FANTOM II Long Lesion Study – 24 Month Outcomes
Safety & Performance of the Fantom Encore Bioresorbable Scaffold

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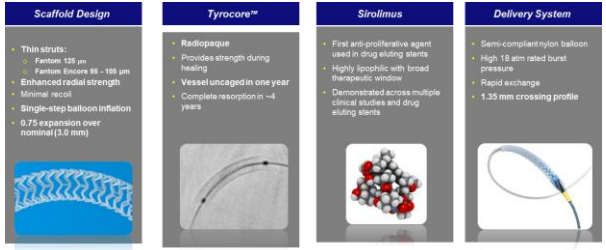
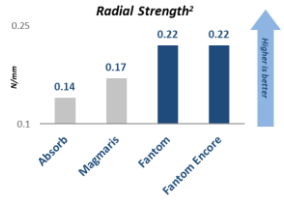
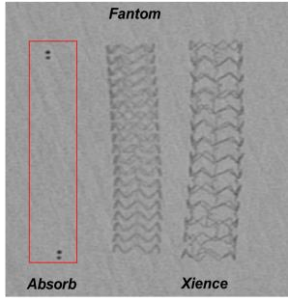
Background

The objective of this study was to evaluate the safety and performance of native coronary artery stenting using the novel Fantom Bioresorbable Scaffold in a more complex patient population consisting of lesions ≥ 20mm in length. Fantom is manufactured from TyroCore, which is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque with thin struts (125 microns) in the 2nd generation device and as low as 95 micron struts in the 3rd generation version.







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Study Design

- Safety and Performance Trial
- 32 patients enrolled
- 2.5mm to 3.5mm vessels
- Lesion length ≥ 20mm
  - Lesions requiring implant of two of more Fantom Scaffolds
- Angiography Assessment
  - Baseline
  - 6 months
- OCT Assessment
  - Baseline
  - 6 months

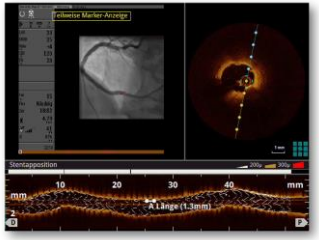
Patient Characteristics (N=32)	
Patient Age (average years)	60.3 ± 9.9
Male	81.3%
Diabetes	31.3%
Current/Former Smoker	71.9%
Hypertension	93.8%
Hyperlipidemia	75.0%
Prior PCI	75.0%
Prior CABG	3.1%
Prior MI	50.0%
Recent LVEF <40%	0.0% (N=31)

Methods

FANTOM II Cohort C is a prospective, multi-center, safety and performance study of patients with myocardial ischemia or a positive functional study. The study included patients with single de novo lesions in native coronary vessels ranging in diameter from 2.5 to 3.5 mm and lesion lengths greater than 20 mm.

The primary objective of the study is to evaluate the safety and performance of the Fantom Encore sirolimus-eluting bioresorbable scaffold in long lesion applications by assessing the incidence of Major Adverse Cardiac Events (MACE) and Late Lumen Loss at 6 months and subsequent up to 5 years.

Scaffold Usage Data	
Avg. Scaffolds Per Patient	2.0
Patients treated with 1 scaffold	4
Patients treated with 2 scaffolds	24
Patients treated with 3 scaffolds	4
Avg. Total Scaffold Length (mm)	39.6



Results

FANTOM II Long Lesion Study enrolled 32 patients across multiple centers in Germany. Acute technical success, acute procedural success, and clinical procedural success were 100%, 100% and 100%, respectively. All patients have completed 12 months of follow-up with zero incidence of MACE or thrombosis.

Components of 6-Month Primary Endpoint (ITT): non-Hierarchical	In Hospital (n = 32)	12 Month (n = 32)	24 Month (n = 32)
MACE	0% (0)	0% (0)	0% (0)
Cardiac Death	0% (0)	0% (0)	0% (0)
MI	0% (0)	0% (0)	0% (0)
Clinically Driven TLR	0% (0)	0% (0)	0% (0)

Definite or Probable Scaffold thrombosis (N=240)	
Acute (0 - 1 day)	0% (0)
Sub-acute (2 – 30 days)	0% (0)
Late (31 – 365 days)	0% (0)

Conclusion

FANTOM II Long Lesion study continues to support the results observed in the initial FANTOM II Cohort A & B trial. This trial has demonstrated initial device safety & performance in a more complex patient population.