Designation: F 1781 – ~~97~~03

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.

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[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. 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 ~~an~~ 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 ~~604 Specification~~ 748 Practice for ~~Silicone Elastomers Used in Medical Applications~~[3] Selecting Generic Biological Test Methods for Materials and Devices

F ~~74~~981 Practice for ~~Selecting Generic Biological Test Methods~~ Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and ~~Devices~~[3] Bone

F 981~~3~~ Practice for ~~Assessment~~ Permanent Marking of ~~Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone~~[3] Orthopaedic Implant Components

F ~~983 Practice~~ 2038 Guide for ~~Permanent Marking of Orthopaedic Implant Components~~[3] 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 Devices[4]

MIL STD 177A Rubber Products, Terms for Visible Defects[3]

2.3 *Other Standard:*

EN 30993-1 Biological Evaluations of Medical Devices Part 1: Guidance on Selection of Tests[3]

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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, ~~Vol 09.01.~~ volume information, refer to the standard's Document Summary page on the ASTM website.

~~[3] Discontinued; See 2000 *Annual Book of ASTM*~~

[3] Available from American National Standards ~~, Vol 13.01.~~ Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

~~*Annual Book*~~

[4] Available from Superintendent of ~~ASTM Standards, Vol 13.01.~~ Documents, U.S. Government Printing Office, Washington, DC 20402.

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.~~ Guides F 2038 and F 2042. Test and evaluation parameters that could be considered for the elastomeric implant materials are ~~Specification F 604,~~ Guides F 2038 and F 2042, 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~~ manufacturers must ~~be~~ comply with 5.4.

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.

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~~* 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.

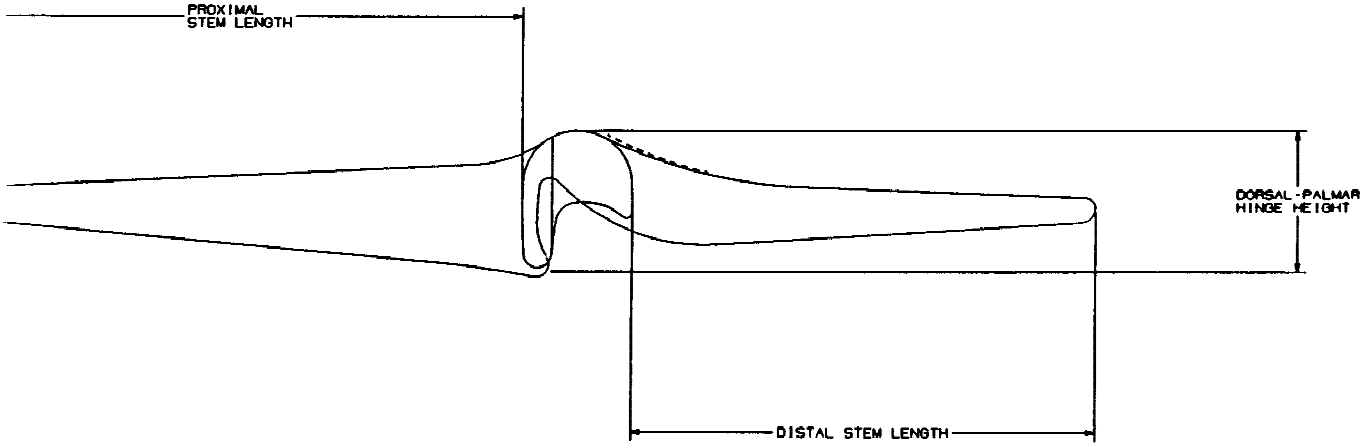

FIG. 1 Dimensions of Finger and Joint Replacement Components

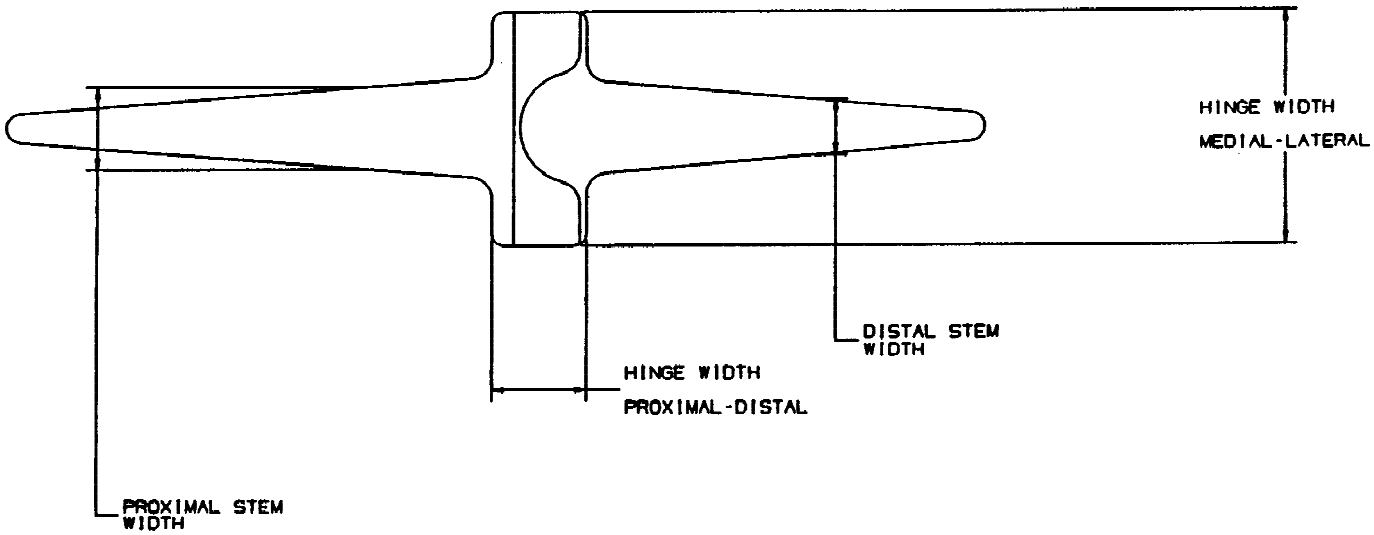

FIG. 2 Dimensions of Finger and Joint Replacement Components

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.

10. Keywords

10.1 elastomer; finger; implant

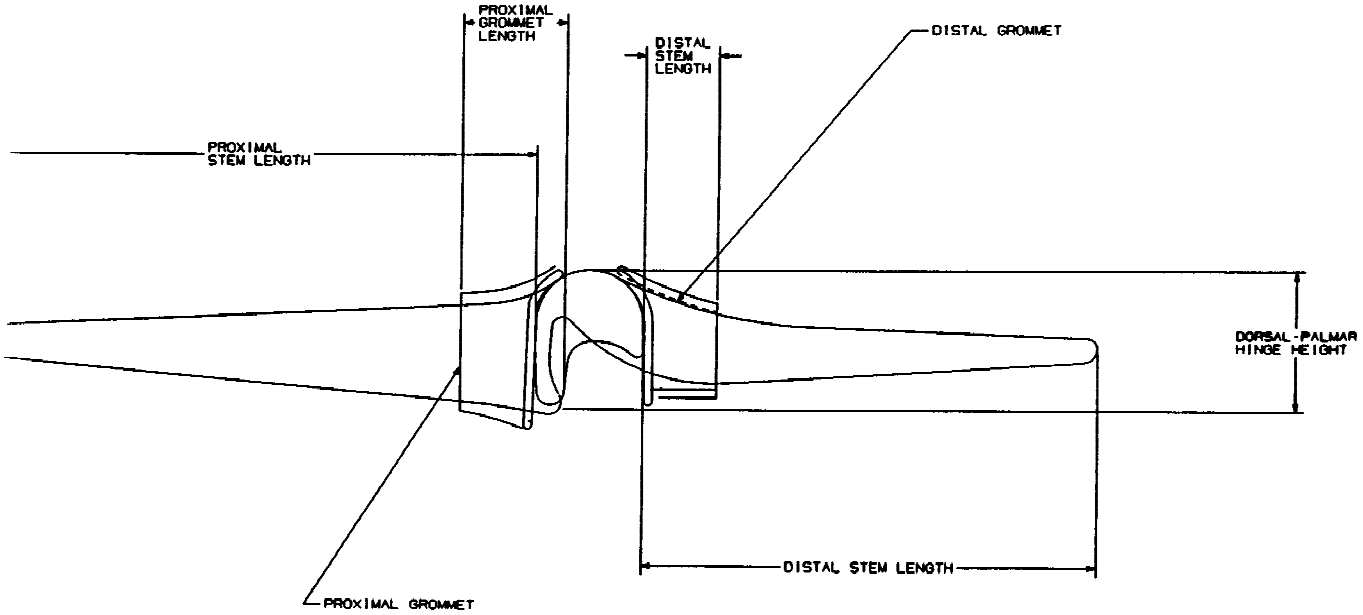

FIG. 3 Dimensions of Finger Implant

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The objective of this specification is the provision of guidelines for the physical characteristics of the components for elastomeric total finger joint replacement. Total finger joint replacement parts are intended for use in a patient who is skeletally mature under conditions of imposed dynamic loads, in a corrosive environment and subject to motion at the bearing surfaces, (grommet-hinge interface, hinge-bone interface, or grommet-bone interface). Laboratory tests for finger joints which accurately simulate imposed loads, appropriate ranges of motion, aggressive electrolytes, and the complex constituents of body fluids have not been developed. Long term projections of satisfactory performance over many decades can be suggested but not accurately predicted using available screening procedures. This document identifies those factors felt to be important to assure a satisfactory prosthetic life. It is recognized that failure of an arthroplasty can occur, even while the components are intact. This is due to the composite nature of the arthroplasty procedure, which includes the implants, the surgical procedure, post-operative care, patient use, and the physiological environment.

X1.1.1 This specification excludes those implants that do not have an across-the-joint elastomeric linkage and is limited to implants made from one material in a single, one-step molding procedure. It also excludes implants which utilize bone cement as affixation method, and implants defined as “partially constrained” or “non-constrained.”

X1.1.2 Under applicable documents and materials, the list reflects the current state of the art. It is recognized that should materials not now included appear and be proved acceptable, they shall be inserted into this standard during the process of revision.

X1.2 *Performance Considerations*—Component performance can be predicted only indirectly at this stage by referring to fatigue performance, range of motion, and other parameters. Reference to parameters applicable to materials may or may not adequately describe a device made from the materials. In the future as new materials are developed, other material testing methods not described in the standard, such as Test Method D 1052, may be considered for screening possible materials for flexible hinge implants. If these materials are suitable, this standard will be revised to include them as potential candidate materials for total flexible finger implants. In a period of transition from materials specification standards to device performance standards, both methods of description may be appropriate.

X1.2.1 Component performance shall be considered with regard to patient anatomy. It is well recognized that physical stresses resulting from events or activities out of the ordinary range, as in accidents or especially vigorous sports, predictably exceed allowable stresses in levels in any component design. When mal-alignment, or dislocation/subluxation occurs in a MCP or PIP joint reconstructed with a constrained flexible hinge implant, the forces borne by the implant may cause premature destruction. It is also recognized that other forms of arthroplasty failure are known to occur, related primarily to patient factors, such as osteoporosis, aggressive rheumatoid disease misuse, and others.

X1.2.2 Specific criteria need to be established in assessing the biocompatibility of finger implants made of new materials. Practice F 748 will need to be used to determine which additional biocompatibility tests are required.

X1.2.3 In the course of evaluating new materials, it is recommended that if the material is used in an application that causes small particle formation from abrasion or normal wear processes that the biocompatibility of those particles be determined in addition to the bulk material.

X1.3 *Dimensions*—The methods of dimensional measurement must conform with the industry practice and whenever possible, on an international practice.

X1.4 *Finish and Markings*—Dimensions and tolerances are as described by manufacturers' standards. Material composition can be determined by referring to the manufacturers' information, instead of marking the material on each implant.

X2. ADDITIONAL PUBLICATIONS

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