Designation: ~~F1537 – 11~~ F1537 – 20

Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)[1]

This standard is issued under the fixed designation F1537; 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 three wrought cobalt-28chromium-6molybdenum alloys used for surgical implants. The properties specified apply specifically to wrought bar, rod, and wire.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values ~~given~~stated in ~~parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.~~each system are not necessarily 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 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]

E8/E8M Test Methods for Tension Testing of Metallic Materials

E18 Test Methods for Rockwell Hardness of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E112 Test Methods for Determining Average Grain Size

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Specifications:*[3]

AMS 2248 Chemical Check Analysis Limits, Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys

AMS 2269 Chemical Check Analysis Limits, Nickel, Nickel Alloys and Cobalt Alloys

AMS 2630 Inspection, Ultrasonic Product over 0.5 Inch (12.7 mm) Thick

2.3 *ISO Standards:*[4]

ISO 5832–12 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy

ISO 6892 Metallic Materials - Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

[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.

Current edition approved ~~Nov. 15, 2011~~March 1, 2020. Published ~~December 2011~~April 2020. Originally approved in 1994. Last previous edition approved in ~~2008~~2011 as ~~F1537 – 08.~~F1537 – 11. DOI: ~~10.1520/F1537-11.~~10.1520/F1537-20.

[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.

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

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *lot*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

4. Ordering Information

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

4.1.1 ~~Quantity,~~Quantity;

4.1.2 ASTM designation, alloy number, and date of ~~issue,~~issue;

4.1.3 Mechanical properties ~~(See~~(see Section 7~~),~~);

4.1.4 Units to be certified – SI or inch pound;

4.1.5 Form (bar, rod or ~~wire),~~wire);

4.1.6 Applicable dimensions including size, thickness, width, and length (exact, random, or multiples) or drawing ~~number,~~ number;

4.1.7 Condition ~~(See~~(see Section 5~~),~~);

4.1.8 Special tests (if ~~any),~~any); and

4.1.9 Other requirements.

5. Materials and Manufacture

5.1 Product shall be furnished as specified below:

5.1.1 The annealed condition is typically supplied as a hot rolled and annealed product.

5.1.2 The hot worked condition is typically supplied as a hot rolled and unannealed product.

5.1.3 The warm worked condition is typically supplied as a thermomechanically processed product to achieve a strain-hardened structure.

6. Chemical Requirements

6.1 The cobalt-28chromium-6molybdenum alloys shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1 for the applicable alloy.

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.

6.1.2 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace 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.

6.1.3 Intentional elemental additions other than those specified in Table 1 are not permitted.

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.

TABLE 1 Chemical Composition

Element	Composition % (mass/mass)					
	Alloy 1 UNS R31537 (Low Carbon)		Alloy 2 UNS R31538 (High Carbon)		Alloy 3 UNS R31539 (Dispersion Strengthened)	
	min	max	min	max	min	max
Carbon	......	0.14	0.15	0.35	......	0.14
Aluminum	......	......	......	......	0.30	1.00
Lanthanum	......	......	......	......	0.03	0.20
Chromium	26.0	30.0	26.0	30.0	26.0	30.0
Molybdenum	5.0	7.0	5.0	7.0	5.0	7.0
Nickel	......	1.0	......	1.0	......	1.0
Iron	......	0.75	......	0.75	......	0.75
Silicon	......	1.0	......	1.0	......	1.0
Manganese	......	1.0	......	1.0	......	1.0
Nitrogen	......	0.25	......	0.25	......	0.25
Cobalt[A]	Balance		Balance		Balance	

[A] Approximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of cobalt difference is not required to be reported.

6.2.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

7. Mechanical Requirements

7.1 *Tensile Properties:*

7.1.1 Perform at least two tension tests from each lot. Should any of these test pieces 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.

7.1.2 Tensile test results for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.11.5 of Test Methods E8/E8M.

7.1.3 The mechanical properties of test specimens shall conform to the requirements specified in Table 3.

7.2 *Hardness:*

7.2.1 Hardness values shall be determined in accordance with Test Methods E18.

7.2.2 Hardness values are for information only and shall not be used as a basis for rejection.

8. Microstructure Requirements

8.1 Bar, rod, and wire conforming to this specification shall have a homogeneous microstructure with an average grain size of ASTM No. 5 or finer when measured in accordance with Test Methods E112.

9. Ultrasonic Inspection

9.1 For finished thicknesses ~~0.250 in. (6.35 mm)~~6.35 mm [0.250 in.] and greater, inspection shall be per AMS 2630 Class A1. Equivalent test methods may be substituted when agreed to by purchaser and supplier. AMS 2630 indicates a minimum size of ~~0.500 in. (12.7 mm).~~12.7 mm [0.500 in.]. The use of this specification to a minimum size of ~~0.250 in. (6.35 mm)~~6.35 mm [0.250 in.] is done with agreement of producer and user members of the committee.

9.2 For finished thicknesses less than ~~0.250 in. (6.35 mm)~~6.35 mm [0.250 in.] and for shape bar that cannot be inspected at finish, intermediate size bars or billets shall be ultrasonically inspected per AMS 2630 Class A1 or as agreed upon by the purchaser and supplier.

10. Dimensions, Mass, and Permissible Variations

10.1 *Units of Measure:*

10.2 *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 in order of precedence.

10.3 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.

TABLE 2 Product Analysis Tolerances[A,B]

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, % (mass/mass)[C]
Carbon	0.02
~~Aluminum ≤ 0.50~~	~~0.05~~
Aluminum ≤0.50	0.05
~~Aluminum > 0.50 up to 1.00~~	~~0.10~~
Aluminum >0.50 up to 1.00	0.10
Lanthanum	0.01
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Silicon	0.05
Manganese	0.03
Nitrogen[D]	0.02

[A] See Test Methods E354.
[B] Refer to AMS 2269 for chemical check analysis limits (except nitrogen).
[C] For elements in which only a maximum percentage is indicated, the "under minimum limit" is not applicable.
[D] Refer to AMS 2248.