

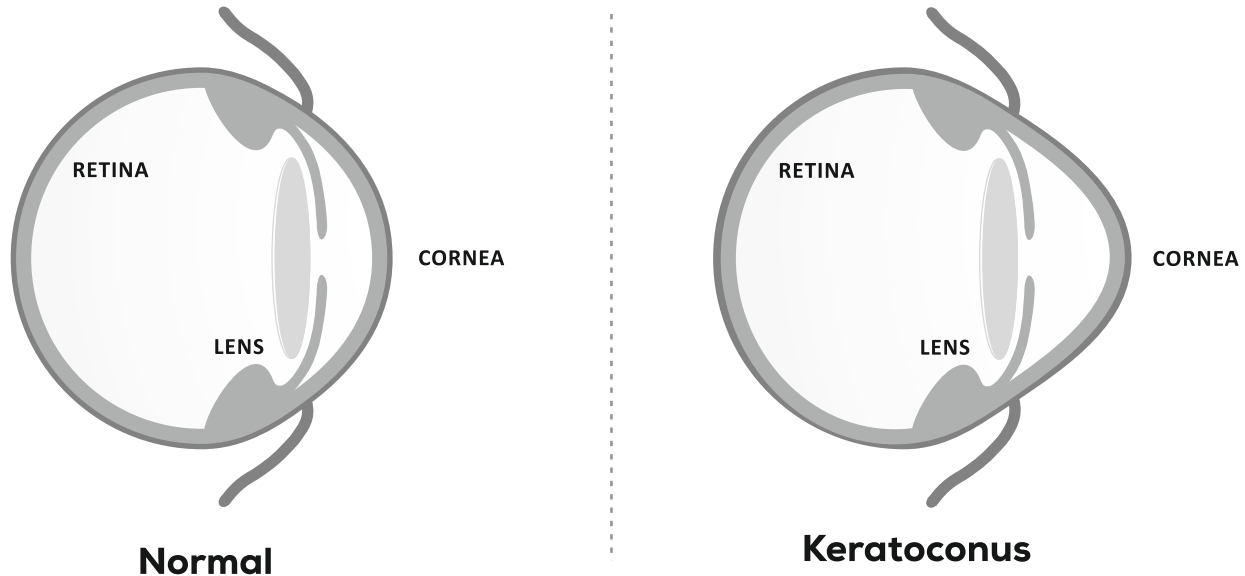
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# BIORING

biotech

VISION CARE

# BIORING



## KERATOCONUS:

Keratoconus is characterized by thinning and steepening of the cornea and results in visual distortion often not correctable by traditional glasses.

Keratoconus is caused by decrease in protective antioxidants in the cornea. The corneal cell produce damaging by-products which increase oxidative stress. Normally, antioxidants protect the collagen fibers against oxidation. If antioxidants levels are low, the collagen weakens and the cornea bulges out

The changes in the shape of the cornea can happen quickly or may occur over several years. The changes can result in blurred vision, glare and halos at night, and the streaking of lights.



Vision through Normal Eye



Vision through Eye with Keratoconus



## BIORING & it's MECHANISM:

BIORING is a non-optical corneal device intended for implantation in corneal stroma, reducing myopia, irregular astigmatism and refraction defect associated with different corneal and ectasic pathologies like Keratoconus. Keratoconus (KC, KCN, and KTCN ) is a disorder of the eye which results in progressive thinning of the cornea.

BIORING is implanted in the Keratoconus patients to reduce the steepness in the cornea and bring it to its regular shape for the patient who is not able to achieve functional vision even with the use of spectacle and contact lenses

**Mechanism:** Corneal remodeling by addition technique keeping the corneal integrity intact.

## BIORING OFFERS...

- When BIORING segment is placed inside the layers of the corneal stroma, it reduces the steepness in the cornea.
- BIORING segments flatten the corneal surface and reduce the refractive error in the eye.
- It also reduces the rate of keratoconus progression by supporting the corneal tissues
- Flattening the conical shape of the cornea also bring down the aberrations and improve the visual acuity
- Corneal topography regularization and refractive correction preserving the natural prolate profile, reducing optical aberrations and improving visual acuity and contact lens tolerance
- Displacement of corneal apex towards the central pupil
- Corneal stabilization, delaying or eliminating the need for corneal transplantation

## INDICATIONS:

- Keratoconus with poor BSCVA and contact lens intolerance.
- Progressive keratoconus
- Pellucid marginal degeneration
- Post Lasik ectasia
- Irregular astigmatism following radial keratotomy
- High astigmatism secondary to penetrating keratoplasty.
- Post-trauma corneal irregularities.
- The specific subset of keratoconic patients proposed to be treated with BIORING Implants are those patients:
  - Who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles;
  - Who are 21 years of age or older
  - Who have clear central corneas

## CONTRAINDICATIONS

- For Very advanced keratoconus with curvatures over 75 diopters and significant apical opacity and scarring
- Hydropsis
- Patients with intense atopia (these should be treated before the implant)
- Any ongoing infectious process, local or systemic
- Following penetrating keratoplasty when graft is decentered.
- Recurring corneal erosion syndrome
- Patient's high expectations to achieve emmetropia
- BIORING is not recommended in patients with systemic diseases likely to affect wound healing such as insulin depended diabetes or severe atopic diseases
- Patients with history of retinal detachment, macular degeneration or diabetic retinopathy
- Patients who have undergone previous cross-linking treatment, having diabetes or auto immune

- Pregnant or nursing women
- Patients who are taking one or more of the following medications: isotretinoin, amiodarone & sumatriptan.
- Patients with a history of ophthalmic Herpes simplex or Herpes zoster.

## PRE-OPERATIVE MEASUREMENTS:

A clear central cornea with a minimum corneal thickness as suggested in table of "Guideline for BIORING segment thickness" at the incision site and a mesopic pupil size of less than 6 mm are preferred. A careful slit lamp examination, refraction (dry and dilated), fundus evaluation and post-mydratic tests need to be done. The peripheral pachymetry at the incision site is evaluated pre-operatively to ensure sufficient corneal thickness and appropriate depth of placement of the BIORING. The incision is planned on the axis of the positive cylinder to achieve maximum effect. Look for any mis-match between the steep K and the axis of the positive cylinder in the manifest refraction. Symmetric segments are used in central ectasic conditions whereas asymmetric segments are used in decentered ectasia.

**Guideline for BIORING segment thickness**

Segment Thickness	150 Micron	200 Micron	250 Micron	300 Micron	350 Micron
Minimum Corneal Thickness Required (6 mm Optical Zone)	250 Micron	335 Micron	420 Micron	500 Micron	580 Micron



## CLINICAL BENEFITS

- Delay or avoid corneal transplantation
- Stop or delay the progression of the keratoconus
- BIORING implantation will result in the flattening the cornea which improve the visual acuity of the patient.

## REVERSIBILITY

BIORING may be explanted at any time, allowing the cornea to revert to its original preoperative shape. The procedure is reversible.

## ADJUSTABILITY

Refractive and topographic results may be easily readjusted by exchanging or repositioning the implant.

## HOW TO USE ONLINE CALCULATOR:

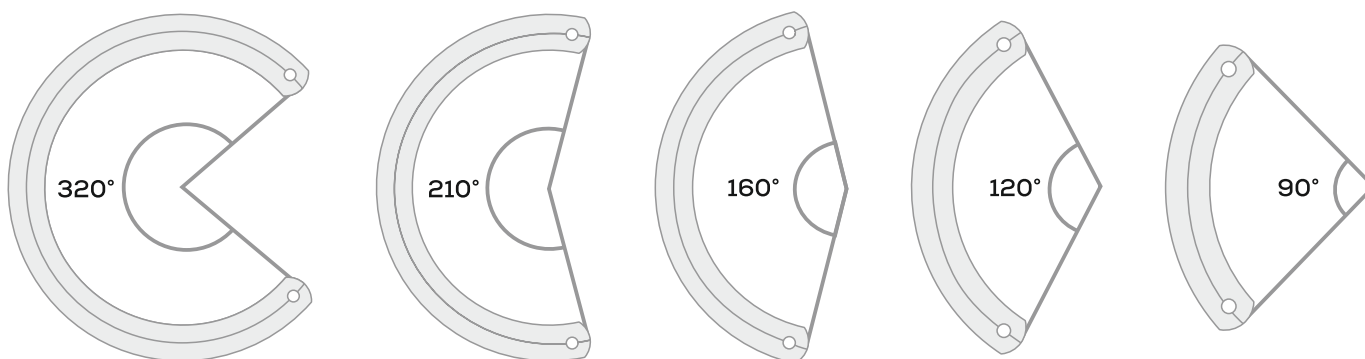
User friendly online calculator: Appropriate segment for particular patient can easily be found out using [www.biotechcalculators.com](http://www.biotechcalculators.com)

- The BIORING CALCULATOR uses multiple variables and each contributes to some extent to the determination of the best surgical strategy for a specific eye.
- The calculator guides the location to be held the incision, the best depth for the tunnel and select which ring model will get the best possible result.
- The BIORING calculator is available at <http://www.biotechcalculators.com> for choosing the correct BIORING Segment and the best surgical strategy.
- BIORING surgical outcomes are greatly dependent on accurate selection of implant size and position for each individual patient.
- The calculator must be filled with several information about the eye to be operated i.e. Keratometry, refraction, Pachymetry and morphology of the ectasic area.



## AVAILABLE THICKNESSES, ARC ANGLES & DIAMETER:

Thickness	150, 200, 250, 300 & 350 $\mu\text{m}$
Diameter	5.0 mm
Arc Angle	90°, 120°, 160°, 210°, 320°



## SURGICAL TECHNIQUE

BIORING implantation is a simple outpatient procedure performed under local anesthesia. An eyelid speculum is used to expose the eye and 2.5% povidone iodine eye drops is instilled into the cornea and conjunctiva.

## IMPLANTATION TECHNIQUE:

BIORING can be implanted using Femtosecond LASER technique as well as Manual technique.

## PARAMETERS REQUIRED FOR FEMTOSECOND LASER TECHNIQUE:

Inner Diameter	4.7 mm
Outer Diameter	5.9 mm

## Manual Technique

The visual axis is marked by pressing the Sinskey hook on the central corneal epithelium while asking the patient to fixate on the corneal light reflex of the microscope light. Using a marker tinted with gentian-violet the tunnel location and the incision site are centered and aligned to the topographic steepest meridian. The size of a square diamond blade is set at 75-80% of corneal thickness at the incision site.

This blade is used to make the incision. Two tunnelers (clockwise and counterclockwise) with a 270° semicircular dissecting spatulas are consecutively inserted through the incision and gently pushed with some, quick, rotary “back and forth” tunneling movements.

Following channel creation, the ring segments are inserted using a special forceps. The rings are properly positioned with the aid of a hook.

## INSTRUMENTS AVAILABLE FOR FEMTOSECOND LASER TECHNIQUE:

1. Spreader
2. Double Hook
3. Guide
4. Ring Holder Forceps
5. Clockwise Tunneler
6. Counter-clockwise Tunneler
7. 380° Tunneler

## COMPATIBILITY WITH OTHER PROCEDURES

BIORING implants may be synergistically combined with other techniques such as corneal collagen crosslinking, PRK and Phakic IOL implantation

BIORING does not interfere with normal execution of lamellar or penetrating keratoplasty, if needed.

## VISUAL AND TOPOGRAPHIC RECOVERY

Minimally invasive technique allows patients to rapidly resume their normal activities

Topographic and refraction changes are noticeable right after implantation and stabilize in 3 months on average

## Instruments available for Manual Technique:



Double Marker



Spreader



Double Fixation Forceps



Ring Holder Forceps



Guide



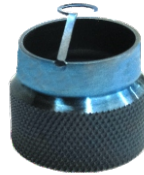
Double Hook



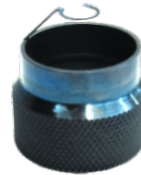
Gauge



Pre-delaminator



Counter - Clockwise Tunneler



Clockwise Tunneler

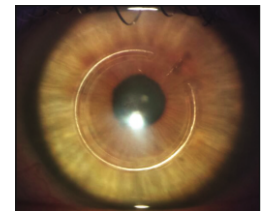


380° Tunneler

Diamond Knife



BIORING provides excellent outcome with precision:





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