Designation: F1314 – 13a$^{\varepsilon 1}$

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 F1314; 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.

ε[1] NOTE—The designation was corrected editorially in December 2013.

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 either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels

A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings

A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

E8/E8M Test Methods for Tension Testing of Metallic Materials

E10 Test Method for Brinell Hardness of Metallic Materials

E18 Test Methods for Rockwell Hardness of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E45 Test Methods for Determining the Inclusion Content of Steel

E112 Test Methods for Determining Average Grain Size

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

E407 Practice for Microetching Metals and Alloys

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Materials Specification:*[3]

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

AMS 2630 Inspection, Ultrasonic Product Over 0.5 inch (12.7 mm) Thick

AMS 2632 Ultrasonic Inspection of Thin Materials

2.3 *ISO Standards:*[4]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *bar, n*—round bars and flats from 0.1875 in. [4.75 mm] to 4.00 in. [101.60 mm] in diameter or thickness (other sizes and shapes by special order).

3.1.2 *forging bar, n*—as described in 3.1.2 used for production of forgings, may be furnished in the hot rolled condition.

[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] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

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

3.1.3 *lot, n*—the total number mill products produced under the same melt heat under the same conditions at essentially the same time.

3.1.4 *wire, n*—rounds less than 0.1875 in. [4.75 mm] in diameter.

4. Ordering Information

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

4.1.1 Quantity;

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 Tolerances—unless otherwise specified by purchaser, tolerances must meet the requirements of Specification A484/A484M, A555/A555M, or both, as applicable;

4.1.7 Condition (see 5.1);

4.1.8 Finish (see 5.2);

4.1.9 Special tests (if any); and

4.1.10 Other requirements.

5. Materials and Manufacture

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

5.2 *Finish*—Bar and wire shall be furnished bright annealed, cold drawn, pickled, ground, or ground and polished, 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 with chemistry outside the requirements 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.

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. Reporting of the iron difference is not required.

6.1.2 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751.

6.2 *Product Analysis*—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.

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.

6.2.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods E354.

7. Metallurgical Requirements

7.1 The material shall contain no delta ferrite, chi, or sigma phases when it is examined metallographically at 100× magnification in accordance with Practice E407.

7.2 The microcleanliness of the material, as determined by Practice E45, Method A, except using Plate Ir, on representative billet or bar samples from the heat shall not exceed the following:

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 E8/E8M.

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

TABLE 2 Product Analysis Tolerances[A]

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

[A] Refer to AMS 2248 for chemical check analysis limits (except nitrogen).
[B] For elements in which only a maximum percentage is indicated, the "under minimum limit" is not applicable.
[C] The specified range for this element is not covered by AMS 2248 and permissible variation has been established through industrial practice.

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	0.063 to 0.750 [1.59 to 19.1][D] , incl	150 000 [1035]	125 000 [862]	12	...

[A]Elongation of material 0.063 in. [1.6 mm] or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 2 in. or 4*D* or 4*W*. The gauge length shall be reported with the test results. The method for determining elongation of material under 0.063 in. [1.6 mm] in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to ISO 6892 (5.65 times the square root of So, where So is the original cross sectional area) may be used when agreed upon between the 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.

8.2 *Hardness:*

8.2.1 Hardness values shall be determined in accordance with Test Method E10 or Test Methods E18.

8.2.2 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 the cross section is adequate.

8.3 *Number of Tests—Bar, Forging Bar, Shapes and Wire:*

8.3.1 Perform tension testing per Test Methods E8/E8M. Should any of the test specimens 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.

8.3.2 Tensile test results for which any specimen fractures outside the gauge length shall be considered acceptable if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.11.5 of Test Method E8/E8M. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

9. Dimensions and Permissible Variations

9.1 *Units of Measure:*

9.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

9.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

9.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

9.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of that standard provides conversion tables and Annex B provides rules for conversion and significance.

10. Special Tests

10.1 Bar and wire conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A262.

10.2 Bar and wire 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 E112.

10.2.1 If samples are selected after a final cold working, specimens shall be tested in accordance with Test Method E112 or as agreed between the supplier and purchaser.

10.3 All centerless ground or peeled and polished round bar ≥0.375 in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2630, Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2630 specifies a minimum size limit of 0.50 in. [12.7 mm]. F04.12 committee has intentionally specified the use of AMS 2630 below 0.50 in. [12.7 mm] based on the experience of users and producers on the committee. There is disagreement in the industry as to whether AMS 2632, which does apply to sizes under 0.50 in. [12.7 mm], applies to solid round bar.

10.4 Billet shall be ultrasonically inspected prior to being hot rolled if ultrasonic inspection is not performed at a final diameter as specified in 10.3. Acceptance criteria shall be agreed to between the purchaser and supplier.

10.4.1 Alternatively, the purchaser may request that billet be ultrasonically inspected prior to being hot rolled even if ultrasonic inspection is performed at a final diameter. Acceptance criteria shall be agreed to between the purchaser and supplier.

10.5 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 of Practice E29.

12. Certification

12.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

13. Quality Program Requirements

13.1 The bar and wire producer and any processors shall maintain a quality program, such as defined in ISO 9001ISO 9001, or similar.

14. Keywords

14.1 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 to ensure consistency in the starting material used, directly or as modified by forging, in the manufacturing of medical devices.

X1.2 The metallurgical requirements include fine-grained austenitic structure free of ferrite, chi, and sigma phases with low micro-inclusion content and the capability of passing an intergranular corrosion susceptibility test.

X1.3 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.

X1.4 This alloy is capable of being cold worked to ultimate tensile strengths exceeding 200 000 psi [1380 MPa] for high-strength surgical implant applications. There is an associated reduction in ductility with these higher strength levels.

X1.5 This alloy has been tested in accordance with Test Method F746 and exhibits a pitting potential greater than Specification F138 reference material.

X1.6 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.

X1.7 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.

X1.8 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 the preferred ASTM standard may be agreed upon between the purchaser and supplier.

X1.9 *Units of Measure*:

X1.9.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications shall be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

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 alloy has been shown to produce an acceptable level of local biological response that is similar to Specification F138 reference material.[5]

X2.3 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. Long-term clinical experience with the use of 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.

[5] FDA Submission No. K830196.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F138 – 07) that may impact the use of this standard. (Approved April 1, 2013.)

(1) Made editorial corrections in order to meet terminology and formatting guidelines established for implant material standards within F04.12.
(2) Replaced former units language in 1.2 with wording allowing independent SI and Inch-Pound units.
(3) Added IEEE/ASTM SI 10 to Section 2.
(4) Added AMS 2630 and AMS 2632 and appropriate footnotes to Section 2; removed ASQ C1.
(5) Added Section 9, Dimensions and Permissible Variations, to allow selection of units to be certified.
(6) Added 10.3 covering ultrasonic inspection of round bar; added Note 1 for clarification purposes; added new 10.4 on billet ultrasonic inspection; renumbered subsequent sections.
(7) Updated Section 12, Certification.
(8) Removed reference to ASQ C1 quality program in Section 13.
(9) Added X1.9 to support the use of SI units.