enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens

DEVICE DESCRIPTION

The enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens (enVista Toric IOL) is a single-piece ultra-violet absorbing posterior chamber intraocular lens developed to replace the natural crystalline lens in adult patients in whom the cataractous lens has been removed. The enVista Toric IOL has an aspheric optic that is designed to be free of spherical aberration through the incorporation of a proprietary spherical aberration-neutral optic design that does not influence the pre-surgical corneal spherical aberration profile. The optic is designed with the SureEdge™, posterior squared step edge to provide a 360 degree PCO barrier. The enVista Toric IOL employs an Accuset™ haptic with a broad, modified C-loop design and optic-haptic offset to facilitate improved contact and stability within the capsular bag. The posterior located cylinder axis marks denote the meridian with the lowest power. The enVista material that makes up the TruSight™ optic has been assessed for glistening-free capacity and scratch resistance.

PHYSICAL CHARACTERISTICS OF enVista TORIC IOL MODEL MX60T

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Lens / Haptic Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)-polyethylene glycol phenyl ether acrylate (poly(EG)PEA)-styrene copolymer, crosslinked with ethylene glycol dimethacrylate)						
Material Characteristics	Index Of Refraction: 1.54 @ 35°C ; Specific Gravity: 1.19 g/ml						
Optic Type / Powers	Aspheric / +6.0 to +30.0 Diopters in 0.5 Diopter increments (SE – Spherical Equivalent)						
Cylinder Powers (CYL) – IOL Plane		1.25 D	2.00 D	2.75 D	3.50 D	4.25 D	5.00 D	5.75 D
Cylinder Powers (CYL) – Corneal Plane		0.90 D	1.40 D	1.93 D	2.45 D	2.98 D	3.50 D	4.03 D
Dimensions	Body Diameter: 6.0 mm ; Overall Diameter: 12.5 mm ; Haptic Angle: 0°							
Spectral Transmittance	**Ultraviolet:** UV(363) for +20.0 diopter IOL See figure **1** with chart's **X** value = Wavelength (nm) and **Y** value = % Transmittance; chart compares the transmittance curve of an enVista Toric MX60T Lens to a 53 Year Old Human Lens. **A** = + 20 Diopter enVista Toric MX60T Lens and **B** = 53 Year Old Human Lens. **NOTE:** Light transmittance values for an IOL material may vary slightly depending on the method of measurement. **Reference:** 53 year old human lens data from Boettner, E.A. and Wolter, J. R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962						

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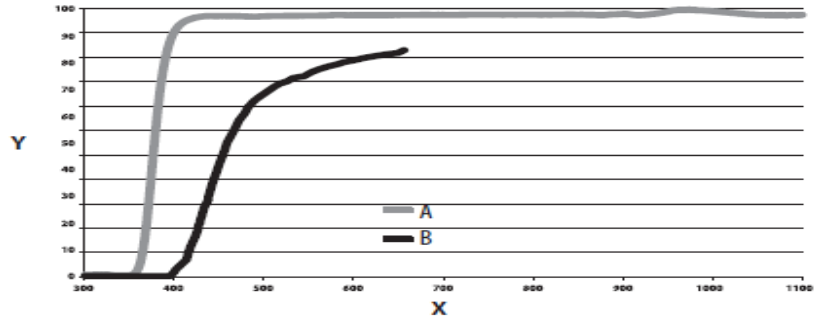

INDICATIONS

The enVista One-Piece Hydrophobic Acrylic Toric IOL (Model MX60T) is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision.

WARNINGS

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
8. Rotation of enVista Toric IOL away from the intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens positioning should occur prior to capsule fibrosis and lens encapsulation.

PRECAUTIONS

1. Do not attempt to resterilize the lens as this can produce undesirable side effects.
2. Do not use if product sterility or quality is thought to be compromised due to damaged packaging or signs of leakage (such as the loss of saline storage solution, or the presence of salt crystallization).
3. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
4. Do not store the lens at a temperature greater than 43˚C (109˚F) or lower than 0˚C (32˚F). Do not autoclave the intraocular lens.
5. Do not re-use the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
6. The safety and effectiveness of the enVista Toric IOL have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions. Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

Before Surgery

Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
• Amblyopia
• Clinically severe corneal dystrophy (e.g., Fuchs')
• Rubella, congenital, traumatic or complicated cataracts
• Extremely shallow anterior chamber, not due to swollen cataract
• Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
• Aniridia
• Iris neovascularization

• Glaucoma (uncontrolled or controlled with medication)
• Microphthalmos or microphthalmos
• Optic nerve atrophy
• Previous corneal transplant
• Pre-existing ocular conditions which may negatively impact stability of the implant.

During Surgery
• Mechanical or surgical manipulation required to enlarge the pupil
• Vitreous loss (significant)
• Anterior chamber bleeding (significant)
• Uncontrollable positive intraocular pressure
• Complications in which the IOL stability could be compromised.

7. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
8. 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 lenses.
9. 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: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, acute corneal decompensation, toxic anterior segment syndrome (TASS), and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
10. Care should be taken to remove all viscoelastic from the anterior and posterior surfaces of the lens, to minimize the possibility of lens rotation causing misalignment of enVista Toric IOL from the intended axis placement.
11. Effectiveness of implanting a toric lens in reducing postoperative astigmatism is affected by many factors, including the following:
• The degree of mismatch between the postoperative magnitude of corneal astigmatism and effective IOL power in the corneal plane.
• Misalignment between the intended axial position and final IOL axial orientation.
• Error in prediction of the postoperative corneal cylinder axis and power. Error in prediction of cylinder axis is greatest for lower levels of preoperative corneal astigmatism.
• Manufacturing variation in power and axis markings can influence intended correction.

Adverse Events

The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ["FDA grid") population (see Table 10). The enVista Toric IOL demonstrated favorable safety compared with the Control IOL and the historical control (cf. ISO 11979-7 SPE) population, with no increase in incidence or severity of adverse events (AEs) compared with the Control IOL and no serious adverse events (SAEs) in the study eye. Overall, no safety signals were associated with the toric IOLs during this study. As with any surgical procedure, risk is involved. Potential adverse events accompanying cataract or implant surgery may include, but are not limited to, the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, acute corneal decompensation, toxic anterior segment syndrome (TASS), and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

SELECTION AND PLACEMENT OF enVista TORIC IOL

Keratometry and biometry data should be used in place of refractive data to determine targeted amount of astigmatism correction. Incision size and location influence amount of postoperative corneal astigmatism and its respective axis. It is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results. To facilitate IOL selection and axis placement, B+L provides a web-based proprietary tool, the enVista Toric Calculator (http://envista.toriccalculator.com) for the surgeon. Preoperative keratometry and biometry data, incision location, spherical equivalent IOL power, and the surgeon's estimated surgically induced corneal astigmatism are used as inputs for the enVista Toric Calculator. These inputs are used to determine the axis of placement in the eye and the predicted residual refractive astigmatism for up to three different enVista Toric IOL models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of the enVista Toric IOL will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a toric IOL. Prior to surgery the operative eye should be marked in the following manner: With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement. Input from the enVista Toric calculator can be used to determine optimal axis of placement. Toric axis markings at the haptic-optic junction identify the flat meridian of the enVista Toric IOL and represent an imaginary line of the plus cylinder axis. After the lens is inserted in the capsular bag, precisely align the axis markings on the enVista Toric IOL with the marked axis of lens placement. Be sure to remove all viscoelastic from the capsular bag. Reconfirm proper alignment of the enVista Toric IOL following viscoelastic removal and/or inflation of the capsular bag at the end of the surgical case. Residual viscoelastic and/or over-inflation of the bag may cause lens rotation away from the intended axis of placement. Deviation from the intended axis of placement may compromise effectiveness of astigmatic correction. Inaccurate astigmatism measurements, errors in corneal markings, inaccurate placement of the enVista Toric IOL axis during surgery, unanticipated surgically induced changes in the cornea, or physical rotation of the lens after implantation may also limit the desired effect of the toric IOL on correction of corneal astigmatism.

CALCULATION OF LENS POWER SUGGESTED A-CONSTANT: 119.1 (OPTICAL BIOMETRY)

The recommended A-Constant of 119.1 is intended for use with axial length measurements obtained by optical biometry. Use of axial length measurements by other techniques (e.g. Applanation A-scan) will normally require a different lens constant. This number is a guideline only and is based on an evaluation of clinical data obtained using the IOL Master. The physician should determine preoperatively the power of the lens to be implanted.

DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the vial in a sterile environment.
3. Remove the lid from the vial.
4. With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
5. Rinse the entire lens with sterile balanced salt solution or sterile normal saline.
6. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
7. The lens may be soaked in sterile balanced salt solution until ready for implantation.
8. Amvisc®, Amvisc Plus™, or OcuCoat® viscoelastic should be used for lubrication of the delivery system when inserting the lens.
9. Bausch + Lomb recommends using a Bausch + Lomb approved delivery system.
10. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

enVista MX60 CLINICAL STUDY RESULTS:

The enVista Hydrophobic Acrylic Intraocular Lens, Model MX60, is the parent lens of the MX60T. A clinical study of the MX60 began in the United States on October 19, 2010. This prospective, single arm, open label study included a total of 122 subjects (122 eyes) at 6 clinical sites. Postoperatively, subjects underwent complete ophthalmic evaluations at regularly scheduled intervals through Form 4 (Postoperative Days 120-180). At the Form 4 visit, 118 subjects (100%) achieved BCVA of 20/40 or better, which exceeds the FDA grid of 96.7%. The rates of FDA defined potentially sight-threatening adverse events that occurred in the clinical trial at Form 4 were found to be less than the "FDA Grid" of Historical Controls. Two cumulative adverse events (2/122; 1.6%) of cystoid macular edema were reported through the Form 4 visit. One persistent adverse event (1/121; 0.8%) of cystoid macular edema was reported at the Form 4 visit. No serious ocular adverse events occurred during this study. All subjects in the safety analysis set were evaluated for IOL glistenings at Form 3 and Form 4 visits. IOL glistenings were evaluated via retroillumination slit lamp examination utilizing a photographic grading scale provided in the protocol. The grading scale consisted of (in order of severity), "none, grade 0 (trace), grade 1, 2, 3, or 4." No glistenings of any grade were reported for any subject at any visit in the clinical study. The results of clinical investigation provided reasonable assurance that the Model MX60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

enVista MX60T CLINICAL TRIAL STUDY RESULTS

The US clinical trial of the enVista® Toric Intraocular Lens was conducted in 191 subjects (191 eyes). The dioptric power range was 16.0 to 27.0 D with cylindrical powers at the lens plane of 1.25 D, 2.00 D, and 2.75 D for the MX60T.

STUDY DESCRIPTION

The study was a prospective, multicenter, parallel-group, partially randomized, partially controlled, double-masked, monocular clinical trial to evaluate the safety and effectiveness of the enVista® Toric IOL, Model MX60T, in reducing postoperative refractive astigmatism in subjects undergoing cataract extraction. Subjects in the lowest astigmatic IOL power (1.25 D) cohort were randomized to undergo implantation of either the toric test lens (enVista® One-Piece Hydrophobic Acrylic Toric IOL, Model MX60T) or the non-toric spherical control lens (enVista® One-Piece Hydrophobic Acrylic IOL, Model MX60) in one eye. Subjects in the higher astigmatic power cohorts (2.00 D, 2.75 D) were implanted with a test lens only in one eye. Postoperatively, subjects underwent complete ophthalmic evaluations at regularly scheduled intervals through Form 4 (Postoperative Days 120-180).The test lens was the enVista® Toric IOL (Model MX60T). The effective corneal powers for each of the test lens plane cylindrical powers of the test IOLs are shown in Table 1.

TABLE 1: ENVISTA TORIC IOL CYLINDER POWER

Cylinder Power at IOL Plane (D)	Cylinder Power at Corneal Plane (D)	Postoperative Corneal Cylinder (D)
1.25	**0.90**	**0.90 – 1.39**
2.00	**1.40**	**1.40 – 1.92**
2.75	**1.93**	**1.93 – 2.40**

Each Surgeon's individual surgically-induced astigmatism (SIA) was added to the recommended preoperative correction range to determine eligibility based on preoperative corneal cylinder. Once the SIA was estimated, this value stayed constant during the study for each investigator. In order to facilitate toric IOL selection and axis placement, the B+L proprietary enVista Toric Calculator was used to determine the appropriate enVista® Toric IOL model and axis of placement for each eye. The calculator accounted for surgically induced astigmatism (SIA), incision location, and the subject's preoperative corneal astigmatism. In this trial all cataract incisions were to be placed on the preoperative keratometric steep axis.

RESULTS

The results of the clinical study provide reasonable assurance that the Model MX60T IOL is safe and effective for the visual correction of aphakia and corneal astigmatism following cataract extraction. The data support a significant dioptric reduction in cylinder and reduction in absolute cylinder, rotational stability of the lens, and improvement of both best corrected and uncorrected visual acuity at distance following implantation of the enVista® Toric IOL. The primary effectiveness endpoints were mean Toric IOL axial stability from Form 3 to Form 4, dioptric reduction in cylinder at Form 4, lens axis misalignment from surgical target markings at Form 4, and best corrected distance visual acuity at Form 4. All subjects in the Toric IOL treatment groups demonstrated ≤5 degrees rotation from Form 3 (Table 2). Mean cylinder reduction from preoperative keratometric cylinder measurements in the randomized ITT population at Form 4 was 0.479 ± 0.665 D among those subjects with control IOLs and 0.865 ± 0.487 D among those subjects with 1.25 D toric IOLs (Table 3), showing a statistically significant improvement favoring the 1.25 D toric IOLs ($P < 0.001$). The mean percent reduction in absolute cylinder at Form 4 was 69.4% for the all Toric IOL Cohort and 36.8% for the control IOL Cohort (Table 4). The percent of eyes within 0.50 D and 1.00 D of intended correction for All Toric Cohort at Form 4 was 57.3% and 90.9%, respectively (Table 5). At Form 4, > 90% of eyes in each toric IOL arm had misalignments of ≤ 10 degrees of intended markings, including 93.3% of all toric IOL eyes (Table 6). Preservation of best-corrected distance visual acuity showed 99.1% of eyes in the ITT population implanted with a Toric IOL reported a VA of 20/40 or better at Form 4. Best-corrected distance visual acuity (BCDVA) results for the all Toric IOL treatment group are presented in Table 7 and Table 8. At Form 4, 109 subjects (99.1%) in the All Toric IOL Cohort achieved BCDVA of 20/40 or better. At Form 4, the mean ± SD UCDVA was 0.19 ± 0.16 logMAR in the control IOL treatment group and 0.11 ± 0.14 logMAR in the 1.25 D toric IOL treatment group (Table 9), which was a significant difference favoring the 1.25 D toric IOL arm ($P < 0.001$). At Form 4, 94.5% of all toric IOL eyes and 83.3% of control eyes had UCDVA of 20/40 or better. The analysis of safety was based on the Safety cohort of 191 subject eyes for the implantation of a study lens (either test or control). The key safety outcomes are presented in Table 10. The rates of FDA defined potentially sight-threatening adverse events that occurred in the clinical trial at Form 4 were found to be less than the "FDA Grid" of historical controls. No serious adverse events occurred in the study eye.

Table 2: MEAN TORIC IOL AXIAL STABILITY FROM FORM 3 TO FORM 4 (ITT POPULATION)

Absolute rotation (degrees)	Toric IOL			All Toric IOL (N=112)
	1.25 D (N=80)	2.00 D (N=20)	2.75 D (N=12)	
Absolute rotation from Form 3 to Form 4				
n	74	15	12	101
Mean ± SD	1.15 ± 1.08	0.92 ± 1.09	1.08 ± 0.73	1.11 ± 1.04
≤ 5 degrees rotation	74 (100.0%)	15 (100.0%)	12 (100.0%)	101 (100.0%)
95% exact CI	95.1% to 100.0%	78.2% to 100.0%	73.5% to 100.0%	96.4% to 100.0%
Five multiple imputations of absolute rotation from Form 3 to Form 4 for missing data				
≤ 5 degrees rotation				560 (100.0%)
Abbreviations: CI = confidence interval; D = diopter; IOL = intraocular lens; Max = maximum; Min = minimum; SD = standard deviation.				

Table 3: MEAN DIOPTRIC CYLINDER REDUCTION FROM PREOPERATIVE MEASUREMENTS, (ITT POPULATION)

Cylinder reduction (D)	Control IOL (N=79)	Toric IOL			All Toric IOL (N=112)
		1.25 D (N=80)	2.00 D (N=20)	2.75 D (N=12)	
Form 2					
n	77	80	20	12	112
Mean reduction ± SD	0.640 ± 0.591	0.966 ± 0.466	1.486 ± 0.498	2.115 ± 0.328	1.182 ± 0.594
Form 3					
n	79	79	18	12	109
Mean reduction ± SD	0.532 ± 0.627	0.864 ± 0.455	1.446 ± 0.519	1.926 ± 0.364	1.077 ± 0.584
Form 4					
n	78	80	18	12	110
Mean reduction ± SD	0.479 ± 0.665	0.865 ± 0.487	1.413 ± 0.532	1.944 ± 0.327	1.072 ± 0.601
Treatment effect at Form 4		0.39			
95% CI of effect		0.228 to 0.545			
Multiple imputation p-value[a]		< 0.001			

***Abbreviations**: CI = confidence interval; D = diopter; IOL = intraocular lens; Max = maximum; Min = minimum; SD = standard deviation.*

[a] *P-values and treatment effects are from a linear model Type II analysis, which include an effect for investigator and compare the control and 1.25 D toric IOLs at Form 4.* ***Note**: Dioptric change in cylinder = preoperative keratometric cylinder- postoperative manifest cylinder*

Table 4: MEAN PERCENT REDUCTION IN ABSOLUTE CYLINDER AT FORM 4

	Control IOL, Mean ± SD (N=79)	Toric IOL 1.25 D Mean ± SD (N=80)	Toric IOL 2.00 D Mean ± SD (N=20)	Toric IOL 2.75 D Mean ± SD (N=12)	All Toric IOL Mean ± SD (N=112)
Number of Subjects at Form 4, n	78	80	18	12	110
Mean[1] % Reduction in Absolute Cylinder (± SD)	36.8% ±50.49%	64.8% ±36.80%	81.0% ±31.3%	82.8% ±13.0%	69.4% ±34.8%

[1]Mean of all subject (N) results at Form 4 - n (%)

Table 5: PERCENT OF EYES WITH REDUCTION IN CYLINDER WITHIN 0.50 D AND 1.00 D OF INTENDED – FORM 4 (EFFECTIVENESS)

	Control IOL (N=79)	Toric IOL 1.25 D (N=80)	Toric IOL 2.00 D (N=20)	Toric IOL 2.75 D (N=12)	All Toric IOL (N=112)
Total Non- Missing, n	78	80	18	12	110
Within 0.50 D of Intended, n (%)	27 (34.6%)	43 (53.8%)	12 (66.7%)	8 (66.7%)	63 (57.3%)
Within 1.00 D of Intended, n (%)	45 (57.7%)	71 (88.8%)	17 (94.4%)	12 (100.0%)	100 (90.9%)

TABLE 6: MEAN TORIC LENS AXIS MISALIGNMENT FROM SURGICAL MARKINGS AT FORM 4 (ITT POPULATION)

Axis misalignment	Toric IOL 1.25 D (N=80)	Toric IOL 2.00 D (N=20)	Toric IOL 2.75 D (N=12)	All Toric IOL (N=112)
Form 4 signed axis misalignment, degrees				
n	77	16	11	104
Mean ± SD	1.11 ± 8.69	3.08 ± 10.51	2.52 ± 3.03	1.56 ± 8.57
95% tolerance interval for 90% of the population	-15.51 to 17.73	-22.54 to 28.70	-5.78 to 10.82	-14.45 to 17.57
Form 4 absolute axis misalignment, degrees				
n	77	16	11	104
Mean ± SD	4.77 ± 7.33	5.15 ± 9.61	3.32 ± 2.01	4.68 ± 7.33
95% tolerance interval for 90% of the population	-9.25 to 18.79	-18.28 to 28.58	-2.19 to 8.83	-9.02 to 18.38
Form 4 absolute axis misalignment category, n (%)				
≤ 5 degrees	56 (72.7%)	13 (81.3%)	9 (81.8%)	78 (75.0%)
≤ 10 degrees	71 (92.2%)	15 (93.8%)	11 (100.0%)	97 (93.3%)
Form 4 signed axis misalignment category, n (%)				
-10.00 to -5.01 degrees	4 (5.2%)	2 (12.5%)	0 (0.0%)	6 (5.8%)
-5.00 to -0.01 degrees	31 (40.3%)	3 (18.8%)	2 (18.2%)	36 (34.6%)
0.00 degrees	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
+0.01 to +5.00 degrees	25 (32.5%)	10 (62.5%)	7 (63.6%)	42 (40.4%)
+5.01 to +10.00 degrees	11 (14.3%)	0 (0.0%)	2 (18.2%)	13 (12.5%)

Table 7: PRESERVATION OF BCDVA AT EACH EXAMINATION (ALL TORIC IOLS, IMPLANTED SAFETY SUBJECTS)

	Preoperative N=112	Form 2 N=112	Form 3 N=109	Form 4 N=110
20/40 or Better, n (%)	27 (24.1%)	108 (96.4%)	109 (100%)	109 (99.1%)
Worse than 20/40, n (%)	85 (75.9%)	4 (3.6%)	0 (0.0%)	1 (0.9%)

TABLE 8: BCDVA WITHOUT GLARE AT FORM 4 (ITT POPULATION)

	Control IOL (N=79)	Toric IOL 1.25 D (N=80)	Toric IOL 2.00 D (N=20)	Toric IOL 2.75 D (N=12)	All Toric IOL (N=112)
BCDVA (logMAR)					
Total Non-Missing, n	78	80	18	12	110
Mean (±SD)	0.01 (±0.09)	0.00 (±0.09)	0.05 (±0.10)	0.13 (±0.18)	0.11 (±0.14)
BCDVA (Snellen)					
20/40 or Better, n (%)	78 (100.0%)	79 (98.8%)	18 (100.0%)	12 (100%)	109 (99.1%)
Worse than 20/40, n (%)	0	1 (1.3%)	0	0	1 (0.9%)

TABLE 9: UCDVA AT FORM 4 (ITT POPULATION)

	Control IOL (N=79)	Toric IOL 1.25 D (N=80)	Toric IOL 2.00 D (N=20)	Toric IOL 2.75 D (N=12)	All Toric IOL (N=112)
UCDVA (logMAR)					
Total Non-Missing, n	78	80	18	12	110
Mean (±SD)	0.19 (±0.16)	0.11(±0.14)	0.12 (±0.11)	-0.01 (±0.09)	0.01 (±0.09)
UCDVA (Snellen)					
20/40 or Better, n (%)	65 (83.3%)	76 (95.0%)	18 (100.0%)	10 (83.3%)	104 (94.5%)
Worse than 20/40, n (%)	13 (16.7%)	4 (5.0%)	0	2 (16.7%)	6 (5.5%)

Table 10: ISO 11979-7 SAFETY AND PERFORMANCE ENDPOINTS (SPE) ADVERSE EVENTS REPORTED AT EACH POSTOPERATIVE VISIT, IMPLANTED SUBJECTS (SAFETY, ALL TORIC IOL)

Adverse Event	Form 1 n/N (%)[1]	Form 2 n/N (%)[1]	Form 3 n/N (%)[1]	Form 4 n/N (%)[1]	Cumulative n/N (%)[1]	ISO 11979-7	p-value
Endophthalmitis	0/112	0/112	0/112	0/112	0/112	0.1	>0.999
Hypopyon	0/112	0/112	0/112	0/112	0/112	0.3	>0.999
Lens Dislocated From Posterior Chamber	0/112	0/112	0/112	0/112	0/112	0.1	>0.999
Cystoid Macular Edema	0/112	1/112 (0.9)	1/112 (0.9)	0/112	2/112 (1.8)	3.0	0.853
Pupillary Block	0/112	0/112	0/112	0/112	0/112	0.1	>0.999
Retinal Detachment	0/112	0/112	0/112	0/112	0/112	0.3	>0.999
Secondary Surgical Intervention	0/112	0/112	0/112	0/112	0/112	0.8	>0.999
Persistent Adverse Events Noted at Form 4							
Corneal Stromal Edema				0/112		0.3	>0.999
Iritis				0/112		0.3	>0.999
Cystoid Macular Edema				0/112		0.5	>0.999
Raised IOP Requiring Treatment				0/112		0.4	>0.999

Cumulative versus persistent AEs are defined by the FDA SPE Grid and ISO 11979-7 as those occurring at Form 4 in this clinical study.

HOW SUPPLIED

The lens is individually packaged in a sterile vial (containing a 0.9% saline solution), within a peel pouch, and should only be opened under sterile conditions. A patient card and self-adhesive labels are supplied to provide traceability of the lens. The package is sterilized by gamma irradiation**.**

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

ADVERSE EVENT REPORTING

Adverse events and/or potentially sight threatening complications that may be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch +Lomb Incorporated. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general. If you wish to report a problem, please call Bausch + Lomb at 1-800-338-2020.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives an enVista IOL must be registered with Bausch + Lomb at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Bausch + Lomb. Patient registration is essential and will assist Bausch + Lomb in responding to adverse reaction reports and/or potentially sight-threatening complications. An implant identification card is supplied in the lens package and must be given to the patient.

RETURNED GOODS POLICY

All lenses being returned must be accompanied by a returned goods authorization number issued by Bausch + Lomb Customer Service. Call 1-800-338-2020 for return authorization and full policy information.

WARRANTY

Bausch & Lomb Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such intraocular lens in all material respects and will be free from defects in material and workmanship.

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SYMBOLS USED ON LABELING

Symbol	Description	Symbol	Description
IOL	Intraocular Lens	STERILE R	Sterilized Using Irradiation
PC	Posterior Chamber	Rx ONLY	Prescription Only (USA)
	Use-By Date		Caution
UV	Ultraviolet		Temperature Limit
D	Diopter		Do Not Resterilize
$Ø_B$	Body Diameter (Optic Diameter)		Meets EU Packaging Directive
$Ø_T$	Overall Diameter (Overall Length)		Do Not Use if Package is Damaged
SN	Serial Number		Manufacturer
	Do Not Re-use		eIFU Indicator
EC REP	Authorized representative in the European Community		

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

EC REP
Bausch & Lomb Incorporated
106 London Road
Kingston-upon-Thames
KT2 6TN, UK

CE 0197

Manufactured by: Bausch & Lomb Incorporated
21 Park Place Blvd. North, Clearwater, FL 33759 USA

US Patents: 6281319 and 6635731.

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Rev. 2018-06