



Designation: F 1350 – 01

Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

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.

Current edition approved May 10, 2001. Published May 2001. Originally published as F 1350 – 91. Last previous edition F 1350 – 96 (2000).

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.

TABLE 1 Mechanical and Dimensional Requirements for 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

^AFor reference purposes only (U.S. Pharmacopeia).

^BDiameter 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.

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

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

^EMinimum elongation for spooled wire is six percentage points lower than table value.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize the mechanical properties of annealed stainless steel wire for implant applications.

X1.2 This specification combines and replaces Specifications F 642 and F 666.

X1.3 The title has been changed and the UNS designation has been added to more readily identify the material.

The American Society for Testing and Materials takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org).