



Designation: F90 – 23

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 chemical, mechanical, and metallurgical 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 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, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems 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

2.1 ASTM Standards:²

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

A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

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.

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

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)

IEEE/ASTM SI 10 American National Standard for Metric Practice

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

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

2.2 Aerospace Material 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-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

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 103 cm² [16 in.²].

3.2 *Wire*—Round, rectangular, or other complex 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 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;
- 4.1.2 ASTM designation and date of issue;
- 4.1.3 Mechanical properties (see Section 8);
- 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 *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);
- 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, 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 supplier's heat analysis shall conform to the chemical composition prescribed in **Table 1**. The supplier shall not ship material with chemistry outside the requirements 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.

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.

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 (check) analysis tolerances shall conform to the product tolerances in **Table 2** 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

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.

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>.

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.

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 (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 Methods and practices relating to chemical analysis required by this specification shall be in 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.

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

8.1 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.

TABLE 3 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 |

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.

9. Dimensions and Permissible Variations

9.1 Units of Measure:

9.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

9.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

9.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

9.1.2 *Conversion of Units*—If the supplier's test equipment does not 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 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 significance.

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, ISO 13485, or other similar quality program.

12.2 The purchaser may audit the producer's quality management system for conformance to the intent of ISO 9001, ISO 13485, or other similar recognized quality management system.