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 m sur poly(lactide) — Essais de dégradation in vitro

ats chiru oly(lactide) Implants chirurgicaux — Homopolymères, copolymères et mélanges





© ISO 2017, Published in Switzerland

nroduced or utilized be internet or an or ISO's mem All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

Contents			Page
Fore	word		iv
Introduction			v
1	Scop	e	1
2		native references	
3		ns and definitions	
4	Degradation evaluation		
	Degr 4.1	General	
	4.1	Apparatus and reagents	
	4.3	Real-time degradation — Sample conditioning procedure	
		4.3.1 Sample loading and placement	
		4.3.2 Control of temperature	5
		4.3.3 Control of buffer solution	
		4.3.4 Sample retrieval	5
5	Physical, chemical and mechanical tests		6
	5.1	General	
	5.2	Loss of sample mass	
		5.2.1 Apparatus	
		5.2.2 Number of test samples 5.2.3 Procedure	
		5.2.4 Reusability of test specimens	
	5.3	Evaluation of molar mass	
	0.0	5.3.1 Via inherent viscosity	
		5.3.2 Via gel permeation chromatography/size exclusion chromatography	
	5.4	Mechanical tests	
		5.4.1 General	
		5.4.2 Conditioning of test samples	8
	5.5	5.4.3 Test methods Additional evaluation methods for consideration	
_			
6		termination	
7	Test report		10
Ann	ex A (in	formative) Nomenclature of absorb, degrade and related terms	12
Ann	ex B (in	formative) Additional analytic methods for consideration	13
Rihlingranhy			14

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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 of constantion ar in situ. 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.

This document is a previous generated by tills

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