

MEDICAL DEVICES

MaRVis Technologies GMBH

MRI-compatible medical devices

DENNEWARTSTR. 25
52068 AACHEN
GERMANY
Phone: +49 2234 962908
Web Site: WWW.MARVISTECH.COM

Contact: Klaus Duering, PhD, CEO
Business: Medical devices compatible and visible with MRI
Founded: January 2008
Founders: Klaus Duering; Joachim Pfeffer, MD, CTO
Employees: 2
Financing to Date: \$1 million
Investors: The BioScience Ventures Group; Seed Fonds fur die Region Aachen GMBH & C. KG

Physicians continue to wait patiently for the day they can perform interventional cardiovascular and neurological procedures using magnetic resonance imaging (MRI) for guidance instead of x-ray, to more accurately treat a patient by viewing soft tissue without the need for an injectable contrast agent. However, current guidewires and catheters do not allow for this superior treatment because they contain metal components that can distort MR imaging or potentially heat up inside the patient.

To the rescue: **MaRVis Technologies GMBH**, a German start-up company that constructs guidewires and catheters in a completely different process. Not only do these medical devices lack a metal core, but they are built in a multi-composite manner from core rods composed of fiberglass filaments enclosed with epoxy resin and doped with small metal particles, for MRI compatibility and visualization and to maintain the desirable material characteristics of current guidewires and catheters.

MaRVis is initially developing guidewires, a basic medical device used to direct catheters to their target position (e.g., for placement of a stent within a blood vessel or for delivery of a diagnostic liquid). "Our guidewires and catheters are compatible with both x-ray imaging and MRI," says Klaus Duering, CEO.

MRI-guided procedures offer numerous advantages over x-ray: better imaging quality (especially for visualization of soft tissues that usually are the target

of radiological interventions), no x-ray burden to patients and personnel, and elimination of contrast agents with negative effects on patients. "Although we currently have available open magnets and real-time imaging, MRI-compatible and visible medical devices remain unavailable," Duering notes.

The most recent data (from 2003) indicate that about 7.4 million interventional procedures are performed annually in US hospitals and outpatient settings, according to Medicare and the American College of Radiology. "The majority of these are x-ray-guided procedures," Duering says. The cardiovascular guidewire and catheter market is a billion-dollar market. "Millions of patients might benefit from the availability of MRI-compatible and visible medical devices," he says.

The company was initiated by Duering and Joachim Pfeffer, a seasoned medical engineer, on the basis of a first basic patent application that Duering had acquired, which had originated from a group of scientists at the **University of Aachen**, Germany. "The scientists were interested in reaching the material characteristics needed for a guidewire or a catheter, without metal, so the device would be compatible with MRI," Duering conveys. "Although it is quite a simple idea, no one else had pursued it." Pfeffer is the lead inventor on this patent application. Meanwhile, considerably broader intellectual property, including a second patent application, has been cre-

ated. Two patent families are pending.

Duering is a serial life science entrepreneur, business consultant (Axara Consulting) and pre-seed investor, with a background in chemistry, biochemistry, and molecular biology. After a successful career in public research, Duering shifted to the life science sector when in 1998 he incorporated his first biotech company in Germany, MPB Cologne GMBH, which used potatoes as a manufacturing platform for pharmaceutical proteins as an alternative to mammalian cell culture. Besides MaRVis, Duering is active in two other medical device companies: AIS GMBH (developers of a percutaneously insertable blood pump of minimal size) and Alaxo GMBH (makers of a reusable nasal stent for treatment of apnea and snoring). Pfeffer is involved in AIS and Alaxo as well.

Today's guidewires often contain a metal core (e.g., non-ferromagnetic nitinol) for x-ray imaging purposes that achieves the necessary material characteristics for high axial stiffness, torsion capability, general stability, and suffi-

cient flexibility. “However, this continuous metal core usually leads to much too strong artifacts, which distort imaging of the target tissue,” Duering explains. “Sufficiently controlled artifact generation in MRI is more or less impossible with metal/nitinol cores.” There is also the problem of heat generation and electric conductivity for patient safety.

“For use in an MRI system, a device should be well MR visible in the sense that it has its own identifiable magnetic resonance signal in the presence of the combined magnetic and RF fields and concurrently is not perceptible to conduction of electric current,” Duering says.

MaRVis’ platform technology enables the necessary combination of high axial stiffness, torsion capability, general stability, and flexibility as essential material characteristics; controlled artifact generation for directed visualization; and no electric conductivity in MRI. For instance, the epoxy resin used to enclose the glass fibers as a matrix material is doped with metal particles to produce controlled artifacts for directed visualization in MRI. A multitude of MaRVis rods enclosed in another polymeric shell material (without metal particles) forms a guidewire.

For construction of a catheter, the rods are radially inserted into the catheter wall. “This multi-composite construction concept is the main reason for delivering the required material characteristics as found in current gold-standard products containing metal cores,” Duering says.

The company’s basic building blocks and medical devices are built generally from commercially available materials, applying known material combinations. “The challenge in developing the platform technology is miniaturization of such materials for application in guidewires and catheters and the integrated

use of the optimal materials for achieving the technical goals,” Duering says.

The patent literature reveals that in recent years many companies have tried to develop MRI-compatible and visible medical devices, especially guidewires and catheters. “But none have used an integrated development approach as we have,” Duering points out. For example, a proposed guidewire from **Cordis Corp.** consists of a single glass core as the non-conductive material. “However, due to the stiffness of a single, comparably thick glass core, the material characteristics are not at all sufficient,” he says. “Furthermore, the risk of breakage is present, which may lead to strong injury to the patient. Therefore, the inventors designed a complex construct of multiple coatings to improve patient safety and material properties. This non-imageable guidewire was combined with an antenna on its tip as an active MR marker that allows only visualization of the tip of the guidewire.”

Duering also singles out **Biotronik GMBH & Co.**, which has focused on using a single polyetheretherketone (PEEK) polymer core with small iron particles embedded in the coating as a visualization marker. Although Biotronik published a first scientific validation of the visualization concept of using small metal particles for MRI imaging without the risk of electric conduction and heating of the device, “this technology

suffers from insufficient material characteristics,” Duering says.

MaRVis is seeking to partner with one or more established medical device firms that will take the lead in developing final products. For that reason, it has decided not to pursue human trials for its guidewire at this time. “We anticipate that an industrial partner, who will develop the final products, will conduct the first human clinical trial,” Duering says. He added that all critical information for human application for this type of guidewire can be gleaned from animal studies (most likely pig), the first of which is planned to begin the middle of 2009.

Duering is hopeful that a yet-to-be identified partner will be granted a CE mark for a guidewire by 2011, followed by FDA approval in 2013.

MaRVis’ partnering strategy “will substantially increase the efficiency of bringing products to the market after proof-of-concept,” Duering says. Its partners will also market and sell the products. “If in the end, we end up with an extremely valuable and useful product, there may be premium pricing over standard guidewires and catheters,” Duering says. In any event, no new DRG code is expected.

In April 2008, the company completed its first round of financing (comparable to a series A) in the amount of roughly \$1 million. No future capitalization is planned for the near future.

Down the road, with increased development effort, the novel technology could be used for stents, too, current versions of which are not compatible with MRI,” Duering notes.

[A#2009900047]

—BOB KRONMEYER

“We had the idea in mind to link up with an overseas company when we created Itero.”
— Bryan Lawlis