Instructions for use

Hydrophobic acrylic Foldable Intraocular Lens

Products to which these instructions for use apply
These instructions for use apply to the following products

Brand Name & Generic Name	Models	Material	Performance Characteristics
EYECRYL PLUS Monofocal Hydrophobic Acrylic Foldable Intraocular Lens	HF600	Hydrophobic Clear	Spheric, Monofocal
EYECRYL PLUS Monofocal Hydrophobic Acrylic Foldable Intraocular Lens	ASHF600	Hydrophobic Clear	Aspheric Monofocal
EYECRYL PLUS Monofocal Hydrophobic Acrylic Foldable Intraocular Lens	ASHFY600	Hydrophobic NY	Aspheric Monofocal
EYECRYL TORIC Hydrophobic Toric Foldable Intraocular Lens	HFY-10, HFY-20, HFY-30, HFY-35, HFY-40, HFY-50, HFY-60, HFY-05	Hydrophobic NY	Aspheric Toric
EYECRYL ACTV Multifocal Hydrophobic Acrylic Foldable Intraocular Lens	DIHFY600	Hydrophobic NY	Aspheric Bifocal
EYECRYL ACTV TORIC Hydrophobic Diffractive Refractive Aspheric Multifocal Toric Foldable Intraocular Lens	HFYD-10, HFYD-20, HFYD-30, HFYD-35, HFYD-40, HFYD-50, HFYD-60, HFYD-05	Hydrophobic NY	Aspheric Bifocal Toric
EYECRYL TRI ACTV Hydrophobic Diffractive Refractive Aspheric Trifocal Foldable Intraocular Lens	TRHFY600	Hydrophobic NY	Aspheric Trifocal
EYECRYL PLUS Refractive Diffractive multifocal Hydrophobic Aspheric Tri EDOF Lens	HFY600	Hydrophobic NY	Aspheric, EDOF & EDOF Toric

*NY- Natural Yellow

DEVICE DESCRIPTION

Eyecryl hydrophobic intraocular lenses (IOL) are acrylic foldable single piece posterior chamber IOLs. These IOLs are designed to be surgically implanted in the human eye as a replacement for the natural crystalline lens. These IOLs are made from medical implantable grade hydrophobic material with less than4%water content. There are two variants of hydrophobic IOL material: Hydrophobic clear and Hydrophobic Natural Yellow (NY). Both hydrophobic clear and hydrophobic NY material have the same refractive index of 1.48 at 35°C. Hydrophobic NY incorporates natural yellow chromophore which absorbs the UV light and filter violet light. It has <2 % transmission at 400 nm. Hydrophobic clear material includes a covalently bound UV blocker and 10% Cut-off at 360 nm wavelength.

Refer label on the outer box for lens type, lens type attributes, and refractive power/diopter. The overall diameter of the lens is 13 mm and the optic diameter is 6 mm.

The spectral transmittance curve (figure 1) represents the transmittance values of both hydrophobic clear and hydrophobic NY type of IOL.

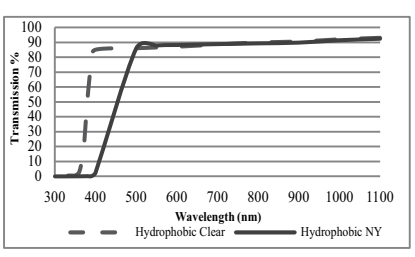

Figure 1: Transmittance graph of hydrophobic clear and Natural yellow

HOW EACH IOL SUPPLIED

Each Eyecryl Hydrophobic acrylic Intraocular Lens is supplied sterile in a unique holder for easy handling during surgery. The IOL & holder are placed inside a 5ml glass vial filled with water for injection and secured by a rubber stopper and a screw cap. The vial is packaged in a medical-grade blister pack and sealed with a Tyvek Lid.

The IOL is gamma sterilized and should be opened only under sterile conditions.

Each carton box contains one IOL, one lens delivery system, an implant card, instructions for completion of implant card and product traceability labels.

INDICATION

Eyecryl hydrophobic acrylic IOLs are intended to be implanted into the capsular bag in the posterior chamber of the eye for the visual correction of aphakia secondary to the removal of the crystalline lens in patients with cataracts.

Eyecryl hydrophobic acrylic multifocal IOLs (**EYECRYL ACTV DIHFY600 & EYECRYL TRI ACTV TRHFY600**) are also indicated for non-cataractous, presbyopic patients who seek greater independence from glasses for intermediate and/or neardistances.

Eyecryl hydrophobic acrylic toric IOLs (**EYECRYL TORIC HFY and EYECRYL ACTV TORIC HFYD)** are also indicated for the correction of regular corneal astigmatism.

Eyecryl hydrophobic acrylic EDOF and EDOF TORIC IOLs (EYECRYL PLUS HFY600) are also indicated for non-cataractous, presbyopic patients who seek greater independence from glasses for intermediate and/or near distances with or without regular corneal astigmatism.

Patient target group:
Aphakic adult patients (18 years old or older).

MODE OF ACTION

Eyecryl Hydrophobic acrylic IOLs are intended to be implanted into the capsular bag replacing the natural crystalline lens. It functions asa refractive element help to focus the light rays which are coming from cornea on the retina. Hydrophobic acrylic multifocal IOL also provides anextra focal point which helps to see the Intermediate and/or near objects. The aspheric optic surface of the IOL compensates for the positive spherical aberration of the cornea when implanted in the eye.

CALCULATION OF LENS POWER

Prerequisites of successful visual outcomes of cataract surgery include accurate biometry. Presurgery calculation of required lens power to be implanted in the case of Eyecryl Hydrophobic IOL (either monofocal or multifocal IOL) should be determined using expertise by the surgeon as per the preference. An estimated theoretical A-Constant value is mentioned on the IOL packaging outer label. These reference A-Constants anticipate the use of other parameters corneal curvature and axial length values from respective biometry equipment, required for power calculation and a spectacle distance vision at 6 meters or 20 feet. IOL power calculation methods are often included with biometry equipment, and they are also described in the references mentioned below. It is recommended to personalize the lens A-constants to compensate differences in instrumentation, surgical techniques, and IOL power calculation formulas that may exist between clinical practice.

- Retzlaff, J.A., Sanders D.R., and Kraff, M.C., "Development of the SRK/T intraocular lens implant power calculation formula," Journal of Cataract and Refractive Surgery, Vol. pp. 222-240, 1990; ERRATA, Vol. 16 pp. 528, 1990.
- Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J. Cataract Refract Sur. 1993;19(6):700-12.
- Holladay JT. et al Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J. Cataract RefractSurg. 1997;23(9):1356-70.
- Sanders, D.R., Retzlaff, J., and Kraff, M.C., "Comparison of the SRKII formula and other second generation formulas," Journal of Cataract and Refractive Surgery Vol. 14, pp. 136-141, 1988

For Toric IOL

- Astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results.
- The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. To optimize IOL selection and axis placement, Biotech provides a web-based tool (www.biotechcalculators.com) for the surgeon.

Preoperative keratometry and biometry data, incision location and the surgeon's estimated surgically induced astigmatism are used to determine the appropriate EYECRYL ACTV Toric IOL model, spherical equivalent lens power and axis of placement in the eye.

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected.

- Patients receiving chloroquine treatment.
- Microphthalmia.
- Chronic Uveitis.
- Corneal dystrophy or endothelial insufficiency.
- Active ocular diseases (active diabetic retinopathy, uncontrolled glaucoma)

WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISK

The complications listed below may occur following implantation of an IOL and may require treatment, or in severe cases can lead to secondary surgery for which the surgeon should carefully evaluate the risk/benefit ratio.

Possible complications linked to surgery for crystalline lens removal and IOL implantation include, but are not limited to, those listed below:

Intraoperative Complications

- Glaucoma
- Vitreous herniation
- Secondary membrane
- Retro lenticular membrane
- Retinal detachment
- Iridial atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intra Operative vitreous loss or Hemorrhage
- Cystoid Macular Edema
- Inflammatory reaction (e.g. Vitritis, iritis, iridocyclitis, hypopyon, cyclitic membrane)
- Ocular infection (endophthalmitis, microbial keratitis)
- Toxic anterior segment syndrome
- Wound leakage
- Iris prolapse
- Elevated intraocular pressure requiring treatment
- Corneal endothelial damage

Postoperative Complications

As with any surgical procedure, there is risk involved. Potential 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.

Possible complications related to toric IOLs (EYECRYL TORIC HFY, EYECRYL PLUS HFY600 and EYECRYL ACTV TORIC HFYD)

- Rotation of toric IOLs from their intended axis can reduce their astigmatic correction function.
- Misalignment of the IOL axis greater than 30 degrees can increase postoperative refractive cylinder values. If necessary, lens repositioning should occur as early as possible before lens encapsulation

Possible complications related to multifocal IOLs and EDOF IOLs (EYECRYL ACTV DIHFY600 , EYECRYL TRI ACTV TRHFY600 and EYECRYL PLUS HFY600)

- Patients may have a contrast sensitivity reduction in low light conditions (compared to monofocal IOLs) and may need to take extra care when driving at night.

Warnings specific to Multifocal IOLs and EDOF IOLs (EYECRYL ACTV DIHFY600, EYECRYL TRI ACTV TRHFY600 and EYECRYL PLUS HFY600)

- One may experience some visual effects when focusing on several images at the same time. These effects may include rings or halos around lights at night.
- One may experience some difficulty in distinguishing objects from a dark background. This effect may be more noticeable in areas with less light, therefore, one should take extra care when driving at night.
- Patients with predicted postoperative astigmatism of >1 D may not be a suitable candidate for multifocal IOL implantation since they may not fully benefit from a Multifocal IOL in terms of potential spectacle independence.
- It is necessary to achieve perfect centration of the IOL
- The surgeon must target the emmetropic outcome for the surgery

Warnings specific to Toric IOLs (EYECRYL TORIC HFY, EYECRYL ACTV TORIC HFYD and EDOF TORIC IOL (EYECRYL PLUS HFY600)

- Do not implant the EYECRYL Toric IOL if neither the posterior capsule nor the zonules are intact enough to provide support for IOL.
- The intended axis must be perfectly aligned with EYECRYL Toric IOL's axis to get the desired visual outcome. Misalignment from the intended axis can a ffect the astigmatism correction.
- Remove viscoelastic from both the anterior and posterior side of the lens because residual viscoelastic may rotate the EYECRYL Toric IOL causing misalignment of the lens with the intended axis of placement.

Warnings specific to Multifocal Toric IOLs and EDOF Toric IOLs (EYECRYL ACTV TORIC HFYD and EYECRYL PLUS HFY600)

Note : *In addition to warnings specific to Multifocal IOLs, Toric IOLs, EDOF IOLs as mentioned above following must be considered while implanting EYECRYL ACTV Mutifocal Toric IOLs.*

- The long term effect of EYECRYL ACTV Toric IOL and EYECRYL PLUS HFY600 EDOF TORIC IOL are not studied and hence patients must be observed postoperatively at regular intervals by the ophthalmologists.

PRECAUTIONS

Precautions for use and storage

- IOLs must be handled by health professionals and implanted by physicians/trained Ophthalmologists only. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
- Single-use only.
- Do not reuse any of the parts. The used lens should be considered as biological waste. It may lead to any biological reactions including but not limited to inflammation, infection, injury , or any unknown clinical condition.
- Do not resterilize the product.
- Reuse and/or resterilization may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not use the product if the package is damaged or there are signs of leakage from the IOL vial.
- Do not use the product if the package was unintentionally opened before use.
- Do not use the product beyond the expiration date.
- Do not store the lens in direct sunlight or at a temperature greater than 45 °C.
- Do not freeze.
- Do not use the product if the package is wet.
- Do not use IOL if there is no fluid in the lens container.
- Do not use the storage liquid from the blister pack for intraocular irrigation. Use the only sterile intraocular irrigating solution to rinse/soak lenses.
- Do not allow the IOL to dehydrate during the procedure.
- Handle lenses carefully to avoid damage to the lens surfaces or haptics using smooth- edged forceps and lifting. Locking forceps or needle holders should never be used.
- Do not implant IOLs that are not compliant with the patient's specific biometrical parameters.
- Avoid decentration and tilt of the optical axis of the lens (risk of high-order aberrations).
- When inserting the lens with an injector system, the lens may form fold lines. These lines are reversible and are therefore not a reason to explant the lens.
- Discard cartridge & injector system used for the procedure after use.
- For toric IOLs: The reference axis of the cornea (normally 0°) must be identified before implantation.
- For toric IOLs: Pay special attention to the labeling as the dioptric power for toric IOLs can be stated either as "sphere (SPH) and cylinder (CYL)" or "spherical equivalent (SE) and cylinder (CYL)", please check the label carefully

Precautions should be exercised when considering the implantation of Monofocal IOLs

The safety and effectiveness of the IOLs have not been demonstrated in patients with the following pre-existing ocular conditions and intraoperative complications listed below. Careful pre- and perioperative evaluation and sound clinical judgment should be used by the surgeon to determine the risk/benefit ratio before implanting a lens in a patient with one or more of the conditions below:

- Perioperative complications (such as posterior capsule rupture, zonular damage, vitreous loss, significant anterior chamber bleeding, or choroidal hemorrhage)
- Uncontrollable positive intraocular pressure or glaucoma
- Aniridia
- Microphthalmos or macrophthalmos

Precautions should be exercised when considering the implantation of Multifocal and EDOF IOLs

- Progressive or unstable eye disease
- Macular degenerations
- Severe optic nerve atrophy
- Retinal conditions or predisposition to retinal conditions, previous history of or predisposition to retinal detachment or proliferative diabetic retinopathy
- Multifocal IOLS may slightly decrease the level of retinal detail during examination or treatment. This could make retinal laser surgery and the diagnosis of some conditions more challenging.
- Progressive diseases of the anterior segment of the eye (e.g. Rubeosis iridis, essential iris atrophy)
- Chronic anterior or posterior segment inflammation such as uveitis
- Corneal changes affecting visual acuity (such as endothelial corneal dystrophy or previous corneal transplant)
- Non-senile cataract (such as rubella or congenital cataract)

Precautions should be exercised when considering the implantation ofToric IOL s

- The surgeon should carefully conduct the preoperative evaluation and weigh the benefits Vs risk before implanting a lens in a patient with one or more of the following conditions:
- Pharmacologically non dilating pupils
- Vitreous Loss
- Uncontrollable Intraocular Pressure
- Inadequate capsular support
- Previous corneal transplant
- Glaucoma
- Aniridia
- Amblyopia
- Colour vision deficiency
- Irregular corneal aberration
- Corneal Endothelial Disease
- Retinal Degeneration

DIRECTIONS FOR USE

Preparatory Steps

- Prior to the implant, examine the IOL package for IOL size, Spherical Power, Cylinder Power, Axis of the IOL, expiration date and other specifications
- Check the integrity of the sterile packaging before use.
- Do not use if packaging integrity is found compromised.
- The IOL must be opened in a sterile environment and used as soon as possible after opening the box.
- After opening, verify primary package information (e.g., model, power, serial number) is consistent with the information on the outer package labeling.
- Open the blister pack then remove the screw cap from the vial by turning in the anticlockwise direction and remove the IOL from the holder in a sterile environment.
- Pick the lens haptic gently with the help of forceps while ensuring that no optic part is in contact with the forceps.
- Examine the lens optics as well as haptics part to ensure that no dust or particles have attached to it, and examine the lens optical surface for other defects.
- Soak & Rinse the IOL with a sterile balanced salt solution until ready for implantation.

Implanting Steps

- Surgery must be performed using non-toothed, polished instruments, especially when the IOL is handled prior to loading into the injector.
- It is recommended to use Bio Hydroject lens delivery system to implant the IOL.

Irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule

- Toric IOL: The flatter curvature (flatter meridian) is marked with two opposing lines that provide orientation for correcpositioning in the capsular bag. To obtain a correct position, align the orientation marks of the IOL (flat curvature) with the steeper meridian of the cornea. Residual viscoelastic may allow the lens to rotate causing misalignment of the toric IOL from the intended axis of placement.

OPERATIVE PROTOCOL

The protocol of implantation is the responsibility of the surgeon. He must decide the procedure which is the most adequate based on the techniques which are most current and best executed on his own experience.

DISPOSAL

Discarded IOLs (used or unused) are classified as medical (clinical) waste that harbors a potential infection or microbial hazard and must be disposed of accordingly

CLINICAL BENEFITS

- The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.
- Eyecryl Hydrophobic acrylic IOL provides functional far vision, imp roves patients' quality of life.
- Eyecryl Multifocal Hydrophobic acrylic IOLs provideintermediate and/or near vision along with far vision.
- Eyecryl Toric Hydrophobic acrylic IOLs correct corneal astigmatism.

STORAGE CONDITIONS

Store the product between 0°C to 45°C temperature

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

IMPLANT CARD

The implant card supplied with this device is to be completed by the healthcare provider. There is instruction for implant cards supplied with the product box. A product traceability label also supplied with this device must be affixed to the implant card as per the instructions for completion of the implant card provided.The additional labels can be used for the patient file or clinical follow up. Completed implant cards must be provided to the patient post-procedure.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Summary of Safety and Clinical Performance (SSCP) of this device is available on the EUDAMED website https://ec.europa.eu/tools/eudamed

REPORTING OF SERIOUS INCIDENTS:

Users should report the serious incident with medical device information to the manufacturer and/or to the national competent authority depending on the national practice.

Once corrective (or other) action is identified from the manufacturer, hospital administrators, medical practitioners, and other health-care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER.

For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medical-devices/contacts/index_en.htm

RETURN AND EXCHANGE POLICY

To return or exchange a product, please contact the manufacturer or your local distributor.

LIMITATION OF WARRANTY AND LIABILITY

Biotech accepts no liability for any injury suffered to patients as a result of any implantation method or technique used by a physician to implant the lens, any prescription, and use of the lens for any individual patient or patient's conditions. Biotech makes no expressed or implied warranties in connection with the sale of the IOL.

ELECTRONIC IFU

Any national version has been translated from the core English text. In case of discrepancy, English text shall be considered final. For the latest version of the IFU, please refer the English version of electronic IFU. The content of this document is subject to change without prior notice.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	Consult Instructions for use		Do not use if the package is damaged
	Use-by date (YYYY-MM)		Do not resterilize.
LOT	Batch Number		Do not re-use
SN	Serial number	STERILE R	Sterilized using irradiation
STER-LOT	Sterilization batch number	EC REP	European Representative
	Date of manufacture		Manufacturer
MD	Medical Device		Caution
	Temperature Limit		Keep Dry
	Keep away from sunlight	$Ø_B$	Body Diameter
A	A-Constant	$Ø_T$	Overall Diameter

biotech

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