



Designation: F 2181 – 02

## 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 (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)<sup>2</sup>

F 1314 Specification for Wrought Nitrogen Strengthened-22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S20910)<sup>2</sup>

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

#### 2.2 ASTM Tubing Standards:

A 269 Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service<sup>3</sup>

A 632 Specification for Seamless and Welded Austenitic Stainless Steel Tubing (Small Diameter) for General Service<sup>3</sup>

#### 2.3 ISO Standards:

ISO 5832-1 Implants for Surgery—Metallic Materials—

Part 1: Wrought Stainless Steel<sup>4</sup>

ISO 5832-9 Implants for Surgery—Metallic Materials—

Part 9: Wrought High Nitrogen Stainless Steel<sup>4</sup>

2.4 American Society for Quality Standard:

C1 Specification of General Requirements for a Quality Program<sup>5</sup>

### 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*—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:

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

The calculated percent concentricity may be added to and subtracted from the average wall thickness to express the actual range of wall variation due to concentricity. Percent concentricity may also be used as a plus and minus tolerance which when applied to the nominal wall thickness defines the allowable range of wall variation due to concentricity.

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.

<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.

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<sup>2</sup> Annual Book of ASTM Standards, Vol 13.01.

<sup>3</sup> Annual Book of ASTM Standards, Vol 01.01.

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

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