Magmaris

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Disclosure

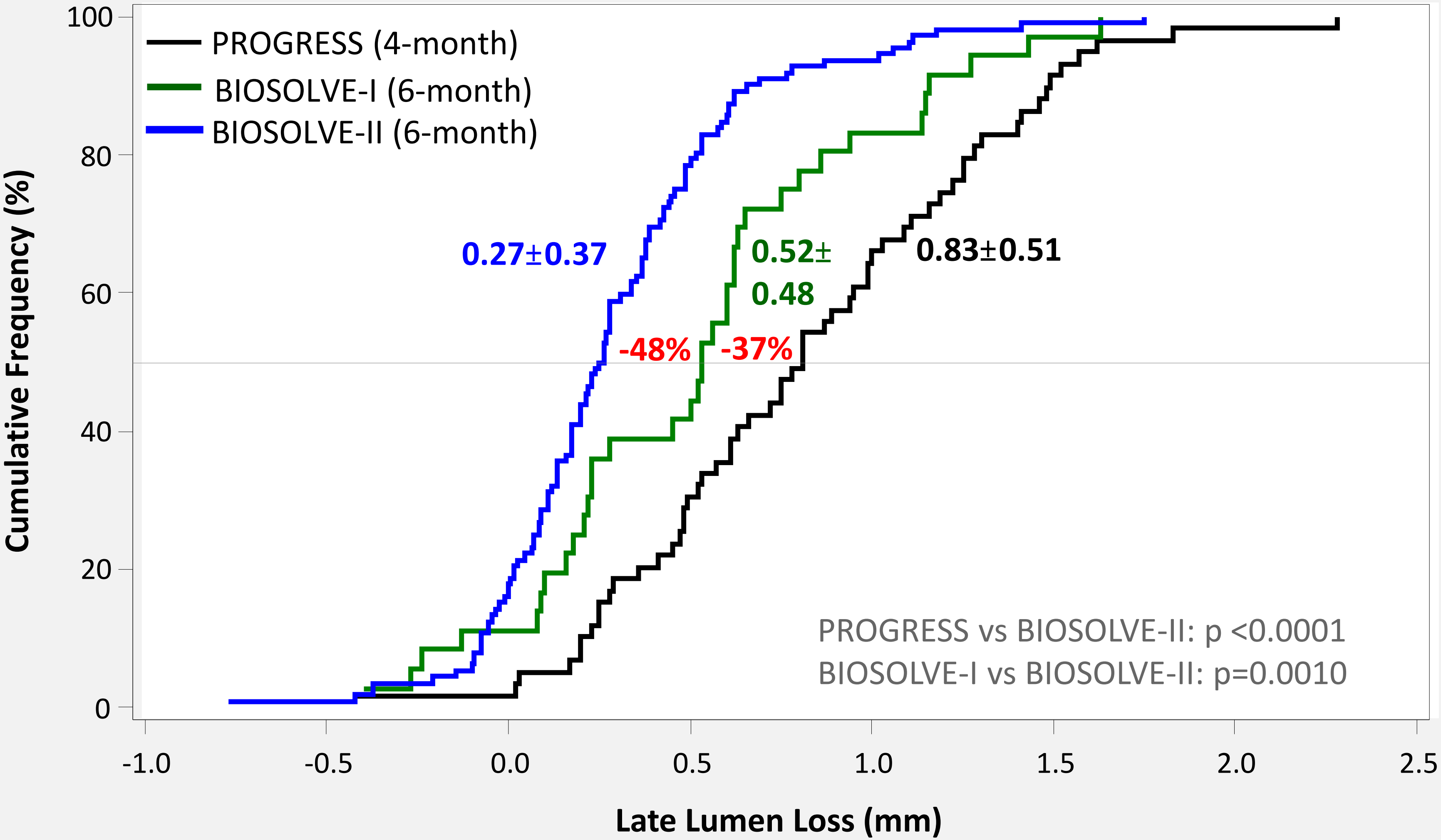
Speaker : Medtronic,Biotronik

Evolution of the BIOTRONIK Magnesium Scaffold

	Device Generation	AMS 4-Month	DREAMS 1G 6-Month	Magmaris 6-Month
Design	**Diameter / length (mm)**	3.0 & 3.5 / 15, 20	3.25 & 3.5 / 15	2.5, 3.0 & 3.5 / 15, 20, 25
Design	**Backbone**	Mg alloy	Refined Mg alloy	Refined Mg alloy
Design	**Strut thickness / width (µm)**	165 / 80	120 / 130	120 / 120 (Ø 2.5) 150 / 150 (Ø 3.0 & 3.5)
Design	**Markers**	none	none	Tantalum composite
Design	**Coating - drug**	none	PLGA / PTX	PLLA / SIR
Design	**Crossing profile (mm)**	1.6	1.5	1.75
Kinetics	**Drug elution kinetics**	n.a.	like Taxus	like Orsiro
Kinetics	**Absorption period in months**	1-2	3-4 (Mg)	≈ 12 (Mg)
Results	**In-segment late lumen loss (mm)**	0.83 ± 0.51	0.52 ± 0.48	0.27±0.37
Results	**TLF* (%)**	23.8	4.3	3.3
Results	**Definite-or-probable scaffold thrombosis (%)**	0.0	0.0	0.0

*Composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization and CABG

Comparison of in-segment LLL in PROGRESS, BIOSOLVE-I and BIOSOLVE-II



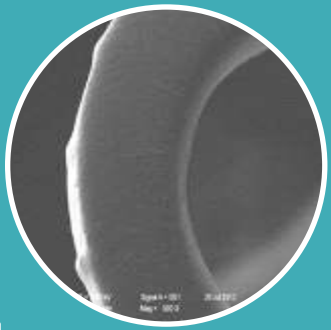
R Erbel et al., Lancet 2007; 369:1869-75,
M Haude et al., Lancet 2013; 381:836-44.

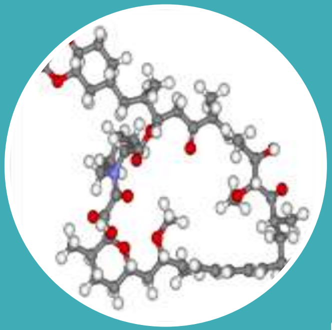
Magmaris – key features

- First clinically proven resorbable Magnesium scaffold
- Compelling safety data[1]
- Better deliverability than leading polymeric scaffolds[2]
- ~95% of Magnesium resorbed at 12 months[3]

[1]BIOSOLVE-II
[2] Bench testing, BIOTRONIK data on file
[3] Pre-clinical trial. BIOTRONIK data on file

Magmaris – the first clinically proven magnesium bioresorbable scaffold





BIOlute

Backbone

Mg alloy
Tantalum markers

6-crown & 2-link design

150 µm strut thickness and width

~95% of Magnesium resorbed at 12 months

Coating

PLLA

PLLA degrades ≥ 24 months*

Proven technology

Drug

Limus drug

1.4 µg/mm²

Controlled drug release up to 90 days

Delivery system

RX, 0.014”

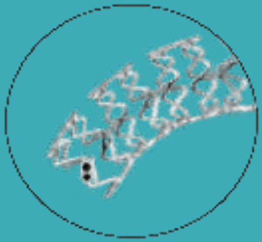
6F compatible

*In Raman Spectroscopy at 24 months, the PLLA characteristic peak pattern in the scaffold coating was partially not detectable; however an average signal of the pattern was detected in all samples.

The Magmaris backbone
CE mark since June 2016

Corrugated rings

Open cell
design for
acute flexibility



2 links, ***90°shifted***

Uniform flexibility
in all 3D directions
of the vessel

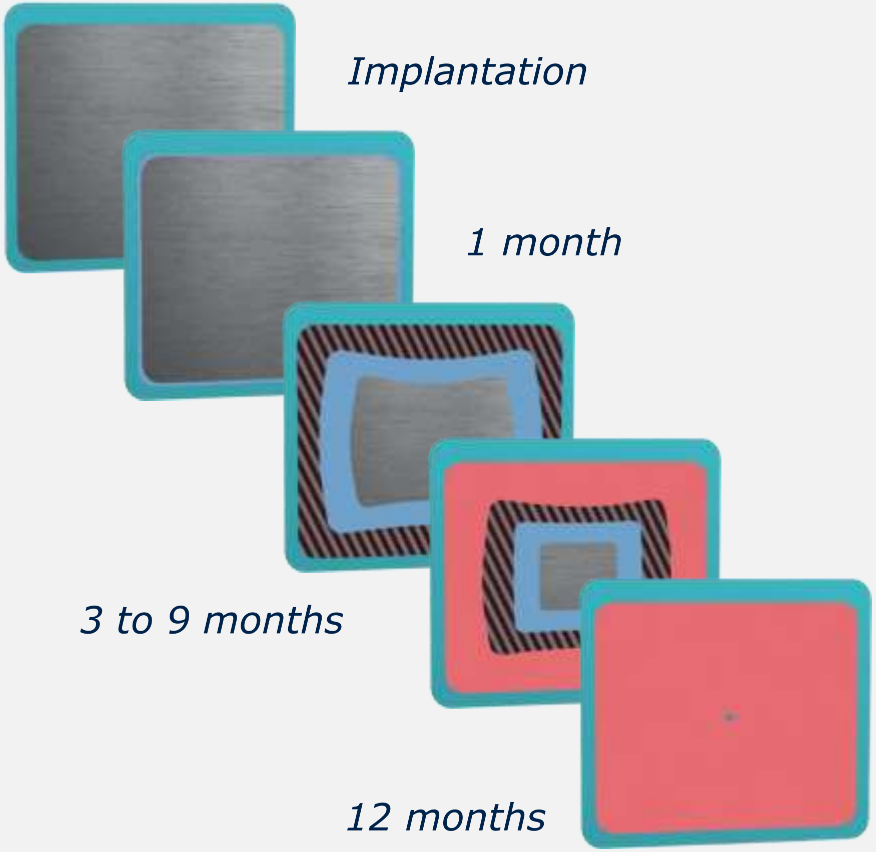
6 crown design

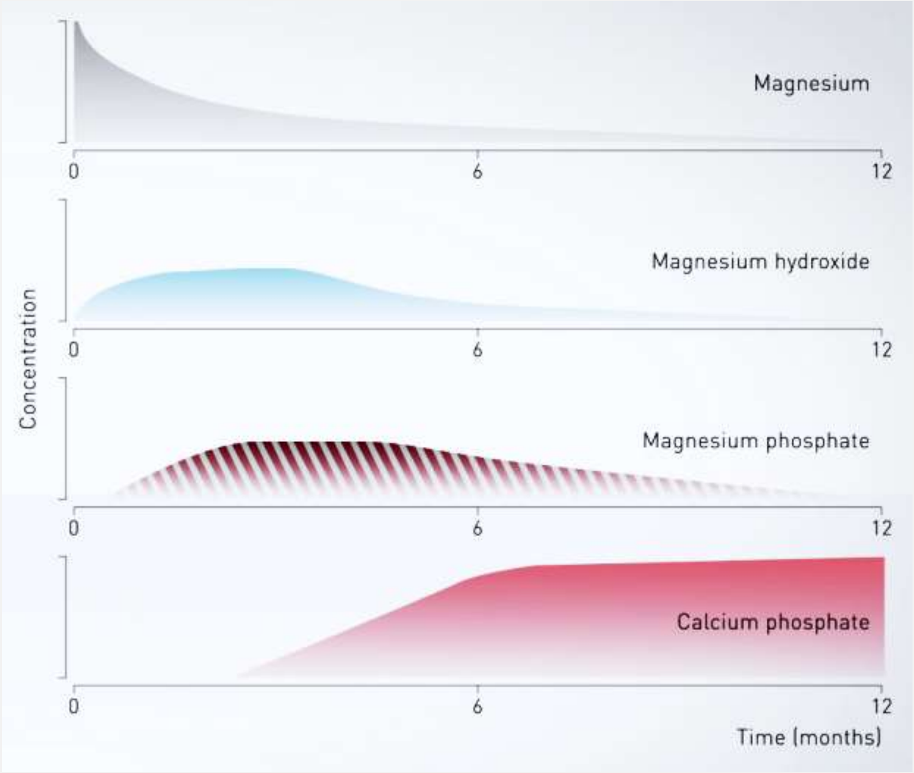
Radial support

Strut dimension
150x150µm

Radial support

Resorption process of the magnesium backbone



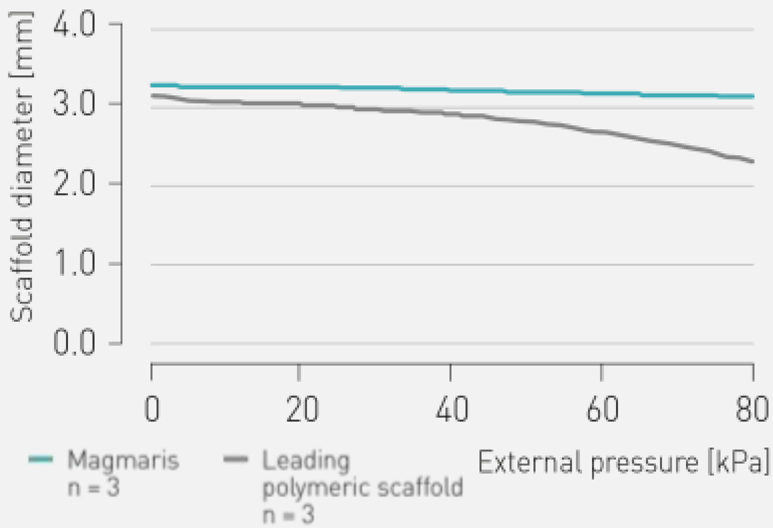


The graph shows the resorption process of Magnesium with the intermediate steps of Magnesium hydroxide and Magnesium phosphate until the moment where only a footprint (amorphous Calcium phosphate) is left.

Magmaris backbone features: radial resistance and acute recoil

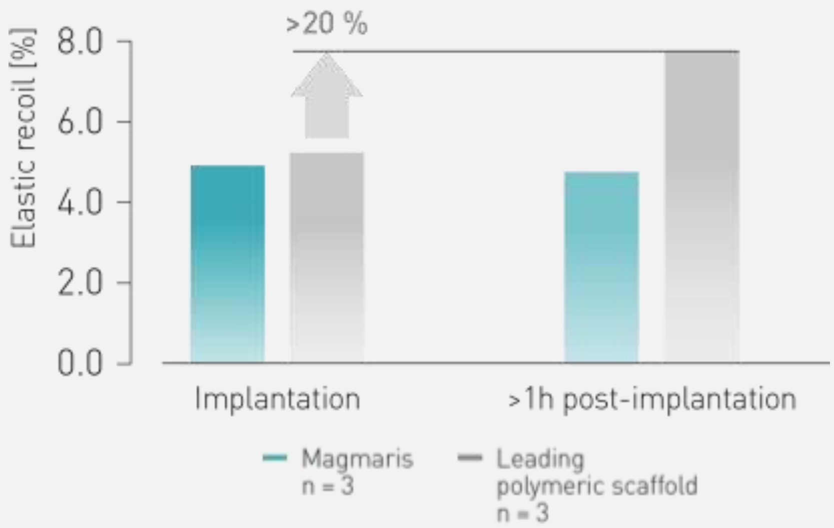
Radial resistance

Strong radial resistance: Magmaris has no significant diameter change under increasing physiological pressure, whereas leading polymeric scaffold diameter is decreasing under increasing pressure



Acute recoil

No recoil increase: Conventional leading polymeric scaffold diameter decrease >20% within the first hour

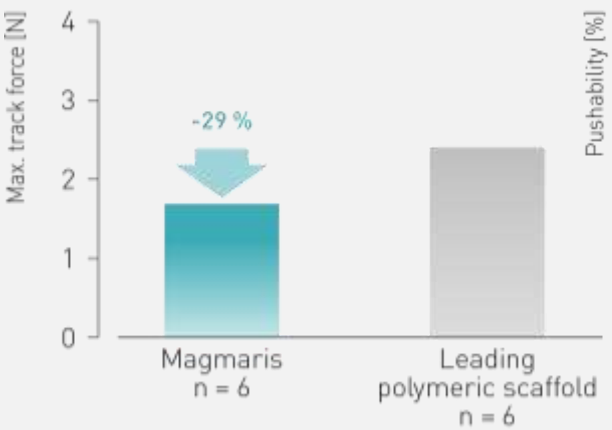


Test set up by IIB; BIOTRONIK data on file

Magmaris deliverability: trackability, pushability and crossability

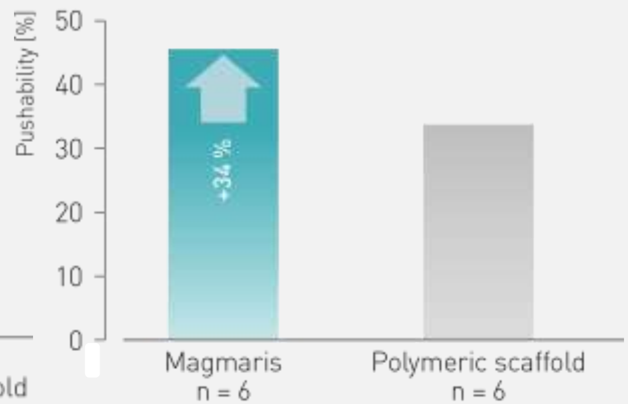
Trackability

Better trackability in tortuous anatomy: Magmaris has 29% less peak force compared to the leading polymeric scaffold



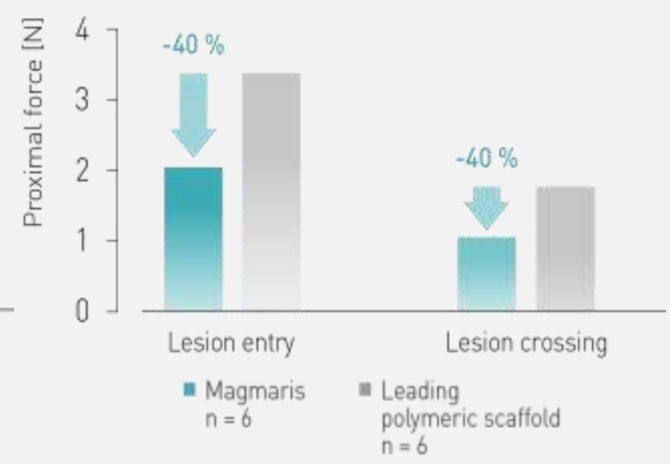
Pushability

Better pushability: Magmaris has 34% more force transmitted from hub to tip compared to the leading polymeric scaffold



Crossability

Better lesion crossing: Magmaris needs up to 40% lower lesion entry and crossing force compared to the leading polymeric scaffold



Test set up by IIB; BIOTRONIK data on file

Magmaris shows a rapid endothelial coverage

Preclinical test

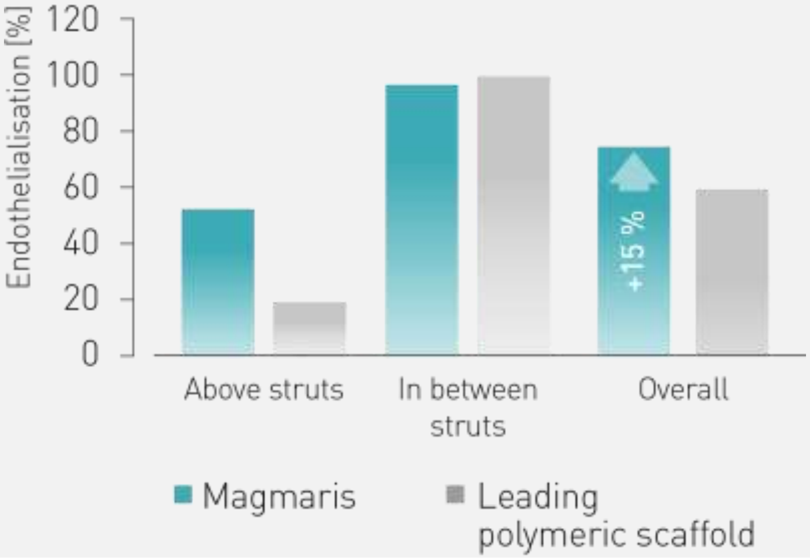
In a rabbit study, endothelialisation was evalutated with SEM* 28 days after implantation. Higher endothelialisation is associated with a lower thrombosis risk.

Magmaris

Leading polymeric scaffold

Endothelial coverage at 28 days

Rapid endothelial coverage:
Magmaris shows 15 % better endothel-ialization compared to the leading polymeric scaffold, especially above struts



*SEM=Scanning Electron Microscope
BIOTRONIK data on file

Clinical Outcome until 12-month follow-up

BIOSOLVE-II

	6-Month		12-Month	
	N=120	%	N=118	%
TLF[1]	4	3.3	4	3.4
Cardiac death	1[2]	0.8	1[2]	0.8
Target vessel MI	1	0.8	1	0.8
Clinically driven TLR	2	1.7	2	1.7
CABG	0	0.0	0	0
Definite-or-probable scaffold thrombosis	0	0.0	0	0.0

1. Composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization or CABG
2. A 58-year old man (CV RF: smoking, hypertension and hyperlipidemia, stable angina CCS Class II) was treated with a DREAMS 2G 3.0x20 mm in the distal RCA. The patient experienced an unwitnessed death 134 days after the procedure. Since a cardiac cause could not be ruled out, the independent Clinical Event Committee adjudicated the event as a cardiac death.

Conclusion

- Approximately 95% of magnesium of the Magmaris scaffold is resorbed at 1-year follow-up
- In the BIOSOLVE-II trial, there was no definite or probable scaffold thrombosis at 6 or 12-month follow-up[1,2]
- Cautious use with careful selection of patients and lesions is currently recommended to optimize patient outcomes after treatment with this technology[3]
- Magmaris is the first clinically proven magnesium bioresorbable scaffold
- Magmaris offers a viable alternative to polymeric scaffold
- Ongoing and future studies will better define the role of this bioresorbable scaffold

1. Haude M. et al. Lancet 2016;387:31-9.
2. Haude M. et al. Eur Heart J 2016; 37: 2701-9.
3. Fajadet J. et al. EuroIntervention 2016; 12: 828-33.