Designation: F 2181 – 02a

Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants[1]

This standard is issued under the fixed designation F 2181; 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 three compositions of wrought seamless stainless steel tubing for the manufacture of surgical implants. Material shall conform to the applicable requirements of Specifications F 138, F 1314, or F 1586. This specification addresses those product variables that differentiate wrought seamless tubing from the bar and wire product forms covered in these specifications.

1.2 This specification applies to cold finished, straight length tubing from 0.125 to 1.315 in. (3.18 to 33.4 mm) nominal outside diameter (OD) and 0.018 in. (0.46 mm) and greater 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.

1.4 The specifications in 2.1 will be referred to as the ASTM material standard(s) in the remainder of this specification.

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 1314 Specification for Wrought Nitrogen Strengthened-22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S20910)[2]

F 1586 Specification for Wrought Nitrogen Strengthened-21Chromium-10Nickel-3Manganese-2.5Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)[2]

2.2 *ASTM Tubing Standards:*

A 269 Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service[3]

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

2.3 *ISO Standards:*

ISO 5832-1 Implants for Surgery—Metallic Materials—Part 1: Wrought Stainless Steel[4]

ISO 5832-9 Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel[4]

2.4 *American Society for Quality Standard:*

C1 Specification of General Requirements for a Quality Program[5]

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 outside diameter (OD) and 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 wall thickness*—the wall thickness specified by the purchaser without regard to tolerance.

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 seamless tubing requirements of Specification A 269 or Specification A 632 shall apply. Flare testing is not applicable.

4.3 In the case where a conflict exists between this specification and those listed in Section 2 or in the case where a conflict exists between those specifications listed in 2.1 and those listed in 2.2 and 2.3, the following order of precedence

[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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[5] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, MI 53203.

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 and date of issue,

5.1.3 ASTM material standard and date of issue,

5.1.4 Condition (see 6.1.2),

5.1.5 Surface finish (see 6.2),

5.1.6 Applicable dimensions including OD and ID, OD and wall or ID and wall, length (exact, random, multiples) or engineering drawing reference number,

5.1.7 Dimensional tolerances (see Tables 1 and 2),

5.1.8 Certification requirements, and

5.1.9 Special requirements or supplements, if any.

6. Materials and Manufacture

6.1 *Method of Manufacture*:

6.1.1 Tubing shall be made by a seamless process in which the tube periphery is continuous at all stages of the process.

6.1.2 Tubing shall be furnished, as specified, in the annealed, cold worked, medium hard, hard or extra hard condition as defined in the appropriate ASTM material standard.

6.2 *Surface Finish*:

6.2.1 Tubing outer surface shall be furnished with a pickled, cold drawn, ground, or polished finish. Outer surface roughness will be 30 µin. (0.75 µm) Ra maximum.

6.2.2 Tubing inner surface shall be furnished with a pickled, cold drawn, or blasted finish. Inner surface roughness will be 60 µin. (1.5 µm) Ra maximum.

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

7. Chemical Composition, Metallurgical Requirements, and Mechanical Properties

7.1 The chemical composition, metallurgical requirements and mechanical properties shall conform to the requirements of the appropriate ASTM material standard.

7.2 In the event that 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.

8. Permissible Variation in Dimensions

8.1 *OD and ID*:

8.1.1 The permissible variations of OD and ID from the nominal dimension on the purchase order, or engineering drawing are listed in Tables 1 and 2.

8.2 *Wall Thickness*:

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

8.2.2 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 negotiated between purchaser and supplier.

TABLE 1 Permissible Variation in OD Dimensions

Nominal OD, in. (mm)	Permissible Variation from Nominal[A]	
	Standard Tolerance, in. (mm)	½ Standard Tolerance,[B] in. (mm)
0.125 to 0.500 excl. (3.2 to 12.7)	±0.002 (0.051)	±0.001 (0.025)
0.500 to 1.00 excl. (12.7 to 25.4)	±0.003 (0.076)	±0.0015 (0.038)
1.00 to 1.315 incl. (25.4 to 33.4)	±0.004 (0.102)	±0.002 (0.051)

[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.

[B] ½ standard tolerance may be used when specifying tubing for use on machining centers with tight collet clearance.

TABLE 2 Permissible Variation in ID Dimensions

Nominal ID, in. (mm)	Permissible Variation from Nominal, in. (mm)[A]
Up to 0.500 excl. (3.18 to 12.7)	±0.002 (0.051)
0.500 to 1.00 excl. (12.7 to 25.4)	±0.003 (0.076)
1.00 (and over) (25.4)	±0.004 (0.102)

[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.

8.2.3 Wall thickness measurement shall be made directly with a micrometer or linear variable displacement transducer (LVDT) or by optical measurement on a transverse metallographic cross section or other appropriate method. The method of wall thickness measurement shall be agreed upon between purchaser and supplier.

8.3 *Length*:

8.3.1 Length variation on all cut lengths up to and including 24 ft (7300 mm) shall be plus ⅛ in. (3 mm), minus 0.

8.3.2 On 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. In no case shall any length be less than 5 ft (1500 mm).

8.4 *Straightness*:

8.4.1 The deviation from straightness shall not exceed 0.012 in./ft (0.25 mm per 300 mm) of tube length.

9. Permissible Outer and Inner Surface Imperfections

9.1 For tubes with wall thickness greater than or equal to 0.060 in. (1.5 mm) and less than 0.250 in. (6.4 mm), neither outer nor inner surface imperfections shall exceed 0.003 in. (0.08 mm) in depth. For tubes with wall thickness greater than or equal to 0.250 in. (6.4 mm), neither outer nor inner surface imperfections shall exceed 0.005 in. (0.13 mm) in depth. For tubes with wall thickness less than 0.060 in. (1.5 mm), outer and inner surface imperfection depth shall be negotiated between purchaser and supplier.

9.2 The method of inspecting for these imperfections shall be negotiated between the purchaser and supplier.

9.3 Outer surface imperfections may be removed by grinding or polishing providing that the resultant wall thickness does

not violate the minimum wall thickness. The ground or polished surface shall meet the surface finish requirements of 6.2.1.

10. Special Tests

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

10.2 When required by the appropriate ASTM material standard, intergranular corrosion susceptibility testing shall be performed on both OD and ID surfaces.

11. Certification

11.1 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. Quality Program Requirements

12.1 The producer shall maintain a quality program such as defined in ASQ C1.

13. Keywords

13.1 metals (for surgical implant); seamless tubing; stainless steel; surgical applications tubing; surgical implants

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to establish a tubular product standard for Specifications F 138, F 1314, and F 1586 stainless steels typically used in cannulated intramedullary nails and medical bone screws.

X1.2 ISO Standards are listed for reference only. Although the ISO Standards listed in 2.4 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier. In this specification, ISO 5832-1 Composition D is similar to Specification F 138. The Composition of ISO 5832-9 is similar to Specification F 1586.

X1.3 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 nominal size and tolerance. The third dimension is determined by the interaction of the two controlled dimensions.

X1.4 When measuring wall thickness, tubing to be measured shall be sufficiently prepared to eliminate any burr or other material that will interfere with accurate contact or optical measurement. This preparation can be done by end finishing procedures such as reaming and deburring or wire EDM cutting, (for micrometer or LVDT measurement) or metallographic mounting, grinding and polishing (for optical measurement). Metallographic preparation for optical measurement will be performed in such a way as to maximize sample edge retention and minimize sample deviation from perpendicular. Micrometers shall have a pin diameter or effective anvil diameter less than the tube minimum ID size. LVDT's shall have a precision consistent with the required wall thickness tolerance.

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 plus/minus 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 the 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 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 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 section X1.3.

X2. BIOCOMPATIBILITY

X2.1 Biocompatibility is addressed in the ASTM material standards.