

ANSI Z80.29-2015 (R2020)

# American National Standard

*for Ophthalmics –  
Accommodative Intraocular Lenses*

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**Z80.29-2015 (R2020)**  
Reaffirmation of  
ANSI Z80.29-2015

American National Standard  
for Ophthalmics –

## Accommodative Intraocular Lenses

Secretariat

**The Vision Council**

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### *Developed by*

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## Contents

	Page
Foreword .....	iv
<b>1</b> Scope and purpose .....	1
<b>2</b> Normative references .....	1
<b>3</b> Definitions .....	2
<b>4</b> Physical requirements .....	2
4.1 Scope .....	2
4.2 Requirements .....	2
4.2.1 Tolerances and dimensions .....	3
<b>5</b> Optical requirements .....	3
5.1 Scope .....	3
5.2 Requirements .....	3
5.2.1 Optical characterization .....	3
5.2.2 Dioptric power .....	3
5.2.3 Imaging quality .....	3
5.2.4 Spectral transmittance .....	4
<b>6</b> Mechanical requirements .....	4
6.1 Scope .....	4
6.2 Requirements .....	4
6.2.1 Mechanical characterization .....	4
6.2.2 Mechanical Testing .....	4
<b>7</b> Biocompatibility requirements .....	5
7.1 Scope .....	5
7.2 General Guidelines .....	5
7.3 Biological test requirements .....	5
7.4 Physicochemical test requirements .....	5
<b>8</b> Sterility/package integrity requirements .....	6
8.1 Scope .....	6
8.2 Requirements .....	6
<b>9</b> Shelf-life and transport stability requirements .....	6
9.1 Scope .....	6
9.2 Requirements .....	6
<b>10</b> Clinical evaluation .....	6
10.1 Scope .....	6
10.2 Clinical investigation plan .....	6
10.3 Effectiveness requirements .....	7
<b>11</b> Labeling .....	8

	Page
<b>Annexes</b>	
<b>A</b> Optical characterization .....	9
A.1 General .....	9
A.2 Optical characterization .....	9
A.2.1 Theoretical evaluation.....	9
A.2.2 Optical testing .....	9
<b>B</b> Clinical investigation .....	10
B.1 General .....	10
B.1.1 Clinical measurements .....	11
B.2 Objectives of the clinical investigation .....	11
B.3 Design of the clinical investigation .....	11
B.3.1 Investigation duration.....	12
B.3.2 Enrollment of subjects .....	13
B.3.3 Inclusion and exclusion criteria for subject selection .....	13
B.3.3.1 Inclusion criteria .....	13
B.3.3.2 Exclusion criteria.....	13
B.3.4 Examination schedule.....	14
B.4 Clinical tests.....	17
B.4.1 Visual acuity and manifest refraction .....	17
B.4.1.1 Minimum near add procedure at 40 cm .....	18
B.4.1.2 Luminance .....	19
B.4.1.3 Data recording procedures .....	19
B.4.2 Specular Microscopy .....	19
B.4.3 Contrast sensitivity.....	19
B.4.4 Pupil size .....	20
B.4.5 Slit lamp exam .....	20
B.4.6 Measurement of intraocular pressure .....	21
B.4.7 Subject questionnaire .....	21
B.4.8 Accommodation measures .....	21
B.4.8.1 Objective accommodation measures.....	21
B.4.8.1.1 Objective optical/refractive methods.....	22
B.4.8.1.1.1 Autorefractors .....	22
B.4.8.1.1.2 Wavefront aberrometry .....	22
B.4.8.1.2 Objective biometric methods .....	22
B.4.8.2 Subjective accommodation measures .....	24
B.4.8.2.1 Defocus curves .....	24
B.4.8.2.2 Push-down test .....	25
B.4.9 Reading ability test .....	26
B.5 Investigation analyses .....	27

	Page
B.5.1	Safety analyses ..... 27
B.5.2	Effectiveness analyses ..... 27
B.5.3	Accountability analyses ..... 29
B.5.4	Stability analyses ..... 30
B.5.4.1	Objective accommodative stability ..... 30
B.5.4.2	Manifest refraction spherical equivalent (MRSE) stability ..... 31
B.6	Adverse events and adverse device effects ..... 31
<b>C</b>	<b>Labeling for AIOLs ..... 32</b>
C.1	Scope ..... 32
C.2	Information to be found on the outer container ..... 32
C.3	Labeling for inner container and/or pouch ..... 32
C.4	Physician package insert ..... 32
C.5	Patient labeling ..... 33
<b>D</b>	<b>Determination of sample sizes for the clinical investigation ..... 34</b>
D.1	Statistical symbols and definitions ..... 34
D.2	Calculation of necessary sample sizes ..... 35
D.2.1	Sample size of the AIOL arm, based on safety considerations ..... 35
D.2.2	Sample size for the primary effectiveness endpoint ..... 35
D.2.3	Sample size based on effectiveness estimates using noninferiority hypothesis testing ..... 36
D.3	Substudies ..... 36
D.3.1	Sample size for a contrast sensitivity substudy ..... 36
<b>E</b>	<b>Bibliography ..... 37</b>
<b>Tables</b>	
<b>B.1</b>	<b>Minimum sample size (subjects) for evaluation ..... 12</b>
<b>B.2</b>	<b>Recommended postoperative examination schedule ..... 15</b>
<b>B.3</b>	<b>Accountability at each post-operative visit ..... 29</b>
<b>D.1</b>	<b>Symbol definitions ..... 34</b>
<b>D.2</b>	<b>Normal quantities to use in equations ..... 35</b>

**Foreword** (This foreword is not part of American National Standard ANSI Z80.29-2015 (R2020).)

This standard contains five annexes. Annex A is normative and is considered part of the standard. Annexes B through E are informative and are not considered part of the standard.

Suggestions for improvement of this standard are welcome. They should be sent to the Vision Council, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Optics, Z80. Committee approval of this standard indicates general consensus but in no way implies that all committee members voted for approval. At the time it approved this standard, the Z80 Committee had the following members:

Thomas C. White, M.D., Chairman  
 Guido Cappelli, Vice-Chairman  
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## American National Standard for Ophthalmics –

# Accommodative Intraocular Lenses

## 1 Scope and purpose

This standard applies to any ocular implant whose primary indication is the correction of aphakia and is designed to provide vision over a continuous range of distances by affecting a change in the vergence power of the eye resulting from the implant design that changes eye optical power or implant position in response to a stimulus. For the purposes of this standard, these implants are referred to as accommodative intraocular lenses (AIOLs).

This standard addresses specific requirements for AIOLs that are not addressed in the normative references, and include 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 with 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. At the time of publication, the editions indicated were valid. 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, *Ophthalmics – Intraocular lenses*

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

ISO 10993-6, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

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

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

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

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

ISO 11979-7, *Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations*

ISO/DIS 11979-8, *Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements*