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INFORMED CONSENT FOR INTACS INSERTS® PRESCRIPTION INSERTS FOR TREATMENT OF PATIENTS WITH KERATOCONUS

A. INTRODUCTION:

You are being offered the opportunity to receive a medical device called INTACS® prescription inserts to treat your keratoconus. Before agreeing to undergo the INTACS surgical procedure it is important that you read this "Informed Consent" form which describes the purpose of this procedure and the possible benefits and risks of this procedure. This Informed Consent form describes the alternative procedures that are available to you and your right to choose other forms of treatment for your disease. No promises or guarantees can be made as to the results of the INTACS procedure in treating your keratoconus. The following information is being provided so that you can make an informed decision about having INTACS prescription inserts to treat your nearsightedness and astigmatism as a result of your keratoconus. Please take as much time as you need to read, fully understand and to ask any questions that you may have before signing this Informed Consent form.

B. WHAT ARE INTACS® PRESCRIPTION INSERTS?

INTACS prescription inserts were originally approved by the U.S. Food and Drug Administration (FDA) in April 1999 for the correction of low levels of nearsightedness (-1.00 to -3.00 diopters). The INTACS inserts are two small, plastic crescents or arcs and are made from the same material that has been safely used in contact lenses and cataract surgery for nearly 50 years. 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.

Additional clinical data have shown that INTACS inserts are safe for the treatment of keratoconus, a disease of the eye. This degenerative, corneal disease is characterized by generalized thinning and a cone-shaped protrusion of the central cornea. This condition usually affects the vision in both eyes of a patient, although the rates of progression of the disease can be different in each eye. In July 2004, FDA approved INTACS inserts for the treatment of keratoconus as a Humanitarian Use Device.

C. WHAT IS A HUMANITARIAN USE DEVICE?

A Humanitarian Use Device is a special category of medical devices that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the U.S. per year. Addition Technology, the company responsible for the development and manufacture of INTACS inserts has received approval from the FDA to market this product in the U.S. as a Humanitarian Use Device for the treatment of keratoconus.

D. WHAT IS KERATOCONUS?

You are being offered the opportunity to consider receiving INTACS inserts because you have been diagnosed with keratoconus, a corneal disease that occurs when the normally round dome-shaped cornea (the clear outer area of your eye) progressively thins causing a cone-like bulge to develop. The bulging or "cone-shaped" protrusion is caused by the normal pressure of the eye pushing out on the thinned areas of the cornea. Since the cornea is responsible for refracting most of the light coming into your eye, an abnormal-shaped cornea can create reduced visual acuity and affect the way you see. This reduced visual acuity can make even simple daily tasks, such as driving, watching television or reading, difficult to perform. The actual cause of keratoconus is not yet known, but there have been studies to suggest a genetic link to the disease.

E. ARE YOU A GOOD CANDIDATE FOR INTACS PRESCRIPTION INSERTS?

If you are considering INTACS inserts for treatment of keratoconus, 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.

F. WHO SHOULD NOT HAVE THE INTACS PROCEDURE:

You should **NOT** have INTACS 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[1](isotretinoin) or Cordarone[2] (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.

If you know that you have any of the above conditions, you should inform your doctor. In addition, if you have any other concerns or possible conditions that might affect your decision to have INTACS surgery, you should discuss them with your doctor.

G. DESCRIPTION OF INTACS SURGERY:

The two tiny INTACS inserts are surgically placed into the periphery of your cornea through a tiny cut that is made on the cornea after numbing drops have been applied. A specially designed instrument creates a tunnel by separating the tissue layers in the outside periphery of your cornea. The INTACS inserts are placed in the periphery of your cornea much like placing a pencil in between the pages of a book. The INTACS inserts are placed into this tunnel where they remain. INTACS inserts work by reshaping and adding support to the thinning areas of your cornea to prevent or decrease the forward bulging of your keratoconic cornea. The INTACS inserts cause your cornea to flatten, which will help to better focus light rays onto your retina to achieve clearer vision. The structural support provided by INTACS inserts will also help to create a more regular surface for your cornea, which may allow you to be fitted with contact lenses or glasses again to improve your vision.

[1] Accutane® is a registered trademark of Hoffman-La Roche Inc.
[2] Cordarone® is a registered trademark of Sanofi.

H. WHAT ARE THE BENEFITS?

- **INTACS inserts may improve your vision by creating a more regular surface for your cornea, which may allow you to be successfully fitted again 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.**

I. WHAT ARE THE RISKS?

As with any refractive surgical procedure, there are certain risks and complications associated with the INTACS procedure. These risks include infection, shallow placement of the INTACS inserts into the tunnel, deposits in the tunnel where the INTACS inserts are placed, haze in the incision area, visual symptoms (including discomfort, burning, itching, tearing, double vision, increased sensitivity to light, glare and halos around lights, fluctuating vision, and reduced vision at night), shallow segment placement, a non-infectious healing response and developing blood vessels in the cornea. 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 associated with INTACS inserts that cannot be foreseen at this time.

Other Possible Complications: Other possible risks 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; retinal detachment and hemorrhaging. Complications could also develop that require 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 instrument that creates the tunnel 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 inserts until the eye healed. It is also possible the instrument could create a tunnel that was too shallow and exit the front of the cornea, which may preclude inserting the INTACS inserts until the eye healed. 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 Informed Consent form does not provide a comprehensive listing of every conceivable problem that you may encounter.

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: The INTACS procedure 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 inserts may not prevent the need for corneal transplant at some point in the future. It is unknown how INTACS inserts will affect the course of your keratoconus. This is why it is important we continue long-term follow-up on you, either in our clinic or through other health care providers, if you live far away.

Risks of Not Undergoing the INTACS Procedure: 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 your 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 glasses or contact lenses in the eye.

J. WHAT IS INVOLVED TO HAVE THE INTACS PROCEDURE?

If you agree to have INTACS inserts implanted in your eye(s) for treatment of your keratoconus, the following will happen:

1. You will need to have a physical examination, and your medical chart will be reviewed to make certain that you are a candidate for this procedure.
2. If it is determined that you are eligible to receive INTACS inserts, you will be taken to the surgical suite, where you will have the INTACS inserts placed into one (or both) of your eyes through a tiny cut in your cornea(s). You will be given medication prior to, during and following the procedure. At the end of the INTACS procedure, the tiny cut is typically closed with a suture(s).
3. After the INTACS surgery, you will be given medications by your doctor. A protective shield may be placed over your surgery eye for protection and will be removed on the first day after surgery.
4. You will be asked to wear this shield at night for the first several weeks following surgery to protect your surgery eye while you are sleeping.
5. Your doctor will schedule follow-up examinations with you.
6. If you develop any significant pain or discomfort following your INTACS procedure, please **contact your doctor immediately**.
7. If the INTACS inserts do not correct your vision to your satisfaction, your doctor and you will discuss the possibility of removing them or exchanging them for a different size. An INTACS removal and/or exchange will involve another surgical procedure.

K. WHAT ARE THE ALTERNATIVE PROCEDURES?

The INTACS procedure is purely an elective procedure. You may decide not to have the INTACS procedure at all. Other possible alternatives for treating your keratoconus may be:

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

You may wish to discuss these other options with your physician.

L. WHAT ARE THE COSTS?

Note: Each site will need to provide their specific information here.
Example Wording: Costs for post-procedure, follow-up care, and any INTACS inserts enhancements for one year are included in the cost of the INTACS procedure. Initial post-operative medications are included in the INTACS procedure cost. You will be responsible for costs related to travel for exams, medications (other than the initial post-operative medications) and corrective lenses as needed.

M. WHAT IS INVOLVED FOR PRE-AND POST-TREATMENT CARE?

Before the INTACS Procedure:

- **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.

- **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 procedure 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.

- **Eye makeup:** If you wear eye makeup, you should stop 2-3 days before your procedure to reduce the risk of infection after your procedure.

After the INTACS Procedure:

Note: Refer to the handout entitled "INTACS® Prescription Inserts Patient Postoperative Care Information" for more details or to your keratoconus Patient Booklet.

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower for the first few weeks following your procedure, as non-sterile water may expose the eye to increased risks of infection. Avoid swimming in pools for the first week after your procedure. Lake and ocean swimming should be avoided for the first month. Always wear protective goggles while swimming. Wear sunglasses during the first day after having surgery. The eye shield, which protects your surgery eye while you are sleeping, should be worn nightly until your doctor advises you to stop wearing it. Avoid rubbing your surgery eye. 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 inserts, 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. Avoid water skiing or jet skiing for 2 months after surgery.

- **Operating Motor Vehicles:** You should not drive on the day of the INTACS procedure and for your Day 1 postoperative appointment, therefore you should arrange to have a driver for both days. 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.

- **Pain and Discomfort:** Most patients do not experience significant pain following the procedure. However, the amount of pain and discomfort that can be expected after the INTACS procedure will vary 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 swelling. Some patients report the sensation of a foreign object in their surgery eye, itching, sensitivity to light, fluctuating vision and/or dryness for the first few days following the INTACS procedure. If you do experience pain, ask your doctor about taking medication, such as a pain reliever, to ease the discomfort.

N. QUESTIONS:

This procedure and use of INTACS inserts to treat my keratoconus has been explained by Dr. _____ or his/her associate and your questions were answered. If you have any other questions about the INTACS procedure you may call Dr. _____ at _____(phone number).

O. 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 FDA-approved informational booklet entitled, "Facts You Need to Know About INTACS® Prescription Inserts for Treatment of Nearsightedness and Astigmatism Associated with Keratoconus," provided to me by my doctor's office. I have signed the Patient Labeling Acknowledgement Form to document that I have received and reviewed the FDA-approved patient labeling.

- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with INTACS inserts to treat keratoconus. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that because INTACS inserts for keratoconus 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 inserts, for treating patients with keratoconus, has been approved by the FDA as a Humanitarian Use Device. After discussing this option with my doctor, we have decided that this is the best medical decision for the treatment of my keratoconus.

- My decision to undergo the INTACS procedure was made without duress of any kind. I understand that while the INTACS procedure maybe helpful in treating my keratoconus, it is an elective procedure and that my keratoconus may also be treated by alternative means, such as glasses, other forms of refractive surgery or a corneal transplant procedure. It is hoped that INTACS inserts will restore my functional vision so that I may be successfully re-fitted with contact lenses or glasses again and that the need for a corneal transplant procedure may potentially be deferred.

- I authorize the physicians and other health care personnel involved in performing my INTACS procedure and in providing my pre-procedure 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 Informed 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 to treat my keratoconus. I have received a signed copy of this consent for my personal records.

I consent to have Dr. _____ perform the surgical procedure to implant INTACS prescription inserts in my right eye / left eye / both eyes. (Circle eye to have surgery)

_____
Patient Name (Printed)

_____ _____
Patient Signature Date/Time

_____
Witness Name (Printed)

_____ _____
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 hereby consent to have INTACS prescription inserts implanted in the patient's right eye/ left eye/ both eyes (Circle eye to have surgery).

_____
Name of Surrogate

_____ _____
Surrogate Signature Date/Time

_____
Nature of Relationship to Patient

_____
Witness Signature