



Designation: F 1058 – 97

Standard Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications¹

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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 Products²

E 8 Methods of Tension Testing of Metallic Materials³

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials³

E 45 Practice for Determining the Inclusion Content of Steel⁴

E 92 Test Method for Vickers Hardness of Metallic Materials³

E 112 Methods for Determining the Average Grain Size⁴

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 Alloys⁵

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 Control:

C1 Specification of General Requirements for a Quality Program⁶

2.4 ISO Standard:

ISO 5832-7 Implants for Surgery—Metal Based Products—Part 7 Forgeable and Cold Formed Co-Cr-Ni-Mo-Fe Alloy⁷

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.

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.