

Vascular Intervention // **Coronary**
Resorbable Magnesium Scaffold (RMS)

Magmaris[®]



Compelling safety data



Fast Magnesium resorption time



Better deliverability



BIOTRONIK
excellence for life

Magmaris

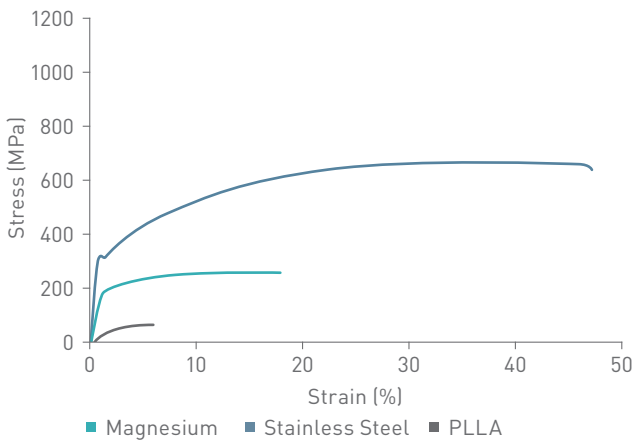
Compelling safety data, fast Magnesium resorption time and better deliverability.

Why Magnesium?

Magnesium alloy: favorable mechanical properties of a robust Magnesium backbone

Robust Magnesium backbone

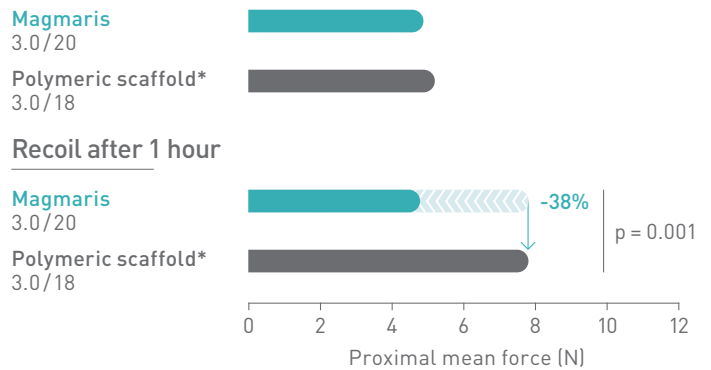
The mechanical strength of Magnesium is superior to polymers like PLLA.¹



Stable recoil

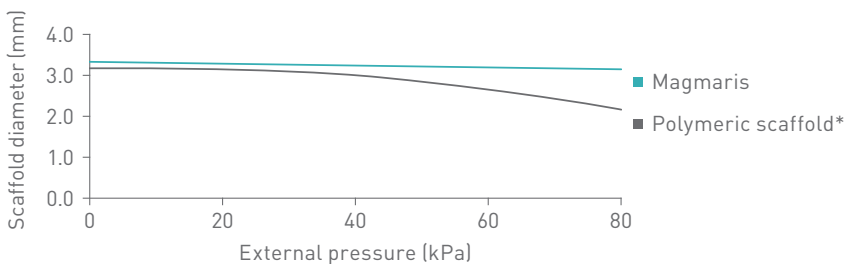
Magmaris has a 38% lower recoil after 1 hour.²

Acute recoil



Strong radial resistance

No significant diameter change under increasing physiological pressure.³

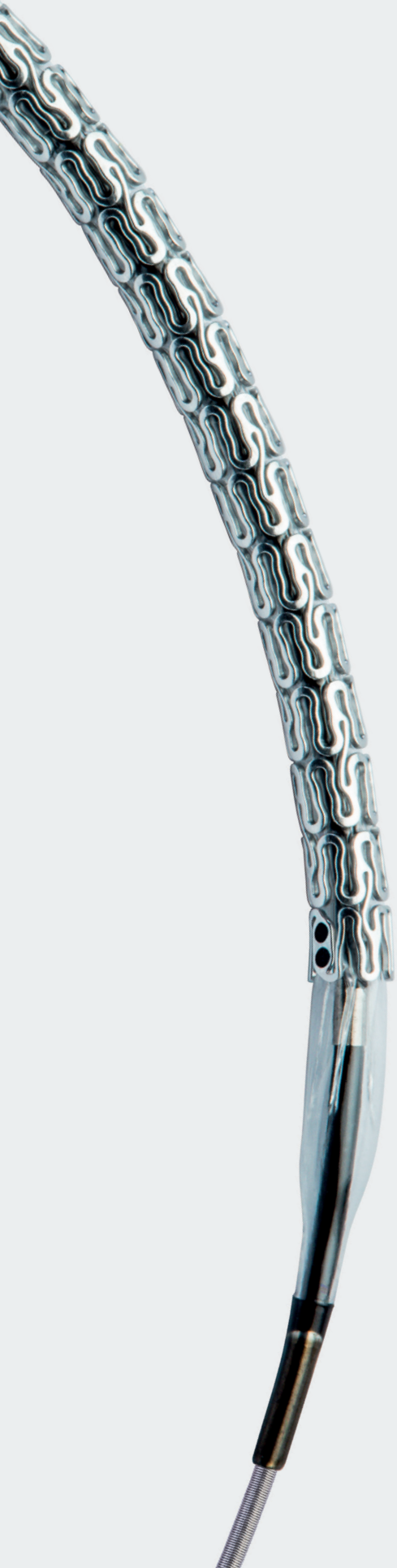


*Absorb, Abbott

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.





Compelling safety data

Confidence through evidence

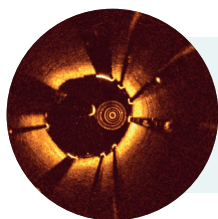
Magmaris	12 months (First cohort) BIOSOLVE-IV⁴ (n=1,071) 4.3% TLF*	0.5%** Definite/probable scaffold thrombosis
	36 months BIOSOLVE-II/-III⁵ (n=174) 6.4% TLF*	0.0% Definite/probable scaffold thrombosis
	36 months BIOSOLVE-II⁶ (n=117) 6.8% TLF*	0.0% Definite/probable scaffold thrombosis
Precursor	36 months BIOSOLVE-I⁷ (n=46) 6.6% TLF*	0.0% Definite/probable scaffold thrombosis

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

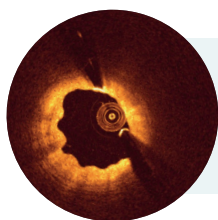
** Four out of five cases having early DAPT or anticoagulant interruption at post procedure.

Fast resorption time

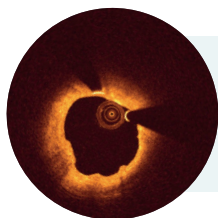
~95% of Magnesium resorbed at 12 months⁸



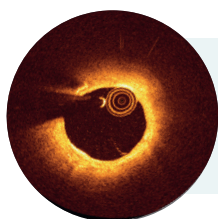
OCT post implantation⁹
Immediately after implantation, struts are well apposed to the vessel wall.



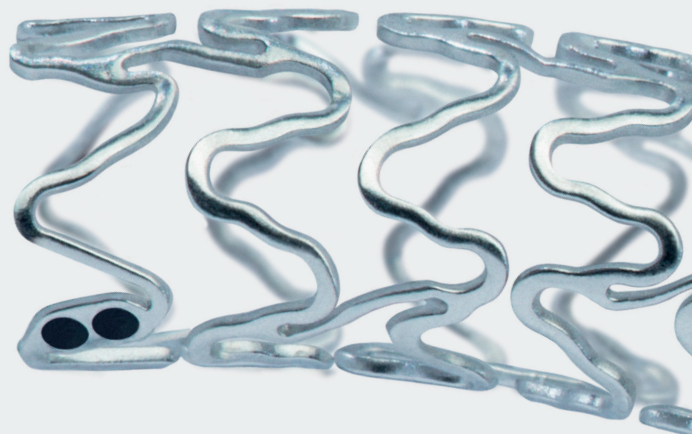
OCT at 6 months⁹
While the Magnesium resorption process continues, endothelialization progresses.



OCT at 12 months⁹
At 12 months after implantation, the Magnesium resorption is almost completed.



OCT at 36 months⁹
At 36 months the lumen is well preserved with a homogeneous surface.



~95%
resorbed at
12 months⁸



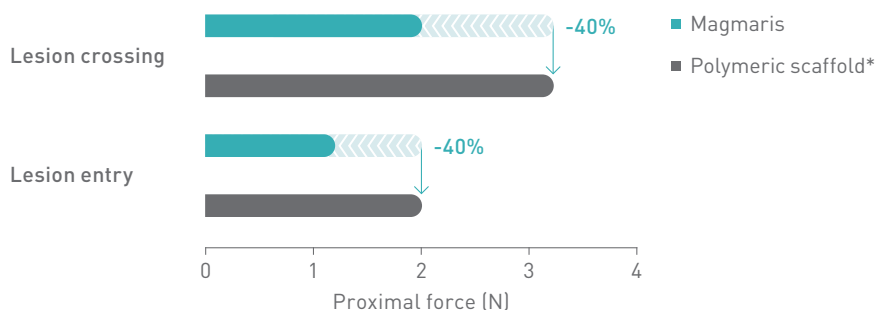


A more deliverable scaffold

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*}

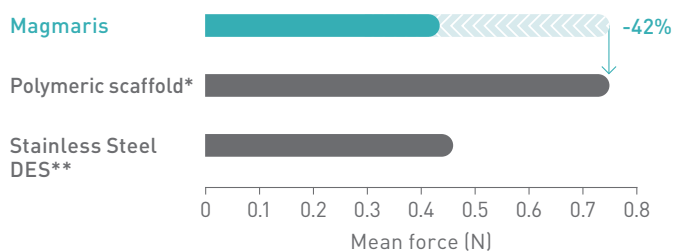
Better lesion crossing

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



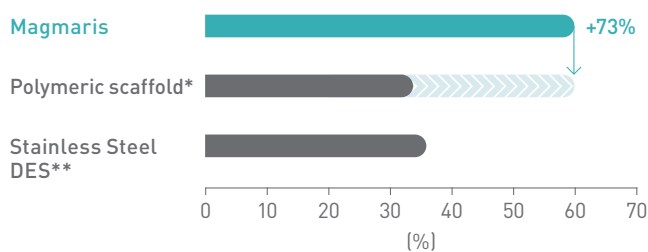
Better trackability in tortuous anatomy

42% less peak force.¹²



Better pushability

73% more force transmitted from hub to tip.¹³



Stent/Scaffold strut thickness in perspective

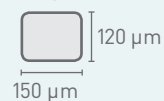
Magmaris RMS



Polymeric scaffold*



Stainless Steel DES**



>70%
of physicians rate
Magmaris better
than polymeric
scaffolds^{10*}



*Absorb, Abbott
**BioFreedom, Biosensors

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	BIOLute (resorbable Poly-L-Lactide (PLLA) eluting a limus drug)		
		Drug dose	1.4 µg/mm ²		
		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. Verheye S. Safety and Performance of the Resorbable Magnesium Scaffold, Magmaris in a Real World Setting - First Cohort Subjects at 12-month Follow-up of the BIOSOLVE-IV Registry. Presented at: TCT; September 25, 2019; San Francisco, USA. NCT02817802; (n = 2,054; 1,075 patients presented); 5. Haude M. Safety and Clinical Performance of the Drug Eluting Absorbable Metal Scaffold in the Treatment of Subjects with de Novo Lesions in Native Coronary Arteries at 36-month Follow-up BIOSOLVE-II and -III, Presented at: TCT; September 27, 2019; San Francisco, USA; 6. Haude M, Ince H, Abizaid A. Long-term clinical data and multimodality imaging analysis 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: EuroPCR; May 23, 2018; Paris, France; 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-e166; 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.

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*Indication as per IFU

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