Designation: F2083 – 12

Standard Specification for Knee Replacement 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 is intended to cover all the widely used generic types of knee replacement prostheses used to provide functioning articulation. This includes total knee replacement (TKR) and unicondylar knee replacement (UKR) prostheses of both fixed and mobile bearing varieties, and for primary or revision surgeries. 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.

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; 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)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of

[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 Nov. 1, 2012. Published April 2013. Originally approved in 2001. Last previous edition approved in 2011 as F2083 – 11. DOI: 10.1520/F2083-12.

[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.

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 Practice 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)
F2722 Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
F2723 Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
F2724 Test Method for Evaluating Mobile Bearing Knee Dislocation
F2777 Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion

2.2 *ISO Standards:*[4]
ISO 6474 Implants for Surgery—Ceramic Materials Based on 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 *mobile bearing knee (MBK), n*—a knee replacement system which includes an ultra-high molecular weight polyethylene (UHMWPE) component which, by design, articulates with both the femoral bearing and the tibial tray.

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

3.1.9 *radiographic marker, n*—a nonstructural radiopaque component, generally thin wire, designed to permit radiographic visualization after implantation of components manufactured of non-radiopaque materials that would otherwise not be visible on radiographs.

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

3.1.10.1 *Discussion*—Modular assemblies may be either fixed or mobile.

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

3.1.12 *unicondylar knee replacement (UKR), n*—prosthetic parts that substitute for the natural opposing tibial and femoral articulating surfaces on one condyle.

[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.

4. Classification

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

4.1.1 *Constrained*—A joint prosthesis used for joint replacement, and 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 joint prosthesis used for partial or total joint replacement, and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

4.1.3 *Non-constrained*—A "non-constrained" joint prosthesis is used for partial or total joint replacement, and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

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*—Some examples of materials from which knee replacement components have been successfully fabricated include Specifications F75, F90, F136, F138, F562, F563, F745, F799, F1108, F1377, F1472, F1537, F1580, and F2384. Polymeric bearing components have been fabricated from UHMWPE as specified in Specification F648. Porous coatings have been fabricated from the materials specified in Specifications F67 and F75. 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 applications shall 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 F746. If the corrosion resistance of a material is less than one of the materials listed in 5.1.1 when tested in accordance with Test Method F746, its use would need to be justified.

5.1.3 *Biocompatibility*—Materials with limited or no history of successful use for orthopaedic implant applications shall 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 F748, F981, or ISO 10993 for a given application. If the material is not one of the materials listed in 5.1.1, then its biocompatibility shall be verified in accordance with Practices F748, F981, or ISO 10993.

6. Performance Requirements

6.1 Although the testing methodologies described in this specification attempt to identify physiologically relevant test conditions, the interpretation of results is limited to an *in vitro* comparison between knee designs under the stated test conditions.

6.2 *Component Function*—Each component for 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 for the intended use and environment without compromise to their function. All components used for experimental measures of performance shall be equivalent to the finished product in form and material. Components shall be sterilized if this would 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.

6.2.1 Individual tibial baseplates, femoral components, and all-polyethylene tibial components should be fatigue-tested using relevant test methods under appropriate loading conditions to address loss of supporting foundation.

6.2.1.1 Tibial baseplate (tray) components shall be evaluated in accordance with Test Method F1800. Each of five specimens shall be tested and pass for 10 million cycles with no failures using a maximum load of 900 N (**1**)[6] as a minimum requirement. The baseplate components (if any) of unicondylar knee replacement systems should also be tested with an appropriate adaptation of Test Method F1800. A portion of bone loss/support should be simulated and the assumptions/adaptation explained and justified in the test report.

6.2.1.2 When the potential for bearing overhang exists, mobile bearing components shall be evaluated for their endurance and deformation. Test Method F2777 may be used for such evaluation. At least five specimens of the UHMWPE bearing component should be tested.

6.2.2 Contact area and contact pressure distributions may be determined to provide a representation of stresses applied to the bearing surfaces and to the components. For TKR, the contact pressure tests using one of several published methods (**2-7**) should be performed at various flexion angles, with 0°, 15°, 30°, 60°, and 90° 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 6.2.3. 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 shall 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. For

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

unicondylar knee replacement designs, adaptations of the above should be performed and justified.

6.2.3 The flexion-extension range of motion shall include angles from less than or equal to 0 flexion to greater than or equal to 110° flexion. 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, the center of contact areas or patches, in terms of dimensions from the outside edges of the components. The initial positioning or location of the neutral alignment point will alter the range of motion values for certain TKR prostheses.

NOTE 2—The range of motion of a total knee replacement or a unicondylar knee replacement can be estimated using the Computer Aided Design (CAD) drawings of an implant. The researcher should report how 0° of flexion was defined. Maximum flexion may be defined as the highest angle at which the following conditions are met: (*a*) bony impingement is not expected; (*b*) one or both posterior femoral condyles do not dig (that is, cause polyethylene deformation in the form of an edge or line) into the implant tibial component; or (*c*) subluxation of one of the posterior femoral condyles or full dislocation does not occur as the knee is flexed and experiences posterior motion or internal-external rotation of the femoral component

6.2.4 Total knee replacement constraint data for internal-external rotation, anterior-posterior displacement, and medial-lateral displacement may be determined in accordance with Test Method F1223. Testing implants at 0°, 15°, 90°, and maximum flexion is recommended. Test Method F1223 covers special provisions for mobile bearing knees, allowing the constraint of the inferior articular surfaces to be estimated as well as that of the entire implant with both superior and inferior articulations. For unicondylar knees, adaptations of the Test Method of F1223 should be devised to test and characterize constraint. Any such adaptation or verifications of special design claims on constraint/laxity of a unicondylar knee system shall be described and justified in test reports with special emphasis on how it applies to the individual UKR design tested.

NOTE 3—Depending on the sign/direction, a knee joint internal-external rotation can cause (or require) extra linear AP motion of a unicondylar component due to its offset location towards one condyle.

6.2.5 In order to verify that there is sufficient implant constraint against subluxation and sufficient laxity (no digging-in of posterior condyle edges) at maximum flexion (as measured in 6.2.3), total knee replacement constraint data for internal-external rotation and for anterior-posterior motion should be determined at maximum flexion. At maximum flexion, the device should be able to support anticipated physiologic loading conditions and allow internal-external rotation of ±15° without subluxation (**8**). Constrained knee systems, as defined in this standard and 21 CFR 888.6, are linked across the joint and may be too constrained by design to allow for ±15° of rotation at maximum flexion. The range of motion for such constrained devices can be estimated in other ways, but justification shall be reported. The criterion above is also applicable to a unicondylar knee replacement but the ±15° internal-external rotation at which max flexion should be verified remains that of the whole knee system, and not the individual UKR. Depending on the size/width of the knee joint indicated for implantation of the UKR, the ±15° internal-external rotation of the whole knee implies some AP translation as well as rotation of the UKR tibial component. A simple mathematical calculation should be carried out to determine the resulting combination of anterior-posterior and internal-external positions/locations expected of the UKR femoral component relative to its tibial component at each extreme (±15°) of whole knee joint rotation. The UKR should not subluxate under constraint testing with this determined combination of anterior-posterior translation and rotation. All mobile bearing knees (whether total or unicondylar) should be evaluated for dislocation (spinout or spit-out) resistance. Test Method F2724 may be used for such evaluation.

6.3 All modular components shall be evaluated for the integrity of their connecting mechanisms. As suggested in Guide F1814, static and dynamic shear tests, bending tests, and tensile tests or any combination may be necessary to determine the performance characteristics. The connection mechanisms shall show sufficient integrity for the range (or appropriate share) of loads anticipated for the application. Any mobile bearings featuring mechanical stops (for example, rotational stops in rotating platform designs) should be evaluated for robustness of the stops. Test Method F2722 may be used for such evaluation. Five specimens should be tested. All mobile bearing knee designs should also be evaluated for any form of dynamic dislodgement or dissociation of any bearing retention mechanism. Test Method F2723 may be used for such evaluation. Five specimens should be tested.

6.4 It is important to understand the wear performance for articulating surfaces. Any new or different material couple shall not exceed the wear rates of the following material couple when tested under physiological conditions. The current standard wear couple that has demonstrated good clinical performance is CoCrMo alloy (see Specification F75) against UHMWPE (see Specification F648), both having prosthetic-quality surface finishes as described in 8.2 and 8.3.

6.4.1 Materials may be preliminarily tested in a pin-on-flat or pin-on-disk test apparatus such as described in Test Method F732 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 4—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.

6.4.2 Functional (simulated) wear tests of the device may be performed to evaluate the tibiofemoral articulation according to ISO 14243–1 or ISO 14243–3. 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. For unicondylar knee replacement designs, adaptations of ISO 14243–1 or ISO 14243–3 should be performed and justified. One example of such is the use of two UKR designs tested under TKR conditions.

6.4.3 Evaluation of wear may be performed 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.

6.4.4 It may be important to understand the characteristics of debris generated during the wear tests, especially when extra articulations and potential new wear mechanisms can be introduced such as in (unicondylar and total) mobile bearing knees. Wear debris generated from specific wear tests of new materials or designs with mobile bearings 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 F748 or ISO 10993.

6.5 Porous metal coatings shall be tested in accordance with Test Method F1044 (shear strength) and Test Method F1147 (tensile strength) and the average for each test should exceed 20 MPa. The fatigue properties may be evaluated in accordance with Test Method F1160.

7. Dimensions

7.1 Dimensions of total knee replacement components may be designated in accordance with Fig. 1and the items specified in the glossary. For mobile bearing TKRs and unicondylar knee replacement, all or an appropriate subset of those same dimensions should be designated, clearly highlighting all articular mobility features and any mechanical stops to limit them, if any. The tolerance and methods of dimensional measurement shall conform to 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 F86, 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. The following details should be documented: stylus tip radius, cutoff length of the

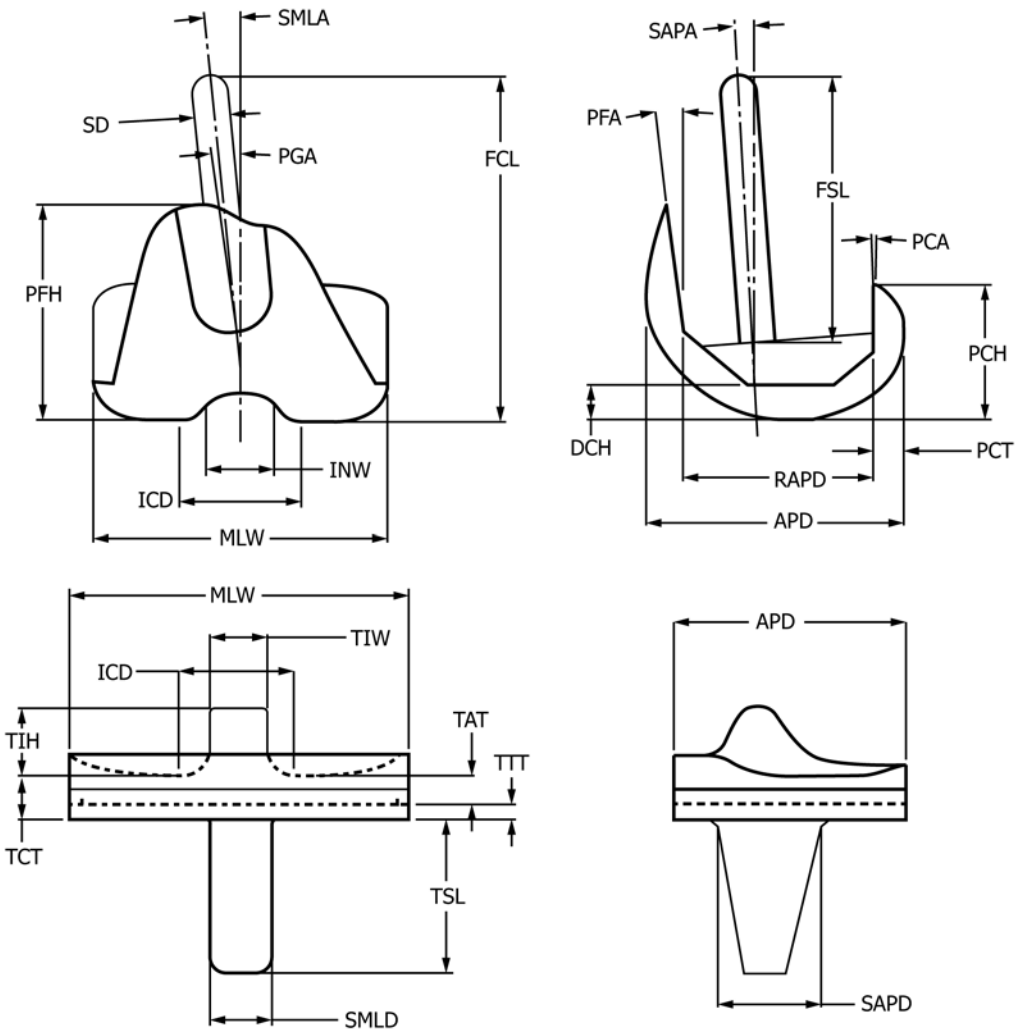

FIG. 1 General Depiction of Important Attributes of Total Knee Arthroplasty Components

measuring instrument (0.25 mm recommended), and the position of measurement on the specimen. When inspected visually, the component shall be free from embedded particles, defects with raised edges, scratches, and score marks.

8.3 *Polymeric Bearing Surface*—The main bearing surface of a UHMWPE component shall have a surface roughness no greater than 2-µm (80-µin.) roughness average, R_a, when measured in accordance with the principles given in ANSI/ASME B46.1. The following details should be documented: stylus tip radius, cutoff length of the measuring instrument (0.80 mm recommended), and the position of measurement on the specimen. When inspected with normal or corrected vision, the bearing surface shall be free from scale, embedded particles, scratches, and score marks other than those arising from the finishing process.

NOTE 5—Measurements should be taken in at least two orthogonal directions.

8.4 In accordance with Practices F86 and F983, items conforming to this specification shall be marked as follows in order of priority where space permits: manufacturer, material, lot number, catalog number, and size. Additional markings may be included, that is, left, right, front, and so forth.

8.5 If one of the components is not radiographic opaque, it may be appropriately marked for radiographic evaluation. Radiographic markers have been used in the past, but are considered noncritical, and may not be necessary. If a radiographic marker is used, it should be placed in a noncritical area to avoid degrading the structural and functional properties of the device.

9. Packaging and Package Marking

9.1 An adequate description of overall size and shape shall be included in the packaging. Dimensions, when used, shall conform to the convention described in the glossary and Fig. 1, or with appropriately derived similar parameters in the case of a UKR and mobile bearing knees.

9.2 The end user shall be able to determine the minimum thickness (TAT) of the UHMWPE in the main bearing area for either integral or modular systems from the package material. This may be achieved by directly specifying the TAT dimension or by providing a means to calculate the TAT dimension (see X2.12).

9.3 Packaging material for the TKR or a UKR prosthesis system (femoral and tibial components) may include information developed from Test Method F1223.

10. Keywords

10.1 arthroplasty; contact area; contact pressure; fatigue; knee; knee constraint; knee prosthesis; knee wear; particles; surface roughness; total knee replacement; TKR; unicondylar knee replacement (UKR); UHMWPE

APPENDIXES

(Nonmandatory Information)

X1. GLOSSARY (Refer to Fig. 1)

X1.1 *anteroposterior distance (APD), n*—for both femoral and tibial components, the maximum A-P distance in a sagittal plane.

X1.2 *distal condylar height (DCH), n*—thickness of the femoral component from the transverse resection plane to the functional surface.

X1.3 *effective bone resection distance, n*—is numerically equal to the distal condylar height (DCH) plus the tibial component thickness (TCT).

X1.4 *femoral stem length (FSL), n*—that portion of the prosthesis intended for intramedullary fixation measured from stem origin, if this is the superior surface of the intercondylar box, to the tip of the stem. The length of a modular stem attachment shall also be described this way.

X1.5 *intercondylar dimension (ICD), n*—mediolateral distance between most distal point of each condyle of the femoral and the tibial components, respectively. Not applicable to hinged joints.

X1.6 *intercondylar notch width (INW), n*—the mediolateral width of the notch between the femoral condyles.

X1.7 *mediolateral distance width (MLW), n*—for both femoral and tibial components, the maximum width of the components in the frontal elevation.

X1.8 *overall femoral component length (FCL), n*—the overall length of the femoral component from the most distal articular surface to the most proximal surface. This may be equivalent to PFH in many cases.

X1.9 *patellar flange angle (PFA), n*—the angle formed by the anterior patellar articulating surface of the femoral component with respect to the distal articular surface in the neutral position in the saggital plane.

X1.10 *patellar flange height (PFH), n*—the distance from the most superior tip of the anterior patellar articulating surface of the femoral component to the distal articular surface in the neutral position.

X1.11 *patellar groove angle (PGA), n*—the angle formed by the patellar articulating depression in the patellar flange and the neutral axis of the femoral component in the frontal plane.

X1.12 *posterior condylar angle (PCA), n*—the angle formed by the posterior condylar flange with respect to the

distal articular surface of the femoral component in the neutral position.

X1.13 *posterior condylar height (PCH), n*—the distance from the most superior tip of the posterior condylar flange to the distal articular surface of the femoral component in the neutral position.

X1.14 *posterior condylar thickness (PCT), n*—thickness of the femoral component from the posterior plane to the posterior articular surface.

X1.15 *resected anteroposterior distance (RAPD), n*—the minimum distance from the posterior condylar resection surface to the anterior condylar resection surface.

X1.16 *stem anteroposterior angle (SAPA), n*—the angle formed by the femoral stem relative to the neutral axis of the femoral component in the saggital plane.

X1.17 *stem mediolateral angle (SMLA), n*—the angle formed by the femoral stem relative to the neutral axis of the femoral component in the frontal plane.

X1.18 *stem diameter (SD), n*—the stem diameter for either femoral or tibial components. If the stem does not have a uniform diameter, such as wedge shaped tibial stems, then the mediolateral and anteroposterior dimensions shall be specified.

X1.19 *stem mediolateral dimension (SMLD), n*—the cross-sectional mediolateral width of a non-symmetrical stem at its midpoint on the frontal plane.

X1.20 *stem anterioposterior dimension (SAPD), n*—the cross-sectional anterioposterior distance of a non-symmetrical stem at its midpoint on the saggital plane.

X1.21 *tibial component thickness (TCT), n*—the thickness from the functional articular surface to the distal inferior surface of the plateau. This is equal to TAT plus TPT for any multicomponent system. This is equal to TAT for all single material systems.

X1.22 *tibial articular surface thickness (TAT), n*—the minimum distance from the articular surface of the tibial component to the superior surface of the supporting plateau.

X1.23 *tibial tray thickness (TTT), n*—the minimum thickness of the tibial tray when measured from the superior surface to the inferior surface. In the case of a single component, this dimension is TAT.

X1.24 *tibial stem length (TSL), n*—that portion of the tibial component intended for intramedullary fixation. It is measured from stem origin at the inferior surface of the plateau to the distal tip of the stem.

X1.25 *tibial intercondylar spine width (TIW), n*—the mediolateral width of the posterior stabilization spine.

X1.26 *tibial intercondylar spine height (TIH), n*—the distance from the superior condylar articulating surface to the top of the posterior stabilization spine.

X2. RATIONALE

X2.1 The objectives of this specification are to establish guidelines for the manufacture and function of components for total knee replacement. This specification describes the femoral and tibial components and relies on Specification F1672 to describe the patella component for a total knee replacement. It also refers to standardized TKR test methods and applies adaptations of them to uncicondylar and mobile bearing system. These knee replacement parts are intended for use in a patient who is skeletally mature under conditions of imposed dynamic loads in a corrosive environment and virtually continuous motion at the bearing surfaces. Laboratory tests to accurately simulate imposed loads, aggressive electrolytes, and complex constituents of body fluids cannot be usefully accelerated. Long-term projections of satisfactory performance over many decades can be suggested, but not accurately predicted, using currently available screening procedures.

X2.2 This specification identifies those factors felt to be important to assure a satisfactory useful prosthesis life. It is here recognized that failure of an arthroplasty can occur even while the components are intact. This specification is expected to provide reasonable assurance that devices in compliance with the standard will not experience mechanical failure or undesirable tissue reaction to the materials of the device or its design. Other factors affecting outcome of the arthroplasty not addressed by this specification include infection, surgical technique, misuse by the patient, and unpredicted tissue response.

X2.3 Under applicable documents and materials, the content reflects the portion of the current state of the art in which consensus has been reached to allow standardization. It is recognized that should materials or further generic design types not covered here (for example, replacement of damaged partial cartilage with artificial surfaces) appear and be proven acceptable, they shall be inserted in the process of revisions. To date, a majority of knee prosthesis components have been implanted using a bone bonding agent, such as acrylic bone cement in accordance with Specification F451. Although the bone bonding agent is not considered part of the knee prosthesis, it may play an important role in the performance of the prosthesis and, therefore, should be considered during testing and evaluation.

X2.4 *Constraint Classification*—Total knee prosthetic components in common use comprise three recognized classes of prosthetic pairs: constrained, partially or semi-constrained, and non-constrained. No general consensus has emerged to establish clearly the most widely acceptable classification; nor is this

classification necessarily applicable to all types of knee replacement designs. However, the qualitative descriptors included herein have been adopted by the U.S. Food and Drug Administration for the purposes of evaluating new device applications. It is also anticipated that through the application of Test Method F1223 appropriate categorization may be achieved and data sufficient to allow proper selection of a device for a particular patient will be available. Note that devices within a particular classification may allow significantly different degrees of freedom (that is, translation, rotation, or flexion ranges or limits) from other devices within the same classification, depending on device geometry and the means and relative amount of constraint. Conversely, devices in different classifications may allow similar degrees of freedom and provide comparable motion and clinical results.

X2.5 In the course of evaluating new materials, it is recommended that if the material is used in an application that causes small particle formation from abrasion or normal wear processes then the biocompatibility of these particles be determined in addition to that of the bulk material.

X2.6 *Performance Considerations*—Component performance can be predicted only indirectly at this stage by referring to strength levels and other parameters. Reference to parameters applicable to materials may or may not adequately describe structures made from them. In a period of transition from device specification standards to device performance standards, both methods of description may be appropriate. Mechanical values derived from materials testing and cited as minimum allowable levels shall be applicable to the structures described in the specifications. Usual and customary sampling procedures shall be considered adequate assurance of compliance. Exemption from sampling is justified where no degradation in mechanical properties is to be expected during fabrication of components.

X2.7 It is anticipated that as new performance data becomes available, they will be incorporated into the body of this specification.

X2.8 Component performance should be considered with regard to body weight, with unusually small patients being well served by small components. It is well recognized that physical stresses resulting from events or activities out of the ordinary range, as in accidents or especially vigorous sports, or due to excessive misalignments of installation during surgery, predictably exceed allowable stress levels in any component design. It is also recognized here that other forms of arthroplasty failure are known to occur, related primarily to patient and surgical factors, such as osteoporosis, Paget's disease, misuse, disuse, improper installation and others.

X2.9 Radiographic markers have been used to make components radiographically detectable. They may not be necessary, but when they are used, they shall be located in a noncritical area to avoid any contribution to device failure. They shall not be located in critical wear areas or regions that may see high stresses since this could reduce the service life of the component.

X2.10 For marking of the components, it is desirable to have complete information, where space is available to do so, including the manufacturer's trademark, material, lot number, size, orientation (if any), and date in that order.

X2.11 For the purposes of this specification, packaging may include product brochures and associated literature.

X2.12 It is important to allow the end user to determine the minimum thickness of a bearing material in the areas that may undergo high loading. One common region, as described in Fig. 1, is the minimum amount of UHMWPE in the tibial component under the femoral condyle at full extension. Although the thickness does not necessarily determine clinical performance, it may be helpful to the end user.

X2.13 The tibial tray Test Method F1800 is a simplified means to evaluate performance and does address some, but not all, clinical failure modes. The minimum performance level of 900 N is based on literature and the experience of several test laboratories. It is recognized that investigators have used other test methods to evaluate tibial components of total knee prostheses for similar and different failure modes.

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