Designation: 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 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 11manganese-17chromium-3molybdenum 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.

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

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 Standard:*[4]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

[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 Oct. 1, 2012. Published October 2012. Originally approved in 2007. Last previous edition approved in 2007 as F2581 – 07. DOI: 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.

[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**

ISO 9001 Quality Management Systems—Requirements

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 cm^2].

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*—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. 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 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; 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.

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.

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]

[A]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.

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 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

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 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 *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.

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.

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	. . .

[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 may be used when agreed upon between supplier and purchaser ($5.65 \times S_o^{1/2}$, where S_o is the original cross sectional area of the gauge length).

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, 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 and 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 rounding method of Practice E29.

13. Certification

13.1 Certification shall be provided by the supplier that the material meets the requirements of this specification. A report of the test results shall be furnished 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 11manganese-17chromium-3molybdenum 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 delta ferrite, 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.

X1.6 Prolonged heat treating this alloy at solution-annealing temperature (typically 1050°C) may result in the formation of a ferritic surface layer. This surface layer shall be removed from the finished product prior to its use as a medical or surgical device. Formation of ferrite is caused by de-nitrogenization. This effect is typical for high-nitrogen stainless steels. Since the nitrogen content in the composition of the steel described in this standard is at medium level the tendency of de-nitrogenization is minimized. To avoid this effect during processing, heating cycles shall be kept as short as possible.

X1.7 This alloy has been tested in accordance with Test Method F746 and exhibits pitting and crevice corrosion resistance much greater than Specification F138 reference material and exceeds values of material specified in Specification F1314 and Specification F1586. Additional information on the corrosion resistance and the physical, mechanical, and metallurgical properties of this alloy has been published (**1-4**).[5]

X1.8 Molybdenum-enriched chi and sigma intermetallic compounds must not be present in the microstructure because of reduced autenitic corrosion resistance and possible embrittlement effects.

X1.9 Delta ferrite is a magnetic phase that must be absent in order to provide a completely nonmagnetic microstructure that will not cause torque, displacement, or heating in a Magnetic Resonance Imaging (MRI) environment.

X1.10 Chemical composition of this steel exposes a high level of carbon which in conventional metallurgy of chromium-nickel-stainless steels is deemed to be critical. In high-nitrogen stainless steels it replaces nitrogen since it also has a strong effect on stabilizing the austenitic phase. Replacing nitrogen by carbon has advantageous effects on corrosion resistance, widens the range of austenite stability towards lower solution annealing temperatures, and will result in better toughness properties.

X1.11 *Units of Measure*:

X1.11.1 *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 a 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. As of the time of the original approval of this standard, this stainless steel alloy had a limited history of clinical use in humans.

X2.3 Extensive series of testing has been performed to document the biocompatibility of this material (**5-10**). In all cases, the biocompatibility test results for this material were favorable and met the requirements of the test standards used.`

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SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2581 – 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) Hardness testing information has been added to the Mechanical Properties section.
(3) Ultrasonic inspection language has been added.
(4) Language has been added to address the selection of units of measure for material certification.
(5) Many of the old references were removed and replaced with newer, more accessible references.
(6) Renumbering and reordering of sections have been performed to align the format of this specification with other ASTM F04 stainless steel alloy standards.