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Implants for surgery — Hydroxyapatite —

Part 4: Determination of coating adhesion strength

Implants chirurgicaux — Hydroxyapatite —

Partie 4: Détermination de la résistance à l'adhésion du revêtement

Reference number
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 13779-4:2002), which has been technically revised.

A list of all parts in the ISO 13779 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Hydroxyapatite coatings are designed to promote adhesion to bone and to be colonized by bone. As a consequence, the mechanical strains in the coating and mechanical properties of the coating after implantation will change with time during the osteointegration of the coating. The aim of initial measurements of the adhesion properties of the coating, in dry conditions, detailed in this document is to guarantee minimum mechanical properties of the coating during implantation. Those minimal properties defined in ISO 13779-2 are for the coating to keep its morphology (thickness, roughness, etc.) during the implantation and to avoid chipping and spalling of the coating during implantation.

Implants for surgery — Hydroxyapatite —

Part 4: Determination of coating adhesion strength

1 Scope

This document specifies a test method for measurement of the adhesion strength of hydroxyapatite coatings intended for use on metallic-substrate components of surgical implants.

NOTE Requirements for the competence of testing laboratories can be found in ISO/IEC 17025.

2 Normative reference

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

ISO 13779-3, *Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity and phase purity*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13779-3 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
adhesion strength
tensile strength at the interface between the coating and the substrate or within the coating

Note 1 to entry: For the purpose of this document, both adhesion and cohesion strength are summarized under the term adhesion strength.

4 Determination of hydroxyapatite coating adhesion strength

4.1 Principle

Coating adhesion strength is determined by applying a uniaxial tensile load to a cylindrical test assembly composed of one hydroxyapatite-coated coupon bonded to an uncoated counterface.