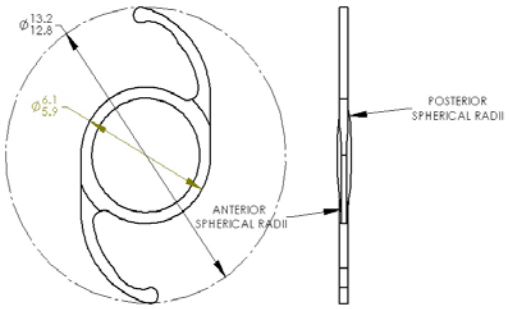
## DEVICE DESCRIPTION

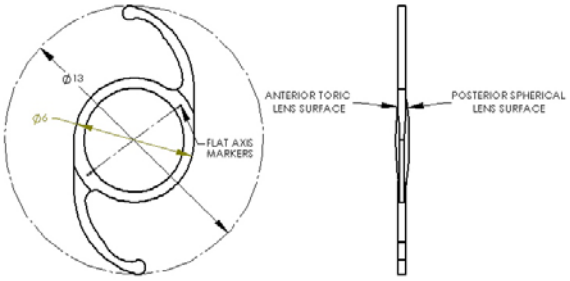
The 1stQ Basis V Hydrophobic Acrylic Intraocular Lenses (IOLs) are sterile foldable one-piece posterior chamber, UV or UV+blue light filtering aspheric optical implant lenses with a square edge, used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. The yellow IOL also contains 1stQ's 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.

### Physical Characteristics of Basis V IOLs (all dimensions in mm)

Monofocal

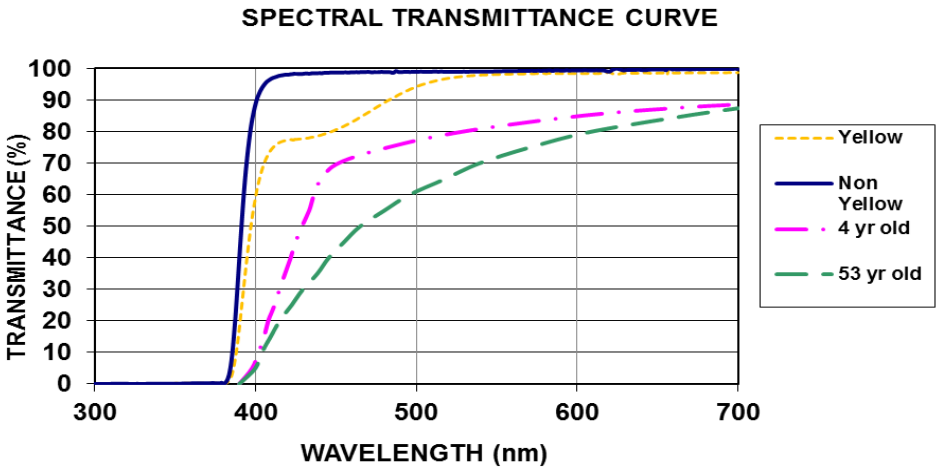



Toric




### Physical Characteristics of Basis V IOLs

| Characteristics | Model | | | |
|---|---|---|---|---|
| | B5ADY0 | B5AD00 | B5TDY0 | B5TD00 |
| | Monofocal IOL | | Toric IOL | |
| Optic Type | Biconvex Aspheric Optic | | Biconvex Toric Aspheric Optic | |
| Optic/Haptic Material | Ultraviolet and blue light filtering Acrylic | Ultraviolet filtering Acrylic | Ultraviolet and blue light filtering Acrylic | Ultraviolet filtering Acrylic |
| IOL Powers (diopter) | +1.0 to +30.0 | | +10.0 to +30.0 | |
| IOL Cylinder Power (diopter) | 0 | | +1.0 to +6.0 | |
| Index of Refraction | 1.50 | | | |
| Optic Edge | Square | | | |
| Optic Diameter (mm) | 6.0 | | | |
| Overall Length (mm) | 13.0 | | | |
| Haptic Angle | 0° | | | |




NOTE:
• Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center of a 20.0 D lens.
• Human lens data from Boettner and Wolter (1962).

Average % Transmittance of B5ADY0 and B5TDY0 (20.0 D)

| Model | 400 nm | 425 nm | 450 nm | 475 nm |
|---|---|---|---|---|
| B5ADY0/B5TDY0 | 55 | 75 | 78 | 87 |

## MODE OF ACTION

The 1stQ Basis V posterior chamber intraocular lenses are intended to be implanted 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 toric IOLs have a biconvex toric aspheric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL cylinder axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism.

## INDICATIONS

The 1stQ Basis V monofocal and toric posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia and pre-existing corneal astigmatism, respectively, in adult patients when extracapsular cataract extraction or phacoemulsification is performed. The Basis V toric lenses provide patients with improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision following removal of a cataractous lens. These lenses are intended for placement in the capsular bag.

## WARNINGS

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances that could increase complications or impact patient outcomes. This lens should not be implanted under the following conditions:

1. If the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. The 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.

## PRECAUTIONS

1. Do not resterilize the lens by any method.
2. Do not store the lens at a temperature greater than 45°C (113°F).
3. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to 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.
7. For Basis V Toric Lenses:
    a. Accurate keratometry and biometry in addition to the use of the Toric Calculator (www.1stQ.eu) are recommended to achieve optimal visual outcome.
    b. Rotation of Basis V Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, the lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.
    c. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the Basis V Toric IOL with the intended axis of placement.

## 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.

Before Surgery:

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Extremely shallow anterior chamber
4. Microphthalmos
5. Non-age-related cataract
6. (Proliferative) diabetic retinophathy
7. Severe corneal dystrophy
8. Severe optic nerve atrophy
9. Irregular corneal astigmatism
10. Medically uncontrolled glaucoma
11. Chronic uveitis
12. Clinically significant macular/RPE changes

During Surgery:

1. Excessive vitreous loss
2. Capsulotomy by any technique other than a circular tear

3. The presence of radial tears known or suspected at the time of surgery
4. Situation in which the integrity of the circular tear cannot be confirmed by direct visualization
5. Cataract extraction by techniques other than phacoemulsification or liquefaction
6. Situation where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
7. Posterior capsular rupture (preventing fixation of IOL)
8. Zonular damage (Preventing fixation of IOL)
9. Uncontrollable positive pressure
10. Significant anterior chamber hyphema

## 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. Corneal endothelial damage
2. Infection (endophthalmitis)
3. Hyphema
4. Hypopyon
5. Lens Dislocation
6. Cystoid macular edema
7. Corneal edema
8. Pupillary block
9. Cyclitic membrane
10. Isis prolapse
11. Retinal detachment
12. Vitritis
13. Transient or persistent glaucoma
14. Secondary surgical intervention (excluding retinal detachment and posterior capsulotomy), include, 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
    f) Wound leak repair

Persistent Adverse Events:

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

## DIRECTION FOR USE

1. Examine the label on the lens box for proper lens model, diopter power and expiration date.
2. Open the lens box to remove the sealed pouch and verify that the label information (e.g. power, model, serial number, and expiration date) is consistent with the information on the outer box.
3. Ensure that the pouch is not damaged and the seal is not broken.
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens. When removing the lens from the case, DO NOT grasp the optic area with forceps. Prior to actual folding process, the lens should be handled by the haptic portion only.
5. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
6. To minimize the occurrence of marks on the lens due to folding, all instrument should be scrupulously clean.

7. DO NOT reuse or resterilize this IOL. This device is for single use only.

## HOW SUPPLIED

The 1stQ Basis V Acrylic Intraocular Lenses are supplied dry, in a lens tray packaged in a peel pouch and terminally sterilized by ethylene oxide. The lens system must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

## EXPIRATION DATE

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

## SYMBOLS USED ON BOX

| SYMBOL | ENGLISH | SYMBOL | ENGLISH |
|---|---|---|---|
| D (dpt.) | Diopter (power, spherical) |  | Do not reuse |
| CYL | Cylinder |  | See instruction for use |
|   | Sterilized by Ethylene Oxide |  | Do not use if box is damaged |
|  | Use by YYYY-MM |  | Manufacturer |
|   | Storage temperature |   | Serial number |
|  | Protect from sunlight |  | CE-certified |
|  | Protect from humidity | | |


**Manufacturer:**

GEMMA Medical AG
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CH-2555 Bruegg/Switzerland

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