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Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

Implants ophtalmiques — Lentilles intraoculaires —

Partie 1: Vocabulaire

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Foreword

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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

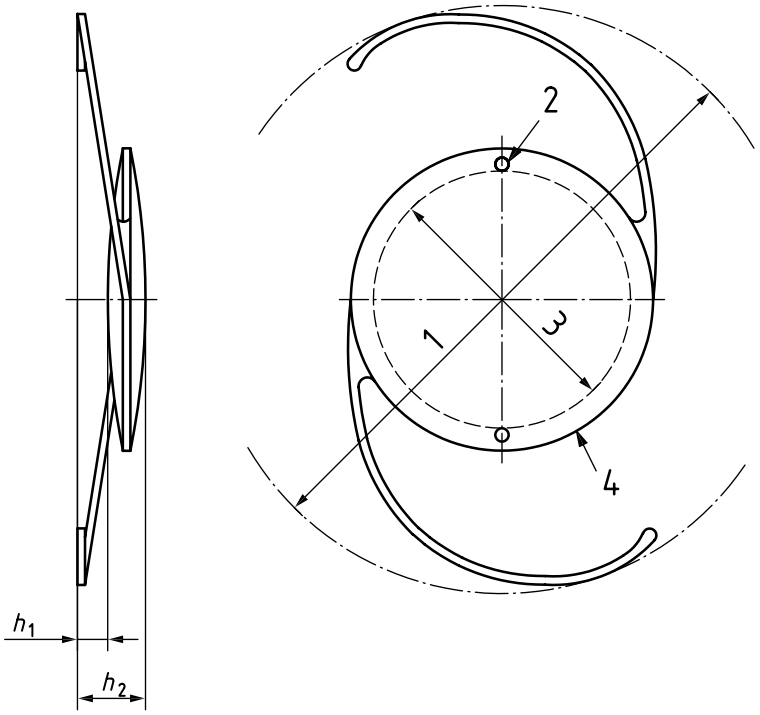
3.1.8
axis mark
indicator of the meridian of lowest optical power

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 °C ± 2 °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.