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Standard Specification for Metallic Implantable Strands and Cables[1]

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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. 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 Surgical Implants[3]

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications[3]

F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications[3]

F 138 Specification for Wrought 18Chromium-14Nickel 2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants[3]

F 562 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications[3]

F 1058 Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications (UNS R30003 and R30008)[3]

F 1295 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications[3]

F 1314 Specification for Wrought Nitrogen Strengthened-22Chromium-12.5Nickel-5Manganese-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S20910)[3]

F 1341 Specification for Unalloyed Titanium Wire (UNS R50250)[3]

2.2 *American Society for Quality (ASQ) Standard:*[4]

C1 Specification of General Requirements for a Quality Program

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*—a group of strands helically twisted together.

3.1.2 *diameter*—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)*—the helical form taken by the wires in a strand and by the strands in a cable (see MIL-DTL-83420J). 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)*—the distance parallel to the axis of the strand (or cable) in which the wire (or strand) makes one complete turn about the axis.

3.1.5 $M \times N$—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. 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*—a group of wires helically twisted together.

3.1.7 *wire*—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 F 90,

[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.

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

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

[4] Available from the American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

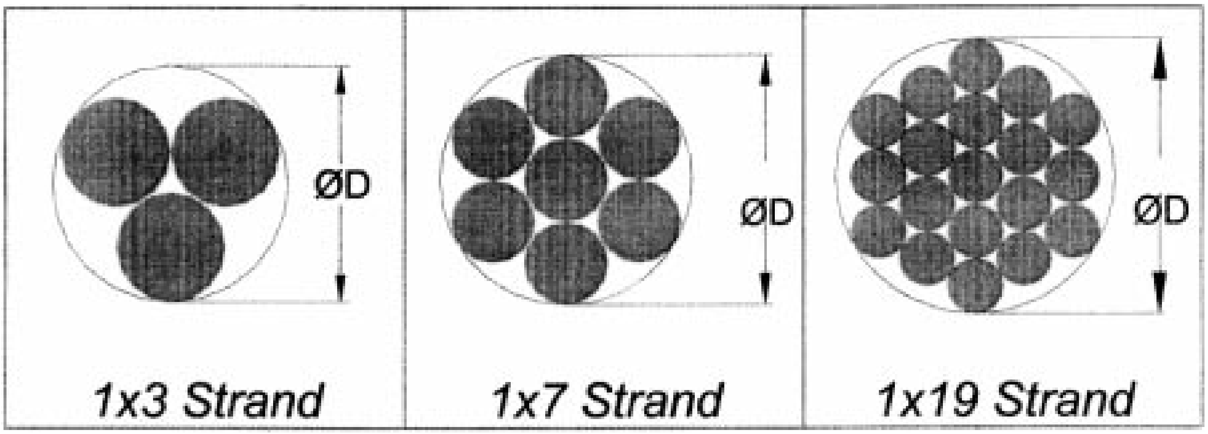

FIG. 1 Standard Stranding Constructions

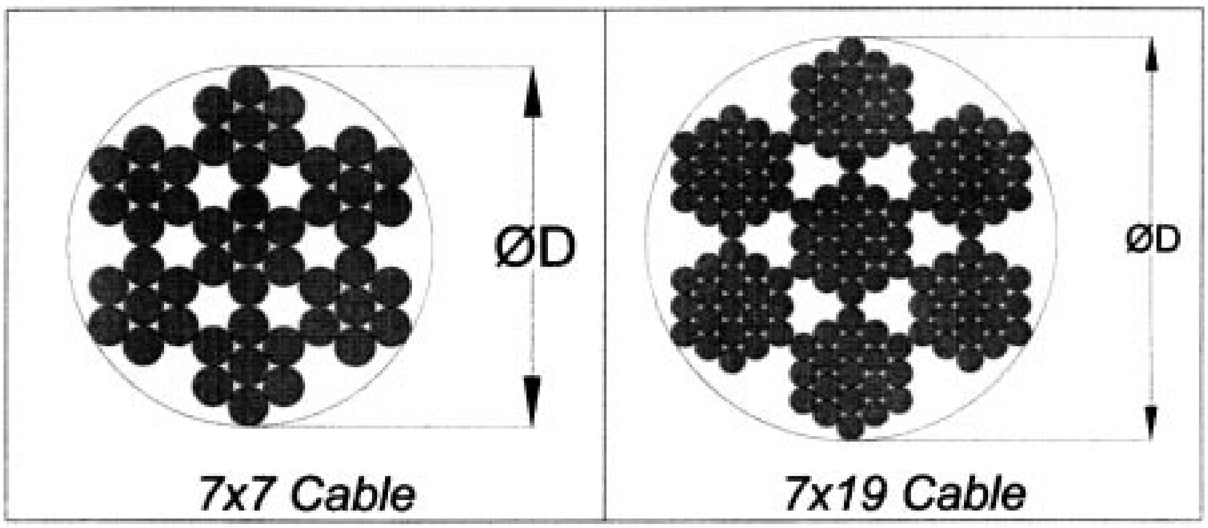

FIG. 2 Standard Cabling Constructions

F 136, F 138, F 562, F 1058, F 1295, F 1314, and F 1341 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 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 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 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 in accordance with Test Method E 8. When tensile testing strands and cables, use a gage length of 254 mm (10 in.).

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. 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.

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 F 86.

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

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 defined in ASQ C1.

14.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQ C1 or other recognized program.

TABLE 1 Dimensional Requirements for Metallic Implantable Strands and Cables

Specified Diameter, mm (in.)	Diameter Tolerance, ±mm (in.)	Out-of-Round Tolerance, mm (in.)
Under 0.12 (0.0048)	0.0075 (0.0003)	0.0075 (0.0003)
0.12 to under 0.20 (0.008)	0.015 (0.0006)	0.015 (0.0006)
0.20 to under 0.30 (0.012)	0.022 (0.0009)	0.022 (0.0009)
0.30 to under 0.60 (0.024)	0.030 (0.0012)	0.030 (0.0012)
0.60 to under 0.82 (0.033)	0.037 (0.0015)	0.037 (0.0015)
0.82 to under 1.10 (0.044)	0.060 (0.0024)	0.060 (0.0024)
1.10 to under 2.50 (0.100)	0.075 (0.0030)	0.075 (0.0030)
2.50 to under 4.10 (0.160)	0.150 (0.0060)	0.150 (0.0060)

TABLE 2 Mechanical Requirement for Metallic Implantable Strands and Cables

ASTM Material	Condition	Ultimate Tensile Strength min.	
		MPa	(ksi)
F 90	Annealed	860	(125)
F 136	Annealed	860	(125)
F 138	Annealed	490	(71)
	Cold-worked	860	(125)
F 562	Annealed	793	(115)
	Cold-worked	1793	(260)
F 1058	Cold-worked	1515	(220)
F 1295	Annealed	900	(130.5)
F 1314	Annealed	690	(100)
	Cold-worked	1035	(150)
F 1341 Grade 1	Annealed	240	(35)
F 1341 Grade 2	Annealed	345	(50)
F 1341 Grade 3	Annealed	450	(65)
F 1341 Grade 4	Annealed	550	(80)

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.