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## Standard Test Method for Corrosion of Surgical Instruments<sup>1</sup>

This standard is issued under the fixed designation F1089; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### 1. Scope\*

1.1 This test method covers general test procedures and evaluation criteria for the corrosion resistance of surgical instruments intended for reuse in surgery and fabricated from stainless steel such as, but not limited to, those listed in Specification F899.

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

~~1.3 Ferritic (Class 6) materials shall use the copper sulfate test.~~

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

~~1.5 The copper sulfate test is used to detect improper heat treatment of martensitic materials.~~

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

~~1.7 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.~~

1.2 Austenitic (Class 3), martensitic (Class 4), precipitation hardenable (Class 5), and ferritic (Class 6) materials shall use the boil test.

1.3 Ferritic (Class 6) materials with a minimum 16 % chromium content, austenitic (Class 3), and precipitation hardenable (Class 5) materials shall use the boil test and the copper sulfate test.

1.4 The copper sulfate test is used to detect the presence of metallic iron and iron oxide on the surface of materials.

1.5 The copper sulfate test is not recommended for martensitic materials. (See Note X1.1.)

1.6 The boil test is applicable to martensitic, austenitic, ferritic, and precipitation hardenable materials to detect free iron or any other anodic surface contaminants on stainless steel.

1.7 Values in either inch-pound or SI are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore each system shall be used independent of the other. Combining values from the two systems may result in non-conformance with the specification.

1.8 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*:<sup>2</sup>

A380 [Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems](#)

A967 [Specification for Chemical Passivation Treatments for Stainless Steel Parts](#)

F899 [Specification for Wrought Stainless Steels for Surgical Instruments](#)

### 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 ( $\text{CuSO}_4$  Copper Sulfate—Copper sulfate pentahydrate ( $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ ), 1 g. O).

<sup>1</sup> 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 F04.15 on Material Test Methods.

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<sup>2</sup> 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.

\*A Summary of Changes section appears at the end of this standard.

- 4.2 *Sulfuric Acid*—Sulfuric acid AR ( $H_2SO_4$ ), sp gr 1.84, 2.5 g-, sp gr 1.84.
- 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, 26 to 51°C (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, 26 to 51°C (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).

### 5.3 *Passivation*:

5.3.1 Instruments shall be chemically passivated or electropolished according to the passivation treatments specified in Specification A967 prior to evaluating the corrosion resistance according to this test method.

5.3.2 Passivated parts shall exhibit a chemically clean surface and shall, on visual inspection, show no etching, pitting, or frosting resulting from the passivation procedures.

5.3.3 Passivated parts shall be marked by vibratory, impact, chemical, or laser methods. If marking is performed after the final surface treatment, it must be evaluated whether a secondary passivation treatment is necessary or not.

## 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  $30 \pm 1$  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.

### 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, 26 to 51°C (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.~~

6.2.1.1 Fill a nonreactive container with 250 mL of distilled water.

6.2.1.2 Add 1 mL of sulfuric acid ( $H_2SO_4$ , sp gr 1.84).

6.2.1.3 Add 4 g of copper sulfate pentahydrate ( $CuSO_4 \cdot 5H_2O$ ) and stir until the crystals are completely dissolved.

#### 6.2.2 *Test Procedure*:

6.2.2.1 ~~Submerge the instrument(s) in a nonreactive container containing copper sulfate solution at a temperature of 17 to 20°C (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 ~~The copper sulfate solution shall be allowed to remain in contact with the instrument for  $6 \text{ min} \pm 30$  s.~~

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.~~

6.2.2.1 The test solution is swabbed on the surface of the sample representing the lot of passivated parts.

6.2.2.2 Apply additional solution as needed to keep the surface wet for a period of at least 6 min.

6.2.2.3 Rinse the instrument(s) thoroughly with distilled water and dry with care not to disturb copper deposits if present.

## 7. Interpretation of Results

### 7.1 *Boil Test*:

7.1.1 All surfaces shall 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), and so forth, shall not be cause for rejection.