HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS

STERILE EO

INSTRUCTIONS FOR USE

Enhancing vision

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INSTRUCTION FOR USE PRELOADED INTRAOCULAR LENS

INTENDED PURPOSE

The Intraocular lenses (IOLs) are intended for the replacement of the human crystalline lens in the visual correction of the aphakia. The preloaded Intraocular lens is a device intended to be inserted into the eyes during surgery, to direct the insertion of an Hydrophobic intraocular lens and remove the Intraocular Lens guide after insertion is completed.

DEVICE DESCRIPTION

The GLOBAL OPHTHALMIC PRIVATE LIMITED manufactured Sterile Single Use Preloaded Intraocular Lens (IOL+ Intraocular Lens Guide). The Preloaded Intraocular Lens is a device to implant GLOBAL OPHTHALMIC manufactured Single Piece Acrylic Foldable Intraocular Lens (IOL). The Global Ophthalmic private limited manufactured Hydrophobic Acrylic Foldable single piece posterior chamber Intraocular lens (IOL) is an ultraviolet (UV) light filtering which compensates for the optical function of the natural crystalline lens in the human eye. The Intraocular Lens Guide provides a tubular pathway through an incision over The iris to the centre of the pupil. The IOL may then be gently injected from the tube into eye.

Brand Names: Macwatson,Barxton,Macphob.

Variant/Model			Optic Dia	Overall Dia	Diopter
Macwatson	Braxton	Macphob			
WHA 6025P, WHY 6025P.	BHA 6025P, BHY 6025P.	CHA 6025P, CHY 6025P.	6.00 mm	12.50 mm	-5.0 D to +35.0 D
WHA 6030P, WHY 6030P.	BHA 6030P, BHY 6030P.	CHA 6030P, CHY 6030P.		13.00 mm	

MEDICAL INDICATION

Cataract

INTENDED USER

Ophthalmic Surgeon

TARGET PATIENT POPULATION

Above age of 18 years(Male or Female)

STERILITY

These preloaded intraocular lens are supplied in a package terminally sterilized by using ethylene oxide. Do not use the device if the package is damaged. If used it leads to infection.

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)
- An injection system is relatively easy to use.
- Less wound manipulation.
- Reduce loading time and IOL injector variability.
- Improved visual outcomes.
- Improved refractive stability and faster postoperative recovery.
- Less incision enlargement.
- Less postoperative inflammation and wound leak.
- Limiting surgical time and costs.
- Reduce potential damage to the IOL.
- Minimize the trauma of corneal wounds

INSTRUCTION FOR USE

1. Open or Peel the two blister cup one by one and take the preloaded intraocular lens.
2. As in Fig 1, Ensure the lens protector cap is locked well.
3. As in Fig 2, Apply the thin layer of viscoelastic on the bottom hole of the protector cap.
4. As in Fig 3, Again apply the thin layer of viscoelastic on the top hole of the protector cap as required for the free movement of lens during injections.
5. As in Fig 4, Lock the cartridge well.
6. As in Fig 5, Make sure that the cartridge is locked well at the same time protector cap is removed automatically..
7. Ensure that there is no gap between the shutters and then gently push the plunger towards the lens.
8. As in Fig 6, Then lens moves through the cartridge.
9. As in Fig 7, Deliver the IOL in to the patient eye by applying the even pressure on the pusher. Push the lens through the cartridge slowly and monitor the release of the IOL from the cartridge carefully, finishing before the silicon pusher reaches the end of the cartridge tip as in Fig 8, and simultaneously withdraw the device from the eye.
10. Remove the viscoelastic material from the eye with the standard irrigation and aspiration techniques.

Figure 1

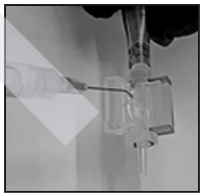

Figure 2

Figure 3

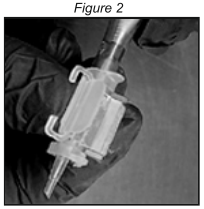

Figure 4

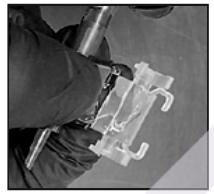

Figure 5

Figure 6

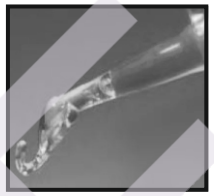

Figure 7

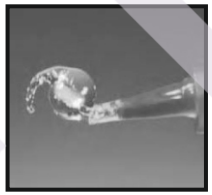

Figure 8

CONTRAINDICATIONS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio.Do not use the Preloaded Intraocular lens appears nicked or damaged in any way.

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. The IOL should be injected immediately after being introduced into the cartridge tunnel. Viscoelastic materials may lose their lubricating properties when exposed to air for a longer period of time.

WARNINGS

Do Not Resterilized the Preloaded Intraocular Lens.
Do Not Reuse - Single Use Only.

Complications / Adverse Events

- IOL instability
- Haptic breakage
- IOL marking
- IOL Crimping
- Posterior capsule rupture
- Zonular dialysis

RESIDUAL RISK

- 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

Store in cool and dry place. Do not store the Preloaded Intraocular Lens Temperature below 5° C (41°F) and over 45°C (113°F).

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MATERIAL USED

Injector Material Name : Polycarbonate
Cartridge Material Name : Polypropylene
IOL Material Name: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.

HOW SUPPLIED

The preloaded intraocular lens is supplied in heat sealed Blister pack- sterilized with Ethylene Oxide. The preloaded Intraocular lens and product labels are enclosed in a shelf pack

EXPIRATION DATE

The expiration date on the Preloaded Intraocular Lens package is the sterility expiration date. This Intraocular Lens Should not be implanted after the indicated sterility expiration date.

RETURN OF DAMAGED PRODUCT

Return the Preloaded Intraocular Lens in its original container identified by the Model, Batch Number purchase Information, your reference and reason for the return, please contact your local distribution office regarding Preloaded Intraocular Lens return or exchange.

DISPOSAL CONDITION

Ensure safe and proper disposal used/ discarded product and packaging to avoid adverse effect to environment, children and stray animals. The disposal should be in compliance to local loss related to disposal of biomedical waste, in the country of use.

REPORTING

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.

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)		Double Sterile Barrier System
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.

Manufactured by

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