Designation: F 563 – 00

Standard Specification for Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)[1]

This standard is issued under the fixed designation F 563; 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 a wrought cobalt-20nickel-20chromium-3.5molybdenum-3.5tungsten-5 iron alloy in the form of bars, wires, and forgings used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI units given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 8 Test Methods for Tension Testing of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 92 Test Method for Vickers Hardness of Metallic Materials[3]

E 112 Test Methods for Determining Average Grain Size[3]

E 140 Hardness Conversion Tables for Metals (Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Rockwell Superficial Hardness, Knoop Hardness, and Scleroscope Hardness)[3]

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[4]

2.2 *Aerospace Material Specification:*

AMS 2269 Chemical Check Analysis Limits Wrought Nickel Alloys and Cobalt Alloys[5]

2.3 *ISO Standard:*

ISO 5832-8 Implant for Surgery—Metallic Materials—Part 8: Wrought Cobalt-Nickel-Chromium-Tungsten-Iron Alloy[6]

2.4 *ASQ Stamdard:*

Cl Specification of General Requirements for a Quality Program[7]

3. Ordering Information

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

3.1.1 Quantity (weight or number of pieces),

3.1.2 Condition (4.1),

3.1.3 Finish (4.2),

3.1.4 Mechanical properties (if applicable, for special conditions) (7.1),

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

3.1.6 Special tests, and

3.1.7 Supplementary requirements (if applicable),

3.1.8 Product uniformity, and

3.1.9 Additional tests or inspections, supplementary composition limits, if any, as required by the manufacturing process and intended application, and other supplementary requirements.

4. Materials and Manufacture

4.1 *Condition*:

4.1.1 Bar and wire shall be furnished to the implant manufacturer as specified, in the annealed, medium hard, hard, or, for special applications, extra hard condition, depending on the degree of cold work and aging treatment, if any.

4.1.2 Forging shall be furnished to the implant manufacturer as specified, in the forged or forged and solution heattreated and aged condition.

4.2 *Finish*—Surface finish shall be as specified and required by the subsequent manufacturing process and the intended application, if pertinent.

5. Chemical Composition

5.1 The heat analysis shall conform to the requirements as

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[2] *Annual Book of ASTM Standards*, Vol 01.01.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 03.05.

[5] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[6] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[7] Available from American Society for Quality, 161 West Wisconsin Ave., Milwaukee, WI 53203.

to chemical composition specified in Table 1. The product analysis tolerances shall conform to the requirements prescribed in Table 2.

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 For referee purposes, Test Methods E 354 shall be used.

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

5.4 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements, but 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.

5.4.1 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.

5.4.2 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this check analysis.

6. Metallurgical Requirements

6.1 The microstructure of the material shall be single phased as observed at 100× magnification.

6.2 The grain size shall be No. 5 or finer, based on the appropriate chart of Test Methods E 112.

TABLE 1 Chemical Requirements, Ladle Analysis

Element	Composition, (%), Mass/Mass	
	min	max
Carbon	...	0.05
Manganese	...	1.00
Sulfur	...	0.010
Silicon	...	0.50
Chromium	18.00	22.00
Molybdenum	3.00	4.00
Tungsten	3.00	4.00
Nickel	15.00	25.00
Titanium	0.50	3.50
Iron	4.00	6.00
Cobalt	balance	balance

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerances over the max (upper limit) or under the min (lower limit), %, Mass/Mass	
Carbon	0.01	
Manganese	0.03	
Sulfur	0.003	
Silicon	0.03	
Chromium	0.25	
Molybdenum	0.10	
Tungsten	0.15	
	under min	over max
Nickel	0.20	0.25
Titanium	0.03	0.07
Iron	0.07	0.10

[A] Refer to AMS 2269.

7. Mechanical Requirements

7.1 The material shall conform to the appropriate minimum mechanical properties specified in Table 3. Test Methods E 8 shall apply.

7.2 When desired, hardness limits may be specified. Test Methods E 18 or E 92 and Standard Tables E140 shall be used. Hardness determination of cold-worked material shall be made on a product cross section, midway between the center and the surface, if the cross section size is adequate.

7.3 If any manufacturing operations of the implant manufacturer alter the properties of the material, the specimens shall be subjected to the same operations prior to testing.

8. Certification

8.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results requested shall be furnished at the time of shipment.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as that defined in ASQ Cl.

9.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program for conformance to the intent of ASQ Cl, or any other recognized program.

10. Keywords

10.1 cobalt alloys; cobalt alloys (for surgical implants); cobalt-nickel alloy; metals (for surgical implants)

TABLE 3 Mechanical Properties

Conditions	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength, (0.2 % Offset) min, psi (MPa)	Elongation[A] in 4*D* or 4*W*, min, %	Reduction of Area, min, %
Fully annealed	87 000 (600)	40 000 (276)	50	65
Cold worked or cold worked and aged[B]:				
medium hard	145 000 (1000)	120 000 (827)	18	50
hard	190 000 (1310)	170 000 (1172)	12	45
Cold worked and aged (for special purposes), extra hard	230 000 (1586)	190 000 (1310)	...	...

[A] 4 D = 4 × diameter: 4 W = 4 × width.
[B] Aging in the temperature range from 400 to 550°C.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary purpose of this specification is to characterize composition and properties to assure consistency in the starting material used in the manufacture of medical devices.

X1.2 Acceptable metal conditions supplied to the medical device manufacturer include annealed, cold worked, and cold worked and aged depending upon the medical device design and its intended application.

X1.3 The title has been changed to include the nominal composition of the major elements; UNS designation has been added; the scope was changed to include the nominal analysis; ISO 5832-8 specification has been included under 2 on Referenced Documents; product analysis information was added in 5.4 and Section 8 on Certification; and Section 9 on Quality Program Requirements were updated; as well as Appendix X2 Biocompatibility added.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this standard has been employed successfully in contact with soft tissue and bone for over a decade **(1-7)**.[8]

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.

[8] The boldface numbers in parentheses refer to the list of references appended to this specification.

REFERENCES

(**1**) Hulliger, L., Pohler, O., and Straumann, F., "Effect of Pure Metals and Alloys on the Growth of Fibroblast Cultures," *Zeitschrift Fuer Die Gesamte Experimentelle Medizin*, Vol 114, 1967, p. 145.

(**2**) Straumann, F., Steinemann, S., Pohler, O., Willenegger, H., and Schenk, R., "Recent Experimental and Clinical Results on Metallosis," *Langenbecks Archiv Fuer Klinische*, Vol 305, 1963, p. 21.

(**3**) Contzen, H., Straumann, F., and Paschke, E., *Basics of the Alloplastic with Metals and Plastic Materials*, published by Georg Thieme, Stuttgart, 1967.

(**4**) Hagmann, R., "Investigations on New Bone Formation After Intrafemoral Implantation of Different Metal Screws in Rats," *Acta Anatomica*, Vol 64, 1966, p. 311.

(**5**) Hutzschenreuter, P., Perren, S. M., Steinemann, S., Geret, V., and Klebl, M., "Some Effects of Rigidity of Internal Fixation on the Healing Pattern of Osteotomies," *Injury 1*, 1969, p. 77.

(**6**) Wirz, J. "Die Transfixation von Stegpfeilern," *Zahnärztliche Rundschau*, Vol 79, 1970, p. 721.

(**7**) Wirz, J., *Die Transfixation von Stegpfeilern*, published by Alfred Huethig, Heidelberg, 1973.