



Designation: ~~F2181-08~~ Designation: F 2181 - 09

# Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants<sup>1</sup>

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 ( $\epsilon$ ) 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 F 138, F 1314, F 1586, F 2229, or F 2581. 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.~~

1.2 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 will be referred to as the ASTM material standard(s) in this specification.~~

~~1.4 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard. 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:<sup>2</sup>

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

F 1314 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)

F 1586 Specification for Wrought Nitrogen Strengthened 21Chromium10Nickel3Manganese2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)

F 2229 Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)

~~F 2257 Specification for Wrought Seamless or Welded and Drawn 18-Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)~~

F 2581 Specification for Wrought Nitrogen Strengthened 11Manganese-17Chromium-3Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29225)

### 2.2 ASTM Tubing Standards:

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels

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

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

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

<sup>1</sup> 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.

Current edition approved ~~May~~ Feb. 1, 2008-2009. Published ~~June~~ 2008-July 2009. Originally approved in 2002. Last previous edition approved 2002-2008 as F2181-02a-F 2181 - 08.

<sup>2</sup> 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.

F 2257 Specification for Wrought Seamless or Welded and Drawn 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants (UNS S31673)

SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.3 ISO Standards:<sup>3</sup>

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

ISO 9001 Quality Management System—Requirements

2.4 American Society for Quality Standard:

ASQ C1 Specification of General Requirements for a Quality Program

2.5

2.4 ASME Standard:<sup>4</sup>

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, n*

3.1.2 *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 *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 by the purchaser without regard to tolerance.

3.1.6 *nominal wall thickness*—the wall thickness specified by the purchaser 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 concentricity. Also for purposes of this specification, sample concentricity shall be expressed as a percent and shall be calculated using the following equation: —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:~~

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

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.

~~3.1.9.1 Discussion—In practice, the sample maximum wall thickness may be the largest of no less than four individual wall thickness measurements taken at uniformly spaced locations around the circumference of a single sample of the 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.

~~3.1.10.1 Discussion—In practice, the sample minimum wall thickness may be the smallest of no less than four individual wall thickness measurements taken at uniformly spaced locations around the circumference of a single sample of the tube.~~

<sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

<sup>4</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

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

#### 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 event that~~ 4.3 If a conflict exists between this specification and those listed in Section 2, or ~~in the event that~~ 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 ~~designations~~specification and date of issue,

5.1.3 The appropriate ASTM material standard and date of issue,

~~5.1.4 Applicable dimensions including OD and ID, OD and wall or ID and wall, length (exact, random, multiples) or engineering drawing reference number,~~

~~5.1.5 Dimensional tolerances (see~~

~~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),~~

~~5.1.6 Condition (see~~

~~5.1.9 Condition (see 6.2),~~

~~5.1.7 Surface finish (see~~

~~5.1.10 Surface finish (see 6.3),~~

5.1.811 Special requirements or supplements, if any, and

5.1.912 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 ~~30  $\mu$ m. (0.75  $\mu$ m)~~ 0.8  $\mu$ m (30  $\mu$ in.) Ra maximum.

**TABLE 1 Permissible Variation in OD Dimensions**

Nominal OD, mm (in. <del>(mm)</del> )	Permissible Variation from Nominal <sup>A</sup>	
	Standard Tolerance, mm (in. <del>(mm)</del> )	Half Standard Tolerance, <sup>B</sup> mm (in. <del>(mm)</del> )
0.125 to 0.500 excl. <del>(3.2 to 12.7)</del>	$\pm 0.002$ (0.051)	$\pm 0.001$ (0.025)
3.2 to 12.7 excl. (0.125 to 0.500)	$\pm 0.050$ (0.002)	$\pm 0.025$ (0.001)
0.500 to 1.000 excl. <del>(12.7 to 25.4)</del>	$\pm 0.003$ (0.076)	$\pm 0.0015$ (0.038)
12.7 to 25.4 excl. (0.500 to 1.00)	$\pm 0.075$ (0.003)	$\pm 0.038$ (0.0015)
1.00 to 1.315 incl. <del>(25.4 to 33.4)</del>	$\pm 0.004$ (0.102)	$\pm 0.002$ (0.051)
25.4 to 34 incl. (1.00 to 1.315)	$\pm 0.100$ (0.004)	$\pm 0.050$ (0.002)

<sup>A</sup> 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.

<sup>B</sup> Half standard tolerance may be used when specifying tubing for use on machining centers with tight collet clearance.