



Designation: F 1586 – 95

Standard Specification for Wrought Nitrogen Strengthened-21 Chromium—10 Nickel— 3 Manganese—2.5 Molybdenum Stainless Steel Bar for Surgical Implants¹

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1. Scope

1.1 This specification covers the requirements for wrought nitrogen strengthened-21 chromium—10 nickel—3 manganese—2.5 molybdenum stainless steel 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 units 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 Steels²

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 10 Test for Brinell Hardness of Metallic Materials⁴

E 18 Tests for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials⁴

E 45 Practice for Determining the Inclusion Content of Steel⁴

E 112 Test Methods for Determining Average Grain Size⁴

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials⁵

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone⁵

2.2 ASQC Standard:

C1 Specification of General Requirements for a Quality Program⁶

2.3 ISO Standard:

ISO 5832-9/1992: Wrought High Nitrogen Stainless Steel⁷

3. General Requirement for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484/A 484M shall apply.

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

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),

4.1.2 ASTM designation,

4.1.3 Form,

4.1.4 Condition (see 5.1),

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

4.1.6 Finish (see 5.2),

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

4.1.8 Special 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.

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

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements as to chemical composition 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.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices is under 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 W. Wisconsin Ave., Milwaukee, WI 53203.

⁷ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition, %
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
Niobium	0.25 to 0.8
Copper	0.25 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.

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

7. Metallurgical Requirements

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

7.2 The microcleanliness of the steel, as determined by Method A in Practice E 45, except using Plate III and Plate I, 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	2.0	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 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 desired, hardness limits may be specified. Hardness determination on cold-worked material 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.

TABLE 2 Mechanical Requirements of Bars

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

^A 4D = 4 × diameter.

^B Corresponds to ISO 5832-9.

^C Other sizes may be furnished by agreement between the producer and the purchaser.

9. Special Tests

9.1 The steel shall be capable for 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 The grain size shall be five or finer when tested in accordance with Test Methods E 112.

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

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

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 C1, or other recognized program.

12. Keywords

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