



Resolute **Onyx**[™]
ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

Complex Lesions with Resolute Onyx

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TCT AP 2015

Disclosures

Speaker: Prof. [Seung-Woon Rha](#)

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
 - Receipt of honoraria and travel support
 - Participation in a company sponsored speakers' bureau
 - Employment in industry
 - Shareholder in a healthcare company
 - Owner of a healthcare company
-
- I do not have any potential conflict of interest

A FUTURE OF UNMATCHED INNOVATION

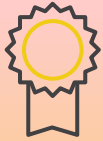


Introducing Resolute Onyx™ DES

The latest addition to the Medtronic Interventional Portfolio

Resolute Onyx™
Drug-Eluting
Stent

Resolute Onyx™ DES: THE ADVANCED WORKHORSE



PROCEDURAL SUCCESS

Most deliverable DES,*
featuring Core Wire
Technology



COMPLEX CASES

Broad size matrix to optimise
treatment of complex
clinical scenarios



SAFETY ASSURED

Proven long-term safety and
efficacy shown in the Global
RESOLUTE Program

*Based on bench test data vs. Promus Premier™ DES, Synergy™ II DES, Xience Xpedition™ DES and Resolute Integrity™ DES.

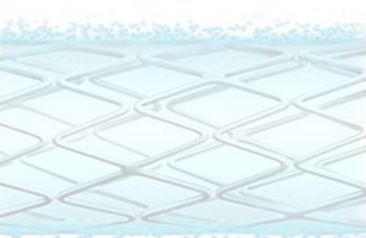
ADVANCING DES TECHNOLOGY

Evolved from Continuous Sinusoid Technology, **Core Wire Technology** is the next advancement in DES technology

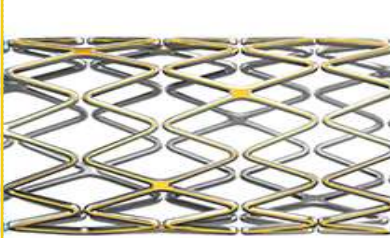
Integrity™
Bare Metal Stent



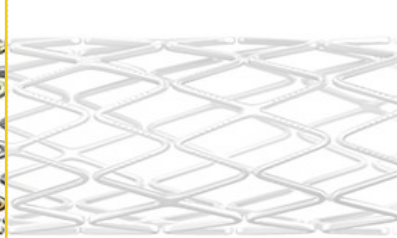
Resolute Integrity™
Drug-Eluting Stent



Core Wire Technology
Drug-Eluting Stent



Polymer-Free Drug-
Eluting Technology



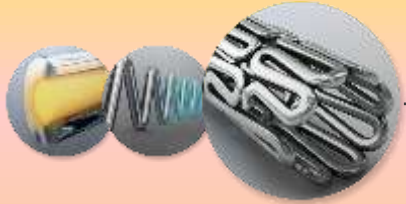
Bioabsorbable
Technology



Today's Stents

→ Tomorrow's Technologies

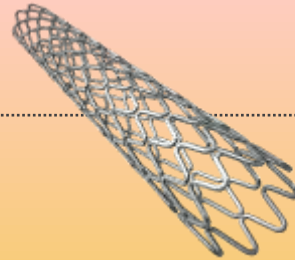
PROVEN COMPONENTS ENHANCED BY NEW TECHNOLOGIES



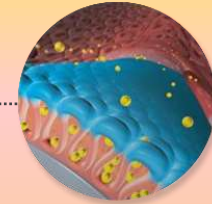
Continuous Sinusoid Technology
and Core Wire Technology



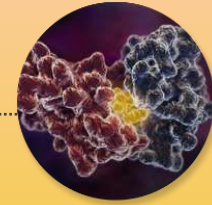
Advanced delivery system with
PowerTrac™ technology



Resolute Onyx™ DES

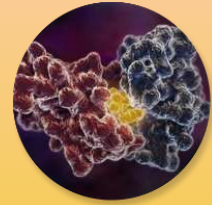
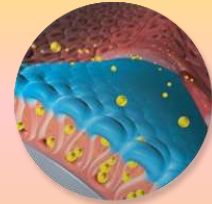
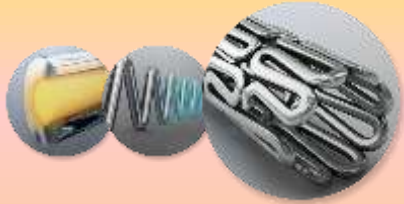


Proven, durable
BioLinX™ polymer

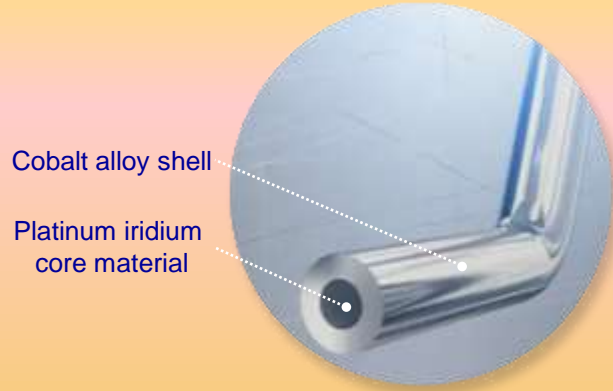


Proven zotarolimus drug

PROVEN COMPONENTS ENHANCED BY NEW TECHNOLOGIES



BENEFITS OF CORE WIRE TECHNOLOGY



Increased deliverability

Thinner struts with enhanced radiopacity

No compromise to structural strength

Continuous Sinusoid Technology
and Core Wire Technology



CORE WIRE INNOVATION

Evolved from Continuous Sinusoid Technology, **Core Wire Technology** is the next advancement in DES technology



Helical wrap



Laser-fused



Fluid range of motion

Resolute Onyx™ DES is manufactured from a single strand of core wire into a continuous sinusoidal wave form to provide a fluid range of motion.

Continuous Sinusoid Technology
and Core Wire Technology

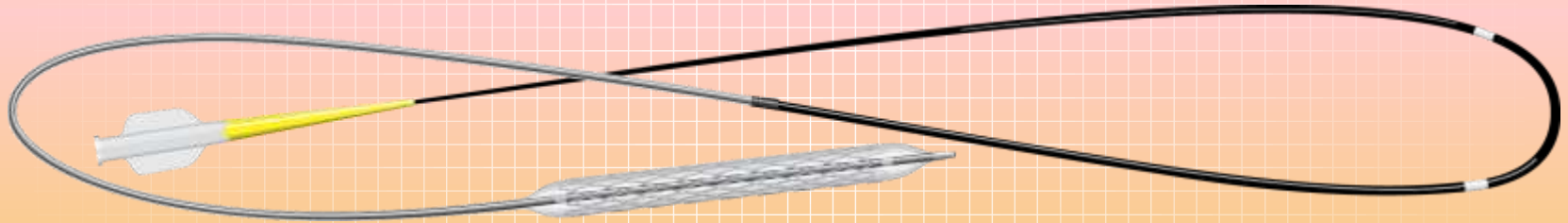


DELIVERY SYSTEM ENHANCES DEVICE PERFORMANCE*

Lubricious hydrophilic coating
for reduced drag

PowerTrac™ technology enhances
deliverability

Resilient hypotube for high shaft
column strength



New Pebax™ blend balloon
material improves nominal
pressure and balloon compliance

Platinum Iridium markers for
reduced crossing profile

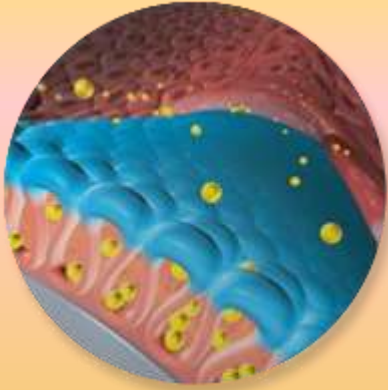
Reduced catheter profile under
the stent enables lower
crossing profiles

Advanced delivery system with
PowerTrac™ technology



*Based on bench test data. May not be indicative of clinical performance.

PROVEN COMPONENTS OF Resolute Onyx™ DES



Biocompatible BioLinx™ polymer:

Minimal inflammation*

Low thrombotic risk*

Rapid, complete and functional endothelial healing*

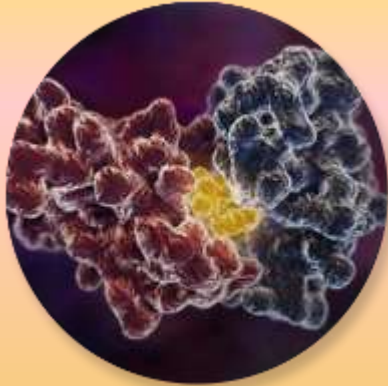
Proven long-term safety:

Sustained safety of 1.2% ST through five years in more than 7500 patients from the RESOLUTE Pooled analysis

Proven, durable
BioLinx™ polymer

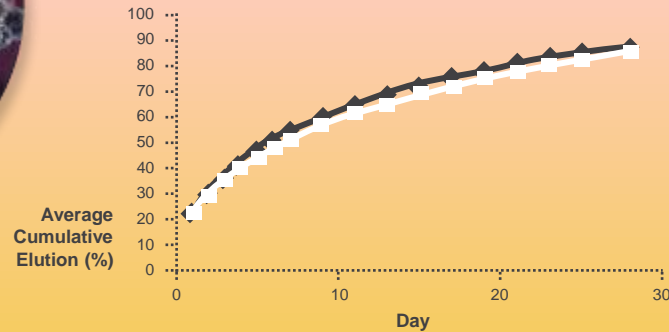


PROVEN COMPONENTS OF Resolute Onyx™ DES



Zotarolimus drug delivery:

Similar *in vivo** elution results for Resolute Onyx™ DES



In vitro† elution:
Comparison of Resolute Onyx DES
and Resolute Integrity™ DES

- ◆ Resolute Onyx DES
- Resolute Integrity DES

Proven
zotarolimus drug

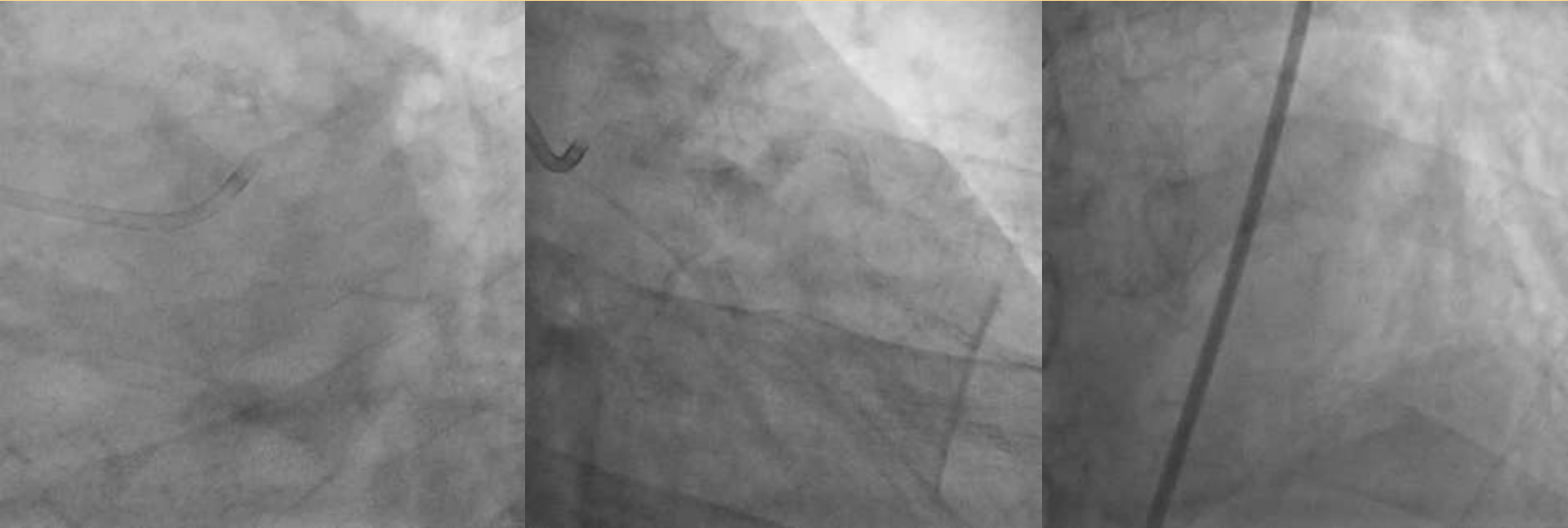


*In porcine models. Based on test data on file at Medtronic, Inc. May not be indicative of clinical performance.
†Based on bench test data. May not be indicative of clinical performance.

Onyx Case (1)

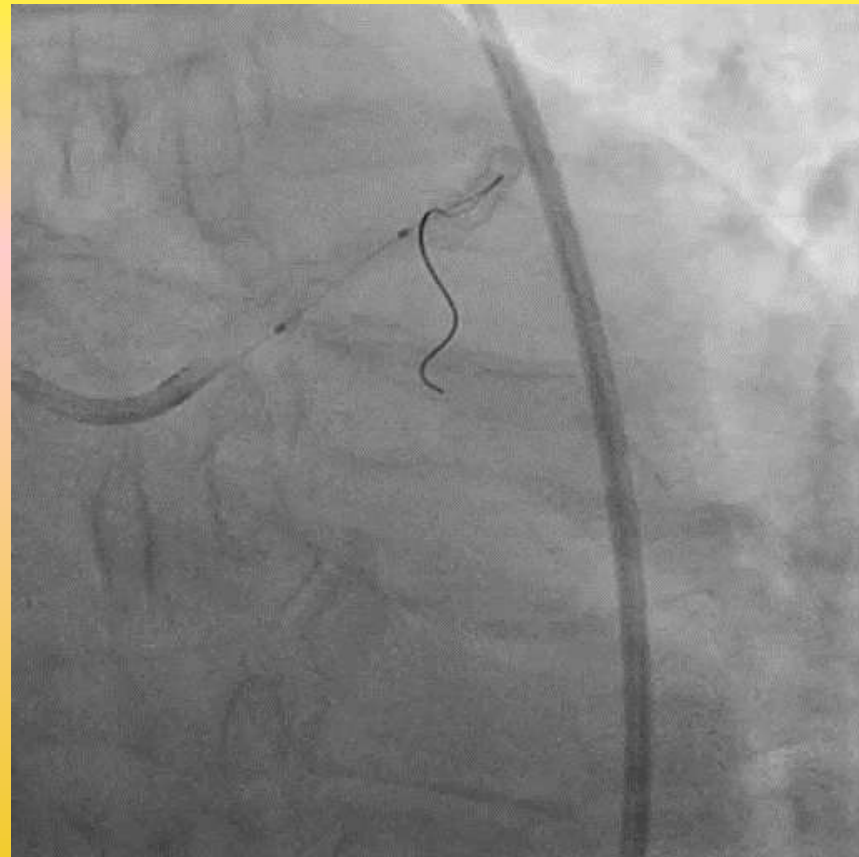
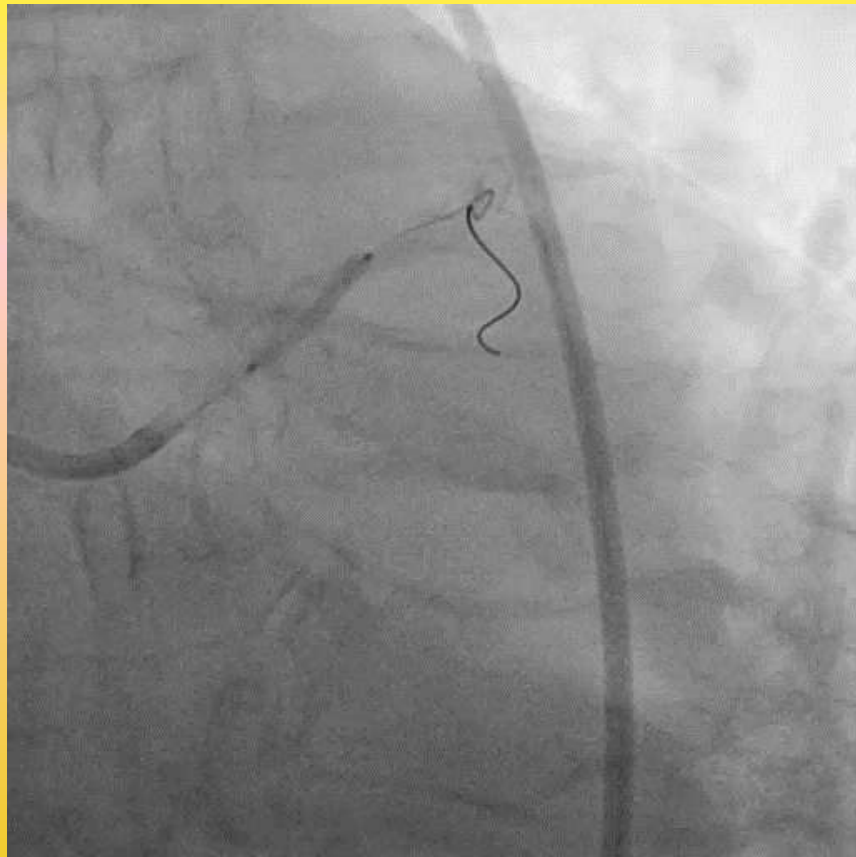
Left Main Disease

Baseline Angiography



6F JL4 SH

Predilation



Tamarine 2.0X15mm

LM Stenting; Onyx



Resolute Onyx 3.5X15mm (12 atm/5sec, 18/5)

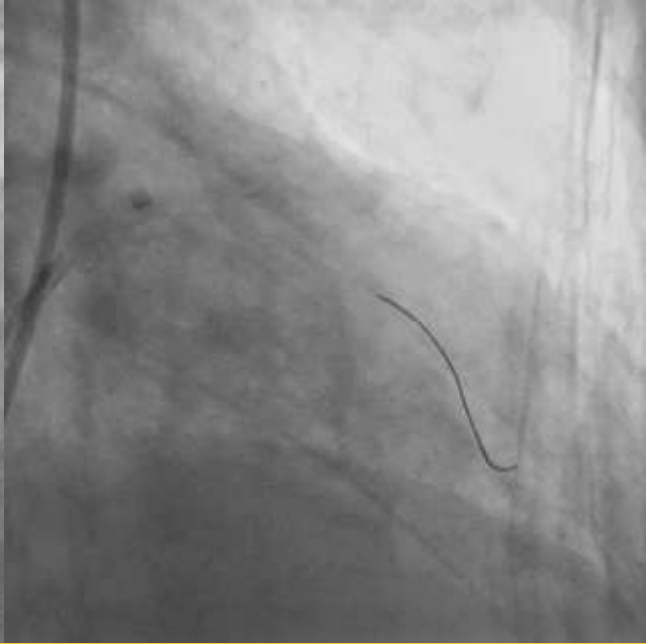
IVUS-guided Stent Optimization



Boston IVUS; Opticross

NC Lacross 4.0X10mm
Quantum 5.0X8mm (20/5)

LM-Final Angiography



Resolute Onyx™ DES: COMPLIANCE DATA

Pressure kPa (atm)	Stent Diameter							Deployed Stent I.D. (mm)	
	2.00*	2.25*	2.50*	2.75*	3.00*	3.50*	4.00*		
709 (7)	1.85	2.05	2.25	2.45	2.75	3.05	3.60		
811 (8)	1.90	2.10	2.30	2.55	2.80	3.15	3.70		
912 (9)	1.90	2.15	2.35	2.60	2.90	3.25	3.80		
1013 (10)	1.95	2.20	2.45	2.65	2.95	3.35	3.85		
1115 (11)	2.00	2.25	2.50	2.70	3.00	3.40	3.95		
1216 (12)	2.05	2.30	2.55	2.75	3.05	3.45	4.00		
1317 (13)	2.05	2.35	2.55	2.80	3.10	3.50	4.05		
1419 (14)	2.10	2.35	2.60	2.80	3.10	3.55	4.05		
1520 (15)	2.10	2.35	2.60	2.85	3.15	3.55	4.10		
1621 (16)	2.15	2.40	2.65	2.90	3.20	3.60	4.15		
1723 (17)	2.15	2.40	2.70	2.90	3.20	3.65	4.20		
1824 (18)	2.20	2.45	2.70	2.95	3.25	3.70	4.25		
1925 (19)	2.20	2.45	2.75	3.00	3.30	3.75	4.30		
2027 (20)	2.25	2.50	2.75	3.00	3.35	3.80	4.35		
2128 (21)	2.25	2.50	2.80	3.05	3.40	3.80	4.40		
MSID	3.25 mm	3.25 mm	3.25 mm	3.75 mm	3.75 mm	4.75 mm	4.75 mm		

Nominal Pressure
 Rated burst pressure†

*Do not postdilate the 2.00–2.50-mm stents to greater than 3.25 mm; do not postdilate the 2.75–3.00-mm stents to greater than 3.75 mm; do not postdilate the 3.50–4.00-mm stents to greater than 4.75 mm.

†Do not exceed rated burst pressure.

Onyx Case (2)

Left Circumflex CTO with Bifurcation

LCA-Baseline Angiography

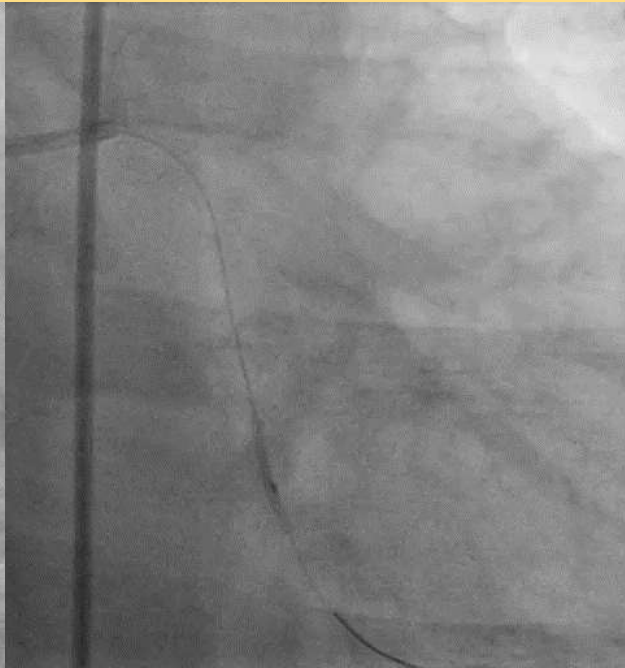


6F EBU 3.5

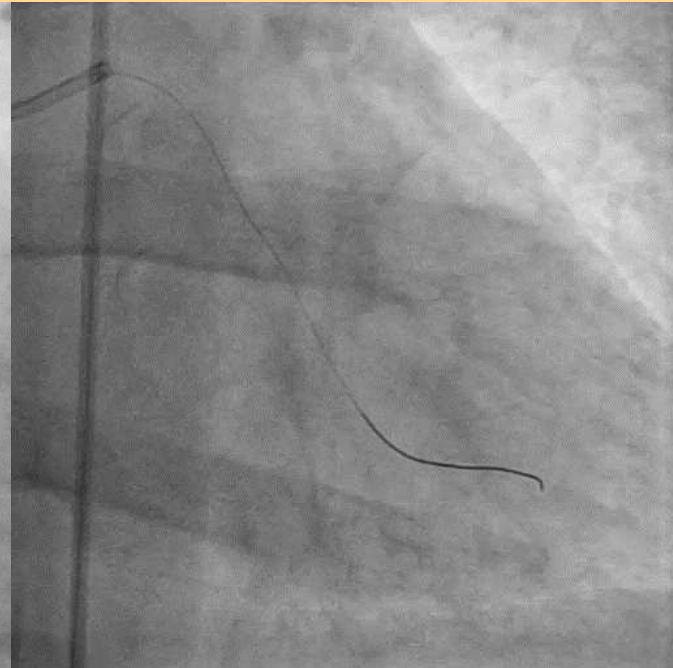
Wiring and Predilation



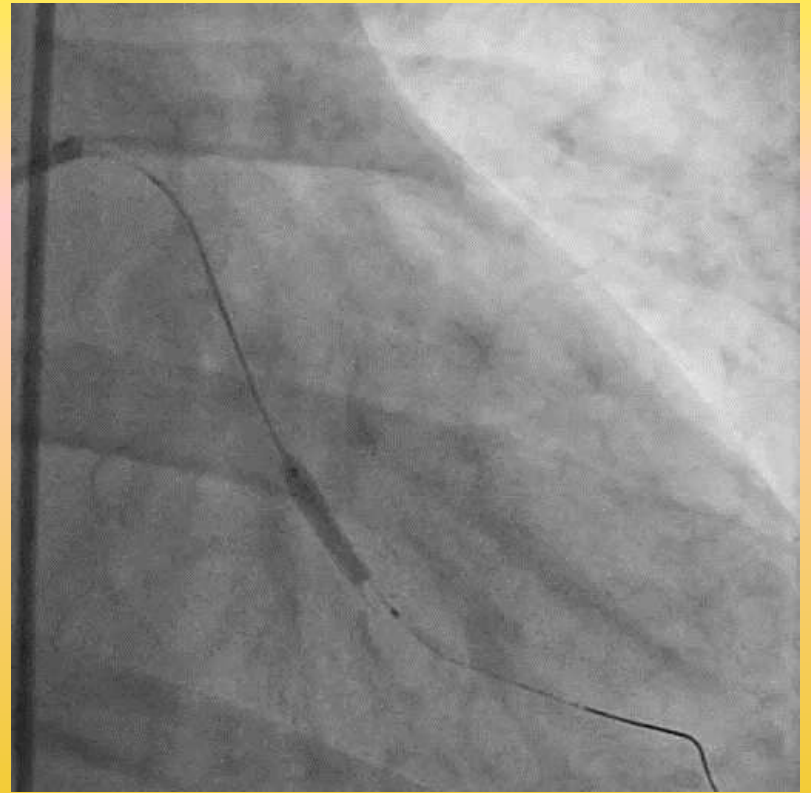
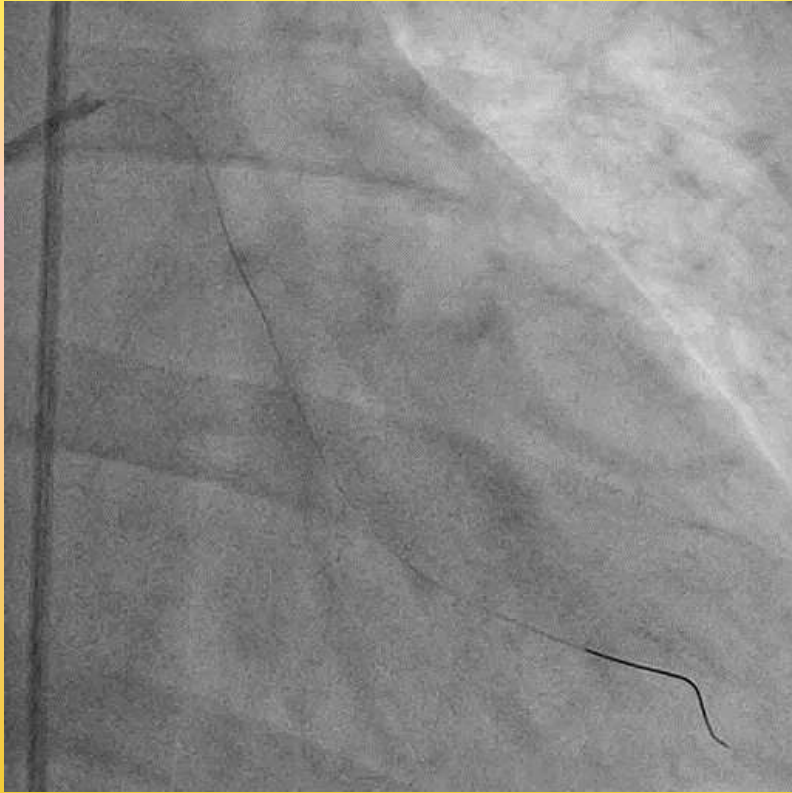
Sion Black wire



Minitrek 1.5X15mm
Laxa 2.0X15mm

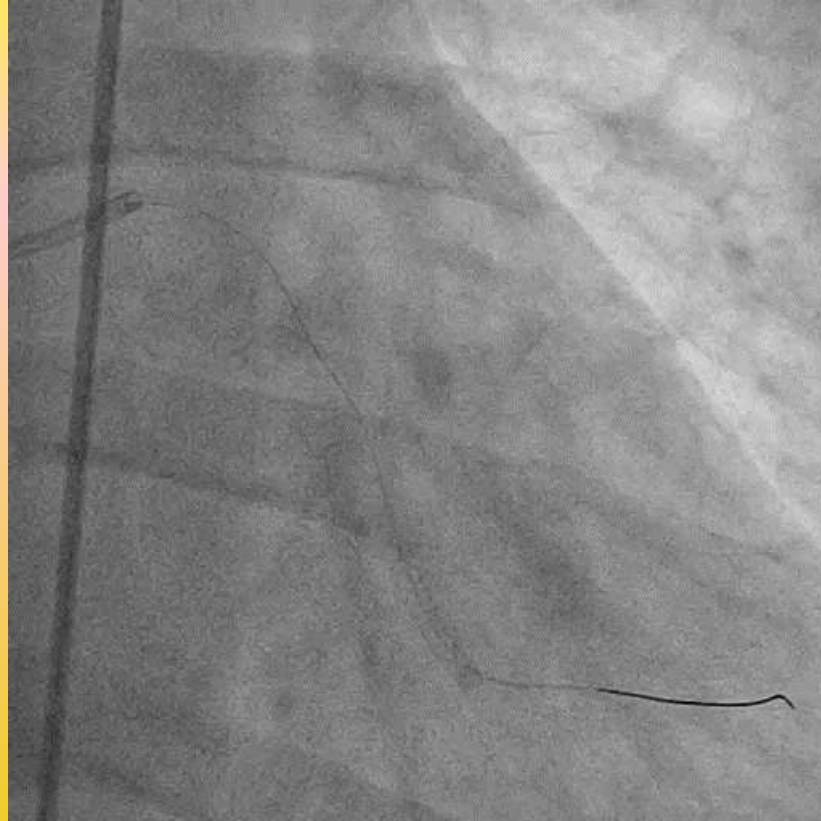


LCX distal; Onyx

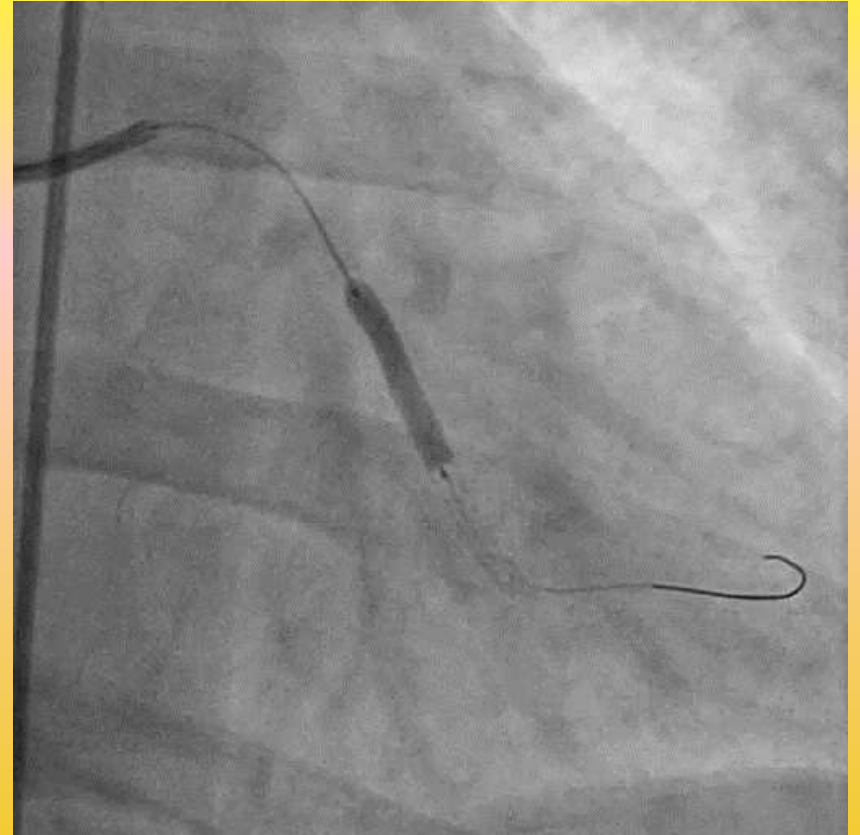
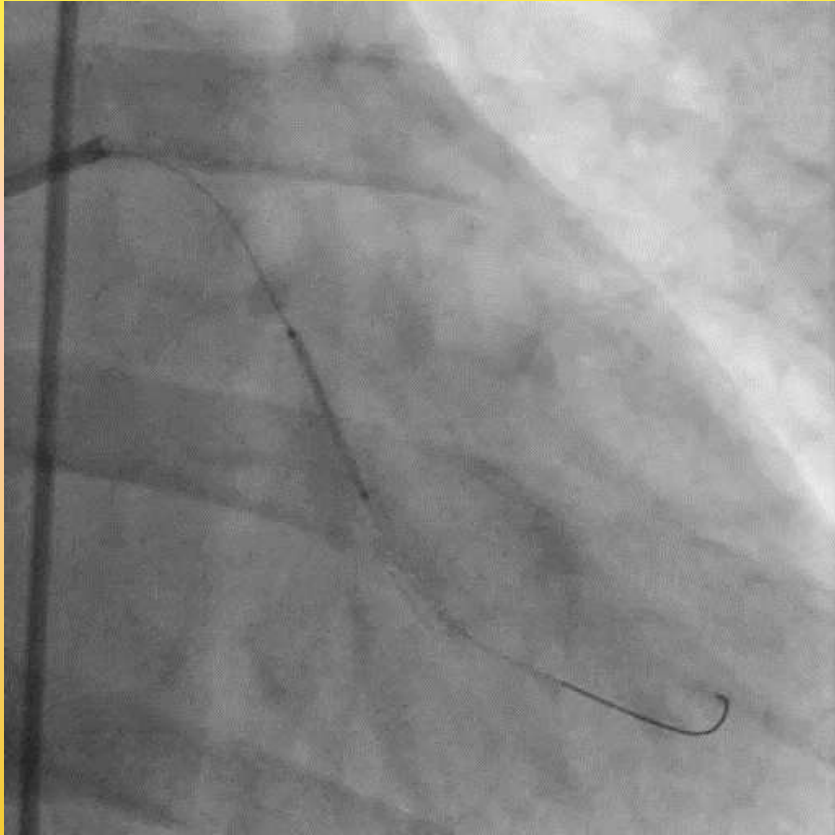


Resolute Onyx 2.5X15mm (12/5, 14/10)

Post Onyx Stenting

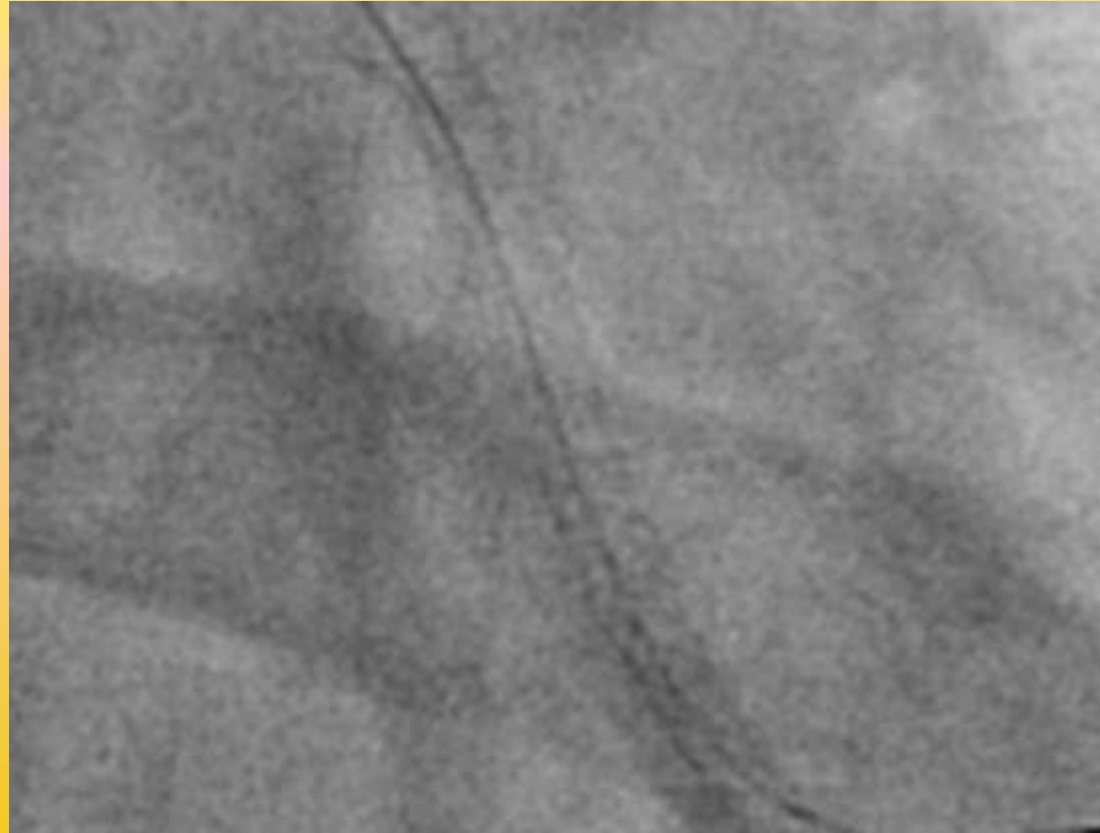


LCX Proximal; Resolute Integrity



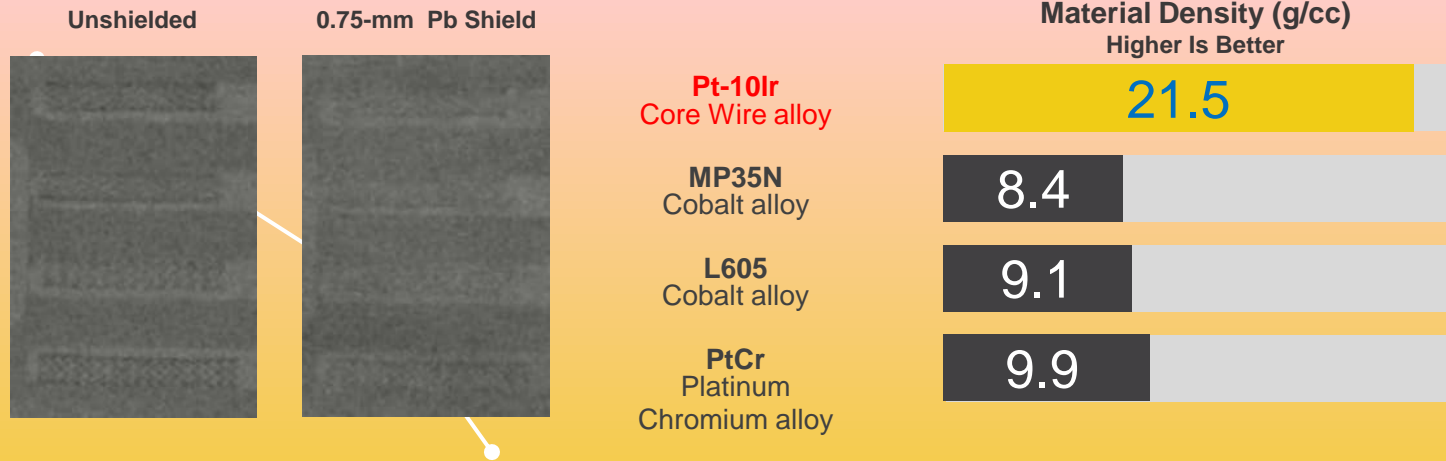
Resolute Integrity 2.75X22mm (16/5, 14/5)

Stent Boost Image and Magnified Image

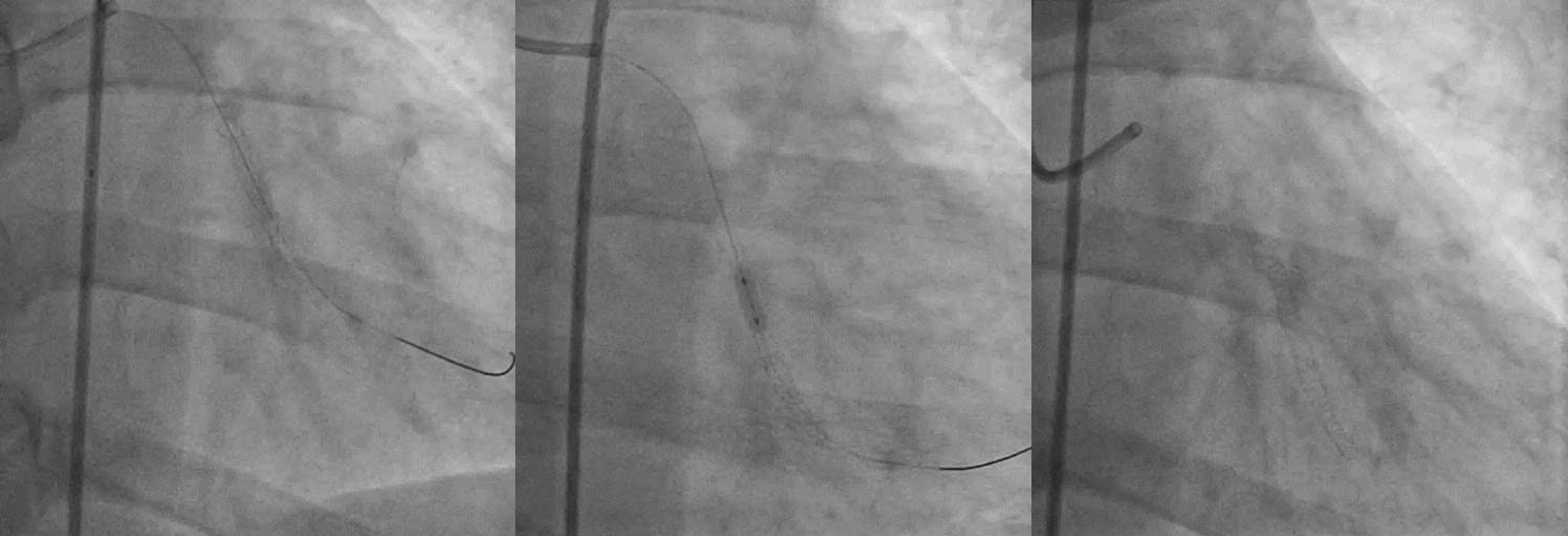


THINNER STRUTS, ENHANCED RADIOOPACITY

Dense platinum iridium core material provides better radiopacity and MP35N cobalt alloy provides excellent structural strength



Post Stenting and Adjuvant Ballooning



NC Lacrosse 2.75X8mm (28/5)

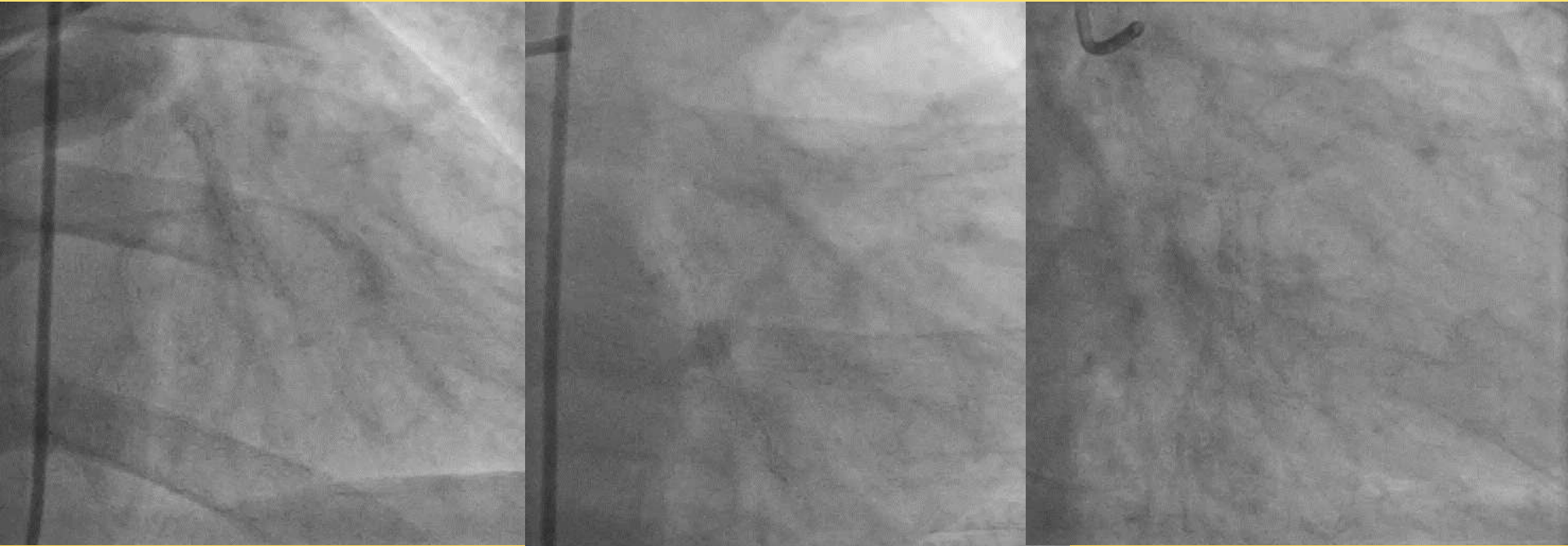
LCX distal-Bifurcation Management



Minitrek 1.5X15mm

Onyx balloon 2.5X15mm

LCX-Final Angiography

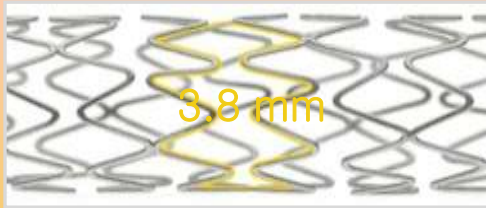


Excellent Radioopacity!
Excellent Bifurcation Management!

OPEN CELL DESIGN, INCREASED ACCESS

Open cell design for excellent sidebranch sizing

Test Setup Cell Size After Expansion 3.00-mm Stent Design



Resolute Onyx™ DES



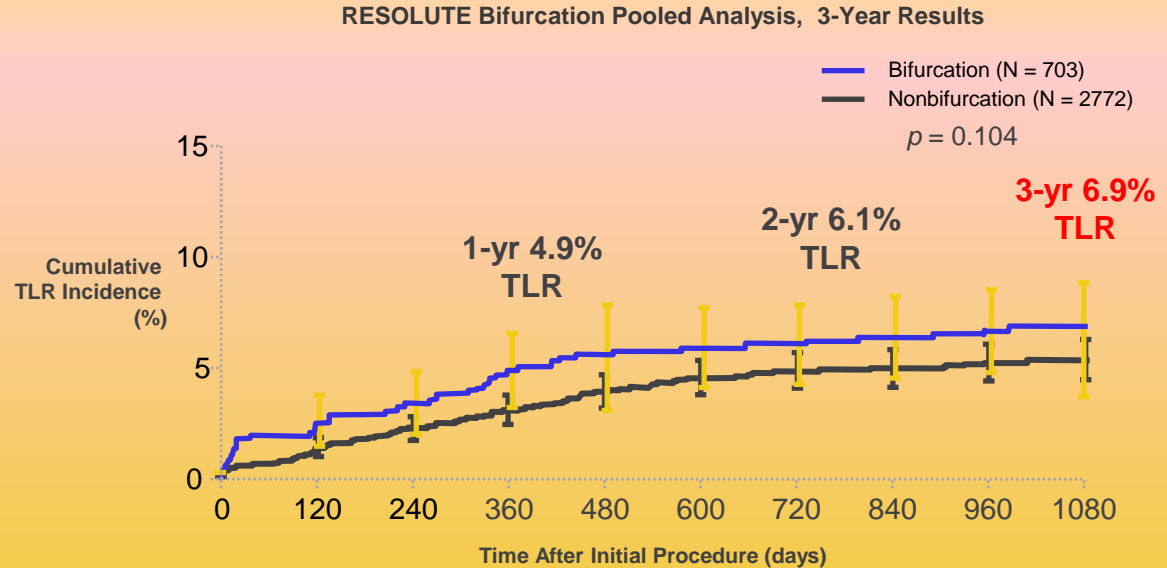
Xience Xpedition™ DES



Promus Premier™ DES

PROVEN LONG-TERM OUTCOMES IN COMPLEX BIFURCATION LESIONS

Outstanding TLR
performance similar
to nonbifurcation
lesions



Onyx Case (3)

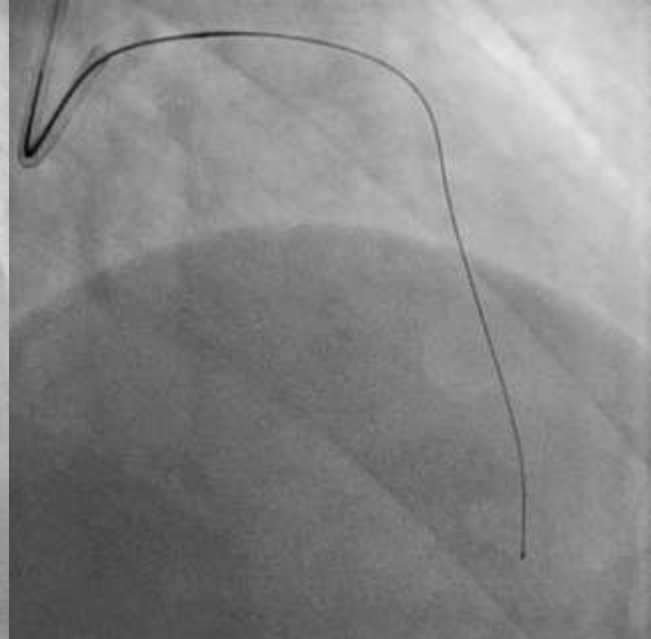
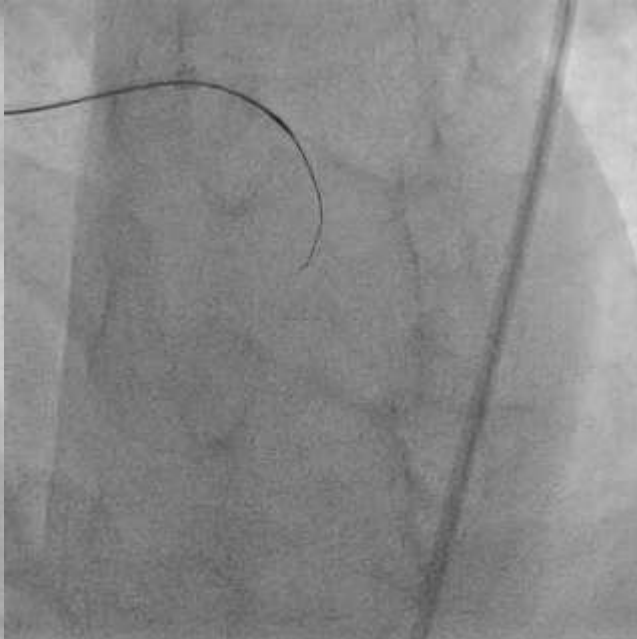
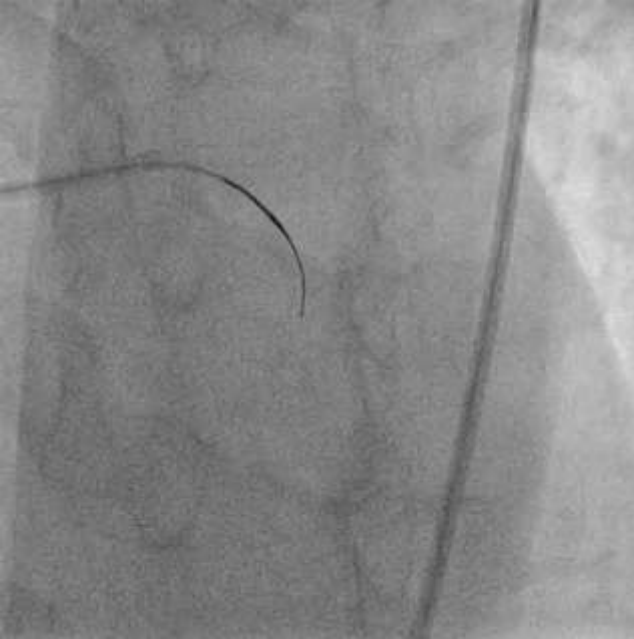
Triple Vessel Disease including Two
CTO Lesions

Baseline Angiography; LCA



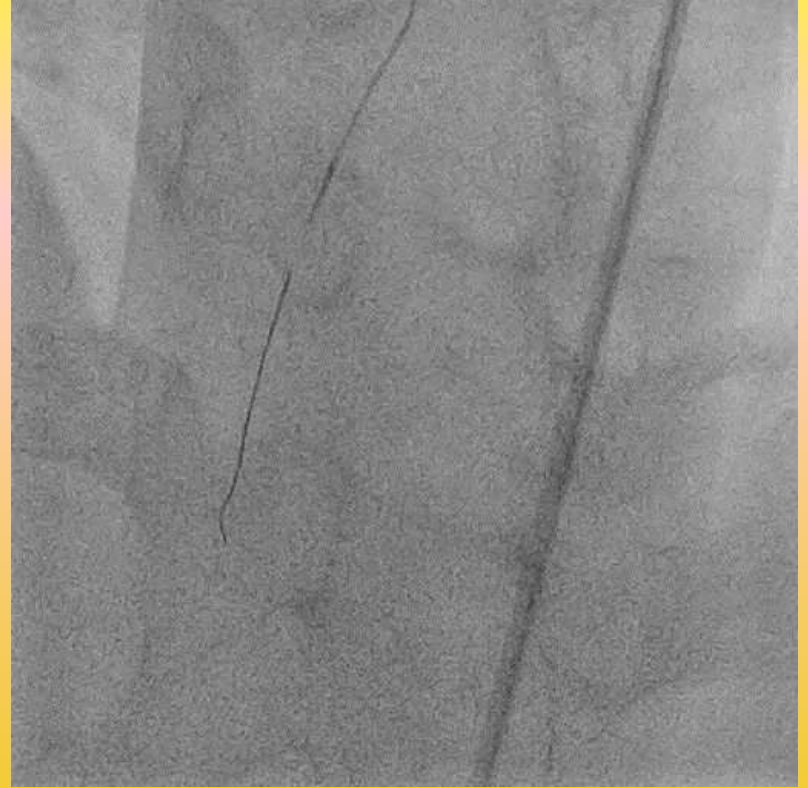
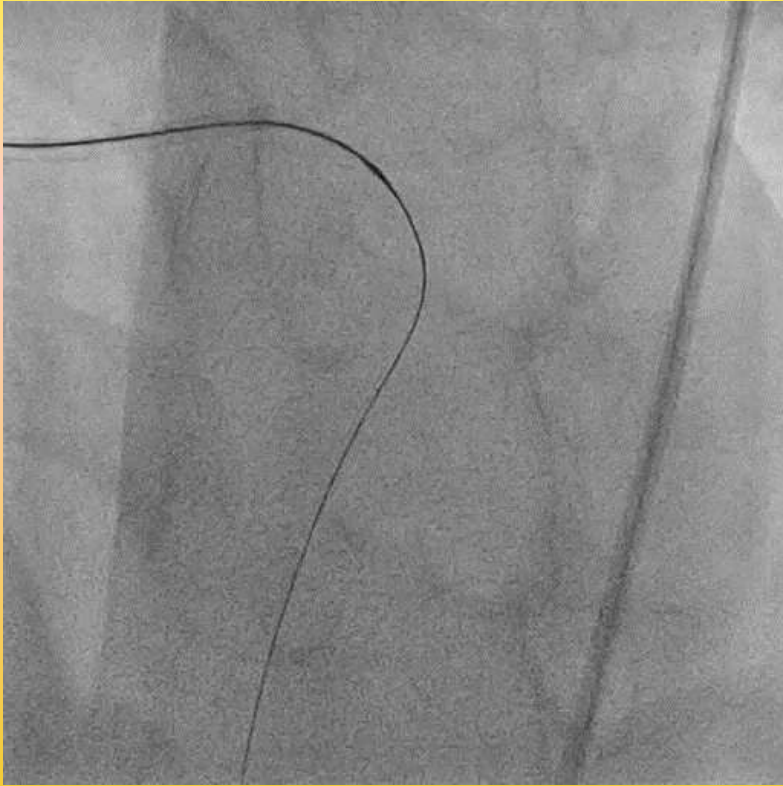
7F EBU 3.5 SH

LAD CTO-wiring



Corsair 135cm
Fielder XTR

Wire Exchange



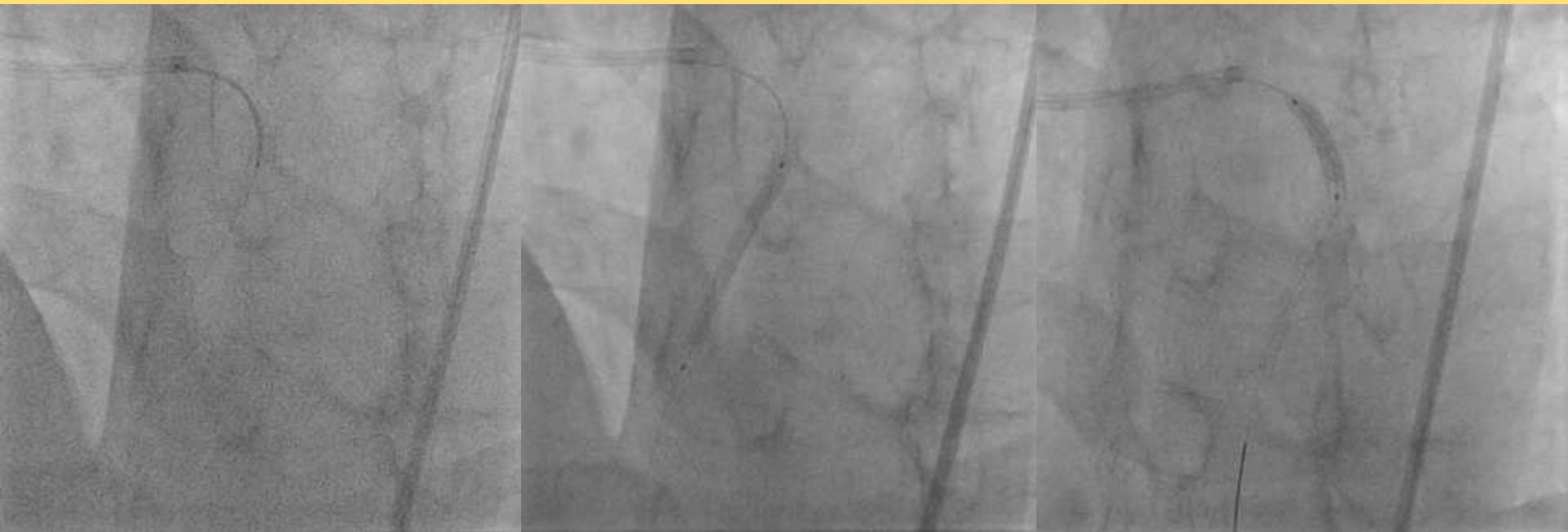
Fielder XTR → Runthrough NS wire

LAD-Predilatation



Pantera 2.0X15mm

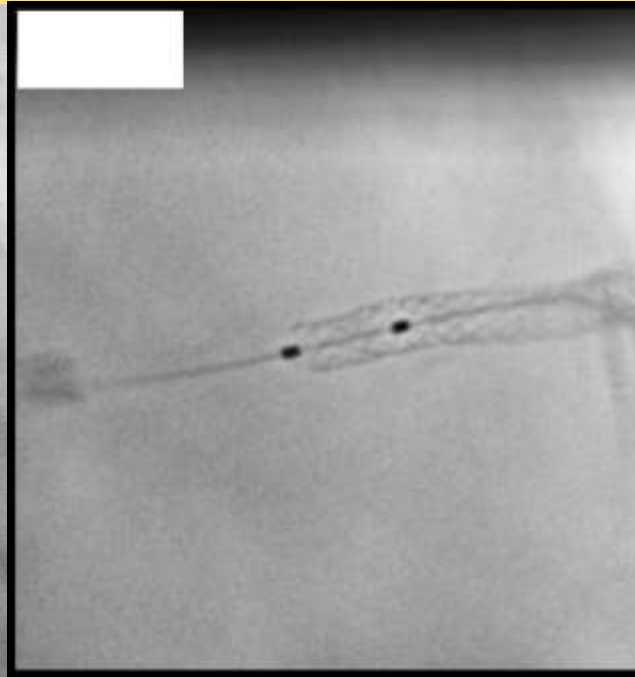
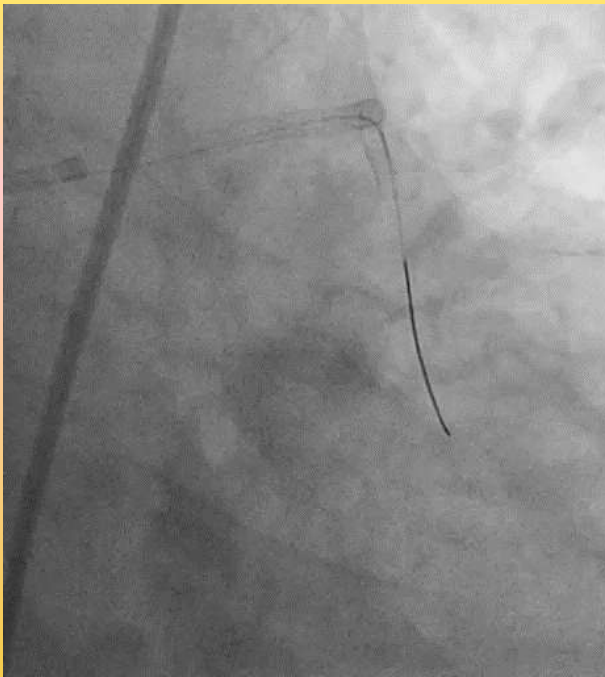
LAD stenting-Onyx



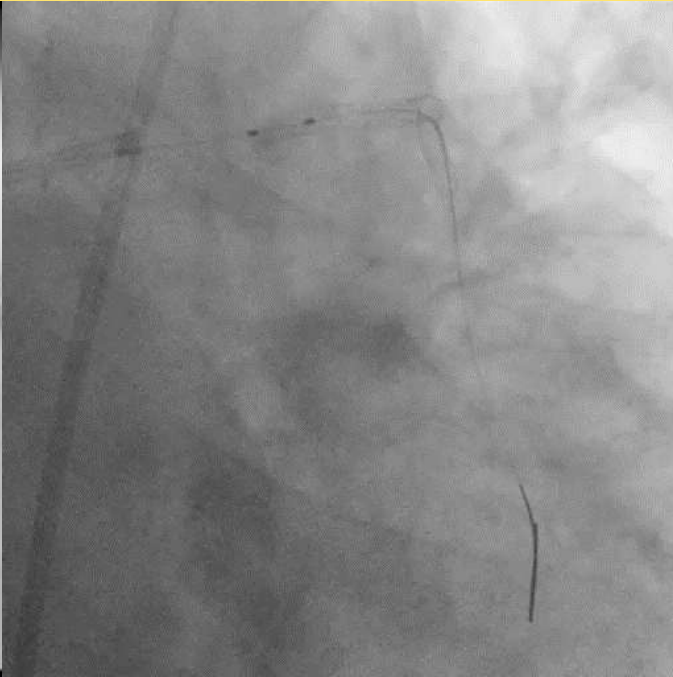
Resolute Onyx 2.5X34mm (12/5)

Resolute Onyx 3.0X22mm (12/5)

LAD; Stent Boost-guided Onyx Optimization

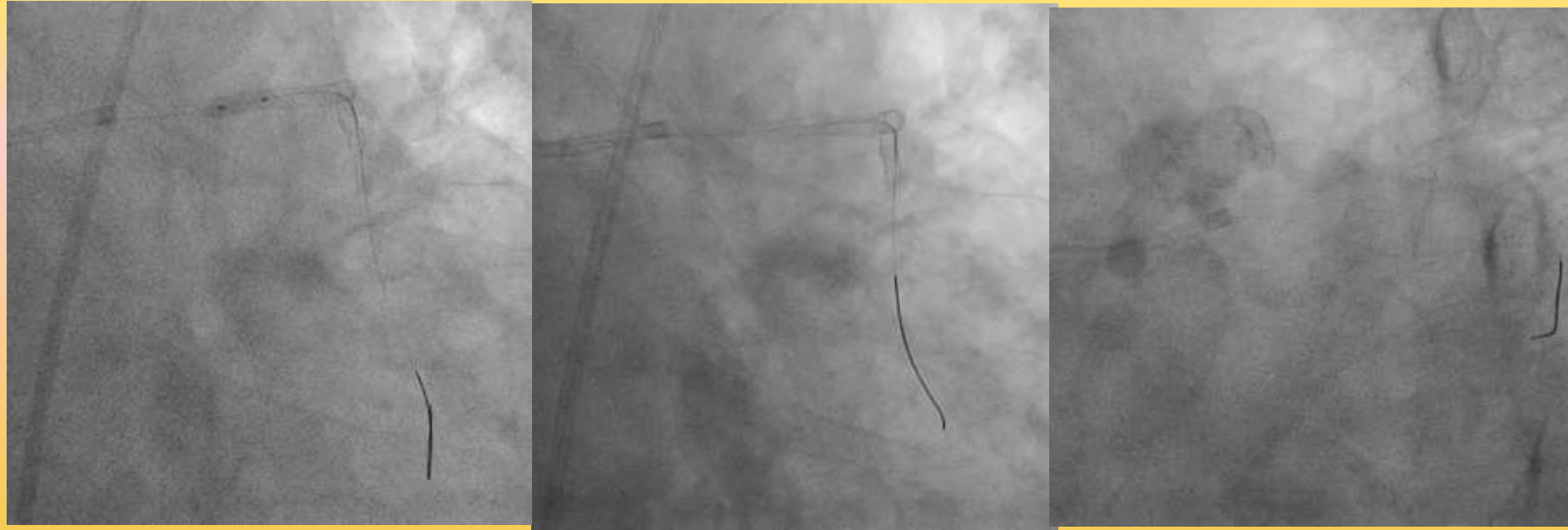


Stent Boost



Cine 15F/sec

Post-dilation and Suspicious of Prox Edge Injury



Pantera Leo 3.0X8mm (18/5)

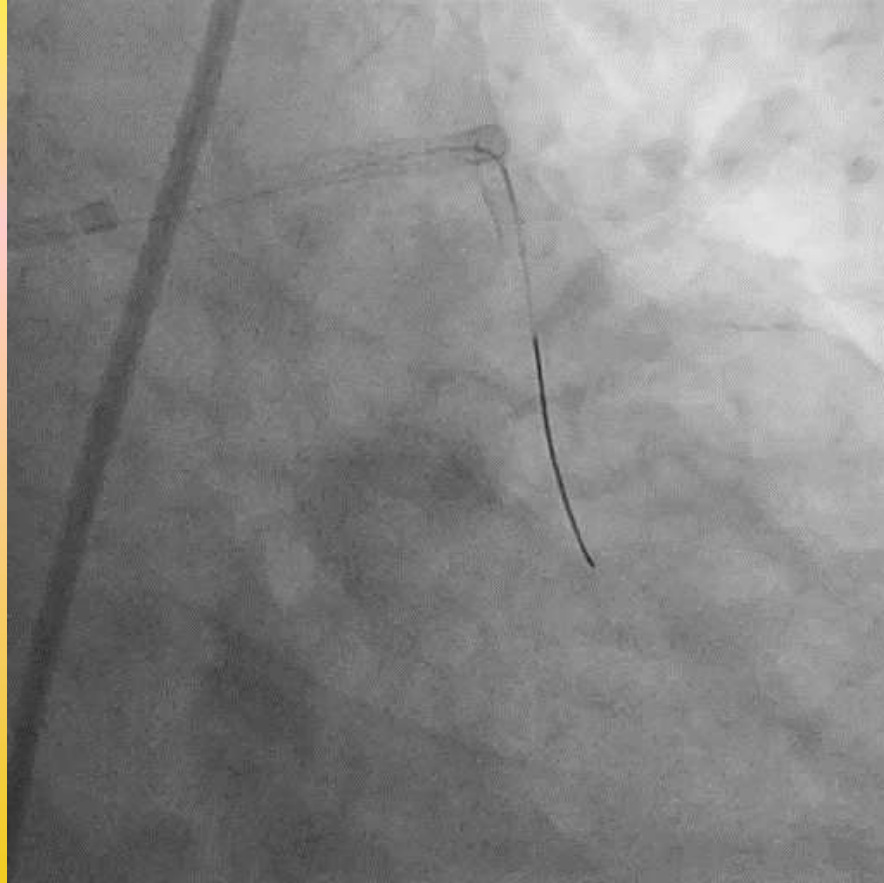
Proximal LAD Final Onyx Stenting



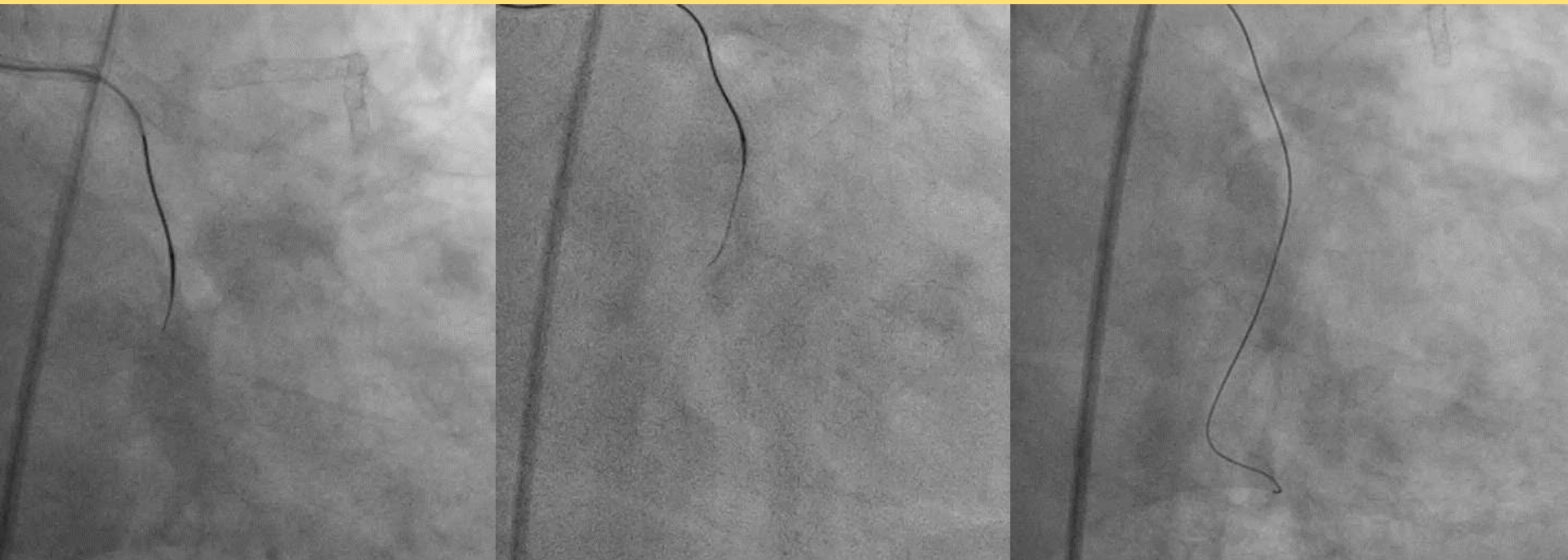
Resolute Onyx 3.0X22mm (14/5)



LCX-Baseline Angiography

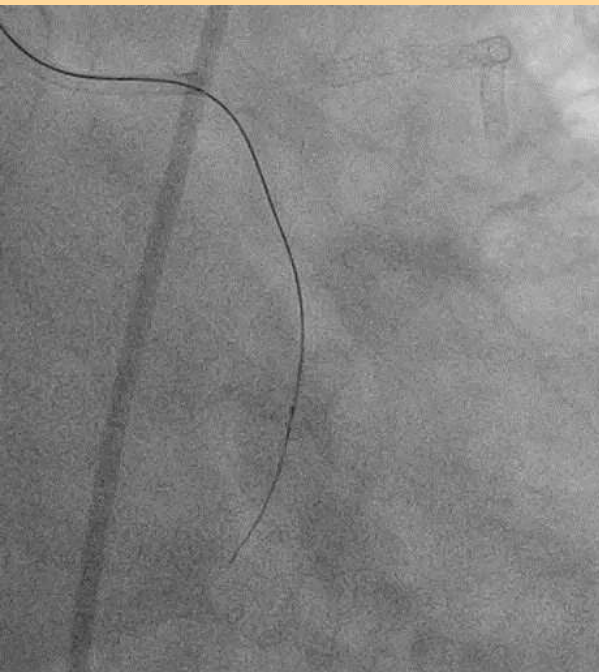


LCX CTO -Wiring

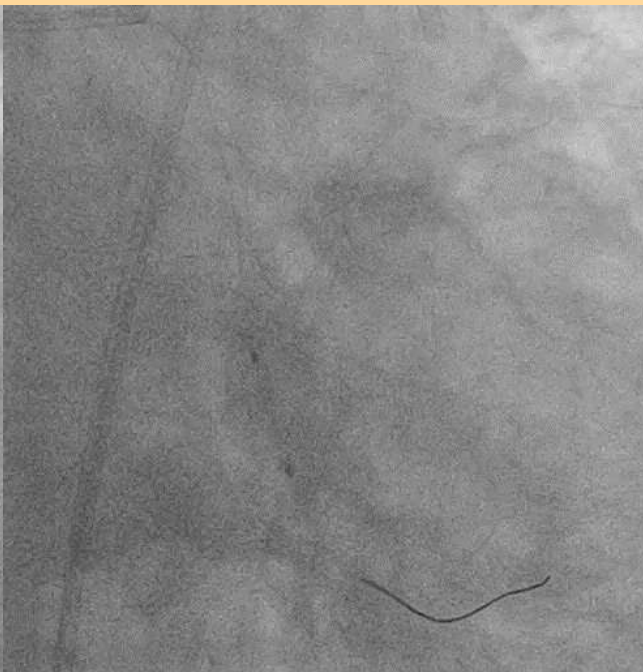


Corsair 135cm
Fielder XTR

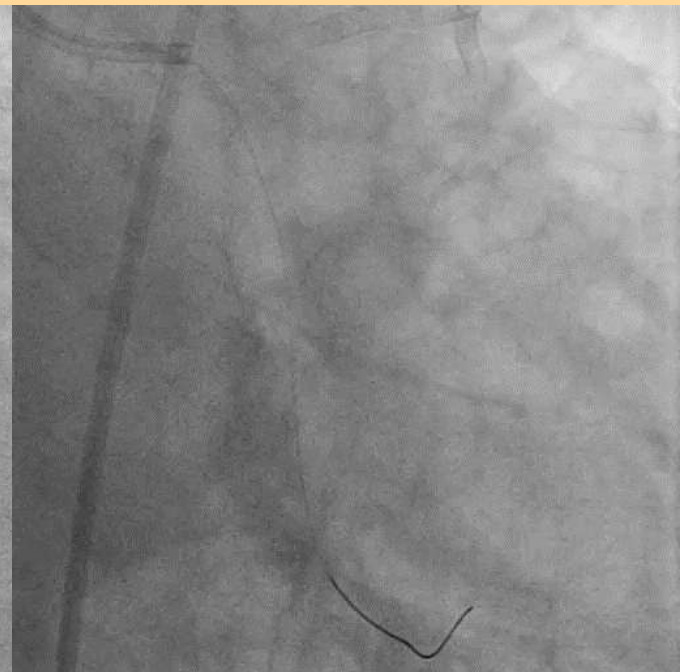
Predilation



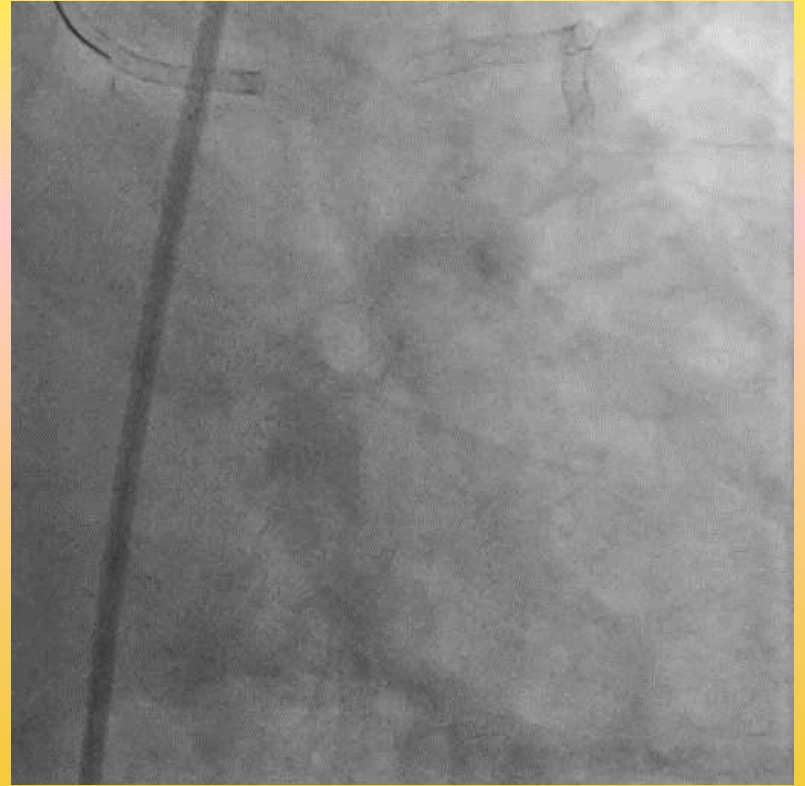
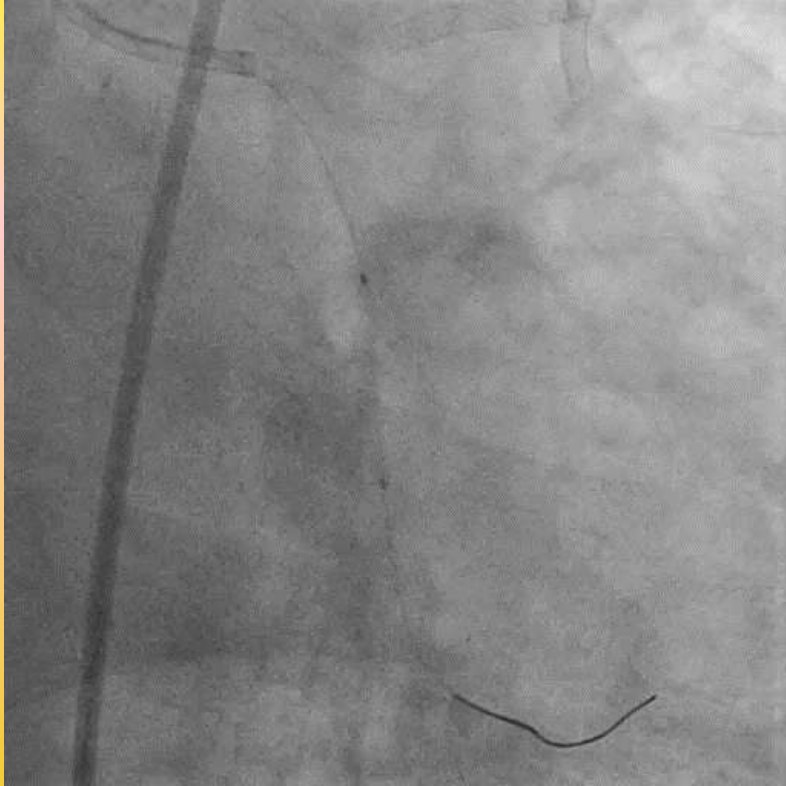
Minitrek 1.25X6mm



Pantera 2.0X15mm

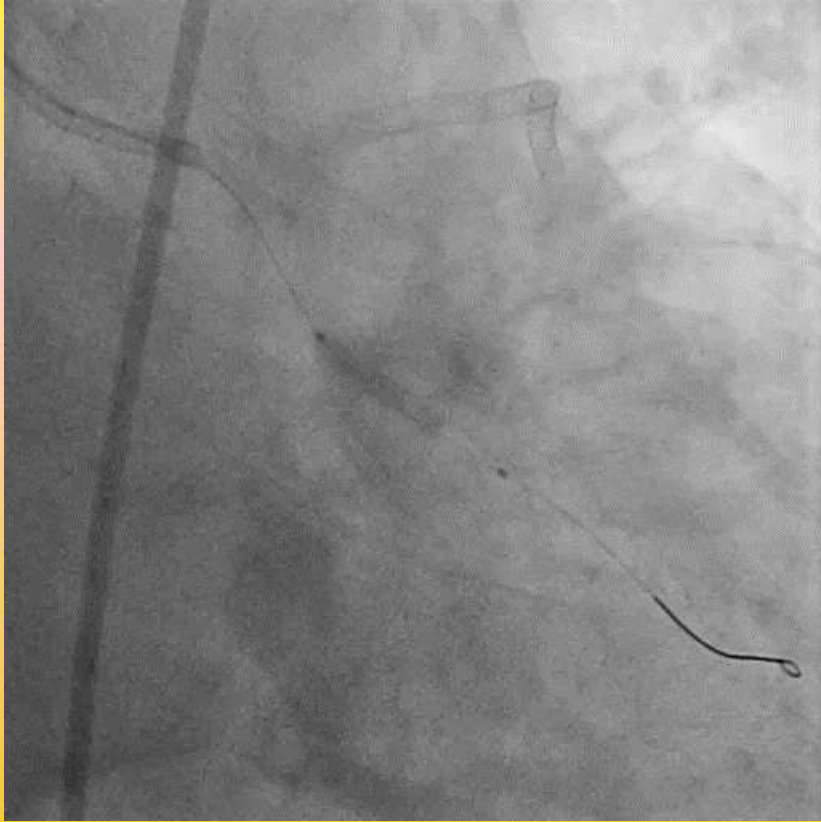


DEB to LCX distal

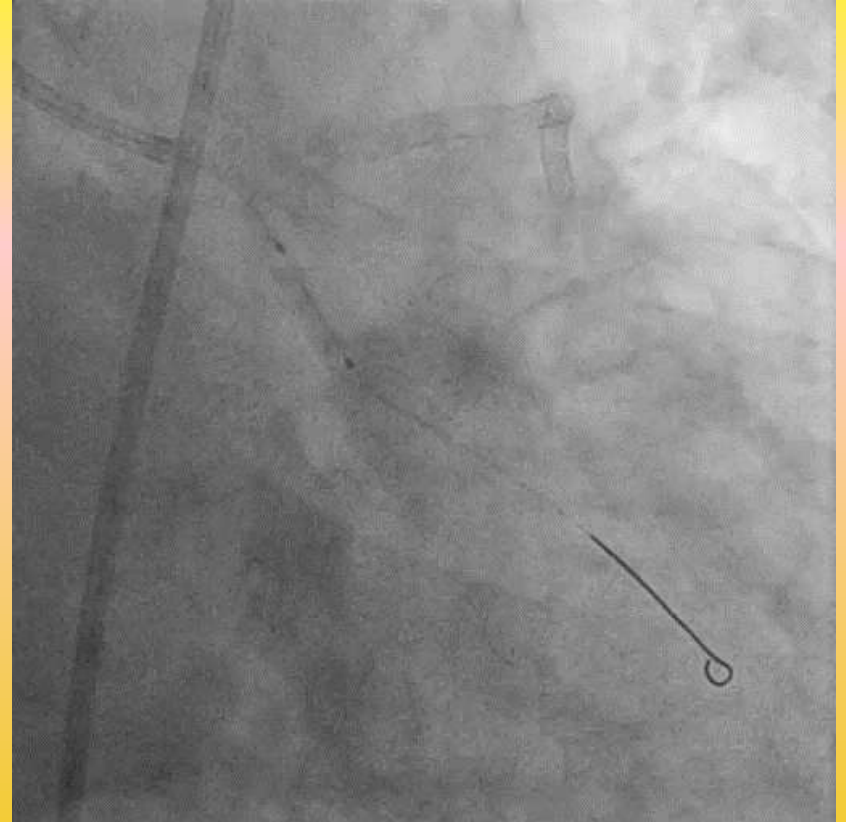


Sequent Please 2.0X20mm (DEB, B Braun)

OM Stenting; Resolute integrity

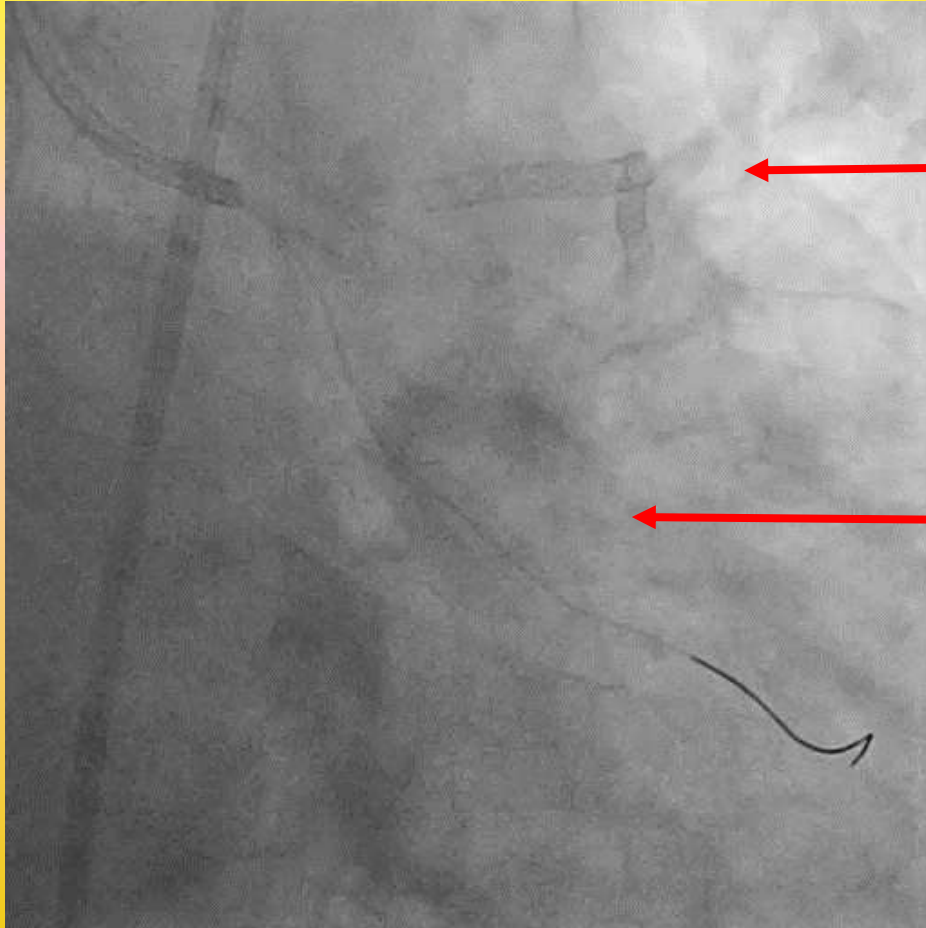


Resolute Integrity 2.5X22mm



Resolute Integrity 2.75X14mm

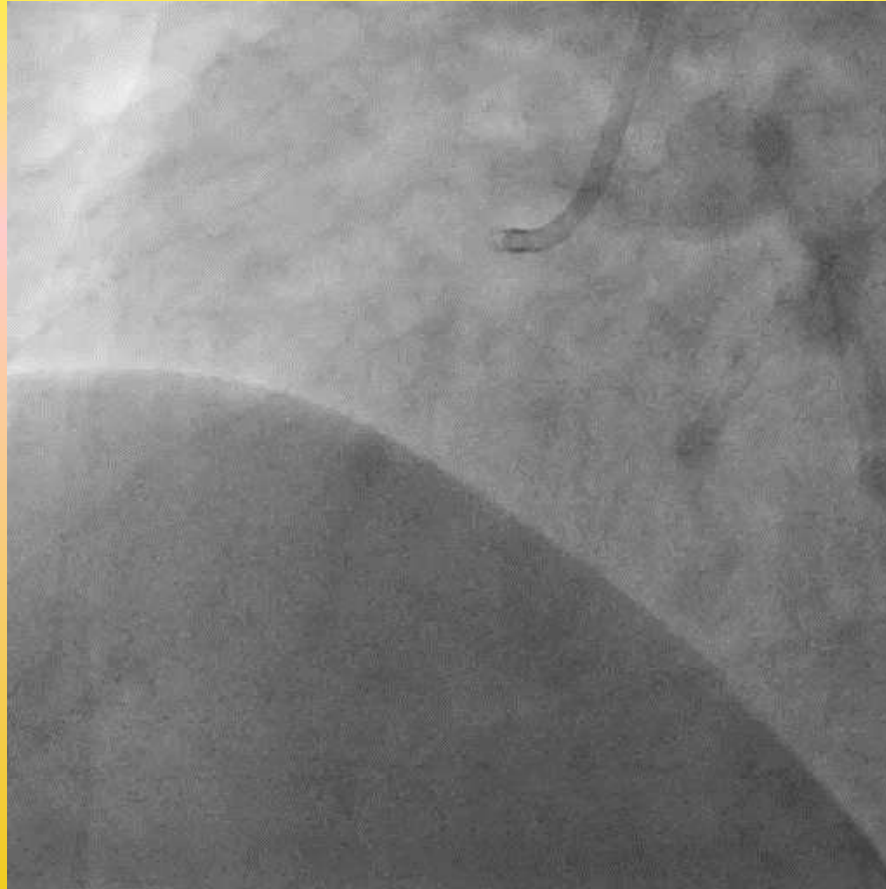
LCX-Final Angiography



Onyx

Integrity

RCA-Baseline Angiography



6F JR4

RCA Stenting; Resolute Integrity

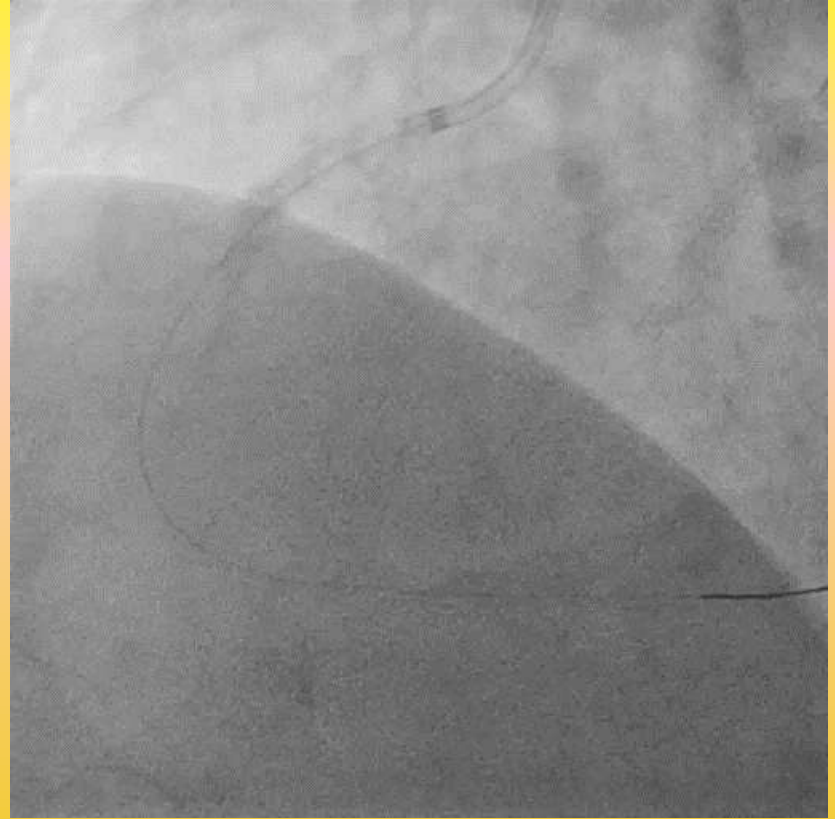


Resolute Integrity 2.75X14mm



Resolute 3.0X22mm

Final Angiography (3 Onyx, 4 Integrity, 1 DEB)



LAD-3 Onyx, LCX to OM- 2 Integrity, LCXd-DEB, RCA-2 Integrity

Prolonged Procedure up to finish
more than 10 years...



7 월 20 일 (수)

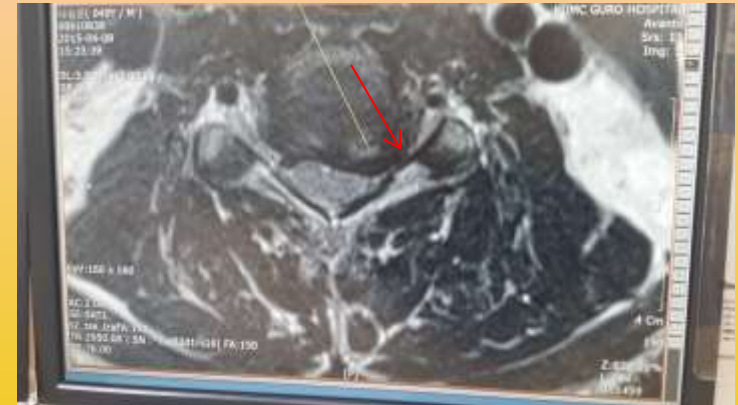
R U 9 25 김 영 준 (H/62) CAG
 R U 11 25 김 영 준 (H/66) CAG
 R U 12 05 김 영 준 (H/70) CAG
 O. 이 훈 (H/60) CAG

① R 박 영 준 (H/54) Spasm
 당일 ① R 이 의 현 (H/55) Spasm → PCI
 ② P. 김 영 준 (H/65) Spasm
 ③ P. 박 영 준 (H/60) Spasm

④ 4399 R 김영민 M/77 PTA G 100 CT11
 ⑤ 9386 R 조경숙 F/42 PTA 85
 ④ 8399 R 나현호 M/29 PTA
 ✓ 4387 S 김호준 F/73 CAB/PCI
 ⑥ ICU23 R 이은수 M/44 CAB (Final) 100
 CAB/PCI
 ✓ 17283 N 원영자 F/73 PTA 100
 ⑩ 8048 R 신복희 M/50 PTA 100
 ⑤ 8159 R 김영희 M/47 PTA
 ④ 8157 R 김재홍 M/41 PTA
 ④ 8281 R 이종남 M/73 PTA
 ⑤ 8388 F 이은 F/34 PTA
 ② 태자 R 권준환 F/60 CAB/PCI



Longer Procedure Time and Prolonged Gravity Burden to Operator's Spine



My C-spine and L-spine MRI on April 8, 2015

Suffering from C & L-HNP



Everything can be changed...but you need regular exercise!!



1985 Summer at KUMC
(187cm, 85kg)

2011 Summer at KUMC
(186cm, 108 kg)



Despite the risk of Injury (5 screws/1 plate), I cannot stop exercise;
Higher Radiation → Bone Weakness



OS professor said, I can't trust this patient. Let's do the emergent surgery....

Balancing Between Patient's Best Outcomes and Operator's Safety

1. Control procedure-related factors

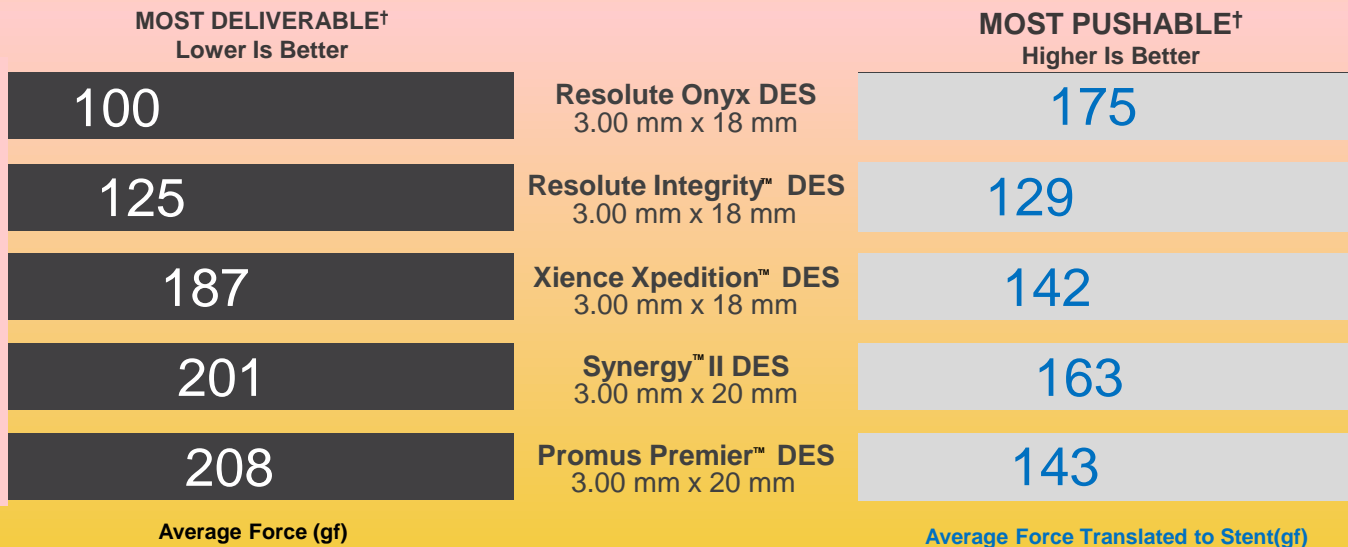
- 1) Preventing contrast nephropathy in high risk patients
; Sono-guided, CO2 angiography-guided, or Diluted contrast
- 2) Reducing radiation hazard
; lower-dose (7.5 F/sec), Fluoroscopic storage, less oblique view, shorter procedure time, and radiation protection equipment

2. Consider operator's safety

- 1) Share the cases with your colleagues or juniors
- 2) Maximally reducing radiation hazard
- 3) Control the procedure time and adequate recovery time
- 4) Regular exercise for improving physical strength
- 5) Reducing stress with hobbies (Basket ball, Piano..) and others (Church activities, good friends...)

GREATER DELIVERABILITY AND PUSHABILITY

Resolute Onyx™ DES builds on the Integrity™ platform's acute procedural success*

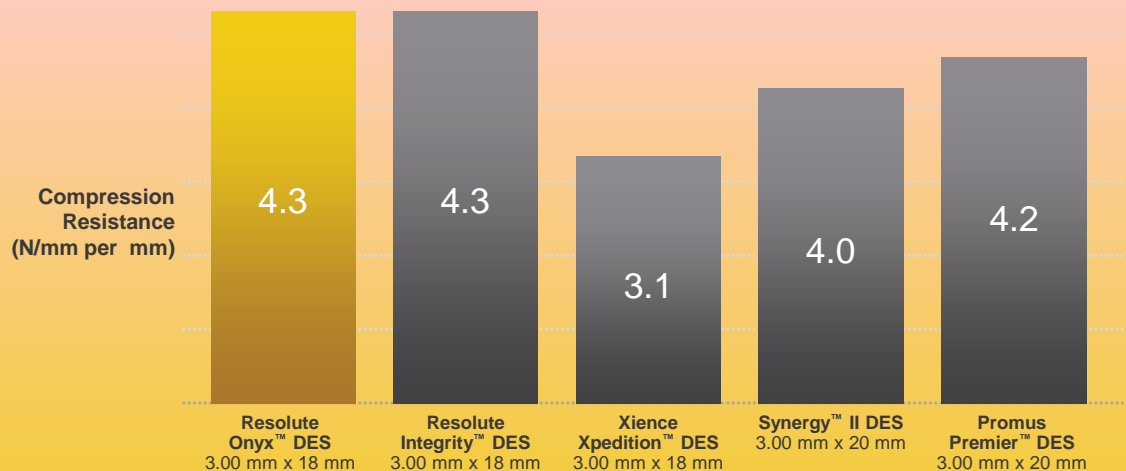


*DELIVER study

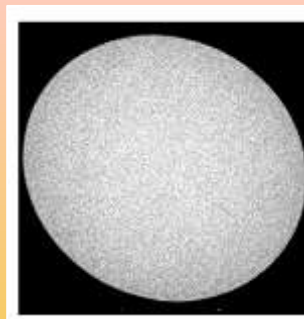
†Based on bench test data vs. Promus Premier DES, Synergy II DES, Xience Xpedition DES and Resolute Integrity DES.

SUSTAINED RADIAL STRENGTH

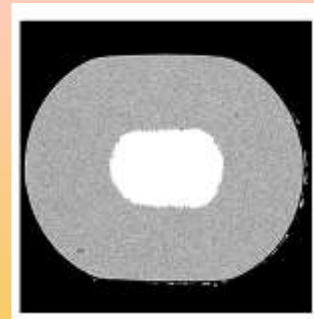
Radial Strength Higher Is Better



Resolute Integrity DES

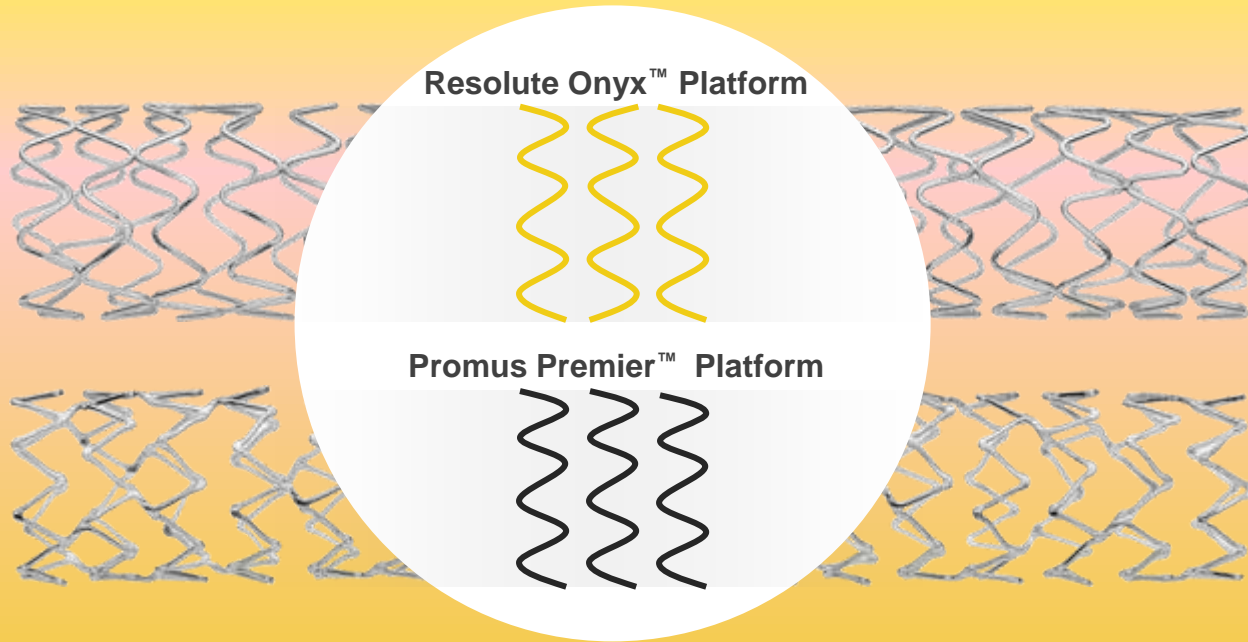


Resolute Onyx DES



COMPRESSION-RESISTANT DESIGN

Peak-to-peak design provides longitudinal compression resistance*†‡



*Ormiston J. How to select a DES; geometry, recoil, strut thickness and bifurcation considerations. TCT 2011.

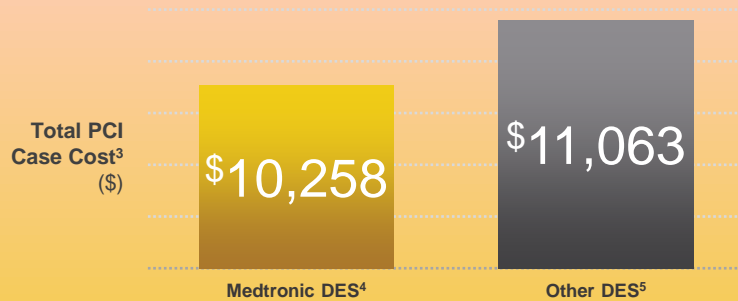
†Prabhu S et al. *EuroIntervention* ahead of print Nov 7, 2011.

‡Based on bench test data. May not be indicative of clinical performance.

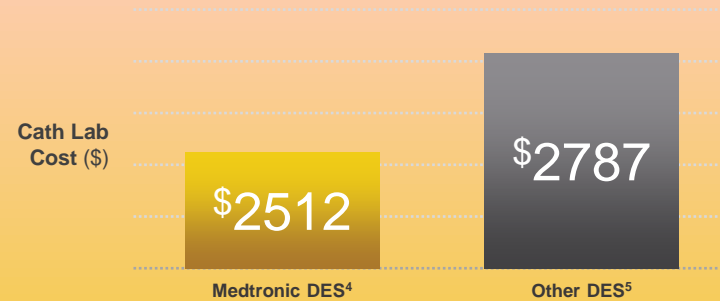
COULD INCREASED PROCEDURAL SUCCESS IMPACT COST SAVINGS?

Recent findings from more than 2300 patients from a large hospital system database

Analysis¹ of outpatient PCI cases showed a per-case total cost difference of 7% when Medtronic DES were used (n = 2390, p = 0.0025)



Cath lab costs² were shown to be a major contributor to overall savings (n = 2390, p = 0.0070)



¹ Premier PCI Case Cost Advantage Analysis by CTI/S2.

² Cath lab costs include cath lab per minute costs, cath lab labor costs per case, cath lab miscellaneous expenses (gloves, etc.) and allocated expenses (utilities, overhead, physical plant).

³ PCI case costs include all costs associated with a given PCI case. Cost categories included within total case cost are: supply, cardiology/EKG (cath lab costs), pharmacy, OR, lab, radiology, room and board, ER, respiratory, therapy, and other.

⁴ Medtronic DES include Endeavor™, Resolute Integrity™ and Resolute™ stents.

⁵ Other DES include Abbott Xience™, Boston Scientific Promus™ and J&J Cypher™ stents.

NEW SIZES OPTIMISED FOR COMPLEX CASES

Resolute Onyx™ DES introduces meaningful new sizes for the treatment of extra-small vessels and long lesions



Small vessels
 Long lesions
 CTOs
 Total occlusions
 AMIs
 ISR
 Multivessels
 Diabetes
 ACS
 UA
 Bifurcations

Diameter (mm)	Length (mm)								-	-
	8	12	15	18	22	26	30	34		
2.00	8	12	15	18	22	26	30	-	-	
2.25	8	12	15	18	22	26	30	34	38	
2.50	8	12	15	18	22	26	30	34	38	
2.75	8	12	15	18	22	26	30	34	38	
3.00	8	12	15	18	22	26	30	34	38	
3.50	8	12	15	18	22	26	30	34	38	
4.00	8	12	15	18	22	26	30	34	38	

 Indicates new sizes

DAPT: Low risk of ST after one month*

First and only FDA-approved DES for patients with diabetes (Resolute Integrity™ DES)

*One-year data from the RESOLUTE Clinical Program indicates low stent thrombosis rates for those that interrupted or discontinued DAPT any time after one month. While physicians should adhere to current ESC or ACC/AHA/SCAI Guidelines for PCI, patients who interrupt or discontinue DAPT medication one month or more after stent implantation are considered at low risk and showed no increased risk for stent thrombosis. Early discontinuation of prescribed antiplatelet medication could result in a higher risk of thrombosis, MI or death.

Resolute Onyx™ DES: THE ADVANCED WORKHORSE



PROCEDURAL SUCCESS

Most deliverable DES,*
featuring Core Wire
Technology

Resolute Onyx™ DES builds on the
Integrity™ platform's acute procedural
success† for even greater flexibility
and conformability

Core Wire Technology enables thinner
struts with increased radiopacity and no
compromise to radial or longitudinal strength



COMPLEX CASES

Broad size matrix to
optimise treatment of
complex clinical scenarios

A new 2.00-mm diameter with longer
stent lengths expands treatment
options for patients with diabetes
and diffuse disease



SAFETY ASSURED

Proven long-term safety
and efficacy shown in the
Global RESOLUTE Program

No increased risk for stent thrombosis
with interruption or discontinuation of
DAPT after one month‡

Sustained safety of 1.2% ST through five
years in more than 7500 patients from
the RESOLUTE Pooled analysis

*Based on bench test data vs. Promus Premier™ DES, Synergy™ II DES, Xience Xpedition™ DES and Resolute Integrity™ DES.

†DELIVER study

‡Silber S et al. *Eur Heart J.* 2014;35(29):1949–1956.