SLOVENSKI STANDARD
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Očesni vsadki (implantati) - Intraokularne leče - 10. del: Klinične preiskave intraokularnih leč za popravek ametropije pri lečah »phakic« (ISO/DIS 11979-10:2017)

Ophthalmic implants - Intraocular lenses - Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes (ISO/DIS 11979-10:2017)

Ophthalmische Implantate - Intraokularlinsen - Teil 10: Klinische Prüfungen von Intraokularlinsen zur Korrektion der Ametrophie in phaken Augen (ISO/DIS 11979-10:2017)

Implants ophtalmiques - Lentilles intraoculaires - Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phaques (ISO/DIS 11979-10:2017)

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Ophthalmic implants — Intraocular lenses —

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

Implants ophtalmiques — Lentilles intraoculaires

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

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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 first edition (ISO 11979-10:2006) and its amendment ISO 11979-10/Amd 1:2014.

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.

Ophthalmic implants — Intraocular lenses —

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

1 Scope

This document specifies particular requirements for any intraocular lenses to be implanted in the anterior segment of the eye whose primary indication is the modification of the refractive power of the phakic eye.

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

a) Phakic monofocal (PIOL)

b) Phakic multifocal (PMIOL)

c) Phakic toric (PTIOL)

Each of these categories is further designated for implantation in either the anterior or posterior chamber 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 requirements for phakic IOLs 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*

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

For the purposes of this document the terms and definitions given in ISO 11979-1 and ISO 14155 and the following abbreviated terms 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 http://www.iso.org/obp

3.1 Uncorrected visual acuity

a) UDVA: uncorrected distance (far) visual acuity

b) UIVA: uncorrected intermediate visual acuity

c) UNVA: uncorrected near visual acuity

3.2 Corrected visual acuity

a) CDVA: corrected distance (far) visual acuity

b) CIVA: corrected intermediate visual acuity

c) CNVA: corrected near visual acuity

d) DCIVA: distance (far) corrected intermediate visual acuity

e) DCNVA: distance (far) corrected near visual acuity

4 Optical requirements

The applicable requirements of ISO 11979-2 apply.

5 Mechanical requirements

The applicable requirements of ISO 11979-3 apply.

6 Biocompatibility requirements

The applicable requirements of ISO 11979-5 apply.

7 Shelf-life and transport stability requirements

The requirements of ISO 11979-6 apply.

8 Fundamental requirements

The requirements of ISO 11979-8 apply.

9 Justification for a clinical investigation

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