INTERNATIONAL STANDARD

ISO 13781

Second edition
2017-07

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

Reference number
ISO 13781:2017(E)

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Foreword

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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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For an explanation on 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 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*.

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

1 Scope

This document describes methods for the determination of chemical and mechanical changes in poly(lactide)-based homopolymers, copolymers and/or blends induced under *in vitro* degradation testing conditions. This document covers polymers based on L-lactide, D-lactide, and/or D, L-lactide monomeric units.

The purpose of this document is to compare and/or evaluate materials or processing conditions. This document also describes the fundamental physical and mechanical evaluations needed for an *in vitro* degradation characterization of an absorbable poly(lactide) or other hydrolysable material or device.

This document is applicable to poly(lactide)-based homopolymers, copolymers and/or blends in bulk or processed forms and used for the manufacture of surgical implants, including finished products (packaged and sterilized implants).

The test methods specified in this document are also intended to determine the *in vitro* degradation rate and related changes in material properties of polylactide-based copolymers and/or blends with various other comonomers, such as glycolid, trimethylene, carbonate and/or ε-caprolactone. Unless otherwise validated for a specific device, these *in vitro* methods cannot be used to definitively predict device behaviour under *in vivo* conditions.

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 178, *Plastics — Determination of flexural properties*

ISO 180, *Plastics — Determination of Izod impact strength*

ISO 527-1, *Plastics — Determination of tensile properties — Part 1: General principles*

ISO 527-2, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*

ISO 527-3, *Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets*

ISO 604,*Plastics — Determination of compressive properties*

ISO 1628-1, *Plastics — Determination of the viscosity of polymers in dilute solution using capillary viscometers — Part 1: General principles*

ISO 1805, *Fishing nets — Determination of breaking force and knot breaking force of netting yarns*

ISO 2062, *Textiles — Yarns from packages — Determination of single-end breaking force and elongation at break using constant rate of extension (CRE) tester*

ISO 6721-2, *Plastics — Determination of dynamic mechanical properties — Part 2: Torsion-pendulum method*

ISO 13934-1, *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method*