

Designation: F1058 – 08

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

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 ( $\varepsilon$ ) 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 and strip used for the manufacture of surgical implants.

1.2 The values stated in SI units are to be regarded as standard. The inch-pound equivalents of the SI units in parentheses are for information only.

## 2. Referenced Documents

- 2.1 ASTM Standards:<sup>2</sup>
- A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products
- E8 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- E92 Test Method for Vickers Hardness of Metallic Materials (Withdrawn 2010)<sup>3</sup>
- 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, and Scleroscope Hardness
- E354 Test Methods for Chemical Analysis of High-

Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

- 2.2 Aerospace Material Specifications:<sup>4</sup>
- 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 American Society for Quality Standards:

ASQ C1 Specification of General Requirements for a Qual-08ity Program<sup>5</sup>

2.4 ISO Standards:<sup>6</sup>

ISO 5832-7 Implants for Surgery—Metallic Materials—Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy ISO 6892 Metallic Materials—Tensile Testing ISO 9001 Quality Management Systems—Requirements

#### 3. Terminology

3.1 Definitions of Terms Specific to This Standard:

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

## 4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

<sup>&</sup>lt;sup>1</sup>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 May 1, 2008. Published June 2008. Originally approved in 1991. Last previous edition approved in 2002 as F1058-02. DOI: 10.1520/F1058-08.

<sup>&</sup>lt;sup>2</sup> 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.

 $<sup>^{3}\,\</sup>text{The}$  last approved version of this historical standard is referenced on www.astm.org.

<sup>&</sup>lt;sup>4</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

<sup>&</sup>lt;sup>5</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

<sup>&</sup>lt;sup>6</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation, grade, and date of issue,

4.1.3 Form (wire or strip),

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.

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.

### 6. Chemical Requirements

6.1 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.

6.1.1 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.

6.2 *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.

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

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Composition, (% mass/mass)				
Grade 1 (U	NS R30003)	Grade 2 (UI	NS R30008)	
min	max	min	max	
	0.15		0.15	
1.5	2.5	1.0	2.0	
	1.20		1.20	
	0.015		0.015	
	0.015		0.015	
39.0	41.0	39.0	42.0	
19.0	21.0	18.5	21.5	
14.0	16.0	15.0	18.0	
6.0	8.0	6.5	7.5	
	0.10		0.001	
Balance	Balance	Balance	Balance	
	Grade 1 (U min 1.5  39.0 19.0 14.0 6.0  Balance	Composition, (%   Grade 1 (UNS R30003)   min max    0.15   1.5 2.5    1.20    0.015    0.015    0.015    0.015    0.10   14.0 16.0   6.0 8.0    0.10   Balance Balance	Composition, (% mass/mass)   Grade 1 (UNS R30003) Grade 2 (UI   min max min    0.15    1.5 2.5 1.0    1.20     0.015     0.015     0.015     0.015     0.015     0.15     0.15     0.015     0.10 18.5   14.0 16.0 15.0   6.0 8.0 6.5    0.10    Balance Balance Balance	

<sup>A</sup> 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.

6.2.2 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.

6.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods, Practices, and Terminology A751.

## 7. Mechanical Requirements

#### 7.1 Tensile Properties:

7.1.1 Perform tension tests per Test Methods E8. 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. 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, or Table 7.

### 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. Special Tests and Requirements

8.1 *Microstructure:* 

TABLE 2 Pr	oduct Ana	lysis To	lerances <sup>A</sup>
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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, <sup>B</sup>	0.010	0.0001	

A Refer to AMS 2269.

<sup>B</sup> Based on beryllium analysis by flame atomic absorption with a detection limit of 0.0000001 % (1 ppb).