BIOMAG-I

A new resorbable magnesium scaffold for de novo coronary lesions (Freesolve): 24-month results of the BIOMAG-I first-in-human study[6]

Conclusions

- Freesolve RMS has an improved angiographic In-Scaffold Late Lumen Loss (LLL) compared to its precursor Magmaris[2] at 12-month follow-up, making Freesolve RMS a potential alternative to permanent DES.[3]
- Furthermore, at 12-month follow-up, patients treated with Freesolve RMS demonstrated a return of vasomotion.[4]
- OCT analysis revealed that 99.3% of struts were no longer visible at 12 months confirming the preclinical data.[5]
- At 24-month follow-up, Freesolve RMS shows an excellent safety and efficacy profile: No Scaffold Thrombosis (ST), Myocardial Infarction (MI) or Cardiac Death (CD) and a low Target Lesion Failure (TLF) rate of 3.5%, comparable with second generation DES.[6,7]

Study design

- Prospective, multi-center, single arm
- Subjects with single de novo coronary artery lesions in up to two coronary arteries
- Reference Vessel Diameter (RVD) between 2.5-4.2 mm and lesion length ⩽ 28 mm long

Patients

20.7% of NSTEMI patients included

Endpoints

Primary endpoint

- In-Scaffold LLL at 6 months

Angiographic Endpoints (at 6 and 12 months)

- In-Segment LLL
- Binary restenosis rate
- % In-Scaffold and In-Segment Diameter Stenosis
- In-Scaffold LLL (powered for both time points)

Clinical Endpoints

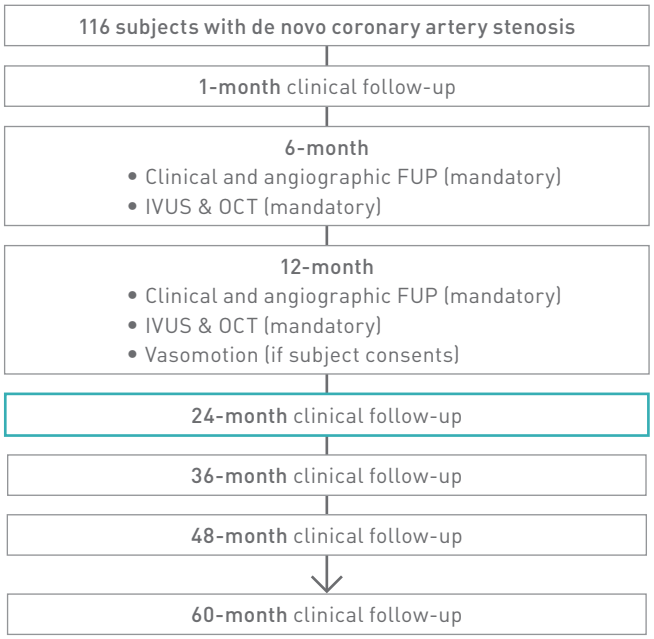
- Target Lesion Failure*
- Definite or Probable Scaffold Thrombosis

Imaging and Physiological Endpoint

- Procedure and device success
- Descriptive analysis of vessel morphology, lesion composition and scaffold strut data (IVUS and OCT)
- Descriptive analysis of vasomotion

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 location

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

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 characteristics are estimated by core lab.

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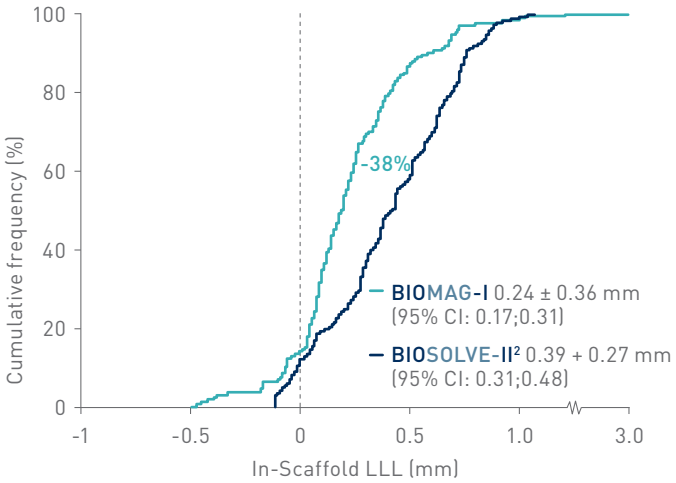
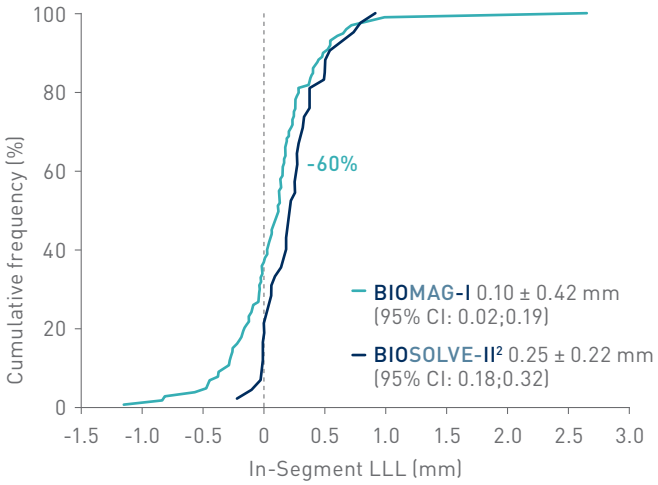
In-Scaffold Late Lumen Loss at 12 months[1] (n = 100)



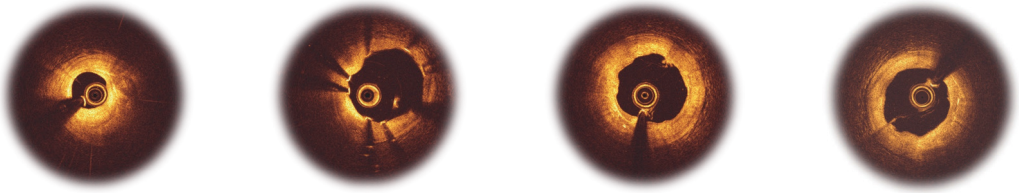
In-Segment Late Lumen Loss at 12 months[1] (n = 100)



Comparison of the clinical outcomes at 6, 12 and 24 months

	BIOMAG-I 6m n = 116	BIOMAG-I 12m n = 116	BIOMAG-I[6] 24m n = 115
Target lesion failure*	0.9%	2.6%°	3.5%
Cardiac death	0.0%	0.0%	0.0%
TV-MI**	0.0%	0.0%	0.0%
CD-TLR	0.9%	2.6%	3.5%
Definite or probable ST	0.0%	0.0%	0.0%

Serial OCT Analysis at 12 months



Pre-procedure	Post-procedure	6m follow-up	12m follow-up
	• Malapposed† struts %: 4.62 ± 4.69 • Total incomplete strut apposition area mm²: 0.08 ± 0.11	Struts hardly discernable	Struts were not discernable anymore

Coordinating investigator

Michael Haude, MD, PhD, Rheinland Klinikum, Neuss, Germany

*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, M "1-Year Clinical Outcomes of the new resorbable Magnesium scaffold DREAMS 3G, from the first in-human BIOMAG-I study" presented at EuroPCR May 2024; 2. Haude M, et al., Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. Eur Heart J 2016;37:2701-2709; 3. Byrne RA, et al., Report of a European Society of Cardiology-European Association of Percutaneous Cardiovascular Interventions task force on the evaluation of coronary stents in Europe: executive summary. Eur Heart J 2015;36:2608-262; 4. Haude, M "First in human study BIOMAG-I: 12 months results of the sirolimus eluting resorbable coronary magnesium scaffold system (DREAMS 3G) in the treatment of subjects with de novo coronary artery lesions" presented at ESC August 2023; 5. Seguchi, M "Twelve-months vessel healing profile following the novel resorbable magnesium scaffold implantation: an intravascular OCT analysis of the BIOMAG-I trial" presented at ESC August 2023; 6. Poster presentation "BIOMAG-I: two-year clinical outcomes of the resorbable magnesium Scaffold-DREAMS 3G" by Prof. Haude at EuroPCR 2024; 7. Buiten RA, et al. Thin Composite-Wire-Strut Zotarolimus-Eluting Stents Versus Ultrathin-Strut Sirolimus-Eluting Stents in BIONYX at 2 Years, JACC: Cardiovascular Interventions, Volume 13, Issue 9, 2020, Pages 1100-1109, ISSN 1936-8798.

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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BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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excellence for life