

PRESS RELEASE

19 October 2016. Veryan Medical announces the completion of subject enrolment into the MIMICS-2 clinical study of its BioMimics 3D[®] Self-Expanding Stent System (BioMimics 3D), which features patented three dimensional (3D) helical geometry.

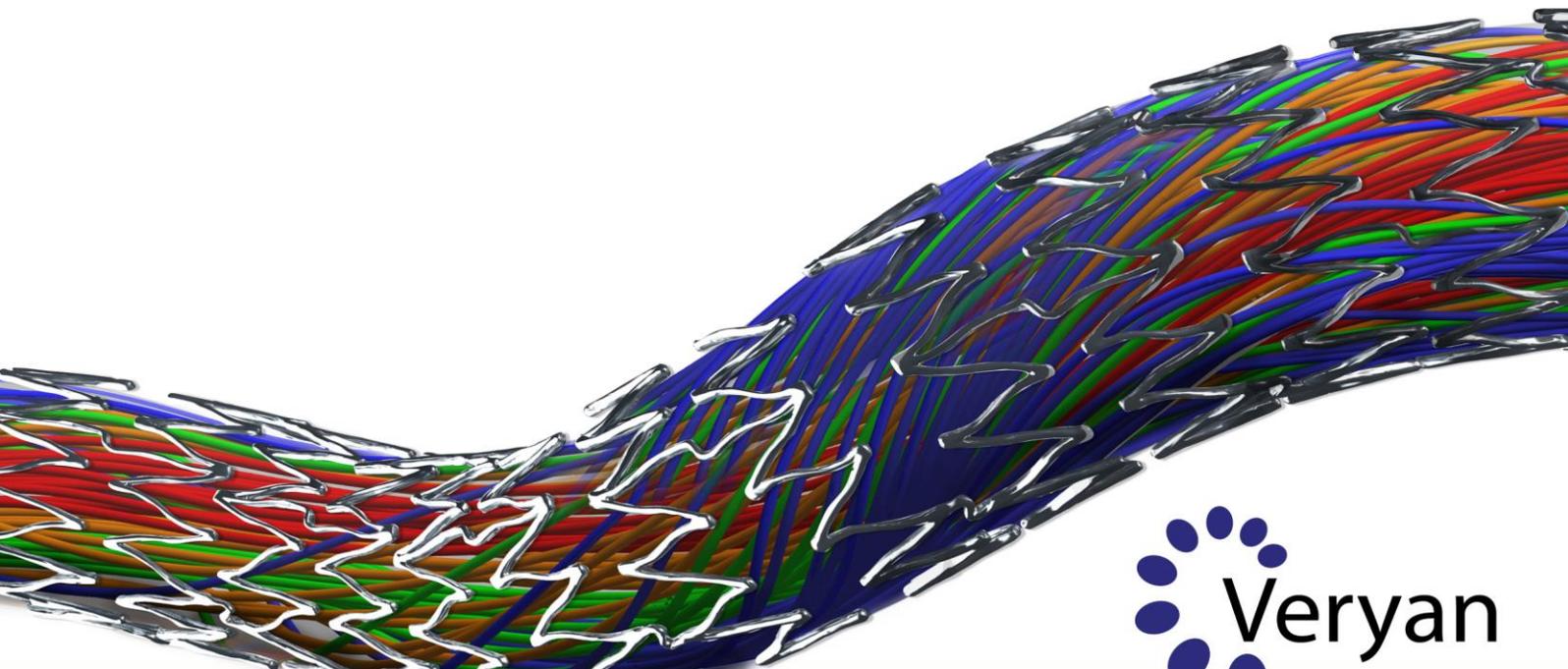
The MIMICS-2 study is a prospective, multicentre, interventional study designed to evaluate the safety and effectiveness of BioMimics 3D in the treatment of patients with symptomatic femoropopliteal disease. The Study is being conducted under a USA Food and Drug Administration (FDA) Investigational Device Exemption (IDE), with Japanese Pharmaceuticals and Medical Devices Agency (PMDA) concurrence under the “Harmonisation By Doing” initiative, in order to provide safety and effectiveness data that are intended to support future marketing applications for BioMimics 3D in both the USA and Japan.

Enrolment in the MIMICS-2 study concluded with a total of 271 patients who were enrolled across 47 investigational sites in Germany, the USA and Japan.

Chas Taylor, Veryan CEO commented: “This is yet another valuable milestone for Veryan on our path to global commercialisation of the unique BioMimics 3D stent technology. We are hugely grateful for the enthusiasm and willingness of the MIMICS-2 Principal Investigators and their research staff at our investigational sites. Their interest in Veryan’s swirling flow stent has made MIMICS-2 the fastest enrolling femoropopliteal stent study. In conjunction with our recently announced, and now enrolling, MIMICS-3D Registry, we are looking to an evolving clinical use database that will extend to more than 1000 cases.”

BioMimics 3D Stent System

BioMimics 3D, the CE-Marked nitinol stent with unique three-dimensional helical geometry, has been developed by Veryan, based on pioneering research by Prof Colin Caro at Imperial College London into the link between blood flow mechanics and vascular disease.¹ The BioMimics 3D nitinol stent has unique helical geometry to impart natural, non-planar curvature to the diseased artery,



promoting secondary (swirling) flow and elevated wall shear stress, which has a protective effect on the endothelium.² The helical geometry of the BioMimics 3D femoropopliteal stent is also designed to facilitate shortening of the stented segment during knee flexion and mitigate the risk of stented segment compression causing localised strains that in a straight stent may lead to stent fracture and chronic vascular injury.^{3,4}

About Veryan Medical Ltd.

Veryan is developing innovative solutions to improve the performance of vascular stents using the principles of biomimicry. Veryan's BioMimics 3D[®] stent technology involves adapting traditional straight stent designs to a patented three-dimensional helical shape, which more closely mimics the natural geometry of the human vascular system. BioMimics 3D technology is designed to enhance clinical performance by improving flow conditions in, and biomechanical performance of, stented vessels. The advanced, biomimetic design of the BioMimics 3D stent is intended to provide more flexibility, kink and fracture resistance than other laser-cut nitinol tube stents, making its unique design of particular importance in the hostile environment of the femoropopliteal artery. Veryan's Head Office is in Horsham, UK and its Research & Development facility is located in Galway, Ireland.

1. Caro, C. G. Discovery of the role of wall shear in atherosclerosis. *Arterioscler Thromb Vasc Biol* 29, 158–61 (2009).
2. Zeller T. Oral Presentation VIVA 2014
3. BH Smouse et al, *Endovasc. Today*, vol 4, no. 6, pp. 60-66, 2005
4. Scheinert D et al, *J Am Coll Cardiol* 2005;45:312–5 doi:10.1016/j.jacc.2004.11.026

BioMimics 3D is a registered trademark of Veryan Medical Ltd, and the BioMimics 3D Stent System has CE Mark approval for European marketing.

CAUTION: Investigational Device. Limited by Federal (or United States) Law to Investigational Use.

For further information, please visit: www.veryanmed.com

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