



Standard Specification and Test Method for Metallic Bone Plates¹

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1. Scope

1.1 This standard 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:

¹ This test method is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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F 67 Specification for Unalloyed Titanium for Surgical Implant Applications²

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications²

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

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications²

F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications²

F 138 Specification for Stainless Steel Bars and Wire for Surgical Implants (Special Quality)²

F 139 Specification for Stainless Steel Sheet and Strip for Surgical Implants (Special Quality)²

F 543 Specification for Cortical Bone Screws²

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

F 620 Specification for Titanium 6Al-ELI 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 Wrought Titanium - 6 Aluminum - 7 Niobium Alloy for Surgical Implant Applications²

F 1314 Wrought Nitrogen Strengthened - 22 Chromium - 12.5 Nickel - 5 Manganese - 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants²

F 1472 Wrought Titanium Ti-6Al-4V Alloy for Surgical Implant Applications²

F 1713 Standard Specification for Wrought Titanium 13Nb-13Zr Alloy for Surgical Implant Applications²

2.2 ISO Standard:³

FDIS 14602 Non-active surgical implants—Implants for Osteosynthesis particular requirements.

3. Terminology

3.1 Definitions—Geometric:

3.1.1 *auto compression*—a type of bone plate that by its design can generate a compressive force between adjacent unconnected bone fragments through the use of one or more ramped holes or another type of slot geometry. This ramp or

² *Annual Book of ASTM Standards*, Vol 13.01.

³ Available from International Standards Organization, Rue de Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland.