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Dentistry — Soft lining materials for removable dentures —

Part 1: Materials for short-term use

*Art dentaire — Produits souples pour intrados de prothèses dentaires
amovibles —*

Partie 1: Produits pour usage à court terme



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 10139-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 10139-1:1991), which has been technically revised.

ISO 10139 consists of the following parts, under the general title *Dentistry — Soft lining materials for removable dentures*:

- *Part 1: Materials for short-term use*
- *Part 2: Materials for long-term use*

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Introduction

Clinically, short-term denture-lining materials are used commonly as tissue conditioners and as temporary soft lining materials. It is believed that their use as functional impression materials is now less common. Therefore, the tests are designed to cover the more common usages.

It is recognized that the short-term material, when used as a tissue conditioner, is commonly changed every few days with the aim of returning the mucosa to a healthy condition as quickly as possible. As a temporary soft lining, the material is commonly placed in immediate dentures and in dentures that need to be modified as part of implant treatment. Therefore the specification has been so designed to necessitate that a material exhibit the required properties over a 7-d period. It is of course recognized that there are a number of clinical situations where it is appropriate to retain the soft lining in the denture for periods longer than 7 d. It is also recognized that manufacturers may wish to provide more than one set of times, temperatures, proportions and procedures to mix or prepare the material properly in order that the material can satisfy the requirements of more than one type or class.

In its earliest stage, the soft lining material is usually removed from the mouth so that it can be adjusted and tidied. If the material attains a particular level of elastic recovery, removal from the mouth will not result in unacceptable distortion. Therefore, denture lining materials for short-term use are classified in this part of ISO 10139 according to the time at which 10 % elastic recovery is established. (When stating the time at which 10 % elastic recovery is established, the manufacturer is to take, as zero time, the end of mixing.)

The other classification is related to initial compliance.

Although it is not claimed that any particular time at which 10 % elastic recovery is attained or level of compliance is superior to another, these classifications are intended to assist clinicians who will now have more information with which to make an informed choice.

In an attempt to establish some degree of harmony with the procedures used to evaluate related dental materials, the displacement rheometer, which is used to measure the setting characteristics of elastomeric impression materials, has been adopted to measure elastic recovery of the short-term soft lining materials (ISO 4823:2000). This method supersedes the consistency test.

This part of ISO 10139 does not include specific qualitative and quantitative requirements for freedom from biological hazard. When possible biological or toxicological hazards need to be assessed, refer to ISO 7405 (see the Bibliography).