AMERICAN NATIONAL STANDARD

OLA®

for Ophthalmics –

Aqueous Shunts for Glaucoma Application

ANSI®
Z80.27-2001

American National Standard
for Ophthalmics –

Aqueous Shunts for Glaucoma Application

Sponsor

Optical Laboratories Association

Approved May 11, 2001

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Foreword (This foreword is not part of American National Standard ANSI Z80.27-2001.)

ANSI Z80.27-2001 was developed by a group of experts under the direct chairmanship of Prof. Dale Heuer. This standard on aqueous shunts for glaucoma application applies to the physical and mechanical properties and performance of finished aqueous shunts, their biocompatibility properties, and describes elements of a clinical protocol that may be used to assess the clinical performance of these devices for treatment of glaucoma. This is the first such standard developed. The committee, which consisted of scientists, industrialists, government and clinicians (several of them developers and/or manufacturers of shunts), did an excellent job in opening up this new area of a medical device standard.

Z80.27 is a subcommittee on Medical Ophthalmic Devices of Accredited Standards Committee Z80.

In 1982, the Optical Laboratories Association (OLA) assumed the responsibility of the Secretariat; and in 1985, the Z80 Committee became an accredited standards committee. The scope of the Z80 committee is for the establishment of standards that shall apply to ophthalmic lenses and to equipment, instruments and processes used in the final fabrication level that affect their performance; to ophthalmic frames, sunglasses and fashion eyewear; to contact lenses and accessories for their use; to intraocular implant lenses both monofocal and multifocal, as well as optical devices used to change the refractive capability of the eye (such as phakic intraocular lenses, intraocular contact lenses, corneal rings), as well as laser equipment to reshape the cornea for refractive purposes; to low vision aids and ophthalmic contact devices in addition to contact lenses; and to optical instrumentation used in ophthalmic procedures and vision evaluation; to computers to allow the use of such computers in conjunction with ophthalmic equipment, etc. The Medical Ophthalmic Devices subcommittee deals with the different intraocular lenses, whether phakic or aphakic; different devices to change the refractive power of the eye, including lasers, viscoelastic devices, ophthalmic irrigating solutions and glaucoma shunts.

This standard contains five annexes. Annex C is normative and is considered part of the standard. Annexes A, B, D, and 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 Optical Laboratories Association, P.O. Box 200, Merrifield, VA 22116-2000.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Optics, 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:

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The Subcommittee on Medical Ophthalmic Devices, which developed this standard, had the following members:

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for Ophthalmics –

Aqueous Shunts for Glaucoma Application

1 Scope and purpose

This standard applies to the physical and mechanical properties and performance of finished aqueous shunts, their biocompatibility properties, and describes elements of a clinical protocol that may be used to assess the clinical performance of these devices for treatment of glaucoma.

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.

ASTM D4169-99, *Standard Practice for Performance Testing of Shipping Containers and Systems*[1)]

ASTM D4332-89(1994)e1, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*[1)]

ISO 2248, *Packaging - Complete, Filled Transport Packages - Vertical Impact Test by Dropping*

ISO 8318, *Packaging - Complete Filled Transport Packages - Vibration Tests with a Sinusoidal Variable Frequency*

ISO 8597, *Optics and Optical Instruments - Visual Acuity Testing - Method of Correlating Optotypes*

ANSI/AAMI/ISO 10993-1-1997, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*

ANSI/AAMI/ISO 10993-5-1992, *Biological Evaluation of Medical Devices - Part 5: Tests for Cytotoxicity: In vitro methods*

ANSI/AAMI/ISO 11607-2000, *Sterilization for Health Care Products - Packaging for Terminally Sterilized Medical Devices*

ANSI/AAMI/ISO 14155-2000, *Clinical Investigation of Medical Devices*

ISO 14630, *Non-Active Surgical Implants - General Requirements*

ANSI Z80.7-1994, *Ophthalmics - Intraocular Lenses*

ANSI/AAMI/ISO 11134-1993, *Sterilization of Health Care Products - Requirements for Validation and Routine Control - Industrial Moist Heat Sterilization*

ANSI/AAMI/ISO 11135-1994, *Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization*

ANSI/AAMI/ISO 11137-1994, *Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization*

ISO/FDIS 11979-3, *Ophthalmic Implants - Intraocular lenses - Part 3: Mechanical Properties and Test Methods*

Organization for Economic Cooperation and Development (OECD) Test No. 471 (7/97) - *Bacterial Reverse Mutation Test* [2)]

Recommended Practice for Determining Residual Ethylene Oxide in Medical Devices, ST29-1988[3)]

U.S. Pharmacopeia, Ed. XXII, 1990

[1)] Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

[2)] Available from the Office of Pollution, Prevention, and Toxics, US-EPA (7403), 401 M Street, SW, Washington, DC 20460, phone: (202) 260-1240, fax: (202) 260-1236.

[3)] Available from the Association for Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201.