

Australian Standard™

**Ophthalmic implants—Intraocular
lenses**

Part 7: Clinical investigations

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 16 May 2003 and published on 30 June 2003.

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Australian Dental Association
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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard.

This Standard is identical with and has been reproduced from ISO 11979-7:2001, *Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations*.

The objective of this Standard is to specify particular requirements for clinical investigation protocols for posterior and anterior chamber monofocal intraocular lenses for the correction of aphakia.

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

As this Standard is reproduced from an international Standard, the following applies:

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text ‘this International Standard’ should read ‘this Australian Standard’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards as follows:

<i>Reference to International Standard</i>		<i>Australian Standard</i>	
ISO		AS ISO	
14155	Clinical investigation of medical devices	14155	Clinical investigation of medical devices
11979	Ophthalmic implants—Intraocular lenses	11979	Ophthalmic implants—Intraocular lenses
11979-1	Part 1: Vocabulary	11979.1	Part 1: Vocabulary
11979-3	Part 3: Mechanical properties and test methods	11979.3	Part 3: Mechanical properties and test methods

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INTRODUCTION

This part of ISO 11979 provides fundamental requirements of a general nature for intraocular lenses. It refers to other standards applicable to intraocular lenses for specific methods and requirements.

It always was and still is the intention of Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of this part of ISO 11979, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards become available.

AUSTRALIAN STANDARD

Ophthalmic implants—Intraocular lenses

Part 7: Clinical investigations

1 Scope

This part of ISO 11979 specifies particular requirements for clinical investigation protocols for posterior and anterior chamber monofocal intraocular lenses (IOLs) for the correction of aphakia.

NOTE Any other type of IOL not directly covered by ISO 11979 and any IOL for which the sponsor wishes to investigate claims in addition to those defined in ISO 11979 may be clinically evaluated by reference to ISO 14155.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14155: 1996, *Clinical investigation of medical devices*.

ISO 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*.

ISO 11979-3: 1999, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*.

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 14155 and ISO 11979-1 apply, together with the following.

For the convenience of users of this part of ISO 11979, some definitions from ISO 11979-1 are reproduced in annex A. Terms relating to the design of IOLs are given in ISO 11979-3.

3.1 serious adverse event

event which is potentially sight threatening

NOTE 1 The definition for serious adverse event given in the ICH *Harmonized tripartite guideline for good clinical practice* also applies (see reference [1] in the bibliography).

NOTE 2 Examples of potentially sight-threatening adverse events are included in Tables D.1 and D.2.