MEDIA FACT SHEET

Magmaris®: The First Resorbable Magnesium Scaffold (RMS)

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Like stents, resorbable scaffolds support an artery's inner wall to restore blood flow through narrowed or blocked arteries.[1] Stents stay in the body permanently. This popular method of vascular restoration therapy may have some limitations, such as a chronic local inflammatory reaction due to permanent implantation of a foreign body, restriction of vascular vasomotion due to a metal cage, and the risk of late and very late stent thrombosis.[2]

Resorbable scaffolds support the vessel during a defined period and are thereafter resorbed by the body. The vessel is left "uncaged" and has the potential to overcome some of the issues associated with drug-eluting stents.2 Restoration of physiological vasomotion (blood vessels' capacity to change in diameter), functional endothelial coverage, and the absence of residual foreign material in the vessel can potentially reduce the risk of stent thrombosis.[3]

Magmaris®[4] is the only resorbable magnesium scaffold (RMS) approved to treat de novo coronary artery lesions by percutaneous coronary intervention.[5]

Benefits of Magmaris RMS

Magmaris Resorbable Magnesium Scaffold (RMS) shows confirmed clinical safety and efficacy*[6-9] and at 12 months after implantation, magnesium resorption is almost complete.[10] This may help prevent scaffold thrombosis, a potentially dangerous complication.

The magnesium backbone of the Magmaris RMS can be electrochemically polished for a smooth scaffold surface with rounded edges, enabling a more deliverable scaffold. In comparison to a polymer-based scaffold, Magmaris RMS requires 40 percent less force to enter and cross a lesion[11]. It is also easier to steer through vascular anatomy, as 73 percent more force is transmitted to the end of the delivery system.[12]

Once implanted, the magnesium backbone gives the scaffold the ability to withstand external force within the vessel, meaning the vessel remains firmly open, preventing potential complications. Magmaris RMS' diameter remains constant within the first hour after implantation, whereas a polymer-based scaffold's diameter recoils (decreases) by over 20 percent.[12]

Efficacy and safety results

Magmaris Resorbable Magnesium Scaffold (RMS) was initially tested in 123 patients with de novo lesions, as part of BIOSOLVE-II—a prospective, multi-center, first-in-human trial. The data is extremely promising with a 0.0 percent rate of definite or probable Scaffold Thrombosis (ST) and a low Target Lesion Failure (TLF) rate of 8.0 percent at 60 months, results that are comparable to second generation DES tested in similar non-complex patients. The Magmaris scaffold showed favorable long-term safety and clinical performance with only one TLF-event occurred beyond 3 years.[9] The evidence for the resorbable magnesium scaffold was further increased with the results of the BIOSOLVE-IV registry, with 2'066 enrolled patients. The TLF** rate at 36 months for 1075 patients in the first cohort, is 8.2 percent and is comparable to low TLF rates of a contemporary DES[13,14] over the same time period.[6] BIOSOLVE-IV first cohort also demonstrates consistently low scaffold thrombosis rates up to 36 months.[6]

Also the data for the full cohort of 2066 Patients show an excellent safety and efficacy profile up to 24-month follow-up.[7] The TLF rate is comparable to contemporary newer generation drug-eluting stents.[15,16,17]The definite/probable scaffold thrombosis rate is 0.8 percent.[7,18]

References:

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

** TLF defined as a composite of Cardiac Death, Target-Vessel Myocardial Infarction (TV-MI), Clinically-Driven Target Lesion Revascularization (CD-TLR) and emergent Coronary Artery Bypass Grafting (CABG). SCAI Def. for periprocedural MIs and Extended Historical Def. for spontaneous MIs All events have been adjudicated by an independent clinical event committee. BIOSOLVE-IV data based on Kaplan-Meier failure estimate analysis including censored observations.

1 US National Heart, Lung and Blood Institute: www.nhlbi.nih.gov/health/health-topics/topics/stents

2 Wiebe J, Nef HM, Hamm CW. Current Status of bioresorbable scaffolds in the treatment of coronary artery disease. Journal of American College of Cardiology. 2014, 64(23). DOI: 10.1016/j.jacc.2014.09.041.

3 Wijns W. Why do we need scaffolds? Presented at: EuroPCR; May 22, 2018; Paris, France.

4 Not currently available in the United States.

5 CE approved. Indication as per IFU.

6 Torzewski J. Safety and performance of Magmaris at 36-months: BIOSOLVE-IV first cohort. Presented at: EuroPCR; 2022; ClinicalTrials.gov: NCT02817802;

7 Bennett, J et al, "Safety and Efficacy of the Resorbable Magnesium Scaffold, Magmaris in a Real-World Setting – 24-month Follow-up of the Full Cohort (2066 subjects) of the BIOSOLVE-IV Registry", presented at TCT 2022, ClinicalTrials.gov: NCT02817802

8 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.

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10 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. pii: EIJ-D-17-00708. DOI: 10.4244/EIJ-D-17-00708.

11 BIOTRONIK Data on file

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14 Kandzari D.E et al. Ultrathin Bioresorbable-Polymer Sirolimus-Eluting Stents Versus Thin Durable-Polymer Everolimus-Eluting Stents for Coronary Revascularization 3-Year Outcomes From the Randomized BIOFLOW V Trial. JACC: CARDIOVASCULARINTERVENTIONS. 2020. 13 (11): 1343-53. doi: 10.1016/j.jcin.2020.02.019;

15 Kandzari D.E. et al. JACC: Cardiovascular Interventions 2018. doi: 10.1016/j.jacc.2018.09.019;

16 Kok M. et al. Euro Intervention 2018 doi: 10.4244/EIJ-D-18-00336;

17 Buiten RA. et al. JACC: Cardiovascular Interventions 2020 doi:doi:0.1016/j.jcin.2020.01.230;

18 0.4% scaffold thrombosis rate excluding cases with early antiplatelet or anticoagulant interruption

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.

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