



Designation: F 138 – 97

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

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

1. Scope

1.1 This specification covers the requirements for wrought 18 chromium-14 nickel-2.5 molybdenum stainless steel bar and wire used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI units given in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels²

A 484/A 484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings²

A 555/A 555M Specification for General Requirements for Stainless Steel Wire and Wire Rods²

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products²

E 8/E 8M Test Methods for Tension Testing of Metallic Materials³

E 45 Test Methods for Determining the Inclusion Content of Steel³

E 112 Test Methods for Determining Average Grain Size³

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone⁴

F 1350 Specification for Stainless Steel Surgical Fixation Wire⁴

2.2 ISO Standards:

ISO 5832-1 Implants for Surgery—Metallic Materials—Part 1:Wrought Stainless Steel⁵

ISO 6892 Metallic Materials—Tensile Testing⁵

2.3 ASQ Standard:

Q1 Specification of General Requirements for a Quality Program⁶

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484/A 484M and A 555/A 555M shall apply.

3.2 In the case where a conflict exists between this specification and those listed in 2.1 and 2.2, this specification shall take precedence.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation,

4.1.3 Form (bar, wire, fine wire),

4.1.4 Condition (see 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, and length (exact, random or multiples) or print number, and

4.1.8 Special requirements.

5. Materials and Manufacture

5.1 Condition:

5.1.1 Bar and wire shall be furnished, as specified, in the hot-worked, annealed, cold -worked, or extra hard condition (see Table 1).

5.1.2 Fine wire shall be furnished, as specified, in the cold-drawn condition (see Table 2).

5.2 Finish:

5.2.1 Types of finish available for bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the purchase order.

¹ This specification is under the jurisdiction of ASTM Committee F-14 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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² Annual Book of ASTM Standards, Vol 01.03.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Annual Book of ASTM Standards, Vol 13.01.

⁵ Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

⁶ Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

TABLE 1 Mechanical Requirements, Wire and Bar

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 4D = 4 × diameter; 4W = 4 × width. Alternatively, a gage length corresponding to ISO 6892 may be used when agreed upon between 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, in. (mm)	Ultimate ^C Tensile Strength, psi (MPa)	Elongation in 10 in. (254 mm), min, %
Cold-drawn	under 0.063 (1.60)	125 000 to 150 000 (860 to 1035)	5

^A Annealed fine wire requirements are covered in Specification F 1350.

^B Recommended crosshead speed for cold-drawn fine wire is 5 in./min (2.0 mm/s).

^C Cold-drawn wire may be ordered to tensile strengths up to 300 000 psi (2070 MPa) with lower elongation as determined by customer and supplier.

5.2.2 Types of finish available for fine wire products are cold-drawn, ground, ground and polished, or as specified in the purchase order.

6. Chemical Composition

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

6.1.1 The pitting resistance equivalent (PRE) shall meet the following:

$$\% \text{Cr} + 3.3 \times \% \text{Mo} \geq 26 \quad (1)$$

6.1.2 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.

6.2 *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 manufacturer shall not ship material that is outside the limits specified in Table 3. Product analysis limits shall be as specified in Table 4.

6.2.1 The product analysis is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat.

TABLE 3 Chemical Requirements, Heat Analysis

Element	Composition, %
Carbon	0.030 max
Manganese	2.00 max
Phosphorous	0.025 max
Sulfur	0.010 max
Silicon	0.75 max
Chromium ^A	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum ^A	2.25 to 3.00
Nitrogen	0.10 max
Copper	0.50 max
Iron ^B	balance

^A The pitting resistance equivalent (PRE) shall meet the following:

$$\% \text{Cr} + 3.3 \times \% \text{Mo} \geq 26.$$

^B Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage iron content by difference is not required to be reported.

TABLE 4 Product Analysis Tolerance^A

Element	Tolerance Under the Minimum or Over the Maximum Limit ^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

^A Refer to Specification A 555/A 555M.

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

6.2.2 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this check analysis.

6.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A 751.

7. Metallurgical Requirements

7.1 The material shall contain no free ferrite phase when it is examined metallographically at 100× magnification.

7.2 The microcleanliness of the steel as determined by Method A of Test Methods E 45, 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

8. Mechanical Properties

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