



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, define the geometric characteristics, 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 standard 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 standard 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.

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

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

1.6 *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:

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications²

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)²

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants²

F 90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R56401)²

F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)²

F 138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)²

F 139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)²

F 543 Specification and Test Methods for Metallic Medical Bone Screws²

F 565 Practice for Care and Handling of Orthopedic Implants and Instruments²

F 620 Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants²

F 621 Specification for Stainless Steel Forgings for Surgical Implants²

F 983 Practice for Permanent Marking of Orthopaedic Implant Components²

F 1295 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications²

F 1314 Wrought Nitrogen Strengthened-22Chromium-12.5Nickel-5Manganese-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S20910)²

F 1472 Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants²

F 1713 Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications²

¹ This 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 Annual Book of ASTM Standards, Vol 13.01.