
**Ophthalmic implants — Intraocular
lenses —**

**Part 10:
Clinical investigations of intraocular
lenses for correction of ametropia in
phakic eyes**

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Implants ophtalmiques — Lentilles intraoculaires —

*Partie 10: Investigations cliniques de lentilles intraoculaires pour la
correction de l'amétropie des yeux phaques*

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html. (standards.iteh.ai)

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This second edition cancels and replaces the first edition (ISO 11979-10:2006) and its amendment (ISO 11979-10:2006/Amd 1:2014), which has been technically revised.

The main changes compared to the previous edition are as follows.

- modified the scope to include phakic multifocal and phakic toric intraocular lenses;
- added references to the requirements in ISO 11979-6, ISO 11979-7, and ISO 11979-8;
- modified the clinical requirements to include those for phakic multifocal and phakic toric intraocular lenses; and
- modified the informative [Annex A](#) to include elements associated with the clinical investigation of phakic multifocal and phakic toric intraocular lenses.

A list of all parts in the ISO 11979 series can be found on the ISO website.

Introduction

Phakic intraocular lenses are used to correct refractive errors in patients with a non-cataractous crystalline lens. They are typically used for patients with higher amounts of myopia or hyperopia. Originally, they contained a spherical monofocal optic to correct spherical errors but later variations utilized a toric optic to also correct refractive astigmatism. Phakic intraocular lenses with a multifocal optic can be used to correct presbyopia in patients that have lost the ability to accommodate.

The requirements and recommendations in the ISO series of standards for aphakic intraocular lenses for the most part also apply to phakic intraocular lenses. Those standards should be reviewed for guidance that would also be applicable to phakic intraocular lenses (e.g. shelf-life testing, biocompatibility testing, etc.).

This document provides requirements and recommendations for phakic intraocular lens investigations of new models. Risk analysis should be used to determine the investigational design, if needed, for models that are modifications of parent phakic models. For modifications of a parent phakic model refer to ISO/TR 22979.

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Ophthalmic implants — Intraocular lenses —

Part 10:

Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes

1 Scope

This document specifies requirements for any intraocular lenses to be implanted in the anterior segment of the eye with the primary indication to modify its refractive power.

There are three main categories of phakic intraocular lenses depending on the optical design:

- a) Phakic monofocal (PIOL);
- b) Phakic multifocal (PMIOL); and
- c) Phakic toric (PTIOL).

Each of these categories is further designated for implantation in either the anterior or posterior chamber of the anterior segment of the eye.

The basic phakic IOL requirements apply to all the types. Additional requirements apply to PMIOL and PTIOL designs.

This document addresses specific clinical requirements for phakic IOLs that are not addressed in the other parts of ISO 11979.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing*

ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of lenses for the correction of aphakia*

ISO 11979-8, *Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 11979-1 and ISO 14155 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.2 Abbreviated terms

UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
CDVA	corrected distance visual acuity
CIVA	corrected intermediate visual acuity
CNVA	corrected near visual acuity
DCIVA	distance corrected intermediate visual acuity
DCNVA	distance corrected near visual acuity

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4 Optical requirements

The applicable requirements of ISO 11979-2 shall apply.

5 Mechanical requirements

The applicable requirements of ISO 11979-3 shall apply.

6 Biocompatibility requirements

The applicable requirements of ISO 11979-5 shall apply.

7 Shelf-life and transport stability requirements

The requirements of ISO 11979-6 shall apply.

8 Fundamental requirements

The requirements of ISO 11979-8 shall apply.

9 Justification for a clinical investigation

A risk analysis shall be implemented in accordance with ISO 14971. If the risk analysis identifies the need for a clinical investigation, the requirements of ISO 14155 shall apply, with additional requirements given in this document.

If a new phakic IOL model is a modification of a parent phakic IOL for which the safety and performance have already been established through clinical investigation in accordance with this document, then a limited or no additional clinical investigation can suffice. ISO/TR 22979^[4] provides guidance in determining the need for a clinical investigation.

10 General clinical requirements

10.1 General

The requirements for a clinical investigation given in ISO 14155 shall apply, with additional requirements given below.

10.2 Design of a clinical investigation

10.2.1 Requirements for all types of phakic IOLs

A non-controlled clinical investigation shall be designed to investigate the safety and performance of PIOL designs, and PTIOL designs of higher cylinder power.

A controlled clinical investigation shall be designed to investigate the safety and performance of PMIOL designs, and PTIOL designs of lower cylinder power (i.e. cylinder powers of 1,5 D or less).

The primary safety endpoint for all phakic IOL investigations is endothelial cell density.

NOTE In the case of the non-controlled clinical investigations, data describing changes in endothelial cell density over time for levels of ametropia similar to the levels for the subjects in the investigation from either literature or from a sub-study of non-operated eyes will be useful in assessing the significance of the endothelial cell density changes in the study subjects.

10.2.2 Additional requirements for PTIOLs

During the clinical investigation of a PTIOL, the rotational stability shall be demonstrated.

The following performance criteria for rotational stability shall be fulfilled:

The IOL rotation is defined as the difference in postoperative orientation of the meridian defined by the IOL axis indicator between that intended on the day of surgery and that measured at the final reporting period for the investigation. Absolute rotation shall be less than 10° in 90 % of the cases, and less than 20° in 95 % of the cases.

The clinical performance of low cylinder power PTIOLs shall be demonstrated compared to the non-toric control PIOL.

In such a clinical investigation, subjects that undergo secondary surgery to correct postoperative phakic IOL rotational misalignment shall have their clinical results prior to the secondary surgery carried forward as the final results for that subject, and examinations scheduled to be performed later in the clinical investigation be performed prior to the secondary surgery, if possible.

The TIOL clinical design provisions in ISO 11979-7 shall be used to determine the additional evaluations needed to be incorporated into the general phakic clinical investigational design described in Annex A to evaluate the performance of the PTIOL design.

10.2.3 Additional requirements for PMIOLs

For PMIOL designs, a clinical investigation shall evaluate the safety and performance of vision at far distance and near distances, and at any intended intermediate focal distances. The MIOL clinical design recommendations in ISO 11979-7 shall be used to determine the additional evaluations needed to be incorporated into the general phakic IOL clinical investigation design described in [Annex A](#) to evaluate the visual performance of the PMIOL design.

In all cases, the clinical investigation plan shall include defocus evaluation.

10.3 Characteristics

10.3.1 General

The clinical investigational plan shall provide information regarding characteristics to be studied, and instructions regarding the grading and documentation of these characteristics. Whenever possible, objective methods, such as photographic imaging, shall be used.

The following characteristics shall be considered. If additional claims are to be made, additional corresponding characteristics shall be studied.

If several types of phakic IOLs are combined, the characteristics of all of them shall be considered.

10.3.2 Characteristics applying to the clinical evaluations for all types of phakic IOLs

- a) UDVA;
- b) CDVA;
- c) subjective refraction;
- d) contrast sensitivity;
- e) pupil size;
- f) intraocular pressure;
- g) corneal status, including endothelial cell density status;
- i) signs of inflammation:
 - anterior chamber cells;
 - anterior chamber flare;
 - cystoid macular oedema;
 - hypopyon;
 - endophthalmitis;
- j) pupillary block;
- k) retinal detachment;
- l) status of anterior and posterior capsule;
- m) status of the crystalline lens;
- n) status of anterior chamber angle;
- o) status of iris;

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- p) anterior chamber depth;
- q) IOL decentration;
- r) IOL tilt;
- s) IOL discoloration; and
- t) IOL opacity.

If justified by the risk analysis, cycloplegic refraction shall be considered for all phakic IOL investigations.

10.3.3 Additional characteristics applying to PTIOLs

- a) keratometry; and
- b) IOL axis mark rotation.

10.3.4 Additional characteristics applying to PMIOLs

- a) UNVA, and if applicable UIVA;
- b) DCNVA, and if applicable DCIVA;
- c) subject questionnaire;
- d) defocus evaluation; and
- e) fundus visualization.

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10.4 Duration of the investigation ISO 11979-10:2018

The minimum duration of the clinical investigations shall be 3 years (see [Annex A](#) for visit window tolerances) for all parent phakic IOLs which are not modifications of a model for which safety and performance data have been established through clinical investigation.

When a phakic IOL is a modification of a parent phakic IOL, ISO/TR 22979 is used as guidance to determine the need for a clinical investigation.

All subjects in a clinical investigation that have not been discontinued shall complete all visits of the investigation. The clinical investigation shall be considered completed when all subjects that have been enrolled in the investigation, including subjects whose phakic IOL was removed or replaced, have either completed follow-up according to the protocol or have past the final visit window.

10.5 Enrolment

To minimize the risks associated with the clinical investigation of a new phakic IOL, subject enrolment shall occur in stages. The subject data from each stage shall be evaluated and found acceptable by the sponsor and the coordinating investigator (and by the regulatory body, where applicable) prior to the continuation of the clinical investigation. Guidance on phased enrolment is included in [Annex A](#).

10.6 Bilateral implantation

Any plans for fellow eye implantation shall be described in the clinical investigation plan. Bilateral implantation shall not be implemented until initial safety and performance data have been collected, evaluated and confirmed by the sponsor and coordinating investigator (and by risk analysis, if applicable).

When implantation of fellow eyes is permitted, the clinical investigation plan shall specify the time period between implantation of first eye and fellow eye, based upon risk analysis.