Designation: F2257 – 14

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 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 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.

[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.

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

***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:

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

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 *So*, where *So* is the original cross sectional area) may be used when agreed upon between purchaser and supplier.

TABLE 2 Permissible Variation in OD and ID Dimensions

Nominal OD or ID mm [in.]	Permissible Variation from Nominal, mm [in.][A]
Less than 1.5 [0.060]	±0.013 [0.0005]
1.5 to 3.2 [0.060 to 0.125] incl.	±0.025 [0.001]

[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.

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.

6.2 *Condition*—Tubing shall be furnished, as specified, in the annealed or cold worked condition as defined in Table 1.

6.3 *Surface Finish:*

6.3.1 The tubing outer surface shall be furnished with a cold-drawn, bright annealed, ground, or polished finish. The outer surface roughness shall be a maximum of 0.6 µm [25 µin.] Ra.

6.3.2 The tubing inner surface shall be furnished with an as-drawn finish or bright annealed finish. The inner surface roughness shall be a maximum of 0.8 µm [30 µin.] Ra maximum.

6.3.3 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 F138 shall apply. For welded and drawn tubing, the heat analysis limits and product analysis tolerances of Specification F139 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 E8/E8M. Mechanical properties for material in conditions other than those in Table 1 shall be agreed upon between purchaser and supplier.

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

9. Permissible Outer and Inner Surface Imperfections

9.1 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 6.3.1.

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

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

10. Dimensions and Permissible Variation

10.1 *Units of Measure:*

10.1.1 *Selection*—This specification requires that the purchaser selects the units of measure (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

10.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

10.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

10.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between purchaser and supplier.

10.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.

10.2 *Permissible Variation in Dimensions:*

10.2.1 *OD and ID:*

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

10.2.1.2 OD may be measured by hand micrometer, linear variable differential transducer (LVDT), coordinate measuring machine (CMM), laser micrometer, or other non-contact method.

10.2.2 *Wall Thickness:*

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

10.2.2.2 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.

10.2.2.3 Wall thickness shall be measured directly with a hand micrometer, LVDT, CMM, or by optical measurement on a transverse metallographic cross section, or by some other

appropriate method. The method of wall thickness measurement shall be agreed upon between purchaser and supplier.

10.2.3 *Length:*

10.2.3.1 For exact length orders, length variation on all lengths up to and including 7.5 m [24 ft] shall be ±3 mm [0.125 in.].

10.2.3.2 For random length orders, a maximum and minimum length shall be specified by the purchaser. Up to 5 % of the shipped order quantity may be shorter than the minimum length specified. No length shall be less than 0.6 m [2 ft], unless permitted by the purchaser.

10.2.4 *Straightness*—The deviation from straightness shall not exceed 3 mm per 3 m [0.012 in. per ft] of tube length.

11. Special Tests

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

11.2 The grain size shall be ASTM 6 or finer when evaluated after the final annealing operation in accordance with Test Method E112. In addition, on any one of the transverse metallographic sections examined, there shall 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, the specimens shall be tested in accordance with Test Method E112 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× 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. Significance of Numerical Limits

12.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

13. Certification

13.1 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.

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

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program such as defined in ISO 9001 or ISO 13485.

14.2 The purchaser may audit the producer's quality program for conformance to the intent of ISO 9001, ISO 13485, or other recognized quality program.

15. Keywords

15.1 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 greater than or equal to 1.5 mm [0.060 in.] shall meet the requirements of ASTM A632 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 such as coronary stents. A similar specification, ASTM F2181, covers stainless steel tubing typically used in cannulated intramedullary nails and medical bone screws.

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 is similar to Specification F138 and Specification F139.

X1.3 When measuring wall thickness, tubing to be measured must 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, Electro-Chemical Machining (ECM) cutting or ElectroDischarge Machining (EDM) wire cutting (for micrometer, Linear Variable Displacement Transducers (LVDT), and Coordinate Measuring Machine (CMM) measurement) or metallographic mounting, grinding, and polishing (for optical measurement).

X1.3.1 Metallographic preparation for optical measurement must 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 must have a pin diameter or effective anvil diameter less than the minimum tube ID size.

X1.3.3 LVDTs and CMMs 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 ensure 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 0.005 mm [0.0002 in.] of the specification limits.

X1.5 Percent concentricity as defined in 3.1.8 represents the full range of concentricity. This definition is consistent with the general definition for concentricity offered in ASME Y14.5.1M It is preferred that purchasers specify this full range of concentricity with no ± 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 3.1.8 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 If 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.

X1.8 Surface imperfections may be detected by a number of methods, including visual inspection. The suspect defect may be metallographically prepared and measured using a measuring reticule on a light microscope. This method is particularly suited for measuring long continuous imperfections such as “scratches” or “draw lines”. Other methods that may be used to evaluate surface imperfection depth include removal of some amount of material from the surface containing the imperfection (to see if the imperfection is still visible at a specified material removal), or use of a Z-axis measuring microscope to directly measure the depth. These same methods may be applied to ID defects by carefully splitting or exposing the tube ID for inspection using wire EDM, diamond saw, fine abrasive saw.or grinding to remove some portion of the tube.

X1.9 *Lot Definition*—The definition of lot in 3.1.2 includes the conversion from solid billet or bar by extrusion, gundrilling, or other method.

X2. BIOCOMPATIBILITY

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

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2257 – 09) that may impact the use of this standard. (Approved Nov. 1, 2015.)

(1) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards within Subcommittee F04.12.
(2) Added definitions and made numerous editorial changes to reflect the current language used in the more recent Subcommittee F04.12 tube specifications.
(3) Changed Units of Measure paragraph location and content to reflect the latest Subcommittee F04.12 template language.
(4) Deleted X1.9.1 concerning ASTM policy on SI units.
(5) Added ISO 13485 as an option to the ISO 9001 quality system.