



Compelling safety data



Fast Magnesium resorption time



Better deliverability



Technical data / ordering info

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

BIOTRONIK
excellence for life

Magmaris

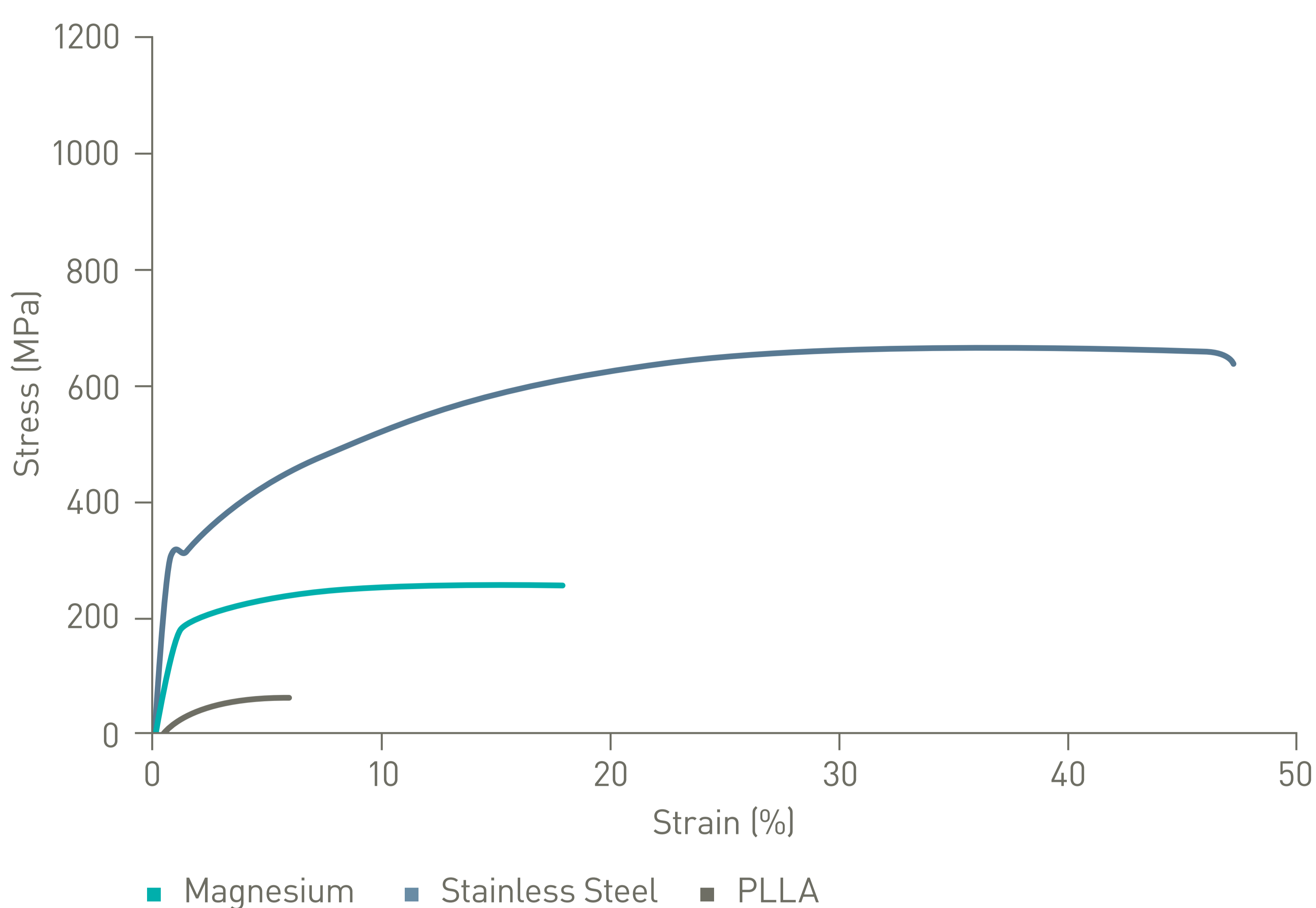


Why Magnesium?

Magnesium alloy: favourable mechanical properties of a robust Magnesium backbone

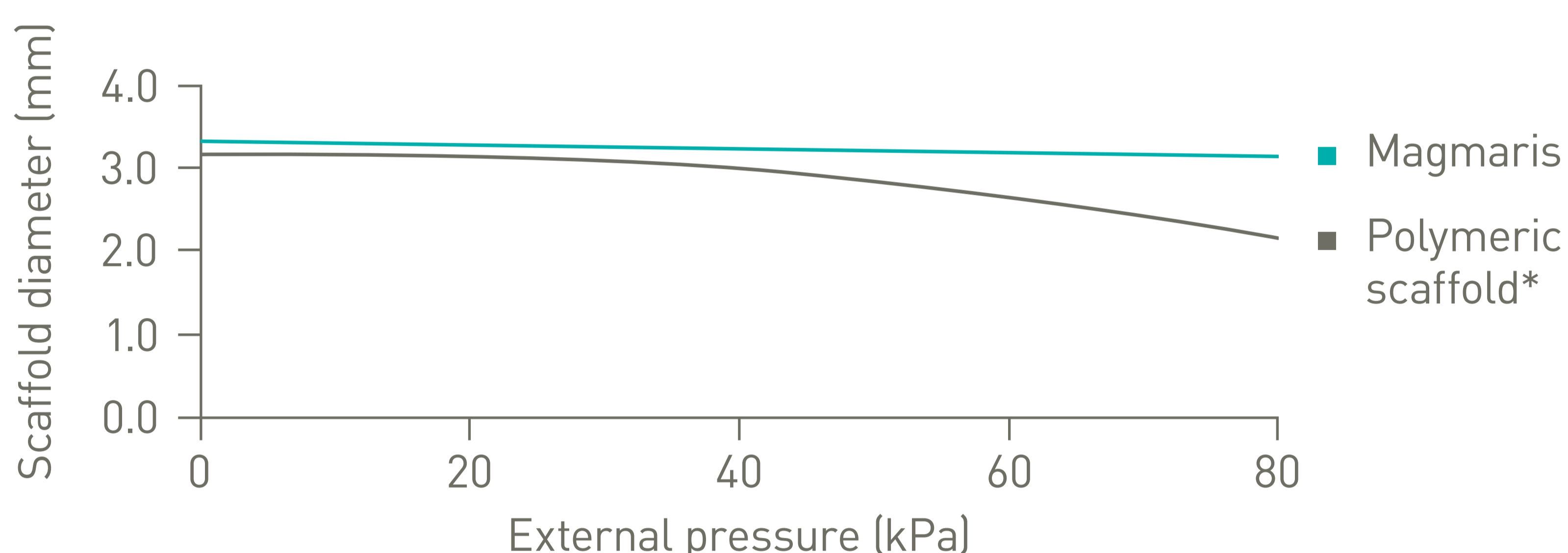
Robust Magnesium backbone

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



Strong radial resistance

No significant diameter change under increasing physiological pressure.³



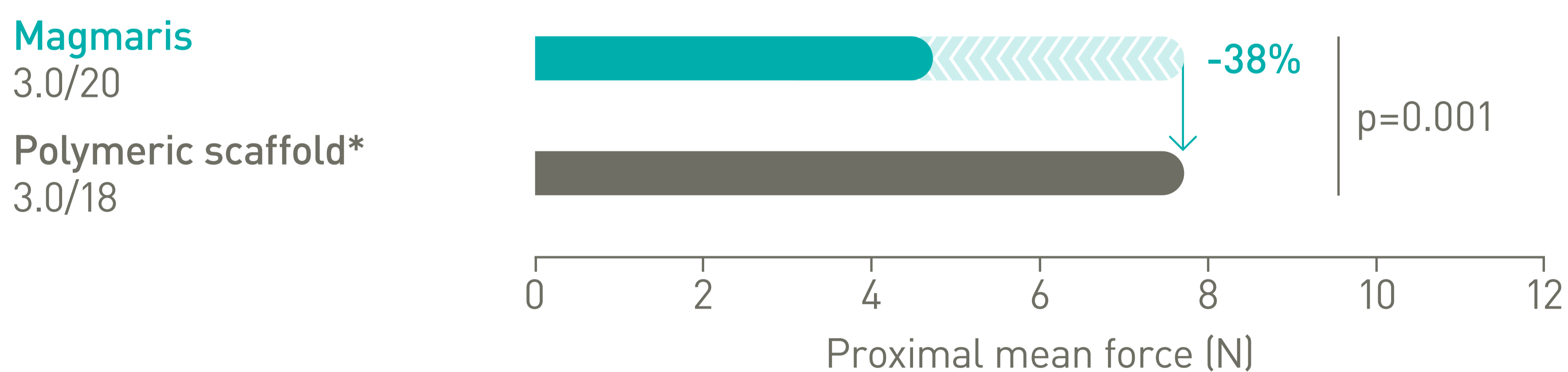
Stable recoil

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

Acute recoil



Recoil after 1 hour



*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 BIOSOLVE-IV ⁴ (n=198) 4.6% TLF*	0.5%** Definite/probable scaffold thrombosis
	12 months BIOSOLVE-II/III ^{5, 6} (n=180) 3.3% TLF*	0.0% Definite/probable scaffold thrombosis
	36 months BIOSOLVE-II ⁷ (n=117) 6.8% TLF*	0.0% Definite/probable scaffold thrombosis
Precursor	36 months BIOSOLVE-I ⁸ (n=44) 6.6% TLF*	0.0% Definite/probable scaffold thrombosis

*Target Lesion Failure. Composite of cardiac and unknown death, target vessel myocardial infarction, clinically driven target lesion revascularization and CABG.

**Patient underwent MIDCAB with subsequent DAPT interruption 5 days after the procedure.

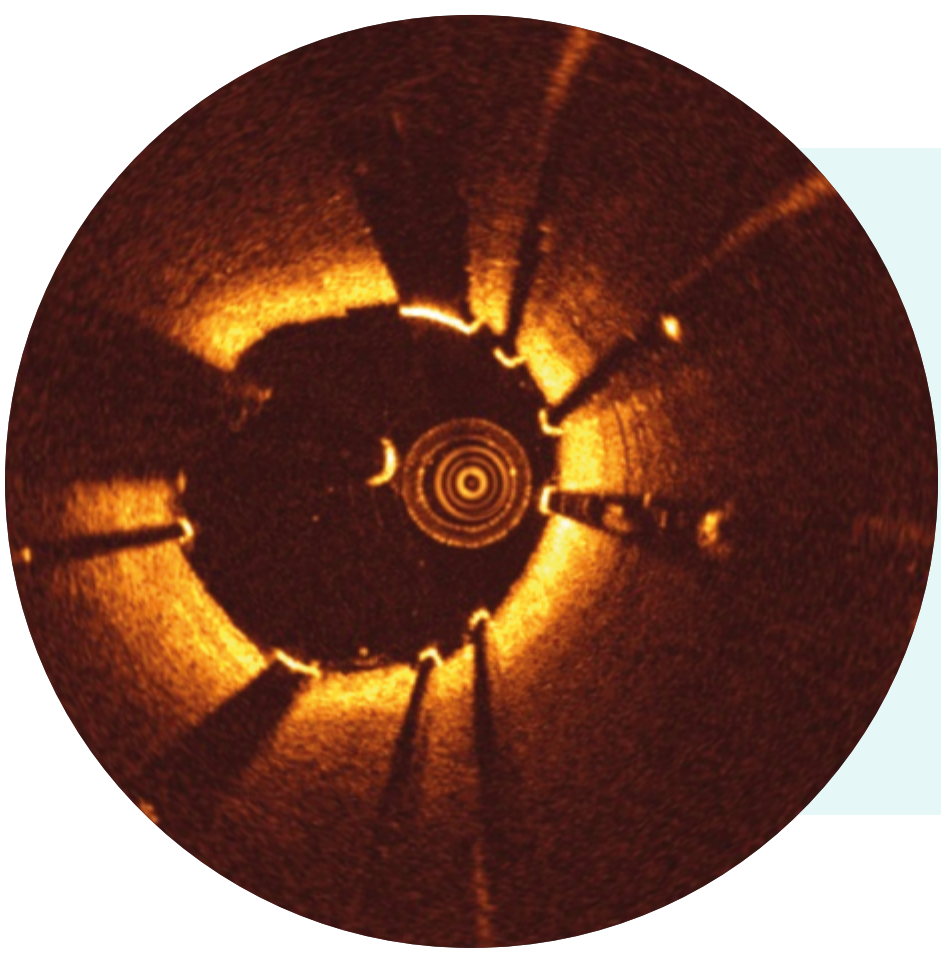




~95%
resorbed at
12 months⁹

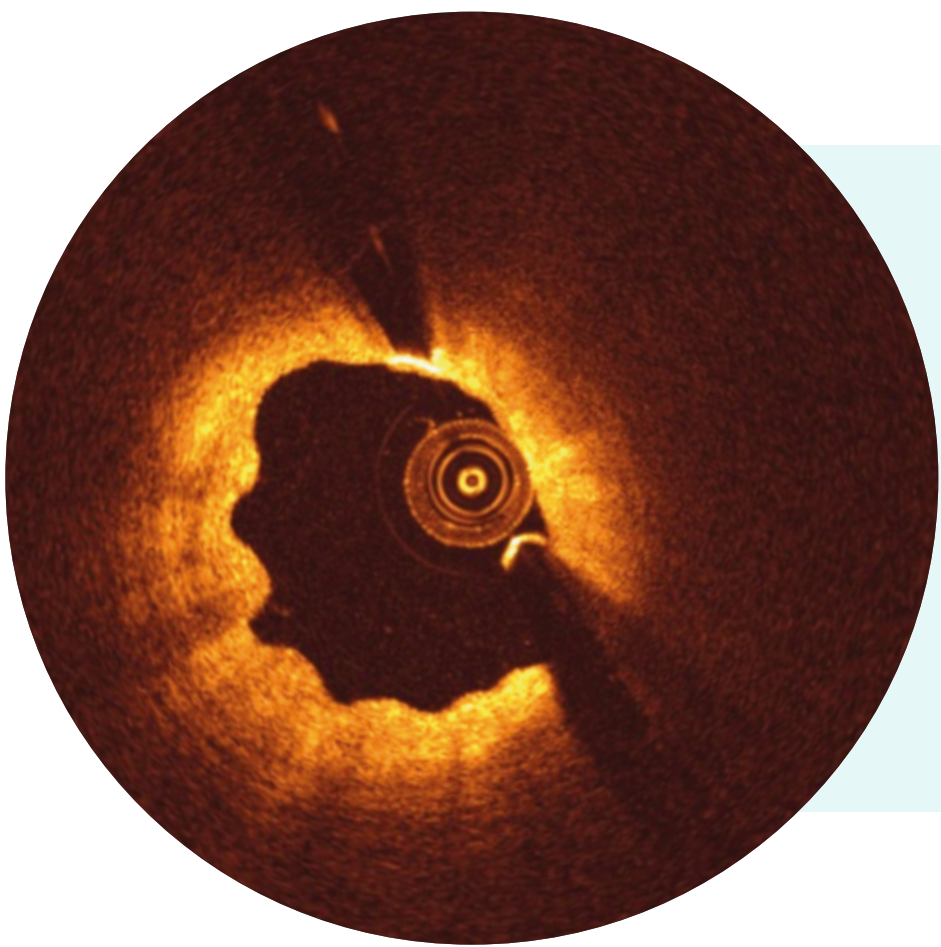
Fast resorption time

~95% of Magnesium resorbed at 12 months⁹



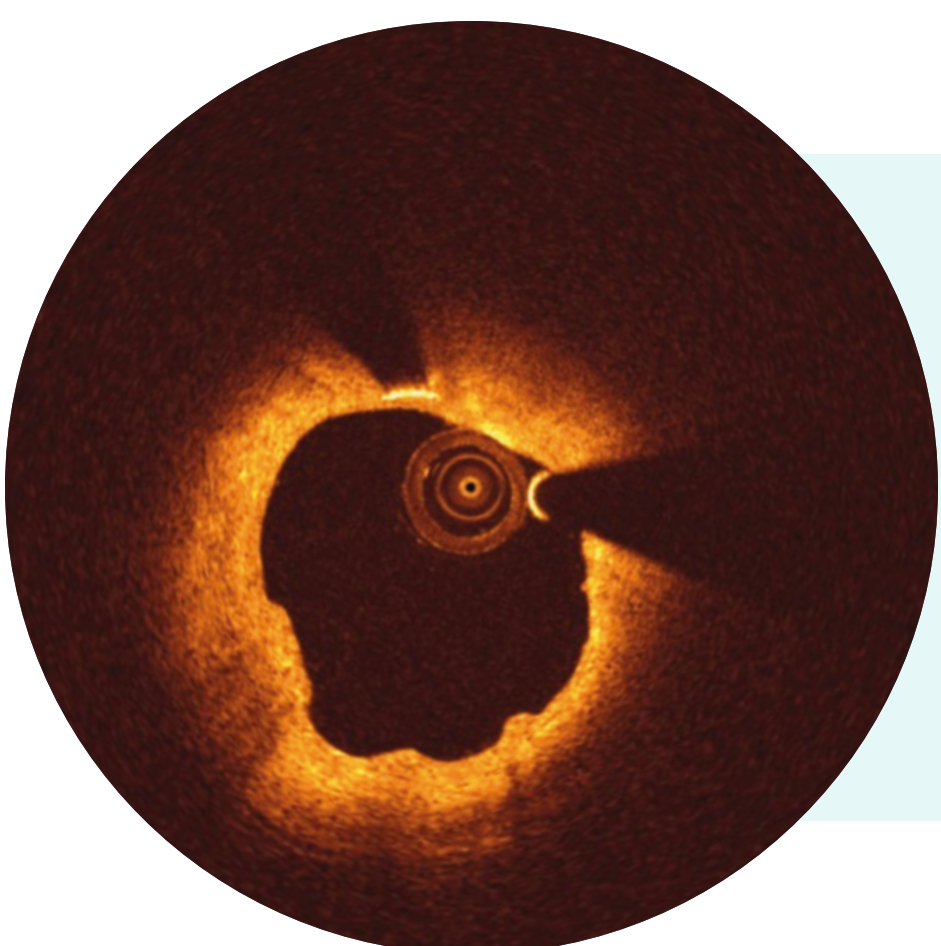
OCT post implantation¹⁰

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



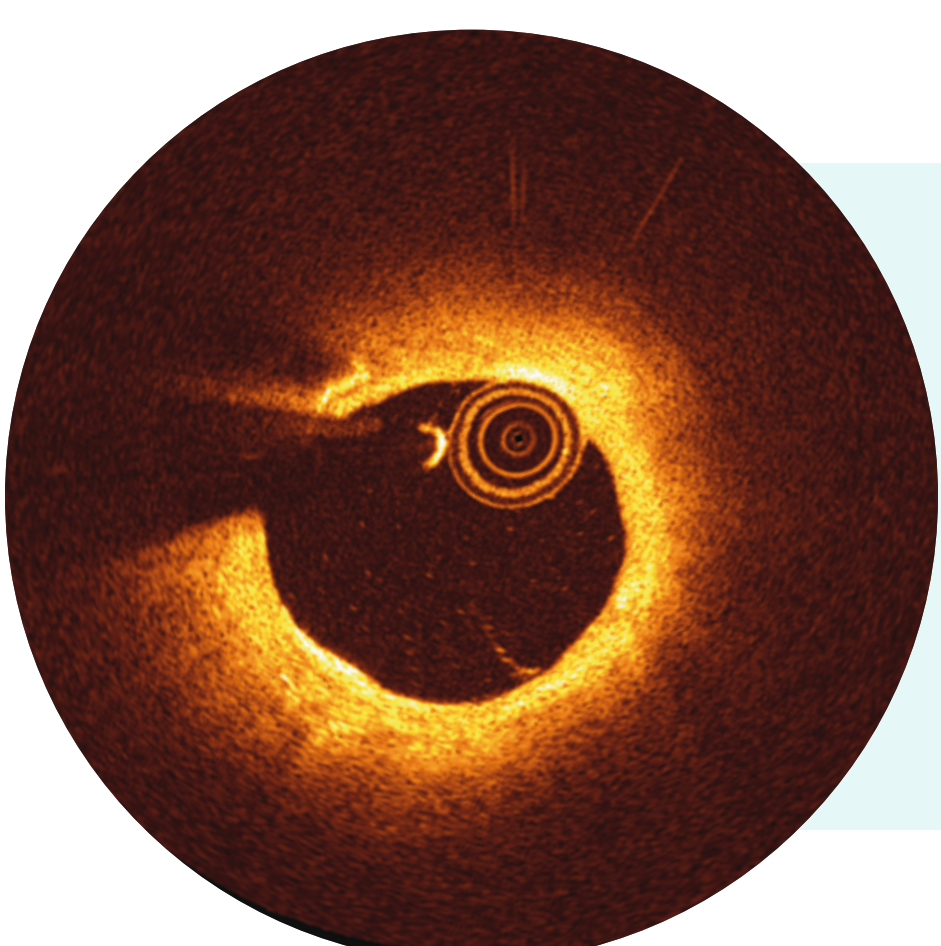
OCT at 6 months¹⁰

While the Magnesium resorption process continues, endothelialization progresses.



OCT at 12 months¹⁰

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



OCT at 36 months¹⁰

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

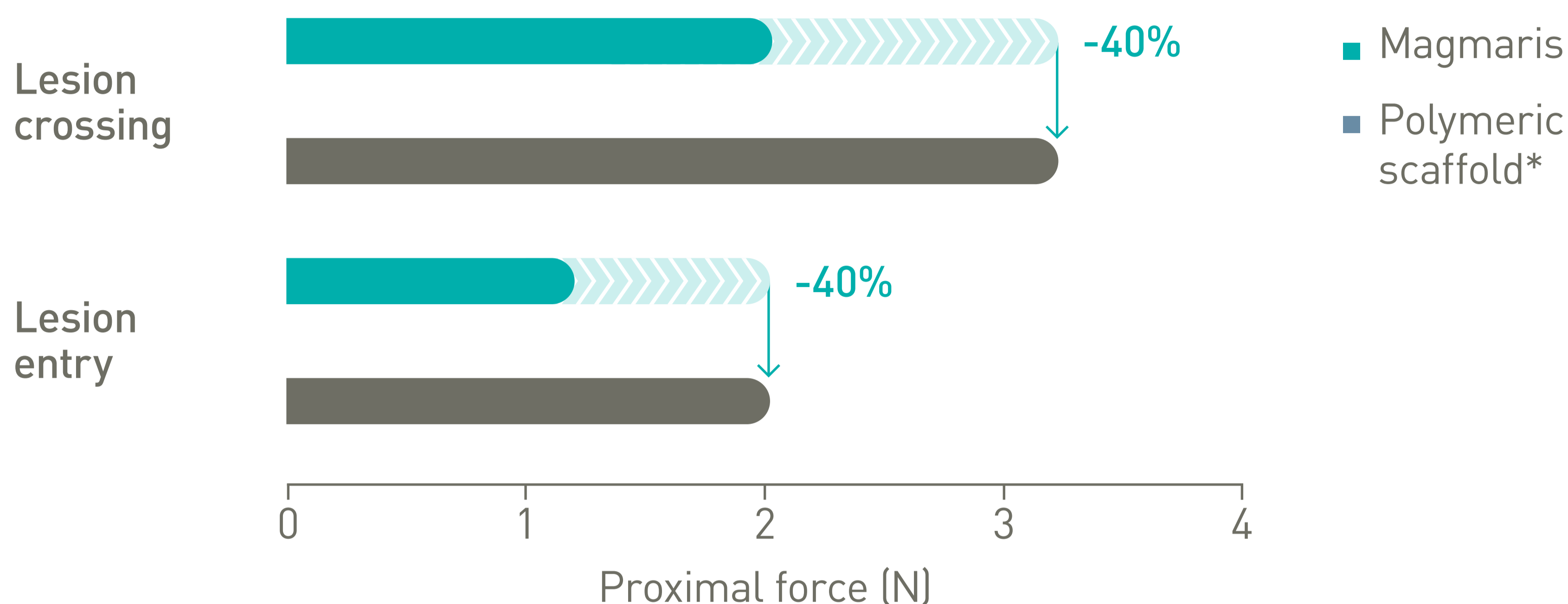


A more deliverable scaffold

More than 70% of physicians who have used Magmaris RMS in clinical practice have rated the device to be better than a polymeric scaffold.^{11*}

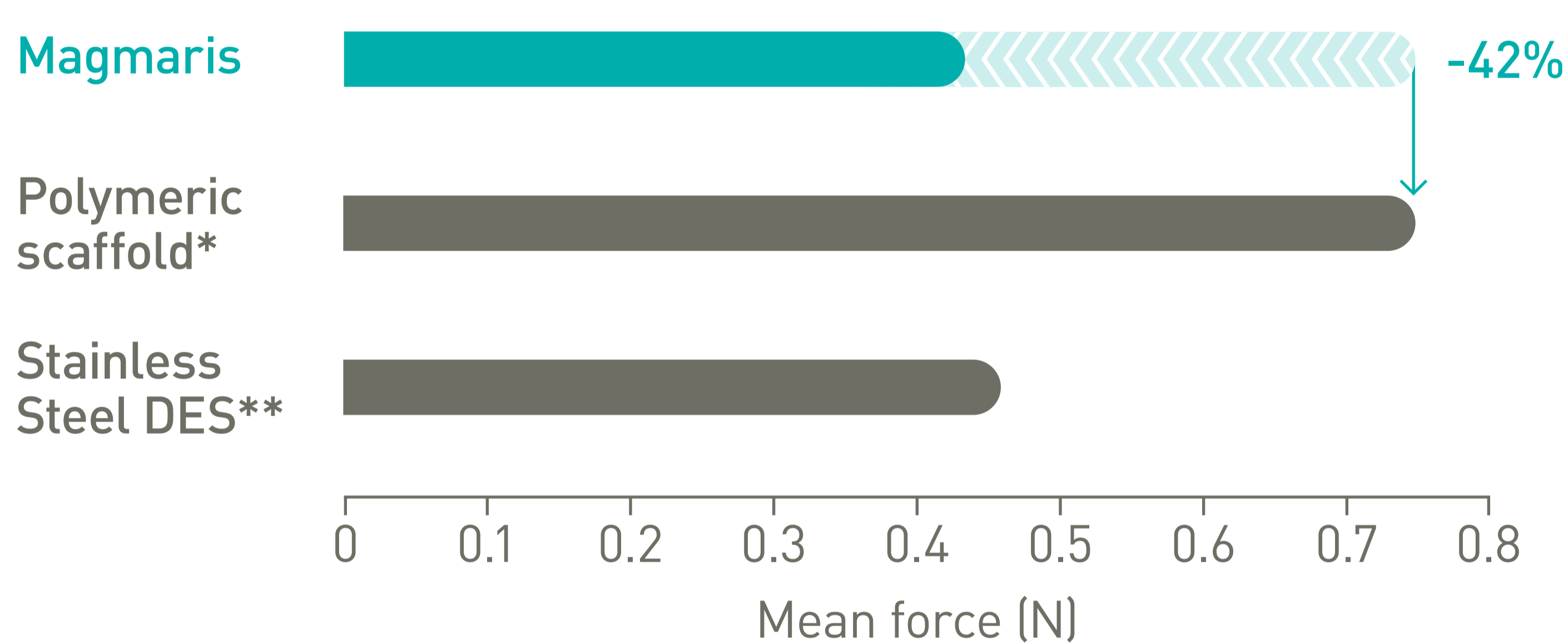
Better lesion crossing

Up to 40% lower lesion entry and crossing force.¹²



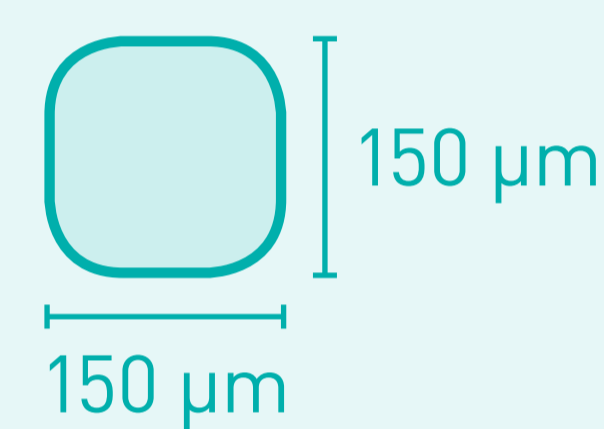
Better trackability in tortuous anatomy

42% less peak force.¹³

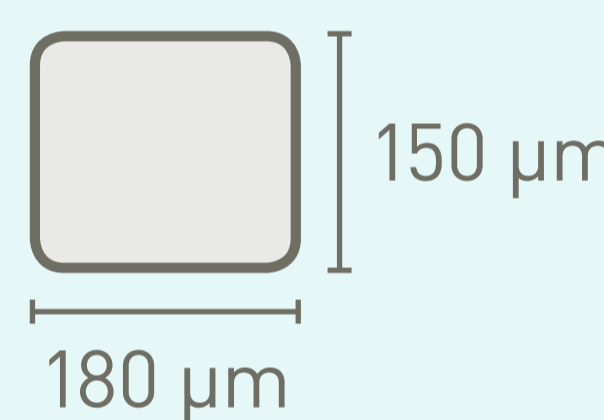


Stent/Scaffold strut thickness in perspective

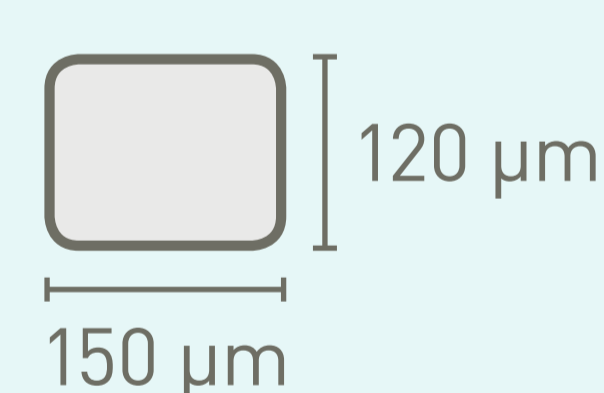
Magmaris RMS



Polymeric scaffold*

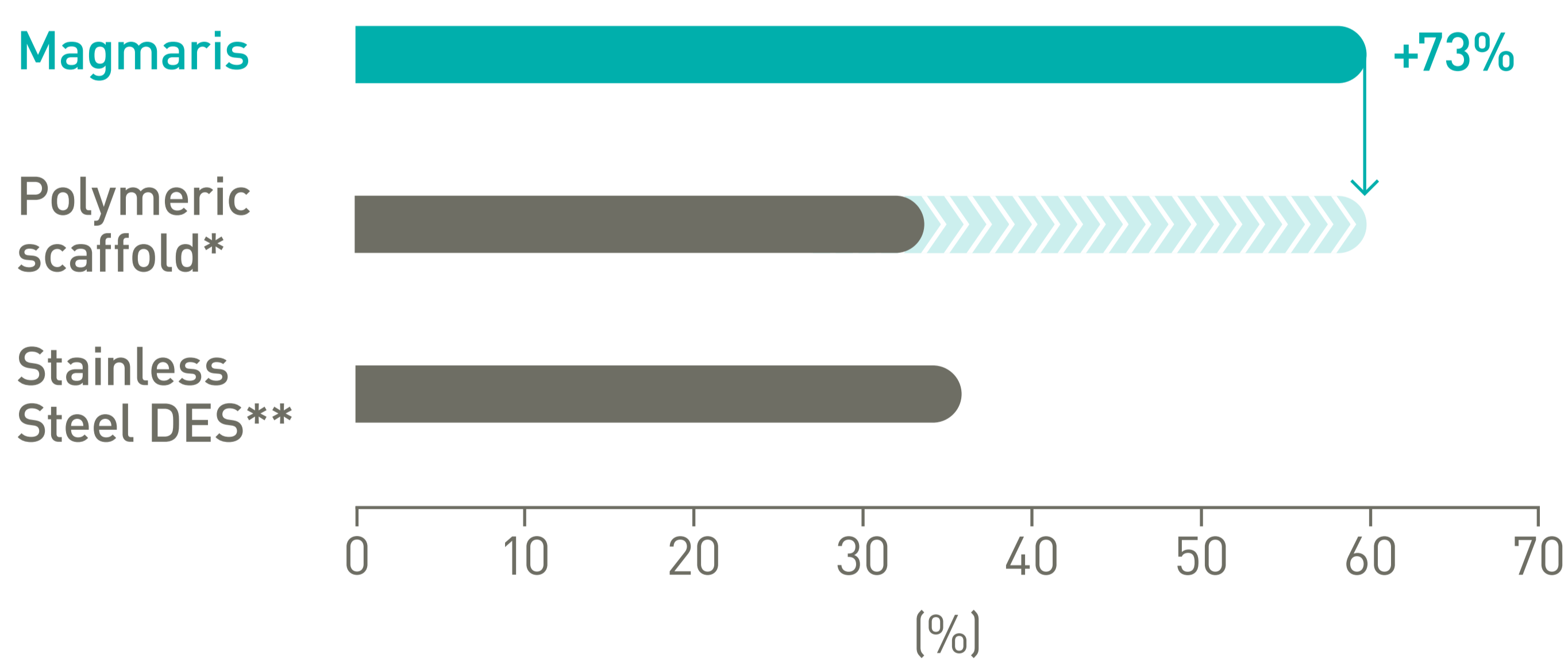


Stainless Steel DES**



Better pushability

73% more force transmitted from hub to tip.¹⁴



* Absorb, Abbott
 ** BioFreedom, Biosensors



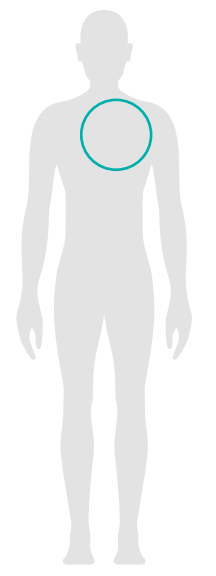
>70%
 of physicians rate
 Magmaris better
 than polymeric
 scaffolds^{11*}



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
		Rate 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, 11-14. BIOTRONIK data on file; 4. Verheye S. Safety and performance of the resorbable magnesium scaffold, Magmaris in a real world setting - First 200 subjects at 12-month follow-up of the BIOSOLVE-IV registry. Presented at: EuroPCR; May 22, 2018; Paris, France. ClinicalTrials.gov: NCT028; 5. Haude M, Ince H, Kische S, et al. 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 12-month follow-up- BIOSOLVE-II and BIOSOLVE-III. Journal of the American College of Cardiology. 2017; 70(18). DOI: 10.1016/j.jacc.2017.09.071; 6. Waksman R. 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 12-month follow-up- BIOSOLVE-II and BIOSOLVE-III. Presented at : TCT; Oct 31, 2017; Denver, USA; 7. 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; 8. 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(2): e160-6; 9. 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]; 10. 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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