BIOSOLVE-IV FIRST COHORT

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

Conclusions

- Magmaris® Resorbable Magnesium Scaffold (RMS) shows a good safety profile of the scaffold in a real-world setting up to 36 months for the first cohort.[1]
- The Target Lesion Failure (TLF)* rate of 8.2% at 36 months for the first cohort is comparable to low TLF rates of contemporary drug-eluting stents (DES)[2,3] over the same time period.
- Only 1 very late scaffold thrombosis (ST)** case occurred up to 36 months for the first cohort of BIOSOLVE-IV.

Study design

Prospective, multi-center, real-world setting registry

Patients

19.2% of NSTEMI patients included

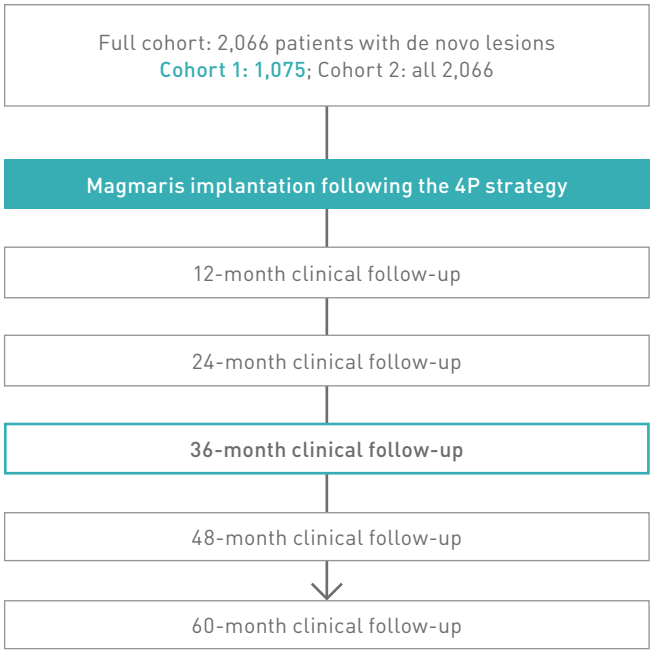
Endpoints

Primary endpoint

- TLF* at 12 months

Secondary endpoints

- Clinically-driven Target Lesion Revascularization (Clinically-driven 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	60.8%
Diabetes mellitus	228	21.2%
Insulin dependent	45	19.7%
Non-insulin dependent	183	80.3%
History of MI	219	20.4%
Previous percutaneous coronary 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

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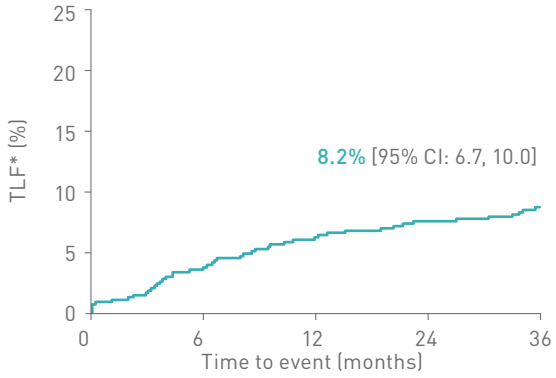
TLF* of Magmaris[1] up to 36 months



TLF of contemporary DES[2,3] up to 36 months

BIORESORT[2] TLF						BIOFLOW-V[3] TLF			
SES n = 1,169		EES n = 1,172		ZES n = 1,173		SES n = 884		DP EES n = 450	
77	6.7%	86	7.5%	96	8.3%	70	8.2%	59	13.6%

The event rates, expressed as n (%), were calculated with the use of the Kaplan-Meier method at 36 months.

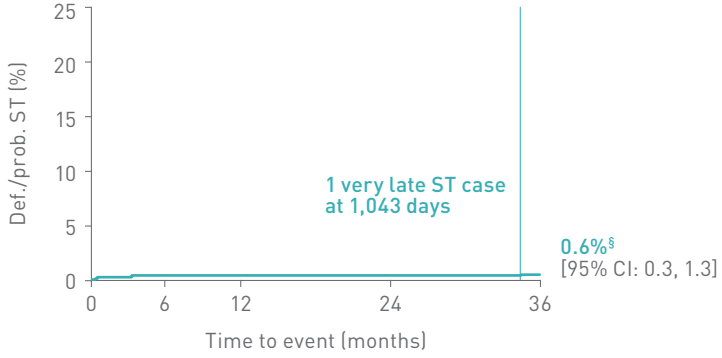
DP EES = Durable-polymer everolimus-eluting stent
EES = Everolimus-eluting stent
SES = Sirolimus-eluting stent
ZES = Zotarolimus-eluting stent

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[1] 36-month FUP n = 1,071◊	
TLF*	**45**	**4.3%**	**70**	**6.6%**	**86**	**8.2%**
Cardiac death	2	0.2%	5	0.5%	10	1.0%
TV-MI	12	1.1%	16	1.5%	21	2.0%
Clinically-driven TLR	41	3.9%	62	5.9%	72	6.8%
Emergent CABG	0	0.0%	0	0.0%	0	0.0%
Scaffold Thrombosis (definite or probable)	**5**	**0.5%Δ**	**5**	**0.5%Δ**	**6**	**0.6%§**

n-values are based on BIOTRONIK data on file and assessed by Kaplan-Meier failure estimate analysis.
◊Rational for the n-value calculation: 1,075-4 devices not implanted = 1,071

Def./ prob. ST up to 36 months



0.5%Δ def./prob. ST at 24 months

0.6%§ def./prob. ST at 36 months

BIOSOLVE-IV first cohort demonstrates consistently low scaffold thrombosis rates up to 36 months.[1]

§ 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

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1. Torzewski J. Safety and performance of Magmaris at 36-months: BIOSOLVE-IV first cohort. Presented at: EuroPCR; 2022; ClinicalTrials.gov: NCT02817802; 2. Buiten A et al. Thin, Very Thin, or Ultrathin Strut Biodegradable - or Durable-Polymer-Coated Drug-Eluting Stents 3-Year Outcomes of BIO-RESORT. JACC: CARDIOVASCULAR INTERVENTIONS. 2019. doi: 10.1016/j.jcin.2019.04.054; 3. Kandzari D.E et al. Ultrathin Bioresorbable-Polymer Sirolimus-Eluting Stents Versus Thin Durable-Polymer Everolimus-Eluting Stents for Coronary Revascularization 3-Year Outcomes From the Randomized BIOFLOW V Trial. JACC: CARDIOVASCULARINTERVENTIONS. 2020. 13 (11): 1343-53. doi: 10.1016/j.jcin.2020.02.019 ; 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.

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. Please consult IFU for indications and use in special populations.

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