Designation: F 138 – 08

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 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 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 inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1 *ASTM Standards:* [2]

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

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

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

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

E 8 Test Methods for Tension Testing of Metallic Materials

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

E 10 Test Method for Brinell Hardness of Metallic Materials

E 18 Test Methods for Rockwell Hardness of Metallic Materials

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E 45 Test Methods for Determining the Inclusion Content of Steel

E 112 Test Methods for Determining Average Grain Size

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

E 407 Practice for Microetching Metals and Alloys

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

F 1350 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)

2.2 *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

2.3 *ASQ Standard:*[5]

ASQ C1 Specification of General Requirements for a Quality Program

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.

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

[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] Withdrawn.

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

[5] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

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4. General Requirements for Delivery

4.1 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.

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

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:

$$\%\ \mathrm{Cr} + 3.3 \times \%\ \mathrm{Mo} \geq 26.0 \qquad (1)$$

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 A 751.

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 E 354.

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 E 407.

8.2 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

9. Mechanical Properties

9.1 *Tensile Properties*:

9.1.1 Tensile properties shall be determined in accordance with Test Methods E 8 or E 8M.

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.

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 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] The gage length must be reported with the test results. 4*D* = 4 × diameter; 4*W* = 4 × width. Alternatively, a gage length corresponding to Test Methods E 8M 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.

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 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[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:
$$\% Cr + 3.3 \times \% Mo \geq 26.0.$$
[B] The percentage of iron content by difference is not required to be determined or certified.

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

[A] Refer to Specification A 555/A 555M.
[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.

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 E 10 or Test Methods E 18.

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 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 Test Methods E 8 and section 7.11.4 of Test Methods E 8M. 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.

10. Special Tests

10.1 Bar, forging bar, wire, and fine wire conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A 262.

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

10.2 Bar, forging bar, wire, and fine wire conforming to this specification shall have a grain size of ASTM No. 5 or finer when measured in accordance with Test Methods E 112.

10.2.1 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.

10.2.2 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 supplier and purchaser.

10.3 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 purchaser and supplier.

10.4 Any other special requirements shall be specified by the purchaser.

11. Significance of Numerical Limits

11.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E 29.

12. Certification

12.1 The supplier shall provide a certification that the material meets the requirements of this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

13. Quality Program Requirements

13.1 The supplier shall maintain a quality program, such as defined in ASQ C1, ISO 9001, or similar.

14. Keywords

14.1 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 ISO standards are listed for reference only. Although ISO standards listed in Section 2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

X1.10 Molybdenum-enriched chi and sigma intermetallic compounds must not be present in the microstructure because of reduced austenitic corrosion resistance and possible embrittlement effects.

X1.11 Delta ferrite is a magnetic phase that must be absent in order to provide a completely nonmagnetic microstructure that will not cause torque, displacement, or heating in a Magnetic Resonance Imaging (MRI) environment.

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.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 138 – 03) that may impact the use of this standard. (Approved May 1, 2008.)

(*1*) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards within F04.12.
(*2*) Additional fine wire finishes were added in 6.2.2.
(*3*) Test Method E 354 added for chemical analysis in 7.2.3.
(*4*) Hardness section added in 9.2.
(*5*) Testing per Test Methods E 10 and E 18 added in 9.2.1.
(*6*) Number of Tests section added in 9.3.
(*7*) Significance of Numerical Limits section and Test Method E 29 added in new Section 11.
(*8*) ISO 9001 added to 13.1.

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