

## Press Release

### **MR Safe MaRVIS guidewires received CE Mark and strong interest by interventional experts at the iMRI2018 conference in Boston**

*October 9, 2018 – The MaRVIS MR Safe guidewire portfolio is the first one worldwide comprising 0.035" guidewires of different stiffness, and the exclusive one offering a 0.014" micro guidewire. Besides the good handling properties, the MaRVIS MR guidewires are unique with their patent-protected iron particle-based MR marker system. The new product line MaRVIS Golden Wire now received the CE Mark Class IIa, enabling peripheral and percutaneous interventions. During the interventional MRI conference 'iMRI 2018' held in Boston the interest in the MaRVIS MR guidewire portfolio by physicians, MR experts and industry was strong. The unique MaRVIS micro guidewire is of special relevance in particular to neuroradiologists for preclinical development in interventional oncology and stroke treatment.*

MaRVIS Interventional GmbH has developed a comprehensive portfolio of fiber-composite – based novel MR Safe guidewires. Being a unique offer to the interventional medical community, this portfolio comprises the commonly used three types of guidewires: 0.035" diameter in two different stiffnesses (standard and stiff) fulfilling the mechanical requirements for various interventions, and a 0.014" micro guidewire for a broad range of interventions in small vessels. The new product line 'MaRVIS Golden Wire' now received the CE Mark Class IIa, enabling peripheral and percutaneous interventions. This is a major step forward for the interventional community as now a range of MRI-guided endovascular interventions can be brought forward into the clinical routine.

The lack of appropriate MR guidewires for more than a decade has blocked exploitation of MRI with its numerous benefits also for endovascular interventions, where the use of guidewires is a requirement by Good Clinical Practice (GCP). These benefits comprise good soft tissue visualization (e.g. of organs and blood vessels), availability of additional functional information from the same imaging process (e.g. blood flow and temperature), avoidance of X-ray burden and iodine contrast agents. Furthermore, the intervention can be continuously visualized by MRI over its entire duration. This is not possible with X-ray guidance due to the radiation burden.

These minimally invasive MRI-guided interventions will deliver a great benefit to doctors and patients as well as the healthcare systems, as they promise a higher level precision medicine, less complications, and eventually overall increased treatment efficiency.

During the interventional MRI conference 'iMRI 2018' held in Boston MaRVIS experienced a strong interest by the medical community and the medical device industry in its MR Safe and visible guidewires. Dr. Klaus Düring, CEO of MaRVIS Interventional, summarized: "We talked to numerous interventional physicians of different medical disciplines and perceived their strong interest in getting at hand guidewires which can be safely used and well visualized in MRI-guided interventions. The fields of application reached from radiology and cardiology to neuroradiology and interventional oncology. For many applications the unique MaRVIS micro guidewire is of particular interest. There is no other micro MR guidewire available worldwide."

A requirement for success in establishing such MRI-guided inventions in the clinics is cooperation of the industry in the fields of MR scanners and optimized MR imaging technology, additional equipment for the operating room, and on the other hand the necessary disposables such as MR Safe and visible guidewires and catheters. Only then the entire portfolio of necessary devices and technologies will become available at short-term.

An example for successful interaction between clinicians, physicists and industry providing novel disposables for animal trials has been presented at 'iMRI 2018' by Prof. Michael Bock (Radiology – Medical Physics) and Prof. Constantin von zur Mühlen and Dr. Timo Heidt (German Heart Center Freiburg-Bad Krozingen) of University of Freiburg. Prof. Bock presented in his lecture successful MRI-guided coronary interventions in pigs, repeatedly delivering an MR translucent bio-resorbable vascular scaffold (Abbott) to the coronaries using a micro MR guidewire (MaRVIS Interventional).

Besides the good handling properties, the MaRVIS MR guidewires are unique with their patent-protected iron particle-based MR marker system which provides visualization by a continuous line over the entire length with artifacts of only 2-3 mm width, and an additional discrete MR tip marker for unambiguous identification of the distal end of the guidewire. MaRVIS strives to achieve a CE Mark Class III for the next product line as well as FDA approval as soon as possible to enable more clinicians to use the MaRVIS MR guidewires not only in animal trials but also in humans.

MaRVIS Interventional GmbH is a German medical device company dedicated to development, regulatory approval and marketing of MR safe and MR visible interventional devices. It has developed a patent-protected comprehensive platform technology integrating optimal mechanical properties with sharp and precise visualization of the devices in magnetic resonance imaging (MRI). The first focus of MaRVIS is on MR safe and visible guidewires, which has been realized in the world's first full portfolio of 0.035" standard and stiff guidewires and 0.014" micro guidewires. The MaRVIS guidewires offer superior mechanical handling and MR visibility and have been successfully tested in numerous model and animal trials in European and U.S. centers in various medical fields of application. The product lines 'MaRVIS Amber Wire' and 'MaRVIS Golden Wire' bear the CE Mark. This first-in-class platform technology provides high flexibility and is a powerful basis for the design of a broad spectrum of diverse interventional devices.

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