Designation: F1058 – 16

Standard Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire, Strip, and Strip Bar for Surgical Implant Applications (UNS R30003 and UNS R30008)[1]

This standard is issued under the fixed designation F1058; 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 two grades of wrought 40cobalt-20chromium-16iron-15nickel-7molybdenum alloy in the form of wire, strip and bar used for 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 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

E18 Test Methods for Rockwell Hardness of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E45 Test Methods for Determining the Inclusion Content of Steel

E92 Test Methods for Vickers Hardness and Knoop Hardness of Metallic Materials

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

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

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Specifications:*[3]

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

AMS 5833 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Treated and Cold Drawn

AMS 5834 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Drawn, and Aged

AMS 5875 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Rolled, and Aged

AMS 5876 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated and Cold Rolled

2.3 *ISO Standards:*[4]

ISO 5832-7 Implants for Surgery—Metallic Materials—Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy

ISO 6892–1 Metallic materials—Tensile testing—Part 1: Method of test at room temperature

ISO 9001 Quality Management Systems—Requirements

2.4 *Society of Automotive Engineers:*[5]

SAE J1086 Practice for Numbering Metals and Alloys (UNS)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

[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.

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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 Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096, http://www.sae.org.

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

3.1.1 *bar, n*—round bars and flats from 4.75 to 101.60 mm [0.1875 to 4.00 in.] in diameter or thickness (other shapes by special order).

3.1.2 *fine wire, n*—wire as described in 3.1.5, less than 1.60 mm [0.063 in.] in diameter or thickness.

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

3.1.4 *strip, n*—any product under 4.76 mm [0.188 in.] in thickness and under 610 mm [24 in.] wide.

3.1.5 *wire, n*—rounds, flats or other shapes less than 4.76 mm [0.1875 in.] 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 (weight or number of pieces);

4.1.2 ASTM designation, grade, and date of issue;

4.1.3 Form (wire, strip, or bar);

4.1.4 Applicable dimensions, including size, thickness, width, and length (exact, random, multiples) and tolerances where critical, and drawing number;

4.1.5 Condition;

4.1.6 Finish;

4.1.7 Mechanical properties, if applicable, for special conditions;

4.1.8 Special tests (if any); and

4.1.9 Other requirements (if applicable).

5. Materials and Manufacture

5.1 *Condition*—Wire and strip shall be furnished to the purchaser in the annealed, cold worked, or cold worked and aged condition. Bars shall be furnished to the purchaser in the cold worked or cold worked and aged condition.

5.2 *Finish:*

5.2.1 Types of finish available for wire are bright-annealed, pickled, cold-drawn, ground, ground and polished, or as specified in the purchase order.

5.2.2 Types of finish available for strip are bright-annealed, pickled, cold-rolled, polished, or as specified in the purchase order.

5.2.3 Types of finish available for bar are cold-drawn, cold-drawn and aged, ground, ground and polished, or as specified in the purchase order.

6. Chemical Requirements

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

6.2 The 40cobalt-20chromium-16iron-15nickel-7molybdenum alloy heat analysis shall conform to the chemical requirements of Grade 1 or 2 as specified in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1 for the applicable grade.

6.2.1 Requirements for the major and minor elemental constituents for Grade 1 and 2 of this alloy are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required but is allowed to verify compliance with this specification.

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition, (% mass/mass)			
	Grade 1 (UNS R30003)		Grade 2 (UNS R30008)	
	min	max	min	max
Carbon	...	0.15	...	0.15
Manganese	1.5	2.5	1.0	2.0
Silicon	...	1.20	...	1.20
Phosphorus	...	0.015	...	0.015
Sulfur	...	0.015	...	0.015
Cobalt	39.0	41.0	39.0	42.0
Chromium	19.0	21.0	18.5	21.5
Nickel	14.0	16.0	15.0	18.0
Molybdenum	6.0	8.0	6.5	7.5
Beryllium	...	0.001[B]	...	0.001
Iron[A]	Balance	Balance	Balance	Balance

[A] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage iron content by difference is not required to be reported.
[B] Denotes more restrictive limit than UNS.

6.2.2 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace 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.

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 a 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 2 Product Analysis Tolerances[A]

Element	Tolerances over the max (upper limit) or under the min (lower limit), % mass/mass	
	Grade 1 (UNS R30003)	Grade 2 (UNS R30008)
Carbon	0.01	0.01
Manganese	0.04	0.04
Silicon	0.10	0.10
Phosphorous	0.005	0.005
Sulfur	0.003	0.003
Cobalt	0.50	0.50
Chromium	0.25	0.25
Nickel	0.20	0.20
Molybdenum	0.15	0.15
Beryllium,[B]	0.0001	0.0001

[A] Refer to AMS 2269.
[B] Based on beryllium analysis by flame atomic absorption with a detection limit of 0.0000001 % (1 ppb).

7. Mechanical Requirements

7.1 *Tensile Properties:*

TABLE 3 Mechanical Requirements, Cold Worked Wire

Diameter, mm [in.]	Ultimate Tensile Strength, min, MPa [psi]
0.02 to 0.12, incl [0.001 to 0.005]	1795 [260 000]
Over 0.12 to 1.00, incl [0.005 to 0.040]	1655 [240 000]
Over 1.0 to 1.50, incl [0.040 to 0.060]	1620 [235 000]
Over 1.50 to 2.50, incl [0.060 to 0.100]	1550 [225 000]
Over 2.5 to 3.50, incl [0.100 to 0.140]	1515 [220 000]

TABLE 4 Mechanical Requirements, Cold Worked and Aged[A] Wire

Diameter mm [in.]	Ultimate Tensile Strength, min, MPa [psi]	Yield Strength (0.2 % offset), min, MPa [psi]
0.02 to 0.12, incl [0.001 to 0.005]	2275 [330 000]	...
Over 0.12 to 1.00, incl [0.005 to 0.040]	2000 [290 000]	1450 [210 000]
Over 1.00 to 1.50, incl [0.040 to 0.060]	1965 [285 000]	1380 [200 000]
Over 1.50 to 2.00, incl [0.060 to 0.080]	1895 [275 000]	1380 [200 000]
Over 2.00 to 2.50, incl [0.080 to 0.100]	1895 [275 000]	1345 [195 000]
Over 2.50 to 3.00, incl [0.100 to 0.120]	1860 [270 000]	1275 [185 000]
Over 3.00 to 3.50, incl [0.120 to 0.140]	1860 [270 000]	1240 [180 000]

[A] Thermally aged, for example, by heating to a temperature within the range 480 to 540°C [900 to 1000°F], holding at the selected temperature within ±15°C [±25°F] for 5 to 5½ h, and cooling in air to room temperature.

TABLE 5 Mechanical Requirements, Cold Worked Strip

Thickness, mm [in.]	Ultimate Tensile Strength, min, MPa [psi]
Up to 0.110, incl [0.0043]	1795 [260 000]
Over 0.110 to 0.4688, incl [0.0043 to 0.01875]	1725 [250 000]
Over 0.4688 to 0.62, incl [0.01875 to 0.025]	1655 [240 000]
Over 0.62 to 1.18, incl [0.025 to 0.047]	1515 [220 000]
Over 1.18 to 1.88, incl [0.047 to 0.075]	1240 [180 000]
Over 1.88 to 2.50, incl [0.075 to 0.100]	895 [130 000]

TABLE 6 Mechanical Requirements, Cold Worked and Aged[A] Strip

Thickness, mm [in.]	Ultimate Tensile Strength, min, MPa [psi]	Yield Strength (0.2 % offset) min, MPa [psi]	Elongation in 50 mm or 2 in, min, %
Up to 0.110, incl [0.0043]	2240 [325 000]	1725 [250 000]	...
>0.110 to 0.4688, incl [0.0043 to 0.01875]	2170 [315 000]	1550 [225 000]	...
>0.4688 to 0.62, incl [0.01875 to 0.025]	2070 [300 000]	1550 [225 000]	1
>0.62 to 1.18, incl [0.025 to 0.047]	1895 [275 000]	1550 [225 000]	1
>1.18 to 1.88, incl [0.047 to 0.075]	1550 [225 000]	1105 [160 000]	3
>1.88 to 2.50, incl [0.075 to 0.100]	1170 [170 000]	690 [100 000]	17

[A] Thermally aged, for example, by heating to a temperature within the range 455 to 510°C [850 to 950°F], holding at the selected temperature within ±15°C [±25°F] for 5 to 5½ h, and cooling in air to room temperature.

TABLE 7 Mechanical Requirements, Annealed Wire and Strip

Ultimate Tensile Strength, min, MPa [psi]	Yield Strength, (0.2 % offset) min, MPa [psi]	Elongation[A] min, %
850 [123 000]	450 [62 250]	65

[A] Gage length shall be 4 D, 4 W, 50 mm [2 in.], or equal to 5.65 square root So, minimum 25 mm, corresponding to ISO 6892-1. The gage length shall be reported.

7.1.1 Tension properties shall be determined in accordance with Test Methods E8/E8M. Perform at least one tension test from each lot. Should any of the test specimens 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 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 subsections 7.11.4 and 7.11.5 of Test Methods E8/E8M. 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.

7.1.3 The mechanical properties of test specimens shall conform to the appropriate mechanical requirements specified in Table 3, Table 4, Table 5, Table 6, Table 7, Table 8, or as specified on the purchase order

7.2 *Hardness:*

7.2.1 When desired, hardness properties may be specified. Test Methods E18 or E92 and Tables E140 shall be used. Hardness determination of cold worked or cold worked and aged material shall be made on a product cross section, midway between the center and surface, if the cross section size is adequate.

7.2.2 Hardness values are for information only and shall not be used as a basis for rejection.

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 alternate 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.

TABLE 8 Mechanical Requirements, Bar

Diameter, mm [in.]	Condition	Ultimate Tensile Strength min, MPa [psi]	Yield Strength, (0.2 % offset) min. MPa [psi]	Elongation[A]
3.5 to 15.53.5 [0.138 to 0.610]	Cold Worked	1400 [203 000]	...	...
3.5 to 115.53.5 [0.138 to 0.610]	Cold Worked and Aged	1550 [225 000]	1200 [174 000]	...

[A] Gage length shall be 4 D, 4 W, 50 mm [2 in.], or equal to 5.65 square root So, minimum 25 mm, corresponding to ISO 6892-1. The gage length shall be reported.

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 standard provides conversion tables and Annex B provides rules for conversion and significance.

9. Special Tests and Requirements

9.1 *Microstructure:*

9.1.1 The materials shall have a homogeneous microstructure as observed at 100× magnification.

9.1.2 The grain size shall be ASTM 5 or finer, based on the appropriate chart of Test Methods E112.

9.1.3 It is preferred that samples for grain size determination shall be selected after the last annealing operation prior to the final cold working or cold working and aging operation.

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

9.1.5 The microcleanliness of the alloy as determined by Practice E45, Method A, Plate I-r, on representative billet, bar, or hot band samples from the heat shall not exceed the limits in Table 9.

TABLE 9 Microcleanliness Requirements

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1.0	3.0	1.0	3.0
Heavy	0.0	0.0	0.0	0.0

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 met 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 9001, or similar.

13. Keywords

13.1 cobalt alloys (for surgical implants); metals for surgical implants; wrought cobalt-chromium-nickel-molybdenum-iron alloy

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

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

X1.2 The chemical composition and mechanical properties of Grade 1 and the mechanical properties of Grade 2 are in accordance with AMS 5833, 5834, 5875, and 5876. The chemical composition of Grade 2 is in agreement with the composition limits specified in ISO 5832-7, except for Si.

X1.3 There is a general consensus that a homogeneous metallurgical structure will be superior with respect to corrosion and fatigue resistance, based upon this, metallurgical requirements include fine grained single phase microstructure with low micro-inclusion content.

X1.4 Acceptable alloy conditions supplied to the implant manufacturer include annealed, cold worked, or cold worked and thermally aged, the choice dependent upon the implant design and application.

X1.5 Grade 1 is commonly referred to as Elgiloy alloy while Grade 2 is commonly referred to as Phynox alloy.

X1.6 ISO standards are listed for reference only. Although 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.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this standard has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade.(**1-6**)[6]

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 of the use of the material referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

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

REFERENCES

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(4) Wible, J., "Spring Valve Mitral Prosthesis," *Journal of the Michigan State Medical Society*, June 1957, p. 731.

(5) Dujovny, M., Kossovsky, N., Kossowsky, R., Segal, R., Diaz, F., Kaufman, H., Perlin, A., Cook, E., "Mechanical and Metallurgical Properties of Carotid Artery Clamps," *Neurosurgery*, 1985, pp. 760–767.

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SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1058 – 08) that may impact the use of this standard. (Approved November 1, 2016.)

(1) Adopted the dual standard unit of measure language per IEEE/ASTM SI 10.

(2) Addition of bar stock properties.