



## **Professional Use**

# **Information Manual for Correction of Myopia and Astigmatism Associated with Keratoconus Using Intacs<sup>®</sup> Corneal Implants**

## **Physician Booklet**

**HUMANITARIAN DEVICE:** Authorized by U.S. Federal Law for use in the treatment of myopia and astigmatism associated with keratoconus. The effectiveness of this device for this use has not been demonstrated.

**RESTRICTED DEVICE:** U.S. Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

This document provides information concerning the intended use of Intacs Corneal Implants. For additional information, refer to the Intacs<sup>®</sup> Surgeon Training Manual for Treatment of Keratoconus.

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

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CorneaGen, Inc.

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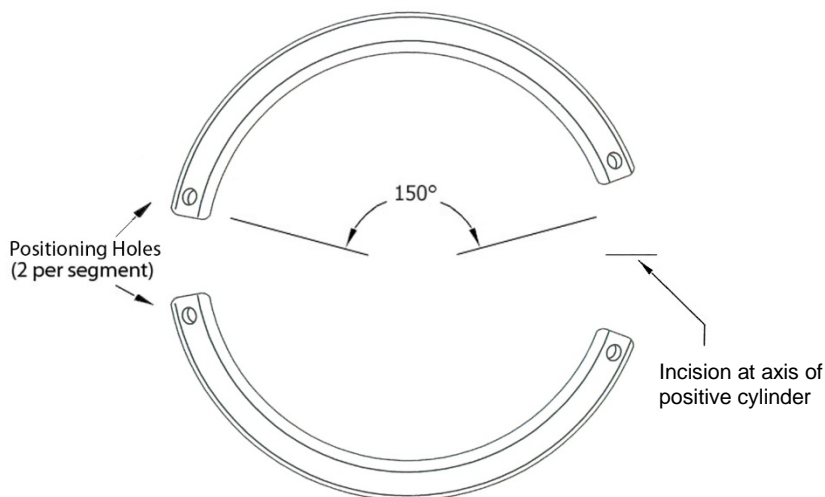
### General Warnings

- **RESTRICTED DEVICE:** U.S. Federal Law restricts this device to sale, distribution and use by or on the order of a physician.
- **HUMANITARIAN DEVICE:** Authorized by U.S. Federal Law for use in the treatment of myopia and astigmatism associated with keratoconus. The effectiveness of this device for this use has not been demonstrated.
- Specific training is required before a physician is qualified to perform the Intacs Corneal Implants procedure for treatment of keratoconus. Physicians must successfully complete an Addition Technology-approved training program, read and understand this booklet, and the Intacs® Surgeon Training Manual for Keratoconus, prior to performing the procedure.
- Performance of the Intacs Corneal Implants procedure, other than as specified in this booklet and the Intacs® Surgeon Training Manual for Keratoconus, may result in an undesirable outcome.
- All patients must be given the opportunity to read and understand the Patient Information Booklet, entitled “Facts You Need to Know About Intacs® Corneal Implants for Treatment of Nearsightedness and Astigmatism Associated with Keratoconus,” and to have you answer all their questions to their satisfaction before giving consent for the Intacs procedure.

**I. Device Description**

Intacs® Corneal Implants are an ophthalmic medical device designed for the reduction or elimination of myopia and astigmatism in patients with keratoconus (KC) so that their functional vision may be restored and the need for a corneal transplant procedure can potentially be deferred. When placed in the corneal stroma, outside of the patient's central optical zone, the product reduces the cone by flattening the cornea and for non-central keratoconus, repositions the cone centrally. Intacs segments are designed to be placed in the periphery of the cornea, at approximately two-thirds depth, and are surgically inserted through a small radial incision in the corneal stroma. The placement of the incision will be typically temporal at the axis of positive cylinder; however may vary depending on the location of the cone and the amount of keratoconus present in the specific eye to be treated. The Intacs segments are to be placed equidistant on each side of the incision. The Intacs product has been designed to allow removal or replacement, if desired.

Intacs Corneal Implants are composed of two clear segments, each having an arc length of 150° (see diagram below). They are manufactured from polymethylmethacrylate (PMMA) and are available in six thicknesses: 0.210 mm, 0.250 mm, 0.300 mm, 0.350 mm, 0.400 mm and 0.450 mm. In order to reduce the myopia and the irregular astigmatism induced by keratoconus, two Intacs segments ranging from 0.210 mm to 0.450 mm may be implanted depending on the patient's preoperative manifest refraction spherical equivalent (MRSE), the orientation of the cone and the degree of asymmetric astigmatism. The product is designed with a fixed outer diameter and width. Intacs Corneal Implants have two positioning holes, located at each end of the segment, to aid in surgical manipulation.



**Diagram of Intacs Corneal Implants**

**II. Treatment Nomogram**

The Intacs Corneal Implants treatment nomogram for keratoconus is based on the clinical results from implanting the 0.250 mm, 0.300 mm, 0.350 mm, 0.400 mm and 0.450 mm

thicknesses of Intacs segments in keratoconus patients. The 0.210 mm Intacs thickness is proposed to be used to treat those keratoconus patients who require only a minimal amount of corneal flattening and/or corneal stabilization, who are contact lens intolerant and who can no longer be effectively corrected with spectacles to restore their functional vision. The specific determination of which thicknesses of the Intacs segments to implant is dependent upon the nomogram and a number of variables; the most significant being the patient's preoperative manifest refraction spherical equivalent, the location of the cone and the degree of asymmetric astigmatism present.

- The surgical technique for keratoconus is similar to the standard Intacs surgical technique used for low myopia, except that the location of the incision is often placed temporally.
- Pachymetry is to be measured during surgery at the peripheral location of the entry incision. All patients shall have a corneal thickness of 450 microns or greater at the proposed incision site. The incision depth should be at 68% of the corneal thickness measured at the peripheral location of the entry incision.
- A temporal incision is typically used depending on the location of the astigmatism. Some corneal surgeons place the entry incision in the same meridian as the axis of positive cylinder.

Note: Patients may be allowed to manually adjust the axis of cylinder at the Phoropter to achieve the clearest subjective image. This technique may work better than the Jackson cross-cylinder technique for patients with irregular astigmatism.

- An asymmetrical cone is treated with a thinner Intacs segment placed superiorly and a thicker Intacs segment placed inferiorly.
- Global and central cones are typically treated using two segments of the same thickness.
- The thicker Intacs segment is typically placed to correspond to the keratoconus cone (inferiorly) to lift the cone and produce the maximum flattening effect and the thinner Intacs segment is placed in the opposite corneal half (superiorly) to counterbalance the thicker segment and to flatten the rest of the corneal surface across the visual axis.

There are two primary criteria used in determining the surgical nomogram related to the use of Intacs Corneal Implants for keratoconus. The first criterion is whether the cone is centered or decentered (asymmetric cone). Keratoconus which is **centrally** present as determined by a topographical map, will require two Intacs segments of the same thickness. The thickness of the Intacs segments to be used is determined based on the preoperative spherical equivalent of less than or equal to -3.00 D or greater than -3.00 D. This would also apply to **global** keratoconus in which the keratoconus is central but its circumference extends beyond 5.0 mm from the center.

As for asymmetric cones, it is necessary to evaluate the degree to which the cone is decentered. This is done by reviewing a topographical map of the cornea. **Moderate asymmetry** exists when the cone is off-center in placement at the 3.0 millimeter ring on the topographical map. **High asymmetric** cones are typically 5.0 millimeters or more off-center, as exhibited on a topographical map. In each of these cases, two different thicknesses of Intacs segments are used. The Intacs thicknesses used will depend on whether the preoperative spherical equivalent is less than or equal to -3.00 D or greater than -3.00 D. The thicker Intacs segment is recommended to be placed inferiorly and the thinner Intacs segment is to recommended be placed superiorly.

The recommended Intacs placement and thickness nomogram to be used for keratoconus is presented below:

<b>Recommended Intacs Placement Nomogram for Keratoconus</b>	
<b>Type of Keratoconus</b>	<b>Intacs Product Configuration</b>
Asymmetrical Cone	Two Intacs segments of different thicknesses implanted <i>(One thinner Intacs segment placed superiorly – One thicker Intacs segment placed inferiorly)</i>
Global Cone	Two Intacs segments of the same thickness implanted <i>(One Intacs segment placed superiorly – One Intacs segment placed inferiorly)</i>
Central Cone	Two Intacs segments of the same thickness implanted <i>(One Intacs segment placed superiorly – One Intacs segment placed inferiorly)</i>

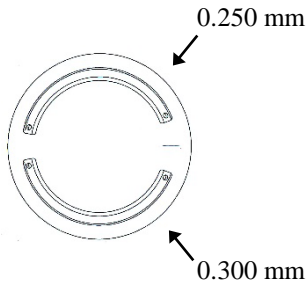
<b>Recommended Intacs Thickness Nomogram for Keratoconus</b>		
<b>Type of Cone</b>	<b>Preop MRSE <math>\leq</math> 3.00 D</b>	<b>Preop MRSE <math>&gt;</math> 3.00 D</b>
Asymmetrical Cone:		
Moderate asymmetry	0.250 mm/0.300 mm	0.250 mm/0.350 mm
High asymmetry	0.350 mm/0.400 mm	0.400 mm/0.450 mm
	0.250 mm/0.400 mm	0.250 mm/0.450 mm

Global Cone	0.400 mm/0.400 mm	0.450 mm/0.450 mm
Central Cone	0.400 mm/0.400 mm	0.450 mm/0.450 mm

Some of the different product configurations recommended for the treatment of keratoconus are illustrated below in Diagrams 1- 3:

**Diagram 1**

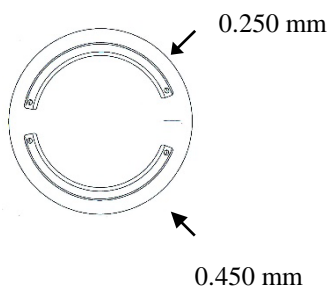
***Asymmetrical Cone - Moderate***



For patients with a preoperative MRSE  $\leq 3.00$  D, one thinner Intacs segment (e.g., 0.250 mm) is placed superiorly and one thicker Intacs segment is placed inferiorly (e.g., 0.300 mm), temporal incision placement is used (9:00 for right eye and 3:00 for left eye).

**Diagram 2**

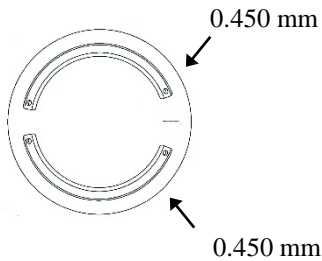
***Asymmetrical Cone - High***



For patients with a preoperative MRSE  $> 3.00$  D, one thinner Intacs segment (e.g., 0.250 mm) is placed superiorly and one thicker Intacs segment is placed inferiorly (e.g., 0.450 mm), temporal incision placement is used (9:00 for right eye and 3:00 for left eye).

**Diagram 3**

***Global Cone/Central Cone***



For patients with a preoperative MRSE  $> 3.00$  D, two Intacs segments of the same thickness are placed – one Intacs segment is placed superiorly and one Intacs segment is placed inferiorly, temporal incision placement is used (9:00 for right eye and 3:00 for left eye).

### III. Surgeon Training Manual

The Intacs® Surgeon Training Manual for Keratoconus contains detailed information regarding the treatment nomogram, the surgical procedure, equipment, medications and patient management. Please refer to the Surgeon Training Manual for additional information.

### IV. Indication for Use

Intacs® Corneal Implants are intended for the reduction or elimination of myopia and astigmatism in patients with keratoconus, who are no longer able to achieve adequate vision with their contact lenses or spectacles, so that their functional vision may be restored and the need for a corneal transplant procedure may potentially be deferred.

The specific subset of keratoconic patients proposed to be treated with Intacs Corneal 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;
- who have a corneal thickness of 450 microns or greater at the proposed incision site; and
- who have corneal transplantation as the only remaining option to improve their functional vision.

### V. Contraindications for Use

Intacs Corneal Implants for keratoconus are contraindicated:

- in patients who have abnormally thin corneas or who have a corneal thickness of 449 microns or less at the proposed incision site;
- in patients with collagen vascular, autoimmune or immunodeficiency diseases;
- in pregnant or nursing women;
- in the presence of ocular conditions, such as recurrent corneal erosion syndrome or corneal dystrophy, that may predispose the patient to future complications; or
- in patients who are taking one or more of the following medications: isotretinoin (Accutane<sup>1</sup>); amiodarone hydrochloride (Cordarone<sup>2</sup>).
- in patients who have Fuchs' dystrophy or have suspect endothelial cell deficiency are not candidates for Intacs Corneal Implants.

### VI. Warnings

- Some patients with large dilated pupil diameters ( $\geq 7.0$  mm) are predisposed to low light visual symptoms postoperatively and should be appropriately advised.
- The long-term effect of Intacs Corneal Implants on endothelial cell density has not been established. Central endothelial cell density loss for myopic eyes implanted with 0.250 mm, 0.300 mm and 0.350 mm Intacs Corneal Implants was  $1.4\% \pm 3.9\%$

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<sup>1</sup> Accutane® is a registered trademark of Hoffman-LaRoche Inc.

<sup>2</sup> Cordarone® is a registered trademark of Sanofi.



(n=105) during the first postoperative year, 1.6% ± 4.1% (n=95) during the second postoperative year, 1.7% ± 4.4% (n=70) during the third postoperative year, 1.3% ± 4.7% (n=19) during the fourth year and 1.3% ± 6.4% (n=28) during the fifth postoperative year.

- Patients who have the 0.400 mm or 0.450 mm Intacs Corneal Implants should be monitored on a more frequent basis in order to detect peripheral endothelial cell loss and/or related corneal edema. These patients should be advised about the potential risk of developing peripheral endothelial cell loss and/or corneal edema, possibly requiring corneal transplantation, with potential unforeseen impact of peripheral endothelial cell loss on the success of future PKP.

**Annualized Percent Change in Endothelial Cell Density, 0.400 mm and 0.450 mm Intacs Corneal Implants<sup>1</sup>**

<b>Region</b>	<b>Central</b>	<b>6:00 Peripheral</b>	<b>10:00 Peripheral</b>
<b>N</b>	17	12	15
<b>Mean ± SD (%/year)</b>	-1.63% ± 0.79%	-2.22% ± 0.86%	-1.85% ± 0.56%
<b>95% Confidence Interval (%/year)</b>	-1.99% : -1.26%	-2.71% : -1.73%	-2.13% : -1.56%

<sup>1</sup> Data from point-in-time assessment performed on some of the 0.400 mm and 0.450 mm Intacs subjects who were originally implanted as part of the Intacs Phase III Cohort B myopia study. Endothelial cell density was measured for subjects at 9-11 years following their Intacs placement in order to evaluate the long-term endothelial cell loss associated with these subjects.

- Under mesopic conditions, patients may experience some loss in contrast sensitivity at low spatial frequencies (1.5 cycles per degree).

**VII. Precautions**

- Use of the Vacuum Centering Guide subjects the eye to increased intraocular pressure. **Continuous application of vacuum should be limited to 3 minutes or less and to no more than 750 mBar.** If it is necessary to reapply the Vacuum Centering Guide, wait 5 minutes to allow normal vascular perfusion of the eye to occur before re-establishing suction.
- Intacs Corneal Implants are not recommended in patients with systemic diseases likely to affect wound healing, such as insulin-dependent diabetes or severe atopic disease.

- It is critical that the Intacs Corneal Implants are properly oriented during the Intacs surgical procedure so that the Intacs segments are not left beneath the incision area in order to avoid potential wound healing issues. The alignment of the implanted Intacs segments is to be verified against the placement marks made on the cornea at the beginning of the Intacs procedure. If the Intacs segments are not properly oriented at the time of surgery or if they migrate beneath the incision post-operatively, the segments should be immediately re-positioned.
- Some patients (7/334 or 2.1%) who received the 0.400 mm and 0.450 mm Intacs Corneal Implants for the treatment of myopia experienced a temporary decrease of two or more lines of BSCVA during the U.S. myopia trial. The BSCVA was 20/20 or better upon resolution for all patients and the BSVCA for all patients returned to within 2-8 letters of their preoperative BSCVA.
- Patients who received the 0.350 mm, 0.400 mm or 0.450 mm Intacs Corneal Implants for the treatment of myopia experienced a reduced outcome as compared to patients who received other Intacs Corneal Implants thicknesses during the U.S. myopia trial. Additionally, there was an increased removal rate for the 0.350 mm, 0.400 mm and 0.450 mm patients due to dissatisfaction with their outcomes. The following table provides a summary of the key safety and efficacy outcomes from the U.S. myopia trial that would be applicable for the Intacs Corneal Implants keratoconus indication.

Intacs Corneal Implants Performance Summary – Key Safety and Efficacy Variables

Variables	0.210 mm		0.250 mm		0.300 mm		0.350 mm		0.400 mm		0.450 mm	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
Predictability CRSE ± 1.00 D	91/91	100%	127/134	94.8%	127/138	92.0%	114/136	83.8%	71/84	84.5%	69/85	81.2%
MRSE Stability ± 1.00 D	99/99	100%	144/144	100%	138/145	95.2%	139/146	95.2%	103/108	95.4%	96/103	93.2%
Loss of ≥10 Letters or ≥2 Lines BSCVA	0/146	0%	1/194	0.5%	1/212	0.5%	0/196	0%	2/165	1.2%	5/169	3.0%
BSCVA worse than 20/40	0/146	0%	0/194	0%	0/212	0%	0/196	0%	0/165	0%	0/169	0%
Induced Cylinder >2.00 D	0/146	0%	0/194	0%	0/212	0%	0/196	0%	0/165	0%	0/169	0%
Safety-Related Removals	0/146	0%	0/148	0%	0/150	0%	0/151	0%	1/165	0.6%	3/169	1.8%
Dissatisfaction-Related Removals	4/146	2.7%	4/148	2.7%	10/150	6.7%	17/151	11.3%	24/165	14.5%	34/169	20.1%

- It is recommended that the corneal thickness at the 6 mm to 9 mm optical zone be at least 350 microns to allow for an adequate amount of corneal tissue above the Intacs Corneal Implants.
- Intacs Corneal Implants are not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster*.
- Intacs Corneal Implants are not recommended in patients who are taking sumatriptan (Imitrex<sup>3</sup>) for migraine headaches.
- A temporary decrease in central corneal sensation has been noted in some patients. No clinical consequences were demonstrated in the U.S. myopia clinical trials.
- The safety and effectiveness of alternative refractive procedures or a corneal transplant procedure following the removal of Intacs Corneal Implants have not been established.
- Intacs Corneal Implants are intended for single use only; do not reuse or resterilize. In the event that different thicknesses of Intacs Corneal Implants are used during a procedure, please discard the unused segments.
- The safety of Intacs Corneal Implants for keratoconus have **NOT** been established:
  - in patients with progressive myopia or astigmatism, nuclear sclerosis or other crystalline lens opacity, corneal abnormality, or previous corneal surgery or trauma;
  - for patients under 21 years of age;
  - for corneas with a central thickness less than 480 microns, or peripheral thickness less than 570 microns; or
  - in long-term use.

### VIII. Clinical Findings/Adverse Events

There were no significant operative or postoperative clinical findings observed during the European keratoconus clinical study or noted from published peer-reviewed articles where Intacs segments were used in the treatment of keratoconus. The European keratoconus study was conducted to support CE marking of the Intacs Corneal Implants (also referred to as INTACS prescription inserts) for the treatment of keratoconus. Ocular observations at all postoperative exams for the European keratoconus study were minor and were not considered to be clinically significant by the investigators. There were no reports of any safety-related findings including ocular infection, extrusion of the implant or stromal thinning over the implant at any postoperative exam. The most commonly reported postoperative observations were intrastromal deposits on or near the Intacs segments and haze in the incision area. The

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<sup>3</sup> Imitrex® is a registered trademark of Glaxo Group Ltd.

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peer-reviewed literature on the use of Intacs segments for keratoconus indicates similar clinical findings of: lamellar channel deposits, incisional haze, visual symptoms, superficial placement, non-infectious lamellar keratitis, neovascularization and conjunctival injection/foreign body sensation associated with a patient having gotten sand in his eye. There do not appear to be any new clinical findings associated with Intacs segments used to treat patients with keratoconus. The observations reported for Intacs segments for keratoconus are similar to those reported for the myopia indication.

A summary of the adverse events that were reported for the Intacs prescription inserts myopia indication is provided in this section for information only. Adverse events reported during the clinical trials for myopia have been rare and were primarily associated with the surgical technique. Reported adverse events include infiltrative keratitis and a small perforation of the anterior chamber related to an incorrect knife setting. Other reported clinical findings include: corneal staining, epithelial cysts, induced astigmatism, a temporary reduction in central corneal sensation, elevated IOP, epithelial plug formation, neovascularization (pannus), conjunctival discharge, incision gape, aqueous flare, corneal infiltrate, anterior uveitis/iritis and stromal haze. The most prevalent ocular observations during the myopia clinical trials were lamellar tunnel haze, conjunctival injection and lamellar tunnel deposits.

Patients undergoing the Intacs surgical procedure, for both the keratoconus and myopia indications, have reported certain visual side effects. The most prevalent of these side effects include: glare, halos, fluctuating vision, double images, difficulty with night vision and decreased quality of vision. The clinical results for both keratoconus and myopia indicate that the incidence of these visual side effects tends to decrease over time, unless the patient has a large pupil ( $\geq 7.0$  mm in diameter), which may predispose the patient to having visual symptoms.

## **IX. Patient Instructions and Identification Card**

### **Patient Instructions**

- If patients wear contact lenses, they should be instructed to stop wearing them 2-3 weeks before their preoperative examination in order to obtain an accurate refraction.
- If patients wear eye makeup, they should be instructed to stop 2-3 days before the Intacs surgical procedure and to avoid using eye makeup for the first 7 days after the procedure to reduce the risk of infection.
- Patients should be instructed on the importance of using all medications as directed.
- Patients should be instructed to use the nighttime eye shield as directed to avoid injuring their surgery eye during sleep.
- Patients should be instructed to not rub their surgery eye for the first six months after the procedure. This is important to promote proper healing of the incision.

- Patients should be instructed to avoid getting tap water in their surgery eye for the first few weeks following the procedure.
- Patients should be advised to avoid swimming in pools for the first week after the procedure. Lake and ocean swimming should be avoided for the first month. Protective goggles should be worn at all times when swimming.
- Patients should be instructed to contact you immediately if they experience any pain, discomfort, have a sensation that something is in their eye or experience a change in their vision after the initial postoperative recovery period (typically 7 days).
- Patients should be instructed to report any unusual symptoms that could be associated with prolonged topical steroid use, if applicable.

### **Identification Card**

A Patient Identification Card is enclosed in the Intacs Corneal Implants product package. Please complete this card and provide it to the patient at the time of surgery. The Patient Identification Card is intended as an implant card to be kept in the patient's wallet.

## **X. Medical Device Reporting**

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to the Intacs Corneal Implants for keratoconus and that were not previously expected in nature, severity or incidence rate should be reported to Addition Technology immediately. This information is being requested from all surgeons in order to document potential long-term effects of placement of Intacs segments.

Physicians must report these events in order to aid in identifying any emerging or potential problems with Intacs Corneal Implants. Use the following toll-free number when reporting adverse events or potentially sight-threatening complications involving Intacs Corneal Implants:

1-877-888-5372






## **XI. Conformance to Standards**

Intacs Corneal Implants have been designed, manufactured and distributed in conformance with requirements of the FDA Quality System Regulation (QSR), ISO 13485:2003 and other relevant ISO standards, and the Medical Device Directive (MDD) 93/42/EEC.

## **XII. How Supplied**

Intacs Corneal Implants for keratoconus are supplied sterile and are nonpyrogenic. Intacs Corneal Implants are intended for single use only; do not reuse or resterilize. In the event that one segment from a package is not used, please discard the unused segment; **do not resterilize or attempt to use it at a later date**. In the event that the packaging for the Intacs Corneal Implants is damaged, do not use the product or attempt to resterilize. Contact Addition Technology regarding any products that are observed to be damaged during shipment. Properly dispose of all packaging materials and recycle when possible.

**XIII. Symbols and Their Explanations**

	<b>REF</b>				
“Attention, See Instructions for Use”	“Model Number or Catalogue Number”	“Lot Number”	“Method of Sterilization Using Ethylene Oxide”	“Do Not Reuse”	“Use By”

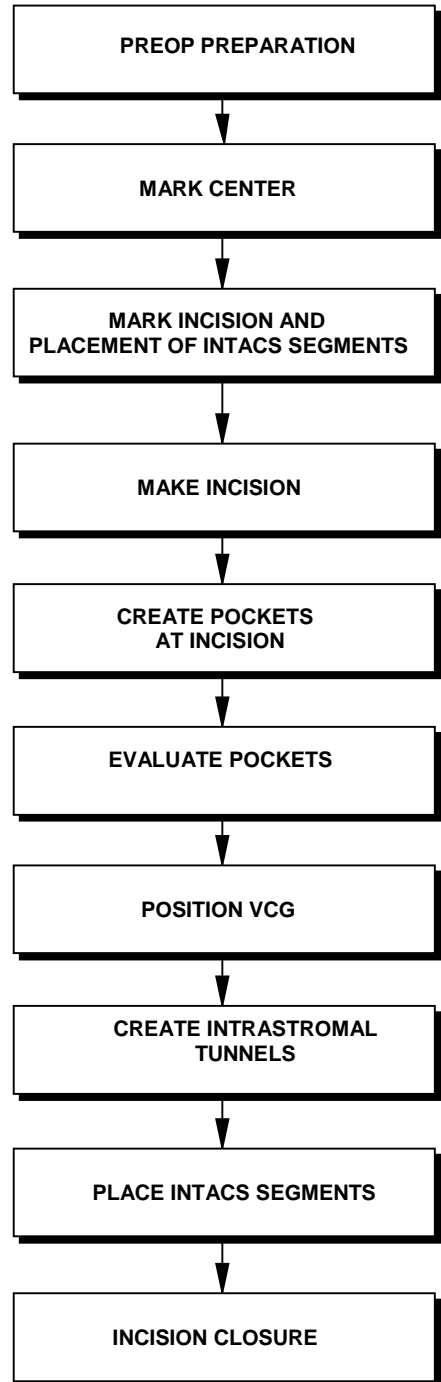
**XIV. Directions For Use**

Refer to Figure 1 for a flow chart of the Intacs surgical procedure for keratoconus. The Intacs<sup>®</sup> Surgeon Training Manual for the Treatment of Keratoconus contains detailed information regarding the surgical procedure, recommended equipment, medications and patient management.

**Figure 1: Intacs Corneal Implants Surgical Procedure Flow Chart (10-Step Prolate System)**

**Instruments/Materials**

- Anesthesia Ring (for use with topical anesthesia)
- Inspection Gauge
- Povidone-Iodine 2.5% and 5% Solution
- Lid Speculum
  
- Sterile Marking Pen
- 11 mm Zone Marker
- Sinsky Hook
  
- Sterile Marking Pen
- Procedure Marker
  
- Calibrated Diamond Knife with 15° angled blade (or rectangular blade of 1 mm or less)
  
- Pocketing Hook
  
- Symmetric Glide
  
- Anesthesia Ring (Remove prior to placing VCG)
- Topical Anesthetic
- Vacuum Centering Guide (VCG)
- Procedure Marker
  
- Vacuum Centering Guide (VCG)
- Symmetric Glide
- Corneal Separators (CW/CCW)
  
- Intacs Forceps
- Sinsky Hook
- Intacs Carrier
  
- Ophthalmic Suture (11-0 or 10-0; 11-0 recommended)



**Key Points**

- Iodine preparation of eye
- Avoid excessive manipulation or irritation of the conjunctiva
- Use lint-free drapes & talc-free gloves
- Mark the geometric center of the cornea
- Reference off the geometric center mark
- Incision mark is placed at the axis of positive cylinder
- Verify that the placement marks are at least 1 mm from the limbus
  
- Cut entire length of incision mark
- Remove loose epithelium from incision area
- Irrigate incision area
  
- From the base of the incision, create a corneal pocket on each side of the incision using the Pocketing Hook
- Pockets should be at the same depth across the full width of incision, within the same stromal plane and slightly longer than the Symmetric Glide
  
- Estimate pocket depth
- Create deeper pockets, if necessary
  
- Locate VCG & Procedure Marker on center mark
- Apply vacuum at 400-500 mBar
- Confirm proper placement
- Increase vacuum to 600-667 mBar
  
- Insert Symmetric Glide into the first pocket
- Rotate Corneal Separator blade tip under Symmetric Glide
- Rotate Corneal Separator to create tunnel
- Create intrastromal tunnel on the second side
- Release vacuum, remove VCG
  
- Irrigate incision area
- Insert one Intacs segment into each intrastromal tunnel
- One Intacs segment is placed inferiorly and the other is placed superiorly
- Align the outer edge of each segment under the appropriate placement mark
  
- Approximate incision edges to ensure proper healing
- Place one or two interrupted sutures, evenly spaced. Suture depth should be to the level of the stromal pocket
- Suture knots should be buried

**Warnings/Precautions**

- Completely isolate eyelashes
- Avoid overtightening the lid speculum
- Frequently irrigate the cornea with balanced saline solution during the operative procedure
- Chemosis may result if local anesthesia used
- Avoid contacting the Intacs segments & instruments with the lids, lid margins, lashes & lacrimal fluid
- Visually inspect instruments prior to use
- Inspect Corneal Separators with Inspection Gauge
- Pilocarpine to constrict pupil is not recommended
  
- Set diamond knife to 68% of pachometry reading at the incision site
- Verify diamond knife setting
- Stay 1 mm away from the limbus
  
- Create pockets at the full depth of the incision to avoid shallow implant depth
  
- Position vacuum port temporally
- Limit continuous VCG time to 3 minutes or less and applied vacuum to 750 mBar
  
- Stop creating the tunnel if excessive resistance or “tissue wave” is encountered, consider creating a deeper pocket and tunnel
- Stop the procedure in the event of a posterior chamber perforation or anterior corneal surface perforation
  
- Visually inspect Intacs segments prior to insertion
- Avoid contact of the Intacs segments with iodine and/or epithelial surface
  
- Reposition the Intacs segments if they are not properly aligned
  
- Avoid epithelial ingrowth into stroma
- Tension across the sutures should be evenly applied
- Avoid overtightening sutures
- Incision edges must be apposed at end of procedure



**XV. Return Goods Policy**

For information on returning any damaged product, contact your local representative or call Addition Technology at 1-877-888-5372 for return authorization and full policy information. All products returned to Addition Technology must be accompanied by a Return Goods Authorization Number.

**CAUTION:** U.S. Law restricts this device to sale by or on the order of a physician.

The device, the surgical instruments and the method of use may be protected by one or more U.S. Patent Numbers: U.S. 5,824,086, U.S. 5,403,355, U.S. 5,843,105, U.S. 5,846,256 and U.S. 6,447,528.

**WARRANTY AND LIMITATION OF LIABILITY**

Addition Technology warrants that the product when delivered is free from defect in materials and workmanship and conforms to the manufacturer's then-current version of its published specifications. This warranty applies for the period of time up to and including the expiration date for the product. At its option, Addition Technology will replace or provide a refund for any product manufactured by it and found to be defective, so long as the product is returned to Addition Technology according to the return goods policy. Addition Technology shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of, or inability to use, its product.

**THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

Addition Technology neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product other than as set forth in writing herein.



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**About CorneaGen, Inc.**

CorneaGen is a mission-driven company committed to transforming how corneal surgeons treat and care for the cornea. Based in Seattle, the company is innovating the next generation of cornea care, from new medical devices and biologics to therapeutics and interventions. CorneaGen supports corneal surgeons and their patients with a spectrum of services, including the latest innovative products, delivery of the highest quality tissue, surgeon education, and advocacy for patient access and reimbursement policies.

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**About Addition Technology, Inc.**

Addition Technology, a vision care company, was founded in 2001. Addition Technology purchased the INTACS technology, which is a new approach to treating vision problems. The INTACS technology is an additive platform that surgically reshapes the cornea by adding materials rather than cutting or permanently removing tissue like other refractive surgery techniques. Addition Technology is also developing potential applications of INTACS prescription inserts for the treatment of hyperopia and astigmatism. It is estimated that over 50% of the world's population experience vision problems.

Located in Lombard, Illinois, Addition Technology works closely with a worldwide team of ophthalmic surgeons and scientists who are leaders in the fields of keratoconus and vision correction.

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