International Standard

ISO 11979-1

Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

Implants ophtalmiques — Lentilles intraoculaires —

Partie 1: Vocabulaire

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Foreword

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This fifth edition cancels and replaces the fourth edition (ISO 11979-1:2018), which has been technically revised.

The main changes are as follows:

— definitions of non-accommodative posterior chamber “simultaneous vision” (SVIOL) lenses that include the subtypes of MIOL (multifocal), EDF (extended depth of focus) and FVR (full visual range) IOLs have been added;

— definitions of properties related to SVIOLs have been added.

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

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Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

1 Scope

This document contains definitions of terms related to intraocular lenses as well as definitions related to the methods used to evaluate these IOLs.

NOTE The terms are listed in the alphabetical order of the English terms.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
accelerated shelf-life study
study to establish an initial expiration dating period by using exaggerated storage conditions by increased temperature to be validated by real time study

3.2
accommodating intraocular lens
AIOL
IOL providing focusing from far point to near point by changing the dioptric power of the eye

3.3
accommodative amplitude
difference in refractive power between the near point and the far point of the eye

3.4
addition power
difference between the far power and the near power

3.5
additional wrapping
protective packaging used in addition to the primary packaging which can be used to maintain sterility of the intraocular lens

3.6
anterior chamber lens
IOL designed to be placed entirely in the anterior chamber of the eye

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3.7
aspheric intraocular lens
IOL having at least one optical surface whose curvature varies radially from the vertex to the periphery

3.8
axial displacement in compression
displacement of optic along the optical axis when the IOL is compressed to a specified diameter taking the uncompressed state as reference

3.9
axis mark
indicator of the meridian of lowest dioptric power of a toric IOL

Note 1 to entry: See Figure 1.

3.10
back focal length
BFL
distance from the back vertex of the IOL to the focal point with collimated light incident on-axis upon the IOL

3.11
base power
dioptric power that is intended to provide an in-focus image of an object at far (infinity)

Note 1 to entry: Base power is the same as far power.

3.12
best-case subject
subject with no pre-operative ocular pathology detected at any time, e.g. no macular degeneration, and no previous surgery for the correction of refractive errors

3.13
body
part of an IOL incorporating the optic excluding the haptics

Note 1 to entry: See Figure 1.

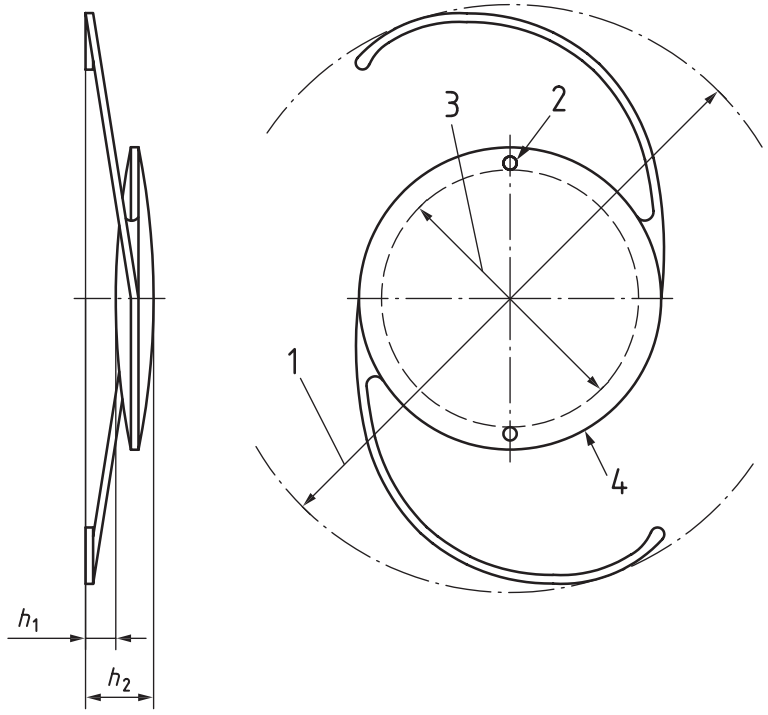
3.14
clear optic
diameter of concentric circle with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

Note 1 to entry: See Figure 1.

3.15
closed-loop intraocular lens
IOL model which contains two loops, each loop having both ends attached to the body of the optic

3.16
compression force
force exerted by the haptics of the IOL when compressed to a specified diameter

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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, positioning hole and axis mark

3.17
cumulative adverse events
total number of adverse events that have occurred at any time up to a specified post-operative time point

3.18
custom-made device
device specifically made in accordance with a duly qualified medical practitioner's written prescription, which gives, under his/her 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.

3.19
cut-off wavelength
wavelength at which spectral transmission drops below a defined level

3.20
cylindrical power
difference in dioptric power between the meridians with the highest and the lowest dioptric powers

3.21
delivery system
system, either preloaded or combined, in which the IOL is compressed and/or folded and delivered into the eye

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3.22
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

3.23
dioptric power
reciprocal of the reduced paraxial focal length in situ, 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.

Note 2 to entry: Refer to ISO 11979-2 for the test conditions.

Note 3 to entry: For certain IOL optical designs, the use of paraxial focal length is not appropriate.

3.24
dynamic fatigue
durability of an IOL following cyclic compressive loading of the IOL haptic to a specified dimension

3.25
effective focal length
EFL
distance from the back principal plane to the focal point with collimated light incident on-axis upon the IOL

3.26
expiration date
termination of shelf-life, after which the IOL is not to be used

3.27
extended depth of focus intraocular lens
EDF IOL
SVIOL providing useful visual acuity levels from far through intermediate focal distances

Note 1 to entry: Useful visual acuity levels are provided in ISO 11979-7.

3.28
far point
farthest distance at which an object can be focused on

3.29
far power
dioptric power that is intended to provide an in-focus image of an object at far (infinity)

Note 1 to entry: Far power is the same as base power.

3.30
far power configuration
configuration of an accommodating intraocular lens in the eye that is intended to result in a distant object being in focus on the retinal plane

3.31
finished intraocular lens lot
specific quantity of uniform IOLs intended to fall within a set of specified characteristics produced according to a single manufacturing order or during the same cycle of manufacture, and completed by sterilization, packaging and labelling

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3.32
full visual range intraocular lens
FVR IOL
SVIOL providing useful visual acuity levels from far through intermediate and up to near focal distances

Note 1 to entry: Useful visual acuity levels are provided in ISO 11979-7.

3.33
haptic
non-optical peripheral component of an IOL that is intended to keep the IOL in place and centrates it to the optical axis of the eye

3.34
hybrid open-loop/closed-loop intraocular lens
IOL model that 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

3.35
in situ
condition matching aqueous humour at 35 °C ± 2 °C

3.36
intraocular lens
IOL
ophthalmic lens intended for implantation inside the eye

3.37
intraocular lens model
series of IOLs which are identical in all design specifications except for features related to base power and cylindrical power such as optic central thickness

3.38
loop
type of haptic, either a peripheral extension of the body or a filament attached to the body at one or more points serving to position the IOL in the eye

3.39
lost to follow-up subject
subject who has missed the post-operative case report form and for whom no information was available beyond that time

3.40
manufacturer
natural or legal person with responsibility for the design, manufacturing, packaging and labelling of a device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person or on their 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.

3.41
manufacturing date
date when the medical device is manufactured, as defined by the manufacturer and which can be tracked from the device history record (e.g. the date of starting manufacturing, the date of final packing, the date of sterilization)

3.42
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

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3.43
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

3.44
monofocal intraocular lens
IOL having only the base power

3.45
multifocal intraocular lens
MIOL
SVIOL providing useful acuity levels at far distance and also providing improved vision at near focal distance superior to monofocal IOL

Note 1 to entry: Useful visual acuity levels are provided in ISO 11979-7.

3.46
multi-piece intraocular lens
IOL assembled from separate haptics and body components

3.47
Nd-YAG laser exposure test
test that determines the physical and chemical effects of Nd-YAG laser exposure on a test material

3.48
near point
nearest distance at which an object can be focussed on

3.49
near power
power that is intended to provide an in-focus image of an object at near or intermediate distances

3.50
non-ocular implantation test
test that evaluates the mutual tolerance of a test material and local tissue after implantation of the test material in a non-ocular site in an animal

3.51
null lens
lens used to neutralize toric lens cylindrical power

3.52
objective refraction
combination of sphere and cylindrical powers that corrects the refractive errors of a subject´s eye determined by using techniques and instruments, without relying on the subject's responses or feedback, and/or process of its determination

3.53
ocular implantation test
test that evaluates biocompatibility of a test material after implantation in the eye of an appropriate animal

3.54
one-piece intraocular lens
IOL where the haptics are integrally bonded with the body manufactured together with the body from a single piece, or the haptics are made of the same material

3.55
open-loop intraocular lens
IOL model which contains two loops, each loop having one end attached to the body of the IOL and the other end free

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3.56
optic
image-forming component of an IOL

3.57
optic decentration
displacement between the centre of optic body and the centre of well when compressed to a specified diameter in the well

3.58
optic shape factor
factor 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

3.59
optic tilt
angle between the optical axis in the uncompressed state and that in the compressed state, with the intraocular lens being confined to a specified diameter

3.60
optical power of the eye
reciprocal of the reduced focal length of an eye

3.61
overall diameter
diameter of the circumscribing geometric cylinder of an IOL

Note 1 to entry: The axis of cylinder being parallel with the optical axis of the IOL.

Note 2 to entry: See Figure 1.

3.62
package system
combination of a sterile barrier and mechanical protection

3.63
paraxial focal length
distance between the back principal plane and the back paraxial focal point

3.64
parent intraocular lens model
IOL model that a manufacturer has qualified based on a clinical investigation

Note 1 to entry: This lens model meets the requirements of all applicable parts of the ISO 11979 series.

3.65
patient information leaflets
PIL
information material providing information that can be used to inform patients and help the discussions on the decision to implant a type of medical device

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3.66
patient implant card
PIC
information material used to record the details of the specific device implanted in the patient to enable improved traceability of the device after the surgery

3.67
persistent adverse event
adverse event that is present at the end of a clinical investigation

3.68
phakic intraocular lens
PIOL
IOL with indication to correct the refractive power of a phakic eye

3.69
phakic multifocal intraocular lens
PMIOL
PIOL providing far power and at least one addition power providing near vision superior to monofocal PIOL

3.70
phakic toric intraocular lens
PTIOL
PIOL providing different powers in orthogonal meridians

3.71
plate haptic intraocular lens
IOL having a solid haptic partially surrounding or extending from the optic body

3.72
positioning hole
hole, whether penetrating or not, intended to be used for surgical manipulation

Note 1 to entry: See Figure 1.

3.73
posterior chamber lens
posterior chamber intraocular lens
IOL designed to be placed entirely in the posterior chamber of the eye

3.74
pre-loaded injector system
single-use delivery system or part thereof that is packaged and sterilized with a pre-placed IOL

3.75
primary package
packaging that comes into direct contact with the IOL

3.76
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

3.77
reduced focal length
focal length divided by the refractive index of the medium in image space

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3.78
sagittal distance
maximum distance between the planes, normal to the optical axis, which contact the most anterior and the most posterior points, be it haptic or optic, of an uncompressed IOL

Note 1 to entry: See Figure 1.

3.79
seal/closure integrity
packaging characteristics of a closure to minimize the risk of ingress of microorganisms

3.80
self-adhesive label
label included in the protective packaging with specific information of the IOL

3.81
shelf-life
period during which an IOL remains suitable for implantation in the human eye

3.82
simulated visual acuity
predicted visual acuity computed using measured modulation transfer function value(s) or other objective optical performance metrics/objective optical tests

3.83
simultaneous vision intraocular lens
SVIOL
non-accommodative IOL providing simultaneous vision at multiple distances

Note 1 to entry: Sub-categories are MIOL, FVR IOL and EDF IOL.

3.84
spherical equivalent power
mean of the dioptric powers in the meridians with the highest and lowest dioptric powers

3.85
spherical intraocular lens
IOL in which both optical surfaces consist of a segment from a sphere with same dioptric power on all meridians, one of the surfaces may also potentially be flat

3.86
stability
extent to which a product retains properties and characteristics within the manufacturer's specified limits, throughout its period of storage such as shelf-life or transport

3.87
sterile barrier system
package to minimize the risk of ingress of microorganisms

3.88
sterilization load
quantity of products to be, or that have been, sterilized together using a given sterilization process

3.89
subjective refraction
combination of sphere and cylinder correction that optimizes a subject´s visual acuity utilizing the subject's response, and/or process of its determination

3.90
surgical manipulations
manipulations of an IOL that take place during the surgical implantation procedure that the IOL, especially the haptics, must withstand without failure

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3.91
test material
sterile finished IOL as intended for human implantation, or representative sample material manufactured and processed using a procedure equivalent to that used for the IOL

Note 1 to entry: If using IOLs as test material, it is preferable to choose lenses with powers within ±2 D of the mean of the power range, e.g. in general 18 D to 22 D.

3.92
test of photostability
test that determines the potential for degradation of a test material due to exposure to light

3.93
toric intraocular lens
TIOL
IOL having different powers in orthogonal meridians

3.94
vault height
distance from a plane normal to the optical axis, containing the point most proximal to the iris of the uncompressed haptic of an IOL, to the plane normal to the optical axis, containing the vertex of the iris proximal optical surface

Note 1 to entry: See Figure 1.

Note 2 to entry: The iris proximal side of the IOL refers to the intended position as implanted.

Note 3 to entry: The vault height is positive if the distance defined is in the direction towards the retina as implanted, and negative if not.

3.95
vertex
point of intersection of the optical axis with the surface of a lens

3.96
visual acuity
number characterizing the ability of the visual system to recognize optotypes

4 Abbreviated terms

The following abbreviations are used:

CDVA	corrected distance visual acuity
CNVA	corrected near visual acuity
DCIVA	distance corrected intermediate visual acuity
DCNVA	distance corrected near visual acuity
UDVA	uncorrected distance visual acuity
UIVA	uncorrected intermediate visual acuity
UNVA	uncorrected near visual acuity
PRO	patient reported outcome
SE	spherical equivalent power
CYL	cylindrical power

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