SLOVENSKI STANDARD
SIST EN ISO 11979-7:2018

01-julij-2018

Nadomešča:
SIST EN ISO 11979-7:2014
SIST EN ISO 11979-9:2006
SIST EN ISO 11979-9:2006/A1:2014

Očesni vsadki (implantati) - Intraokularne leče - 7. del: Klinične raziskave intraokularnih leč za korekcijo afakije (ISO 11979-7:2018)

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen von Intraokularlinsen für die Korrektion von Aphakie (ISO 11979-7:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques de lentilles intraoculaires pour la correction de l'aphakie (ISO 11979-7:2018)

Ta slovenski standard je istoveten z: **EN ISO 11979-7:2018**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11979-7:2018 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-7

May 2018

ICS 11.040.70

Supersedes EN ISO 11979-7:2014, EN ISO 11979-9:2006

English Version

Ophthalmic implants - Intraocular lenses - Part 7: Clinical investigations of intraocular lenses for the correction of aphakia (ISO 11979-7:2018)

Implants ophtalmiques - Lentilles intraoculaires - Partie 7: Investigations cliniques de lentilles intraoculaires pour la correction de l'aphakie (ISO 11979-7:2018)

Ophthalmische Implantate - Intraokularlinsen - Teil 7: Klinische Prüfungen von Intraokularlinsen für die Korrektion von Aphakie (ISO 11979-7:2018)

This European Standard was approved by CEN on 28 February 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword **3**

European foreword

This document (EN ISO 11979-7:2018) 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 November 2018, and conflicting national standards shall be withdrawn at the latest by November 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11979-7:2014 and EN ISO 11979-9:2006.

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

Endorsement notice

The text of ISO 11979-7:2018 has been approved by CEN as EN ISO 11979-7:2018 without any modification.

INTERNATIONAL STANDARD

ISO 11979-7

Fourth edition
2018-03

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations of intraocular lenses for the correction of aphakia

Implants ophtalmiques — Lentilles intraoculaires —

Partie 7: Investigations cliniques de lentilles intraoculaires pour la correction de l'aphakie

Reference number
ISO 11979-7:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword .... **iv**
Introduction .... **v**
1 Scope **1**
2 Normative references **1**
3 Terms, definitions and abbreviated terms **1**
3.1 Terms and definitions 1
3.2 Abbreviated terms 1
4 Justification for a clinical investigation **2**
5 Ethical considerations **2**
6 General requirements **2**
6.1 General 2
6.2 Design of a clinical investigation 2
6.2.1 Requirements for all types of IOLs 2
6.2.2 Additional requirements for toric IOLs (TIOLs) 3
6.2.3 Additional requirements for multifocal IOLs (MIOLs) 3
6.2.4 Additional requirements for accommodating IOLs (AIOLs) 3
6.2.5 Additional requirements for anterior chamber IOLs 3
6.3 Characteristics of clinical investigations 4
6.3.1 General 4
6.3.2 Characteristics to be studied for all types of IOLs 4
6.3.3 Additional characteristics to be studied for TIOLs 4
6.3.4 Additional characteristics to be studied for MIOLs 5
6.3.5 Additional characteristics to be studied for AIOLs 5
6.3.6 Additional characteristics applying to anterior chamber IOLs 5
6.3.7 Additional characteristics 5
6.4 Duration of the investigations 5
6.5 Enrolment 6
6.6 Bilateral implantation 6
6.7 Surgical technique 6
6.8 Examination and treatment of subjects 6
6.9 Adverse events reports 7
6.10 Inclusion and exclusion criteria 7
6.10.1 General 7
6.10.2 Additional inclusion criteria for TIOLs 7
6.10.3 Additional exclusion criteria for MIOLs 7
6.10.4 Additional exclusion criteria for anterior chamber IOLs 8
Annex A (informative) **General elements in the clinical investigation of IOLs** **9**
Annex B (informative) **Additional elements for the clinical investigation of TIOLs** **14**
Annex C (informative) **Additional elements for the clinical investigation of multifocal IOLs** **19**
Annex D (informative) **Additional elements in the clinical investigation of accommodating IOLs** **22**
Annex E (informative) **Evaluation of post-operative adverse events and visual acuity rates** **27**
Annex F (informative) **Clinical tests** **31**
Annex G (informative) **Statistical methods and sample size calculations** **37**
Bibliography **42**

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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

This fourth edition cancels and replaces the third edition (ISO 11979-7:2014). It also cancels and replaces the first edition of ISO 11979-9:2006 and its amendment ISO 11979-9:2006/Amd 1:2014.

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

— Integration of the multifocal intraocular lens document (ISO 11979-9:2006);

— Technical updates concerning the safety and efficacy of the intraocular lens subtypes monofocal, multifocal, toric and accommodating;

— Recommendations for the clinical investigations of novel lens models; and

— The separation of guidance for intraocular lenses used in cases of aphakia, and intraocular lens used for the correction of ametropia in phakic patients.

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

Introduction

Intraocular lenses (IOLs) are used to correct residual refractive errors in subjects who have aphakia. Such residual refractive errors typically include sphere and astigmatism, but can also include accommodation. Different designs of IOLs can be used to correct for specific refractive errors. In the case where an IOL is designed to provide more than one type of refractive correction, that IOL will have to satisfy each of the separate requirements of those correction designs.

This document provides requirements and recommendations for intraocular lens investigations of new IOL models. In the case where an IOL model is a modification of a parent IOL model, a risk analysis can be used in order to determine the appropriate level of testing.

Ophthalmic implants — Intraocular lenses —

Part 7: Clinical investigations of intraocular lenses for the correction of aphakia

1 Scope

This document specifies the particular requirements for the clinical investigations of intraocular lenses that are implanted in the eye in order to correct aphakia.

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 11979-10:2018, *Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes*

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

4 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 IOL model is a modification of a parent 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[1] provides guidance in determining the need for a clinical investigation.

5 Ethical considerations

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

6 General requirements

6.1 General

There are four main categories of intraocular lenses that are determined by optical design:

a) monofocal (IOL);

b) multifocal (MIOL);

c) toric (TIOL); and

d) accommodating (AIOL).

The same basic requirements apply to all of the IOL types. Additional requirements apply to MIOL, TIOL, and AIOL.

There is a further subdivision depending on anatomic placement of the IOL:

— posterior chamber; and

— anterior chamber.

Posterior chamber lenses are placed behind (posterior to) the iris. Anterior chamber lenses are placed in front of (anterior to) the iris. Additional requirements apply in the case of anterior chamber lenses.

6.2 Design of a clinical investigation

6.2.1 Requirements for all types of IOLs

A clinical investigation shall be designed to compare the rates of adverse events and visual acuities above defined thresholds of the model IOL to the results of historical data. Annex A provides general guidance for the design of a clinical investigation of IOLs. Historical data can be found in Annex E.

6.2.2 Additional requirements for toric IOLs (TIOLs)

Prior to any clinical investigation of a toric intraocular lens, the rotational stability of a mechanically and geometrically equivalent non-toric version of that IOL model 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 (Form 0) and that measured at Form 4 and subsequent Forms. (See A.3 for recommendations on reporting periods). The absolute value of the rotation shall be less than 10° in 90 % of the cases and less than 20° in 95 % of the cases.

Subsequently, if found necessary by risk analysis (e.g. to assess the clinical performance of low cylinder power TIOLs), a clinical investigation can be performed using the toric version of the model.

Subjects that undergo a secondary surgery to correct postoperative 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 later in the clinical investigation shall be performed prior to the secondary surgery, wherever possible. (See Annex D.)

Additional elements for investigations of TIOLs are outlined in Annex B.

6.2.3 Additional requirements for multifocal IOLs (MIOLs)

For multifocal designs with two or more intended foci, a clinical investigation shall evaluate the safety and performance of vision at far as well as any additional intended focal distances.

The clinical investigation plan shall include a defocus evaluation.

A phased enrolment as outlined in Annex C shall be considered.

Additional elements for MIOLs are outlined in Annex C.

6.2.4 Additional requirements for accommodating IOLs (AIOLs)

A controlled clinical investigation of an AIOL shall evaluate the accommodative amplitude and the additional safety and performance aspects related to the risk assessment. Annex D identifies safety and performance aspects for consideration. The clinical investigation plan shall include at least one objective method to measure accommodative amplitude.

The investigation enrolment shall consist of two phases (see Annex D). The second phase shall begin only if the first phase has demonstrated that the IOL design provides an average of at least 1,0 D of objective accommodation. In order for the design to be designated as an AIOL, the overall investigation shall demonstrate objective accommodation of 1,0 D or more at the point of accommodative stability (see Annex D).

Additional elements for AIOLs are outlined in Annex D.

6.2.5 Additional requirements for anterior chamber IOLs

A clinical investigation of an anterior chamber IOL shall evaluate the change in endothelial cell density, hexagonality and coefficient of variation of endothelial cell area, the clearance between the surfaces of the anterior chamber IOL and the posterior surface of the cornea and the iris, the anterior chamber angle (including observations of pigment and synechiae), and any additional safety and performance aspects related to the risk assessment.