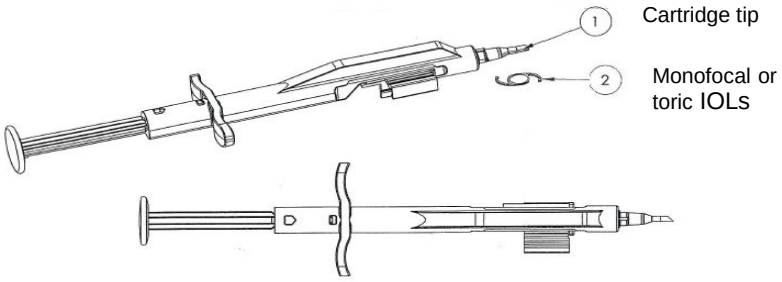
DEVICE DESCRIPTION

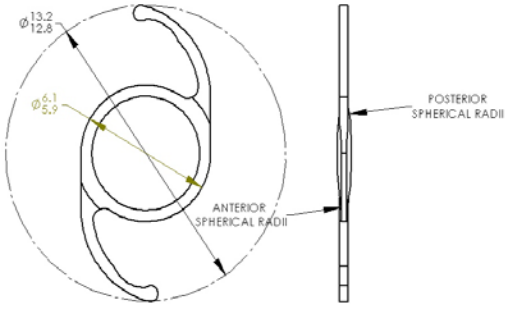
The 1stQ Basis V Preloaded Hydrophobic Acrylic Intraocular Lens System is a fully preloaded implantation system at 2.4 mm or less incision with clear (UV filtering) and yellow (UV+blue light filtering) monofocal (B5ABY0 and B5AB00) or toric (B5TBY0 and B5TB00) IOL for a safe, reliable and efficient minimal invasive surgery.

The 1stQ Basis V 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.

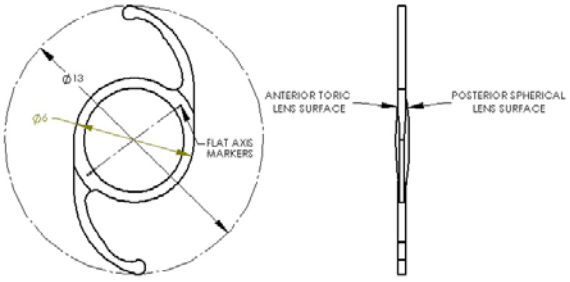
Physical Characteristics of Basis V Preloaded IOL Systems (all dimensions in mm)



Monofocal

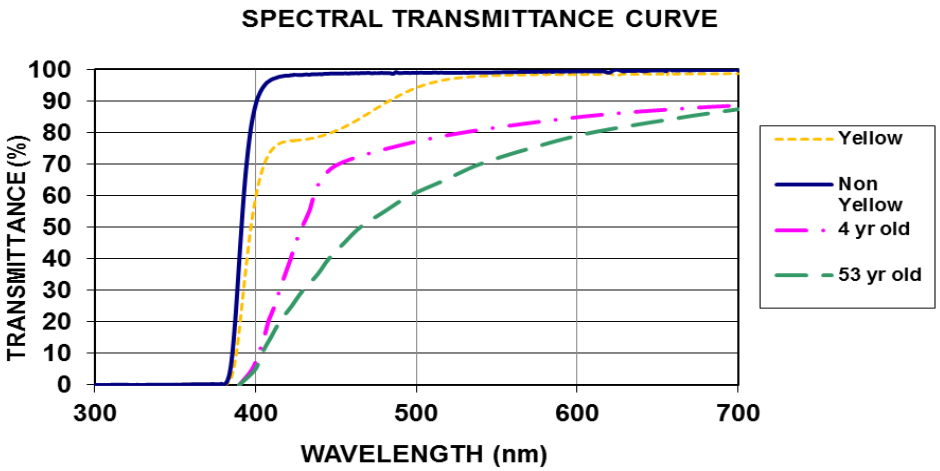


Toric



Physical Characteristics of Basis V Preloaded IOLs

Characteristics	Model			
	B5ABY0	B5AB00	B5TBY0	B5TB00
	Preloaded Monofocal IOL		Preloaded 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 B5ABY0 and B5TBY0 (20.0 D)

Model	400 nm	425 nm	450 nm	475 nm
B5ABY0/B5TBY0	55	75	78	87

MODE OF ACTION

The 1stQ Basis V preloaded posterior chamber intraocular lenses are fully preloaded and offer surgeons with ease of use for a safe, reliable and efficient minimally invasive surgery. The lenses are intended to be delivered in the preloaded injector and 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 preloaded 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 Tyvek cover of the blister pack 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. Do not re-use the device. The device is for single use only. Re-use of the lens and/or injector may cause re- or cross-infection leading to patient infection or lens explanted.
4. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse/or soak lenses.
5. Handle lenses carefully to avoid damage to lens surface or haptics.
6. Do not attempt to reshape haptics in any way.
7. 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.
8. For Basis V Preloaded 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 (severe)
7. Severe corneal dystrophy
8. Severe optic nerve atrophy
9. Irregular corneal astigmatism
10. Medically uncontrolled glaucoma
11. Chronic severe uveitis
12. Diabetic retinopathy
13. 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. Toxic anterior segment syndrome (TASS)
4. Hyphema
5. Hypopyon
6. Lens Dislocation
7. Cystoid macular edema
8. Corneal edema
9. Pupillary block
10. Cyclitic membrane
11. Iris prolapse
12. Retinal detachment

13. Vitritis
14. Transient or persistent glaucoma
15. 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 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 in the preloaded lens injector chamber and verify that the label information on the Tyvek cover (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. Grip the corner of blister pack, carefully peel open the Tyvek cover fully and transfer the device to a sterile environment. If the device appears to have damage, particulates or deformation after inspection, use another preloaded lens injectable system.
   NOTE: When ready to prepare the device for delivery, perform steps 5 and 6, with minimal delay between steps.
5. Apply ophthalmic viscosurgical device (OVD), either sodium hyalauronate (HA) or preferably HPMC (hydroxypropylmethylcellulose) based viscoelastic materials, in two places as shown in the photos :
    a. Insert the OVD cannula in the front of the injector tip and fill the tip with OVD. (Figure 1)
    b. Fill very small amount of the OVD only under the lens by placing the OVD cannula alongside the plunger under the loading chamber cover under the lens. (Figure 2)

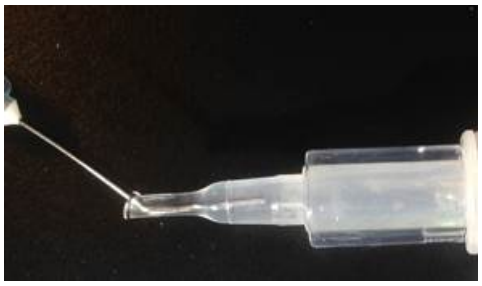


Figure 1

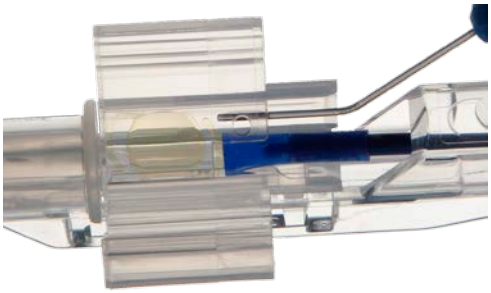


Figure 2

6. Close the preloading chamber flap (the IOL automatically folds in chamber) until the click-lock mechanism engages (Figure 3, 4). Do not advance the plunger forward.

   IMPORTANT: The IOL can be left in this folded position (Figure 4) for a period of 30 seconds to 3 minutes. Do not advance the plunger forward until ready for step #7 below

Figure 3

Figure 4

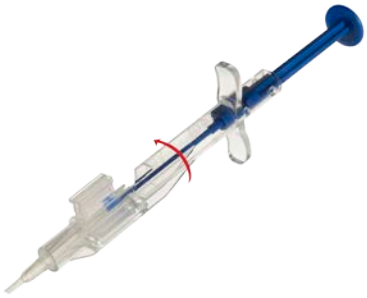


Figure 5

7. Rotate the injector counterclockwise 90°, as indicated in the photo above (Figure 5). Insert the cartridge tip in the incision. Proceed to push the plunger forward smoothly but continuously until the lens is properly placed in the capsular bag.
8. There are various surgical procedures, which can be utilized, and the surgeon should select a procedure, which is appropriate for the patient.
9. DO NOT reuse this preloaded IOL system. This device is for single use only.

HOW SUPPLIED

The 1stQ Preloaded Basis V Acrylic Intraocular Lenses are supplied dry, fully preloaded in an injector packaged in a blister pack sealed with a Tyvek peel cover and terminally sterilized by ethylene oxide. The preloaded lens system must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

EXPIRATION DATE

The packaged Basis V preloaded Hydrophobic Acrylic Intraocular Lens is sterile unless the Tyvek cover seal is damaged or opened. There is a sterility expiration date clearly indicated on the blister pack and the outside box label. The Preloaded 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	RX only	By prescription or order of a physician only
	Protect from humidity		CE-certified

Manufacturer:

GEMMA Medical AG
Mattenstrasse 11
CH-2555 Bruegg/Switzerland

Distributor:

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

Injector supplied by:

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