FANTOM II trial: Clinical results from the Fantom® Sirolimus-Eluting BRS

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Potential conflicts of interest

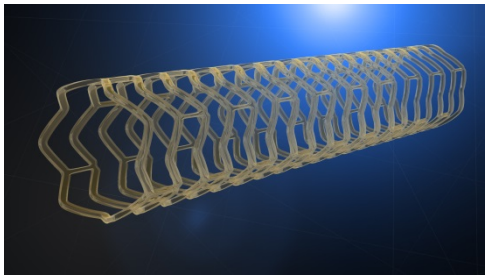
Speaker's name: Dr. Norbert Frey

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

Consultant to REVA Medical, Inc.

Fantom Bioresorbable Scaffold

Clinical Program Overview

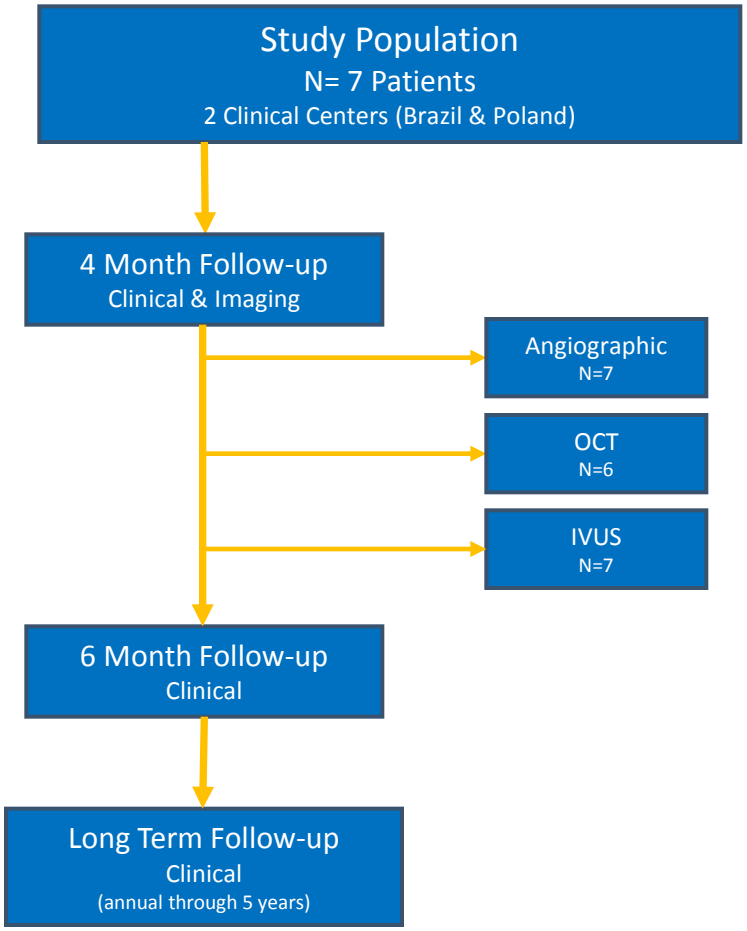


- **FANTOM I** (Pilot Trial)
  - 7 patients, 2 clinical sites
  - Goal: verification of acute performance

- **FANTOM II Trial**
  - 240 patients, 28 clinical sites
    - Cohort A - 117 patients for CE Mark application data set
    - Cohort B - 123 patients for additional data to support product use
  - Goal: safety & performance evaluation to support CE Mark

FANTOM I

Study Design and Baseline Characteristics



Patient Characteristics	N=7
Patient Age (average years)	55.9±7.7
Male	100%
Diabetes	42.9%
Current/Former Smoker	100%
Hypertension	85.7%
Hyperlipidemia	71.4%
Prior PCI	57.1%
Prior CABG	0%
Prior MI	57.1%
LVEF	50.7±12.2% (n=6)

FANTOM I

Lesion Characteristics and Procedural Outcomes

Target Lesion Location (n=7)	
LAD	42.9% (3)
LCX	42.9% (3)
RCA	14.3% (1)
ACC/AHA Lesion Class (n=7)	
Type A	14.3% (1)
Type B1	71.4% (5)
Type B2	14.3% (1)
Type C	0.0% (0)

Acute Procedural Outcomes		
Delivery Success [1]	100%	n=7
Acute Procedural Success [2]	100%	n=7
Clinical Procedural Success [3]	100%	n=7

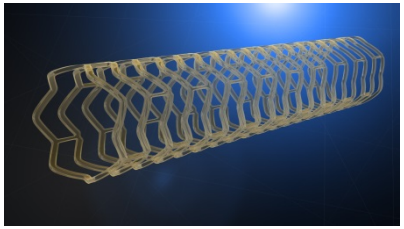
(1) Defined as successful delivery and deployment of a REVA scaffold in the intended lesion with no immediate MACE events.

(2) Defined as acute delivery 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 I

MACE Results



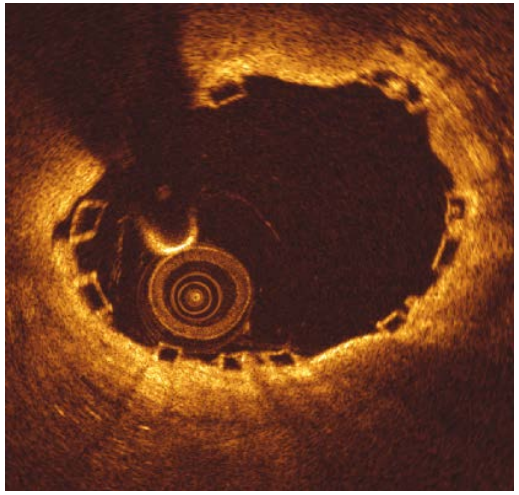
MACE Results (n=7) Timeframe	Events
In-Hospital	0
30-Day Follow-up	0
6-Month Angiographic Follow-up	0
12-Month Follow-up	0

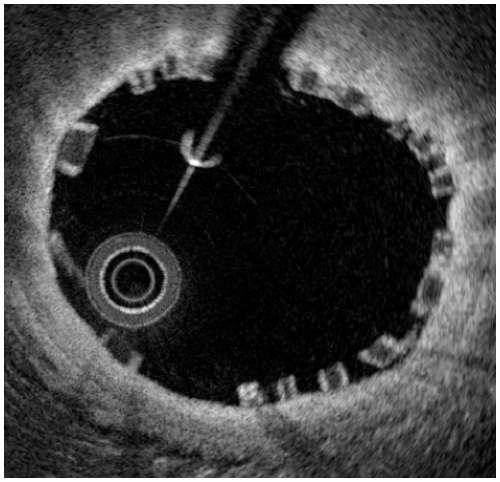
Fantom

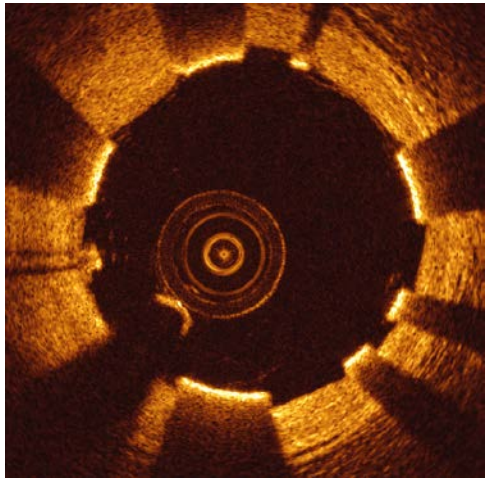
Optical Properties Comparison*

Differences and Similarities

Absorb	**DESolve NX**	**Fantom**
ABBOTT	ELIXIR	REVA MEDICAL
Poly-L-lactic acid	Poly-L-lactic acid	poly(I_2DAT-co-lactic acid)
157µm	150µm	125 µm
Crossing profile ~1.5mm	Crossing profile ~1.5mm	Crossing profile ~1.3mm







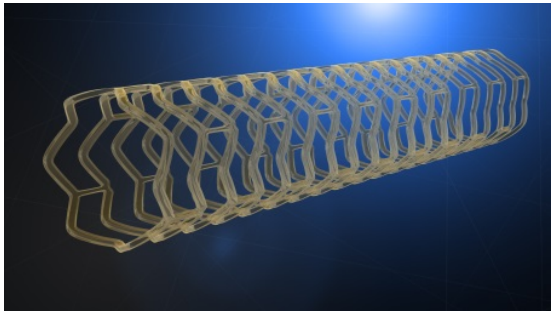
* Courtesy Dr. D. Chamie – CRC OCT corelab – São Paulo

FANTOM I

OCT Results*

	Post-Procedure N=6	4-Month FU N=6	Difference (95% CI)	P
Analyzed Scaffold Length, mm	17.63 ± 2.09	18.38 ± 1.42	0.75 (-1.95 to 3.45)	0.916
Analyzed cross-sections per lesion	30.0 ± 3.57	31.17 ± 2.31	1.16 (-3.30 to 5.63)	0.684
Mean Scaffold Area, mm^2	7.06 ± 0.76	6.56 ± 0.77	-0.50 (-1.12 to 0.1)	0.058
Min. Scaffold Area, mm^2	5.96 ± 0.99	5.49 ± 0.67	-0.47 (-1.18 to 0.24)	0.116
Strut Core Area, mm^2	0.04 ± 0.00	0.04 ± 0.00	-0.00 (-0.0 to 0.00)	0.317
Mean Scaffold Expansion, %	119.78 ± 29.16	128.20 ± 18.12	8.42 (-20.78 to 37.63)	0.753
Mean Lumen Area, mm^2	6.89 ± 0.68	5.08 ± 0.83	-1.80 (-2.43 to -1.18)	0.028
Min. Lumen Area, mm^2	5.63 ± 0.91	3.87 ± 0.82	-1.76 (-2.90 to -0.62)	0.028
Flow Area, mm^2	6.51 ± 0.62	5.08 ± 0.83	-1.42 (-2.10 to -0.75)	0.028
Analyzed struts per scaffolds	252.16 ± 32.62	255.50 ± 19.39	3.33 (-27.68 to 34.34)	0.917
Freq. of covered struts per lesion, %	N/A	99.14 ± 1.01	N/A	N/A
Freq. malapposed struts per lesion, %	2.11 ± 4.03	0.00 ± 0.00	-2.11 (-6.34 to 2.12)	0.068
Mean NIH thickness over cov. struts, mm	N/A	0.08 ± 0.03	N/A	N/A

* Analyzed by an independent OCT core lab (Dr. D. Chamie – CRC, São Paulo, Brazil)



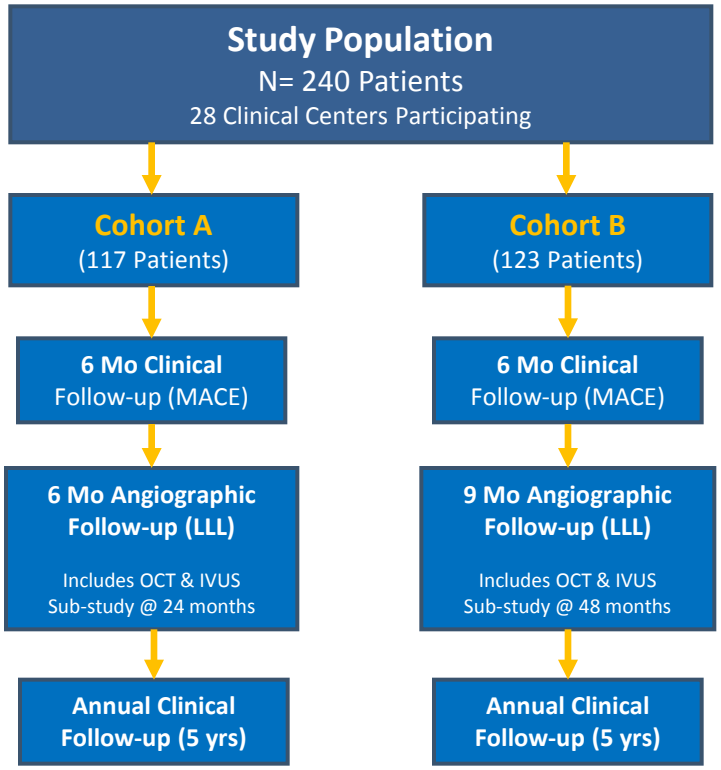
FANTOM II Trial

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

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
    - Cohort B: 48 months



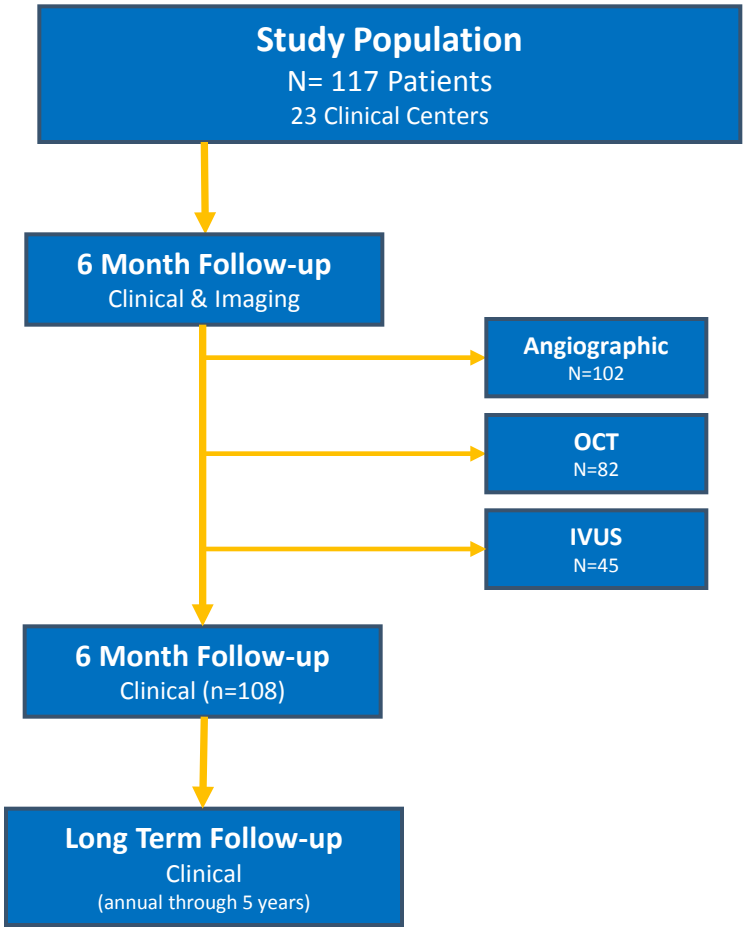
FANTOM II

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 – Cohort A

Study Overview and Baseline Characteristics



Patient Characteristics (N=117)	
Patient Age (average years)	62.7 ± 9.7
Male	70.1%
Diabetes	21.4%
Current/Former Smoker	50.4%
Hypertension	76.9%
Hyperlipidemia	70.9%
Prior PCI	40.2%
Prior CABG	6.0%
Prior MI	26.5%
Recent LVEF <40%	2.0% (N=113)

FANTOM II – Cohort A

Lesion Characteristics and Procedural Outcomes

Target Lesion Location (n=117)	
LAD	49.6% (58)
LCX	30.8% (36)
RCA	19.7% (23)
ACC/AHA Lesion Class (n=115)*	
Type A	24.3% (28)
Type B1	42.6% (49)
Type B2	33.0% (38)
Type C	0.0% (0)

*As assessed by an independent core lab

Acute Procedural Outcomes		
Acute Technical Success (1)	96.6%	n=117
Acute Procedural Success (2)	99.1%	n=113
Clinical Procedural Success (3)	99.1%	n=112

(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

Angiographic – QCA Results*

In-Scaffold Analysis	Baseline (n=115)	Post Procedure (n=112)	6 Months (n=100)
RVD (mm)	2.68 ± 0.37	2.75 ± 0.40	2.69 ± 0.35 (n=101)
MLD (mm)	0.79 ± 0.29	2.47 ± 0.37	2.20 ± 0.39
Diameter Stenosis (%)	70.3 ± 10.4	10.7 ± 7.6	16.8 ± 11.5 (n=99)
Acute Gain (mm)	1.67 ± 0.41		
Acute Recoil (%)	2.9 ± 8.8		
Mean LLL (mm)			0.29 ± 0.38
Median LLL (mm)			0.22 (-0.43, 1.77)
In-Segment Analysis			
Mean LLL (mm)			0.21 ± 0.32
Median LLL (mm)			0.16 (-0.43, 1.67)

* Preliminary Results: Analyzed by an independent QCA core lab (Yale Cardiovascular Research Group, New Haven, US)

FANTOM II – Cohort A

MACE Results

6 Month MACE Results Timeframe	Event
In-Hospital	1 (Post Procedure MI)
30-Day Follow-up	1 (MI/TLR/SAT)
90-Day Follow-up	0
6-Month Follow-up	0

Components of the Primary Endpoint (ITT): Hierarchical	N=117
MACE[1]	1.71%
Cardiac Death	0.0 %
Target vessel MI	1.71%
Clinically Driven TLR	0.0%

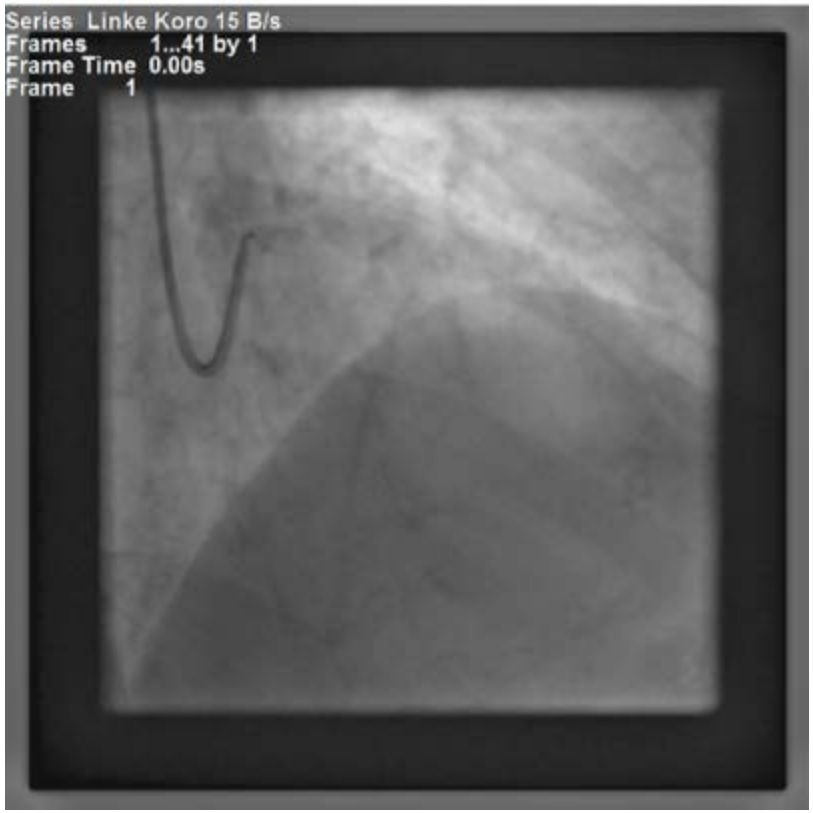
1) As adjudicated by an independent Clinical Events Committee
2) One event pending final adjudication review

144-007

Patient Demographics

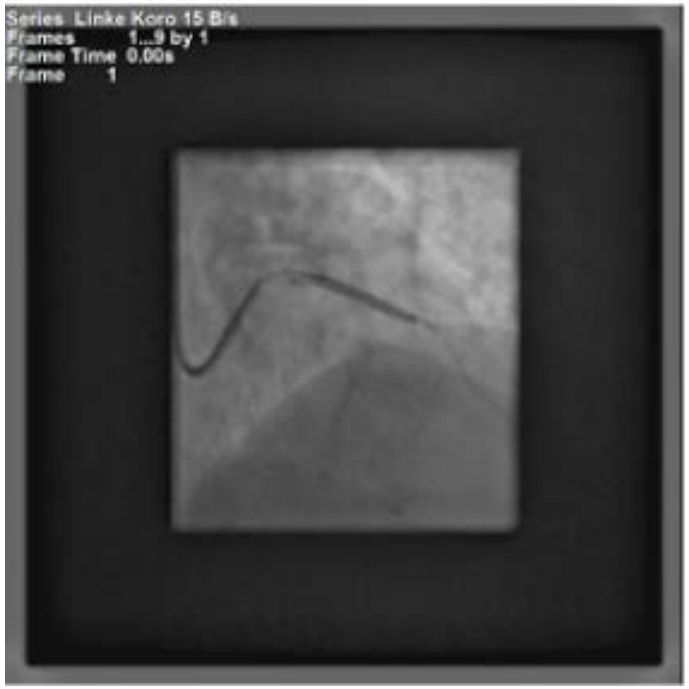
- Demographics & Physical Exam
  - Age = 74
  - Gender = Female
  - Height = 165 cm
  - Weight = 67 kg
  - Heart Rate = 64 bpm
  - Blood Pressure = 100/50
- History
  - No angina
  - No history of Hypertension and Hyperlipidemia
  - Prior PCI (04-Jul-2015)
  - Most recent MI (04-July-2015)
  - Prior smoker
  - No Diabetes
  - LVEF = 40%

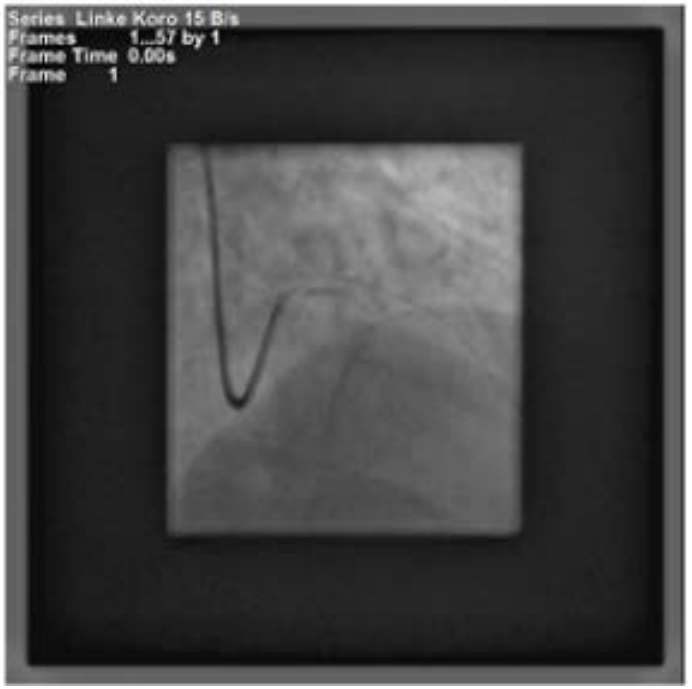
144-007 Pre-implant



[IMAGING VIDEO]

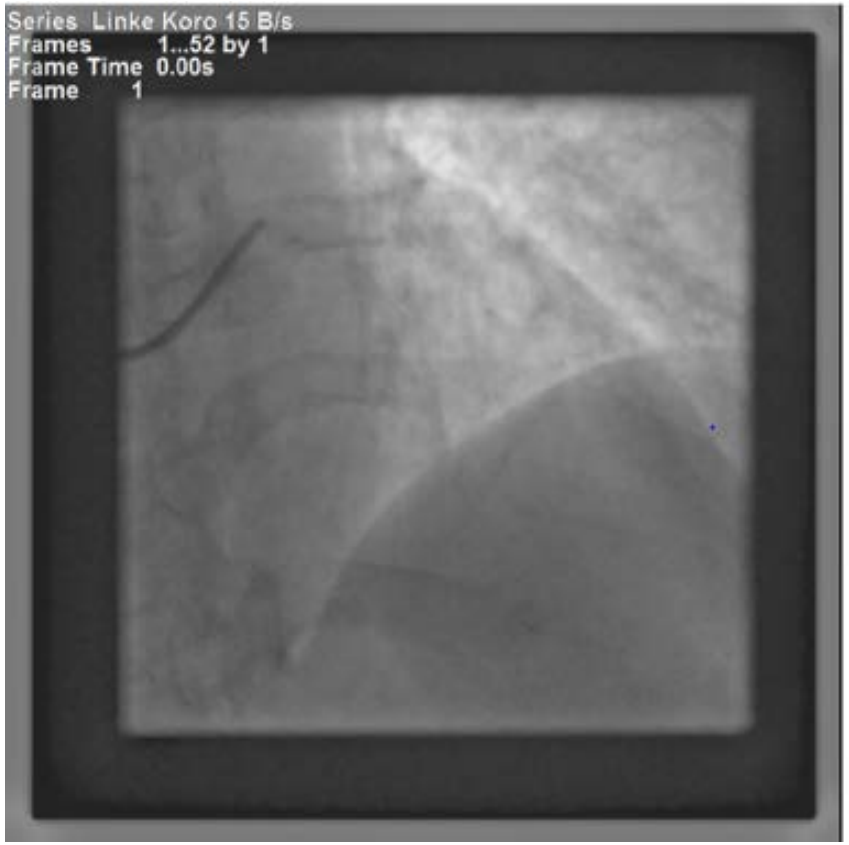
144-007 Fantom implantation





[IMAGING VIDEOS]

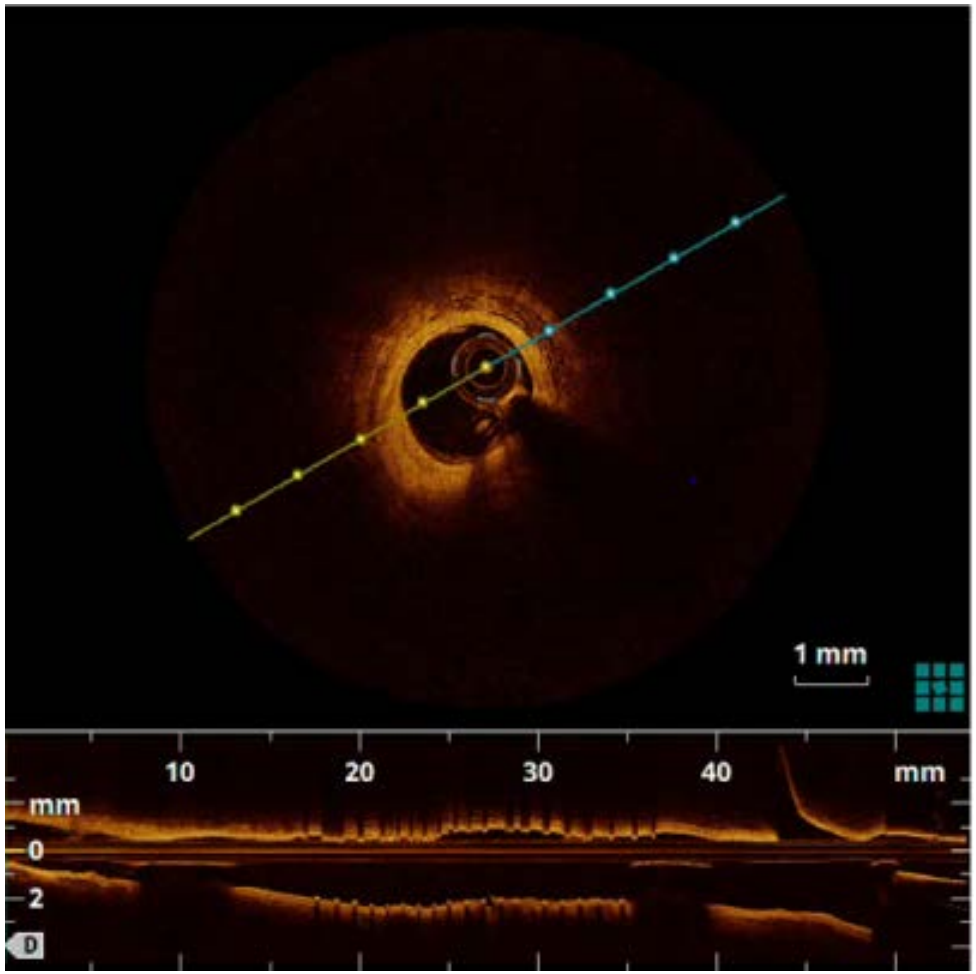
144-007 Post-implant final



Post-dilatation:
Hiryu 3.00 x 15 mm
12 atm, 30 sec

[IMAGING VIDEO]

144-007 Post-implant OCT



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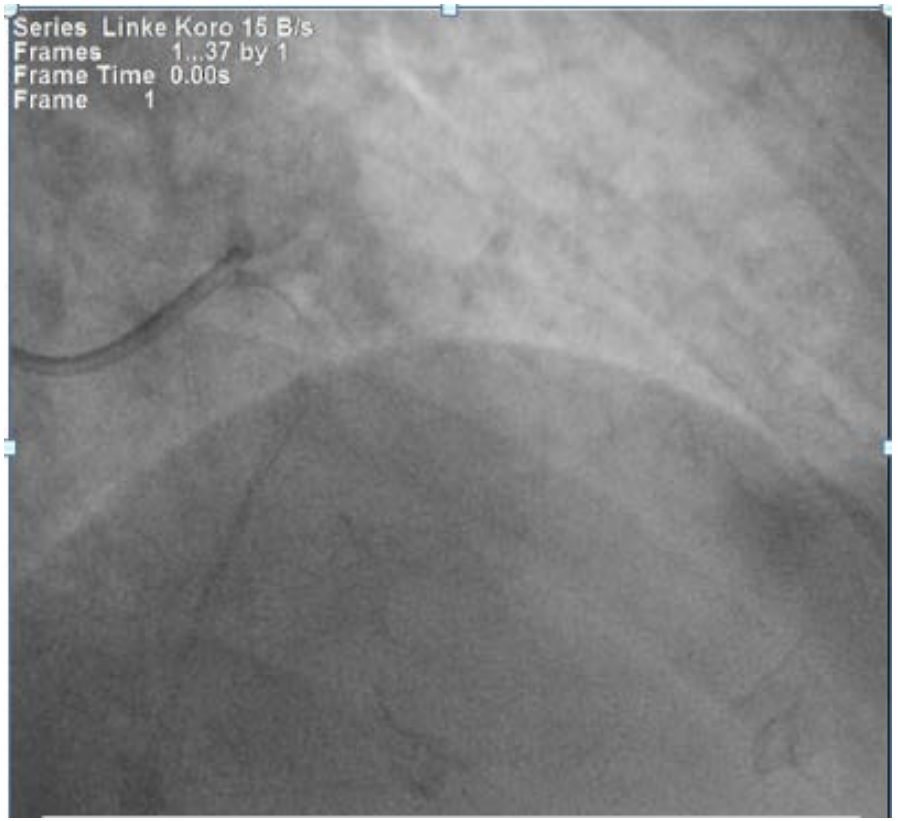
144-007 6-month follow up



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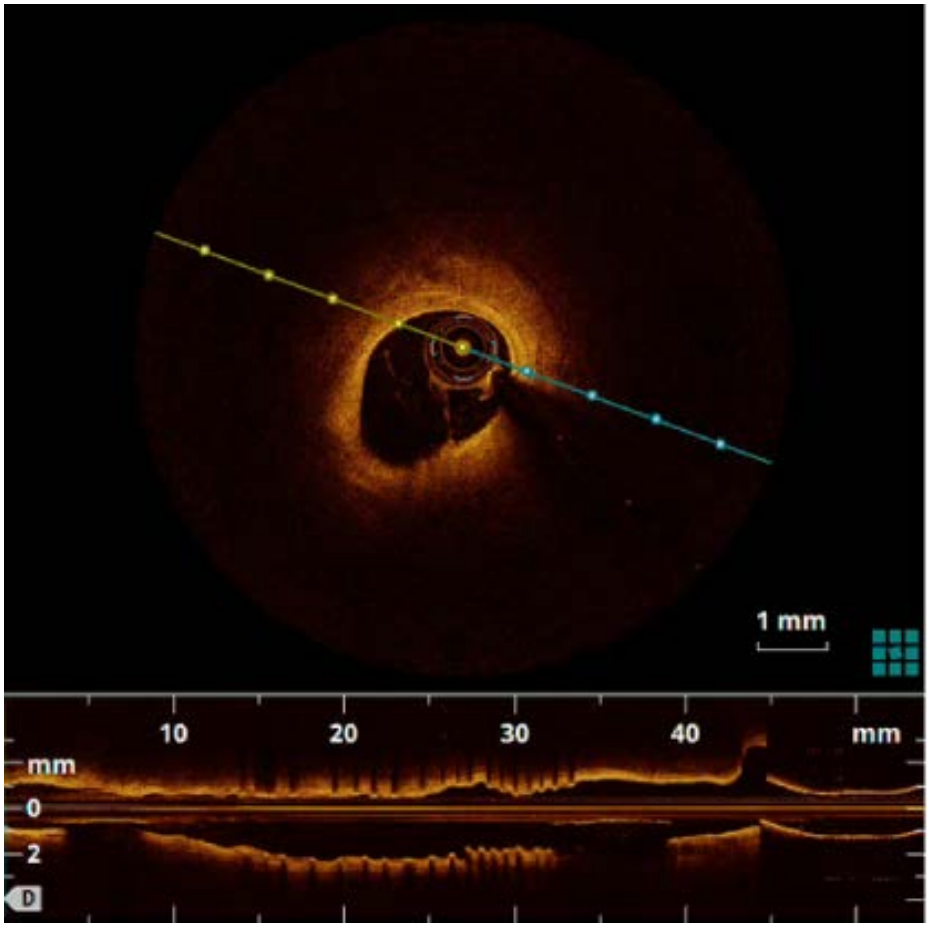
144-007 6 Month Follow-up OCT



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FANTOM Program

Clinical Summary

Initial clinical data demonstrates

- Good acute performance
  - Excellent device deliverability
  - Minimal residual stenosis and acute recoil
- Sustained performance and safety through 6 months
  - Low MACE Rate
  - Minimal late lumen loss