Designation: F 1091 – 91 (Reapproved 2000)

Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel 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. 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[2]

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants[3]

F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)[3]

2.2 *USP Standards:*[4]

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

[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.

Current edition approved Feb. 22, 1991. Published June 1991.

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

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

[4] U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.