Designation: F2193 – 14

Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System[1]

This standard is issued under the fixed designation F2193; 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 These specifications and test methods are intended to provide a comprehensive reference for the components of systems used in the surgical fixation of the spinal skeletal system. The document catalogs standard specifications that specify material, labeling, and handling requirements. The specifications and test methods also establish common terminology that can be used to describe the size and other physical characteristics of spinal components and performance definitions related to the performance of spinal components. Additionally, the specifications and test methods establish performance requirements and standard test methods to consistently measure performance-related mechanical characteristics of spinal components.

1.2 These specifications and test methods are part of a series of standards addressing systems used in the surgical fixation of the spinal skeletal system. These specifications and test methods concentrate on the individual components, which are found in many spinal fixation systems. If the user is interested in evaluating the next level in the spinal fixation system chain, the interconnections between individual components and subassemblies (two or more components), the user should consult Guide F1798. At the highest level in this chain is Test Methods F1717, which is used to evaluate an entire construct assembled from many components and involves numerous interconnections and several subassemblies.

1.3 It is not the intention of these specifications and test methods to define levels of performance or case-specific clinical performance for spinal components addressed by this document. Insufficient knowledge to predict the consequences of using any of these components in individual patients for specific activities of daily living is available. Furthermore, it is not the intention of this document to describe or specify specific designs for the individual components of systems used in the surgical internal fixation of the spinal skeletal system.

1.4 These specifications and test methods may not be appropriate for all types of spinal surgical fixation systems. The user is cautioned to consider the appropriateness of this document in view of the particular implant system and its potential application.

1.5 This document includes the following specifications and test methods that are used in determining the spinal component's mechanical performance characteristics:

1.5.1 Specification for Metallic Spinal Screws—Annex A1.

1.5.2 Specification for Metallic Spinal Plates—Annex A2.

1.5.3 Specification for Metallic Spinal Rods—Annex A3.

1.5.4 Test Method for Measuring the Static and Fatigue Bending Strength of Metallic Spinal Screws—Annex A4.

1.6 Unless otherwise indicated, the values stated in SI units shall be regarded as the standard.

1.7 This standard may involve hazardous materials, operations, and equipment. *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: General*[2]

E4 Practices for Force Verification of Testing Machines

E6 Terminology Relating to Methods of Mechanical Testing

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System

E1823 Terminology Relating to Fatigue and Fracture Testing

E1942 Guide for Evaluating Data Acquisition Systems Used in Cyclic Fatigue and Fracture Mechanics Testing

F382 Specification and Test Method for Metallic Bone Plates

F543 Specification and Test Methods for Metallic Medical Bone Screws

[1] These specifications and test methods are 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.

F565 Practice for Care and Handling of Orthopedic Implants and Instruments
F983 Practice for Permanent Marking of Orthopaedic Implant Components
F1582 Terminology Relating to Spinal Implants
F1717 Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
F1798 Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments
F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
F2943 Guide for Presentation of End User Labeling Information for Musculoskeletal Implants

2.2 *ASTM Standards: Materials*[2]

D4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials
F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
F1295 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)
F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium–13 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

2.3 *ISO Standards:*

ISO 14630 Non-active Surgical Implants—General Requirements[3]

3. Terminology

3.1 Unless otherwise defined in these specifications and test methods, the terminology used in this document that is related to spinal implants will be in accordance with the definitions of Specification F382, Specification F543, and Terminology F1582.

3.2 Unless otherwise defined in these specifications and test methods, the terminology related to mechanical testing that is used in this document will be in accordance with the definitions of Terminology E6, Terminology E1823, Specification F382, Terminology F1582, Test Methods F1717, and Guide F1798.

3.3 *Terminology—General:*

3.3.1 *expansion head screw, n*—threaded anchor that is designed so that the head can be elastically deformed, through mechanical means, to establish an interconnection with another spinal construct element.

3.3.2 *locking screw, n*—threaded anchor that is rigidly connected to the longitudinal element of the spinal construct.

3.3.3 *self-locking screw, n*—threaded anchor design that undergoes a deformation process at the end of the insertion process which results in the screw's locking to the mating spinal construct element.

3.3.4 *shaft screw, n*—threaded anchor having an unthreaded shank equal to its thread diameter.

3.4 *Terminology—Geometric:*

3.4.1 *rod diameter (mm), n*—length in mm of a chord passing through the center of the rod's cross-section.

3.4.2 *rod length (mm), n*—overall dimension measured in mm between the ends of a given rod.

3.5 *Terminology—Mechanical/Structural:*

3.5.1 *0.2 % offset displacement (mm), n*—permanent displacement equal to 0.002 times the test gage section length for the specific test, in mm. The test gage section length is equal to the bending moment arm for spinal screw tests. The test gage section length is equal to the center span distance for spinal plate and rod tests where the loading rollers are directly contacting the test specimen (Fig. A2.1 and Fig. A3.1). The test gage section length is equal to the unsupported distance between the ends of the extension segments for spinal plate and rod tests where extension segments are used to load the test sample (Fig. A2.2). (distance *0B* in Fig. A4.1).

3.5.2 *axial pull-out load (N), n*—tensile force in N required to fail or remove a screw from a material into which the screw has been inserted when tested in accordance with Specification and Test Methods F543, Annex A3.

3.5.3 *bending fatigue runout moment (N·m), n*—value in N-m of the maximum moment that can be applied to a spinal component where all of the tested samples have experienced 2 500 000 loading cycles without a failure at a specific *R*-ratio.

3.5.4 *bending moment arm, L (mm), n*—distance in mm between the point where the test sample is gripped (typically the axis of the longitudinal element) and the line-of-action for the applied force prior to any deformation of of the assembly. (See dimension *L* of Fig. A4.2).

3.5.5 *bending stiffness, S (N/mm), n*—slope in N/mm of the initial linear elastic portion of the load versus total displacement curve (slope of line *0m* in Fig. A4.1).

3.5.6 *bending ultimate moment (N·m), n*—maximum bending moment in N-m that can be applied to a test sample. This would correspond to the bending moment at Point *E* in Fig. A4.1.

3.5.7 *bending yield moment (N·m), n*— bending moment in N-m necessary to produce a 0.2 % offset displacement in the spinal component. If the specimen fractures before the test

[3] Available from International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland.

reaches the 0.2 % offset displacement point, the bending yield moment shall be defined as the bending moment at fracture (point *D* in Fig. A4.1).

3.5.8 *exposed length (mm), n*—linear distance measured in mm between the surface of the test block that the screw is embedded in during the test and the location where the screw is anchored (typically the axis of the longitudinal element) in the test fixture (see Fig. A4.2).

3.5.9 *gross failure, n*—permanent displacement resulting from fracture or plastic deformation in excess of the yield displacement that renders the spinal component ineffective in fulfilling its intended function.

3.5.10 *insertion depth (mm), n*—linear advancement in mm of the screw into the test block measured relative to its seated position at the test block's surface prior to testing.

3.5.11 *median bending fatigue moment at N cycles (N·m), n*—value in N-m of the maximum moment that can be applied to a spinal component for which 50 % of the test specimens of a given sample can be expected to survive *N* loading cycles at a specific *R*-ratio.

3.5.12 *permanent displacement (mm), n*—total displacement in mm remaining after the applied load has been removed from the test specimen.

3.5.13 *torsion yield moment (N·m), n*— applied torque in N-m at which the screw reaches its proportional limit when tested in accordance with Specification and Test Methods F543, Annex A1. The value is determined by using an offset method with a 2° angular offset.

3.5.14 *total displacement (mm), n*—distance in mm, in the direction of the applied load, which the load application point has moved relative to the zero load intercept of the initial linear segment of the load versus displacement curve (point *0* in Fig. A4.1).

3.5.15 *yield displacement (mm), n*—total displacement in mm associated with the bending yield strength (distance *0A* in Fig. A4.1).

4. Significance and Use

4.1 Spinal implant constructs are typically a compilation of several components. Screws, plates, and rods are integral components of many spinal implant constructs. These components are designed to transfer load between the bone and the longitudinal or transverse element, or both. These specifications and test methods identify specifications for such components and define standard equivalent test methods that can be used when evaluating different related component designs.

4.2 Since the loading of spinal components *in-vivo* may differ from the loading configurations addressed in these specifications and test methods, the results obtained from this document may not predict *in-vivo* performance of either the components or the construct as a whole. Such tests can, however, be used to compare different component designs in terms of relevant mechanical performance characteristics.

4.3 The performance-related mechanical characteristics determined by these specifications and test methods will supply the user with information that may be used to predict the mechanical performance of different design variations of similar (function and indication) spinal construct components.

5. Requirements

5.1 The following spinal components shall conform to the requirements of the listed standard specification:

5.1.1 *Screws*—Standard Specification for Metallic Spinal Screws (see Annex A1).

5.1.2 *Plates*—Standard Specification for Metallic Spinal Plates (see Annex A2).

5.1.3 *Rods*—Standard Specification for Metallic Spinal Rods (see Annex A3).

6. Marking, Packaging, Labeling, and Handling

6.1 Mark spinal components using the methods specified in Practice F983.

6.2 Markings on spinal components shall identify the manufacturer or distributor. When size permits, the following information should be legibly marked on the spinal component (items listed in order of preference):

6.2.1 Manufacturer's name or logo,

6.2.2 Material and, when applicable, the ASTM designation,

6.2.3 Catalog number,

6.2.4 Manufacturing lot number, and

6.2.5 If the component is manufactured according to an ASTM specification, the ASTM designation.

6.3 Packaging shall be adequate to protect the spinal component during shipment.

6.4 Package labeling for spinal components shall include the following information:

6.4.1 Manufacturer and product name,

6.4.2 Catalog number,

6.4.3 Lot or serial number,

6.4.4 Material and, when applicable, the ASTM designation for the material, and

6.4.5 The sterility condition of the packaged spinal component.

6.5 Package labeling may elect to follow guidance in Guide F2943 for package label presentation.

6.6 Product labeling may include marking for safety in the Magnetic Resonance Environment in accordance with Practice F2503.

6.7 Spinal components shall be cared for and handled according to the requirements specified in Practice F565.

7. Materials

7.1 The manufacturer is responsible for ensuring that materials used to manufacture spinal components are suitable for implanting into the body. Material suitability can be verified with the methods described in ISO 14630.

7.2 The manufacturer should also consider the materials of other spinal components within the spinal implant construct when selecting a material. Avoid the mixing of materials within a spinal implant construct in order to prevent the development of undesirable corrosion conditions.

7.3 All spinal components that are made of materials that have an ASTM standard designation shall meet those requirements given in the ASTM standards. The following is a list of some materials that have been used for spinal components:

7.3.1 Unalloyed Titanium (see Specification F67).

7.3.2 Wrought Titanium–6Aluminum–4Vanadium ELI (Extra Low Interstitial) Alloy (see Specification F136).

7.3.3 Stainless Steel Bar and Wire (see Specification F138).

7.3.4 Wrought Titanium–6Aluminum–7Niobium Alloy (see Specification F1295).

7.3.5 Wrought Nitrogen Strengthened – 22Chromium–12.5Nickel–5Manganese–2.5Molybdenum Stainless Steel Bar and Wire (see Specification F1314).

7.3.6 Wrought Titanium Ti-6Al-4V Alloy (see Specification F1472).

8. Keywords

8.1 bend testing–plate; bend testing–rod; bend testing–screw; bend testing–surgical implants; fatigue test–plate; fatigue test–rod; fatigue test–screw; fatigue test–surgical implants; orthopedic medical device–plate; orthopedic medical device–rod; orthopedic medical device–screw; orthopedic spinal devices; performance; spinal arthrodesis; surgical devices; terminology; test methods–surgical implants

ANNEXES

(Mandatory Information)

A1. SPECIFICATION FOR METALLIC SPINAL SCREWS

A1.1 Scope

A1.1.1 This specification describes metallic spinal screws that are used as anchor elements in spinal arthrodesis implants for the surgical fixation of the skeletal spinal system.

A1.2 Classification

A1.2.1 Classify spinal screws according to the classification methods identified in Specification F543.

A1.2.2 Spinal screws can also be classified with regard to the screw's interconnecting capabilities with other spinal fixation system components such as expansion head, locking, and self-locking.

A1.3 Marking, Packaging, Labeling, and Handling

A1.3.1 Dimensions of spinal screws shall follow the nomenclature established in Section 3.

A1.3.2 In addition to the requirements of Section 6, add the screw diameter on the spinal screw labeling (when size permits).

A1.3.3 In addition to the packaging information contained in Section 6, include the screw diameter and screw length.

A1.4 Materials

A1.4.1 Select spinal screw materials in accordance with the requirements and recommendations of Section 7.

A1.5 General Requirements, Performance Considerations, and Test Methods

A1.5.1 *Drive Connection*—Suggested drive recesses for spinal screws can be found in Specification F543, Annex A6.

A1.5.2 *Torsion Properties*—Determine the screw's torsion strength characteristics (torsional yield moment, maximum torque, and breaking angle) using the test method of Specification F543. Annex A1.

A1.5.3 *Driving Torque Requirements*—Determine the driving torque requirements (insertion and removal torque) for self-tapping and self-drilling spinal screws according to the test method found in Specification F543, Annex A2 with the following conditional requirements:

A1.5.3.1 Manufacture the test blocks from Grade 40, Specification F1839 rigid polyurethane foam whose length is no less than the insertion depth of the test being conducted.

A1.5.3.2 Conduct the driving torque tests at a motor speed of 30 r/min.

A1.5.3.3 *Specific Screw Performance Tests*—Measure the driving torque of the longest length spinal screw of a given design until the insertion depth is equal to the screw's thread length.

A1.5.3.4 *Comparative Screw Performance Tests*—Measure the driving torque until an insertion depth is reached that is equal to the shortest maximum screw thread length possible for the screw designs being compared.

A1.5.4 *Axial Pull-Out Load*—Determine the screw's axial pull-out load using the standard test method of Specification F543, Annex A3 with the following conditional requirements:

A1.5.4.1 Manufacture the test blocks from Grade 20, Specification F1839 rigid polyurethane foam.

A1.5.4.2 Insert each screw into the test block at a motor speed of 30 r/min.

A1.5.4.3 *Specific Screw Performance Tests*—Insert the shortest spinal screw of a given design until the insertion depth is equal to the screw's thread length.

A1.5.4.4 *Comparative Screw Performance Tests*—Insert each spinal screw until an insertion depth is reached that is equal to the shortest maximum screw thread length possible for the screw designs being compared.

A1.5.5 *Bending Properties*—Determine the screw's bending structural stiffness, bending yield moment, bending ultimate moment, bending fatigue runout moment, and when applicable,

the median fatigue bending moment at 2 500 000 cycles using the test methods described in Annex A4.

A2. SPECIFICATION FOR METALLIC SPINAL PLATES

A2.1 Scope

A2.1.1 This specification describes metallic spinal plates that are used as longitudinal elements in spinal arthrodesis implants for the surgical fixation of the skeletal spinal system.

A2.2 Classification

A2.2.1 Plates intended for spinal applications can be classified with regard to the following characteristics:

A2.2.2 *Preferred Anatomic Location*—The spinal region where the plate is indicated (such as cervical, thoracic, lumbar, and sacral) and position (anterior versus posterior).

A2.2.3 *Preferred Use Limited to Specific Procedures*—The type of surgical procedure where the plate is indicated (such as reconstruction, trauma, deformity, degenerative).

A2.3 Marking, Packaging, Labeling, and Handling

A2.3.1 Dimensions of bone plates shall follow the nomenclature established in Section 3.

A2.3.2 In addition to the requirements of Section 6, include the plate length on spinal plate labeling.

A2.4 Materials

A2.4.1 Select spinal plate materials in accordance with the requirements and recommendations of Section 7.

A2.5 Performance Considerations and Test Methods

A2.5.1 Determine the spinal plate's bending structural stiffness, bending yield moment, bending ultimate moment, bending fatigue runout moment, and, when applicable, the median bending fatigue moment at 2 500 000 cycles using the methods of Specification F382 and in accordance with the following requirements.

A2.5.2 Configure the four-point bending test fixtures so that the loading rollers (inner rollers that are located dimension "a" apart) are positioned in accordance with the requirements of Table A2.1 (see also Fig. A2.1).

A2.5.3 Position the test fixture support rollers (outer rollers that are located dimension "h" from the nearest loading roller) far enough away from the loading rollers so that the test article is free to respond to the applied bending moment (see Fig. A2.1). Under ideal conditions, position the support rollers in accordance with the recommended dimensions of Table A2.1.

TABLE A2.1

Spinal Location	h (mm)	a (mm)
Cervical	35.00	35.00
Thoracic and Lumbar	76.00	76.00

The dimension "h" may be reduced to a/2 in order to accomodate testing of shorter plates, but this condition must be documented in the final report.

A2.5.4 Maintain the test fixture configuration consistent for comparative tests.

A2.5.5 Only unused and untested specimens shall be included in the sample for a given spinal plate design. Include only final form and finished components in the sample.

Static Tests

A2.5.6 The sample size used for static tests shall be determined according to the methods defined in Practice E122 for any given loading condition. If insufficient information is available to determine a suitable sample size with Practice E122, use a minimum sample size of five.

A2.5.7 Load the test specimen during static tests at a displacement rate not to exceed 10 mm/min.

Fatigue Tests

A2.5.8 Test at least two specimens at each of three different maximum moment levels. One of the three maximum moment levels shall satisfy the maximum runout moment condition. Several references have been compiled that can provide the user with guidance and recommendations for selecting suitable sample sizes for fatigue studies used to develop an *M-N* diagram. (**1 and 2**)[4]

A2.5.9 Conduct the recommended fatigue test in a laboratory air environment at room temperature. Other test environments (simulated body fluid, 9-g NaCl per 1000 mL water saline, a saline drip, or water) may be used while testing, but the suitability of using the respective test environment must be justified, given the accelerated nature of the laboratory fatigue test. If an alternative test environment is used, record all pertinent parameters related to the environmental conditions (temperature, pH, solution strengths, and so forth) before, during, and after the test.

A2.5.10 Apply sinusoidal cyclic loads in load control at an *R* ratio of 0.10 for testing of devices intended for either the lumbar and thoracic spine regions. Apply sinusoidal cyclic loads in load control at an *R* ratio of -1.0 for testing of devices intended for the cervical spine region. Fig. A2.2 illustrates a test setup for spinal plates that is capable of applying fully reversed loads (*R* = -1). Other *R* ratios may be used but must be documented in the report.

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

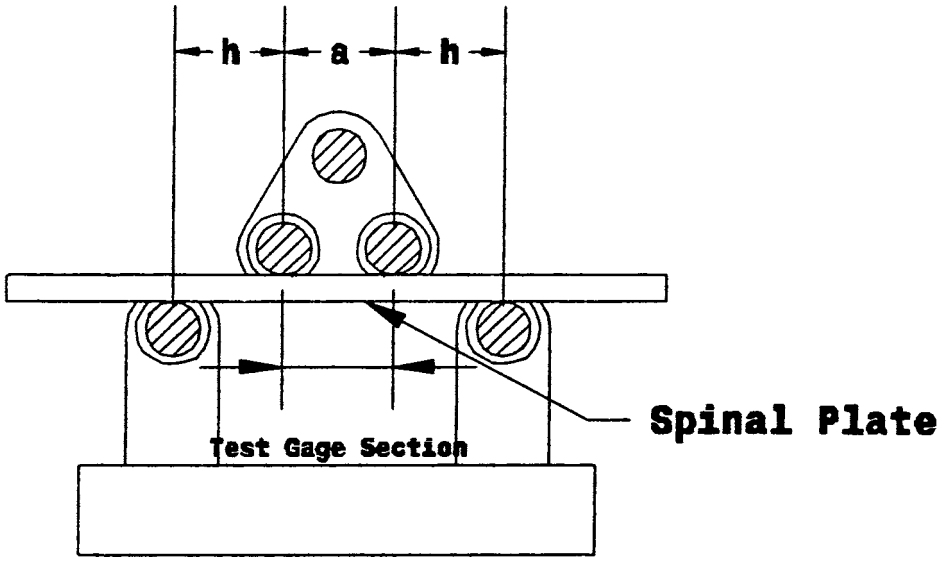

FIG. A2.1 Spinal Plate Test Configuration

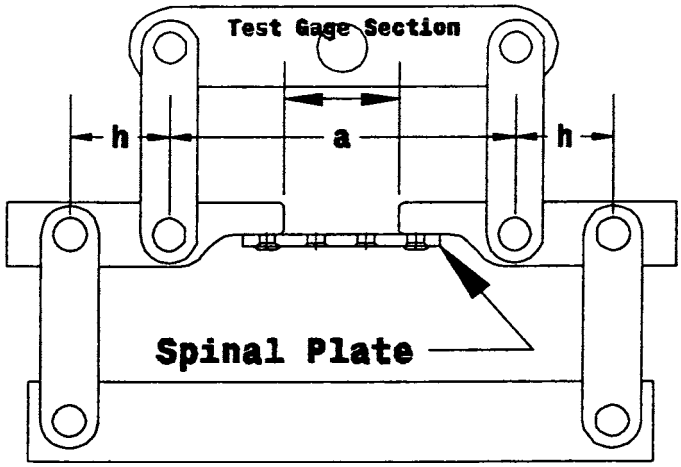

FIG. A2.2 Spinal Plate Test Configuration, *R* = -1 Loading

A2.5.11 The user shall determine the frequency at which to conduct the fatigue test, but the maximum frequency of cyclic loading shall be 30 Hz.

A2.5.12 Initial fatigue maximum moment levels that are 75, 50, and 25 % of the bending ultimate moment determined with the static test method are suggested for the fatigue study. One maximum moment level should have specimens that do not fail before 2 500 000 cycles. The difference between the maximum moment value resulting in specimen failure and the maximum runout moment value must be less than 10 % of the device's bending ultimate moment.

A3. SPECIFICATION FOR METALLIC SPINAL RODS

A3.1 Scope

A3.1.1 This specification describes spinal rods that are used as longitudinal elements in spinal arthrodesis implants for the surgical fixation of the skeletal spinal system.

A3.2 Classification

A3.2.1 Spinal rods indicated for spinal applications can be classified with regard to the following characteristics:

A3.2.2 *Preferred Anatomic Location*—The spinal region where the rod is indicated (such as cervical, thoracic, lumbar, and sacral) and position (anterior versus posterior).

A3.2.3 *Preferred Use Limited to Specific Procedures*—The type of surgical procedure where the rod is indicated (such as reconstruction, trauma, deformity, degenerative).

A3.3 Marking, Packaging, Labeling, and Handling

A3.3.1 Dimensions of spinal rods shall follow the nomenclature established in Section 3.

A3.3.2 In addition to the requirements of Section 6, include the rod diameter and rod length on spinal rod labeling.

A3.4 Materials

A3.4.1 Select spinal rod materials in accordance with the requirements and recommendations of Section 7.

A3.5 Performance Considerations and Test Methods

A3.5.1 Determine the spinal rod's bending structural stiffness, bending yield moment, bending ultimate moment, bending fatigue runout moment, and when applicable, the median bending fatigue moment at 2 500 000 cycles using the methods of Specification F382 and in accordance with the following requirements.

A3.5.2 Fit the test fixture with 90° "V" alignment notched rollers. This roller profile will allow the testing of a range of rod sizes with a single roller set. Such rollers will also prevent the application of the load at the most highly stressed point on the circumference of the rod.

A3.5.3 Configure the four-point bending test fixtures so that the loading rollers (inner rollers that are located dimension "a" apart) are positioned in accordance with the requirements of Table A2.1 (see also Fig. A3.1).

A3.5.4 Position the test fixture support rollers (outer rollers that are located dimension "h" from the nearest loading roller) in accordance with the recommended dimensions of Table A2.1.

A3.5.5 Maintain the test fixture configuration consistent for comparative tests.

A3.5.6 Only unused and untested specimens shall be included in the sample for a given spinal plate design. Include only final form and finished components in the sample.

Static Test Method

A3.5.7 The sample size used for static tests shall be determined according to the methods defined in Practice E122 for any given loading condition. If insufficient information is available to determine a suitable sample size with Practice E122, use a minimum sample size of five.

A3.5.8 Load the test specimen during static tests at a displacement rate not exceeding 10 mm/min.

Fatigue Test Method

A3.5.9 For fatigue studies, test at least two specimens at each of three different maximum moment levels. One of the three maximum moment levels shall satisfy the maximum runout moment condition. Several references have be compiled that can provide the user with guidance and recommendations for selecting suitable sample sizes for fatigue studies used to develop an *M-N* diagram. (**1 and 2**)

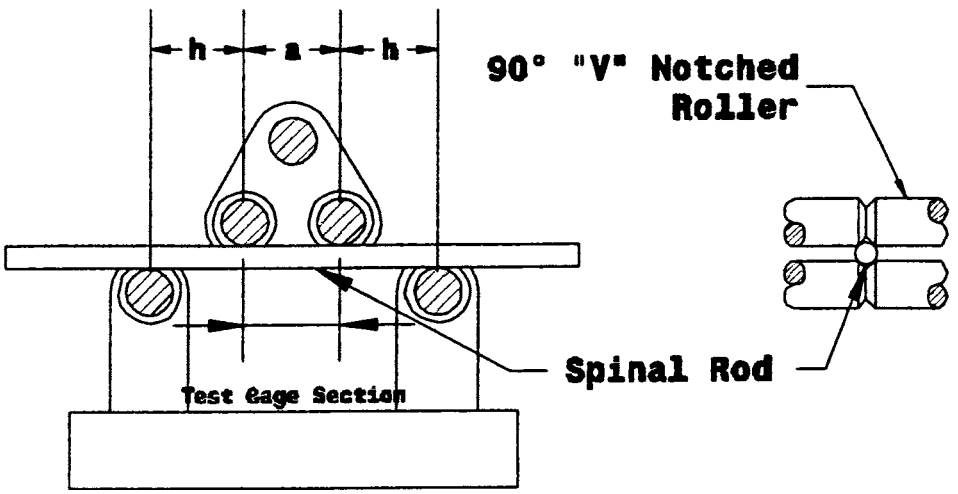

FIG. A3.1 Spinal Rod Test Configuration

A3.5.10 Conduct the recommended fatigue test in a laboratory air environment at room temperature. Other test environments (simulated body fluid, 9-g NaCl per 1000 mL water saline, a saline drip, or water) may be used while testing, but the suitability of using the respective test environment must be justified, given the accelerated nature of the laboratory fatigue test. If an alternative test environment is used, record all pertinent parameters related to the environmental conditions (temperature, pH, solution strengths, and so forth) before, during, and after the test.

A3.5.11 Apply sinusoidal cyclic loads in load control at an *R* ratio of 0.10 for testing of devices intended for either the lumbar and thoracic spine regions. Apply sinusoidal cyclic loads in load control at an *R* ratio of -1.0 for testing of devices intended for the cervical spine region. Fig. A2.2 illustrates a test setup for spinal plates that can be similarly adapted in order to apply fully reversed loads ($R = -1$) to spinal rods. Other *R* ratios may be used but must be documented in the report.

A3.5.12 The user shall determine the frequency at which to conduct the fatigue test, but the maximum recommended frequency of cyclic loading shall be 30 Hz.

A3.5.13 Initial fatigue maximum moment levels that are 75, 50, and 25 % of the bending ultimate moment determined with the static test method are suggested for the fatigue study. One maximum moment level should have specimens that do not fail before 2 500 000 cycles. The difference between the maximum moment value resulting in specimen failure and the maximum runout moment value must be less than 10 % of the device's bending ultimate moment.

A4. TEST METHOD FOR MEASURING THE STATIC AND FATIGUE BENDING STRENGTH OF METALLIC SPINAL SCREWS

A4.1 Scope

A4.1.1 This test method describes the methods for determining the static and dynamic bending properties of metallic spinal screws that are used in spinal arthrodesis implants.

A4.1.2 This test method is intended to provide a means of mechanically characterizing different component designs of spinal screws. It is not the intention of this test method to define levels of performance of spinal screws since insufficient information is available to predict the consequences of the use of a particular screw design.

A4.2 Summary of Method

A4.2.1 Spinal screws are loaded in quasi-static cantilever bending in order to record the component's mechanical response to the applied load. The load-versus-deflection curve is then analyzed in order to determine data used to derive the remaining bending properties of the spinal screw.

A4.2.2 Samples of a given spinal screw are loaded under cantilever bending in a sinusoidal cyclic manner at a predetermined frequency. The fatigue loading is continued until the specimen fails, a limit is reached which terminates the test, or until a predetermined cycle count (runout limit) is reached. The resulting test information is then used to develop a moment versus number of cycles curve that will characterize the general fatigue behavior for the given spinal screw design over a range of applied bending moments. Additionally, the information can be used, when applicable, to determine the spinal screw's median bending fatigue moment determined for a specified *N* number of cycles.

A4.3 Significance and Use

A4.3.1 This test method establishes a uniform static and dynamic bending test that will characterize, and can be used to compare, the static bending characteristics and fatigue performance of different designs of spinal screws. This test method is used to determine a spinal screw's fatigue life over a range of maximum bending moment conditions. Additionally, the method may be used to estimate the spinal screw's fatigue characteristics for a specified number of fatigue cycles.

A4.3.2 Spinal screws are integral components of many spinal implant constructs. They are designed to anchor the longitudinal or transverse elements, or both, to the bone. This test method defines standard equivalent test methods that can be used when evaluating different designs of spinal screws.

A4.3.3 This test method assumes that the spinal screw is manufactured from a material that exhibits linear-elastic material behavior. Therefore, the test method is not applicable for testing spinal screws made from materials that exhibit nonlinear elastic behavior.

A4.3.4 The fatigue test method described in this document is restricted to the testing of the spinal screw within the material's linear-elastic range. Therefore, the fatigue test method is not applicable for testing spinal screws under conditions that would approach or exceed the bending strength of the spinal screw being tested.

A4.3.5 The reporting of static and fatigue bending properties determined by this testing technique are only suitable for comparative evaluations between screws of different sizes, designs, and materials.

A4.4 Apparatus

Test System Requirements: Static Bend Tests

A4.4.1 *Axial Load Frame*—A test machine capable of applying tensile or compressive loads at a constant displacement rate.

A4.4.2 *Force Transducer*—A calibrated sensor capable of measuring axial loads per the requirements of Practice E4, and providing an output readable by a suitable recording device.

A4.4.3 *Displacement Transducer*—A calibrated sensor capable of measuring axial displacements with an accuracy of ±1 % of its full scale range, and providing an output readable by a suitable recording device.

A4.4.4 *Recording Device*—A calibrated recording device capable of monitoring the output of the force and displacement transducers and capable of generating a force versus displacement curve.

A4.4.5 The suitability of any data acquisition system used in monitoring the progress of these tests should be evaluated in accordance with the guidelines of Guide E1942.

Test System Requirements: Bending Fatigue Tests

A4.4.6 *Force Transducer*—A calibrated sensor capable of measuring dynamic tensile or compressive loads, or both, in accordance with Practice E467.

A4.4.7 *Cycle Counter*—A device capable of counting the number of loading cycles applied to a test sample during the course of a fatigue test.

A4.4.8 *Limit*—A device capable of detecting when a test parameter (for example, load, actuator displacement, DC error, and so forth) reaches a limiting value, at which time the test is stopped and the current cycle count is maintained.

A4.4.9 The suitability of any data acquisition systems used in monitoring the progress of these tests should be evaluated in accordance with the guidelines of Guide E1942.

Test Fixture Requirements

A4.4.10 Any test fixture implemented shall be sufficiently rigid so that its deformation under the maximum load is less than 1 % of the test sample's deformation.

A4.4.11 The threaded region of the spinal screw is embedded into a test block made from a synthetic material that is easily processed with standard spinal fixation system instruments. The user may manufacture a more rigid metallic test block (that is, hardened stainless steel at 40 HRC min.), if so desired, but may substitute Specification D4020 or Specification F648 UHMWPE or Grade 40, Specification F1839 rigid polyurethane foam, for the test block material.

A4.4.12 An anchoring fixture is rigidly attached to the spinal screw's head so that the screw's head is fully constrained during the test. The load is applied to the test sample at the end containing the test block, which is protected from localized failure by a protection sleeve placed around the test block. (See Fig. A4.2)

A4.5 Sampling

A4.5.1 Only unused and untested specimens shall be included in the sample for a given spinal component design. Include only final form and finished components in the sample.

A4.5.2 The sample size used for static tests shall be determined according to the methods defined in Practice E122 for any given loading condition. If insufficient information is available to determine a suitable sample size with Practice E122, then use a minimum sample size of five.

A4.5.3 For fatigue studies, test at least two specimens at each of three different maximum moment levels. One of the three maximum moment levels shall satisfy the maximum runout moment condition. Several references have been compiled that can provide the user with guidance and recommendations for selecting suitable sample sizes for fatigue studies used to develop an *M-N* diagram. (**1 and 2**)

A4.5.4 Use spinal screws of sufficient length so that at least 5 mm of screw thread length is included in the exposed length (see Fig. A4.2).

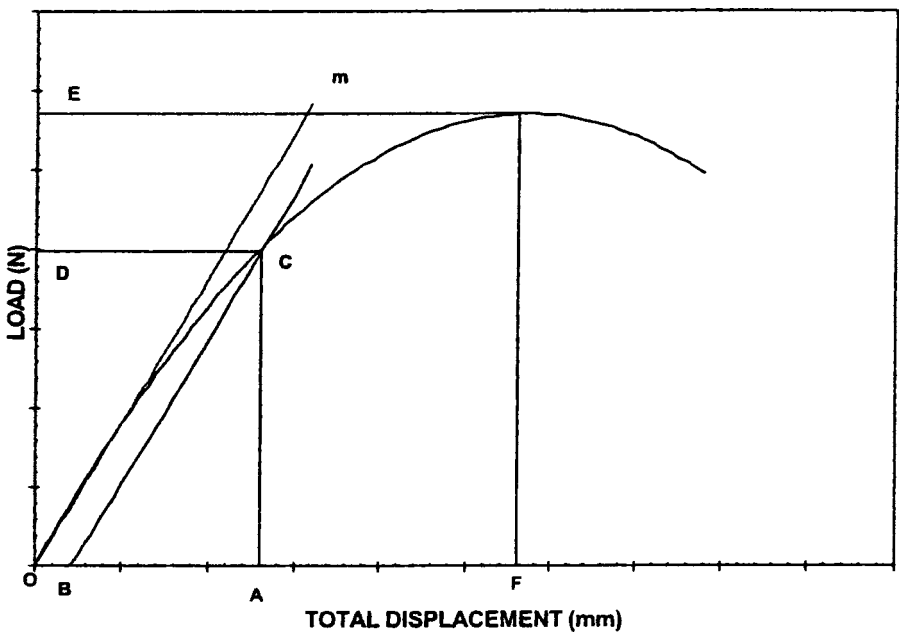

FIG. A4.1 Typical Static Bending Test Record

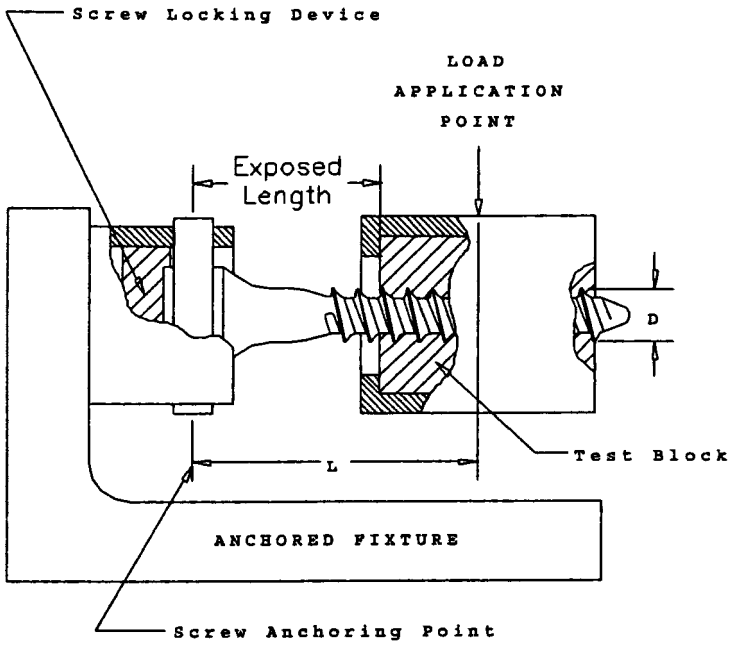

FIG. A4.2 Spinal Screw Test Configuration

A4.6 Preparation of Apparatus

A4.6.1 Manufacture test blocks so that the surface defined by the outside diameter of the screw is at least one screw thread diameter away from the test block's outer surface and 10 mm long (measured in the direction of the screw's longitudinal axis). Check to ensure that the test block surfaces are oriented so that the spinal screw's undeflected longitudinal axis is aligned perpendicular to the direction of the applied load.

A4.6.2 Drill pilot holes in the test block for insertion of the test specimen. The holes shall be drilled coincident to the test block's longitudinal axis. The drill used shall be the size specified by the manufacturer for the specimen being tested. When testing self-drilling spinal screws, a pilot hole that is no larger than 75 % of the screw's core diameter is recommended simply to ensure the screw's orientation for testing. Drill the pilot hole straight and true at 90º to the surface of the test block that will be penetrated. Tapered holes are allowed when tapered screws are to be tested. Complete the test block's hole preparation according to the given spinal screw's surgical technique (such as tapping when required).

A4.6.3 Insert the test sample into the test block to a depth of approximately 10 mm to create the same moment arm (*L*) for all screws having the same nominal length. For screws whose nominal length is less than 30 mm, inset the screw until one-third the length of the screw (measured from the longitudinal element interconnection and the screw's tip) is engaged in the test block.

A4.6.4 Mount the test sample in the test machine so that the screw's head is rigidly constrained as illustrated in Fig. A4.2. The test fixture depicted in Fig. A4.2 can be modified so that the interconnection mechanism can be used for anchoring the screw.

A4.6.5 Position the test setup so that the load is applied to the center of the test block, 5 mm from each end. The bending moment arm (*L*) shall be held constant for all diameter screws of a given length. Install the protection sleeve over the test block.

A4.6.6 Record the exposed length and bending moment arm (*L*) for the final test setup.

A4.7 Procedure

Static Test Method

A4.7.1 Apply loads of increasing magnitude (in displacement control), and generate a load-versus-displacement diagram either automatically or from numeric data acquired during the test. Bending characteristics shall be measured using the apparatus described in A4.4.

A4.7.2 Load the test specimen at a displacement rate not exceeding 25 mm/min. Continue loading the test specimen until the slope of the load-versus-displacement curve, beyond the linear elastic region, changes "sign."

A4.7.3 Unload the test specimen and record the failure location and failure mode, if applicable.

Fatigue Test Method

A4.7.4 Conduct the recommended fatigue test in a laboratory air environment at room temperature. Other test environments (simulated body fluid, 9-g NaCl per 1000 mL water saline, a saline drip, or water) may be used while testing, but the suitability of using the respective test environment must be justified, given the accelerated nature of the laboratory fatigue test. If an alternative test environment is used, record all pertinent parameters related to the environmental conditions (temperature, pH, solution strengths, and so forth) before, during, and after the test.

A4.7.5 Apply sinusoidal cyclic loads in load control at an *R* ratio of 0.10 for testing of devices intended for either the

lumbar or thoracic spine regions. Apply sinusoidal cyclic loads in load control at an *R* ratio of -1.0 for testing of devices intended for the cervical spine region. Other *R* ratios may be used but must be documented in the report.

A4.7.6 The user shall determine the frequency at which to conduct the fatigue test, but the maximum recommended frequency of cyclic loading shall be 30 Hz.

A4.7.7 Initial fatigue maximum moment levels that are 75, 50, and 25 % of the bending ultimate moment determined with the static test method are suggested for the fatigue study. One maximum moment level should have specimens that do not fail before 2 500 000 cycles. The difference between the maximum moment value resulting in specimen failure and the maximum runout moment value must be less than 10 % of the device's bending ultimate moment.

A4.7.8 The cycle counter shall record the cumulative number of cycles applied to the test specimen, and the appropriate limits should be set to indicate specimen failure or deviations from the intended load system performance.

A4.7.9 Testing shall continue until the specimen breaks, a limit is reached which terminates the test, or the runout criterion is reached.

A4.7.10 Record the results of each test, including the maximum moment, cycle count at test termination, and the failure location and failure mode, if applicable.

A4.8 Calculation and Interpretation of Results

Static Test Method

A4.8.1 Determine the bending stiffness, bending structural stiffness, 0.2 % offset displacement, bending yield moment, and bending ultimate moment in the following manner:

A4.8.2 On the test record that was generated during the test, draw a best fit straight line (*0m*) through the initial linear portion of the load-versus-total-displacement curve (see Fig. A4.1).

A4.8.3 Determine the spinal component's bending stiffness by calculating the slope of line *0m*.

A4.8.4 Calculate the spinal screw's bending structural stiffness using the following specified relationship:

$$EI_e = \frac{SL^3}{3}$$

where:

EI_e = bending structural stiffness (N·m^2),
S = bending stiffness expressed in units of N/m, and
L = bending moment arm expressed in units of m.

A4.8.5 Calculate the 0.2 % offset displacement value (see 3.5). On the load-versus-total-displacement curve lay off the line *BC* parallel to line *0m* and offset by the 0.2 % offset displacement value.

A4.8.6 Determine the load at the intersection point between line *BC* and the load-versus-total-displacement curve (point *D* of Fig. A4.1). Determine the spinal component's bending yield moment (N·m) with the following specified relationship:

$$\text{Bending Yield Moment} = PL$$

where:

P = the load (N) at point D of Fig. A4.1, and
L = bending moment arm expressed in units of m.

A4.8.7 Determine the peak load during the static test (point *E* of Fig. A4.1). Determine the spinal component's bending ultimate moment (N·m) with the equation of A4.8.6 and substitute the load (N) at point *E* of Fig. A4.1 for variable *P*.

Fatigue Test Method

A4.8.8 Plot the maximum moment (N·m) and cycles to test termination on an *M-N* diagram. Various techniques may be used to estimate mean or median fatigue lives, statistical differences between groups, curve fits of the fatigue data, probability of survival curves, and so forth. (**3-8**)

A4.8.9 If determining median fatigue bending moment at 2 500 000 cycles, it is recommended that the fatigue bending moment be determined as the median fatigue moment (50 % probability of survival), using a technique or criteria described in the literature. (**1-6**)

A4.9 Report

A4.9.1 The test report shall specify the following spinal screw characteristics:

A4.9.2 Manufacturer's name or logo.

A4.9.3 Screw descriptions, including any relevant geometric characteristics.

A4.9.4 The ASTM designation, if the screw is manufactured according to an ASTM specification.

A4.9.5 Material and the ASTM designation, if applicable.

A4.9.6 Catalog number.

A4.9.7 Manufacturing lot number.

A4.9.8 Test block material and dimensional information for spinal screw tests.

A4.9.9 Intended spinal location for the spinal screw.

A4.9.10 Illustration of the loading configuration used during the investigation. Describe the similarities and differences to the relevant figures contained therein.

A4.9.11 Any deviations from the recommended test method.

A4.9.12 Measurements for the bending moment arm, the gripped length, and the exposed length.

A4.9.13 Number of specimens tested for each sample and the rationale for the sample size selected for the static test.

A4.9.14 Test specimen static test failure modes observed.

A4.9.15 Load versus total displacement curves for all static tests.

A4.9.16 0.2 % offset displacement value.

A4.9.17 Mean and standard deviation for the test component's bending stiffness, bending structural stiffness, bending yield moment, and bending ultimate moment.

A4.9.18 *R*-ratio used during the fatigue tests.

A4.9.19 Fatigue test frequency.

A4.9.20 Description of the fatigue test environment if other than the recommended room temperature laboratory air environment.

A4.9.21 Description of the fatigue failure mode and failure location for each specimen that failed.

A4.9.22 Number of specimens tested for each sample and the rationale for the sample size selected for the fatigue tests.

A4.9.23 Tabular listing that summarizes the maximum moment and the resulting cycles to test termination data for the fatigue tests.

A4.9.24 Bending fatigue runout moment.

A4.9.25 All initial and secondary fatigue failures and the failure modes.

A4.9.26 Pictures of the failure surfaces.

A4.9.27 Plot a semi-log *M-N* diagram of the maximum moment versus number of cycles to test termination. Uniquely identify specimens that have not failed prior to accumulating 2 500 000 fatigue-loading cycles.

A4.9.28 Regression analysis results for the maximum moment versus number of cycles to failure data (including descriptions of any analytical or statistical techniques used when interpreting the fatigue data).

A4.10 Precision and Bias

A4.10.1 *Precision*—Data establishing the precision of this method have not yet been obtained.

A4.10.2 *Bias*—No statement can be made as to bias of this test method since no acceptable reference values are available, nor can they be obtained because of the destructive nature of the tests.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR THE OVERALL SPECIFICATION

X1.1 These specifications and test methods are intended to provide useful and consistent information related to the terminology, performance, application of test methods, and the application of components used in spinal constructs. Spinal construct component geometrical definitions, dimensions, classification and terminology; material specifications; and performance definitions are provided.

X1.2 The surgeon should be able to select the spinal device that he feels is appropriate for the indication. In order to do this, the surgeon must have confidence that the designation of size and its instrumentation has a specific, known meaning that is quantifiable and reliable, regardless of the manufacturer or design. The mechanical behavior and material properties must also be described in a reliable, known manner that is irrespective of the manufacturer or design. In order to accomplish this uniformity of designations, the terminology, dimensions, mechanical properties, and material properties must be standardized.

X1.3 These specifications and test methods are not intended to define performance levels of spinal implants, as insufficient knowledge to predict the consequence of the use of particular spinal implant design and assemblies is available.

X1.4 These specifications and test methods include a test method that covers the static and dynamic evaluation of spinal components used as either anchorage elements or longitudinal elements of spinal constructs. The purpose of spinal implants is to provide short-term stability while arthrodesis takes place. This test method does not address the long-term mechanical issues of spinal components, nor does it address the performance of implants that do not lead to spinal fusion.

X1.5 One of the objectives of these specifications and test methods was to provide a consistent methodology for determining an estimate of the spinal component's fatigue strength at a meaningful cycle count. The estimated number of cycles seen *in vivo* in a twelve month period, which can be considered the approximate average time until fusion, ranges from 1 to 2.5 million cycles. Doubling the 2.5 million cycles to 5 million provides a safety factor, but substantially increases the cost of testing without providing additional meaningful data. Even if a failure is noted in the 2.5 to 5 million cycle range, it generally occurs below the horizontal runout portion of the curve, and does not significantly affect the curve itself. Therefore, 2.5 million cycles was chosen as the cyclic runout limit.

X1.6 The influence of simulated body fluid or saline may affect the relative performance of tested spinal components. The performance tests identified in these specifications and test methods are specified for ambient laboratory conditions in order to reduce variability within the results. An individual investigator may consider additional evaluations in simulated body fluids, saline, or water to address environmental factors.

X2. RATIONALE FOR ANNEX A1

X2.1 This annex is intended to provide useful and consistent information related to the terminology, performance, application of test methods, and the application of spinal screws. Spinal screw geometrical definitions, dimensions, classification and terminology; material specifications; and performance definitions are provided in A1.1 – A1.5.

X2.2 The following mechanical performance characteristics of spinal screws are considered to be important to the surgeon for various reasons.

X2.2.1 *Maximum Torque*—This characteristic identifies the limiting torsional capacity of the spinal screw. This characteristic is particularly important when dealing with self-tapping and self-drilling screws. These screw designs have the potential to stress the screw to the torsional limit when they are inserted into thick cortical bone.

X2.2.2 *Driving Torque Requirements*—These requirements identify the potential level that the screw could be stressed in torque upon insertion. This characteristic is particularly important when dealing with self-tapping and self-drilling screws. These screw designs have the potential to stress the screw to the torsion limit when it is inserted into thick cortical bone.

X2.2.3 *Bending Properties*—Bending properties are critical characteristics of spinal screws since the screw provides the primary means of transferring the load from the longitudinal element to the bony element. Additionally, the bending stiffness of the screw may directly affect the rate and ability of healing or fusion.

X2.2.4 *Axial Pull-Out Load*—Axial pull-out load is a critical characteristic of spinal screws since the screw provides the primary means of transferring the load from the longitudinal element to the bony element.

X2.3 The driving torque test requirements in this specification call for the insertion of the spinal screw into test blocks manufactured from Grade 40, Specification F1839 rigid polyurethane foam. This density material was chosen for two reasons. First, the material closely replicates cortical bone and will, therefore, provide tests results that are representative of the worst case clinical situation. Second, the referenced material provides a uniform material for testing.

X2.4 The axial pull-out load test requirements in this specification call for the insertion of the spinal screw into test blocks manufactured from Grade 20, Specification F1839 rigid polyurethane foam. This density material was chosen for two reasons. First, the material closely replicates cancellous bone and will, therefore, provide tests results that are representative of the worst case situation. Second, the referenced material provides a uniform material for testing.

X2.5 An insertion speed of 30 r/min (one-half turn per second) was chosen for the screw insertion processes since this speed better represents the clinical insertion speed for screws than the 3 r/min specified in Specification F543, Annex A2.

X2.6 Spinal screws are inserted into the test block to specific insertion depths that are correlated to the specific test. The greatest insertion depth was selected for the driving torque test and the smallest insertion depth was chosen for the axial pull-out load test since these conditions each represent the worst case clinical condition for the respective performance test.

X3. RATIONALE FOR ANNEX A2

X3.1 This annex is intended to provide useful and consistent information related to spinal plates.

X3.2 Spinal plate bending properties are the critical performance characteristic since the plate provides the primary means of stabilizing the motion segments. Additionally, the bending stiffness of the plate may directly affect the rate and ability of healing.

X3.3 A four-point bending load is specified for spinal plates since that loading configuration can reproduce the dominant stress condition within an implanted spinal plate.

X3.4 The specified bending test roller positions in this method have been selected so that the spinal plate section being tested is equivalent to the active length of the spinal plate when tested according to Test Methods F1717. It is important that all spinal plate design features that would normally be tested during an Test Methods F1717 test be included in the spinal plate component test. This would ensure that all stress concentrating features of a given plate design are considered during the component test.

X4. RATIONALE FOR ANNEX A3

X4.1 This annex is intended to provide useful and consistent information related to spinal rods.

X4.2 Spinal rod bending properties are the critical performance characteristic since the rod(s) provides the primary means of stabilizing the motion segments. Additionally, the bending stiffness of the rod may directly affect the rate and ability of healing.

X4.3 A four-point bending load is specified for spinal rods since that loading configuration can reproduce the dominant stress condition within an implanted spinal rod.

X4.4 The user is allowed to freely pick the test fixture configuration (roller contact points) for spinal rod testing since the rod's cross section is uniform along the rod's length and lacks any design features along its length that would be considered stress concentrators. Therefore, any rod section selected for the test would be representative of the overall rod's mechanical properties.

X5. RATIONALE FOR ANNEX A4

X5.1 This test method is designed to measure the mechanical properties of spinal components subjected to both static and fatigue-bending loads, which are the most common types of loading encountered *in vivo*. This test method addresses itself to properties of the component rather than the material from which the spinal component is manufactured.

X5.2 A cantilever-bending load is specified for spinal screws since it provides a simplification of the dominant stress condition within an implanted spinal screw.

REFERENCES

(1) Little, R. E., *Statistical Planning and Analysis*, ASTM STP 588, American Society of Testing and Materials, Philadelphia, PA.

(2) Little, R. E. and Ekvall, *Statistical Analysis of Fatigue Data*, ASTM STP 744, American Society of Testing and Materials, Philadelphia, PA.

(3) Little, R. E. and Jebe, E. H., *Manual on Statistical Planning and Analysis of Fatigue Experiments*, ASTM STP 588, American Society of Testing and Materials, Philadelphia, PA, 1975.

(4) Conway, J. B. and Sjodahl, L. H., *Analysis and Representation of Fatigue Data*, ASM International, Materials Park, OH, 1991.

(5) Collins, J. A., *Failure of Materials in Mechanical Design*, John Wiley and Sons, New York, NY, 1981.

(6) Swanson, *Handbook of Fatigue Testing*, ASTM STP 566, American Society of Testing and Materials, Philadelphia, PA.

(7) Little, R. E., "Optimal Stress Amplitude Selection in Estimating Median Fatigue Limits Using Small Samples," *J. of Testing and Evaluation*, ASTM, 1990, pp. 115-122.

(8) International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland.