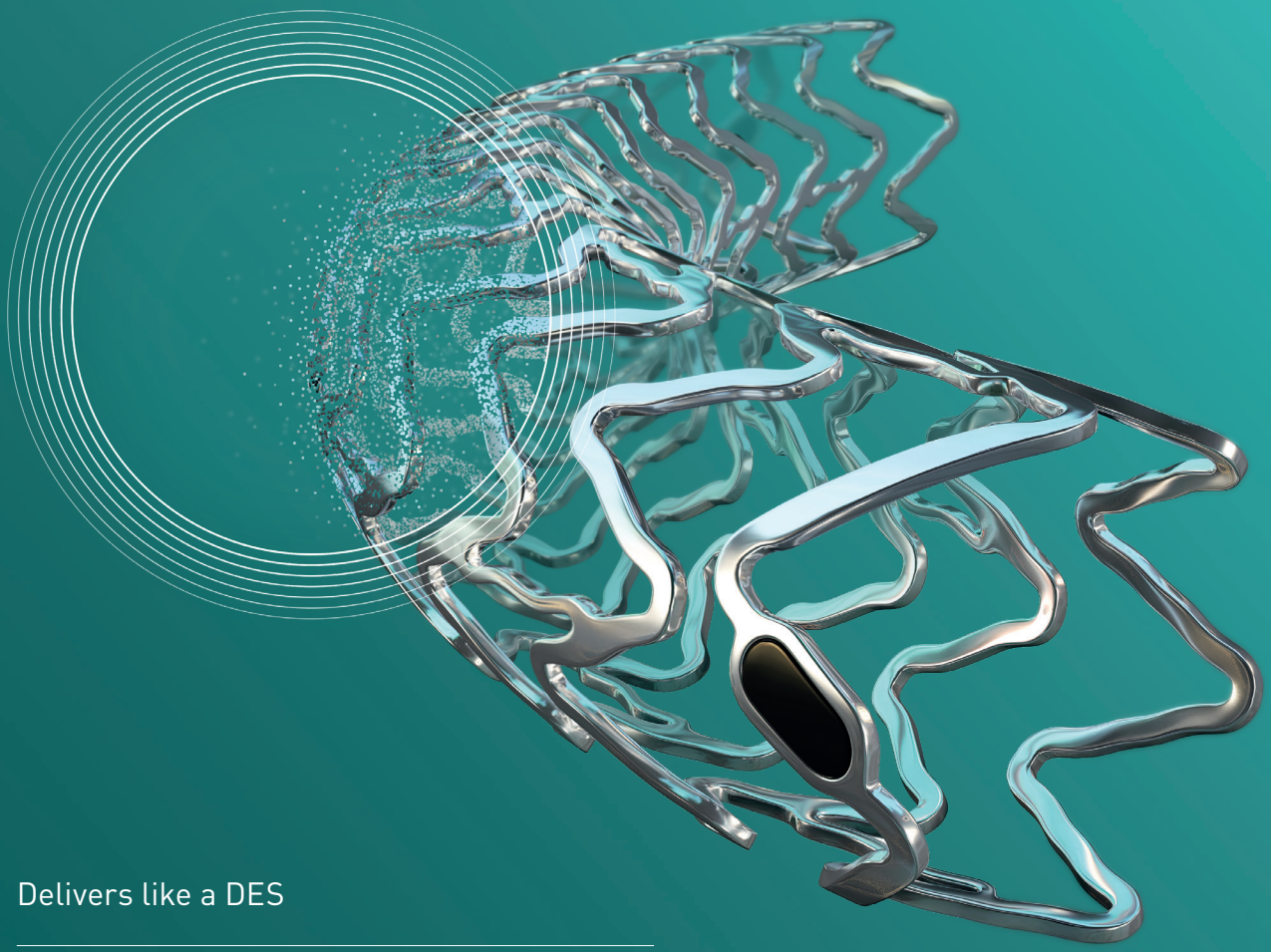
Vascular Intervention // Coronary
Resorbable Magnesium Scaffold (RMS)

Freesolve™

Metallic Performance. Fully Resorbable.



- Delivers like a DES
- Optimal vessel support
- Magnesium fully resorbed after 12 months
- Excellent safety and efficacy

BIOTRONIK
excellence for life

Freesolve™ RMS

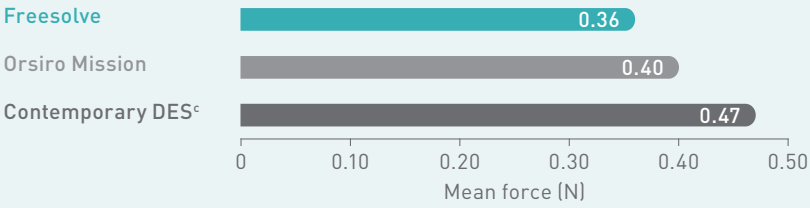
Metallic Performance[1-3]. Fully Resorbable[a,4].

Delivers like a DES[5]

Proven Orsiro® Mission DES delivery system[6]

Push[5]

Track[5]



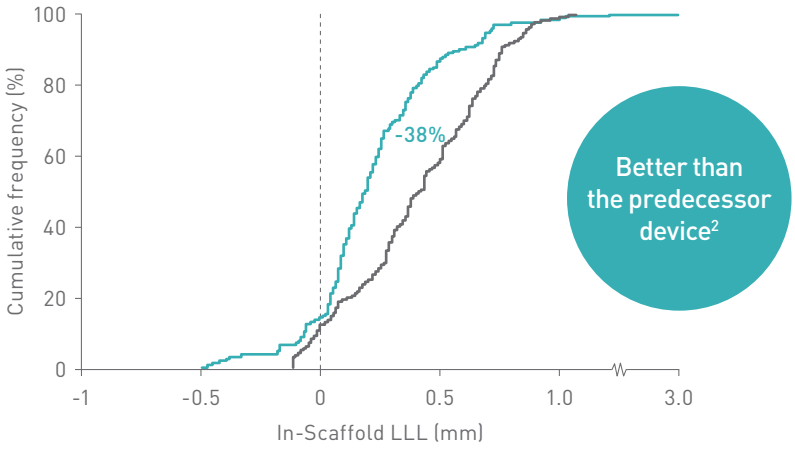
Better than contemporary DES[5]

Clinical data

Excellent safety and efficacy[2,3]

BIOMAG-I First-In-Human (FIH) trial[3]

In-Scaffold Late Lumen Loss (LLL)
in comparison to predecessor study at 12 months



— BIOMAG-I trial with Freesolve RMS 0.24 ± 0.36 mm (95% CI: 0.17;0.31)*
— BIOSOLVE-II trial with Magmaris RMS 0.39 + 0.27 mm (95% CI: 0.31;0.48)*,[11]

The in-scaffold Late Lumen Loss (LLL) for Freesolve[3] RMS is on the level of a contemporary DES.[10]

Freesolve RMS Median LLL: 0.19 mm[3]
Contemp. DES Median LLL: 0.18 mm[10]

Excellent safety profile at 12 months[2,3]

2.6% Target Lesion Failure

0.0% Scaffold Thrombosis

0.0% Myocardial Infarction

0.0% Cardiac Death

Benefits of implant free

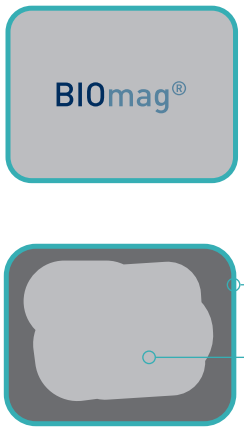
Support
Resorbable coronary scaffolds widen coronary artery stenoses and provide temporary vessel support. Thereby, scaffolds enable unobstructed blood flow in the coronary arteries with low rates of stent thrombosis (ST) and target lesion revascularization (TLR).

Resorb
By degrading after fulfilling their scaffolding function, they offer all options of future therapies.

Pre-clinical data

Optimal vessel support[7,8]

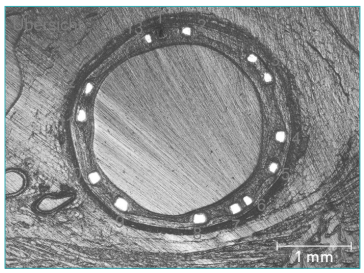
Predictable, homogenous resorption process[7]



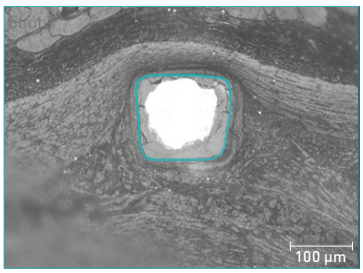
BIOmag® backbone
A strong Magnesium alloy[6]

BIOlute® coating

BIOmag® core
A strong[6], uniform shape[7]



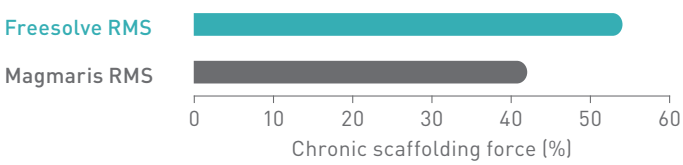
Equal resorption between struts[7]



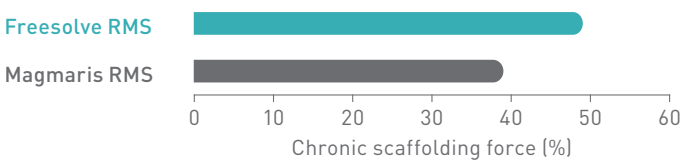
Uniform shape due to homogenous strut resorption[7]

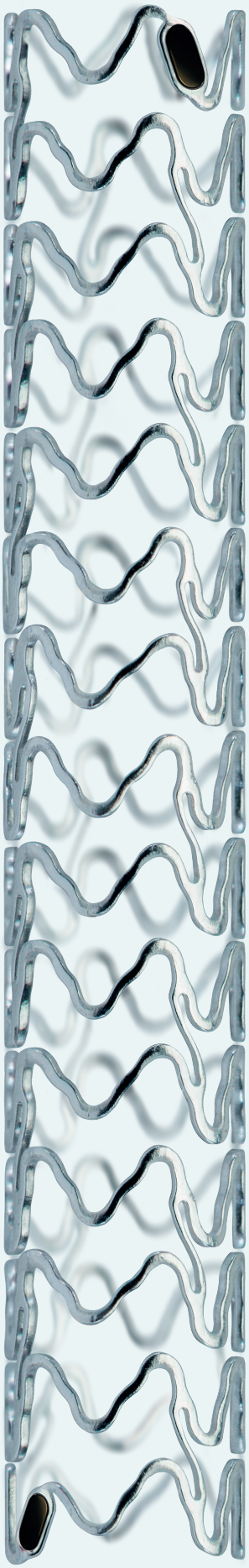
More than 3 months vessel support[7,8]

Pre-clinical data at 3 months



Pre-clinical data at 4 months

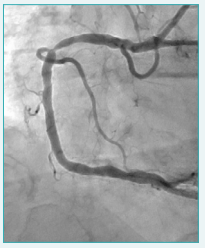
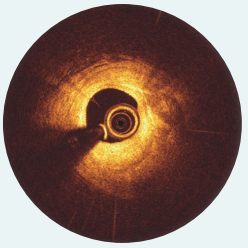
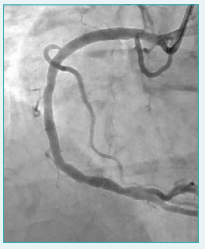
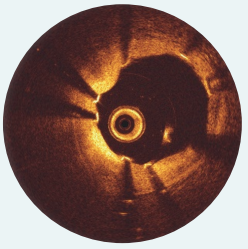
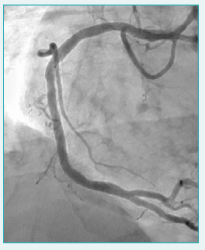
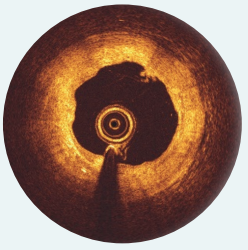
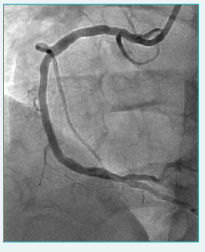
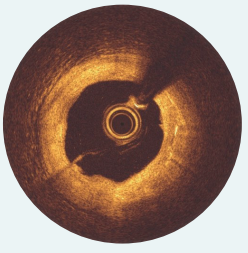




Clinical data

>99%
of struts no longer visible at 12 months[9]

Magnesium fully resorbed after 12 months[9]

	Angiographic Analysis[d,e]	OCT Analysis[d,e]	
Pre-procedure			Initial diagnostic
Post Implantation			Immediately after implantation, struts are well apposed to the vessel wall.
6-month follow-up			While the Magnesium resorption process continues, endothelialization progresses.
12-month follow-up			The Magnesium resorption is completed. No struts appear in OCT.

Freesolve™ RMS

Indicated for de novo coronary artery lesions.[f]

Vascular Intervention Coronary

Technical Data

Scaffold

Scaffold material	Proprietary **BIO**mag® Magnesium alloy
Strut thickness	ø 2.5 mm: 99 µm; ø 3.0/3.5 mm: 117 µm; ø 4.0 mm: 147 µm
Maximum expandable diameter	Nominal diameter + 0.6 mm
Markers	One oval Tantalum marker at each end
Drug coating	**BIO**lute® resorbable Poly-L-Lactide (PLLA) eluting a limus drug

Delivery system

Catheter type	Rapid exchange
Catheter length	140 cm
Recommended guide catheter	6F
Crossing profile	ø 2.5 mm ⩽ 1.3 mm; ø 3.0-4.0 mm ⩽ 1.4 mm
Guide wire diameter	0.014"
Nominal Pressure (NP)	10 atm
Rated Burst Pressure (RBP)	16 atm

Vessel Sizing

Scaffold ø (mm) (SD)	Recommended ø (mm) (RVD)
2.50	2.50 - 2.70
3.00	2.70 - 3.20
3.50	3.20 - 3.70
4.00	3.70 - 4.20

Compliance Chart

Balloon diameter (mm)

		ø 2.50	ø 3.00	ø 3.50	ø 4.00
Nominal Pressure (NP)	atm*	10	10	10	10
	ø (mm)	2.52	3.04	3.54	4.02
Rated Burst Pressure (RBP)	atm*	16	16	16	16
	ø (mm)	2.72	3.29	3.79	4.35

*1 atm = 1.013 bar

Ordering Information

Scaffold ø (mm)	Scaffold length (mm) 13	18	22	26	30
2.50	443103	443104	443105	-	-
3.00	443108	443109	443110	482156	443111
3.50	443113	443114	443115	482157	443116
4.00	443118	443119	443120	482158	443121

Target Lesion Failure (TLF) is a composite of Target-Vessel Myocardial Infarction (TV-MI), clinically-driven Target Lesion Revascularization (CD-TLR) and Cardiac Death.

*based on QCA paired data; a. 99.3% resorbed at 12 months (markers are not resorbable), based on clinical data; b. BIOMAG-I case in normal cine projection, courtesy of Prof. Michael Haude, Rheinland Klinikum Neuss GmbH, Lukaskrankenhaus, Neuss, Germany; c. Xience Sierra DES (Abbott); d. Angiographic and OCT Analyses derived from two different BIOMAG-I cases, courtesy of Prof. Michael Haude, Rheinland Klinikum Neuss GmbH, Lukaskrankenhaus, Neuss, Germany; e. The 4P protocol was respected; f. Indications as per IFU.

1. IIB Benchtest data, BIOTRONIK data on file; 2. Haude M. et al., the Lancet eClinicalMedicine 2023;59: 101940; 3. Haude, M. et al., EuroIntervention 2023;19:1-1 published online May 2023; 4. Seguchi M et al. OCT-Analysis 12M, presented at ESC 2023; 5. BIOTRONIK data on file, IIB Benchtest data: Freesolve in comparison to BIOTRONIK Orsiro Mission and Abbott Xience Sierra; 6. BIOTRONIK data on file; 7. Based on pre-clinical data, Seguchi, M. et al., EuroIntervention 2023;18-online publish-ahead-of-print January 2023; 8. BIOTRONIK data on file, in comparison to predecessor device; 9. Based on intravascular OCT analysis of the BIOMAG-I trial presented by Dr. M. Seguchi at ESC 2023; 10. Byrne, RA. et al., Eur Heart J 2015;36:2608-2620; 11. Haude M., et al. Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. Eur Heart J. 2016;37:2701-9.

BIOSOLVE-II and BIOMAG-I based on Kaplan-Meier failure estimate analysis.

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000-05-619/A/472231_Dec_2023