



Designation: F2068 – 09

Standard Specification for Femoral Prostheses—Metallic Implants¹

This standard is issued under the fixed designation F2068; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

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.

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.

Current edition approved Sept. 1, 2009. Published September 2009. Originally approved in 2000. Last previous edition approved in 2003 as F2068 – 03. DOI: 10.1520/F2068-09.

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

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

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 The last approved version of this historical standard is referenced on www.astm.org.

- 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
- 2.2 ISO Documents:**⁴
- ISO 5832-1:1997** 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** 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** 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** Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics materials
- 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 Torsion
- 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
- 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 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.
- 3.1.4 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 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.

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