

ADDITION TECHNOLOGY



**Professional Use  
Information Manual  
for Correction of Myopia and Astigmatism  
Associated with Keratoconus Using  
INTACS<sup>®</sup> Prescription Inserts  
  
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 prescription inserts. For additional information, refer to the INTACS 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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### 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 inserts procedure for treatment of keratoconus. Physicians must successfully complete an Addition Technology approved training program, read and understand this booklet, and the INTACS<sup>®</sup> Surgeon Training Manual for Keratoconus, prior to performing the procedure.
- Performance of the INTACS inserts 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<sup>®</sup> Prescription Inserts 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<sup>®</sup> prescription inserts 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 prescription inserts 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, however may vary depending on the astigmatic axis and the amount of keratoconus present in the specific eye to be treated. The INTACS inserts 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 prescription inserts 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 3 thicknesses: 0.250 mm, 0.300 mm and 0.350 mm. In order to reduce the myopia and the irregular astigmatism induced by keratoconus, two INTACS inserts ranging from 0.250 mm to 0.350 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 inserts have a positioning hole located in the superior end of each segment to aid in surgical manipulation.

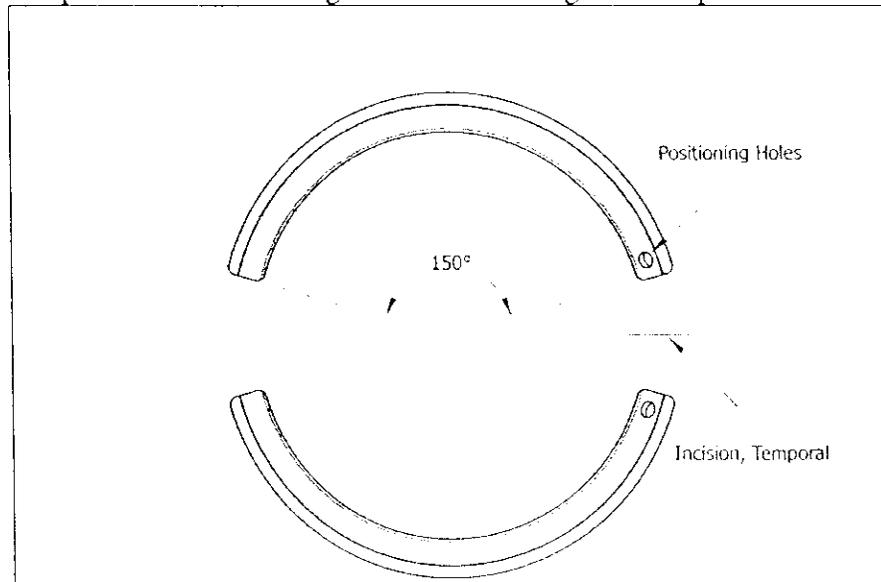


Diagram of INTACS prescription inserts

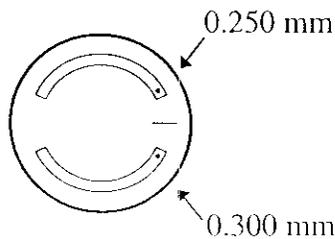
## II. Treatment Nomogram

The INTACS prescription inserts treatment nomograms for keratoconus are based on the use of the 0.250 mm, 0.300 mm, and 0.350 mm thickness INTACS inserts in physician-sponsored studies. Because each keratoconic patient's eyes and disease state are unique, determination of the specific INTACS product placement and the thickness of the INTACS inserts to be implanted will vary from patient to patient. The determination of which thicknesses of INTACS inserts to implant is dependent upon a number of variables; the most

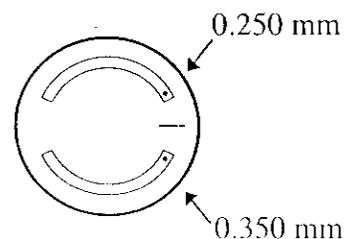
significant being the patient's preoperative manifest refraction spherical equivalent and the degree of asymmetric astigmatism.

- The surgical technique for keratoconus is similar to the standard INTACS 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. The incision depth should be at 68% of the corneal thickness measured at the peripheral location of the entry incision.
- The entry incision is placed in the same meridian as the axis of the positive cylinder in the manifest refraction, unless the meridian of topographic astigmatism is 90° away from the positive axis. In these rare cases, the incision is to be placed in the axis of topographic astigmatism (90° away from the refractive axis.)
  - Note: Subjects 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 subjects with irregular astigmatism.
- The nomogram for selecting INTACS segment thickness is to be based on the patient's manifest refraction spherical equivalent as follows:
  - For spherical equivalent  $\leq -3.00$  diopters (D), a combination of a 0.250 mm segment placed superiorly and 0.300 mm segment placed inferiorly is to be used (0.250 mm/0.300 mm);
  - For spherical equivalent  $> -3.00$  D, a combination of a 0.250 mm segment placed superiorly and a 0.350 mm segment placed inferiorly is to be used (0.250 mm/0.350 mm).
  - The rationale for this nomogram is that thicker segments will induce greater local flattening immediately central to the segment itself.

The product configuration recommended for the treatment of keratoconus is one thinner INTACS insert placed superiorly and one thicker INTACS insert placed inferiorly, with temporal incision placement (9:00 for OD and 3:00 for OS). The two representative configurations are illustrated below:



Preoperative Spherical Equivalent  $\leq -3.00$  D



Preoperative Spherical Equivalent  $> -3.00$  D

**Recommended INTACS Inserts Nomogram**

<b>Preoperative Spherical Equivalent <math>\leq</math>-3.00 D</b>	<b>Preoperative Spherical Equivalent <math>&gt;</math>-3.00 D</b>
0.250 mm/0.300 mm (Superior/Inferior placement)	0.250 mm/0.350 mm (Superior/Inferior placement)

**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<sup>®</sup> prescription inserts 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 can potentially be deferred.

The specific subset of keratoconus patients proposed to be treated with INTACS prescription inserts 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 prescription inserts 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>).

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

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

## 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 prescription inserts on endothelial cell density has not been established. Central endothelial cell density loss for myopic eyes implanted with INTACS inserts was  $1.4\% \pm 4.2\%$  (n=61) during the first postoperative year,  $1.8\% \pm 3.8\%$  (n=62) during the second postoperative year and  $1.8\% \pm 4.3\%$  (n=63) during the third postoperative year. Additional long-term data are being collected in the 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).

## 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.
- Patients who received 0.350 mm INTACS prescription inserts for the treatment of myopia experienced a reduced outcome as compared to patients who received other INTACS inserts thicknesses during the U.S. myopia trial. Additionally, there was an increased removal rate for the 0.350 mm patients due to dissatisfaction with their outcomes.
- INTACS prescription inserts are not recommended in patients with systemic diseases likely to affect wound healing, such as insulin-dependent diabetes or severe atopic disease.
- 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 inserts.
- INTACS prescription inserts are not recommended in patients with a history of ophthalmic *Herpes simplex* or *Herpes zoster*.
- INTACS prescription inserts 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 prescription inserts have not been established.

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

- The safety and effectiveness of alternative refractive procedures or a corneal transplant procedure following the removal of INTACS prescription inserts have not been established.
- INTACS prescription inserts are intended for single use only; do not reuse or resterilize. In the event that different thicknesses of INTACS prescription inserts are used during a procedure, please return the unused segments to Addition Technology.
- The safety of INTACS prescription inserts 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 inserts were used in the treatment of keratoconus. The European keratoconus study was conducted to support CE marking of the 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 inserts and haze in the incision area. The peer-reviewed literature on the use of INTACS inserts 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 inserts used to treat patients with keratoconus. The observations reported for INTACS inserts for keratoconus are similar to those reported for the myopia indication.

A summary of the adverse events that were reported for the INTACS 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 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 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 prescription inserts 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 INTACS prescription inserts 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 inserts.

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

1-877-888-5372

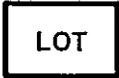
#### **XI. Conformance to Standards**

INTACS prescription inserts have been designed, manufactured and distributed in conformance with requirements of the FDA Quality System Regulations (QSR), ISO 9001:1994, ISO 13485:1996 and the Medical Device Directive (MDD) 93/42/EEC.

**XII. How Supplied**

INTACS prescription inserts for keratoconus are supplied sterile and are nonpyrogenic. INTACS inserts are intended for single use only; do not reuse or resterilize. In the event that one segment from a package is not used, please return this segment to Addition Technology and do not resterilize or attempt to reuse it. In the event that the packaging for INTACS inserts 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”

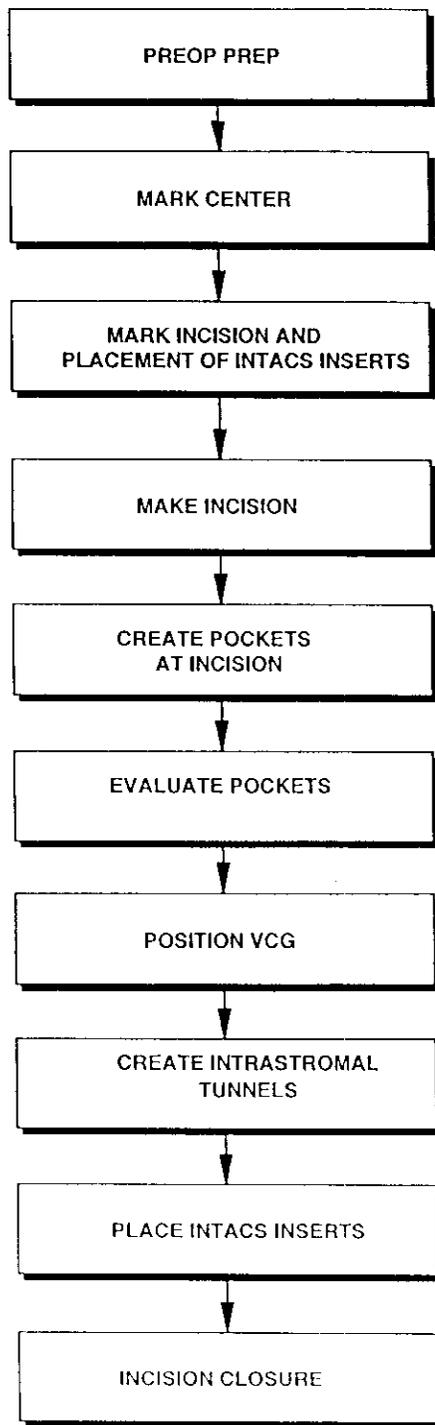
**XIV. Directions For Use**

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

Figure 1: INTACS Prescription Inserts 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
  
- Symmetric Glide
- Corneal Separators (CW/CCW)
- Vacuum Centering Guide (VCG)
  
- INTACS Forceps
- Sinsky Hook
- INTACS Inserts 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 9:00 (OD) and 3:00 (OS)
- 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 insert into each intrastromal tunnel with the positioning hole adjacent to the incision
- One INTACS insert is placed inferiorly and the other is placed superiorly
- Align the outer edge of each insert 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 inserts & 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 temporarily
- 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 inserts 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

**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 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 repair, 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 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 Sunnyvale, California, 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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ADDITION TECHNOLOGY



**Facts You Need to Know About  
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of Nearsightedness and Astigmatism Associated  
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**Patient Booklet**

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Please read this entire booklet. Discuss its contents with your doctor so that you have all of your questions answered to your satisfaction. Ask any questions you may have before you agree to the INTACS procedure.

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## GLOSSARY

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

**Antibiotic Medication:** a drug used to treat or prevent infection.

**Anti-inflammatory Medication:** a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

**Astigmatism:** a condition resulting in an uneven shape of the cornea. Light rays are focused at multiple points and at differing distances from the retina due to the uneven corneal shape. The multiple focal points result in blurred distance and/or near vision.

**Cataract:** an opacity or clouding of the lens inside the eye that can cause a loss of vision.

**Collagen Vascular Disease:** a condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

**Contraindications:** any special condition that results in the proposed treatment not being recommended.

**Cornea:** the clear front surface of the eye. Refractive surgery procedures reshape or flatten this surface to correct vision.

**Corneal Epithelium:** the top layer of the cornea that may become disrupted during refractive surgery. The epithelium typically heals after a few days.

**Corneal Haze:** a cloudiness of the cornea that may occur after a refractive procedure.

**Corneal Ulcer:** an infection of the cornea that may result in a loss of vision.

**Diopter (D):** a unit used to measure the amount of refractive error present from myopia, hyperopia, or astigmatism in an eye.

**Glaucoma:** a condition usually associated with high pressure in the eye. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

**Halos:** circular flares or rings of light that may appear around a headlight or other lighted object.

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**Herpes Simplex:** a type of infection caused by a virus that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body.

**Herpes Zoster:** a type of infection caused by a virus that can recur. Vesicles typically appear on only one side of the body.

**Hyperopia:** the cornea and lens focus light rays from near objects beyond the retina, causing images of near objects to appear blurry. Farsightedness is another term for hyperopia.

**Immunodeficiency Disease:** a condition that alters the body's ability to heal. An example is AIDS.

**Intraocular Pressure (IOP):** fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

**Keratoconus:** a condition that results in a progressive thinning of the cornea. As the cornea continues to thin, it typically becomes shaped like a cone, which distorts vision.

**Lens:** a structure inside the eye that helps to focus light onto the back of the eye.

**Myopia:** the cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

**Ocular Hypertension:** an increase in the pressure inside the eye.

**Refractive Error:** parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Examples of refractive errors are myopia (nearsightedness), astigmatism, or hyperopia (farsightedness).

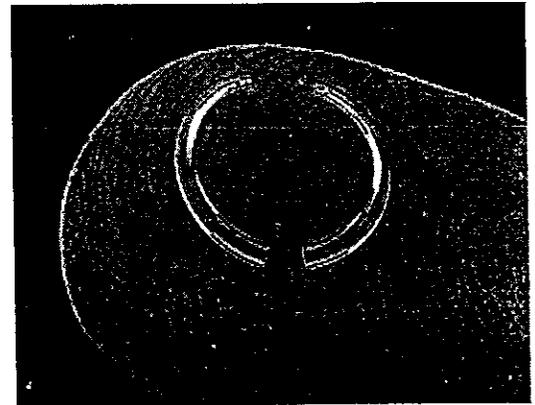
**Retina:** the back surface of the eye. The retina takes focused light and transfers the image to the brain.

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

## A. Introduction

Do you have keratoconus, also known as “KC,” and are you no longer able to achieve adequate vision with your contact lenses or glasses? Are your contact lenses so uncomfortable that you are unable to wear them for as long as you would like to? Have you been told by your doctor that the only remaining option to restore your vision is for you to undergo a corneal transplant procedure? The information in this booklet is provided to help you decide whether or not you want to undergo a procedure to improve your nearsightedness and astigmatism with INTACS® prescription inserts.

INTACS prescription inserts may provide an alternative to restore your vision and to possibly defer the need for a corneal transplant procedure. INTACS prescription inserts work by reshaping your cornea to a more normal shape. The goal, in most cases, for the INTACS procedure is to allow you to be successfully fitted with contact lenses or glasses again so that your vision can be restored.



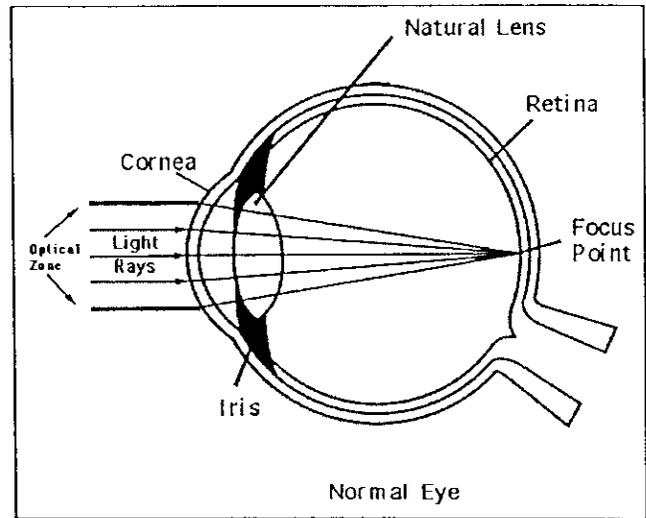
INTACS prescription inserts

INTACS prescription inserts are tiny plastic segments that are placed in your cornea (the clear front surface of your eye). They work by reshaping your cornea and thereby correcting its refraction (optical power) and may allow you to be comfortably fitted with contact lenses or glasses again to achieve optimal vision. INTACS prescription inserts are the same product as currently approved by the FDA for the reduction or elimination of mild myopia (nearsightedness).

Your doctor will place the INTACS prescription inserts in your cornea during an outpatient surgical procedure. The procedure for placing INTACS inserts does not involve the cutting or removal of tissue from the cornea's central optical zone—the part of the cornea that is most important for your vision. Your doctor can help you decide what is the best treatment for you.

**B. How the Eye Functions**

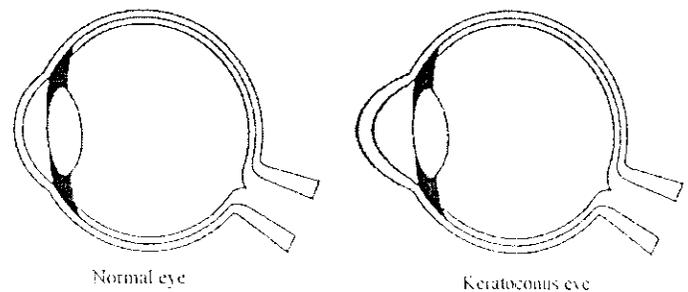
In order to understand how INTACS prescription inserts will reshape your cornea and help to correct your nearsightedness and astigmatism, it is important to understand how the eye functions. The cornea of the eye is composed of transparent tissue and is comparable in size to a contact lens. The cornea functions as a window through which light rays travel to the retina. The retina sends the “picture” of the viewed object to the brain where the object is then “seen.” In the normal eye with perfect vision, the light rays enter the eye and are focused precisely on the retina. In this situation, a clear image is sent to the brain.



The cornea provides about 75 percent of the eye’s focusing or refractive power. The natural lens inside the eye provides the remaining focusing power. The shape, or curvature, of the cornea determines how well you see and how “in focus” an image is when it reaches the retina. Nearly all of the light that reaches the retina must pass through the central area of the cornea or the “optical zone.” Because the optical zone is so crucial for clear vision, INTACS prescription inserts were designed to be placed at the outer edge of the cornea, away from the optical zone.

**C. What is Keratoconus?**

Keratoconus, pronounced as (KEHR-a-toh-kohn-nus), is a vision disorder that occurs when the normally round dome-shaped cornea progressively thins causing a cone-like bulge to develop. Examples of a normal-shaped eye and a domed-shaped keratoconus eye are shown here.



Since the cornea is responsible for refracting most of the light coming into the eye, abnormalities of the cornea can create an associated reduction in visual acuity. The abnormal shape of the keratoconic cornea prevents the light entering the eye from being properly focused on the retina for sharp, clear vision. The bulging or “cone-shape” protrusion is caused by the normal pressure of the eye pushing out on the thinned areas of the cornea. The changes in the cornea’s natural domed shape often lead to significant distortion and a reduction in vision sharpness.

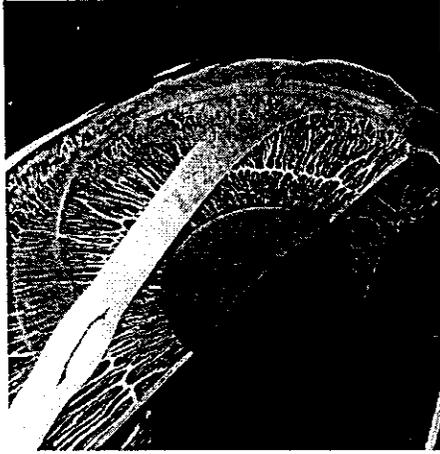
(visual acuity). This impairment in vision can severely affect a keratoconus patient's life by making even simple daily tasks, such as driving, watching television or reading a book, difficult to perform. The actual cause of keratoconus is not yet known, but there have been studies that suggest a genetic link to the disease. The disease typically affects both eyes, but they may not be affected at the same rate.

In the early stages of the disease, keratoconus causes slight blurring and distortion of vision along with an increased sensitivity to glare and light. These symptoms usually first appear during one's teen years to early twenties. Keratoconus may progress for another 10-20 years, with the rate of progression typically slowing during one's forties. As keratoconus progresses, vision often becomes more distorted. Glasses or soft contact lenses may be used to correct the mild nearsightedness and astigmatism that is created in the early stages of keratoconus. As the disease progresses and the cornea continues to thin and change shape, rigid gas permeable (RGP) lenses are often prescribed because glasses and soft contact lenses are no longer adequate to correct one's vision. The RGP lenses must be carefully fitted and frequent checkups and lens changes are often required to continue to achieve good vision. However, over time the cornea may become scarred, the contact lenses may no longer be comfortable to wear on a daily basis, and/or the contact lenses are no longer able to adequately correct vision. In severe cases of keratoconus, the last resort is to have a corneal transplant procedure, also known as a penetrating keratoplasty procedure (PKP), due to the development of corneal scarring, corneal thinning or the inability to wear contact lenses any longer. A corneal transplant procedure involves removing the patient's cornea and replacing it with healthy corneal tissue from a donor. Most patients will still need to wear glasses or contact lenses for clear vision following a corneal transplant.

When RGP lenses no longer are effective or have become uncomfortable to wear on a daily basis, a corneal transplant has been a keratoconus patient's only option to attempt to restore their visual acuity until now. INTACS inserts may offer an alternative to restore functional vision and potentially to defer the need for a corneal transplant procedure.

**D. What Are INTACS Prescription Inserts?**

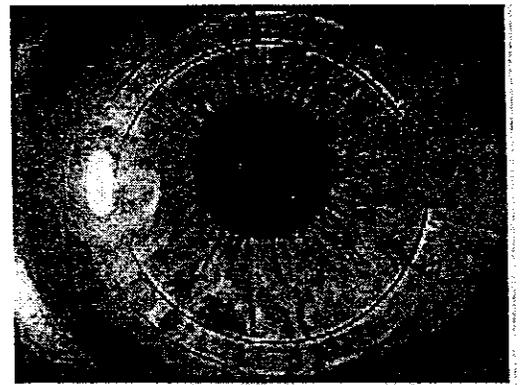
INTACS prescription inserts are two small, plastic crescents or arcs. They are composed of the same material (PMMA) that has been safely used for nearly 50 years in intraocular lenses used to treat patients with cataracts (clouding of the eye's natural lens).



Cross section of cornea showing INTACS prescription inserts placement.

INTACS inserts are designed to remain permanently in the eye, yet they can also be removed or replaced, if desired. The INTACS procedure is typically performed in an outpatient setting using drops to numb your eye. The total procedure for one eye, including preparation time, is usually completed in less than one hour.

INTACS inserts are surgically placed through a tiny cut that is made on the cornea, after numbing drops have been applied. Once in place, the two arcs flatten the cornea so that light rays can properly focus on the retina. Since INTACS inserts are placed in the outer edge of the cornea, the center of the cornea remains untouched. INTACS prescription inserts reshape and add support to the thinning areas of the keratoconic cornea to prevent or decrease the forward bulging of the cornea. The structural support provided by INTACS inserts will help create a more regular surface of your cornea, which may allow you to be fitted with contact lenses or glasses again to improve your vision.



INTACS prescription inserts placed in the cornea.

**E. What Are the Benefits of INTACS Prescription Inserts?**

- INTACS inserts may improve your vision by creating a more regular surface for your cornea, which may allow you to be successfully fitted with contact lenses, glasses or both.
- INTACS inserts may reduce the nearsightedness and astigmatism associated with your keratoconus.
- INTACS inserts preserve the central part of the cornea which is most important for your vision.
- INTACS inserts may defer the need for a corneal transplant procedure.
- INTACS inserts can be surgically removed or replaced.

**F. What Are the Risks of INTACS Prescription Inserts?**

As with any refractive surgical procedure, there are certain risks and complications associated with the INTACS procedure. It is important to discuss these risks with your doctor before you make the decision to have your surgery. If the results of your INTACS procedure are not satisfactory you may need to have the INTACS inserts removed or replaced. If your INTACS inserts are removed, you may need to have a corneal transplant procedure. The long-term safety risks of using INTACS inserts in the keratoconus population are unknown. There may be other risks that cannot be foreseen.

The adverse events and complications observed using INTACS inserts to treat patients with keratoconus are summarized below. There have been very few surgical or postoperative complications associated with using INTACS inserts to treat patients with keratoconus. Three clinical studies, involving a total of 164 keratoconus patient eyes, have been performed using INTACS inserts. The reported postoperative complications/adverse events from the three keratoconus studies include: channel deposits, incision haze, visual symptoms, shallow segment placement, non-infectious healing response, blood vessels in the cornea and redness/discomfort due to a patient getting sand in his eye (not related to INTACS inserts).

INTACS inserts have been successfully removed from 14/164 (8.5%) of patient eyes from the three keratoconus clinical studies. The primary reasons for removal included: visual symptoms (n=10), shallow segment placement (n=2) and astigmatism/surface irregularities (n=2). In the cases where the INTACS inserts were removed, the patients returned to their preoperative condition. Several of these patients have gone on to have successful corneal transplant procedures performed after their INTACS inserts were removed. Surgeons generally recommend that a corneal transplant procedure be performed at least three months after removal of the INTACS inserts.

INTACS inserts were removed from 34/452 (7.5%) of eyes in the U.S. clinical studies for myopia (nearsightedness). Reasons for removal of INTACS inserts included: 1 for infection, 12 for patient dissatisfaction with correction achieved (undercorrection, overcorrection, astigmatism), 19 for patient dissatisfaction with visual symptoms (glare, halos, difficulty with night vision, etc.) and 2 for other reasons (delayed replacement procedure, Federal Aviation Administration (FAA) restrictions).

### Removals and Replacements

If the results of the INTACS procedure are not satisfactory, you may need to have another surgical procedure to remove or replace your INTACS inserts. If your correction requires an adjustment, then your INTACS inserts can be replaced with either a thicker or thinner size. INTACS inserts can be easily removed in a brief, outpatient procedure.

The removal results from patients in the INTACS clinical studies demonstrate that:

- Patients' vision returned to their preoperative levels by 3 months following removal, in most cases.
- The central cornea remained clear for all patients.
- A small percentage of patients reported more frequent and/or more severe vision symptoms three months following removal of INTACS inserts than they had prior to their procedure.

**G. Contraindications**

You should **NOT** have INTACS prescription inserts placed if:

- you have extensive corneal thinning as a result of your keratoconus;
- you have autoimmune or immunodeficiency diseases (for example: lupus, rheumatoid arthritis, AIDS);
- you are pregnant or nursing;
- you have known conditions of the eye that may increase the likelihood of future problems; or
- you are taking prescription medications, such as Accutane<sup>1</sup>(isotretinoin) or Cordarone<sup>2</sup> (amiodarone hydrochloride), that may affect corneal healing or your vision. You should discuss all medications you take, even over-the-counter medications, with your eye doctor.

**H. Warnings**

- If your pupils are large under low light conditions, you are more likely to experience some visual symptoms such as glare and sensitivity to light.
- The long term effect of INTACS inserts on the cornea has not been established. Additional long-term data are being collected.
- Under poor visibility conditions, such as dim light or fog, you may have some reduction in the sharpness of your vision.

**I. Precautions**

- INTACS inserts are not recommended if you have insulin-dependent diabetes or other medical conditions that affect wound healing.
- INTACS inserts are not recommended if you have had a *Herpes* infection in your eyes.
- If your INTACS inserts are removed, the results of future surgical procedures to correct your vision are not known.
- If you are taking Imitrex<sup>3</sup> (sumatriptan) for migraine headaches.

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

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

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

**J. Are You A Good Candidate For INTACS Prescription Inserts?**

If you are considering INTACS inserts, you must:

- be at least 21 years of age;
- have nearsightedness and astigmatism as a result of keratoconus;
- be unable to achieve adequate vision correction with contact lenses or glasses;
- have clear central corneas (for example: no scarring or infection present);
- have a corneal transplant procedure as the only remaining option to improve your vision;
- be informed of the risks and benefits as compared to other available treatments for vision correction associated with keratoconus; and
- be willing to sign an informed consent form and to understand that the effectiveness of using INTACS inserts in treating patients with keratoconus has not been established, that the INTACS procedure is likely to only temporarily stop the progression of your keratoconus and that you may still be required to undergo corneal transplantation as the next course of therapy.

**K. What You Need to Know About the INTACS Procedure**

It is important that you are informed of what to expect before, during and after the procedure. Detailed instructions about how to care for your eye following the INTACS procedure can be found in Attachment 1.

**Before the Procedure**

You will need to have a preoperative eye examination to determine if your eye is healthy and is suitable for this procedure. Your examination will include a variety of standard ophthalmic tests, general medical tests and a review of your medical history.

**Important:**

- **If you wear contact lenses, it is very important to stop wearing them 2-3 weeks before your preoperative examination per your doctor's instructions. Failure to do this may produce poor results.**
- **If you wear eye makeup, you should stop 2-3 days before the procedure to reduce the risk of infection after your procedure.**

Please tell your doctor whether you are taking any medications or have any known allergies or reactions to medication. Your doctor will advise you on whether or not you will be allowed to eat or drink prior to the procedure. You should arrange for

transportation after the procedure and to your next examination, since you should not drive immediately after the procedure. Your doctor will advise you when it is safe to resume driving.

### **The Day of the Procedure**

Your physician will briefly discuss the details of the INTACS procedure and what to expect during your procedure. Your presurgical preparation will vary depending on the type of anesthesia your doctor chooses. You will be positioned comfortably, facing up, on a surgical table or reclining chair. Your face will be covered with a surgical drape exposing only the surgery eye. The surgeon will place an instrument between your eyelids to hold your eye open during the procedure. Anesthetic (numbing) drops may be placed in the procedure eye. The procedure will be performed using an operating microscope. A special surgical knife will be used to make a single small incision. A device will be placed on your eye to keep it steady during the procedure. You may experience some discomfort (typically a pressure sensation) during this part of the procedure. The total procedure, including the presurgical preparation, is usually completed in less than one hour.

After INTACS inserts are placed in your eye, your doctor will put some drops or ointment into your eye to reduce swelling. Your eye may then be covered for your protection and comfort. You may experience some discomfort or pain in your eye following the procedure. Most patients describe their discomfort as moderate and it typically diminishes within 48 hours. Your doctor may recommend a medication to help ease your discomfort. Please remember to make arrangements for transportation as you should not drive the day of your procedure.

### **The First Weeks After the Procedure**

Your doctor will typically examine your eye the day following your procedure. You will be mildly sensitive to light and will have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

#### **Important:**

- Do not rub your eye for the first six months after the procedure. This is important to promote proper healing of the incision.

For the first few weeks following the procedure, your eye will be healing. During this time, you will need to take special precautions with your eye to keep it clean and to protect it from injury and infection.

Your doctor should prescribe an antibiotic to be used following the procedure. Apply the antibiotic directly into your eye as instructed. Your doctor may prescribe steroid drops for the first week or two following the procedure to decrease irritation and redness of your eye.

**IMPORTANT:**

- Use the steroid eye drops and lubricants, as instructed by your doctor. Your surgical results depend upon following your doctor's directions.

Your doctor may recommend that you wear an eye shield at night. The shield should be worn to protect your eye from irritation and injury, such as rubbing or scratching, while you sleep.

Most patients do not experience significant pain following the procedure. If you do experience pain, ask your doctor about taking medication, such as a pain reliever, to ease the discomfort. Other pain medication may be prescribed by your doctor.

**WARNING:**

- You should **immediately** contact your doctor if you experience any pain, discomfort, feeling that something is in your eye or change in your vision after the initial postoperative recovery period (typically 7 days).
- Your doctor will monitor you for any side effects if steroid eye drops are used following the procedure. Prolonged topical steroid use may cause ocular hypertension (an increase in the pressure inside the eye), glaucoma (a condition usually associated with high eye pressure that can result in damage to the nerve at the back of the eye and possible loss of vision) or cataract formation (an opacity or clouding of the natural lens inside the eye that can cause a loss of vision).

**L. Questions to Ask Your Doctor**

You may want to ask the following questions to help you decide if INTACS inserts are right for you:

- What other options are available for correcting my vision?
- Will I have to limit my activities after the INTACS procedure, and for how long?
- What are the benefits of INTACS inserts for the amount of nearsightedness and astigmatism that is associated with my keratoconus?
- What type of vision can I expect in the first few weeks after the procedure?
- If INTACS inserts do not adequately correct my vision, what are my options?

- After having the procedure will my cornea heal differently if injured?
- Should I have INTACS inserts placed in my other eye? If so, how long will I have to wait before I can have the procedure performed on my other eye?
- When will I be able to return to work/resume normal activities?

Discuss the cost of the INTACS procedure and follow-up care requirements with your doctor.

**M. Self-Test****Are You an Informed Patient?**

Take the test below and see if you can correctly answer these questions after reading this booklet.

	<u>TRUE</u>	<u>FALSE</u>
1. The procedure for placing INTACS inserts is risk-free.	<input type="checkbox"/>	<input type="checkbox"/>
2. All treatments for keratoconus are the same.	<input type="checkbox"/>	<input type="checkbox"/>
3. It does not matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the INTACS procedure, there is a good chance that my keratoconus will be cured.	<input type="checkbox"/>	<input type="checkbox"/>
5. I will be able to drive immediately after the procedure.	<input type="checkbox"/>	<input type="checkbox"/>
6. I may still need to wear glasses or contact lenses after the INTACS procedure.	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk that I may have difficulty driving at night.	<input type="checkbox"/>	<input type="checkbox"/>
8. It does not matter if I am pregnant and plan to undergo this procedure.	<input type="checkbox"/>	<input type="checkbox"/>
9. If I have an autoimmune disease, I am still a good candidate for INTACS inserts.	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers to the Self-Test at the bottom of Page 13.

**N. Summary of Important Information**

- The INTACS procedure does not permanently alter the central part of the cornea and INTACS inserts can be removed or replaced.
- You may still need glasses or contact lenses after having INTACS inserts placed.
- Pregnant or nursing women should wait until they are not pregnant or not nursing to have the procedure performed.
- You would **NOT** be a good candidate if you have autoimmune or immunodeficiency diseases (for example: lupus, rheumatoid arthritis, AIDS), insulin-dependent diabetes or other conditions that make wound healing difficult.
- The INTACS procedure may result in some discomfort. The procedure is not risk-free. Please carefully read this entire booklet, especially the sections on Benefits and Risks, before you agree to the procedure.
- Alternatives to INTACS inserts for the treatment of keratoconus include, but are not limited to, glasses, contact lenses or a corneal transplant procedure.
- The procedure to place INTACS inserts is not a version of Radial Keratotomy (RK) or laser refractive surgery.
- The vision requirements of some occupations such as a pilot, policeman or the military cannot be met by having any refractive surgery, including INTACS inserts.
- Before considering INTACS inserts you should:
  - a. have a complete eye examination
  - b. talk with one or more eye care professionals familiar with refractive surgery about the potential risks and benefits of INTACS inserts.

Answers to Self-Test Questions:

1. False (see Page 5); 2. False (see Page 3); 3. False (see Page 9); 4. False (see Page 9); 5. False (see Page 9); 6. True (see Page 1); 7. True (see Page 8); 8. False (see Page 7); 9. False (see Page 7).

**O. Patient Assistance Information**

*Primary Eye Care Professional*

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

*INTACS Doctor*

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

*Procedure Location*

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

## Attachment 1

### Patient Postoperative Care Information

Now that you have received your INTACS inserts, it's very important to care for and protect your operative eye while it is healing. You may experience a temporary distortion of vision for several days after your procedure; this is normal and will be discussed with you during your regularly scheduled follow-up examinations.

There are a number of simple things you can do to avoid potential problems with your eye. The following guidelines have been developed by your eye doctor and Addition Technology to help you understand how to care for your eye following the INTACS procedure. Please read and follow these guidelines carefully.

#### FOLLOW DIRECTIONS ON ALL OF YOUR MEDICATIONS

- Use all eye drops, ointments or other medications as prescribed. Do not use any over-the-counter substitutes, unless instructed to do so by your eye doctor.
- When putting eye drops into your eye, take special care not to touch the tip of the applicator to your eye or your fingers.
- **If you have a reaction (redness, sensitivity or other symptoms) to any medication, stop using the medication and notify your eye doctor immediately.** An alternate medication may be prescribed.

#### DON'T LET YOUR EYES BECOME IRRITATED

- **Do not rub your operative eye for the first six months after surgery.** This is important to promote proper healing of the incision.
- Avoid rubbing or injuring your eye while you sleep. Use the nighttime eye shield for the entire time period your eye doctor recommends.
- Keep the area around your eyelid clean. To avoid contamination, use disposable tissues rather than cloth handkerchiefs or fuzzy towels.
- **Do not get tap water in your eyes for the first few weeks following your procedure.**

- Don't let shampoo, face creams, sprays or facial cleansers get into your operative eye. During the early months following your procedure, these products may irritate your eye more than usual. If you do get something in your eye, immediately flush your eye with sterile preservative-free artificial tears or sterile eye wash.
- Avoid using eye makeup for the first 7 days after your procedure or until your eye doctor says that your cornea has healed.
- Avoid areas where there may be a lot of dust, pollen or airborne debris and particles. Protect your eyes; wear safety glasses or protective goggles when appropriate, during work or sports activities. When in doubt, ask your eye doctor.
- **Do not wear a contact lens on your operative eye until advised to by your doctor.**
- If your eyes tend to be dry, or are frequently exposed to drying conditions, sterile, preservative-free artificial tears may be prescribed to ease any discomfort. You should also consider taking artificial tears with you for air travel, as cabin air can dry your eyes.
- Wear sunglasses with UV protection to ease any discomfort due to light sensitivity.

#### POSTPONE STRENUOUS EXERCISE

- Lifting or moving anything over 15 pounds can increase your eye's intraocular pressure. While this is normally not a concern, it should be avoided during the early months following your procedure.
- Avoid swimming in pools for the first week after your procedure. Lake and ocean swimming should be avoided for the first month. When swimming, always wear protective goggles.
- If you are involved in aggressive sports involving body contact or sudden jarring motions, always wear protective goggles.

#### ENJOY YOUR NORMAL ACTIVITIES

- Don't be afraid to use your eyes as you normally would. It will not harm your eyes to read, watch TV, work on the computer or to resume moderate exercise, such as jogging, walking or aerobics.

### CARRY YOUR PATIENT ID CARD

- Shortly after your procedure, you were given a patient ID card that contains information about your INTACS inserts. **Please carry this card with you at all times.** You may also want to keep a copy of this card with your personal medical files.
- In the event of an emergency, your patient ID card will provide vital information about your INTACS inserts, including the name and phone number of the eye doctor who performed the procedure.
- When visiting your family physician, or other medical professionals, be sure to show them your patient ID card.
- If you misplace your patient ID card, contact your eye doctor for a replacement.

### KEEP YOUR FOLLOW-UP APPOINTMENTS

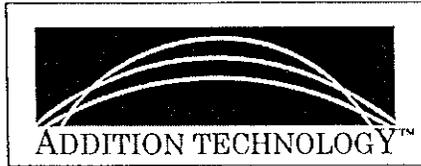
- Careful monitoring of your operative eye is essential, so please make every effort to keep all of your follow-up appointments. If you need to cancel an appointment, be prepared to reschedule your appointment when you call.
- If you become pregnant or initiate hormone replacement therapy, notify your eye doctor. Your vision may fluctuate during this time as a result of hormonal changes.
- Inform your eye doctor of any address or phone number changes.

### TAKE QUICK ACTION IF PROBLEMS OCCUR

If you experience any symptoms, inform your eye doctor as soon as possible, no matter how minor your symptoms may seem.

If you experience pain, significant discomfort or worsening of vision, call your eye doctor immediately.

**In the event of a medical emergency involving your operative eye, contact the eye doctor who performed your procedure.** If this is not possible, go directly to the local hospital. Be sure to inform them of your INTACS inserts, give them your patient ID card and have them notify your eye doctor as soon as possible.

*INTACS Prescription Inserts Manufacturer*

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USA

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Fax: 1-408-541-1411  
Toll-Free: 1-877-888-5372  
[www.getintacs.com](http://www.getintacs.com)

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

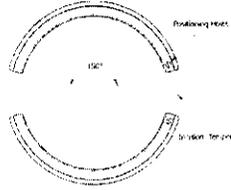
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MK 50230 01/Rev. A/Text Draft 7/20/04



# New Humanitarian Device Approval



FDA approved this device under the Humanitarian Device Exemption (HDE) program <http://www.fda.gov/cdrh/ode/hdeinfo.html>. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

**Product Name:** INTACS<sup>®</sup> Prescription Inserts for Keratoconus

**Manufacturer:** Addition Technology, Inc.

**Address:** 155 Moffett Park Drive, Suite B-1  
Sunnyvale, CA 94089-1330

**Approval Date:** July 27, 2004

**Approval Letter:** A link to web for the approval letter

## What is it?

INTACS<sup>®</sup> Inserts are two curved, clear plastic segments that are implanted in the perimeter of the cornea to reduce nearsightedness (myopia) in patients with keratoconus. Keratoconus is a visual disorder that occurs when the normally round and dome-shaped cornea progressively thins, causing a cone-like bulge to develop.

## How does it work?

INTACS<sup>®</sup> Inserts are implanted through a small surgical incision on the perimeter of the cornea. The inserts help restore clear vision in keratoconus patients by flattening and repositioning the cornea.

## When is it used?

INTACS<sup>®</sup> Inserts are intended for patients with keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option.

## What will it accomplish?

The inserts may restore functional vision and postpone the need for a corneal transplant.

## When should it not be used?

INTACS<sup>®</sup> Inserts should not be used in keratoconus patients who:

- can achieve functional vision on a daily basis using contact lenses
- are younger than 21 years of age,
- do not have clear central corneas, and
- have a corneal thickness less than 450 microns at the proposed incision site

## Additional information:

**SSPB and Labeling:**

Information on keratoconus:

**<http://www.nlm.nih.gov/medlineplus/ency/article/001013.htm>**

Information on refractive eye disorders:

**<http://www.nlm.nih.gov/medlineplus/refractiveerrors.html>**

Information on myopia:

**<http://www.nlm.nih.gov/medlineplus/ency/article/001023.htm>**

Information on astigmatism:

**<http://www.nlm.nih.gov/medlineplus/ency/article/001015.htm>**