

**PROVIDING TECHNICAL SOLUTIONS
FOR MEDICAL DEVICES**





Fraunhofer has recognized the need for a new generation of equipment to enable medical detection and clinical intervention. Our objective is to minimize physical stress for the patient while reducing the costs of both diagnosis and therapy. The rapid advances made in material sciences and in optical and electronic sensor technologies together with the trend toward product miniaturization have opened up new opportunities for innovation. Fraunhofer has developed a number of unique devices and technologies to facilitate clinicians in diagnosing and treating patients in the operating room. Medical professionals communicated the need for each device and Fraunhofer has worked with doctors and surgeons to design, develop, and test the prototype devices.

Endoscopic Forceps

The Life Sciences Engineering team at Fraunhofer has developed biopsy forceps for use in endoscopes and similar medical instruments with working channels. The unique feature of this device is the co-axial working channel in the forceps, which enables additional functionalities to be used concurrently with the tissue collection, such as optical spectroscopy (e.g. elastic scattering spectroscopy, fluorescence spectroscopy, Raman spectroscopy). This multifunctional surgical tool has the ability to improve the chances of cancer detection significantly. The tool has been used successfully in initial clinical research.

Fine Needle Aspiration-Spectroscopy Tool

The Fraunhofer LSE team has developed a prototype medical device that can perform both a fine needle aspiration (FNA) biopsy and elastic scattering spectroscopy (ESS) measurements. The FNA-ESS tool allows for in vivo measurement of tumor nodules during a fine needle biopsy and can differentiate between benign (non-cancerous) or malignant (cancerous) tumors, with a much higher accuracy than other available tools. This innovation can potentially revolutionize the treatment of thyroid cancers by sharply reducing the number of unnecessary surgeries. The instrument is currently undergoing testing in initial clinical research.

Medical Devices for Interventional MRI

Minimally invasive interventions can potentially reduce health-care costs while minimizing patient stress and suffering. For high-resolution imaging, better visualization of the soft tissue compared to X-rays or Computer Tomography (CT) without exposure to ionizing radiation can be achieved with Magnetic Resonance Imaging (MRI). However, the need for strong magnetic fields in MRI limits the use of metallic devices. The Life Sciences Engineering team at Fraunhofer has therefore developed miniaturized, navigable medical devices made of fiber-reinforced plastics (FRP). The use of FRP gives the best mechanical properties while allowing visualization of the tool during MRI without interfering artifacts. Product examples developed at Fraunhofer are multifunctional puncture needles, guidewires and catheters, all made from FRP and MRI-safe. Furthermore, the visibility in both MRI and CT can be freely adjusted by integration of contrast agents. We have also developed and automated the required manufacturing technologies, such as micro-pultrusion and micro-pullwinding, so that these products can be manufactured serially.



Application of Optical Coherence Tomography

Optical Coherence Tomography (OCT) is a non-contact imaging method that is well-suited for tomographic imaging of semitransparent materials and tissues. The technology is based on detecting the optical echo reflected by fine changes in structures or diffraction indices. It allows for high resolution cross sectional imaging with an imaging depth of up to 3 mm. We have developed a custom-designed OCT system that is operating in the near infrared spectral range. As a result of the modular architecture of the fiber optics-based system, a technology transfer to various medical metrology applications is viable. Recently, the LSE team developed automatic detection software based on image processing algorithms, to measure defects and layer structures within the tissue. In close collaboration with university hospitals, the methods have been tested on the early detection of osteoarthritis based on in vitro studies.

Surface Functionalization by Laser Manufacturing

The functionalization of material surfaces plays a major role in the field of medical technology and for many applications in biotechnology, such as tissue engineering. Besides the selection of suitable bulk or coating materials, the surface topography is critical for tissue compatibility and specific interactions with the human body. Surface structures of specific dimensions are able to enhance or inhibit the growth behavior of cells in the laboratory (in vitro) as well as in patients (in vivo). Laser surface structuring, in terms of pulsed laser material ablation, can be utilized for conditioning of surfaces. Defined topographies ranging from the millimeter scale to the nanometer scale can be generated. By precisely removing surface material, custom-designed structures and textures of high complexity can be formed. The technique can generate tailored surfaces on three dimensional components (e.g. implants or bone screws) of different biocompatible materials.

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