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Standard Specification for Wrought Nitrogen Strengthened- 21 Chromium—10 Nickel— 3 Manganese—2.5 Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)¹

This standard is issued under the fixed designation F 1586; 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- 21 chromium—10 nickel—3 manganese—2.5 molybdenum stainless steel alloy bar for ~~the manufacture of~~ 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 ~~in parentheses are for information only. may be approximate.~~

2. Referenced Documents

2.1 *ASTM Standards:*

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels²

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

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- ~~A 484/A 484M~~ Specification for General Requirements for Stainless and Heat-Resisting Steel Bars, Billets, and Forgings³
 - ~~A 751~~ Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products²
 - ~~E 108~~ Test Methods for ~~Brinell Hardness~~ Tension Testing of Metallic Materials⁴
 - ~~E 180~~ Tests Method for ~~Rockwell Hardness and Rockwell Superficial~~ Brinell Hardness of Metallic Materials⁴
 - ~~E 45~~ Practice 18 Test Methods for ~~Determining the Inclusion Content~~ Rockwell Hardness and Rockwell Superficial Hardness of Steel Metallic Materials⁴
 - ~~E 45~~ Test Method for Determining the Inclusion Content of Steel⁴
 - ~~E 112~~ Test Methods for Determining Average Grain Size⁴
 - ~~FE 73546~~ Test Methods for ~~Pitting or Crevice Corrosion~~ Chemical Analysis of ~~Metallic Surgical Implant Materials~~ High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys⁵
 - ~~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 (UNS 31673)⁶
 - ~~F 746~~ Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials in Muscle and Bone^{5,6}
- 2.2 ~~ASQC Standard:~~
- ~~E1~~ Specification of General Requirements for a Quality Program⁶ Aerospace Material Specifications:

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 W. Wisconsin Ave., Milwaukee, WI 53203.

⁶ Annual Book of ASTM Standards, Vol 13.01.

AMS 2248 Chemical Check Analysis Limits, Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys⁷

2.3 ASQC Standard:

ASQ C1 Specification of General Requirements for a Quality Program⁸

2.4 ISO Standard:

ISO-5832-9/1992: ~~Wrought High Nitrogen Stainless Steel~~⁷ 6892 Metallic Materials Tensile Testing at Ambient Temperature¹⁰

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/A 484M~~ Specification A 484 shall apply.

3.2 In cases ~~where in which~~ a conflict exists between this specification and the standards listed in ~~2.1 and 2.2~~, 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 Quantity (weight or number of pieces);~~

4.1.1 Quantity,

~~4.1.2 ASTM designation;~~

~~4.1.3 Form;~~

~~4.1.4 Condition (see 5.1);~~

~~4.1.5 Mechanical designation and date of issue;~~

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

~~4.1.6 Finish (see 5.2);~~

~~4.1.7 Applicable~~

4.1.4 Form,

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

a

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

5.1 Condition—~~Bars shall be furnished to the implant manufacturer, as specified,~~ in the annealed, medium hard, or hard condition, as specified.

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

6. Chemical Composition Requirements

6.1 The supplier's heat analysis shall conform to the requirements as to chemical composition specified 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 free delta ferrite ~~phase~~ when it is examined metallographically at 100× magnification.

⁷ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036; Society of Automotive Engineers, Inc., 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁸ Supporting data available

¹⁰ Available from ASTM Headquarters. Request RR-F04-1007; American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition, % (Mass/Mass)
Carbon	0.08 max
Manganese	2.00 to 4.25
Phosphorus	0.025 max
Sulfur	0.01 max
Silicon	0.75 max
Chromium	19.5 to 22.0
Nickel	9.0 to 11.0
Molybdenum	2.0 to 3.0
Nitrogen	0.25 to 0.5
Nitrogen	0.25 to 0.50
Niobium	0.25 to 0.8
Niobium	0.25 to 0.80
Copper	0.25 max
Iron	balance ^A

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

TABLE 2 Mechanical Requirements of Balances^{A,B}

Element	Permissible Variation Under Limit For Over thickness, Maximum	Ultimate Tensile Strength, min, psi % (MPa)
— Annealed ^B	all	0.01
— Annealed ^B	Carbon	
107 000 (740)	0.05	
Manganese	0.05	
62 400 (430)	0.005	
Phosphorus	0.005	
— Medium hard		
Sulfur	0.005	
1/16 to (1.59 to 19.1) ^C		
Silicon	0.05	
145 000 (1000)	0.25	
Chromium	0.25	
102 000 (700)	0.15	
Nickel	0.15	
— Hard		
Molybdenum	0.10	
1/16 to (1.59 to 19.1) ^C		
Nitrogen ^D	0.02 under minimum; 0.04 over maximum	
160 000 (1100)	0.05	
Niobium	0.05	
145 000 (1000)	0.03	
Copper	0.03	

^A $4D = 4 \times \text{diam}$ See Test Methods E 354.
^B Refer to AMS 2248 for chemical check analysis limits (except nitrogen-ISO 5832-9gen).
^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.

7.2 The microcleanliness of the steel material, as determined by Test Method A in Practice E 45, Method A, except using Plate H 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)
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¹⁰ Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

				<u>oxide)</u> <u>Oxide)</u>
Thin	1.5	2.0	2.0	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.

8. Mechanical Requirements

8.1 Material

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

8.2 When 3.

8.2 Hardness:

8.2.1 When desired, hardness limits may be specified by the purchaser. Hardness determination on cold-worked material determinations shall be made in accordance with Test Method E 10 or Test Method E 18 on a product cross section, midway between the center and surface, if cross section size 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 The steel

9.1 Material conforming to this specification shall be capable for 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 shall be five of ASTM No. 5 or finer when tested measured in accordance with Test Methods 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 before the final cold-working operation.

9.2.2 If grain size samples are selected after a final cold-working operation, transverse cold working, specimens shall be p tested according to Test Methods E 112 or as agreed upon between supplier and purchaser.

9.3 Any other special requirements shall be specified on by the purchase order. 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 ASQC C1.

11.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1, or other recognized program.

TABLE 3 Mechanical Requirements of Bars

Condition	Diameter or Thickness, in. (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elonga- tion ^A in 4D, min, %
Annealed	all	107 000 (740)	62 400 (430)	35
Medium hard ^B	1/16 to 3/4 (1.59 to 19.1) ^C	145 000 (1000)	102 000 (700)	20
Hard ^B	1/16 to 3/4 (1.59 to 19.1) ^C	160 000 (1100)	145 000 (1000)	10

^AElongation 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. (1.575 mm) in diameter or width may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser.

^BThe word "hard" is used to express strength relative to annealed material and is not intended to specify a hardness value.

^COther sizes may be furnished by agreement between the supplier and the purchaser.

12. Keywords

12.1 manganese; metals (for surgical implants); nitrogen strengthened; stainless steel; surgical applications; 734 alloy

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE ⁸

~~X1.1 The primary purpose of this specification is to characterize the composition and properties of a wrought nitrogen strengthened a 21 chromium—10 nickel—3 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.~~ alloy bar for surgical implants.

~~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, medium hard, and all cold-worked hard 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 F 138, Grade 2 reference material.~~

~~X1.5~~

~~X1.3 This alloy has been tested in accordance with Test Method F 746 and exhibits a pitting potential greater than F 138, Grade 2 reference material.~~

~~X1.6 is capable of being cold worked to tensile strengths exceeding 200 000 psi (1380 MPa) for high strength surgical implant applications.~~

X1.4 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.

X1.5 ISO standards are listed for reference only. Although ISO standards are similar to the corresponding ASTM International standards, they are not identical. Use of an ISO standard in addition to or instead of a preferred ASTM International standard may be negotiated between purchaser and supplier.

X2. BIOCOMPATIBILITY¹⁰

X2.1 The alloy composition covered by this specification has been used 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 Specification F 138 reference material.

X2.3 This alloy has been tested in accordance with Test Method F 746 and exhibits a pitting potential greater than Specification F 138 reference material.

X2.4 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.

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