Designation: F1781 – 15

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

This standard is issued under the fixed designation F1781; 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. 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

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 Defects[3]

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 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

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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.

[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.

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

5.2 Test and evaluation parameters that could be considered for the elastomeric implant materials are Test Methods D813, D1052, D2240, D412 and D624. Before implants can be manufactured from other materials, manufacturers shall comply with 5.3.

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 or 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.

8. Finish and Marking

8.1 Items conforming to this specification shall be finished and marked in accordance with Practices F86 and F983, where applicable.

8.2 *Polymeric Surface Finish*—Polymeric Surface Finish shall conform to manufacturer's documented standards concerning roughness, knit lines, voids, bubbles, mold fill, color,

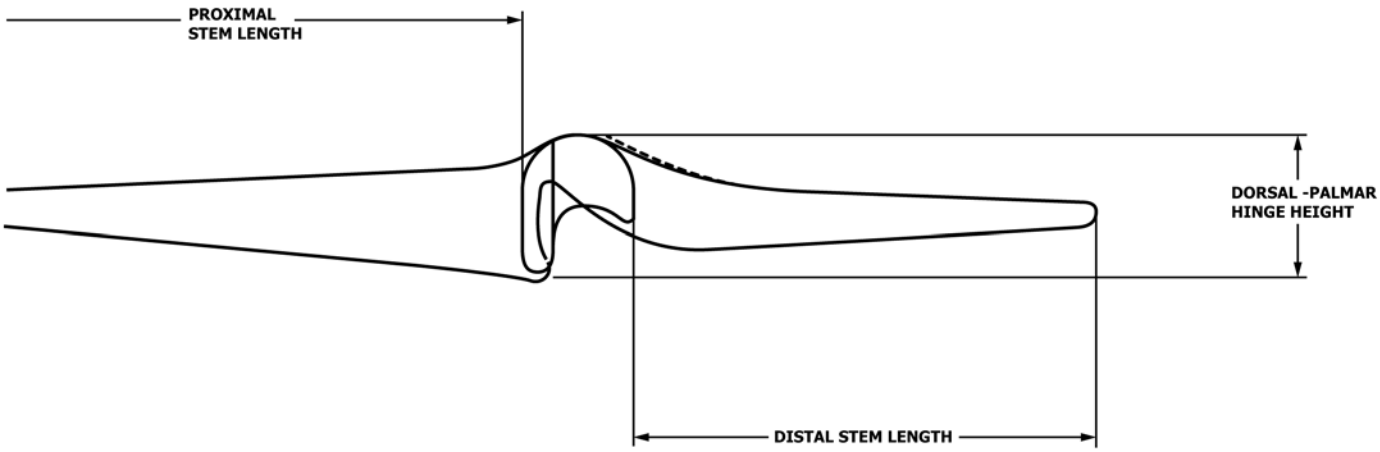

FIG. 1 Dimensions of Finger and Joint Replacement Components

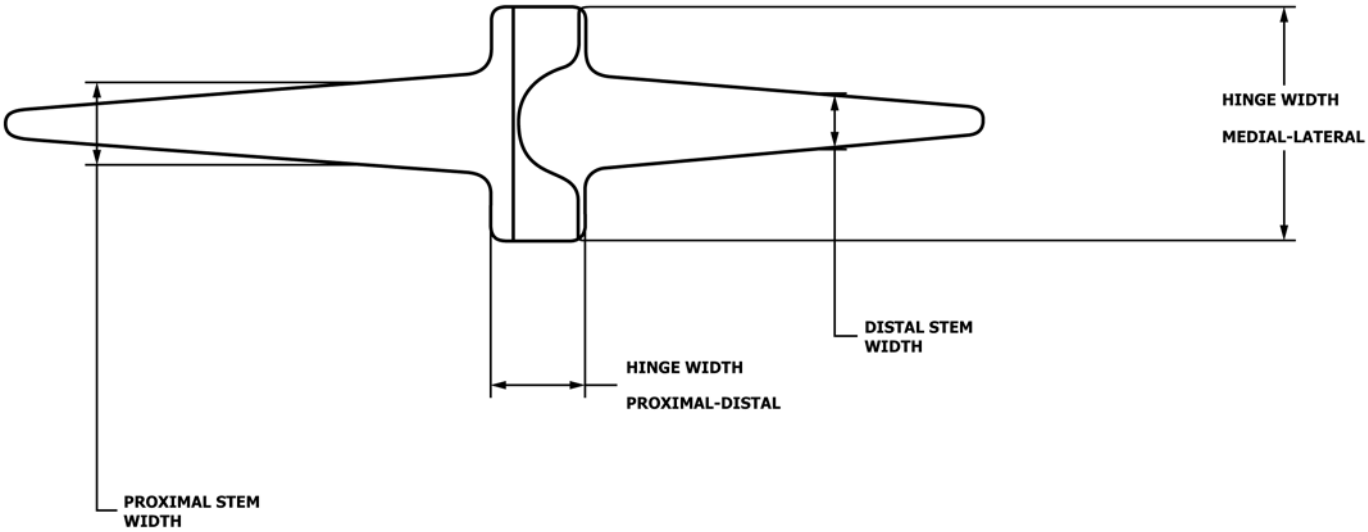

FIG. 2 Dimensions of Finger and Joint Replacement Components

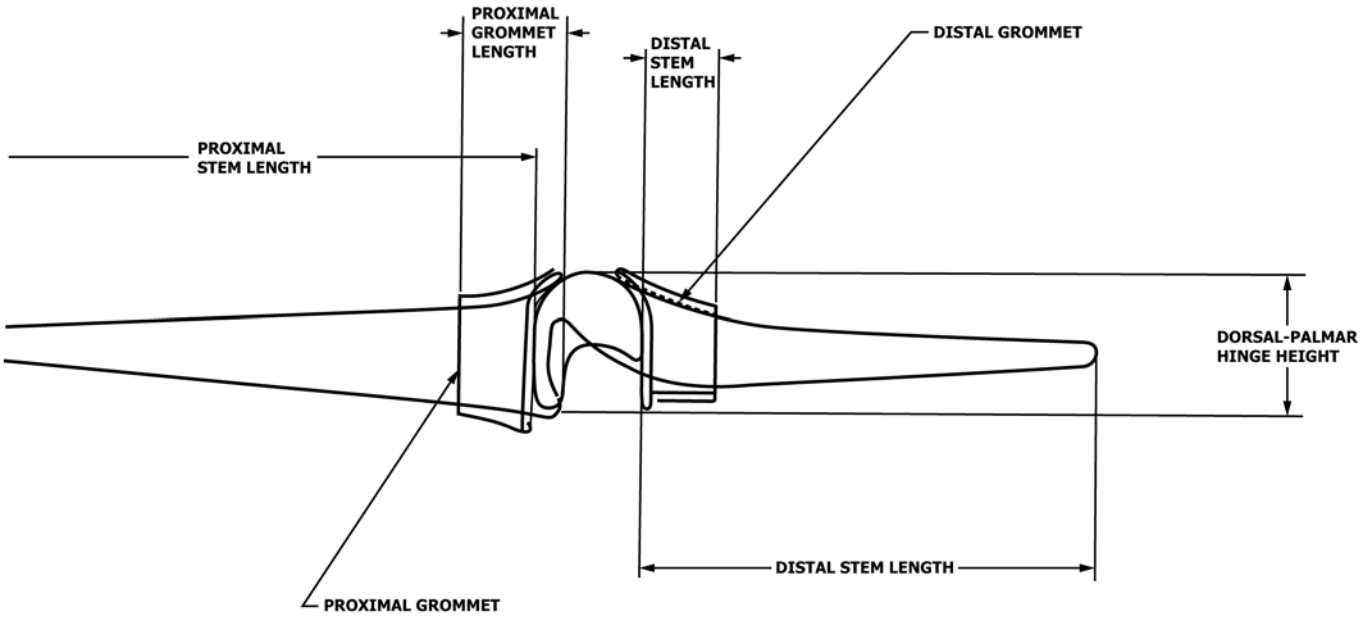

FIG. 3 Dimensions of Finger Implant

inclusions, and dimensions, when applicable. Descriptions of these terms can be found 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 the product 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 in the labeling.

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

10. Keywords

10.1 elastomer; finger; implant

APPENDIX

(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 D1052, 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 flexible total finger joint 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 misalignment 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 F748 and/or ISO 10993-1 shall 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.

RELATED MATERIAL

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