



Designation: **F2581—07 F2581 – 12**

Standard Specification for Wrought Nitrogen Strengthened 11Manganese-17Chromium- 3Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29225)¹

This standard is issued under the fixed designation F2581; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

1. Scope-~~Scope~~*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought nitrogen strengthened 11manganese-17chromium-3molybdenum low-nickel stainless steel alloy bar and wire for surgical implants.

~~1.2 As of the time of the original approval of this specification no product utilizing this alloy had been approved through a 510(k) submission.~~

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as the standard. The values given in parentheses are for information only. 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.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

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](#)

[A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods](#)

[A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products](#)

[E8E8/E8M 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](#)

[E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys](#)

[E407 Practice for Microetching Metals and Alloys](#)

[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](#)

[F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices](#)

[F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium – 13 Nickel – 5 Manganese – 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants \(UNS S20910\)](#)

[F1586 Specification for Wrought Nitrogen Strengthened 21Chromium—10Nickel—3Manganese—2.5Molybdenum Stainless](#)

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

Current edition approved Jan. 1, 2007/Oct. 1, 2012. Published January 2007/October 2012. Originally approved in 2007. Last previous edition approved in 2007 as F2581 – 07. DOI: 10.1520/F2581-07-10.1520/F2581-12.

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

Steel Alloy Bar for Surgical Implants (UNS S31675)

[IEEE/ASTM SI 10 American National Standard for Metric Practice](#)

2.2 *Aerospace Material Specification*.³

[AMS 2248 Chemical Check Analysis Limits, Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys](#)

[AMS 2630 Inspection, Ultrasonic Product over 0.5 Inch \(12.7 mm\) Thick](#)

2.3 *ISO Standard*.⁴

[ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature](#)

[ISO 9001 Quality Management Systems—Requirements](#)

2.4 *American Society for 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 *bar*—round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths, with a maximum cross-sectional area of 16 in.² [103 cm²].

3.1.2 *fine wire*—wire with diameter or major dimension less than 0.063 in. [1.6 mm].

3.1.3 *forging bar*—bar as described in 3.1.1 used for production of forgings, may be furnished in the hot-rolled and descaled condition.

3.1.4 *lot*—A lot is defined as the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

3.1.5 *wire*—rounds, rectangular, or other complex shaped product produced and delivered in coils.

4. Product Classification

4.1 *Bar*—Round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths, with a maximum cross-sectional area of 16 in.² (103 cm²).

4.2 *Forging bar*—Bar as described in 4.1 used for production of forgings, may be furnished in the hot-rolled and descaled condition.

4.3 *Wire*—Rounds, rectangular, or other complex shaped product produced and delivered in coils.

4.4 *Fine Wire*—Wire with diameter or major dimension less than 0.063 in. (1.6 mm).

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:^{5/astm-f2581-12}

4.1.1 ~~Quantity~~; Quantity;

4.1.2 ASTM designation and date of ~~issue~~; issue;

4.1.3 Mechanical ~~properties~~; properties;

4.1.4 ~~Form~~; Form;

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

4.1.6 *Tolerances*—~~Condition~~; Unless otherwise specified by the purchaser, tolerances must meet the requirements of Specifications [A484/A484M](#) and [A555/A555M](#), as applicable;

4.1.7 *Condition* (see [5.1](#));

4.1.8 *Finish* (see [5.2](#));

4.1.9 Special tests, if ~~any~~; any; and

4.1.10 Other requirements.

5. Materials and Manufacture

5.1 *Condition*—Bar and wire shall be furnished, as specified, in the annealed or cold-worked condition. Bar used for the production of forgings may be furnished in the hot worked and descaled condition, as agreed upon between the purchaser and supplier.

5.2 *Finish*—Types of finish available in bar and wire are cold-drawn, pickled, ground, ground and polished, shaved, or as specified by the purchaser.

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>.

6. Chemical 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 **A751**.

6.1.3 For reference purposes, Test Methods **E354** shall apply.

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~~ 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 contain no delta ferrite, chi, or sigma phases when it is examined metallographically at 100× magnification in accordance with Practice **E407**.

7.2 The microcleanliness of the steel, as determined by Test Method **E45**, Method A, on representative billet or bar samples from the heat shall not exceed the following:

Inclusion Type	A (Sulphide)	B (Alumina)	C (Silicate)	D (Globular oxide)
Thin	1.5	1.5	1.5	1.5
Heavy	1.0	1.0	1.0	1.0

8. Mechanical Properties

8.1 *Tensile Properties:*

8.1.1 Tensile properties shall be determined in accordance with Test Methods **E8/E8M**.

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

8.1.3 The level of mechanical properties for material in other conditions shall be specified in the purchase order.

8.2 *Hardness:*

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

8.2.2 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.

8.3 *Tensile Properties:—Number of Tests:*

8.3.1 Tensile properties shall be determined in accordance with Perform tension testing per Test Methods **E8E8/E8M**. Perform at least two tension test from each lot. Should any test piece Should any of the test specimens 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 1 Chemical Composition

Element	Composition, % (mass/mass)
Carbon	0.15 to 0.25
Manganese	9.50 to 12.50
Phosphorus	0.020 max
Sulfur	0.010 max
Silicon	0.2 to 0.6
Chromium	16.50 to 18.00
Nickel	0.05 max
Molybdenum	2.70 to 3.70
Nitrogen	0.45 to 0.55
Copper	0.25 max
Iron	balance ^A

^AApproximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of iron difference is not required to be reported.

TABLE 2 Product Analysis Tolerances^A

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, % (mass/mass) ^B
Carbon	0.01
Manganese ^C	0.20
Phosphorus	0.005
Sulfur	0.005
Silicon	0.05
Chromium	0.25
Nickel	0.03
Molybdenum	0.05
Nitrogen ^C	0.05
Copper	0.03

^ARefer to AMS 2248 for chemical check analysis limits (except nitrogen).

^BFor elements in which only a maximum percentage is indicated, the “under minimum limit” is not applicable.

^CThe specified range for this element is not covered by AMS 2248 and has been established through industrial practice.

8.3.2 Tensile test results for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Test Methods subsections 7.11.4 and 7.11.5 of Test Methods E8E8/E8M sections 7.11.4 and 7.11.5. 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.

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

9.3 The level of mechanical properties for material in other conditions shall be specified in the purchase order

9. Ultrasonic Inspection

9.1 All centerless ground or peeled and polished round bar 0.375 in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2630, Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2630 specifies a minimum size limit of 0.50 in. [12.7 mm]. F04.12 subcommittee has intentionally specified the use of AMS 2630 below 0.50 in. [12.7 mm] based on the experience of users and producers on the committee. There is disagreement in the industry as to whether AMS 2632, which does apply to sizes under 0.50 in. [12.7 mm], applies to solid round bar.

10. Dimensions and Permissible 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.

10.1.1.1 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.

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

TABLE 3 Mechanical Requirements

Condition	Ultimate Tensile Strength min, psi (MPa)	Yield Strength (0.2% offset), min, psi (MPa)	Elongation ^A min, %	Reduction in Area min, %
Annealed	120 000 (827)	70 000 (482)	40	50
Cold-Worked	160 000 (1103)	120 000 (827)	12	...

^ARefer to AMS 2248 for chemical check analysis limits (except nitrogen).

^BFor elements in which only a maximum percentage is indicated, the “under minimum limit” is not applicable.

^CThe specified range for this element is not covered by AMS 2248 and has been established through industrial practice.