

**Advances in Cardiac Arrhythmias and Great Innovations in Cardiology -
Torino, 27/28 ottobre 2017**

**Management of complex cases with Onyx:
the benefit of a dedicated stent for small and large vessel**



**Claudio Moretti, MD, PhD
Division of Cardiology
Department of Medical Sciences
University of Turin**

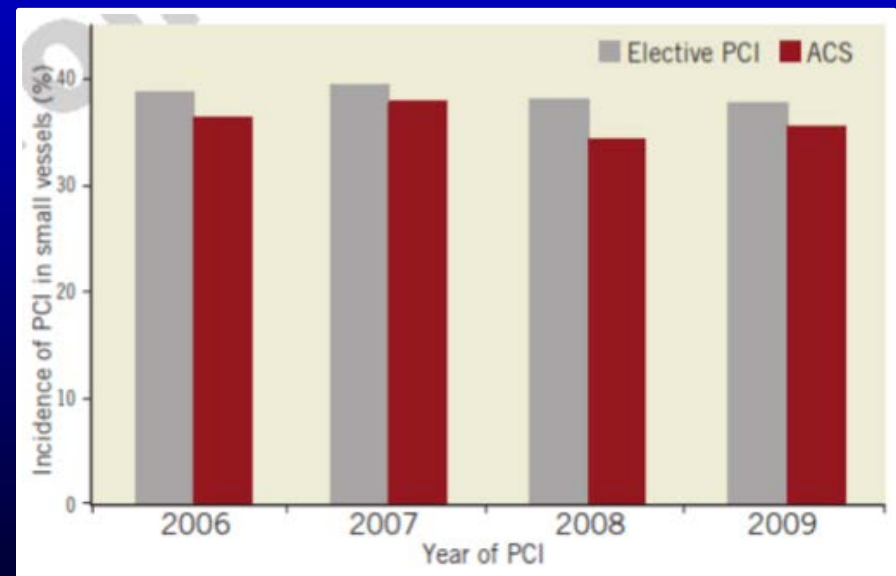


WHAT ARE SMALL VESSELS ?

- ❑ Variably defined
- ❑ Coronary arteries <2.8 mm in diameters
- ❑ Commonly, coronary arteries < 2.5 mm in diameter
- ❑ Not uncommon

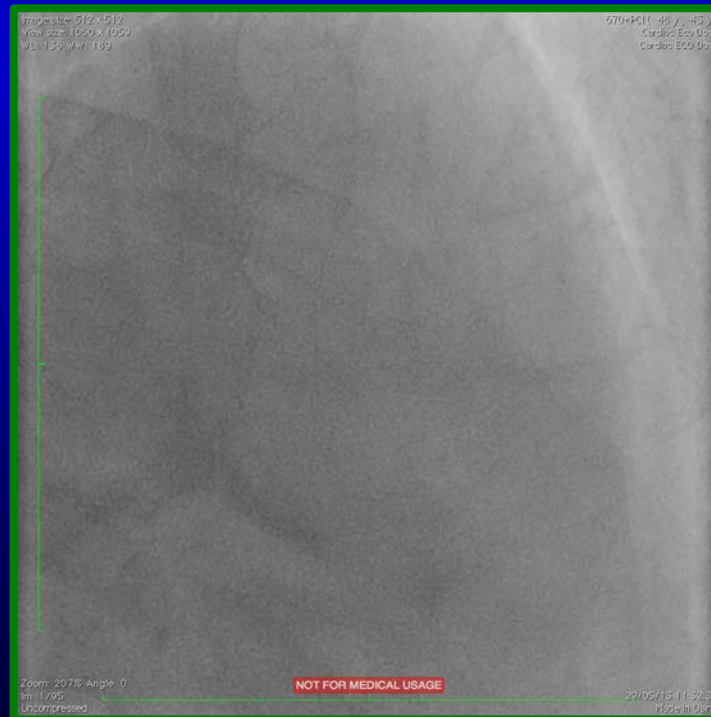
35-40% in German ALKK-PCI Registry

(Eurointervention 2011;7:k 57-70)



SMALL VESSELS – scope of the problem

- ❑ Reference vessel diameter is a key determinant of restenosis and TLF after PCI
- ❑ Even in DES era pts present lower rates of survival free from MACEs
- ❑ Distal small vessel disease is seen in ptz with multiple comorbidities



First Report of the Resolute Onyx 2.0-mm Zotarolimus-Eluting Stent for the Treatment of Coronary Lesions With Very Small Reference Vessel Diameter

Matthew J. Price, MD,^a Shigeru Saito, MD,^b Richard A. Shlofmitz, MD,^c Douglas J. Spriggs, MD,^d Michael Attubato, MD,^e Brent McLaurin, MD,^f Alexandra Popma Almonacid, MD,^g Sandeep Brar, MD,^h Minglei Liu, PhD,^h Elizabeth Moe, BA,^h Roxana Mehran, MDⁱ

TABLE 3 Clinical Outcomes at 12-Month Follow-Up (N = 100)

TLF	5.0 (5/100)
TVF	5.0 (5/100)
TV-MI	3.0 (3/100)
MACE	5.0 (5/100)
Cardiac death	0.0 (0/100)
Noncardiac death	0.0 (0/100)
Cardiac death or TV-MI	3.0 (3/100)
TLR	2.0 (2/100)
TVR	2.0 (2/100)
Stent thrombosis (ARC) definite/probable	0.0 (0/100)
Early thrombosis (≤ 30 days)	0.0 (0/100)
Late thrombosis (31–360 days)	0.0 (0/100)

Values are % (n/N).

ARC = Academic Research Consortium; MACE = major adverse cardiac event(s); TLF = target lesion failure; TVF = target vessel failure; TV-MI = target vessel myocardial infarction.



Continuous Sinusoid Technology **Resolute Onyx stent**

Flexible stent platform for outstanding flexibility and conformability



Sinusoid-formed wire



Helical wrap



Laser-fused

A single strand of cobalt alloy is formed into a sinusoid, wrapped in a helical pattern, and laser fused

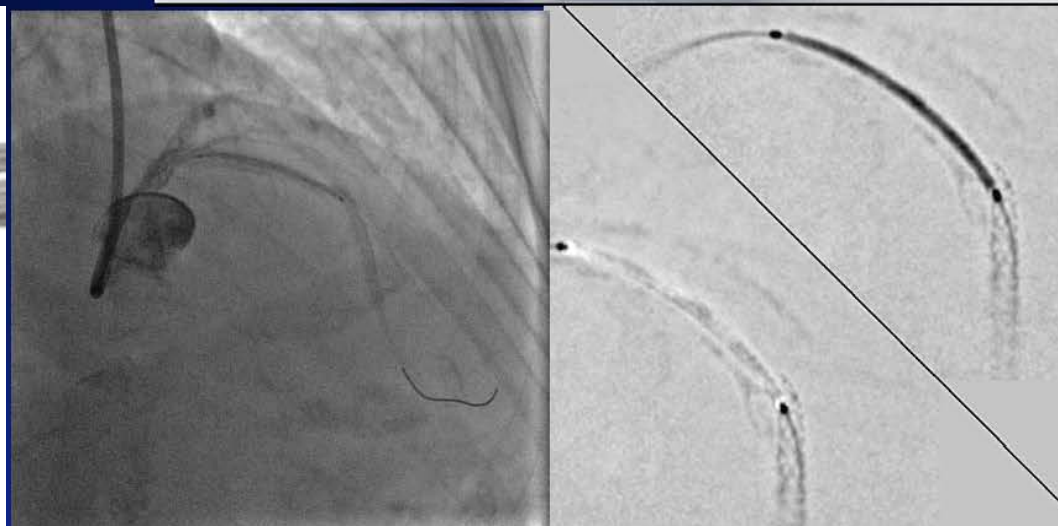
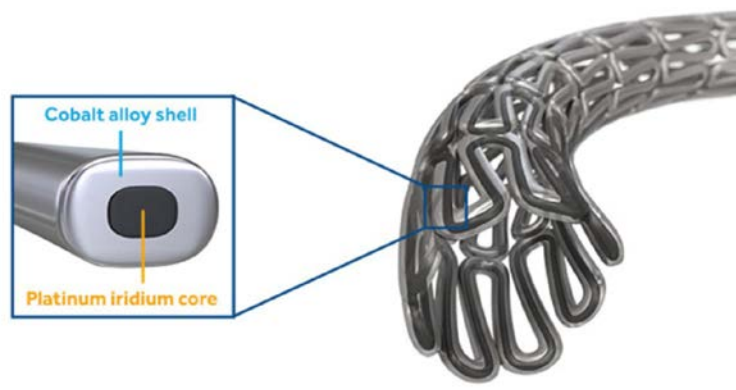
Resolute Onyx stent

- Core wire technology – platinum core in the wire
- Thinner struts with
 - enhanced radiopacity
 - No loss of radial strength

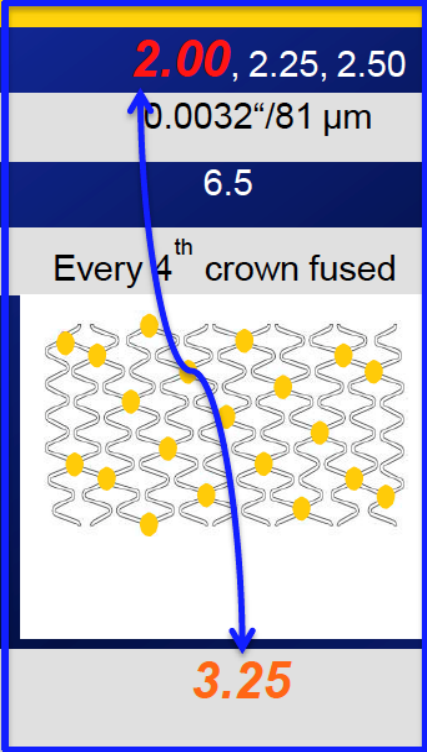
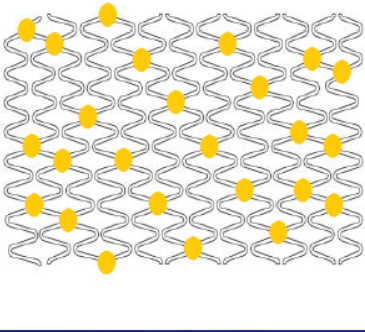
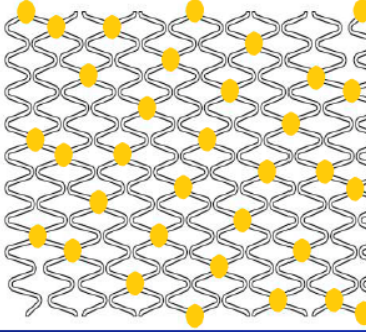


Core Wire Technology

Thinner struts with enhanced stent visibility for accurate stent placement



Resolute Onyx stent

Characteristic	Resolute Onyx™ DES		
Stent size (mm)	2.00 , 2.25, 2.50	2.75, 3.00	3.50, 4.00
Strut dimensions	0.0032"/81 μm	0.0032"/81 μm	0.0032"/81 μm
Crowns	6.5	8.5	9.5
Fusion pattern	Every 4 th crown fused	Every 5 th crown fused	Every 4 th crown fused
			
Maximum expansion (mm)—MSID*	3.25	3.75	4.75
Open cell area for bifurcation (mm)	3.7	3.8	3.8

Data on file at Medtronic, Inc.

*MSID = maximum stent inner diameter



The diagram illustrates a multi-layered membrane structure. At the top is a **CELL MEMBRANE** composed of phospholipids with white heads and yellow tails. Below it is a **HYDROPHILIC LAYER** containing blue, ring-like structures. At the bottom is a **HYDROPHOBIC LAYER** containing a dense layer of small yellow particles. The entire structure is set against a dark blue background with small yellow dots.

CELL MEMBRANE

HYDROPHILIC LAYER

Biocompatibility

HYDROPHOBIC LAYER

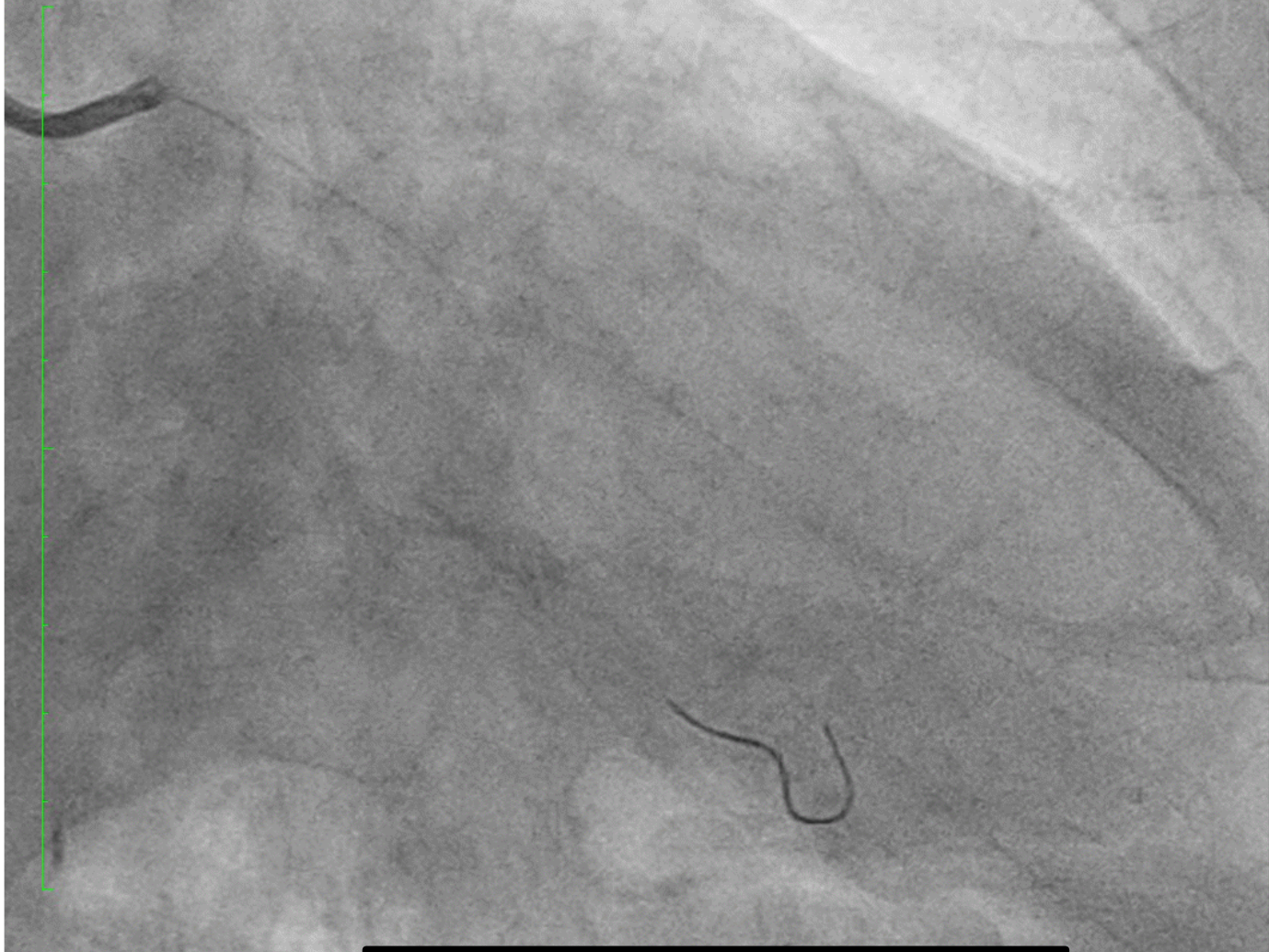
Controlled drug release

Conclusion

- Small vessels are a problem particularly if calcified
- Drug-eluting balloon angioplasty is one option
- Often stenting is required
- Dedicated small vessel stent like Resolute Onyx enables stenting of small vessels
- Added quality of excellent trackability and radioopacity

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

165 pci (77 y , 75 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
1



Zoom: 207% Angle: 0
Im: 10/59
Uncompressed

DIFFUSE TWO-VESSEL DISEASE

05/02/16 15:51:44
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

339+pci (77 y, 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
3

Zoom: 207% Angle: 0
Im: 12/76
Uncompressed

LAD/D1 minicrush + OM1

03/04/17 09:52:24
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

339+pc1 (77 y, 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
6

Zoom: 207% Angle: 0
Im: 1/79
Uncompressed

DISTAL LAD/SMALL VESSEL

03/04/17 09:56:13
Made In OsiriX

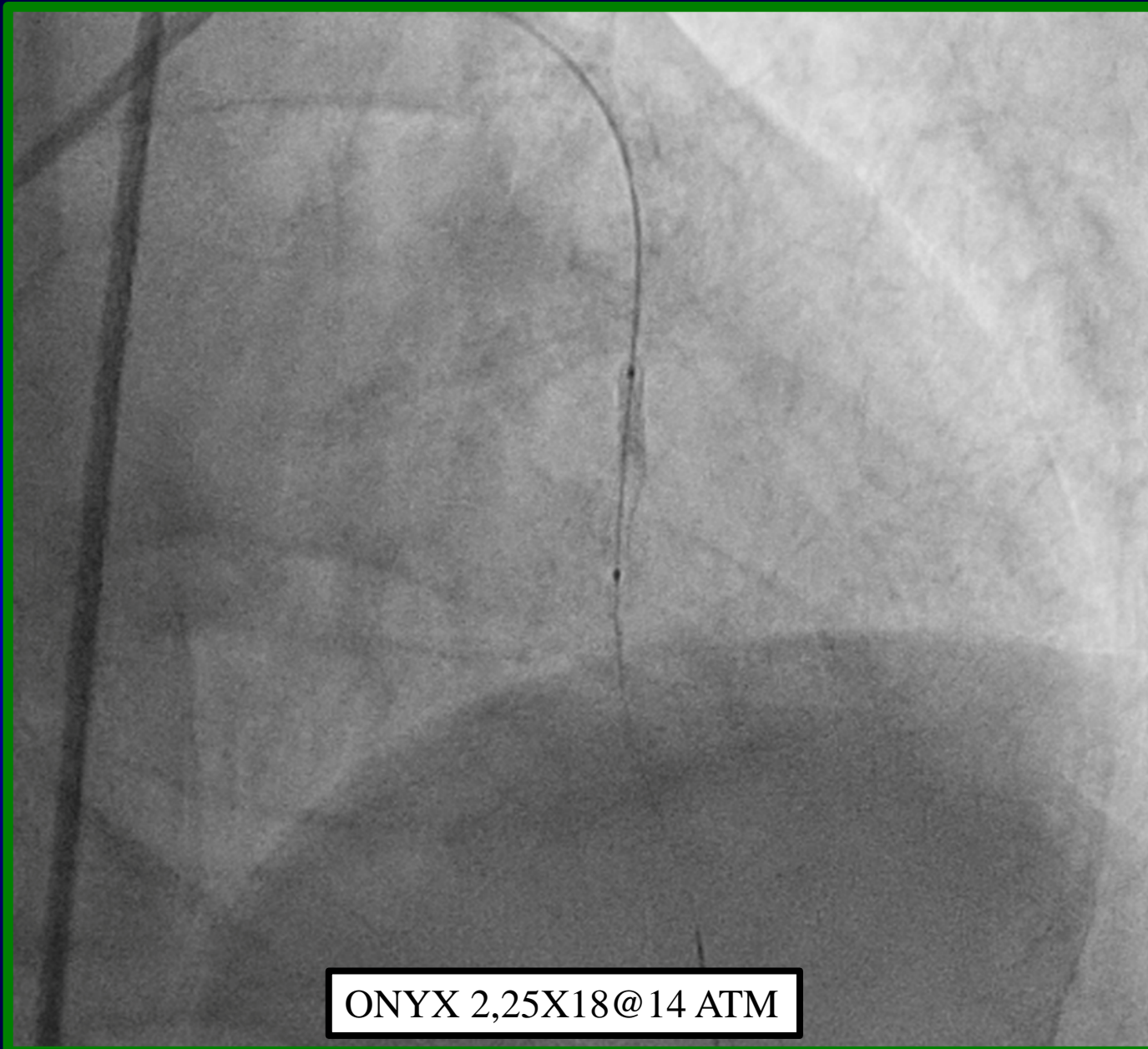
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WL: 128 WW: 179

339+pci (77 y , 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
11

Zoom: 207% Angle: 0
Im: 1/48
Uncompressed

NOT FOR MEDICAL USAGE

03/04/17 10:25:08
Made In OsiriX



ONYX 2,25X18@14 ATM

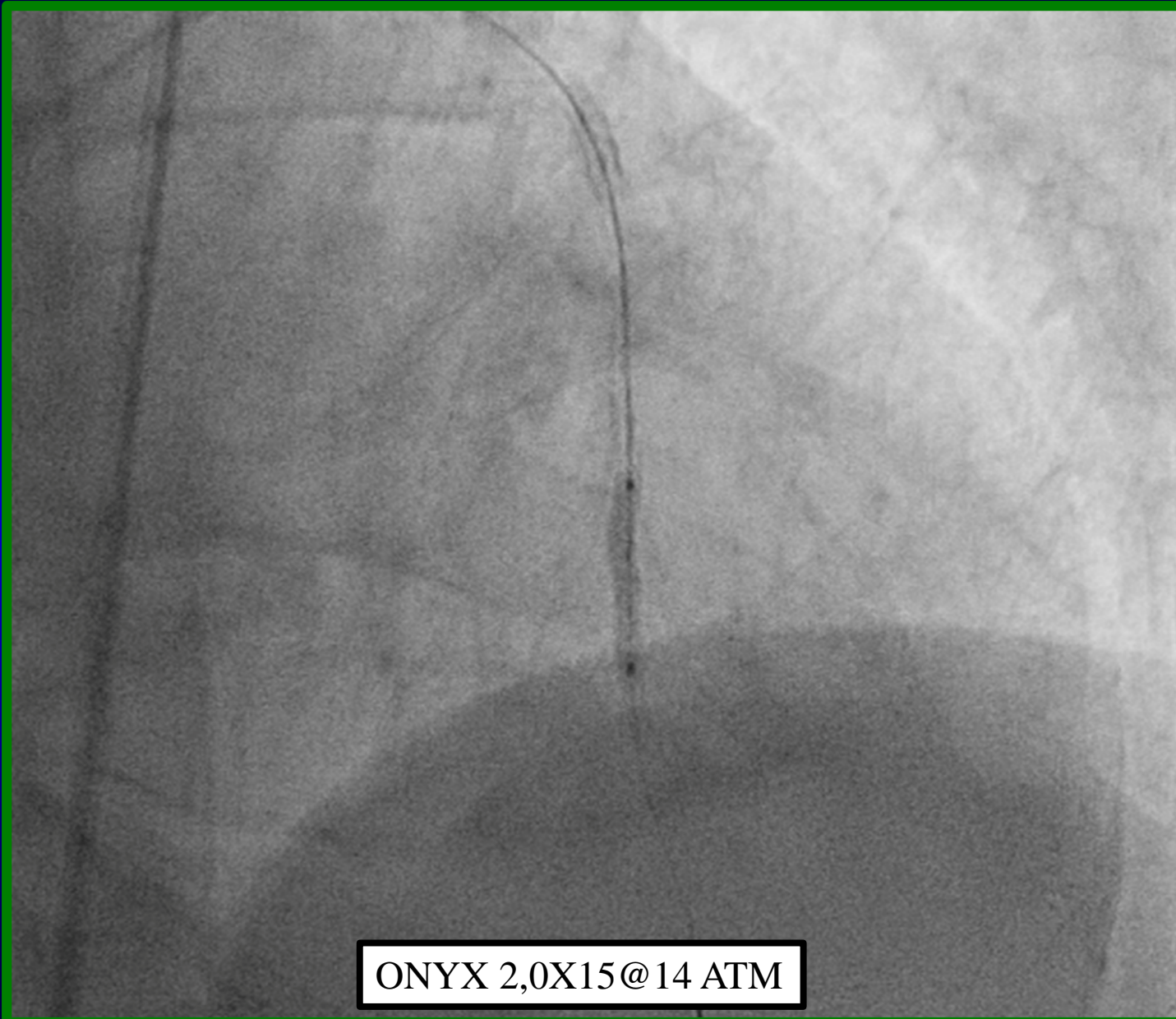
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339+pci (77 y, 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
13

Zoom: 207% Angle: 0
Im: 1/67
Uncompressed

“SUB-OPTIMAL” RESULT

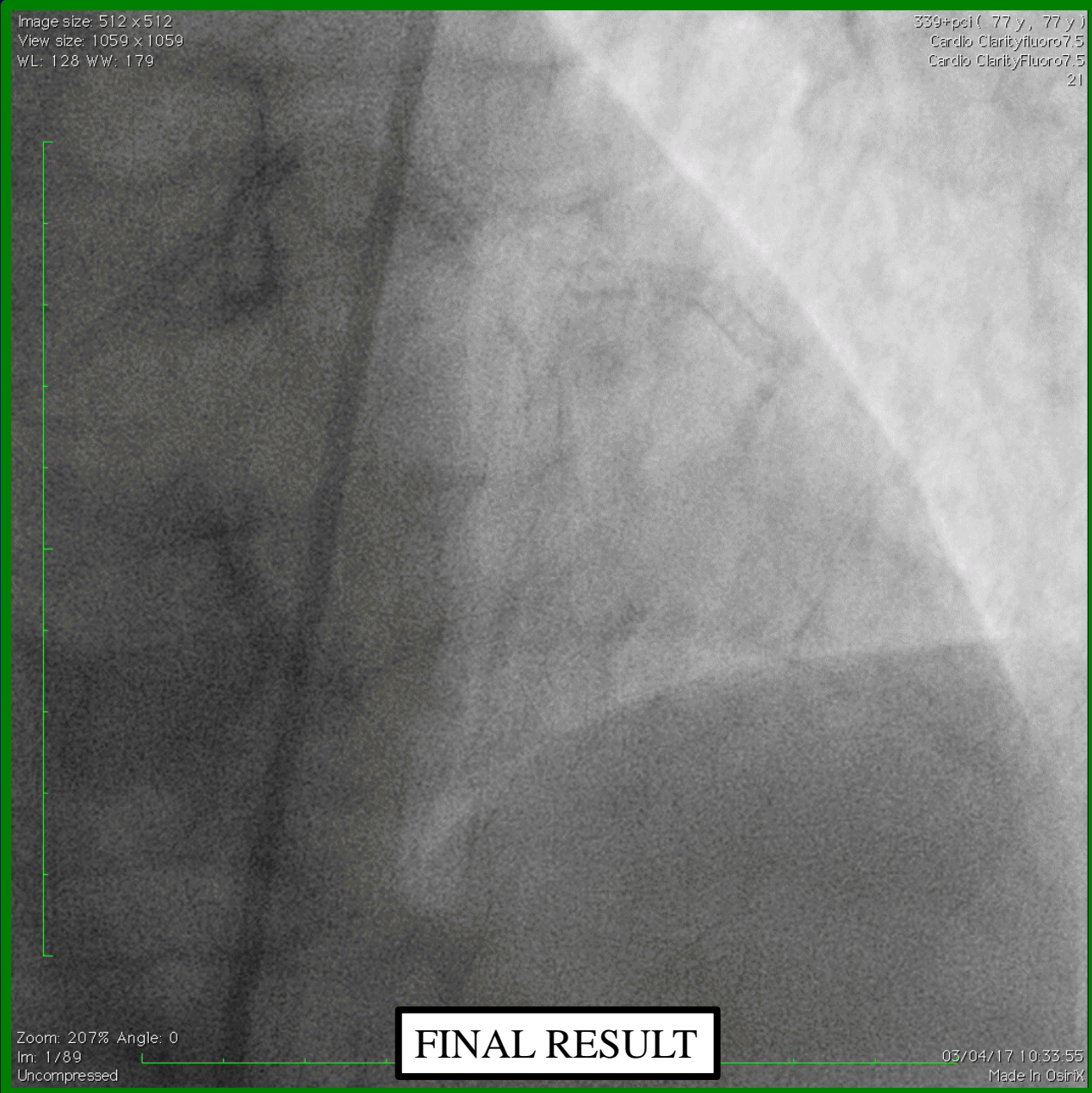
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Made In Osirix



ONYX 2,0X15@14 ATM

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View size: 1059 x 1059
WL: 128 WW: 179

339+pci (77 y, 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
21



Zoom: 207% Angle: 0
Im: 1/89
Uncompressed

FINAL RESULT

03/04/17 10:33:55
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

339+pci (77 y, 77 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
22

Zoom: 207% Angle: 0
In: 1/118
Uncompressed

FINAL RESULT

03/04/17 10:34:22
Made In Osiris



6-MONTH F.UP ANGIO

Percutaneous coronary intervention for coronary bifurcation disease: 11th consensus document from the European Bifurcation Club

Published on 16 May 2016



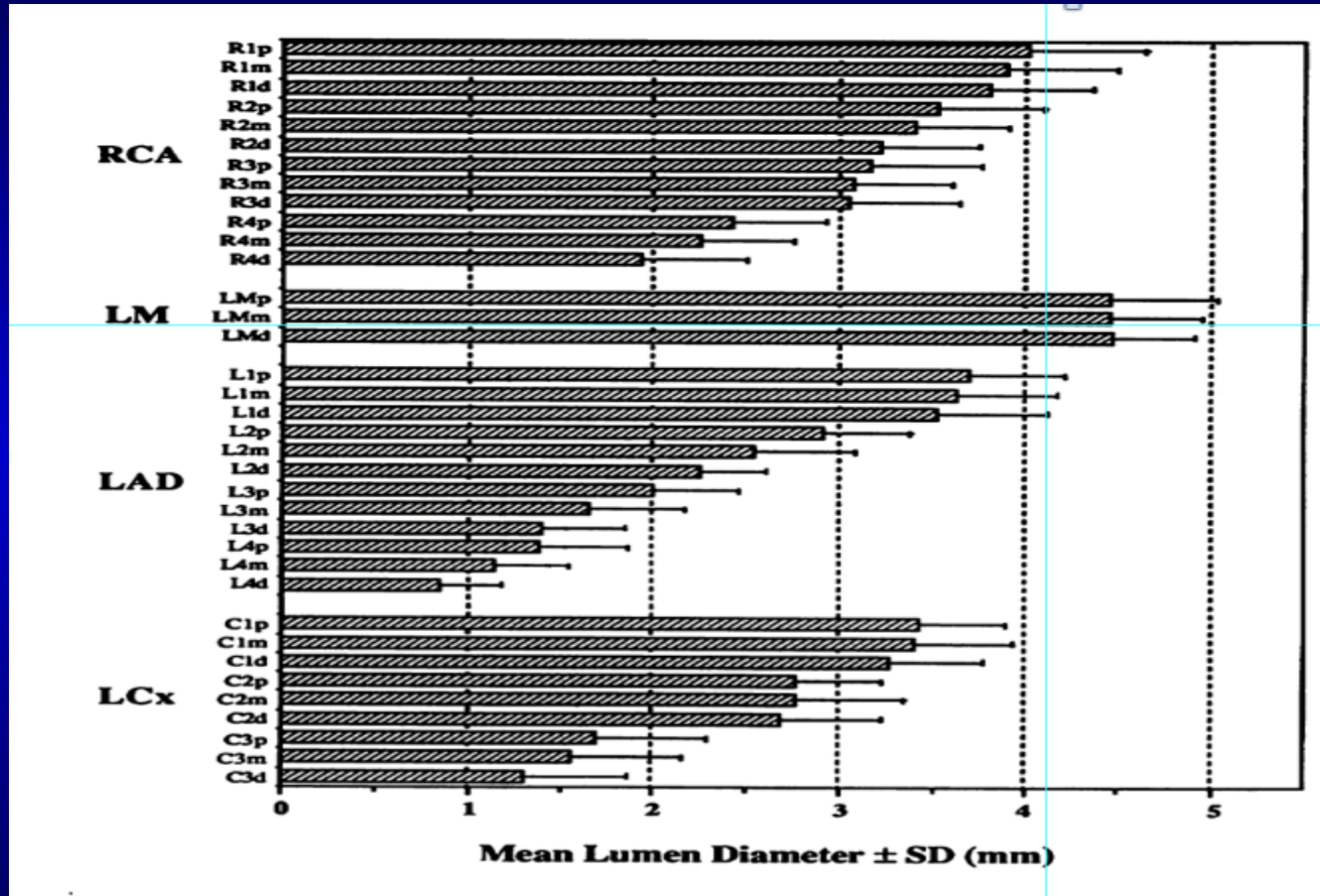
Jens Flensted Lassen^{1*}, MD, PhD; Niels Ramsing Holm², MD; Adrian Banning³, MD, PhD; Francesco Burzotta⁴, MD, PhD; Thierry Lefèvre⁵, MD; Alaide Chieffo⁶, MD; David Hildick-Smith⁷, MD; Yves Louvard⁵, MD; Goran Stankovic⁸, MD, PhD

1. Department of Cardiology, The Heart Centre, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; 2. Department of Cardiology, Aarhus University Hospital, Skejby, Aarhus, Denmark; 3. Cardiovascular Medicine Division, Radcliffe Department of Medicine, John Radcliffe Hospital, Oxford, United Kingdom; 4. Institute of Cardiology, Catholic University of the Sacred Heart, Rome, Italy; 5. Institut Cardiovasculaire Paris Sud, Massy, France; 6. Interventional Cardiology Unit, San Raffaele Scientific Institute, Milan, Italy; 7. Sussex Cardiac Centre, Brighton and Sussex University Hospitals, United Kingdom; 8. Department of Cardiology, Clinical Center of Serbia, and Faculty of Medicine, University of Belgrade, Belgrade, Serbia

Differences between the LM and other bifurcations

The LM is the largest bifurcation of the coronary tree and has a number of unique features, which may demand different technical approaches from non-left main bifurcations²⁸. The most important differences are the following. 1) The myocardium supplied by the LM generally accounts for considerably more than 50% of the total myocardial mass. 2) The SB is most often the circumflex artery (Cx) which generally has a large diameter, and is not always easy to access. Occlusion of the Cx is not acceptable since it often results in ischaemia of a large myocardial territory and may induce acute ischaemic mitral regurgitation. 3) The LM is the only bifurcation where the proximal MB originates directly from the aorta. 4) The proximal reference diameter generally measures between 4.5 and 5.5 mm - close to, or above, the dilatation limit of most currently available coronary stents. 5) Trifurcations

LUMEN DIAMETER OF NORMAL HUMAN CORONARY ARTERIES

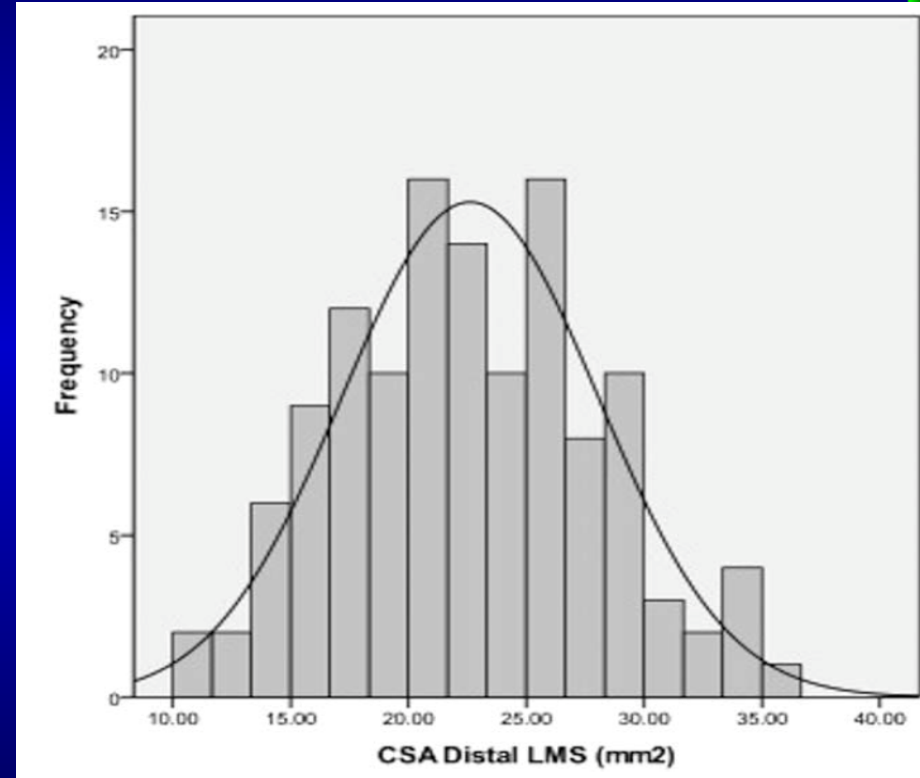


A Prospective Intravascular Ultrasound Investigation of the Necessity for and Efficacy of Postdilation Beyond Nominal Diameter of 3 Current Generation DES Platforms for the Percutaneous Treatment of the Left Main Coronary Artery

TABLE I. Distal LMS Dimensions in 125 Patients with $\geq 70\%$ Stenosis in ≥ 1 Major Left Epicardial Artery

LMS dimension	Mean	SD	Range
CSA (mm ²)	22.6	± 5.4	10.9–35.5
LA (mm ²)	12.7	± 5.4	2.3–27.8
Maximal Vessel Diameter (mm)	5.7	± 0.7	4.0–7.4

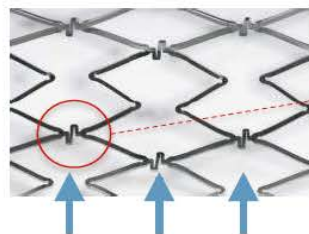
LMS: left mainstem coronary artery; SD: standard deviation; mm: millimeter.



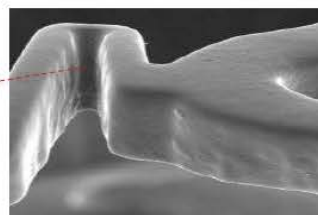
STENTYS Self-Apposing[®] Stent



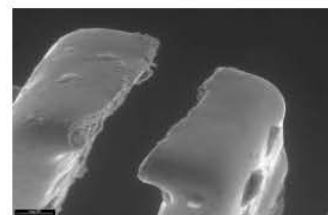
- Self-expanding nitinol stent constrained inside a Splitable Sheath over the balloon
- Bare or Sirolimus-eluting with ProTector biostable polymer
- 6 French, single-wire, rapid exchange
- Disconnecting bridges over full length* for side-branch access



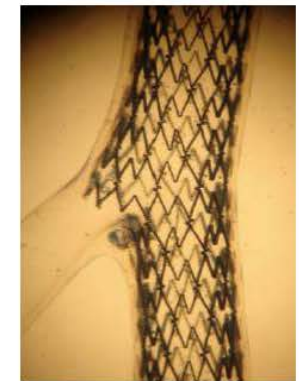
Disconnectors
along the stent



Disconnectable
interconnector



Disconnection



Shaping an ectatic coronary artery: Stentys implantation

Claudio Moretti*, Pierluigi Omedè, Davide Giacomo Presutti, Fabrizio D'Ascenzo, Chiara Colaci, Maurizio Bertaina, Ilaria Vilardi, Fiorenzo Gaita

Division of Cardiology, Department of Internal Medicine, Città Della Salute e Della Scienza, Turin, Italy

How should I treat a patient with a proximal left anterior descending large plaque burden embolising plaque?

Claudio Moretti*, MD, PhD; Jacopo Perversi, MD; Pierluigi Omedè, MD; Fabrizio D'Ascenzo, MD; Serena Bergerone, MD; Fiorenzo Gaita, MD

Cardiology Division, Department of Medical Sciences, University of Turin, Turin, Italy



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Correspondence

Never underestimate the comeback kid; a case report of very early side branch occlusion after Stentys Exposition implantation without kissing balloon

Antonio Montefusco, Paolo Scacciatella, Pierluigi Omedè, Fabrizio D'Ascenzo*, Fiorenzo Gaita, Claudio Moretti

Division of Cardiology, Department of Internal Medicine



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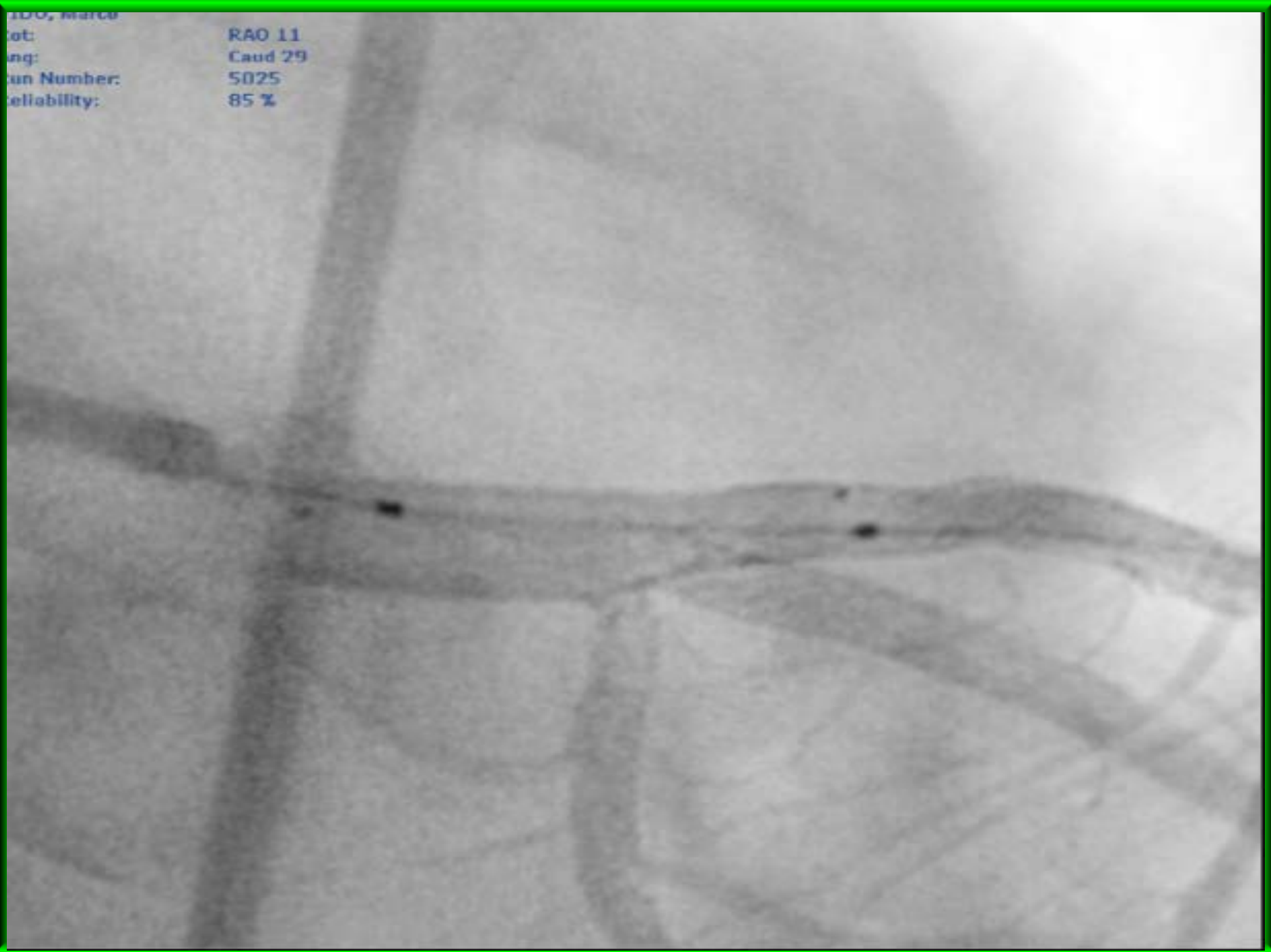
Minding the gap between left main and branch vessels: Second-generation self-apposing, balloon-expandable, drug-eluting stent on trifurcated unprotected left main

Antonio Montefusco, Sebastiano Gili*, Fabrizio D'Ascenzo, Pierluigi Omedè, Claudio Moretti

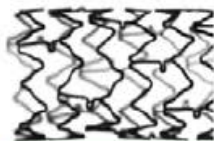
Division of Cardiology, Department of Medical Sciences, Città della Salute e della Scienza Hospital, University of Turin, Turin, Italy

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eliability:

RAO 11
Caud 29
5025
85 %

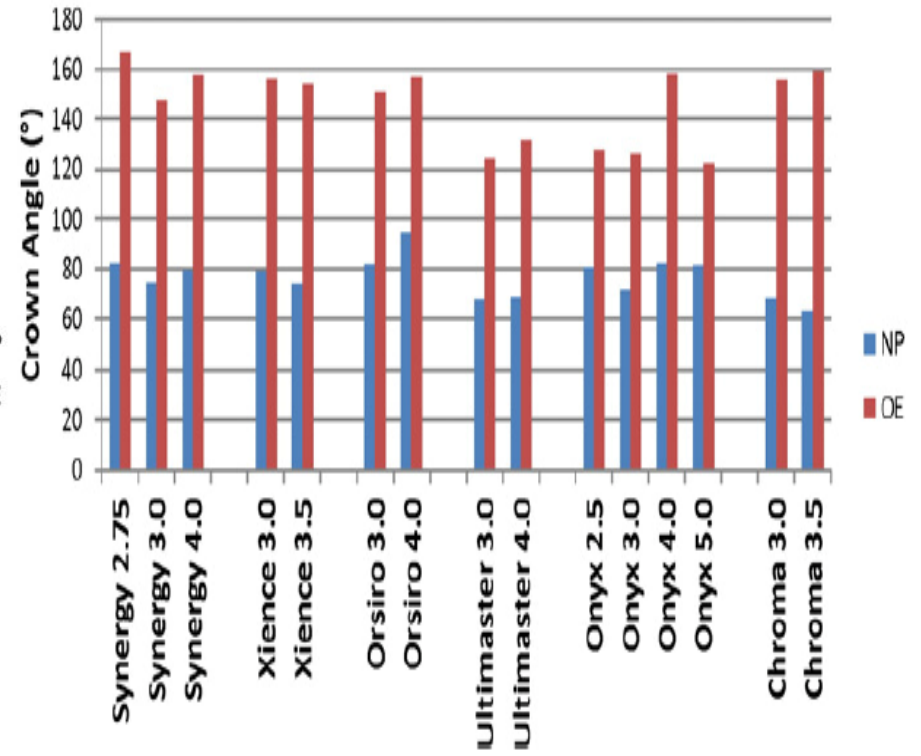
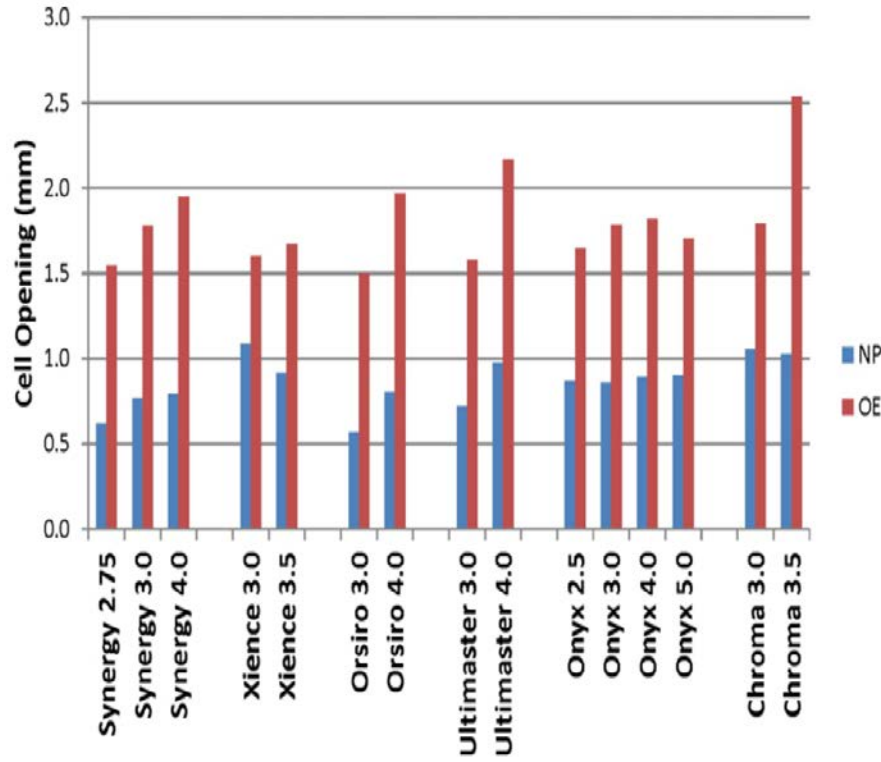


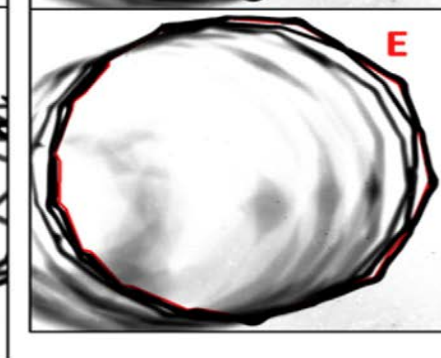
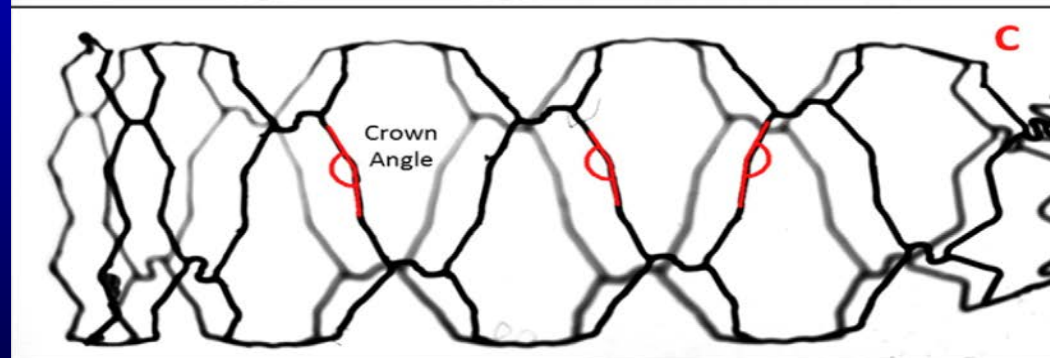
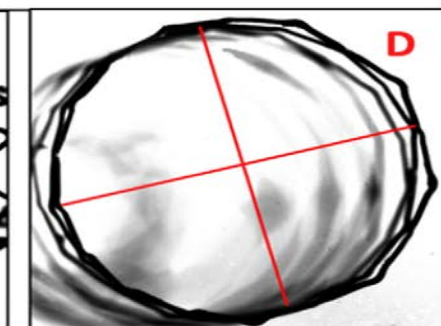
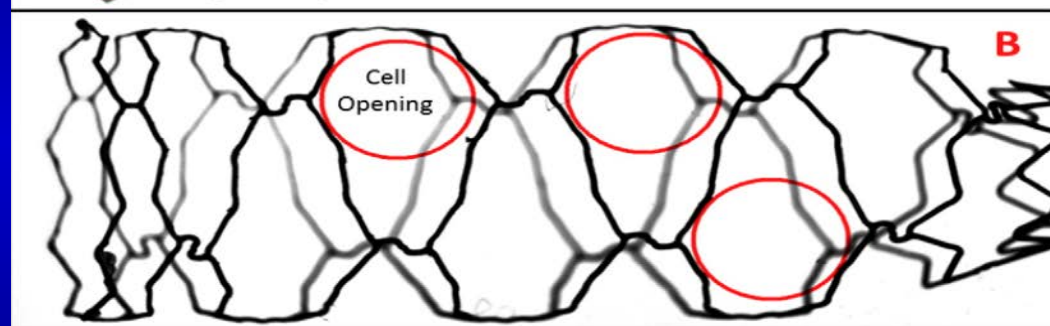
NEW DES WORKHORSE AND MODEL DESIGNS



	Synergy	Xpedition	Res. Onyx	Ultimaster	BioMatrix A	Orsiro
2.25	Small vessel (8 crowns, 2-4 connectors)	Small vessel (6 crowns, 3 connectors)	Small vessel (6.5 crowns, 2 connectors)	Small vessel (8 crowns, 2 connectors)	Small vessel (6 crowns, 2 connectors)	Small vessel (6 crowns, 3 connectors)
2.50						
2.75			Medium vessel (8.5 crowns, 2 connectors)			
3.00	Workhorse (8 crowns, 2-4 connectors)					
3.50		Large vessel (9 crowns, 3 connectors)	Large vessel (9.5 crowns, 2.5 connectors)	Large vessel (8 crowns, 2 connectors)	Large vessel (9 crowns, 3 connectors)	Large vessel (6 crowns, 3 connectors)
4.00	Large vessel (10 crowns, 2-5 connectors)					
4.50			Extra-Large vessel (10.5 crowns, 2.5 connectors)			
5.00						

NEW DES WORKHORSE CELL OPENING AND CROWN ANGLE





SUSTAINED RADIAL STRENGTH

Resolute Onyx™ XLV DES
5.00 mm x 18 mm (0.0036"/91 μm)

4.6

Resolute Onyx™ DES
3.00 mm x 18 mm (0.0032"/81 μm)

4.3

Resolute Integrity™ DES
3.00 mm x 18 mm (0.0036"/91 μm)

4.3

Promus Premier™* DES
3.00 mm x 20 mm 0.0032"/81 μm)

4.2

Synergy II™* DES
3.00 mm x 20 mm (0.0031"/79 μm)

4.0

Xience™* DES
3.00 mm x 18 mm (0.0032"/81 μm)

3.1

Higher Is Better

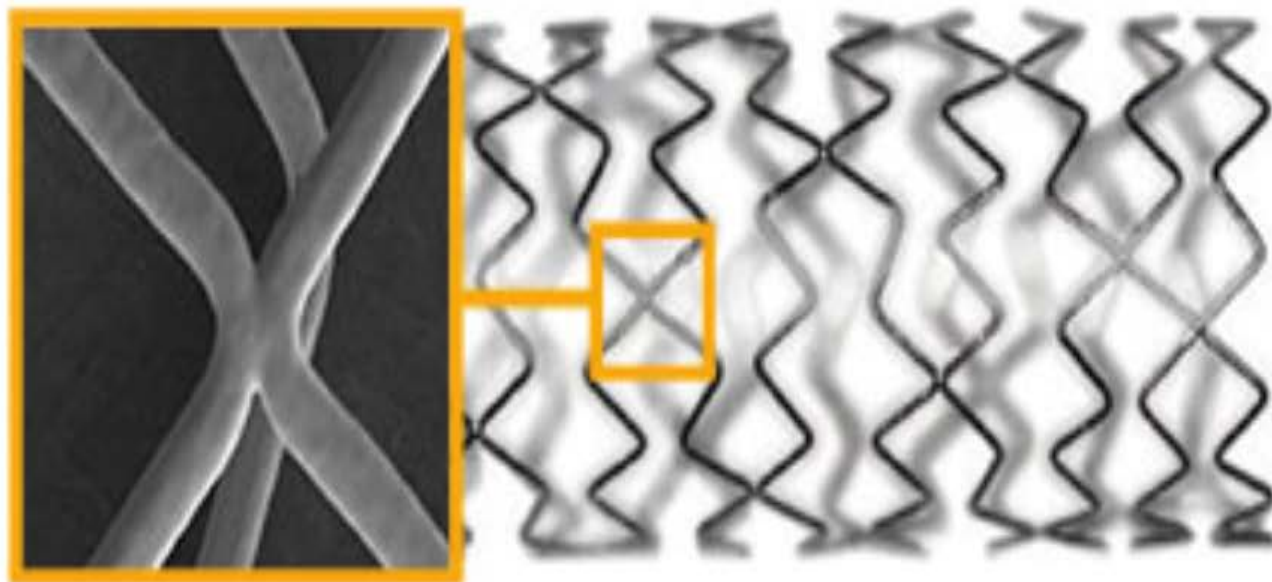
Compression resistance (N/mm per mm)

Bench test data on file at Medtronic. Stents expanded to nominal diameter.

Resolute Onyx™ DES

5.0 mm x 18 mm

Deployed to 5.75 per IFU maximum
overexpansion

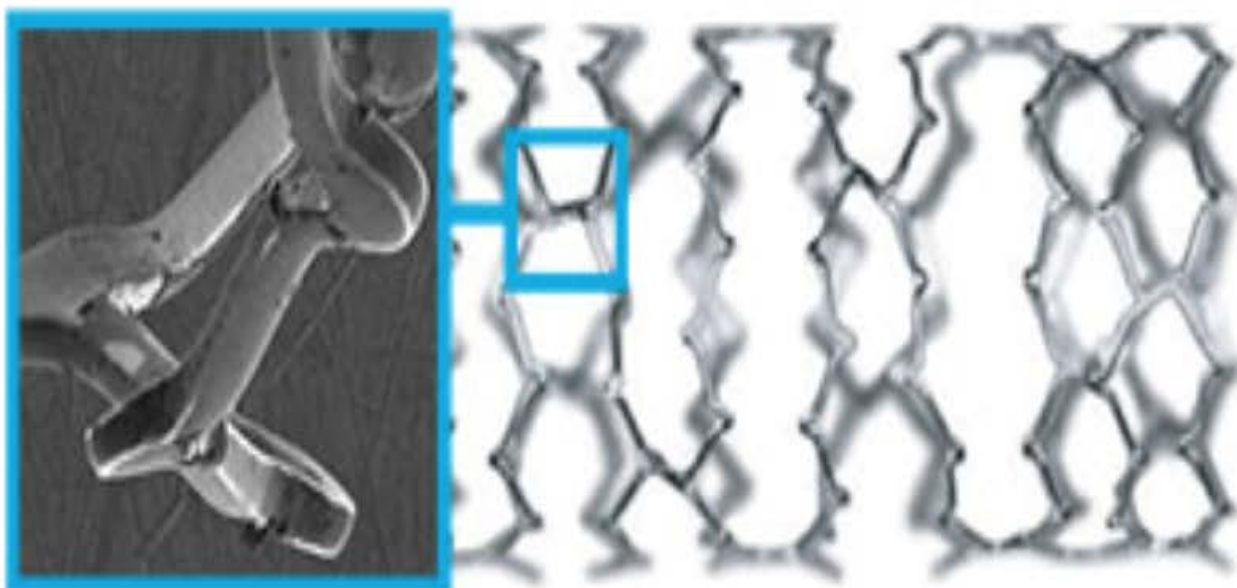


0.8%
foreshortening

Synergy™* DES

4.0 mm x 20 mm

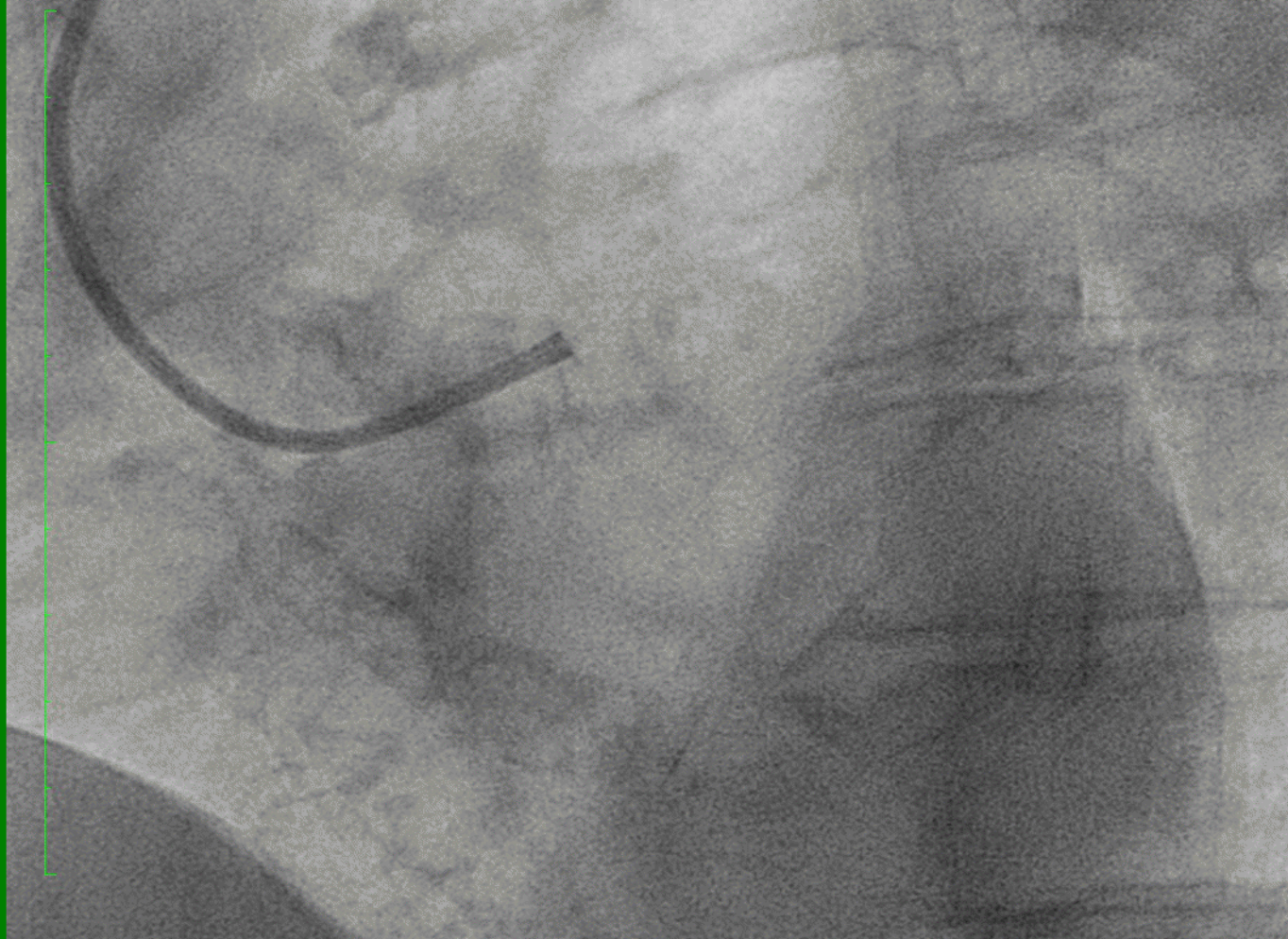
Deployed to 5.75 per IFU maximum
overexpansion



14.7%
foreshortening

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

1157 + PCI (87 y , 87 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
2



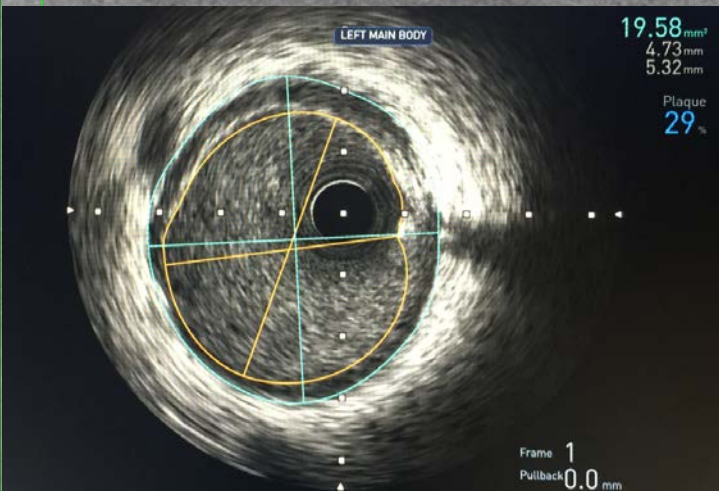
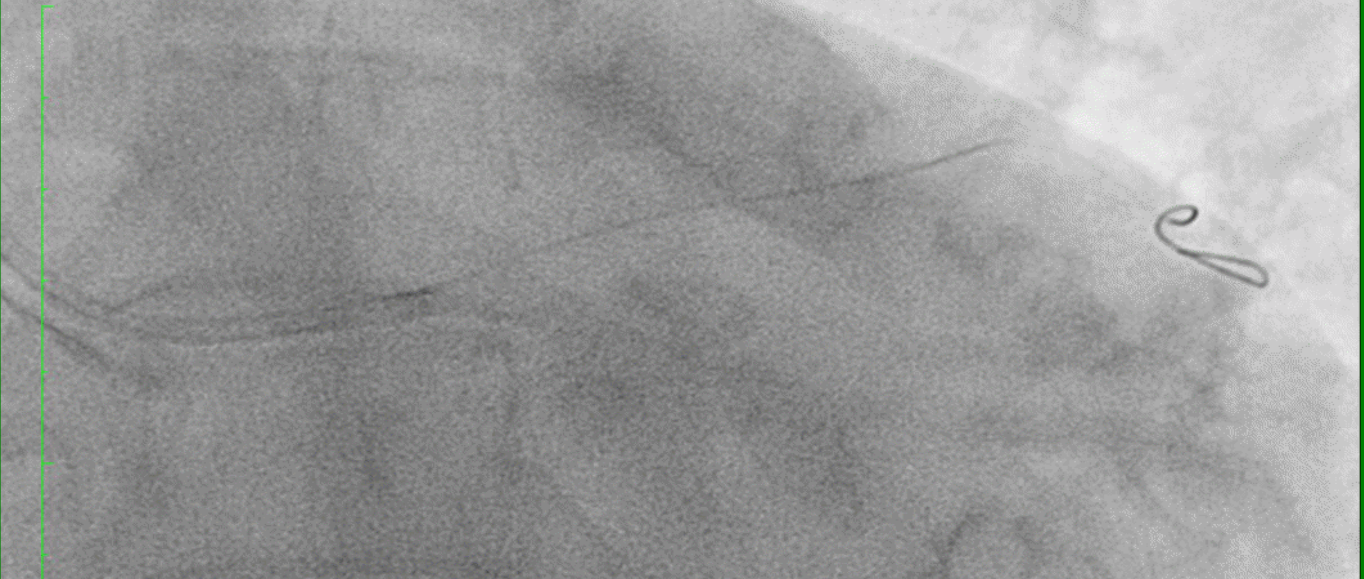
Zoom: 207% Angle: 0
In: 1/54
Uncompressed

NOT FOR MEDICAL USAGE

12/10/17 12:20:27
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

1157 + PCI (87 y , 87 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
5



AL USAGE

12/10/17 12:26:11
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

1157 + PCI (87 y , 87 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
7

Zoom: 207% Angle: 0
Im: 1/65
Uncompressed

NOT FOR MEDICAL USAGE

12/10/17 12:28:26
Made In OsiriX



Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

1157 + PCI (87 y , 87 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
8

Zoom: 207% Angle: 0
Im: 1/8
Uncompressed

ONYX 5.0X12@18 atm

12/10/17 12:28:43
Made In OsiriX

Image size: 512 x 512
View size: 1059 x 1059
WL: 128 WW: 179

1157 + PCI (87 y , 87 y)
Cardio ClarityFluoro7.5
Cardio ClarityFluoro7.5
10

Zoom: 207% Angle: 0
Im: 1/78
Uncompressed

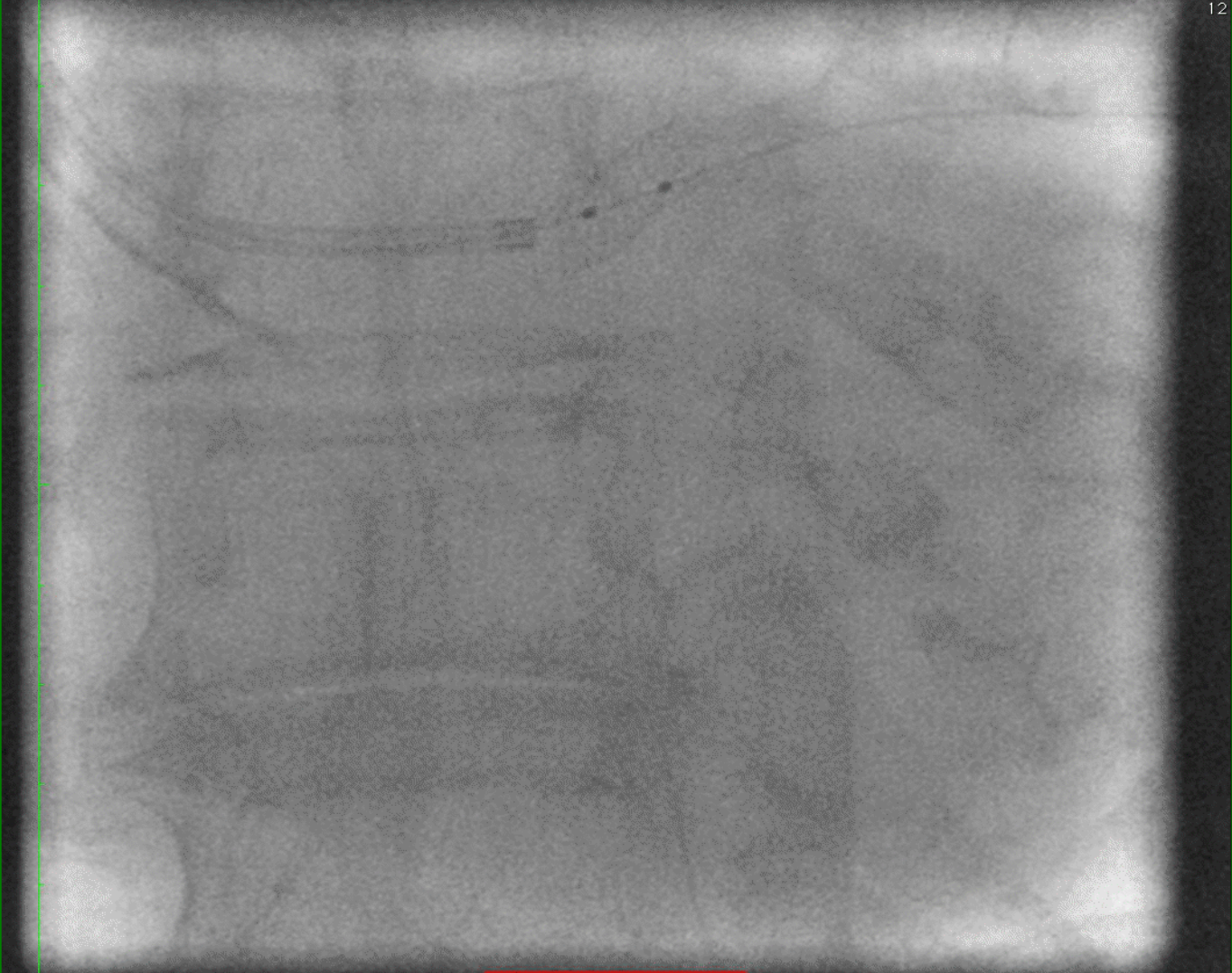
NOT FOR MEDICAL USAGE

12/10/17 12:29:45
Made In OsiriX

2

Image size: 512 x 512
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WL: 133 WW: 189

1157 + PCI (87 y , 87 y)
Cardio Clarityfluoro7.5
Cardiac Special
12

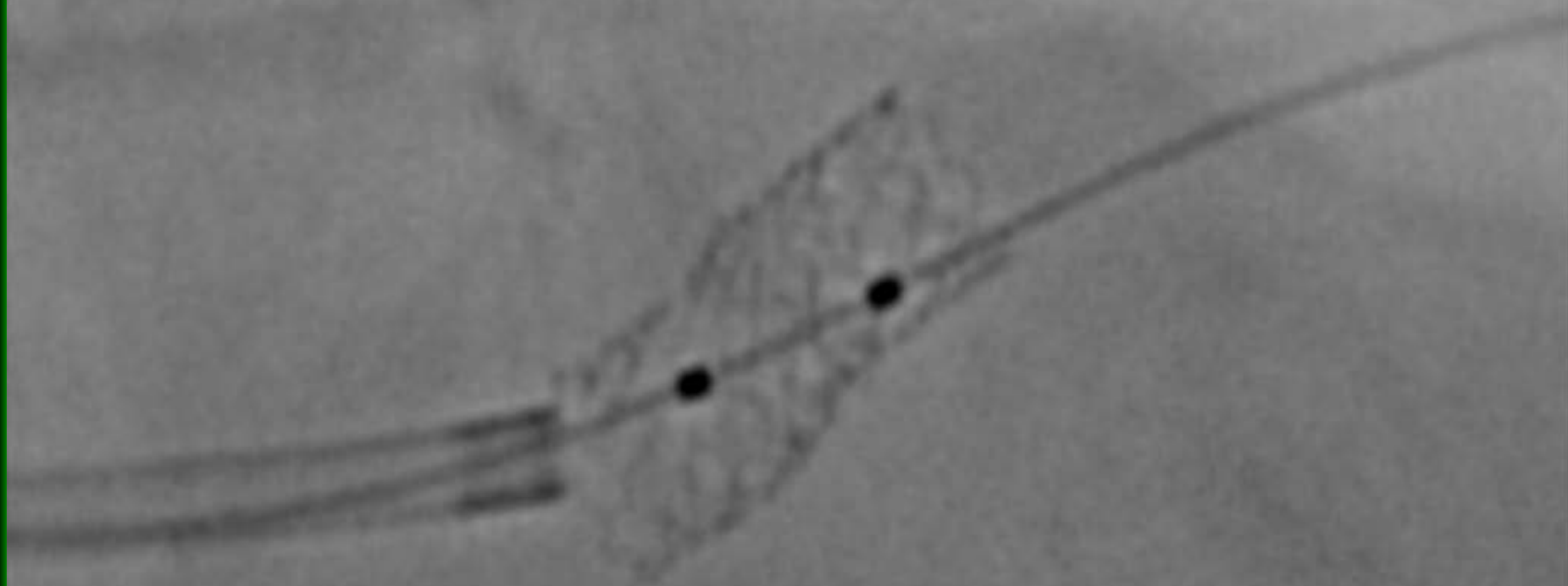


Zoom: 207% Angle: 0
Im: 1/40
Uncompressed

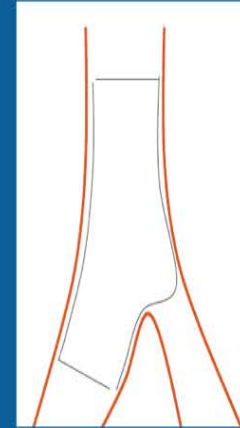
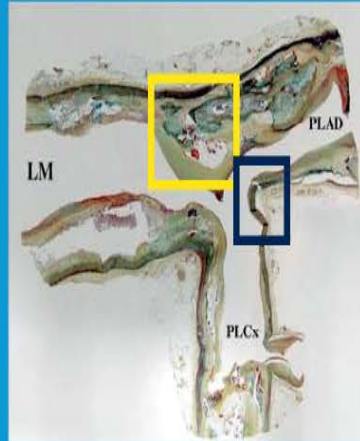
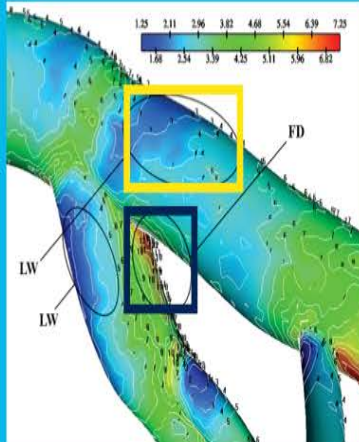
NOT FOR MEDICAL USAGE

12/10/17 12:31:50
Made In OsiriX

Rot: RAO 1
Ang: Caud 19
Reliability: 100 %



LEFT MAIN BIFURCATION FLOW DYNAMICS FAVOR PROVISIONAL STENTING



Atherosclerotic lesions tend to form in areas of low shear stress¹

In the left main bifurcation, wall shear stress is typically **low on the lateral walls** and **high at the carina**²

Atherosclerosis is accelerated along the lateral wall of the left main, close to the bifurcation^{3,4}

The carina is frequently free of disease^{3,4}

Left main bifurcation physiology is favorable towards provisional stenting

EBC consensus:⁵
Provisional stenting is the preferred strategy in LMCA bifurcation lesions⁶

DESIGN CONSIDERATIONS FOR LEFT MAIN BIFURCATION STENTING

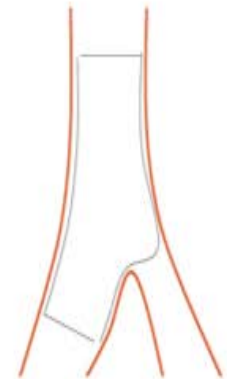
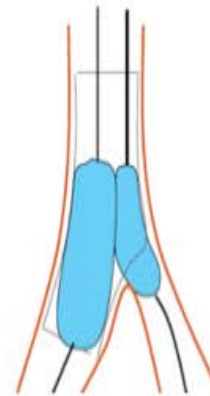
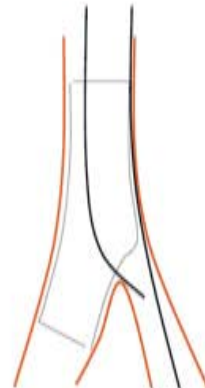
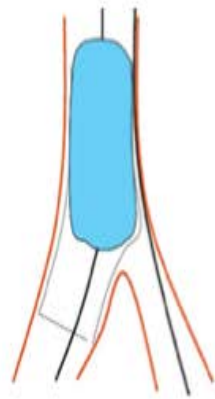
PROCEDURAL STEP

Proximal
Optimisation
Technique (POT)

Sidebranch
Access

Kissing Balloon
Technique (KBT)

Final Scaffold



CONSIDERATIONS

Appropriate sizing;
scaffold integrity
maintained with
overexpansion

Potential for catching
and longitudinal
deformation; open cell
structure to facilitate
sidebranch access

Expandable cell area
for large sidebranch
sizing

Flexibility and
conformability for
adequate stent
apposition

RESOLUTE ONYX™ DES IS IDEALLY SUITED FOR LEFT MAIN BIFURCATION

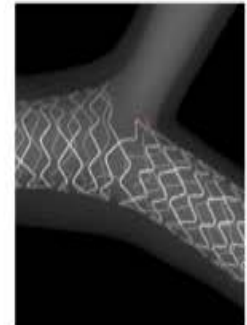
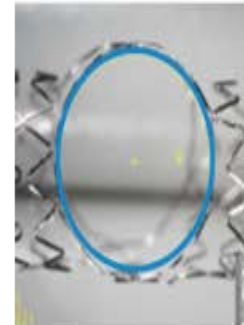
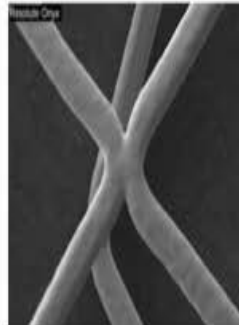
PROCEDURAL
STEP

Proximal
Optimisation
Technique (POT)

Sidebranch
Access

Kissing Balloon
Technique (KBT)

Final Scaffold



RESOLUTE ONYX™
DES ADVANTAGE

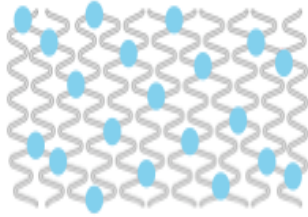
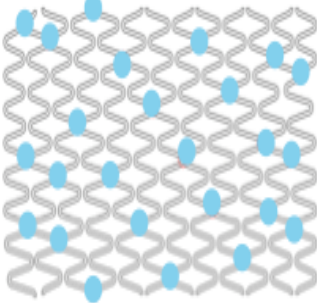
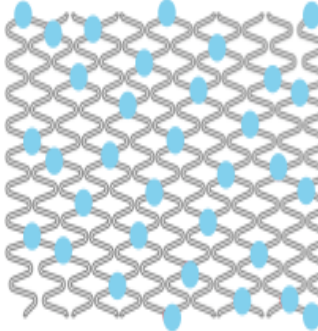
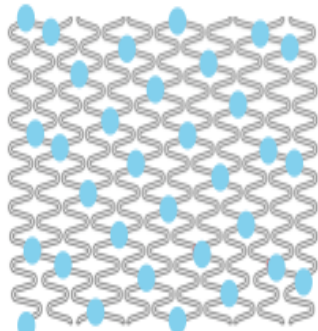
Scaffold integrity
maintained with
overexpansion

Resistance to
catching and LSD

Large sidebranch
sizing

Superior strut
apposition¹

RESOLUTE ONYX™ THIS IS WHY I LIKE IT...

Characteristic	Resolute Onyx™ DES			
● Stent size (mm)	2.00, 2.25, 2.50	2.75, 3.00	3.50, 4.00	4.50, 5.00
● Outer material	Cobalt alloy conforming to ASTM F562-02			
Core material	Platinum iridium			
● Strut thickness dimensions	0.0032"/81 µm	0.0032"/81 µm	0.0032"/81 µm	0.0036"/91 µm
Crowns	6.5	8.5	9.5	10.5
Fusion pattern	Every fourth crown fused	Every fifth crown fused	Every fourth crown fused	Every fourth crown fused
				
● Maximum expansion (mm) — MSID ¹	3.25	3.75	4.75	5.75
● Cell diameter for bifurcation (mm)	3.7	3.9	3.8	4.9



THANKS FOR YOUR KIND ATTENTION







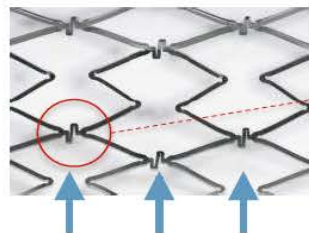




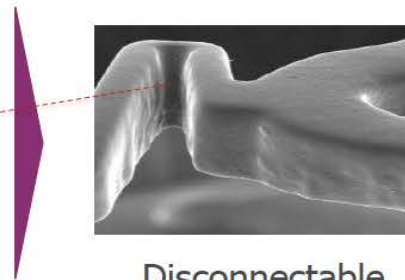
STENTYS Self-Apposing[®] Stent



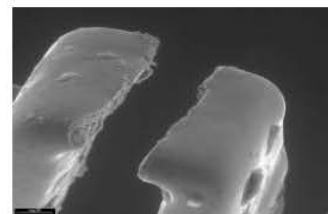
- Self-expanding nitinol stent constrained inside a Splitable Sheath over the balloon
- Bare or Sirolimus-eluting with ProTector biostable polymer
- 6 French, single-wire, rapid exchange
- Disconnecting bridges over full length* for side-branch access



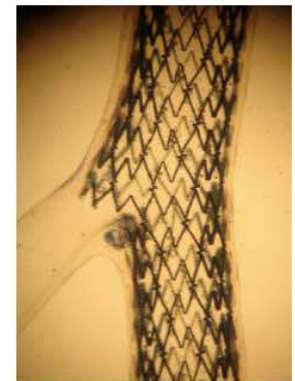
Disconnectors
along the stent



Disconnectable
interconnector



Disconnection



Shaping an ectatic coronary artery: Stentys implantation

Claudio Moretti*, Pierluigi Omedè, Davide Giacomo Presutti, Fabrizio D'Ascenzo, Chiara Colaci, Maurizio Bertaina, Ilaria Vilardi, Fiorenzo Gaita

Division of Cardiology, Department of Internal Medicine, Città Della Salute e Della Scienza, Turin, Italy

How should I treat a patient with a proximal left anterior descending large plaque burden embolising plaque?

Claudio Moretti*, MD, PhD; Jacopo Perversi, MD; Pierluigi Omedè, MD; Fabrizio D'Ascenzo, MD; Serena Bergerone, MD; Fiorenzo Gaita, MD

Cardiology Division, Department of Medical Sciences, University of Turin, Turin, Italy



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Correspondence

Never underestimate the comeback kid; a case report of very early side branch occlusion after Stentys Exposition implantation without kissing balloon

Antonio Montefusco, Paolo Scacciatella, Pierluigi Omedè, Fabrizio D'Ascenzo*, Fiorenzo Gaita, Claudio Moretti

Division of Cardiology, Department of Internal Medicine



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Minding the gap between left main and branch vessels: Second-generation self-apposing, balloon-expandable, drug-eluting stent on trifurcated unprotected left main

Antonio Montefusco, Sebastiano Gili*, Fabrizio D'Ascenzo, Pierluigi Omedè, Claudio Moretti

Division of Cardiology, Department of Medical Sciences, Città della Salute e della Scienza Hospital, University of Turin, Turin, Italy



IDO, Marco
ot:
ing:
un Number:
eliability:

RAO 11
Caud 29
5025
85 %









Conclusion on Resolute Onyx

Most deliverable stent

- stent thickness – thinner (81 um)
- delivery system – improved

Conformable

Radiopacity - good

Stent through stent – easy to cross

Balloon – can go to high pressure (26 Atm!)

Wide range of sizes: 2.0 – 5.0 mm diameter,
Length (depending on size): 8 – 38 mm