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Standard Specification for STAINLESS STEEL BAR AND WIRE FOR SURGICAL IMPLANTS[1]

This standard is issued under the fixed designation F 55; 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.

This specification has been approved for use by agencies of the Department of Defense and for listing in the DoD Index of Specifications and Standards.

1. Scope

1.1 This specification covers the requirements for two compositions of stainless steel bar and wire, except suture wire, used for the manufacture of surgical implants.

NOTE 1—Exposure to temperatures above 800°F (425°C) during fabrication may impair corrosion resistance unless such exposure is followed by a solution-annealing treatment.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Applicable Documents

2.1 *ASTM Standards*:

A 262 Recommended Practices for Detecting Susceptibility to Intergranular Attack in Stainless Steel[2]

A 484 Specification for General Requirements for Stainless and Heat-Resisting Wrought Steel Products (Except Wire)[3]

A 555 Specification for General Requirements for Stainless and Heat-Resisting Steel Wire[2]

A 751 Methods, Practices, and Definitions for Chemical Analysis of Steel Products[2]

E 112 Estimating the Average Grain Size of Metals[4]

2.2 *American Society for Quality Control (ASQC) Standard*:

C1-1968 Specification of General Requirements for a Quality Program[5]

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484 and A 555 shall apply.

3.2 In the case where a conflict exists between this standard and those listed in 2.1 and 2.2, this standard 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 (weight or number of pieces),

4.1.2 Grade (1 or 2),

4.1.3 ASTM designation,

4.1.4 Form (bar, wire, fine wire),

4.1.5 Condition (see 5.1),

4.1.6 Mechanical properties (if applicable, for special conditions),

4.1.7 Finish (see 5.2),

4.1.8 Applicable dimensions including size, thickness, width, and length (exact, random or multiples) or print number, and

4.1.9 Special requirements.

5. Manufacture

5.1 *Condition*:

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

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[2] *Annual Book of ASTM Standards*, Part 3.

[3] *Annual Book of ASTM Standards*, Part 5.

[4] *Annual Book of ASTM Standards*, Part 11.

[5] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, Wis. 53203.

5.1.1 Bar and wire shall be furnished to the implant manufacturer; as specified, in the hot-worked, annealed, or cold-worked condition (see Table 1).

5.1.2 Fine wire shall be furnished to the implant manufacturer, as specified, in the annealed, or cold-drawn condition (see Table 2).

5.2 *Finish*:

5.2.1 Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

5.2.2 Types of finish available for fine wire products are cold-drawn, bright-annealed, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

6. Chemical Requirements

6.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 3.

6.2 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Methods A 751.

7. Metallurgical Requirements

7.1 The material shall contain no free ferrite phase when it is examined metallographically at 100× magnification.

8. Mechanical Requirements

8.1 Material shall conform to the appropriate requirements as to mechanical properties specified in Table 1 and 2. The level of mechanical properties for material in other than the annealed condition shall be specified in the implant manufacturer's purchase order.

8.2 Brinell hardness number (HB) is the preferred method of reporting the hardness of hot-worked material.

8.3 When desired, Rockwell hardness, B scale (HRB) or Rockwell hardness, C scale (HRC), limits may be specified. Hardness determination on cold-worked material shall be made on a product cross section, midway between the center and surface, if cross-section size is adequate.

9. Special Tests

9.1 The steel shall be capable of passing the intergranular corrosion susceptibility test in accordance with Recommended Practices A 262, Practice E.

9.1.1 Samples in the hot-worked condition shall be annealed prior to Recommended Practices A 262, Practice E, sensitization heat treatment.

9.2 The grain size shall be five or finer when tested in accordance with Methods E 112.

9.2.1 It is preferred that samples for grain size determination be selected after the hot-working operation or after the final-annealing operation prior to the final cold-working operation.

9.2.2 If samples are selected after a final cold-working operation, transverse specimens shall be prepared.

9.3 Any other special requirements shall be specified on the purchase order.

10. Certification

10.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program, such as defined in ASQC C1-1968.

11.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1-1968, or other recognized program.