



Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials¹

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1. Scope

1.1 This guide is intended to educate potential users of silicone elastomers, gels, and foams relative to their formulation and use. It does not provide information relative to silicone powders, fluids, and other silicones. The information provided is offered to guide users in the selection of appropriate materials, after consideration of the chemical, physical, and toxicological properties of individual ingredients or by-products. This guide offers general information about silicone materials typically used for medical applications. Detail on the crosslinking and fabrication of silicone materials is found in Part II of this guide.

1.2 Fabrication and properties of elastomers is covered in the companion document, F604, Part II. This monograph addresses only components of uncured elastomers, gels, and foams.

1.3 Silicone biocompatibility issues can be addressed at several levels, but ultimately the device manufacturer must assess biological suitability relative to intended use.

1.4 Biological and physical properties tend to be more reproducible when materials are manufactured in accordance with accepted quality standards such as ANSI ISO 9001 and current FDA Quality System Regulations/Good Manufacturing Practice Regulations.

1.5 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* Users are also advised to refer to Material Safety Data Sheets provided with uncured silicone components.

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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2. Referenced Documents

2.1 ASTM Standards:²

D1566 Terminology Relating to Rubber

F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices

2.2 Sterility Standards:³

ANSI/AAMI ST41 Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance

ANSI/AAMI ST50 Dry Heat (Heated Air) Sterilizers

ANSI/AAMI ST29 Recommended Practice for Determining Ethylene Oxide in Medical Devices

ANSI/AAMI ST30 Determining Residual Ethylene Chlorohydrin and Ethylene Glycol in Medical Devices

AAMI 13409-251 Sterilization of Health Care Products—Radiation Sterilization—Substantiation of 25kGy as a Sterilization Dose for Small or Infrequent Production Batches

AAMI TIR5-251 Microbiological Methods for Gamma Irradiation Sterilization of Medical Devices

2.3 Quality Standards:⁴

ANSI/ASQC Q9001 Quality Systems—Model for Quality Assurance in Design, Development Production, Installation, and Servicing

21 CFR 820 Quality System Regulation (current revision)

21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General (current revision)

21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals (current revision)

3. Terminology

3.1 Additional pertinent definitions can be found in Terminology D1566.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁴ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.