

INDICATIONS: Akreos®MICS™ posterior chamber lenses are indicated for primary implantation for the visual correction of aphakia in adult patients where a cataractous lens has been removed by phacoemulsification. The lens is intended for placement in the capsular bag.

CONTRAINDICATIONS: Implantation is not advisable when the IOL may aggravate an existing condition, interfere with the diagnosis or the treatment of a pathology, or present a risk to the sight of the patient. These conditions are uncontrolled glaucoma, rubeotic cataract, retinal detachment, atrophy of the iris, microphthalmia, developing chronic eye infections, endothelial corneal dystrophy, perioperative complications (such as vitreous loss, hemorrhage...), foreseeable postoperative complications.

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: a. Recurrent severe anterior or posterior segment inflammation or uveitis. b. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases. c. Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss). d. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible. e. Circumstances that would result in damage to the endothelium during implantation. f. Suspected microbial infection. g. Children under the age of 2 years are not suitable candidates for intraocular lenses. h. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support. •Since the clinical study for the Akreos intraocular lens was conducted with the lens being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus. •Improper handling or folding techniques may cause damage to the haptic or optic portions of Akreos foldable lenses. If lenses are not folded according to directions, optic tears may result (see “Directions for Use”). Physicians should not attempt to implant lenses that have radial optic tears or separations. •Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic damage) that might require IOL explantation. •To avoid the creation of permanent forcep marks in the central optic zone, exercise care during handling and insertion of the lens. Read and follow the folding and insertion instructions carefully.

PRECAUTIONS: 1. Do not attempt to resterilize these lenses. 2. Do not store the IOL package in direct sunlight or at temperatures below freezing (<0°C). Store at room temperature. Avoid high temperatures (>45°C). 3. Do not implant the IOL if the outer pouch or vial is opened or damaged. 4. Do not reuse the IOL. 5. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent. 6. A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses. 7. The IOL should be used in the shortest possible time after opening the vial. 8. Do not implant the IOL if the lens is not completely immersed in solution under any vial orientation. 9. Akreos IOLs can absorb substances that they contact (disinfectant, drug...). Do not place the lens in contact with surfaces where such contamination can occur. 10. If a YAG laser posterior capsulotomy is performed, assure that the laser beam is focused slightly behind the posterior capsule. 11. As with any surgical procedure, there is risk involved. Potential adverse events and complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to, lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair. Amongst those directly related to the IOL are decentering and subluxation, precipitates on the surface of the IOL. Silicone oil, particularly when used in the surgical treatment of detached retina, may stick to the IOL if the posterior capsule of the crystalline lens is not intact.

*Clinical studies have not been conducted with the Akreos MICS to assess the effect of the added aspheric surface to the parent lens Model Akreos on spherical aberration, visual acuity and contrast sensitivity.

Crystalens® Accommodating Posterior Chamber Intraocular Lens
BRIEF STATEMENT

Rx only.

Indications for Use: The Crystalens® is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia. The Crystalens® provides approximately one diopter of monocular accommodation which allows for near, intermediate, and distance vision without spectacles

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. Some adverse events which have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation, and secondary surgical intervention.

Precautions: Do not resterilize; do not store over 45°C.

ATTENTION: Refer to the Physician Labeling for complete prescribing information.