Designation: F881 – 94(Reapproved 2006)

Standard Specification for Silicone Elastomer Facial Implants[1]

This standard is issued under the fixed designation F881; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 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:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers

D2240 Test Method for Rubber Property—Durometer Hardness

F604 Specification for Silicone Elastomers Used in Medical Applications (Withdrawn 2001)[3]

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

2.2 *Other Documents:*

United States Pharmacopeia, Volume XX[4]

Federal Register, Title 21, Part 820[5]

Dow Corning Corporate Test Method—CTM 0930—Adhesion—OneHundred Eighty Degree Shear—Thin Elastometric Substrates[6]

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 F748 and F981.

[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 F04.32 on Plastic and Reconstructive Surgery.

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[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from Mack Publishing Co., 1991 N Hampton St. Easton, PA. 18042.

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

[6] Available from Dow Corning Corp., P.O. Box 994, Midland, MI 48686-0994.