

Gebauer announces Breakthrough in the Advancement of Less-Invasive Epi-LASIK Eye Surgery

Neuhausen, Germany – Friday, March 05, 2004 – Gebauer Medizintechnik announces results from the first 100 Epi-LASIK patients treated in Europe using its minimally Invasive, alcohol free, Epi-Lasitome™. The company announced positive clinical results for all of the first 100 patients treated in Europe with its Epi-Lasitome. The data is available at the company.

Dr Chris P. Lohmann from the University Eye Clinic, Regensburg, Germany is the leading clinical investigator for the Epi-Lasitome. Commenting on his results, Dr. Lohmann stated, "I was extremely pleased with the ease with which the Epi-Lasitome created an epithelial flap without incident and without the use of alcohol or other chemicals. The clinical results were excellent." He added, "Six of the first 100 patients treated were prior LASEK re-treatments. Making the Epi-flap in this group posed no problems and the outcomes were no different."

Gebauer's Managing Director, Steffen Gebauer stated, "The Epi-Lasitome's performance as reported by our investigators has been very gratifying. In conjunction with the extensive engineering development surrounding the Epi-Lasitome, Gebauer's team of technologists and ophthalmic surgeons has pioneered a proprietary epithelial flap dissection technique - which we believe will result in superior results to other approaches for effecting the creation of an epithelial flap for performing Epi-LASIK."

The Epi-Lasitome has received European CE (Conformité Européenne) Mark and based on its positive clinical evaluation, Gebauer has begun its commercial introduction in several European countries. The Company plans to file a 510(k) premarket notification submission with the FDA within the next 60 days seeking marketing clearance in the US.

During the past 25 years, Gebauer has gained a wealth of experience in turning new technology ideas into fully developed products that deliver superior and affordable performance. A privately held company based in Neuhausen, Germany, Gebauer brings precision engineering design, component integration, electronics development, software creation and the highest level of quality assurance to its entire medical device manufacturing.

All of Gebauer's processes and procedures are subjected to continuous monitoring by a quality assurance system that complies with DIN EN ISO 9000; ISO 13485; RL 93/42 EWG ("MDD"); as well as FDA GMP. This ensures that Gebauer's medical device manufacturing meets all the demanding requirements for single-use ophthalmic products.

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