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StandardSpecification for Total Knee Prosthesis[1]

This standard is issued under the fixed designation F2083; 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 total knee replacement (TKR) prostheses used to provide functioning articulation by employing femoral and tibial components, allowing a minimum of 110° of flexion to high flexion. 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 F1672.

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. However, compliance with this specification does not itself define a device that will provide adequate clinical performance.

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

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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)

F451 Specification for Acrylic Bone Cement

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]

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

F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

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

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)

[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.

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

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
F1223 Test Method for Determination of Total Knee Replacement Constraint
F1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)
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
F1672 Specification for Resurfacing Patellar Prosthesis
F1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
F1814 Guide for Evaluating Modular Hip and Knee Joint Components
F2384 Specification for Wrought Zirconium-2.5Niobium Alloy for Surgical Implant Applications (UNS R60901)

2.2 *ISO Standards:*[4]
ISO 6474–1 Implants for Surgery—Ceramic Materials—Part 1: Ceramic Materials Based on High Purity Alumina
ISO 10993 Biological Evaluation of Medical Devices
ISO 14243–1 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 1: Loading and Displacement Parameters for Wear-Testing Machines with Load Control and Corresponding Environmental Conditions for Test
ISO 14243–2 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 2: Methods of Measurement
ISO 14243–3 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 3: Loading and Displacement Parameters for Wear-Testing Machines with Displacement Control and Corresponding Environmental Conditions for Test

2.3 *FDA Document:*
US FDA 21 CFR 888.6 Degree of Constraint[5]

2.4 *ANSI/ASME Standard:*
ANSI/ASME B46.1 Surface Texture (Surface Roughness, Waviness, and Lay)[4]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *constraint, n*—the relative inability of a TKR to be further displaced in a specific direction under a given set of loading conditions as dictated by the TKR's geometric design.

3.1.2 *extension, n*—motion of the tibia toward bringing it into axial alignment with the femur.

3.1.3 *femoral component, n*—bearing member fixed to the femur for articulation with the tibial component and the patellar component or natural patella.

3.1.4 *flexion, n*—motion of the tibia toward bringing it into contact with the posterior femoral surface.

3.1.5 *high flexion, n*—a total knee prosthesis designed to function at flexion angles above 125°.

3.1.6 *interlock, n*—the mechanical design feature used to increase capture of one component within another and to restrict unwanted displacement between components, (that is, a component locking mechanism for modular components).

3.1.7 *patella component, n*—bearing member fixed to the natural patella for articulation with the femoral component, which is described in Specification F1672.

3.1.8 *radiographic marker, n*—a nonstructural, generally thin wire, designed to be apparent on X-rays taken after implantation for those components that would otherwise be nonapparent on such X-rays.

3.1.9 *tibial component, n*—bearing member fixed to the tibia for articulation with the femoral component, typically either monoblock UHMWPE or consisting of two major components, a metallic tibial tray and a UHMWPE bearing surface.

3.1.10 *total knee replacement (TKR), n*—prosthetic parts that substitute for the natural opposing tibial, patellar, and femoral articulating surfaces.

4. Classification

4.1 The following classification by degree of constraint is suggested, based on the concepts adopted by the U.S. Food and Drug Administration (see 2.3).

4.1.1 *Constrained*—A constrained joint prosthesis prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

4.1.2 *Semi-constrained*—A semi-constrained joint prosthesis limits translation or rotation, or both, of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkages.

4.1.3 *Non-constrained*—A non-constrained joint prosthesis minimally restricts prosthesis movement in one or more planes. Its components have no across-the-joint linkages.

5. Material

5.1 The choice of materials is understood to be a necessary but not sufficient assurance of function of the device made

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[5] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov.