Designation: F 1314 – 01

Standard Specification for Wrought Nitrogen Strengthened 22 Chromium – 13 Nickel – 5 Manganese – 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)[1]

This standard is issued under the fixed designation F 1314; 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.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought nitrogen strengthened 22 chromium – 13 nickel – 5 manganese – 2.5 molybdenum stainless steel alloy bar and wire for surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents of the inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels[2]

A 484 Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings[3]

A 555 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 Test Methods for Tension Testing of Metallic Materials[4]

E 10 Test Methods for Brinell Hardness of Metallic Materials[4]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[4]

E 45 Test Method for Determining the Inclusion Content of Steel[4]

E 112 Test Methods for Determining Average Grain Size[4]

E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[5]

F 138 Specification for Wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS 31673)[6]

F 746 Test Method for Pitting and Crevice Corrosion of Metallic Surgical Implant Materials[6]

2.2 *Aerospace Materials Specification:*

AMS 2248 Chemical Check Analysis Limits, Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys[7]

2.3 *ASQC Standard:*

ASQ C1 Specification of General Requirements for a Quality Program[8]

2.4 *ISO Standard:*

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature[9]

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 and A 555 shall apply.

3.2 In cases in which a conflict exists between this specification and the standards listed in Section 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 Quality,

4.1.2 ASTM designation and date of issue,

4.1.3 Mechanical properties (if applicable for special conditions),

4.1.4 Form (bar or wire),

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

4.1.6 Condition (see 5.1),

4.1.7 Finish (see 5.2),

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[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 01.05.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

[7] Available from the American Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096-0001.

[8] Available from the American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

[9] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

4.1.8 Special tests (if applicable), and

4.1.9 Other requirements.

5. Materials and Manufacture

5.1 *Condition*—Bar and wire shall be furnished to the implant manufacturer in the hot-worked, annealed, or cold-worked condition, as specified.

5.2 *Finish*—Types of bar and wire finishes available are cold-drawn, pickled, ground, ground and polished, or as specified by the purchaser.

6. Chemical Requirements

6.1 The supplier's heat analysis shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1.

6.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

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

6.2 *Product Analysis*—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.

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

6.2.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

7. Metallurgical Requirements

7.1 The material shall exhibit no delta ferrite when it is examined metallographically at 100× magnification.

7.2 The microcleanliness of the material, as determined by Practice E 45, Method A, except using Plate Ir, on representative billet or bar samples from the heat shall not exceed the following:

TABLE 1 Chemical Composition

Element	Composition, % (Mass/Mass)
Carbon	0.030 max
Manganese	4.00 to 6.00
Phosphorus	0.025 max
Sulfur	0.010 max
Silicon	0.75 max
Chromium	20.50 to 23.50
Nickel	11.50 to 13.50
Molybdenum	2.00 to 3.00
Nitrogen	0.20 to 0.40
Niobium	0.10 to 0.30
Vanadium	0.10 to 0.30
Copper	0.50 max
Iron	balance[A]

[A] Approximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of iron difference is not required to be reported.

TABLE 2 Product Analysis Tolerances[A,B]

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, % (Mass/Mass)[C]
Carbon	0.005
Manganese	0.05
Phosphorus	0.005
Sulfur	0.005
Silicon	0.05
Chromium	0.25
Nickel	0.15
Molybdenum	0.10
Nitrogen[D]	0.02 under min; 0.04 over max
Niobium	0.05
Vanadium	0.03
Copper	0.03

[A] See Test Methods E 354.

[B] Refer to AMS 2248 for chemical check analysis limits (except nitrogen).

[C] For elements in which only a maximum percentage is indicated, the "under minimum limit" is not applicable.

[D] The specified range for this element is not covered by AMS 2248 and permissible variation has been established through industrial practice.

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1.5	2.5	2.5	2.5
Heavy	1.5	1.5	1.5	1.5

8. Mechanical Requirements

8.1 *Tensile Properties*:

8.1.1 Tensile properties shall be determined in accordance with Test Methods E 8.

8.1.2 The mechanical properties of test specimens shall conform to the requirements specified in Table 3.

8.2 *Hardness*:

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

8.2.2 Hardness values shall be determined in accordance with Test Method E 10 or Test Methods E 18.

9. Special Tests

9.1 Material conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A 262. The test shall be performed on a sample sensitized at 1250°F for 1 h.

9.2 Material conforming to this specification shall have a homogeneous microstructure with an average grain size of ASTM No. 5 or finer when measured in accordance with Test Method 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 grain size samples are selected after a final cold working, specimens shall be tested according to Test Method E 112 or as agreed upon between supplier and purchaser.

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

10. Certification

10.1 Certification shall be provided by the supplier that the

TABLE 3 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] min, %	Brinell[B] Hardness, max, HB
Hot worked[C]	Up to 2 (50.8)[D], incl	...	...	...	325
Annealed	All	100 000 (690)	55 000 (380)	35	...
Cold worked	1/16 to 3/4 (1.59 to 19.1)[D], incl	150 000 (1035)	125 000 (862)	12	...

[A] Elongation of material 0.062 in. (1.575 mm) or greater in diameter (*D*) or thickness shall be measured using a gage length of 2 in. or 4*D* or 4*W* (*W* = width). The gage length must be reported with the test results. The method for determining elongation of material under 0.062-in. (1.57-mm) in diameter or thickness may be negotiated between supplier and purchaser. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser.

[B] 3000-kgf (29 430 N) load.

[C] Typically supplied as-hot-rolled bar for forging applications.

[D] Other sizes may be furnished by agreement between the supplier and the purchaser.

material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The bar and wire producer and any processors shall maintain a quality program, such as that which is defined in ASQ C1.

12. Keywords

12.1 manganese; metals (for surgical implants); nitrogen strengthened; stainless steel; surgical applications

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the composition and properties of wrought nitrogen strengthened 22 chromium – 13 nickel – 5 manganese – 2.5 molybdenum stainless steel alloy bar and wire for surgical implants.

X1.2 Acceptable metal conditions supplied to the implant manufacturer include hot-worked, annealed, and cold-worked conditions, the choice dependent upon the implant design and application.

X1.3 This alloy is capable of being cold worked to ultimate tensile strengths exceeding 200 000 psi (1380 MPa) for high-strength surgical implant applications.

X1.4 This alloy has been tested in accordance with Test Method F 746 and exhibits a passivation and pitting potential greater than Specification F 138 reference material.

X1.5 The low carbon composition has been selected to provide an extra measure of assurance that the material will be free from susceptibility to intergranular corrosion.

X1.6 The nitrogen used for strengthening this steel can result in the formation of carbonitrides. Carbonitrides can be revealed by etching electrolytically in a solution of potassium hydroxide (56 g of K(OH) in 100 mL of water for 3 s at 2 V). These small, dispersed second-phase particles exert a strengthening effect but do not significantly alter the corrosion properties of the alloy. They may affect the finish of electropolished surfaces.

X1.7 ISO standards are listed for reference only. Although ISO standards are similar to the corresponding ASTM standards, they are not identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between purchaser and supplier.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade.

X2.2 The material has been shown to produce an acceptable level of local biological response that is similar to F 138 reference material.[10]

X2.3 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human

[10] FDA Submission No. K830196.

body. The material referred to in this specification has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.