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JUN 2019



# Preuves scientifiques Retour d'expérience

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APPAC 2019

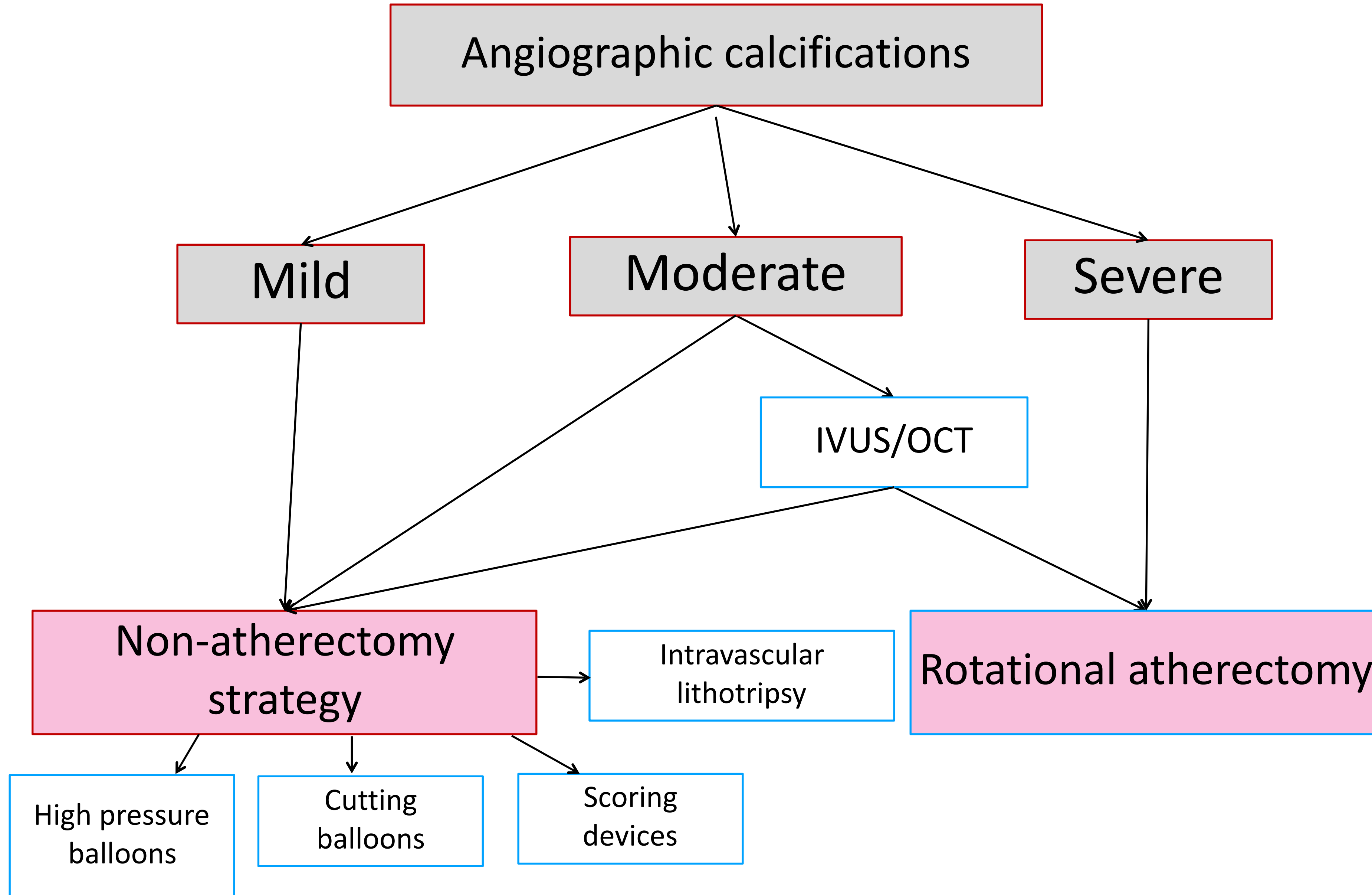
## Calcification Grading

None/mild

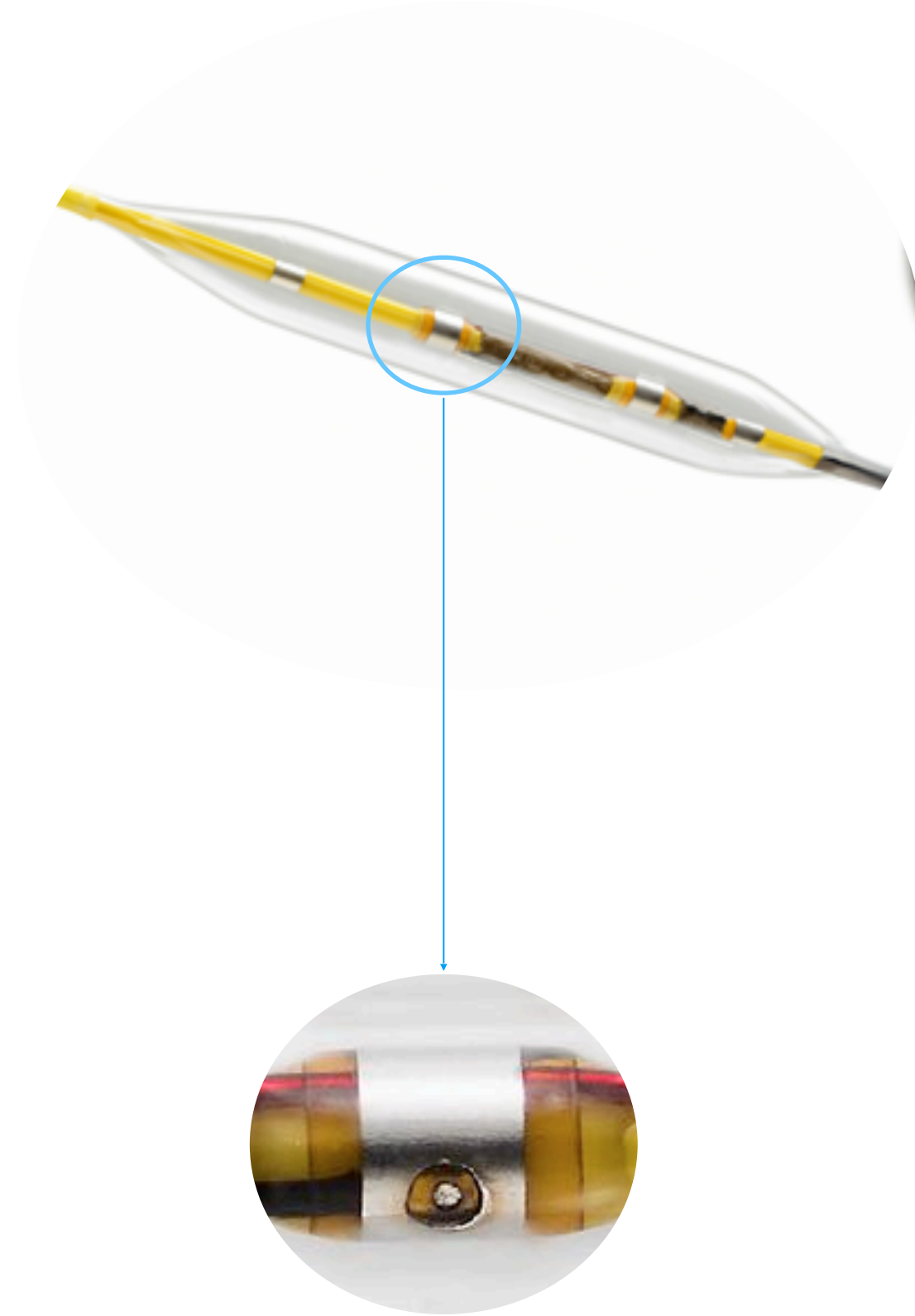
**Moderate** - densities noted only during the cardiac cycle before contrast injection

**Severe** - radiopacities noted without cardiac motion before contrast injection generally involving both sides of the arterial wall

# Decision-making Algorithm



# IVL : Matériel



## Emetteur

Pulse 1/s – Max 80 pulses



## Générateur

Rechargeable / secteur

## Connecteur

Plug magnétique

## Cathéter

Usage unique

# Catheter : Schockwave Catheter IVL C<sup>2</sup>

Diamètre (mm)	Long. (mm)	Impulsion Max.	Compatibilité Guide	Compatibilité Cath. Guide	Long. Utile (cm)	Profil de l'Extrémité*	Profil de Franchissement
2.5	12	80	0.014"	6F	138	0.023"	0.042" ±0.002
3.0							
3.5							
4.0							

## Ballon de 12mm Semi-compliant

IVL =4 atm - Nominal =6 atm - Rupture =10 atm

2 marqueurs radio-opaques

2 émetteurs

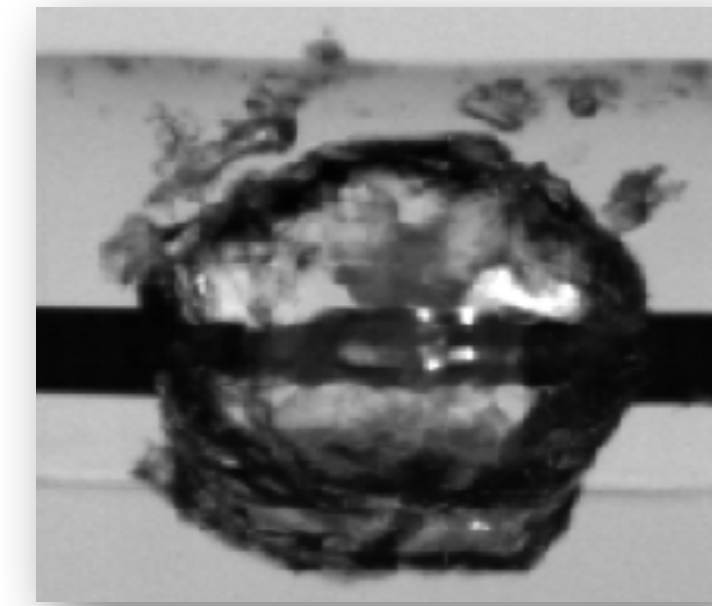
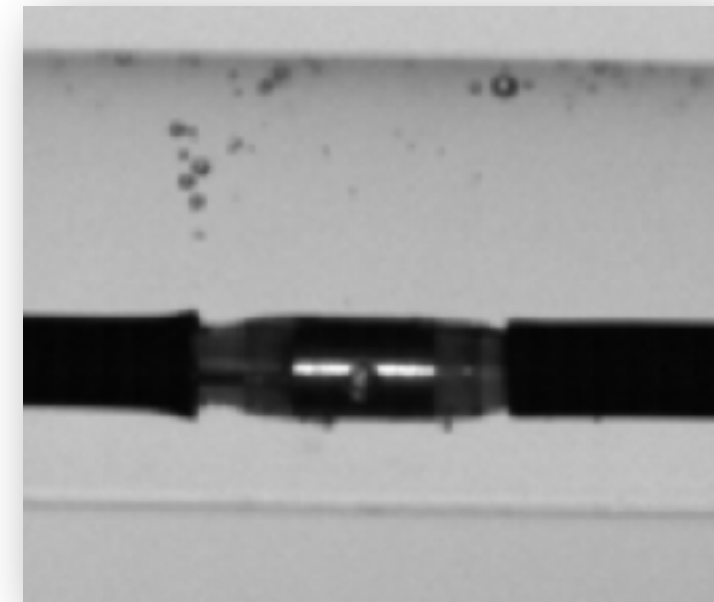
Monorail



**Marque CE**

Avril 2017

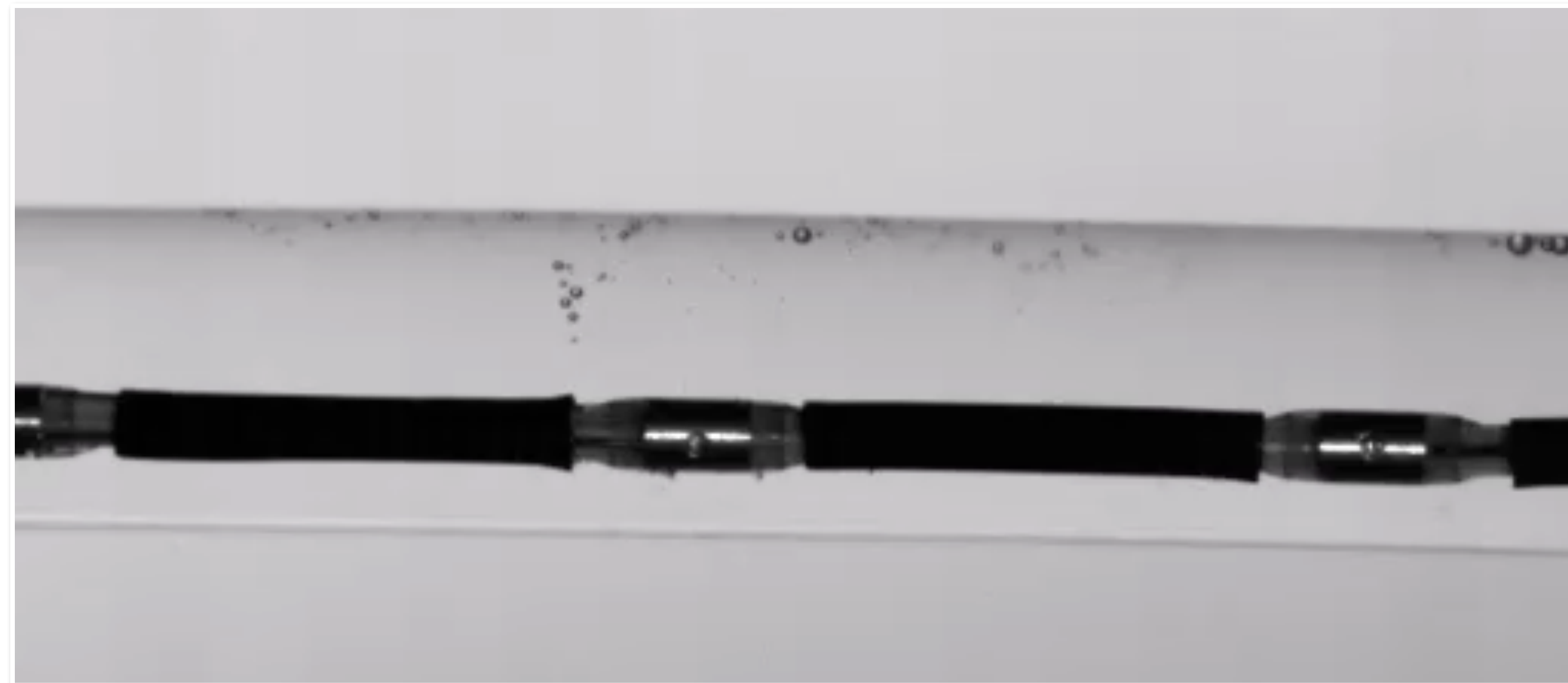
# Catheter : Schockwave Catheter IVL C2



Energie Electrique transmise à  
l'émetteur

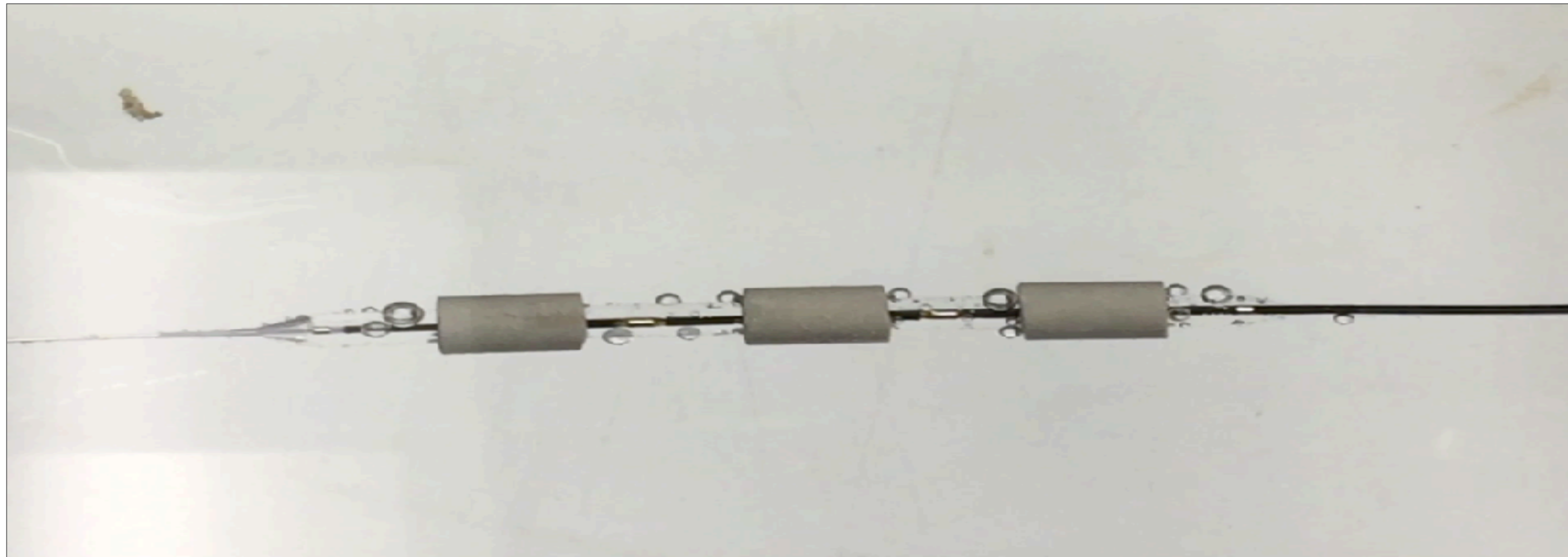
Formation d'une bulle de vapeur qui se  
dilate puis s'effondre

**Création d'une Onde Acoustique**



## Catheter : Schockwave Catheter IVL C2

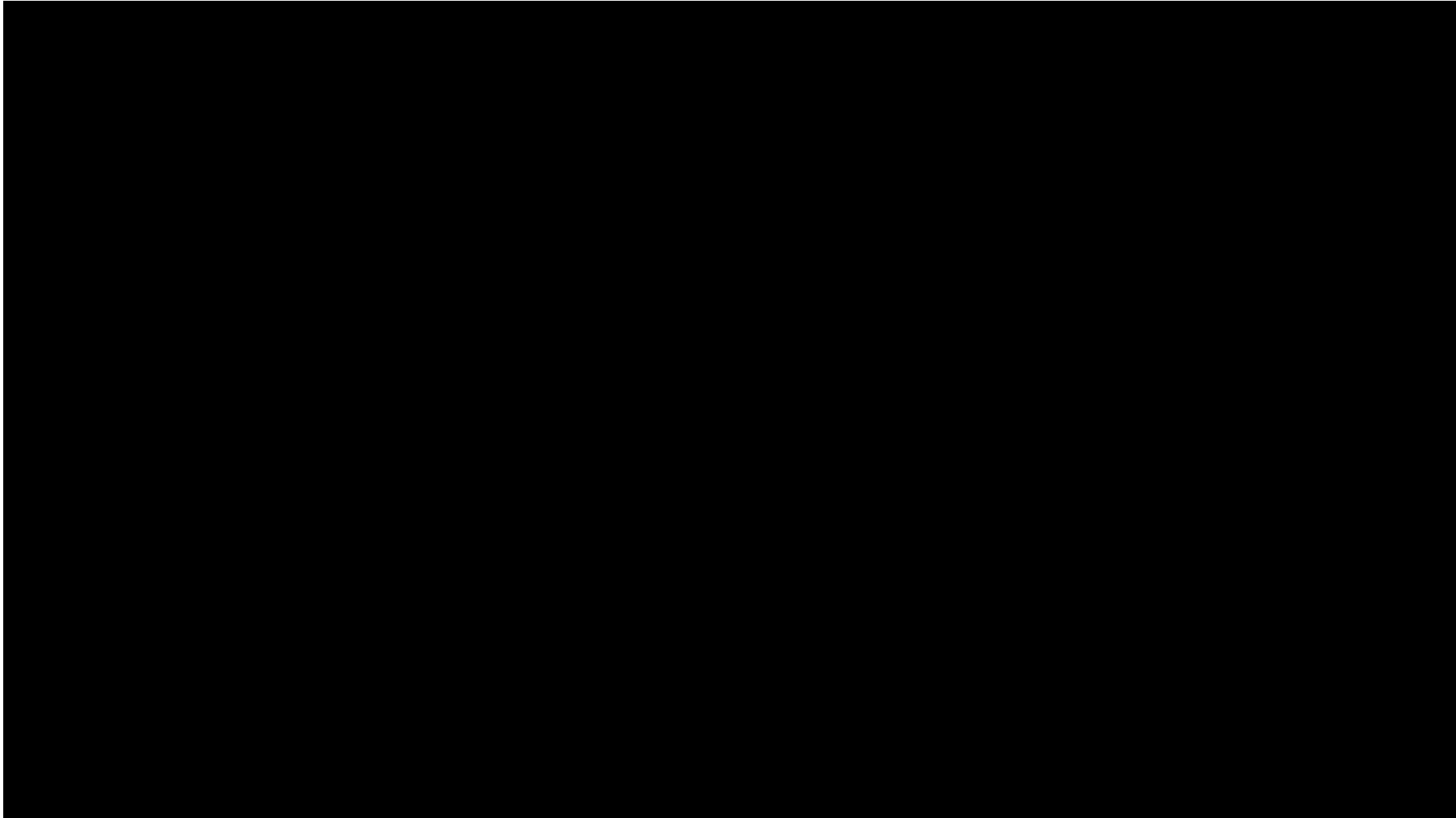
Onde Acoustique Pulsatile Circonférentielle  
Interagit avec les tissus calciques de haute densité



Lithotripsie endovasculaire = Lithoplastie

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# Catheter : Schockwave Catheter IVL C2





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# Lithoplastie endovasculaire : Preuves Scientifiques

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# DISRUPT CAD Clinical Program



## DISRUPT CAD I

Single-arm, pre-market European study demonstrating the safety and performance of IVL in heavily calcified, coronary lesions prior to stenting and followed to 6 months; also included an OCT Sub-study demonstrating IVL's mechanism of action.

Publié



## DISRUPT CAD II

Post-market, European registry examining the ongoing safety and performance of coronary IVL in heavily calcified coronary lesions up to 30 days in more centers and more patients.

Enrollement  
terminé



## DISRUPT CAD III

A prospective, multicenter, single-arm, investigational device exemption (IDE) study to evaluate the safety and effectiveness of the Shockwave Coronary IVL System taking place in the United States, United Kingdom, Germany and France. The goal of this study is to generate the data needed to obtain FDA approval for use of coronary IVL in the United States.

Jan 2019  
Juin 2020

# IVL Coronary Disease : DISRUPT CAD I

## Disrupt CAD Study Design

Stable angina, unstable angina or silent ischemia



Moderate and severely calcified, *de novo* coronary lesions  
RVD 2.5 – 4.0 mm, stenosis  $\geq 50\%$ ,  
Lesion length  $\leq 32$  mm

60 patients enrolled  
31 subject OCT sub-study  
30 day & 6 months follow-up  
Core Angiographic & OCT Labs  
(Yale University & CRF)

Pre Market  
Study

- **Objective:** To assess the safety and performance of the Lithoplasty® System
- **Primary Safety Endpoint:** 30-day MACE (Cardiac death, MI or TVR)
- **Primary Performance Endpoint:** Clinical success (residual stenosis  $< 50\%$ ) post-PCI with no evidence of in-hospital MACE.

## Investigational Sites

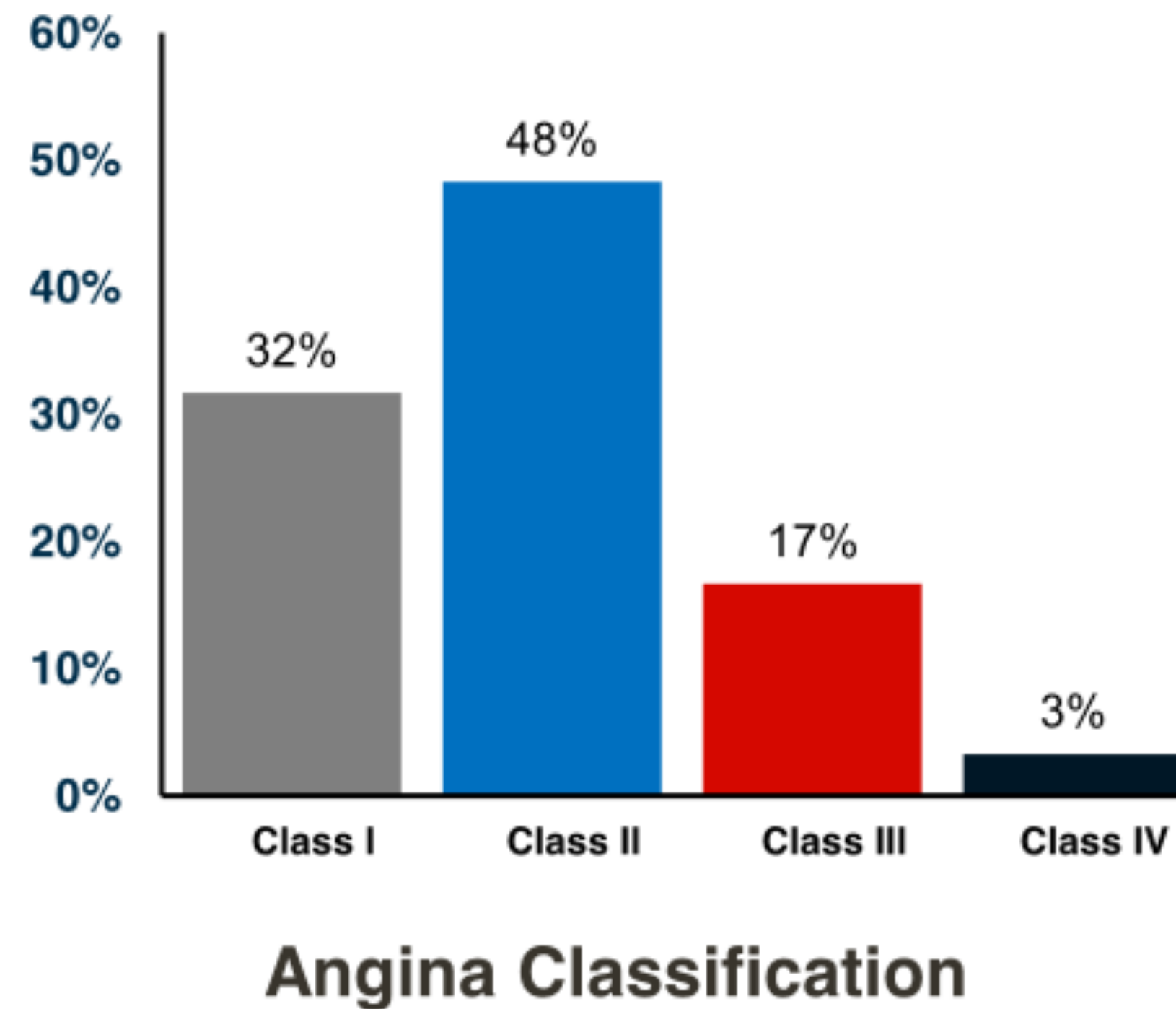
60 patients enrollment completed in Sep 2016

Investigator	Site	Enrollment
Jean Fajadet, MD (PI)	Clinic Pasteur, France	10
Carlo Di Mario, MD (Co-PI)	Royal Brompton, England	15
Ian Meredith, MD	Monash Health, Australia	13
Jonathan Hill, MD	King's College, England	14
Nicolas Van Mieghem, MD	Erasmus, Netherlands	4
Robert Whitbourn, MD	St Vincent's, Australia	3
Matthias Götberg, MD	Skane University Hospital, Sweden	1

# DISRUPT CAD

## Baseline Characteristics

	Medical History N= 60
Age	72.1 (9.6)
Male gender	80.0%(48)
Diabetes	30.0% (18)
Hypertension	80.0% (48)
Hyperlipidemia	80.0% (48)
Myocardial Infarction	40.0% (24)
Prior CABG	23.3% (14)
Stroke/TIA	13.3% (8)
Current Smoker	15.0% (9)
Renal insufficiency	10.0% (6)



# IVL Coronary Disease : DISRUPT CAD I

	Pre-Procedure N=60
RVD (mm)	3.0 ± 0.5
MLD (mm)	0.9 ± 0.4
% Diameter stenosis	68.1 ± 13.1
Lesion length (mm)	20.3 ± 10.5
Calcified length (mm)	22.3 ± 12.5
Calcification	
Moderate	13.3% (8)
Severe	80.0% (48)
Lesion Assessment	
Concentric	78.3% (47)
Eccentric	21.7% (13)
Side branch involvement	28.3% (17)

	Procedural Details N= 60
Pre-dilatation > 1.5mm PTCA *	15% (9)
Number of Lithoplasty balloons	2.0
Number of pulses	88
Mean Lithoplasty inflation pressure (atm)	6.0
Avg. Number of stents	1.4
Post-dilatation	86.7% (52)

## Primary Performance Endpoint :

## Safety Endpoint :

30-day MACE (Cardiac death, MI or TVR)

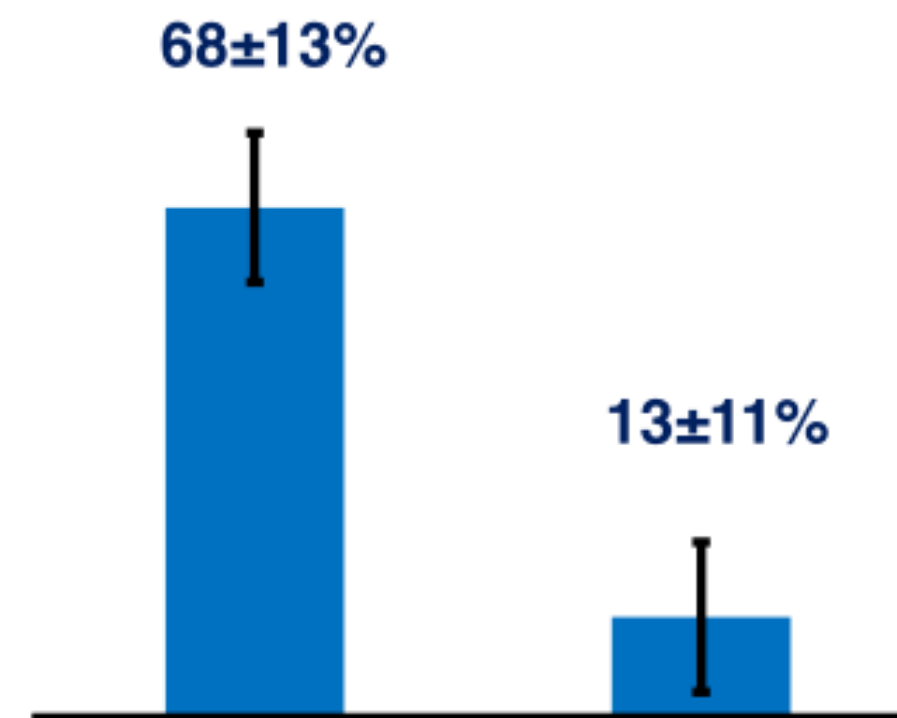
Clinical success (residual stenosis <50%) post-PCI with no evidence of in-hospital MACE.

Device success defined as successful device delivery and Lithoplasty treatment at the target lesion.

# IVL Coronary Disease : DISRUPT CAD I

	<b>N= 60</b>
Clinical Success	95.0% (57)
Device Success	98.3% (59)
Facilitated Stent Delivery	100% (60)

## Diameter Stenosis %



	<b>Pre</b>	<b>Final</b>
MLD (mm)	0.9 ± 0.4	2.6 ± 0.5
Acute Gain (mm)	NA	1.7 ± 0.6

## Safety Outcomes

### Post Lithoplasty Angiographic Complications

	Final N = 60
Dissections (D-F)	
D	3.3% (2)
E	0.0%
F	0.0%
Perforation	0.0%
Abrupt Closure	0.0%
Slow flow	0.0%
No reflow	0.0%

Angiographic core lab adjudicated

### Final Angiographic Complications

	Final N = 60
Residual Dissections	0.0%
Perforation	0.0%
Abrupt Closure	0.0%
Slow flow	0.0%
No reflow	0.0%

Angiographic core lab adjudicated



## Safety Outcomes

 Freedom from 30-day  
MACE: 95%

	Final N = 60
MACE at 30-days	5.0% (3)
Cardiac Death	0.0%
Non-Q-wave MI	5.0% (3)
Q-wave MI	0.0%
TVR	0.0%

Freedom from 6-Months  
MACE: 91.5%

	Final N = 59
MACE at 6-Months	8.5% (5)
Cardiac Death	3.4% (2)
Non-Q-wave MI	5.1% (3)
Q-wave MI	0.0%
TVR	0.0%

# OCT Sub-study : DISRUPT CAD I

	Pre-Lithoplasty	Post-Lithoplasty	Post-Stent
Lesion length, mm	31.50 ± 9.74	-	-
Minimal lumen area, mm <sup>2</sup>	2.23 ± 1.11	4.16 ± 1.86	5.99 ± 1.97
Mean lumen area, mm <sup>2</sup>	4.85 ± 1.86	-	8.49 ± 3.04
Area stenosis, %	66.50 ± 11.30	39.80 ± 24.20	20.50 ± 20.30
Acute area gain, mm <sup>2</sup>	-	2.08 ± 1.65	3.69 ± 1.52
Mean stent area, mm <sup>2</sup>	-	-	8.37 ± 3.17
Mean stent expansion, %	-	-	112.00 ± 37.20

	Lowest Tertile	Middle Tertile	Highest Tertile	Low vs. Middle	Low vs. Highest	Middle vs. Highest
Calcium length, mm	11.70 (8.00-14.00)	16.30 (13.80-25.80)	30.20 (23.10-35.60)	0.011	<0.001	0.006
Calcium angle, °	90.7 (76.5-98.0)	128 (91.4-179)	144 (124-229)	0.029	<0.001	0.291
Calcium volume index, ° × mm	1,104 (727.0-1,524)	2677 (1,697-2,910)	4,894 (3,379-5,409)	<0.001	<0.001	<0.001
Calcium fracture, %	22.2 (2/9)	54.5 (6/11)	77.8 (7/9)	0.197	0.057	0.374
Calcium fracture per lesion, n	0.00 (0.00-0.00)	1.00 (0.00-2.00)	2.00 (1.00-4.00)	0.099	0.009	0.106

# OCT Sub-study : DISRUPT CAD I

	Post-Lithoplasty (n = 28)	Post-Stent (n = 31)	p Value
Calcium fracture, %	12 (42.9)	17 (54.8)	0.08
Fracture length, mm	2.79 ± 4.49	3.36 ± 4.99	0.02
Fracture depth, mm	0.42 ± 0.21	0.43 ± 0.25	0.72
Fracture angle, °	20.50 ± 19.50	29.50 ± 33.70	0.06
Calcium fractures per lesion	0.00 (0.00-1.50)	1.00 (0.00-2.00)	0.03
Multiple calcium fracture/frame	7 (26.2)	9 (29)	0.34

Post-lithoplasty complications (worst morphology)	
Dissection ≥ type B	4 (12.9)
Slow flow or no reflow	0 (0.0)
Abrupt closure	0 (0.0)
Perforation	0 (0.0)

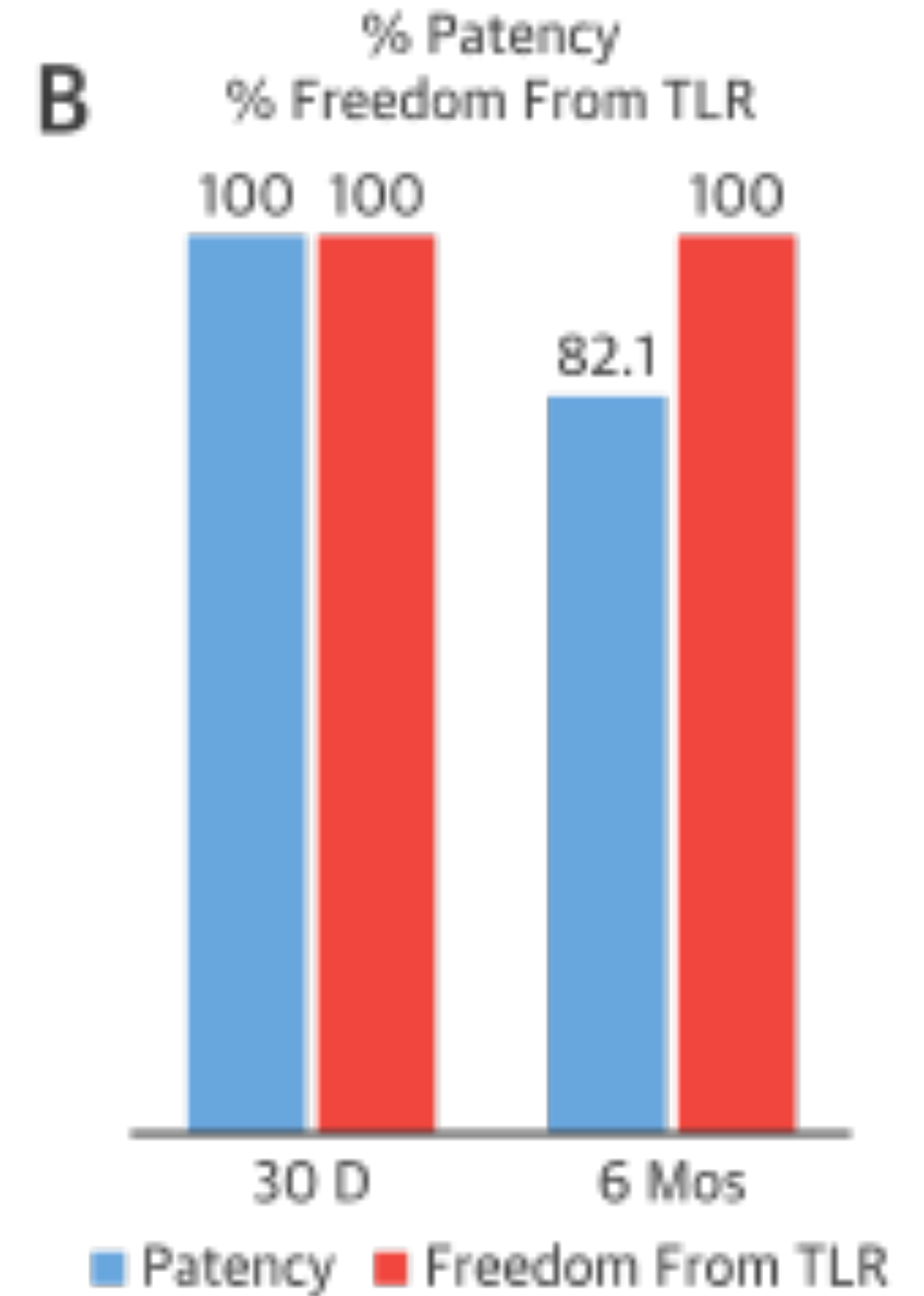
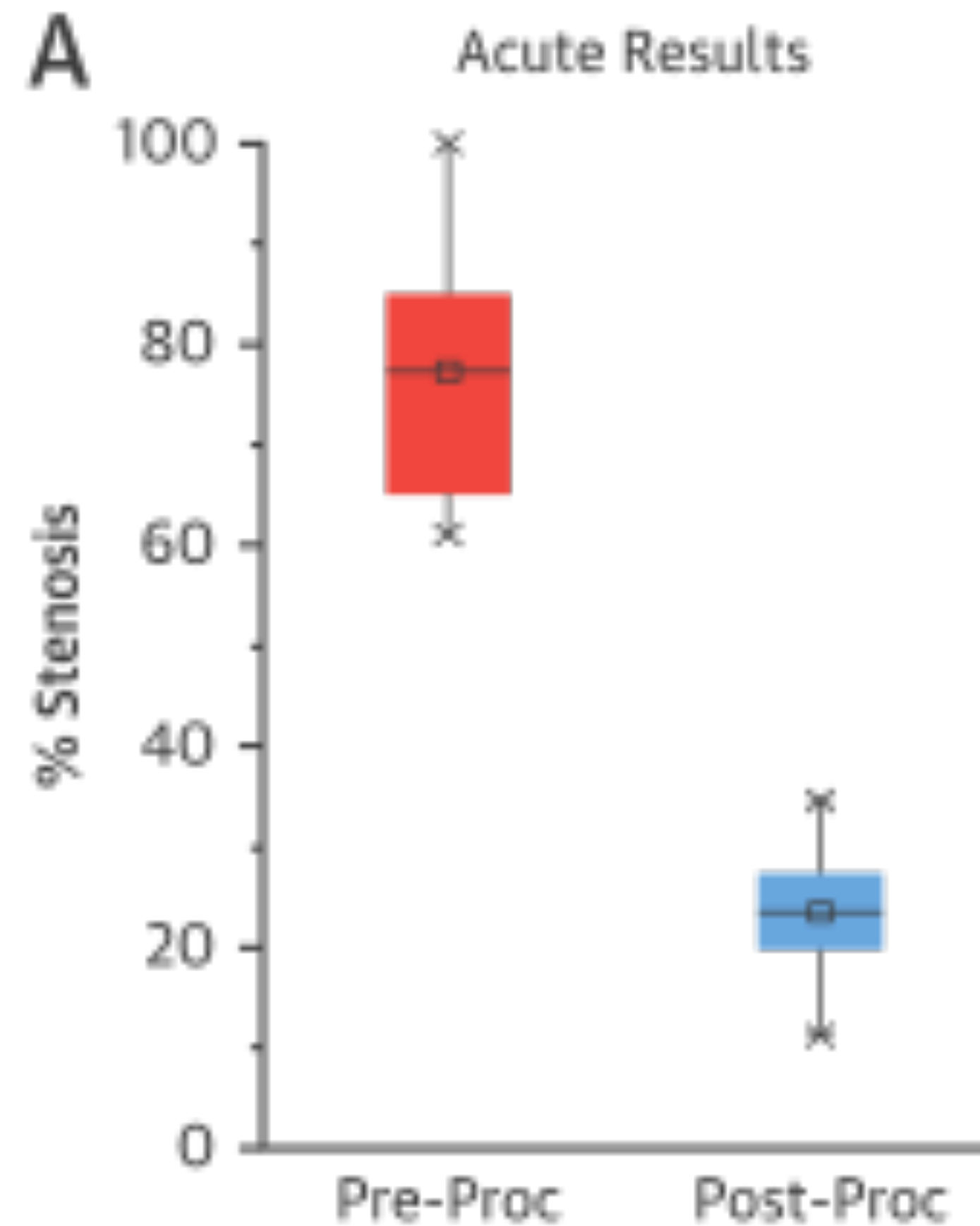
## Safety and Performance of Lithoplasty for Treatment of Calcified Peripheral Artery Lesions

N=35

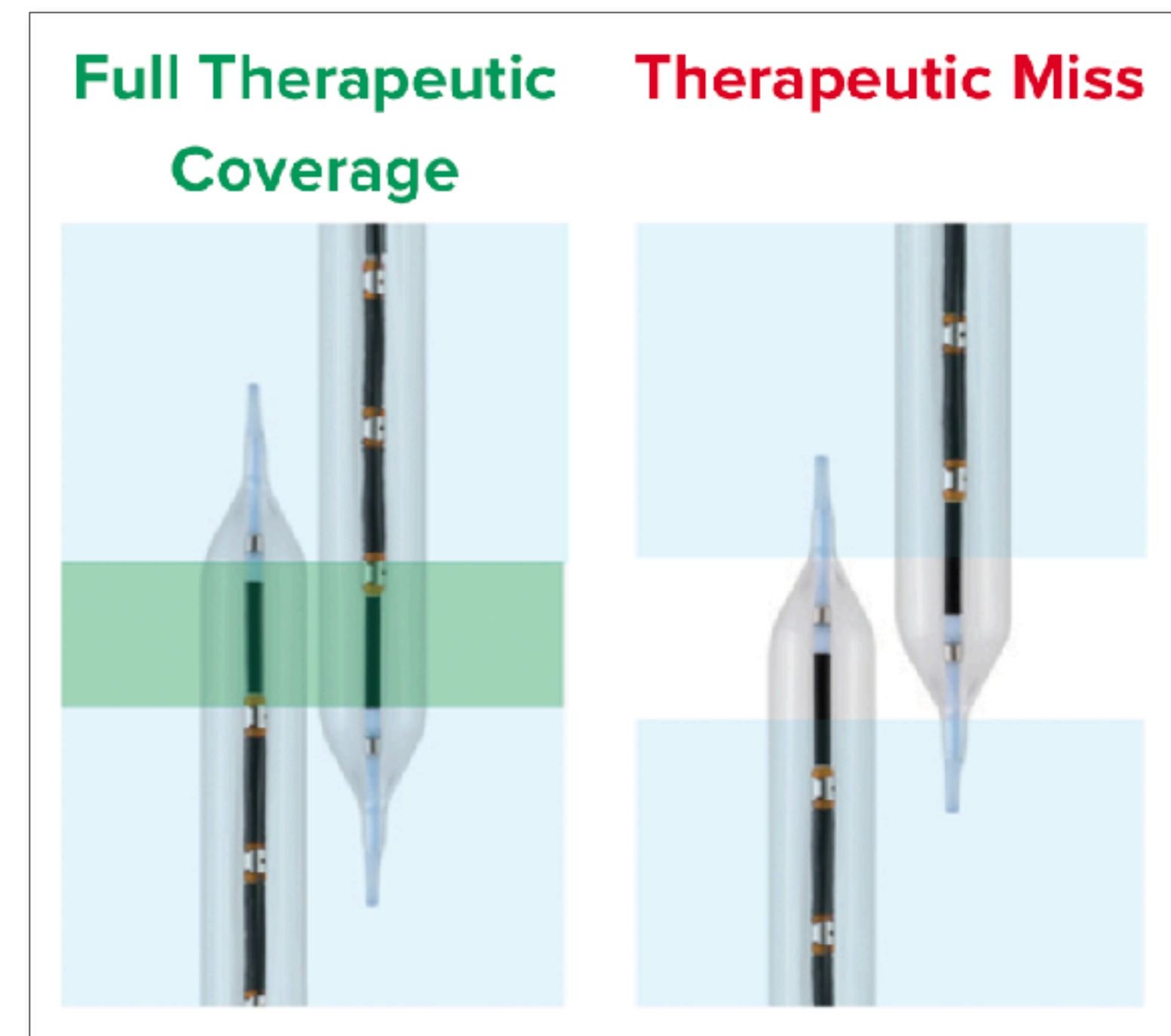
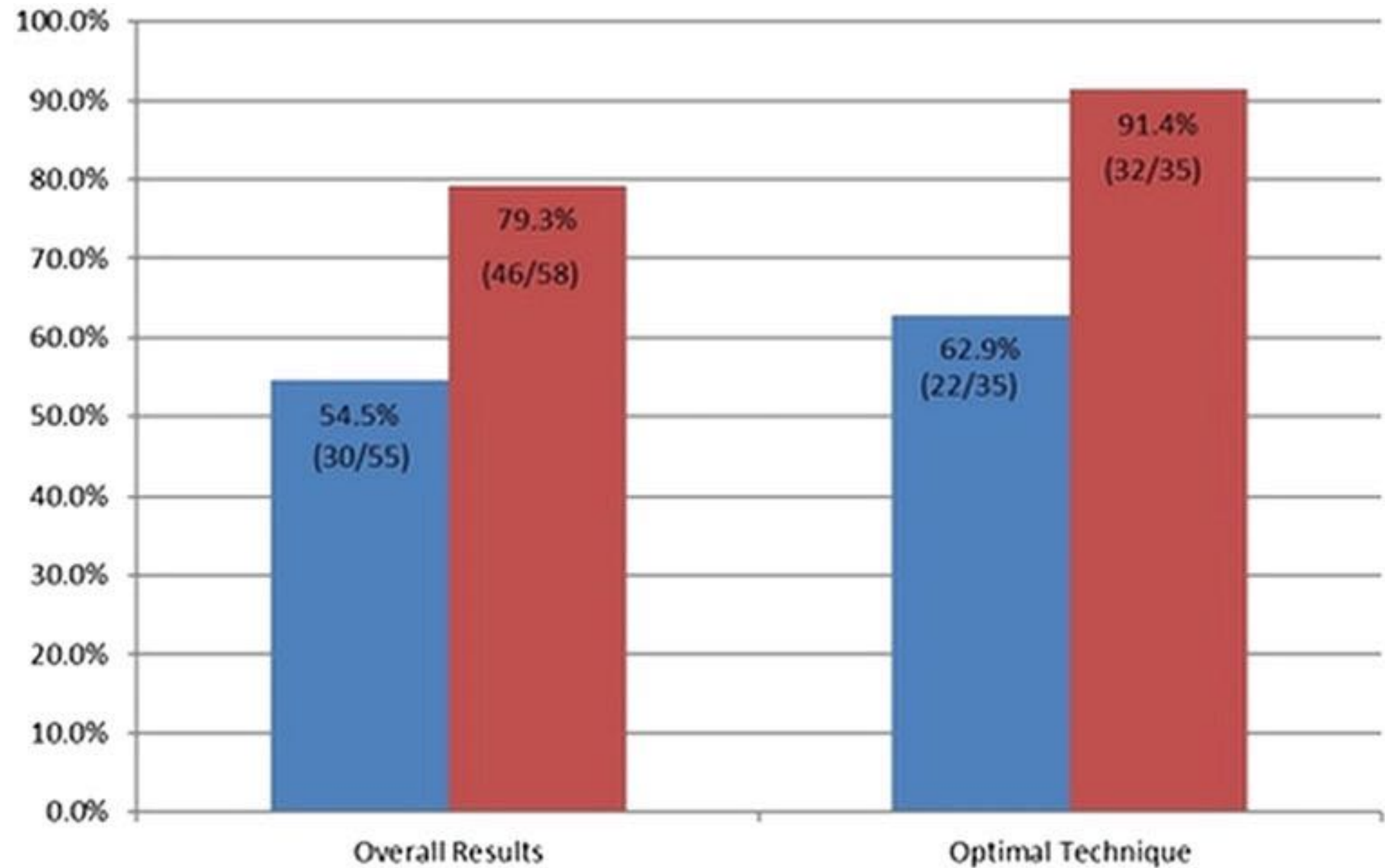
Calcified Femoro-popliteal lesion

Ratio Balloon/Artery : 1/1

Minimum of 60 pulses



# IVL PAD : DISRUPT PAD II



- 12m Primary Patency
- 12m FF TLR

## DISRUPT PAD III

## Randomized Study with Combined Therapy

A prospective, randomized, multicenter, study to evaluate the benefit of IVL combined with drug-coated balloons vs standalone DCB in heavily calcified fem-pop lesions followed out to 24 months. It also includes an all-comers registry arm to assess the real-world acute performance of IVL in lower extremities, including iliac, femoral, fem-pop, popliteal and infrapopliteal lesions.

60 centers Worldwide (US – EU)  
N= 400 randomized et N= 500 All comers registry  
Lithoplasty + DCB vs DCB

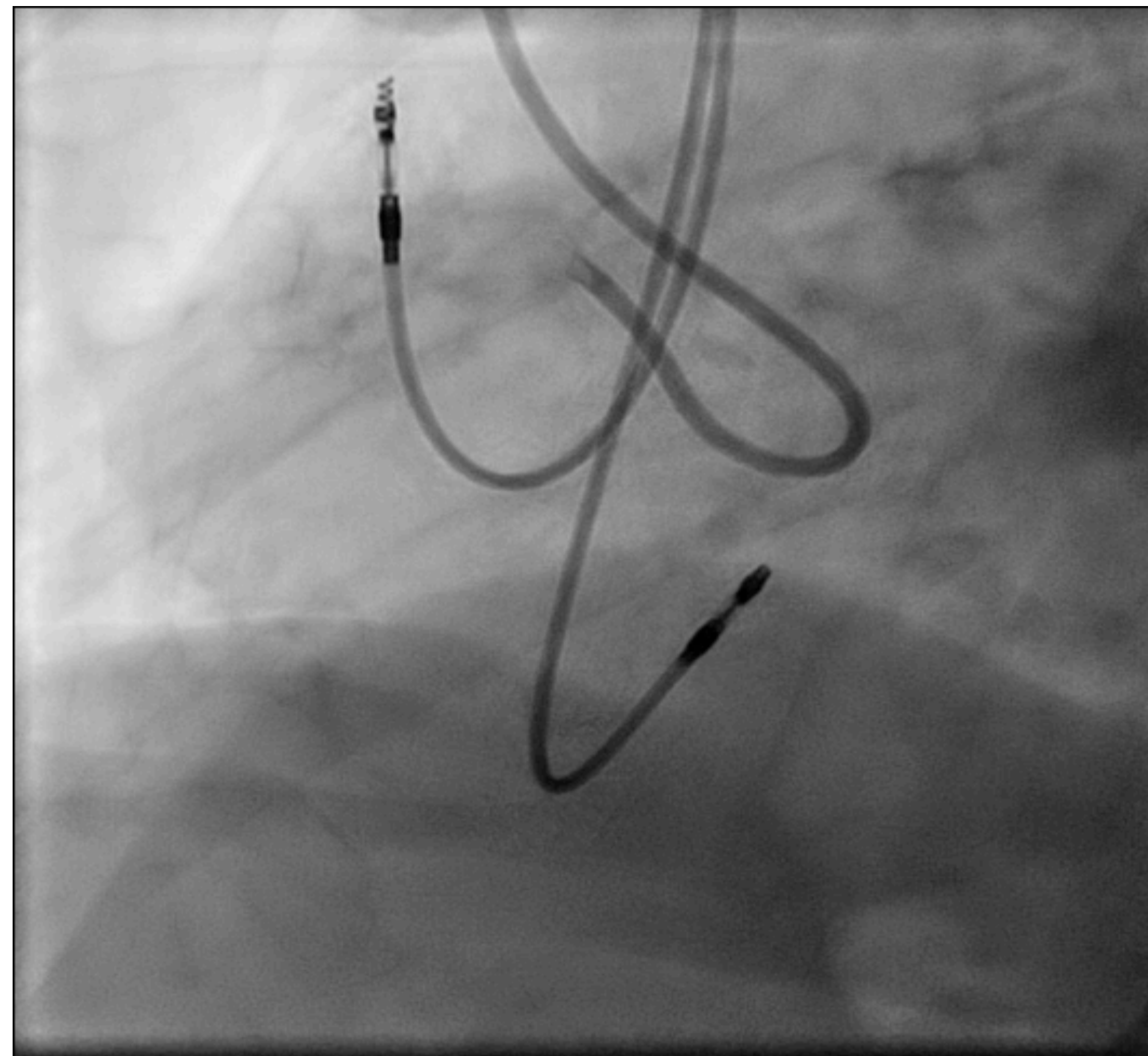
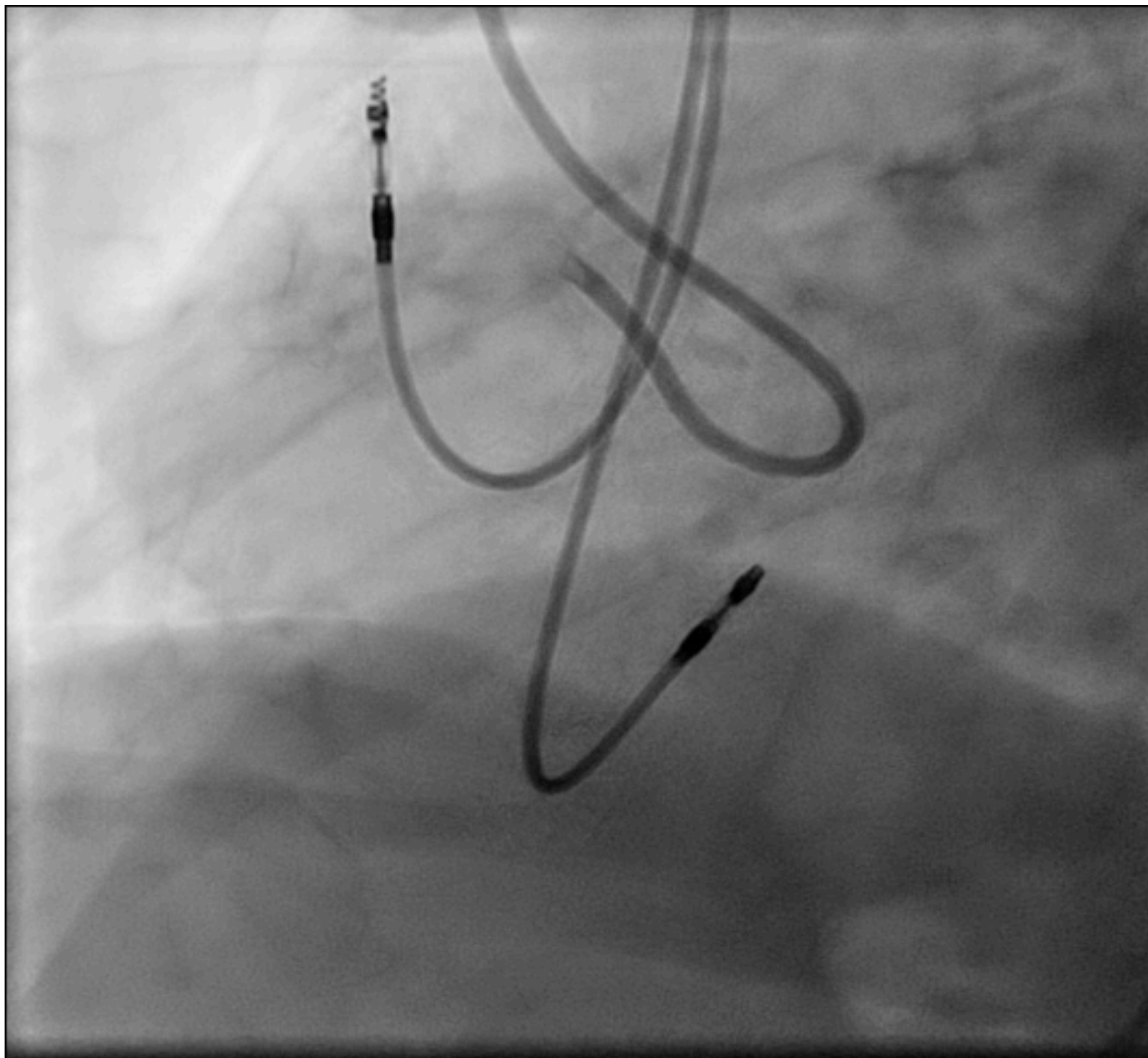
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# Lithoplastie endovasculaire : Retour d'expérience

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# Lesion Excentrique Coronaire droite ostiale

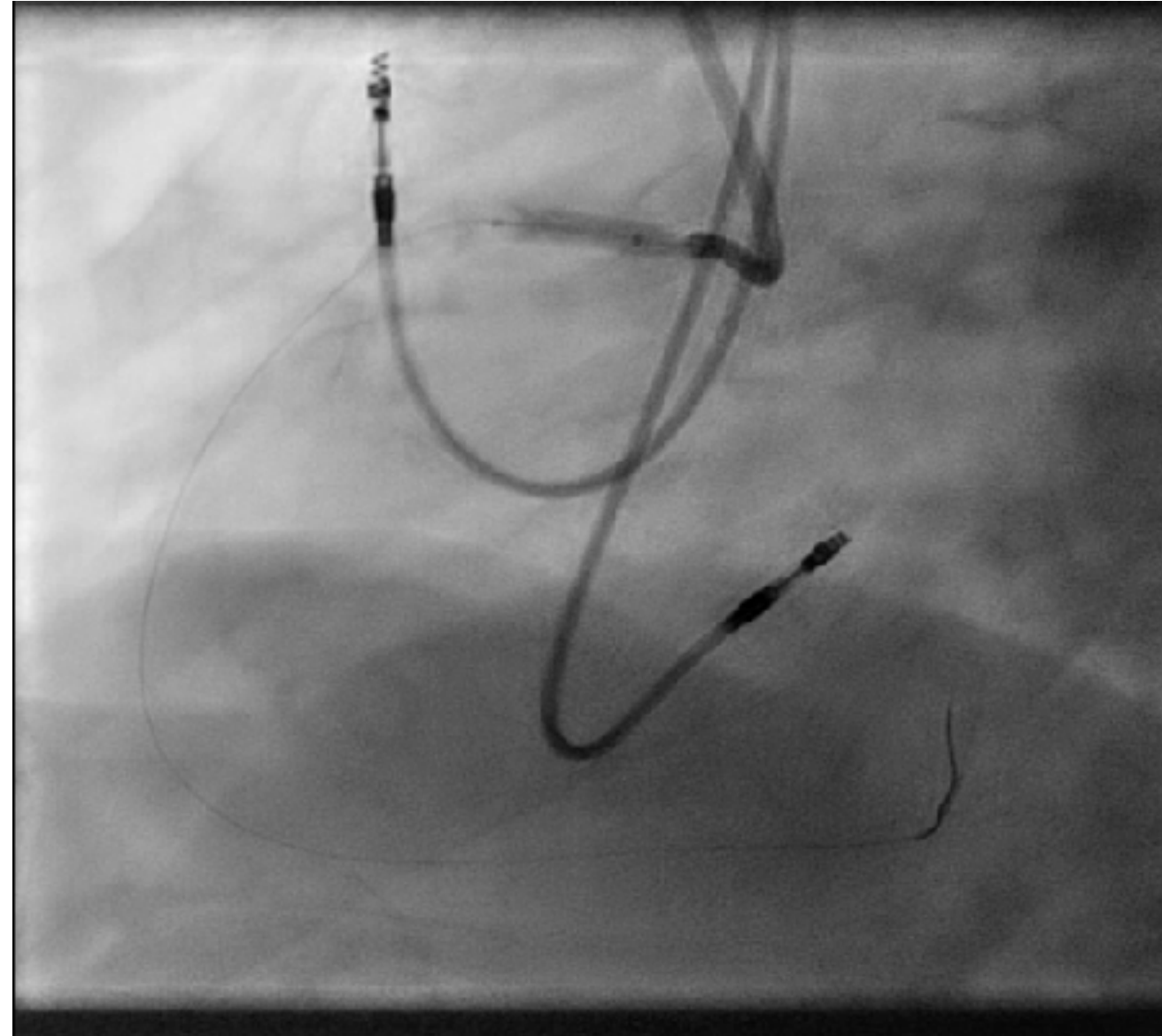




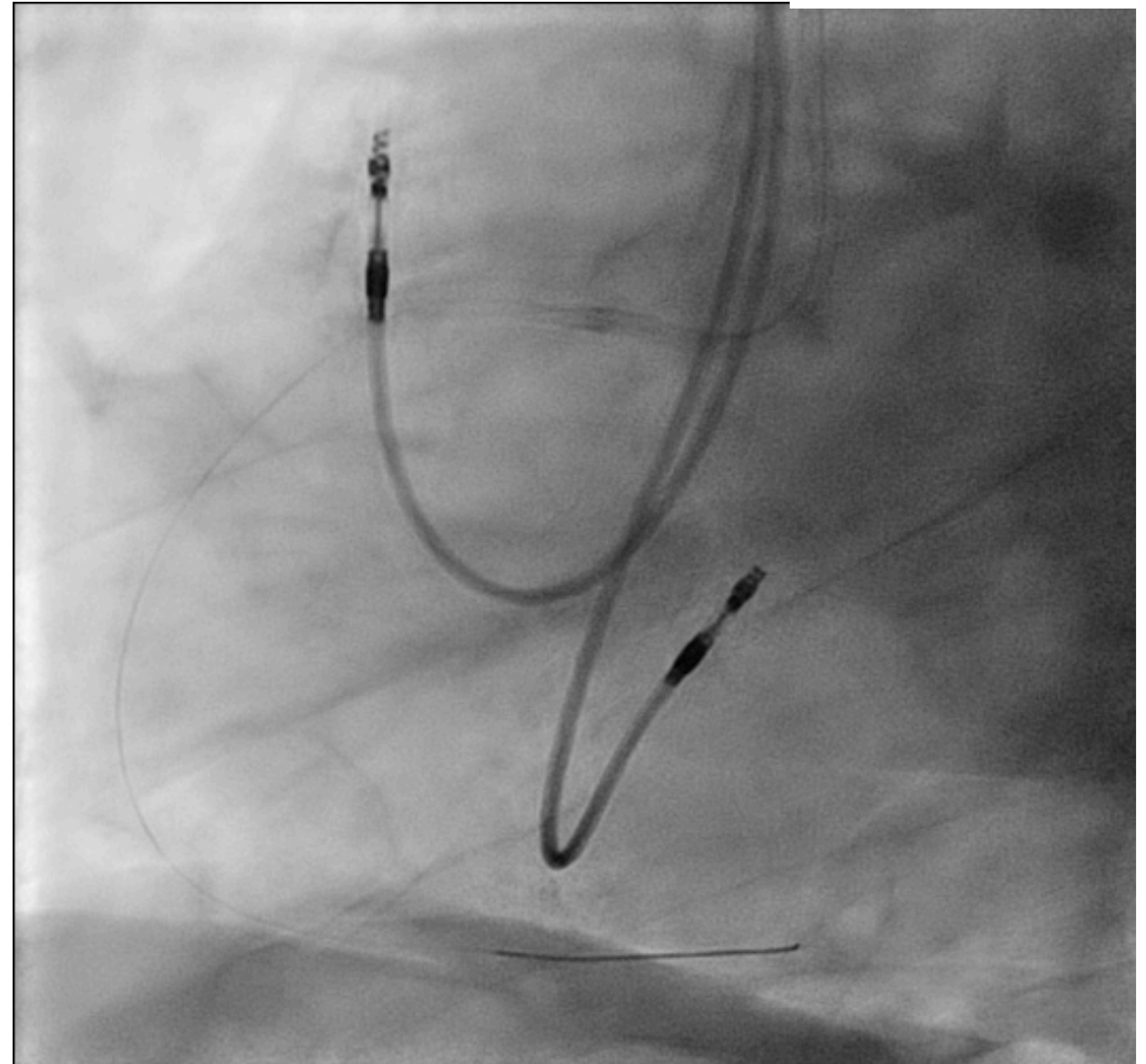
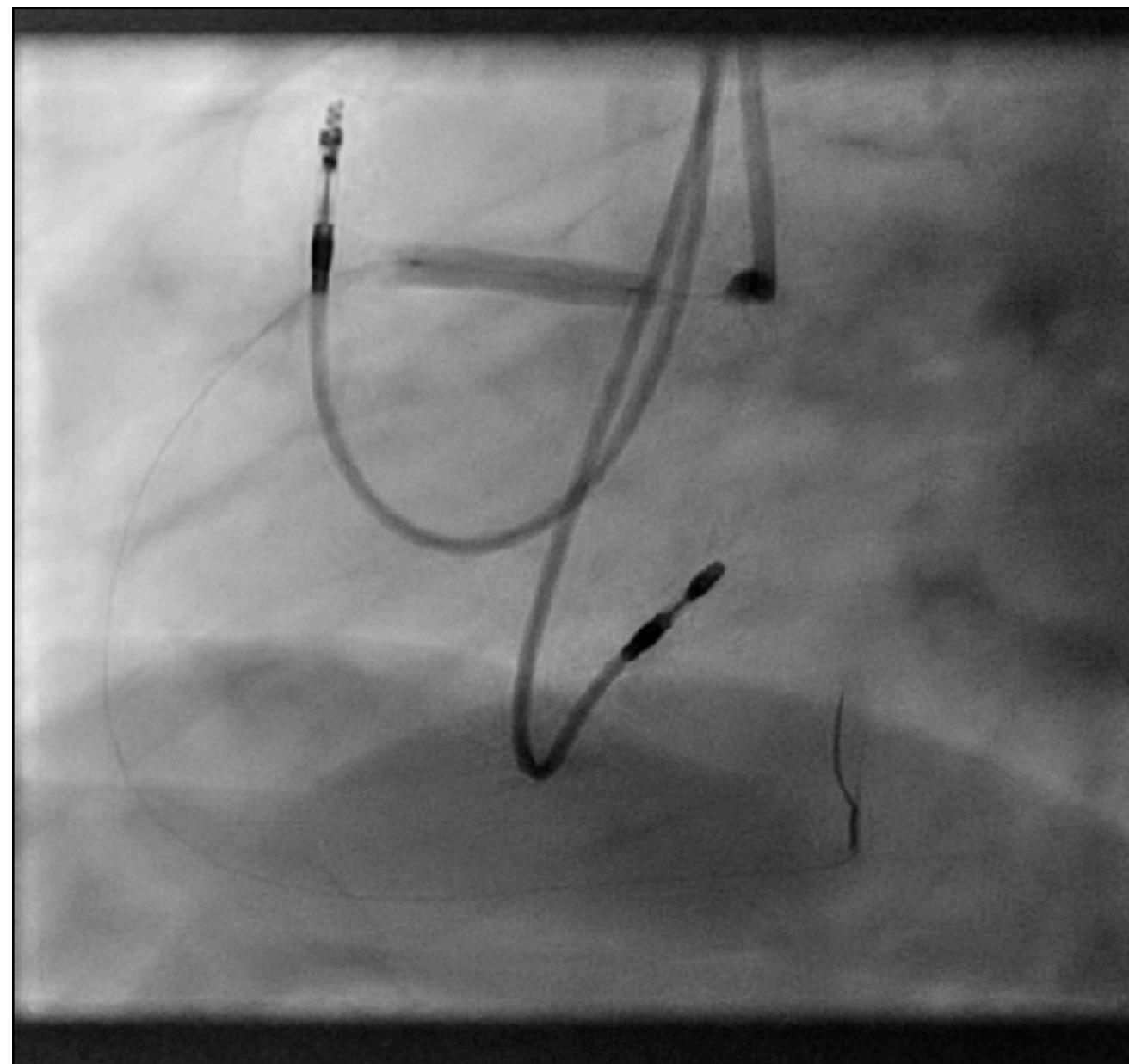
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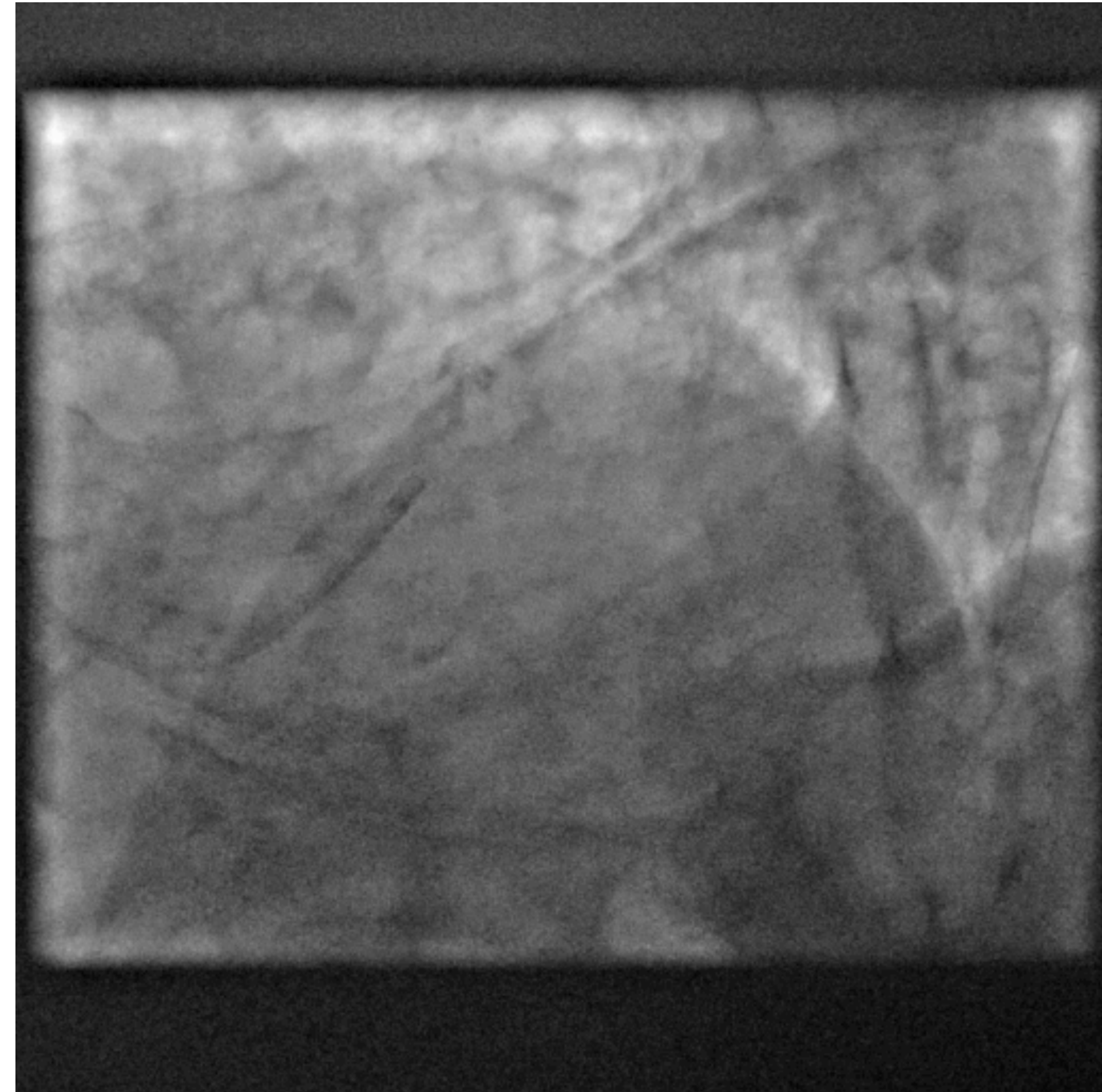
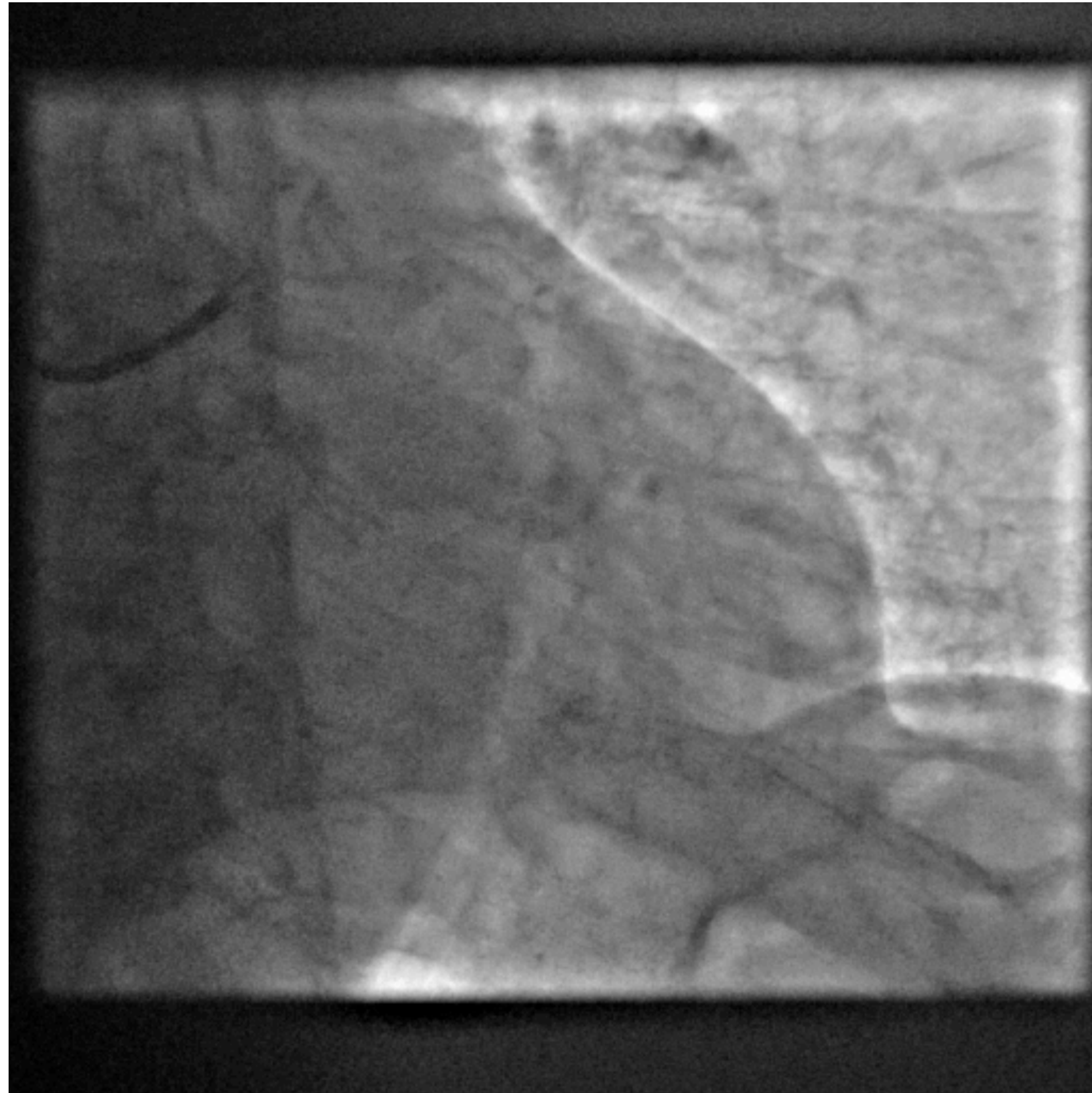
# Lesion Excentrique Coronaire droite ostiale

IVL Therapy  
3.5x12 mm



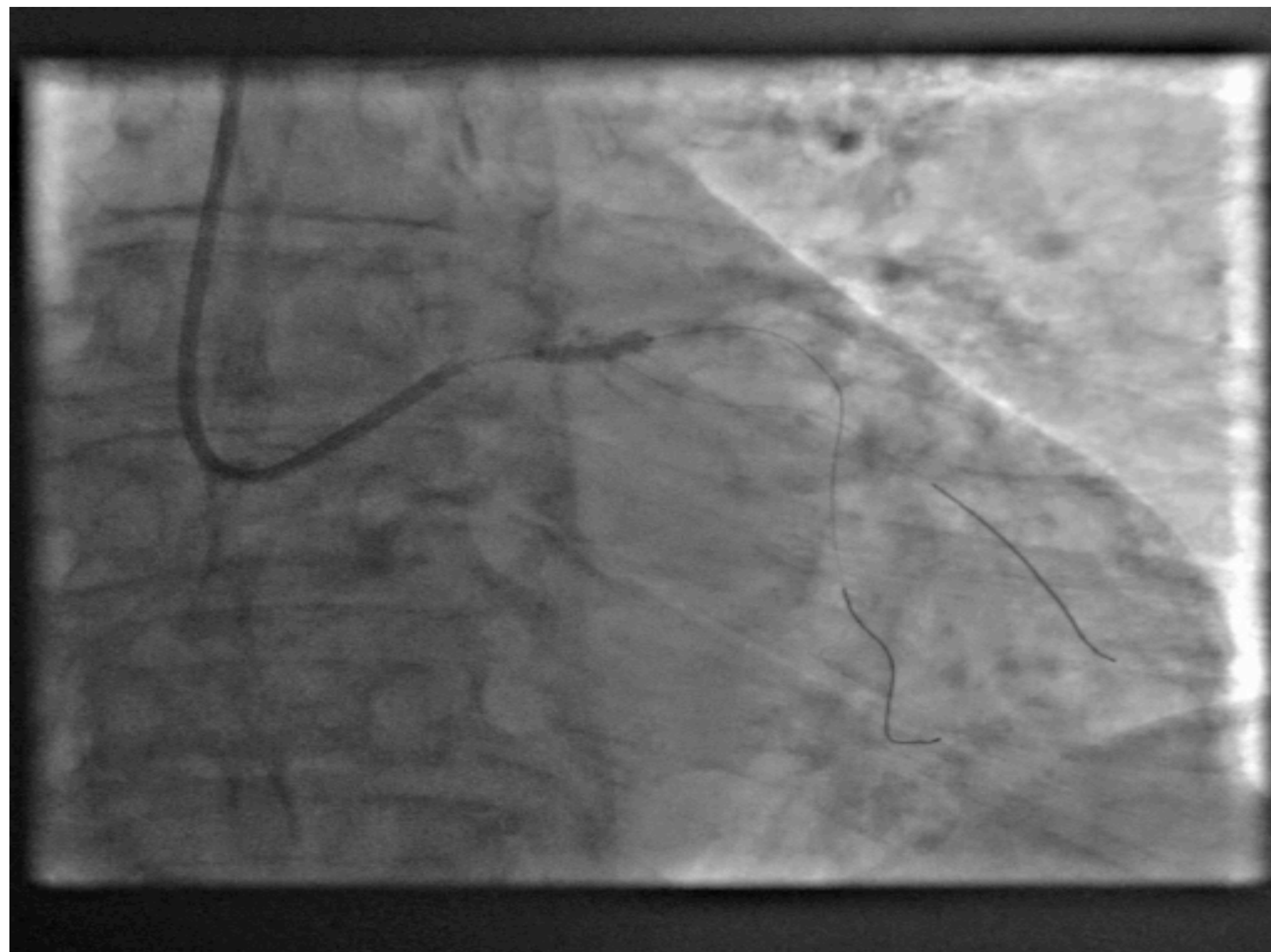
DES  
3,5x22 mm



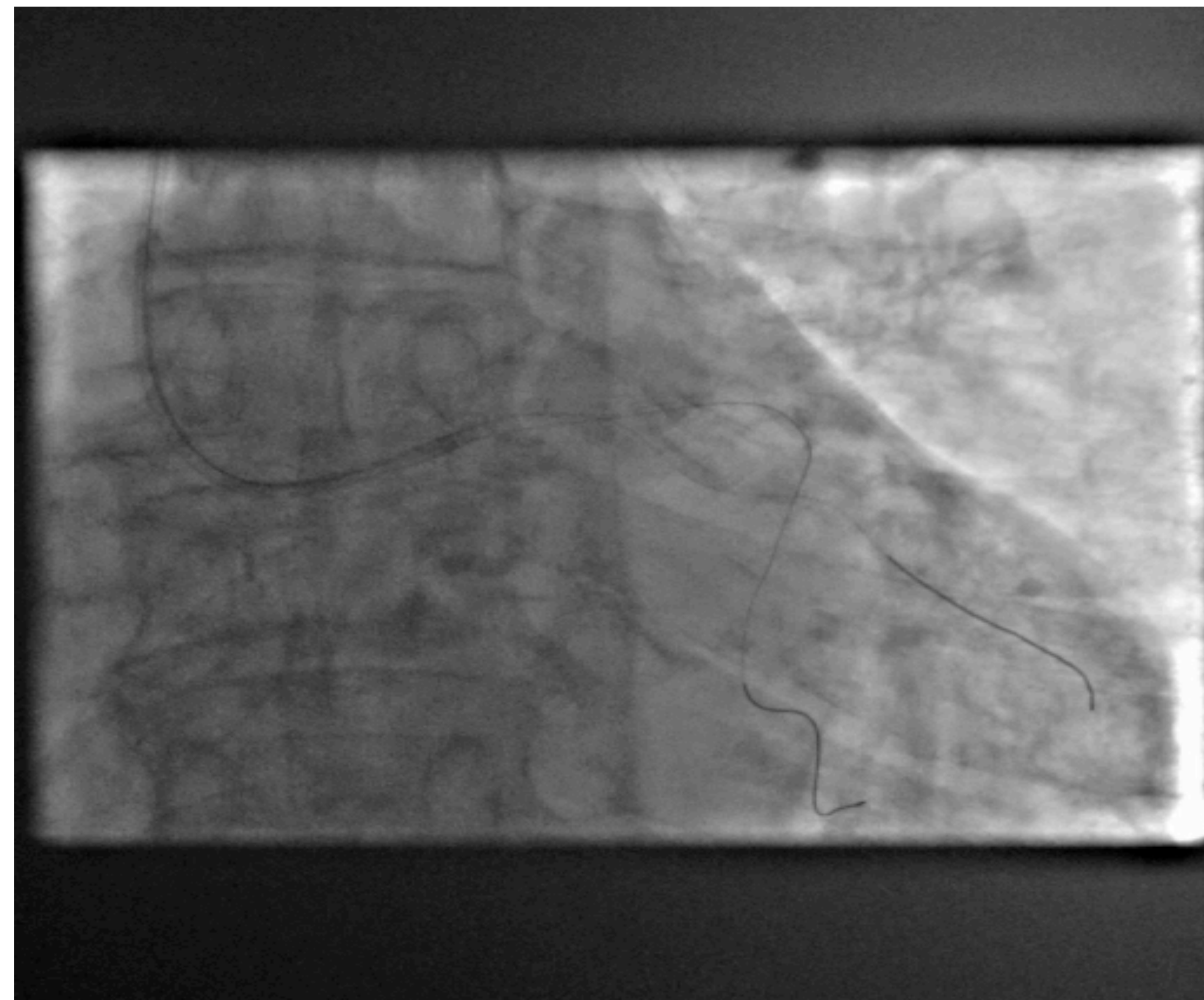


**Distal LM bifurcation stenosis**

Tronc commun gauche distal



IVL Therapy: 3.5x12 mm



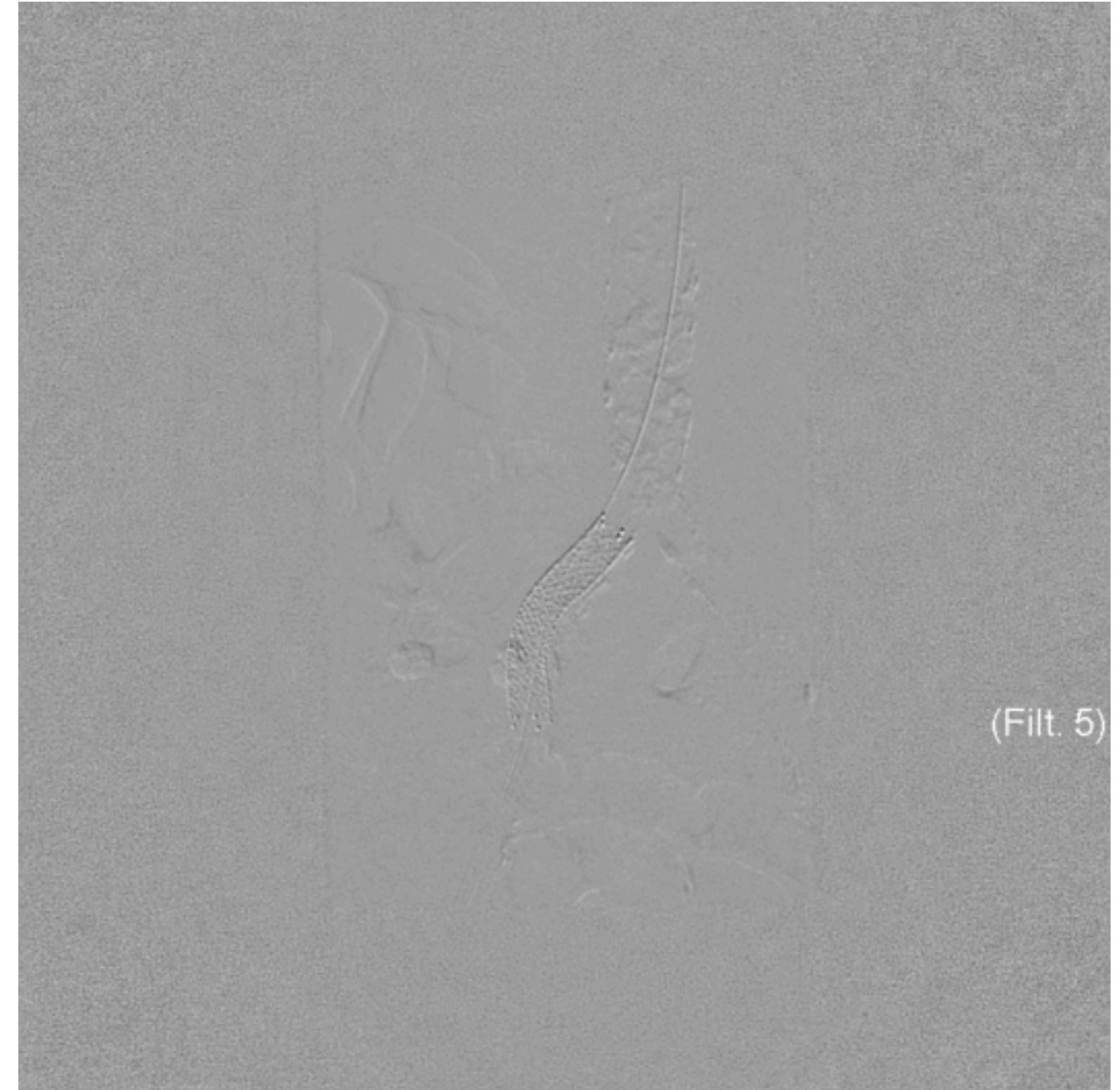
Final Angio  
DES 3.5 x 22 mm LM-IVA  
POT 5 mm  
Kissing LM- IVA-CX  
RePOT



Eccentric RCI stenosis



IVL Therapy:  
7x60 mm



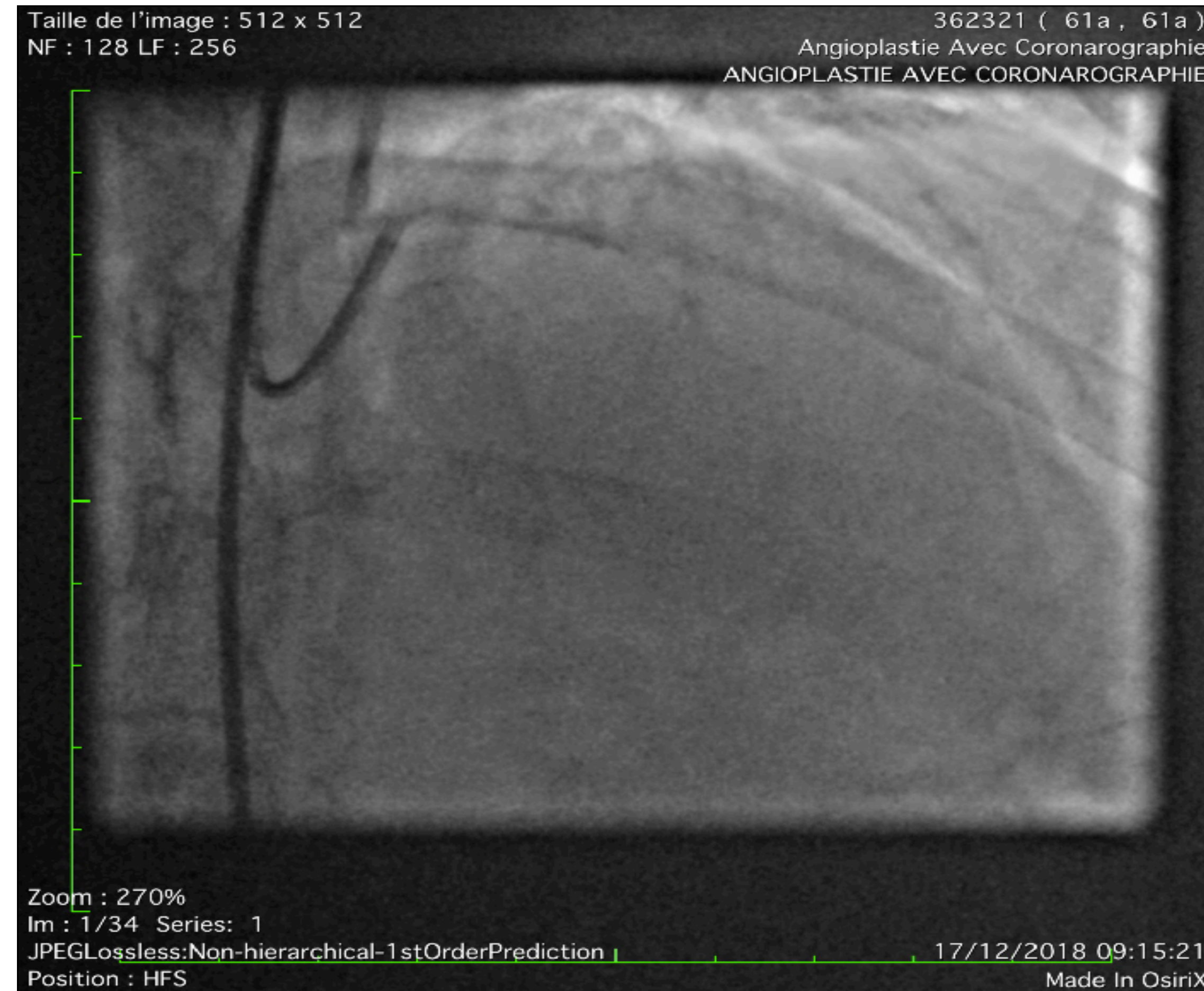
Final Angio  
Stent 9x37 mm

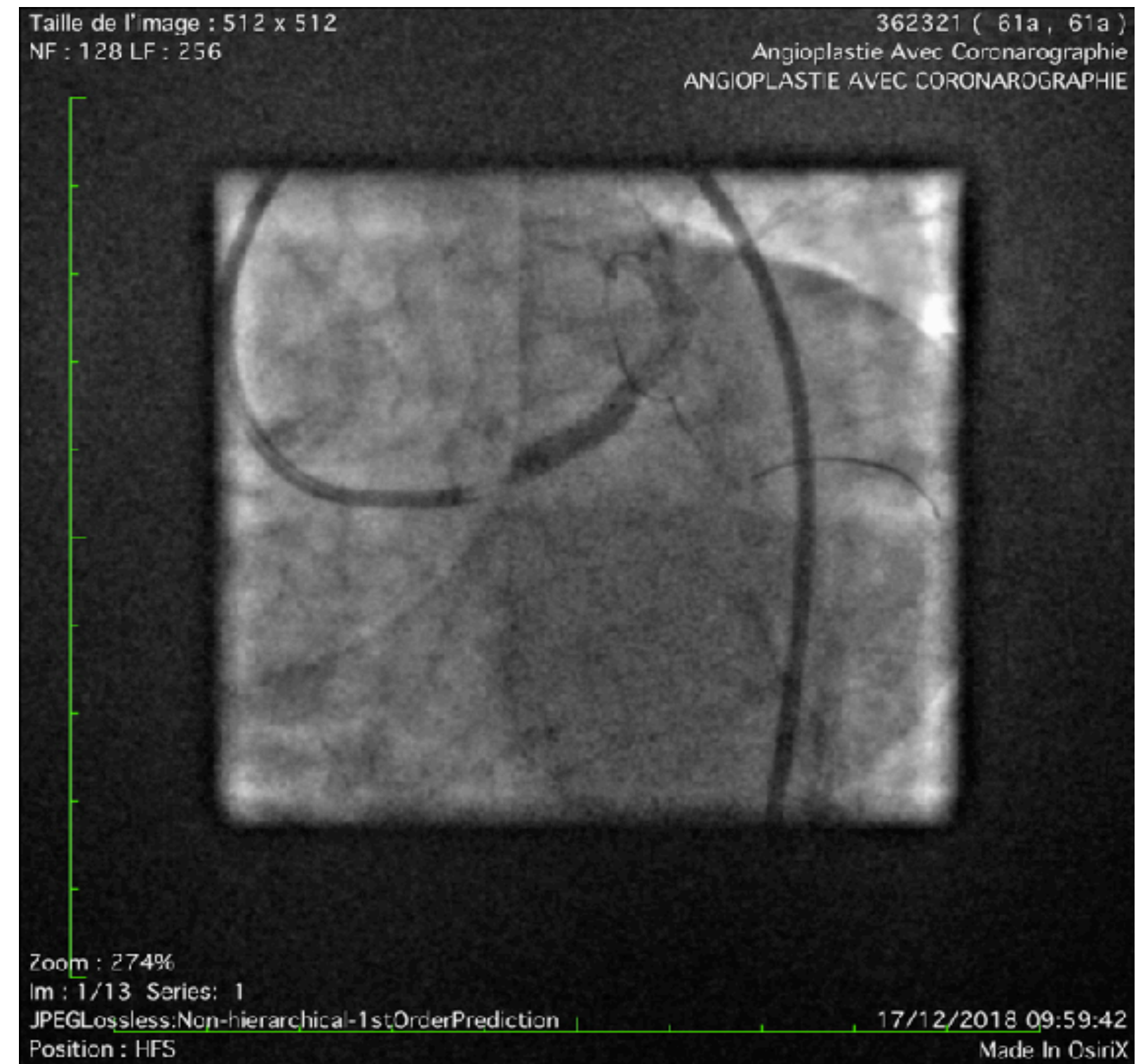
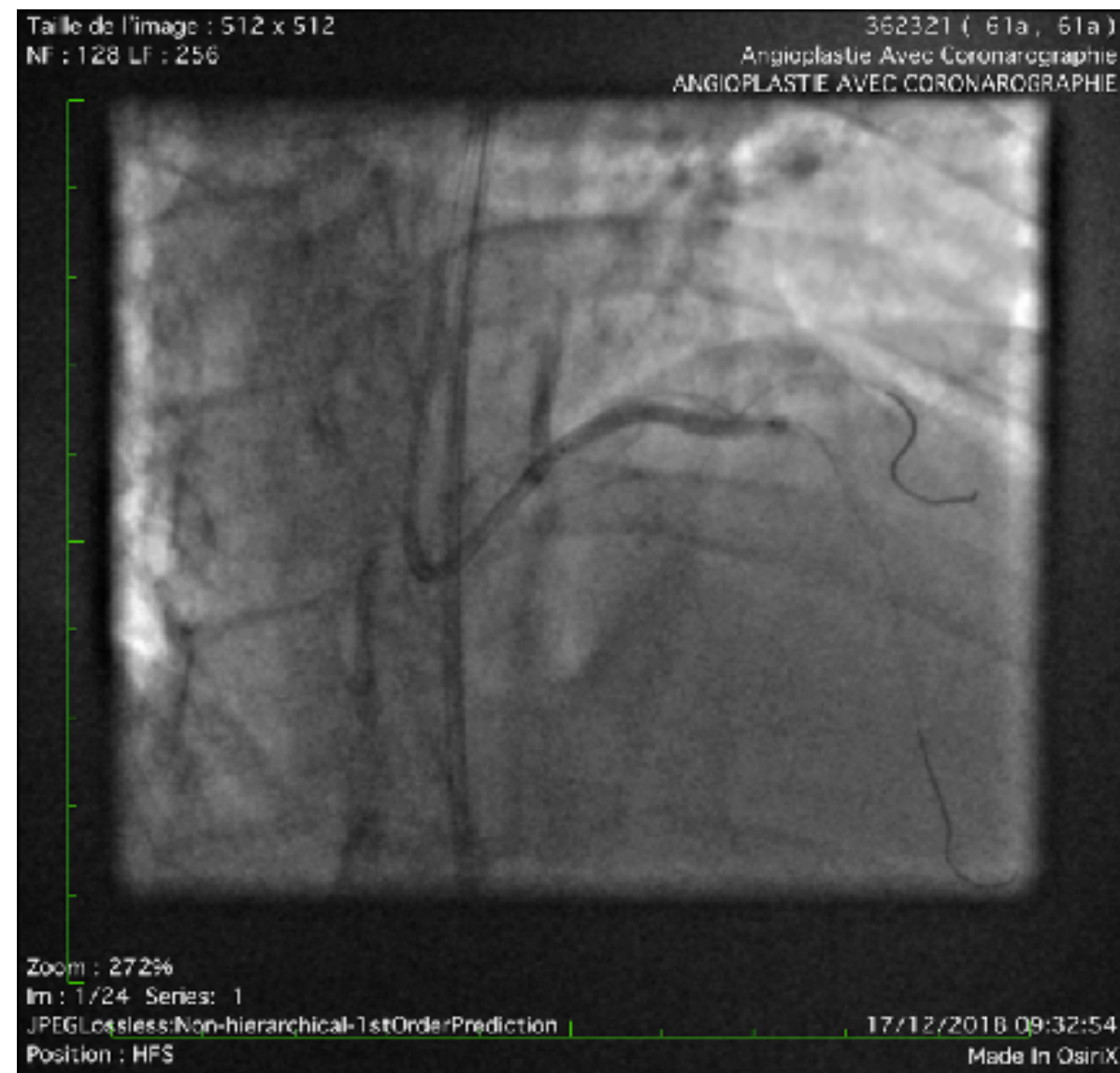
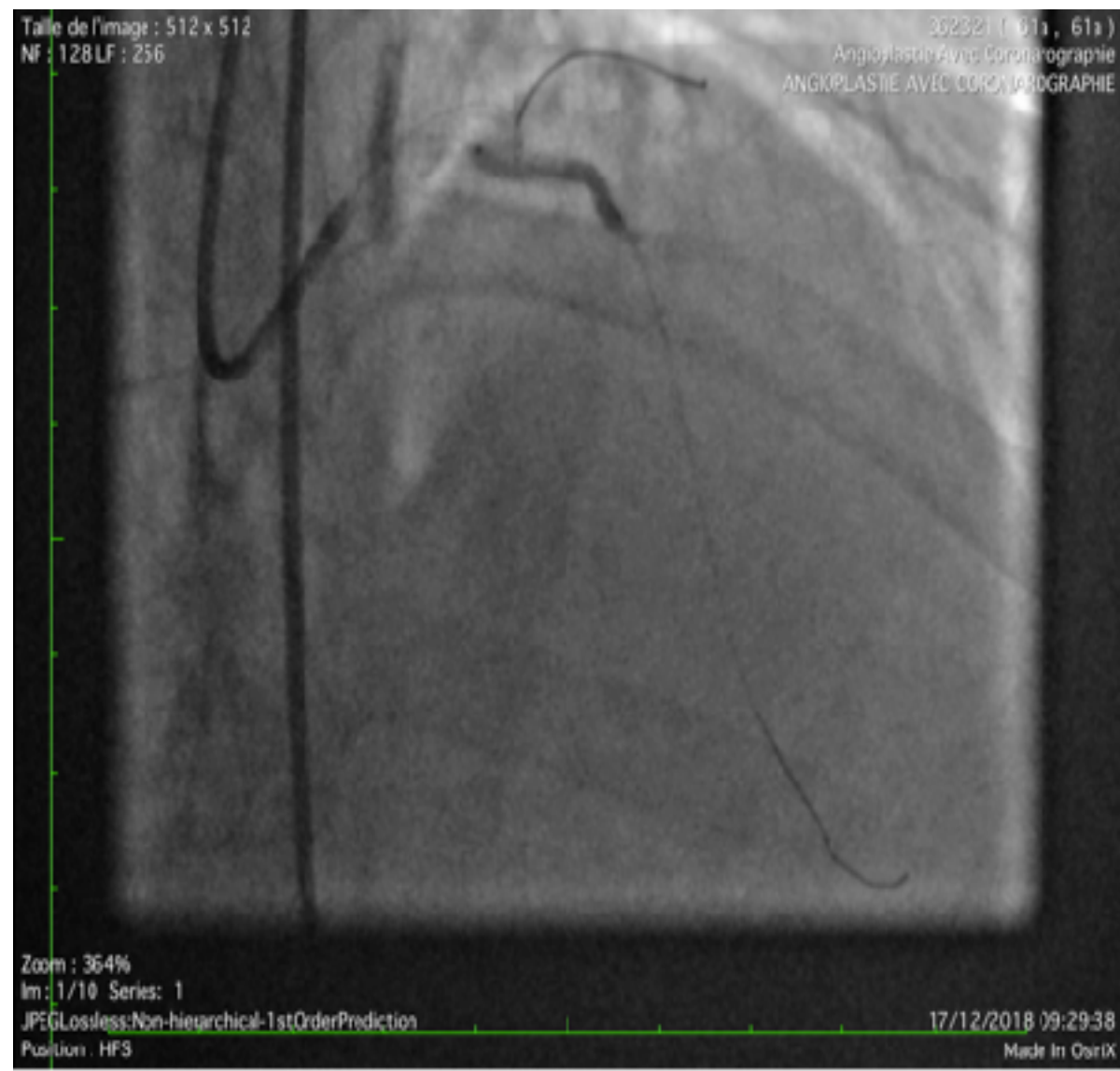
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# Accessibilité TAVI

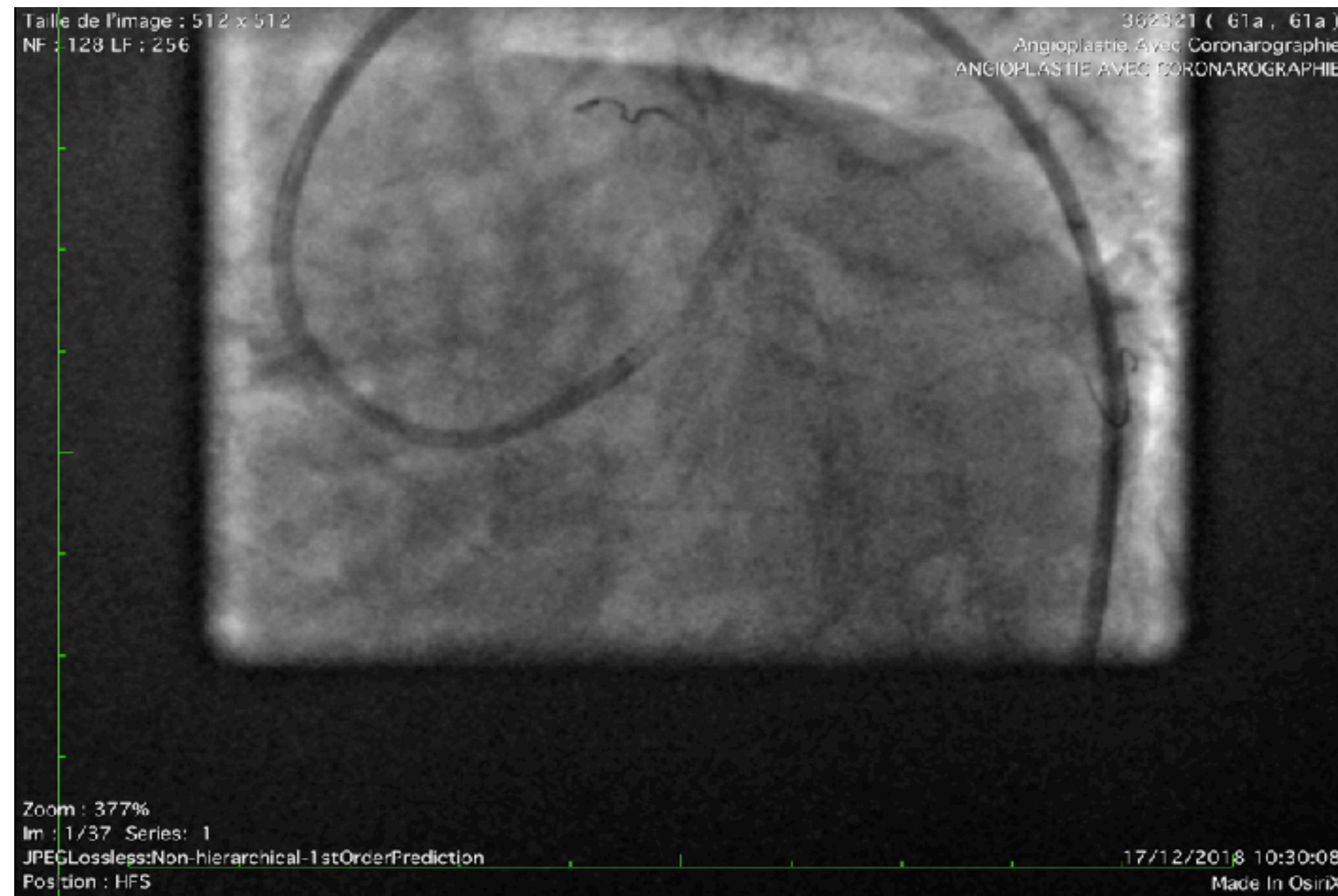


# Restenose IS



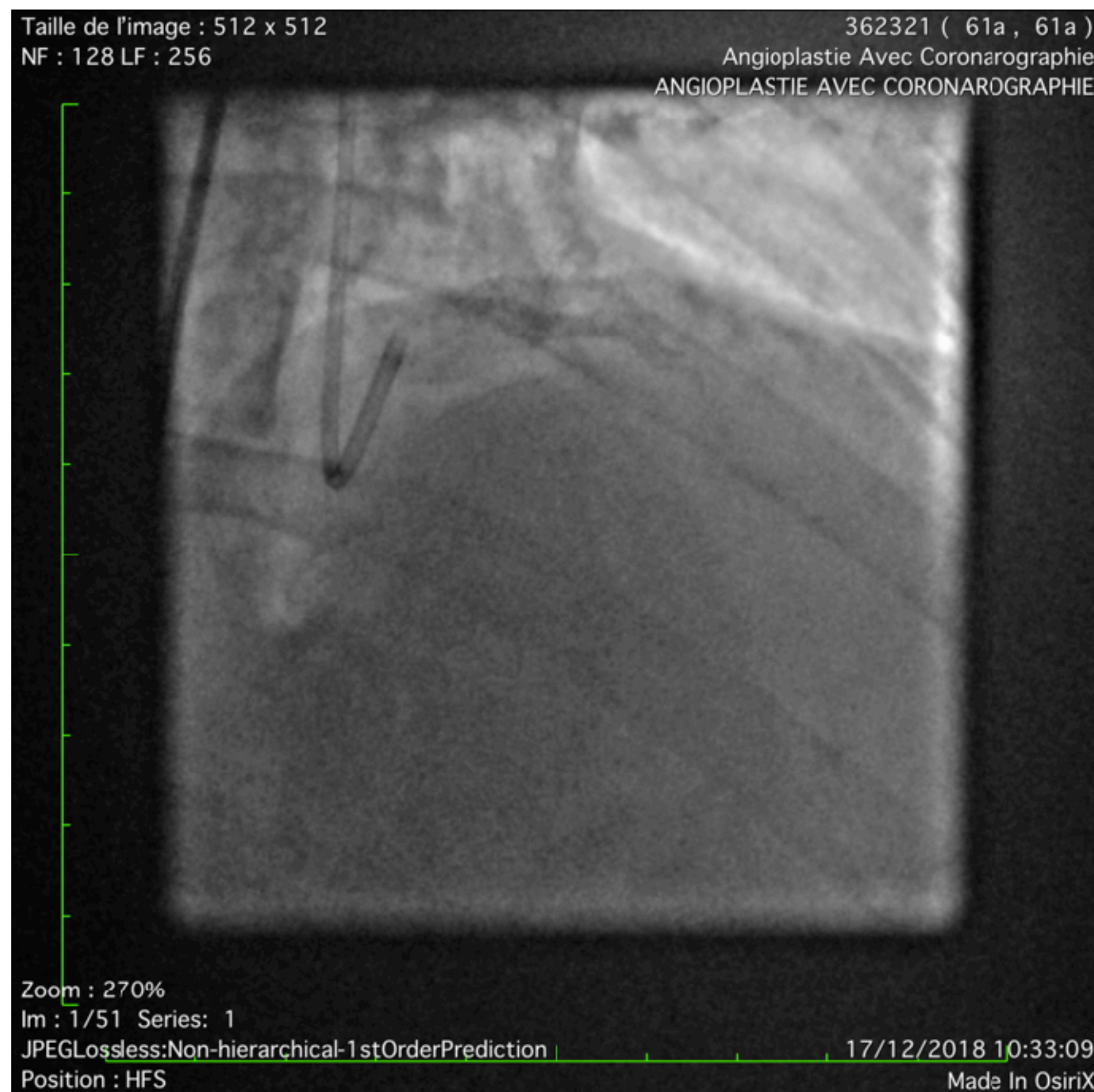


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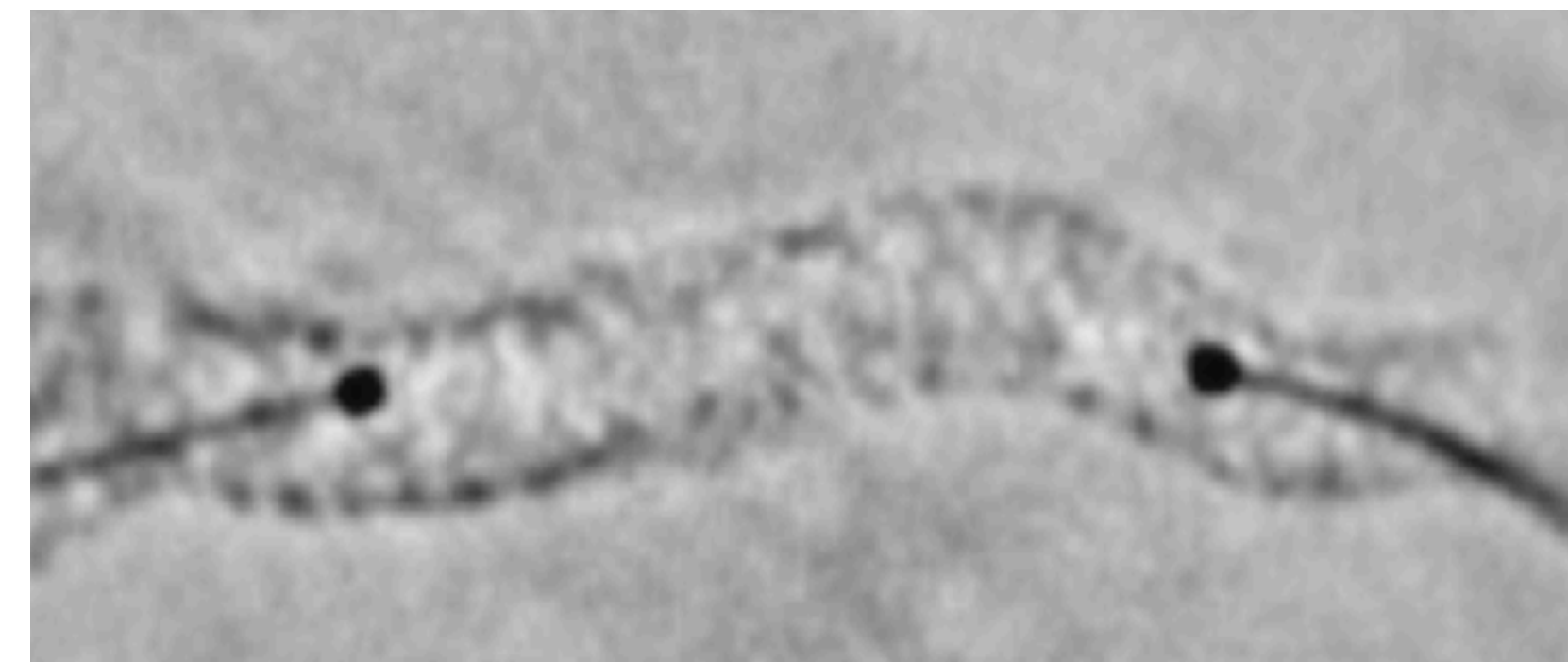
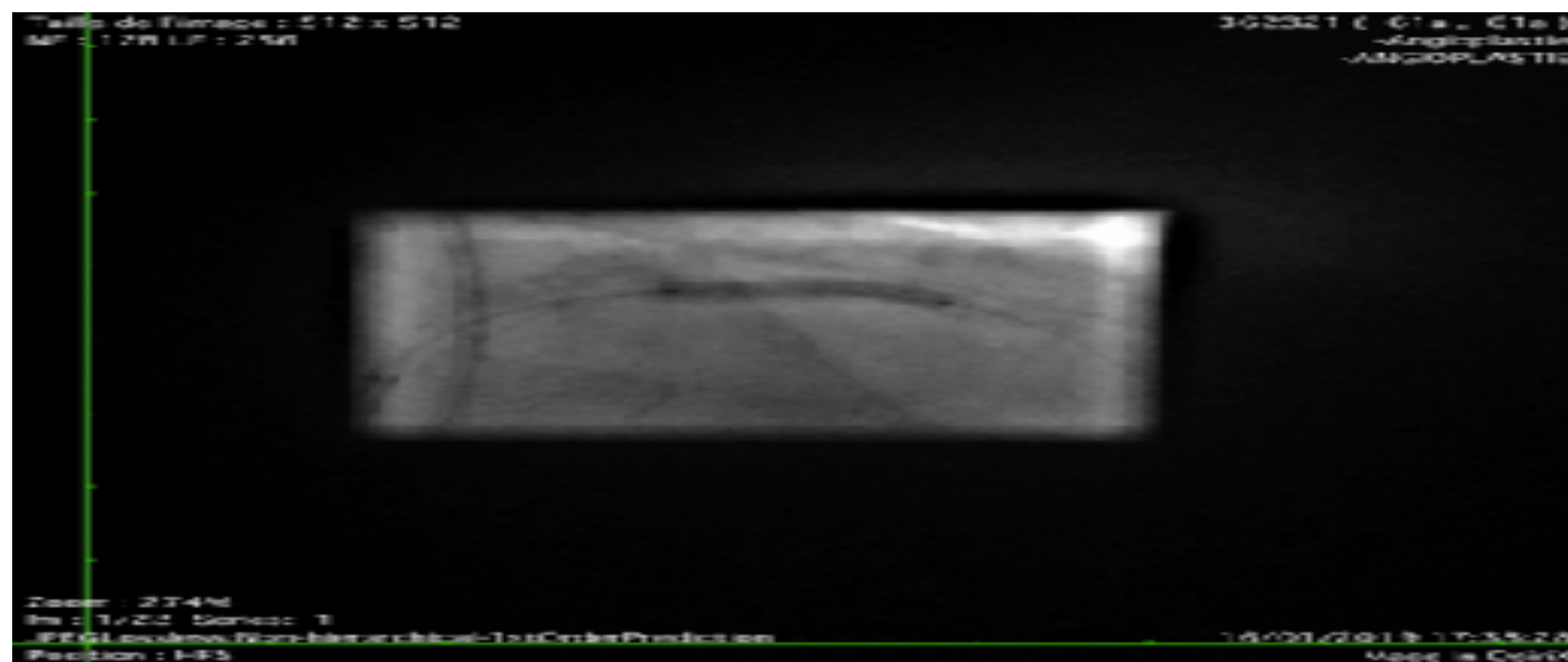
# Restenose IS



# Restenose IS



# Restenose IS



# Restenose IS

