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Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 16672:2015), which has been technically revised.

The main changes compared to the previous edition are as follows:

a) the following terms and their definitions have been included: "secondary packaging", surgical invasive medical product" and "minimum utilization pressure";

b) the subclause on chemical description and contaminants has been substantially revised;

c) the bacterial endotoxin limit has been revised from 0,5 to 0,2 Endotoxin Units per ml;

d) the total level of EO in the product has been revised: it shall not exceed 1,25 µg/dose for EO and 5,0 µg/dose for ethylene chlorohydrin (ECH);

e) minimum utilization pressure has been included in the list of information supplied by the manufacturer;

f) B.2.2 giving the clinical variables in a clinical investigation has been revised;

g) Annex C "Method for quantifying incompletely fluorinated contaminants in perfluorocarbon liquids" has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Ophthalmic implants — Ocular endotamponades

1 Scope

This document applies to ocular endotamponades (OE), a group of non-solid surgically invasive medical devices introduced into the vitreous cavity of the eye to flatten and position a detached retina onto the retinal pigment epithelium (RPE), or to tamponade the retina.

With regard to the safety and efficacy of OE, this document specifies requirements for their intended performance, design attributes, pre-clinical and clinical evaluation, sterilization, product packaging, product labelling and the information supplied by the manufacturer.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 1041+A1, *Information supplied by the manufacturer with medical devices*

OECD Guidelines for the Testing of Chemicals, Section 1: Physical-Chemical properties, Test No. 104: Vapour Pressure

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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3.1
delivery system
sealed container in which the product is supplied including any additional component provided to introduce the product into the eye

3.2
dynamic viscosity
quotient of shear stress and shear velocity

Note 1 to entry: The dynamic viscosity is expressed in pascal seconds (Pa·s).

3.3
interfacial tension
tension against liquids

Note 1 to entry: The interfacial tension is expressed in newton per metre (N/m).

3.4
kinematic viscosity
quotient of *dynamic viscosity* (3.2) and gravity

Note 1 to entry: The kinematic viscosity is expressed in square metres per second (m^2/s).

3.5
ocular endotamponade
OE
non-solid *surgically invasive medical device* (3.11) introduced into the vitreous cavity of the eye to flatten and position a detached retina onto the retinal pigment epithelium (RPE), or to tamponade the retina

3.6
primary container
container providing mechanical and microbiological protection of the content

3.7
sterile barrier
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

3.8
storage container
part of the packaging intended to protect the device during transport and storage, containing the *sterile barrier* (3.7)

3.9
secondary packaging
container external to and providing protection and support for the *primary container* (3.6)

3.10
surface tension
tension against air

Note 1 to entry: Surface tension is expressed in newton per metre (N/m).

3.11
surgically invasive medical device
invasive device which penetrates inside the body through the surface with the aid or in the context of a surgical operation

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3.12
vapour pressure
pressure exerted by the vapour of a liquid OE when in equilibrium with the liquid OE

Note 1 to entry: Vapour pressure is expressed in pascal (Pa) at (35 ± 2) °C.

3.13
minimum utilization pressure
limiting value of the pressure below which the gas or gases mixture shall no longer be withdrawn from the container for its intended use

4 Intended performance

The general requirements for the intended performance of non-active surgical implants specified in ISO 14630 shall apply.

This document describes surgically invasive medical devices that are compatible with the internal ocular environment and, through a primary mechanical action, are used to reposition and/or tamponade a detached retina. They are used either intra-operatively and removed at the end of surgery, as in the case of perfluorocarbon liquids, or are designed to remain in the vitreous cavity until removal at a later date as in the case of silicone oils, or they are completely absorbed as in the case of gaseous OE.

The manufacturer shall describe and document the functional characteristics of the OE in terms of its chemical composition and physical properties, the intended surgical applications, the conditions of use and the maximum duration of contact with, and effects upon ocular tissues, with particular regard to safety.

All available published standards and published scientific and clinical literature, validated test results, clinical investigations, and pre-clinical and clinical evaluations shall be considered in determining the intended device.

5 Design attributes

5.1 General

The general requirements for non-active surgical implants specified in ISO 14630 shall apply.

All testing requirements specified below shall be performed with finished and sterilized product, ready for release. Any analytical methods utilized shall be validated.

NOTE Tests described herein are intended to apply when qualifying materials and not necessarily as a routine quality assurance/control programme.

5.2 Chemical description and contaminants

The manufacturer shall provide a description of each of the components in the finished product, and their respective quality specifications and concentrations.

If the component material is derived from biological sources, the organism from which it is obtained shall be stated along with its source.

Whenever possible, for all polymers, the backbone, any side groups and end-groups shall be identified.

The identification of potentially hazardous chemical or biological contaminants shall be determined by a risk analysis. For raw materials of biological origin, these impurities can include proteins, nucleic acids, or other biological materials.

Contaminants of the finished product derived from the source materials or from the manufacturing process, such as by-products, residual monomers, cross-linking agents, catalysts, products derived from

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