Designation: F 2257 – 03

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 F 2257; 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 F 138 (for seamless) or Specification F 139 (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 straight length tubing with 0.125 in. (3.15 mm) and smaller nominal outside diameter (OD) and 0.018 in. (0.46 mm) and thinner nominal wall thickness.

1.3 The values stated in inch-pound units are to be regarded as the standard. The SI units in parentheses are approximate.

2. Referenced Documents

2.1 *ASTM Material Standards:*

F 138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[2]

F 139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Sheet and Strip for Surgical Implants (UNS S31673)[2]

2.2 *ASTM Standards:*

A 632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small Diameter) for General Service[3]

E 8 Test Methods for Tension Testing of Metallic Materials[4]

E 112 Test Method for Determining Average Grain Size[4]

2.3 *ISO Standards:*

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

ISO 6892 Metallic Materials—Tensile Testing[5]

2.4 *American Society for Quality Standard:*

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

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *average wall thickness*—the arithmetic average of the minimum wall thickness and the maximum wall thickness measured on any one transverse cross section of the tube.

3.1.2 *concentricity*—two times the offset between the centers of two circles, representing the outside diameter (OD) and the inside diameter (ID) of the tube. For purposes of this specification, the minimum wall and the maximum wall measured on any one transverse cross section shall be used to calculate concentricity. The percent concentricity shall be calculated using the equation:

$$\text{Percent Concentricity} = 2 \times \left(\frac{\text{maximum wall} - \text{minimum wall}}{\text{maximum wall} + \text{minimum wall}} \right) \times 100$$

3.1.3 *nominal outside diameter (OD)*—the outside diameter specified on the customer order or engineering drawing without regard to tolerance.

3.1.4 *nominal wall thickness*—the wall thickness specified on the customer order or engineering drawing without regard to tolerance.

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

3.1.6 *welded and drawn tubing*—tubing 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

[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 13.01.

[3] *Annual Book of ASTM Standards*, Vol 01.01.

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

[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.

TABLE 1 Mechanical Properties

Condition	Wall Thickness, in. (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % offset), min psi (MPa)	Elongation (% in 2 in. or 4D),[A] min (%)
Annealed	0.008 (0.20) to 0.018 incl (0.46)	71 000 (490)	27 500 (190)	40
	0.002 (0.05) to 0.008 excl (0.20)	80 000 (550)	30 000 (205)	35
	Less than 0.002 (0.05)	85 000 (585)	35 000 (240)	20
Cold worked	0.008 (0.20) to 0.018 incl (0.46)	125 000 (860)	100 000 (690)	10
	0.002 (0.05) to 0.008 excl (0.20)	125 000 (860)	100 000 (690)	8
	Less than 0.002 (0.05)	125 000 (860)	100 000 (690)	4

[A] Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) shall be measured using a gage length of 2 in. (50 mm) or 4D. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) shall be agreed upon between purchaser and supplier. Alternatively, a gauge 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 purchaser and supplier.

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. 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 A 632 shall apply.

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 designation and date of issue,

5.1.3 ASTM material standard (Specification F 138 for seamless or Specification F 139 for welded and drawn) and date of issue,

5.1.4 Method of Manufacture (see 6.1),

5.1.5 Condition (see Table 1),

5.1.6 Surface Finish (see 6.2),

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

5.1.8 Dimensional Tolerances (see Table 2),

5.1.9 Certification requirements, and

5.1.10 Special requirements or supplements, if any.

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.

6.2 *Surface Finish*:

6.2.1 The tubing outer surface shall be furnished with a cold-drawn, bright annealed, ground, or polished finish. Outer surface roughness shall be a maximum of 25 µin. (0.63 µm) Ra.

6.2.2 The tubing inner surface shall be furnished with an as-drawn finish or bright annealed finish. Inner surface roughness shall be a maximum of 30 µin. (0.75 µm) Ra.

6.2.3 The method used to determine surface roughness shall be agreed upon between purchaser and supplier.

TABLE 2 Permissible Variation in OD and ID Dimensions

Nominal OD or ID in. (mm)	Permissible Variation from Nominal, in. (mm)[A]
Less than 0.060 (1.53)	±0.0005 (.013)
0.060 to 0.125 (1.54 to 3.18) incl.	±0.001 (.025)

[A] Unless otherwise specified, size tolerances are plus and minus as shown in the table. When required by the purchaser, tolerances may be specified all plus and nothing minus, or all minus and nothing plus, or any combination of plus and minus if the total spread in size tolerance is not less than the total spread shown in the table.

7. Chemical Composition

7.1 For seamless tubing, the heat analysis limits and product analysis tolerances of Specification F 138 shall apply. For welded and drawn tubing, the heat analysis limits and product analysis tolerances of Specification F 139 shall apply.

8. Mechanical Properties

8.1 Material shall meet the appropriate mechanical properties specified in Table 1, when tested in accordance with Test Method E 8. Mechanical properties for material in conditions other than those in Table 1 shall be agreed upon between purchaser and supplier.

8.2 In the event that both tensile properties and hardness are specified on the purchase order, tensile properties will be used to accept or reject. Hardness will be reported for information only.

9. Permissible Variation in Dimensions

9.1 *OD and ID*:

9.1.1 Permissible variations of OD and ID from the nominal dimension on the purchase order or engineering drawing are listed in Table 2.

9.1.2 OD may be measured by hand micrometer, by linear variable differential transducer (LVDT), by laser micrometer or by other non-contact method.

9.2 *Wall Thickness*:

9.2.1 The range of total wall variation (including concentricity and average wall variation) shall not exceed 14 % (±7 %) of nominal wall thickness.

9.2.2 Concentricity shall not exceed 10 % (±5 %) of average wall thickness for tubing with nominal wall thickness greater than or equal to 10 % of the nominal OD dimension. For tubing with nominal wall thickness less than 10 % of the nominal OD dimension, concentricity shall be agreed upon between purchaser and supplier.

9.2.3 Wall thickness measurement shall be made directly with a hand micrometer, LVDT, by optical measurement on a