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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 the standard.

2. Referenced Documents

2.1 ASTM Standards:

- F 67 Specification for Unalloyed Titanium for Surgical Implant Applications²
- F 75 Specification for Cast Cobalt—Chromium-Molybdenum Alloy for Surgical Implant Applications²
- F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²
- F 90 Specification for Wrought Cobalt-Chromium-

- Tungsten-Nickel Alloy for Surgical Implant Applications²
- 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 Applications²
- F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications²
- F 620 Specification for Titanium 6Al-4V ELI 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 Implants²
- 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 Orthopedic Implant Components²
- F 1044 Test Method for Shear Testing of Porous Metal Coatings²
- F 1108 Specification for Ti6Al4V Alloy Castings for Surgical Implants²
- F 1147 Test Method for Tension Testing of Porous Metal Coatings²
- F 1440 Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion²
- F 1472 Specification for Wrought Ti-6Al-4V Alloy for Surgical Implant Applications²
- F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants²
- F 1580 Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants²

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.

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