

## Press Release

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

*Just launched in Bruxelles the European project OPENMIND, which is going to run for 3 years. The demonstrator device of the OPENMIND project will be manufactured without any macroscopic metallic components and thus will be inherently MRI (Magnetic Resonance Imaging) safe. Aim of the project is to develop a flexible technology for medical disposable manufacturing.*

November 2015 - 9 European partners, active in 6 different countries, present the first generation of new compatible minimally invasive devices (like guide wires, catheters, micro instruments) in the MRI (Magnetic Resonance Imaging) technology. The ambition of the OPENMIND project –involving **Fraunhofer Institute for Production Technology IPT** (coordinator), **Diribet spol. s.r.o.**, **IRIS Innovation Research Industrial Sostenibility**, **Fondazione Politecnico di Milano**, **Nano4imaging GmbH**, **Blueacre Technology Ltd**, **Tamponcolor GmbH**, **Gimac International**, **ICS In-Core Systèmes**– is to develop a flexible technology for medical disposable manufacturing. A metal free product design based on fibre-reinforced plastics will offer multi-modal compatibility (X-Ray, CT and even MRI).

The implementation of powerful imaging technologies has led to a **massive rise in the number of minimally invasive interventions** over the last decades. In addition, every year about 10 million people get an MRI scan, but mainly for diagnostics. Even though the sector of minimally invasive surgery has grown massively in the past, the physician still has to choose from a limited, predefined spectrum of “off-the-shelf” products. However, for a successful outcome of advanced minimally invasive interventions, it is essential to fulfil the needs of the physician who has to solve a complex task: navigating and operating in the human vascular system without having a direct view. That's why each doctor has in mind his or her ideal device for a specific intervention in terms of handling and visibility. Therefore to maximize the ease of use of the medical devices and, thus, to optimise the outcome of the intervention **a customised product** would be the perfect solution.

In this context, the OPENMIND project will realise **the first flexible process chain for customised medical disposable manufacturing**. This process chain will close the gap between efficiently produced standard products and individually designed products, enabling even the production of small batches. The process chain will be able to perform automated optimisation of the running process. For this reason, all acquired data will be processed and analyzed by advanced data mining algorithms based on similarity considerations. The generated data base will furthermore be used to apply predictions on process parameters for future device configurations and thus will simplify product development cycles significantly.

Another important aspect of the OPENMIND project is the focus on the multi-modal capabilities of the future products. Despite its clear advantages in terms of soft tissue visualisation, vessel imaging and its lack of radiation, surgical interventions using MRI are still rare. The main reason for the poor therapeutic relevance of this powerful imaging technique is the lack of compatible medical devices.

## partners

Many state-of-the-art minimally invasive devices contain metals or metal pieces, and these are not compatible with MRI.

The new production chain is based on **FRP (fibre-reinforced plastics) production processes (micro-pullwinding)**. The OPENMIND project will adapt these FRP processes in order to introduce a completely new generation of multi-modal minimally invasive devices that will be widely customizable by doctors. The use of innovative FRP material is important for mechanical individualisation of the device (the strength and stiffness of the product depends on the fibre orientation). With a deliberate choice of the employed high tech fibres in a multi material profile, the devices are neither magnetic nor electrically conductive. **This gives the new devices the unique property of being fully and inherently MRI safe which will boost the evolution of MRI from a sophisticated diagnostic technology to a powerful therapeutic tool.**

As first implementation, a **guide wire** will be used as **demonstrator device** for showing the successful outcome of the project. Guide wires are essential tools for many minimally invasive procedures, such as **cardiac interventions**. Cardiovascular diseases are still the number 1 cause of death globally but at the same time, more and more people survive heart attacks and strokes due to repair of lesions using minimally invasive methods such as stenting, valve replacement and resolving aneurysms. With the outcome of the OPENMIND project transferred to other kinds of minimally invasive devices, physicians will be able to work with tailored tools every day.

### Expected results

Thanks to the OPENMIND concept, combining highly flexible processes and intelligent data mining functionality, new perspectives for personalised medical devices will open. Improvements are expected in terms of reduction of lead-times for manufacturing of custom made parts (by 50%) due to continuous manufacturing, as well as reduction of process development time (by 50%) and costs (by 20%) due to data mining assisted parametrisation resulting in a reduced time to market (by 30%). Besides this industrial perspective, the project will also have a **strong social impact**: regardless of the direct health care costs, the productivity loss due to cardiovascular diseases adds up to over 45 billion € per year only in Europe. With the help of customised minimally invasive medical devices physicians will be able to maximise the outcome of modern keyhole surgery reducing the time for recovery and the risk of medical complications. In addition, the multi-modal compatibility of the new generation of medical devices will pave the way to completely new therapies bringing together the most powerful imaging methods.

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