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

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



Reference number
ISO 3630-4:2009(E)

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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.

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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*
- *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.

ISO 1797-1, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals*

ISO 1797-2, *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics*

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_3 diameter of core or working part at length l_3 ;

h height of barb;

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

l_2 length for measuring point d_2 ;

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_4 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

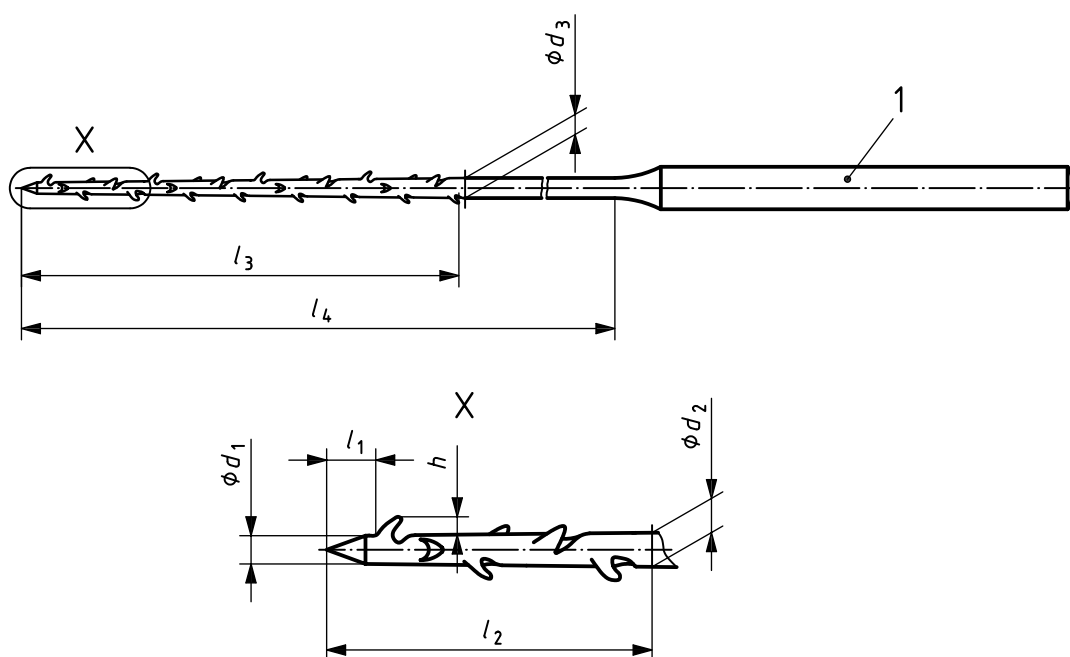
5.2.1 General

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.



Key

1 handle

Figure 1 — Type 1 instruments (barbed broaches)

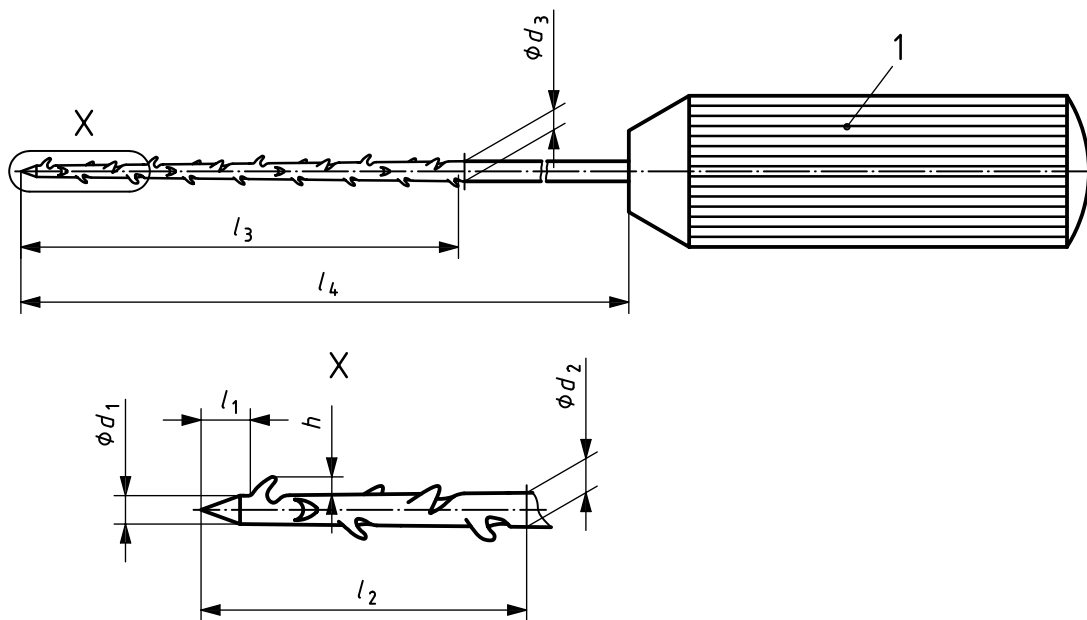
Table 1 — Dimensions and designations for Type 1 instruments (barbed broaches)

Dimensions in millimetres

Nominal size	d_1	Tolerance	d_2	Tolerance	d_3	Tolerance	l_2	l_3 $\pm 1,5$	l_4 min.	h	Number of barbs min.	Designation by	
												colour	number of rings
020	0,12	$\pm 0,02$	0,15	$\pm 0,02$	0,22	$\pm 0,02$	3	10,5	20	0,075	36	purple	0
025	0,14		0,17		0,24					0,085		white	1
030	0,16		0,19		0,26					0,096		yellow	2
035	0,18	$\pm 0,03$	0,21	$\pm 0,03$	0,28	$\pm 0,03$				0,105		red	3
040	0,21		0,24		0,31	$\pm 0,03$				0,120		blue	4
050	0,25	$\pm 0,04$	0,28	$\pm 0,04$	0,35	$\pm 0,04$				0,140		green	5
060	0,29		0,32		0,39	$\pm 0,04$				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.



Key
1 handle

Figure 2 — Type 2 instruments (rasps)

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

Dimensions in millimetres

Nominal size ^a	d_1 +0,03 0	d_2 +0,03 0	d_3 +0,03 0	l_2	l_3 $\pm 1,5$	l_4 min.	h	Number of barbs min.	Designation by	
									colour	number of rings
025	0,15	0,20	0,31	3	10,5	20	0,05	50	white	1
030	0,18	0,23	0,34				0,06		yellow	2
035	0,21	0,26	0,37				0,07		red	3
040	0,24	0,29	0,40				0,08		blue	4
045	0,27	0,32	0,43				0,09		green	5
050	0,30	0,35	0,46				0,10		black	6

^a 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.

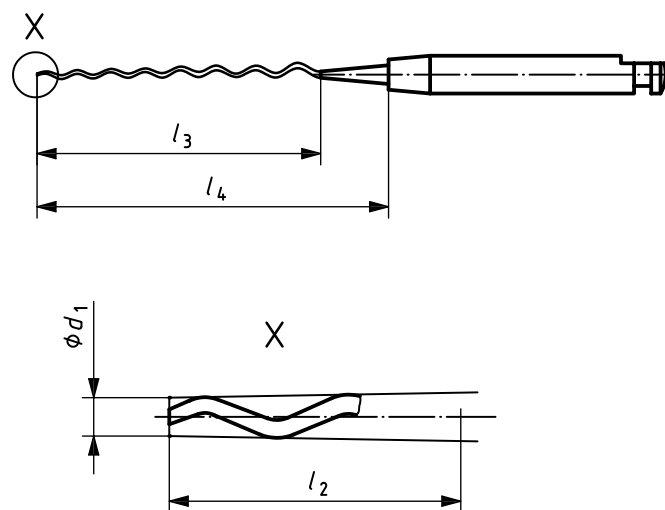


Figure 3 — Type 3 instruments (paste carriers)

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

Dimensions in millimetres

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

5.2.5 Explorers and cotton broaches (Type 4 instruments)

Type 4 instruments shall meet the dimensions and tolerances specified in Figure 4 and Table 4. The taper along the operative part shall be 0,007:1, with a tolerance of +0,003.

The cross-section along the operative part (e.g. round or polygonal) shall be at the discretion of the manufacturer.

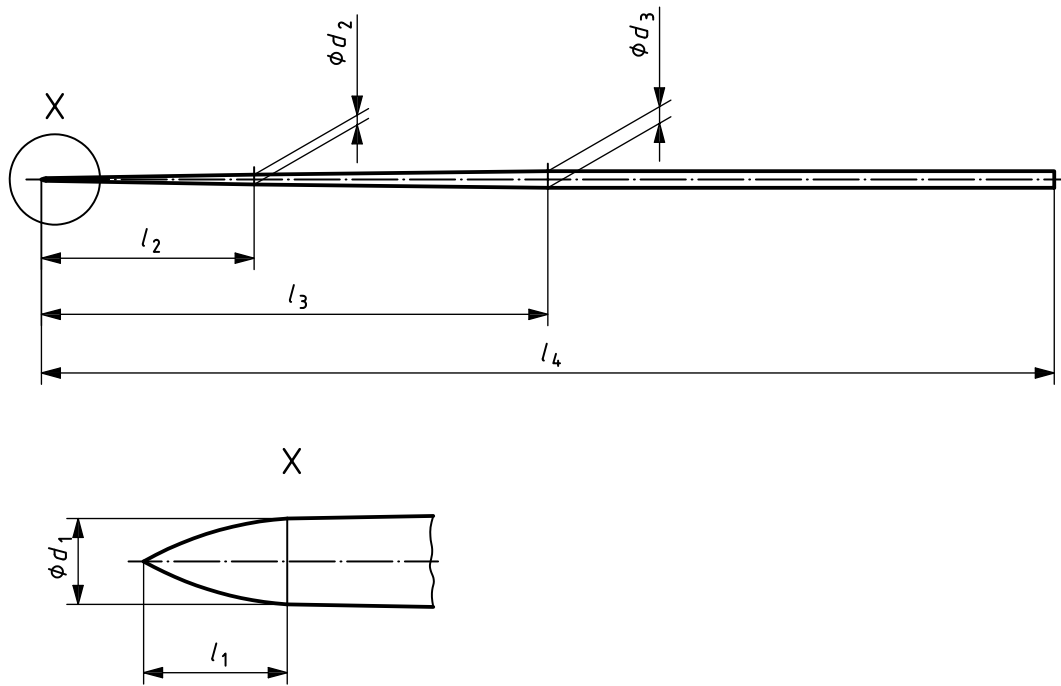


Figure 4 — Type 4 instruments (explorers and cotton broaches)

Table 4 — Dimensions and designations for Type 4 instruments (explorers and cotton broaches)

Dimensions in millimetres

Nominal size	d_1 ± 0,02	d_2 ± 0,02	d_3 max.	l_1	l_2	l_3	l_4 ± 1,5	Designation by	
								colour	number of rings
012	0,12	0,20	0,8	$2 \times d_1$	10,5	25	50	purple	1
015	0,14	0,23						white	2
017	0,16	0,25						yellow	3
020	0,18	0,28						blue	4
025	0,21	0,33						green	5
030	0,25	0,38						black	6

5.3 Colour designation and size marking with rings

If the manufacturer uses colours and/or rings to identify the size of the instrument, such marking(s) shall comply with the requirements of Tables 1 to 4.

5.4 Mechanical requirements

5.4.1 Resistance to fracture by twisting (torque) and angular deflection

When barbed broaches and rasps are tested in accordance with ISO 3630-1:2008, 7.4, the instrument shall not fracture at less than the minimum value for the resistance to fracture by twisting (torque) and angular deflection, as specified in Table 5 and Table 6.

Table 5 — Resistance to fracture by twisting (torque)

Nominal size	Resistance to fracture by twisting (torque) mN·m min.		
	Type 1 (barbed broaches)	Type 2 (rasps)	Type 4 (explorers and cotton broaches)
020	0,5	n/a ^a	1,2
025	0,6	0,8	2,1
030	0,8	1,0	3,5
035	1,0	1,2	n/a
040	1,2	2,0	n/a
045	n/a	2,6	n/a
050	2,0	3,4	n/a
060	3,4	n/a	n/a

^a n/a = Not applicable; these instrument sizes are not manufactured.

Table 6 — Resistance to fracture by angular deflection

Nominal size			Angular deflection ° min.
Type 1 (barbed broaches)	Type 2 (rasps)	Type 4 (explorers and cotton broaches)	
020	020	012	90
025	025	015	
030	030	017	
035	035	020	
040	040	025	
045	045	030	
050	050	n/a ^a	
060	060	n/a	

^a n/a = Not applicable; these instrument sizes are not manufactured.

5.4.2 Stiffness (resistance to bending)

When barbed broaches and rasps are tested in accordance with ISO 3630-1:2008, 7.5, the instrument shall not fracture and the maximum value given in Table 7 shall not be exceeded.

Table 7 — Stiffness (resistance to bending)

Nominal size	Bending moment		
	Type 1 (barbed broaches)	Type 2 (rasps)	Type 4 (explorers and cotton broaches)
020	2,5	n/a ^a	n/a
025	2,9	4,9	7,8
030	3,9	6,9	11,7
035	4,9	8,8	16,6
040	7,8	13,7	n/a
045	n/a	16,7	n/a
050	11,8	20,6	n/a
060	16,7	n/a	n/a

^a n/a = Not applicable; these instrument sizes are not manufactured.

5.4.3 Handle and shank security

The handle shall meet the requirements of ISO 3630-1:2008, 5.9.3.

5.4.4 Resistance to fatigue (only applicable for Type 3 instruments)

The following requirement is only applicable for paste carriers:

When paste carriers are tested in accordance with ISO 3630-2:2000, 6.5, all of the tested instruments shall meet the minimum number of revolutions given in Table 8.

Table 8 — Resistance to fatigue for Type 3 instruments (paste carriers)

Nominal size	Diameter mm	Number of revolutions min.
025	0,25	4 000
030	0,30	2 400
035	0,35	1 500
040	0,40	1 000

5.5 Resistance to corrosion

The root-canal instrument shall meet the requirements of ISO 3630-1:2008, 5.10.

5.6 Heat effects of sterilization

5.6.1 General

The root-canal instrument shall meet the requirements of ISO 3630-1:2008, 5.10.2.

5.6.2 Single-use instruments

Following one cycle of sterilization by autoclave and dry heat, the instrument shall comply with the requirements specified in 5.4.1, 5.4.2, 5.4.3 and 5.4.4, when tested as specified in ISO 3630-1:2008, 7.8.

5.6.3 Multi-use instruments

Following five cycles of sterilization by autoclave and dry heat, the instrument shall comply with the requirements specified in 5.4.1, 5.4.2, 5.4.3 and 5.4.4, when tested as specified in ISO 3630-1:2008, 7.8.

6 Sampling

For each test, unless otherwise specified, more than 90 % of the samples shall comply. The sampling plan is as follows:

Test ten instruments of each size. If all ten samples pass, the product batch passes. If eight or fewer samples pass, the product batch fails. If nine samples pass, test five additional samples. When five additional samples are to be tested, all five shall pass for the product batch to be accepted.

7 Testing

7.1 General

Use the test methods specified in ISO 3630-1:2008, Clause 7.

7.2 Dimensions

7.2.1 General

If present, remove the handle from the instrument. Insert the shank of the instrument into a suitable holder.

7.2.2 Diameter of core or working part

Measure d_2 and d_3 using the procedure described in ISO 3630-1:2008, 7.3.

7.2.3 Barbed broaches and rasps

7.2.3.1 Location of barbs

Rotate the instrument to locate the position in full view of the barb closest to the tip. Measure the distance from the tip of the instrument to the base of the first barb as l_1 .

Rotate the instrument to locate the position in the full view of the barb most distant from the tip. Measure the distance from the tip of the instrument to the tip of the last barb as l_3 .

7.2.3.2 Height of barbs

Rotate the instrument to locate the barb nearest the point situated 3 mm from the tip. Measure the vertical distance from the barb base to the barb tip.

NOTE This procedure is intended as information only to be used for the calculation of nominal size. The barb height is a reference dimension.

7.2.3.3 Number of barbs

Count the number of barbs from the tip to the end of the working part, while rotating the instrument.

7.2.3.4 Tip

Rotate the instrument, as described in 7.2.3.1, to locate the first barb. Visually determine the point at which the barb base and core surface meet. Measure the length l_1 .

7.2.4 Taper

Use the same set-up as described in 7.2.3.1. Locate the first barb and measure the core diameters and calculate the taper from Equation (1):

$$\text{Taper} = \frac{(d_3 - d_2)}{(l_3 - l_2)} \times 100 \quad (1)$$

8 Designation, marking and identification

The nominal size of the root-canal instrument shall be marked on the handle or shank. Identification symbols shall comply with ISO 3630-1:2008, 8.2.

9 Packaging

Packaging shall comply with the requirements specified in ISO 3630-1:2008, Clause 9.

10 Labelling

Labelling shall comply with the requirements specified in ISO 3630-1:2008, Clause 11.

Bibliography

- [1] ISO 6360-1, *Dentistry — Number coding system for rotary instruments — Part 1: General characteristics*
- [2] ISO 6360-2, *Dentistry — Number coding system for rotary instruments — Part 2: Shapes*
- [3] ISO 6360-5, *Dentistry — Number coding system for rotary instruments — Part 5: Specific characteristics of root-canal instruments*
- [4] ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
- [5] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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