# INTERNATIONAL STANDARD

ISO 3630-4

First edition 2009-07-01

# Dentistry — Root canal instruments — Part 4: Auxiliary instruments

Art dentaire — Instruments pour canaux radiculaires — Partie 4: Instruments auxiliaires

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 3630-4:2009 https://standards.iteh.ai/catalog/standards/sist/2abeece8-dbfb-4b36-b145-78f229a8d233/iso-3630-4-2009



#### 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.

# iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 3630-4:2009 https://standards.iteh.ai/catalog/standards/sist/2abeece8-dbfb-4b36-b145-78f229a8d233/iso-3630-4-2009



#### **COPYRIGHT PROTECTED DOCUMENT**

#### © ISO 2009

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

### Contents

Page

Forewo	ord	i\
1	Scope	1
2	Normative references	1
3 3.1 3.2	Terms, definitions and symbols Terms and definitions Symbols	<i>'</i>
4	Classification	2
5 5.1 5.2 5.3 5.4 5.5 5.6	Requirements  Material  Dimensions  Colour designation and size marking with rings  Mechanical requirements  Resistance to corrosion  Heat effects of sterilization	3 6 5
6 7 7.1 7.2	Testing General (standards.iteh.ai) Dimensions	9 9
8	Designation, marking and identification 1.42009	10
9 10	Packaging https://standards.iteh.ai/catalog/standards/sist/2abeece8-dbfb-4b36-b145-78f229a8d233/iso-3630-4-2009  Labelling	10 10
Riblion	ıranhv	11

#### **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 3630-4 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 3630 consists of the following parts, under the general title *Dentistry* — *Root canal instruments*:

- Part 1: General requirements and test methods
- Part 2: Enlargers ISO 3630-4:2009

https://standards.iteh.ai/catalog/standards/sist/2abeece8-dbfb-4b36-b145-

- Part 3: Condensers, pluggers and spreaders
- Part 4: Auxiliary instruments

The following part is under preparation:

— Part 5: Shaping and cleaning instruments

### Dentistry — Root canal instruments —

#### Part 4:

## **Auxiliary instruments**

#### 1 Scope

This part of ISO 3630 specifies requirements and test methods for hand-held or mechanically operated instruments for performing root canal procedures not cited in ISO 3630-1, 3630-2, 3630-3 or 3630-5.

This part of ISO 3630 specifies requirements for size, product designation, safety considerations, instructions and labelling.

#### 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 results.

ISO 1797-1, Dental rotary instruments — Shanks — Part 1: Shanks made of metals ISO 3630-4:2009

ISO 1797-2, Dental rotary instruments alca Shanks dar Part 2 Shanks made of plastics 78f229a8d233/iso-3630-4-2009

ISO 1942, Dentistry — Vocabulary

ISO 3630-1:2008, Dentistry — Root-canal instruments — Part 1: General requirements and test methods

ISO 3630-2:2000, Dental root-canal instruments — Part 2: Enlargers

#### 3 Terms, definitions and symbols

#### 3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following apply.

#### 3.1.1

#### barbed broach

root-canal instrument with barbs designed for removing the pulp tissue

#### 3.1.2

#### rasp

root-canal instrument in which sharp prominences have been formed on the working part and which is designed to enlarge a root canal by abrasive action

#### 3.1.3

#### paste carrier

root-canal instrument designed for conveying filling material or medicaments into a root canal

#### 3.1.4

#### root-canal explorer

root-canal instrument designed for exploring the root canal system

#### 3.1.5

#### cotton broach

root-canal instrument used with cotton for drying root canals or placing medicaments

#### 3.1.6

#### height of barb

height measured perpendicularly from the outside of the core to the barbed tip

#### 3.1.7

#### core diameter of the instrument

diameter of the solid portion of the barbed broach or rasp

#### 3.2 Symbols

For the purposes of this document, the following symbols apply.

- $d_1$  diameter of core or working part at length  $l_1$ ;
- $d_2$  diameter of core or working part at length  $l_2$ ;
- d<sub>3</sub> diameter of core or working part at length l<sub>3</sub> DARD PREVIEW
- h height of barb;

### (standards.iteh.ai)

 $l_1$  tip length, measured from tip point (for Type 1 and Type 2) to base of first barb;

ISO 3630-4:2009

- length for measuring point adards.iteh.ai/catalog/standards/sist/2abeece8-dbfb-4b36-b145-78f229a8d233/iso-3630-4-2009
- $l_3$  length for measuring point  $d_3$  and minimum length of working part, distance from the tip of the instrument to the tip of the last barb;
- $l_{\Delta}$  length of operative part.

#### 4 Classification

For the purposes of this document, root-canal instruments are classified according to the shape and intended endodontic application of the instrument as follows:

- Type 1: barbed broaches;
- Type 2: rasps;
- Type 3: paste carriers;
- Type 4: explorers and cotton broaches.

#### 5 Requirements

#### 5.1 Material

The material for the working part of the root-canal instrument and for the handle or shank is left to the discretion of the manufacturer. The handle and shank security shall meet the requirement specified in ISO 3630-1:2008, 5.7.

#### 5.2 Dimensions

#### 5.2.1 General

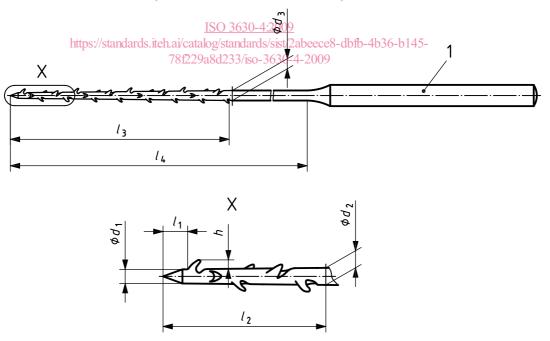
The nominal diameters, selected by the manufacturer, represent the sizes of the instrument and shall meet the requirements included in Figures 1 to 4 and Tables 1 to 4.

The length of the operative part of the root-canal instrument shall be the nominal length as specified by the manufacturer with a tolerance of  $\pm$  0,5 mm.

#### 5.2.2 Barbed broaches (Type 1 instruments)

Type 1 instruments shall meet the dimensions and tolerances specified in Figure 1 and Table 1. The shape of the tip and the design of the handle for hand use are at the discretion of the manufacturer.

# iTeh STANDARD PREVIEW (standards.iteh.ai)



Key

1 handle

Figure 1 — Type 1 instruments (barbed broaches)

Table 1 — Dimensions and designations for Type 1 instruments (barbed broaches)

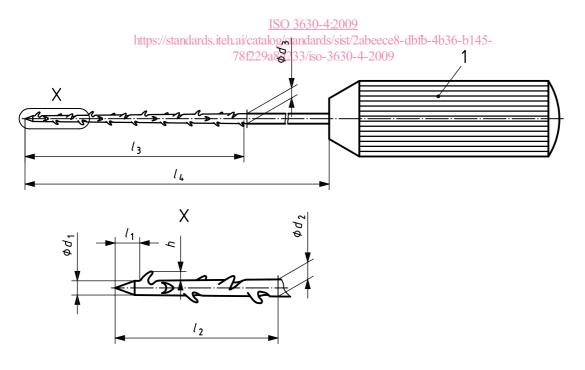
Dimensions in millimetres

Nominal size	<i>d</i> <sub>1</sub>	Tolerance	d <sub>2</sub>	Tolerance	$d_3$	Tolerance	$l_2$	<i>l</i> <sub>3</sub> ± 1,5	l <sub>4</sub> min.	h	Number of barbs min.	Designation by	
												colour	number of rings
020	0,12		0,15		0,22					0,075		purple	0
025	0,14	± 0,02	0,17 ± 0,02	0,24	± 0,02				0,085		white	1	
030	0,16		0,19		0,26					0,096		yellow	2
035	0,18	. 0.00	0,21	± 0,03	0,28	± 0,03	3	10,5	20	0,105	36	red	3
040	0,21	± 0,03	0,24	1 ± 0,03	0,31	± 0,03				0,120		blue	4
050	0,25	+ 0.04	0,28	+ 0.04	0,35	+ 0.04				0,140		green	5
060	0,29	⊥ 0,04	± 0,04 0,32	± 0,04	0,39	± 0,04				0,160		black	6

#### 5.2.3 Rasps (Type 2 instruments)

Type 2 instruments shall meet the dimensions and tolerances specified in Figure 2 and Table 2. The shape of the tip and the design of the handle are at the discretion of the manufacturer.

## (standards.iteh.ai)



#### Key

1 handle

Figure 2 — Type 2 instruments (rasps)

Table 2 — Dimensions and designations for Type 2 instruments (rasps)

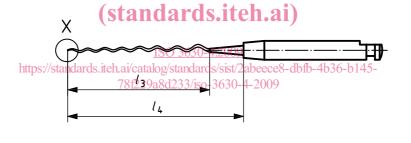
Dimensions in millimetres

Nominal	d <sub>1</sub> +0,03 0	<i>d</i> <sub>2</sub> +0,03 0	<i>d</i> <sub>3</sub> +0,03 0	$l_2$	<i>l</i> <sub>3</sub> ± 1,5	l <sub>4</sub> min.	h	Number of barbs	Designation by			
size <sup>a</sup>									colour	number of rings		
025	0,15	0,20	0,31	3			0,05		white	1		
030	0,18	0,23	0,34			10.5		0,06		yellow	2	
035	0,21	0,26	0,37		3 10,5		10.5	3 10.5	20	0,07	50	red
040	0,24	0,29	0,40		10,5	20	0,08	30	blue	4		
045	0,27	0,32	0,43				0,09		green	5		
050	0,30	0,35	0,46				0,10		black	6		
Nominal size = $h \times 2 + d_1$ because of 50 barbs.												

#### 5.2.4 Paste carriers (Type 3 instruments)

Type 3 instruments shall meet the dimensions and tolerances specified in Figure 3 and Table 3. The taper of the working part shall be from 0 % to 2 %. Shanks shall be of Types 1 and 2 of ISO 1797-1 and ISO 1797-2.

The winding of the spiral shall be such as to convey the material to the tip of the instrument when rotated clockwise as viewed from the handle or shank end. R D PRFVIEW



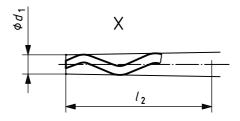


Figure 3 — Type 3 instruments (paste carriers)

Table 3 — Dimensions and designations for Type 3 instruments (paste carriers)

Dimensions in millimetres

Nominal size	$d_1$	1.	$l_3$	Designation by		
	± 0,02	$l_2$	min.	colour	number of rings	
025	0,25			red	1	
030	0,30	3	3	16	blue	2
035	0,35	3	10	green	3	
040	0,40			black	4	