AS ISO 11979.6—2003
ISO 11979-6:2002

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 6: Shelf-life and transport stability

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 Standards may also be withdrawn.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 03111.

Australian Standard™

Ophthalmic implants—Intraocular lenses

Part 6: Shelf-life and transport stability

First published as AS ISO 11979.6—2003.

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

ISBN 0 7337 5333 7

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 11979-6:2002, *Ophthalmic implants—Intraocular lenses—Part 6: Shelf-life and transport stability.*

The objective of this Standard is to specify tests by which the shelf-life of sterile intraocular lenses in their final packaging can be determined. These tests include procedures to establish the stability of intraocular lenses in distribution and storage.

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
11979-3	Part 3: Mechanical properties and test methods	11979.3	Part 3: Mechanical properties and test methods

CONTENTS

Annexes

INTRODUCTION

The purpose of a stability study is to ascertain that the properties of the intraocular lens (IOL) remain within specified limits for a sufficiently long period of time under the influence of a variety of environmental conditions.

The storage stability of the intraocular lens material is an important factor in the overall investigation of a new lens material, a new combination of given lens materials, a new packaging material or a new manufacturing process. To assess this, a study of the ageing of the lenses in their containers is performed.

Changes in the composition and material, material suppliers, manufacturing conditions (including the sterilization process), or the package design or material may affect the shelf-life and may therefore necessitate renewed investigations.

The design of the stability tests should be based on the known properties of the material from which the intraocular lens is made and the recommendations for use of the intraocular lens. Knowledge of the quantity and identity of extractable substances found after storage or accelerated ageing studies is of importance in evaluating new intraocular lens materials.

On the basis of the information obtained, transport and storage conditions can be recommended that will maintain the quality of the intraocular lens in relation to its safety, efficacy and acceptability throughout the proposed shelf-life, i.e. during storage and distribution up until the moment of dispensing. The results obtained are also used to determine the expiration date.

In practical terms, it is the stability of the material from which the intraocular lens is made that is being tested, along with the integrity of the packaging that maintains the necessary environment of the intraocular lens. Stability studies for intraocular lenses are thus material specific, i.e. this type of study does not need to be performed for more than one intraocular lens model for a given combination of IOL material(s), packaging materials and manufacturing processes.

Stability studies of intraocular lenses will allow the determination of the shelf-life and package suitability, as well as recommendations for transport and storage conditions.

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 ultimately have identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

AUSTRALIAN STANDARD

Ophthalmic implants—Intraocular lenses

Part 6: Shelf-life and transport stability

1 Scope

This part of ISO 11979 specifies tests by which the shelf-life of sterile intraocular lenses (IOLs) in their final packaging can be determined. These tests include procedures to establish the stability of IOLs in distribution and storage.

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 2248:1985, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 8318:2000, *Packaging — Complete, filled transport packages and unit loads — Sinusoidal vibration tests using a variable frequency*

ISO 11607:1997, *Packaging for terminally sterilized 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 11979-1 and the following apply.

3.1
device history record
compilation of records containing the production history

3.2
finished intraocular lens lot
all units of an intraocular lens which have undergone a single series of manufacturing operations including the sterilization operation and which are identified on a single device history record

NOTE Some definitions of ISO 11979-1, relevant to this part of ISO 11979, are reproduced in annex D.