Designation: F139 – 12

Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)[1]

This standard is issued under the fixed designation F139; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought 18chromium-14nickel-2.5molybdenum stainless steel sheet and strip used for the manufacture of 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

A480/A480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip

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

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *ISO Standards:*[3]

ISO 5832-1 Implants for Surgery-Metallic Materials—Part 1: Wrought Stainless Steel

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:*

3.1.1 *lot, n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

3.1.2 *sheet*—any product under 0.1875 in. [4.76 mm] in thickness and 24 in. [610 mm] or more in width.

3.1.3 *strip*—any product under 0.1875 in. [4.76 mm] in thickness and under 24 in. [610 mm] wide.

4. General Requirements for Delivery

4.1 In addition to the requirements of this specification, all requirements of the current edition of Specification A480/A480M shall apply.

4.2 In the case where a conflict exists between this specification and those listed in 2.1 and 2.2, this specification shall take precedence.

5. Ordering Information

5.1 Inquiries and orders for material under this specification shall include the following information:

5.1.1 Quantity (weight or number of pieces);

5.1.2 ASTM designation and date of issue;

5.1.3 Form (sheet or strip);

[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.

[3] 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**

5.1.4 Condition (see 6.1);
5.1.5 Mechanical properties (if applicable, for special conditions);
5.1.6 Finish (see 6.2);
5.1.7 Applicable dimensions including size, thickness, width, and length (exact, random, multiples) or drawing number;
5.1.8 Special tests, if any; and
5.1.9 Other requirements.

6. Materials and Manufacture

6.1 *Condition*—Sheet and strip shall be furnished as specified, in the annealed or cold-worked condition (see Table 1).

6.2 *Finish*—Types of finish available in sheet and strip are dull cold rolled, bright cold rolled, intermediate polished, general-purpose polished, dull satin-finished, high luster finish, mirror finish, or as specified by the purchaser.

7. Chemical Requirements

7.1 The supplier's heat analysis shall conform to the requirements specified in Table 2. The supplier shall not ship material with chemistry outside the requirements of Table 2.

7.1.1 The compositional requirement shall meet the following:

$$\%\ \mathrm{Cr} + 3.3 \times \%\ \mathrm{Mo} \geq 26.0 \qquad (1)$$

7.1.2 Requirements for the major and minor elemental constituents are listed in Table 2. Also listed are important residual elements. Analysis for elements not listed in Table 2 is not required to certify compliance with this specification.

7.1.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751.

7.2 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements, but cover variations between laboratories in the measurement of chemical content. The supplier shall not ship material that is outside the limits specified in Table 2. Product analysis limits shall be as specified in Table 3.

7.2.1 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 Mechanical Requirements

Condition	Ultimate Tensile Strength[A], min, psi [MPa]	Yield Strength[A] (0.2 % Offset), min, psi [MPa]	Elongation[B] in 2 in. [50 mm] min, %	Rockwell Hardness, max
Annealed	71 000 [490]	27 500 [190]	40	95 HRB
Cold-worked	125 000 [860]	100 000 [690]	10	...

[A] Minimum limits apply to tests taken longitudinal to the direction of rolling.
[B] The gage length shall be reported with the test results. The method for determining elongation of material under 0.063 in. [1.6 mm] in thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 (5.65 times the square root of So, where So is the original cross sectional area) may be used when agreed upon between the supplier and purchaser.

TABLE 2 Chemical Requirements, Heat Analysis

Element	Composition, % (mass/mass)
Carbon	0.030 max
Manganese	2.00 max
Phosphorus	0.025 max
Sulfur	0.010 max
Silicon	0.75 max
Chromium[A]	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum[A]	2.25 to 3.00
Nitrogen	0.10 max
Copper	0.50 max
Iron[B]	balance

[A] The compositional requirement shall meet the following:
$\%\ \mathrm{Cr} + 3.3 \times \%\ \mathrm{Mo} \geq 26.0$
[B] The percentage of iron content by difference is not required to be determined or certified.

TABLE 3 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit, % (mass/mass)[B]
Carbon	0.005
Manganese	0.04
Phosphorus	0.005
Sulfur	0.005
Silicon	0.05
Chromium	0.20
Nickel	0.15
Molybdenum	0.10
Nitrogen	0.01
Copper	0.03

[A] Refer to Specification A480/A480M.
[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.

7.2.2 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.

7.2.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods E354.

8. Metallurgical Requirements

8.1 The material shall exhibit no delta ferrite, chi, or sigma phases when examined metallographically at 100× magnification when etched in accordance with Practice E407.

8.2 The microcleanliness of the steel as determined by Test Methods E45, Method A, except using Plate I-r on representative hot-rolled band from the heat shall not exceed the following:

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1.5	1.5	1.5	1.5
Heavy	1.5	1.0	1.5	1.0

9. Mechanical Requirements

9.1 *Tensile Properties:*

9.1.1 Tensile properties shall be determined in accordance with Test Methods E8/E8M.

9.1.2 Material shall conform to the appropriate requirements as to mechanical properties specified in Table 1.

9.1.3 The level of mechanical properties for material in conditions other than those included in Table 1 shall be specified in the purchase order.

9.2 *Hardness:*

9.2.1 Hardness values shall be determined in accordance with Test Methods E10 or Test Methods E18.

9.2.2 When desired, hardness limits may be specified by the purchaser. Hardness determinations shall be made on the product cross section, midway between the center and surface, if the cross section is adequate.

9.2.3 Hardness values are for information only and shall not be used as a basis for rejection.

9.3 *Number of Tests:*

9.3.1 Perform at least one tension test from each lot. Should any of the test pieces 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.

9.3.2 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable, if the elongation meets the minimum requirement specified. Refer to subsection 7.11.4 of Test Methods E8/E8M. If the elongation is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

10. Dimensions and Permissable 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 (PO), 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 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 Sheet and strip conforming to this specification shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A262.

11.2 Sheet and strip 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 final annealing operation and prior to a final cold-working operation.

11.2.2 If samples are selected after a final cold-working operation, specimens shall be tested according to Test Methods E112, or as agreed to 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 and met all the requirements of 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 supplier shall maintain a quality program, such as defined in ISO 9001, or similar.

15. Keywords

15.1 metals (for surgical implants); stainless steel; surgical implants

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize composition and properties to ensure consistency in the starting material used directly, or as modified by shape forming in the manufacturing of medical devices.

X1.2 This low-carbon alloy is selected to provide an extra measure of assurance that the material will be free from susceptibility to intergranular corrosion.

X1.3 There is a general consensus that a homogeneous metallurgical structure will be superior with respect to corrosion and fatigue resistance. Based upon this, metallurgical requirements include fine-grained austenitic structure free of ferrite, with low micro-inclusion content and capability of passing an intergranular corrosion susceptibility test.

X1.4 Acceptable metal conditions include annealed and all cold-worked conditions, the choice dependent upon the particular implant design and application.

NOTE X1.1—Exposure to temperatures above 800°F [425°C] during fabrication may impair corrosion resistance unless such exposure is followed by a solution annealing treatment.

X1.5 Upper composition limits for nickel and lower composition limits for molybdenum have been changed in order to meet the latest requirements specified in ISO 5832-1.

X1.6 A maximum nitrogen limit was previously added in accordance with the specified element requirements of similar austenitic stainless steels standardized by ASTM.

X1.7 The maximum copper value is considered a practical limit based on a statistical evaluation of commercially available material. Published information has shown no adverse effect for compositions containing up to 1.0 % copper content.

X1.8 The nickel range had previously been increased to ensure that compositions melted to the upper end of the molybdenum range would be free of delta ferrite.

X1.9 ISO standards are listed for reference only. Although ISO standards listed in Section 2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

X1.10 Molybdenum-enriched chi and sigma intermetallic compounds must not be present in the microstructure because of reduced austenitic corrosion resistance and possible embrittlement effects.

X1.11 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.

X1.12 *Units of Measure*:

X1.12.1 *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.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F139 – 08) that may impact the use of this standard. (Approved Oct. 1, 2012.)

(1) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards in Subcommittee F04.12.
(2) Former wording in 1.2 was replaced with wording allowing independent SI and inch-pound units.
(3) Section 2, ASTM Standards, added IEEE/ASTM SI 10, American National Standard for Metric Practice.
(4) Former subsection 2.3, ASQ C1 Specification of General Requirements for a Quality Program and former footnote 5 were deleted.
(5) Section 10, Dimensions and Permissible Variations, was added to allow selection of units to be certified.
(6) Section 13, Certification, was updated.
(7) Reference to ASQ C1 quality program was deleted from Section 14, Quality Program Requirements.
(8) Appendix subsection X1.12 was added to support the use of SI units.
(9) Summary of Changes was updated.