AS ISO 11979.3—2003
ISO 11979-3:1999

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 3: Mechanical properties and test methods

Standards Australia

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.

The following are represented on Committee HE-012:

Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

Australian Dental Association

Australian Industry Group

Australian Orthopaedic Association

Australian Society for Biomaterials

Commonwealth Department of Health and Ageing

Department of Defence (Australia)

Medical Industry Association of Australia Inc

Neurological Society of Australasia

Royal Australasian College of Surgeons

Royal Perth Hospital

University of New South Wales

University of Sydney

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia website at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Global Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001.

This Standard was issued in draft form for comment as DR 03108.

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 3: Mechanical properties and test methods

First published as AS ISO 11979.3—2003.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5330 2

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

The objective of this Standard is to specify requirements and test methods for certain mechanical properties of intraocular lenses intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular intraocular lens design.

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:

Reference to International Standard		*Australian Standard*	
ISO		AS ISO	
11979	Ophthalmic implants—Intraocular lenses	11979	Ophthalmic implants—Intraocular lenses
11979-1	Part 1: Vocabulary	11979.1	Part 1: Vocabulary
11979-2	Part 2: Optical properties and test methods	11979.2	Part 2: Optical properties and test methods
11979-4	Part 4: Labelling and information	11979.4	Part 4: Labelling and information

CONTENTS

INTRODUCTION

This part of ISO 11979 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ISO 11979-7 [1]. Because of the complexity of this analysis, detailed descriptions and examples have been given in annex I.

Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards, it is then up to the parties using the standard to modify or develop corresponding methods, and give rationale and validation for them in a spirit that is consistent with this International Standard.

In the cases where different tolerances have been given depending on material or design, they reflect an already existing situation with well-established products.

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 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 3: Mechanical properties and test methods

1 Scope

This part of ISO 11979 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular IOL design.

NOTE For certain designs and certain applications, a specific test method described in this part of ISO 11979 may not be applicable. In such instances, the IOL manufacturer should devise corresponding test methods and provide validation and rationale for them.

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 11979-1:—[1)], *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary.*

ISO 11979-2:—[1)], *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods.*

ISO 11979-4:—[1)], *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information.*

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply. For the convenience of the reader, some of these terms and definitions are reproduced here.

3.1
body
central part of an intraocular lens incorporating the optic

See Figure 1.

---

1) To be published.