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Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants[1]

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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

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

~~F2083~~F2038 ~~Specification for Knee Replacement Prosthesis~~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 Defects[3]

2.3 ~~*Other*~~*ISO Standard:*[4]

~~EN 30993-1~~ISO 10993-1 Biological Evaluations of Medical Devices — Part 1: ~~Guidance on Selection of Tests~~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.

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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 F04.22 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~~standard's Document Summary page on the ASTM website.

[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, ~~Error! Hyperlink reference not valid.>~~ http://www.ansi.org.

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 affined.

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 adequate mechanical strength, durability and biocompatibility. All elastomeric components shall conform to Guides F2038 and F2042.

5.2 ~~All elastomeric components shall conform to Guides F2083 and F2042.~~ Test and evaluation parameters that could be considered for the elastomeric implant materials are ~~Guides F2083 and F2042, Practice F748,~~ Test Methods D813, D1052, D2240, D412 and D624. Before implants can be manufactured from other materials, manufacturers ~~must~~shall comply with ~~5.4~~5.3.

~~5.3 Titanium used as a material of construction for metal grommets shall conform to Specification F67. Metal grommets shall match the shape of the implant and not interfere with the flexible hinge implant function.~~

5.3 *Biocompatibility*—Flexible hinge implants shall be manufactured from the materials listed in 5.2 and 5.3. Before implants can be manufactured from other materials, their biocompatibility shall be demonstrated by producing an acceptable response after testing in accordance with Practices F748 ~~and~~or ~~F981, and others (see EN 30993-1) as needed.~~ISO 10993-1.

5.4 Titanium used as a material of construction for metal grommets shall conform to Specification F67. Metal grommets shall match the shape of the implant and not interfere with the flexible hinge implant function.

5.5 When appropriate for metallic grommets, fluorescent penetrant inspection shall be performed in accordance with Practice F601.

5.6 Design and manufacture shall follow 21 CFR 820.

6. Performance Requirements

6.1 *Fatigue Testing*—The fatigue characteristics of material from which the elastomeric components are fabricated shall be evaluated according to Test Method D813. Any test should be designed to measure fatigue rate (for example, crack growth length) as a function of a million(s) cycles.

6.2 *Range of Motion of the Device Before Implantation*—The implant shall be evaluated to determine the maximum flexion and extension possible before subluxation occurs or the motion is arrested by the implant (elastomer-to-elastomer contact within the hinge). These results shall be reported in the product labeling.

6.3 *Guidelines for* in vitro *Laboratory Testing*—No ASTM standards for testing finger implants have been developed. Laboratory testing that simulates the conditions of use, by a joint function simulator, is desirable to compare materials and designs and to provide an indication of clinical performance. Implant testing shall be done in keeping with the implant's intended function. Implants intended to partially stabilize or stabilize a joint shall be subjected to the maximum destabilizing force or motion, or both, anticipated in clinical application during flexural testing.

6.4 *Durometer*—The hardness of elastomeric components shall be measured according to Test Method D2240.

6.5 The mechanical properties (such as tensile strength, percentage elongation, modulus, and tear strength) of the elastomeric materials used in components shall be determined according to Test Methods D412 and D624.

7. Dimensions

7.1 The following dimensions of finger and joint replacement components shall be reported in labeling (see Figs. 1 and 2):
7.1.1 Distal stem length,
7.1.2 Proximal stem length,
7.1.3 Hinge width in medial/lateral plane,
7.1.4 Hinge height in dorsal/palmar plane,
7.1.5 Distal stem width,
7.1.6 Proximal stem width, and
7.1.7 Distal-proximal hinge width.

7.2 The following dimensions of finger implant with metal grommets shall be reported in labeling (see Fig. 3):
7.2.1 Distal stem length,
7.2.2 Proximal stem length,
7.2.3 Distal grommet length,
7.2.4 Proximal grommet length, and
7.2.5 Hinge height in dorsal/palmar plane.