Designation: F2229 – 12

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 The values stated in either SI units or inch-pound 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

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/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

AMS 2630 Inspection, Ultrasonic Product over 0.5 Inch (12.7 mm) Thick

2.3 *ISO Standards:*[4]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

[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.

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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.

***A Summary of Changes section appears at the end of 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).

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 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.

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.

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.

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 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

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.

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:*

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 Methods 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 7.11.5 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 ≥ 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.

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 Condition A	120 000 [827]	75 000 [517]	30	50
Cold Worked Condition B	150 000 [1034]	120 000 [827]	20	50
Cold Worked Condition C	200 000 [1379]	180 000 [1241]	12	40

[A] Elongation of material 0.063 in. [1.6 mm] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length shall be reported with the test results. The method for determining elongation of material under 0.063 in. [1.6 mm] 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 .

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.

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.

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 Method 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.

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 200 000 psi [1380 MPa] 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 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 (**10-13**).

X1.9 *Units of Measure*:

X1.9.1 *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 his purchase documentation. In the second phase of this transition, the specifications shall be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

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

X2. BIOCOMPATIBILITY

X2.1 The suitability of this material from a human implant perspective is dependent on the specific application. The biological tests appropriate for the specific site, such as recommended in Practice F748 should be used as a guideline. A summary of the testing that has been performed to-date is provided in X2.3 and the reference list.

X2.2 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. Since the time of the original approval of this specification, this stainless steel alloy has been used clinically in humans in several different medical device applications.

X2.3 An extensive series of testing has been performed to document the biocompatibility of this material **(3-9)**. In all cases, the biocompatibility test results for this material were favorable and met the requirements of the test standards used.

X2.4 Refer to 510k number K003496.

REFERENCES

(1) Brown, R. S., and Gebeau, R. C., "Strength and Corrosion Resistance of BioDur®108 Alloy," Society for Biomaterials, *Sixth World Biomaterials Congress Transactions*, Vol II (USA), May 2000, p. 828.

(2) Disegi, J. A., Zardiakas, L. D., and Mitchell, D. W., "Anodic Polarization Evaluation of Nickel-Free Implant Quality Stainless Steel," Society for Biomaterials, *Sixth World Biomaterials Congress Transactions*, Vol II (USA), May 2000, p. 816.

(3) Toxikon Corporation (15 Wiggens Avenue, Bedford, MA 01730, USA) cytotoxicity study based on the procedure described in ANSI/AAMI/ISO 10993-5: 1993; Biological Evaluation of Medical Devices—Part 5: Test for Cytotoxicity. The test article was concluded to be non-cytotoxic and meeting the requirements of the Elution Test, ISO 10993.

(4) Toxikon Corporation irritation testing based upon ISO Biological Testing of Medical Devices—Part 10: Irritation and Sensitization Tests; ISO 10993-10, 1995. Extraction procedures were based upon ISO 10993-12, 1996. The test sites did not exhibit any signs of erythema, edema or necrosis and the test article was concluded to be a negligible irritant.

(5) Toxikon Corporation acute systemic toxicity testing based on ISO Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity; ISO 10993-11, 1993. Extraction procedures were based upon ISO 10993-12, 1996. No signs of toxicity were observed and the test article was concluded to meet the requirements of ISO 10993-11, Systemic Injection Test.

(6) Toxikon Corporation pyrogenicity testing based on ISO Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity; ISO 10993-11, 1993, and upon the standards set by the current version of the United States Phamacopia. Extraction procedures were based upon ISO 10993-12, 1996. The test article was concluded to meet the requirements of ISO 10993-11 for the absence of pyrogens as specified for the Pyrogen Test.

(7) Toxikon Corporation mutagenicity testing based on ISO Biological Evaluation of Medical Devices—Part 3: Tests Genotoxicity, Carcinogenicity and Reproductive Toxicity; ISO 10993-3, 1992, and revised methods for the Salmonella Mutagenicity test, Maron, D. M., Ames, B. N., Mutation Research, 113: 173-215 (1993). Extraction procedures were based upon ISO 10993-12, 1996. The test article was concluded to be non-mutagenic based on the methods employed.

(8) Toxikon Corporation implantation with histopathology testing based on ANSI/AAMI/ISO 10993-6: 1995; Biological Testing of Medical Devices—Part 6: Tests for Local Effects After Implantation; and ASTM Standards Section 13, Vol 13.01, Medical Devices, Designation: F981-93 (1996). No signs of toxicity were exhibited after 14 and 28 day implantation test periods and the test article was concluded to be non-toxic.

(9) Toxikon Corporation hemocompatibility testing based on the following references: DHEW publication # (NIH) 77-1294, 9.213, 1977: ISO Biological Evaluation of Medical Devices—Part 4, Selection of Tests for Interactions with Blood, ISO 10993-4 (1992); Extraction Procedures were based on ISO 10993-12, 1996; Autian Method described in ATTP-I, University of Tennessee Center for the Health Sciences, Memphis TN, 18-Apr-77; Veterinary Hematology, Schalm O. W., pp 51-53, 1965, Leas & Feviger, Philadelphia. The test article was concluded to be non-hemolytic based on the methods employed.

(10) Gebeau, R. C., and Brown, R. S., "Corrosion Resistance and Strength of BioDur®108 Alloy, a Nickel-Free Austenitic Stainless Steel," pp. 157-164, *Structural Biomaterials for the 21st Century*, a publication of TMS (The Minerals, Metals & Materials Society), published 2001.

(11) Roach, M. D., Zardiackas, L. D., Brown, R. S., and Gebeau, R. C., "Physical, Metallurgical and Mechanical Comparison of a Low-Nickel Stainless Steel," *Society for Biomaterials 27th Annual Meeting Transactions (USA)*, April 24-29, 2001, p. 343 .

(12) Roach, M. D., Zardiackas, L. D., Brown, R. S., and Gebeau, R. C., "Stress Corrosion Cracking of a Low-Nickel Steel," *Society for Biomaterials 27th Annual Meeting Transactions (USA)*, April 24-29, 2001, p. 469.

(13) Gebeau, R. C., and Brown, R. S., "Biomedical Implant Alloy," *Advanced Materials & Processes (USA)*, Vol 159, No. 9, September 2001, pp. 46-48.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2229 – 07) that may impact the use of this standard. (Approved Oct. 1, 2012.)

(1) Editorial changes have been made in order to meet the terminology and formatting guidelines that have been established for implant specifications.

(2) Ultrasonic inspection language has been added.

(3) Language has been added to address the selection of units of measurement for material certification.