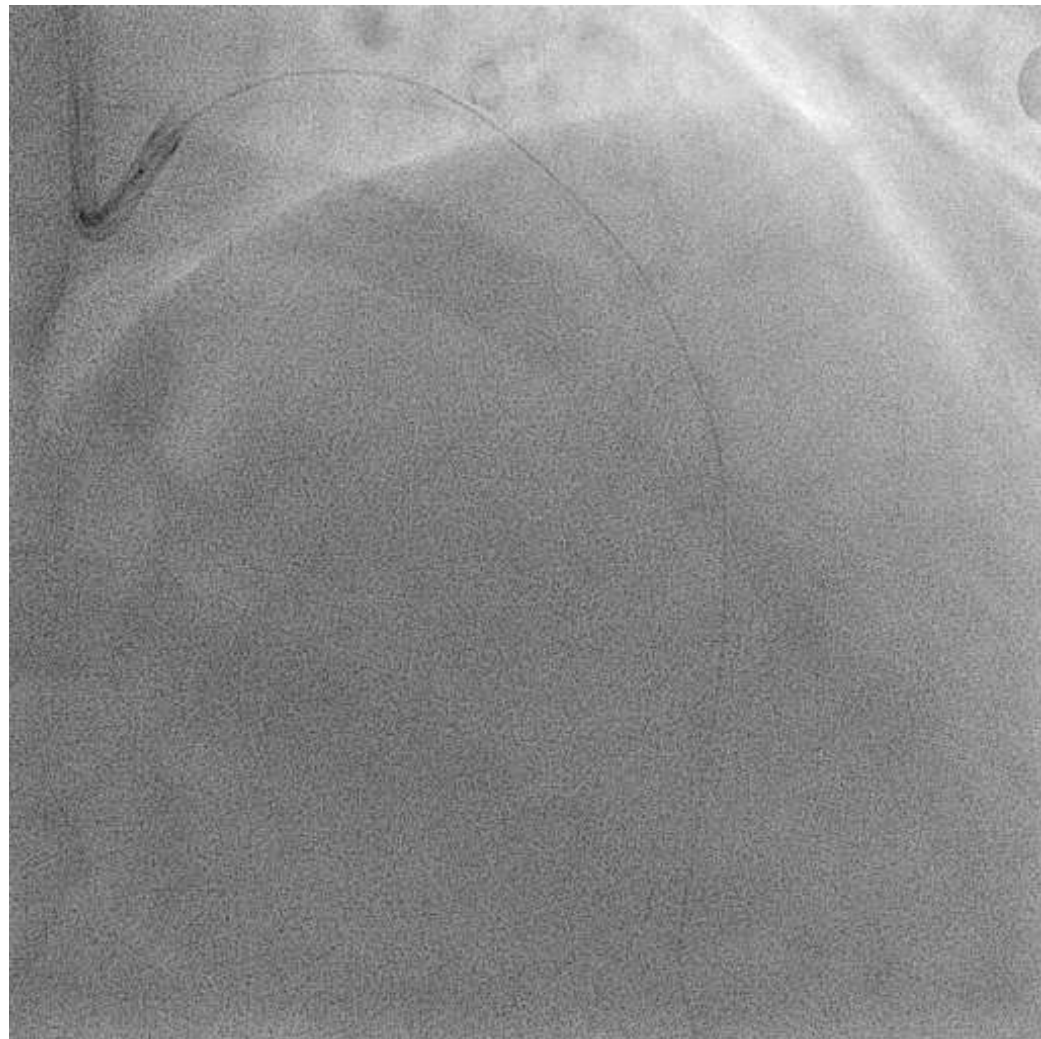




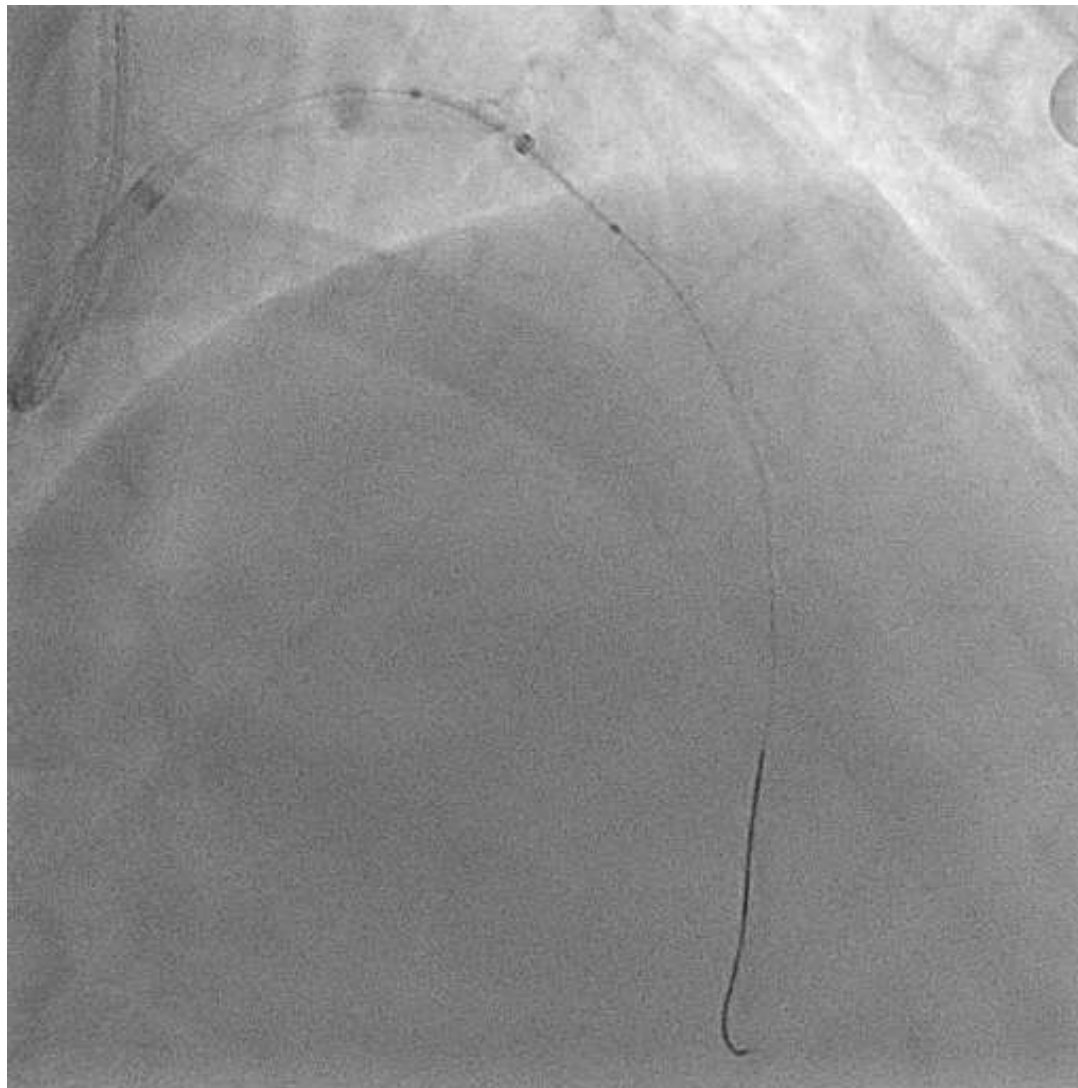
2.5 x 15 mm NC balloon
14 to 18 Atm

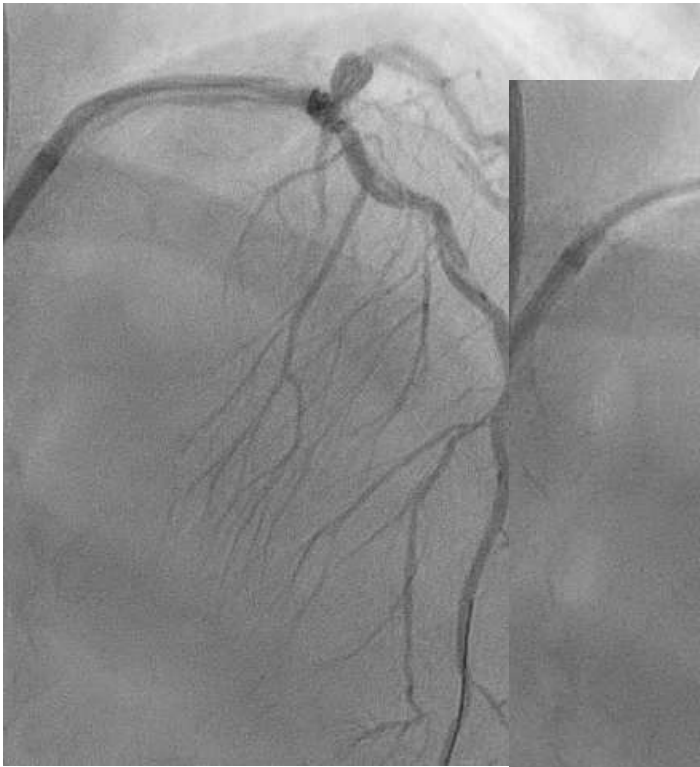


Runthrough floppy
Coroflex ISAR 2.5 x 19 mm



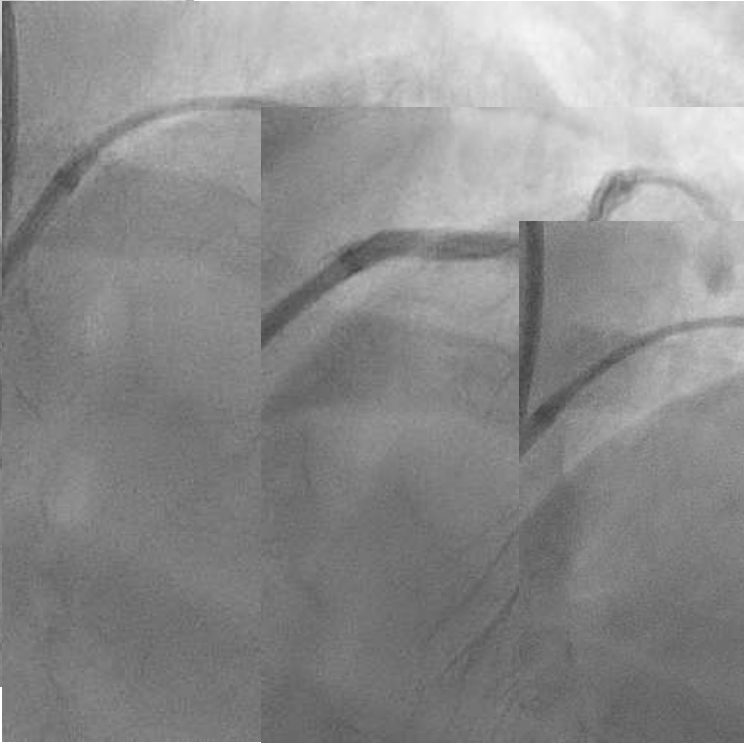
Guideliner 6 Fr



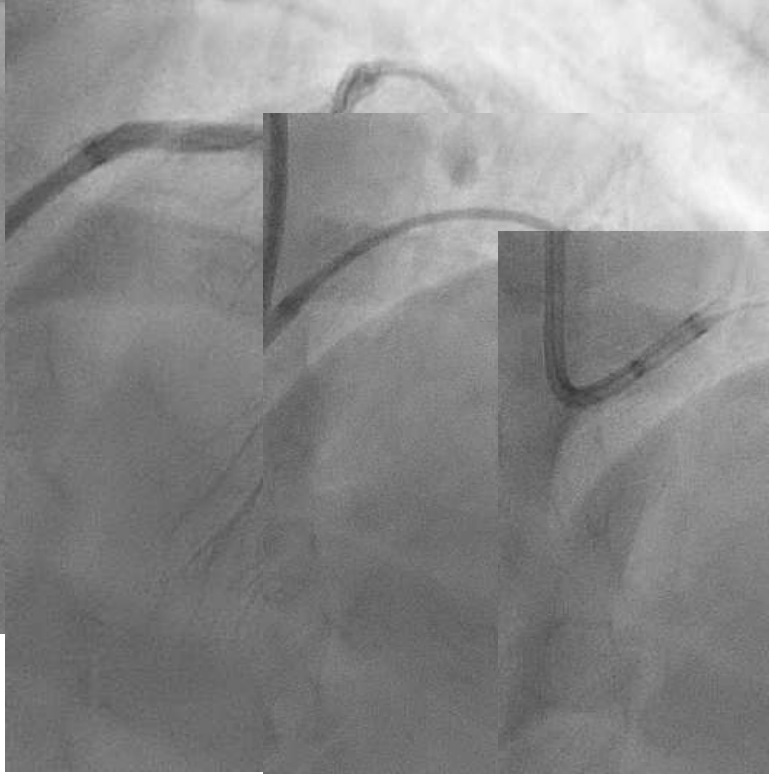


Positioning of distal stent
2.5 x 19 mm

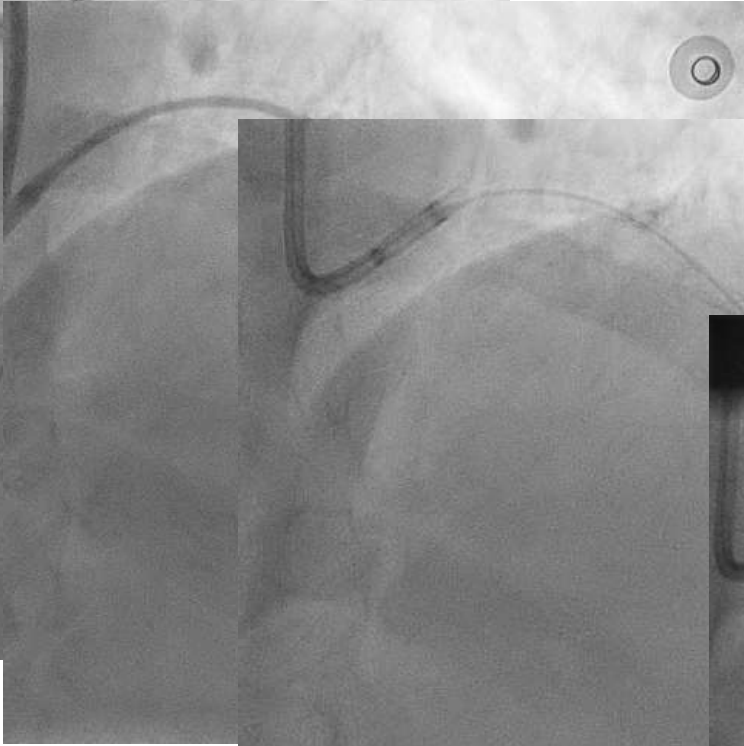
Deployment of distal stent 16 Atm



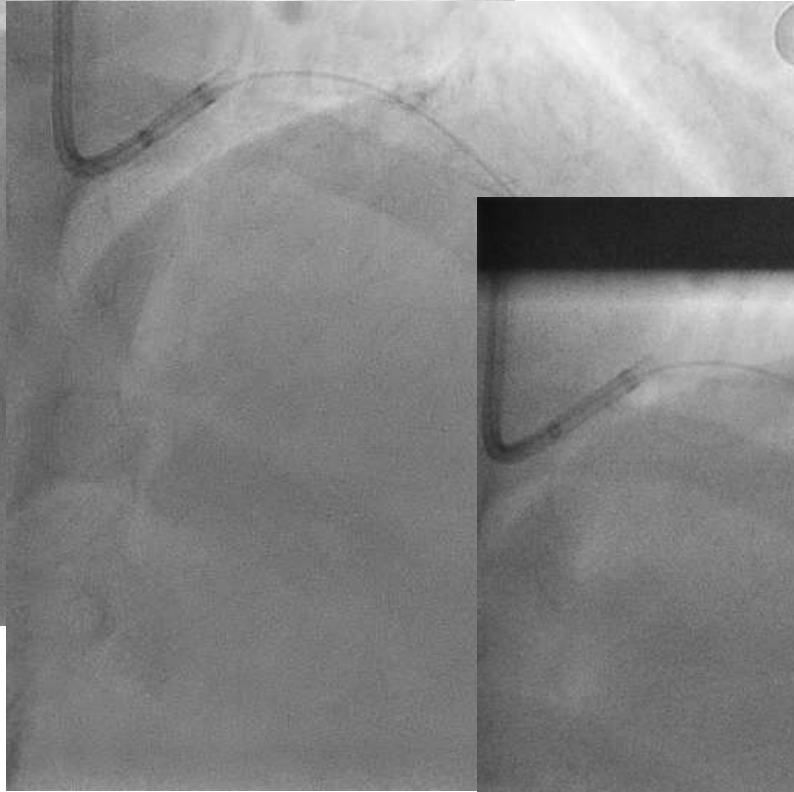
Post deployment of distal stent & placement of prox. stent



Deployment of prox. stent 16 Atm
Coroflex ISAR 3.0 x 27 mm



NC Balloon
2.5 mm at 20 Atm



NC Balloon
3.0 mm at 20 Atm



Pre PCI



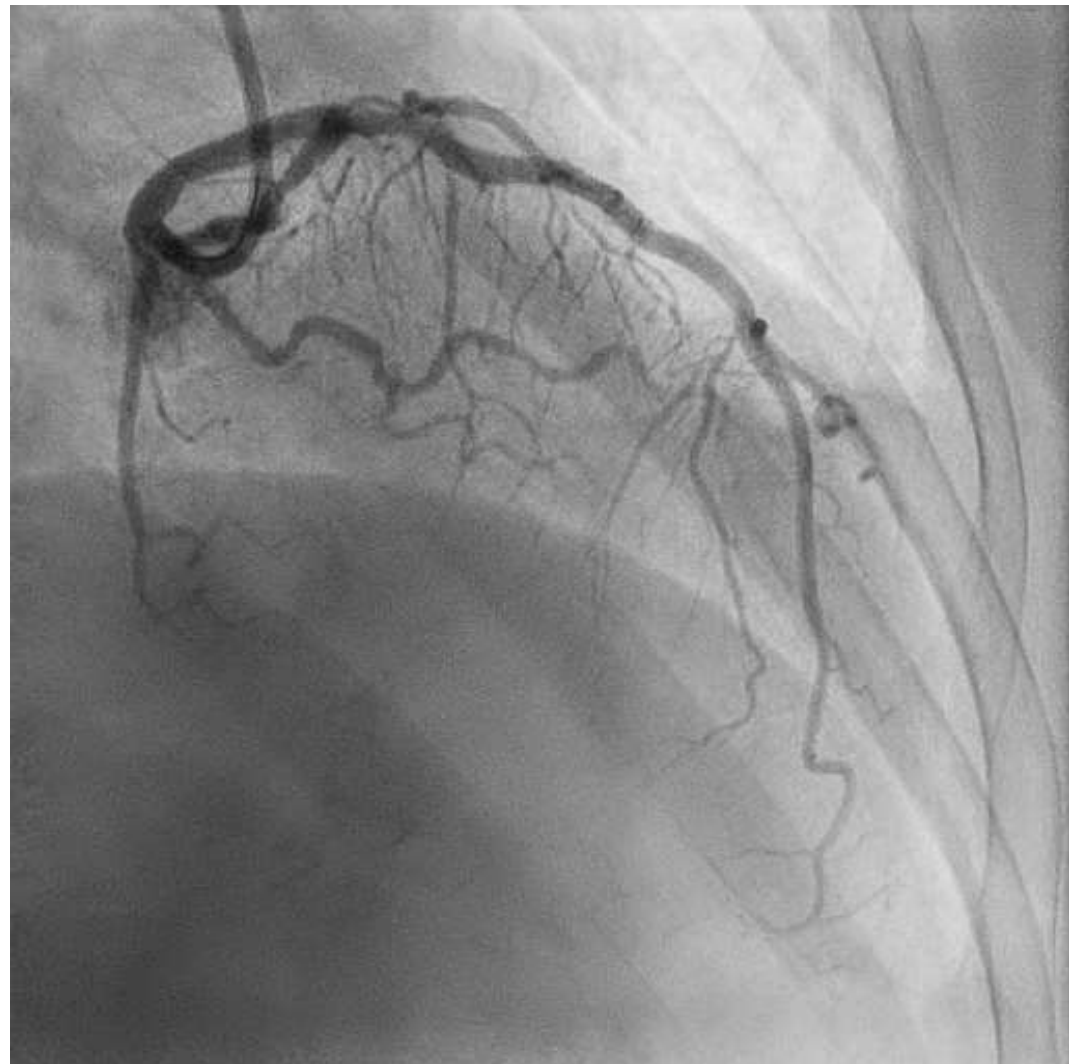
Post PCI



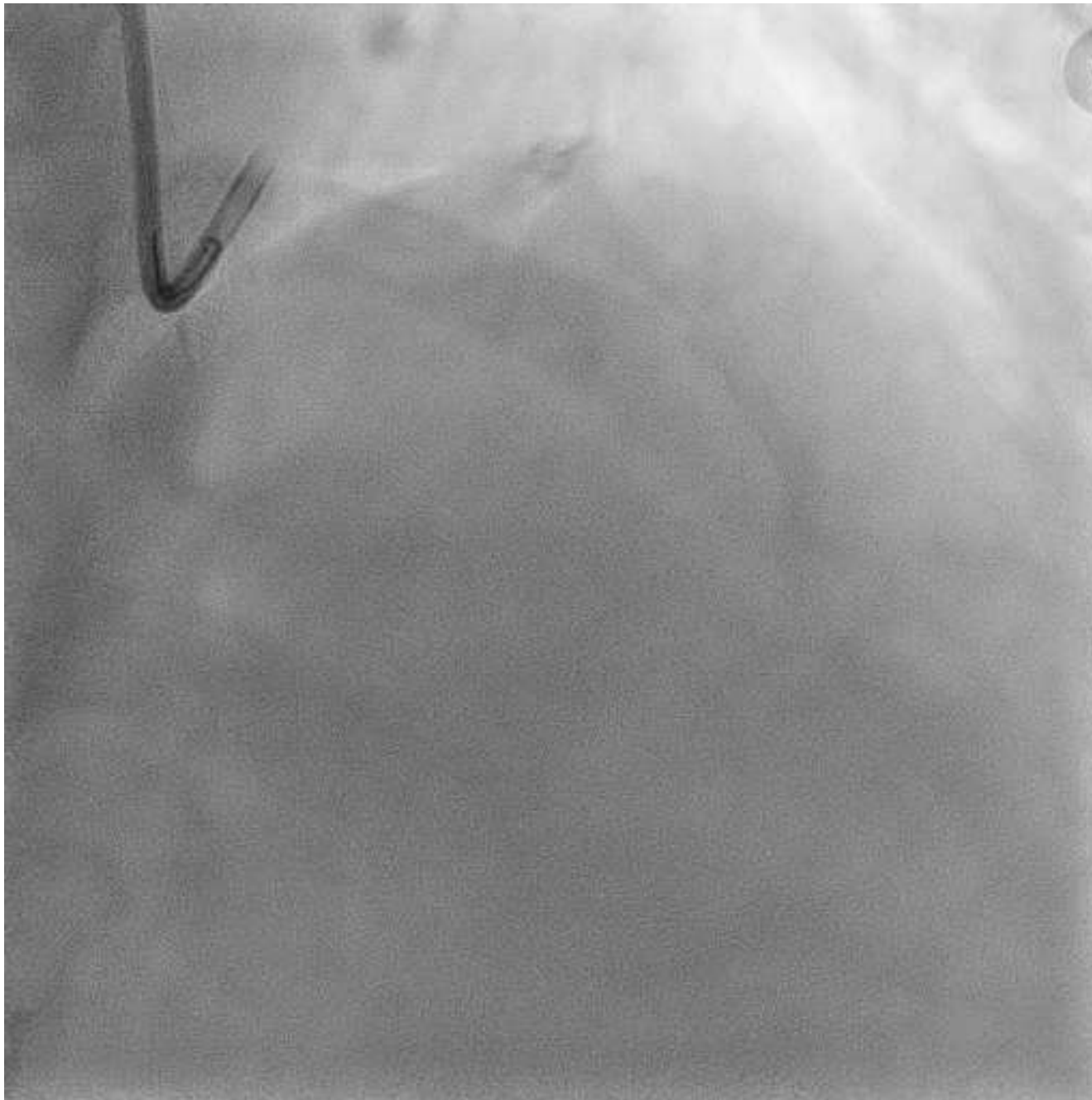
Pre PCI



Post PCI



Conformable
Still fairly visible



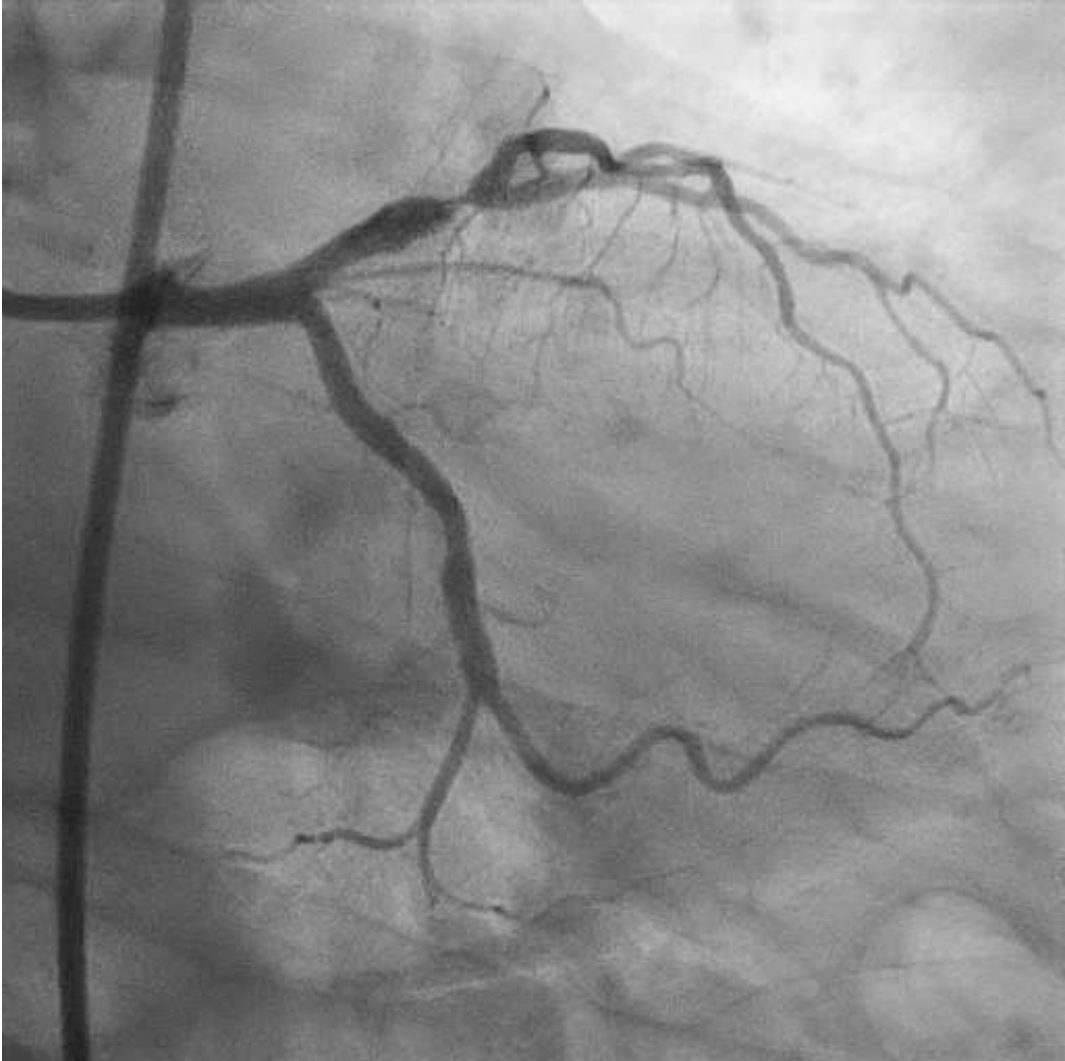
57 yr old man

Inferior STEMI 5 days prior with Rescue PCI to RCA

Dyslipidaemia, HT

EBU 3.5, 7 Fr

LAD/D1 Medina 1,1,1

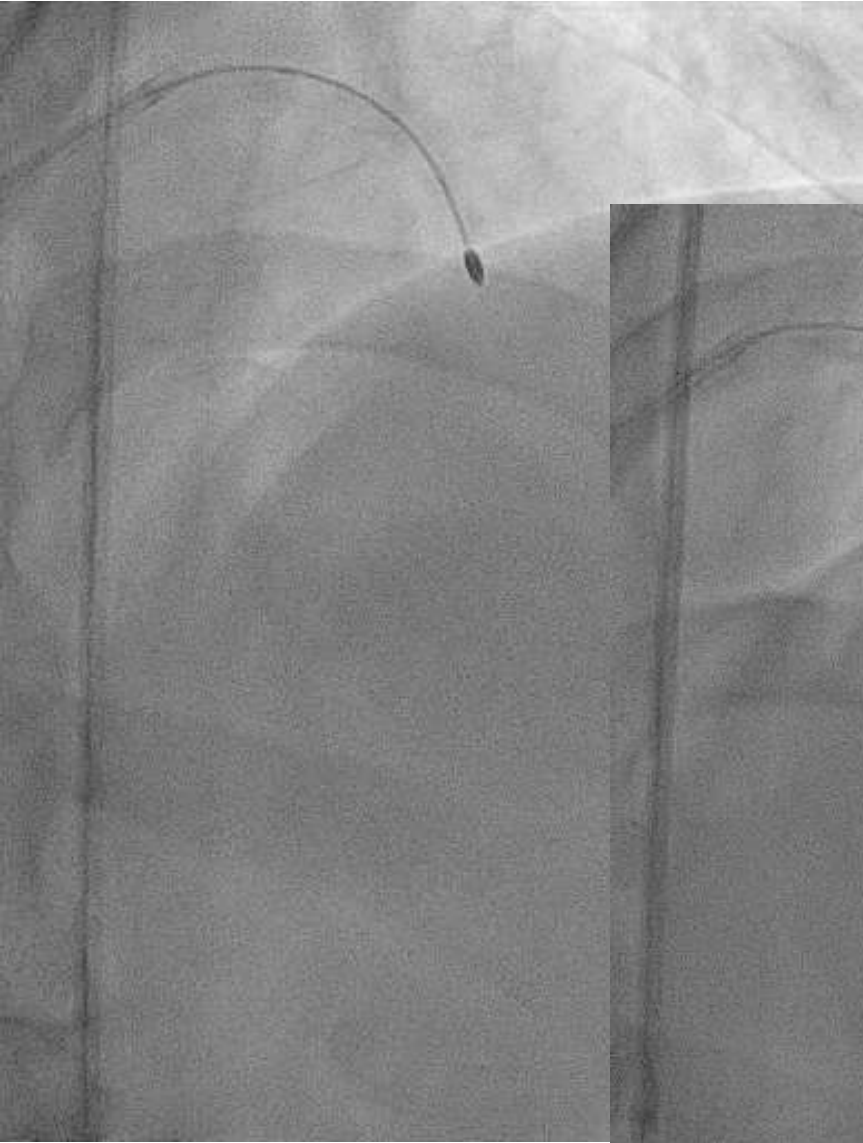


Calcified LAD & Ostial D1
Medina 1,1,1

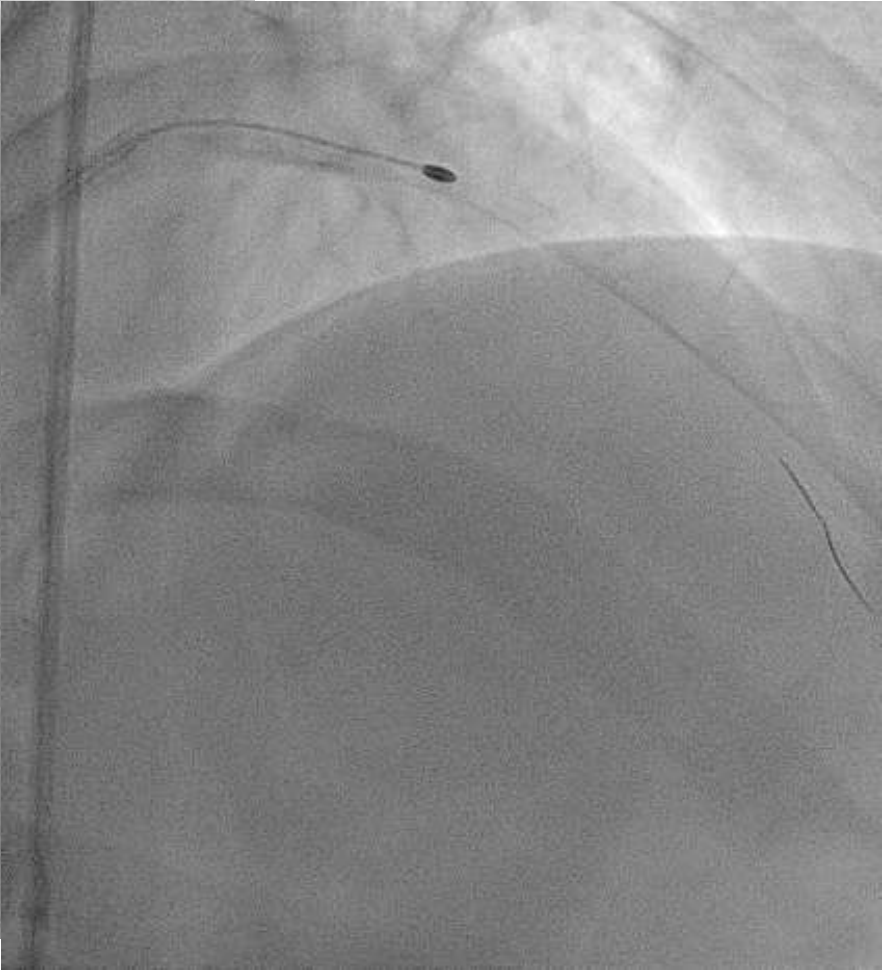


Plan for :
rotablation
2 stent strategy – Double Kissing Culotte





Rotablate LAD 1.75 mm Burr
3 runs at 160,000 rpm

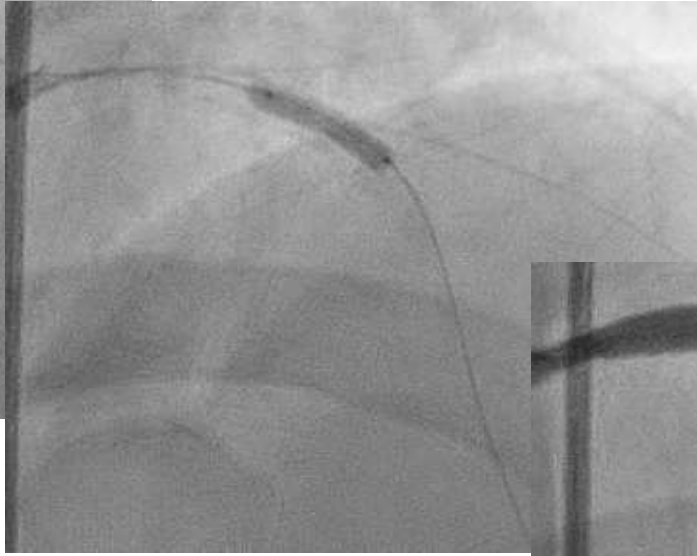
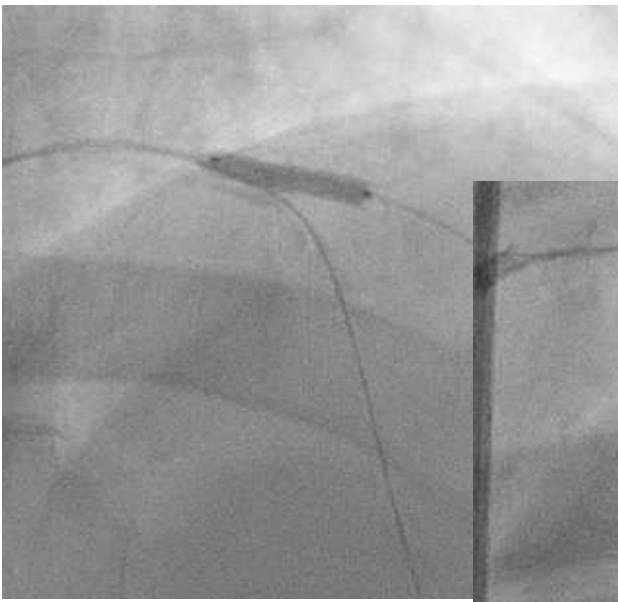


Rotablate D1 1.75 mm Burr
2 runs 160,000 rpm

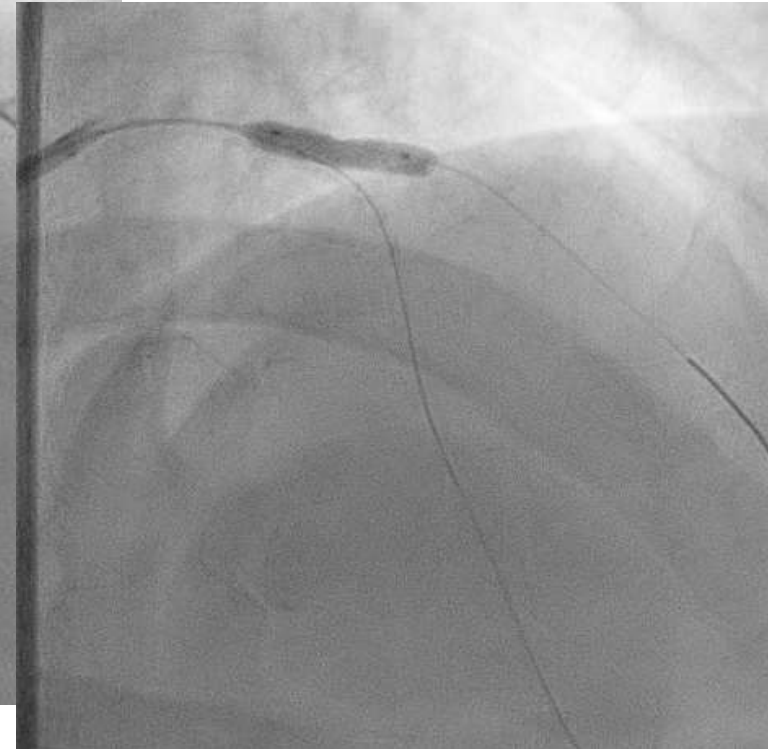
Post Rotablation



POBA post rota with NC balloon 3.0 x 15 mm

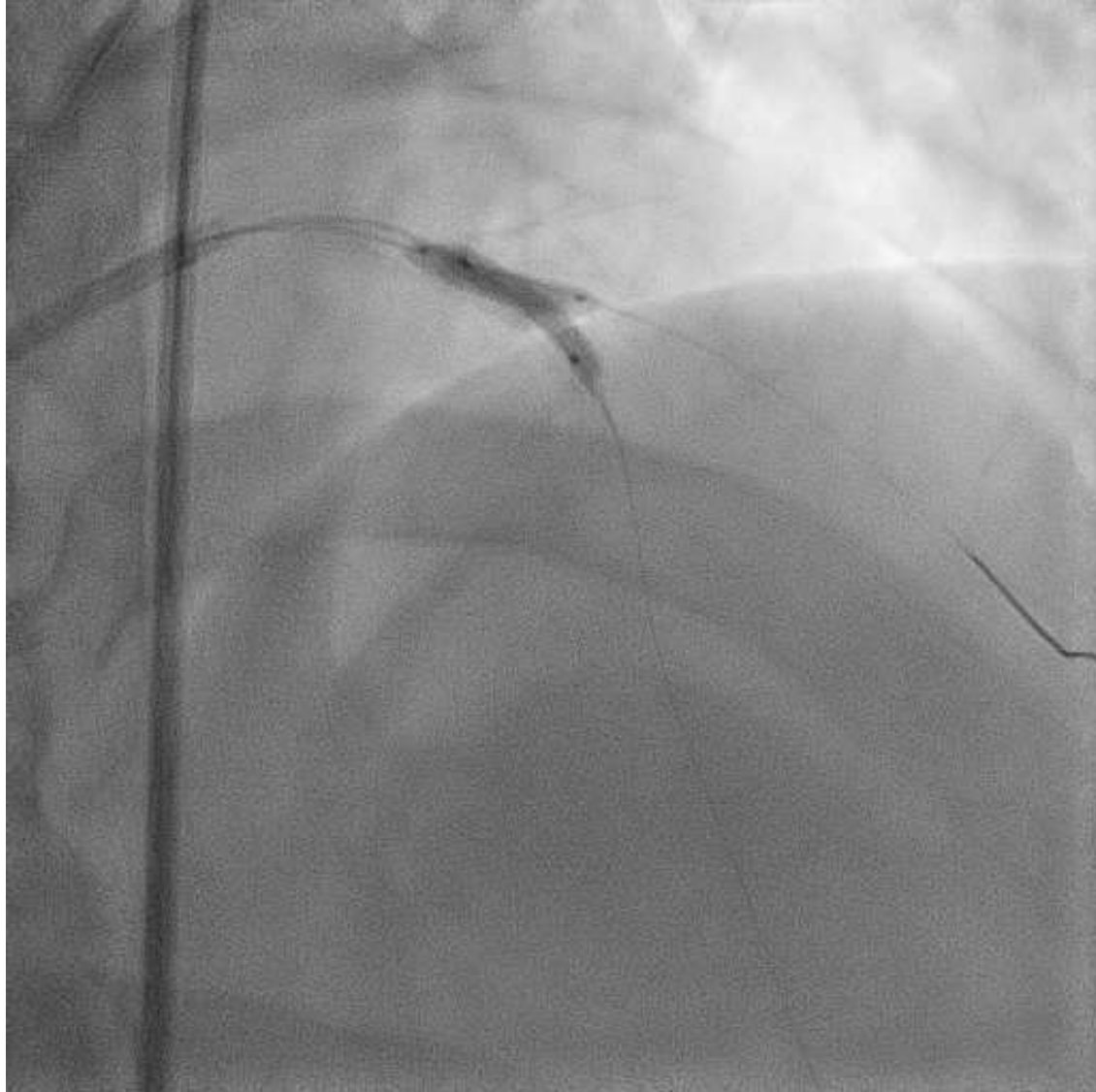


Placement & Deployment of
Coroflex ISAR 3.0 x 13 mm
At 16 to 19 Atm
Culotte Technique

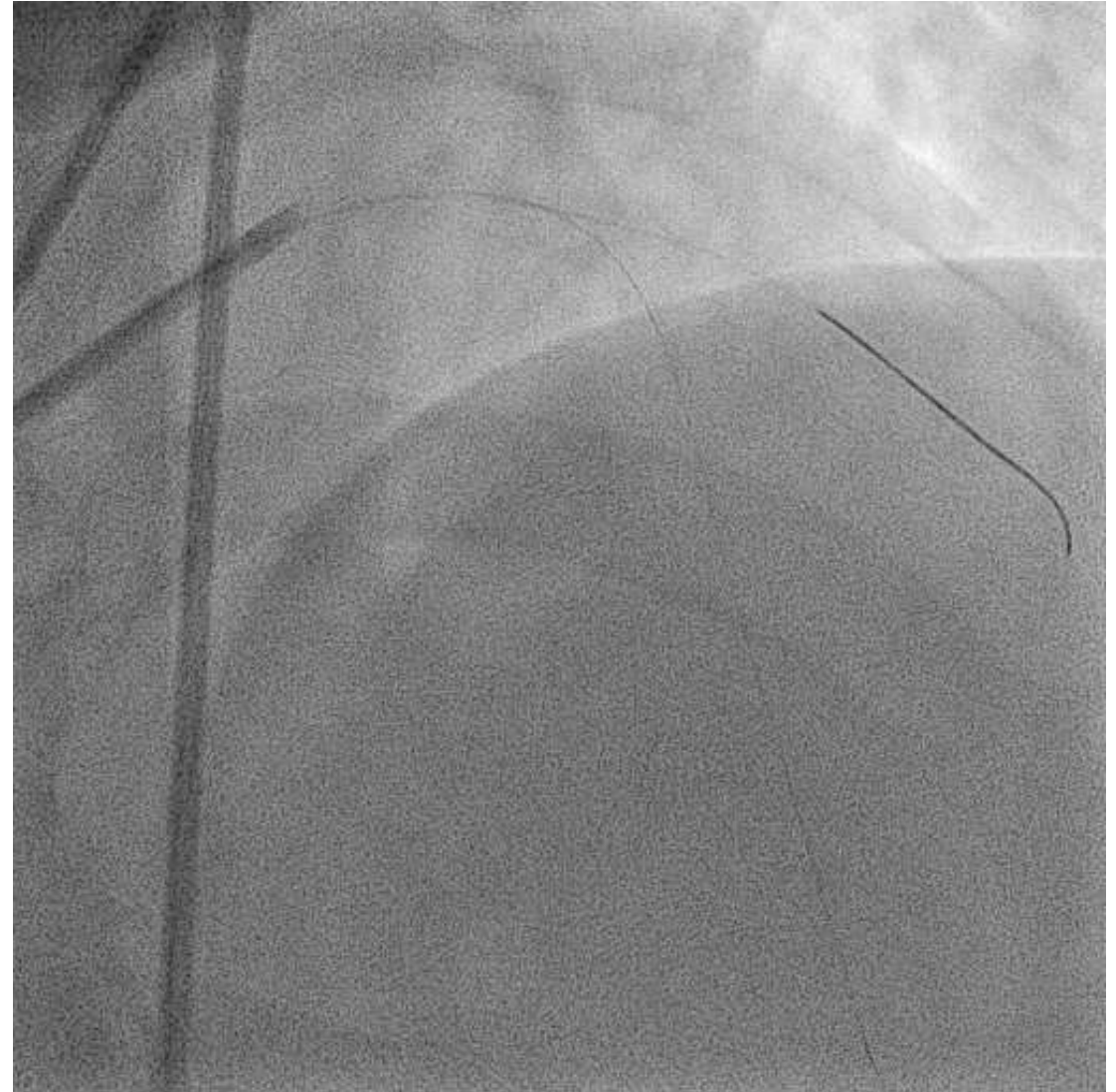


Recross wire thru' stent struts

1st Kiss (Double kissing culotte) LAD – 2.5 mm x 15 mm, D1 - 3.0 mm stent balloon



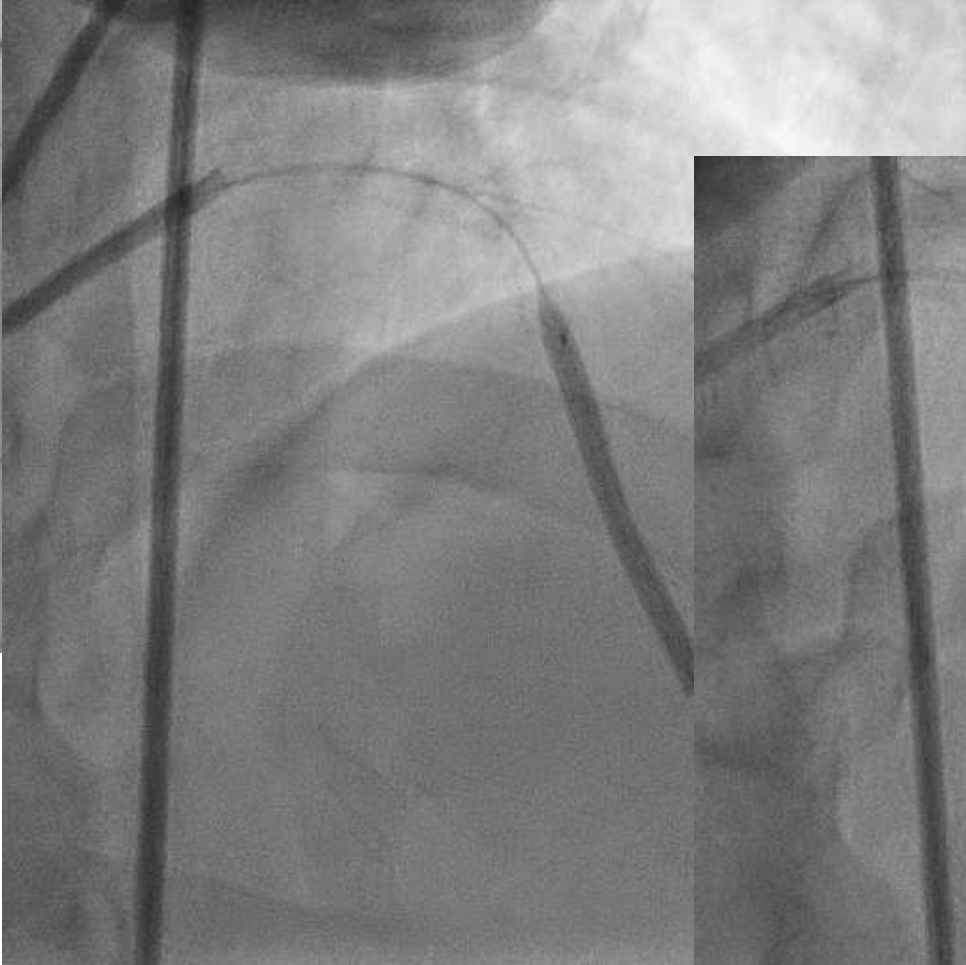
Coroflex ISAR 2.75 x 32 mm



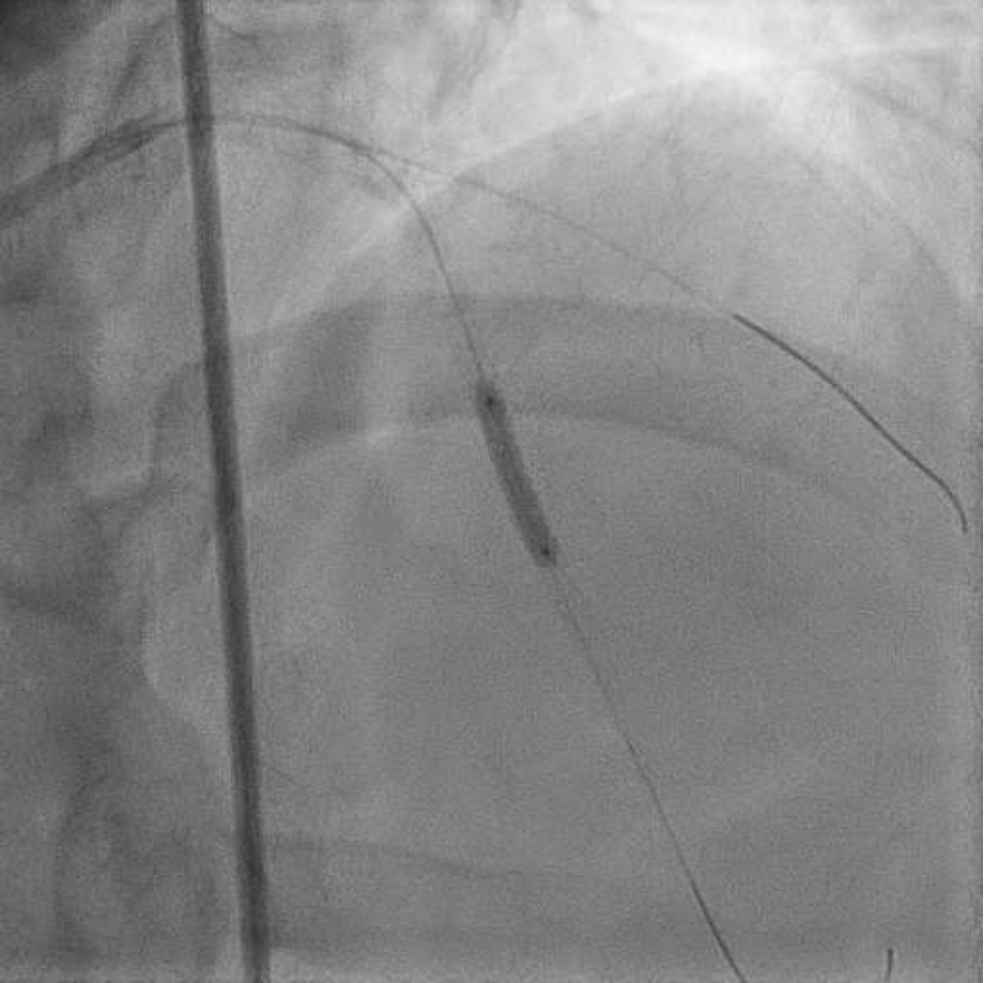


Positioning of distal stent

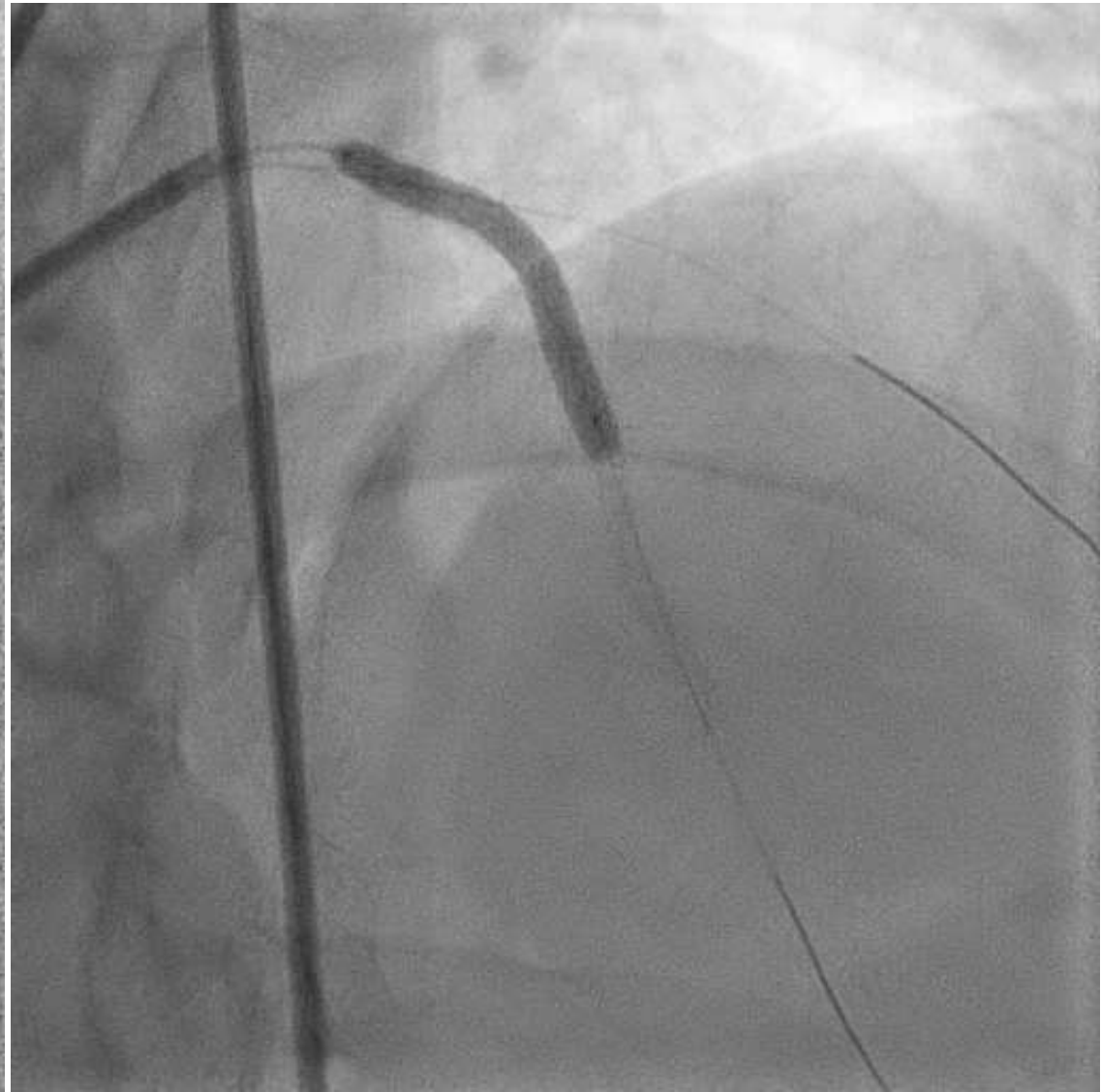
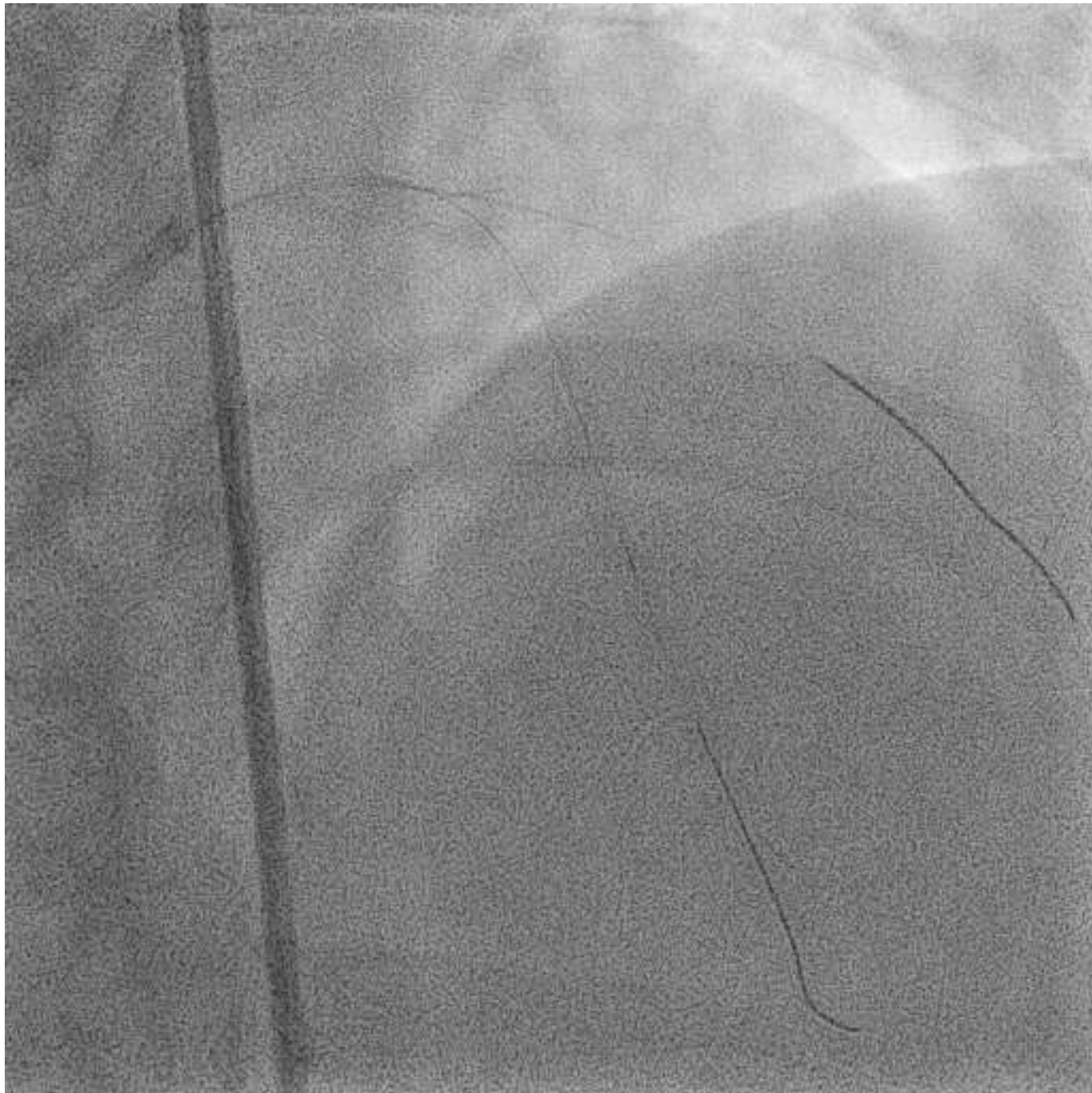
Deploy distal stent 2.75 x 32 mm at 14 to 19 Atm



Post dil 3.0 x 15 mm NC balloon
At 20 Atm

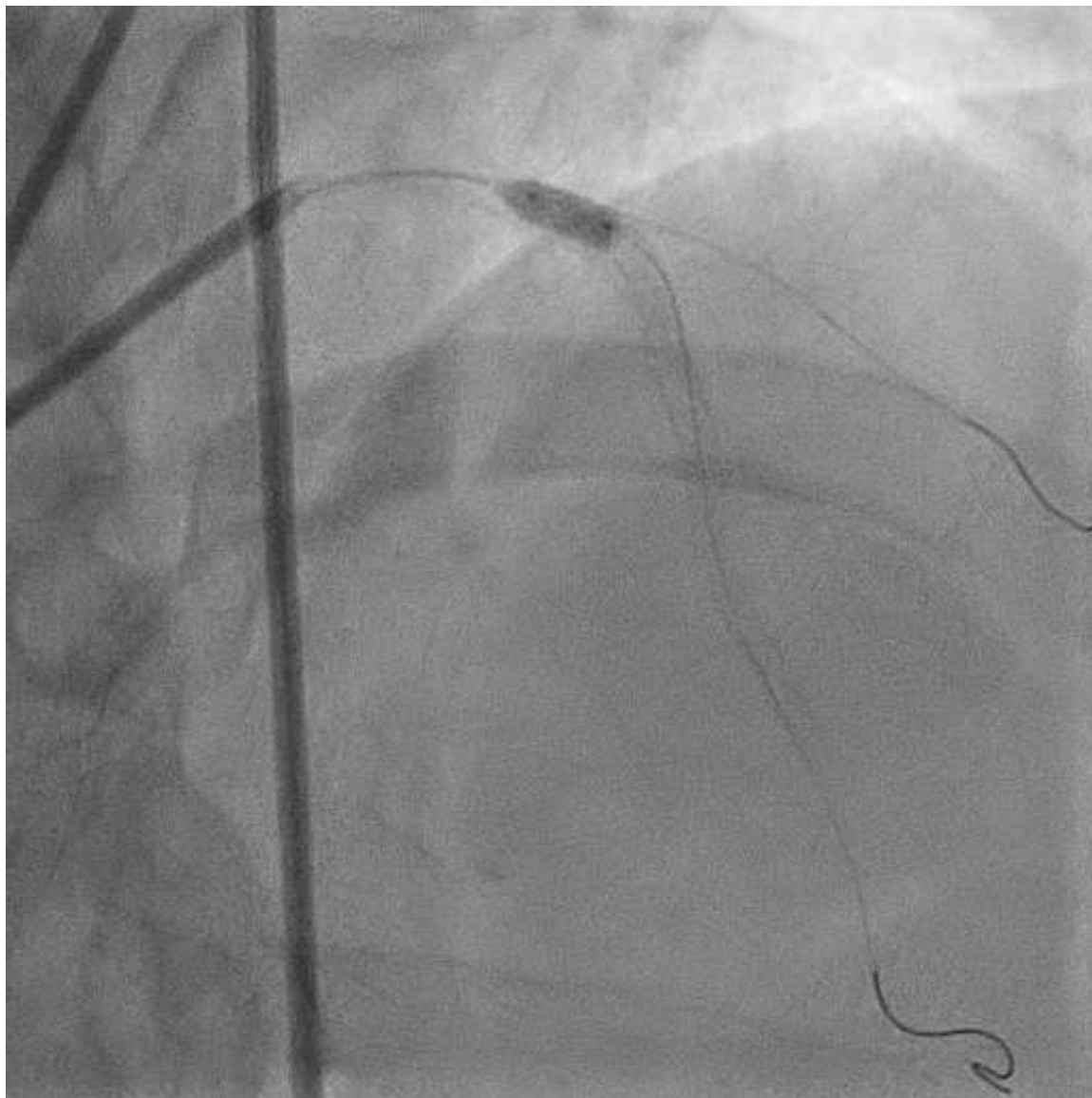


Coroflex ISAR 3.0 x 32 mm
Deployed at 16 to 19 Atm

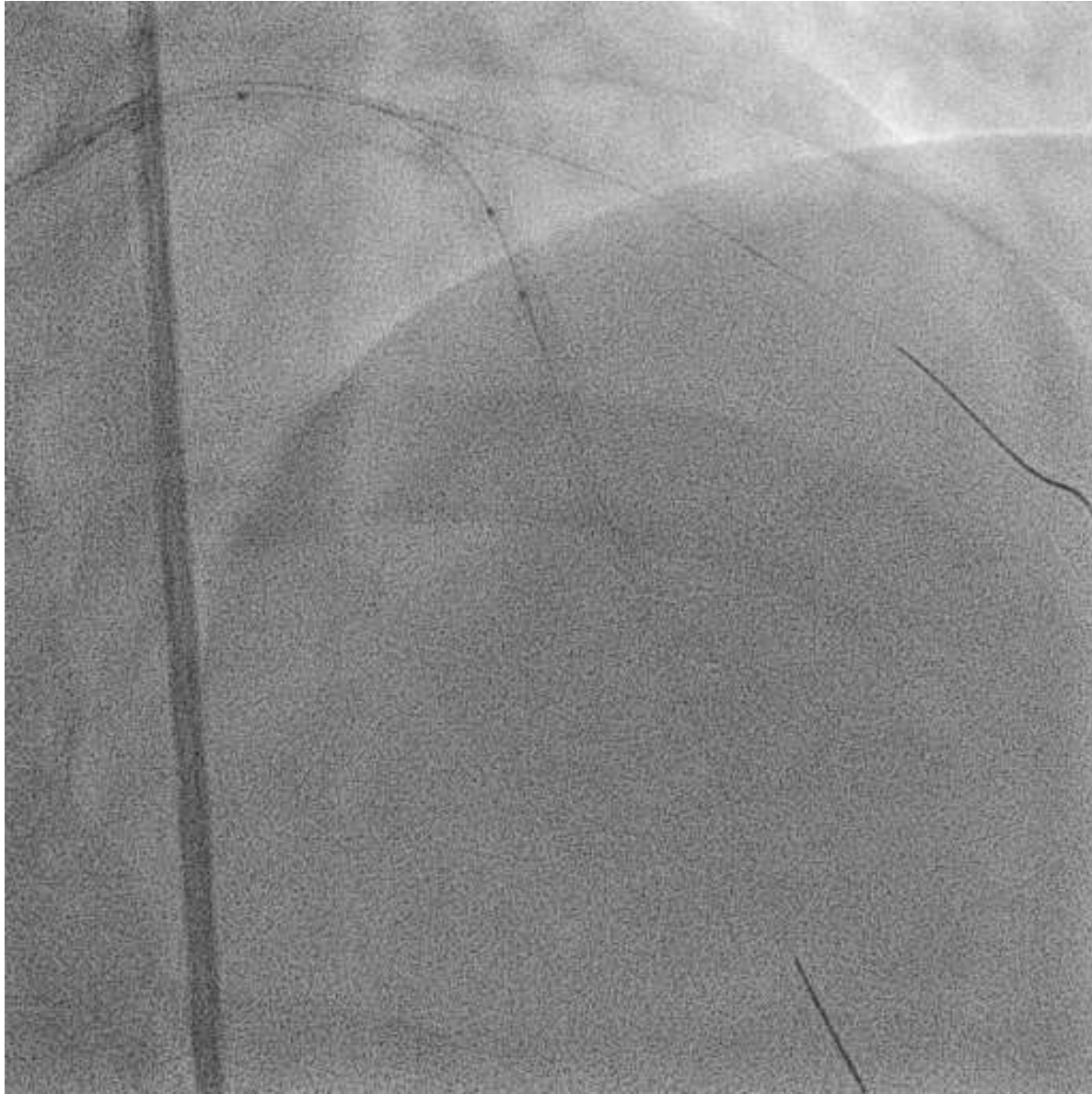


POT Technique

LAD – 3.75 x 8 mm at 20 Atm



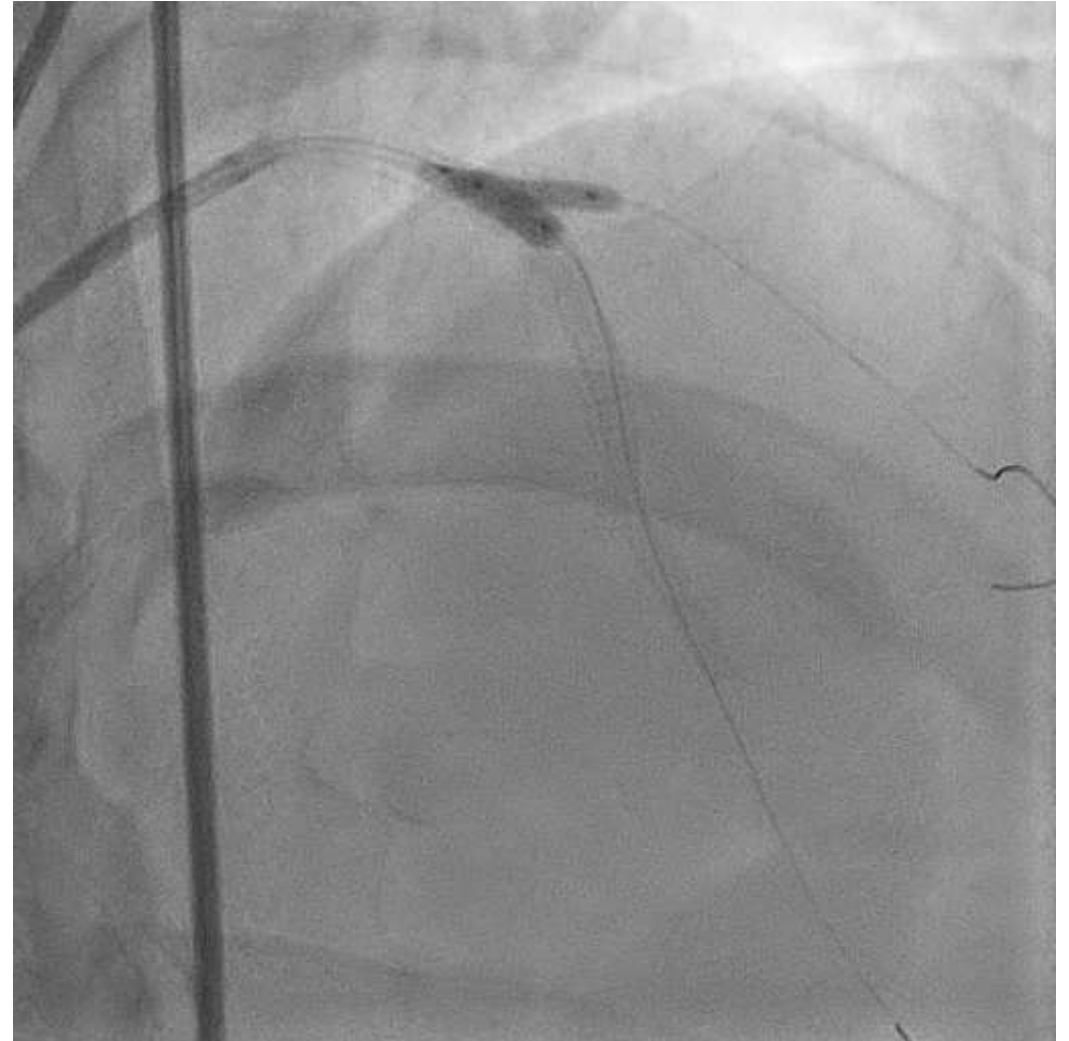
Crossing into D1 thru' stent struts



2nd kissing culotte

LAD - 3.75 x 8 mm NC balloon at 8 Atm

D1 - 2.5 x 15 mm balloon at 8 Atm





Post PCI

LAD – Coroflex ISAR 2.75 x 32 mm &

3.0 x 32 mm (upsized prox. With 3.5 mm balloon)

D1 – Coroflex ISAR 3.0 x 13 mm



Post PCI

Double Kissing Culotte

Visible struts

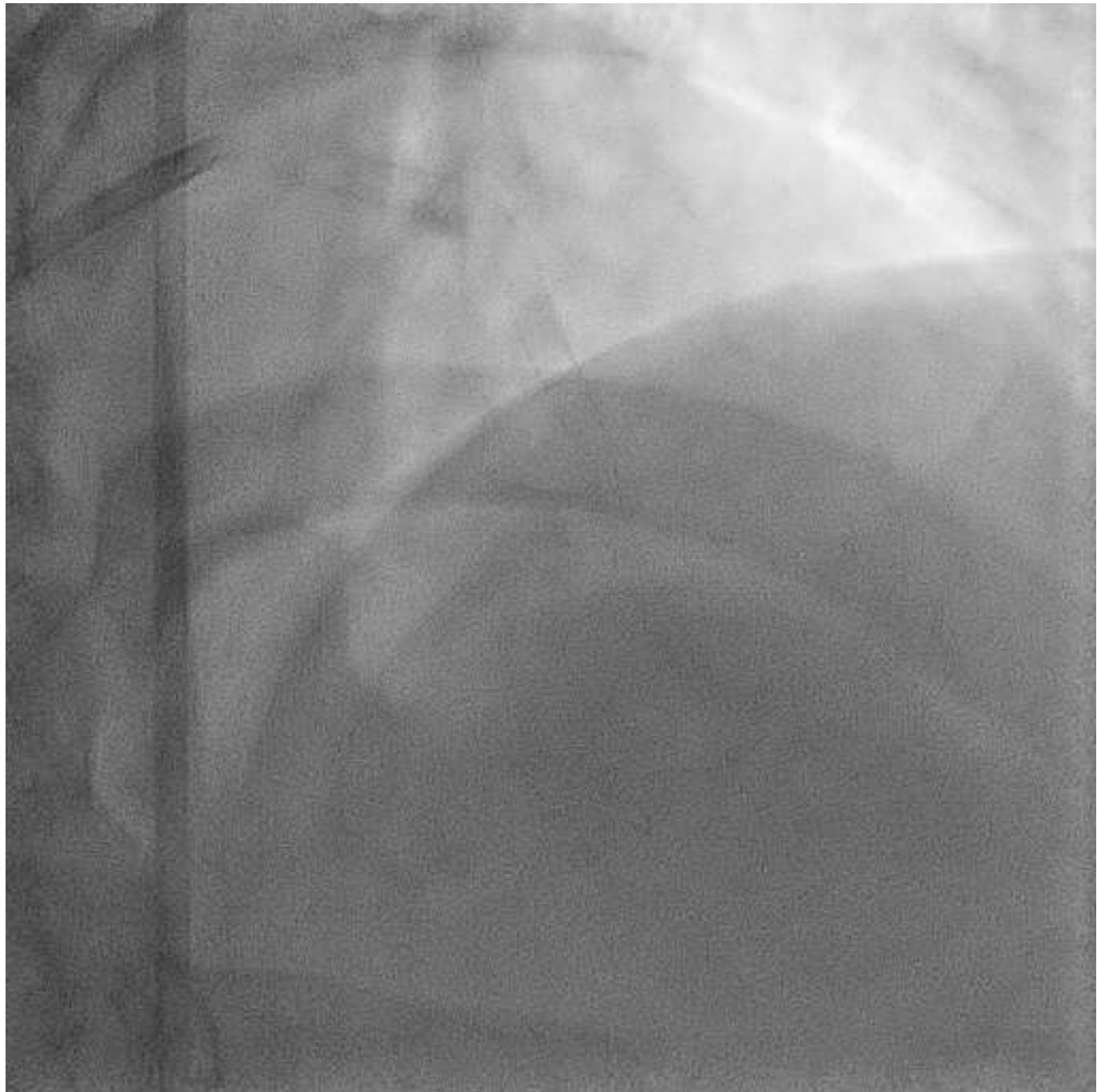
Crossed thru' stent strut

Conformable

(For all stents

Cell size for side-branch

access – 4.3 mm)



PTCA-Catheter platform:
SeQuent Neo

Bare metal stent platform:
Coroflex Blue Ultra & Neo
ultra-low strut thickness

*2.0 , 2.25 & 2.5 mm – 50 microns
(max. dilatation diameter - 3.0 mm)*

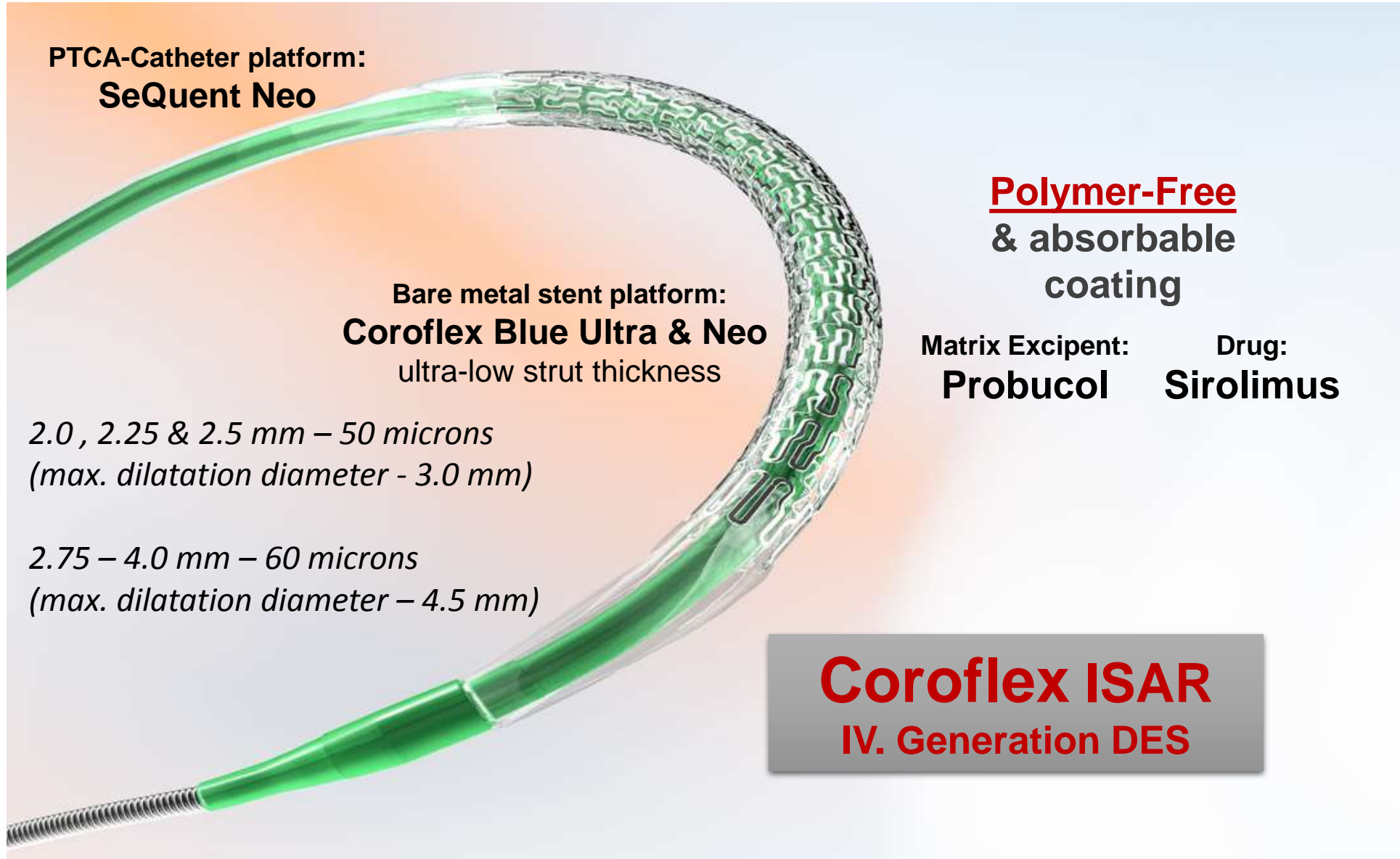
*2.75 – 4.0 mm – 60 microns
(max. dilatation diameter – 4.5 mm)*

Polymer-Free
& absorbable
coating

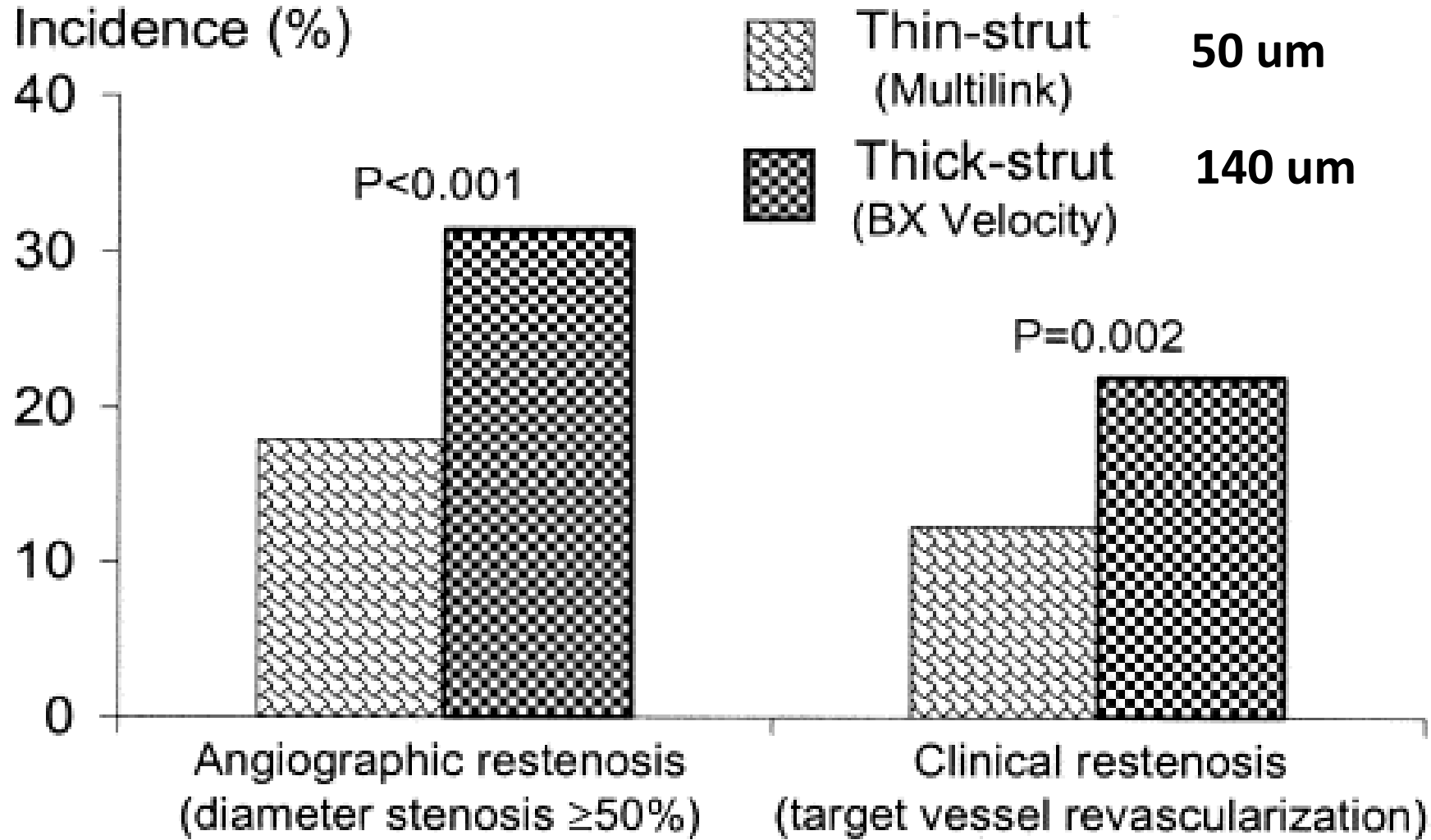
Matrix Excipient:
Probucol

Drug:
Sirolimus

Coroflex ISAR
IV. Generation DES

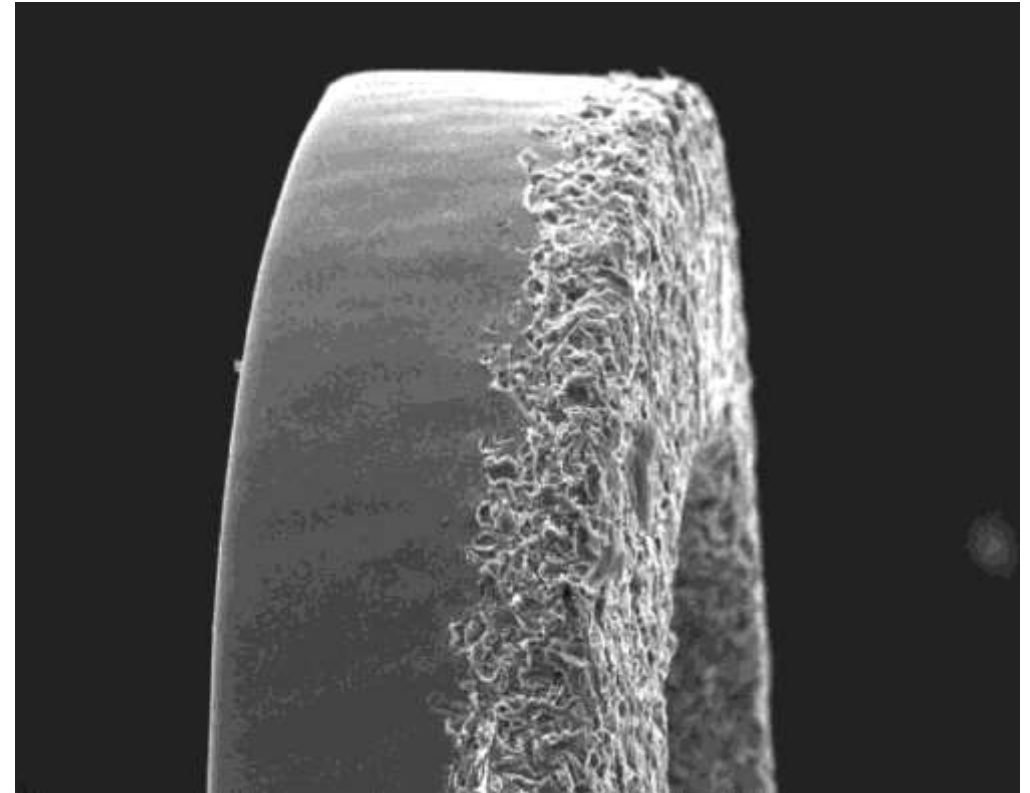
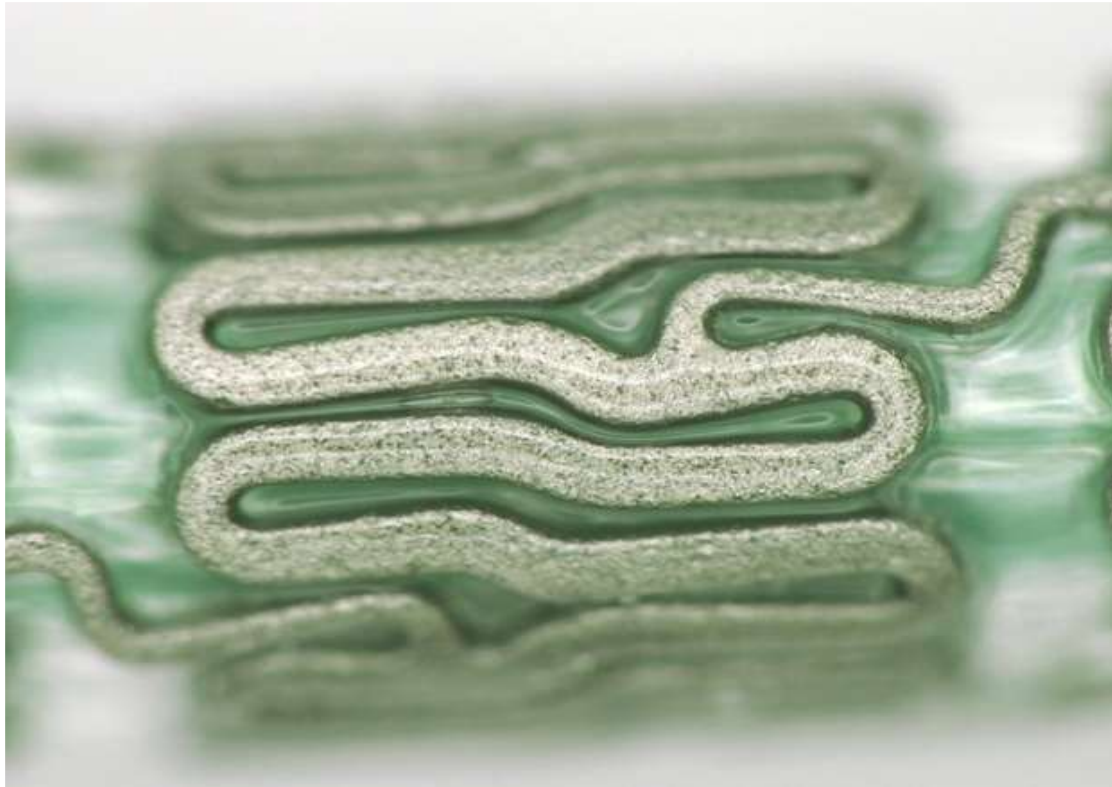


ISAR STEREO 2



Coroflex ISAR: Next Generation Polymer-Free Sirolimus DES

Coroflex ISAR: Abluminal Coating on Roughened Surface
(Microporous Stent Surface Modification)



A defined abluminal surface roughness binds the drug matrix and supports a controlled drug release into the vascular tissue

Coroflex ISAR: Matrix Coating Technology

The Matrix Coating Technology

- Covered with a sirolimus containing matrix, which consists in equal shares (1:1) of the drug sirolimus and probucol
- Probucol is needed to bind the drug on the stent and to facilitate a controlled & continuous drug release
- Probucol mimics the function of a polymer by retarding the release of sirolimus over a time period of several weeks
- The drug load is $1.2\mu\text{g}/\text{mm}^2$ sirolimus
- The Matrix Coating is applied only on the abluminal surface



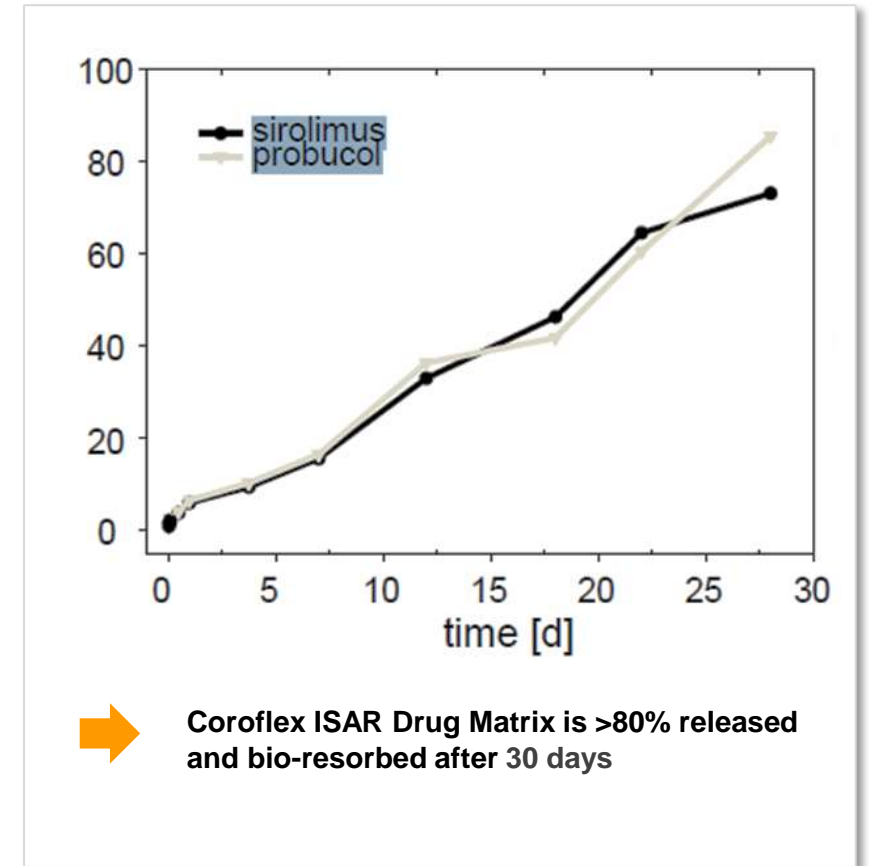
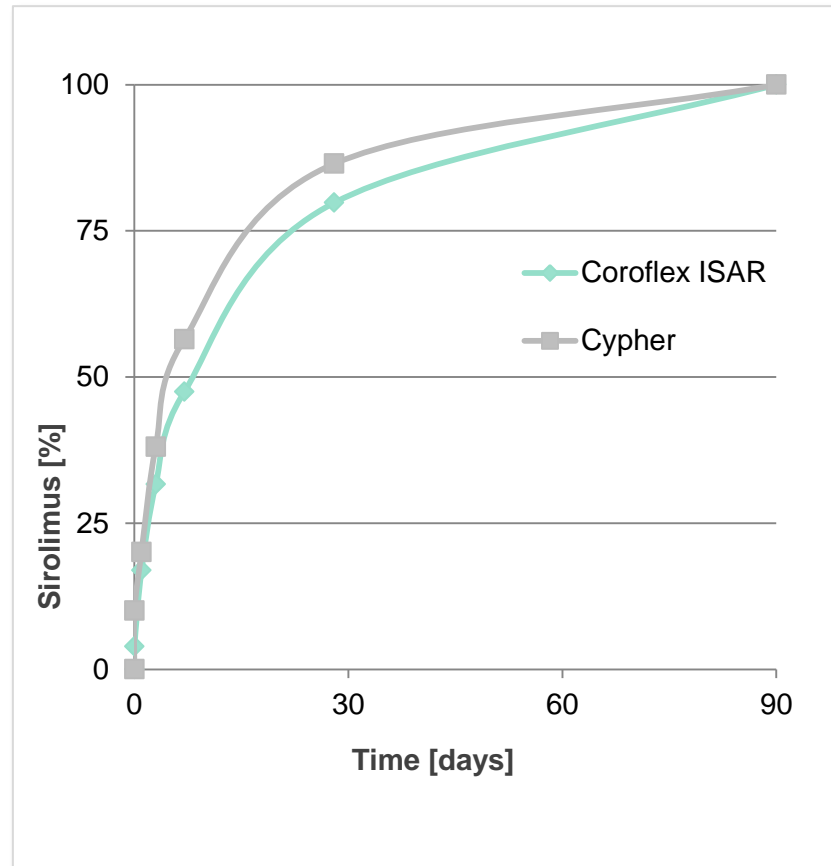
**Coroflex ISAR Cobalt Chromium –
Abluminal, Polymer-Free Drug Delivery**

Coroflex ISAR: Matrix Coating Technology

Coroflex ISAR Sirolimus Release Kinetics in-vivo

100% polymer-free Matrix Coating

- Improved endothelial healing
- Efficacy in drug elution equivalent to Cypher
- Hydrophobic matrix-builder (probucol) extends drug release over time



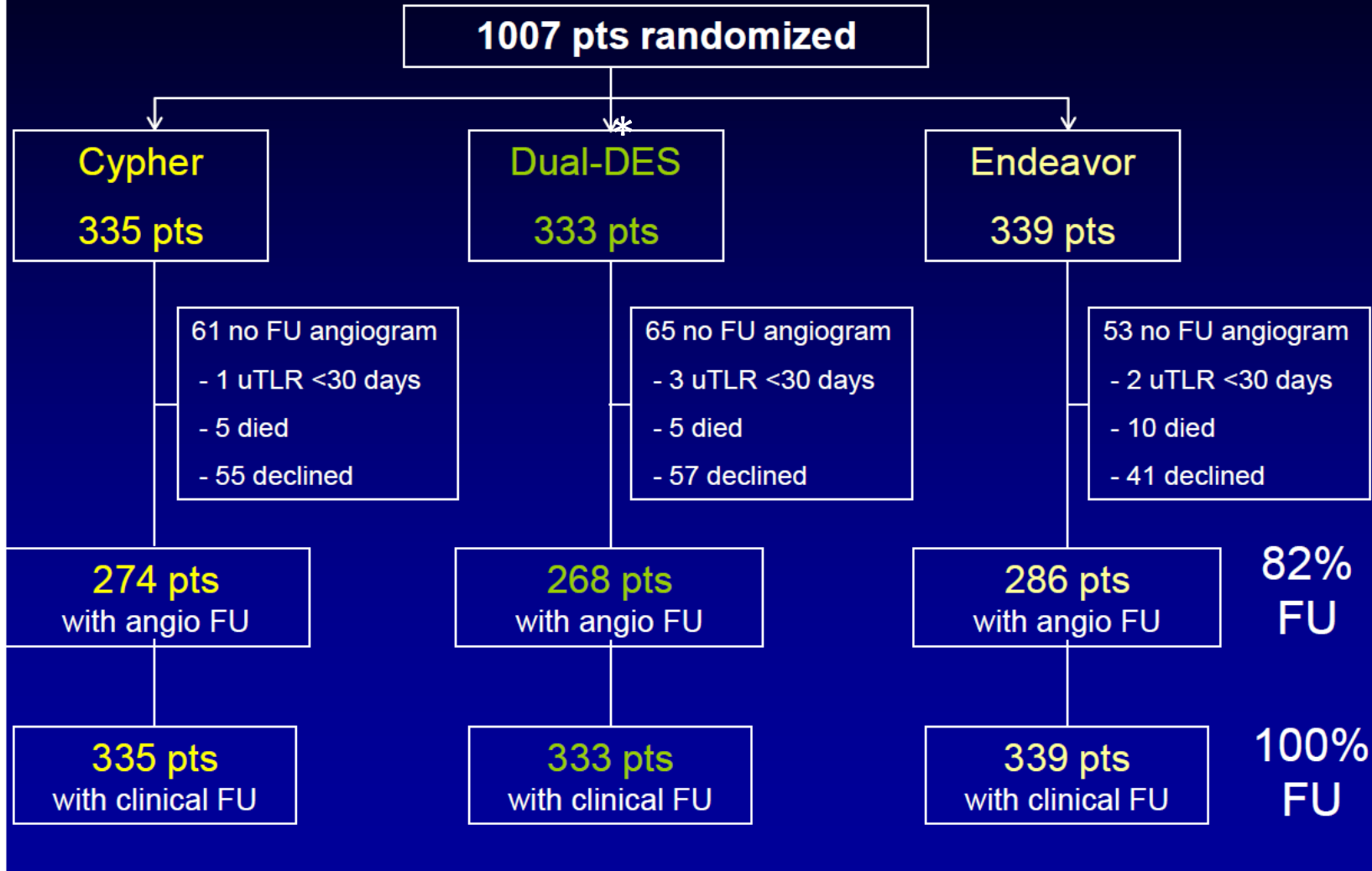


Study Flow Chart



Primary Safety Endpoint
At 2 yrs
1. Composite of Death & MI
2. Definite stent thrombosis

Primary Efficacy Endpoint
TLR at 2 yrs



*Dual DES – 87 um stainless steel stent



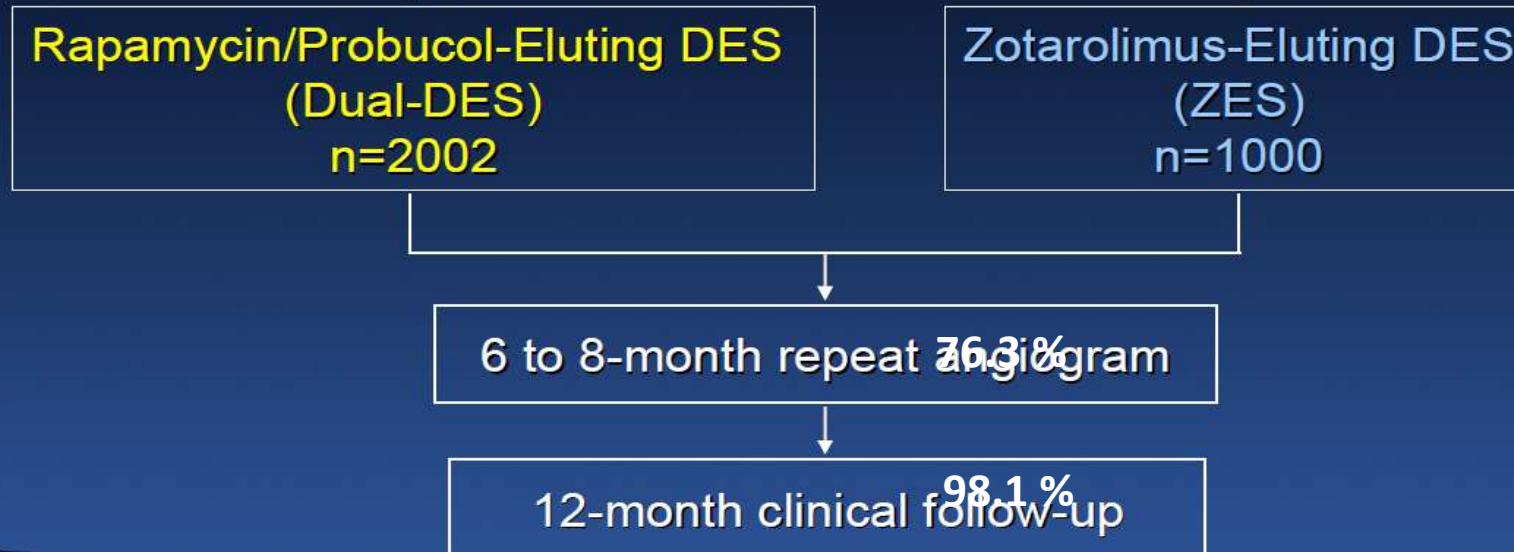
ISAR-TEST-5



Intracoronary Stenting and Angiographic Results:
Test Efficacy of Rapamycin/Probucol- and Zotarolimus-Eluting STents - 5

Primary Endpoint
composite of
Cardiac death
TV MI or
TLR at 1 yr

3002 patients with de novo lesions

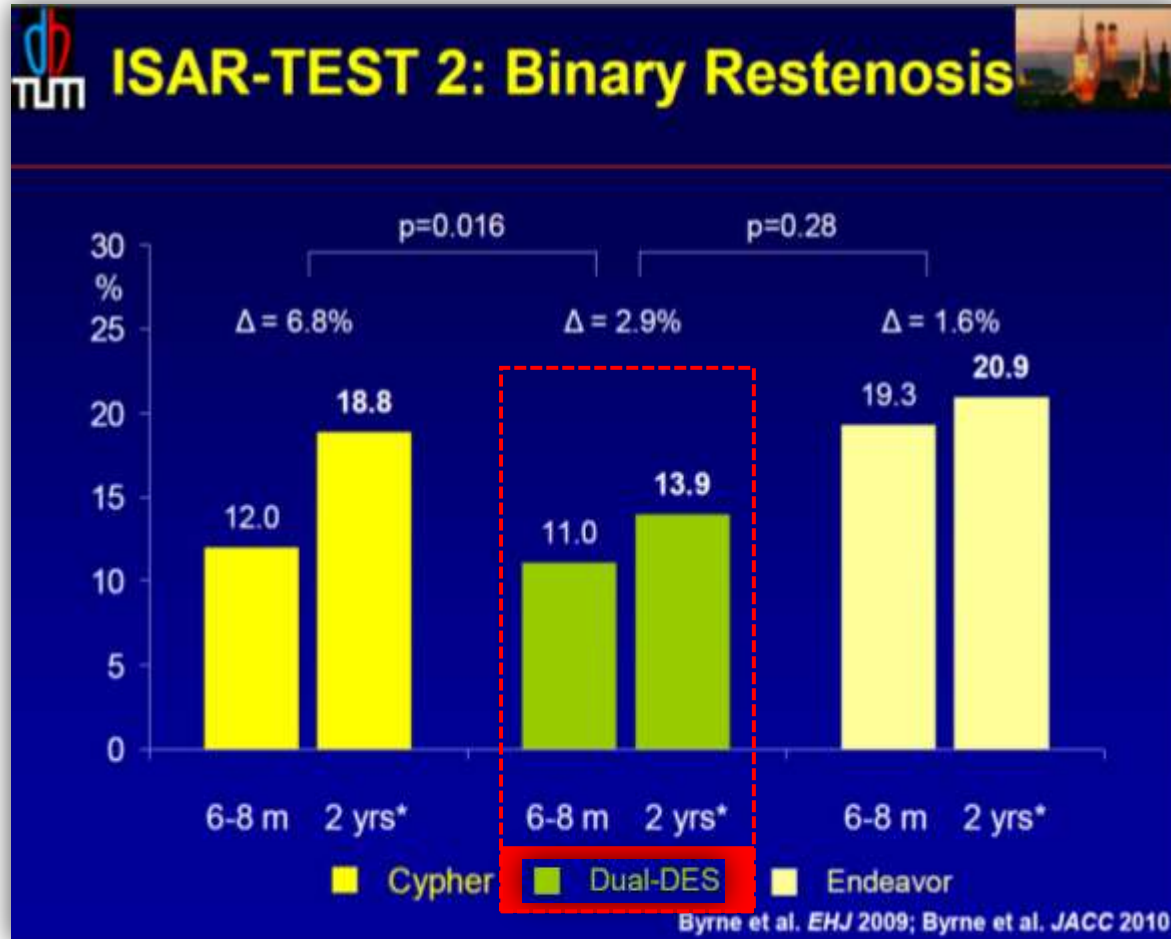


* Dual DES – 87 um stainless steel stent

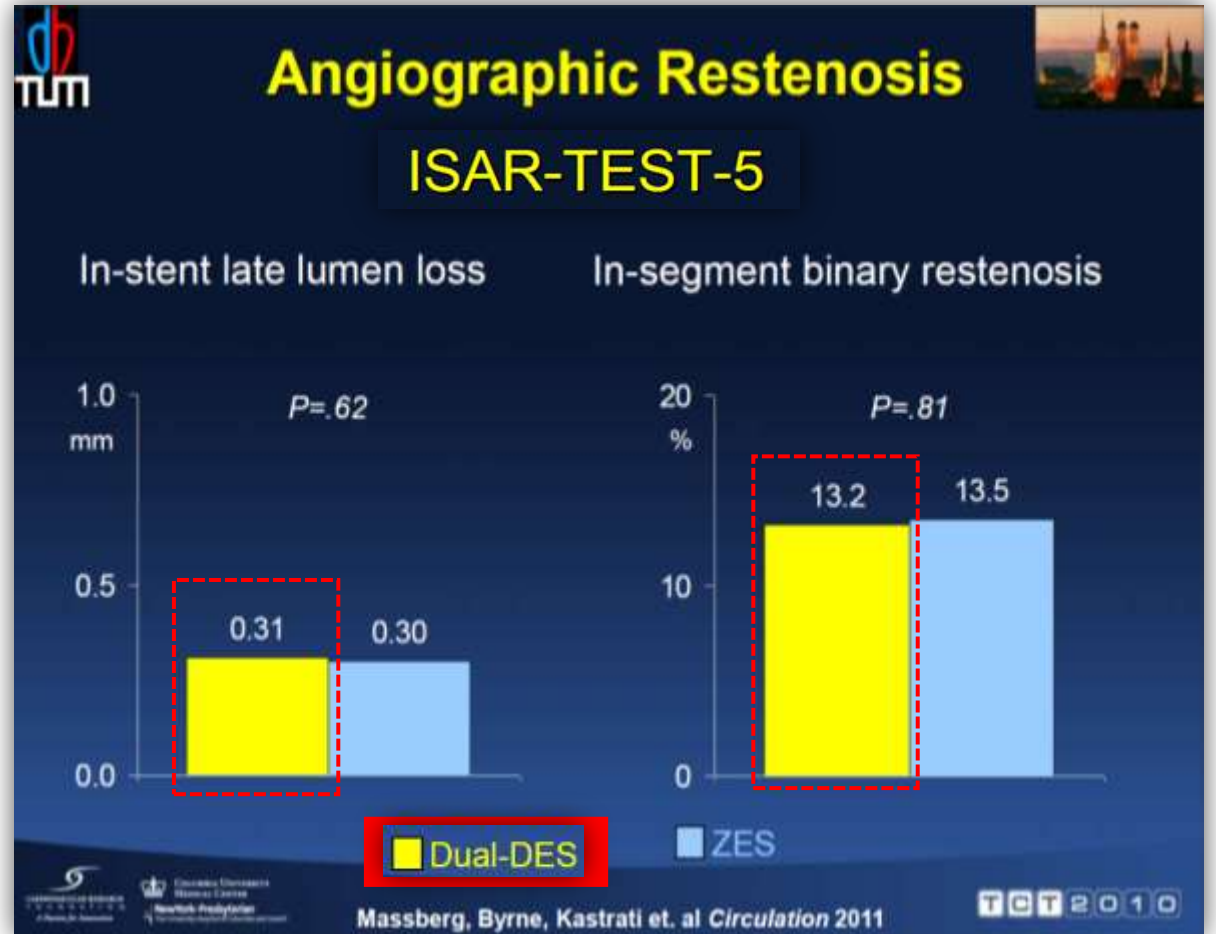
Massberg, Bryne, Kastrati *Circulation*. 2011 Aug 2;124(5):624-32. Epub 2011 Jul 18

Coroflex ISAR: Clinical Evidence

Results of ISAR TEST 2 and ISAR TEST 5



Rpt angiogram 6 – 8 mo & 24 mo



Rpt angiogram 6 – 8 mo & 12 mo

*Clinical proven concept with more than 4,000 patients documented in the ISAR Test 2 and 5 trials.
Efficacy equivalent to Cypher / Endeavor Resolute Integrity*

Coroflex ISAR: Benefits

The offer...

**NO Polymer
Complete Absorption**

**Strut Thickness of only
50/60 μm**

**Lowest Crossing Profile
0.031" – 0.035"**

Optimized Stent Design

**Full Stent Portfolio from
2.0 to 4.0 mm**

The benefits

...

**Low Rate of Stent
Thrombosis**

**Less Trauma
Fast Endothelialization**

Excellent Crossability

Highest Flexibility

**Ideal for all lesion types
from SVD towards LM**