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

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. Scope

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

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

### 2. Referenced Documents

#### 2.1 ASTM Standards:

E 8 Test Methods for Tension Testing of Metallic Materials<sup>2</sup>

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants<sup>3</sup>

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)<sup>3</sup>

#### 2.2 USP Standards:<sup>4</sup>

Nonabsorbable Surgical Suture, U.S. Pharmacopoeia

### 3. Material Requirements

3.1 Surgical fixation wire shall conform to the specified chemical composition 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 the bright annealed condition and finish.

### 4. Mechanical Requirements

4.1 Surgical fixation wire shall conform to the appropriate

mechanical properties specified in Table 1.

4.2 Mechanical testing shall be performed in accordance with Test Methods E 8 using a 254-mm (10-in.) gage length and crosshead speed of 254 mm/min (10 in./min).

4.3 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 Practice F 86.

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

### 7. General Requirements

7.1 In addition to the requirements of this specification, all requirements of the current edition of Specification F 90 shall apply.

7.2 In cases of conflict between this standard and those listed in 2.1, this standard shall take precedence.

### 8. Keywords

8.1 fixation; mechanical properties; surgical implant; suture; tolerances; wire; wrought cobalt-chromium alloy

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>4</sup> U.S. Pharmacopoeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

**TABLE 1 Mechanical and Dimensional Requirements for Wrought Cobalt-Chromium Alloy Surgical Fixation Wire**

Range of Sizes Diameter, mm (in.)	USP Size <sup>A</sup>	Diameter Tolerance <sup>B,C</sup>	Tensile Strength max, MPa (ksi) <sup>D</sup>	Elong. min, % <sup>E</sup>
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

<sup>A</sup>For reference purposes only (U.S. Pharmacopoeia.)

<sup>B</sup> 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.

<sup>C</sup>The maximum out-of-round tolerance for round wire is one half of the total size tolerance given in this table.

<sup>D</sup>Maximum tensile strength is specified to assure proper wire-handling characteristics.

<sup>E</sup>Minimum elongation for spooled wire is six percentage points lower than table value.

## APPENDIX

### (Nonmandatory Information)

#### X1. RATIONALE

X1.1 The primary reason for this standard is to characterize the mechanical properties of annealed wrought cobalt-chrome monofilament wire for implant applications.

Alloy Flexible Wire for Surgical Fixations for Soft Tissue and Standard Specification for Wrought Cobalt Chromium Alloy Flexible Wire for Surgical Fixations for Bone.

X1.2 This standard combines and replaces F 643 and F 644; Standard Specification for Wrought Cobalt-Chromium

X1.3 The title has been changed and the UNS designation has been added to more readily identify the material.

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