



Designation: F1091 – 08

Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)¹

This standard is issued under the fixed designation F1091; 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 cobalt-20chromium-15tungsten-10nickel surgical fixation wire.

1.2 The values stated in SI units are to be regarded as the standard. The inch-pound values given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*²

E8 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

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

2.2 *USP Standards:*³

Nonabsorbable Surgical Suture, *U.S. Pharmacopeia*

2.3 *ISO Standard:*⁴

ISO 9001 Quality Management Systems—Requirements

2.4 *American Society for Quality Standard:*⁵

ASQ C1 Specification of General Requirements for a Quality Program

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.

⁵ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specification F90 shall 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:*

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 (Section 6),

5.1.4 Mechanical properties (7),

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 Specification F90.

6.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification F90.

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 using a 254-mm (10-in.) gage length and crosshead speed of 254 mm/min (10 in./min). Should any of the test specimens not meet the specified requirements, test two additional test

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