DIDACTIC SESSION: BIORESORBABLE VASCULAR SCAFFOLDS, PART 1 - DEVICES AND EMERGING DATA

Session III. Next Generation Scaffolds Part 1: Design Iterations, Data, and Clinical Development

Colorado Convention Center, Mile High Ballroom 4E-4F, Ballroom Level
Tuesday, October 31, 4:43 PM - 4:53 PM

Fantom:

A Radio-Opaque "Stent-Like" BRS With Improved Expansion Characteristics

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Edwards, Medtronic, Abbott, BSC
• Consulting Fees/Honoraria	• Edwards, Medtronic, Abbott, BSC

Fantom®

Sirolimus Eluting Bioresorbable Coronary Scaffold

1st and Only BRS Make with Tyrocore™:

- Uniquely designed for vascular scaffolds
- Derived from naturally occurring tyrosine amino acid
- Bound iodine for radiopacity
- Proprietary, patent protected, and manufactured by REVA Medical

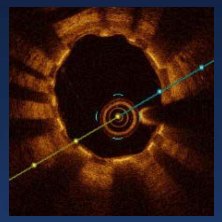
RADIOPAQUE

Procedural accuracy

Accurate lesion coverage

Precise Placement

Full structural assessment



STRONG

Large expansion range

0.75mm for 3.0mm scaffold

Maintains vessel patency

Deliverable

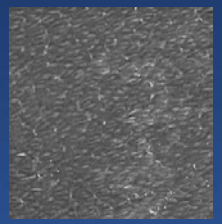
Thin 125µ struts

Lower crossing profile

Improved flexiblity

Single step inflation

Reduced procedure time



BIOCOMPATIBLE

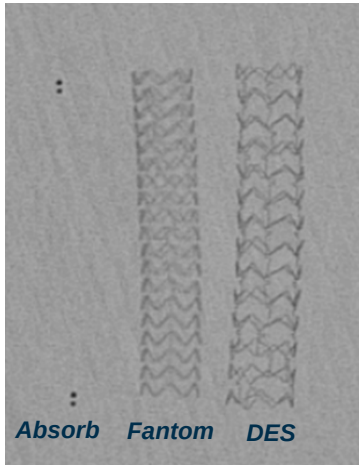
Rapid vessel healing

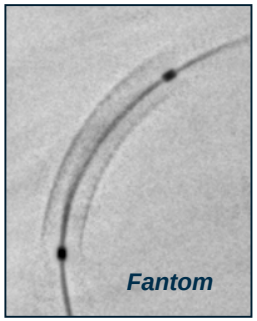
Vasomotion restoration

Fantom Ease of Use Features

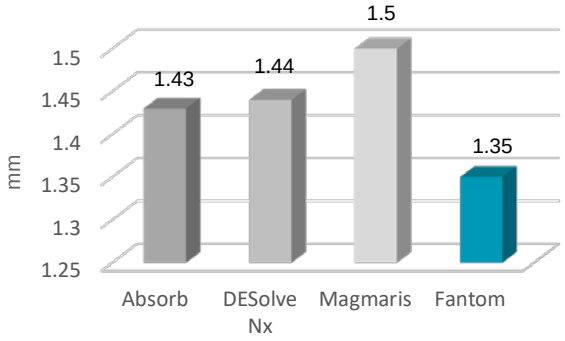
Makes the Implant Procedure Easier

Visibility

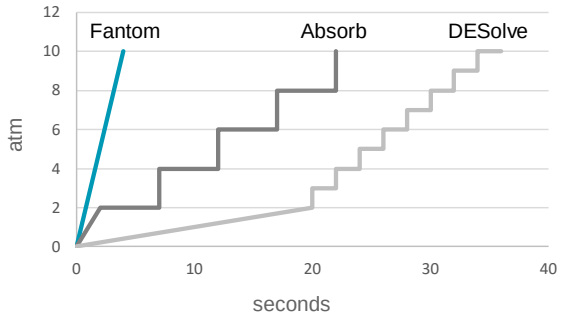




Lower Crossing Profile[2]

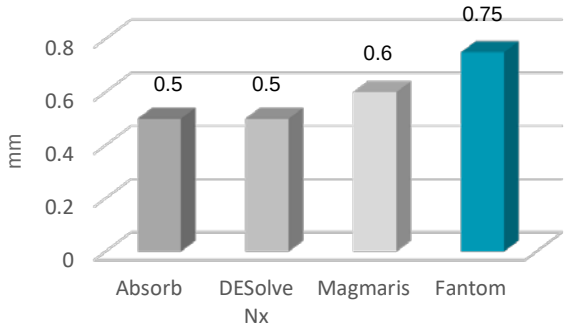


Single Step Balloon Inflation[1]

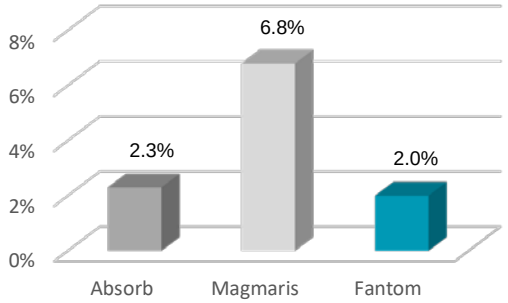


Higher Expansion Tolerance[2]

Limit of Expansion over Nominal, 3.0 mm Scaffolds



Low Recoil[3]

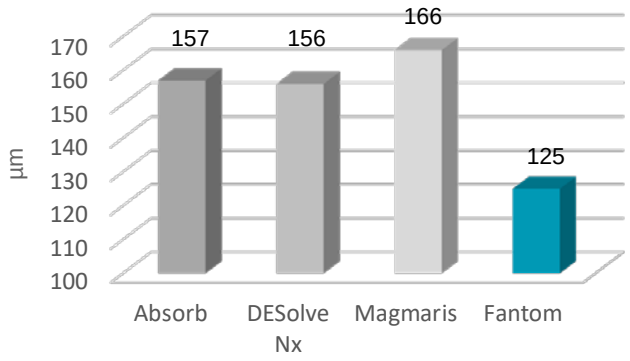


1. Product Instructions for Use. 2. Manufacturer reported data on file at Reva Medical. 3. Tests performed by and data on file at Reva Medical.

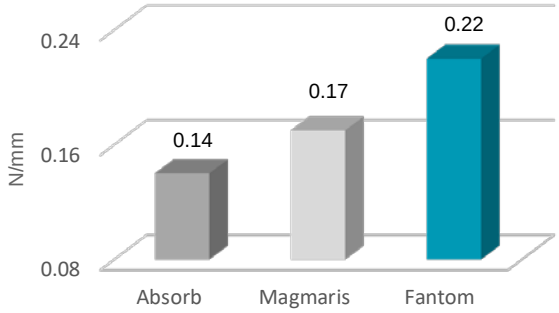
Fantom's Improved Healing

Thin Struts and High Radial Strength Contribute to Excellent Healing

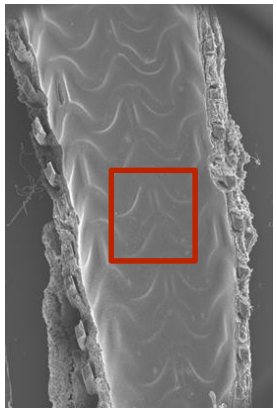
Reduced Strut Thickness[1]



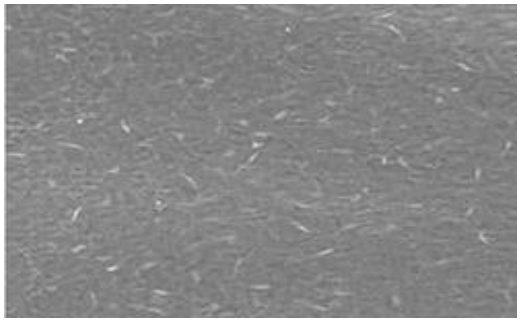
High Radial Strength[2]



Bench testing on 3.0 mm scaffolds in water at 37°C

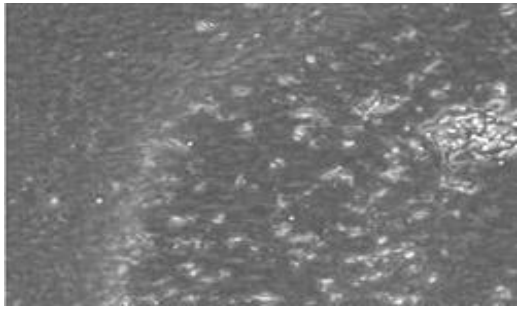


Fantom Scaffold



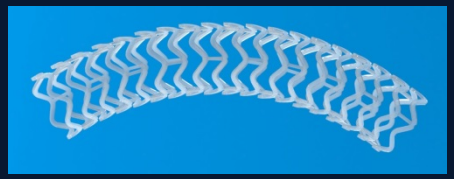
Fantom Healing at 3 Months
Mature, oriented cells; few platelets

PLLA Scaffold



PLLA Scaffold Healing at 3 Months
Mature & immature cells; persistent platelets

1) Values include coating. Absorb, DESolve, Magmaris source: Foin, N. Biomechanical Assessment of Bioresorbable Devices. CRT 2017. Fantom source: Holm, N. REVA Fantom II performance and healing patterns by OCT. REVA Symposium EuroPCR 2017. 2) Radial strength measured at 15% compression. Tests performed by and data on file at Reva Medical.



FANTOM II Trial

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

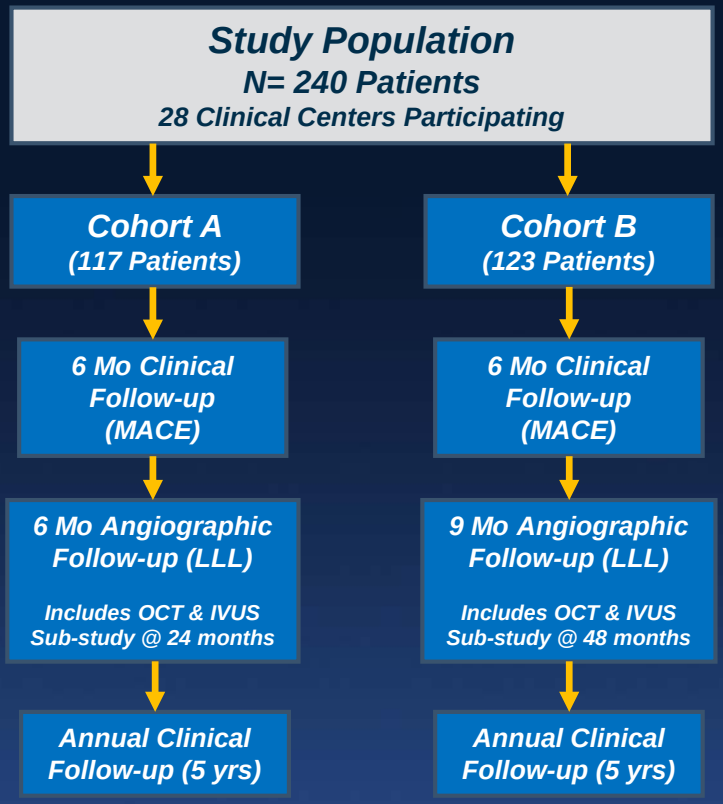
FANTOM II
Study Investigators

- **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. Brachmann
- **Netherlands**
  - Dr. Amoroso, Dr. Wykrzykowska, Dr. Daemen
- **Poland**
  - Dr. Dudek, Dr. Kochman, Dr. Koltowski, Dr. Lesiak, Dr. Wojdyla

FANTOM II

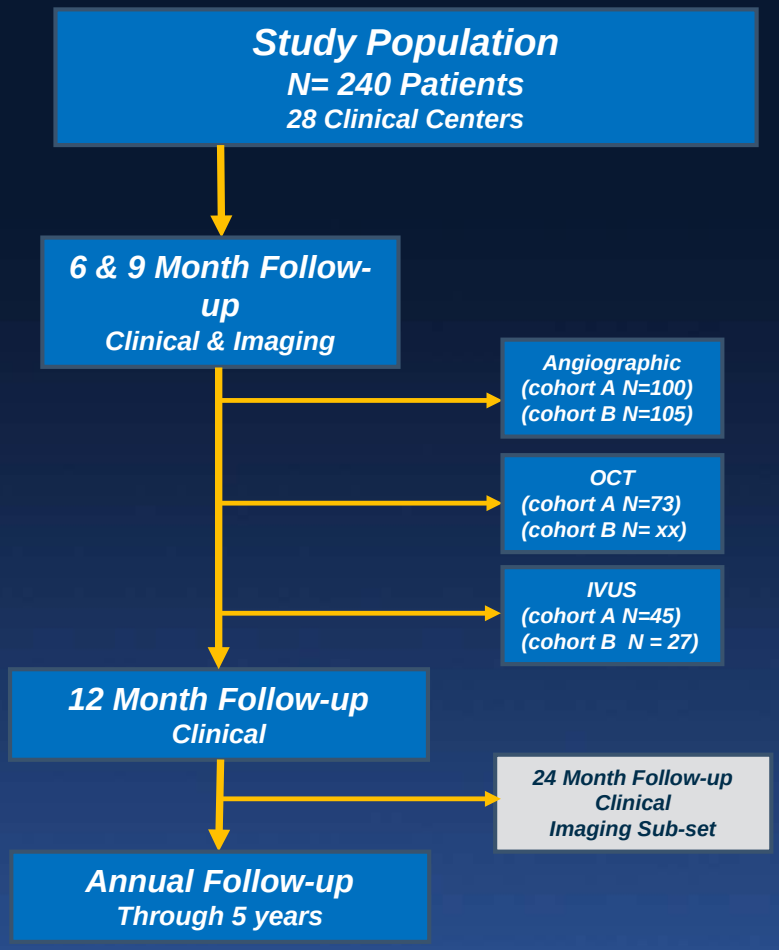
Study Design and Endpoints

- ***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 – Cohorts 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 – Cohorts A & B

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	6 Month (n = 240)	12 Months (n = 240)	24 Month Ongoing *(N = 125)*
MACE	**2.1% (5)**	**4.2% (10)**	**5.6% (7)**
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 (1)[2]
MI	1.3% (3)	1.3% (3)	2.4 (3)
Clinically Driven TLR	0.8% (2)	2.5% (6)	3.2 (4)

Preliminary
Interim Data set

** As adjudicated by an independent Clinical Events Committee*

(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

Definite or Probable Scaffold Thrombosis	
Acute (0 – 1 day)	0.0% (0)
Sub-acute (2 – 30 days)	0.4% (1)
Late (31 – 365 days)	0.0% (0)
Very Late (>365 days) - *Interim data set*	*1 event*

All 240 patients beyond 18 months - 125 patients beyond 24 months of follow-up

** As adjudicated by an independent Clinical Events Committee*

FANTOM II

Angiographic – QCA Results

Preliminary
Interim Data Set

In-Scaffold Analysis	Baseline (n=238)[1]	Cohort A – 6 Mo. (n=100)	Cohort A – 24 Mo. (Subset n=25)
RVD (mm)	2.71 ± 0.37	2.70 ± 0.36	2.64 ± 0.35
MLD (mm)	0.82 ± 0.31	2.23 ± 0.41	2.14 ± 0.55
Diameter Stenosis (%)	69.5 ± 11.0	15.3 ± 15.2	16.9 ± 20.3
Acute Gain (mm)	1.68 ± 0.41		
Acute Recoil (%)	4.0 ± 8.3[2]		
Mean LLL (mm)		0.25 ± 0.40	0.25 ± 0.56
In-Segment Analysis			
Mean LLL (mm)		0.17 ± 0.34	0.21 ± 0.52

(1) Baseline angiographic data was not available for two enrolled patients
(2) N = 156 patients available for recoil analysis

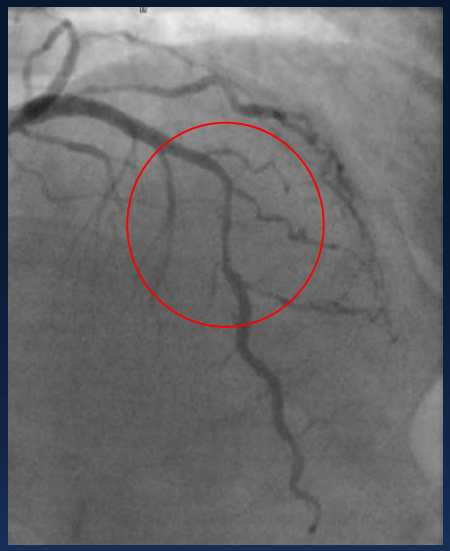
FANTOM II
Long Term Follow-up Case Sample

- Female, 63 years old
- No angina, 50% LVEF, no family history of CAD
- Hypertension, Hyperlipidemia, non-smoker
- Prior PCI/DES May 14, 2015 in prox CX (MI May 10, 2015)
- 80% stenosis of the mid-LAD
- Treated with a 3.0 x 18mm Fantom scaffold
- Enrollment and Follow-up History
  - Treated with a 3.0 x 18mm Fantom scaffold : July 28, 2015
  - 6M Follow-up with Imaging: March 1, 2016
  - 12M Follow-up (clinical only): July 28, 2016
  - 24M Follow-up with Imaging: August 28 2017

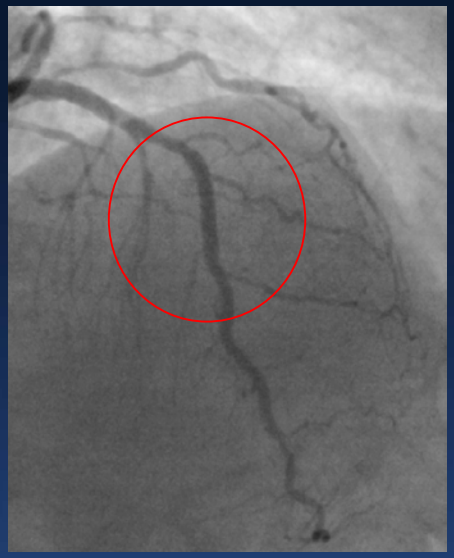
FANTOM II

Long Term Follow-up Case Sample

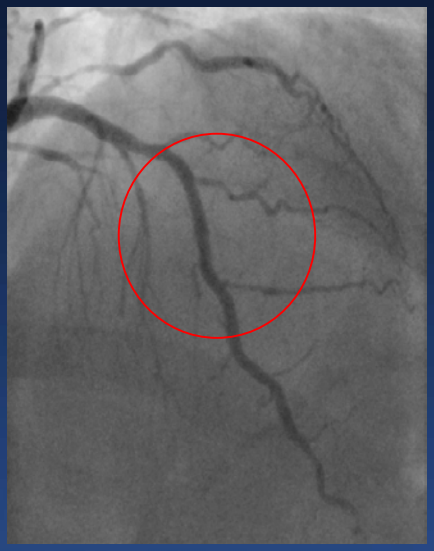
Index - Pretreatment



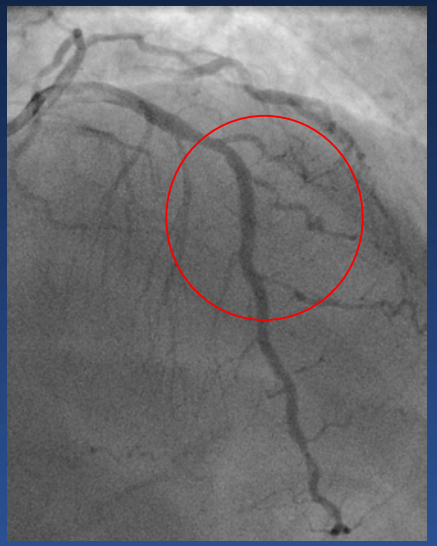
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



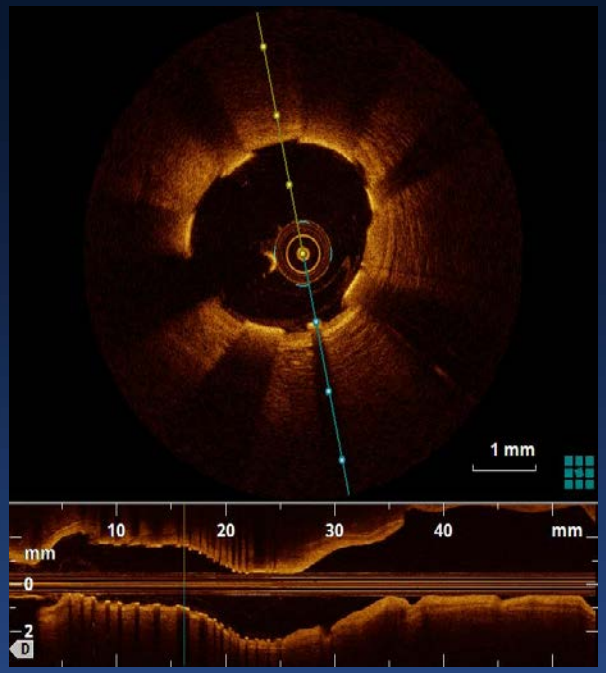
Procedure Details

- Pre-dilation performed
  - BSC Maverick 2.5 x 15mm balloon
- Fantom Scaffold implant
  - 3.0 x 18mm Fantom deployed at 14atm
- Post Dilation Performed
  - 3.25 x 6mm NC Sprinter to 16atm

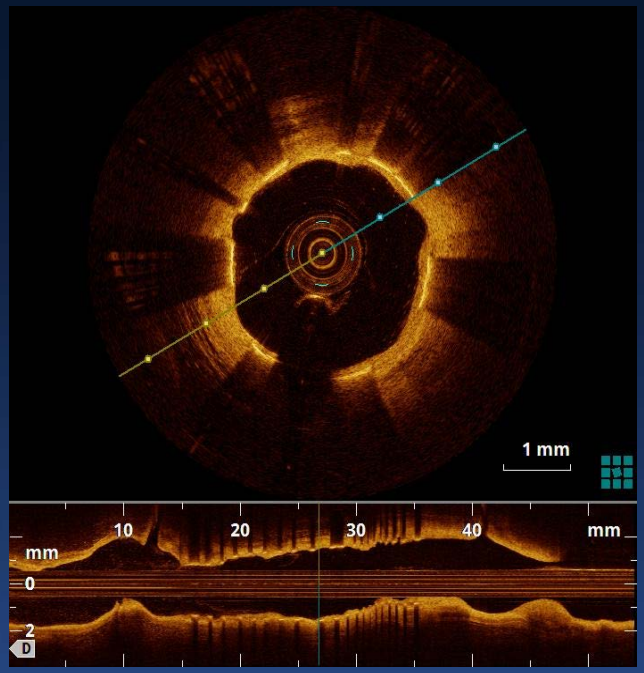
FANTOM II

Long Term Follow-up Case Sample

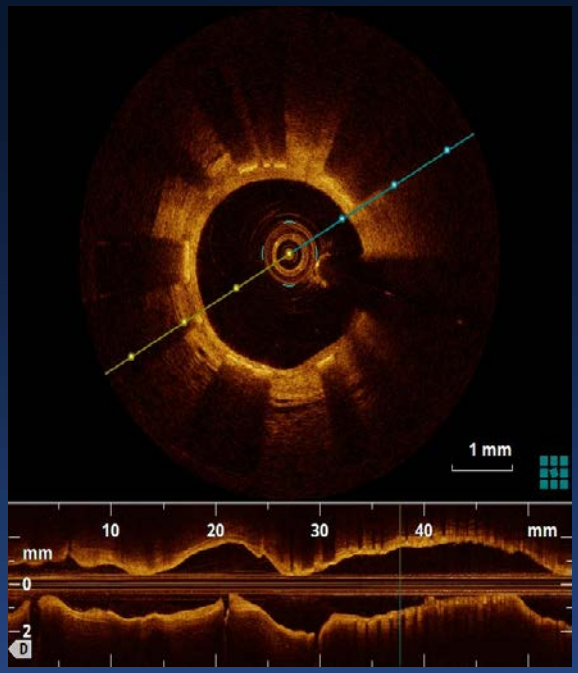
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



FANTOM Program
Clinical Summary

- **Fantom offers new and clinically important features**
  - **Ease-of-use**
    - **Radiopacity with complete scaffold visibility**
    - **Low crossing profile with high flexibility**
    - **Single-step inflation, no special handling requirements**
    - **Favorable expansion profile**
  - **Thin struts and radial strength to facilitate vessel healing**
- **Data demonstrates continued safety through 24 mo.**
  - **Low MACE Rate (5.6%)**
- **Imaging sub-study shows sustained results**
  - **No change in average late lumen loss from 6 to 24 months**
  - **No evidence of late or chronic scaffold recoil**

Fantom Global Clinical Program

Enrollment Complete – In Follow Up			
FANTOM I	First-in-human safety study (n=7)		Year 3
FANTOM II Cohorts A&B	Multi-center safety and performance study (n=240)		Year 2
Enrolling			
FANTOM II Cohort C	Long lesion and multiple vessel, multi-center study (n=50)		enrolling
FANTOM STEMI	Single center pilot study in STEMI (n=20)		enrolling
Planning			
FANTOM Registry	European post-market multi-center registry (n=125+)		planning
FANTOM III (US pivotal trial)	Multi-center RCT vs. metallic DES (n=1,800-2,200)		planning
FANTOM Japan (pivotal trial)	Multi-center RCT vs. metallic DES (n=350-400)		planning

Fantom Product Evolution

Next Generation: Fantom Encore

- Thinner struts without compromising radial strength
  - **95 micron** on 2.5 mm diameter
- No changes to Tyrocore™ polymer composition or scaffold design
- Improved polymer processing and manufacturing technique
- European approval and launch anticipated in 2018

Diameter	Fantom	Fantom Encore
2.5 mm	125 µm	**95 µm**
3.0 mm	125 µm	to be announced
3.5 mm	125 µm	to be announced

Thank you!