Designation: F 1058 – 97

Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications[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 cobalt-chromium-nickel-molybdenum-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.

2. Referenced Documents

2.1 *ASTM Standards:*

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

E 8 Methods of Tension Testing of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 45 Practice for Determining the Inclusion Content of Steel[4]

E 92 Test Method for Vickers Hardness of Metallic Materials[3]

E 112 Methods for Determining the Average Grain Size[4]

E 140 Hardness Conversion Tables for Metals (Relationship Between Brinell Hardness, Rockwell Hardness, Rockwell Superficial Hardness, and Knoop Hardness)[3]

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:*

C1 Specification of General Requirements for a Quality Program[6]

2.4 *ISO Standard:*

ISO 5832-7 Implants for Surgery—Metal Based Products—Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy[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 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, if any as required by the manufacturing process and intended application, and other supplementary requirements.

4. Materials and Manufacture

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

4.2 *Finish*—Surface finish shall be as specified and required by the subsequent manufacturing process and the intended application.

5. Chemical Requirements

5.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 1.

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

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

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

[7] Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition, (%)			
	Grade 1		Grade 2	
	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.

5.1.1 Requirements for the major and minor elemental constituents for 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 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 Methods A 751.

6. Metallurgical Requirements

6.1 The material shall have a homogeneous cold worked microstructure as observed at 100× magnification.

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

6.3 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, on representative billet, bar, or hot band samples from the heat shall not exceed the following:

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.

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)

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,

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.

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.

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

9.1 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. Quality Program Requirements

10.1 The producer 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. Keywords

11.1 cobalt alloys (for surgical implants); cobalt-chromium

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.

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 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.

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

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