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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.

~~1.2This 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.~~

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

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:*

~~F138Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)[2]~~

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

F 139 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~~

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

~~E8Test Methods for Tension Testing of Metallic Materials~~ E 8/E 8M Test Methods for Tension Testing of Metallic Materials

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

~~E112Test Method for Determining Average Grain Size[4]~~ E 112 Test Methods for Determining Average Grain Size

F 2181 Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants

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[5]~~ Metallic Materials—Tensile Testing

ISO 9001 Quality Management Systems—Requirements

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[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* ~~, Vol 13.01,~~ volume information, refer to the standard's Document Summary page on the ASTM website.

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

[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 American Society for Quality Standard: ASME Standards:[4]
C1Specification of General Requirements for a Quality Program 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 *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.

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 *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:

$$\text{PercentConcentricity} = 2\times\left(\frac{\text{maximumwall}-\text{minimumwall}}{\text{maximumwall}+\text{minimumwall}}\right)\times 100$$

lot—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

3.1.3 *nominal outside diameter (OD)*—the outside diameter specified on the customer order or engineering drawing without regard to tolerance. lot average concentricity—the arithmetic average of the sample concentricities measured on a statistically representative number of samples from the lot.

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

3.1.6 *sample average wall thickness*—the arithmetic average of all individual wall thickness measurements measured on a single sample.

3.1.7 *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.

3.1.7.1 *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.

3.1.8 *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.

3.1.9 *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.

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

3.1.6

3.1.11 *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 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. —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] Annual Book of ASTM Standards, Vol 03.01.
[4] Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Three Park Ave., New York, NY 10016-5990, http://www.asme.org.

4.2 In addition to the requirements of this specification, all applicable requirements of Specification A 632 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 ~~designation~~specification and date of issue,

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

~~5.1.4Method of Manufacture (see~~

5.1.4 Units to be certified—SI or inch-pound.

5.1.5 Method of Manufacture (see 6.1),

~~5.1.5Condition (see~~

5.1.6 Condition (see Table 1),

~~5.1.6Surface Finish (see 6.2~~

5.1.7 Surface Finish (see 6.3),

5.1.~~7~~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.~~8~~9 Dimensional Tolerances (see Table 2),

~~5.1.9Certification requirements, and~~

~~5.1.10Special requirements or supplements, if any.~~

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.

~~6.2~~

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*:

~~6.2.1~~6.3.1 The tubing outer surface shall be furnished with a cold-drawn, bright annealed, ground, or polished finish. ~~Outer~~ The outer surface roughness shall be a maximum of ~~25 µin. (0.63 µm) Ra.~~ 0.6 µm (25 µin.) Ra maximum.

~~6.2.2The~~6.3.2 The tubing inner surface shall be furnished with an as-drawn finish or bright annealed finish. ~~Inner~~ The inner surface roughness shall be a maximum of ~~30 µin. (0.75 µm) Ra.~~ 0.8 µm (30 µin.) Ra maximum.

TABLE 1 Mechanical Properties

Condition	Wall Thickness, mm (in.~~ (mm)~~	Ultimate Tensile Strength, min~~, psi (~~ MPa (psi)	Yield Strength (0.2 % offset), min~~ psi (~~ MPa (psi)	Elongation (% in 50 mm (2 in.) or 4D),[A] min (%)
~~Annealed~~	~~0.008 (0.20) to 0.018 incl (0.46)~~	~~71 000 (490)~~	~~27 500 (190)~~	~~40~~
Annealed	0.20 (0.008) to 0.46 (0.018) incl	490 (71 000)	190 (27 500)	40
	~~0.002 (0.05) to 0.008 excl (0.20)~~	~~80 000 (550)~~	~~30 000 (205)~~	~~35~~
	0.05 (0.002) to 0.20 (0.008) excl	550 (80 000)	207 (30 000)	35
	~~Less than 0.002 (0.05)~~	~~85 000 (585)~~	~~35 000 (240)~~	~~20~~
	Less than 0.05 (0.002)	586 (85 000)	241 (35 000)	20
~~Cold worked~~	~~0.008 (0.20) to 0.018 incl (0.46)~~	~~125 000 (860)~~	~~100 000 (690)~~	~~10~~
Cold worked	0.20 (0.008) to 0.46 (0.018) incl	860 (125 000)	690 (100 000)	10
	~~0.002 (0.05) to 0.008 excl (0.20)~~	~~125 000 (860)~~	~~100 000 (690)~~	~~8~~
	0.05 (0.002) to 0.20 (0.008) excl	860 (125 000)	690 (100 000)	8
	~~Less than 0.002 (0.05)~~	~~125 000 (860)~~	~~100 000 (690)~~	~~4~~
	Less than 0.05 (0.002)	860 (125 000)	690 (100 000)	4

[A] Elongation of material 1.6 mm (0.063 in.~~ (1.6 mm)~~ or greater in diameter (D) shall be measured using a gage length of~~ 2 in. (~~ 50 mm (2 in.) or 4D. The gage length ~~mu~~ s~~h~~all be reported with the test results. The method for determining elongation of material under 1.6 mm (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.