



# INTACS CONSENT

## For the Correction of Myopia (Nearsightedness)

2 Wisconsin Circle, Suite 200 • Chevy Chase, MD 20815  
240.482-1200 • FAX: 240.482-1235 • Toll Free: 866.578-2020

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The following information is being provided so that you can make an informed decision about having INTACS to correct your nearsightedness (myopia). You may take as much time as you need to read, fully understand, and ask any questions you may have before signing this Consent Form.

### ***Introduction:***

Every surgery has risks as well as benefits, and each person must evaluate this risk/benefit ratio for himself or herself based on the patient information given to the patient as well as the conversation with the patient's physician and staff. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery.

### ***Expected Benefits:***

1. INTACS may correct nearsightedness between -1.00 and -3.00 Diopters with 1.00 Diopter or less of astigmatism.
2. INTACS may reduce overall nearsightedness while also reducing or eliminating dependency upon eyeglasses.
3. INTACS correct nearsightedness without permanently altering the central part of the cornea which is critical for clear vision.
4. INTACS can be removed and replaced, if desired.

### ***Possible Risks:***

As with any refractive surgery procedure, there are certain risks and complications you need to be aware of when considering INTACS.

1. If the results of INTACS are not satisfactory or sufficiently effective, you may need to have an additional procedure to replace your INTACS or to have them removed.
2. You may have discomfort and/or pain for up to 48 hours following the procedure.
3. Your doctor may recommend a medication to help ease your discomfort.
4. You may have blurred vision, fluctuating vision, and tearing following the procedure.
5. You may be sensitive to bright light or glare following the procedure.
6. You may experience astigmatism (a temporary blurring or distortion of your vision) for several days after the procedure. This type of visual distortion is normal during the healing process and, in most cases, decreases over time; however, in rare instances, it may be permanent.
7. Infection is a risk with any surgical procedure.
8. Certain patients have reported continued visual distortion related to INTACS.
9. The U.S. studies showed that the following potential vision-threatening events happened less than 1% of the time after INTACS. All patients returned to the vision they had prior to the procedure.
  - Infection: 0.2%
  - Stromal thinning due to shallow placement: 0.2%

Initials \_\_\_\_\_

There are risks associated with any surgery. Since it is impossible to state every risk or complication that may occur as a result of any surgery, the possible risks and complications listed in this informed consent may be incomplete. There may be risks or complications associated with this surgery that are unknown because this is a relatively new procedure.

**By signing this form, I acknowledge that I understand the following:**

1. The procedure to be performed on my eye or eyes consists of inserting two small transparent half-rings into the peripheral cornea through a tiny incision. INTACS are designed to remain permanently in the eye, yet they can also be removed and replaced, if desired.
2. INTACS is purely an elective procedure.
3. The alternatives to INTACS for correcting myopia include eyeglasses, contact lenses, and other types of refractive surgery procedures such as Radial Keratotomy (RK), Photorefractive Keratectomy (PRK) and Laser In-situ Keratomileusis (LASIK).
4. INTACS will not prevent the development of naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration, or retinal detachment.
5. INTACS do not correct the condition known as "presbyopia" (the aging of the eye) which may require reading glasses for close-up work.
6. I understand that having INTACS does not necessarily mean total freedom from eyeglasses because excellent vision without eyeglasses cannot be guaranteed.
7. It has been brought to my attention that INTACS are not risk-free. The complications that may occur include improper correction, decrease in best corrected visual acuity, fluctuating vision, glare, halo, corneal edema, corneal perforation, and infection. There is a possibility of other complications due to anesthetic drops, eye drop reaction, or other factors.
8. I understand that there may be risks associated with any surgery, including this procedure. There may be risks and complications associated with this surgery that are unknown because this is a relatively new procedure.
9. I understand that there is a possibility that my surgeon may not be able to insert INTACS into my cornea and that the surgery may have to be canceled.
10. It is understood that further procedures may be required to reach the desired result. However, there is no guarantee with an additional procedure that the desired change in refractive error can be obtained, though there could be significant improvement in uncorrected vision.
11. I authorize the sharing of my relevant medical information among doctors regarding my pre- and post-operative care.
12. I have arranged for transportation after the procedure and to my first post-operative appointment. I understand that my doctor will advise me when I can safely resume driving.
13. I accept full personal financial responsibility for payment for all fees related to my INTACS. These include the procedure itself, possibly necessary medications, eyeglasses required after the procedure, and expenses connected with my travel to and from the surgery site or office.
14. I understand, and I am acknowledging my willingness to follow the doctor's instructions and attend regular post-operative visits to reduce the risk of long-term complications.
15. Although it is impossible to be informed regarding every possible complication that may occur, all my questions have been answered to my satisfaction. The decision to undergo INTACS has been my own and has been made without duress of any kind.
16. I understand that I will receive a copy of this form, if requested.
17. I have been given a copy of the patient book about INTACS for nearsightedness.
18. In signing this form, I am stating that I have read this consent (or it has been read to me), and I understand the risks, benefits, alternatives, and complications. I have had the opportunity to ask questions and have them answered to my satisfaction.

Initials \_\_\_\_\_

