



Designation: **F1089 – 10 F1089 – 18**

## 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 reappraisal. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reappraisal.

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

1.2 Austenitic (Class 3), martensitic (Class 4), precipitation hardenable 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 (Class 6) materials shall use the boil test. materials (Class 6) containing equal or greater than 16 % chromium.

1.3 Ferritic (Class 6) materials with a minimum 16 % chromium content, austenitic (Class 3), and precipitation hardenable (Class 5) materials Instruments containing any of the following stainless steel materials shall use the boil test and the copper sulfate 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 metallic iron and iron oxide-free iron on the surface of materials.

1.5 The copper sulfate test as described in 6.2 is not recommended for martensitic materials. (See materials or Note X1.1.) 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 hardenable hardening materials to detect surface imperfections, 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. 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, safety, health, and health 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:*<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](#)

[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](#)

<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

[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<sup>3</sup>](#)

[MIL-STD-753 Corrosion-Resistant Steel Parts: Sampling, Inspection and Testing for Surface Passivation](#)

### 3. Significance and Use

3.1 This test method provides ~~a corrosion test methodology~~ methodologies and means of evaluation consistent to both producers and users alike. ~~The corrosion tests serve as an indicator that serve as indicators of proper material processing selection by the manufacturers selection and proper care processing by the user.~~ 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.

### 4. Reagents and Materials

4.1 *Copper Sulfate*—Copper sulfate pentahydrate (CuSO<sub>4</sub>·5H<sub>2</sub>O).

4.2 *Sulfuric Acid*—Sulfuric acid AR (H<sub>2</sub>SO<sub>4</sub>), sp gr 1.84.

4.3 ~~Distilled Water.~~ 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 ~~Boil Test:~~ Rinse the instrument(s) thoroughly at room temperature in distilled water, reagent water, 95 % ethyl alcohol, or isopropyl alcohol.

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.

5.3 ~~Copper Sulfate Corrosion Test:~~ Dry using a paper towel or soft cloth.

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).

5.4 ~~Passivation:~~ 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.

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 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.

<sup>3</sup> Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.