



Designation: F562 – 22

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

This standard is issued under the fixed designation F562; 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 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 aging to attain a variety of combinations of strength and ductility.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other and values from the two systems shall not be combined.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- A751 Test Methods and Practices for Chemical Analysis of Steel Products
- E8/E8M Test Methods for Tension Testing of Metallic Materials
- E29 Practice for Using Significant Digits in Test Data to

Determine Conformance with Specifications

- E112 Test Methods for Determining Average Grain Size
- E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys
- F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone
- IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 ISO Standards:³

- ISO 5832/6 Implants for Surgery—Metallic Materials Part 6: Wrought cobalt-nickel-chromium-molybdenum Alloy
- ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature
- ISO 9001 Quality Management Systems
- ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

2.3 Aerospace Material Specifications:⁴

- AMS 2269 Chemical Check Analysis Limits—Wrought Nickel Alloys and Cobalt Alloys
- AMS 2630 Inspection, Ultrasonic Product over 0.5 inch (12.7 mm) Thick
- AMS 2632 Ultrasonic Inspection of Thin Materials

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

- 3.1.1 *bar, n*—round, rectangular, or other complex-shaped product delivered straightened and cut to defined lengths.
- 3.1.2 *fine wire, n*—round, rectangular, or other complex shapes of uniform cross section along its whole length less than 1.60 mm [0.063 in.] in diameter or thickness furnished in coils, or on spools, reels, or other packaging as specified.
- 3.1.3 *forging bar, n*—bar as described in 3.1.1, used for the production of forgings; may be furnished in the hot-worked condition.

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 F04.12 on Metallurgical Materials.

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² 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.

³ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

⁴ Available from Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096-0001.

*A Summary of Changes section appears at the end of this standard

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

3.1.5 *wire, n*—round, rectangular, or other complex shapes of uniform cross section along its entire length less than 4.76 mm [0.1875 in.] in diameter or thickness furnished in coils, or on spools, reels, or other packaging as specified.

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, cold-worked and aged, or hot-worked condition.

5.2 *Finish*—Bar and wire shall be furnished in cold-drawn, pickled, ground, or ground and polished, as specified by the purchaser.

6. Chemical Requirements

6.1 The supplier's heat analysis shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material with chemistry that is outside the limits specified in Table 1.

6.1.1 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.

TABLE 1 Chemical Requirements

Element	Composition, % (mass/mass)	
	min	max
Carbon	...	0.025
Manganese	...	0.15
Silicon	...	0.15
Phosphorus	...	0.015
Sulfur	...	0.010
Chromium	19.0	21.0
Nickel	33.0	37.0
Molybdenum	9.0	10.5
Iron	...	1.0
Titanium	...	1.0
Boron	...	0.015
Cobalt ^A	balance	balance

^A 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.

6.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between purchaser and supplier.

6.1.3 Intentional elemental additions other than those specified in Table 1 are not permitted, unless previously agreed to between purchaser and supplier.

6.1.4 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification, unless previously agreed to between purchaser and supplier.

6.1.5 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751 and E354.

6.2 Product (Check) Analysis:

6.2.1 Product (check) analysis limits shall conform to the product tolerances in Table 2 per AMS 2269. Product (check) analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

6.2.2 Product (check) analysis limits are not for use at supplier's/producer's acceptance testing. Product (check) analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in Table 1.

6.2.3 A product (check) analysis is one performed by purchaser or supplier of the metal after it has been worked into bar and wire, and is either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.

6.2.4 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product (check) analysis. Product (check) analysis outside the tolerance limits allowed in Table 2 is cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

TABLE 2 Product Analysis Tolerances^{A,B}

Element	Tolerance Under the Minimum or Over the Maximum Limit % (mass/mass) ^C
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

^A See Test Methods E354.

^B See AMS 2269 for chemical check analysis limits.

^C Under minimum limit not applicable for elements where only a maximum percentage is indicated.