CORNEAT KPRO | SYNTHETIC CORNEA



CorNeat KPro

The CorNeat KPro is a synthetic cornea, keratoprosthesis (KPro), which provides a long-lasting medical solution for corneal blindness, pathology and injury. The CorNeat KPro utilizes advanced cell technology to integrate synthetic optics within resident ocular tissue. It is produced using nanoscale chemical engineering, which stimulates cellular growth. The current biological solution (keratoplasty), and previous KPros, are either sutured to, or attempted integration with, the native corneal tissue – a tissue that lacks blood vessels and heals very poorly. The CorNeat KPro integrates underneath the conjunctiva, the white part of the eye, a site rich with fibroblasts, which heals quickly and vigorously.

The CorNeat KPro is combined with a novel and relatively simple surgical procedure to provide an efficient, therapeutic and affordable remedy for millions of people with cornea-related visual impairments and is far superior to any available alternatives.

Indications

- Failed keratoplasty
- Corneal indications not suitable for keratoplasty, such as: Herpes keratitis | Corneal degenerations | ICE syndrome | Aniridia | SJS | OCP | Alkali burns | Vascularized cornea

CorNeat KPro Advantages



Optical Performance

- •• Replicating optimal corneal optics
- •• Wide field of view
- Simplifying the surgical procedure via direct visualization while enabling future procedures in a similar fashion



Scalability

- •• Relatively simple, 45-minute operation
- •• Affordable price
- No time constraints placed on scheduling of the implantation



Healing & Retention

- •• Device integrates to the eye wall using nano-fabric that imitates the native ECM
- •• Fast to hea
- Progressive integration
- •• Straight forward post operation recovery



Safe

- •• No need for tissue
- •• Cannot carry any infectious agent including COVID-19

Development Phase

CorNeat Vision designed, produced and tested several versions of the CorNeat KPro, successfully completing the pre-clinical phase.

The first-in-human (FIH) clinical trial for the CorNeat KPro took place in January 2021. The surgery was conducted by Prof. Irit Bahar at Rabin Medical Center, Israel. Additional sites are planned for the United States, Canada, France and the Netherlands. We are working toward FDA (510K) clearance (USA) and CE

mark (Europe), with the plan to release the CorNeat KPro to market in 2023.

In China, we are planning a study which will facilitate turning the CorNeat KPro into a primary solution for corneal blindness. The study is planned to begin in 2021 toward the NMPA (previously CFDA) approval.

The plans above are subject to regulatory approvals and requirements.





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Revolutionary innovation in corneal replacement therapy

Features | Surgical Kit | Procedure

The CorNeat KPro implantation procedure is relatively short and simple when compared to other KPros and even when compared to keratoplasty. Unlike current procedures requiring delicate suturing of donor tissue to the patient's native cornea, a process which can only be performed by very skilled and thoroughly trained specialists, the CorNeat KPro snaps into the patient's trephined cornea and is then sutured to the eye using three non-degradable sutures.



The surgical tools supplied as part of the implantation kit: the marker and the snapper, yield a systematic and accurate implantation process. This procedure is easy to teach and can be learned within a couple of days. The operation minimizes the time the eye's contents are exposed to the outside world, a step called "open sky," to less than one minute, significantly reducing associated risks.

The CorNeat KPro implant patented design is the result of an extensive, multidisciplinary (Physics, Chemistry, Biology) research and development process. The device, and its wide aperture PMMA lens, provides unprecedented visual performance and a wide visual field. The KPro lens' posterior side is designed to easily snap into a trephined cornea and maintain the eye's integrity and as a result normal intraocular pressure, post-operation. The lens is surrounded by a non-degradable porous integrating skirt, which is implanted subconjunctivally.

The skirt embeds itself into the sclera within weeks as it stimulates anchoring cellular growth. Grooves on the circumference of the lens are filled with porous material and as a result are colonized with tissue. This novel integration method of biological stitching further secures the device through its optical member thus ensuring reliable and quick healing, coupled with long-term retention.

Three pairs of suturing holes on the rim of the lens increase safety. These holes enable the ophthalmologist to secure the device quickly and easily to the eye. Suturing the device eases and shortens the implantation procedure and stabilizes both the lens and the skirt post-operation. This physical stability ensures progressive and uninterrupted bio-integration.

The CorNeat KPro lens is designed to enable post-operative ophthalmic examinations and subsequent anterior and posterior segment surgeries (i.e. cataract and retinal surgeries). This is achieved with four openings or "ports," located on the rim of the lens, corresponding to the limbal zone. Four corresponding port indicators can be viewed through an ophthalmic microscope directing the surgeon to these port's locations. This is required as the ports are located and placed subconjunctivally.

Being 100% synthetic, sterile, and composed of inert materials, the device is not expected to bear infectious agents or cause excessive inflammation. This will result in improved quality of life and more effective patient care.



