Confirmed clinical safety and efficacy*

Fast Magnesium resorption time

Better deliverability

Technical data / ordering info

Vascular Intervention // Coronary
Resorbable Magnesium Scaffold (RMS)

BIOTRONIK
excellence for life

# Magmaris®

In a class of its own.

Magmaris
Mg
RMS

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

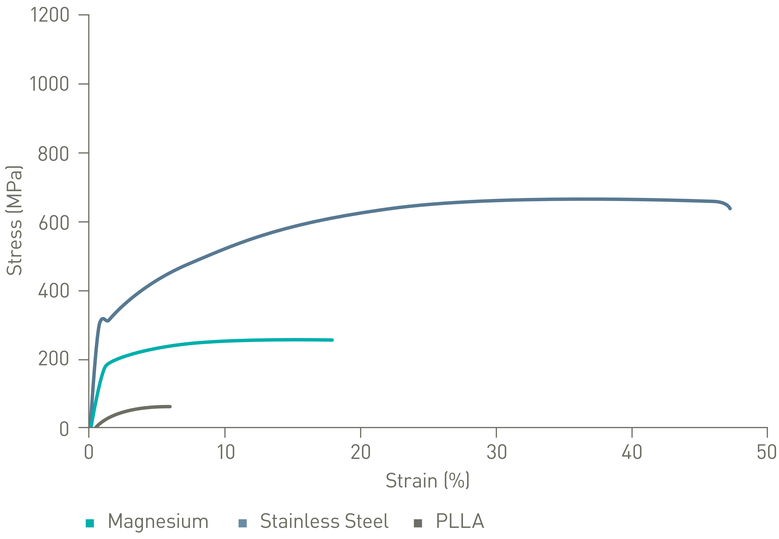
# Magmaris
In a class of its own.

## Why Magnesium?

### Magnesium alloy: favorable mechanical properties of a robust Magnesium backbone

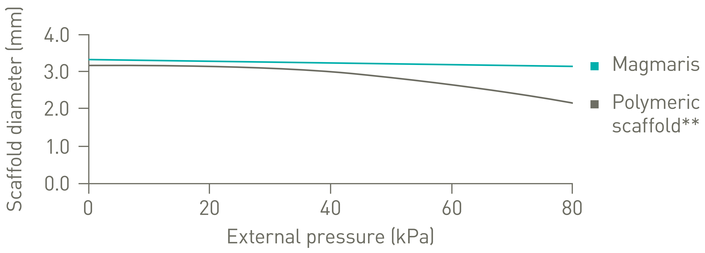
#### Robust Magnesium backbone

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




#### 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

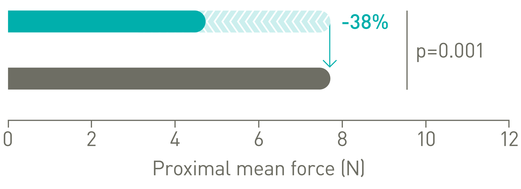
**Magmaris**
3.0/20

**Polymeric scaffold****
3.0/18

#### Recoil after 1 hour

**Magmaris**
3.0/20

**Polymeric scaffold****
3.0/18




**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.

# Confirmed clinical safety and efficacy*

## Confidence through evidence

| | |
|---|---|
| 12 months<br>(Full cohort)<br>BIOSOLVE-IV[4] (n=2,066)<br>**5.0%** TLF◊ | **0.8%**Δ<br>Definite/probable scaffold thrombosis |
| 36 months<br>(First cohort)<br>BIOSOLVE-IV[5] (n=1,075)<br>**8.2%** TLF◊ | **0.6%**°<br>Definite/probable scaffold thrombosis |
| 36 months<br>BIOSOLVE-II/-III[6](n=184)<br>**6.3%** TLF◊ | **0.0%**<br>Definite/probable scaffold thrombosis |
| 60 months<br>BIOSOLVE-II[7] (n=123)<br>**8.0%** TLF◊ | **0.0%**<br>Definite/probable scaffold thrombosis |

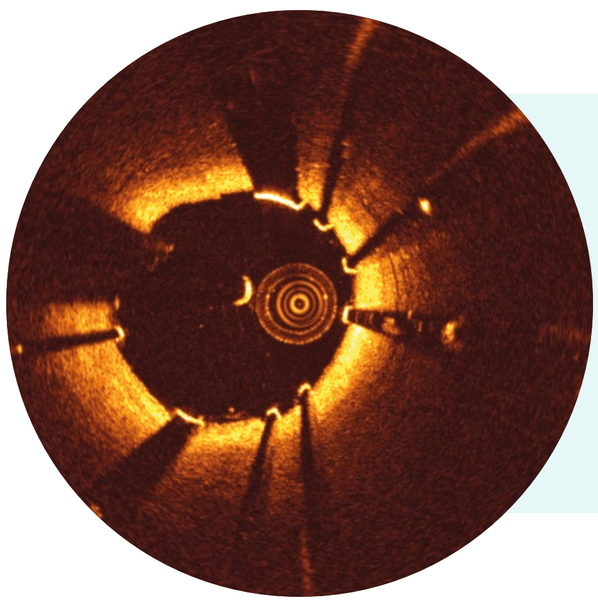
All n-values represent the actual number of patients enrolled.

* 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 (eCABG), and Clinically-Driven Target Lesion Revascularization (CD-TLR).
° 0.5% scaffold thrombosis rate excluding cases with early antiplatelet or anticoagulant interruption.
Δ 0.4% of cases without early antiplatelet or anticoagulant interruption at post procedure.

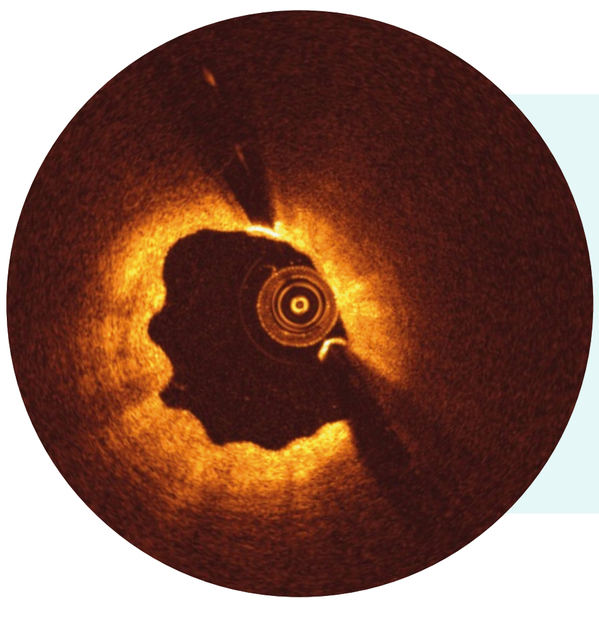
~95%
resorbed at
12 months[8]

# Fast resorption time

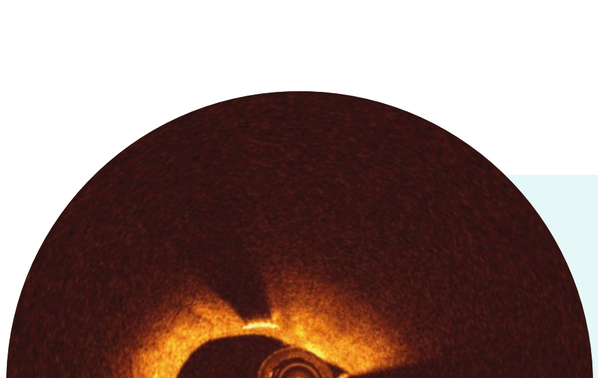
**~95% of Magnesium resorbed at 12 months[8]**



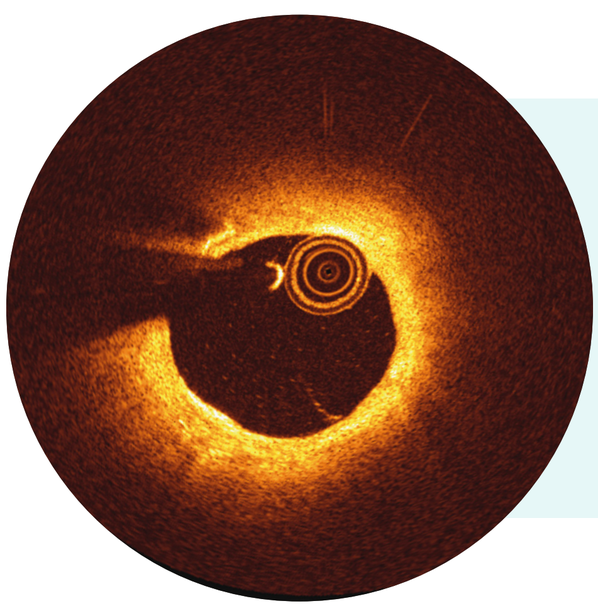
**OCT post implantation[9]**
Immediately after implantation, struts are well apposed to the vessel wall.



**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.



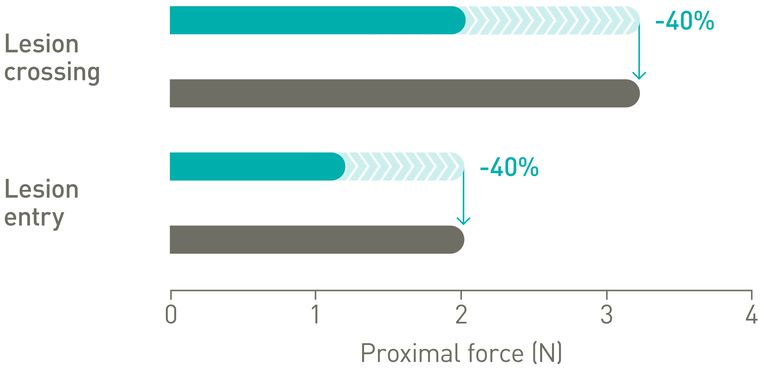
**OCT at 36 months[9]**
At 36 months the lumen is well preserved with a homogeneous surface.

# 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]*

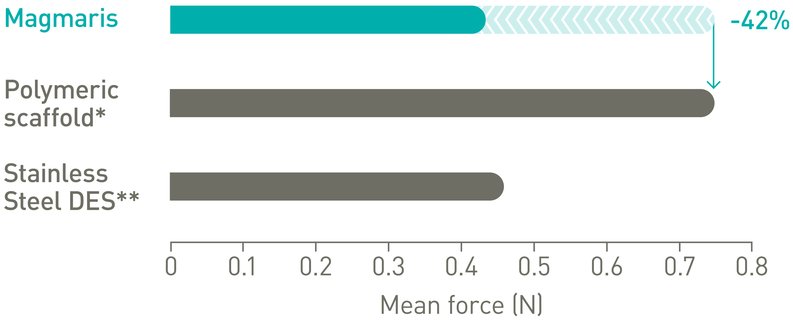
## Better lesion crossing

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



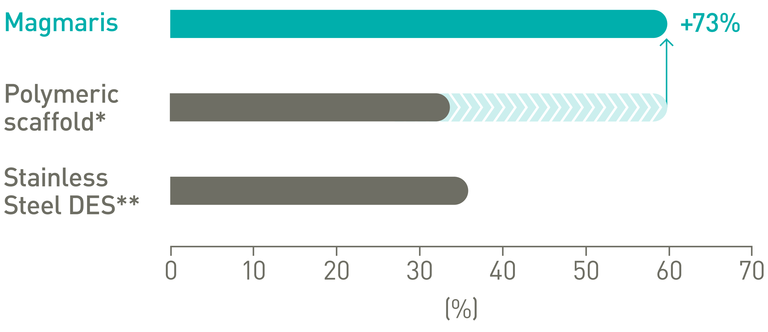

## Better trackability in tortuous anatomy

42% less peak force.[12]




## Better pushability

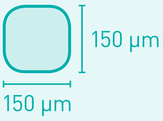
73% more force transmitted from hub to tip.[13]



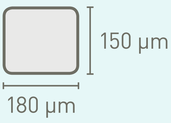

*Absorb, Abbott
**BioFreedom, Biosensors

### Stent/Scaffold strut thickness in perspective

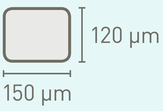
**Magmaris RMS**




**Polymeric scaffold***




**Stainless Steel DES****




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

# 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 / $mm^2$ |
| 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, 10-13. BIOTRONIK data on file; 4. Bennett J. Performance and safety of the resorbable magnesium scaffold, Magmaris in a real-world setting – Primary and secondary endpoint analysis of the full cohort (2,066 subjects) of the BIOSOLVE-IV, Presented at: TCT 2021, November 2021, Orlando, USA. ClinicalTrials.gov: NCT02817802; 5. Torzewski J. Safety and performance of Magmaris at 36-months: BIOSOLVE-IV first cohort. Presented at: EuroPCR; 2022; ClinicalTrials.gov: NCT02817802; 6. 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; 7. Haude M, Toelg R , Lemos P.A et al. Sustained safety and performance of a second-generation sirolimus-eluting absorbable metal scaffold: Long-term data of the BIOSOLVE-II first-in-man trial at 5 years. Cardiovascular Revascularization Medicine. 2021. doi: 10.1016/j.carrev.2021.07.017; 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 Prof. M. Haude, Rheinland Klinikum Neuss GmbH, Neuss, Germany 2015.

BIOSOLVE-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.

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