



Keranova's FemtoMatrix technology produces unprecedented results in clinical regulatory trials

Robotic laser technology used in world-first PhotoEmulsification® procedure, opening door to new technique in cataract surgery for first time in decades

Keranova aims to secure CE marking in coming months to bring product to market in 2023

Saint-Etienne, France, January 11, 2023 – Keranova, a company specializing in the development of surgical ophthalmology equipment, today announces the finalization of the regulatory clinical studies of FemtoMatrix®, its robotic laser technology. With these exceptional and unprecedented results, the company will now apply for CE marking for this new class of surgical equipment in cataract surgery.

This is the first time that a new surgical technique, PhotoEmulsification®, has been performed, the latest landmark in cataract surgery since phacoemulsification in the late 1980s. The results are extremely positive and should benefit both surgeons and patients.

A randomized comparative multicenter pivotal study was carried out at end of Q2, 2022 in the Czech Republic, with 54 patients enrolled. The contralateral eye of each patient was treated using the traditional method by phacoemulsification to serve as control. The study demonstrated FemtoMatrix's ability to eliminate the use of ultrasound in the vast majority of cases on a standard population, or to reduce it drastically.

During this pivotal study, a subpopulation of 20 patients with a cataract of grade ≤ 3 (grade 2 on average) was operated on with FemtoMatrix on one eye and phacoemulsification on the other. The reduction in Effective Phacoemulsification Time (EPT) was 100%, compared to an average of 20-30% in various comparative meta-analyses in the existing literature ([Kolb, Meta-analysis, JSCRS 2020](#)).

In a further two studies, on a total number of 35 patients living with a cataract of higher than grade 3 (3.6 on average), approximately 72% of the surgeries were performed without ultrasound. On the ten patients who received ultrasound (grade 4.3 on average) the average EPT was 2.3 seconds, four of them with less than 0.6 second. This result was deemed extraordinary in the context of current literature on cataract surgery.

Surgeons will be able to perform perfectly calibrated cataract surgery and reduce the risks associated with handling the ultrasound device used in a classic phacoemulsification. They can now perform cataract surgery without ultrasound as efficiently as current techniques - but with greater precision and reduced risks of corneal/iris damage, capsular ruptures or adverse consequences on the retina, all within the same operating time. Patients will benefit from a safer and less operator-dependent procedure, with more consistent outcomes.

"These outstanding results, achieved after six years of hard work, will soon allow Keranova to offer PhotoEmulsification® technology to surgeons. This will be the third generation of cataract surgery technology, after manual extracapsular and phacoemulsification," said



Fabrice Romano, founder and CEO of Keranova. "Keranova will therefore be the first company to provide surgeons with a medical device that complies with today's standard in cataract surgery, including an ultra-fast laser, an element modifying the laser based on photonic science, a robot, artificial intelligence that automatically adjusts the energy input and a fiber. In short, a device using today's technologies for the benefit of patients living with cataracts."

Keranova's PhotoEmulsification® technique is made possible by the unique combination of patented technologies within the FemtoMatrix device, an ultra-fast robotized laser to treat cataract patients. The company's innovative approach aims to transform cataract surgery by reducing manual procedures in favor of automation and precision, to encourage reproducibility and reduce clinical risks.

"The results are extremely promising, as the FemtoMatrix device has proven to be safe to perform phaco-free laser cataract surgery in less than eight minutes in one operating room, something which is impossible to do with current techniques," said Dr Damien Gatinel, head of the Anterior and Refractive Surgery Department of the Rothschild Foundation (Paris, France) and member of Keranova's scientific advisory board. "I look forward to continuing working with Keranova on more innovative solutions to ensure surgeons and patients have access to the best possible technologies to treat cataracts."

Keranova presented the preliminary results of its clinical regulatory studies into robotic laser surgery during iNovation Day at the 2022 European Society of Cataract and Refractive Surgeons (ESCRS) Congress in Milan, Italy. The full results of Keranova's clinical regulatory studies will be published in several peer-reviewed journals in 2023.

The company aims to secure a CE mark in 2023, which will allow it to market the first version of FemtoMatrix. To meet demand, its production unit will be operational at the end of 2023. Keranova will continue to work on the FemtoMatrix technology to include new and innovative features to be released in 2024. Users will be able to perform the update via software upgrades.

[With 94 million people affected by cataracts globally](#), innovations such as this are essential in improving patient care and easing procedural risks for both surgeon and patient.

About FemtoMatrix

FemtoMatrix is the only surgical laser enabling real PhotoEmulsification® of the lens; instead of simple pre-cutting into quarters or sticks, as with all current devices. This unique capability is made possible by disruptive laser wavefront modification technology, which results in arrays of laser spots that dramatically speed up cutting.

The system allows for precise and automatic adjustment of the laser energy at each location on the lens and the use of a surgical robot greatly simplifies the procedure. The device is quick and easy to maneuver and fits easily into the operating room, removing the need for both surgeon and patient to move during the procedure. The surgeon can perform an entire cataract procedure without having to reposition the patient; a substantial gain in time and safety. Thanks to the fiber technology and the robot, the machine's optical head is mobile, which saves time during the procedure and is comfortable for the surgeon, who can perform the laser treatment alone in the OR. These characteristics considerably reduce the usage costs of such a sophisticated machine, which is also simpler for surgeons and results in quicker operating times.



About Keranova

Keranova is developing new generation ophthalmic surgical devices featuring unique technology; utilizing the emerging science of photonics to construct ultra-fast medical lasers. This new approach to current ophthalmic surgical procedures aims at substantially reducing manual intervention in favor of automation. Keranova is leveraging the results of research undertaken jointly by two world-renowned multidisciplinary teams at Jean Monnet University in Saint-Etienne, France.

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