

INTRACORNEAL RINGS

Intacs™ vs. Keratacx™

Introduction

Intra-stromal implants are called Rings, Segments or ICRs and were designed and developed to be used as a correction for reducing or eliminating myopia of -0.5 to -8.0 diopters. They are also used for the correction of keratoconus if properly implanted into the stroma of the cornea, outside of the optic zone.

The implant changes the surface shape of the cornea following implantation because they are implanted approximately 2/3 of the way into the periphery of the cornea thru a small radial incision and tunnel created in the stroma.

The tunnel or elongated pocket can be created by using an manual instrument or a laser following the wound puncture, which must not be too deep so as to perforate the cornea.

Once formed, the implant is carefully inserted into the tunnel and the shape of the cornea is changed so as to create better vision for the patient.

Intacs™, Ferrara Rings™, KeraRings™ and Keratacx™ are on the market today and each has its own specific design completely different from the other but all create a post operative result of better vision. Since Intacs is the only FDA approved intrastromal segment this document chooses to compare Intacs with Keratacx.

What are INTACS™?

INTACS™ are small prescription ring inserts that are implanted in the cornea for the correction of Keratoconus and mild myopia (-0.5 to -4.00D).

They are particularly well suited to those who have been turned down for Laser vision correction because of thin corneas and also those worried about the irreversibility of laser surgery. The implants can be removed or exchanged if necessary.

INTACS™ are clear, thin prescription inserts placed in the periphery of the cornea by an ophthalmologist during a brief outpatient procedure. INTACS™ inserts reshape the curvature of the cornea from within, enhancing the natural shape of your eye to correct mild nearsightedness. Because no tissue is removed (as would be in Lasik or other Eye laser surgery), natural optics are enhanced and the structural integrity of the cornea is maintained.

- FDA-approved as safe and effective
- FAA-approved for pilots
- Excellent results – in US clinical studies, 97% of patients saw 20/40 or better with INTACS inserts, 74% saw 20/20 or better, and greater than 50% saw 20/16 or better
- Maintenance-free correction
- Greater flexibility because INTACS inserts can be removed or replaced with a new prescription should your vision needs change.

What are KERATACx™?

KERATACx™

Keratacx was designed and developed to be used as a correction for reducing or eliminating myopia of -0.5 to -7.0 diopters and for correction of keratoconus if properly implanted into the stroma of the cornea outside the optical zone.

Keratacx changes the surface shape of the cornea because they are implanted 2/3 of the way into the periphery of the cornea thru a small radial incision or tunnel in the stroma.

The design of Keratacx allows for their extraction from either end and replacement if necessary.

They are transparent and each ring covers 160° degrees. They are manufactured from the world's finest PMMA and are currently available from 150 microns to 500 microns in 25 micron increments. The amount of correction depends upon the thickness of the implant and they are designed to be used in pairs.

They may be implanted in a clockwise or counter clockwise direction depending on the intra-stromal tunnel and surgical technique due to the hole at each end. This hole may be used for manipulation and removal.

The Differences:

- Keratacx correct a higher degree of myopia. i.e. -7.0 diopters vs -4.0 diopters.
- This is due to the smaller pupil zone of Keratacx. 4.8mm vs. > 6.0mm.
- Shape – Keratacx shape is unique, triangular shape vs shape of a house.
- Keratacx have extremely rounded edges vs sharper edges.
- Keratacx have an arc of 320° vs Intacs of 300°.

How do INTACS™ work?

INTACS™ inserts gently enhance the natural shape of the cornea to allow light rays to focus precisely on the retina, thus producing a clear, sharp image.

To understand how INTACS™ inserts produce good vision, imagine a tent with a domed top, a shape similar to that of your cornea. If the sides of the tent are extended outward, the top flattens slightly.

INTACS™ inserts work in a similar fashion. When INTACS™ inserts are placed in the periphery (sides) of the cornea, outside the vital central optical zone, they gently reshape the center or “top” of the cornea. This prescription reshaping flattens the center just enough to allow light rays entering your eyes to focus properly. For most patients, the result is clear vision.

In the US today, there are over 20 million adults who have myopic error between -1.00 and -3.00D with astigmatism of 1.00 or less. INTACS™ are specially designed for these patients.

The degree of correction is determined by the thickness of the INTACS™, which are available in 0.25, 0.275, 0.30, 0.325, and 0.35mm. The thicker the INTACS™ the greater the amount of correction achieved.

INTACS™ is two tiny prescription inserts made of polymethylmethacrylate (PMMA), the same biocompatible material that's been safely used in contact lenses and IOLs for over fifty years. Each INTACS segment has an arc of 150° degrees.

How do KERATACx™ work?

Keratacx also change the surface shape of the cornea but not by pushing out on the edge of the cornea like Intacs. Keratacx simply flatten the cornea like putting a pillow under the bed covers and changing the shape of the covers or bedding. A small smooth, rounded mass creates a bulge near the center of the cornea.

INTACS™ Indication for Use:

Intacs is intended for the reduction or elimination of mild myopia (-1.00 to -3.00 diopters spherical equivalent at the spectacle plane) in patients:

- Who are 21 years of age or older.
- With documented stability of refraction as demonstrated by a change of less than or equal to 0.50 diopter for at least 12 months prior to the preoperative examination.
- Where the astigmatic component is +1.00 diopter or less.

KERATACx™ Indication for Use:

Keratacx are indicated to reduce or to eliminate myopia or keratoconus from (-0.5 to -5.0 diopters):

- Caution should be used for anyone under 18 years of age.
- The patient’s refraction should be stable for a period of 12 months preceding implantation.
- Astigmatism should be less than +1.00D.

Indication differences:

All intra-stromal implants if used properly can be helpful in creating a new shape to the patient’s cornea. It is believed that Intacs were not originally indicated for Keratoconus because of the USFDA filing and the limits put on the company by the USFDA.

Keratacx can correct to a higher degree of correction and surgeons should decide which style of intra-stromal implant is best for the patient. Many believe that the newer generations of implantable segments such as KERATACx™ are easier on the corneal surface and provide longer visual acuity. Long term clinical data will, in the future, provide evidence of this theory. Initial results with three (3) year follow-up seem to indicate that KERATACx™ are less invasive than other shapes.

Contraindications:

INTACS™ are contraindicated;

- In patients with collagen vacular, autoimmune or immunodeficiency diseases
- In pregnant or nursing women
- In the presence of ocular conditions, such as keratoconus, recurrent corneal erosion syndrome or corneal dystrophy, that may predispose the patient to future complications
- In patients who are taking one of more of the following medications; isotretinoin (Accutane), amiodarone (Cordarone), sumatriptan (Imitrex)

Contraindications:

Keratacx™ are NOT recommended for:

- Patients with vascular problems or disease.
- Patients with auto.immune / immuno-deficiencies
- Pregnant or breast feeding mothers
- Patients with eye infections/corneal diseases
- Patients on Accutane, Cordarone, Imitrex or other similar medications.

Differences: As you can see, the Contraindications for intra-stromal rings are all similar and surgeons should use caution in all patient selection and treatments.

Calculating Diopter:

Determining the implant needed for the proper correction of the patient’s myopia will depend on each surgeon’s specific implantation technique. Surgeons should use their own calculation and experience for product selection remembering that the optical zone (Diameter) of Keratacx is 6.2mm as opposed to INTACS™ 6.8mm. Therefore, Keratacx will tend to make a slightly higher correction.

The Chart Below is ONLY a guideline. Surgical technique & experience should always be used first.

**KERATACx™
NOMOGRAM**

SIZE	NOMINAL CORRECTION	RANGE
150µ	0.25	< 0.5 D
200µ	0.8	0.6 – 1.0 D
250µ	1.5	1.3 – 1.7 D
300µ	2.2	2.0 – 2.4 D
350µ	2.9	2.7 – 3.1 D
400µ	3.6	3.4 – 3.8 D
450µ	4.2	4.0 – 4.4 D
500µ	4.9	4.7 – 5.1 D

NOTE: The chart above is only a guideline and Surgeons must use their own experience and expertise.

Summary:

Intra-stromal segments are now becoming a normal tool in the surgeon’s arsenal against poor vision. Unlike the original segments that necessitated the surgeon purchasing a multi-thousand dollar piece of equipment and special instrumentation, products like Keratacx can be used by most surgeons without expensive instrumentation.

Improvements in Pachymetry and corneal topography have increased the use of intra-stromal segments, rings or implants.

Note: INTACS™ is a registered trademark of Keravision / Alcon, Technologies, Inc., Kera Rings is a trademark of Mediphacos