BIOMAG-I

Clinical outcomes of the third-generation resorbable magnesium scaffold for coronary artery lesions: three-year results of the BIOMAG-I[1]

Conclusions

- **The low TLF rate at three years** – particularly with only one event occurring beyond the scaffold resorption period – **is highly encouraging**.[1]
- Freedom from cardiac death, target vessel myocardial infarction, and any device thrombosis up to three years attests to **excellent device performance**.[1]
- The favorable 3-year outcomes support renewed interest in bioresorbable scaffolds as a viable therapeutic option that combines **temporary mechanical support with excellent long-term safety and efficacy**.[1]

Study objective

Assessment of angiographic, clinical and safety performance of the **sirolimus eluting magnesium scaffold Freesolve** in patients with de novo coronary artery lesions

Primary endpoint

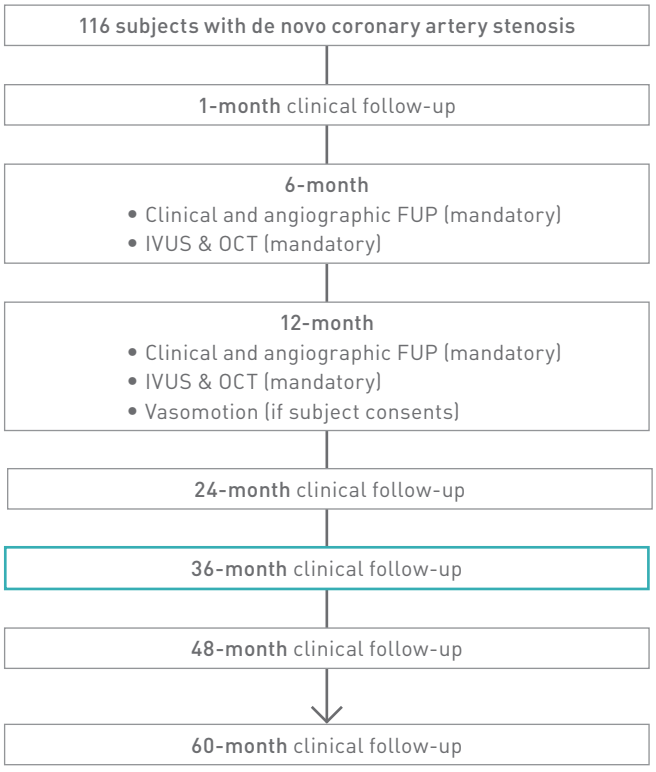
- In-Scaffold LLL at 6 months

Secondary endpoints at 12 months

- Angiographic in-scaffold and in-segment LLL
- Binary restenosis
- Diameter stenosis
- IVUS/OCT descriptive analysis

Clinical endpoints

- Target Lesion Failure*
- Definite or Probable Scaffold Thrombosis



Patient characteristics	n = 116	%
Age, years	61.0 ± 9	
Male	90	77.6%
Hypertension	86	74.1%
Hypercholesterolemia	72	62.1%
Diabetes	32	27.6%
History of smoking	75	64.7%
History of myocardial infarction	39	33.6%
NSTEMI	**24**	**20.7%**

Lesion characteristics	n	
Lesion length (mm)	12.3 ± 5.1	
Reference vessel diameter (mm)	2.72 ± 0.46	
AHA/ACC lesion class B2/C	**90**	**76.9%**
Side branch involvement	25	21.4%

Lesion location	n	
LAD	53	45.3%
LCx	22	18.8%
RCA	40	34.2%
Ramus intermedius	2	1.7%

Lesion characteristics are estimated by core lab.

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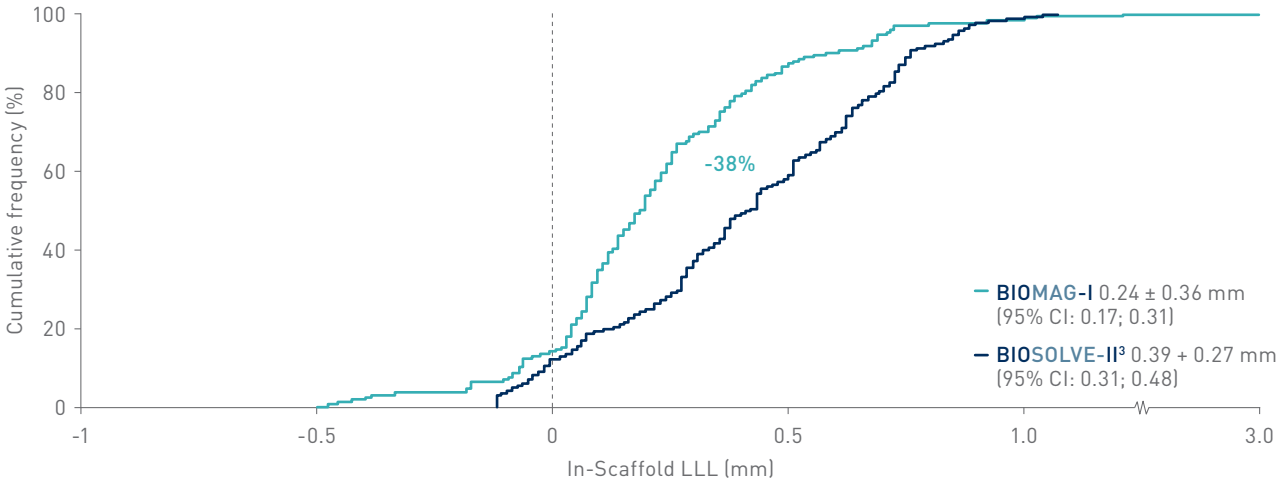
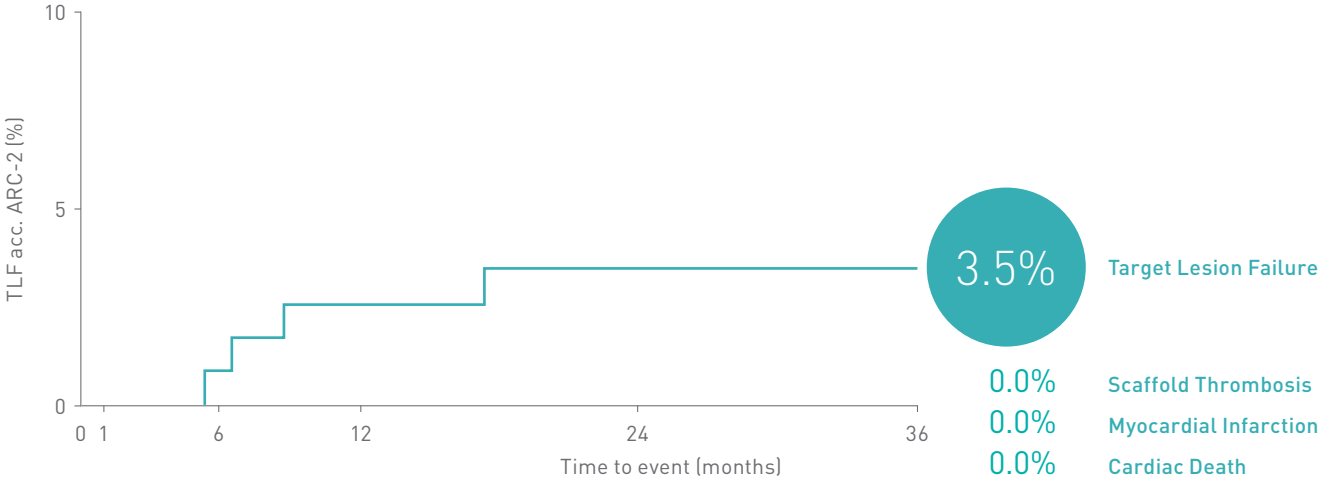
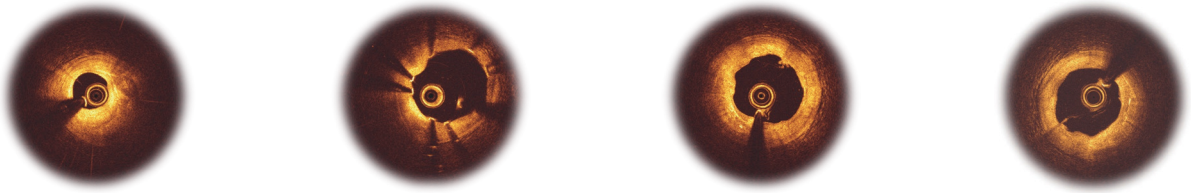
In-Scaffold Late Lumen Loss at 12 months[2] (n = 100)



Target Lesion Failure



Serial OCT Analysis at 12 months



Pre-procedure

Post-procedure
- Malapposed† struts %: 4.62 ± 4.69
- Total incomplete strut apposition area mm²: 0.08 ± 0.11

6m follow-up
Struts hardly discernable

12m follow-up
Struts were not discernable anymore

Coordinating investigator

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*TLF is defined as Composite of Cardiac Death, TV-MI, CD-TLR (Kaplan-Meyer estimate); **peri-procedural target vessel MI according to SCAI definition and non-peri-procedural target vessel MI according to Universal MI Definition; °driven by three clinically-driven target lesion revascularization; †Definition of malapposition: if the distance between outer contour of the strut and vessel wall is more than the individual strut thickness; ‡p < 0.05 for 12-month vs post-procedure. 1. Haude et Al. EuroIntervention 2025;21:e1-e3. 2. Haude et Al. EuroIntervention 2023;19:e414-e422. 3. Haude et Al. Eur Heart J 2016;37:2701-2709.

All endpoint related events have been adjudicated by an independent clinical event committee. BIOMAG-I and BIOSOLVE-II are based on Kaplan-Meier failure estimate analysis including censored observations.

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