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Standard Specification for ~~Total~~ Knee Replacement Prosthesis[1]

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1. Scope

1.1 This specification ~~covers total knee replacement (TKR)~~ is intended to cover all the widely used generic types of knee replacement prostheses used to provide functioning ~~articulation by employing femoral and tibial components, allowing a minimum of 110° of flexion to high flexion.~~ 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. ~~This includes primary and revision prostheses and also covers fixed and mobile bearing knee designs.~~

1.3 This specification is intended to provide basic descriptions of material and prosthesis geometry. Additionally, those characteristics determined to be important to *in vivo* performance of the prosthesis are defined. However, compliance with this specification does not itself define a device that will provide adequate clinical performance.

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

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F451 Specification for Acrylic Bone Cement

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F563 Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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

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

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

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

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

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

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

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

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

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,~~ nonstructural radiopaque component, generally thin wire, designed to ~~be apparent on X-rays taken~~ permit radiographic visualization after implantation ~~for those components~~ of components manufactured of non-radiopaque materials that would otherwise not be ~~nonapparent~~visible on ~~such X-rays.~~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 ~~tray~~ 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. 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 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 ~~semi-constrained joint prosthesis limits translation or rotation, or both,~~ 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 ~~linkages.~~linkage.

4.1.3 *Non-constrained*—A ~~non-constrained joint prosthesis minimally restricts~~ "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 ~~linkages.~~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*—~~Various components of total~~ Some examples of materials from which knee replacement ~~devices~~components have been successfully fabricated ~~from the following materials. See~~ include Specifications F75, F90, F136, F138, F562, F563, F745, F799, F1108, F1377, F1472, F1537, F1580, ~~F2384,~~and F2384~~and ISO 6474–1.~~ . 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 ~~must~~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 ~~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 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 ~~it will~~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 ~~and femoral components may be fatigue tested~~ 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 ~~tray~~ baseplate (tray) components shall be evaluated in accordance with Test Method F1800. Each of five specimens shall be tested ~~with~~ and pass for 10 million cycles with no failures using a maximum load of 900 N ~~((1))~~[6] ~~for 10 million cycles with no failures. All tibial components designated by this specification shall pass this minimum requirement.~~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 ~~at various flexion angles~~ 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**) ~~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~~ 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 ~~must~~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 unicondylar knee replacement designs, adaptations of the above should be performed and justified.

6.2.3 ~~Range~~ The flexion-extension range of motion ~~in extension shall be greater~~shall include angles from less than or equal to ~~0°,~~0 flexion ~~shall be~~ to greater than or equal to ~~110°.~~ 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 ~~determined~~estimated using the ~~CAD~~ 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**).

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

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 ~~8.4~~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.~~ 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

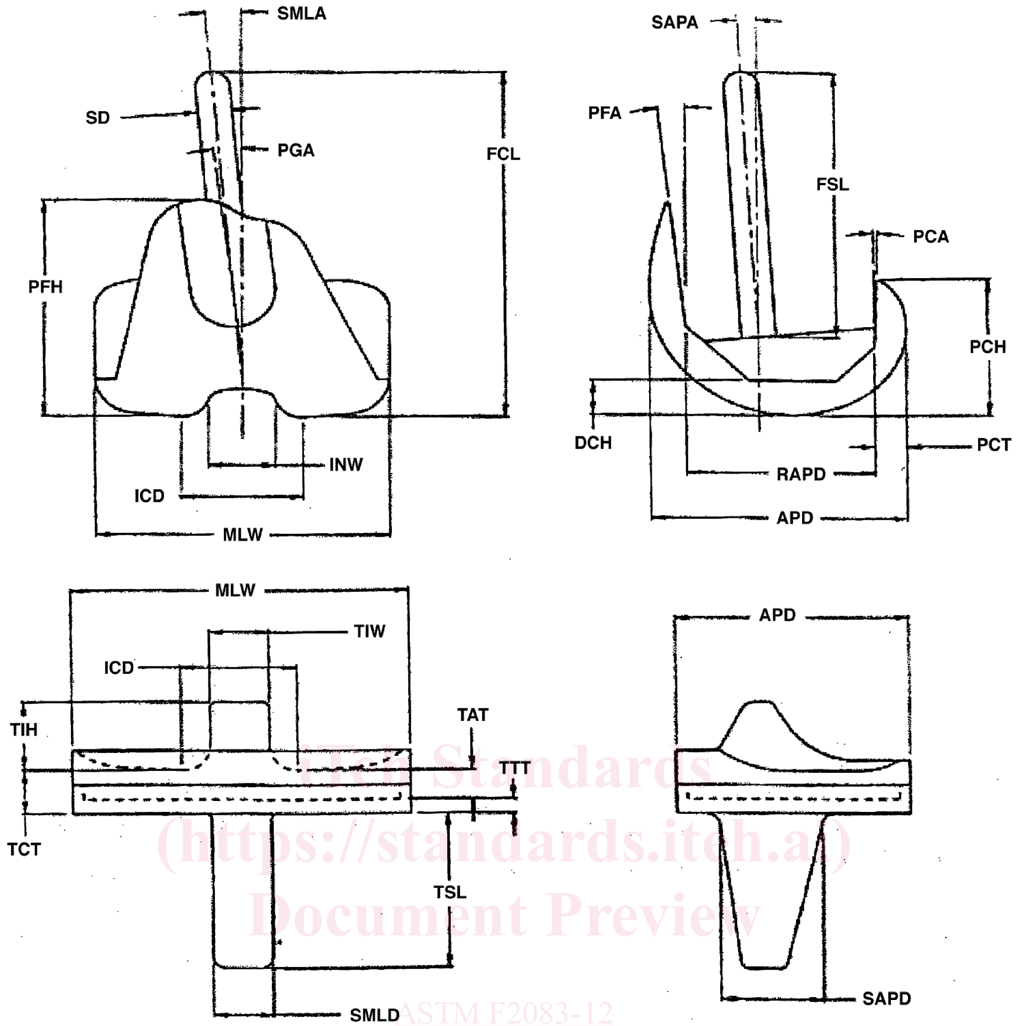

FIG. 1 General Depiction of Important Attributes of Total Knee Arthroplasty Components

documented: stylus tip radius, cutoff length of the 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 *Ceramic Bearing Surface*—The main bearing surfaces of ceramic components shall have a surface finish no rougher than 0.10-µm roughness average, Ra, where measured in accordance with the principles given in ANSI/ASME B46.1. 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 components 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.