



Designation: F2722 – 08

Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops¹

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1. Scope

1.1 This test method covers a laboratory-based *in vitro* method for evaluating the mechanical performance of materials and devices being considered for replacement of the tibio-femoral joint in human knee joint replacement prostheses in mobile bearing knee systems.

1.2 Mobile bearing knee systems permit internal external rotation to take place on one or both articulating surfaces. Some designs place physical limits or stops to the amount of rotation. Other designs may have increases of a resistance force with increases in rotation.

1.3 Although the methodology describes attempts to identify physiologically relevant motions and force conditions, the interpretation of results is limited to an *in vitro* comparison between mobile bearing knee designs and their ability to maintain the integrity of the rotational stop feature and tibial bearing component under the stated test conditions.

1.4 This test method is only applicable to mobile knee tibial systems with a rotational stop.

1.5 The values stated in SI units are regarded as standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards*:²

F2083 Specification for Total Knee Prosthesis

F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air

¹ This test method 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.

3. Terminology

3.1 *Definitions*:

3.1.1 *bearing axis*—the line connecting the lowest points on both the lateral and medial condyles of the superior surface of the mobile bearing.

3.1.2 *inferior articulating interfaces*—any interface in which relative motion occurs between the underside of the mobile bearing component and the tibial tray.

3.1.3 *mobile bearing*—the component between fixed femoral and tibial knee components with an articulating surface on both the inferior and superior sides.

3.1.4 *mobile bearing knee system*—a knee prosthesis system, comprised of a tibial component, a mobile bearing component that can rotate or rotate and translate relative to the tibial component, and a femoral component.

3.1.5 *neutral point*—midpoint of the bearing axis.

3.1.6 *rotational stop*—a feature that prevents relative rotation between two articulating joint surfaces beyond a specific angle of rotation or creates resistance to rotation beyond a specific angle of rotation.

3.1.7 *superior articulating interfaces*—any interface in which relative motion occurs between the topside of the mobile bearing component and the femoral bearing component.

4. Significance and Use

4.1 Fundamental aspects of this test method include the use of dynamic rotational force and motion representative of the human knee joint during an activity of daily living (deep flexion) and the effect of these forces and motions on the design features which stop or limit rotation in a mobile bearing knee design.

4.2 This test is required if rotational stops are designed to limit motion to $\pm 20^\circ$ or less; or there are other resistances to rotational motion with this $\pm 20^\circ$ range. In some instances, the rotational displacement could occur in both the inferior and superior interfaces.

5. Apparatus and Materials

5.1 *Component Configurations*:

5.1.1 A test construct of the femoral component, mobile bearing component, and tibial tray should be used to provide appropriate interface geometries.

5.1.2 The knee joint tibial and femoral components should be assembled and oriented in a manner similar to that in which they would function *in vivo* as depicted in Fig. 1. The femoral component is mounted at the maximum flexion angle claimed for the device by the manufacturer.

5.1.3 The tibial component is mounted at zero slope. This means that the flat portion of the superior tibial surface will be perpendicular to the force axis.

5.2 Mechanical Testing Systems:

5.2.1 *Test Chambers*—Design each chamber entirely of noncorrosive materials, such as acrylic plastic or stainless steel, and ensure that it is easily removable from the machine for thorough cleaning between tests. Design the chambers such that the bearing surfaces are immersed in lubricant throughout the test.

5.2.2 The system should be capable of maintaining an axial force of 2000 N force as illustrated in Fig. 1. (Although this force is representative of a normal range compressive force, it is mainly intended as a uniform force to keep the components in contact during the test.)

5.2.3 The system should be capable of applying under torque control a peak torque of 14 N-m ($2\times$ the peak torque measured from a telemeterized knee study (1)³) and cycling back to near zero torque in both internal and external rotation directions.

5.2.4 If the rotational stop geometries for internal and external rotation are non-symmetrical, both the internal and external rotational stops should be tested. The same sample may be used for both tests if the results of the first test do not cause any damage that could affect the results of the second test.

5.2.5 *Rotational Test Frequency*—Rotate the relative rotational motion at a nominal rate of 0.5 to 3.0 cycles per second (0.5 to 3.0 Hz) per complete cycle to minimize viscoelastic high frequency effects.

5.2.6 *Cycle Counter*—Include with the mechanical testing system a method to monitor and count the number of cycles.

5.2.7 *Lubricant*—Lubricate the specimen by immersion in deionized water, mineral oil, olive oil or other suitable lubricant and maintained at $37 \pm 2^\circ\text{C}$.

6. Specimen Preparation

6.1 The geometry of the parts must be within the specified tolerance ranges of final production designs.

6.2 The metallic components should follow the complete manufacturing process (machining, surface treatment, laser marking, passivation, cleaning, and so forth) until the sterilization stage. Because sterilization has no known effect on the mechanical properties for metallic components, it is not necessary for these to be sterilized. The polymeric components

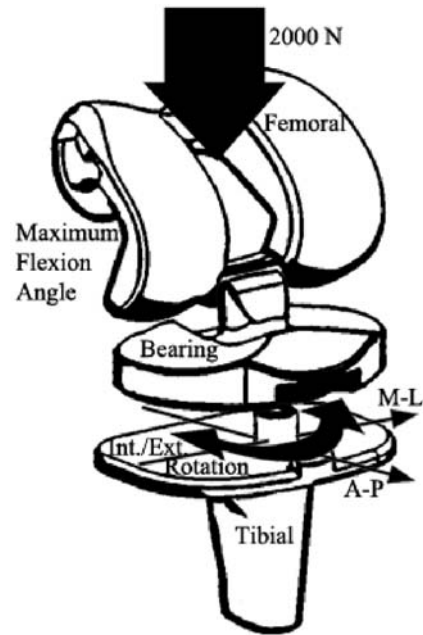


FIG. 1 Schematic of Test Setup

should be sterilized in a manner consistent with the clinical use for such devices, as this may affect the mechanical properties of the material.

6.3 The ultra-high molecular weight polyethylene (UHMWPE) components should be artificially aged according to Practice F2003, except when the mechanical properties of the UHMWPE have been proven not to be detrimentally affected by the aging.

6.4 Because the cold flow of the bearing component depends on its thickness, the thinnest bearing component in the knee system should be used.

7. Procedure

7.1 Rigidly mount the femoral component at the maximum flexion angle of the knee as determined in Specification F2083 to the compressive force axis. The femoral component should contact the mobile bearing component at the bearing axis to allow rotation about the neutral point.

NOTE 1—Although in high flexion the femoral component is more posterior on the bearing, such a position would make it difficult to rotate the bearing around the neutral point.

7.2 The tibial base plate articulating surface (or the flat portion thereof) should be mounted perpendicular to the compressive force axis.

7.3 Mounting of the tibial base plate should not interfere with tibiofemoral rotation.

7.4 Either the femoral component or the tibial base plate component may be articulated, based upon the mechanical testing equipment capabilities.

7.5 Place the components in the testing system in zero degrees rotational alignment, add lubricant, apply the axial force, and commence cyclic rotational motions.

7.6 Apply the 2000 N force and maintain it.

³ The boldface numbers in parentheses refer to the list of references at the end of this standard.