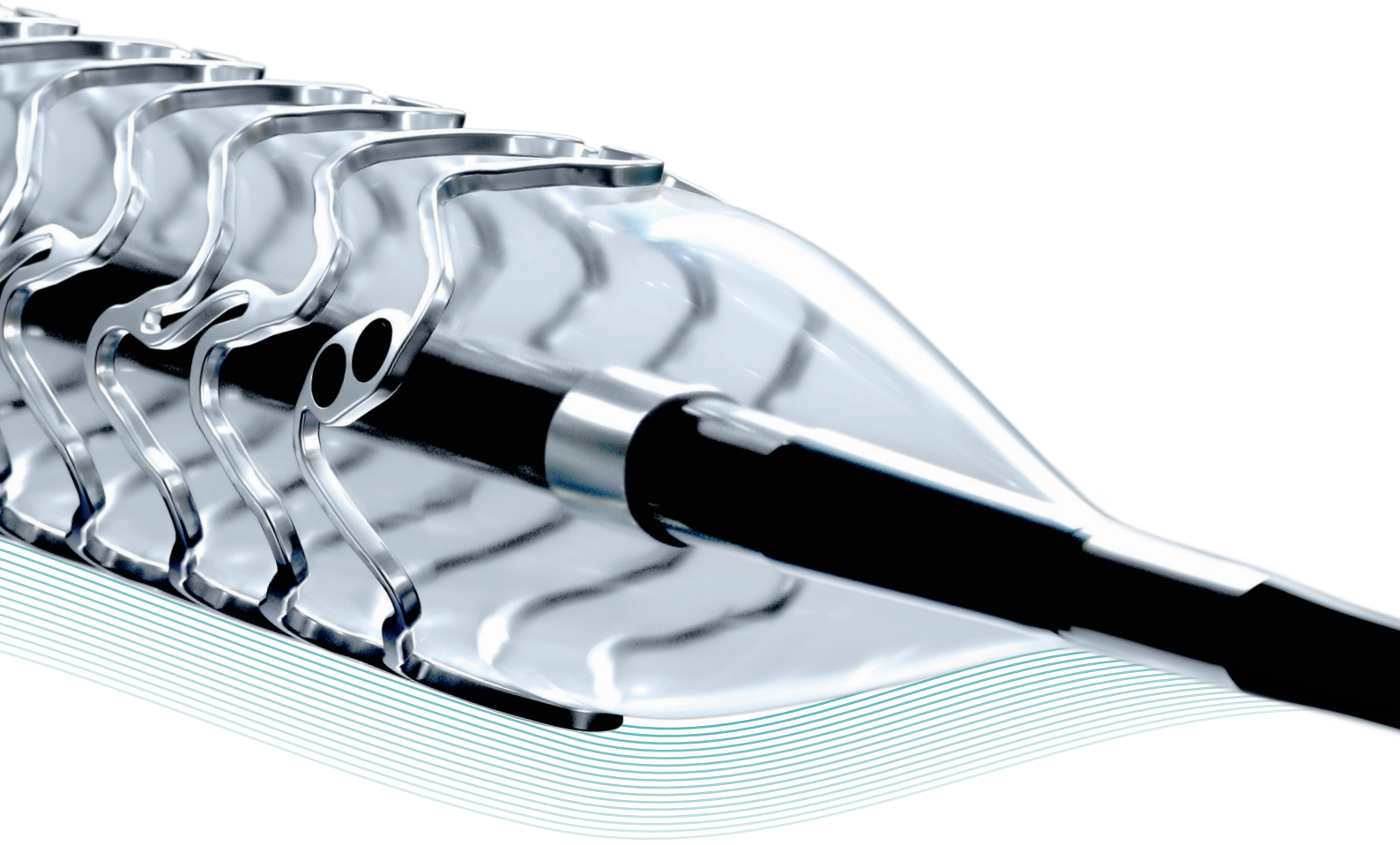
Vascular Intervention // Coronary
Resorbable Magnesium Scaffold (RMS)

Magmaris®

In a class of its own



- Confirmed clinical safety and efficacy*
- Fast Magnesium resorption time
- Better deliverability

Magmaris Mg RMS

* Based on BIOSOLVE-II, -II/-III and -IV, for patient populations see study details.

BIOTRONIK
excellence for life

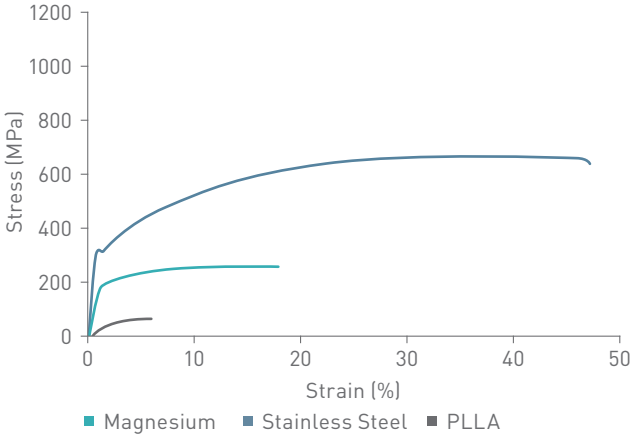
Magmaris
In a class of its own

Why Magnesium?

Magnesium alloy: favorable mechanical properties of a robust Magnesium backbone

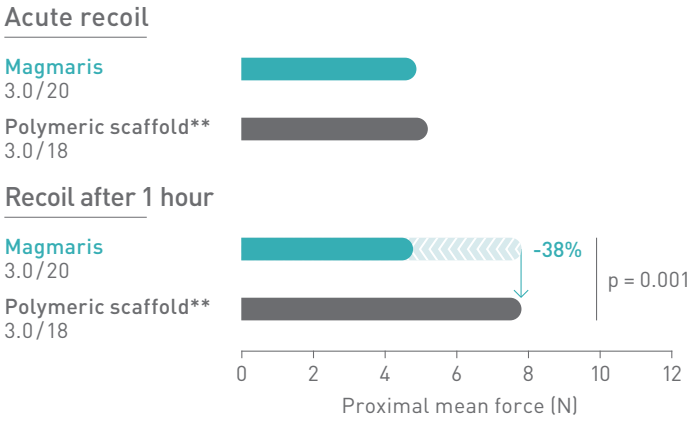
Robust Magnesium backbone

The mechanical strength of Magnesium is superior to polymers like PLLA.[1]



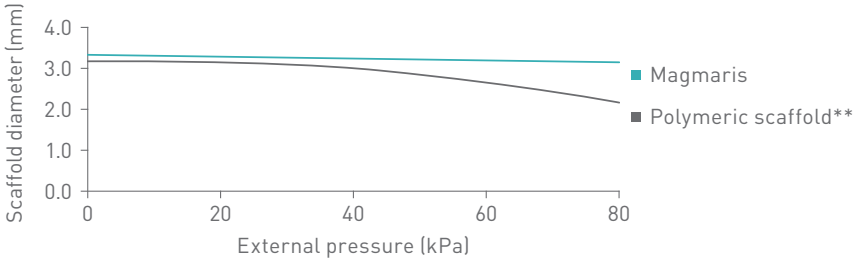
Stable recoil

Magmaris has a 38% lower recoil after 1 hour.[2]



Strong radial resistance

No significant diameter change under increasing physiological pressure.[3]



Rounded edges and smooth surface

The electropolished rounded edges and smooth surface of the Magmaris scaffold generate less resistance during delivery of the scaffold to the lesion.

**Absorb, Abbott

Confirmed clinical safety and efficacy*

Confidence through evidence

Magmaris	24 months (First cohort) **BIOSOLVE-IV[4] (n=1,071)**	6.6% TLF**	0.5%° Definite/probable scaffold thrombosis
Magmaris	36 months **BIOSOLVE-II/-III[5] (n=174)**	6.3% TLF**	0.0% Definite/probable scaffold thrombosis
Magmaris	60 months **BIOSOLVE-II[6] (n=121)**	8.0% TLF **	0.0% Definite/probable scaffold thrombosis
Precursor	36 months **BIOSOLVE-I[7] (n=46)**	6.6% TLF**	0.0% Definite/probable scaffold thrombosis

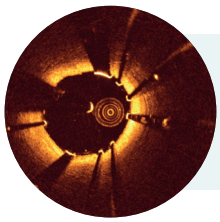
* Based on BIOSOLVE-II, -II/-III and -IV, for patient populations see study details.

** Target Lesion Failure (TLF) defined as a composite of Cardiac Death, Target-Vessel Myocardial Infarction (TV-MI), emergent Coronary Artery Bypass Grafting (CABG), and Clinically-Driven Target Lesion Revascularization (CD-TLR).

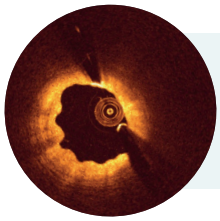
° Four out of five cases having early antiplatelet or anticoagulant interruption at post procedure.

Fast resorption time

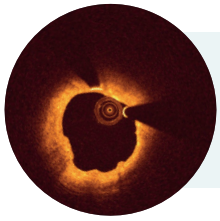
~95% of Magnesium resorbed at 12 months[8]



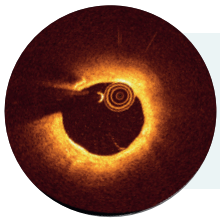
OCT post implantation[9]
Immediately after implantation, struts are well apposed to the vessel wall.



OCT at 6 months[9]
While the Magnesium resorption process continues, endothelialization progresses.



OCT at 12 months[9]
At 12 months after implantation, the Magnesium resorption is almost completed.



OCT at 36 months[9]
At 36 months the lumen is well preserved with a homogeneous surface.

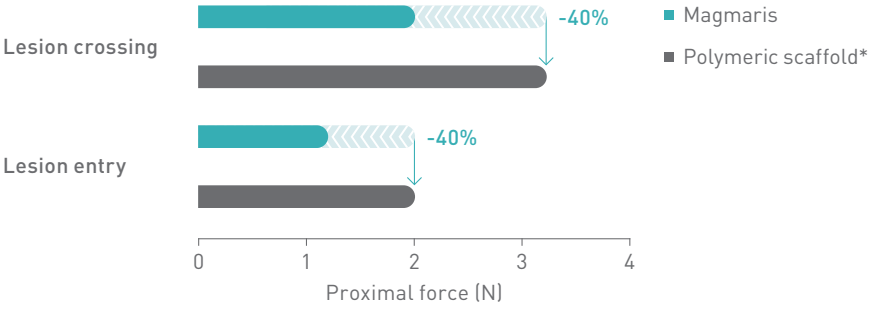
~95%
resorbed at
12 months[8]

A more deliverable scaffold

More than 70% of physicians who have used Magmaris RMS in clinical practice have rated the device to be better than a polymeric scaffold.[10]*

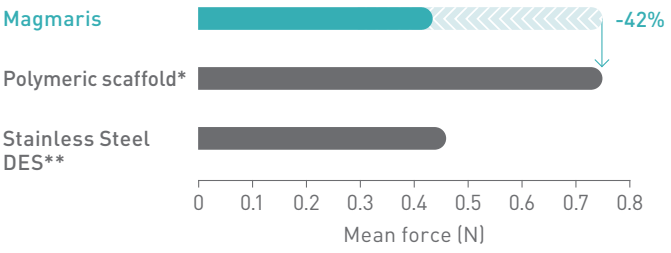
Better lesion crossing

Up to 40% lower lesion entry and crossing force.[11]



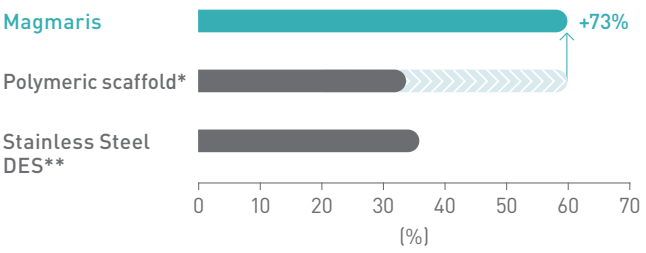
Better trackability in tortuous anatomy

42% less peak force.[12]



Better pushability

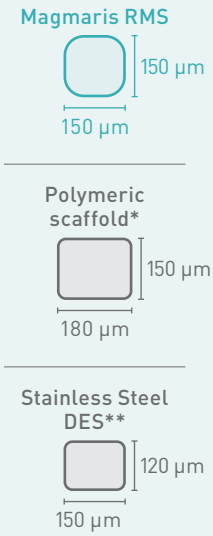
73% more force transmitted from hub to tip.[13]



>70%
of physicians rate Magmaris better than polymeric scaffolds[10]*

*Absorb, Abbott
**BioFreedom, Biosensors

Stent/Scaffold strut thickness in perspective



Magmaris®

Indicated for de novo coronary artery lesions.*

Vascular
Intervention
Coronary

Technical Data

Scaffold	
Scaffold material	Proprietary Magnesium alloy
Markers	Two tantalum markers at each end
Active coating	**BIO**lute (resorbable Poly-L-Lactide (PLLA) eluting a limus drug)
Drug dose	1.4 µg/mm²
Strut thickness/width	150 µm/150 µm
Maximum expandable diameter	Nominal Diameter +0.6 mm

Delivery system	
Catheter type	Rapid exchange
Recommended guide catheter	6F (min. I.D. 0.070")
Crossing profile	1.5 mm
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi-crystalline polymer
Coating (distal shaft)	Dual coated
Marker bands	Two swaged platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	2.9F
Nominal pressure (NP)	10 atm
Rated burst pressure (RBP)	16 atm

Compliance Chart

		Balloon diameter (mm)	
		ø 3.00	ø 3.50
Nominal Pressure (NP)	atm**	10	10
	ø (mm)	3.00	3.54
Rated Burst Pressure (RBP)	atm**	16	16
	ø (mm)	3.29	3.82

**1 atm = 1.013 bar

Ordering Information

Scaffold ø (mm)	Scaffold length (mm)		
	15	20	25
3.00	412526	412527	412528
3.50	412529	412530	412531

1-3, 10-13. BIOTRONIK data on file; 4. Torzewski J. Safety and performance of Magmaris at 24-month follow-up of BIOSOLVE-IV. Presented at: eEuroPCR; 2021; virtual congress. ClinicalTrials.gov: NCT02817802; 5. Haude M, Ince H, Kische S, et al. Sustained safety and performance of the second-generation sirolimus-eluting absorbable metal scaffold: Pooled outcomes of the BIOSOLVE-II and -III trials at 3 years. Cardiovascular Revascularization Medicine. 2020. doi: 10.1016/j.carrev.2020.04.006; 6. Haude M. Long-term clinical data of the BIOSOLVE-II study with the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries - BIOSOLVE-II. Presented at: e-Course PCR; June 25, 2020; Paris, France. ClinicalTrials.gov: NCT01960504; 7. Haude M, Erbel R, Erne P, et al. Safety and performance of the Drug-Eluting Absorbable Metal Scaffold (DREAMS) in patients with de novo coronary lesions: 3-year results of the prospective, multicenter, first-in-man BIOSOLVE-I trial. EuroIntervention. 2016; 12: e160-6. doi: 10.4244/EIJY16M06_01; 8. Joner M, Ruppelt P, Zumstein P, et al. Preclinical Evaluation of Degradation Kinetics and Elemental Mapping of First and Second Generation Bioresorbable Magnesium Scaffolds. EuroIntervention. 2018 Feb 20. pii: EIJ-D-17-00708. doi: 10.4244/EIJ-D-17-00708. [Epub ahead of print]; 9. BIOSOLVE-II case, GER443-012. Courtesy of M. Haude, Lukaskrankenhaus Neuss, Germany 2015.

BIOSOLVE-I,-II and -IV based on Kaplan-Meier failure estimate analysis including censored observations. The pooled analysis of BIOSOLVE-II and -III based on frequency analysis. The 36-month data of BIOSOLVE-II and -III analysis reflecting a period up to 1'125 days at 3 years. Magmaris and BIOlute are trademarks or registered trademarks of the BIOTRONIK Group of Companies. Absorb is a trademark or registered trademark of the Abbott Group of Companies. BioFreedom is a trademark or registered trademark of Biosensors International Group, Ltd.

*Indication as per IFU.

426444/G/Jun_2021

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life