



Designation: F1089 – 10

Standard Test Method for Corrosion of Surgical Instruments¹

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.*

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. 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 ($\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$).

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 non-metallic 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:

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