Designation: F 138 – 00

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

This standard is issued under the fixed designation F 138; 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 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 Steels[2]

A 484/A 484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings[2]

A 555/A 555M Specification for General Requirements for Stainless Steel Wire and Wire Rods[2]

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 8/E 8M Test Methods for Tension Testing of Metallic Materials[3]

E 45 Test Methods for Determining the Inclusion Content of Steel[3]

E 112 Test Methods for Determining Average Grain Size[3]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[4]

F 1350 Specification for Stainless Steel Surgical Fixation Wire[4]

2.2 *ISO Standards:*

ISO 5832–1 Implants for Surgery—Metallic Materials—Part 1:Wrought Stainless Steel[5]

ISO 6892 Metallic Materials—Tensile Testing[5]

2.3 *ASQ Standard:*

C1 Specification of General Requirements for a Quality Program[6]

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.

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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 Instititute, 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 4*D* or 4*W*, 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] 4*D* = 4 × diameter; 4*W* = 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 compositional requirement shall meet the following:

$$\% \text{ Cr} + 3.3 \times \% \text{ Mo} \geq 26.0 \quad (1)$$

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 compositional requirement shall meet the following:
$\% \text{ Cr} + 3.3 \times \% \text{ Mo} \geq 26.0$.
[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 delta 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.

8.1.1 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.

8.1.2 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.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8/E 8M.

8.3 Brinell hardness number (HB) is the preferred method of reporting the hardness of hot-worked material.

8.4 When desired, Rockwell hardness, B scale (HRB), Rockwell hardness, C scale (HRC), or other hardness limits may be specified. Hardness determination on cold-worked material shall be made on a product cross-section, midway between the center and surface, if cross-section size is adequate.

9. Special Tests

9.1 The steel shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A 262.

9.1.1 Samples in the hot-worked condition shall be annealed prior to Practice E of Practices A 262, sensitization heat treatment.

9.2 The grain size shall be five or finer when tested in accordance with Test Methods E 112.

9.2.1 It is preferred that samples for grain size determination be selected after the hot working operation or after the final annealing operation prior to the final cold working operation.

9.2.2 If samples are selected after a final cold working operation, specimens shall be tested in accordance with Test Methods E 112 or as agreed to between suppplier and purchaser.

9.3 Finished round bar greater than 0.250 in. (6.35 mm) diameter shall be inspected using ultrasonic or equivalent test methods. Billet shall also be ultrasonically tested prior to being hot rolled and should be free of internal defects. Acceptance criteria shall be agreed to between pruchaser and supplier.

9.4 Any other special requirements shall be specified on the purchase order.

10. Certification

10.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results, shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program, such as defined in ASQ C1.

11.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQ C1, or other recognized program.

12. Keywords

12.1 metals (for surgical implants); stainless steel; surgical applications wire; surgical implants

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize composition and properties to ensure consistency in the starting material used directly, or as modified by forging, in the manufacturing of medical devices.

X1.2 This low carbon alloy is selected to provide an extra measure of assurance that the material will be free from susceptibility to intergranular corrosion.

X1.3 There is a general consensus that a homogeneous metallurgical structure will be superior with respect to corrosion and fatigue resistance. Based upon this, metallurgical requirements include fine-grained austenitic structure free of ferrite, with low micro-inclusion content, and capability of passing an intergranular corrosion susceptibility test.

X1.4 Acceptable metal conditions include hot-worked, annealed, and all cold-worked conditions, the choice dependent upon the implant design and application.

NOTE X1.1—Exposure to temperatures above 800°F (425°C) during fabrication may impair corrosion resistance unless such exposure is followed by a solution annealing treatment.

X1.5 Upper composition limits for nickel and lower composition limits for molybdenum have been changed in order to meet the latest requirements specified in ISO 5832–1, Composition D.

X1.6 A maximum nitrogen limit was previously added in accordance with the specified element requirements of similar austenitic stainless steels standardized by ASTM.

X1.7 The maximum copper value is considered a practical limit based on a statistical evaluation of commercially available material. Published information has shown no adverse effect for compositions containing up to 1.0 % copper content.

X1.8 The nickel range had previously been increased to ensure that compositions melted to the upper end of the molybdenum range would be free of delta ferrite.

X1.9 The title has been changed; the high carbon composition previously identified as Grade 1 has been deleted, product analysis tolerance limits have been included, UNS designation has been added, annealed fine wire was removed

from Table 2, cold-drawn fine wire requirements were revised in Table 2, and Test Methods E 8/E 8M was added.

X1.10 The mechanical requirements and size ranges have been changed, the pitting resistance equivalent (PRE) and extra hard condition have been added, ISO tension test gage length requirements may be used when agreed to between supplier and purchaser, and X2.2 biocompatibility information has been added to coincide with ISO requirements.

X1.11 The pitting resistance equivalent (PRE) has been reidentified as a compositional requirement, free ferrite has been changed to delta ferrite, and grain size determination for cold-worked samples was changed to meet Test Methods E 112 or as agreed to between supplier and purchaser.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of local biological response established by this material, it has been used as a control material in Practice F 981.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.