



Standard Specification for Acetabular Prostheses¹

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1. Scope

1.1 This specification covers acetabular resurfacing devices used to provide a functioning articulation between the bones of the acetabulum and the femur.

1.2 This specification is intended to provide basic descriptions of materials and device geometry. Additionally, those characteristics determined to be important to *in vivo* performance of the device are defined.

1.3 Acetabular 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, the use of bone screws or similar means of mechanical fixation, or through biological fixation of host bone and/or soft connective tissue into a porous surface.

1.4 Custom (designed explicitly for a single patient), revision, or constrained acetabular prostheses are not covered within the scope of this specification.

1.5 This specification does not cover the details for quality assurance, design control, production control contained in 21 CFR 820 (Quality System Regulation) and ISO 9001.

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)

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application

F629 Practice for Radiography of Cast Metallic Surgical Implants

F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

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

F1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings

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 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.