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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 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 equivalents of the SI units may be approximate. Values in parentheses are for information only.~~

2. Referenced Documents

2.1 *ASTM Standards:*²

A555 555/A 555M Specification for General Requirements for Stainless Steel Wire and Wire Rods

E 8 Test Methods for Tension Testing of Metallic Materials

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

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

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

F 981 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

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 A 555/A 555M and F 138 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. Ordering Information

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

~~4.1.1 Quantity;~~

~~4.1.2 ASTM designation and date of issue;~~

~~4.1.3 Material requirements;~~

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 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* Vol 01-03 volume information, refer to the standard's Document Summary page on the ASTM website.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

⁵ Annual Book of ASTM Standards, Vol 13.01.

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁷ Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852.

⁸ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

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

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

5.1 The starting material used to make fixation wire must meet the requirements of F138 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 F 138.

6.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification F 138. Conformance with this standard shall be so identified by suitable packaging or labeling, or both.

6.7. Mechanical Requirements

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

6.2 Mechanical testing shall be performed in accordance with Methods E8 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 meet the requirements of the latest version of USP for Nonabsorbable Surgical Sutures, when tested in accordance with 6.2

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 ^{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 (*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 assure proper wire-handling characteristics.

^E Minimum elongation for spooled wire is 6 percentage points lower than values given in this table.