~~Designation:F2423–05~~ Designation: F2423 – 11

Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses[1]

This standard is issued under the fixed designation F2423; 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 guide ~~is intended to provide~~ provides guidance for ~~the functional, kinematic, and wear~~ wear and/or fatigue testing of total disc prostheses under functional and kinematic conditions and, to this end, describes test methods for assessment of the wear or functional characteristics, or both, of total disc prostheses.

1.2 Both lumbar and cervical prostheses are addressed.

1.3 Load and kinematic profiles for lumbar and cervical devices are not identical and, therefore, are addressed separately in the guide.

1.4 Partial disc replacements, such as nucleus replacements or facet joint replacements, are not intended to be addressed.

1.5 Wear is assessed using a weight loss method in a testing medium as defined in this guide.

1.6 This guide ~~is~~does not ~~intended to~~ address any potential failure mode as it relates to the fixation of the implant to its bony interfaces.

1.7 It is the intent of this guide to enable comparison of intervertebral disc (IVD) prostheses with regard to ~~kinematic, functional,~~ wear and ~~wear~~fatigue characteristics when tested under the specified conditions. It must be recognized, however, that there are many possible variations in the *in vivo* ~~conditions. A single laboratory simulation with a fixed set of parameters may not be universally representative.~~

~~1.8In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures are established. This guide is intended to facilitate uniform methods for testing and reporting of data for total disc replacement prostheses.~~

~~1.9Without a substantial clinical retrieval history of IVD prostheses, actual loading profiles and patterns cannot be delineated at the time of the writing of this guide. It therefore follows that the load and motion conditions specified by this guide do not necessarily accurately reproduce those occurring~~ *conditions. A single laboratory simulation with a fixed set of parameters might not be universally representative.*

1.8 Most IVD prostheses primarily fall into two classifications: articulating ball-in-socket type prostheses, and elastomeric or compliant type prostheses. For the former, this guide primarily addresses Mode 1 wear (defined herein); whereas for the latter, this guide addresses potential failure of the prosthesis when the implant is subjected to a range of motion and/or loads that fall within the full range of possible physiologic motions and loads.

1.9 For articulating components, this guide predominantly describes a Mode 1 test. The user is cautioned that other modes of wear may occur and may have significant influence on the functionality and performance of an articulating IVD prosthesis, and therefore the user should consider the effects of other wear modes on the performance of the prosthesis.

1.10 In order that the data be reproducible and comparable within and between laboratories, it is essential that uniform procedures are established. This guide is intended to facilitate uniform methods for testing and reporting of data for total disc replacement prostheses.

1.11 Without a substantial clinical retrieval history of IVD prostheses, actual loading profiles and patterns cannot be delineated at the time of the writing of this guide. It therefore follows that the load and motion conditions specified by this guide do not necessarily accurately reproduce those occurring *in vivo*. ~~Rather, the maximum loads and motions specified in this guide represent a severe and therefore conservative case for testing the wear properties of IVD prostheses. Because of this, a substantially greater rate of wear may be realized than that which may occur during the routine daily activities of a typical patient. It should be noted, however, that a full characterization of a candidate IVD prosthesis should include testing under both typical and extreme conditions.~~

[1] This guide 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.

~~Current edition approved Nov. 15, 2005. Published January 2006. DOI: 10.1520/F2423-05.~~

Current edition approved July 1, 2011. Published August 2011. Originally approved in 2005. Last previous edition approved in 2005 as F2423 – 05. DOI: 10.1520/F2423-11.

~~1.10The 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.~~

~~1.11This guide is not intended to be a performance standard. It is the responsibility of the user of this guide to characterize the safety and effectiveness of the prosthesis under evaluation.~~

~~1.12~~. *Rather, this guide provides useful boundary/endpoint conditions for evaluating prosthesis designs in a functional manner.*

1.12 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.

1.13 This guide is not intended to be a performance standard. It is the responsibility of the user of this guide to characterize the safety and effectiveness of the prosthesis under evaluation.

1.14 *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

F1582 Terminology Relating to Spinal Implants

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

F1877 Practice for Characterization of Particles

F2077 ~~Test Methods For Intervertebral Body Fusion Devices~~ Test Methods For Intervertebral Body Fusion Devices

[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.

2.2 *ISO Standard:*[3]

ISO 18192–1 Implants for Surgery—Wear of Total Intervertebral Spinal Disc Prostheses—Part 1: Loading and Displacement Parameters for Wear Testing and Corresponding Environmental Conditions for Test

3. Terminology

3.1 *Definitions*—~~All functional and kinematic testing terminology is consistent with the referenced standards, unless otherwise stated.~~ All functional and kinematic testing terminology is consistent with the referenced standards (for example, Test Methods F2077, Terminology F1582, and so forth), unless otherwise stated.

3.1.1 *axial load*, *n*—the resultant force F_{axial} applied to the superior or inferior fixture-end plate that simulates the *in vivo* load that an IVD prosthesis (original healthy disc) must resist.

3.1.1.1 *Discussion*—Based on a healthy disc, the primary component would be an axial compressive force F_Z in the direction of the negative global *Z* axis, and it would pass through the origin of the IVD prosthesis. Shear components in the *XY* plane would be F_X and F_Y. Lateral bending moment M_X and flexion/extension moment M_Y components would be created about the origin when the axial load does not pass through it.

3.1.2 *coordinate system/axes*, *n*—global *XYZ* orthogonal axes are defined following a right-handed Cartesian coordinate system in which the *XY* plane is to bisect the sagittal plane angle between superior and inferior surfaces that are intended to simulate the adjacent vertebral end plates. The global axes are stationary relative to the IVD prostheses' inferior end plate fixture, which, in this guide, 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 end plate ~~fixturing~~fixture with directions initially coincident with those of the global *XYZ* axes, respectively. The 3-D motion of the superior relative to inferior end plate fixture is specified and is to be measured in terms of sequential Eulerian angular rotations about the *xyz* axes, respectively (*z*, axial rotation; *x*, lateral bending; and *y*, flexion-extension).

~~3.1.1.1~~

3.1.2.1 *origin, n*—center of the global coordinate system is located at the initial position of the total disc replacement's instantaneous center of rotation (COR). ~~F1582~~

~~3.1.1.2~~

3.1.2.2 *Discussion*—Some articulating devices do not have a single center of rotation, but instead have either a mobile center of rotation or multiple distinct centers of rotation, depending on the direction of movement. In this case, the origin should be explicitly defined by the user with a rationale for that definition.

3.1.2.3 *X-axis, n*—positive *X*-axis is a global fixed axis relative to the ~~testing~~test machine's stationary base, and is to be directed anteriorly relative to the specimen's initial unloaded position.

~~3.1.1.3~~3.1.2.4 *Y-axis, n*—positive *Y*-axis is a global fixed axis relative to the ~~testing~~test machine's stationary base, and is directed laterally relative to the specimen's initial unloaded position.

~~3.1.1.4~~3.1.2.5 *Z-axis, n*—positive *Z*-axis is a global fixed axis relative to the ~~testing~~test machine's stationary base, and is to be directed superiorly relative to the specimen's initial unloaded position.

~~3.1.1.5~~3.1.2.6 *x-axis, n*—positive *x*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed anteriorly relative to the prosthesis.

~~3.1.1.6~~3.1.2.7 *y-axis, n*—positive *y*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed laterally relative to the prosthesis.

~~3.1.1.7~~3.1.2.8 *z-axis, n*—positive *z*-axis is a fixed axis relative to the IVD prosthesis and a moving axis relative to the global coordinate system, and is directed superiorly relative to the prosthesis.

~~3.1.2~~3.1.3 *degradation*, *n*—loss of material or function or material properties as a result of causes other than that associated with wear.

~~3.1.3~~

3.1.4 *fluid absorption*, *n*~~—fluid absorbed by the device material during testing or while implanted *in vivo*.~~

~~3.1.4—*fluid absorbed by the device material during testing.*~~

3.1.5 *functional failure*, *n*—permanent deformation or wear that renders the IVD prosthesis assembly ineffective or unable to resist load/motion or any secondary effects that result in a reduction of clinically relevant motions or the motions intended by the design of the device.

~~3.1.5~~*3.1.6 interval net volumetric wear rate* VR_i *during cycle interval i (mm*^{3}*/million cycles)*, *n*—$VR_i = WR_i/\rho$, where ρ = mass density (for example, units of g/mm^3) of the wear material.

~~3.1.6~~*3.1.7 interval net wear rate* WR_i *during cycle interval i (g/million cycles)*, *n*—$WR_i = ((NW_i - NW_{i-1})/$(number of cycles in interval *i*~~))*10)~~$)\times 10^6$.

~~3.1.6.1~~

3.1.7.1 *Discussion*—For $i = 1$, $NW_{i-1} = 0$.

~~[3] The boldface numbers in parentheses refer to the list of references at the end of this standard.~~

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

~~3.1.7~~

3.1.8 *intervertebral disc (IVD) prosthesis*, *n*—nonbiologic structure intended to restore the support and motion or a portion thereof between adjacent vertebral bodies.

~~3.1.8~~

3.1.9 *kinematic profile*, *n*—relative motion between adjacent vertebral bodies that the IVD prosthesis is subjected to while being tested.

~~3.1.9~~

3.1.10 *limit*, *n*—a significant change in stiffness during a given motion, indicating the implant has reached its designed endpoint in range of motion.

3.1.11 *load profile*, *n*—loading that the device experiences while being tested under ~~a defined~~an applied kinematic profile or the loading that the IVD prosthesis is subjected to if tested in load control.

~~3.1.10~~3.1.12 *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.

3.1.13 *Wear modes* **(1)**[4] *for articulating type designs:*

3.1.13.1 Mode 1 refers to the articulation between two primary bearing surfaces only.

3.1.13.2 Mode 2 occurs whenever a primary surface articulates directly against a secondary, nonbearing surface.

3.1.13.3 Mode 3 occurs when the two primary bearing surfaces are still articulating together, but third-body particles have become entrapped between them.

3.1.13.4 Mode 4 refers to any contact and motion occurring between two secondary, nonbearing surfaces.

~~3.1.11~~*3.1.14 net wear* NW_i *of wear specimen (g)*, *n*— $NW_i = (W_0 - W_i) + (S_i - S_0)$; loss in weight of the wear specimen corrected for fluid absorption at end of cycle interval *i*.

~~3.1.12~~

3.1.15 *net volumetric wear* NV_i *of wear specimen (mm³)*, *n*— $NV_i = NW_i/\rho$ at end of cycle interval *i* where ρ = mass density (for example, units of g/mm³) of the wear material.

~~3.1.13*preload*, *n*—The resultant force $F_{preload}$ applied to the superior or inferior fixture-end plate that simulates the *in vivo* load that an IVD prosthesis (original healthy disc) must resist.~~

~~3.1.13.1*Discussion*—Based on a healthy disc, the primary component would be an axial compressive force F_Z in the direction of the negative global *Z* axis, and it would pass through the *in vivo* physiologic instantaneous center of rotation (COR) of the IVD prosthesis. Shear components in the *XY* plane would be F_X and F_Y. Lateral bending moment M_X and flexion/extension moment M_Y components would be created about the initial COR when the preload force does not pass through it.~~

~~3.1.14~~

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

~~3.1.15~~

3.1.17 *wear*, *n*—~~progressive loss of material from the device(s) or device components as a result of relative motion at the surface with another body as measured by the change in mass of the IVD prosthesis or components of the IVD prosthesis. Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis.~~

~~3.1.15.1~~*—progressive loss of material from the device(s) as a result of relative motion at the surfaces as measured by the change in mass of the IVD prosthesis or components of the IVD prosthesis.*

3.1.17.1 *Discussion*—~~Note that inferior and superior bone interface components are excluded from this definition; see~~ —Or in the case of a nonarticulating, compliant IVD prosthesis, wear is defined simply as the loss of material from the prosthesis. Note that inferior and superior bone interface components are excluded from this definition; see 5.2.2.

~~3.1.16~~*3.1.18 weight* S_i *of soak control specimen (g)*, *n*—S_0 initial and S_i at end of cycle interval *i*.

~~3.1.17~~*3.1.19 weight* W_i *of wear specimen (g)*, *n*—W_0 initial and W_i at end of cycle interval *i*.

4. Significance and Use

4.1 This guide can be used to ~~describe~~determine the ~~function, kinematics,~~ fatigue and wear behavior of IVD prostheses subjected to functional and kinematic cyclic loading/motion for relatively large numbers of cycles (for example, various designs of IVD prostheses, as well as the effects of materials, manufacturing techniques and other design variables on one particular design can be ~~studied~~determined using this guide).

4.2 This guide is intended to be applicable to IVD prostheses that support load and transmit motion by means of an articulating joint or by use of compliant materials. Ceramics, metals, or polymers, or combination thereof, are used in IVD ~~prosthesis design,~~ prosthesis, and it is the goal of this guide to enable a kinematic wear and/or fatigue comparison of these devices, regardless of material and type of device.

5. Apparatus

5.1 *Total Disc Prosthesis Components*—The total disc replacement may comprise a variety of shapes and configurations. Some

[4] The boldface numbers in parentheses refer to the list of references at the end of this standard.

known forms include ball-and-socket articulating joints, biconcave joints having a free-floating or semi-constrained third body, metallic endplates bonded to elastomer cores, and single-axis hinge joints.

5.2 *Spinal Testing Apparatus*:

5.2.1 *Test Chambers*—In case of a multispecimen machine, each chamber shall be isolated to prevent cross-contamination of the test specimens. The chamber shall be made entirely of noncorrosive components, such as acrylic plastic or stainless steel, and shall be easily removable from the machine for thorough cleaning between tests.

5.2.2 *Component Clamping/Fixturing*—Since the purpose of the test is to characterize the wear ~~and kinematic function~~and/or fatigue properties of the IVD prosthesis under functional and kinematic conditions, the method for mounting components in the test chamber shall not compromise the accuracy of assessment of the weight loss or stiffness variation during the test. For example, prostheses having complicated superior and inferior surfaces for contacting bone (for example, sintered beads, hydroxylapatite (HA) coating, plasma spray) may be specially manufactured to modify that surface in a manner that does not affect the wear simulation.

5.2.3 The device should be securely (rigidly) attached at its bone-implant interface to the mating test fixtures.

5.2.4 The motion of the superior test fixture relative to the inferior testing fixture shall be unconstrained in three-dimensional space except for the components in the direction of specified test motions/loads.

5.2.5 *Load and Motion (components in* Table 1 *and* Table 2*)*:

5.2.5.1 An axial ~~preload~~load is to be a compressive load applied in the direction of the negative *Z*-axis. Deviations from this as the IVD moves from its initial position are to be reported as shear components F_X, F_Y, and moments M_X and M_Y.

5.2.5.2 Flexion load and motion are positive moment, M_Y, and rotation about the *y*~~-axis.~~ -axis, respectively.

5.2.5.3 Extension load and motion are negative moment, M_Y, and rotation about the *y*~~-axis.~~ -axis, respectively.

5.2.5.4 Lateral bend load and motion are positive and negative moments, M_X, and rotations about the *x*~~-axis.~~ -axis, respectively.

5.2.5.5 Torsional load and motion are positive and negative moments, M_Z and rotations about the *z*~~-axis.~~ -axis, respectively.

5.2.6 *Frequency*—Test frequency is to be determined and justified by the user of this guide, and shall not exceed 2 Hz without adequate justification ensuring that the applied motion (load) profiles remain within specified tolerances and that the IVD prosthesis' wear and functional characteristics are not significantly affected. See 6.1.5.

5.2.7 *Cycle Counter*—One complete ~~motion~~cycle is the entire range from starting position through the range of motion (or load when in load control) and returning to the starting position (load). Cycles are to be counted using an automated counting device.

6. Reagents and Materials

6.1 *Testing Medium*:

6.1.1 A solution containing bovine serum diluted to a protein concentration of 20 g/L in deionized water shall be used as the testing medium.

~~6.1.2To retard bacterial degradation, freeze and store the serum until needed for test. In addition, the testing medium may contain 0.2% sodium azide (or other suitable antibiotic/antimycotic) to minimize bacterial degradation. Other lubricants should be evaluated to determine appropriate storage conditions.~~

6.1.2 To retard bacterial degradation, freeze and store the serum until needed for test. In addition, the testing medium should contain 0.2 % sodium azide (or other suitable antibiotic/antimycotic) to prevent the growth of microorganisms (fungi, yeast, bacteria, and so forth) that can degrade the lubricating properties of the serum, and can contaminate samples of wear particles that are subsequently isolated from the serum. Other lubricants should be evaluated to determine appropriate storage conditions.

6.1.3 It is recommended that ethylene-diaminetetraacetic acid (EDTA) be added to the serum at a concentration of 20m*M* to bind calcium in solution and minimize precipitation of calcium phosphate onto the bearing surfaces. The latter event has been shown to affect the friction and wear properties strongly, particularly of polyethylene/ceramic combinations. The addition of EDTA to other testing media should be evaluated.

6.1.4 The bulk temperature of the testing medium shall be maintained at 37 ± 3°C, unless otherwise specified.

6.1.5 ~~The user is cautioned that internal heating of the prosthesis may cause localized temperatures to fall outside the 37 ± 3°C of the testing medium. Internal local temperatures may depend on a number of factors, including but not limited to joint friction, material hysteresis, conductivity of the device-fixture materials, design, and test frequency. Localized elevated temperatures may~~

TABLE 1 Test Profiles and Associated Parameters for Cervical IVD Prostheses

Test Profile	Axial ~~Prel~~Load, N (~~32~~-~~54~~)	Preferred Displacement Control: Range of Motion (ROM),[A] degree (~~43~~)	Alternate Load Control: Applied Moment Ranges, Nm (~~43~~)
Flexion/extension	100	±7.5	±2.0
Lateral bend/ rotation	100	±6 ±6	±2.0 ±4.0

[A] The user of the guide must determine whether the ROM will be equally divided between flexion and extension or weighted more toward one of the motion directions.

TABLE 2 Test Profiles and Associated Parameters for Lumbar IVD Prostheses

Test Profile	Axial ~~Prel~~Load, N **(68)**	Cyclic Axial Load, N (min–max) **(9)**	Preferred Displacement Control: Range of Motion (ROM), degree	Alternate Load Control: Applied Moments, Nm[A]
~~Flexion/extension~~	~~1200~~		~~±7.5~~[B]	~~±10~~
Flexion/extension	1200	(900 – 1850)	±7.5[B]	±10
~~Rotation~~	~~1200~~		~~±3 (7,9)~~	~~±10~~
Rotation	1200	(900 – 1850)	±3 **(8,10)**	±10
~~Lateral bending~~	~~1200~~		~~±6 (7,9)~~	~~±12~~
Lateral bending	1200	(900 – 1850)	±6 **(8,10)**	±12

[A] Approximated based on a review of ROM (p. 111) and average flexibility and stiffness coefficients (p. 47) **(~~7~~9)**.

[B] Depending on the device design, the balance of ROM should be appropriate to the expected ROM in a clinical situation **(8~~1~~11)**.

~~have an effect on the mechanical as well as wear properties of the prosthesis. If the device experiences localized elevated temperatures, the user must describe the effect that the selected frequency and resultant localized temperature have on the test results, or justify that the effects are physiologically relevant. Refer to X1.6 for further information.~~ The user is cautioned that the non-stop articulation typically used in wear simulations may cause the bearing surfaces and/or the contacting lubricant to become substantially hotter than will occur *in vivo*, that is, when motions typically are interrupted periodically **(5-7)**. The maximum temperatures reached may depend on a number of factors including but not limited to joint friction, material hysteresis, conductivity of the device-fixture materials, design, and test frequency. Under such conditions, there can be non-physiological thermal damage to the bearing materials and/or the lubricant (for example, degradation of lubricating proteins.) This can, in turn, increase the friction, further increasing the temperatures above those that will occur *in vivo* in the vast majority of situations. It is recommended, therefore, that the test be closely monitored for evidence of excessively high temperatures and corrective measured taken if needed. These can include running the test at a lower frequency, stopping the test periodically to allow the bearing and lubricant to cool, and cooling the lubricant bath by, for example, circulating it through a cooling apparatus.

7. Sampling and Test Specimens

7.1 It is suggested that a minimum sample size of five be used for each kinematic/load profile. However, note that, as for any experimental comparison, the total number of needed specimens will depend on the magnitude of the difference to be established, the repeatability of the results (standard deviation), and the level of statistical significance desired.

7.2 The test assemblies (that is, IVD prosthesis components in the tested configuration) shall be labeled so they can be traced, and must be kept in a clean environment to avoid contamination. The test assembly can be disassembled to facilitate examination of surface conditions.

8. Preparation of Apparatus

~~8.1The~~ 8.1 As closely as practical, the functional portion (components ~~producing~~permitting motion between vertebral bodies) of the device to be tested must be produced using equivalent manufacturing methods as the implantable form of the IVD prosthesis, including sterilization.

8.2 It is permissible to exclude nonfunctional features that may interfere with obtaining wear/fatigue functional measurements. For example, bone-implant interfaces such as HA, plasma-spray titanium, and beads may be omitted, since they may abrade the fixtures and, thereby, produce an unwanted mixture of functional and nonfunctional component wear particles (see 5.2.2).

8.3 It is permissible to ~~fabricate~~make entirely different bone-implant interface components (that is, superior and inferior surfaces) provided that the modification does not ~~interfere with an accurate measurement of~~ substantially alter the wear and functional characteristics of the device. For example, a ball-and-socket joint prosthesis may be manufactured having the polished articulation component (that is, ~~the~~ functional surfaces or features of the device) and an opposite side that mounts directly to the testing apparatus, thereby simplifying the fixturing demands.

8.4 The requirements of Guide F1714, Specimen Preparation section, shall be followed.

9. Procedure

9.1 As a weight control for the testing, a minimum of two identical loaded soak control specimens in testing medium (see 6.1) shall be used. In other words, the loaded soak control specimen must be loaded statically with the same ~~preload as is applied to the wear test specimens,~~axial load vector as described in Fig. 1 since it is well known that load can significantly affect fluid absorption.

NOTE 1—The user of this guide may justify not performing soak control tests in certain circumstances (for example, all metal components). Before, and at all specified time intervals (determined by the user) of the presoak period (defined in Guide F1714), the wear components and soak controls should be removed from the soak bath, cleaned, dried, and weighed three times, in rotation, keeping the same specimen sequence each time. The average of the three weights may be used for the wear calculations. An analytical balance with a sensitivity of ±10 µg or less shall be used. This degree of sensitivity for weighing is necessary to detect the slight loss in weight of highly wear-resistant bearing materials **(~~1~~13)**.