Designation: F 1058 – ~~97~~02

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

This standard is issued under the fixed designation F 1058; 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 two grades of wrought 40cobalt-20chromium-16iron-15nickel-7molybdenum-~~iron~~ alloy in the form of wire and strip 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 equivalents of the inch-pound untis may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

A 751 Test Methods, Practices, and ~~Definitions~~ Terminology for Chemical Analysis of Steel Products[2]

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[1] This specification is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F4.12 on Metallurgical Materials.

Current edition approved ~~July~~ Apr. 10, ~~1997.~~ 2002. Published ~~March 1998.~~ June 2002. Originally approved as F 1058 - 91. Last previous edition F 1058 - 9~~1~~7.

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

E 8 Test Methods ~~o~~ for Tension Testing of Metallic Materials[3]
E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]
E ~~45 Practice~~ 45 Test Methods for Determining the Inclusion Content of Steel[3]
E 92 Test Method for Vickers Hardness of Metallic Materials[3]
E 112 Test Methods for Determining the Average Grain Size[3]
E 140 Standard Hardness Conversion Tables for Metals ~~(Relationship Between Brinell Hardness, Rockwell Hardness, Rockwell Superficial Hardness, and Knoop Hardness)~~[3]
E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[4]

2.2 *Aerospace Material Specifications:*
AMS 2269 Chemical Check Analysis Limits Wrought Nickel and Alloys and Cobalt Alloys[5]
AMS 5833 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Treated and Cold Drawn[5]
AMS 5834 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Drawn, and Aged[5]
AMS 5875 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Rolled, and Aged[5]
AMS 5876 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated and Cold Rolled[5]

2.3 *American Society for ~~Quality Control:~~ Quality:*
C1 Specification of General Requirements for a Quality Program[6]

2.4 *ISO Standard:*
ISO 5832-7 Implants for ~~Surgery—Metal Based Products—Part~~ Surgery—Metallic Materials—Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy[7]
ISO 6892 Metallic Materials—Tensile Testing[7]

3. Ordering Information

3.1 Inquiries and orders for material under this specification shall include the following information:
3.1.1 Quantity (weight or number of pieces),
~~3.1.2 Condition (4.11),~~
~~3.1.3 Finish (4.2),~~
~~3.1.4 Mechanical properties (if applicable, for special conditions) (7.1),~~
~~3.1.5 Applicable~~
3.1.2 ASTM designation, grade, and date of issue,
3.1.3 Form (wire or strip),
3.1.4 Applicable dimensions, including size, thickness, width, and length (exact, random, ~~multiples), or print number,~~
~~3.1.6 Special tests, and~~
~~3.1.7 Supplementary requirements (if applicable):~~
~~3.1.7.1 Product uniformity, and~~
~~3.1.7.2 Additional tests or inspections, supplementary composition limits,~~ multiples) and tolerances where critical, and drawing number,
3.1.5 Condition,
3.1.6 Finish,
3.1.7 Mechanical properties, if ~~any as required by the manufacturing process and intended application, and other supplementary requirements.~~ applicable, for special conditions,
3.1.8 Special tests (if any), and
3.1.9 Other requirements (if applicable).

4. Materials and Manufacture

4.1 *Condition*—Wire and strip shall be furnished to the ~~implant manufacturer~~ purchaser in the annealed, cold worked, or cold worked and aged ~~condition, as specified.~~ condition.

4.2 *Finish*—Surface:
4.2.1 Types of finish ~~shall be~~ available for wire are bright-annealed, pickled, cold-drawn, ground, ground and polished, or as specified ~~and required by~~ in the ~~subsequent manufacturing process and~~ purchase order.

[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 03.03~~5~~.
[5] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096–0001.
[6] Available from American Society for Quality Control, ~~161 West Wisconsin~~ 600 N. Plankinton Ave., Milwaukee, WI 53203.
[7] Available from American National Standards Institute, ~~1430 Broadway,~~ 25 W. 43rd St., 4th Floor, New York, NY ~~10018.~~ 10036.

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

5. Chemical Requirements

5.1 The heat analysis shall conform to the chemical requirements of Grade 1 or 2 as ~~to chemical composition~~ specified in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1 for the applicable grade.

5.1.1 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 to verify compliance with this specification.

5.2 *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 a heat.

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

5.2.2 Product analysis tolerances do not broaden the specified heat analysis requirements, but cover variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. Product analysis limits shall be specified in Table 2 ~~and in accordance with AMS 2269.~~ .

5.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A 751.

6. ~~Metallurgical~~Mechanical Requirements

~~6.1 The material~~

6.1 *Tensile Properties*:

6.1.1 Tensile properties shall ~~have a homogeneous cold worked microstructure as observed at 100× magnification.~~ be determined in accordance with Test Methods E 8.

6.1.2 The mechanical properties of test specimens shall conform to the appropriate mechanical requirements specified in Table 3

~~6.2 The grain size shall be ASTM 5 or finer, based on the appropriate chart of Methods E 112~~, Table 4, Table 5~~.~~

~~6.3~~ , Table 6, or Table 7.

6.2 *Hardness*:

6.2.1 When desired, hardness properties may be specified. Test Methods E 18 or E 92 and Tables E 140 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.

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

7. Special Tests and Requirements

7.1 *Microstructure*:

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

7.1.2 The grain size shall be ASTM 5 or finer, based on the appropriate chart of Test Methods E 112.

7.1.3 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.

7.1.4 If samples are selected after a final cold working or cold working and aging operation, specimens shall be tested in accordance with Test Methods E 112 or as agreed between supplier and purchaser.

7.1.5 The microcleanliness of the alloy as determined by Practice E 45, Method A, ~~except using~~ Plate ~~III for counts ½ through 2½ and Plate I for counts 3 through 5,~~ I-r, on representative billet, bar, or hot band samples from the heat shall not exceed the following:

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	...	0.10	...	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.

TABLE 2 Product Analysis Tolerances[A]

Element		Tolerances over the max (upper limit) or under the min (lower limit), %
Carbon		0.01
Manganese		0.04
Silicon		0.10
Phosphorous		0.005
Sulfur		0.003
Cobalt		0.50
Chromium		0.25
Nickel		0.20
Molybdenum		0.15
Beryllium,[B]	max 0.10	0.01
	max 0.001	0.0001

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

TABLE 3 Mechanical Requirements, Cold Worked Wire

Diameter inch (mm)	Ultimate Tensile Strength, min, psi (MPa)
0.001 to 0.005, incl (0.02 to 0.12)	260 000 (1795)
Over 0.005 to 0.040, incl (0.12 to 1.00)	240 000 (1655)
Over 0.040 to 0.060, incl (1.00 to 1.50)	235 000 (1620)
Over 0.060 to 0.100, incl (1.50 to 2.50)	225 000 (1550)
Over 0.100 to 0.140, incl (2.50 to 3.50)	220 000 (1515)

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

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

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

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1	3	1	3
Heavy	0	0	0	0

7. Mechanical Requirements

7.1 The material shall conform to the appropriate minimum mechanical properties specified in Table 3, Table 4, Table 5, or Table 6. Methods E 8 shall apply.

7.2 When desired, hardness limits may be specified. Test Methods E 18 or E 92 and Tables E 140 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.

7.3 If any manufacturing operations of the implant manufacturer alter the properties of the material, the specimens shall be subjected to the same operations prior to testing.

TABLE 5 Mechanical Requirements, Cold Worked Strip

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

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

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

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

TABLE 7 Mechanical Requirements, Annealed Wire and Strip

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

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

8. Special Tests

8.1 Unless otherwise permitted, 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.

8.1.1 If samples are selected after a final cold working or cold working and aging operation, transverse specimens shall be prepared.

8.2 Any other special requirements shall be specified on the purchase order.

9. Certification

98.1 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.

9. Quality Program Requirements

109.1 The supplierо andи any processors shall maintain a quality program, such as defined in ASQC C1.

10.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1, or other recognized program.

11.

10. Keywords

110.1 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 assure 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 overa decade.**(1-6)**

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.

REFERENCES

(**1**) Yokoo, A., Sugita, K., and Kobayashi, S., "Tissue Reaction Caused by Implanted Aneurysm Clips", *Shinsu Medical Journal*, Volume 28, 1980. pp. 555–557.
(**2**) Greatbach, W., "Electrochemical Polarization of Physiological Electrodes" *Medical Research Engineering*, Volume 6, No. 2, 1967, pp. 13–18.
(**3**) Braunwald, N., "Accelerated Fatigue Testing of Available Pacemaker Electrodes and Elgiloy Wire Coils", *Surgery*, 1965, p. 846.
(**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.
(**6**) Winkler, W., Ungethum, M., "Metallic Materials in Neurosurgery and Vascular Surgery", *Aesculap Scientific Information*, March 1987, 1st Edition.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 1058 – 97) that may impact the use of this standard.

(*1*) The title of the standard was changed.
(*2*) UNS designations and annealed conditions were added.
(*3*) Annealed mechanical properties (Table 7) that meet ISO 5832-7 were added.
(*4*) Formatting changes were made, and editorial corrections were made that were standardized by Subcommittee F04.12.