FRONT

care GROUP
LOOK FORWARD

FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (STERILE)

OcuFlex™

DESCRIPTION
The foldable intraocular lenses (IOL) are single piece ultraviolet absorbing posterior chamber intraocular lense for the treatment of aphakia in adult patient. The optical device is manufactured from medical grade Hydrophilic acrylate co-polymer with a polymerisable UV blockers. The powers are available in whole steps from -10 diopter to +35 diopter and in 0.5 diopters steps. The lenses have an A constant of 118.0 and an A/C depth of 4.8. The water content is 26% and lens has a refractive index of 1.49 in the dry state and 1.465 in the wet state. Hydrophilic acrylate is a highly biocompatible material.

INDICATION
Monofocal intraocular lens (IOL) is anoptical implant for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery.

MODE OF ACTION
The Foldable Hydrophilic IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

CONTRAINDICATIONS
Implantation is not advisable when the IOL may aggravate an existing condition, interfere with the diagnosis or the treatment of pathology or present a risk to the sight of the patient. Among those conditions are but not limited to the following:

- Chronic or recurrent uveitis
- Proliferative diabetic retinopathy
- Corneal endothelial dystrophy
- Acute eye disease or infection, external or internal
- Severe complication during surgery
- Choroidal hemorrhage
- Non-age-related cataract
- Microphthalmos
- Suspected microbial infection
- Medically uncontrolled glaucoma
- Severe optic atrophy
- Uncontrollable positive pressure.

Patients with preoperative ocular conditions such as (but not limited to the following) chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment may not achieve the visual acuity of patients without such problems. The surgeon must determine the potential risk/benefit to be derived from IOL implantation when such conditions exist.

POTENTIAL COMPLICATIONS AND SIDE EFFECTS
As with all surgical procedures, cataract surgery with IOL implantation can presents risks. The surgeon must evaluate risk/benefit ratio. Some of the potential complications of cataract surgery are but not limited to the following:

- Wound leak
- Retinal detachment
- Cystoid macular edema
- Corneal decompensation
- Corneal edema
- Pupillary block
- Iritis
- Corneal endothelial damage
- Endophthalmitis
- Iris prolapse
- Hypopyon
- Glaucoma
- Capsular rupture
- Vitreous loss
- Lens decentration
- Subluxation

Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, & retinal detachment repair. Some of the listed complications may require second surgical intervention.

PRECAUTIONS
- An IOL should only be implanted by an experienced surgeon or a surgeon who has observed and/or assisted in numerous implants
- The IOL style, power and expiration date should be verified before opening the blister / case
- Do not use the device if the sterile package has been opened or damaged
- Do not re-sterilize the lens. Product integrity may compromise

250 mm

90 mm

BACK

- Do not reuse. If reuse, it may lead to toxic effect.
- The safety and effectiveness of a posterior chamber lens, if placed in the anterior chamber, has not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe.
- Unused medical device waste should be sent to local waste management regulatory body.

DIRECTION FOR USE
- Examine the label on the unopened package for model, power and expiration date
- After opening the IOL box verify lens case information (model, power and serial number) is consistent with information on outer package labeling. This device is sterile until the inner pouch is opened. Inspect the pouch carefully.
- For tears, cuts, punctures, or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised.
- To remove the lens, open the pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
- To minimize the occurrences of marks on the lens due to handling, all instrumentation should be clean. Any forceps used for lens handling must have round edges and smooth surfaces.
- When removing the lens from the case, DO NOT grasp the optical are a with forceps. The IOL should only be handled by the haptics. Handle the lens carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape in any way.
- Rinse the lens thoroughly using sterile intraocular irrigating solution. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling
- The IOL should be stored at room temperature.
- CARE GROUP SIGHT SOLUTION PRIVATE LIMITED recommends using the qualified CARE GROUP SIGHT SOLUTION PRIVATE LIMITED's IOL Delivery System.

HOW SUPPLIED
The IOL is supplied in heat sealed blister containing 0.9 % normal saline solution. A package sterilized with steam sterilization and must be opened only under aseptic conditions.

CALCULATION OF LENS POWER
The A-constant is presented as a starting point for the lens power calculation. When calculating the exact lens power, it is recommended that calculations be performed individually, based on the equipment used and operating surgeon's own experience. The power of the lens to be implanted should be determined preoperatively.

DISCLAIMER OF LIABILITY
The manufacture will not be liable for any injury suffered to patient as a result of:
1. Any implantation method or technique used by a surgeon to implant the lens
2. Any prescription selection and use of the lens for any individual patient or patient's condition

REPORTING
Adverse reactions and potentially sight threatening complications that may reasonably be regarded as lens related, need to be reported to CARE GROUP SIGHT SOLUTION PRIVATE LIMITED or local distributor.

RETURN OF DAMAGED GOODS
Return the lens in its original container to your local distributor with the lot number, style, power, and reason for return.

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See instruction for use
Do not resterilise
Do not reuse
Do not store below 0°C & above 45°C
Store away from sunlight
Do not use if package damaged
Store in dry place

STERILE

CE 2460

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