Xience Skypoint in Bifurcation/Complex lesions

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Seoul St. Mary's Hospital

The Catholic University of Korea



XIENCE[™] Design: Continuously improving¹

$\left(\begin{array}{c} \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\$						
Catheter Technology	XIENCE V TM MULTI-LINK VISION TM	XIENCE PRIME [™]	XIENCE XPEDITION TM	XIENCE ALPINE [™]	XIENCE SIERRA™ Improved Crossability¹	XIENCE Skypoint™ Slimmer Catheter Profile ³
Balloon	Single Layer Balloon	Single Layer Balloon	Thin, Multilayer Balloon	Thin, Multilayer Balloon	Ultra Thin Single Layer Balloon Reduced Profile¹	Ultra Thin Single Layer Balloon
Stent Design and Material	MULTI-LINK VISION CoCr	MULTI-LINK 8 CoCr	MULTI-LINK 8 CoCr	MULTI-LINK 8 CoCr	Enhanced Stent Design Smaller Crimped Profile and Larger post-dil expansion ² CoCr Stent	Larger Post-Dilation Expansion – 5.75 mm ⁴ CoCr Stent
Drug/Dosage	Everolimus 100 μg/cm²					
Coating	PVDF-HFP Fluoropolymer					

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XIENCE Skypoint[™] Stent is the latest generation XIENCE[™] Stent and has some additional innovation enhancements from XIENCE Sierra[™] Stent



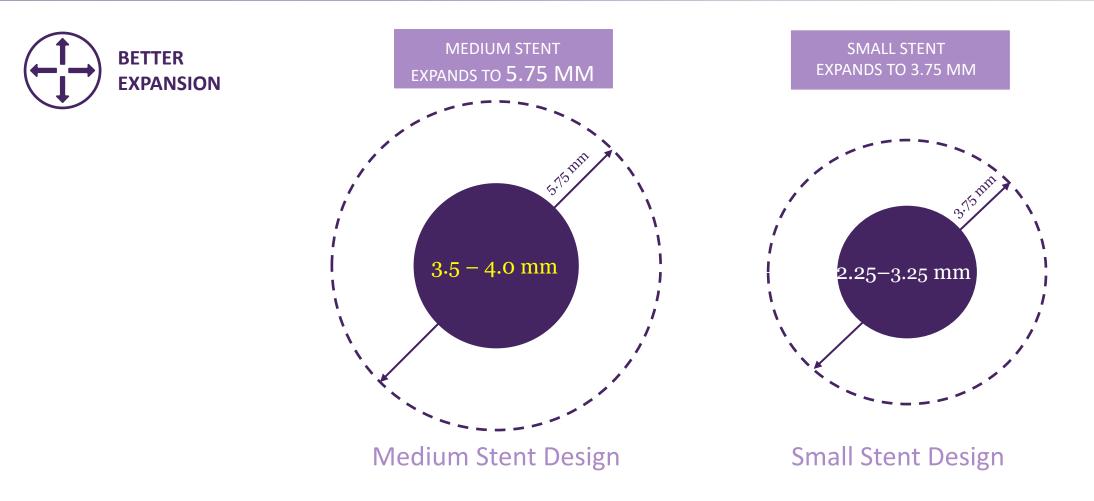
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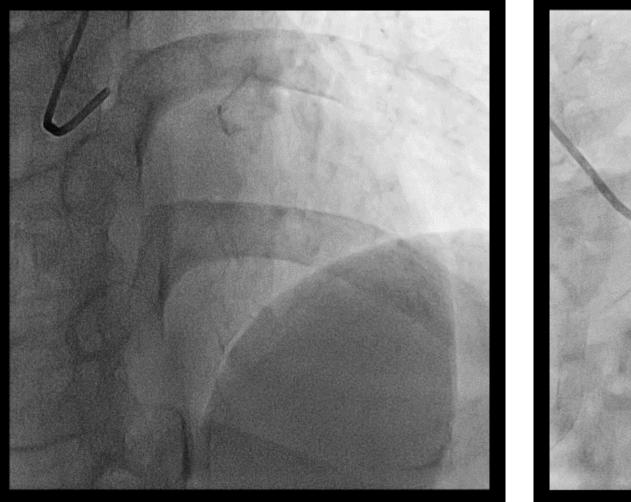
XIENCE Skypoint[™] Stent has **better maximum expansion** up to **5.75 mm** helping treat patients with larger vessels

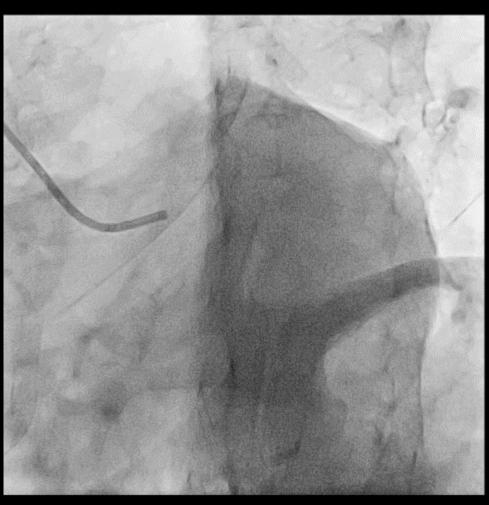


Data on file at Abbott.

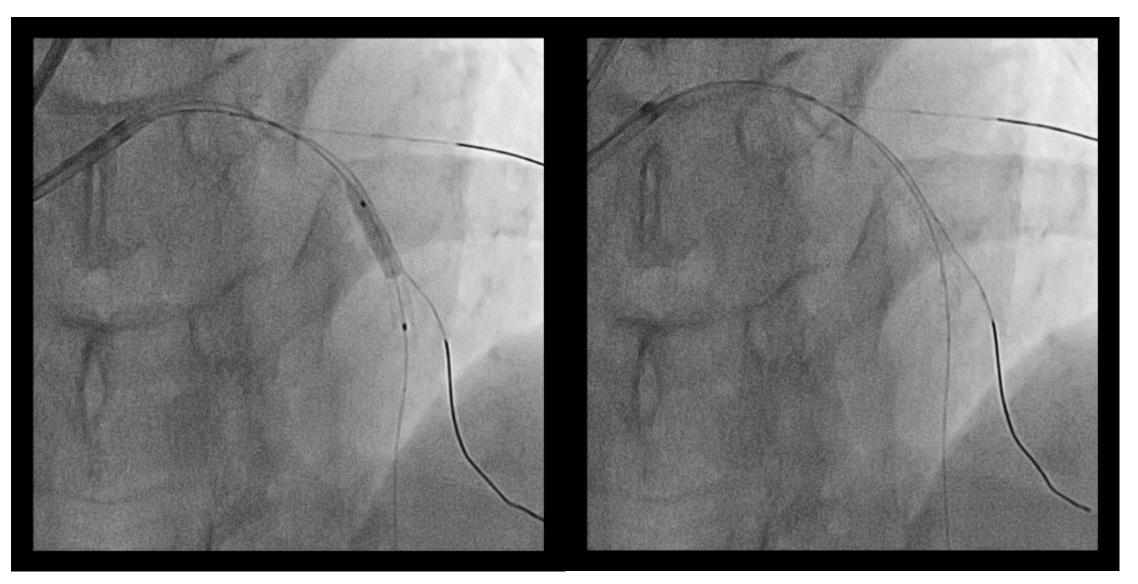
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61/F, Unstable angina



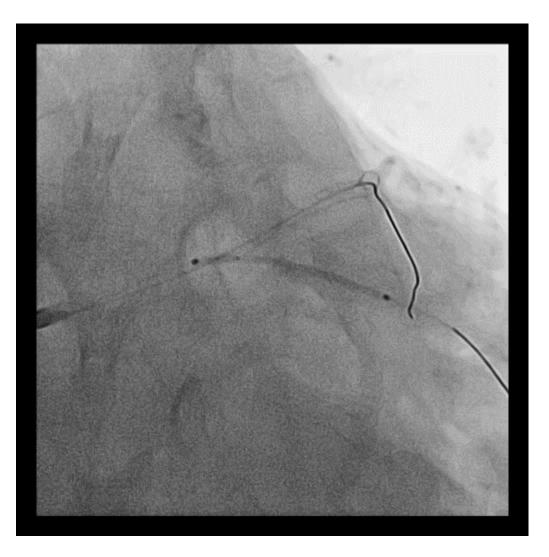


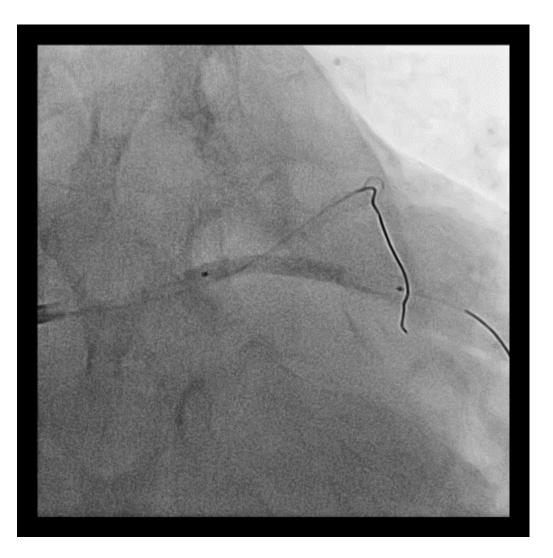




Xience skypoint 2.75 x 15







Xience skypoint 2.75 x 28

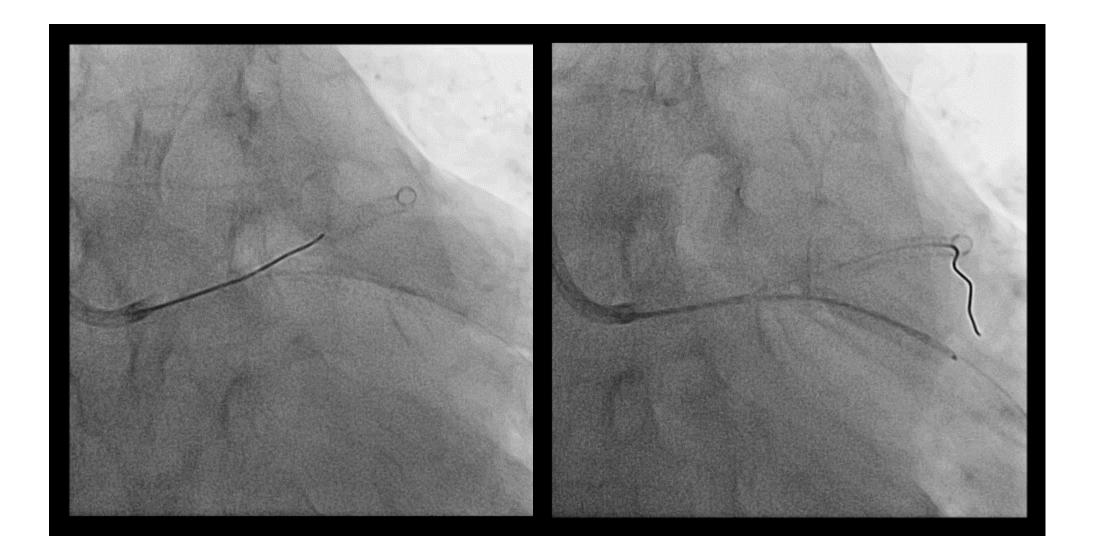




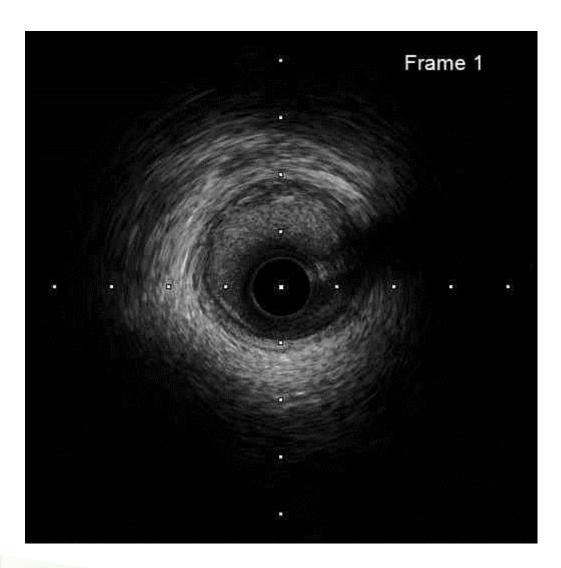


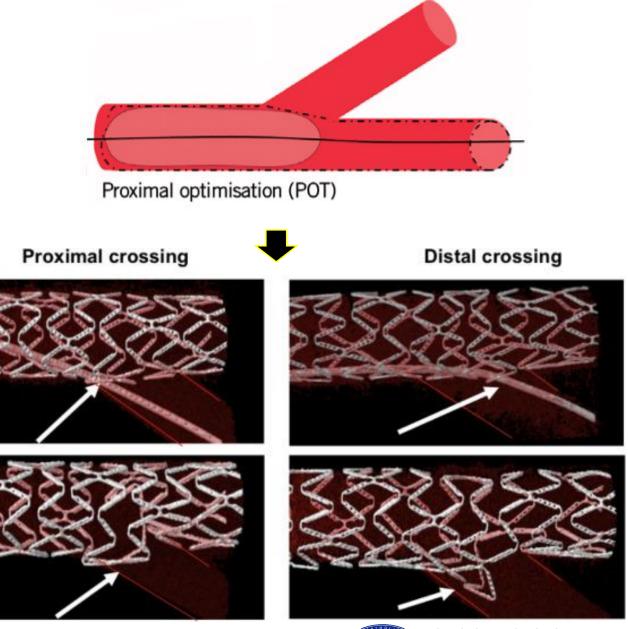
Selecthru NC 3.5x6



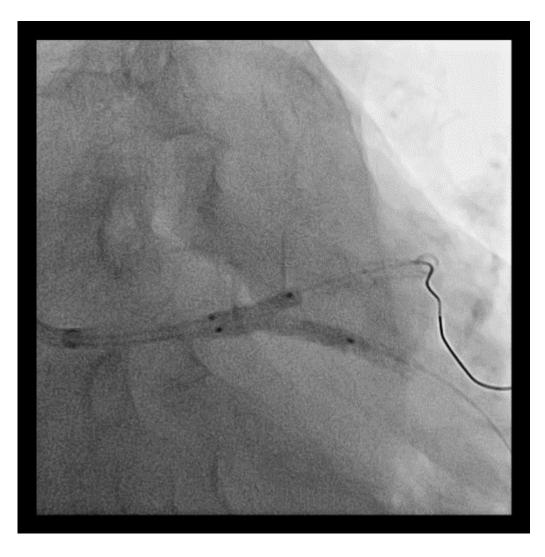


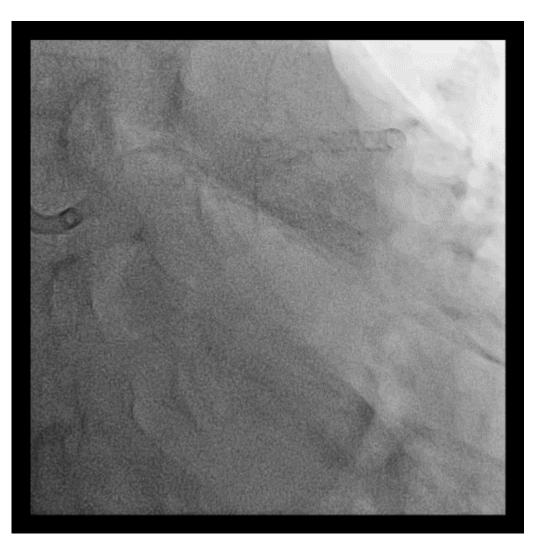






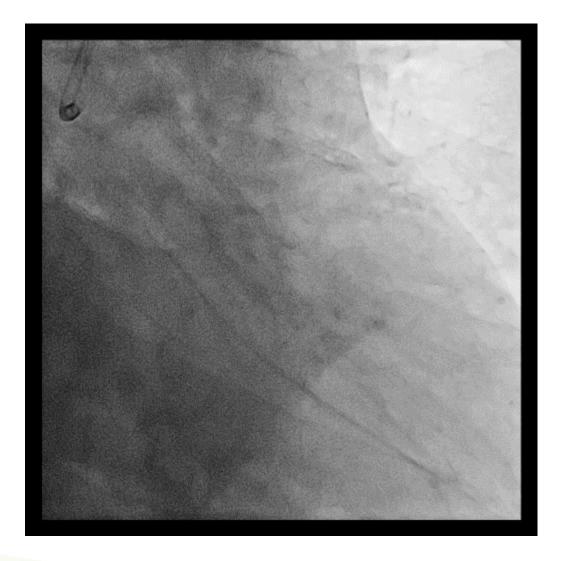






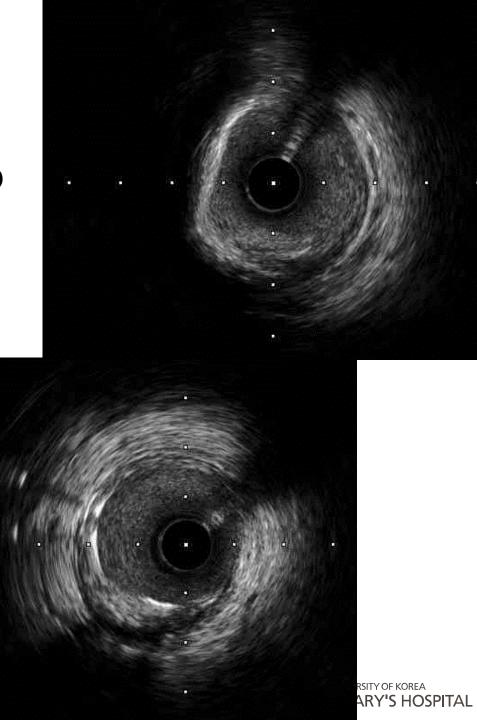
NC Emerge 3.0x12 (LAD) + 2.75x15 (LCX)





LAD

LCX



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XIENCE Skypoint[™] Stent has a **slimmer catheter** and seamless one-piece catheter shaft



Slimmer catheter profile and seamless one-piece shaft with reduced profile (0.001") to optimize deliverability and pushability¹.

XIENCE™

XIENCE Skypoint[™]

Seamless one-piece catheter shaft Guide Wire Exit Notch

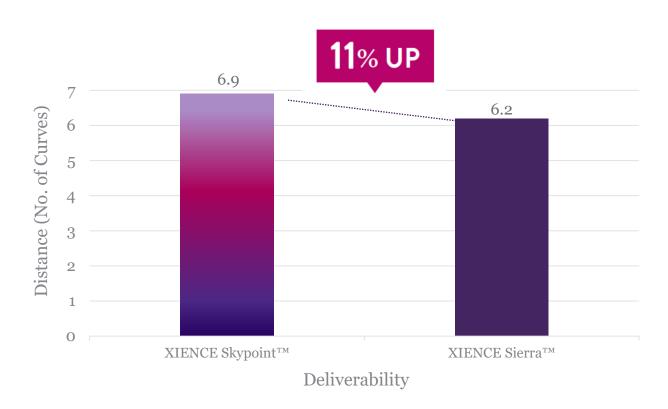
0.001" / 0.0025 mm reduction in guide-wire notch profile

1. Data on file at Abbott. XIENCE Skypoint[™] compared with XIENCE Sierra[™]. Reduction in profile is not applicable for 48 mm sizes.

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XIENCE Skypoint[™] Stent improved **deliverability** to help optimize acute performance





Tests performed and data on file at Abbott. 3.0 x 18 mm stents tested using a simulated arterial model.

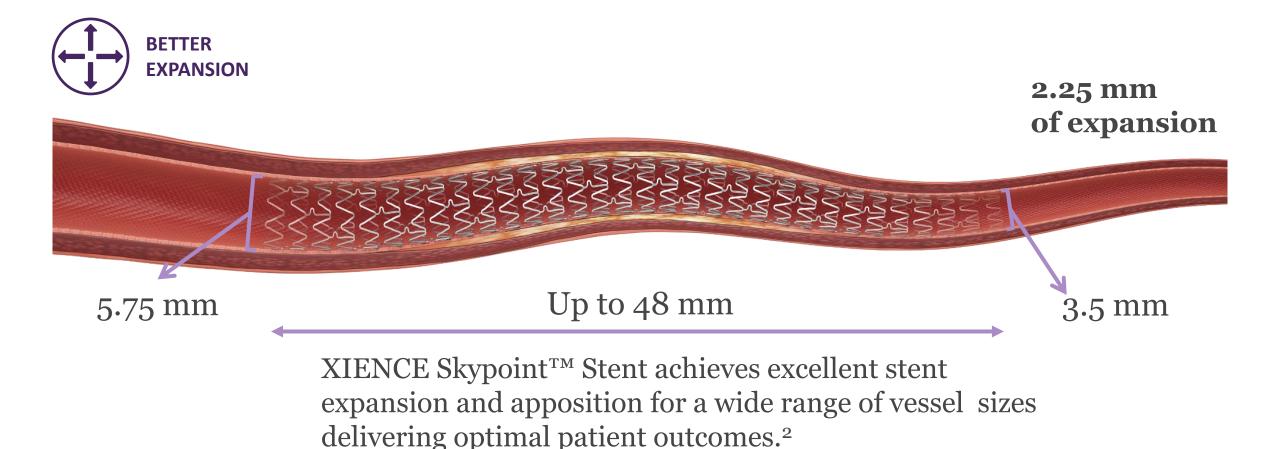
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XIENCE Skypoint[™] Stent can treat **tapered lesions** in large vessels using a single stent¹

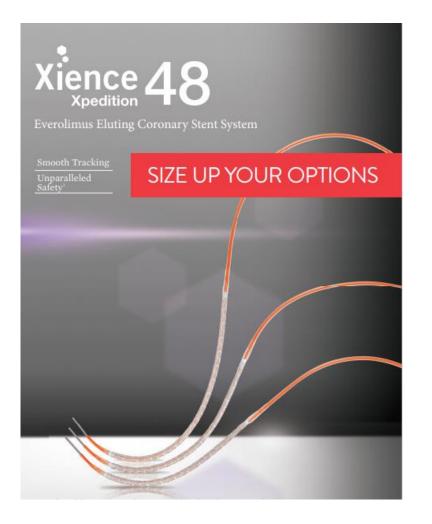


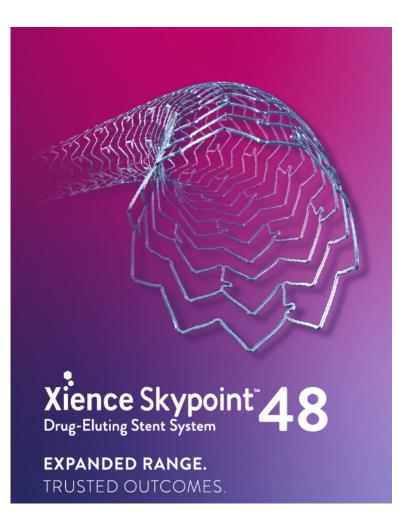
1. Date on file at Abbott.

2. Sudhir K, et al. ISRN Cardiol. 2013:748736.

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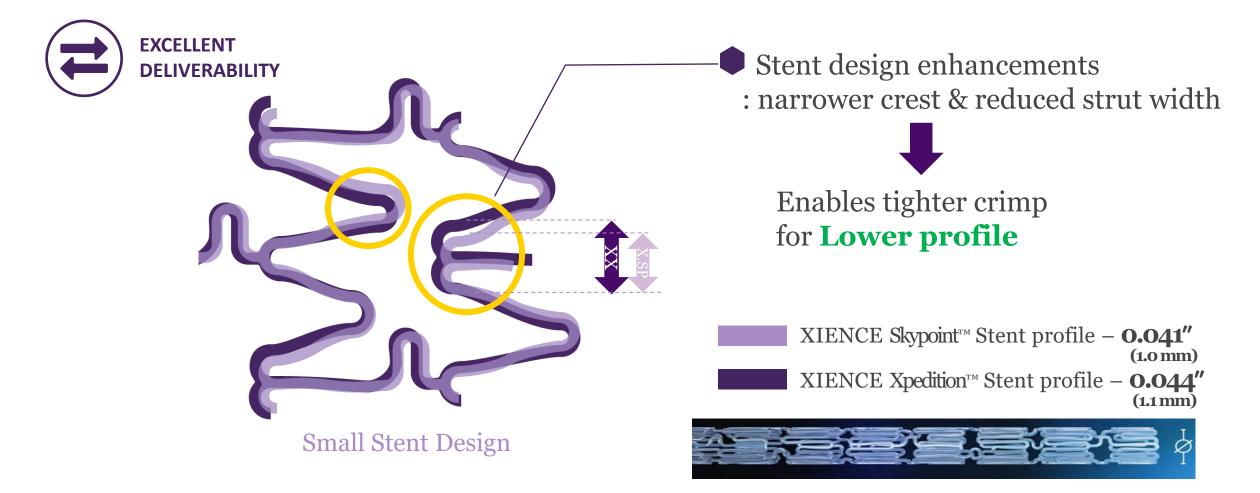
X.Xpedition 48 vs. X. Skypoint 48





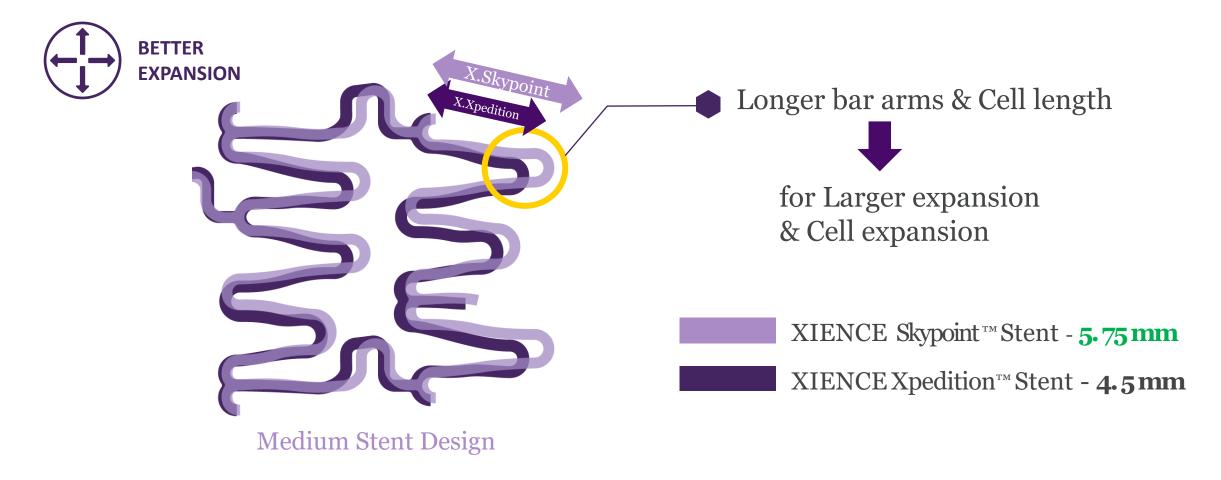
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XIENCE Skypoint[™] Stent 48 mm has a **lower crossing profile** compared with XIENCE Xpedition[™] Stent 48 mm



Data on file at Abbott. Average stent profile – XIENCE Skypoint[™] 3.0 x 48 mm compared with XIENCE Xpedition[™] 3.0 x 48 mm. Applicable only to 2.5 - 3.0 mm stent sizes. Information contained herein for DISTRIBUTION outside the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force. Page 20 of 47 © 2021 Abbott. All rights reserved. MAT-2106626 v2.0

XIENCE Skypoint[™] Stent 48 mm has **an enhanced stent design** compared with XIENCE Xpedition[™] Stent 48 mm



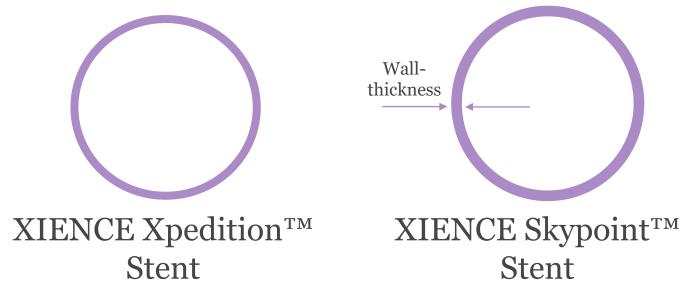
Data on file at Abbott. Note: Elongated bar arms is for medium stent design (9-crest design), 3.5 mm and 4.00 mm.

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XIENCE Skypoint[™] Stent 48 mm hypotube has a larger wall-thickness to support **excellent pushability**



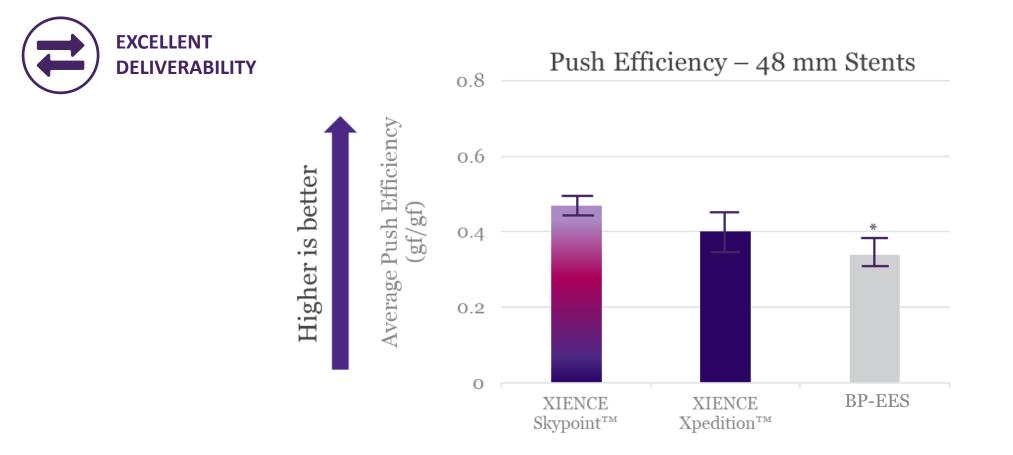
Hypotube wall thickness increased and optimized for excellent pushability and deliverability – **33% increase** in wall thickness.



Data on file at Abbott – Hypotube wall thickness information – XIENCE Skypoint[™] Stent 0.004" compared with XIENCE Xpedition Stent – 0.003".

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XIENCE Skypoint[™] Stent – 48 mm design – shows **better pushability** than competitor DES¹



1. Test performed and data on file at Abbott. Bench model – 3.0 x 48 mm stents tested.

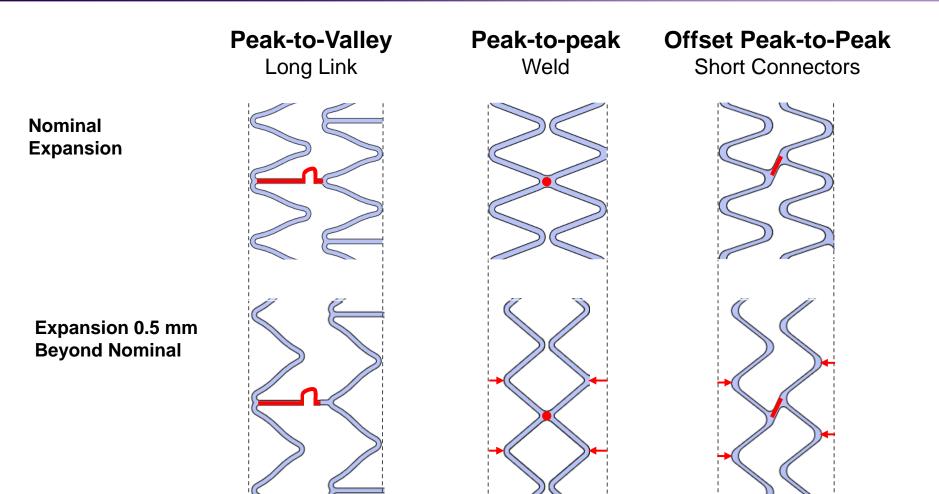
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XIENCE[™] stent has a consistent stent design.

XIENCE 3.0x18 mm Orsiro[™] 3.0x18 mm 3-Link 3-Link Peak to Mid-Strut Link Valley Synergy[™] 3.0x20 mm Onyx[™] 3.0x18 mm 2-Links 2-Link (4 links between Peak to two proximal end Peak rings)

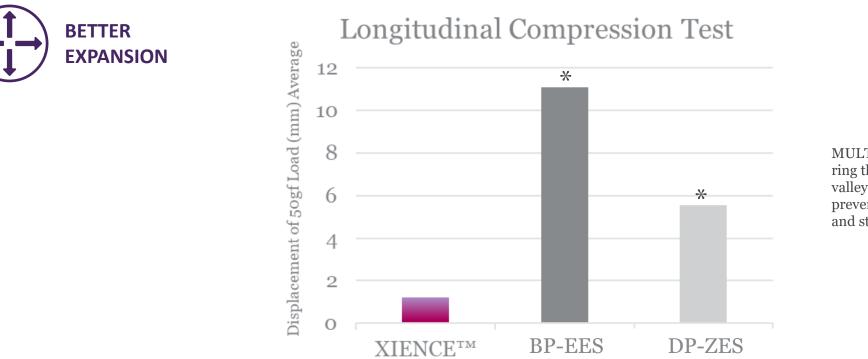
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Stent Design



Illustrations are artists' renditions.

XIENCE[™] Stent platform shows excellent **longitudinal strength** providing scaffolding and stability¹



MULTI-LINK stent platform has 3 links per ring that connect peaks of one ring to the valleys of the adjacent ring. This design prevents struts from compressing together and stretching apart (elongating).

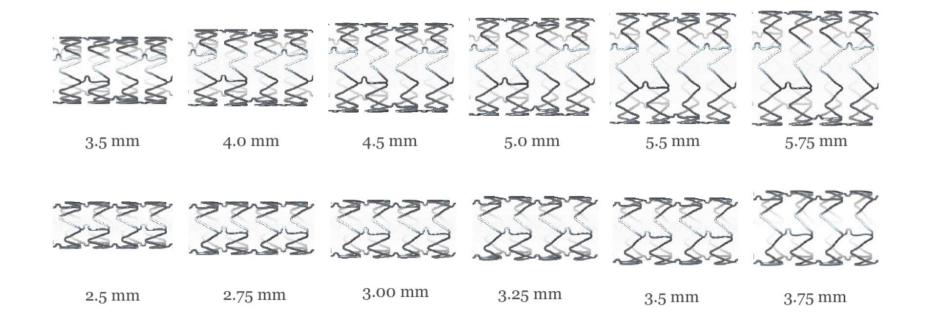


XIENCE Skypoint[™] Stent has significantly better longitudinal strength to help ensure optimal procedural outcomes.

1. Test performed by and data on file at Abbott. XIENCE Sierra[™] Stent (3.0 x 28 mm) n=5, BP-EES[‡] (3.0 x 28 mm) n=5, DP-ZES[‡] (3.0 x 28 mm) n=5. *Denotes statistically significant difference compared with XIENCE[™] Stent.

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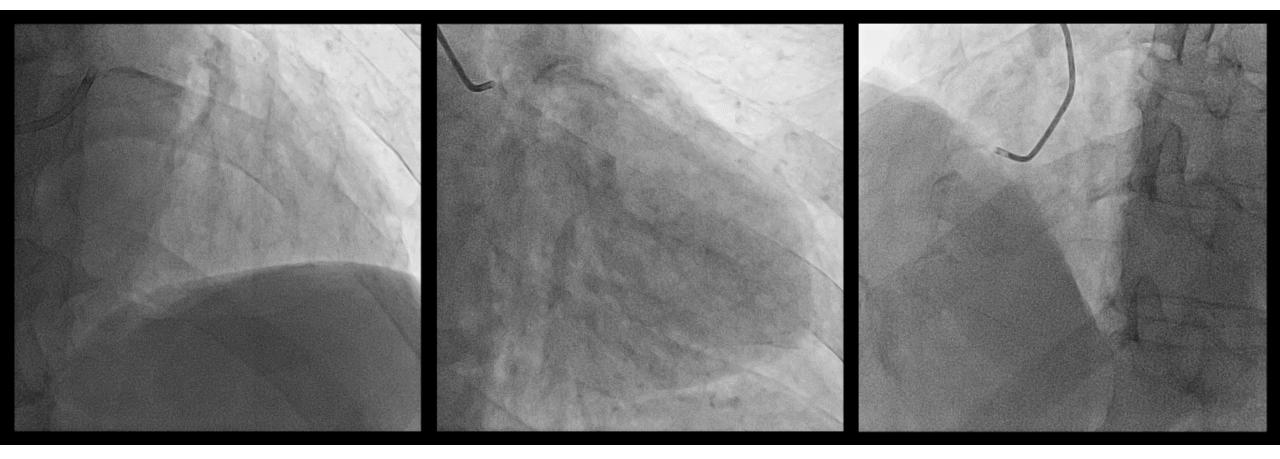
XIENCE[™] stent has a consistent stent design.



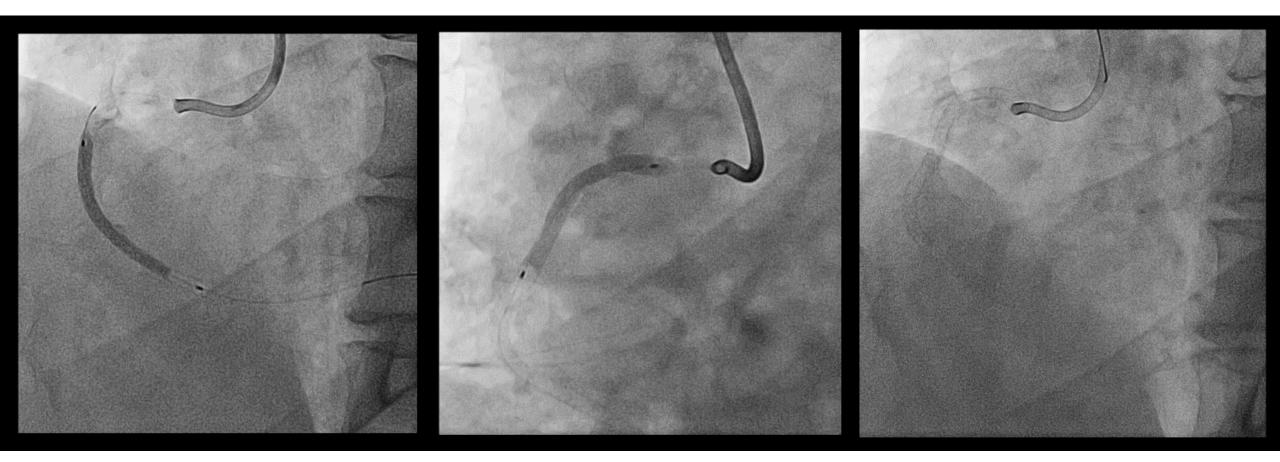
Less stent pattern deformation potentially leads to better apposition, lesion scaffolding and more uniform drug distribution.

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66/F, NSTEMI, refused CABG



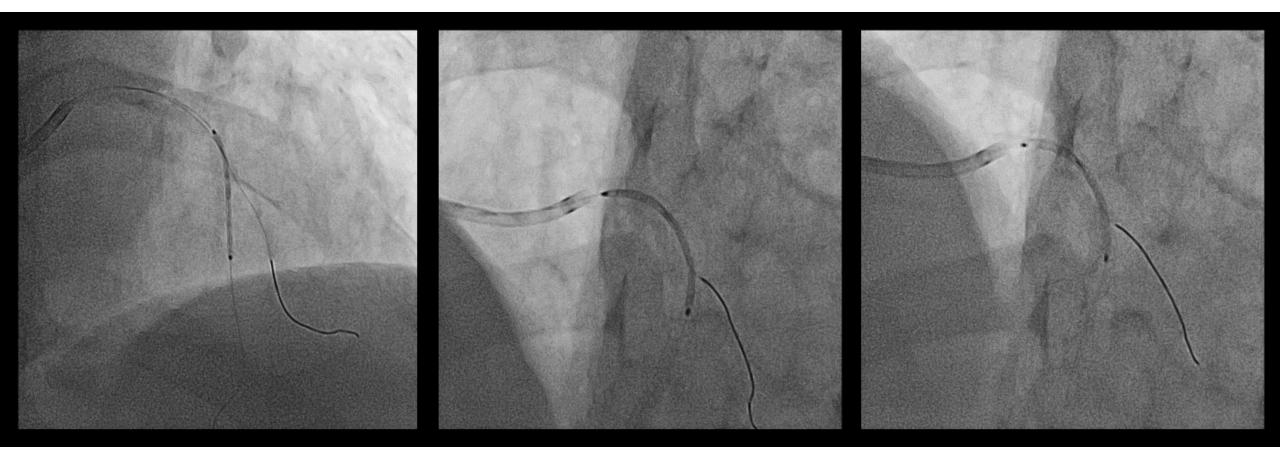




Xience skypoint 3.0x48

Xience skypoint 4.0x33



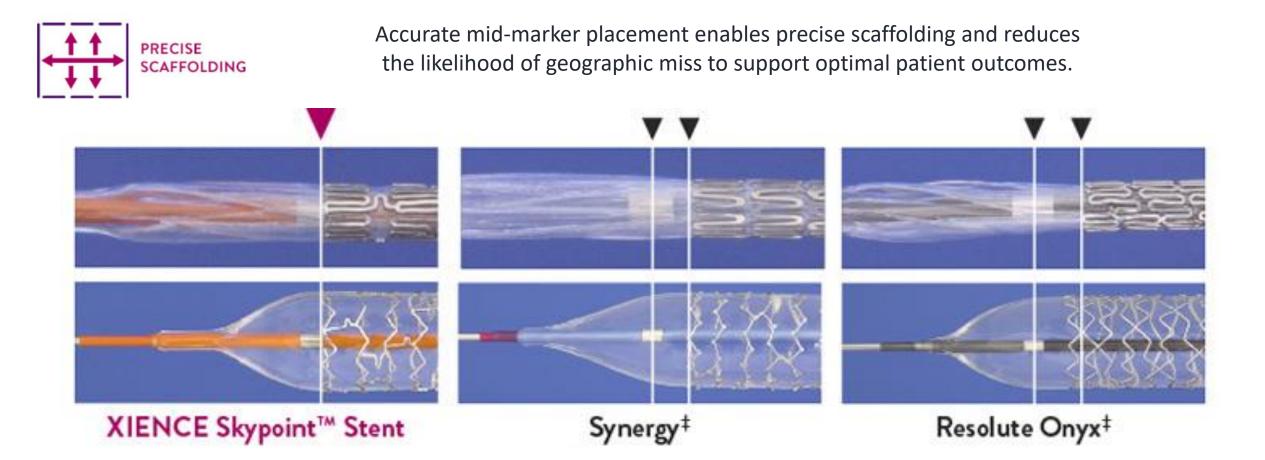


Xience skypoint 3.0 x 28

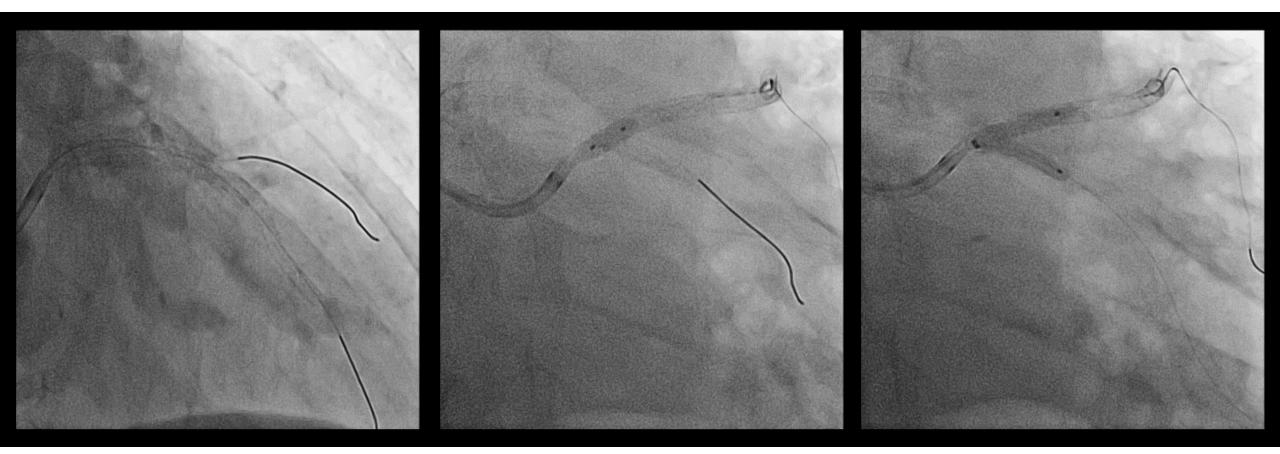
Xience skypoint 3.5 x 38



XIENCE Skypoint[™] Stent Supports Accurate Stent Placement Through Precise Stent and Marker Placement



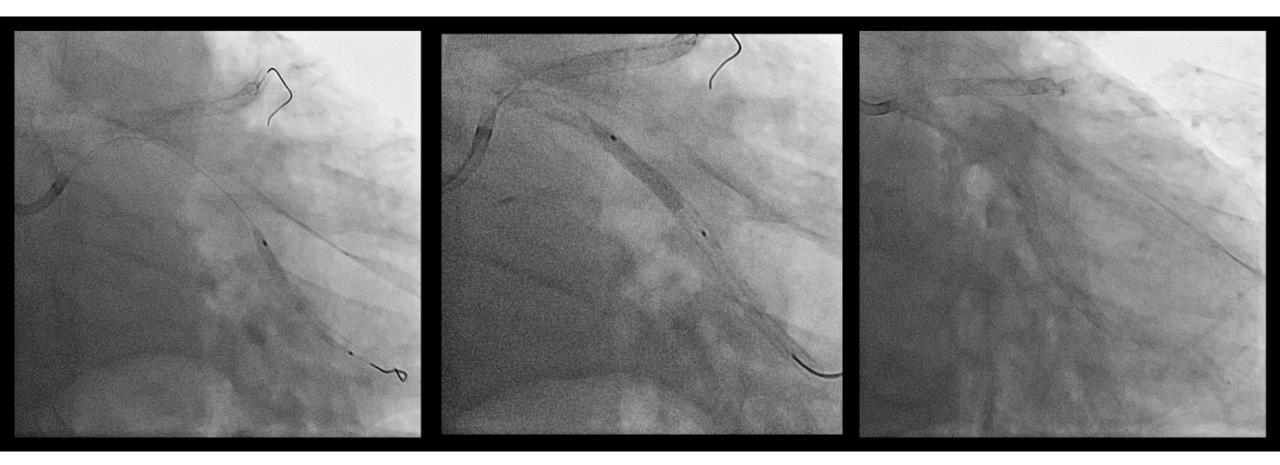
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Selecthru NC 4.0x6

NC Accuforce 3.5x15 (LAD) + 3.0x15 (LCX)





Xience skypoint 3.5 x 33

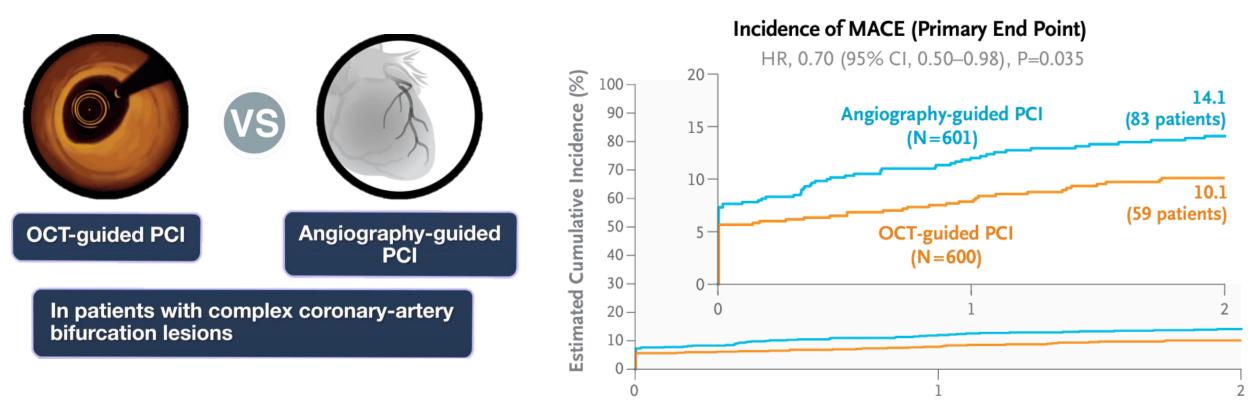
Xience skypoint 3.5 x 23



OCTBER Trial

OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions

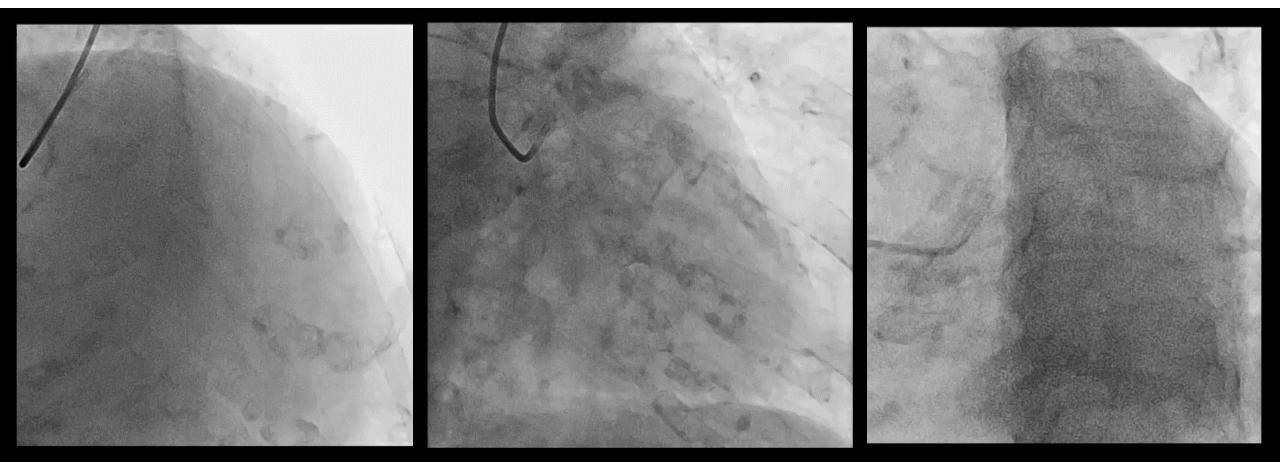
Holm NR et al. DOI: 10.1056/NEJMoa2307770



Years of Follow-up

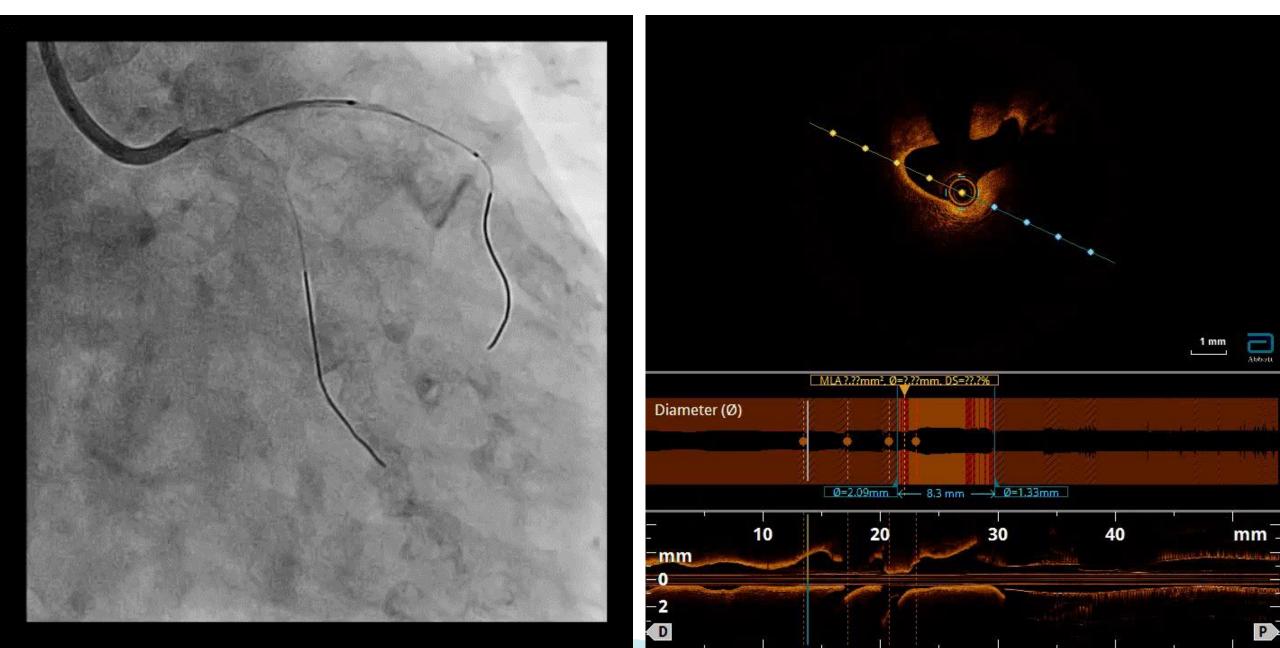


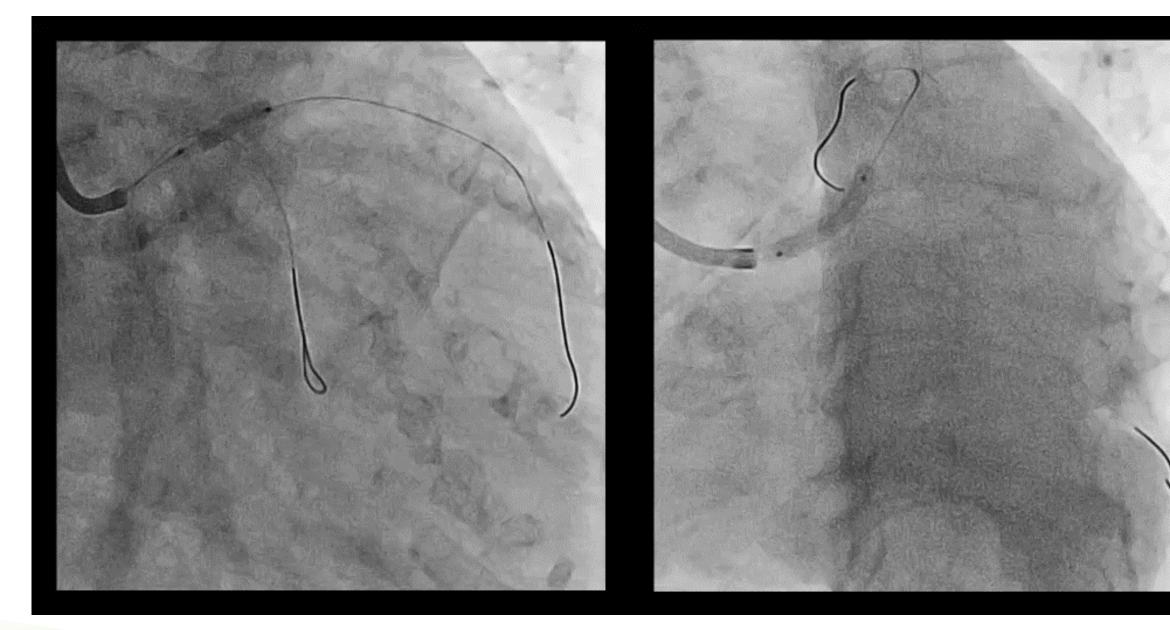
85/F, Stable angina, DOE (+)





LAD OCT(Pre-PCI)

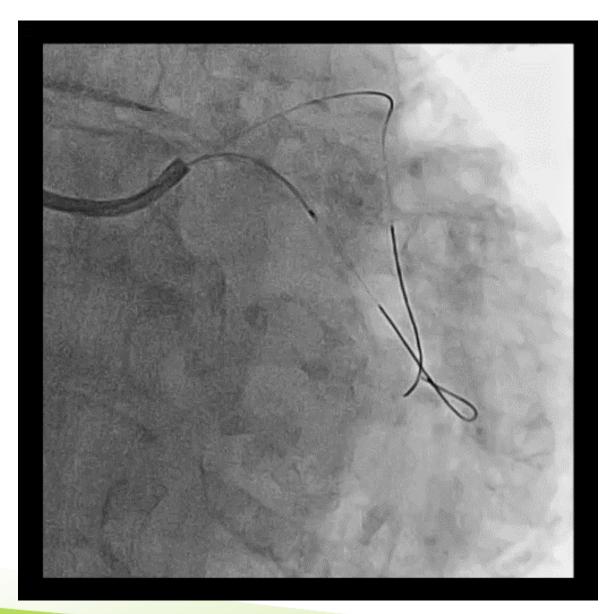


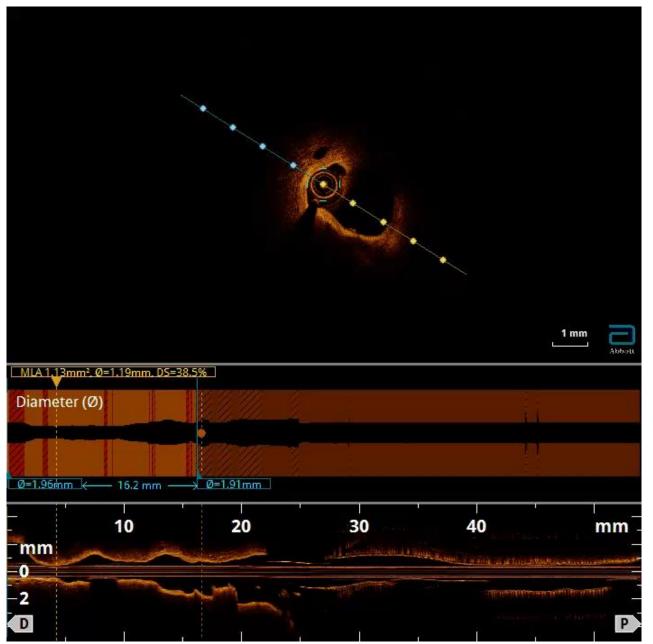


3.0x15mm NC balloon at Left main to LAD



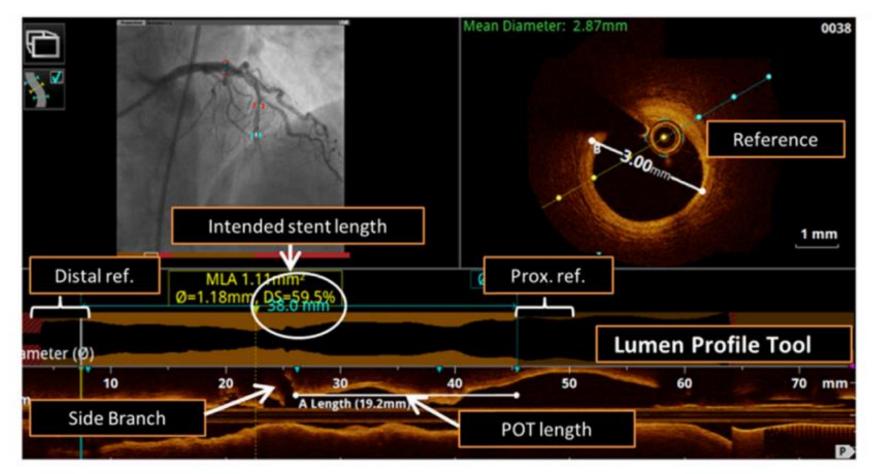
LCX OCT after LM-LAD ballooning







Pre-stent OCT assessment (after pre-dilatation)

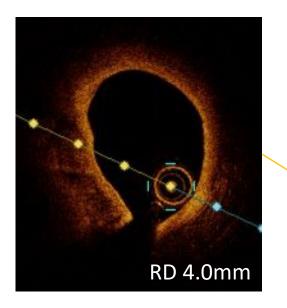


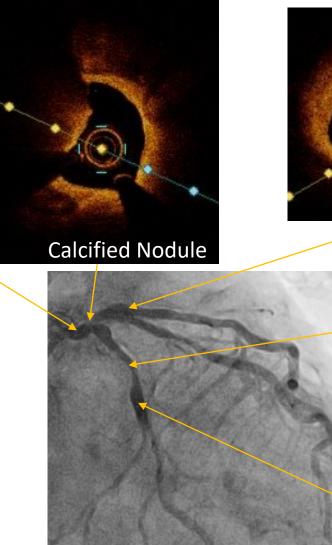
- 1) Evaluation of pre-dilatation result for dissections and cracked fibro-calcific plaques
- 2) Identification of stent landing zone (position and length)
- 3) Reference sizes for each segment to be stented are measured
 - Nominal stent size is selected according to the distal reference size

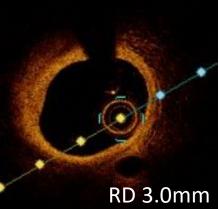
THE CATHOLIC UNIVERSITY OF KOREA

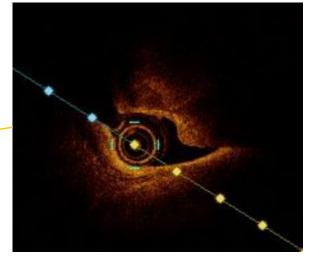
SEOUL ST. MARY'S HOSPITAL

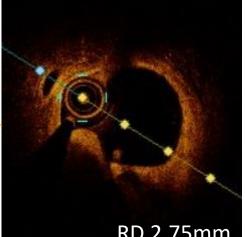
 Ensure that stent length in proximal MV segment at least is 6 or 8 mm to accommodate the POT balloon

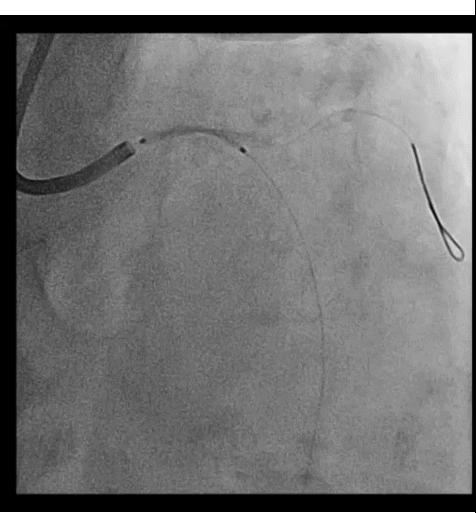


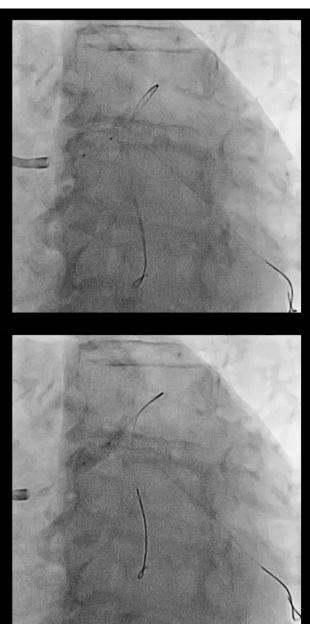


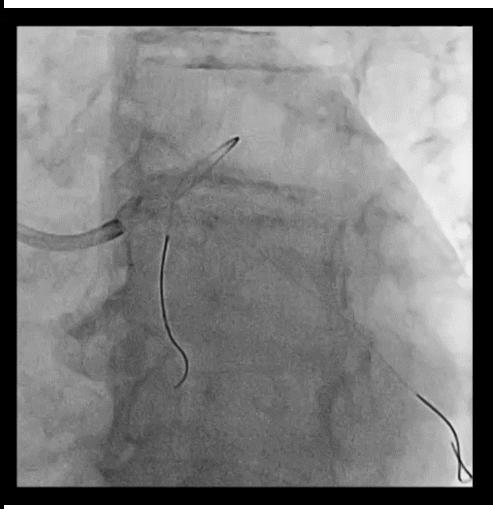








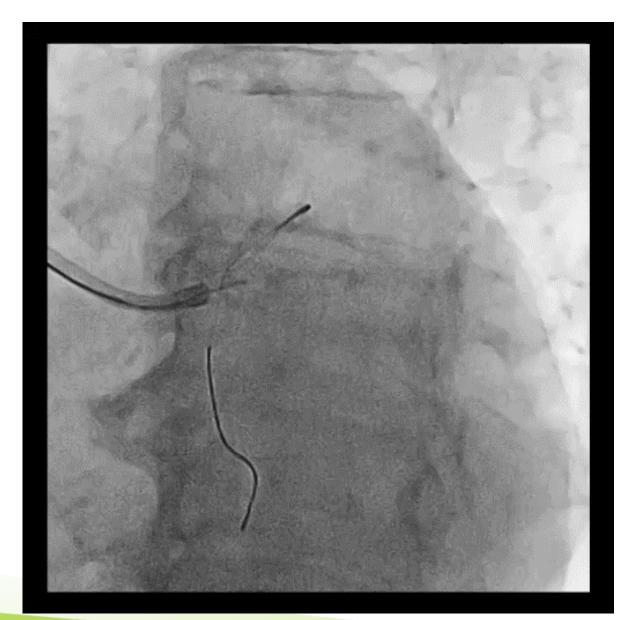


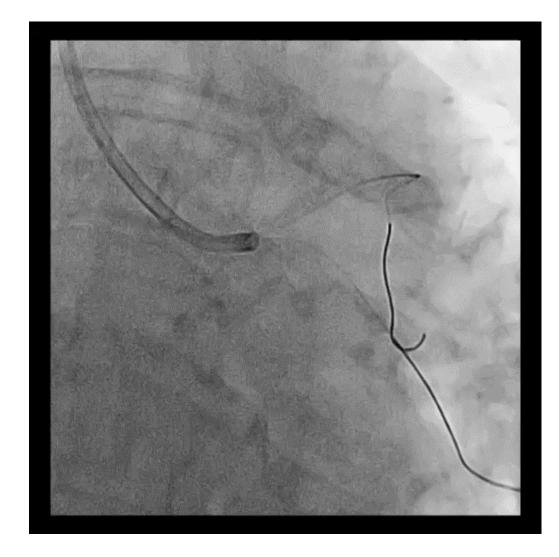


Left main to LAD Stent deployment and POT Xience skypoint 3.0 x 18mm / POT 4.0 x 8 NC balloon



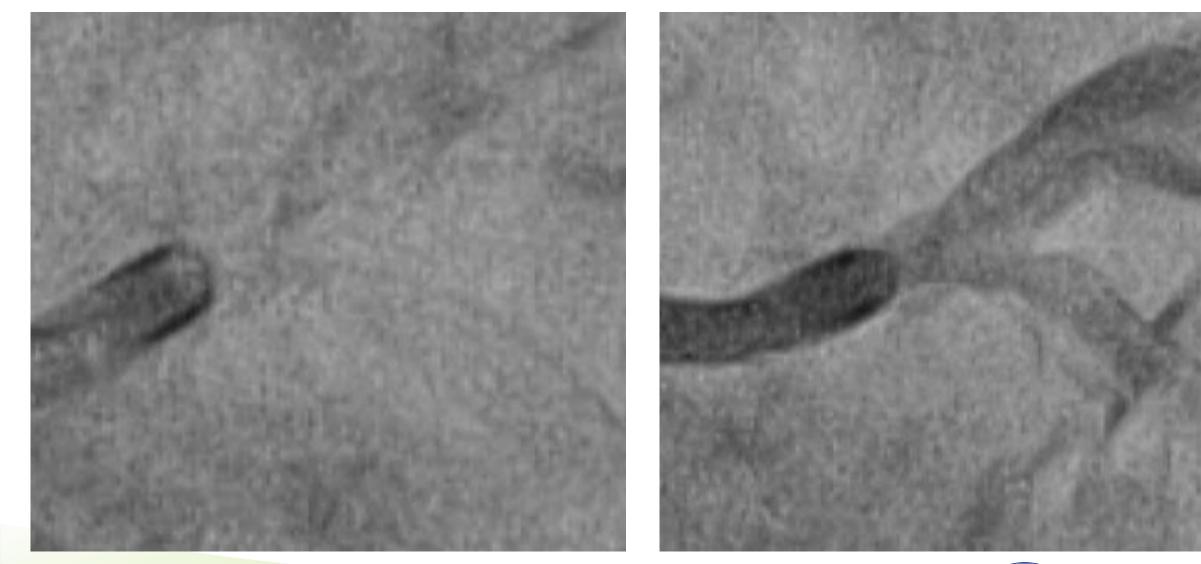
LCX 1st rewiring





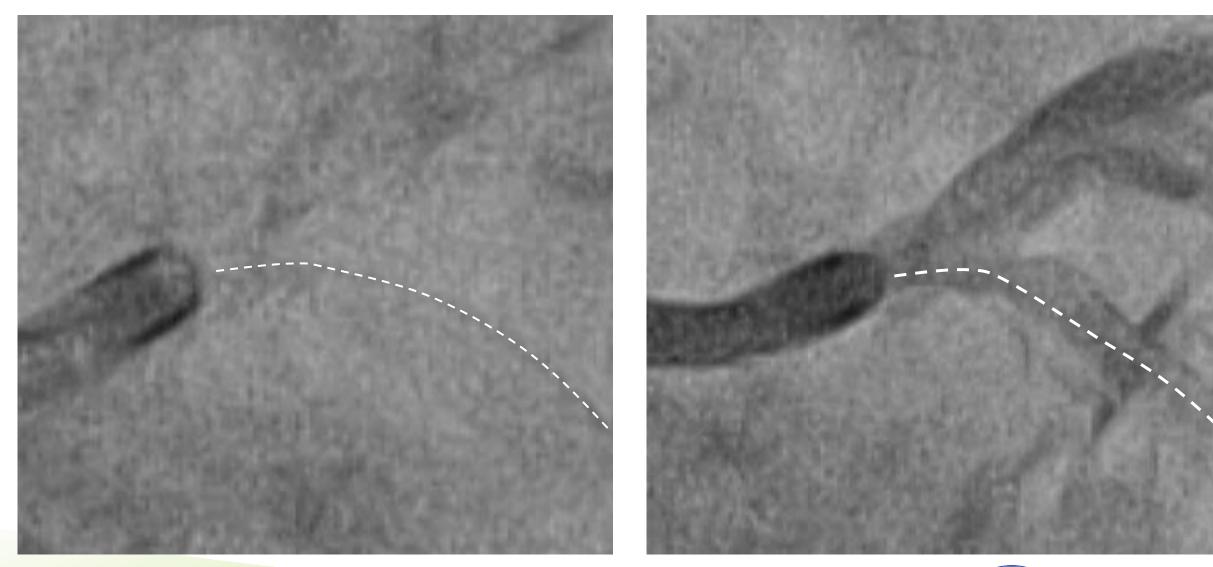


Proximal wiring ? Distal wiring ?





Proximal wiring ? Distal wiring ?





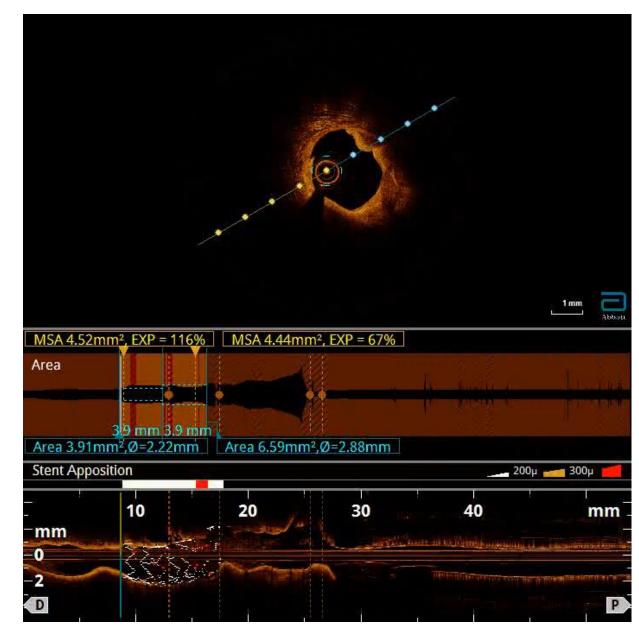
Pre- SB stent evaluation by OCT

20 30 40 50 60	1) Full lesion coverage Exclude residual edge stenosis or major lipid plaques at or near the stent edge
	 2) Expansion Ensure adequate stent expansion for each segment Optimal expansion ≥ 90% ref. size
	3) Stent apposition Identification of segments with malapposed struts
	4) Abluminal rewiring Exclude accidental abluminal rewiring
10 11.4mm)	5) Wireposition Wire position is evaluated aiming for distal recrossing in provisional stenting and mid- distal recrossing in two-stent techniques

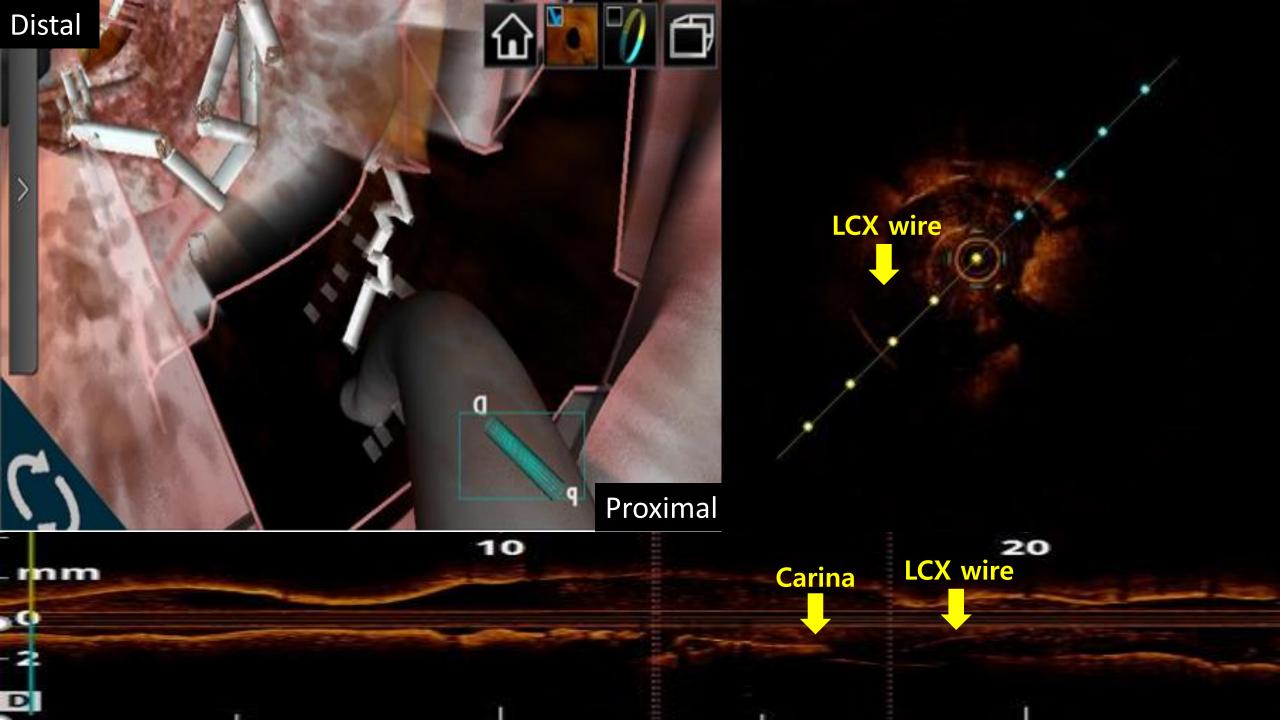
LAD OCT after 1st LCX rewiring



Full lesion coverage Expansion Stent apposition Abluminal wiring Wire position







Distal

Distal Strut E

......

Proximal

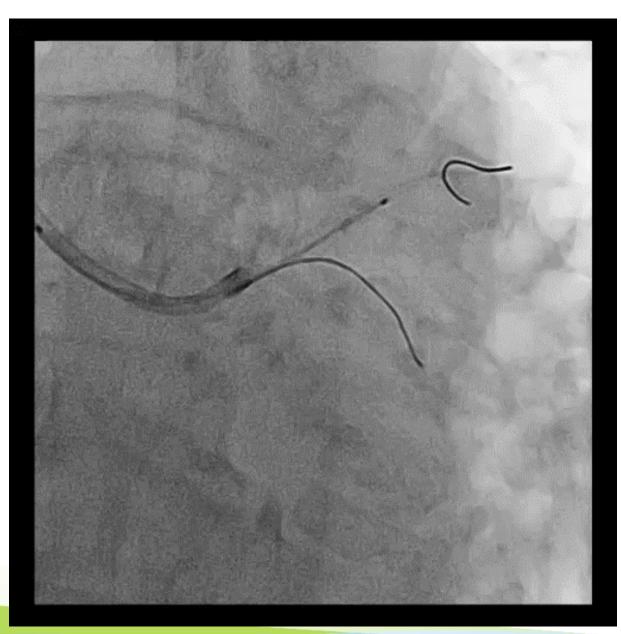
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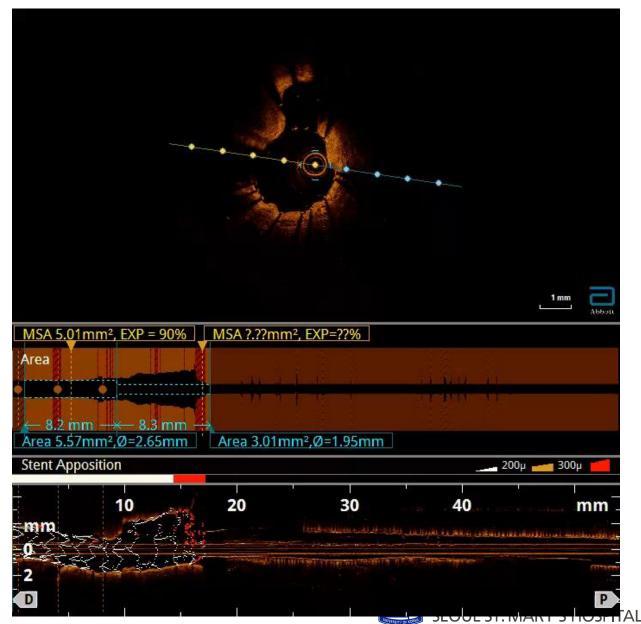
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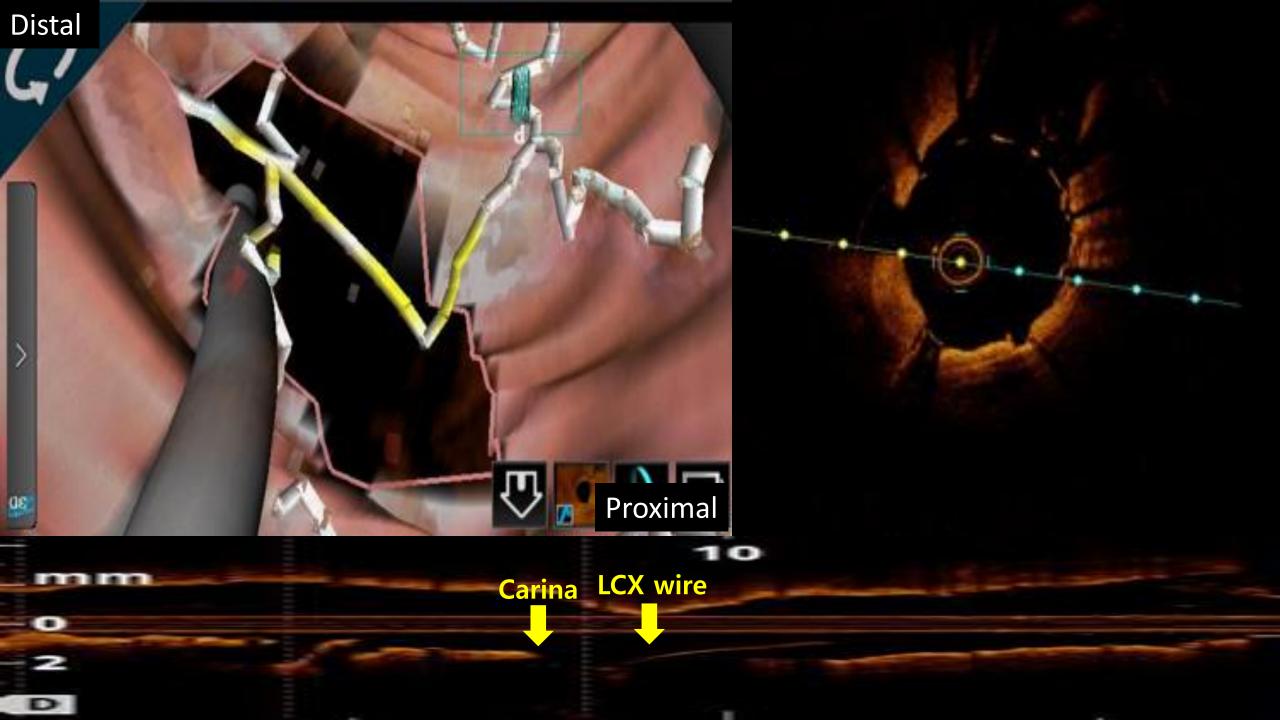
q

a

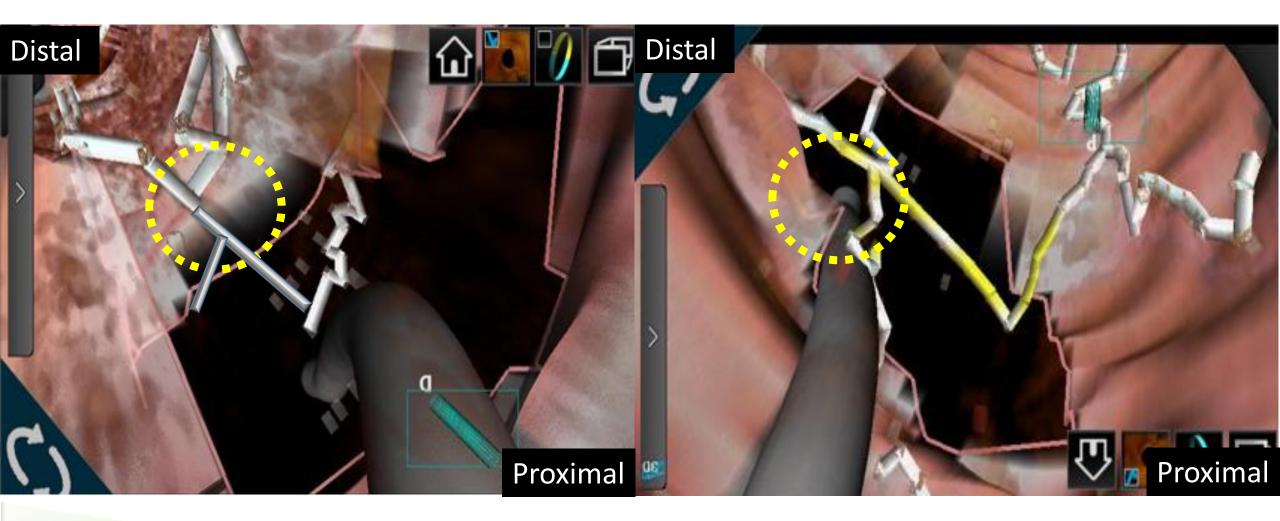
LAD OCT after 2nd LCX rewiring



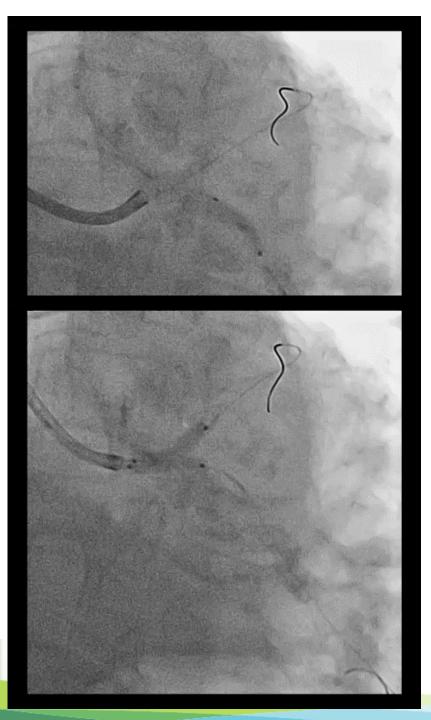




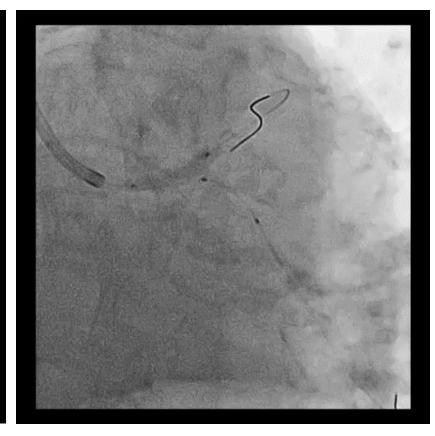
Comparison of 1st wiring (left) and 2nd wiring (right)







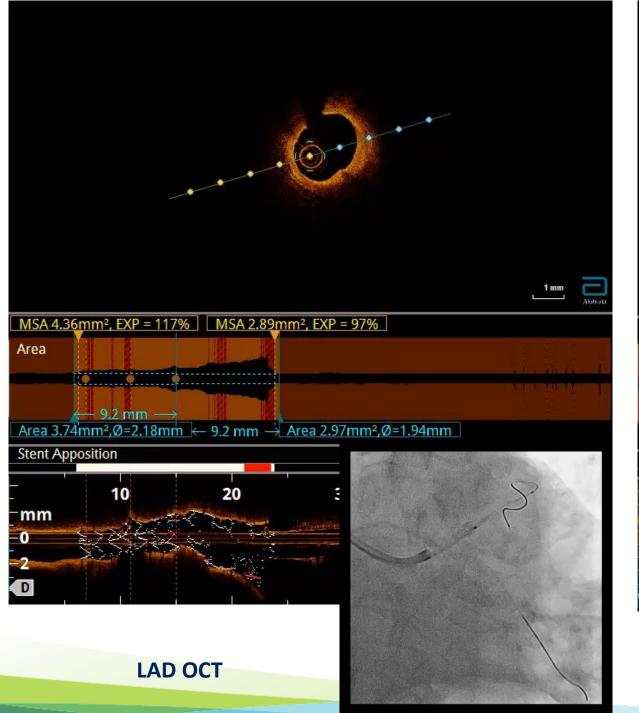


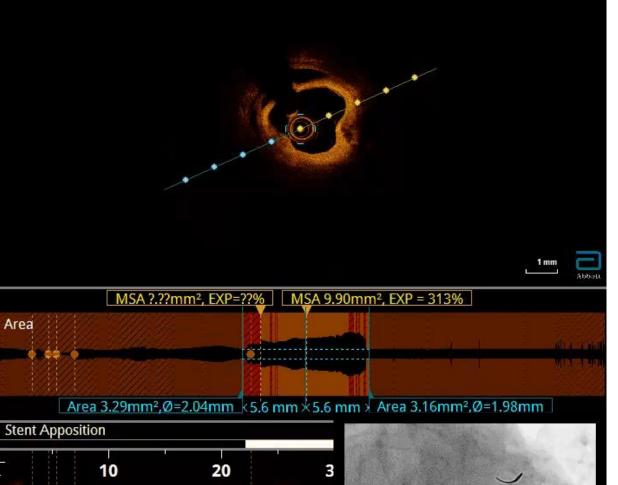


Kissing balloon

LAD 3.0 x 15mm NC balloon LCX 2.5 x 15mm NC balloon

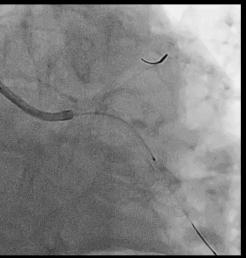




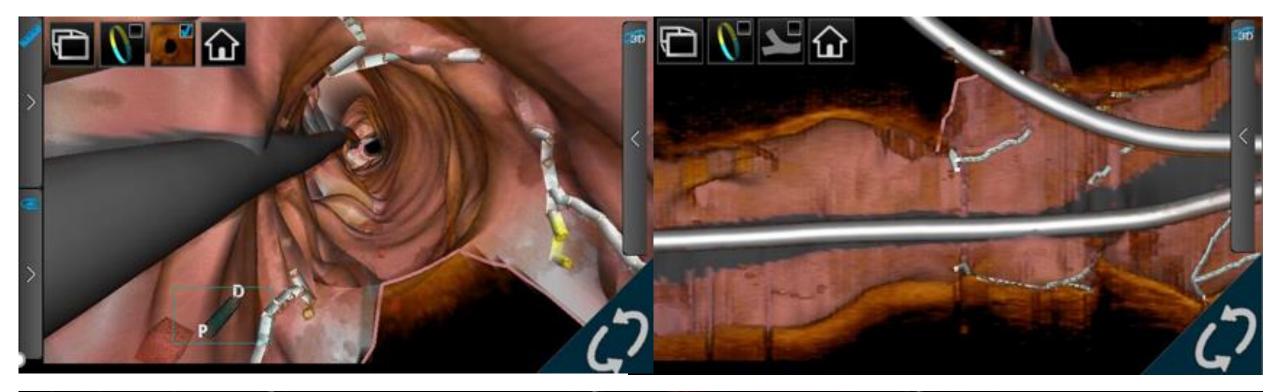


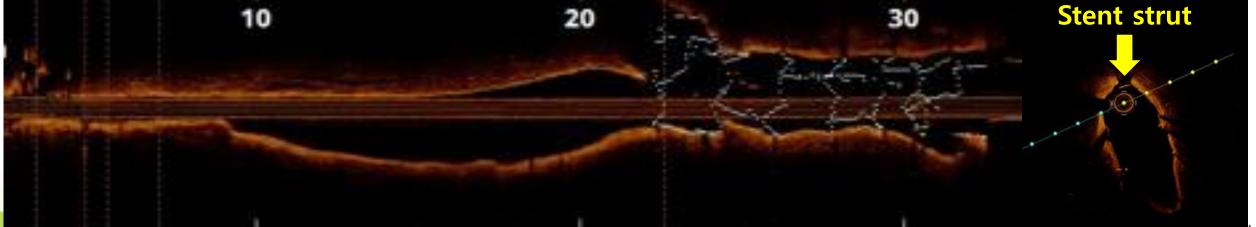
Stent Apposition 10 20 3 mm 0 -2 D

LCX OCT



LCX OCT : Cover of LCX wall opposite LAD



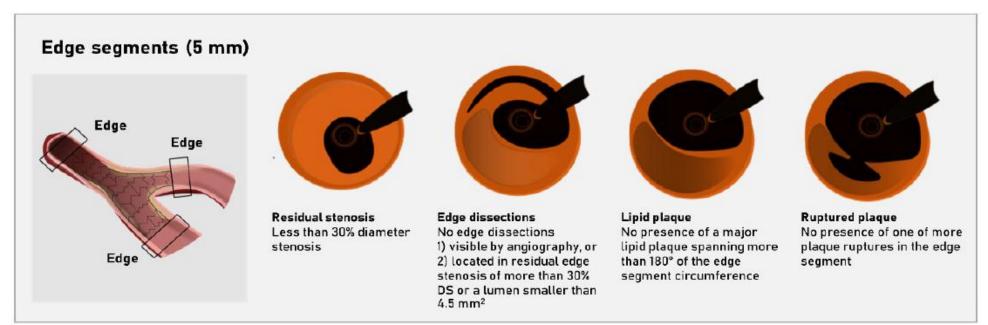


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T-Stent(2.75 x 23mm) Final KBT(Stent balloon with 3.0 x 15mm NC balloon)



Criteria for optimization in OCTOBER trial



Stented segments





Rewiring Wire passing through a strut

cell in front of the mid or distal part of the ostium. No unintended abluminal rewiring

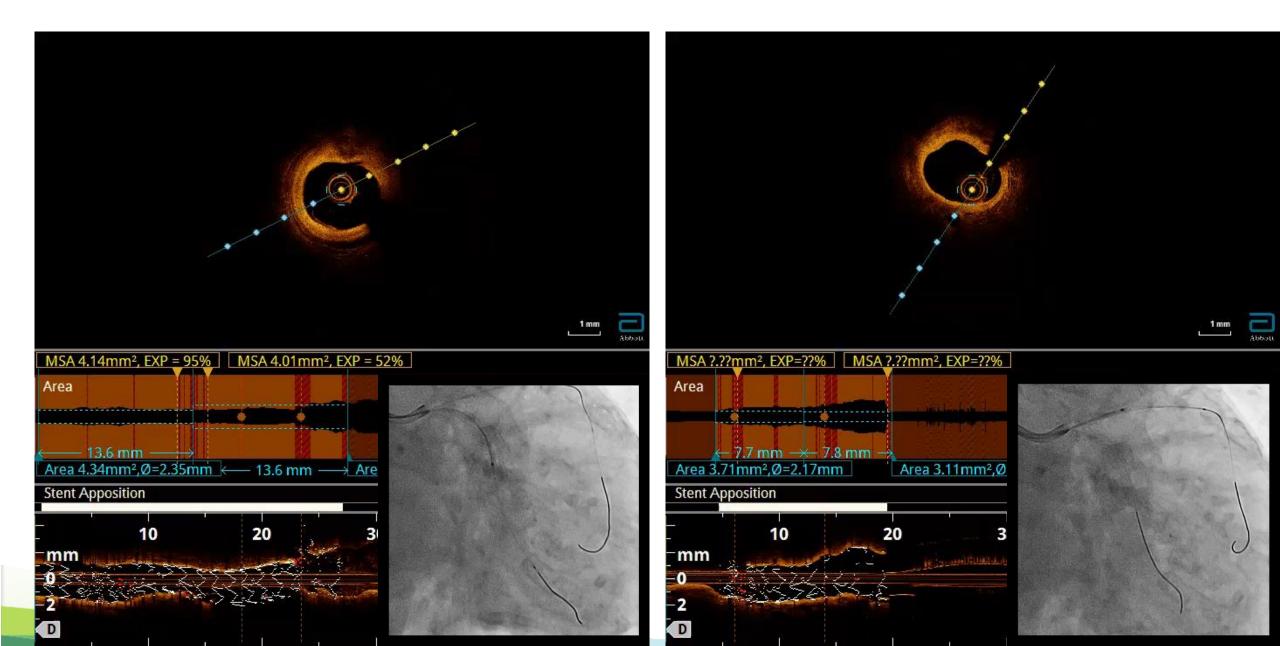


Stent malapposion No malapposition

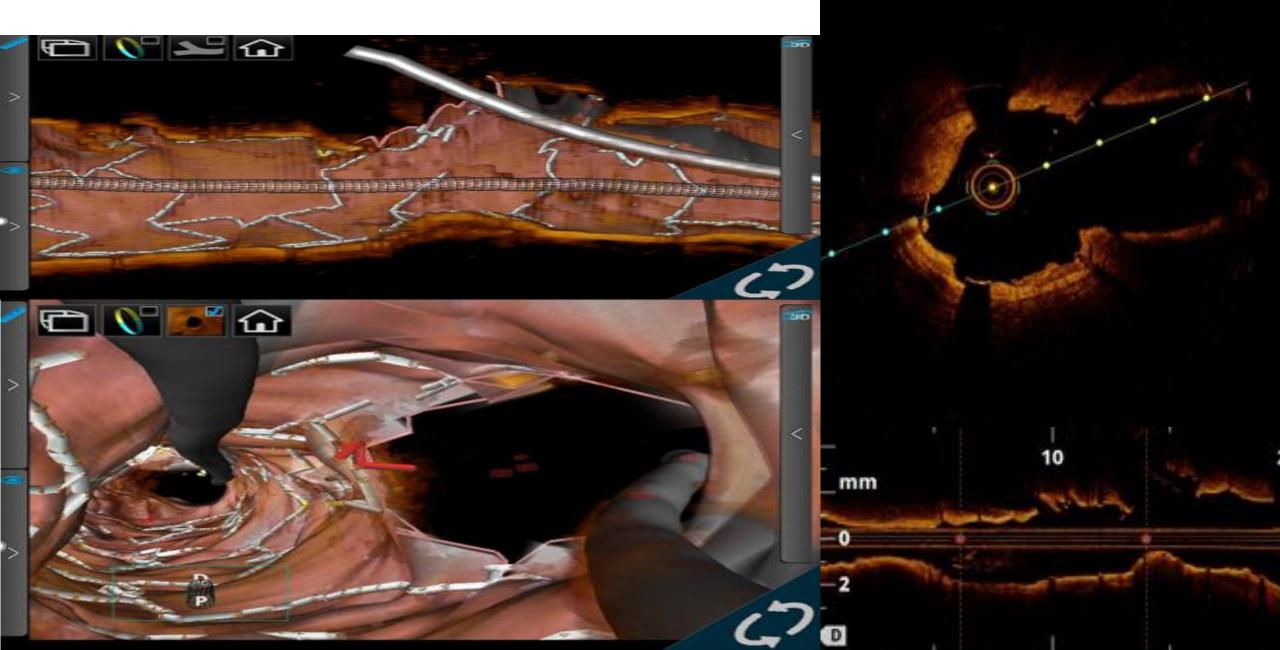


Accidental crushed stent segments No unintend major distortion or crush of implanted stents Stent expansion Stent diameter ≥ 90% of the corresponding segment's reference diameter Side branch ostium in onestent technique Minimal lumen diameter ≥ 50% of the reference diameter

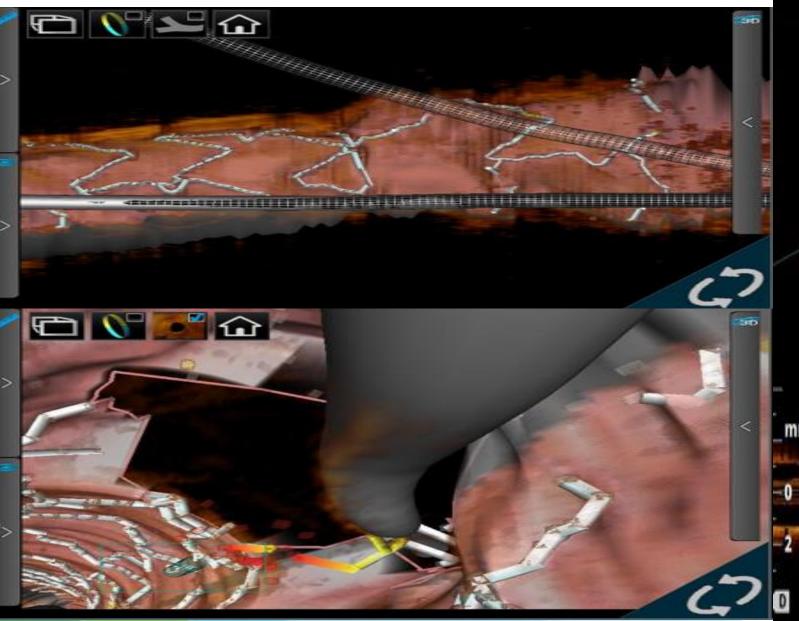
Final OCT

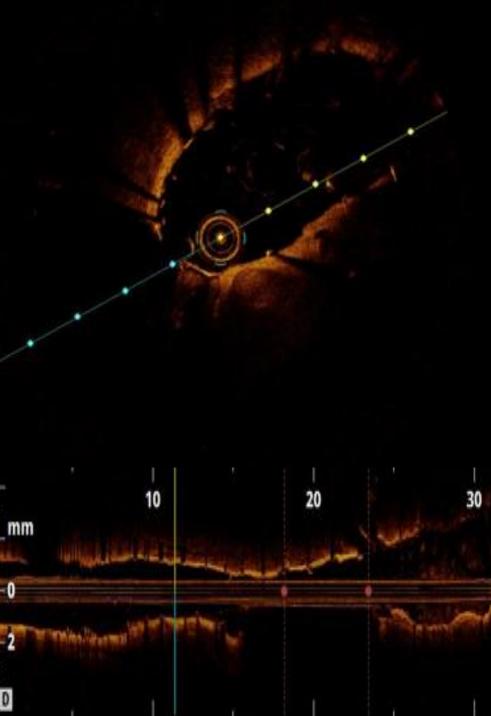


LAD OCT : Minimal neocarina

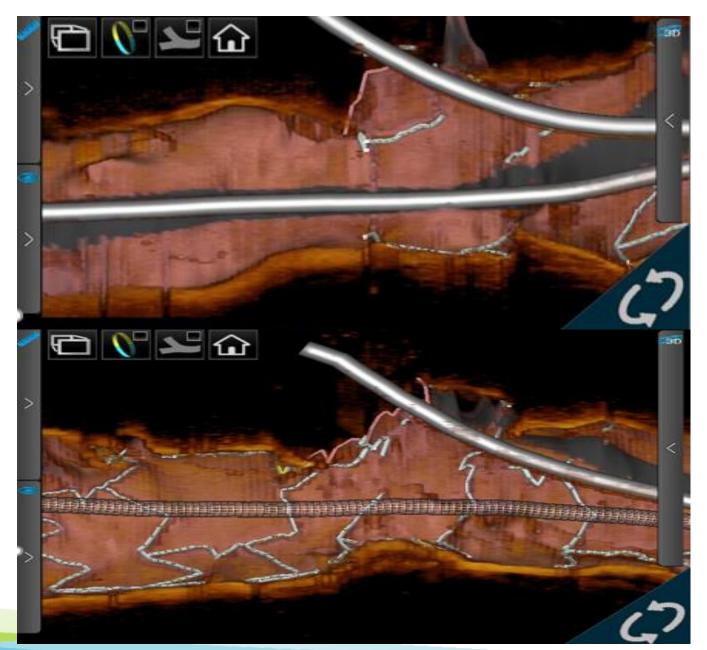


LCX OCT : Minimal neocarina and LCX os full-coverage



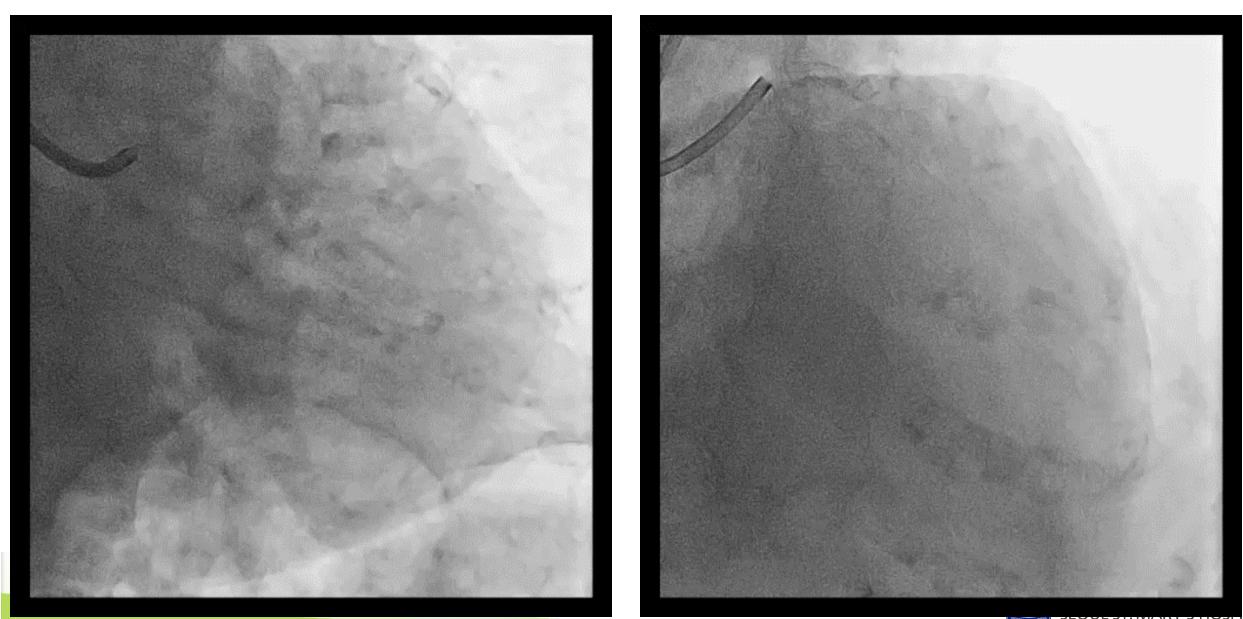


LCX OCT : LCX os Full-coverage

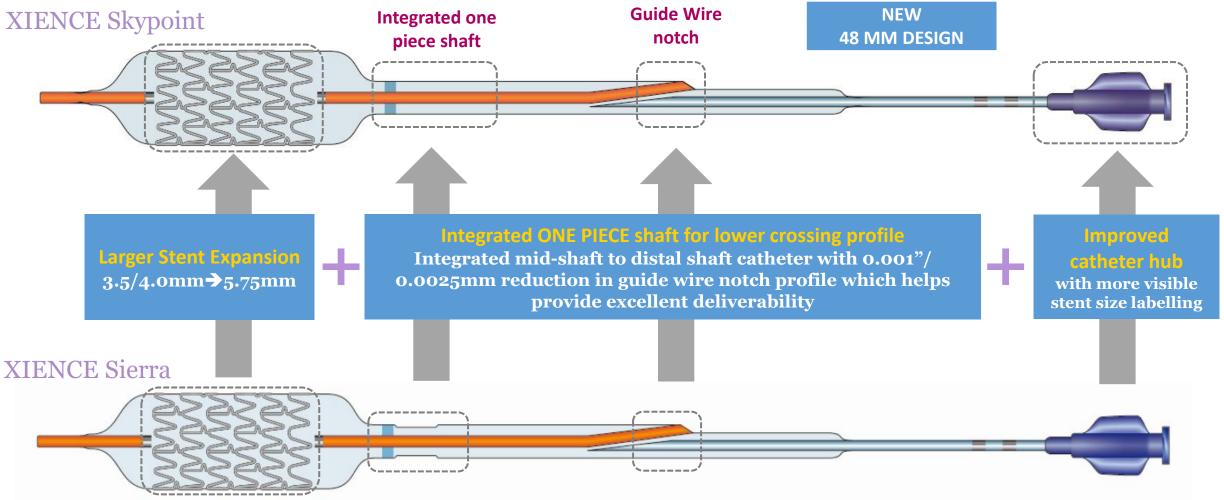




Final angiography



XIENCE Skypoint[™] has a number of improvements



Data on file at Abbott.



What does the name 'XIENCE Skypoint' MEAN?

XIENCE Skypoint

Combines the ideas of **expansiveness** (sky) and

→ Better Expansion

being able to **deliver to a specific spot** (point)

 \rightarrow Deliverability