TECHNICAL SPECIFICATION

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Biological evaluation of absorbable medical devices —

Part 1: General requirements

Évaluation biologique des dispositifs médicaux résorbables —

Partie 1: Exigences générales

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Foreword

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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

A list of all parts in the ISO 37137 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

Absorbable implants are intentionally designed to degrade and therefore release degradation products into the patient, a feature making these products fundamentally different from other medical devices that are not intended to be absorbed by the patient's body.

The provided content is intended to describe potential approaches to perform biological evaluation of absorbable implants to support the safety of such absorbable medical devices.

Biological evaluation of absorbable medical devices —

Part 1:
General requirements

1 Scope

This document specifies the requirements for the evaluation of absorbable medical devices during a biological risk assessment based on ISO 10993-1, including a clarification of the terms "absorb", "degrade" and other related terms (see Annex A).

2 Normative references

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 10993 (all parts), *Biological evaluation of medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/

NOTE For further discussion of utilized terminology and for a list of potential terms to be included in a literature search see Annex A.

3.1
absorb
absorption
<biomaterials> action of a non-endogenous (foreign) material or substance, or its decomposition products passing through or being assimilated by either cells or tissue, or both over time

[SOURCE: ISO 10993-6:2016, 3.1]

3.2
degradation product
intermediate or final substance which results from the physical, metabolic, and/or chemical decomposition of a material or agent

3.3
degrade
physically, metabolically, and/or chemically decompose a material or substance