



Designation: F 1350 – 01²

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

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 (ϵ) 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 ~~metric~~ 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:*

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 F04.212 on ~~Osteosynthesis—Metallurgical Materials.~~

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

- ~~A 262 Practices 555 Specification for Detecting Susceptibility to Intergranular Attack in Austenitic General Requirements for Stainless Steel Wire and Wire Rods²~~
- ~~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 458 Test Methods for Determining the Inclusion Content Tension Testing of Steel Metallic Materials³~~
- ~~F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants⁴~~
- ~~F 138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)⁴~~
- ~~F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁴~~
- ~~2.2 USP Standard:⁵~~
- ~~Nonabsorbable Surgical Suture, U.S. Pharmacopeia⁵~~

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.

2.3 American Society for Quality Standard.⁶

ASQ C1 Specification of General Requirements for a Quality Program

3. Materials and Manufacture

~~3.1 Surgical fixation wire shall conform General Requirements for Delivery~~

~~3.1 In addition to the specified chemical composition requirements of Specification F 138 material. Conformance with this specification shall be so identified by suitable packaging or labeling, or both.~~

~~3.2 The microcleanliness specification, all requirements 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 current editions of Specifications A 555 and F 138 apply.~~

~~3.2 In cases where a conflict exists between this specification and the intergranular corrosion susceptibility test standards listed in accordance with Practices A 262, Practice E as specified in Specification F 138. Conformance Section 2, this specification shall be stated on material certification.~~

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

4. Mechanical Properties

~~4.1 Surgical fixation wire Ordering Information~~

~~4.1 Inquiries and orders for material under this specification shall conform to include 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 following information:~~

~~4.1.1 Quantity,~~

~~4.1.2 ASTM designation and crosshead speed date 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. 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,~~

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

TABLE 1 Mechanical and Dimensional Requirements for Wrought Annealed 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire

Range of Sizes Diameter, mm (in.)	USP Size ^A	Diameter Tolerance ^{B,C}	Tensile Strength max, MPa (ksi) ^D	Elong. min % ^E
0.010 to under 0.020 (0.0004 to 0.0008)	...	0.0015 (0.000 06)	1380 (200)	15
0.020 to under 0.030 (0.0008 to 0.0012)	10-0	0.0015 (0.000 06)	1240 (180)	15
0.030 to under 0.040 (0.0012 to 0.0016)	9-0	0.0025 (0.0001)	1100 (160)	20
0.040 to under 0.050 (0.0016 to 0.0020)	8-0	0.0025 (0.0001)	1100 (160)	20
0.050 to under 0.070 (0.0020 to 0.0028)	7-0	0.0025 (0.0001)	960 (140)	25
0.070 to under 0.100 (0.0028 to 0.0039)	6-0	0.0025 (0.0001)	965 (140)	25
0.100 to under 0.150 (0.0039 to 0.0059)	5-0	0.0050 (0.0002)	895 (130)	30
0.150 to under 0.200 (0.0059 to 0.0079)	4-0	0.0050 (0.0002)	895 (130)	30
0.200 to under 0.250 (0.0079 to 0.0098)	3-0	0.0075 (0.0003)	860 (125)	30
0.250 to under 0.300 (0.0098 to 0.0118)	...	0.0075 (0.0003)	860 (125)	30
0.300 to under 0.340 (0.0118 to 0.0134)	2-0	0.0100 (0.0004)	860 (125)	30
0.340 to under 0.350 (0.0134 to 0.0138)	...	0.0100 (0.0004)	860 (125)	30
0.350 to under 0.400 (0.0138 to 0.0158)	1-0	0.0100 (0.0004)	825 (120)	35
0.400 to under 0.500 (0.0158 to 0.0197)	1	0.0100 (0.0004)	825 (120)	35
0.500 to under 0.600 (0.0196 to 0.0236)	2	0.0100 (0.0004)	790 (115)	35
0.600 to under 0.700 (0.0236 to 0.0276)	3 and 4	0.0130 (0.0005)	790 (115)	35
0.700 to under 0.800 (0.0276 to 0.0315)	5	0.0130 (0.0005)	760 (110)	35
0.800 to under 0.900 (0.0315 to 0.0354)	6	0.0200 (0.0008)	760 (110)	35
0.900 to under 1.000 (0.0354 to 0.0394)	7	0.0200 (0.0008)	760 (110)	40
1.000 to under 1.100 (0.0394 to 0.0433)	...	0.0200 (0.0008)	690 (100)	40
1.100 to under 1.600 (0.0433 to 0.0630)	...	0.0250 (0.0010)	690 (100)	40

^A For reference purposes only. (U.S. Pharmacopeia). *U.S. Pharmacopeia*.

^B Diameter tolerances are over and under as given in this table. Also, round wire can be produced to tolerances all over and nothing under, or all under and nothing over, or any combination over and under, if the total spread in diameter tolerance for a specified diameter is not less than the total spread given in this table.

^C The maximum out-of-round tolerance for round wire is one half of the total size tolerance given in this table.

^D Maximum tensile strength is specified to assure proper wire-handling characteristics.

^E Minimum elongation for spooled wire is 6 percentage points lower than table value.

- 4.1.8 Special tests (if applicable), and
- 4.1.9 Other requirements.

5. ~~Dimensional~~Material Requirements

- 5.1 ~~5.1~~ The starting material used to make fixation wire must meet the requirements of F 138.
- 5.2 ~~Surgical fixation wire shall be fabricated in accordance with~~ conform to the dimensions and tolerances specified ~~chemical requirements of Specification F 138. Conformance with this standard shall be so identified by suitable~~ packaging or labeling or both.

6. ~~Surface Condition and Handling~~

- 6.1 ~~The surface of surgical~~Mechanical Requirements
- 6.1 ~~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 conform to a passivation process if requested by the customer. Such passivation process appropriate mechanical properties specified in Table 1.~~
- 6.2 ~~Mechanical testing shall be performed in accordance with Practice F 86.~~
- 6.3 ~~Surgical fixation 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 be handled with care and packaged adequately to prevent damage and contamination~~ meet the requirements of the latest version of USP for Nonabsorbable Surgical Sutures, when tested in accordance with 6.2.

7. ~~General~~Dimensional Requirements

- 7.1 ~~In Surgical~~ fixation wire shall be fabricated in accordance with the requirements of this specification, all requirements of 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 current editions of Specifications A 555 purchaser, round wire tolerances may be specified all plus and F 138 shall apply.~~
- 7.2 ~~In cases nothing minus, or all minus and nothing plus, or any combination of conflict between this specification plus and those listed minus if the total spread in 2.1, this specification shall take precedence. size tolerance is not less than the total spread shown in Table 1.~~
- 7.3 ~~The maximum out-of-round tolerance for round wire is one half of the size tolerance given in Table 1.~~

8. Surface Condition Requirements

- 8.1 Surgical fixation wire is usually furnished in the bright-annealed condition. Other surface finishes shall be specified as agreed to between supplier and purchaser.
- 8.2 The surface of surgical fixation wire conforming to this specification shall be processed to minimize imperfections such as tool marks, nicks, scratches, cracks, cavities, spurs, and other defects that would impair the serviceability of the wire. The surfaces shall be cleaned to minimize the presence of foreign material.
- 8.3 The wire may be subjected to a passivation process if requested by the purchaser. Such passivation process shall be performed in accordance with F 86.

9. Quality Program Requirements

- 9.1 The surgical wire producer and any processors shall maintain a quality program such as that which is defined in ASQ C1.

10. Certification

- 10.1 Certification shall be provided by the supplier that the material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

11. Keywords

- 811.1 fixation; mechanical properties; stainless steel; surgical implant; suture; tolerances; wire; wrought iron-chromium-nickel-molybdenum alloy; 316L alloy

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 ~~The primary reason for purpose of this specification is to characterize specify the mechanical properties requirements for the manufacture of annealed wrought 18 chromium-14 nickel-2.5 molybdenum stainless steel wire for implant applications, in the form of surgical fixation wire.~~

X1.2 ~~This specification combines Surgical fixation wire shall be handled with care and replaces Specifications F 642 adequately packaged to prevent damage and F 666. contamination of the surface.~~

X1.3 For this product, SI units are regarded as the standard historic means of size measurement.

X2. BIOCOMPATIBILITY

X2.1 ~~The alloy composition covered by this specification has been changed employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the UNS designation well-characterized level of biological response exhibited by this alloy, it has been added used as a control material in Practice F 981.~~

X2.2 No known surgical implant material has ever been shown to more readily identify be completely free of adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 1350 – 01) that may impact the use of this standard.

- (1) The responsibility for this specification was transferred from Subcommittee F04.21 to Subcommittee F04.12.
- (2) The specification was modified to incorporate the standard format (template) used by F04.12.

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