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Ophthalmic implants — Ophthalmic viscosurgical devices

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15798:2013 and its Amendment, ISO 15798:2013/Amd.1:2017), which has been technically revised.

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

a) Inclusion of applicable sections from ISO 14630 throughout the document, but removal of any reference to that standard. It was further clarified that ophthalmic viscosurgical devices (OVD) are no implant by their intended use but are likely to share some of the risks related to non-active implants. Therefore, the following clauses and subclauses have been revised: Clauses 4 and 5, 6.1, 6.2.1, Clause 7. A new subclause 5.4 has been added.

b) minor clarifications in Clause 3 (3.3, 3.4) and addition of term *surgical invasive medical device*;

c) clarification in Clause 4 that a recommended removal procedure shall enable removal of the OVD as completely as possible;

d) revised wording in 5.2 to align with defined terminology from Clause 3;

e) revised note in 5.3.2: narrowed recommended measuring range;

f) revised note in 5.3.8: more accurate description of the risk;

g) clarification that control OVD for the intraocular implantation test and the clinical investigation shall be the same in both studies; therefore, the following subclauses have been revised: 6.1, 6.2.5, 6.3.2, and Annex A;

h) revised wording in 6.2.2 of this document to include ISO 15798:2013/Amd.1:2017 and guidance on standard LAL-test;

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i) revised wording in 6.2.3 to address the potential risk of interaction of the OVD with fluorescence or radioisotope labelling;

j) revised 6.3 to clarify requirement of a clinical evaluation, clarification of the clinical investigation protocol, revision of the clinical investigation design, and additional standardization for evaluation and reporting of result from the clinical investigation;

k) inclusion of reference to ISO 10993-7 for acceptable levels of ethylene oxide and ethylene chlorohydrin in Clause 7;

l) packaging integrity has been specifically included into the scope of product stability Clause 8; in addition, reference to ISO 14971 has been included into this clause;

m) "Do not use if sterile barrier is breached" has been aligned with the recommended wording from ISO 15223-1 "Do not use if package is damaged"; in addition, molecular mass distribution has been removed from the list of information to be supplied by the manufacturer in Table 1;

n) major revision of Annex A;

o) correction of a typo in the formula for calculating the minimum number of evaluable patients per treatment group in Annex B.

p) Addition of new informative Annex C on analyses of OVD clinical data.

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 — Ophthalmic viscosurgical devices

1 Scope

This document is applicable to ophthalmic viscosurgical devices (OVDs), a class of surgical invasive medical devices with viscous and/or viscoelastic properties, intended for use during surgery in the anterior segment of the human eye. OVDs are designed to create and maintain space, to protect intraocular tissues and to manipulate tissues during surgery.

This document specifies requirements with regard to safety for the intended performance, design attributes, preclinical and clinical evaluation, sterilization, product packaging, product labelling and information supplied by the manufacturer of these devices.

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-16, *Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

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

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

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ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

EN 1041, *Information supplied by the manufacturer of medical devices*

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/

3.1
absolute complex viscosity
$|\eta^*| = \left[(\eta')^2 + (\eta'')^2\right]^{0,5}$
absolute value of *complex viscosity* (3.2)

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

3.2
complex viscosity
$\eta^* = \eta' - i \cdot \eta''$
viscosity consisting of a viscous η' and an elastic η'' component where i is an imaginary number defined by $i = (-1)^{0,5}$

3.3
delivery system
primary container in which the product is supplied and any additional components provided to introduce the product into the eye

3.4
elasticity
$G' = \sigma_0/\varepsilon_0 \cdot \cos\delta$
tendency of a body to return to its original shape after having been deformed

Note 1 to entry: Elasticity is quantitatively defined as stress (the force generated within the body) divided by strain (the change in dimensions of the body) multiplied by cosine of the phase lag between stress and strain.

Note 2 to entry: Elasticity is expressed in pascal (Pa).

3.5
lost to follow-up subject
subject for which the final post-operative case report form is overdue and who cannot be contacted despite extensive written and telephone follow-ups to determine the final clinical outcome

Note 1 to entry: This category does not include subjects who have died.

3.6
ophthalmic viscosurgical device
OVD
generic term that includes a variety of materials with viscous and/or viscoelastic properties, which are designed to create and maintain space, to protect intraocular tissues and to manipulate tissues during surgery in the anterior segment of the human eye

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3.7
primary container
vial or syringe that contains the OVD

Note 1 to entry: This container forms part of the delivery system.

3.8
rheologically active component
compound or mixture of compounds in the finished OVD giving the product viscous and/or viscoelastic properties

3.9
shear viscosity
tendency of a fluid to resist flow when subjected to stress

Note 1 to entry: Quantitatively, shear viscosity is the quotient of shear stress divided by shear rate in steady shear flow.

Note 2 to entry: Shear viscosity is expressed in pascal seconds (Pa·s), traditionally in millipascal seconds (mPa·s).

Note 3 to entry: Shear rate is the velocity gradient in a flowing fluid, expressed in s^{-1} (per second).

Note 4 to entry: The shear viscosity divided by the solution density gives the *kinematic viscosity,* which is a measure of the viscosity of a fluid influenced by inertia (e.g. gravity).

3.10
sterile barrier
sealed packaging, containing the product and *delivery system* (3.3), which maintains sterility during transport and storage

3.11
storage container
that part of the packaging intended to protect the device during transport and storage, containing the sterile barrier

3.12
surgical invasive medical device
invasive device which penetrates inside the body through the surface of the body with the aid or in the context of a surgical operation

3.13
viscoelasticity
characteristics of a fluid having both viscous and elastic properties

Note 1 to entry: The viscous modulus, G'', is frequently called the loss modulus and the elastic modulus, G', is frequently called the storage modulus, both moduli are expressed in Pascal (Pa). The moduli can be combined to show the elasticity of the OVD (see 5.3.5).

3.14
zero shear viscosity
plateau viscosity at vanishing shear rate in a log-log plot of viscosity versus shear rate

Note 1 to entry: Zero shear viscosity is expressed in pascal seconds (Pa·s), traditionally in millipascal seconds (mPa·s), or as a logarithm of the zero shear viscosity.

4 Intended performance

OVDs are surgically invasive medical devices. They shall be compatible with the internal ocular environment. Intended performance is primarily provided for by their viscous and/or viscoelastic properties, which are designed to create and maintain space, to protect intraocular tissues and to manipulate tissues during surgery in the anterior segment of the human eye. OVDs are used intra-

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