PD ISO/TR 22979:2017

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Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

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National foreword

This Published Document is the UK implementation of ISO/TR 22979:2017. It supersedes PD ISO/TR 22979:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/172/7, Eye implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2017

ISBN 978 0 580 85343 2

ICS 11.040.70

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2017.

Amendments/corrigenda issued since publication

Date	Text affected

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TECHNICAL REPORT

ISO/TR 22979

Second edition
2017-05

Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

Implants ophtalmiques — Lentilles intraoculaires — Directives relatives à l'évaluation de la nécessité d'investigation clinique pour les modifications de conception des lentilles intraoculaires

Reference number
ISO/TR 22979:2017(E)

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

This second edition cancels and replaces the first edition (ISO/TR 22979:2006), which has been technically revised.

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Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications

1 Scope

This document provides guidance on the application of all parts of the ISO 11979 series of International Standards for intraocular lenses (IOLs).[1–9] It addresses factors to be considered in the risk management process of modifications to anterior and posterior chamber IOLs in accordance with ISO 14971.[11] It also suggests methods of data analysis and interpretation that can be used to determine the need for a clinical investigation and its design.

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 11979-1, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11979-1 and the following apply.

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

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

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

NOTE The terms listed are related to Annex B.

3.1
open-loop IOL
IOL model which contains two loops, each loop having one end attached to the body of the IOL and the other end free

3.2
closed-loop IOL
IOL model, which contains two loops, each loop having both ends attached to the body of the optic

3.3
hybrid open-loop/closed-loop IOL
IOL model which contains two loops, with one loop having one end attached to the body of the IOL and the other end free, and the other loop having both ends attached to the body of the IOL

4 Modifications to parent models

4.1 General

IOLs, that are modifications of a parent IOL, have different requirements for clinical investigations depending on the risk associated with the modifications and depending on their location in the eye.

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This document provides considerations for the risk assessment to determine the clinical investigation effort that is needed based on the level of modification which is defined in 4.2.

ISO 13485[10] provides requirements for the design and development of medical devices, which are applicable to intraocular lenses including modifications of existing models. The risk assessment and design evaluation are part of the risk management in the design control process in accordance with ISO 14971, and can be used as input for the clinical evaluation. ISO 14971 describes sources for data and information for estimating risks. To determine and evaluate the hazards associated with the modification of IOL models, the manufacturer can additionally use the following sources:

a) clinical data;

b) literature study of equivalent features of similar IOL models. The literature can be general published and unpublished reports, proprietary evaluations and post-market surveillance reports;

c) physical model-eyes, laboratory bench testing or numerical/computational models, which have been verified and validated for evaluation of optical and mechanical behaviour;

d) usability and human factor engineering data resulting from the application of IEC 62366-1[12] or ANSI/AAMI HE75[13] such as the use of error risk analysis, formative and summative evaluation results, including studies to evaluate surgical manipulation and delivery of the IOL in the eye.

Modifications to the delivery system are subject to the design control process in accordance with ISO 13485 and factors that pertain to the interaction of IOL and delivery system, as described in ISO 11979-3, and user interaction during surgery are to be considered in a risk assessment.

4.2 Modification levels

4.2.1 General

Design modifications to parent model IOLs are classified as Level A, B or C. The classification depends on the safety and performance risks that are identified. Examples of risks associated with design modifications are provided in Annex A.

4.2.2 Level A modifications

Level A modifications of a parent model are those for which all safety and performance questions can be adequately addressed without clinical investigation. The modified model is essentially equivalent to the parent model(s). All risks resulting from risk assessment to the modification are adequately addressed by existing clinical evidence. The residual risk will have to be outweighed by the benefits.

4.2.3 Level B modifications

Level B modifications of a parent model are those that raise safety and/or performance risks that can be adequately addressed with a limited clinical investigation of a justified number of subjects followed up for a justified period.

NOTE Typically 100 subjects followed up for 4 months to 6 months. The statistical precision of a 100-subject investigation to detect differences from the safety and performance end points (SPE) ratings is provided in ISO 11979-7.

4.2.4 Level C modifications

Level C modifications are modifications that raise safety and/or performance risks that can only be addressed with a full clinical investigation as defined in ISO 11979-7 and ISO 11979-10.

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4.2.5 Clinical investigation with multiple IOL models

More than one IOL model can be studied in the same investigation and with the same study end points if supported by a risk assessment and provided these models are Level A modifications of one another. If the intent is that data from the various models are to be pooled, a justification from the manufacturer is required per study end point to demonstrate that the design differences between models will affect neither investigation outcomes nor investigation execution nor interfere with the application of statistically sound test design techniques such as randomization and masking.

5 Considerations for the assignment of modification level

5.1 General

The process of assignment of a modification level is illustrated in Figure A.1. A risk assessment of the model modifications is performed, especially considering any safety and performance changes due to the differential design aspects compared with the parent models. Multiple parent models can be considered in the evaluation given the premise that the modifications are related to these parent model(s).

The assigned modification level depends on the additional potential hazards or hazardous situations, their probability of occurrence and the probability that they will lead to harm, as well as the severity of the harm(s) compared with that of the parent model. For additional guidance, see ISO 14971.

Overall, the risk assessment would weigh the risk/performance impact and benefit to determine modification Level A, B or C. Examples of potential Level A modifications to parent models are provided in Annex A. A plurality of modifications may change the level assignment. If there is insufficient data to assess the risk of plurality of modifications, as compared with parent IOLs, a suitable clinical investigation should be performed.

5.2 Risk assessment

In the risk assessment, the hazards and hazardous situations that are related to the modification(s) relative to the parent model will be considered. By assigning modification Level A, B or C, the clinical performance relative to the parent model is addressed. Table A.5 includes examples of potential hazards and harms that may be associated with the modification and that can be included in the risk assessment. Table A.5 also includes references to test methods described in the ISO 11979 series, which can be considered to assess the potential risks. The risk assessment addresses all changes made to the product and includes changes of labelling, packaging and package inserts.

5.3 Special considerations

5.3.1 Phakic lenses

Phakic lenses require additional considerations in the risk assessment to determine the modification level because of the proximity of other tissue compared with aphakic anterior and posterior chamber lenses. The clinical requirements are outlined in ISO 11979-10.

5.3.2 Anterior chamber lenses

Additional hazards may arise from the potential direct IOL-tissue interaction, static or dynamic, which needs to be evaluated including the risk of rotation, displacement, aqueous flow and corneal damage. The clearance analysis described in ISO 11979-3 can be used to assess the clearance to the cornea.

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