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
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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.
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.