

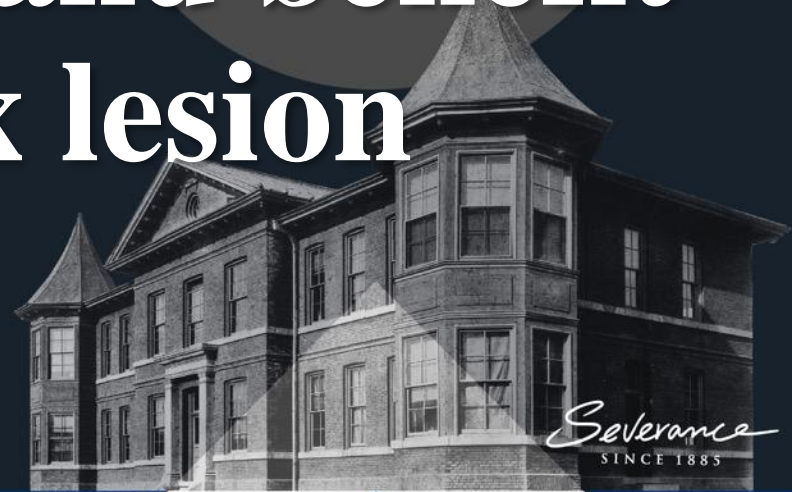


YONSEI  
UNIVERSITY

# Sierra feature and benefit in complex lesion

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Severance Cardiovascular Hospital,  
Yonsei University College of Medicine



# PCI for complex lesions

- AMI
- CTO
- Diffuse long lesions
- Calcified lesion
- Bifurcation
- Unprotected left main disease
- Small vessel diseases
- Intracoronary thrombus
- Stent thrombosis / In-stent restenosis

*All DESs, same?*

→ Successful PCI could make the successful outcomes.  
→ Easy procedure, less time, less cost, and a big success after PCI.

**Essential to success?**



# Essential of DES to successful complex PCI?




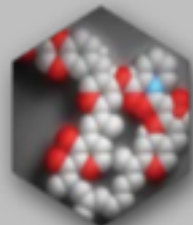



## 1. Deliverability

Best results in diffuse long lesions (tortuous or angulated lesions), CTO, or severe calcification

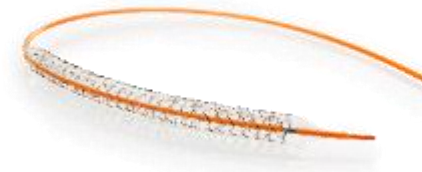


# SIERRA'S NEW STENT DESIGN AND DELIVERY SYSTEM



	 <b>DELIVERY SYSTEM</b>	 <b>BALLOON</b>	 <b>STENT DESIGN</b>	 <b>DRUG/DOSE</b>	 <b>POLYMER/ STENT MATERIAL</b>
<b>XIENCE Alpine</b>	XIENCE Alpine	Multi-Layer balloon	PRIME design	Everolimus 100 µg/mm <sup>2</sup>	Durable Fluoropolymer/ Cobalt Chromium
<b>XIENCE Sierra</b>	<b>NEW!</b> Improved pushability through a more robust single piece outer member	<b>NEW!</b> Reduced crimped profile through a single layer balloon with stronger material	<b>NEW Design!</b> Smaller crimped profile & larger post-dilatation expansion achieved by stent pattern modification		
Optimized for improved performance in the most difficult lesions				Maintain excellent clinical outcomes	

# 1. SIERRA CROSSING PROFILE



**ULTRA-LOW  
STENT CROSSING  
PROFILE OF 0.039”<sup>1</sup>**



$\varnothing$  0.039”

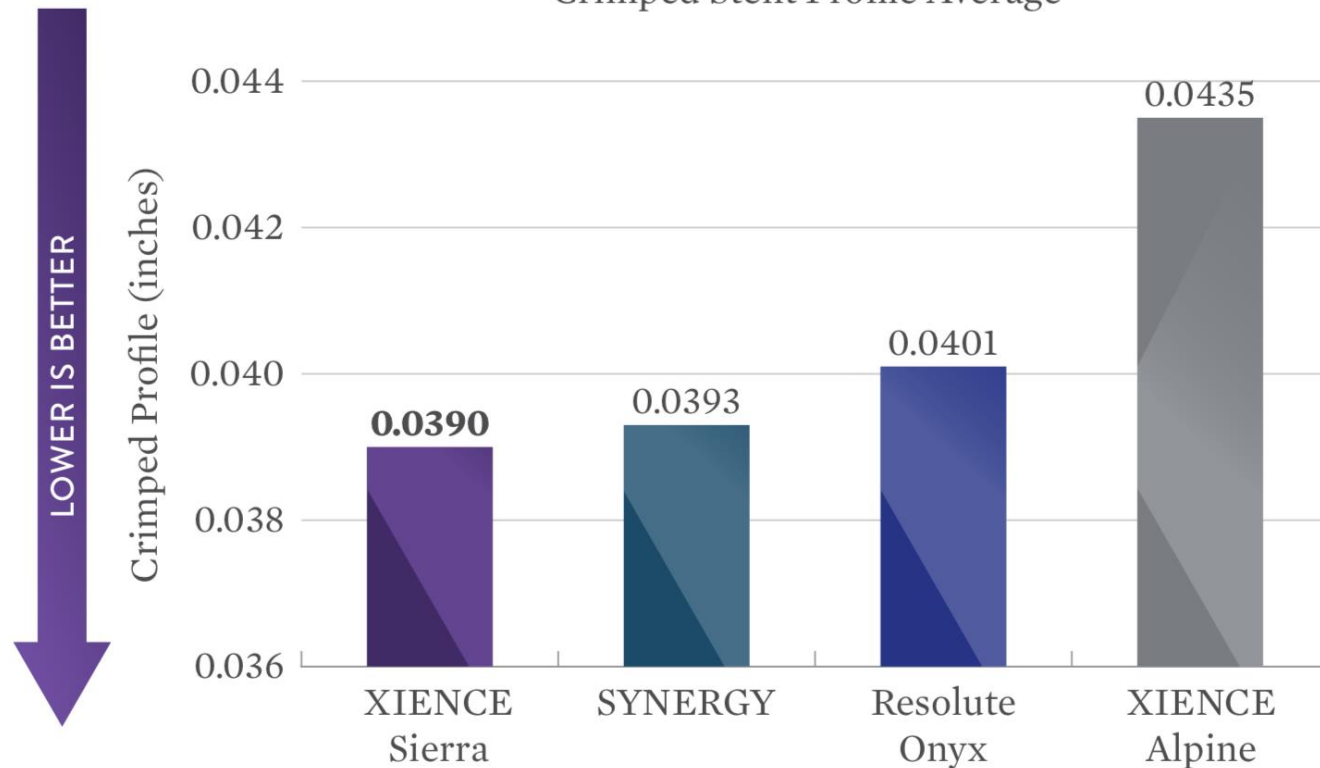
1. Test performed by and data on file at Abbott Vascular on (3.0 x 18 mm)

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Ultra low stent crimped profile of 0.0390”  
for crossing tight lesions enabled by the  
new stent design and balloon technology<sup>1</sup>

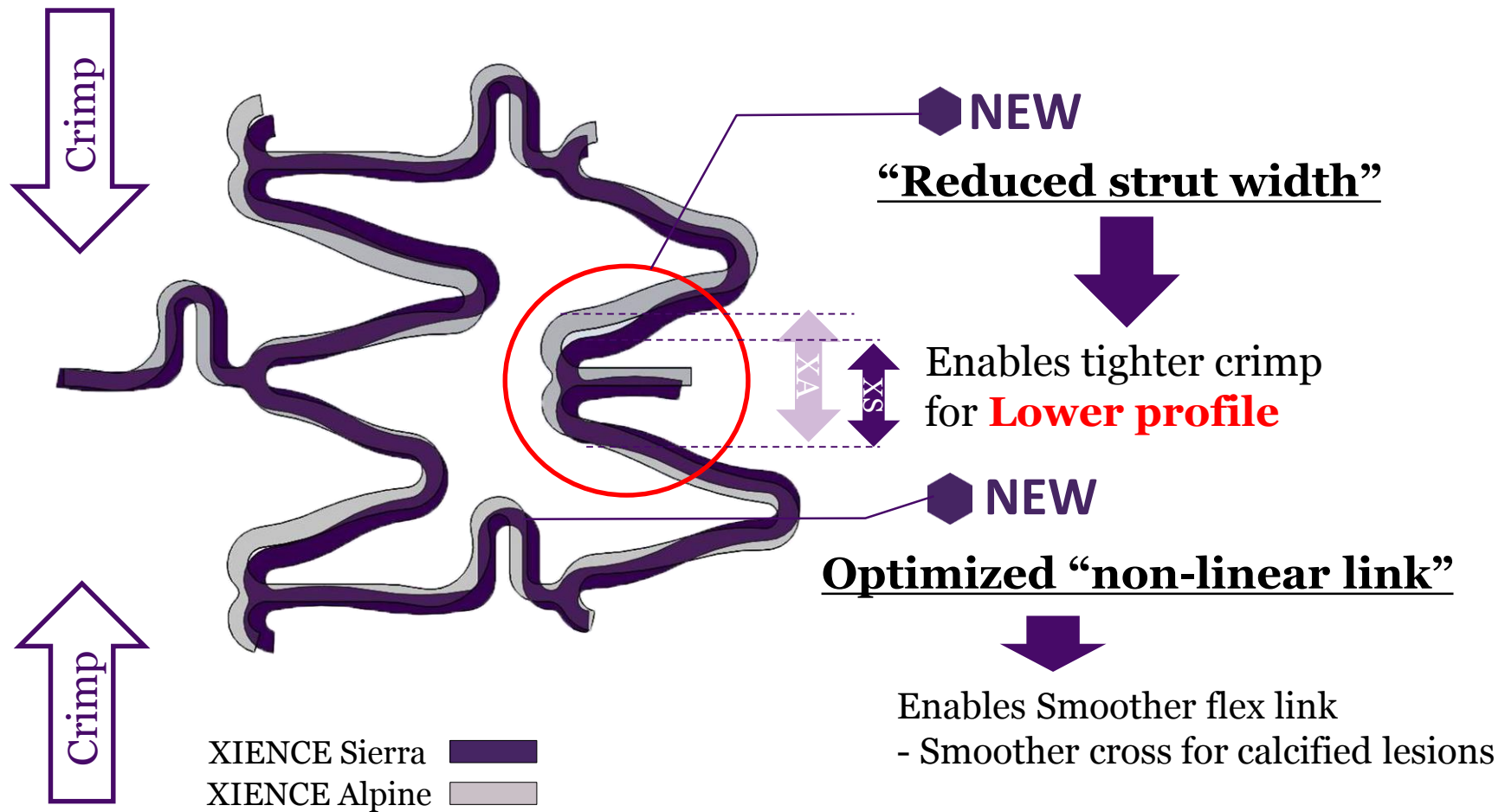
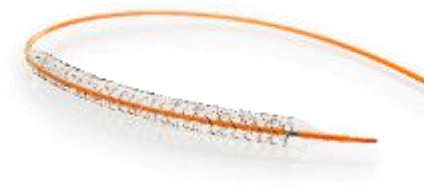


Crimped Stent Profile Average



# 1. Stent

## STENT DESIGN (6 CREST , 2.25~3.25MM) - REDUCE PROFILE



1. Data on file at Abbott.

## 2. Balloon

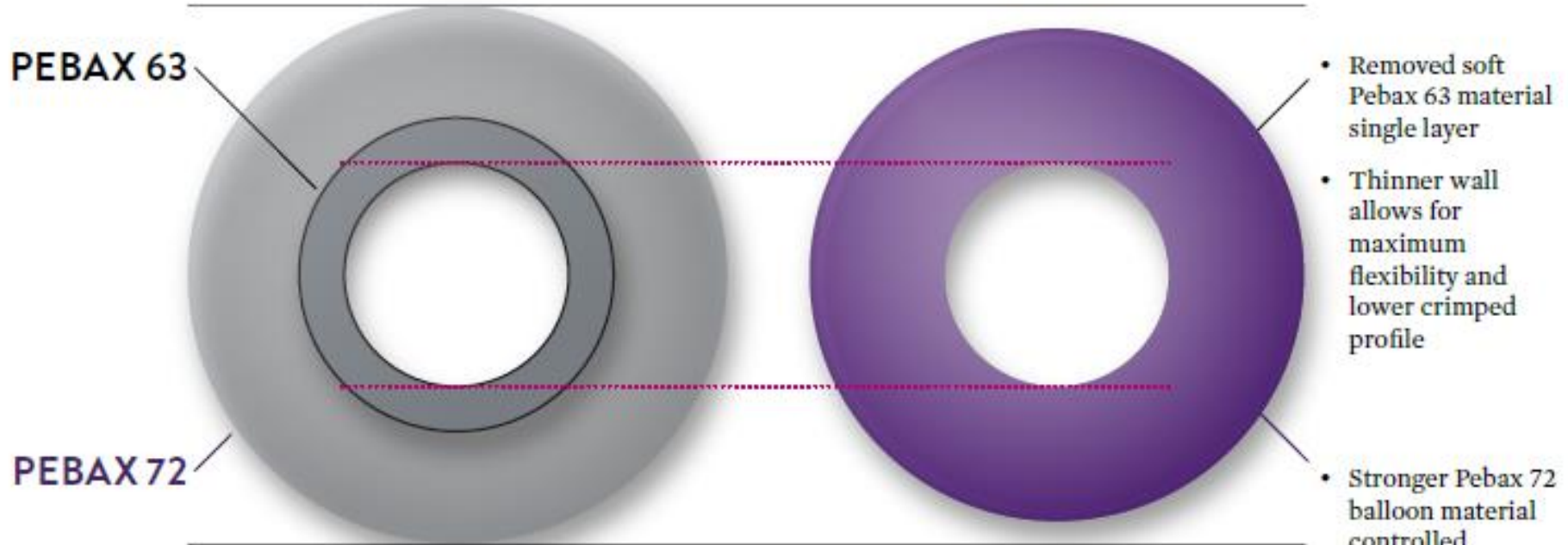
# THIN & SOFT BALLOON

XIENCE Sierra changed balloon (dual to single layer) further lowered crimped profile<sup>1</sup> for better crossing and improved flexibility in challenging anatomy



XIENCE Alpine Balloon

XIENCE Sierra Balloon



Dual layer



**Single layer**

(enable to be low profile)

**XIENCE Sierra<sup>®</sup>**



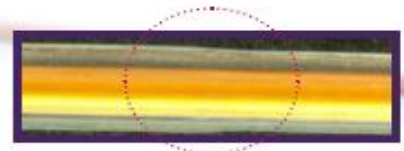
# 3. Catheter

## CATHETER TECHNOLOGY

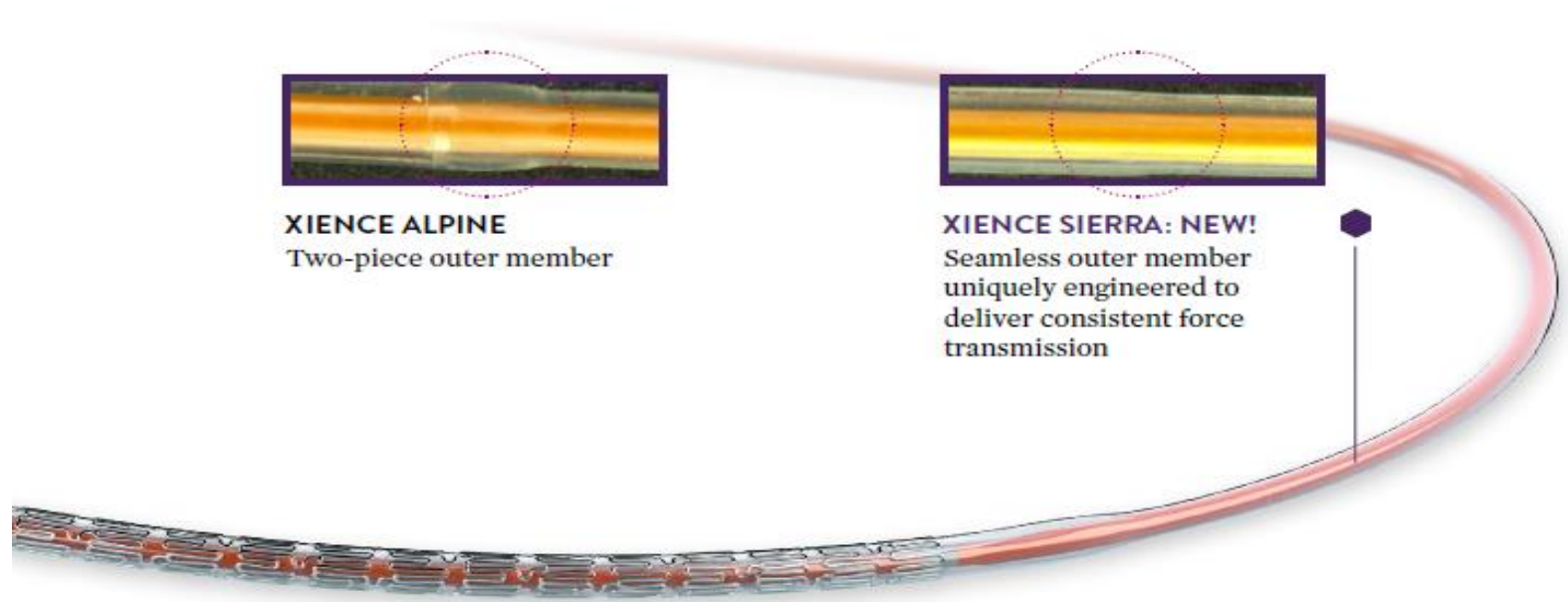
A single-piece outer member (→ consistent force transmission) has added pushability and trackability in complex PCI.



**XIENCE ALPINE**  
Two-piece outer member

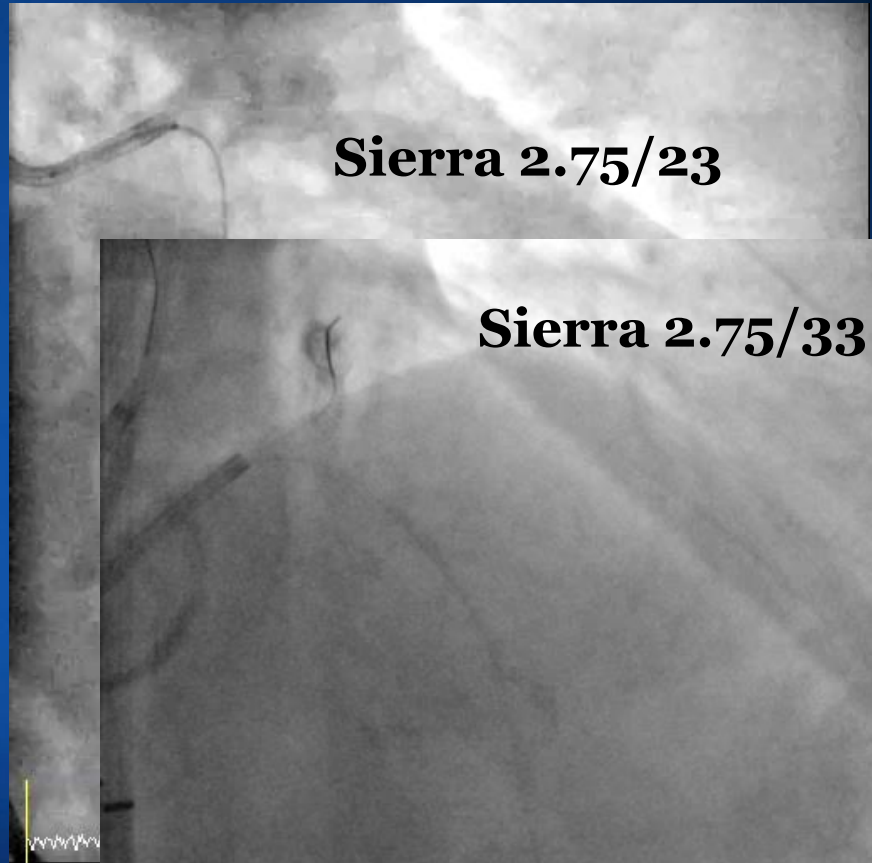


**XIENCE SIERRA: NEW!**  
Seamless outer member uniquely engineered to deliver consistent force transmission



Data on file at Abbott.

# Tortuous angulated LCx & diffuse long calcified lesions



# Essential of DES to successful complex PCI?

## 2. Overcome “Size-discrepancy”

Optimized DES for LM or very long lesions (large & long tapered vessels)



## 2. MAX EXPANSION LIMIT 5.5MM!



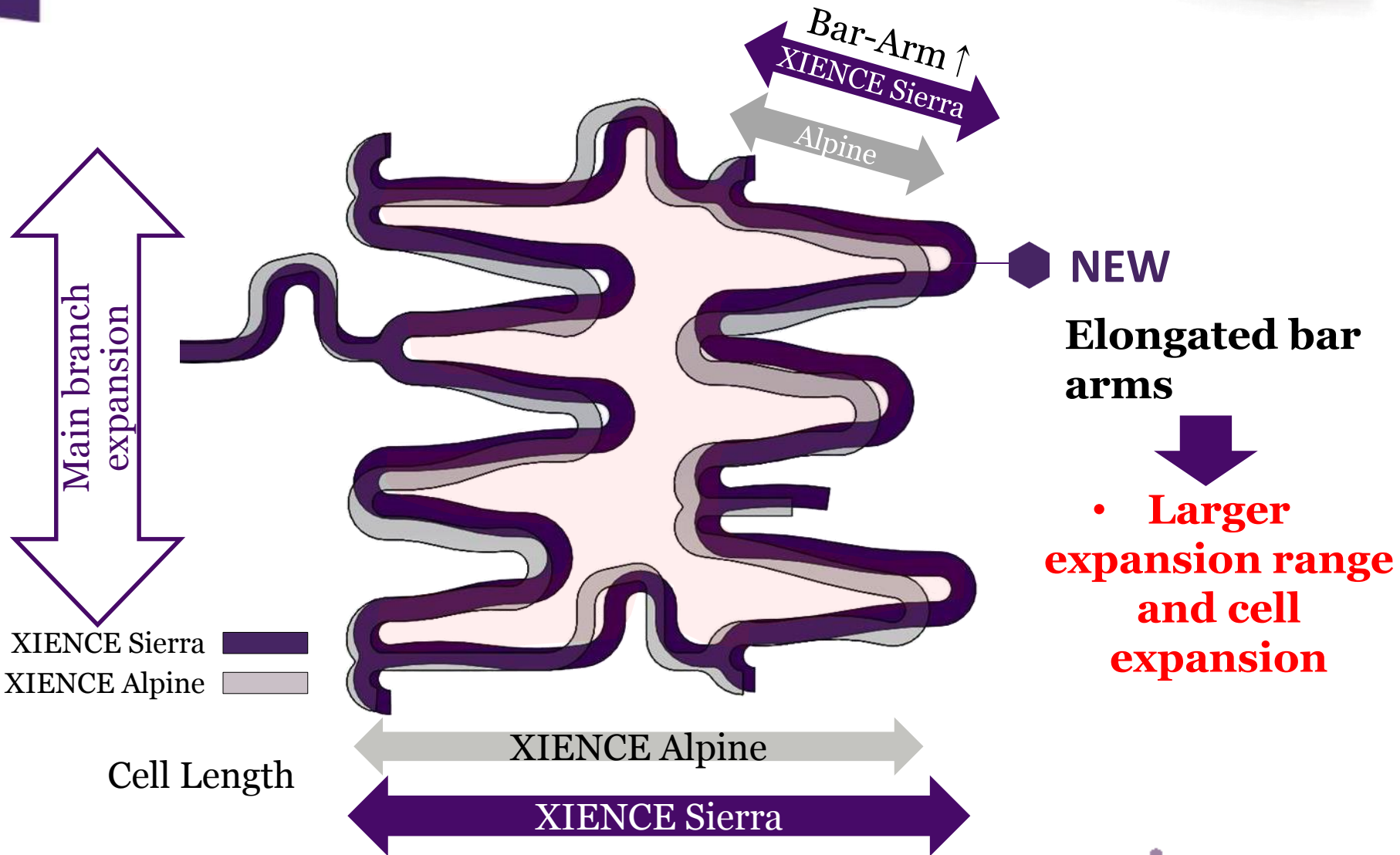
**UNIQUELY DESIGNED  
TO POST DILATE  
TO 5.5 MM<sup>1</sup>**



1. Maximum expansion for 3.5 mm and 4.0 mm

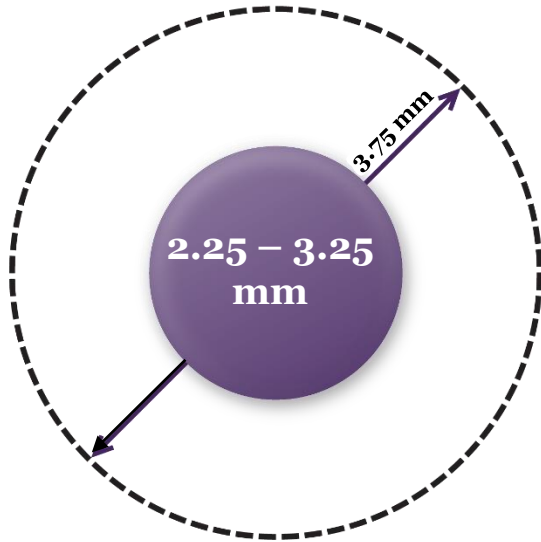
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# STENT DESIGN (9CREST, 3.5~4.0MM) -LARGE EXPANSION DIAMETER

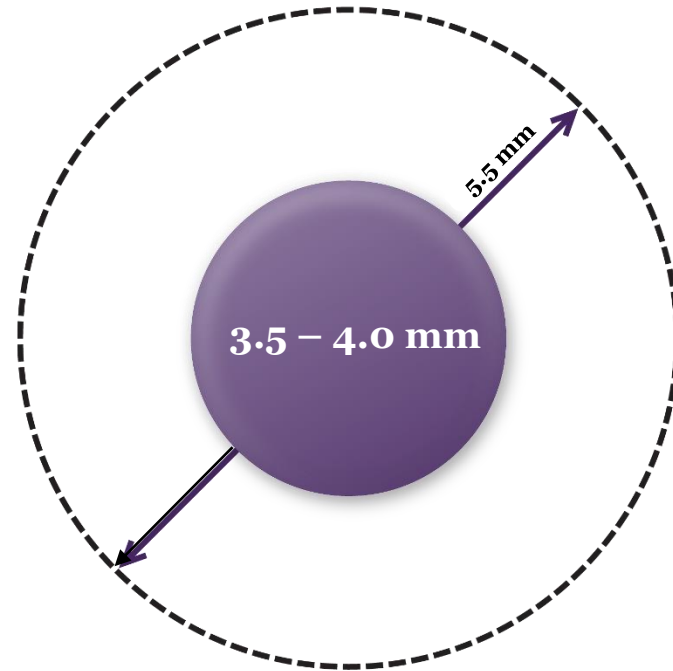


Greater dilation is good.  
However, some essential requirements are  
needed after maximal stent expansion

Sizes: 2.25 – 3.25 → **3.75 mm**

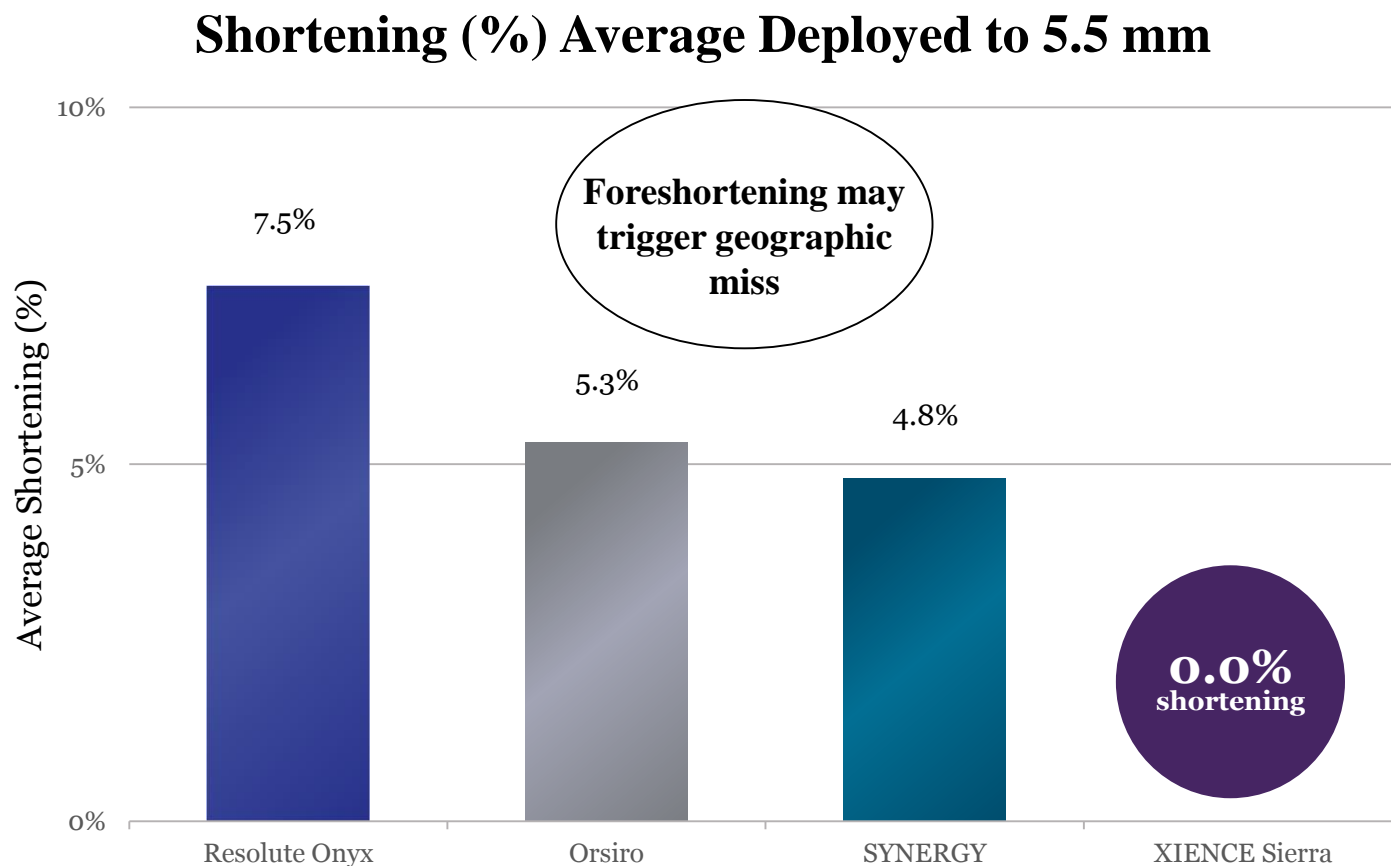


Sizes: 3.5 – 4.0 → **5.5 mm**



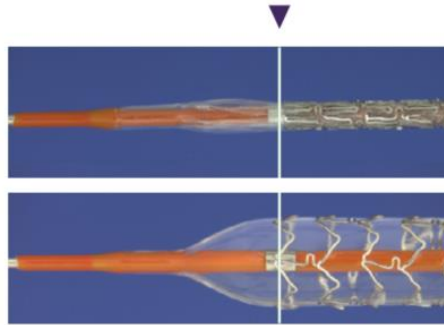
Data on file at Abbott. \*0% applies to the 4.0x18mm Sierra when post-dilated to 5.5mm

# 1. Unsurpassed precision in placement with **ZERO shortening** even at max expansion<sup>1</sup>

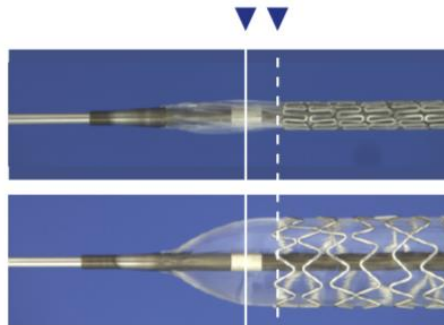
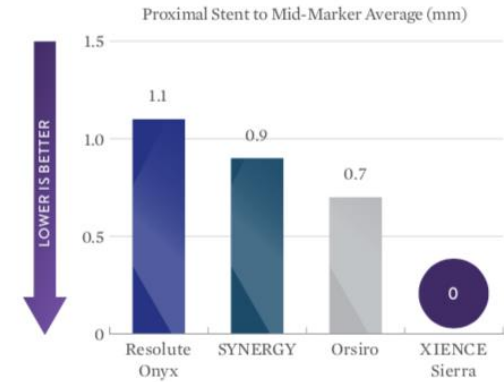
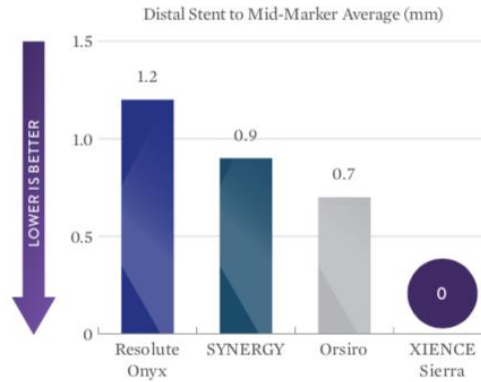


1. Test performed by and data on file at Abbott. XIENCE Sierra Everolimus Eluting Coronary Stent System (4.0 x 18 mm) n=5, SYNERGY Stent System (4.0 x 20 mm) n=5, Resolute Onyx Stent System (4.5 x 18 mm) n=5.

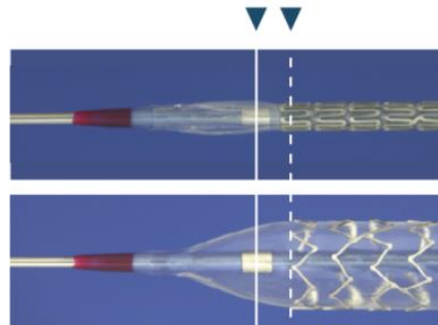
# 100% accurate mid-marker placement for precise stent placement<sup>1</sup>



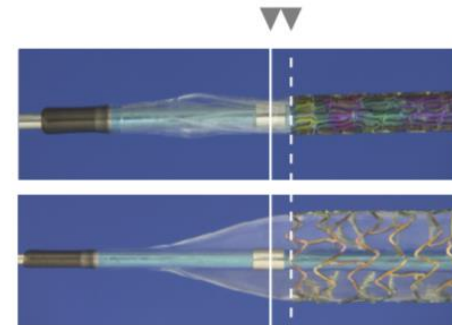
**XIENCE Sierra**  
3.0 x 18 mm



**Resolute Onyx**  
3.0 x 18 mm



**SYNERGY**  
3.0 x 20 mm



**Orsiro**  
3.0 x 18 mm

1. Data on file at Abbott. XIENCE Sierra Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY Stent System (3.0 x 20 mm) n=5, Resolute Onyx Stent System (3.0 x 18 mm) n=5, Orsiro (3.0 x 18 mm) n=5.

Information contained herein for presentation outside the U.S. only. Check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.

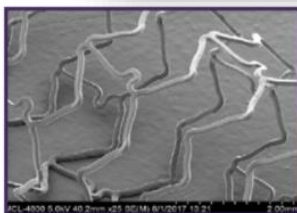
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# 2. Surface coating integrity at max expansion

DELIVER WITH CONFIDENCE

## Superior coating integrity even at max expansion<sup>1</sup>

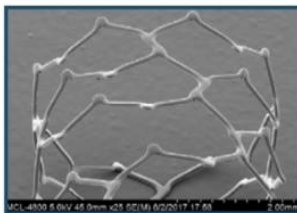


**XIENCE Sierra** (3.5 x 18 mm)  
25x magnification at max expansion of 5.5 mm



**XIENCE Sierra** (3.5 x 18 mm)  
150x magnification at max expansion of 5.5 mm

XIENCE Sierra coating remains intact at maximum post-dilatation expansion of 5.5 mm from 3.5 mm

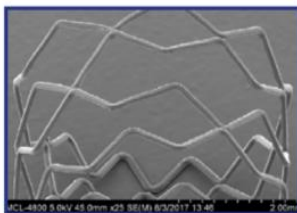


**SYNERGY** (3.5 x 20 mm)  
25x magnification at max expansion of 4.25 mm

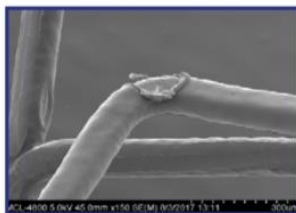


**SYNERGY** (3.5 x 20 mm)  
150x magnification at max expansion of 4.25 mm

SYNERGY coating shows multiple cracks with delamination at its max expansion of 4.25 mm from 3.5 mm



**Resolute Onyx** (3.5 x 18 mm)  
25x magnification at max expansion of 4.75 mm



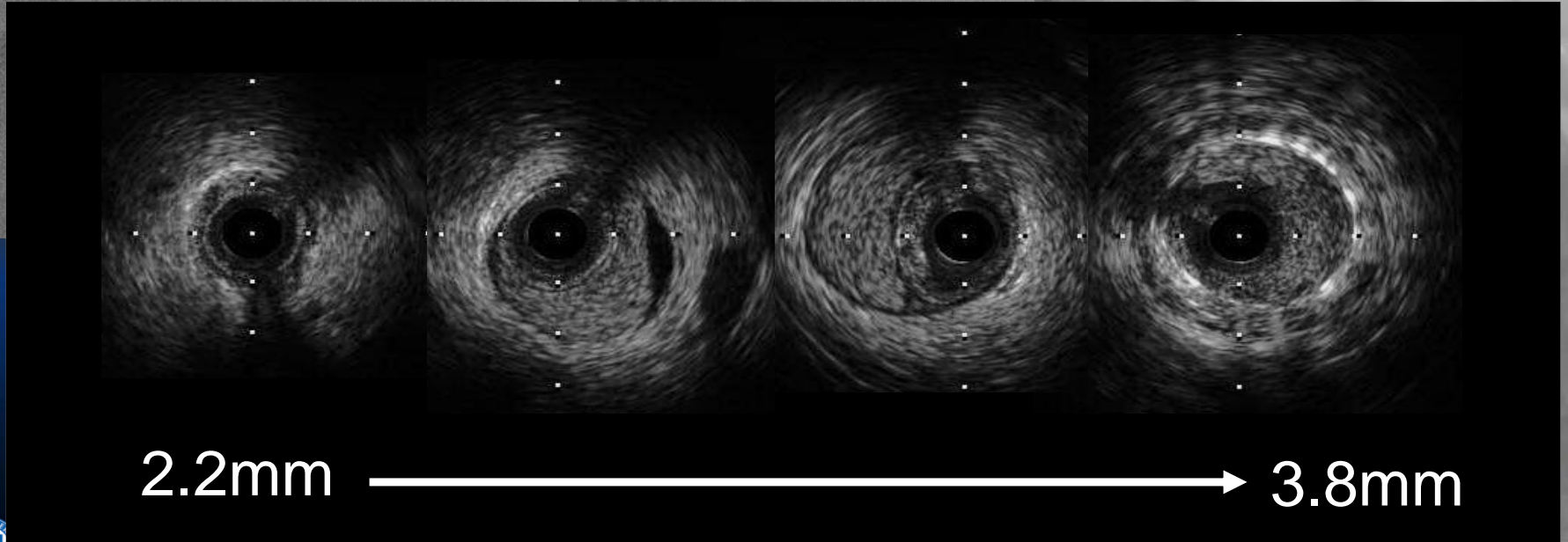
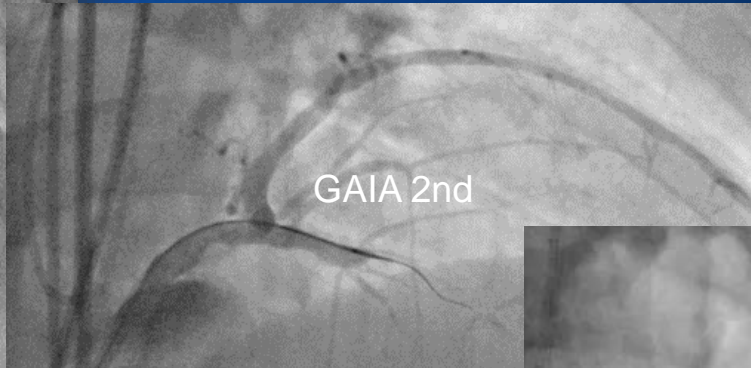
**Resolute Onyx** (3.5 x 18 mm)  
150x magnification at max expansion of 4.75 mm

Resolute Onyx coating peels off and shows exposed metal at its max expansion of 4.75 mm from 3.5 mm

1. Data on file at Abbott.

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# Long stent ISR CTO



2.2mm

3.8mm



# Relatively small DESs implanted for improving deliverability

Xience Sierra  
2.5 x 38mm

Xience Sierra  
2.25 x 18mm

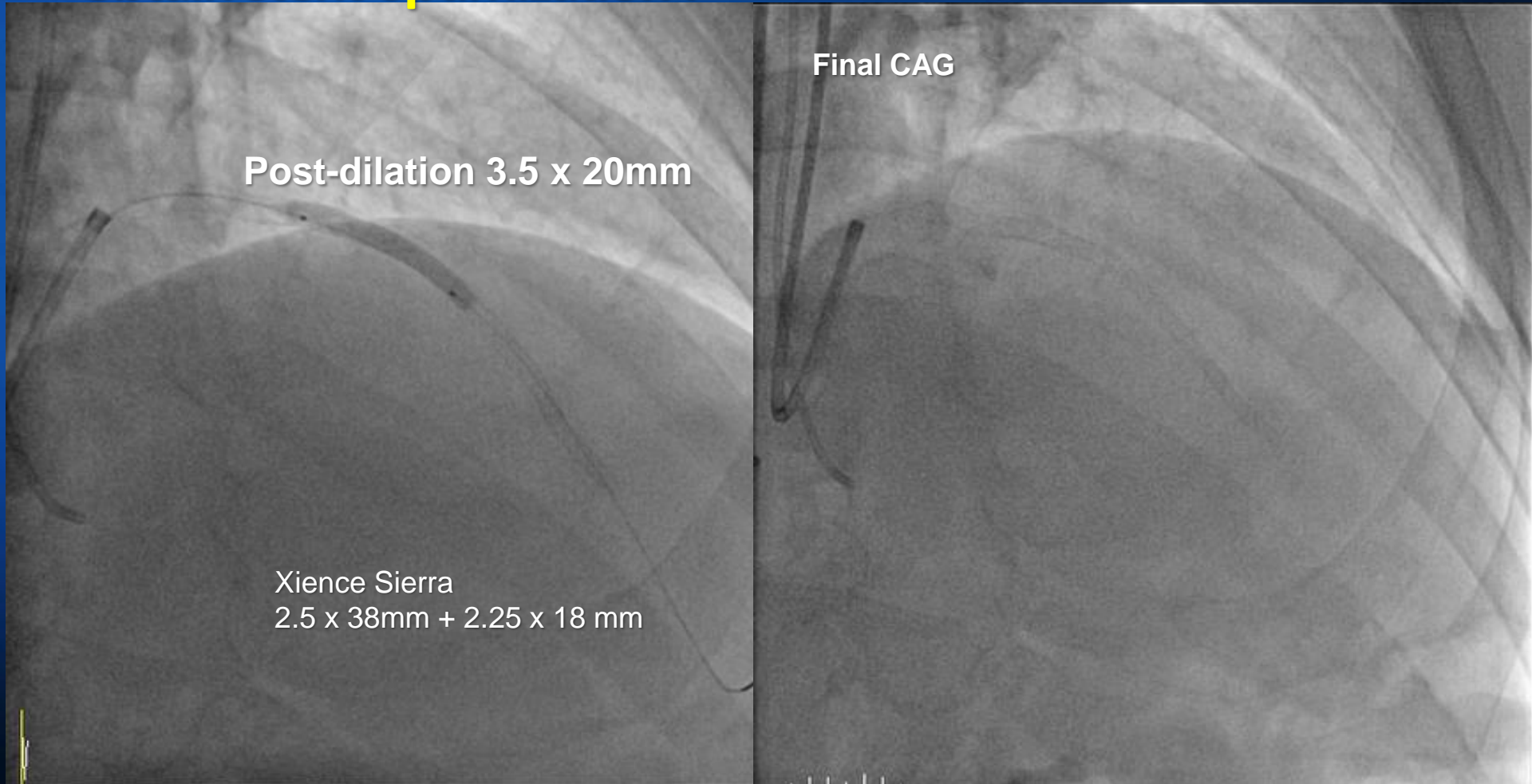
# Long tapered LAD lesion with big size difference

After a small-sized DES implantation, a bigger balloon for post-dilation was chosen to overcome size-discrepancy & obtain stent optimization .

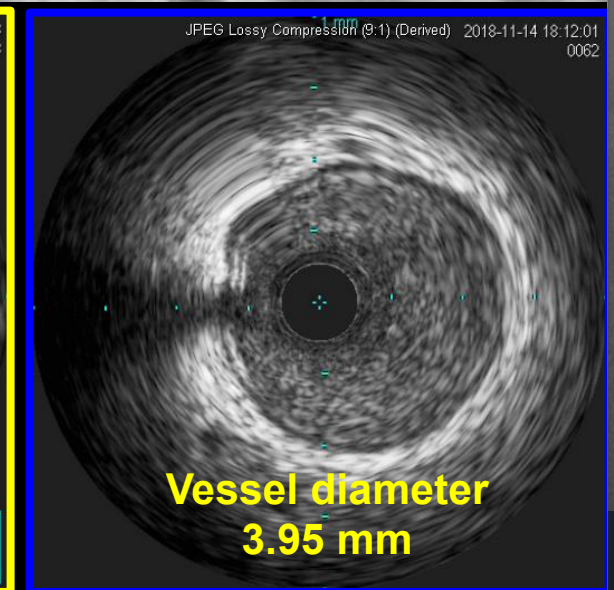
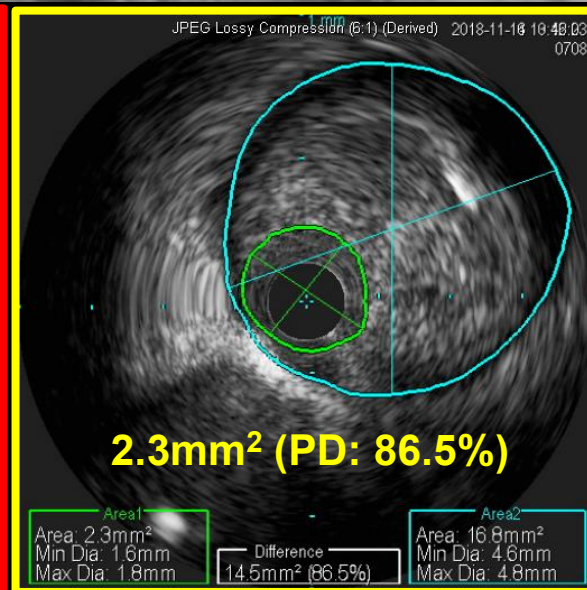
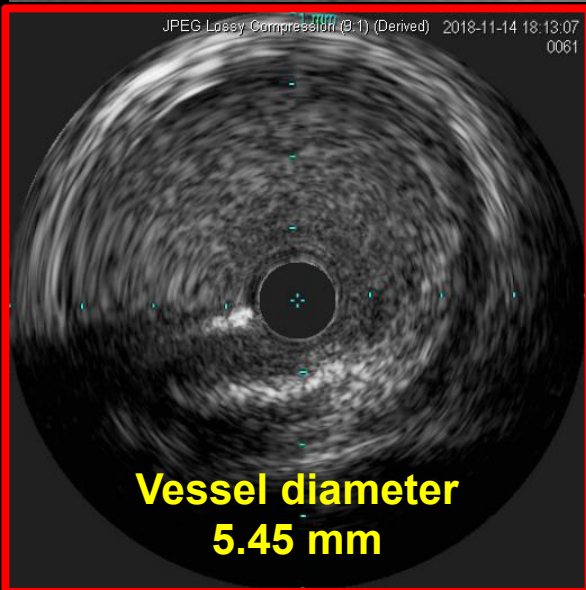
Post-dilation 3.5 x 20mm

Xience Sierra  
2.5 x 38mm + 2.25 x 18 mm

Final CAG



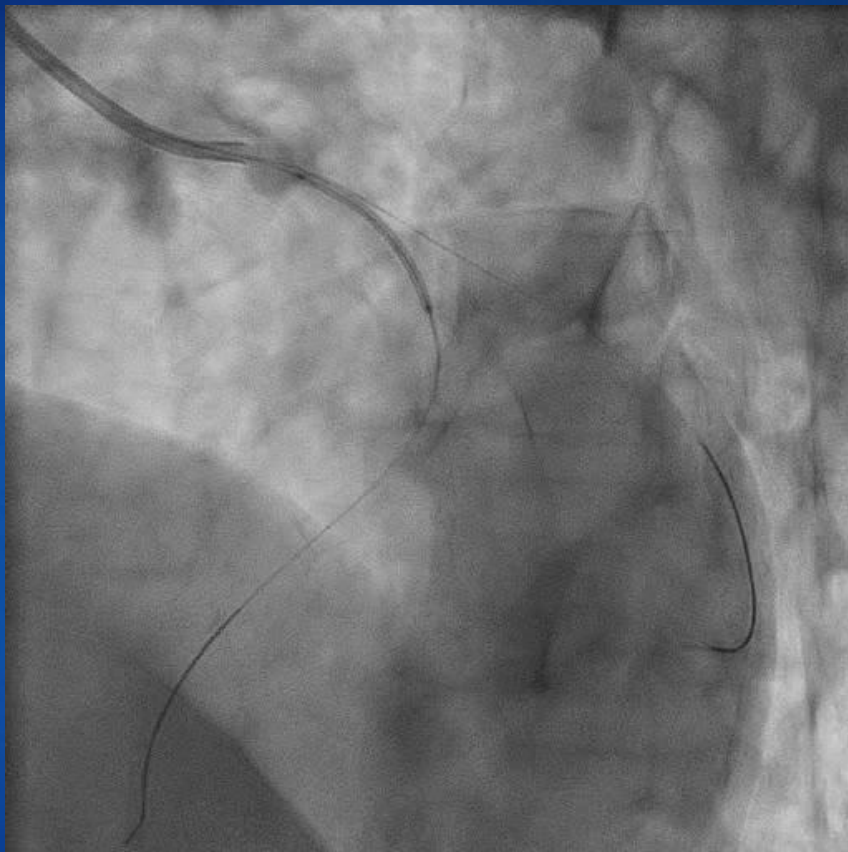
# True left main bifurcation lesion (MEDINA 1,1,0) extending proximal LAD



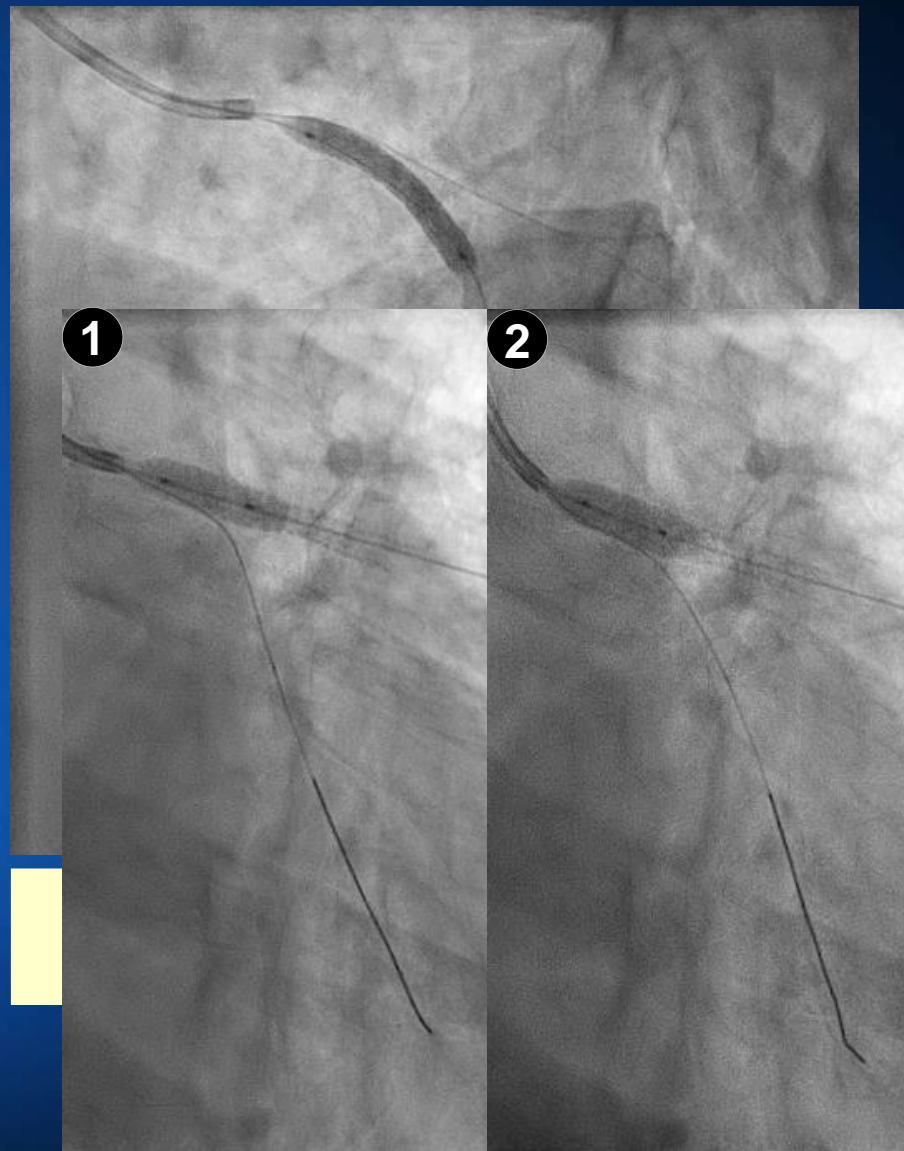
Proximal reference site

MLA site

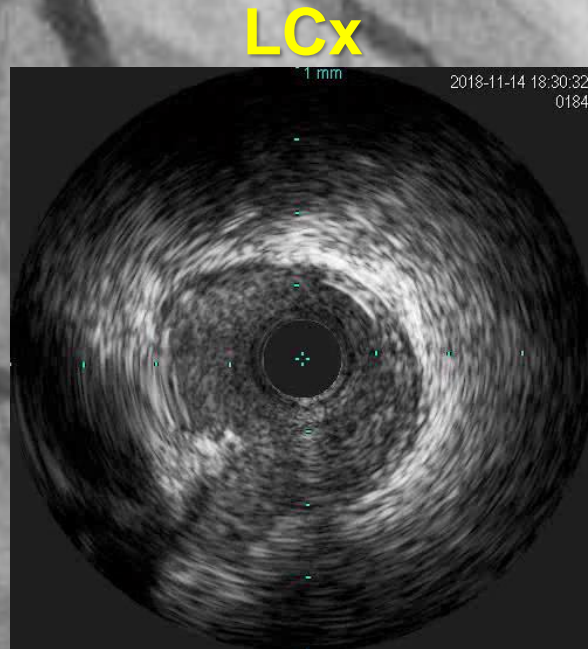
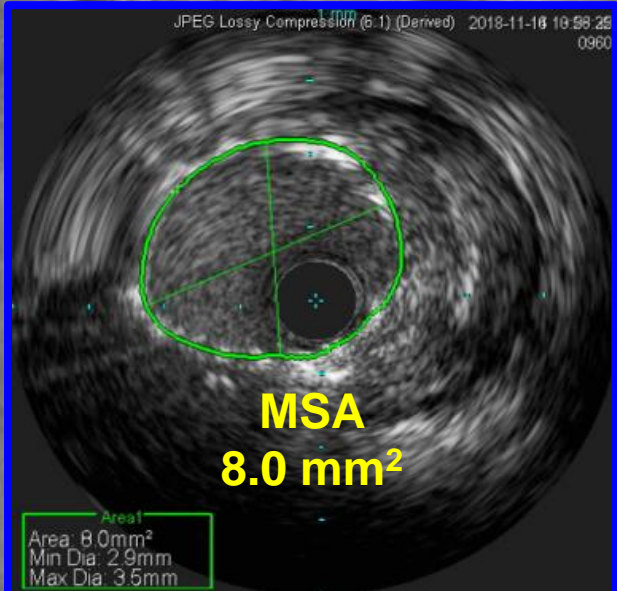
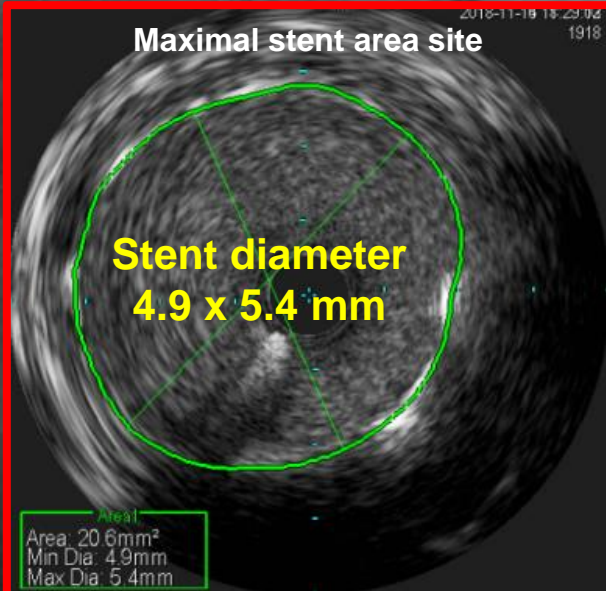
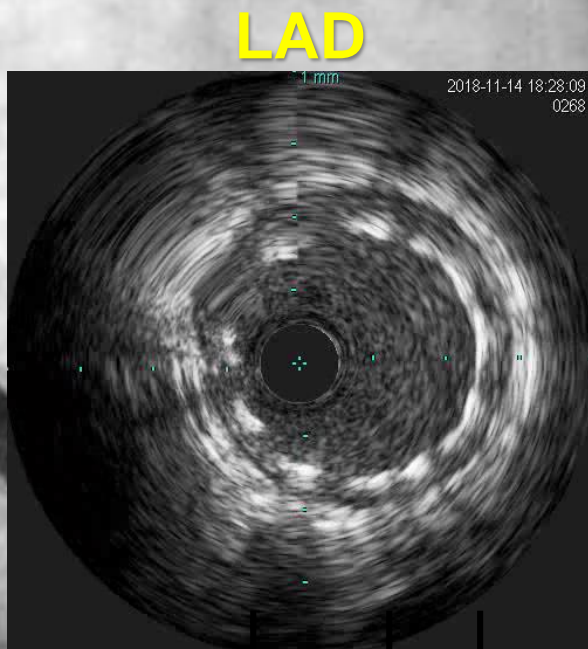
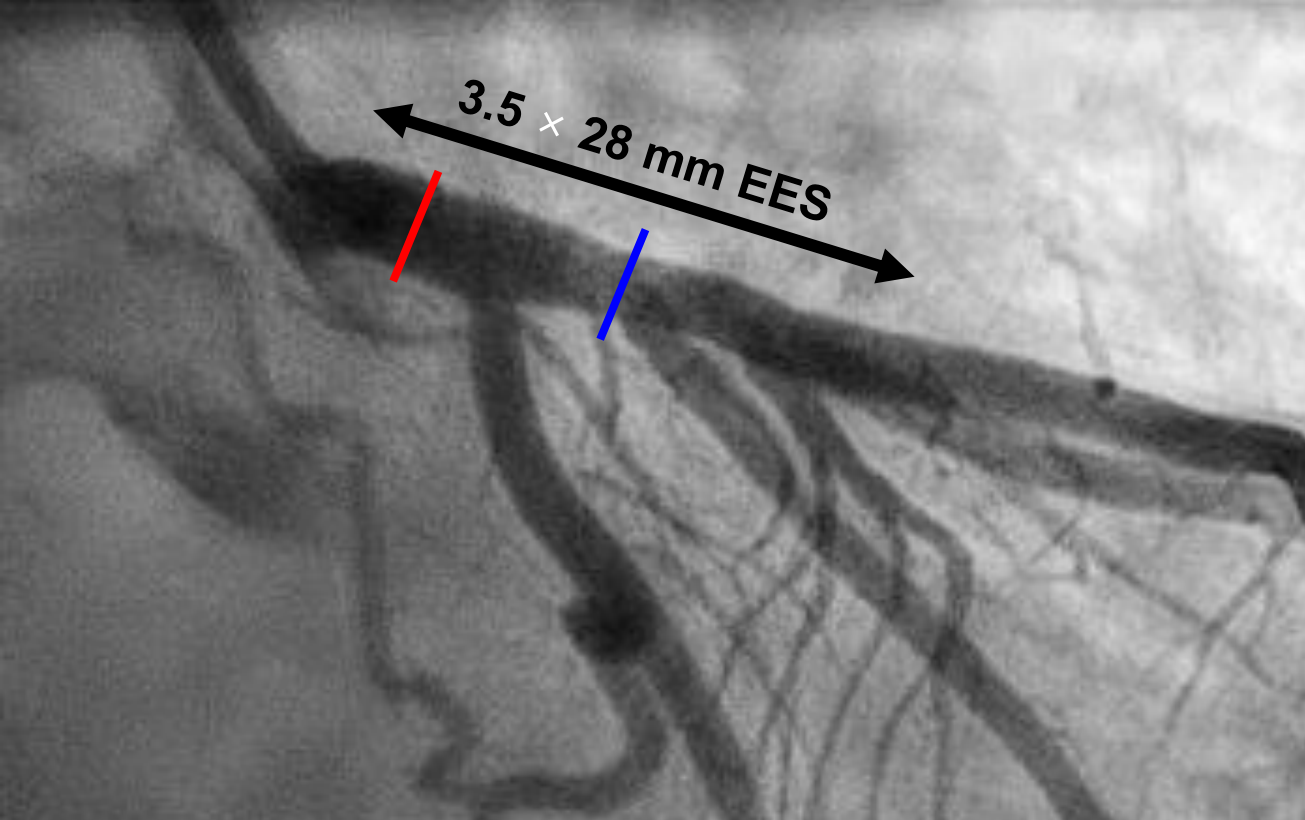
Distal reference site



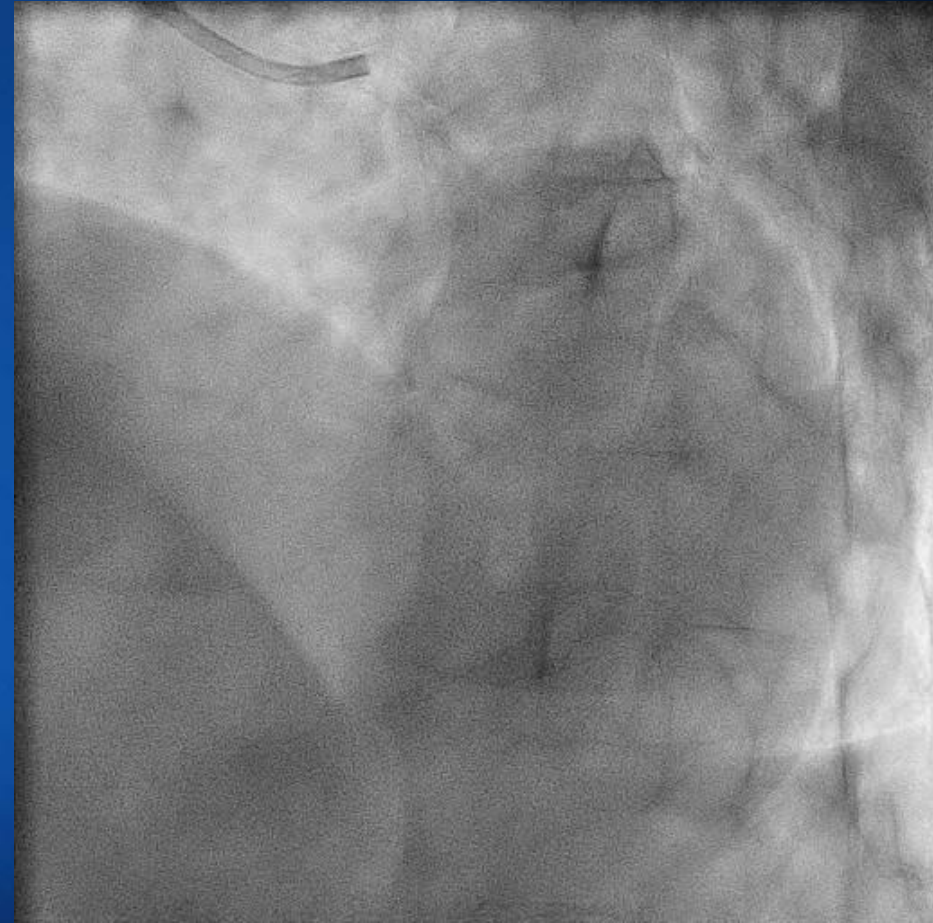
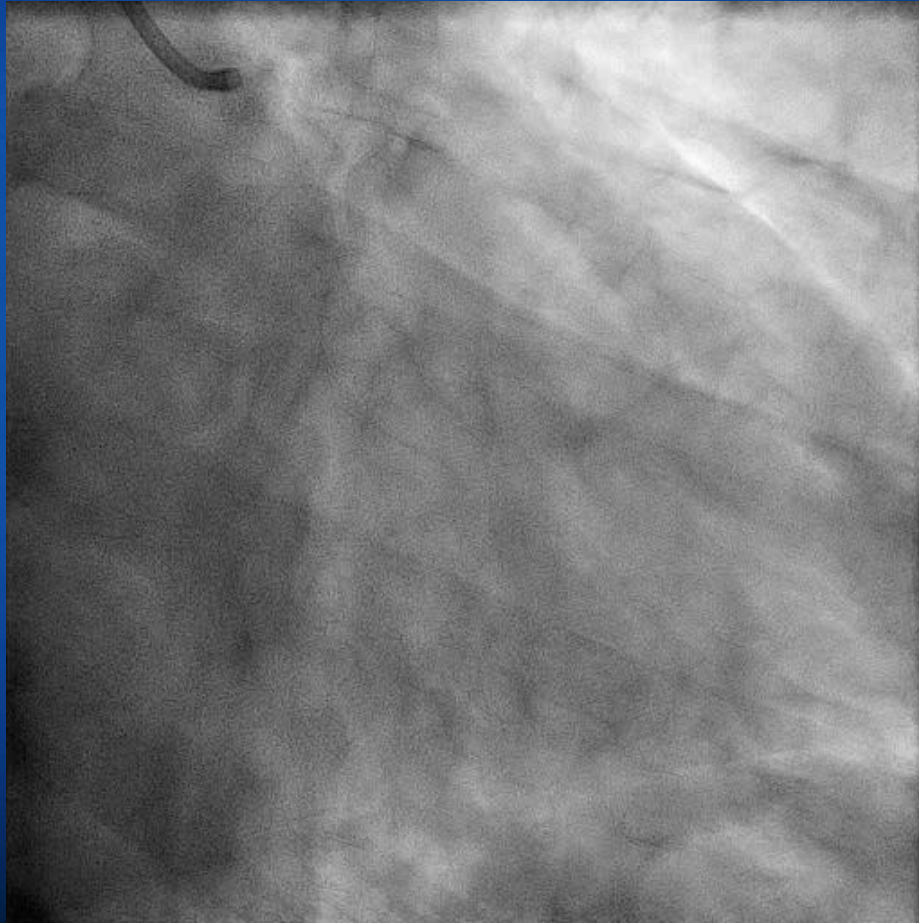
Direct stenting with **3.5 x 28 mm**  
**XIENCE Sierra** from LM shaft to pLAD



Postdilation with a **5.0 x 12 mm NC**  
**balloon** after side brance rewiring



# Successful IVUS-guided stent optimization via left snuffbox approach



**Final CAG**

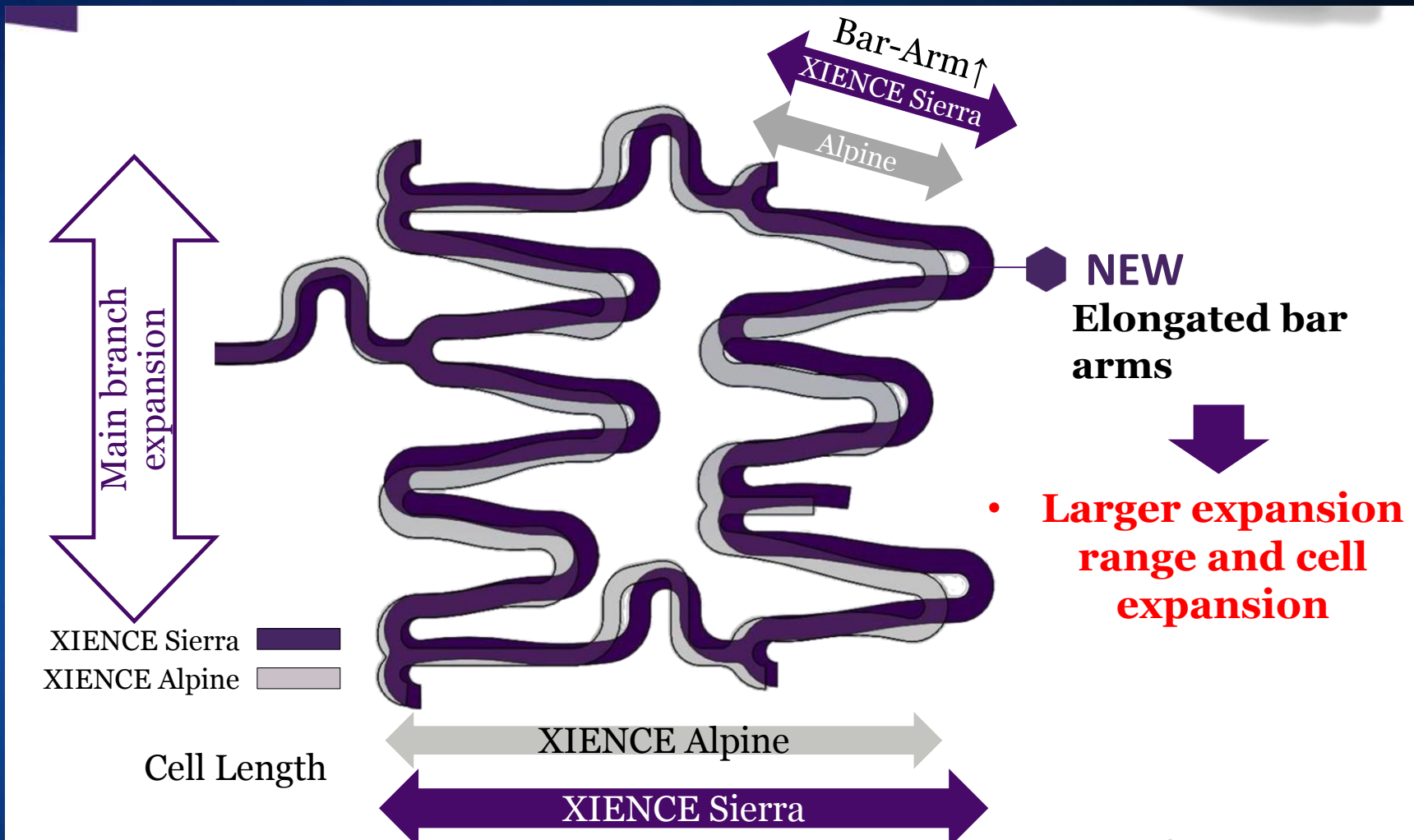




# Essential of DES to successful complex PCI?

3. Easy rewiring & access to side branch after stenting in bifurcation lesions





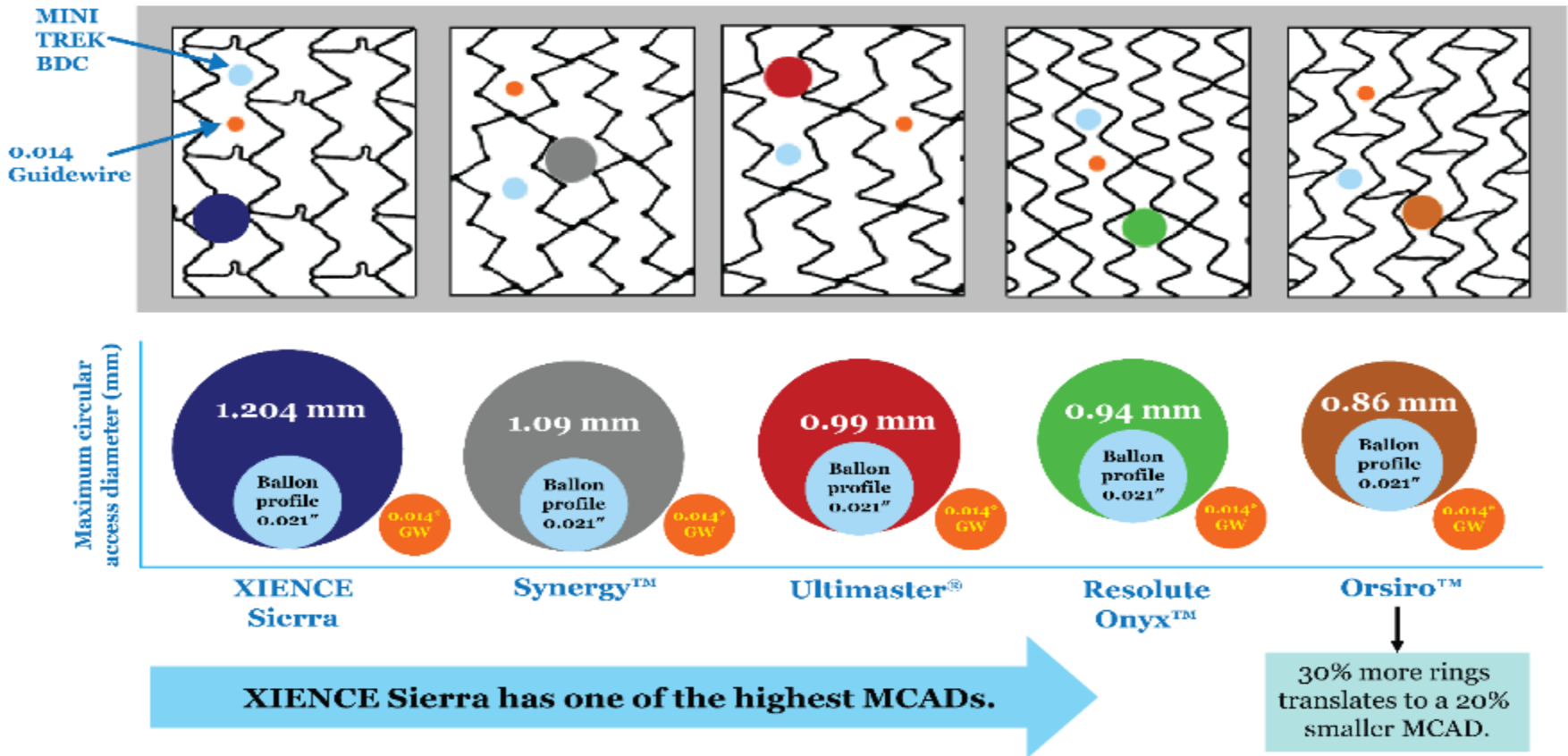
## Unique stent design of Sierra

- **Easy access for side branch**
- **Optimized stents for various bifurcation techniques**

# SIDE BRANCH ACCESS



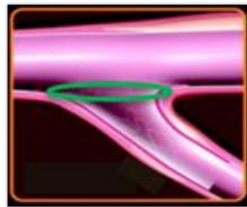
High MCAD (**Maximum circular Access diameter**) of XIENCE Sierra provides better side branch access



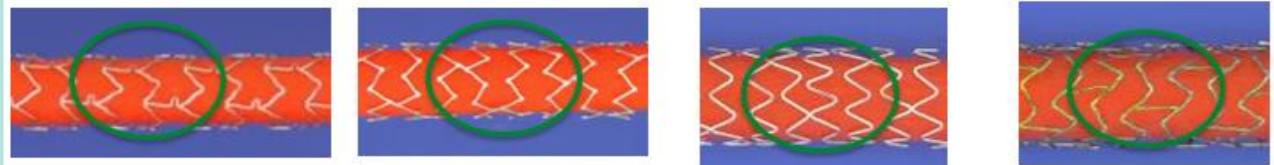
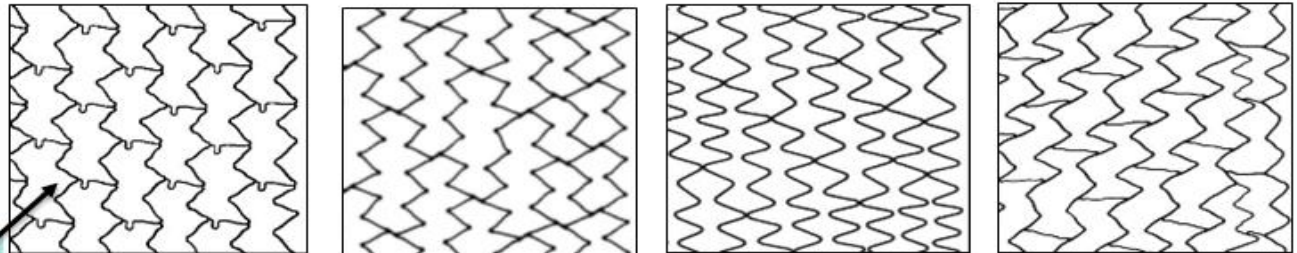
# MATAL-TO-ARTERY RATIO



**XIENCE sierra has a smaller metal-to-artery ratio, allowing better side branch access**



Maximal spacing between rings and least amount of metal in the vessel for minimal occlusion of SB



**Metal-to-artery ratio**  
(Probability of GW crossing =  $100 - [\text{metal-to-artery}]$  ratio)

<b>XIENCE</b> (Peak-to-valley) 10.4%	<b>Synergy</b> (Peak-to-peak offset) 14.0%	<b>Resolute Onyx™</b> (Peak-to-peak) 14.52%	<b>Orsiro™</b> (Mid-strut link) 12.28%
--	--	---	--

More rings translates to higher M/A ratio.

SB: Side branch; GW: Guidewire; M/A ratio: Metal-to-artery ratio.  
Data on file at Abbott. Photos on file at Abbott.

# Superior side branch accessibility with workhorse diameter (3 mm): ideal to treat bifurcation



## 3.0 mm XIENCE Sierra tested highest in side branch accessibility for 2.5 mm side branch opening

## 3.0 mm XIENCE Sierra tested highest in side branch accessibility for 3.0 mm side branch opening

**XIENCE Sierra**  
1.67 mm<sup>1</sup>

**SYNERGY**  
1.46 mm

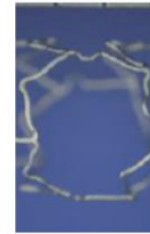
**Resolute Onyx**  
1.45 mm

**XIENCE Sierra**  
2.04 mm<sup>1</sup>

**Resolute Onyx**  
1.64 mm

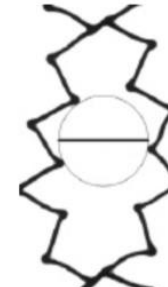
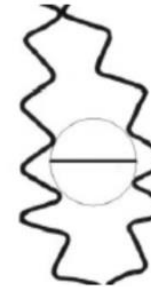
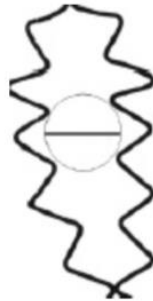
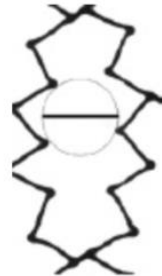
**SYNERGY**  
1.62 mm

1. Open up 3.0 mm stent's side branch with a 2.5 mm dilatation balloon



1. Open up 3.0 mm stent's side branch with a 3.0 mm dilatation balloon

2. Measure the maximum circular side branch area diameter



2. Measure the maximum circular side branch area diameter

1. Tests performed by and data on file at Abbott. XIENCE Sierra Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY Stent System (3.0 x 20 mm) n=5, Resolute Onyx Stent System (3.0 x 18 mm) n=5.

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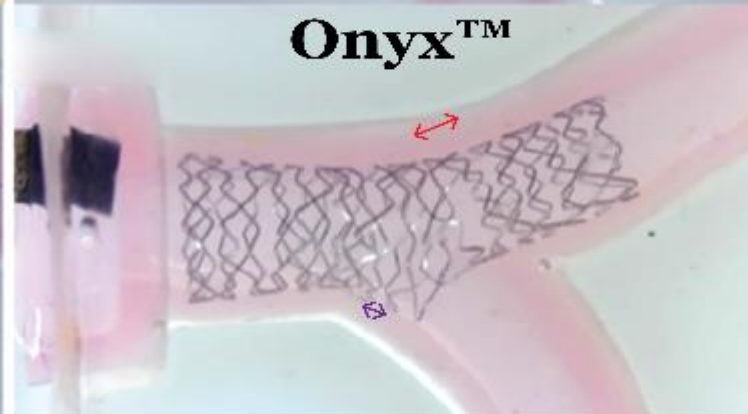
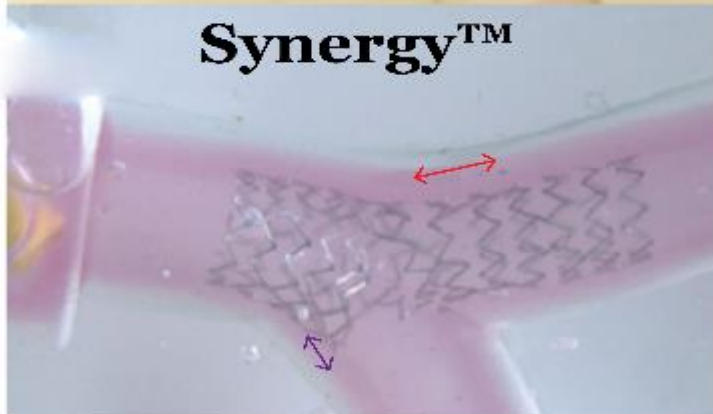
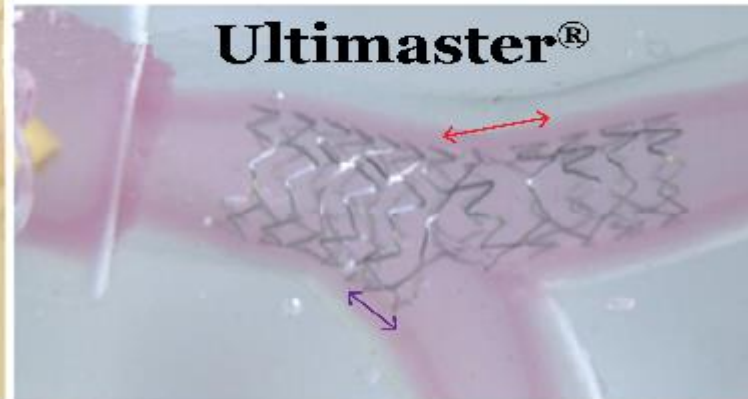
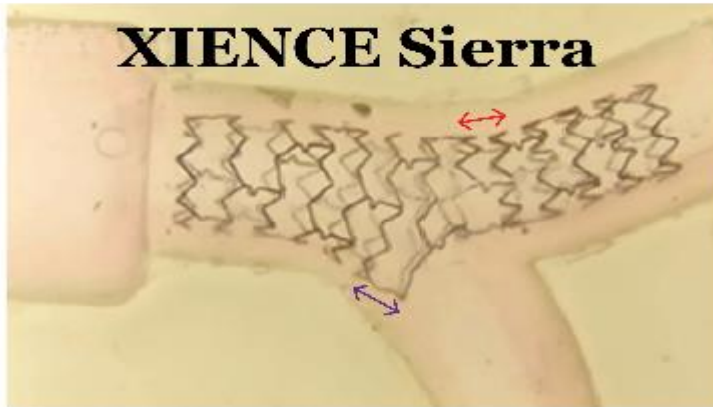
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# SIDE BRANCH ACCESS



The 3 link design of XIENCE Sierra assures better scaffolding and lesser stent deformation

## Lesser MB stent deformation with 3-link



# RCA bifurcation

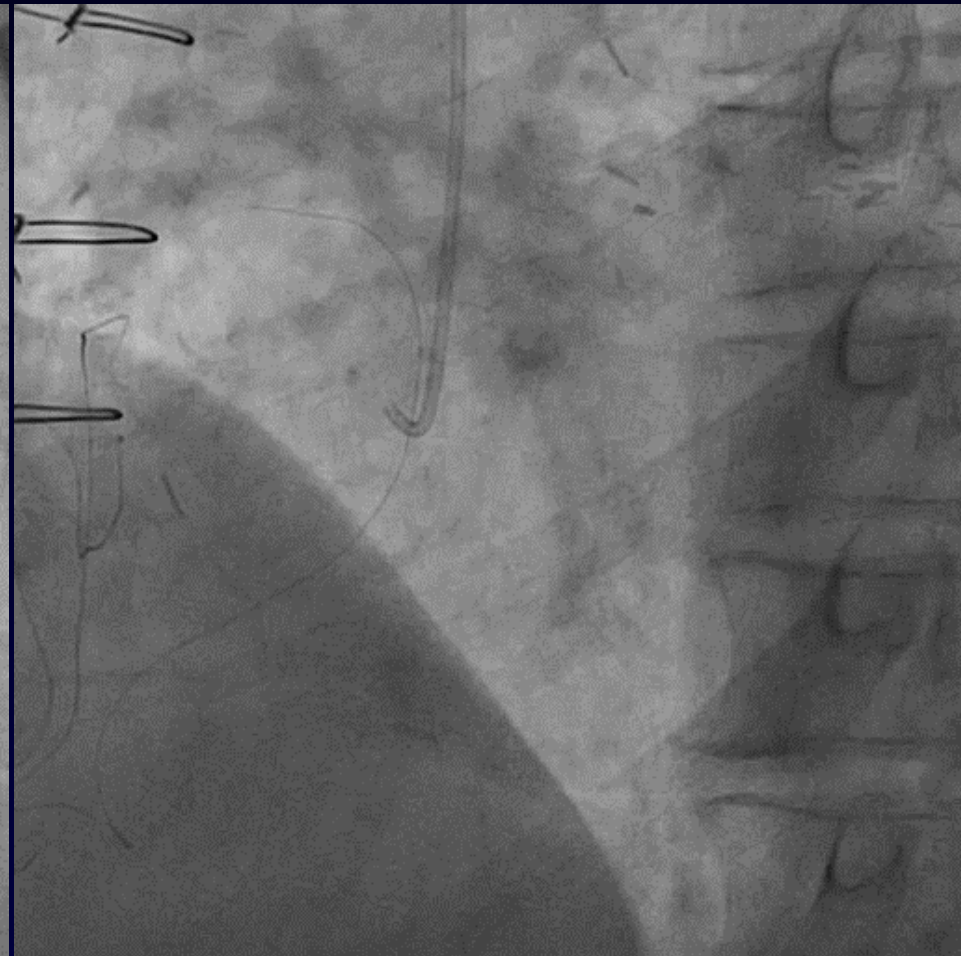
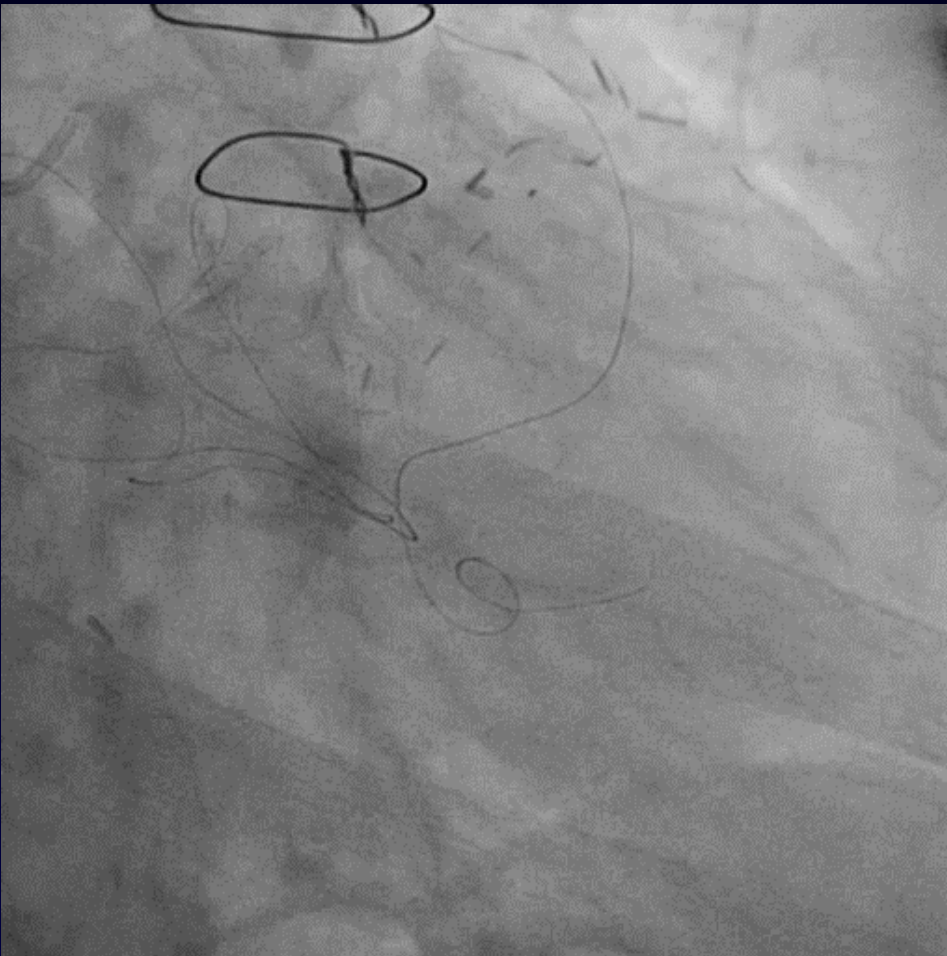


# Workhorse DESs for complex lesions

- **M / 77**
- **Diagnosis, Stable angina, s/p CABG due to 3VD**
- **PHx**
  - **Stable angina**
  - **CABG due to 3-vessel diseases (2001-6-13)**  
5 grafts (1. LIMA – dLAD, 2.3. Ao - dRCA, PL br. c SVG, 4.5. Ao - Dg, OM br c SVG)
- **MIBI : Moderate sized, moderate degree, partial reversibility in the anterior wall**



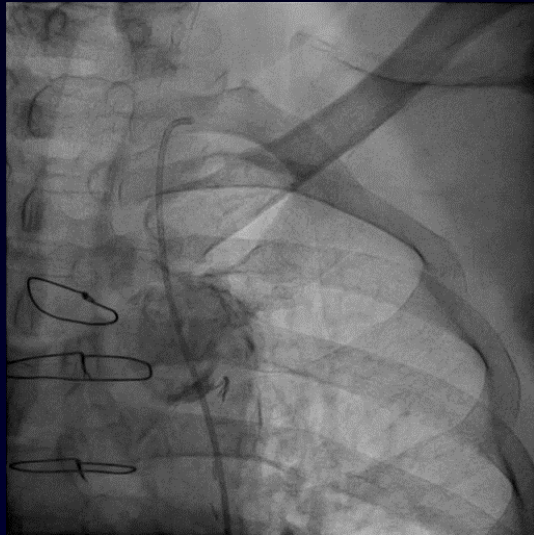
# Coronary angiography (2019-03-27)



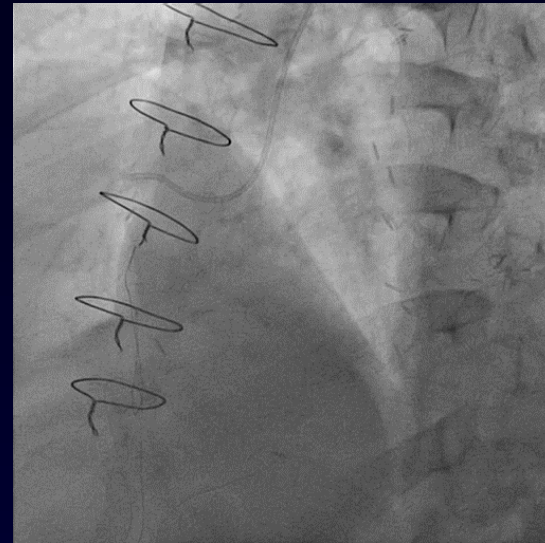
- CTO of p-LAD c severe calcification & fighting flow
- CTO of d-LCX c bridging collateral

- CTO of pRCA

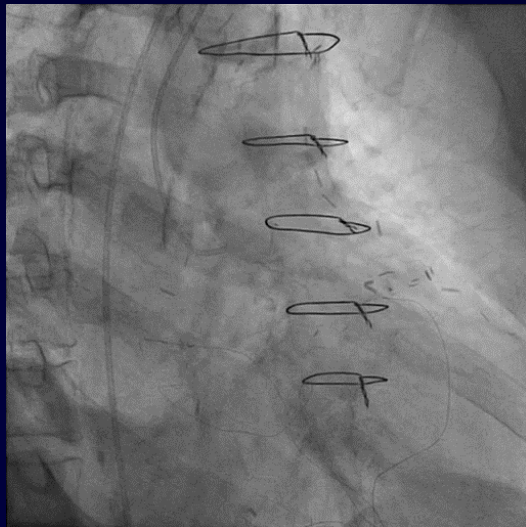
# Graft angiography (2019-03-27)



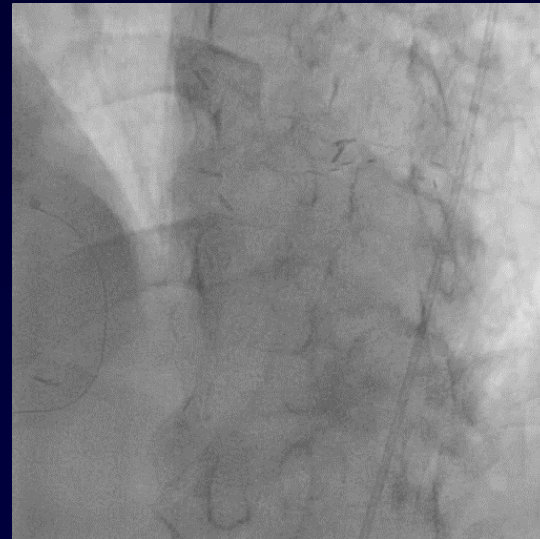
- Total occlusion of LIMA to d-LAD



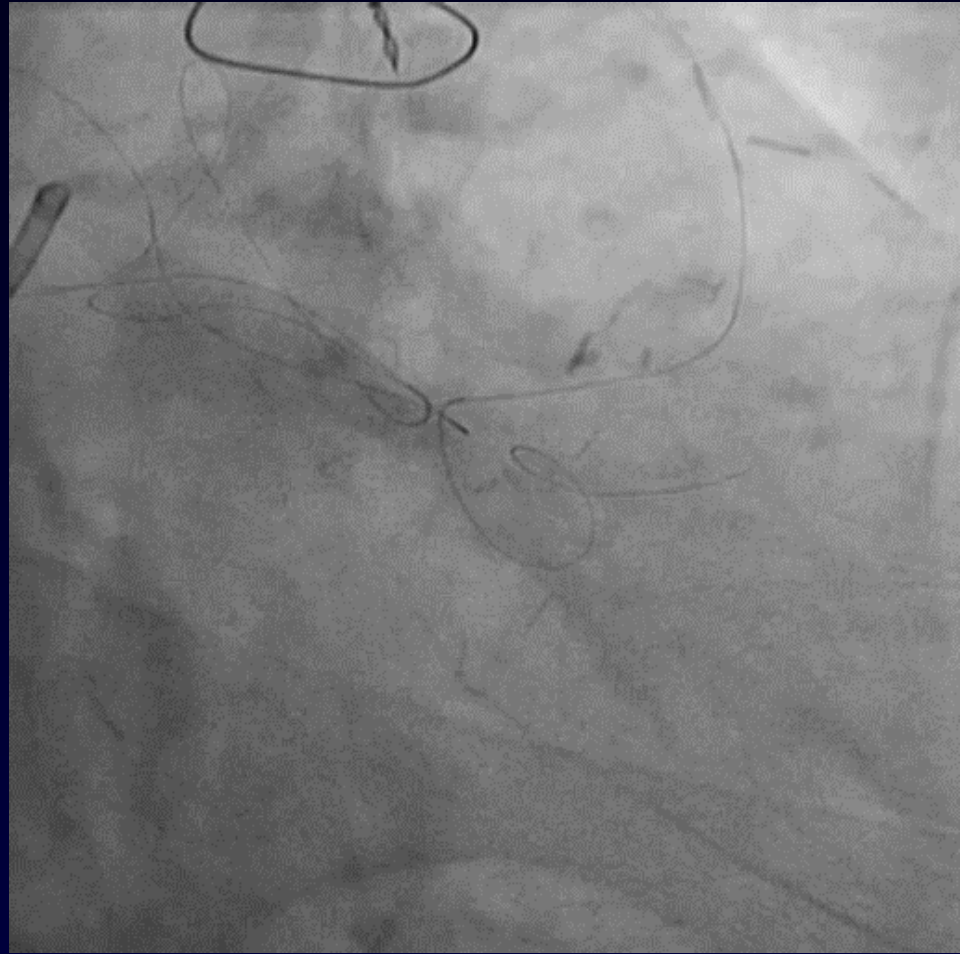
- Patent aorta to d-RCA to PL br. c SVG



- Patent aorta to DG to OM c SVG



# PCI of de-novo LAD-CTO

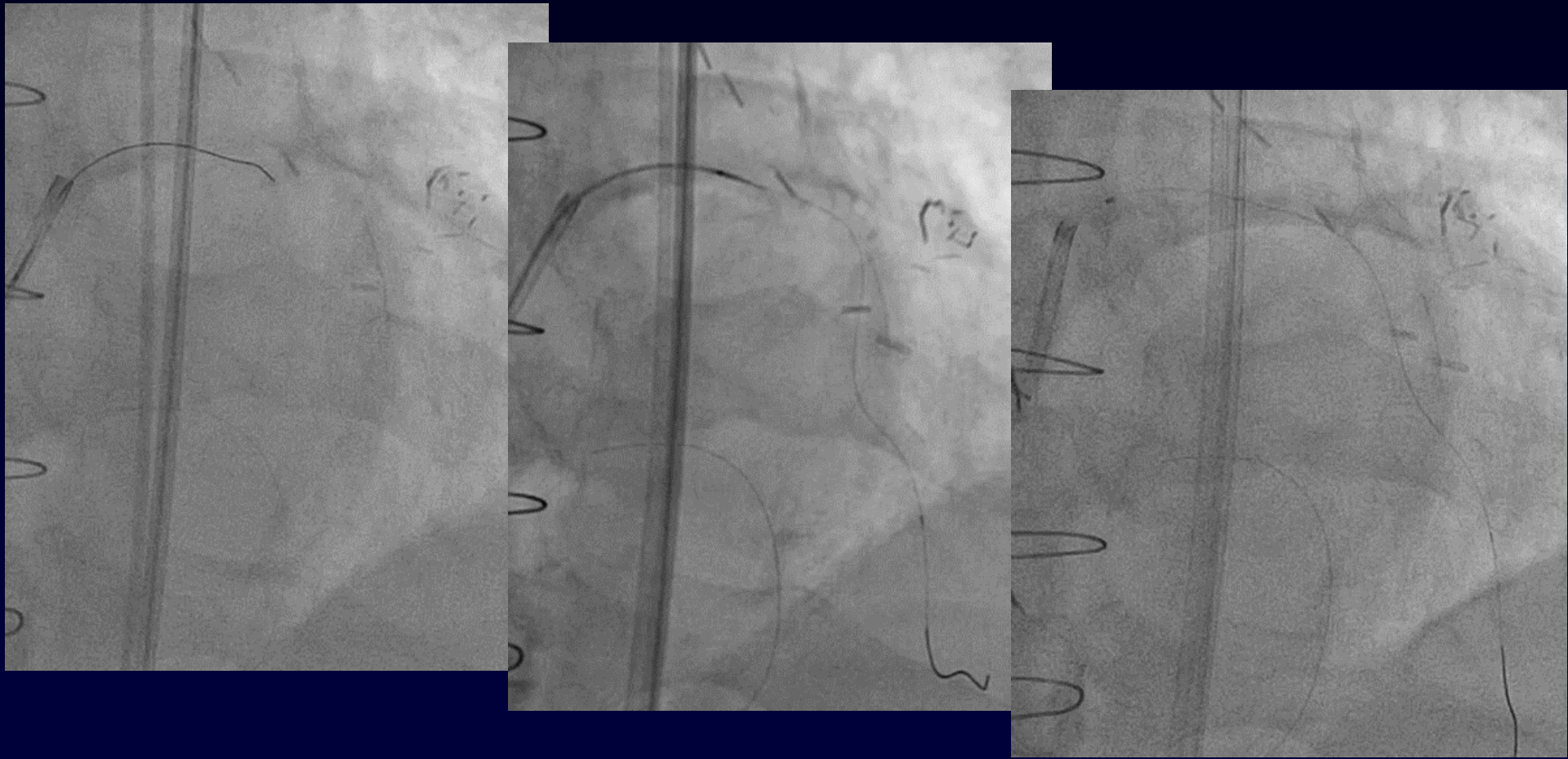


Nearly connected with de-novo LAD lesion, ***“Functional LAD CTO”***

- Lt guiding : XB3.5 7-Fr
- Contralateral Graft angiography – diagnostic catheter

# 1. Wiring

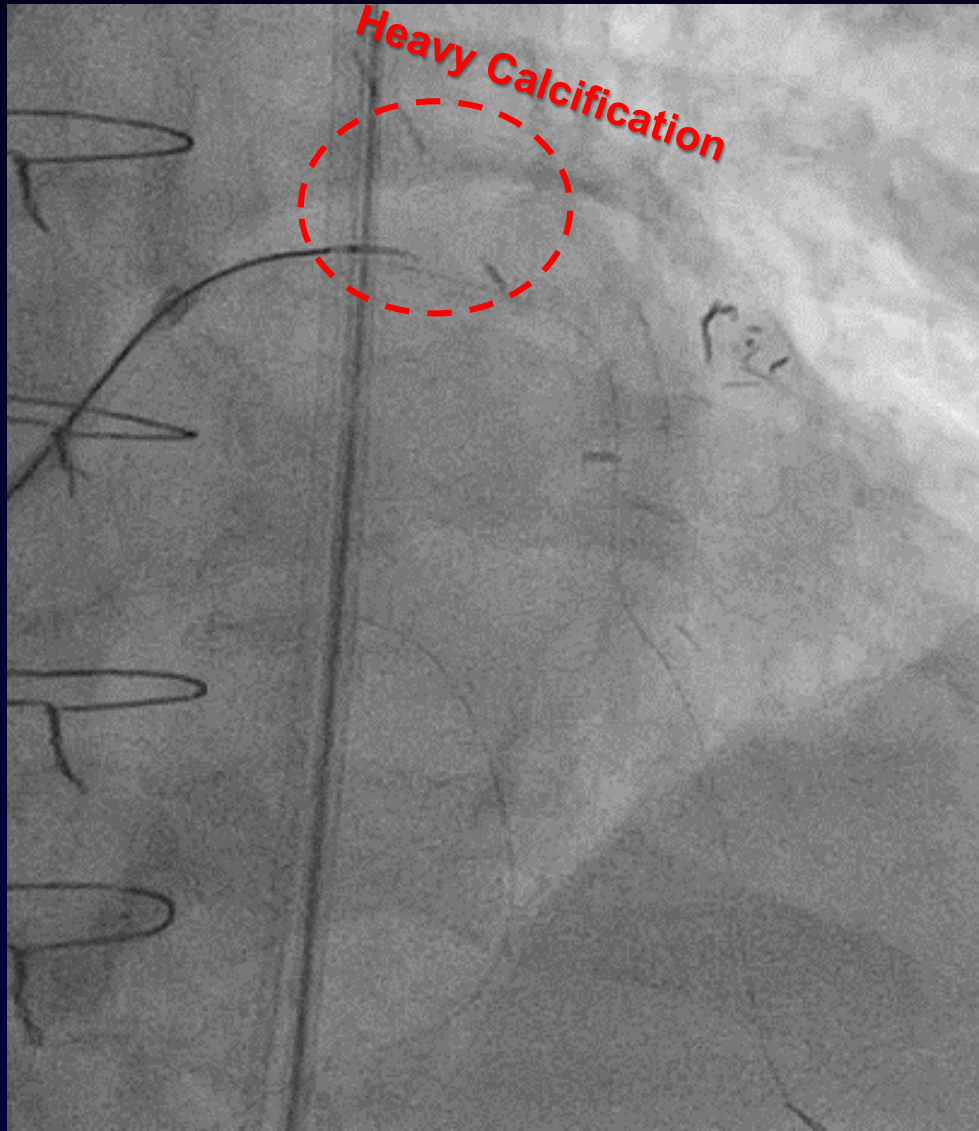
Successful wiring by using soft wire (Pilot®)



However, **Corsair, 1.25-sized balloon & Caravel crossing failed ...**

# Wire-cracking

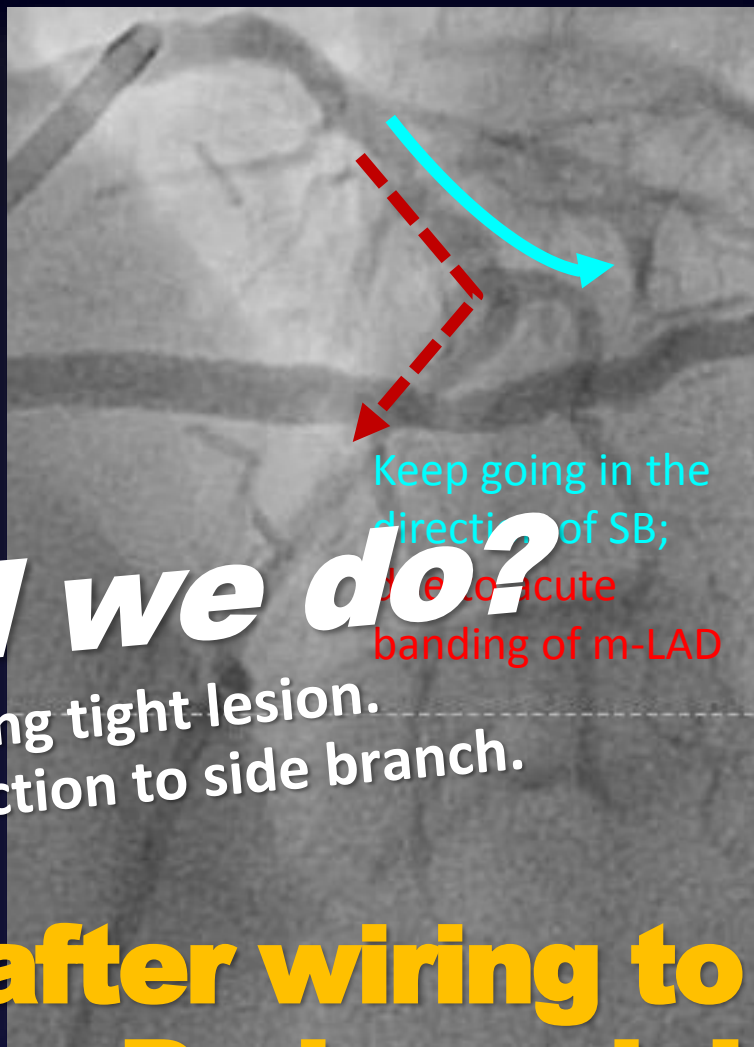
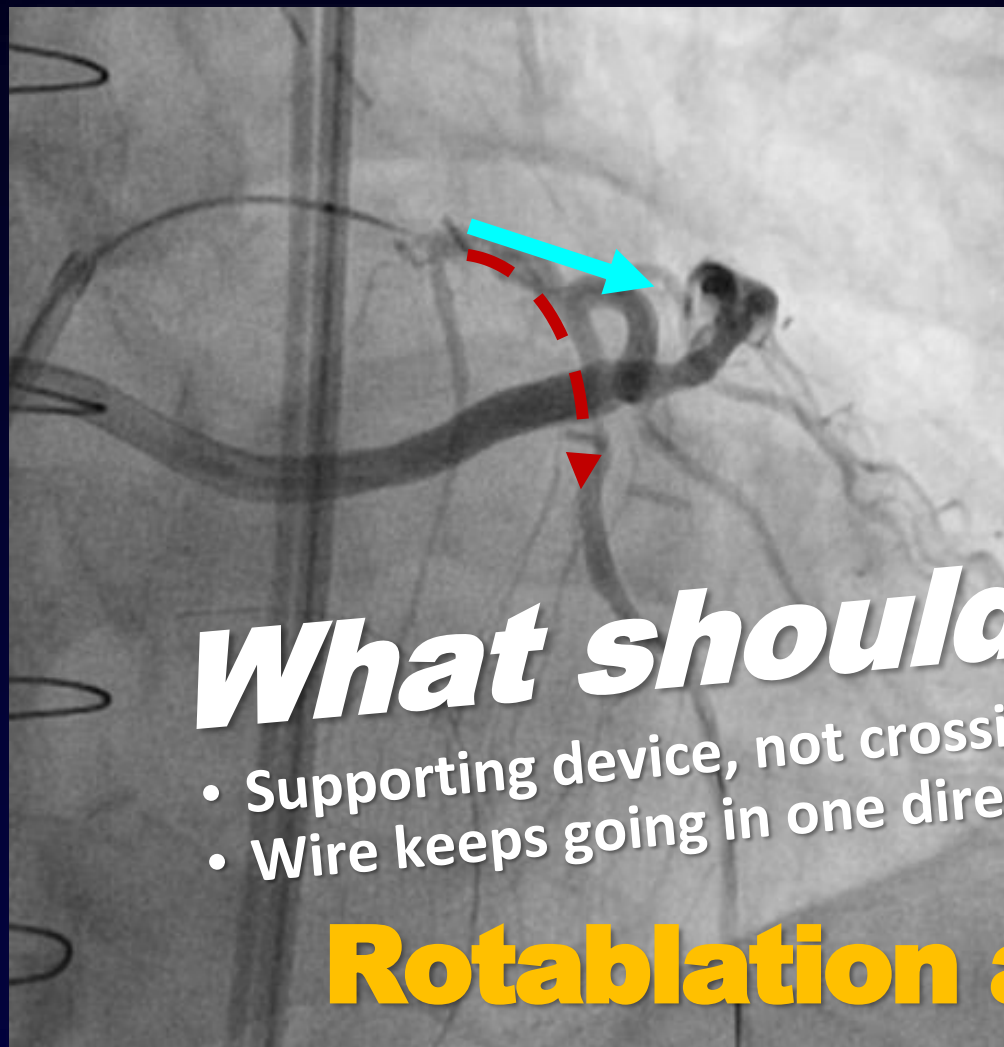
- Additional wires crossing failed ...



- Corsair + pilot → Miracle 3 → Miracle 6 → pass failed.
- Caravel + Pilot → miracle 6 → pass failed.

## 2. Rotablation; Direct Rota-wire crossing?

... crossed p-LAD lesion but not to tortuous d-LAD, only to Dx branch.



**What should we do?**

- Supporting device, not crossing tight lesion.
- Wire keeps going in one direction to side branch.

**Rotablation after wiring to  
Dx branch !**

# Rotablation of LAD after wiring to Dx branch (1.25 burr)

Caravel crossing to DG br.

Wiring to LAD  
& Caravel crossing to d-LAD

Post-balloon CAG

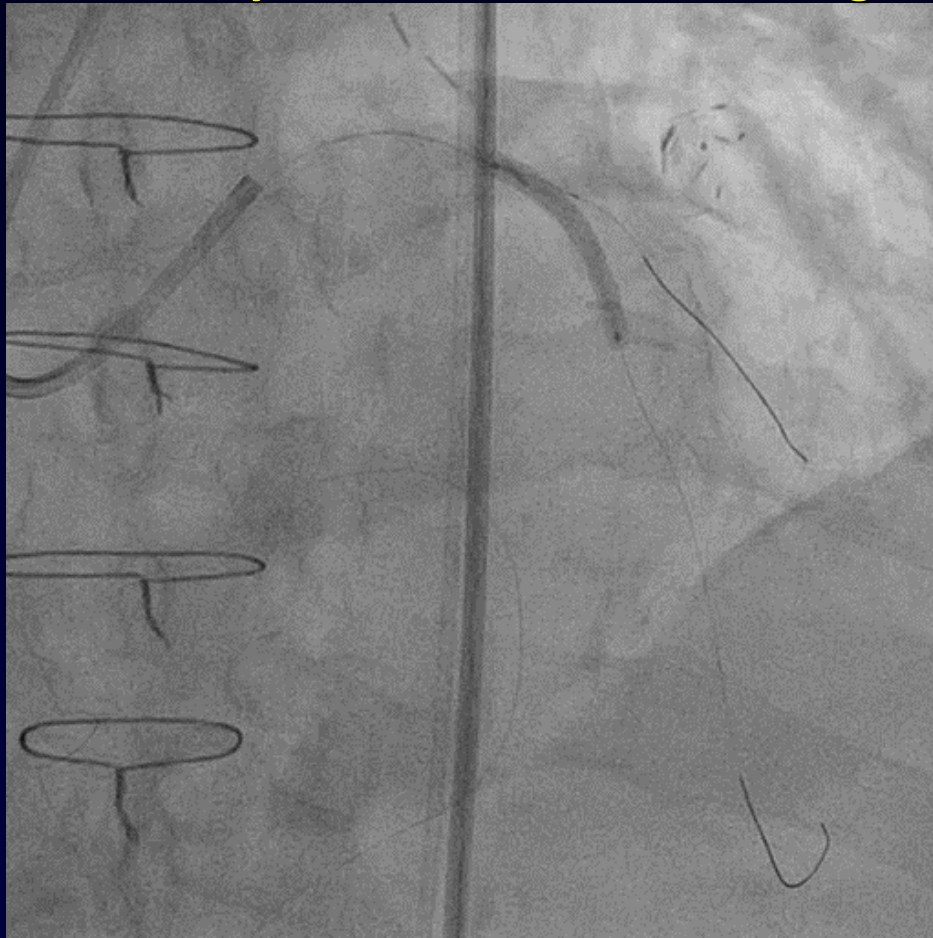
We need the “Easy stents”, to be easily delivered and expanded.  
All members including operator were fully exhausted  
... could not afford to do other things.

### 3. Stenting

Successful 2 Xience Sierra stents overlapping

→ Easy delivery & good expansion

→ Easy size selection considering vessel size discrepancy



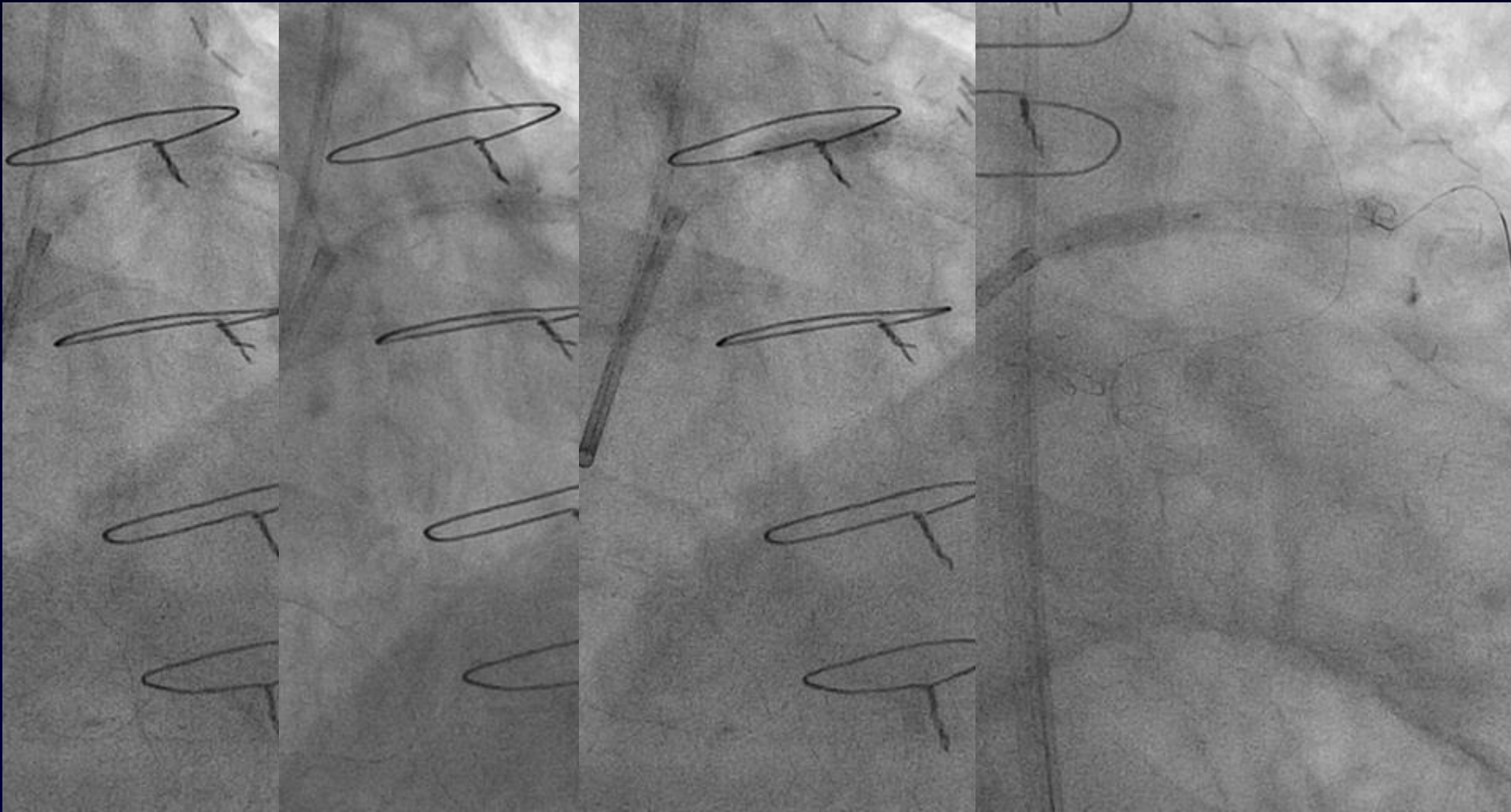
- m-LAD stent (Sierra 3.0 x 28mm)



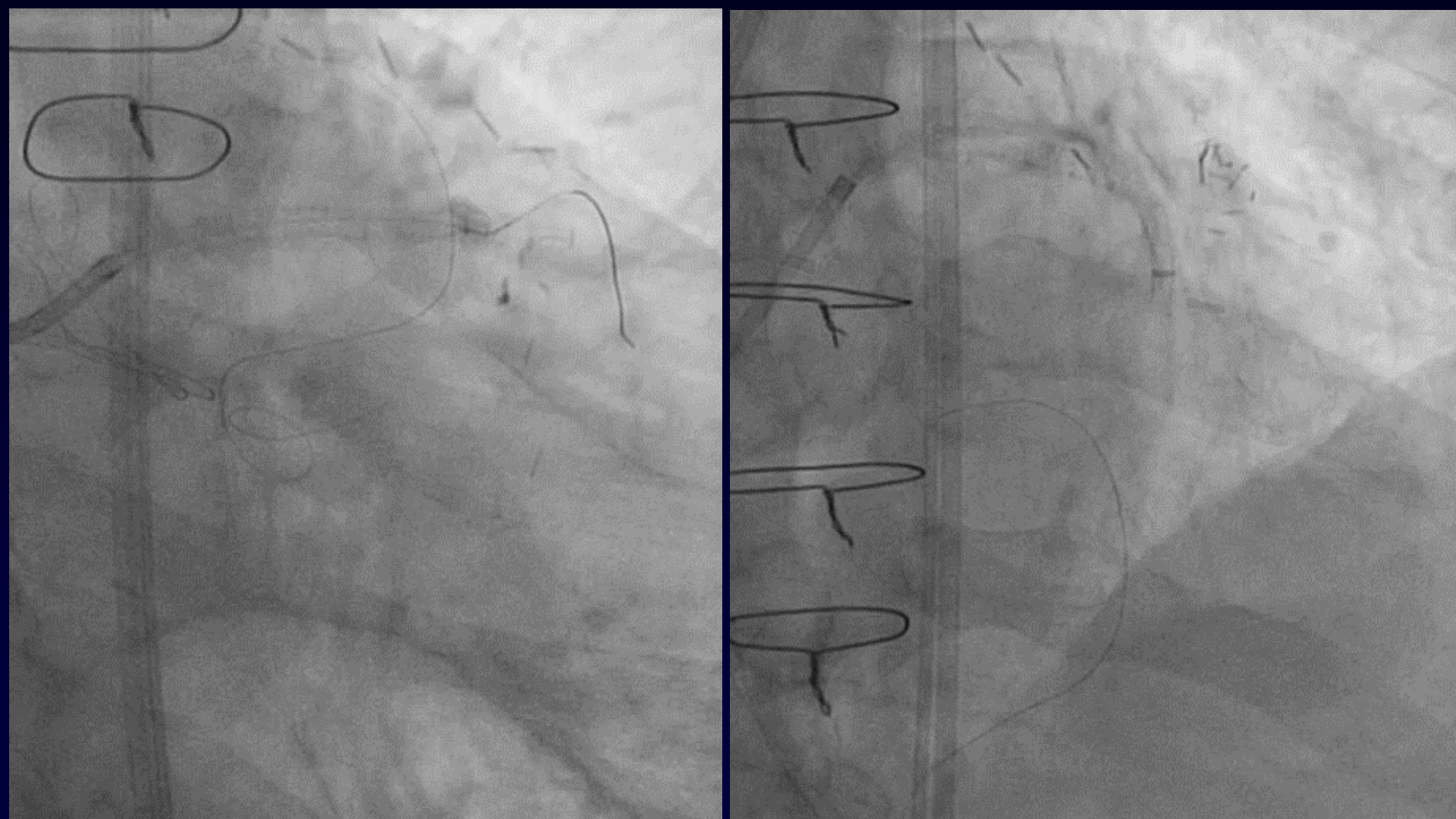
- p-LAD stent (Sierra 3.5 x 23mm)



## 4. Adjuvant ballooning (NC balloon 3.5x15, up to 26 atm)



# 5. Final CAG



# XIENCE Sierra for complex lesions

... optimized DESs for various complex lesions

LARGE AND LONG  
CALCIFIED VESSELS

BIFURCATION

HIGHLY  
CALCIFIED  
LESIONS

- Slim, but Bigger ! thinner and wider XIENCE Sierra
  - Single stent can cover from small vessel to larger LM with post-dilation
- Easy & Safe procedure! Superior deliverability
  - Time-saving, radiation-dose reduction
  - Cost-reduction for patients & hospital (fee for the further uses of balloons, wires, and stents)

*Severance*

**Thank you for  
your attention!**

