INTERNATIONAL STANDARD

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Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

Implants ophtalmiques — Lentilles intraoculaires —
Partie 10: Lentilles intraoculaires 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11979-10 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Ophthalmic implants — Intraocular lenses —

Part 10:
Phakic intraocular lenses

1 Scope

This part of ISO 11979 is applicable to any intraocular lens (IOL) whose primary indication is the modification of the refractive power of a phakic eye, but excludes phakic IOLs (PIOLs) that utilize multifocal or other simultaneous vision optics to address presbyopic loss of accommodation and PIOLs that correct astigmatism.

This part of ISO 11979 addresses specific requirements for PIOLs not addressed in the other parts of ISO 11979.

2 Normative references

The following referenced documents are indispensable for the application 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 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1, ISO 14155-1 and ISO 14155-2 apply.

4 Optical requirements

4.1 General

This clause applies to the optical properties and performance requirements of PIOLs in their final form, as intended for implantation in the human eye.

4.2 Dioptric power

The requirements of ISO 11979-2 apply.

4.3 Imaging quality

The requirements of ISO 11979-2 apply.

NOTE A modified bench (e.g. additional converging lens, a microscope objective of appropriate numerical aperture, etc.) can be needed to quantify the image quality of negative power PIOLs.

4.4 Spectral transmittance

The requirements of ISO 11979-2 apply.

5 Mechanical requirements

Where applicable to the PIOL design, the mechanical requirements given in ISO 11979-3 apply. Furthermore, an analysis of the location of the PIOL surfaces with respect to ocular tissue shall be conducted to establish the minimal anatomical dimensions acceptable for the design and the range of dioptric powers for which it applies.

NOTE Guidance for performing this analysis is provided in ISO 11979-3.

6 Clinical investigation

6.1 General

The general requirements for a clinical investigation given in ISO 14155-1 and the clinical investigation plan requirements in ISO 14155-2 apply. Additional requirements are given in 6.2 and in 6.3.

NOTE Annex A of this part of ISO 11979 contains suggested details concerning a clinical investigation.

6.2 Clinical assessments

The following assessments shall be considered for the clinical investigation plan:

a) visual acuity (VA);

b) refraction;

c) contrast sensitivity;

d) intraocular pressure;

e) corneal status;

f) iritis;

g) IOL decentration;

h) IOL tilt;

i) IOL discoloration;

j) IOL opacity;

k) cystoid macular edema;

l) hypopyon;

m) endophthalmitis;

n) pupillary block;

o) retinal detachment;

p) status of crystalline lens;

q) status of anterior chamber angle;

r) status of iris;

s) pupil size;

t) corneal thickness.

6.3 Other considerations

To minimize the risks associated with the clinical investigation of a new PIOL, subject enrollment shall occur in stages. The subject data from each stage shall be evaluated and found acceptable by the sponsor and the principal investigator prior to the continuation of the clinical investigation. Guidance on phased enrollment is included in Annex A.

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 and evaluated by the sponsor and the principal investigator.

The review of data from at least 50 eyes with six months of follow-up is recommended. Previous clinical experience, i.e. results from well-documented clinical investigations, could be adequate justification to begin bilateral implantation earlier in the study.

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 variations from these recommendations shall be recorded on the case report forms.

All subjects in a clinical investigation shall be monitored for the duration of the investigation. The clinical investigation shall be considered completed when all subjects that have been enrolled in the investigation, including subjects whose PIOL was removed or replaced, have reached the final reporting period.

Serious ophthalmic adverse events and all adverse device effects shall be reported using a special case report form and forwarded to the sponsor for investigation. A drop in best spectacle corrected visual acuity of two or more lines shall be considered a serious ophthalmic adverse event. All other ophthalmic adverse events shall be reported using the standard visit case report forms and are collected during monitoring.

If a specific calculation procedure is to be used to determine the appropriate power for implantation, the calculation procedure and its derivation shall also be included in the clinical investigation plan. Clinical data shall be evaluated at intervals during the investigation to refine the power calculation procedure, if necessary.

7 Information supplied by the manufacturer

The requirements of ISO 11979-4 apply, with the following additional information that shall be made available to the user:

a) a summary of the results of the clinical investigation, if any;

b) any recommendations for periodic evaluations after implantation, based on the risk analysis and/ or any clinical investigation performed;

c) any restrictions in the indications for use if necessitated by the anatomical clearance analysis and clinical evaluation.

The general requirements for information provided by the manufacturer with medical devices specified in EN 1041 [1] should be considered. Symbols can be used instead of text, where appropriate. When symbols are used, the requirements of ISO 15223 [2] and EN 980 [3] should be considered.

Annex A
(informative)

Clinical investigation

A.1 Objectives

The objectives of the clinical investigation are to determine the safety and performance of the PIOL.

A.2 Design

The type of clinical investigation recommended is a non-controlled study.

The clinical investigation plan should describe how subject visits in between reporting periods will be handled.

Each investigator should contribute a minimum of 20 subjects, but not more than 25 % of the subjects in the study.

A minimum study duration of three years is recommended to adequately evaluate the maintenance of endothelial cell density and the rate of cataract development. The clinical investigation plan should inform subjects and investigators that longer term follow-up could be necessary.

Guidance for accountability is provided in ISO 11979-7 [4].

A.2.1 Primary endpoint

The recommended primary endpoint is endothelial cell density.

The null hypothesis is that the true rate of decrease in endothelial cell density is less than or equal to the normal rate. The alternative hypothesis is that the true rate is greater than the normal rate. Sample size guidance using this endpoint is provided in Annex B.

A.2.2 Inclusion and exclusion criteria

A.2.2.1 Inclusion criteria

The following inclusion criteria for subjects should be considered:

a) subject meets specified refractive criteria (spherical and cylindrical components);

b) subject has specified minimum best spectacle corrected visual acuity (BSCVA) in each eye;

c) subject has uncorrected visual acuity (UCVA) 0,5 or worse;

d) subject has less than 0,75 D difference between cycloplegic and manifest refractions;

e) subject has had a stable refraction (± 0,5 D; ± 1,0 D for high refractive errors), as expressed by manifest refraction spherical equivalent (MRSE) for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history;

f) subject who is a current contact lens wearer, needs to demonstrate a stable refraction (± 0,5 D), expressed as MRSE, on two consecutive examination dates and stability of the refraction is determined by the following criteria:

   1) contact lenses were not worn for at least 2 weeks (rigid and toric contact lenses) or 3 days (soft contact lenses) prior to the first refraction,

   2) two refractions were performed at least 7 days apart;

g) subject, who is expected to have residual postoperative cylindrical refractive error of ⩾ 1 D, has been given the opportunity to experience his/her best spectacle vision with the anticipated correction.

A.2.2.2 Exclusion criteria

The following exclusion criteria for subjects should be considered:

a) subject has an acute or chronic disease or illness that would increase the operative risk or confound the outcome(s) of the study;

b) subject is taking systemic medications that can confound the outcome of the study or increase the risk to the subject;

c) subject has ocular condition that can predispose for future complications;

d) subject has had previous intraocular or corneal surgery;

e) subject with less than the minimum endothelial cell density (ECD) at time of enrollment as described by Table A.1;

f) subject with coefficient of variation of endothelial cell area ⩾ 0,45 (in both eyes);

g) subject is pregnant, plans to become pregnant, or is lactating during the course of the study, or has another condition associated with the fluctuation of hormones that could lead to refractive changes;

h) monocular subjects;

i) insufficient space for the intended implant;

j) subjects that are not adults.

Table A.1 — Recommended minimum ECD

Age at time of enrollment years	Minimum endothelial cell density cells/mm^2
21 to 25	2 800
26 to 30	2 650
31 to 35	2 400
36 to 45	2 200
⩾ 46	2 000

NOTE With the rate of endothelial cell density decrease unknown during the clinical investigation, minimum endothelial cell density values were selected for this table that are based on conservative assumptions in order to protect the subjects in the investigation. The recommended endothelial cell density (ECD) in this table represents the average minimum ECD necessary to leave 1 000 cells/mm^2 at 72 years of age assuming a 10 % surgical decrease and a yearly rate of decrease of 2 %.

A.2.3 Enrollment of subjects

A.2.3.1 For clinical studies of a single refractive indication, the following phased enrollment plans are recommended.

a) Phase I: 10 subjects, followed for 6 months.

b) Phase II: 100 additional subjects. A clinical evaluation of all available data is done when 50 subjects have been followed for 6 months and all 110 subjects have been enrolled. If the performance of the PIOL is acceptable, the sponsor can begin the last phase of the investigation.

c) Phase III: remainder of the subjects.

A.2.3.2 For clinical studies of more than one refractive indication ongoing simultaneously, the following phased enrollment plans are recommended.

a) Phase I: 20 subjects (10 of each indication), followed for 6 months.

b) Phase II: 150 additional subjects (no more than 100 per indication). A clinical evaluation of all available data is done when 50 subjects with one indication have been followed for 6 months. If the performance of the PIOL is acceptable, the sponsor can begin the last phase of the investigation for that indication.

c) Phase III: remainder of the subjects for each indication.

A.2.3.3 Depending on the design of the refractive implant, a different phase-in can be appropriate. The data from each stage is evaluated and found acceptable by the sponsor and the principal investigator prior to proceeding to the next stage.

NOTE Previous clinical experience, i.e. results from well-documented clinical investigations, can be used as a justification to support faster enrollment.

A.2.4 Examination schedule

The following reporting periods are recommended for postoperative examination (see Table A.2):

a) preoperative (Preop);

b) operative (Op);

c) Day 1 (1 day);

d) Week 1 (5 to 9 days);

e) Month 1 (3 to 5 weeks);

f) Month 3 (10 to 14 weeks);

g) Month 6 (21 to 26 weeks);

h) Month 12 (11 to 14 months);

i) Month 18 (17 to 21 months);

j) Month 24 (23 to 27 months);

k) Month 30 (29 to 33 months);

l) Month 36 (35 to 39 months).