



## Standard Specification for Stainless Steel Forgings for Surgical Implants<sup>1</sup>

This standard is issued under the fixed designation F 621; 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 of forged stainless steel for surgical implants when the material forged conforms to F 138 (R31673), F 1314 (S21910), or F 1586.

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

### 2. Referenced Documents

#### 2.1 ASTM Standards:

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels<sup>2</sup>

A 370 Test Methods and Definitions for Mechanical Testing of Steel Products<sup>2</sup>

A 473 Specification for Stainless and Heat-Resisting Steel Forgings<sup>3</sup>

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

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

E 165 Practice for Liquid Penetrant Inspection Method<sup>5</sup>

E 353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys<sup>6</sup>

F 138 Specification for Stainless Steel Bars and Wire for Surgical Implants (Special Quality)<sup>7</sup>

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants<sup>7</sup>

F 1314 Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants<sup>7</sup>

F 1586 Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants<sup>7</sup>

#### 2.2 ASQC Standard:

CI Specifications of General Requirements for a Quality Control Program<sup>8</sup>

### 3. Ordering Information

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

3.1.1 Quality; number of pieces,

3.1.2 ASTM designation; material grade,

3.1.3 Condition,

3.1.4 Mechanical properties (other than those specified herein),

3.1.5 Finish,

3.1.6 Applicable dimensions or print number,

3.1.7 Special tests, and

3.1.8 Special requirements.

### 4. General Requirements for Delivery

4.1 Material furnished to this specification shall conform to the applicable requirements in the current edition of Specification A 473.

4.2 In the case where a conflict exists between this specification and that listed in 4.1, this specification shall take precedence.

### 5. Materials and Manufacture

5.1 Material for forgings shall be bars or wire fabricated in accordance with Specification F 138, F 1314, or F 1586, generally in the unannealed condition with a finish suitable for forging.

5.2 The material shall be forged by hammering, pressing, rolling, extruding, or upsetting, and shall be processed, if practicable, so as to cause metal flow during the hot-working operation in the direction most favorable for resisting stresses encountered in service, as may be indicated to the fabricator by the implant manufacturer.

5.3 Forgings shall be free of splits, scale, cracks, inequalities, flaws, and other imperfections not consistent with good commercial practice (see Note 1). Offset or mismatch allowance, dependent upon part size and configuration, shall be within standard forging tolerances.

NOTE 1—Compliance to these requirements may be verified by Practices E 165 or F 601 or other suitable methods.

<sup>8</sup> Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

<sup>1</sup> 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.

Current edition approved April 10, 1997. Published March 1998. Originally published as F 621 – 79. Last previous edition F 621 – 92.

<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 03.03.

<sup>6</sup> Annual Book of ASTM Standards, Vol 03.05.

<sup>7</sup> Annual Book of ASTM Standards, Vol 13.01.