BAUSCH + LOMB

Trulign™ Toric
Posterior Chamber Intraocular Lens

PHYSICIAN LABELING

DEVICE DESCRIPTION

EN

The Bausch + Lomb Trulign™ Toric Posterior Chamber Intraocular Lens is a modified plate haptic lens with hinges across the plates adjacent to the optic. Trulign Toric Lens Model AT50T has a spherical front (anterior) surface with alignment marks and a toric back (posterior) surface. Trulign Toric Lens Models BL1AT/BL1UT have an aspheric front (anterior) surface with alignment marks and an aspheric toric back (posterior) surface.

The physical characteristics of the Trulign Toric Posterior Chamber Intraocular Lens are described below.

PHYSICAL CHARACTERISTICS OF TRULIGN TORIC POSTERIOR CHAMBER INTRAOCULAR LENS

	Models		
Feature	AT50T	BL1AT	BL1UT
Power Range	+4.0 to +10.0 Diopters (1.0 Diopter Increments) SE +10.5 to +33.0 Diopters (0.5 Diopter Increments) SE SE - Spherical Equivalent		
Cylinder Powers	1.25, 2.00, and 2.75 Diopters (CYL) CYL - Cylinder		
Anterior Surface	Spherical with Axis-mark	Aspheric with Axis-mark	
Posterior Surface	Spherical Toric	Aspheric Toric	
Overall Diameter	11.5mm		
Optic Diameter	5.0 mm		
Plate Overall	10.5mm		
Plate Configuration	Rectangular		
Material Body & Plates	Silicone (10% UV Cutoff at 354nm)		Silicone (10% UV Cutoff at 400nm)
Loop (haptic) material	Polyimide		
Index of Refraction at 546nm	1.4301		

INDICATIONS FOR USE

The Trulign Toric Posterior Chamber Intraocular Lens is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision.

WARNINGS

1. Rotation of toric lenses away from their intended axis can reduce their effectiveness. Misalignment can increase postoperative refractive cylinder. Repositioning of this lens to the intended axis should only be performed when a significant reduction in effectiveness of the Trulign Toric IOL is noticed. This lens should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye.
2. Small amounts of lens decentration occurring with an IOL having a narrow or small optic (< 5.5 mm) may cause glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential complication before implanting an IOL with a small or narrow optic. This lens incorporates a 5.0 mm optic.
3. YAG-laser posterior capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be limited to no more than 4 mm. Consistent with other IOLs, there is an increased risk of lens dislocation and/or secondary surgical re-intervention with early or large YAG capsulotomies.
4. The TrulignToric IOL should not be implanted if the capsular bag is not intact or if there is any zonular rupture.
5. The rate of cystoid macular edema may increase with sulcus-bag placement of the haptics.
6. Do not implant this lens in the anterior chamber.
7. **A wound leak could cause forward vaulting of the optic.** Therefore, a scleral tunnel or long multiplane limbal/ corneal incision is recommended with a long narrow paracentesis. These incisions are less likely to require suturing, which could cause astigmatism and reduce the postoperative uncorrected vision.

PRECAUTIONS

1. Some patients may still require glasses to perform certain tasks.
2. There is no clinical data to support placing this lens in the ciliary sulcus.
3. The safety and effectiveness of this lens have not been evaluated in patients under 50 years of age.
4. Before implantation of the Trulign Toric IOL, surgeons should verify that the cornea is appropriately marked for the steep axis.
5. The effect of vitrectomy on near performance of the Trulign Toric IOL is unknown.
6. The safety and effectiveness of the device has not been established in patients with the following ocular conditions:
   a. Chronic drug miosis
   b. Amblyopia
   c. Diabetic retinopathy
   d. Previous corneal transplant
   e. History of retinal detachment
   f. Congenital bilateral cataracts
   g. Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
   h. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose, or treat posterior segment diseases.
   i. Surgical difficulties at the time of intraocular lens implantation which might increase the potential for complications (e.g., persistent bleeding, significant vitreous prolapse or loss).
   j. Corneal endothelial dystrophy.
   k. Pseudo exfoliation syndrome.
   l. Suspected microbial infection.

   Surgeons considering lens implantation in such patients should explore the potential risk/benefit ratio.
7. Mechanical hinge testing has been evaluated in a laboratory setting.
   Hinge movements of 1,000,000 cycles at 10 cycles per second have been documented with no degradation of hinge integrity or stability. However, long-term stability in the human eye has not been established. Therefore, surgeons should continue to monitor implant patients postoperatively on a regular basis.
8. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established.
9. **The potential for the lens to rotate causing misalignments that will reduce the effectiveness of the Trulign Toric IOL may be greater in some eyes.**
10. **Lens rotation less than 5° may not warrant reorientation.**
11. Do not resterilize this intraocular lens by any method (See Returned Lens Policy).
12. Do not store lenses at temperatures over 45°C (113°F).
13. The optic should be vaulted backward to a position corresponding to the normal location of the posterior capsule. **Attempts to position the lens further posteriorly by hyper-inflating the globe with Balanced Salt Solution could lead to hyperopic outcomes and should be avoided.**
14. The safety and effectiveness of the toric intraocular lenses have not been substantiated in patients with the following 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.
    a. Before Surgery
    - Choroidal hemorrhage
    - Chronic severe uveitis
    - Concomitant severe eye disease
    - Extremely shallow anterior chamber

- Medically uncontrolled glaucoma
- Microphthalmos
- Non-age-related cataract
- Severe optic nerve atrophy
- Irregular corneal astigmatism

b. During Surgery
- Excessive vitreous loss
- Capsulotomy by any technique other than a circular tear
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
- Capsular rupture
- Significant anterior chamber hyphema

15. The effectiveness of the Trulign Toric IOL in reducing the visual effect of preoperative corneal astigmatism of less than 1.33 diopters has not been established.
16. If a surgeon chooses to implant an eye with greater than 3.00 diopters of preoperative corneal astigmatism or greater than 2.50 diopters of predicted postoperative corneal astigmatism, it is likely that only a limited correction will be achieved and device effectiveness is expected to be less than that seen in the clinical trial described in this labeling.
17. In the clinical trial conducted for FDA device approval, all corneal incisions were placed at the preoperative keratometric steep axis. If the surgeon chooses to place the incision at a different location (or in some other way differing from the practice in the clinical trial) results may be different from those portrayed in the clinical study results section of this labeling. It is unknown to what extent the angle between the incision and the meridian of steepest corneal curvature affects the accuracy of the prediction of the Trulign Toric IOL Calculator.
18. If the surgeon uses methods other than the Trulign Toric IOL Calculator, to determine appropriate toric cylinder power and appropriate axis placement, the results achieved may not be similar to those described in the clinical study results section of the labeling.
19. The intermediate and near performance in lenses below 16 diopter spherical equivalent power has not been clinically studied.

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 11-12**). 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: lens subluxation, corneal endothelial damage, non-pigment precipitates, cystoid macular edema, infection (endophthalmitis), retinal detachment, vitreous loss, pupillary block, corneal edema, hypopyon, secondary glaucoma, iris prolapse, vitreous- wick syndrome, uveitis, secondary surgical intervention and pupillary membrane. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair and retinal detachment repair.

CLINICAL TRIAL (TRULIGN TORIC IOL)

The US clinical trial of the Trulign Toric Posterior Chamber Intraocular Lens was conducted in 229 eyes of 229 patients (227 eyes implanted). 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 AT50T/AT52T.

STUDY DESCRIPTION

The study was a prospective, randomized, single-masked clinical trial to evaluate the safety and effectiveness of the Trulign Toric IOL (Models AT50T/AT52T) in reducing postoperative refractive astigmatism in subjects undergoing cataract extraction. IOL implantation was conducted in the US and Canada with study duration of up to 1 year.

Subjects in the lowest astigmatic power (1.25D) cohort were randomized to undergo implantation of either the toric test lens or the non-toric spherical control lens in one eye. Subjects in the higher astigmatic power cohorts (2.00D, 2.75D) were implanted with the test lens in one eye.

The test lens was the Trulign Toric IOL (Models AT50T/AT52T). The effective corneal powers for each of the lens plane cylindrical powers of the test IOLs are shown in the table below:

Trulign Toric IOL Cylinder Power

Cylinder Power at IOL Plane (D)	Cylinder Power at Corneal Plane (D)	Range of Predicted Postoperative Corneal Cylinder* (D)
1.25	0.83	0.83 – 1.32
2.00	1.33	1.33 – 1.82
2.75	1.83	1.83 – 2.50

*based upon inclusion criteria and the expectation of 0.50 D incisional effect

The Crystalens Accommodating IOL Models AT50SE/AT52SE (non-toric optic) were used as the control lenses.

In order to facilitate toric IOL selection and axis placement, a proprietary Toric Calculator was used to determine the appropriate Trulign Toric IOL model and axis of placement for each eye. The Trulign Toric IOL Calculator was used to calculate the predicted postoperative corneal astigmatism using preoperative keratometry, phaco/insertion incision location, and predicted magnitude of surgically induced astigmatism (SIA) inputs entered by the physician. The calculator accounted for SIA, incision location, and the subject's preoperative corneal astigmatism, and determined the Toric IOL cylinder

power needed and placement orientation to best correct a subject's predicted postoperative corneal astigmatism. In this trial, all cataract incisions were to be placed on the preoperative keratometric steep axis and a fixed SIA value of 0.50 D was used in the Trulign Toric IOL Calculator for all study subjects.

	Control IOL 0.00D (n = 76)	Toric IOL 1.25D (n = 82)	Toric IOL 2.00D (n = 47)	Toric IOL 2.75D (n = 24)
# eyes implanted	76	80	47	24
Available at Form 4	72	79	46	22
Preoperative Corneal Astigmatism	1.34 – 1.80	1.33 – 1.81	1.83 – 2.30	2.34 – 3.00
Predicted Postoperative Corneal Astigmatism	0.84 – 1.30	0.83 – 1.31	1.33 – 1.80	1.84 – 2.50

Minimum preoperative keratometric cylinder treated in the trial was 1.33 D, and the incision was placed at the preoperative keratometric steep axis for all test and control eyes.

RESULTS

The results achieved by 227 patients followed postoperatively for six months provide data to support the conclusion that eyes implanted with a Trulign Toric IOL following cataract extraction achieve visual correction of aphakia and astigmatism.

The data support a percent reduction in absolute cylinder, rotational stability of the lens, and improvement of uncorrected visual acuity at distance following implantation of Trulign Toric IOL.

The primary effectiveness endpoint was the mean percent reduction in absolute cylinder. The percent reduction in absolute cylinder is defined as the difference between the postoperative magnitude of the subjective Manifest Refractive cylinder (converted to the corneal plane) and the preoperative magnitude of the keratometric cylinder, divided by the intended reduction in cylinder expressed as a percentage. The intended reduction in cylinder is the difference between the "intended" magnitude of the postoperative Manifest Refractive cylinder (converted to the corneal plane) and the magnitude of the preoperative keratometric cylinder. When comparing the mean (SD) for the Control Cohort 46.5% (43.8%) to that of the 1.25 toric Cohort 79.9% (31.8%), a statistically significant difference ($p < 0.001$) was demonstrated. The mean (SD) percent reduction of cylinder for the 2.00 toric Cohort was 88.0% (27.1%); for the 2.75 toric Cohort it was 97.4% (19.2%), and for the all toric cohort it was 85.0% (29.3%). The percent reduction of cylinder within 0.50D and 1.00D of intended correction for the Trulign Toric Posterior Chamber Intraocular Lens was 78.4% and 95.5%, respectively. The minimum preoperative keratometric cylinder treated was 1.33 D. The results are shown in **Table 1**. Preservation of best-corrected visual acuity show 98.0% and 100.0% of eyes implanted with a toric lens reported a VA of 20/40 or better at six months at distance and near, respectively. All visual acuity results are presented in **Tables 2-10.** The rotational stability of the toric lens was demonstrated in a cohort of patients across the Form 3 to Form 4 (1-2 months to 3-6 months) postoperative intervals. A total of 100% (122/122 eyes) of subjects demonstrated less than or equal to 5 degrees of rotation between Consecutive Visits. Additionally, 96.1% of eyes exhibited rotation of less than or equal to 5 degrees between the day of surgery and the Form 4 visit, demonstrating rotational stability in the early postoperative period. The results are shown in **Table 13**. No eyes (0%, 0/20) in the highest available cylinder correction (2.75D) reported significant visual disturbances through Form 4. The results are shown in **Table 14**. **Tables 15-19** provide device effectiveness across the range of preoperative corneal astigmatism. **Tables 20-21**provide information on the predictive error of the Trulign Toric IOL calculator *Note: The data provided below includes all subjects enrolled in Clinical Trial 650, including 4 eyes with the control lens AT52, and 6 eyes with the test lens AT52T. The AT52T is not approved.*

TABLE 1
PERCENT OF EYES WITH REDUCTION IN CYLINDER WITHIN 0.50 D AND 1.00 D OF INTENDED – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
Total Non-Missing	68	74	39	21	134
Within 0.50 D of Intended	30 (44.1%)	59 (79.7%)	31 (79.5%)	15 (71.4%)	105 (78.4%)
Within 1.00 D of Intended	49 (72.1%)	71 (95.9%)	36 (92.3%)	21 (100.0%)	128 (95.5%)

TABLE 2
PRESERVATION OF BCDVA AT EACH EXAMINATION (ALL TORIC IOLS, IMPLANTED SAFETY SUBJECTS)

	Preop	Form 3	Form 4	Form 5	Form 6	Unscheduled
20/40 or Better	108 (72.0%)	143 (99.3%)	144 (98.0%)	143 (98.6%)	141 (98.6%)	39 (97.5%)
Worse than 20/40	42 (28.0%)	1 (0.7%)	3 (2.0%)	2 (1.4%)	2 (1.4%)	1 (2.5%)

TABLE 3
PRESERVATION OF BCNVA AT EACH EXAMINATION (ALL TORIC IOLS, IMPLANTED SAFETY SUBJECTS)

	Preop	Form 3	Form 4	Form 5	Form 6	Unscheduled
20/40 or Better	124 (89.2%)	141 (98.6%)	147 (100.0%)	142 (98.6%)	142 (99.3%)	30 (100.0%)
Worse than 20/40	15 (10.8%)	2 (1.4%)	0	2 (1.4%)	1 (0.7%)	0

TABLE 4
DCIVA AT 32 INCHES (80 CM) – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCIVA (logMAR)					
Total Non-Missing	67	74	38	21	133
Mean (SD)	0.074 (0.142)	0.060 (0.107)	0.059 (0.149)	0.024 (0.139)	0.054 (0.125)
DCIVA (Snellen)					
20/40 or Better	64 (95.5%)	74 (100.0%)	38 (100.0%)	21 (100.0%)	133 (100.0%)
Worse than 20/41	3 (4.5%)	0	0	0	0

TABLE 5
DCNVA AT 16 INCHES (40 CM) – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCNVA (logMAR)					
Total Non-Missing	67	74	38	21	133
Mean (SD)	0.309 (0.138)	0.308 (0.130)	0.310 (0.154)	0.258 (0.172)	0.301 (0.144)
DCNVA (Snellen)					
20/40 or Better	42 (62.7%)	47 (63.5%)	22 (57.9%)	16 (76.2%)	85 (63.9%)
Worse than 20/41	25 (37.3%)	27 (36.5%)	16 (42.1%)	5 (23.8%)	48 (36.1%)

TABLE 6
DCNVA AT 16 INCHES (40 CM) WITH ADD – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
DCNVA with Add (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.045 (0.072)	0.039 (0.075)	0.031 (0.066)	0.038 (0.074)	0.036 (0.072)
DCNVA with Add (Snellen)					
20/40 or Better	68 (100.0%)	74 (100.0%)	39 (100.0%)	21 (100.0%)	134 (100.0%)
Add (D)					
Mean (SD)	1.599 (0.575)	1.473 (0.451)	1.423 (0.494)	1.405 (0.599)	1.448 (0.486)

TABLE 7
BCDVA WITHOUT GLARE – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
BCDVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.012 (0.094)	0.003 (0.073)	-0.003 (0.076)	0.019 (0.180)	0.004 (0.097)
BCDVA (Snellen)					
20/40 or Better	68 (100.0%)	74 (100.0%)	39 (100.0%)	20 (95.2%)	133 (99.3%)
Worse than 20/41	0	0	0	1 (4.8%)	1 (0.7%)

TABLE 8
UCDVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCDVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.189 (0.181)	0.099 (0.140)	0.082 (0.119)	0.091 (0.130)	0.093 (0.132)
UCDVA (Snellen)					
20/40 or Better	51 (75.0%)	71 (95.9%)	39 (100.0%)	21 (100.0%)	131 (97.8%)
Worse than 20/41	17 (25.0%)	3 (4.1%)	0	0	3 (2.2%)

TABLE 9
UCIVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCIVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.069 (0.153)	0.044 (0.116)	0.058 (0.155)	0.004 (0.117)	0.042 (0.129)
UCIVA (Snellen)					
20/40 or Better	64 (94.1%)	73 (98.6%)	37 (94.9%)	21 (100.0%)	131 (97.8%)
Worse than 20/41	4 (5.9%)	1 (1.4%)	2 (5.1%)	0	3 (2.2%)

TABLE 10
UCNVA – FORM 4 (EFFECTIVENESS)

	Control IOL (N=72)	Toric IOL 1.25 D (N=75)	Toric IOL 2.00 D (N=40)	Toric IOL 2.75 D (N=23)	All Toric IOL (N=138)
UCNVA (logMAR)					
Total Non-Missing	68	74	39	21	134
Mean (SD)	0.286 (0.137)	0.284 (0.155)	0.310 (0.142)	0.268 (0.149)	0.289 (0.150)
UCNVA (Snellen)					
20/40 or Better	49 (72.1%)	53 (71.6%)	24 (61.5%)	17 (81.0%)	94 (70.1%)
Worse than 20/41	19 (27.9%)	21 (28.4%)	15 (38.5%)	4 (19.0%)	40 (29.9%)

TABLE 11
FDA GRID ADVERSE EVENTS REPORTED AT EACH POSTOPERATIVE VISIT, IMPLANTED SUBJECTS (SAFETY, CONTROL IOL)

Adverse Event	Unscheduled n/N (%)	Form 1 n/N (%)	Form 2 n/N (%)	Form 3 n/N (%)	Form 4 n/N (%)	Form 5 n/N (%)	Form 6 n/N (%)	Cumulative n/N (%)	FDA grid (%)	p-value
Cumulative										
Endophthalmitis	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Hypopyon	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.3	>0.999
Lens Dislocated From Posterior Chamber	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Macular Edema	0/44	0/76	0/75	1/74 (1.4)	1/73 (1.4)	0/70	0/69	1/76 (1.3)	3.0	0.901
Pupillary Block	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.1	>0.999
Retinal Detachment	0/44	0/76	0/75	0/74	0/72	0/70	0/69	0/76	0.3	>0.999
Secondary Surgical Intervention	0/44	0/76	1/75 (1.3)	0/74	0/72	1/70 (1.4)	0/69	2*/76 (2.6)	0.8	0.124
Persistent										
Corneal Edema								0/69	0.3	>0.999
Iritis								0/69	0.3	>0.999
Macular Edema								0/69	0.5	>0.999
Raised IOP Requiring Treatment								0/69	0.4	>0.999
*Reason for SSI: 1) IOL reposition due to IOL malposition; 2) IOL Exchange.										

TABLE 12
FDA GRID ADVERSE EVENTS REPORTED AT EACH POSTOPERATIVE VISIT, IMPLANTED SUBJECTS (SAFETY, ALL TORIC IOL)

Adverse Event	Unscheduled n/N (%)	Form 1 n/N (%)	Form 2 n/N (%)	Form 3 n/N (%)	Form 4 n/N (%)	Form 5 n/N (%)	Form 6 n/N (%)	Cumulative n/N (%)	FDA grid (%)	p-value
Cumulative										
Endophthalmitis	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Hypopyon	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.3	>0.999
Lens Dislocated From Posterior Chamber	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Macular Edema	0/77	0/151	0/148	1/145 (0.7)	1/147 (0.7)	0/145	0/143	1/151 (0.7)	3.0	0.990
Pupillary Block	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.1	>0.999
Retinal Detachment	0/77	0/151	0/148	0/145	0/147	0/145	0/143	0/151	0.3	>0.999
Secondary Surgical Intervention	0/77	0/151	0/148	0/145	1/147 (0.7)	0/145	0/143	1*/151 (0.7)	0.8	0.703
Persistent										
Corneal Edema								0/143	0.3	>0.999
Iritis								0/143	0.3	>0.999
Macular Edema								0/143	0.5	>0.999
Raised IOP Requiring Treatment								0/143	0.4	>0.999
*Reason for SSI: Reposition of IOL (2.00 D Cohort) not related to lens axis misalignment or rotation.										

TABLE 13
ROTATIONAL STABILITY BETWEEN CONSECUTIVE VISITS – FORM 4 (CONSISTENT)

	Toric IOL 1.25 D (N=69)	Toric IOL 2.00 D (N=34)	Toric IOL 2.75 D (N=19)	All Toric IOL (N=122)
Absolute Value of Rotation (°)				
Total Non-Missing	69	34	19	122
Mean (SD)	1.074 (0.966)	1.166 (0.906)	1.537 (1.406)	1.172 (1.034)
Lenses Rotating ≤5° Since Last Visit	69 (100.0%)	34 (100.0%)	19 (100.0%)	122 (100.0%)

TABLE 14
SUBJECTS EXPERIENCING ONE OR MORE SIGNIFICANT VISUAL DISTURBANCES – FORM 4
(EFFECTIVENESS, SUBJECTS WHOSE LENS WAS NOT REPOSITIONED)

	Control IOL (N=72) n(%)	Toric IOL 1.25 D (N=75) n(%)	Toric IOL 2.00 D (N=40) n(%)	Toric IOL 2.75 D (N=23) n(%)	All Toric IOL (N=138) n(%)
Total Non-Missing	66	74	39	20	133
Significant Visual Disturbance	6 (9.1)	0	1 (2.6)	0	1 (0.8)
No Significant Visual Disturbance	60 (90.9)	74 (100.0)	38 (97.4)	20 (100.0)	132 (99.2)

Table 15
Percentage reduction of cylinder (ANSI) stratified by predicted postoperative corneal cylinder

Predicted Postoperative Corneal Cylinder (D)	Percentage Reduction of Cylinder (ANSI) Toric IOL 1.25 D n	mean	Sphere IOL n	mean
0.83 to 1.07	45	77.52	51	44.59
1.08 to 1.32	29	83.55	17	52.23

Notes: Percentage reduction of cylinder (ANSI) = percentage of intended reduction achieved from preoperative keratometric cylinder to postoperative manifest cylinder

Table 16
Percent reduction of preoperative corneal cylinder stratified by preoperative keratometric cylinder

Preoperative Keratometric Cylinder (D)	Percent Reduction of Cylinder Toric IOL 1.25 D n	mean	Sphere IOL n	mean
1.33 to 1.57	43	71.12	50	41.23
1.58 to 1.82	29	65.50	17	41.33

Notes: Percent reduction of cylinder = (preoperative keratometric cylinder - postoperative refractive cylinder) / preoperative keratometric cylinder

Table 17
Refractive cylinder stratified by preoperative keratometric cylinder

Preoperative Keratometric Cylinder (D)	Magnitude of Refractive Cylinder (D) Toric IOL 1.25 D n	mean	Sphere IOL n	mean
1.33 to 1.57	43	0.41	50	0.86
1.58 to 1.82	29	0.59	17	1.01

Table 18
logMAR uncorrected distance visual acuity (UCDVA) stratified by preoperative keratometric cylinder

Preoperative Keratometric Cylinder (D)	logMAR UCDVA Toric IOL 1.25 D n	mean	Sphere IOL n	mean
1.33 to 1.57	43	0.10	50	0.20
1.58 to 1.82	29	0.11	17	0.16

Table 19

Change in absolute cylinder stratified by preoperative keratometric cylinder

Preoperative Keratometric Cylinder (D)	Change in Absolute Cylinder (D)	Toric IOL 1.25 D	Sphere IOL
1.33 to 1.57	Total Non-Missing	43	50
	Mean (SD)	-1.020 (0.407)	-0.573 (0.609)
	Median	-1.010	-0.610
	Min, Max	-1.52, 0.14	-1.56, 1.23
	< 0.50 D	43 100.0%	48 96.0%
	> 0.50 D	0	2 4.0%
	≤ 0.50 D	6 14.0%	21 42.0%
	>-0.50 D	6 14.0%	23 46.0%
	<-0.50 D	37 86.0%	27 54.0%
	<-0.75 D	33 76.7%	22 44.0%
	<-1.00 D	22 51.2%	11 22.0%
	Missing	0	0
1.58 to 1.82	Total Non-Missing	29	17
	Mean (SD)	-1.104 (0.454)	-0.679 (0.564)
	Median	-1.100	-0.780
	Min, Max	-1.81, 0.16	-1.69, 0.49
	< 0.50 D	29 100.0%	17 100.0%
	> 0.50 D	0	0
	≤ 0.50 D	3 10.3%	6 35.3%
	>-0.50 D	3 10.3%	6 35.3%
	<-0.50 D	26 89.7%	11 64.7%
	<-0.75 D	25 86.2%	9 52.9%
	<-1.00 D	20 69.0%	4 23.5%
	Missing	0	0

Notes: Change in absolute cylinder = |postoperative refractive cylinder| - |preoperative keratometric cylinder|

Table 20

Error in the predicted postoperative keratometric astigmatism at 120 to 180 days after surgery

	Randomized Eyes (N=150)
Signed Bias versus Predicted (D)	
Total Non-Missing	141
Mean (SD)	0.132 (0.398)
Median	0.120
Min, Max	-0.78, 1.24
Absolute Error (D)	
Total Non-Missing	141
Mean (SD)	0.335 (0.250)
Median	0.270
Min, Max	0.01, 1.24

Table 21

Error in the predicted postoperative keratometric steep axis at 120 to 180 days after surgery

	Randomized Eyes (N=150)
Signed Bias versus Predicted (degrees)	
Total Non-Missing	141
Mean (SD)	-0.1 (17.9)
Median	-1.0
Min, Max	-49, 88
Absolute Error (degrees)	
Total Non-Missing	141
Mean (SD)	11.7 (13.6)
Median	7.0
Min, Max	0, 88

Table 22

Dioptric change in cylinder (D) by IOL cylinder power including control

	Sphere	Toric 1.25D	Toric 2.00D	Toric 2.75D
N	68	74	39	21
Mean (SD)	-0.61 (0.59)	-1.06 (0.42)	-1.61 (0.50)	-2.27 (0.45)
Median	-0.64	-1.07	-1.73	-2.37
Min, Max	-1.69, 1.23	-1.81, 0.16	-2.11, 0.46	-2.93, -1.34

Notes: Dioptric change in cylinder = |postoperative manifest cylinder| - |preoperative keratometric cylinder|

CLINICAL TRIAL (PARENT MODEL AT-45)

The US clinical trial of the Crystalens® Model AT-45 was conducted in 497 eyes of 324 patients with ≤1D of cylinder. The range of axial lengths studied in the clinical trial of the Crystalens® was 21.0 to 26.6 mm and the dioptric power range was 16.5 to 27.5 D. The clinical results were obtained using an 'A' Constant of 119.0, the SRK/T formula, immersion biometry or interferometry and manual keratometry.

RESULTS

The adverse event data for the US clinical trial through 12 months is presented in **Table 23** below.

TABLE 23
ADVERSE EVENTS REPORTED AT 12 MONTHS

ADVERSE EVENT	CUMULATIVE		FDA GRID	PERSISTENT		FDA GRID
	PRIMARY EYES	ALL EYES		PRIMARY EYES	ALL EYES	
Endophthalmitis	1/324 (0.3%)	1/497 (0.2%)	0.1%	----	----	----
Hyphema	1/324 (0.3%)	1/497 (0.2%)	2.2%	----	----	----
Hypopyon	0/324	0/497	0.3%	----	----	----
IOL Dislocation	0/324	0/497	0.1%	----	----	----
Cystoid Macular Edema	12/324 (3.7%)	13/497 (2.6%)	3.0%	2/304 (0.7%)	3/450 (0.7%)	0.5%
Pupillary Block	0/324	0/497	0.1%	----	----	----
Retinal Detachment	0/324	0/497	0.3%	----	----	----
Secondary Surgical Reintervention	2/324 (0.6%)	4/497 (0.8%)	0.8%	----	----	----
Corneal Edema	----	----	----	0/298	0/440	0.3%
Iritis	----	----	----	2/298 (0.7%)	3/440 (0.7%)	0.3%
Raised IOP Requiring Treatment	----	----	----	0/304	0/450	0.4%

The results achieved by 304 patients followed for one year provide the data that were used to support the effectiveness of the Crystalens® AT-45 IOL in providing near, intermediate, and distance vision without spectacles. Visual acuity with or without correction at all distances improves when both eyes are implanted with a Crystalens.

1. In 124 bilaterally-implanted patients, the portion of patients achieving uncorrected visual acuities of 20/32 (J2) or better at one year was:	
Distance	97.6%
Intermediate	100% at 80cm
Near	93.5% at 40 cm
2. In 74 bilaterally-implanted patients who were within ±0.5D of plano in each eye, the portion of patients achieving uncorrected visual acuities of 20/32 (J2) or better at one year was:	
Distance	100%
Intermediate	100% at 80cm
Near	97.3% at 40 cm

In a substudy comparing the Crystalens® with a control population comprised of several models of standard IOLs of varying types (e.g., single piece, multipiece) and materials (e.g., silicone, acrylic), the visual acuity at all distances at 3-6 months postoperative was significantly greater in Crystalens® implanted eyes than in eyes implanted with a standard IOL. The results are shown in **Table 24.**

TABLE 24
CRYSTALENS® VS STANDARD IOL VISUAL ACUITY
(BEST SPECTACLE CORRECTED DISTANCE AND NEAR AND INTERMEDIATE ACUITY THROUGH THE DISTANCE CORRECTION)

	CRYSTALENS®		STANDARD IOL	
20/20 or better	1/121	0.8%	0/64	0.0%
20/25 or better	29/121	24.0%	0/64	0.0%
20/32 or better	61/121	50.4%	3/64	4.7%
20/40 or better	107/121	88.4%	23/64	35.9%
Worse than 20/40	14/121	11.6%	41/64	64.1%

The visual acuity results are presented in **Tables 25-29.**

The stability of the outcomes was demonstrated in a consistent cohort of patients across the Form 3 to Form 4 (1-2 months to 3-6 months) and Form 4 to Form 5 (3-6 months to 11-15- months) postoperative intervals. Stability was measured using both the manifest spherical equivalent (MRSE) and visual acuity.

TABLE 25
BILATERAL - UNCORRECTED VISUAL ACUITY

	NEAR AT 40 CM		INTERMEDIATE AT 80 CM		DISTANCE	
20/20 or better	39/124	31.5%	120/124	96.8%	98/123	79.7%
20/25 or better	90/124	72.6%	122/124	98.4%	113/123	91.9%
20/32 or better	116/124	93.5%	124/124	100%	120/123	97.6%
20/40 or better	122/124	98.4%	124/124	100%	121/123	98.4%
Worse than 20/40	2/124	1.6%	0/124	0%	2/123	1.6%

TABLE 26
BILATERAL - UNCORRECTED VISUAL ACUITY
FOR PATIENTS WITHIN ±0.5D OF PLANO IN EACH EYE

	NEAR AT 40 CM		INTERMEDIATE AT 80 CM		DISTANCE	
20/20 or better	17/74	23.0%	NA	NA	67/74	90.5%
20/25 or better	49/74	66.2%	74/74	100%	73/74	98.6%
20/32 or better	72/74	97.3%	74/74	100%	74/74	100%
20/40 or better	74/74	100%	74/74	100%	74/74	100%
Worse than 20/40	0/74	0%	0/74	0%	0/74	0%

TABLE 27
BILATERAL UNCORRECTED VISUAL ACUITY (1 YEAR VERSUS 3 YEAR)

	NEAR AT 40 CM				DISTANCE			
	1 Year		3 Year		1 Year		3 Year	
20/25 or better	90/124	72.6%	36/50	72.0%	113/123	91.9%	46/50	92.0%
20/32 or better	116/124	93.5%	43/50	86.0%	120/123	97.6%	47/50	94.0%
20/40 or better	122/124	98.4%	49/50	98.0%	121/123	98.4%	49/50	98.0%
Worse than 20/40	2/124	1.6%	1/50	2.0%	2/123	1.6%	1/50	2.0%

TABLE 28
BILATERAL DISTANCE CORRECTED NEAR VISUAL ACUITY (1 YEAR VERSUS 3 YEAR)

	1 YEAR		3 YEAR	
20/25 or better	64/124	51.6%	29/50	58.0%
20/32 or better	104/124	83.9%	42/50	84.0%
20/40 or better	124/124	100%	50/50	100%
Worse than 20/40	0/124	0%	0/50	0%

TABLE 29
UNILATERAL - UNCORRECTED VISUAL ACUITY (ALL EYES)

	NEAR AT 40 CM		INTERMEDIATE AT 80 CM		DISTANCE	
20/20 or better	52/368	14.1%	--	--	184/371	49.6%
20/25 or better	161/368	43.8%	--	--	269/371	72.5%
20/32 or better	256/368	69.6%	--	--	311/371	83.8%
20/40 or better	328/368	89.1%	--	--	339/371	91.4%
Worse than 20/40	40/368	10.9%	--	--	32/371	8.6%

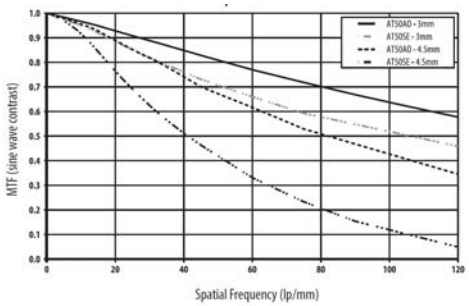
ASPHERIC INFORMATION

The Trulign Toric IOL models BL1AT/BL1UT have prolate aspheric surfaces, similar to Crystalens AO, and is designed to be free of spherical aberration. The image quality of the Crystalens AO is illustrated in the figure below in the form of a modulation transfer function curve.

NOTE: Based on bench testing, the lens models with aspheric surfaces may provide somewhat reduced near acuity compared to the spherical model. No clinical study was performed to verify these findings or to assess the effect of the added aspheric surface on spherical aberration, night-time distance visual acuity, and contrast sensitivity compared to the parent model Crystalens® model AT-45.

NOTE: The image quality of models AT50AO and AT50SE was characterized by measuring modulation transfer function (MTF) in a model eye described in ISO 11979-2 through 3 mm and 4.5 mm lens apertures.

Modulation Transfer Function of AT50AO & AT50SE
+22 Diopter Lenses



HAPTICS

The plate haptics are 0° +/-2° from the optic plane and have hinges across the face of the plates adjacent to the optic. Two flexible colored polyimide (Kapton) loops are attached to each distal extremity of the plates (see lens illustrations for overall length per model). The length of the plate is 10.5 mm.

MECHANISM OF ACTION

The Trulign Toric IOL was designed to move in a backward and forward motion along the axis of the eye in response to pressure changes in the vitreous cavity and anterior chamber that result from relaxation and contraction of the ciliary muscle. The exact mechanism of action has not been fully elucidated.

Trulign Toric IOL has axis marks on the anterior surface denoting the flat meridian of the lens. Aligning the axis mark with the post-operative steep corneal meridian allows the lens to correct astigmatism.

DIRECTIONS FOR USE

Trulign TORIC IOL CALCULATOR

The Trulign Toric IOL Calculator may be accessed at http://trulign.toriccalculator.com/

For optimal results, the Trulign Toric IOL Calculator will be used to select the appropriate cylinder power of the toric lens. The Trulign Toric IOL Calculator will calculate the predicted post-operative corneal astigmatism using pre-operative keratometry, phaco/insertion incision location and expected magnitude of surgically-induced astigmatism inputs from the Surgeon. The calculator will account for surgically induced astigmatism, incision location and the patient's pre-operative corneal astigmatism, and will determine the Toric IOL cylinder power needed and placement orientation in order to best correct a patient's expected post-operative corneal astigmatism. For optimal toric IOL calculations, it is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results. An example of this calculation can be found within the following reference (Holladay JT, Cravy TV, Koch DD. "Calculating the surgically induced refractive change following ocular surgery", JCataract Refract Surg. 1992;18:429-43).

Complete the following steps:

1. Measure patient keratometry and axis
2. Start the Trulign Toric IOL Calculator software program
3. Enter the requested information into the calculator program.
4. Press the calculate button.
5. Identify the toric IOL cylinder power that needs to be implanted.
6. Identify the correct Lens.
7. Print the results.

PLACEMENT OF TRULIGN TORIC IOL

The surgeon must ensure correct placement and orientation of the lens within the eye. All lenses will be oriented along the expected post-op steep meridian of the cornea. The surgeon should keep in mind misalignment of the long axis of the lens with the steep keratometric meridian will reduce its effectiveness by approximately 3% for every 1 degree of misalignment.

The Toric lens is marked with two lines at the edge of the optic that are aligned with the long axis of the lens. Since the preoperative refraction is frequently not accurate or can be influenced by lenticular astigmatism, it is necessary to align the lens with the expected post-op steep axis of the cornea as indicated by the toric calculator rather than use refractive data. For example: 45.00 D at 180, 43.00 D at 90, align the long axis of the Trulign Toric IOL at 180.

MARKING THE CORNEA PRIOR TO SURGERY

NOTE: Use the Trulign Toric IOL Calculator software to determine the appropriate lens cylinder power and axis placement which accounts for both pre-existing corneal astigmatism and the surgically induced astigmatism from the incision (see below).

Immediately prior to surgery the subject's operative eye will be marked to identify the axis of placement while seated at the slit-lamp. The following procedure will be followed.

- Ensure there is adequate corneal anesthesia.
- Seat the subject at the CSO slit lamp microscope and ensure the head is erect and straight with no head rotation that could affect the correct orientation of the intended axis placement.
- Ensure that the patient's pupil is dilated.
- Direct the subject to look at a distance fixation object visible to the non-operative eye.
- Using a full height slit that is approximately 0.2mm wide, rotate the lamp housing and use the degree scale to select the approximate axis of placement.
- With the slit beam indicating the correct axis of placement, mark the eye with the surgeon's preferred method referenced for marking the cornea.
- After marking the cornea, capture a digital photo to record the axis of placement marks with respect to the reference blood vessels.

1. Prior to implanting, examine the lens package for IOL type, power, and expiration date.
2. Open the peel pouch and remove the lens from the sterile packaging by pressing and lifting the cover off the plastic lens case (holder). Place the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surface for other defects.
4. Position the lower blade of the forceps in the slot of the lens case beneath the lens. A Cumming intraocular lens forceps is recommended. Grasp the lens so that the forceps extends across the *distal hinge* to stabilize the *leading plate haptic*. **Do not grasp the lens by the haptics.**
5. Remove the lens in its position for implantation with a single grasp.

INSERTION DEVICE DETAILS

6. The Crystalsert® delivery system may be used to inject the Trulign Toric IOL. A cohesive viscoelastic should be used for lubrication of the injector when inserting the IOL. The IOL should be injected within three minutes after loading. Refer to the instructions for use supplied with the injector. See **http://www.crystalens.com** for further details on the use of the injector with the Trulign Toric IOL.

INSERTION BY FORCEPS

7. Advance the forceps to place the *leading plate haptic* of the lens into the distal capsular bag, which should be completely filled with a cohesive viscoelastic.
8. The round knob on the loop of the leading haptic should be on the right to ensure that the hinge's "open" side is "right side up" and is facing the anterior part of the eye on implantation.
9. With a second instrument, hold the proximal *polyimide* loop to maintain the position of the lens in the capsular bag as the implantation forceps are withdrawn from the eye.
10. Regrasp at the tip of the *trailing plate haptic* with the implantation forceps.
11. As you advance the *trailing plate haptic* into the anterior chamber, the polyimide loops will bend back on themselves as they traverse the small incision. Advance the leading plate up towards the cornea. *This will cause the leading plate haptic to bend to a right angle deep into the bag.*
12. Maintain your grasp at the tip of the *trailing plate haptic*. Tuck the polyimide loops, one by one, into the capsular bag. **Do not release the tip until the loops are in the bag.**
13. Release and withdraw the forceps. The lens will self-center.

NOTE: The lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to its surface.

LENS POWER CALCULATIONS

The surgeon should determine preoperatively the power of the lens to be implanted by using either immersion or IOL Master biometry and manual keratometry. Lens power calculation methods are described in the following references:

- Holladay JT et al. A Three Part System for Refining Intraocular Lens Power Calculations. J Cataract Surg 14, January 1988.
- Retzlaff JA et al. Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16, May 1990.
- Hoffer KJ. The Hoffer Q Formula. A comparison of theoretical and regression formulas. J Cataract Refract Surg 19, November 1993.

NOTE: The Surgeon Factor, 'A' Constant and ACD values, which are located on the outside of the package, are estimates only. It is recommended that the surgeon determine his/her own values based on their individual clinical experience. Surgeons requiring additional information on lens power calculation may contact Bausch + Lomb.

FACTORS TO CONSIDER IN DECIDING WHETHER TO IMPLANT A TORIC LENS

Effectiveness of implanting a toric lens in reducing postoperative astigmatism is affected by many factors, including the following:

- Accurate determination of the magnitude and axis of postoperative corneal astigmatism which is impacted by:
  - Accurate keratometry to determine the magnitude and axis of the preoperative corneal astigmatism
  - Surgeon customized SIA (surgically induced astigmatism)
  - Precise incision location
- The degree of mismatch between the postoperative magnitude of corneal astigmatism and effective IOL power in the corneal plane
- Toric IOL 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. Based on the tolerances, cylinder power variation may cause the intended correction at the corneal plane to vary by up to ± 0.35 D, and cylinder axis tolerance may reduce intended correction by up to 16.5%.

RECOMMENDATIONS FOR MAXIMIZING P A T I E N T OUTCOMES

- IOL Master or manual keratometry, immersion biometry or interferometry is strongly recommended to obtain optimum patient outcomes.
- A waiting period of two weeks between the first and second eye is recommended in order to accurately determine the lens power for the second eye.
- If inserting with forceps, the incision width should be 3.5 to 3.7 mm but no larger than 4 mm and should be at least 2.5 mm long. The paracentesis should be approximately 1.0 to 1.5 mm in width and approximately 2.0 mm long.
- The capsulorhexis should be round (5.5 to 6.0 mm) with the anterior capsule covering the plate haptics. If the capsulorhexis is oval, then the lens should be rotated to ensure maximum coverage of the plate haptics.
- Meticulous cortical clean-up should be performed and the lens rotated at least 90° to dislodge any hidden or trapped cortex.
- Patients should be kept on a tapering course of anti-inflammatory agents for a minimum of 4 weeks.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives a Trulign Toric 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.

REPORTING

Adverse Reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported to Bausch + Lomb at 866-393-6642 (USA). This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

HOW SUPPLIED

The contents of the inner and outer peel pouches are sterile unless the packages are damaged or opened. The intraocular lenses are moist heat sterilized and supplied in a lens case within a double aseptic transfer peel pouch.

EXPIRATION DATE

Sterility is guaranteed unless the sterile pouch is damaged or opened. In addition, there is a sterility expiration date that is clearly indicated on the outside of the package. The lens should not be used after the indicated date.

RETURNED LENS POLICY

Please contact your local Bausch + Lomb office regarding lens exchange.

BIBLIOGRAPHY

1. Boettner, EA and Wolter JR 1962. Transmission of the ocular media. Invest Ophthal 1: 776-783.
2. Busacca, A. La Physiologie Du Muscle Ciliaire Etudiee Par La Gonioscopie. Annales D'Oculistique 1955; 1–21.
3. Coleman J. On the hydraulic suspension theory of accommodation. Trans Am Ophth Soc 1986; 846-868.
4. Colin, J. Clinical results of implanting a silicone haptic-anchor-plate intraocular lens. J Cataract Refract Surg, 1996;2:1286–1290.
5. Cumming JS et al. Clinical evaluation of the Model AT-45 silicone accommodating intraocular lens. Ophthalmology 2001;108:2005-2010.
6. Cumming JS, Ritter J. The Measurement of Vitreous Cavity Length and its Comparison Pre- and Postoperatively. Eur J Implant Ref Surg 1994;6:261–272.
7. Fisher R. The ciliary body in accommodation. Tran Ophthalmol Soc UK 1986;105:208-219.
8. Girard LJ et al. Complications of the Simcoe Flexible Loop Phacoprosthesis in the anterior chamber. Ophthalmic Surg 14(4)
9. Glasser A and Kaufman PL. The mechanism of accommodation in primates. Ophthalmol 1999;106: 863-872.
10. Kammann J. Vitreous-stabilizing, single-piece, mini-loop, plate-haptic silicone intraocular lens. J Cataract Refract Surg 1998;24:98–106.
11. Thornton S. Accommodation in pseudophakia. Color Atlas of Lens Implantation. 1991;159–162.
12. Willis DA, Stewart RH, Kimbrough RL. Pupillary block associated with posterior chamber lenses. Ophthalmic Surg 1985; 16:108-9.

FIGURE 1 MODEL AT50T/BL1AT/BL1UT

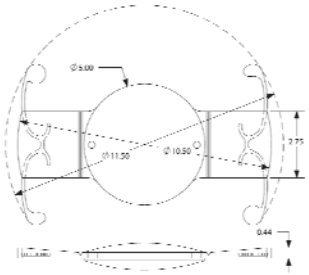
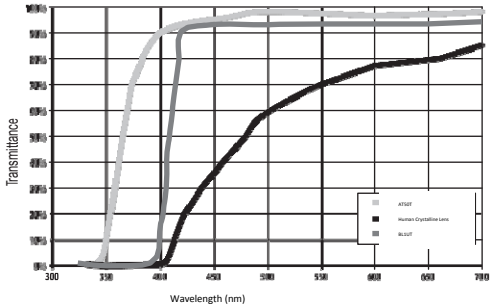


FIGURE 2 – SPECTRAL TRANSMITTANCE WITH MODEL AT50T (REPRESENTATIVE OF AT50T AND BL1AT), HUMAN CRYSTALLINE LENS, AND BL1UT



NOTES:

Spectral Transmittance Curve for AT50T & BL1AT (20.0D equivalent) have a 10% UV cut off at 354 nm

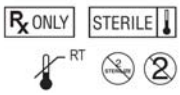
Spectral Transmittance Curve Corresponding to 53 year-old Phakic Eye (see Bibliography reference #1)

Spectral Transmittance Curve for BL1UT (20.0D equivalent) has a 10% UV cut off at 400 nm

SYMBOLS USED ON LABELING

SYMBOLS	ENGLISH
	Manufacturer
	Do not reuse
	YYYY-MM
	Date of Manufacture (YYYY-MM)
	Caution: Consult Instructions for Use
	Sterilized Using Steam or Dry Heat
	STORE AT ROOM TEMPERATURE (RT)
	Do not resterilize
	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed practitioner
	Do not use if the package is damaged

Bausch & Lomb Incorporated
Aliso Viejo, CA 92656 USA
Manufacturing site:
Bausch & Lomb Incorporated
10574 Acacia Street, Suite D-1, Rancho Cucamonga, CA 91730 USA



50-0233NEW / 4105300

Revised: May-2013