DEVICE DESCRIPTION

The 1stQ Preloaded Soft Hydrophobic Acrylic lens Injection System contains an intraocular lens loaded in a Single Use compatible injector.

The 1stQ Soft Hydrophobic Acrylic intraocular lenses (IOLs) are foldable posterior chamber, UV absorbing optical implant lenses used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. The yellow IOL also contains 1stQ's proprietary blue light filtering chromophore that filters light in a manner that approximates a young human crystalline lens in the 400-475 nm blue light wavelength range.

MODELS OF BASIS V HYDROPHOBIC ACRYLIC LENS

Model	One Piece	Aspheric	Monofocal	Toric	Multifocal	Yellow	Non-Yellow	Preloaded
B5ADY0	X	X	X			X		
B5AD00	X	X	X				X	
B5ABY0	X	X	X			X		X
B5AB00	X	X	X				X	X
B5TDY0	X	X		X		X		
B5TD00	X	X		X			X	
B5TBY0	X	X		X		X		X
B5TB00	X	X		X			X	X
B5EDY1	X	X			X	X		
B5ED01	X	X			X		X	
B5EBY1	X	X			X	X		X
B5EB01	X	X			X		X	X

The Models of Basis V are a foldable posterior chamber, one-piece acrylic lens with square edge, a 6.0 mm bioconvex optic, and an overall length of 13.0 mm used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. All models are manufactured at the following diopter power range: 0 to +10 in 1 diopter increments, and +10 to +30 diopters in 0.5 diopter increments. Refractive index of the material is 1.5.

The Basis V, Models B5AB-, Models, are preloaded aspheric monofocal intraocular lenses positioned and packaged in an injector system.

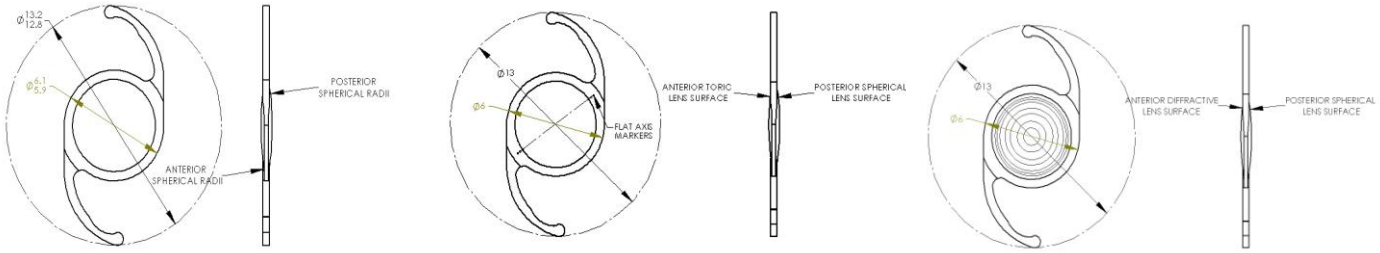
The Basis V toric, Models Model B5TB-, are preloaded aspheric intraocular lenses (positioned and packaged in an injector) with cylinders from +1.0D to +6.0D for the correction of corneal astigmatism, along with identification marks on the anterior optic to locate the axis of this toric correction to be matched with the steep axis of the cornea. The astigmatism to be corrected by the Basis V toric, Model B5T-, has to be determined by keratometry and biometry data keeping in mind that the size and location of the surgical incision can affect the amount and axis of corneal astigmatism. To optimize the selection of the proper IOL, a web-based calculator (www.1stq.de) is

provided for the surgeon. When the pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are entered, the web-based calculator will determine the appropriate Basis V toric, Model B5T-, cylinder power and axis of placement in the eye to be used.

The Models Basis V multifocal, Model B5EB-, are preloaded aspheric intraocular lenses (positioned and packaged in an injector system) with diffractive anterior optic with a near sight correction addition.

PHYSICAL CHARACTERISTICS

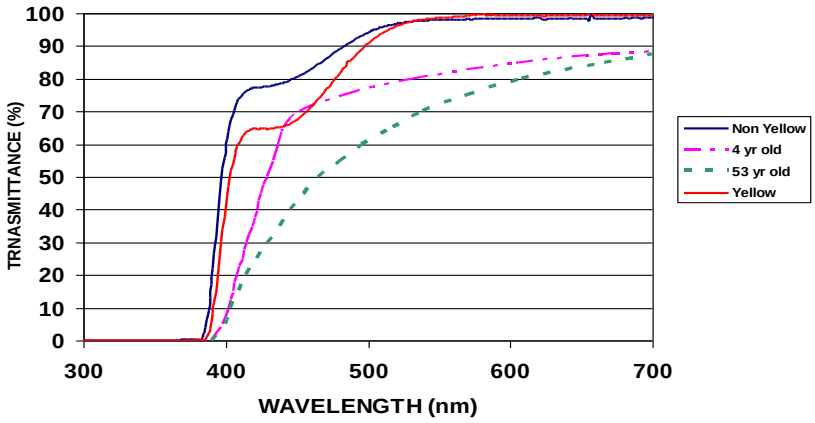
Monofocal Toric Multifocal



TRANSMITTANCE COMPARISON

Material	Characteristics	UV Cutoff at 10% T
Yellow	UV-Absorber + blue light filter	390nm
Non-Yellow	UV-Absorber	385 nm

SPECTRAL TRANSMITTANCE CURVE



DETAILED DEVICE DESCRIPTION

Lens Optic:

- Material: Soft Hydrophobic Acrylic with UV absorber
- Light transmission: UV cut-off at 10% T for a +20 diopter lens (non yellow) = 385nm

- Light transmission: UV cut-off at 10% T for a +20 diopter lens (yellow) = 388nm
- Index of refraction: 1.497
- Diopter power: +10 to +30 diopters in 0.5 diopter increments, and +18 to +28 diopters in 0.25 diopter increments
- Optic type: Biconvex
- Optic edge: Square on posterior surface and round on anterior surface
- Overall diameter: 13.0 mm
- Optic diameter: 6.0 mm
- Cylinder (Toric Lenses only- Anterior Optic): 1.0D to 6.0D in 0.5 diopter increments
- The Multifocal lens also has a near sight correction addition.

MODE OF ACTION

The Basis V posterior chamber intraocular lenses are 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. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established.

INDICATIONS

The Basis V posterior chamber intraocular lenses are indicated for the placement of the human lens to achieve visual correction of aphakia in adult patients when extracapsular cataract extraction or phacoemulsification is performed. These lenses are intended for placement in the capsular bag.

PRECAUTIONS

1. Do not resterilize the lens by any method.
2. Do not store the lens at a temperature greater than 45^{o}C (113^{o}F).
3. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse rinse/or soak lenses.
4. Handle lenses carefully to avoid damage to lens surface or haptics.
5. Do not attempt to reshape haptics in any way.
6. 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 lens.

CONTRAINDICATIONS

Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ration before implanting a lens in a patient with one or more of the following conditions.

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Excessive vitreous loss
4. Extremely shallow anterior chamber
5. Microphthalmos
6. Non-age-related cataract
7. Posterior capsular rupture (preventing fixation of IOL)
8. Severe corneal dystrophy

9. Severe optic atrophy
10. Uncontrollable positive pressure
11. Zonular separation (Preventing fixation of IOL)
12. Color vision deficiencies
13. Glaucoma
14. Chronic uveitis
15. Diabetic retinopathy
16. Clinically significant macular/RPE changes

Additionally for Basis V multifocal IOL implantation:

1. Patients with ocular disorders, other than cataract, that could potentially cause future acuity losses up to a level of 0,66 or worse in either eye
2. Patients who are expected to require retinal laser treatment
3. Patients unlikely to achieve less than 1,5 diopters of post-operative astigmatism
4. Patients unlikely to adopt to simultaneous multiple retinal images
5. Patients who need very good near vision in semi darkness
6. Individuals who drive at night for a living or whose occupation or hobbies depend on good night vision,
7. Individuals who are amateur or commercial airline pilots
8. Individuals who are happy wearing glasses

WARNINGS

The lens should not be implanted in the following conditions:

1. The posterior capsule is ruptured or if a primary capsulotomy is to be performed.
2. The peel pouch is found to be damaged or opened.
3. Suspected microbial infection.
4. Recurrent severe anterior or posterior segment inflammation or uveitis.
5. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
6. Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
7. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
8. Circumstances that would result in damage to the endothelium during implantation.
9. Children under the age of 2 years are not suitable for intraocular lenses.
10. For Toric IOLs only: rotation away from intended axis may reduce the astigmatism correction. Any misalignment greater than 30° can increase postoperative refractive cylinder.

Note: Device is intended for single use only. Violation of this requirement may result in degradation of the device which will cause diminished visual acuity and / or cross-contamination / infection of the patient.

COMPLICATIONS

The following lists the complications which have been associated with the implantation of intraocular lenses (this list is not intended to be all-inclusive):

Cumulative Adverse Events:

1. Hyphema
2. Hypopyon
3. Lens Dislocation

4. Cystoid Macular Edema
5. Pupillary Block
6. Retinal Detachment
7. Intraocular Infection
8. Secondary surgical intervention (excluding retinal detachment and posterior capsulotomy), including, but not limited to, the following:
   a) Iridectomy for papillary block
   b) Vitreous aspiration for papillary block
   c) Repositioning of lens
   d) IOL removal for inflammation
   e) IOL replacement

Persistent Adverse Events:

1. Corneal Stroma Edema
2. Cystoid Macular Edema
3. Iritis
4. Raised IOP requiring treatment

DIRECTION FOR USE (PRELOADED)

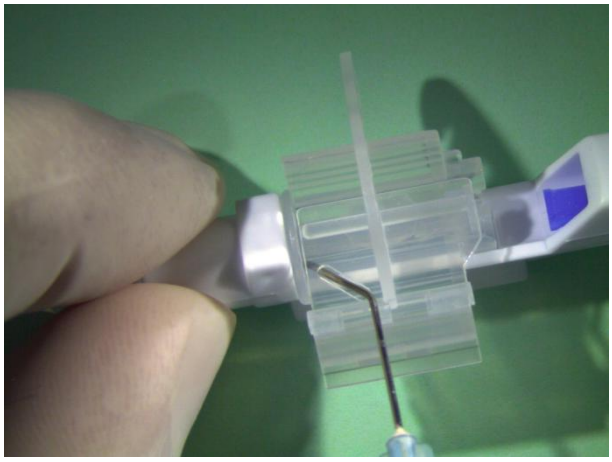
1. Examine the label on the preloaded lens box for proper lens model, diopter power and expiration date.

2. Open the preloaded lens box to remove the sealed blister pack containing the intraocular lens inside an injector and verify that the label information on the Tyvek seal (e.g. power, model, serial number, and expiration date) is consistent with the information on the outer box.

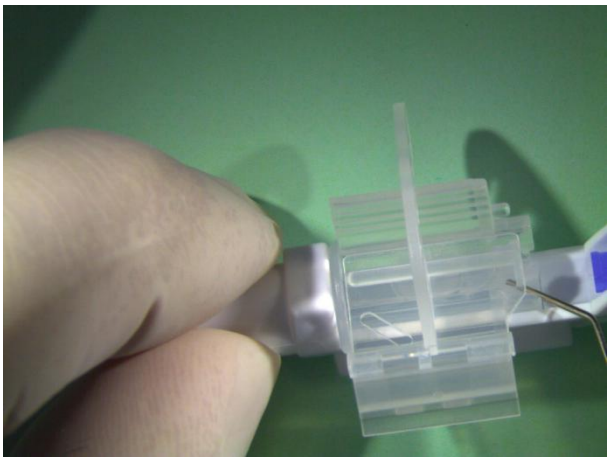
3. Ensure that the blister pack is not damaged and the seal is not broken.

4. Remove the injector from the blister pack.

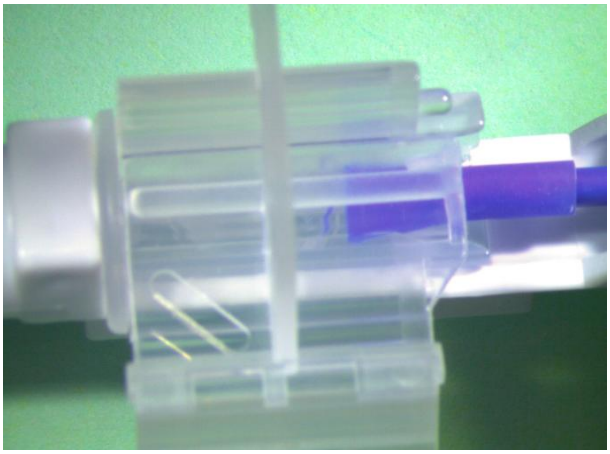
5. Inject a generous amount of commercially available viscoelastic material into the injector cartridge through the slot of the lens holder until it is filled to the very tip.



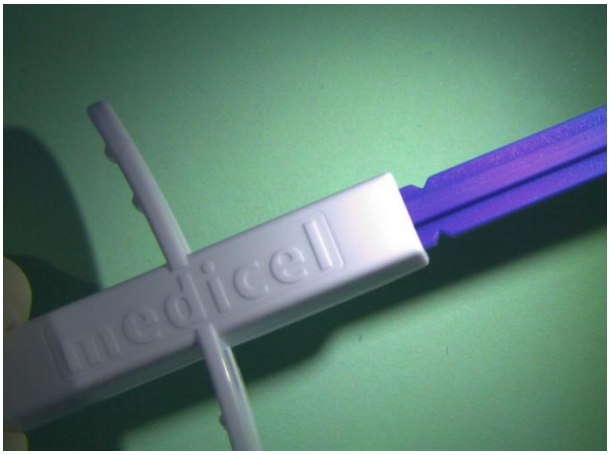
6. Inject a small amount of viscoelastic material into the rear area of the lens holder and underneath the intraocular lens. Put a drop of viscoelatic at the very end of the lens holder to ensure easy entry of the soft tip.



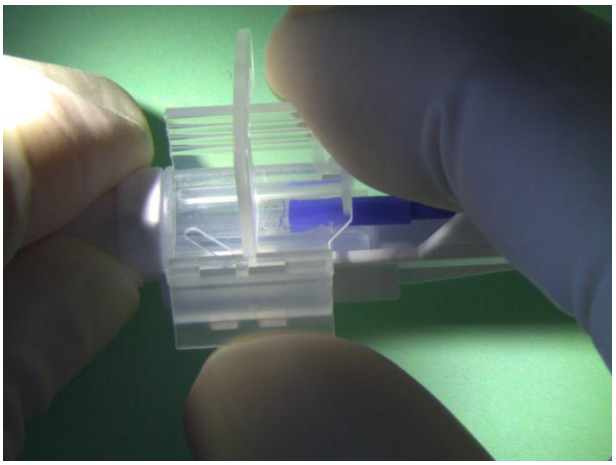
7. In order to pre-fold the haptics, advance the plunger carefully.



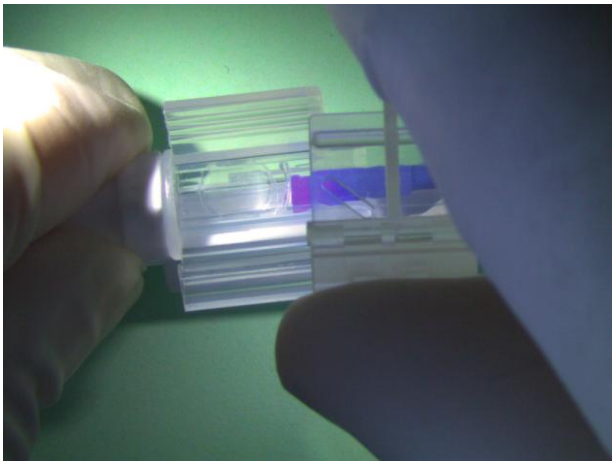
8. As soon as the mark on the plunger matches the end of the injector body and the snapper on the plunger snaps into the second hole of the injector body, stop pushing. Haptics are now properly pre-folded.



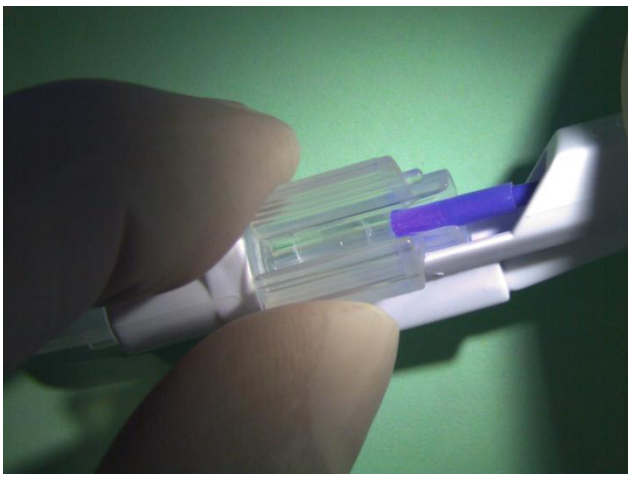
9. Release the lens holder by lifting up the clip with your thumb.



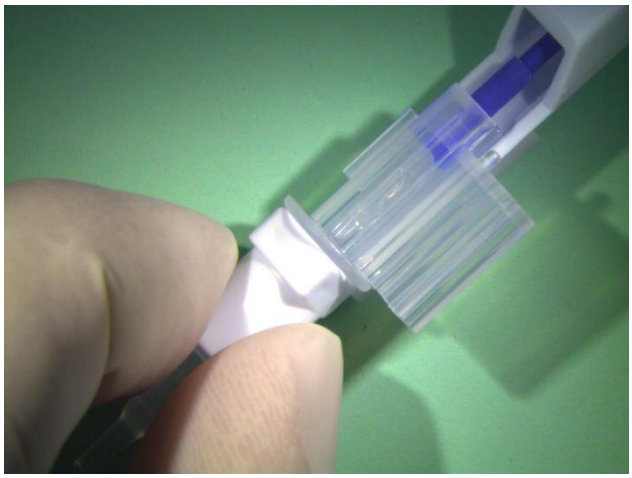
10. Remove the lens holder carefully and ensure that IOL and silicone cushion are not displaced and the leading and trailing haptics remain positioned underneath the ridges.



11. Close the loading chamber (the IOL automatically folds into the chamber) until the click-lock mechanism engages.



12. Advance the injector plunger and push the IOL out of the loading chamber into the conical tip of the cartridge. Ensure that the lens moves forward smoothly. If excessive resistance is felt, retract the plunger to allow the cushion to separate from the IOL.



13. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.

14. DO NOT RESTERILIZE.

HOW SUPPLIED

The preloaded system for the Soft Hydrophobic Acrylic Intraocular Lenses are supplied dry, in an injector in a blister pack covered with a Tyvek peel cover and terminally sterilized by ethylene oxide. The preloaded system must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

EXPIRATION DATE

The packaged preloaded Soft Hydrophobic Acrylic Intraocular Lens is sterile unless the peel tyvek seal is damaged or opened. There is a sterility expiration date clearly indicated on the peel tyvek seal and the outside box label. The Soft Hydrophobic Acrylic Intraocular Lens should not be used after that date.

SYMBOLS USED ON BOX

SYMBOL	ENGLISH
D (dpt.)	Diopter (power, spherical)
CYL	Cylinder
	Sterilized by Ethylene Oxide
	Use by YYYY, MM
	Watch storage temperature
	Protect from sunlight
	Protect from humidity
	DO NOT REUSE
	See instruction for use
	Do not use if box is damaged
	Manufacturer
	Serial number
RX only	By prescription or order of a physician only

Manufacturer:

GEMMA Medical AG
Mattenstrasse 11
CH-2555 Bruegg/Schweiz

CE 1250

Distributor:

1stQ GmbH
Harrlachweg 1
D-68163 Mannheim/Deutschland
Tel.: +49-621-78953790
Fax: +49-621-78953791
www.1stq.de info@1stq.de

Injector supplied by:

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