

## INFORMED CONSENT FOR THE ALCON ReSTOR

1. The Alcon ReSTOR intraocular lens implant is a new apodized diffractive intraocular lens implant that will allow for better distance and near vision without glasses. However, it does not always eliminate the need for glasses. This implant offers two benefits. First, it allows presbyops ( or people that need bifocals) to achieve some spectacle independence, and secondly, it takes care of the implant in cataract surgery. The ReSTOR apodized diffractive intraocular lens implant is made with concentric circles in the implant that have decreasingly smaller power to decrease optical disturbances compared to previous similar intraocular lenses.

2. \_\_\_\_ (initial) if you have the ReSTOR implant, when do you want to wear glasses?  
(Circle one)   SOMETIMES           ALWAYS           NEVER

If you circled never, you are not a good candidate for the ReSTOR. The ReSTOR has its limitations. The ReSTOR works best for people who are willing to compromise increased spectacle independence for vision that is not as good as it would be with glasses. Some adverse effects might be halos and glare around lights at night, a reading distance of approximately 13 inches, the risks of cataract surgery, and significantly increased cost.

3. The ReSTOR works best if both eyes have the ReSTOR. This is called binocular summation. With ReSTOR in both eyes 97% of people could see 20/40 or better both distance and near, as long as the rest of the eyes are normal without glasses.

Most people after cataract surgery that correct for distance only with the standard IOL, will still need glasses for both distance and near. Without the Premium ReSTOR lens you will require +1.25 reading glasses to see a computer screen and a stronger +2.25 for near work. The purpose of the ReSTOR IOL is to reduce your dependence on these glasses.

4. When driving at night, 5% of people had severe halos around lights and 19% of people had moderate halos. 5% of people had severe glare and 21% of people had moderate glare at night. The ReSTOR lens is not good for pilots or people who drive at night all the time.

5. The ReSTOR is no panacea. There is no guarantee to not wear glasses. There are definite limitations to the ReSTOR. Everyone needs to watch out for UNREALISTIC EXPECTATIONS.

6. Calculating the power of intraocular lens implants is not an exact science. There are many variables. You may have residual astigmatism, myopia, or hyperopia. If you have any residual astigmatism, myopia, or hyperopia, you can have a touch-up LASIK refractive procedure done after 3 months. The cost of a LASIK is not included with the cost of the intraocular lens implant. It is also normal to have a YAG laser posterior capsulotomy performed in the future. The cost of the YAG laser is also not included in the cost of the intraocular lens implant.

7. Avid readers are usually not good candidates for the ReSTOR. People who are very critical about having perfect vision are not candidates for the ReSTOR. People who are very demanding about their visual acuity or who have unrealistic expectations about not wearing glasses and insist on perfect vision are not good candidates for the ReSTOR. Night drivers and pilots are not good candidates. Patients with greater than 1 diopter of corneal astigmatism are not good candidates unless they understand that a LASIK touch-up will be needed in the future. People with macular degeneration or similar ocular pathology, previous refractive surgery, and other multi-focal intraocular lens implants except the ReSTOR are not good candidates. Males with axial lengths of greater than 25 mm are not good candidates because of the higher incidence of retinal detachments. The ReSTOR should be used in people who are willing to compromise the above problems for increased spectacle independence.
8. Medicare and insurance companies do not pay for the increased cost of the ReSTOR and associated costs related to the ReSTOR over what they approve for cataract surgery. Patients who are having cataract surgery can elect to upgrade to the ReSTOR and pay the difference. This cost is not covered. You may need a YAG laser posterior capsulotomy in the future which is a normal occurrence after cataract surgery. This cost is also not covered with the ReSTOR. This new technology ReSTOR intraocular lens costs approximately 150% of the cost of cataract pre-operative care, cataract surgery, and three months follow-up care.
9. I understand the following things related to the ReSTOR lens:
  1. Presbyopic hyperopes (far-sighted people in bi-focals) are the best candidates.
  2. Patients need to accept the risk of cataract surgery (bleeding, infection, and retinal detachments), along with the problems related to the ReSTOR lens. A YAG laser posterior capsulotomy may be needed in the future. Eye drops will be used for five (5) weeks after surgery. A LASIK refractive touch-up after three (3) months may be necessary and is not covered with the cost of the ReSTOR.
  3. Binocular summation (meaning ReSTOR implants in both eyes) will give the best vision.
  4. There are no guarantees of never wearing glasses. People who are willing to compromise some new vision problems for increased spectacle independence are candidates.
  5. Patients who are avid readers or who are very critical of their visual acuity are not candidates. 5% of people will have severe halos and glare at night. Pilots and people who drive at night are not good candidates. Intermediate vision at arms length is only 20/40 without glasses, but can be improved with glasses.
  6. Males with an axial length of greater than 25 mm are not candidates because of the increased incidence of retinal detachments.
  7. Patients with macular degeneration or similar conditions or other ocular pathology are not candidates.
  8. Patients who have had previous refractive surgery, such as radial keratotomy, PRK, or LASIK are not candidates.

I elect to upgrade my cataract surgery and pay for the ReSTOR intraocular lens implant and extended care package. I understand the restrictions and limitations of the ReSTOR listed above.

PATIENT SIGNATURE/LEGALLY RESPONSIBLE PARTY \_\_\_\_\_

WITNESS:

ADDRESS:

CITY/STATE/ZIP:

DATE:

M.D.

EXPLAINED BY:

Cecille Taylor M.D.

TIME: