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INTACS INFORMED CONSENT

In*tacs*™
(Keratoconus)

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) has approved Intacs for the correction of low myopia (-1.00 to –3.00) in patient who are 21 years of age or older and have had a stable refraction for at least 12 months. However, Intacs has not been approved by the Federal Drug Administration for the treatment of Keratoconus. Instead, Intacs for the treatment of Keratoconus is considered an unregulated or "off label" use of an approved medical device. Your surgeon is not precluded from using Intacs for the treatment of Keratoconus if he and the patient are in agreement.

AN OVERVIEW OF THE INTACS PROCEDURE

Diagnosis: You have been diagnosed with Keratoconus.

Intacs Surgery Described: Intacs can permanently change the shape of your cornea but it is also removable if that is desired after surgery. Two tiny plastic segments (**In*tacs*™**) 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 are slid in 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 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 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. If you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses, you may need them at a later age. Intacs surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

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 the six months following the Intacs procedure;
- 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 of 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; retinal detachment; hemorrhage. 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.

- **Later-Discovered Complications:** Intacs is a relatively new technique. You should be aware that other complications might 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. Intacs may not prevent the need for corneal transplant in the future. It is unknown how Intacs affects the course of the keratoconus in the future. This is why it is important we have long term follow-up on you either in our clinic or through other care providers if you live far away.

- **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
- Laser Assisted in Situ Keratomileusis (LASIK)
- Photorefractive keratectomy (PRK)
- Radial Keratotomy (RK)
- Automated lamellar keratoplasty (ALK)
- Orthokeratology
- Hexagonal keratotomy
- Corneal relaxing incision
- Corneal transplant

You may wish to discuss these options with your physician.

Cost of Post-Procedure Care: Costs for post-procedure, follow-up care, and Intacs enhancements for 1 (one) year are included in the cost of the Intacs procedure. Initial post operative medications are included in the Intacs cost.

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, or expecting to become pregnant, you should not undergo the Intacs procedure until after the pregnancy. If you become pregnant in the six (6) months 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:** After the eligibility exam, you may wear your contacts up until 24 hours prior to surgery. In patients with keratoconus, due to the location in which you live and the degree of keratoconus you may have, it may not be practical for you to keep your contact lens out and wear glasses for the usual period of time.

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.

Patient Statement

- I have read this Informed Consent form (or it has been read to me). The Intacs procedure has been explained to me in terms that I understand. I have read the informational pamphlet provided by my physician's office.

- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with Intacs. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that because Intacs is a relatively new procedure, there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any

questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.

- I understand that the use of Intacs for Keratocounus is an "off label" use of an FDA approved medical device. After discussing this option with my surgeon we have decided that this is the best medical decision for the treatment of my Keratacounus.

- My decision to undertake the Intacs procedure was made without duress of any kind. I understand that Intacs is an elective procedure, and my myopia or hyperopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that Intacs will reduce or possibly eliminate my dependence on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.

- I authorize the physicians and other health care personnel involved in performing my Intacs procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my Intacs procedure that they deem relevant to providing me with care.

- I have had sufficient time to review this consent form. A physician or an associate has adequately addressed my questions and/or concerns. By signing below, I am making an informed decision to undergo the Intacs procedure. I have received a copy of this consent for my own records.

I consent to have Dr. Brian S. Boxer Wachler, MD to perform the Intacs procedure on my right eye/ left eye/ both eyes.

_____
Patient Name

_____ _____
Patient Signature Date/Time

_____
Witness Name

_____ _____
Witness Signature Date/Time

For Surrogate Consent:

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have Intacs performed on the patient's right eye/ left eye/ both eyes.

_____
Name of Surrogate

_____ _____
Surrogate Signature Date/Time

_____
Nature of Relationship to Patient

_____
Witness Signature

MANAGEMENT CONSENT FORM

It is my desire to have Doctor _____, perform my preoperative/ postoperative follow-up care for refractive surgery. I have been assured that UCLA Laser Refractive Center will be contacted immediately if I experience any complications related to my eye surgery.

Reason for Management by this doctor, is: (please check one)

___ Maintain established eye care relationship.
___ Difficult to return to UCLA for follow-up care because of location.
___ Other (please give reason) _____

Patient Signature _____Date_____

Witness Signature _____Date_____