



Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants¹

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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. No other units of measurement are included in this standard.

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](#)
- [D813 Test Method for Rubber Deterioration—Crack Growth](#)
- [D1052 Test Method for Measuring Rubber Deterioration—Cut Growth Using Ross Flexing Apparatus](#)
- [D2240 Test Method for Rubber Property—Durometer Hardness](#)
- [F67 Specification for Unalloyed Titanium, for Surgical Implant Applications \(UNS R50250, UNS R50400, UNS R50550, UNS R50700\)](#)
- [F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants](#)
- [F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants](#)
- [F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices](#)

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 F04.22 on Arthroplasty.

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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.

[F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone](#)

[F983 Practice for Permanent Marking of Orthopaedic Implant Components](#)

[F2038 Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials](#)

[F2042 Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II—Crosslinking and Fabrication](#)

2.2 Government Standards:³

[21 CFR 820 Good Manufacturing Practices for Medical Devices](#)

[MIL STD 177A Rubber Products, Terms for Visible Defects³](#)

2.3 ISO Standard:⁴

[ISO 10993-1 Biological Evaluations of Medical Devices — Part 1: Evaluation and testing within a risk management process](#)

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 functioning of a device. All devices conforming to this specification shall be fabricated from materials with

³ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.