



Designation: F2229 – 21

Standard Specification 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 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

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.

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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.

- A751 Test Methods and Practices for Chemical Analysis of Steel Products
- E8/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 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

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

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

AMS 2630 Inspection, Ultrasonic Product over 0.5 Inch (12.7 mm) Thick
 AMS 2632 Ultrasonic Inspection Of Thin Materials 0.5 Inch (13 mm) and Thinner

2.3 ISO Standards:⁴

ISO 6892 Metallic materials—Tensile testing—Part 1: Method of test at room temperature
 ISO 9001 Quality management systems—Requirements
 ISO 13485 Medical devices—Quality management systems—Requirements for regulatory purposes

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 bar, n—round, rectangular, or other complex-shaped product delivered straightened and cut to a defined length.

3.1.2 forging bar, n—bar (see 3.1.1) used for the production of forgings. It may be furnished in the hot-rolled condition.

3.1.3 lot, n—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, n—round, rectangular, or other complex-shaped product produced and delivered in coils, spools, or other packaging as specified.

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 the 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.

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 with a composition outside the requirements 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.

6.2 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 Test Methods E45, Method A, except using plate I-r, 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	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×.

TABLE 1 Chemical Composition

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.

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.

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

8. Mechanical Requirements

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**.

8.2 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 Number of Tests:

8.3.1 Perform tension testing per Test Methods **E8/E8M**. 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.

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 subsections 7.11.4 and 7.12.5 of Test Methods **E8/E8M**. 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. Ultrasonic Inspection

9.1 All centerless ground or peeled and polished round bar ≥ 9.5 mm [0.375 in.] 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 12.7 mm [0.50 in.]. Subcommittee F04.12 has intentionally specified the use of AMS 2630 below 12.7 mm [0.50 in.] 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 12.7 mm [0.50 in.], should apply 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.

10.1.1.3 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. **IEEE/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 Bar and wire conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices **A262**.

11.2 Bar and wire 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**.

TABLE 3 Mechanical Requirements

Condition	Ultimate Tensile Strength min, MPa [psi]	Yield Strength (0.2 % offset), min, MPa [psi]	Elongation ^A min, %	Reduction in Area min, %
Annealed	825	515	30	50
Condition A	[120 000]	[75 000]		
Cold Worked	1030	825	20	50
Condition B	[150 000]	[120 000]		
Cold Worked	1375	1240	12	40
Condition C	[200 000]	[180 000]		

^A Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of 50 mm [2 in.] or 4D or 4W. The gauge length shall be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to ISO 6892 ($5.65 \times S_o^{1/2}$, where S_o is the original cross-sectional area of the gauge length) may be used when agreed upon between the supplier and purchaser.

11.2.1 It is preferred that samples for grain size determination be selected after the hot working operation or after the final annealing operation prior to the final cold working operation.

11.2.2 If grain size samples are selected after a final cold working, the specimens shall be tested according to Test Methods **E112** or as agreed upon between the 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 bar and wire producer and any processors shall maintain a quality program such as that which is defined in ISO 9001 or a similar quality program.

15. Keywords

15.1 low-nickel; 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 low-nickel, nitrogen-strengthened 21 chromium-23 manganese-1 molybdenum bar and wire to ensure consistency in the starting material used, directly or as modified by forging, in the manufacturing of medical devices.

X1.2 ISO standards are listed for reference only. Use of an ISO standard instead of a preferred ASTM standard may be negotiated between the purchaser and the supplier.

X1.3 The metallurgical requirements include a fine-grained austenitic structure free of ferrite, chi, and sigma phases with a defined inclusion content and the capability of passing an intergranular corrosion susceptibility test. Also, delta ferrite is a magnetic phase that must be absent in order to provide a paramagnetic material that will cause minimal magnetically induced torque and displacement in or near a magnetic resonance imaging (MRI) scanner.

X1.4 This alloy can be supplied in either the annealed or cold-worked condition.

X1.5 This alloy is capable of being cold worked to ultimate tensile strengths exceeding 1380 MPa [200 000 psi] for high-strength surgical implant applications. There is an associated

reduction in ductility with these higher strength levels.

X1.6 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 KOH in 100 mL of water for 3 s at 2 V). They may affect the finish of electropolished surfaces.

X1.7 Heat treating this alloy in an oxidizing, reducing, or hydrogen atmosphere can result in the formation of a magnetic (ferritic) surface layer on the heat-treated product. This surface layer shall be removed from the finished product prior to its use as a medical or surgical device.

X1.8 This alloy has been tested in accordance with Test Method **F746** and exhibits pitting and crevice corrosion resistance greater than Specification **F138** reference material and is equivalent to Specifications **F1314** and **F1586** alloys **(1)**.⁵ Cyclic anodic polarization testing in 37 °C Ringer's solution indicated better corrosion resistance than Specification **F138** reference material **(1, 2)**. Additional information on the corrosion resistance and the physical, mechanical, and metallurgical properties of this alloy has also been published **(3-6)**.

⁵ The boldface numbers in parentheses refer to the list of references at the end of this standard.