Designation: F 1537 – ~~94~~00

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 F 1537; 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 ~~material~~ requirements ~~of~~ for three wrought cobalt - 28chromium - 6molybdenum alloys used for surgical implants. ~~Material conforming to this specification has been evaluated for biocompatibility and corrosion resistance and has been found to be comparable to material conforming to Specification F 75.~~ The properties specified ~~in this specification~~ apply specifically to wrought ~~bar product.~~ bar, rod, and wire.

1.2 The values stated in inch-pound units are to be regarded as the standard. The ~~metric~~ SI equivalents of the inch-pound units may be approximate.

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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E 8 Test Methods ~~of~~ for Tension Testing of Metallic Materials[2]
E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]
E 112 Test Methods for Determining ~~the~~ Average Grain Size[2]
E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[3]
F 75 Specification for Cast Cobalt-Chromium Molybdenum Alloy for Surgical Implant Applications[4]
~~F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[4]~~
2.2 *Aerospace Material Specifications:*
AMS 2269 Chemical Check Analysis Limits, Nickel, Nickel Alloys and Cobalt Alloys[5]
AMS 22~~69C~~48 Chemical Check Analysis Limits, ~~Wrought Nickel Alloy~~ Corrosion and ~~Cobalt Alloys~~
~~AMS 2248B Chemical Check Analysis Limits, Wrought Heat, and Corrosion-Resistant~~ Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys[5]
AMS ~~2630, Class A1, Ultrasonic~~ 2630 Ultrasonic Inspection[5]
2.3 *American Society for Quality ~~Control Standard:~~*[6]
~~ASQC C1-1985 Specification~~ Standard:
ASQ C1 Specification of General Requirements for a Quality Program[6]

[2] *Annual Book of ASTM Standards*, Vol 03.01.
[3] *Annual Book of ASTM Standards*, Vol 03.05.
[4] *Annual Book of ASTM Standards*, Vol 13.01.
[5] Available from Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096-0001.
[6] Available from American Society for ~~Quality Control, 161 W.~~ Quality, 611 East Wisconsin Ave~~.~~nue, Milwaukee, WI 53203.

3. Ordering Information

3.1 InquiriesSignificance and orders for material under Use

3.1 The purpose of this specification shall include is to characterize the following information:

3.1.1 Quantity,

3.1.2 ASTM designation chemical, mechanical, and date metallurgical requirements of issue,

3.1.3 Mechanical properties,

3.1.4 Form,

3.1.5 Applicable dimensions or print number,

3.1.6 Condition,

3.1.7 Special tests, and

3.1.8 Other requirements. wrought cobalt - 28chromium - 6 molybdenum bar, rod, and wire.

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 alloy number,

4.1.3 Mechanical properties (See Section 6),

4.1.4 Form (bar, rod or wire),

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

4.1.6 Condition (See Section8,

4.1.7 Special tests (if any), and

4.1.8 Other requirements.

5. Chemical Requirements

4.1 The cobalt-chromium-molybdenum alloy supplied to the manufacturer for the production of surgical implants

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

5.1.1 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.

5.2 *Product Analysis*—The product analysis tolerances shall conform 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 cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2 . See Test Methods E 354.

TABLE 1 Chemical Require Comentposition

Element	Composition % (mass/mass)					
	Alloy 1 UNS R31537 (Low Carbompn)		Allosy 2 UNS R31538 (Hitgh 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
Molybdenum	5.0	7.0	5.0	7.0	5.0	7.0
Nickel	...	1.0	.....	1.0	.....	1.0
Nickel	.....	1.0	.....	1.0	.....	1.0
Iron	...	0.75	Carbon	...	.....	0.35
Iron	.....	0.75	.....	0.75	.....	0.75
Silicon	...	1.0	.....	1.0	.....	1.0
Silicon	.....	1.0	.....	1.0	.....	1.0
Manganese	...	1.0	.....	1.0	.....	1.0
Manganese	.....	1.0	.....	1.0	.....	1.0
Nitrogen	...	0.25A	.....	0.25	.....	0.25
Nitrogen	.....	0.25	.....	0.25	.....	0.25
Cobalt[B]	balance		Balance		Balance	
Cobalt[A]	Balance		Balance		Balance	

[A] If N < 0.10, content does not have to be reported.

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

TABLE 2 Product Analysis Tolerances[A,B]

Element	Permissible Variation Under the Minimum Limit or Over the Maximum Limit, %[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 up to 1.00	0.10
Lanthanum	0.01
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03
Nitrogen[C]	0.02
Nitrogen[D]	0.02

[A] Refer to AMS 2269C for chemical check analy Tesis limits (Mexcept nitrhogen)ds E 354.

[B] ForRelfemenr ts in whichonly a maximum pe AMS 2269 for chentagemis indicated, tl che "uck ander malysinimums limit" is not a (exceppit nicabltrogen).

[C] RFor eflements in which only a maximum percentage is indicated, the "under minimum limit" is no AMS 2248Bt applicable.

[D] Refer to AMS 2248.

4.2 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.

5. Significance and Use

5.1 The purpose of this specification is to characterize the material properties of currently available cobalt-28-chromium-6-molybdenum wrought bar product.

6. Condition

6.1 Bar product shall be furnished to the implant manufacturer, as specified, in the annealed, hot worked, or warm worked condition.

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

6.3 The hot worked condition is typically supplied as a hot rolled and unannealed bar product that is referred to as "forge quality."

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

7. Mechanical Requirements

76.1 *Tensile Properties*:

76.1.1 Tensile properties shall be determined in accordance with Test Methods E 8.

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

76.2 *Hardness*—:

6.2.1 Hardness values shall be determined in accordance with Test Methods E 18.

6.2.2 Hardness values are for guidelines information only and shall not be used as a basis for rejection. (See Test Method E 18.)

8. rejection.

7. Special Tests

8.1 Bar product

7.1 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 E 112.

87.2 Ultrasonic inspection should be per AMS 2630, Class A1.

8. Condition

8.1 Product shall be furnished as specified below:

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

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

TABLE 3 Mechanical Requirements

Condition	Ultimate Tensile Strength min, psi (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation,[A] min, %	Reduction in Area, min, %	Hardness, HRC, Typical
Annealed	130 000 (897)	75 000 (517)	20	20	25
Hot Worked	145 000 (1000)	101 000 (700)	Hot worked	145 000	101 000 12 12 28
Warm Worked	170 000 (1172)	120 000 (827)	Warm worked	170 000	120 000 12 12 35

[A] Elongation of material 0.062 in. (1.575 mm) or greater in diameter or thickness 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. (1.57mm) in diamter or thickness nay be negotiated.

8.1.3 The warm worked condition is typically supplied as a thermomechanically processed product to achieve a strainhardened structure.

8.1.4 Other conditions may be provided as agreed upon between purchaser and supplier.

9. Certification

9.1 Certification shall be provided by the alloy producer supplier that the material meets the requirements specified in of this specification. A report of the test results shall be furnished at the time of shipment.

10. Quality Program Requirements

10.1 The alloy producer and any processors shall maintain a quality program such as, for example, as that which is defined in ASQC C1.

10.2 The manufacturer of surgical implants or medical devices shall be assured of 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-28chromium-6molybdenum; metals (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize composition and properties to ensure consistency in wrought cobalt-28chromium-6molybdenum bar p, rod uct, and wire used in the manufacturing of medical devices.

X1.2 Material conforming The carbon content of commercially available F 1537 barstock varies to this specification has been evaluated for biocompatibility meet specific customer needs. The chemical composition was expanded into low and corrosion resistance high carbon alloys (Alloys 1 and has been found to be identical to material conforming to Specification F 75. Materials conforming to Specification F 75 have been used as a control 2 in Practice F 981. Table 1). Alloy 2 contains a greater volume fraction of carbides compared to Alloy 1.

X1.3 Alloy 3 was added in Table 1 since bar, rod, and wire produced with this composition meet the current ASTM F 1537

requirements. Alloy 3 is a dispersion-strengthened alloy containing fine aluminum-lanthanum oxides/nitrides.[7,8]

X1.4 The minimum mechanical properties of wrought bar, rod, and wire conforming to this specification are superior to the minimum mechanical properties of Specification F 75 material in the as-cast condition.

X1.5 Some complex metallic phases, such as carbides, oxides, or carbonitrides, or combinations thereof, may be present in the microstructure of this alloy.

[7] Wang, Kathy K., Gustavson, Larry J., and Dumbleton, John H., U.S. Patent #4,668,290, "Dispersion Strengthened Cobalt-Chromium-Molybdenum Alloy Produced By Gas Atomization", Filed August 13, 1985, Issued May 26, 1987.

[8] Wang, Kathy K., Gustavson, Larry J., and Dumbleton, John H., "The Development of a New Dispersion Strengthened Vitallium Alloy for Medical Implants", *Modern Developments in Powder Metallurgy*, Volume 20, 1988, pp. 361-375, Metal Powder Industries Federation, 105 College Road East, Princeton, NJ 08540-6692

X2. BIOCOMPATIBILITY

X2.1 The alloy compositions covered by this specification have been employed successfully in human implant applications in contact with soft tissue and bone for over a decade (reference 510k #K852964 for Alloy 3, which has been used since 1985).

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. Long term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.