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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 ~~may not be exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other. Combining other, and values from the two systems may result in non-conformance with the standard; 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 Recommendations 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)

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

- 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
- E8E8/E8M** Test Methods for Tension Testing of Metallic Materials—~~Metric~~—~~E0008~~—~~E0008M~~
- 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
- 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 ~~Use of the International System of Units (SI): The Modern Metric System~~Metric Practice

2.3 ISO Standards:³

- ISO 5832–55832-5** Implants for Surgery—Metallic Materials Part 5: Wrought Cobalt, Chromium, Tungsten, Nickel Alloy
- ISO 5832–65832-6** Implants for Surgery—Metallic Materials Part 6: Wrought Cobalt, Nickel, Chromium, Molybdenum Alloy
- ISO 5832–75832-7** Implants for Surgery—Metallic Materials Part 7: Wrought Cobalt, Chromium, Molybdenum Alloy
- ISO 5832–85832-8** Implants for Surgery—Metallic Materials Part 8: Wrought Cobalt, Nickel, Chromium, Molybdenum, Tungsten, Iron Alloy
- ISO 5832–125832-12** 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)** ~~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~~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~~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~~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~~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,

5.1.9 Dimensional tolerances (see Section 10 and Table 1),

TABLE 1 Permissible Variation in OD and ID Dimensions

Nominal OD or ID mm [in.]	Permissible Variation from Nominal ^A mm [in.]
Less than 1.5 [0.060]	±0.013 [0.0005]
1.5 to 6.3 [0.060 to 0.250] incl.	±0.025 [0.001]

^A 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.

5.1.10 Special requirements or supplementary requirements, if any, and

5.1.11 Certification requirements.

6. Materials and Manufacture

6.1 Method of Manufacture:

6.1.1 Tubing shall be made by the seamless or the welded and drawn process.

6.1.1.1 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.

6.1.1.2 Seamless tubing shall be made by a process consistent with the definition in 3.1.12.

6.1.2 Welded and drawn tubing shall be fabricated from strip or sheet using welding, drawing, and annealing operations. 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.

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, ground₁ or polished finish. Outer surface roughness shall be a maximum of 0.6 μm [25 μin.] Ra.

6.3.2 The tubing inner surface shall be furnished with an as-drawn finish, bright annealed₂ or conditioned finish. Inner surface roughness shall be a maximum of 0.8 μm [30 μin.] 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