36-Month Outcomes of the BIOSOLVE-IV Registry

Gregor Starmer, MD on behalf of the BIOSOLVE-IV investigators

36-Month Outcomes of the BIOSOLVE-IV Registry

Gregory Starmer, MD

Safety and Efficacy of the Resorbable Magnesium Scaffold Magmaris in a Real-World Setting

Disclosure of Relevant Financial Relationships

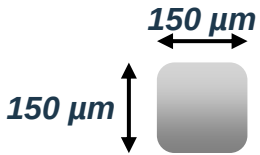
Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	BIOTRONIK AG
Consultant Fees/Honoraria	W.L. Gore & Associates, Boehringer Ingelheim, Bayer AG

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

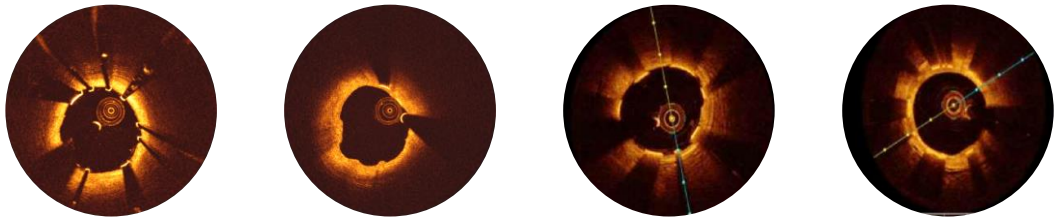
Magmaris (DREAMS 2G)
Sirolimus Eluting Magnesium Scaffold

Sirolimus + PLLA (BIOlute)



- 6-crown 2-link design
- Optimized scaffold design for
  - Higher bending flexibility
  - Higher acute radial force
  - Slower resorption rate: 95% at 12 months
- Sirolimus drug elution & PLLA (ORSIRO BIOlute coating) on Magnesium backbone
- Tantalum radiopaque markers
- Gained CE mark in June 2016

Resorbable Magnesium Scaffold ***Polymeric Scaffolds***



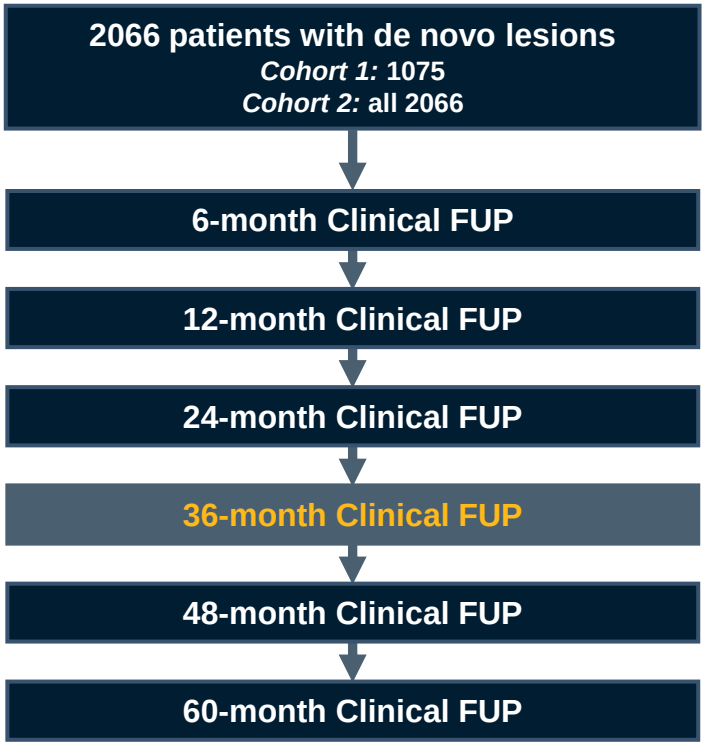
Post-Implant *12-month* *Post-Implant*[1] *24 month*[1]

[1]Abizaid A. Presented at EuroPCR 2018; May, 2018; Paris, France

Real World Registry Design

Design

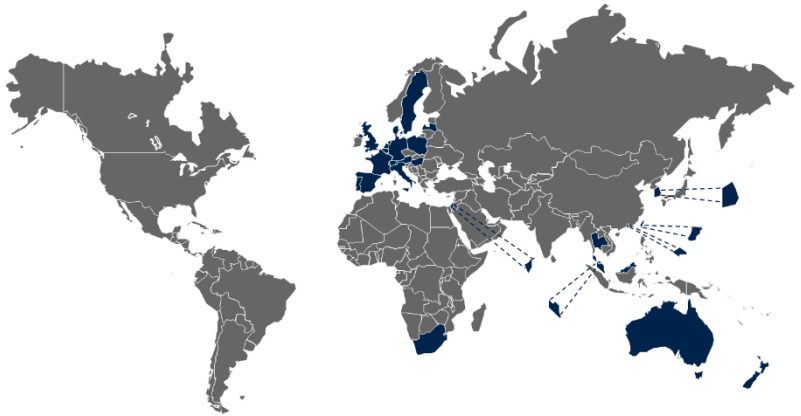
- **DESIGN:** Prospective, multi-center, real world setting registry
- **PRIMARY ENDPOINT:** Target Lesion Failure (TLF*) at 12 months (powered for Cohort 1)
- **SECONDARY ENDPOINTS:**
  at 6 months, thereafter yearly 1 to 5 years
  - Cardiac Death
  - Clinically Driven-TLR
  - Target Vessel MI
  - Scaffold Thrombosis; scaffold thrombosis at 12 month powered for superiority of Magmaris compared to Absorb for Cohort 2
  - Procedure and Device Success



*TLF: composite of target vessel myocardial infarction, clinically driven TLR, cardiac death and emergent CABG

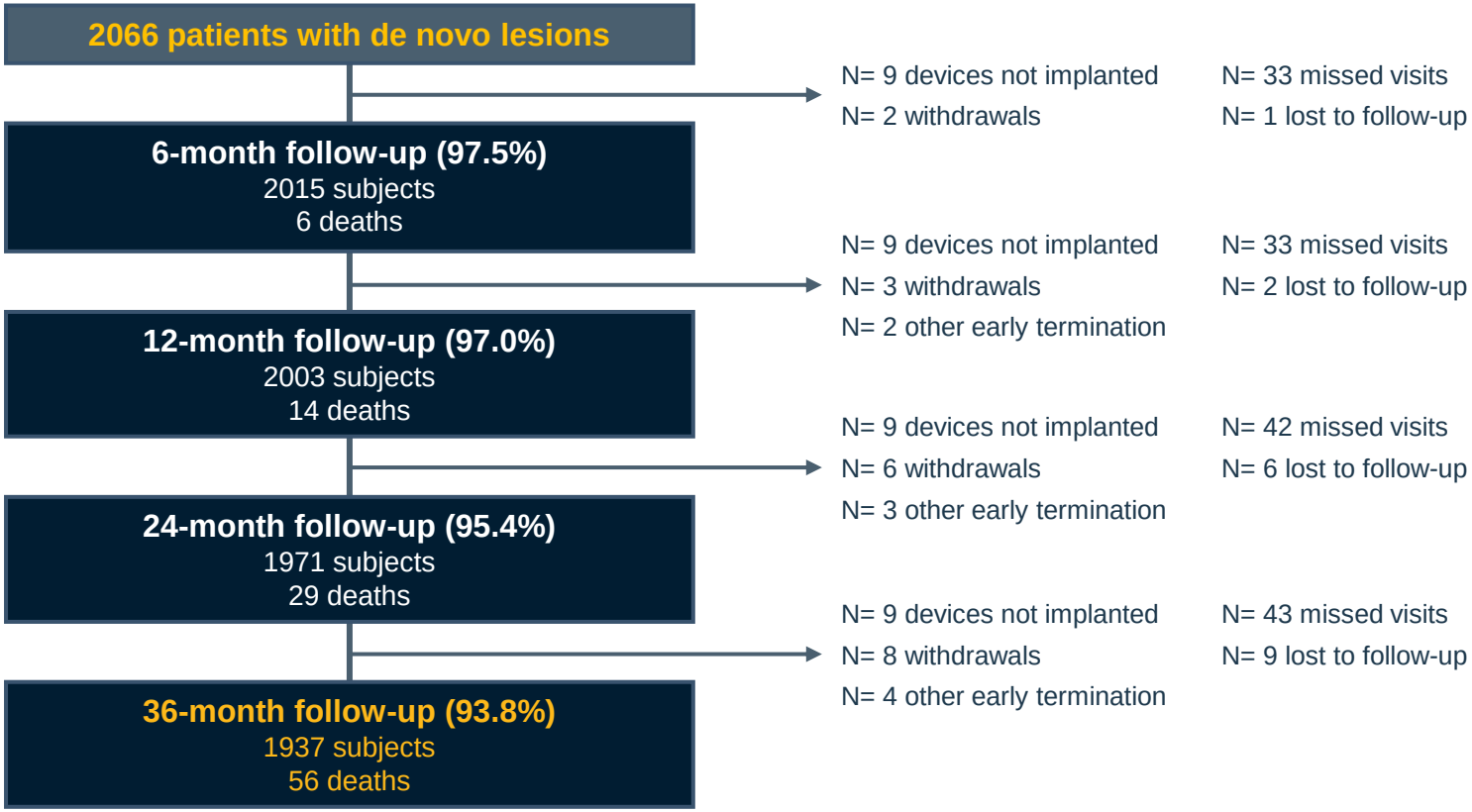
Countries & Sites

Country	Site #	Country	Site #
Germany	38	New Zealand	3
Belgium	8	Spain	3
France	7	Denmark	2
The Netherlands	7	Poland	2
Australia	5	Singapore	2
Austria	5	South Africa	2
Switzerland	4	South Korea	2
Taiwan	4	Sweden	2
Hong Kong	3	Thailand	2
Hungary	3	Israel	1
Italy	3	Latvia	1
Portugal	3	Malaysia	1
United Kingdom	3		



Over 100 sites in 25 countries

Patient Flow



Baseline Patient & Lesion Characteristics

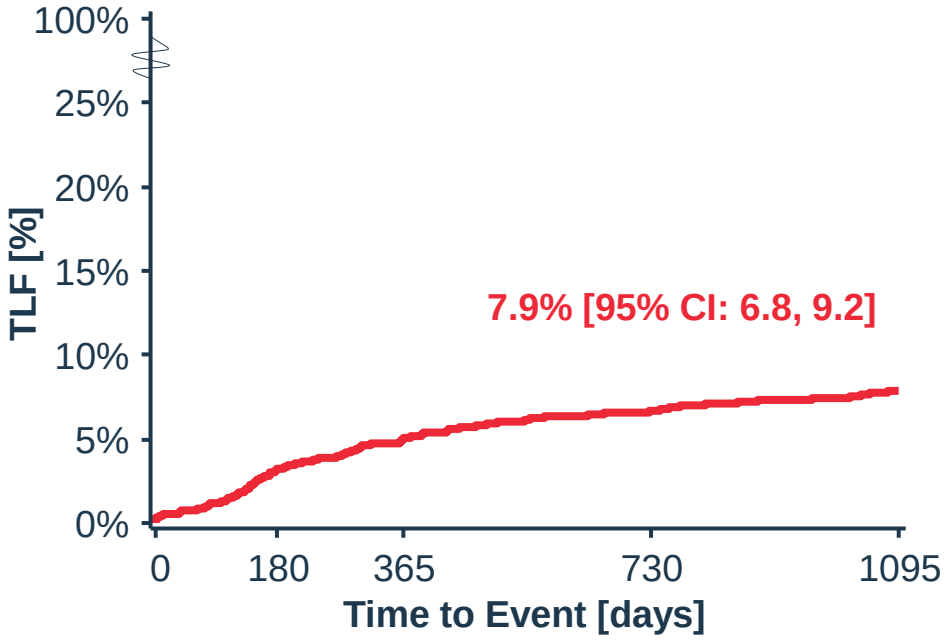
Baseline Characteristics	N = 2066
Age (mean ± SD)	61.9 ± 10.5
Male (%)	74.5
Hypertension (%)	66.4
Hyperlipidemia (%)	65.2
Smoking history (%)	59.2
Diabetes mellitus (%) Insulin dependent (%) Non-Insulin dependent (%)	21.6 21.1 78.9
History of MI (%)	21.7
Previous percutaneous Intervention (%)	28.8
NSTEMI (%)	18.5

Lesion Location	N (%)
LAD (%)	49.5
LCX (%)	20.5
RCA (%)	28.8
Ramus Intermedius (%)	1.2

Lesion Characteristics*	N = 2154
Lesion length (mm ± SD)	14.8 ± 4.0
RVD (mm ± SD)	3.2 ± 0.3
AHA / ACC Lesion Class B2 / C (%)	15.2
Calcification moderate / severe (%)	7.5
Bifurcation lesions (%)	4.6

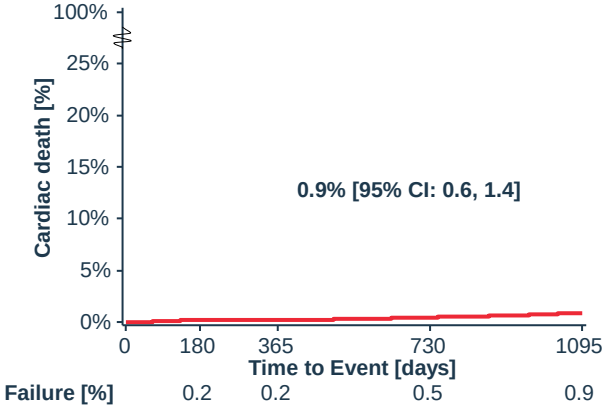
*: Lesion characteristics are estimated by investigators

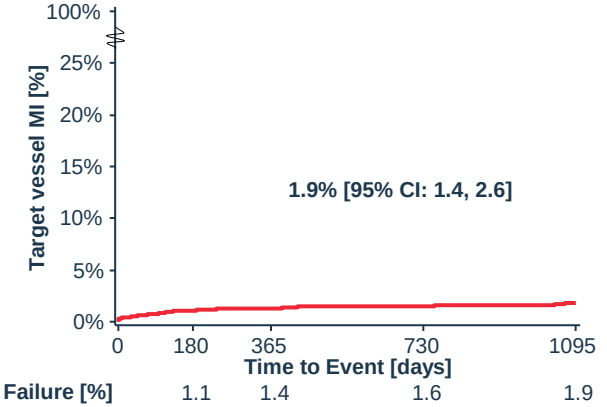
Target Lesion Failure up to 36-months

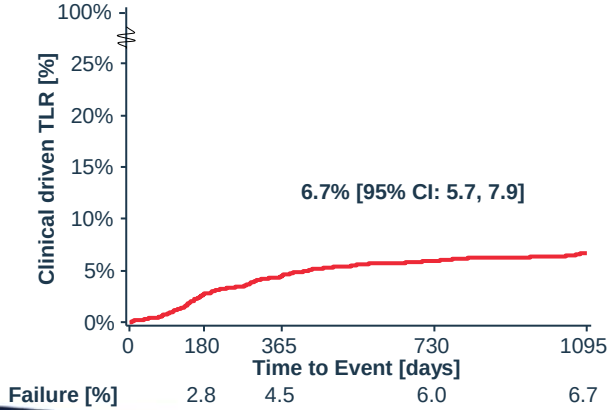


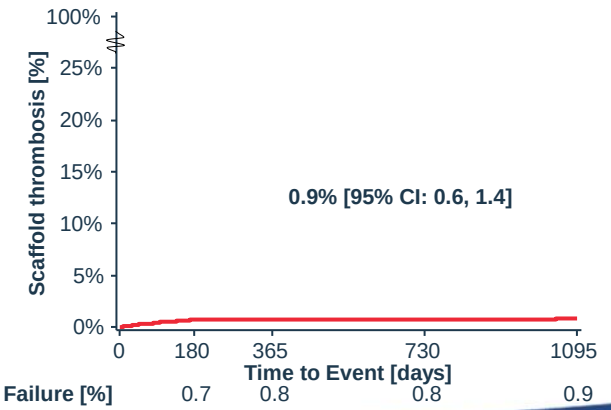
Failure [%]	5.0	6.7	7.9

Composite Endpoints & Definite / Probable Scaffold Thrombosis up to 36 Months









Summary & Conclusions

- TLF rate at 36-months with 7.9% is comparable to various contemporary drug-eluting stents[1,2]
- Very good safety profile of the scaffold up to 36-month
  - 0.9% cardiac death,
  - 1.9% target vessel-MI (according to SCAI/Ext. Historical MI Definition)
  - 0.9% scaffold thrombosis, in particular only 0.1% increase of event rate after 1 year (2 cases/2066)

[1]Kandzari D. et al., J Am Coll Cardiol Intv., 2020, 13 (11) 1343-1353

[2]Buiten R. et al., J Am Coll Cardiol Intv., 2019, 12 (17) 1650-1660