Designation: F 745 – ~~95~~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.

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[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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~~1.2 This material has been subjected to animal implant studies[2] and has been shown to produce a well-characterized level of biological response which is equal to or less than that produced by the reference material when tested by the procedures of Practice F 981, or equivalent. This material has been used clinically.[3]~~

~~1.3 The~~

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

1.3 *The~~is stan~~ch-p~~dard doues nd~~ot pu~~nir~~port to addres-giv~~s all of the safety concerns, if an-py, associated with its use. It is the responsibility of the user of this standard to e-f~~stablish appropriate safety and health practices and determine the applicability of regulatory limitations prio~~nly~~r 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 of 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
F 55 Specification for Stainless Steel Bar and Wire for Surgical Implants[4]
F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[6]
F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[6]
F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[65]
2.2 *American Society for Quality Control (ASQC) (ASQ) Standard:*[6]
ASQC C 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.
5.2 The chemical composition. The manufacturer shall conform to not ship material that is outside the chemical requirements 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.

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[2] Report No. NV-5410 dated July 31, 1975, by Northview Laboratories, Inc., Northbrook, Illinois, to Richards Manufacturing Co., titled," Comparative Intramuscular Implant Test with Cast 316SS and
[2] *Annual Book of ASTM F55, Type A316SS." Copies available, upon request, from ASTM Headquarters, 1916 Race St., Philadelphia, PA 19103. Request RR: F04-1004. Standards,* Vol 01.02.
[3] Bechtol, C. O.; Failure
[3] *Annual Book of Femoral Implant Components in Total Hip Replacement Operations; Orthopedic Review; Vol. IV, Number XI, p. 23–29, November, 1975. ASTM Standards,* Vol 03.01.
Annual Book
[4] Bechtol, C.O.; Failure of ASTM Standards, Vol 13.01. Femoral Implant Components in Total Hip Replacement Operations; Orphopedic Revue; Vol. IV, Number XI, p. 23-29, November 1975.
[5] *Annual Book of ASTM Standards,* Vol 03.01 5.
Annual Book of ASTM Standards, Vol 03.05.
[6] 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

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

~~5.4 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. Mechanical ~~Requirements~~ Properties

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

~~6.2 Mechanical properties~~

6.2 Specimens for tension tests shall be ~~determined in accordance with Methods E 8.~~

~~6.3 Mechanical test specimens shall be produced, (melted, cast, and solution-annealed)~~ cast from ~~the metal under test~~ remelted material from each master heat by the same general procedures used in casting surgical ~~implants and shall~~ implants.

6.2.1 Specimens may be cast, ground, or machined to final dimensions in accordance with the ~~¼~~ 0.25 in. (6.35~~-~~ mm) diameter specimen in Fig. 8 of Test Methods ~~E 8 which may have a ground finish on~~ E 8.

6.2.2 Specimens shall be solution annealed using the same proceduereds useed to solution anneal surgical implants.

6.4~~3~~ A minimum of two tenstion specimens shall be tested. If one specimen fa~~i~~ils below the specified mechanical ~~requirements or breaks outside the gage limits,~~ requirements, two additional specimens shall be tested and both must pass.

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 ~~vendor.~~ supplier.

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, such as, for example, is~~ program as defined in ASQC ~~C1.~~ 1.

10.2 The ~~manufacturer of surgical implants or medical appliances~~ purchaser shall be assured of the producer's quality program ~~for~~ conformance to the intent of ASQC ~~C1,~~ 1, or other recognized programs.

11. Keywords

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

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

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 and providing a statement of the biocompatibility information.~~ implants.

X1.2 ~~The scope of this~~ 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. It describes the non-human laboratory and human clinical experiences with the material.~~ themselves.

X1.3 ~~Cast stainless steel implants produced from alloy of this chemical composition and these mechanical strengths have been used in the United States since 1970. Implant producers have found that this material can be used to fabricate implants of complex design and shape. Patients have benefited from the implantation of these devices.~~

~~X1.4 As with any implant or any other manufactured product, there are many factors that contribute to the product's success. These factors include design, material properties, manufacturing methods, nondestructive testing, proper application of the device for the particular patient, proper surgical practice, patient cooperation, and a variety of other parameters.~~

~~X1.5 Manufacturers, surgeons, and users should be aware that some of the mechanical properties of the material covered by this specification are equivalent to those for wrought annealed stainless steel (Specifications F 138 and F 55) but are lower than those for cold-worked stainless steel (Specifications F 138 and F 55) or cast cobalt-chromium-molybdenum alloy (Specification F 75). This factor and those previously mentioned should be evaluated when considering the use of any cast stainless steel device.~~

~~X1.6~~ 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. ~~There have been no reports of intergranular corrosion occurring in solution-annealed implants produced from this alloy in the United States.~~

X2. Biocompatibility

X2.1 The ~~annealing treatment is a standard casting industry practice.~~

~~X1.7 This~~ material composition covered by this standard has been employed successfully in contact with soft tissue and bone for ~~limited~~ over a decade.[4]

X2.2 No known surgical implant ~~applications since 1970. The chemical composition listed in Table 1 was formulated~~ has ever been shown to be ~~similar to Specification F 55 – 66, the standard for wrought stainless steel in 1970. A minimum tensile strength~~ completely free of ~~70 ksi (identical to the requirement for Specification F 55 – 66 Grade B) was desired. A low carbon (0.03 % maximum) formulation was tried, but the resulting tensile strength was only 60 to 70 ksi. The higher carbon (0.06 % maximum) formulation described~~ adverse reactions in ~~this specification consistently yields material with a tensilestrength greater than~~ the ~~70 ksi minimum. Minimum mechanical properties~~ human body. However, long term clinical experience has shown an acceptable level of ~~five common implant materials are compared to~~ biological response can be expected, if the ~~properties of this cast stainless steel~~ material is used in ~~Table X1.1.~~

appropriate applications.