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INTERNATIONAL

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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*

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

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

<u>1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought 18chromium-14nickel-</u> 2.5molybdenum stainless steel bar and wire used for the manufacture of surgical implants.

<u>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.</u>

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

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 14-416b-9920-519b8a0684ae/astm-f138-08

E 112Test Methods for Determining Average Grain Size³ <u>Test Methods for Determining Average Grain Size</u>

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 in<u>on</u> Muscle and Bone

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

2.2 ISO Standards:

ISO 5832-1 Implants for Surgery—Metallic Materials—Part 1:Wrought Stainless Steel ISO 6892Metallic Materials—Tensile Testing⁵.³ ISO 5832–1 Implants for Surgery—Metallic Materials—Part 1:Wrought Stainless Steel

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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 , Vol 01:03; volume information, refer to the standard's Document Summary page on the ASTM website.

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

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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 entrol approved may 1, 2006, rubinited May 2006, Originally approved in 1971. Last previous entrol approved in 2005 as F 156 - 05. ² For referenced ASTM standard, visit the ASTM website www.astm.org.or contact ASTM Customer Service as service assumed as F 156 - 05.

³ Annual Book of ASTM Standards, Vol 03.01.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

ISO 6892 Metallic Materials—Tensile Testing

ISO 9001 Quality Management Systems-Requirements

2.3 ASQ Standard:⁴

ASQ C1 Specification of General Requirements for a Quality Program

3. General Requirements for Delivery

3.1In addition to the requirements of this specification, all requirements of the current editions of Specifications A484Terminology

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.

<u>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</u> 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.

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.

3.2In4.2 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

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

4.1.1Quantity (weight or number of pieces),

4.1.2ASTM designation,

4.1.3Form (bar, wire, fine wire),

4.1.4Condition (see 5.1

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), ASIM FI

5.1.2 ASTM designation and date of issue, lards/sist/4308938e-0a14-416b-9920-519b8a0684ae/astm-f138-08

5.1.3 Form (bar, wire, fine wire),

5.1.4 Condition (see 6.1),

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

4<u>5</u>.1.6 Finish (see <u>5.26.2</u>),

4.1.7Applicable dimensions including size, thickness, width, and length (exact, random or multiples) or print number, and 4.1.8Special requirements.

5.Materials and Manufacture

5.1

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

<u>6.1</u> *Condition*:

5.1.1Bar<u>6.1.1</u> Bar and wire shall be furnished, as specified, in the hot- worked, annealed, cold -worked, worked, or extra hard condition (see Table 1).

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

5.2

6.2 Finish:

⁴ Annual Book of ASTM Standards, Vol 13.01.

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

🕼 F 138 – 08

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 <i>D</i> or 4 <i>W,</i> min, %	Brinell ^{<i>B</i>} Hardness, max, HB
Hot- worked ^C	all				250
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	
Cold worked	0.063 to 1.500 (1.60 to 38.1)	125 000 (860)	100 000 (690)	12	<u></u>
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. 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	-125 000 to 150 000	5
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.

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

56.2.2 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.

6.7. Chemical Composition Requirements // Standards.iten

6.1The7.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 3. 6.1.1The7.1.1 The compositional requirement shall meet the following:

(1)

67.1.2 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 ttps://standards.iteh.ai/catalog/standards/sist/4308938e-0a14-416b-9920-519b8a0684ae/astm-f138-08

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.

<u>7.2</u> *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 manufacturersupplier 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 <u>manufacturing</u> lot or to determine variations in the composition within the heat.

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 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.