American National Standard

for Ophthalmics –

Implantable Glaucoma Devices

ANSI Z80.27-2014 (R2025)

Approved American National Standard

ANSI

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American National Standard
for Ophthalmics –

Implantable Glaucoma Devices

Secretariat

The Vision Council

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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 Z80.27-2014 (R2025).)

ANSI Z80.27-2014 was developed by a group of experts under the direct chairmanship of Dr. Carl Tubbs, with detailed editing by the group secretary, Jane Ellen Giamporcaro. The current standard represents a revision of the original and first 2001 document chaired by Dr. Dale Heuer, and pertains to the physical, biocompatibility, and mechanical properties, as well as to performance properties of implantable medical devices that are designed to lower IOP (intraocular pressure). The revision was completed by an active group of basic scientists, industrialists, regulatory agencies, clinicians, and clinician researchers, and involved spirited discussion on several fronts. Z80.27 is a subcommittee on Medical Ophthalmic Devices of ANSI (Accredited Standards Committee) Z80.

Z80 Committee was established in 1956, and is now a U.S. standards developer and accredited by ANSI. The Vision Council became Secretariat for Z80 in January of 2009. The Z80 committee, made up of 19 voting organizations and more than 200 participants, meets at least twice a year in order to regularly create and to rewrite draft standards. There are eight subcommittees that operate under the Z80 parent committee. The Medical Ophthalmic Devices (SC4) subcommittee deals with intraocular lenses (whether phakic or aphakic, toric or accommodative); devices to change the refractive power of the eye including lasers; viscoelastic devices; ophthalmic irrigating solutions; and finally, implantable glaucoma devices.

The Z80.27 standard contains nine annexes, A through I. The annexes are informative and supply additional guidance, but 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:

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Quido Cappelli, Vice-Chairman
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American National Standard for Ophthalmics –

Implantable Glaucoma Devices

1 Scope and purpose

The scope of this standard applies to devices that are implanted in the eye to treat glaucoma by facilitating aqueous outflow. The standard excludes glaucoma devices whose effect depends upon metabolic and/or pharmacologic mechanisms.

The purpose of the standard is to describe the physical, mechanical and biocompatibility properties, as well as the elements of clinical protocols that may be useful in assessing the clinical performance of these devices.

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/AAMI ST72:2002, *Bacterial endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing*

ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*

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

ISO 10993-3:2003, *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*

ISO 10993-10:2002/Amd 1:2006, *Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects – Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans*

ISO 14630:2008, *Non-active surgical implants – General requirements*

U.S. Code of Federal Regulations 21, Part 58: Good Laboratory Practices