



Designation: F139 – 08

# Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)<sup>1</sup>

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 ( $\epsilon$ ) 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 inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

## 2. Referenced Documents

2.1 *ASTM Standards*:<sup>2</sup>

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 Test Methods for Tension Testing of Metallic Materials

E8M Test Methods for Tension Testing of Metallic Materials [Metric] (Withdrawn 2008)<sup>3</sup>

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

2.2 *ISO Standards*:<sup>4</sup>

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

2.3 *American Society for Quality (ASQ) Standard*:<sup>5</sup>

ASQ C1 Specification of General Requirements for a Quality Program

## 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:

<sup>4</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

<sup>5</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

<sup>1</sup> 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> The last approved version of this historical standard is referenced on [www.astm.org](http://www.astm.org).

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

- 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),
- 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:

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

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.

**TABLE 1 Mechanical Requirements**

Condition	Ultimate Tensile Strength <sup>A</sup> , min, psi (MPa)	Yield Strength <sup>A</sup> (0.2 % Offset), min, psi (MPa)	Elongation <sup>B</sup> 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	...

<sup>A</sup> Minimum limits apply to tests taken longitudinal to the direction of rolling.

<sup>B</sup> The gage length must 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 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area).

**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 <sup>A</sup>	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum <sup>A</sup>	2.25 to 3.00
Nitrogen	0.10 max
Copper	0.50 max
Iron <sup>B</sup>	balance

<sup>A</sup> The compositional requirement shall meet the following:

$$\% \text{Cr} + 3.3 \times \% \text{Mo} \geq 26.0$$

<sup>B</sup> The percentage of iron content by difference is not required to be determined or certified.

**TABLE 3 Product Analysis Tolerances<sup>A</sup>**

Element	Tolerance Under the Minimum or Over the Maximum Limit, % (mass/mass) <sup>B</sup>
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

<sup>A</sup> Refer to Specification A480/A480M.

<sup>B</sup> Under minimum limit not applicable for elements where only a maximum percentage is indicated.

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.

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 or E8M.