



Designation: F 1350 – 02

## Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)<sup>1</sup>

This standard is issued under the fixed designation F 1350; 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 the manufacture of wrought 18 chromium-14 nickel-2.5 molybdenum stainless steel in the form of surgical fixation wire.

1.2 The values stated in SI units are to be regarded as the standard. The inch-pound equivalents of the SI units may be approximate.

### 2. Referenced Documents

#### 2.1 ASTM Standards:

A 555 Specification for General Requirements for Stainless Steel Wire and Wire Rods<sup>2</sup>

E 8 Test Methods for Tension Testing of Metallic Materials<sup>3</sup>

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants<sup>4</sup>

F 138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)<sup>4</sup>

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone<sup>4</sup>

2.2 USP Standard:<sup>5</sup>  
Nonabsorbable Surgical Suture, U.S. Pharmacopeia

2.3 American Society for Quality Standard:<sup>6</sup>

ASQ C1 Specification of General Requirements for a Quality Program

### 3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 555 and F 138 apply.

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is 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 03.01.

<sup>4</sup> Annual Book of ASTM Standards, Vol 13.01.

<sup>5</sup> Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852.

<sup>6</sup> Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

3.2 In cases where a conflict exists between this specification and the standards listed in Section 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,

4.1.2 ASTM designation and date of issue,

4.1.3 Material requirements,

4.1.4 Mechanical properties,

4.1.5 Form,

4.1.6 Dimensional requirements, including diameter and diameter tolerance,

4.1.7 Surface condition and handling,

4.1.8 Special tests (if applicable), and

4.1.9 Other requirements.

### 5. Material Requirements

5.1 The starting material used to make fixation wire must meet the requirements of F 138.

5.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification F 138. Conformance with this standard shall be so identified by suitable packaging or labeling or both.

### 6. Mechanical Requirements

6.1 Surgical fixation wire shall conform to the appropriate mechanical properties specified in Table 1.

6.2 Mechanical testing shall be performed in accordance with Methods E 8 using a 254 mm (10 in.) gage length and a cross-head speed of 254 mm/min (10 in./min).

6.3 The wire shall meet the requirements of the latest version of USP for Nonabsorbable Surgical Sutures, when tested in accordance with 6.2.

### 7. Dimensional Requirements

7.1 Surgical fixation wire shall be fabricated in accordance with the dimensions and tolerances specified in Table 1.

7.2 Unless otherwise specified, size tolerances are plus and minus as shown in Table 1. When required by the purchaser, round wire tolerances may be specified all plus and nothing

\*A Summary of Changes section appears at the end of this standard.