



Designation: F2694 – 16

Standard Practice for Functional and Wear Evaluation of Motion-Preserving Lumbar Total Facet Prostheses¹

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1. Scope

1.1 This practice provides guidance for the functional, kinematic, and wear testing of motion-preserving total facet prostheses for the lumbar spine. These implants are intended to allow motion and lend support to the functional spinal unit(s) through replacement of the natural facets.

1.2 This test method is not intended to address the bone implant interface or the static characteristics of the prosthesis components. Fatigue characteristics are included, but only as a by-product of cyclic wear testing under facet load and thus are not addressed in the typical process of generating a Stress-Life (S-N) characterization.

1.3 Biocompatibility of the materials used in a total facet prosthesis are not addressed in this practice.

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

1.4.1 The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in either degrees or radians.

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

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F732 Test Method for Wear Testing of Polymeric Materials

Used in Total Joint Prostheses

F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices

F1877 Practice for Characterization of Particles

F2346 Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs

F2423 Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses

3. Terminology

3.1 All functional and kinematic testing terminology is consistent with the referenced standards, unless otherwise stated.

3.2 Definitions of Terms:

3.2.1 *mechanical failure, n*—failure associated with a defect in the material (for example, *fatigue crack*) or of the bonding between materials that may or may not produce functional failure. **F2423**

3.2.2 *run out (cycles), n*—maximum number of cycles that a test needs to be carried to if functional failure has not yet occurred. **F2423**

3.3 Definitions of Terms Specific to This Standard:

3.3.1 *coordinate systems/axes, n*—global XYZ orthogonal axes are defined following a right-handed Cartesian coordinate system in which the XY plane is parallel to and co-planar with the superior endplate of the inferior vertebral body. The global axes are fixed relative to the inferior vertebral body, which in this practice is also considered to be stationary with respect to the test machine's frame. Lower case letters, *xyz*, denote a local moving orthogonal coordinate system attached to the superior vertebral body with directions initially coincident with those of the global XYZ axes, respectively. The 3D motion of the superior relative to the inferior vertebra is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z* axial rotation, *x* lateral bend, and *y* flexion-extension).

3.3.1.1 *origin, n*—center of the global coordinate system that is located at the posterior medial position on the superior endplate of the inferior vertebral body.

3.3.1.2 *X-axis, n*—positive X-axis is to be directed anteriorly relative to the specimen's initial unloaded position.

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.25 on Spinal Devices.

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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.