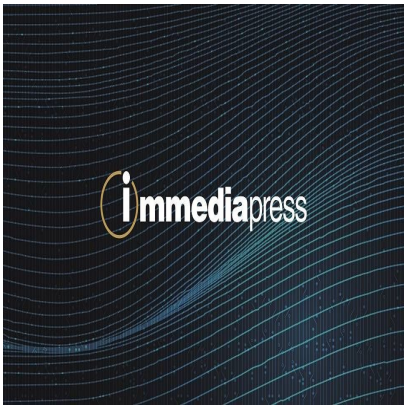


# EYE PCR Receives CE Mark for fixOflex Endocapsular Device, Enabling European Market Introduction

## Descrizione



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HERAKLION, Greece, Feb. 13, 2026 /PRNewswire/ â?? EYE PCR announces that its fixOflex endocapsular device has received CE Mark certification under the European Union Medical Device Regulation (EU MDR 2017/745), enabling commercialization in Europe and other markets that recognize the CE Mark. This regulatory milestone validates the deviceâ??s safety and efficacy, positioning EYE PCR for controlled market introduction.

Developed under the leadership of Professor Ioannis Pallikaris over more than fifteen years of research and refinement, fixOflex is designed to preserve the form of the capsular bag and its intracapsular space during and after cataract surgery and to optimise the optical performance surgeons aim to achieve for their patients.

â??For more than fifteen years, our team has worked to address one of the persistent challenges in cataract surgery: preserving the form of the capsular bag after lens removal,â?• said Professor Ioannis Pallikaris, Founder of EYE PCR. â??fixOflex was designed to preserve capsular form and optimise the optical performance that surgeons aim to achieve for their patients. CE marking of the device is an important step, and EYE PCR is planning to invest in global expansion of availability for the fixOflex technology. We look forward to sharing further developments as production and distribution plans are finalised.â?•

Clinical Evidence

A prospective study of 121 patients showed that fixOflex achieved comparable safety to standard cataract surgery with PCO incidence of 0.83% at 12 months, compared to 13.0% in a retrospective control group. No fixOflex patients required Nd:YAG laser capsulotomy, versus 3 patients in the control group.1

About Posterior Capsule Opacification (PCO)

PCO is one of the most common complications following cataract surgery, with literature reporting incidence rates of at least 11.8% at one year.2 PCO affects visual acuity and often requires Nd:YAG laser capsulotomy to restore clear vision with some 10% requiring Nd:YAG laser capsulotomy at one year postoperatively.3 fixOflex is designed to create a barrier to lens epithelial cell migration.

About EYE PCR

EYE PCR applies science-based innovation to address some of ophthalmologyâ??s most challenging issues. Founded by Professor Ioannis Pallikaris, the company builds on decades of pioneering research in cataract and refractive surgery. EYE PCR is headquartered in Amsterdam, The Netherlands, with research and clinical operations based in Heraklion, Greece.

For more information, visit
eyepcr.com or follow EYE PCR on LinkedIn.



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For professional use only. For indications, contraindications and warnings, please refer to the Instructions for Use (IFU). fixOflex is a registered product of EYE PCR B.V.

References

Photo â?? https://mma.prnewswire.com/media/2891556/EYE_PCR_fixOflex_Image.jpg

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