Designation: F2181 – 14

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

This standard is issued under the fixed designation F2181; 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 five compositions of wrought seamless stainless steel tubing for the manufacture of surgical implants. Material shall conform to the applicable requirements of Specifications F138, F1314, F1586, F2229, or F2581. 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 3 to 34 mm [0.125 to 1.315 in.] nominal outside diameter (OD) and 0.5 mm [0.020 in.] and greater 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 SI units or inch-pound units are to be regarded separately as standard. 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 nonconformance 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)

F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium–13 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)

F1586 Specification for Wrought Nitrogen Strengthened 21Chromium—10Nickel—3Manganese—2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)

F2229 Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)

F2581 Specification for Wrought Nitrogen Strengthened 11Manganese-17Chromium-3Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29225)

2.2 *ASTM Standards:*

A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels

A269 Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service

A632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small-Diameter) for General Service

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

F2257 Specification for Wrought Seamless or Welded and Drawn 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)

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

[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.

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

ISO 9001 Quality Management System—Requirements
ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes

2.4 *ASME Standard:*[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 around the circumference on any one transverse cross section of a single sample of tube.

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.

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 A269 or Specification A632 shall apply. Flare testing is not applicable.

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 and date of issue,
5.1.4 Units to be certified—SI or inch-pound,
5.1.5 Condition (see 6.2),
5.1.6 Surface finish (see 6.3),
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 1 and Table 2),
5.1.9 Condition (see 6.2),
5.1.10 Surface finish (see 6.3),
5.1.11 Special requirements or supplements, if any, and

TABLE 1 Permissible Variation in OD Dimensions

Nominal OD, mm [in.]	Permissible Variation from Nominal[A]	
	Standard Tolerance, mm [in.]	Half Standard Tolerance,[B] mm [in.]
3.2 to 12.7 excl. [0.125 to 0.500]	± 0.050 [0.002]	±0.025 [0.001]
12.7 to 25.4 excl. [0.500 to 1.00]	±0.075 [0.003]	±0.038 [0.0015]
25.4 to 34 incl. [1.00 to 1.315]	±0.100 [0.004]	±0.050 [0.002]

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

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

TABLE 2 Permissible Variation in ID Dimensions

Nominal ID, mm [in.]	Permissible Variation from Nominal, mm [in.][A]
Up to 12.7 excl. [0.500]	±0.050 [0.002]
12.7 to 25.4 excl. [0.500 to 1.00]	±0.075 [0.003]
25.4 and over [1.00]	±0.100 (0.004]

[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.

5.1.12 Certification requirements.

6. Materials and Manufacture

6.1 *Method of Manufacture:*

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

6.2 *Condition:*

6.2.1 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.

6.3 *Surface Finish:*

6.3.1 The tubing outer surface shall be furnished with a pickled, cold drawn, bright annealed, ground, or polished finish. Outer surface roughness shall be 0.8 µm [30 µin.] Ra maximum.

6.3.2 The tubing inner surface shall be furnished with a pickled, cold drawn, bright annealed, or abrasive conditioned finish. Inner surface roughness shall be 1.5 µm [60 µin.] Ra maximum.

6.3.3 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 of the finished tube shall conform to the requirements of the appropriate ASTM material standard. Alternative mechanical properties may be agreed upon between the purchaser and the supplier.

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

8. Permissible Outer and Inner Surface Imperfections

8.1 For tubes with wall thickness greater than or equal to 1.5 mm [0.060 in.] and less than 6.5 mm [0.250 in.], neither outer nor inner surface imperfections shall exceed 0.08 mm [0.003 in.] in depth. For tubes with wall thickness greater than or equal to 6.5 mm. [0.250 in], neither outer nor inner surface imperfections shall exceed 0.13 mm [0.005 in.] in depth. For tubes with wall thickness less than 1.5 mm [0.060 in.], outer and inner surface imperfection depth shall be agreed upon between purchaser and supplier.

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

8.3 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 6.3.1.

9. Special Tests

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

9.2 When required by the appropriate ASTM material standard, both OD and ID surfaces of the finished tube shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practice E of Practices A262.

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 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*—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.

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 negotiated between purchaser and supplier.

10.2.2.3 Wall thickness shall be measured directly with a micrometer or linear variable displacement transducer (LVDT), coordinate measuring machine (CMM), 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.

10.3 *Length:*

10.3.1 For exact length orders up to and including 7.5 m [24 ft], the length tolerance shall be ±3 mm [±0.125 in.].

10.3.2 On 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 1.5 m [5 ft] unless permitted by the purchaser.

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

11. Significance of Numerical Limits

11.1 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.

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 to the purchaser at the time of shipment.

13. Quality Program Requirements

13.1 1 The producer shall maintain a quality program such as defined in ISO 9001 or ISO 13485.

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

14. Keywords

14.1 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 F138, F1314, F1586, F2229, and F2581 stainless steels typically used in cannulated intramedullary nails and medical bone screws. A similar specification, Specification F2257 covers the use of austenitic stainless steels in smaller diameter implantable tubing typically used for coronary stents.

X1.2 ISO Standards are listed for reference only. Although the ISO Standards listed in 2.3 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 F138. The Composition of ISO 5832-9 is similar to Specification F1586. There is no corresponding ISO document at this time for Specifications F1314, F2229, or F2581.

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

X1.4 When measuring wall thickness, tube to be measured shall be sufficiently prepared to eliminate any burr or other material that may interfere with accurate mechanical or optical measurement. This preparation can be done by end finishing procedures such as reaming and deburring, ElectroChemical Machining (ECM) cutting, or ElectroDischarge machining (EDM) wire cutting (for direct micrometer, dial indicator, Linear Variable Displacement Transducers LVDT, and Coordinate Measuring Machines CMM measurement) or metallographic mounting, grinding, and polishing (for optical measurement). Metallographic preparation for optical measurement shall be performed in such a way as to maximize sample edge retention and minimize sample deviation from perpendicular. Micrometers used for wall measurement shall have a pin diameter or effective anvil diameter less than the minimum tube ID size. Dial indicators, LVDTs, and CMMs shall have a precision consistent with the required wall thickness tolerance.

X1.5 Percent concentricity as defined in 3.1.8 represents the full range of concentricity expressed as a percent of the sample average wall thickness. 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 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 3.1.8, 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 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.

X1.7 Surface imperfections may be detected by a number of methods. This includes visual inspection methods. 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.

X1.8 Heat treating the wrought nitrogen strengthened stainless steels listed in Specifications F2229 and F2581 in an oxidizing atmosphere results in the formation of a magnetic (ferritic) surface layer on the heat treated product. This surface layer shall be removed from the finished tube surfaces prior to its use in a medical device.

X1.9 *Units of Measure:*

X1.9.1 *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 The biocompatibility of Specifications F138, F1314, F1586, F2229, and F2581 is addressed in each ASTM material standard.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2181 – 09) that may impact the use of this standard. (Approved Oct. 1, 2014.)

(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 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 related to ASTM policy on SI units.
(5) Added ISO 13485 as an option to the ISO 9001 quality system.