Designation: F90 – 14

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 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 inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore each system shall be used independent of the other. Combining values from the two systems may result in non-conformance with the specification.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A751 Test Methods, Practices, and Terminology 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

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

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

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

F2527 Specification for Wrought Seamless and Welded and Drawn Cobalt Alloy Small Diameter Tubing for Surgical Implants (UNS R30003, UNS R30008, UNS R30035, UNS R30605, and UNS R31537)

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

2.2 *Aerospace Material Specification:*[3]

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, Solution Heat Treated

2.3 *ISO Standards:*[4]

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

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality System—Requirements

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

C1 Specification of General Requirements for a Quality Program[5]

3. 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.^{2} (103 cm^2).

3.2 *Wire*—Round, rectangular, or other complex shaped product produced and delivered in coils.

3.3 *Fine Wire*—Wire with diameter or major dimension less than 0.063 in. (1.6 mm).

4. Ordering Information

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

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

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

[5] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

4.1.1 Quantity,
4.1.2 ASTM designation and date of issue,
4.1.3 Mechanical properties (see Section 7),
4.1.4 Form (bar, rod, wire, sheet, strip),
4.1.5 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing number,
4.1.6 Condition (see 5.1),
4.1.7 Finish (see 5.2),
4.1.8 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, 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 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.
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.

6.2 *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.
6.2.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.
6.2.2 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.

6.3 For referee purposes, Test Methods E354 shall be used.

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.

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.

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

7. 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.

7.3 The cold worked and aged condition may be ordered in accordance with mechanical property requirements agreed upon between supplier and purchaser.

7.4 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.
7.4.1 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

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

9.2 *Conversion of Units*—If the supplier's test equipment does not normally report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use

TABLE 3 Mechanical Requirements, Bar and Wire[A]

Condition	Ultimate Tensile Strength, MPa (psi), min	Yield Strength (0.2 % Offset), MPa (psi), min	Elongation[B],[C] in *4D* or *4W*, min, %
Annealed	860 (125 000)	310 (45 000)	30
Cold-worked[D]	1250 (180 000)	760 (110 000)	15

[A] Annealed wire less than 0.063 in. (160 mm) diameter is covered in Specification F1091.
[B] $4D = 4 \times$ diameter; $4W = 4 \times$ width.
[C] Elongation of material 0.062 in. (1.575 mm) or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 2 in. or 4*D* or 4*W*. The gauge length shall 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 gauge length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser; 5.65 times the square root of S_o, where S_o is the original cross-sectional area).
[D] Cold worked and aged condition may be ordered in accordance with mechanical requirements agreed upon between supplier and purchaser.

TABLE 4 Mechanical Requirements, Sheet and Strip

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

TABLE 5 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

of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.

10. Significance of Numerical Limits

10.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

11. Certification

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program, such as defined in ISO 9001, or similar.

13. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize composition and properties to ensure 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.

X1.5 Units of Measure

X1.5.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch - pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents will be considered when assigning the SI values.

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 F981.

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

Committee F04 has identified the location of selected changes to this standard since the last issue (F90 – 09) that may impact the use of this standard. (Approved Nov. 1, 2015)

(1) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards within F04.12.
(2) Section 1.2 was changed to make SI units the primary units.
(3) Designation for Test Methods E8 was corrected to Test Methods E8/E8M.
(4) Cold worked and aged condition was added to 5.1, Table 3, and new 7.3.
(5) Units of measure information was added as new Section 9. and new X1.5.