Designation: F1781 – 21

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. This 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.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 Insertion into 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

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

F2943 Guide for Presentation of End User Labeling Information for Musculoskeletal Implants

2.2 *Government Standards:*[3]

21 CFR 820 Quality System Regulation

21 CFR 888.6 Degree of Constraint

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

2.3 *ISO Standard:*[4]

ISO 10993-1 Biological Evaluation 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

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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.

more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined (21 CFR 888.6).

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 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 elastomeric materials, manufacturers shall comply with 5.3.

5.3 *Biocompatibility*—Devices made from materials with limited or no history of successful use for orthopedic implant applications shall be determined to exhibit acceptable biological response when tested in accordance with Practice F748 or F981 or ISO 10993-1. While no known surgical implant material has ever been shown to be completely free of adverse reactions in the human body, long-term clinical experience has shown an acceptable level of biological response can be expected if materials meeting the specification and guidelines in 5.1 and 5.4 are used. However, the specification and guidelines listed in 5.1 and 5.4 cover raw materials and not finished medical devices, where the design and fabrication process of the device can impact biological response. Hence, for a device made from material(s) meeting the specification and guidelines in 5.1 and 5.4, its biocompatibility shall be verified in accordance with Practice F748 or F981 or ISO 10993-1, unless justification can be provided for why design and processing will not impact the biocompatibility of the final, sterilized device.

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 *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 intended function of the implant. Implants intended to fully or partially stabilize a joint shall be subjected to loads and kinematics expected to be experienced during activities of daily living.

6.2 *Fatigue Testing*—Clinical failure modes such as fracture at the hinge and fracture at the junction of the distal stem and hinge have been reported (**1-3**).[5] The fatigue characteristics of the implant shall be evaluated. Testing shall evaluate the resistance of the implant to failure under high cycle fatigue conditions (that is, when cycled through the intended range of motion) as well as under low cycle fatigue conditions (that is, when subjected to pinch and grip loads, such as key pinch or jar opening). Testing shall be performed at 37 ± 2 °C in a physiological solution (for example, saline, serum). Frequency of fatigue testing shall be no greater than 3 Hz (see X1.2.5).

6.2.1 Testing shall be conducted for a minimum of 4 million cycles under high cycle fatigue conditions and a minimum of 1330 cycles under low cycle fatigue conditions (**4, 5**) (see X1.2.6) or until failure. Mode of failure shall be reported for each sample tested.

6.2.2 Justification shall be provided for the following test parameters:

6.2.2.1 Preconditioning of samples prior to testing (such as, samples should be tested in a maximum shelf-life aging condition; testing of maximum shelf-life aged samples may not be necessary if justification can be provided to ensure the material properties will not be affected by shelf-aging).

6.2.2.2 Test solution.

6.2.2.3 Frequency.

6.2.2.4 Load during high cycle and low cycle fatigue conditions.

6.2.2.5 Kinematics (that is, flexion/extension for high cycle conditions and kinematics selected for low cycle conditions).

6.2.2.6 Number of samples.

6.2.2.7 Choice of potting medium, if applicable (given that the elastomeric material does not allow osseointegration, the potting medium shall be selected such that the test can replicate the pistoning effect of the implant's stems into the intramedullary canal).

6.2.3 Examples of fatigue test methods are included in the published literature for reference (**4-7**).

6.2.4 Justification of fatigue performance may be based on comparison to physiological loading parameters expected to be encountered throughout the lifetime of the implant and/or comparison to performance of a legally marketed device and in accordance with the requirements of the regulatory regime in which the device is to be marketed.

6.3 *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.

6.4 *Durometer*—The hardness of elastomeric material used in the implant 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.

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.

7. Dimensions

7.1 The following dimensions of the implant 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,

7.1.7 Distal-proximal hinge width, and

7.1.8 Angulation of the distal stem axis with respect to the proximal stem axis.

7.2 The following additional dimensions of the implant with metal grommets shall be reported in labeling (see Fig. 3):

7.2.1 Distal grommet length,

7.2.2 Proximal grommet length,

7.2.3 Distal grommet medial/lateral width,

7.2.4 Proximal grommet medial/lateral width, and

7.2.5 Minimum grommet thickness.

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*—The polymeric surface finish shall conform to the manufacturer's documented standards concerning roughness, knit lines, voids, bubbles, mold fill, color, inclusions, and dimensions, when applicable. Descriptions of these terms can be found in MIL STD 177A.

8.3 Consider Practice F2503 to identify potential hazards produced by interactions between the device and the MR environment, and for terms that may be used to label the device for safety in the MR environment.

9. Labeling and Packaging

9.1 The maximum range of motion values as determined by 6.3 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.

9.5 When creating the end user labeling information, consider using the information in Guide F2943 for the content and relative location of information necessary for final implant selection within an implant's overall package labeling.

10. Keywords

10.1 elastomer; finger; implant

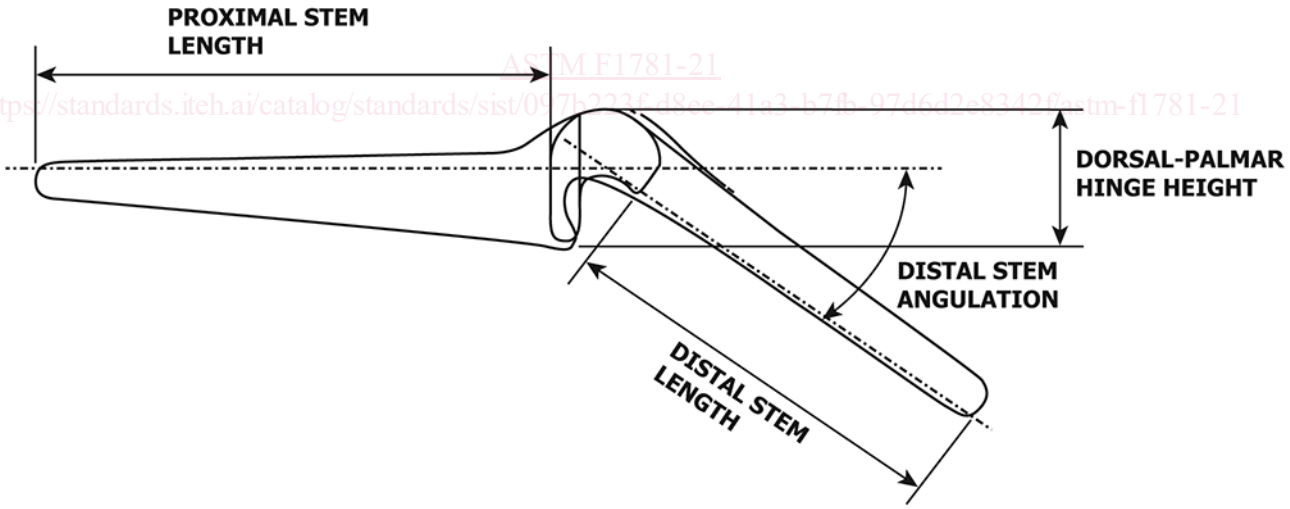

FIG. 1 Dimensions of Finger Joint Replacement Implant

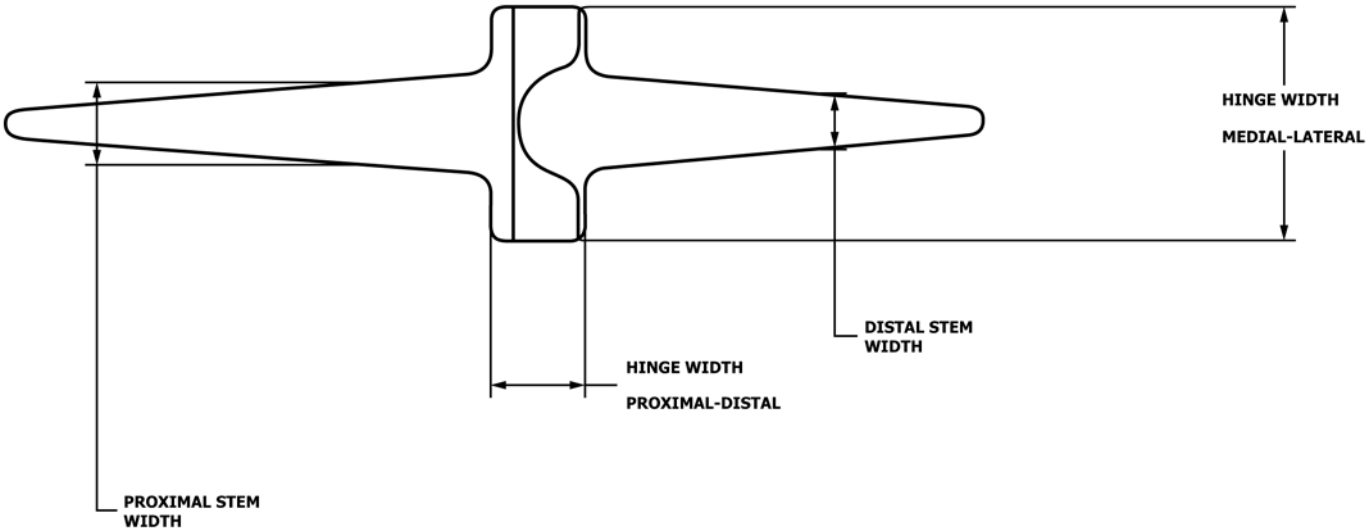

FIG. 2 Dimensions of Finger Joint Replacement Implant

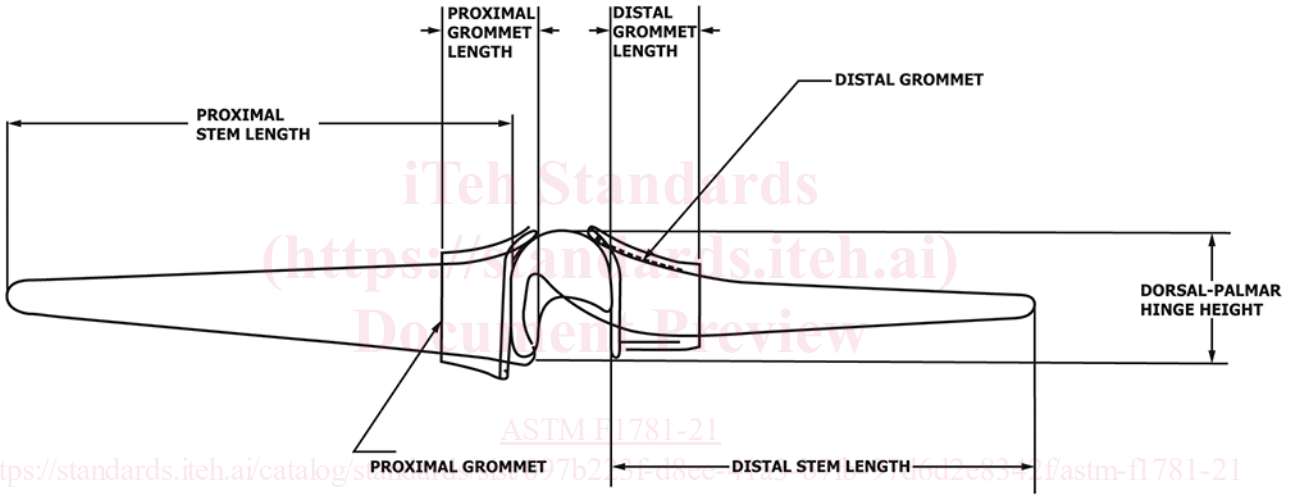

FIG. 3 Dimensions of Finger Joint Replacement Implant with Grommets

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 *Objective*—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 ensure 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 for fixation and implants defined as “partially constrained” or “non-constrained.”