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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]

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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, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

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 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

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

SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

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

[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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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

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 Principles[4]

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.

3.1.8 *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 simple sample of the tube. Sample concentricity shall be expressed as a percent of the wall thickness and shall be calculated using the following equation:

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

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),

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.

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.

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

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, ground 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 annealed 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 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 If 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.

8.3 Elongation of bar and wire material 1.6 mm [0.063 in.] or greater in diameter (D) shall be measured using a gauge length of 50 mm [2 in.], or 4D. The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] shall be agreed upon between purchaser and supplier. Alternatively, a gauge length corresponding to ISO 6892 (5.65 times the square root of So, where So is the original cross sectional area) may be used when agreed upon between purchaser and supplier.

8.4 Elongation for sheet and strip product shall be tested and reported as required in the appropriate material specification.

9. Permissible Outer and Inner Surface Imperfections

9.1 Outer surface imperfection shall not exceed 10 % of wall thickness in depth. Outer surface imperfections may be removed by grinding or polishing prior to shipment, providing that the resultant wall thickness meets the minimum wall thickness, and that the ground or polished surface meets the surface finish requirements of 6.3.1.

9.2 Inner surface imperfections shall not exceed 10 % of wall thickness in depth.

9.3 The method of inspecting for these imperfections shall be agreed upon between the purchaser and supplier.

10. Dimensions and Permissible Variation

10.1 *Units of Measure:*

10.1.1 *Selection*—This specification requires that the purchaser selects the units of measure (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

10.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

10.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's PO, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

10.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between purchaser and supplier.

10.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. ASTM SI 10 provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits.

10.2 *Permissible Variation in Dimensions:*

10.2.1 *OD and ID—*

10.2.1.1 Permissible variations of OD and ID from the nominal dimension on the purchase order or engineering drawing are listed in Table 1.

10.2.1.2 OD may be measured by hand micrometer, by linear variable displacement transducer (LVDT), by laser micrometer or by other non-contact method.

10.3 *Wall Thickness:*

10.3.1 For wall thickness of 0.10 mm [0.004 in.] or greater, the range of total wall variation (including concentricity and average wall variation) shall not exceed 14 % (±7 %) of