

## **Intacs® SK Corneal Implants for Keratoconus Instructions for Use**

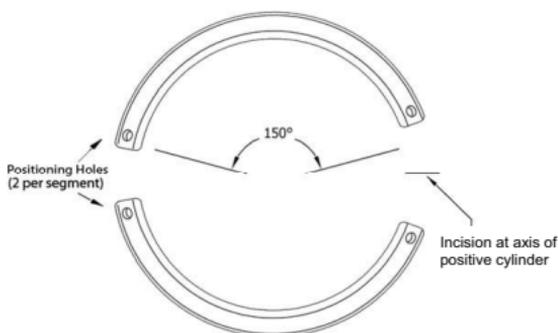
### **General Warnings**

- **RESTRICTED DEVICE:** U.S. Law restricts this device to sale, distribution and use by or on the order of a physician.
- Specific training is required before a physician is qualified to perform the Intacs SK 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 the Treatment of Keratoconus, prior to performing the procedure.
- Performance of the Intacs SK Corneal Implants procedure, other than as specified in this booklet and the Intacs® Surgeon Training Manual for the Treatment of Keratoconus, may result in an undesirable outcome.

## Description of the Device

Intacs<sup>®</sup> SK Corneal Implants, are an ophthalmic medical device designed for the reduction or elimination of myopia and astigmatism in patients with keratoconus 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. The Intacs SK segments are designed to be placed slightly outside of the central optical zone of the cornea, at approximately two-thirds depth, and are surgically inserted through a small radial incision in the corneal stroma. The Intacs SK product has been designed to allow removal or replacement.

The Intacs SK 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 currently available in seven thicknesses: 0.210 mm, 0.250 mm, 0.300 mm, 0.350 mm, 0.400 mm, 0.450 mm and .500 mm. In order to reduce the myopia and the irregular astigmatism induced by keratoconus, two Intacs SK segments ranging from 0.210 mm to 0.500 mm may be implanted depending on the orientation of the cone and the amount of myopia and astigmatism to be reduced. The product is designed with a fixed outer diameter and width. Intacs SK Corneal Implants have a positioning hole located at each end of the segment to aid in surgical manipulation. The Intacs SK segments are designed with rounded edges to potentially reduce the incidence of visual symptoms since the SK segments are placed closer to the patient's central optical zone than the standard Intacs segments. Four SK Surgical Instruments (SK Procedure Marker, SK Corneal Separator-Clockwise, SK Corneal Separator-Counterclockwise and SK Inspection Gauge) have also been developed to accommodate the placement position in the cornea.



**Diagram of Intacs SK Corneal Implants**

## Treatment Nomograms

Because each keratoconic patient's eyes and disease state are unique, determination of the specific Intacs SK product placement and the thickness of the Intacs SK segments to be implanted will vary from patient to patient. The determination of which thicknesses of the Intacs SK segments to implant is dependent upon a number of variables with the most significant being the patient's manifest refraction, preoperative corneal topography,

keratometry readings, the location of the cone (in posterior view) and the type of astigmatism.

### Recommended Intacs SK Corneal Implants Treatment Nomograms

The following treatment nomograms have been developed for implanting Intacs SK Corneal Implants into patients with keratoconus.

It is recommended that two symmetric segments be implanted at the periphery of the patient's 6.0 mm optical zone, in accordance with the guidelines provided below:

SYMMETRIC		
Spherical Power (Plus Cylinder Notation)	Inferior Intacs SK	Superior Intacs SK
Plano to -0.75D	0.210 mm	0.210 mm
-1.00 D to -1.75 D	0.250 mm	0.250 mm
-2.00 D to -3.75 D	0.300 mm	0.300 mm
-4.00 D to -5.75 D	0.350 mm	0.350 mm
-6.00 D to -7.75 D	0.400 mm	0.400 mm
-8.00 D to -9.75D	0.450 mm	0.450 mm
-10.00 D and higher*	0.500 mm	0.500 mm

- 0.500 mm Intacs can be used if the 6mm peripheral Pachymetry is over 500 $\mu$ . Otherwise, use 0.450 mm Intacs.

It is recommended that asymmetric segments be implanted at the periphery of the patient's 6.0 mm optical zone, in accordance with the guidelines provided below:

ASYMMETRIC		
Cylinder Power (Plus Cylinder Notation)	Inferior Intacs SK	Superior Intacs SK
2.00 to 3.00	0.350 mm	0.210 mm
3.00 to 4.00	0.400 mm	0.210 mm
4.00 and higher	0.450 mm	0.210 mm

### Surgeon Training Manual

The Intacs<sup>®</sup> Surgeon Training Manual for the Treatment of Keratoconus contains detailed information regarding the treatment nomograms, the surgical procedure, equipment, medications and management for keratoconus patients. Please refer to the Surgeon Training Manual for any detailed information not contained in this document or the various Intacs Surgical Instruments Instructions for Handling and Use.

### Indications for Use

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

The specific subset of keratoconus patients proposed to be treated with Intacs SK Corneal Implants are those patients:

- who have keratometric readings of 46 D or greater;

- who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision with their contact lenses or spectacles;
- who have clear central corneas;
- who have, at the proposed incision site, a minimum corneal thickness of 450 $\mu$  or, for 0.500 mm thickness segments, a minimum corneal thickness of 500 $\mu$ ; and
- who have corneal transplantation as the only remaining option to improve their functional vision.

### Contraindications for Use

Intacs SK Corneal Implants for keratoconus are contraindicated:

- 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 (Cordarone<sup>2</sup>); sumatriptan (Imitrex<sup>3</sup>).

### 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 SK Corneal Implants on endothelial cell density has not been established. Additional long-term data have been collected in the Intacs U.S. myopia clinical trials.
- Under mesopic conditions, patients may experience some loss in contrast sensitivity at low spatial frequencies (1.5 cycles per degree).

### 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 reestablishing suction.
- Intacs SK Corneal Implants are not recommended in patients with systemic diseases likely to affect wound healing, such as insulin-dependent diabetes or severe atopic disease.
- Intacs SK Corneal Implants are not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster*.
- A temporary decrease in central corneal sensation has been noted in some patients. No clinical consequences were demonstrated in the Intacs U.S. myopia clinical trials.

<sup>1</sup> Accutane<sup>®</sup> is a registered trademark of Roche Pharmaceuticals.

<sup>2</sup> Cordarone<sup>®</sup> is a registered trademark of Wyeth-Ayerst Laboratories.

<sup>3</sup> Imitrex<sup>®</sup> is a registered trademark of Glaxo-Wellcome, Inc.

- The safety and effectiveness of alternative refractive procedures following the removal of Intacs SK Corneal Implants have not been established.
- Intacs SK Corneal Implants are intended for single use only; do not reuse or resterilize.
- Some patients may experience visual symptoms due to the placement of the Intacs SK Corneal Implants in close proximity to the central optical zone.
- The safety and effectiveness of Intacs SK Corneal Implants 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 that are less than 450 $\mu$  (See indications for use) thick at the proposed incision site, 500 $\mu$  when inserting .500 thickness; or
  - in long-term use.

### Preoperative Anesthesia

**Precaution: Chemosis may result if local anesthesia is used. If significant chemosis occurs, it is recommended that the surgical procedure be rescheduled.**

Either oral or intravenous conscious sedation with topical or local anesthesia is recommended for this procedure, based on the individual preferences of the surgeon and the patient. This procedure can also be performed under general anesthesia.

### Preoperative Preparation

**Note: Avoid excessive manipulation or irritation of the patient's conjunctiva during the preoperative preparation or chemosis may result.**

1. Povidone-iodine scrubs and/or paint should be used for preparation of the operative field. In the event of patient allergy to povidone-iodine, alternate scrub solutions may be used.
2. Apply povidone-iodine 2.5% solution to the cul-de-sac to minimize the introduction of microorganisms into the incision or the stromal tunnel. Leave in place for two minutes and thoroughly flush with balanced saline solution.
3. Five to ten minutes prior to surgery, paint eyelid margins with a 5% povidone-iodine solution. Do not dilute! Allow to air dry and remain on lid margins throughout surgery.
4. Standard ophthalmic draping procedure should be followed. **ISOLATE THE EYELASHES FROM THE SURGICAL FIELD.**

The Intacs surgery should be performed in a lint-free environment; gauze and other materials with cotton fibers should not be used. The surgeon and scrub nurse should wear talc-free gloves.

### Surgical Procedure

**Note: Refer to Figure 1 for a flow chart of the Intacs SK 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. In addition, please refer to “Intacs® SK Surgical Instruments Instructions for Handling and Use”, “Intacs® Surgical Instruments Instructions for Handling and Use,” and “Intacs® Vacuum System Instructions for Handling and Use.”**

### **Removal of Intacs SK Segments From the Carrier Package**

The Intacs SK segments are packaged inside a plastic carrier designed to securely hold and protect the segments prior to implantation into the eye. To facilitate movement of the product into the sterile field, the plastic carrier is sealed inside a dual sterile barrier system consisting of inner and outer sealed plastic trays.

To open the outer tray, grasp the tray lid by the indicated corner and gently peel away the lid. Using standard sterile technique, transfer the inner tray (containing the plastic carrier) into the sterile field. Once in the sterile field, grasp the tray lid by the indicated corner, gently peel away the lid and remove the plastic carrier.

Note that each Intacs SK segment contains a positioning hole located near each end of the segment. The recommended technique for opening and removal of the Intacs segments from the carrier is provided below:

- To remove the segment from the Intacs carrier, stabilize the carrier on a flat stable surface with the rounded end etched with the logo facing up and pointing away from you.
- Gradually slide the cover of the carrier back, using your thumb, until the first Intacs segment is exposed and the cover snaps into the first position.
- Without breaking the sterile field, add 1-2 drops of a sterile, broad-spectrum antibiotic solution to the surface of the Intacs segment in the “well” of the carrier. There are several benefits of adding the antibiotic drops to the surface of the Intacs segment. First, the addition of the antibiotic will help to eliminate any built up electrostatic charge thereby reducing the risk of the segments from “popping” or “jumping” (ejecting) out of the carrier. Secondly, the addition of the antibiotic provides a lubricant to the surface of the Intacs segment, which may provide improved ease of placement. Finally, the use of antibiotic on the surface of the Intacs segment provides an added level of comfort for the surgeon and patient as it may help to reduce the risk of infection postoperatively.
- Grasp the Intacs® Forceps so the prongs of the forceps point straight down. Lower the forceps over the carrier until the prongs contact the base of the cross-slot on each side of the segment. Gently grasp the segment at its mid-section (the inner and outer edges of the segment should nest in the slots of the forceps) and lift the segment out of the carrier.
- Without repositioning the segment in the forceps, insert the segment directly through the corneal incision and into the clockwise (CW) intrastromal tunnel.
- If it is necessary to reposition the segment within the forceps, do so by placing the segment back into the carrier, then regripping the segment with the forceps. **THE SEGMENT IS NOT TO BE PLACED DIRECTLY ONTO THE SURFACE OF THE CORNEA.**
- Once the segment is inserted approximately halfway into the intrastromal tunnel, reposition the forceps to complete insertion.
- Using the carrier opening technique described above, advance the carrier lid to the second position until it locks. Add 1-2 drops of the sterile, broad-spectrum antibiotic

solution to the second Intacs segment in the second “well” of the carrier. Remove the second segment from the carrier and place the segment into the counterclockwise (CCW) intrastromal tunnel.

- Remove any stromal debris from the incision area. Thoroughly irrigate the incision area with balanced salt solution.

Final segment position should be as indicated by the marks created by the SK Procedure Marker.

### **Postoperative Procedure**

An antibiotic-steroid combination (0.1% dexamethasone/0.3% tobramycin or equivalent) ointment or solution should be applied to the operative eye at the end of the procedure.

The operative eye should be protected overnight using an eye shield. The shield should be worn at night for a period of three to six weeks to prevent rubbing while the eye is healing.

### **Surgical Procedure Points to Consider**

- **The specially designed SK Surgical Instruments (SK Procedure Marker, SK Corneal Separators-CW/CCW and SK Inspection Gauge) must be used for the Intacs SK surgical procedure. The SK Surgical Instruments have been developed to accommodate the requirement for implanting the Intacs SK segments closer to the central optical zone. The remaining standard Intacs Surgical Instruments are to be used for completion of the Intacs SK surgical procedure.**
- **Use all Intacs Surgical Instruments according to the recommended surgical procedure. See the Intacs<sup>®</sup> Surgeon Training Manual for the Treatment of Keratoconus for detailed information on the surgical procedure. Handle all surgical instruments with care.**
- **All surgical instruments are supplied NONSTERILE and must be cleaned and sterilized prior to each use. Inspect all surgical instruments and Intacs Corneal Implants packaging for damage or any defects prior to use.**
- **The use of pilocarpine to constrict the patient’s pupil during the surgical procedure is not recommended because it can cause chemosis, which could lead to subsequent fixation problems with the Vacuum Centering Guide.**
- **To avoid neovascularization into the incision region, special care should be taken to ensure that the incision is kept approximately 1 mm away from the limbus.**
- **Immediately discontinue the operative procedure and remove any implanted segments in the event of an anterior chamber perforation.**
- **Verify that the diamond knife is set to 68% of the pachymetry reading at the incision site.**
- **Thoroughly irrigate the incision area after completing the incision and prior to inserting any instrument or the Intacs segments into the tunnel.**

- To avoid shallow stromal tunnels, create the pockets at the full depth of the incision and evaluate pocket depth.
- Monitor the tunnel dissection closely. If increasing resistance is felt, or if a corneal “tissue wave” is observed ahead of the dissector tip, the tunnel may be too shallow. Consider stopping the dissection and creating a deeper pocket and tunnel.
- To minimize dehydration of the corneal epithelium, frequently irrigate the cornea and avoid using excessive illumination during the operative procedure.
- The Intacs segments should not be placed on the surface of the cornea prior to insertion as this may result in epithelial cell adherence or the introduction of bacteria into the intrastromal tunnel. Additionally, the Intacs segments should not be allowed to come into contact with iodine prior to insertion into the intrastromal tunnel.
- To minimize the risk of corneal infection, the surgeon should avoid contacting the Intacs segments as well as any of the surgical instruments with the lid margins, the epithelial surface, the eyelashes, meibomian gland secretions or the lacrimal fluid that can accumulate during the surgery.
- Prior to closing the incision site, verify that each segment is properly placed with the positioning hole located near the incision site.
- To prevent epithelial cells from entering the incision, the anterior incision edges must be completely apposed at the conclusion of the procedure.
- Care should be taken to ensure that tension across the sutures is evenly applied; however, over tightening of the sutures should be avoided as this may induce astigmatism.

## **Patient Instructions, Identification Card and Reporting**

### **Patients 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 to reduce the risk of infection.
- 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 on the importance of using all medications as directed.
- Patients should be instructed to contact you immediately if they experience any pain, discomfort, feel 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 SK Corneal Implants product package. Please provide this card 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.

### **Clinical Incidents/Adverse Device Effects**

There were no significant operative or postoperative clinical findings observed during the European Keratoconus Clinical Study. This study was conducted to support CE marking of the Intacs Corneal Implants for the treatment of keratoconus. Ocular observations at all postoperative exams 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. These observations were also reported for the myopia indication of Intacs Corneal Implants.

A summary of the adverse events that were reported for the 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.

### **Medical Device Reporting/Adverse Device Effect Reporting**

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to Intacs SK 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 SK segments.

Physicians must report these events in order to aid in identifying any emerging or potential problems with Intacs SK segments. Any potential incident involving Intacs SK Corneal Implants for the treatment of keratoconus, Intacs SK surgical instruments or other Addition Technology products should be reported to Addition Technology immediately at one of the following numbers:

USA: 1-847-297-8419

Spain: +34 945 298256 / 945 298289

## Conformance to Standards

Intacs SK Corneal Implants have been designed, manufactured and distributed in conformance with requirements of the U.S. FDA Quality System Regulation (QSR), ISO 13485:2003 and other relevant ISO standards, the Medical Device Directive (MDD) 93/42/EEC and SOR/98-282 Medical Devices Regulations.

## How Supplied

Intacs SK Corneal Implants for keratoconus are supplied sterile and are nonpyrogenic. Intacs SK Corneal Implants are intended for single patient use only. Do not reuse, reprocess or re-sterilize. Risks for reuse include infection as well as other injuries that may require medical intervention. Reprocessing or re-sterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury. In the event that one segment from a package is not used, please discard this segment and do not re-sterilize or attempt to re-use it. In the event that the packaging for the Intacs SK Corneal Implants is damaged, do not use the product or attempt to re-sterilize. Contact Addition Technology regarding any products that are observed to be damaged during shipment. Properly dispose of all packaging materials and recycle when possible.

## Symbols and Their Explanations

					
"Attention, See Physician Booklet"	"Model Number"	"Lot Number"	"Method of Sterilization Using Ethylene Oxide"	"Do Not Reuse"	"Use By"

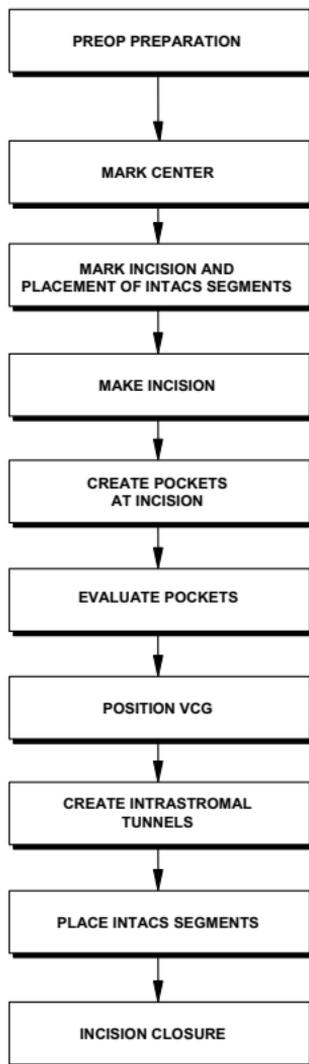
## Directions For Use

Refer to Figure 1 for a flow chart of the Intacs SK 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 SK Corneal Implants Surgical Procedure Flow Chart (10-Step Prolate System)**

**Instruments/Materials**

- Anesthesia Ring (for use with topical anesthesia)
- SK Inspection Gauge
- Povidone-Iodine 2.5% and 5% Solution
  
- Sterile Marking Pen
- 11 mm Zone Marker
- Sinsky Hooks
  
- Sterile Marking Pen
- SK Procedure Marker
  
- Calibrated Diamond Knife with 15° angled blade (or rectangular blade of 1 mm or less)
  
- Pocketing Hook
  
- Anesthesia Ring (Remove prior to VCG application)
- Vacuum Centering Guide (VCG)
- SK Procedure Marker
  
- Symmetric Glide
- SK Corneal Separators (CW/CCW)
  
- Intacs Forceps
- Sinsky Hooks
- 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 on the temporal side
- Verify that the placement marks are at least 2 mm from the limbus
- Irrigate incision area
- Cut entire length of incision mark
- Remove loose epithelium from incision area
- Keep entire cornea hydrated for the remainder of the procedure
- 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 as long as the Symmetric Glide
- Estimate pocket depth
- Create deeper pockets if necessary
- Locate VCG & SK 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 SK Corneal Separator blade tip under Symmetric Glide
- Rotate SK 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 noting minimum tissue thickness requirements for the 500mm segments.
- Verify diamond knife setting
- Stay 2 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
- Avoid contact of Intacs segments with iodine and/or epithelial surface
- 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

## **Return Goods Policy**

For information on returning any damaged instrument, 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, U.S. 6,447,528, U.S. 5,466,260, U.S. 6,508,837, U.S. 5,665,584, R.E. 35,947 and E.U. 2,001,407.

## **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.

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11276-032614

