



Designation: **F139 – 12 F139 – 19**

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.

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 ~~are~~ may not necessarily be exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and ~~neither~~ other. Combining values from the two systems ~~shall not be combined~~ 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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](#)

[ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes](#)

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

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] 4.76 mm [0.1875 in.] in thickness and 24 in. [610 mm] 610 mm [24 in.] or more in width.

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

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:

TABLE 1 Mechanical Requirements

Condition	Ultimate Tensile Strength ^A , min, MPa [psi]	Yield Strength ^A (0.2 % Offset), min, MPa [psi]	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	...

TABLE 1 Mechanical Requirements

Condition	Ultimate Tensile Strength ^A , min, MPa [psi]	Yield Strength ^A (0.2 % Offset), min, MPa [psi]	Elongation ^B in 50 mm [2 in.] min, %	Rockwell Hardness, max
Annealed	490 [71 000]	190 [27 500]	40	95 HRB
Cold-worked	860 [125 000]	690 [100 000]	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] 1.6 mm [0.063 in.] 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
Carbon	0.030 max
Manganese	–2.00 max
Manganese	2.00 max
Phosphorus	–0.025 max
Phosphorus	0.025 max
Sulfur	–0.010 max
Sulfur	0.010 max
Silicon	–0.75 max
Silicon	0.75 max
Chromium ^A	17.00 to 19.00
Chromium	17.00 to 19.00
Nickel	13.00 to 15.00
Molybdenum ^A	–2.25 to 3.00
Molybdenum	2.25 to 3.00
Cobalt	<0.10
Nitrogen	–0.10 max
Nitrogen	0.10 max
Copper	–0.50 max
Copper	0.50 max
Iron ^B	balance
Iron ^A	balance
Composition Index = % Cr + 3.3 × % Mo	26.0 min

^AThe compositional requirement shall meet the following:

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

^A The percentage of iron content by difference is not required to be determined or certified.

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

(1)

7.1.1 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.

7.1.2 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace elements, that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection.

7.1.3 Intentional elemental additions other than those specified in **Table 3** are not permitted.

7.1.4 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.

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.

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
Cobalt	0.01

^A Refer to Specification **A480/A480M**.

^B Under minimum limit not applicable for elements where only a maximum percentage is indicated.