Openmind

On demand medical devices

n°5

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Dear reader,

a very warm welcome to the 5th and last newsletter of the OPENMIND project. Half a year has passed since the last update and there is accordingly much to report about. After finalization of all software- and hardware-related developments of our 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. You can find photographs and 3D-renderings of the overall OPENMIND process below.
For continuous production of guidewire prototypes, the overall assembly is currently tested and fine-tuned in cooperation with the project consortium, but first things first: After manufacturing of the physical modules in the laboratory of our partners, the modules were shipped and assembled at IPT. This includes two laser modules (Blueacre Ltd.) for ablating and structuring processes, a printing unit (Tamponcolor TC-Druckmaschinen GmbH) to mark the medical device in terms of MRI visibility and a coating unit (Gimac International Srl) to generate a biocompatible surface. In combination with metrology systems (INCORE Systèmes) all hardware components have been successfully integrated into the existing setup.
Beyond the physical assembly on the shopfloor, the machine units were connected software wise.
Therefore, we developed an overall control unit, which is able to interconnect the different control units of the machining modules. To realize a production process with high flexibility, a comprehensive monitoring and data mining system has been developed. By storing a multitude of process-generated data on a database server, a digital image of the overall production system occurs, which not only helps to optimize the process itself in terms of quality assurance, but also allows parameter-predicting algorithms to simplify the production of future device configurations.
In the *FocusOn* part of this newsletter, we will have a deep dive into project results focusing on individual hardware modules as well as their functionalities and the quality control of the guidewires.
If you want to keep in touch, you can join the OPENMIND community and follow us on LinkedIn and Twitter or visit our homepage (**www.openmind-project.eu**).

Kind Regards,
Jonas Dorißen & **Jonathan von Helden**
Fraunhofer IPT, Coordinators
July 2018

Figure 1: The first segment of the overall process chain, consisting of the Pullwinding unit (Fraunhofer IPT) and a subsequent exchangeable Laser module (Blueacre Ltd.)

Figure 2: The second segment of the overall process chain, consisting of a printing module (Tamponcolor TC-Druckmaschinen GmbH) and a subsequent coating module (Gimac International Srl)

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FOCUS ON

Process development

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.

This FocusOn will consider the process chain, the results in process development as well as first results of product quality.

The OPENMIND Process Chain

While the process chain is split into two segments, the production itself can be classified in the following three steps (see figure 1):

1. Core production and machining
2. Winding and surface structuring
3. Finishing: printing, coating and cutting

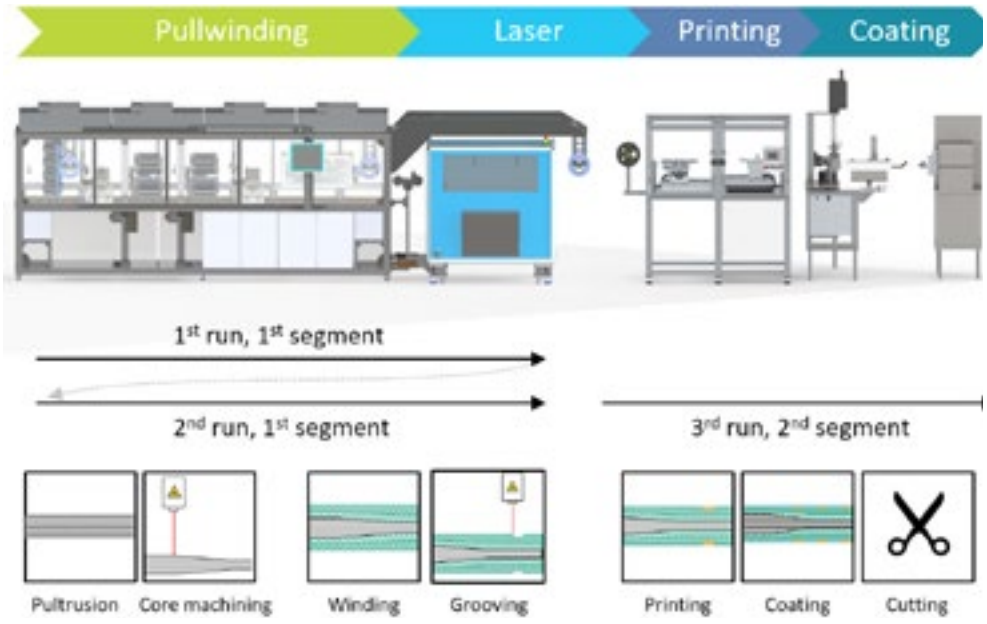

Figure 1: Concept of OPENMIND process

After the successful implementation and commissioning of all software- and hardware-related developments on the shopfloor of Fraunhofer IPT, the overall process chain is finally operational for the manufacturing of guidewire prototypes. Hereafter, the above-mentioned production steps will be described to give a better understanding of the fundamental functionality of the process: The pulling unit conveys basalt fibres through the pullwinding unit, where they are impregnated with epoxy resin and consolidated in a forming die. After an integrated laser-based metrology device (figure 2, top left) measures the core diameter, a 3-galvanometer laser system subsequently decreases the profile's diameter and stiffness by 360° ablation. In the second production phase, the guidewire's cores is winded with two layers of aramid fibres with variable winding angles, which consequently result in specific customizable mechanical properties. An image acquisition solution (figure 2 top right) as well as the laser-based diameter measurement device from INCORE Systèmes provide information about winding angle and diameter for OPENMIND's data mining system. For the second segment and third production step of the overall process, the surface of the profile is finally laser machined to generate grooves for MRI-visible markers. Figure 2 shows Tamponcolor's on-the-fly printing module (bottom right) as well as a close-up picture of Gimac's micro extrusion system, which adds medical grade and approved biocompatibility to the product. In terms of data mining and quality assurance, metrology systems (figure 2, top centre) once again analyse the product optically.

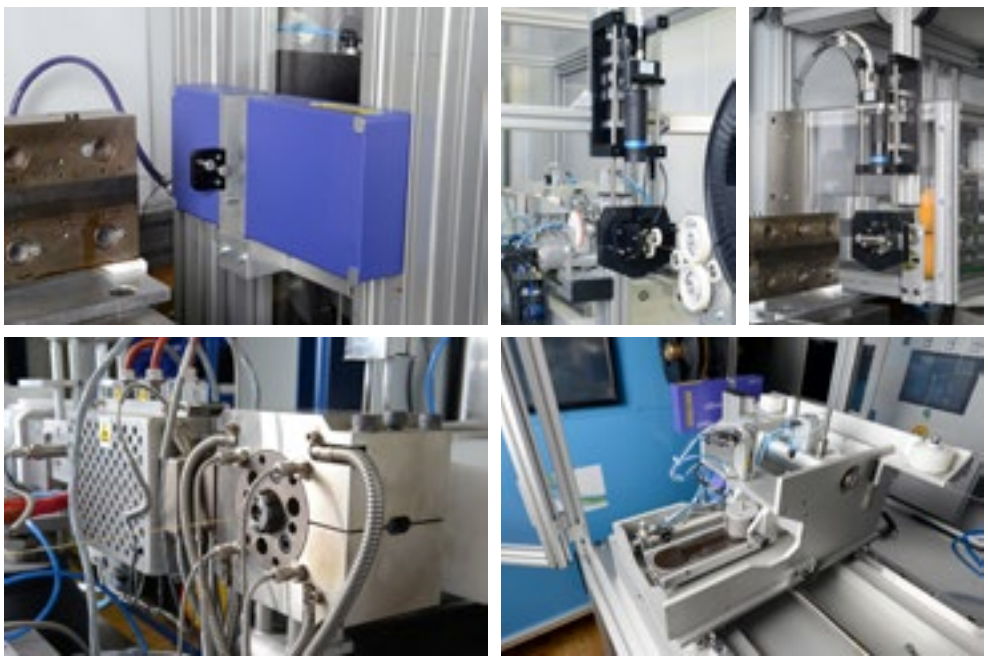

Figure 2: OPENMIND metrology systems (pictures on the top), printing module (bottom right) and coating module (bottom left)

The minimally invasive medical devices represent the project's demonstrator and they are currently manufactured and evaluated, based on their mechanical and optical properties. Figure 3 shows an actual prototype of a guidewire, in which the winding angle is very good visible due to the aramid contrast fibre.

Figure 3: First prototypes of OPENMIND guidewires (contrast aramid fiber and coating visible)

Because of the continuously generation of process data including in-line measurements and quality evaluation, the OPENMIND process chain works without initial testing of a configuration. By using a process model, which predicts the optimal machine parameters for the mechanical characteristics, and the 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 much 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. The realized software architecture is depicted in figure 4.

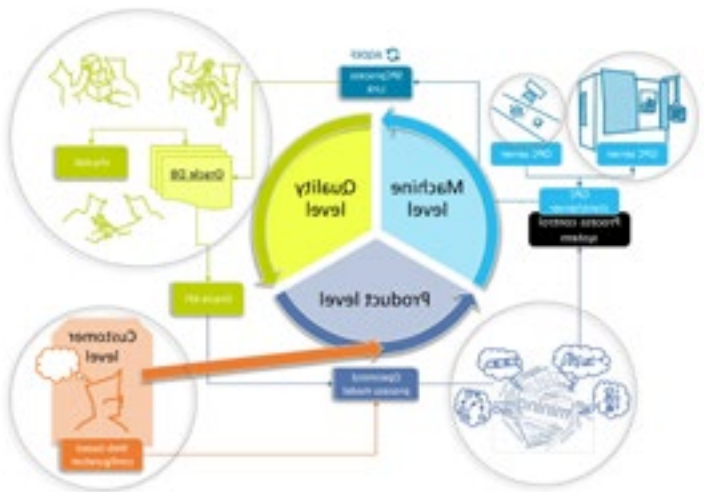

Figure 4: Software architecture and data cycle

With us in this issue...

Norbert Sparrow

PlasticsToday

Editor in chief of PlasticsToday *(www.plasticstoday.com), business-to-business media for plastics industry professionals. Prior to joining PlasticsToday in 2015, Sparrow was editor in chief of several B-to-B magazines, websites and newsletters for more than 15 years, covering the medical technology industry and associated supply chain in Europe, China and Japan. The publications included* European Medical Device Manufacturer, European Medical Device Technology, medtechinsider, IVD Technology and China Medical Device Manufacturer.
He earned his master's degree in journalism at the Centre universitaire d'enseignement du journalisme in Strasbourg, France. You can follow him @norbertcsparrow.

The results of the OPENMIND project will enable physicians to work with tailored tools. Combining highly flexible processes and intelligent data mining functionality. Do you think that new horizons will be opened up for personalized medical devices with Openmind project?

Mass customization is often cited as one of the game-changing possibilities of 3D printing in applications ranging from athletic shoes to medical devices. But what is fundamentally disruptive in this proposition is mass customization—the technological/manufacturing vehicle used to achieve that is almost secondary. The OPENMIND project, as I understand it, achieves this objective as it relates to disposable medical devices—specifically to catheter guidewires and related instruments in the first stage—through a continuous production process that is truly innovative and filled with potential. Pediatrics is one field that would benefit immensely. The development of pediatric medical devices is not a high priority for medical technology companies because the population that would benefit is relatively small, making the return on investment problematic. By enabling the production of small lots of personalized devices in an uninterrupted process, OPENMIND would provide pediatric patients with access to medical technology that fits their needs.

Which are the next challenges that OPENMIND will meet in the future according to Industry 4.0 and innovative technologies?

It borders on foolishness to attempt to develop a new manufacturing process today that does not align with Industry 4.0 principles. Choosing not to use the tools that Industry 4.0 makes available—sensors, automation, data exchange, interoperability, and more—is akin to perfecting the horseless carriage at a time when Henry Ford began mass production of the Model T.
Given the brain trust within the OPENMIND project and its forward-thinking ambition, I don't doubt that it will overcome the technical challenges in applying Industry 4.0 to this process. My one concern is cost. If the resulting device is significantly costlier to manufacture than existing products, even if it provides demonstrably superior outcomes, it will have a difficult time navigating the reimbursement route and penetrating the marketplace.

Meet the partners...

David Nettleton and Elodie Bugnicourt
IRIS

IRIS is an advanced engineering and R&D company. In OPENMIND IRIS is responsible for developing suitable data mining approaches to support optimisation of the process for the personalised medical devices that doctors needs. IRIS is also involved in obtaining the necessary inputs for the developed models and provides assistance on use of the developed software for process optimisation.
More info at ***www.iris-eng.com***

We arrived to the last step of Openmind.
What is the added value of Iris in the project?
To tackle the challenges of complex process calibration and manufacturing on demand, IRIS' OpenMind automatic parameter selection system makes it possible to calibrate each interdependent production process in an integrated manner to establish the control parameters, such as winding speed, die temperatures, extrusion rate, while maintaining within tolerances for friction force, guidewire diameter and stiffness. While the approach is applicable very broadly, the models developed in OpenMind find utility in a number of materials production processes not only applicable to tailored medical devices but also to other fibre reinforced products, continuous production of customized electrical cabling, etc. By automating a time-consuming artisan calibration process, automatic parameter selection systems can be applied to most processes for ramp up, optimization, reducing scrap and reducing re-calibration down time to make it possible to achieve customized mass-production.

How do you imagine the market of the medical devices in the future, thanks to the Openmind project? Your expectations for it...
IRIS is not an expert in the medical device business but from our OpenMind experience, we believe that such an industry 4.0 approach, including the use of predictive models, can be a key to accelerate the development of what are currently somewhat manual FRP processes. This will make on-demand customized production viable, significantly reducing re-calibration time and minimizing the generation of scrap which currently make it unviable to customize parts for each individual patient. The successful implementation of the new materials for guidewires and the quick ramp up of the new resulting products could be a flagship example for the medical device industry to adopt a more advanced manufacturing paradigm and support the use of less invasive devices and more sustainable materials in other applications. tools produced according to the patients' needs and his preference.

NEWS

OPENMIND – Final workshop

August 29, 2018 – 9:30

RWTH Aachen University, Laboratory for Machine Tools and Production Engineering (WZL) - Manfred-Weck Haus - Steinbachstraße 19, Aachen (Germany)

OPENMIND – On-demand production of entirely customised minimally invasive medical devices – project **provides an innovative new production chain based on FRP** (fibre-reinforced plastics) **production processes** (micro-pullwinding). Thanks to the OPENMIND concept, **combining highly flexible processes and intelligent data mining functionality, new perspectives for personalised medical devices will be open**.

At the end of the project, beyond the physical assembly, the machine units were connected software wise. To realize a production process with high flexibility, a comprehensive monitoring and data mining system has been developed. By storing a multitude of process-generated data on a database server, a digital image of the overall production system occurs, which not only helps to optimize the process itself in terms of quality assurance, but also allows **parameter-predicting algorithms to simplify the production of future device configurations**.

If you want to learn more about OPENMIND you just have to attend the **final workshop** of the project which will be held on **August 29, 2018 at RWTH Aachen University**, in Aachen (Germany). The event is organized by Fraunhofer IPT in cooperation with all the project partners: Diribet spol. s.r.o., Fondazione Politecnico di Milano, IRIS Technology Group, Nano4imaging GmbH, Blueacre Technology Ltd, Tamponcolor GmbH, Gimac International Srl, ICS In-Core Systèmes.

The OPENMIND project has received funding from the **European Union's Horizon 2020 Research and Innovation Programme**, under Grant Agreement number 680820. OPENMIND is a quite demanding challenge, an important initiative lead at an international level in 6 different countries: Italy, Spain, Germany, Ireland, France and Czech Republic.

Further information and registration at
www.openmind-project.eu/events

EVENTS

Do you want to meet the partners and know more about the project? Make a note of the following events.

ICADMA 2018: 20th International Conference on Advanced Data Mining and Applications

IRIS

August 20-21, 2018 • Barcelona, Spain

Learn more:

www.waset.org/conference/2018/08/barcelona/ICADMA

OPENMIND – Final workshop

All partners

August 29, 2018 • Aachen, Germany

Learn more: **www.openmind-project.eu**

Composites Europe 2018

Fraunhofer IPT

November 6-8, 2018 • Stuttgart, Germany

Learn more: **www.composites-europe.com**

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partners