



Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices¹

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1. Scope

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

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

1.3 This standard may not be appropriate for all types of angled devices. The user is cautioned to consider the appropriateness of this standard in view of a particular angled device and its potential application.

1.4 This standard includes the following test methods used in determining the following angled device mechanical performance characteristics:

1.4.1 Standard test method for single cycle compression bend testing of metallic angled orthopedic fracture fixation devices (see Annex A1).

1.4.2 Standard test method for determining the bending fatigue properties of metallic angled orthopedic fracture fixation devices (see Annex A2).

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

NOTE 1—There is currently no ISO standard that is either similar to equivalent to this standard.

¹ These specifications and test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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2. Referenced Documents

2.1 ASTM Standards:

E 4 Practices for Force Verification of Testing Machines²

E 8 Test Methods for Tension Testing of Metallic Materials²

E 122 Practice for Choice of Sample Size to Estimate the Average Quality of a Lot or Process³

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications⁴

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS R30075)⁴

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (R30605)⁴

F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications⁴

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

F 139 Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)⁴

F 382 Specification and Test Methods for Metallic Bone Plates⁴

F 543 Specification for Metallic Medical Bone Screws⁴

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

F 620 Specification for Titanium-6 Aluminum-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)⁴

F 621 Specification for Stainless Steel Forgings for Surgical Implants⁴

F 983 Practice for Permanent Marking of Orthopedic Implant Components⁴

F 1295 Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700)⁴

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.