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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 Test Method 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards: General*[2]

E4 Practices for Force Calibration and 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

[1] These specifications and test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are 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 www.astm.org/contact. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
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
F565 Practice for Care and Handling of Orthopedic Implants and Instruments
F983 Practice for Permanent Marking of Orthopaedic Implant Components
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
F3574 Test Methods for Sacroiliac Joint Fusion Devices

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 22Chromium-13Nickel-5Manganese-2.5Molybdenum 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)
F3001 Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion

2.3 *ISO Standards:*[3]

ISO 14630 Non-active Surgical Implants—General Requirements

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 Specifications F382 and F543.

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 Terminologies E6 and E1823, Specification F382, and Test Methods F1717, F1798, and F3574.

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 (or Test Methods F3574, Annex A2).

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] Available from American National Standards Institute (ANSI), 1180 Avenue of the Americas, 10th Floor, New York, NY 10036, http://www.ansi.org.