



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

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)<sup>2</sup>

F 139 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Sheet and Strip for Surgical Implants (UNS S31673)<sup>2</sup>

### 2.2 ASTM Standards:

A 632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small Diameter) for General Service<sup>3</sup>

E 8 Test Methods for Tension Testing of Metallic Materials<sup>4</sup>

E 112 Test Method for Determining Average Grain Size<sup>4</sup>

### 2.3 ISO Standards:

ISO 5832-1 Implants for Surgery—Metallic Materials Part 1: Wrought Stainless Steel<sup>5</sup>

ISO 6892 Metallic Materials—Tensile Testing<sup>5</sup>

2.4 *American Society for Quality Standard:*

C1 Specification of General Requirements for a Quality Program<sup>6</sup>

## 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

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 01.01.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>5</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

<sup>6</sup> 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), <sup>A</sup> 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

<sup>A</sup> 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  $S_o$ , where  $S_o$  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 micro-structurally 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  $\mu\text{in.}$  (0.63  $\mu\text{m}$ ) 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  $\mu\text{in.}$  (0.75  $\mu\text{m}$ ) Ra.

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

#### 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 % ( $\pm 7$  %) of nominal wall thickness.

9.2.2 Concentricity shall not exceed 10 % ( $\pm 5$  %) 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

**TABLE 2 Permissible Variation in OD and ID Dimensions**

Nominal OD or ID in. (mm)	Permissible Variation from Nominal, in. (mm) <sup>A</sup>
Less than 0.060 (1.53)	$\pm 0.0005$ (.013)
0.060 to 0.125 (1.54 to 3.18) incl.	$\pm 0.001$ (.025)

<sup>A</sup> 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.

transverse metallographic cross section, or by some other appropriate method. The method of wall thickness measurement shall be agreed upon between purchaser and supplier.

#### 9.3 Length:

9.3.1 For exact length orders, length variation on all lengths up to and including 24 ft (7.3 m) shall be plus or minus  $\frac{1}{8}$  in. (3 mm).

9.3.2 For random length orders, a maximum and minimum length shall be specified by the purchaser. Up to 5 % of the order may ship short of the minimum length specified. No length shall be less than 2 ft (0.6 m), unless permitted by the purchaser.

#### 9.4 Straightness:

9.4.1 The deviation from straightness shall not exceed 0.012 in. per ft (0.30 mm per 300 mm) of tube length.

### 10. Permissible Outer and Inner Surface Imperfections

10.1 Outer surface imperfection shall not exceed 10 % of wall thickness in depth. Outer surface imperfections may be removed by grinding or polishing prior to shipment, providing that the resultant wall thickness meets the minimum wall thickness, and that the ground or polished surface meets the surface finish requirements of 6.2.1.

10.2 Inner surface imperfections shall not exceed 10 % of wall thickness in depth.

10.3 The method of inspecting for these imperfections shall be agreed upon between the purchaser and supplier.

### 11. Special Tests

11.1 The material shall conform to the special test requirements of the appropriate ASTM material standard listed in 2.1.

11.2 The grain size shall be ASTM 6 or finer when evaluated after the final annealing operation in accordance with

Test Method E 112. In addition, on one of the transverse metallographic sections examined, there must be a minimum of three grains intercepted by any radial line drawn across the wall thickness.

11.2.1 If samples are selected after a final cold working operation, specimens shall be tested in accordance with Test Method E 112 or as agreed upon between purchaser and supplier.

11.3 For welded and drawn tubing, the weld bead shall be metallographically mounted on a transverse section and viewed at 100 times magnification. The weld bead and heat affected zone microstructures shall exhibit a grain size and grain morphology similar to the parent metal. The wall thickness at the weld bead shall be the same as the parent metal.

### 12. Certification

12.1 The supplier shall provide certification that the material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

12.2 The method of manufacture (seamless or welded and drawn) shall be stated on the certification.

### 13. Quality Program Requirements

13.1 The supplier shall maintain a quality program such as defined in ASQ C1.

13.2 The purchaser may audit the producer's quality program for conformance to the intent of ASQ C1 or other recognized quality program.

### 14. Keywords

14.1 metals (for surgical implant); small diameter; stainless steel; surgical applications tubing; surgical implants; tubing

## SUPPLEMENTARY REQUIREMENTS

The following supplementary requirements shall apply only when specified by the purchaser in the inquiry, contract, or order.

### S1. Inside Surface Cleanliness

S1.1 Tubing with ID size of greater than or equal to 0.060 in. (1.5 mm) shall meet the requirements of ASTM A 632

Supplement 3 for cleanliness. The method for inspecting inside surface cleanliness for smaller ID sizes shall be agreed upon between purchaser and supplier.

## APPENDIXES

## (Nonmandatory Information)

## X1. RATIONALE

X1.1 The primary reason for this specification is to establish a tubular product standard for 18 Chromium-14 Nickel-2.5 Molybdenum stainless steel used in fabricated stents and other small diameter implantable devices.

X1.2 ISO Standards are listed for reference only. Although the ISO 5832-1 Standard listed in 2.3 is similar to the corresponding ASTM standards, they are not identical. Use of the ISO standard instead of the preferred ASTM standards may be agreed upon between the purchaser and supplier. The composition of ISO 5832-1 Composition D is similar to Specification F 138 and Specification F 139.

X1.3 When measuring wall thickness, tubing to be measured will be sufficiently prepared to eliminate any burr or other material that will interfere with accurate mechanical or optical measurement. This preparation can be done by end finishing procedures such as reaming and deburring, ECM cutting or EDM wire cutting (for micrometer and LVDT measurement) or metallographic mounting, grinding and polishing (for optical measurement).

X1.3.1 Metallographic preparation for optical measurement will be performed in such a way as to maximize sample edge retention and minimize sample deviation from perpendicular.

X1.3.2 Micrometers used for wall measurement will have a pin diameter or effective anvil diameter less than the minimum tube ID size.

X1.3.3 LVDT's shall have a precision consistent with the required wall thickness tolerance.

X1.4 *Precision and Bias*—The choice of wall thickness measurement technique is critical for tubing with very thin walls. Once a method is agreed upon between purchaser and

supplier, the bias and precision of the method should be evaluated to insure the method is accurate and repeatable. In the absence of bias and precision data, no test method shall be used to reject tubing with measured wall thickness within 0.0002 in. (0.005 mm) of the specification limits.

X1.5 Percent concentricity as defined in 3.1.2 represents the full range of concentricity. It is preferred that purchasers specify this full range of concentricity with no  $\pm$  modifier. For purposes of tolerancing, however, the percent concentricity may be divided by two and the resulting value may be used as a plus and minus tolerance which when applied to the nominal wall thickness will define the allowable range of wall variation due to concentricity. In addition, the percent concentricity calculated using equation in 3.1.2 when divided by two may be added to and subtracted from the average wall thickness to express the actual range of wall variation due to concentricity.

X1.6 In the event that OD, ID, and wall thickness are specified on the purchase order, the supplier and purchaser shall resolve which two of these will apply. Only two of these three tube dimensions can be controlled to a normal size and tolerance. The third dimension is determined by the interaction of the two controlled dimensions.

X1.7 Concentricity may be used in conjunction with OD, ID, or wall tolerances to better define the allowable variation in wall thickness. For example, when a tube is specified using OD and ID dimensions and tolerances, concentricity may be used to limit wall variation within the larger range allowed by a comparison of the upper and lower OD and ID tolerance limits. In this application, concentricity should not be interpreted as a wall tolerance requiring resolution per X1.6.

## X2. BIOCOMPATIBILITY

X2.1 Biocompatibility is addressed in the appropriate ASTM material standard.

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