

Designation: F1350 – 08

StandardSpecification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)¹

This standard is issued under the fixed designation F1350; 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 chemical, mechanical, and metallurgical 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 values in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:²

A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

E8 Test Methods for Tension Testing of Metallic Materials

- E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 USP Standard:³

Nonabsorbable Surgical Suture, U.S. Pharmacopeia

2.3 ISO Standard:⁴

ISO 9001 Quality Management System—Requirements

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

2.4 American Society for Quality Standard:⁵ 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 A555/ A555M and F138 apply.

3.2 In cases where a conflict exists between this specification and the standards listed in Section 2, this specification shall take precedence.

4. Terminology

4.1 Definitions of Terms Specific to This Standard:

4.1.1 *lot*, n—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

5. Ordering Information

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

5.1.1 Quantity,

- 5.1.2 ASTM designation and date of issue,
- 5.1.3 Material requirements,
- 5.1.4 Mechanical properties,
- 5.1.5 Form,

5.1.6 Dimensional requirements, including diameter and diameter tolerance,

- 5.1.7 Surface condition and handling,
- 5.1.8 Special tests (if applicable), and
- 5.1.9 Other requirements.

6. Material Requirements

6.1 The starting material used to make fixation wire must meet the requirements of Specification F138.

6.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification F138. Conformance with this standard shall be so identified by suitable packaging, labeling, or both.

¹This 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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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

⁵ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.