Designation: F2724 – 08 (Reapproved 2014)

Standard Test Method for Evaluating Mobile Bearing Knee Dislocation[1]

This standard is issued under the fixed designation F2724; 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 test method is designed to provide a standardized method to determine the dislocation resistance of mobile-bearing knee designs with regard to femoral component disassociation and spin-out/spit-out of the mobile bearing insert.

1.2 Although the methodology described does not replicate all physiological loading conditions, it is a means of *in-vitro* comparison of mobile bearing knee designs and their ability to resist dislocation of the mobile bearing from the femoral or tibial components under stated test conditions.

1.3 The test method applies only to mobile bearing total knee designs.

1.4 The values stated in SI units are regarded as standard. The values given in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered 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. Referenced Documents

2.1 *ASTM Standards:*[2]

F1223 Test Method for Determination of Total Knee Replacement Constraint

3. Terminology

3.1 *Definitions:*

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

3.1.2 *centerline axis, n*—a line through the neutral point perpendicular to the bearing axis and in a plane parallel to the plane of the flat portion of the inferior articulating surface of the mobile bearing at 0° posterior tibial slope.

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

3.1.4 *neutral point, n*—midpoint of the bearing axis.

3.1.5 *spin-out, n*—excessive rotation of the bearing component in a rotating platform knee or multi-directional platform knee such that there is dislocation between the femoral or tibial components and the mobile bearing.

3.1.6 *spit-out, n*—escape of the bearing component from beneath the femoral component either anteriorly or posteriorly.

3.1.7 *2-axis orthogonal load frame, n*—a test machine capable of applying forces and displacements that act at 90° to each other.

4. Significance and Use

4.1 This test method is designed to provide a standardized method to determine the constraint of mobile-bearing knee designs with regards to spin-out and spit-out of the mobile bearing.

4.2 Similar to constraint testing of total knees (see Test Method F1223), it is important to note that the test method does not simulate the soft tissues and laxity of the knee joint, which may be key factors related to the occurrence of spin-out or spit-out.[3] For instance, a patient with good soft tissue restraints will perhaps require a lower spin-out/spit-out resistance whereas a patient with major bone loss or destroyed ligamentous structures will likely require an implant with a higher spin-out/spit-out resistance. Therefore, the results from the test should be taken into account along with the condition of the patient's soft tissues to determine the relative safety for the device.

5. Apparatus and Materials

5.1 A engineering analysis should be performed on all sizes of a knee design to justify a "worst case" size for this test. At

[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] Weale, A. E., et al, "In Vitro Evaluation of the Resistance to Dislocation of a Meniscal-Bearing Total Knee Prosthesis Between 30° and 90° of Knee Flexion," *J. Arthroplasty*, 17(4), 2002, pp. 475–483.