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Second edition
2018-03

Ophthalmic implants — Intraocular lenses —

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

Implants ophtalmiques — Lentilles intraoculaires —

Partie 10: Investigations cliniques de lentilles intraoculaires pour la correction de l'amétropie des yeux phaques



Reference number
ISO 11979-10:2018(E)

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Published in Switzerland

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviated terms	2
3.1 Terms and definitions.....	2
3.2 Abbreviated terms.....	2
4 Optical requirements	2
5 Mechanical requirements	2
6 Biocompatibility requirements	2
7 Shelf-life and transport stability requirements	2
8 Fundamental requirements	2
9 Justification for a clinical investigation	3
10 General clinical requirements	3
10.1 General.....	3
10.2 Design of a clinical investigation.....	3
10.2.1 Requirements for all types of phakic IOLs.....	3
10.2.2 Additional requirements for PTIOLs.....	3
10.2.3 Additional requirements for PMIOLs.....	4
10.3 Characteristics.....	4
10.3.1 General.....	4
10.3.2 Characteristics applying to the clinical evaluations for all types of phakic IOLs.....	4
10.3.3 Additional characteristics applying to PTIOLs.....	5
10.3.4 Additional characteristics applying to PMIOLs.....	5
10.4 Duration of the investigation.....	5
10.5 Enrolment.....	5
10.6 Bilateral implantation.....	5
10.7 Surgical technique.....	6
10.8 Examination and treatment of subjects.....	6
10.9 Adverse events reports.....	6
10.10 Inclusion and exclusion criteria.....	6
10.10.1 General criteria for all phakic IOLs.....	6
10.10.2 Additional criteria for PTIOLs.....	9
10.10.3 Additional criteria for multifocal IOLs.....	9
11 Information supplied by the manufacturer	9
Annex A (informative) Elements in a phakic IOL clinical investigation	10
Annex B (informative) Statistical methods and sample size calculations	16
Bibliography	17

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).

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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 second edition cancels and replaces the first edition (ISO 11979-10:2006) and its amendment (ISO 11979-10:2006/Amd 1:2014), which has been technically revised.

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

- modified the scope to include phakic multifocal and phakic toric intraocular lenses;
- added references to the requirements in ISO 11979-6, ISO 11979-7, and ISO 11979-8;
- modified the clinical requirements to include those for phakic multifocal and phakic toric intraocular lenses; and
- modified the informative [Annex A](#) to include elements associated with the clinical investigation of phakic multifocal and phakic toric intraocular lenses.

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

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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. For modifications of a parent phakic model refer to ISO/TR 22979.