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Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)¹

This standard is issued under the fixed designation F90; 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 the <u>chemical, mechanical, and metallurgical</u> requirements for wrought cobalt-20chromium-15tungsten-10nickel alloy used for surgical implants. The properties specified apply specifically to wrought bar, rod, wire, sheet, and strip, but do not apply to surgical fixation wire (see Specification F1091).
- 1.2 The SI units in this standard are the primary units. Values in primary SI or secondary 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 therefore, to ensure conformance with the standard, each system shall be used independent independently of the other. Combiningother, and values from the two systems may result in non-conformance with the specification 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 hai/catalog/standards/sist/1a3962a3-0402-423d-9105-1bb8e1bedb09/astm-f90-23

2.1 ASTM Standards:²

A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings

A751A555/A555M Test Methods and Practices for Chemical Analysis of Steel Products Specification for General Requirements for Stainless Steel Wire and Wire Rods

E8/E8M Test Methods for Tension Testing 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

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

E539 Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry

E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion

E1447 Test Method for Determination of Hydrogen in Reactive Metals and Reactive Metal Alloys by Inert Gas Fusion with Detection by Thermal Conductivity or Infrared Spectrometry

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.



E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis
E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge
Atomic Emission Spectrometry (Performance-Based Method)

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals (Withdrawn 2017)³

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone

F1091 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)

F2527 Specification for Wrought Scamless and Welded and Drawn Cobalt Alloy Small Diameter Tubing for Surgical Implants (UNS R30003, UNS R30008, UNS R30005, and UNS R31537)

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric SystemMetric Practice

2.2 Aerospace Material Specification: Specifications: 4

AMS 2269 Chemical Check Analysis Limits, Wrought Nickel Alloys and Cobalt Alloys

AMS 5759 Cobalt Alloy, Corrosion and Heat Resistant Bars, Forgings, and Rings, 52Co - 20 Cr - 10Ni - 15W 52Co-20Cr-10Ni-15W, Solution Heat Treated

2.3 ISO Standards:⁵

ISO 5832-5 Wrought Cobalt-Chromium-Tungsten-Nickel Alloy

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality System—Requirements

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

2.4 American Society for Quality (ASQ) Standard:

C1 Specification of General Requirements for a Quality Program⁵

3. Product Classification

- 3.1 *Bar*—Round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths, with a maximum cross-sectional area of 16 in.103 cm² (103 cm [16 in.²).].
- 3.2 *Wire*—Round, rectangular, or other complex shaped product produced and delivered in coils. shapes of uniform cross section along its entire length furnished in coils, or on spools, reels, or other packaging as specified.
- 3.3 Fine Wire—Wire with diameter or major dimension less than 0.063 in. (1.6 mm). 1.6 mm. [0.063 in.].

4. Ordering Information

- 4.1 Inquiries and orders for material under this specification shall include the following information:
- 4.1.1 Quantity, Quantity;
- 4.1.2 ASTM designation and date of issue,issue;
- 4.1.3 Mechanical properties (see Section 78););
- 4.1.4 Form (bar, rod, wire, sheet, strip), strip);
 - 4.1.5 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing number, number, num
 - 4.1.6 *Tolerances*—Unless otherwise specified by purchaser, tolerances must meet the requirements of Specification A484/A484M or A555/A555M, or both, as applicable;
- 4.1.7 Condition (see 5.1),);

³ The last approved version of this historical standard is referenced on www.astm.org.

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

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

- 4.1.8 Finish (see 5.2),);
- 4.1.9 Special tests (if any); and
- 4.1.10 Other requirements.

5. Materials and Manufacture

- 5.1 *Condition*—Bar, wire, sheet, and strip shall be furnished to the purchaser, as specified, in the annealed cold-worked, or cold worked and aged condition.
- 5.2 Finish:
- 5.2.1 Bar and wire shall be furnished bright annealed, eold drawn, cold-drawn, pickled, ground, or ground and polished, as specified by the purchaser.
 - 5.2.2 Sheet shall be furnished bright annealed, pickled, cold-rolled, or polished, as specified by the purchaser.

6. Chemical Requirements

- 6.1 The <u>supplier's</u> heat analysis shall conform to the chemical composition <u>of prescribed in Table 1</u>. The supplier shall not ship material <u>that is with chemistry</u> outside the <u>limits requirements</u> specified in <u>Table 1</u>.
- 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.
- 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.
- 6.1.4 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)/mas	
	min	-max max
Carbon	0.05	-0.15
Carbon	0.05	0.15
Manganese	1.00	2.00
Manganese	1.00	2.00
Silicon		0.40
Silicon	<u></u>	0.40
Phosphorus		- 0.04 0
Phosphorus		0.040
Sulfur		0.030
Sulfur		0.030
Chromium	19.00	21.00
Nickel Nickel	-9.00-	11.00
Nickel	9.00	11.00
Tungsten	14.00	16.00
Iron		-3.00
Iron		3.00
Cob alt ^A	balance	balance
<u>Cobalt^A</u>	<u>balance</u>	balance

^A Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage of the cobalt difference is not required to be reported.



- 6.1.5 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods E354.
- 6.2 Product (Check) Analysis—The product analysis is either for the purpose of verifying (check) analysis tolerances shall conform to the product tolerances in Table 2the composition of a heat or lot or to determine variations in the composition within the heat. per AMS 2269. Product analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.
- 6.2.1 Product (check) analysis limits are not for the supplier/producer's use at acceptance testing. Product 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.
- 6.2.2 A product (check) analysis is one performed by the purchaser or the supplier of the metal after it has been worked into one of the forms listed in Section 3 on Product Classification, 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.
- 6.2.3 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis. (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.
- 6.2.4 Product analysis tolerances do not broaden the specified heat analysis requirements but instead cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified Methods and practices relating to chemical analysis required by this specification shall be in Table 2 accordance with Test Methods E354.
- 6.2.5 For referee purposes, use Test Methods E539, E1409, E1447, E1941, E2994, and E2371 and Guide E2626, or other analytical methods agreed upon between the purchaser and the supplier.
- 6.3 For referee purposes, Test Methods E354 shall be used.
- 6.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751.

7. Metallurgical Requirements

7.1 The microcleanliness of the alloy as determined by Method A of Test Methods E45, except using Plate I-r, on representative billet or bar samples from the heat shall not exceed the limits of Table 3.

8. Mechanical Requirements

- 7.1 The material in the annealed condition shall conform to the mechanical properties specified in Tables 3 and 4.
- 7.2 Material in the cold worked condition shall conform to the mechanical properties specified in Table 3.

TABLE 2 Product Analysis Tolerances^A

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit ⁸	
Carbon	0.01	
Manganese	0.04	
Silicon	0.03	
Phosphorous	0.005	
Sulfur	0.005	
Chromium	0.25	
Nickel	0.15 under min; 0.20 over max	
Tungsten	0.25	
Iron	0.07	

A Refer to AMS 2269

 $^{^{\}mathcal{B}}$ Under minimum limit not applicable for elements where only a maximum percentage is indicated.

TABLE 53 Microcleanliness Requirements

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxides)
Thin	1.5	1.5	1.5	1.5
Heavy	1.0	1.0	1.0	1.0

- 7.3 The cold worked and aged condition may be ordered in accordance with mechanical property requirements agreed upon between supplier and purchaser.
- 8.1 Tensile properties shall be determined in accordance with Test Methods E8/E8M. Perform at least one tension test from each lot. Should any test piece 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. Tensile Properties:
- 8.1.1 Tensile properties shall be determined in accordance with Test Methods E8/E8M.
- 8.1.2 The mechanical properties of test specimens shall conform to the requirements specified in Tables 4 and 5.
- 8.1.3 The cold worked and aged condition may be ordered in accordance with mechanical property requirements agreed upon between supplier and purchaser.
- 8.1.4 Perform at least one tension test from each lot. Should any test piece 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.
- 8.1.5 Tensile tests results for which any specimen fractures outside the gauge length shall be considered acceptable if the elongation meets the minimum requirement specified. Refer to 7.11.4 of Test Methods E8/E8M. 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 requirements.

8. Metallurgical Requirements

8.1 The microcleanliness of the alloy as determined by Method A of Test Methods E45, except using Plate I-r, on representative billet or bar samples from the heat shall not exceed the limits of Table 5.

9. Units of Measure Dimensions and Permissible Variations

9.1 Selection—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification.

TABLE 3 Mechanical Requirements, Bar and Wire^A

Condition	Ultimate Tensile Strength,	Yield Strength (0.2 % Offset),	Elongation $^{B}_{\tau}^{C}$ in ^{4}D or ^{4}W ,				
	MPa (psi), min	MPa (psi), min	min, %				
Annealed	860 (125 000)	310 (45 000)	30				
Cold-worked ^D	1250 (180 000)	760 (110 000)	15				
	TABLE 4 Mechanical Requirements, Bar and Wire ^A						
Condition	Ultimate Tensile Strength,	Yield Strength (0.2 % Offset),	Elongation B,C in $4D$ or $4W$,				
Condition	MPa [psi], min	MPa [psi], min	min, %				
Annealed	860 [125 000]	310 [45 000]	<u>30</u>				
Cold-worked	1250 [180 000]	760 [110 000]	<u>15</u>				

^A Annealed wire less than 0.063 in. (160 mm)160 mm [0.063 in.] diameter is covered in Specification F1091.

 $^{^{}B}$ - 4 4 D = 4 × diameter; 4W = 4 × width.

 $^{^{}C}$ Elongation of material 0.062 in. (1.575 mm)1.575 mm [0.062 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of $\frac{2 \text{ in.}}{50.8}$ mm [2 in.] or 4D or 4W: W The gauge length shall be reported with the test results. The minimum. The method for determining elongation of material under 0.062 in. (1.575 mm)1.575 mm [0.062 in.] in diameter or thicknesswidth may be negotiated. Alternately, a minimum gauge length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser; 5.65 (5.65 times the square root of S_o , where S_o is the original cross-sectional area) may be used when agreed upon between supplier and purchaser. The gauge length shall be reported with the test results.

⁹Cold worked and aged condition may be ordered in accordance with mechanical requirements agreed upon between supplier and purchaser.