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## Dentistry — Endodontic instruments —

### Part 4: Auxiliary instruments

*Médecine bucco-dentaire — Instruments d'endodontie —*

*Partie 4: Instruments auxiliaires*

ICS: 11.060.20

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ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 3630-4:2009), which has been technically revised.

The main changes compared to the previous edition are as follows:

Removal of rasps requirements in this standard.

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

- *Part 1: General requirements and test methods*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*
- *Part 5: Shaping and cleaning instruments*
- *Part 6: Numeric coding system*
- *Part 7: Ultrasonic inserts*
- *Part 8: Accuracy of apex locator*

# Dentistry — Endodontic 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 and which are 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 labeling.

### 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, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 3630-2, *Dentistry — Endodontic instruments — Part 2: Enlargers*

### 3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

#### 3.1

##### **barbed broach**

endodontic instrument with barbs designed for removing the pulp tissue

#### 3.2

##### **paste carrier**

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

#### 3.3

##### **explorer**

endodontic instrument designed for exploring the root canal system

#### 3.4

##### **cotton broach**

endodontic instrument used with cotton for drying root canals or placing medicaments

**3.5**

**height of barb**

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

**3.6**

**core diameter of the instrument**

diameter of the solid portion of the barbed broach

**3.7**

**delivery device**

powered endodontic instrument designed for placing thermoplastic obturation material into a root canal

**3.8**

**cannula**

tube connected to thermoplastic delivery device

## 4 Classification and Symbols

### 4.1 Classification

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

- Type 1: barbed broaches
- Type 2: paste carriers
- Type 3: explorers and cotton broaches
- Type 4: cannulae

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### 4.2 Symbols

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

- $D$  diameter of core (projected core for paste carriers) measured at the tip
- $d_n$  diameter of core or working part at length  $l_n$
- $d_w$  diameter of core or working part at length  $l_w$
- $h$  height of barb
- $l_b$  tip length, measured from tip point of broaches to base of first barb
- $l_n$  length for measuring point  $d_n$
- $l_{op}$  length of operative part
- $l_{tot}$  total length of instrument
- $l_w$  length of working part, measured from the tip
- $d_{od}$  outer diameter of cannula
- $d_{id}$  inner diameter of cannula

## 5 Requirements

### 5.1 Material

The material for the endodontic instrument and for the handle or shank is left to the discretion of the manufacturer.

The handle or shank security shall meet the requirement specified in ISO 3630-1:2019, 5.9.3.

### 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 endodontic instrument shall be the nominal length as specified by the manufacturer with a tolerance of  $\pm 0,5$  mm.

The dimensions of the shank shall meet the requirements of ISO 1797.

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

Type 1 instruments shall meet the dimensions and tolerances specified in [Figure 1](#) and [Table 1](#).

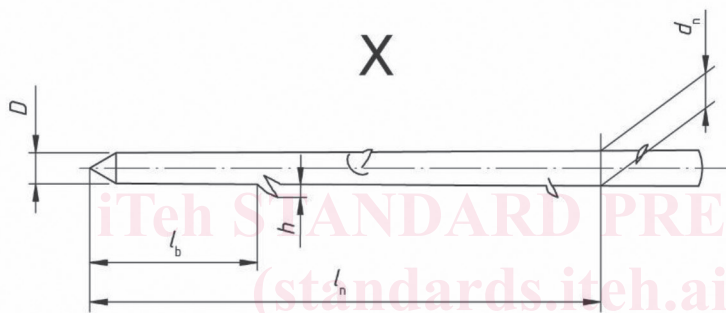
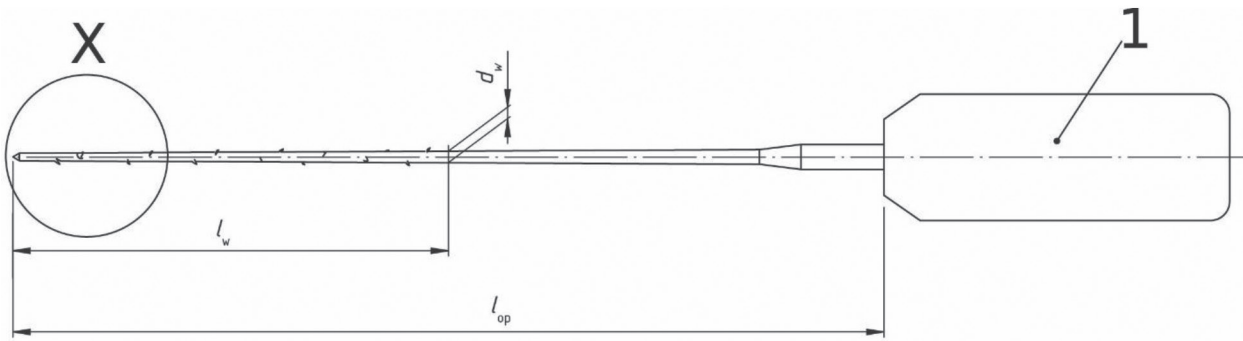
The shape of the tip and the design of the handle for hand use are at the discretion of the manufacturer.

The working length  $l_w$  shall be at least 8mm. The operative length shall be at least 20mm. There shall be 3 barbs per mm with the first barb starting 1mm from the tip ( $l_b$ ).

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Dimensions in millimetres



**Key**

1 handle

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**Figure 1 — Barbed broaches (Type 1 instruments)**

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

Dimensions in millimetres

| Nominal size | $D$  | Tolerance  | $l_b$<br>min | $d_3$ | Tolerance  | $d_{16}$ | Tolerance  | $h (\pm 0,02)$ | Designation by |                 |
|--------------|------|------------|--------------|-------|------------|----------|------------|----------------|----------------|-----------------|
|              |      |            |              |       |            |          |            |                | colour         | number of rings |
| 020          | 0,12 | $\pm 0,02$ | 1            | 0,15  | $\pm 0,02$ | 0,22     | $\pm 0,02$ | 0,075          | 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     |            | 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     |            | 0,160          | black          | 6               |

**5.2.3 Paste carriers (Type 2 instruments)**

Type 3 instruments shall meet the dimensions and tolerances specified in [Figure 2](#) and [Table 2](#).

The minimum working length ( $l_w$ ) shall be 16 mm. The taper of the working part shall be from 0 % to 2 %. operative length ( $l_{op}$ ) is left to the discretion of the manufacturer. 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. The minimum number of spirals shall be 10 spirals and the design of these spirals is left to the discretion of the manufacturer.

Shanks shall be designed according to 3630-1: 2019, clause 5.8.3.2. Test according to 7.3.

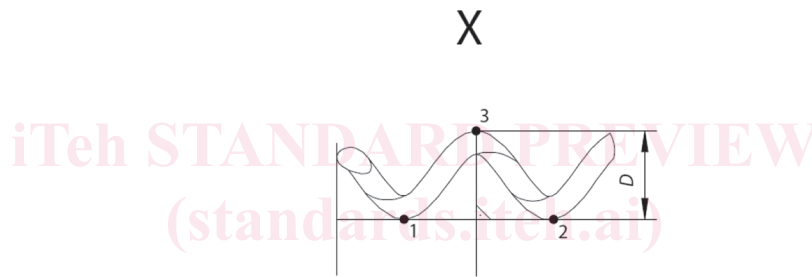
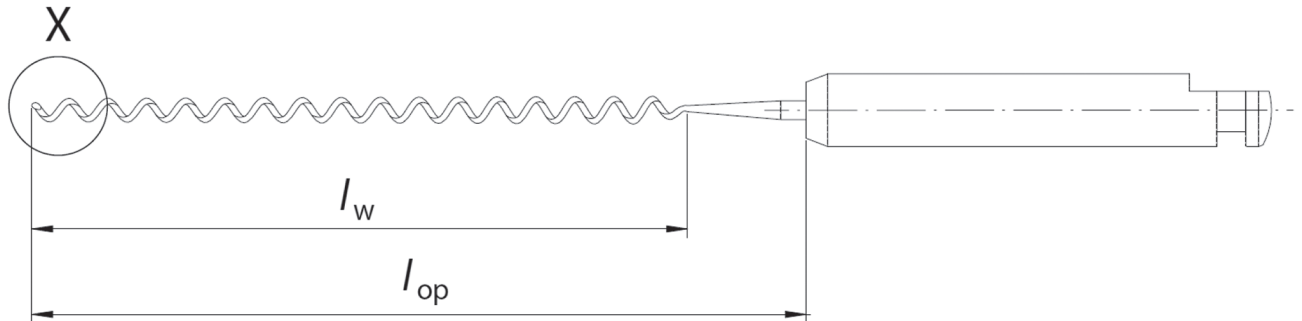


Figure 2 — Paste carriers (Type 2 instruments)

Table 2 — Dimensions and designations for paste carriers (Type 2 instruments)

Dimensions in millimetres

| Nominal size | $D$  | $d_n$                         | Tolerance  | Colour | Rings |
|--------------|------|-------------------------------|------------|--------|-------|
| 25           | 0,25 | $D + \text{taper} \times l_n$ | $\pm 0,05$ | Red    | I     |
| 30           | 0,30 |                               |            | Blue   | II    |
| 35           | 0,35 |                               |            | Green  | III   |
| 40           | 0,40 |                               |            | Black  | III   |

5.2.4 Explorers and cotton broaches (Type 3 instruments)

Type 3 instruments shall meet the dimensions and tolerances specified in Figure 3 and Table 3.

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

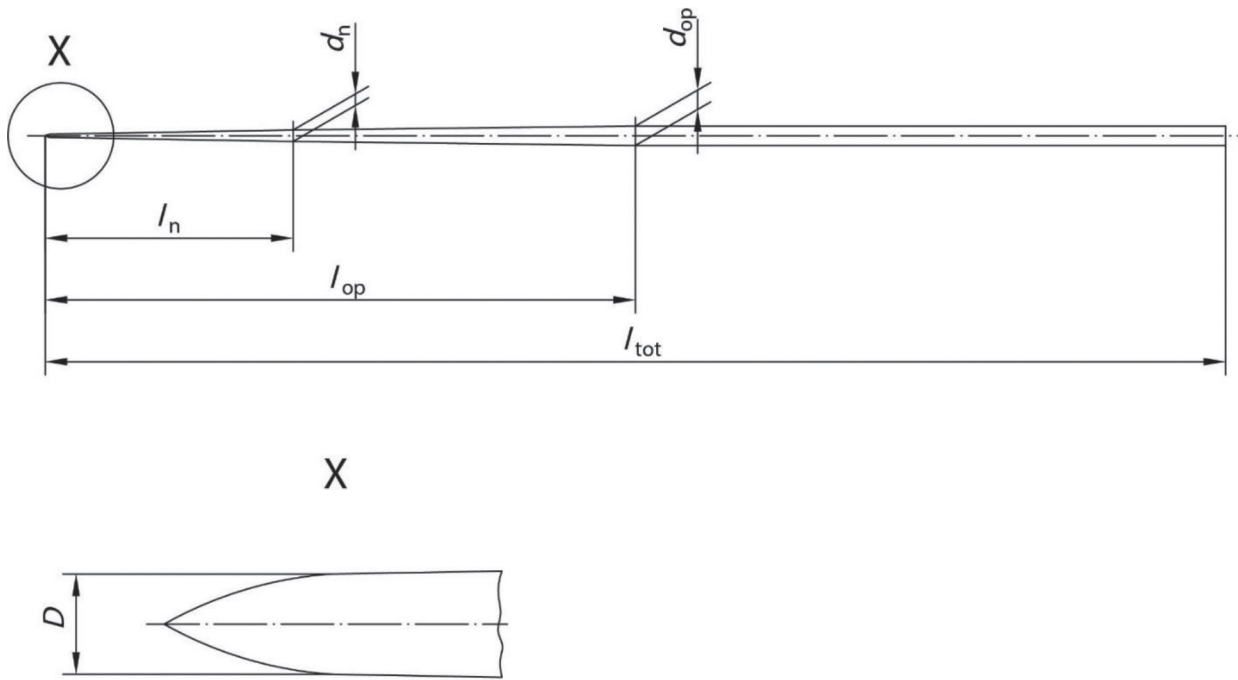


Figure 3 — Explorers and cotton broaches (Type 3 instruments)

Table 3 — Dimensions and designations for explorers and cotton broaches (Type 3 instruments)

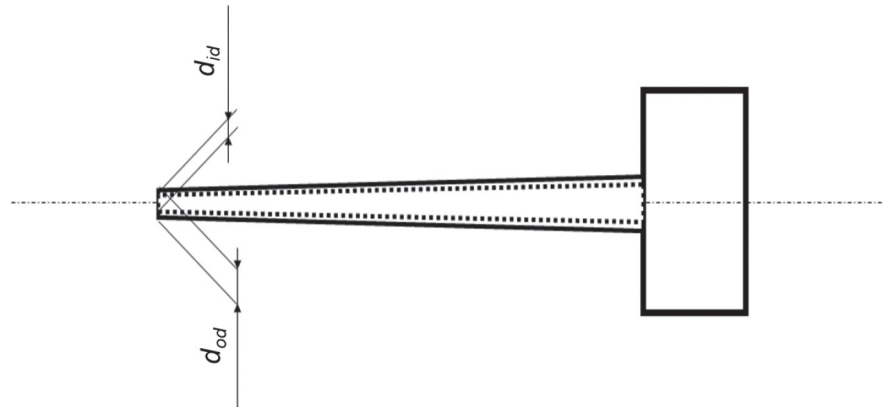
Dimensions in millimetres

| Nominal size | $D$<br>$\pm 0,02$ | $d_3$<br>$\pm 0,02$ | $d_{16}$<br>max. | Designation by |                 |
|--------------|-------------------|---------------------|------------------|----------------|-----------------|
|              |                   |                     |                  | colour         | number of rings |
| 012          | 0,12              | 0,20                | 0,8              | 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               |

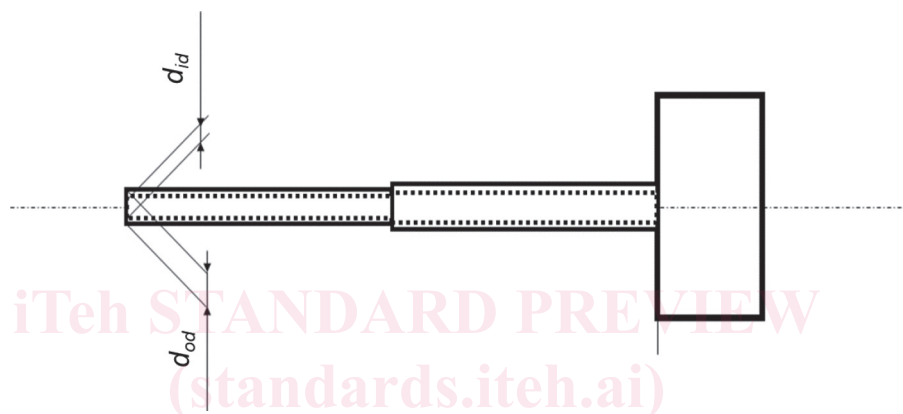
The minimum operative length shall be 25 mm and the total length of the instrument shall be 50 mm  $\pm$  1,5 mm.

### 5.2.5 Cannulae (Type 4 instruments)

Type 4 instruments shall meet the dimensions and tolerances specified in [Figure 4](#) and [Table 4](#). The shape of the cannula and the design of the connective part are at the discretion of the manufacturer.



a) Tapered



b) Staged

Figure 4 — Cannulae (Type 4 instruments)

Table 4 — Dimensions and designations for Cannulae (Type 4 instruments)

| N° | Size | $D \varnothing$ ext.<br>+/- 0.006<br>(mm) |
|----|------|-------------------------------------------|
| 01 | 30Ga | 0,311                                     |
| 02 | 28Ga | 0,362                                     |
| 03 | 25Ga | 0,514                                     |
| 04 | 24Ga | 0,565                                     |
| 05 | 23Ga | 0,641                                     |

### 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 [3](#).

### 5.4 Mechanical requirements

#### 5.4.1 Resistance to fracture by twisting (torque) and angular deflection (Types 1 and 3)

When barbed broaches and explorers and cotton broaches 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