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WISE enrolls first patient in pivotal clinical study of novel neuro-electrodes for brain monitoring

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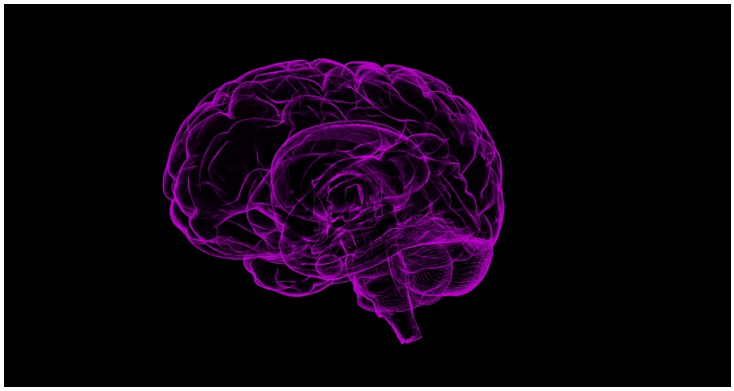

WISE Srl, a medical device company developing next-generation implantable leads for neuromonitoring and neuromodulation, has enrolled its first patient in the pivotal clinical study of its WISE Cortical Strip.

The WISE Cortical Strip is a single use medical device for IntraOperative Neurophysiological Monitoring during brain tumour and epilepsy surgeries. It is used for continuous recording of the brain's electrical activity and for brain stimulation.

The WIN Study (WISE Cortical Strip for Intraoperative Neurophysiological Monitoring study) is a prospective, interventional, multi-center, open-label premarket study, expected to enroll approximately 33 patients. Designed to confirm the safety and performance of the WISE Cortical Strip, the first patient has been enrolled at Universitätsspital Zürich. The study is being carried out at four clinical centres in Germany and Switzerland: Munich University Hospital, Inselspital Bern and Kantonspital Luzern in addition to the Zurich centre.

The WISE Cortical Strip is unique as it is made of pliable platinum electrodes embedded in a soft, thin film of silicone, overcoming the stiffness and rigidity of traditional cortical strips. It is highly ergonomic and conformable even on surfaces as soft and wrinkly as the brain. WISE's proprietary and patented metallization technology enables stretchable and pliable electronic microcircuits to be inserted into biocompatible silicones. This allows much better adhesion to the brain surface, minimal invasion, excellent adaptability and low impedance of the electrical circuit.

The study is due to conclude in Q3 2019, with the results to be published shortly afterwards.

CEO of WISE, Dr. Luca Ravagnan said: "Initiating the pivotal study of our WISE Cortical Strip is a key milestone for us as we work towards CE approval and commercialization. Patient enrollment is on schedule and we look forward to feedback from the surgeons on ease of use and low electrical impedance."

PD Dr. med. Neidert from Universitätsspital Zürich said: "We have been impressed so far with the ability of the WISE Cortical Strip to tightly adhere to the brain surface without the need of any pressure, allowing it to obtain low impedance contact from

all the electrodes of the strip. The electrodes are also easy to position, which is not something you would expect in a very flexible electrode."

Prof. Dr. med. A. Szelényi from Munich University Hospital, coordinating investigator of the WIN Study concluded: "The WISE Cortical Strip is an exciting technology and we look forward to seeing the final study results."