INTERNATIONAL STANDARD

ISO 11979-4

First edition
2000-06-15

Ophthalmic implants — Intraocular lenses —

Part 4: Labelling and information

Implants ophtalmiques — Lentilles intraoculaires —
Partie 4: Étiquetage et informations

Reference number
ISO 11979-4:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 11979 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11979-4 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 11979 consists of the following 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*

Annex A of this part of ISO 11979 is for information only.

Introduction

This part of ISO 11979 contains requirements and guidance for the labelling of intraocular lenses and the information supplied with them.

Labelling requirements for medical devices in general are given in EN 1041. However, in order to provide correct and necessary information to the ophthalmic surgeon, some additional information is required for intraocular lenses. This information concerns technical and optical data as well as information about the materials used.

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 11979-4 and EN ISO 11979-4). 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 4:
Labelling and information

1 Scope

This part of ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.

NOTE This part of ISO 11979 attempts to harmonize the recognized labelling requirements for IOLs throughout the world. However, there may be additional national requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply.

NOTE Some terms and definitions of ISO 11979-1 relevant to this part of ISO 11979 are reproduced for information in annex A.

4 Labelling

Table 1 lists minimal information that shall be included in the labelling of intraocular lenses and indicates where on the packaging it shall be given. Table 2 lists additional information that shall be given if applicable.

Table 1 — Information to be included with the packaging of intraocular lenses

Item	Information	Location		Comments
		Primary package and/or additional wrapping(s)[a]	Storage container	
1	Name or trade name of the manufacturer	X	X	The manufacturer's logotype may be added
2	Address of the manufacturer and country of manufacture		X	
3	Trade name and/or model designation of the product	X	X	
4	Batch code or serial number	X	X	The symbol(s) given in EN 980 may be used
5	The word "STERILE"	X	X[b]	The symbol(s) given in EN 980 may be used
6	Method of sterilization		X	Standardized symbol(s) may be used (revision of EN 980 in preparation)
7	The statement "Do not resterilize"		X	
8	The statement "For single use"		X	The symbol given in EN 980 may be used
9	Expiration date (year and month; format: YYYY MM)		X	The symbol given in EN 980 may be used
10	Dioptric power	X	X	The unit is the reciprocal metre (m^{-1}); in ophthalmic optics often denoted by the symbol D for dioptre
11	Overall diameter, in mm	X	X	May be indicated by the symbol ∅ or in a drawing
12	Diameter (min. and max. dimensions if non-circular) of the body, in mm	X	X	May be indicated in a drawing
13	Drawing depicting the configuration of the lens		X	
14	Statement about intended placement		X	For instance anterior chamber; posterior chamber; in the bag; etc.
15	Information aiding the surgeon to calculate the dioptric power to implant		X	At this time, there is no standardized methodology available

[a] Different systems are in use with regard to primary container and additional wrapping(s). The information listed in this column shall be given on the appropriate component to guarantee safe use and proper handling of the device.

[b] If a statement about sterility is made on the storage container, it shall read "contains (number) sterile intraocular lens(es)", if the storage container contains more than one IOL.

Table 2 — Information to be included with the packaging of intraocular lenses if applicable

Item	Information	Location		Comments
		Primary package and/or additional wrapping(s) [a]	Storage container	
16	Additional descriptions the manufacturer wishes to provide		X	For instance about optic shape, type and material; haptic type and material; UV-absorber; foldable; etc.
17	Statement “Custom made device”		X	
18	Statement “Exclusively for clinical investigation”		X	

[a] Different systems are in use with regard to primary container and additional wrapping(s). The information listed in this column shall be given on the appropriate component to guarantee safe use and proper handling of the device.

5 Package insert

The package insert, in the form of a leaflet or similar, shall be included in the storage container in such a way that it can be consulted without damage to the sterile packaging. It shall contain at least the following information:

a) name or trade name and address of the manufacturer;

b) detailed description of the lens, including material(s) used;

c) method of sterilization;

d) conditions of storage and transport (if appropriate);

e) instructions for the removal of the IOL from the primary container;

f) instructions for use;

g) indication(s) of the circumstances under which the IOL can be used;

h) contraindication(s) of the circumstances under which the IOL should not to be used;

i) complication(s) that may occur;

j) warning not to implant the IOL if the container which maintains sterility has been opened or damaged;

k) warning not to re-use the IOL;

l) warning not to re-sterilize the IOL;

m) other appropriate warning(s).

6 Self-adhesive label

If supplied, a self-adhesive label shall contain at least the following information:

a) name or trade name of the manufacturer;