

Preceyes B.V. gains CE marking approval for its eye surgery robot

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<http://www.preceyes.nl/#latestnews>

EINDHOVEN, The Netherlands, June 4, 2019 - Preceyes B.V., the world leader in robot-assisted precision eye surgery, today announced that the company has received CE marking approval for its PRECEYES Surgical System R1.1, enabling the Dutch firm to market their system in Europe. The system assists trained surgeons during certain tasks during vitreoretinal surgery in patients under local or general anesthesia. This technology is anticipated to enable not only a better treatment to be provided to patients, it also offers the possibility of developing completely new treatments.

The Baby Boomer Vision Time bomb

“The PRECEYES Surgical System holds the potential to transform eye surgery - and it's a development that can't come fast enough,” explains Preceyes' Chief Medical Officer, Prof. Marc de Smet M.D. “The problem is one of demographics. People born in the years after World War II - the baby boomers - might be able to have wrinkles filled and hips replaced, but they cannot escape age-related eye diseases. Many of these eye diseases can be treated successfully, but the big problem is that many countries haven't trained enough eye doctors to deal with this huge workload - a workload that is only going to get larger as the baby boomers get older.”

Vision loss is disastrous not only for the person it affects, but their friends, families and society too. Personal freedom is lost. Their ability to work is diminished. They require more help from their friends, family and healthcare systems. Cumulatively, the burden on society is huge. But in many cases, these diseases are treatable by skilled surgeons - and this transforms lives and benefits society. But if the number of eye surgeons isn't going to increase fast enough to meet this demand, society needs to take another approach. Preceyes' answer was to develop a robotic assistant for eye surgeons.



The robotic manipulator of the PRECEYES Surgical System holds and positions a surgical instrument inside the eye, following positioning commands that the surgeon provides with a controller.

The Aim: Better, Smarter, Safer

To meet these demands, more patients have to be treated by the same number of surgeons. The PRECEYES Surgical System is designed to do this in a number of ways. The robotic assistant, which is developed for retinal surgery, operates within the eye, is controlled directly by the surgeon through intuitive hand movements, and can perform multiple injection, peeling and tissue manipulation tasks. Crucially, the system is able to execute motion profiles, including limiting of instrument movement to avoid performing dangerous actions - with the target of avoiding surgical complications and their consequences.

Prof. de Smet explains a second feature of the PRECEYES Surgical System: "The robotic assistant promises to extend surgeons' OR lifespan. Surgeons undergo a learning curve; they continue to learn and get better with experience, until another natural consequence of ageing kicks in: hand tremor. Fortunately, the PRECEYES Surgical System filters tremor, meaning those highly experienced surgeons no longer need to retire from surgery when tremor starts; instead, they can retire when they want. The ergonomic design and the ability to be used with 3D head-up displays also means that surgeons can be spared the back pain that can come from spending long periods at the surgical microscope - something that can also extend careers."

These advances should increase the number of surgeons available and the number of patients a surgical center can treat in a day.

Getting to Successful Retinal Gene Therapy

The PRECEYES Surgical System is playing an important role in the future of eye care, specifically retinal gene therapy. Administering gene therapy to the retina is a very delicate and time-consuming procedure that requires the surgeon to not only hold a syringe with a fine needle in a specific place for an extended period, but also to press the plunger to deliver the gene therapy solution slowly into the eye, to avoid any damage. Sometimes, repeat doses are required, and need to be administered to exactly the same spot. With the ability to hold the tip of the needle in exactly the same space without tremor. This currently requires some of the best surgeons in the world to operate in order to have a successful outcome.

Human physiological limits mean that the smallest structures surgeons can operate on is around 0.1mm in size. The PRECEYES Surgical System, however allows surgeons to operate on structures down to 0.02mm for prolonged periods of time. Surgeons are simply not able to offer this type of high-precision treatment to their patients with manual surgery. This feature makes the system ideal for the highly precise drug delivery requirements required by the rapidly developing field of gene therapy treatments. Moreover, the robot can record movement data of the surgeon, which can be analyzed to improve future treatments. This will allow for improved reproducibility of treatments, which has the potential to further improve both patient safety and patient outcomes.

"We are pleased to bring the PRECEYES Surgical System to market in Europe," said Gerrit Naus, Preceyes B.V.'s Chief Executive Officer. "The PRECEYES Surgical System represents the most advanced robotic option in eye care available to date. While we are focusing on vitreoretinal applications at the moment, we believe our versatile technology can be developed to assist surgeons in performing most surgical procedures in the eye. We will leverage the CE marking approval for further industrialization of our technology and to access new markets outside of the EU in the near future."

Further information

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About Preceyes B.V.

Preceyes is a medical robotics company focused on ocular surgery. The company develops, builds and commercializes innovative robotic solutions to assist eye surgeons in performing the most demanding surgical tasks. The company's first target is vitreoretinal surgery. The robot supports the surgeon in improving existing surgery and enables the development of new, high-precision treatments. Preceyes is a spin-out of the Eindhoven University of Technology and is located at the TU/e Science Park in Eindhoven, the Netherlands. Preceyes leverages the mechatronics capability of the Dutch Brainport region. www.preceyes.nl

Intended Use

The PRECEYES Surgical System R1.1 received CE mark approval for the following intended use: to assist trained surgeons during vitreoretinal surgical tasks in patients requiring vitreoretinal intervention under local or general anesthesia.