



Standard Specification for Total Knee Prosthesis¹

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1. Scope

1.1 This specification covers total knee replacement (TKR) prostheses used to provide functioning articulation by employing femoral and tibial components. Although a patellar component may be considered an integral part of a TKR, the detailed description of this component is excluded here since it is provided in Specification F 1672.

1.2 Included within the scope of this specification are replaceable components of modular designs, for example, tibial articulating surfaces and all components labeled for or capable of being used with cement, regardless of whether the same components can also be used without cement. This includes primary and revision prostheses and also covers fixed and mobile bearing knee designs.

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

1.4 Excluded from the scope are hemiarthroplasty devices that replace only the femoral or tibial surface, but not both; unicompartamental designs, which replace the articulating surfaces of only one condyle; and patellofemoral prostheses. Also excluded are devices designed for custom applications.

2. Referenced Documents

2.1 ASTM Standards:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, 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 (R30605)²

F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) 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 451 Specification for Acrylic Bone Cement²

F 562 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)²

F 563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)²

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments²

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants²

F 732 Test Method for Wear Testing for Polymeric Materials for Use in Total Joint Prostheses²

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-28Chromium-6Molybdenum Alloy 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 Material 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

F 1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings²

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.