HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS

STERILE EO

INSTRUCTIONS FOR USE

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Intended Purpose

The Intraocular lenses (IOLs) are intended for the replacement of the human crystalline lens in the visual correction of the aphakia.

Device Description

Intraocular Lens is composed of two elements: 1) Optic and 2) Haptic. The Optic is the small centre portion that acts as an artificial lens and the haptic is the side structure that holds the lens in place in a capsular bag.

The raw materials used to manufacture of HYDROPHOBIC intraocular lens is Hydrophobic Disc (HI56) and Blanks material is a copolymer of phenylethyl acrylate (PEA) and phenylethyl methacrylate (PEMA) which is cross-linked with butanediol diacrylate(BDDA)+ UV Blocker benzotriazole.

The HYDROPHOBIC IOL material have very low water content, a high refractive index which makes it a suitable choice. In addition to a wide range of material types, IOLS are also available in may optic designs such as monofocal.

Brand Names:Clearoccu

Variant/Model	Optic Dia	Overall Dia	Diopter
Clearoccu			
DHA 6025, DHA 6025.	6.00 mm	12.50 mm	-5.0 D to +35.0 D
DHA 6030, DHA 6030.		13.00 mm	

Medical Indication
Cataract.
Intended User
Ophthalmic Surgeon
Target Patient Population
Above age of 18 years(Male or Female)
A Constant Information
The constant listed on the outer label is presented as a guideline and is a starting point for implant power calculation. It is recommended that surgeon calculates their own personalized A constant based on clinical experience with the particular IOL models, surgical techniques, measuring equipment and postoperative results.
Sterility
These posterior chamber intraocular lenses are supplied in a package terminally sterilized by using Ethylene Oxide Sterilization. Do not use the lens if the package is damaged. If used it leads to Inflammation.

Clinical benefits
- Excellent visual outcomes and a low incidence of PCO.
- Effective for the visual correction of aphakia.
- Excellent optical performance, good centration, and a low incidence of intra and postoperative complications.
- Visual improvement or stability in the majority of eyes (91.3%).
- Long-term safety, efficacy and rotational stability.
- Good uveal biocompatibility
- Low potential for endothelial damage
- Good resistance and low degree of adhesion
- Minimizing posterior capsule opacification (PCO)

Summary of Safety and Clinical Performance Referred
https://health.ec.europa.eu/system/files/2022-03/md_ndcg_2019_9_sscp_en.pdf
Recommendation for Choosing Lens Delivery System
The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of the injector with silicone tip and a cartridge.
Directions For Use

- The Device is used to be by a qualified and trained ophthalmic surgeon only.
- The IOL should be maintain the temperature between 5°C (41°F) to 45°C (113°F).
- Information of the model, dioptry (power) and expiration date shown on the box label must be checked.
- peel and open the pouch and remove the lens container under the sterile environment.
- The Dioptry of the IOL must be checked again from the label on the lens container.
- unfold the lens case and remove the lens carefully.
- Soak or rinse lens in sterile balanced salt solution (BSS) or their equivalent solution.
- Ensure that the lens is in good conditions of optic and haptics surfaces for adherence of any particles.
- Before implantation examine the lens configuration data and optical surfaces.
- During insertion carefully handle lenses by haptics portion only. To avoid breakage do not attempt to expand the haptics, flex the haptics out of the plane of the lens or twist or torque the lens.
- Packing box contains surgeons record label and patient ID card labels. These are for convenience in maintaining and reporting records of implantable lenses during clinical investigation.

Patient card:
The relevant details should be entered onto the patient card enclosed. One of the stickers with the IOL details from the label set enclosed should be affixed on the back of the patient card. This card is to be given to the patient, who should take care of it so as to present it to any eye specialist in the future.
Contraindications
Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio.
Do not use in patients with pre-existing ocular conditions not explicitly listed below that may be aggravated by the implant or where the implant may interfere with the assessment or management of ocular disease.
- Progressive disturbances on the front segment of the eye such as rubeosis iridis, essential iris atrophy.
- Chronic or recurrent Uveitis.
- Proliferate diabetic retinopathy.
- Glaucoma Problem.
- Concomitant Severe Eye Disease.
- Severe optic nerve atrophy.
- Cataract associated with congenital rubella syndrome.
- Epithelial Systrophy.
- Rubella Cataract.
- Massive Vitreous loss.
- Microphthalmus.
- Do not use under age of 18 years.
- Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
- Suspected microbial infection.

During surgery
Flat anterior chamber following clear lens extraction Circumstances that would result in damage to the endothelium during implantation. Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, Hyphema, significant iris damage, retina detachment, uncontrolled positive pressure or significant vitreous prolapse or loss).
Pre-Caution
Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.
Warnings

- Do not re-use the IOL.
- Do not re-sterilized or autoclave again. single use only.
- Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
- IOLs are not to be placed in the moisture, direct sunlight.
- Never handle IOL by its optics, Care should be taken to avoid breakage of haptic while inserting lens through the scleral tunnel or small incision
- The effectiveness of UV - filtering intraocular lenses in reducing the incidence of retinal disorders has not been established.
- The safety of the use of the Neodymium - YAG laser on IOLs with UV filtering materials has not been established.
- The surgeon is urged to use extreme caution in such cases where a patient with UV filtering IOLs is treated with a Neodymium YAG laser.
- The compression force exerted on the eye tissue by the lens is not established.
- Not to implant the IOL if the container which maintains sterility has been opened or damaged.
- The physician should have knowledge in selecting type of the lens depending on the eye dimensions.
- Do not use if the product is subjected to magnetic fields, external electrical interference, electrostatic discharges, acceleration forces, or thermal ignition sources.

Complications/Adverse Events
The Complications related to the implantation of any intraocular lens are essentially the same as for cataract surgery and may require secondary surgical intervention. Complications seen with the same type of IOL may include but are not limited to : Corneal Edema, Iritis, Hyphema, Macular Edema, Pupillary Block, Secondary Glaucoma, Cyclitic Membrane, Vitritis, Endophthalmitis, Retinal Detachment, Lens Dislocation.Adverse events seen with same type of IOL may include but are not limited to : Hypopyon, Intraocular Infection, Acute Corneal Decompensation, Secondary Surgical Intervention: a) Lens replacement remover, b) Retinal Detachment Repair, c) Repositioning of lens, d) Iridectomy, e) Vitrectomy, f) Wound Repair Leak, g) Photocoagulation, h) Removal of Residual Cortex material, I)Anterior Capsulotomy.
Residual Risks
- Eye damage or loss of vision(May result in temporary or permanent vision loss or serious eye injury).
- Posterior Capsule Opacification (PCO) (Clouding of the lens capsule that may reduce vision), IOL dislocation (The implanted lens may shift from its intended position, affecting vision and possibly requiring surgical repositioning), Inflammation or infection (Endophthalmitis) (Postoperative inflammation or infection inside the eye may cause pain, redness, and vision impairment)
- Corneal Edema (Swelling of the cornea may cause blurred or hazy vision, which is usually temporary but can occasionally persist),Blurred Vision (Vision may be temporarily or permanently unclear following the procedure),Allergic Reaction (Rare allergic responses to lens materials or medications may cause ocular redness, swelling, or discomfort), Inconvenience to patient (night glares, halos) (Visual disturbances such as glare or halos may occur, particularly under low-light conditions).
- Reduced contrast sensitivity (trouble seeing things when they don't stand out well from the background).

Storage and Transport
Keep in cool and dry place. Store the Intraocular Lenses at temperatures between 5°C (41°F) to 45°C (113°F). Do not expose containers to direct sun light. Protect from freezing.
Material Used:
The HI56 material is a copolymer of Phenylethyl acrylate (PEA) and Phenylethyl methacrylate (PEMA) which is cross-linked with Butanediol diacrylate (BDDIA) + UV Blocker benzotriazole biologically compatible material. Under which the lens becomes Yellow in color and blocks blue light.
Disposal Condition:
Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children and stray animals. The disposal should be in compliance to local laws related to disposal of biomedical waste, in the country of use.

IOL Dioptric Power Calculations
The physician should determine preoperatively the power of the lens to be implanted Lens power calculation methods are described in the following references:

1. Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. Journal of Cataract and Refractive Surgery.1993;19:700-712; ERRATAL;1994; 20:677.
2. Holladay, J.T., Musgrove, K.H., Prager, T.C., and Ruiz, R.S. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery. 1988; 14:17-24.
3. Holladay, J.T. Standardizing constants for ultrasonic biometery, keratometry and intraocular lens power calculations. Journal of Cataract and Refractive Surgery. 1997; 23:1356-1370.
4.Norrby NES. Unfortunate discrepancies. Letter to the editor and reply by Holladay, J.T. Journal of Cataract and Refractive Surgery. 1998; 24:433-434.

How Supplied
The Global Ophthalmic IOLs are supplied sterile in a lens case within a heat sealed Tyvek peel pouch is sterilized with ethylene oxide. The pouch and product labels are enclosed in a shelf pack.
Expiration Date
The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.
Return of Damaged product
Return the lens in its original container identified by the batch number and serial number, model, purchase information, your reference and reason for the return. Please contact your local distribution office regarding lens return or exchange.
Reporting
Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or incidence must be report to Global Ophthalmic Private Limited Company. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Patient Information
Each patient should receive information regarding IOL prior to the decision to implant an intraocular lens.

Symbols

Symbol	Description	Symbol	Description
IOL	Intraocular Lens		Date of manufacturing
UV	Ultraviolet		Use by (YYYY-MM: year - month)
PC	Posterior chamber	EU REP	Authorized representative in the European Community
$Ø_B$	Body diameter (Optic diameter)		Consult instruction for use
$Ø_T$	Overall diameter (Overall length)		Single sterile barrier system with protective packaging outside
STERILE EO	Sterilized by Ethylene Oxide	MD	Medical device
	Do not re-use	REF	Catalogue Number
	Do not Resterilize	SN	Serial Number
	Do not use if package is damaged		Country of Manufacturer
	Caution		Manufacturer
	Keep away from sunlight	#	Model number
5°C 45°C	Storage between 5° to 45° C	UDI	Unique Device Identifier
	Keep dry		Patient Identification
LOT	Lot number " / "Batch number		Date
			Health Care Centre or Doctor
			Patient Information Website.

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