



Designation: F 1314 – 95

Standard Specification for Wrought Nitrogen Strengthened–22 Chromium–12.5 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants¹

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1. Scope

1.1 This specification covers the requirements for wrought nitrogen strengthened–22 chromium–12.5 nickel–5 manganese–2.5 molybdenum stainless steel bar and wire (except suture wire) used for the manufacture of surgical implants.

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

2. Referenced Documents

2.1 ASTM Standards:

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels²

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets, and Forgings³

A 555/A 555M Specification for General Requirements for Stainless and Heat-Resisting Steel Wire and Wire Rods²

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products²

E 45 Practice for Determining the Inclusion Content of Steel⁴

E 112 Test Methods for Determining Average Grain Size⁴

F 746 Test Method for Pitting and Crevice Corrosion of Metallic Surgical Implant Materials⁵

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁵

2.2 American Society for Quality Control (ASQC) Standard:

CI Specification of General Requirements for a Quality Program⁶

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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² Annual Book of ASTM Standards, Vol 01.03.

³ Annual Book of ASTM Standards, Vol 01.05.

⁴ Annual Book of ASTM Standards, Vol 03.01.

⁵ Annual Book of ASTM Standards, Vol 13.01.

⁶ Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

3. Ordering Information

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

3.1.1 Quality (weight or number of pieces),

3.1.2 ASTM designation,

3.1.3 Form (bar or wire),

3.1.4 Condition (see 4.1),

3.1.5 Mechanical properties (if applicable, for special conditions),

3.1.6 Finish (see 4.2),

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

3.1.8 Special requirements.

4. Materials and Manufacture

4.1 *Condition*—Bar and wire shall be furnished to the implant manufacturer, as specified, in the hot-worked, annealed, or cold-worked condition.

4.2 *Finish*—Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

5. Chemical Composition

5.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 1.

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

5.3 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. Metallurgical Requirements

6.1 The material shall exhibit no free ferrite phase when it is examined metallographically at 100 \times magnification.

6.2 The microcleanliness of the steel, as determined by Practice E 45, Method A, except using Plate III and Plate I, on representative billet or bar samples from the heat shall not exceed the following: