SLOVENSKI STANDARD
SIST EN 13503-3:2000

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Oļ esni vsadki (implantati) - Intraokularne leļ e - 3. del: Mehanske lastnosti in preskusne metode (ISO 11979-3:1999, spremenjen)

Ophthalmic implants - Intraocular lenses - Part 3: Mechanical properties and test methods (ISO 11979-3:1999, modified)

Ophthalmische Implantate - Intraokularlinsen - Teil 3: Mechanische Anforderungen und Prüfverfahren (ISO 11979-3:1999, modifiziert)

Implants ophtalmiques - Lentilles intraoculaires - Partie 3: Propriétés mécaniques et méthodes d'essai (ISO 11979-3:1999, modifié)

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ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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EUROPEAN STANDARD
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English version

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This European Standard was approved by CEN on 12 May 2000.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 13503-3:2000 E

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2000, and conflicting national standards shall be withdrawn at the latest by December 2000.

European Standard EN 13503 was developed by CEN/TC 170, *Ophthalmic optics*, in cooperation with ISO/TC 172/SC 7, *Ophthalmic optics and instruments*, and is published in several parts under the general title *Ophthalmic implants - Intraocular lenses*:

Part 1: Vocabulary
Part 2: Optical properties and test methods
Part 3: Mechanical properties and test methods
Part 4: Labelling and information
Part 5: Biocompatibility
Part 6: Shelf-life and transport stability
Part 7: Clinical investigations
Part 8: Fundamental requirements

EN 13503 is the modified ISO 11979. The main difference between both series of standards is that ISO 11979 is based on the reference to ISO 14155 *Clinical investigation of medical devices* while EN 13503 is based on the reference to EN 540 *Clinical investigation of medical devices for human subjects*.

Compared with ISO 11979-3 the present European Standard EN 13503-3 does not contain the informative annex detailing mechanical data analysis (Annex I of ISO 11979-3).

Modifications of ISO 11979-3 are indicated as follows:
- text which has been deleted is striked out;
- text which has been changed or added is underlined.

Cross references to ISO 11979-3 are given where possible.

This Part 3 of EN 13503 contains seven normative annexes, A to G, and one informative annex, Annex H.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the draft International Standard ISO 11979-3:1999 was approved by CEN as a draft European Standard with agreed commun modifications as given in the Foreword and indicated in the text by strike-out and underlining.

Introduction

This part of ~~ISO 11979~~ EN 13503 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ~~ISO 11979-7~~ EN 13503-7 [1]. ~~Because of the complexity of this analysis detailed descriptions and examples have been given in Annex I.~~

Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards it is then up to the parties using the standard to modify or develop corresponding methods, and give rationale and validation for them in a spirit that is consistent with this ~~International~~ European Standard.

In the cases where different tolerances have been given depending on material or design they reflect an already existing situation with well established products.

NOTE: It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) Standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical European and International Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. It is the intention of CEN/TC 170 and ISO/TC 172/SC 7 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigation become available.

1 Scope

This part of ~~ISO 11979~~ EN 13503 specifies requirements and test methods for certain mechanical properties of intraocular lenses (IOLs).

It is applicable to all types of IOLs intended for implantation in the anterior segment of the human eye, excluding corneal implants, provided that the test method is appropriate to the particular design.

NOTE: For certain designs and certain applications, a specific test method described in this part of ~~ISO 11979~~ EN 13503 may not be applicable. In such instances the IOL manufacturer should devise corresponding test methods and provide validation and rationale for them.

2 Normative references

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN ISO 11979-1:1999, Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary.

EN ISO 11979-2:1999, Ophthalmic implants - Intraocular lenses - Part 2: Optical properties and test methods.

EN ISO 11979-4:2000, Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information.

3 Terms and definitions

For the purposes of this part of ~~ISO 11979~~ EN 13503, the terms and definitions given in EN ISO 11979-1:1999 apply. For the conveniance of the reader, some of these terms and definitions are reproduced here.

3.1
body
central part of an intraocular lens incorporating the optic

See Figure 1.

3.2
clear optic
diameter of the circle, concentric with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

See Figure 1.

3.3
in situ
in equilibrium with aqueous humour at 35 °C

See also EN ISO 11979-2:1999.

3.4
multipiece intraocular lens
intraocular lens assembled from separate loop and body components

NOTE: An intraocular lens with a body and two loops is often referred to as a three-piece intraocular lens.

3.5
one-piece intraocular lens
intraocular lens in which the haptic is an integral part of the body

3.6
optic decentration
lateral displacement of the optic due to compression of the haptic(s), measured as distance between the geometric centre of the clear optic and the centre of a cylinder of a specified diameter to which the intraocular lens is confined

See Figure C.1.

3.7
optic tilt
angle between the optical axis of the intraocular lens in the uncompressed state and that in the compressed state, with the intraocular lens being confined to a specified diameter

3.8
overall diameter
diameter of the cylinder circumscribing an intraocular lens, be it haptic or optic, with the axis of the cylinder coincident with the optical axis of the intraocular lens

See Figure 1.

3.9
positioning hole
hole, whether penetrating or not, intended to be used for clinical manipulation

See Figure 1.

3.10
sagitta
maximum distance between the planes, normal to the optical axis, which contact respectively the most anterior and the most posterior points, be it haptic or optic, of an uncompressed intraocular lens

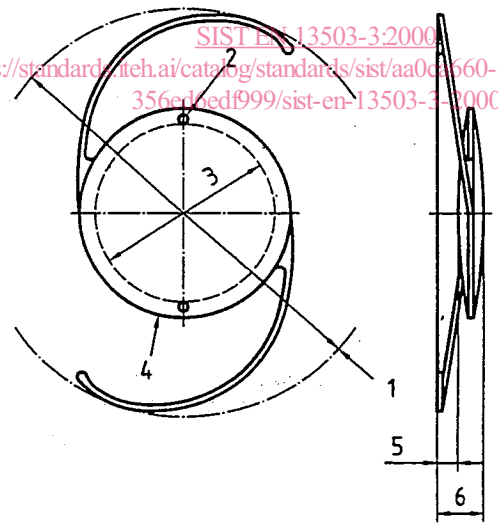
See Figure 1.

3.11
vault height
distance between the plane, normal to the optical axis, containing the vertex of the iris-proximal optical surface and the plane, normal to the optical axis, containing the most iris-proximal point of the uncompressed haptic of an intraocular lens

See Figure 1.

NOTE 1: The iris-proximal side of the intraocular lens refers to the intended position as implanted.

NOTE 2: The vault height is positive if the distance defined is in the direction towards the retina as implanted, and negative if not.



Key
1 Overall diameter
2 Positioning holes
3 Clear optic
4 Body
5 Vault height
6 Sagitta

Figure 1 - Indicative illustration of some dimensional parameters of an intraocular lens

4 Requirements

4.1 General

Properties of IOLs that do not change their dimensions after implantation shall be determined at 23 °C ± 2 °C and relative humidity (RH) 50 % RH ± 10 % RH. For all other IOLs, properties shall be determined at *in situ* conditions within the temperature tolerance of ± 2°C. The precise composition of the solution used shall be reported in all cases.

IOLs which are intended for clinical manipulations of folding or other optic deformation shall undergo such manipulations prior to being tested, to ensure maintenance of critical performance parameters after manipulation. Since the lens thickness is critical in these manipulations, samples of the highest and lowest dioptric power shall be included. Applicable mechanical and optical properties, defined elsewhere in this ~~International~~ European Standard, shall be measured. The folding or other deformation shall correspond to the configuration required by the IOL for actual implantation, and this condition shall be maintained for a minimum of 3 min. The folding or other deformation shall be performed by the same method and instrumentation, or their equivalent, as intended for clinical use. The IOL shall be allowed to return to its original and designed configuration. Compliance with applicable mechanical and optical requirements shall be demonstrated at (24 ± 2) h after release from folding or other deformation.

For each of the methods described below, tests shall be performed on a minimum of three IOL lots. If dioptric power affects the property tested, the lots shall comprise one each of low, medium and high dioptric powers. The minimum sample size for each test shall be 10 IOLs per lot. The lots shall be representative of IOLs being marketed. In all cases, the sampling criteria applied shall be reported.

4.2 Tolerances and dimensions

For all types of IOLs except multi-piece posterior chamber IOLs, the tolerance on the overall diameter shall be ± 0,20 mm. For multi-piece posterior chamber IOLs, the tolerance on the overall diameter shall be ± 0,30 mm.

NOTE: For symmetrically designed IOLs with two haptics, the overall diameter equals the distance between haptic vertices.

The tolerance on the vault height shall be as follows:

a) for anterior chamber IOLs, ± 0,15 mm;

b) for posterior chamber IOLs with polypropylene loop(s), ± 0,35 mm; and

c) for other IOLs, ± 0,25 mm.

The tolerance on the sagitta shall be as follows:

a) for anterior chamber IOLs, ± 0,25 mm;

b) for posterior chamber IOLs with polypropylene loop(s), ± 0,45 mm; and

c) for other IOLs, ± 0,35 mm.

The tolerance on the clear optic shall be ± 0,10 mm.

The tolerance on the dimensions of the body shall be ± 0,10 mm. For ellipsoid IOLs, the dimensions of the body shall be reported as (short axis) × (long axis).

The tolerance on the diameter of the positioning hole shall be (+0,05/ 0,00) mm.

Dimensions for which tolerances are given above shall be specified in the manufacturer's design documentation. Some dimensions may vary with dioptric power, hence different specifications may apply to individual powers of an intraocular lens design. Some dimensions, as specified in EN ISO 11979-4:2000, shall be given in the labelling of the product.

4.3 Compression force

Using the method described in annex A, the compression force shall be measured and reported as follows:

a) for IOLs intended for capsular bag placement, at a diameter of 10 mm;

b) for IOLs intended for sulcus placement, at a diameter of 11 mm;

c) for IOLs intended for both capsular bag and sulcus placement, both at a diameter of 10 mm and at a diameter of 11 mm; and

d) for anterior chamber IOLs, at the minimum and maximum intended compressed diameters recommended by the manufacturer in the product literature.

4.4 Axial displacement in compression

Using the method described in annex B, the axial displacement in compression shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

In addition, for anterior chamber IOLs, the vault height and the sagitta in the compressed state shall be given in the product literature as a function of dioptric power at the minimum and maximum intended compressed diameters, as specified in 4.3.

4.5 Optic decentration

Using the method described in annex C, the optic decentration shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

If the sum of the arithmetic mean and two standard deviations of the optic decentration exceeds 10 % of the clear optic, it shall be demonstrated that the modulation transfer function of the IOL in a model eye in accordance with EN ISO 11979-2:1999 is within the limits specified therein, at an optic decentration equal to the sum of the arithmetic mean and two standard deviations for the whole range of dioptric powers being marketed.

4.6 Optic tilt

Using the method described in annex D, the optic tilt shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

If the sum of the arithmetic mean and two standard deviations of the optic tilt exceeds 5°, it shall be demonstrated that the modulation transfer function of the IOL in a model eye in accordance with EN ISO 11979-2:1999 is within the limits specified therein, at an optic tilt equal to the sum of the arithmetic mean and two standard deviations for the whole range of dioptric powers being marketed.

4.7 Angle of contact

Using the method described in annex E, the angle of contact shall be measured and reported at the same diameters that were used for the measurement of compression force (see 4.3).

NOTE: The angle of contact is a measured approximation of the total haptic contact with the supporting ocular tissue.

4.8 Compression force decay

Using the method described in annex F, the compression force decay shall be tested and reported at the same diameters that were used for the measurement of compression force (see 4.3).

NOTE 1: The loops of IOLs are designed to exert some pressure on eye structures as a means of keeping the IOL in position and should continue to do so for some time after implantation.

Results shall be reported as residual compression force after 24 h in compression at each required compressed diameter under *in situ* conditions within the temperature tolerance of ± 2°C.

NOTE 2: Reduction in compression force may in part be caused by water uptake by the haptic material.

4.9 Dynamic fatigue durability

All loops shall be capable of withstanding, without breaking, 250 000 cycles of near-sinusoidal deformation of ± 0,25 mm around the compressed distance.

Using the method described in annex G, fatigue testing shall be performed as follows:

a) for IOLs intended for capsular bag placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic;

b) for IOLs intended for sulcus placement, at a compressed distance of 5,5 mm between the testing plate and the centre of the optic;

c) for IOLs intended for both capsular bag and sulcus placement, at a compressed distance of 5,0 mm between the testing plate and the centre of the optic; and

d) for anterior chamber IOLs, at two different compressed distances between the testing plate and the centre of the optic, corresponding to half the minimum intended compressed diameter and half the maximum intended compressed diameter, respectively, as recommended by the manufacturer in the product literature.

This test shall be carried out only for IOL designs in which the loop will be in a compressed state when implanted. The frequency shall be between 1 Hz and 10 Hz.

NOTE: Higher frequencies may be used if it is verified that the loop follows the testing plate without lag at all times.

No loop tested shall break.

4.10 Loop strength

The IOL manufacturer shall provide evidence that the loops of an IOL design are capable of withstanding surgical manipulations without failure.

A test method useful for many designs is given in annex H.

4.11 Surface and bulk homogeneity

The IOL shall be essentially free from defects (see note) and all edges shall appear smooth when viewed at 10x magnification with a stereomicroscope using optimal lighting conditions.

NOTE: By defects are meant deviations from surface and bulk homogeneity that are not intended features of the design, including all kinds of surface defects such as scratches, digs, protrusions, cracks, roughness, etc., as well as bulk defects such as inclusions, bubbles, striae, discoloration, etc.

5 Supplementary information available from the manufacturer

In addition to the information specified in EN ISO 11979-4:2000, the manufacturer shall have on record the information required by the tests specified in this part of ~~ISO 11979~~ EN 13503, as well as the evidence of loop strength required by 4.10.