



Designation: F 1586 – 95

# Standard Specification for Wrought Nitrogen Strengthened-21 Chromium—10 Nickel— 3 Manganese—2.5 Molybdenum Stainless Steel Bar for Surgical Implants<sup>1</sup>

This standard is issued under the fixed designation F 1586; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This specification covers the requirements for wrought nitrogen strengthened-21 chromium—10 nickel—3 manganese—2.5 molybdenum stainless steel bar for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI units 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 Steels<sup>2</sup>

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Steel Bars, Billets, and Forgings<sup>3</sup>

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products<sup>2</sup>

E 10 Test for Brinell Hardness of Metallic Materials<sup>4</sup>

E 18 Tests for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials<sup>4</sup>

E 45 Practice for Determining the Inclusion Content of Steel<sup>4</sup>

E 112 Test Methods for Determining Average Grain Size<sup>4</sup>

F 746 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials<sup>5</sup>

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone<sup>5</sup>

### 2.2 ASQC Standard:

C1 Specification of General Requirements for a Quality Program<sup>6</sup>

### 2.3 ISO Standard:

ISO 5832-9/1992: Wrought High Nitrogen Stainless Steel<sup>7</sup>

## 3. General Requirement for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484/A 484M shall apply.

3.2 In cases where a conflict exists between this specification and the standards listed in 2.1 and 2.2, this specification shall take precedence.

## 4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation,

4.1.3 Form,

4.1.4 Condition (see 5.1),

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

4.1.6 Finish (see 5.2),

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

4.1.8 Special requirements.

## 5. Materials and Manufacture

5.1 *Condition*—Bars shall be furnished to the implant manufacturer, as specified, in the annealed, medium hard, or hard condition.

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

## 6. Chemical Composition

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

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.

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

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 01.03.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 01.05.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>5</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>6</sup> Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

<sup>7</sup> Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.