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Standard Test Method for Corrosion of Surgical Instruments[1]

This standard is issued under the fixed designation F 1089; 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.

ϵ^1 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 Systems[2]

F 899 Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments[3]

F 921 Definitions of Terms Relating to Hemostatic Forceps[3]

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

4. Reagents and Materials

4.1 *Cupric Sulfate*—Cupric sulfate crystals ($CuSO_4 \cdot 5H_2O$), 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 nonmetallic 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 nonmetallic 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 h± 15 min.

6.1.6 Remove the instrument(s) from the water and set on a towel to air dry (ambient air) for 2 h ± 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.

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[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.

6.2 *Copper Sulfate Corrosion Test*:

6.2.1 *Copper Sulfate Solution Preparation*:

6.2.1.1 Fill a nonreactive container with 22.5 mL of warm distilled water (80 to 125 °F).

6.2.1.2 Add 1 g of cupric sulfate crystals and stir until the crystals are completely dissolved.

6.2.1.3 Add 2.5 g of sulfuric acid and mix thoroughly.

6.2.2 *Test Procedure*:

6.2.2.1 Submerge the instrument(s) into a nonreactive container of copper sulfate solution of 63 to 67 °F.

6.2.2.2 Instruments too large for complete immersion shall have partial immersion or test by drops of the solution.

6.2.2.3 Copper sulfate solution shall be allowed to remain in contact with the instrument for 5½08to 6½ min.

6.2.2.4 Rinse the instrument(s) thoroughly with tap water and vigorously clean with cloth or nonmetallic soft bristle brush to remove any nonadherent copper plating.

7. Interpretation of Results

7.1 *Boil Test*:

7.1.1 All surfaces are to show no signs of corrosion (without magnification).

7.1.2 A slight evidence of rust (ferrous oxide) in serrations, teeth, locks, ratchets, inserts (brazed or soldered junctions), etc., shall not be cause for rejection.

7.2 *Copper Sulfate Corrosion Test*:

7.2.1 All surfaces are to show no visual signs of copper plating (without magnification) with the exceptions noted in 7.2.1.1 and 7.2.1.2.

7.2.1.1 Copper plating in serrations, teeth, locks, ratchets, braze junctions, solder junctions or dulling of polished surfaces shall not be cause for rejection.

7.2.1.2 Copper plating at the periphery of the copper sulfate solution drops shall not be cause for rejection.

8. Keywords

8.1 boil test; copper sulfate corrosion test; corrosion-surgical implants; immersion

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The function of this test method is to provide a test methodology and means of evaluation consistent to both producers and users alike.

X1.2 The corrosion tests serve as indicator of proper material processing selection by the manufacturers and proper care by the user.

X1.3 Both the boil test and copper sulfate test serve as an indicator that the surface has achieved a passive state as well as remove chemical and free iron contaminants. Heat treatment has an important effect on corrosion resistance in martensitic stainless steel. Carbide formation does reduce corrosion resistance. Proper heat treatment dissolves free carbon. The copper sulfate detects carbide formation from free carbon. 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. The boil test is applicable to martensitic, austenitic, and precipitation hardened materials to detect surface imperfections.

NOTE X1.1—Practice 4380 states that a specialized copper sulfate test is used extensively on surgical and dental instruments made of hardenable martensitic stainless steel.

X1.4 Specific instrument design/manufacturing processes will influence corrosion test results. Accumulated testing experience is an important factor in determining the significance of corrosion results obtained for stainless steel.

X1.5 The copper sulfate test was developed to detect chromium depletion at the grain boundaries of austenitic material due to improper heat treatment (in the 900 to 1100 °F range) or improper cold working. The boil test would not readily show these defects, but would show cracks and pitting. The austenitic materials should be subjected to both tests. Improper heat treatment can result in carbide formation in the martensitic materials. Proper heat treatment results in the dissolution of free carbon into the martensitic structure. It is recognized in 7.2.1.1 that plating of unpolished surfaces may occur, and trouble areas are specifically excluded. This exclusion would negate the phenomena of plating in these areas with Type 410. The boil test is important for these materials for surface imperfections. The copper sulfate test is important to detect improper heat treatment. The precipitation hardening steels are included for the same rationale as the austenitics.