Designation: F 139 – 03

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 F 139; 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 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 inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels[2]

A 480/A480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip[2]

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 45 Test Methods for Determining the Inclusion Content of Steel[3]

E 112 Test Methods for Determining the Average Grain Size[3]

E 407 Practice for Microetching Metals and Alloys[3]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants With Respect to Effect of Materials on Muscle and Bone[4]

2.2 *ISO Standard:*

ISO 5832-1 Implants for Surgery-Metallic Materials—Part 1: Wrought Stainless Steel[5]

2.3 *American Society for Quality (ASQ) Standard:*

C1 Specification of General Requirements for a Quality Program[6]

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current edition of Specification A 480/A 480M shall apply.

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

4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation,

4.1.3 Form (sheet or strip),

4.1.4 Condition (see 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, and length (exact, random, multiples) or print number, and

4.1.8 Special requirements.

5. Materials and Manufacture

5.1 *Condition*:

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

5.2 *Finish*:

5.2.1 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 in the purchase order.

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[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] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[6] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

TABLE 1 Mechanical Requirements

Condition	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation 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	...

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 2.

6.1.1 The compositional requirement shall meet the following:

$$\% \text{ Cr} + 3.3 \times \% \text{ Mo} \geq 26.0 \quad (1)$$

6.1.2 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.

6.2 *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 manufacturer shall not ship material that is outside the limits specified in Table 2. Product analysis limits shall be as specified in Table 3.

6.2.1 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.

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

6.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A 751.

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 E 407.

7.2 The microcleanliness of the steel as determined by Test Methods E 45, Method A, except using Plate I-r on representative samples from the 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

TABLE 2 Chemical Requirements, Heat Analysis

Element	Composition, %
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:
$\% \text{ Cr} + 3.3 \times \% \text{ Mo} \geq 26.0$

[B] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage iron content by difference is not required to be reported.

TABLE 3 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit[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 A 480/A 480M.

[B] Under minimum limit not applicable for elements where only a minimum percentage is indicated.

8. Mechanical Properties

8.1 Material shall conform to the appropriate requirements as to mechanical properties specified in Table 1. The level of mechanical properties for material in conditions other than those included in Table 1 shall be specified in the purchase order.

8.2 When desired, Rockwell hardness, A scale (HRA), Rockwell hardness, B scale (HRB) or Rockwell hardness, C Scale (HRC), limits may be specified.

9. Special Tests

9.1 The steel shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practices A 262, Practice E.

9.2 The grain size shall be five or finer when tested in accordance with Test Methods E 112.

9.2.1 It is preferred that samples for grain size determination be selected after the final annealing operation and prior to a final cold-working operation.

9.2.2 If samples are selected after a final cold-working operation, specimens shall be tested according to Test Method E 112, or as agreed to between the supplier and purchaser.

9.3 Any other special requirements shall be specified on the purchase order.

10. Certification

10.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program, such as defined in ASQ C1.

11.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQ C1, or other recognized programs.

12. Keywords

12.1 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, Composition D.

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 The title has been changed, the high carbon composition previously identified as Grade 1 has been deleted, product analysis tolerance limits have been included, inclusion limits have been changed in accordance with industry practice, and the UNS designation has been added.

X1.10 The mechanical requirements have been changed, the Pitting Resistance Equivalent (PRE) has been added, and X2.2 biocompatibility information has been added to coincide with ISO requirements.

X1.11 The Pitting Resistance Equivalent (PRE) has been reidentified as a compositional requirement, free ferrite has been changed to delta ferrite, and grain size determination for cold worked samples was changed to meet Test Method E112 or as agreed to between supplier and purchaser.

X1.12 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.

X1.13 Molybdenum-enriched chi and sigma intermetallic compounds must be not be present in the microstructure because of reduced austenitic corrosion resistance and possible embrittlement effects.

X1.14 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.

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 (F 139 – 00) that may impact the use of this standard. (Approved June 10, 2003.)

(*1*) Paragraph 7.1 specifies that chi and sigma phases must not be present in the microstructure when examined at 100× magnification.

(*2*) X1.12 represents information standardized by Subcommittee F04.12.

(*3*) X1.13 and X1.14 were added for information purposes.

(*4*) Practice E 407 was added to the Referenced Documents section.