Designation: ~~F562 – 13~~ F562 – 22

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 ~~are~~may not ~~necessarily~~be exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the ~~other,~~other and values from the two systems shall not be combined.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A751 Test Methods and Practices 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 Insertion into 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

[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.

Current edition approved ~~March 1, 2013~~Jan. 1, 2022. Published ~~March 2013~~January 2022. Originally approved in 1978. Last previous edition approved in ~~2007~~2013 as ~~F562 – 07.~~F562 – 13. DOI: ~~10.1520/F0562-13.~~10.1520/F0562-22.

[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.

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

ISO 9001 Quality Management Systems
ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes
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).~~round, rectangular, or other complex-shaped product delivered straightened and cut to defined lengths.

3.1.2 *fine wire, n*—~~rounds, flats,~~round, rectangular, or other ~~shapes less than 0.063 in. [1.60 mm]~~ complex shapes of uniform cross section along its whole length less than 1.60 mm [0.063 in.] in diameter or ~~thickness.~~thickness furnished in coils, or on spools, reels, or other packaging as specified.

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,~~rectangular, or other ~~shapes less than 0.1875 in. [4.76 mm]~~complex shapes of uniform cross section along its entire length less than 4.76 mm [0.1875 in.] in diameter or ~~thickness.~~ thickness furnished in coils, or on spools, reels, or other packaging as specified.

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),

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.

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

6. Chemical Requirements

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

6.1 The ~~cobalt-35nickel-20chromium-10molybdenum alloy~~ supplier's heat analysis shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material with chemistry 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.

6.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between purchaser and supplier.

6.1.3 Intentional elemental additions other than those specified in Table 1 are not permitted, unless previously agreed to between purchaser and supplier.

6.1.4 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification, unless previously agreed to between purchaser and supplier.

6.1.5 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751 and E354.

6.2 *Product ~~Analysis~~ (Check) 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 Product (check) analysis limits shall conform to the product tolerances in Table 2 per AMS 2269. Product (check) analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

6.2.2 Product (check) analysis limits are not for use at supplier's/producer's acceptance testing. Product (check) analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in Table 1.

6.2.3 A product (check) analysis is one performed by purchaser or supplier of the metal after it has been worked into bar and wire, and is either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.

6.2.4 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product

TABLE 1 Chemical Requirements

Element	~~Composition,%~~ 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.

~~analysis.~~(check) analysis. Product (check) analysis outside the tolerance limits allowed in Table 2 is cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

6.2.5 ~~Product analysis tolerances do not broaden the~~For referee purposes, use Test Methods A751 ~~specified~~and E354~~heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in~~ , or other analytical methods agreed upon between the purchaser and supplier.~~Table 2~~.

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~~Methods 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.

7.2 ~~*Tensile Properties:*~~ *Number of Tests – Bar, Forging Bar, Shapes, and Wire:*

7.2.1 ~~Tensile properties shall be determined in accordance with Test Methods E8/E8M.~~ Perform a ~~tension test~~minimum of two tension tests on at least one piece from each lot. Should any of the test ~~piece~~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.

7.2.2 Tensile ~~tests result~~test results 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.~~ specified and all other results conform to Tables 3 and 4. Refer to subsections 7.11.4 and ~~7.11.5~~7.12.5 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~~ requirements.

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

7.2.4 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.

~~7.2 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.~~

TABLE 3 Mechanical Properties (Bar Products)

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

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

[B] ~~Elongation~~ Elongation of material ~~0.063 in. [1.6 mm]~~1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of ~~2 in.~~ 50.8 mm [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]~~1.6 mm [0.063 in.] 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~~ cross-sectional area).

[C] ~~1925 ± 25°F [1050° ± 15°C],~~ 1050 ± 15 °C [1925 ± 25 °F], 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~~ of 540 to ~~1200°F~~645 °C ± ~~25°F [540~~15 °C [1000 to ~~645°C~~1200 °F ± ~~15°C]~~25 °F] for 4 h and air cooled.

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

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

[A] Mechanical properties for material under ~~0.063 in. [1.6 mm]~~1.6 mm [0.063 in.] 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]~~1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of ~~2 in.~~ 50.8 mm [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]~~1.63 mm [0.063 in.] 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~~ cross-sectional area.)

7.3 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.

7.4 The ~~level~~limits 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 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~~IEEE/ASTM SI 10 ~~specification~~ provides conversion tables and Annex B of IEEE/ASTM SI 10 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.

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

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

[A] The method for determining elongation of material under ~~0.063 in. [1.6 mm]~~1.6 mm [0.063 in.] in diameter or thickness may be negotiated, or a ~~10 in. [254 mm]~~254 mm [10 in.] 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~~ cross-sectional area.) The gauge length shall be reported with the test ~~results~~results.

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~~ 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]~~≥9.5 mm [0.375 in.] 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~~ 12.7 mm [0.50 in.]. Subcommittee F04.12 has intentionally specified the use of AMS 2630 below ~~0.50 in. [12.7 mm]~~12.7 mm [0.50 in.] 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],~~12.7 mm [0.50 in.], applies to solid round ~~bar.~~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~~ right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.