



Standard Specification for Wrought Seamless or Welded and Drawn 18 Chromium- 14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)¹

This standard is issued under the fixed designation F2257; 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 requirements for wrought 18chromium-14nickel-2.5molybdenum stainless steel tubing used for the manufacture of surgical implants. Material shall conform to the applicable requirements of Specification F138 (for seamless) or Specification F139 (for welded and drawn). This specification addresses those product variables that differentiate small-diameter medical grade tubing from the bar, wire, sheet, and strip product forms covered in these specifications.

1.2 This specification applies to cold finished straight length tubing with 3 mm [0.125 in.] and smaller nominal outside diameter (OD) and 0.5 mm [0.020 in.] and thinner nominal wall thickness.

1.3 The specifications in 2.1 are referred to as the ASTM material standard(s) in this specification.

1.4 The values stated in either inch-pound or SI units are to be regarded separately as standard. Inch-pound units are shown in parentheses. 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 Material Standards:²

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Sur-

gical Implants (UNS S31673)

2.2 ASTM Standards:²

A632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small-Diameter) for General Service

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E112 Test Methods for Determining Average Grain Size

F2181 Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.3 ISO Standards:³

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

ISO 6892 Metallic Materials — Tensile Testing

ISO 9001 Quality Management Systems — Requirements

ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes

2.4 ASME Standards:⁴

ASME Y14.5.1M Mathematical Definition of Dimensioning and Tolerancing Principles

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *individual wall thickness measurement*— any one of the wall thickness measurements taken around the circumference on any one transverse cross section of a single sample of the tube.

3.1.2 *lot*—the total number of product produced from the same melt heat under the same conditions at essentially the same time.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁴ Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Three Park Ave., New York, NY 10016-5990, <http://www.asme.org>.

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 Nov. 1, 2014. Published February 2015. Originally approved in 2003. Last previous edition approved in 2009 as F2257 – 09. DOI: 10.1520/F2257-14.

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.

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

3.1.3 *lot average concentricity*—the arithmetic average of the sample concentricities measured on a statistically representative number of samples from the lot.

3.1.4 *lot average wall thickness*—the arithmetic average of the sample average wall thicknesses measured on a statistically representative number of samples from the lot.

3.1.5 *nominal outside diameter (OD)*—the outside diameter specified on the purchaser’s order or engineering drawing without regard to tolerance.

3.1.6 *nominal wall thickness*—the wall thickness specified on the purchaser’s order or engineering drawing without regard to tolerance.

3.1.7 *sample average wall thickness*—the arithmetic average of all individual wall thickness measurements measured on a single sample.

3.1.8 *sample concentricity*—two times the offset between the centers of the two circles representing the outside diameter (OD) and the inside diameter (ID) of the tube.

3.1.8.1 *Discussion*—For the purposes of this specification, the sample minimum wall and the sample maximum wall measured on any one transverse cross section of a single sample shall be used to calculate sample concentricity. The sample maximum, and sample minimum wall thickness shall be the largest and smallest respectively of no less than four individual wall thickness measurements taken at uniformly spaced locations around the circumference of a single sample of the tube. Sample concentricity shall be expressed as a percent of the wall thickness and shall be calculated using the following equation:

$$\text{sample concentricity percent} = 2 \times \left(\frac{A - B}{A + B} \right) \times 100$$

where:

A = sample maximum wall, and

B = sample minimum wall.

3.1.9 *sample maximum wall thickness*—the largest individual wall thickness measurement taken around the circumference on any one transverse cross section of a single sample of tube.

3.1.10 *sample minimum wall thickness*—the smallest individual wall thickness measurement taken around the circumference on any one transverse cross section of a single sample of tube.

3.1.11 *seamless tubing*—tubing made by a process in which the tube periphery is continuous at all stages of the process.

3.1.12 *welded and drawn tubing*—tubing fabricated from strip or sheet using welding, drawing, and annealing operations.

4. General Requirements for Delivery

4.1 In addition to the requirements of this specification, all applicable requirements of the appropriate ASTM material standard shall apply.

4.2 In addition to the requirements of this specification, all applicable requirements of Specification A632 shall apply.

4.3 If a conflict exists between this specification and those listed in Section 2, or if a conflict exists between those specifications listed in 2.1 and those listed in 2.2 and 2.3, the following order of precedence applies: (1) this specification, (2) the ASTM material standard referenced on the purchase order, and (3) all other referenced specifications.

5. Ordering Information

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

5.1.1 Quantity (weight, total length or number of pieces),

5.1.2 This ASTM specification and date of issue,

5.1.3 The appropriate ASTM material standard (Specification F138 for seamless or Specification F139 for welded and drawn) and date of issue,

5.1.4 Units to be certified—SI or inch-pound.

5.1.5 Method of Manufacture (see 6.1),

5.1.6 Condition (see Table 1),

5.1.7 Surface Finish (see 6.3),

5.1.8 Applicable Dimensions—including OD and ID; OD and wall or ID and wall; length (exact, random, multiples); or engineering drawing reference number,

5.1.9 Dimensional Tolerances (see Table 2),

5.1.10 Special requirements or supplements, if any, and

5.1.11 Certification requirements.

6. Materials and Manufacture

6.1 *Method of Manufacture:*

6.1.1 Tubing shall be made by the seamless or the welded and drawn process.

TABLE 1 Mechanical Properties

Condition	Wall Thickness, mm [in.]	Ultimate Tensile Strength, min MPa [psi]	Yield Strength (0.2 % offset), min MPa [psi]	Elongation (% in 50 mm [2 in.] or 4D), ^A min (%)
Annealed	0.20 [0.008] to 0.46 [0.018] incl	490 [71 000]	190 [27 500]	40
	0.05 [0.002] to 0.20 [0.008] excl	550 [80 000]	207 [30 000]	35
	Less than 0.05 [0.002]	586 [85 000]	241 [35 000]	20
Cold worked	0.20 [0.008] to 0.46 [0.018] incl	860 [125 000]	690 [100 000]	10
	0.05 [0.002] to 0.20 [0.008] excl	860 [125 000]	690 [100 000]	8
	Less than 0.05 [0.002]	860 [125 000]	690 [100 000]	4

^A Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) shall be measured using a gage length of 50 mm [2 in.] or 4D. The gage length shall be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] shall be agreed upon between purchaser and supplier. Alternatively, a gauge length corresponding to ISO 6892 (5.65 times the square root of S_o, where S_o is the original cross sectional area) may be used when agreed upon between purchaser and supplier.