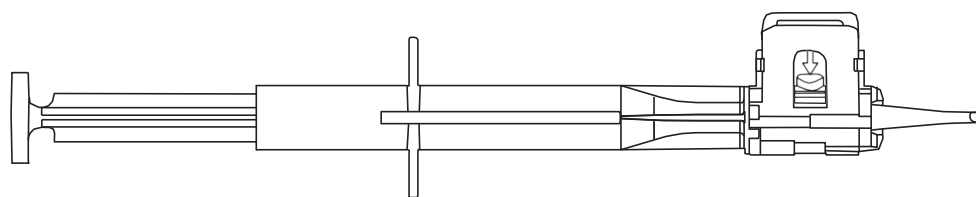


RayOne

EMV TORIC



MR



Rayner Intraocular Lenses Limited
The Ridley Innovation Centre,
10 Dominion Way, Worthing, West
Sussex, BN14 8AQ, UK
Tel: +44 (0)1903 258900, rayner.com

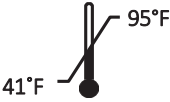
Prescription device: Federal U.S. law restricts this device to sale by, or on the order of, a physician.

RayOne EMV Toric US eIFU PF000199, Version 1, Issue Date: 8th October 2025

 Rayner

EN

Symbol/Explanation

	Single use, do not reuse		Do not re-sterilize
	Steam Sterilized		Do not use if the sterile barrier system or packaging is damaged
	Store between 41-95°F temperature		Keep away from sunlight
	Keep dry		Consult Instructions for use
	Model Number		Consult electronic instructions for use
	Batch code		Serial Number
	Manufacturer		Use-by date
	Date of Manufacture		Country of Manufacture
	Caution		Unique Device Identifier
	Medical Device		Double sterile barrier system
	MR safe		Patient Name
	Date of Implant		Hospital



Rayner Intraocular Lenses Limited The Ridley
Innovation Centre,
10 Dominion Way, Worthing, West
Sussex, BN14 8AQ, UK
Tel: +44 (0)1903 258900, rayner.com



rayner.com/ifu
80013579135

Loading Instructions

Figure 1



Figure 2

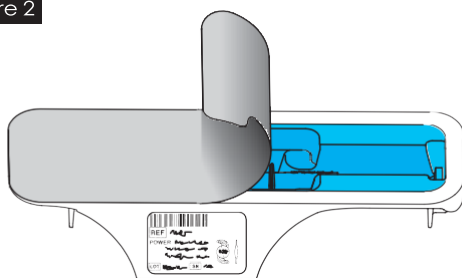


Figure 3

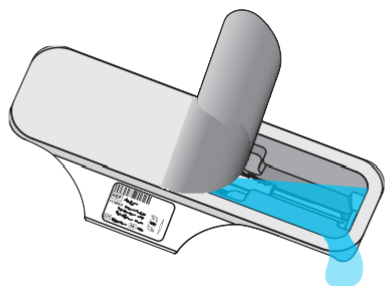


Figure 4

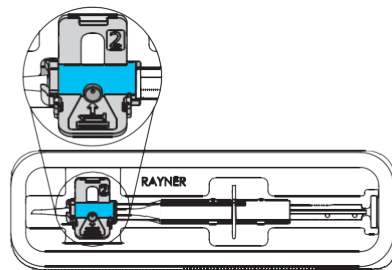


Figure 5

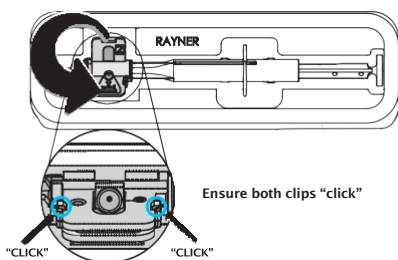


Figure 6

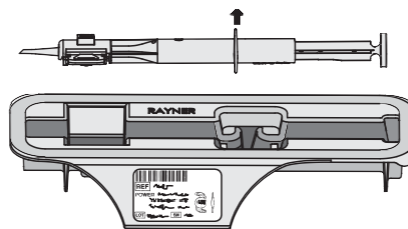


Figure 7

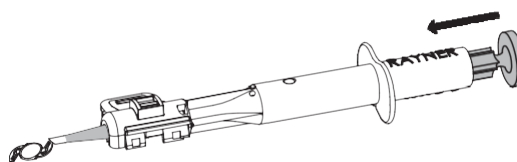


Figure 8

IOL Material UV Light Transmission

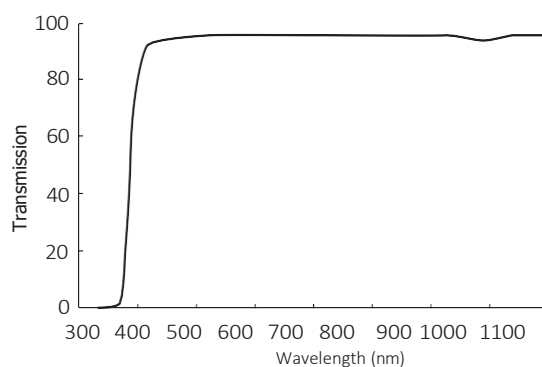
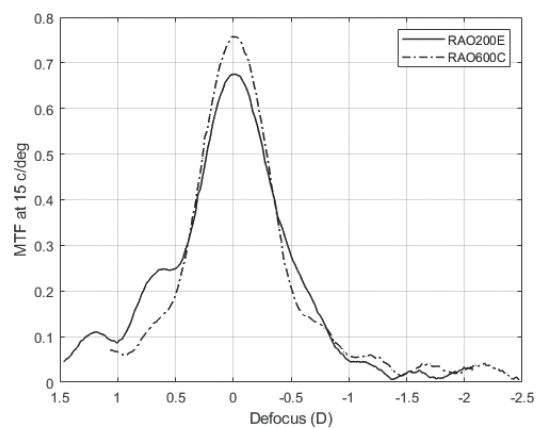


Figure 9

Through focus MTF for 20.0 D non-Toric version (200E) of the EMV Toric (210T) and Aspheric (600C) IOLs at 3.0 mm aperture in ISO 11979-2 (2014) model eye 2 with +0.2 μm corneal spherical aberration using monochromatic light (546 nm)



Device Description

Rayner intraocular lenses (IOLs) are single piece optical devices, manufactured from hydrophilic Rayacryl (hydroxyethyl methacrylate/methyl methacrylate copolymer with UV blocker). These devices are designed to be surgically implanted in the human eye as a replacement for the crystalline lens, and are intended for placement in the capsular bag following phacoemulsification.

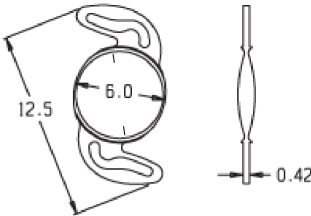
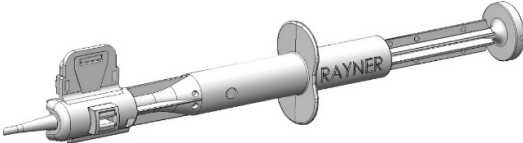
Rayner IOLs are intended to provide adjustment to the dioptric power of the eye. Toric models are intended to provide adjustment to the astigmatism of the eye.

The RayOne EMV Toric has an aspheric posterior surface designed to control the spherical aberration of the IOL; this lens is designed to have positive spherical aberration and is intended to add to the positive spherical aberration of the cornea. This addition to positive spherical aberration is controlled with pupil size and smooth transitions to negative spherical aberration towards the edge of the optic to prevent excessive positive spherical aberration reducing image quality at larger pupil sizes. In addition, RayOne EMV Toric is intended to provide adjustment to the astigmatism of the eye.

The RayOne injection system is a Fully Preloaded system that delivers a 6 mm optic diameter lens into the eye through a micro incision. The RayOne injector is designed to mechanically fold a lens and insert it into the eye during routine cataract surgery.

The physical characteristics of RayOne EMV Toric are shown in **TABLE 1**.

TABLE 1 RAYONE EMV TORIC PHYSICAL CHARACTERISTICS

Parameter	RayOne EMV Toric
Lens image	Front view of IOL and side view of IOL All dimensions in mm 
Injector image	
Lens material	Rayacryl
Injector material	Polypropylene & TPE
Design features	Aspheric, Toric, Monofocal capsular bag fixated
Injection system	Fully preloaded
Overall diameter (mm)	12.5 ± 0.2
Optic diameter (mm)	6.0 ± 0.1
Limb width (mm)	0.38 ± 0.1
Limb thickness (mm)	0.41 ± 0.15
Haptic style	Closed C-loop
Square edge	360° posterior Enhanced Square Edge
Sphere power range (increments)	+7.75 to 23.875 D
Spherical equivalence (increments)	+10 to 25 D (0.5 D)
Cylinder power range (increments)	+1.5 to 4.5 D (0.75 D)
Index of refraction	1.46

The effective corneal powers for each of the test lens plane cylindrical powers of the test IOLs are shown in **TABLE 2**.

TABLE 2 CYLINDER POWER AND CORNEAL ASTIGMATISM CORRECTION RANGE

IOL Type	IOL Power at IOL Plane (D)	Cyl Power on Corneal Plane (D)	Specified Range (D) Lower	Specified Range (D) Upper
T3	1.5	1.03	1.03	1.53
T4	2.25	1.54	1.54	2.04
T5	3	2.05	2.05	2.56
T6	3.75	2.57	2.57	3.07
T7	4.5	3.08	3.08	3.59

RayOne EMV Toric is available from:

SE: +10.0 D to +25.0 D in 0.5 D increments

Cylinder: +1.5 D to +4.5 D in 0.75 D increments

Suggested “A” Constant

Optical Biometry 118.6

Contact Ultrasound Biometry 118.0

Barrett Toric Calculator constants LF=1.67, DF=0

IOL Material (Rayacryl) Characteristics

- Water content: 26% in equilibrium
- Refractive index: 1.46
- UV light transmission: shown in Figure 8 (UV 10% cut-off is 380 nm)
- Nd: YAG laser compatible

Indications for Use

The RayOne EMV Toric (Model RAO210T) consists of the EMV Toric IOL (210T) preloaded within the RayOne injection system (RAO). The EMV Toric IOL is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia, in adult patients in whom a cataractous lens has been removed by phacoemulsification and providing reduction of residual refractive astigmatism in adult patients with greater than or equal to 1.00 diopter (D) of corneal astigmatism. The RayOne injection system is used to fold and assist in inserting the IOL into the eye.

Contraindications

There are no known contraindications.

Adverse Events

Cataract surgery for IOL implantation presents risks which the surgeon must evaluate. Potential complications of cataract surgery are:

- Secondary glaucoma
- IOL replacement or extraction
- Precipitates
- Reduced vision
- Vitreous herniation
- Excessive intraoperative vitreous loss
- IOL decentration
- Secondary membrane
- Expulsive hemorrhage
- IOL dislocation and subluxation
- Retrolenticular membrane

- Corneal edema
- Endophthalmitis and panophthalmitis
- Retinal detachment
- Corneal dystrophy
- Hemorrhage
- Iris atrophy
- Pupillary block
- Cystoid macular edema
- Severe ametropia and aniseikonia
- Iridocyclitis and hyalitis
- Deviation from target refraction
- Fibrin reaction.

Warnings

- RayOne EMV Toric cannot be reused, as it is not designed to perform as intended after the first and only usage. Changes in mechanical, physical or chemical characteristics, under conditions of repeated use, cleaning and resterilization, will compromise the integrity of the device.
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to dehydrate during the procedure.
- Do not use balanced salt solution (saline) as the sole lubricating agent, always use in combination with an ophthalmic viscosurgical device (OVD).
- Do not attempt to disassemble, modify or alter this device or any of its components, as this can significantly affect the function and/or structural integrity of the design.
- The sterility of the contents is guaranteed only if the outer tray has not been opened or damaged.
- Do not use if the pack has been damaged.
- Do not store in direct sunlight.
- Do not store the pack outside of the recommended storage conditions; store between 41°F - 95°F.
- Do not use after the expiration date.
- Do not attempt to reuse this device.
- Do not resterilize.
- Do not use system at temperature below 70°F (equilibration takes approximately 90 minutes from an initial temperature of 41°F).

Precautions

- Healthcare professionals considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
 - Active or recurrent ocular disease (e.g. uveitis, diabetic retinopathy, pars planitis, chronic glaucoma not responsive to medication)
 - Corneal endothelial compromise, including corneal decompensation, edema, endothelial insufficiency
 - Previous ocular surgery or conditions to complicate cataract extraction (e.g. iris atrophy or pseudo exfoliation)
 - Severe aniseikonia
 - Macular degeneration or other retinal pathologies, need for retinal laser treatment, potentially limiting postoperative visual performance

- Zonular weakness or dehiscence (consider a capsular tension ring (CTR) to support the capsular bag)
 - Ruptured posterior capsule or planned posterior capsulotomy
 - Patients with ocular comorbidities that may prevent stable visual acuity or require frequent posterior segment interventions
 - Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases
 - Surgical complications 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 or ocular hemorrhage)
 - Anatomic abnormalities of the eye, such as microphthalmia, trauma, distorted eye or developmental defect preventing adequate IOL fixation
 - Circumstances that could cause endothelial trauma during implantation
 - Suspected or active ocular microbial infection or inflammation
 - Children under the age of 21 years
 - Patients with ocular disorders, other than cataract, could potentially cause future acuity losses to a level of 20/30 or worse in either eye
- The lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
 - Rotation of the IOL away from the intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, IOL positioning should occur prior to capsule fibrosis and IOL encapsulation.
 - The clinical study of the RayOne EMV Toric was conducted with the lens implanted into the capsular bag only. There are no clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus.

How Supplied

Rayner EMV Toric IOLs (210T) are supplied in a 0.9% saline solution preloaded in the RayOne (RAO) injection system within the blister pack terminally sterilized with moist heat and should only be opened under aseptic conditions.

Expiration Date

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

Directions for Use

The RayOne preloaded injector should only be used for the placement of Rayner IOLs into the eye.

To ensure optimum injection performance of the IOLs, the blister pack should be allowed to equilibrate to a temperature of 70°F or above before use. The use of a sodium hyaluronate based OVD is recommended. Insert the IOL into the eye within 3 minutes of closing the cartridge.

Use of RayOne

Fig 1 Peel open the outer pouch as directed. Prior to implanting, examine the lens label on the unopened inner package for model, type, power, proper configuration and expiration date. The lens may be soaked in sterile balanced salt solution until ready for implantation.

Fig 2 Carefully peel back the lid halfway down the second blister pack.

Fig 3 Carefully drain the saline from the blister tray and peel off remaining lid. Do not remove the injector from the blister tray. Do not wait more than 3 minutes before adding OVD - Dehydration risk. Non-toothed, polished instruments must be used when handling the IOL. Rayner recommends that saline is not used as the sole lubricating agent, but in combination with a viscoelastic solution. The use of a sodium hyaluronate-based viscoelastic is recommended. Insert the viscoelastic cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge.

Fig 4 Insert the viscoelastic cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge. **NOTE:** Rayner's patented "lock and roll" injector technology uses the mechanical force of OVD

inserted into the indicated port to move the IOL from 'storage' to 'roll ready' position at the bottom of the cartridge; do not add OVD directly via the nozzle tip.

Fig 5 Keep the injector in the tray and close the cartridge firmly together by pushing the moving half of the cartridge (Labelled 2) against the fixed half until you hear it click closed. Check both clips have “clicked” shut and secured the cartridge.

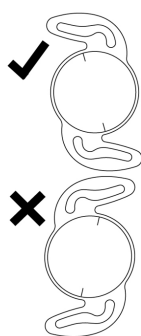
Fig 6 Gently lift out the injector from the tray.

Fig 7 Press the plunger in a slow and controlled manner. If excessive resistance is felt this could indicate a blockage; discontinue use of the product and return the product and all packaging to Rayner. In the case of IOL rotation during ejection from the nozzle, gently rotate the injector in the opposite direction to counteract any movement. Stop depressing the plunger when the IOL exits the nozzle. Discard the injector after use. Following implantation, irrigate/aspirate to eliminate any OVD residues from the eye, especially between the IOL and posterior capsule. The anterior continuous curvilinear capsulorhexis should be 360° and just cover the anterior edge of the IOL optic by 0.5 to 1.0 mm.

IOL Placement

Ensure that the IOL is implanted in the capsular bag with the correct anterior/posterior placement. Correct anterior/posterior placement is achieved when the haptics sweep away from the optic in a counterclockwise direction (anterior view Figure 10). The IOL can be dialed clockwise as is usual for posterior chamber IOLs. The anterior continuous curvilinear capsulorhexis should be positioned just covering the 360° anterior edge of the IOL optic by 0.5 to 1.0 mm.

Figure 10
IOL Haptic Orientation



Correct rotational orientation for toric IOLs is achieved when the IOL's axis marks (the lowest IOL power meridian) aligns with the cornea's highest power meridian. The IOL axis marks are therefore oriented in parallel to (or on) the steeper corneal meridian.

Calculation of IOL Power

The surgeon should preoperatively determine the power of the EMV Toric IOL to be implanted by using the acknowledged Barrett Toric Calculator. The Barrett constants for RayOne EMV Toric calculation are $LF=1.67$, $DF=0$ ("A" constant Optical Biometry 118.6 and Contact Ultrasound Biometry 118.0). Barrett Toric Calculator IOL power calculation methods are described in the following references:

1. Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of Methods to Predict Residual Astigmatism After Intraocular Lens Implantation. *J Refract Surg.* 2015 Oct;31(10):699-707. doi: 10.3928/1081597X-20150928-03. PMID: 26469077.
2. Abulafia A, Barrett GD, Kleinmann G, Ofir S, Levy A, Marcovich AL, Michaeli A, Koch DD, Wang L, Assia EI. Prediction of refractive outcomes with toric intraocular lens implantation. *J Cataract Refract Surg.* 2015 May;41(5):936-44. doi: 10.1016/j.jcrs.2014.08.036. Epub 2015 Apr 30. PMID: 25936681.
3. Barrett GD, Abulafia A, "Improving Outcomes With Toric Intraocular Lenses," presented at the XXXII Congress of the European Society of Cataract and Refractive Surgeons, London, United Kingdom, September 2014

Patient Registration and Reporting

A Patient Identification Card is included in the package. This is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye practitioner the patient consults in future.

Self-adhesive lens identification labels are provided for use on the Patient Identification Card, Implant Tracking Card and other clinical records.

Adverse events/complaints 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 Rayner Intraocular Lenses Limited, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, United Kingdom.

Tel. +44 (0) 1903 258900, Fax. +44 (0) 1903 258901, Email: feedback@rayner.com through the Rayner U.S. Distribution Center, 1255 Lynnfield Road, Suite 257 Memphis, TN 38119, United States, Tel: 844-RAYNER1.

The intraocular lens in this pack is for implantation into the capsular bag. A non-exhaustive list of risks, instructions for use, cautions and precautions and warnings are provided in this IFU which should be given to the patient prior to surgery. Rayner hereby disclaims all liability associated with any injuries or harm that may be suffered by the patient caused by: The method or technique of implantation used by the surgeon if the manufacturer's recommendations and instructions were not followed; an unsuitable prescription, selection or implantation of an unsuitable intraocular lens.

References:

- Kane JX, Connell B. A Comparison of the Accuracy of 6 Modern Toric Intraocular Lens Formulas. *Ophthalmology*. 2020 Nov;127(11):1472-1486. doi: 10.1016/j.ophtha.2020.04.039. Epub 2020 May 1. PMID: 32371252 <https://www.iolformula.com/>
- Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of Methods to Predict Residual Astigmatism After Intraocular Lens Implantation. *J Refract Surg*. 2015 Oct;31(10):699-707. doi: 10.3928/1081597X-20150928-03. PMID: 26469077
- Liu C, Wang M, Long D, Zhang Y, Chen Y, Wu Q. Comparison of the Accuracy of Toric Intraocular Lens Formulas Used by the Online Calculator of the European Society of Cataract and Refractive Surgeons. *J Refract Surg*. 2025 Feb;41(2):e120-e130. doi: 10.3928/1081597X-20241219-01. Epub 2025 Feb 1. PMID: 39937979

©2025 Rayner. Rayner, RayOne and Rayacryl are proprietary marks of Rayner. Rayner Intraocular Lenses Limited, The Ridley Innovation Centre, 10 Dominion Way, Worthing, West Sussex, BN14 8AQ, United Kingdom. Registered in England: 615539.

Summary of Clinical Studies

Clinical studies have been conducted on the C-flex 570C IOL and the RayOne EMV Toric. The RayOne EMV Toric is a combination of the optical design of the C-flex and RayOne EMV parents.

Clinical Data on C-flex

The Rayner C-flex 570C intraocular lens study was a multi-center clinical trial, with a historical control designed to assess safety and efficacy. Three hundred and one (301) C-flex patients were enrolled (unilateral implants) in this investigation. Additionally, data from one hundred and eighty-two (182) model Centerflex IOL patients was used as supportive data. The Centerflex IOL is identical to the C-flex model in all aspects except that the C-flex additionally features an Enhanced Square Edge. This feature is a 360° raised ridge encircling the periphery of both the anterior and posterior surfaces of the optic body (including the optic-haptic junction). The Rayner C-flex IOL met or exceeded historical controls for posterior chamber IOLs in all areas, for best corrected visual acuity at the 12 months post-operative examination. Safety was evaluated regarding specific cumulative adverse event rates and persistent adverse events rates as specified in the FDA Intraocular Lens Guidelines, 19997 and ISO 11979-7. Primary safety analyses were based on data from all enrolled procedures with follow-up to at least one-year post implantation. The pooled C-flex[™] and Centerflex accumulative and persistent adverse event rates at 12-months are lower than the FDA historical control grid in all areas except persistent macular edema, persistent corneal edema and cumulative pupillary block. These rates were higher than the grid rate, but the differences were not statistically significant. The results achieved by 283 patients in the C-flex 570C study and 166 patients in the Centerflex IOL study followed for one year, provide the basis for the data which were used to support that the EMV IOL (200E) design can be used for the visual correction of aphakia. Clinical studies were not conducted with the EMV IOL (200E) to assess the effect of its aspheric surface or increased optic size and overall diameter on spherical aberration, visual acuity or contrast sensitivity.

Clinical Data on RayOne EMV Toric

Study Description

The U.S. clinical trial of the RayOne EMV Toric was conducted as a prospective, multicenter, randomized, active controlled, masked investigation to determine the safety and performance of the 1.50 D toric IOL compared to an aspheric monofocal control. Key assessments included manifest refraction, visual acuity, IOL axis misalignment and orientation stability which were evaluated at follow-up visits. A total of 238 eligible subjects were randomized 1:1 to receive either the RayOne EMV Toric (n=118, Toric IOL group) or the RayOne Aspheric (n=120, Monofocal IOL group) in one eye following cataract extraction. Subjects underwent preoperative baseline assessments and postoperative follow-up visits at predefined intervals through Visit 4 (Day 120–180). The primary effectiveness endpoints were mean magnitude of residual manifest cylinder (as measured by manifest refraction) at Visit 4 (Day 120–180), toric IOL axis misalignment from pre-operatively marked intended axis at Visit 4, and rotational stability between Visit 3 (Day 30–60) and Visit 4. The primary effectiveness endpoints were assessed against the ANSI Z80.30 performance criteria. The primary safety endpoints included rates of cumulative and persistent adverse events listed in ISO 11979-7 at Visit 4, rates of all other adverse events not included in IOL adverse events from ISO 11979-7 at Visit 4, rates of secondary surgical interventions for IOL repositioning due to IOL misalignment at Visit 4, and rate of BCDVA 0.30 logMAR or better at Visit 4. Adverse events and safety outcomes were assessed against ISO 11979-7 criteria.

RayOne EMV Toric Clinical Trial Study Results

The clinical trial results provide reasonable assurance that the RayOne EMV Toric is safe and effective for the visual correction of aphakia and residual refractive astigmatism following cataract extraction.

Subject Population

A total of 274 subjects were enrolled (consented) in the study across 9 clinical sites in the United States. Of these, 238 subjects met the criteria for randomization. 233/274 (85.0%) subjects were available for analysis at study completion, the 6-month postoperative visit (Day 120–180) (TABLE 3). The demographics of the study population were typical for an IOL study performed in the U.S. Subjects ranged in age from 48 to 85 years in the Toric group (Mean: 67.7 ± 7.4 years) and 44 to 85 years in the Monofocal group (Mean: 69.4 ± 7.0 years). Females comprised 56% (66/118) in the Toric group and 58% (70/120) of the subjects enrolled in the Monofocal group. The

study eye was the right eye in a majority of subjects in both groups (TABLE 4). The distribution of axial length, pre-operative keratometry cylinder, and the grade of cataract were similar between randomized groups. (TABLE 5).

TABLE 3 ACCOUNTABILITY OF SUBJECTS AT EACH FORM VISIT (ITT SET)

Randomized Lens	Accountability	Operative n (%)	Visit 1 (Day 1-2) n (%)	Visit 2 (Day 7-14) n (%)	Visit 3 (Day 30-60) n (%)	Visit 4 (Day 120-180) n (%)
Toric IOL (N=118)	Available for Analysis (in Window)	117 (99.2%)	117 (99.2%)	116 (98.3%)	115 (97.5%)	117 (99.2%)
	Visit Out of Window	0	0	0	1 (0.8%)	0
	Missed Visit	0	0	1 (0.8%)	1 (0.8%)	0
	Discontinued	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)	1 (0.8%)
	Lost to Follow-up	0	0	0	0	0
	% Accountability	117 (100%)	117 (100%)	116 (99.1%)	115 (98.3%)	117 (100%)
Monofocal IOL (N=120)	Available for Analysis (in Window)	117 (97.5%)	115 (95.8%)	115 (95.8%)	113 (94.2%)	116 (96.7%)
	Visit Out of Window	0	1 (0.8%)	1 (0.8%)	3 (2.5%)	0
	Missed Visit	0	0	0	0	0
	Discontinued	3 (2.5%)	4 (3.3%)	4 (3.3%)	4 (3.3%)	4 (3.3%)
	Lost to Follow-up	0	0	0	0	0
	% Accountability	117 (100%)	115 (99.1%)	115 (99.1%)	113 (97.4%)	116 (100%)

N = total eyes in the analysis set

n = total number of eyes in the specified row category at that visit

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 4 DEMOGRAPHICS (ITT SET)

		Randomized Lens	
Demographic Parameter		Toric IOL (N=118)	Monofocal IOL (N=120)
Age (years)	n	118	120
	Mean ± SD	67.7 ± 7.4	69.4 ± 7.0
	Median	68	70
	Min, Max	48, 85	44, 85
Age Group, n (%)	< 65 years	36 (30.5%)	23 (19.2%)
	≥ 65 years	82 (69.5%)	97 (80.8%)
Sex, n (%)	Male	52 (44.1%)	50 (41.7%)
	Female	66 (55.9%)	70 (58.3%)
Study Eye, n (%)	OD	62 (52.5%)	73 (60.8%)
	OS	56 (47.5%)	47 (39.2%)

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 5 BASELINE PARAMETERS (ITT SET)

		Randomized Lens	
Parameter	Statistic	Toric IOL	Monofocal IOL
Axial Length (mm)	n	118	120
	Mean $\pm$ SD	24.2 $\pm$ 1.1	24.1 $\pm$ 1.1
	Median	24.1	24.1
	Min, Max	21.9, 27.5	21.8, 26.7
Keratometric Cylinder (D)	n	118	120
	Mean $\pm$ SD	1.21 $\pm$ 0.15	1.25 $\pm$ 0.14
	Median	1.18	1.23
	Min, Max	1.00, 1.50	1.02, 1.50
LOCS III: Nuclear Opalescence, n (%)	NO1	11 (9.4%)	7 (5.8%)
	NO2	31 (26.5%)	38 (31.7%)
	NO3	44 (37.6%)	43 (35.8%)
	NO4	6 (5.1%)	7 (5.8%)
	NO5	6 (5.1%)	4 (3.3%)
	NO6	1 (0.9%)	0
	N/A	18 (15.4%)	21 (17.5%)
LOCS III: Cortical Opacity, n (%)	C1	28 (24.1%)	29 (24.4%)
	C2	20 (17.2%)	34 (28.6%)
	C3	18 (15.5%)	18 (15.1%)
	C4	4 (3.4%)	3 (2.5%)
	C5	2 (1.7%)	1 (0.8%)
	N/A	44 (37.9%)	34 (28.6%)
LOCS III: Posterior Subcapsular, n (%)	P1	27 (23.3%)	27 (22.9%)
	P2	12 (10.3%)	13 (11.0%)
	P3	5 (4.3%)	4 (3.4%)
	P4	3 (2.6%)	4 (3.4%)
	P5	0	0
	N/A	69 (59.5%)	70 (59.3%)

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

Effectiveness Results

The Intent to Treat Analysis Set (ITT) was the primary set for the analyses of the effectiveness endpoints and included all randomized subjects. The analysis of effectiveness was based on the 238 evaluable patients at the 6-month time point (Day 120-180, Visit 4).

Visual Acuity

Photopic distance visual acuity testing was performed with the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts using the M&S Clinical Trial Suite system (M&S Technologies, Niles, IL) at 4 meters.

All three co-primary effectiveness endpoints were met according to the ANSI Z80.30 performance criteria: the adjusted mean difference in magnitude of residual manifest cylinder between the randomized groups was -0.430 D (95% CI [-0.544, -0.316]), which was statistically ($P < 0.0001$) and clinically significant, meeting the minimum clinically important difference (MCID) of -0.40 D

recommended by FDA (**TABLE 6**); the percentages of Toric IOL axis misalignment (from pre-operatively marked intended axis) under 10 degrees and 20 degrees exceeded the minimum percentages of 90% and 95%, respectively, (93.1%, 95% CI [86.1%, 96.8%] less than 10 degrees and 99.99%, 95% CI [96.9%, 100%] less than 20 degrees) per the primary imputation analysis (**TABLE 7**) and the percentage of Toric IOLs that rotated $\leq$ five degrees between Visit 3 (Day 30-60) and Visit 4 (Day 120-180) was 99.0% (95% CI [93.5%, 99.9%]), and exceeded the pre-specified success criteria of 90% for rotational stability using the primary imputation strategy (**TABLE 8**).

The results of the secondary effectiveness endpoints are as follows: at Visit 4, residual manifest cylinder stratified by preoperative keratometric cylinder was described for the Toric group compared with the Monofocal group, with between-group differences of $0.381 \text{ D} \pm 0.078 \text{ D}$ in the 1.00 to $<1.25 \text{ D}$ subgroup and $0.478 \text{ D} \pm 0.088 \text{ D}$ in the 1.25 to 1.50 D subgroup. Percent reduction in absolute cylinder at Visit 4 was 68.6% in the Toric group versus 36.1% in the Monofocal group (**TABLE 9** and **TABLE 10**).

In addition to the co-primary and secondary effectiveness endpoints, several additional effectiveness analyses were performed to further characterize visual and refractive outcomes. These included uncorrected and best-corrected distance visual acuity (**TABLE 11** and **TABLE 12**), accuracy of cylinder to target (**TABLE 13**), lens axis misalignment (**TABLE 14**), mean reduction in cylinder power overall and by preoperative keratometric cylinder subgroup (**TABLE 15** and **TABLE 16**) and the percentage of eyes with reduction in cylinder within 0.50 D and 1.00 D of intended (**TABLE 17**). These analyses were evaluated descriptively using summary statistics.

Safety Results

Safety Set (SAF) consisting of all ITT subjects who underwent surgery was the pre-specified primary analysis set for safety endpoints. Among 234 subjects included in the SAF, 117 subjects received the test Toric IOL and 116 received the control Monofocal IOL. In addition, the rate of BCDVA of 0.30 logMAR or better at Month 6 was also planned to be evaluated based on the Best Case Set (BCS) consisting of all SAF subjects who were successfully implanted with a study lens, without major protocol deviations, and also met the following criteria: no clinically significant pre-operative ocular pathology; no macular degeneration detected at any time; and no previous surgery for the correction of refractive errors, which would have resulted in exclusion of the subject from the study. Among 222 subjects included in the Best-Case Set (BCS), 111 subjects received the test Toric IOL and 111 received the control Monofocal IOL.

The first co-primary safety endpoint was to evaluate rates of cumulative and persistent adverse events in first operative eyes at Month 6 (Visit 4) in comparison to ISO 11979-7 Safety and Performance Endpoints grid (SPE rates). Of the AEs listed in the ISO grid, the two cumulative AEs observed in this study were cystoid macular edema (2/117 subjects, 1.7%) and secondary surgical interventions (SSIs) (2/117 subjects, 1.7%). At Visit 4, no rates of the adverse events in the Toric group were identified to be statistically higher than the ISO grid at one-sided 0.05 significance level, and this endpoint was successfully met according to the ISO performance criteria.

The second co-primary safety endpoint was to evaluate the rates of all other adverse events not included in the IOL adverse event list from ISO 11979-7 through Visit 4. The most common adverse events reported (out of an N=117) were posterior capsular opacification (14 subjects, 12.0%), posterior vitreous detachment (7 subjects, 6.0%) and corneal edema (7 subjects, 6.0%). No unexpected safety concerns were identified with the RayOne EMV Toric.

The third co-primary safety endpoint was to evaluate the rates of secondary surgical interventions for IOL repositioning due to IOL misalignment through Visit 4. One toric subject (1/117, 0.9%) underwent IOL repositioning surgery within the first few weeks. The need for repositioning was not attributed to the device itself, but to the initial placement.

The fourth co-primary safety endpoint was to evaluate the rate of BCDVA of 0.30 logMAR or better at Month 6 compared to the ISO SPE rates as described in ISO 11979-7. All Toric subjects achieved BCDVA of 0.30 logMAR (20/40) or Month 6 post-operatively based the Safety set (117/117, 100%, 95% CI [96.9%, 100%]) and the Best Case set (111/111, 100%, 95% CI [96.7%, 100%]). The rate of BCDVA of 0.30 logMAR or better at Visit 4 for the test Toric group was not identified to be statistically significantly lower than the corresponding ISO SPE rate based on both the Safety (92.5%) and Best Case sets (96.7%), therefore this endpoint was successfully met per the ISO performance criteria.

Therefore, all co-primary safety endpoints were met.

The ISO grid (SPE rate) outcomes for this study are presented below in (**TABLE 18**). The results of adverse events analyses based on the consensus definitions as set forth by American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in (**TABLE 19**). All ocular adverse events (serious and non-serious combined) are reported in (**TABLE 20**). Secondary Surgical Interventions (SSIs) due to IOL misalignment are reported in (**TABLE 21**). The rate of BCDVA of 0.30 logMAR or better at Month 6 compared to the ISO SPE rates as described in ISO 11979-7 are below in (**TABLE 22**).

TABLE 6 RESIDUAL MANIFEST CYLINDER (D) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY (ITT SET)

Statistic	Result
Observed Data	
Toric IOL	117/118
Mean ± SD	0.368 ± 0.334
Median	0.25
Min, Max	0.00, 1.25
Q1, Q3	0.00, 0.50
Monofocal (Control) IOL	116/120
Mean ± SD	0.780 ± 0.532
Median	0.75
Min, Max	0.00, 2.50
Q1, Q3	0.38, 1.25
Difference in Means ± SE	-0.413 ± 0.0582
With Imputation	
Number of Imputations ^[1]	50
LS Mean Difference ± SE	-0.430 ± 0.058 ^[2]
95% Confidence Interval	[-0.544, -0.316]
t Value	-7.39
P-value	<.0001

Results are presented in absolute cylinder (D); more negative differences are more favorable for the Toric lens.

One toric IOL subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

^[1] Missing values imputed with the Markov chain Monte Carlo (MCMC) method.

Following imputation, the primary hypothesis was tested using an Analysis of Covariance (ANCOVA) model with randomized treatment as factor and preoperative keratometric cylinder as covariate.

^[2] Meets the minimum clinically significant difference of -0.40 D

TABLE 7 ABSOLUTE IOL AXIS MISALIGNMENT (DEGREES) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY (ITT SET)

	< 10 Degrees Misalignment at V4	< 20 Degrees Misalignment at V4
Absolute Misalignment (degrees), at Visit 4		
% (n/N), observed	93.9% (92/98)	100% (98/98)
%, with imputation ^[1]	93.1% (5492/5900)	99.99%
95% Confidence Interval ^[2] , with imputation ^[1,3]	[86.1%, 96.8%]	[96.9%, 100%]

IOL Axis Misalignment is the difference in intended axis of orientation, marked pre-operatively on the day of surgery (Day 0), and the IOL axis at the postoperative visit.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last IOL Misalignment (9.04°) prior to the SSI was carried forward to subsequent Visits 3 and 4.

The IOL axis misalignment endpoint is successful if IOL axis misalignment is less than 10 degrees for 90% of eyes and less than 20 degrees for 95% of eyes from the Toric test group in the fifty imputed datasets.

^[1] Missing values were handled through multiple imputations (50 sets) using with the Markov chain Monte Carlo (MCMC) method.

^[2] 95% Exact (Clopper-Pearson) confidence interval (CI), without multiplicity adjustment.

^[3] All Missing data were imputed as <20 degrees misalignment in 49/50 imputations. The 95% CI presented for the percent of eyes with <20 degrees misalignment is based on a single imputation with 118/118 successes.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 8 STABILITY OF TORIC IOL AXIS ORIENTATION (DEGREES) AT VISIT 4 - PRIMARY IMPUTATION STRATEGY

	Absolute IOL Axis Rotation ≤ 5 degrees between Visit 3 and Visit 4
Stability of Toric IOL Axis Orientation (degrees) at Visit 4	
% (n/N), observed	99.0% (100/101)
%, with imputation ^[1]	99.0%
95% Confidence Interval ^[2] , with imputation ^[1]	[93.5%, 99.9%]

Absolute IOL Axis Rotation is the absolute difference in the actual IOL axis at the postoperative visits

The IOL axis stability endpoint is successful if at least 90% of all toric lenses in the fifty imputed datasets rotate less than or equal to five degrees between Visits 3 and 4.

^[1] Missing values were handled through multiple imputations (50 sets) using the Markov chain Monte Carlo (MCMC) method.

^[2] 95% Exact (Clopper-Pearson) confidence interval (CI), without multiplicity adjustment.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 9 RESIDUAL MANIFEST CYLINDER (D) AT VISIT 4 STRATIFIED BY PREOPERATIVE KERATOMETRIC CYLINDER

	Residual Manifest Cylinder (D) at Visit 4		
Pre-operative Keratometric cylinder	Toric IOL Mean $\pm$ SD	Monofocal IOL Mean $\pm$ SD	Difference Difference in means ($\pm$ SD) [95% CI of difference]
1.00 to < 1.25 D			
n	75	62	
	0.413 $\pm$ 0.333	0.794 $\pm$ 0.535	-0.381 ($\pm$ 0.078)
1.25 to 1.50 D			
n	42	54	
	0.286 $\pm$ 0.325	0.764 $\pm$ 0.533	-0.478 ($\pm$ 0.088)

Abbreviations: D=Diopter; SD=Standard deviation; SE=Standard Error

Results are presented in absolute cylinder (D) ; more negative differences are more favorable for the Toric lens.

For one subject who underwent an SSI for IOL repositioning, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4, per ANSI Z80.30.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 10 PERCENT REDUCTION IN ABSOLUTE CYLINDER (ITT SET)

Percent Reduction in cylinder at Visit 4	Toric IOL Mean $\pm$ SD	Monofocal IOL Mean $\pm$ SD
n	117	116
Mean $\pm$ SD	68.59% $\pm$ 29.17 %	36.11% $\pm$ 45.69 %
Difference		
Difference in means ($\pm$ SE)	32.48 ($\pm$ 5.03) %	

Abbreviations: SD=Standard deviation; SE=Standard Error

Percent Reduction in absolute cylinder is calculated for each eye as $(1 - |\text{residual manifest cylinder}| / (\text{preoperative keratometric cylinder})) \times 100\%$.

For one subject who underwent an SSI for IOL repositioning, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4, per ANSI Z80.30.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal); subjects implanted with the Toric IOL (N=117) and Monofocal IOL (N=116).

TABLE 11 UNCORRECTED DISTANCE VISUAL ACUITY (4M) AT VISIT 4 (ALL TORIC IOLS, ITT SET)

UCDVA (logMAR) Outcomes	UCDVA (Snellen Equivalent)	Visit 4 (Day 120-180) n (%)
N (eyes)		117
-0.20 or better	20/12	1 (0.9%)
-0.10 or better	20/15	10 (8.5%)
0.00 or better	20/20	44 (37.6%)
0.10 or better	20/25	83 (70.9%)
0.20 or better	20/32	102 (87.2%)
0.30 or better	20/40	112 (95.7%)
Count Fingers	Worse than 20/800	0
N (eyes)		117
Mean ± SD		0.061 ± 0.130
Median		0.02
Min, Max		-0.20, 0.52
Q1, Q3		-0.02, 0.14
Not Done		0

N = total number of Toric eyes analyzed at the specified visit

n = total number of Toric eyes meeting each UCDVA outcome threshold

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 12 BEST CORRECTED DISTANCE VISUAL ACUITY (4M) AT VISIT 4 (ALL IOLS, ITT SET)

Randomized Lens	BCDVA (logMAR) Outcomes	BCDVA (Snellen Equivalent)	Visit 4 (Day 120-180) n (%)
Toric IOL	N (eyes)		117
	-0.20 or better	20/12	7 (6.0%)
	-0.10 or better	20/15	43 (36.8%)
	0.00 or better	20/20	90 (76.9%)
	0.10 or better	20/25	114 (97.4%)
	0.20 or better	20/32	116 (99.1%)
	0.30 or better	20/40	117 (100%)
	Mean ± SD		-0.055 ± 0.084
	Median		-0.06
	Min, Max		-0.20, 0.24

Randomized Lens	BCDVA (logMAR) Outcomes	BCDVA (Snellen Equivalent)	Visit 4 (Day 120-180) n (%)
	Q1, Q3		-0.10, 0.00
	Not Done		0
Monofocal IOL	N (eyes)		116
	-0.20 or better	20/12	3 (2.6%)
	-0.10 or better	20/15	34 (29.3%)
	0.00 or better	20/20	83 (71.6%)
	0.10 or better	20/25	114 (98.3%)
	0.20 or better	20/32	116 (100%)
	0.30 or better	20/40	116 (100%)
	Mean $\pm$ SD		-0.039 $\pm$ 0.081
	Median		-0.04
	Min, Max		-0.20, 0.20
	Q1, Q3		-0.10, 0.02
	Not Done		0

Categorical outcomes include count and percentage (%)

N = total number of Toric and Monofocal eyes analyzed at the specified visit for each group

n = total number of Toric and Monofocal eyes meeting each BCDVA outcome threshold for each group

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 13 ACCURACY OF CYLINDER TO TARGET (ITT SET)

Randomized Lens	Accuracy of Cylinder to Target	Visit 4 (Day 120-180)
Toric IOL	± 0.25 D	66/117 (56.4%)
	± 0.50 D	100/117 (85.5%)
	± 0.75 D	110/117 (94.0%)
Monofocal IOL	> 0.75 D	7/117 (6.0%)
	± 0.25 D	32/116 (27.6%)
	± 0.50 D	56/116 (48.3%)
	± 0.75 D	76/116 (65.5%)
	> 0.75 D	40/116 (34.5%)

Accuracy of Cylinder is calculated for each eye as the difference between the magnitude of the postoperative manifest refraction cylinder and the magnitude of the target postoperative residual astigmatism per the Toric IOL calculator.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 14 IOL AXIS MISALIGNMENT (DEGREES) BY VISIT (ITT SET)

	Statistic	Op	Visit 1 (Day 1-2)	Visit 2 (Day 7-14)	Visit 3 (Day 30-60)	Visit 4 (Day 120-180)
Absolute Misalignment (degrees)	N	106	99	97	97	98
	Mean ± SD	3.101 ± 3.787	3.086 ± 3.598	3.125 ± 3.306	3.071 ± 3.261	3.481 ± 3.418
	Median	1.88	1.94	1.93	1.90	2.61
	Min, Max	0.01, 20.33	0.01, 18.07	0.05, 16.67	0.02, 16.40	0.01, 16.50
	Q1, Q3	0.59, 4.25	0.68, 4.22	0.62, 3.88	0.86, 4.24	1.18, 4.29
	Ungradable Op Image	11	NA	NA	NA	NA
	Ungradable Op Image and Ungradable Postop Image	NA	4	4	4	4
	Ungradable Op Image and Gradable Postop Image	NA	6	6	7	7
	Gradable Op Image and Ungradable Postop Image	NA	5	7	5	8
	Data Not Available	NA	3	2	3	0
Absolute Misalignment (degrees), n (%)	< 5 degrees	84 (79.2%)	82 (82.8%)	77 (79.4%)	78 (80.4%)	76 (77.6%)
	< 10 degrees	101 (95.3%)	95 (96.0%)	92 (94.8%)	93 (95.9%)	92 (93.9%)
	< 20 degrees	105 (99.1%)	99 (100%)	97 (100%)	97 (100%)	98 (100%)
	≤ 30 degrees	106 (100%)	99 (100%)	97 (100%)	97 (100%)	98 (100%)
	> 30 degrees	0	0	0	0	0
Signed IOL Misalignment	N	106	99	97	97	98
	Mean ± SD	1.583 ± 4.639	1.345 ± 4.554	1.183 ± 4.403	1.104 ± 4.351	1.041 ± 4.778
	Median	0.64	0.68	0.57	0.61	0.16
	Min, Max	-9.54, 20.33	-10.62, 18.07	-10.83, 16.67	-10.93, 16.40	-10.95, 16.50
	Q1, Q3	-0.57, 3.60	-0.73, 2.82	-1.01, 3.09	-1.11, 2.88	-1.55, 3.16

IOL Axis Misalignment is the difference in intended axis of orientation, marked pre-operatively on the day of surgery (Day 0), and the IOL axis at the postoperative visit

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last IOL Misalignment (9.04°) prior to the SSI was carried forward to subsequent Visits 3 and 4.

^[1] The image was gradable but Operative visit image was not gradable / not done.

^[2] For signed misalignment, Clockwise=Negative, Counterclockwise=Positive

N = total number of Toric eyes analyzed at the specified visit

n = total number of eyes meeting each absolute misalignment threshold

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 15 REDUCTION IN CYLINDER POWER (D) (ITT SET)

Randomized Lens	Statistic	Visit 4 (Day 120-180)
Toric IOL	n	117
	Mean $\pm$ SD	0.839 $\pm$ 0.385
	Median	0.84
	Min, Max	-0.24, 1.48
	Q1, Q3	0.60, 1.13
Monofocal IOL	n	116
	Mean $\pm$ SD	0.466 $\pm$ 0.565
	Median	0.52
	Min, Max	-1.40, 1.49
	Q1, Q3	0.08, 0.92
	Difference in Means $\pm$ SE	0.373 $\pm$ 0.0634

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 16 REDUCTION IN CYLINDER POWER (D) BY PREOPERATIVE KERATOMETRIC CYLINDER (ITT SET)

Preoperative Keratometric Cylinder	Randomized Lens	Statistic	Visit 4 (Day 120-180)
1.0 to <1.25 D	Toric IOL	n	75
		Mean $\pm$ SD	0.699 $\pm$ 0.342
		Median	0.73
		Min, Max	-0.24, 1.24
		Q1, Q3	0.51, 0.95
	Monofocal IOL	n	62
		Mean $\pm$ SD	0.346 $\pm$ 0.547
		Median	0.46
		Min, Max	-1.40, 1.21
		Q1, Q3	-0.03, 0.73
	Difference in Means $\pm$ SD		0.353 $\pm$ 0.0799
1.25 to 1.5 D	Toric IOL	n	42

Preoperative Keratometric Cylinder	Randomized Lens	Statistic	Visit 4 (Day 120-180)
		Mean $\pm$ SD	1.089 $\pm$ 0.330
		Median	1.23
		Min, Max	0.00, 1.48
		Q1, Q3	0.92, 1.34
	Monofocal IOL	n	54
		Mean $\pm$ SD	0.604 $\pm$ 0.558
		Median	0.65
		Min, Max	-0.72, 1.49
		Q1, Q3	0.25, 1.02
	Difference in Means $\pm$ SD		0.486 $\pm$ 0.0914

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 17 PERCENTAGE OF EYES WITH REDUCTION OF CYLINDER POWER (D) (ITT SET)

Randomized Lens	Reduction of Cylinder Power within Intended	Visit 4 (Day 120-180)
Toric IOL	≤ 0.50 D	100/117 (85.5%)
	≤ 1.00 D	113/117 (96.6%)
	> 1.00 D	4/117 (3.4%)
Monofocal IOL	≤ 0.50 D	56/116 (48.3%)
	≤ 1.00 D	92/116 (79.3%)
	> 1.00 D	24/116 (20.7%)

Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the postoperative manifest refraction cylinder. Intended Reduction in Cylinder Power is calculated for each eye as the difference between the magnitude of the preoperative keratometric cylinder and the magnitude of the target postoperative residual astigmatism per the Toric IOL calculator.

One subject underwent an SSI for IOL repositioning; Per ANSI Z80.30, the last Residual Manifest cylinder (1.25 D) prior to the SSI was carried forward to subsequent Visits 3 and 4.

Total number of subjects (Toric or Monofocal) in the ITT Set (N=118 Toric; N=120 Monofocal)

TABLE 18 RATES OF TORIC IOL ADVERSE EVENTS COMPARED TO ISO 11979-7 GRID SAFETY AND PERFORMANCE ENDPOINTS (SPE) RATES (SAFETY SET, TORIC IOLS)

Adverse Event	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Cumulative				
Cystoid macular edema	2/117 (1.7%)	3.0	0.8691	(0.208%, 6.039%)
Hypopyon	0/117 (0.0%)	0.3	>.9999	(0%, 3.104%)
Endophthalmitis*	0/117 (0.0%)	0.1	>.9999	(0%, 3.104%)
Lens dislocation from posterior chamber	0/117 (0.0%)	0.1	>.9999	(0%, 3.104%)
Mechanical pupillary block	0/117 (0.0%)	0.1	>.9999	(0%, 3.104%)
Retinal detachment	0/117 (0.0%)	0.3	>.9999	(0%, 3.104%)
Secondary Surgical Intervention ^[3]	2/117 (1.7%)	0.8	0.2406	(0.208%, 6.039%)
Persistent				
Cornea stroma edema	0/117 (0.0%)	0.3	>.9999	(0%, 3.104%)
Cystoid macular edema	0/117 (0.0%)	0.5	>.9999	(0%, 3.104%)
Iritis	0/117 (0.0%)	0.3	>.9999	(0%, 3.104%)
Increased IOP	0/117 (0.0%)	0.4	>.9999	(0%, 3.104%)

^[1]One-sided Exact Binomial Test comparing the proportion of Toric eyes to the SPE Rate, without multiplicity adjustment.

^[2]Two-sided 95% Exact (Clopper-Pearson) confidence interval for the Toric IOL AE Rate, without multiplicity adjustment.

^[3]Excludes Wound Burp SSI. Posterior capsulotomies were excluded as SSIs.

* Endophthalmitis is defined as inflammatory reaction (sterile or infectious) involving the vitreous body.

n=number of subjects that experienced the event; N = total number of subjects in the Safety Set implanted with the Toric IOL.

TABLE 19 RATES OF ADVERSE EVENTS BASED ON A MODIFIED VERSION OF THE AAO TASK FORCE CONSENSUS (MASKET ET AL, 2017), SAFETY SET

Adverse Event	Toric IOL (N=117)			Monofocal IOL (N=116)		
Subjects with at least one Masket et al Study Eye AE	5 (4.3%)			4 (3.4%)		
	n (%)	Two-sided 95% CI ^[1]	E ^[2]	n (%)	Two-sided 95% CI ^[1]	E ^[2]
Chronic anterior uveitis	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Clinically significant cystoid macular edema: Macular edema diagnosed by exam and testing (e.g., OCT, FA) resulting in BCDVA of 0.30 logMAR or worse at ≥ Visit 3	1 (0.9%)	[0.0%, 4.7%]	1	0	[0.0%, 3.1%]	0
Visually significant corneal edema	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Endophthalmitis	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Mechanical pupillary block	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Increased IOP: Elevation of IOP by ≥10 mmHg above baseline to a minimum of 25mmHg	3 (2.6%)	[0.5%, 7.3%]	3	4 (3.4%)	[0.9%, 8.6%]	4
Rhegmatogenous RD	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Toxic anterior segment syndrome	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Secondary IOL Intervention	1 (0.9%)	[0.0%, 4.7%]	1	0	[0.0%, 3.1%]	0
Exchange (the investigational device is replaced with the same lens model)	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
Removal (the investigational device is removed and replaced with a non-investigational lens or no lens is implanted)	0	[0.0%, 3.1%]	0	0	[0.0%, 3.1%]	0
IOL repositioning (existing IOL is surgically moved to another location or rotated)	1 (0.9%)	[0.0%, 4.7%]	1	0	[0.0%, 3.1%]	0

^[1] Two-sided 95% Exact (Clopper-Pearson) confidence interval for the AE Rate, without multiplicity adjustment.

^[2] E = Number of events.

n=number of subjects that experienced the event; N = total number of subjects in the Safety Set (N=117 Toric; N=116 Monofocal)

TABLE 20 OCULAR ADVERSE EVENTS (SERIOUS AND NON-SERIOUS COMBINED), SAFETY SET

	Toric IOL (N=117)			Monofocal IOL (N=116)		
Adverse Event	n (%)	Two-sided 95% CI ^[1]	E ^[2]	n (%)	Two-sided 95% CI ^[1]	E ^[2]
Subjects with at least one Study Eye AE	49 (41.9%)	[32.8%, 51.4%]	75	40 (34.5%)	[25.9%, 43.9%]	49

	Toric IOL (N=117)			Monofocal IOL (N=116)		
Adverse Event	n (%)	Two-sided 95% CI ^[1]	E ^[2]	n (%)	Two-sided 95% CI ^[1]	E ^[2]
Posterior capsular opacification requiring YAG capsulotomy	14 (12.0%)	[6.7%, 19.3%]	14	4 (3.4%)	[0.9%, 8.6%]	4
Posterior vitreous detachment	7 (6.0%)	[2.4%, 11.9%]	7	11 (9.5%)	[4.8%, 16.3%]	11
Corneal edema ^[3]	7 (6.0%)	[2.4%, 11.9%]	7	7 (6.0%)	[2.5%, 12.0%]	7
Cornea Stroma Edema ^[4]	6 (5.1%)	[1.9%, 10.8%]	6	5 (4.3%)	[1.4%, 9.8%]	5
Increased IOP	4 (3.4%)	[0.9%, 8.5%]	4	7 (6.0%)	[2.5%, 12.0%]	7
Anterior chamber cells greater than Grade 2 at Visit 1	5 (4.3%)	[1.4%, 9.7%]	5	1 (0.9%)	[0.0%, 4.7%]	1
Corneal abrasion	3 (2.6%)	[0.5%, 7.3%]	3	0	[0%, 3.1%]	0
Cystoid macular edema	2 (1.7%)	[0.2%, 6.0%]	2	1 (0.9%)	[0.0%, 4.7%]	1
Epithelial defect	2 (1.7%)	[0.2%, 6.0%]	2	1 (0.9%)	[0.0%, 4.7%]	1
Epiretinal membrane	2 (1.7%)	[0.2%, 6.0%]	2	0	[0%, 3.1%]	0
Choroidal nevus	1 (0.9%)	[0.0%, 4.7%]	1	1 (0.9%)	[0.0%, 4.7%]	1
Corneal dellen	1 (0.9%)	[0.0%, 4.7%]	1	1 (0.9%)	[0.0%, 4.7%]	1
Dermatochalasis	1 (0.9%)	[0.0%, 4.7%]	1	1 (0.9%)	[0.0%, 4.7%]	1
Subconjunctival hemorrhage	1 (0.9%)	[0.0%, 4.7%]	1	1 (0.9%)	[0.0%, 4.7%]	1
Worsening dry eye disease	1 (0.9%)	[0.0%, 4.7%]	1	1 (0.9%)	[0.0%, 4.7%]	1
Conjunctival injection	0	[0%, 3.1%]	0	2 (1.7%)	[0.2%, 6.1%]	2
Central capsular wrinkle	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Chemosis	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Double vision secondary to neurological adjustment following cataract surgery	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Epithelial basement membrane dystrophy	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
IOL decentration/malposition resulting in secondary surgical intervention	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
IOL repositioning (existing IOL is surgically moved to another location or rotated)	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Intraretinal hemorrhage	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Iris pigment epithelium loss	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Photophobia	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Progression or onset diabetic retinopathy	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Retained lens material	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Retinal pigment epithelial mottling	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Superficial punctate keratitis	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Surgical removal of retained lens fragment	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Trace punctate epithelial erosions	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0

	Toric IOL (N=117)			Monofocal IOL (N=116)		
Adverse Event	n (%)	Two-sided 95% CI ^[1]	E ^[2]	n (%)	Two-sided 95% CI ^[1]	E ^[2]
Visually significant corneal edema resulting in BCDVA of 0.3 or worse	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Worsening punctate epithelial erosion	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Wound burp (aqueous tap, or paracentesis)	1 (0.9%)	[0.0%, 4.7%]	1	0	[0%, 3.1%]	0
Dry eye disease	0	[0%, 3.1%]	0	1 (0.9%)	[0.0%, 4.7%]	1
Iritis	0	[0%, 3.1%]	0	1 (0.9%)	[0.0%, 4.7%]	1
Keratoconjunctivitis Sicca, not specified as Sjogrens	0	[0%, 3.1%]	0	1 (0.9%)	[0.0%, 4.7%]	1
Retinal pigment epithelial changes	0	[0%, 3.1%]	0	1 (0.9%)	[0.0%, 4.7%]	1

^[1]Two-sided 95% Exact (Clopper-Pearson) confidence interval for the AE Rate, without multiplicity adjustment.

^[2]E = Number of events.

^[3] Corneal edema of grade 2+ or more reported after IOL surgery in the early post-operative period (prior to one week).

^[4] Edema of corneal stroma of any degree at any location regardless of effect on BCDVA at Visit 2 (Day 7-14) or later.

n=number of subjects that experienced the event; N = total number of subjects in the Safety Set (N=117 Toric; N=116 Monofocal)

Secondary Surgical Interventions (SSI) Due to IOL Misalignment

TABLE 21 RATE OF SECONDARY SURGICAL INTERVENTION (SSI) DUE TO IOL MISALIGNMENT (SAFETY, TORIC IOLS)

	n/N (%)	95% Confidence Interval ^[1]
Secondary Surgical Intervention for IOL Repositioning due to IOL Misalignment	1/117 (0.9%)	(0.022%, 4.670%)

^[1]Two-sided 95% Exact (Clopper-Pearson) confidence interval for the Toric IOL AE Rate, without multiplicity adjustment.

n=number of subjects that experienced the event; N = total number of subjects in the Safety Set implanted with the Toric IOL.

TABLE 22 RATE OF BCDVA OF 0.30 LOGMAR OR BETTER AT VISIT 4 (SAFETY AND BEST-CASE SETS)

Analysis Population	Implanted Lens	n/N (%)	SPE Rate (%)	P-value ^[1]	95% Confidence Interval ^[2]
Safety Set	Toric IOL	117/117 (100.0%)	92.5	>.9999	(96.90%, 100%)
	Monofocal IOL	116/116 (100.0%)	92.5	>.9999	(96.87%, 100%)
Best Case Set	Toric IOL	111/111 (100.0%)	96.7	>.9999	(96.73%, 100%)
	Monofocal IOL	111/111 (100.0%)	96.7	>.9999	(96.73%, 100%)

^[1]One-sided Exact Binomial Test comparing the proportion of Toric eyes to the SPE Rate, without multiplicity adjustment.

^[2]Two-sided 95% Exact (Clopper-Pearson) confidence interval for the Toric IOL AE Rate, without multiplicity adjustment.

Total number of subjects (Toric or Monofocal) in the Safety Set (N=117 Toric; N=116 Monofocal)