Orbital Atherectomy

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& OF CENTRAL JERSEY

CVI Cardiac & Vascular Interventions of New Jersey,LLC

2023 Cors at the Shore

Disclosures

- CSI
- Boston Scientific
- Shockwave Medical
- Abbott
- Philips Medical
- Terumo Medical
- Cordis

Diamondback 360® Coronary OAS

Coronary OAS Components

The Diamondback 360® Coronary Atherectomy System* is a percutaneous system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions. The system includes:

OAS Pump

Orbital Atherectomy Device (OAD)
- Features a 1.25 mm Classic Crown

ViperSlide® Lubricant

Coronary Guide Wire:
- *ViperWire Advance*®
- *ViperWire Advance*® *with Flex Tip*

The Diamondback 360® Coronary Atherectomy System is:
- The only device indicated for severe calcium
- Easy to setup; the prep time is < 2 minutes
- Controlled within the operating field
- Compatible with 6 Fr guide

*All components are sold separately

Diamondback 360® Coronary OAS

Orbital Atherectomy Device (OAD)

The Orbital Atherectomy Device provides enhanced procedural control and smart software for the operator to increase procedural efficiency.[1] It is designed to reduce severe calcification on the vessel wall in order to facilitate stent delivery by using an orbiting diamond-coated crown.*

On-Handle Controls

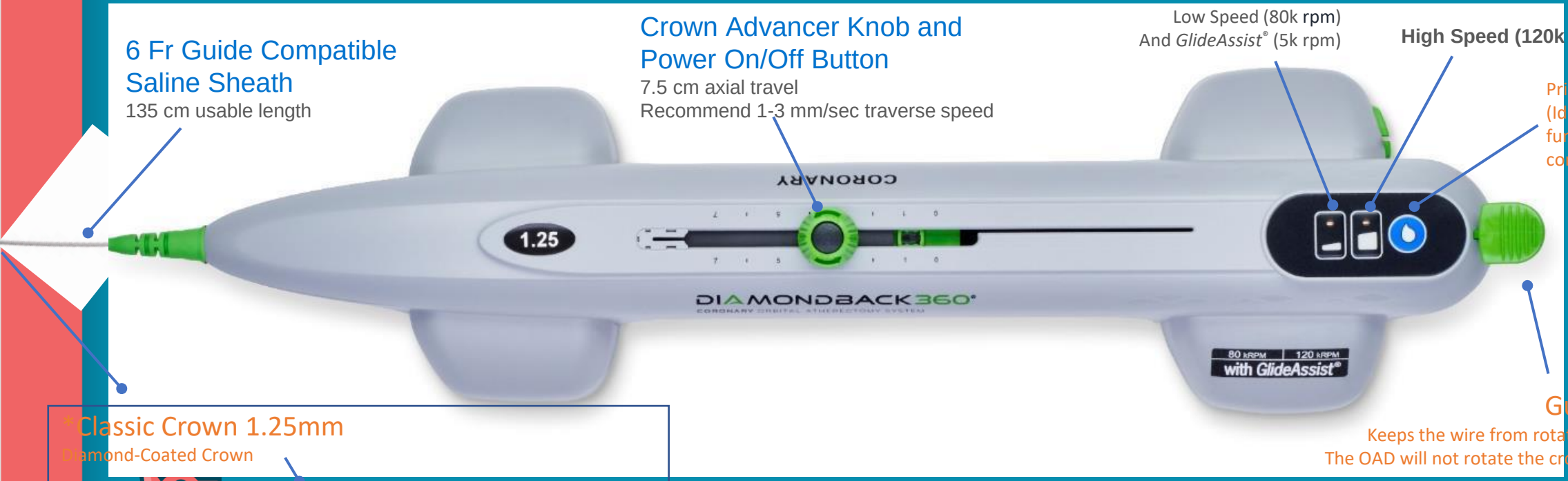
6 Fr Guide Compatible Saline Sheath
135 cm usable length

Crown Advancer Knob and Power On/Off Button
7.5 cm axial travel
Recommend 1-3 mm/sec traverse speed

Low Speed (80k rpm) And *GlideAssist*® (5k rpm)

High Speed (120k rpm)

Prime Button (Identical functionality to the control on pump)



Guidewire Brake
Keeps the wire from rotating or moving axially.
The OAD will not rotate the crown if the brake is up.

* Classic Crown 1.25mm
Diamond-Coated Crown

1. In comparison to the 1st generation device.

Diamondback 360® Coronary OAS

Orbital Atherectomy Device (OAD)

The Orbital Atherectomy Device includes a variety of features, including Smart Suite Software to offer constant progress in procedural control and efficiency.

Smart Suite Software

Smart Feature	Description
Stable Speed Controller	Software allows the device to maintain the rotational speed.
Torque Guard	Software monitors the rotation and is designed to stop the device if it is working too hard when traversing a difficult lesion.
Control Check	If Torque Guard stops the device, the on/off button is inactive for 5 seconds. If the On/Off button is pressed during this 5 second lockout period, the lockout period will begin again. Preventive measure to reduce potential case complications if the rotating driveshaft and crown encounter excessive resistance and become stalled.
Diagnostic Data Return (DDR)	CSI can provide device usage information if the device is returned to CSI.

Additional Features	Description
GlideAssist®	This feature allows the operator to spin the crown at a slow speed (5k rpm) to advance or retract the OAD crown over the ViperWire Advance® Guide Wire
Motor Speed Ramp Time	1.5 seconds
System Error Indication	All LEDs blink On/Off continuously until the power of the OAD is turned off
Boot Time	1.2 seconds from when the OAS pump is turned on to when a connected device is operational
End of Life	The device will be disabled 12 hours after use

Diamondback 360® Coronary Orbital Atherectomy

Dual Mechanism of Action

Atherectomy:

Bi-directional Differential Sanding

Reduces superficial calcium[1,2]

Calcium Modification:

Pulsatile Forces

May contribute to compliance change[2]

1. Shlofmitz, E. et al. Expert Rev Med Dev. 2017;14(11):867-879.
2. CSI Data on File: based on cadaver atherosclerotic lesions, porcine coronary lesions, and graphite block test models.

New Flex Tip Wire

TRACKABILITY

Shapeable floppy tip and flexible nitinol body for navigation in complex anatomy

Nitinol core 2.5cm 1.0g tip with stainless steel support coil (.014”)

PERFORMANCE

Flexible nitinol body providing reduced wire bias in complex anatomy, plus kink resistance

Solid nitinol core, 325cm length (.012”)

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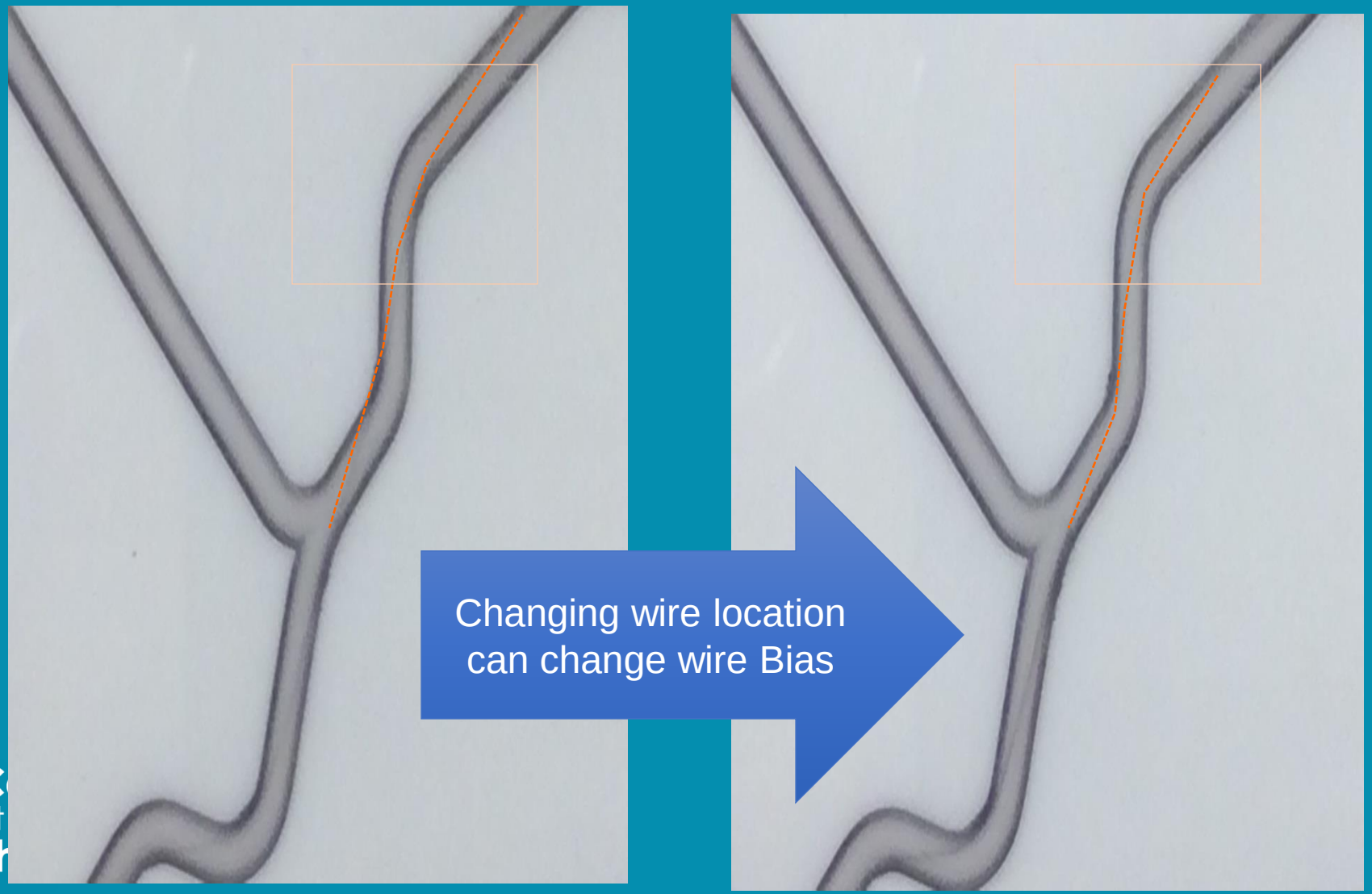
Diamondback 360® Coronary OAS

ViperWire Advance® Coronary Guide Wires

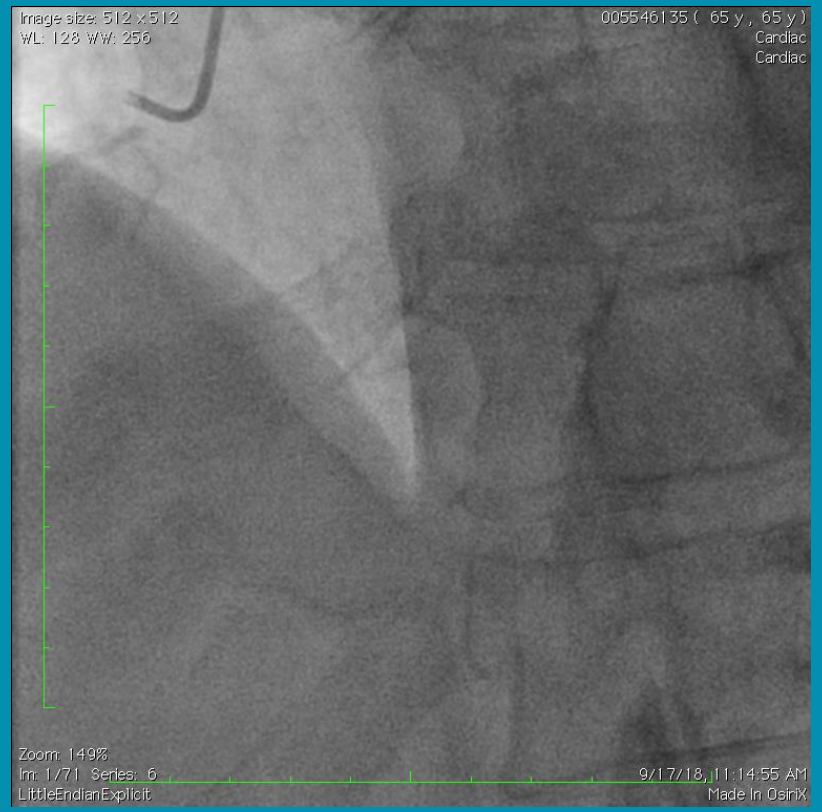
The ViperWire Advance® coronary guide wire allows for proper positioning of the crown and provides a center of rotation for the flexible drive shaft.

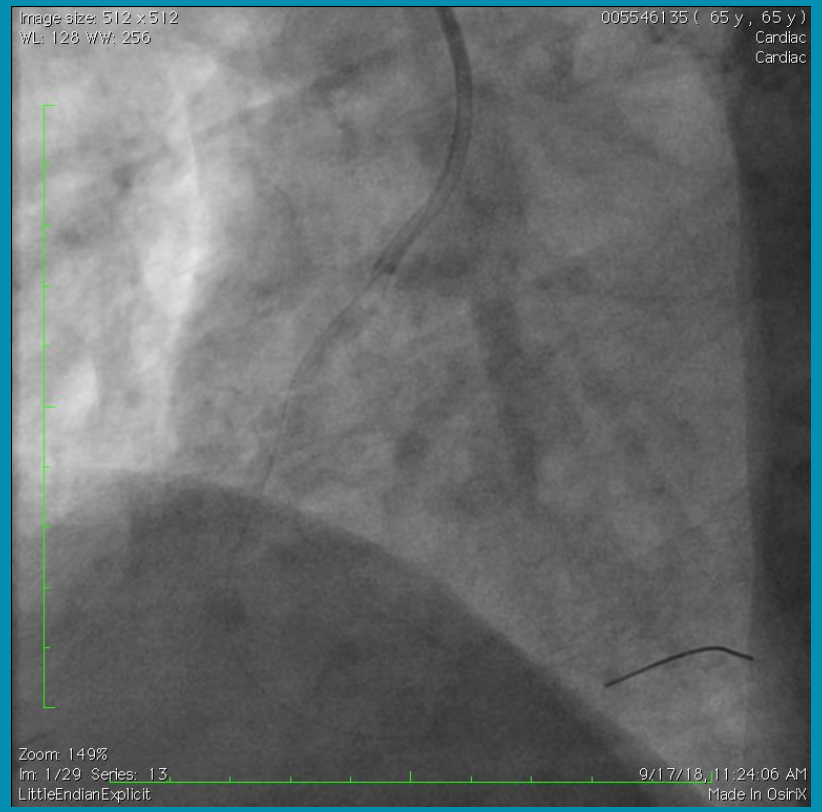
	Core Wire	Support Coil	Tip	Coating	Spring Tip Load	Dimensions
ViperWire Advance® Established performance	Stainless Steel	NA	Platinum / Tungsten	Silicone	1.4 gf	
ViperWire Advance® with Flex Tip First and only Nitinol-core coronary atherectomy wire Designed for reduced wire bias and kink resistance	Nitinol	Stainless Steel	Platinum / Tungsten	Silicone	1.0 gf	

Coronary Wire Bias Illustration



Wire bias after Viper wire





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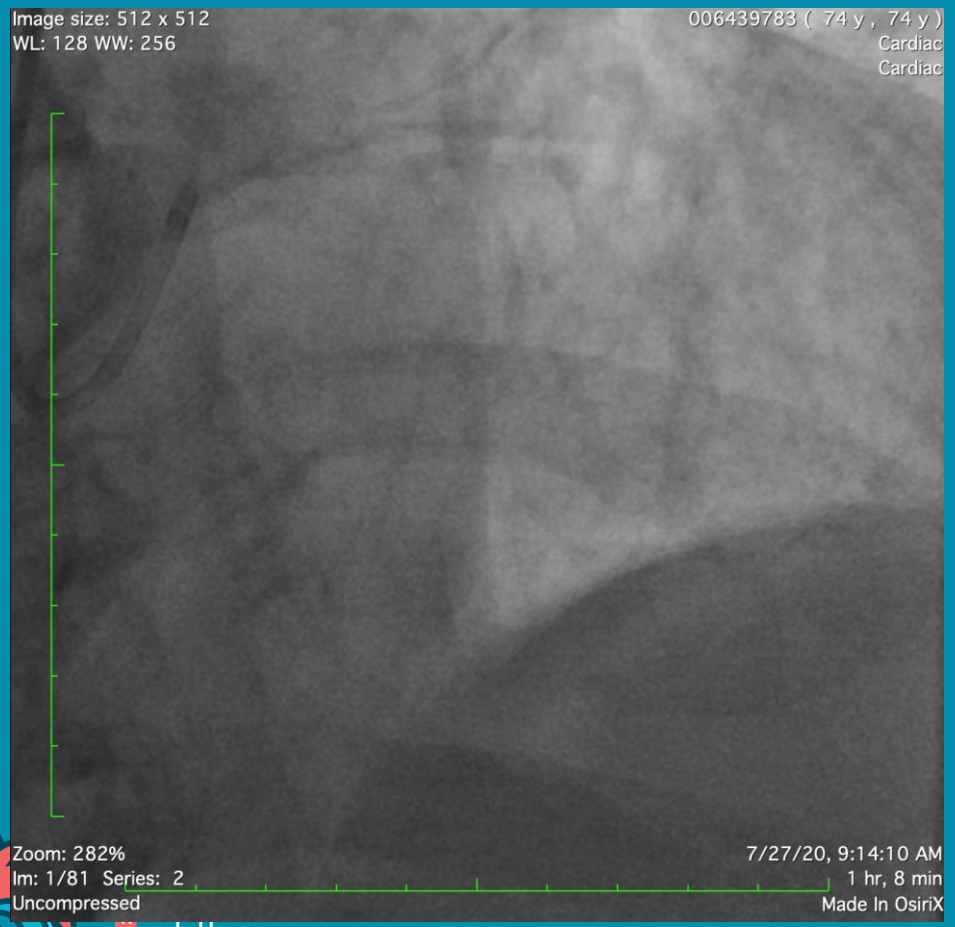
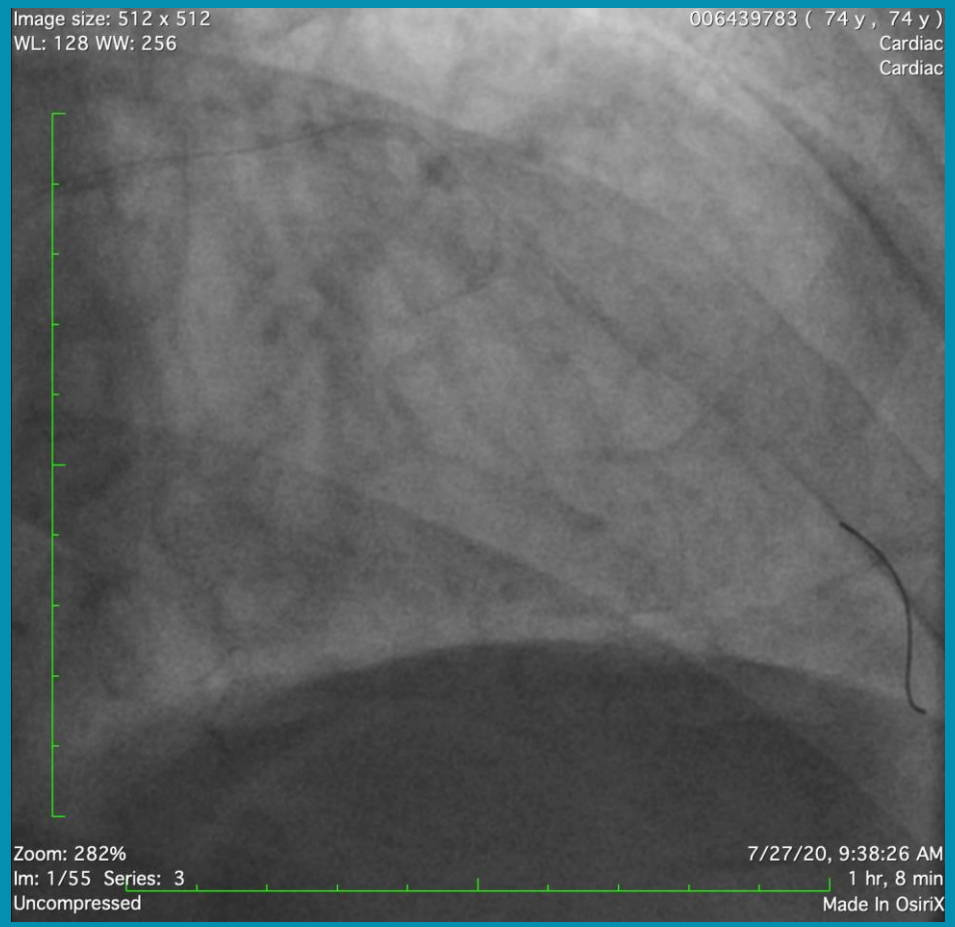
Case showing benefits of flex tip





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ECLIPSE Trial

*E*valuation of Treatment Strategies for Severe *Ca*a*L*cif*I*c Coronary Arteries:
Orbital Atherectomy vs. Conventional Angioplasty *P*rior to Implantation of Drug Eluting *St*E*n*ts

~2000 Patients with Severely Calcified Lesions[1]

Randomize 1:1

Orbital Atherectomy Strategy

1.25 mm Classic Crown followed by balloon pre-dilation

Conventional Angioplasty Strategy

Conventional and/or specialty balloons per operator discretion

2nd generation DES implantation and optimization

2nd generation DES implantation and optimization

1° Endpoints: 1) Post-PCI in-stent MSA by OCT (N=~500 in imaging sub-study)
2) 1-year TVF (all subjects)

2° Endpoints: 1) Procedural Success: Successful stent delivery (all subjects)
2) Strategy Success: Procedural success without crossover

Key Endpoints

MSA ~500 subjects in OCT cohort

OAS ≥ 1 mm^2 superior MSA vs. POBA

TVF All subjects

OAS ≥ 5% reduction in TVF vs. POBA

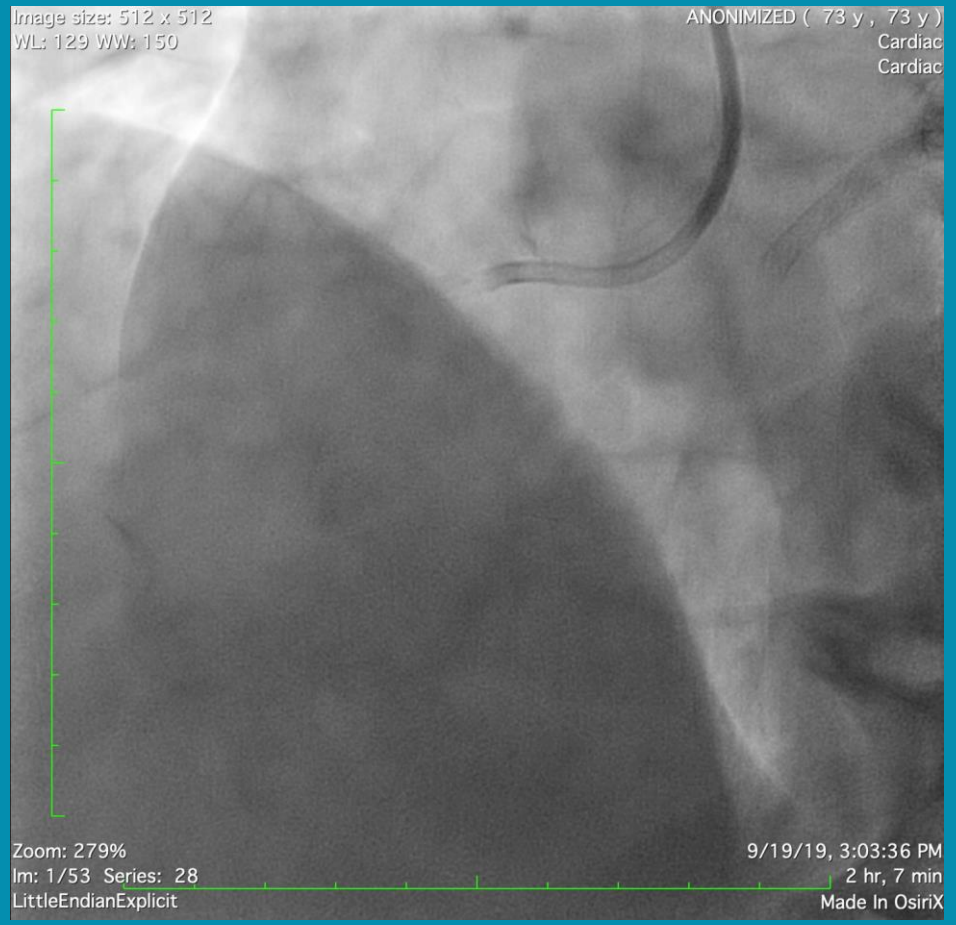
2° All Subjects

OAS ≥ 7% higher procedural success vs. POBA

[1]Patients are enrolled at physician discretion with post-procedure calcium confirmation by the Core Lab

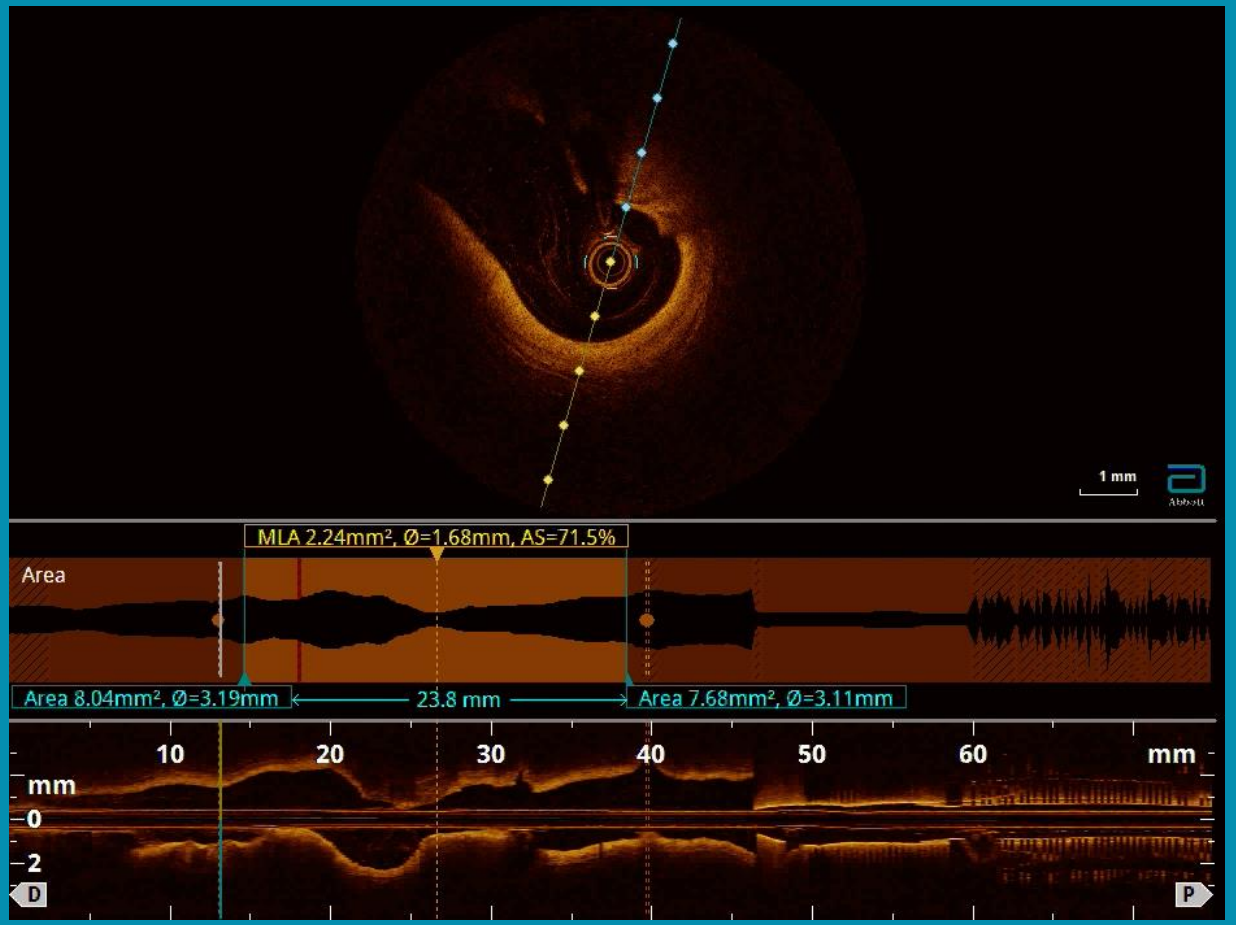
Principal Investigators: Ajay Kirtane, MD; Philippe Généreux, MD;
Study Chairman: Gregg W. Stone, MD
Sponsor: Cardiovascular Systems Inc.

Case 1: Utilizing Glide Assist and Bidirectional Capabilty



Cors at the Shore 2023

Initial OCT run



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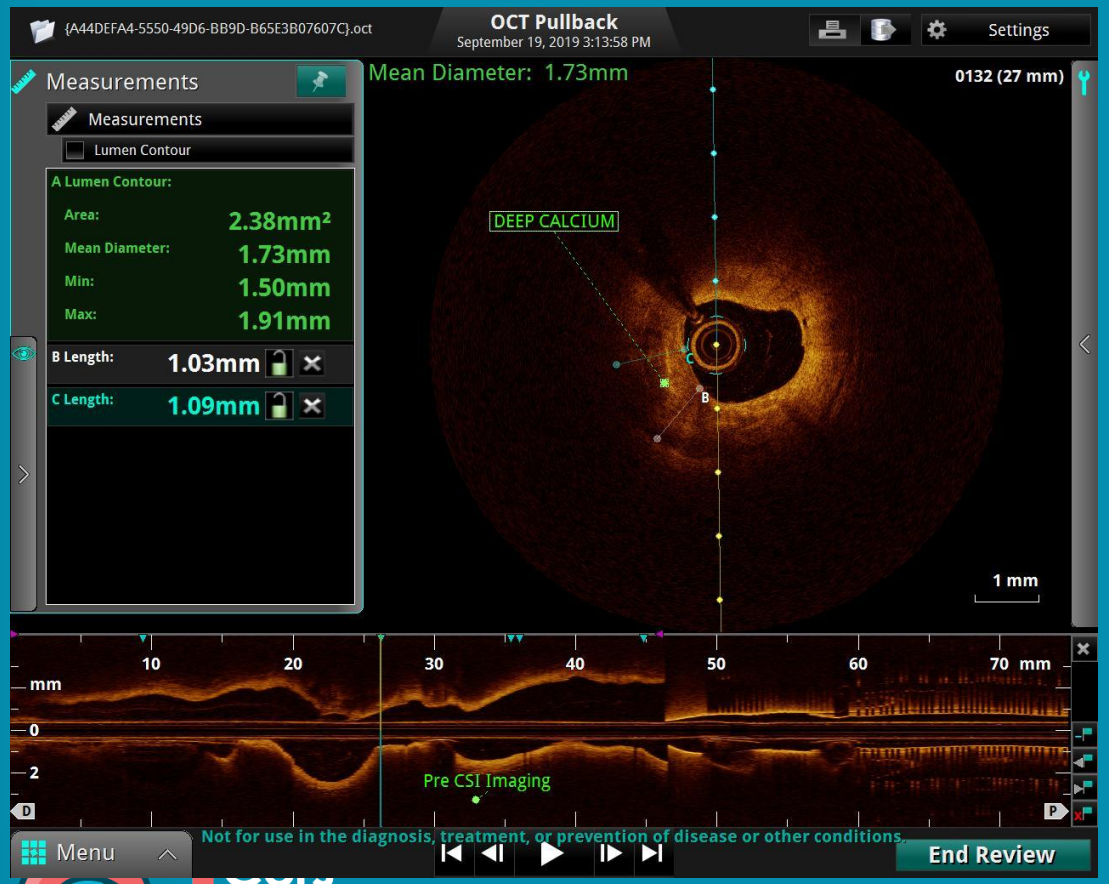
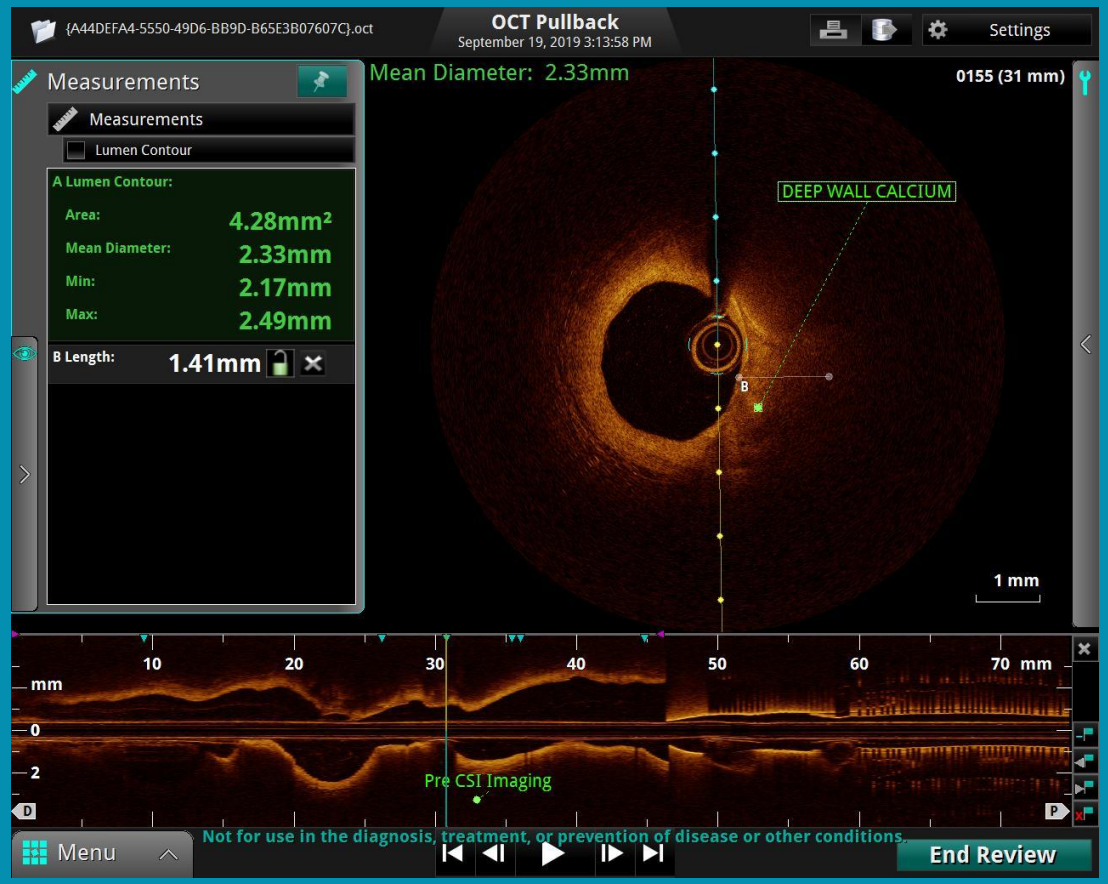
OCT Showing Deep Calcium





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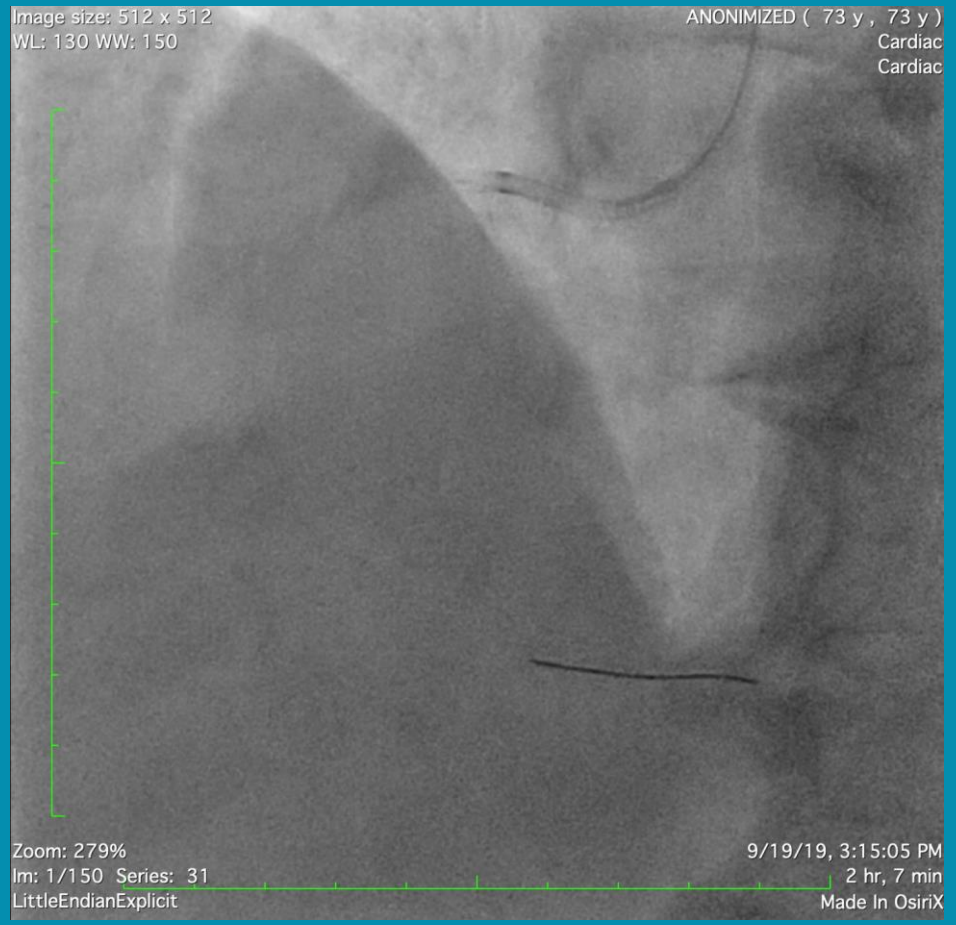
Glide Assist Past The Lesion



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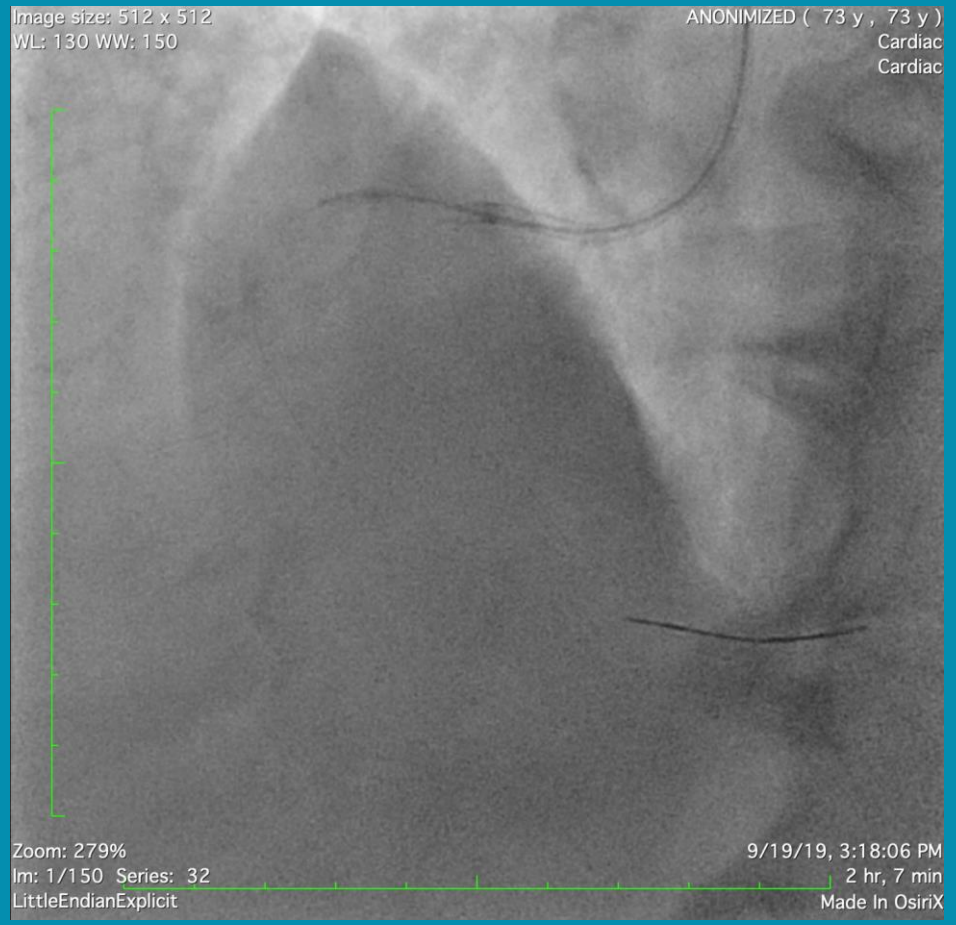
CSI Run 1



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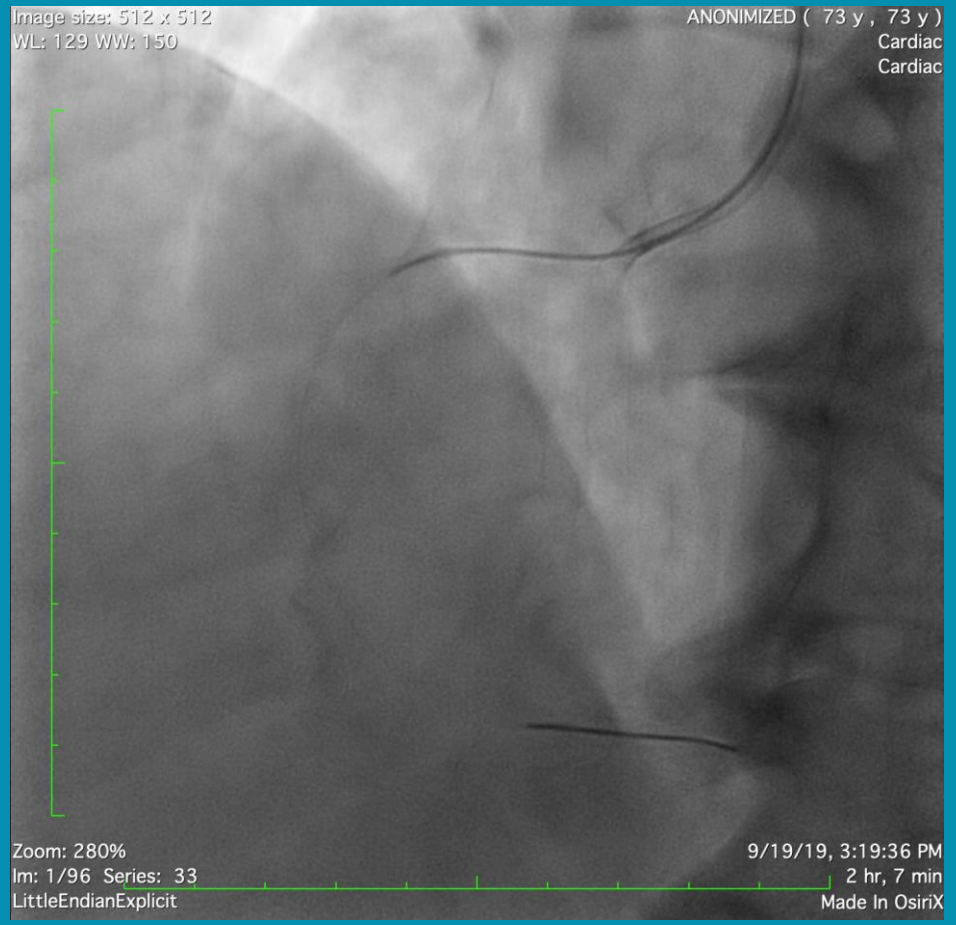
CSI Run 2



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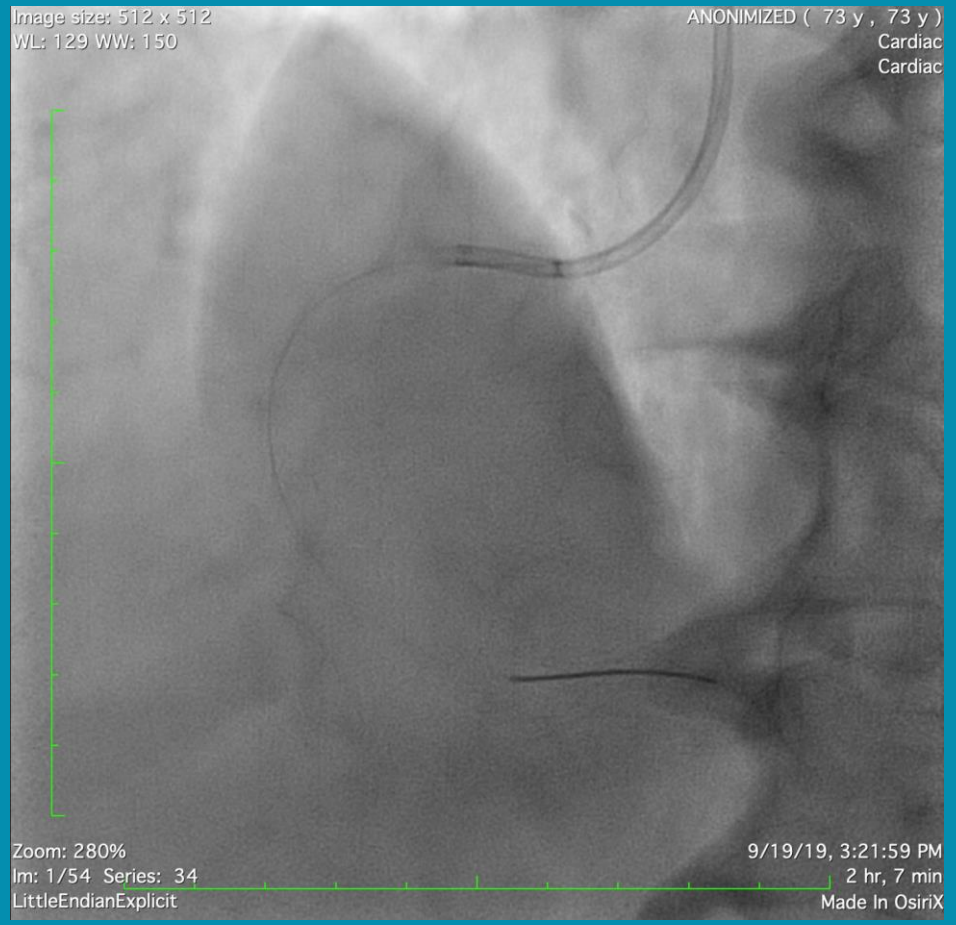
Post CSI



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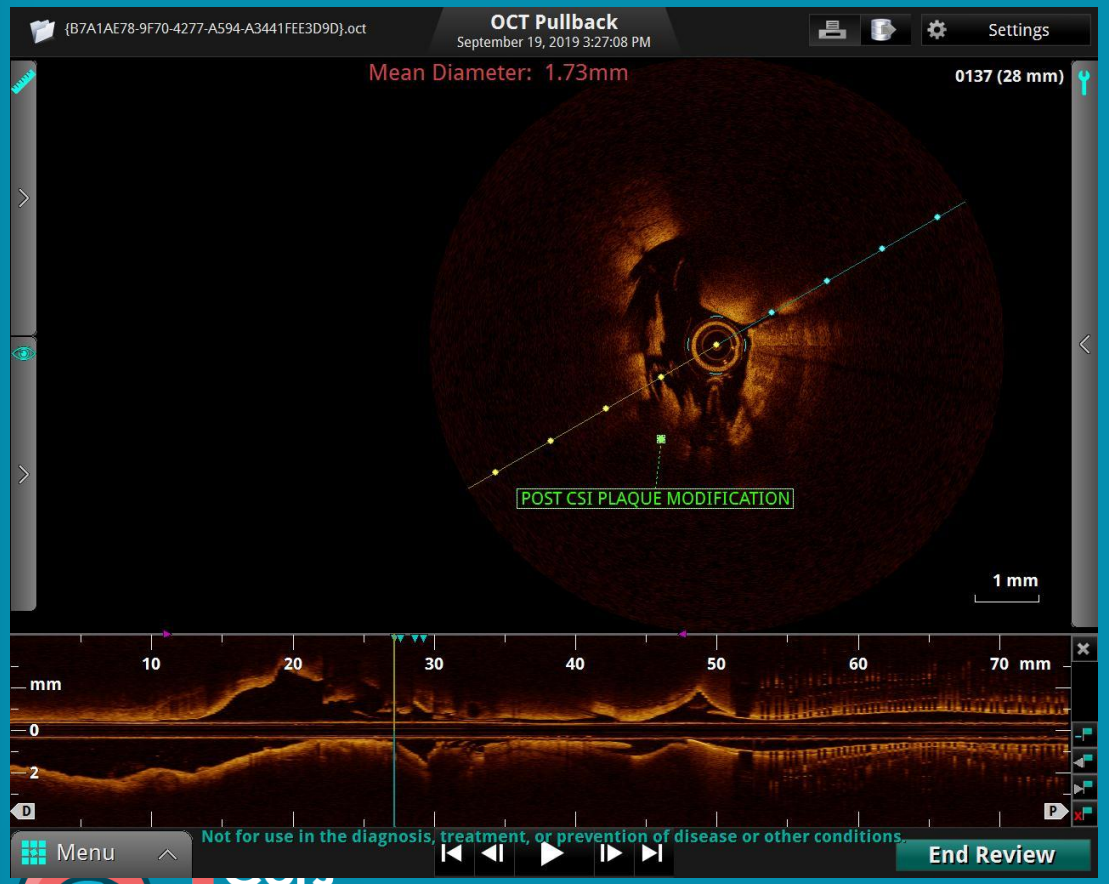
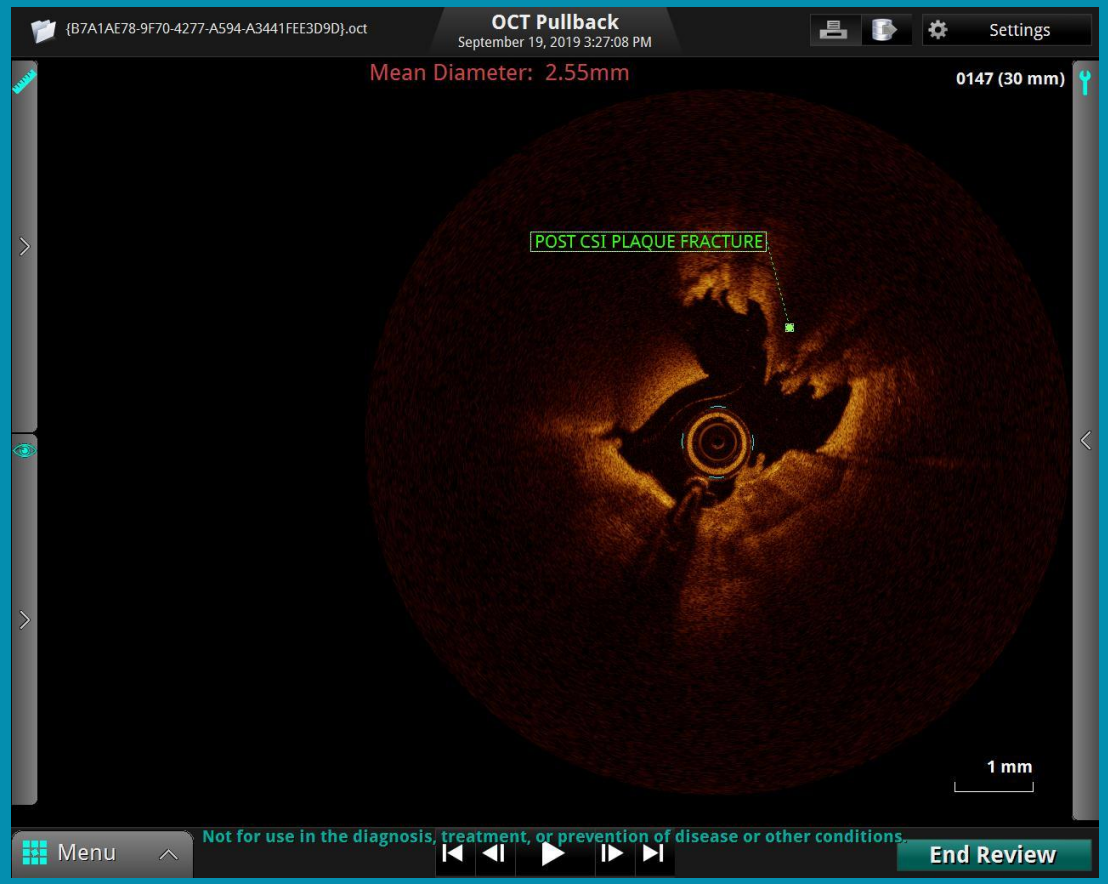
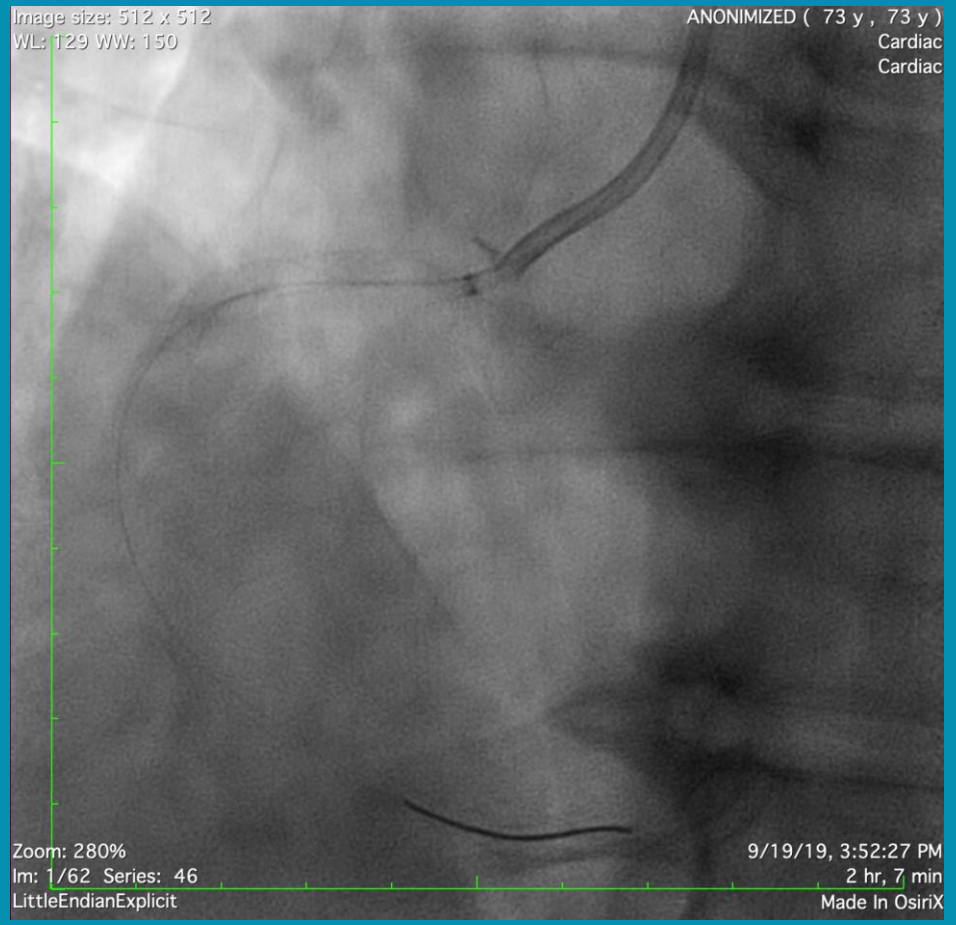
OCT Demonstrating Calcium Fracture





Final Angiogram



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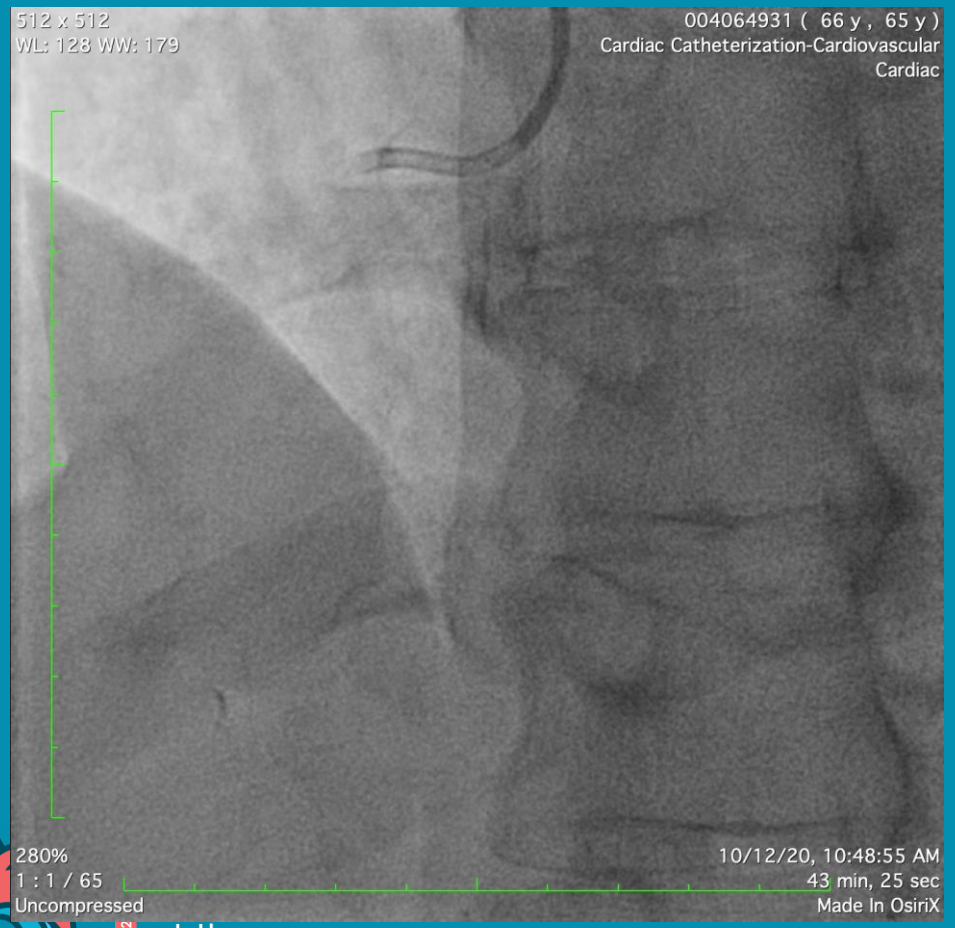
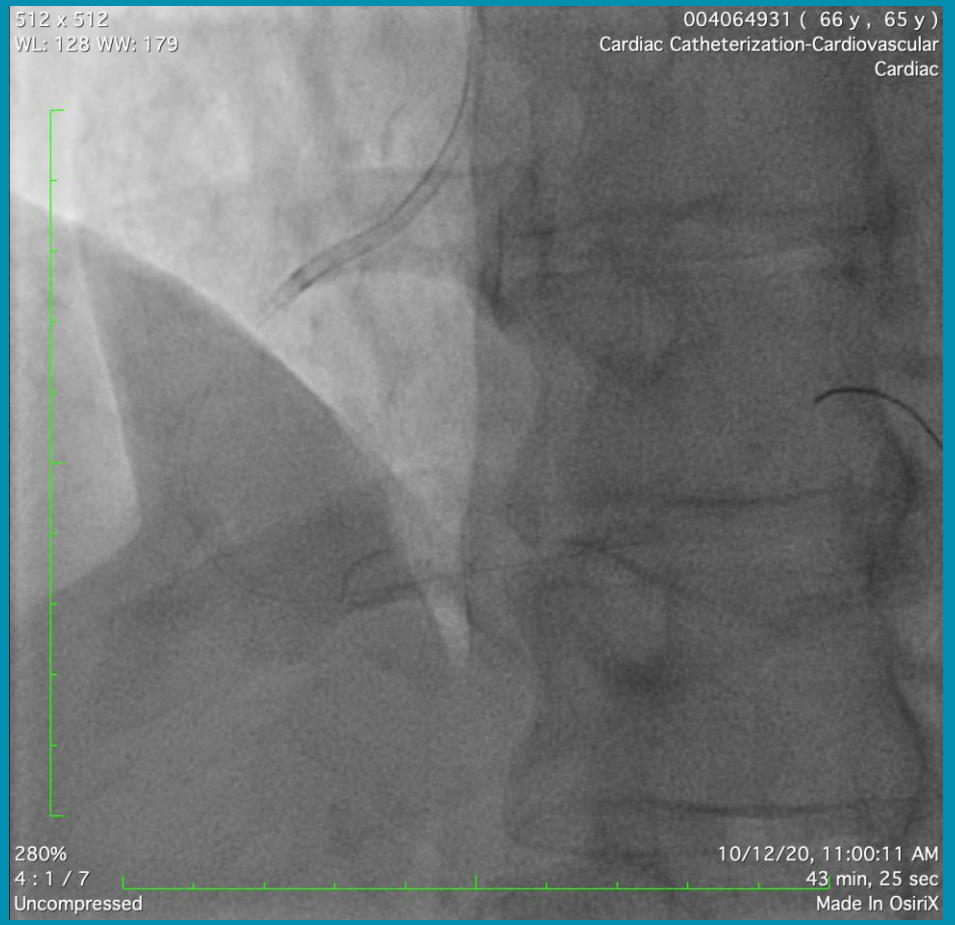
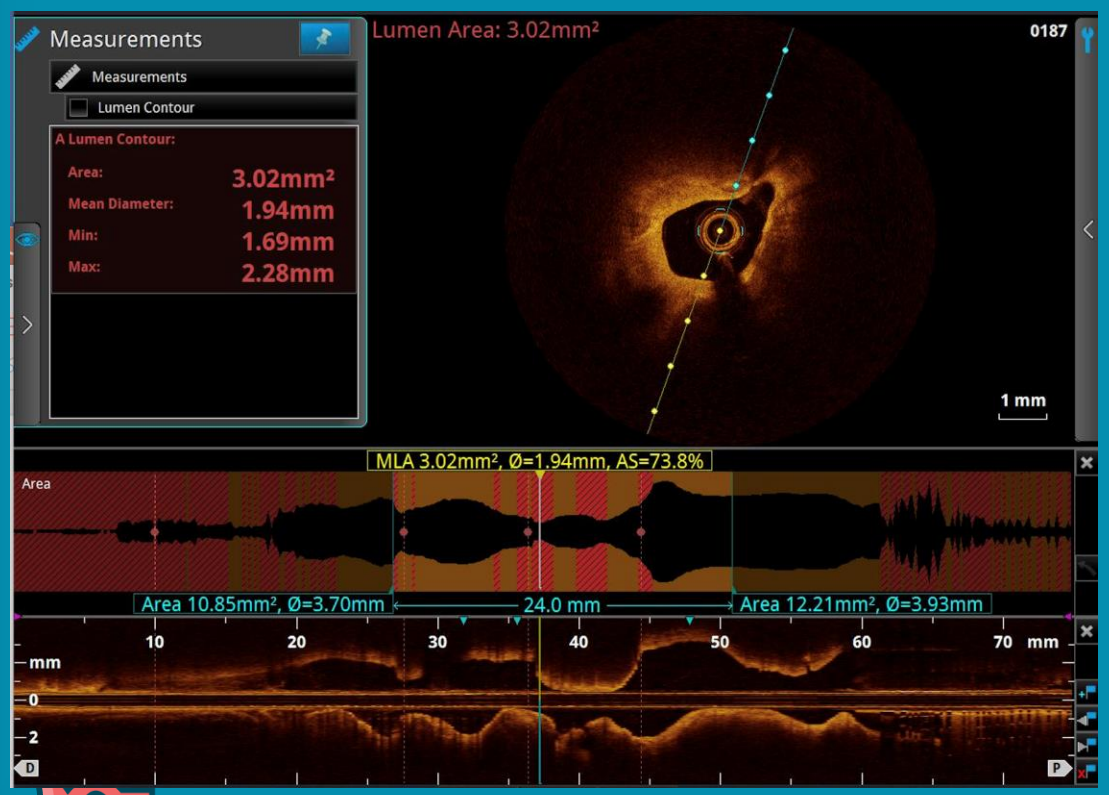
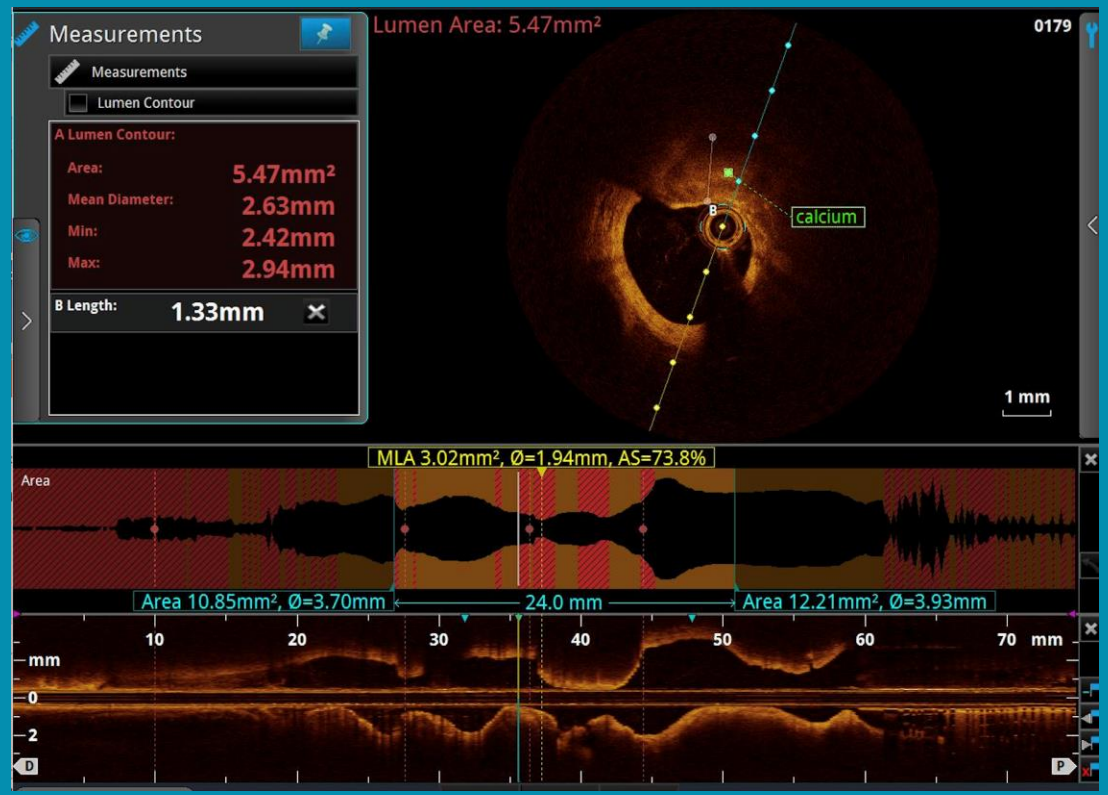
Case 2 Tortuous RCA





2020 at the Shore





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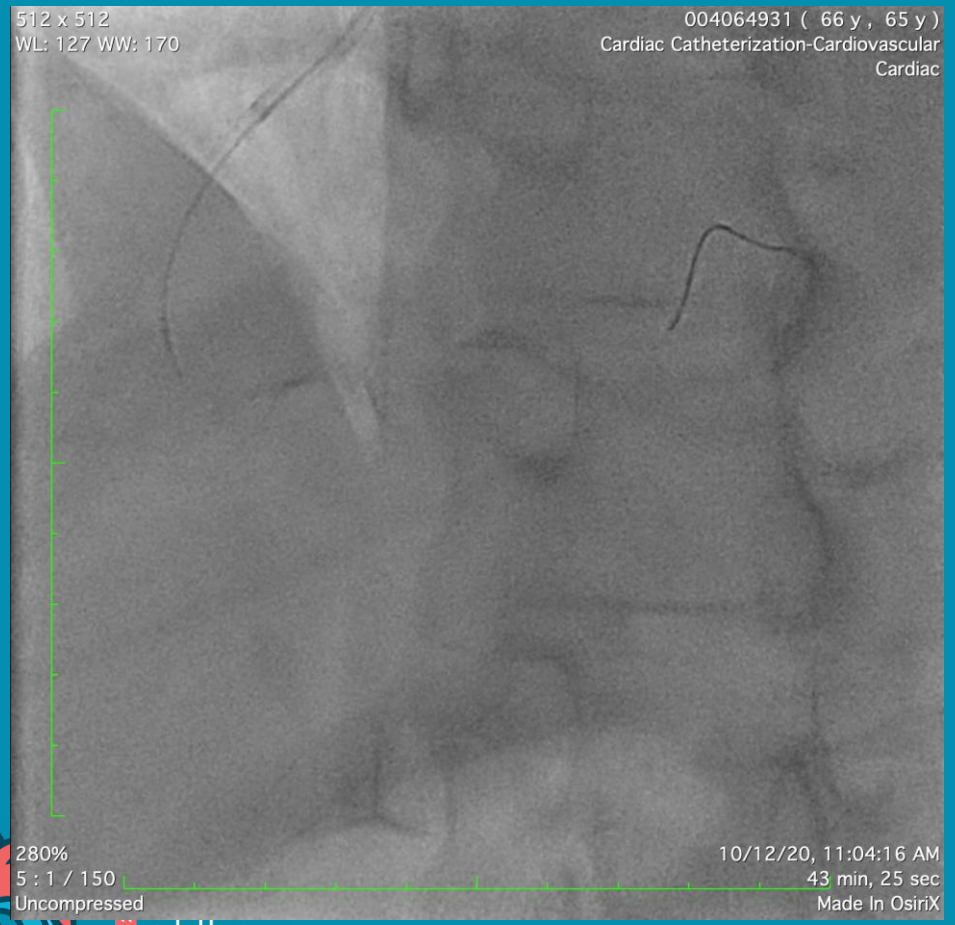
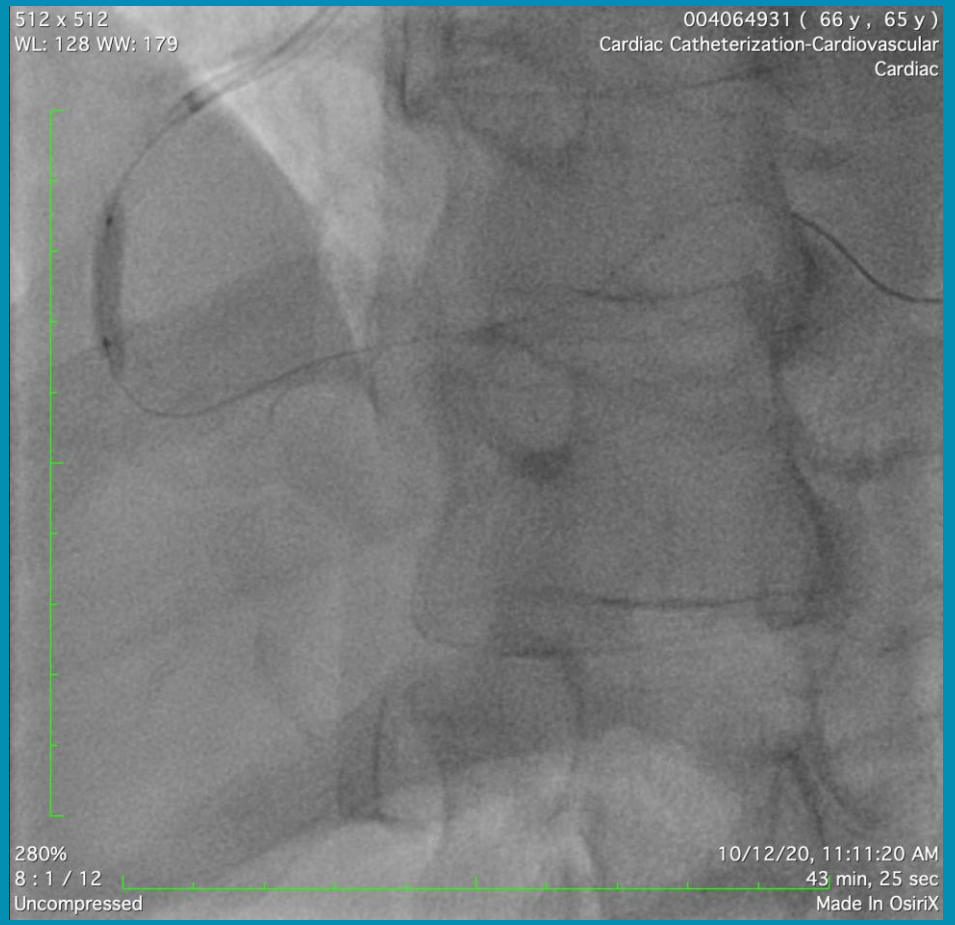
Glide Assist to lesion, Then perform atherectomy





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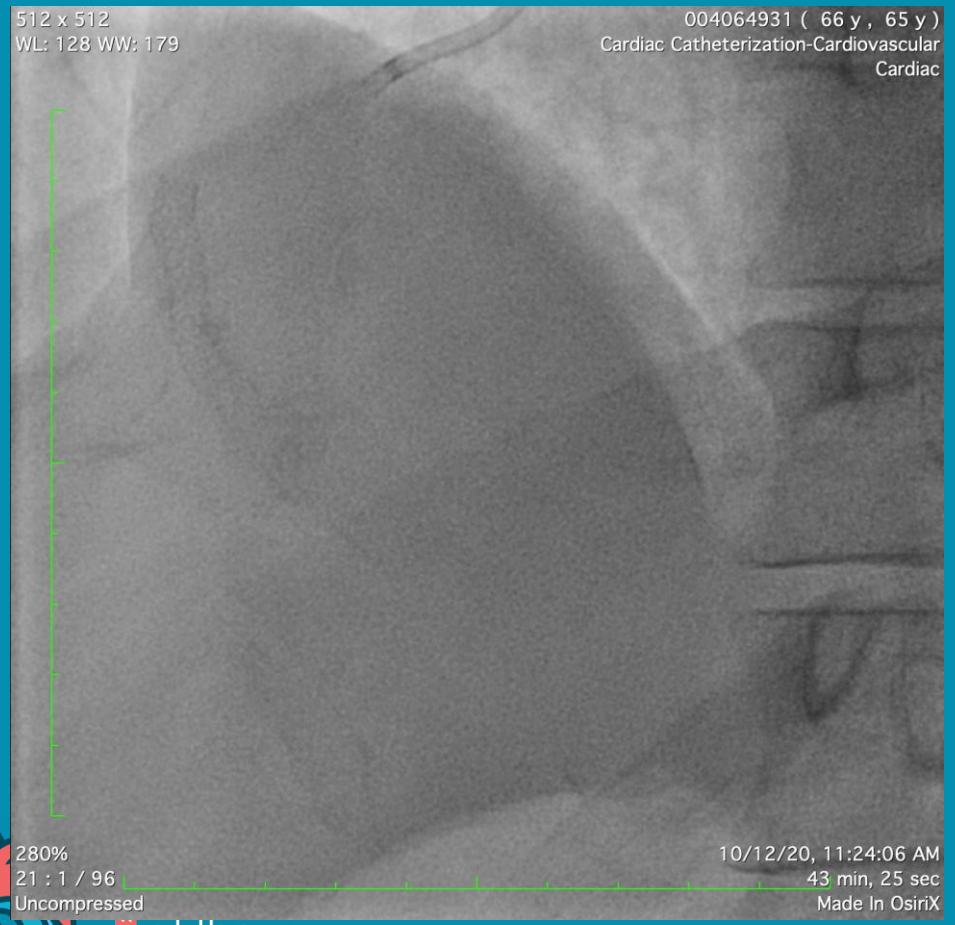
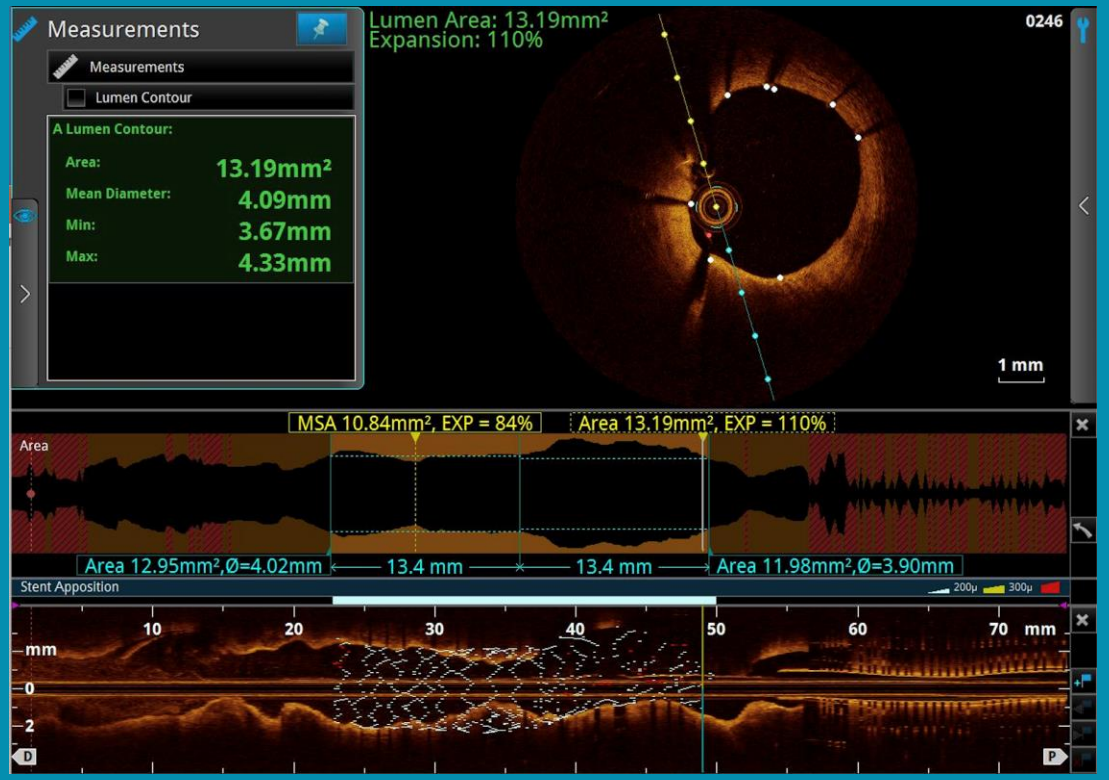
Final Angiogram, 4.0 X 24 Synergy, post-dilated with a 5.0 X 12 NC





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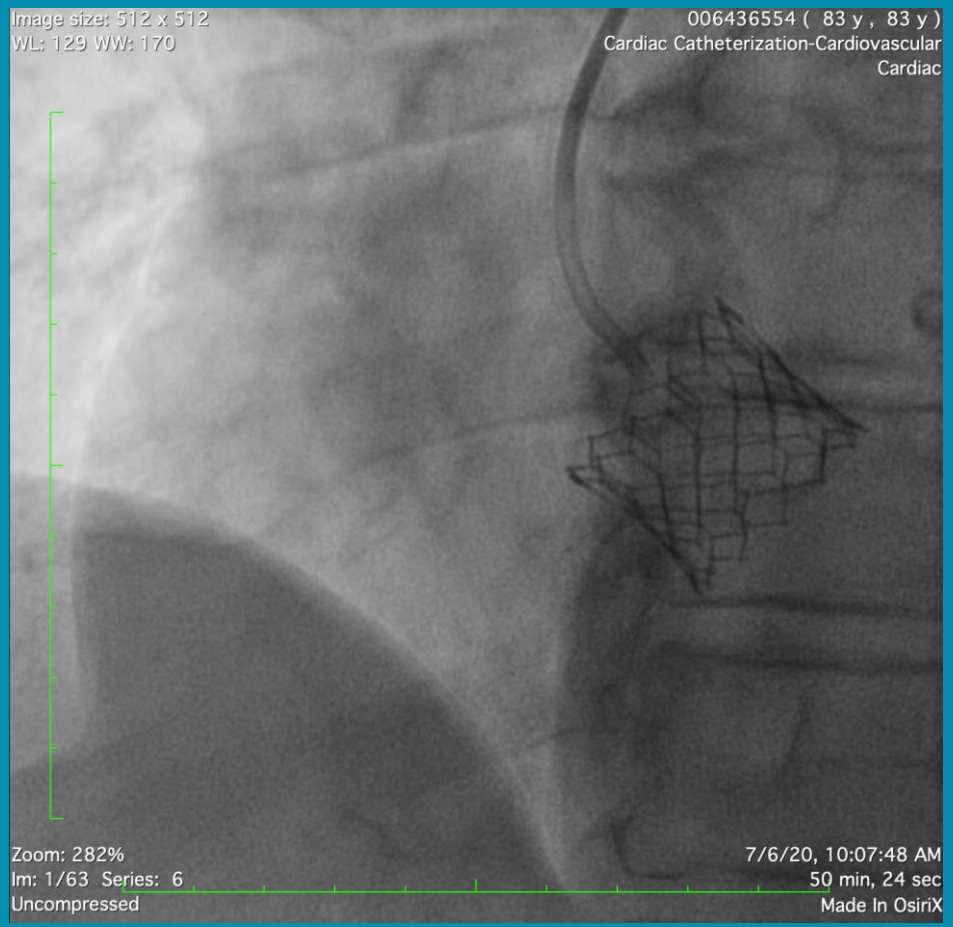
Case showing Atherectomy via 6fr guideliner



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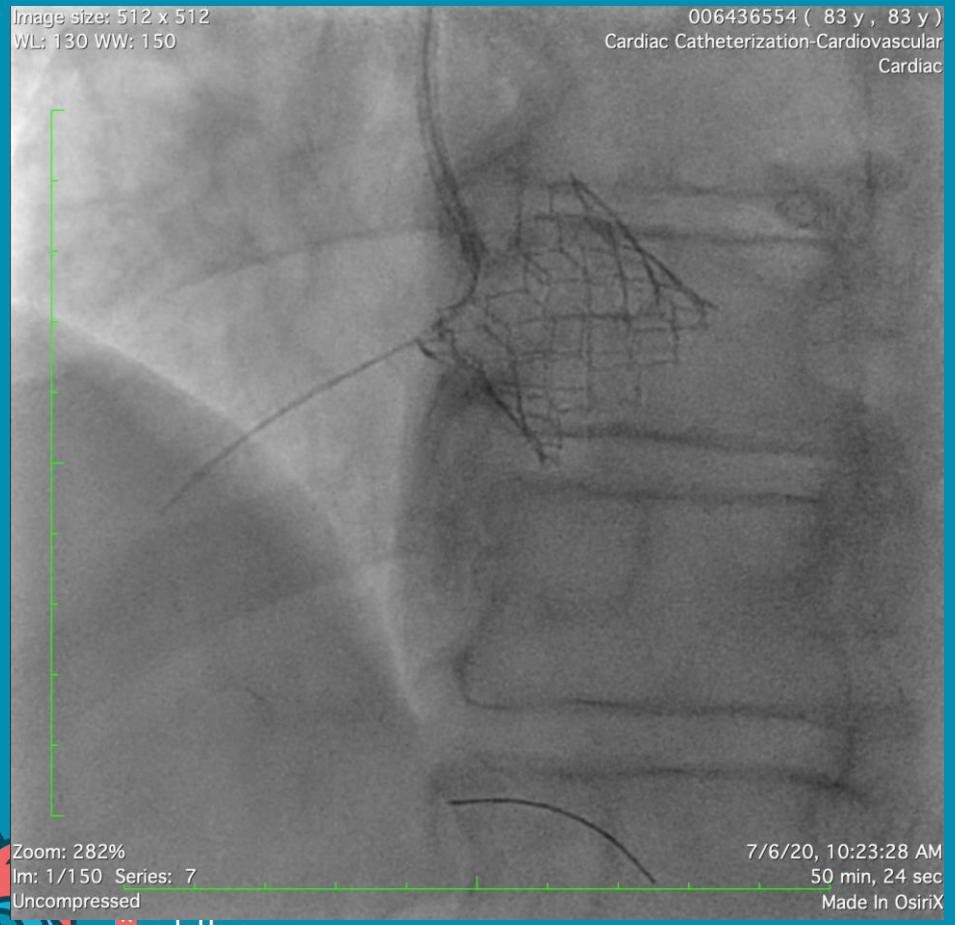
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006436554 (83 y , 83 y)
Cardiac Catheterization-Cardiovascular
Cardiac
Zoom: 282%
Im: 1/150 Series: 7
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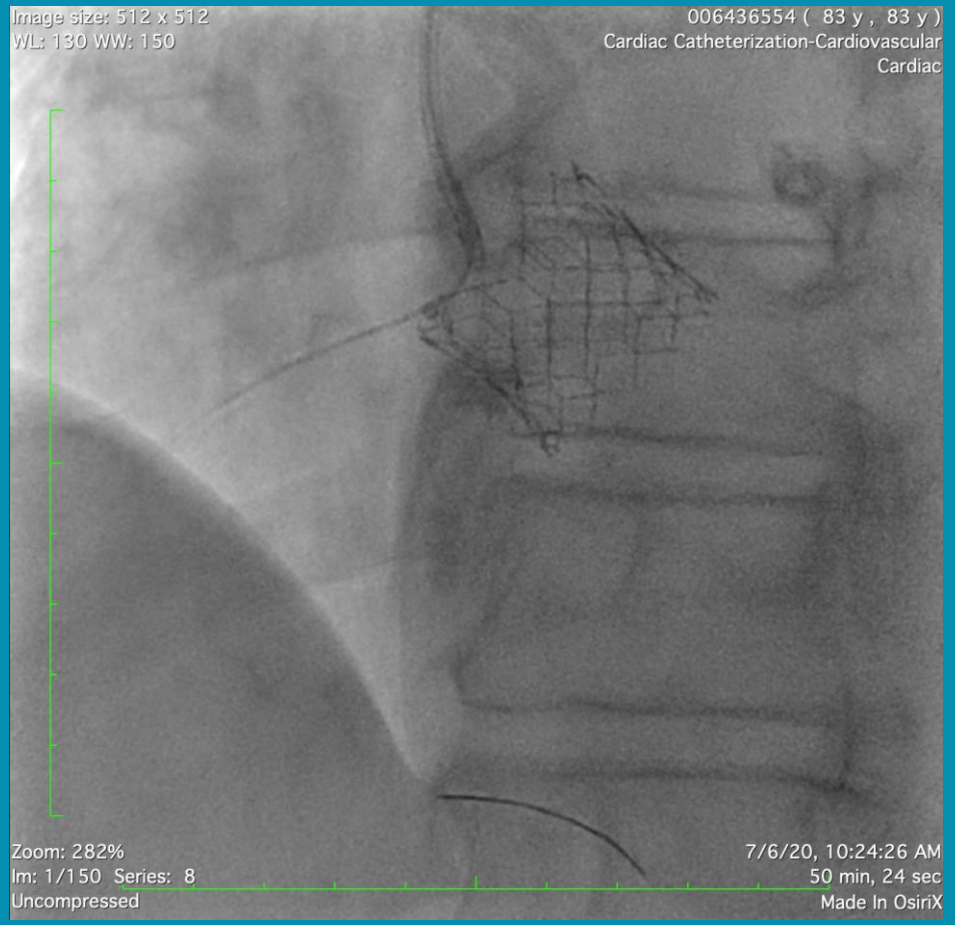
50 min, 24 sec
Made In OsiriX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Cardiac
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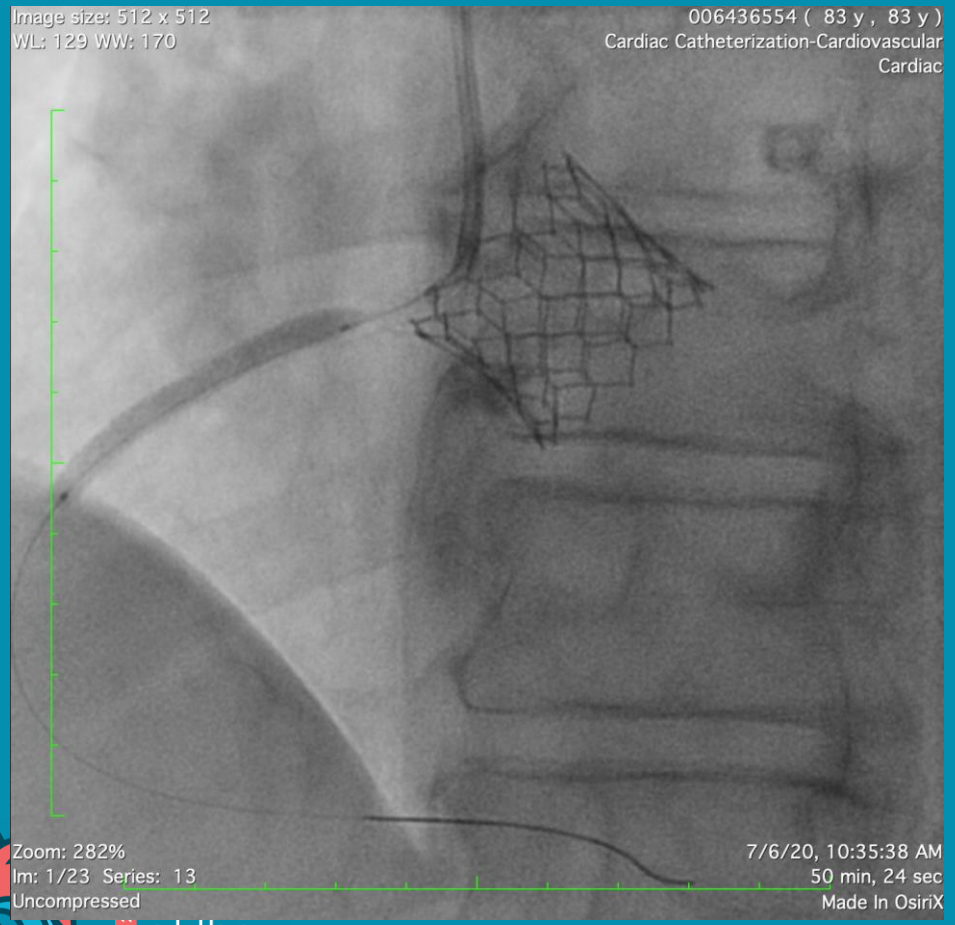
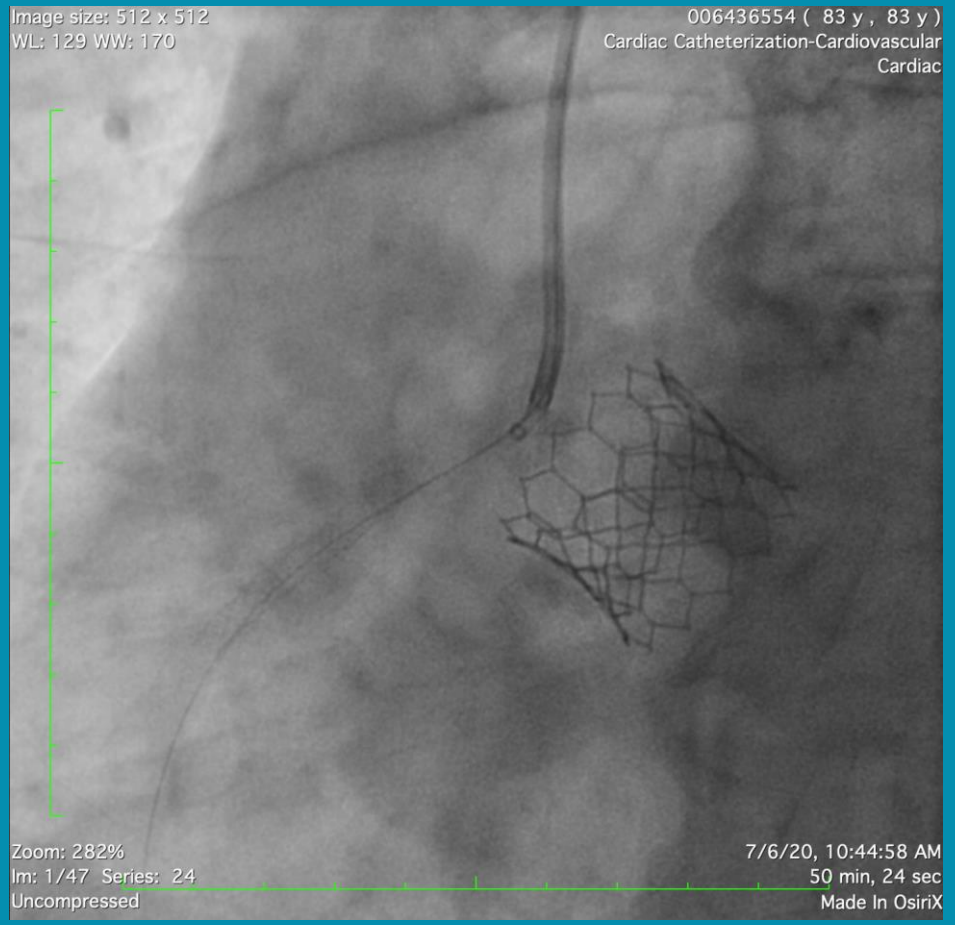
at the
Shore

Final Angios





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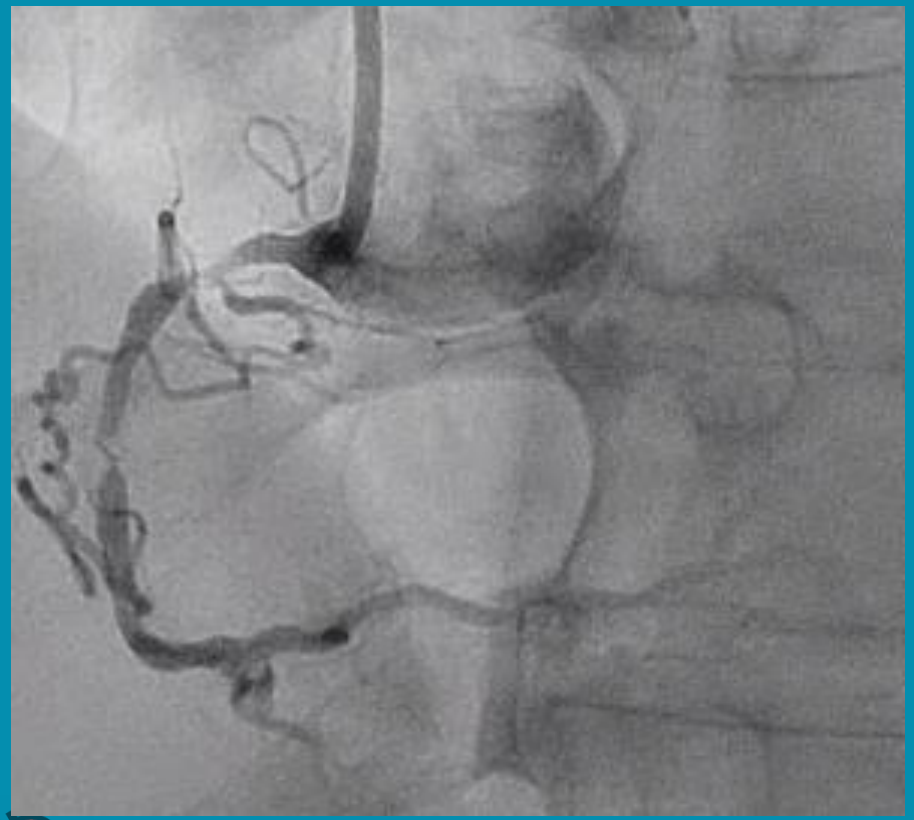
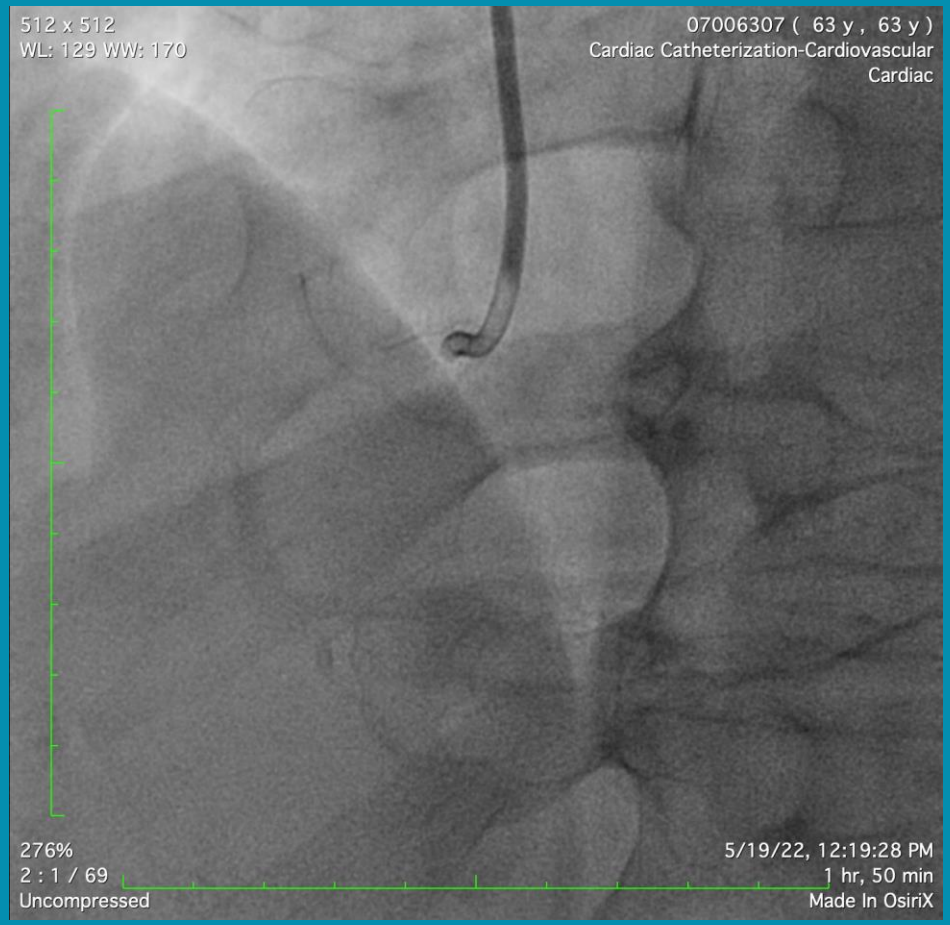
Case 4 Torque Guard





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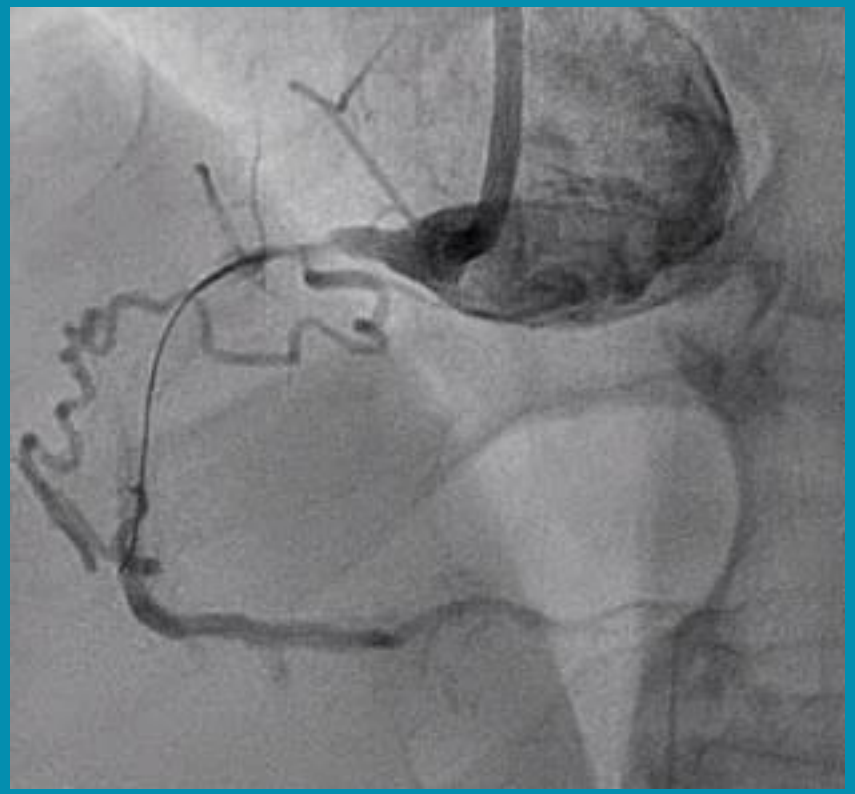
Wire Advancement



We were able to cross the lesion eventually with a Pilot 200 wire

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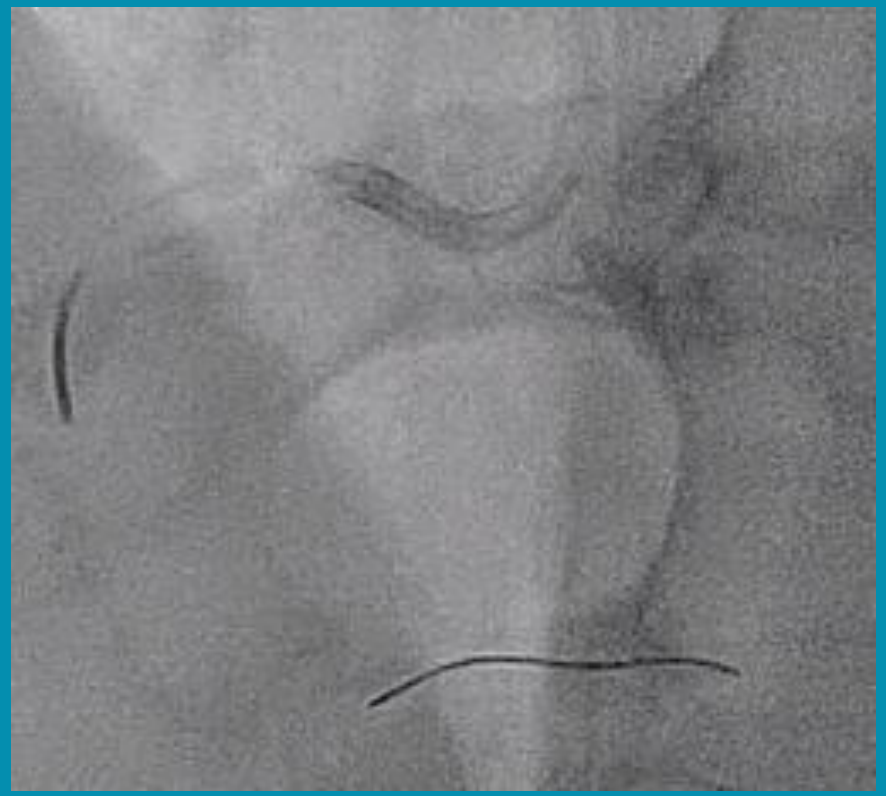
Turnpike LP



We were also unable to advance the Turnpike LP and even a 1.0 sapphire balloon across the mid lesion with guideliner support

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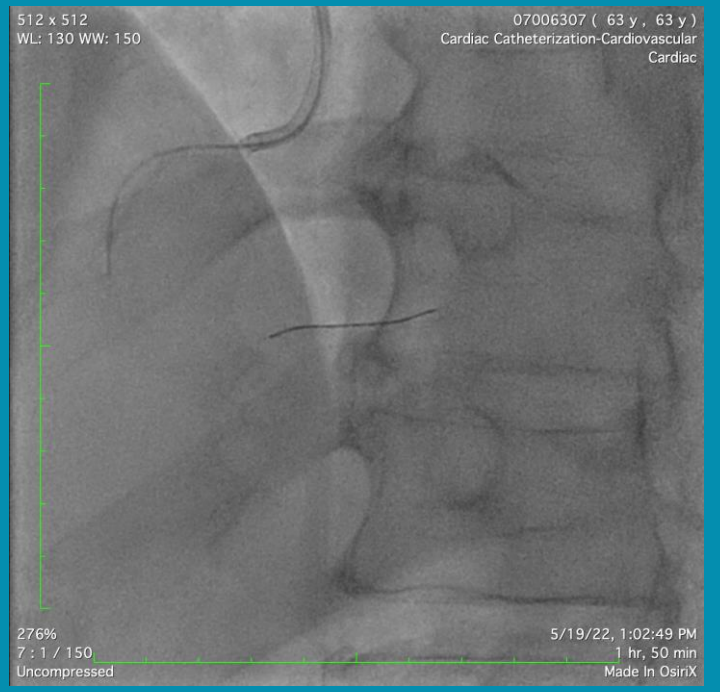
Strategy

- At this time the 1.0 Sapphire balloon was removed.
- The Turnpike LP was then wedged into the mid RCA lesion and the Pilot wire was carefully withdrawn out of the guide
- The Viper wire was able to successfully cross the lesion through the Turnpike LP and was parked in the distal vessel
- We then prepared the CSI orbital atherectomy device

Orbital Atherectomy



We then performed orbital atherectomy of the prox and mid RCA at low speed. After a few passes, it crossed the mid RCA lesion. At this point, the torque guard activated and the device stalled, and was removed.

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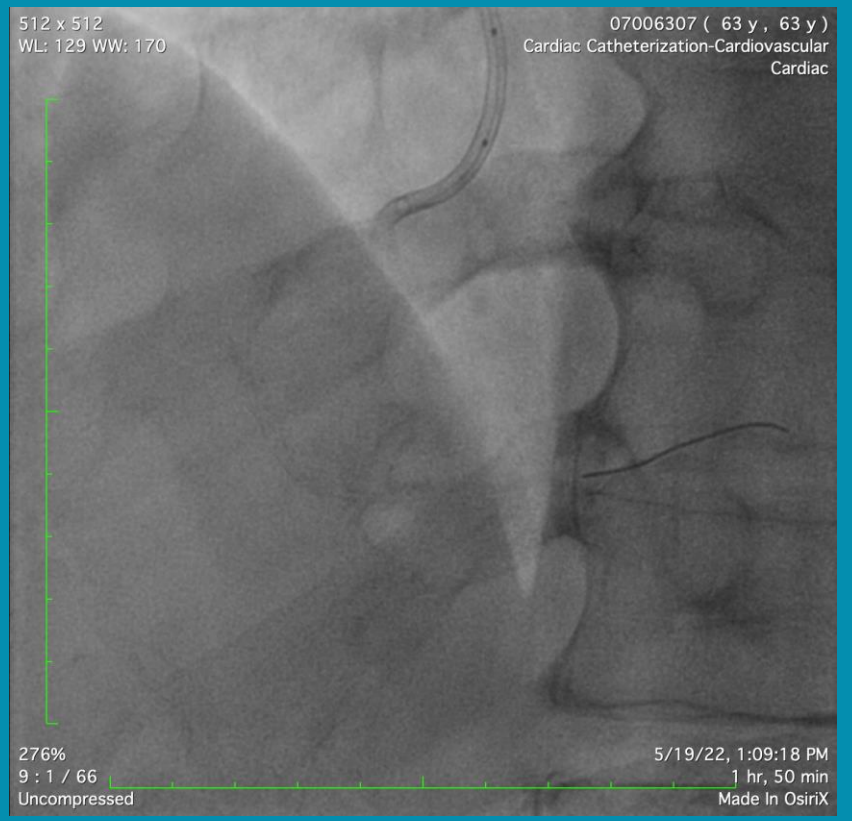
Post CSI Angiogram



Subsequent angiogram showed a small contained rupture of the mid RCA. Imaging in multiple projections did not show that it was actively expanding and thus a covered stent was not used

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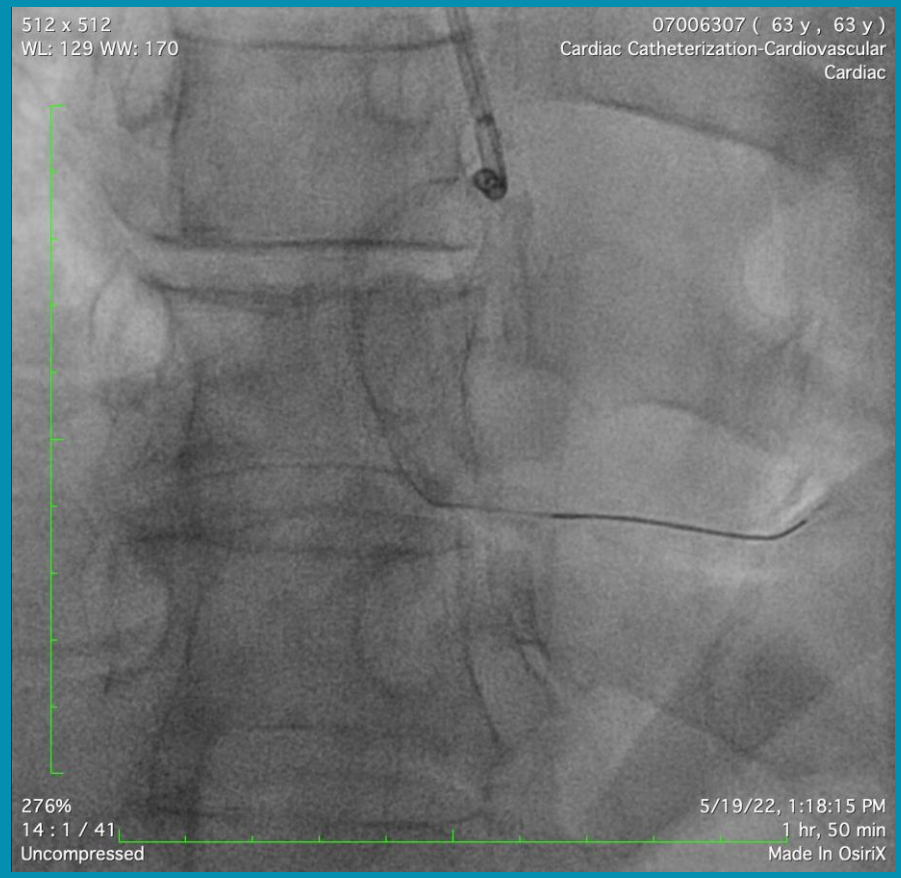
Post CSI Angiogram



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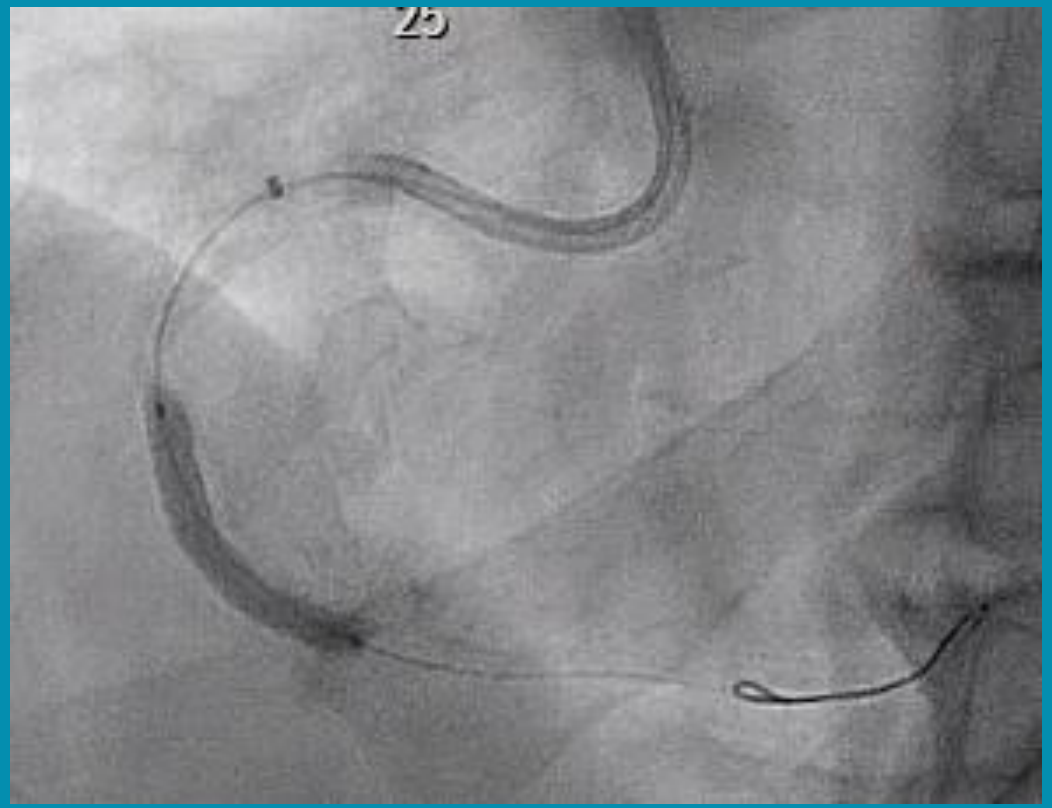
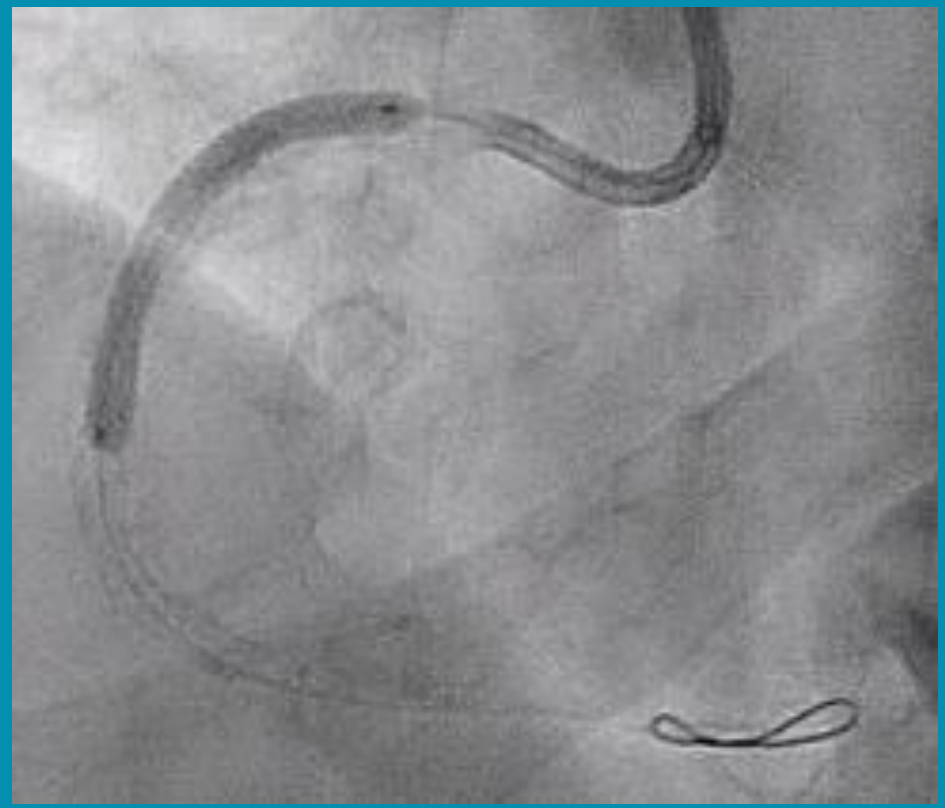
Subsequent angiogram showed a small contained rupture of the mid RCA. Imaging in multiple projections did not show that it was actively expanding and thus a covered stent was not used

DES Placement





The mid and proximal RCA were then successfully treated with drug eluting stent placement and postdilatation.

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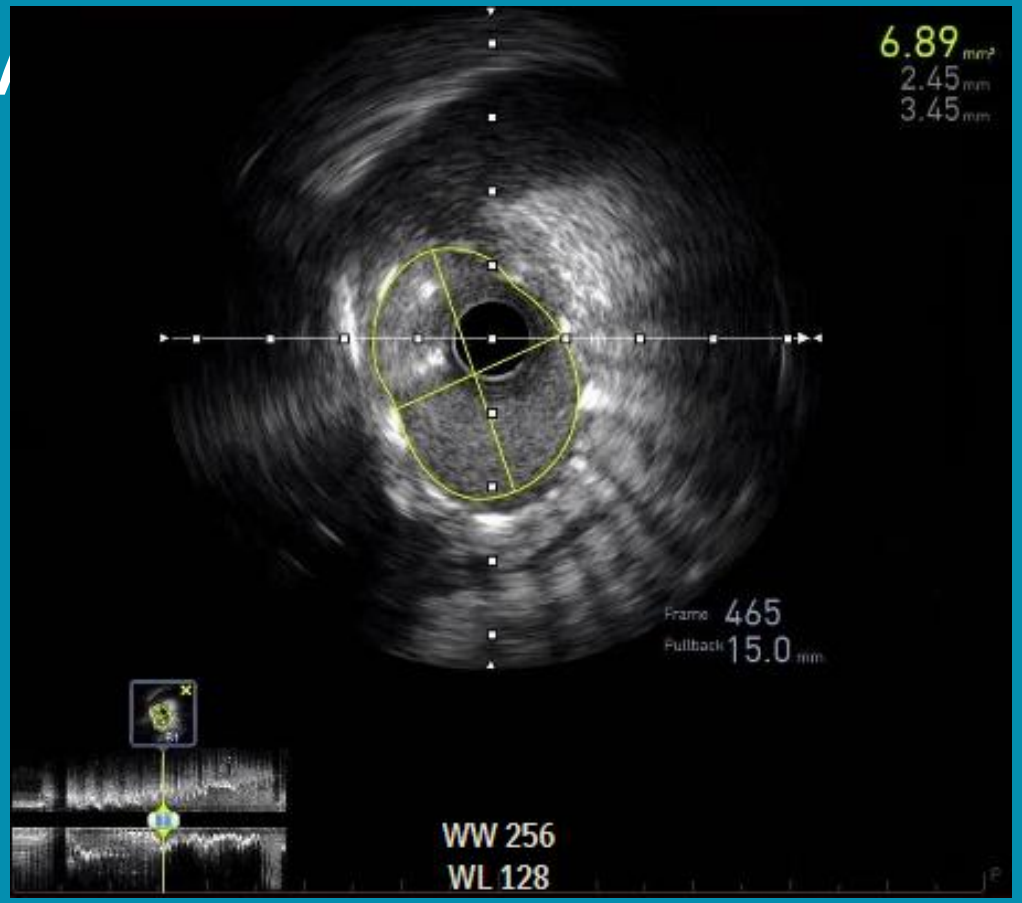
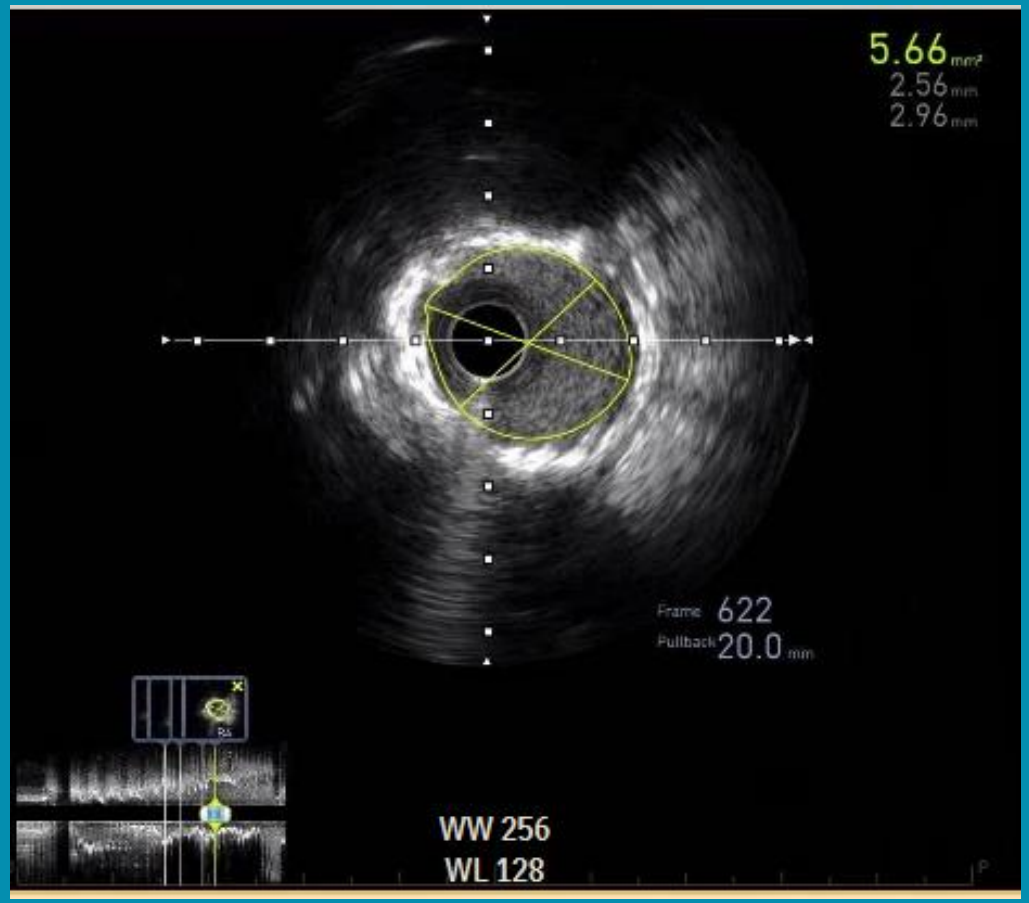
IV





The vessel was imaged with IVUS to ensure adequate stent apposition and to evaluate the contained rupture.

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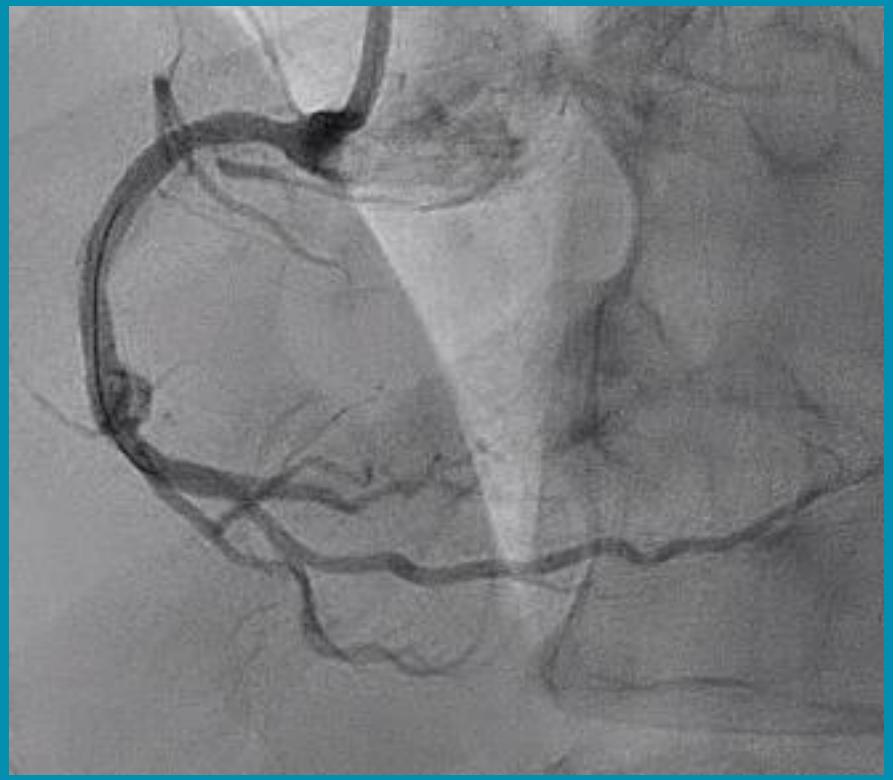
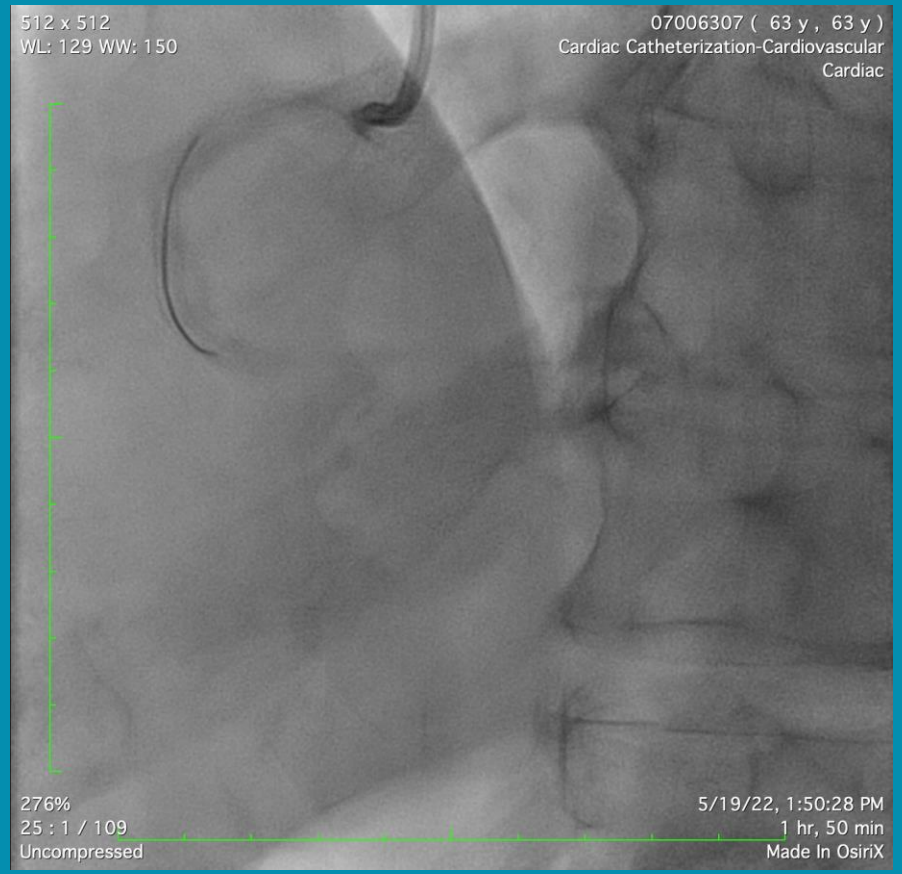
Final RCA angiogram





Final angiogram showed intact vessel architecture and unchanged size of the contained rupture

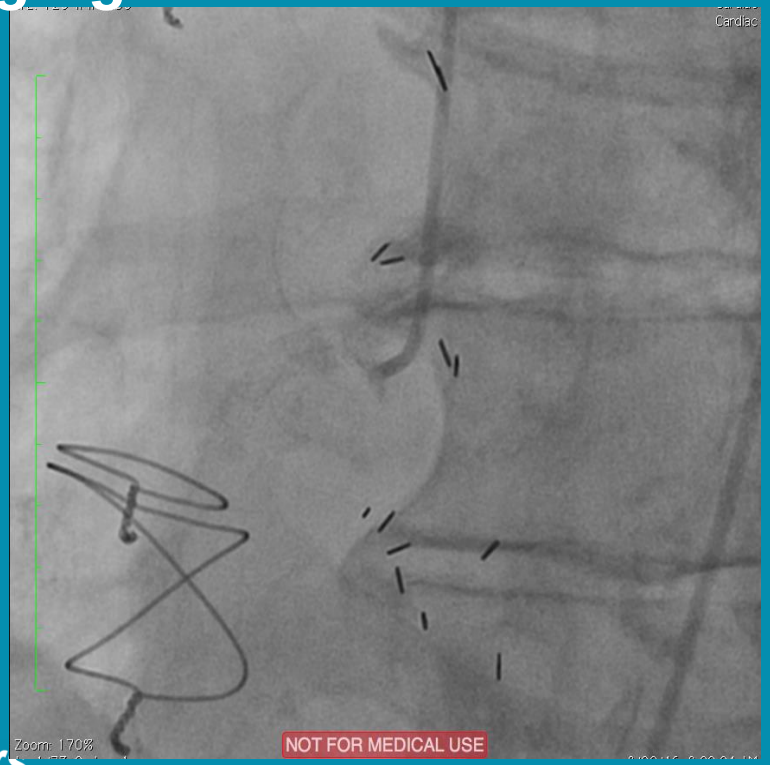
Cors at the Shore 2023

Case 4

- 86 y/o male with CKD, COPD, CAD s/p PCI proximal RCA, unsuccessful rotablator of mid RCA (unable to dilate lesion after multiple passes with 2.0 burr admitted with decompensated HF and elevated troponins (peak 9.0)
- Unable to control medically, pt underwent cardiac catheterization

Cors at the Shore 2023

Initial Angiogram

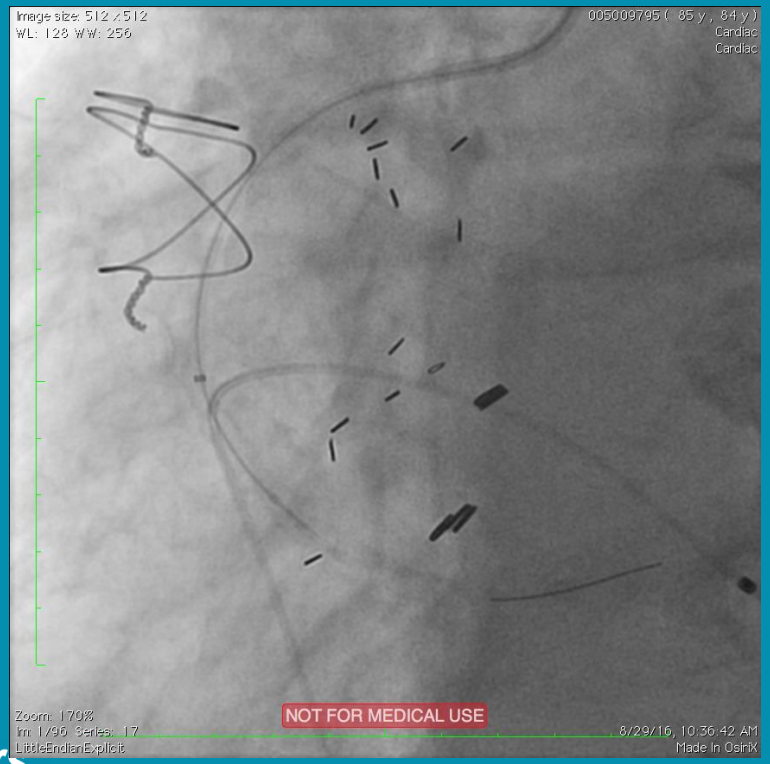


- Patent stent in prox RCA
- Severely calcified high grade lesion in mid RCA

Cors at the Shore 2023

- With balloon inflated was able to pass guideliner through proximal stents into mid RCA

Cors at the Shore 2023



- CSI catheter advanced into position through 7fr guideliner and orbital atherectomy at 4 runs at low and 2 runs at high speed successfully performed

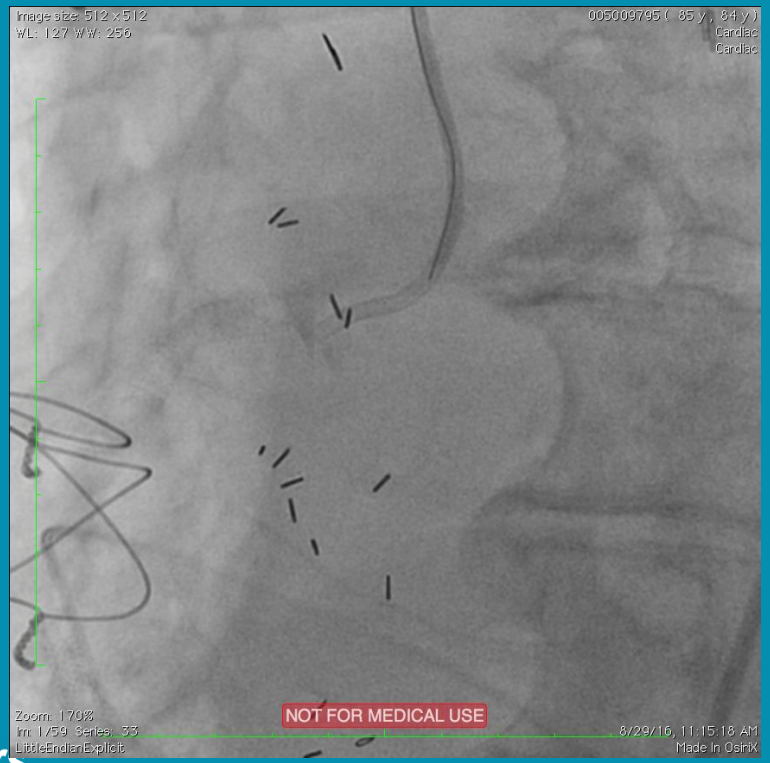
Cors at the Shore 2023

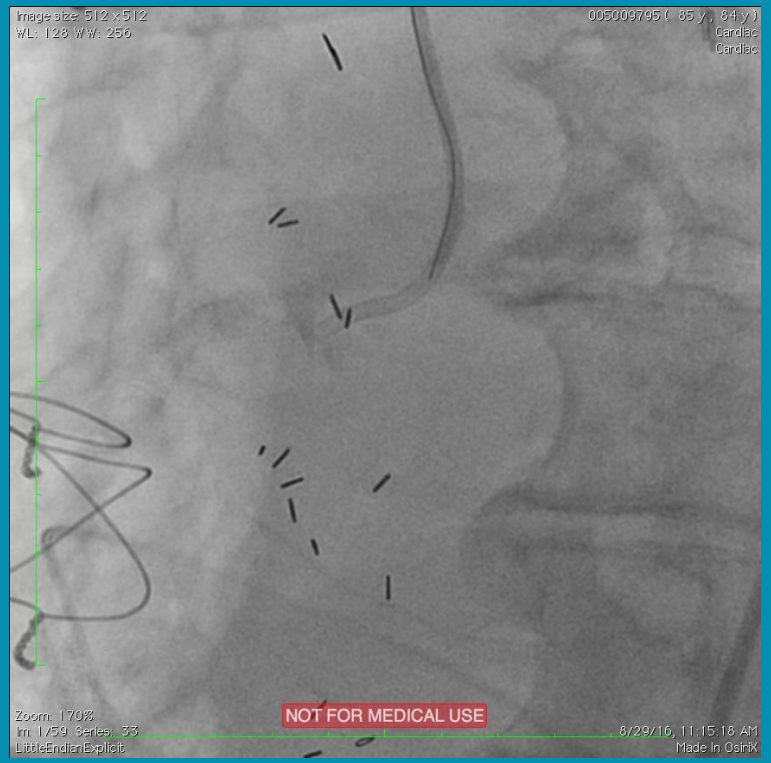
Lesion dilated

DES Expanded

Cors at the Shore 2023

Final Angiography





Cors at the Shore 2023

Case 5

- 74 y/o male HTN, dyslipidemia with progressively worsening angina over last 5 months, now occurs with minimal exertion
- Balloon or Microcatheter Uncrossable

Cors

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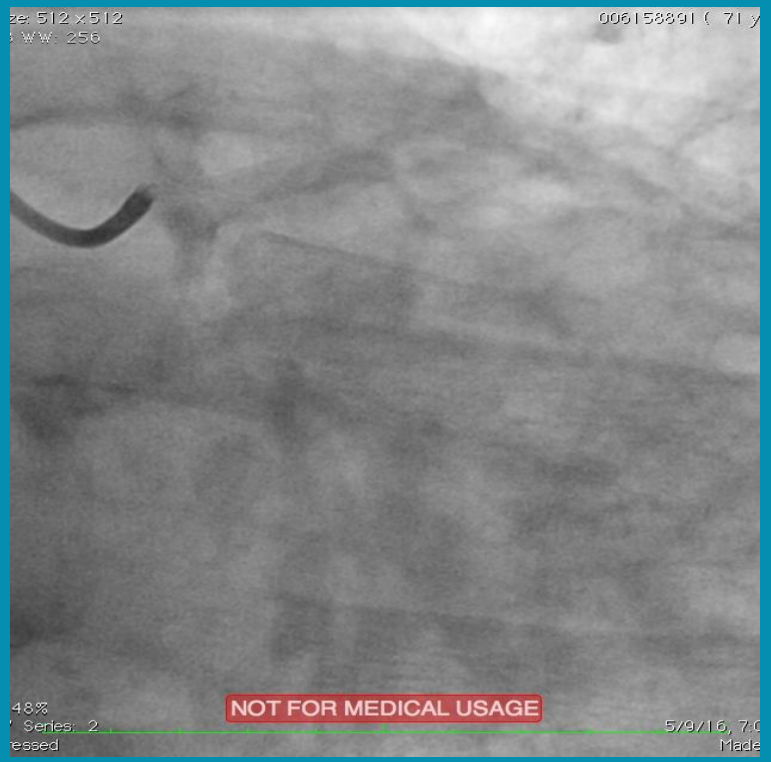
OF CENTRAL JERSEY

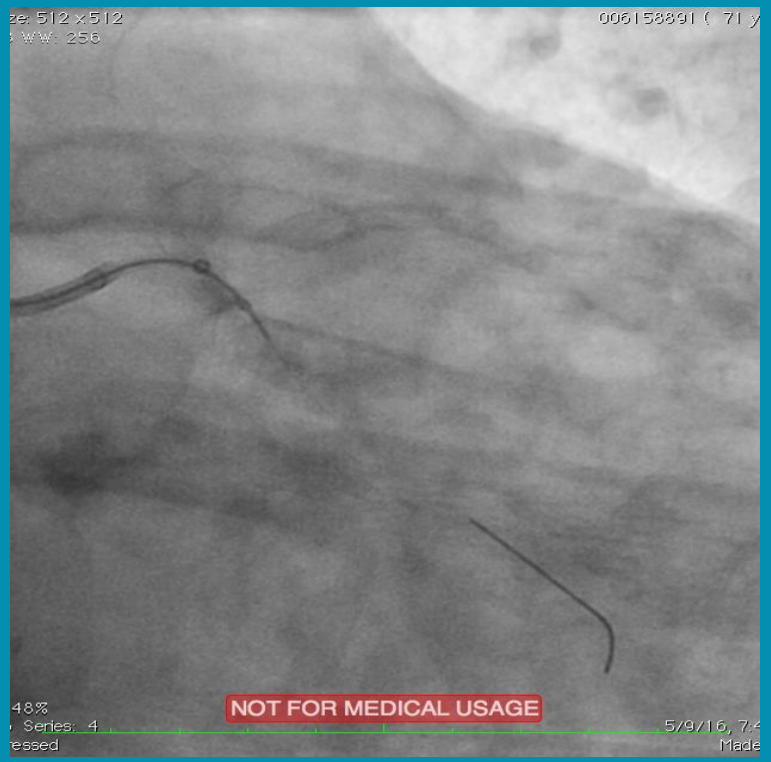
Initial angiogram



- Severely calcified, nearly occluded lesion at a sharp angle
- Wired with fielder XT, unable to exchange for Viper wire due to inability of microcatheter to cross lesion
- Patience and persistent, able to direct wire with viper

Cors

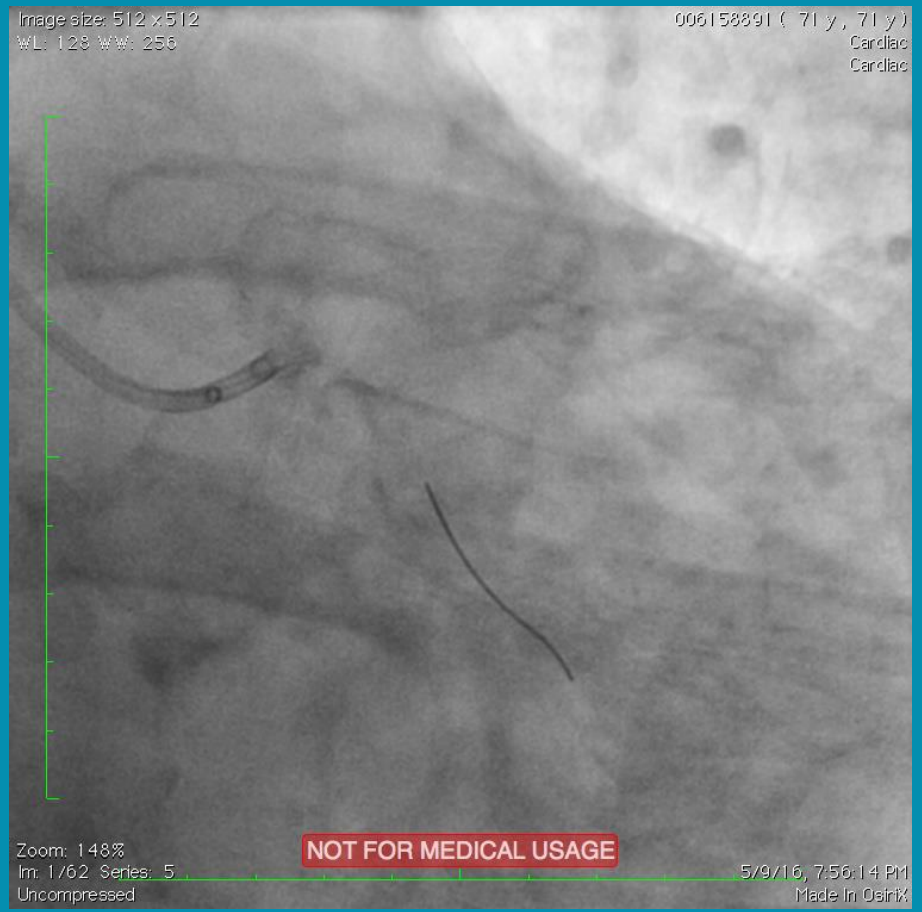
HEART & VASCULAR INSTITUTE
OF CENTRAL JERSEY



- Guideliner support able to get CSI catheter in place and perform atherectomy
- 5 runs on low
- 1 run on high

Cors

HEART & VASCULAR INSTITUTE
OF CENTRAL JERSEY



Cors

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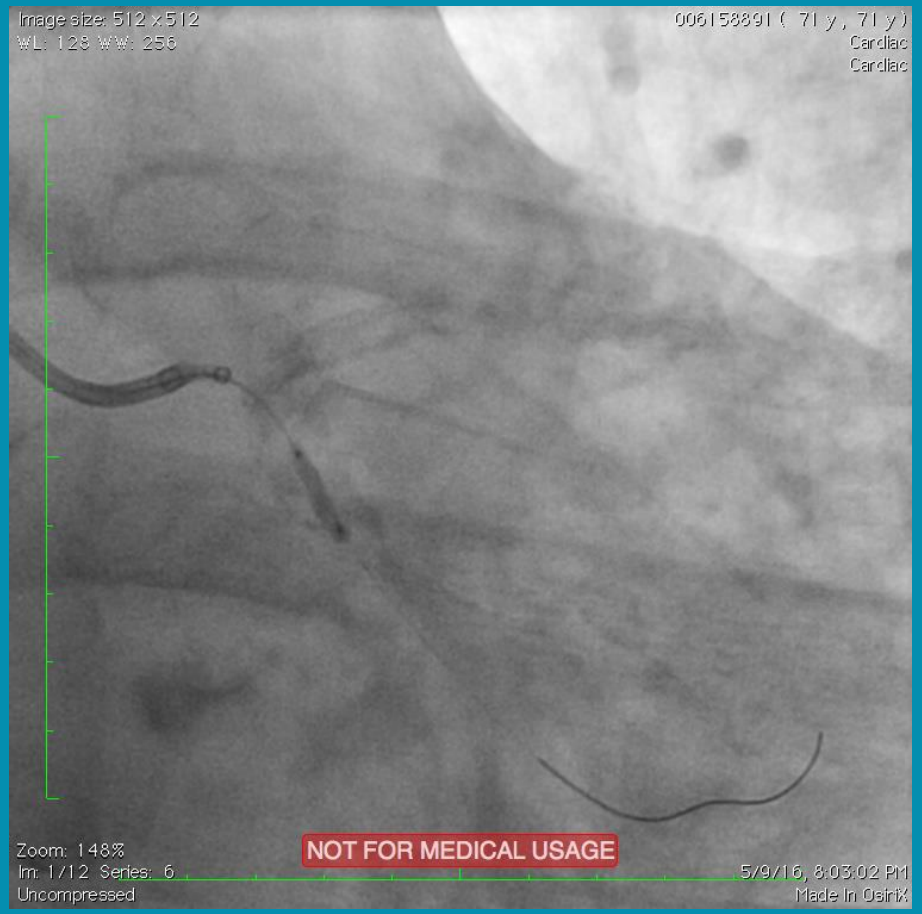
OF CENTRAL JERSEY



Cors

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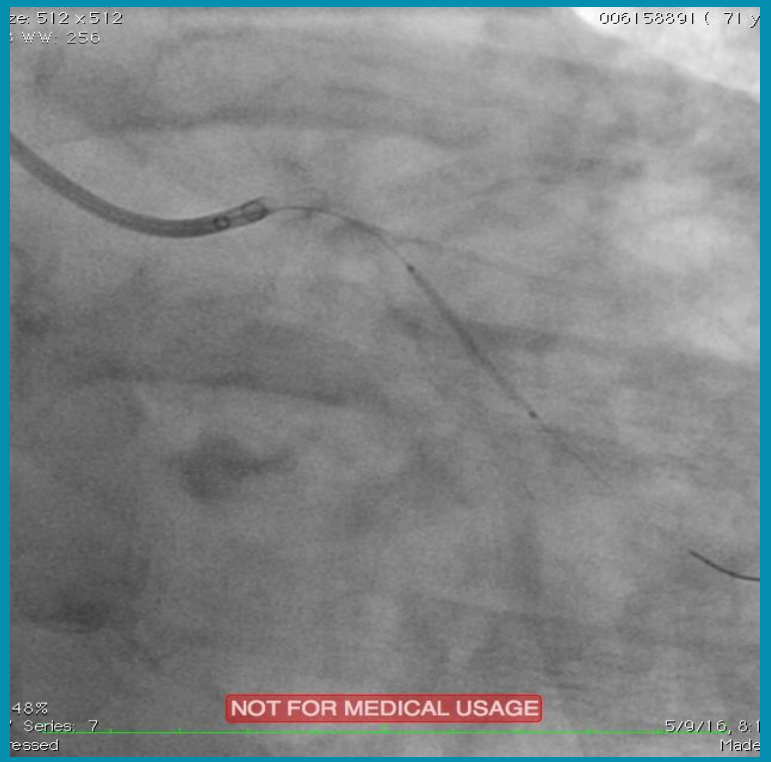
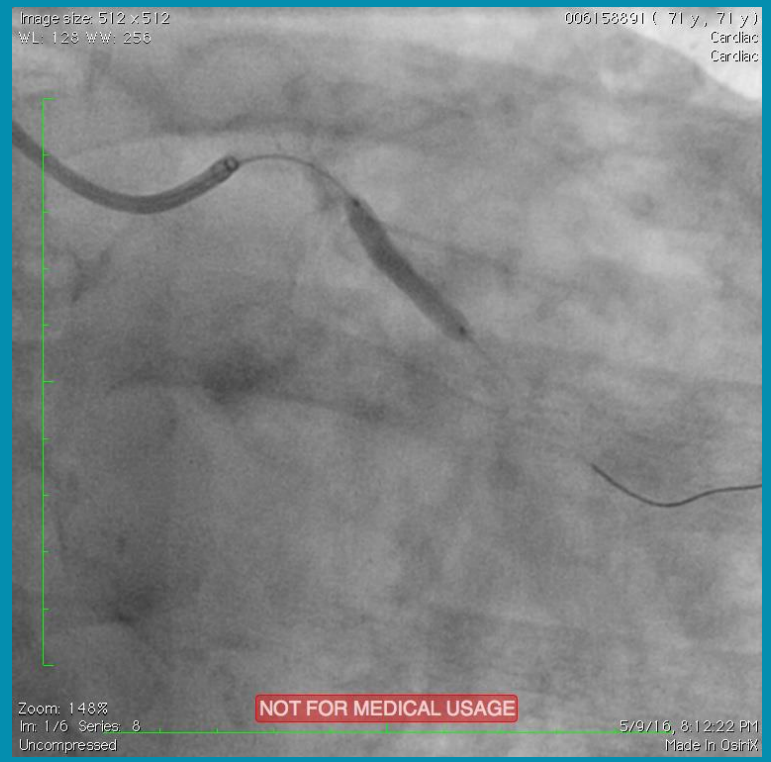
OF CENTRAL JERSEY



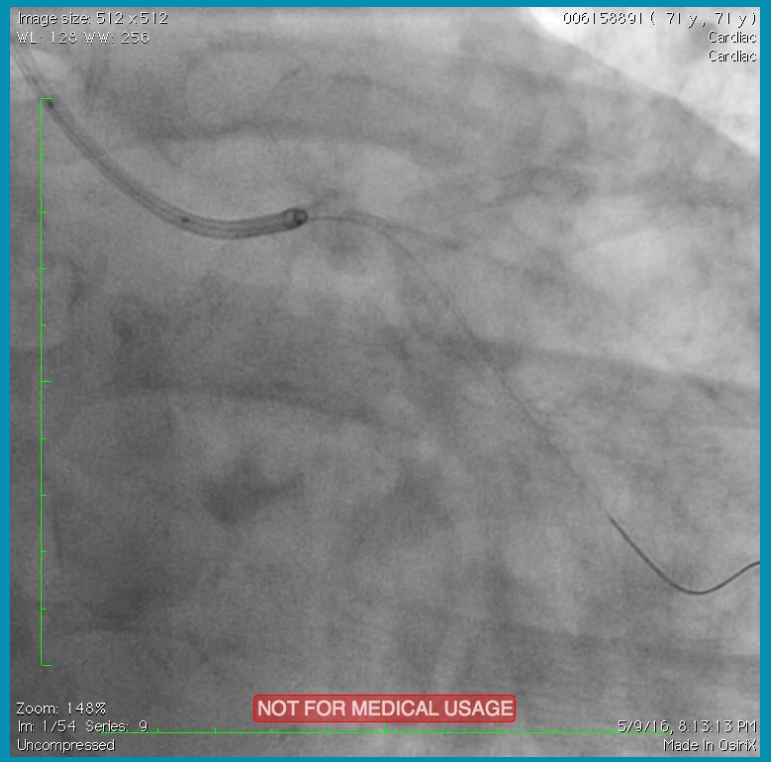


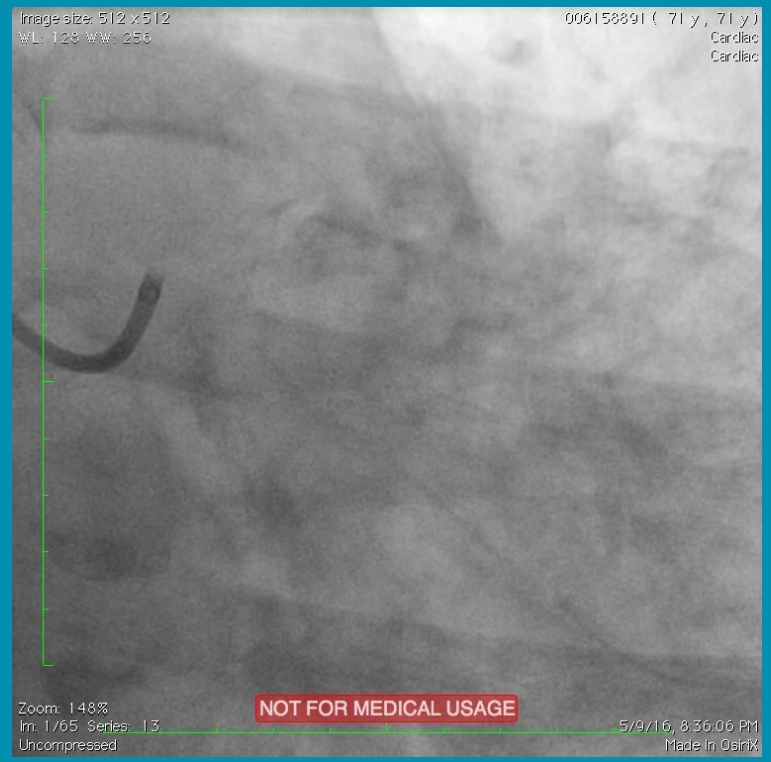
Cors

&

OF CENTRAL JERSEY

Final Angiography





Cors

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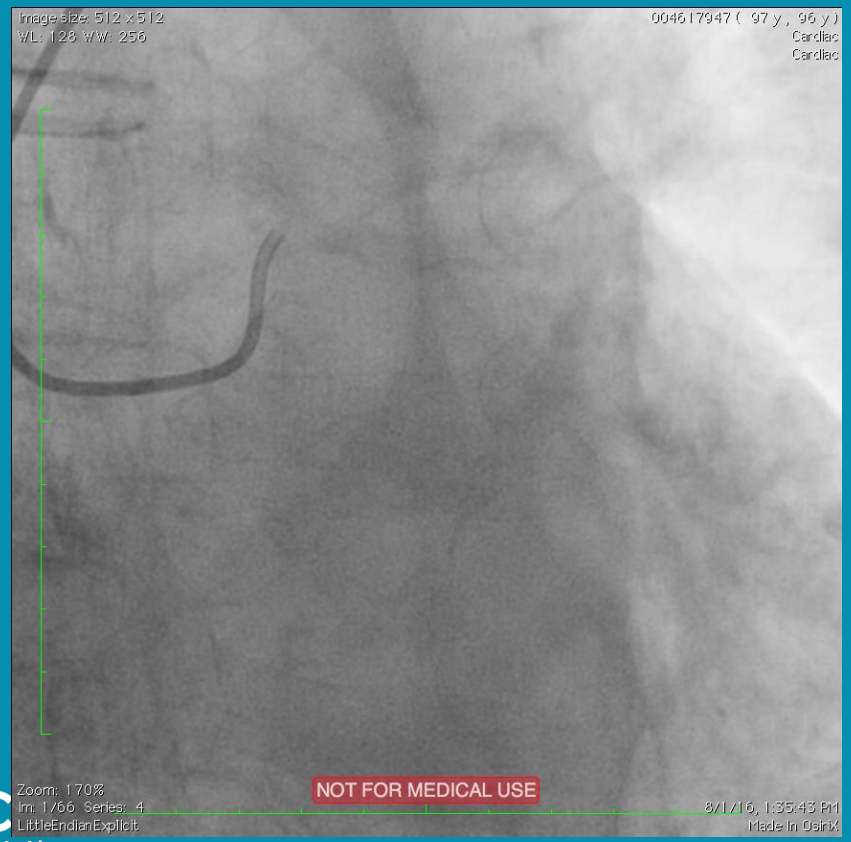
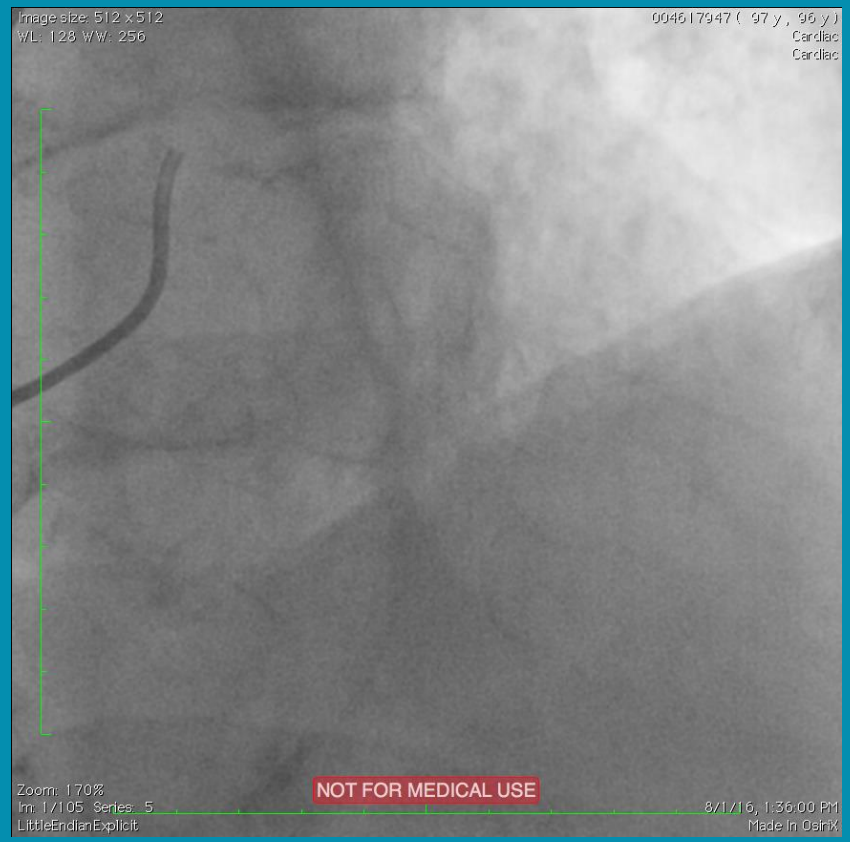
OF CENTRAL JERSEY

Case 6

- 94 y/o male with HTN, dyslipidemia admitted with NSTEMI

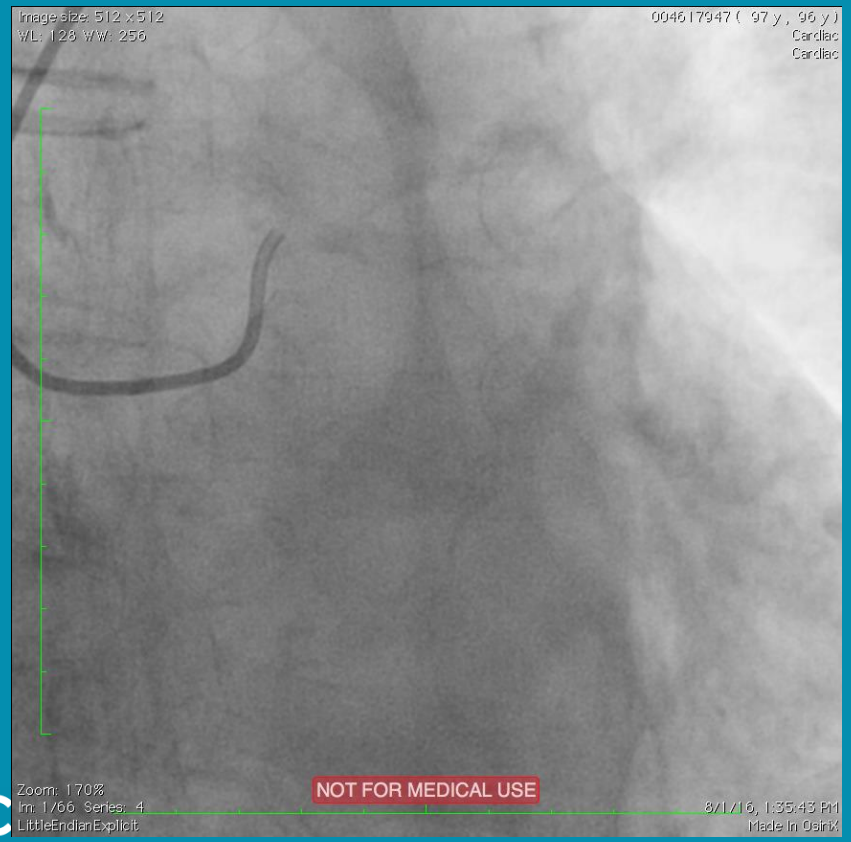
Initial Angiography

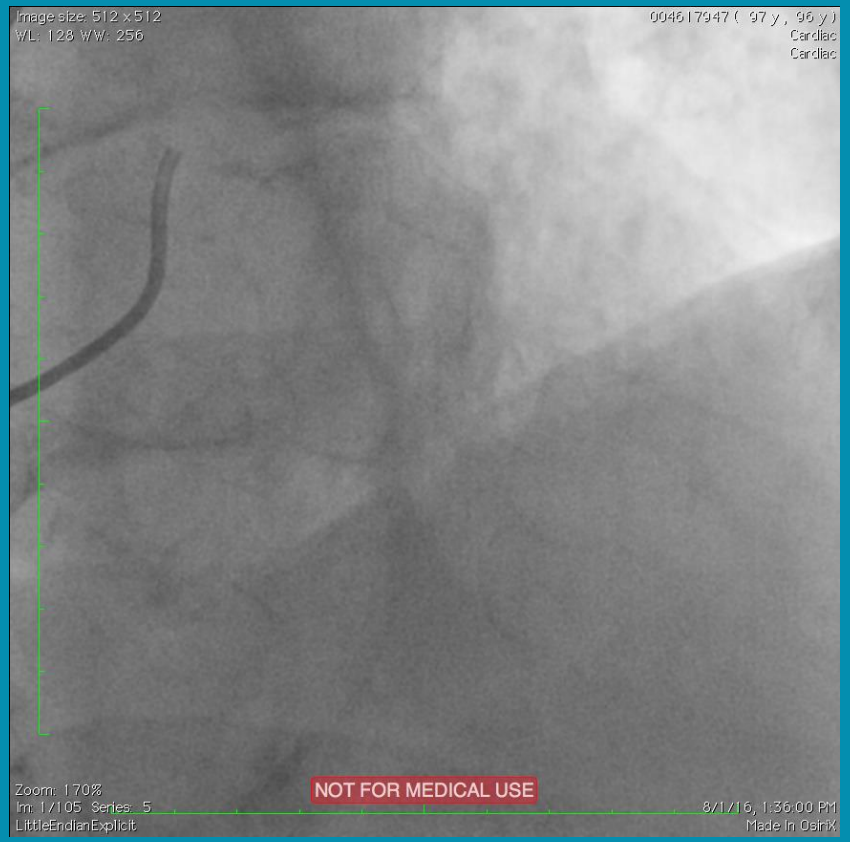




2023 C at the Shore

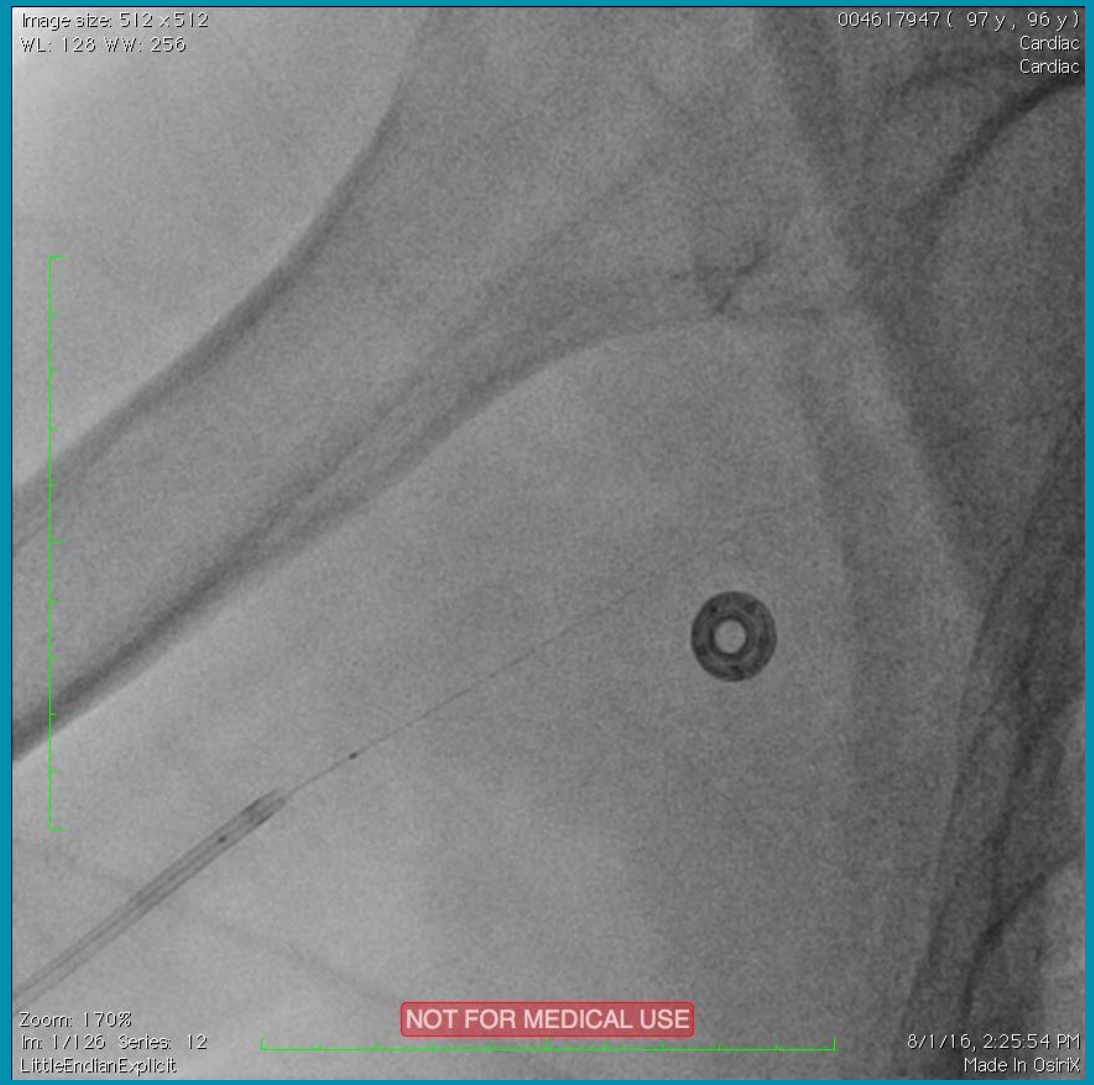
Initial Angiography





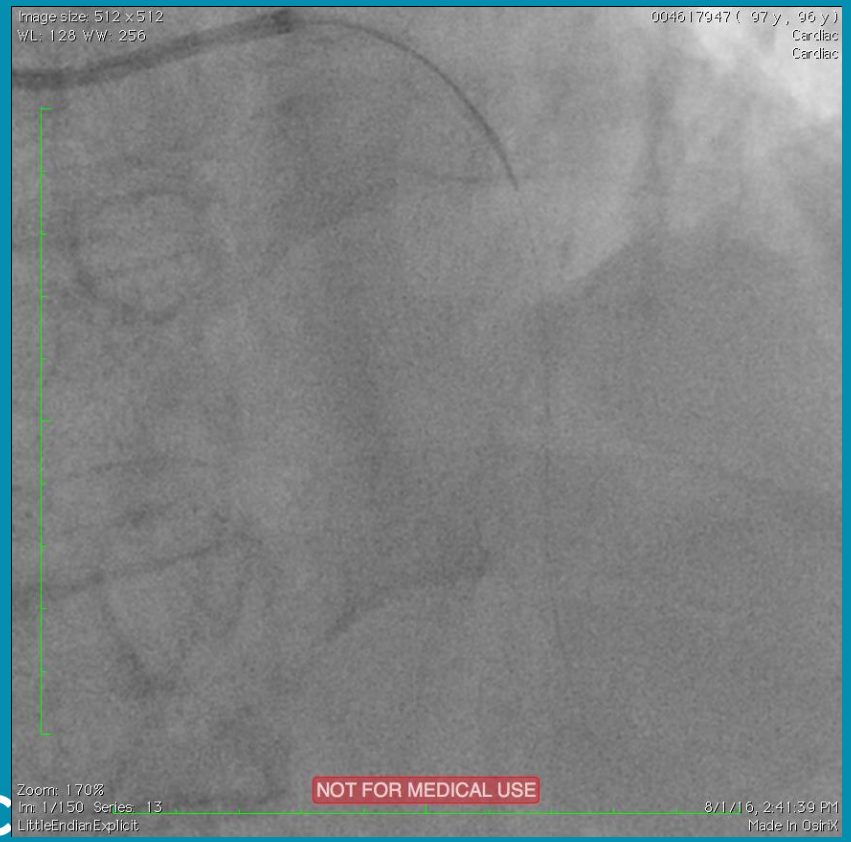
2023 C at the Shore

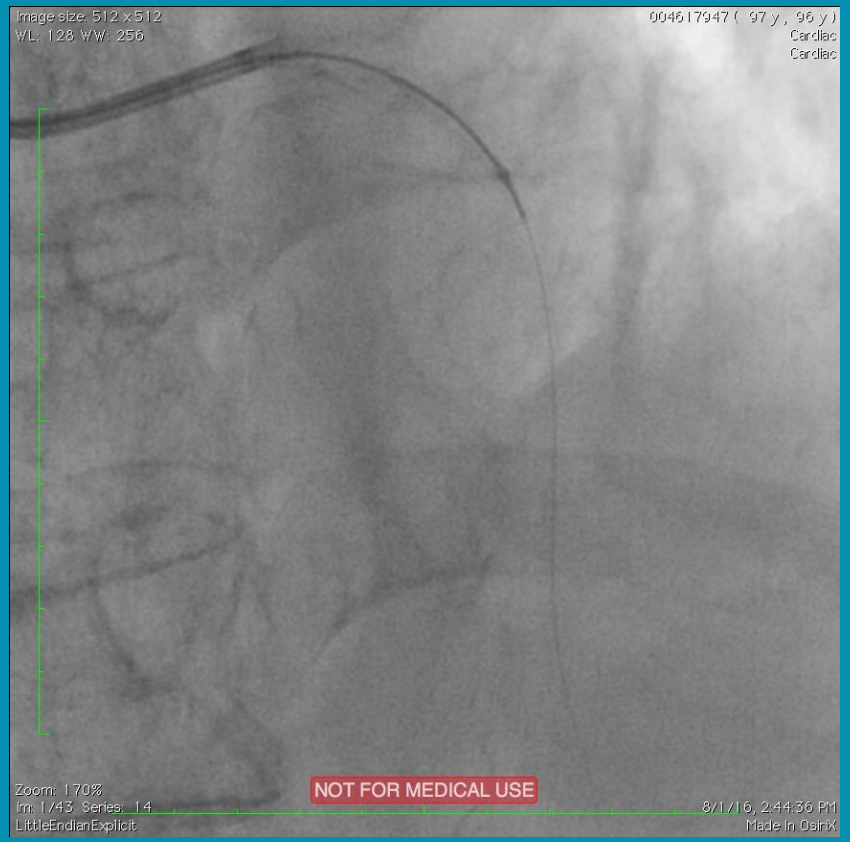
Balloon Assisted Tracking



Cors at the Shore 2023

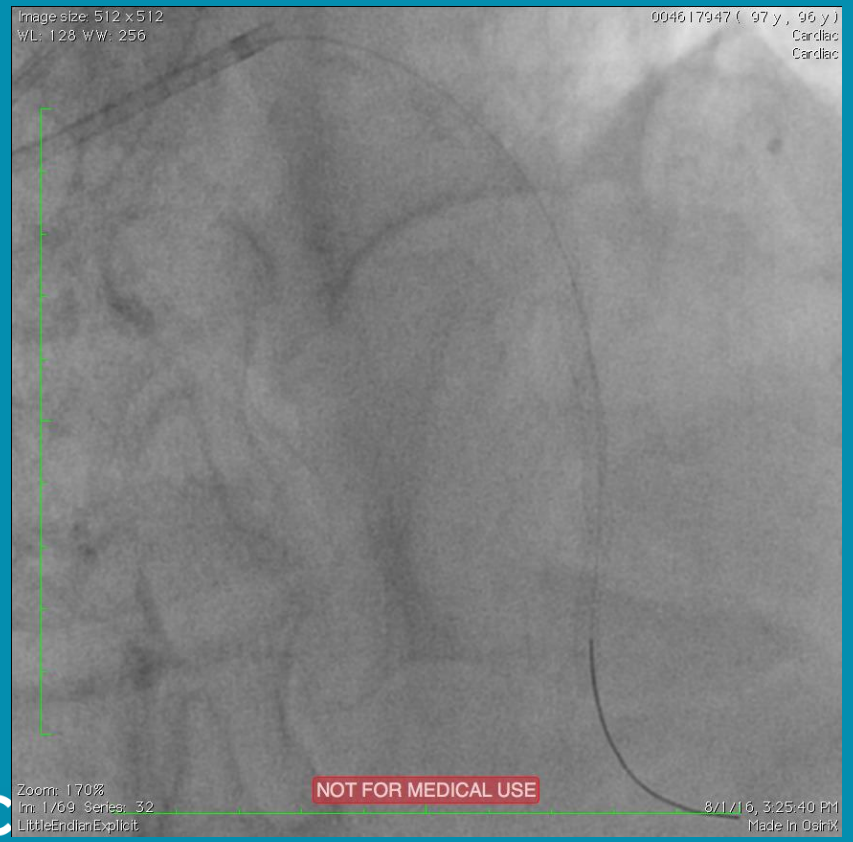
Orbital Atherectomy at low speed
4 runs

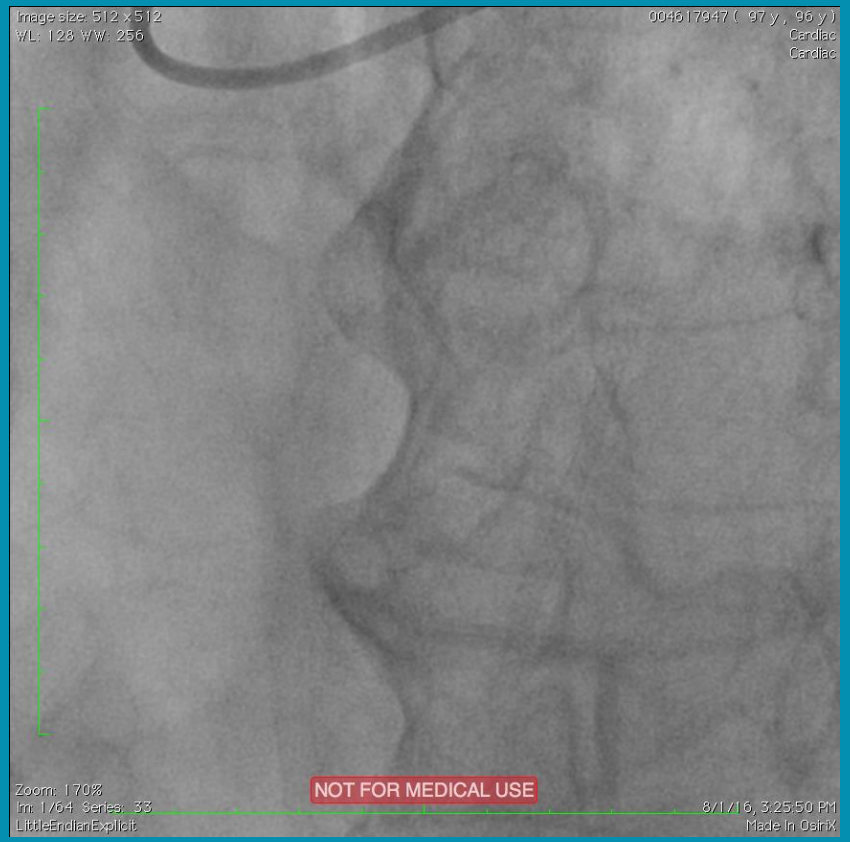




2023 C at the Shore

Final Angiograms after post dilatation





2023 C at the Shore