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Standard Specification for Silicone Elastomers Used in Medical Applications[1]

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1. Scope

1.1 This specification covers silicone elastomers intended for use as materials of construction for fabrication of medical devices.

1.2 Variations in ingredients, processing, and vulcanization (crosslinking/cure) systems of silicone elastomer are necessary to achieve the properties required in specific medical device applications.

1.2.1 An alphabetical/numerical code abbreviation is defined in this specification as what may be used to specify ingredients, crosslinking systems, processing conditions, and physical properties of many silicone elastomers used in medical device applications by a standard, abbreviated designation.

1.3 In all cases where the provisions of this specification are in conflict with those of the detailed specifications for a particular product, the latter shall take precedence.

1.3.1 When silicone elastomers are used in medical device applications where the materials requirements cannot be completely achieved by the technology prescribed in this specification, it may be necessary to adjust ingredients, processing, or cure systems to a greater extent to obtain the properties needed in these specific medical device applications.

1.3.1.1 When silicone elastomers are adjusted more extensively than prescribed in this specification, such adjustments shall be completely described and controlled in specifications for each specific material.

1.3.1.2 All sections of this specification that contain requirements pertinent to safety and effectiveness apply to all silicone elastomers used as materials of construction for medical devices, including those adjusted more broadly than defined in this specification.

1.4 While silicone elastomers have demonstrated excellent biocompatibility in medical device applications, the biocompatibility of silicone elastomers as a generic class has not been established. Many compositions and formulations are possible. Manufacturing practices, facilities, controls, process validation, and other considerations that ensure batch-to-batch duplication, assurance of identity, and quality of ingredients, as well as freedom from contamination or cross-contamination may vary widely within the silicone elastomer industry. Medical device manufacturers must ensure safety and effectiveness of each specific composition or formulation from each supplier in its intended applications. Historic, clinical, and biocompatibility data are pertinent prospectively only when all compounding, formulating, and fabrication are done in accordance with the provisions of Good Manufacturing Practice Regulations,[2] which help ensure medical materials and devices are reasonably duplicated each time they are manufactured.

1.5 This specification is intended to assist in the development of specifications for formulated silicone elastomer compounds. It is also recommended for use in materials and finished device labeling to specify the type or types of silicone elastomers contained.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies[3]

D 150 Test Methods for A-C Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulating Materials[3]

D 257 Test Methods for D-C Resistance or Conductance of Insulating Materials[3]

D 395 Test Methods for Rubber Property—Compression Set[4]

D 412 Test Methods for Rubber Properties in Tension[4]

D 430 Test Methods for Rubber Deterioration—Dynamic Fatigue[4]

D 570 Test Method for Water Absorption of Plastics[5]

D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers[4]

D 792 Test Methods for Specific Gravity (Relative Density) and Density of Plastics by Displacement[5]

D 813 Test Method for Rubber Deterioration—Crack Growth[4]

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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[2] Federal Register, Vol 43, No. 141, Friday, July 21, 1978, Part II.

[3] *Annual Book of ASTM Standards*, Vol 10.01.

[4] *Annual Book of ASTM Standards*, Vol 09.01.

[5] *Annual Book of ASTM Standards*, Vol 08.01.

D 814 Test Method for Rubber Property—Vapor Transmission of Volatile Liquids[4]
D 865 Test Method for Rubber—Deterioration by Heating in Air (Test Tube Enclosure)[4]
D 926 Test Method for Rubber Property—Plasticity and Recovery (Parallel Plate Method)[4]
D 955 Test Method of Measuring Shrinkage from Mold Dimensions of Molded Plastics[5]
D 991 Test Method for Rubber Property—Volume Resistivity of Electrically Conductive and Antistatic Products[4]
D 1349 Practice for Rubber—Standard Temperatures for Testing[4]
D 1418 Practice for Rubber and Rubber Latices—Nomenclature[4]
D 1566 Terminology Relating to Rubber[4]
D 1898 Practice for Sampling of Plastics[5]
D 2240 Test Method for Rubber Property—Durometer Hardness[4]
D 3137 Test Method for Rubber Property—Hydrolytic Stability[4]
F 619 Practice for Extraction of Medical Plastics[6]
F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[6]
F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[6]
F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[6]

2.2 *ANSI Standard:*
Z1.8 General Requirements for a Quality Program[7]
2.3 *AAMI Standard:*
EOS-DE-O Sterilization Standard[8]
2.4 United States Pharmacopeia, XXII Edition, 1989[9]

2.5 Federal Register, Title 21, Part 820

3. Terminology

3.1 *Definitions:*

3.1.1 *catalyst/crosslinking agent*—an ingredient contained in a silicone elastomer formulation that either initiates or is a reactant in the crosslinking chemistry when the material is vulcanized.

3.1.2 *filler*—a finely divided, solid material that is intimately blended with silicone polymers during mixing and compounding to achieve specific properties. The filler used with silicone elastomer is typically high surface area, amorphous, fumed silica, an ingredient essential to high strength and elastomeric physical properties.

3.1.3 *lot or batch*—material with a fixed, specified formulation made in a single, continuous manufacturing run from single lots of all ingredients and processed by the same techniques at same conditions.

3.1.4 *post cure*—typically refers to heat processing of molded or fabricated silicone elastomer parts done in an air circulating oven for a specified time and temperature. Post cure is generally necessary to complete the vulcanization/crosslinking chemistry, stabilize properties, and drive off any volatile materials such as residuals or break down products of catalysts generated during vulcanization.

3.1.5 *silicone compound*—an unvulcanized, uniformly blended formulation containing silicone polymers and fillers. Silicone compounds may be one-part or two-part. One-part compounds may be supplied either catalyzed and ready to process, or uncatalyzed, requiring the addition of a catalyst prior to use. Two-part silicone compounds must be blended together prior to use and may have limited shelf life after blending.

3.1.6 *silicone elastomer*—an elastomer containing crosslinked silicone polymer and filler, typically fumed silica.

3.1.7 *silicone polymer*—polymer chains with chemical structure of repeating diorganosiloxy groups, typically repeating dimethylsiloxy groups in elastomers used in medical device applications. Polymer chains contain repeating silicon and oxygen atoms.

3.1.8 *vulcanization*—an irreversible process where covalent chemical crosslinks are formed between silicone polymers chains contained in silicone elastomer compounds. During vulcanization the material changes from a flowable compound, which can vary widely in viscosity, to an elastomeric material, which cannot again be reshaped except by its physical destruction.

4. Fabrication, Vulcanization, Postcure, and Physical Properties

4.1 Fabrication and vulcanization conditions shall be designated by a letter code as listed in 4.1.1, followed by numerical designations of time/temperature. Time shall be listed as h (hours), m (minutes), or s (seconds). Temperature shall be defined as °C or °F.

4.1.1 *Fabrication Codes*:

CM	compression molding
TM	transfer molding
E	extrusion
D	dispersion dipping
CA	calendaring
HL	hand lay-up
Z	other, to be specified

4.2 Postcure shall be designated by the letters “PC” followed by numerical designation of time/temperature (h/temperature° F or °C). (See Practice D 1349, Section 2.) Designate as “PC none” when no postcure has been used or when none is recommended in material processing.

4.3 *Physical Properties*—Measurements of durometer, tensile strength, and elongation are typically considered essential for defining and controlling a silicone elastomer. Designate in series as durometer/tensile strength/elongation as defined in 4.3.1, 4.3.2, and 4.3.3, respectively.

4.3.1 *Durometer (Hardness), Shore A*—Measure in keeping with Test Method D 2240. Designate by D followed by a number as selected from the following:

[6] *Annual Book of ASTM Standards*, Vol 13.01.
[7] Available from American National Standards Institute, 11 West 42nd St., 13th Floor, New York, NY 10036.
[8] Available from Association for Advancement of Medical Instrumentation, 1500 Wilson Blvd., Suite 417, Arlington, VA 22209.
[9] Available from Mack Publishing Co., Easton, PA.