Press Release
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First CorTec Product Receives FDA Clearance

CorTec has announced today that the US Food and Drug Administration (FDA) has cleared AirRay Cortical Electrode, an electrode for invasive neuromonitoring. As the young company's first medical device that has received market clearance in the USA it will be used as a diagnostic tool, for example before brain surgery.

"For us as a company, the market clearance of our AirRay electrodes is an important milestone," said Dr. Jörn Rickert, Chief Executive Officer of CorTec. "It shows to us and to our customers that we have been working in the right direction. Together with our new premises, including our own production facility we are now ideally positioned as a partner for the development of innovative neurotherapies."

Some brain diseases may require surgical resection of the affected parts of the brain. AirRay Cortical Electrode is used for invasive neuromonitoring which comprises recording and stimulation of brain activity from the cortical surface over a period of time. In order to precisely locate diseased brain tissue such as epileptogenic foci or brain tumors while protecting healthy areas responsible for important brain functions, the brain must be 'mapped' prior to surgery. The electrode may be used for up to 29 days.

CorTec introduces several innovations into this long-established method of treatment. The planar grid and strip electrodes are produced in a proprietary laser-assisted manufacturing process. This results in a very soft, thin, and flexible electrode that adapts well to the curved surface of the brain.

In combination with new analytical methods AirRay Cortical Electrode may enable shorter surgery durations and more precise diagnostics in the future: For example with the aid of automated mapping of the brain in real-time, as enabled by the CortiQ system from g.tec (Austria), it will be possible to locate functional brain areas faster and more reliably in the future. A research group led by Nuri F. Ince at the University of Houston, Texas, is investigating high-frequency oscillations in brain activity as biomarkers for a more precise determination of epileptogenic foci. "Regulatory approval of CorTec's AirRay Cortical Electrode opens up exciting new options both in clinical applications and in research using intracranial recording and stimulation methods," commented neuroscientist Dr. Gerwin Schalk, Chair of the International Workshop on Advances in Electrocorticography series and Deputy Director of the National Center for Adaptive Neurotechnologies in Albany.

The product also contains important safety features. "Health and well-being of the patient are of the utmost importance to us. Therefore, we emphasize safe electrode design," said Dr. Martin Schüttler, Chief Technology Officer and also Chief Executive Officer of CorTec. °AirRay Cortical Electrode has an even surface with individual electrode contacts almost being impalpable. Additionally, to prevent the contacts from dislocating or detaching from the silicone carrier material each contact safely interlocks with the material.

CorTec plans to market the AirRay Cortical Electrode through distribution partners. Corresponding contracts are currently in preparation.

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About CorTec

CorTec was founded in 2010 in Freiburg, Germany. In summer 2018, the company, with currently about 50 employees, moved to new premises with 1,000 square meters of office space and 400 square meters of laboratories and clean rooms for development and production.

Based on Brain Interchange technology, CorTec develops and markets neurotechnological components that enable communication with the nervous system such as electrodes, hermetic encapsulations, software or electronics. CorTec's closed-loop implant platform technology Brain Interchange are designed for measuring and stimulating brain activity in long-term use. CorTec thus offers the necessary cornerstones for the development of innovative personalized therapies for various neural diseases such as epilepsy, Parkinson's or applications in the field of bioelectronic medicine.

The proprietary AirRay electrode technology developed by CorTec for use in the central and peripheral nervous system is an important component of this system. With AirRay Cortical Electrode, a portfolio of strip and grid electrodes has now received market clearance for clinical use in the central nervous system. In the past, special electrode designs have been used to achieve relevant successes, such as in the case of a six-year-old epilepsy patient at the Goethe University Hospital in Frankfurt.

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