Designation: F562 – 13

Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)[1]

This standard is issued under the fixed designation F562; 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 35cobalt-35nickel-20chromium-10molybdenum alloy (UNS R30035) in the form of bar and wire, used for the manufacture of surgical implants. This alloy depends on combinations of work strengthening and aging to attain a variety of combinations of strength and ductility.

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]

A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

E8/E8M Test Methods for Tension Testing 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

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

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 Metric Practice

2.2 *ISO Standards:*[3]

ISO 5832/6 Implants for Surgery—Metallic Materials Part 6: Wrought cobalt-nickel-chromium-molybdenum Alloy

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems

2.3 *Aerospace Material Specifications:*[4]

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

AMS 2630 Inspection, Ultrasonic Product over 0.5 inch (12.7 mm) Thick

AMS 2632 Ultrasonic Inspection of Thin Materials

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *bar, n*—rounds, flats, or other shapes from 0.1875 to 4.00 in. [4.76 to 101.60 mm] in diameter or thickness (other sizes and shapes by special order).

3.1.2 *fine wire, n*—rounds, flats, or other shapes less than 0.063 in. [1.60 mm] in diameter or thickness.

3.1.3 *forging bar, n*—bar as described in 3.1.1, used for the production of forgings; may be furnished in the hot-worked condition.

3.1.4 *lot, n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

3.1.5 *wire, n*—round, flats, or other shapes less than 0.1875 in. [4.76 mm] in diameter or thickness.

4. Ordering Information

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

4.1.1 Quantity,

4.1.2 ASTM designation and date of issue,

4.1.3 Mechanical properties (Section 7),

4.1.4 Form (bar or wire),

[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.

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

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

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

4.1.5 Applicable dimensions, including size, thickness, width, and length (exact, random, multiples), or drawing number,
4.1.6 Condition (5.1),
4.1.7 Finish (5.2),
4.1.8 Special tests, if applicable, and
4.1.9 Other requirements.

5. Materials and Manufacture

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

5.2 *Finish*—Bar and wire shall be furnished in cold-drawn, pickled, ground, or ground and polished, as specified by the purchaser.

6. Chemical Requirements

6.1 Chemical analysis shall be in accordance with Test Methods E354 and A751.

6.2 The cobalt-35nickel-20chromium-10molybdenum 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.

6.2.1 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.

6.3 *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.

6.3.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.

6.3.2 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.

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.

TABLE 2 Product Analysis Tolerances[A,B]

Element	Tolerance Under the Minimum or Over the Maximum Limit % (mass/mass)[C]
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] See Test Method E354.
[B] See AMS 2269 for chemical check analysis limits.
[C] Under minimum limit not applicable for elements where only a maximum percentage is indicated.

7. Mechanical Requirements

7.1 *Tensile Properties:*

7.1.1 Tensile properties shall be determined in accordance with Test Methods E8/E8M. Perform a tension test on at least one piece from each lot. Should any test piece 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.

7.1.2 Tensile tests result for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.11.5 of Test Methods E8/E8M. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements

7.2 Solution-annealed bar and wire shall conform to the mechanical properties specified in Tables 3 and 4.

7.3 Mechanical properties for the cold-worked and cold-worked and aged conditions: medium hard, hard and extra hard shall conform to the mechanical property requirements specified in Tables 3 and 4.

7.3.1 Material may be provided in the cold-worked condition, capable of meeting the cold-worked and aged condition. In this case, the capability heat-treated tensile properties shall be tested and reported.

7.4 Mechanical properties for fine wire in the annealed, cold-worked hard and spring conditions shall conform to the mechanical property requirements specified in Table 5.

7.5 The level of mechanical properties for material in other conditions shall be specified in the purchase order.

8. Dimensions and Permissible Variations

8.1 *Units of Measure:*

8.1.1 *Selection*—This specification requires that the purchaser select the units (SI or inch-pound) to be used for product clarification. In the absence of a stated selection of units on the

TABLE 3 Mechanical Properties (Bar Products)

Condition	Tensile Strength,[A] psi [MPa]	Yield Strength,[A] (0.2 % Offset) psi [MPa]	Elongation[B] min, %	Reduction in Area, min, %
Solution-annealed[C]	115 000 to 155 000 [793 to 1069]	35 000 to 85 000 [241 to 586]	50.0	65.0
Cold-worked:				
medium hard	145 000 [1000] min.	95 000 [655] min.	20.0	60.0
hard	175 000 [1207] min.	145 000 [1000] min.	10.0	50.0
Cold-worked and aged[D]	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] Elongation of material 0.063 in. [1.6 mm] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length shall be reported with the test results. The method for determining elongation of material under 0.063 in. [1.6 mm] in diameter or thickness may be negotiated. Alternately, a gauge length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser (5.65 square root So, where So is the original cross sectional area).
[C] 1925 ± 25°F [1050° ± 15°C], 1 to 2 h at temperature, air cooled or water quenched to room temperature.
[D] Capability Test—Cold-worked and aged within the range 1000 to 1200°F ± 25°F [540 to 645°C ± 15°C] for 4 h and air cooled.

TABLE 4 Mechanical Properties—Wire Products (d ≥ 0.063 in. [1.6 mm])[A]

Condition	Tensile Strength,[B] psi [MPa]	Yield Strength,[B] (0.2 % Offset) psi [MPa]	Elongation[C] min, %	Reduction in Area, min, %
Solution-annealed	115 000 to 155 000 [793 to 1069]	35 000 to 85 000 [241 to 586]	50.0	65.0
Cold-worked:				
medium hard	145 000 [1000] min.	95 000 [655] min.	20.0	60.0
hard	175 000 [1207] min.	145 000 [1000] min.	10.0	50.0
extra hard[D]	260 000 [1793] min	230 000 [1586] min	8.0	35.0

[A] Mechanical properties for material under 0.063 in. [1.6 mm] shall be in accordance with Table 5.
[B] Tension and yield requirements apply to tests taken longitudinally to the direction of rolling.
[C] Elongation of material 0.063 in. [1.6 mm] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length shall be reported with the test results. The method for determining elongation of material under 0.063 in. [1.6 mm] in diameter or thickness may be negotiated. Alternately, a gauge length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser. (5.65 square root So, where So is the original cross sectional area.)

TABLE 5 Mechanical Properties—Fine Wire (d < 0.063 in. [1.6 mm])

	Condition					
	Annealed		Cold-Worked			
			Hard		Spring	
Diameter, in. [mm]	Tensile Strength, psi [MPa]	Elongation min, %	Tensile Strength, psi [MPa]	Elongation min, %	Tensile Strength, psi [MPa]	Elongation[A] min, %
<0.063 to 0.058 [<1.600 to 1.473]	120 000 to 150 000 [827 to 1034]	40.0 %	240 000 to 270 000 [1655 to 1862]	2.0 %	270 000 to 300 000 [1862 to 2068]	2.0 %
<0.058 to 0.034 [<1.473 to 0.864]	125 000 to 155 000 [862 to 1069]	40.0 %	245 000 to 275 000 [1689 to 1896]	2.0 %	275 000 to 305 000 [1896 to 2103]	2.0 %
<0.034 to 0.016 [<0.864 to 0.406]	135 000 to 165 000 [931 to 1138]	40.0 %	255 000 to 285 000 [1758 to 1965]	2.0 %	285 000 to 315 000 [1965 to 2172]	2.0 %
<0.016 to 0.003 [<0.406 to 0.0762]	145 000 to 175 000 [1000 to 1207]	30.0 %	265 000 to 295 000 [1827 to 2034]	2.0 %	295 000 to 325 000 [2034 to 2241]	2.0 %
<0.003 to 0.002 [<0.0762 to 0.0508]	150 000 to 190 000 [1034 to 1310]	30.0 %	275 000 to 305 000 [1896 to 2103]	2.0 %	305 000 to 335 000 [2103 to 2310]	2.0 %
<0.002 [<0.0508]	170 000 to 210 000 [1172 to 1448]	25.0 %	290 000 to 330 000 [1999 to 2275]	1.8 %	320 000 to 360 000 [2206 to 2482]	1.8 %

[A] The method for determining elongation of material under 0.063 in. [1.6 mm] in diameter or thickness may be negotiated, or a 10 in. [254 mm] gauge length may be used. Alternatively, a gauge length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.) The gauge length shall be reported with the test results

purchase order, this selection may be expressed by the purchaser in several alternative 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 purchase order (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 the 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. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of this specification provides conversion tables and Annex B provides rules for conversion and significance.

9. Special Tests

9.1 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 E112.

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

9.1.2 If samples are selected after a final cold working operation, specimens shall be tested in accordance with Test Methods E112 or as agreed upon between supplier and purchaser.

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

9.3 All centerless ground or peeled and polished round bar ≥0.375 in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2630, Class A1. Equivalent test methods may be substituted when agreed upon by purchaser and supplier.

NOTE 1—AMS 2630 specifies a minimum size limit of 0.50 in. [12.7 mm]. F04.12 subcommittee has intentionally specified the use of AMS 2630 below 0.50 in. [12.7 mm] based on the experience of users and producers on the committee. There is disagreement in the industry as to whether AMS 2632, which does apply to sizes under 0.50 in. [12.7 mm], applies to solid round bar.

9.4 Any other special requirements shall be specified by the purchaser.

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 The supplier shall provide a certification that the material was tested in accordance with this specification and meets all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program, such as defined in ISO 9000, or similar.

13. Keywords

13.1 cobalt alloys (for surgical implants) cobalt-nickel-chromium-molybdenum 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 solution-annealed, cold-worked or cold-worked and 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.

X1.4 ISO standards (such as ISO 5832/6) are listed for reference only. Although the ISO standards listed in Section 2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

X1.5 *Units of Measure*:

X1.5.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F04.12 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between 2012 and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been successfully employed in human implants (**1-5**)[5] 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 F981 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.

[5] 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.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F562 – 07) that may impact the use of this standard. (Approved Mar. 1, 2013.)

(1) Made editorial corrections in order to meet terminology and formatting guidelines established for implant material standards within F04.12.
(2) Revised wording in 1.2 to allow independent SI and inch-pound units.
(3) Added IEEE/ASTM SI 10 to subsection 2.1.
(4) Added AMS 2630 to subsection 2.2.
(5) Combined previous Section 4, Classification, with Section 3, Terminology. Added 3.1.3, forging bar. Deleted previous Section 4 and renumbered following sections accordingly.
(6) Added Section 8, Dimensions and Permissible Variations, to allow selection of units to be certified.
(7) Added subsections 9.3 (Ultrasonic Testing) and 9.4.
(8) Updated Sections 11 and 12 to current template language.
(9) Added Appendix section X1.5 to support the use of SI units.