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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 covered by this specification are intended to be used in conjunction with a femoral prosthesis and host bone. The ingrowth of host bone into the porous coating of the femoral head is not covered by this specification.

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.

¹This 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.

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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 Implants (UNS R30041)

F137 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30042)

F138 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30043)

F139 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30044)

F140 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30045)

F141 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30046)

F142 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30047)

F143 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30048)

F144 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30049)

F145 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30050)

F146 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30051)

F147 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30052)

F148 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30053)

F149 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30054)

F150 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30055)

F151 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30056)

F152 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30057)

F153 Specification for Wrought Titanium-6Aluminum-2Zirconium-1Iron-1Nickel-0.1Carbon Alloy for Surgical Implants (UNS R30058)

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- 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
- 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)
- 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 Sprayed Coatings Using a Wheel Abraser
- F2996 Practice for Finishing and Polishing of Modular Metallic Components
- 2.2 *ISO Documents:*³
- 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 5832-9:2007 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 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 7206-2:2011 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics materials
- 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

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 7206-6:2013 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 6: Endurance Properties 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.

3.1.4 *distal stem, n*—region of the implant that extends from the proximal body to the distal end. This part of the implant is integral with the proximal body and does not extend into the femoral medullary canal. The distal stem may be attached to the bone with bone or may be attached to the bone 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).

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