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Ophthalmic implants — Ophthalmic viscosurgical devices

Implants ophtalmiques — Dispositifs ophtalmiques viscoélastiques



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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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Contents

	Page
Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Intended performance	3
5 Design attributes	4
5.1 General.....	4
5.2 Characterization of the components.....	4
5.3 Characterization of the finished product.....	4
5.3.1 General.....	4
5.3.2 Absolute complex viscosity.....	5
5.3.3 Chemical and biological contaminants.....	5
5.3.4 Concentration.....	5
5.3.5 Elasticity.....	5
5.3.6 Molecular mass distribution.....	5
5.3.7 Osmolality.....	5
5.3.8 Particulates.....	6
5.3.9 pH.....	6
5.3.10 Refractive index.....	6
5.3.11 Shear viscosity.....	6
5.3.12 Spectral transmittance.....	6
5.4 Usability.....	7
6 Design evaluation	7
6.1 General.....	7
6.2 Evaluation of biological safety.....	7
6.2.1 General.....	7
6.2.2 Bacterial endotoxins test.....	8
6.2.3 Clearance of residual OVD from the anterior chamber.....	8
6.2.4 Degradation and toxicokinetics.....	8
6.2.5 Evaluation of inflammation and intraocular pressure.....	8
6.3 Clinical evaluation.....	8
6.3.1 General.....	8
6.3.2 Clinical investigation design.....	9
6.3.3 Corneal endothelial cell density.....	9
6.3.4 Postoperative inflammation.....	9
6.3.5 Post-operative intraocular pressure change.....	10
6.3.6 Adverse events.....	10
7 Sterilization	10
8 Product stability	11
9 Integrity and performance of the delivery system	11
10 Packaging	11
10.1 Protection from damage during storage and transport.....	11
10.2 Maintenance of sterility in transit.....	11
11 Information to be supplied by the manufacturer	11
Annex A (normative) Intraocular implantation test	13
Annex B (informative) Patient numbers for clinical investigation of intraocular pressure	16
Annex C (informative) Analyses of OVD clinical data	17
Bibliography	19

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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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.