INTERNATIONAL STANDARD

ISO 11979-1

First edition
1999-12-01

Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

Implants ophtalmiques — Lentilles intraoculaires — Partie 1: Vocabulaire

Reference number
ISO 11979-1:1999(E)

Contents

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Printed in Switzerland

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 3.

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.

International Standard ISO 11979-1 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 11979 consists of 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*

Introduction

This part of ISO 11979 contains definitions of terms related to intraocular lenses and methods to evaluate them.

In addition to general terms, terms have been grouped in clauses corresponding to the various parts of ISO 11979. The terms are presented alphabetically in each clause.

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 International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-1 and EN ISO 11979-1). For those parts where no identical versions exist, it is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

Ophthalmic implants — Intraocular lenses —

Part 1:
Vocabulary

1 Scope

This part of ISO 11979 defines terms applicable to intraocular lenses and the methods used to evaluate them.

2 General terms and definitions

2.1
anterior chamber (intraocular) lens
intraocular lens designed to be placed entirely in the anterior chamber of the eye

2.2
body
central part of an intraocular lens incorporating the optic

See Figure 1.

2.3
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.

2.4
haptic
non-optical, generally peripheral, component(s) of an intraocular lens intended to keep it in place in the eye

2.5
in situ
in equilibrium with aqueous humour at 35 °C

NOTE 1 The refractive index of aqueous humour is taken to be 1,336 at 546,07 nm.

NOTE 2 For practical testing purposes, physiological saline may in many cases be used as a substitute for aqueous humour.

NOTE 3 Actual testing may be carried out at other conditions if, by validated correction procedures, values can be shown to apply under *in situ* conditions.

2.6
intraocular lens
IOL
ophthalmic lens intended for implantation inside the eye

2.7
loop
peripheral extension on the body, serving to position the lens in the eye

NOTE Loops are parts of the haptic (see 2.4), or may be the haptic.

2.8
monofocal intraocular lens
intraocular lens designed to provide one dioptric power

2.9
multifocal intraocular lens
intraocular lens designed to provide two or more dioptric powers

2.10
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.

2.11
one-piece intraocular lens
intraocular lens in which the haptic is an integral part of the body

2.12
optic
image-forming, generally central, component of an intraocular lens

2.13
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.

2.14
positioning hole
hole, whether penetrating or not, intended to be used for surgical manipulation

See Figure 1.

2.15
posterior chamber (intraocular) lens
intraocular lens designed to be placed entirely in the posterior chamber of the eye

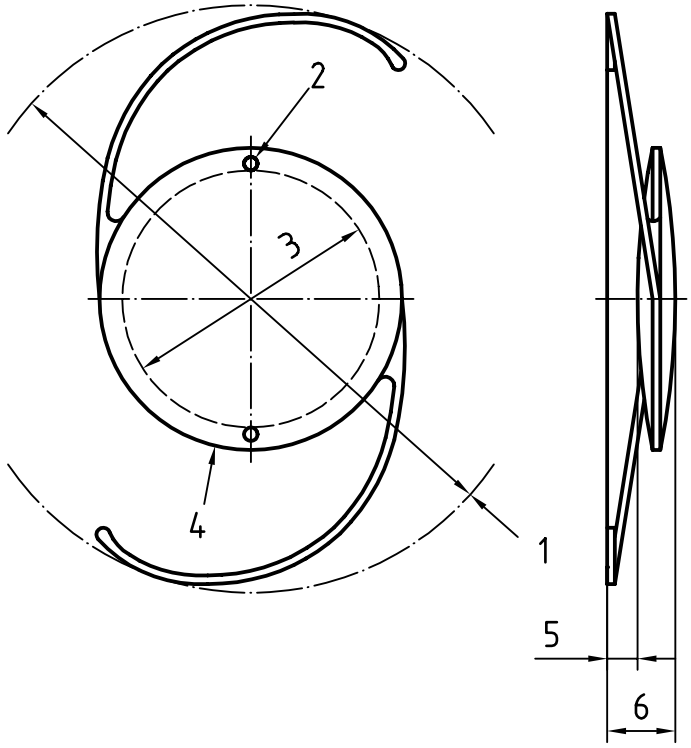
3 Terms related to optical properties and their test methods (ISO 11979-2)

3.1
dioptric power
reciprocal of the reduced paraxial focal length *in situ* for light with a wavelength of 546,07 nm

NOTE The unit for expressing dioptric power is the reciprocal metre (m^{-1}). The special name for this unit is “dioptre”, for which the symbol D is used.

3.2
paraxial focal length
distance between the back principal plane and the back paraxial focal point

3.3
reduced focal length
focal length divided by the refractive index of the surrounding medium



Key

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

Figure 1 — Overall diameter, vault height, sagitta, clear optic, body and positioning hole

4 Terms related to mechanical properties and their test methods (ISO 11979-3)

4.1
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

4.2
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

4.3
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.

4.4
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.

5 Terms related to labelling and information (ISO 11979-4)

5.1
additional wrapping
container(s) used, in addition to the primary packaging that may be used to maintain sterility of the lens

5.2
custom-made device
any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient

NOTE Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner are not considered to be custom-made devices.

5.3
device intended for clinical investigation
any device intended for use by a duly qualified medical practitioner when conducting a clinical investigation

5.4
manufacturer
the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person him/herself or on his/her behalf by a third party

NOTE The obligations to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels a product with a view to its being placed on the market under his/her own name.

5.5
primary package
container that physically and directly protects the lens and which may maintain sterility

5.6
self-adhesive label
label included in the storage container for hospital record use

5.7
storage container
packaging intended to protect the device during storage and distribution

6 Terms related to biocompatibility (ISO 11979-5)

6.1
material degradation test
test that determines the potential for degradation of a material

6.2
Nd-YAG laser exposure test
test that determines the physical and chemical effects of Nd-YAG laser exposure on a test material

6.3
non-ocular implantation test
test that evaluates the local toxicity and irritation of a test material and/or extracts of it on non-ocular tissue, using an appropriate implant site in an animal

6.4
ocular implantation test
test that evaluates the local toxicity effect on ocular tissue at both the gross level and the microscopic level of a test material that is surgically implanted into the anterior segment of the eye of an appropriate animal

6.5
test material
either the finished sterile intraocular lens, as intended for human implantation, or facsimile material manufactured and processed in a validated procedure equivalent to that used for the intraocular lens

NOTE If using intraocular lenses as test material, preferably lenses with powers within ± 2 D of the mean of the power range should be chosen, e.g. in general 18 D to 22 D.

6.6
photostability test
test that determines the potential for degradation of a test material due to exposure to light

7 Terms related to shelf-life and transport stability (ISO 11979-6)

7.1
expiration date
date of termination of shelf-life, after which the intraocular lens is not to be used

7.2
package integrity
container's ability to protect the intraocular lens from contamination

7.3
shelf-life
period during which an intraocular lens remains suitable for implantation in the human eye

7.4
stability
extent to which a product retains properties and characteristics within the manufacturer's specified limits, throughout its period of storage, i.e. its shelf-life

8 Terms related to clinical investigation (ISO 11979-7)

8.1
best-case subject
subject with no pre-operative pathology

8.2
cumulative adverse events
total number of adverse events which have occurred at any time up to a specified point in time post-operatively

8.3
intraocular lens model
identification by which the features of an intraocular lens, including those of its body and its loops, and the material(s) used in its construction, have been fully specified

EXAMPLES of body features are body diameter, optic diameter, optic shape factor; examples of loop features are configuration, calibre, angulation.

NOTE Any significant change in the specification of the materials (including their formulation or synthesis procedures) results in it being considered a new model.

8.4
level A modification of a parent intraocular lens model
modifications of a parent model which are considered minor and are not expected to result in any safety hazards or loss in effectiveness when compared to the parent model