Vascular Intervention // Coronary
Resorbable Magnesium Scaffold (RMS)

Magmaris®

- Compelling safety data
- Fast Magnesium resorption time
- Better deliverability

Magmaris
Mg
RMS

BIOTRONIK
excellence for life

Compelling safety data

Confidence through evidence

Magmaris	12 months (First cohort) **BIOSOLVE-IV[4] (n=1,071)** 4.3% TLF*	0.5%** Definite/probable scaffold thrombosis
Magmaris	24 months **BIOSOLVE-II/III[5] (n=180)** 5.5% TLF*	0.0% Definite/probable scaffold thrombosis
Magmaris	36 months **BIOSOLVE-II[6] (n=117)** 6.8% TLF*	0.0% Definite/probable scaffold thrombosis
Precursor	36 months **BIOSOLVE-I[7] (n=46)** 6.6% TLF*	0.0% Definite/probable scaffold thrombosis

* Target Lesion Failure (TLF) is defined as a composite of Cardiac death and unknown 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.

Magmaris

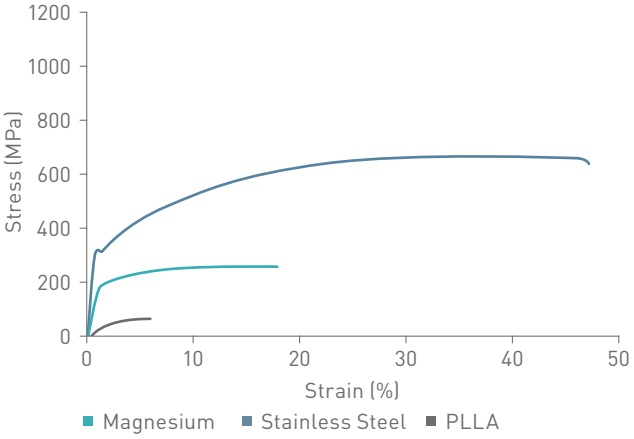
Compelling safety data, fast Magnesium resorption time and better deliverability.

Why Magnesium?

Magnesium alloy: favourable mechanical properties of a robust Magnesium backbone

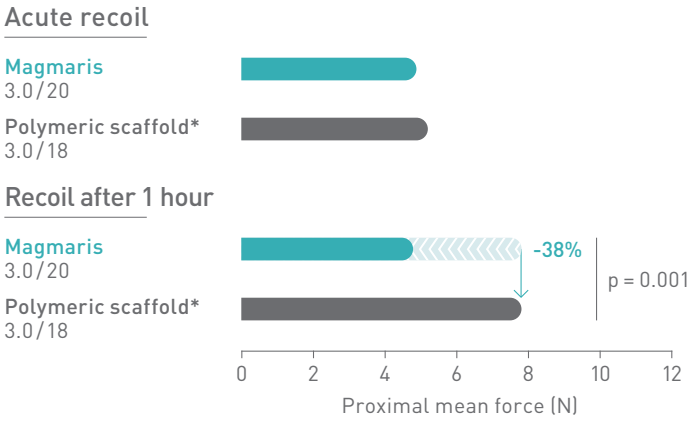
Robust Magnesium backbone

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



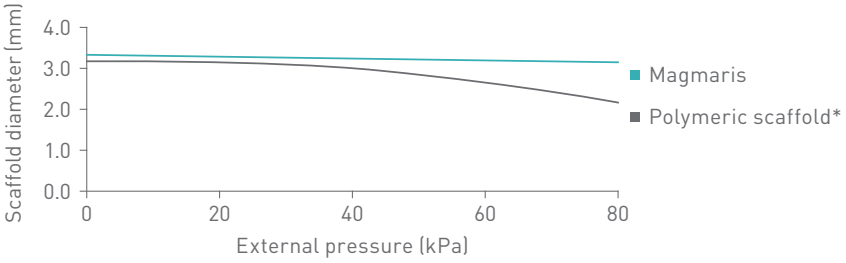
Stable recoil

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



Strong radial resistance

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



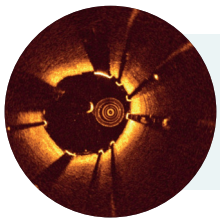
*Absorb, Abbott

Rounded edges and smooth surface

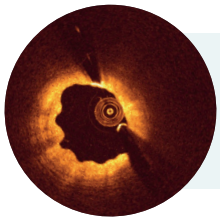
The electropolished rounded edges and smooth surface of the Magmaris scaffold generate less resistance during delivery of the scaffold to the lesion.

Fast resorption time

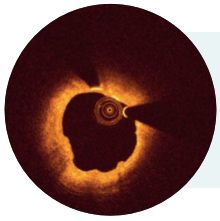
~95% of Magnesium resorbed at 12 months[8]



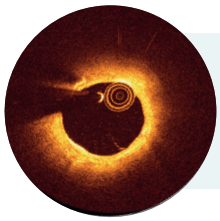
OCT post implantation[9]
Immediately after implantation, struts are well apposed to the vessel wall.



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.

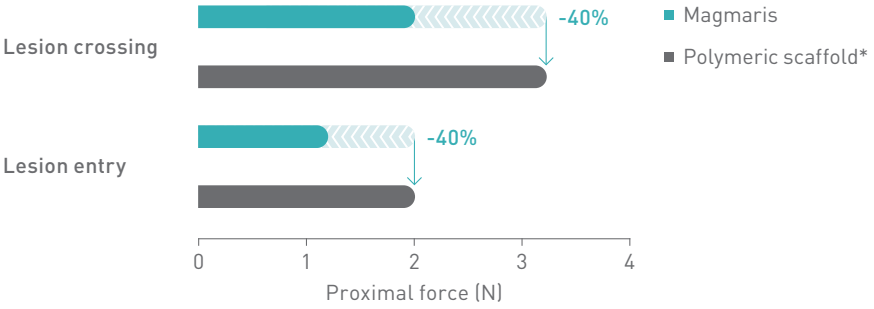
~95%
resorbed at
12 months[8]

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]*

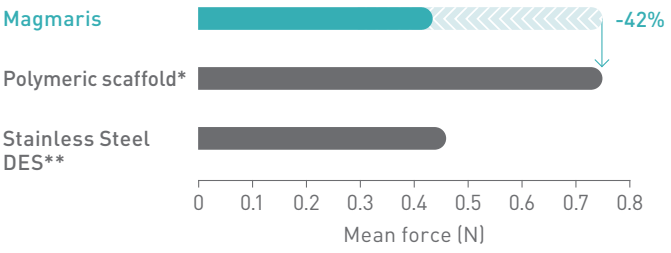
Better lesion crossing

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



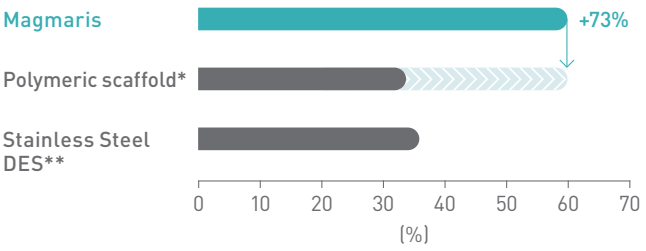
Better trackability in tortuous anatomy

42% less peak force.[12]



Better pushability

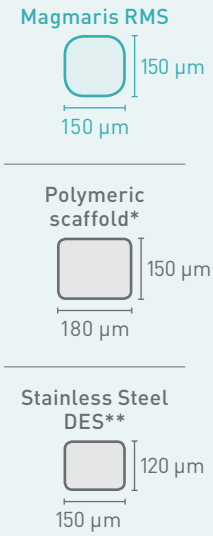
73% more force transmitted from hub to tip.[13]



>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. 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 = 2054; 1075 patients presented); 5. 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; 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.

*Indication as per IFU

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