



Designation: F1350 – 24

Standard Specification 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 18chromium-14nickel-2.5molybdenum stainless steel in the form of surgical fixation wire.

1.2 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

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

E8/E8M 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 Metal-

lic 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 Muscle and Bone Tissue Responses to Long-Term Implantable Materials Used in Medical Devices

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *USP Standard*:³

U.S. Pharmacopeia Nonabsorbable Surgical Suture

2.3 *ISO Standards*:⁴

ISO 9001 Quality Management System—Requirements

ISO 13485 Quality Management Systems—Requirements for Regulatory Purposes

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

4. General Requirements for Delivery

4.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications **A555/A555M** and **F138** apply.

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

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,

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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>.

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

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

- 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.

7. Mechanical Properties

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

7.2 Perform tension tests in accordance with Test Methods **E8/E8M** using a 254 mm [10 in.] gage length and a cross-head speed of 254 mm/min [10 in./min]. Should any of the test specimens not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

7.3 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable if the elongation meets the minimum requirements and all other

results conform to **Table 1**. Refer to subsections 7.11.4 and 7.12.5 of Test Methods **E8/E8M**. If the elongation is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirement.

7.4 The wire shall meet the requirements of the latest version of Nonabsorbable Surgical Suture, U.S. Pharmacopeia, when tested in accordance with **7.2**.

8. Dimensions and Permissible Variations

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

8.2 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 minus, or all minus and nothing plus, or any combination of plus and minus if the total spread in size tolerance is not less than the total spread shown in **Table 1**.

8.3 The maximum out-of-round tolerance for round wire is one half of the size tolerance given in **Table 1**.

8.4 Units of Measure:

8.4.1 *Selection*—This specification requires that the purchaser select the units (SI or inch-pound) to be used for product clarification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

8.4.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

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

Range of Sizes Diameter, mm [in.]	USP Size ^A	Diameter Tolerance ^{BC}	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 (Nonabsorbable Surgical Suture, U.S. Pharmacopeia).

^B Diameter tolerances are over and under as given in this table. When required by the purchaser, round wire tolerances may be specified all plus and nothing minus, or all minus and nothing plus, or any combination of plus and minus if the total spread in size tolerance is not less than the total spread shown 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 in ksi (1 ksi = 1000 psi) is specified to ensure proper wire-handling characteristics.

^E Minimum elongation for spooled wire is six percentage points lower than values given in this table.