

MEDIA FACT SHEET

Freesolve™:

A True BIOTRONIK Innovation Establishing a New Benchmark for Resorbable Scaffolds

Developed to improve the lives of patients with de novo coronary artery lesions, the Freesolve device represents the new generation in Resorbable Magnesium Scaffold (RMS) technology.

Featuring the unique BIOmag® magnesium alloy, Freesolve RMS degrades¹ and provides safety,^{*2,3} excellent deliverability, and optimal vessel support during and after implantation.

As the next generation of Resorbable Magnesium Scaffold (RMS), Freesolve RMS stands out with an impressive 99.3% magnesium strut degradation at 12 months¹, and reliable vasomotion⁴.

Supported by clinical evidence from the [BIOMAG-I trial](#), Freesolve RMS establishes itself as a cutting-edge and market-leading solution.

Elevating the Future of Scaffold Performance with Breakthrough Advancements

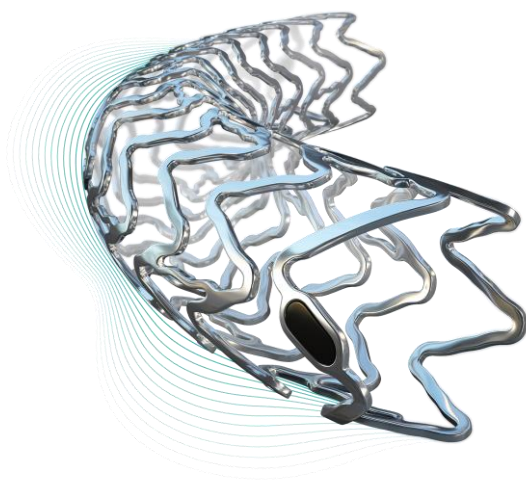
Building on Magmaris RMS' success, Freesolve RMS is poised to become the prime alternative to current drug-eluting stents (DES), featuring the following technical enhancements:

- **Mitigation of Late Clinical Events:** Aiming to reduce late clinical events compared to permanent stent implants, excellent deliverability, and optimal vessel support minimize risks during and post-procedure.
- **Adaptability and Tailored Treatments:** Tailored for diverse patient populations as per instruction for use, it solidifies a unique market position with a size range in diameter from 2.5 – 4.0mm

- **Magnesium Alloy for Optimal Vessel Support:** Freesolve RMS stands out with the BIOmag® magnesium alloy⁵, allowing improved mechanical properties and prolonged radial support.^{6,7}
- **Timely Resorption:** It achieves a remarkable 99.6% magnesium resorption within 12-months¹ after implantation.
- **Technological Precision paved by Orsiro® Mission DES:** Utilizing the Orsiro Mission DES delivery system, Freesolve RMS profits from excellent pushability and trackability.⁷
- **Advancements in Safety and Efficacy:** It exhibits notable improvement in angiographic Late Lumen Loss compared to its predecessor, emphasizing safety and enhanced efficacy up to 12 months.^{2,3}

BIOTRONIK's Next Step in Expanding Evidence of the Freesolve RMS

In 2024, BIOTRONIK will initiate the BIOMAG-II RCT study to expand on clinical evidence and efficacy of the Freesolve RMS. Comparing Freesolve RMS to a contemporary DES, this randomized controlled trial builds on prior findings, aiming to enroll over 1,800 individuals across CE and APAC regions.



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References:

*based on available data from the BIOMAG-I study

1. Seguchi, M "Twelve-months vessel healing profile following the novel resorbable magnesium scaffold implantation: an intravascular OCT analysis of the BIOMAG-I trial" presented at ESC August 2023.
2. Haude et al, the Lancet eClinicalMedicine2023;59: 101940
3. Haude, M et al, EuroIntervention 2023;19:1-1 published online May 2023
4. Haude M., BIOMAG-I: A new resorbable magnesium scaffold for de novo coronary lesions (DREAMS 3G): 12-month results of the BIOMAG I first in human study, presented at ESC 2023.
5. BIOTRONIK data on file compared to Magmaris® RMS, applicable for the scaffold diameter sizes 3.0 and 3.5 mm.
6. Masaru Seguchi et al. Preclinical evaluation of the degradation kinetics of third generation resorbable magnesium scaffolds. Eurointervention; 2023;18-online publish-ahead-of-print January 2023. DOI: 10.4244/EIJ-D-22-00718.
7. BIOTRONIK data on file.



BIOTRONIK at a Glance

At BIOTRONIK [🌐](#), patient well-being is our top priority and has been for more than 60 years. BIOTRONIK is a leading global medical technology company with products and services that save and improve the lives of millions suffering from heart and blood vessel diseases as well as chronic pain. BIOTRONIK is headquartered in Berlin, Germany, and is represented in over 100 countries.



Global Impact

Physicians have implanted more than 20 million BIOTRONIK devices in over 100 countries.



Business Areas

BIOTRONIK is active in cardiac rhythm management, electrophysiology, vascular intervention and neuromodulation.



R&D

BIOTRONIK is headquartered in Berlin and researches, develops and manufactures exclusively in the high-tech countries of Germany, Singapore, Switzerland and the United States.

All critical components are manufactured in-house to ensure uncompromised safety, the highest quality and reliability. One in five employees at Berlin headquarters work in research and development.

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