



Standard Specification and Test Method for Metallic Bone Plates¹

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1. Scope

1.1 This specification and test method is intended to provide a comprehensive reference for bone plates used in the surgical internal fixation of the skeletal system. The standard establishes consistent methods to classify and define the geometric and performance characteristics of bone plates. The standard also presents a catalog of standard specifications that specify material; labeling and handling requirements; and standard test methods for measuring performance related mechanical characteristics determined to be important to the *in vivo* performance of bone plates.

1.2 It is not the intention of the standard to define levels of performance or case-specific clinical performance for bone plates, as insufficient knowledge is available to predict the consequences or their use in individual patients for specific activities of daily living. Furthermore, it is not the intention of the standard to describe or specify specific designs for bone plates used in the surgical internal fixation of the skeletal system.

1.3 This document may not be appropriate for all types of bone plates. The user is cautioned to consider the appropriateness of the standard in view of a particular bone plate and its potential application.

1.4 This document includes the following test methods used in determining the following bone plate mechanical performance characteristics:

1.4.1 Standard Test Method for Single Cycle Bend Testing of Metallic Bone Plates—**Annex A1**, and

1.4.2 Standard Test Method for Determining the Bending Fatigue Properties Of Metallic Bone Plates—**Annex A2**.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *Multiple test methods are included in this standard. However, it must be noted that the user is not obligated to test*

using all of the described methods. Instead, the user should only select test methods that are appropriate for a particular device design. In most instances, only a subset of the herein described test methods will be required.

1.7 *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

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

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

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)

F139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)

F543 Specification and Test Methods for Metallic Medical Bone Screws

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

¹ This specification and test method is under the jurisdiction of ASTM Committee **F04** on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee **F04.21** on Osteosynthesis.

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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.