



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

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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.