

Designation: F 1058 – 02

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

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1. Scope

1.1 This specification covers the requirements for two grades of wrought 40cobalt-20chromium-16iron-15nickel-7molybdenum 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 Terminology for Chemical Analysis of Steel Products²
- E 8 Test Methods for Tension Testing of Metallic Materials³
- E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials³
- E 45 Test Methods for Determining the Inclusion Content of Steel³
- E 92 Test Method for Vickers Hardness of Metallic Materials³
- E 112 Test Methods for Determining the Average Grain Size³
- E 140 Standard Hardness Conversion Tables for Metals³
- E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys⁴
- 2.2 Aerospace Material Specifications:
- AMS 2269 Chemical Check Analysis Limits Wrought Nickel and Alloys and Cobalt Alloys⁵

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- AMS 5833 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Treated and Cold Drawn⁵
- AMS 5834 Alloy Wire, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Drawn, and Aged⁵
- AMS 5875 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated, Cold Rolled, and Aged⁵
- AMS 5876 Alloy Strip, Corrosion and Heat Resistant 20Cr-15Ni-40Co-7.0Mo-16Fe Solution Heat Treated and Cold Rolled⁵
- 2.3 American Society for Quality:
- C1 Specification of General Requirements for a Quality Program⁶
- 2.4 ISO Standard:
- ISO 5832-7 Implants for Surgery—Metallic Materials— Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy⁷
- **SISO 6892** Metallic Materials—Tensile Testing⁷

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 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) and tolerances where critical, and drawing number,
 - 3.1.5 Condition,
 - 3.1.6 Finish,

3.1.7 Mechanical properties, if applicable, for special conditions,

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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 F4.12 on Metallurgical Materials.

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 03.05.

⁵ Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096–0001.

⁶ Available from American Society for Quality Control, 600 N. Plankinton Ave., Milwaukee, WI 53203.

 $^{^7}$ Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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 purchaser in the annealed, cold worked, or cold worked and aged condition.

4.2 Finish:

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

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

5. Chemical Requirements

5.1 The 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.

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.

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

6. Mechanical Requirements

6.1 Tensile Properties:

TABLE 1 Che	mical Requir	ements, He	at Analysis
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	Composition, (% mass/mass)			
Element	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		r the max (upper limit) or 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.

 $^{\it B}$ Based on beryllium analysis by flame atomic absorption with a detection limit of 0.0000001 % (1 ppb).

6.1.1 Tensile properties shall 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, Table 4, Table 5, 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 $100 \times$ 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, Plate I-r, on representative billet, bar, or hot band samples from the heat shall not exceed the following:

TABLE 3	Mechanical	Requirements,	Cold	Worked	Wire
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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)