



Standard Specification for Silicone Elastomer Facial Implants¹

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1. Scope

1.1 This specification covers the requirements for silicone elastomer implants used in facial surgery (that is, chin, nasal, malar, and ear implants).

1.2 *Limitations*—This specification does not cover implants containing silicone gels or other gels or liquids. It does not necessarily cover any custom-fabricated prosthesis manufactured to any other specification.

1.3 The following safety hazards caveat pertains only to the mechanical testing and test methods portion, Section 7, of this specification: *This standard does not purport to address all of the safety problems, 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 412 Test Methods for Rubber Properties in Tension²

D 624 Test Method for Rubber Property—Tear Resistance²

D 2240 Test Method for Rubber Property—Durometer Hardness²

F 604 Classification for Silicone Elastomers Used in Medical Applications³

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁴

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁴

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices⁴

2.2 Other Documents:

United States Pharmacopeia, Volume XX⁵

Federal Register, Title 21, Part 820⁶

Dow Corning Corporate Test Method—CTM 0930—Adhesion—One Hundred Eighty Degree Shear—Thin Elastometric Substrates⁷

3. Terminology

3.1 Definitions:

3.1.1 *fixation site*—an area on the surface of the implant which has material on it that allows tissue ingrowth.

3.1.2 *fused or adhered joints*—all junctures of dissimilar materials; and all junctures of fully or partly formed or preformed materials bonded or fused together to form a single implant unit.

3.1.3 *Discussion*—Implants made from one material by a single charge of unvulcanized elastomer by one-step compression, transfer, or reactive injection molding are not considered to have fused or adhered joints.

3.1.4 *orientation means*—any locus on the surface of the implant that is modified to assist the surgeon to position the implant.

4. Significance and Use

4.1 The prostheses described in this specification are intended for implant use in the facial area.

5. Materials

5.1 The primary material of construction shall be fully vulcanized silicone elastomer.

5.1.1 Implants may have orientation means or sites of attached fixation materials, or both.

5.2 Biocompatibility:

5.2.1 Biological testing to ensure the safety of facial implant devices shall be selected and conducted in accordance with Practices F 748 and F 981.

5.2.2 In addition to biological testing as recommended by Practices F 748 and F 981, other biological testing may be appropriate.

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² *Annual Book of ASTM Standards*, Vol 09.01.

³ Discontinued; See 2000 *Annual Book of ASTM Standards*, Vol 13.01.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.

⁵ Available from Mack Publishing Co., 1991 N Hampton St. Easton, PA. 18042.

⁶ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

⁷ Available from Dow Corning Corp., Midland, MI 48686-0994 Phone: (517) 496-5461