



CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS:

The AcrySof® ReSTOR® Apodized Diffractive Optic 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 with or without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNINGS:

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 Directions for Use 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). As a result of the 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.

PRECAUTIONS:

Do not resterilize. Do not store over 45° C. Use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solution. Clinical studies with the AcrySof® ReSTOR® IOL indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (eg, glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. The long-term effects of filtering blue light and the clinical efficacy of that filtering on the retina have not been conclusively established.

ATTENTION:

Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings, and precautions.