Designation: F1586 – 13ε1

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; 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.

ε[1] NOTE—The designation was editorially corrected in August 2013.

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.

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

[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.

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

5. Ordering Information

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

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.

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.

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

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

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.

TABLE 3 Mechanical Properties

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	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

[A] Elongation of material 0.063 in. (1.6 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 0.063 in. (1.6 mm) in diameter or width may be negotiated. Alternatively, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.)
[B] The word "hard" is used to express strength relative to annealed material and is not intended to specify a hardness value.
[C] Other sizes may be furnished by agreement between the supplier and the purchaser.

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.

9.3.2 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable if both the elongation and reduction of area meet the minimum requirements specified. Refer to sections 7.11.4 and 7.11.5 of Test Method E8. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

10. Dimensions and Permissable Variations

10.1 *Units of Measure:*

10.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

(1) If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

(2) In the absence of historic precedence, if the units used to define the product on the purchaser's PO, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

(3) If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

10.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. ASTM SI 10™ provides guidelines for the use of SI units. Annex A of that standard provides conversion tables and Annex B provides rules for conversion and significance.

11. Special Tests

11.1 Material conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A262.

11.2 Material conforming to this specification shall have a homogeneous microstructure with an average grain size of ASTM No. 5 or finer when measured in accordance with Test Methods E112.

11.2.1 If grain size samples are selected after final cold working operation, specimens shall be tested according to Test Methods E112 or as agreed upon between supplier and purchaser.

11.3 Any other special requirements shall be specified by the purchaser.

12. Significance of Numerical Limits

12.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

13. Certification

13.1 The supplier shall provide a certification that the material was tested in accordance with this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program such as defined in ASQ C1, ISO 9001, or similar.

14.2 The supplier shall maintain a quality program such as defined in ISO 9001, or similar quality program.

15. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the composition and properties of wrought nitrogen strengthened 21chromium—10nickel—3manganese—2.5molybdenum stainless steel alloy bar for surgical implants.

X1.2 Acceptable metal conditions supplied to the implant manufacturer include annealed, medium hard, and hard conditions, the choice dependent upon the implant design and application.

X1.3 This alloy 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.

X1.6 Units of Measure: ASTM Policy – ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through the purchase documentation. In the second phase of this transition, the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning SI values.

X2. BIOCOMPATIBILITY[6]

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 F138 reference material.

X2.3 This alloy has been tested in accordance with Test Method F746 and exhibits a pitting potential greater than Specification F138 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.

[6] Supporting data available from ASTM Headquarters. Request RR:F04-1007.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1586 – 08) that may impact the use of this standard. (Approved June 1, 2013.)

(1) The standard sections have been re-ordered and renumbered as needed to align this specification with similar ASTM F04 stainless steel alloy standards.
(2) A tolerances section has been added under ordering information.
(3) Standard language has been added to address both SI and English units of measure.