

INTERNATIONAL
STANDARD

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**Poly(L-lactide) resins and fabricated forms
for surgical implants — *In vitro* degradation
testing**

*Résines et éléments à base de poly(L-lactide) pour implants chirurgicaux —
Essais de dégradation in vitro*



Reference number
ISO 13781:1997(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13781 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Annexes A and B of this International Standard are for information only.

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Poly(L-lactide) resins and fabricated forms for surgical implants — *In vitro* degradation testing

1 Scope

This International Standard describes methods for the determination of chemical and mechanical changes in properties of poly(L-lactide) under *in vitro* degradation testing conditions.

The purpose of this International Standard is to compare and/or evaluate materials or processing conditions.

This International Standard applies to poly(L-lactide) in various forms, used for the manufacture of surgical implants, including:

- a) bulk material;
- b) processed material;
- c) finished products (packaged and sterilized implants).

The test methods specified in this International Standard are intended to determine the degradation rate and the changes in material properties of poly(L-lactide) *in vitro*. These *in vitro* methods cannot be used to predict definitely the behaviour under *in vivo* conditions.

NOTE — It is recommended that copolymers and/or blends from poly(L-lactide) and/or its stereoisomers also be tested according to this International Standard as long as no relevant International Standard is available.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 178:1993, *Plastics — Determination of flexural properties*.

ISO 180:1993, *Plastics — Determination of Izod impact strength of rigid materials*.

ISO 527-1:1993, *Plastics — Determination of tensile properties - Part 1: General principles*.

ISO 527-2:1993, *Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics*.

ISO 527-3:1995, *Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets*.

ISO 604:1993, *Plastics — Determination of compressive properties*.

ISO 1628-1:1984, *Guidelines for the standardization of methods for the determination of viscosity number and limiting viscosity number of polymers in dilute solution — Part 1: General conditions*.

ISO 1805:1973, *Fishing nets — Determination of breaking load and knot breaking load of netting yarns*.

ISO 2062:1993, *Textiles — Yarns from packages — Determination of single-end breaking force and elongation at break.*

ISO 5081:1977, *Textiles — Woven fabrics — Determination of breaking strength and elongation (Strip method).*

ISO 6721-2:1994, *Plastics — Determination of dynamic mechanical properties — Part 2: Torsion-pendulum method.*

ASTM D 4475:1990, *Test method for apparent horizontal shear strength of pultruded reinforced plastic rods by the short-beam method.*

DIN 53137:1977, *Testing of filter paper, determination of rate filtration on freely suspended filters.*

3 Definitions

For the purposes of this International Standard, the following definitions apply:

3.1 degradation:

Loss of mechanical properties and/or chemical integrity through chemical changes in the material induced by environmental conditions, which can be followed by mass loss and morphological change.

3.2 *in vitro* degradation:

Degradation induced by storage in physiological fluids or simulating environment.

3.3 resorbable polymer:

Polymer deliberately designed to be transformed *in vivo* to nonharmful byproducts which are subsequently eliminated from the organism.

3.4 poly(L-lactide):

Polymeric material which consists of L-lactide units.

4 Degradation methods

4.1 General

The initial values for all tests shall be determined directly before starting the degradation test (time zero). All tests shall be carried out on degraded samples at each test period.

4.2 Apparatus and reagents

4.2.1 Soaking solution (phosphate buffer solution; Sørensen buffer), consisting of potassium dihydrogen phosphate and disodium hydrogen phosphate in sterile double-distilled water.

The salts used for the preparation of the buffer solution shall be of analytical grade and dried to constant mass.

Solution a) 1/15 mol/l KH_2PO_4 , prepared by dissolving 9,078 g KH_2PO_4 in 1 litre water.

Solution b) 1/15 mol/l Na_2HPO_4 , prepared by dissolving 11,876 g $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$ in 1 litre water.

The buffer comprises a mixture of a volume fraction of 18,2 % from solution a) and a volume fraction of 81,8 % from solution b).

No other additives shall be used for the solution.

The pH value of the buffer solution shall be $7,4 \pm 0,2$.