



# Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II—Crosslinking and Fabrication<sup>1</sup>

This standard is issued under the fixed designation F2042; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This guide is intended to educate potential users of silicone elastomers, gels and foams relative to their fabrication and processing. It does not provide information relative to silicone powders, fluids, pressure sensitive adhesives, or other types of silicone products.

1.2 The information provided is offered to guide users in the selection of appropriate processing conditions for specific medical device applications.

1.3 Formulation and selection of appropriate starting materials is covered in the companion document, **F2038** Part I. This monograph addresses only the curing, post-curing, and processing of elastomers, gels and foams as well as how the resulting product is evaluated.

1.4 Silicone biocompatibility issues can be addressed at several levels, but ultimately the device manufacturer must assess biological suitability relative to intended use. Biocompatibility testing may be done on cured elastomers prior to final fabrication, but the most relevant data are those obtained on the finished device. Data on selected lots of material are only representative when compounding, and fabrication are performed under accepted quality systems such as ISO 9001 and current Good Manufacturing Practice Regulations. Extractables analyses may also be of interest for investigation of biocompatibility, and the procedures for obtaining such data depend on the goal of the study (see **F619**, the HIMA Memorandum 7/14/93, and USP 23, for examples of extraction methods).

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

**D395** Test Methods for Rubber Property—Compression Set

<sup>1</sup> This guide 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

**D412** Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

**D430** Test Methods for Rubber Deterioration—Dynamic Fatigue

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

**D792** Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

**D813** Test Method for Rubber Deterioration—Crack Growth

**D814** Test Method for Rubber Property—Vapor Transmission of Volatile Liquids

**D926** Test Method for Rubber Property—Plasticity and Recovery (Parallel Plate Method)

**D955** Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics

**D1349** Practice for Rubber—Standard Conditions for Testing

**D1566** Terminology Relating to Rubber

**D2240** Test Method for Rubber Property—Durometer Hardness

**F619** Practice for Extraction of Medical Plastics

**F719** Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation

**F720** Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test

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

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

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

**F1905** Practice For Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity (Withdrawn 2011)<sup>3</sup>

**F1906** Practice for Evaluation of Immune Responses In Biocompatibility Testing Using ELISA Tests, Lymphocyte Proliferation, and Cell Migration (Withdrawn 2011)<sup>3</sup>

**F1984** Practice for Testing for Whole Complement Activation in Serum by Solid Materials

<sup>3</sup> The last approved version of this historical standard is referenced on [www.astm.org](http://www.astm.org).