Designation: F 562 – 00

Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications UNS R 30035[1]

This standard is issued under the fixed designation F 562; 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 requirements of wrought cobalt-35 nickel-20 chromium-10 molybdenum alloy in the form of bars and wires, used for the manufacture of surgical implants. This alloy depends on combinations of work-strengthening, and work-strengthening and aging to attain a variety of combinations of strength and ductility.

1.2 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents of the inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods for Tension Testing of Metallic Materials[2]

E 112 Test Methods for Determining the Average Grain Size[2]

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[3]

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 *Federal Standard:*

Federal Test Method No. 151 Metals; Test Methods[5]

2.3 *Aerospace Material Specifications:*

AMS 2269 Chemical Check Analysis Limits—Wrought Nickel Alloys and Cobalt Alloys[6]

2.4 *American Society for Quality Standard:*

ASQC1 Specification of General Requirements for a Quality Program[7]

2.5 *Society of Automotive Engineers:*

SAE J1086 Practice for Numbering Metals and Alloys (UNS)[6]

3. Terminology

3.1 *Description of Term Specific to This Standard:*

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

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 and date of issue,

4.1.3 Form (1.1),

4.1.4 Condition (5.1),

4.1.5 Mechanical properties (if applicable),

4.1.6 Finish (9.2),

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

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 *Condition*—Bar and wire shall be furnished , as specified, in the solution-annealed, cold-worked, or cold-worked and aged condition.

6. Chemical Requirements

6.1 The cobalt-35 nickel-20 chromium-10 molybdenum alloy shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1.

6.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

6.2 *Product Analysis*—The product analysis is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat.

6.2.1 Acceptance or rejection of a heat or lot of material

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

[3] *Annual Book of ASTM Standards*, Vol 03.05.

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

[5] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[6] Available from Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001.

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

TABLE 1 Chemical Requirements

Element	Composition,% (mass/mass)	
	min	max
Carbon	...	0.025
Manganese	...	0.15
Silicon	...	0.15
Phosphorus	...	0.015
Sulfur	...	0.010
Chromium	19.0	21.0
Nickel	33.0	37.0
Molybdenum	9.0	10.5
Iron	...	1.0
Titanium	...	1.0
Boron	...	0.015
Cobalt[A]	balance	balance

[A] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage cobalt content by difference is not required to be reported.

may be made by the purchaser on the basis of this product analysis.

6.2.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

7. Mechanical Requirements

7.1 Solution-annealed bar and wire product shall conform to the mechanical properties specified in Table 3. Test Methods E 8 shall apply.

7.2 Mechanical properties for the cold-worked and aged condition shall conform to the mechanical property requirements specified in Table 3.

7.3 Should it be necessary to illustrate the work strengthening capability of this alloy, the referee procedure will be the use of a straight draw bench at room temperature. A round bar shall be cold drawn 53 % to a smaller round bar.

7.4 The level of mechanical properties for material in other than the solution-annealed or 53 % cold-worked and aged condition shall be specified in the purchase order.

TABLE 2 Product Analysis Tolerances (% (mass/mass))[A]

Element	Tolerances over the max (upper limit) or under the min (lower limit), %[B]
Carbon	0.01
Manganese	0.03
Silicon	0.02
Phosphorus	0.005
Sulfur	0.005
Chromium	0.25
Nickel	0.30
Molybdenum	0.15
Iron	0.05
Titanium	0.04
Boron	0.005

[A] Refer to AMS 2269.

[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.

8. Special Tests

8.1 The grain size of bar product shall be predominantly No. 4 or finer with occasional grains as large as No. 2 permissible when tested in accordance with Test Methods E 112.

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

8.1.2 If samples are selected after final cold-working operations, transverse specimens shall be prepared.

8.2 For other than bar product, the grain size shall be agreed upon between the purchaser and the manufacturer.

9. Workmanship, Finish, and Appearance

9.1 All products shall be free from external and internal imperfections detrimental to the intended purpose.

9.2 *Finish*—Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

10. Test Methods

10.1 Chemical analysis shall be in accordance with Test Methods E 354, Federal Test Method No. 151, or as agreed upon between the purchaser and the manufacturer. The product after consumable electrode vacuum remelting may be used for reporting the chemical composition.

11. Certification

11.1 Upon request of the purchaser in the contract or order, a certification shall be provided by the manufacturer that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

12. Quality Program Requirements

12.1 The producer shall maintain a quality program, such as that defined in Specification ASQ 1.

12.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program conformance to the intent of Specification ASQ 1, or any other recognized program.

13. Keywords

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

TABLE 3 Mechanical Properties (Bar Products)

Condition	Tensile Strength,[A] psi (MPa)	Yield Strength,[A] 0.2 % Offset, psi (MPa)	Elongation in 4D or 4W, min, %	Reduction of Area, min, %
Solution annealed[B]	115 000 to 145 000 (793 to 1000)	35 000 to 65 000 (241 to 448)	50.0	65.0
Cold-worked and aged[C]	260 000 (1793) min	230 000 (1586) min	8.0	35.0

[A] Tension and yield requirements apply to tests taken longitudinally to the direction of rolling.
[B] 1925 ± 25°F (1050° + 15°C), 1 to 2 h at temperature, air cool or water quench to room temperature.
[C] Cold worked 53 % and aged within the range 1000 to 1200°F ± 25°F (540 to 645°C± 15°C) for 4 h and air cool.

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 solution annealed, cold worked or cold worked and capability aged, the choice dependent upon the medical device design and its intended application.

X1.3 A boron limit has been added to the chemical requirements to coincide with industry melting practice for this alloy.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been successfully employed in human implants **(1-5)**[8] for over a decade. This material has been found to produce a well characterized level of local biological response when tested in accordance with Practice F 981 or equivalent.

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 this material is used in appropriate applications.

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

REFERENCES

(**1**) Gaechter, A., 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., 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., 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 am Main/Frg, 1975.

(**4**) Bauman, R., Semlitsch, M., *Biological and Mechanical Behavior or 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 056509, Part 2, *Comments on Biocompatibility*, Davos Meeting, June 1974.