Designation: F 1781 – 97

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

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:*

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension[2]

D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers[2]

D 813 Test Method for Rubber-Deterioration—Crack Growth[2]

D 1052 Test Method for Measuring Rubber Deterioration—Cut Growth Using Ross Flexing Apparatus[2]

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

F 67 Specification for an Unalloyed Titanium for Surgical Implant Application[3]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[3]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[3]

F 604 Specification for Silicone Elastomers Used in Medical Applications[4]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[3]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[3]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[3]

2.2 *Government Standards:*

21 CFR Part 820 Good Manufacturing Practices for Medical Devices[5]

MIL STD 177A Rubber Products, Terms for Visible Defects[5]

2.3 *Other Standard:*

EN 30993-1 Biological Evaluations of Medical Devices Part 1: Guidance on Selection of Tests[6]

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 Specification F 604. Test and evaluation parameters that could be considered for the elastomeric implant materials are Specification F 604, Practice F 748, Test Methods D 813, D 1052, D 2240, D 412 and D 624. Before implants can be manufactured from other materials, 5.4 must be comply.

5.3 Titanium used as a material of construction for metal grommets shall conform to Specification F 67. Metal grommets must match the shape of the implant and not interfere with the flexible hinge implant function.

[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.

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[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Discontinued; See 2000 *Annual Book of ASTM Standards*, Vol 13.01.

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

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

5.4 *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 must be demonstrated by producing an acceptable response after testing in accordance with Practices F 748 and F 981, and others (see EN 30993-1) as needed.

5.5 When appropriate for metallic grommets, fluorescent penetrant inspection shall be performed in accordance with Practice F 601.

5.6 Design and manufacture will follow 21 CFR Part 820.

6. Performance Requirements

6.1 *Fatigue Testing*—The fatigue characteristics of material from which the elastomeric components are fabricated must be evaluated according to Test Method D 813. 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 implants intended function, that is, 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 D 2240.

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 D 412 and D 624.

7. Dimensions

7.1 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 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.

8. Finish and Marking

8.1 Items conforming to this specification shall be finished and marked in accordance with Practice F 86 and F 983, where applicable.

8.2 *Polymeric Surface Finish*—Polymeric Surface Finish shall conform to manufacturer's documented standards concerning roughness, knit lines, void, bubbles, mold fill, color, inclusions, and dimensions, when applicable. Descriptions of these terms can be located in MIL STD 177A.

9. Labeling and Packaging

9.1 The maximum range of motion values as determined by 6.2 shall be included in the product labeling. The minimum limits for the mechanical properties of the elastomeric material(s) used in components shall be included in theproduct labeling.

9.2 The dimensions shall be included in the product labeling.

9.3 The material(s) used for the implant shall be specified in the package labeling.

9.4 The site, orientation (if any), and catalog number if space permits should be present on the component or within the labeling.

NOTE 1—If space permits the manufacturer's trademark must appear legibly on each of the components. If space does not permit such, the information must be written in the labeling.

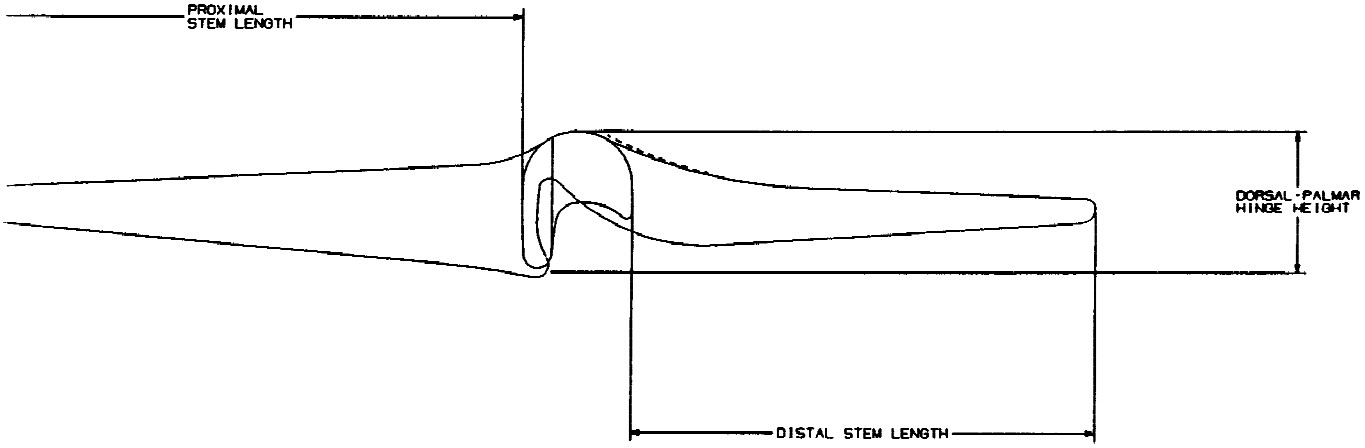

FIG. 1 Dimensions of Finger and Joint Replacement Components