~~Designation:F688–05~~ Designation: F688 – 10

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

This standard is issued under the fixed designation F688; 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 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.

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

1.2 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 Standards:*[2]

E8~~8~~/E8M 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 ~~E92Test 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 Knoop and Vickers 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~~ Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

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

2.2 ~~*American Society for Quality Standard:*~~ *ISO Standards:*

~~ASQ C1Specification of General Requirements for a Quality Program~~ISO 9001 Quality Management Systems—Requirements[3]

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.

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[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 Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.~~

[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.**

3.1.2 *foil*—material under 0.005 in. (0.127 mm) in thickness. —material under 0.13 mm [0.005 in.] in thickness.

3.1.3 *lot*—the total number of mill products produced from the same melt 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)4.75 mm [0.1875 in.] 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. —as used in this specification, material 0.13 mm [0.005 in.] to under 4.75 mm [0.1875 in.] 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),

4.1.2ASTM Designation,

4.1.3Form (plate, sheet, foil),

4.1.4Condition (see

4.1.2 ASTM Designation, alloy number, and date of issue,

4.1.3 Units to be used for certification—SI or inch-pound,

4.1.4 Form (plate, sheet, foil),

4.1.5 Condition (see 5.1),

4.1.56 Mechanical properties (if applicable for special conditions),

4.1.67 Finish (see 5.2 and 5.3),

4.1.7Edge (see

4.1.8 Edge (see 5.4 and 5.5),

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

4.1.10 Special tests (if any), and

4.1.9Special4.1.11 Other 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.

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)1.5 mm [0.060 in.] in thickness, an approximate square edge produced by abrasive sawing; For sizes under 0.060 in. (1.524 mm)1.5 mm [0.060 in.] an edge produced by slitting or shearing.

6. Chemical Composition Chemical Requirements

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 E8/E8M 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 bothall 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/E8M sections, section 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.

TABLE 1 Sheet Mechanical Properties

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

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

[B] 0.5 mm [0.0197 in. ~~(0.5 mm)~~] sheet, vacuum annealed at 1~~875°F (1022°C)~~ [1875°F], 2 h at temperature.

~~7.1.6Product~~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.

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.~~

8. Dimensions and Permissible Variation

8.1 *Units of Measure*:

8.1.1 *Selection*—This specification requires that the purchaser select 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.

8.1.1.1 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.

8.1.1.2 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.

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

8.1.2 *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.

9. Special Tests

~~8.1If~~9.1 If supplied in the annealed condition, the average grain size shall be predominantly four or finer when tested in accordance with Test Methods E112.

~~8.1.1It~~9.1.1 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.

~~8.1.2If~~9.1.2 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.

~~8.2Any~~9.2 Any other special requirements shall be agreed upon between the supplier and purchaser.

~~9.~~10. Significance of Numerical Limits

~~9.1The~~10.1 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~~Rounding Method of Practice E29.

~~10.Certification~~

~~10.1Certification 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. Certification

11.1 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.