



Designation: F745 – 07

Standard Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications¹

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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. This material is known to be paramagnetic.

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

2. Referenced Documents

2.1 ASTM Standards:²

A800/A800M Practice for Steel Casting, Austenitic Alloy, Estimating Ferrite Content Thereof

A957 Specification for Investment Castings, Steel and Alloy, Common Requirements, for General Industrial Use

E8 Test Methods for Tension Testing of Metallic Materials

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

E353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys

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

2.3 ISO Standards:⁴

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.

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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.

2.4 American Society for Quality (ASQ) Standard:⁵

ASQ C1 Specification of General Requirements for a Quality Program

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *investment casting, n*—a metal casting that is produced in a mold obtained by investing (surrounding) an expendable pattern with a ceramic slurry that is allowed to solidify. The expendable pattern may consist of wax, plastic, or other material and is removed prior to filling the mold with liquid metal.

3.1.2 *master heat, n*—a quantity of metal processed in a single furnace or refining vessel at one time in such a manner as to produce the desired composition and properties.

3.1.3 *sub-heat, n*—a portion of a master heat remelted without additional processing for pouring into castings. Synonyms: melt, production heat.

3.1.3.1 *Discussion*—Terminology section taken from Specification A957.

4. Ordering Information

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

- 4.1.1 Quantity (weight),
- 4.1.2 ASTM designation and date of issue,
- 4.1.3 Form (Section 5.1),
- 4.1.4 Special tests, and
- 4.1.5 Other requirements.

5. Materials and Manufacture

5.1 The master heat furnished to the supplier for purposes of casting surgical implants shall be supplied in the form of bar, shot, or ingot.

6. Chemical Composition

6.1 The product castings and casting alloy 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.

⁵ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

TABLE 1 Chemical Requirements (Master and Sub Heat Analysis)

Element	Composition, % mass/mass	
	min	max
Carbon	...	0.06
Manganese	...	2.0
Phosphorus	...	0.045
Sulfur	...	0.030
Silicon	...	1.0
Chromium	16.50	19.00
Nickel	11.00	14.50
Molybdenum	2.00	3.00
Nitrogen		0.20
Copper		0.50
Iron	balance ^A	
Ferrite Content		1 % max

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

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.

6.2 *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.

6.2.2 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**.

6.3 For referee purposes, Test Methods **E353** shall be used.

6.4 *Ferrite Content*—Ferrite content shall be determined on the master heat and on at least one sub heat using Practice **A800/A800M** or by another method as agreed upon by the purchaser and supplier.

7. Mechanical Properties

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

TABLE 2 Product Analysis Tolerances^A

Element	Tolerance Under the Minimum or over the Maximum Limit ^B
Carbon	0.01
Manganese ^C	0.04
Phosphorus	0.010
Sulfur	0.005
Silicon	0.05
Chromium	0.20
Nickel	0.15
Molybdenum	0.10
Nitrogen ^C	0.02
Copper	0.05

^A Refer to **AMS 2248** for chemical check analysis limits (except nitrogen).

^B For elements in which only a maximum percentage is indicated, the “under minimum limit” is not applicable.

^C The specified range for this element is not covered by **AMS 2248** and has been established through industrial practice.

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), ^A min, %	30
Reduction of area, min, %	50

^A Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to **ISO 6892** may be used when agreed upon between supplier and purchaser. (5.65 times the square root of S_o, where S_o is the original cross sectional area.)

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

7.2.1 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 **E8**.

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

7.3 Perform at least two tension tests per master heat. Should any of these test pieces not meet the specified requirements, test two additional test pieces representative of the same master heat 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.

7.3.1 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Test Method **E8**, sections 7.11.4 and 7.11.5. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

8. Special Tests

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

9. Significance of Numerical Limits

9.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice **E29**.

10. Certification

10.1 A certification, including a complete test report, shall be provided by the supplier at the time of shipment stating that the material was manufactured and tested in accordance with this specification.

11. Quality Program Requirements

11.1 The producer and any processors shall maintain a quality program such as defined in **ASQ C1** or other recognized quality management system such as **ISO 9001**.