

## **Intacs® Corneal Segments for Myopia Instructions for Use**

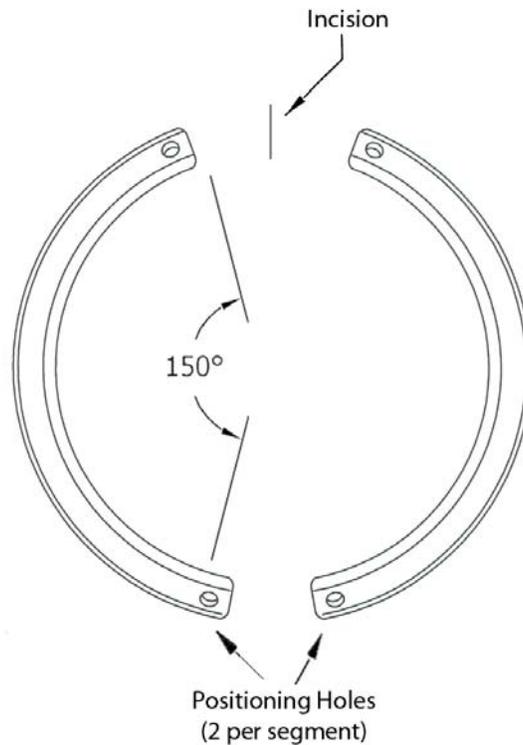
### **General Warnings**

- **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 Corneal Implants procedure. Physicians must successfully complete an Addition Technology-approved training program and read and understand this booklet and the Intacs® Surgeon Training Manual, 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, 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 Nearsightedness,” and to have you answer all their questions to their satisfaction before giving consent for the Intacs procedure.

### **Description of the Device**

Intacs<sup>®</sup> Corneal Implants are an ophthalmic medical device designed for the reduction or elimination of myopia from -0.50 to -5.00 diopters. When placed in the corneal stroma, outside of the patient's central optical zone, the product reshapes the anterior surface of the cornea. Intacs Corneal Implants 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 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 11 thicknesses: 0.210 mm, 0.230 mm, 0.250 mm, 0.275 mm, 0.300 mm, 0.325 mm, 0.350 mm, 0.375 mm, 0.400 mm, 0.425 mm and 0.450 mm. The degree of correction is determined by the thickness of the Intacs segments implanted. The product is designed with a fixed outer diameter and width. Intacs Corneal Implants have a positioning hole located at each end of the segment, to aid in surgical manipulation.



**Diagram of Intacs<sup>®</sup> Corneal Implants**

Based on the U.S. clinical trial results, a continuous but non-overlapping recommended prescribing range was initially created for the 0.250 mm, 0.300 mm, 0.350 mm, 0.400 mm and 0.450 mm Intacs Corneal Implants. The 0.210 mm and 0.230 mm thicknesses were developed to treat myopia of -1.0 diopter or less and the 0.275 mm, 0.325 mm, 0.375 mm and 0.425 mm thicknesses were developed to provide for smaller correction increments between the existing Intacs segment thicknesses. The recommended prescribing range for the 0.210 mm, 0.230 mm, 0.275 mm, 0.325 mm, 0.375 mm and 0.425 mm Intacs segments has been determined by using a performance model as a means to predict refractive change across a range of Intacs segment thicknesses. The Intacs segments performance model has been developed based upon clinical results for the initial thicknesses. These six additional Intacs segments thicknesses will provide for lower levels and smaller increments of predicted correction, compared to the currently approved range of correction provided by the Intacs segments, and as a result should allow for improved patient outcomes. The recommended prescribing range for all thicknesses is shown below.

<b>Intacs Thickness</b>	<b>Predicted Nominal Correction</b>	<b>Recommended Prescribing Range</b>
<b>0.210 mm</b>	<b>-0.75 D</b>	<b>-0.500 to -0.875 D</b>
<b>0.230 mm</b>	<b>-1.00 D</b>	<b>-1.000 to -1.125 D</b>
<b>0.250 mm</b>	<b>-1.30 D</b>	<b>-1.250 to -1.500 D</b>
<b>0.275 mm</b>	<b>-1.70 D</b>	<b>-1.625 to -1.750 D</b>
<b>0.300 mm</b>	<b>-2.00 D</b>	<b>-1.875 to -2.125 D</b>
<b>0.325 mm</b>	<b>-2.30 D</b>	<b>-2.250 to -2.500 D</b>
<b>0.350 mm</b>	<b>-2.70 D</b>	<b>-2.625 to -2.750 D</b>
<b>0.375 mm</b>	<b>-3.00 D</b>	<b>-2.875 to -3.125 D</b>
<b>0.400 mm</b>	<b>-3.40 D</b>	<b>-3.250 to -3.500 D</b>
<b>0.425 mm</b>	<b>-3.70 D</b>	<b>-3.625 to -3.875 D</b>
<b>0.450 mm</b>	<b>-4.10 D</b>	<b>-4.000 to -4.250 D</b>

### **Surgeon Training Manual**

The Intacs<sup>®</sup> Surgeon Training Manual contains detailed information regarding the surgical procedure, equipment, medications and patient management. 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<sup>®</sup> Corneal Implants are intended for the reduction or elimination of low to moderate myopia (-0.50 to -5.00 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; and
- where the astigmatic component is +1.00 diopter or less.

## Contraindications for Use

Intacs Corneal Implants are contraindicated:

- in patients with collagen vascular, 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; 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 Corneal Implants on endothelial cell density has not been established. Additional long-term data are being collected.
- 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 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 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 U.S. clinical trials.
- The safety and effectiveness of alternative refractive procedures 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.

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

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

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

- The safety and effectiveness of Intacs 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 steeper than 46 diopters or flatter than 40 diopters;
  - for corneas with a central thickness less than 480 microns or peripheral thickness less than 570 microns;
  - in patients with greater than -5.00 diopters of myopia or with astigmatism greater than +1.00 diopter; 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 surgical procedure. The Intacs® Surgeon Training Manual contains detailed information regarding the surgical procedure, recommended equipment, medications and patient management. In addition, please refer to “Intacs® Corneal Separators and Accessories 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 Corneal Implants From the Carrier Package**

Two Intacs 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 segment contains a single positioning hole near one end. When placed in the prepared intrastromal tunnel, the hole is to be positioned near the incision site. The carrier indicates, with an arrow, the direction of segment insertion to properly position the segment.

To remove the first segment from the carrier, hold the carrier in the palm of one hand with the rounded end etched with “Intacs” facing up and pointing away from you. Using your thumb, slowly slide the cover back until the first segment is exposed and the cover snaps into its first position. With the other hand, 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 prepared intrastromal tunnel on the left side of the incision as indicated by the package arrow. If it is necessary to reposition the segment within the forceps, do so by placing the segment back into the carrier, then regrasping 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.

To remove the second segment from the carrier, slowly slide the cover back until it completely exposes the second segment and locks open. Using the technique described above, remove the second segment from the carrier and insert the segment into the second intrastromal tunnel on the right side of the incision as indicated by the package arrow.

Final segment position should be as indicated by the marks created by the 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**

- **Use Intacs Surgical Instruments according to the recommended surgical procedure. See the Intacs<sup>®</sup> Surgeon Training Manual 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 the Intacs Corneal Implants packaging for damage or 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 pachometry reading at the incision site (no less than 450 $\mu$  of corneal tissue is required to be at the incision site).**
- **Thoroughly irrigate the incision area after completing the incision and prior to inserting any instrument or 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 Corneal Implants 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 at the top of the eye, near the incision site. If upon inspection, the positioning hole is found to be at the bottom of the eye (away from the incision site), remove the segment and repeat the insertion procedure to correct the positioning. Placement of the positioning holes at the bottom of the eye may compromise future access to the product for potential explantation or repositioning after the eye has healed.**
- **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, overtightening 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 Intacs surgical 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 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**

Adverse events reported during Intacs clinical trials have been rare and 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 clinical trials were lamellar tunnel haze, conjunctival injection and lamellar tunnel deposits.

Patients undergoing the Intacs surgical procedure 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 indicate that the incidence of these visual side effects may decrease over time, unless the patient has a large pupil ( $\geq 7.0$  mm in diameter).

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

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as related to Intacs Corneal Implants 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. Any potential incident involving Intacs Corneal Implants, Intacs 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

England: 44-14-62-89-32-54

## **Conformance to Standards**

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

## **How Supplied**

Intacs Corneal Implants are supplied sterile and are nonpyrogenic. The Intacs Corneal Implants are intended for single use only; do not reuse or resterilize. 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. Properly dispose of all packaging materials and recycle when possible.

### Symbols and Their Explanations

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

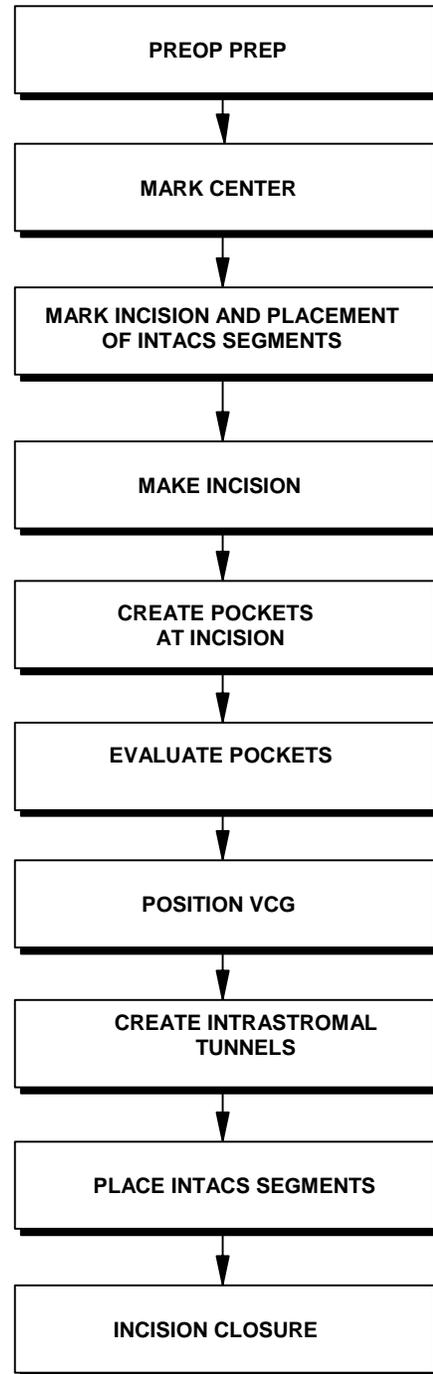
### Directions For Use

Refer to Figure 1 for a flow chart of the Intacs surgical procedure. The Intacs<sup>®</sup> Surgeon Training Manual 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
- Sinskey 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 VCG application.)
- Topical Anesthetic
- Vacuum Centering Guide (VCG)
- Procedure Marker
  
- Vacuum Centering Guide (VCG)
- Symmetric Glide
- Corneal Separators (CW/CCW)
  
- Intacs Forceps
- Sinskey 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 at 12:00
- 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
- Visually inspect the Intacs segments prior to insertion
  
- Irrigate incision area
- Insert one Intacs segment into each intrastromal tunnel
- 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
  
- Avoid contact of the 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 1-847-297-8419 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.

## **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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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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