American National Standard

for Ophthalmics –
Toric Intraocular Lenses

ANSI Z80.30-2010

Approved American National Standard
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Z80.30-2010

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for Ophthalmics –

Toric Intraocular Lenses

Secretariat

The Vision Council

Approved March 24, 2010

American National Standards Institute, Inc.

American National Standard

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Developed by

The Accredited Committee Z80 for Ophthalmic Standards

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Foreword (This foreword is not part of American National Standard ANSI Z80.30-2010.)

In 1985, the Z80 committee became an ANSI accredited standards committee. The scope of the Z80 committee is the development of standards for the field of ophthalmic optics.

The Z80.30 standard deals with toric intraocular lenses used to correct for astigmatism in either phakic or aphakic eyes. The Z80.30 committee originated from the Z80.7 committee on intraocular lenses. Intraocular lenses have become the most common functional prosthetic implanted in the world today. Reproducibility is such that these lenses are no longer meant just restore basic visual function but are expected to achieve excellent visual function. The Z80.30 standard addresses the additional requirements for a new generation of intraocular lenses that correct for pre-existing and surgically induced astigmatism. Unlike the Z80.7 standard, the Z80.30 toric standard is for both aphakic and phakic lenses.

This standard contains four annexes. Annex A is normative and is considered part of this standard. Annexes B, C, and D are informative and are not considered part of this standard.

Suggestions for improvement of this standard will be welcome. They should be sent to: The Vision Council, 1700 Diagonal Road, Suite 500, Alexandria, VA 22033

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Standards, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z80 Committee had the following members:

Thomas C. White, Chairperson
Quido Cappelli, Vice-Chairperson
Robert Rosenberg, Secretary
Ken Wood, Secretariat

Organization Represented	*Name of Representative*
Advance Medical Technologies Association	Douglas J. Fortunato
	Richard Courtney (Alt.)
	Glenn Davies (Alt.)
	Bernie Liebler (Alt.)
American Academy of Optometry	David S. Loshin
American Academy of Ophthalmology	Thomas C. White
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	Pradeep Ramulu (Alt.)
	Rebecca Hyder (Alt.)
American Ceramic Society	Lyle Rubin
	Herbert Hoover (Alt.)
American Glaucoma Society	Steven Gedde
	Douglas Rhee (Alt.)
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	Robert Rosenberg (Alt.)
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American Society of Cateract and Refractive Surgery	Stephen Klyce
	Jack T. Holladay (Alt.)
Contact Lens Institute	Stan Rogaski
	Peter Mathers (Alt.)
Contact Lens Manufacturer's Association	Quido Cappelli
	Jan Svochack (Alt.)
	John Walfoort (Alt.)

Organization Represented	*Name of Representative*
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	David Glasser (Alt.)
Food & Drug Administration	Don Calogero
	Robert James
National Association of Optometrists & Opticians	Nick Mileti
	Joe Dezenzo (Alt.)
	Franklin Rozak (Alt.)
Optical Laboratories Association	Daniel Torgersen
	Virginia (Susie) Lesher (Alt.)
	Richard Tinson (Alt.)
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Opticians Association of Amerca	Tom Hicks
	Chris Allen (Alt.)
Sunglass Association of America	Kenneth Frederick
	Scott MacGuffie (Alt.)
	Rick Van Arnam (Alt.)
US Leader to ISO TC 172/SC7	Charles E. Campbell
US Department of Veterans Affairs	John Townsend
	Sharon R. Atkin (Alt.)
The Vision Council	Jeff Endres
	Steve Drake (Alt.)
	Neil Roche (Alt.)
	Dick Whitney (Alt.)
	Kenneth Wo[illegible]

The subcommittee on Intraocular Lenses, which developed this standard, had the following members:

Carl Tubbs, SC4 Chair
George Green, AIOL Leader

Timothy Adkins	Richard DeRisio	Rick McCarley
Undraa Altangerel	David Evans	Barbara Niksch
Sheryl Berman	Barbara Fant	Donald Sanders
Michael Breen	Adrian Glasser	Robert Sheehan
Don Calogero	Emily Graham	Nicholas Tarantino
Jeannie Cecka	Gene Hilmantel	Bruce Weber
Jimmy Chacko	Rebecca Lyder	Ari Zak
Shiao Chang	Yasuhi[illegible]	Steven Ziemba

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Toric Intraocular Lenses

1 Scope and purpose

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

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

ANSI Z80.13-2007, *Ophthalmics – Phakic intraocular lenses*

ISO 10993-2:2006, *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

ISO 10993-6:1994, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

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*

ISO 11979-1:2006, *Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary*

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

ISO 11979-3:2006, *Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods*

ISO 11979-5:2006, *Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility*