



Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion¹

This standard is issued under the fixed designation F2777; 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 standard specifies a test method for determining the endurance properties and deformation, under specified laboratory conditions, of ultra high molecular weight polyethylene (UHMWPE) tibial bearing components used in bicompartmen- tal or tricompartmental knee prosthesis designs.

1.2 This test method is intended to simulate near posterior edge loading similar to the type of loading that would occur during high flexion motions such as squatting or kneeling.

1.3 Although the methodology described attempts to iden- tify physiological orientations and loading conditions, the interpretation of results is limited to an *in vitro* comparison between knee prosthesis designs and their ability to resist deformation and fracture under stated test conditions.

1.4 This test method applies to bearing components manu- factured from UHMWPE.

1.5 This test method could be adapted to address unicom- partmental total knee replacement (TKR) systems, provided that the designs of the unicompartmental systems have suffi- cient constraint to allow use of this test method. This test method does not include instructions for testing two unicom- partmental knees as a bicompartmental system.

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

1.7 *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 appro- priate safety and health practices and determine the applica- bility of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F1223 Test Method for Determination of Total Knee Re- placement Constraint

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

F2083 Specification for Knee Replacement Prosthesis

2.2 Other Standards:³

ISO 4965–1 Metallic materials—Dynamic Force Calibration for uniaxial fatigue testing —Part 1: Testing system

ISO 5833 Implants for Surgery—Acrylic Resin Cements

3. Terminology

3.1 Definitions:

3.1.1 *anatomic (mechanical) axis of the femur*—the line between the center of the femoral head and the center of the femoral knee.

3.1.2 *bearing centerline*—the line running anteroposterior that is the mirror line of the femoral articulating surface. For asymmetric bearing tibial tray designs, the appropriate tibial tray centerline shall be determined and reported along with the rationale for the location.

3.1.3 *bearing retention mechanism*—mechanical means for preventing tibial tray/bearing disassociation.

3.1.4 *femoral component centerline*—a line running antero- posterior between the femoral condyles and parallel to the femoral condyles. The line should be equidistant between the condyles. For asymmetric or non-parallel condyles designs, the appropriate centerline shall be determined, and the rationale for that location reported.

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.

Current edition approved July 1, 2016. Published August 2016. Originally approved in 2010. Last previous edition approved in 2010 as F2777–10. DOI: 10.1520/F2777-16.

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 Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.