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Standard Specification for Femoral Prostheses—Metallic Implants¹

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^{ε1} NOTE—Note 2 was editorially corrected in May 2003.

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 the standard.

2. Referenced Documents

2.1 ASTM Standards:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications²

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants²

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²

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

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra-Low Interstitial) Alloy (R56401) for Surgical Implant Applications²

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 R 30035²

F 563 Specification for Wrought Cobalt-20 Nickel-20 Chromium-3.5 Molybdenum-3.5 Tungsten-5 Iron Alloy for Surgical Implant Applications (UNS R30563)²

F 620 Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants²

F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications²

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials²

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices²

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 Bone²

F 983 Practice for Permanent Marking of Orthopaedic Implant Components²

F 1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings²

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

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

- F 1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings²
- F 1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion²
- F 1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy (UNS R56400) for Surgical Implant Applications²
- F 1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R 31538, and UNS R31539)²
- F 1580 Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants²
- F 1612 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion²
- F 1636 Specification for Bores and Cones for Modular Femoral Heads²
- F 1814 Specification for Evaluating Module Hip and Knee Joint Components²
- F 1854 Test Method for Stereological Evaluation of Porous Coatings on Medical Implants²
- F 1978 Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the TaberTM Abraser²

2.2 ISO Documents:

- ISO 5832-1:1997 Implants for Surgery—Metallic Materials—Part 1: Wrought Stainless Steel³
- ISO 5832-3:1996 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy³
- ISO 5832-4:1996 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy³
- ISO 5832-9:1992 Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel³
- ISO 7206-2:1996 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics materials³
- ISO 7206-4:1989 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion³
- ISO 7206-8:1995 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion³

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.

3.1.4 *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 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 of 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 F 1854). 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

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

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 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 prostheses 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 F 67, F 75, F 90, F 136, F 138, F 562, F 563, F 620, F 745, F 799, F 1108, F 1472, F 1537, and F 1580 and ISO Standards 5832/1:1997/3:1996/4:1996/9:1992.

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 meet the performance requirements of Section 6.

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 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 when tested in accordance with Practices F 748 and F 981.

5.1.4 The selection, strength, and processing of implant materials shall be consistent with the performance requirements contained in Section 6, 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 F 1612, or Practice F 1440. 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 F 1612, or cyclic loading with a minimum load of 300 N and a maximum load of 3.3 kN when tested in accordance with Practice F 1440. For ASTM test methods, use an unsupported implant length of 50 mm in accordance with the ASTM definition. The representative test samples should be selected from the standard (average patient) size range and which presents the worse case stress conditions for the design series. To meet the worse case stress recommendation, implants should be tested with the worst-case offset head.

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 F 1612, or Practice F 1440, shall be equivalent to or exceed the demonstrated fatigue strength of a comparable, clinically successful femoral implant design.

NOTE 2—While ISO 7206-4:1989 specifies testing in a saline environment, some researchers test in saline and some researchers test in ambient laboratory air. 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 which the sensitivity level is not known, should be tested in a simulated physiological environment as recommended in ISO 7602-4:1989 and suggested in Practices F 1440 and F 1612.

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 a manner to maximize both the interfacial strength and ingrowth potential.

6.2.1 *Shear Strength*—When tested in accordance with Test Method F 1044, the average shear strength of the surface/substrate interface shall equal or exceed 20 MPa (2900 psi).