
**Ophthalmic implants — Intraocular
lenses —**

**Part 1:
Vocabulary**

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 1: Vocabulaire*



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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*.

This fourth edition cancels and replaces the third edition (ISO 11979-1:2012), which has been technically revised.

A list of all parts in the ISO 11979 series can be found on the ISO website.

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.

Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

1 Scope

This document defines terms applicable to intraocular lenses, and to the methods used to evaluate them.

NOTE Terms are listed in the alphabetical order of the English terms in the English version of this document.

2 Normative references

No normative references are given in this document.

3 Terms, definitions and abbreviated terms

3.1 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/>

3.1.1

accelerated shelf-life study

stability study designed to increase the rate of chemical or physical degradation of a product by using exaggerated storage conditions (e.g. temperature, humidity) to determine kinetic degradation parameters to predict the tentative expiration dating period

3.1.2

accommodating intraocular lens

AIOL

intraocular lens which provides continuous focusing from far point to near point by changing the dioptric power of the eye

3.1.3

accommodative amplitude

difference in refractive power between the near point and the far point of the eye

3.1.4

additional wrapping

container used in addition to the primary packaging and which could be used to maintain sterility of the intraocular lens

3.1.5

addition power

difference between the distance power and the near power of the lens portion, measured under specified conditions

3.1.6

anterior chamber lens

anterior chamber intraocular lens

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

3.1.7

aspheric intraocular lens

intraocular lens having at least one surface with a monotonically continuously variable curvature from the vertex to the periphery

3.1.8

axis mark

indicator of the meridian of lowest optical power

3.1.9

base power

distance power

far power

power that is intended to provide an in-focus image of an object at far (infinite)

3.1.10

best-case subject

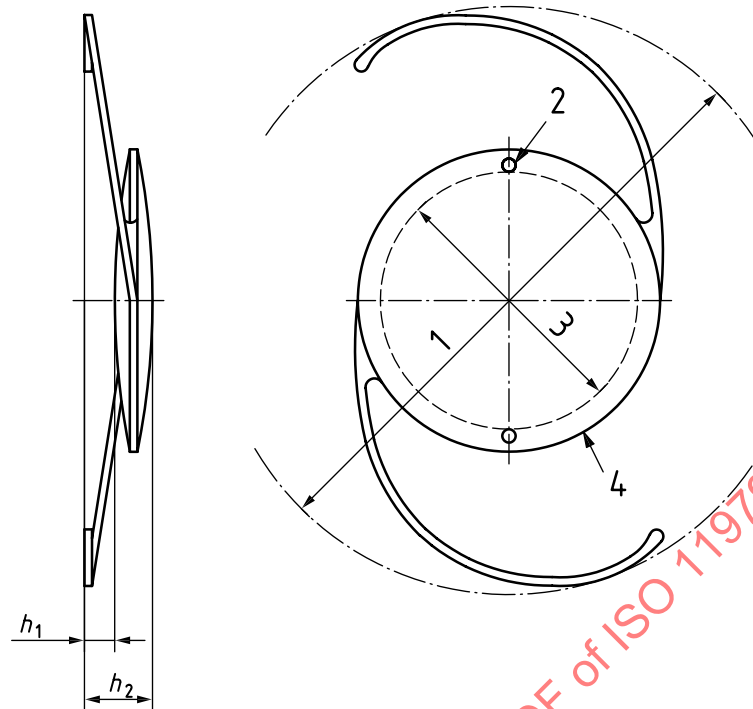
subject with no pre-operative ocular pathology, no macular degeneration detected at any time, and no previous surgery for the correction of refractive errors

3.1.11

body

central part of an intraocular lens incorporating the optic

Note 1 to entry: See [Figure 1](#).

**Key**

- 1 overall diameter
- 2 positioning hole
- 3 clear optic
- 4 body
- h_1 vault height
- h_2 sagittal distance

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

3.1.12**clear optic**

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

Note 1 to entry: See [Figure 1](#).

3.1.13**closed-loop IOL**

IOL model, which contains two or more loops, each loop having both ends attached to the body of the optic

3.1.14**compression force**

force exerted by the loops of the IOL when compressed to a given diameter

3.1.15**cumulative adverse events**

total number of adverse events that have occurred at any time up to a specified time point post-operatively

3.1.16

custom-made device

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 1 to entry: 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.

3.1.17

cut-off wavelength

minimum wavelength at which transmission drops below defined level

3.1.18

cylindrical power

difference in dioptric power between the meridians with the highest and the lowest dioptric powers

3.1.19

device history record

collection of records and reports assembled in a batch package, containing, or referring to, the relevant information pertaining to the manufacture and control of that batch of devices

3.1.20

device

<clinical investigation> device intended for use by a duly qualified medical practitioner when conducting a clinical investigation

3.1.21

dioptric power

reciprocal of the reduced paraxial focal length in situ for light with a wavelength of 546,07 nm, where paraxial focal length is the distance between the back principal plane and the back paraxial focal point, and reduced paraxial focal length is the paraxial focal length divided by the refractive index of the surrounding medium

Note 1 to entry: 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.

3.1.22

delivery system

instrument(s) or system used to implant the IOL in the eye

3.1.23

distance power configuration

configuration of an accommodating intraocular lens in the eye that is intended to result in a distant object being in focus in the retinal plane

3.1.24

expiration date

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

3.1.25

far point

farthest distance at which one can focus on an object

3.1.26

far power

power that is intended to provide an in-focus image of a far object

3.1.27**finished intraocular lens lot**

specific quantity of intraocular lenses that is intended to have uniform characteristics and quality, within specified limits, which is produced according to a single manufacturing order or during the same cycle of manufacture, and is packaged, labelled and sterilized

3.1.28**haptic**

non-optical, generally peripheral, component of an intraocular lens that is intended to keep the intraocular lens in place in the eye

3.1.29**hybrid open-loop closed-loop IOL**

IOL model which contains two or more loops, with one loop having one end attached to the body of the IOL and the other end free, and with the other loop having both ends attached to the body of the IOL

3.1.30**indicator of meridian with lowest dioptric power**

physical identification of the meridian with the lowest dioptric power

3.1.31**injector system**

delivery system in which the IOL is compressed and/or folded and implanted through a cannula

3.1.32**in situ**

in equilibrium with aqueous humour at $35\text{ °C} \pm 2\text{ °C}$

3.1.33**intraocular lens****IOL**

ophthalmic lens intended for implantation inside the eye

3.1.34**intraocular lens model**

identification by which the features of an intraocular lens, including its body and its haptics, general optical design features, and the material(s) used in its construction, have been fully specified

Note 1 to entry: Any significant change in the specification of the materials (including their formulation or synthesis procedures) will result in it being considered a new model.

3.1.35**loop**

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

Note 1 to entry: Loops are parts of the haptic, or can be the haptic.

3.1.36**lost to follow-up subject**

subject that has missed the final post-operative case report form and for which there is no information available

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

3.1.37

manufacturer

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 himself or on his behalf by a third party

Note 1 to entry: 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 own name.

3.1.38

material degradation test

test that determines the potential for degradation of a material

3.1.39

meridian of highest dioptric power

meridian with the most positive or least negative dioptric power which is orthogonal to the meridian of lowest dioptric power

3.1.40

meridian of lowest dioptric power

meridian with the least positive or most negative dioptric power which is orthogonal to the meridian of highest dioptric power

3.1.41

monofocal intraocular lens

intraocular lens having one primary focus

3.1.42

multifocal intraocular lens

MIOL

intraocular lens having two or more foci

3.1.43

multi-piece intraocular lens

intraocular lens assembled from separate loop and body components

Note 1 to entry: Intraocular lens with a body and two loops is often referred to as a 3-piece intraocular lens.

3.1.44

Nd-YAG laser exposure test

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

3.1.45

near point

nearest distance at which one can focus on an object

3.1.46

near power

power that is intended to provide an in-focus image of a near object

3.1.47

near power configuration

configuration of the accommodating intraocular lens in the eye that is intended to result in a near object in focus in the retinal plane

3.1.48

non-ocular implantation test

test that evaluates the reciprocal tolerance of a test material and local tissue after implantation of the test material in a non-ocular site in an animal

3.1.49**null lens**

lens used to neutralize toric lens cylinder power

3.1.50**ocular implantation test**

test that evaluates the reciprocal tolerance of a test material and local tissue after implantation into the anterior segment of the eye of an appropriate animal

3.1.51**one-piece intraocular lens**

intraocular lens where the haptic is an integral part with the body

3.1.52**open-loop IOL**

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

3.1.53**optic**

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

3.1.54**optical power of the eye**

reciprocal of the reduced focal length of an eye

3.1.55**optic decentration**

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

3.1.56**optic shape factor**

term associated with the curvatures of the refracting surfaces of the optic (e.g. plano-convex, bi-convex)

$$S = \frac{R_1 + R_2}{R_1 - R_2}$$

where

S is the shape factor;

R_1 is the vertex radius of the anterior surface with respect to the eye;

R_2 is the vertex radius of the posterior surface with respect to the eye.

3.1.57**optic tilt**

angle between the optical axis in the uncompressed state and that in the compressed state, with the intra-ocular lens being confined to a prescribed diameter

3.1.58**overall diameter**

diameter of the cylinder circumscribing an intraocular lens, just making contact with it, be it haptic or optic, with the axis of the cylinder being coincident with the optical axis of the intraocular lens

Note 1 to entry: See [Figure 1](#).

3.1.59

package integrity

container's ability to protect the intraocular lens from contamination

3.1.60

paraxial focal length

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

3.1.61

parent intraocular lens model

intraocular lens model that a manufacturer has qualified based on a clinical investigation based on the requirements of all parts of ISO 11979

3.1.62

persistent adverse event

adverse event that is present at the conclusion of a clinical investigation

3.1.63

phakic intraocular lens

PIOL

intraocular lens, the primary indication for which is the modification of the refractive power of a phakic eye

3.1.64

positioning hole

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

Note 1 to entry: See [Figure 1](#).

3.1.65

posterior chamber lens

posterior chamber intraocular lens

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

3.1.66

pre-loaded delivery system

package for the IOL with the additional functionality to act as delivery system

3.1.67

primary package

container that physically and directly protects the intraocular lens, and which could maintain sterility

3.1.68

reduced focal length

focal length divided by the refractive index of the medium in image space

3.1.69

sagittal distance

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

Note 1 to entry: See [Figure 1](#).

3.1.70

self-adhesive label

label included in the storage container for hospital record use

3.1.71

shelf-life

period during which an intraocular lens remains suitable for implantation in the human eye