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Standard Specification for Wrought Seamless or Welded and Drawn 18Chromium- 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 SI units or inch-pound units are to be regarded separately as standard. Inch-pound units are shown in brackets. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other and values from the two systems shall not be combined.

1.5 *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.*

1.6 *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 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 Surgical 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 Metric Practice

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

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

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.

3.1.3 *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.

6.1.2 Seamless tubing shall be made by a seamless process in which the tube periphery is continuous at all stages of the process.

6.1.3 Welded and drawn tubing shall be fabricated from strip or sheet using welding, drawing, and annealing operations. Welding shall be performed using a liquid phase weld process with no filler metal. Typical weld processes are tungsten inert gas (TIG) and laser. The drawing and annealing operations shall be performed in such a way that the weld bead and heat-affected zone are virtually indistinguishable microstructurally and dimensionally from the parent metal when examined per 11.3.

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