



Designation: F384 – 17

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

This standard is issued under the fixed designation F384; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

1. Scope

1.1 These specifications and test methods 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, 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 or 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, this standard does not 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.

NOTE 1—This standard is not intended to address intramedullary hip screw nails or other angled devices without a sideplate.

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 The values stated in SI units are to be regarded as standard. No other units of measurement are included in 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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NOTE 2—There is currently no ISO standard that is either similar to equivalent to this standard.

1.6 Multiple test methods are included in this standard. However, the user is not necessarily obligated to test using all of the described methods. Instead, the user should only select, with justification, test methods that are appropriate for a particular device design. This may be only a subset of the herein described test methods.

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- E4 Practices for Force Verification of Testing Machines
- E8 Test Methods for Tension Testing of Metallic Materials
- 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)
- 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)

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.