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Standard Specification for Shoulder Prostheses[1]

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1. Scope

1.1 This specification covers shoulder prostheses for total or hemiarthroplasty used to provide functioning articulation by employing glenoid and humeral components.

1.2 Devices for custom applications are not covered by this specification. Modular prostheses are included in this specification.

1.3 The values stated in SI are to be regarded as the standard. The inch-pound units given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[2]

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Application[2]

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[2]

F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[2]

F 562 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications[2]

F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications[2]

F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Applications[2]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[2]

F 745 Specification for Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications[2]

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials[2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[2]

F 799 Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants[2]

F 981 Practice for Assessment of Compatibility of Bio-Materials (Non-Porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[2]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[2]

F 1044 Test Method for Shear Testing of Porous Metal Coatings[2]

F 1108 Specification for Ti6A14V Alloy Castings for Surgical Implants[2]

F 1147 Test Method for Tension Testing of Porous Metal Coatings[2]

F 1537 Specification for Wrought Cobalt-Chromium-Molybdenum Alloy for Surgical Implants[2]

F 1829 Test Method for Static Evaluation of the Glenoid Locking Mechanism in Shear[2]

F 2028 Test Methods for the Dynamic Evaluation of Glenoid Loosening or Dissociation[2]

2.2 *ANSI Standard:*[3]

ASME B46.1–1995

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *collar*—flange at junction of neck and stem.

3.1.2 *glenoid component*—the prosthetic portion that replaces, in part or in total, the glenoid fossa of the scapula and articulates with the natural humeral head or a prosthetic replacement.

3.1.3 *head*—bearing member for articulation with the glenoid.

3.1.4 *humeral component*—the prosthetic portion that replaces, in part or in toto, the proximal humerus or humeral head and articulates with the natural glenoid fossa or a prosthetic replacement.

3.1.5 *keel, (or pegs)*—single or multiple projections that provide resistance to translation or rotation of the glenoid component, or both, by mating with cavities created in the glenoid fossa.

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

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

3.1.6 *neck*—segment connecting the head and the stem.

3.1.7 *stem*—segment intended for insertion within the humeral medullary canal.

4. Classification

4.1 *Constrained*— A constrained joint prosthesis is used for joint replacement and resists 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.

4.2 *Partially Constrained*—A semi-constrained joint prosthesis is used for partial or total joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkages.

4.3 *Unconstrained*— An unconstrained joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

5. Materials and Manufacture

5.1 The choice of materials is understood to be a necessary but not sufficient ensurance of function of the device made from them. All devices conforming to this specification shall be fabricated from materials, with adequate mechanical strength and durability, corrosion resistance, and biocompatibility.

5.1.1 *Mechanical Strength*—Various components of shoulder prostheses have been successfully fabricated from the following materials. However, not all of these materials may possess sufficient mechanical strength for critical highly-stressed components. See Specifications F 75, F 90, F 136, F 138, F 562, F 563 (nonbearing use only), F 603, F 648, F 745, F 799, F 1108, F 1537.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application must be determined to exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Test Method F 746.

5.1.3 *Biocompatibility*— Materials with limited or no history of successful use for orthopedic implant application must be determined to exhibit acceptable biological response equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Practices F 748 and F 981.

6. Performance Requirements

6.1 *Wear of Alternative Materials*—It is important to understand the wear performance for articulating surfaces. Any new or different material should not exceed the wear rates of the following material couple when tested under physiological conditions. The current standard wear couple is CoCrMo alloy (Specification F 75) against ultra high molecular weight polyethylene (Specification F 648), both having prosthetic quality surface finishes according to 8.2.

NOTE 1—In situations where the pin-on-flat test may not be considered appropriate, other test methods may be considered.

6.2 *Range of Motion of Shoulder Prosthesis Prior to Implantation*—Flexion shall be equal to or greater than 90°. Abduction shall be equal to or greater than 90°. Internal rotation shall be equal to or greater than 90°. External rotation shall be equal to or greater than 45°. Extension shall be equal to or greater than 45°.

6.3 Porous metal coatings shall be tested according to Test Method F 1044 (shear strength) and Test Method F 1147 (tensile strength).

6.4 *Guidelines for In-Vitro Laboratory Testing*:

6.4.1 Implant testing should reflect current clinical failures and potential failure modes particular to the implant. These tests may be directed towards subluxation, glenoid loosening, insert disassociation from a metal backing, and humeral head disassociation.

6.4.2 All modular implants should be tested in accordance with Test Method F 1829.

6.4.3 All prosthetic glenoid components should be tested in accordance with Test Method F2028.

7. Dimensions

7.1 Dimensions of shoulder joint replacement components shall be as designated in Figs. 1-3.

8. Finish and Product Marking

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

8.2 *Articulating Surface Finishes*:

8.2.1 *Metallic Bearing Surface*— The main bearing surface shall have a surface finish no rougher than 0.10 µm (4 µin.) roughness average, R_a, with a cutoff length of 0.25 mm, when measured according to the principles given in ASME B46.1–1995.

8.2.2 *Polymeric Bearing Surface (if used)*—The main bearing surface shall have a surface finish no rougher than 2 µm roughness, R_a, with a cut-off length of 0.8 mm, when measured according to the priniciples given in ASME B46.1–1995.

8.3 In accordance with Practices F 86 and F 983, items conforming to this specification shall be marked as follows in order of priority where space permits: manufacturer, material, lot number, catalog number, and size. Additional information may include a designation for left or right and front.

8.3.1 Optional glenoid marking may specify orientation (top, if applicable; right or left, if applicable).

8.4 If one of the components is not radiographic opaque, it is strongly encouraged that it shall contain a marker wire or other means of radiographic detection. It may be located at the manufacturer's discretion.

9. Labeling

9.1 The dimensions shown in Figs. 1-3 shall be included in the product labeling.

9.2 The material(s) used for the implant shall be specified on the package labels and inserts.

10. Keywords

10.1 arthroplasty; glenoid; humeral; prostheses; hemi-shoulder replacement; total shoulder replacement