Designation: F 2083 – 01a

Standard Specification for Total Knee Prosthesis[1]

This standard is issued under the fixed designation F 2083; 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. 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 standard 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; unicompartmental 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 (UNS R50250, UNS R50400, UNS R50550, UNS R50700) for Surgical Implant Applications

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)[2]

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications[2]

F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[2]

F 451 Specification for Acrylic Bone Cement[2]

F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum 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 Instruments[2]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[2]

F 732 Test Method for Wear Testing for Polymeric Materials Used in Total Joint Prostheses[2]

F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications[2]

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials[2]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[2]

F 799 Specification for Cobalt-28 Chromium-6 Molybdenum 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 Bone[2]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[2]

F 1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings[2]

F 1108 Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)[2]

F 1147 Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings[2]

F 1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings[2]

[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.

Current edition approved June 10, 2001. Published June 2001. Originally published as F 2083 - 01. Last previous edition F 2083 - 01.

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

F 1223 Test Method for Determination of Total Knee Replacement Constraint[2]
F 1377 Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS-R30075)[2]
F 1472 Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy (UNS R56400) for Surgical Implant Applications[2]
F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31529)[2]
F 1580 Specification for Titanium and Titanium-6 % Aluminum-4 % Vanadium Alloy Powders for Coatings of Surgical Implants[2]
F 1672 Specification for Resurfacing Patellar Prosthesis[2]
F 1715 Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices[2]
F 1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements[2]
F 1814 Guide for Evaluating Modular Hip and Knee Joint Replacement Components[2]

2.2 *ISO Standard:*
ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina[3]

2.3 *FDA Document:*
US FDA 21 CFR 888.6 Degree of Constraint[4]

2.4 *ANSI/ASME Standard:*
ANSI/ASME B46.1-1995, Surface Texture (Surface Roughness, Waviness, and Lay)[3]

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

3.1.6 *patella component*, *n*—bearing member fixed to the natural patella for articulation with the femoral component, which is described in Specification F 1672.

3.1.7 *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.

3.1.8 *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.

3.1.9 *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 *Semiconstrained*—A semiconstrained joint prosthesis limits translation and/or rotation 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 *Nonconstrained*—A nonconstrained 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 from them. All devices conforming to this specification shall be fabricated from materials with adequate mechanical strength and durability, corrosion resistance, and biocompatibility.

5.1.1 *Mechanical Strength*—Various components of total knee replacement devices have been successfully fabricated from the following materials. See Specifications F 75, F 90, F 136, F 138, F 562, F 563, F 745, F 799, F 1108, F 1377, F 1472, F 1537, and F 1580. Polymeric bearing components have been fabricated from UHMWPE as specified in Specification F 648. Porous coatings have been fabricated from the materials specified in Specifications F 67 and F 75. Not all of these materials may possess sufficient mechanical strength for critical highly stressed components nor for articulating surfaces.

5.1.2 *Corrosion Resistance*—Materials with limited or no history of successful use for orthopaedic implant application must be determined to exhibit corrosion resistance equal to or better than one of the materials listed in 5.1.1 when tested in accordance to Test Method F 746.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopaedic implant application must be determined to exhibit acceptable biological response equal to or better than one of the materials listed in 5.1.1 when tested in accordance with Practices F 748 and F 981 for a given application.

6. Performance Requirements

6.1 *Component Function*—Each component for total knee arthroplasty is expected to function as intended when manufactured in accordance with good manufacturing practices and to the requirements of this specification. The components shall

[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from the Food and Drug Administration, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850.

be capable of withstanding static and dynamic physiologic loads without compromise to their function for the intended use and environment. All components used for experimental measures of performance shall be equivalent to the finished product in form and material. Components shall be sterilized if it will affect their performance.

NOTE 1—Computer models may be used to evaluate many of the functional characteristics if appropriate material properties and functional constraints are included and the computer models have been validated with experimental tests.

6.1.1 Individual tibial and femoral components may be fatigue tested using relevant test methods under appropriate loading conditions to address loss of supporting foundation (see Test Method F 1800).

6.1.2 Contact area and contact pressure distributions may be determined at various flexion angles using one of several published methods[5,6,7] to provide a representation of stresses applied to the bearing surfaces and to the components. Flexion angles of 0, 15, 30, 60, and 90° are recommended. If these tests are performed, it is important to maintain consistent test parameters and to evaluate other TKR prostheses under the same conditions.

6.1.3 Range of motion in flexion/extension shall be greater than or equal to 0°, flexion shall be greater than or equal to 110°. These measurements apply to components mounted in neutral alignment in bone or in an anatomically representative substitute. It is critical to define the location of the neutral alignment position, for example, center of contact areas or patches, in terms of dimensions from outside edges of the components. The initial positioning or location of the neutral alignment point will affect the range of motion values for certain TKR prostheses.

6.1.4 Total knee replacement constraint data for internal-external rotation, anterior-posterior displacement, and medial-lateral displacement may be determined in accordance with Test Method F 1223. Testing implants at 0 and 90° of flexion at a minimum is recommended.

6.2 All modular components must be evaluated for the integrity of their connecting mechanisms. As suggested in Guide F 1814, static and dynamic shear tests, bending tests, and tensile tests or any combination may be necessary to determine the performance characteristics. The connection mechanisms must show sufficient integrity for the range of loads anticipated for the application.

6.3 It is important to understand the wear performance for articulating surfaces. Any new or different material couple must not exceed the wear rates of the following material couple when tested under physiological conditions. The current standard wear couple is CoCrMo alloy (see Specification F 75) against UHMWPE (see Specification F 648) both having prosthetic-quality surface finishes as described in 8.2 and 8.3.

6.3.1 Materials may be tested in a pin-on-flat or pin-on-disk test apparatus such as described in Test Method F 732 with adequate controls for comparison. A number of different load levels may be used to cover the range of anticipated stresses between articulating components.

NOTE 2—In situations in which the pin-on-flat test may not be considered appropriate, other tests may be considered, that is, knee simulation modes of prosthesis wear performance testing or those described in ISO 6474 or other published documents.

6.3.2 Functional wear tests also may be performed to evaluate material and design performance. Since it is unlikely that one set of test conditions can simulate all aspects of knee function, it is recommended that various test conditions be used. Among the simulated conditions, there should be consideration of the effect of third-body abrasive interaction.

6.3.3 Evaluation of wear may be done gravimetrically in accordance with Guide F 1715. Consideration should also be given to other evaluation methods such as volumetric measurements through the use of contact and noncontact profilometry and three dimensional scanning techniques, semiquantitative measures of damage assessment, and measurement of friction factors.

6.3.4 It may be important to understand the characteristics of debris generated during the wear tests. Wear debris generated from specific wear tests of new materials may be characterized for morphology and size distribution and compared to wear debris from standard controls or to wear debris collected from in-vivo clinical service or animal studies. The wear debris also may be characterized for biological response in accordance with Practice F 748.

6.4 Porous metal coatings shall be tested in accordance with Test Method F 1044 (shear strength) and Test Method F 1147 (tensile strength) and the average for each test should exceed 20 MPa. The fatigue properties may be evaluated in accordance with Test Method F 1160.

7. Dimensions

7.1 Dimensions of total knee replacement components may be designated in accordance with Fig. 1 and the items specified in the glossary. The tolerance and methods of dimensional measurement must be sought to conform with industry practice and, whenever possible, on an international basis.

8. Finishing and Marking

8.1 Metallic components conforming to this specification shall be finished and marked in accordance with Practice F 86, where applicable.

8.2 *Metallic Bearing Surface*—The main bearing surfaces shall have a surface finish no rougher than 0.10-µm (4-µin.) roughness average, R_a, when measured in accordance with the principles given in ANSI/ASME B46.1-1995. The following details should be documented: stylus tip radius, cutoff length of measuring instrument (0.25 mm recommended), and position of measurement on specimen. When inspected visually, the component shall be free from embedded particles, defects with raised edges, and scratches and score marks.

8.3 *Polymeric Bearing Surface*—The main bearing surface

[5] McNamara, J.L., Collier, J.P., Mayor, M.B., Jensen, R.E., "A Comparison of Contact Pressures in Tibial and Patellar Total Knee Components Before and After Service In-Vivo," *Clin. Orthop. Rel. Res.*, No. 299, pp. 104–113, February 1994.

[6] Szivek, J.A., Cutignola, L., Volz, R.G., "Tibiofemoral Contact Stress and Stress Distribution Evaluation of Total Knee Arthroplasties," *J. Arthroplasty*, 10(4), pp. 480–491, August 1995.

[7] Hara, T., Horii, E., An, K.N., Cooney, W.P., Linscheid, R.L., Chao, E.Y.S., "Force Distribution Across Wrist Joint: Application of Pressure-Sensitive Conductive Rubber," *J. Hand Surg. [Am]*, 17(2), pp. 339–347, March 1992.