



Designation: F2527 – 24

Standard Specification for Wrought Seamless and Welded and Drawn Cobalt Alloy Small Diameter Tubing for Surgical Implants (UNS R30003, UNS R30008, UNS R30035, UNS R30605, and UNS R31537)¹

This standard is issued under the fixed designation F2527; 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 wrought seamless and welded and drawn cobalt alloy small diameter tubing used for the manufacture of surgical implants. Material shall conform to the applicable requirements of Specifications **F90**, **F562**, **F688**, **F1058** or **F1537**, Alloy 1. This specification addresses those product variables that differentiate small diameter medical tubing from the bar, wire, sheet, and strip product forms covered in these specifications.

1.2 This specification applies to straight length tubing with 6.3 mm [0.250 in.] and smaller nominal outside diameter (OD) and 0.76 mm [0.030 in.] and thinner 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 are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recom-*

mendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 ASTM Material Standards:²

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F688 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)

F1058 Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire, Strip, and Strip Bar for Surgical Implant Applications (UNS R30003 and UNS R30008)

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

2.2 ASTM Standards:

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

E8/E8M Test Methods for Tension Testing of Metallic Materials

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

E45 Test Methods for Determining the Inclusion Content of Steel

E112 Test Methods for Determining Average Grain Size

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.

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

F2819 Test Methods for Measurement of Straightness of Bar, Rod, Tubing and Wire to be used for Medical Devices
IEEE/ASTM SI 10 American National Standard for Metric Practice

2.3 ISO Standards:³

ISO 5832-5 Implants for Surgery—Metallic Materials Part 5: Wrought Cobalt, Chromium, Tungsten, Nickel Alloy

ISO 5832-6 Implants for Surgery—Metallic Materials Part 6: Wrought Cobalt, Nickel, Chromium, Molybdenum Alloy

ISO 5832-7 Implants for Surgery—Metallic Materials Part 7: Wrought Cobalt, Chromium, Molybdenum Alloy

ISO 5832-8 Implants for Surgery—Metallic Materials Part 8: Wrought Cobalt, Nickel, Chromium, Molybdenum, Tungsten, Iron Alloy

ISO 5832-12 Implants for Surgery—Metallic Materials Part 12: Wrought Cobalt, Chromium, Molybdenum Alloy

ISO 6892 Metallic Materials—Tensile Testing

ISO 9001 Medical Devices—Quality Management Systems—Requirements

ISO 13485 Medical Devices—Quality Management Systems—Requirements

2.4 ASME Standard:

ASME Y14.5.1M 1994 (R2004) Mathematical Definition of Dimensioning and Tolerancing Principles⁴

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 *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.

3.1.3 *lot*—the total quantity of product produced from the same melt heat under the same conditions, at essentially the same time.

3.1.4 *lot average concentricity*—the arithmetic average of the sample concentricities measured on a statistically representative number of samples from the lot.

3.1.5 *lot average wall thickness*—the arithmetic average of the sample average wall thicknesses measured on a statistically representative number of samples from the lot.

3.1.6 *nominal outside diameter (OD)*—the outside diameter specified on the customer order or engineering drawing without regard to tolerance.

3.1.7 *nominal wall thickness*—the wall thickness specified on the customer order or engineering drawing without regard to tolerance.

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

3.1.8 *sample average wall thickness*—the arithmetic average of all individual wall thickness measurements measured on a single sample.

3.1.9 *sample concentricity*—two times the offset between the centers of two circles, representing the outside diameter (OD) and the inside diameter (ID) of the tube.

3.1.9.1 *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. 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:

$$\text{Sample Concentricity Percent} = 2 \times \left(\frac{A - B}{A + B} \right) \times 100 \quad (1)$$

where:

A = sample maximum wall, and

B = sample minimum wall.

3.1.10 *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.

3.1.11 *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.

3.1.12 *seamless tubing*—tubing made by a process in which the tube periphery is continuous at all stages of the process.

3.1.13 *welded and drawn tubing*—tubing fabricated from strip or sheet using welding, drawing, and annealing operations.

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.

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 Method of manufacture (seamless or welded and drawn; see 6.1),

5.1.6 Condition (see 6.2),

5.1.7 Surface finish (see 6.3),

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