



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

This standard is issued under the fixed designation F 90; 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 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 F 1091).

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

2. Referenced Documents

2.1 ASTM Standards:

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products²

E 8 Test Methods for Tension Testing of Metallic Materials³

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys⁴

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone⁵

F 1091 Specification for Wrought Cobalt-Chromium Alloy Surgical Fixation Wire⁵

2.2 Aerospace Material Specification:

AMS 2269 Chemical Check Analysis Limits, Wrought Nickel Alloys and Cobalt Alloys⁶

AMS 5759 Cobalt Alloy, Corrosion and Heat Resistant Bars, Forgings, and Rings, 52Co – 20 Cr – 10Ni – 15W, Solution Heat Treated⁶

2.3 ISO Standards

ISO 5832-5 Wrought Cobalt-Chromium-Tungsten-Nickel Alloy⁷

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature⁷

2.4 *American Society for Quality (ASQ) Standard:*

C1 Specification of General Requirements for a Quality Program⁸

3. Ordering Information

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

3.1.1 Quantity,

3.1.2 ASTM designation and date of issue,

3.1.3 Mechanical properties (see Section 6),

3.1.4 Form (bar, rod, wire, sheet, strip),

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

3.1.6 Condition (see 4.1),

3.1.7 Finish (see 4.2),

3.1.8 Other requirements.

4. Materials and Manufacture

4.1 *Condition*—Bar, wire, sheet, and strip shall be furnished to the purchaser, as specified, in the annealed or cold-worked condition.

4.2 *Finish*:

4.2.1 Types of finish available for bar and wire are bright annealed, pickled, cold-drawn, ground, ground and polished, or as specified in the purchase order.

4.2.2 Types of finish available for sheet and strip are bright annealed, pickled, cold-rolled, polished, or as specified in the purchase order.

5. Chemical Requirements

5.1 The heat analysis shall conform to the chemical composition of Table 1. The supplier shall not ship material that is outside the limits specified in Table 1.

5.1.1 Requirements for the major and minor elemental

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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 03.05.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

⁶ Available from Society of Automotive Engineers, Inc., 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁷ Available from American National Standards Association, 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁸ Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements

Element	Composition, % (mass/mass)	
	min	max
Carbon	0.05	0.15
Manganese	1.00	2.00
Silicon	...	0.40
Phosphorus	...	0.040
Sulfur	...	0.030
Chromium	19.00	21.00
Nickel	9.00	11.00
Tungsten	14.00	16.00
Iron	...	3.00
Cobalt ^A	balance	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.

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.

5.2 *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 the heat.

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

5.2.2 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 in Table 2.

5.3 For referee purposes, Test Methods E 354 shall be used.

5.4 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A 751.

6. Mechanical Requirements

6.1 The material in the annealed condition shall conform to the mechanical properties specified in Tables 3 and 4.

TABLE 2 Product Analysis Tolerances^A

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit ^B
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.

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

6.2 The level of mechanical properties for material in other than the annealed condition shall be specified in the purchase order.

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

7. Certification

7.1 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.

8. Quality Program Requirements

8.1 The alloy producer and any processors shall maintain a quality program, such as defined in ASQ C1.

9. Keywords

9.1 cobalt alloys (for surgical implants); cobalt chromium; L-605 alloy; metals (for surgical implants)—cobalt alloys

TABLE 3 Mechanical Requirements, Bar and Wire^A

Condition	Ultimate Tensile Strength, min psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation ^{B,C} in 4D or 4W, min, %
Annealed	125 000 (860)	45 000 (310)	30

^A Annealed wire less than 0.063 in. (1.60 mm) diameter is covered in Specification F 1091.

^B 4D = 4 × diameter; 4W = 4 × width.

^C Elongation of material 0.062 in. (1.575 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4D or 4W. The gage length must be reported with the test results. The method for determining elongation of material under 0.062 in. (1.575 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser ($5.65 \sqrt{S_0}$ where S_0 is the original cross-sectional area).

TABLE 4 Mechanical Requirements, Sheet and Strip

Condition	Thickness, in. (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation in 2 in. (50 mm), min, %
Annealed	0.010 to 0.020 (0.254 to 0.508), incl	130 000 (896)	55 000 (379)	30
	over 0.020 to 0.032 (0.508 to 0.813), incl	130 000 (896)	55 000 (379)	35
	over 0.032 to 0.043 (0.813 to 1.09), incl	130 000 (896)	55 000 (379)	40
	over 0.043 to 0.187 (1.09 to 4.75), incl	130 000 (896)	55 000 (379)	45

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize composition and properties to assure consistency in the starting material used, directly or as modified by forging, casting, or shape forming, in the manufacturing of medical devices.

X1.2 The minimum mechanical properties for sheet and strip supplied in the annealed condition are generally recognized as commercially attainable for the thickness range cited in this specification.

X1.3 ISO standards are listed for reference only. Use of an ISO standard, in addition to, or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

X1.4 This cobalt base alloy, UNS R30605, is known generically as “L-605” and has been used extensively in the aerospace industry since the early 1980s. Aerospace Material Specification AMS 5759 includes the chemical and mechanical properties for the UNS 30605, Cobalt Alloy, Corrosion and Heat Resistant, Bars, Forgings, and Rings, 52Co - 20Cr - 10Ni 15W, Solution Heat-Treated. ISO standard 5832-5 for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy also describes cobalt base alloy UNS R30605.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this standard has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of local biological response established by this material, it has been used as a control material in Practice F 981.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

In 1.1, exception was taken to surgical fixation wire, and reference was made to ISO 6892 in Section 2, in a footnote to Table 3, and in the new section X1.4 in the Appendix. Section 3 was deleted, and reference to the documents mentioned in 3.1 was eliminated in Section 2. Footnote C was inserted in Table 3. Sections X1.2, X1.3, X1.4, and X1.6 were deleted from the Appendix because they refer back to a much older version of this standard (F 90 - 76), and the remaining sections were renumbered as appropriate. Section X1.4 was added in the Appendix and the AMS 5759 and UNS 5832-5 standards were mentioned. Several editorial changes were made to update the text to current format and style templates.

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