Designation: F 90 – 97

Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel 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-20 chromium-15 tungsten-10 nickel alloy bar, wire, sheet, and strip used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

A 480/A 480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip[2]

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets, and Forgings[3]

A 555/A 555M Specification for General Requirements for Stainless Steel Wire and Wire Rods[2]

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 8 Test Method for Tension Testing of Metallic Materials[3]

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[5]

F 1091 Specification for Wrought Cobalt-Chromium Alloy Surgical Fixation Wire[5]

2.2 *Aerospace Material Specification:*

AMS 2269 Chemical Check Analysis Limits, Wrought Nickel Alloys and Cobalt Alloys[5]

2.3 *American Society for Quality Control (ASQC) Standard:*

C1 Specification of General Requirements for a Quality Program[6]

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 480/A 480M, A484/A 484M, and A 555/A 555M shall apply.

3.2 In the case where a conflict exists between this specification and those listed in 2.1-2.3, this specification shall take precedence.

4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation,

4.1.3 Form (bar, wire, sheet, strip),

4.1.4 Condition (see 6.1),

4.1.5 Finish (see 6.2),

4.1.6 Mechanical properties (if applicable, for special conditions),

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

4.1.8 Other requirements.

5. Manufacture

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

5.2 *Finish*:

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

5.2.2 Types of finish available for sheet and strip are brightannealed, pickled, cold-rolled, polished or as specified in the implant manufacturer's purchase order.

6. Chemical Requirements

6.1 The heat analysis shall conform to the requirements as to chemical composition 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 certify compliance with this specification.

6.2 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements, but cover

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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 American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements

Element	Composition, %	
	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 cobalt content by difference is not required to be reported.

variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. Product analysis limits shall be as specified in Table 2.

6.2.1 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.

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.

6.2.2 Acceptance or rejection of a heat or lot may be made by the purchaser on the basis of this check analysis.

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

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

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 The level of mechanical properties for material in other than the annealed condition shall be specified in the implant manufacturer's purchase order.

7.3 Specimens for tension tests shall be machined and tested in accordance with Test Method E 8.

8. Additional Requirements

8.1 Any additional requirements shall be specified on the purchase order.

9. Certification

9.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

10. Quality Program Requirements

10.1 The producer shall maintain a quality program, such as defined in ASQC C1.

10.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1, or other recognized programs.

11. Keywords

11.1 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] in 4*D* or 4*W*, min, %
Annealed	125 000 (860)	45 000 (310)	30

[A] Annealed wire less than 0.063 in. (160 mm) diameter is covered in Specification F 1091.
[B] $4D = 4 \times$ diameter; $4W = 4 \times$ width.

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 This cobalt-chromium-tungsten-nickel containing alloy has the requisite mechanical and corrosion resistance properties considered necessary for certain implant applications.

X1.3 The maximum silicon content has been lowered from the value stated in Specification F 90–76, a minimum manganese limit has been included, and maximum sulfur and phosphorus limits have been specified to meet the most recent composition requirements for this alloy.

X1.4 The minimum elongation for bar and wire in the annealed condition has been increased from 10 in Specification F 90–76 to 30 % and is considered a practical limit based on manufacturing experience and published statistical data that is presently available.

X1.5 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.

X1.6 Specifications A 480/A 480M, A 484/A 484M, and A 555/A 555M have been included as applicable documents to cover the general delivery requirements for Specification F 90 bar, wire, sheet, and strip manufactured for surgical implant applications. Dimensional tolerance, requirements previously specified in Paragraph 5 are covered by Specifications A 480/A 480M, A 484/A 484M, and A 555/A 555M.

X1.7 The UNS designation has been added, residual element language has been included, product analysis tolerance information has been expanded, Specification F 1091 has been included as a referenced document that replaces Specifications F 643 and F 644, and Appendix X2 Biocompatibility section has been added to the Rationale, and E 8 tension testing method has been documented.

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.