The FANTOM II Study

First Report for the 12-month clinical outcomes of the Fantom sirolimus-eluting bioresorbable scaffold

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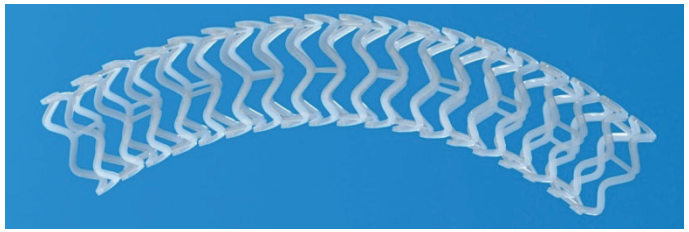
Potential conflicts of interest

Speaker's name: Dr. Alexandre Abizaid

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

Consultant to REVA Medical, Inc.

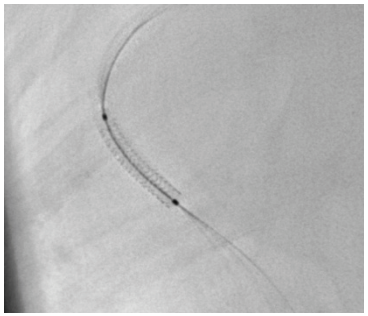
Fantom Bioresorbable Scaffold



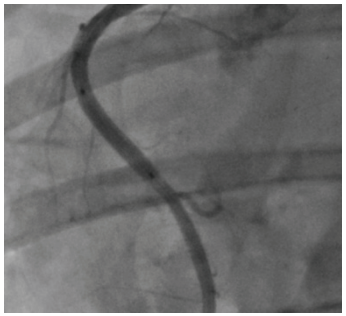
***Fantom*® (REVA Medical)**
Sirolimus-Eluting Bioresorbable Scaffold
Desaminotyrosine Polycarbonate

Key Scaffold Features

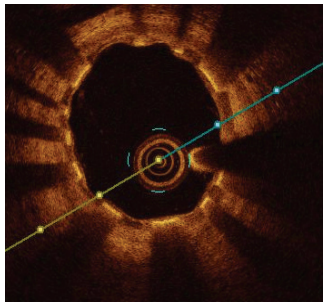
- Complete scaffold visibility under x-ray
- Single-step continuous inflation
- Clinically significant expansion range
- Optimal radial strength at 125 µm thickness
- Vasomotion restoration ~1 year
- No special storage or handling



Visibility



Deliverability



Vessel Patency

Fantom
Radiographic Visibility

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

  (Covalently bound Iodine to polymer)

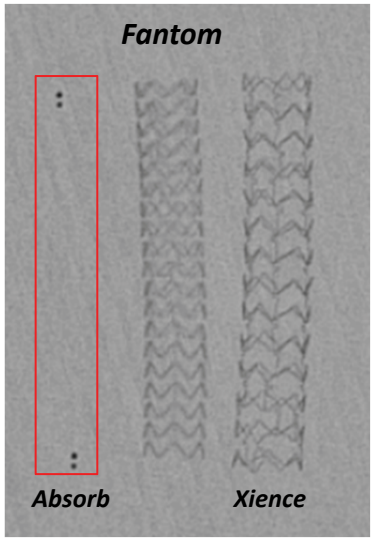
  Allows for:

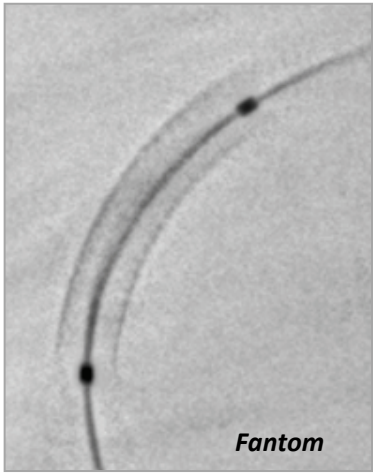
  – Precise scaffold placement

  – Accurate lesion coverage

  – Full structural assessment after deployment

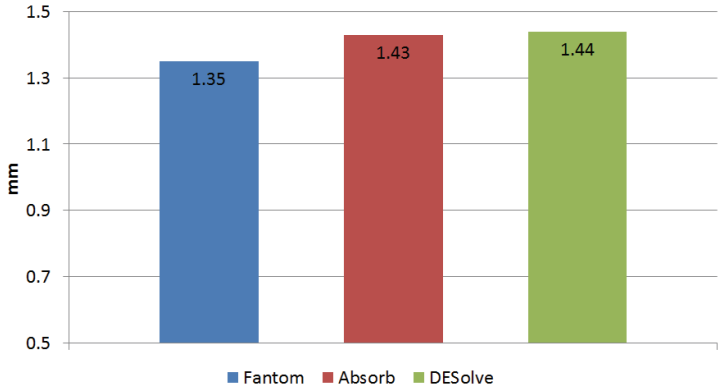
  – Less reliance on invasive imaging compared to other BRS (IVUS/OCT)

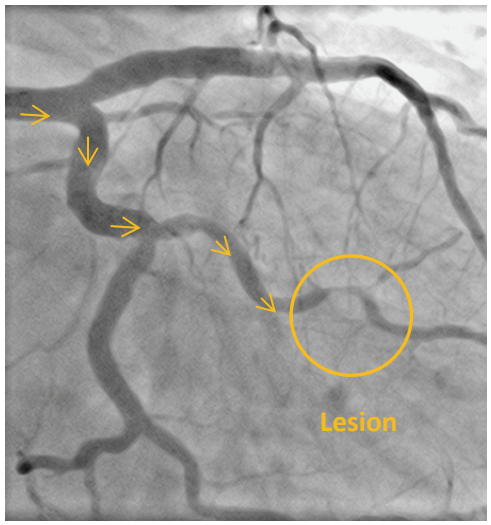


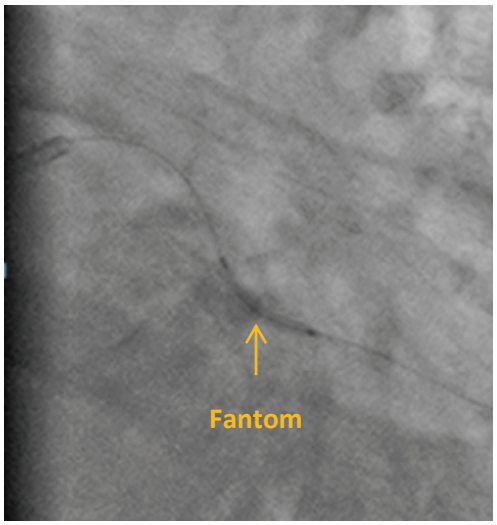


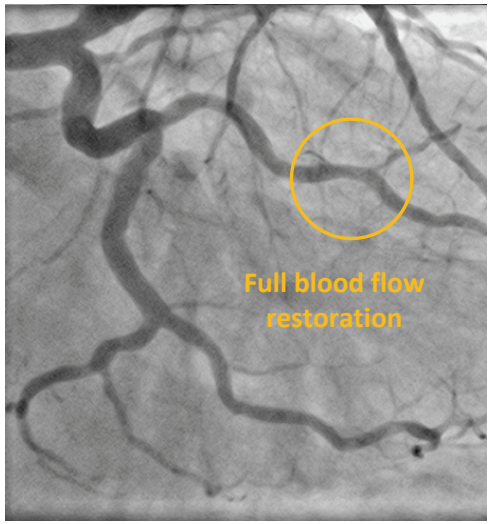
Fantom
Enhanced Deliverability

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





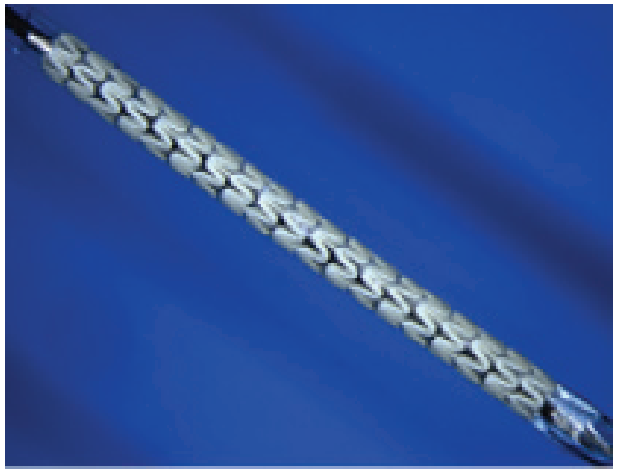




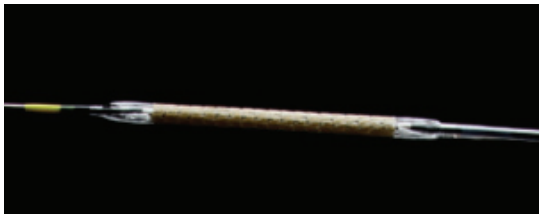
Courtesy of A. Abizaid, Dante Pazzanese, Sao Paulo, Brazil

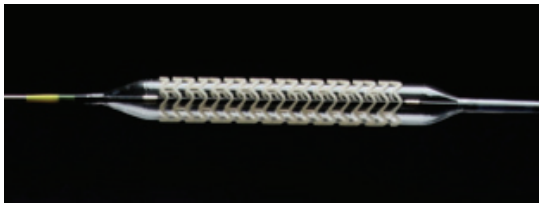
Fantom
Single-Step Inflation

- **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



[VIDEO]



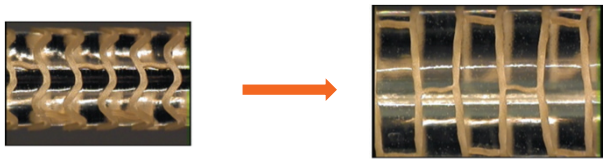


REVA's advanced polymer enables single-step inflation

Fantom
Bioresorbable Scaffold Features

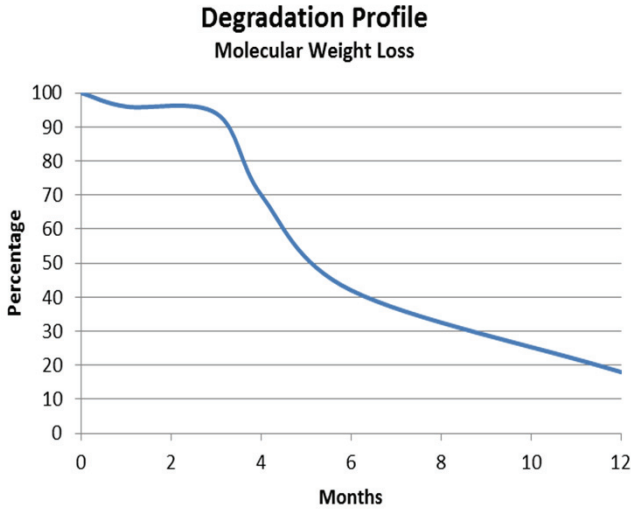
- **Post-dilation without compromise**
  - Substantial expansion safety margin
    - 0.75 to 1.0 mm depending upon device size
  - Able to adjust for vessel taper

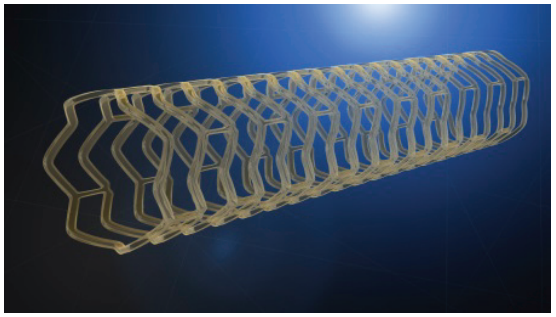
3.0mm Nominal Device



Polymer enables expansion to 3.75 mm without fracture

- **Restoration of vasomotion**
  - Maintains radial strength during healing
  - Restoration of vasomotion approx. 1 yr.
  - 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

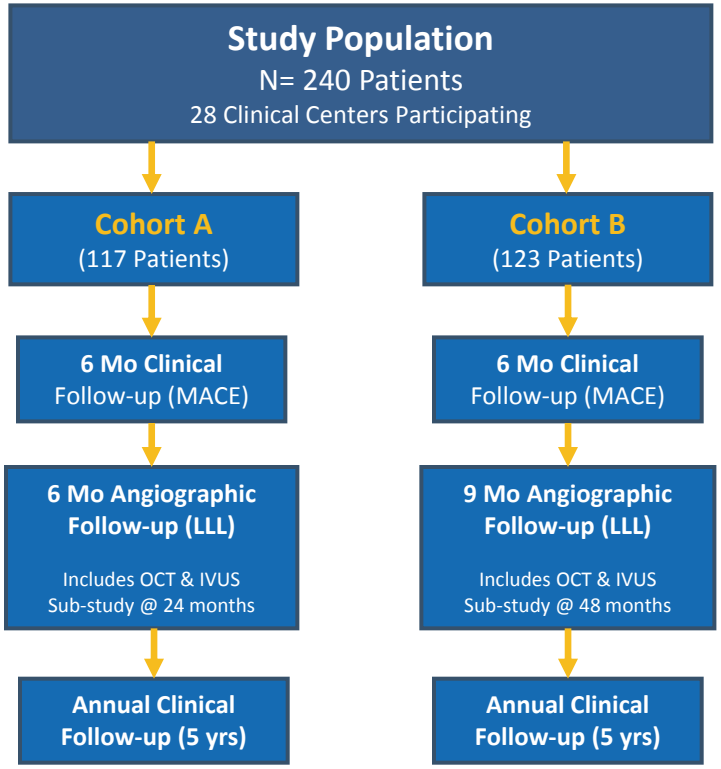
Study Investigators

- 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

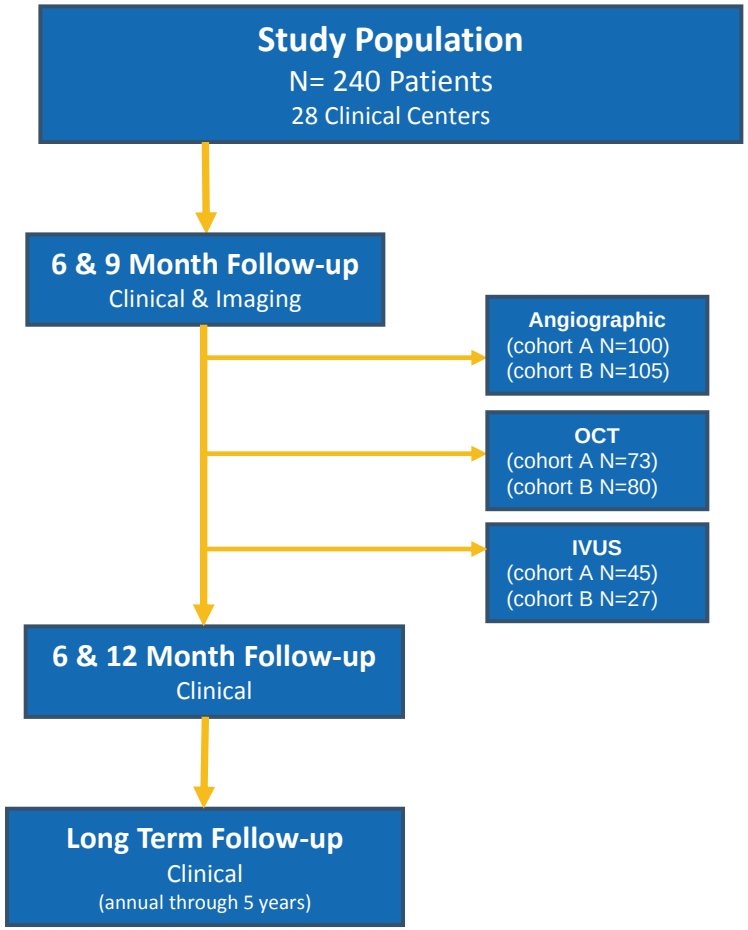
Study Design and Endpoints

- **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 (25 Patients)
    - Cohort B: 48 months (25 Patients)



FANTOM II – Cohort A & B

Study Overview and Baseline Characteristics



Patient Characteristics (N=240)	
Patient Age (average years)	62.7 ± 10.1
Male	70.4%
Diabetes	23.8%
Current/Former Smoker	59.6%
Hypertension	73.8%
Hyperlipidemia	70.8%
Prior PCI	43.8%
Prior CABG	2.9%
Prior MI	26.3%
Recent LVEF <40%	0.0% (N=231)

FANTOM II – Cohort A

Lesion Characteristics and Procedural Outcomes

Lesion Characteristics

Target Lesion Location (n=238)[1]	
LAD	48.7% (116)
LCX	31.3% (74)
RCA	20.2% (48)
ACC/AHA Lesion Class (n=238)[1]	
Type A	18.5% (44)
Type B1	49.6% (118)
Type B2	29.4% (70)
Type C	2.5% (6)

(1) Two pre-procedure angiograms were not available

Initial Outcomes

Acute Procedural Outcomes	
Acute Technical Success (1)	95.8%
Acute Procedural Success (2)	99.1%
Clinical Procedural Success (3)	99.6%

(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 & B

Safety Results

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	N=240 (%), (N)
MACE	2.1% (5)
Cardiac Death	0.4% (1)[1]
Target vessel MI	1.3% (3)
Clinically Driven TLR	0.8% (2)

Components of 12-Month Secondary Endpoint (modified ITT): non-Hierarchical	N=240 N, (%)
MACE	4.2% (10)
Cardiac Death	0.8% (2)[1,2]
Target vessel MI	1.3% (3)
Clinically Driven TLR	2.5% (6)

(1) One patient died between 0-6 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.

(2) One death occurred between 6-12 months. Patient was reported to have died of COPD by treating physician but cardiac relation could not be excluded.

FANTOM II – Cohort A & B

Safety Results

Scaffold Thrombosis Assessment 12-Months Event Rate	N=240 (%), (N)
Scaffold Thrombosis Per Protocol Definitions	0.4% (1)[1]
Scaffold Thrombosis Per ACR Definition	
Definite	0.4% (1)
Probable	0.0% (0)

Only 1 case of scaffold thrombosis reported to date

Current Long-Term Follow-up	
Patients through 12 month follow-up	240
Patients through 18 month follow-up	*Approx.: 140*
Patients through 24 month follow-up	*Approx.: 10*

(1) Target lesion was not fully covered with scaffold. Significant untreated stenosis was present at index procedure. Patient returned 5 days post procedure with a scaffold thrombosis

FANTOM II – Cohort A & B

Angiographic – QCA Results

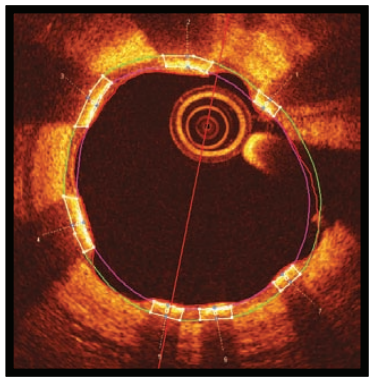
In-Scaffold Analysis	Baseline (n=238)[1]	Cohort A – 6 Mo. (n=100)	Cohort B – 9 Mo. (n=105)
RVD (mm)	2.71 ± 0.37	2.70 ± 0.36	2.73 ± 0.37
MLD (mm)	0.82 ± 0.31	2.23 ± 0.41	2.22 ± 0.43
Diameter Stenosis (%)	69.5 ± 11.0	15.3 ± 15.2	16.4 ± 14.3
Acute Gain (mm)	1.68 ± 0.41		
Acute Recoil (%)	4.0 ± 8.3[2]		
Mean LLL (mm)		0.25 ± 0.40	0.33 ± 0.36
In-Segment Analysis			
Mean LLL (mm)		**0.17 ± 0.34**	**0.29 ± 0.41**

(1) Baseline angiographic data was not available for two enrolled patients

(2) N = 156 patients available for recoil analysis

Fantom Scaffold OCT

Mean Lumen Area Analysis



PCI Research
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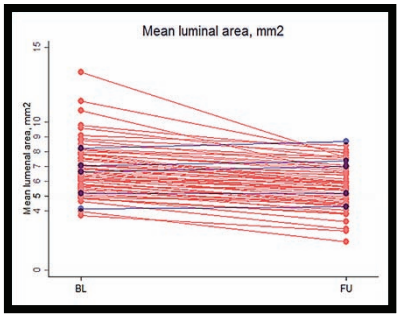
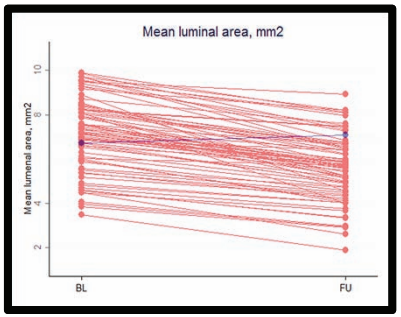


6 Month Assessment

	Baseline	Follow-up	Difference	p-value
Mean lumen area (mm^2)	6.8 (1.7)	5.7 (1.4)	-1.1 (-1.3;-0.9)	<0.0001
Minimal lumen area (mm^2)	5.3 (1.4)	4.4 (1.4)	-1.0 (-1.3;-0.7)	<0.0001

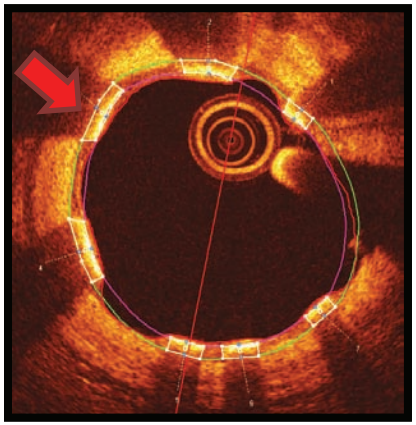


9 Month Assessment

	Baseline	Follow-up	Difference	p-value
Mean lumen area (mm^2)	*7.1 (1.6)*	*5.6 (1.5)*	*-1.6 (-1.7;-1.4)*	*<0.0001*
Minimal lumen area (mm^2)	*5.7 (1.4)*	*4.0 (1.4)*	*-1.7 (-1.9;-1.4)*	*<0.0001*

Fantom Scaffold OCT

Stent Area Analysis



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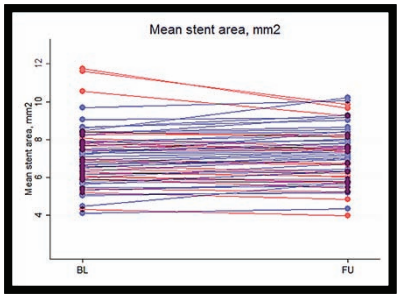
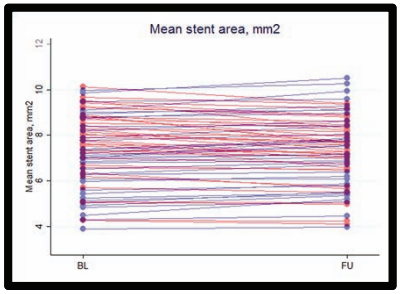


6 Month Assessment

	Baseline	Follow-up	Difference	p-value
Mean stent area (mm^2)	7.1 (1.5)	7.2 (1.4)	0.1 (-0.02;0.24)	0.12
Minimal stent area (mm^2)	5.9 (1.3)	6.0 (1.3)	0.1 (-0.02;0.25)	0.08

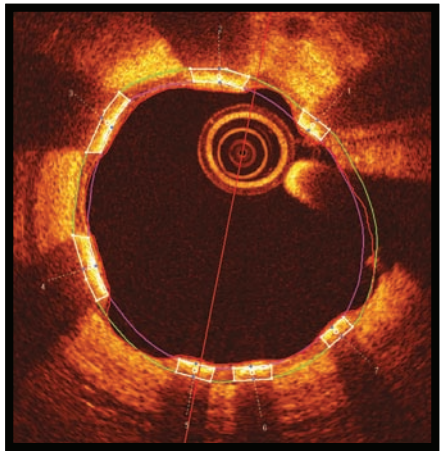


9 Month Assessment

	Baseline	Follow-up	Difference	p-value
Mean stent area (mm^2)	7.4 (1.6)	7.3 (1.5)	-0.1 (-0.2;0.0)	0.16
Minimal stent area (mm^2)	6.1 (1.4)	6.0 (1.3)	-0.1 (-0.2;0.1)	0.43

Fantom Scaffold OCT

Strut Coverage



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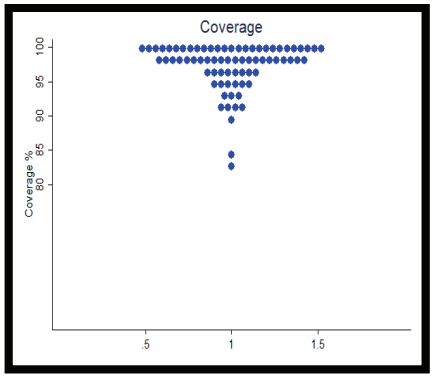
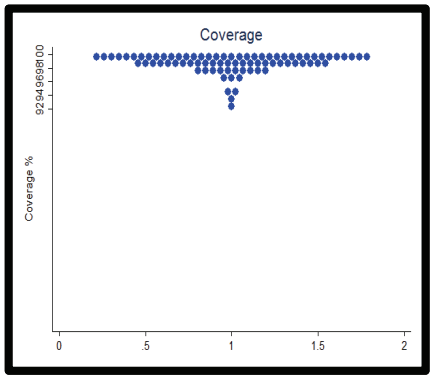


6 Month Assessment

	Follow-up
Covered struts	**98.1%** (95.9;99.4)



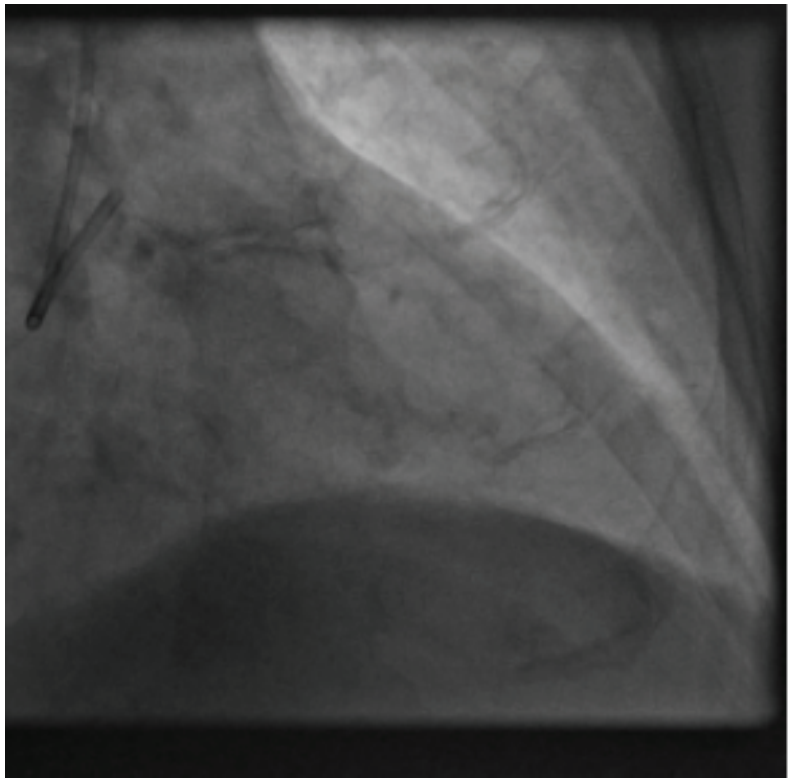
9 Month Assessment

	Follow-up
Covered struts	**99.0%** (98.3;100.0)

Case Sample

Baseline assessment and Pre-dilatation

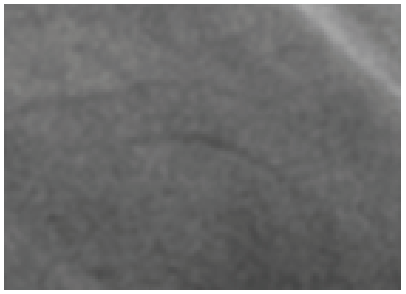
- 68 yo. Female
  - History of Hypertension
  - No prior PCI
  - Non-smoker
  - No Diabetes
  - LVEF = 66%
- Baseline Assessment
  - Mid LAD Lesion
  - Est. Stenosis = 80%
  - Est. RVD = 2.79mm
  - Lesion Length = 14 mm



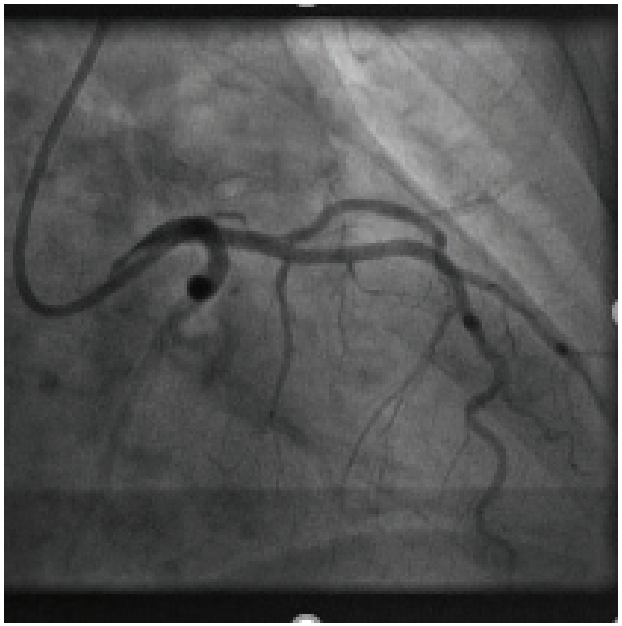
[VIDEO]

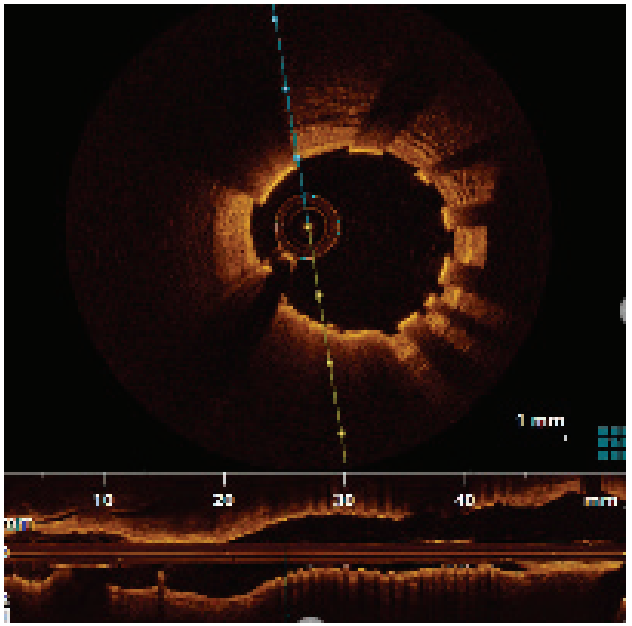
Case Sample

Index Procedure



- Actual Deployment Data
  - Scaffold: 3.00 x 18.00 mm
  - Actual Deployment Pressure = 12 atm
  - Diameter stenosis result = 10%
  - Post-dilatation: 3.25 x 15 mm, 16 atm, 15 sec

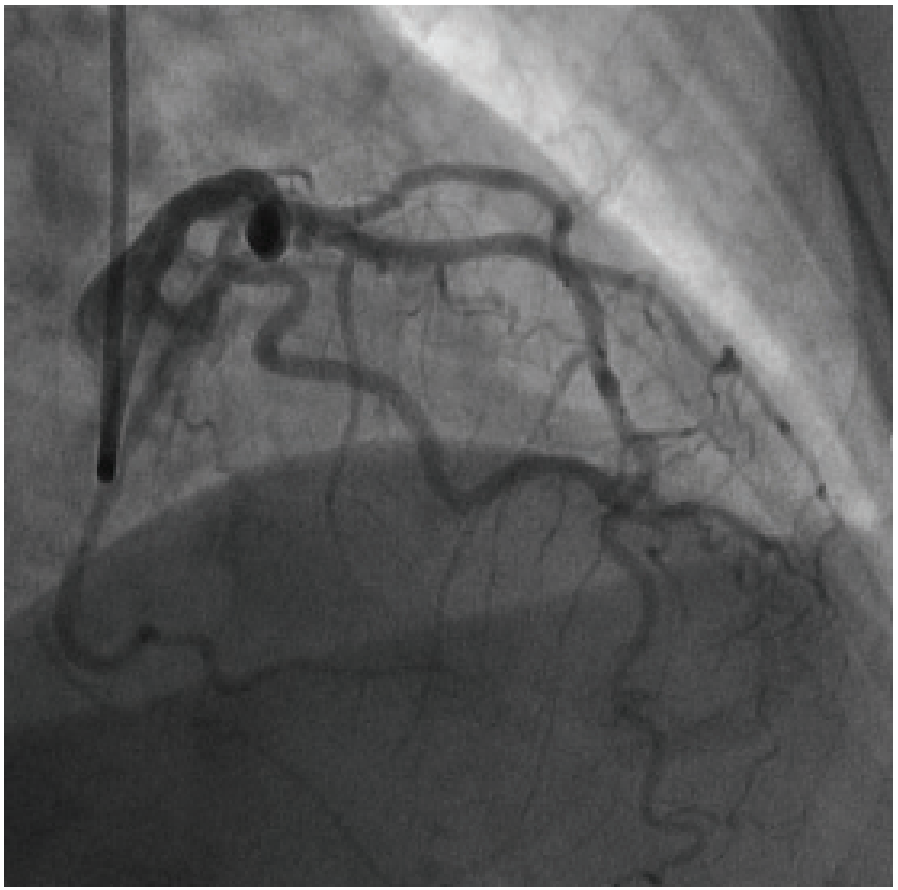


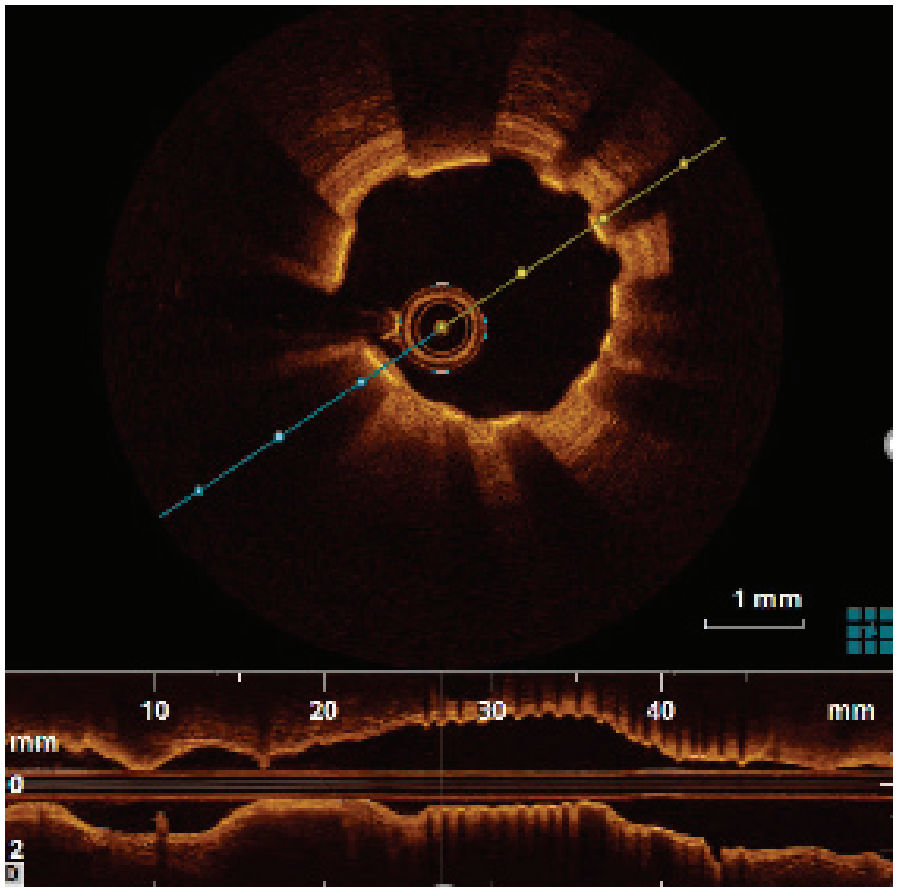


[VIDEO] Post-Implant **[VIDEO]**

Case Sample

6 Month Follow-up Procedure





[VIDEO] **[VIDEO]**

Vessel remains widely patent at 6 months

FANTOM Program

Clinical Summary

- **Fantom offers new and clinically important features**
  - Radiopacity
  - Deliverability
  - Single-step inflation
  - No special handling requirements
- **Initial clinical data demonstrates**
  - Good acute performance
    - Enhanced device deliverability
    - Minimal residual stenosis and acute recoil (4%)
  - Sustained performance and safety through 12 months
    - Low MACE Rate (4.2%)
    - No evidence of late scaffold thrombosis

Thank you!