Designation: F1089 – 18

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 new and reusable surgical instruments fabricated from stainless steel alloys, such as, but not limited to, those listed in Specification F899.

1.2 Instruments containing stainless steel materials that are exclusive to the following shall use the boil test and the copper sulfate test: austenitic materials (Class 3), precipitation hardening materials (Class 5), and ferritic materials (Class 6) containing equal or greater than 16 % chromium.

1.3 Instruments containing any of the following stainless steel materials shall use the boil test: martensitic materials (Class 4) and ferritic materials (Class 6) containing less than 16 % chromium.

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

1.5 The copper sulfate test as described in 6.2 is not recommended for martensitic materials or for ferritic materials containing less than 16% chromium because these steels may give a positive indication irrespective of the presence or absence of anodic surface contaminants (see X1.5).

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

1.7 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

B912 Specification for Passivation of Stainless Steels Using Electropolishing

D1193 Specification for Reagent Water

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E1402 Guide for Sampling Design

F899 Specification for Wrought Stainless Steels for Surgical Instruments

F1744 Guide for Care and Handling of Stainless Steel Surgical Instruments

2.2 *Federal Specifications*[3]

MIL-STD-753 Corrosion-Resistant Steel Parts: Sampling, Inspection and Testing for Surface Passivation

3. Significance and Use

3.1 This test method provides corrosion test methodologies and means of evaluation that serve as indicators of proper material selection and proper processing by the manufacturer.

NOTE 1—It is recommended that instruments be chemically passivated according to one of the treatments in Specification A967, electropolished according to Specification B912, or both, prior to evaluating the corrosion resistance according to this test method. The likelihood of failure may be higher for non-passivated instruments.

[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 F04.15 on Material Test Methods.

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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.

[3] Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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

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 or Reagent Water* conforming to Specification D1193, Type IV.

4.4 *Isopropyl Alcohol or 95 % Ethyl Alcohol.*

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

5. Specimen Preparation

5.1 Wash the instrument(s) with mild soap using an appropriate nonmetallic bristle brush and warm (25 to 50°C) tap water.

5.2 Rinse the instrument(s) thoroughly at room temperature in distilled water, reagent water, 95 % ethyl alcohol, or isopropyl alcohol.

5.3 Dry using a paper towel or soft cloth.

5.4 Use plastic tongs and gloves during cleaning and handling. Avoid contact with steel or stainless steel tongs or other metallic items that may damage or contaminate the surface after cleaning.

6. Procedure

6.1 *Boil Test:*

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

6.1.2 Bring the water to a boil.

6.1.3 Maintain at 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 the test water be recorded immediately at the conclusion of the test. If the pH is outside the range of 6.5 to 7.0, the instrument was not cleaned thoroughly and should be retested accordingly.

6.2 *Copper Sulfate Test:*

6.2.1 *Copper Sulfate Solution Preparation:*

6.2.1.1 Fill a nonreactive container with 250 mL of distilled or reagent 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 Apply the test solution onto the surface of the instrument(s).

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 or reagent water and dry, with care taken to not disturb copper deposits if present.

7. Interpretation of Results

7.1 *Boil Test:*

7.1.1 Surfaces shall show no signs of corrosion (without magnification) with the following exceptions:

7.1.1.1 Rust (ferrous oxide) on serrations, teeth, locks, ratchets, inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks shall not be cause for rejection.

7.2 *Copper Sulfate Test:*

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

7.2.1.1 Copper plating on serrations, teeth, locks, ratchets, brazed junctions, soldered junctions, etched areas, engravings, laser marks, 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.

NOTE 2—See Guide F1744 for discussion on the higher susceptibility of serrations, teeth, locks, ratchets, inserts, etc. to corrosion.

8. Sampling Plan

8.1 Each instrument manufacturer shall define an appropriate sampling plan for ensuring instrument safety and quality.

8.2 Rejected lots are often re-passivated and retested, typically using an increased sample size of instruments. If the lot is rejected a second time, it is recommended that the cause of the repeat failure be evaluated before proceeding.

NOTE 3—Practice E122 and Guide E1402 may be useful in the development of the sampling plan.

9. Part Disposition

9.1 Instruments that were tested with copper sulfate solution shall be discarded.

NOTE 4—Instruments that fail the boil test may be discarded or remediated (see 8.2).

10. Precision and Bias

10.1 No statement is made concerning either the precision or bias of the boil test and the copper sulfate test because the results state merely whether there is conformance to the criteria for success specified in the procedure.

11. Keywords

11.1 boil test; copper sulfate test; corrosion tests; immersion test; surgical instruments