FANTOM II Trial

Safety & Performance of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold

First Report 5 Year Clinical Outcomes

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Disclosure Statement of Financial Interest

I, Matthias Lutz DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Faculty disclosure information can be found on the app

Disclosure Statement of Financial Interest

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

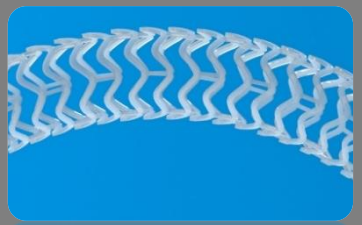
Affiliation/Financial Relationship	Company
Grant/Research Support	REVA Medical
Consulting Fees/Honoraria	REVA Medical

Faculty disclosure information can be found on the app

Second Generation Fantom Bioresorbable Scaffold

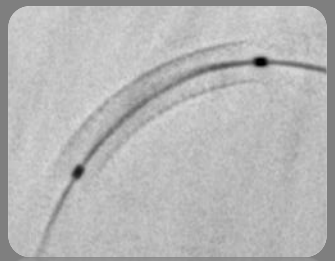
Scaffold Design

- **Thin struts: 125 µm**
- **Enhanced radial strength**
- Minimal recoil
- **Single-step balloon inflation**
- **0.75 expansion over nominal (3.0 mm)**



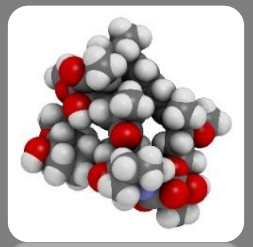
Tyrocore™

- **Radiopaque**
- Provides strength during healing
- **Vessel uncaged in one year**
- Complete resorption in ~4 years



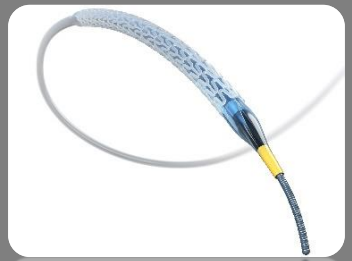
Sirolimus

- First anti-proliferative agent used in drug eluting stents
- Highly lipophilic with broad therapeutic window
- Demonstrated across multiple clinical studies and drug eluting stents



Delivery System

- Semi-compliant nylon balloon
- High 18 atm rated burst pressure
- Rapid exchange
- **1.35 mm crossing profile**

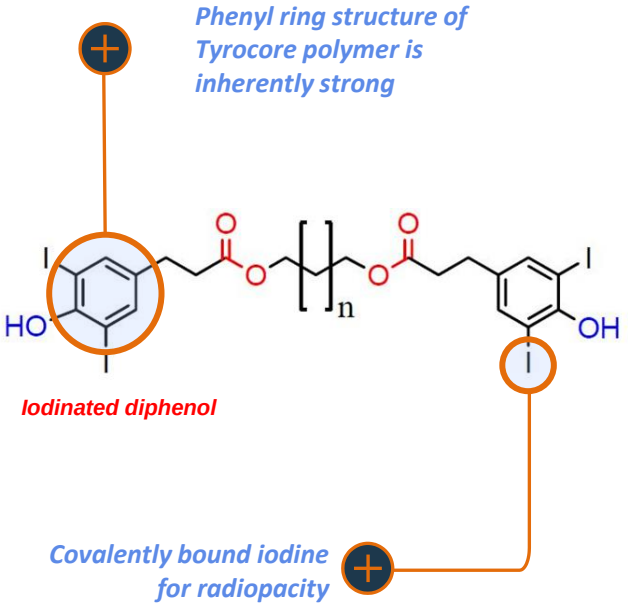


Fantom's Disruptive Technology: Tyrocore™

The World's Only Radiopaque, Bioresorbable Polymer Approved for Use[1] in Medical Devices

Tyrocore Properties

- ***Proprietary bioresorbable polymer***
- ***Strong for excellent mechanical properties***
- ***X-ray visible, ideal for vascular procedures***
- ***Naturally biocompatible: derived from the tyrosine amino acid***
- ***Polymer properties are tailorable to meet a clinical application by modifying:***
  - ***Strength***
  - ***Flexibility***
  - ***Degradation time***
  - ***Drug delivery profile***



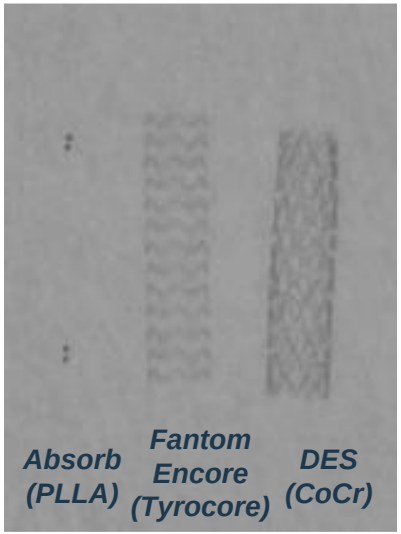
[1] CE Mark Approved in Europe

Tyrocore®
Twice as Strong and 10 Times More Ductile than PLLA

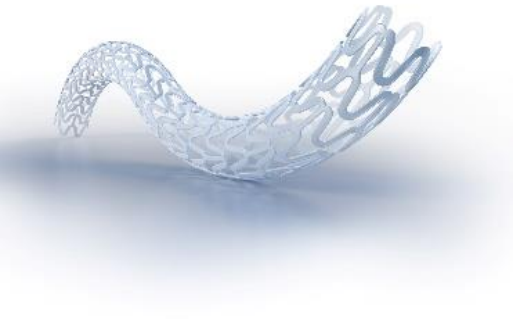
Properties of Tyrocore versus PLLA

Attribute	Tyrocore	PLLA[1]	Benefit
Ultimate Tensile Strength	100-110 MPa	50-70 MPa	Thinner struts Radial strength
Elongation at Break (Ductility)	120-200%	2-10%	Single-step inflation Larger expansion range
X-Ray Visible	Yes	No	Accurate placement

1) Poly(Lactic acid): Synthesis, Structure, Properties, and Applications. Edited by R.Auras, L-T.Lim, S.E.M.Selke, H.Tsuji. 2010 John Wiley & Sons, Inc.; p.141



A single scaffold contains < 1% of the iodine found in 1 mL of contrast media



FANTOM II Trial

Safety & Performance Study of the Fantom Bioresorbable Scaffold

Preliminary 5 Year Results

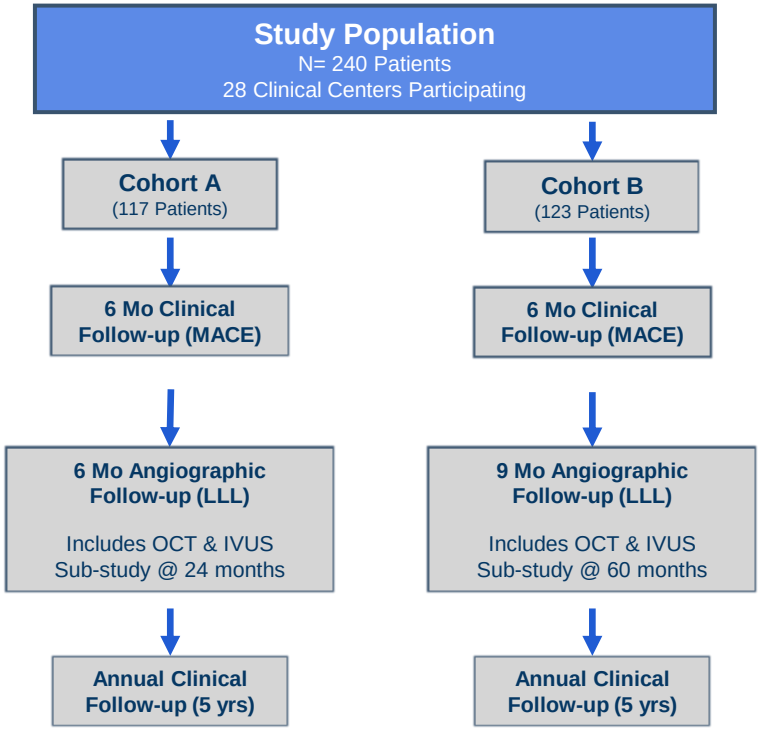
FANTOM II Study Investigators

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

FANTOM II
Study Design and Endpoints

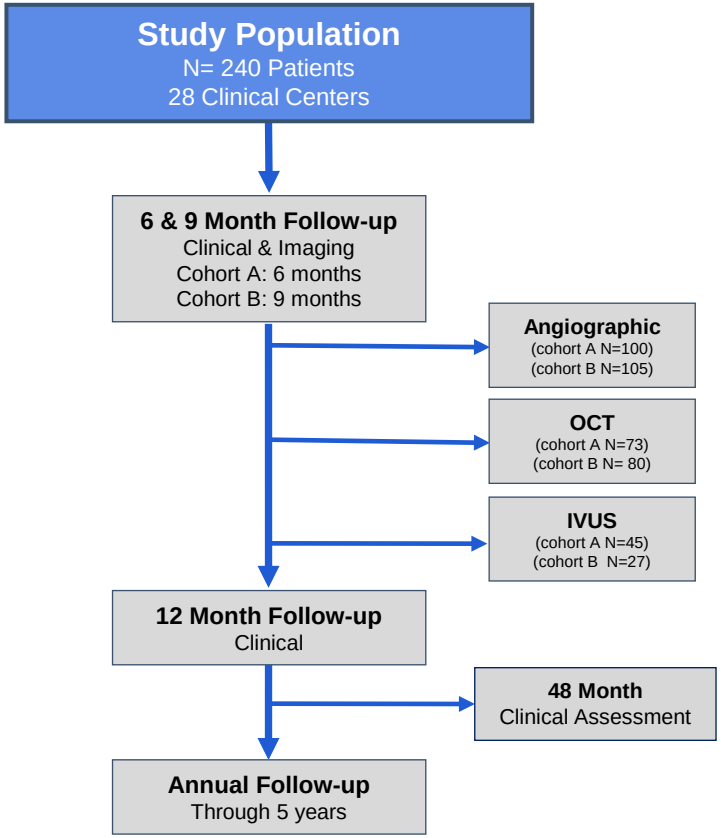
Study Design

- 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: 60 months (25 Patients)



FANTOM II – Cohorts A & B

Patient Flow 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

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 (Cohorts A&B)

Preliminary 60-Month Outcomes

Components of 6-Month Primary Endpoint (modified ITT): non-Hierarchical	6 Month (n = 240)	12 Months (n = 240)	24 Months (n=240)	36 Months (n=240)[5]	48 Months (n=240)[5]
MACE	2.1% (5)	4.2% (10)	5.0% (12)	5.0% (12)	5.4% (13)
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 % (2)	0.8 % (2)	1.3 % (3)[1,2,3]
MI (All MI Events)	1.3% (3)	1.3% (3)	1.7% (4)[4]	1.7% (4)[4]	1.7% (4)[4]
Clinically Driven TLR	0.8% (2)	2.5% (6)	2.9% (7)	2.9% (7)	2.9% (7)
TLF	2.1% (5)	4.2% (10)	4.6% (11)	4.6% (11)	5.0% (12)

Non- Adjudicated 60-Month Outcomes

60 Months (n=240)[5]
5.8% (14)
1.7 % (4)[1,2,3]
1.7% (4)[4]
2.9% (7)
5.4% (13)

(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.
(3) One death occurred between 3 and 4 years. Patient was treated for an occlusion in a non-target vessel and had an IABP implanted, but subsequently died due to cardiogenic shock.
(4) Three target vessel related MIs and one non-target vessel related MI.
(5) Event rate percentages are based upon the full 240 patient cohort in the denominator.

FANTOM II (Cohorts A&B)
Preliminary 48-Month Outcomes

No new events between 36 and 48 months

Definite or Probable Scaffold Thrombosis (N = 240 Patients)	
Acute (0 – 1 day)	0.0% (0)
Sub-acute (2 – 30 days)	0.4% (1)[1,4]
Late (31 – 365 days)	0.0% (0)[4]
Very Late (>365 days)	0.8 (2)[2,3,4]

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

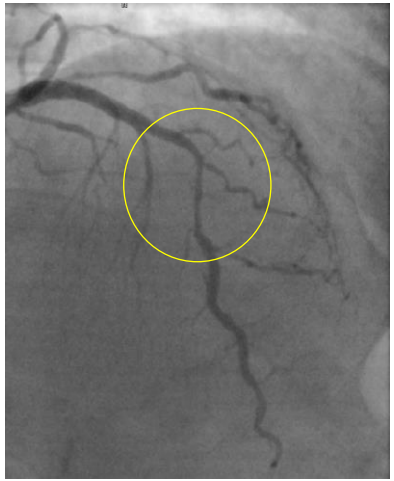
(2) Clear Protocol Violation: Patient Selection outside of protocol limits: Distal segment of scaffold was in a 2.0mm vessel and the scaffold had significant malaposition that was not corrected at the index procedure

(3) One new event was reported between 24 and 36 months. The patient was treated for a Non-Clinically Driven TLR. The site reported a “Thrombus Flake” at the edge of the scaffold.

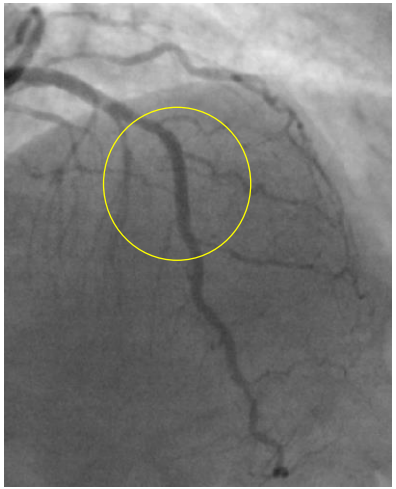
(4) Event rate percentages are based upon the full 240 patient cohort in the denominator

FANTOM II
Long Term Follow-up Case Sample

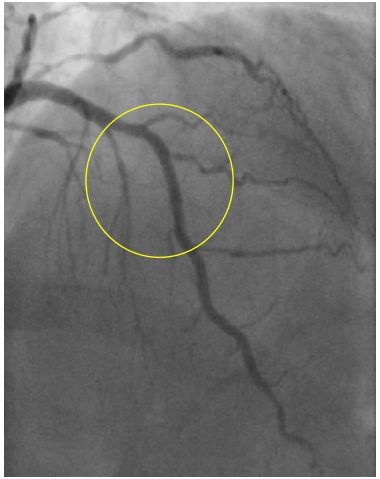
Index - Pretreatment



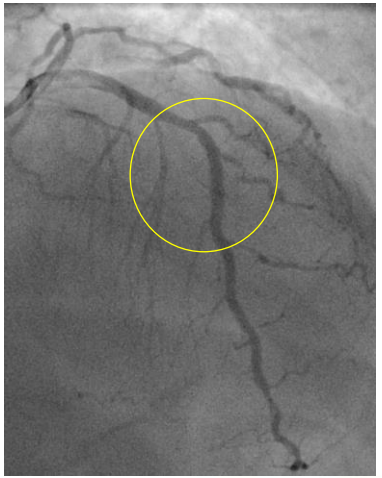
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.

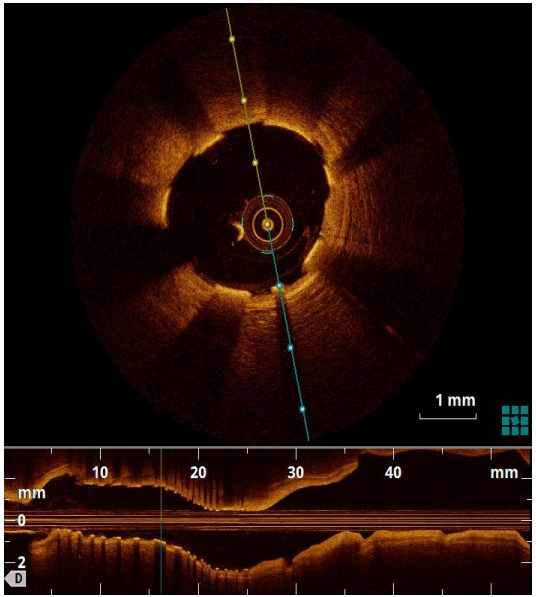


Procedure Details

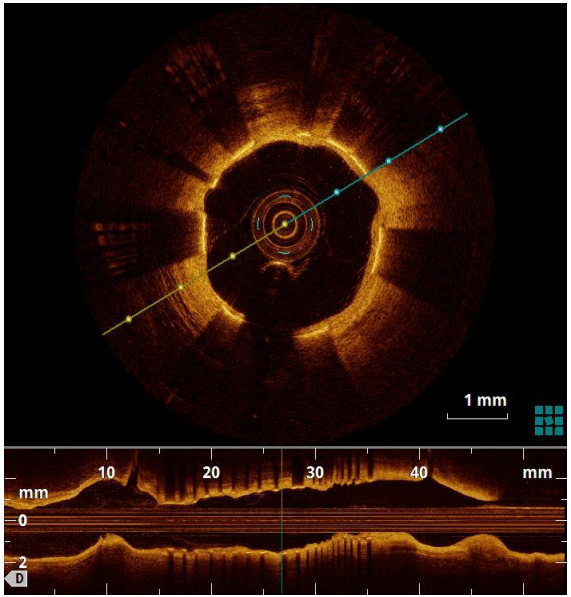
- **Pre-dilation performed**
  - BSC Maverick 2.5 x 15mm balloon
- **Fantom Scaffold implant**
  - 3.0 x 18mm Fantom deployed at 14atm
- **Post Dilation Performed**
  - 3.25 x 6mm NC Sprinter to 16atm

FANTOM II
Long Term Follow-up Case Sample

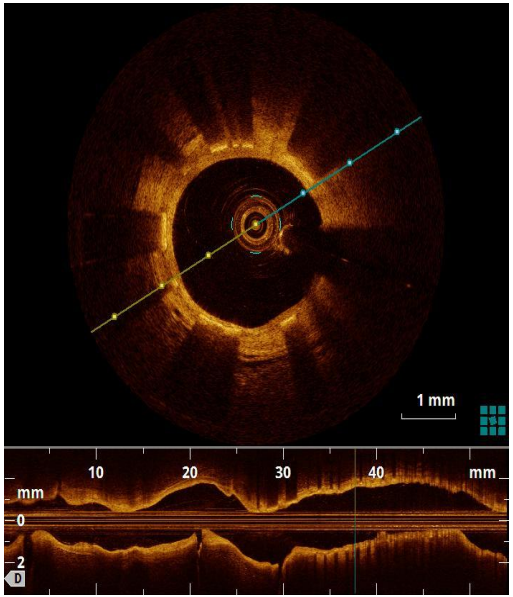
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



Fantom Global Clinical Trial Program

Enrollment Complete – In Follow Up

FANTOM I	First-in-human safety study (n=7)	Year 5 – Complete
FANTOM II Cohorts A&B	Multi-center safety and performance study (n=240)	Year 5 – Complete
FANTOM II Cohorts C	Long lesion and multiple vessel study (n=32)	Year 2+
FANTOM STEMI	Single center pilot study in STEMI (n=20)	Year 2+

Enrolling

FANTOM Post Market Trial	European post-market trial (n=1,500)	Actively Enrolling

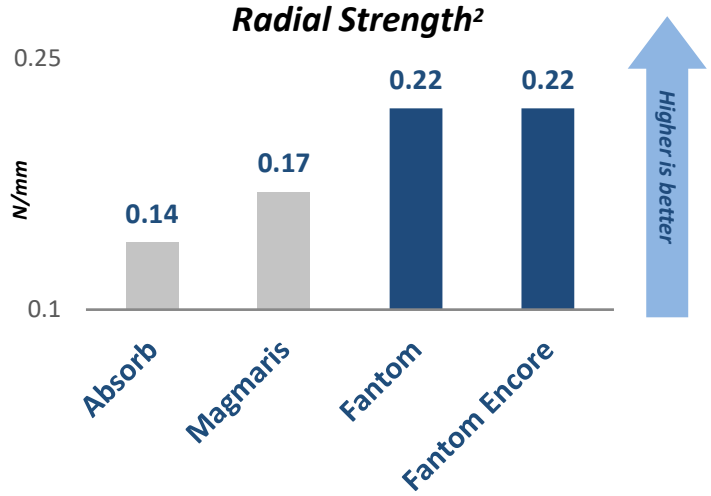
Fantom Encore – CE Mark Approved

3rd Generation Bioresorbable Scaffold

Thinner Struts without Compromising Radial Strength

Strut Thickness (µm)				
	Absorb[1]	**Magmaris[1]**	Fantom	**Fantom Encore**
2.5 mm	157 µm	n/a	125 µm	**95 µm**
3.0 mm	157 µm	166 µm	125 µm	**105 µm**
3.5 mm	157 µm	166 µm	125 µm	**115 µm**

- **No changes to Tyrocore polymer composition or scaffold design**
- **Improved polymer processing and manufacturing techniques**



Commercially available in Europe

1) Includes coating. Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017.
2) Bench testing on 3.0 mm scaffolds in water at 37°C. Radial strength measured at 15% compression. Tests performed by and data on file at REVA Medical.

FANTOM Program Clinical Summary

- Only BRS with unique Tyrocore polymer
  - Thin struts, Radiopaque, Enhanced radial force, Fully biocompatible
- Sustained safety and efficacy through 60-months:
  - **Low TLF Rate (5.4)%**
  - **Low MACE Rate (5.8%)**
  - **Equal or better safety than best in class DES**
- Fantom Encore, a 3rd generation BRS
  - The thinnest struts of any clinically available BRS[1]
    - No compromise to radial strength or radiopacity
    - Unique Tyrocore polymer