Designation: F1091 – 12

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 either SI units or inch-pound units are to be regarded separately as standard. The values 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 the standard.

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

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 (see Section 6),

5.1.4 Mechanical properties (see Section 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

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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**

TABLE 1 Mechanical and Dimensional Requirements for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire

Range of Sizes Diameter, mm (in.)	USP Size[A]	Diameter Tolerance[B,C]	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)	1730 (250)	20
0.020 to under 0.030 (0.0008 to 0.0012)	10-0	0.0015 (0.000 06)	1660 (240)	20
0.030 to under 0.040 (0.0012 to 0.0016)	9-0	0.0025 (0.0001)	1590 (230)	25
0.040 to under 0.050 (0.0016 to 0.0020)	8-0	0.0025 (0.0001)	1555 (225)	30
0.050 to under 0.070 (0.0020 to 0.0028)	7-0	0.0025 (0.0001)	1520 (220)	30
0.070 to under 0.100 (0.0028 to 0.0039)	6-0	0.0025 (0.0001)	1385 (215)	35
0.100 to under 0.150 (0.0039 to 0.0059)	5-0	0.0050 (0.0002)	1450 (210)	35
0.150 to under 0.200 (0.0059 to 0.0079)	4-0	0.0050 (0.0002)	1415 (205)	35
0.200 to under 0.250 (0.0079 to 0.0098)	3-0	0.0075 (0.0003)	1380 (200)	40
0.250 to under 0.300 (0.0098 to 0.0118)	...	0.0075 (0.0003)	1380 (200)	40
0.300 to under 0.340 (0.0118 to 0.0134)	2-0	0.0100 (0.0004)	1310 (190)	40
0.340 to under 0.350 (0.0134 to 0.0138)	...	0.0100 (0.0004)	1310 (190)	40
0.350 to under 0.400 (0.0138 to 0.0158)	1-0	0.0100 (0.0004)	1275 (185)	40
0.400 to under 0.500 (0.0158 to 0.0197)	1	0.0100 (0.0004)	1275 (185)	40
0.500 to under 0.600 (0.0197 to 0.0236)	2	0.0100 (0.0004)	1275 (185)	45
0.600 to under 0.700 (0.0236 to 0.0276)	3 and 4	0.0130 (0.0005)	1240 (180)	45
0.700 to under 0.800 (0.0276 to 0.0315)	5	0.0130 (0.0005)	1240 (180)	45
0.800 to under 0.900 (0.0315 to 0.0354)	6	0.0200 (0.0008)	1240 (180)	45
0.900 to under 1.000 (0.0354 to 0.0394)	7	0.0200 (0.0008)	1170 (170)	45
1.000 to under 1.100 (0.0394 to 0.0433)	...	0.0200 (0.0008)	1170 (170)	45
1.100 to under 1.600 (0.0433 to 0.0630)	...	0.0250 (0.0010)	1140 (165)	45

[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 shall be 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 six percentage points lower than values given in this table.

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. 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

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 shall be one-half of the size tolerance given in Table 1.

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.

9.2 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.

9.3 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.

10. Significance of Numerical Limits

10.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

11. Certification

11.1 The supplier shall provide a certification that the material was manufactured and tested in accordance with the requirements of this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program or quality management system, such as ISO 9001.

13. Keywords

13.1 fixation; L-605 alloy; mechanical properties; surgical implant; suture; tolerances; wire; wrought cobalt-chromium-tungsten-nickel alloy

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to specify the requirements for the manufacture of wrought cobalt-20chromium-15tungsten-10nickel alloy in the form of surgical fixation wire.

X1.2 Surgical fixation wire shall be handled with care and adequately packaged to prevent damage and contamination of the surface.

X1.3 For this product, SI units are regarded as the standard historic means of size measurement.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1091 – 08) that may impact the use of this standard. (Approved Dec. 1, 2012.)

(*1*) Editorial corrections have been made throughout in order to meet formatting guidelines established for implant material standards. Units information was updated.