Designation: F1089 – 10

Standard Test Method for Corrosion of Surgical Instruments[1]

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 (ε) 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), 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:*[2]

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 *Copper Sulfate*—Copper sulfate pentahydrate ($CuSO_4 \cdot 5H_2O$).

4.2 *Sulfuric Acid*—Sulfuric acid AR (H_2SO_4), 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:*

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[2] 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**

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 ± 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.

6.2 *Copper Sulfate Corrosion Test:*

6.2.1 *Copper Sulfate Solution Preparation:*

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 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.

7.2 *Copper Sulfate Corrosion Test:*

7.2.1 All surfaces shall show no visual signs of copper plating (without magnification) with the following exceptions:

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 caused by concentration of the solution due to evaporation shall not be cause for rejection.

8. Rejection and Retest

8.1 Any lot failing to meet the specified test requirements of the purchase order shall be rejected.

8.1.1 A rejected lot may, at the option of the processor, be re-passivated, with or without re-pretreatment, and then be retested.

8.2 The number of samples tested from a lot subject to retest shall be twice the original specified test frequency, to the limit of the number of pieces in the lot.

8.2.1 All samples must pass the specified acceptance criterion for the specified test for the retested lot to be accepted.

9. Part Disposition

9.1 Instruments that were tested in copper sulfate solution and instruments that failed the boil test shall be discarded.

10. Keywords

10.1 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, both producers and users alike, a consistent test methodology and means of evaluating test results.

NOTE X1.1—Practice A380 states that a specialized copper sulfate test is used extensively on surgical and dental instruments made of hardenable martensitic stainless steel for the purpose of detecting free iron and determining overall good manufacturing practice.

X1.1.1 *Solution Preparation*—Add 5.4 mL of sulfuric acid (H_2SO_4, sp. gr 1.84) to 90 mL of distilled water and then add 4 g of copper sulfate pentahydrate ($CuSO_4 \cdot 5H_2O$) and stir until the crystals are completely dissolved.

X1.1.2 *Test Procedure*—The test solution is swabbed on the surface of the sample representing the lot of passivated parts. Apply additional solution as needed to keep the surface wet for a period of at least 6 min. Rinse the instruments thoroughly with distilled water and wipe with moderate vigor to determine if the copper is adherent or nonadherent.

X1.1.3 *Interpretation of Results*—Instruments with nonadherent copper are considered acceptable. Copper plating in serrations, teeth, locks, ratchets, braze junctions, solder junctions, or dulling of polished surfaces shall not be cause for rejection.

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 detecting the presence of free iron or any other anodic surface contaminants. Heat treatment has an important effect on corrosion resistance of 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.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1089 – 02) that may impact the use of this standard. (Approved Sept. 1, 2010.)

Changes from the previous document include:
(1) Updating the scope to agree with the latest information in Specification A967,
(2) Adding Specification A967 as a Referenced Document,
(3) Adding 5.3 instrument passivation information,
(4) Updating 6.2 and 7.2.1.2 Copper Sulfate Corrosion Test,
(5) Adding new Sections 8, Rejection and Retest, and 9, Part Disposition,
(6) Adding information in X1.1.1, X1.1.2, and X1.1.3 to describe the specialized copper sulfate test used for martensitic stainless steels (nonmandatory information), and
(7) Deleting X1.5 grain boundary chromium depletion information, which involves a different type of copper sulfate test method.