

Australian Standard™

**Ophthalmic implants—Intraocular
lenses**

Part 1: Vocabulary

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 College of Operating Room Nurses
Australian Dental Association
Australian Industry Group
Australian Orthopaedic Association
Australian Society for Biomaterials
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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 11979-1:1999, *Ophthalmic implants—Intraocular lenses—Part 1: Vocabulary*.

The objective of this Standard is to specify terms applicable to intraocular lenses and the methods used to evaluate them.

The terms ‘normative’ and ‘informative’ are used to define the application of the annexes 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.

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INTRODUCTION

This part of ISO 11979 contains definitions of terms related to intraocular lenses and methods to evaluate them.

In addition to general terms, terms have been grouped in clauses corresponding to the various parts of ISO 11979. The terms are presented alphabetically in each clause.

NOTE It always was and still is the intention of the 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 part 7 of this series, problems were encountered with normative references to the existing ISO 14133 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. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-1 and EN ISO 11979-1). For those parts where no identical versions exist, 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 on clinical investigations become available.

AUSTRALIAN STANDARD

Ophthalmic implants—Intraocular lenses

Part 1: Vocabulary

1 Scope

This part of ISO 11979 defines terms applicable to intraocular lenses and the methods used to evaluate them.

2 General terms and definitions**2.1****anterior chamber (intraocular) lens**

intraocular lens designed to be placed entirely in the anterior chamber of the eye

2.2**body**

central part of an intraocular lens incorporating the optic

See Figure 1.

2.3**clear optic**

diameter of the circle, concentric with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

See Figure 1.

2.4**haptic**

non-optical, generally peripheral, component(s) of an intraocular lens intended to keep it in place in the eye

2.5***in situ***

in equilibrium with aqueous humour at 35 °C

NOTE 1 The refractive index of aqueous humour is taken to be 1,336 at 546,07 nm.

NOTE 2 For practical testing purposes, physiological saline may in many cases be used as a substitute for aqueous humour.

NOTE 3 Actual testing may be carried out at other conditions if, by validated correction procedures, values can be shown to apply under *in situ* conditions.

2.6**intraocular lens**

ICL
ophthalmic lens intended for implantation inside the eye

2.7**loop**

peripheral extension on the body, serving to position the lens in the eye

NOTE Loops are parts of the haptic (see 2.4), or may be the haptic.