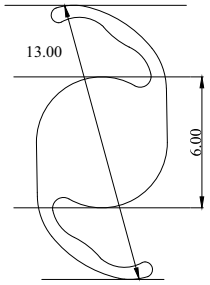
Foldable Hydrophobic Intraocular Lens (Sterile)

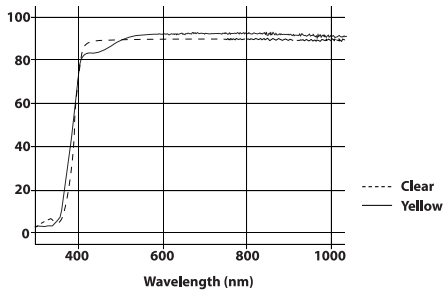
Overview AS and Overview AS Natural Preloaded IOL

DESCRIPTION

The Overview AS and Overview AS Natural are Clear and Yellow Foldable Hydrophobic Intraocular Lenses. These hydrophobic one piece posterior chamber IOLs are manufactured from a medical grade acrylate co-polymer with a 360-degree square edge. The edges of the lenses are made Square Edged to reduce the occurrence of Posterior Capsular Opacification.

Optic Material Overview As	: Clear hydrophobic acrylate Copolymer
Optic Material Overview As Natural	: Yellow hydrophobic acrylate Copolymer
Optic Design	: Monofocal, Aspheric
Configuration	: Biconvex optic
Diopter range	: +0.00 to +40.0 diopters in 0.5 steps
Refractive Index	: 1.53
Estimated A-Constant	: 118.8





INDICATION

Monofocal intraocular lens (IOL) is an optical implant for the replacement of the human crystalline lens in the visual correction of aphakia following cataract surgery.

PATIENT POPULATION

Cataract patients 18 years of age or above

MODE OF ACTION

The Foldable Hydrophobic 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.

CLINICAL BENEFIT

The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.

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.

Note 1- The device does not contain ED/CMR substances
2- The implanted IOL does not contain any metallic components and are safe with no potential for interaction with the Magnetic Resonance (MR) Field.

PRECAUTIONS

- IOL should be only implanted by experienced surgeon. The IOL is intended to be used by qualified ophthalmic surgeon only
- The IOL style, dioptric power and expiration date should be verified before opening the blister/case for use
- Do not use the device if the sterile package has been opened or damaged
- Do not re-sterilize the lens. Product integrity may compromise
- Do not reuse the IOL. If reused, it may lead to toxic effects, it may lose its performance characteristics, or it may produce infection
- The safety and performance of posterior chamber lens, has not been established for its use in anterior chamber. Implantation of posterior chamber lens in the anterior chamber may produce unsafe results
- Unused medical device waste and consumables should be sent to local waste management regulatory body for disposal

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:

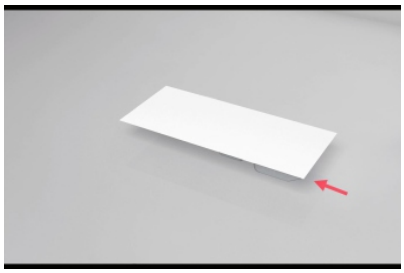
- Wound leak
- Retinal detachment
- Cystoid macular edema
- Corneal decompensation
- Corneal edema
- Pupillary block
- Iritis
- Corneal endothelial damage
- Endophthalmitis
- Iris prolapse
- Hypopyon
- Glaucoma
- Capsular rupture
- Vitreous loss
- Lens decentration
- Subluxation
- Secondary surgical interventions include, but are not limited to: TASS, halos, night glares, 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

DIRECTION FOR USE

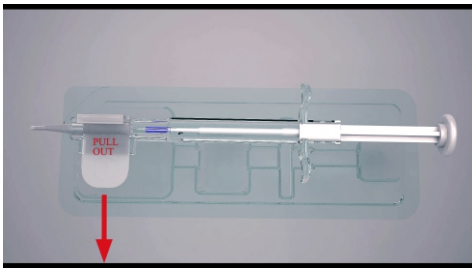
- Prior to opening the box, verify the label for correct model, dioptric power and the expiration date
- After opening the IOL box verify lens blister information (model, power and serial number) and make sure it is consistent with the information printed on the outer box
- This device is sterile until the blister is opened. Inspect the blister carefully for tears, cuts, punctures, or other signs that the blister has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised
- To remove the lens, open the blister and transfer to a sterile environment. Carefully open the blister to expose the lens / delivery system in aseptic environment
- To minimize the occurrences of marks on the lens surface during handling, the instruments being used for handling the lens should be gently used. Any forceps used for handling the lens must have round edges and a smooth surface
- DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure no particles have adhered on instrument surfaces e.g. forceps
- The IOL should be stored at room temperature as recommended in the product IFU
- To facilitate IOL insertion viscoelastic solution should be used with BSS / Saline water
- Kindly follow instructions as below for implantation :

STEPS FOR IMPLANTATION (PRE-LOADED INJECTION SYSTEM)

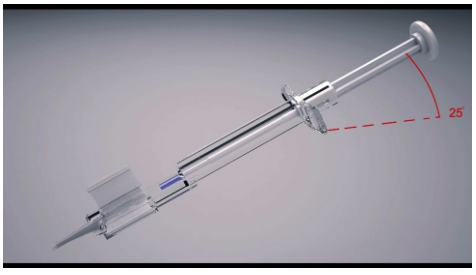
Step 1: Peal off tyvek lead



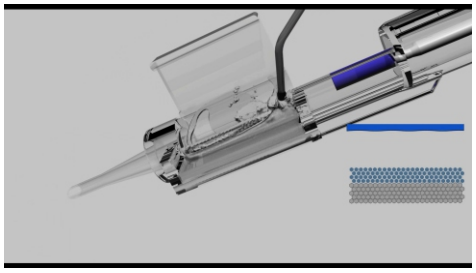
Step 2: Pull out the flap



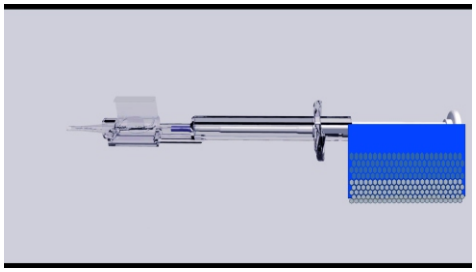
Step 3: Hold the preloaded system bottom up around 25° - 45°



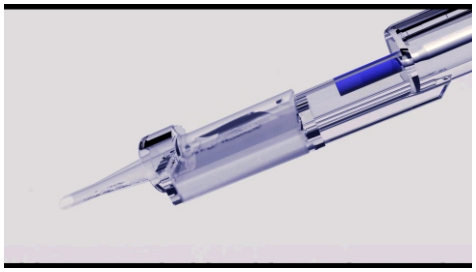
Step 4: Inject BSS/ Saline water throughly on the lens surface and cartridge until it starts coming out from cartridge nozzle.
NOTE: BSS / Saline water temperature must be above 20°C



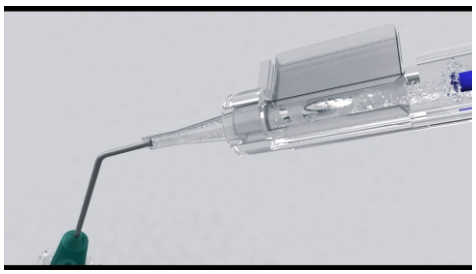
Step 5: Hold the preloaded system horizontally for 20 seconds so that cartridge coating activates fully.



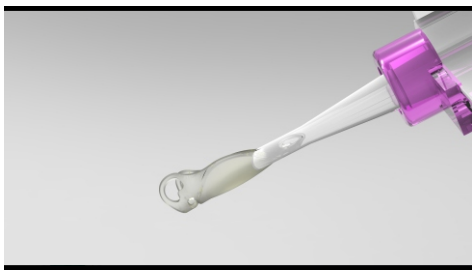
Step 6: Close the cartridge wing gently



Step 7: Inject few drops of BSS / Saline water from cartridge nozzle. Now enter the cartridge nozzle into the incision and push the injector plunger gently till the lens comes out fully.
NOTE: BSS / Saline water temperature must be above 20°C



Step 8: Push the plunger in controlled manner to advance the lens outside of the eye up to the front part of the cartridge tip. Anticipate an initial delivery force; however the excessive delivery force indicates that the lens is trapped or the soft cushion is overridden the lens.



HOW SUPPLIED
The IOL in a preloaded delivery system is supplied dry in a package sterilized with ethylene oxide 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

DISCLAIMERS OF LIABILITY
The manufacture will not be liable for any injury suffered to patient as a result of:
- Any implantation method or technique used by a surgeon to implant the lens
- 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 I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH or Authorized Representative and competent authority of the member state where patient and/or user is located.

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

PROVISION FOR SSCP
Summary of Safety and Clinical Performance (SSCP) of this device is available on the
EUDAMED website https://ec.europa.eu/tools/eudamed
Note : Once the SSCP is reviewed by notified body and uploaded in EUDAMED.

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

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