SLOVENSKI STANDARD
SIST EN ISO 11979-10:2006

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Oļ esni vsadki (implantati) - Intraokularne leļ e - 10. del: Intraokularne leļ e èphakicç (ISO 11979-10:2006)

Ophthalmic implants - Intraocular lenses - Part 10: Phakic intraocular lenses (ISO 11979-10:2006)

Ophthalmische Implantate - Intraokularlinsen - Teil 10: Phake Intraokularlinsen (ISO 11979-10:2006)

Implants ophtalmiques - Lentilles intraoculaires - Partie 10: Lentilles intraoculaires phaques (ISO 11979-10:2006)

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This European Standard was approved by CEN on 7 August 2006.

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Foreword

This document (EN ISO 11979-10:2006) has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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of an identical text or by endorsement, at the latest by February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11979-10:2006 has been approved by CEN as EN ISO 11979-10:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 11979-10

First edition
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Ophthalmic implants — Intraocular lenses —

Part 10: Phakic intraocular lenses

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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.

