Designation: F 688 – 00

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

This standard is issued under the fixed designation F 688; 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 a wrought cobalt-35 nickel-20 chromium-10 molybdenum alloy plate, sheet, and foil used for the manufacture of surgical implants.

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

2. Referenced Documents

2.1 *ASTM Standards:*

A 480 Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip[2]

E 8 Methods for Tension Testing of Metallic Materials[3]

E 10 Test Method for Brinell Hardness of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 92 Test Method for Vickers Hardness of Metallic Materials[3]

E 112 Test Methods for Determining Average Grain Size[3]

E 140 Hardness Conversion Tables for Metals (Relationship Between Brinell Hardness, Vickers Hardness, Rockwell Hardness, Rockwell Superficial Hardness, and Knoop Hardness)[3]

E 345 Methods for Tension Testing of Metallic Foil[3]

E 384 Test Method for Microhardness of Materials[3]

F 562 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[4]

2.2 *Aerospace Materials Specification:*

AMS 2269 Chemical Check Analysis Limits—Wrought Nickel Alloys and Cobalt Alloys[5]

2.3 *American Society for Quality Standard:*

C 1 Specification of General Requirements for a Quality Program[6]

3. Terminology

3.1 *Descriptions of Terms Specific to This Standard:*

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

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

3.1.3 *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 5.2-5.4),

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

4.1.8 Special requirements.

5. Manufacture

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

5.2 *Finishes Available for Plate*:

5.2.1 Ground finish produced by surface grinding or continuous belt sanding.

5.2.2 Dull finish produced by chemical descaling.

5.3 *Finishes Available for Sheet*:

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[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[6] Available from the American Society for Quality, 161 West Wisconsin Ave., Milwaukee, WI 53203.

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

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5.3.1 Ground finish produced by continuous belt sanding for sizes 0.060 in. (1.524 mm) to under 0.1875 in. (4.76 mm).

5.3.2 Bright rolled finish for sizes under 0.060 in. (1.524 mm).

5.3.3 Dull finish on annealed or aged material.

5.4 *Finishes Available for Foil*:

5.4.1 Bright rolled finish.

5.4.2 Dull finish on annealed or aged material.

5.4.3 Mirror finish on rolled material.

5.5 *Edges Available for Plate*:

5.5.1 Rolled edge.

5.5.2 Approximate square edge produced by abrasive sawing.

5.6 *Edges Available for Sheet*:

5.6.1 For sizes greater than 0.060 in. (1.524 mm) in thickness, an approximate square edge produced by abrasive sawing.

5.6.2 For sizes under 0.060 in. (1.524 mm) an edge produced by slitting or shearing.

5.7 *Edge Available for Foil*—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 F 562.

7. Mechanical Requirements

7.1 Material ordered in the annealed condition shall conform to the requirements as to mechanical properties as agreed upon between the implant manufacturer and the vendor. Minimum mechanical property requirements for annealed products are listed in Table 1.

7.2 The current edition of Specification A 480 shall be used as a reference in the selection of tension test specimens.

7.2.1 The tension test specimens shall conform to the appropriate sections of Methods E 8 and E 345.

7.3 Material ordered in the cold-worked condition shall conform to the requirements as to mechanical properties as agreed upon between the implant manufacturer and the vendor.

TABLE 1 Sheet Mechanical Properties

Condition	Ultimate Tensile Strength, min, psi (MPa)[A]	Yield Strength (0.2 % offset), min, psi (MPa)[A]	Elongation, min, % in 2 in. or 50 mm	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

[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.

Mechanical property requirements for a 48 % cold-worked sheet product, etc. listed in Table 1.

7.4 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 implant manufacturer and the supplier. Test Methods E 10, E 18, E 92, E 384 and Standard Tables E 140 shall be used.

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 Methods E 112.

8.1.1 Samples for grain size determination shall be selected after the final annealing operation.

8.1.2 Any other special requirements shall be agreed upon between the implant manufacturer and the supplier.

9. Certification

9.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification, together with a report of the test results shall be furnished at the time of shipment.

10. Quality Program Requirements

10.1 The producer shall maintain a quality program, such as that defined in ASQ Specification C1 or any other recognized program.

11. Keywords

11.1 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, or cold worked. 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)**[7] 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 F 981.

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

[7] The boldface numerals 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 (F688–95) that may impact the use of this standard.

(1) The UNS designation has been added.
(2) Product analysis tolerance information was referred to F562.
(3) Test Specimens paragraph was deleted and requirements were included in the appropriate sub-paragraphs.
(4) F981, AMS 2269 and ASQ C1 specifications were updated.
(5) X2. Biocompatibility section was added to the Appendix.

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