



Press release from Ortoma AB
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Ortoma obtains CE certification for Spine Module

Ortoma has obtained CE certification for its spine module OTS Spine Plan now included in the platform Ortoma Treatment Solution (OTS). The spine module is a pre-operative planning solution for spine surgery. The OTS platform is a surgical system that is assisted by AI (Artificial Intelligence) for improved accuracy, efficiency and surgical outcome.

CE certification for OTS Spine Plan is approved by the Notified Body and the CE-marked product is approved for use clinically in Europe. The OTS platform now includes CE marked products for hip replacement surgery and spine surgery. In addition, OTS for hip replacement surgery is FDA 510(k) cleared for marketing in the USA.

“OTS Spine Plan is an important extension of OTS and proves the scalability and flexibility of the AI assisted platform. With the CE-marked product, we are ready to take the next step and offer the product for use clinically,” says Linus Byström, CEO of Ortoma.

The CE-marked spine module significantly extends the market potential of OTS. The global spine surgery market is estimated to reach \$14.3 billion in 2022 from \$10.8 billion in 2017, at a CAGR of 5.8%. Factors driving the growth of the industry include growing incidence of spinal disorders, accessibility of minimally invasive spine surgical techniques, and the increase of Minimally Invasive Spine Surgery in health care centers. The OTS Spine Plan is built on the OTS platform that is assisted by AI, and is designed to address the challenges of the spine surgery market.

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About Ortoma AB (publ)

Ortoma AB develops surgical systems for the planning and positioning of implants in hip, knee and spinal surgery. The purpose of the company's surgical system, Ortoma Treatment Solution™ (OTS) is to enable the surgeon to accurately measure and plan 3D surgery for the placement of a joint implant and during the surgery, to optimally position the implant in the patient. Ortoma's surgical system is aimed at providing better patient outcomes, fewer complications and less follow-up surgeries - and thus better long-term survival rates for the implant. Another aim is to create a system that can be integrated easily into the processes and routines that are currently used in surgeries, thereby increasing efficiency. Ortoma's B shares are noted on Spotlight Stock Market. Globally, more than 7.5 million orthopedic procedures are performed each year where OTS could be used in hip, knee and spinal surgery. In Sweden last year around 42,000 surgical procedures were performed involving hip, knee or spinal surgery.