



Designation: F688 – 05

Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)¹

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1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought cobalt-35nickel-20chromium-10molybdenum alloy (UNS R30035) in the form of plate, sheet, and foil to be used in the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards*:²

E8 Test Methods for Tension Testing of Metallic Materials

E10 Test Method for Brinell Hardness of Metallic Materials

E18 Test Methods for Rockwell Hardness of Metallic Materials

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

E92 Test Method for Vickers Hardness of Metallic Materials

E112 Test Methods for Determining Average Grain Size

E140 Hardness Conversion Tables for Metals Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Superficial Hardness, Knoop Hardness, and Scleroscope Hardness

E345 Test Methods of Tension Testing of Metallic Foil

E384 Test Method for Microindentation Hardness of Materials

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

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of

Materials on Muscle and Bone

2.2 *American Society for Quality Standard:*

ASQ C1 Specification of General Requirements for a Quality Program³

3. Terminology

3.1 *Descriptions of Terms Specific to This Standard:*

3.1.1 *capability*—used to indicate the ability of cold worked material to attain specific mechanical properties after thermal aging treatment.

3.1.2 *foil*—material under 0.005 in. (0.127 mm) in thickness.

3.1.3 *lot*—the total number of mill products produced from the same mill heat under the same conditions at essentially the same time.

3.1.4 *plate*—as used in this specification, material 0.1875 in. (4.76 mm) and over in thickness.

3.1.5 *sheet*—as used in this specification, material 0.005 in. (0.127 mm) to under 0.1875 in. (4.76 mm) in thickness.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM Designation,

4.1.3 Form (plate, sheet, foil),

4.1.4 Condition (see 5.1),

4.1.5 Mechanical properties (if applicable for special conditions),

4.1.6 Finish (see 5.2 and 5.3),

4.1.7 Edge (see 5.4 and 5.5),

4.1.8 Applicable dimensions, including size, thickness, width, and length (exact, random, or multiples) or print number, and

4.1.9 Special requirements.

5. Manufacture

5.1 *Condition*—Plate, sheet, and foil shall be furnished as specified in the annealed, cold-worked, or cold-worked and capability-aged condition.

³ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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.

5.2 Finishes for Plate:

5.2.1 Types of finish available for plate are ground finish produced by surface grinding or continuous belt sanding and dull finish produced by chemical descaling.

5.3 Finishes for Sheet and Foil:

5.3.1 Types of finish available for sheet and foil are dull cold rolled, bright cold rolled, intermediate polished, general-purpose polished, dull satin-finished, high luster finish, mirror finish, or as specified in the purchase order.

5.4 Edges for Plate:

5.4.1 Rolled edge or approximate square edge produced by abrasive sawing.

5.5 Edges for Sheet and Foil:

5.5.1 For sizes greater than 0.060 in. (1.524 mm) in thickness, an approximate square edge produced by abrasive sawing; For sizes under 0.060 in. (1.524 mm) an edge produced by slitting or shearing.

6. Chemical Composition

6.1 The heat analysis and product analysis tolerance shall conform to the requirements as to chemical composition as specified in Specification **F562**.

7. Mechanical Requirements

7.1 Tensile Properties:

7.1.1 Tensile properties for plate and sheet shall be determined in accordance with Test Methods **E8** while tensile properties for foil shall be determined in accordance with Test Methods **E345**.

7.1.2 Perform at least one tension test from each lot. Should any of the test pieces not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if both additional test pieces meet the specified requirements.

7.1.3 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable if the elongation meets the minimum requirements specified. Refer to Test Methods **E8** sections 7.11.4. If the elongation is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirement.

7.1.4 Product forms in the annealed condition shall meet the mechanical property requirements specified in **Table 1**.

7.1.5 Sheet product in the 48 % cold-worked condition shall meet the mechanical property requirements specified in **Table 1**. Other product forms and cold-worked conditions shall meet the mechanical property requirements as agreed upon between the supplier and purchaser.

7.1.6 Product forms in the cold-worked and capability-aged condition shall meet the mechanical property requirements as agreed upon between the supplier and purchaser.

TABLE 1 Sheet Mechanical Properties

Condition	Ultimate Tensile Strength, min, psi	Yield Strength (0.2 % offset), min, psi (MPa) ^A	Elongation, min, % in 2 in. or 50 mm	Rockwell Hardness, min
	(MPa) ^A	(MPa) ^A		
Annealed ^B	115 000 (792)	45 000 (310)	45	87 HRB
48 % cold worked	197 000 (1357)	195 000 (1343)	3	43 HRC

^A Tensile and yield requirements apply to tests taken longitudinally to the rolling direction.

^B 0.0197 in. (0.5 mm) sheet, vacuum annealed at 1875°F (1022°C), 2 h at temperature.

7.2 Hardness:

7.2.1 When desired, Rockwell hardness B scale (HRB), Rockwell hardness C scale (HRC), or Vickers hardness (HV) limits may be specified, as agreed upon between the purchaser and the supplier. Test Methods **E10**, **E18**, **E92**, **E384** and Hardness Conversion Tables **E140** shall be used.

7.2.2 Hardness values are for information only and shall not be used as a basis for rejection.

8. Special Tests

8.1 If supplied in the annealed condition, the average grain size shall be predominantly four or finer when tested in accordance with Test Methods **E112**.

8.1.1 It is preferred that samples for grain size determination be selected after the final annealing operation and prior to a final cold-working operation or prior to final cold-working and capability-aging operations.

8.1.2 If samples are selected after a final cold-working operation or after final cold-working and capability-aging operations, specimens shall be tested according to Test Method **E112**, or as agreed to between supplier and purchaser.

8.2 Any other special requirements shall be agreed upon between the supplier and purchaser.

9. Significance of Numerical Limits

9.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding of Practice **E29**.

10. Certification

10.1 Certification shall be provided by the supplier that the material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The supplier shall maintain a quality program such as defined in **ASQ C1**.

12. Keywords

12.1 cobalt alloys (for surgical implants); cobalt-nickel alloy; metals (for surgical implants)—cobalt alloys