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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.

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

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]

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F745 Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications

F746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

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

F1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)

F1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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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.

F1829 Test Method for Static Evaluation of Glenoid Locking Mechanism in Shear
F2028 Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
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 the junction of the 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.
3.1.6 *neck*—segment connecting the head and the stem.
3.1.7 *reverse design shoulder implants*—implants that have a ball-shaped glenoid component and a concave humeral design.
3.1.8 *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 F75, F90, F136, F138, F562, F563 (nonbearing use only), F603, F648, F745, F799, F1108, and F1537.
5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application shall 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 F746.
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 F748 and F981.

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 F75) against ultra high molecular weight polyethylene (Specification F648), both having prosthetic quality surface finishes in accordance with 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 F1044 (shear strength) and Test Method F1147 (tensile strength).
6.4 *Guidelines for In-Vitro Laboratory Testing*:

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