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Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods

Implants chirurgicaux — Mesurages sur de longues périodes du potentiel en circuit ouvert pour l'évaluation du comportement à la corrosion des matériaux métalliques 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.

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ISO 16429 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Introduction

This International Standard was developed because, in contrast to polarization measurements which are well described in ASTM G5 [6] and literature, there is no standard available on typical open-circuit potential measurements over extended time periods.

Relating to corrosion behaviour of implant materials and surgical implant devices, the long-term electrochemical behaviour in the body environment is of interest.

Metal surfaces undergo spontaneous changes at their interface with an electrolytic environment to reach a state of equilibrium. Depending on the conditions, the corresponding physico-chemical and electrochemical reactions can be highly active and corrosive, or very sluggish and passive. For passivating metals such as those usually used for surgical implants, the formation and stability of the passive film is an important prerequisite for corrosion resistance of these materials, under given conditions.

With the measurement of the open-circuit potential over a longer time period, the spontaneous reaction to the environment (electrolyte) in the form of passivation or activation, the formation of a steady state potential and its stability can be assessed. Regarding surgical implant materials and devices, the measurements of these properties is of interest because they help to characterize implant material systems and to optimize processing, surface treatments and properties. Furthermore, measurements of the long-term open-circuit potential in combination with mechanical loading give information on the effect of mechanical, dynamic conditions on the electrochemical potential, passivity and corrosion behaviour.

This International Standard specifies conditions for the measurement of the open-circuit potential over extended periods of time. Isotonic 0,9 % NaCl (see 3.5) is used as the electrolyte (testing solution). This solution is related to body fluid in that it contains approximately the same concentration of Cl ions, and Cl ions are the most likely species in this solution to cause metal corrosion due to their aggressivity. For more stringent testing conditions, solutions with higher concentrations of Cl ions are given in Annex A.