



Designation: F2527 – 05<sup>ε1</sup>

# 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)<sup>1</sup>

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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

<sup>ε1</sup> NOTE—Section references in Section 5 were editorially changed in April 2006.

## 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 0.250 in. (6.3 mm) and smaller nominal outside diameter (OD) and 0.030 in. (0.76 mm) and thinner nominal wall thickness.

1.3 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:*<sup>2</sup>

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 and Strip 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 Test Methods for Tension Testing of Metallic Materials

E45 Test Methods for Determining the Inclusion Content of Steel

E112 Test Methods for Determining Average Grain Size

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

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

2.4 *American Society for Quality Standard:*

ASQ C1 Specification of General Requirements for a Quality Program<sup>4</sup>

<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> 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.

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

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

### 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 the outside diameter (OD) and the inside diameter (ID) of the tube.

3.1.2.1 *Discussion*—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:

$$\text{Percent Concentricity} = 2 \times \left( \frac{\text{maximum wall} - \text{minimum wall}}{\text{maximum wall} + \text{minimum wall}} \right) \times 100 \quad (1)$$

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

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

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

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

3.1.6.1 *Discussion*—Welding shall be performed using a liquid phase weld process with no filler metal. Typical weld processes are tungsten inert gas (TIG) and laser. The drawing and annealing operations shall be performed in such a way that the weld bead and heat affected zone are virtually indistinguishable microstructurally and dimensionally from the parent metal when examined per 11.3.

### 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 designation and date of issue,
- 5.1.3 ASTM material standard and date of issue,
- 5.1.4 Method of manufacture (seamless or welded and drawn; see 6.1),
- 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 Section 9 and Table 1),
- 5.1.9 Certification requirements, and
- 5.1.10 Special requirements or supplementary requirements, if any.

**TABLE 1 Permissible Variation in OD and ID Dimensions**

Nominal OD or ID in. (mm)	Permissible Variation from Nominal <sup>A</sup> in. (mm)
Less than 0.060 (1.54)	±0.0005 (0.013)
0.060 to 0.250 (1.54 to 6.30) incl.	±0.001 (0.025)

<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 range of size tolerance is not less than the total range shown in the table.

### 6. Materials and Manufacture

#### 6.1 Method of Manufacture:

6.1.1 Seamless tubing shall be made from bar, hollow bar, rod, or hollow rod raw material forms that meet the chemical requirements of the appropriate material specification.

6.1.1.1 Seamless tubing shall be made by a process consistent with the definition in 3.1.5.

6.1.2 Welded and drawn tubing shall be made from strip or sheet raw material forms that meet the chemical requirements of the appropriate material specification.

6.1.2.1 Welded and drawn tubing shall be made by a process consistent with the definition in 3.1.6.

6.2 *Condition*—Tubing shall be furnished, as specified, in the annealed, solution annealed, warm worked or cold worked and aged 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 cold-drawn, bright annealed, ground or polished finish. Outer surface roughness shall be a maximum of 25 μin. (0.63 μm) Ra.

6.3.2 The tubing inner surface shall be furnished with an as-drawn finish, bright annealed or conditioned finish. Inner surface roughness shall be a maximum of 30 μin. (0.75 μm) Ra.

6.3.3 The method used to determine surface roughness shall be agreed upon between purchaser and supplier.

### 7. Chemical Composition

7.1 The heat analysis limits and product analysis tolerances of the appropriate ASTM material specification shall apply.

7.2 Alternative chemistries with more restrictive limits than those in the ASTM material specifications may be specified as agreed upon by purchaser and supplier.

### 8. Mechanical Properties

8.1 The required mechanical properties shall be selected from the tables for similar product forms in the appropriate material specification. Where bar or wire data is presented, the mechanical properties listed for bar or wire of similar OD size shall apply. Where sheet or strip data is presented, the mechanical properties for sheet or strip with thickness similar to the tubing wall thickness shall apply. Tensile testing shall be in accordance with Test Methods E8 using unmachined tubular specimens. Alternative mechanical properties may be agreed upon between purchaser and supplier.

8.2 In the event that both tensile properties and hardness are specified on the purchase order, tensile properties shall be used to accept or reject. Hardness shall be reported for information only.