# INSTRUCTIONS FOR USE

Trufold™
HYDROPHILIC FOLDABLE INTRAOCULAR LENS

**DEVICE DESCRIPTION:**

**Trufold - Multifocal Clear & Toric – Hydrophilic Foldable Intraocular Lenses** are UV absorbing optical implants for the replacement of human crystalline lenses. This special quality Lenses is manufactured from hi-quality clinical grade UV absorbing Hydroxyl Ethyl Methacrylate (HEMA). Trufold lenses are targeted for implantation in the capsular bag for the visual correction of aphakia in patients of old age or in whose case cataract lens has been removed. The optical portion is designed for folding prior to insertion, allowing the lens to be inserted through an incision size between 2.2 and 3.7 mm, depending upon the model. The lenses are available in powers (in situ) from -10.00 to 40.00 diopters with increments of 0.5 diopters.

Multifocal IOL is based on the principle of refractivity, whereby the incoming light is refracted to different focal points, due to the different radius of curvature on the posterior side of the optical part of the IOL. This model IOL reaches Multifocality by their different refractive power zones to provide far, Intermediate and near vision.

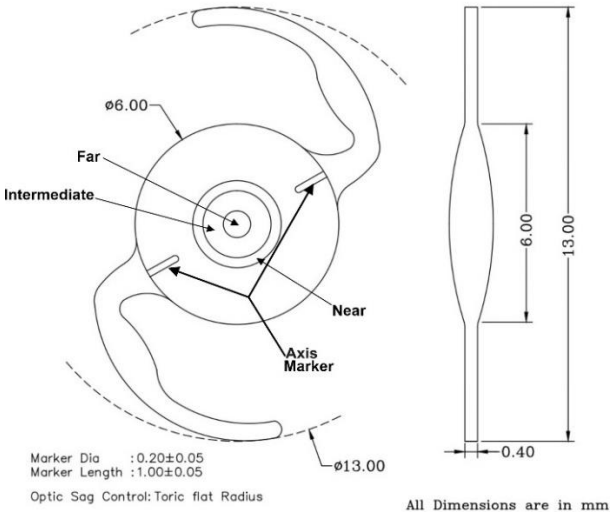
**Multifocal Toric – Clear:** Hydrophilic Multifocal Toric IOL offers combined advantages of Asphericity and Toricity. Biconvex Aspheric Optic with 360° posterior square edge. Anterior optic has additional power to offer cylindrical correction. The correction of Astigmatism of the Cornea is possible by the insertion of a TORIC IMPLANT that generates an astigmatism in opposite direction of the corneal one. It allows to neutralize the entire eye astigmatism. The Toric implant compensates for astigmatism induced by corneal. Multifocal lens implants are often a good choice if you suffer from both myopia or hyperopia and age – related focus problems(presbyopia). Standard multifocal lenses don't correct astigmatism, but there's now a premium multifocal/Toric lens that can do so.

Optic Material: Hydroxyl Ethyl Methacrylate (HEMA)
Optic Design: Multifocal, Spherical
Edge Design: Continuous 360° Posterior Square edge
Configuration: Biconvex
Diopter range: -10.00 to +40.0 diopters in 0.5 increments
Refractive:1.46
A-Constant :119.0
Toric IOL Cylinder Power available:1.5 to 4.0

**PRODUCT TECHNICAL SPECIFICATION:**

| Model | Optic size (mm) | Overall length (mm) | Position hole | Optic Design | Placement | Haptic Design | Image |
|---|---|---|---|---|---|---|---|
| TF 6013MF-Toric | 6.00 | 13.00 | 0 | Biconvex | Posterior Chamber | Flex Haptics |  |

# INSTRUCTIONS FOR USE




**Multifocal Clear & Toric Lens**

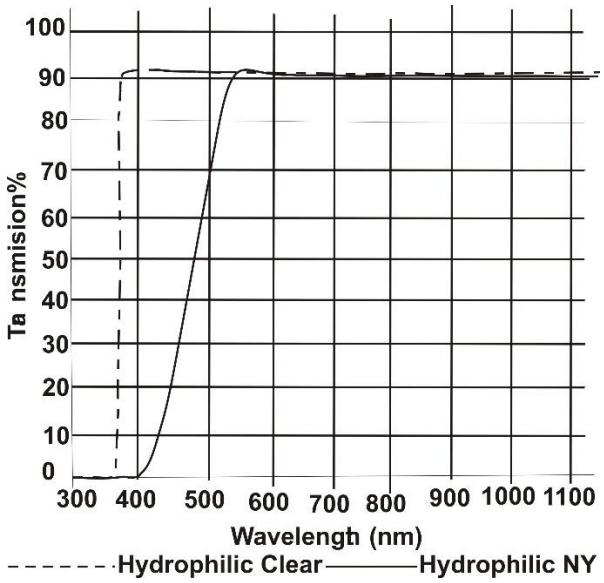



Figure 1 Transmittance graph of Hydrophilic Material

**INDICATIONS**

**Trufold - Multifocal Clear & Toric – Hydrophilic Foldable Intraocular Lens** is a clear HEMA one-piece Posterior Chamber Intraocular Lens. The intraocular lens is designed to be used for visual correction of aphakia for primary implantation for the visual correction of aphakia with adult patients where a cataractous lens has been removed by extracapsular extraction methods. It is intended for implanting in the Posterior chamber of the eye.

**INTENDED USER:**

Ophthalmic surgeons only.

**INTENDED PURPOSE:**

The Lens is intended to provide vision correction after the eyes natural lens is removed because of cataract surgery.

**PATIENT TARGET GROUP:**

Aphakic adult patients of age 18 years and above.

**MODE OF ACTION:**

# INSTRUCTIONS FOR USE

The **Trufold - Multifocal Clear & Toric – Hydrophilic Foldable Intraocular Lens** 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.
It functions as a refractive element to help in focusing the light rays which are coming through the cornea on to the retina.

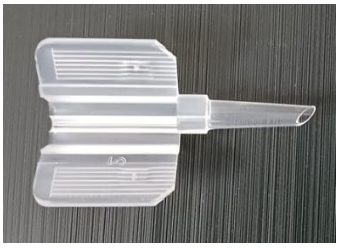
**CALCULATION OF LENS POWER**

The power of the lens to be implanted should be determined preoperatively.
Prerequisites of successful visual outcomes of cataract surgery include accurate biometry. Pre-surgery calculation of required lens power 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 Refract Surg. 1997;23(9):1356-70.

**RECOMMENDATION FOR CHOOSING LENS DELIVERY SYSTEM:**

The use of a lens delivery system is essential for the implantation of intraocular lens. It consists of cartridge, injector, and cushion.
All Monofocal Hydrophobic IOL is supplied in Single/Regular pack,
Lens Delivery System also can be supplied in Single pack along with IOL depending upon Surgeon's requirement.



**CONTRAINDICATIONS:**

- Patients with the following conditions are not suitable candidates for IOL operation. If doing so, it may pose unreasonable risk to the patient's eyesight.
- Prior intraocular surgery in the operative eye,
- Multiple surgical procedures,
- Acute infection or inflammation in the eye,
- Chronic use of steroids, or antineoplastic agents,

# INSTRUCTIONS FOR USE

- Aniridia
- Significant corneal or external surface disease e.g. dry eye, keratoconus,
- Rubella, traumatic or congenital / development of cataract
- Corneal dystrophy especially endothelial dystrophy, marked microphthalmous, marked macrophthalmous, Chronic medically uncontrolled glaucoma,
- Systematic diseases with ocular manifestations (e.g. diabetes, complications of AIDS) which may contribute to postoperative. confounding of data interpretation,
- Congenital bilateral cataracts,
- Patients with recurrent anterior or posterior segment inflammation of other forms of chronic angle closure glaucoma, and patients in whom IOL interfere with the ability to observe, diagnose, or treat posterior segment disease,
- Patients with only one eye with potentially good vision.

Certain surgical complications may occur which contraindicate the use of hydrogel lenses.
They include:

- Posterior capsular rupture,
- Detached Descemet's membrane,
- Significant anterior chamber bleeding,
- Iris damage, Vitreous loss,
- Persistent bleeding,
- Inability to clean the anterior chamber of vitreous.
- Uncontrollable positive pressure.

**WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISKS:**

- The complications listed below may occur following implantation of any 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. The risks of accidents and side effects are practically same as found during the extraction of cataract in particular: lens dislocation, non-pigment precipitates, corneal endothelial damage, high intraocular pressure, infection (endophthalmitis),corneal edema, pupillary membranes, flat anterior chamber, iris prolapse, hypopyon, and secondary glaucoma, Temporary Collapse of the anterior Chamber, Retinal detachment, Pupillary block, Iridocyclitis, Vitritis, Temporary Fistula, Cystoid macular edema, Formation of a posterior membrane, Hyphema, Vascular occlusion , Dystrophy of corneal endothelium, Striated Keratitis, Hernia of vitreous in anterior chamber, Subluxation or luxation of lens, Secondary reopacification, Evisceration or enucleation, Presence of Intra-ocular debris, Ophthalmitis, Malposition of the lens, Ablation of the lens.
- The effectiveness of UV-inhibiting intraocular lenses in reducing the incidence of retinal disorders has not been established.
- Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical clearances in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness and overall lens size on a patient's long-term clinical outcome must be carefully weighed against the potential benefit associated with the implantation of an intraocular lens. This is particularly true for anterior chamber lenses. The patient's clinical progress should be carefully monitored.
- Patient's regular follow-up is especially important after the implantation of the anterior chamber lens which includes the monitoring of the changes in the intraocular pressure and corneal endothelial cell count.

**PRECAUTIONS:**

- Do not attempt to re-sterilize this lens,
- Do not store the lens in direct sunlight, keep away from freezing.
- Do not use the lens if the sterile packaging has been opened or damaged,
- Do not soak the lens in solutions other than balanced salt solution or equivalent,
- A high level of surgical skill is required for intraocular lens implantation.

# INSTRUCTIONS FOR USE

- A surgeon should have observed or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
- Use injectors supplied by only Excel for implementing Foldable lenses, which minimize surgical trauma and in turn immediate post-operative inflammations.

**Note:** Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

Implantation of intraocular lenses should not be performed in patients under the age of 18.

**DIRECTIONS FOR USE:**

**Preparatory Steps:**

- Prior to implantation examine the lens of power, type, proper configuration, and optical surfaces.
- During insertion handle lenses by haptic portion only.
- Carton box contains extra labels. These are for convenience in maintaining and reporting records of implantable lenses during clinical investigation. One the labels could be affixed in patients case sheet, for future reference.
- "Rinse the lenses in sterile B.S. Solution before implantation to minimize the static discharge which enhance the microbial contamination".

**Implanting Steps:**

- In a sterile environment, peel apart to open the pouch and remove the lens case.
- Unscrew the lens case with care and grasp the lens optics using smooth edged forceps and lift.
- Soak or rinse lens in sterile balanced salt solution or sterile normal saline solution.
- The lens, due to some static charge produced while opening the lens case, may stick to the cap in rare instances.
- Ensure that the lens is in good condition for optic and haptic surfaces for adherence of any particles.
- Do not attempt to re sterilize this lens.
- Do not autoclave this lens.
- Handle the lens carefully. Locking forceps or needle holders should never be used to pick up lenses.
- Follow the instructions given in "INJECTING TECHNIQUE "given at the end of this IFU to Implant the IOL.

**CLINICAL BENEFITS:**

- The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.
- Trufold Lens provides functional far vision, improves patients' quality of life.

**HOW SUPPLIED:**

Each carton box contains one IOL, Injector, Cartridge, an implant card, (instructions for completion of implant card is given below) and product traceability labels. Trufold Intraocular lenses are supplied in a lens case contained within a heat-sealed Paper peel pouch and terminally sterilized using Steam Sterilization. IOL Disposable Injector and Cartridge are sterilized using Ethylene Oxide. The contents of the pouch are sterile unless the package is opened or damaged.

The outer box should be opened in sterile condition only.

**IMPLANT CARD**

The implant card supplied with this device is to be completed by the healthcare provider. A product traceability label also supplied with this device must be affixed to the implant card after completion of the surgery. 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. Patients should be instructed to keep the card as a permanent record of their implant. The patient should also be instructed to show the card to any eye practitioner he or she may see in the future.

**WARNINGS:**

- 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: Lens dislocation, non-pigment percolates, corneal endothelial damage, high intraocular pressure, infection, iritis, corneal edema etc.,

# INSTRUCTIONS FOR USE

- The safety of intraocular lens implantation has not been substantiated in patients with pre-existing ocular conditions (chronic drug myosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, history of retinal detachment or iritis etc) Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternative is deemed unsatisfactory to meet the needs of the patients.
- The long-term effect of intraocular lens implantation has not been determined. Therefore, Physicians should continue to monitor the patient's post-operative on a regular basis.
- Patients with ocular pathology, e.g. glaucoma or Corneal diseases may not achieve the visual acuity of patients without such problems. The intraocular pressure of implant patients with ocular pathology should be monitored post-operatively.
- Patients who experience operative complications should be carefully monitored for occurrence of these complications.
- The safety and effectiveness of the lens, if placed in anterior chamber lenses in the anterior chamber have been shown to be unsafe in some cases.
- The need for secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of intraocular implantation.
- The effectiveness of UV absorbing lenses in reducing the incidence of retinal disorder has not been established.
- Improper handling or folding techniques may cause damage to the haptic or optic portions of hydrophilic foldable lenses. If lenses are not folded according to directions, optic tears may result. Physicians should not attempt to implant lenses that have radial optic tears.

**REPORTING OF SERIOUS INCIDIENTS:**

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/medicaldevices/contacts/index_en.html

**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE:**

Summary of Safety and Clinical Performance (SSCP) of this device will be available on the EUDAMED website https://ec.europa.eu/tools/eudamed after notified body acceptance of SSCP.

**CAUTION:**

GOVERNMENT LAWS RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

**DISPOSAL**

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

**STORAGE CONDITIONS:**

Store 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.

**LIMITATION OF WARRANTY AND LIABILITY**

EXCEL OPTICS (P) LIMITED 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.

Excel Optics (P) Limited, makes no expressed or implied warranties in connection with the sale of the IOL.

**Symbols and their explanations**

# INSTRUCTIONS FOR USE

| | | | |
|---|---|---|---|
| EC REP | Authorized Representative in the European community | IOL | Intraocular Lenses |
| STERILE | Sterilized using Steam Sterilization | | Do not re-sterilize |
| 40°C 5°C | Storage Condition between 5°C to 40°C | | Keep away from sunlight |
| | Manufacturer | | Consult Instructions for Use |
| LOT | Sterile Batch No | | Keep Dry |
| UDI | Unique device identifier | MD | Medical Device |
| | For Cartridge - Single sterile barrier system | | Double sterile barrier system |
| # | Model Number | | Use by Date |
| | Do not Use If package is Damaged | | Date of Manufacturer |
| IN | Country of Manufacture | PC | Posterior Chamber |
| UV | Ultraviolet | | Do Not re-use |
| | Caution | SN | Serial Number |

EC REP

**MED DEVICES LIFESCIENCES B.V.**
Keizersgracht 482,
1017EG Amsterdam,
The Netherlands
Phone: +31 – 202254558,
Email:info@meddevices.net

**EXCEL OPTICS (P) LIMITED** CE XXXX
New No: 31A & 31B, Old. No: 15A & 15 B,
2nd Street, Logan than Nagar,
Choolaimedu, Chennai – 600 094.INDIA **ISO 13485:2016**
E-mail: excel_factory@hotmail.com **Certified Company**
www.exceloptics.net

# INSTRUCTIONS FOR USE

## INJECTING TECHNIQUE

### STEP BY STEP: INTRAOCULAR LENS.

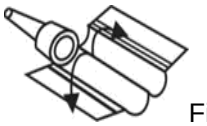


Fig.01

1. The Cartridge is to be opened 180° open position for most suitable position for loading the Lens.

2. Apply a thin layer of Viscoelastic in the lens loading chamber and a very small amount in the barrel and hinge will serve as a lubricant for the free movement of lens during the injection process**.**

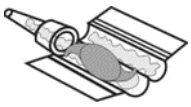


Fig.03

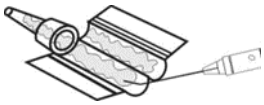


Fig.02

3. After the lens is well placed I the cartridge, ensure that it is correctly centered (Pl. See Fig.03)

4. Applying a few drops of BS
solution on the surface of the lens, as in Fig.04,will help to keep the lens in hydrated condition.As the lens is Hydrophilic in nature, this is helpful.

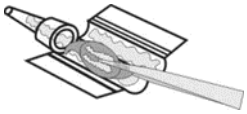


Fig.05

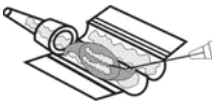


Fig.04

5. Using Flat Forceps gently press the center of the lens and at the same time closes the cartridge without pinching the loop or the sides of the optic.

6. Make sure neither the haptic nor the optics is caught in between the shutters (if it happens some gap will be observed between the shutters after closing the cartridge) as shown in Fig.06.If the gap is observed, repeat step no. 3,4& 5

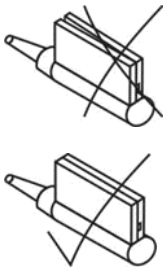


Fig.06

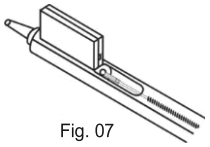


Fig. 07

7. Load the cartridge into the injector as shown in Fig .07 only if there is no gap between the shutters.

**Recommendation:** Do not push the plunger tip forcefully till the end of Cartridge- as shown in Fig.08.It may damage the cartridge and lens.

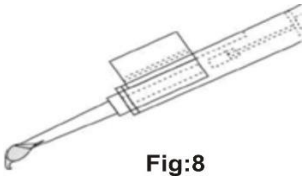
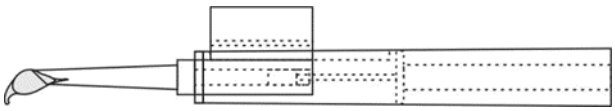


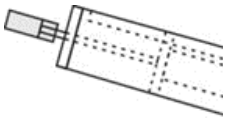
**Fig:8**

**Note:** Pushing the plunger tip till the end of cartridge tip is not necessary to deliver the lens. While pushing if you feel any resistance release the thumb and take the lens out. Immense the lens in BSS solution. Again reload the lens as per step no. 3,4 & 5



8. Gently push the lens and release the thumb, the same action can be repeated until the lens moves towards the cartridge tip end – as shown in Fig.09.

9.Gently release the thumb pressure given to plunger, when 80% of the lens is out.The Plunger will automatically come back, and at the same time the lens will pull itself out from the cartridge.If required, small push may be given to get the lens out fully.To avoid rotating of Lens while it is coming from the cartridge the lens has to be properly loaded in center of cartridge and near by barrel area.



**Applicable for soft disposable tip Injectors only**

Disposable tip has asoft silicone sleeve attached to one end of the plunger tip.

Hold the silicone covered end and insert the other end in to the tip of the plunger and straighten it tightly.

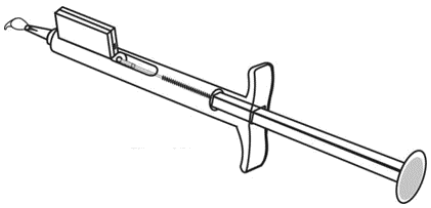


Fig.10

# INSTRUCTIONS FOR USE

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Rev. No MDR: 00
Rev.Date:01/2024