Designation: F688 – 14

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.

1.2 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 this standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/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

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, Scleroscope Hardness, and Leeb 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

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

2.2 *ISO Standards:*

ISO 9001 Quality Management Systems—Requirements[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.2 *foil*—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 4.75 mm [0.1875 in.] and over in thickness.

3.1.5 *sheet*—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);

4.1.2 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);

4.1.6 Mechanical properties (if applicable for special conditions);

4.1.7 Finish (see 5.2 and 5.3);

4.1.8 Edge (see 5.4 and 5.5);

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

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

Current edition approved Oct. 1, 2014. Published November 2014. Originally approved in 1980. Last previous edition approved in 2010 as F688 – 10. DOI: 10.1520/F0688-14.

[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**

4.1.10 Special tests (if any); and
4.1.11 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 1.5 mm [0.060 in.] in thickness, an approximate square edge produced by abrasive sawing ; For sizes under 1.5 mm [0.060 in.] an edge produced by slitting or shearing.

6. Chemical Requirements

6.1 The heat analysis and product analysis tolerances shall conform to the requirements for 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/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 all 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, 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, MPa [psi][A]	Yield Strength (0.2 % offset), min, MPa [psi][A]	Elongation, min, % in 50 mm or 2 in.	Rockwell Hardness, min
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.] sheet, vacuum annealed at 1022°C [1875°F], 2 h at temperature.

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, 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 ASTM grain size number four or finer when tested in accordance with Test Methods E112.

8.1.1 It is preferable 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 in accordance with Test Methods E112, or as agreed upon between the supplier and purchaser.

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

9. Dimensions and Permissible Variation

9.1 *Units of Measure:*

9.1.1 *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.

9.1.1.1 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.

9.1.1.2 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.

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

9.1.2 *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. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.

10. Significance of Numerical Limits

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 Method of Practice E29.

11. Certification

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

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program such as defined in ISO 9001 or similar quality program.

13. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize the composition and properties to assure consistency in the starting material used in the manufacture of medical devices.

X1.2 The acceptable metal conditions include annealed, cold-worked, or cold-worked and capability-aged. The choice is dependent upon the medical device design and its intended application.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been successfully employed in human implants (**1-5**)[4] for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F981.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications

[4] The boldface numbers in parentheses refer to the list of references at the end of this specification.

REFERENCES

(1) Gaechter, A., and Galante, G., "MP35N, A Corrosion Resistant High-Strength Alloy for Orthopaedic or Surgical Implants: Two Year Bioassay," *Journal of Biomedical Materials Research*, Vol 10, 1976, pp. 829–831.

(2) Escales, F., Galante, J., Rostoker, W., and Coogan, P. S., "MP35N, A Corrosion Resistant High Strength Alloy for Orthopaedic Surgical Implants: Bioassay Results," *Journal of Biomedical Materials Research*, Vol 9, No. 3, 1976, pp. 303–313.

(3) Kuehne, D., and Willert H. G., "The Tissue Compatibility of the Forging Alloy (Protasul 10) with the Hitherto Used Implant Alloys (Co-Cr-Mo Casting Alloy) and (AISI 316L) After an Implantation Period of One Year," Doctoral Thesis, Osteological Research Laboratory of Orthopaedic University, Frankfurt on Main/Frg, 1975.

(4) Bauman, R., and Semlitsch, M., "Biological and Mechanical Behavior of Newly Developed Implant Materials in Animal Studies," *Sulzer Reprint*, Re/28.09.00, 1974, pp 1–9.

(5) ISO/TC-150/SC-1/WG-1, Swiss Standard Association, Group 129-Surgical Implants, Draft Report of WG-1, Swiss Proposal 9056509, Part 2, Comments on Biocompatibility, Davos Meeting, June 1974.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F688 – 10) that may impact the use of this standard. (Approved Oct. 1, 2014)

(1) Editorial corrections have been made to meet terminology and formatting guidelines established for implant material standards within Subcommittee F04.12.
(2) Inverted the order of Dimensions and Permissible Variations and Special Tests sections and renumbered to comply with formatting guidelines of Subcommittee F04.12 documents.

(3) Deleted X1.3, Units of Measure, from the Appendix.