INTERNATIONAL STANDARD

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Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

Instruments chirurgicaux et dentaires à main — Détermination de la résistance au passage à l'autoclave, à la corrosion et à l'explosion à la chaleur

Reference number
ISO 13402:1995(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13402 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

Annex A of this International Standard is for information only.

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Introduction

The procedures described in this International Standard are intended to form a harmonized series of tests that may be referred to, individually or in combination, in other separate product standards. The requirements for such tests shall be defined and stated within the body of the product standard along with the number of cycles for each test procedure.

The tests apply to dental and surgical instruments and are already standardized in relevant product standards (e.g. ISO 7151, *Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods*; ISO 9173-1 *Dental extraction forceps — Part 1: Screw and pin joint types*). However, the test procedures as stated in the product standards differ in minor details. An alignment and a compilation was established. The most important test methods for dental and surgical instruments have been brought together in one general International Standard.

Other, additional, tests may also be required in individual product standards; those procedures and requirements will be determined by the members of the working groups concerned. When established, it is intended that these additional test procedures are incorporated in this International Standard as an addendum or at the next revision.

This International Standard does not specify any test sequence nor any requirements related to specific instruments. The requirements, the test sequence and the number of test cycles have to be defined in the relevant product standards or, if no standard is available, it has to be left to the decision of the purchaser and/or the manufacturer.

Apart from the boiling water test, the autoclave test applies for determining corrosion resistance. In this sense, this International Standard specifies two test methods for determining corrosion resistance. When placing an order, it is intended that the purchaser state whether both tests are to be carried out or which of the two tests. If the purchaser does not so indicate, the choice is left to the discretion of the manufacturer.

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Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

1 Scope

This International Standard describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.

The requirements for such tests are defined and stated in the product standard along with the number of cycles for each test procedure.

Other, additional, tests may also be required (see the Introduction).

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Autoclave test for corrosion

The autoclave test attempts to simulate the service environment; it is therefore based on recommended methods of sterilization.

3.1 Reagent

The water used for the test shall be of quality 3 in accordance with ISO 3696:1987.

3.2 Apparatus

Autoclave, operating in the non-vacuum mode, capable of being operated at 134° C to 138° C and 0,22 $MN \cdot m^{-2}$.

3.3 Preparation

Scrub the instrument using soap and warm water. Rinse thoroughly in water (3.1) and dry.

3.4 Test procedure

Place the instrument, unwrapped on a tray, into the autoclave. Using the water (3.1) subject the instrument to an autoclaving cycle of $(3\ ^{+0,5}_{0})$ min at 134 °C to 138 °C and 0,22 $MN \cdot m^{-2}$. After the cycle, open the door. Remove the tray and allow the contents to cool to room temperature.

3.5 Evaluation

Refer to the appropriate product standard for specific requirements.

4 Boiling water test for corrosion

The boiling water test is specified for determining corrosion resistance.

4.1 Reagent

The water used for the test shall be of quality 3 in accordance with ISO 3696:1987.

4.2 Apparatus

Glass or ceramic beaker or suitable corrosion-resistant stainless steel vessel.

4.3 Preparation

Scrub the instrument using soap and warm water. Rinse thoroughly in water (3.1) and dry.

4.4 Test procedure

Immerse the instrument in boiling water (3.1) in the beaker or vessel (4.2) for 30 min. Then allow the instrument to cool for 1 h in the water used for the test.

Remove the instrument from the water and leave it exposed to the air for 2 h. Rub the instrument vigorously with a dry cloth.

4.5 Evaluation

Examine the instrument for the presence of blemishes.

5 Copper sulfate test

The copper sulfate test is used to detect improper heat treatment (see annex A for the test rationale).

5.1 Reagent

Reagents used shall be of recognized analytical grade.

5.1.1 Cupric sulfate: hydrated cupric sulfate crystals ($CuSO_4 \cdot 5H_2O$), 1 g.

5.1.2 Sulfuric acid: sulfuric acid AR (H_2SO_4), $\rho = 1{,}84$ g/cm^3, 2,5 g.

5.1.3 Water of quality 3 in accordance with ISO 3696:1987.

5.1.4 Isopropyl alcohol or **95 % ethyl alcohol.**

5.2 Apparatus

Non-reactive vessel, such as glass or ceramic container.

5.3 Preparation

5.3.1 Preparation of instrument

Scrub the instrument using soap and warm water, rinse thoroughly in water (5.1.3) and dry using isopropyl alcohol or 95 % ethyl alcohol (5.1.4).

5.3.2 Preparation of copper sulfate solution

Fill a non-reactive container with 22,5 ml of warm distilled water (5.1.3). Add 1 g of cupric sulfate crystals (5.1.1) and stir until the crystals are completely dissolved. Then add 2,5 g of sulfuric acid (5.1.2) and mix thoroughly.

5.4 Test procedure

Submerge the instrument in a non-reactive container of copper sulfate solution at room temperature.

Instruments too large for complete immersion shall be partially immersed, or tested by drops of the solution.

The copper sulfate solution shall remain in contact with the instrument for 5,5 min to 6,5 min.

Rinse the instrument thoroughly with tap water and vigorously rub it with a cloth to remove any non-adherent copper plating.

5.5 Evaluation

Refer to the appropriate product standard for specific requirements.

6 Thermal test

The thermal test is specified for determining the resistance against thermal exposure.

6.1 Apparatus

A dry heat oven capable of being operated at (175 ± 5) °C.

6.2 Test procedure

Place the instrument in the dry heat oven at (175 ± 5) °C and, after allowing the oven to recover its set temperature, leave it for (30 ± 1) min.

Remove the instrument from the dry heat oven and allow it to cool, in the open air, to room temperature.

6.3 Evaluation

Refer to the appropriate product standard for specific requirements.

Annex A
(informative)

Rationale

NOTE 1 This text is taken from ASTM-F 1089-87.

A.1 The function of these test methods is to provide test methodology and means of evaluation consistent to both producers and users alike.

A.2 The corrosion tests serve as an indicator of proper material processing selection by the manufacturers and proper care by the user.

A.3 The autoclave test, the boil test and copper sulfate test serve as an indicator that the surface has achieved a passive state and as a means of removing chemical and free iron contaminants. Heat treatment has an important effect on corrosion resistance in martensitic stainless steel. Carbide formation does reduce corrosion resistance. Proper heat treatment dissolves free carbon. The copper sulfate detects carbide formation from the carbon. The copper sulfate test is used in austenitic materials to detect chromium depletion at the grain boundary caused by improper heat treatment or improper cold working. The boil test is applicable to martensitic, austenitic and precipitation-hardened materials to detect surface imperfections.

A.4 Specific instrument design/manufacturing processes will influence corrosion test results. Accumulated test experience is an important factor in determining the significance of corrosion results obtained for stainless steel.

A.5 The copper sulfate test was developed to detect chromium depletion at the grain boundaries of austenitic material due to improper heat treatment (in the 900 °F to 1100 °F range) or improper cold working. The boil test would not readily show these defects, but would show cracks and pitting. The austenitic materials should be subjected to both tests. Improper heat treatment can result in carbide formation in the martensitic materials. Proper heat treatment results in the dissolution of free carbon into martensitic structure.

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