Second edition
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Implants for surgery — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing

Implants chirurgicaux — Homopolymères, copolymères et mélanges sur poly(lactide) — Essais de dégradation in vitro

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Foreword

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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 13781:1997) and ISO 15814, which have been technically revised.

The main change compared to the previous edition is as follows:

— the principle contents of ISO 15814 are incorporated into this document.

Introduction

With the development of absorbable polymers for use in implantable devices, there is a need to define standard test methods to evaluate the behaviour of bulk material or devices under simulated physiological environments. On the other hand, the behaviour of absorbable materials and devices *in situ* depends on the conditions in which the material is implanted. These conditions differ, so that the site-specific behaviour of the material or device can differ. The interpretation of *in vitro* test results therefore needs to be considered carefully, taking into account any correlation of test results under *in vitro* and *in vivo* conditions. Only functional *in vivo* tests with the final product can answer actual degradation behaviour *in situ*.