

Your Complete Guide

CorneaGen)*



About CorneaGen

CorneaGen's mission is to provide the highest quality donor tissue, unparalleled customer service and superior products that transform how ophthalmologists treat and care for every person impacted by corneal disease. Through continuous innovations in tissue processing technology and surgical devices, advocacy for patient access and simplified payor reimbursement policies, CorneaGen is advancing the next generation of cornea care.

CorneaGen's latest innovation provides an exciting option for the treatment of keratoconus. Corneal Tissue Addition for Keratoplasty (CTAK) is an innovative solution for keratoconic eyes and offers advanced corneal contouring with patient-specific, laser-cut tissue inlays.

As the world's leading eye bank, CorneaGen has multiple locations and local partnerships throughout the U.S. to deliver the life-changing gift of sight to tens of thousands of people each year.

CTAK

Corneal Tissue Addition for Keratoplasty

CTAK is the latest advancement in keratoconus treatment, focused on accuracy and precision for both patients and surgeons. This innovative procedure involves the use custom tissue inlays, designed to optimize corneal flattening, improve visual acuity, and add thickness to the cornea.

Using a Ziemer Neo Z8 Femtosecond Laser, CorneaGen processes tissue to the precise parameters for each patient. The tissue is sterilized, packaged and shipped with custom surgical plan options.



Advantages of CTAK

CTAK creates an offering to improve outcomes by treating each patient for the unique progression of keratoconus they've experienced.

- Precision and accuracy of a Ziemer Z8 laser-cut custom tissue inlay
- Biocompatible and fully customizable
- Clinical study showed no rejection of tissue post-transplant
- Custom surgical options detail inlay placement and sizing
- Topography flattening and visual acuity improvement
- Gamma-irradiation adds rigidity to the inlay and stability for the surgeon

Recommended Patients

Moderate keratoconus: 50D-75D. Patients with ectasia need more care and can schedule a consultation.

- Moderate sized cones: ≤4.0mm in width
- No cone which extends outside of the central 6mm optical zone (~3.0mm from the center of the pupil)
- No scarring in the visual axis
- BCVA < 20/20

International Onboarding Process

TRAINING PATIENT SEND SELECTION SCANS

During the CTAK onboarding process, CorneaGen

partners with you to ensure a seamless integration

into your practice.

Training: Comprehensive online modules to ensure understanding of techniques. Wet labs are available at major ophthalmology conferences (ASCRS, AAO, ESCRS).



Scan or visit CorneaGen.com/CTAKtraining and start today!

Patient Selection: Guidance on identifying suitable patients before scheduling.

Sending Scans: If using a Pentacam, take scan using Pentacam with iris camera. Export .U12 file from Patient Data Management and send file to CTAK@CorneaGen.com. CorneaGen expects to support other diagnostic devices starting in July of 2025. To submit scans export PDF of axial, pachemetry, keratometry maps and send PDF file to CTAK@CorneaGen.com.

Surgical Plan: Receive surgical plan options for each patient based on their specific needs.

Request Tissue:* Place order using *Tissue Request Form* and include a copy of your selected surgical plan.

Surgery:** Execute the procedure with support from the CorneaGen team's tools and resources.

*Please anticipate a 5-week period from CTAK order to delivery date.

**To honor the processing of donor generated tissue and quality controls, any cancellation will result in invoiced responsibility to surgical facility. SURGICAL PLAN OPTIONS REQUEST TISSUE

SURGERY

Practice Responsibilities

To ensure a successful partnership, the following items are required from your practice:

Instruments: Corza Medical has a CTAK specific surgical tool kit available for purchase.

Pentacam: 2012 or newer model with iris camera including HR, AXL, and AXL Wave. CorneaGen expects to support other diagnostic devices starting in July of 2025. Please confirm via email to **CTAK@CorneaGen.com** if your diagnostic device is supported.

Laser: Femtosecond laser with corneal ring application installed – may require laser representative assistance. The following lasers are currently applicable for the CTAK procedure:

- Alcon: FS200 and LenSx
- Zeiss: VisuMax 500
- **Ziemer:** Z4, Z6, Z8
- J&J: IntraLase (iFS)

International Vendor Guide

Lasers

Ziemer - Worldwide

Femto LDV Z4, Femto LDV Z6, Femto LDV Z8

The all-in-one femtosecond laser for refractive, cataract and therapeutic surgery.

marketing@ziemergroup.com

Alcon

WaveLight® FS200 The WaveLight® FS200

Femtosecond Laser offers a large variety of personalized treatment options Provides consistent, stable energy delivery for a highly reproducible, precise performance.

alcon.medinfo@alcon.com

LenSx

The Alcon LenSx is a high-repetition rate femtosecond laser used for precise and customizable incisions in cataract refractive procedures.

alcon.medinfo@alcon.com

Zeiss

VizuMax 500

With its cutting precision, speed and gentle treatment approach, the ZEISS VisuMax is the ideal platform for cutting-edge corneal surgery applications – including Flaps, Keratoplasty, and Incisions for ICR and ZEISS SMILE.

vertrieb.meditec.de@zeiss.com

Johnson & Johnson Vision

iFS (IntraLase)

The iFS Laser is a comprehensive platform built on intraLase[™] Technology's legacy of surgical precision.

JJV-International.Support@its.jnj.com

Diagnostics

OCULUS

Pentacam HR, AXL, AXL Wave Contact-free

Pentacam® measurement provides the basis for precise and reliable diagnostics and successful treatment of the anterior segment.

export@oculus.de

Ziemer

Galilei G4 & G6

All-in-one diagnostic device integrating Optical Biometry with Dual Scheimpflug Tomography and Placido Topography.

marketing@ziemergroup.com

Cross-Linking

Glaukos

iLink®

iLink® is the first and only FDAapproved corneal cross-linking procedure that slows or halts the progression of keratoconus and helps preserve vision.

info@glaukos-ilink.com

Instruments

Corza

CTAK Instruments

A set of specialized instruments, tailored for accurate marking, dissection, and tissue implantation and manipulation are utilized during the CTAK procedure.

corzaeye@corza.com

Procedure Overview

Preparing the patient for channel creation



Mark the graft angles. Then mark the distance from center of pupil, inferior and temporal based on surgical plan. Using an Optical Zone Marker encompass the inferior and temporal marks.



Center the laser over the optical zone marker, perform the laser cut, and clear the channel.

Inserting the inlay



Hold the CTAK tissue near the proximal end. While holding the channel open with straight forceps begin inserting the segment into the channel. Continue to progress the inlay throughout the channel.



Once you cannot advance the inlay further, use the CTAK Manipulator to clear the final turn.



Use the CTAK Applinator to smooth the inlay out, matching the incision angles provided on the surgical plan.

Example Surgical Plan

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Example Plan - 180 deg

СТАК

Patient Information

CorneaGen)

First Name	
Last Name	
Date of Birth	
Eye	OS

Doctor Name	
Design Generated	
Scan Instrument	
Scan Date	

Corneal Tissue Addition for Keratoplasty

Tissue: (*)

* CTAK design options provided below are based on uploaded scan data, which is reviewed by a CorneaGen Medical Director/Designee and approved by the requesting surgeon. Design options are provided to allow for correction modifications based on surgeon discretion.

Parameter	Option 1	Option 2	Option 3
CTAK Inner Diameter	4.5 mm	4.5 mm	4.5 mm
CTAK Outer Diameter	8.0 mm	8.0 mm	8.0 mm
CTAK Thickness	350 µm	250 µm	450 µm
CTAK Length	180 deg	180 deg	180 deg

Laser: (*)

* Laser parameters are based on CTAK design options, which are reviewed by a CorneaGen Medical Director/Designee and approved by the requested surgeon. Laser parameters are solely to aid during the input of information into a femtosecond laser.

Channel Inner Diameter	4.5 mm
Channel Outer Diameter	8.0 mm
Channel Depth	200 µm
Incision Angle	15 deg



Disclaimer:

This CTAK Design Plan is meant to serve as an adjunct tool for CorneaGen. It is intended to be used in conjunction with a comprehensive ophthalmic examination and the appropriate diagnostic tests and measurements necessary for corneal surgery candidates being considered for a CTAK surgery. The results obtained by the designer are not intended to serve as medical or surgical instruction from CorneaGen or CTAK LLC, nor can CorneaGen or CTAK LLC guarantee that the results will be accurate in every case. Physicians who receive and accept this design plan need to make their own independent determinations regarding the proper treatment for their patients and are solely responsible for the outcome. By using this CTAK design plan, you agree to waive and hold CorneaGen and CTAK LLC harmless from any claims you may have arising out of your use of the plan reviewed with the CorneaGen Medical Director/Designee.

The information and/or materials on this plan are provided without warranty of any kind, express or implied. CorneaGen and its employees, CTAK LLC and its employees and consultants, and anyone connected to the construction or content of this report, are not liable for damages of any kind, whether indirect or consequential, arising from the use of information supplied herein, or for any errors or omissions. It is the transplant surgeon's responsibility to determine suitability of the plan.

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Example Surgical Plan

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Placement: (*)

* Placement of the CTAK inlay is approximate and is intended solely as an aid based on a review by a CorneaGen Medical Director/Designee. Markings are measured from the pupil center to the inner radius of the CTAK inlay. See green lines in the diagram for reference.

Inferior Offset	2.75 mm
Inf-Temporal Offset	2.50 mm
Temporal Offset	2.25 mm
CTAK Edge Angle 1	0 deg
CTAK Edge Angle 2	180 deg

Contact us for questions or assistance. ctak@corneagen.com 1-888-CorneaGen

Pentacam Overview

The Pentacam General Overview screen is the main screen that should be used when sending scans. This screen includes the external software button that will be used to send your scans to CorneaGen.



Learn More About CTAK

Educational Videos

Presentation at AAO 2024



Peter S. Hersh, M.D. and **Brandon Ayres, M.D.** showcase CTAK in this presentation from AAO 2024. They cover what is CTAK, which patients are good candidates, and the step-by-step of the procedure. *Scan or visit* CorneaGen.com/CTAK-AAO to watch the talk.

Webinar: CTAK – Reshaping Sight for Keratoconous



David Hardten, M.D. and Elizabeth Davis, M.D., F.A.C.S. team up to discuss CTAK, the latest innovation in keratoconus treatment. During this webinar they cover patient selection, instruments, procedure steps, and when to do crosslinking. *Scan or visit* CorneaGen.com/CTAK-Webinar to watch today.

Surgical Demonstration



Brandon Ayres, M.D. present his CTAK surgical footage, showcasing the procedure from beginning to end. Scan or visit CorneaGen.com/CTAK-Ayres to watch.

Additional Resources

Visit CorneaGen.com for additional resources including regularly updated educational materials such as world-class webinars, surgical pearls from top ophthalmologists and surgical demonstration videos.



Scan or visit CorneaGen.com/CTAK-International

Contact Us

CorneaGen's team of international surgical product specialists are here to answer any questions you have about getting started with CTAK.

Greg Davis Mobile: +1 (602) 909-2519 Greg.Davis@CorneaGen.com Scott Davis Mobile: +1 (602) 909-2519 Scott.Davis-CW@CorneaGen.com

Start Your Training Today!

We're excited to help you take the first step toward offering this innovative procedure by offering a short 15-20 minute online training course for surgeons interested in offering CTAK in their practice.

The online CTAK training will:

- Introduce you to CTAK and its procedural requirements
- Provide insights into patient selection and surgical planning
- Offer step-by-step instructions to prepare you for hands-on practice



Scan or visit CorneaGen.com/CTAKtraining and start today!



Corneal Tissue Addition for Keratoplasty



Improved Visual Acuity: Patients report significant visual improvements at day 1 post-op*



Personalized Surgical Plan Options: CTAK provides personalized surgical plan options for every patient, saving valuable time and focus in the O.R.



Maximizes Tissue Donation: Honors the gift of donation by utilizing underused cornea tissue

