Press Release

MaRVis MR safe and visible guidewires for MRI-guided interventions comprehensively tested by Saarland University Medical Center, Germany

April 18th, 2017 – MaRVis Interventional GmbH has developed a unique portfolio of MR safe and visible, fiber-reinforced polymer – based guidewires, which enable the development and clinical set-up of MRI – guided interventions. MRI – guidance offers numerous advantages over conventional X-ray – based guidance, amongst others optimal visualization of soft tissue (e.g. blood vessels, organs, tumors), continuous real-time imaging and, thereby, control over the entire duration of the intervention, and freedom from radiation burden. Dr. Alexander Massmann, MD, et al. of the Saarland University Medical Center (Germany) recently published a scientific paper (Radiology, 2017; DOI: http://dx.doi.org/10.1148/radiol.2017152742) describing extensive comparative testing of the MaRVis guidewires to gold-standard commercial metal-based guidewires in a phantom model and in pigs. The authors concluded that excellent visualization of the guidewires combined with good handling properties – as evidenced in 1,296 cannulations and 27 stent placements in a variety of radiological interventional endovascular procedures in the pigs – result in handling of the MaRVis guidewires in MRI – guided interventions being comparable to that of the commercial reference products in conventional X-ray angiography.

For most of the minimally invasive medical interventions in radiology, cardiology, oncology or neuroradiology essentially three different types of guidewires are required. These are 0.035 inch standard and stiff guidewires and 0.014 inch and 0.018 inch micro guidewires. Often two of these guidewire types are necessary to perform a single intervention. Such guidewires are commercially available built from metal cores (e.g. stainless steel or nitinol). These metal-based guidewires are unsafe in the magnetic resonance imaging (MRI) environment due to electric conductivity and heating induced by the radiofrequency fields of MR scanners. Therefore, there is a need to develop and make commercially available MR safe guidewires in order to enable clinical development of endovascular MRI – guided interventions.

MRI – guidance of medical interventions offers numerous advantages over X-ray – based guidance. In particular, optimal visualization of soft tissue (e.g. blood vessels, organs, tumours) is achieved. It is less well visible in computed tomography (CT) and not at all visible in X-ray fluoroscopy. Another key advantage is continuous real-time imaging of the soft tissue in the body, and, thereby, enables excellent operative control over the entire duration of the intervention. Due to the accumulating radiation burden throughout an intervention continuous control is not possible with X-ray – guidance. As MRI is radiation-free, continuous real-time imaging over long time periods is possible. Furthermore, complete freedom from radiation burden is a strong health benefit for patients and physicians. In addition, the use of X-ray contrast agents with their inherent health-affecting properties is avoided. Moreover, additional structural and functional information can easily be retrieved from MR images

without a need for additional imaging, which may simplify a number of interventions, and may make them more cost-efficient, too.

MaRVis Interventional GmbH, a German medical device start-up company, has developed a unique portfolio of MR safe and visible, fiber-reinforced polymer – based guidewires. These MaRVis guidewires are constructed from glass/aramid fiber – epoxy rods, so-called ´MaRVis rods´. All three required product types have been developed and extensively tested. The multi-composite design, based on these MaRVis rods, enables handling properties similar to those of metal-based guidewires. MRI visibility is achieved by the proprietary MaRVis MR marker system. This comprises metal particle doping of the entire guidewire plus a separate MR tip marker, resulting in a continuous line representation, as used to from commercial guidewires in X-ray imaging, and precise identifiability of the tip of the guidewire.

The group of Dr. Alexander Massmann, Prof. Arno Bücker and Prof. Günther Schneider at the Clinic for Diagnostic and Interventional Radiology at the Saarland University Medical Center Homburg/Saar (Germany) described extensive comparative testing of the MaRVis guidewires to commercial metal-based gold-standard guidewires in a model system and in pigs in a recently published scientific paper (Radiology, 2017; DOI: http://dx.doi.org/10.1148/radiol.2017152742). The authors performed 180 cannulations in the phantom model for initial characterization, and subsequently 1,296 cannulations and 27 stent placements in a variety of radiological endovascular procedures in nine pigs. Interventions performed were balloon dilation as well as stent implantations into the aorto-iliac and visceral arteries and into the vena cava. Some of these represent difficult to access anatomical regions. The MR sequence (i.e. imaging settings) was a standard real-time sequence with 5 images per second on a 1.5 Tesla commercial MR scanner.

Visualization and handling of the guidewires have been rated by two interventionalists, and catheterization times for different vessel regions have been determined for the reference and for the MaRVis guidewires. The authors reported that visibility of the MaRVis guidewires in MRI is appropriate and that adequate mechanical properties allow for safe endovascular handling in standard radiological interventions. Visibility has been rated in vitro and in vivo as good to excellent. All in vitro and in vivo procedures required equivalent times for both the MaRVis and the reference guidewires in their respective imaging system. Dr. Alexander Massmann, an experienced interventional radiologist, stated: "MaRVis guidewires combine excellent visualization and handling properties. This is an essential milestone for setting up MRI – guided endovascular interventions." The authors concluded that handling of the MaRVis guidewires in MRI – guided interventions is comparable to that of the commercial reference products in conventional X-ray angiography.

Furthermore, intentional destruction of the glass fiber – based MaRVis guidewires by manual bending by 180° and kinking – which leads to glass fiber breakage – has been carried out. Such broken guidewires have been tested for usability in completing the ongoing procedure as a worst case scenario. The authors confirmed that the surface of the kinked MaRVis guidewires remained smooth and intact. Catheter and sheath exchange over the straightened kinked guidewires could be performed

without complications and without disruption of the kinked MaRVis guidewire. This is a proof that the safety means built into the MaRVis guidewires are effectively functioning.

MaRVis Interventional GmbH is working towards obtaining the CE Mark for its MaRVis MR safe and visible guidewire portfolio. Dr. Hélène Clogenson, Head of Applied and Clinical Development, looks forward to this timepoint: «Clinicians are eagerly awaiting the CE Mark for our unique guidewire portfolio as they want to move forward from phantom and animal trials to MRI – guided interventions in clinical routine. Commercial availability of the MaRVis guidewires will be a key step forward to switch interventions from X-ray to MRI – guidance.» Dr. Klaus Düring, CEO, added: «The scientific publication by the radiological interventionalists at Saarland University Medical Center, who possess two decades of dedicated experience in development of MRI – guided interventions, is a strong proof for medical usability of our patent-protected platform technology for MR safe and visible medical devices. The MaRVis guidewires are the first product portfolio derived from this platform technology. We are optimistic that commercial use of the MaRVis guidewires will soon start with the first human applications being brought to clinical routine after the CE Mark has been obtained. The benefits for patients and physicians will be huge.»

About MaRVis Intervenional GmbH

MaRVis Interventional GmbH is a German medical device start-up company dedicated to development, regulatory approval and marketing of MR safe and 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 inch standard and stiff guidewires and 0.014 inch and 0.018 inch 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. clinics in various medical fields of application. This first-in-class platform technology provides high flexibility and is a powerful basis for the design of a large number of individual interventional devices. The major benefits of MRI – guided interventions are optimal soft tissue visibility, continuous operative control over the entire length of the intervention, and avoidance of X-ray contrast agents as well as X-ray burden. Furthermore, additional physiological information can be obtained in MRI without the need for additional imaging.

Contact:

Dr. Klaus Düring
MaRVis Interventional GmbH
Auf dem Rotental 47
50226 Frechen
Germany
Phone: +49 2234 962908
Fax: +49 2234 962907
k.duering@marvistech.com
www.marvistech.com