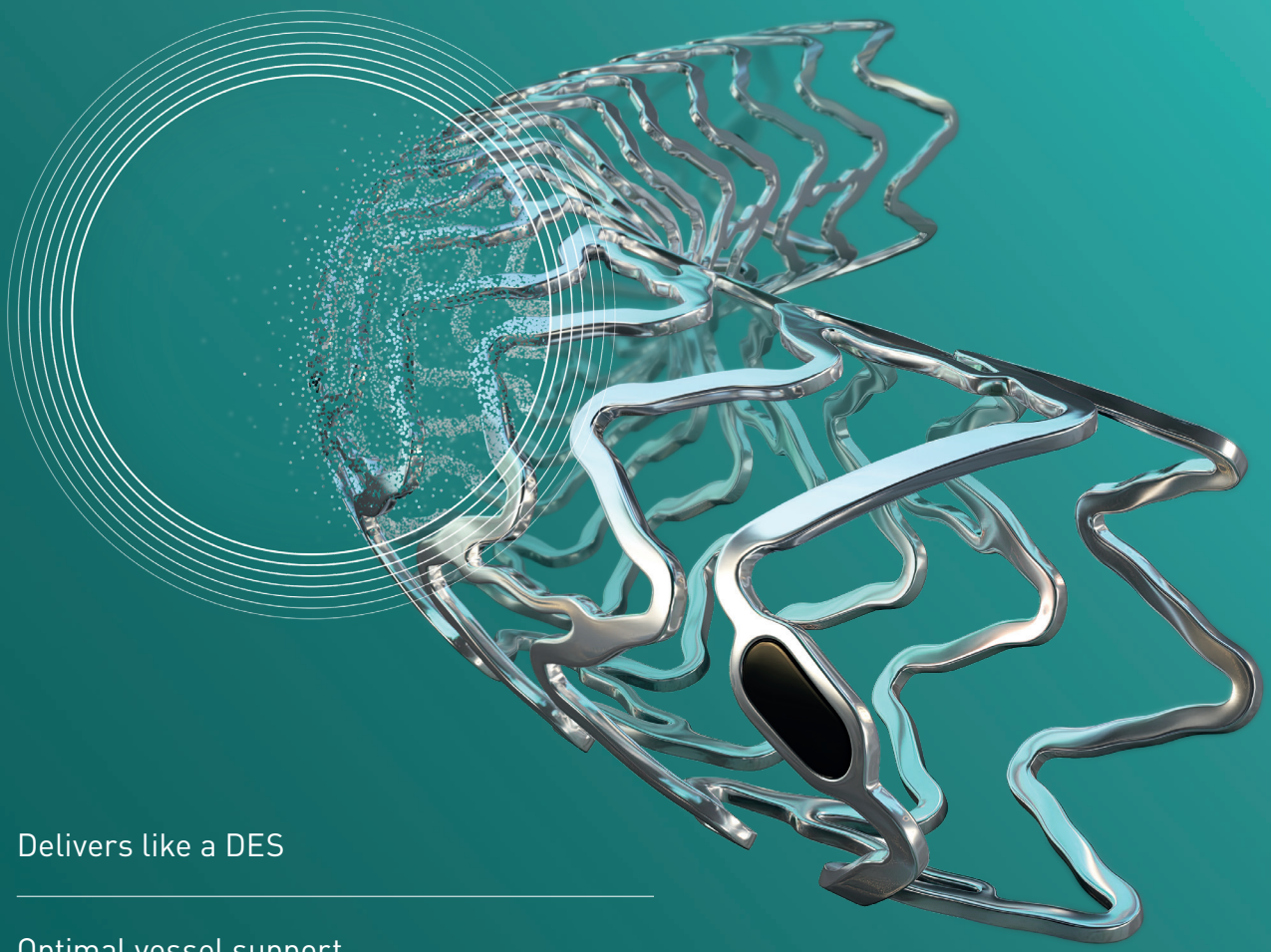
Vascular Intervention // Coronary
Resorbable Magnesium Scaffold (RMS)

Freesolve™

Metallic Performance. Fully Resorbable.



- Delivers like a DES
- Optimal vessel support
- Fully resorbed after 12 months
- Proven safety and efficacy

BIOTRONIK
excellence for life

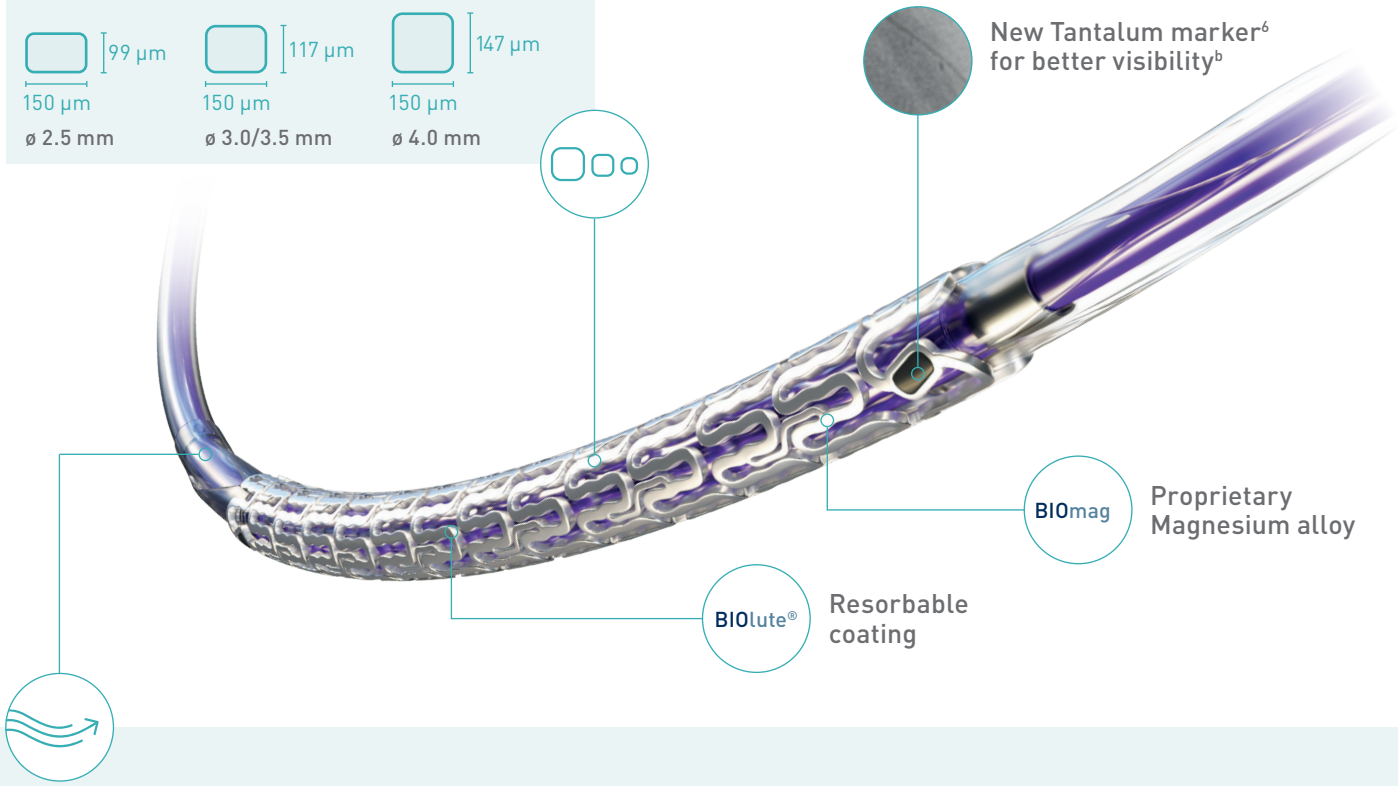
Freesolve™ RMS

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

Delivers like a DES[5]

Thin struts of Freesolve[6]

99 µm	117 µm	147 µm
150 µm	150 µm	150 µm
ø 2.5 mm	ø 3.0/3.5 mm	ø 4.0 mm



Proven Orsiro® Mission DES delivery system[6]

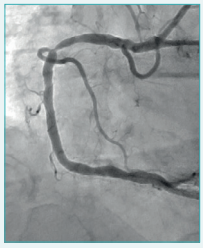
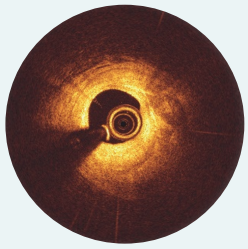
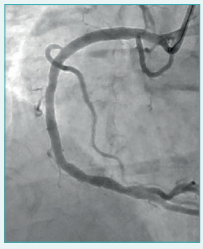
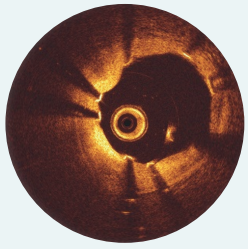
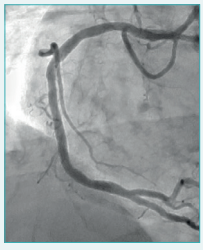
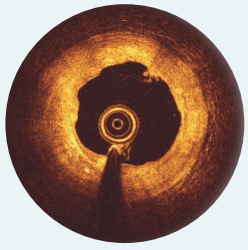
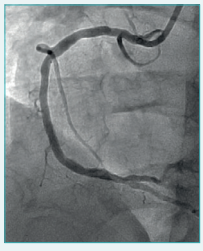
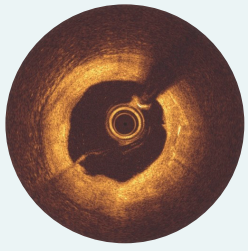
Pushability[5]

Trackability[5]

Better deliverability than contemporary DES[5]

>99%
of struts no longer visible at 12 months[7]

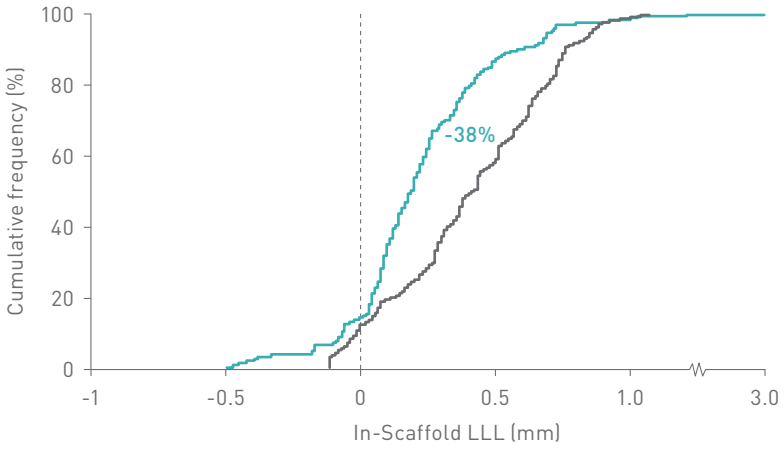
Fully resorbed after 12 months[7]

	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, endothelialisation progresses.
12-month follow-up			The Magnesium resorption is completed. No struts appear in OCT.

Proven safety and efficacy[2,3]

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

Comparison of In-Scaffold Late Lumen Loss (LLL) at 12 months
Freesolve RMS (BIOMAG-I) versus Magmaris RMS (BIOSOLVE-II)



— 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)*,[10]

Freesolve RMS demonstrated 38% improvement of LLL versus Magmaris RMS at 12 months[3].

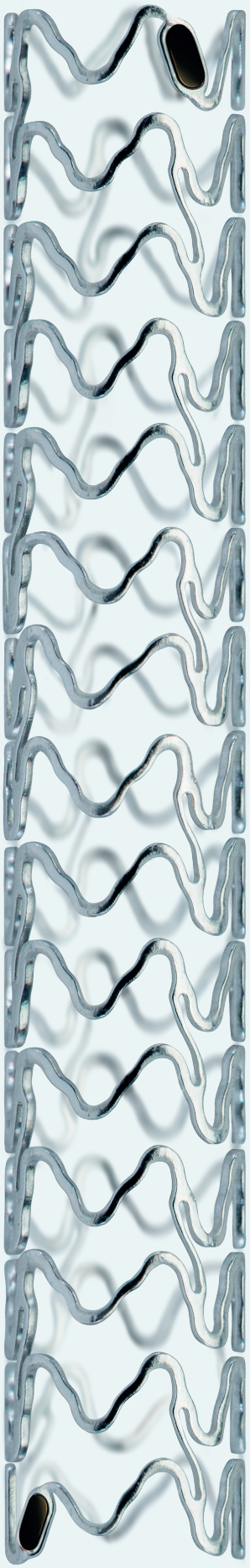
Excellent safety profile at 24 months[11]

3.5%
Target Lesion Failure

0.0%
Scaffold Thrombosis

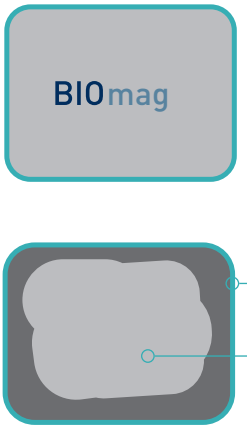
0.0%
Myocardial Infarction

0.0%
Cardiac Death



Optimal vessel support[8,9]

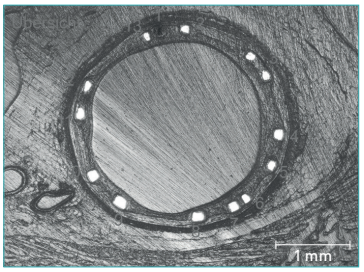
Predictable, homogeneous resorption process[8]



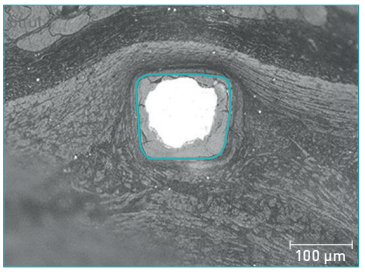
BIOmag backbone
A strong Magnesium alloy[6]

BIOlute® coating

BIOmag core
A strong[7], uniform shape[8]



Equal resorption between struts[8]



Uniform shape due to homogenous strut resorption[8]

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 Diameter ø (mm)	Recommended Vessel Diameter ø (mm)	Maximum Diameter for Post Dilation ø (mm)
2.50	2.50 - 2.70	3.1
3.00	2.70 - 3.20	3.6
3.50	3.20 - 3.70	4.1
4.00	3.70 - 4.20	4.6

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 Revascularisation (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 intravascular OCT analysis of the BIOMAG-I trial presented by Dr. M. Seguchi at ESC 2023; 8. Based on pre-clinical data, Seguchi, M. et al., EuroIntervention 2023, 18-online publish-ahead-of-print January 2023; 9. BIOTRONIK data on file, in comparison to predecessor device; 10. 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; 11. Poster presentation "BIOMAG-I: two-year clinical outcomes of the resorbable magnesium Scaffold-DREAMS 3G" by Prof. Haude at EuroPCR 2024.

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

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