



Designation: F 1350 – 01

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

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1. Scope

1.1 This specification covers the requirements for the manufacture of stainless steel surgical fixation wire.

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

2. Referenced Documents

2.1 ASTM Standards:

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

A 370 Test Methods and Definitions for Mechanical Testing of Steel Products²

A 555 Specification for General Requirements for Stainless Steel Wire and Wire Rods²

E 45 Test Methods for Determining the Inclusion Content of Steel³

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants⁴

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

2.2 USP Standard:

Nonabsorbable Surgical Suture, *U.S. Pharmacopeia*⁵

3. Materials and Manufacture

3.1 Surgical fixation wire shall conform to the specified chemical composition of Specification F 138 material. Conformance with this specification shall be so identified by suitable packaging or labeling, or both.

3.2 The microcleanliness of the steel as determined by Test Methods E 45, Method A shall conform to Specification F 138. Microcleanliness conformance shall be stated on the material certification.

3.3 The steel shall be capable of passing the intergranular

corrosion susceptibility test in accordance with Practices A 262, Practice E as specified in Specification F 138. Conformance shall be stated on material certification.

3.4 Surgical fixation wire shall be furnished in the bright annealed condition and finish.

4. Mechanical Properties

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

4.2 Mechanical testing shall be performed in accordance with Test Methods A 370 using a 254-mm (10-in.) gage length and crosshead speed of 254 mm/min (10 in./min).

4.3 The wire shall meet the requirements of USP for Nonabsorbable Surgical Sutures, (latest revision) when tested in accordance with 4.2.

5. Dimensional Requirements

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

6. Surface Condition and Handling

6.1 The surface of surgical fixation wire conforming to this specification shall be free of imperfections such as toolmarks, nicks, scratches, cracks, cavities, spurs, and other defects that would impair the serviceability of the wire. The surface shall be free of embedded or deposited finishing materials and other undesirable contaminants.

6.2 The wire may be subjected to a passivation process if requested by the customer. Such passivation process shall be performed in accordance with Practice F 86.

6.3 Surgical fixation wire shall be handled with care and packaged adequately to prevent damage and contamination of the surface.

7. General Requirements

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

7.2 In cases of conflict between this specification and those listed in 2.1, this specification shall take precedence.

8. Keywords

8.1 fixation; mechanical properties; stainless steel; surgical implant; suture; tolerances; wire

¹ 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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² *Annual Book of ASTM Standards*, Vol 01.03.

³ *Annual Book of ASTM Standards*, Vol 03.01.

⁴ *Annual Book of ASTM Standards*, Vol 13.01.

⁵ Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852.