**Designation: F 90 ~~– 97~~ – 01**

# 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 used for the manufacture of~~ strip, but do not apply to surgical ~~implants.~~ 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:*

[1] This specification is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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

A 480/A 480M Specification for General Requirements for Flat-Rolled Stainless 751 Test Methods, Practices, and Heat-Resisting Terminology for Chemical Analysis of Steel Plate, Sheet, and Strip Products[2]
A 484/A 484M Specification
E 8 Test Methods for General Requirements for Stainless and Heat-Resisting Bars, Billets, and Forgings Tension Testing of Metallic Materials[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[6]
AMS 5759 Cobalt Alloy, Corrosion and Heat Resistant Bars, Forgings, and Rings, 52Co – 20 Cr – 10Ni – 15W, Solution Heat Treated[6]

2.3 *ISO Standards*

ISO 5832-5 Wrought Cobalt-Chromium-Tungsten-Nickel Alloy[7]
ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature[7]

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

C1 Specification of General Requirements for a Quality Program[8]

## 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

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

4.1.1 Quantity (weight or number
3.1.1 Quantity,
3.1.2 ASTM designation and date of pieces),
4.1.2 ASTM designation,
4.1.3 Form issue,
3.1.3 Mechanical properties (see Section 6),
3.1.4 Form (bar, rod, 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
3.1.5 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or p drawintg number, a
3.1.6 Condition (see 4.1),
3.1.7 Finish (see 4.2),
3.1.8 Other requirements.

## 54. Materials and Manufacture

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

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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. 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.

54.2 *Finish*:

54.2.1 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.

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

**65. Chemical Requirements**

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

65.1.1 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 verify compliance with this specification.

65.2 *Product Analysis*—PThe 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. 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.

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 .

6.2.1 The product analysis is either for the purpose4.

6.2 The level of verifying the composition of a heat or lot or to determine variations mechanical properties for material in other than the composition within the heat.

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

6.3 For referee purposes, Test Methods E 354 purchase order.

6.3 Tensile properties shall be used.

6.4 Methods and practices relating to chemical analysis required by this specification shall be determined in accordance with Test Methods A 751. E 8.

**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**

97.1 A cCertification shall be provided by the manufacturer of the material supplier that the material was manufactured and

**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 cobalt content by 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.

**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 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.
[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 ($5.65\sqrt{So}$ where So 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 |

~~tested in accordance with~~ meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

~~**10.**~~

## 8. Quality Program Requirements

~~10~~8.1 The alloy producer and any processors shall maintain a quality program, such as defined in ASQ~~C~~ 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.**~~

## 9. Keywords

~~11~~9.1 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 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

X1.3 ISO standards are listed for Specification F 90 bar, wire, sheet, and strip manufactured for surgical implant applications. Dimensional tolerance, requirements previously specified reference only. Use of an ISO standard, in Paragraph 5 are covered by Specifications A 480/A 480M, A 484/A 484M, addition to, or instead of a preferred ASTM standard may be negotiated between the purchaser and A 555/A 555M.

X1.7 The supplier.

X1.4 This cobalt base alloy, UNS designation has been added, residual element language has been included, product analysis tolerance information has been expanded, Specification F 1091 has been included R30605, is known generically as a referenced document that replaces Specifications F 643 "L-605" and F 644, and Appendix X2 Biocompatibility section has been added to used extensively in the Rationale, aerospace industry since the early 1980s. Aerospace Material Specification AMS 5759 includes the chemical and E 8 tension testing method has been documented. 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.