Designation: F 745 – 95

Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum 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 18 chromium-12.5 nickel-2.5 molybdenum stainless steel alloy, shot, bar, or ingot used for the manufacture of cast and solution-annealed surgical implants.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Methods of Tension Testing of Metallic Materials[4]

E 353 Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys[5]

F 55 Specification for Stainless Steel Bar and Wire for Surgical Implants[6]

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[6]

2.2 *American Society for Quality Control (ASQC) Standard:*[7]

ASQC C1 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 shall conform to the chemical requirements in Table 1 with product analysis tolerances shown in Table 2.

5.3 For referee purposes, Method 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

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

6.2 Mechanical properties shall be determined in accordance with Methods E 8.

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

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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 ASTM F55, Type A316SS." Copies available, upon request, from ASTM Headquarters, 1916 Race St., Philadelphia, PA 19103. Request RR: F04-1004.

[3] Bechtol, C. O.; Failure of Femoral Implant Components in Total Hip Replacement Operations; Orthopedic Review; Vol. IV, Number XI, p. 23–29, November, 1975.

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

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

[6] *Annual Book of ASTM Standards*, Vol 13.01.

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