2019 euro PCR

FANTOM II Trial
Safety & Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold
First Report: 3 Year Clinical Outcomes

FANTOM II – 3 Year Outcomes

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☑ I have the following potential conflicts of interest to declare: None

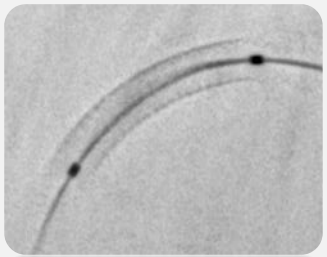
Second Generation Fantom Bioresorbable Scaffold

Scaffold Design

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

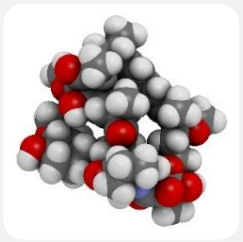
Tyrocore™

- **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



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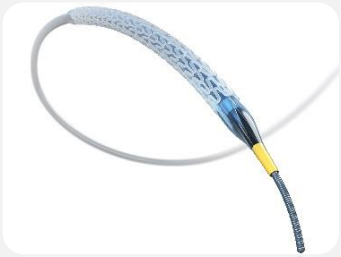
Delivery System

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



FANTOM II Trial

Safety & Performance Study of the
Fantom Bioresorbable Scaffold

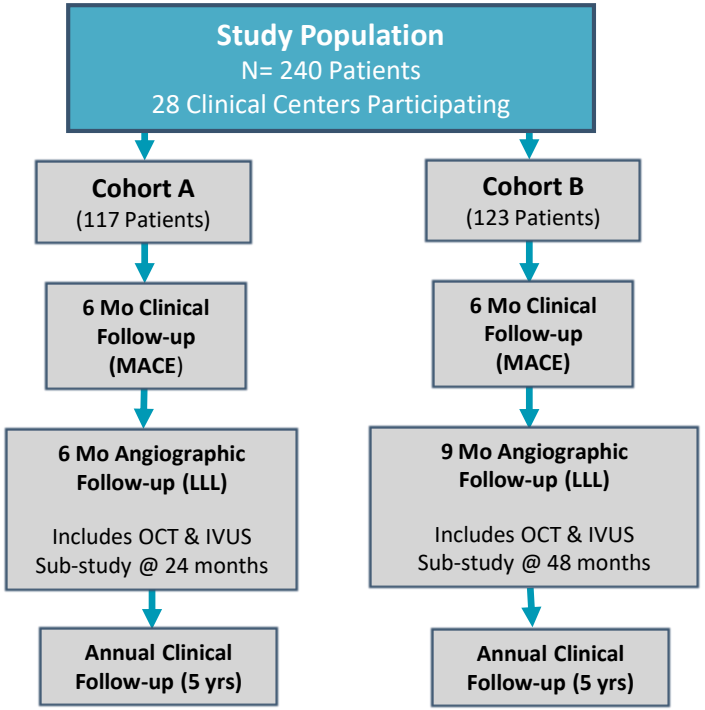
FANTOM II Study Investigators

- 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
  - 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

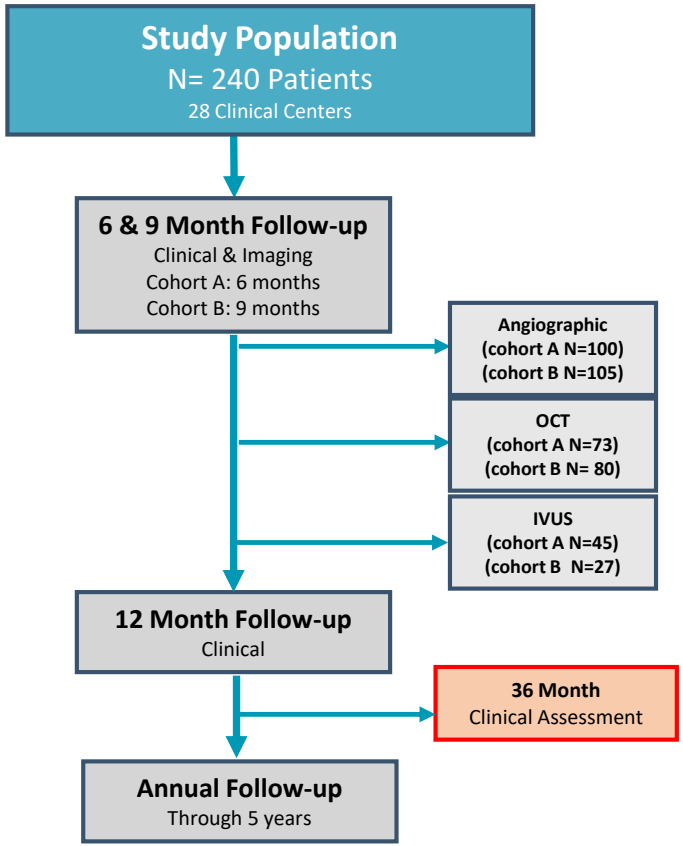
FANTOM II
Study Design and Endpoints

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: 48 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

Procedural 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 (Cohorts A&B)
Adjudicated 36-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)[4]
MACE	**2.1% (5)**	**4.2% (10)**	**5.0% (12)**	**5.0% (12)**
Cardiac Death	0.4% (1)[1]	0.8% (2)[1,2]	0.8 % (2)	0.8 % (2)
MI *(All MI Events)*	1.3% (3)	1.3% (3)	1.7% (4)[3]	1.7% (4)[3]
Clinically Driven TLR	0.8% (2)	2.5% (6)	2.9% (7)	2.9% (7)
TLF	**2.1% (5)**	**4.2% (10)**	**4.6% (11)**	**4.6% (11)**

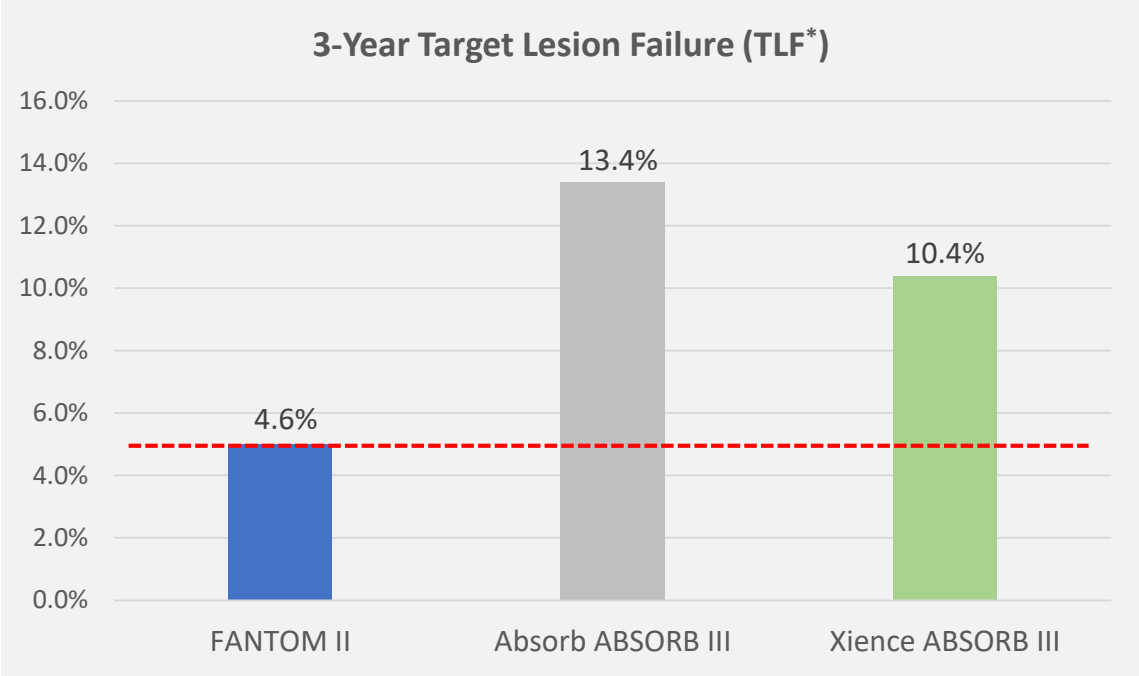
(1) One patient died between 0-6 months. Exact cause of death not determined. Patient died at home 4 weeks after subsequent TAVI procedure.

(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) Three target vessel related MIs and one non-target vessel related MI.

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

FANTOM II (Cohorts A&B)
Adjudicated 36-Month Outcomes



*TLF = cardiac death + target vessel MI + target lesion revascularization. The FANTOM II primary endpoint was Major Adverse Cardiac Events (MACE) = cardiac death + all MI + target lesion revascularization.

FANTOM II (Cohorts A&B)

Adjudicated 36-Month Outcomes

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

(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

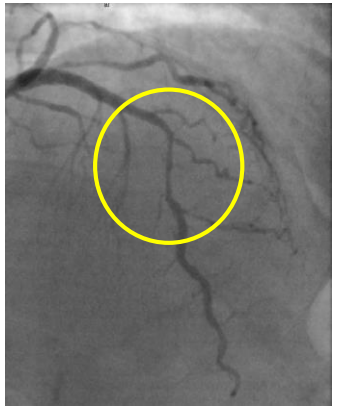
(2) Clear Protocol Violation: Patient Selection outside of protocol limits: Distal segment of scaffold was in a 2.0mm vessel and the scaffold had significant malaposition that was not corrected at the index procedure

(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.

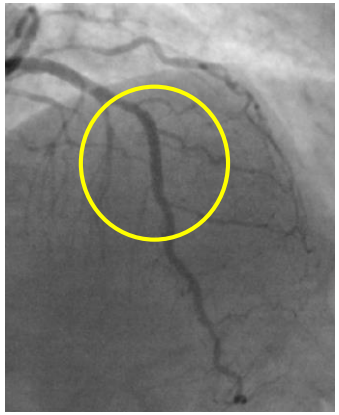
FANTOM II

Long Term Follow-up Case Sample

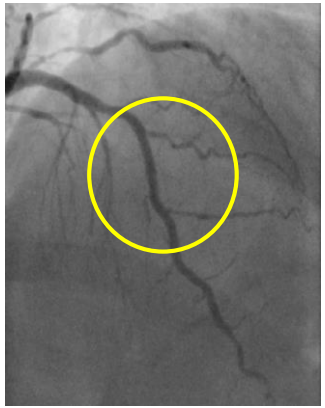
Index - Pretreatment



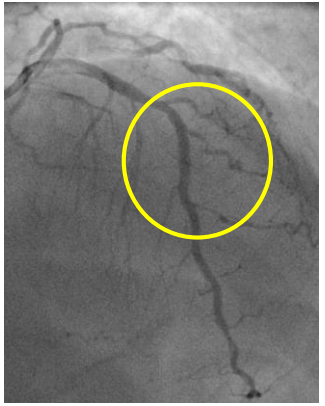
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



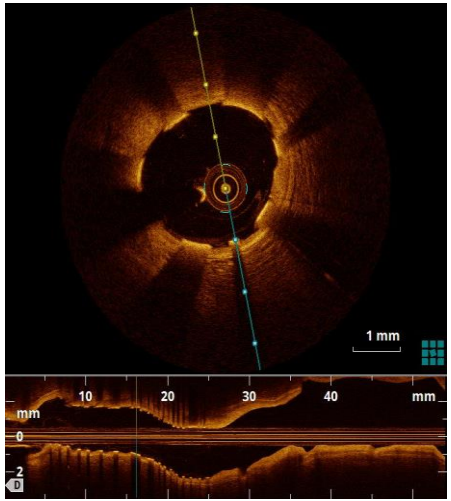
Procedure Details

- 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

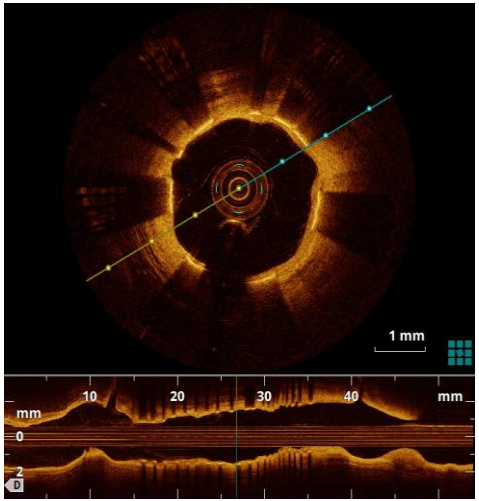
FANTOM II

Long Term Follow-up Case Sample

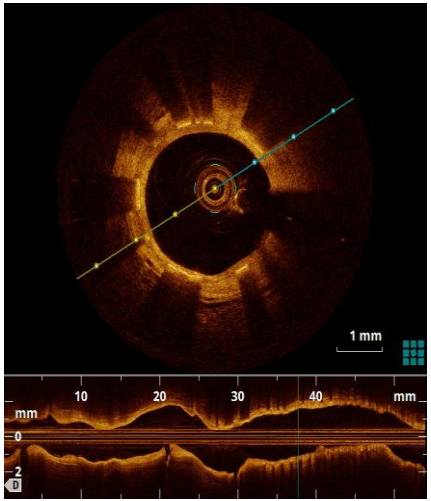
Index – Post Implant



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 4
FANTOM II Cohorts A&B	Multi-center safety and performance study (n=240)	Year 3
FANTOM II Cohorts C	Long lesion and multiple vessel study (n=30-50)	Month 6

Enrolling

FANTOM STEMI	Single center pilot study in STEMI (n=20)	Enrolling
FANTOM Post Market Trial	European post-market trial (n=1,500)	Enrolling

Planning

FANTOM III (RCT)	Multi-center RCT vs. metallic DES (n=1,800-2,200)	planning
FANTOM Asia	Multi-center RCT vs. metallic DES (n=350-400)	planning

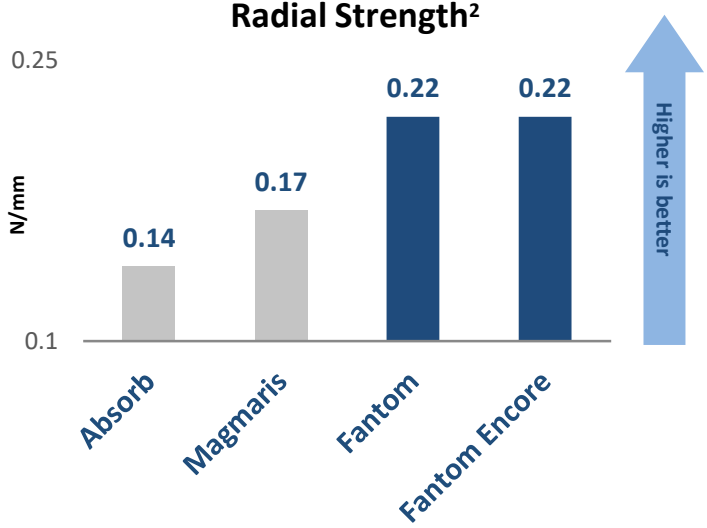
Fantom Encore – CE Mark Approved
3rd Generation Bioresorbable Scaffold

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

Radial Strength[2]



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

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.

Commericaly available in Europe

FANTOM Program Clinical Summary

- **Only BRS with unique Tyrocore polymer**
  - Thin struts, Radiopaque, Enhanced radial force, Fully biocompatible
- **Sustained safety and efficacy through 36-months:**
  - Low MACE Rate (5.0%)
  - Low TLF Rate 4.6%
  - No increase in adverse events between 24 & 36 months
- **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