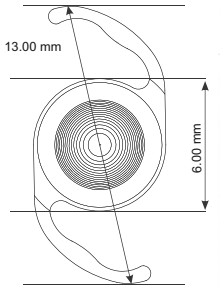
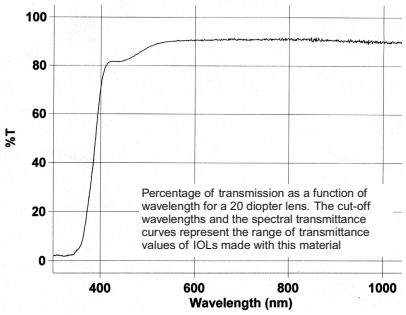
Foldable Hydrophobic Intraocular Lens (Sterile)

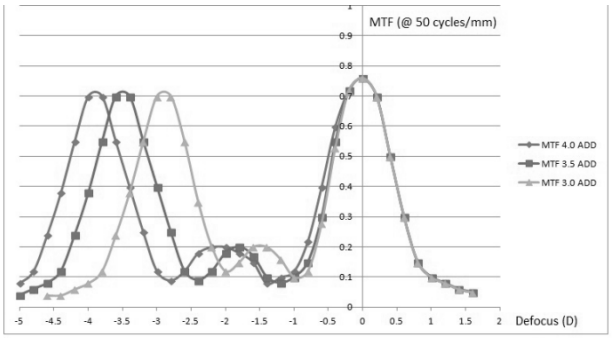
i-HTDIFF IOL +3.5

DESCRIPTION
The i-HTDIFF IOL +3.5 is yellow Foldable Hydrophobic Intraocular Lens. This hydrophobic one piece posterior chamber IOLs is 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. The surface of the lens has been modified refractive- diffractive and aspheric to allow distance, near and Good visual acuity in the intermediate range with sharper contrast.

Optic Material	: Hydrophobic Yellow Acrylate Copolymer
Optic Design	: Modified refractive - diffractive & aspheric surface
Configuration	: Biconvex optics
Diopter Range	: +0.0 D to +40.0 D (in 0.5 D Steps)
Addition	: +3.5 D (near vision) and +1.80 D (Intermediate vision)
Refractive Distance focus	: 50%
Diffractive Near focus	: 30%
Diffractive Intermediate focus	: 20%
Refractive Index	:1.53
Estimated A-Constant	: 118.8







INDICATION
Multifocal Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataract lens in patients (18 year or older) with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

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. These biconvex optic IOLs have an aspheric apodized diffractive structure on the anterior surface. The biconvex aspheric optic reduces spherical aberration as compared to a standard spherical optic in an average eye.

CLINICAL BENEFIT
The summary of safety and clinical performance will be added in IFU, Once the SSCP is reviewed by notified body and uploaded in EUDAMED.

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
- Amblyopia
- Squint
- Astigmatism > 1.5 D

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: 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

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 only be implanted by an experienced surgeon or a surgeon who has observed and/or assisted in numerous implantations procedures
- 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 unintentionally 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

DIRECTION FOR USE
- Prior to opening the box, verify the label for correct model, dioptric power and the expiration date
- After opening the box, verify case label information (model, dioptric power and serial number) and make sure it is consistent with the information printed on the outer box.
- This device is sterile until the inner pouch is opened. Inspect the pouch carefully for any residues
- In case tears, cuts, punctures, or other similar sign is observed, chances are that the pouch is 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 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.
- While removing lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled from the haptics. Handle the lens carefully to avoid damage to the lens surface or breaking of haptics. DO NOT attempt to reshape the device 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 no particles have adhered on instrument surfaces e.g. forceps
- The IOL should be stored at room temperature as recommended in the product IFU.
- I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH recommends using the lens delivery system manufactured by I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH.
- Kindly follow instructions given in Injector-Cartridge Information leaflet (IFU) for use of IOL delivery system
- To facilitate IOL insertion viscoelastic solution should be used

HOW SUPPLIED
The IOL 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.

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

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 EO

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