Designation: F2180 – 17

Standard Specification for Metallic Implantable Strands and Cables[1]

This standard is issued under the fixed designation F2180; 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 materials, dimensional tolerances, constructions, and mechanical properties for standard metallic implantable strands and cables.

1.2 This specification is intended to assist in the development of specific strand and cable specifications. It is particularly appropriate for high load bearing applications. It is not intended however, to address all of the possible variations in construction, material, or properties.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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]

E8 Test Methods for Tension Testing of Metallic Materials

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)

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)

F1058 Specification for Wrought 40Cobalt-20Chromium-16Iron-15Nickel-7Molybdenum Alloy Wire, Strip, and Strip Bar for Surgical Implant Applications (UNS R30003 and UNS R30008)

F1295 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)

F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium–13 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)

F1341 Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50550, UNS R50700, for Surgical Implant Applications (Withdrawn 2006)[3]

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *ISO Standards:*[4]

ISO 9001 Quality Management Systems—Requirements

2.3 *Department of Defense Specifications:*[5]

MIL-DTL-83420J Wire Rope, Flexible, For Aircraft Control

MIL-DTL-83420/1B Wire Rope, Flexible, Type 1, Composition A

MIL-DTL-83420/2B Wire Rope, Flexible, Type 1, Composition B

3. Terminology

3.1 *Definitions:*

3.1.1 *cable, n*—a group of strands helically twisted together.

3.1.2 *diameter, n*—the distance between opposing points across the circle circumscribing either the strand or cable as illustrated in Figs. 1 and 2 (see MIL-DTL-83420J, MIL-DTL-83420/1B and MIL-DTL-83420/2B).

3.1.3 *lay (or twist), n*—the helical form taken by the wires in a strand and by the strands in a cable (see MIL-DTL-83420J).

[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 F04.21 on Osteosynthesis.

Current edition approved Feb. 1, 2017. Published March 2017. Originally approved in 2002. Last previous edition approved in 2015 as F2180 – 02 (2015). DOI: 10.1520/F2180-17.

[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] Available from DODSSP, Building 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111–5098.

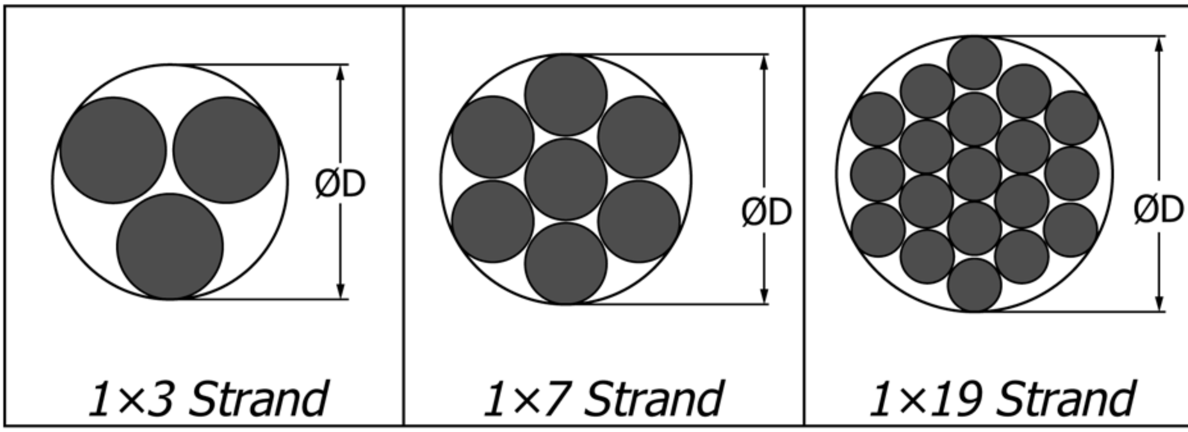

FIG. 1 Standard Stranding Constructions

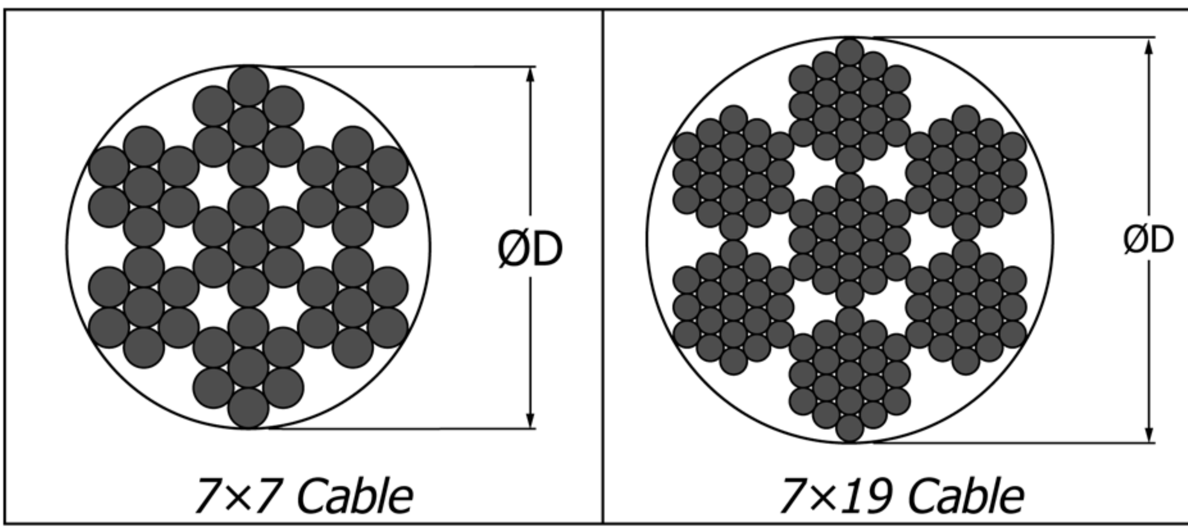

FIG. 2 Standard Cabling Constructions

3.1.3.1 *Discussion*—In a "Right Lay" situation, the wires of the strand (or the strands in a cable) are oriented in the same direction as the thread on a right-hand screw.

3.1.4 *length of lay (or pitch), n*—the distance parallel to the axis of the strand (or cable) in which a wire (or strand) makes one complete turn about the axis.

3.1.5 *M*×*N, n*—the construction designation for strands and cables. In this construction designation *M* represents the number of strands in the cable and *N* represents the number of wires in each strand.

3.1.5.1 *Discussion*— Some examples of strand constructions are 1×7 and 1×3. Similar examples of cable constructions are 7×7 and 7×19.

3.1.6 *strand, n*—a group of wires helically twisted together.

3.1.7 *wire, n*—an individual element (typically a cylindrical rod) making up a strand.

4. General Requirements

4.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications F90, F136, F138, F562, F1058, F1295, F1314, and F1341 shall apply.

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

5. Ordering Information

5.1 Inquiries and orders under this specification shall include the following information:

5.1.1 Quantity (weight, length, or number of pieces),
5.1.2 ASTM designation,
5.1.3 Material (ASTM designation),
5.1.4 Condition,
5.1.5 Construction,
5.1.6 Applicable dimensions (including diameter, length(s) of lay, and length),
5.1.7 Mechanical properties (including breaking force),
5.1.8 Special requirements, and
5.1.9 Special tests.

6. Materials and Manufacture

6.1 *Wires*—Implantable strands and cables shall be manufactured using equivalent size wires.

6.2 *Condition*—Implantable strands and cables shall be supplied in the cold-worked, cold-worked and stress-relieved, or annealed condition.

6.3 *Finish*—Types of finish available in strands and cables are cold-drawn, pickled, swaged, or as specified by the customer.

7. Stranding

7.1 The standard strand constructions are illustrated in Fig. 1. These constructions are described in the following manner:

7.1.1 *1×3 Strand*—This construction is characterized by a left-hand lay with a uniform pitch of 4 to 10 times the nominal strand diameter.

7.1.2 *1×7 Strand*—This construction is characterized by a left-hand lay with a uniform pitch of 8 to 16 times the nominal strand diameter.

7.1.3 *1×19 Strand*—This construction is characterized by an inner 1×7 strand with a right-hand lay and a uniform pitch of 8 to 12 times the nominal strand diameter. The outer 12 wires have a left-hand lay with a uniform pitch of 9 to 11 times the nominal strand diameter.

7.2 Strands may be ordered to constructions other than those specified above as determined by the customer and supplier.

8. Cabling

8.1 The standard cabling constructions are illustrated in Fig. 2. These constructions are described in the following manner:

8.1.1 *7×7 Cable*—This construction is characterized by an inner 1×7 strand that has a right-hand lay with a uniform pitch of 12 to 16 times the nominal strand diameter. The outer 1×7 strands have a left-hand lay with a uniform pitch of 8 to 16 times the nominal strand diameter. Overall, the 7×7 cable has a right-hand lay with a uniform pitch of 7 to 10 times the nominal cable diameter.

8.1.2 *7×19 Cable*—The construction is composed of a core 1×19 strand where the inner 7 wire strand has a right-hand lay with a uniform pitch of 12 to 16 times the nominal strand diameter. The remaining outer 12 wires of the core 1×19 strand have a right-hand lay with a uniform pitch of 9 to 11 times the nominal strand diameter. The outer 1×19 stands of this configuration have an inner 7 wire strand that has a left-hand lay with a uniform pitch of 8 to 16 times the nominal strand diameter. The remaining outer 12 wires of the outer 1×19 strands have a left-hand lay with a uniform pitch of 9 to 11 times the nominal strand diameter. Overall, the 7×19 cable has a right-hand lay with a uniform pitch of 7 to 10 times the nominal cable diameter.

8.2 Cables may be ordered to constructions other than those specified above as determined by the customer and supplier.

9. Joints

9.1 There shall be no welds or splices in the completed strand or cable except at terminal ends.

10. Dimensional Requirements

10.1 Strands and cables shall be fabricated in accordance with the dimensions and tolerances specified in Table 1.

11. Mechanical Requirements

11.1 Test strands and cables shall be in accordance with Test Method E8. When tensile testing strands and cables, use a gauge length of 254 mm.

TABLE 1 Dimensional Requirements for Metallic Implantable Strands and Cables

Specified Diameter, mm	Diameter Tolerance, ±mm	Out-of-Round Tolerance, mm
Under 0.12	0.0075	0.0075
0.12 to under 0.20	0.015	0.015
0.20 to under 0.30	0.022	0.022
0.30 to under 0.60	0.030	0.030
0.60 to under 0.82	0.037	0.037
0.82 to under 1.10	0.060	0.060
1.10 to under 2.50	0.075	0.075
2.50 to under 4.10	0.150	0.150

11.2 Use the following formulas for determining the effective cross-sectional area for standard construction strands or cables being tested (see section X1.4). The variable "D" in each equation is the measured diameter of the strand or cable.

11.2.1 *1×3 strand*—$3\pi(D/4.15)^2$.

11.2.2 *1×7 strand*—$7\pi(D/6)^2$.

11.2.3 *1×19 strand*—$19\pi(D/10)^2$.

11.2.4 *7×7 cable*—$49\pi(D/18)^2$.

11.2.5 *7×19 cable*—$133\pi(D/30)^2$.

11.3 Calculate the minimum breaking force for standard construction strands and cables by multiplying the material's tensile strength found in Table 2 times the stand or cable area as determined by the formulas in 11.2.

11.3.1 Table 2 specifies mechanical requirements for strands and cables of standard construction. The supplier and customer shall determine mechanical requirements for non-standard, swaged, or drawn strands and cables.

11.4 Verify that all tested strands and cable samples meet the minimum breaking force.

12. Surface Finish and Handling

12.1 The surface of strands and cables conforming to this specification shall be free of imperfections such as tool marks, nicks, scratches, cracks, cavities, spurs, die marks, 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.

TABLE 2 Mechanical Requirement for Metallic Implantable Strands and Cables

ASTM Material	Condition	Ultimate Tensile Strength min. MPa
F90	Annealed	860
F136	Annealed	860
F138	Annealed	490
	Cold-worked	860
F562	Annealed	793
	Cold-worked	1793
F1058	Cold-worked	1515
F1295	Annealed	900
F1314	Annealed	690
	Cold-worked	1035
F1341 Grade 1	Annealed	240
F1341 Grade 2	Annealed	345
F1341 Grade 3	Annealed	450
F1341 Grade 4	Annealed	550

12.2 Finish operations such as drawing or swaging may be performed on the strands or cables as specified by the customer.

12.3 The strands or cables may be subjected to a passivation process if requested by the customer. Such passivation process shall be performed in accordance with Practice F86.

12.4 The strands or cables shall be handled with care and packaged adequately to prevent damage and contamination of the surface during transport and storage.

12.5 Consider Practice F2503 to identify potential hazards produced by interactions between the device and the MR environment and for terms that may be used to label the device for safety in the MR environment.

13. Certification

13.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification and that strands and cables of standard construction meet the requirements of this specification (including a report of the test results) shall be furnished at the time of product shipment.

14. Quality Program Requirements

14.1 The producer shall maintain a quality program, such as that defined in ISO 9001.

14.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ISO 9001 or other recognized program.

15. Keywords

15.1 cable; cobalt alloys; metal (for surgical implants); stainless steel; strand; surgical implants; titanium/titanium alloy; wire; 316L

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary purpose of this specification is to characterize the materials, dimensional tolerances, construction, and mechanical properties of commonly used strands and cables for implant applications.

X1.2 Tensile strength properties are included in this specification in order to characterize the relative mechanical properties exhibited by the various materials.

X1.3 Due to the vast number of cabling configurations and possible cable and strand diameters available, this specification relies upon the calculation of the breaking force instead of supplying an extensive tabular listing.

X1.4 The effective cross-sectional area of the strand or cable as determined in 11.2 is calculated in a manner that uses a relationship between the measured cable or strand diameter and the diameter of the individual wires. For example, as shown in Fig. 1 for the 1×7 strand, the diameter of the strand is composed of three individual wires. Therefore, the formula for the effective strand area in 11.2.2 divides the strand diameter by the number of wires across the diameter of the strand (n=3) in order to determine the wire diameter and then by two (2) in order to determine the wire radius. The effective cross-sectional area for the strand is then the number of wires in the strand (n =7) times the wire area.