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Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2014)

Ophthalmische Implantate – Intraokularlinsen - Teil 7: Klinische Prüfungen (ISO 11979-7:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques (ISO 11979-7:2014)

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English Version

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations (ISO 11979-7:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7:
Investigations cliniques (ISO 11979-7:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 7:
Klinische Prüfungen (ISO 11979-7:2014)

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Foreword

This document (EN ISO 11979-7:2014) has been prepared by Technical Committee ISO/TC 172 “Optics and photonics” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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Part 7: Clinical investigations

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Partie 7: Investigations cliniques
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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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the third edition (ISO 11979-7:2006), which has been technically revised. It also incorporates the Amendment ISO 11979-7:2006/Amd 1:2012.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

- Part 1: Vocabulary
- Part 2: Optical properties and test methods
- Part 3: Mechanical properties and test methods
- Part 4: Labelling and information
- Part 5: Biocompatibility
- Part 6: Shelf-life and transport stability testing
- Part 7: Clinical investigations
- Part 8: Fundamental requirements
- Part 9: Multifocal intraocular lenses
- Part 10: Phakic intraocular lenses

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations

1 Scope

This part of ISO 11979 specifies particular requirements for clinical investigations for posterior and anterior chamber intraocular lenses (IOLs).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

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 and definitions

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

4 Justification for a clinical investigation

If the need for a clinical investigation is identified, the requirements of ISO 14155 shall apply, with additional requirements given below.

If a new IOL model is a modification of a model for which the safety and performance have been established through clinical investigation in accordance with this part of ISO 11979 no or limited clinical investigation is needed. ISO/TR 22979^[1] provides guidance in determining whether or not a modification is minor.

5 Ethical considerations

For clinical investigations of medical devices for human subjects, the requirements in ISO 14155 shall apply.

6 General requirements

6.1 General

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

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6.2 Design

6.2.1 General

A clinical investigation shall be designed to compare results to historical data on adverse events and visual acuity rates. [Annex A](#) provides general guidance for the design of a clinical investigation. Historical data can be found in [Annex B](#).

6.2.2 Additional requirements for toric IOLs

For all toric IOLs, the rotational stability of a non-toric version that is mechanically and geometrically equivalent to the toric IOL shall be demonstrated.

The following performance criteria for rotational stability shall be fulfilled: the rotation of the meridian defined by the IOL axis indicator as measured and compared between Day 0 (the day of surgery) post-operative examination and the form 4 examination shall be less than 10° in 90 % of the cases, less than 20° in 95 % of the cases, and less than 30° in 99 % of the cases.

Then, if necessary due to risk analysis, a clinical investigation shall be performed using the toric version of the model.

In the event that a toric IOL clinical investigation is required due to risk analysis, the subjects that undergo secondary surgery to correct IOL axis mark rotation shall have their clinical results prior to the secondary surgery carried forward as the final results for that subject. In the case of examinations scheduled to be performed later in the clinical investigation, the sponsor shall consider requiring each of these examinations to be performed prior to the secondary surgery, if possible.

Additional elements for toric IOLs are outlined in [Annex C](#).

6.2.3 Additional requirements for accommodating IOLs

A controlled clinical investigation of an accommodating IOL shall evaluate the additional safety and performance concerns, specifically including the evaluation of accommodative amplitude using at least one objective method. Guidance on clinical investigation of accommodating IOLs is outlined in [Annex D](#). It shall consist of two phases, with phase two beginning only after the first phase has demonstrated that the accommodating IOL provides an average of at least 1 D of objective accommodation. The overall study shall demonstrate that the accommodating IOL also provides 1 D of objective accommodation at the point of stabilization.

6.3 Characteristics

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 shall be used, such as photographic imaging.

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

6.3.1 General characteristics

- a) best spectacle corrected visual acuity (BSCVA);
- b) subjective refraction;
- c) intraocular pressure;
- d) corneal status;

- e) signs of inflammation:
 - 1) anterior chamber cells;
 - 2) anterior chamber flare;
 - 3) cystoid macular oedema;
 - 4) hypopyon;
 - 5) endophthalmitis;
- f) pupillary block;
- g) retinal detachment;
- h) status of anterior and posterior capsule;
- i) IOL decentration;^[2]
- j) IOL tilt;^[2]
- k) IOL discoloration;
- l) IOL opacity.

6.3.2 Toric IOL characteristics

- a) uncorrected visual acuity;
- b) keratometry;
- c) IOL mark axis rotation.

6.3.3 Accommodating IOL characteristics

- a) uncorrected visual acuity at distance, intermediate and near;
- b) visual acuity at near and intermediate with best distance correction;
- c) best corrected near visual acuity;
- d) additional refraction (over best distance subjective correction) required to achieve best corrected near acuity;
- e) objective accommodative amplitude;
- f) contrast sensitivity;
- g) subject questionnaire;
- h) pupil size.

6.3.4 Additional characteristics

If justified by the risk analysis, these additional characteristics shall be considered.

- a) cycloplegic refraction;
- b) specular microscopy;
- c) gonioscopic examination;
- d) pupil size;

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e) anterior chamber depth measurement.

6.4 Investigation duration

The minimum duration of the clinical investigations shall be one year (see [Annex A](#) for visit window tolerance) for aphakic posterior chamber IOLs which are not modifications of a model for which safety and performance data have been established through clinical investigation.

The minimum duration of the clinical investigations shall be three years (see [Annex A](#) for visit window tolerance) for aphakic anterior chamber IOLs which are not modifications of a model for which safety and performance data have been established through clinical investigation.

For all toric IOLs, a six-month study of the non-toric version of the IOL shall be performed to ensure rotational stability. Then for toric IOLs that are a modification of an IOL that has met the requirements of all parts of ISO 11979, risk analysis may require that this rotational stability study is followed by a clinical investigation of the actual toric IOL for six months. Toric IOLs that are not a modification of an IOL that has met the requirements of all parts of ISO 11979 shall require a full clinical investigation of one year duration.

The minimum study duration for accommodating IOLs through clinical investigation shall be one year but may require up to three years based on the risk analysis.

Consult ISO/TR 22979[1] for guidance on investigation duration for modifications of lens models for which safety and performance have been established through 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 IOL was removed or replaced, have reached the final reporting period.

6.5 Enrollment

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To minimize the risks associated with the clinical investigation of a new IOL, subject enrollment 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, if applicable) prior to the continuation of the clinical investigation. Guidance on phased enrollment is included in [Annex A](#) (monofocal IOL), [Annex C](#) (toric IOL) and [Annex D](#) (accommodating IOL).

Risk analysis should be used to determine if an earlier phase than the phase 1 listed in the Annexes above is needed to address safety issues associated with the IOL design.

6.6 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 the risk analysis, if applicable). Only the first eye of each subject shall be included in the primary statistical analysis.

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

NOTE The review of data from at least 50 eyes with six months of follow-up is recommended prior to fellow eye implantation. Risk analysis might allow an earlier implantation in fellow eyes if sufficiently justified by previous clinical experience.

6.7 Surgical technique

The clinical investigation plan shall contain descriptions of the surgical technique, the intraoperative use of ophthalmic viscosurgical devices, and the use of preoperative, intraoperative and postoperative medications. Any deviation shall be recorded on the case report forms.

For toric IOLs, the clinical investigation plan shall specify the type and location of the incision. The estimated effect of the incision on the corneal astigmatism shall be used in the protocol for choosing the appropriate cylindrical power.

6.8 Examination and treatment of subjects

The reporting periods are described in [Annex A](#).

The clinical investigation plan shall describe how subject visits and ophthalmic adverse events that occur between standard reporting periods will be handled in the data analyses.

6.9 Adverse events reports

Serious adverse events and all adverse device effects shall be reported using a special case report form and forwarded to the sponsor as required. All other ophthalmic adverse events shall be reported using either the standard visit case report form or specific adverse event forms and be collected during monitoring. Non-ophthalmic events that are non-serious are not required to be reported.

6.10 Inclusion and exclusion criteria

6.10.1 General

The following inclusion/exclusion criteria shall be considered. Additional criteria shall be included depending on the risk analysis for the particular IOL model.

6.10.1.1 Inclusion criteria

- a) adult;
- b) cataract (does not apply for phakic IOL);
- c) best corrected visual acuity projected to be 0,2 logMAR or lower;
- d) calculated IOL power is within the range of the investigational IOL;
- e) signed informed consent form.

6.10.1.2 Exclusion criteria

- a) previous intraocular and corneal surgery;
- b) traumatic cataract;
- c) pregnancy and lactation;
- d) concurrent participation in another drug or device investigation.

6.10.2 Additional criteria for toric IOL

6.10.2.1 Inclusion criteria

- a) corneal cylindrical error within the range defined in the clinical investigation plan (CIP);
- b) stability of the cornea has been demonstrated by keratometry;
- c) expected dilated pupil size at least large enough to visualize the axis markings.

6.10.2.1.1 Additional inclusion criteria for phakic toric IOLs