

an investigational

The KeraKlear<sup>™</sup> is a ~~revolutionary~~ new type of foldable artificial cornea that is designed for synthetic anterior lamellar keratoplasty through small incisions.

The KeraKlear<sup>™</sup> is able to restore vision by replacing the anterior portion of the cornea, in which the majority of the focusing of light rays occurs. This device is implanted into a femtosecond laser-created lamellar corneal pocket after the removal of the central anterior cornea. The posterior cornea including the patient's endothelium is retained and less than 5% of the recipient corneal tissue is removed.

This design helps to avoid a number of common complications of other artificial corneas, including endophthalmitis and retroprosthetic membranes. The KeraKlear<sup>™</sup> is made of a proprietary biocompatible material that is flexible which allows implantation through a 3.5 mm incision using forceps.

The optic diameter is 4 mm, which provides a large enough optical zone to afford a full visual field and a good view of the fundus.



# KeraKlear XT<sup>™</sup>

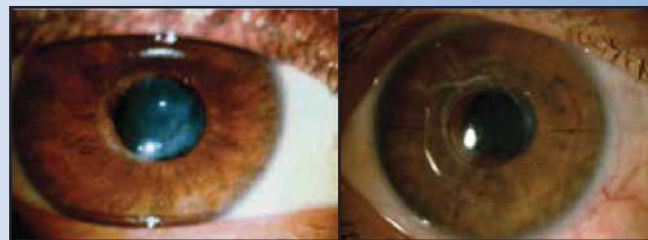
- Now with a range of thicknesses
- Can be implanted in corneas with a thickness between 300 and 800 microns.
- Expands range of patients and diagnoses which can be treated
- Can be used for treatment of corneal scars, limbal stem cell deficiency, corneal dystrophies, failed corneal transplants and keratoconus.

Dr. Jose M. Vargas of Valencia Venezuela, has used the KeraKlear<sup>™</sup> in patients with corneal graft rejection, corneal scars and keratoconus. He and his patients have been very pleased with the results of the KeraKlear<sup>™</sup>. Visual improvements have occurred immediately after surgery.

## Example Cases

### Case 1

A patient had keratoconus, apical scarring and preoperative vision of 20/400. After the KeraKlear<sup>™</sup> procedure, uncorrected vision improved to 20/30 on postoperative day 1



Preoperative and postoperative day 1 appearance of a keratoconus cornea after KeraKlear<sup>™</sup> procedure.

### Case 2

A patient with a history of two failed cornea transplants secondary to endothelial rejection and hand motion vision underwent the KeraKlear procedure.

On day 1 after surgery, his uncorrected vision was 20/100 and he could read large print (Figure 1). Additionally, on postop day 1, the iris details were visible through the artificial cornea (Figure 2) and the fundus could be visualized (Figure 3).

At 1 month, uncorrected vision improved to 20/60

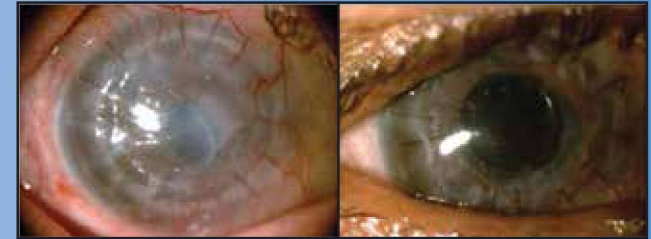


Figure 1. Preoperative and postoperative photographs after KeraKlear<sup>™</sup> procedure.

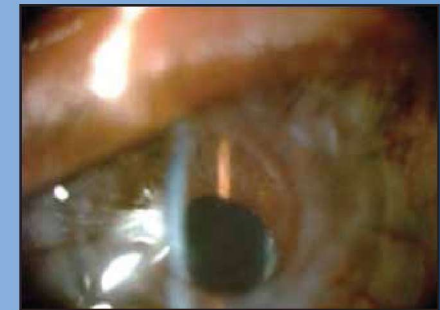


Figure 2. On day 1 after KeraKlear<sup>™</sup> procedure, the iris details are visible.



Figure 3. Fundus visualization is possible on day 1 after KeraKlear<sup>™</sup> procedure.



Yichieh (EJ) Shiuey, MD

Dr. Shiuey, formerly Associate Chief of Ophthalmology at Harvard Medical School, recognized the need for an artificial cornea that would be simple to use in the absence of donor tissue.

This artificial cornea merges the principles of small-incision cataract surgery and femtosecond laser refractive surgery. The result is an artificial cornea procedure that can be learned easily and provides rapid recovery for the patient.

**Advantages of the KeraKlear™ Artificial Cornea**

- No Immunologic Rejection
- Controls Astigmatism
- Fast Improvement in Vision (Days)
- Non-penetrating Surgery
- No Cadaveric Tissue
- Can be performed as an in office procedure
- Keeps other surgical options viable e.g. PKP and DALK

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Dedicated to Corneal Surgery

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**KeraKlear™  
Foldable Artificial Cornea**



**The KeraKlear™ is a revolutionary new type of foldable artificial cornea that is designed for synthetic anterior lamellar keratoplasty through small incisions.**

The KeraKlear™ has received European CE Mark approval.

The KeraKlear™ has not received U.S. FDA Clearance and may not be used in the U.S.A.

The statements in this brochure have not been evaluated by the US FDA and this brochure is not intended for distribution to US surgeons.

