
Dentistry — Root canal sealing materials

*Médecine bucco-dentaire — Matériaux de scellement des canaux
radiculaires*



This document is a preview generated by EVS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 6876 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6876:2001), which has been technically revised. The main modifications are the following:

- the test procedures for flow, working time and solubility have been revised and a new limit value has been set;
- the test to determine dimensional change following setting has been removed.

Introduction

Following the publication of the second edition of this International Standard (ISO 6876:2001), test houses reported difficulties with some of the test procedures. In an attempt to improve the test procedures, a planned programme of revision began in 2006. The following should be taken into account when using this International Standard.

- Verification for a claim of sterility is the responsibility of the manufacturer. This International Standard does not specify requirements or test methods for sterility and it is recommended that reference be made to any national requirements that may exist. When no national requirements exist, reference should be made to the United States, European or Japanese Pharmacopoeia.
- If a therapeutic effect is claimed, the purity and sterility of the constituents are expected to comply with the relevant pharmacopoeia applicable in the country in which the sealer is marketed, or with such national regulations as are applicable to purity and sterility of pharmaceutical products.
- Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

Dentistry — Root canal sealing materials

1 Scope

This International Standard specifies requirements and test methods for root canal (endodontic) sealing materials which set with or without the assistance of moisture and are used for permanent obturation of the root canal with or without the aid of obturating points/cones. It only covers sealers intended for orthograde use i.e. a root filling placed from the coronal aspect of a tooth.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

2 Normative references

The following referenced documents are indispensable for the application 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 1942, *Dentistry — Vocabulary*

ISO 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 6873, *Dentistry — Gypsum products*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

root canal sealing material

endodontic material intended to permanently seal the root canal filling material into the cavities previously occupied by the removed pulp

3.2

root canal filling material

endodontic material intended to permanently obturate the cavities previously occupied by the pulp

3.3

mixing time

that part of the working time required in order to obtain a satisfactory mix of the components

3.4

working time

period of time, measured from the start of mixing, during which it is possible to manipulate the root canal sealer without any adverse effect on its properties