Designation: F 745 – 00

Standard Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications[1]

This standard is issued under the fixed designation F 745; 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 18chromium-12.5nickel-2.5molybdenum stainless steel alloy shot, bar, or ingot used for the manufacture of cast and solution-annealed surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

A 744/A 774M Specification for Castings, Iron-Chromium-Nickel, Corrosion Resistant, for Severe Service[2]

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

E 353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys[4]

2.2 *American Society for Quality (ASQ) Standard:*[5]

ASQC 1 Specification of General Requirements for a Quality Program

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 ASTM Designation,

3.1.3 Form (Section 4.1),

3.1.4 Special tests, and

3.1.5 Special requirements.

4. Materials and Manufacture

4.1 The base material furnished to the implant manufacturer for purposes of casting surgical implants shall be supplied in the form of bar, shot, or ingot.

5. Chemical Composition

5.1 The heat analysis shall conform to the chemical composition listed in Table 1. The manufacturer shall not ship material that is outside the limits specified in Table 1.

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 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 variation between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

5.3 For referee purposes, Test Methods E 353 shall be used.

6. Mechanical Properties

6.1 The material shall conform to the mechanical property requirements prescribed in Table 3.

6.2 Specimens for tension tests shall be cast from remelted material from each master heat by the same general procedures used in casting surgical implants.

6.2.1 Specimens may be cast, ground, or machined to final dimensions in accordance with the 0.25 in. (6.35 mm) diameter specimen in Fig. 8 of Test Methods E 8.

6.2.2 Specimens shall be solution annealed using the same procedures used to solution anneal surgical implants.

6.3 A minimum of two tension specimens shall be tested. If one specimen fails below the specified mechanical requirements, two additional specimens shall be tested and both must pass.

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[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. 10, 2000. Published February 2001. Originally published as F 745 – 81. Last previous edition F 745 – 95.

[2] *Annual Book of ASTM Standards,* Vol 01.02.

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

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

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

TABLE 1 Chemical Requirements (Heat Analysis)

Element	Composition, %	
	min	max
Carbon	...	0.06
Manganese	...	2.0
Phosphorus	...	0.045
Sulfur	...	0.030
Silicon	...	1.0
Chromium	17.00	19.00
Nickel	11.00	14.00
Molybdenum	2.00	3.00
Iron	balance	balance

TABLE 2 Product Analysis Tolerances

NOTE 1—Tolerances are over the maximum limit or under the minimum limit.

Element	Tolerance, %
Carbon	0.01
Manganese	0.04
Phosphorus	0.010
Sulfur	0.005
Silicon	0.05
Chromium	0.20
Nickel	0.15
Molybdenum	0.10

6.3.1 Test results for any specimen which fractures outside of the gage length shall be considered invalid and void; and a replacement specimen shall be tested.

7. Special Tests

7.1 Other tests may be required by agreement, between the purchaser and the supplier.

TABLE 3 Mechanical Property Requirements (As-Cast and Solution-Annealed)

Property	Requirement
Tensile strength, min, psi (MPa)	70000 (483)
Yield strength (0.2 % offset), min, psi (MPa)	30000 (207)
Elongation (in 4× diameter), min, %	30
Reduction of area, min,%	50

8. Special Requirements

8.1 Special requirements shall be specified on the purchase order by the purchaser.

9. Certification

9.1 Upon request of the purchaser in the contract or order a 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.

10. Quality Program Requirements

10.1 The producer shall maintain a quality program as defined in ASQC 1.

10.2 The purchaser shall be assured of the producer's quality program conformance to the intent of ASQC 1, or other recognized programs.

11. Keywords

11.1 castings; metals (for surgical implants); stainless steel; surgical applications

APPENDIXES

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE FOR SPECIFICATION F745

X1.1 The intent of this document is to provide a standard material specification by specifying the chemical and mechanical properties of the material used to manufacture cast stainless steel surgical implants.

X1.2 This specification states that requirements are included for the stainless steel alloy from which cast surgical implants will be produced. The specification document does not cover the requirements for the implants themselves.

X1.3 Implants made from this material are solution-annealed to redissolve any carbides that have precipitated on the grain boundaries during casting. This treatment greatly improves the intergranular corrosion resistance of the casting.

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.[6]

X2.2 No known surgical implant 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.

[6] Bechtol, C.O.; Failure of Femoral Implant Components in Total Hip Replacement Operations; Orphopedic Revue; Vol. IV, Number XI, p. 23-29, November 1975.