2016 euroPCR

Fantom®

Bioresorbable Sirolimus-Eluting Scaffold

EAPCI

EUROPEAN SOCIETY OF CARDIOLOGY®

EACTS

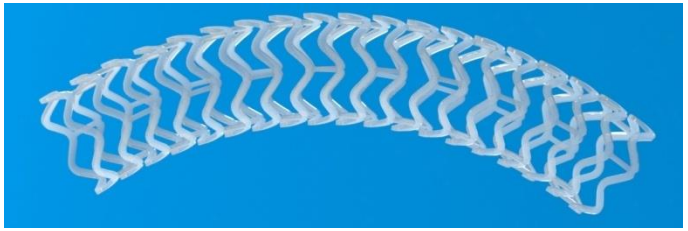
Potential conflicts of interest

Speaker's name: Dr. Alexandre Abizaid

☑ **I have the following potential conflicts of interest to report:**

Consultant to REVA Medical, Inc.

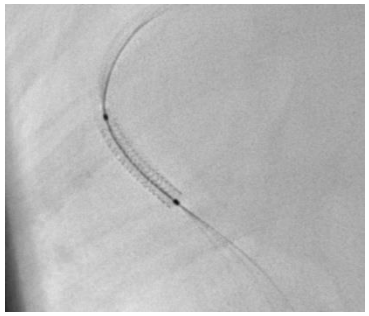
Fantom Bioresorbable Scaffold



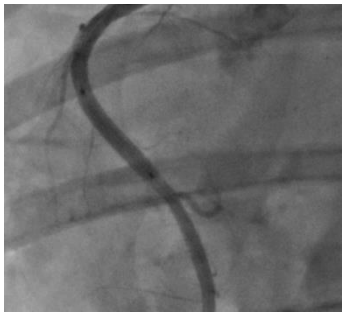
***Fantom*® (REVA Medical)**
Sirolimus-Eluting Bioresorbable Scaffold
Desaminotyrosine Polycarbonate

Key Scaffold Features

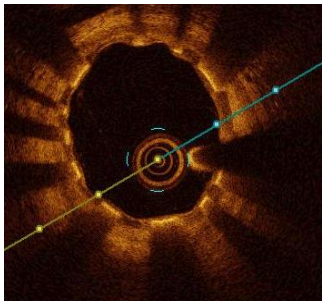
- **Complete scaffold visibility under x-ray**
- **Single-step continuous inflation**
- **Clinically significant expansion range**
- **Optimal radial strength at 125 µm thickness**
- **Vasomotion restoration ~1 year**
- **No special storage or handling**



Visibility



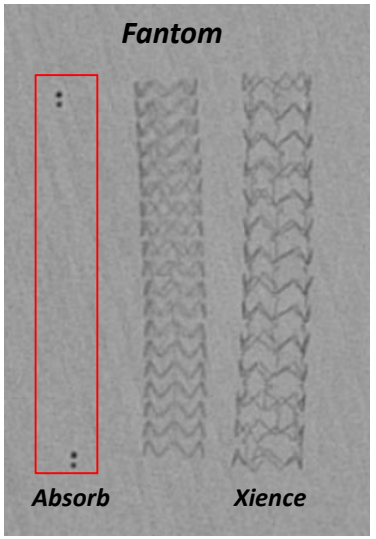
Deliverability



Vessel Patency

Fantom

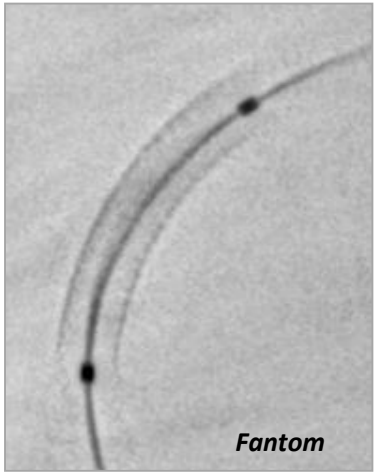
Radiographic Visibility



- **Fantom's (x-ray) visibility**

  <u>Allows for</u>:

  - **Precise scaffold placement**
  - **Accurate lesion coverage**
  - **Full structural assessment after deployment**
  - **Less reliance on invasive imaging compared to other BRS (IVUS/OCT)**



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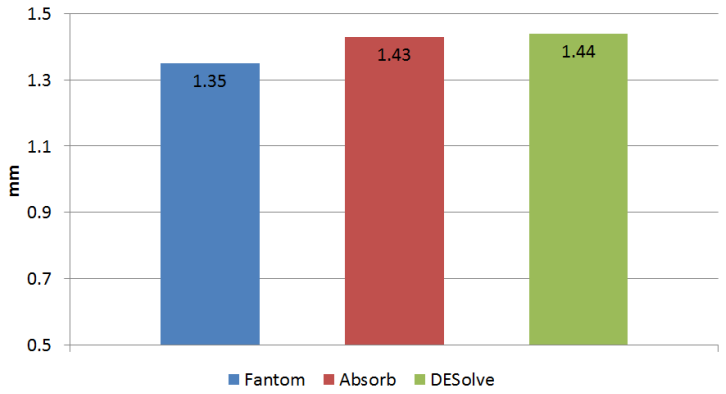
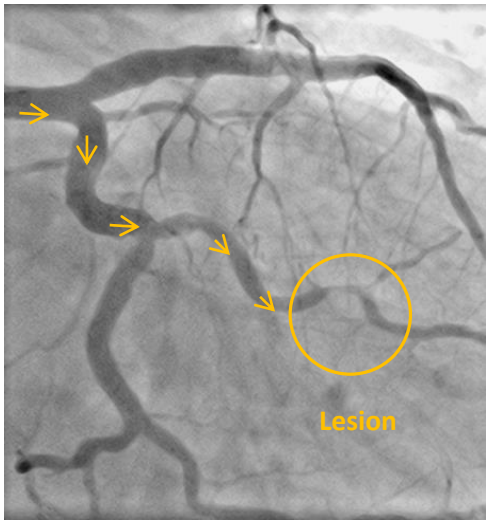
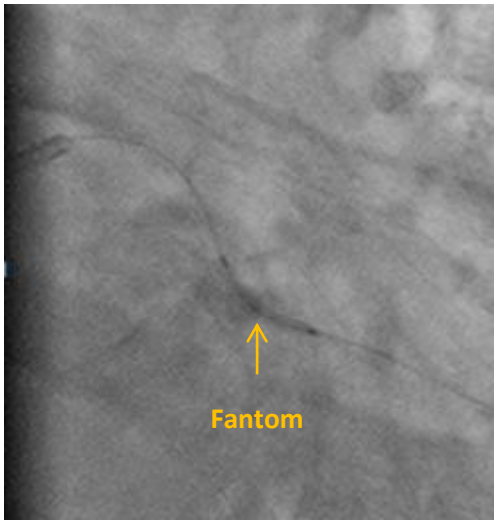
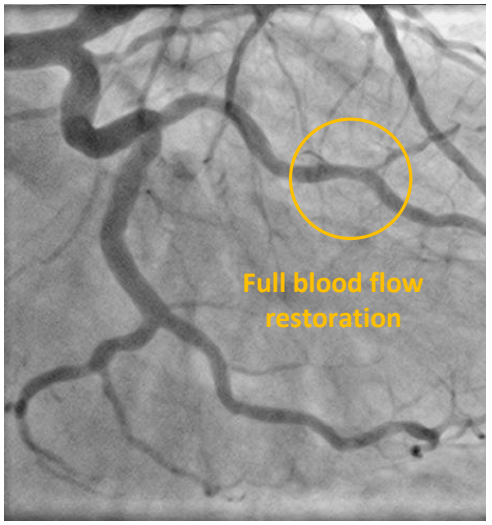
Enhanced Deliverability

- **Thin 125µm strut design enables:**
  - Reduced scaffold crossing profile
  - Greater device flexibility
  - Increased access to a greater number of lesions









Courtesy of A. Abizaid, Dante Pazzanese, Sao Paulo, Brazil

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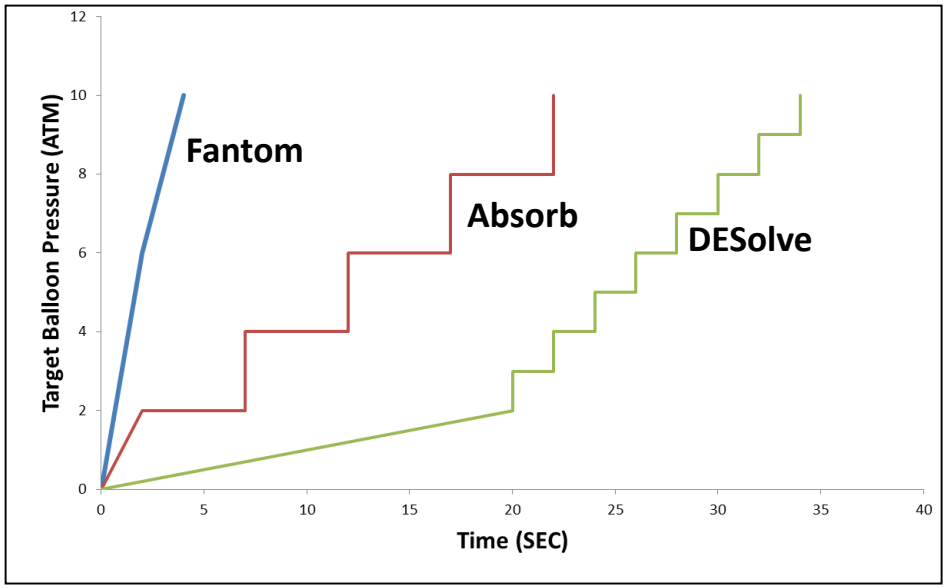
Continuous Inflation

- **Inflation process:**
  - Continuous inflation to intended diameter
  - Reduces arterial occlusion time for the patient
  - Increases speed for scaffold delivery for the physician
  - Eliminates the need to recall multiple inflation schemes



Based upon manufactures instructions for use

Fantom Bioresorbable Scaffold

Single Step Inflation

REVAs Advanced Polymer enables single step inflation

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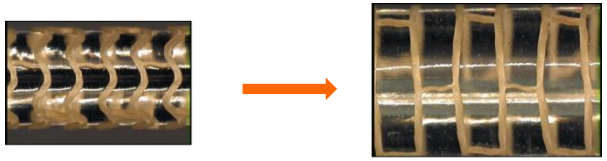
Bioresorbable Scaffold Features

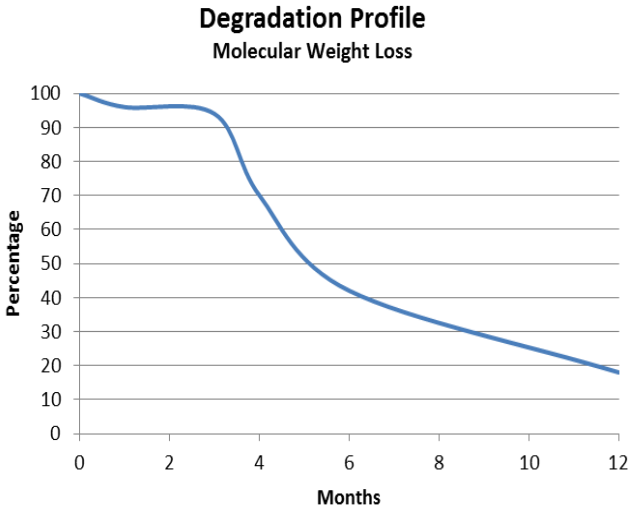
- **Post-dilation without compromise**
  - Substantial expansion safety margin
    - 0.75 to 1.0 mm depending upon device size
  - Able to adjust for vessel taper

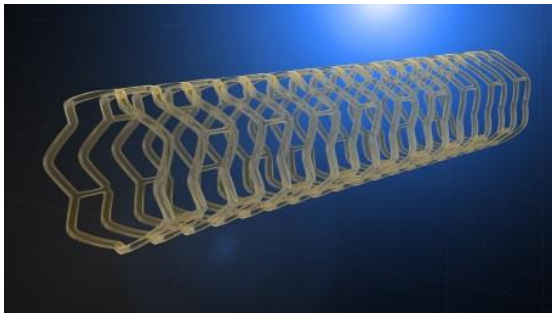
3.0mm Nominal Device



Polymer enables expansion to 4.0 mm without fracture

- **Restoration of vasomotion**
  - Maintains radial strength during healing
  - Restoration of vasomotion approx. 1 yr.
    - > 80% molecular weight loss within 12 months
  - Eliminates undesirable shear stress induced by a permanent implant





FANTOM II Trial

Safety & Performance Study for the
Fantom Sirolimus-Eluting Bioresorbable
Coronary Scaffold

FANTOM II

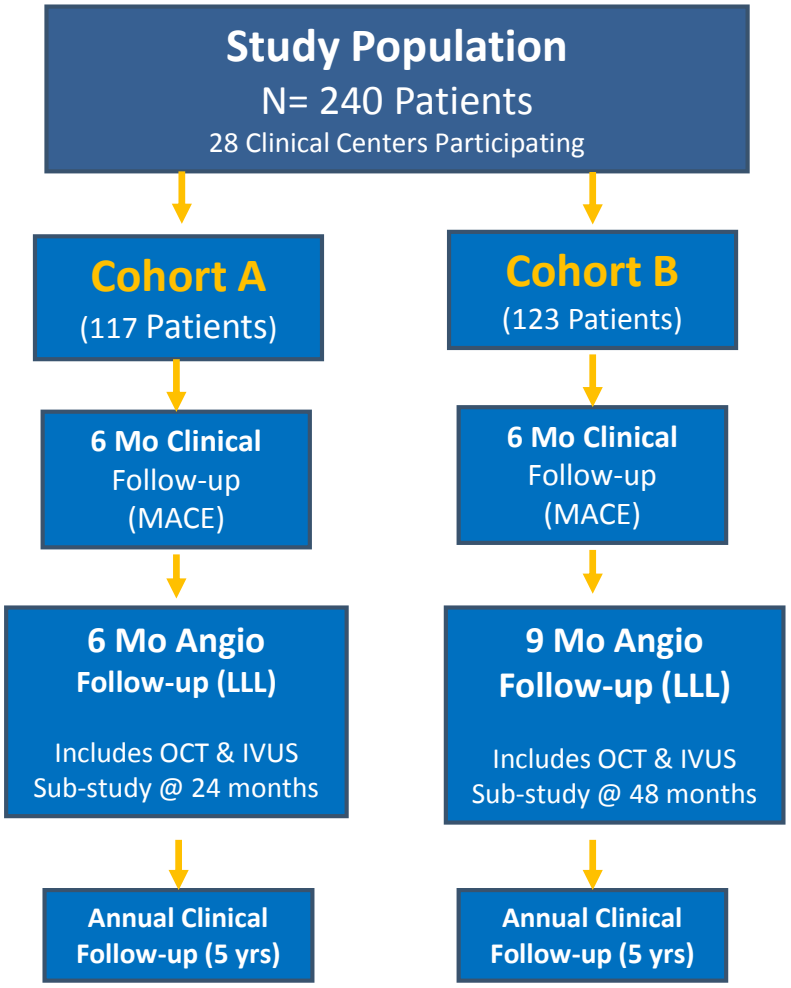
Study Investigators

- Australia
  - Dr. Muller, Dr. Jepson, Dr. Walters
- Belgium
  - Dr. De Bruyne
- Brazil
  - Dr. Abizaid, Dr. Costa, Dr. Chamie, Dr. Perin
- Denmark
  - Dr. Christiansen, Dr. Lassen, Dr. Okkels-Jensen
- France
  - Dr. Carrié, Dr. Chevalier, Dr. Fajadet, Dr. Collet
- Germany
  - Dr. Weber-Albers, Dr. Naber, Dr. Achenbach, Dr. Frey, Dr. Lutz, Dr. Kische, Dr. Ince, Dr. Brachman
- Netherlands
  - Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen
- Poland
  - Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla

FANTOM II

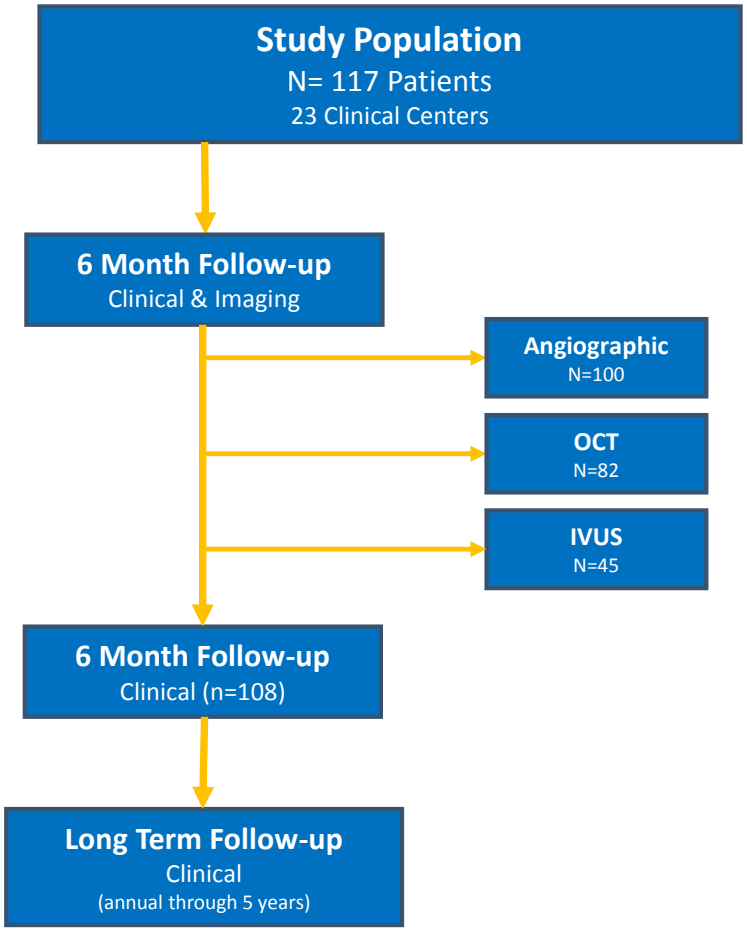
Study Design and Endpoints

- **Study Design**
  - Safety and Performance Trial
  - 240 patients in 2 cohorts
  - 2.5mm to 3.5mm vessels
  - Lesion length ≤ 20mm
  - Angiographic follow-up
    - Cohort A: 6 months 117 Pts.
    - Cohort B: 9 months 123 Pts.
  - Serial imaging sub-studies
    - Cohort A: 24 months
    - Cohort B: 48 months



FANTOM II – Cohort A

Study Overview and Baseline Characteristics



Patient Characteristics (N=117)	
Patient Age (average years)	62.7 ± 9.7
Male	70.1%
Diabetes	21.4%
Current/Former Smoker	50.4%
Hypertension	76.9%
Hyperlipidemia	70.9%
Prior PCI	40.2%
Prior CABG	6.0%
Prior MI	26.5%
Recent LVEF <40%	2.0% (N=113)

FANTOM II – Cohort A

Lesion Characteristics and Procedural Outcomes

Target Lesion Location (n=117)	
LAD	49.6% (58)
LCX	30.8% (36)
RCA	19.7% (23)
ACC/AHA Lesion Class (n=115)*	
Type A	24.3% (28)
Type B1	42.6% (49)
Type B2	33.0% (38)
Type C	0.0% (0)

*As assessed by an independent core lab

Acute Procedural Outcomes		
Acute Technical Success (1)	96.6%	n=117
Acute Procedural Success (2)	99.1%	n=113
Clinical Procedural Success (3)	99.1%	n=112

(1) Defined as successful delivery and deployment of the intended scaffold in the intended lesion without device related complications.

(2) Defined as acute technical success (see definition above), resulting in a residual stenosis of ≤50 percent with no immediate (in-hospital) MACE.

(3) Defined as acute procedural success (see definition above), with no MACE thirty days post-intervention and with a final diameter stenosis ≤50 percent.

FANTOM II – Cohort A

Angiographic – QCA Results*

In-Scaffold Analysis	Baseline (n=115)	Post Procedure (n=112)	6 Months (n=100)
RVD (mm)	2.68 ± 0.37	2.75 ± 0.40	2.69 ± 0.35 (n=101)
MLD (mm)	0.79 ± 0.29	2.47 ± 0.37	2.20 ± 0.39
Diameter Stenosis (%)	70.3 ± 10.4	10.7 ± 7.6	16.8 ± 11.5 (n=99)
Acute Gain (mm)	1.67 ± 0.41		
Acute Recoil (%)	2.9 ± 8.8		
Mean LLL (mm)			0.29 ± 0.38
Median LLL (mm)			0.22 (-0.43, 1.77)
In-Segment Analysis			
Mean LLL (mm)			0.21 ± 0.32
Median LLL (mm)			0.16 (-0.43, 1.67)

* Preliminary Results: Analyzed by an independent QCA core lab (Yale Cardiovascular Research Group, New Haven, US)

FANTOM II – Cohort A

MACE Results

6 Month MACE Results Timeframe	Event
In-Hospital	1 (Post Procedure MI)
30-Day Follow-up	1 (MI/TLR/SAT)
90-Day Follow-up	0
6-Month Follow-up	0

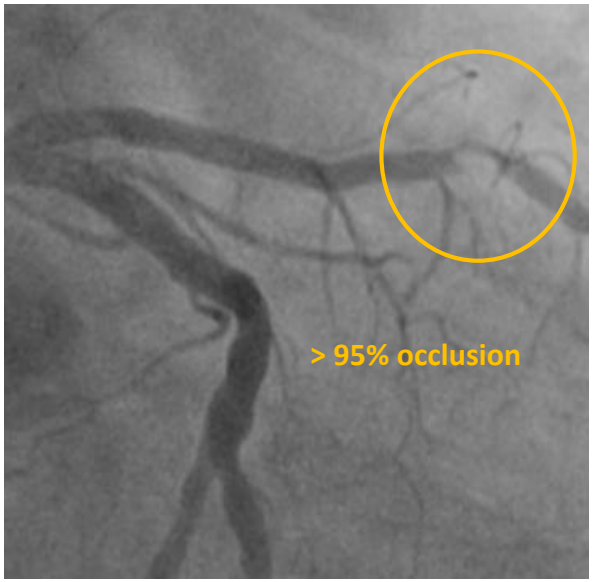
Components of the Primary Endpoint (ITT): Hierarchical	N=117
MACE[1]	1.71%
Cardiac Death	0.0 %
Target vessel MI	1.71%
Clinically Driven TLR	0.0%

1) As adjudicated by an independent Clinical Events Committee
2) One event pending final adjudication review (non ischemic driven TLR)

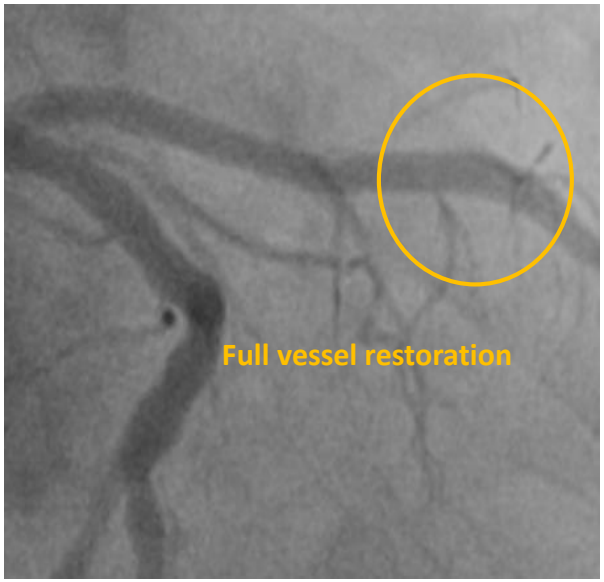
FANTOM II Case Sample

Angiographic Assessment

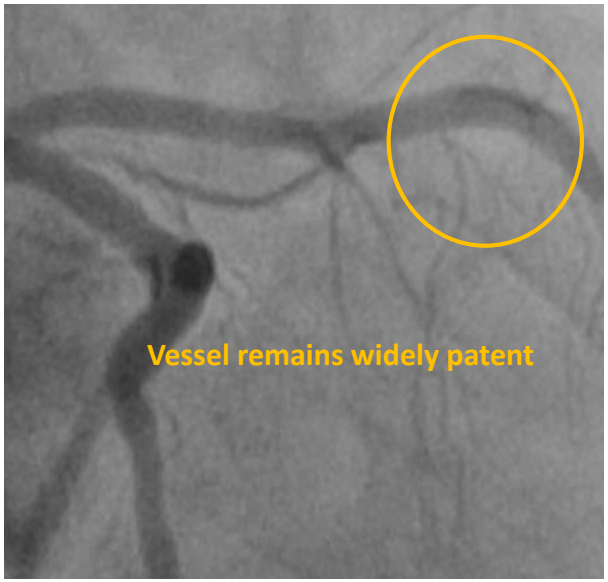
Pre-Implant



Post-Implant



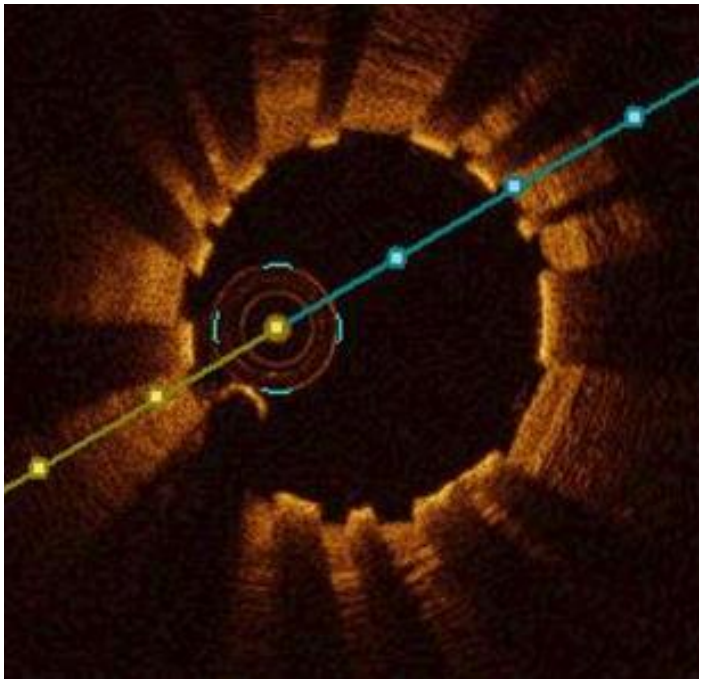
6-Month Follow-up



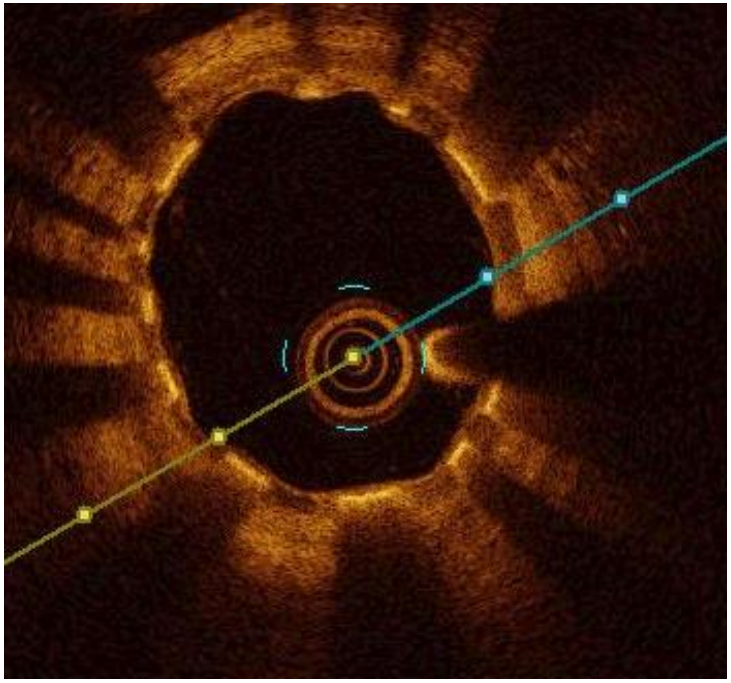
FANTOM II Case Sample

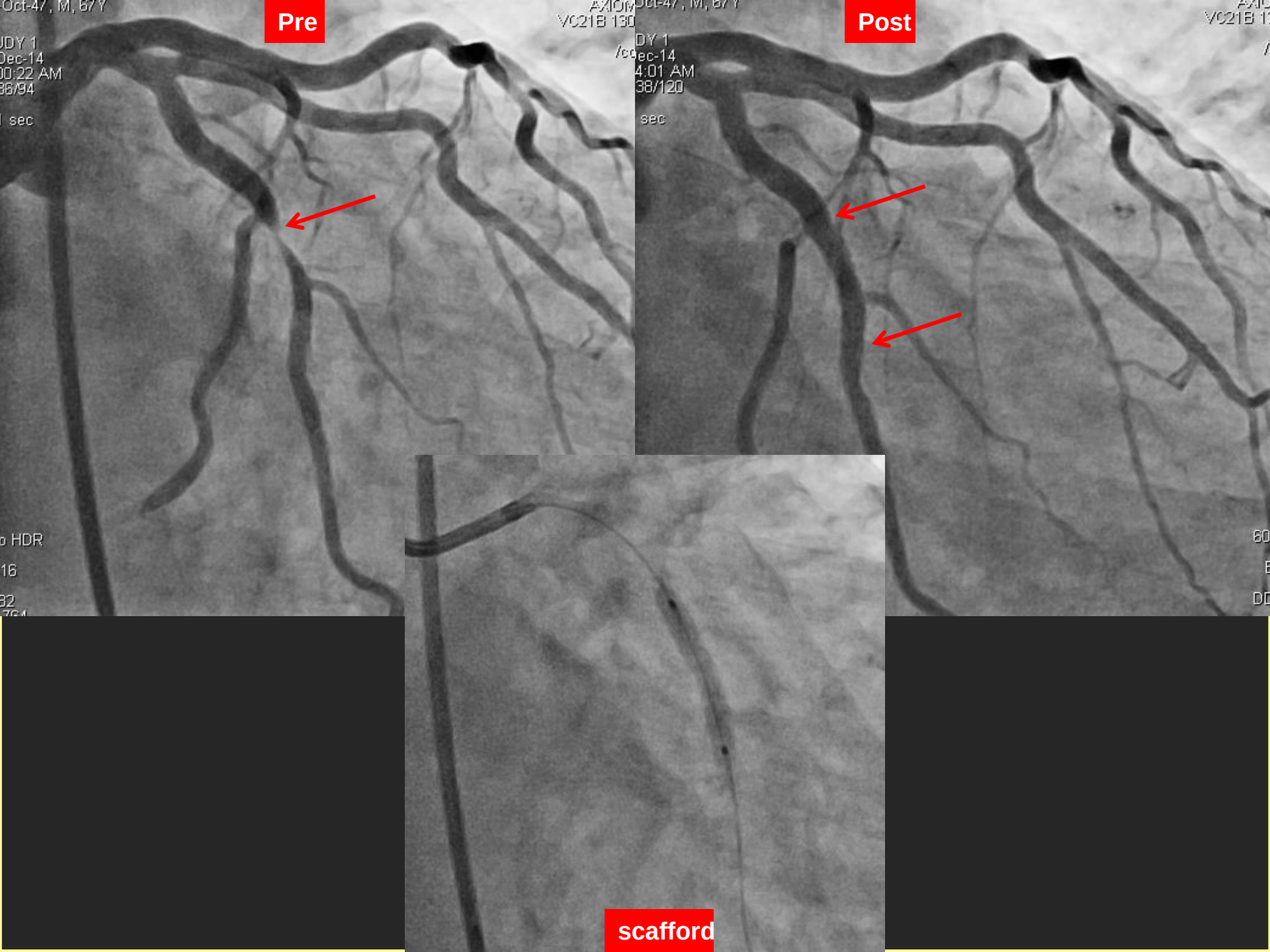
OCT Assessment

Post-Implant



6-Month Follow-up




Pre
Post
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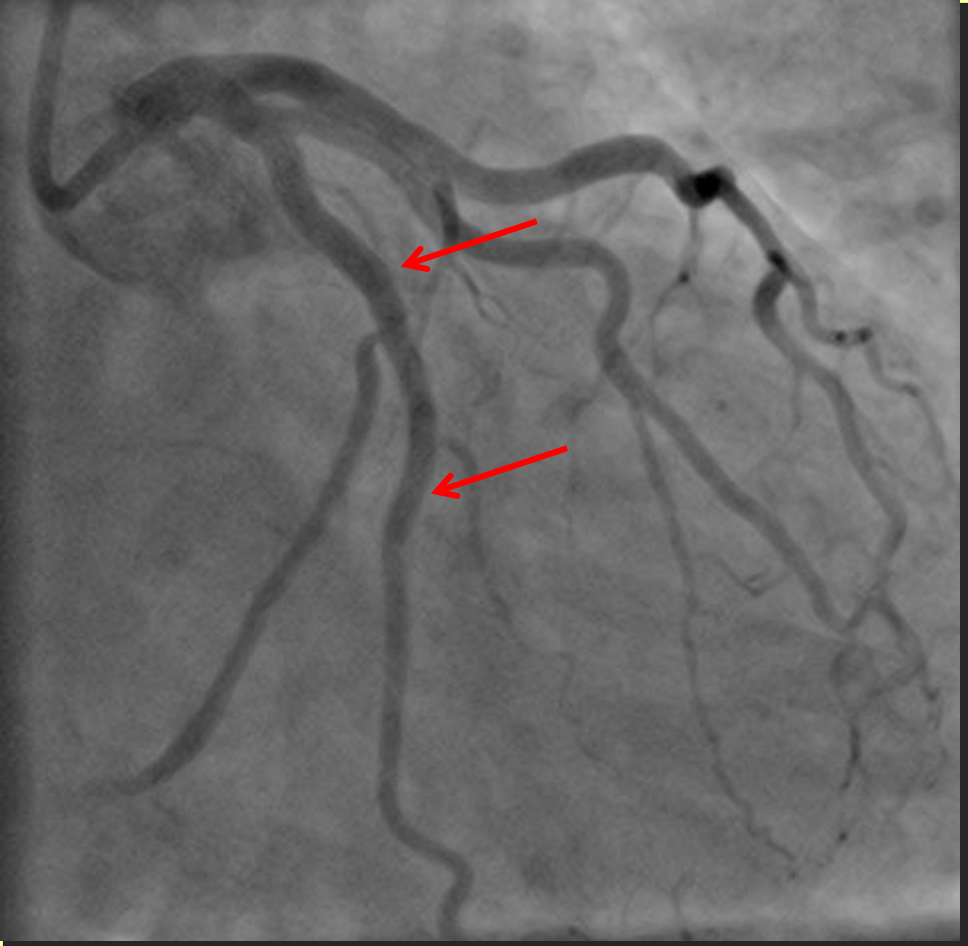
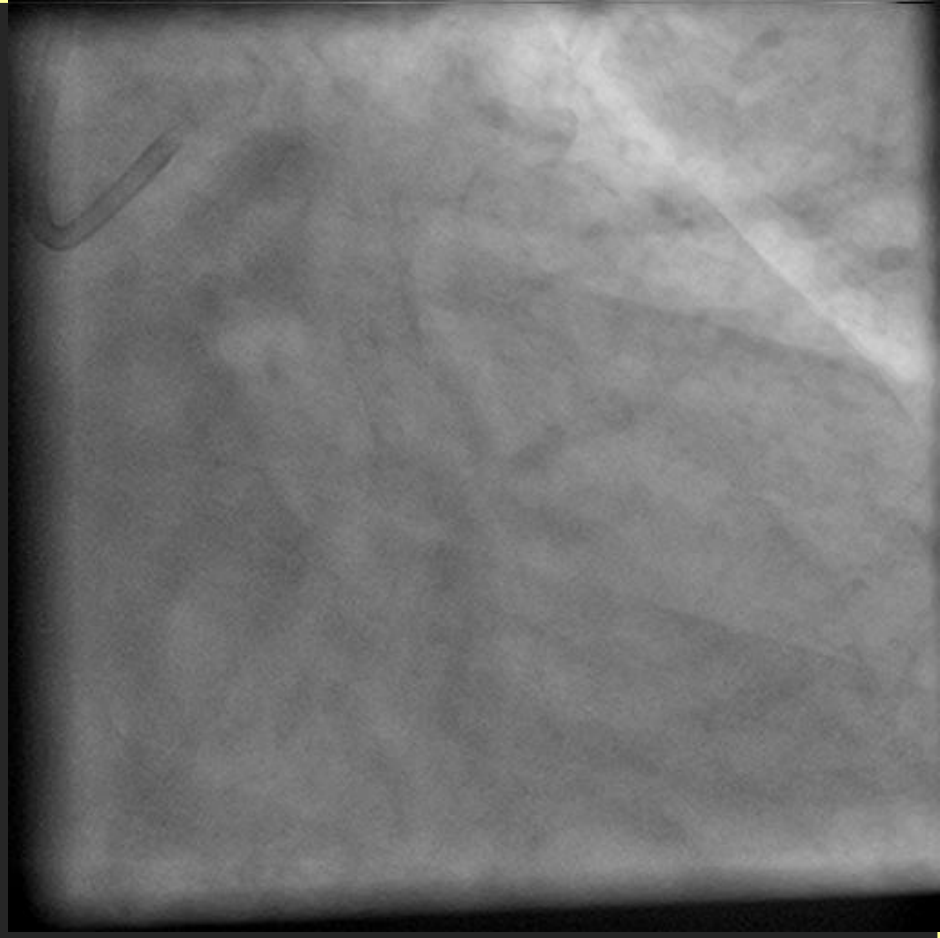
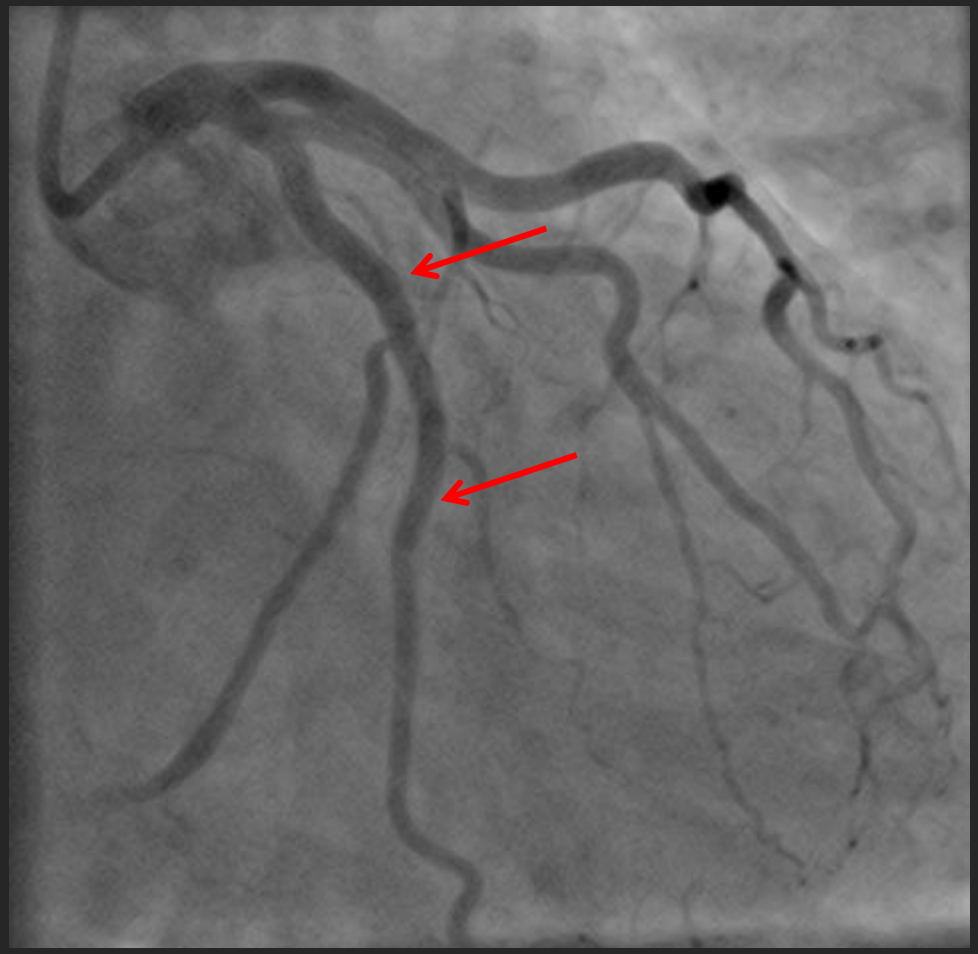
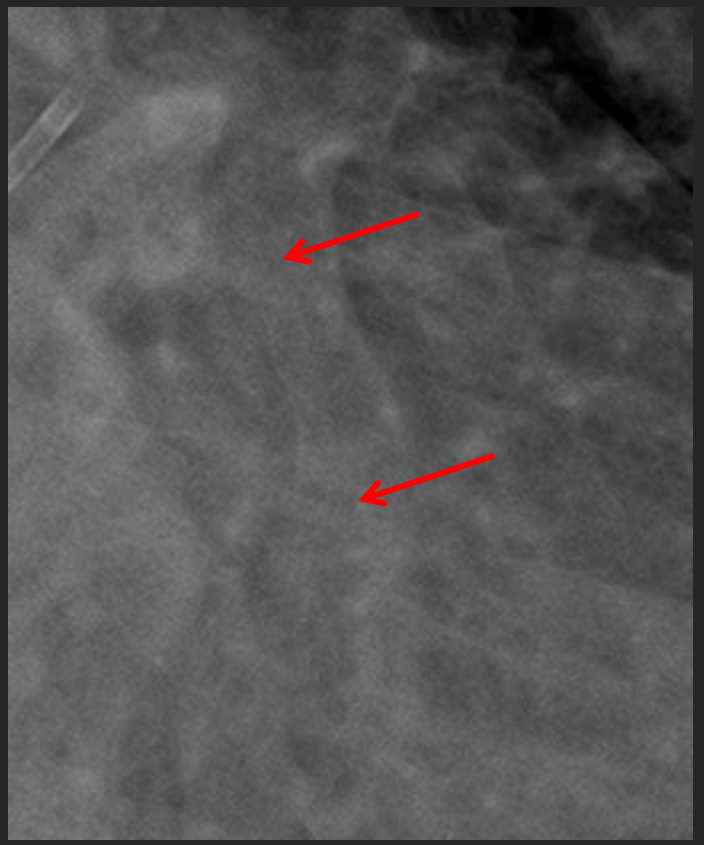


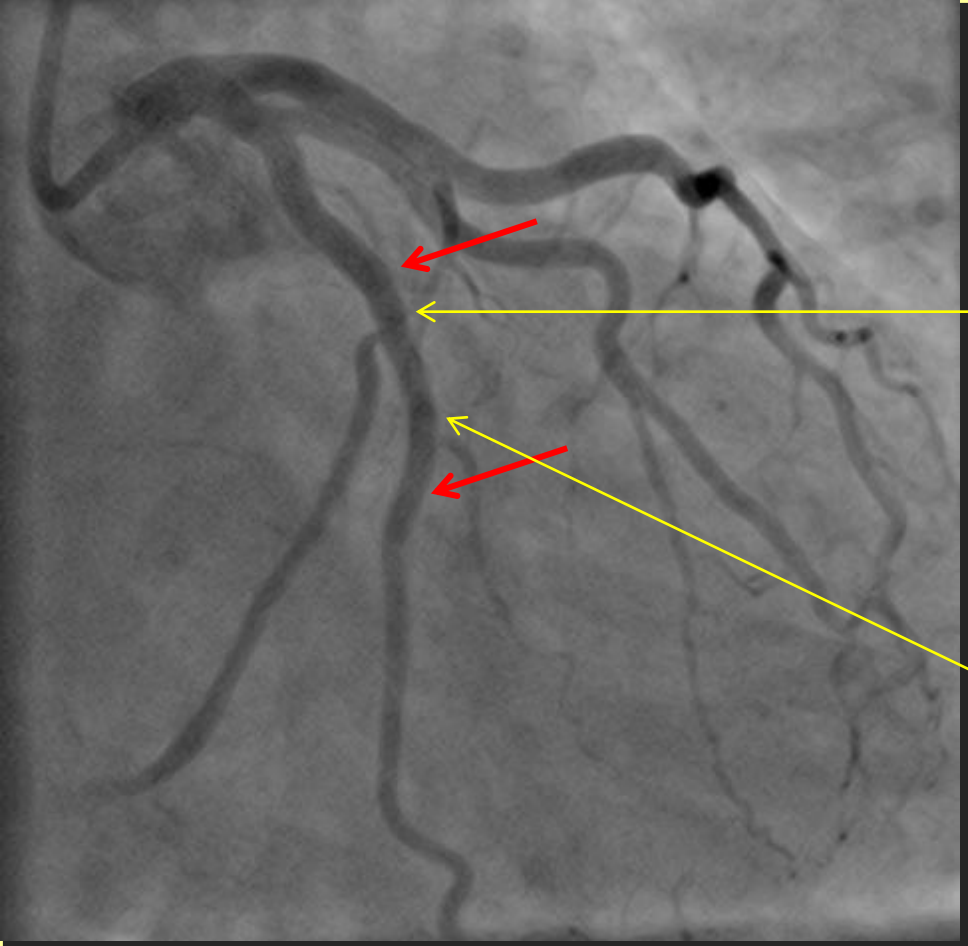


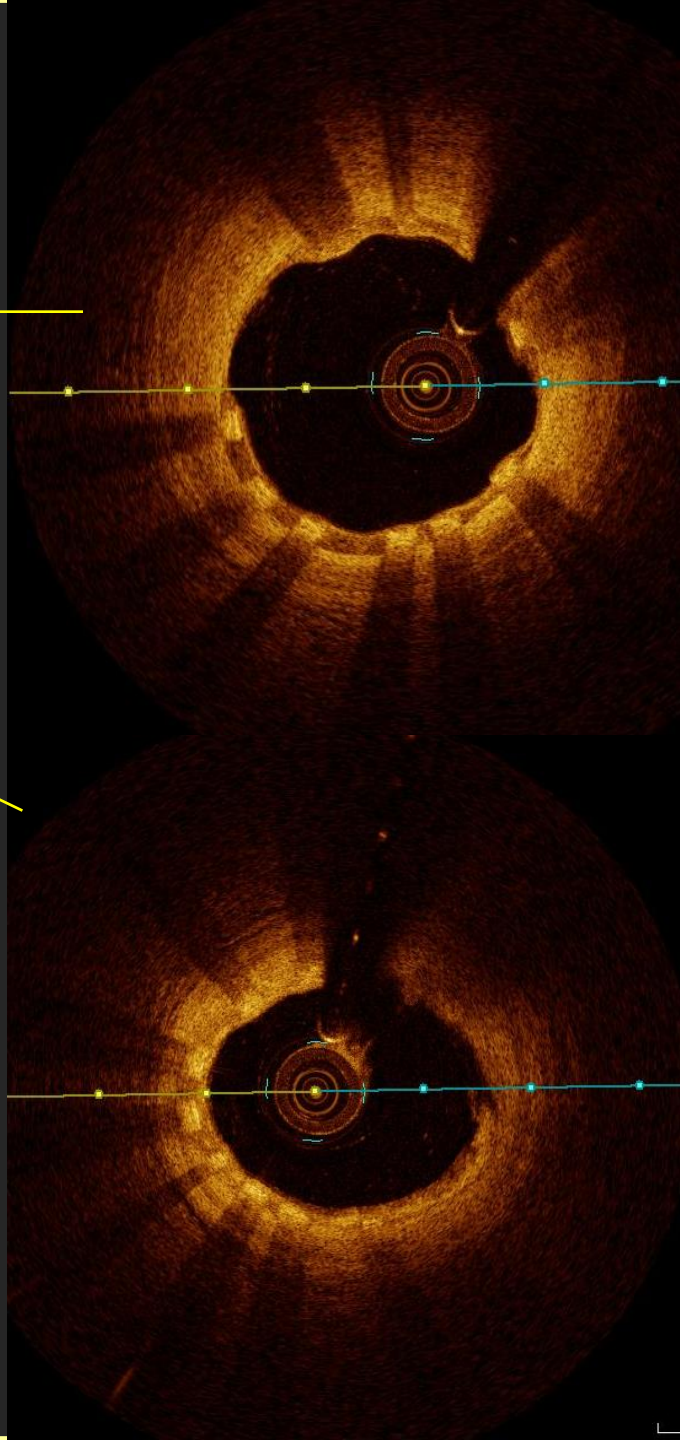
4-month Follow-up





4-month Follow-up





4-month Follow-up

FANTOM Program

Clinical Summary

- **Fantom offers new and interesting features**
  - Radiopacity
  - Enhanced deliverability
  - Single-step inflation
  - No special handling requirements

- **Initial clinical data demonstrates**
  - Good acute performance
    - Excellent device deliverability
    - Minimal residual stenosis and acute recoil
  - Sustained performance and safety through 6 months
    - Low MACE Rate
    - Low late lumen loss

Thanks!