

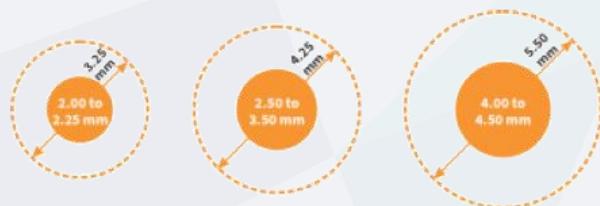
Supraflex Cruz Nevo, el nuevo Gold Standard en Navegabilidad

Rafael Romaguera, MD, PhD

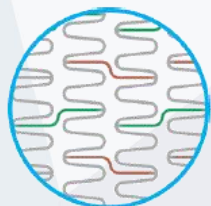
Head, Interventional Cardiology Department
Bellvitge University Hospital



Comprehensive Overexpansion Limits



4, 6 & 8 crown design



Alternate LDZ link to navigate through tortuosity

Biodegradable Polymer Matrix

Circumferential Coating

Sirolimus: $1.4 \mu\text{g}/\text{mm}^2$

About 80% of the drug is released at 4 weeks in biological media while 100% drug is released at a slow rate within 3 months.

0% foreshortening

(4 mm Supraflex Cruz overexpanded to 5.5 mm)¹

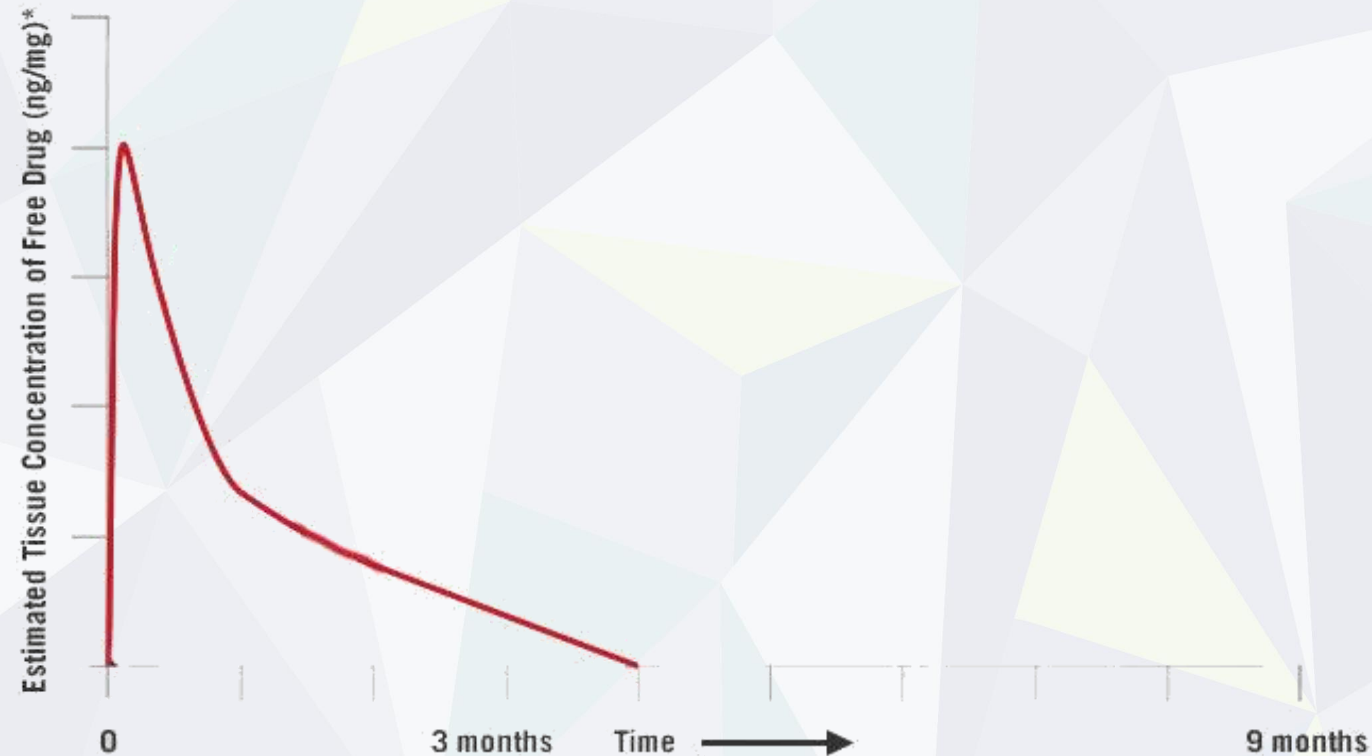
Low crossing profile* (0.97")

1. Test performed by and data on file at SMT. Testing performed on Supraflex Cruz Sirolimus Eluting Coronary Stent System (4.00 x 24 mm), n=3. Bench test results may not necessarily be indicative of clinical performance.. *Crossing profile for size 3 x 16 mm. Supraflex Cruz is a trademark of Sahajanand Medical Technologies Ltd. or its affiliates.

	Orsiro	CoroFlex IsarNeo	Biomime	Biomime Morph	Evermine 50	MiStent	Supraflex Cruz
							
Company	Biotronik	B. Braun	Meril	Meril	Meril	Stentys	Sahajanand Medical Technologies (SMT)
Platform material and Strut thickness (µm)	2.5 to 3 mm 60 3.5 to 4 mm 80	2 to 3 mm 55 3.5 to 4 mm 65	65	65	50	64	60
Crossing Profile	0.95 mm	0.79 to 0.96 mm	0.83 to 1.19 mm	0.93 to 1.03	0.83 to 1.19	n.a.	0.95 mm
Available diameters (mm)	2.25, 2.5, 2.75, 3.0, 3.5, 4.0	2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0	2.0, 2.25, 2.75, 3.0, 3.5, 4.0, 4.5	2.75-2.25, 3.0-2.5, 3.5-3.0	2.0, 2.25, 2.50, 2.75, 3.0, 3.5, 4.0, 4.5	n.a.	2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, 4.5
Lengths available (mm)	9 to 40	9 to 38	8 to 48	30 to 60	8 to 48	n.a.	8 to 48 mm
Polymer type	Biodegradable (proBIO®)	Polymer free	Biodegradable Biocompatible	Biodegradable Biocompatible	Biodegradable Biocompatible	Biodegradable	Biodegradable
Coating distribution	Circumferential	-	Circumferential	Circumferential	Circumferential	Circumferential	Circumferential
Polymer material and thickness	3.5 µm abluminal 7.5 µm luminal	-	2 µm	2 µm	2 µm	5 µm/ 15 µm	4-5 µm
Polymer absorption	15 months	-	60 days	60 days	60 days	3 months	9-12 months
Eluted drug	Sirolimus	Sirolimus and Probucol	Sirolimus	Sirolimus	Everolimus	Sirolimus (microcrystals)	Sirolimus
Drug dose	1.4 µg/mm²	1.2 µg/mm²	1.25 µg/mm²	1.25 µg/mm²	1.25 µg/mm²	2.4 µg/mm²	1.4 µg/mm²
Drug release	50% by 1 month 80% by 3 months	80% by 28 days 100% by 90 days	30-40 days	30-40 days	30-40 days	9 months	70% by 1 week 100% by 3-4 months
							
	Cobalt-Chromium	PLLA	PLLA and PLGA	PLLA + PCL + PVP			

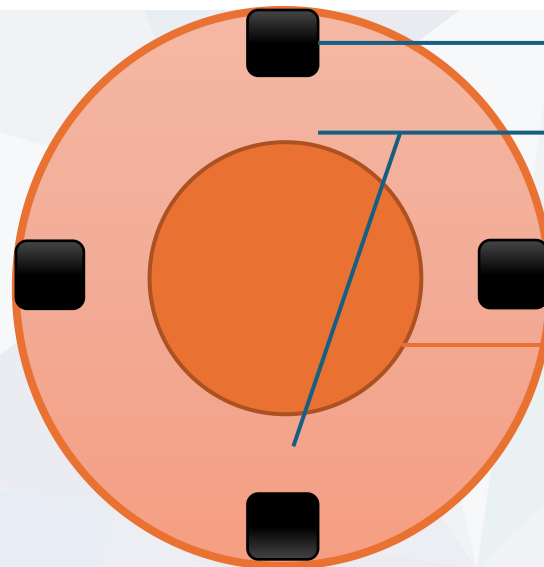
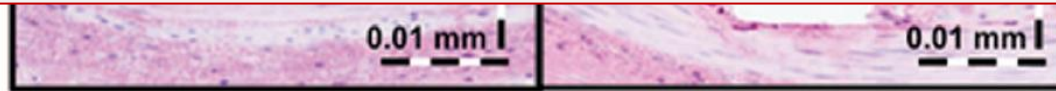
Drug-release kinetics

Estimated Tissue Concentration of Free Drug* over time



DEVICE THICKNESS + LATE LOSS

**IN SV, DEVICE THICKNESS & ANTIPROLIFERATIVE EFFICACY
ARE OF REMARKABLE INTEREST**



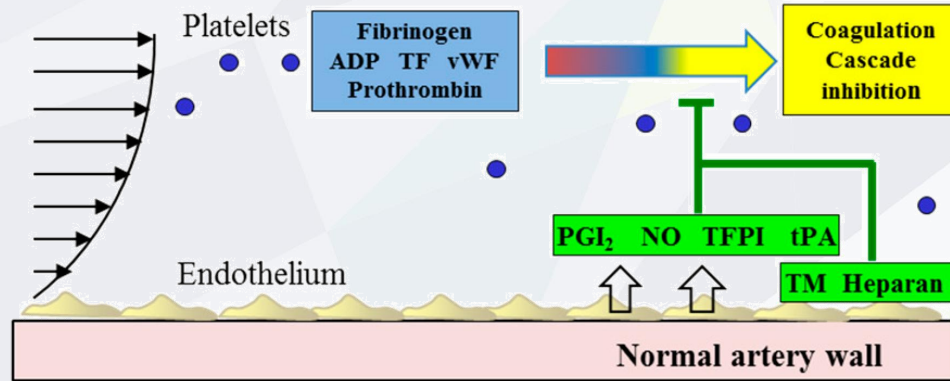
100 μ m (0.1 mm) DEVICE THICKNESS

400 μ m (0.4 mm) TISSUE GROWTH

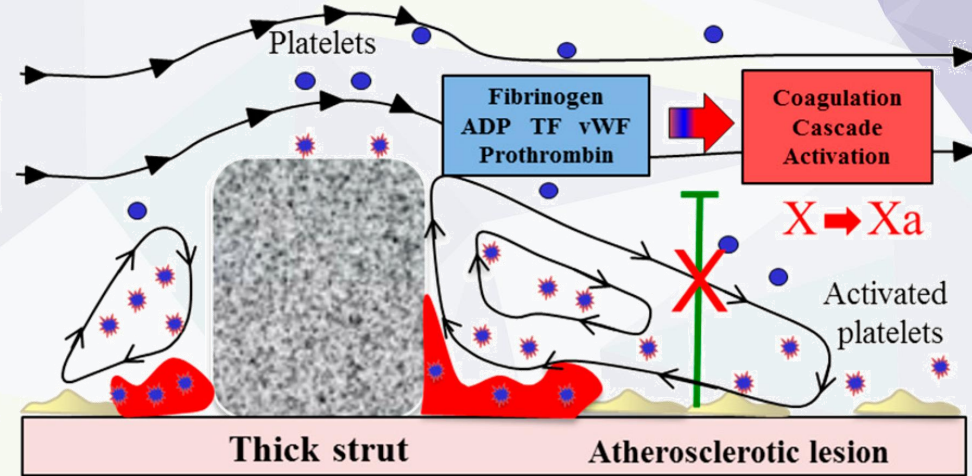
$2.25 - (0.1 \times 2) - (0.4 \times 2) = 1.25$ mm MEDIAN LUMEN

$1\text{mm} / 2.25 =$ **50 % patients** with **>45% stenosis**

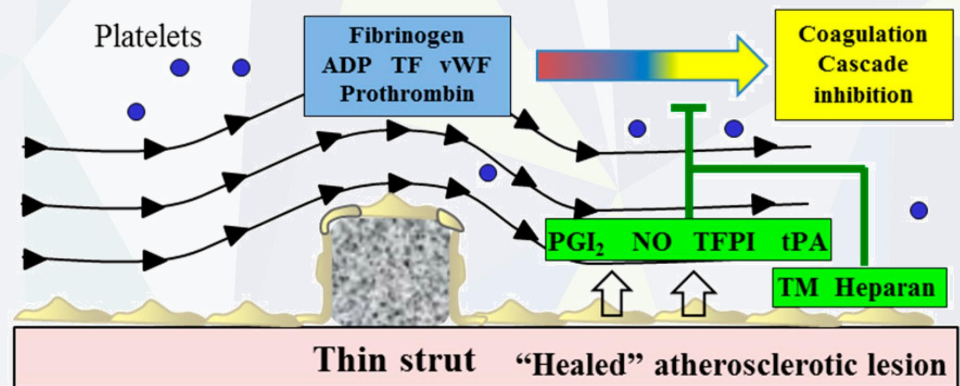
(A)



(B)



(C)



Comprehensive Overexpansion Possibilities for all Diameters



Zero Foreshortening

Coating Integrity not Compromised

No Change in Drug Release
Characteristics

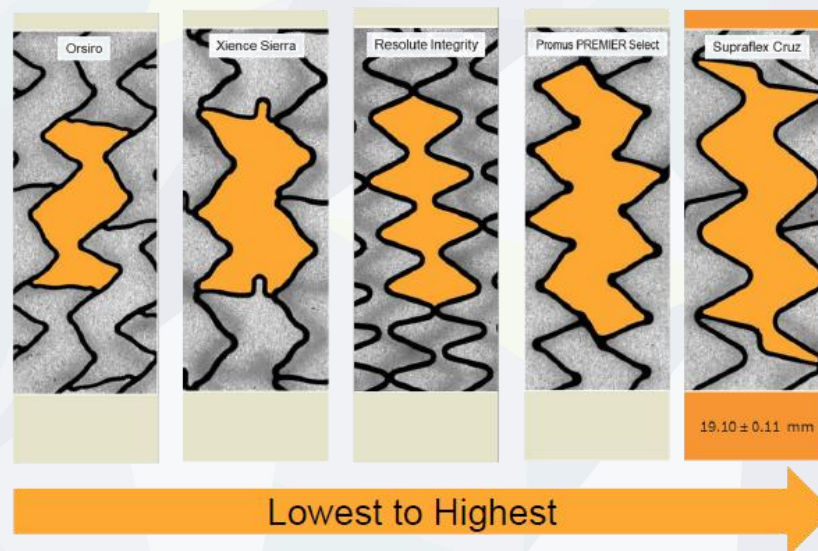
Negligible Particulate Matter

Supraflex Cruz is a trademark of Sahajanand Medical Technologies Ltd. or its affiliates. Overexpansion limits as per the IFU

— Labeled Nominal
- - - Labeled Post-Dilatation Limit



Ideal Choice for Bifurcation Lesions



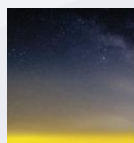
- Provides **largest cell area**, cell size (diameter) and **highest cell perimeter** for ease of crossing the side branch through the stent
- **Highest side branch expansion** possibility across wide range of balloon diameters as compared to the available contemporary DES options

Disclaimer: Supraflex Cruz is a trademark of Sahajanand Medical Technologies Ltd. or its affiliates. Xience Sierra is trademark of the Abbott Group of Companies. Promus Premier Select is a trademark of Boston Scientific Corporation or its affiliates. Resolute Integrity is a trademark of Medtronic, Inc. Orsiro is a trademark of Biotronik SE & Co.

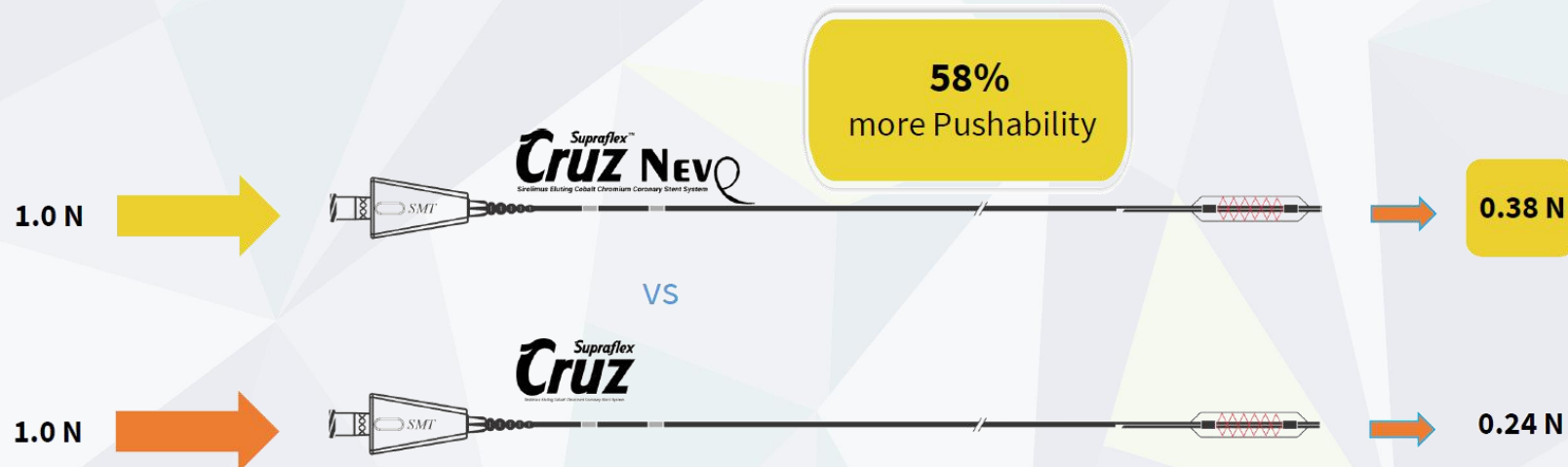
Ref: Eur J Med Res. 2021 Oct 12;26(1):121. Doi: 10.1186/s40001-021-00595-7



- Mejor transmisión de la fuerza a través del hipotubo para una **mayor Capacidad de Empuje**:



Pushability @ 1.0 N



1.0 N force applied at proximal end



❑ Sistema de Crimpado exclusivo mejorado para una **mayor Capacidad de Retención del Stent:**



Stent retention force



35%
Improvement in stent
retention force

Comprehensive testing of various crimping protocols was done before finalizing the best crimping protocol

Highly rigorous testing set-up to simulate real-life clinical scenarios

Stent retention testing as per the new method was conducted on more than 5000 samples (destructive tests)

Testing beyond the industry-standards

Supraflex™ Cruz Nevo

Sirolimus Eluting Cobalt Chromium Coronary Stent System

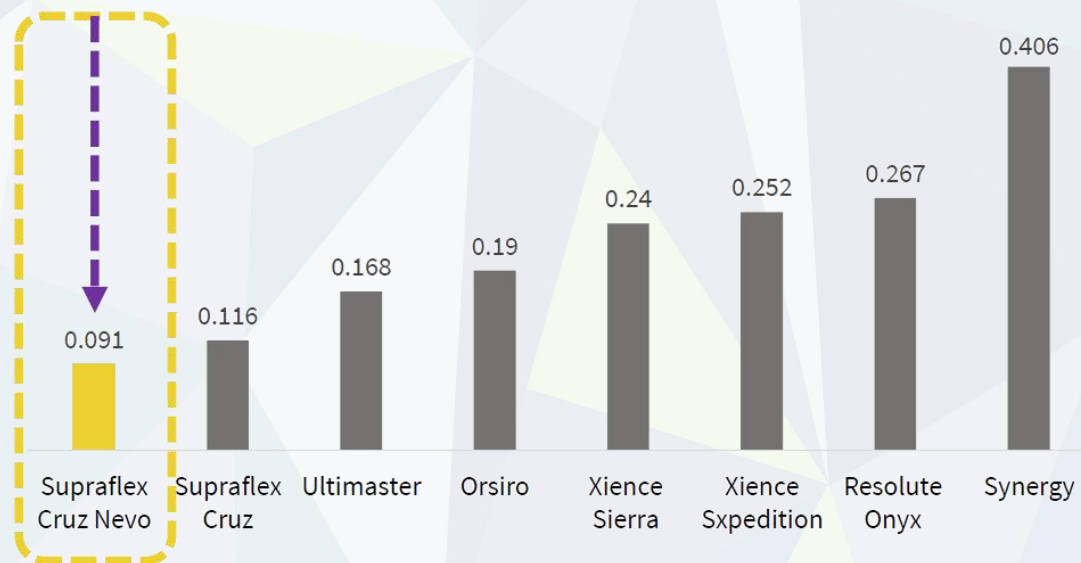


Deliverability Redefined

84%
better
than
Ultimaster

346%
better
than
Synergy

Supraflex Cruz Nevo is
10% better than
Supraflex Cruz



Mean force in Newton (N) for stents with 38 to 40 mm length

EVIDENCIA

- Más de 28.000 pacientes incluidos en diferentes estudios publicados



TALENT

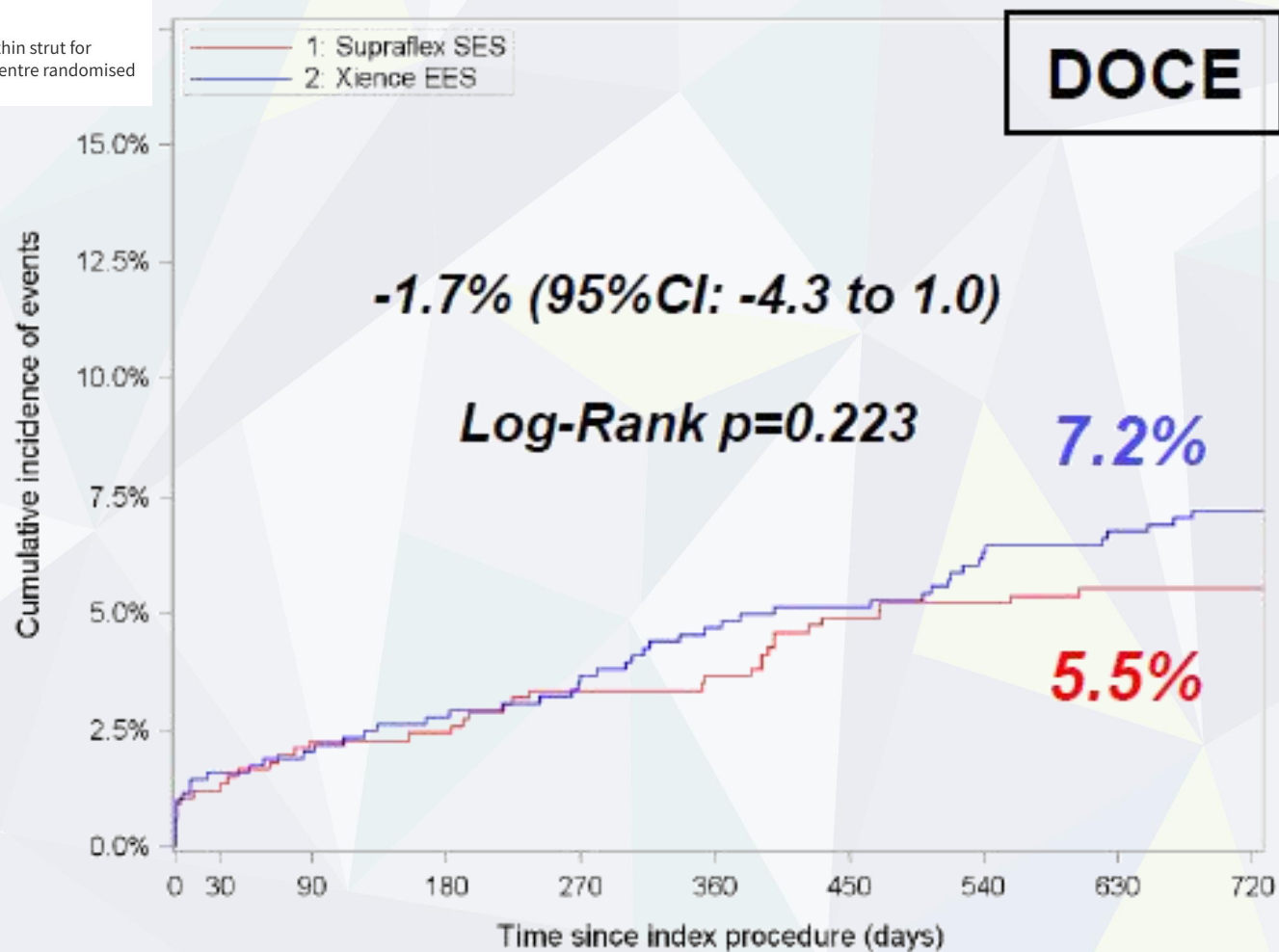
THE LANCET

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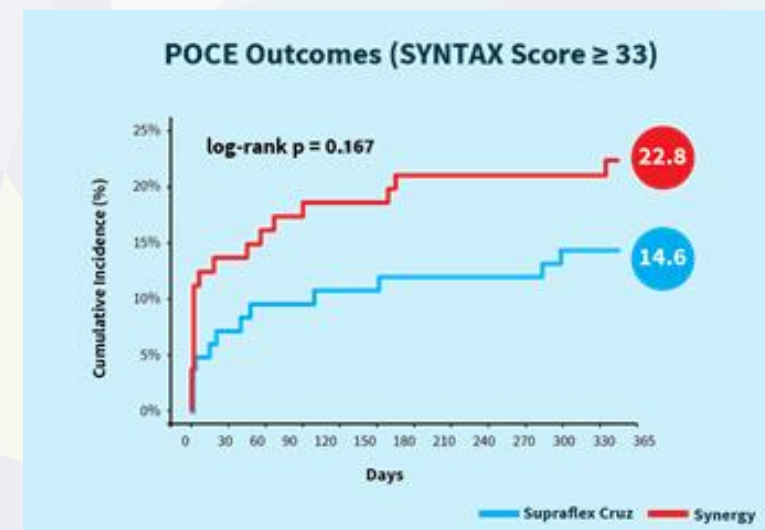
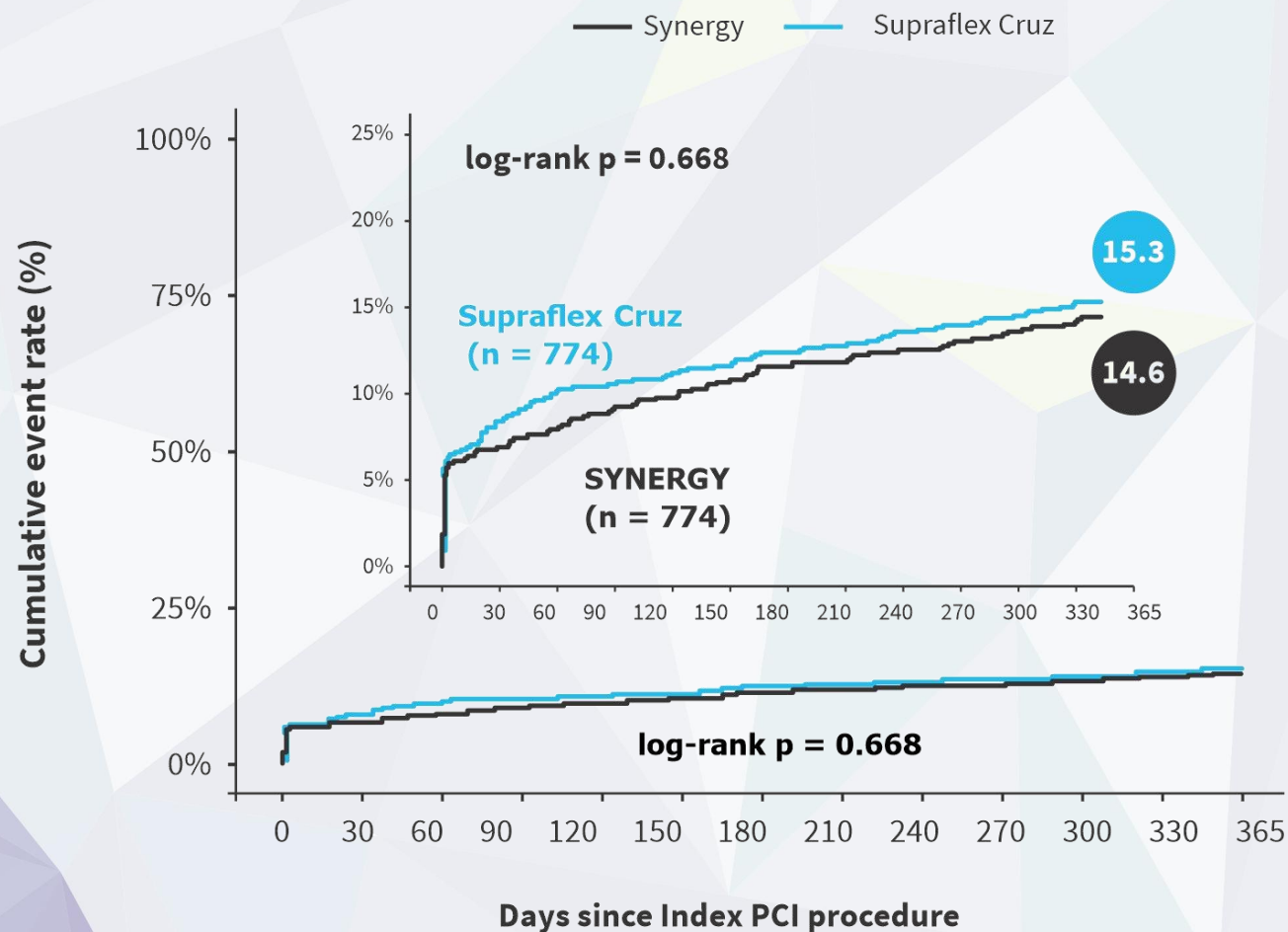
ARTICLES · Volume 393, Issue 10175, P987-997, March 09, 2019

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Safety and efficacy of a sirolimus-eluting coronary stent with ultra-thin strut for treatment of atherosclerotic lesions (TALENT): a prospective multicentre randomised controlled trial



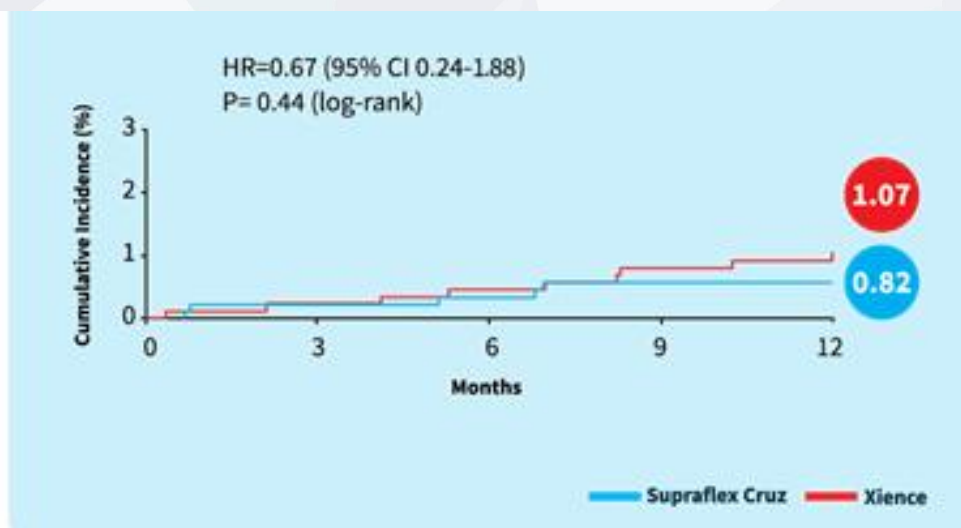
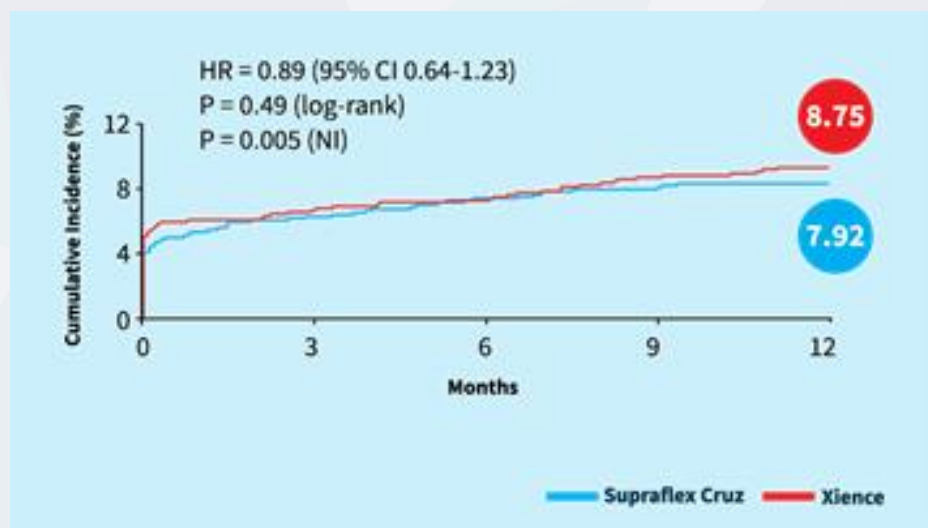
MULTIVESSEL TALENT

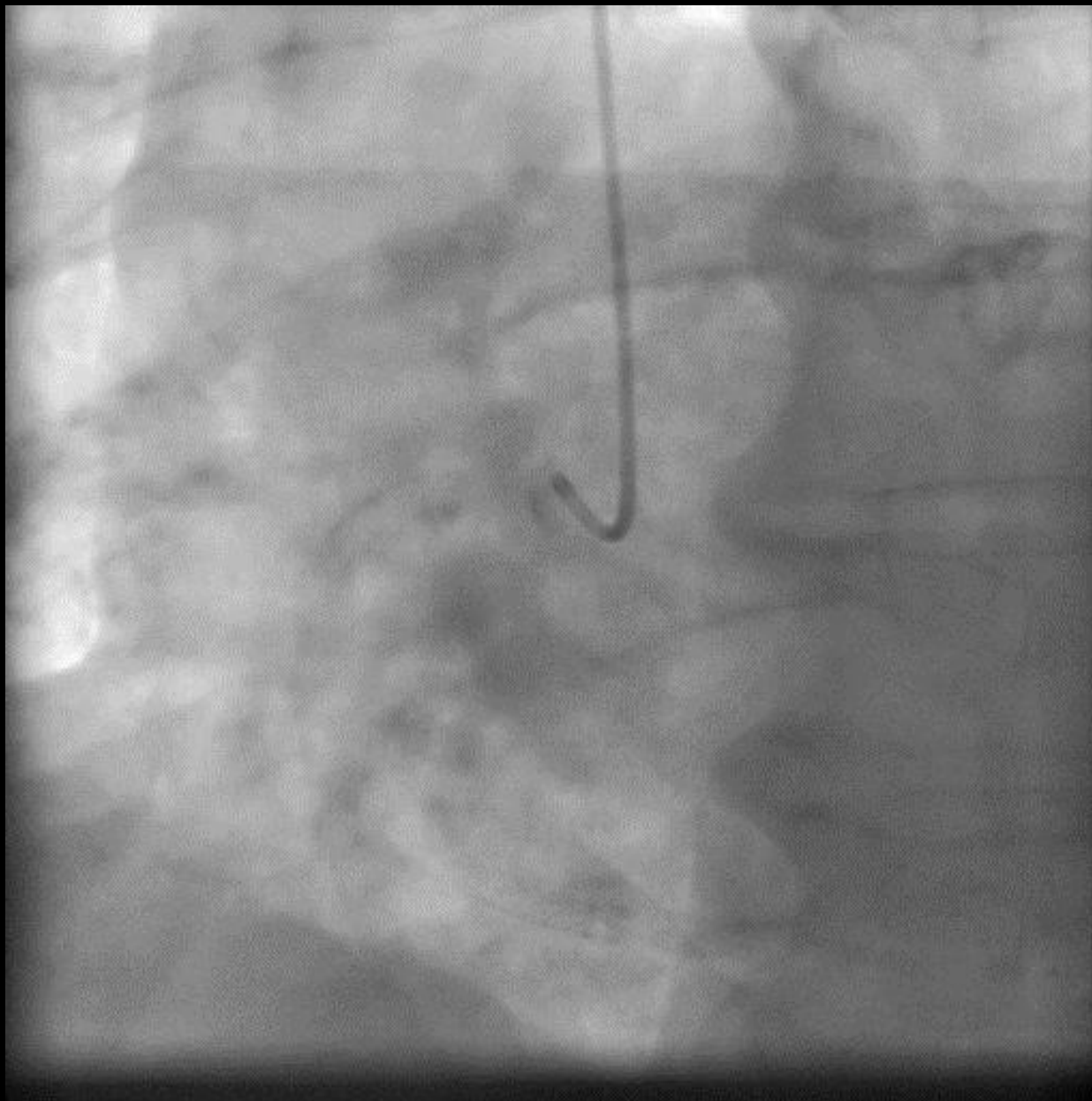




1-Year Outcomes from TUXEDO-II

Supraflex Cruz vs Xience in Patients with Diabetes and MVD, Undergoing PCI

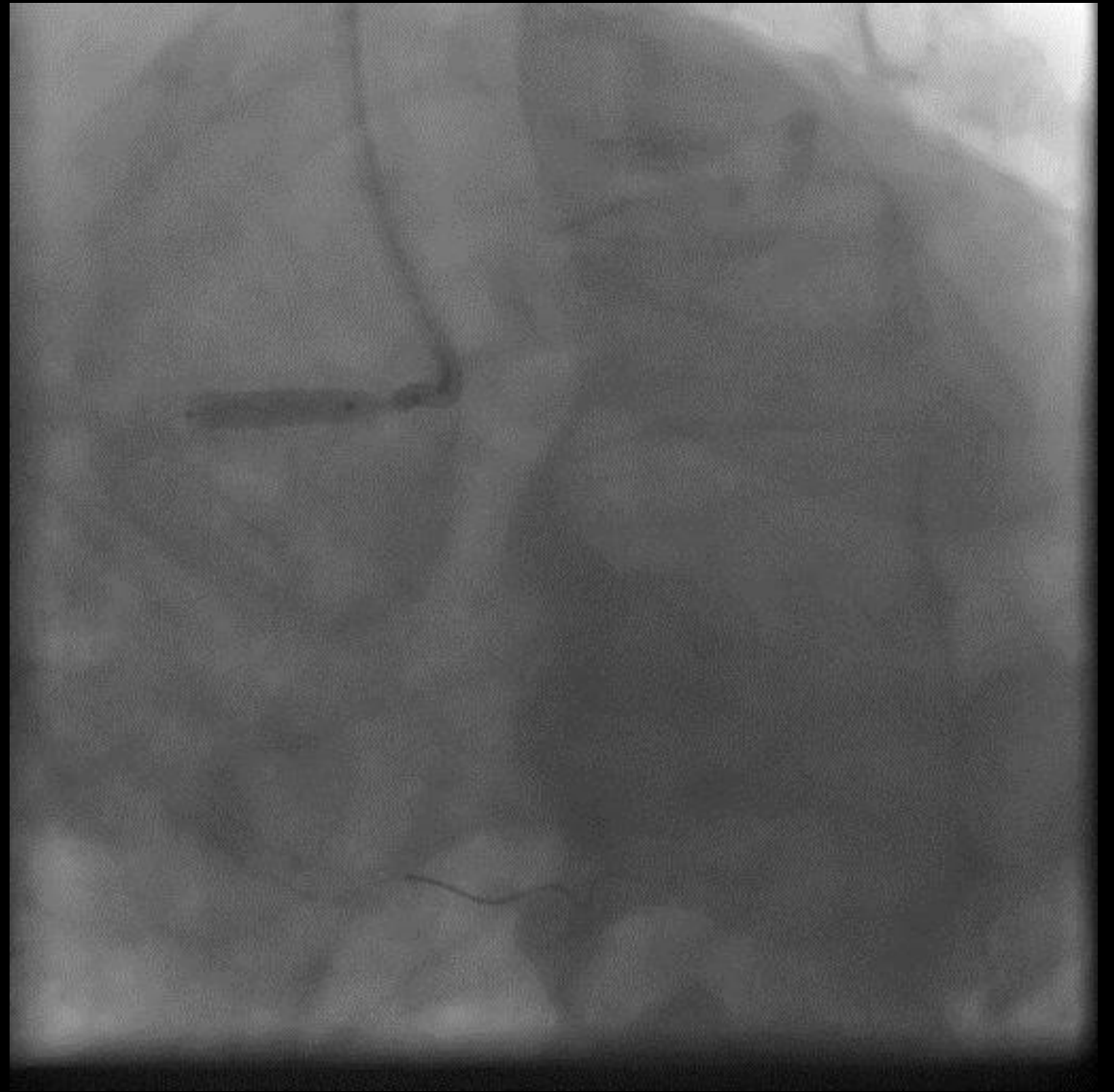




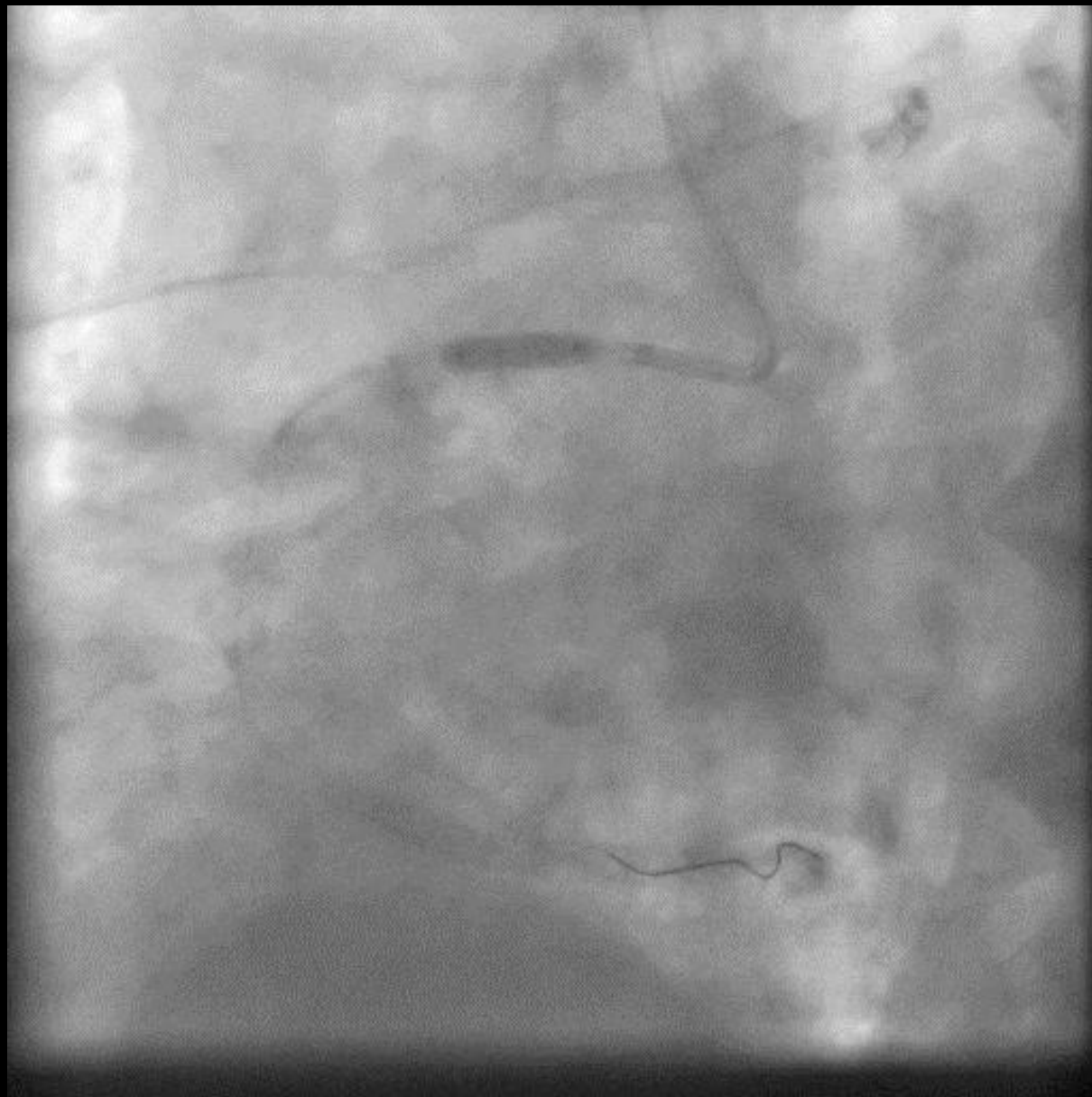
RCA



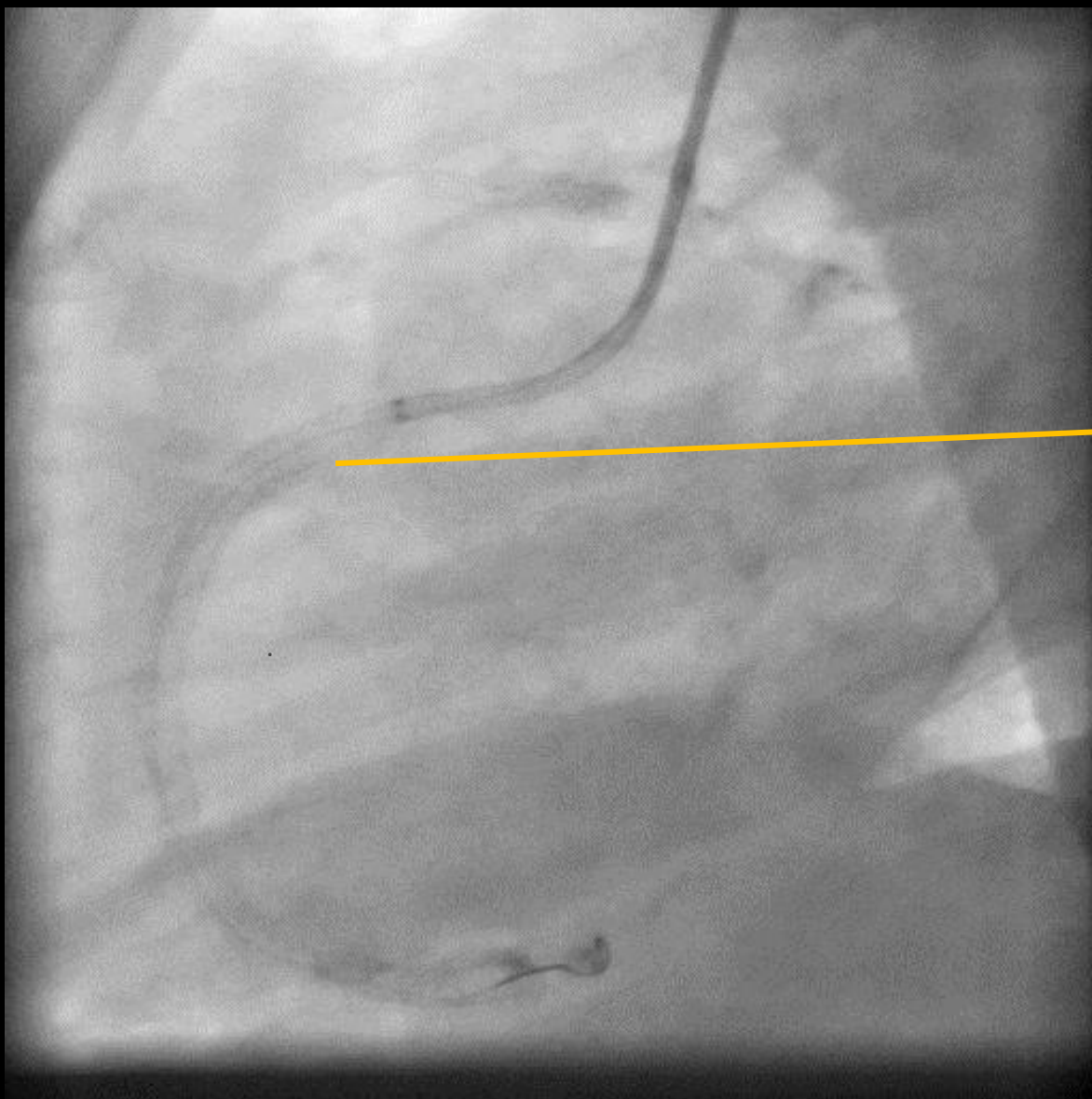
Supraflex Cruz Nevo 3.5x28mm



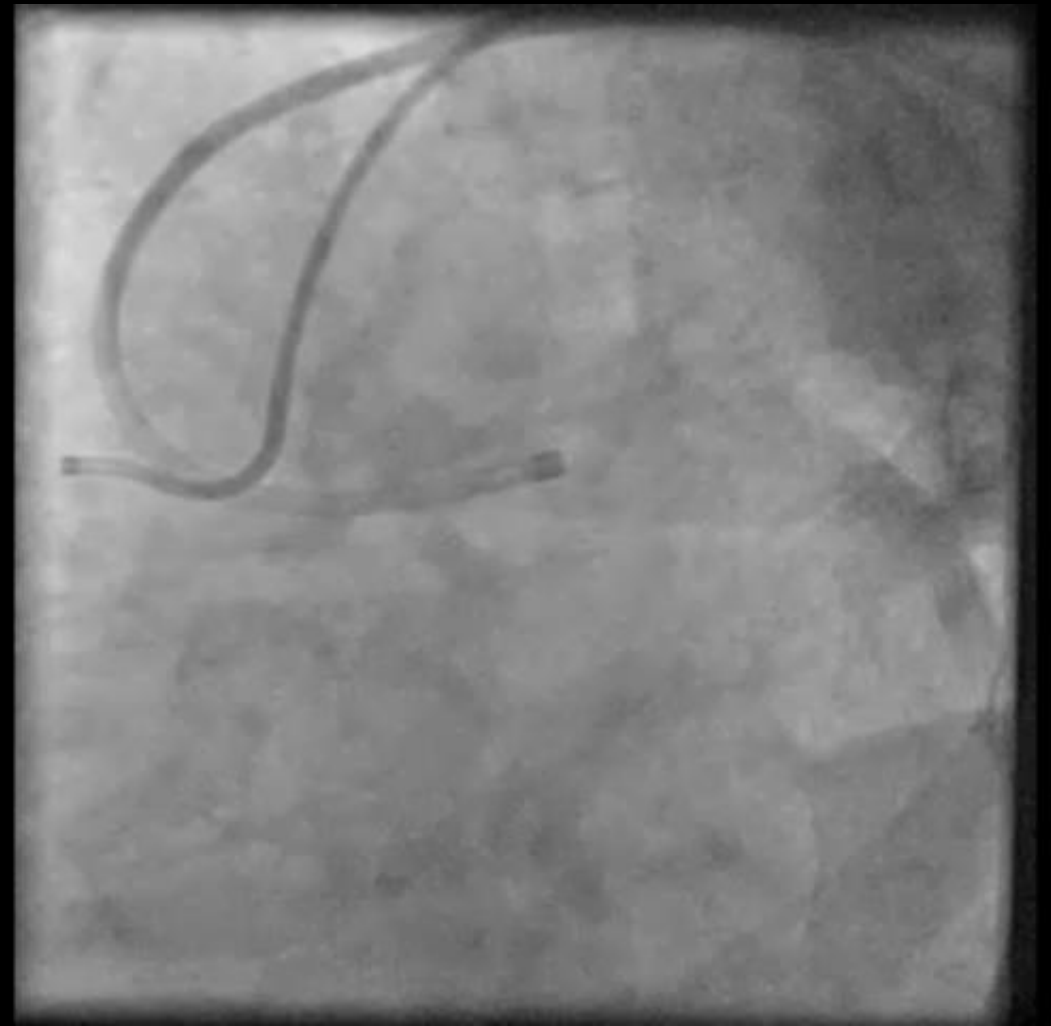
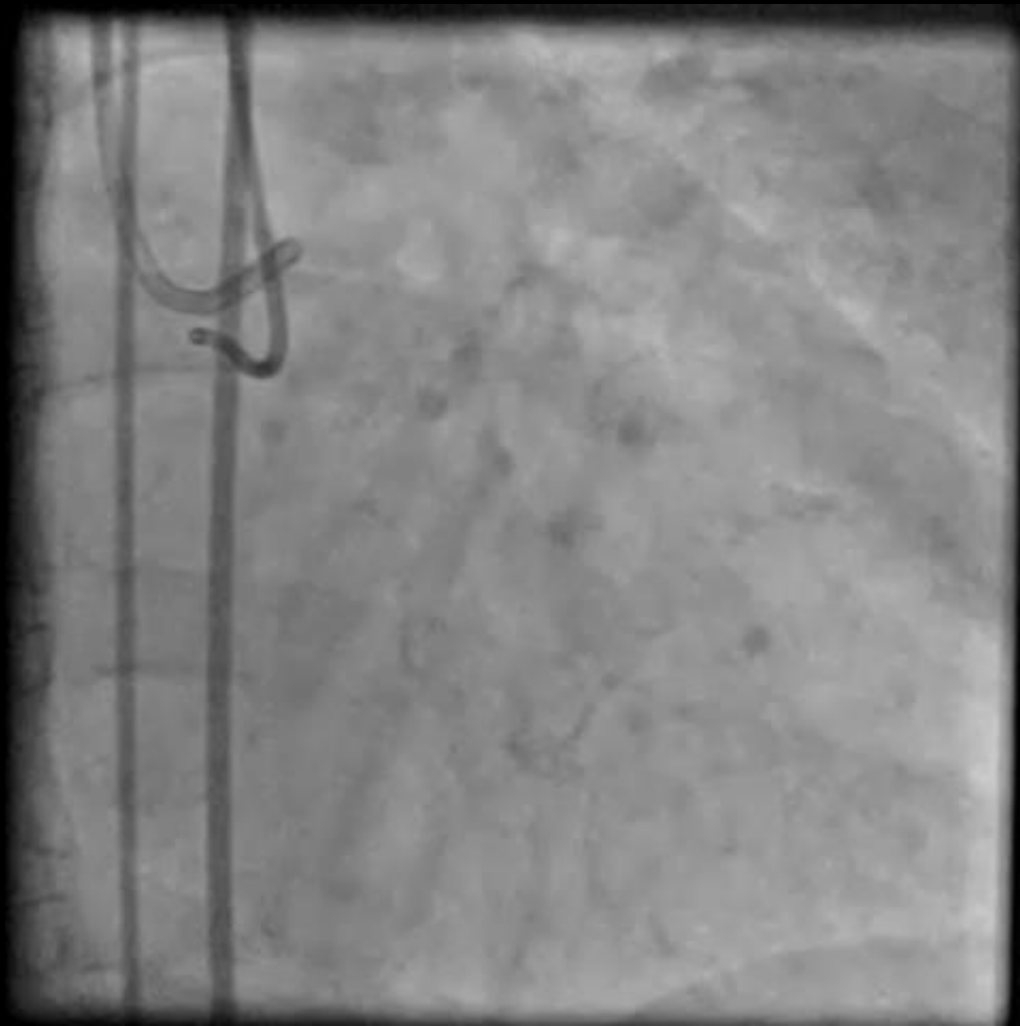
Supraflex Nevo 3.5x16mm



3.75mm NC balloon



Final result



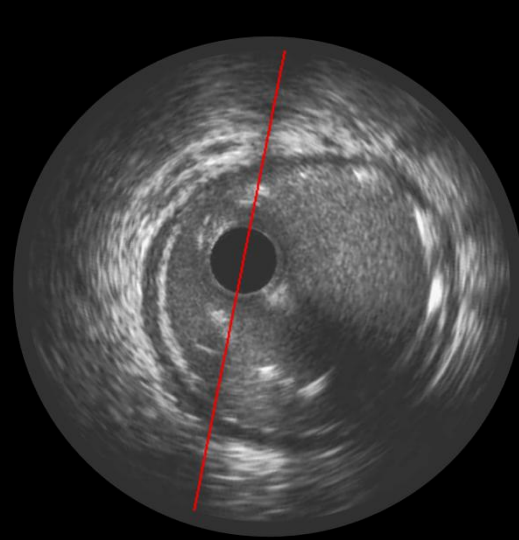
IVUS guided antegrade approach



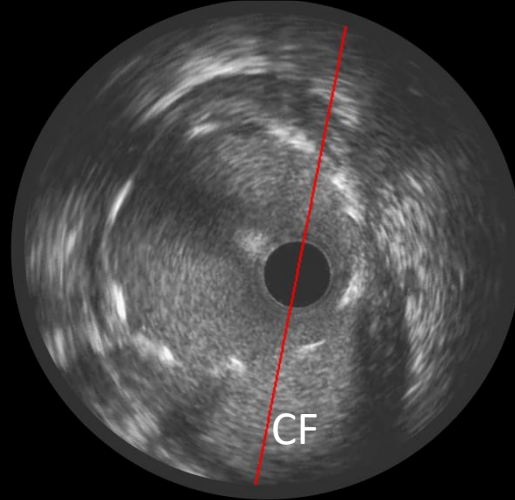
Supraflex Cruz Nevo 2.75x24 mm



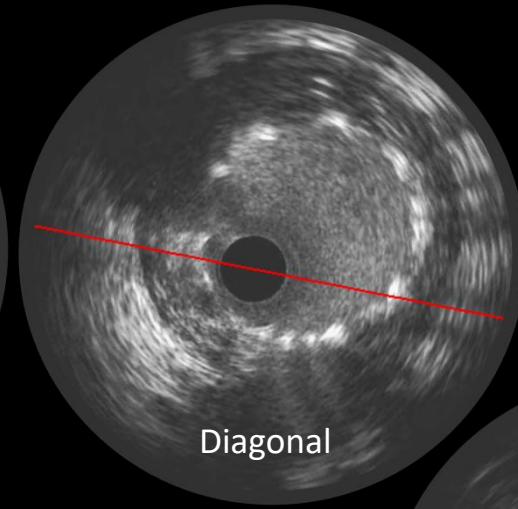
Supraflex Cruz Nevo 3.5x32 mm



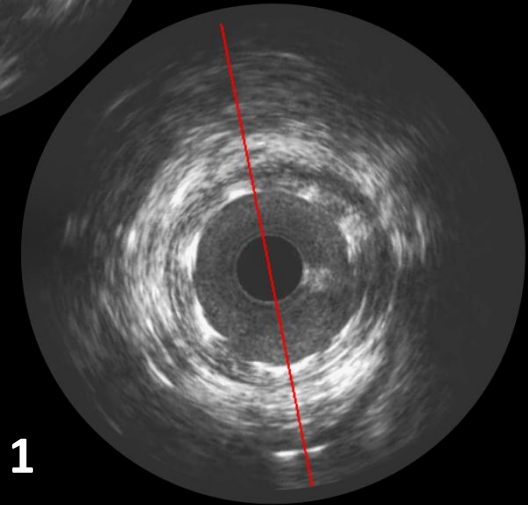
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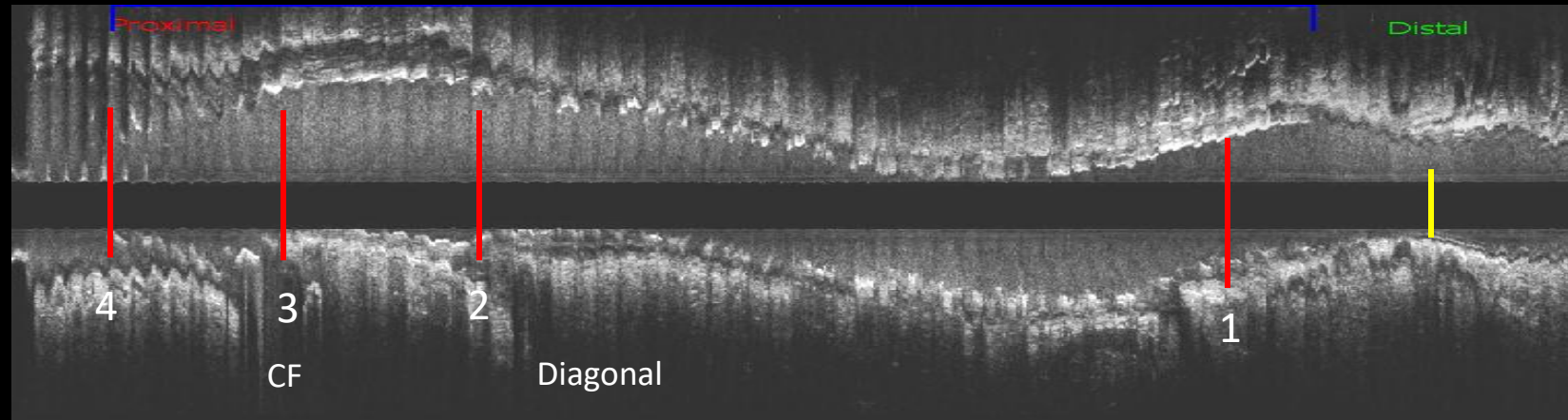
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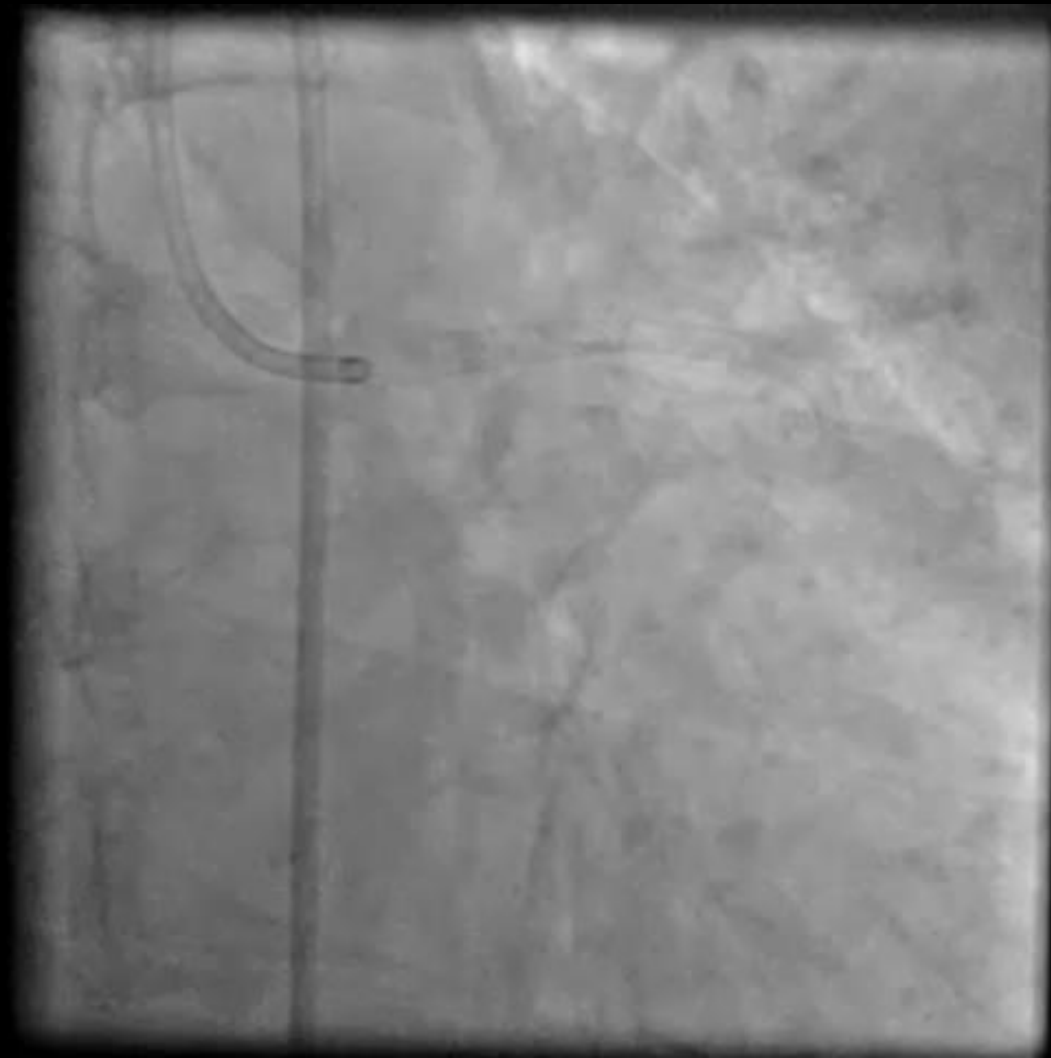
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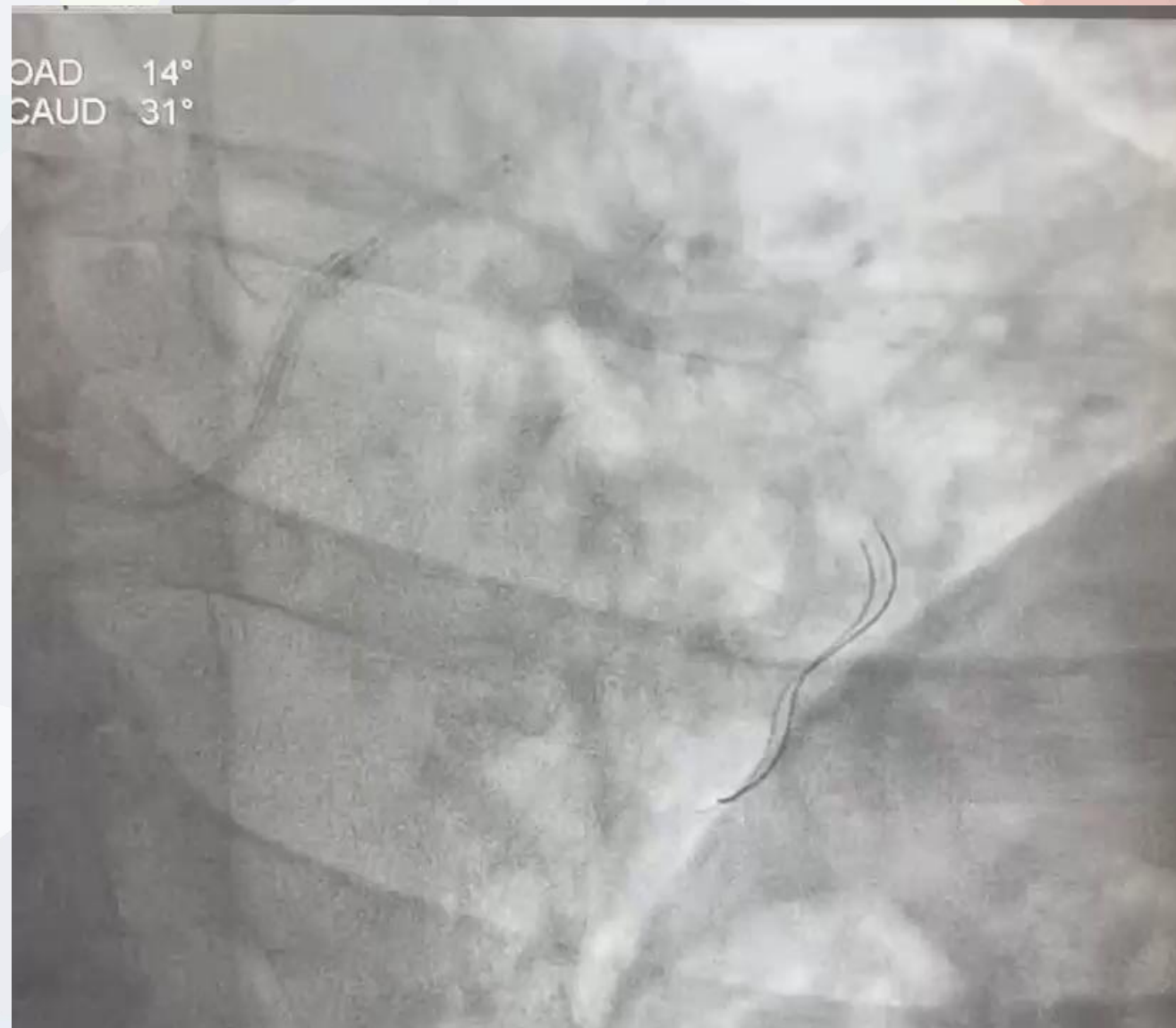
1



IVUS



POT with NC balloon 4.5x15mm

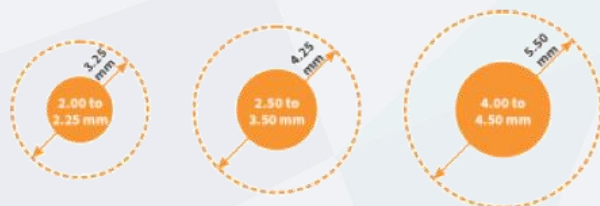


* Cortesía de Arturo G. Touchard

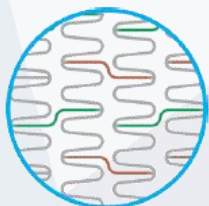
TAKE-HOME MESSAGE



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4, 6 & 8 crown design



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