Designation: F 1314 – 95

Standard Specification for Wrought Nitrogen Strengthened–22 Chromium–12.5 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants[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 requirements for wrought nitrogen strengthened–22 chromium–12.5 nickel–5 manganese–2.5 molybdenum stainless steel bar and wire (except suture 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 values 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 and Heat-Resisting Bars, Billets, and Forgings[3]

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

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

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

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

F 746 Test Method for Pitting and Crevice Corrosion of Metallic Surgical Implant Materials[5]

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

2.2 *American Society for Quality Control (ASQC) Standard:*

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

3. Ordering Information

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

3.1.1 Quality (weight or number of pieces),

3.1.2 ASTM designation,

3.1.3 Form (bar or wire),

3.1.4 Condition (see 4.1),

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

3.1.6 Finish (see 4.2),

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

3.1.8 Special requirements.

4. Materials and Manufacture

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

4.2 *Finish*—Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

5. Chemical Composition

5.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 1.

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

5.3 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. Metallurgical Requirements

6.1 The material shall exhibit no free ferrite phase when it is examined metallographically at 100× magnification.

6.2 The microcleanliness of the steel, as determined by Practice E 45, Method A, except using Plate III and Plate I, on representative billet or bar samples from the heat shall not exceed the following:

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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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 13.01.

[6] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition, %
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[A]	balance

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

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

NOTE 1—General practice is to use electroslag remelted steel to comply with these cleanliness requirements and to give other additional benefits.

7. Mechanical Requirements

7.1 Material shall conform to the appropriate requirements as to mechanical properties specified in Table 2. The level of mechanical properties for material in other than the annealed condition shall be specified in the implant manufacturer's purchase order.

7.2 Brinell hardness number (HB) is the preferred method of reporting the hardness of hot-worked material. Hardness determinations shall be made on a product cross section midway between the center and the surface, if the cross section size is adequate.

7.3 When desired, 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.

8. Special Tests

8.1 The steel shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practices A 262, Practice E. The test shall be performed on a sample sensitized at 1250°F for 1 h.

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

8.2.1 If grain size samples are selected after a final cold-working operation, transverse specimens shall be prepared.

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

9. General Requirements for Delivery

9.1 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.

9.2 In cases where a conflict exists between this specification and the standards listed in 2.1 and 2.2, this specification shall take precedence.

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 ASQC C1.

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

12. Keywords

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

TABLE 2 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*, min, %	Brinell[B] Hardness, max, HB
Hot-worked[C]	Up to 2 (50.8), 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] 4D = 4 × diameter.
[B] 3000-kgf (20 400-N) load.
[C] Typically supplied as hot-rolled bar for forging applications.
[D] Other sizes may be furnished by agreement between the producer and the purchaser.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary purpose of this specification is to characterize composition and properties of a nitrogen strengthened austenitic stainless steel 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, with low micro-inclusion content and capability of passing an intergranular corrosion susceptibility test.

X1.3 Acceptable metal conditions supplied to the implant manufacturer include hot-worked, annealed, and all cold-worked conditions, the choice dependent upon the implant design and application.

X1.4 The material has been shown to produce an acceptable level of local biological response that is similar to F138, Grade 2 reference material.[7] 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.

X1.5 This alloy is capable of being cold worked to ultimate tensile strengths exceeding 200 000 psi (1380 Mpa) for high-strength surgical implant applications.

X1.6 This alloy has been tested in accordance with Test Method F 746 and exhibits a pitting potential greater than F138, Grade 2 reference material.

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 effect the finish of electropolished surfaces.

[7] FDA Submission No. K830196.