BIOSOLVE-IV FIRST COHORT

48-month follow-up of **first** cohort with **1,075 patients**[1]

Conclusions

- TLF rate* at 48 months with 9.1% is comparable to various contemporary drug-eluting stents.[2,3]
- **Magmaris®** Resorbable Magnesium Scaffold has a good safety profile up to 48 months with 1.2 % cardiac death, 2.4 % target vessel-MI and 0.6 % scaffold thrombosis, including one very late, definite scaffold thrombosis after device resorption**.

Study design

Prospective, multi-center, real-world setting registry

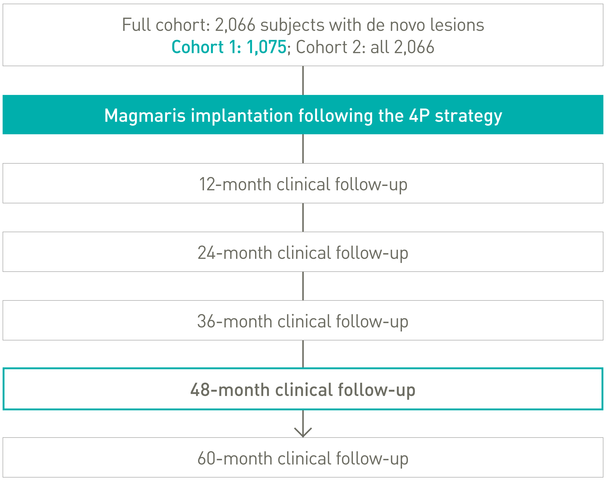
Patients

19.2% of NSTEMI patients included

Endpoints

Primary endpoint
- TLF* at 12 months

Secondary endpoints
- Clinically-driven Target Lesion Revascularization (CD-TLR) and Target Vessel Revascularization (TVR)
- Cardiac death
- Target-Vessel Myocardial Infarction (TV-MI)
- Definite or probable ST at 12 months powered to show the superiority of Magmaris vs. historical data of Absorb for full cohort based on a one one-sided exact binomial test
- Procedure and device success



Patient characteristics	n = 1,075	
Age, yrs°	61.3 ± 10.5	
Male	806	75.0%
Hypertension	724	67.3%
Hyperlipidemia	713	66.3%
Smoking	654	61.1%
Diabetes mellitus	228	21.2%
Insulin dependent	45	19.7%
Non-insulin dependent	183	80.3%
History of MI	219	20.4%
Previous percutaneous intervention	287	26.7%
NSTEMI	**206**	**19.2%**

Lesion location	n	
LAD	561	50.0%
LCx	213	19.0%
RCA	333	29.7%
Ramus intermedius	14	1.2%

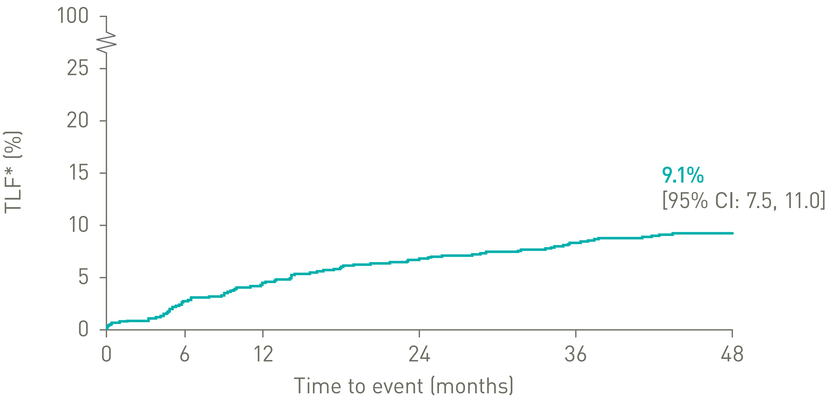
Lesion characteristics	n	
Lesion length (mm)°	14.9 ± 4.2	
Reference vessel diameter (mm)°	3.2 ± 0.3	
AHA/ ACC lesion class B2/C	**170**	**15.2%**
Calcification moderate/severe	82	7.3%
Bifurcation lesions	**57**	**5.1%**

* TLF is defined as a composite of Cardiac Death, TV-MI, emergent Coronary Artery Bypass Grafting (eCABG), and Clinically-driven TLR. Peri-procedural MI according to SCAI definition and spontaneous MI according to the extended historical definition.

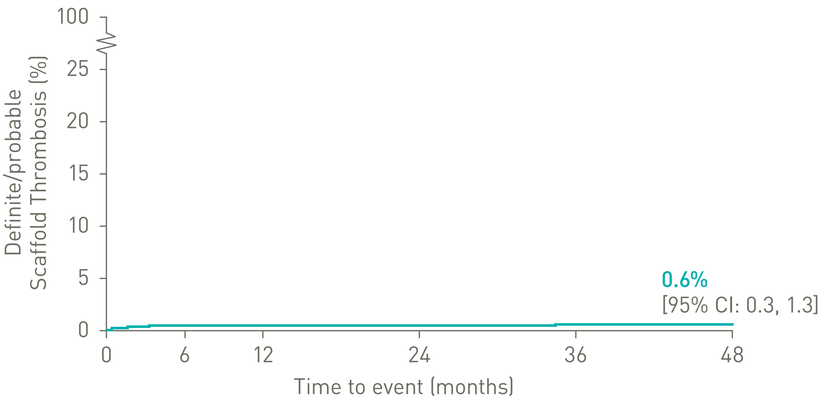
** At 1,043 days post procedure: Patient presented with inferior STEMI. Thrombotic occlusion of the previously scaffolded segment in the proximal RCA (about 3 years before). TLR with a DES performed

° Data shown as mean ± SD

TLF* of Magmaris up to 48 months[1]



Scaffold Thrombosis of Magmaris up to 48 months[1]



BIOSOLVE-IV First cohort[1] TLF* and selected components

	BIOSOLVE-IV[4] 12-month FUP n = 1,071◊		BIOSOLVE-IV[5] 24-month FUP n =1,071◊		BIOSOLVE-IV[6] 36-month FUP n = 1,071◊		BIOSOLVE-IV[6] 48-month FUP n = 1,071◊
TLF*	**45**	**4.3%**	**70**	**6.6%**	**86**	**8.2%**	**9.1%**
Cardiac Death	2	0.2%	5	0.5%	10	1.0%	
Target-Vessel MI	12	1.1%	16	1.5%	21	2.0%	2.4%
Clinically-Driven TLR	41	3.9%	62	5.9%	72	6.8%	7.5%
Scaffold Thrombosis (definite or probable)	**5**	**0.5%Δ**	**5**	**0.5%Δ**	**6**	**0.6%§**	**0.6%§**

n-values are based on BIOTRONIK data on file and assessed by Kaplan-Meier failure estimate analysis.

Coordinating investigators

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* TLF is defined as a composite of Cardiac Death, TV-MI, emergent Coronary Artery Bypass Grafting (CABG), and CD-TLR. Peri-procedural MI according to SCAI definition and spontaneous MI according to the extended historical definition; ◊ Rational for the n-value calculation: 1,075-4 devices not implanted = 1,071; § 0.5% scaffold thrombosis rate excluding cases with early antiplatelet or anticoagulant interruption; Δ 4 out of 5 (0.1%) scaffold thrombosis cases had early antiplatelet or anticoagulant interruption after procedure.

1. Torzewski J. Safety and performance of Magmaris at 48 months: BIOSOLVE-IV first cohort. Presented at: EuroPCR; 2023; ClinicalTrials.gov: NCT02817802; 2. Slagboom et al. presented at TCT 2016; 3. Slagboom et al., presented at EuroPCR 2017; 4. Verheye S, Wlodarczak A, Montorsi P, et al., BIOSOLVE-IV-registry: Safety and performance of the Magmaris scaffold: 12-month outcomes of the first cohort of 1,075 patients. Catheter Cardiovasc Interv. 2020; 1–8. doi.org/10.1002/ccd.29260; 5. Torzewski J. Safety and performance of Magmaris at 24 month follow up of BIOSOLVE IV. Presented at: eEuroPCR; 2021; virtual congress. ClinicalTrials.gov: NCT02817802; 6. Torzewski J. Safety and performance of Magmaris at 36-months: BIOSOLVE-IV first cohort. Presented at: EuroPCR; 2022; ClinicalTrials.gov: NCT02817802.

All events have been adjudicated by an independent clinical event committee. BIOSOLVE-IV registry is based on Kaplan-Meier failure estimate analysis including censored observations.

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