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Clinical Trial Protocol

Clinical Investigation of the Clareon® IOL

Protocol Number:	ILJ466-C001/NCT03170154
Sponsor Name & Address:	Alcon Research, Ltd. and its affiliates ("Alcon") 6201 South Freeway Fort Worth, Texas 76134-2099
Project Name / Number:	[redacted]
Test Article(s) / Product(s):	Clareon® aspheric hydrophobic acrylic monofocal IOL [redacted]
Release Date:	Refer to e-signature date
Investigator Agreement:	I have read the clinical study described herein, recognize its confidentiality, and agree to conduct the described trial in compliance with Good Clinical Practice (GCP), the ethical principles contained within the Declaration of Helsinki, this protocol, and all applicable regulatory requirements.

Principal Investigator:

Signature Date

Principal Investigator Name:

Principal Investigator Address:

1 PROTOCOL SYNOPSIS

[redacted]	[redacted]	
Test Article(s) / Product(s):	Clareon aspheric hydrophobic acrylic monofocal intraocular lens (IOL) [redacted] Hereto referred to as Clareon IOL	
Objective(s):	The objective of this study is to demonstrate favorable visual acuity and adverse event outcomes for the Clareon IOL compared to historical safety and performance endpoint (SPE) rates as reported in EN ISO 11979-7:2014.	
Clinical Trial Design:	A prospective, multicenter, single group safety and performance clinical trial.	
No. of Subjects:	Planned: Approximately 350 subjects unilaterally implanted Required: 300 evaluable subjects complete the study	
Region(s):	US	
Clinical Trial Duration:	• Total expected duration of the clinical investigation: Approximately 19 months • Expected duration of each subject's participation: Approximately 13 months • Planned follow-up duration: 12 months post-surgery • Estimated time needed to select the number of subjects (ie, enrollment period): Approximately 6 months	
Clinical Trial Population:	Adult subjects, 22 years of age or older, with no ocular pathology (other than cataract) that could confound study outcomes, who require cataract extraction in at least one eye. Full details are found in Section 10 SUBJECT POPULATION.	
Treatments:	***Test Article***:	Clareon IOL [redacted]
	Administration:	Routine small incision cataract surgery with unilateral IOL implantation.
	General Description:	A range of commonly used spherical powers (diopters) will be available.
	Duration of Treatment:	Intraocular lenses are implantable medical devices and are intended for long term use over the lifetime of the cataract subject.

	Control Article:	Not applicable (N/A) ***Note:*** Historical safety and performance endpoints rates (EN ISO 11979-7:2014) will serve as a comparator.
	Administration:	N/A
	General Description:	N/A
	Duration of Treatment:	N/A
Inclusion & Exclusion Criteria:	Details can be found in Section 10: SUBJECT POPULATION	
Co-Primary Effectiveness Endpoints	• Percentage of all-implanted subjects achieving best corrected monocular distance visual acuity (BCDVA) of 0.3 logMAR or better at 12 months postoperative (Visit 5) • Percentage of best-case subjects achieving BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5)	
Secondary Effectiveness Endpoint	IOL rotation at 6 months postoperative (Visit 4), defined as the difference in IOL axis of orientation from the day of surgery to 6 months postoperative (Visit 4)	
[redacted]	[redacted]	
Primary Safety Endpoint	Rate of adverse events (ocular and nonocular, serious and non-serious) including secondary surgical interventions (SSIs)	
[redacted]	[redacted]	
[redacted]	[redacted]	
Planned Analyses	The primary analysis set for effectiveness analyses will be the All-Implanted Analysis Set (AAS). AAS includes all eyes with successful test article implantation. Additional analyses, including	

	the co-primary analysis, will be conducted using the Best-Case Analysis Set (BAS). BAS includes all eyes successfully implanted with the test article that had: ≠ at least 1 postoperative visit; ≠ no pre-operative ocular pathology; ≠ no macular degeneration detected at any time; and ≠ no previous surgery for the correction of refractive errors. The Rotation Analysis Set (RAS) will include all eyes with successful test article implantation from a sub-set of approximately 6 clinical sites that examine subjects for rotational stability. The Safety Analysis Set will include all eyes with attempted implantation with the test article (successful or aborted after contact with the eye) and will be used for the safety analyses. The primary effectiveness objective is to demonstrate that the one-sided exact 95% upper confidence limit for the percentage of subjects with monocular BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than or equal to the SPE rates of 92.5% for the AAS and 96.7% for the BAS (as reported in EN ISO 11979-7:2014). A successful outcome on the co-primary effectiveness endpoints is indicated by successful outcomes on both of these endpoints. The number and percentage of subjects with BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) will be presented with the corresponding two-sided exact 95% confidence interval as well. The secondary effectiveness objectives are ≠ To demonstrate rotational stability by showing IOL rotation at 6 months postoperative (Visit 4) is o less than 10° in 90% of eyes in the RAS o less than 20° in 95% of eyes in the RAS o less than 30° in 99% of eyes in the RAS ≠ To describe IOL misplacement, IOL rotation, and IOL misalignment IOL rotation at Visit [x] is defined as the difference between axis of IOL orientation on the day of surgery and the postoperative Visit [x]. IOL misplacement is defined as the difference between intended axis of placement and actual axis of IOL orientation on the day of surgery. IOL misalignment at Visit [x] is defined as the summation of IOL misplacement and IOL misalignment at Visit [x]. In order to summarize IOL rotation, IOL misplacement and IOL misalignment, sample size, number, percent, and cumulative percent for the following categories will be provided: (< 10, < 20,

	and < 30 degrees respectively, and 0-5, > 5-10, > 10-15, > 15-20, > 20-30, and > 30 degrees, respectively). Descriptive statistics (mean, median, standard deviation, number of subjects/eyes, minimum, maximum, and the two-sided 95% confidence interval) will be provided for effectiveness endpoints for study eyes. Descriptive statistics for adverse events (including SSI) will be presented for study eyes. The rates of all adverse events will be provided with counts and percentages, and these rates will be accompanied by two-sided exact 95% confidence intervals. The one-sided exact 95% lower confidence limit for incidence rates observed for study eyes will be compared to the cumulative and persistent adverse event SPE rates that include SSIs (as reported in EN ISO 11979-7:2014) In general, descriptive statistics generated for effectiveness and safety parameters will be based upon the type of parameter (ie, whether the data were categorical or continuous) being analyzed. For categorical parameters, the statistics used to summarize the data descriptively included sample size, number in the category, and percent in the category. For continuous parameters, sample size, mean, median, standard deviation, minimum, and maximum will be presented. One-year follow-up analyses will be conducted to summarize the effectiveness and safety outcomes at Month 12 (Visit 5).
Sample Size Justification	With a sample size of 300 evaluable eyes, the probability to demonstrate that at least 270 (90%) of evaluable eyes implanted with Clareon IOL having monocular BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than 99% assuming the mean BCDVA is 0.0 logMAR (SD = 0.18 for All-Implanted Analysis Set). Similarly, with a sample size of 300 evaluable eyes, the probability to demonstrate that at least 285 (95%) of evaluable eyes implanted with Clareon IOL having monocular BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than 97% assuming the mean BCDVA is 0.0 logMAR (SD = 0.16 for Best-Case Analysis Set). For any adverse event where zero incidence is observed in 300 eyes with Clareon IOL, the one-sided exact 95% upper confidence is less than 1%. Thus, with 95% confidence, the true adverse event rate is less than 1%. Approximately 350 subjects will be unilaterally implanted with the Clareon IOL in order to ensure at least 300 evaluable subjects complete the study.

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3 ABBREVIATIONS

Abbreviation	Definition
AAS	All-Implanted Analysis Set
ADE	Adverse device effect
AE	Adverse event
ASADE	Anticipated serious adverse device effect
BAS	Best-Case Analysis Set
BCDVA	Best corrected distance visual acuity
BSS	Balanced salt solution
CFR	Code of Federal Regulations
CM	Clinical manager
CRF	Case report form
CSM	Clinical site manager
D	Diopter
DFE	Dilated fundus examination
DFU	Directions for use
DoH	Declaration of Helsinki
eCRF	Electronic case report form
EDC	Electronic data capture
ETDRS	Early Treatment Diabetic Retinopathy Study
EN	European Standard
EU	European Union
FA	Fluorescein angiography
FDA	Food and Drug Administration
[redacted]	[redacted]
GCP	Good Clinical Practice
GPCMS	Global Product Complaint System
IB	Investigator's brochure
ICF	Informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Humans Use
IDE	Investigational Device Exemption
IEC	Independent ethics committee
IOL	Intraocular lens
IOP	Intraocular pressure
IRB	Independent review board
IP	Investigational product
ISO	International Organization for Standardization
LASIK	Laser-assisted in-situ keratomileusis
LCSM	Lead clinical site manager
logMAR	Logarithm of minimum angle of resolution
MedDRA®	Medical Dictionary for Regulatory Activities
m	Meter
mm	Millimeter

Abbreviation	Definition
MOP	Manual of procedures
N/A	Not applicable
Nd:YAG	Neodymium-doped yttrium aluminium garnet
OCT	Optical coherence tomography
OD	Right eye
OS	Left eye
OVD	Ophthalmic viscosurgical device
[redacted]	[redacted]
RAS	Rotation Analysis Set
RD	Retinal detachment
SADE	Serious adverse device effect
SAE	Serious adverse event
SOP	Standard operating procedure
SPE	Safety and Performance Endpoints
SSI	Secondary surgical intervention
[redacted]	[redacted]
USADE	Unanticipated serious adverse device effect
USV	Unscheduled visit
US	United States
UV	Ultraviolet
WHO	World Health Organization

4 GLOSSARY OF TERMS

Adverse Device Effect (ADE)	Adverse event related to the use of an investigational medical device or comparator, if applicable. ***Note:*** *This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation; any malfunction; and use error or intentional misuse of the investigational medical device or comparator, if applicable.*
Adverse Event (AE)	Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device. ***Note:*** *For subjects, this definition includes events related to the investigational medical device or the procedures involved. For users or other persons, this definition is restricted to events related to investigational medical devices.*
Anticipated Serious Adverse Device Effect (ASADE)	Serious adverse device effect which by its nature, incidence, severity, or outcome has been identified in the risk analysis.
Assessment	A procedure used to generate data required by the study.
[redacted]	[redacted]
Performance (Clinical)	Behavior of a medical device or response of the subject to that medical device in relation to its intended use, when correctly applied to appropriate subjects.
Malfunction	Failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or clinical investigation plan.
Non-serious Adverse Event	Adverse event that does not meet the criteria for a serious adverse event.
Period	A minor subdivision of the study timeline; divides phases into smaller functional segments such as screening, baseline, operative, postoperative, etc.
Serious Adverse Device Effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Serious Adverse Event (SAE)	Adverse event that led to any of the following: • Death. • A serious deterioration in health that either resulted in:

	a) A life-threatening illness or injury. ***Note:*** *Life-threatening means that the individual was at immediate risk of death from the event as it occurred, ie, it does not include an event which hypothetically might have caused death had it occurred in a more severe form.* b) Permanent impairment to a body structure or a body function. c) Inpatient hospitalization or prolonged hospitalization. ***Note:*** *Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigation plan, without serious deterioration in health, is not considered a serious adverse event. In general, hospitalization signifies that the individual remained at the hospital or emergency ward for observation and/or treatment (usually involving an overnight stay) that would not have been appropriate in the physician's office or an outpatient setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred, the event should be considered serious.* d) a medical or surgical intervention to prevent a) or b). Any indirect harm as a consequence of incorrect diagnostic test results when used within manufacturer's instructions for use. ≠ Fetal distress, fetal death, or a congenital abnormality or birth defect.
Subject Number	A number assigned to each subject who enrolls in the study. When combined with the site number, a unique identifier is created for each subject in the study.
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the risk analysis.

5 AMENDMENTS

Modification of the protocol is prohibited without prior written agreement in the form of a protocol amendment. All amendments will be created by the Sponsor and must be approved by the IRB/IEC prior to implementation except when required to mitigate immediate safety risks or when the changes involve only logistical or administrative revisions.

[redacted]

6 SCHEDULE OF VISITS

Activity	Visit 0	Visit 00	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5[9]
	Day -30 to 0 Preoperative	Day 0 Operative Visit	1-2 Days Postoperative	7-14 Days Postoperative	30-45 Days Postoperative	120-180 Days Postoperative	330-420 Days Postoperative\ Early Exit
Informed Consent	X						
Demographics	X						
Medical History	X						
Concomitant Medications	X	X	X	X	X	X	X
Urine Pregnancy Test[1]	X						
Inclusion/Exclusion	X	X					
Keratometry	X						
[redacted]	X						
Operative Eye		X					
Surgery/Treatment		X					
Surgical Report [redacted] • Incision size • Implant success [redacted] • Intended axis of placement [redacted]		X					
[redacted]		X					
[redacted]		X					
[redacted]	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Monocular BCDVA	X			X	X	X	X
[redacted]	X		X	X	X	X	X
Slit-Lamp Exam	X		X	X	X	X[7]	X[7]
[redacted]			X	X	X	X	X
[redacted]			X	X	X	X	X

Activity	Visit 0	Visit 00	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5[9]
	Day -30 to 0 Preoperative	Day 0 Operative Visit	1-2 Days Postoperative	7-14 Days Postoperative	30-45 Days Postoperative	120-180 Days Postoperative	330-420 Days Postoperative\ Early Exit
Slit-lamp photography, if applicable[5,7]			X	X	X	X	X
IOL Axis of Orientation Slit-Lamp Imaging[6, 7]		X	X	X	X	X	X[10]
[redacted]	X					X	X
Adverse Events (Including SSIs)	X	X	X	X	X	X	X
[redacted]		X	X	X	X	X	X

[1] Required for women of child-bearing potential

[redacted]

[5] See MOP for Slit-lamp Photography requirements

[6] Sites participating in rotational stability sub-study

[7] Subject must be dilated for assessment

[redacted]

[9] If possible, perform Visit 5 procedures for an early exiting subject

[10] Only required if subject is exiting the study early; at, or prior to, Visit 4

7 INTRODUCTION

7.1 Background

A summary of known and potential risks and benefits to humans, as identified in the literature or through preclinical testing and/or prior clinical evaluations, for the investigational product can be found in the Investigator's Brochure (IB-0146) and Directions for Use (DFU)/Package Insert [redacted]

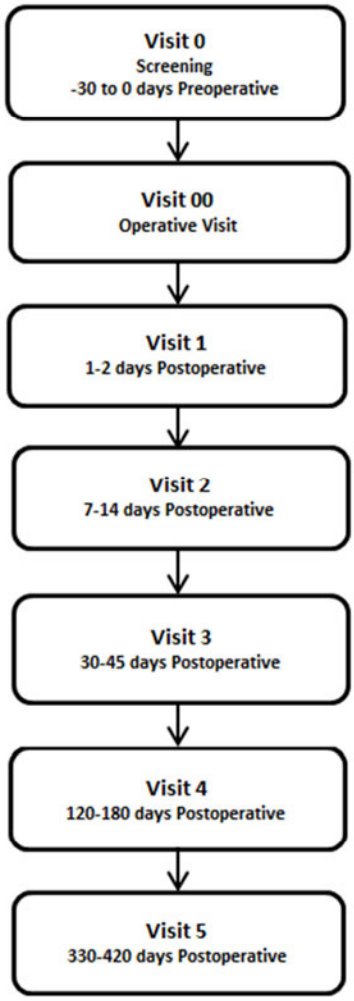
[redacted]

The Clareon IOL is a foldable monofocal IOL intended as an optical implant for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The lens is intended to be placed in the capsular bag in the posterior chamber of the eye.

7.2 Clinical Trial Design

An overview of the study flow is depicted in Figure 7-1.

Figure 7–1 Study Flow



8 CLINICAL TRIAL OBJECTIVES

8.1 Primary Effectiveness Objective

The primary effectiveness objective of this study is to demonstrate favorable visual acuity and adverse event outcomes for the Clareon IOL compared to historical safety and performance endpoint (SPE) rates, as reported in EN ISO 11979-7:2014.

8.1.1 Co-Primary Effectiveness Endpoints

- ≠ Percentage of all-implanted subjects achieving BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5)
- ≠ Percentage of best-case subjects achieving BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5)

8.2 Secondary Effectiveness Objectives

- ≠ To demonstrate rotational stability by showing IOL rotation at 6 months postoperative (Visit 4) is
    - less than 10° in 90 % of eyes in the RAS
    - less than 20° in 95 % of eyes in the RAS
    - less than 30° in 99 % of eyes in the RAS
- ≠ To describe IOL misplacement, IOL rotation, and IOL misalignment

8.2.1 Secondary Effectiveness Endpoints

- ≠ IOL rotation at Visit [x], defined as the difference between axis of IOL orientation on the day of surgery and the postoperative Visit [x]
- ≠ IOL misplacement, defined as the difference between intended axis of placement and actual axis of IOL orientation on the day of surgery
- ≠ IOL misalignment at Visit [x], defined as the summation of IOL misplacement and IOL rotation at t Visit [x].

8.3 Primary Safety Objective

8.3.1 Primary Safety Endpoint

Rate of adverse events (ocular and nonocular, serious and non-serious) including secondary surgical interventions (SSIs)

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

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[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

9 INVESTIGATIONAL PLAN

9.1 Study Design

This is a prospective, multicenter, single-arm safety and performance clinical study, requiring no masking. The trial will evaluate the safety and performance of the Clareon IOL in approximately 350 unilaterally implanted subjects. To qualify for enrollment into the trial, adult (≥ 22 years of age) subjects must require routine cataract surgery in at least one eye; only one eye will be implanted with the study lens. Potential subjects will be screened for enrollment into the trial in accordance with the entry criteria found in Section 10 SUBJECT POPULATION.

Note: *The Investigator should follow standard of care for any visits relating to the follow-up, surgery, and lens choice (as applicable) of the subject's fellow eye.*

Subjects will attend a total of 7 study visits over a period of approximately 13 months. Of these seven visits, one is a preoperative screening visit (Visit 0) and one is an operative visit (Visit 00). The remaining five are postoperative visits (Visits 1-5), which will occur at the following intervals: Visit 1 Day 1-2, Visit 2 Day 7-14, Visit 3 Day 30-45, Visit 4 Day 120-180, and Visit 5 Day 330-420. Visit day calculations for Visits 1-5 are based off of the day of surgery (Visit 00). Unscheduled visits may be conducted if needed for medical attention. Refer to Figure 7-1 above for a study outline diagram.

Primary endpoint data will be collected at the final visit (Visit 5 330-420 days postoperative), and secondary endpoint data will be collected at Visit 3 (30-45 days postoperative) and Visit 4 (120-180 days postoperative). The study will be considered successful if the data indicate a favorable outcome in relation to the SPE rates as reported in EN ISO 11979-7:2014. Additional details, including a risk-benefit assessment can be found in the sections below.

Section 12 CLINICAL TRIAL PROCEDURES outlines the procedures and assessments to be conducted at each study visit. This information is presented in tabular format in Section 6 SCHEDULE OF VISITS.

9.2 Rationale for Study Design

The design of this study follows recommendations as set forth in EN ISO 11979-7:2014 for the purpose of determining the safety and performance of a posterior chamber monofocal IOL.

9.3 Sub-study to Assess Rotational Stability of the Clareon IOL

Toric axis markings will be incorporated on Clareon monofocal investigational lenses for evaluation of rotational stability. IOL rotational stability, defined as the difference in IOL axis of orientation from the day of surgery to 6 months postoperative, will be demonstrated on at least 100 subjects; a sub-set of approximately 6 clinical trial sites will examine subjects for rotational stability. Complete instructions on the procedure will be detailed in the Manual of Procedures. IOL axis of orientation will be assessed on Visit 00 (Operative visit), Visit 1 (Day 1-2), Visit 2 (Day 7-14), Visit 3 (day 30-45 postoperative) and Visit 4 (day 120-180 postoperative) Procedures Per Study Visit. Examination will occur under dilated conditions to assist in visualization of the toric axis markers.

9.4 Risk Benefit Assessment

For a full and comprehensive risk benefit assessment, including a summary of known and potential risks and benefits to humans as identified in the literature, through preclinical testing, or via prior clinical investigations, refer to the study IB (IB-0146). Abbreviated details are provided in Section 9.5 and 9.6 below.

Based on the below outlined risks and benefits, the risk of unanticipated adverse device effects with use of the Clareon IOL is considered to be low and the benefits of receiving the IOL should outweigh the risks for subjects that qualify for implantation in this study.

9.5 Known and Potential Risks

Known and potential risks of the Clareon IOL are outlined here.

Surgical Risk

As with any type of intraocular surgery, there is a possibility of complications due to anesthesia, drug reactions, and surgical problems. The surgical procedure can exacerbate a pre-existing ocular condition. Possible problems during surgery include corneal endothelial touch, detached Descemet's membrane, iris damage, iris prolapse, iris trauma, iris incarceration, zonular rupture, vitreous loss, capsulorhexis tear, capsular rupture, uncontrollable intraocular pressure (IOP), hyphema, and retinal damage. An IOP increase may occur from the surgical procedure, residual viscoelastic in the eye, or a steroid response to postoperative medications.

Postoperative Risk

Potential postoperative adverse events include, but are not limited, to corneal stromal edema, cystoid macular edema, endophthalmitis, hypopyon, iritis, lens dislocation, membrane formation on the IOL, pupillary block, retinal detachment, cyclitic membrane, transient or persistent glaucoma, retinal tear, vitritis, iris touch, pupil ovalization, posterior synechiae, ocular inflammation, ocular discomfort or pain, inflammation, decreased vision, decreased contrast sensitivity, decreased color perception, visual disturbances, and corneal endothelial cell loss.

An IOL replacement or explantation may be appropriate in some cases of significant residual refractive error, ocular infection, subject dissatisfaction, or visual disturbances (eg, glare, halos, starbursts, hazy vision, blurred vision, double vision, visual distortions, and color distortions). In most/majority of cases, spectacles or contact lenses may be prescribed to resolve residual refractive error. Other secondary surgical interventions include, but are not limited to: IOL repositioning, refractive laser treatment, paracentesis, vitreous aspirations, and iridectomy or laser iridotomy for pupillary block, wound leak repair, and retinal detachment repair.

Unknown Risk

There may also be unknown risks with the use of the Clareon IOL. Any foreseen risk to subjects in this clinical study will be minimized by compliance with the eligibility criteria, study procedures, and clinical monitoring.

9.6 Potential Benefits

Known and potential benefits of the Clareon IOL are outlined here.

Cataract surgery with IOL lens implantation benefits patients by restoring sight 0 the result of replacing the natural cataractous lens with an IOL. IOL implantation may also improve color vision, enhance image sharpness, and decrease nighttime photic phenomena (eg, glare, halo). This enhancement of vision may increase overall lifestyle satisfaction (eg, more independence, participation in social and/or sporting activities). The Clareon IOL is expected to have benefits comparable to other available monofocal IOLs.

This clinical trial may benefit the medical community and future cataract patients via contribution to the available scientific literature and the potential availability of an IOL with a new lens material.

10 SUBJECT POPULATION

The study population includes approximately 350 implanted subjects enrolled at approximately 17 investigative sites. Each Investigator will implant approximately 20 subjects with no Investigator implanting more than 20% of the total study population. Site enrollment will monitored closely by the Sponsor to ensure surgeons have the opportunity to enroll 20 subjects each in order to achieve an even distribution across all sites. Each site will use only 1 implanting surgeon.

To participate in the clinical trial, subjects must be an adult (age 22 years or older at time of surgery) requiring routine cataract surgery in at least one qualifying eye. A full list of entry criteria is provided in Sections 10.1 to 10.3 below. The Investigator may also refer to the lens DFU or IB for further guidance, and may exclude potential subjects based upon his/her medical judgement.

Each subject will contribute 1 eye to the study. In the event that both eyes meet entry criteria, the Investigator will identify the study eye based on his/her medical judgement. In the event neither eye qualifies, the subject *may not* be rescreened at a later date for qualification into the study.

Note: For study qualification, the eye identified as the study eye must meet all ocular inclusion/exclusion criteria. The fellow eye is exempt from meeting these criteria.

10.1 Inclusion Criteria

Listed below are criteria that must be met for inclusion into the study.

1. Adults, 22 years of age or older at the time of surgery, of either gender or any race, diagnosed with cataract
2. Planned routine cataract surgery (need determined by the expert opinion of the Investigator)
3. Calculated lens power is within the available range [redacted]
4. Able to comprehend and willing to sign a statement of informed consent and complete all required postoperative visits
5. Clear intraocular media other than cataract

6. [redacted]

10.2 Exclusion Criteria

Listed below are criteria that exclude entry into the study.

1. Any disease or pathology, other than cataract, that (in the expert opinion of the Investigator) is expected to reduce the potential postoperative BCDVA to a level worse than 0.30 logMAR (including, but not limited to the following: amblyopia, clinically severe corneal dystrophy (eg, epithelial, stromal, or endothelial dystrophy), diabetic retinopathy, extremely shallow anterior chamber, not due to swollen cataract, microphthalmos, previous retinal detachment, previous corneal transplant, recurrent severe anterior or posterior segment inflammation of unknown etiology, iris neovascularization, uncontrolled glaucoma, aniridia, optic nerve atrophy, clinically significant macular degeneration, or diagnosis of pseudoexfoliation)
2. Previous corneal surgery
3. Rubella or traumatic cataract
4. Ocular trauma, previous refractive surgery, and refractive surgical procedures
5. Current or recent use of an alpha-1-selective adrenoceptor blocking agent or an antagonist of alpha1A adrenoceptor (eg, Flomax (tamsulosin HCL), Hytrin, or Cardura) that in the opinion of the Investigator would potentially require mechanical or surgical manipulation to enlarge the pupil
6. Any other ocular or systemic comorbidity that, in the expert opinion of the Investigator, may confound the results of this study or prohibit the completion of the study assessments or increase the risk for the subject
7. Pregnancy, plans to become pregnant, is lactating or has other conditions associated with the fluctuations of hormones that could result in refractive status change
8. Any subject currently participating in another investigational drug or device study that may confound the results of this investigation

10.3 Reasons for Discontinuation During Surgery

Listed below are criteria that, when occurring at the time of surgery, may result in discontinuation from the study. A subject discontinuing at the time of surgery will be not be considered a screen failure. In the event that a criterion listed below occurs, do not implant the study lens. Proceed according to the physician's professional medical judgement for what is in the best interest of the subject, including, if warranted, an alternate lens.

9. Any other additional procedures during the cataract removal and IOL implant due to intraoperative complications that require further intervention (including but not limited to posterior rupture, with vitreous loss, zonular dehiscence that may make the IOL implant less stable
10. Mechanical or surgical intervention required to manipulate the pupil
11. Excessive iris mobility
12. Significant vitreous loss
13. Significant anterior chamber hyphema
14. Zonular or capsular rupture
15. Unrecognized (pre-existing but discovered during surgery) ocular conditions or complications in which the IOL positions could be less stable, including zonular weakness
16. Inability to place the IOL in the capsular bag due to surgical complications

If the implantation was aborted and the IOL **did not** touch the eye, then the subject is required to discontinue from the study and standard of care for IOL implantation is followed.

If the implantation was aborted and the IOL **did** touch the eye, then the subject is encouraged to attend all follow-up study visits for safety evaluation on this eye only. See Section 12.16 Aborted Implantation, for additional instructions.

11 TREATMENT

Throughout the clinical study, the Investigator is responsible for the accounting of all IP and must ensure that the clinical study product is used in accordance with the manufacturer's DFU and the IB.

All consented and qualified subjects will be implanted with the test article. No control article is available in this study.

11.1 Investigational Product

Test Article: Refer to Table 11-1 below for test article details.

Control Article: N/A

Table 11–1 Test Article

Test Product	Clareon aspheric hydrophobic acrylic IOL [redacted]
Manufacturer	Alcon
Indication for use	This IOL is intended for primary implantation in the capsular bag in the posterior chamber for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients.
Intended Purpose in the current study	The Clareon Aspheric Hydrophobic Acrylic IOL is a foldable single-piece posterior chamber IOL intended as an optical implant for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The lens is intended to be placed in the capsular bag in the posterior chamber of the eye.
Product description and parameters available for this study	[redacted]

Formulation	N/A
Usage	IOLs are implantable medical devices and are intended for long term use over the lifetime of the pseudophakic subject.
Number/Amount of Product to be Provided to the Subject	Each subject will be implanted with a single test article in his/her study eye.
Packaging description	Each IOL will be individually packaged and will have a unique serial number. The IOL package will contain the following items: ≠ The IOL ≠ A subject registration card (Lens Implant Card) ≠ A subject identification card ≠ Adhesive labels containing the IOL information and unique serial number ≠ A package insert containing directions for use
Labeling description	Packaged in a standard Alcon IOL carton. The carton is labeled with the following information: name of the lens, model number, overall diameter, optic diameter, diopter power, serial number, name of the manufacturer, storage condition, expiration date, sterile, and single use. Each package is also labeled *"Caution – Investigational device. Limited by Federal law to investigational use".*
Storage conditions	The IP must be stored in a safe, secure location with limited access separated from general stock. Transportation of product from one address to another must be documented and a Transportation Log (or similar documentation) used for appropriate accountability.
Additional information	In order to implant the test article in a study subject, the surgeon participating in the study must be a licensed ophthalmologist with cataract surgery experience and trained on the protocol. More information on the test article can be found in the IB (IB-0146) and product DFU (Clareon Aspheric Hydrophobic Acrylic IOL [redacted]
Supply	A designated amount of IOLs will be supplied to the site by the Sponsor.

Figure 11–1 Clareon Aspheric Hydrophobic Acrylic Monofocal Intraocular Lens (IOL) [redacted]

11.2 Usage

The Clareon IOL is a foldable single-piece posterior chamber IOL intended as an optical implant for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The lens is intended to be placed in the capsular bag in the posterior chamber of the eye. Additional information regarding the use of this IOL can be found in the DFU.

Each study surgeon should follow his/her routine cataract procedure for all study surgeries, and according to the site's surgical protocol documented for the study (see Section 14.3, Data Review and Clarifications, for additional details). [redacted]

The IOL must be delivered via an Alcon qualified delivery system and viscoelastic combination. The qualified combinations are provided below in Table 11-2.

Table 11–2 Qualified Combinations of Compatible Products

Lens Model	Cartridge	Handpiece	Viscoelastic
[redacted]	Monarch® III D Product Reference Number: 8065977763	Monarch III (blue) Product Reference Number: 8065977773	Viscoat® Provisc®

[redacted]

The surgeon must have at least 2 IOLs in the subject's required power available for use during the surgery. One IOL will serve as a reserve lens in the event the first lens cannot be implanted. No more than 2 implantation attempts should be initiated. Refer to Section 10.3 Reasons for Discontinuation During Surgery, Section 12.14 Aborted Implantation, and the Manual of Procedures (hereto referred to as MOP) Table 5-1 Subject Status after Exclusion During Surgery, regarding subject study status and required follow-up. [redacted]

11.3 Accountability Procedures

Investigational lenses will be provided by the Sponsor. Throughout the clinical trial, the Investigator will be responsible for the accounting of all investigational product (IP) and will ensure that the clinical trial products are not used in any unauthorized manner.

Upon receipt of the IP, the Investigator will conduct an inventory audit, complete and sign the Receipt of Clinical Supplies form, and return it to the Sponsor. A copy must be retained in the Investigator's clinical trial records. IP must be stored in a safe, secure location with limited access separated from general stock. Transportation of IP from one address to another must

be documented and a Transportation Log (or similar documentation) used for appropriate accountability.

The Investigator is to keep a current record of the inventory and dispensing of all IP. This record will be made available to the Sponsor's monitor to account for all IP. [redacted] All IP sent to the Investigator must be accounted for and in no case should the IP be used in any unauthorized situation.

[redacted]

It is the Investigator's responsibility to return any and all unused IP to the Sponsor, as directed.

12 CLINICAL TRIAL PROCEDURES

12.1 Clinical Trial Assessments

The following section describes in general the assessments to be performed in this clinical trial. Assessments are described in the MOP. Refer to Section 6 SCHEDULE OF VISITS for an overview of assessments by visit.

All ocular assessments are required to be performed on the study eye only. Refer to Section 10 SUBJECT POPULATION for information on study eye selection. AEs are collected and reported for both the study eye and fellow eye [redacted]

12.2 Prescreening

Prescreen potential subjects. Review non-study specific inclusion/exclusion criteria (eg, age, cataract procedure, ocular history) to identify potential subjects most likely to meet the qualifications for participation in the study. Invite those prescreened candidates who may qualify for the study to learn more about the trial. For those interested in participation, carry out the informed consent process. Refer to Section 16.2 Informed Consent Procedures.
Note: Subjects must formally consent to the trial prior to any study specific testing.

12.3 Prohibited Procedures

Refractive surgical procedures are prohibited in the study eye at surgery and throughout the duration of the subject's participation in the clinical study. Prohibited procedures include, but are not limited to, LASIK, astigmatic keratotomy, and limbal relaxing incisions.

12.4 Preoperative Visit (Visit 0)

Subjects will be considered enrolled upon consent. Each subject that signs a consent form must be entered into the Electronic Data Capture (EDC) system. Upon entry into the system, each subject will be assigned a number. This subject number will be used to identify the subject throughout the study.

Below is a list of study procedures to be undertaken at Visit 0 (-30 to 0 days preoperative). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable). NOTE: Only assessments for the study eye will be recorded in eCRFs, however bilateral assessments may be needed/recorded in source documents in the process of determining which eye should be the study eye.

For Visit 0, data from the Investigator's previous routine clinical evaluation for dilated fundus exam may be used, if the data 1) meet the requirements of this protocol and MOP, and 2) were collected within the -30 to 0 day preoperative time period. All other ocular assessments must be collected after the subject signs the Informed Consent Form.

1. Ensure subject has been properly consented for trial participation. Refer to Section 16.2 Informed Consent Procedures.
2. Document demographics, ocular and non-ocular medical history, ocular and non-ocular concomitant medications and pregnancy status (where applicable). Refer to MOP for further instruction.
3. Perform a urine pregnancy test IF the subject is a woman of childbearing potential. Refer to MOP for further instruction.
4. Assess [redacted] keratometry. Refer to MOP for further instruction.
   Note: For sites participating in the rotational stability sub-study, identify the steep corneal meridian. If a steep meridian cannot be identified, a placement axis of 90 should be used. Refer to MOP for further instruction.

[redacted]

6. Perform [redacted] BCDVA testing with study specified equipment. Refer to MOP for further instruction.
   Note: Lighting conditions must be measured and recorded in source prior to vision testing.

[redacted]

10. Assess, document and report adverse events. Refer to Section13 ADVERSE EVENTS.
11. Review inclusion/exclusion criteria and subject's willingness to continue participation. Refer to Section 10 SUBJECT POPULATION.
12. Document study eye (ie, OD or OS).
13. Document the subject status (eg, continuing, screen failure). If the subject is a screen failure, document the primary reason the subject fails to qualify. Refer to MOP for further instruction.
14. Schedule the subject for surgery within 30 days if they qualify.

12.5 Operative Visit (Visit 00)

Below is a list of study procedures to be undertaken at Visit 00 (Day 0, Operative Visit). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Prior to treatment, review inclusion/exclusion criteria and ensure the subject has been properly consented for participation in the trial. Refer to Section 10 SUBJECT POPULATION.
2. Document any changes to ocular and non-ocular concomitant medications. Refer to MOP for further instruction.
3. Record operative eye.
4. Proceed with Investigator's routine cataract procedure while following guidance in Section 11 TREATMENT.
   Note: For sites participating in the rotational stability sub-study, orient the lens so that the toric markers are placed on the steep corneal meridian.
5. At completion of IOL implantation, measure and record incision size and location.

[redacted]

8. Record any AEs including SSIs.
   Note: SAEs including SSIs must be entered into Electronic Data Capture (EDC) system within 24 hours of the Investigator or site's knowledge. [redacted]

[redacted]

10. For sites participating in the rotational stability sub-study, take slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
11. Document the subject status (eg, continuing).

12.6 1-Day Postoperative Visit (Visit 1)

Below is a list of study procedures to be undertaken at Visit 1 (1-2 days postoperative). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications.

[redacted]

7. Record any AEs including SSIs.

   Note: SAEs including SSIs must be entered into EDC system within 24 hours of the Investigator or site's knowledge. [redacted]

8 [redacted]

9. For sites participating in the rotational stability sub-study, take slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
10. Document the subject status (eg, continuing).

12.7 1-Week Postoperative Visit (Visit 2)

Below is a list of study procedures to be undertaken at Visit 2 (7-14 days postoperative). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications.

[redacted]

4. Assess BCDVA. Refer to MOP for further detail.

[redacted]

[redacted]

9. Record any AEs including SSIs.

   Note: SAEs including SSIs must be entered into EDC within 24 hours of the Investigator or site's knowledge. [redacted]

[redacted]

11. For sites participating in the rotational stability sub-study, take slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
12. Document the subject status (eg, continuing).

12.8 1-Month Postoperative Visit (Visit 3)

Below is a list of study procedures to be undertaken at Visit 3 (30-45 days postoperative). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications.

[redacted]

4. Assess BCDVA. Refer to MOP for further detail.

[redacted]

9. For sites participating in the rotational stability sub-study, take slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
10. Record any AEs including SSIs.
    Note: SAEs including SSIs must be entered into EDC within 24 hours of the Investigator or site's knowledge. [redacted]

11 [redacted]

12. Document the subject status (eg, continuing).

12.9 4-6 Month Postoperative Visit (Visit 4)

Below is a list of study procedures to be undertaken at Visit 4 (120-180 days postoperative). The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications.

[redacted]

4. Assess BCDVA. Refer to MOP for further detail.

[redacted]

10. For sites participating in the rotational stability sub-study, obtain slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
11. Record any AEs including SSIs.
    Note: SAEs including SSIs must be entered into EDC within 24 hours of the Investigator or site's knowledge. [redacted]
13. Document the subject status (eg, continuing).

12.10 1-Year Postoperative Visit (Visit 5/ Early Exit Visit)

Below is a list of study procedures to be undertaken at Visit 5 (330-420 days postoperative) or when a subject is exited early from the study. The order of procedures is recommended. All assessments must be documented in source documentation and eCRFs (if applicable).

1. Record changes in medical/ocular history and ocular and non-ocular concomitant medications.

[redacted]

4. Assess BCDVA. Refer to MOP for further detail.

[redacted]

10. ONLY APPLICABLE IF SUBJECT IS EXITING EARLY (at, or prior to, Visit 4): For sites participating in the rotational stability sub-study, obtain slit-lamp images of the lens in the eye post-surgery. Refer to MOP for further details.
11. Record any AEs including SSIs.
    Note: SAEs including SSIs must be entered into EDC within 24 hours of the Investigator or site's knowledge. [redacted]
13. Complete Disposition status.

12.11 Unscheduled Visits

An unscheduled visit (USV) is defined as follows:

- an ocular examination on the study eye that is not standard of care and not required by the protocol

≠ an examination conducted by the study staff

≠ a new finding(s), or a change to a previous finding(s) was discovered

A USV may or may not result in the capture of an adverse event. Likewise an adverse event may be captured without the report of a USV (eg, AE identified subsequent to study eye examination by non-study personnel). The assessments captured at the USV are dictated by the Investigator per his/her medical judgment. The following assessments are recommended.

≠ Concomitant medications

≠ Adverse events

Note: Assessments are not limited to the above list.

If the subject is discontinued at the USV, perform all Early Exit procedures. Refer to Section 6 SCHEDULE OF VISITS. For safety purposes, if a USV is required after the final study visit, document the visit. Refer to Section 13.8 Follow up of Safety Information for further detail.

12.12 Discontinued Subjects

Discontinued subjects withdraw, or are withdrawn from the study after signing consent, and prior to completing all study visits. Subjects signing consent, but withdrawing or withdrawn prior to surgery shall be considered discontinued due to screen failure, and the failed entry criterion documented in source documents and in EDC. Refer to Section 10 SUBJECT POPULATION.

Subjects may discontinue study participation at any time and for any reason. However, it is incumbent upon the Investigator to carefully select subjects who understand the commitment involved in participating in this clinical trial.

Subjects may be discontinued from the study at any time if, in the medical opinion of the Principal Investigator or designated, qualified medical personnel, continued participation poses a health risk to the subject, or other reasonable cause.

Subjects signing consent, but who voluntarily withdraw or are withdrawn by the Investigator prior to the final study visit shall be considered discontinued of study participation. For subjects discontinuing from the study, the Investigator should complete Exit procedures according to Section 12.10 1-Year Postoperative Visit (Visit 5/ Early Exit Visit), if the subject is willing and able, and if in the opinion of the Investigator it is safe for the subject to do so. The reason for discontinuation must be documented in source documents and in EDC. To ensure the safety of all subjects who discontinue early, Investigators must assess each subject and, if necessary, advise them of any therapies and/or medical procedures that may be needed to maintain their health.

Subject numbers from discontinued subjects will not be reissued. Discontinued subjects will not be replaced.

12.13 Missed Visit

If a subject misses a scheduled visit, reschedule the subject within the same visit period. Show diligence in trying to schedule the subject for all visits, and document all attempts to contact the subject in the subject's chart. In documentation, include dates, times, method of contact, etc.

If a subject is unable to return for the final study visit, complete the Exit Case Report Form with the appropriate reason for discontinuation. If attempts to contact the subject are unsuccessful, document the date the subject is considered lost to follow-up. Complete the subject's Exit Case Report Form after the last window closes, indicating the subject is lost to follow-up.

12.14 Subject Lost to Follow-up

If a subject is overdue for a visit and all efforts to contact the subject for an examination have failed, this subject is considered lost to follow-up. The Exit Case Report Form should not be completed until after the subject's last visit window closes, in case the subject is able to attend future visits. Any intermediate visits not attended will be considered Missed Visits.

12.15 Clinical Trial Termination

The Sponsor reserves the right to close an investigational site(s) or terminate the study in its entirety at any time, for reasonable cause. The Investigator also may terminate the study at

his/her site for reasonable cause. Reasons for the closure of an investigational site or termination of a study may include:

- ≠ the Investigator fails to comply with the protocol or GCP guidelines
- ≠ inadequate recruitment of subjects by the Investigator
- ≠ subject safety concerns

If the clinical study is prematurely terminated or suspended, the Sponsor will inform the Investigator and the regulatory authorities of the termination/ suspension and the reason(s) for the termination/suspension. The Investigator should promptly notify the IRB/IEC of the termination or suspension and of the reasons. If the Sponsor terminates the study for safety reasons, it will immediately notify the Investigator(s), and provide written instructions for study termination and applicable subject follow-up.

12.16 Aborted Implantation

[redacted] Specific guidance with regards to aborted implantation is detailed below.

In the sections below, the IOL touching the eye is defined as the time point when any IP first touches the eye.

NOTE: No more than 2 attempts may be made to implant the test article.

If the second attempt to implant the test article is aborted and the IOL **did not** touch the eye on either attempt, then the subject must be discontinued from the study.

If the second attempt to implant the test article is aborted and the IOL **did** touch the eye on either attempt, then

- ≠ The eye must be followed for all study visits for a safety evaluation
- ≠ The test article must **NOT** be implanted

[redacted] **ADVERSE EVENTS**

13.1 General Information

An adverse event (AE) is any untoward medical occurrence in a subject who is administered a clinical trial treatment (ie, implant with an investigational device), regardless of whether or not the event has a causal relationship with the treatment. An AE, therefore, can be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the clinical trial treatment, whether or not related to the treatment. Below are Figures that categorize AEs and SAEs.

Figure 13-1 Categorization of all Adverse Events

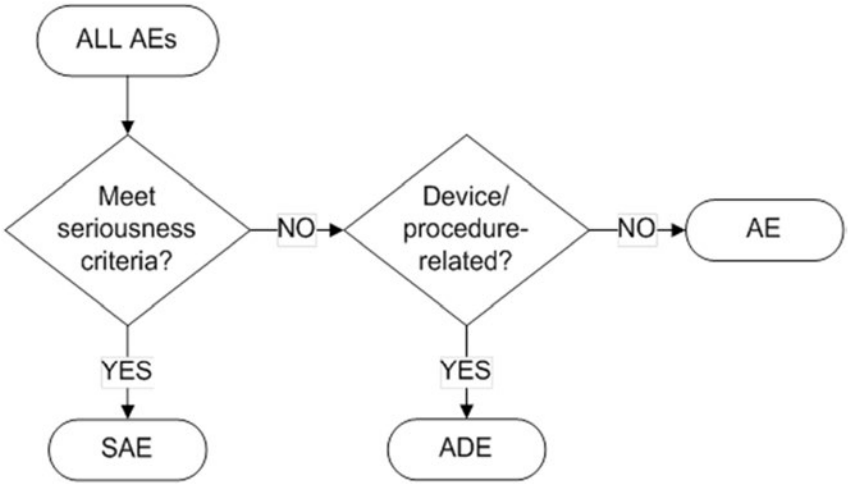
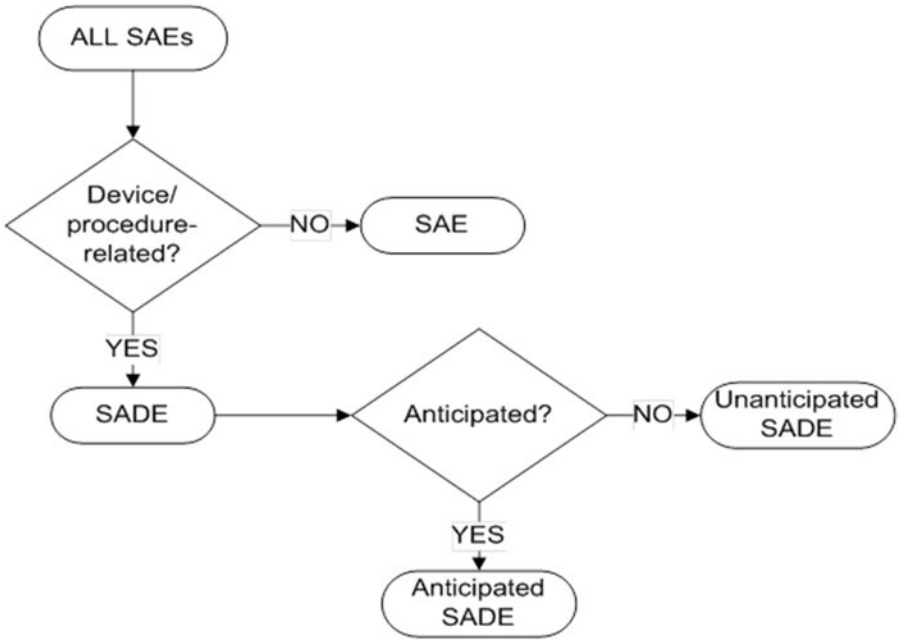


Figure 13–2 Categorization of all Serious Adverse Events



13.2 Serious Adverse Events (SAEs)

A serious adverse event is an AE that led to any of the following:

≠ Death

≠ A serious deterioration in the health of the subject that either resulted in:

a) a life-threatening illness or injury

NOTE: *Life-threatening means that the individual was at immediate risk of death from the event as it occurred, ie, it does not include an event which hypothetically might have caused death had it occurred in a more severe form.*

b) any potentially sight-threatening event or permanent impairment to a body structure or a body function

c) inpatient hospitalization or prolonged hospitalization

NOTE: *Planned hospitalization for a pre-existing condition, without serious deterioration in health, is not considered a SAE. In general, hospitalization signifies that the individual remained at the hospital or emergency ward for observation and/or treatment (usually involving an overnight stay) that would not have been appropriate in the physician's office or an outpatient setting. Complications that occur during*

hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred, the event should be considered serious.

d) a medical or surgical intervention to prevent a) or b) or any ocular secondary surgical intervention (excluding posterior capsulotomy [PC])

e) any indirect harm as a consequence of incorrect diagnostic test results when used within manufacturer's instructions for use

≠ Fetal distress, fetal death, or a congenital abnormality or birth defect

Potentially sight-threatening events may also be considered serious based on the judgment of the Investigator and should be reported appropriately, as delineated in Section 13.7 Procedures for Recording and Reporting.

13.2.1 Cumulative Serious Adverse Events

Total number of Adverse Events that have occurred at any time up to a specified time point postoperatively.

≠ Cystoid macular edema

≠ Hypopyon

≠ Endophthalmitis

≠ Lens dislocation from posterior chamber

≠ Pupillary block

≠ Retinal detachment

≠ Secondary surgical intervention (excluding PC)

13.2.2 Persistent Serious Adverse Events

≠ Corneal stromal edema

≠ Cystoid macular edema

≠ Iritis

≠ Raised IOP requiring treatment

This list is consistent with the categories provided in EN ISO 11979-7:2014. A persistent AE is an AE that is present at the conclusion of a clinical investigation per

EN ISO 11979-7:2014. Any other potentially sight-threatening event may also be considered serious based on the judgement of the Investigator and must be reported appropriately, as delineated in Section 13.2. Serious Adverse Events (SAEs).

[redacted]

13.6 Monitoring for Adverse Events

At each visit, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking the standard questions such as:

- "Have you had any health problems since your last study visit?"
- "Have there been any changes in the medicines you take since your last study visit?"

Changes in any protocol-specific ocular or systemic parameter evaluated during the study are to be reviewed by the Investigator. In addition, the subject's responses to any questionnaire utilized during the study are to be reviewed by the Investigator. Any untoward (unfavorable and unintended) change in a protocol-specific parameter or questionnaire response that is clinically relevant, in the opinion of the Investigator, is to be reported as an AE. These clinically relevant changes will be reported regardless of causality.

13.7 Procedures for Recording and Reporting

AEs are collected from the time of informed consent. Any pre-existing medical conditions or signs/symptoms present in a subject prior to the start of the study (ie, before ICF is signed) are not considered AEs in the study and should be recorded in the Medical History section of the eCRF.

In addition, aqueous cells and flare, corneal edema, raised IOP and superficial punctate keratitis are examples of early postoperative findings that are typically observed following ocular surgery. These are not considered AEs if they can be reasonably expected to resolve within a week and not result in any untoward long term visual outcome impact.

For each recorded event, the ADEs and SAEs documentation must include: date of occurrence, severity, treatment (if applicable), outcome, and assessments of the seriousness and causality. [redacted] The site must submit all available information on ADEs, SAEs, [redacted] to the Study Sponsor immediately as follows:

- ≠ **ADEs or SAEs are documented on the Adverse Device Effect and Serious Adverse Event eCRF within 24 hours of the Investigator's or site's awareness.**
- [redacted]
- ≠ **Additional relevant information after initial reporting is to be entered into the eCRF as soon as the data become available.**
- ≠ **Document any changes to concomitant medications on the appropriate eCRFs.**
- ≠ **All relevant documentation such as Discharge Summary, Autopsy Report, Certificate of Death etc, should be faxed to the Study Sponsor at 1-817-302-1927.**

≠ **USADEs must be reported to the IRB as soon as possible, but not later than 10 working days after the Investigator's or site's awareness.**

NOTE: Should the EDC system become non-operational, the site must complete the appropriate paper Adverse Device Effect and Serious Adverse Event Form [redacted] The completed form is faxed to the Study Sponsor at 1-817-302-1927 or emailed to FTW.medical_safety@alcon.com within 24 hours of the Investigator's or site's awareness; however, the reported information must be entered into the EDC system once it becomes operational.

Any AEs [redacted] for non-study marketed devices/products (ie, BSS, OVD, delivery systems, etc) will be considered and processed as spontaneous (following the postmarket vigilance procedures) and should be communicated to the device's/product's manufacturer as per local requirements.

Study Sponsor representatives and their contact information are provided in the MOP that accompanies this protocol.

Further, depending upon the nature of the AE [redacted] being reported, the Study Sponsor may request copies of applicable portions of the subject's medical records. The Investigator must also report all AEs [redacted] that could have led to a SADE according to the requirements of regulatory authorities or IRB/IEC.

13.7.1 Intensity and Causality Assessments

Where appropriate, the Investigator must assess the intensity (severity) of the AE as mild, moderate, or severe based on medical judgment with consideration of any subjective symptom(s), as defined below:

13.7.1.1 Causality

For every AE in the study, the Investigator must assess the causality (Related or Not Related to the medical device or test procedure). An assessment of causality will also be performed by a Study Sponsor physician utilizing the same definitions, as shown below:

Related — An AE classified as related may be either definitely related or possibly related where a direct cause and effect relationship with the medical device or test procedure has not been demonstrated, but there is a reasonable possibility that the AE was caused by the medical device or test procedure.

Not Related — An AE classified as not related may either be definitely unrelated or simply unlikely to be related (ie, there are other more likely causes for the AE).

13.7.1.2 Intensity (Severity)

Where appropriate, the Investigator must assess the intensity (severity) of the AE as mild, moderate, or severe, based on medical judgment with consideration of any subjective symptom(s), as defined below:

Mild — An AE is mild if the subject is aware of but can easily tolerate the sign or symptom.

Moderate — An AE is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities.

Severe — An AE is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

The Investigator must document any action taken (ie, medication, intervention, or treatment plan) and outcome of the AE [redacted] when applicable.

13.8 Unmasking of the Study Information

Not applicable; this study is open-label.

13.9 Return Product Analysis

Study Sponsor representatives and their contact information are provided in the MOP that accompanies this protocol.

Alcon Products associated with [redacted] product related AEs should be returned and must include the Complaint # which will be provided by the Study Sponsor after the case is entered in the Study Sponsor's Global Product Complaint System (GPCMS).

13.10 Follow-Up of Safety Information

The Investigator is responsible for adequate and safe medical care of subjects during the study and for ensuring that appropriate medical care and relevant follow-up procedures are maintained after the study.

The Investigator must provide the Study Sponsor with any new safety information (which includes new AEs and changes to previously reported AEs) that may affect the safety

evaluation of the device. For AEs that are unresolved/ ongoing at time of subject's exit from study, any additional information received at follow-up should be documented in the eCRFs, up to study completion (ie, database lock).

Any additional data from these follow-up procedures performed up to 6 months after subject discontinuation or exit must be documented and available upon the Study Sponsor's request. All complaints received after this time period will be considered and processed as spontaneous (following the postmarket vigilance procedures) and should be communicated to the medical device's manufacturer as per local requirements.

The Investigator should also report complaints on non-Alcon products directly to the manufacturer, as per the manufacturer's instructions or local regulatory requirements.

13.11 Pregnancy in the Clinical Study

Pregnancy is not reportable as an AE; however, complications may be reportable and will be decided on a case–by-case basis. An Alcon form will be utilized to capture all pregnancy-related information until birth of the child.

14 DATA REVIEW AND HANDLING

14.1 Subject Confidentiality

The Investigator must ensure that the subject's anonymity is maintained throughout the course of the study. In particular, the Investigator must keep an enrollment log with confidential identifying information that corresponds to the subject numbers and initials of each study participant. At the end of the clinical study, the Study Sponsor will collect a copy of the enrollment log **without any identifying subject information**. All documents submitted to the Study Sponsor will identify the subjects exclusively by number and demographic information. No other personally identifying information will be transmitted to the Study Sponsor. The Study Sponsor may release anonymized study data to external researchers for purposes of future research directly related to the study objectives, or future research that is beyond the scope of the current study objectives. The ICF explains this to study subjects. Anonymization means that all identifiable information will be removed from the dataset and all links to the subjects in the study will be removed. Anonymization of the data will maintain confidentiality of the subjects who participate in the study so that they cannot be identified by external researchers. The anonymized data set will contain records from all of the subjects in the current study, but the anonymization process might change the data set in some ways, so external researchers will be informed that they might not be able to duplicate some of the results from this study. External researchers who request permission to

use anonymized data from studies for a new medicine or new indication of a medicine (studies for approved medicinal products, small molecule generics, and devices are excluded) must be approved by a central independent review panel that will adjudicate the scientific request and the competency of the external researcher(s), as well as determine the applicability to current standard operating procedures (SOPs). If approved, a data sharing agreement will be executed between the Study Sponsor and the external researcher(s), committing to a specified analysis and publication timeline. Anonymized data will be released to external researchers only after European Union (EU) and/or United States (US) submission of the investigational drug/biologic for the study indication. The Study Sponsor will not be able to influence the analyses that are performed by external researchers using the data from this study once the anonymized data are released.

14.2 Completion of Source Documents and Case Report Forms

The nature and location of all source documents will be identified to ensure that original data required to complete the electronic case report forms (eCRFs) exists and are accessible for verification by the Clinical Site Manager (CSM). It is required that the author of each entry in the source documents be identifiable (eg, initials or signature and date). At a minimum, source documents should include the following information for each subject:

- ≠ Subject identification (name, date of birth or age, sex)
- ≠ Documentation of subject eligibility
- ≠ Date of informed consent
- ≠ Dates of visits
- ≠ Documentation that protocol-specific procedures were performed
- ≠ Results of study testing, as required by the protocol
- ≠ Test article accountability records
- ≠ Documentation of SAEs and other safety parameters (as applicable)
- ≠ Records regarding medical histories and the use of concomitant therapies prior to and during the study
- ≠ Date of study completion and reason for early discontinuation, if applicable

Note: If electronic source records are maintained, the method of verification must be determined in advance of starting the study.

Direct access to source documentation (medical records) must be allowed for the purpose of verifying that the data recorded on the eCRF are consistent with the original source data. Data reported on the eCRFs shall be derived from source documents and be consistent with these source documents, and any discrepancies shall be explained in writing. Any change or correction to data reported on a source document shall be dated, initialed, and explained if necessary, and shall not obscure the original entry (ie, an audit trail shall be maintained); this applies to both written and electronic changes and corrections. eCRFs shall be signed and dated by the Principal Investigator or his/her authorized designee(s).

14.3 Data Review and Clarifications

Upon completion of the eCRFs, targeted data will be reviewed by the assigned Sponsor global CSM team for accuracy and completeness. The planned source document verification and overall monitoring activities for this study are outlined in a separate document, the Protocol Monitoring Plan. Corrections and/or any necessary additions to the data will be applied and if required, queries will be generated. Designated investigative staff are expected to respond to data queries in a timely manner and ensure that the corrections and changes made to the data are reflected in the subjects' source documentation.

Deviations from this protocol, regulatory requirements and GCP must be recorded. An explanation of the deviation should be included, as applicable. In addition, corrective and preventive action should be identified, implemented and documented within the study records. Prior to study start, a plan for data validation will be completed by Alcon clinical data management, and agreed upon by the study clinical manager (CM) and other team members.

Concomitant medications entered into the database will be coded using the WHO Drug Reference List. Operative medications will be detailed in site-specific surgical study protocols and will not be entered in the eCRFs; any exceptions to the site's standard surgical protocol for the study will require entry into the eCRF. The surgical protocol will be reviewed by the Sponsor prior to the site enrolling subjects, kept with the site's study files, and archived in the Sponsor Trial Master File. Medical history and adverse events will be coded using the medical dictionary for regulatory activities (MedDRA) terminology. In addition, standardized definitions to allow for additional supportive characterization of AEs based on Postoperative Adverse Event Definitions for Intraocular Lenses are provided in the appendices, Table 18-1, and will be collected in eCRFs. Upon completion of the study and once the database is declared completed and accurate, the database will be locked and data will be available for data analysis. Any changes to the database after lock will be implemented upon agreement between the Sponsor's clinical trial management, medical

safety clinical data management, and biostatistics departments, and will be completed following the Sponsor's procedures for changes to a database after database lock.

14.4 Quality Assurance and Quality Control

The Study Sponsor will secure agreement from all involved parties to ensure direct access to all study related sites, source data and documents, and reports for the purpose of monitoring and auditing by the Study Sponsor, and inspection by domestic and foreign regulatory authorities. Quality control will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. Agreements made by the Study Sponsor with the Investigator/Institution and any other parties involved in the clinical study will be provided in writing as part of the protocol or as a separate agreement.

15 ANALYSIS PLAN

15.1 Subject Evaluability

The final subject evaluability will be determined prior to locking the database.

15.2 Analysis Data Sets

The primary analysis set for effectiveness analyses will be the All-Implanted Analysis Set (AAS). AAS includes all eyes with successful test article implantation. Additional analyses, including the co-primary analysis, will be conducted using the Best-Case Analysis Set (BAS). BAS includes all eyes successfully implanted with the test article that had:

- ≠ at least 1 postoperative visit
- ≠ no pre-operative ocular pathology
- ≠ no macular degeneration detected at any time
- ≠ no previous surgery for the correction of refractive errors

The Rotation Analysis Set (RAS) will include all eyes with successful test article implantation from a sub-set of approximately 6 clinical sites that examine subjects for rotational stability.

Safety Analysis Set will include all eyes with attempted implantation with the test article (successful or aborted after contact with the eye) and will be used for the safety analyses.

15.3 Demographics and Baseline Characteristics

Summary statistics will be provided for demographic and baseline characteristics. Number and percentage will be presented for categorical variables and descriptive statistics including mean, standard deviation, minimum, and maximum will be presented for continuous variables.

15.4 Performance Analyses

15.4.1 Primary Performance

The primary effectiveness endpoint is monocular BCDVA. The number and percentage of subjects with BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) will be summarized along with the corresponding one-sided exact 95% upper confidence limit.

The performance targets in support of the primary effectiveness objective is to show that the one-sided exact 95% upper confidence limit for percentage of subjects with monocular BCDVA of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than or equal to the SPE rates of 92.5% for the AAS and 96.7% for the BAS. A successful outcome on the co-primary effectiveness endpoints is indicated by successful outcomes on both of these endpoints.

15.4.1.1 Statistical Hypotheses

Not applicable.

15.4.1.2 Analysis Methods

Categorical statistics (sample size, number in the category, percent in the category, ~~and~~ the corresponding one-sided exact 95% upper confidence limit and two-sided exact 95% confidence interval) will be provided for the primary endpoint. In addition, descriptive statistics (sample size, mean, median, standard deviation, number of subjects/eyes, minimum, maximum, and the two-sided 95% confidence interval) will be provided for BCDVA. In addition, the following subgroup analyses will be performed on BCDVA at 12 months postoperative (Visit 5):

- BCDVA by age (< 65 years vs. ≥ 65 years)
- BCDVA by investigative site
- BCDVA by adverse event (study eyes with ocular adverse events vs. study eyes without ocular adverse events)
- BCDVA by preoperative ocular pathology (study eyes with preoperative ocular pathology vs. study eyes without preoperative ocular pathology)

A listing of BCDVA at every visit for each study eye will also be provided.

Subject narratives will be provided for the following:

- Subject-by-subject analysis of reasons why subject failed to achieve 0.3 logMAR BCDVA;
- Frequency of, and the cause of loss of 10 letters or more on an ETDRS chart (or equivalent) compared to best post-op BCDVA.

15.4.2 Secondary Performance

The performance target in support of the secondary effectiveness objective is to show that IOL rotation at 6 months postoperative (Visit 4) is,

- ≠ less than 10° in 90 % of eyes in the RAS
- ≠ less than 20° in 95 % of eyes in the RAS
- ≠ less than 30° in 99 % of eyes in the RAS

In order to summarize IOL rotation, IOL misplacement and IOL misalignment, sample size, number, percent and cumulative percent for the following categories will be provided: (< 10, < 20, and < 30 degrees, respectively). Additional tables using the following categories will also be provided: (0-5, > 5-10, > 10-15, > 15-20, > 20-30, and > 30 degrees, respectively).

Difference in IOL axis of orientation (in degrees) will be presented for Visit 00 (Operative Visit) to Visit 3 (30-45 days postoperative), Visit 00 (Operative Visit) to Visit 4 (120-180 days postoperative) and Visit 3 (30-45 days postoperative) to Visit 4 (120-180 days postoperative).

15.4.2.1 Statistical Hypotheses

Not applicable. Only descriptive statistics will be presented.

15.4.2.2 Analysis Methods

Categorical statistics will be provided for the secondary endpoint. In addition, descriptive statistics (sample size, mean, median, standard deviation, number of subjects/eyes, minimum and maximum) will be provided for the secondary endpoint.

15.4.3.1 Statistical Hypotheses and Model

Not applicable. Only descriptive statistics will be presented.

15.4.3.2 Analysis Methods

For categorical parameters, the statistics used to summarize the data descriptively include sample size, number in the category, and percent in the category. For continuous parameters, the statistics used to summarize the data descriptively include sample size, mean, median, standard deviation, number of subjects/eyes minimum, and maximum.

15.5 Handling of Missing Data

The AAS and BAS do not include any imputed values. Although missing data will occur, the influence of the missing data is expected to be minimal.

15.6 Multiplicity

Not applicable.

15.7 Safety Analysis

The primary safety objective is to estimate the rate of adverse events (ocular and nonocular, serious and non-serious) including SSIs for study eyes at 12 months postoperative (Visit 5).

Adverse Events

Descriptive statistics for adverse events (including SSIs) will be presented for study eyes. The rates of all adverse events will be provided with counts and percentages, and these rates will be accompanied by two-sided exact 95% confidence intervals. The one-sided exact 95% lower confidence limit for incidence rates observed for study eyes will be compared to the cumulative and persistent adverse event SPE rates that include SSIs (as reported in EN ISO 11979-7:2014). An eye with multiple ocular adverse events of the same preferred term is only counted once toward the total of this preferred term. The frequency of adverse events, separately for cumulative and persistent, will be presented overall, stratified by age (< 65 years vs. ≥ 65 years), and by investigative site.

All information obtained on adverse events will be displayed by subject.

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15.8 Interim Analyses

Interim reports pertaining to the progress of this study will be submitted to the US FDA for review annually until study completion.

15.9 Adaptive Study Design

Not applicable.

15.10 Sample Size Justification

With a sample size of 300 evaluable eyes, the probability to demonstrate that at least 270 (90%) of evaluable eyes implanted with the Clareon IOL having monocular best corrected distance visual acuity (BCDVA) of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than 99%, assuming the mean BCDVA is 0.0 logMAR (SD = 0.18 for All-Implanted Analysis Set).

Similarly, with a sample size of 300 evaluable eyes, the probability to demonstrate that at least 285 (95%) of evaluable eyes implanted with the Clareon IOL having monocular best corrected distance visual acuity (BCDVA) of 0.3 logMAR or better at 12 months postoperative (Visit 5) is greater than 97%, assuming the mean BCDVA is 0.0 logMAR (SD = 0.16 for Best-Case Analysis Set).

For any event where zero incidence is observed in 300 eyes with Clareon IOL, the one-sided exact 95% upper confidence is less than 1%. Thus, with 95% confidence, the true adverse event rate is less than 1%.

Approximately 350 subjects will be unilaterally implanted with the Clareon IOL in order to ensure that at least 300 evaluable subjects complete the study. Sites are expected to enroll subjects that have a likelihood of completing the study in order to ensure implanted subjects

are followed for the duration of the trial and that a minimum of 300 subjects are seen for each reporting period.

16 ADMINISTRATIVE PROCEDURES

16.1 Regulatory and Ethical Compliance

This clinical trial will be conducted in accordance with the ethical principles contained within the following:

- ≠ The Declaration of Helsinki (DoH), and in compliance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 GCP Consolidated Guideline
- ≠ ISO 14155:2011 Clinical investigation of medical devices for human subjects, Good Clinical Practice
- ≠ Code of Federal Regulations (CFR)
- ≠ Standard Operating Procedures of Alcon and Contract Research Organizations participating in the conduct of the clinical trial, and all other applicable regulations.

The Investigator and all clinical trial staff will conduct the clinical trial in compliance with this protocol. The Investigator will ensure that all personnel involved in the conduct of the clinical trial are qualified to perform their assigned duties through relevant education, training, and experience.

16.2 Informed Consent Procedures

Voluntary informed consent must be obtained from every subject prior to the initiation of any screening or other clinical trial-related procedures. The Investigator must have a defined process for obtaining consent. Specifically, the Investigator, or designee, will explain the clinical trial to each potential subject and the subject must indicate voluntary consent by signing and dating the approved informed consent form. The subject must be provided an opportunity to ask questions of the Investigator, and if required by local regulation, other qualified personnel. The Investigator must provide the subject with a copy of the consent form written in a language the subject understands. The consent document must meet all applicable local laws and will provide subjects with information regarding the purpose, procedures, requirements, and restrictions of the clinical trial, along with any known risks and potential benefits associated with the investigational product, the available compensation, and the established provisions for maintaining confidentiality of personal, protected health information. Subjects will be told about the voluntary nature of participation in the clinical trial and will be provided with contact information for the appropriate individuals, should questions or concerns arise during the clinical trial. The subject also will be told that their records may be accessed by appropriate authorities and Sponsor-designated personnel. The

Investigator must keep the original, signed copy of the consent, must provide a duplicate copy to each subject, and will record compliance with the informed consent process in subjects' source records.

Amendments may necessitate that the informed consent and other study-related material be revised. If the consent form is revised, all subjects currently enrolled in the study must sign the approved, revised informed consent, as required by the IRB/IEC.

16.3 Responsibilities of the Investigator and IRB/IEC

Before clinical trial initiation, this protocol, the informed consent form, any other written information provided to a subject, and any advertisements planned for subject recruitment must be approved by an IRB. A master list of IRBs for this clinical trial can be found in the Trial Master File. The Investigator must provide documentation of IRB approval to the Sponsor. The approval must be dated and must identify the applicable protocol, amendments (if any), informed consent form, all applicable recruiting materials (if any), written information for subjects (if any), and subject compensation programs. The IRB must be provided with a copy of the Investigator's Brochure, any periodic safety updates, and all other information, as required by local regulation and/or the IRB. At the end of the clinical trial or in the case of early termination, the Investigator will notify the IRB of the clinical trial's final status. The end of the study is defined as database lock. In case the study is ended prematurely, the Investigator will notify the IRB the reasons for the premature termination. Finally, the Investigator will report to the IRB on the progress of the clinical trial at intervals stipulated by the IRB.

16.4 Sponsor and Monitoring Responsibilities

The Sponsor will designate a monitor to conduct the appropriate site visits at the appropriate intervals. The clinical investigation will be monitored, following the Protocol Monitoring Plan, to ensure that: the rights and well-being of the subjects are protected; the reported data are accurate, complete, and verifiable from the source documents; the equipment used to assess variables in the clinical investigation is maintained and calibrated per manufacturer instructions and Sponsor requirements; the study is conducted in compliance with the current approved protocol (and amendment[s], if applicable), with current GCP, and with applicable regulatory requirements.

All investigative sites will have a site initiation. Monitoring will be conducted periodically while the clinical study is ongoing. Monitoring methods may include site visits, telephone, written and fax correspondence. The assigned CSM will contact each site at appropriate

intervals. The Lead CSM (LCSM) will determine the frequency of site visits. Closeout visits will take place after the last visit of the last subject.

16.5 Regulatory Documentation and Records Retention

Essential documents must be retained by the Investigator in compliance with the US FDA CFR as well as other applicable national regulations. The Investigator(s)/institution(s) must comply with record retention stipulations outlined in the Clinical Study Agreement. Additionally, the Investigator will be supplied with further instruction at study completion.

Additionally, the Investigator must keep study records and source documents until the Study Sponsor provides written approval for their destruction. If the Investigator retires, relocates, or for any other reason withdraws from responsibility of keeping the study records, then the Study Sponsor must be notified and suitable arrangements made for retention of study records and source documents needed to comply with national and international regulations (generally 2 years after discontinuing clinical development or after the last marketing approval). *Note: FDA is notified of transfer of records.*

16.6 Publication of the Clinical Trial

Any information other than that which is disclosed upon registration should not be discussed with persons outside the study. The protocol, study data, and information related to the study or to Alcon's products or research programs that is provided by Alcon (Confidential Information) is to be kept confidential, and not disclosed directly or indirectly to any third party other than those involved in the study who has a need to know.

All data and discoveries arising out of the study, patentable or non-patentable, shall be the sole property of Alcon, Inc. Alcon reserves the right of prior review of any publication or presentation of information related to the study. Alcon may use these data now and in the future for presentation or publication at Alcon's discretion or for submission to government regulatory agencies.

The existence of this clinical study is confidential and should not be discussed with persons outside of the study. You shall hold confidential, and not disclose directly or indirectly to any third party other than those persons involved in the study who have a need to know, the protocol, the data arising out of the study, and any other information related to the study or to Alcon's products or a research program that is provided by Alcon to you (the "Confidential Information"). All such persons must be instructed not to further disseminate this information to others. You shall not use the Confidential Information for any purpose other than the study.

The foregoing obligations of confidence and non-use assumed by you shall not apply to: (a) information which at the time of disclosure is in the public domain; (b) information which thereafter lawfully becomes part of the public domain other than through disclosure by or through you; (c) information which, as evidenced by your written records, was known by you prior to Alcon's disclosure; (d) information which is lawfully disclosed to you by a third party not under any obligation of confidence to Alcon; or (e) information which is required to be disclosed by law or government regulatory agency, provided reasonable advance notice of such disclosure is given to Alcon.

The Study Sponsor assures that the key design elements of this protocol will be registered in www.clinicaltrials.gov as required by current regulations and, if applicable, other public databases as required by local country regulations. In addition, results of this study will be made publicly available in www.clinicaltrials.gov regardless of outcome as required by current regulations and, if applicable, in other public databases as required by local country regulations.

17 REFERENCES

EN ISO 11979-7:2014 Ophthalmic implants – Intraocular lenses – Part 7: Clinical Investigations

Isotani H, Fukumoto Y, Kitaoka H, Furukawa K, Ohsawa N, Utsumi T. Oval pupil in patients with diabetes mellitus: examination by measurement of the dark-adapted pupillary area and pupillary light reflex. Diabetes Res Clin Pract. 1995;29:43-8.

18 APPENDICES

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