Federal Ministry for Economic Affairs and Climate Action





CORTEC GMBH Partially automated production line for the production of innovative new implants

CorTec GmbH is a spin-off of the University of Freiburg and develops, produces and markets innovative, implantable microtechnology and microelectronics-based medical products and components. Many of the innovative microelectronic components, especially sensors, are developed by CorTec itself or in cooperation with other companies and research institutions. CorTec is certified according to ISO 13485 for the development and production of implantable medical devices. The clients are leading clinical research centres and neural clinics.

Challenges

Many people worldwide suffer from neurological and psychiatric diseases such as chronic paralysis, strokes, Parkinson's disease, epilepsy or depression. In addition to drug therapies, neuromodulation therapies are increasingly being used: This means that for pain or symptom relief electrodes are implanted, that act on the nervous system. The electrodes can register neuronal activities in the nervous system and stimulate them as needed. Currently, electrodes mostly used for this purpose, have to be manufactured manually at great expense and each one has to be certified as a medical device.

Objective

CorTec's goal is to produce these electrodes (partially) automatically in an efficient and process-optimised production line. The individual components are assembled into customised electrode arrays that function as neural interfaces. The electrodes are connected to implantable electronics at CorTec. On the one hand, these brain change systems are used to measure and stimulate electrical impulses in the human nervous system, but they can also be used in the scientific field to research the brain and nervous system. Overall, the implant systems and their components are being further developed and miniaturised to make them more precise, more reliable and more efficient. This improves their usability, for example, for severely paralysed people or stroke patients.

Within the project, a clean room certified for medical products will be built and put into operation – including the plant technology required for production. At the same time, a production-accompanying development and service laboratory will be set up, which will have the necessary tools and analysis equipment. In addition, CorTec is establishing a material and component logistics system with which the produced components and systems can be labelled and quality assured.

Approaches

With considerable research and development (R&D) effort, CorTec creates key technologies for a novel type of complex, highly integrated MEMS-based brain interchange system. The novel electrode arrays made of silicone and laser-structured nerve electrodes made of metal foil ("AirRay") are connected to an electronic unit via highly integrated, applicationspecific circuits. For the connection of the electrodes with the electronic unit, CorTec is developing novel high-channel

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and implantable connectors, which are encased in hermetic ceramic capsules. The ceramic capsules are provided with electrical feedthroughs in the capsule wall to protect the electrodes from the corrosive body fluid. These brain interchange systems also have their own power supply and an external evaluation unit. The specially developed electronic unit communicates wirelessly with an external electronic unit (including a computer) and is supplied with energy tele-metrically by the latter. Together, these components form a globally unique implant system that can analyse neuronal activity and act on the nervous system through electrical stimulation depending on the respective state. The following equipment, among others, is procured for the production and assembly of the individual components: coating systems, structuring lasers, spot or laser welders, centrifuges, pressure embedding ovens, soldering stations and disinfection systems.

Perspectives

The results of the project increase the competitiveness and the level of innovation of Germany and Europe in the field of sensor technology as a whole. The sub-areas of implantable sensors and active implants for medical technology in particular are profiting from the microelectronic technology solutions.

The technological building blocks can be used for many implanted medical electronic systems and at the same time serve as key technology for other microtechnology sectors, e.g. for sensors and electronic systems in challenging environments or as protection for chips and microelectronic

modules. This technology forms the basis for modern, needs-based and individualised neuromodulation therapies, which can be used for a variety of neurological and psychiatric diseases. For people with these diseases, the products mean a significant improvement in their quality of life, as they offer new therapeutic options. To ensure the dissemination of the results, cooperation with universities (University of Freiburg, Furtwangen University of Applied Sciences, University of Stuttgart, University of Ulm) and clinical research institutions in the form of scientific papers and articles is planned. The training of young scientists is promoted within the framework of doctoral, bachelor's and master's theses. This results in a large transfer of knowledge.

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