



Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs¹

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1. Scope

1.1 This test method describes methods to assess the static and dynamic properties of single level spinal constructs.

1.2 An option for assessing wear using a weight loss method and a dimensional analysis is given. This method, described herein, is used for the analysis of devices intended for motion preservation, using testing medium as defined in this standard (6.1).

1.3 This test method is not intended to address any potential failure mode as it relates to the fixation of the device to its bony interfaces.

1.4 It is the intent of this test method to enable single level extra-discal spinal constructs with regard to kinematic, functional, and wear characteristics when tested under the specified conditions.

1.5 This test method is not intended to address facet arthroplasty devices.

1.6 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures be established. This test method is intended to facilitate uniform testing methods and data reporting.

1.7 The motion profiles specified by this test method do not necessarily accurately reproduce those occurring *in vivo*. Rather this method provides useful boundary/endpoint conditions for evaluating implant designs in a functional manner.

1.8 This test method is not intended to be a performance standard. It is the responsibility of the user of this test method to characterize the safety and effectiveness of the device under evaluation.

1.9 Multiple test methods are included in this standard. However, it must be noted that the user is not obligated to test using all of the described methods. Instead, the user should only select test methods that are appropriate for a particular

device design. In most instances, only a subset of the herein described test methods will be required.

1.10 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. No other units of measurement are included in this standard.

1.11 *This test method 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 test method to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

- E2309 Practices for Verification of Displacement Measuring Systems and Devices Used in Material Testing Machines
- F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
- F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices
- F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
- F1877 Practice for Characterization of Particles
- F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
- F2423 Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses

3. Terminology

3.1 All terminology is consistent with the referenced standards, unless otherwise stated.

3.2 Definitions:

3.2.1 *center of rotation (COR)*—the point about which the simulated vertebral bodies rotate in performing the range of motion (ROM) specified in this test method.

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 F04.25 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.