



CorNeat KPro Case Study



End-to-End Manufacturing of a Revolutionary Device

Overview

[CorNeat Vision](#) is a clinical-stage biomimetic implants and technology company. CorNeat Vision's breakthrough technology provides the cornerstone for developing a wide array of implants that are safer, more reliable, long lasting, and easier to handle than available alternatives.

The Electrospinning Company provides support to CorNeat Vision on their design and development journey and manufactures the products for clinical trials on three continents.

Corneal Blindness

According to the World Health Organisation (WHO), around 30 million people in the world are suffering with corneal blindness and low vision, and 2 million new cases are reported every year. A study published in *JAMA ophthalmology** discovered that for every available cornea, there are about 70 patients waiting for corneal transplant.

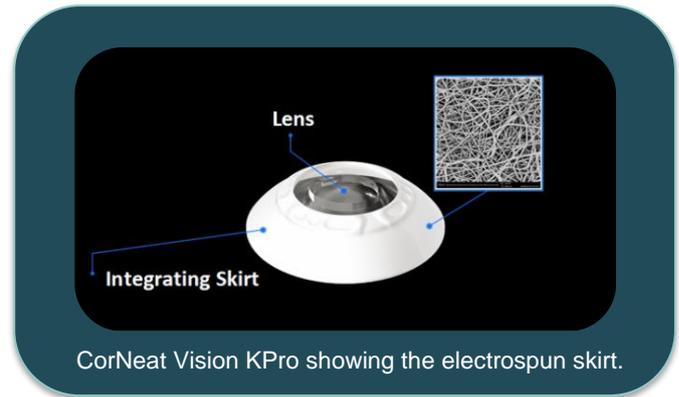
CorNeat Vision is developing a novel solution, a synthetic cornea which is bio-integrated into the eye with a nano-fabric that imitates native extracellular matrix (ECM). This [CorNeat KPro](#) device is designed to be safe, affordable, and scalable for the global population.

We have worked closely with the team at CorNeat Vision to develop an end-to-end manufacturing process, including assembly and packaging of this innovative device. The first-in-human (FIH) clinical trial for the CorNeat KPro took place in January 2021 after an extensive pre-clinical safety testing. This implantation returned sight to the patient, following a decade of blindness.

*Gain P, Jullienne R, He Z, *et al.* Global Survey of Corneal Transplantation and Eye Banking. *JAMA Ophthalmol.* 2016;134(2):167–173. doi:10.1001/jamaophthalmol.2015.4776.

Challenges

The CorNeat KPro product includes a patented synthetic cornea attached to a nano-fabric skirt. Initially, CorNeat Vision approached us to produce just the skirt component of the device. Our working relationship developed over the project duration and they shortly requested us to provide complete start-to-finish manufacturing; from electrospinning the nano-fabric skirt to attaching the skirt to the lens and assembling this into the final package. This evolution presented several complex technical and engineering challenges which was further challenged by Covid-19 travel restrictions, preventing the teams from working together in-person.



Solutions

Multi-discipline teams from both companies worked closely together to address the challenge of manufacturing this novel medical device. Our biomaterial engineers and polymer chemists collaborated with the medical device engineers and ophthalmic experts at CorNeat Vision to develop the equipment and manufacturing techniques, needed to assemble the components into a safe and consistent product. Furthermore, we addressed quality control, sterilisation and packaging integrity in close consultation with the quality and regulatory team at CorNeat Vision.

Our core values of Team, Transparency, Excellence, Consideration and Learning underpinned our partnership with CorNeat Vision at all times.

The restrictive in-person challenges caused by Covid-19 were overcome with regular communication and digital solutions such as video conferences and livestreaming processes in action.



Result

Following extensive pre-clinical safety testing, the first patient in the [first-in-human \(FIH\) clinical trial](#) was treated in January 2021. The surgery was conducted by Professor Irit Bahar at Rabin Medical Center, Israel, working toward FDA (510K) clearance (USA) and CE marking (Europe). Channel 13 news in Israel covered this [pivotal moment](#).

Irrespective of the Covid-19 pandemic and technological challenges, we co-developed a complete end-to-end manufacturing process for CorNeat Vision. Together with CorNeat Vision, we were able to meet target milestones and build a long lasting collaborative relationship.

“The Electrospinning Company is a knowledgeable and experienced R&D company for electrospun solutions. They have been a partner of ours for the past four years and greatly supported our activities. Our collaboration grew from a single R&D project to multiple R&D products currently in the clinical trial stage. The electrospinning team has been responsive to our needs and with their creative thinking approach allowed us to develop a very productive relationship and overcome R&D and production challenges.”

- CorNeat Vision