



Designation: F2581 – 07

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

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 reapproval. A superscript epsilon ( $\epsilon$ ) 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 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.

1.3 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

1.4 *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:*<sup>2</sup>

- A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels
- A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products
- E8 Test Methods for Tension Testing 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 Steel Alloy Bar for Surgical Implants (UNS S31675)

2.2 *Aerospace Material Specification:*<sup>3</sup>

- 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:*<sup>4</sup>

- ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

2.4 *American Society for Quality Standard:*<sup>5</sup>

- 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*—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.

<sup>1</sup> 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.

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<sup>2</sup> 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.

<sup>3</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, <http://www.sae.org>.

<sup>4</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

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

## 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.<sup>2</sup> (103 cm<sup>2</sup>).

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).

## 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,
- 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 Condition,
- 5.1.7 Special tests, if any, and
- 5.1.8 Other requirements.

## 6. Materials and Manufacture

6.1 *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 purchaser and supplier.

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

## 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**.

**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 <sup>A</sup>

<sup>A</sup>Approximately 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.

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 **A751**.

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

7.2 *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.

7.2.1 Acceptance or rejection of a heat or lot of material maybe 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 contain no delta ferrite, chi, or sigma phases when it is examined metallographically at 100× magnification in accordance with Practice **E407**.

8.2 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

## 9. Mechanical Properties

### 9.1 Tensile Properties:

9.1.1 Tensile properties shall be determined in accordance with Test Methods **E8**. Perform at least two tension test from each lot. Should any test piece 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

**TABLE 2 Product Analysis Tolerances<sup>A</sup>**

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

<sup>A</sup>Refer to AMS 2248 for chemical check analysis limits (except nitrogen).

<sup>B</sup>For elements in which only a maximum percentage is indicated, the "under minimum limit" is not applicable.

<sup>C</sup>The specified range for this element is not covered by AMS 2248 and has been established through industrial practice.