



Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants¹

This standard is issued under the fixed designation F 1781; 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 elastomeric flexible hinge finger total joint implants, used with and without metal grommets in the reconstruction of the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints.

1.2 This specification excludes those implants that do not have an across-the-joint elastomeric linkage. The specification is limited to implants made from one material in a single one-step molding procedure.

1.3 The values stated in SI units are to be regarded as standard. The inch-pound units given in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:²

- D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension
- D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers
- D 813 Test Method for Rubber-Deterioration—Crack Growth
- D 1052 Test Method for Measuring Rubber Deterioration—Cut Growth Using Ross Flexing Apparatus
- D 2240 Test Method for Rubber Property—Durometer Hardness
- F 67 Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, R50400, R50550, R50700)
- F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants
- F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
- F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
- F 981 Practice for Assessment of Compatibility of Bioma-

terials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F 983 Practice for Permanent Marking of Orthopaedic Implant Components

F 2038 Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications, Part I—Formulations and Uncured Materials

F 2042 Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications, Part II—Crosslinking and Fabrication

2.2 Government Standards:

21 CFR Part 820 Good Manufacturing Practices for Medical Devices³

MIL STD 177A Rubber Products, Terms for Visible Defects³

2.3 Other Standard:

EN 30993-1 Biological Evaluations of Medical Devices Part 1: Guidance on Selection of Tests⁴

3. Significance and Use

3.1 The prostheses described in this specification are intended for use in the proximal interphalangeal (PIP) and metacarpophalangeal (MCP) joints.

4. Classification

4.1 *Constrained*—A constrained joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomical plane and consists of either a single, flexible, across-the-joint component, or more than one component linked together or affixed.

5. Materials and Manufacture

5.1 Proper material selection is necessary, but insufficient to ensure suitable function of a device. All devices conforming to this specification shall be fabricated from materials with adequate mechanical strength, durability and biocompatibility.

5.2 All elastomeric components shall conform to Guides F 2038 and F 2042. Test and evaluation parameters that could be considered for the elastomeric implant materials are Guides F 2038 and F 2042, Practice F 748, Test Methods D 813,

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Material and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

Current edition approved Nov. 1, 2003. Published December 2003. Originally approved in 1997. Last previous edition approved in 1997 as F 1781 – 97.

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 Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.