

American National Standard

*for Ophthalmics –
Phakic Intraocular Lenses*



Currently in preview, click buy full version

ANSI®
Z80.13-2007 (R2017)
Reaffirmation of
ANSI Z80.13-2007 (R2012)

American National Standard
for Ophthalmics –
Phakic Intraocular Lenses

Secretariat
The Vision Council

Approved March 26, 2007
Reaffirmed April 16, 2012
Reaffirmed December 11, 2017

American National Standards Institute, Inc.

American National Standard

Approval of an American National Standard requires review by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgement of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made towards their resolution.

The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards.

The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council
Z80 Secretariat
225 Reinekers Lane, Suite 700
Alexandria, VA 22314

Published by

The Vision Council
225 Reinekers Lane, Suite 700
Alexandria, VA 22314

Copyright © 2017 by The Vision Council
All rights reserved.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America

Contents

	Page
Foreword	iv
1 Scope and purpose.....	1
2 Normative references.....	1
3 Definitions	2
4 Physical requirements.....	2
4.1 Scope.....	2
4.2 Requirements.....	2
4.2.1 Tolerances and dimensions	2
5 Optical requirements.....	2
5.1 Scope.....	2
5.2 Requirements.....	2
5.2.1 Dioptric power	2
5.2.2 Imaging quality.....	2
5.2.3 Spectral transmittance	2
6 Mechanical requirements.....	3
6.1 Scope.....	3
6.2 Requirements.....	3
6.2.1 Mechanical characterization	3
6.2.2 Mechanical testing	3
6.2.2.1 Surgical manipulation evaluation	3
6.2.2.2 Surface and bulk homogeneity	3
7 Biocompatibility requirements	3
7.1 Scope	3
7.2 General guidelines	3
7.3 Biological test requirements.....	4
7.4 In vivo biochemical test requirements	4
8 Sterility/package integrity requirements	4
8.1 Scope.....	4
8.2 Requirements.....	4
9 Shelf-life and transport stability.....	5
9.1 Scope.....	5
9.2 Requirements.....	5
10 Clinical investigation plan.....	5
10.1 Scope.....	5
10.2 Clinical investigation plan.....	5
11 Labeling	6

Annexes

A	Mechanical characterization and testing of phakic IOLs.....	8
A.1	General	8
A.2	Mechanical characterization	8
A.2.1	Anatomical placement analysis	8
A.2.2	Clear optic diameter.....	8
A.2.3	Compression force.....	8
A.2.4	Compression force decay	8
A.2.5	Axial displacement in compression.....	9
A.2.6	Angle of contact	9
B	Non-ocular implantation test	10
C	Ocular implantation test	11
C.1	Purpose	11
C.2	Test material	11
C.3	Control material	11
C.4	Appratus and supplies	11
C.5	Test procedure.....	11
C.6	Intraoperative observations	12
C.7	Implantation period	12
C.8	Test evaluations.....	13
C.8.1	Postoperative evaluations.....	13
C.8.2	Evaluation of enucleated eyes.....	13
C.8.3	Evaluation of explant lenses	13
D	Clinical guidance	15
D.1	General	15
D.2	Objectives	15
D.3	Design.....	15
D.3.1	Investigation duration.....	15
D.3.2	Enrollment of subjects	15
D.3.3	Inclusion and exclusion criteria for subject selection	16
D.3.3.1	Inclusion criteria.....	16
D.3.3.2	Exclusion criteria.....	17
D.3.4	Examination schedules.....	18

	Page
D.4	Clinical tests 18
D.4.1	Visual acuity 21
D.4.1.1	Luminance..... 22
D.4.1.2	Data recording procedures..... 22
D.4.2	Specular microscopy 22
D.4.3	Contrast sensitivity 24
D.4.4	Crystalline lens status 25
D.4.5	Mesopic pupil size..... 25
D.4.6	Slit lamp exam..... 25
D.4.7	Measurement of intraocular pressure 26
D.4.8	Anatomical placement substudy 26
D.4.9	Subject questionnaire..... 26
D.5	Investigation analyses..... 27
D.5.1	Safety analyses..... 27
D.5.2	Effectiveness analyses..... 28
D.5.3	Accountability analysis 28
D.6	Adverse events and adverse device effects..... 30
E	Statistical sample size considerations..... 31
E.1	General 31
E.2	Sample size guidance 31
E2.1	Safety and performance evaluation 32
E.2.2	Contrast sensitivity substudy..... 33
F	Bibliography 35
Tables	
D.1	Recommended minimum endothelial cell density 17
D.2	Recommended postoperative examination schedule 19
D.3	Accountability at each postoperative visit 29
E.1	Confidence interval parameter definitions..... 32
E.2	Normal distribution statistics and parameters 32
E.3	Normal quantities to use in equations 32

Foreword (This foreword is not part of American National Standard ANSI Z80.13-2007 (R2017).)

ANSI Z80.13-2007, Ophthalmics - Phakic intraocular lenses, was developed by a group of experts consisting of scientists, industrialists, government regulators and clinicians among them developers and/or manufacturers of such lasers. This standard applies to the physical and mechanical properties and performances as well as material biocompatibility and describes elements of clinical protocol to be used to assess the clinical performance of these devices with the crystalline lens in place to correct refractive errors. The standard also contains informative sections.

Suggestions for improvements of the standard are welcome. These should be sent to The Vision Council, 225 Reinkers Lane, Suite 700, Alexandria, VA 22314.

American National Standard for Ophthalmics –

Phakic Intraocular Lenses

1 Scope and purpose

This standard applies to any intraocular lens (IOL) whose primary indication is the modification of the refractive power of a phakic eye. It does not include IOLs used to correct presbyopia or astigmatism.

This standard addresses the vocabulary, optical properties and test methods, mechanical properties and test methods, labeling, biocompatibility, sterility, shelf-life and transport stability, and clinical investigations necessary for this type of device. As applies to any standard, alternative validated test methods may be used.

2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this American National Standard. All standards are subject to revision and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of the IEC and ISO maintain registers of currently valid International Standards.

ANSI Z80.7-2002, *Ophthalmics – Intraocular lenses*

Good Laboratory Practices (GLP), U.S. Code of Federal Regulations, 21, Part 58

ISO 10993-2:1998, *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

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

ISO 11979-2:1999, *Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods*

ISO 11979-3:1999, *Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods*

ISO 11979-5:1999, *Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility*

ISO 11979-6:2002, *Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability*

ISO 14155-1:2003, *Clinical investigation of medical devices - Part 1: General Requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices - Part 2: Clinical investigation plans*