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OPHTHALMIC IMPLANTS - INTRAOCULAR LENSES - PART 6: SHELF-LIFE AND TRANSPORT STABILITY (ISO 11979-6:2002, MODIFIED)

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Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability (ISO 11979-6:2002,modified)

Implants ophtalmiques - Lentilles intraoculaires - Partie 6: Durée de conservation et stabilité pendant le transport (ISO 11979-6:2002,modifié)

Ophthalmische Implantate - Intraokularlinsen - Teil 6: Haltbarkeits-und Transportprüfungen (ISO 11979-6:2002,modifiziert)

This European Standard was approved by CEN on 19 August 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of the International Standard from Technical Committee ISO/TC 172 "Ophthalmic optics and instruments" of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

European Standard EN 13503 was developed by CEN/TC 170, *Ophthalmic optics*, in cooperation with ISO/TC 172/SC 7, *Ophthalmic optics and instruments*, and is published in several parts under the general title *Ophthalmic implants - Intraocular lenses*:

— Part 1: Vocabulary

— Part 2: Optical properties and test methods

— Part 3: Mechanical properties and test methods

— Part 4: Labelling and information

— Part 5: Biocompatibility

— Part 6: Shelf-life and transport stability

— Part 7: Clinical investigations

— Part 8: Fundamental requirements

EN 13503 is the modified ISO 11979. The main difference between both series of standards is that ISO 11979 is based on the reference to ISO 14155 *Clinical investigation of medical devices* while EN 13503 is based on the reference to EN 540 *Clinical investigation of medical devices for human subjects*.

Modifications of ISO 11979-6 are indicated as follows:

— text which has been deleted is striked out;

— text which has been changed or added is underlined.

Annex A is normative and annexes B, C and D are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11979-6:2002 has been approved by CEN as a European Standard with agreed common modifications as given in the foreword and indicated in the text by strike-out and underlining.

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 combinations 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 needs not 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.

1 Scope

This part of EN 13503 ~~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

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

~~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 IEC and ISO maintain registers of currently valid International Standards.~~

EN 13503-3~~ISO 11979-3:1999~~, *Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:1999, modified).*

EN 22248, *Packaging – Complete, filled transport packages – Vertical impact test by dropping* (ISO 2248:1985)

EN ISO 8318, *Packaging – Complete, filled transport packages and unit loads – Sinusoidal vibration tests using a variable frequency* (ISO 8318:2000).

EN ISO 11979-1:1999, *Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:1999).*

ISO 11607:1997, *Packaging for terminally sterilized medical devices.*

3 Terms and definitions

For the purposes of this part of EN 13503 ~~ISO 11979~~, the terms and definitions given in EN ISO 11979-1:1999 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 EN ISO 11979-1, relevant to this part of EN 13503 ~~ISO 11979~~, are reproduced in annex D.

4 Requirements

4.1 General

A study protocol shall be developed prior to initiation of the study.

The study shall demonstrate that the parameters assessed with regard to efficacy, safety and product acceptability are within the original manufacturing specifications at the conclusion of the study.

NOTE In view of the fact that sufficiently long experience of storage of a new intraocular lens may not have been accumulated by the time it is brought to the market, the results of accelerated tests are acceptable. A test in real-time should be carried out under certain conditions (see 4.3.2) to confirm the accelerated shelf-life study.

A maximum of five years of shelf-life should be claimed by a real-time study or an accelerated study regardless of material used in the intraocular lens. In the case where a manufacturer wishes to maintain the possibility to resterilize finished intraocular lens lots, the finished intraocular lens lot(s) used in the stability study shall have undergone the maximum number of sterilization cycles allowed under the manufacturer's procedures.