



Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System¹

This standard is issued under the fixed designation F 2193; 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 a series of standards available for addressing the concerns related to 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 F 1798. At the highest level in this chain is Test Methods F 1717, 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 is available to predict the consequences of using any of these components in individual patients for specific activities of daily living. 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*

E 4 Practices for Load Verification of Testing Machines²

E 6 Terminology Relating to Methods of Mechanical Testing²

E 122 Practice for Calculating Sample Size to Estimate, With a Specified Tolerable Error, the Characteristic of a Lot or Process³

E 467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System²

E 1823 Terminology Relating to Fatigue and Fracture Testing²

E 1942 Guide for Evaluating Data Acquisition Systems Used in Cyclic Fatigue and Fracture Mechanics Testing²

F 382 Specification and Test Method for Metallic Bone Plates⁴

F 543 Specification and Test Methods for Metallic Medical Bone Screws⁴

F 565 Practice for Care and Handling of Orthopaedic Implants and Instruments⁴

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 *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 14.02.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.