

AOT AG Announces First-In-Man Clinical Use of the CARLO® Device at the University Hospital Basel, Performing the First Robotic Bone-Cut with a Laser Worldwide

Basel, July 4, 2019

The Swiss Medtech company, Advanced Osteotomy Tools – AOT AG announced today, the First-In-Man clinical use of the Cold Ablation Robot-guided Laser Osteotome (CARLO®) at the Dept. of Oral & Maxillofacial Surgery, University Hospital Basel, Switzerland. CARLO® was utilized yesterday during the performance of a midface-osteotomy. For the first time, the cut of human bone was performed with a robotic laser osteotome instead of conventional tools, such as saws, drills or mills. AOT is the first company worldwide to develop a surgical robotic platform, named CARLO®, to cut bone with a «cold» photoablation laser, leaving bone structures intact and vital, and thus pioneering the new field of «Laser-Osteotomy».

CARLO® provides an approach to automatically and accurately perform osteotomies according to pre-planned cut lines via its digital workflow. The present First-In-Man study, a pre-market clinical investigation, intends to demonstrate the performance and safety of CARLO® in a clinical context. The three hospitals participating in the study are the University Hospital Basel, the Kantonsspital Aarau, and the Vienna General Hospital (AKH Wien).

Cyrill Bätscher, CEO of AOT, comments, «We are thrilled to have reached First-In-Man clinical use of CARLO®. The device allows contactless robotic surgery for the first-time, which is made possible by our laser-technology». From the initial phase of robotic surgery in the 1990s, we have learned that haptics was playing a crucial role with regards to patient safety, Bätscher adds. «Although the laser itself is not sensitive, CARLO® can be stopped with the speed of light and easily removed should anything unforeseen happen. Something that is not possible with today's conventional robot-assisted devices», Prof. Philipp Jürgens says, Cranio-Maxillo-Facial surgeon at the University Hospital Basel and co-founder of AOT.





The device has undergone an extensive phase of development, design evolution, and testing. Moreover, the performance and safety have been satisfactorily validated in several preclinical studies. It was proven that the bone healing process is faster and the ability to perform freely-defined cutting patterns is offering new and gentler surgical techniques. Furthermore, the laser is universal; in principal one can cut bone from head to toe.

«Digitalization does not stop at the operating theaters. The contactless CARLO® laser-technology enables to completely digitize the entire patient journey. Moreover, there are no longer mechanical elements involved that deform under load», Dr. Erich Platzer, chairman of the Board underlines.

«We anticipate significant clinical interest for this innovative platform once cleared for commercial distribution in the upcoming months», Bätscher concludes. Laser-Osteotomy is an uprising new field in bone surgery offering vast potential. AOT, for instance, is currently also working on real-time tissue analysis. With the help of artificial intelligence and feedback received from the laser, it will be possible to distinguish diseased from healthy tissue in real-time while cutting.

About AOT

AOT has developed a new technology to reinvent bone surgery by the means of robot-assisted «cold» photoablation. The product of the company, based in Basel/Switzerland, is called CARLO®. Currently, the firm is conducting its First-In-Man clinical trial as a basis for CE-mark. The company was founded by Dr. A. Bruno, Prof. Cattin, Prof. Jürgens and Prof. Zeilhofer.





About CARLO®

CARLO® stands for «Cold Ablation Robot-guided Laser Osteotome». «Cold» ablation describes the approach to ablate bone layer-by-layer with the help of a laser. In contrast, in conventional surgical procedures bones are cut in one go, creating microstructural damage, heat and debris. The advantage of the newly developed method is that the bone does not overheat and the microstructure remains intact and viable, enabling better vascularization and quicker healing.

To accomplish this, the laser is mounted on a tactile robotic-arm that was designed specifically for medical use. The device allows the surgeon to perform osteotomies with unprecedented precision, and in freely-defined, curved and functional sectional patient-specific configurations, which are not achievable with conventional instruments.

For more information, please visit <u>www.aot.swiss</u> or contact Daniel Kronberger via Email: <u>info@aot.swiss</u> or phone +41 (0)61 201 10 10.