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Ophthalmic implants — Ocular endotamponades

Implants ophtalmiques — Produits de tamponnement endoculaires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16672 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Ophthalmic implants — Ocular endotamponades

1 Scope

This International Standard applies to ocular endotamponades (OEs), a group of non-solid implants used in ophthalmology to flatten and position a detached retina onto the choroid, or to tamponade the retina.

With regard to the safety and efficacy of OEs, this International Standard 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 referenced documents are indispensable for the application 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.

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ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 10993-6:1994, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

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

ISO 13408-1:1998, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155-1:—[1)], *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:—[1)], *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14630:1997, *Non-active surgical implants — General requirements*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

ISO/TR 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

EN 868-1:1997, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods*

EN 1041:1998, *Information supplied by the manufacturer with medical devices*

USP 24 <85> Jan/2000, *United States Pharmacopoeia <85> Bacterial endotoxins test*

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1) To be published.

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3 Terms and definitions

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

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

3.2
dynamic viscosity
quotient of the part of the stress in phase with the rate of strain divided by the rate of strain under sinusoidal conditions

NOTE The dynamic viscosity is expressed in pascal seconds (Pa·s).

3.3
interfacial tension
tension against liquids

NOTE The interfacial tension is expressed in newtons per metre (N/m).

3.4
kinematic viscosity
quotient of the dynamic viscosity with the gravity

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NOTE The kinematic viscosity is expressed in metres squared per second (m^2/s).

3.5
non-solid implants
tamponade media such as gases, liquids or gels

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3.6
surface tension
tension against air

NOTE Surface tension is expressed in newtons per metre (N/m).

3.7
vapour pressure
vapour pressure of a liquid OE that defines its volatility

NOTE Vapour pressure is expressed in conventional millimetres of mercury (mmHg) at (35 ± 2) °C.

4 Intended performance

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

This International Standard describes non-solid medical devices which are compatible with the ocular environment, used to reposition and/or tamponade a detached retina, and which function primarily mechanically. They are used either intra-operatively and removed at the end of surgery, as in the case of heavy liquids such as perfluorocarbons, or are designed to remain in the vitreous cavity until a reattachment of the retina is achieved.

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.

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The intended performance shall be determined, taking into account published standards, published clinical and scientific literature, pre-clinical and clinical evaluation and clinical investigations.

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, 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 and biological contaminants

The identification of potentially hazardous chemical or biological contaminants shall be determined by a risk analysis. For raw materials of biological origin, these impurities may 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 cross-linking agents and antioxidants, that are potentially hazardous to the tissues of the eye, or systemically, shall be identified, whenever possible, and their concentration in the finished products reported.

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Contaminants shall be determined using standard analytical methods when available, and all methods shall be described. Limits for identified contaminants shall be set and documented. Testing for the biological effects of these contaminants during evaluation of biological safety may be required if the risk analysis determines it necessary.

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5.3 Chemical description

The manufacturer shall provide a description of each chemical component in the finished product and its quality specifications. If the component material is derived from biological sources, the organism from which it is obtained shall be stated along with its source. For synthetic polymers, the backbone and end-groups shall be identified. Residual monomers and reaction by-products shall be quantified and identified, if possible.

5.4 Concentration of the components

The concentration of each component material in the finished product shall be stated. Since the testing methodology may affect the actual concentration reported, the physical or chemical techniques utilized shall be described.

5.5 Density

The density of liquid forms of OEs shall be specified in kilograms per cubic metre (kg/m³).

5.6 Gaseous expansion

For gaseous forms of OEs the intraocular gaseous expansion at (35 ± 2) °C and its dependence on atmospheric pressure shall be expressed.

5.7 Interfacial tension

Where applicable, the interfacial tension shall be expressed in newtons per metre (N/m) at (35 ± 2) °C.

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5.8 Kinematic viscosity

Where applicable, the kinematic viscosity shall be expressed in millimetres squared per second (mm^2/s).

5.9 Molecular mass distribution

If the OE is a polymer, the average molecular mass and the polydispersity shall be reported.

The manufacturer shall conduct and report such additional tests as necessary to provide an adequate description of the molecular mass distribution of the components in the finished product. Whenever possible, standard methods shall be used and specified.

5.10 Particulates

An assessment of risk shall evaluate the potential for contamination by, or formation of, particulates in the product during manufacture, the conditions expected during transport and storage, and during use of the product and the associated hazards.

The manufacturer shall characterize and set limits for the types, range of sizes and levels of particles present in the finished product used in the clinical study. For each type of particle present, a limit which has been validated in a clinical study shall be set and an adequate justification for the limit shall be documented.

5.11 Refractive index

Where applicable, the refractive index between OE and air shall be measured with a refractometer at (35 ± 2) °C and (546 ± 10) nm wavelength.

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5.12 Spectral transmittance

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The spectral transmittance of the OE shall be measured by transmission spectrophotometry over the range 300 nm to 1100 nm. Results shall be presented graphically, plotting percentage transmission against wavelength.

5.13 Surface tension

Where applicable, the surface tension shall be expressed in newtons per metre (N/m) at (35 ± 2) °C.

5.14 Vapour pressure

Where applicable, the vapour pressure shall be expressed in conventional millimetres of mercury (mmHg) at (35 ± 2) °C.

6 Design evaluation

6.1 General

The OE shall be evaluated for safety by performing a risk assessment in accordance with ISO 14971. The results of the risk assessment shall determine the tests required to evaluate the safety of the OE.

The risk assessment shall take into consideration the following:

a) the type of product and the duration of intraocular contact;

b) potential interactions of the OE with other materials likely to be used in ophthalmic surgery;

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c) for intraocular gases, any impurity profile changes as the gas is depleted from the tank.

NOTE Impurity profile changes can occur as the concentration of the chemical species changes due to the differences in vapour pressure as the tank is depleted.

The OE shall be evaluated to demonstrate that the intended performance is achieved. The requirements for evaluation of non-active implants specified in ISO 14630 shall apply.

6.2 Evaluation of biological safety

6.2.1 General

The relevant biocompatibility endpoints specified in ISO 10993-1 and identified by the risk analysis shall be taken into account when selecting the tests to evaluate the biological safety of an OE.

NOTE Based upon the typical clinical applications in the posterior segment, OEs are categorized as “Implant devices, tissue/bone”. The tests for this and other categories of devices identified in Table 1 of ISO 10993-1:1997 are for guidance only; they do not represent maximum or minimum test requirements.

6.2.2 Bacterial endotoxins test

Where applicable, the OE shall be evaluated for the presence of bacterial endotoxins using the Limulus Amebocyte Lysate (LAL) test, in accordance with the procedure described in USP 24 <85> or an equivalent validated test procedure. Any product that exceeds a bacterial endotoxin limit of 0,5 Endotoxin Units (EU) per ml fails the test.

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6.2.3 Intraocular implantation test

Tests for intraocular irritation, inflammation, intraocular pressure (IOP) and other local effects of the OE shall be conducted in a suitable animal model, in accordance with animal welfare requirements specified in ISO 10993-2 or following any local legislation.

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The particular requirements for this intraocular implantation test are specified in Annex A.

The study design shall mirror the intended clinical use as closely as possible.

The study design should assess the intra-operative and postoperative intraocular irritation, inflammation and local effects of the ophthalmic surgery with comparative use of the OE under evaluation and a control OE which has already been proven in clinical use to be acceptable. The volume of OE used should simulate the intended use, accounting for ocular volume differences between the human and animal models.

The post-surgical irritation, inflammation and local effects shall be monitored and graded at intervals appropriate to the duration of the intended use. All adverse events shall be documented.

The OE shall show intraocular irritation, inflammation and local effects results comparable to or less than a control OE of the same intended use. Intraocular irritation, inflammation and local effects in excess of the control OE are acceptable if justified by the risk benefit analysis.

NOTE It may be possible to combine biocompatibility tests, thereby reducing the number of animals required for testing. Two tests can be conducted simultaneously in a single animal provided that the test animals are not subjected to undue pain or distress.

6.2.4 Ethylene oxide

If ethylene oxide (EO) is used during the manufacturing of ingredients or in justified sterilization, the total level of EO in the product shall not exceed 20 µg/g for EO and 100 µg/g for ethylene chlorohydrin (ECH).

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