



Designation: F1586/F1586M – 13

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

This standard is issued under the fixed designation F1586/F1586M; 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 21chromium—10nickel—3manganese—2.5molybdenum stainless steel alloy bar for surgical implants.

1.2 The values stated in either inch-pound units or SI 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
- A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products
- E8 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
- 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

2.2 Aerospace Material Specifications:³

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

2.3 ISO Standard:⁴

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management System—Requirements

2.4 Quality Standard:

SI 10™ American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.5 Quality Standard:⁵

ASQ C1 Specification of General Requirements for a Quality Program

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

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

4. General Requirements for Delivery

4.1 In addition to the requirements of this specification, all requirements of the current edition of Specification A484/A484M shall apply.

4.2 In cases in which a conflict exists between this specification and the standards listed in Section 2, this specification shall take precedence.

5. Ordering Information

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

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>.

⁵ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices under 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.

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

- 5.1.1 Quantity,
- 5.1.2 ASTM designation and date of issue,
- 5.1.3 Mechanical properties (if applicable, for special conditions),
- 5.1.4 Form,
- 5.1.5 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing number,
- 5.1.6 *Tolerances*—Unless otherwise specified by purchaser, tolerances must meet the requirements of Specification **A484/A484M** as applicable.
- 5.1.7 Condition (see **6.1**),
- 5.1.8 Finish (see **6.2**),
- 5.1.9 Special tests (if any), and
- 5.1.10 Other requirements.

6. Materials and Manufacture

6.1 *Condition*—Bars shall be furnished in the annealed, medium hard, or hard condition, as specified.

6.2 *Finish*—Types of bar finishes available are cold-drawn, pickled, ground, ground and polished, or as specified by the purchaser.

7. Chemical Requirements

7.1 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**.

7.1.1 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.

7.1.2 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology **A751**.

7.2 *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.

7.2.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.

TABLE 1 Chemical Requirements

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 0.50
Niobium	0.25 to 0.80
Copper	0.25 max
Iron	balance ^A

^A The percentage of iron is determined by difference and need not be determined or certified.

7.2.2 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**.

8. Metallurgical Requirements

8.1 The material shall exhibit no delta ferrite, chi, or sigma phases when it is examined metallographically at 100× magnification.

8.2 The microcleanliness of the steel, as determined by Test Methods **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	2.0	2.0	2.5
Heavy	1.5	1.5	1.5	1.5

9. Mechanical Requirements

9.1 Tensile Properties:

9.1.1 Tensile properties shall be determined in accordance with Test Methods **E8**.

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

9.2 Hardness:

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

9.2.2 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.

9.3 Number of Tests:

9.3.1 Perform at least one tension and one bend tests from each lot. Should any of these test pieces 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.

TABLE 2 Product Analysis Tolerances^A

Element	Tolerance Under the Minimum or Over the Maximum Limit ^B
Carbon	0.01
Manganese	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 minimum; 0.04 over maximum
Niobium	0.05
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.