Fact Sheet

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BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany
Tel +49 (0) 30 68905-1414
Fax +49 (0) 30 68905-961414
www.biotronik.com

Magmaris: The First Resorbable Magnesium Scaffold (RMS)

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 is the first resorbable magnesium scaffold (RMS) approved to treat de novo coronary artery lesions by percutaneous coronary angioplasty.[4]

Benefits of Magmaris
Magmaris shows compelling safety data.[5,6,7] At 12 months after implantation, magnesium resorption is almost complete.[8] This may help prevent scaffold thrombosis, a potentially dangerous complication.

Magmaris' magnesium backbone can be electrochemically polished for a smooth scaffold surface with rounded edges, enabling a more deliverable scaffold. In comparison to a polymer-based scaffold,[9] Magmaris requires 40 percent less force to enter and cross a lesion. It is also easier to steer through vascular anatomy, as 73 percent more force is transmitted to the end of the delivery system.[10]

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' diameter remains constant starting one hour after implantation, whereas a polymer-based scaffold's[9] diameter recoils (decreases) by over 20 percent.[10]

Efficacy and safety results
Magmaris 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% rate of definite or probable scaffold thrombosis and a 6.8% rate of Target Lesion Failure at 36 months, results that are comparable to 2nd generation DES tested in similar non-complex patients.[5] The evidence for the resorbable magnesium scaffold was further increased with the results of the BIOSOLVE-IV registry, with plans to enroll 2,054 patients. Data from 400 patients available at 12 months shows a low TLF rate of 4.3 percent and only one definite scaffold thrombosis caused by interruption of DAPT 5 days

after device implantation.[7] This confirms Magmaris is a safe and effective option for patients with *de novo* coronary artery lesions.

References:

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