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Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

Implants chirurgicaux — Solutions d'essai et conditions environnementales pour les essais statiques et dynamiques de corrosion sur les matériaux et dispositifs médicaux implantables

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16428 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Introduction

In many instances testing of medical devices and materials in a physiological environment is highly desirable for scientific purposes and development work as well as for the assessment of the performance of surgical implants and devices. The application of original physiological fluids is often difficult because of the rapid deterioration of such media.

The application of artificial media is common, but there is the disadvantage that the compositions vary widely and testing results are often not comparable.

This International Standard specifies basic reproducible environmental conditions using a test fluid of isotonic sodium chloride (NaCl) solution. This solution is appropriate because it is used for injections and irrigation in surgery and has an ion content similar to that of human body fluids. Of particular importance are the chloride (Cl^-) ions because the corrosion resistance of most metals is very sensitive to them. Correspondingly, the isotonic NaCl solution is already widely used in the testing of medical devices.

Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

1 Scope

This International Standard specifies standard environmental conditions for the testing of metallic materials intended for implantation, surgical implants, and medical devices. The test conditions described simulate physiological conditions in a simplified manner controlling the test solution, the temperature, the gaseous atmosphere and the proportions of sample size and volume of solution.

These environmental testing conditions can be employed where necessary in combination with various static or dynamic tests where the effect of the physiological environment is to be considered. Typical applications are corrosion fatigue tests and selected fretting and wear tests, as well as general electrochemical tests.

Typical articulating joint simulator tests and aspects particular to the dental field are not considered by this International Standard. Solutions that attempt to replicate the tribological properties of body fluids, such as those used in wear studies, are outside the scope of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
corrosion fatigue testing
assessment of corrosion fatigue behaviour where cyclic loading tests are carried out in an aqueous test solution which is related to the human physiological environment

NOTE The test solution may either cause visible corrosion effects and/or acceleration of the fatigue process.

3.2
environmental testing conditions
conditions under which a sample (specimen) is tested including the testing fluid, temperature, aeration, the pH, and the volume ratio and exchange of the fluid

3.3
isotonic sodium chloride solution
aqueous solution of sodium chloride (0,9 % NaCl mass fraction) which provides the same osmotic pressure in living tissues as the physiological fluid (blood serum)

NOTE In surgical applications, it prevents the collapse of tissues and serves as an infusion solution.

3.4
Ringer's solution
isotonic aqueous solution of NaCl with additional compounds which are constituents of the human body fluids (blood serum)

NOTE See also Annex A.

3.5
static and dynamic test
mechanical set-up of the test within the context of this International Standard

NOTE This does not refer to electrochemical conditions.

4 Significance and application

4.1 Significance of test solution

The described environmental conditions are intended for applications where a testing environment for metallic medical devices or materials is required that relates to physiological conditions. The isotonic NaCl solution is used for injections [3] and for flushing and cleaning in surgery. Its ion concentration is similar to that of human body fluids. Of particular significance are the Cl^- ions because they have corrosive effects on metals, in particular on such metals and alloys which form passive films that protect against corrosion.

4.2 Application

4.2.1 General

The test conditions described are applicable for static and dynamic mechanical tests to assess the potential susceptibility to corrosion effects related to the physiological environment.

4.2.2 Testing under static conditions

The environmental conditions described are suitable for static immersion tests to study, for example, special corrosion effects such as pitting or crevice corrosion, leaching, or the performance of special surface treatments. Such tests may include uniform mechanical loading.

NOTE On highly corrosion resistant metallic implant materials, no visible surface deterioration might be detectable in purely static immersion tests. The environmental conditions described might show only effects under more stringent polarized conditions or mechanical loading and/or dynamic conditions.

4.2.3 Testing under loaded dynamic conditions

The environmental conditions described are added to mechanical test arrangements which are commonly carried out in air. They are applied, for example, in fatigue testing to assess the susceptibility to corrosion fatigue, or in selected fretting and friction tests where corrosion and wear effects are of concern.

This International Standard is not applicable to typical articulating joint simulator tests and aspects particular to the dental field nor that attempt to replicate the tribological properties of body fluids, such as those used in wear studies. In short-term handling tests (e.g. clamping), where friction or fretting are of concern, the test solution(s) (5.1) may be employed while some of the other environmental conditions (Clause 5) are neglected depending on the issue.

4.2.4 Electrochemical studies

In general, the environmental conditions described are applicable to electrochemical testing. However, depending on the type of tests some more stringent conditions may be required by certain test protocols.

5 Environmental testing conditions

5.1 Test solution

For the preparation of an isotonic aqueous 0,9 % (mass fraction) sodium chloride solution, 9 g of NaCl of analytical quality is added to purified water in accordance with ISO 3696. This results in 1 000 ml of test solution (for additional information see Reference [3]).

If a test solution other than the isotonic NaCl has been used in the testing, this shall be reported indicating some rationale.

There may be specific reasons to use a modified isotonic NaCl solution for the intended testing, for example a phosphate-buffered solution. The latter would have to be applied with technical care. There are various compositions known as “Ringer’s solutions” which contain additions that are constituents of the body fluids; in Annex A, a common composition is given under A.1. Under A.2, a modified solution with low pH is given, in case more stringent testing conditions are desired.

Additional acceptable test solutions related to the human physiological environment include those identified in ASTM F 2129:2003, Annex X2 [8].

5.2 Testing temperature

During the test, the temperature of the solution is kept stable thermostatically at (37 ± 1) °C.

5.3 pH value

The test solution has nearly a neutral pH value. During long-term testing the pH value shall be recorded on a regular basis.

Smaller shifts of the pH may be caused by air (CO_2). Significant changes of the pH value may indicate deterioration of the testing solution. This may be caused by degradation products (such as corrosion products or wear debris) from the test samples or possibly from parts of the test chamber. As soon as the test solution deteriorates, for example indicated by shifting of the pH or by discoloration, the test solution shall be exchanged and the test chamber washed out prior to the refill.

If the degradation products and/or their effects are to be investigated, the test solution may remain unchanged, but this should be recorded and an explanatory note should be included in the test report.

5.4 Aeration

For defined conditions, reproducibility, and assessment of the corrosion behaviour, the test solution shall be flushed with pure gases:

a) with pure oxygen to allow for passivation of the metal surface; or

b) with pure nitrogen to reduce the passivating effect of dissolved oxygen on the specimen surface for more stringent testing.

Depending on the purpose of the investigation, it may be necessary to carry out tests with both gases to investigate the effect on the passivity of the metal surface. For certain tests it may suffice to flush with air.

The conditions of aeration shall be reported.

5.5 Volume of test solution

The ratio of the volume of the test solution to the exposed surface area of the specimen shall be at least 10 ml/cm^2 [1].