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

This standard is issued under the fixed designation F 1091; 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] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.212 on ~~Osteosynthesis.~~ Metallurgical Materials.

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1. Scope*

1.1 This specification covers the requirements for the manufacture of wrought cobalt-20chromium-15tungsten-10nickel surgical fixation wire.

1.2 The values stated in ~~metric~~ SI units are to be regarded as the standard. The inch-pound equivalents of the SI units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods ~~o~~ for Tensi~~le~~on Testing of Metallic Materials[2]

F ~~90 Specification~~ 86 Practice for ~~Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for~~ Surface Preparation and Marking of Metallic Surgical ~~Implant Applications~~ Implants[3]

F ~~86 Practice~~ 90 Specification for ~~Surface Preparation and Marking of Metallic~~ Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)[3]

2.2 *USP Standards:*[4]

Nonabsorbable Surgical Suture, *U.S. Pharmacopeia*

2.3 *American Society for Quality Standard:*[5]

ASQ C1 Specification of General Requirements for a Quality Program

3. ~~Material Requirements~~

~~3.1 Surgical fixation wire shall conform~~General Requirements for Delivery

3.1 In addition to the ~~specified chemical composition~~ requirements of ~~Specification F 90. Conformance with~~ this ~~standard shall be so identified by suitable packaging or labeling, or both.~~

~~3.2 Surgical fixation wire shall be furnished in~~ specification, all requirements of the ~~bright annealed condition~~ current editions of Specification F 90 shall apply.

3.2 In cases where a conflict exists between this specification and ~~f~~ 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,

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,

[2] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from U.S. Pharmacopeia, ~~Mack Publishing Co., Easton, PA.~~ 12601 Twinbrook Pkwy., Rockville, MD 20852.

[5] Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

4.1.8 Special tests (if applicable), and
4.1.9 Other requirements.

5. Material Requirements

5.1 The starting material used to make fixation wire must meet Specification F 90.
5.2 Surgical fixation wire shall conform to the specified chemical requirements of Specification F 90.

6. Mechanical Requirements

46.1 Surgical fixation wire shall conform to the appropriate mechanical properties specified in Table 1.
46.2 Mechanical testing shall be performed in accordance with Test Methods E 8 using a 254-mm (10-in.) gage length and cross-head speed of 254 mm/min (10 in./min).
46.3 The wire shall meet the requirements of USP for Nonabsorbable Surgical Sutures, ~~(latest version)~~ when tested in accordance with ~~4.2.~~

~~5. Dimensional Requirements~~

~~5.1 Surgical fixation wire shall be fabricated in accordance with the dimensions and tolerances specified in Table 1.~~

~~6. Surface Condition and Handling~~

~~6.1 The surface of surgical fixation wire conforming to this specification shall be free of imperfections such as toolmarks, nicks, scratches, cracks, cavities, spurs, and other defects that would impair the serviceability of the wire. The surface shall be free of embedded or deposited finishing materials and other undesirable contaminants.~~
~~6.2 The wire may be subjected to a passivation process if requested by the customer. Such passivation process shall be performed in accordance with F 86.~~
~~6.3 Surgical fixation wire shall be handled with care and packaged adequately to prevent damage and contamination of the surface.~~ 6.2.

7. ~~General~~Dimensional Requirements

7.1 ~~In~~Surgica~~dd~~l fixation wire shall be fabricated in accordance with the ~~r~~ dime~~qu~~nsions and toleranc~~ms~~ specified in~~t~~ Table 1.
7.2 Unless of~~t~~herwise specified, size tolerances a~~t~~re plus and minus as shown in Table 1. When required by the purchaser, round wire tolerances may be specified all ~~requirements~~ plus and nothing minus, or all minus and nothing plus, or any combination of plus and minus if the ~~cu~~ total spread in size tolerance is not less than the total spread shown in Table 1.
7.3 The maximum out-of-round tolerance for round wire is one half of ~~Specification F 90 shall apply.~~
~~7.2 In cases of conflict between this standard and those listed~~ the size tolerance given in ~~2.1, this standard shall take precedence.~~ Table 1.

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 (0.00006)	1730 (250)	20
0.020 to under 0.030 (0.0008 to 0.0012)	10-0	0.0015 (0.00006)	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. Pharmacopoeia.)*U.S. Pharmacopeia*).
[B] Diameter tolerances are over and under as given in this table. Also, round wire can be produced to tolerances all over and nothing under, or all under and nothing over, or any combination over and under, if the total spread in diameter tolerance for a specified diameter is not less than the total spread given 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 is specified to assure proper wire-handling characteristics.
[E] Minimum elongation for spooled wire is 6 percentage points lower than table value.

8. Surface Condition Requirements

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

8.2 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.

8.3 The wire may be subjected to a passivation process if requested by the purchaser. Such passivation process shall be performed in accordance with F 86.

9. Quality Program Requirements

9.1 The surgical wire producer and any processors shall maintain a quality program such as that which is defined in ASQ C1.

10. Certification

10.1 Certification shall be provided by the supplier that the material meets the requirements of this specification. A report of the test results shall be furnished at the time of shipment.

11. Keywords

811.1 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 primary reason for purpose of this standard specification is to characterize specify the mechanical properties requirements for the manufacture of annealed wrought cobalt-chrome monofilament wire for implant applications. cobalt-20chromium-15tungsten-10nickel alloy in the form of surgical fixation wire.

X1.2 This standard combines and replaces F 643 and F 644; Standard Specification for Wrought Cobalt-Chromium Alloy Flexible Wire for Surgical Fixations for Soft Tissue fixation wire shall be handled with care and Standard Specification for Wrought Cobalt Chromium Alloy Flexible Wire for Surgical Fixations for Bone. 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 tthis specification has been changed employed successfully in human implant applications in contact with soft tissue and the UNS designation bone for over a decade.

X2.2 No known surgical implant material has ever been added shown to more readily identify 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 (F 1091 – 91 (2000)) that may impact the use of this standard.

(*1*) The responsibility for this specification was transferred from Subcommittee F04.21 to Subcommittee F04.12.
(*2*) The specification was modified to incorporate the standard format (template) used by Subcommittee F04.12.