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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]

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[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.

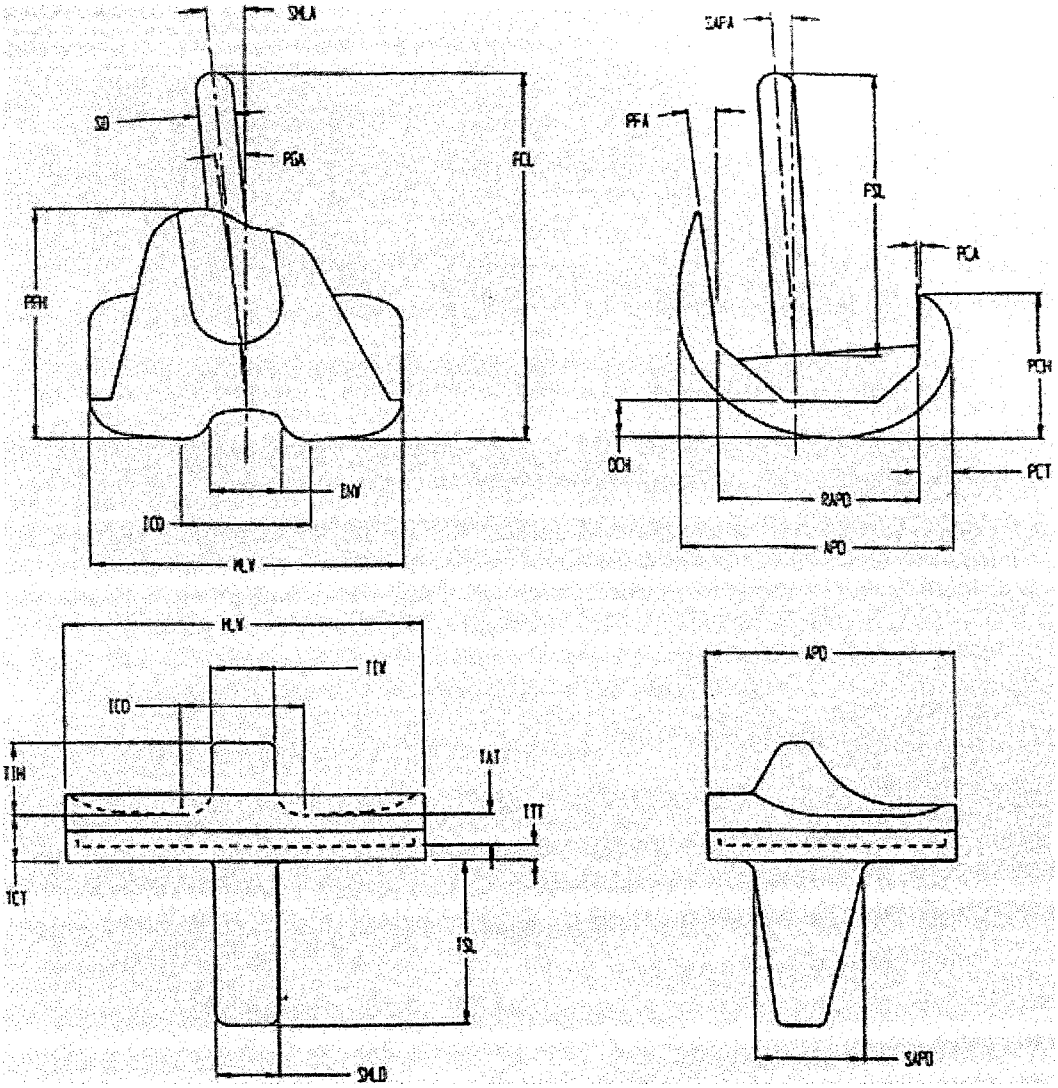

FIG. 1 General Depiction of Important Attributes of Total Knee Arthroplasty Components

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 B46.1-1995. The following details should be documented: stylus tip radius, cutoff length of measuring instrument (0.80 mm recommended), and position of measurement on specimen. When inspected with normal or corrected vision, the bearing surface shall be free from scale, embedded particles, and scratches and score marks other than those arising from the finishing process.

NOTE 3—Measurements should be taken in at least two orthogonal directions.

8.4 In accordance with Practices F 86 and F 983, 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 and 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 Adequate description of overall size and shape shall be included in the packaging. Dimensions, when used, shall conform to the convention as described in the glossary and Fig. 1.

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 prosthesis system (femoral and tibial components) may include information developed from Test Method F 1223.

10. Keywords

10.1 arthroplasty; contact area; contact pressure; fatigue; knee; knee constraint; knee prosthesis; knee wear; particles; surface roughness; total knee replacement; TKR; 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 or overall thickness (OT), n*—the minimum distance that must exist between the femur and tibia to enable implantation of the device. 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 stems are not uniform diameters, such as wedge shaped tibial stems, then specify the mediolateral and anteroposterior dimensions.

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

X1.20 *stem anterioposterior dimension (SAPD), n*—the cross-sectional anterioposterior distance of a nonsymmetric 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. 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 F 1672 to describe the patella component for a total knee replacement. These total 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 simulate accurately imposed loads, aggressive electrolytes, and complex constituents of body fluids cannot be usefully accelerated. Long-term projections of satisfactory performances 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 of the device or undesirable tissue reaction to the materials of the device or its design. Other factors affecting outcome of the arthroplasty not addressed by this standard include infection, surgical technique, misuse by the patient, and unpredicted tissue response.

X2.3 Under applicable documents and materials, the list reflects the current state of the art. It is recognized that should materials not now included appear and be proved 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 F 451. 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 semiconstrained, and nonconstrained. No general consensus has emerged to establish clearly the most widely acceptable classification; 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 F 1223 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 must 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, such as that developed by the task force on standard practice for the cyclic fatigue testing of metal backed tibial tray components of knee joint replacement designs, it will be incorporated into the body of this document.

X2.8 Component performance should be considered with regard to body weight, with unusually small patients being served well 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, 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 factors, such as osteoporosis, Paget's disease, misuse and disuse, and others.

X2.9 Radiographic markers have been used to make components radiographically detectable. They may not be necessary, but when they are used, shall be located in a noncritical area to avoid any contribution to device failure. They shall not be located in critical wear areas nor 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 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.