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Standard Specification for Acetabular Prostheses[1]

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1. Scope

1.1 This standard describes acetabular resurfacing devices used to provide a functioning articulation between the bones of the acetabulum and the femur.

1.2 This standard is intended to provide basic descriptions of materials and device geometry. Additionally, those characteristics determined to be important to in vivo performance of the device are defined.

1.3 Acetabular prostheses included within the scope of this standard are intended for mechanical fixation between the prosthesis and host bone, by the use of bone cement or through biological fixation.

1.4 Custom (designed explicitly for a single patient), revision, or constrained acetabular prostheses are not covered within the scope of this standard.

1.5 This standard does not cover the details for quality assurance, design control, production control contained in 21 CFR 820 (Quality System Regulation) and ISO 9001.

2. Referenced Documents

2.1 *ASTM Standards:*

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[2]

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)[2]

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

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[2]

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications[2]

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[2]

F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications (UNS R30035)[2]

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

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[2]

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

F 629 Practice for Radiography of Cast Metallic Surgical Implants[2]

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

F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum 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 Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)[2]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[2]

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

F 1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings[2]

F 1108 Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)[2]

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

F 1160 Test Method for Sheer and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical Coatings[2]

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants[2]

F 1377 Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)[2]

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

F 1472 Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[2]
F 1501 Test Method for Tension Testing of Calcium Phosphate Coatings[2]
F 1537 Specification for Wrought Cobalt-28 Chromium-8 Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31529)[2]
F 1580 Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants[2]
F 1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices[2]
F 1820 Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device[2]
F 1978 Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber™ Abraser[2]
F 2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials[2]

2.2 *ISO Standards:*

ISO 5832 Implants for surgery—Metallic materials for surgical implants[3]
ISO 5834 Implants for surgery—Ultra high molecular weight polyethylene[3]
ISO 6474 Implants for surgery—Ceramic materials based on alumina[3]
ISO 9001 Quality systems—Model for quality assurance in design/development, production, installation, and servicing[3]

2.3 *Code of Federal Regulations:*

21 CFR 820 Quality System Regulation[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *bearing element*, *n*—articulating surface element between the femoral head and shell or bonding agent (bone cement).

3.1.2 *cavity*, *n*—any slot, cut, hole, or other feature within the shell intended to accommodate modular adjunct fixation elements; instruments for insertion, extraction, and so forth; or for manufacturing purposes.

3.1.3 *fixation element*, *n*—any peg, spike, threadform, or other protrusion from the exterior surface of the shell intended to increase the surface contact or mechanical interlock between the component, the bonding agent, or the natural acetabulum or a combination thereof.

3.1.4 *flange*, *n*—rim extending from the entry diameter of bearing element.

3.1.5 *porous coating*, *n*—a region on the exterior surface of the shell characterized by interconnecting subsurface pores, generally with volume porosity between 30 to 70 %, average pore size between 100 to 1000 μm, and a thickness between 500 to 1500 μm. This porous layer may be manufactured directly into the device by casting or by various electro/chemical/thermal/mechanical means, or applied as a coating of particles, beads, or mesh by processes such as sintering or plasma spray.

3.1.6 *radiographic marker*, *n*—nonstructural, generally thin wire, designed to be apparent on X-rays taken after placement of implants that otherwise would be unapparent on such X-rays.

3.1.7 *retention element*, *n*—any ring, taper, wire, or other protrusion or cavity from the interior surface of the shell or the exterior surface of the bearing element that is intended to affix the bearing element to the shell.

3.1.8 *shell*, *n*—metal structure supporting the articulating surface material, and which may be fixed rigidly to the articulating surface or fixed such that it allows the articulating surface to rotate or translate.

3.1.9 *surface texturing*, *n*—repetitive or random deviations from the nominal surface that forms the three dimensional topography of the surface.

3.2 Dimensions of acetabular prostheses should be designated in accordance with Figs. 1-3 or by an equally acceptable and detailed method.

NOTE 1—Figs. 1-3 are intended to be illustrative of typical acetabular prostheses and to designate dimensions, but representation of the components does not otherwise form part of the standard.

4. Types

4.1 Acetabular prostheses falling within the scope of this specification are of two types, as defined below. There are no distinguishing features (for example, augmentation or lack thereof, holes, and so forth) that would exempt any device from any requirement of this specification.

4.1.1 *Type I*—Single-piece acetabular prostheses.

NOTE 2—Specifications to both bearing elements and shell may apply.

4.1.2 *Type II*—Multipiece, modular structure prostheses.

5. Material

5.1 The choice of materials is understood to be a necessary, but not sufficient, assurance 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 acetabular prostheses have been successfully fabricated from the following materials: See Specifications F 67, F 75, F 90, F 136, F 138, F 562, F 563, F 603, F 648, F 745, F 799, F 1108, F 1185, F 1377, F 1472, F 1537, F 1580; and ISO 5832, ISO 5834, and ISO 6474. However, not all of these materials may possess sufficient mechanical strength for critical highly stressed components nor for articulating surfaces. Associated standards include Practices F 601 and F 629.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopaedic 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 to Test Method F 746.

[3] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland.
[4] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave, Philadelphia, PA 19111-5094, Attn: NPODS.