

Designation: F 562 – 02

# Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)<sup>1</sup>

This standard is issued under the fixed designation F 562; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

# 1. Scope\*

1.1 This specification covers requirements of wrought 35cobalt-35nickel-20chromium-10molybdenum alloy (UNS R30035) in the form of bar and wire, used for the manufacture of surgical implants. This alloy depends on combinations of work-strengthening, and work-strengthening and aging to attain a variety of combinations of strength and ductility.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents of the inch-pound units may be approximate.

## 2. Referenced Documents

- 2.1 ASTM Standards:
- A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products<sup>2</sup>
- E 8 Test Methods for Tension Testing of Metallic Materials<sup>3</sup> E 112 Test Methods for Determining the Average Grain
- Size<sup>3</sup>
- E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys<sup>4</sup>
- F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone<sup>5</sup>
- 2.2 ISO Standards:
- ISO 5832/6 Implants for Surgery—Metallic Materials Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy<sup>6</sup>
- ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature<sup>6</sup>
- 2.3 Aerospace Material Specification:
- AMS 2269 Chemical Check Analysis Limits-Wrought

Nickel Alloys and Cobalt Alloys<sup>7</sup>

- 2.4 American Society for Quality Standard:
- ASQ C1 Specification of General Requirements for a Quality Program<sup>8</sup>
- 2.5 Society of Automotive Engineers:
- SAE J1086 Practice for Numbering Metals and Alloys (UNS)<sup>7</sup>

# 3. Classification

3.1 *Bar*—Round Bars and Flats from 0.1875 in. (4.75 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other shapes by special order).

3.2 *Wire*—Rounds less than 0.1875 in. (4.75 mm) in diameter.

# 4. Ordering Information

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

- 4.1.1 Quantity,
- 4.1.2 ASTM designation and date of issue,
- 4.1.3 Mechanical properties (Section 7),
- 4.1.4 Form (bar or wire),

4.1.5 Applicable dimensions, including size, thickness, width, and length (exact, random, multiples), or drawing number,

- 4.1.6 Condition (5.1),
- 4.1.7 Finish (5.2),
- 4.1.8 Special tests, if applicable, and
- 4.1.9 Other requirements.

# 5. Materials and Manufacture

5.1 *Condition*—Bar and wire shall be furnished, as specified, in the solution-annealed, cold-worked, or cold-worked and aged condition.

5.2 *Finish*—Types of finish available in bar and wire products are cold drawn, pickled, ground, ground and polished, or as specified by the purchaser.

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<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 April 10, 2002. Published June 2002. Originally published as F 562 - 78. Last previous edition F 562 - 00.

<sup>&</sup>lt;sup>2</sup> Annual Book of ASTM Standards, Vol 01.03.

<sup>&</sup>lt;sup>3</sup> Annual Book of ASTM Standards, Vol 03.01.

<sup>&</sup>lt;sup>4</sup> Annual Book of ASTM Standards, Vol 03.05. <sup>5</sup> Annual Book of ASTM Standards, Vol 13.01.

<sup>&</sup>lt;sup>6</sup> Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

<sup>&</sup>lt;sup>7</sup> Available from Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001.

<sup>&</sup>lt;sup>8</sup> Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

## 6. Chemical Requirements

6.1 Chemical analysis shall be in accordance with Test Methods E 354 and A 751.

6.2 The cobalt-35nickel-20chromium-10molybdenum alloy shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1.

6.2.1 Requirements for the major and minor elemental constituents 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.

6.3 *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 the heat.

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

6.3.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

#### 7. Mechanical Requirements

#### 7.1 Tensile Properties:

7.1.1 Tensile properties shall be determined in accordance with Test Methods E 8.

7.2 Solution-annealed bar and wire shall conform to the mechanical properties specified in Tables 3 and 4.

7.3 Mechanical properties for the cold-worked and coldworked and aged conditions: medium hard, hard and extra

TABLE 1 C	hemical R	equirements
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Element	Composition,% (mass/mass)		F5 <sup>u</sup>
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Carbon		0.025	
Manganese		0.15	n
Silicon		0.15	
Phosphorus		0.015	0
Sulfur		0.010	
Chromium	19.0	21.0	1
Nickel	33.0	37.0	
Molybdenum	9.0	10.5	
Iron		1.0	n
Titanium		1.0	
Boron		0.015	1
Cobalt <sup>A</sup>	balance	balance	

<sup>A</sup> Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage cobalt content by difference is not required to be reported.

TABLE 2 Product Analysis Tolerances<sup>A,B</sup>

Element	Tolerance Under the Minimum or Over the Maximum Limit % (mass/mass) <sup>C</sup>
Carbon	0.01
Manganese	0.03
Silicon	0.02
Phosphorus	0.005
Sulfur	0.005
Chromium	0.25
Nickel	0.30
Molybdenum	0.15
Iron	0.05
Titanium	0.04
Boron	0.005

<sup>A</sup> See Test Method E 354.

<sup>B</sup> See AMS 2269 for chemical check analysis limits.

<sup>C</sup> Under minimum limit not applicable for elements where only a maximum percentage is indicated.

hard, shall conform to the mechanical property requirements specified in Tables 3 and 4.

7.4 The level of mechanical properties for material in other conditions shall be specified in the purchase order.

#### 8. Special Tests

8.1 The grain size of bar product shall be predominantly No. 4 or finer with occasional grains as large as No. 2 permissible when tested in accordance with Test Methods E 112.

8.1.1 It is preferred that samples for grain size determination be selected after the final annealing operation and prior to the final cold-working operation.

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

8.2 For other than bar product, the grain size shall be agreed upon between the purchaser and the manufacturer.

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9.1 Certification shall be provided by the supplier that the material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

### 10. Quality Program Requirements

10.1 The bar and wire producer and any processors shall naintain a quality program as defined in ASQ C1.

## 11. Keywords

11.1 cobalt alloys (for surgical implants) cobalt-nickelchromium-molybdenum alloy; metals (for surgical implants)cobalt alloys