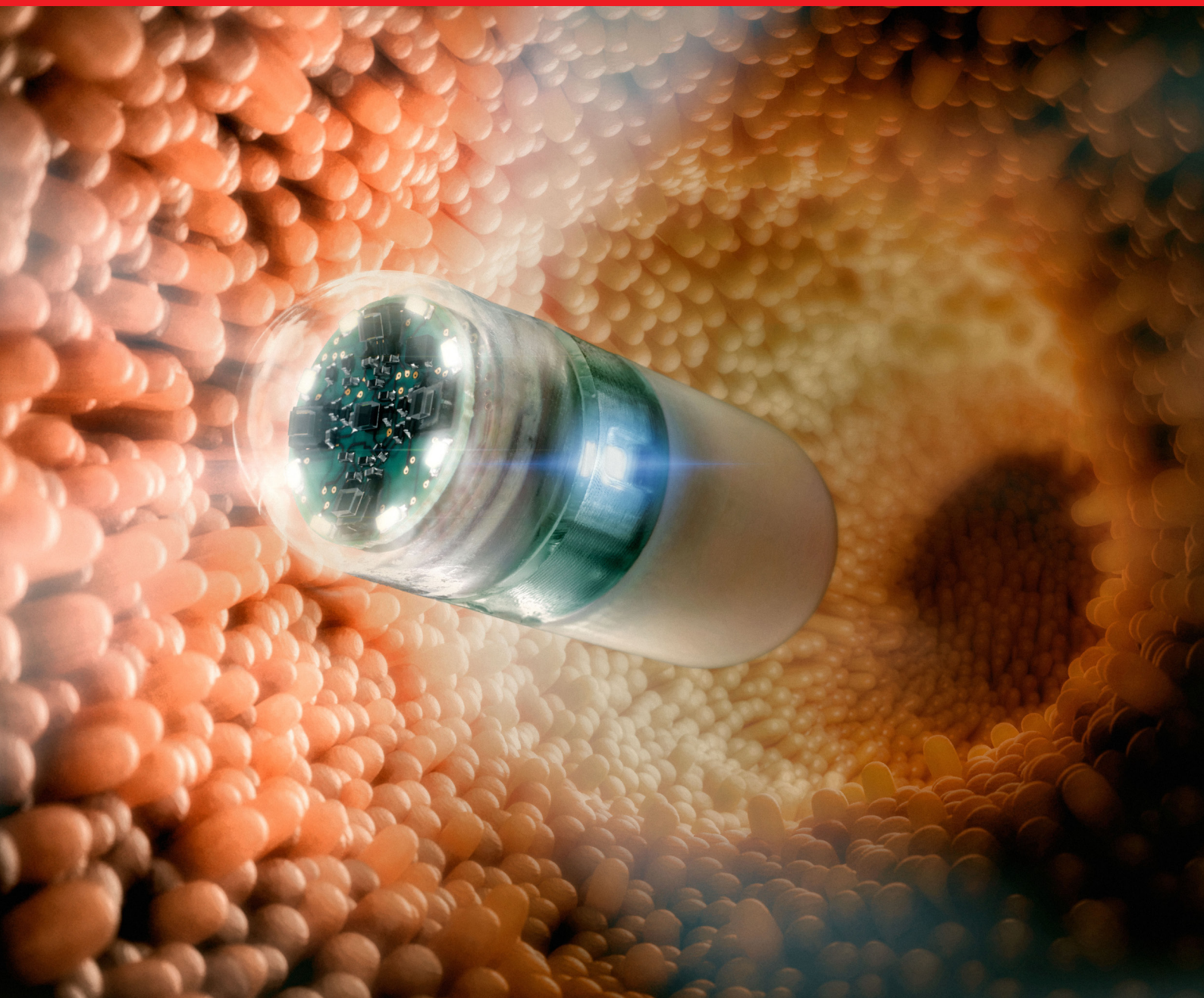
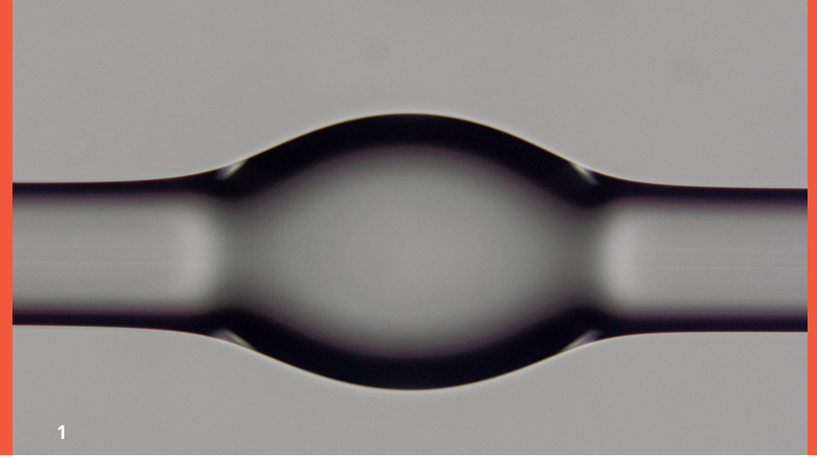
Fraunhofer
IZM

FRAUNHOFER INSTITUTE FOR RELIABILITY AND MICROINTEGRATION IZM

MEDICAL ENGINEERING



MEDICAL PROGRESS THROUGH MICROSYSTEM TECHNOLOGY



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FRAUNHOFER IZM – YOUR PARTNER IN MEDICAL ENGINEERING

Today's hearing aids are so small that they can be completely hidden in the ear canal. Pacemakers offer more functionality and last longer. Neural stimulators help patients get urinary incontinence under control. Many of such innovations, which have improved the lives of patients immeasurably, are the result of advances in microintegration technology. Diagnostics is another area that benefits greatly from such progress. Modern X-ray sensors in dentist practices, microcameras used in endoscopy, high-performance CT sensors or so-called pill cameras, which can simply be swallowed, would not have been possible without miniaturization.

Fraunhofer IZM has been front and center in this development process for over fifteen years. Our know-how in microtechnology and innovative integration processes helps manufacturers bring innovative new medical engineering products onto the market. In recent years, the demand for the institute's services has shifted from technology development support to help at every stage of the development chain ("from concept to prototype"), and the institute has responded by establishing the new research area Medical Engineering.

As of 2019 a new research group has been developing neurotechnologies in the form of tiny, smart and autonomous flexible implants for chronic neuromodulation studies. Our aim is to help neuroscientists increase our understanding of the nervous system and develop effective therapies for conditions such as rheumatoid arthritis or paralysis after spinal cord injury.

Now manufacturers and research partners have a one-stop contact for all of Fraunhofer IZM's services in Medical Engineering, which allows them to select a technology that is precisely tailored to their individual requirements. Of course, Fraunhofer IZM also continues to perform customized reliability analyses, evaluate biocompatibility and assess risk according to ISO standards and based on an understanding of the relevant processes, materials and application-specific failures. Simulation models that utilize the results of the above analyses are also often drawn on to ensure the development process is as precise as possible.

Medical Engineering at Fraunhofer IZM covers the following R&D topics:

- Implants
- Therapeutic and Diagnostic Systems
- Ambient Assisted Living

WE SUPPORT YOUR INNOVATION PROCESS WITH TECHNOLOGICAL LEADERSHIP

COVER *Miniaturized modular encapsulated camera for endoscopy, equipped with integrated image capture and storage, developed in the EndoTrace project*

LEFT *Integrated spectrometer for spectral tissue sensing, functional, low-cost nanospectrometer packaging developed by Fraunhofer IZM (Project InSPECT)*

1 *PoC BoSens (Optical biosensors for early-stage infection diagnostics)*

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MINIATURE MICROSYSTEMS FOR CONTINUOUS MONITORING AND PREVENTIVE DIAGNOSTICS

DIAGNOSTIC SYSTEMS

Correct diagnosis is the vital first step in medical treatment and comprises a number of processes, which are continually being advanced in terms of both technique and technology. An important new tool here is the microfluidic point-of-care system, which delivers fast, accurate diagnostic results from blood, urine, sputum and even tears.

Another key area of focus is long-term monitoring, necessary to both ensure convalescence is progressing or to adapt individual treatment plans where necessary. Moreover, some health issues, such as so-called 'hidden episodes' in COPD and miniscule cardiac events, are only detectable by monitoring vital signs over prolonged periods.

Fraunhofer IZM provides cutting-edge expertise in integrated microfluidics (i. e. capillaries with integrated sensors) to point-of-care diagnostics (PoCD) and has established innovative concepts that combine capillary and digital microfluidics into powerful, single systems. Fraunhofer IZM's know-how is also demonstrated by its wide range of contributions to diagnostic technology – from highly miniaturized pulse oximetry devices integrated into hearing aids, to hand-held systems for monitoring wound healing, through to a capacitive sensor integrated directly into a textile shirt that captures minute EMG signals.

Core technologies for exoskeletal monitoring and support systems as well as next generation CT scanners are developed taking into account industrial needs. In particular, Fraunhofer IZM has broad experience in building up laser-assisted laboratory systems, which provide fiber components with high quality and reproducibility.

Fraunhofer IZM is also involved in designing, manufacturing and packaging optical sensor modules addressed to the developement of portable diagnostic systems and gyroscopes. Optical characterization systems for fiber interconnections and components easily be adapted to customer requeriments. They have active alignment capabilities in the sub-micron range.

The institute is also always looking to the future. Works-in-progress include devices based on non-traditional substrates that can obtain meaningful data from new sites of the body. One example of such a device is our forthcoming contact lens monitoring system

THERAPEUTIC SYSTEMS

Medical technology has an exponentially growing role in healthcare. Not least among the new possibilities is the move away from stationary assistive systems towards mobile solutions. Using technology to bring healthcare to the patient anywhere and at any time will be a key factor in improving healthcare systems while simultaneously reducing costs.

Fraunhofer IZM is putting all its know-how to work to accelerate this process even more. As part of this, we have developed electronic monitoring devices that help patients and orthopedists monitor the quality and improve the longevity of prosthetic feet and lower limb prostheses. The institute has designed light therapy systems that alleviate chronic pain in the form of lightweight and comfortable patches that can be applied by the patient himself.

Robotized systems for rehabilitation or extraskeletal day-to-day support benefit from the integrated sensing and actuator control developed by Fraunhofer IZM, too.

IZM scientists have introduced advanced hearing aids that set new standards in miniaturization, weight and comfort. Smart bandages not only help treat wounds, but simultaneously also monitor the treatment process itself. Last, but not least, Fraunhofer IZM pioneered the integration of electronics into textile systems that use electrostimulation as a treatment for convulsions and cramps.

HIGHER FUNCTIONALITY FOR MINIATURIZED THERAPEUTIC SYSTEMS

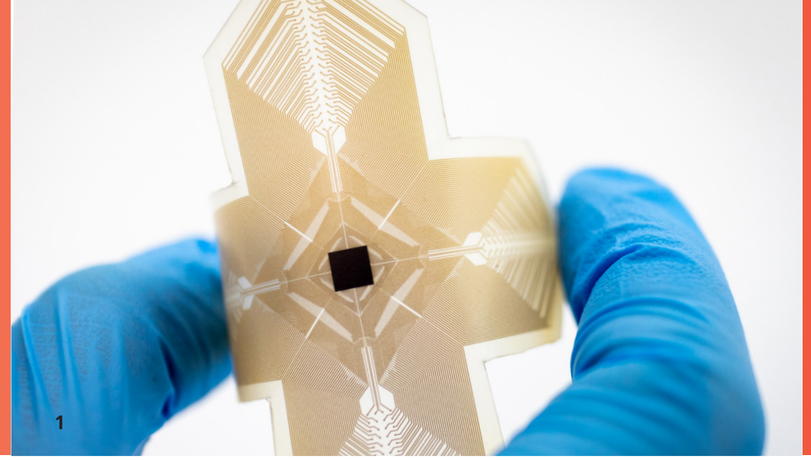
AMBIENT ASSISTED LIVING

Medical care typically starts with the patient experiencing symptoms and visiting the doctor's office. However, many events in the daily routine already offer pro-active means of addressing health issues, both in a preventive manner, as well as in the form of an early indication. Bringing the diagnosis into our daily life is expected to support our ways of living a long healthy life. This Ambient Assisted Living (AAL) has demonstrated to not only support the elderly, but also has started to be endorsed heavily by the active generation with the wearable health devices. Ubiquitous wireless data capture and transmission is key to this paradigm shift.

Fraunhofer IZM as a founding member of the Fraunhofer AAL alliance has since supported the development of the AAL vision by offering technologies for distributed sensor communication, energy scavenging, multi protocol wireless transmission and the implementation of systems suitable for the deployment in housing and everyday apparel.

1 *Hybrid chip cartridge for point-of-care tests*

2 *Knee brace with textile stretch sensor*



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IMPLANTS

HIGHER PERFORMANCE AND SMALLER, FINER GEOMETRIES

Organ failure or damage is caused by a wide variety of factors – disease, accidents, lifestyle or simply the ageing process itself. However, thanks to implants, medicine has been able to return quality of life to patients, prolong life span and alleviate the symptoms that prevent patients from fully participating in everyday life. The heart pacemaker is possibly the most familiar example of an implant. These days, though, cochlea implants, retinal stimulators, bladder control implants, brain-computer interfaces all rival pacemakers in usage, as the functionality and safety of many different implants has reached a point that the devices can remain in the body over decades.

Fraunhofer IZM has a long history of advancing the adoption of implanted medical devices as standard healthcare, with developments including pioneering chip-scale packages for pace-makers, implantable chemotherapy pump control systems, assemblies for retinal implants and wireless brain computer interfaces attached directly to the cortex. Fraunhofer IZM's expertise spans from material selection and miniaturization technology, to reliability testing and risk assessment on technical and biological levels according to ISO 14971and ISO 10993.

Fraunhofer IZM collaborates with leading companies and research institutes in Europe and internationally on such research. One prominent example is its participation in NIH and DARPA projects, which developed brain-computer interfaces capable of wirelessly relaying neural signals through the skull to a powerful computer, thus allowing even tetraplegic patients to control wheelchairs or robotic arms.

Thanks to our biocompatible technology for active neural interfaces small (mm-sized) and thin (~30 µm) stimulating electronics can be embedded into soft and biocompatible polyurethane substrates and stimulate the peripheral nerves using gold (Au) electrodes.

Last not least, we also assist neurotech companies in testing the long-term reliability of their flexible implants using our in-house dedicated accelerated lifetime soak tests. We subject dedicated test structures to elevated temperatures in the presence of electric field, and can assist in failure analysis. We have experience with soft materials as substrates and encapsulation layers for the protection of electronic components.

START-A-FACTORY

FROM IDEA TO PROTOTYPE IN A FEW MONTHS

Start-A-Factory offers aspiring start-ups and forward-thinking small to medium-sized enterprises unparalleled access to the advanced facilities and the invaluable network of Fraunhofer IZM researchers and cooperation partners to turn their ideas into professional working prototypes in record time.

All of this is made possible with an uncompromising commitment to inclusion and participation for your developer team: Every solution is a unique and custom result, and 100 % of the intellectual property remains with the developers.

Start-A-Factory brings together research and development professionals with motivated support and cooperation partners – to give projects the best possible conditions for a successful outcome.

We can support medical technology innovators with

- Risk assessments
- Certification acc. to ISO 13485 (general) and
- ISO 14971 (medical device risk management)

Want to know more? Then visit us at www.start-a-factory.com or contact us directly.

1 *Flexible implant with 324 electrodes and integrated electronics to stimulate neural activity on the brain's surfacec*

3 *Start-A-Factory*

SUMMARY OF SERVICES AT FRAUNHOFER IZM

COMPREHENSIVE DEVELOPMENT SUPPORT FOR ALL PROJECTS, INDEPENDENT OF SIZE OR COMPLEXITY

Fraunhofer IZM develops and provides the following services for bio- and biomedical devices:

- Packaging technology and reliability analysis for miniaturized medical devices and implants
- Lab-on-substrate technologies for patient-friendly laboratory diagnostics
- Improved functionality of neural interfaces and intelligent prostheses
- Flip chip assembly processes for small to large volume fabrication processes
- Thin chip assembly on ultrathin flexible and stretchable materials
- Integration of electronic modules and sensors in / on textiles
- Opto-electro-mechanical systems integration targeting medical devices
- Sensor integrated microfluidics for point-of-care diagnostic devices
- Biohermetic encapsulation for ISO 10993 compatibility
- Technology support from your medical device idea to the product implementation, reliability evaluation and prediction for medical risk assessment
- Wireless transmission concepts for secure medical data
- Energy scavenging technology for prolonged autonomous operation
- Lifetime modeling and failure assessment
- RoHS, WEEE, EuP / ErP and REACh consultancy

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