

Designation: F90 – 23

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

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 ( $\varepsilon$ ) 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:<sup>2</sup>

- 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

### 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)<sup>3</sup>
- 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

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

<sup>&</sup>lt;sup>1</sup>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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<sup>&</sup>lt;sup>2</sup> 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.

 $<sup>^{3}\,\</sup>mathrm{The}$  last approved version of this historical standard is referenced on www.astm.org.

2.2 Aerospace Material Specifications:<sup>4</sup>

- 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

- 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  $103 \text{ cm}^2$  [16 in.<sup>2</sup>].

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 <sup>A</sup>	balance	balance

<sup>A</sup> 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.

<sup>2.3</sup> ISO Standards:<sup>5</sup>

<sup>&</sup>lt;sup>4</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

<sup>&</sup>lt;sup>5</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.