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TREND REPORT

PRODUCTION STRATEGIES FOR THE MEDICAL TECHNOLOGY OF TOMORROW

WHY THE NEXT GENERATION OF MEDICAL PRODUCTS REQUIRES NEW MANUFACTURING TECHNOLOGIES

The European medical technology industry is benefiting from the effects of demographic change: people are living longer, and the costs associated with diagnoses, therapies and rehabilitation are increasing year-on-year – and so is expenditure on prevention and "active ageing" products. The industry has therefore long been regarded as a stable growth market with annual revenues in excess of EUR 100 billion in Europe alone[1] and a projected annual growth rate of 4.5 percent. By the year 2023, global annual revenues will have reached the staggering amount of EUR 400 billion[2].

This growth rate is further accelerated by the industry's powerful innovative momentum: According to the Association of German Engineers (VDI), the medical technology industry invests considerable time and money in areas such as miniaturization, digitalization and networking, biologization, customization and automation[3]. These developments reflect the results of the industry's efforts in the field of applied research which have generated a whole host of new concepts for medical products of the next generation. As soon as a "Proof of Concept" has been established and prototypes as well as small production series have completed their research stages, however, cost-effective and scalable manufacturing technologies need to be developed to guarantee a successful market launch.

Europe's medical technology industry is firmly in the hands of small and medium-sized enterprises: 95 percent of its companies employ fewer than 250 people[4]. As a consequence, few manufacturers can invest unlimited resources in the development and introduction of new production processes. This is why they must involve external experts in the early stages of developing process technology capable of ensuring the safe and smooth market launch of their new products.

The ongoing development of production technologies such as those which form part of Industrie 4.0 and of additive manufacturing processes provide a wide range of opportunities to support, improve and radically redesign existing production techniques. Over the following pages, we shall describe various trends and innovative applications in medical technology that stand to benefit from new manufacturing strategies.

1 *European Commission (2019): Medical devices. Online under: https://ec.europa.eu/growth/sectors/medical-devices_en*
2 *Research and Markets (2018): Medical Devices Market Report. Trends, Forecast and Competitive Analysis. Online under: www.researchandmarkets.com/research/42d8b9/global_medical*
3 *VDI – Verein Deutscher Ingenieure (2017): Medizintechnik – Trends und Perspektiven. VDI-Thesen und Handlungsfelder. April 2017. Online under: www.vdi.de/medizintechnik*
4 *MedTech Europe (2019): The European Medical Technology Industry - In Figures 2019. Online under: https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-2.pdf*

SMART MEDICAL TECHNOLOGY

SMART, SMALL AND MULTIFUNCTIONAL: THE NEXT GENERATION OF MEDICAL PRODUCTS

The more information is available about a given patient and the state of his or her health, the better their doctor will be able to customize the treatment to meet this patient's individual needs. In the near future, miniaturized sensors in smart medical products will be capable of gathering data, thus helping doctors to keep the medical condition of their patients under close observation. Smart surgical instruments, for example, will record data during the operation, while sensors on implants or contact lenses will allow doctors to monitor the development of their patients´ symptoms continuously over long periods of time. The condition of the medical products themselves – such as orthoses, e.g. – can also be supervised in this way, with sensors recording data about levels of mechanical stress and the wear that they cause.

Manufacturers of medical products need to be aware that their products will become significantly more complex. Medical products will evolve from "passive" to "active" systems that feature miniaturized sensors and provide interfaces for external data evaluations and analyses. Even disposable items will have to change: they will still need to be cheap, safe and minimally invasive and at the same time, smart and resilient to mechanical stress. Such product features and the required degrees of complexity cannot easily be squared with the imperatives of low-cost, high-throughput production lines. This is why manufacturers must take an integrated view of the entire process chain at an early stage of developing smart medical products. The choice of suitable miniaturized sensor systems – or, if necessary, their technological design and development – will be as important as the selection of the right types of material.

Printed electronics and micro-fluidic elements for cost-effective disposable products

Lab-on-a-chip systems are a good example of medical products with integrated sensors. These miniaturized products integrate processing sequences and sample analyses in one small micro-fluidic chip. Such systems are typically disposed of after a single use which is why they are manufactured in large numbers. The underlying technology itself is not new, the number of applications is growing continuously, with ever more highly complex diagnoses becoming more accessible. Production technology, meanwhile, remains a challenge: the micro-fluidic elements have so far been mainly manufactured via injection molding which requires an accurate process to mold the miniaturized ducts followed by high-precision micro-assembly of sensors, membranes, valves and plastic components.

Alternatively, however, it is possible to integrate the sensors as early as during the processes of manufacturing individual components. The production of large series in particular requires a fast and cost-effective strategy of manufacturing

integrated sensor systems. For this purpose, printed electronics can be applied in thin layers on to a non-conducting substrate. High-throughput roll-to-roll technologies can apply flat electronic elements to large substrates and seal them immediately afterwards.

This technology works not only for printed circuits but also for the application of micro-fluidic channels on multilayer substrates and for the functionalization of foil surfaces in optical applications[5].

Integrated sensors in medical products made from fiber-reinforced composites

Fiber-reinforced composites (FRC) are excellent for medical applications: carbon-reinforced plastics, for example, are frequently used for orthoses because of their high levels of mechanical stress resistance. More recently, surgical needles, catheters and guide wires have been manufactured from such FRCs, since operations that are performed with the assistance of state-of-the-art magnetic resonance scanners require surgical instruments that can be represented and located in real time and be artefact-free[6, 7].

For products such as these, it makes sense to integrate sensors into the product during the manufacturing process. Some of the existing processes of manufacturing fiber-reinforced composites allow glass fibers to be embedded at the same time. Fiber optic cables can convey measurements and also function as sensors in their own right, recording data about (for example) levels of pressure, temperature and mechanical stress. This opens up the possibility of integrating sensors into orthoses that measure the levels of mechanical stress during use.

Molding miniaturized optical elements in large production batches

In recent years, the production of high-quality miniaturized optical elements has been so cost-effective that the integration of such elements into medical products has become commercially viable. For the purposes of low-cost mass production, optics are increasingly produced from high-quality plastics, while even glass optics are no longer individually cut and polished. For some time now, molding tools capable of replicating even very small and highly complex free-form optics have been used in production technology environments.

An additional potential for further miniaturization can be exploited by further developing and enhancing traditional lithography techniques such as the two-photon polymerization technology that delivers resolutions in the sub-micrometer range. By applying ever shorter wavelengths in high-resolution and high-precision manufacturing processes, increasingly small optics, circuits and antennae can be provided for miniaturized integrated sensors and multifunctional systems. These processes are generally too time-consuming for large series production of individual electronic systems, but they can also be used to produce high-precision molding tools, enabling the multiple replication of designs for electronic components or micro-structures.

Micro-structuring technologies for multifunctional surfaces

It is not only the use of integrated sensor systems which appears to ensure that each generation of medical products is smarter than its predecessor. The purposeful adaptation of material and surface properties can also serve to enhance and improve product functionality. Functional surfaces can, for example, accelerate the integration of implants into the human body, increase the wettability of surfaces or inhibit the growth of pathogens.

Technologies such as the two-photon polymerization, laser structuring and ultra-precision machining can apply miniaturized structures in the micrometer and nanometer range to the products. Such technologies can work on even surfaces as well as on the surfaces of complex three-dimensional objects. This allows structures to be applied to implants that are meant to attract tissue cell populations after surgical intervention. Foils with anti-microbial coatings are another example of smart surfaces: they can be produced on a large scale with the help of the roll-to-roll technology[8]. Such foils may be used to cover the interior of hospitals in order to inhibit the spread of germs and pathogens.

5 Brecher, Baum, Bastuck (2015): Comparison of roll-to-roll replication approaches for microfluidic and optical functions in lab-on- a-chip diagnostic devices, In: Gray, Becker (Eds.): Microfluidics, BioMEMS, and Medical Microsystems XIII. SPIE: Bellingham.

6 Brack et al. (2016): Development of an artifact-free aneurysm clip. In: Current Directions in Biomedical Engineering 2 (1), S. 543-546

7 Brecher et al. (2014): New concepts and materials for the manufacturing of MR-compatible guide wires, In: Biomedical Engineering / Biomedizinische Technik 59 (2), S. 147-151

8 EU project FLEXPOL, www.flexpol.eu

Applications in medical technology

Point of care testing: Standardized minilabs for home examinations of patients

Point of care testing technology (POCT) makes it possible to perform laboratory tests at the GP's clinic, in remote areas with poor infrastructure or directly in the patient's home. Lab-on-a-disc or lab-on-a-chip devices use a standardized method to produce laboratory analyses within a few minutes, combining micro-fluidics, sensor systems and other electronic components in the smallest possible functional space.

High-quality, reliable and cost-effectively manufactured systems require production technologies capable of meeting the high quality standards of medical products. Easily controllable processes such as injection molding have been developed for the production of the plastic wafers that house the miniaturized lab,. It is a greater challenge, however, to accommodate increasing levels of functionality in the narrowly confined space of the chips. This requires more miniaturization and a greater density of the functional micro-fluidic components. New approaches – such as the roll-to-roll technology – allow the controlled production of large series. It is also possible to apply printed circuits to the component surfaces, supplying these with electricity or transmitting data.

PERSONALIZED MEDICINE
NEW MANUFACTURING TECHNOLOGIES FOR PERSONALIZED PRODUCTS AND SMALL SERIES

Both the volume and the diversity of available data have grown significantly over the past few years while the speed at which these data can be collected and evaluated has developed apace. This increase in speed has affected many areas of science and technology including medicine. The data collected by sophisticated new sensor systems and ever more accurate high-resolution examination techniques are paving the way for the emergence of personalized medical products and hold out the promise of products that, one day, can be customized to suit an individual patient's specific needs[9].

Such adjustments to an individual patient's physiology are particularly relevant to manufacturers of orthoses, prostheses and implants. Examples of these include tooth implants, personalized joint implants and personalized foot orthoses that have been customized for individual patients to provide them with maximum support. Traditionally, personalized medical products are hand-crafted individually by highly specialized artisans. New technologies will not only open the door to more cost-effective and more rapid modes of production, they will also allow the personalization of medical products that have so far been available only as standardized bulk commodities.

9 *Huber et al. (2015): Die Philips Gesundheitsstudie. Wie Vertrauen zum Treiber einer neuen Gesundheitskultur wird. Published by Zukunftsinstitut GmbH. Zukunftsinstitut GmbH: Frankfurt*

3D-printing for personalized prostheses and small series of instruments made from new materials

The production of personalized one-off products such as prostheses and small series of medical instruments that have been customized to serve a specific purpose presents challenges that can be mastered via generative production technologies. Individually customized prostheses can already be manufactured using 3D-printing technology. These new technologies extend the range of available materials beyond polymers and resins. Laser-assisted techniques such as selective laser melting in a powder bed and laser metal deposition enable additive manufacturing technologies to be used to produce metal components.

Such highly flexible production technologies for small series, meanwhile, require manufacturers to familiarize themselves thoroughly with the entire process chain and to assess the costs of these technologies in the light of the advantages and drawbacks of available alternatives. These assessments should include comprehensive product models, simulations and projected optimizations of the integrated process as well as comparisons between generative manufacturing techniques and suitable post-processing strategies. An integrated view of this nature allows the manufacturer to identify the financial and technological resources required for additive production– and will ultimately ensure that application of this technology make good business sense.

What is more, Manufacturers must be aware that efficient and scalable production technologies need to be supported by matching quality assurance procedures. Medical products are subject to strict regulatory requirements compelling manufacturers to make sure that their products are functional and safe at all times. This applies equally to customized products which are produced in small batches and where such assurance may present particular challenges.

Quality control procedures can extend beyond the examination of components of the product itself and include data from the manufacturing process. Such a widening of the focus, however, calls for closely networked production processes in which data are continuously collected, recorded and evaluated, either in real time or at the end of the production line. Additionally, new methods and strategies are required to ensure that quality assurance procedures can benefit from the smart use of data relating to customized and personalized medical products. One example of this type of smart use is the statistical validation of data from small series, where product data are compared with historical data from products with similar characteristics.

Applications of medical technology

Theranostic implants: individually customized and smart hip joint prostheses

"Theranostic implants" are endo-prostheses that combine therapeutic and diagnostic functions. The eponymous Fraunhofer flagship project (involving twelve Fraunhofer institutes) has developed a smart hip joint prosthesis equipped with electronic components such as sensors and actors, allowing doctors to monitor the slight changes in position of the prosthesis as well as the body's reactions to the implant and, if necessary, to perform minimally invasive adjustments. Additive techniques may enable the production of individually customized prostheses, but the need to apply complex patterns to prosthesis surfaces still presents a major manufacturing challenge. The Fraunhofer IPT has responded to this challenge by developing and refining existing machining techniques to the point where their surface qualities meet the quality requirements of medical technology. After surface machining it is now possible to apply a biogel to the surface, thereby preparing the scaffolding for a colonization of bone cells that assists the bone regeneration processes[10].

10 McBeth et al. (2017): 3D bioprinting of GelMA scaffolds triggers mineral deposition by primary human osteoblasts. In: Biofabrication 9 (1)

BIOHYBRID MEDICAL PRODUCTS
COMBINING BIOLOGICAL MATERIALS WITH TECHNOLOGICAL COMPONENTS

It is not enough for implants to be safe and functional: they must also have a high level of biocompatibility so that they can integrate well with the patient's body tissue and provide many years of service. Researchers who explore ways of raising such levels of biocompatibility and of actively supporting tissue regeneration processes are increasingly focusing their efforts on biohybrid products that combine technological artefacts with biological or bioactive materials. Biohybrid vascular prostheses that have been colonized with cell populations and artificial hip joints that have been coated with biological materials, for example, may help to reduce rejection risks and immune reactions while assisting and accelerating the integration of the implant in the existing tissue.

Biohybrid medical products are classified as "Advanced Therapy Medicinal Products" (ATMP) and subject to complex approval processes as well as strict regulations. As a consequence, only a few of them are currently commercially available. Most ATMP products are manufactured manually and in small series. The long-term provision of safe and affordable biohybrid medical products requires reliable and adaptive manufacturing technologies. One specific problem is the management of process fluctuations, especially in situations where the biological raw material has been extracted from the patient concerned or provided by a donor. Production processes must be closely monitored and documented in order to assure and guarantee maximum levels of product safety.

Automated laboratory processes for the extraction of cells and tissue for biohybrid products

Scalable production lines that can be fully controlled and comprehensively documented will increasingly require the use of fully and partially automated cell culture processing systems. It is the combination of these automated systems with the developments in regenerative, personalized medicine and tissue engineering that the wide use of biohybrid medical products will be within reach for the first time. Automated processes for handling the cellular material and comprehensive quality management procedures will allow production managers to monitor the manufacturing technologies in detail and to adjust them flexibly to the activities of the cells[11]. At the same time, these new technologies will eliminate the negative effects of handling variations that amplify more inherent process fluctuations.

During the past few years, biotechnology applications have automated a growing number of process steps such as cell reproduction in bioreactors and bioprinting. The safe and reproducible manufacture of cellular products for therapeutic purposes, meanwhile, increasingly requires research into fully automated process chains within closed and self-contained systems.

11 Kulik et al. (2016): Automation in the context of stem cell production – where are we heading with Industrie 4.0? In: Cell Gene Therapy Insight 2 (4), S. 499-506

Automation also requires the networking of individual devices. While the data that are collected throughout the process are used for quality control purposes and for matching processes and process chains to the requirements of the individual product, they also constitute the foundation for the downstream process of applying for official market approval. It is vital to develop automated instruments in compliance with the GMP (Good Manufacturing Practice) and GAMP regulations (Good Automated Manufacturing Practice), specifically in relation to computer-assisted systems and electronic records.

Applications of medical technology

Bone regeneration: Bioactive coatings of implants exploit the strength of stem cells

Biohybrid products combine the powers of technology and nature by acquiring support from the natural properties of biological products. As part of the EU project "EVPRO", for example, scientists are developing an innovative implant coating that can inhibit local infections while accelerating bone regeneration processes. The coating consists of structured, micro-porous titanium dioxide and a biodegradable hydrogel. Extracellular vesicles are embedded in the hydrogel: small capsules made from stem cells that contain bioactive substances. The coating reacts to the situation of the implant's surrounding tissue, releasing anti-inflammatory vesicles in a self-regulating process. The coating is designed to provide the blueprint for an entirely new type of biologically active implants[12].

12 EU project EVPRO, website: www.evpro-implant.eu

INDUSTRIE 4.0
NETWORKED ADAPTIVE SYSTEMS FOR THE PRODUCTION OF MEDICAL TECHNOLOGY

The medical technology industry is powered by its innovative strength and the constant drive to develop new products. The current trends presented here hold out the promise of better and more efficient therapeutic strategies that focus on the needs of the individual patient. The same trends, meanwhile, are driving the increasing complexity of medical products, while both price pressure and safety requirements remain high. This is why the development of new production technologies must be accompanied and supported by the design of new organizational structures for the manufacturing process.

The digitalization of production lines can help to revolutionize manufacturing processes, making them leaner, more flexible and more efficient. This ongoing digitalization is also the key to more flexible and efficient production of complex and personalized medical products. By networking and adapting the processes within sophisticated value-adding chains, it is possible to produce small batches of high-quality products. Serial production also requires continuous optimization of cycle times, use of resources and machine capacity rates. The manufacturers of medical products stand to benefit from the developments of Industrie 4.0 as much as their colleagues in other industries that produce complex, customized and safety-critical products.

Integrated concepts for digitalized production lines provide radically new solutions: one distinguishing feature of Industrie 4.0 is the horizontal as well as vertical integration of all processes – the construction of networks that transcend the various elements of the manufacturing chain as well as different organizational levels of the enterprise. Companies that want to remain in control of the complex mechanisms generated by automated production, must integrate their systems and devices into a common network, provide a comprehensive and continuous data management system and ensure seamless integration of measuring technology within process control procedures. This creates the conditions for the emergence of autonomous systems that are ready to adapt and to optimize their modes of operation in response to changing requirements or target values for small series and customized products.

Digital twins: familiarity with the history of a product aids and supports the market approval process

Networked adaptive production environments require the product and production data including sensor data, operating data and order data of each individual product to be recorded and stored centrally. These so-called "digital twins" contain the entire production history including project and order data. Identification systems can match them with the component in question. By analyzing this information, managers can reliably predict process times and the need for maintenance work. The data also accelerate the process development and optimization carried out by the manufacturer, allowing the cost-effective production and on-schedule delivery of small series and even individually customized medical products.

Digital twins also provide the corporate quality assurance department with detailed and aggregated data about each individual processing step. This information makes it easier to monitor the production process and eventually to gain market approval for new medical products. Order data of personalized products can be stored alongside information about the individualized product design for further reference. Here, Blockchain technology for example, permits product transactions, individual process steps and individual stages of the process chain to be comprehensively documented, ensuring traceability without any risks of tampering or manipulation. For this purpose, the data are cryptographically cross-linked in an extendable list. Any downstream element of this blockchain is based on a previous transaction, making it impossible to change or amend any data or transactions. In the future, blockchains may ensure full transparency across the production and supply chains of medical products, providing additional safety for customers and patients.

5G for wireless data transmission and the integration of metrology into production lines

In the medical technology industry, sophisticated production processes form the basis for competitiveness: only businesses that are ready to continuously optimize their performance, to react flexibly and to meet current quality requirements will survive in tomorrow's markets. Consequently, production lines of the future will need to provide manufacturers with the level of reassurance that only highly accurate and reliable measuring systems can guarantee.

Although modern sensor systems may be capable of collecting the required amounts of data, the analysis for optimization is usually carried out with a time delay. It is therefore imperative for complex manufacturing processes to integrate measuring technology directly into the production line. The conversion to flexible and adaptive production processes and the full documentation of all production steps require integrated quality assurance processes for an immediate collection and analysis of relevant quality parameters, if possible in real time and in maximum proximity to the production site. They also require fast and reliable – which often means: wireless – data transmission strategies.

New communication technologies such as the upcoming 5G mobile radio standard have latency times of less than a millisecond and data transmission rates of up to ten gigabytes per second, allowing complex communication networks and the integration of measurement and control technology into sensor systems. Modularized system architectures enable the cost-effective storage and further processing of data in decentralized systems or clouds.

Measuring systems that have been integrated into the production line and its constituent processes, smart measuring and control strategies in conjunction with sophisticated information technology shorten the response times to changes in manufacturing processes and to deviations of actual from target values, providing the conditions for a networked adaptive production environment.

Big Data: Managing huge data volumes

These are only a few selected examples of the potential of process monitoring in medical technology. The integration of sensors into production environments has expanded continuously over the past few years. This applies to sensors in production facilities and product tracking systems as well as to information about practical applications of the medical products that have been made available to doctors and patients.

Integrated data collection across several steps of the production process creates a database that can be analyzed using Big Data methods. Smart algorithms support the evaluation of large data volumes, providing the foundation for downstream optimization of the production processes. On the basis of this data, model-based and automated simulations inform the decision-making for individual processes as well as the entire process chain.

Applications of medical technology

Customized guide wires: Medical products that can be individually configured

Networked adaptive production strategies can support the development of the next generation of new high-quality medical products: As part of the EU "Openmind" project, a consortium of experts in medical technology and production engineering have designed a new strategy for the production of customized guide wires in minimally invasive surgeries. Based on the micro-pullwinding technique, guide wires with different levels of rigidity and different material properties can be produced in accordance with the wishes and requirements of the operating surgeon. The consortium developed a networked adaptive process chain with a suitable data mining system in order to close the gap between cost-effective mass production and customized products while continuing to comply with the product-specific quality and performance requirements. For this purpose, all process and product parameters have been stored in a central database where they are evaluated on the basis of similarity algorithms in order to improve product quality and to establish the parameters for new product configurations. The large data volumes and a closely integrated measuring and control system guarantee full compliance with the high quality standards of medical technology[13].

13 *Wasiak et al. (2017): Quantification of micro-pullwinding process as basis of data mining algorithms for predictive process model. In: Chinese Society for Composite Materials (Eds.): 21st International Conference on Composite Materials. Chinese Society for Composite Materials: Xian.*

SMART DEVICES
QUALITY CONTROL AND RISK MANAGEMENT IN PRODUCTION AND APPLICATION

Medical technology products are subject to extremely strict safety regulations. A wide range of laws, statutes, standards and guidelines including the German Pharmaceuticals Act or the EU's "Medical Device Regulation" and the "Good Manufacturing Practice" provide a detailed list of risk management requirements and instruct manufacturers on how to document risks and potential side effects.

The increased use of networks in production lines creates new quality management options. Algorithms for the analysis of production data can detect irregularities and anomalies at an early stage, shortening response times and thereby increasing the success rate of interventions. Comprehensive data storage functions enable manufacturers to trace back production processes and to identify the sources of errors. The continuous flow of product quality information also allows manufacturers to verify the effectiveness of their reactions and countermeasures and, if necessary, to review and to optimize them.

Smarter medical products that use sensor systems to communicate continuously updated information about their status can deliver product data not only during the manufacturing stage but across their entire life cycle. In the future, this will allow manufacturers to acquire a deeper understanding of how design and production processes determine the durability and functionality of their medical products. As a result, this will also allow the manufacturers to improve the product properties of their goods.

Smart algorithms for defect detection

"Classic" algorithms are increasingly complemented by learning systems. This process of "machine learning" trains algorithms to recognize certain patterns, based on existing data, and subsequently to make their own decisions. One application for machine learning is image recognition. Such technologies are already used in some biological and medical applications, for example for the purpose of recognizing certain cells or layers in images of organic tissue. Learning algorithms have enormous potential for the production of medical products, particularly in quality control and defect detection. Today, visual checks of surfaces are still performed by specially trained staff. In the future, algorithms capable of evaluating macroscopic or microscopic images will take their place. This promises to be not only more time-efficient but also more accurate, because examinations that are performed by large numbers of different people will always be characterized by a certain degree of subjectivity and bias.

Smart glasses and tablets: New tools for instruction, control and documentation

Data glasses and other smart devices support users in the performance of various manual processes such as prosthesis polishing. Visible defects of a medical product may, for example, be detected and correctly identified in the live camera feed of smart glasses or a tablet PC. Since the virtual marker

will fix the position of the defect even when the smart glasses are moved, the user will be able to locate the marked spot at any time during and after the production process, for example to undertake subsequent improvements.

Smart devices are also useful aids for the systematic training and professional development of the workforce. Smart glasses can deliver instructions together with images and videos, superimposing them on whatever the users may be looking at while they are performing their tasks. Research studies of the Fraunhofer IPT have demonstrated that the use of smart glasses can reduce the error rates in manual processes by more than 50 percent[14]. Integrated cameras can allow the users to scan QR codes, as a confirmation that they have completed certain compulsory process steps (e.g. disinfecting their hands). This facilitates the monitoring of compliance with a wide range of safety-critical regulations and guidelines.

Applications of medical technology

Smart glasses: Digital support for complex production processes

The research project on "SMART-Lay-Up! – Smart devices for the production and repair of fiber-reinforced composites" ,which is supported by the Fraunhofer Society, experiments with the use of smart glasses in support of manual laminating processes. Fiber-reinforced composites are used for the production of hospital patient accommodation and transport systems. The individual FRC layers are manually aligned, laid out and glued. This process requires a great deal of guidance and information which is usually provided in the form of step-by-step instructions on paper or in a handbook. Some manufacturers are using modern, but expensive laser systems that project instructions on the components or molds in question. Smart glasses provide an efficient and cost-effective alternative: positions and alignments can be indicated directly on the component, while additional instructions may be superimposed on what the user is actually looking at. The integrated camera can also be used for the purposes of assisting and supporting visual checks and of recording additional data for documentation purposes.

14 Fraunhofer IPT research studies. Please contact us if you need further information.

CONCLUSION
EFFECTIVE PRODUCTION STRATEGIES FOR THE MEDICAL TECHNOLOGY OF TOMORROW

Medical products are getting smarter, improving their functionality, and focusing ever more on the needs of the individual patient. While patients benefit from new therapeutic strategies and better products, manufacturers are confronted with enormous challenges, because increasingly miniaturized, multi-functional and smart products are also increasingly complex and difficult to make. At the same time, the industry is subject to strict regulatory requirements and strong competitive pressures. New products will only have a long-term future on the market when manufacturers succeed in producing them safely, cost-effectively and with high quality standards.

In facing these challenges, medical technology manufacturers need to focus their minds on the production processes, starting with the selection of the right types of material, sensors and production processes. They have the choice between a wide range of conventional and innovative production techniques. Examples include high-precision technologies for the manufacturing of structured dies in plastic injection molding processes, roll-to-roll technologies and generative manufacturing as well as the reworking of personalized medical products. The development of new product types – whether these are smart, personalized or biohybrid – often involves adaptations and upgrades of existing processes or the exploration of entirely new strategies. Early product development stages should establish whether or not any such effort will be required, so as to prepare the ground for a rapid scaling-up of the production operation.

Industrie 4.0 provides a wide range of design options for networked adaptive production systems within streamlined organizational structures. The consolidation of production equipment into integrated networks, for example, enables manufacturers to acquire a deeper understanding of their production processes and more effective means for their control. Huge volumes of data are becoming available and are opening up new opportunities for analyzing data and collecting information – opportunities that will, eventually, include self-optimizing manufacturing processes. Each process chain in medical technology, however, will continue to end with quality control procedures and the need to obtain official market approval. Comprehensive collection and storage of live data, for example in the form of a digital twin of the product, will allow close supervision and control of the relevant processes. Summarized documentation of the information that has been compiled about the production process will be a useful aid in the bid to acquire market approvals.

New production strategies will become the "enablers" for the medical technology products of the next generation. Some strategies are already under trial, but the potential for more research and development remains huge. Interdisciplinary links between production technology, medicine and medical technology require researchers to cooperate closely in order to provide patients with innovative and effective medical products at affordable prices.

Production Strategies for the
Medical Technology of Tomorrow
Trend Report

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ISBN 978-3-00-064704-8
DOI: 10.24406/ipt-n-552688