

Important Information

INTACS (Intra Corneal Ring Segments)

GENERAL INFORMATION

The following information is intended to help you make an informed decision about having Intacs surgery to correct your vision.

It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or commonly known are not discussed. In addition, because Intacs is a relatively new surgery, there may be long-term effects not yet known or anticipated at the present time.

Intacs were originally developed over 10 years ago and utilizes a material that has been safely used in contact lenses and cataract surgery for nearly 50 years. The U.S. Food and Drug Administration (FDA) originally approved Intacs for the correction of low myopia (-1.00 to -3.00) in patient who are 21 years of age or older. This procedure also has a designation for treatment in individuals with keratoconus. This procedure has been practiced before in other countries such as Canada, Germany, and France.

AN OVERVIEW OF THE INTACS PROCEDURE

Diagnosis: You have been diagnosed with myopia (nearsightedness), astigmatism, or keratoconus.

Intacs Surgery Described: Intacs can permanently change the shape of your cornea but it is also removable if that is desired after surgery. One or two tiny plastic segments (Intacs) are placed in the periphery of your cornea much like placing a pencil in between the pages of a book. A curved glide creates the channel by separating the tissue layers in the outside periphery of your cornea. The Intacs will be slid into the channel where they remain. This causes the cornea to flatten which help focus light rays better on your retina to achieve more clear vision.

Limits of Intacs: Although the goal of Intacs for myopia is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve adequate vision. Intacs surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

If you have a condition called keratoconus, Intacs does not cure keratoconus. You will need to wear contacts or glasses to obtain satisfactory vision after this procedure. The primary goal is to help improve comfort or vision in contacts or glasses, but this can not be guaranteed. Intacs for keratoconus may help prevent or delay the need for a cornea transplant, but this is not guaranteed.

Intacs does not correct the condition known as presbyopia (aging of the eye), which occurs in most people around age 40 and requires them to wear reading glasses for close-up work, sometimes including computer distance. The key question you must ask yourself is: *Can you read up close while looking through the TOP part of your distance glasses?* If you must take off your distance glasses, don't use glasses or use bifocals to read up close, then you have presbyopia. Patients with presbyopia who get both eyes fully corrected for distance vision will then need to use reading glasses to seeing clearly up close, this sometimes includes computer distance as well. Therefore, if you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses because you take off your distance glasses to read, you will likely need reading glasses after this treatment if you have both eyes corrected fully for distance. If you do not need reading glasses now, you will probably need them at a later age. You may consider having the non-dominant eye weighted for midrange near vision (stereovision technique), many patients over the age 40 make this decision and are extremely pleased with both their distance and mid-range near vision (example: computer screen, shopping tags).

Risks and Contraindications

Contraindications: The treatment should not be performed on persons:

- with uncontrolled vascular disease
- with uncontrolled autoimmune disease;
- who are immune-compromised or on drugs or therapy that suppress the immune system;
- who are pregnant, nursing, or expecting to become pregnant within one month following the Intacs procedure; (keratoconus patients are excluded from this contraindication)
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia or hyperopia in either eye;
- with active or residual disease(s) likely to affect wound-healing capability;
- with unstable or uncontrolled diabetes;
- with progressive myopia or hyperopia;
- with uncontrolled glaucoma

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake Intacs surgery, you should discuss them with your physician.

Risks: The risks of Intacs surgery include, but are not limited to:

- **Loss of Vision:** Intacs surgery can possibly cause loss of best-corrected vision. This can be due to infection (internal or external), scarring or other causes. Unless successfully controlled by antibiotics, steroids, or other necessary treatment, it could even cause loss of the infected eye. Vision loss can be due to the cornea healing with an irregular surface, which could cause astigmatism and make wearing glasses or contact lenses necessary. Irregular cornea healing could result in an uneven corneal surface so that distorted vision or “ghosting” occurs. This may or may not be correctable by spectacles or contact lenses.
- **Visual Side Effects:** Other complications and conditions that can occur with Intacs surgery include: epithelial ingrowth (epithelial cells growing inside the channel of the Intacs); anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light that may be incapacitating for some time and may not completely go away; glare and halos around lights, which may not completely go away.
- **Overcorrection or Undercorrection:** It may be that Intacs surgery will not give you the result you desired. Some procedures result in the eye being undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by over treating myopia). It is possible that your initial results could regress over time. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision.
- **Other Risks:** Other reported complications include corneal ulcer formation; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance; new or increased floaters; retinal detachment; hemorrhage; diminished depth perception. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include loss of corneal disc; damage to the corneal disc; disc decentration; progressive corneal thinning (ectasia). Sutures may also be required which could induce astigmatism. It is also possible that the glide that creates the channel goes too deep and passes through the back of the cornea and enters the anterior chamber of the eye which may require suturing. This would preclude inserting the Intacs. It is also possible the glide could go too shallow which could exit the front of the cornea which would preclude inserting the Intacs. There are also potential complications due to anesthesia and medications that may involve other parts of your body. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.
- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies. This procedure may impair your ability to perform your job.
- **Later-Discovered Complications:** Intacs is a relatively new technique. You should be aware that other complications may occur that have not yet been reported. Longer term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Risks of Not Undergoing Intacs:** The risks of not having the surgery are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

Alternatives to Intacs

Intacs is purely an elective procedure, and you may decide not to have this operation at all. Among the alternatives are:

- Eyeglasses/spectacles
- Contact lenses
- Photorefractive keratectomy (PRK)
- Laser in-situ keratomileusis (LASIK)
- Radial Keratotomy (RK)
- Limal Relaxing Incision (LRI)
- Orthokeratology
- Laser Sub-Epithelial Keratectomy (LASEK)
- Cornea Transplant for patients diagnosed with keratoconus

You may wish to discuss these options with your physician.

Pre- and Post-Treatment Care

Before the Intacs Surgery

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are pregnant, you should not undergo the Intacs procedure until after the pregnancy. If you become pregnant in the one month following treatment, you should notify your eye doctor immediately.
- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the Intacs surgery and subsequent treatment.
- **Contact lens wearers:** If treatment is recommended for keratoconus, the patient may wear contact lenses up until 24 hours prior to surgery. If Intacs is recommended for treatment of myopia rather than keratoconus, patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks prior to the procedure. (This period may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least 3 days prior to the procedure.

Post-Treatment Precautions:

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such nonsterile water may expose the eye to increased risks of infection. Wear sunglasses during the first day after having surgery. The eye shield should be worn nightly for 1 week. Avoid rubbing the eye. The eye may be more fragile to trauma from impact. Evidence has shown that, as with any other scar, the corneal incision will not be as strong after healing as the original cornea was at the site of the incision. Therefore, the eye is somewhat more vulnerable to all varieties of injuries after Intacs, at least for the first year after surgery. You must wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high. No water skiing or jet skiing for 2 months after surgery.
- **Operating Motor Vehicles:** After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the Intacs procedure and for your 1 day postoperative appointment, you should arrange to have a driver.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the Intacs procedure varies with the individual. You should expect that the eye will be sore to some extent after the surgery. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensation of a foreign object in the eye, itching, or dryness of the eye.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 29 2003

August 26, 2003

Office of Orphan Products Development (HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Addition Technology, Inc.
155 Moffett Park Drive, Suite B-1
Sunnyvale, California 94089-1330

Attention: Darlene Crockett-Billig
Regulatory Consultant

Dear Ms. Crockett-Billig:

Reference is made to your humanitarian use device (HUD) request of July 11, 2003, submitted pursuant to section 520(m) of the Federal Food, Drug, and Cosmetic Act for the designation of the INTACS[®] Prescription Inserts (request #03-0112).

We have completed the review of this application and have determined that the INTACS[®] Prescription Inserts qualify for Humanitarian Use Device (HUD) designation 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 corneal transplant procedure can potentially be deferred as required by Section 520(m) of the Federal Food, Drug, and Cosmetic Act.

Please refer to this letter as official notification of designation and congratulations on obtaining your HUD designation.

Sincerely yours,

Marlene E. Haffner, M.D., M.P.H.

Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development