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Standard Specification for Femoral Prostheses—Metallic Implants¹

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1. Scope

1.1 This specification covers metallic stemmed femoral prostheses used to replace the natural hip joint by means of hemi-arthroplasty or total hip surgical procedures. Prostheses for hemi-arthroplasty are intended to articulate with the natural acetabulum of the patient. Prostheses for total hip replacement are intended to articulate with prosthetic acetabular cups. Prostheses may have integral femoral heads or cones designed to accept modular heads.

1.2 Modular femoral heads, which may be affixed to cones on implants covered by this specification, are not covered by this specification. The mechanical strength, corrosion resistance, and biocompatibility of the head portions of one-piece integral implants are covered by this specification.

1.3 Femoral prostheses included within the scope of this specification are intended for fixation by press fit between the prosthesis and host bone, the use of bone cement, or through the ingrowth of host bone into a porous coating.

1.4 Custom femoral prostheses, designed explicitly for a single patient, are not covered within the scope of this specification.

1.5 Prostheses incorporating nonmetallic (for example, polymer composite) implants, nonporous bioactive ceramic coatings, or porous-polymer coatings, are specifically excluded from the scope of this specification.

1.6 The requirements for modular connections of multicomponent modular femoral hip prostheses are not covered by this specification.

1.7 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

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) (Withdrawn 2005)~~³

F620 Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition

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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.

- ~~F745 Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications (Withdrawn 2012)³~~
- 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
- ~~F1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion (Withdrawn 2012)³~~
- F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
- 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
- F1586 Specification for Wrought Nitrogen Strengthened 21Chromium—10Nickel—3Manganese—2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)
- ~~F1612 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion (Withdrawn 2011)³~~
- ~~F1636 Specification for Bores and Cones for Modular Femoral Heads (Withdrawn 2001)³~~
- F1813 Specification for Wrought Titanium-12Molybdenum-6Zirconium-2Iron Alloy for Surgical Implant (UNS R58120)
- F1814 Guide for Evaluating Modular Hip and Knee Joint Components
- F1854 Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- F1978 Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- F2996 Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems
- 2.2 *ISO Documents.*³
- ~~ISO 5832-1:1997~~ISO 5832-1:2007/Cor 1:2008 Implants for Surgery—Metallic Materials—Part 1: Wrought Stainless Steel
- ISO 5832-3:1996 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy
- ISO 5832-4:1996 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy
- ~~ISO 5832-9:1992~~ISO 5832-9:2007 Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel
- ISO 5832-12:2007 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy
- ~~ISO 5832-12:2007/Cor 1:2008~~ISO 5832-12:2008 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy, Technical Corrigendum 1
- ISO 5832-14:2007 Implants for Surgery—Metallic Materials—Part 14: Wrought Titanium 15-Molybdenum 5-Zirconium 3-Aluminum Alloy
- ~~ISO 7206-2:1996~~ISO 7206-2:2011 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics materials
- ~~ISO 7206-4:1989~~ISO 7206-4:2010 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties and Performance of Stemmed Femoral Components ~~with Application of Torsion~~
- ~~ISO 7206-7~~ Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 7: Endurance Performance of Stemmed Femoral Components without Application of Torsion (withdrawn)
- ISO 7206-8:1995 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion (withdrawn)
- ~~ISO 7206-6:1992~~ISO 7206-6:2013 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 6: ~~Determination of Endurance Properties of Head and~~ Testing and Performance Requirements of Neck Region of Stemmed Femoral Components

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

- 3.1.1 *bore, n*—an internal cavity, in the form of a truncated right cone, used to engage with the cone of a femoral neck.
- 3.1.2 *collar, n*—flange at the junction of the neck and proximal body.
- 3.1.3 *cone, n*—the truncated conic geometry on a femoral hip prosthesis used to engage with the bore of a femoral head.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

3.1.4 *distal stem, n*—region of the implant that extends distally from the proximal body. This part of the implant is intended for insertion within the femoral medullary canal. The distal stem may be in direct apposition with bone or may be fixed in the femoral medullary canal using bone cement.

3.1.5 *head, n*—convex spherical bearing member for articulation with the natural acetabulum or prosthetic acetabulum.

3.1.6 *hemi-arthroplasty, n*—replacement of the natural femoral head with a prosthetic femoral head held in place by an implant extending into the shaft of the femur. The natural acetabulum is not altered.

3.1.7 *modular (Type II) head, n*—a femoral head that is not integral with the neck and proximal body. It is a convex bearing member for articulation with either a natural acetabulum or the prosthetic acetabulum. It possesses an integrally machined bore for fitting the cone of a modular (Type II) implant.

3.1.8 *modular (Type II) implant, n*—a femoral hip component in which the head is not integral with the neck and proximal body of the implant. The modular implant is intended for insertion within the femoral medullary canal. It possesses a cone that provides a stable connection for the modular (Type II) head.

3.1.9 *mono-block (Type I) implant, n*—a femoral hip component in which the head is integral with the neck and proximal body of the implant.

3.1.10 *neck, n*—the portion of the femoral prosthesis connecting the proximal body and the prosthetic femoral head. The neck is integral with the proximal body, and is either permanently attached to the head (Type I devices) or to a cone designed to accept a modular head (Type II devices).

3.1.11 *porous surface, n*—an outermost layer(s) of all or part of the femoral implant characterized by interconnecting subsurface pores, generally with the volume porosity between 30 and 70 %, average pore size between 100 and 1000 μm , and a thickness between 500 and 1500 μm (in accordance with Test Method F1854). This porous layer may be manufactured directly into the metallic implant 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.

3.1.12 *proximal body, n*—region of the implant which extends distally from the trochanteric region to the diaphyseal region of the femur. This portion of the implant may be in direct apposition with bone or may be fixed in the femoral medullary canal using bone cement.

3.1.13 *total hip arthroplasty, n*—replacement of the natural femoral head with a prosthetic femoral head held in place by an implant extending into the shaft of the femur and replacement of the natural acetabulum with a prosthetic acetabulum. The prosthetic femoral head articulates with the bearing surface of the prosthetic acetabulum.

4. Classification of Implant Type

4.1 Femoral prostheses falling within the scope of this specification are of four types as defined as follows. There are no distinguishing features (for example, collars or lack thereof, fenestrations, and so forth) that would exempt any device from any requirement of this specification.

4.1.1 *Type IA*—Single-piece (mono-block), metallic femoral total hip or hemi-arthroplasty hip prosthesis with an integral stem, neck and head. The stem is designed such that the center of the head, the axis of the neck, and the proximal body, and the distal stem all lie in the same medial/lateral plane.

4.1.2 *Type IB*—Single-piece (mono-block), metallic, femoral total hip or hemi-arthroplasty hip prosthesis with an integral stem, neck, and head. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem do not lie in the same medial/lateral plane. This would include anteverted necks, proximally curved stems, distally bowed stems, and so forth.

4.1.3 *Type IIA*—Modular metallic femoral hip prostheses that could include a modular (Type II) head or other modular components, or both. Such “modular” designs allow for more flexible inventory management and provide a means for adjusting prosthesis neck length and, therefore, leg length at surgery. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem all lie in the same medial/lateral plane.

4.1.4 *Type IIB*—Modular metallic femoral hip prosthesis that could include a modular (Type II) head or other modular components, or both. Such “modular” designs allow for more flexible inventory management and provide a means for adjusting prosthesis neck length and, therefore, leg length at surgery. The stem is designed such that the center of the head, the axis of the neck, the proximal body, and the distal stem do not lie in the same medial/lateral plane. This would include anteverted necks, proximally curved stems, distally bowed stems, and so forth.

5. Materials

5.1 All devices conforming to this specification shall be fabricated from materials with adequate mechanical strength and durability, corrosion resistance, and biocompatibility. Some examples of materials from which femoral hip prostheses have been successfully fabricated include Specifications F67, F75, F90, F136, F138, F562, F563, F620, F745, F799, F1108, F1472, F1537, F1580, F1586, and F1813, and ISO Standards 5832/1:1997/3:1996/4:1996/9:1992/12:2007/Cor 1:2008/14:2007.

5.1.1 *Mechanical Strength*—Not all of the materials listed in 5.1 possess sufficient mechanical strength for critical highly stressed components. Conformance of a selected material to its standard and successful clinical usage of the material in a previous implant design are not sufficient to ensure the strength of an implant. Manufacturing processes and implant design can strongly influence material properties. Therefore, regardless of the material selected, the femoral hip implant ~~must~~shall meet the performance requirements of Section 6—*Performance Considerations*.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopedic implant application ~~must~~shall be determined to exhibit corrosion resistance equal to or better than one of the materials listed in 5.1 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 shall be determined to exhibit acceptable biological response equal to or better than one of the materials listed in 5.1 when tested in accordance with Practices F748 and F981.

5.1.4 The selection, strength, and processing of implant materials shall be consistent with the performance requirements contained in Section 6—*Performance Considerations*, corrosion resistance of 5.1.2, and the biocompatibility requirements of 5.1.3.

6. Performance Considerations

6.1 *Structural Requirements*—Femoral prostheses conforming to this specification shall be capable of withstanding normal static and dynamic loading in the physiological range without overload fracture, plastic deformation, or fatigue fracture.

NOTE 1—Consult the rationale in Appendix X2 for comments regarding the application of 6.1.

6.1.1 Fatigue performance of the femoral hip components may be characterized by testing in accordance with ISO 7206-4:1989, Practice 7206-4:2010, F1612, or Practice F1440. Representative samples shall be able to withstand cyclic loading with a minimum load of 300 N and a maximum load of 2.3 kN in accordance with ISO 7206-8:1995 when tested in accordance with ISO 7206-4:1989 or Practice 7206-4:2010, F1612, or cyclic loading with a minimum load of 300 N and a maximum load of 3.3 kN when tested in accordance with Practice F1440. For ASTM test methods, use an unsupported implant length of 50 mm in accordance with the ASTM definition. ~~The representative~~ The test samples should be selected from the standard (average patient) size range and which presents the ~~represent the~~ worst case stress conditions for the design series. To meet the worst case stress recommendation, implants should be tested with the worst-case offset head. Practice F2996 may be used to identify the worst case stress configuration test samples.

6.1.2 Alternatively, the demonstrated fatigue strength of the implant size with the highest stresses, when tested with the worst-case offset head and in accordance with ISO 7206-4:1989, Practice 7206-4:2010, F1612, or Practice F1440, shall be equivalent to or exceed the demonstrated fatigue strength of a comparable, clinically successful femoral implant ~~design~~. design (see the notes of Figure 2 of ISO 7206-4:2010 for clarification).

NOTE 2—~~While ISO 7206-4:1989~~ 7206-4:2010 and ISO 7206-6:1992 7206-6:2013 specify testing in a saline environment, ~~some researchers test in saline and some researchers test in ambient laboratory air environment for modular stems (excluding the head/neck junction) and in air for non-modular stems. Consideration should always be given to corrosion effects on fatigue and fretting behavior in establishing a test protocol. Materials that are suspected of environmental sensitivity or whose sensitivity level is not known, should be tested in a simulated physiological environment as recommended in ISO 7602-4:1989 and suggested in Practices 7206-4:2010 and ISO 7206-6:2013.~~ F1440 and F1612.

6.1.3 Fatigue performance of the head and neck region of the stemmed femoral components may be characterized by testing in accordance with ISO 7206-6:1992, 7206-6:2013, with the application of ~~torsion (section 7.2).~~ torsion. Representative samples shall be able to withstand cyclic loading with a minimum load of 534 N (120 lb) and a maximum load of 5340 N (1200 lb). Samples shall be able to withstand cyclic loading to 10 000 000 cycles. ~~The representative test samples should be selected from the standard (average patient) size range and present the~~ represent the worst case stress conditions for the design series. To meet the worst case stress recommendation, implants should be tested with the worst-case offset head.

6.1.4 Alternatively, the demonstrated fatigue strength of the implant size with the highest stresses, when tested with the worst-case offset head and in accordance with ISO ~~7206-6:1992~~ 7206-6:2013 with the application of torsion, shall be equivalent to or exceed the demonstrated fatigue strength of a comparable, clinically successful femoral implant design.

6.2 *Coating Integrity: Metal Coating* (for example, plasma spray, porous, and fiber metal)—The porous surface morphology shall be capable of accepting tissue (soft or hard) ingrowth to accomplish firm fixation of the device. The porosity may be uniform, or may be graded from surface to substrate in such a manner as to maximize both the interfacial strength and ingrowth potential.

6.2.1 *Shear Strength*—When tested in accordance with Test Method F1044, the average shear strength of the surface/substrate interface shall equal or exceed 20 MPa (2900 psi).

6.2.2 *Tensile Strength*—When tested in accordance with Test Method F1147, the average tensile strength of the surface/substrate interface shall equal or exceed 20 MPa (2900 psi).

6.2.3 *Abrasion Resistance of Plasma Spray Thermal Coatings*—When tested in accordance with Test Method F1978, samples fabricated and coated using this process shall not have an average mass of liberated porous coating material in excess of 65 mg/100 cycles.