



Designation: ~~F2181-02a~~ Designation: **F 2181 - 08**

Standard Specification for Wrought Seamless Stainless Steel Tubing for Surgical Implants¹

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 F138*~~

~~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, or F1586, 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.~~

~~1.3 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~~

~~1.3 The specifications in 2.1 will be referred to as the ASTM material standard(s) in the remainder of this specification. 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.~~

2. Referenced Documents

~~2.1 ASTM Material Standards: F138 Specification 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)~~

~~F1314 Specification for Wrought Nitrogen Strengthened 22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S20910)²~~

~~<https://standards.iteh.ai/catalog/standards/sist/3b13-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 Bar for Surgical Implants (UNS S31675)²~~

~~<https://standards.iteh.ai/catalog/standards/sist/3b21-chromium-10-nickel-3-manganese-2.5-molybdenum-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~~

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.

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

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2.3-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

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 Steel⁴—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:⁴

C1 Specification of General Requirements for a Quality Program—ASQ C1 Specification of General Requirements for a Quality Program

2.5 ASME Standard:⁵

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.

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:

$$\text{Percent Concentricity} = 2 \times \left(\frac{\text{maximum wall} - \text{minimum wall}}{\text{maximum wall} + \text{minimum wall}} \right) \times 100$$

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—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:

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

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 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>.

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

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

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

⁵ Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Three Park Ave., New York, NY 10016-5990, <http://www.asme.org>.