



Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation¹

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1. Scope

1.1 This test method describes a laboratory method for evaluating the potential for mobile bearing knee tibial baseplate/bearing disassociation under repeated forces.

1.2 The test described is applicable to any bicompartamental mobile bearing knee with a bearing retention mechanism. With modification, the test can be applied to a unicompartmental mobile bearing knee with a bearing retention mechanism.

1.3 Although the methodology described does not replicate all physiological force conditions, it is a means of *in vitro* comparison of mobile bearing knee designs and the strength of the bearing retention mechanism between the tibial baseplate and bearing components under the stated test conditions.

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

1.5 *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. Terminology

2.1 Definitions:

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

2.1.2 *bearing retention mechanism*—mechanical means preventing tibial baseplate/bearing disassociation.

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

2.1.4 *limiting position*—the position of the femoral component relative to the bearing at which the shear force is at a

maximum with anterior-posterior (AP) movement of the femoral component on the bearing.

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

2.1.6 *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.

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

2.1.8 *tibial baseplate/bearing disassociation*—unrecoverable physical separation of the bearing and tibial baseplate components as a result of bearing distraction or tilting.

2.1.9 *2-axis orthogonal load frame*—a test machine capable of applying forces and displacements that act at 90° to each other.

3. Significance and Use

3.1 This test method includes the use of static and fatigue shear and bending force conditions to evaluate the bearing retention mechanism of a mobile bearing knee design and its ability to prevent disassociation.

3.2 In general, disassociation does not occur during activities where the contact locations are within the boundaries of the bearing surfaces. Disassociation is most likely to occur with forces at the edges of the bearing component or with large AP shear forces on a posterior stabilized knee tibial component post. Extreme bearing rotation, bone/bearing impingement, severe varus or valgus moments, high flexion or any combination of the above can increase the likelihood of disassociation.

3.3 The test method described is applicable to any bicompartamental mobile bearing knee with a bearing retention mechanism. With modification, the test can be applied to a unicompartmental mobile bearing knee with a bearing retention mechanism.

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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