

Press Release

Sirius Medical announces CE mark for Pintuition: a non-radioactive localization system to improve breast cancer surgery

EINDHOVEN, Netherlands, June 16, 2020 – Sirius Medical, a MedTech startup, announced that it has received CE mark approval for Sirius Pintuition. With its debut product, Sirius provides an affordable and easy-to-use alternative to traditional surgical localization systems that rely on anchor wires or radioactive seeds. Sirius aims to revolutionize the way tumors are localized during surgery.

The certification, which indicates conformity with the European health and safety standards, paves the way for Sirius' commercial launch in September 2020. The first Sirius Pintuition systems are currently in production and will be implemented in hospitals in the Netherlands, the UK, and several other European countries later this year. The USA will follow in 2021.

"We are pleased to have achieved this important milestone with the help and input of many physicians and engineers," said Hubert Martens, CEO of Sirius Medical. "We are very excited to make our cost-efficient localization system for soft tissue tumors available to hospitals in Europe. This is great news for surgeons and radiologists as our system provides them with more freedom to apply their skills and deliver the best possible outcome for patients."

Tumor localization

With the rapid improvement of breast cancer diagnostics over the past decades, surgeons are facing increasingly challenging procedures as they must localize ever smaller and earlier-stage tumors. Until now, surgeons have been using metal anchor wires or radioactive seeds to localize tumors and soft tissue.

"These methods are far from ideal," said Sirius CEO Martens. "Wire localization is not pleasant for patients and poses logistical challenges because of the required presence of a radiologist on the day of surgery. And many hospitals refrain from using radioactive seeds because of the related safety protocols and their impact on efficiency."

Sirius provides surgical oncologists with a highly precise, easy-to-use, and affordable solution that contributes to an improved hospital workflow. The Sirius Pintuition seed can be placed up to 180 days before the surgery to mark a target within soft tissue*. During surgery, the Sirius Pintuition Probe provides highly accurate, real-time feedback and directional guidance to the marked tissue. The probe is reusable and compatible with metal instruments that are commonly used during surgery.

About Sirius Medical

With its roots in the Netherlands Cancer Institute, Sirius Medical was born to make things better. The Sirius Pintuition system was developed by and for surgeons addressing a clear clinical need with a solution that simply makes sense. Our mission is to improve health for cancer patients by delivering unsurpassed, yet affordable solutions that enable precise and efficient surgical removal of tumors. Please visit www.sirius-medical.com.

*Please refer to the product instructions for use.

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