

This is a preview of "ISO 11979-3:2012". [Click here to purchase the full version from the ANSI store.](#)

Third edition
2012-12-01

Ophthalmic implants — Intraocular lenses —

Part 3: Mechanical properties and test methods

*Implants ophtalmiques — Lentilles intraoculaires —
Partie 3: Propriétés mécaniques et méthodes d'essai*



Reference number
ISO 11979-3:2012(E)

© ISO 2012

This is a preview of "ISO 11979-3:2012". Click here to purchase the full version from the ANSI store.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

This is a preview of "ISO 11979-3:2012". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	1
4.1 General.....	1
4.2 Tolerances and dimensions.....	2
4.3 Clearance analysis (anterior chamber lenses only).....	2
4.4 Compression force.....	2
4.5 Axial displacement in compression.....	2
4.6 Optic decentration.....	3
4.7 Optic tilt.....	3
4.8 Angle of contact.....	3
4.9 Compression force decay.....	3
4.10 Dynamic fatigue durability.....	3
4.11 Surgical manipulation.....	4
4.12 Surface and bulk homogeneity.....	4
5 Recovery of properties following simulated surgical manipulation	4
6 Additions for accommodating IOLs (AIOLs)	4
Annex A (normative) Measurement of compression force	6
Annex B (normative) Measurement of axial displacement in compression	9
Annex C (normative) Measurement of optic decentration	12
Annex D (normative) Measurement of optic tilt	15
Annex E (normative) Measurement of angle of contact	19
Annex F (normative) Testing of compression force decay	22
Annex G (normative) Testing of dynamic fatigue durability	23
Annex H (informative) Measurement of loop pull strength	25
Annex I (informative) Clearance analysis	27
Annex J (informative) Precision	30
Bibliography	31

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11979-3 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-3:2006), which has been technically revised in order to include relevant requirements and test methods for toric intraocular lenses and accommodating intraocular lenses.

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*
- *Part 9: Multifocal intraocular lenses*
- *Part 10: Phakic intraocular lenses*

This is a preview of "ISO 11979-3:2012". [Click here to purchase the full version from the ANSI store.](#)

Introduction

This part of ISO 11979 contains methods for which requirements are given and methods for which no requirements are formulated. The former are considered essential for the safety or performance of the intraocular lens, while the latter provide essential information to the ophthalmic surgeon or are used for other purposes.

A special purpose is the use of mechanical data to assess the need for clinical investigation of modifications of existing models as described in ISO 11979-7^[7]. Because of the complexity of this analysis, detailed descriptions and examples have been given in ISO/TR 22979^[8]. Due to the wide variety of intraocular lens designs already on the market, it has not been possible to devise test methods that are applicable to every design under all circumstances. It can be anticipated that new materials currently under development will result in drastically new designs that will require modified or other test methods. As with all standards, it is then up to the parties using the standard to modify or develop corresponding methods and give rationale and validation for them in a spirit that is consistent with this part of ISO 11979.

In cases where different tolerances have been given depending on material or design, they reflect an existing situation with well-established products.