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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, 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 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:²

F 67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

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

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

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

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

F 451 Specification for Acrylic Bone Cement

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

F 563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)³

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

F 732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses

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

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

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

F 799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F 983 Practice for Permanent Marking of Orthopaedic Implant Components

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

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

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

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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 Withdrawn.

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

F 1223 Test Method for Determination of Total Knee Replacement Constraint

F 1377 Specification for Cobalt-28Chromium-6Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)

F 1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

F 1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

F 1580 Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants

F 1672 Specification for Resurfacing Patellar Prosthesis

F 1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements

F 1814 Guide for Evaluating Modular Hip and Knee Joint Components

F 2384 Specification for Wrought Zirconium-2.5Niobium Alloy for Surgical Implant Applications (UNS R60901)

2.2 *ISO Standard*:⁴

ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina

ISO 14243-2 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 2: Methods of Measurement

2.3 *FDA Document*:

US FDA 21 CFR 888.6 Degree of Constraint⁵

2.4 *ANSI/ASME Standard*:

ANSI/ASME B46.1-1995, 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, 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 **F 1672**.

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 affixed.

4.1.2 *Semiconstrained*—A semiconstrained 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 *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**, **F 1580**, and **F 2384**. 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

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>.

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 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.

6.1.1.1 Tibial tray components shall be evaluated in accordance with Test Method F 1800. Each of five specimens shall be tested with a maximum load of 900 N (1)⁶ for 10 million cycles with no failure. All tibial components designated by this specification shall pass this minimum requirement.

6.1.2 Contact area and contact pressure distributions may be determined at various flexion angles using one of several published methods (2-7) 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 the prosthesis is designed to function at higher flexion angles, then these measurements should also be made at the maximum flexion angle as determined in 6.1.3. At 90° of flexion and the maximum flexion angle, these measurements should be made at 0° of rotation and 15° of internal and external rotation. If an internal or external rotational angle of less than 15° is used, it must be justified. On mobile bearing systems, contact area and contact pressure measurements should be made at all articulating surfaces. On mobile bearing systems, to make these measurements at 15° of internal and external rotation, the femoral component is rotated relative to the tibial base component and the mobile portion of the articulating component is allowed to come to a static position under load before measurements are taken. 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°, 15°, 90°, and maximum flexion 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 using gravimetric techniques and changes in dimensional form (the latter being applicable to hard-on-hard articulating surfaces only) in accordance with ISO 14243-2. Consideration should also be given to other evaluation methods such as 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.

⁶ The boldface numbers in parentheses refer to the list of references at the end of this standard.