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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 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 18 chromium-14 nickel-2.5 molybdenum 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 ~~the~~ standard. The ~~inch-pound~~ values ~~in parentheses are for information only.~~stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with this specification.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

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

~~E8~~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 Metallic 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 Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

IEEE/ASTM SI 10 American National Standard for Metric Practice

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 A555/A555M and F138 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. Terminology

4.1 *Definitions of Terms Specific to This Standard:*

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[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* 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**

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. 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 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 Requirements

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~~E8/E8M using a 254 mm ~~(10 in.)~~[10 in.] gage length and a cross-head speed of 254 mm/min ~~(10 in./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 specified in Table 1. Refer to subsections 7.11.4 and 7.11.5 of Test Methods ~~E8~~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 USP for Nonabsorbable Surgical Sutures, when tested in accordance with 7.2.

8. Dimensional Requirements

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.

8.4.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO) are consistent with the specification and engineering drawing, then these units shall be used by the supplier for product certification.

8.4.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

8.4.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significance.

9. Surface Condition Requirements

9.1 Surgical fixation wire is usually furnished in the bright-annealed condition. Other surface finishes shall be specified as agreed to between supplier and purchaser.