

Designation: F2229 - 07

StandardSpecification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)¹

This standard is issued under the fixed designation F2229; 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 23manganese-21chromium-1molybdenum low-nickel stainless steel alloy bar and wire for surgical implants.
- 1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents of the inch-pound units may be approximate.

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

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
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:³

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

2.3 ISO Standards: 4 9 dadd5 0 d/astm- 12229-07

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 bar and flats from 0.1875 in. (4.75 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other sizes and shaped by special order).

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

Current edition approved Aug. 1, 2007. Published August 2007. Originally approved in 2002. Last previous edition approved in 2002 as F2229 - 02. DOI: 10.1520/F2229-07.

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.

- 3.1.2 *forging bar*—as described in section 3.1.1 used for the production of forgings, may be furnished in the hot rolled condition.
- 3.1.3 *lot*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.
- 3.1.4 *wire*—rounds less than 0.1875 in. (4.75 mm) in diameter.

4. Ordering Information

- 4.1 Inquiries and orders for material under this specification shall include the following information:
 - 4.1.1 Quantity,
 - 4.1.2 ASTM designation and date of issue,
 - 4.1.3 Mechanical properties,
 - 4.1.4 Form,
- 4.1.5 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing number.
- 4.1.6 *Tolerances*—Unless otherwise specified by purchaser, tolerances must meet the requirements of Specifications A484/A484M and/or 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, 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 condition, as agreed upon between purchaser and supplier.
- 5.2 Finish—Types of finish available in bar and wire are cold-drawn, pickled, ground, ground and polished, or as specified by the purchaser.

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 with a composition outside the requirements specified in Table 1.

TABLE 1 Chemical Composition

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Element	Composition, % (mass/mass)
Carbon	0.08 max
Manganese	21.00 to 24.00
Phosphorus	0.03 max
Sulfur	0.01 max
Silicon	0.75 max
Chromium	19.00 to 23.00
Nickel	0.05 max
Molybdenum	0.50 to 1.50
Nitrogen	0.85 to 1.10
Copper	0.25 max
Iron	balance ^A

^A Approximately equal to the difference of 100 % and the sum percentage of the other specified elements. Reporting the percentage of iron difference is not required.

- 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.
- 6.2 *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.
- 6.2.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.
- 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.
- 6.2.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods E354.

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 Practice E45, Method A, except using plate I-r, on representative billet or bar samples from the heat shall not exceed the following:

Inclusion	Α	В	С	D
Type	(Sulphide)	(Alumina)	(Silicate)	(Globular oxide)
Thin	1.5	2.5	2.5	2.5
Heavy	1.5	1.5	1.5	1.5

7.3 The surface of products supplied with a machined or ground surface finish shall have no free ferrite when optically examined at a magnification of 100×.

8. Mechanical Requirements

8.1 Tensile Properties:

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

^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.

 $^{^{\}it C}$ The specified range for this element is not covered by AMS 2248 and has been established through industrial practice.