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Standard Specification for Wrought Seamless or Welded and Drawn ~~18Chromium-14Nickel-2.5Molybdenum-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 ~~inch-pound or SI units or inch-pound units~~ are to be regarded separately as standard. Inch-pound units are shown in ~~parentheses~~ brackets. The values stated in each system ~~may~~ are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other. ~~Combining other and values from the two systems may result in non-conformance with the standard.~~ 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)

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.

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

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 ~~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 Materials—Tensile Testing

ISO 9001 Quality Management Systems—Requirements Systems—Requirements

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

3.1.3 *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~~ maximum and sample minimum wall thickness shall be the largest and ~~smallest~~ 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:

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

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>.

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

where:

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~~ inch-pound,

5.1.5 Method of ~~Manufacture~~ manufacture (see 6.1),

5.1.6 Condition (see **Table 1**),

5.1.7 Surface ~~Finish~~ finish (see 6.3),

5.1.8 Applicable ~~Dimensions—including~~ 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 ~~Tolerance~~ tolerances (see **Table 2**),

5.1.10 Special requirements or supplements, if any, and

5.1.11 Certification requirements.

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–4D minimum. 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.

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. 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.

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 $\mu\text{in.}$] 0.6 μm [25 $\mu\text{in.}$] 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 $\mu\text{in.}$] 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~~select 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