On-going Activities with a Radiopaque Tyrosine-Carbonate-Based Polymeric BRS: Fantom

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Disclosure Statement of Financial Interest

Speaker or

Advisory Honoraria from

Biotronik, Abbott, REVA.

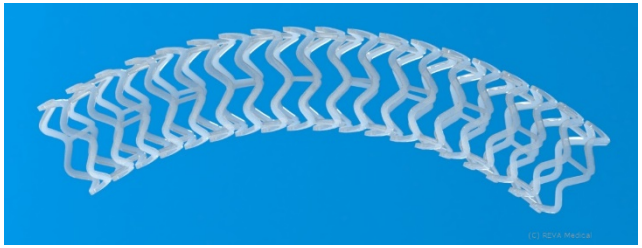
Lessons Learned from 1st Generation BRS

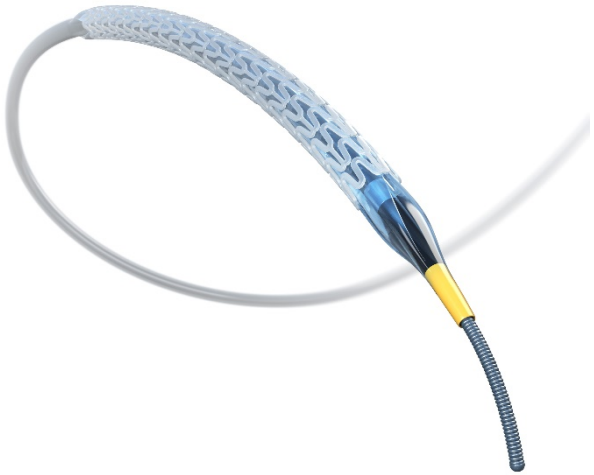
- **Importance of implant technique**
  - Selecting the right patients
  - Accurate sizing
  - Complete scaffold apposition
- **Opportunities for design improvement**
  - Thinner struts
  - Improved deliverability
  - Increased strength and expansion capability

2nd Generation Fantom BRS
Improves Over 1st Generation Devices

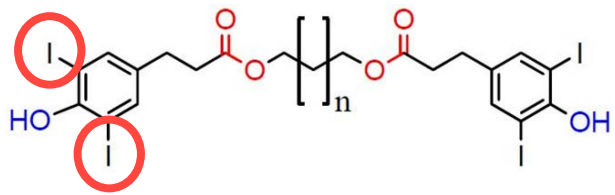
REVA's Advanced Tyrocore Polymer Makes Fantom Unique

- ✓ **Thin strut profile (125 µm)** for deliverability and vessel healing
- ✓ **X-ray visible** for treatment accuracy
- ✓ Key **ease-of-use** features like single-step inflation and higher expansion range
- ✓ **Biocompatible** for safety
- ✓ **Stable** for room temperature shipping and storage

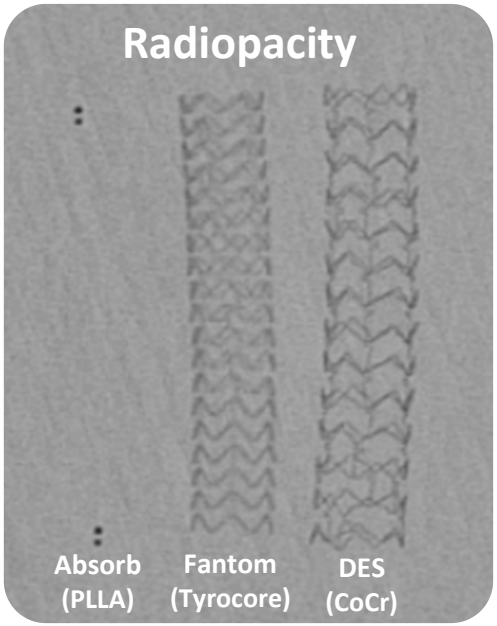




Fantom's Novel Tyrocore Polymer
Designed Specifically for BRS



Iodinated desamino-tyrosine



Tyrocore Characteristics:

- **Biocompatible** - derived from tyrosine amino acid
- **Strong** - phenyl ring structure
- **Radiopaque** - bound iodine
- **Degradation**
  - Vessel uncaged in 1 year
  - Complete resorption in ~ 4 years

Fantom & Fantom Encore
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 (CE-mark Study)	**Multi-center safety and performance study (n=240)**	**Year 2-3**

Enrolling

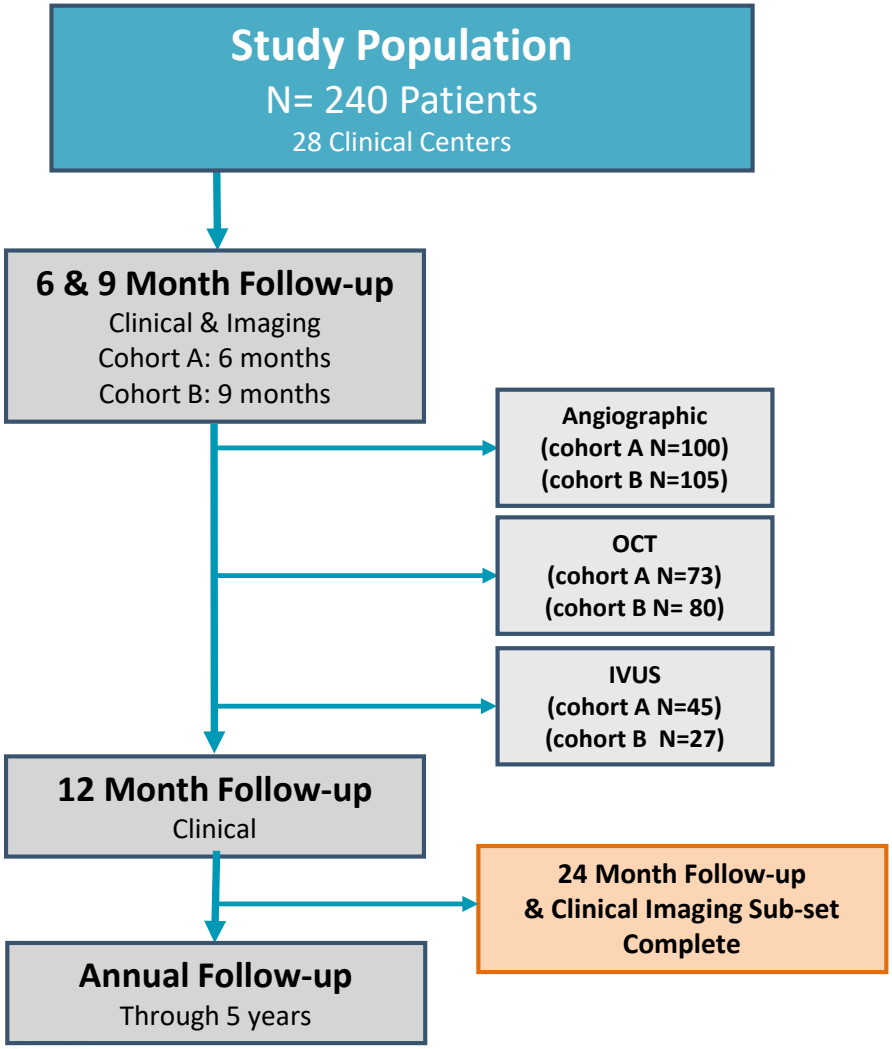
FANTOM II Cohort C	**Long lesion and multiple vessel study (n=30-50)**	**enrolling**
FANTOM STEMI	**Single center pilot study in STEMI (n=10-20)**	**enrolling**
FANTOM Post Market Trial	**Global Post-market Trial (n=1,500)**	**enrolling**

Planning

FANTOM III (Pivotal trial for US approval)	**Multi-center RCT vs. metallic DES (n=1,800-2,200)**	**planning**
FANTOM Asia	**Multi-center RCT vs. metallic DES (n=350-400)**	**planning**

Key Study Overview

FANTOM II Primary Safety Study (CE-approval Study)



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 Clinical Results (CEC-adjudicated)

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

- 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.

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

FANTOM II – Cohorts A & B

24-Month Scaffold Thrombosis (CEC-adjudicated)

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)**	0.4% (1)[2]

- As adjudicated by an independent Clinical Events Committee

** Maximum day=761 days

(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

(2) Distal segment of scaffold was in a 2.0mm vessel and the scaffold had significant malaposition that was not corrected (Below the protocol limit of 2.4 mm)

FANTOM II Angiographic Results (Core lab analysis)

Sustained Performance through 24 Months

In-Scaffold Analysis	Baseline (n=238)[1]	Cohort A – 6 Mo. (n=100)	Cohort A – 24 Mo.[3] (Subset n=36)
RVD (mm)	2.71 ± 0.37	2.70 ± 0.36	2.67 ± 0.33
MLD (mm)	0.82 ± 0.31	2.23 ± 0.41	2.18 ± 0.48
Diameter Stenosis (%)	69.5 ± 11.0	15.3 ± 15.2	15.1 ± 17.9
Acute Gain (mm)	1.68 ± 0.41		
Acute Recoil (%)	4.0 ± 8.3[2]		
Mean LLL (mm)		0.25 ± 0.40	0.23 ± 0.49
In-Segment Analysis			
Mean LLL (mm)		0.17 ± 0.34	0.21 ± 0.49

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

(2) N = 156 patients available for recoil analysis

(3) Average follow up days=744

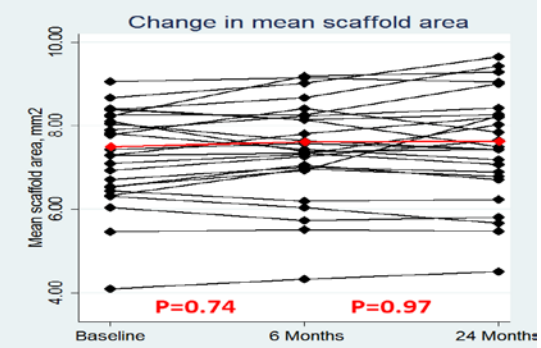
FANTOM II – OCT Substudy Results

Evidence of Healing and Benign Scaffold Degradation through 24 Months (n=25) – OCT Core lab

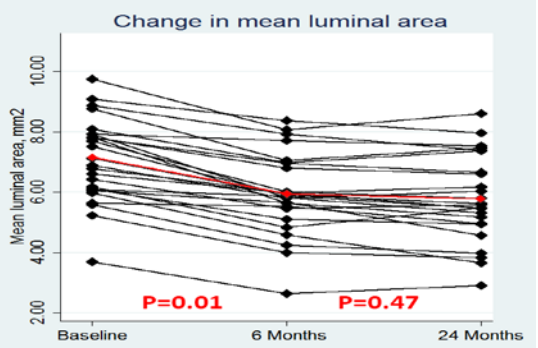
- **Excellent Strength**
  - No late recoil
  - Stable lumen diameter between 6 and 24 months

- **Complete coverage**
  - Early malaposition resolution
  - Complete strut coverage at 24 months

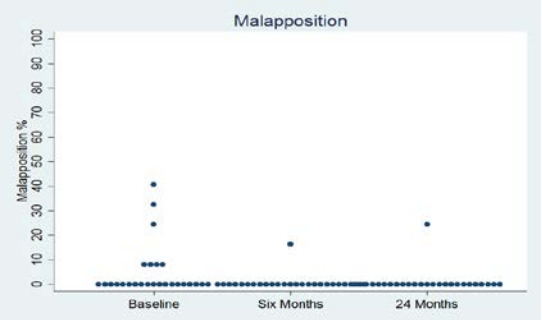
Mean Scaffold Area



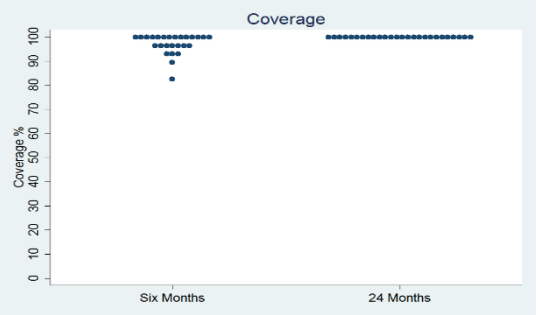
Mean Lumen Area



Scaffold Strut Apposition



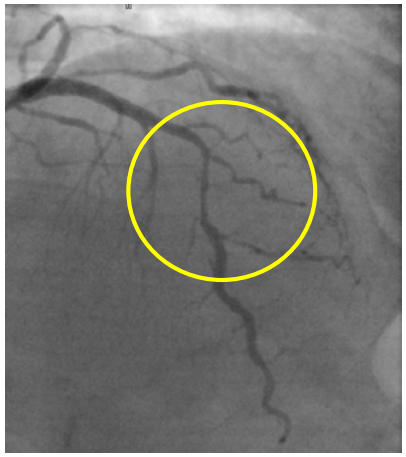
Scaffold Strut Coverage



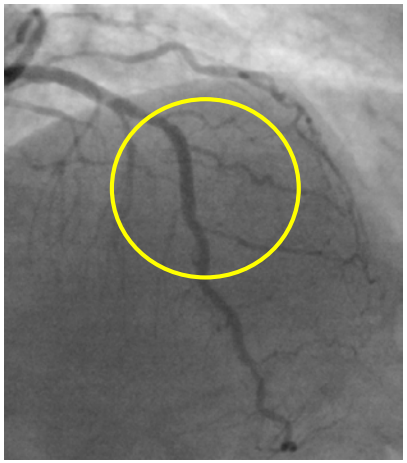
FANTOM II

Long Term Follow-up Case Sample

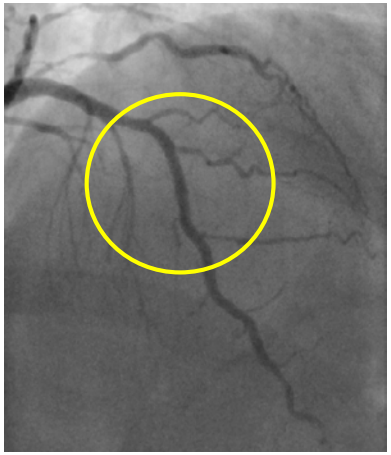
Index - Pretreatment



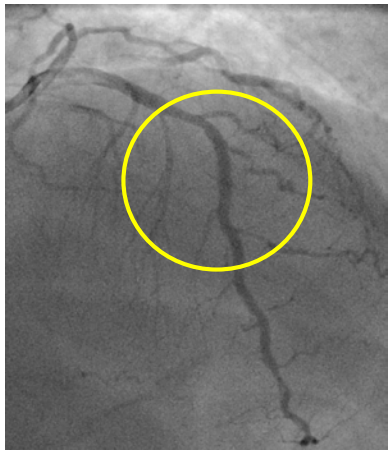
Index – Post Implant



Follow-up 6 Mo.



Follow-up 24 Mo.



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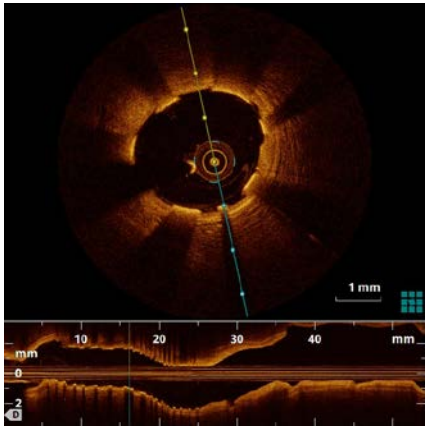
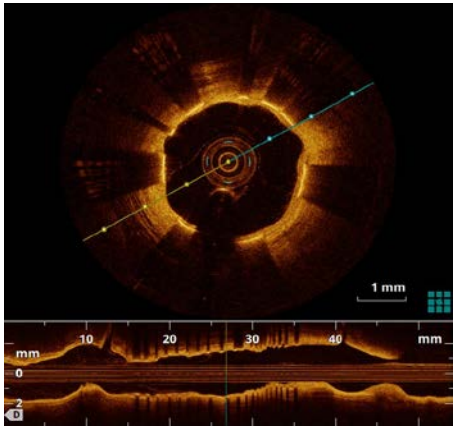
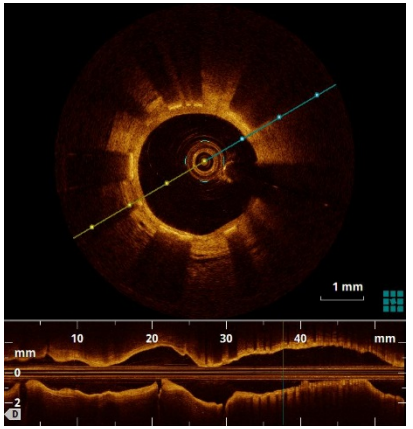


Follow-up 6 Mo.



Follow-up 24 Mo.



Fantom & Fantom Encore
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Key Study Overview
Global Fantom Post Market Trial

Currently Enrolling in Europe

- Global Prospective Study
- Enrolling up to 1,500 patients in appr.100 clinical centers
- Primary endpoint: Target Lesion Failure at 12 months
- Clinical follow-up: 30 days and annual from 1-5 years

  (CEC adjudication of clinical events)
- Independent DSMB to monitor safety and adverse events

Global Fantom Post Market Trial

Currently Enrolling

Focused on Clinical Outcome

R = Right Patient Selection

- Is the patient a good candidate for a scaffold?

E = Excellent Vessel Preparation

- Can a stent like result be achieved in the preparation process?

V = Vessel Sizing

- Is the vessel in the target treatment range ?

A = Apposition

Key Protocol Requirement

Lesion Selection:

- Visually estimated RVD ≥ 2.5 to ≤ 3.75 mm
- No vessel segment < 2.4 mm or > 3.75 mm

Lesion Preparation:

- Mandatory pre-dilatation
- NC balloon sized 1:1 to distal RVD and uniformly expanded to its intended diameter

Post Dilatation:

- Mandatory post-dilatation
- NC balloon sized 0 – max. 0.50 mm larger than distal RVD inflated to ≥ 16 atm
- Goals
  - >90 % Scaffold expansion after post-dilatation
  - Full scaffold apposition to arterial wall

Fantom Encore – CE Mark Approved

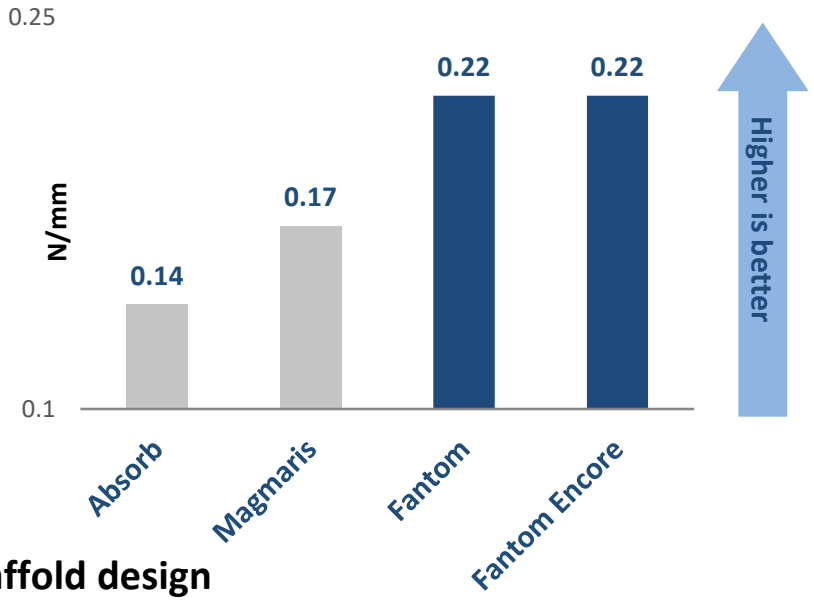
3rd Generation Bioresorbable Scaffold

Thinner Struts (again) 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.

Conclusions

- **Fantom, a 2nd generation BRS**
  - Demonstrated device safety through 24 months
    - 5.0% MACE @ 24 months; 0.4% VLST
- **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
- **Fantom clinical program expanding**
  - Global Fantom Post Market Trial - enrolling
    - 1500 patients across 100 to 150 clinical centers
  - Indication expansion studies in long lesions and STEMI

1) 95 µm strut thickness in the 2.5 mm diameter size