

Important Information

Cataract Extraction or Natural Lens Replacement

INDICATIONS: Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients. Patient may elect to have their lens replaced with various different lenses. Some lenses have the indication for those with and without Presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag in the posterior segment of the eye.

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Physician Labeling. Some adverse reactions that have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation, macular edema, pupillary block, retinal detachment, and secondary surgical intervention (including but not limited to lens repositioning, biometry error, visual disturbances or patient dissatisfaction). If a lens is selected with multifocality, some visual effects (halos or radial lines around point sources of light at night) may also be expected due to the superposition of focused and unfocused multiple images. A reduction in contrast sensitivity may also be experienced by some patients, especially in low lighting conditions such as driving at night. In order to achieve optimal visual performance with this lens, emmetropia must be targeted. Patients with significant preoperative or expected postoperative astigmatism $>1.0D$ may not achieve optimal visual outcomes. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

General Information:

This procedure involves the removal and replacement of the natural (clear/crystalline) lens of the eye which has become cloudy (formation of cataract). The natural lens will be replaced with an artificial lens implant called an intra-ocular lens (IOL) in order to remove the cloudy lens. The advantage of this procedure is that not only is clear vision restored, but your vision can be improved without glasses. Depending on the lens used your distance and near vision can be restored to like when you use to not have to depend on your glasses/bifocals.

Should you agree to have the procedure, you will undergo a complete eye examination. This will include an examination to determine your glasses prescription (refraction), measurement of your vision (visual acuity), measurement of the pressures inside your eye (tonometry), measurement of the cornea curvature (keratometry), ultrasonic measurement of the length of your eye (axial length), intra-ocular lens calculation (biometry) to determine the best estimate of the power for the implanted lens, microscopic examination (slit-lamp examination), and examination of the retina of your eye with pupils dilated (indirect ophthalmoscopy).

Should you decide to proceed with the procedure, you may undergo light sedation by an anesthesiologist while the eye is made numb with drops or local anesthesia. The natural lens in your eye will then be removed by with special instruments through a small entry point. This type of procedure is called phacoemulsification (phaco). After the natural lens is removed, the artificial lens with the power determined during your pre-operative examination will then be placed inside your eye. In rare cases, it may be necessary to implant 2 lenses. The incision required to perform this operation is at times self-sealing but it may require closure (sutures) which will gradually dissolve over time or be removed during an exam. After the procedure, your eye will be examined the next day, then at one to two weeks, possibly at 3 to 4 weeks, and at 3 months. During the immediate recovery period, you will place drops in the eye for 2 to 6 weeks. You should be able to resume normal activities within 2 or 3 days, and your eye will usually be stable within 6 to 12 weeks.

Benefits to you will be clearer, natural vision than you presently have. In some cases this will clear the distance vision and the near vision. You may require additional glasses for reading or distance vision depending on the lens that is placed during the procedure.

Description of risks and side effects and discomforts:

This type of procedure itself is usually quite comfortable for the patient and rare complications arise. This procedure is successfully performed on thousands of patients daily across the country. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual. Complications of Natural Lens Replacement procedure while rare could occur, this is why it is extremely important to follow the prescribe eye drops and follow-up examination schedule. While complications are rare, it is important that you are informed about these possible complications. These include: glare or halos while driving at night; infection, which if serious and non-responsive to treatment can lead to loss of vision; bleeding; swelling in the central area of the retina (called cystoid macular edema which usually improves with time but could lead to loss of vision); clouding of the outer lens of the eye (corneal edema which can be corrected with a corneal transplant); detachment of the retina which can usually be repaired (there is an increased risk in highly near-sighted eyes, therefore you may be requested to have an examination by a retina doctor); damage to the retina or nerve during the administration of the anesthesia if an injection is performed; increased astigmatism; inaccuracy of the intra-ocular lens power requiring additional procedure or glasses or contacts; decentration of the intra-ocular lens, which may provide unwanted images and increased glare/streaks/starbursts; glassy or watery look to the eye from light reflections off the implanted lens; need for subsequent YAG laser to clear thin membrane not removed during procedure; wound leak requiring suturing; new or increased vitreous floaters; impaired ability to perform job; diminished depth perception; or development of increased pressure in the eye (glaucoma). Although all of these complications can occur, their incidence following this procedure is exceptionally low.

If you are a candidate for ReStor or ReZoom multifocal lens versus a single vision lens implant or CrystaLens implant there is a slightly increased chance that you may note some type of glare or halo at night. During clinical trials about 13% of the patient had some difficulty with night vision due to glare and halos, however they elected to not have the lens exchanged due to the high level of freedom from glasses overall. Patients found that 81% of the time they did not require glasses for reading. About 93% of the patients felt that their vision was restored to what it was like during their early-mid forties. Also, if you have undergone previous eye surgery and you elect to have the ReStor or ReZoom Multifocal lens implant or CrystaLens implant this is considered an “off-label” use of this device. During the clinical trial this lens was not used for patients with previous eye surgery. When a physician uses a FDA-approved device that is outside the parameters, it is called “off-label” use of the device. For example, aspirin may be FDA-approved for pain control, but doctors can use it for other uses like prevention of heart attack or stroke. This would be an example of “off-label” use of aspirin. Off-label uses of products and medicines by physicians are performed as part of the practice of medicine. Your physician is permitted to perform “off-label” procedures as long as the patient and physician are in agreement with it. Therefore, the use of the this type of lens for cataract surgery is outside of the original clinical trials parameters , therefore this will be an “off-label” use of this lens.

A possible disadvantage is that although the accuracy of the intra-ocular lens calculations is quite satisfactory, these calculations sometimes do not provide optimal vision. There may be a slight calculation error of the lens. The latest formula will be used to evaluate the power of the lens to be implanted. In the event of an unsatisfactory lens power, the vision can usually be corrected by a glass prescription, which should be considerably weaker than your original prescription. A large error in the lens calculation could be corrected by a stronger pair of glasses, contact lenses, exchange of the implant, insertion of a second implant, or possibly laser procedure.

The procedure will only be performed on one eye at a time. It is possible that you will experience a period of imbalance between the two eyes (anisometropia). This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so the patient will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision. In the absence of complications, procedure in the second eye can usually be accomplished within 1 to 4 weeks, once the first eye is stabilized.

Non-surgical Alternatives:

Non-surgical alternatives to cataract extraction are to continue to wear spectacle lenses or contact lenses. Although there are essentially no risks to wearing glasses, the quality of vision with a clouded lens can be diminished.

Surgical alternatives:

Currently there are no other surgical alternative to cataract surgery.

Currently for patients with Presbyopia and no evidence of cataracts the alternatives may include:

- Eyeglasses/spectacles
- Contact lenses
- Photorefractive keratectomy (PRK)
- Orthokeratology
- Laser Assisted In Situ Keratomileusis (LASIK)
- Laser Sub-Epithelial Keratectomy (LASEK)
- Clear Lens Extraction (aka Refractive Lens Exchange)
- Corneal relaxing incision (AK)
- Conductive Keratoplasty (CK)

You may wish to discuss these options with your physician.