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Standard Specification for Acetabular Prostheses¹

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1. Scope

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

1.2 This specification 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 specification 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 specification.

1.5 This specification 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:²

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

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)³

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application³

F629 Practice for Radiography of Cast Metallic Surgical Implants

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

F1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

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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 Withdrawn.

- F1185** Specification for Composition of Hydroxylapatite for Surgical Implants
- F1377** Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
- F1472** Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)³
- F1501** Test Method for Tension Testing of Calcium Phosphate Coatings (Discontinued 2000)³
- F1537** Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
- F1580** Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants
- F1714** Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices
- F1820** Test Method for Determining the Axial Disassembly Force of a Modular Acetabular Device
- F1978** Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- F2033** Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

2.2 ISO Standards:

- ISO 5832** Implants for surgery—Metallic materials for surgical implants⁴
- ISO 5834** Implants for surgery—Ultra high molecular weight polyethylene⁴
- ISO 6474** Implants for surgery—Ceramic materials based on alumina⁴
- ISO 9001** Quality systems—Model for quality assurance in design/development, production, installation, and servicing⁴

2.3 Code of Federal Regulations:

- 21 CFR 820 Quality System Regulation⁵

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.

⁴ Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland.

⁵ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave, Philadelphia, PA 19111-5094, Attn: NPODS.

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 **F67, F75, F90, F136, F90, F138, F136, F562, F563, F603, F648, F745, F799, F1108, F1185, F1377, F1472, F1537, F1580; F1580 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 **F601 and F629**.