

Designation: F138 - 13a

Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)¹

This standard is issued under the fixed designation F138; 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 reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

- 1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought 18chromium-14nickel-2.5molybdenum stainless steel bar and wire used for the manufacture of surgical implants.
- 1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 ASTM Standards:²

A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels

A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings

A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

E8/E8M Test Methods for Tension Testing of Metallic Materials

E10 Test Method for Brinell Hardness of Metallic MaterialsE18 Test Methods for Rockwell Hardness of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E45 Test Methods for Determining the Inclusion Content of Steel

E112 Test Methods for Determining Average Grain Size
E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron,
Nickel, and Cobalt Alloys

E407 Practice for Microetching Metals and Alloys

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F1350 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 Aerospace Material Standard:³

AMS 2630 Inspection, Ultrasonic Product Over 0.5 inch (12.7 mm) Thick

AMS 2632 Ultrasonic Inspection of Thin Materials 2.3 *ISO Standards*:⁴

ISO 5832–1 Implants for Surgery—Metallic Materials— Part 1:Wrought Stainless Steel

ISO 6892 Metallic Materials—Tensile Testing

ISO 9001 Quality Management Systems—Requirements

3. Terminology

- 3.1 Definitions of Terms Specific to This Standard:
- 3.1.1 *bar*, *n*—rounds, flats, or other shapes from 0.1875 in. [4.76 mm] to 4 in. [101.60 mm] in diameter or thickness. (Other sizes and shapes by special order.)
- 3.1.2 *fine wire*, n—wire as described in 3.1.5, less than 0.063 in. [1.60 mm] in diameter or thickness.
- 3.1.3 *forging bar, n*—bar as described in 3.1.1, used for the production of forgings, may be furnished in the hot worked condition.
- 3.1.4 *lot*, *n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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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.

³ Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://aerospace.sae.org.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.5 *wire, n*—rounds, flats or other shapes less than 0.1875 in. [4.76 mm] in diameter or thickness.

4. General Requirements for Delivery

- 4.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A484/A484M and A555/A555M shall apply.
- 4.2 In the case where a conflict exists between this specification and those listed in 2.1 and 2.3, this specification shall take precedence.

5. Ordering Information

- 5.1 Inquiries and orders for material under this specification shall include the following information:
 - 5.1.1 Quantity (weight or number of pieces);
 - 5.1.2 ASTM designation and date of issue;
 - 5.1.3 Form (bar, wire, fine wire);
 - 5.1.4 Condition (see **6.1**);
- 5.1.5 Mechanical properties (if applicable, for special conditions);
 - 5.1.6 Finish (see 6.2);
- 5.1.7 Applicable dimensions including size, thickness, width, and length (exact, random or multiples) or drawing number;
 - 5.1.8 Special tests, if any; and
 - 5.1.9 Other requirements.

6. Materials and Manufacture

- 6.1 Condition:
- 6.1.1 Bar and wire shall be furnished, as specified, in the hot worked, annealed, cold worked, or extra hard condition (see Table 1)
- 6.1.2 Fine wire shall be furnished, as specified, in the cold drawn condition (see Table 2).
 - 6.2 Finish:
- 6.2.1 Types of finish available for bar and wire products are cold drawn, pickled, ground, ground and polished, or as specified in the purchase order.
- 6.2.2 Types of finish available for fine wire products are descaled or pickled, abrasive-blasted, cold drawn, ground, ground and polished, or as specified in the purchase order.

7. Chemical Requirements

7.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 3.

7.1.1 The compositional requirement shall meet the following:

- 7.1.2 Requirements for the major and minor elemental constituents are listed in Table 3. Also listed are important residual elements. Analysis for elements not listed in Table 3 is not required to certify compliance with this specification.
- 7.1.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A751.
- 7.2 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements, but cover variations between laboratories in the measurement of chemical content. The supplier shall not ship material that is outside the limits specified in Table 3. Product analysis limits shall be as specified in Table 4.
- 7.2.1 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.
- 7.2.2 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.
- 7.2.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods E354.

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- 8.1 The material shall exhibit no delta ferrite, chi, or sigma phases when it is examined metallographically at 100× magnification when etched in accordance with Practice E407.
- 8.2 The microcleanliness of the steel as determined by Method A of Test Methods E45, except using Plate I-r, on representative billet or bar samples from the heat shall not exceed the following:

Inclusion	Α	В	С	D
Type	(Sulfide)	(Alumina)	(Silicate)	(Globular Oxides)
Thin	1.5	1.5	1.5	1.5
Heavy	1.0	1.0	1.0	1.0

9. Mechanical Properties

- 9.1 Tensile Properties:
- 9.1.1 Tensile properties shall be determined in accordance with Test Methods E8/E8M.

TABLE 1 Mechanical Requirements, Bar and Wire

Condition	Diameter or Thickness, in. [mm]	Ultimate Tensile Strength, min, psi [MPa]	Yield Strength (0.2 % offset), min, psi [MPa]	Elongation ^A in 4D or 4W, min, %	Brinell ^B Hardness, max, HB
Hot worked ^C	all				250
Annealed	0.063 and over [1.60]	71 000 [490]	27 500 [190]	40	
Cold worked	0.063 to 1.500 [1.60 to 38.1]	125 000 [860]	100 000 [690]	12	
Extra-hard	0.063 to 0.250 [1.60 to 6.35]	196 000 [1350]	···		

^A The gage length must be reported with the test results. $4D = 4 \times$ diameter; $4W = 4 \times$ width. Alternatively, a gage length corresponding to Test Methods E8/E8M or ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area).

^B 29-kN [3000-kgf] load.

^C Typically supplied as hot rolled bar for forging applications.