

## Press Release

### **A new generation of minimally invasive devices, fully compatible to the MRI technology, to revolutionize surgery**

*The EU funded project OPENMIND has come to an end and presented a new kind of production system for the manufacturing of individualised minimally invasive medical devices fully compatible to MRI technology (Magnetic Resonance Imaging) to open up new perspectives for surgeries and physicians.*

Aachen, August 2018 – A new generation of guidewires for minimally invasive interventions fully compatible to the MRI *Magnetic Resonance Imaging* technology, has been demonstrated at the end of the project OPENMIND, which has been funded by the European Union. This opens up new opportunities for the manufacturing of other kinds of minimally invasive medical devices, like catheters, puncture needles or aneurysm clips. The particular characteristics, all these medical devices have in common, are the use of fiber reinforced plastics and thus a great applicability for MRI guided surgeries.

Involving 9 European partners, active in 6 different countries - **Fraunhofer Institute for Production Technology IPT** (coordinator), **Diribet spol. s.r.o.**, **IRIS Technology Group**, **Fondazione Politecnico di Milano**, **Nano4imaging GmbH**, **Blueacre Technology Ltd**, **Tamponcolor GmbH**, **Gimac International**, **ICS In-Core Systèmes** – OPENMIND has realized the first flexible process chain based on a FRP (fibre-reinforced plastics) production process (micro-pullwinding), which is able to produce customized minimally invasive medical devices and opens up new perspectives for physician's current demand. The final workshop of the project was held at the Laboratory for Machine Tools and Production Engineering (WZL) of RWTH Aachen University in Germany. The event used the opportunity to discuss the overall results of the project as well as the future of medical device industry.

Nowadays, cardiovascular diseases are the **leading cause of death in the European Union**. Each year cardiovascular disease causes **3.9 million deaths in Europe** and **over 1.8 million deaths in the EU**. Overall they are estimated to cost the European Union economy **€210 billion a year**. MRI represents the best way imaging the cardiovascular system in general and the heart in particular. Actually the added value of the OPENMIND project is **the transformation of MRI from a sophisticated diagnostic technology to a powerful therapeutic tool** by developing a flexible technology for metal free operation tools, compatible with diagnostic images.

The MRI approach in cardiology is innovative and **eliminates radiation exposure during**

**vulnerable patient treatment.** More generally, **children and pregnant women can benefit from the lack of radiation in an MRI setting.**

Beyond geometrical and mechanical customization, OPENMIND allows individual configurations of visual properties depending on the physician's preferences. The guidewire's visual appearance for image-guided surgeries can be customized by means of the marker's type, position and absolute frequency. Not only does this help surgeons to navigate through the patient's vascular system with high precision and safety, but also does it increase the appeal of (Magnetic Resonance Imaging) MRI-supported interventions.

Jonathan von Helden representing **Fraunhofer IPT**, says *"The OPENMIND approach aims at the development of a highly flexible process chain for the on-demand production of entirely customized minimally invasive medical devices. Beyond the technological and economical innovations for medical device manufacturing companies, we want to emphasize the great advantages, which physicians will be able to make use of in diagnostic and therapeutic minimal invasive interventions, once the technology reaches a specific readiness level"*.

After finalization of all software- and hardware-related developments of the consortium partners, the individual components have been successfully implemented and commissioned within the overall process chain on the shopfloor of Fraunhofer IPT in Aachen, Germany.

### **Technical aspects**

The concept of the production system consists of a hardware part and a software part. The hardware part is composed of several modules for the different production and machining steps that are required for guidewire manufacturing. The software part consists of a tailored statistical process control system and a process model based on machine learning algorithms. Moreover, due to the continuous generation of process data including inline measurements and quality evaluation, the OPENMIND process chain works without initial testing of new configurations. By using a process model, which predicts the optimal machine parameters for the mechanical characteristics, as well as statistical process control (SPC), which evaluates the quality of the guidewire during production, the system is prepared to identify failures in manufacturing and learn from those. This makes the process development more flexible and enables a much higher automation level, as new combinations of physical properties do not need to be tested before producing the product.

A research issue, that will be addressed in the near future is the transfer of OPENMIND's outcome to other kinds of minimally invasive devices, physicians demand to be customizable.

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