



Designation: **F1091 – 12 F1091 – 20**

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 *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

[A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings](#)

[A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods](#)

[E8E8/E8M Test Methods for Tension Testing of Metallic Materials—\[Metric\] E0008—E0008M](#)

[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 \(UNS R30605\)](#) standards.iteh.ai/catalog/standards/sist/52c796d5-25eb-4c43-8246-6e012ce459a2/astm-f1091-20

[IEEE/ASTM SI 10 American National Standard for Use of the International System of Units \(SI\): The Modern Metric System](#)

2.2 USP Standards:³

[Nonabsorbable Surgical Suture, USP29 Nonabsorbable Surgical Suture, U.S. Pharmacopeia](#)

2.3 ISO Standard:Standards:⁴

[ISO 9001 Quality Management Systems—Requirements](#)

[ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes](#)

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.

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. 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;~~ Quantity;

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

5.1.3 ~~Material requirements (see Section 6);~~ ;

5.1.4 ~~Mechanical properties (see Section 7);~~ ;

5.1.5 ~~Form;~~ Form (bar or wire);

5.1.6 ~~Dimensional requirements, including diameter and diameter tolerance;~~ Applicable dimension, including size, thickness, width, and length (exact, random, or multiples) or drawing number;

5.1.7 ~~Tolerances—Surface condition and handling;~~ Unless otherwise specified by purchaser, tolerances must meet the requirements of Specification [A484/A484M](#), Specification [A555/A555M](#), or both, as applicable;

5.1.8 Condition (see 6.1);

5.1.9 Finish (see 6.2);

5.1.10 Special tests (if applicable); any); and

5.1.11 Other requirements.

6. ~~Material Requirements~~ Materials and Manufacture

~~6.1 The starting material used to make fixation wire must meet Specification [F90](#).~~

~~6.1 Surgical fixation wire shall conform to the specified chemical requirements of Specification [F90](#). Condition:~~

~~6.1.1 The starting material used to make fixation wire must meet Specification [F90](#).~~

~~6.1.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification [F90](#).~~

~~6.2 Finish:~~

~~6.2.1 Surgical fixation wire is usually furnished in the bright-annealed condition. Other surface finishes shall be specified as agreed to between supplier and purchaser.~~

~~6.2.2 The surface of surgical fixation wire conforming to this specification shall be processed to minimize imperfections such as tool marks, nicks, scratches, cracks, cavities, spurs, and other defects that would impair the serviceability of the wire. The surfaces shall be cleaned to minimize the presence of foreign material.~~

~~6.2.3 The wire may be subjected to a passivation process if requested by the purchaser. Such passivation process shall be performed in accordance with Practice [F86](#).~~

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 [E8E8/E8M](#) using a ~~254-mm (10-in.) gage~~ 254 mm [10 in.] gauge length and crosshead speed of ~~254 mm/min [10 in./min]~~ 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~~ gauge 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~~ 7.12.5 of Test Methods [E8E8/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 USP for Nonabsorbable Surgical Sutures, when tested in accordance with [7.2](#).

8. ~~Dimensional Requirements and Permissible Variations~~

~~8.1 Units of Measure:~~

~~8.1.1 Selection—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. 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.~~

~~8.1.1.1 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.~~

~~8.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specifications, and engineering drawing are consistent, these units shall be used by the supplier for product certification.~~