American National Standard

for Ophthalmics –

Toric Intraocular Lenses

ANSI Z80.30-2018

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for Ophthalmics –

Toric Intraocular Lenses

Secretariat

The Vision Council

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American National Standard

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Foreword (This foreword is not part of American National Standard ANSI Z80.30-2018.)

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 preexisting 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, 225 Reinekers Lane, Suite 700, Alexandria, VA 22034.

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
Neil Roche, Vice-Chairman
William J. Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
Advanced Medical Technology Association	Michael Pfleger
American Academy of Ophthalmology	Thomas White
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	Karl Citek
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Optical Laboratory Association	Steve Sutherlin
Opticians Association of America	Tom Hicks
Sunglass Association of America	Tibor Gross
The Vision Council	Michael Vitale
ISO TC 172/SC7	Michael Vitale

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

Carl Tubbs, SC4 Chair
Raj Suryakumar, Leader

Ophelia Biggs
Don Calogero
Carrie Garufis
George Green
Gene Hilmantel
Jame Hoffman
Srichand Jasti
Sanjeev Kasthurirangan
Michael Pleger
Nicholas Tarantino
Steve Van Noy
James Wolffsohn

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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 and regulations 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*

ANSI Z80.13, *Ophthalmics – Phakic 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 14155-1, *Clinical investigation of medical devices – Part 1: General requirements*

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

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