Lacrosse NSE Balloon Using the “Leopard-Crawl” Technique is Efficacious for Predilation of Severely Calcified Lesions

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Cardiovascular Center, Japan

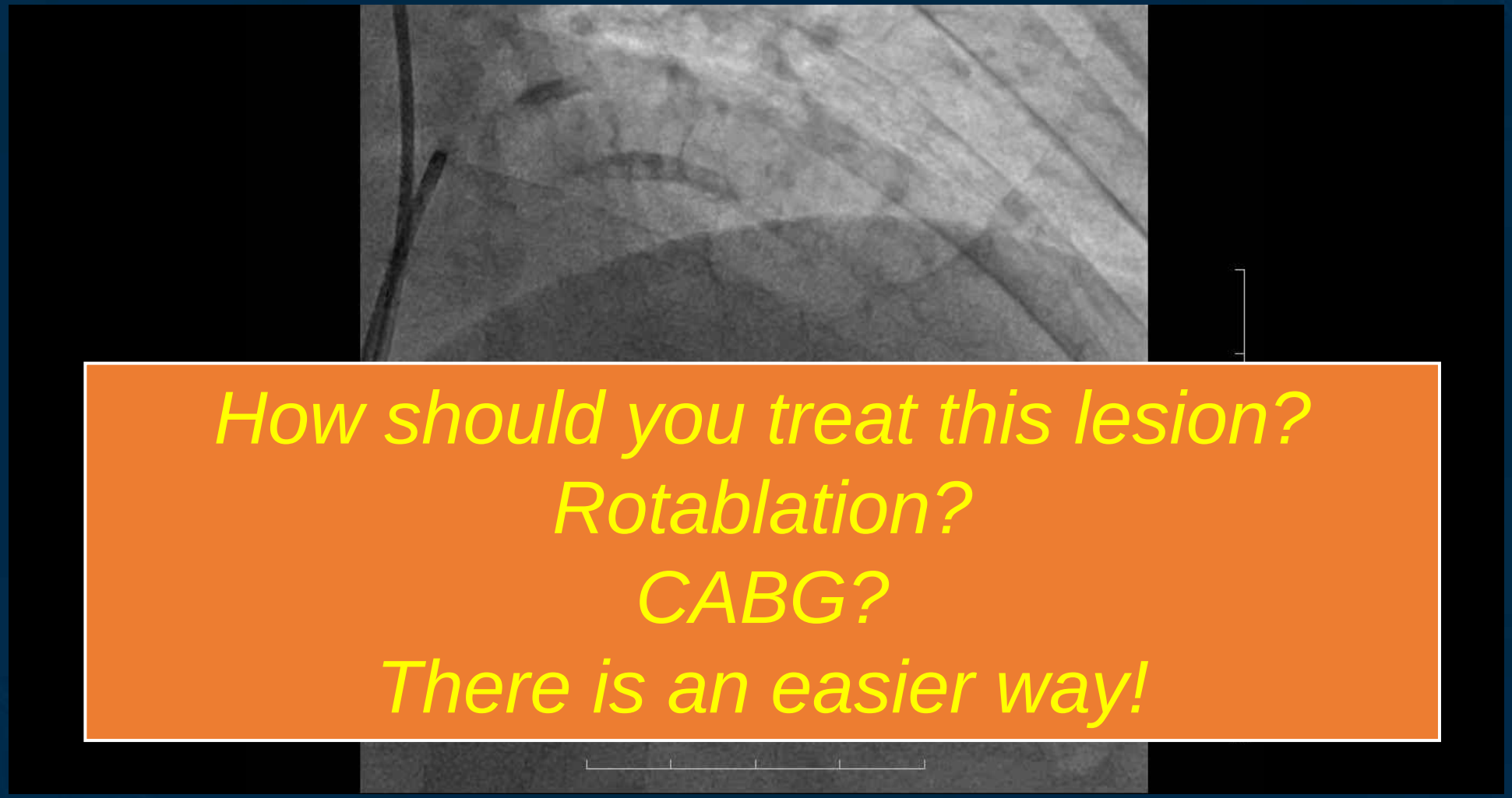
Disclosure

- I, Kazuhiro Ashida, DO NOT have any relevant financial relationships to disclose.

Case:
Severe calcification in LAD

Pre CAG

Pre CAG


How should you treat this lesion?
Rotablation?
CABG?
There is an easier way!

Severe calcification

✓Rotablator?

Good and reasonable option

Large guide catheter is needed.

Original complication; slow/no flow, bur stuck, high cost?

✓CABG?

Open surgery; might be performed CABG to the only one vessel lesion?

Severe calcification

✓Scoring balloon

Especially Lacrosse NSE; good option!!

Relatively easy, and low cost

At our hospital, we treat a lot of severe calcification lesions by *Lacrosse NSE* with *Leopard Crawl technique*!!

Severely calcified lesions

Stent delivery is problematic, easy to incur underexpansion or eccentric expansion

Predilation

Through controlled expansion it is possible to create cracking in multiple locations in order to facilitate adequate expansion.

- ✓ Creating cracking (plaque disruption of calcification)；
  Scoring balloon
  Lacrosse NSE·Cutting balloon·Scoreflex etc
- ✓ What is the dilative effect? How is delivery?

Effective dilation?

Dilation effect for calcified lesion

Bench testing to determine the dilatative results of scoring balloons in a fully circumferential calcified model

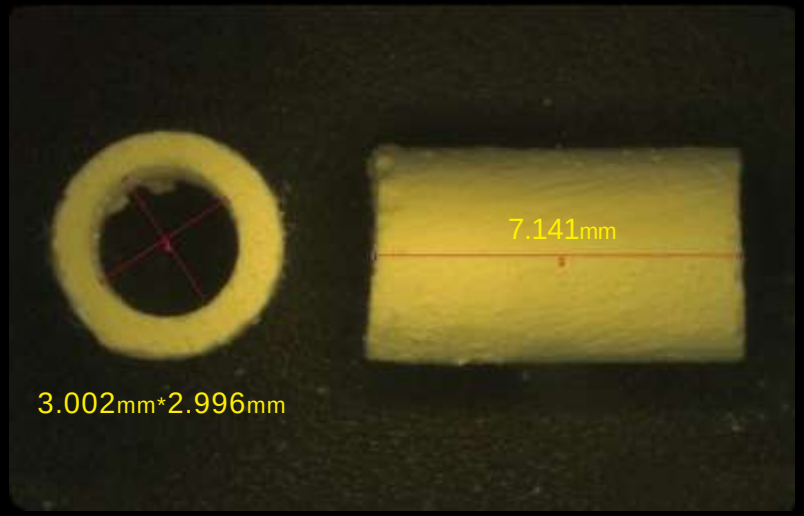
IMSグループ医療法人社団　明芳会
横浜新都市脳神経外科病院

臨床工学科

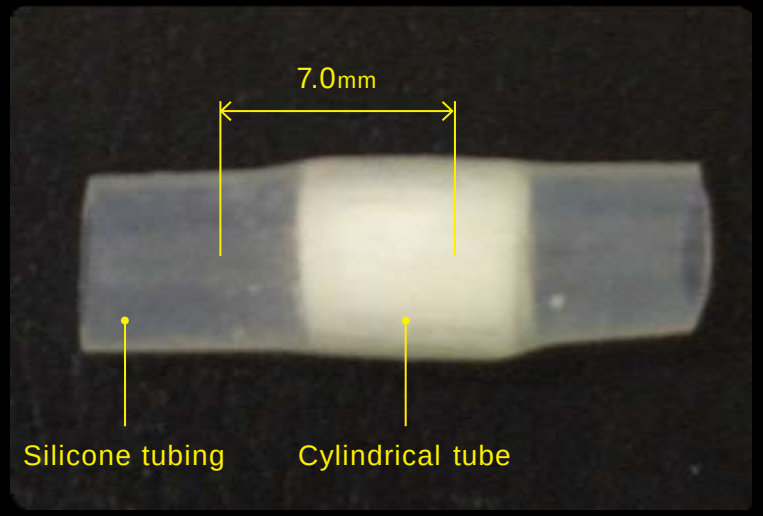
○高橋由亘 小島新一 寺井圭輔 花岡典代

循環器内科

芦田和博 折茂政幸 早瀬太一郎 新村剛透

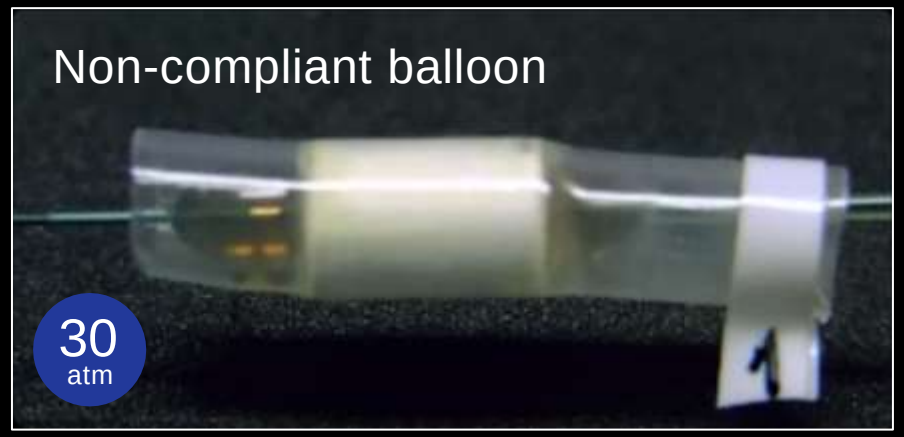

7.141mm
3.002mm*2.996mm


3.0mm


7.0mm
Silicone tubing
Cylindrical tube

Balloon dilatation

Non-compliant balloon



Lacrosse NSE

Flextome cutting balloon

Scoreflex

Bench testing of calcified model

		NC Balloon	Lacrosse NSE	Flextome Cutting Balloon	ScoreFlex
Pressure (atm)	①	30	8	11	14
	②	30	16	10	14
	③	17	10	7	13
(locations)	③	3	2	2	2
	Ave	1.7	2.3	2.3	2.0
Shape of crack	①	None	Full length I shape 2 locations	Full length I shape 2 locations Full length diagonal 1 location	2/3 diagonal 1 location Full length I shape 1 location
	②	Full length V shape 1 location Full length Y shape 1 location	Full length I shape 2 locations Full length diagonal 1 location	Full length Y shape Full length I shape 1 location	1/2 diagonal 1 location Full length I shape 1 location
	③	1/3 diagonal 1 location Full length diagonal 2 locations	Full length I shape 2 locations	Full length I shape 2 locations	Full length I shape 1 location Full length diagonal 1 location

Create a number of cracks the full length of the model

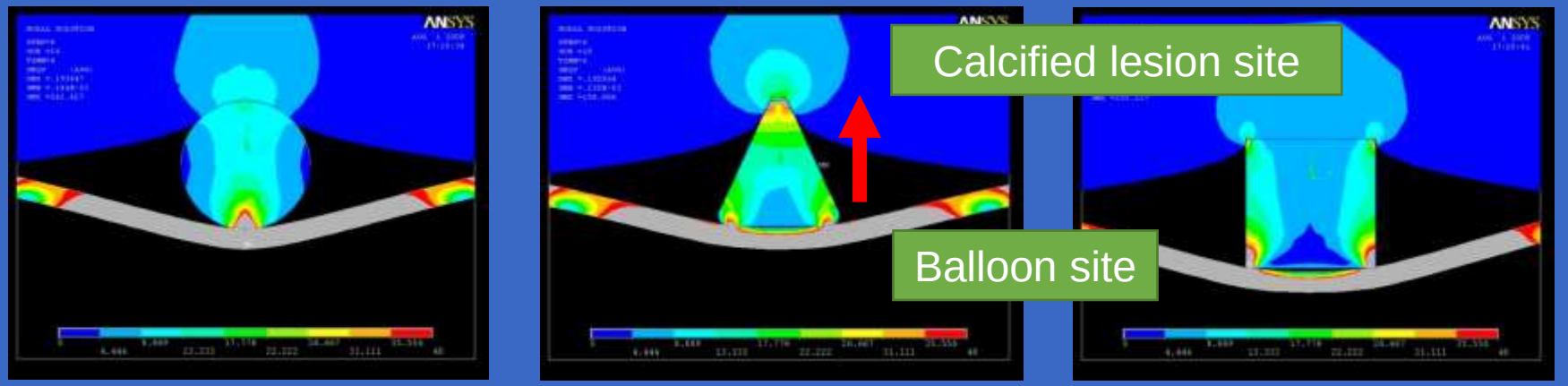
Lacrosse NSE=cutting balloon>ScoreFlex>NC balloon

Lacrosse NSE : Element

3 elements

The Elements are attached at the Distal and Proximal ends only

NSE advance: Element



● NSE ■

Tips for making cracks

We need **high pressure dilatation (18atm)** with NSE because elements should be headed to not balloon (week resistance) but calcification (strong resistance).

Bench testing for dilative effect

Create a number of cracks the full length of the model

Lacrosse NSE=cutting balloon>ScoreFlex>NC balloon

Crossability for calcified lesion

Bench testing for dilative effect

Create a number of cracks the full length of the model

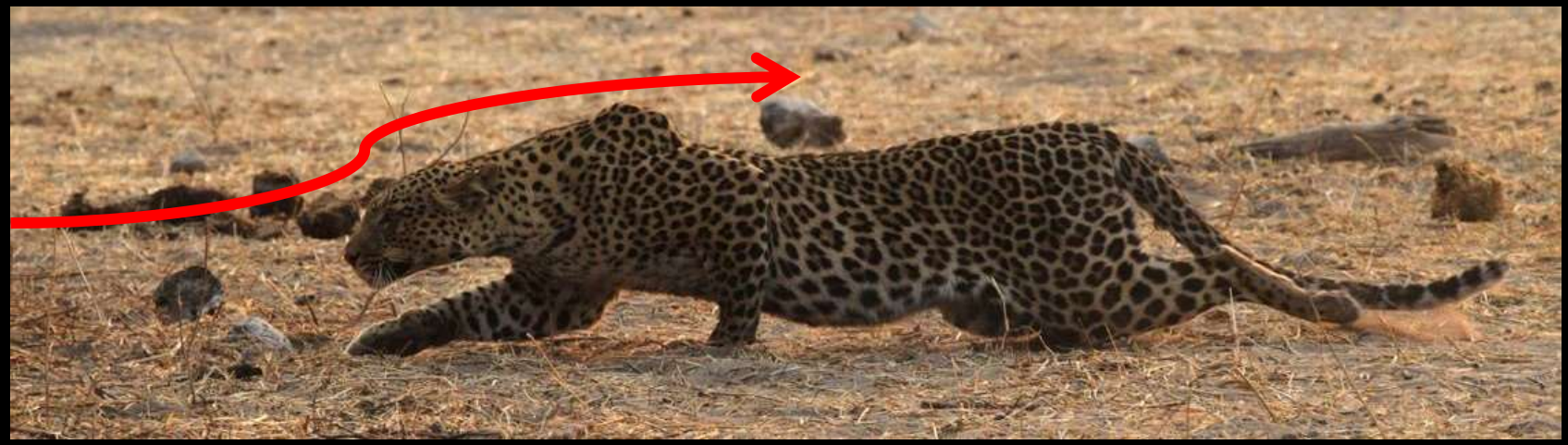
Lacrosse NSE=cutting balloon>ScoreFlex>NC balloon

Delivery efficacy?

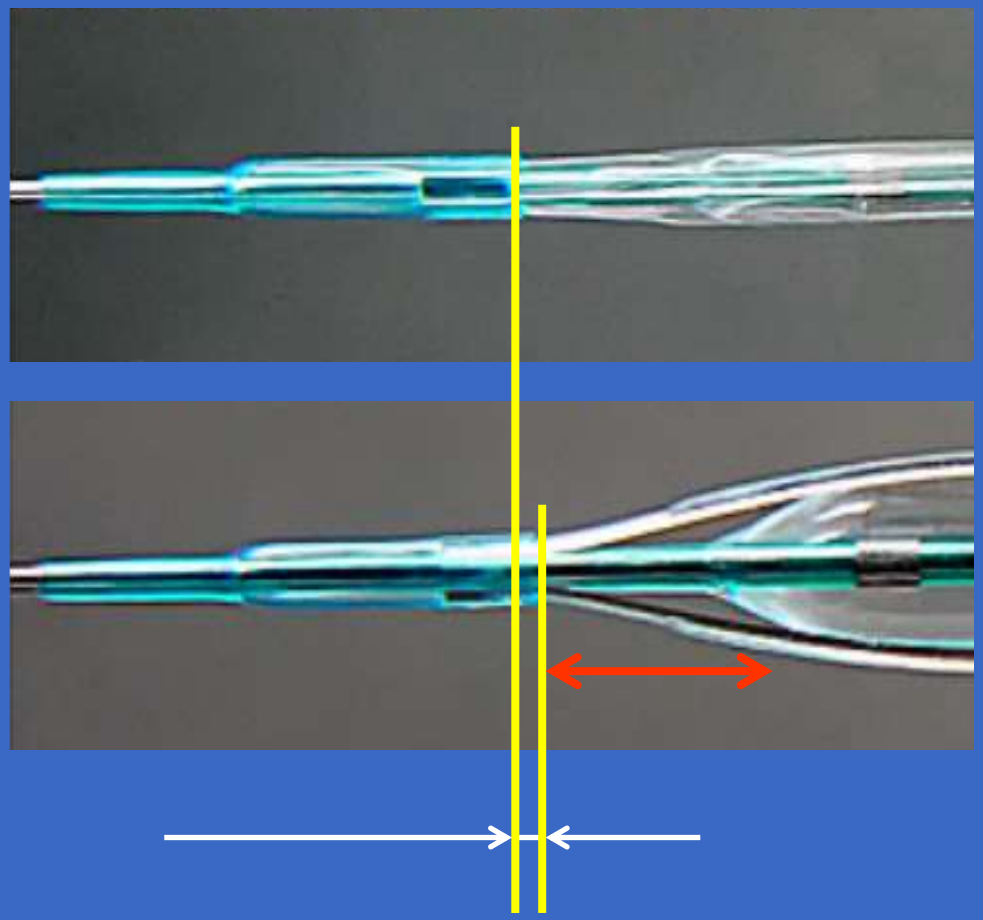
Lacrosse NSE, cutting balloon<ScoreFlex or NC balloon

Lacrosse NSE with
'Leopard Crawl' technique

Leopard crawl



The elements are connected beyond the distal (and proximal location) of the balloon.



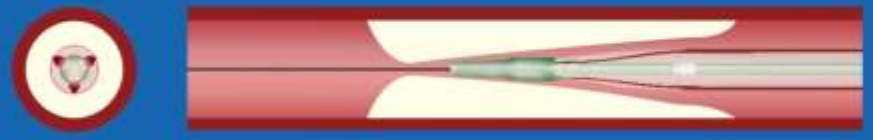
Even when the balloon is not able to advance to target lesion, it is considered that the elements provide a wedge that formulate a cracking effect.

Flow chart of Leopard Crawl Technique

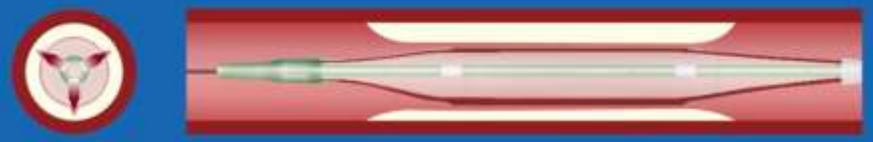
1. Calcified lesion

2. Advance NSE catheter to lesion location

3. Dilate NSE at calcified lesion.
   Repeat Step 2 and 3 until catheter is advanced distally



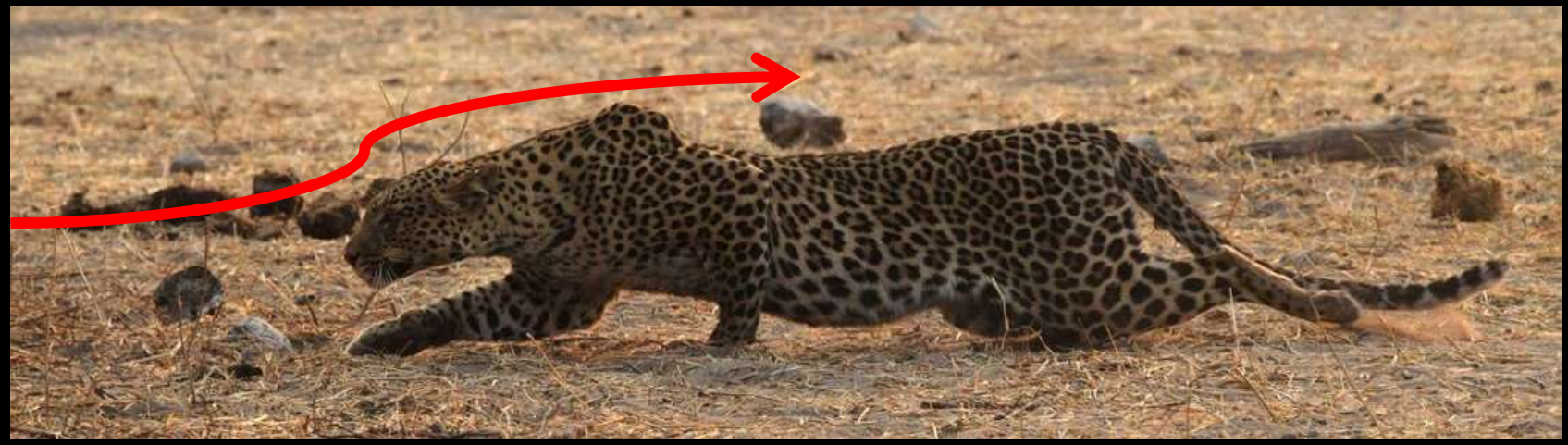
4. Scoring of calcification facilitates catheter advancement



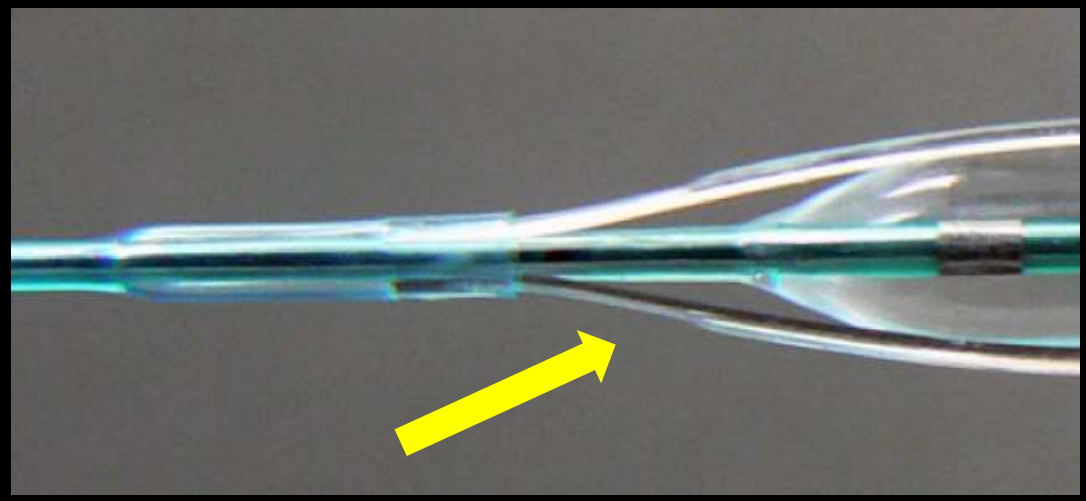
5. Fully dilate lesion with NSE

6. Scoring effect throughout full length of calcified lesion

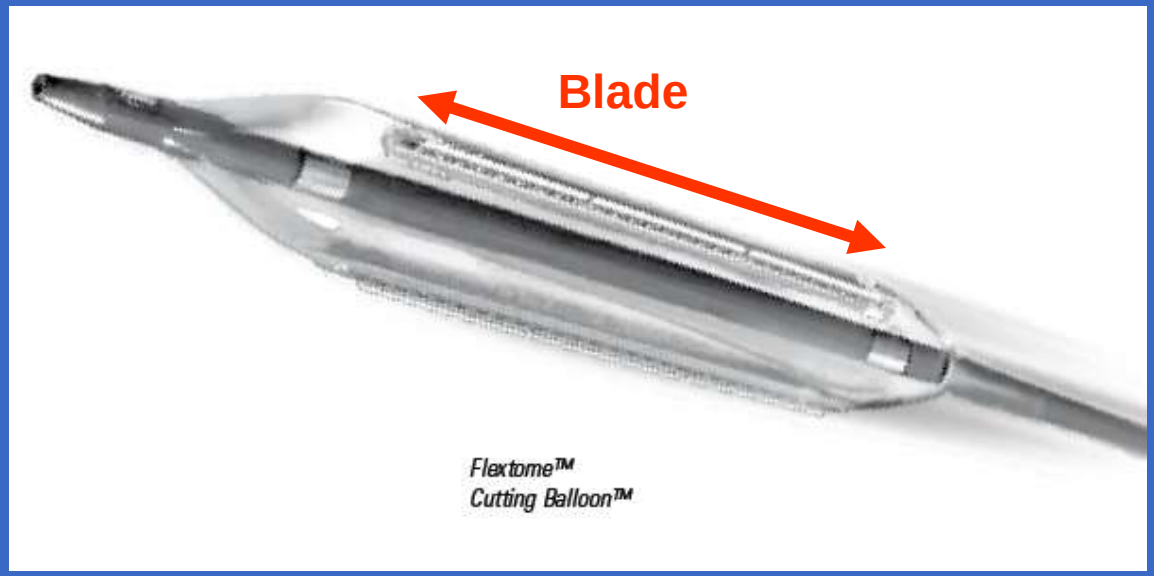
Leopard crawl



The wedge shape provides a gap to allow the catheter to advance



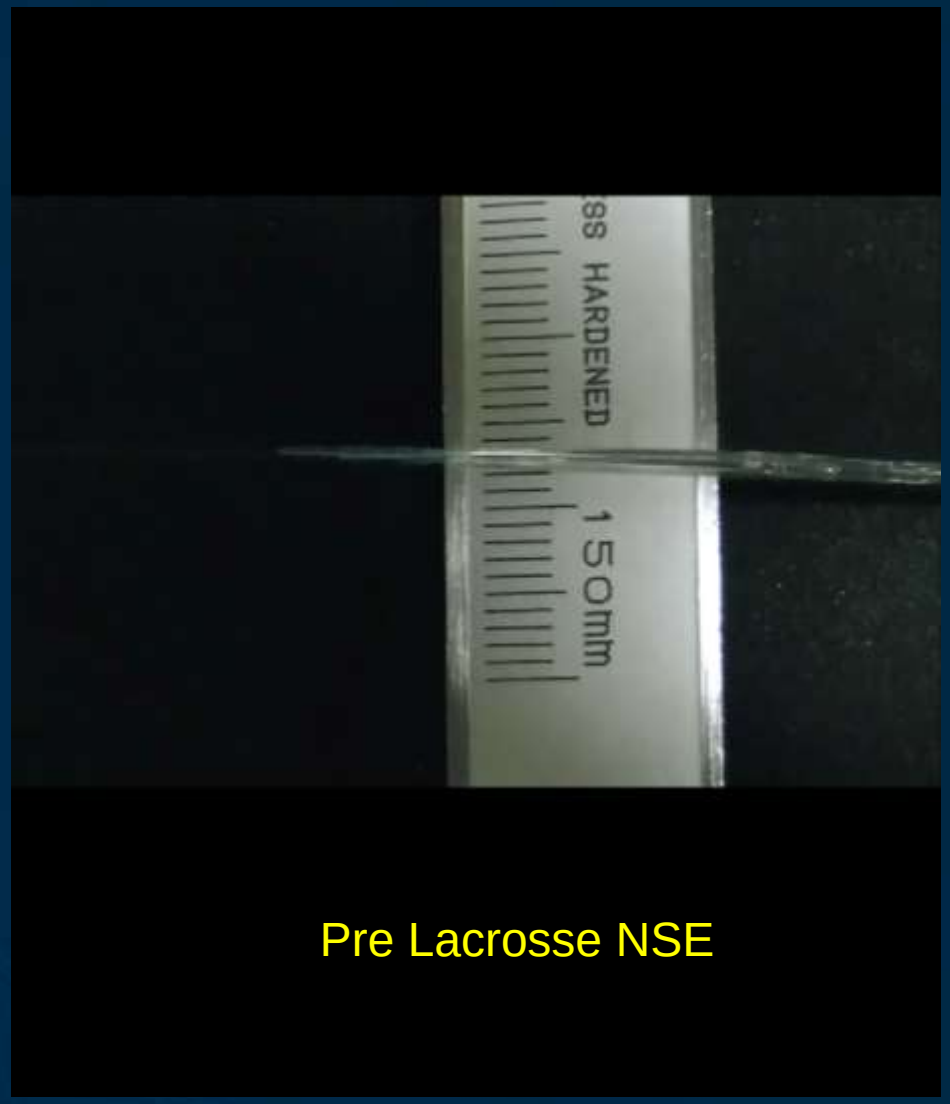
Cutting balloon



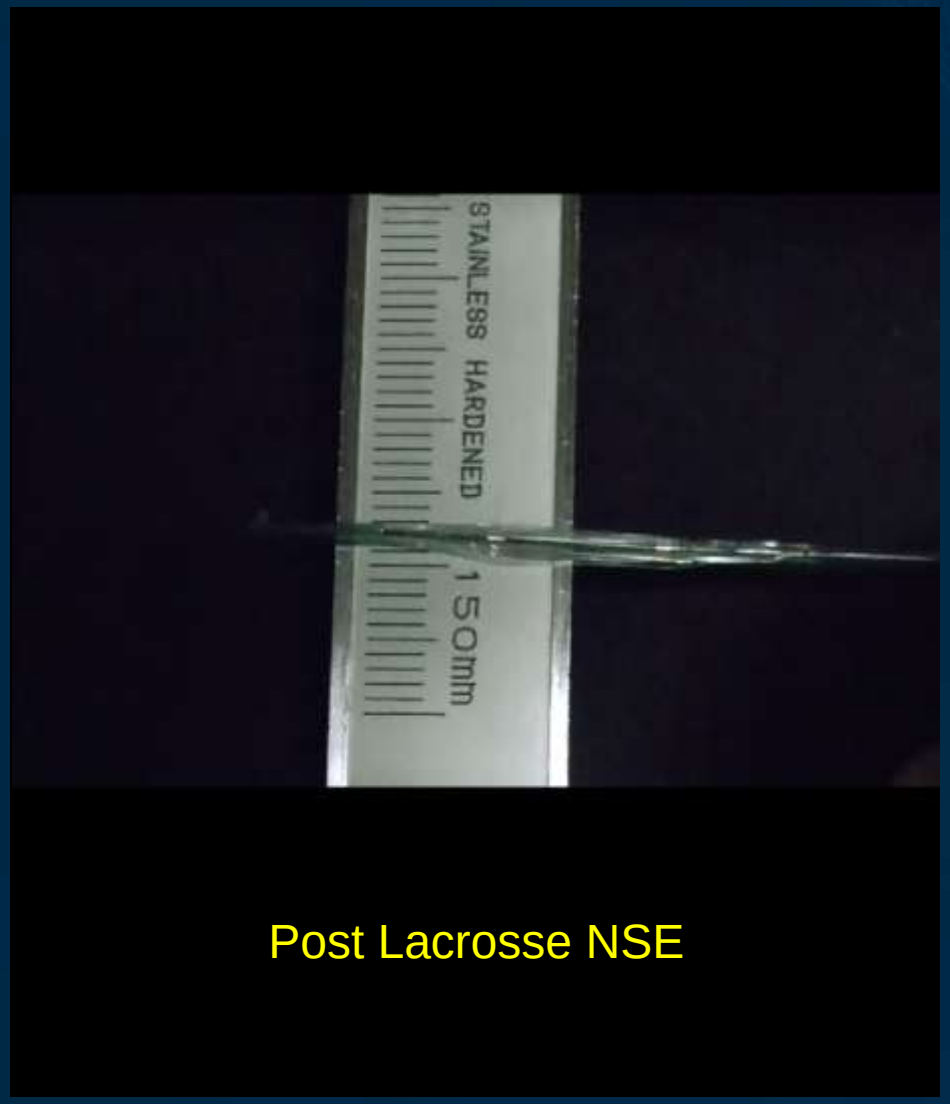
Whether leopard crawl can be utilized relies on the re-wrapping of the balloon

The blade component is shorter than the balloon

Post-deflation of various balloons

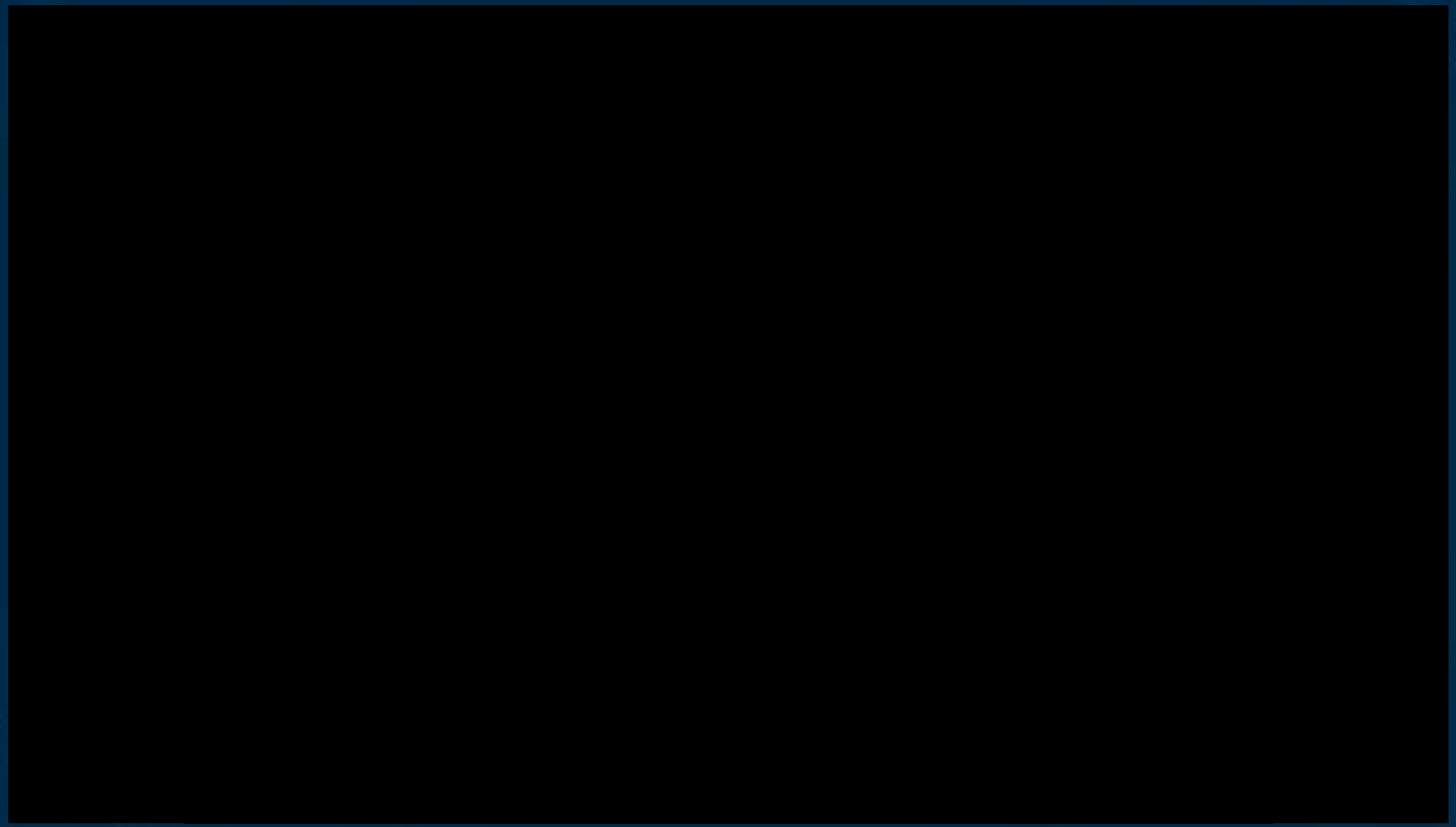


Pre Lacrosse NSE



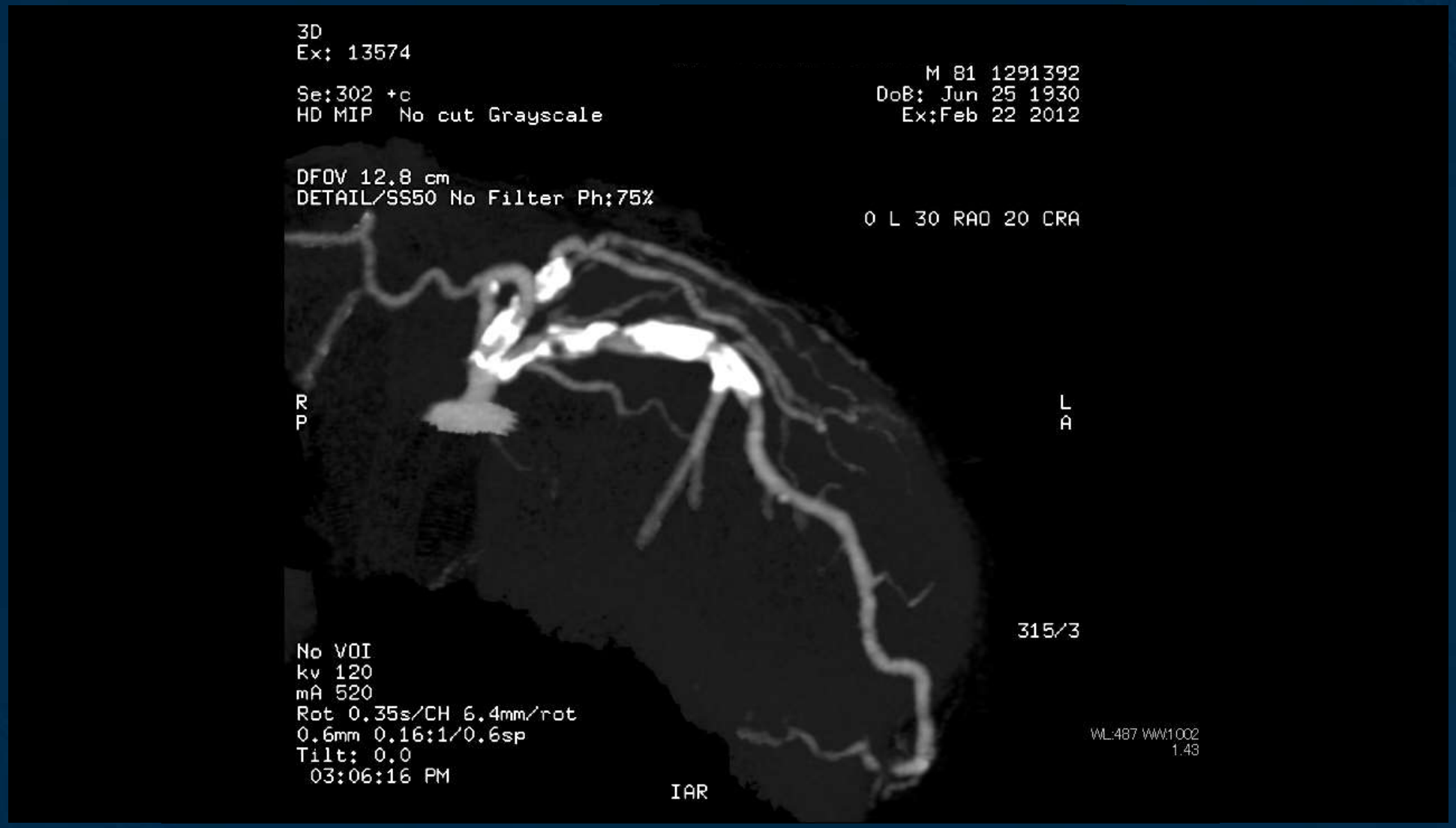
Post Lacrosse NSE

Lacrosse NSE



Case 1:

Diffuse, severely calcified lesion


3D
Ex: 13574
Se:302 +c
HD MIP No cut Grayscale
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
DFOV 12.8 cm
DETAIL/SS50 No Filter Ph:75%
0 L 30 RAO 20 CRA
R
P
L
A
315/3
No VOI
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp
Tilt: 0.0
03:06:16 PM
IAR
WL:487 WW1002
1.43

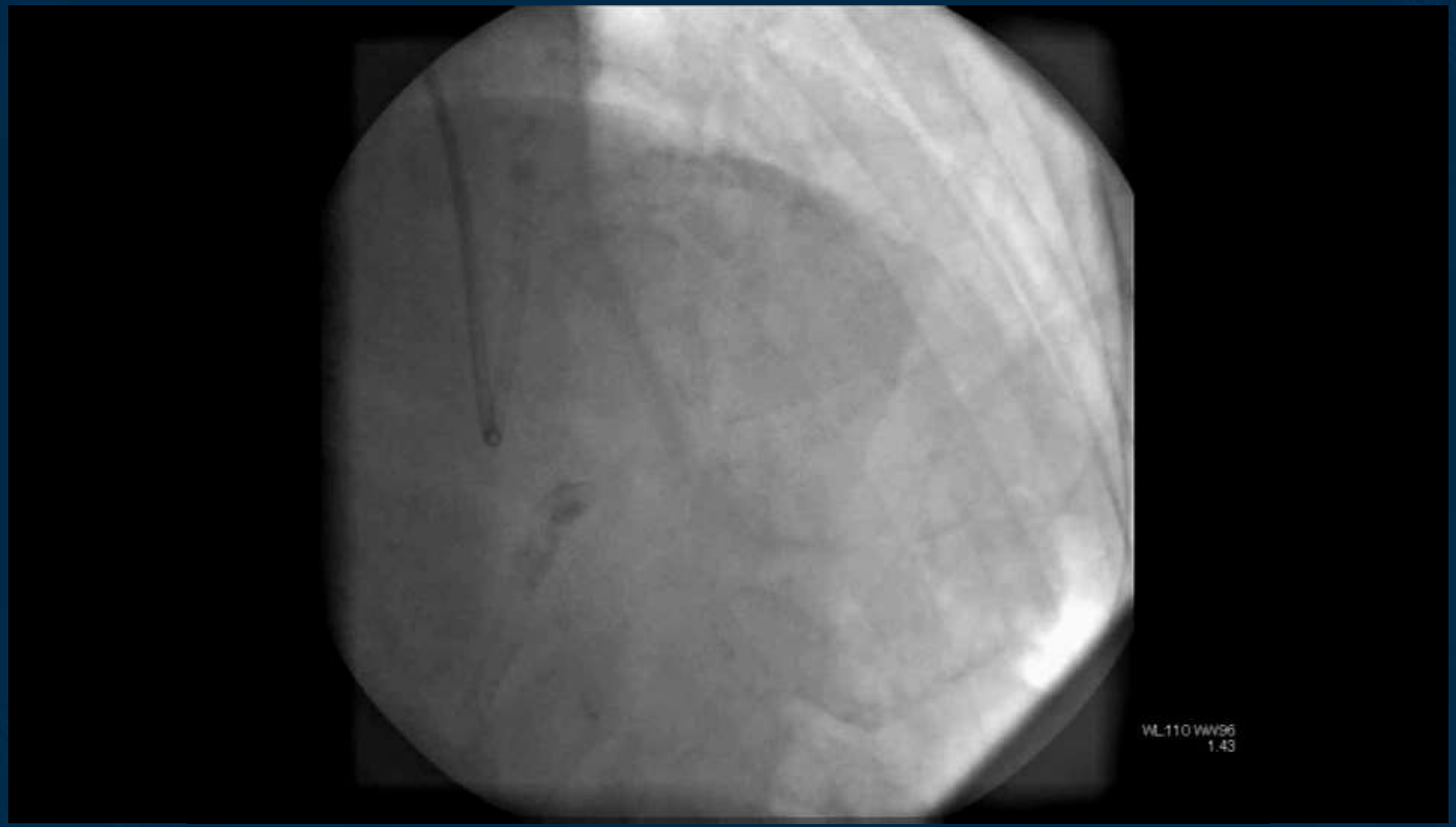

Curved
Ex: 13574
I
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
Se:302 +c
LAD Angle: 60.0
DFOV 17.7 cm
DETAIL/SS50 Ph:75% No Filter
R
L
318/5
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp 0.4/
Tilt: 0.0
03:06:16 PM
WL:410 WW:1201
1.43
S


Curved
Ex: 13574
P
M 81 1291392
DoB: Jun 25 1930
Ex:Feb 22 2012
Se:302 +c
LAD Angle: 135.0
DFOV 17.7 cm
DETAIL/SS50 Ph:75% No Filter
R
L
318/10
kv 120
mA 520
Rot 0.35s/CH 6.4mm/rot
0.6mm 0.16:1/0.6sp 0.4/
Tilt: 0.0
03:06:16 PM
WL:410 WW:1201
1.43
A

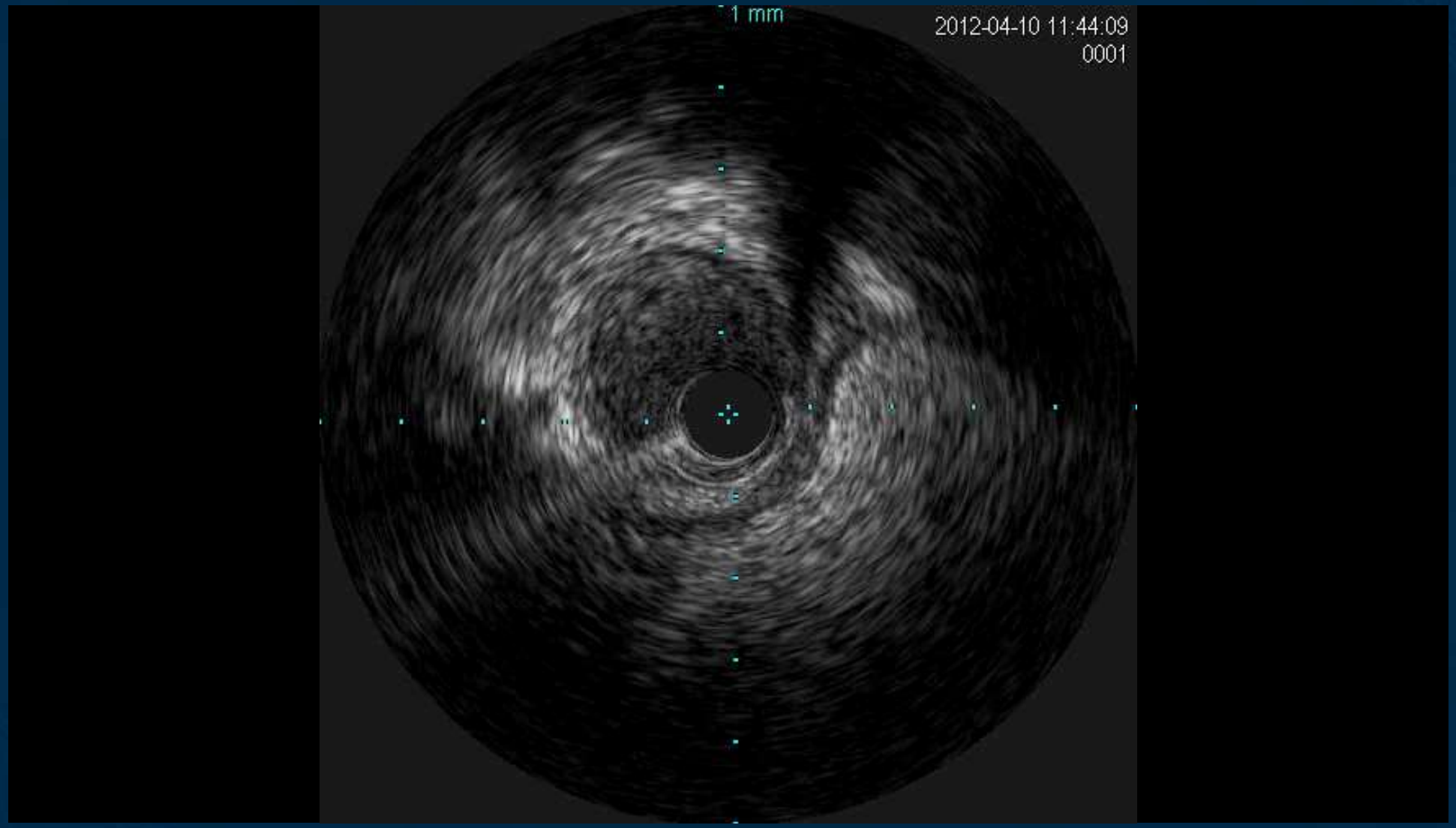

GE MEDICAL SYSTEMS
Optima CT660 CTOPTIMA660
Ex: 13574
Se: 355 RPMT
Im: 3+C
O A33.4 (coi)
DFOV 2.4cm
DETL
SPL
Feb 22 2012
03:06:16 PM
SEGM 240 X 248
Mag = 1.00
FL:
ROT:
R
A
S
L
P
I
kV 120
mA 520
SFOV 32.0cm
0.391mm/6.40 0.16:1
Tilt: 0.0
0.35s /HE
WL:410 WW:1201
1.43
IAR


GE MEDICAL SYSTEMS
Optima CT660 CTOPTIMA660
Ex: 13574
Se: 355 RPMT
Im: 10+C
O I103.2 (coi)
DFOV 2.4cm
DETL
ASR
Feb 22 2012
03:06:16 PM
SEGM 240 X 248
Mag = 1.00
FL:
ROT:
R
I
A
L
S
P
kV 120
mA 520
SFOV 32.0cm
0.891mm/6.40 0.161
Tilt: 0.0
0.35s /HE
WL:410 WW:1201
1.43
PIL

Pre PCI



IVUS


1 mm
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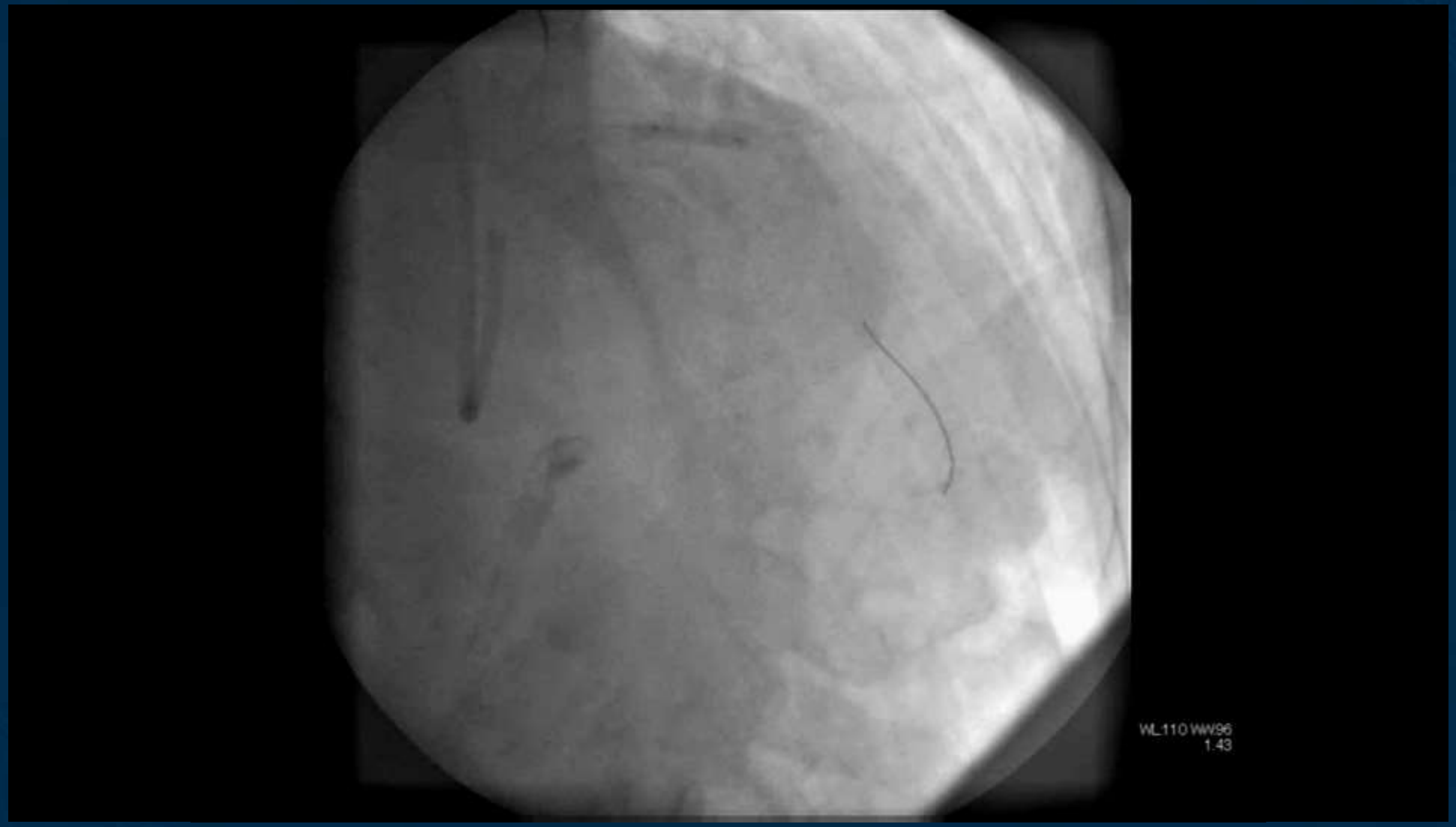
0001

NSE leopard crawl ①; 2.25mm@4-6atm

NSE leopard crawl ②

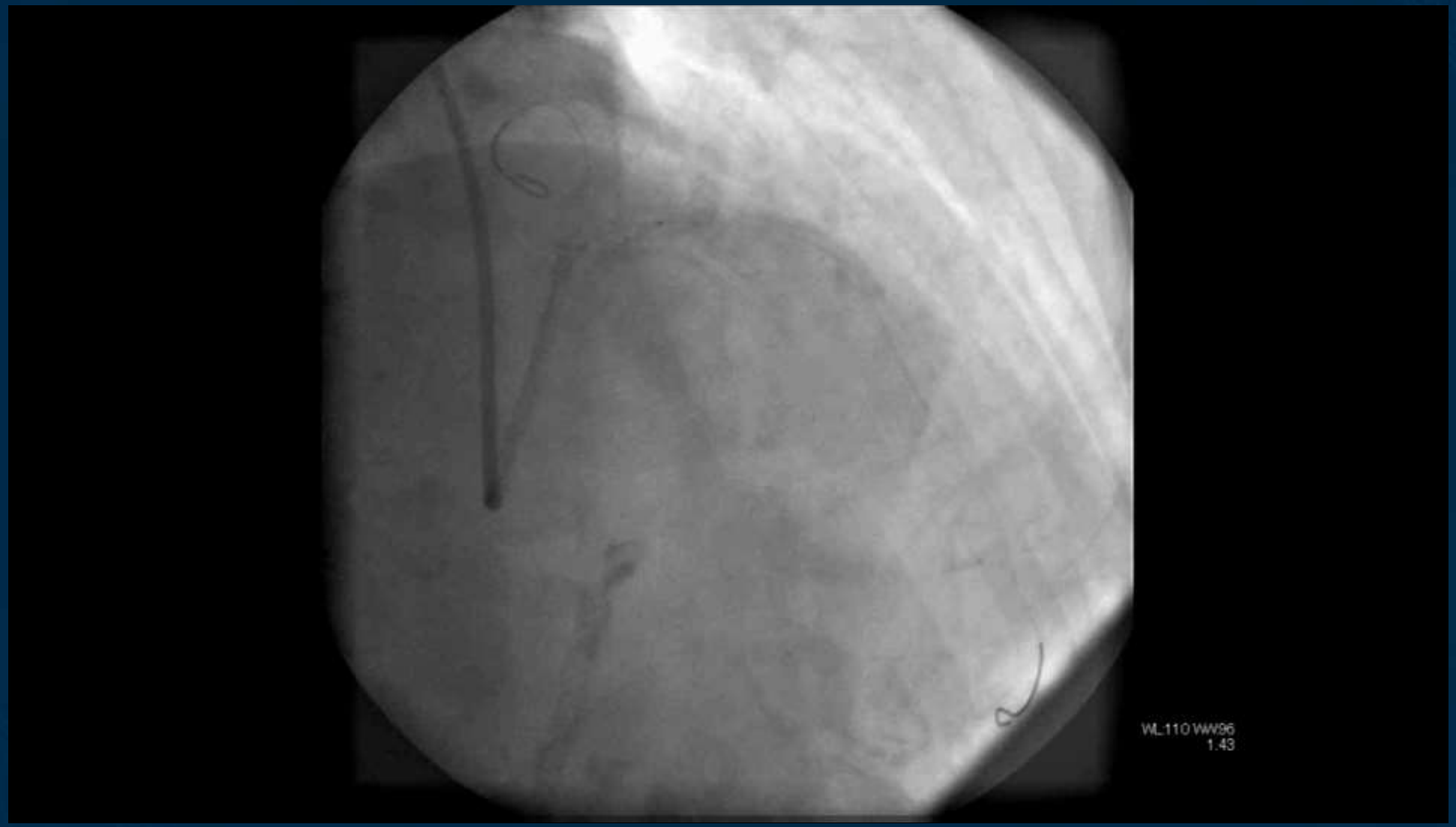


NSE leopard crawl ③

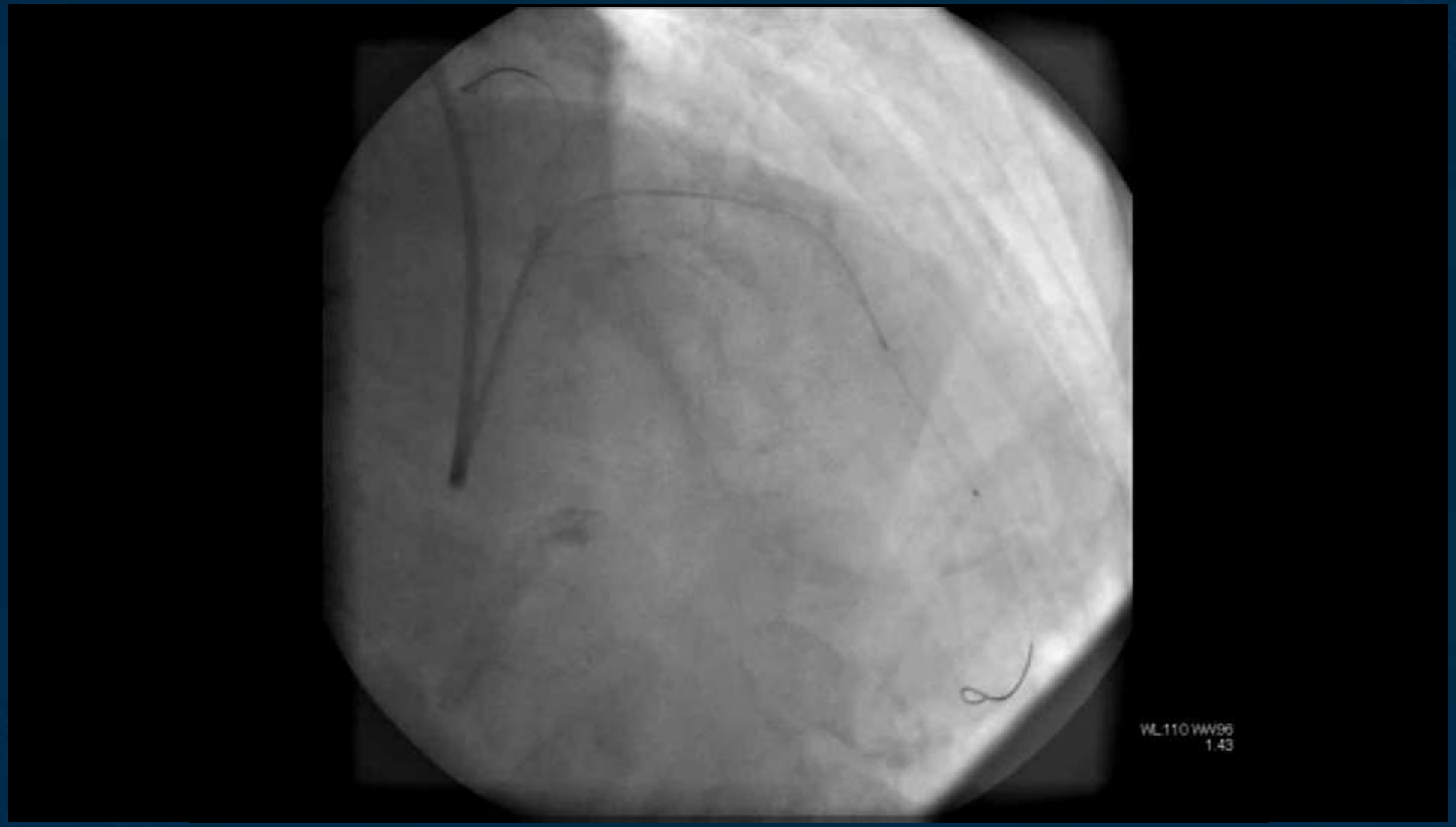
NSE leopard crawl ④

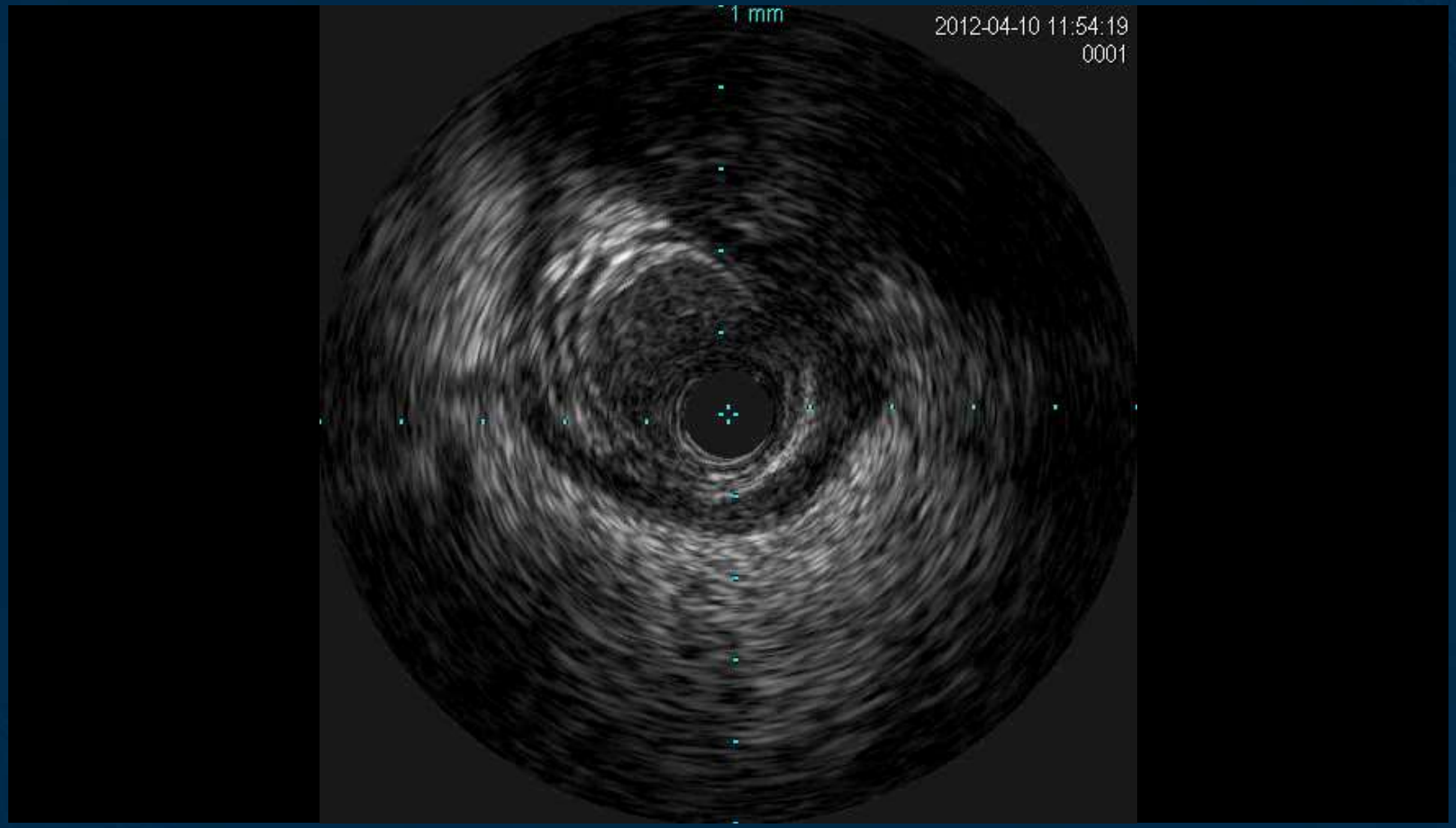
NSE leopard crawl ⑤

NSE post inflation push test



NSE post inflation IVUS

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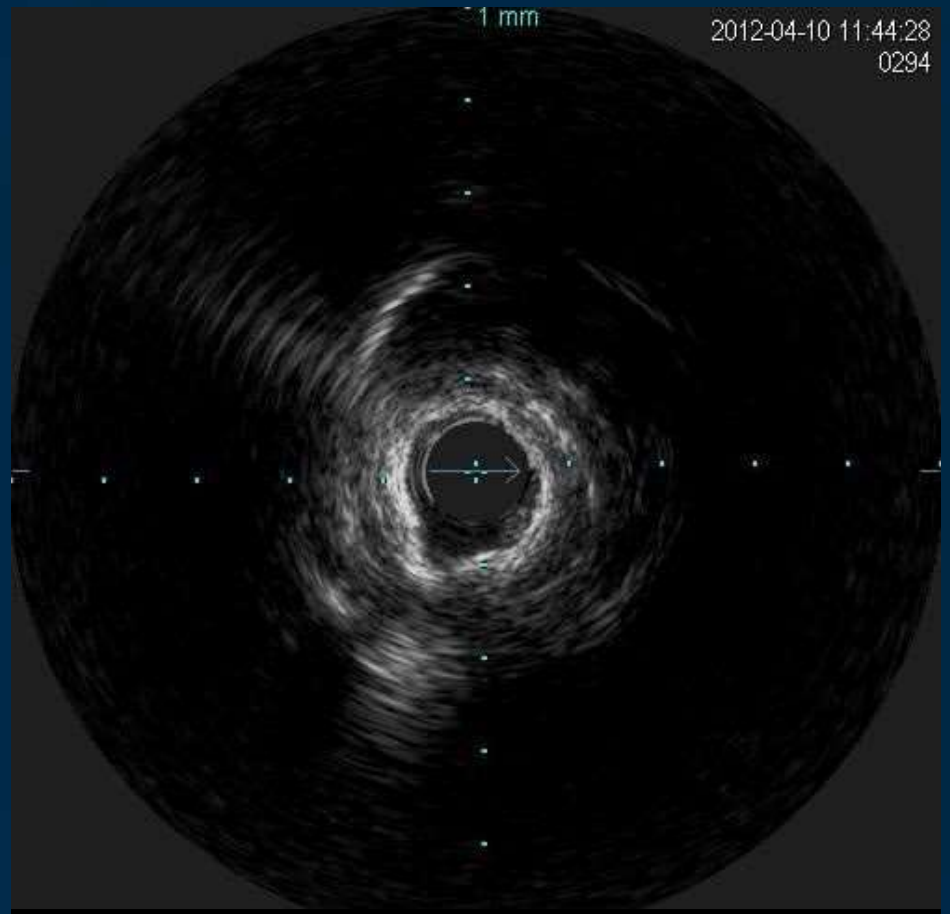
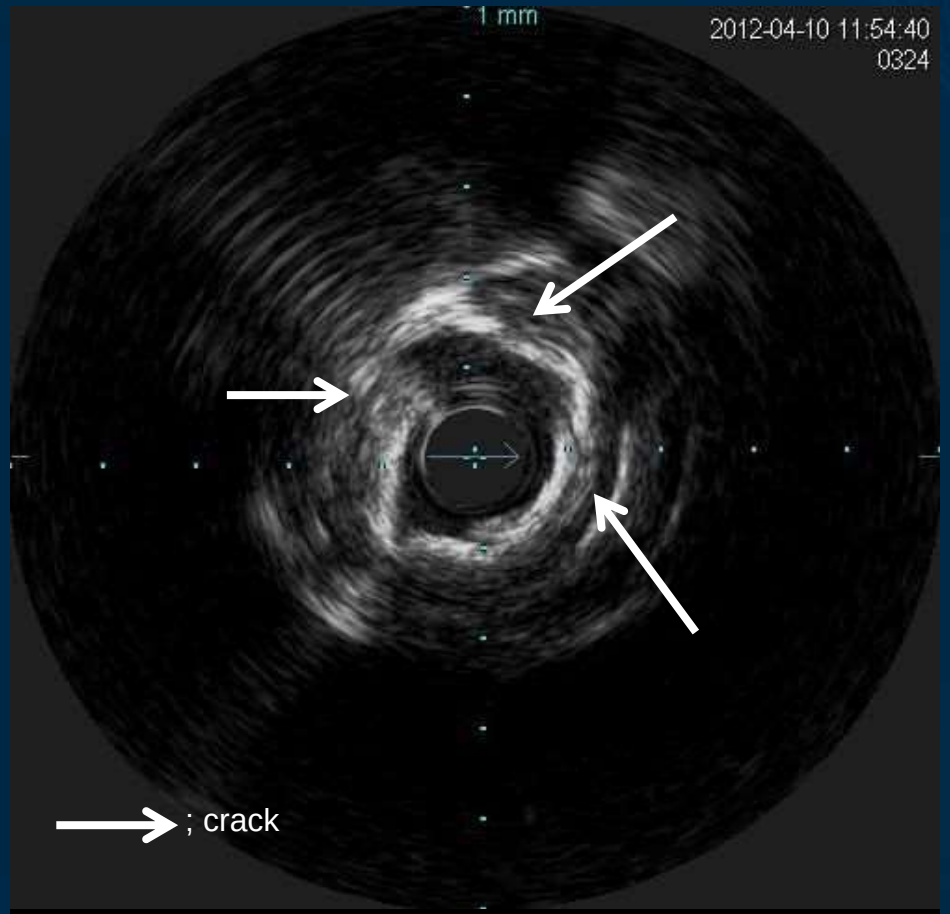
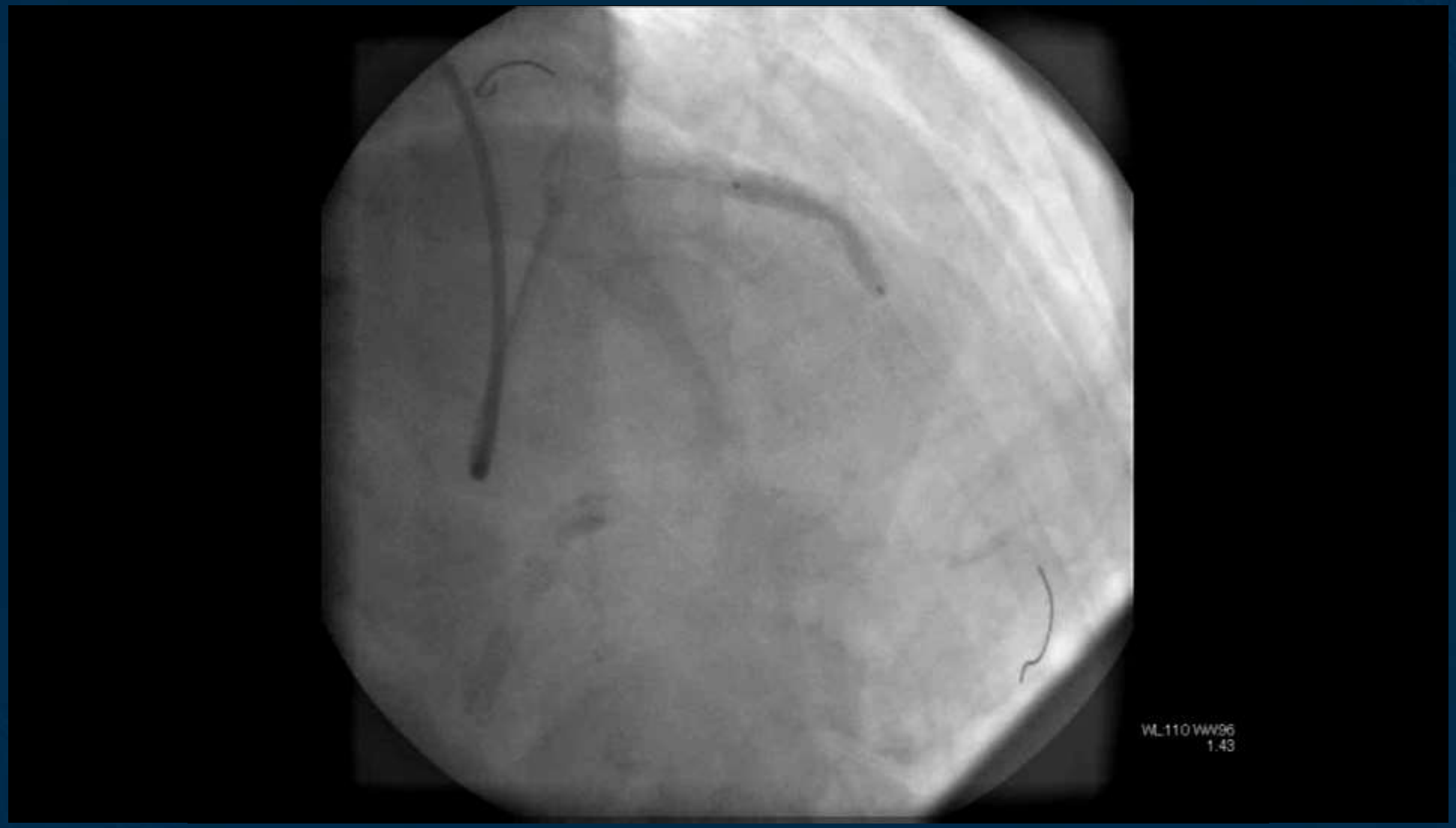


Pre NSE

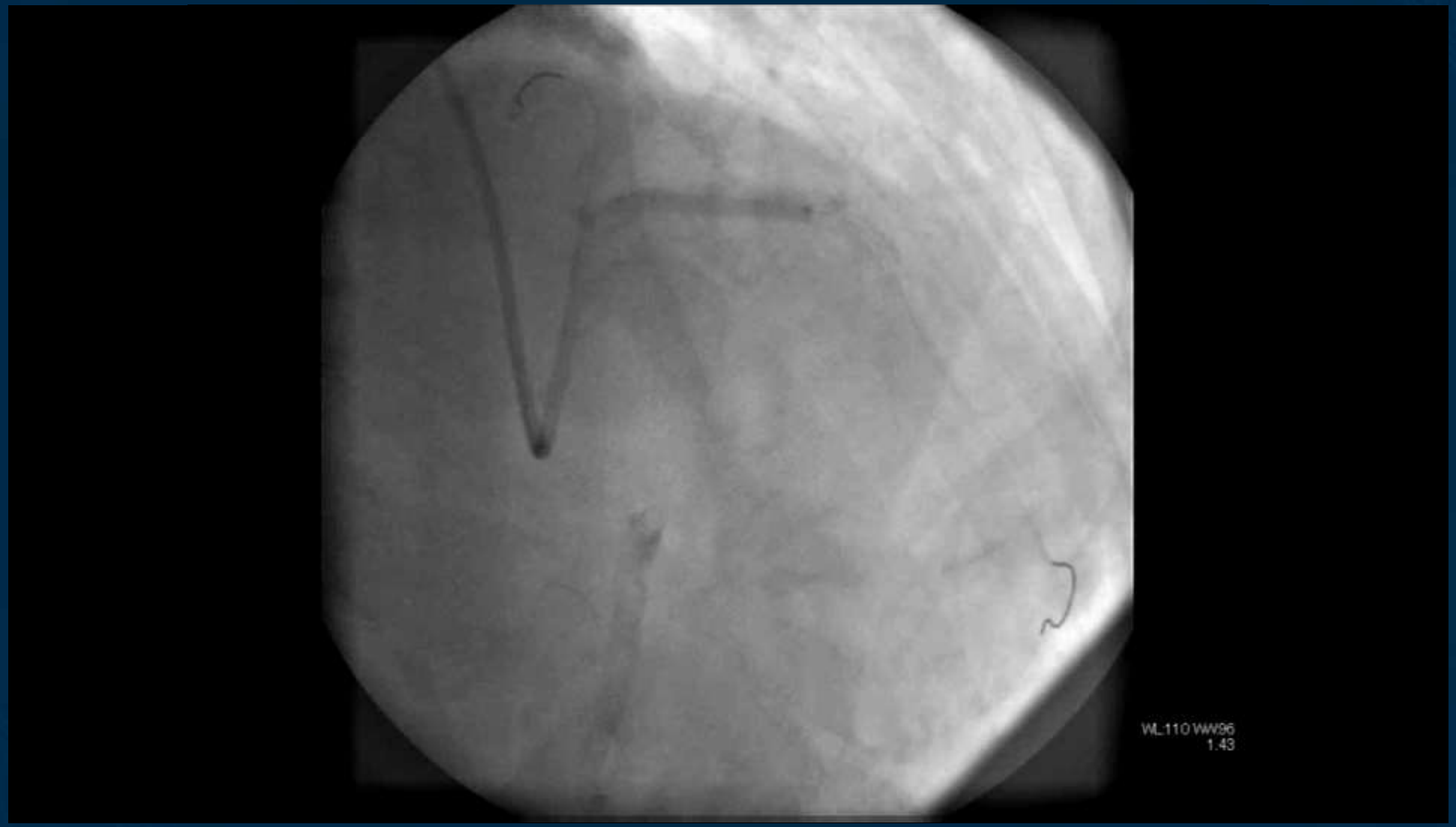


Post NSE

Stent（Xience V 3.5*28mm)

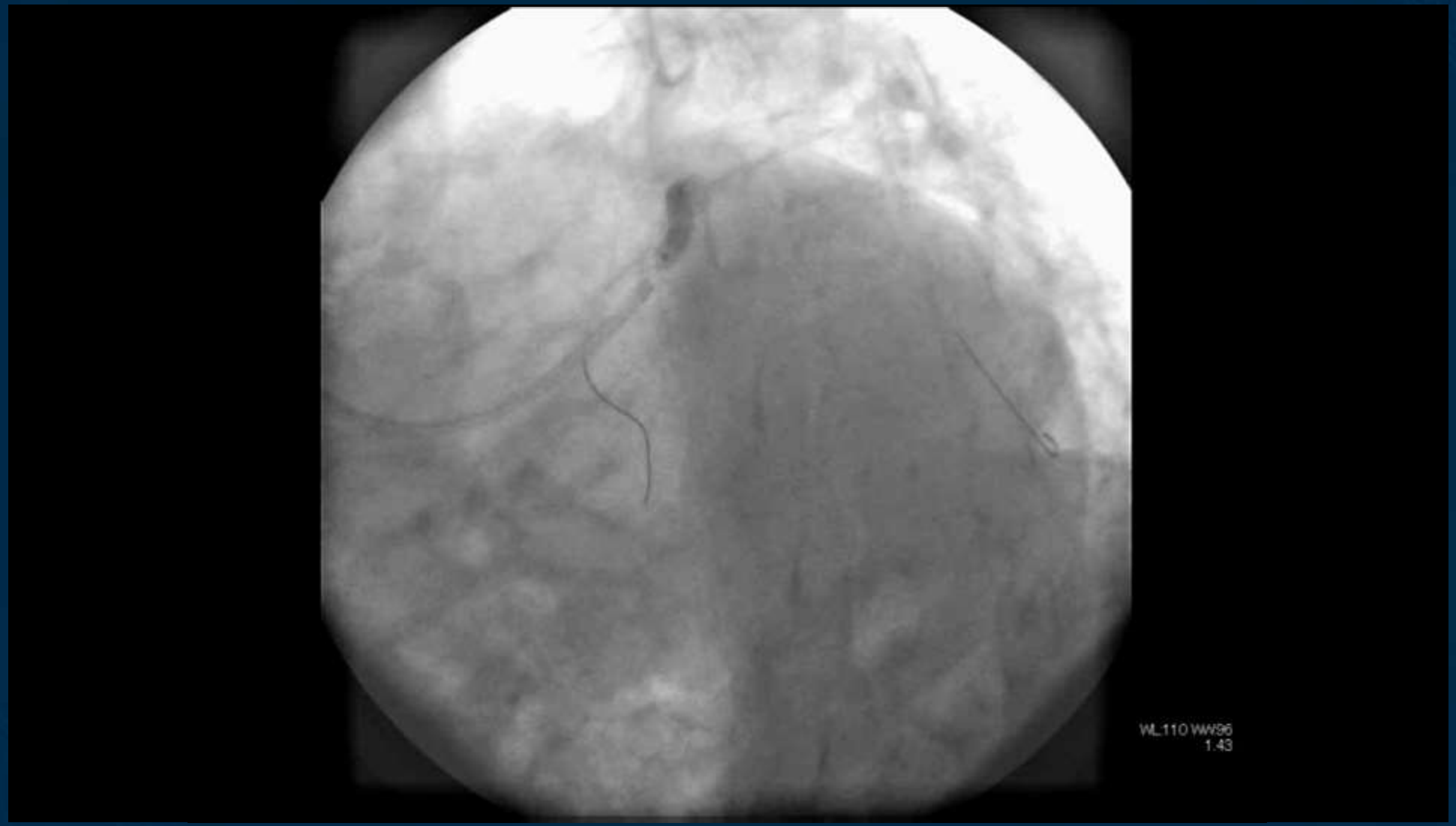


Stent（Xience 3.5*28mm)

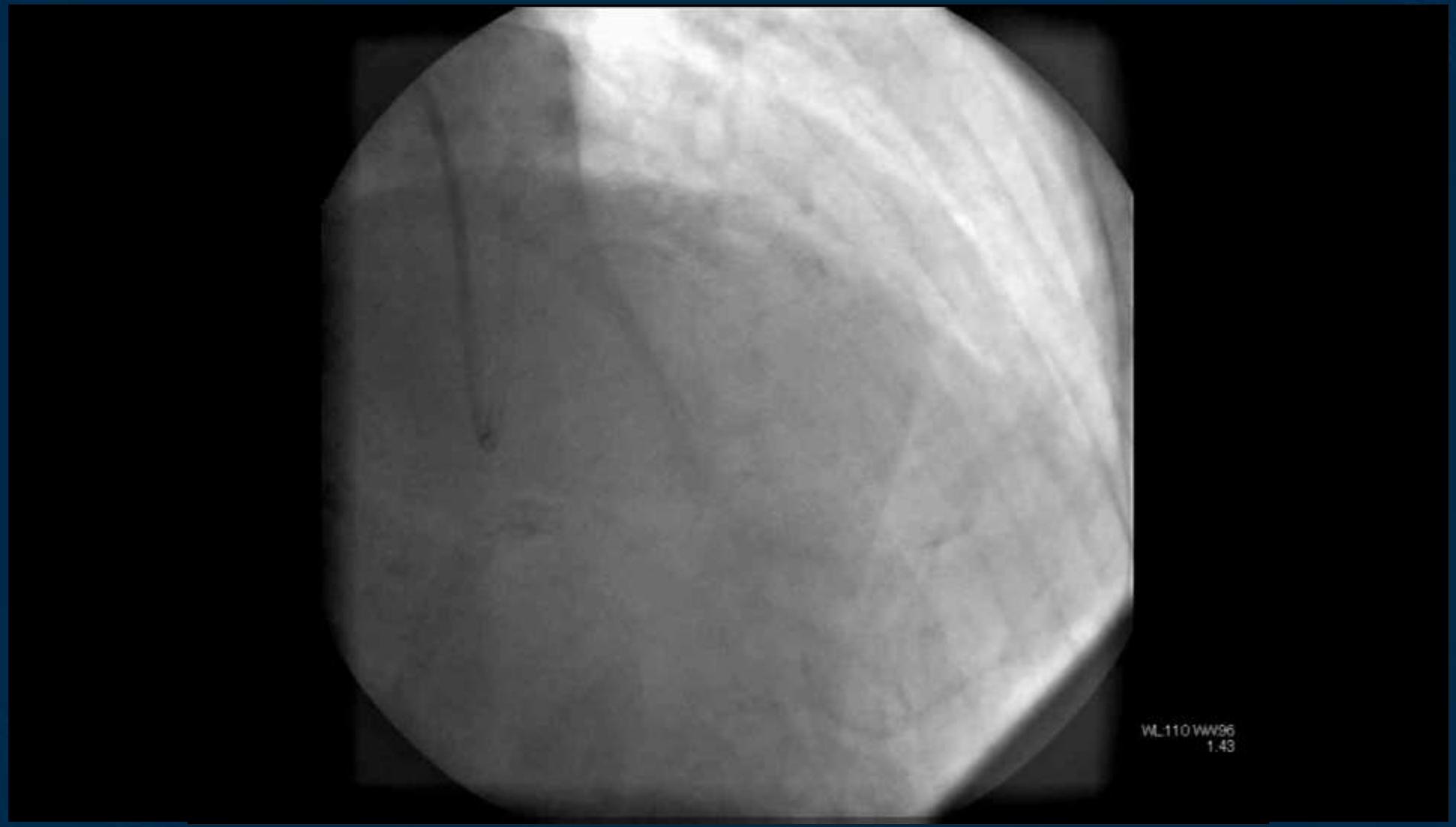


Stent②; LAO caudal

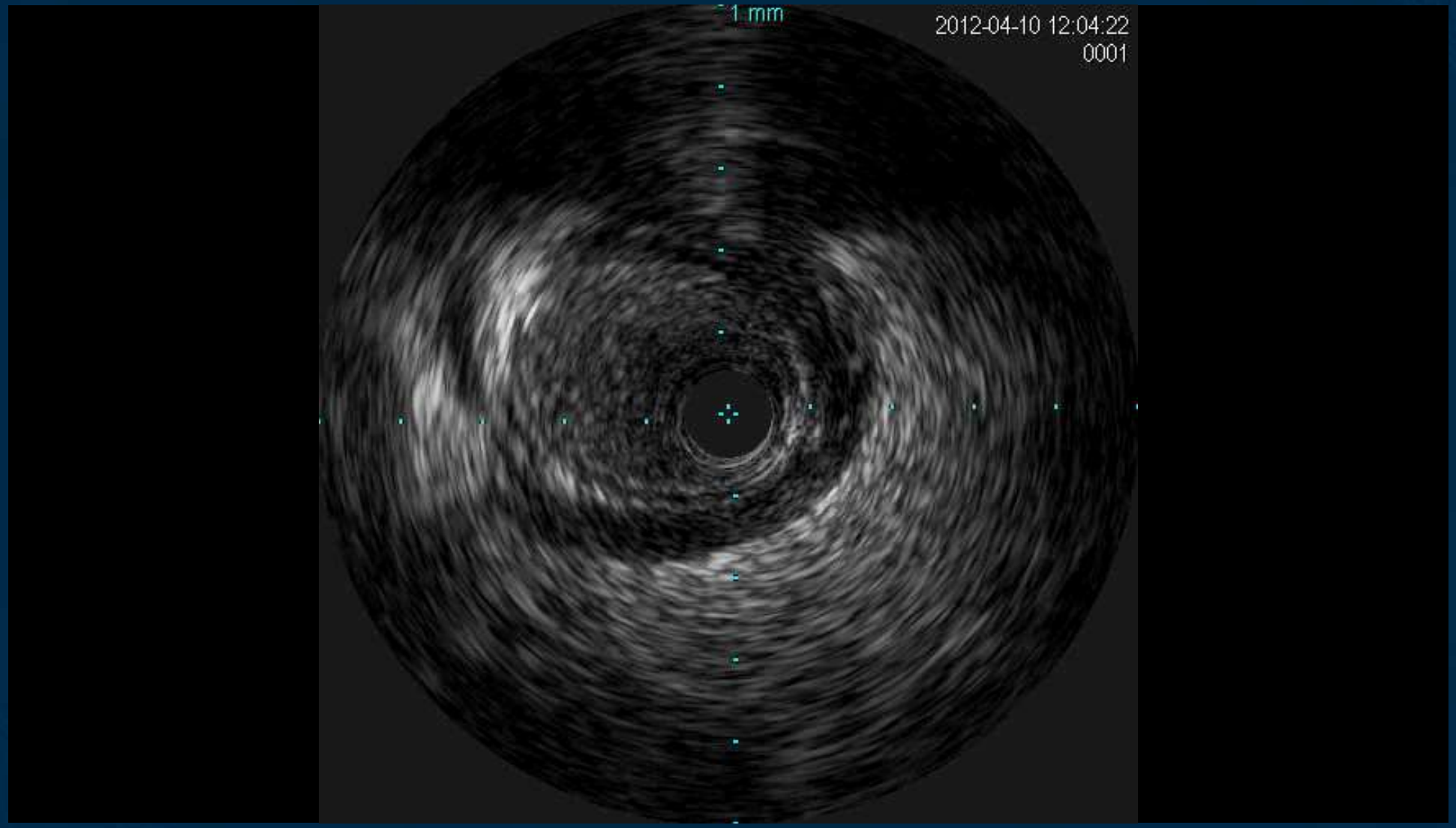
Additional post NSE inflation



Final CAG



Final IVUS



Case 2:
Late 70’s years old female

LAD mid (#6-7) with severe calcified

Approach: 6F TRI

GC: Mach1 CLS3.5 GW: runthrough extrafloppy, EliteⅡ

Diagnosis: dyspnea on exertion

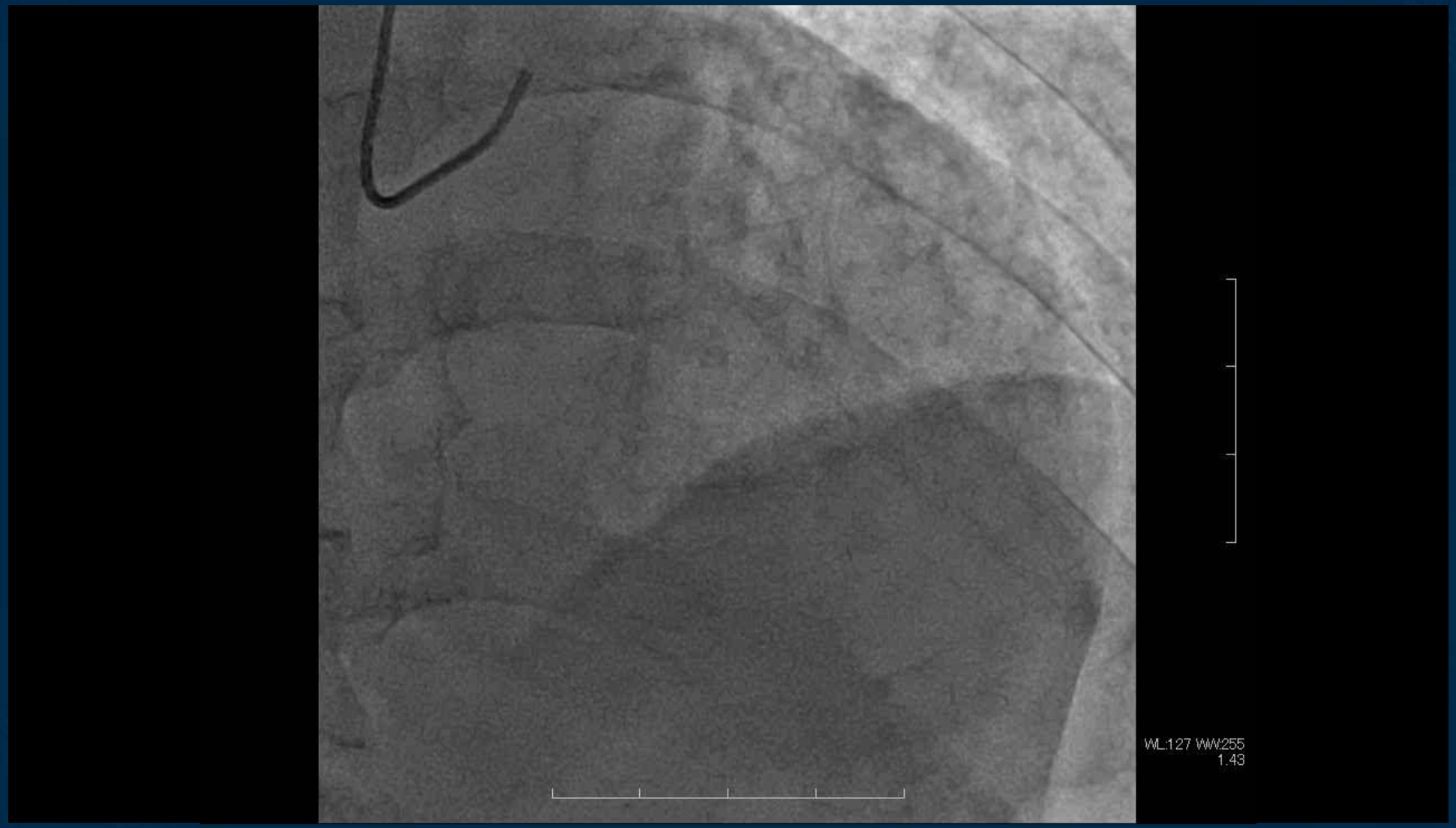
Risk factors: effort angina

Previous history: hypertension, diabetes

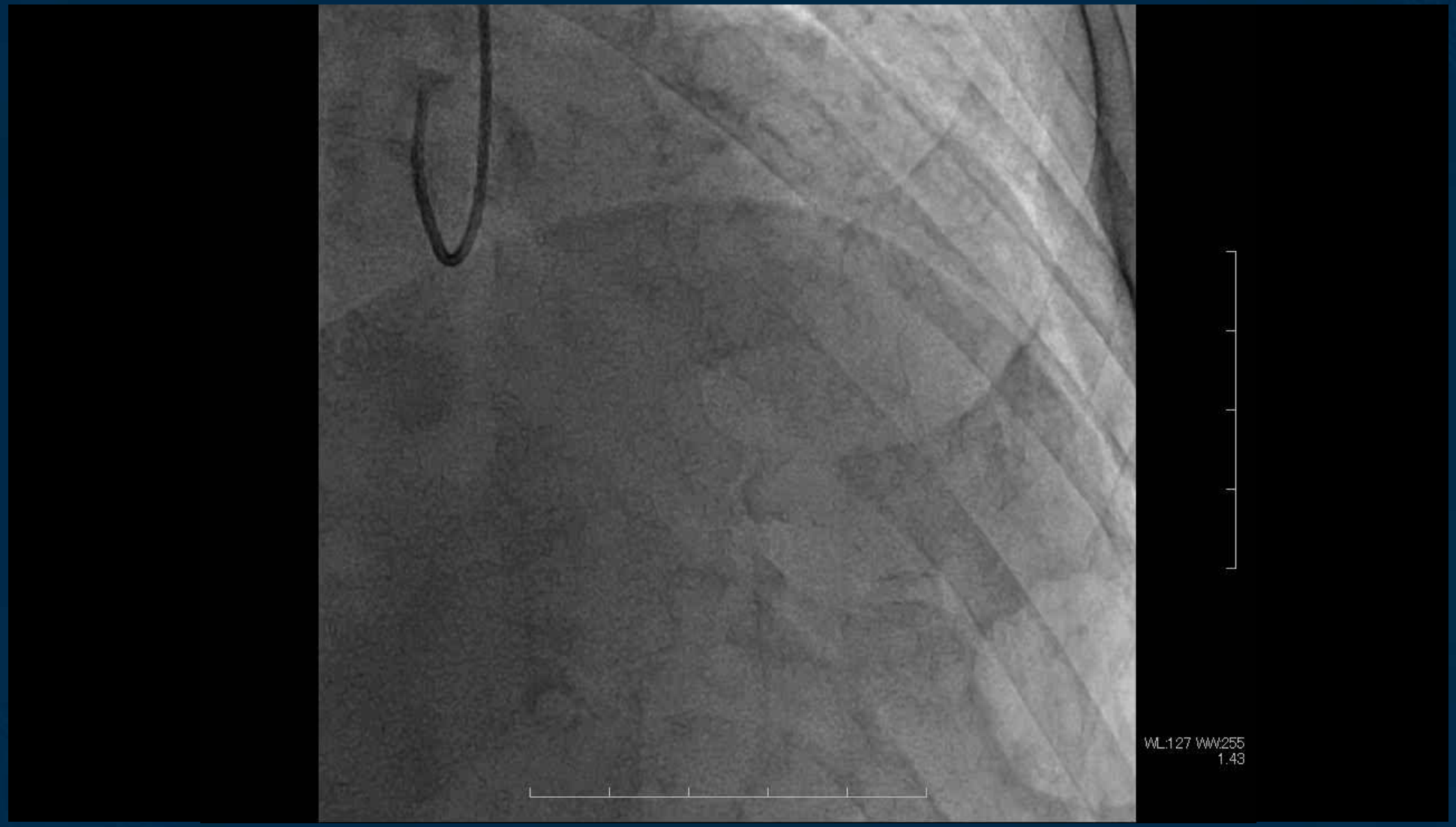
MDCT


Vessel Direction Based
Depth: 0.0 mm
Angle: 0.3 deg
LAD
2013/9/12
17:54:27.000
WL:391 WW:1219
1.43
CPR-A

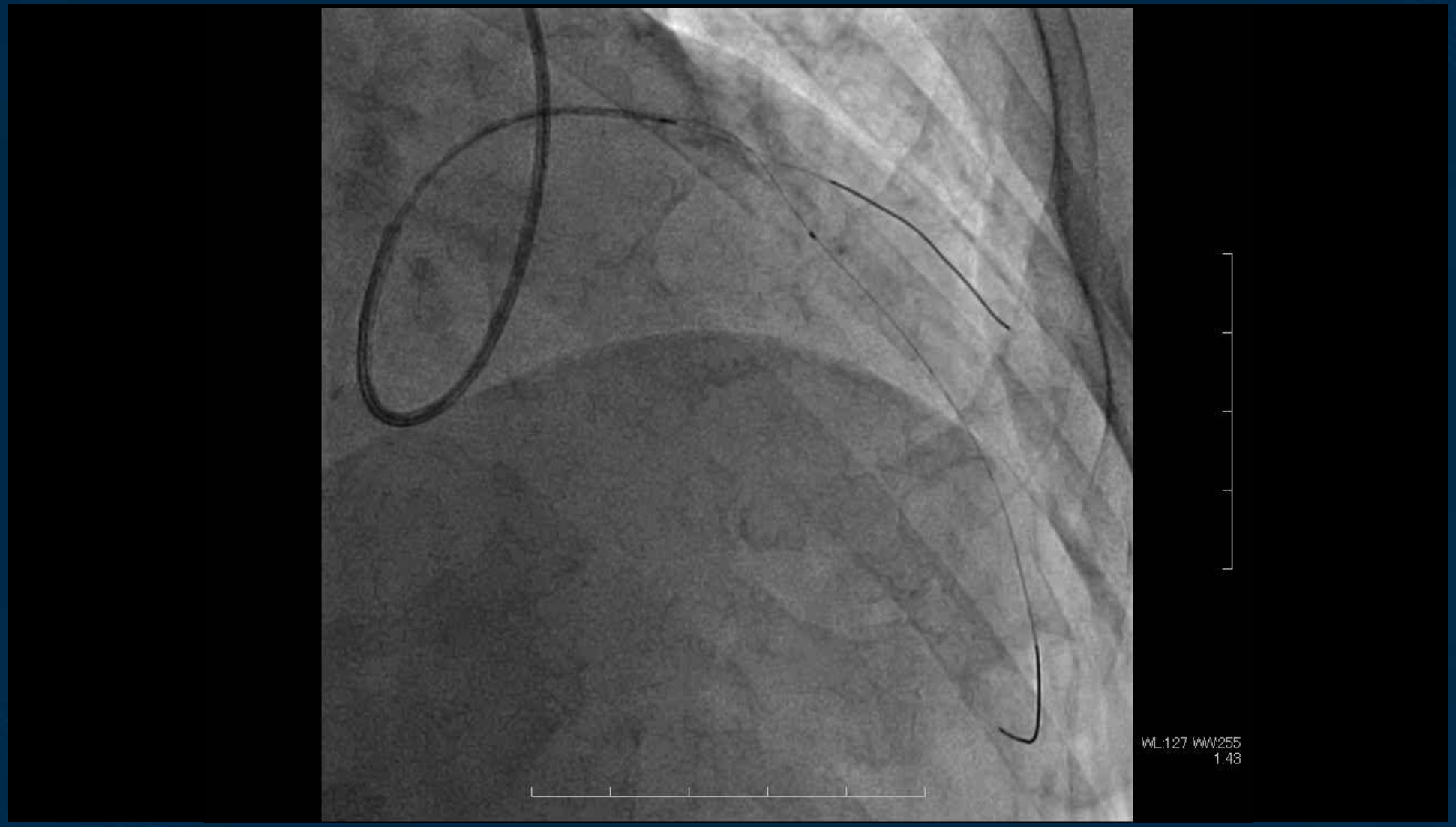
Pre PCI; AP cranial



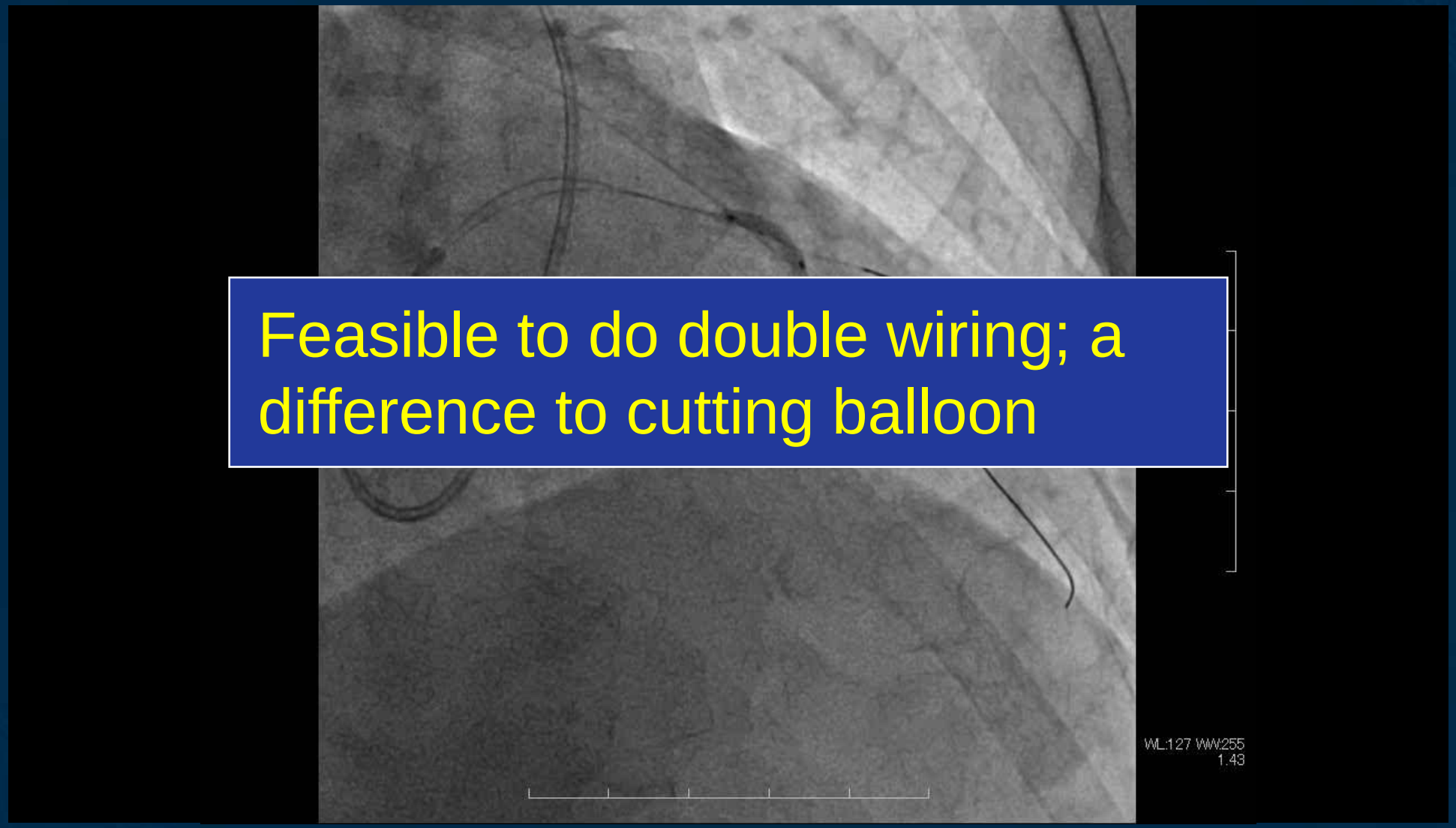
Pre PCI; RAO cranial



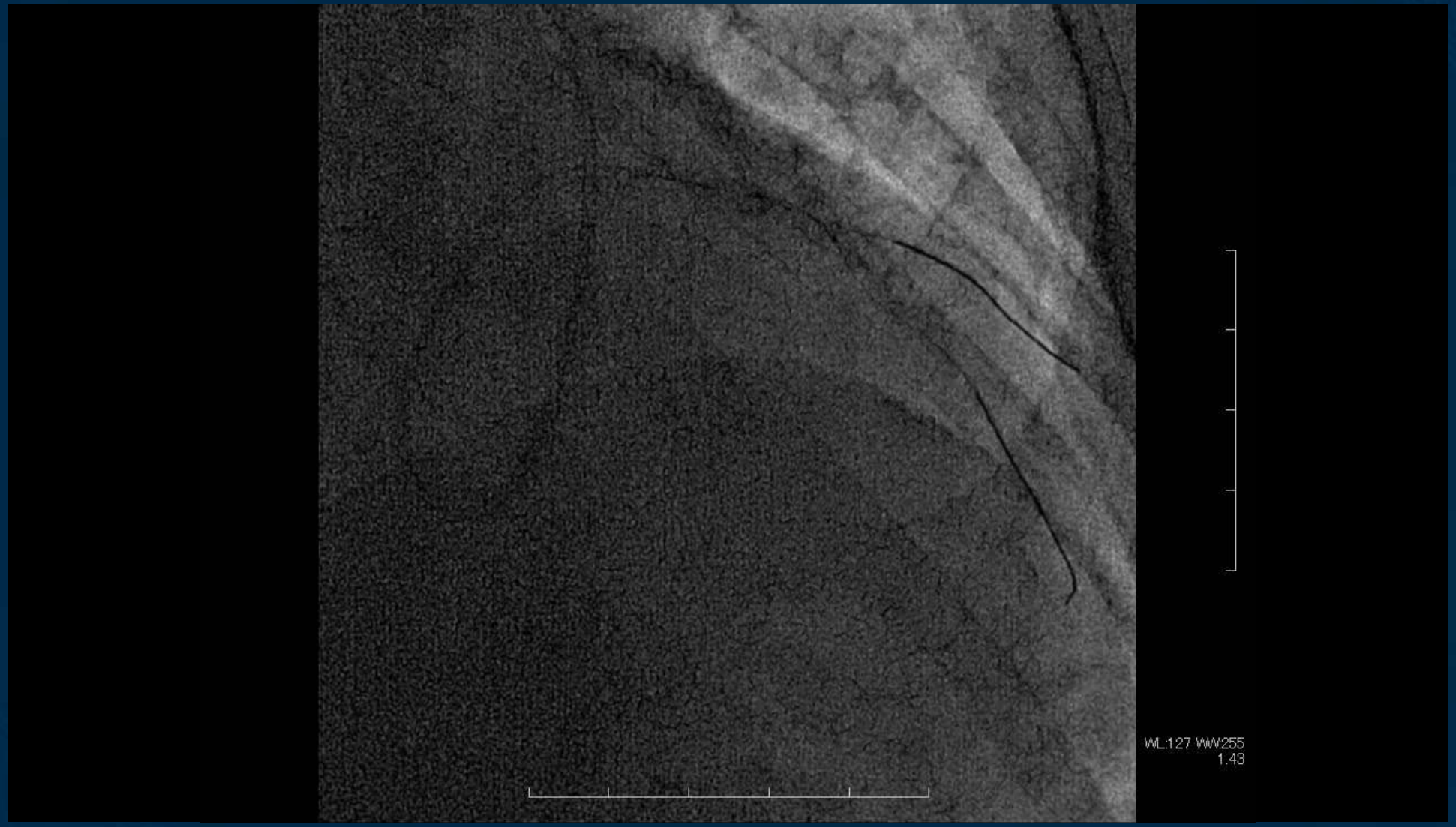
Pre IVUS; unable to cross



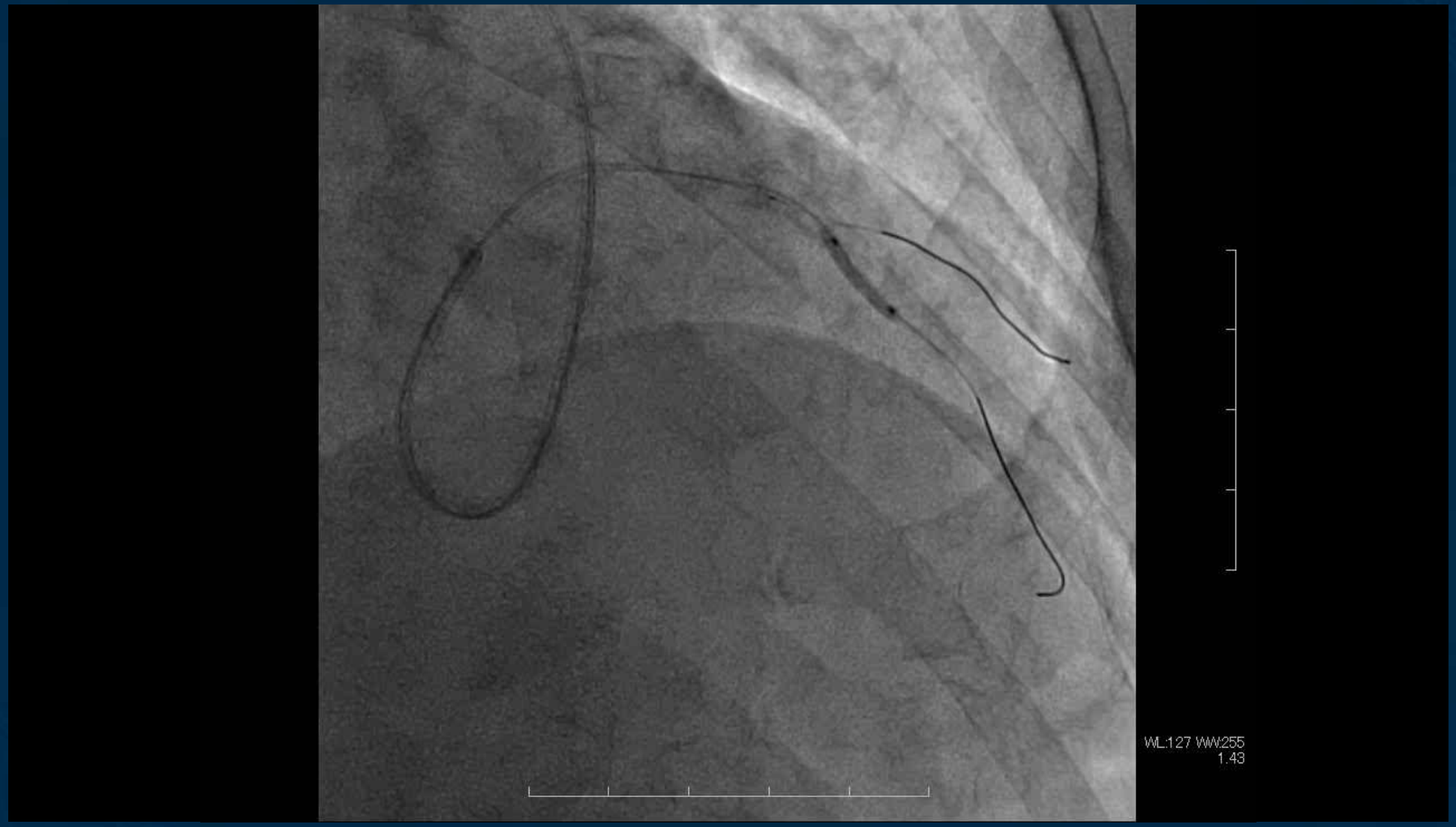
Lacrosse NSEα 2.25mm@6atm



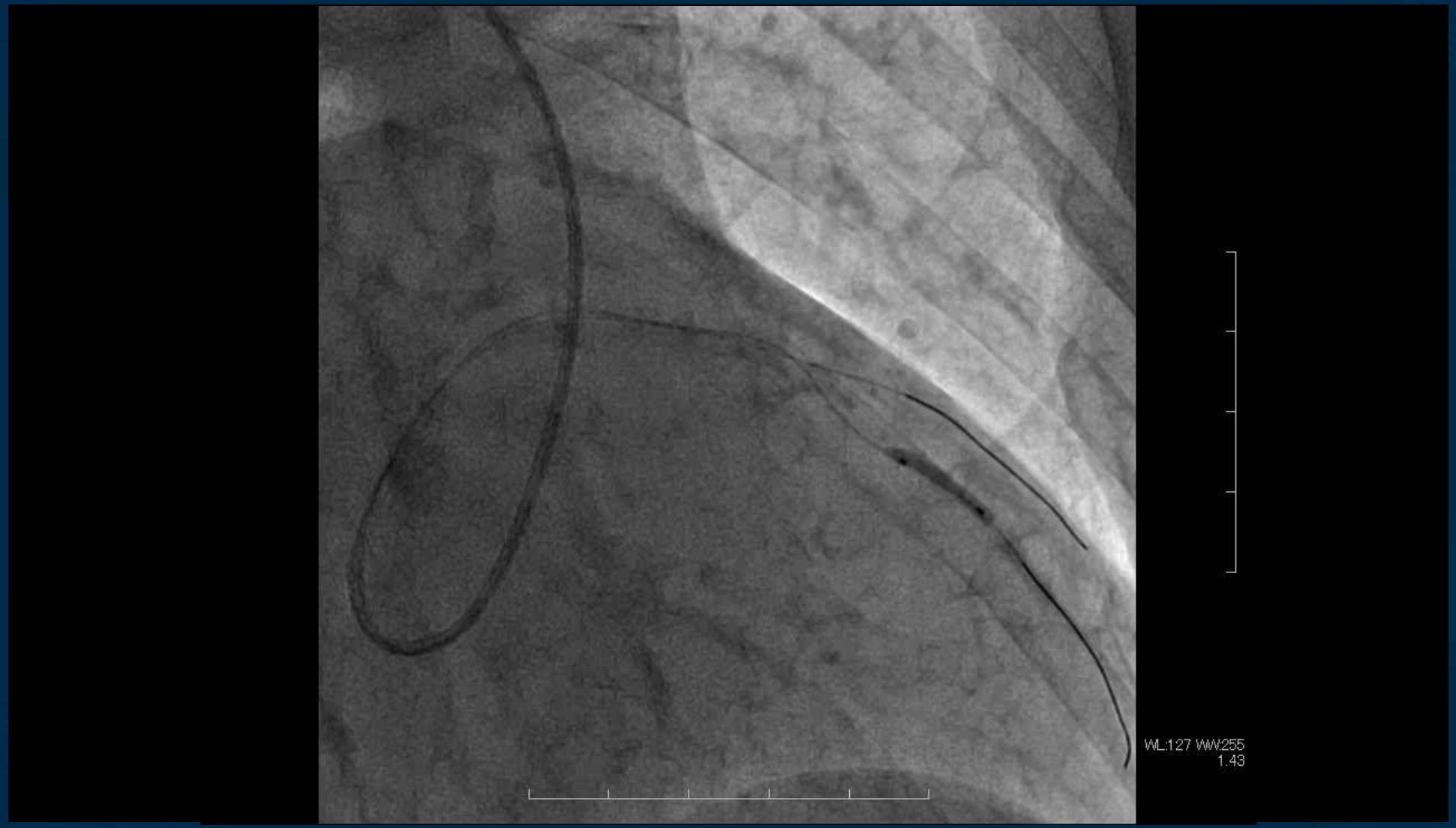
Lacrosse NSEα; leopard crawl



Lacrosse NSEα；distal location

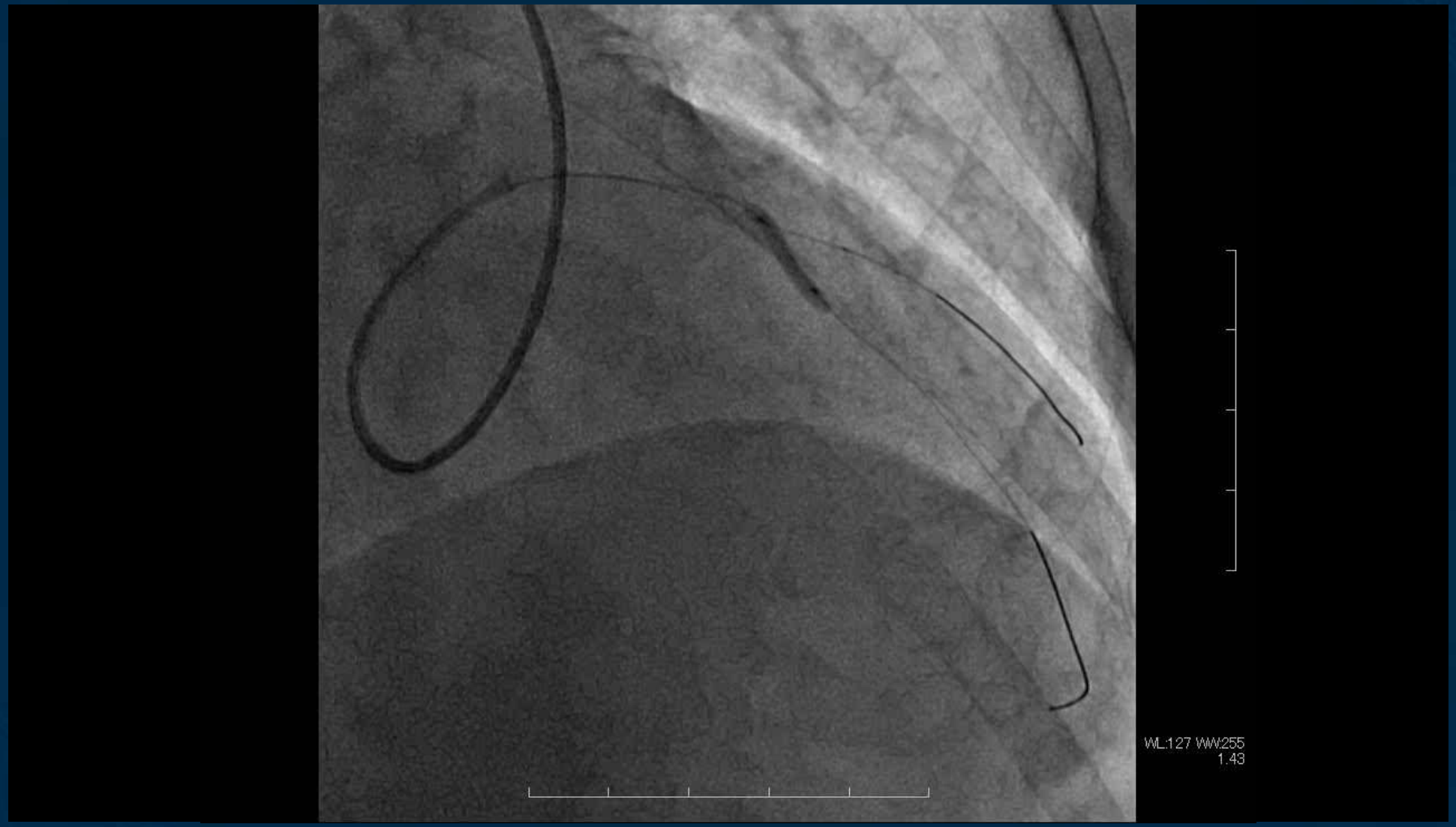


Lacrosse NSEα@12atm

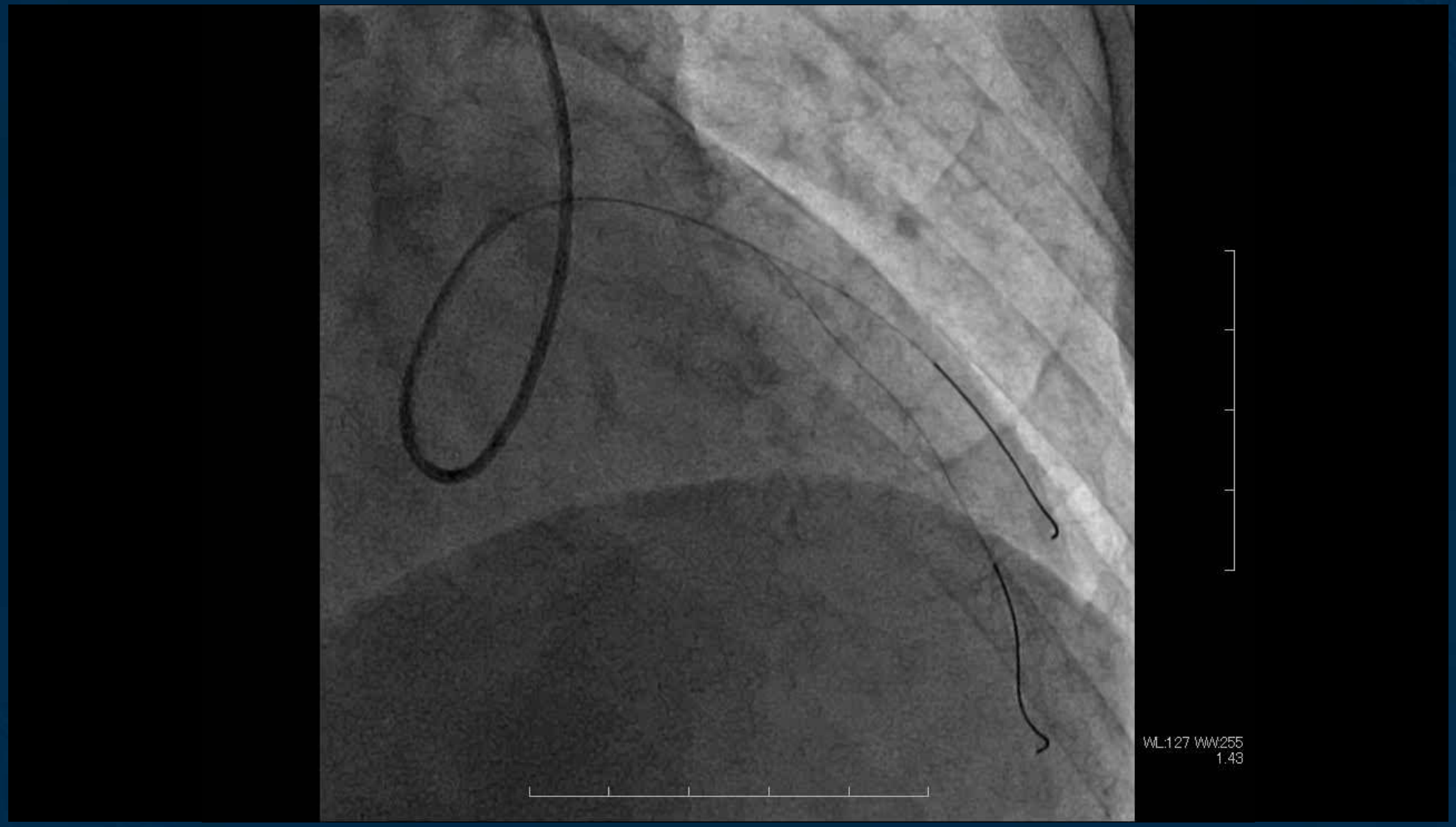


Lacrosse NSE:

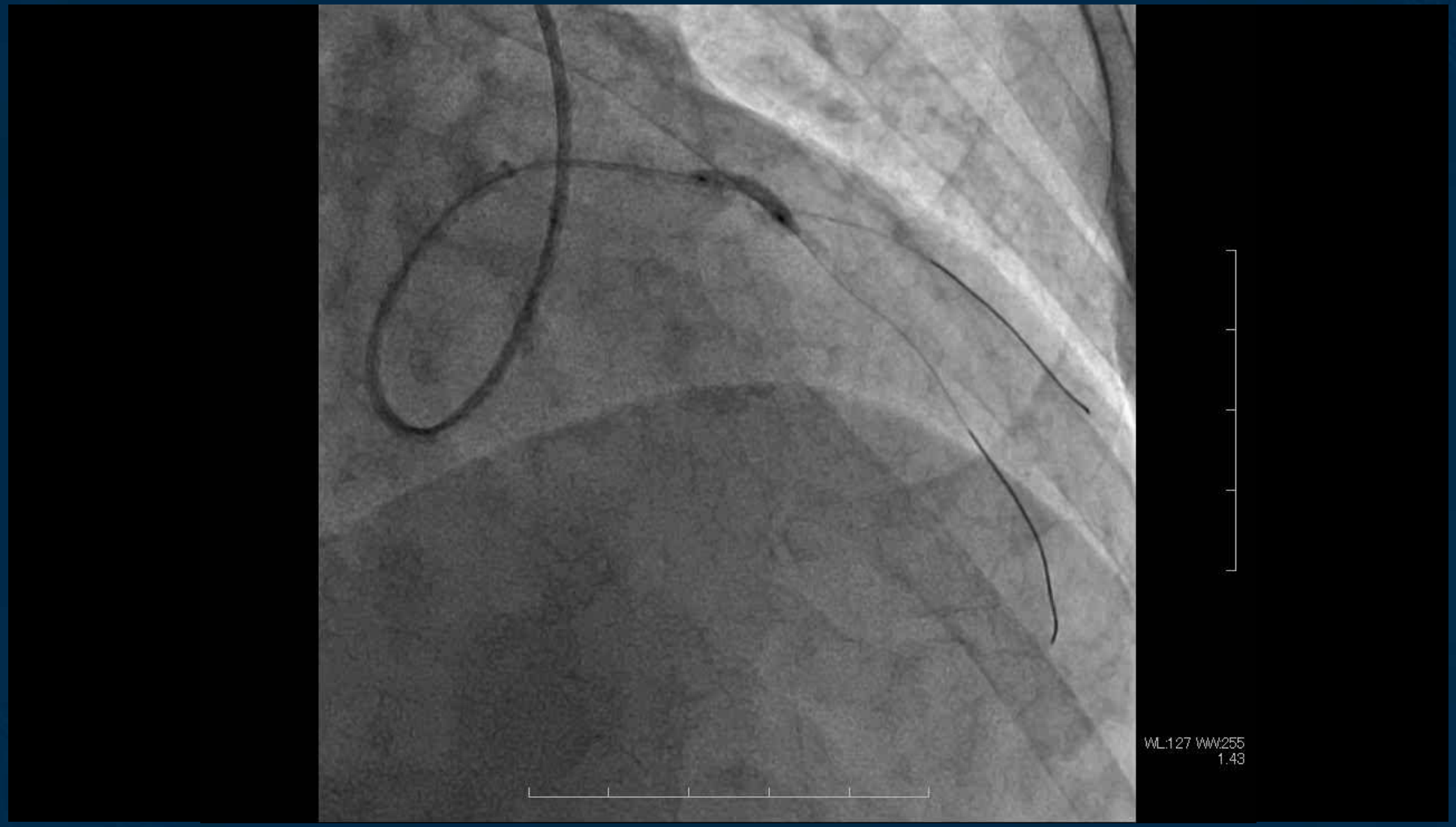
high pressure inflation @14atm upon proximal positioning



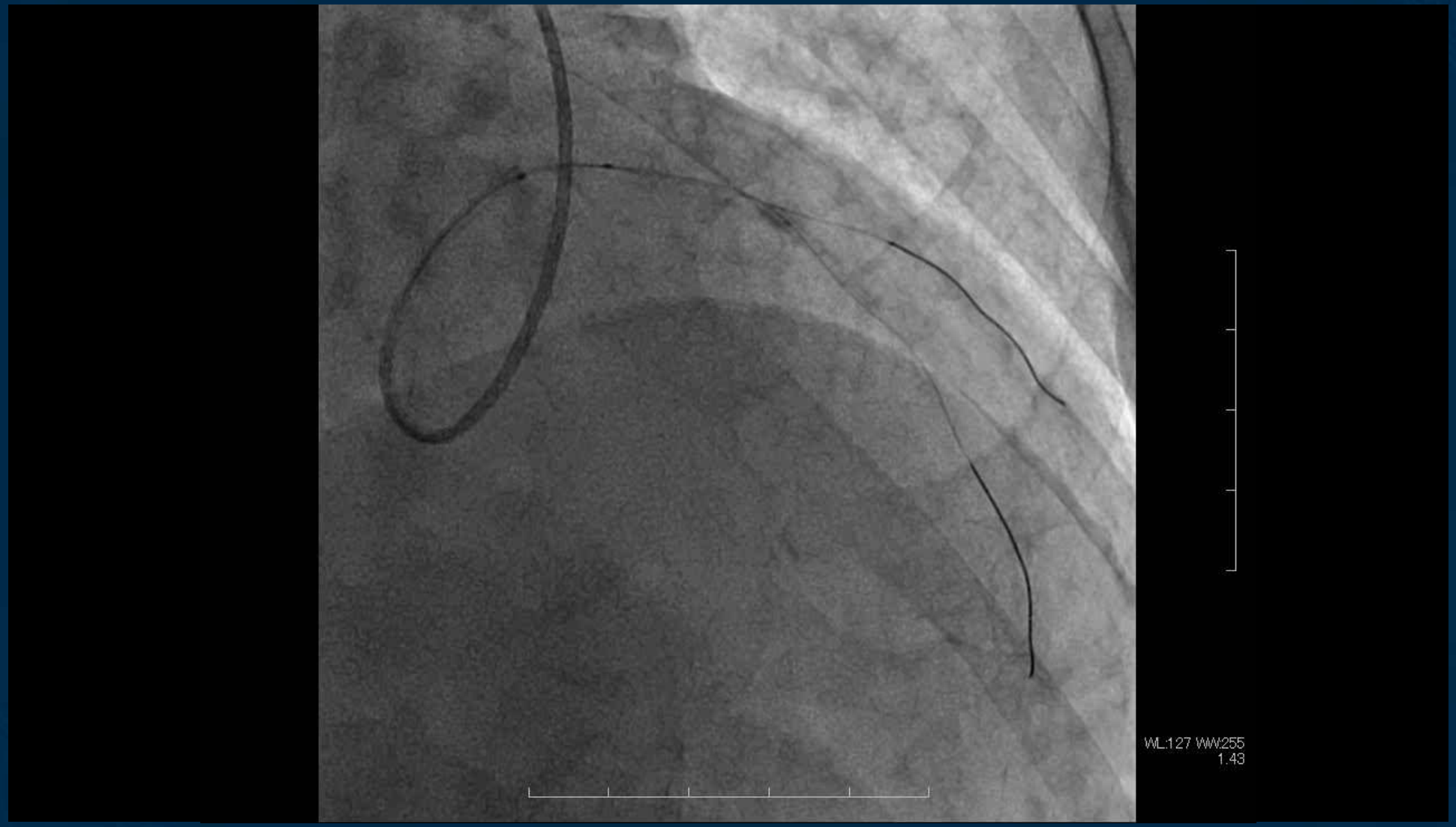
Push test : resistance



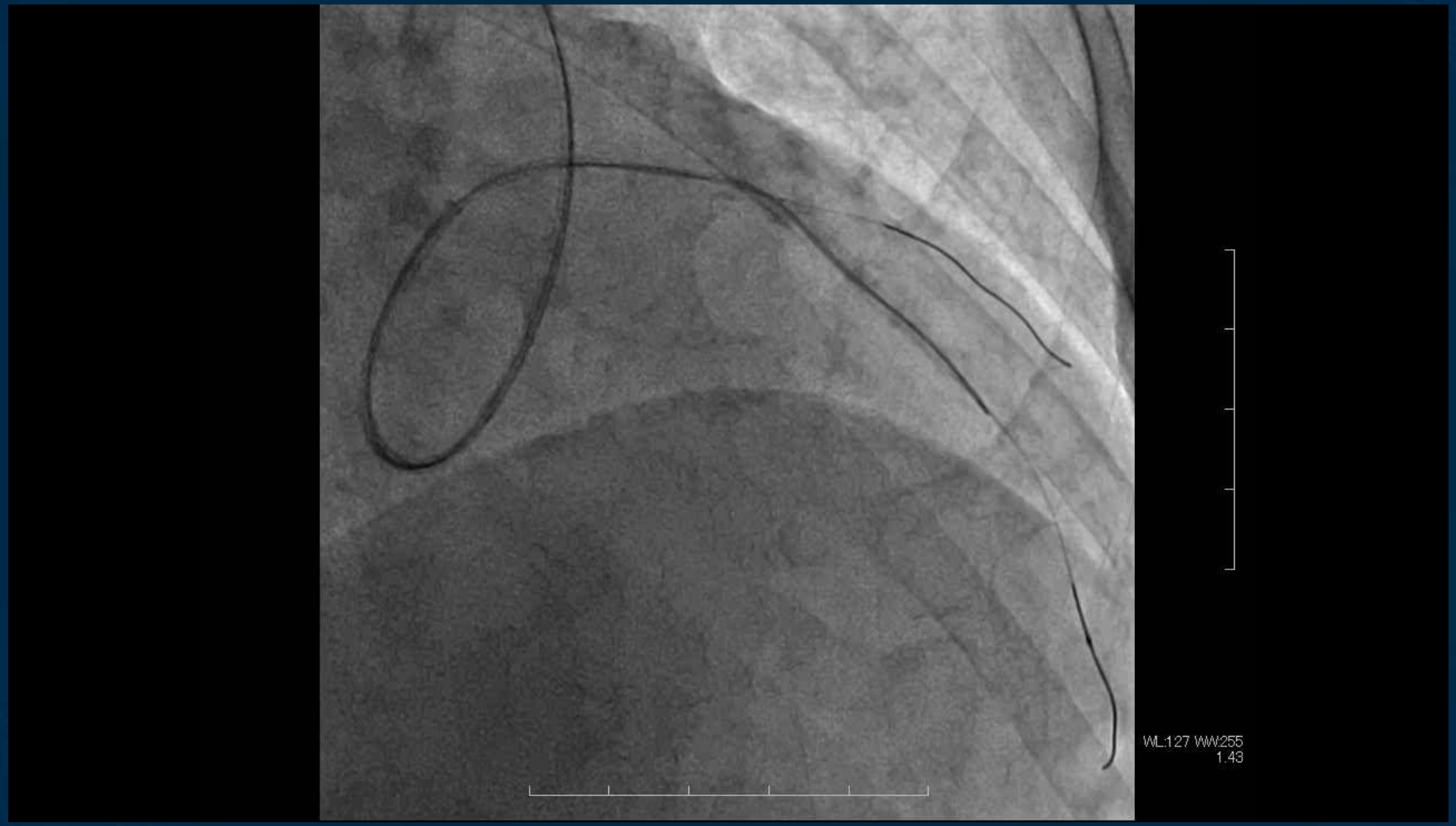
Additional inflation at location of resistance@14-16atm



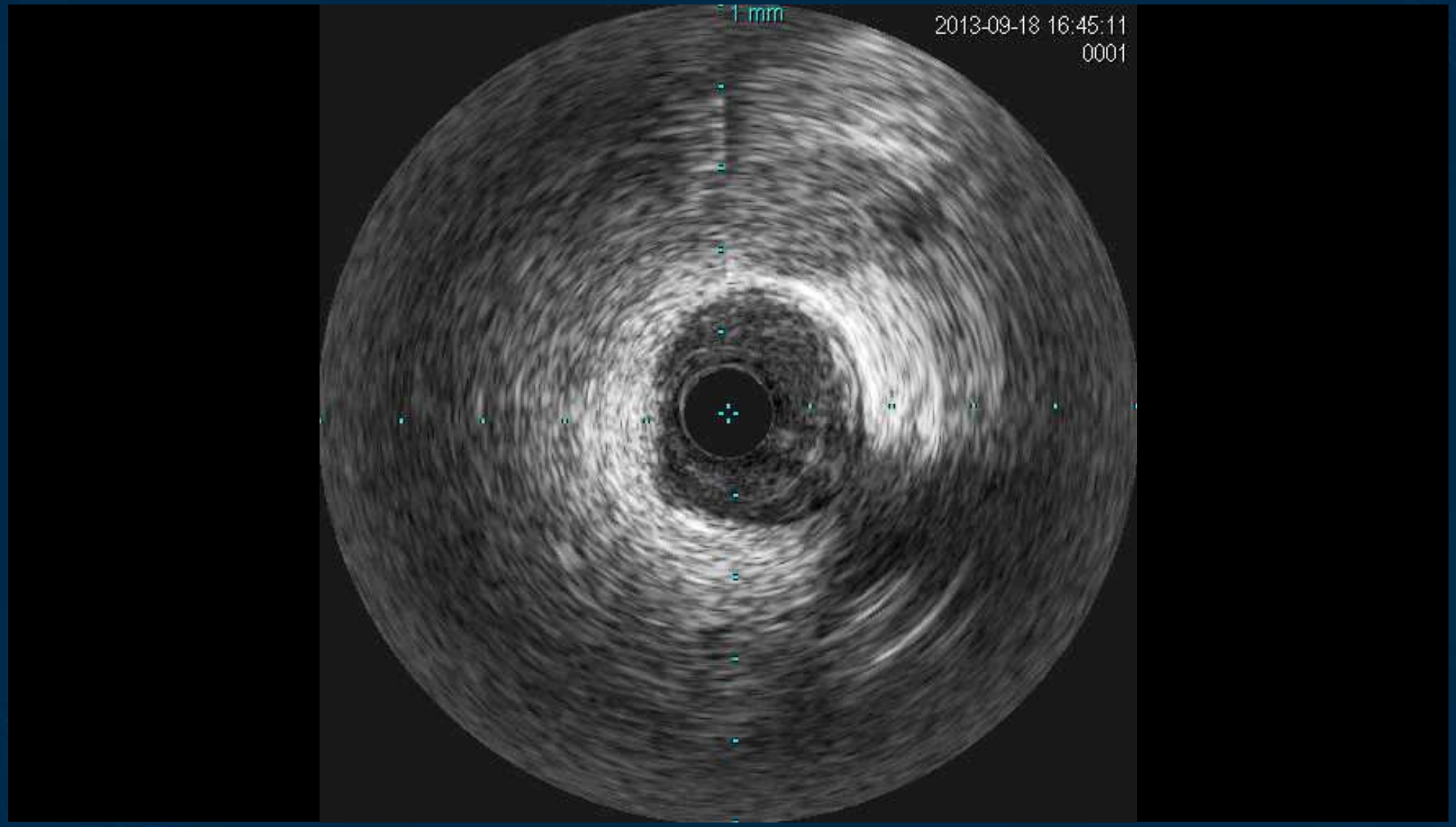
Repeated push test



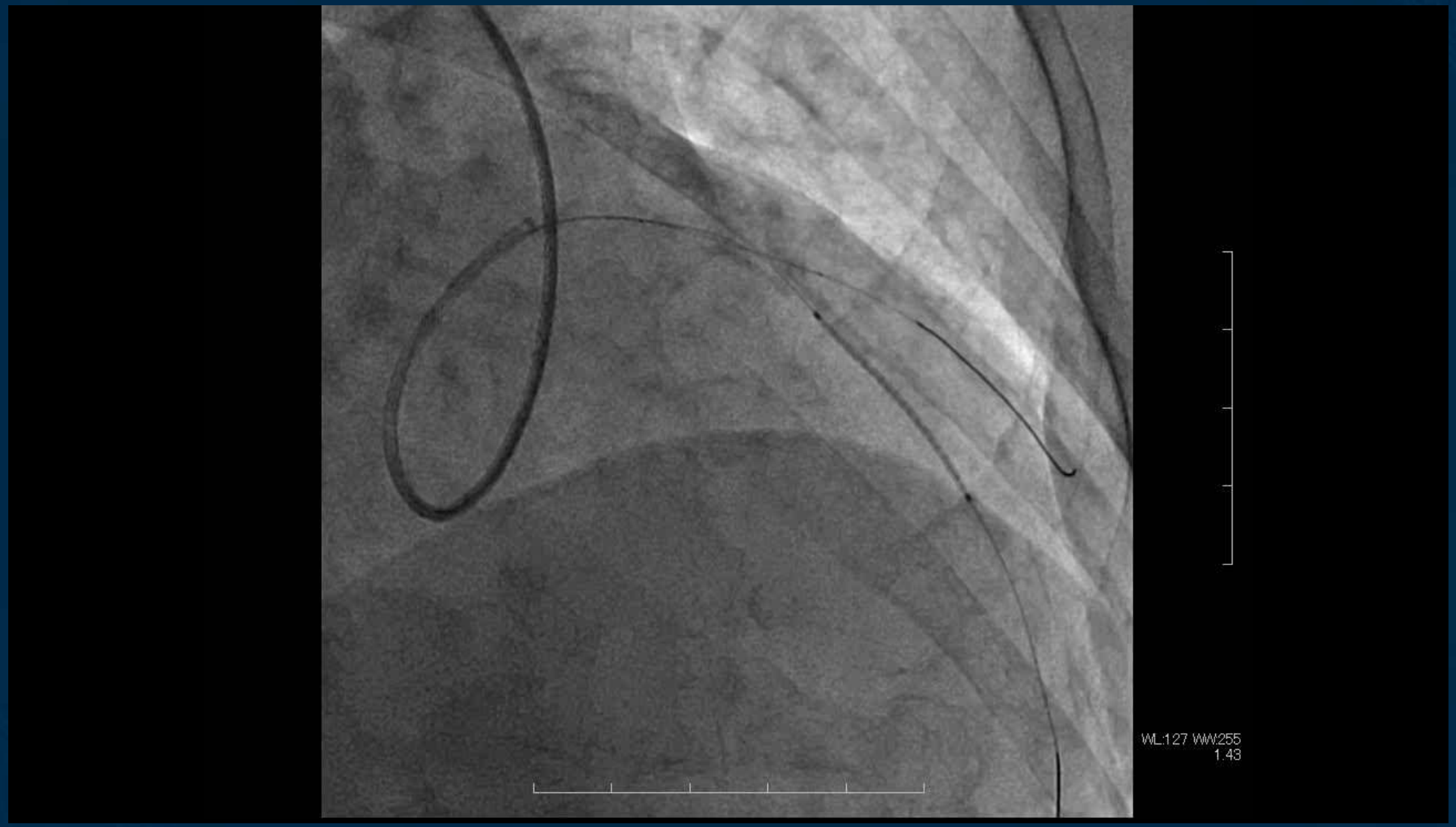
IVUS crossed



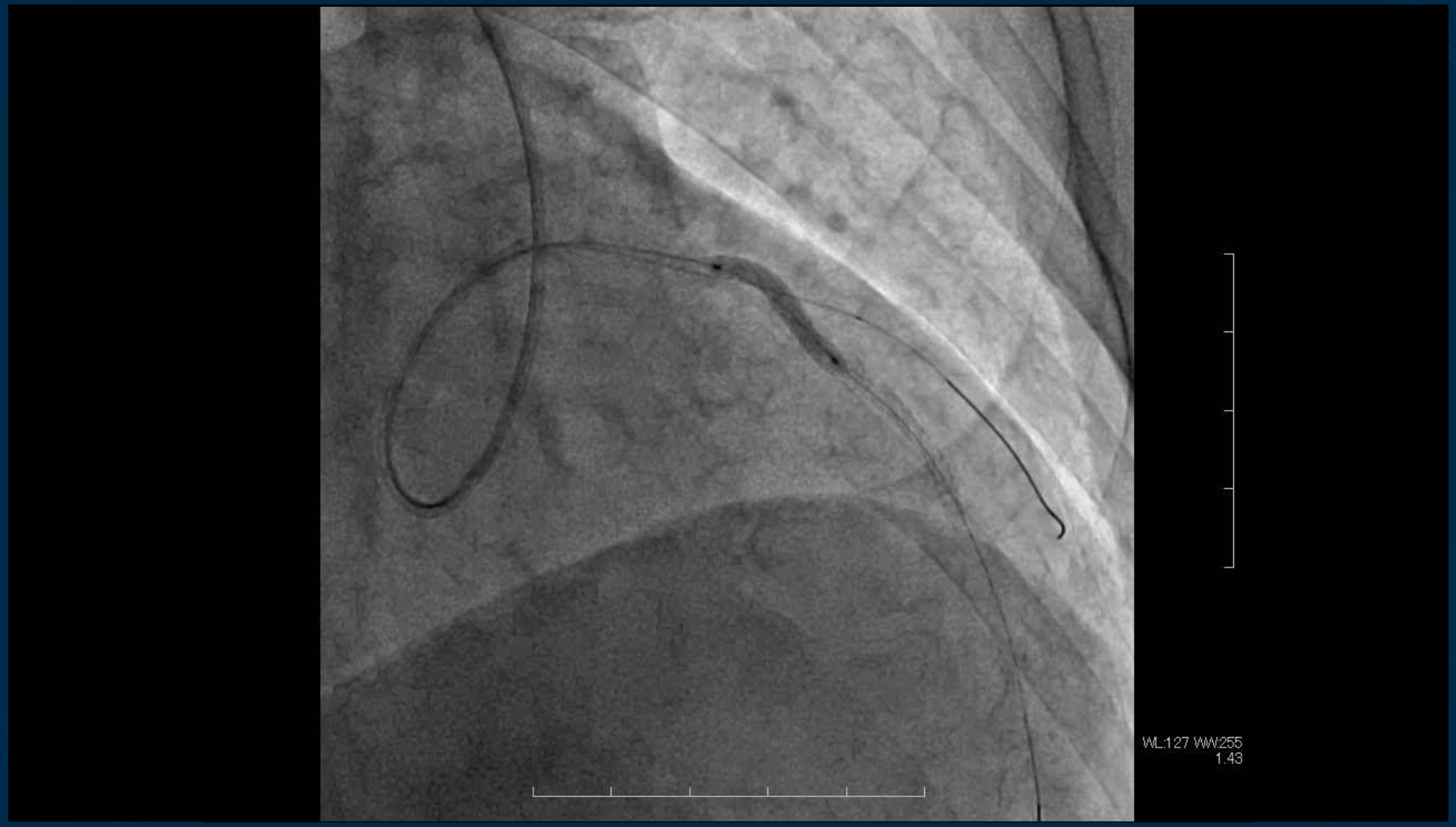
IVUS post NSE inflation



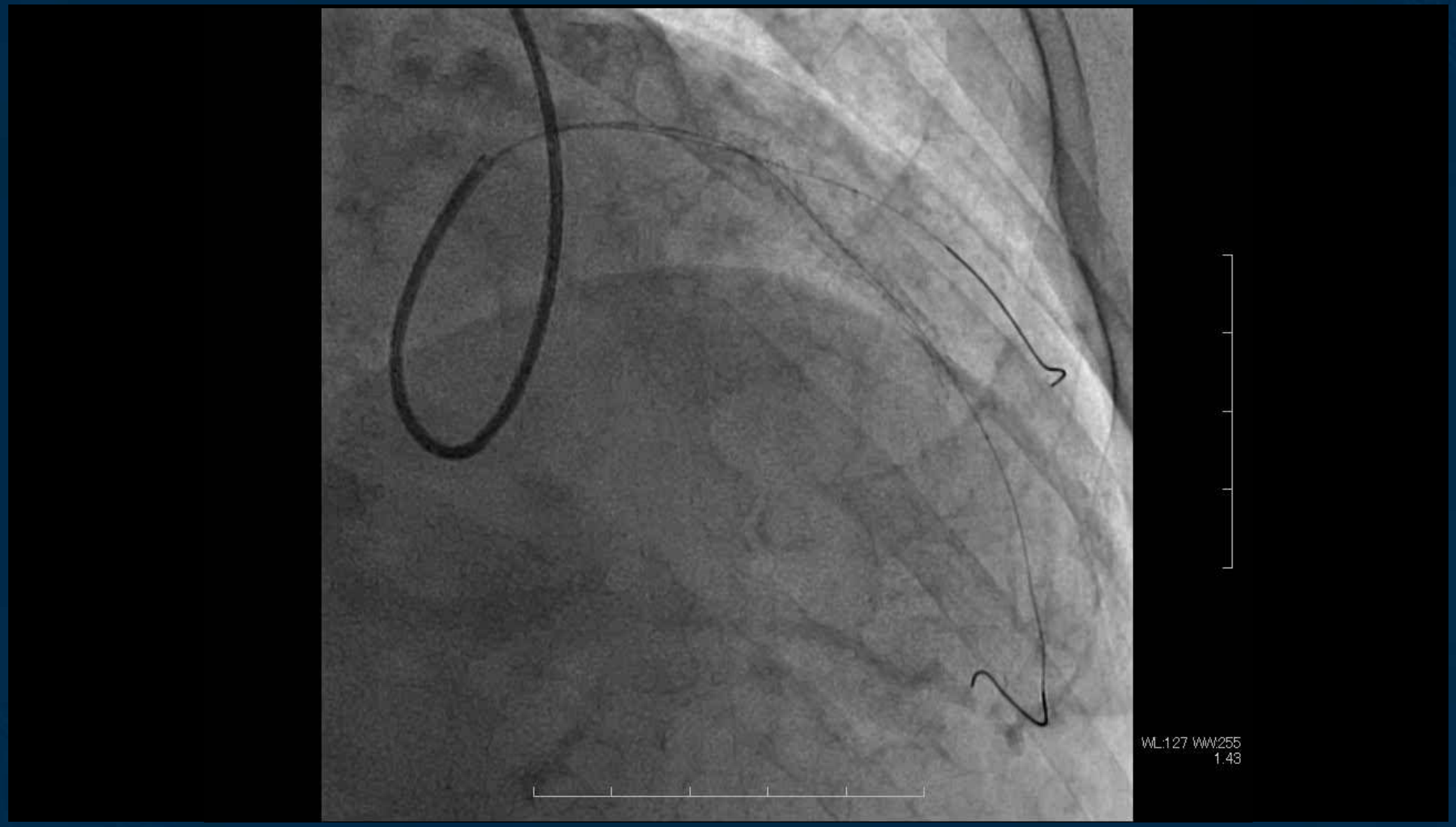
NOBORI 2.5*28mm @12atm



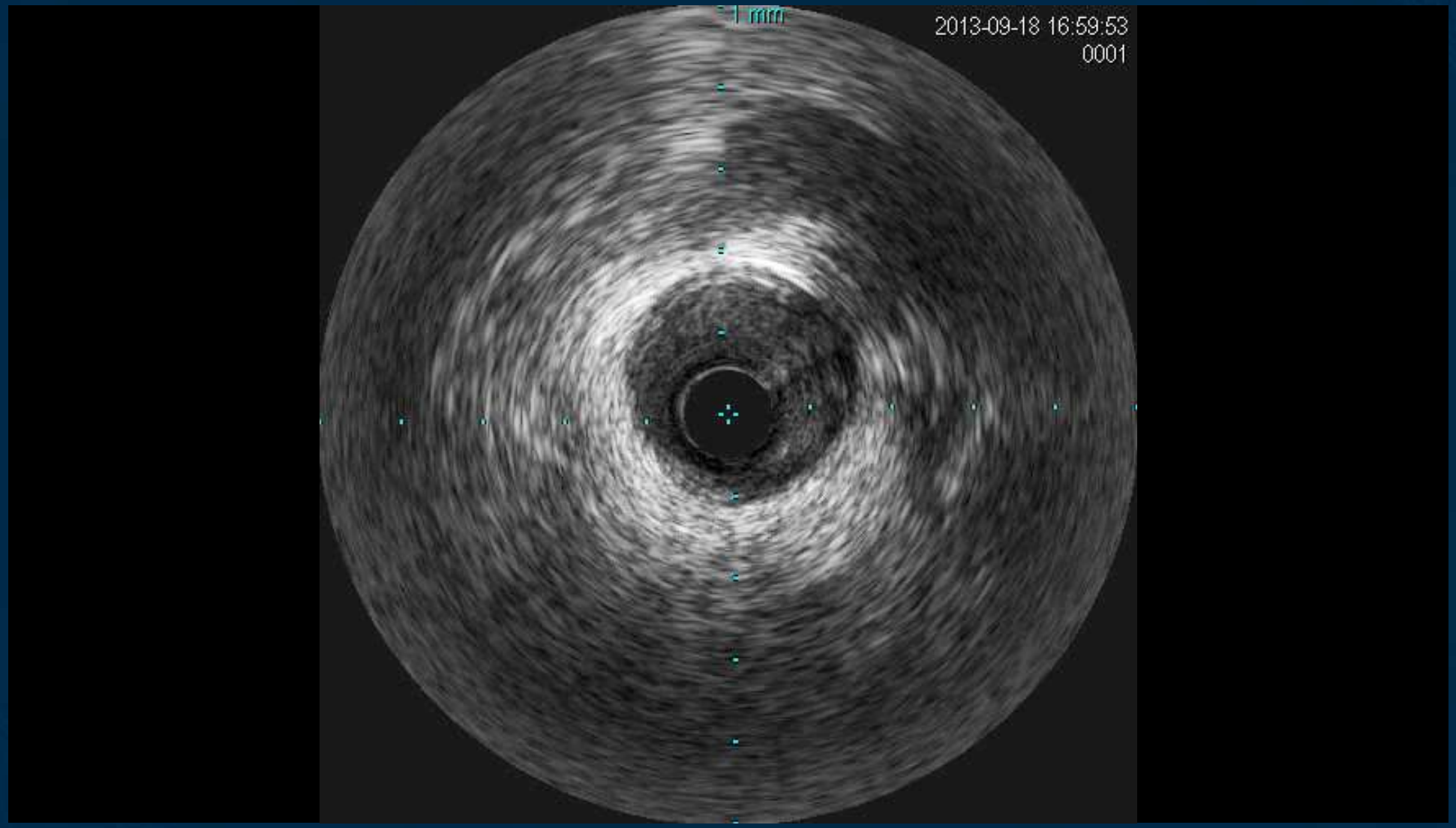
NOBORI 3.0*18mm @12atm



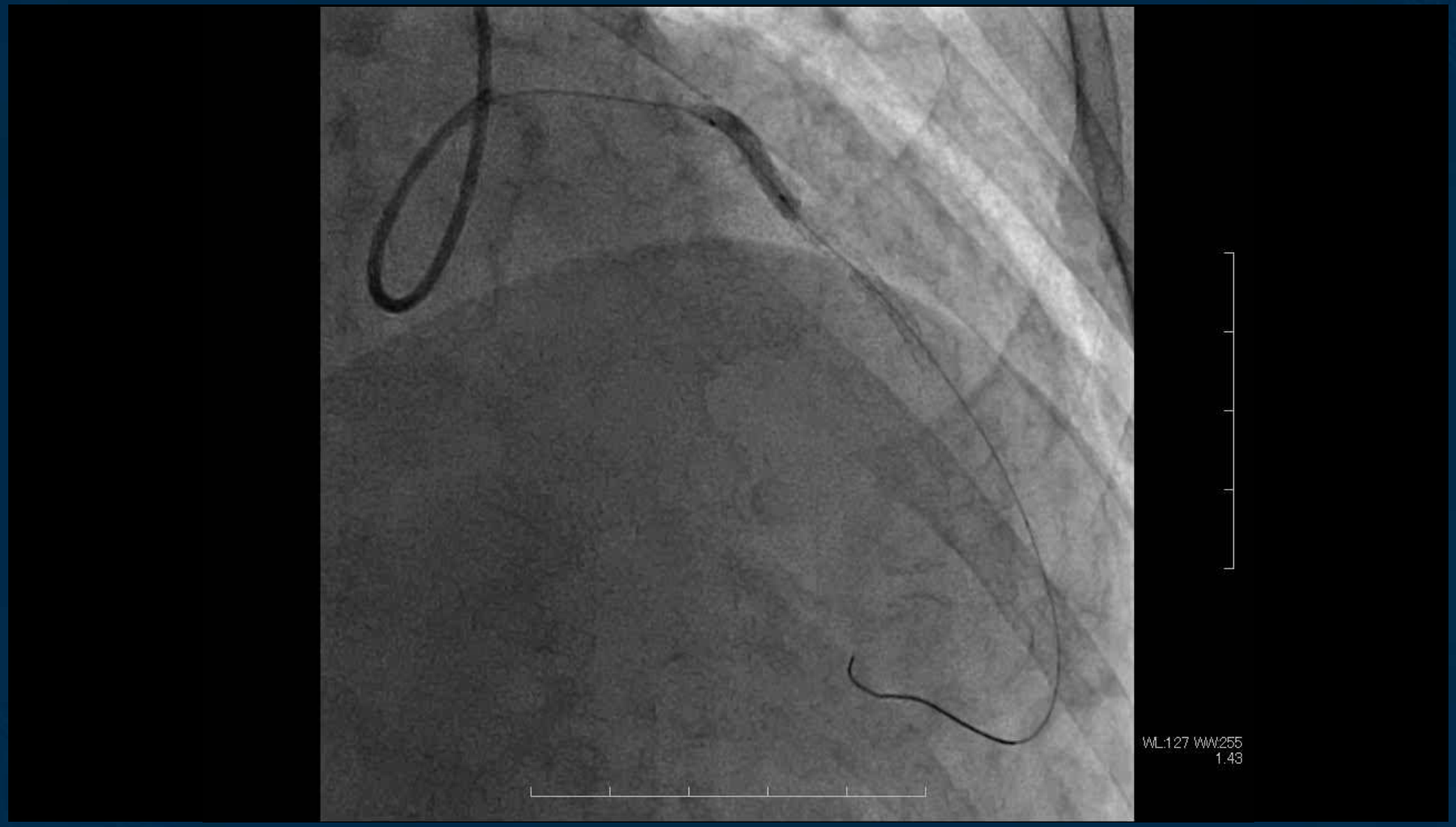
Post stent implantation



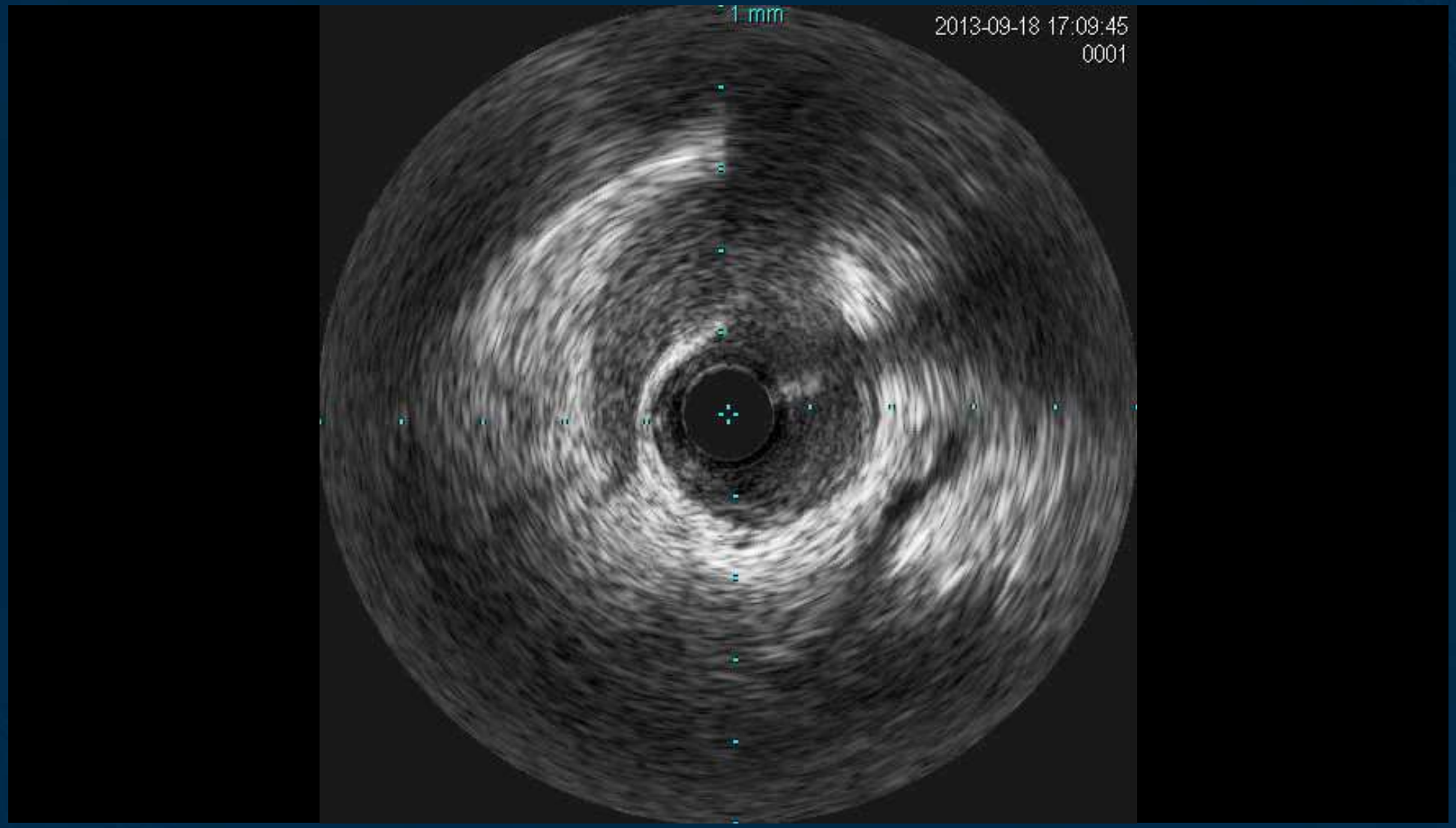
IVUS post stenting



Post balloon; Quantum Apex3.25mm @ 18atm

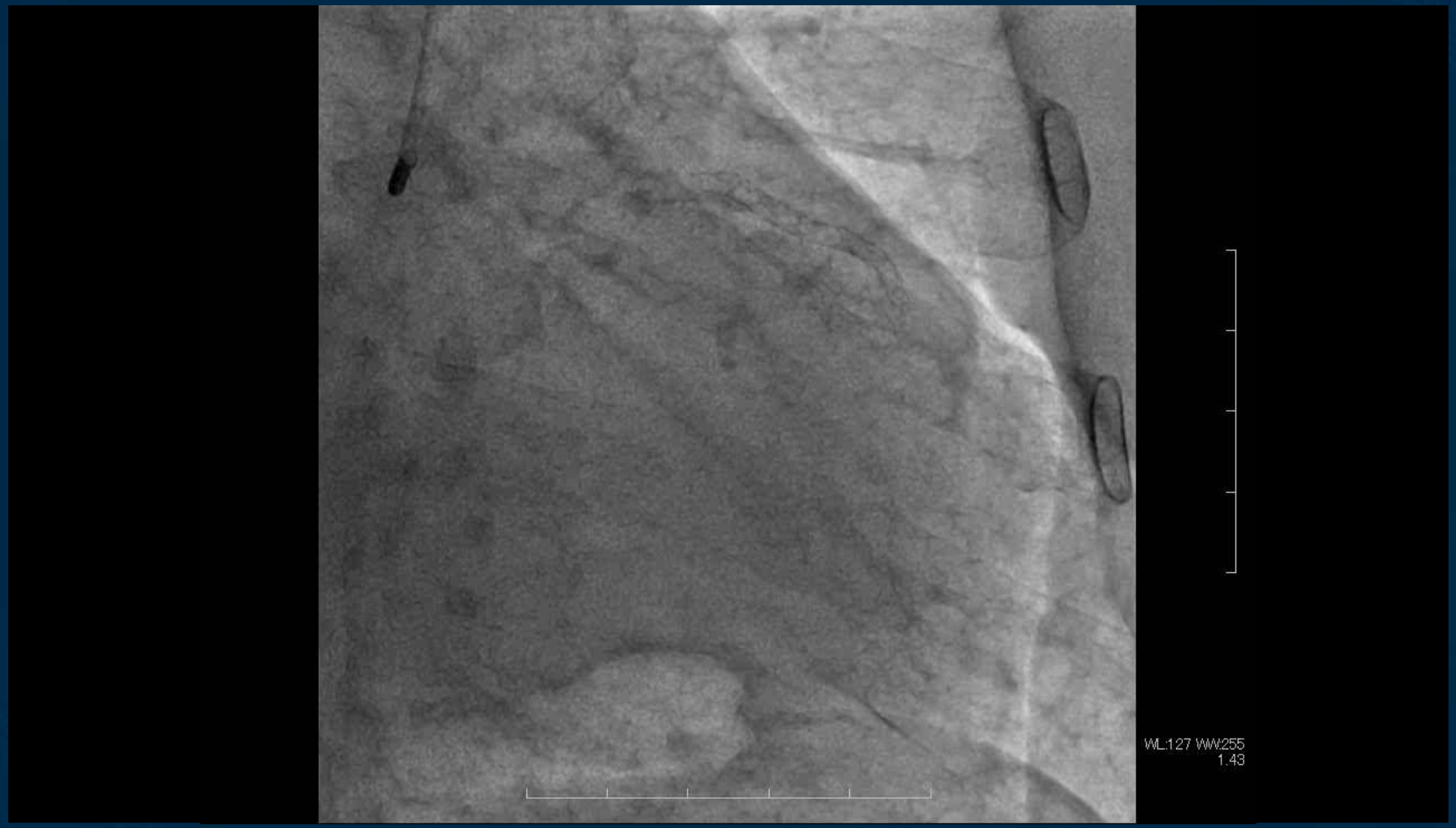


Final IVUS



Final CAG; RAO cranial

Final CAG; RAO caudal



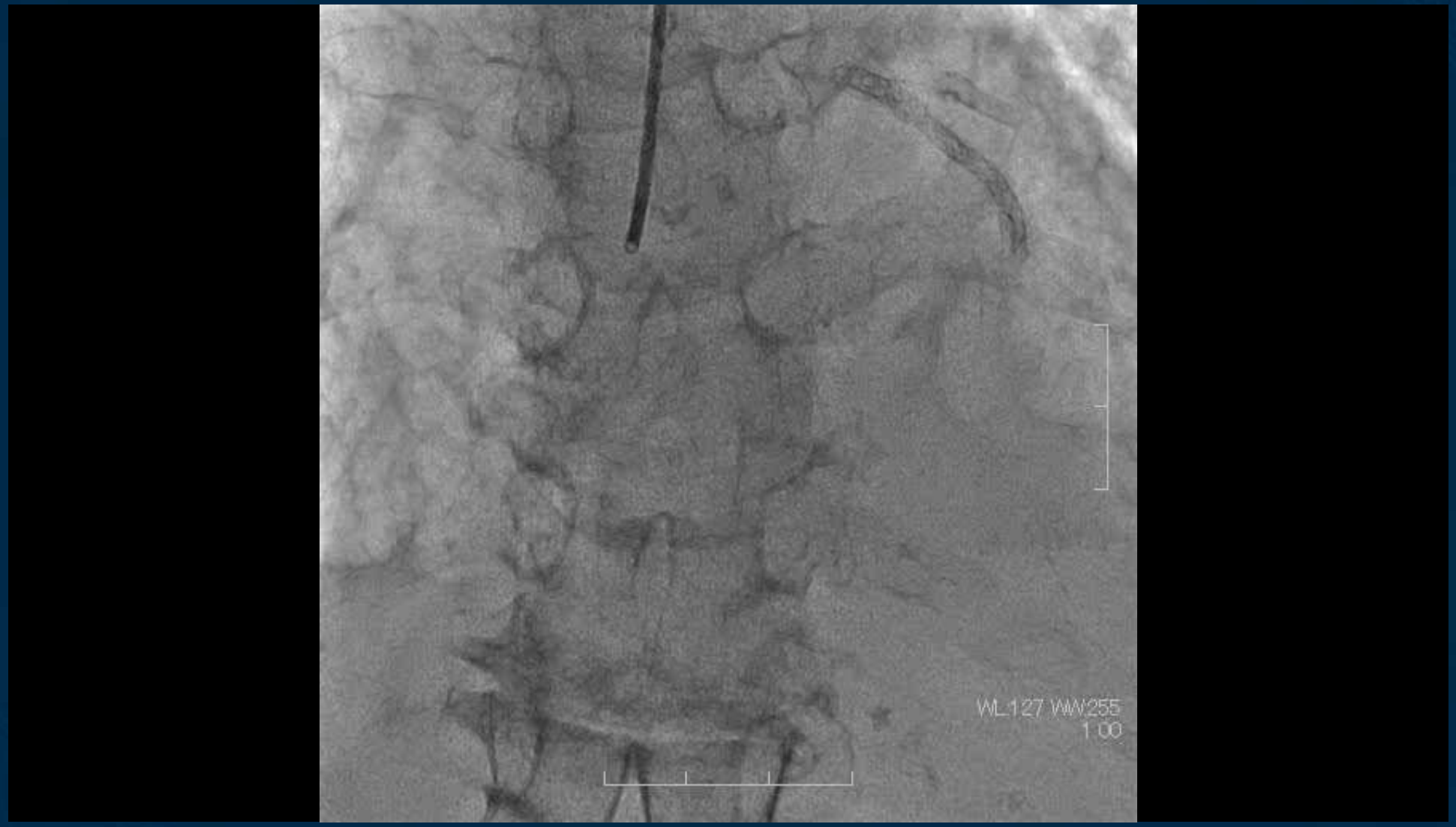
Case 3:

Importance of guide catheter back-up

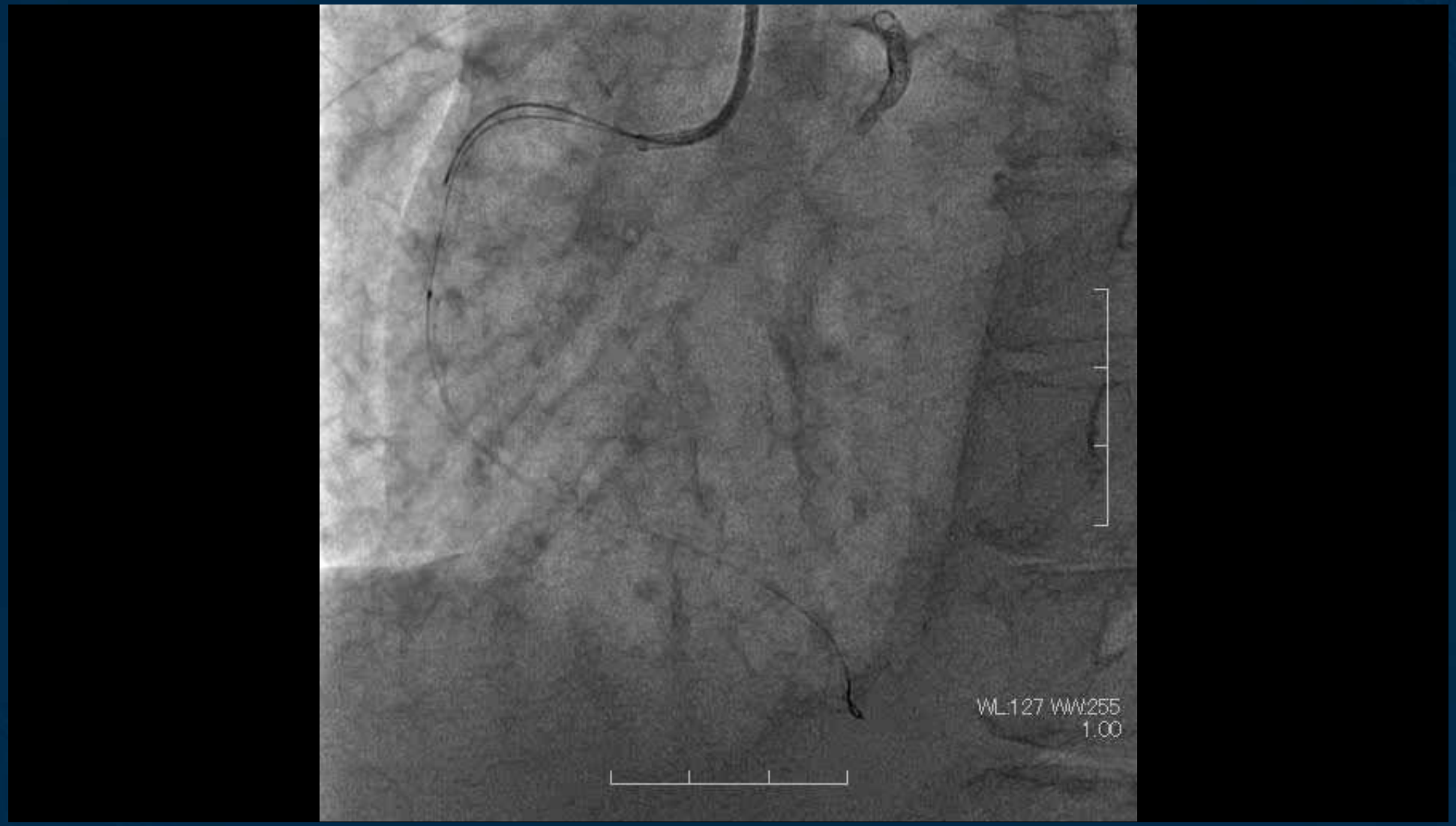
Leopard crawl; action and reaction law

Pre LAO; TRI 6F IR1.0

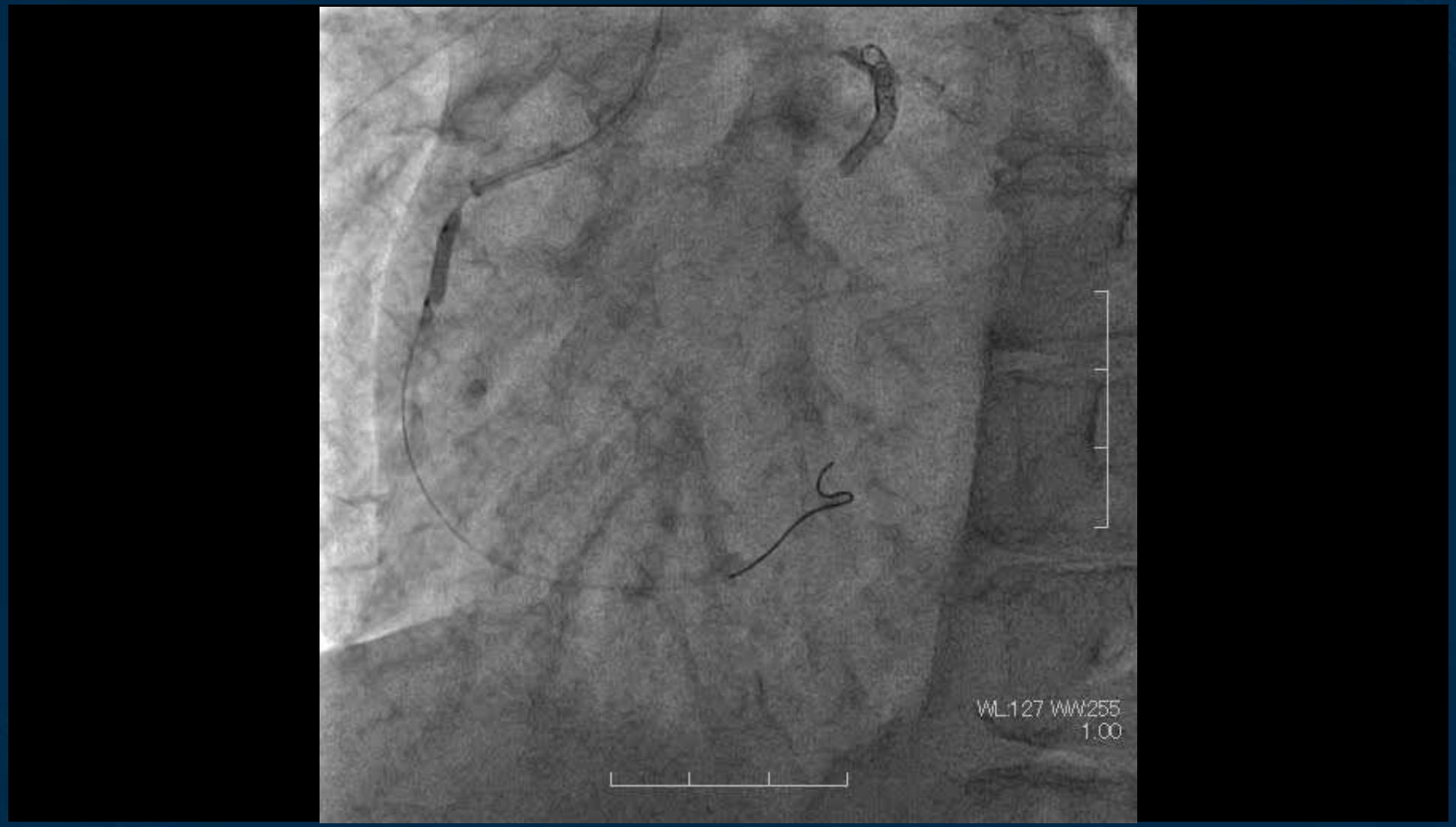
Pre AP cranial



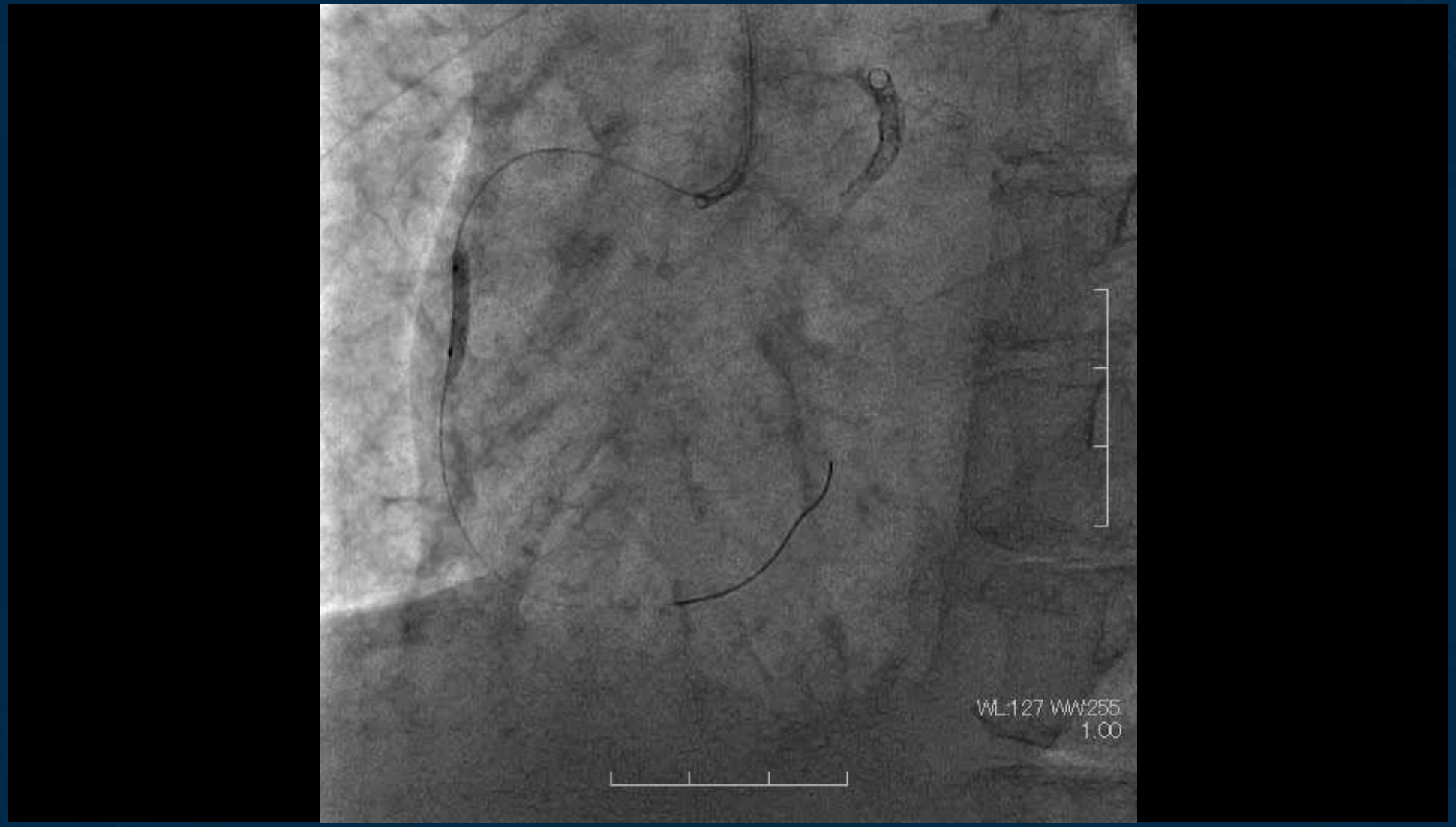
IVUS unable to cross



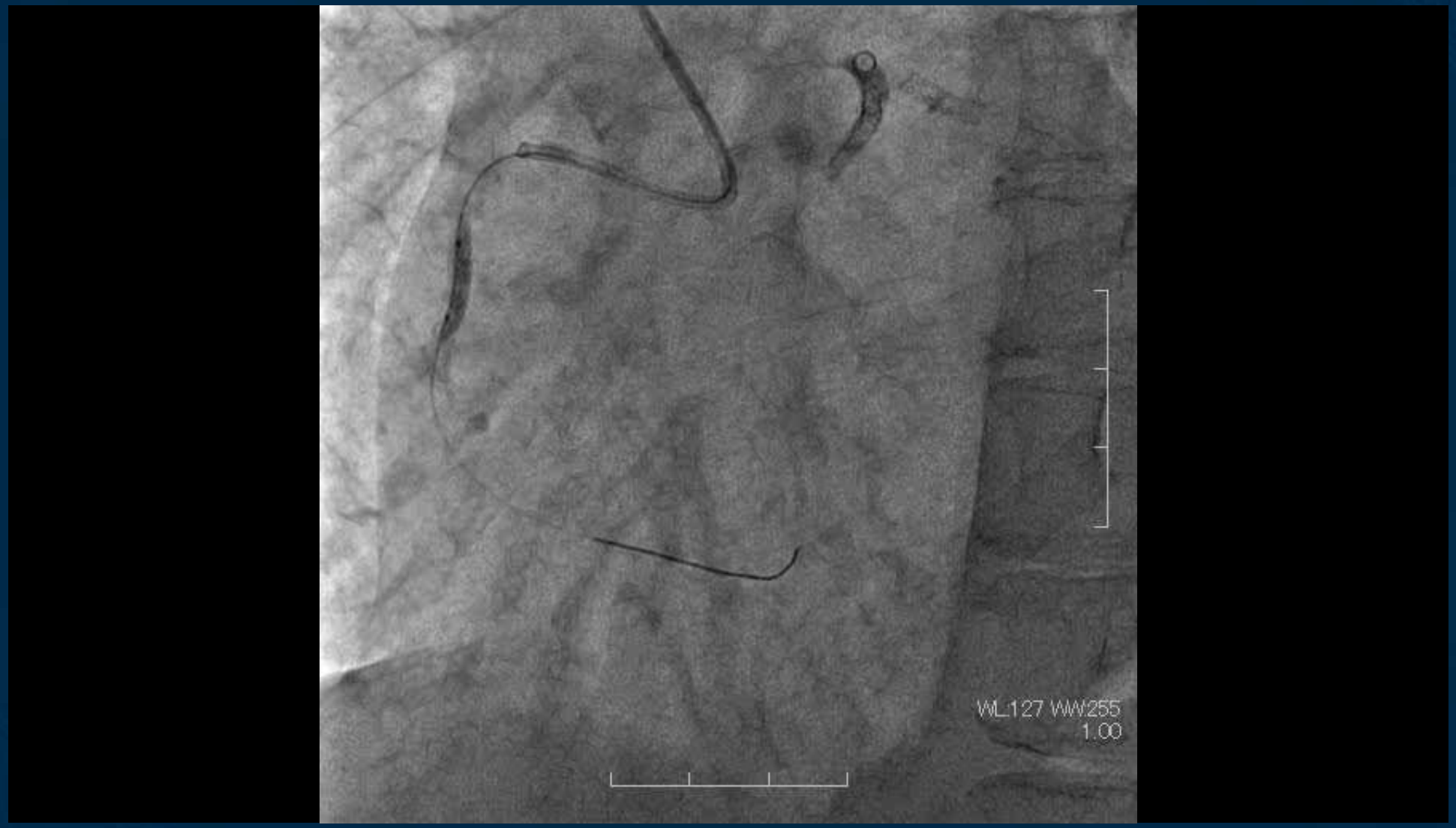
2.25mm Lacrosse NSEα



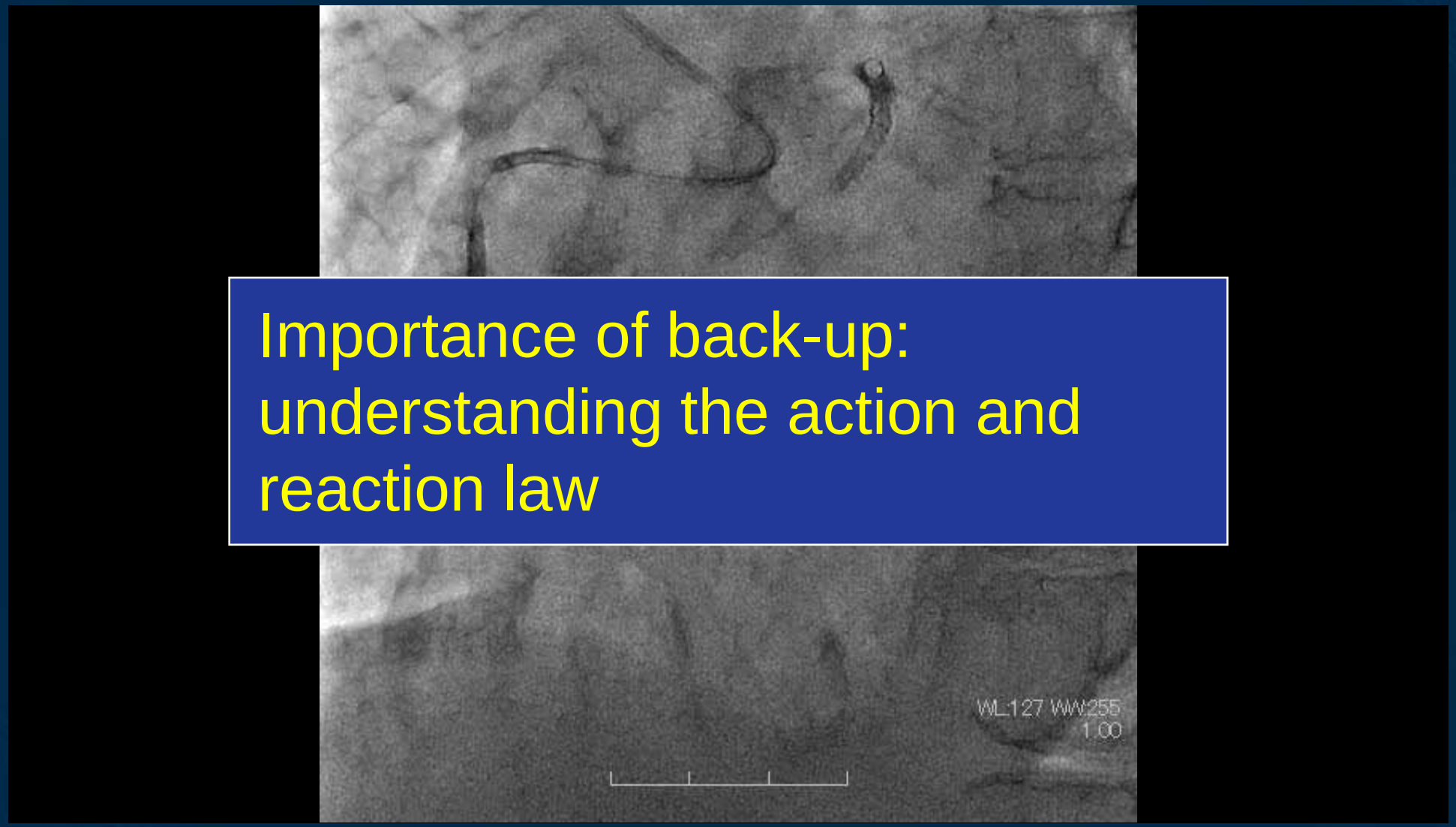
Leopard crawl



Deep seating for guide catheter

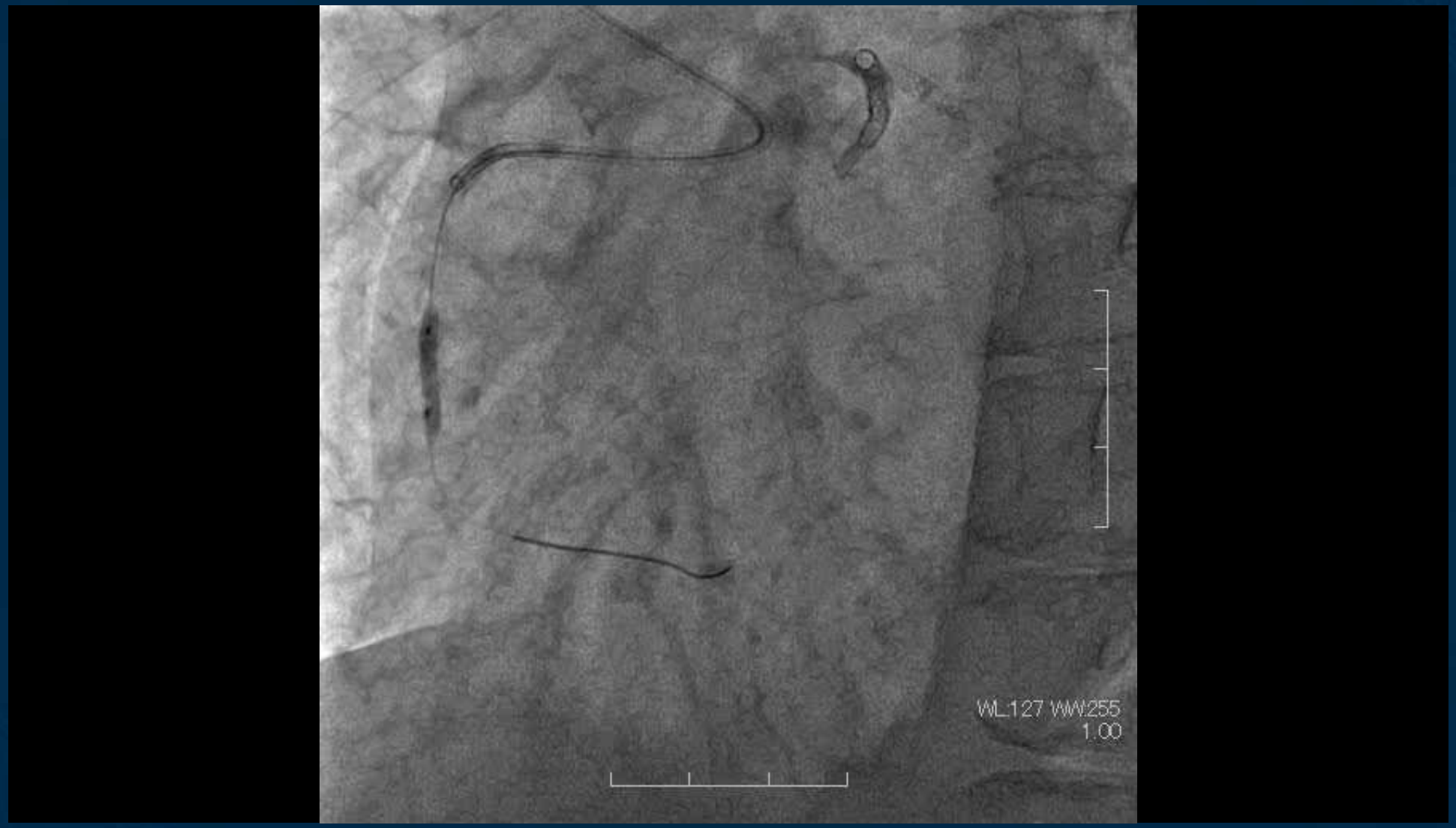


Leopard crawl with deep seating

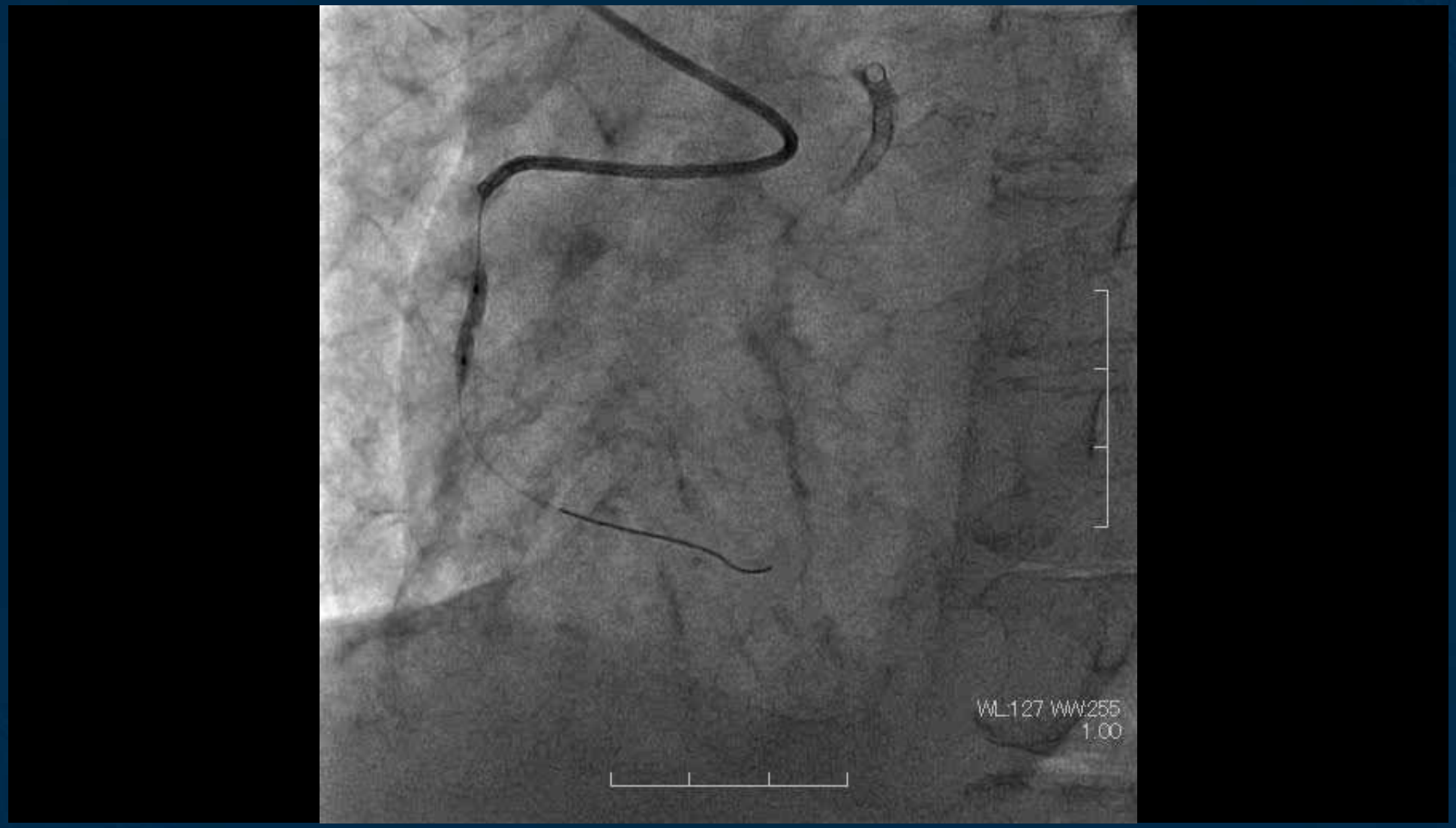


Importance of back-up: understanding the action and reaction law

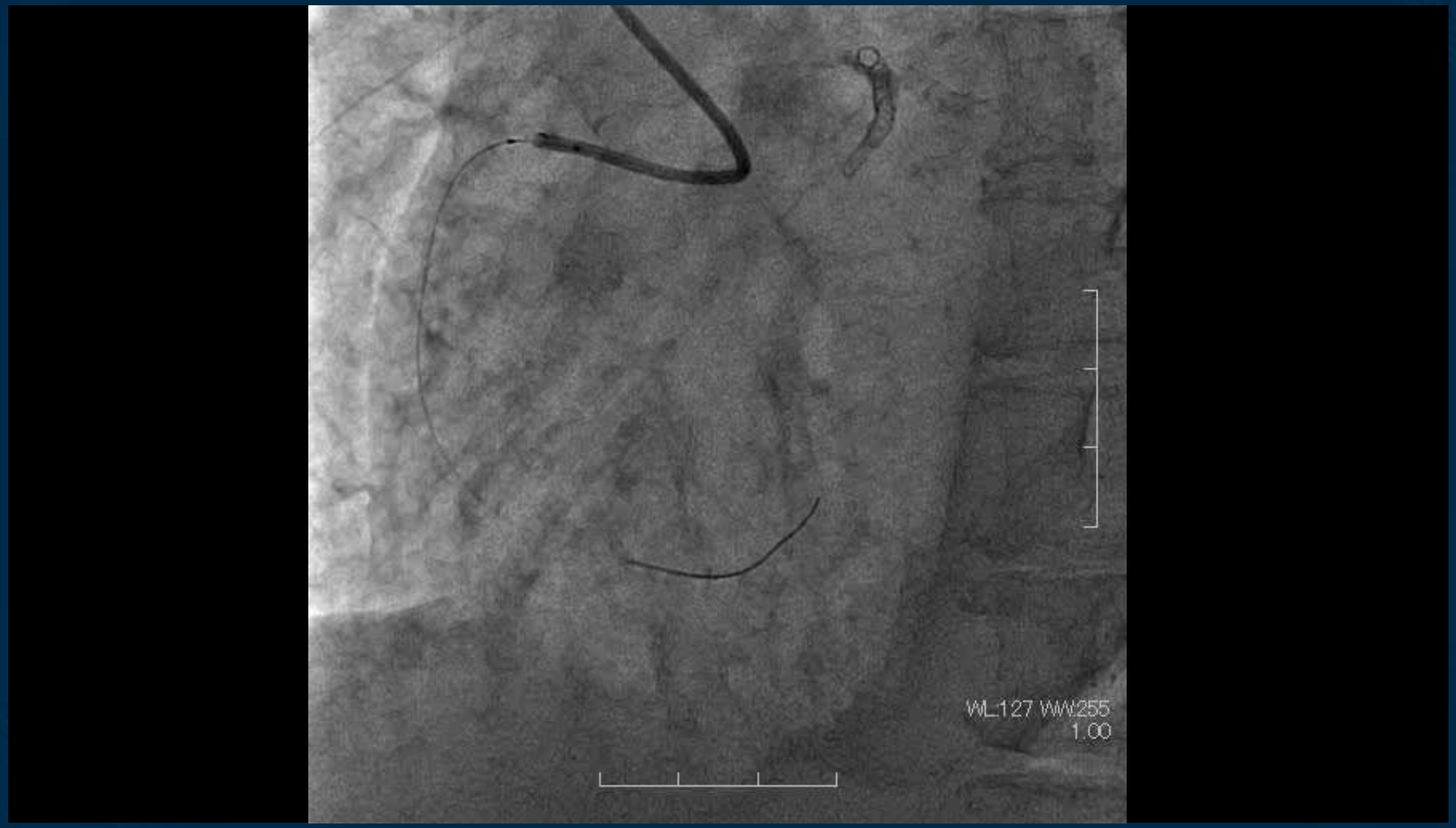
NSE distal dilatation



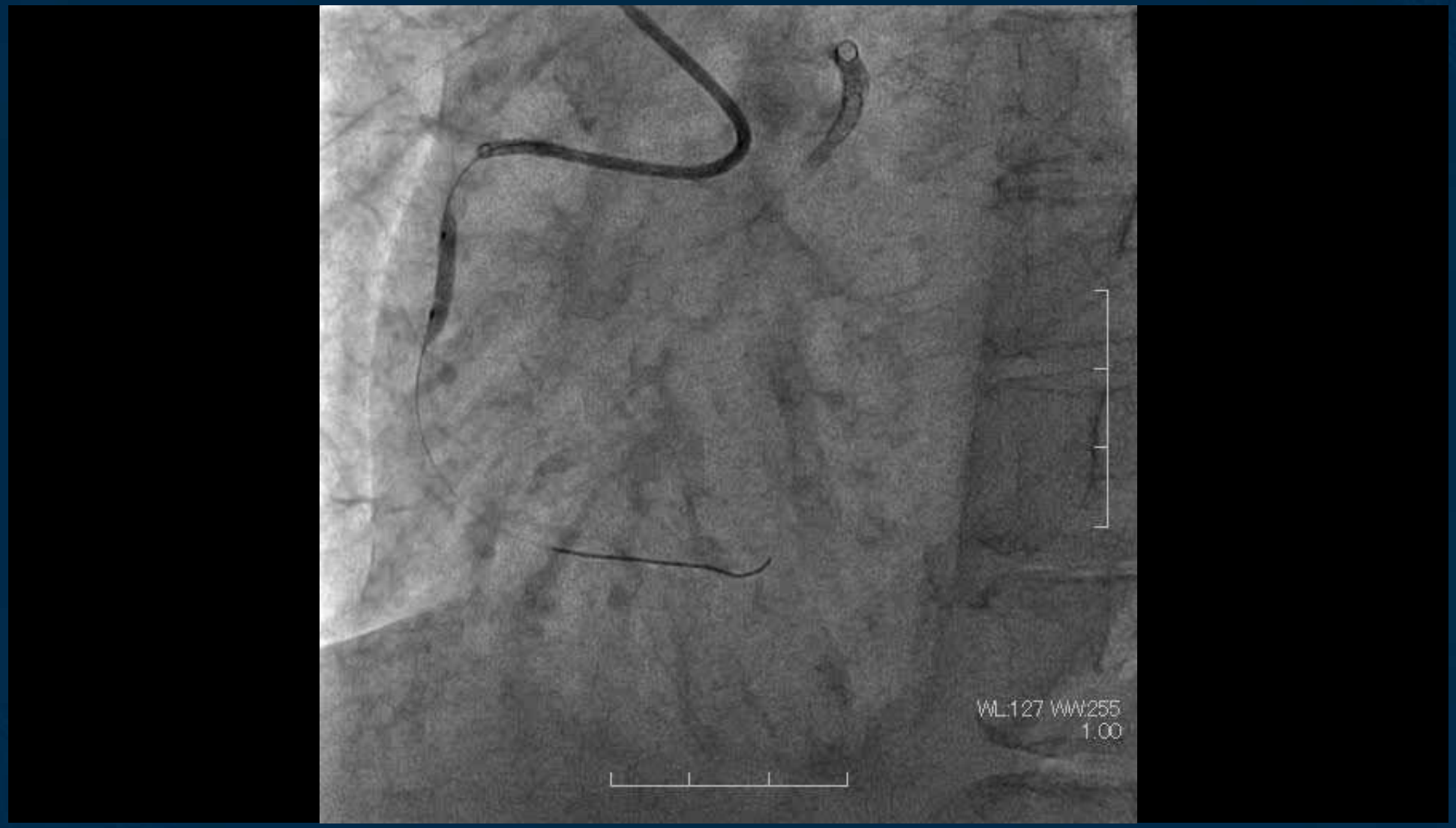
NSE proximal dilatation



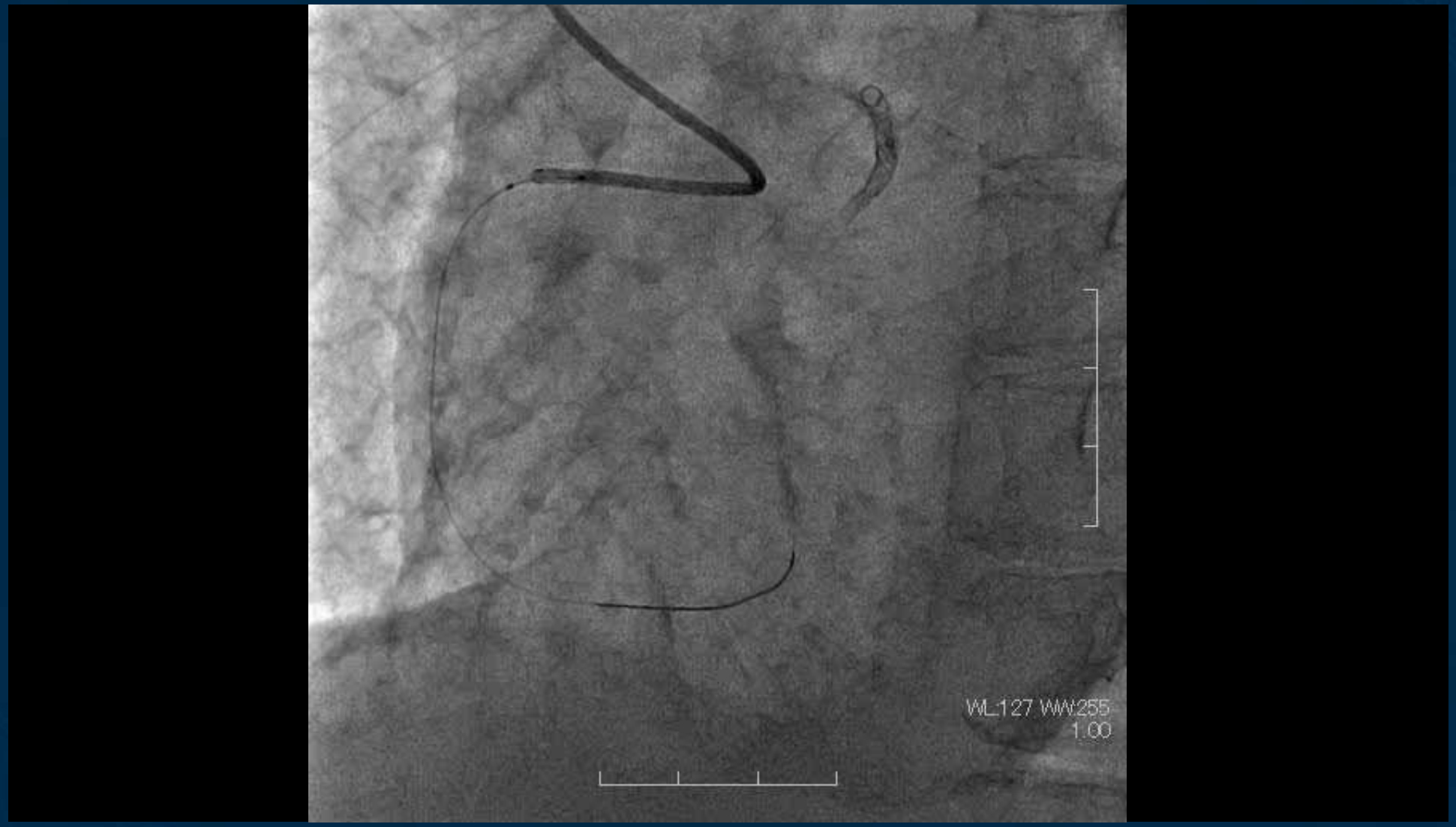
Push test



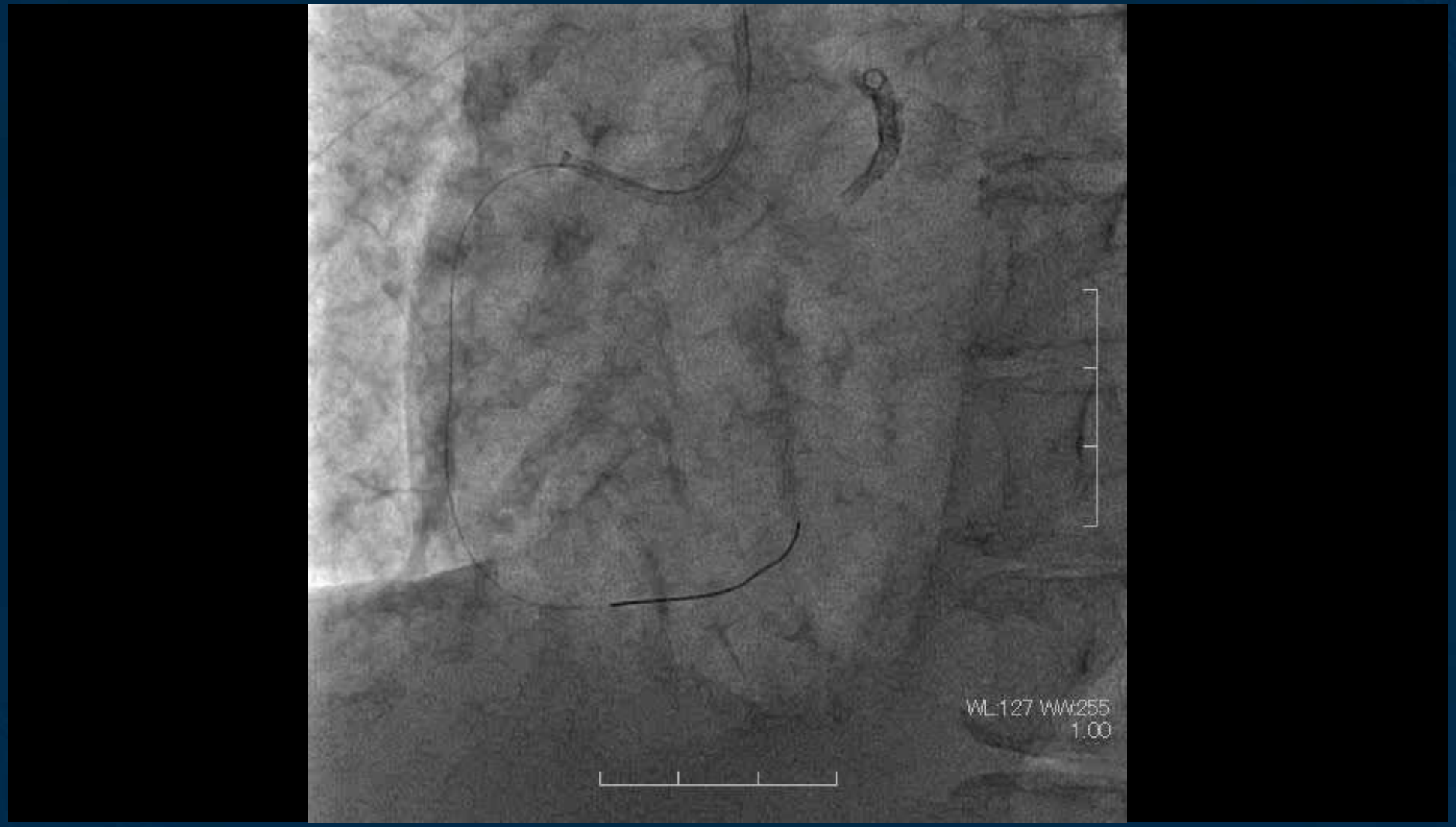
Repeat inflation



Repeated push test

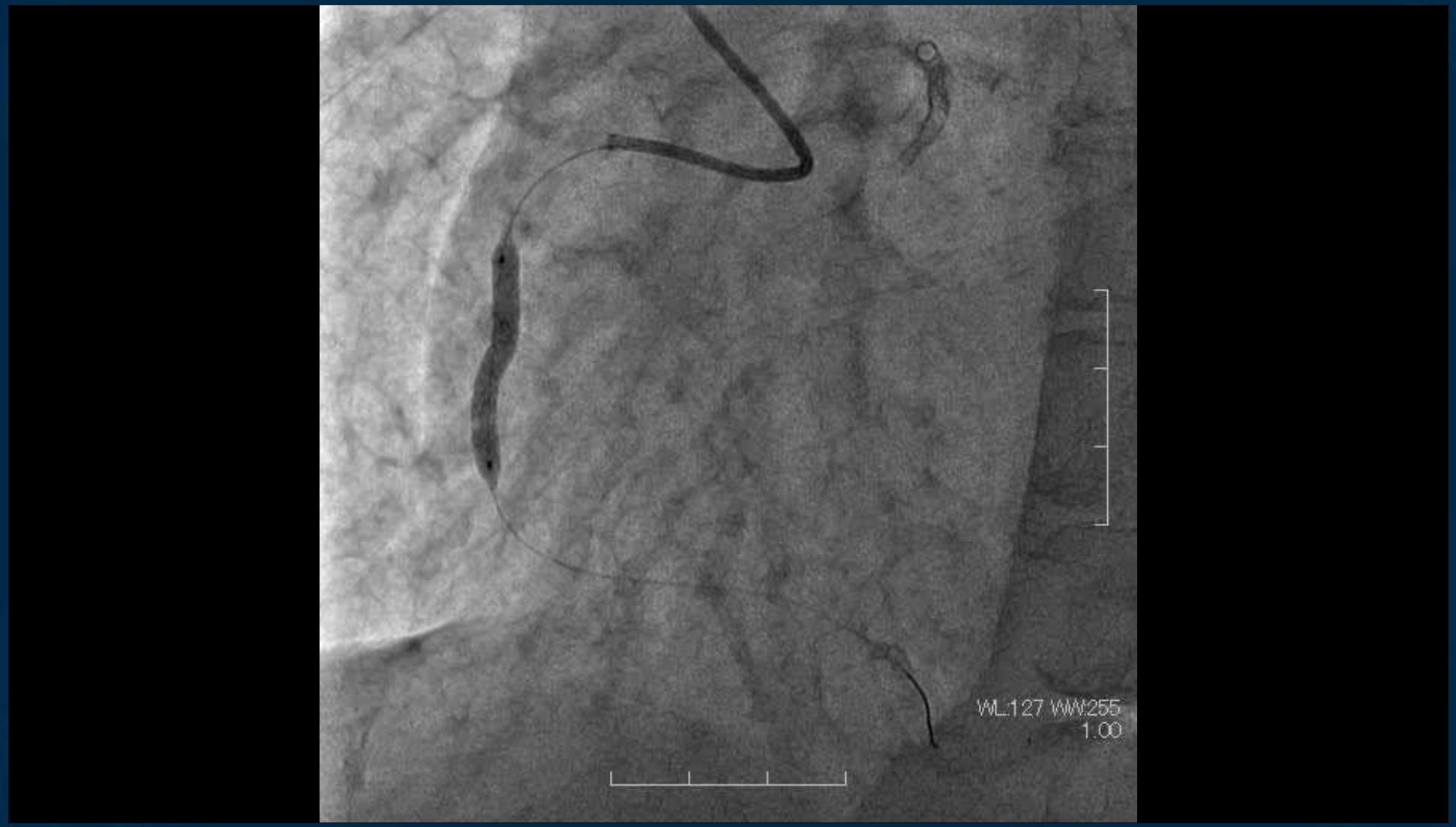


Post NSE



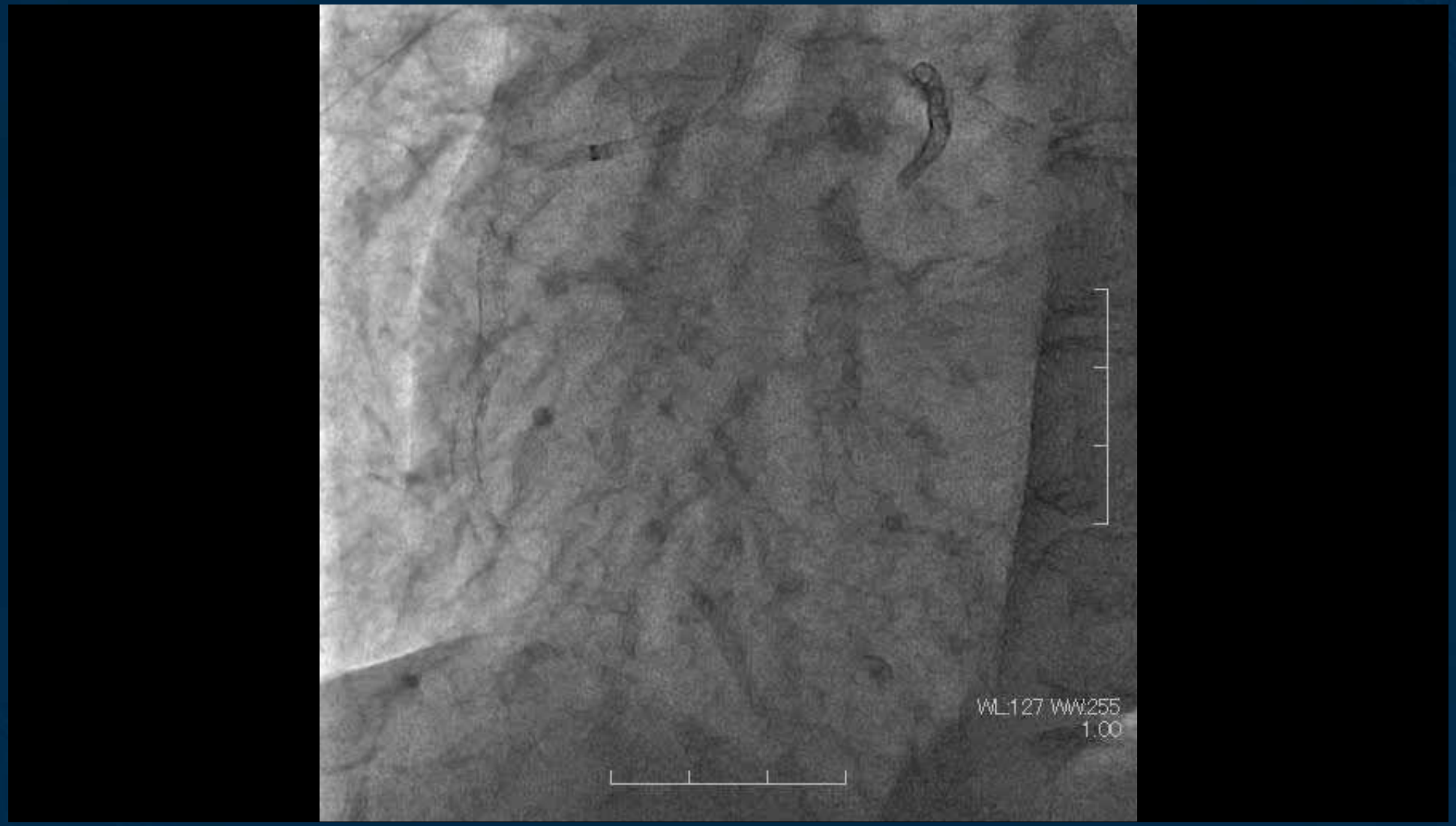
IVUS crossed

3.0*28mm NOBORI@14atm



3.0*18mm PROMUS@14atm

Final CAG LAO



Final CAG AP cranial

Leopard crawl technique

Requirement

Strong back-up guide catheter:

LCA: JL<EBU, RCA: JR<AL

Combination with other technique

Double wire technique, Child in Mother method,
Guideliner or Guidezila is good option.

Leopard crawl technique

if NSE can not advance at the proximal site of the lesion, let's try this technique again and again at the same site, and finally could advance over the lesion.

Never give up!

Lacrosse NSE Sizing from CAG (long axis view image)

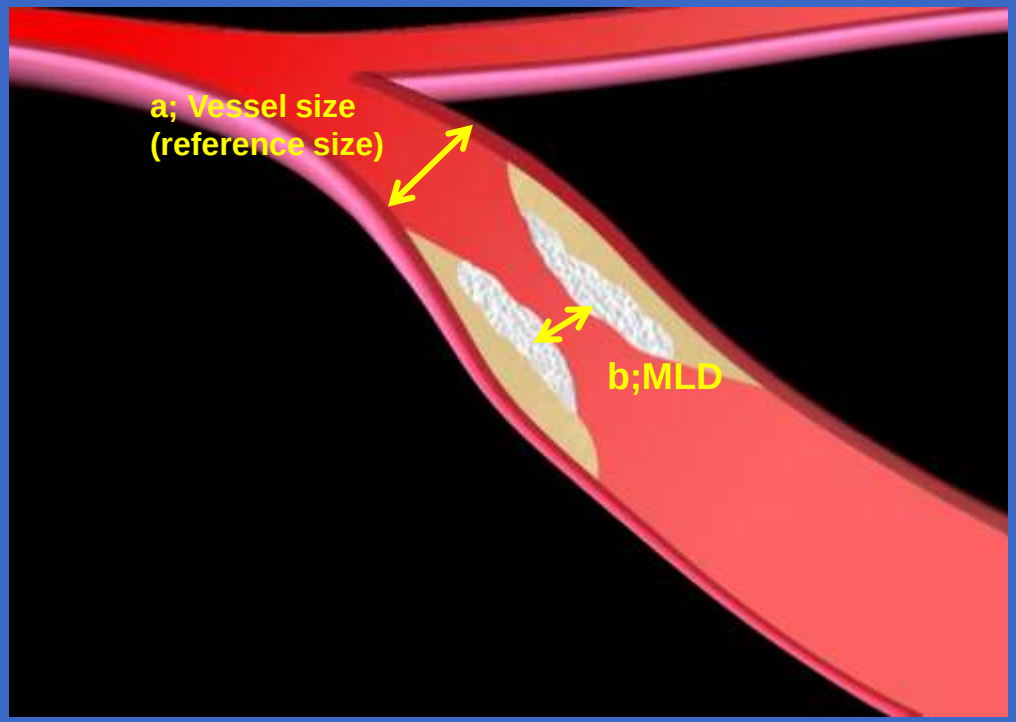
Purpose
to make cracks into the calcification

NSE Size
vessel size (reference vessel); a, minimum lumen diameter(MLD) in calcified lesion; b

Necessary condition
b<X<a

CAG
it is difficult to understand the distribution of calcification

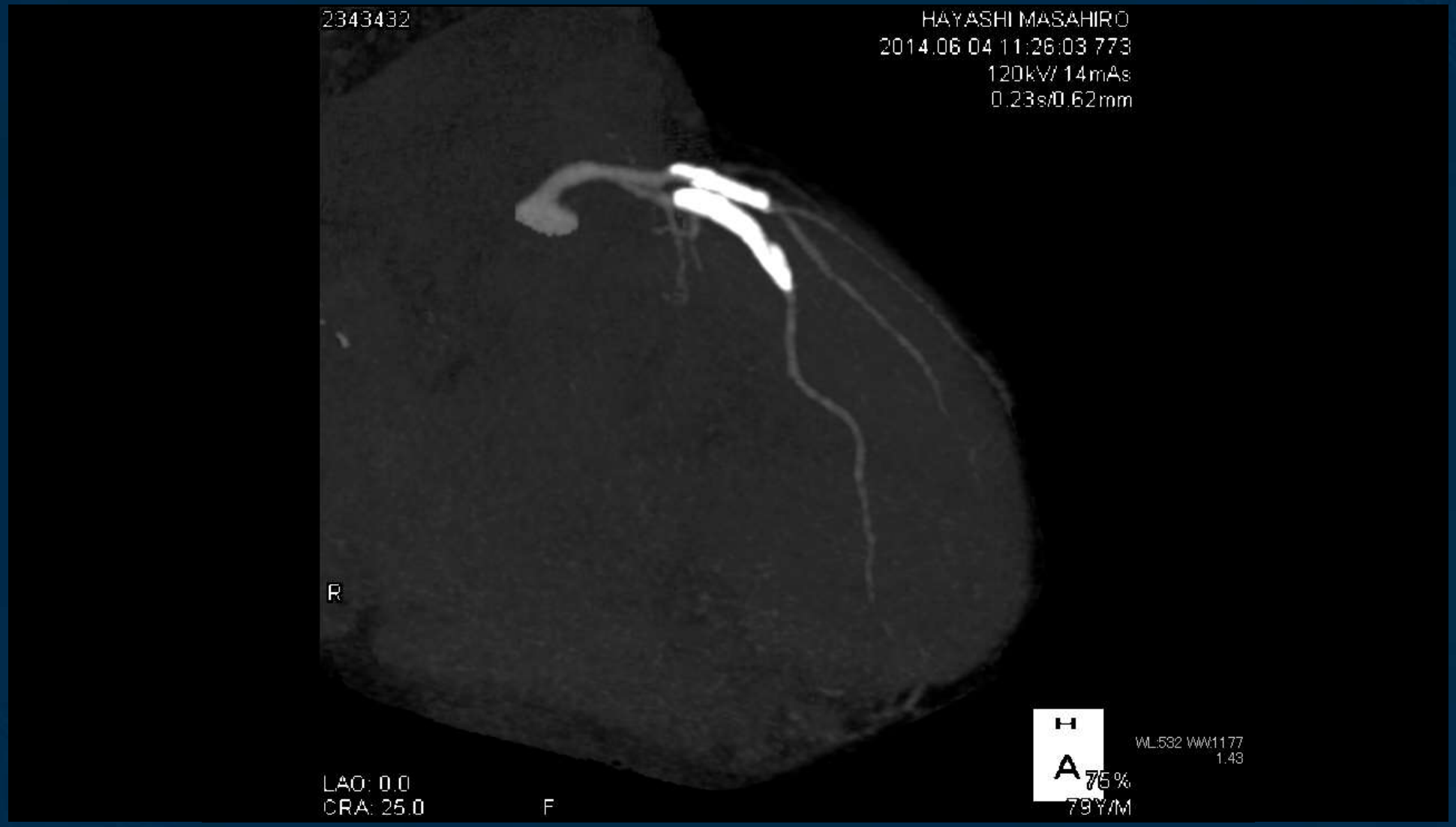
Safety and effective size
b<X<a; **1.25×b**



Case 4:

How effective is NSE for calcified lesions?

MDCT

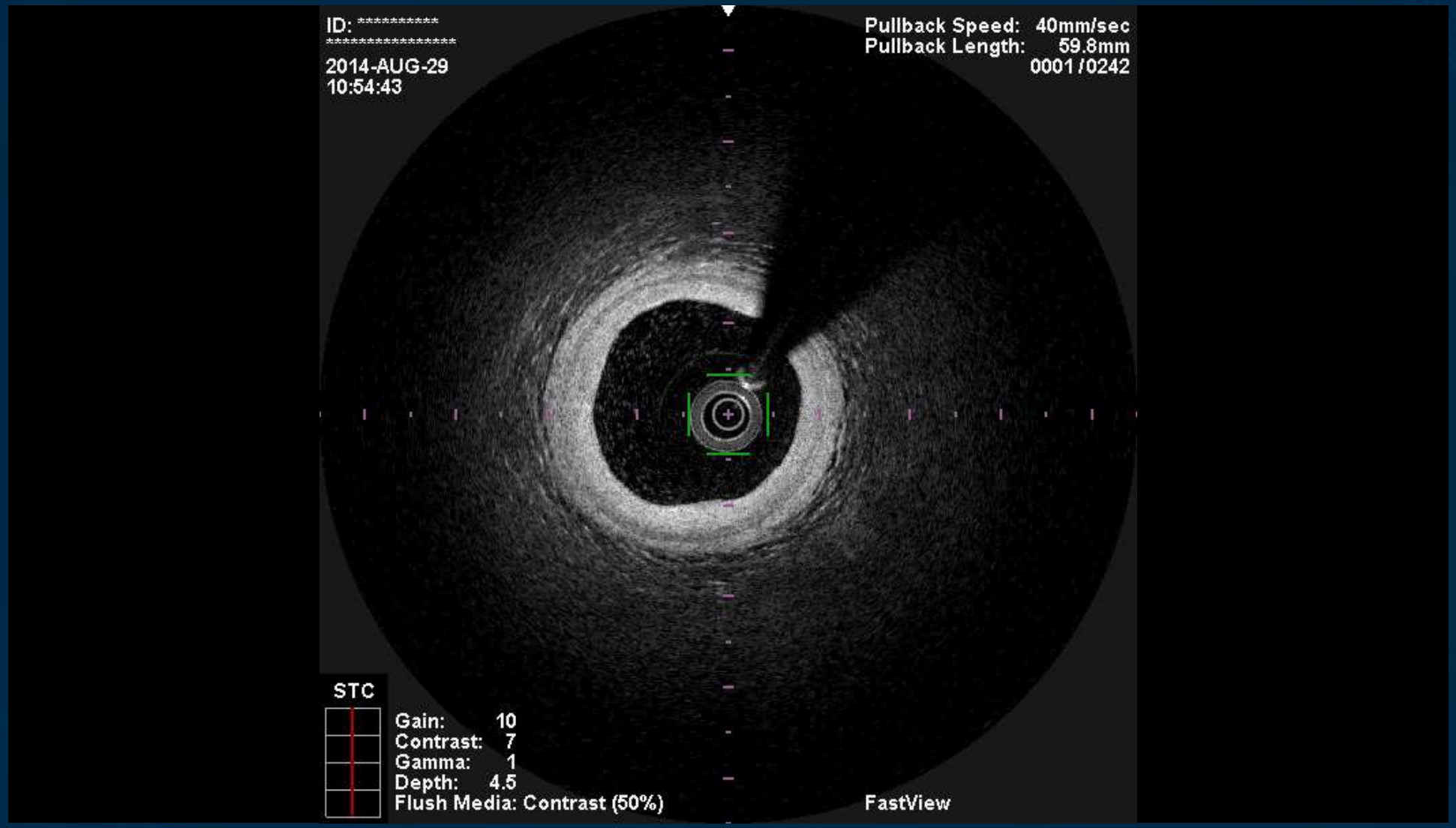

2343432
HAYASHI MASAHIRO
2014.06 04 11:26:03 773
120kV/ 14mAs
0.23s/0.62mm
R
H
A
75%
79Y/M
WL:532 WW:1177
1.43
LAO: 0.0
CRA: 25.0
F

MDCT2


Vessel Direction Based
Depth: 0.0 mm
Angle: 0.0 deg
LAD
YOKOHAMA SHINTOSHI HOSPITAL
HAYASHI MASAHIRO 79Y M
2343432
2014/6/4
11:02:08.000
WL:673 WW:2258
1.43
CPR-A

Pre CAG

Pre OFDI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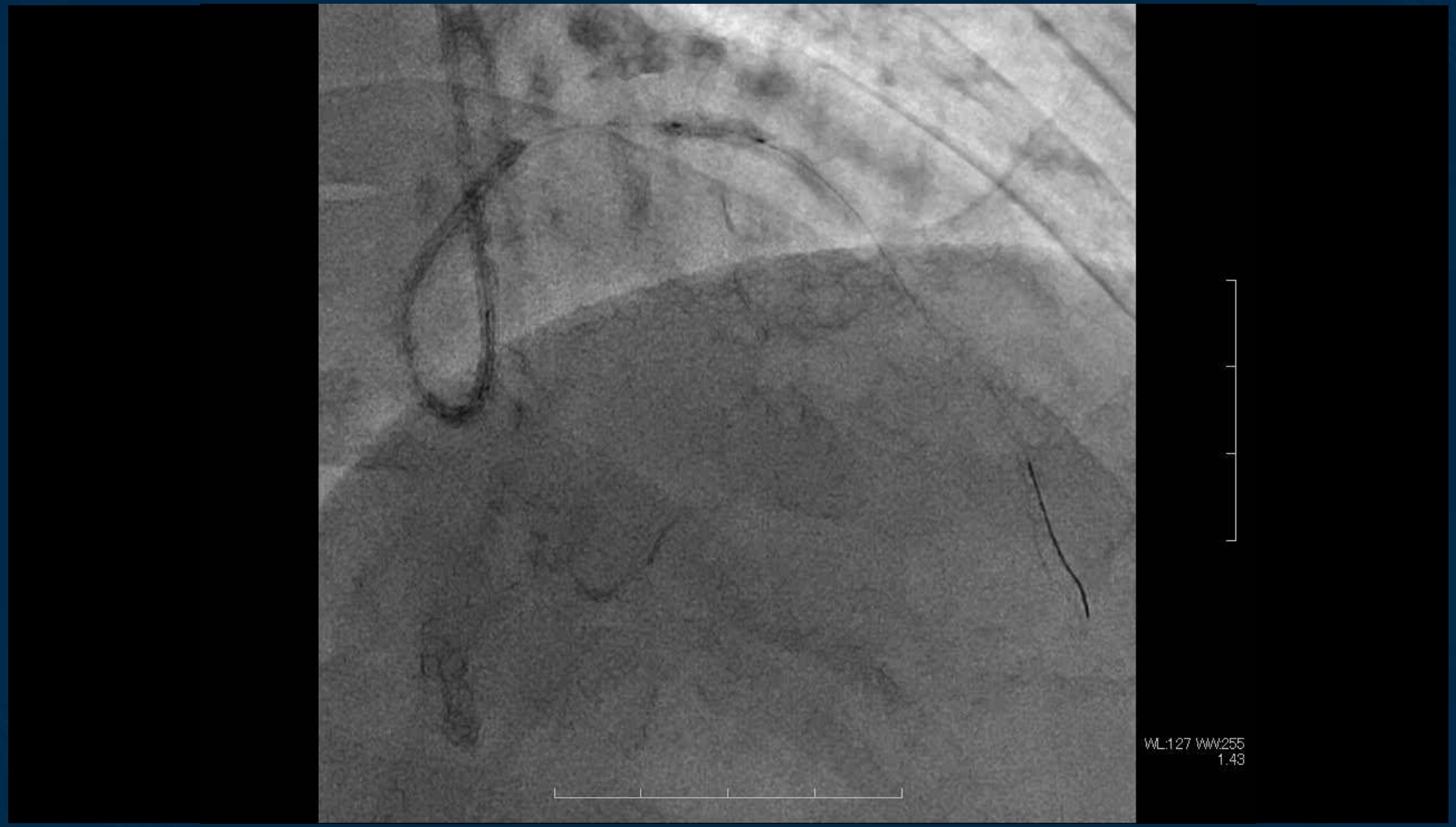
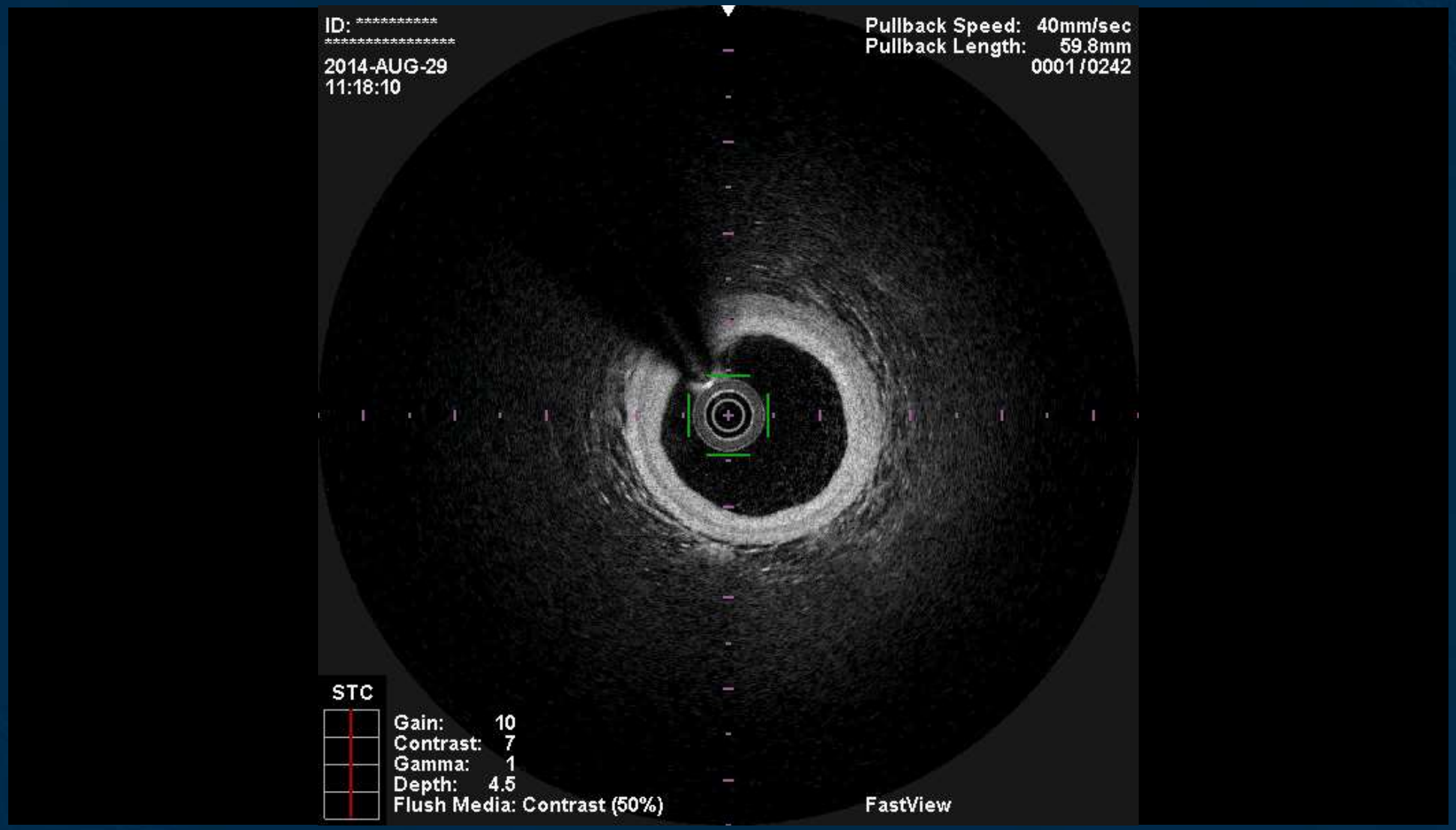
2014-AUG-29
10:54:43
Pullback Speed: 40mm/sec
Pullback Length: 59.8mm
0001/0242
STC
Gain: 10
Contrast: 7
Gamma: 1
Depth: 4.5
Flush Media: Contrast (50%)
FastView

NSE 2.25mm leopard crawl 1



NSE 2.25mm leopard crawl 2

Post NSE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2014-AUG-29
11:18:10
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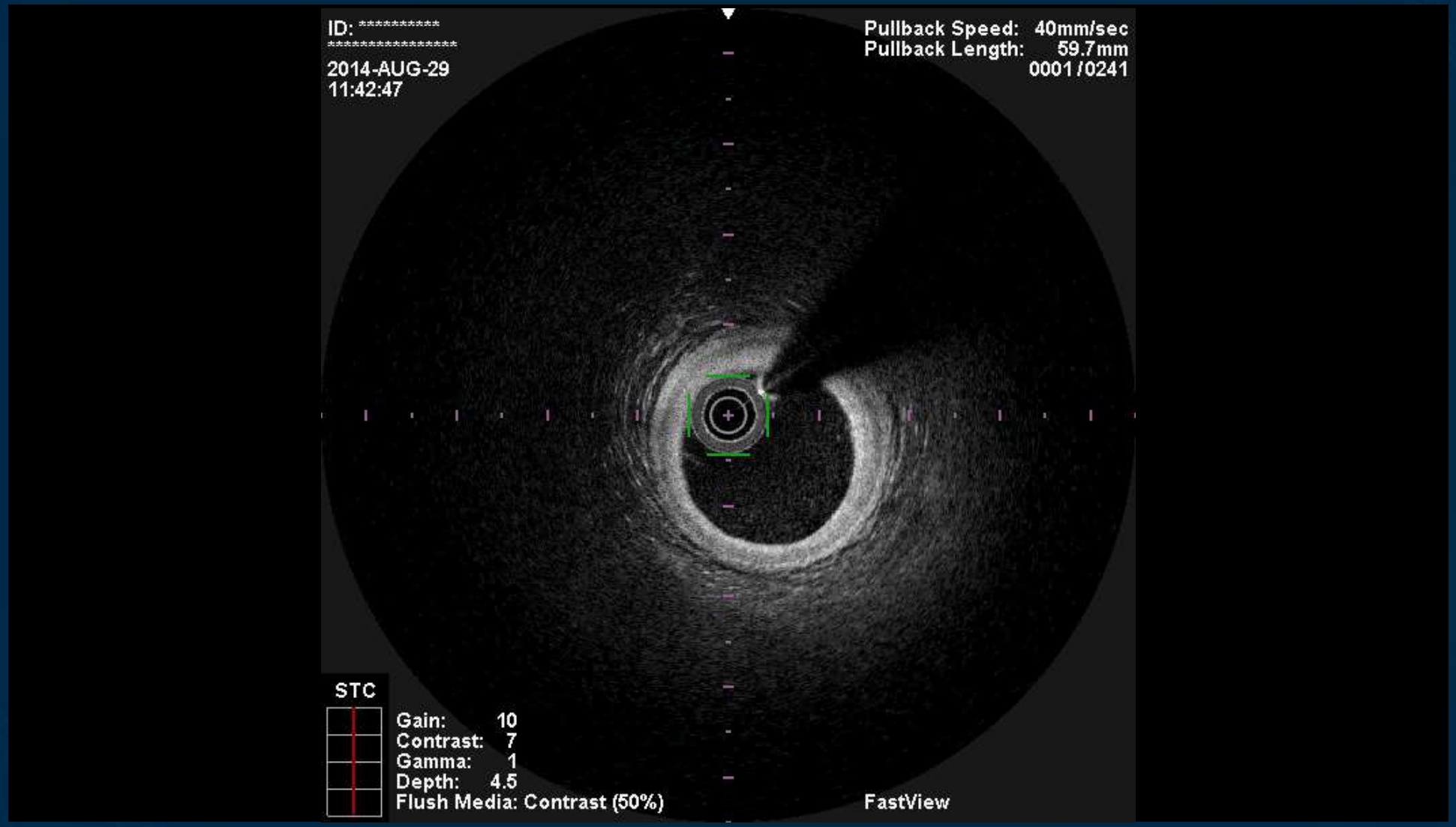
Pullback Length: 59.8mm
0001/0242
STC
Gain: 10
Contrast: 7
Gamma: 1
Depth: 4.5
Flush Media: Contrast (50%)
FastView

Post Stent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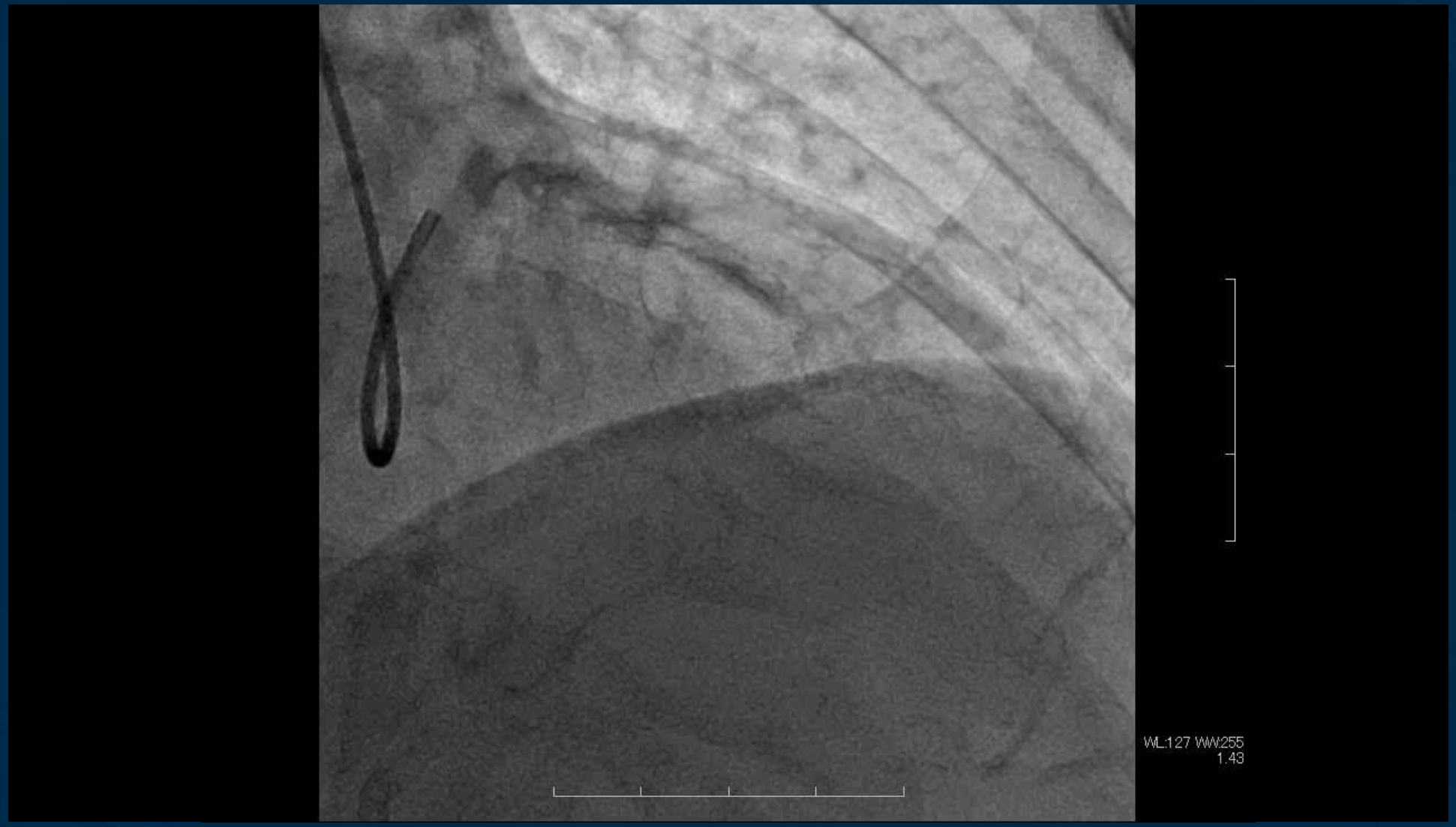
2014-AUG-29
11:42:47
Pullback Speed: 40mm/sec
Pullback Length: 59.7mm
0001/0241
STC
Gain: 10
Contrast: 7
Gamma: 1
Depth: 4.5
Flush Media: Contrast (50%)
FastView

Final CAG

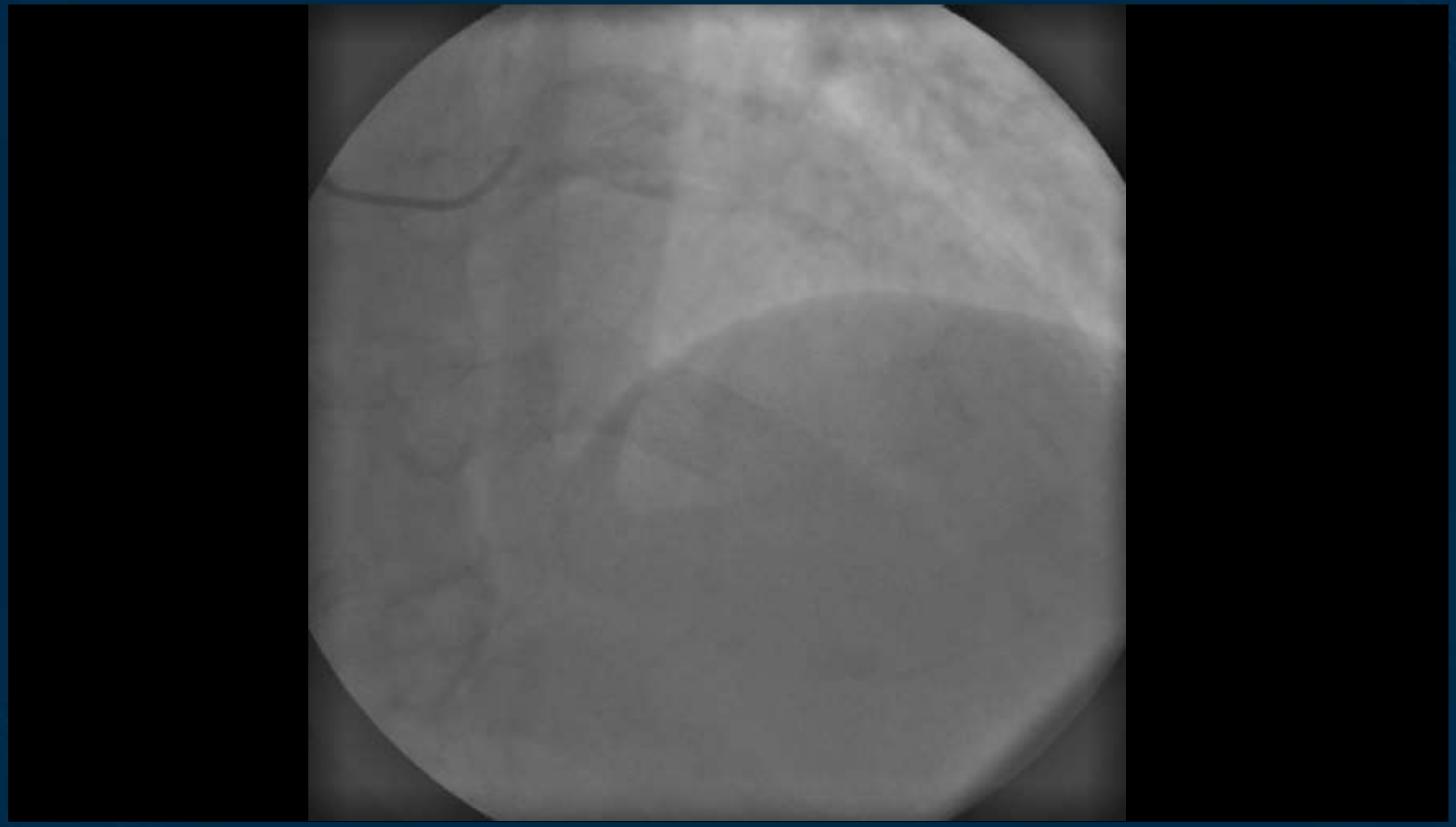


Case 5:
CKD, severe calcification

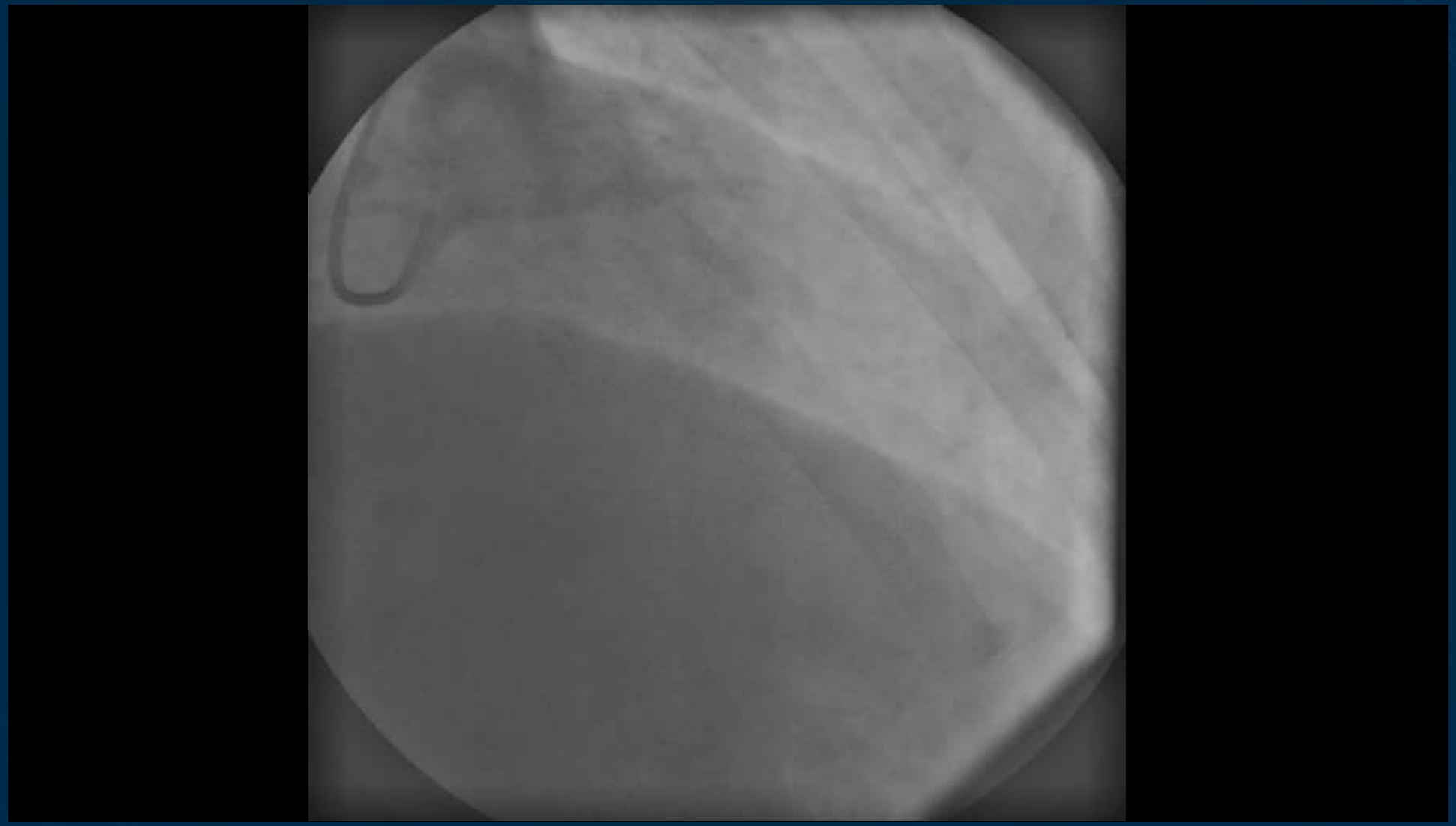
Complex technique

NSE in Guideplus, Mini-contrast,
and Leopard Crawl technique

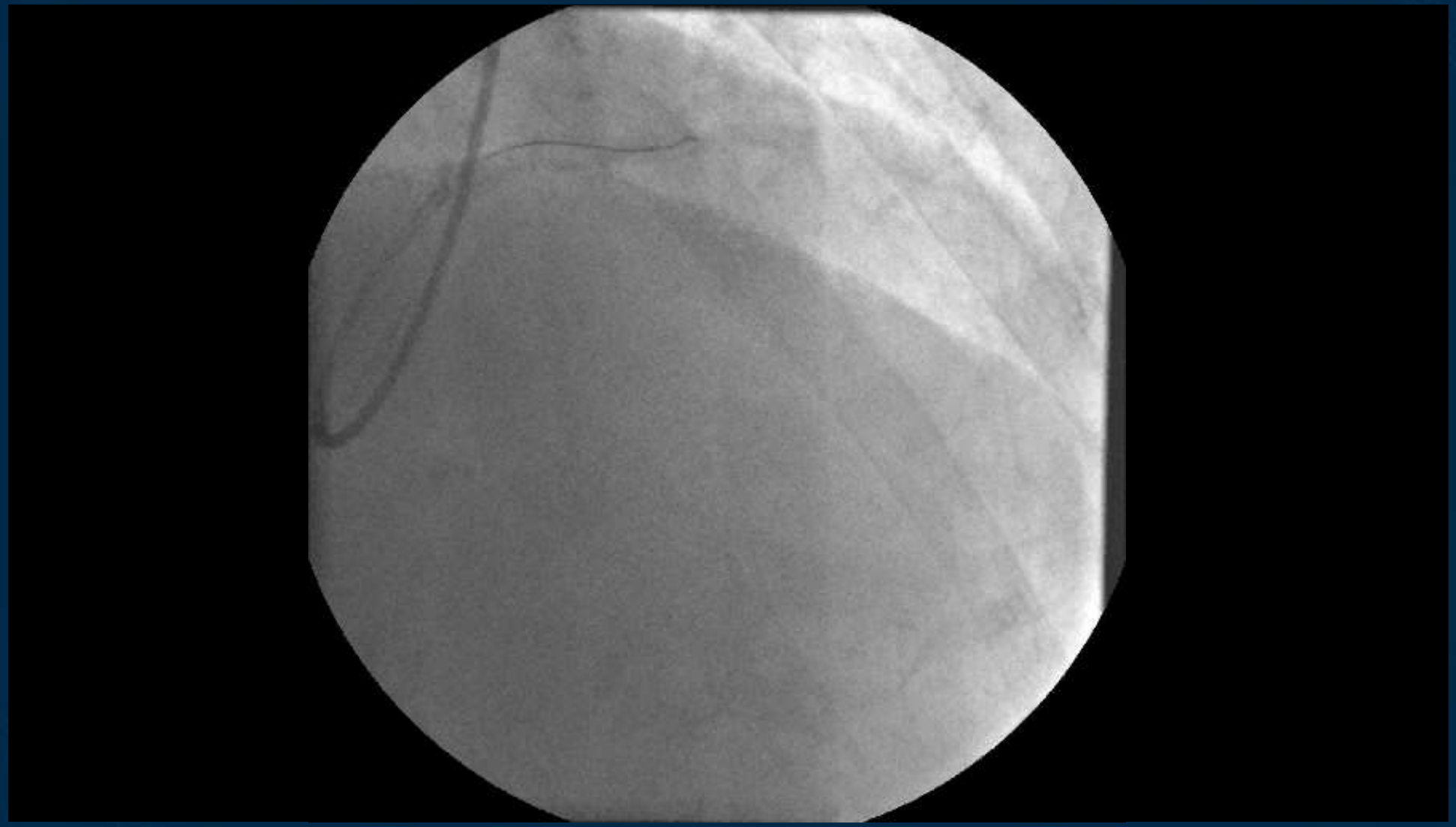
AP cranial



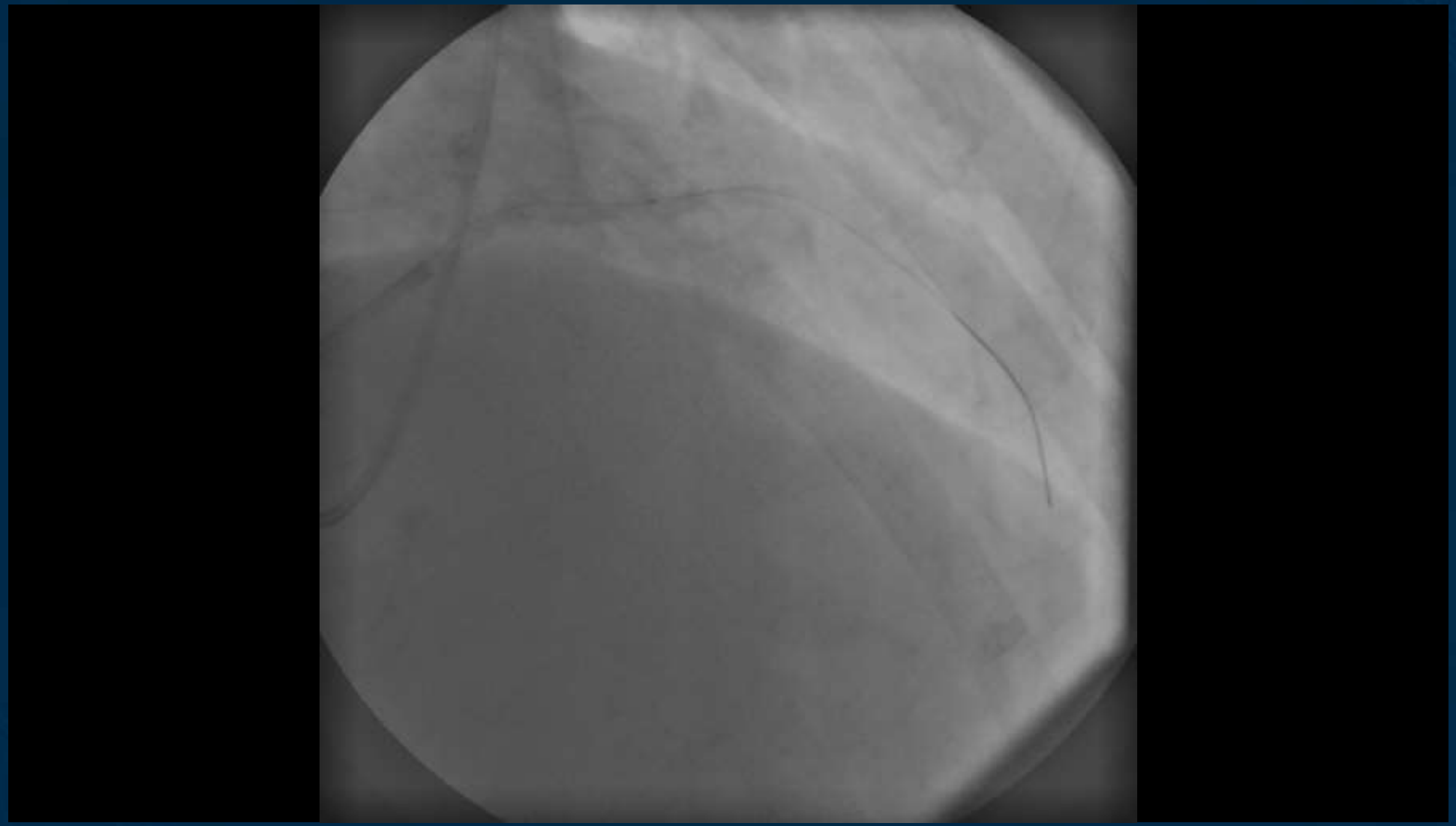
RAO cranial



Guidewire crossing with microcath



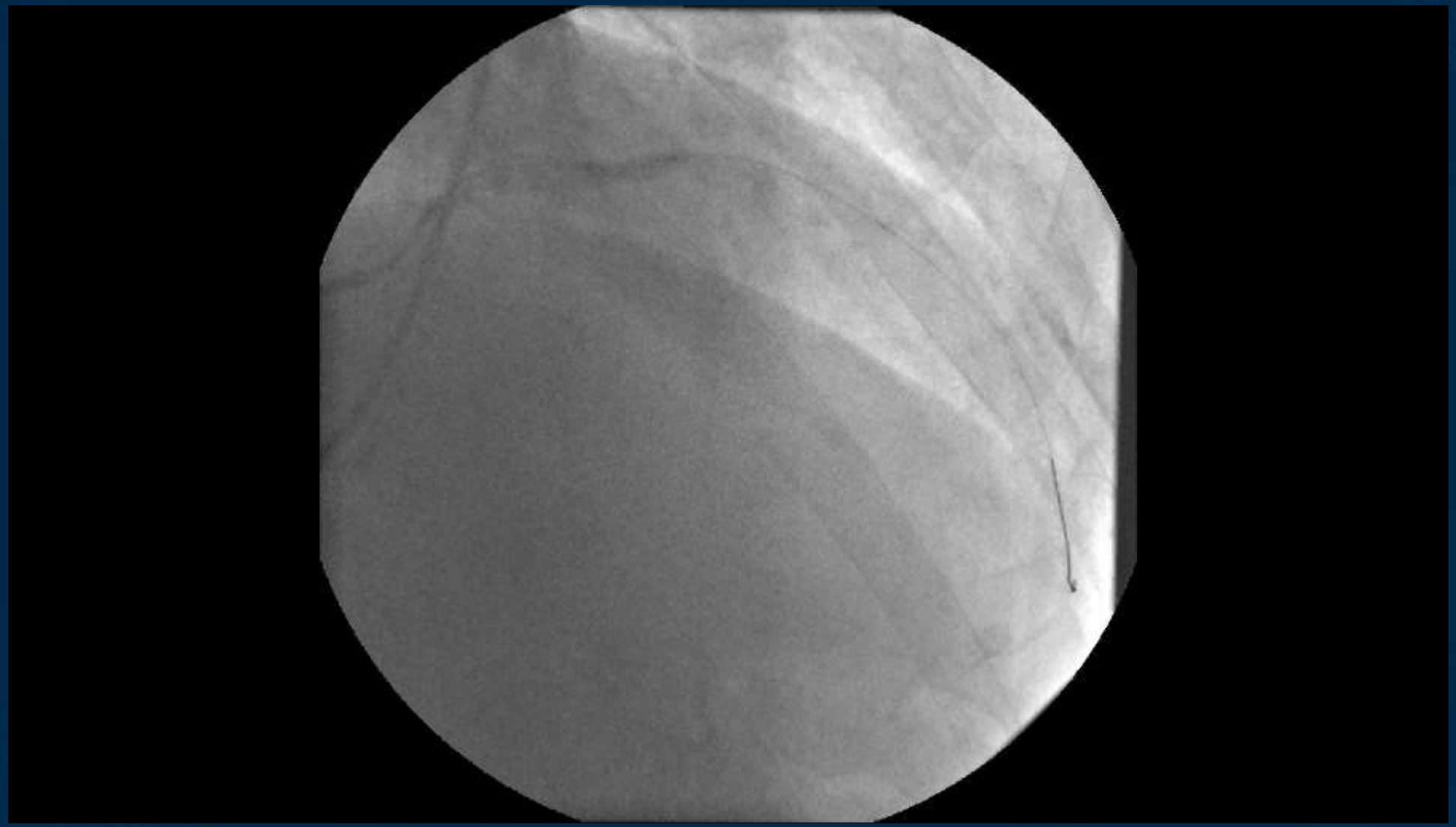
1.5mm balloon could not pass



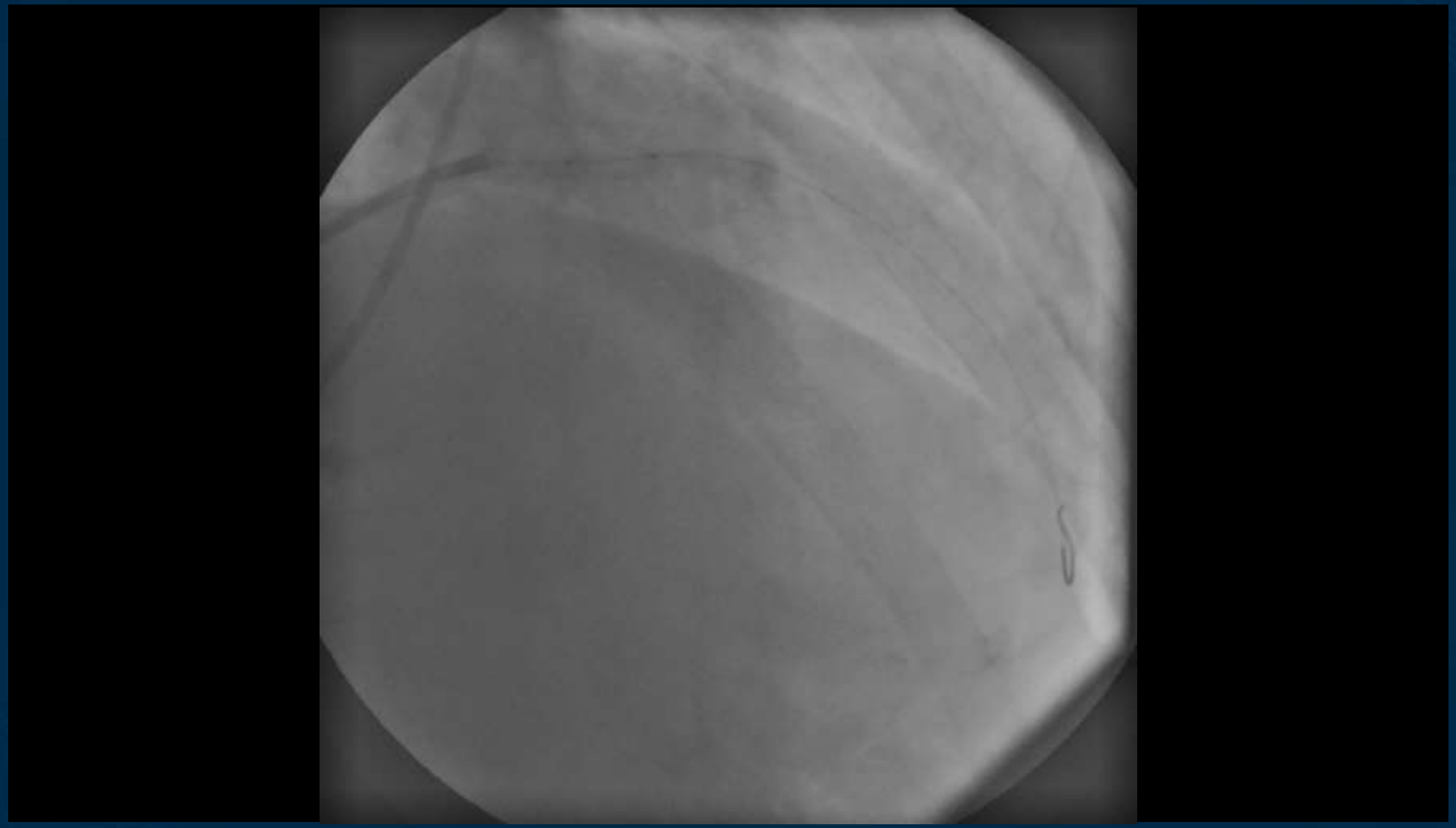
1.5mm balloon with Guideplus

1.5mm balloon could pass

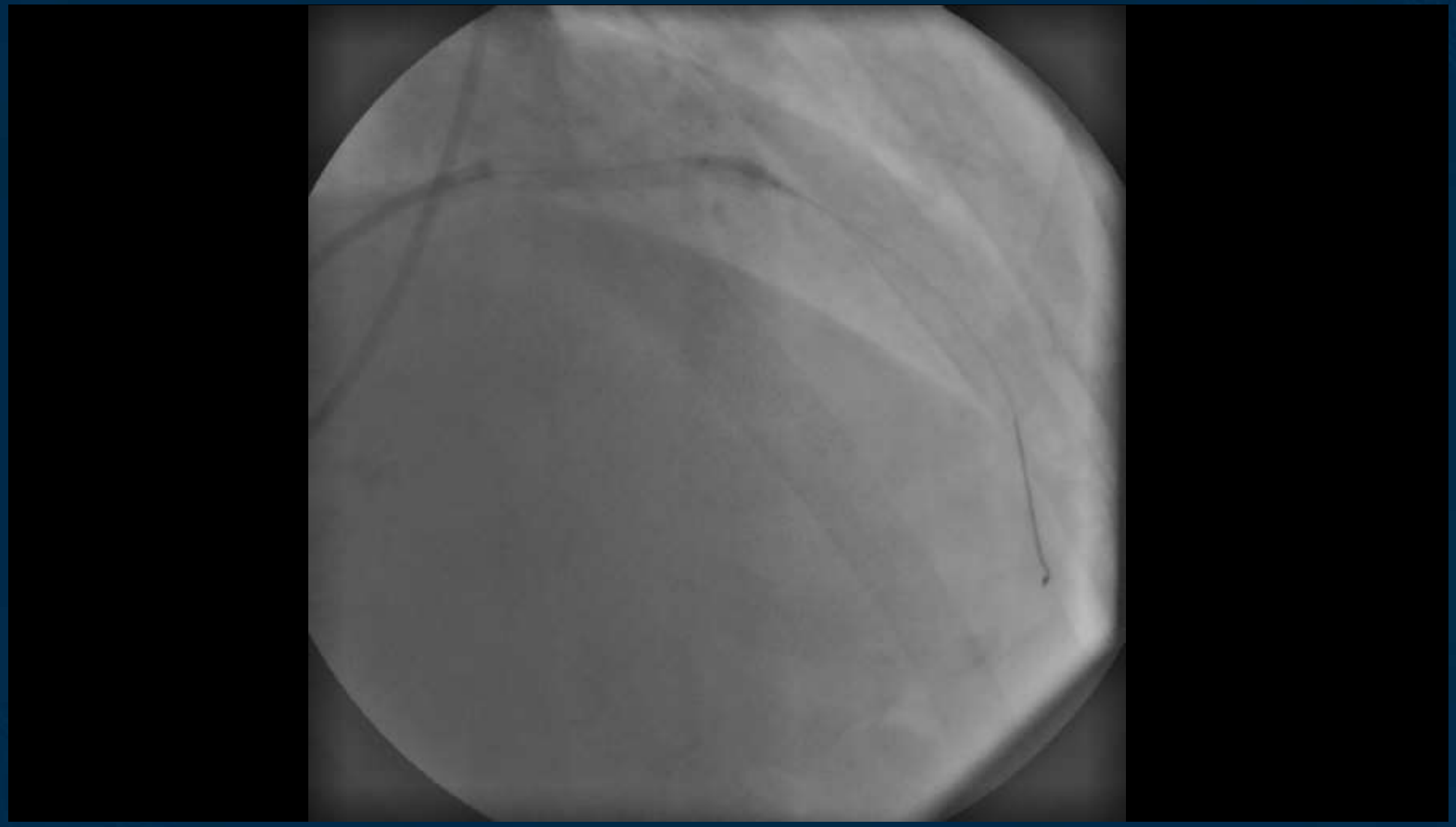
Leopard Crawl technique; 2.0mm NSE with guideplus



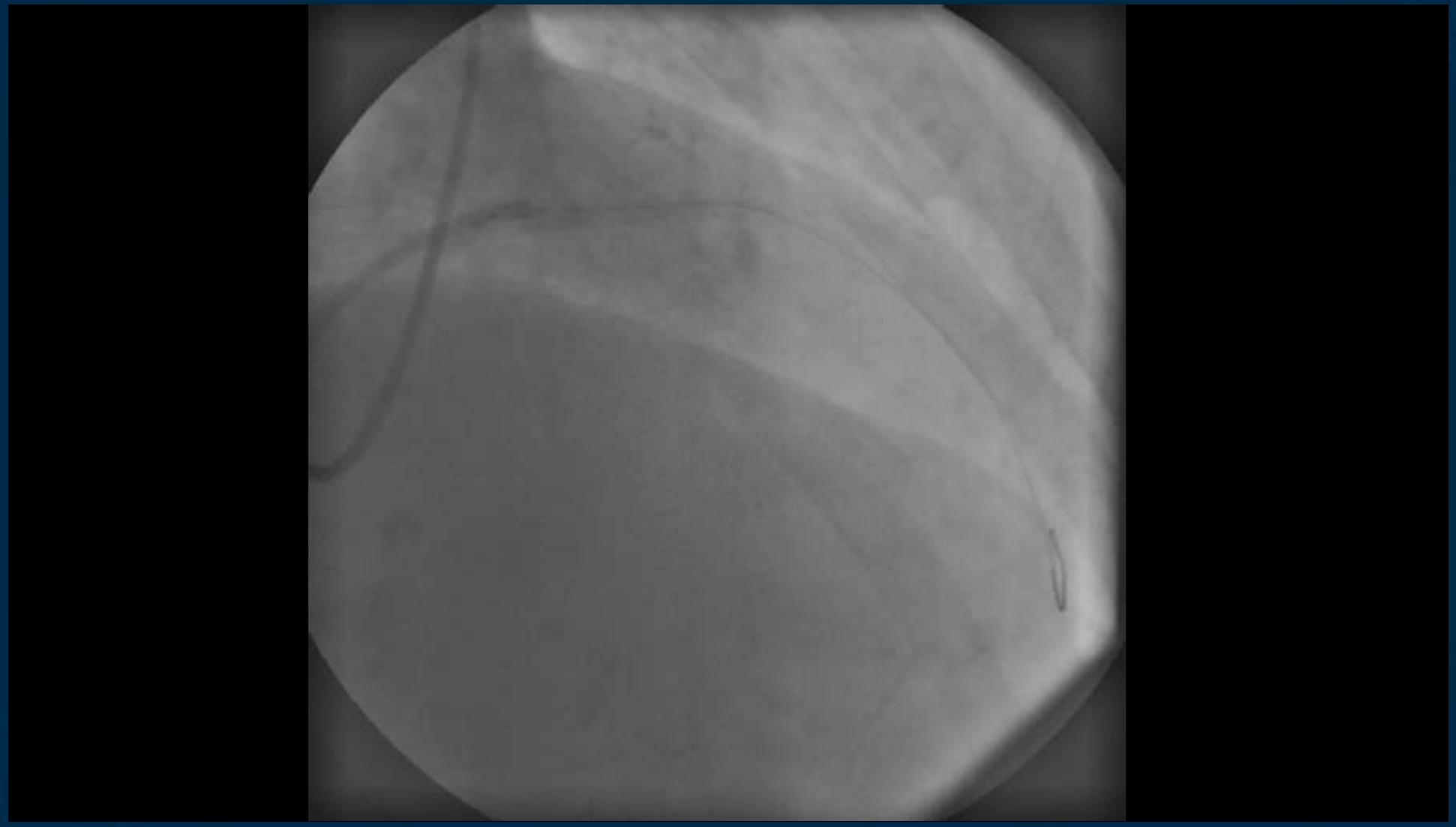
Push test; strong resistance



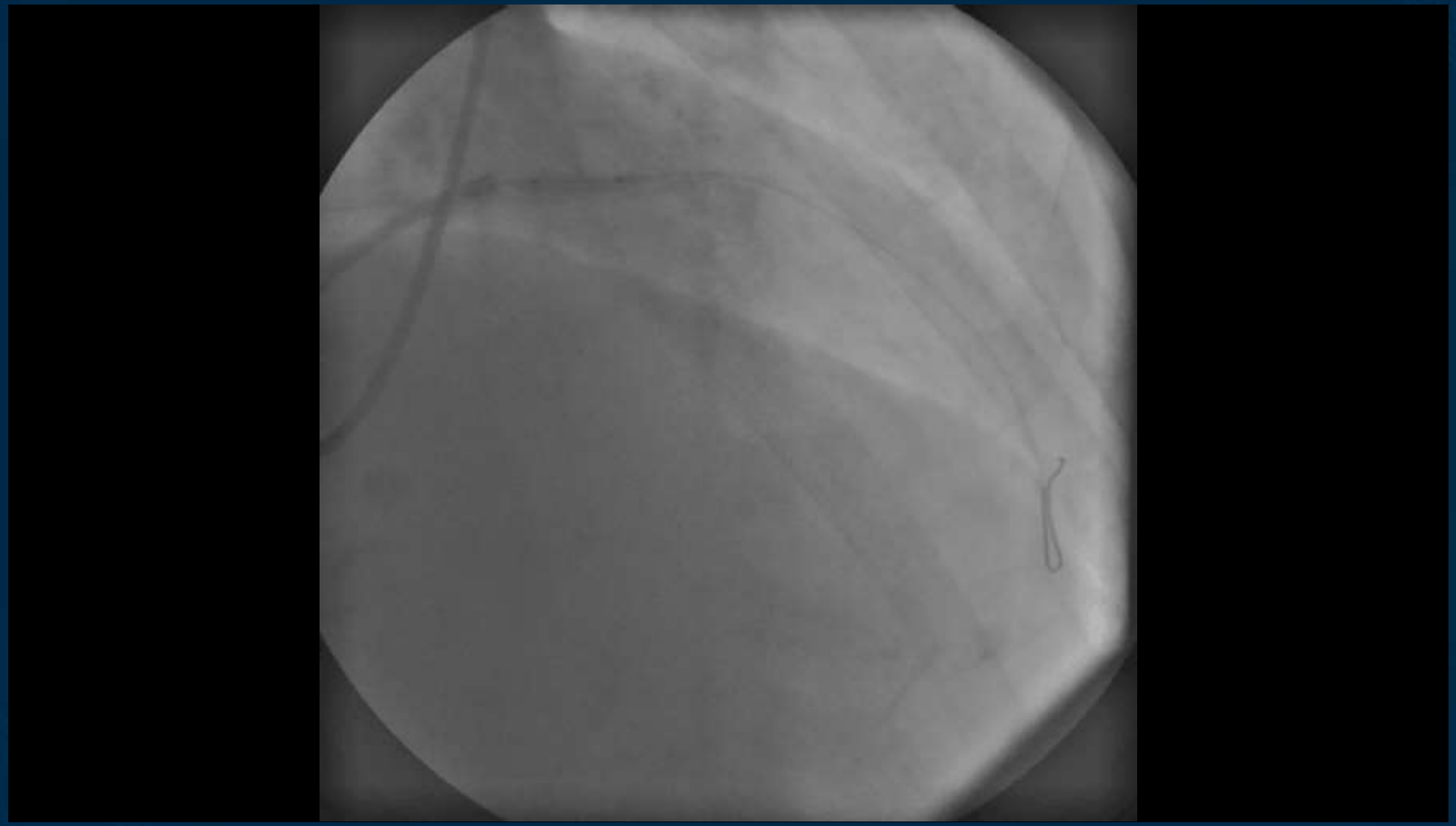
Leopard Crawl technique, again



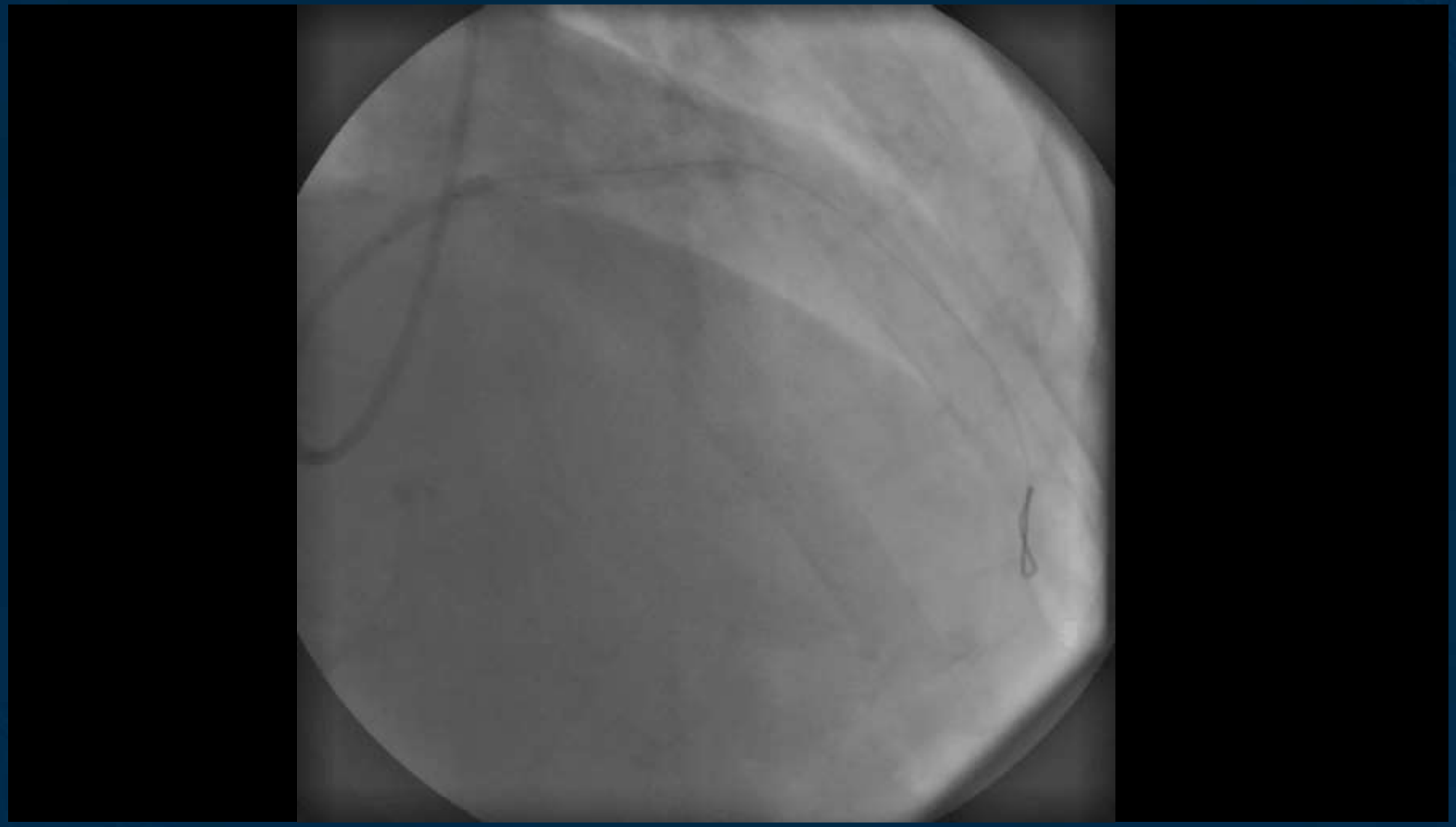
Push test again; but still resistance



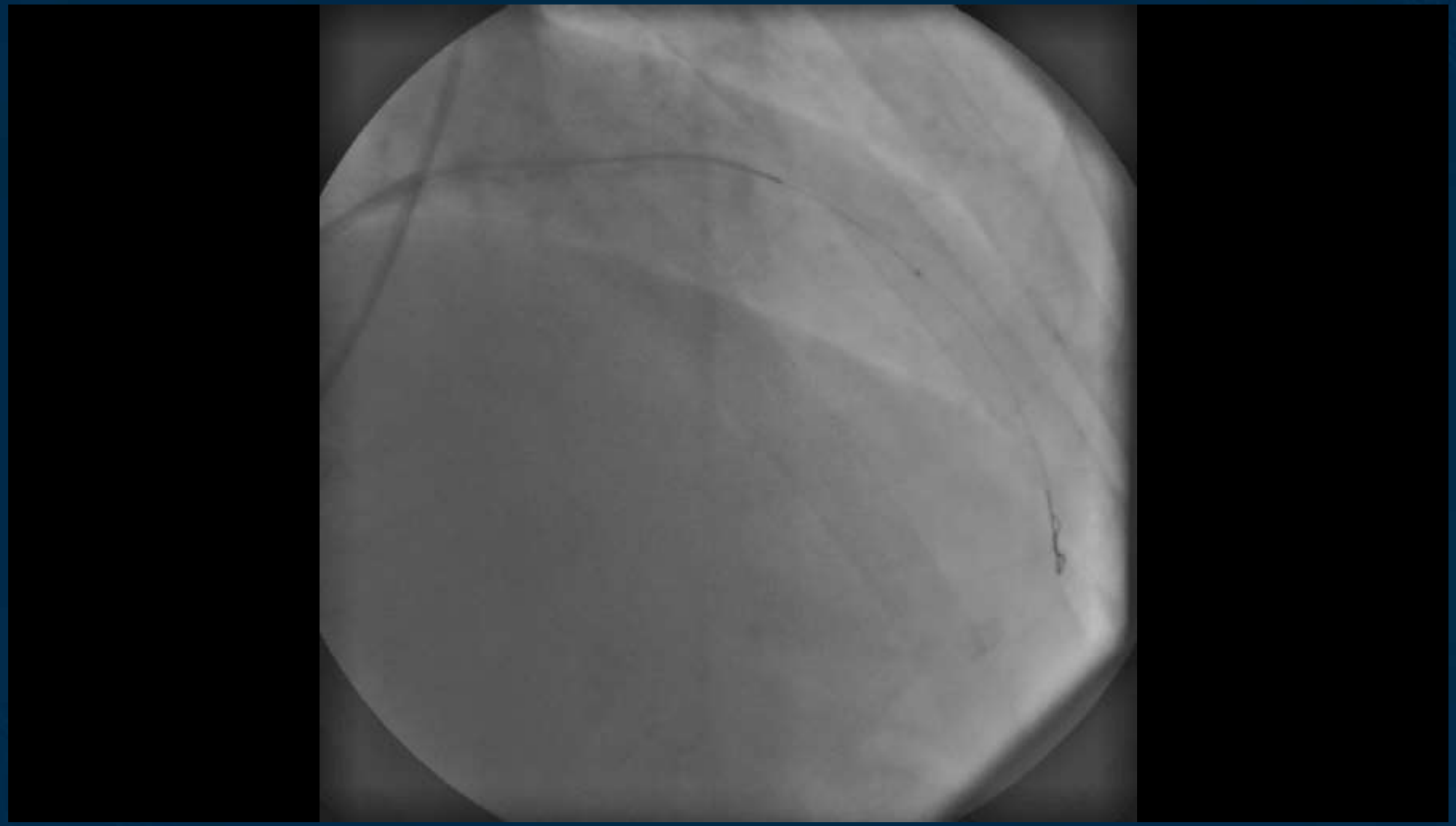
NSE dilation again



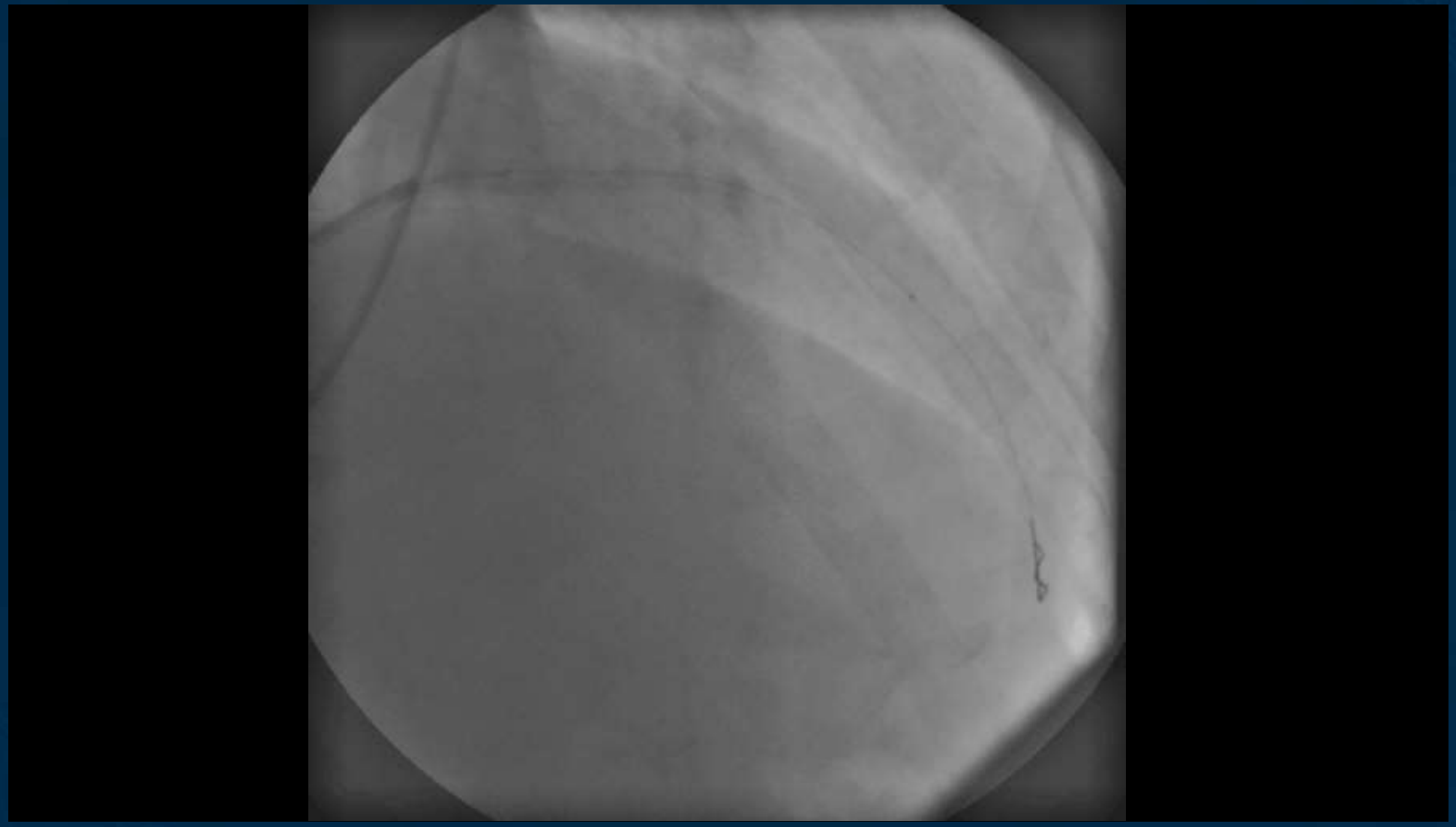
Push test again; no resistance



IVUS marking; distal site



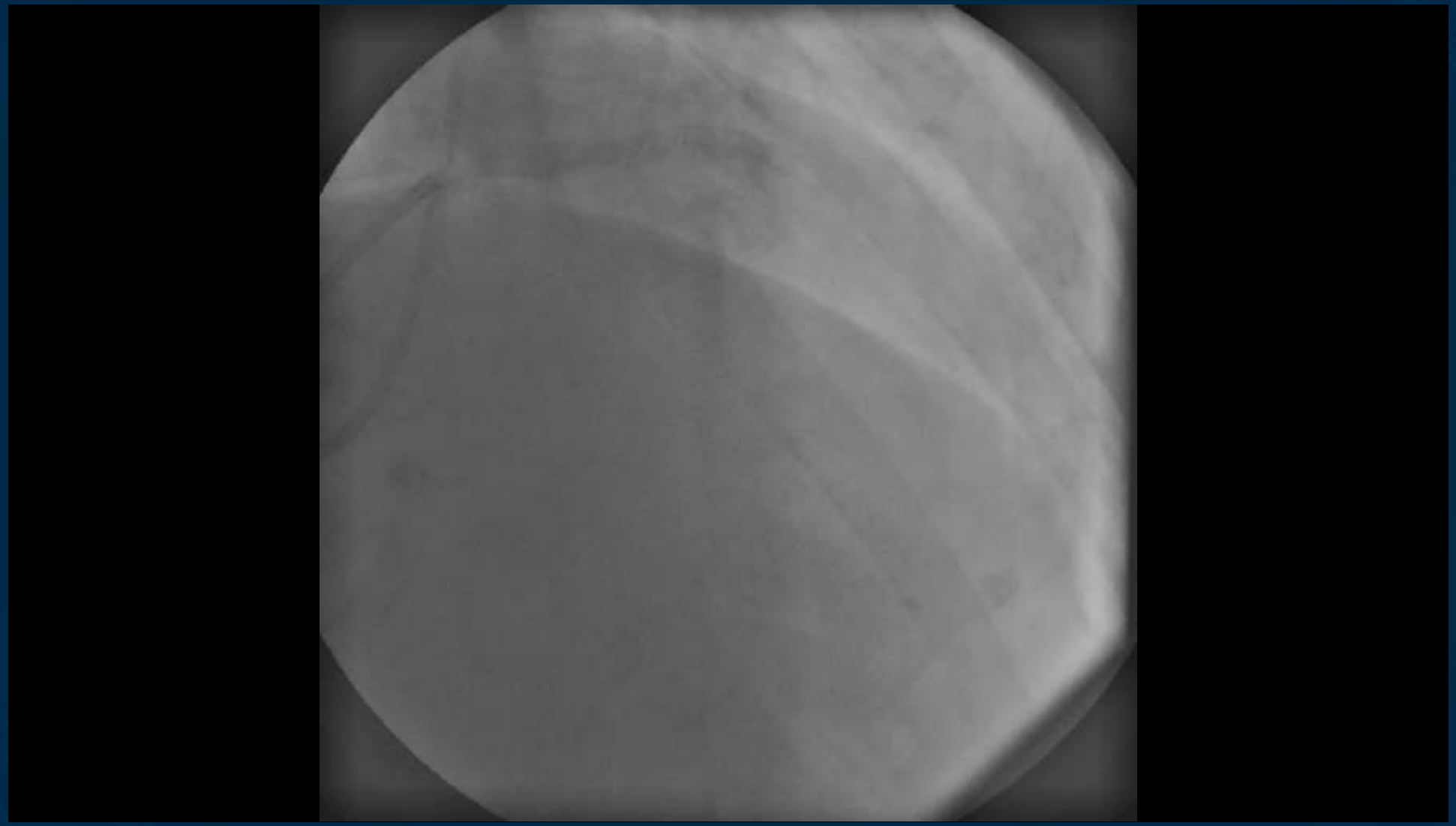
IVUS marking; proximal site



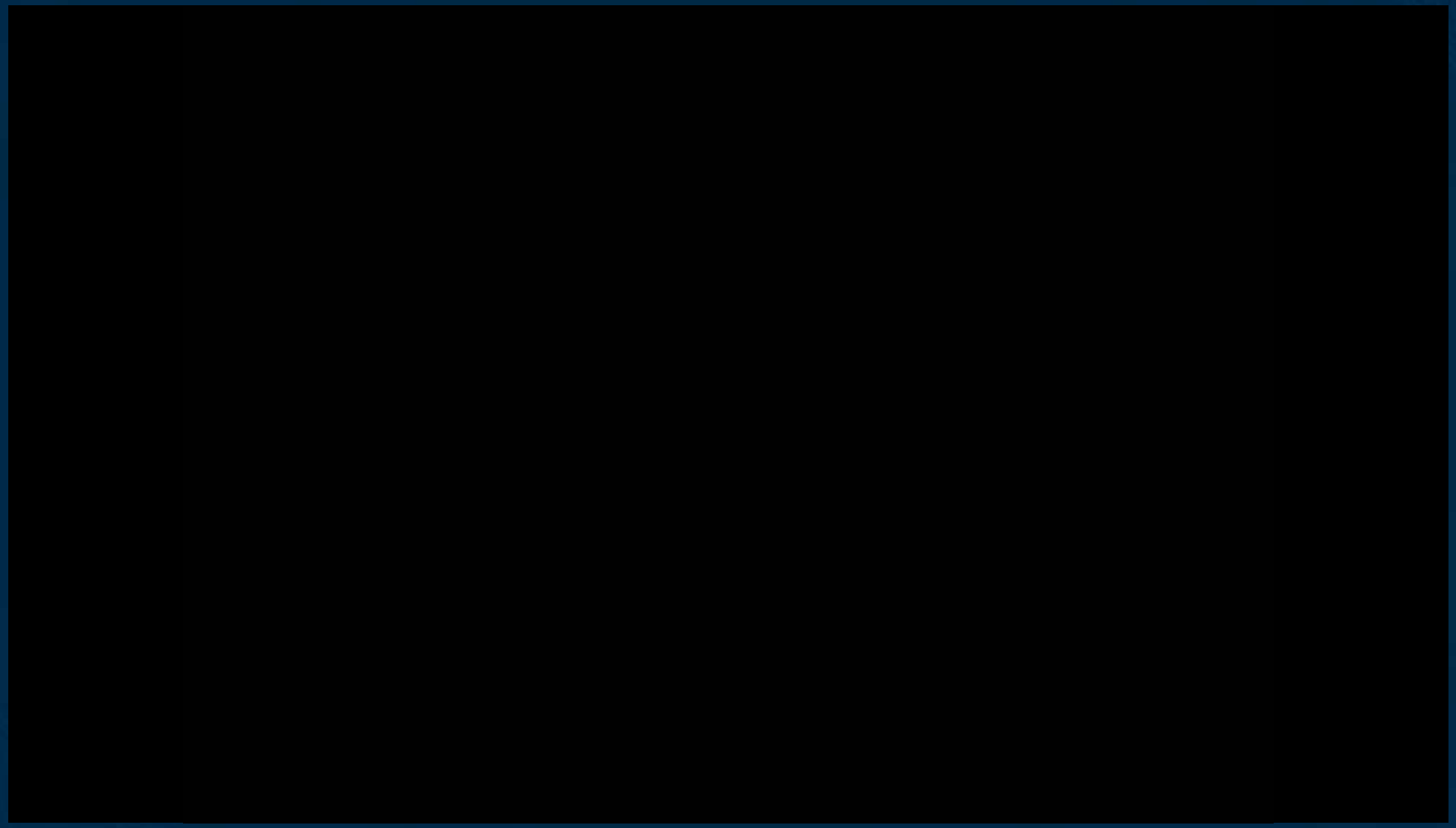
Stent delivery

Stenting

Final CAG



Leopard crawl using Lacrosse NSE.
Pre-dilatation of a calcified lesion



Efficacy of Lacrosse NSE Using the "Leopard-Crawl" Technique on Severely Calcified Lesions

Kazuhiro Ashida, MD, PhD, Taichiro Hayase, MD, Takayuki Shinmura, MD

ABSTRACT: Calcified lesions often encounter difficulties associated with stent delivery and underexpansion. Lesion preparation of calcified lesions prior to stent implantation is important to facilitate stent delivery and provide concentric stent expansion. The Lacrosse NSE, a balloon catheter with 3 nylon elements, provides an efficacious scoring effect when used for predilatation of calcified lesions. Although bench testing on a calcified model verified that Lacrosse NSE and other scoring catheters provide a greater scoring effect compared to conventional plain old balloon angioplasty, delivery to target lesion location using standard delivery techniques for severely calcified lesions is typically more problematic. One method for overcoming the obstacles faced by difficult delivery is use of the "leopard-crawl" technique. This technique uses a low inflation pressure to create a wedge into the calcification and then subsequently advances the catheter during balloon deflation to facilitate catheter delivery across the stenosis. This technique is well suited for the Lacrosse NSE due to the unique catheter design. We hereby report on the initial clinical use of the leopard-crawl technique for facilitating catheter delivery in cases of severely calcified lesions in which standard delivery was unsuccessful, while creating an efficacious scoring effect into the calcified lesion that reflects the results of bench testing.

J INVASIVE CARDIOL 2013;25(10):555-564

Key words: calcified lesion, leopard-crawl technique, intravascular ultrasonic imaging, CT angiography

Abbreviations
CAG – coronary angiography
IVUS – intravascular ultrasound
LAD – left anterior descending artery
LAO – left anterior oblique
LCX – left circumflex coronary artery
OCT – optical coherence tomography
PCI – percutaneous coronary intervention
POBA – plain old balloon angioplasty
RCA – right coronary artery

The scope of cases treated with PCI has increased with further advances in medical devices and techniques. However, treatment of calcified lesions by PCI remains problematic,[1-3] with difficulties associated with stent delivery, underexpansion, and asymmetric expansion resulting in worse patient prognosis. Therefore, it is considered that predilatation to create multiple scoring effects into the lesion prior to stenting leads to better stent expansion.[4,5]

Recently, the novel Lacrosse NSE catheter (Goodman Co, Ltd) has become commercially available. The catheter contains three triangular nylon elements (width, 0.014"; height, 0.015") that are free floating on the outside of the balloon surface, and attached proximal and distal to a 13 mm balloon length. Dilatation using a Lacrosse NSE creates a scoring effect into calcified tissue through a focused transmission of force through the elements. An investigation was performed into the dilative effect of various types of commercially available scoring balloons on fully circumferential calcified models.

Unfortunately, current designs of scoring balloons result in reduced functionality in regard to delivery in comparison to conventional balloons, and difficulties associated with delivery and lesion crossability of scoring catheters occur in a clinical setting.[6] The Lacrosse NSE elements are attached distal to the balloon location, and for instances whereby the catheter is unable to cross lesion location, a "leopard-crawl" technique can assist in facilitating device delivery. The efficacy of the leopard-crawl technique in crossing calcified lesions in a clinical setting is also further addressed.

Methods

Testing method for identifying scoring effect. Twelve cylindrical tubes (inner diameter, 3.0 mm; thickness, 0.7 mm; approximate length, 7.1 mm) comprised of New Diastone Yellow (dental stone; Morita Co, Ltd) (Figure 1) and covered by silicone tubing (thickness, 1.0 mm) were used to represent a calcified lesion (Figure 2) (calcified models were provided by Goodman Co, Ltd). Three catheters of each of the following devices were dilated within the calcified models: 3.5 x 10 mm Powered Lacrosse non-compliant balloon (Goodman Co, Ltd); 3.5 x 13 mm Lacrosse NSE scoring balloon; 3.5 x 10 mm Flextome cutting balloon; and 3.5 x 10 mm Scoreflex (Orbus Neich Medical). Inflation pressure, total number of cracks, and dimensions (longitudinal length) were recorded (Figure 3).

Results

A cracking effect was observed for the various scoring balloons during inflation from nominal burst pressure (NBP) to rated burst pressure (RBP), with multiple cracks observed for two of the scoring devices. For the scoring balloons, both Lacrosse NSE and the Flextome cutting balloon incurred cracking in at least 2 locations and throughout the entire calcified

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Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.
Manuscript submitted March 28, 2013, provisional acceptance given April 22 2013, final version accepted May 28, 2013.
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J INVASIVE CARDIOL 2013;25(10):555-564

Conclusion (1)

- ✓Severely calcified lesions: issues with problematic stent delivery and under-expansion occur often.
- ✓Given the mechanism of stent expansion, it is considered that creating a cracking effect in at least 2 locations is important.
- ✓Create a creating effect with a scoring balloon catheter (Rotablator thins out the calcification).

Conclusion (2)

- ✓The design of Lacrosse NSE provides for distal inflation that facilitates the leopard crawl technique. The profile of cutting balloon, similar to conventional balloons, becomes enlarged upon inflation.
- ✓Use of other scoring balloons is less effective in generating multiple cracking effects.
- ✓Double wire technique is feasible: various delivery techniques can be utilized.
- ✓Considering the distribution of calcification by using MDCT as well as wire bias, cracking can be created safely (process of sizing and inflation method).