



Designation: F138 – 19

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 U.S. 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.

1.3 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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

- 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

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.

Current edition approved Dec. 1, 2019. Published February 2020. Originally approved in 1971. Last previous edition approved in 2013 as F138 – 13a. DOI: 10.1520/F0138-19.

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.

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 Materials

E18 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 Insertion into 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

ISO 13485 Medical Devices—Quality Management Systems—Requirements For Regulatory Purposes

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>.

*A Summary of Changes section appears at the end of this standard

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *bar, n*—round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths, with a maximum cross-sectional area of 103 cm² [16 in.²].

3.1.2 *fine wire, n*—wire as described in 3.1.5, less than 1.60 mm [0.063 in.] 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.

3.1.5 *wire, n*—round, rectangular, or other complex shaped product produced and delivered in coils, spools, or other packaging as specified.

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, 2.2, 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 supplier's heat analysis shall conform to the chemical requirements prescribed in Table 3. The supplier shall not ship material with chemistry outside the requirements specified in Table 3.

7.1.1 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 verify compliance with this specification.

7.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between purchaser and supplier.

7.1.3 Intentional elemental additions other than those specified in Table 3 are not permitted.

7.1.4 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.

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.

TABLE 1 Mechanical Requirements, Bar and Wire

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

^A Elongation of material 1.6 mm [0.063 in.] or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 50 mm [2 in.] or 4*D* or 4*W* per Test Methods E8/E8M. The gauge length shall be reported with the test results. Alternatively, a gauge length corresponding to E 8M or ISO 6892 (5.65 times the square root of *S*_o, where *S*_o is the original cross-sectional area) may be used when agreed upon between the supplier and purchaser.

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

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

TABLE 2 Mechanical Requirements, Fine Wire^A

Condition ^B	Diameter, mm [in.]	Ultimate ^C Tensile Strength, MPa [psi]	Elongation in 254 mm [10 in.], min, %
Cold drawn	under 1.60 [0.063]	860 to 1035 [125 000 to 150 000]	5

^A Annealed fine wire requirements are covered in Specification **F1350**.

^B Recommended crosshead speed for cold drawn fine wire is 2.0 mm/s [5 in./min].

^C Cold drawn wire may be ordered to tensile strengths up to 2070 MPa [300 000 psi] with lower elongation as determined by the purchaser and supplier.

TABLE 3 Chemical Requirements, Heat Analysis

Element	Composition, % (mass/mass)
Carbon	0.030 max
Manganese	2.00 max
Phosphorous	0.025 max
Sulfur	0.010 max
Silicon	0.75 max
Chromium	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum	2.25 to 3.00
Nitrogen	0.10 max
Copper	0.50 max
Cobalt	<0.10
Iron ^A	balance
Composition Index = % Cr + 3.3 × % Mo	26.0 min

^A The percentage of iron content by difference is not required to be determined or certified.

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 Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (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**.

9.1.2 Material shall conform to the appropriate requirements as to mechanical properties specified in **Table 1** and **Table 2**.

9.1.3 The level of mechanical properties for material in conditions other than those included in **Table 1** and **Table 2**, shall be specified in the purchase order.

9.1.4 Bar and wire in the cold worked condition can be supplied to a higher tensile strength and corresponding lower elongation as specified on the purchase order.

9.1.5 Fine wire in the cold drawn condition can be supplied to a higher tensile strength and corresponding lower elongation as specified on the purchase order.

9.2 Hardness:

9.2.1 Hardness values shall be determined in accordance with Test Method **E10** or **E18**.

9.2.2 When desired, hardness limits may be specified by the purchaser. Hardness determinations shall be made on the product cross section, midway between the center and surface, if the cross section is adequate.

9.2.3 Hardness values are for information only and shall not be used as a basis for rejection.

9.3 Number of Tests:

9.3.1 Perform at least one tension test from each lot. Should any of the test pieces not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

9.3.2 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable, if the elongation meets the minimum requirement specified. Refer to section 7.11.4 of Test Methods **E8/E8M**. If the elongation is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

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 Product analysis outside the tolerance limits allowed in **Table 4** are cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7.2.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods **E354**.

8. Metallurgical Requirements

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**.

TABLE 4 Product Analysis Tolerance^A

Element	Tolerance Under the Minimum or Over the Maximum Limit, % (mass/mass) ^B
Carbon	0.005
Manganese	0.04
Phosphorous	0.005
Sulfur	0.005
Silicon	0.05
Chromium	0.20
Nickel	0.15
Molybdenum	0.10
Nitrogen	0.01
Copper	0.03
Cobalt	0.01

^A These limits conform to Specifications **A484/A484M** and **A555/A555M**.

^B Under minimum limit not applicable for elements where only a maximum percentage is indicated.