



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 the standard.

2. Referenced Documents

2.1 ASTM Standards:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R 50400, UNS R 50550, UNS R50700)²

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

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

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

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

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

F 562 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R 30035)²

F 563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron 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 18Chromium-12.5Nickel-2.5Molybdenum 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-28Chromium-6Molybdenum 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-6Aluminum-4Vanadium 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 for Surgical Implant Applications (UNS R56400)²
- 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-6Aluminum-4Vanadium 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 Heads³
- F 1814 Specification for Evaluating Modular 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 Steel⁴
- ISO 5832-3:1996 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy⁴
- ISO 5832-4:1996 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy⁴
- ISO 5832-9:1992 Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel⁴
- ISO 7206-2:1996 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics materials⁴
- 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 Torsion⁴
- ISO 7206-8:1995 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion⁴
- ISO 7206-6:1992 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 6: Determination of Endurance Properties of Head and Neck Region of Stemmed Femoral Components⁴

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

³ Discontinued; See 2000 Annual Book of ASTM Standards, Vol 13.01.

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



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 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 and ISO 7206-6:1992 specify 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.

6.1.3 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, with the application of torsion (section 7.2). 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 which present 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 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 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).

6.2.2 *Tensile Strength*—When tested in accordance with Test Method F 1147, 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 F 1978, 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.

7. Dimensions and Permissible Variations

7.1 *Cone Requirements*—Type II designs, incorporating a modular head concept, should either conform to the dimensional requirements or be dimensionally defined in terms of the parameters in accordance with Specification F 1636.

8. Surface Condition and Marking

8.1 *Surface Condition*—Femoral prostheses conforming to this specification shall be processed in accordance with Practice F 86 and ISO 7206-2:1996.

8.2 *Marking*:

8.2.1 Femoral implants conforming to this specification shall be marked in accordance with Practice F 86 and Practice F 983, where space permits. Marking shall specify the manufacturer's logo and lot number and material.

8.2.2 Implant marking shall be carried out in such a way as to minimize the effects on the performance of the implant in regards to strength or biocompatibility.

8.3 *Femoral Head*—The femoral head bearing surface of Type I femoral prostheses shall be in accordance with ISO 7206-2:1996.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE STATEMENT

X1.1 The objectives of this specification are to augment common terminology, identify currently acceptable materials, set forth dimensional requirements, and provide guidelines for the mechanical performance of femoral components used for partial and total hip replacement. The investigator should also review Specification F 1814 which outlines additional parameters recommended for consideration in the design and fabrication of modular hip implants.

X1.2 Partial hip replacement parts are used in hemi-arthroplasty and are intended for use in patients who are skeletally mature and have joint degradation of only their femoral head or who have fractured the neck of their femur. Total hip replacement parts are intended for use in patients who are skeletally mature and have joint degeneration on both femoral head and acetabulum. The requirements of this speci-

fication are based upon more than forty years of successful clinical experience with these types of implants. They identify those factors recognized to effect prosthesis performance and longevity. It is recognized, however, that failure of an arthroplasty can occur as a result of factors completely unrelated to the characteristics of the prostheses.

X1.3 It is also recognized that failures of a total hip arthroplasty of hemi-arthroplasty can occur even though the components are intact. This is true owing to the goal of the surgical procedure, which is a composite construction comprised of implant components, host bone, surrounding tissue, and body fluids. Failure of the procedure may occur solely as a result of host factors not at all influenced by properties of the device components.



X2. PERFORMANCE REQUIREMENTS

X2.1 It should be recognized that laboratory testing, even with accurately simulated imposed loading and a corrosive environment of electrolytes and complex constituents of body fluids, cannot accurately predict performance over many decades of use *in vivo*. *In vivo* performance is influenced by many factors including surgical technique, patient weight, canal size, activity, and so forth. The recommended test practices described in ISO 7206-6:1992, ISO 7206-4:1989, Practice F 1440 and Practice F 1612 are based on the correlation of clinical fractures with laboratory simulations and should be considered guidelines useful for characterizing fatigue performance.

X2.2 The general requirements provide for generally good workmanship and design. Fatigue strength requirements of 6.1.1 are primarily based on the work of Semlitsch et al,⁵ with allowances for alternative test methodology that provide simulation of specific functional aspects.

X2.3 Implant fatigue requirements, specified in 6.1.1, are derived from this specification and first specified in ISO 7206-7:1993 (obsolete) and ISO 7206-8:1995. The 3.3-kN requirement for Practice F 1440 is based on ISO 7206-7:1993 which defined the requirements for implant strength when tested without torsion. ISO 7206-7:1993 has been withdrawn and is no longer current, but the recommended value is still generally accepted in the industry.

X2.4 The femoral stem fatigue strength performance criterion outlined in ISO 7206-6:1992, ISO 7206-7:1993 (obsolete), and ISO 7206-8:1995 has a relatively vague definition regarding the range of application. Both ISO 7206-8:1995 and ISO 7206-7:1993 indicate that the performance criterion is appropriate for “an average size patient” (in Europe) with a caveat regarding small sizes. This criterion has been successfully used by many manufacturers, resulting in a low incidence of clinical implant fractures. Because the defined range of application is so broad, further refinement may be useful. There is general consensus that the performance criterion is particularly appropriate when applied to the “average” patient whose body size, weight, and lifestyle are consistent with the patients described by Semlitsch. It is also consensus that implants designed for distal canal diameters of 11 mm or larger generally represent

the “average” patient population. Anatomic data gathered by Noble et al⁶ may help manufacturers determine an “average” patient population based on specific femoral prosthesis design and intended use.

X2.5 Implant designs targeted at patient population groups significantly different from the Semlitsch group (such as small canal size or unusual geometries) may not be capable of meeting this broad performance requirement. Our recommendation is that the performance criterion be applied to the “average” population as described in this specification. For those designs that fall outside of the average patient population, it may be appropriate to consider alternative design requirements that reflect device loading conditions specific to the target patient group. The best alternative measure is one based on the historical clinical evidence of a comparable device (in accordance with the guidelines in 6.1.2).

X2.6 In execution of 6.1.1 and 6.1.2, selection of the implant assembly with the worst case stress condition should not be assumed to be configured with the longest offset femoral head. The worse case stress condition depends on the combined effect of the head offset and the cross-sectional properties of the cross section near the cantilever plane. The ISO test method specifies the location to be 80 mm from the center of the head. Longer offset heads naturally produce greater height and a resulting change in the location of the cantilever cross section. In distally tapered implants, the change in cross section may be greater than the increase in offset, decreasing the maximum stress condition. With this effect in mind, the representative samples should produce the worse case stress condition for the possible combinations of head and implant size.

X2.7 The specific requirements on tensile and shear strengths of porous materials are derived from recommendations in FDA guidance documents and are generally accepted in the industry as reasonable lower bound strength limits. FDA guidance documents are living documents and, as such, are not consistent referenceable resources. The investigator is encouraged to review these documents for additional information related to femoral hip testing.

⁵ Semlitsch, M., Panic, B., “Fracture Proof Anchorage Stems of Artificial Hip Joints, Ten Years of Experience with Test Criteria,” *Engineering in Medicine*, Vol.12, No. 4, pp. 185-198.

⁶ Noble, P. C., Alexander, J. W., Lindahl, L. J., Yew, D.T., Granberry, W. M., Tullos, H.S., “The Anatomic Basis of Femoral Component Design”, *Clinical Orthopaedics & Related Research*, 1998, pp. 148-165.

X3. MATERIALS

X3.1 The materials listed in 5.1 represent some of the materials from which femoral hip prostheses have been successfully fabricated. Use of these materials does not, in and of itself, guarantee a successful design, and use of the materials may be equally successful. The necessary corrosion-resistance and biocompatibility requirements provide baseline assurance for the acceptance of new materials by the body.

X3.2 The investigator should also be aware of the galvanic corrosion potential of the materials intended for multicomponent femoral hip prostheses. Evaluation of the galvanic corrosion potential should be conducted as is recommended in 5.3.4 of Specification F 1814.

X4. DIMENSIONS

X4.1 Because of the modularity of designs and the potential for partial revisions of this type of surgery, standard nomenclature and critical dimensions of mating parts must be ensured

to assist the surgeons in selecting appropriate matching components.

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