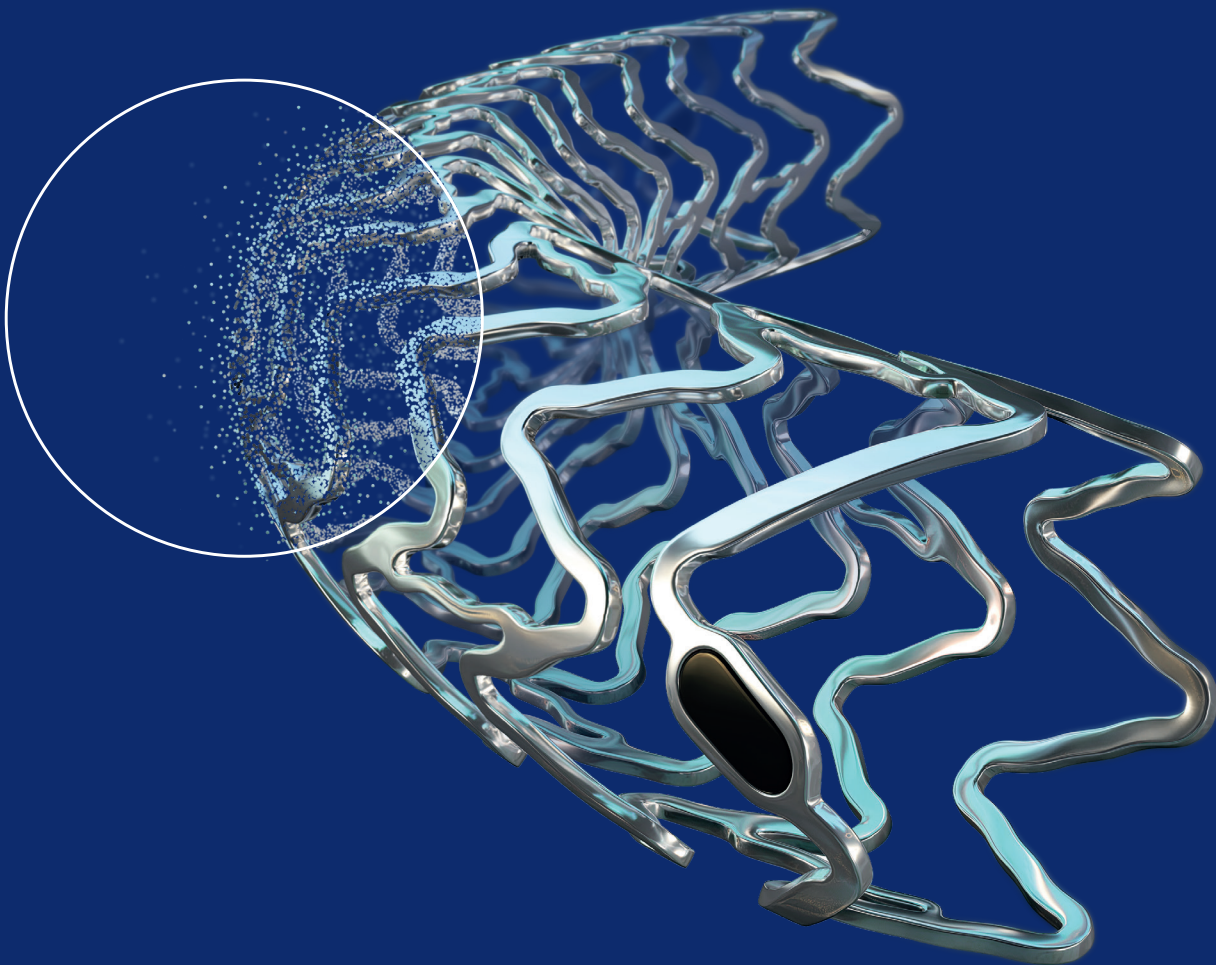


Freesolve™

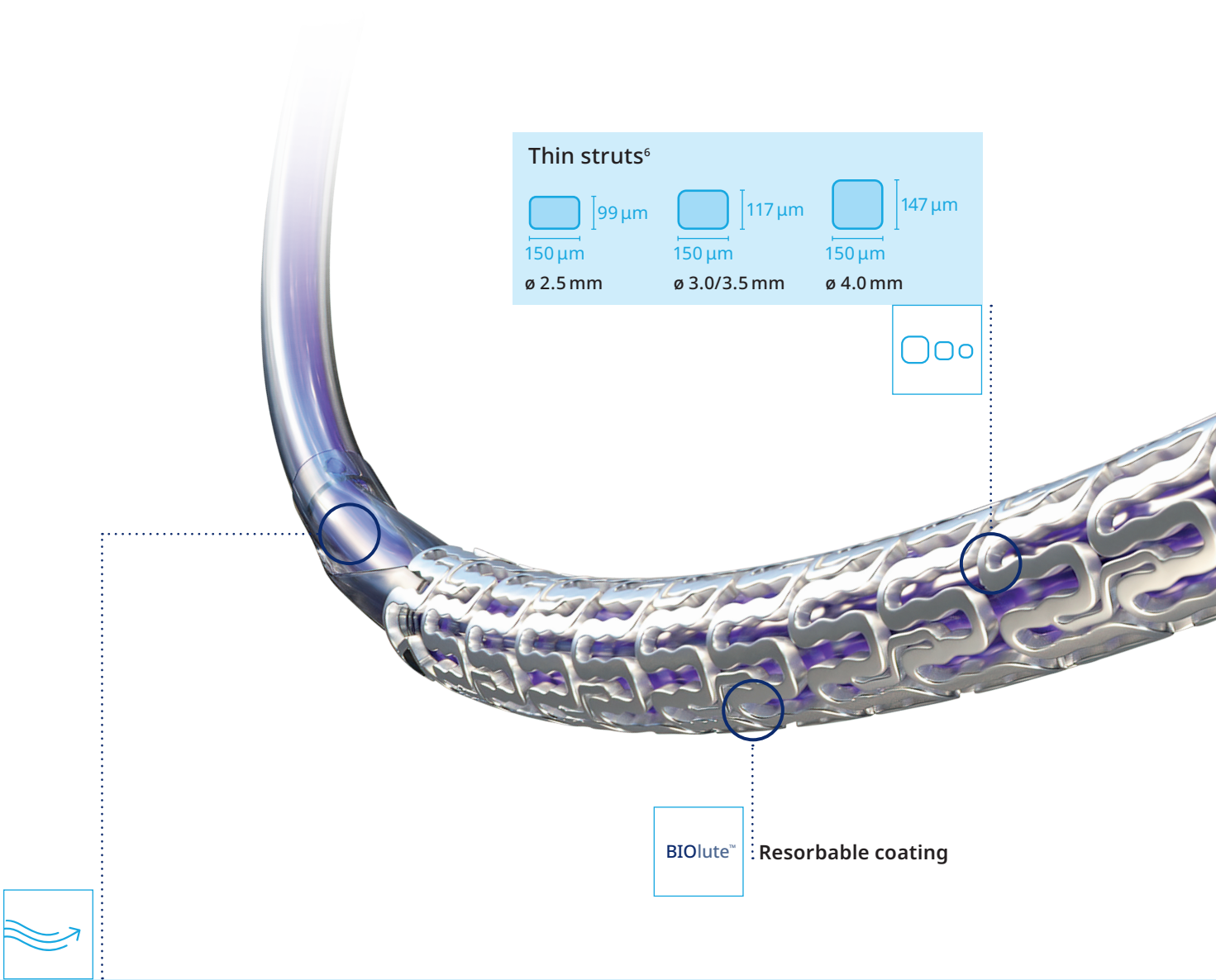
Resorbable Magnesium Scaffold (RMS)

Metallic performance¹⁻³. Fully resorbable^{a,4}.



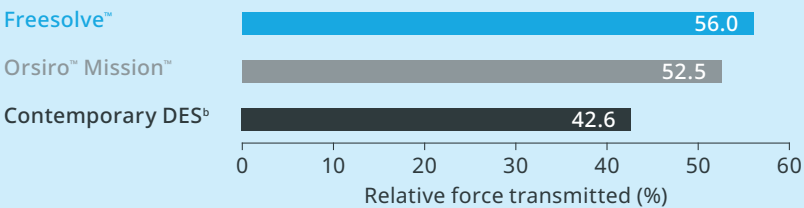
Freesolve™ RMS

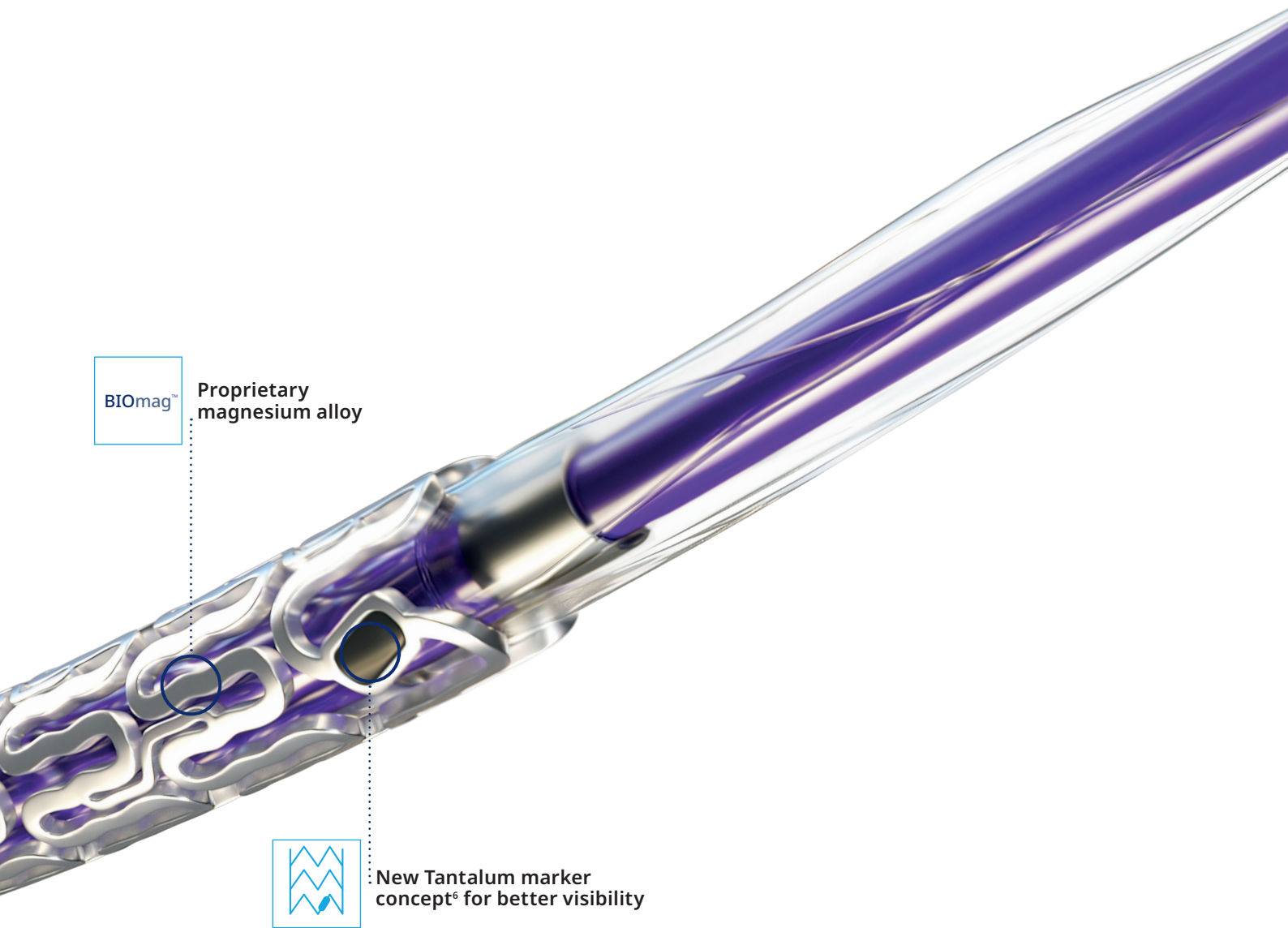
Delivers like a DES⁵



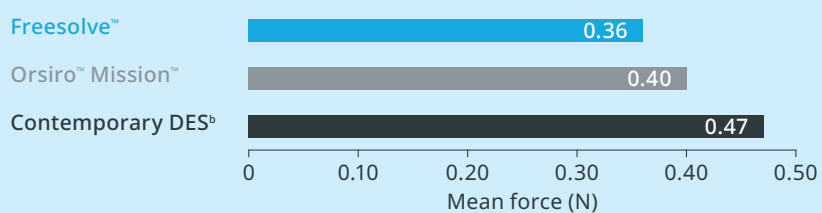
Proven Orsiro™ Mission™ DES delivery system⁶

Push⁵





Track⁵



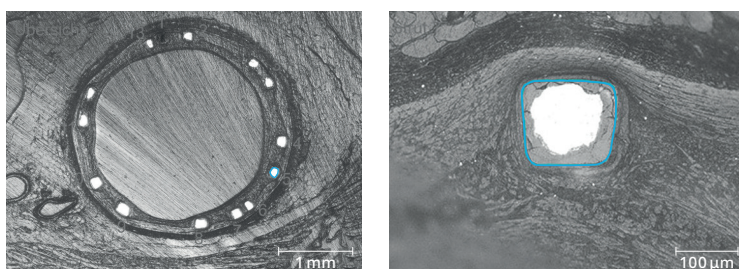
Better than
contemporary
DES⁵

Pre-clinical data

Optimal vessel support^{10,11}



Histology cut at 90 days after implantation¹⁰

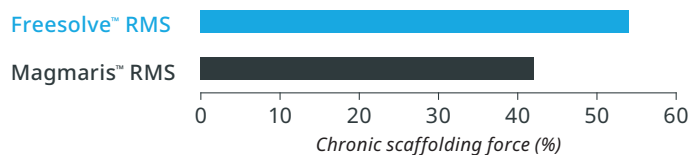


Equal resorption between struts¹⁰

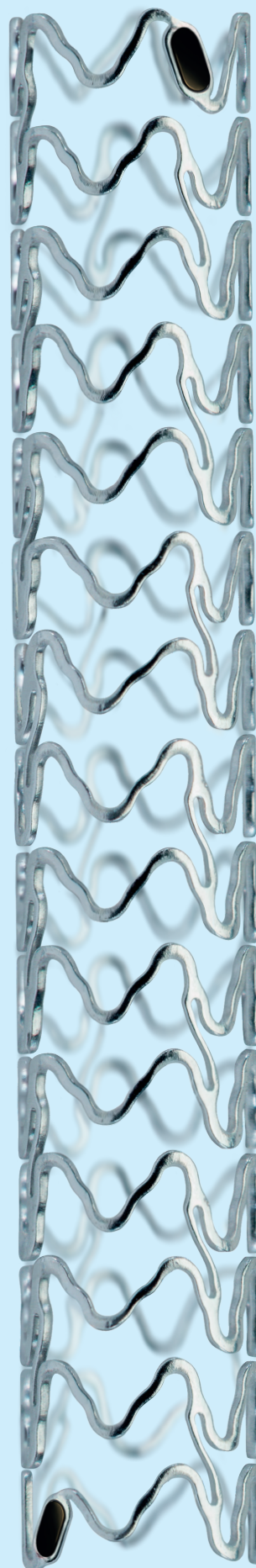
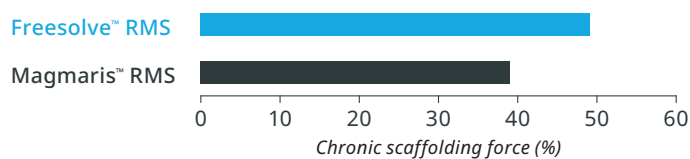
Uniform shape due to homogenous strut resorption¹⁰

More than 3 months vessel support^{10,11}

Pre-clinical data at 3 months



Pre-clinical data at 4 months



Clinical data

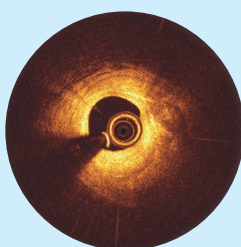
Magnesium fully resorbed after 12 months¹²

>99%
of struts no
longer visible
at 12 months¹²

Angiographic Analysis^{c,d}

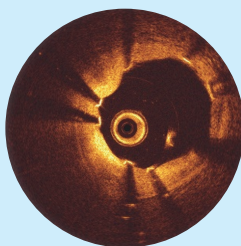
OCT Analysis^{c,d}

Pre-procedure



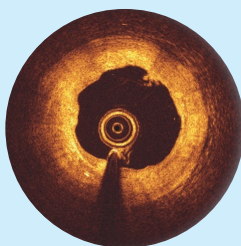
Initial diagnostic

Post Implantation



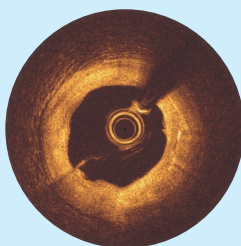
*Immediately after implantation,
struts are well apposed to the vessel wall.*

6-month follow-up



*While the Magnesium resorption process
continues, endothelialization progresses.*

12-month follow-up



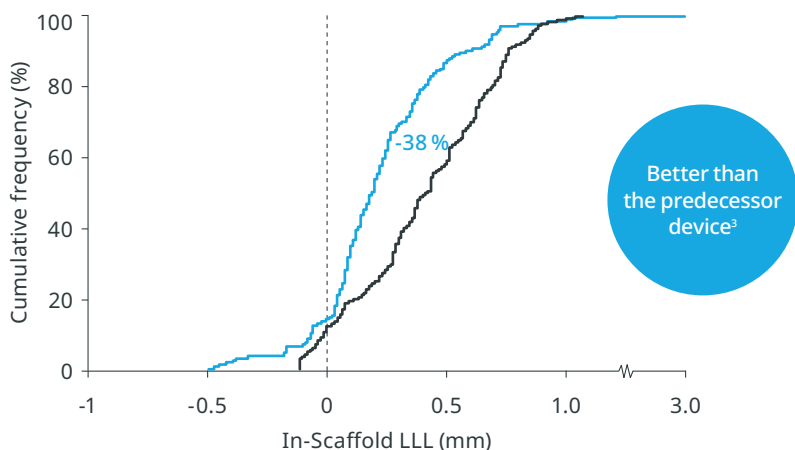
*The Magnesium resorption is
completed. No struts appear in OCT.*

Clinical data

Excellent safety and efficacy^{2,3}

BIOMAG™-I First-In-Human (FIH) trial³

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

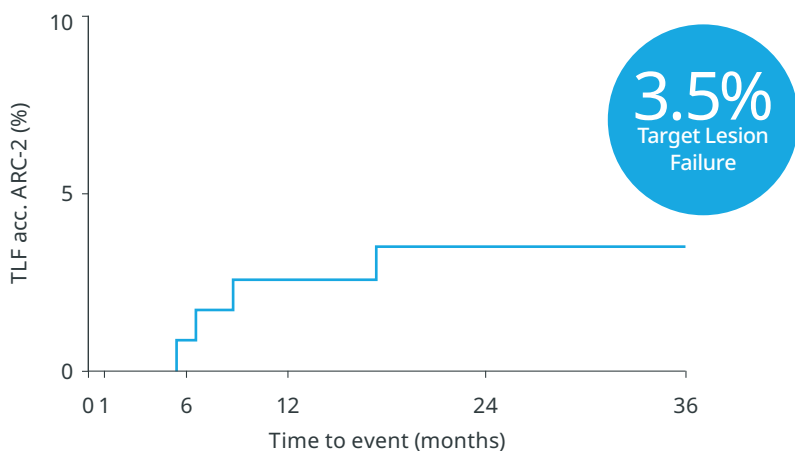


— BIOMAG™-I trial with Freesolve™ RMS 0.24±0.36 mm (95 % CI: 0.17;0.31)*
— BIOSOLVE-II trial with Magmaris™ RMS 0.39 ±0.27 mm (95 % CI: 0.31;0.48)*⁸

The in-scaffold Late Lumen Loss (LLL) for Freesolve™³ RMS is on the level of a contemporary DES.⁷

Freesolve™ RMS Median LLL: 0.19 mm³
Contemp. DES Median LLL: 0.18 mm⁷

Excellent safety and efficacy profile up to 36 months⁹



0.0 % Scaffold Thrombosis | 0.0 % Myocardial Infarction | 0.0 % Cardiac Death

Benefits of implant free

The favorable 3-year outcomes support renewed interest in bioresorbable scaffolds as a viable therapeutic option that combines temporary mechanical support with excellent long-term safety and efficacy.⁹

Resorb

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

Freesolve™ RMS

Vascular
Intervention
Coronary



Indicated for de novo coronary artery lesions.^e

Technical Data

SCAFFOLD	
Scaffold material	Proprietary BIOmag™ 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	BIOlute™ 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 (SD)	RECOMMENDED Ø (RVD)
2.50 mm	2.50–2.70 mm
3.00 mm	2.70–3.20 mm
3.50 mm	3.20–3.70 mm
4.00 mm	3.70–4.20 mm

Compliance Chart

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

1 atm = 1.013 bar

Ordering Information

SCAFFOLD Ø	SCAFFOLD LENGTH				
	13 mm	18 mm	22 mm	26 mm	30 mm
2.50 mm	443103	443104	443105	–	–
3.00 mm	443108	443109	443110	482156	443111
3.50 mm	443113	443114	443115	482157	443116
4.00 mm	443118	443119	443120	482158	443121

References

- 1 Benchtest data, 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 Data on file, Benchtest data: Freesolve in comparison to Orsiro Mission and Xience Sierra.
- 6 Data on file.
- 7 Byrne, RA. et al., Eur Heart J 2015;36:2608-2620.
- 8 Haude, M. et al., Eur Heart J. 2016;37:2701-9.
- 9 Haude et Al. Clinical outcomes of the third-generation resorbable magnesium scaffold for coronary artery lesions: three-year results of the BIOMAG-I study. EuroIntervention 2025;21:e1-e3.
- 10 Based on pre-clinical data, Seguchi, M. et al., EuroIntervention 2023;18-online publish-ahead-of-print January 2023.
- 11 Data on file, in comparison to predecessor device.
- 12 Based on intravascular OCT analysis of the BIOMAG-I trial presented by Dr. M. Seguchi at ESC 2023.

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

^abased on QCA paired data ^b99.3% resorbed at 12 months (markers are not resorbable), based on clinical data ^cXience Sierra DES (Abbott); ^dAngiographic and OCT Analyses derived from two different BIOMAG-I cases, courtesy of Prof. Michael Haude, Rheinland Klinikum Neuss GmbH, Lukaskrankenhaus, Neuss, Germany ^eThe 4P protocol was respected ^fIndications as per IFU.

Refer to IFU

Refer to QR code for a copy of the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.



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

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