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Standard Test Method for Corrosion of Surgical Instruments¹

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^{ε1} NOTE—Section 8 was added editorially in April 1994.

1. Scope

1.1 This test method covers general test procedures and evaluation criteria for the corrosion resistance of surgical instruments fabricated from stainless steel and intended for reuse in surgery.

1.2 Austenitic (Class 3), martensitic (Class 4), and precipitation hardening (Class 5) materials are to use the boil test and the copper sulfate test.

1.3 Ferritic (Class 6) materials are to use the copper sulfate tests.

1.4 The copper sulfate test is used in austenitic materials to detect chromium depletion at the grain boundaries caused by improper heat treatment or improper cold working.

1.5 For martensitic steels, the copper sulfate test is used to detect improper heat treatment.

1.6 The boil test is applicable to martensitic, austenitic, and precipitation hardened materials to detect surface imperfections.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

A 380 Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems²

F 899 Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments³

F 921 Definitions of Terms Relating to Hemostatic Forceps³

3. Significance and Use

3.1 This test method provides a test methodology and means of evaluation consistent to both producers and users alike. The corrosion tests serve as an indicator of proper material pro-

cessing selection by the manufacturers and proper care by the user.

4. Reagents and Materials

4.1 *Cupric Sulfate*—Cupric sulfate crystals ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$), 1 g.

4.2 *Sulfuric Acid*—Sulfuric acid AR (H_2SO_4), sp gr 1.84, 2.5 g.

4.3 *Distilled Water*.

4.4 *Isopropyl Alcohol or 95 % Ethyl Alcohol*.

4.5 *Nonreactive Vessel*, such as a glass or ceramic container.

5. Specimen Preparation

5.1 Boil Test:

5.1.1 Wash the instrument(s) with mild soap using a non-metallic hard bristle brush and warm tap water (80 to 125 °F).

5.1.2 Rinse the instruments thoroughly at room temperature in distilled water, 95 % ethyl alcohol, or isopropyl alcohol.

5.1.3 Dry using paper towel or soft cloth.

5.2 Copper Sulfate Corrosion Test:

5.2.1 Wash the instrument(s) with mild soap using a non-metallic hard bristle brush and warm (80 to 125 °F) tap water.

5.2.2 Rinse the instruments thoroughly at room temperature in distilled water followed by rinsing in 95 % ethyl alcohol or isopropyl alcohol.

5.2.3 Air dry (ambient air).

6. Procedure

6.1 Boil Test:

6.1.1 Immerse the instrument(s) into a nonreactive container of distilled water.

6.1.2 Bring the water to a boil.

6.1.3 Maintain boiling temperature for 30 ± 1 min.

6.1.4 Ensure that the instrument(s) remains immersed.

6.1.5 Remove the heat source and let the instrument(s) stand for $3 \text{ h} \pm 15$ min.

6.1.6 Remove the instrument(s) from the water and set on a towel to air dry (ambient air) for $2 \text{ h} \pm 10$ min.

6.1.7 It is recommended that the pH level of test water is recorded before discarding. If the pH is outside the 6.5 to 7.0 range, the instrument was not cleaned thoroughly and should be retested accordingly.

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.33 on Medical/Surgical Instruments.

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² *Annual Book of ASTM Standards*, Vol 01.03.

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