Designation: F 881 – 94 (Reapproved 2000)

Standard Specification for Silicone Elastomer Facial Implants[1]

This standard is issued under the fixed designation F 881; 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 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 Tension[2]

D 624 Test Method for Rubber Property—Tear Resistance[2]

D 2240 Test Method for Rubber Property—Durometer Hardness[2]

F 604 Classification for Silicone Elastomers Used in Medical Applications[3]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[4]

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[4]

2.2 *Other Documents:*

United States Pharmacopeia, Volume XX[5]

Federal Register, Title 21,Part 820[6]

Dow Corning Corporate Test Method— CTM 0930—Adhesion—OneHundred Eighty Degree Shear—Thin Elastometric Substrates[7]

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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[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] *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

6. Dimensions

6.1 The individual shape, range of sizes, and measurements are determined by the manufacturer.

6.1.1 Define sizing codes by typical dimensions and volumes, where applicable.

7. Mechanical Testing and Test Methods

7.1 *Typical Physical Properties of Elastomers*:

7.1.1 *Elongation at Failure*—The elongation at failure shall be 200 %, minimum, when tested in accordance with Test Methods D 412.

7.1.2 *Durometer*—The durometer shall have a maximum of shore A80, depending on application, when tested in accordance with Test Method D 2240.

7.1.3 *Tensile Strength*—The minimum tensile strength of all silicone elastomers and adhesives used to fabricate facial implants shall be 200 psi when tested in accordance with Test Methods D 412.

7.1.4 *Modulus*—Test in accordance with Test Methods D 412.

7.1.5 *Tear*—Test in accordance with Test Method D 624.

7.1.6 *Durometer*—Test in accordance with Test Method D 2240.

7.2 *Fused or Adhered Joints*:

7.2.1 Techniques and materials used for adhered or fused joints or seams that are critical to the integrity of the implant shall demonstrate a strength greater than 20 ppi when test specimens made of the same materials and fabricated by similar techniques are tested in accordance with Dow Corning Corporate Test Method-CTM 0930.

8. Sterilization

8.1 The units may be supplied presterilized in accordance with the United States Pharmacopeia and good manufacturing practices released by the Food and Drug Administration (FDA).

8.2 Instructions for cleaning and sterilization shall be supplied with the package insert.

9. Packaging, Labeling, and Package Inserts

9.1 *Packaging (Primary)*:

9.1.1 Packages shall be sealed to prevent contamination and to maintain sterility.

9.1.2 Units shall be packaged with suitable containers that will prevent damage in transit.

9.2 *Labeling*:

9.2.1 Each implant shall be labeled in a manner that ensures the labeling arrives at the point of use with the device. Labeling shall include the following information:

9.2.1.1 Product name and manufacturer.

9.2.1.2 Configuration or type.

9.2.1.3 Size, dimensions, and durometer.

9.2.1.4 Special storage requirements, if any.

9.2.2 With each unit, a self-adhering tab shall be provided that is suitable for attaching to the patient's chart. The tab shall include the following information:

9.2.2.1 Product name and manufacturer.

9.2.2.2 Product lot number.

9.2.2.3 Product size and dimensions.

9.3 *Package Insert*—The package insert shall provide specific instructions for use, cleaning, sterilization, and storage.

APPENDIX

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR SPECIFICATION F 881

X1.1 Silicone elastomer facial implants described in this specification have generally been available to hospitals and physicians for surgical procedures requiring tissue augmentation in both aesthetic and reconstructive surgery. The uses of silicone elastomer implants for chin, nasal, malar, and ear augmentation have been reviewed by the plastic and reconstructive surgery sections of the Medical Device Classification Panels in keeping with the provisions of the Medical Device Amendments of 1976 to the Federal Food, Drugs, and Cosmetic Act. This panel recommended a Class II (standards) classification. This specification is thus needed both to satisfy regulatory considerations, and to provide enduser physicians and other health-care professionals with an adequate description of the properties and characteristics of silicone materials used for implant construction.

X1.2 The potential risk and hazards to health identified at the time of review by FDA classification panels included the possible presence of adulterants, adverse tissue reaction, extrusion, rejection, and infection. The test methods and requirements suggested in this specification have been selected specifically to provide reasonable assurance that none of the identified risks and hazards to health occur as a result of defective or adulterated materials. Label copy requirements include directions for handling and use, sterilization, and storage to minimize the occurrence of risks and hazards to health due to technique-of-use considerations.

X1.3 This specification includes suggested test methods and requirements for physical, chemical, and biological properties for silicone elastomer used in facial implant surgery. Criteria for dimensions, volume, physical characteristics, sterilization, packaging, and labeling are discussed thoroughly. Pertinent ASTM methods for biological testing of implant materials are cited. This specification assumes the following: (*1*) all formulations of various ingredients have been qualified by biological testing; (*2*) formulation ingredients and processing procedures are not changed from those used with biological test specimens; (*3*) all manufacturing starts with characterizable, well-characterized materials and is performed in plants

that fully comply with regulatory GMPS; and (*4*) when the conditions stated in X1.1, X1.2 and X1.3 are satisfied and all the requirements as described in this specification for ingredients, and for physical and chemical properties, have been satisfied, silicone elastomers are duplicated adequately on a batch-to-batch basis to provide reasonable assurance of suitability for implant use.