Dentistry - Root-canal obturating points

Dentistry - Root-canal obturating points



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO	This
6877:2006 sisaldab Euroopa standardi EN	687
ISO 6877:2006 ingliskeelset teksti.	the
	687

This Estonian standard EVS-EN ISO 6877:2006 consists of the English text of the European standard EN ISO 6877:2006.

Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.

Standard on kättesaadav Eesti standardiorganisatsioonist.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

Käesolev standard määrab kindlaks mõõtmed ja nõuded koostisele monteeritavate metall- või polümeeril põhinevatele tihvtidele või koonustele, mis sobivad kasutamiseks hambajuurekanali plommimisel, kuid mitte tugielemendiks hambakrooni taastamisel. Standard määrab kindlaks ka numbrilise süsteemi ja värvuskodeerimissüsteemi suuruste tähistamiseks.

Scope:

This International Standard specifies the dimensions and compositional requirements for prefabricated metal or polymeric points or cones suitable for use in the obturation of the dental root-canal, but not for support of a coronal restoration. It also specifies numerical systems and a colour coding system for designating the sizes.

ICS 11.060.10

Võtmesõnad: hambaimplantaadid, hambaraviaparatuur, keemiline koostis, materjalide tehnilised andmed, mõõtmed, sildiga märgistamine, stomatoloogia, tehnilised andmed, testimine, tähistamine, värvuskoodid

EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 6877

April 2006

ICS 11.060.10

Supersedes EN ISO 6877:1998

English Version

Dentistry - Root-canal obturating points (ISO 6877:2006)

Art dentaire - Cônes d'obturation dentaires pour canaux radiculaires (ISO 6877:2006)

Zahnheilkunde - Wurzelkanalfüllstifte (ISO 6877:2006)

This European Standard was approved by CEN on 23 January 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 6877:2006) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2006, and conflicting national standards shall be withdrawn at the latest by October 2006.

This document supersedes EN ISO 6877:1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

ved by The text of ISO 6877:2006 has been approved by CEN as EN ISO 6877:2006 without any modifications.

INTERNATIONAL **STANDARD**

ISO 6877

Second edition 2006-04-01

Dentistry — Root-canal obturating points

art de. Art dentaire — Cônes d'obturation dentaires pour canaux radiculaires



Reference number ISO 6877:2006(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below

© ISO 2006

y used to c printing. Ever, Jenn relating to it is. 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

ii

Contents	Page
F	

Forew	vordiv
Introd	uctionv
1	Scope1
2	Normative references 1
3	Terms and definitions1
4 4.1 4.2 4.3 4.4 4.5 4.6 4.7	Requirements 2 Points 2 Biocompatibility 2 Length 2 Size designation and taper 2 Physical integrity 4 Radio-opacity 4 Colour coding 4
5 6 6.1 6.2 6.3 6.4 6.5 6.6	Procurement of samples 5 Test methods 5 Test conditions 5 Visual examination 5 Length 5 Size designation 6 Physical integrity 7 Radio-opacity for polymeric points 8
7	Packaging9
8	Marking and information to be supplied by manufacturer9
Biblio	graphy

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 6877 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition cancels and replaces the first edition (ISO 6877:1995), which has been technically revised and a typographical error relating to the size of the specimen required to measure the radio-opacity has been corrected.

Introduction

The working group, who have prepared this International Standard have addressed the question of cadmium in polytransisoprene (gutta-percha) points and on the data obtained have concluded that the amount of cadmium in polytransisoprene (gutta-percha) points is most likely not intentionally added either as an inate Junt of Ce. aesthetic (colour) agent for the enhancement of the chemical or physical integrity of the points. It has likely resulted from the contamination of the chemical components in the manufacturing process. Based on the data obtained this trace amount of cadmium has no health implications.

This document is a previous general ded by tiles

Dentistry — Root-canal obturating points

1 Scope

This International Standard specifies the dimensions and compositional requirements for prefabricated metal or polymeric points or cones suitable for use in the obturation of the dental root-canal, but not for support of a coronal restoration. It also specifies numerical systems and a colour coding system for designating the sizes.

Dental root-canal obturating points are marketed sterilized or unsterilized. This International Standard covers the physical attributes expected of such products as supplied. Requirements for sterility are not included, and any claim that the product is sterile is the responsibility of the manufacturer [see 8 f)].

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 3665, Photography — Intra-oral dental radiographic film — Specification

ISO 15223, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

point

prefabricated metal or polymeric material for use in the obturation of the root-canal

NOTE For the purposes of this International Standard the term "root-canal obturating point" is abbreviated as "point".

3.2

unit pack

smallest pack of points distributed, containing one or more sizes of point

3.3

standard taper point

point having uniform 2 % taper throughout all the ranges of sizes available

3.4

greater taper point

point having a taper greater than 2 %

3.5

size designation

numerical indication, "000", of the projected tip diameter, measured in hundredths of a millimetre