Designation: F 1314 – ~~95~~01

Standard Specification for Wrought Nitrogen Strengthened– 22 Chromium – ~~12.5~~3 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 – 1~~2.5~~3 nickel – 5 manganese – 2.5 molybdenum stainless steel alloy 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.~~ SI equivalents of the inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

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

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A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels[2]
A 484/A 484M Specification 484 Specification for General Requirements for Stainless and Heat-Resisting Steel Bars, Billets, and Forgings[3]
A 555/A 555M Specification 555 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 8 Test Methods for Determining the Inclusion Content Tension Testing of Steel Metallic Materials[4]
E 1120 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]
FE 73546 Test Methods for Pitting and Crevice Corrosion Chemical Analysis of Metallic Surgical Implant Materials High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[5]
F 981 Practice 138 Specification for Assessment of Compatibility of Biomaterials (Nonporous) Wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire 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 (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. Ordering Information

3.1 Inquiries and ordersGeneral Requirements for material under Delivery
3.1 In addition to the requirements of this specification shall include specification, all requirements of the following information:
3.1.1 Quality (weight or number current editions 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, Specifications A 484 and length (exact, random or multiples) or print number, and
3.1.8 Special requirements. 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,

[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. 03.05.
[6] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.
[6] *Annual Book of ASTM Standards*, Vol 13.01.
[7] FDA Submission No. K830196.
[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.

4.1.6 Condition (see 5.1),
4.1.7 Finish (see 5.2),
4.1.8 Special tests (if applicable), and
4.1.9 Other requirements.

5. Materials and Manufacture

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

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

5. purchaser.

6. Chemical Composition

5.1 The 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 1 2.

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.

TABLE 2 1 MecChanemical Require Comentpos, Wire ationd Bar

CoElemendition	DiaCometerpor Thsiektioness, % in.(mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (/MPa)[#]
Hot-worked[C]	Up to 2 (50.8), incl	030 max	
Carbon	0.8), incl	030 max	
...	...	00	
Manganese	4.00 to 6.-	00	
...	325		
Phosphorus	0.025 max		
Annealed	ax		
Sulfur	0.010 max		
Sill	100 000 (690) .75 max		
Silicon	0.75 max		
Chromium	55 000 (380)		
Chromium	20.50 to 23.50		
	350		
Nickel	11.50 to 13.50		
Molybdenum			
Molybdenum	2.00 to 3.00		
Cold-worked	to ¾ (1.59 to 19.1)[D],40		
Nitrogen	0.20 to 0.40		
Ninel	150 000 (1035)0		
Niobium	0.10 to 0.30		
Vanadium	125 0 00 (862)		
Vanadium	0.10 to 0.30		
	120.50 max		
Copper	0.50 max		
Iron	[A] 4D = 4 × diameter.		
	[B] 3000-kgf (20 400-N) load.		
Iron	balance[A]		

[C][A] TyApproxiematelly suppli edquas hol t-roll the d-barforfoergiengce of 100 % and the sum ppliercentage of tihe ons.

[D] Other sizpes may becifurnished by agr element bs. Thetw percenthage p of iron dueiffer-aendce is noth re-pquirehased to be reported.

TABLE 1 2 Chemical RequiPremenoducts, Heat Analysis Tolerances[A,B]

Element	CoPermpoissible Variation Under the Minimum Limit or Over the Maximum Limit, % (Mass/Mass)[C]
Carbon	0.030 max
Carbon	0.005
Manganese	4.00 to6.00
Manganese	0.05
Phosphorus	0.025 max
Phosphorus	0.005
Sulfur	0.010 max
Sulfur	0.005
Silicon	0.75 max
Silicon	0.05
Chromium	20.50to23.50
Chromium	0.25
Nickel	11.50 to13.50
Nickel	0.15
Molybdenum	2.00 to3.00
Molybdenum	0.10
Nitrogen	0.20 to 0.40
Nitrogen[D]	0.02 under min; 0.04 over max
Niobium	0.10 to0.30
Niobium	0.05
Vanadium	0.10 to0.30
Vanadium	0.03
Copper	0.50 max
Copper	0.0 max
Iron3	

[A] See Test Methods E 354.

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

[C] AppFoximatr elyequalmento ts in whe diffch only a maximum perence bentwagee is in 100 %dicanted, the s "um pnderee minimum limit" is noth applicable ot.

[D] Ther specified eleme range for ts. This e-plerement ires n-eont coventred by AMS 2248 and permiffssible variation has beene establis nohed threough irendusto bereial poracticed.

6.

7. Metallurgical Requirements

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

67.2 The microcleanliness of the steel, material, as determined by Practice E 45, Method A, except using Plate III and Plate I, 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)
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. SpMechanical T Resquirements

8.1 *Thensile Properties*:

8.1.1 Tensile properties shall be ~~capable of passing the intergranular corrosion susceptibility test~~ determined in accordance with ~~Practices A 262, Practice E. The~~ 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 spercifoied by the purchaser. Hardness determinations shall be made on a ~~sample sensitized at 1250°F for 1 h.~~

~~8.2 The grain size~~ product cross section, midway between the center and surface, if cross section is adequate.

8.2.2 Hardness values shall be ~~five or finer when tested~~ determined in accordance with Test Method E 10 or 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.~~ E 18.

9. ~~General Requirements for Delivery~~

~~9.1 In addition~~Special Tests

9.1 Material conforming to ~~the requirements of~~ this ~~specification, all requirements~~ specification shall be capable of passing the ~~current editions~~ intergranular corrosion susceptibility test in accordance with Practice E of ~~Specifications A 484/A 484M and A 555/A 555M~~ Practices A 262. The test shall ~~apply.~~

~~9.2 In cases where~~ be performed on a ~~conflict exists between~~ sample sensitized at 1250°F for 1 h.

9.2 Material conforming to this specification ~~and the standards listed~~ 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 ~~2.2, this specification~~ purchaser.

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

10. Certification

~~10.1 The manufacturer's certification~~

10.1 Certification shall be provided by the supplier that the material ~~was manufactured and tested in accordance with~~ meets the requirements of this ~~specification together with a~~ 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~~C~~ 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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

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.

X1.1 The ~~primary~~ purpose of this specification is to characterize the composition and properties of ~~a~~ wrought nitrogen strengthened ~~austenitic~~ 22 chromium – 13 nickel – 5 manganese – 2.5 molybdenum 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~~ alloy bar and ~~capability of passing an intergranular corrosion susceptibility test.~~

~~X1.3~~ wire for surgical implants.

X1.2 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~~

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

X1.6~~4~~ This alloy has been tested in accordance with Test Method F 746 and exhibits a passivation and pitting potential greater than ~~F138, Grade 2~~ Specification F 138 reference material.

X1.7~~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 ~~e~~ 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 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.

[10] FDA Submission No. K830196.