
**Dentistry — Endodontic
instruments —**

**Part 4:
Auxiliary instruments**

*Médecine bucco-dentaire — Instruments d'endodontie —
Partie 4: Instruments auxiliaires*

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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
Website: 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 document 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).

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

The main changes are as follows:

- rasps requirements have been removed;
- a cyclic fatigue test of paste carriers has been added;
- the term cannula has been added;
- the cannula symbol has changed;
- [Annexes A](#) and [B](#) have been added.

A list of all parts in the ISO 3630 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Endodontic instruments —

Part 4: Auxiliary instruments

1 Scope

This document specifies requirements and test methods for hand-held or mechanically operated auxiliary instruments for performing root canal procedures such as barbed broaches, paste carriers, explorers, cotton broaches and cannulae. This document specifies requirements for size, product designation, safety considerations, instructions and labelling.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3630-1:2019, *Dentistry — Endodontic instruments — Part 1: General requirements*

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 terminology 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 system

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

instrument core

portion of endodontic instrument that is the centre of the working part

3.6

core diameter of the instrument

diameter of the solid portion of a *barbed broach* (3.1)

3.7

height of barb

height measured perpendicularly from the outside of the instrument core to the tip of the barb of a *barbed broach* (3.1)

3.8

thermoplastic delivery device

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

3.9

cannula

tube, connected to a *thermoplastic delivery device* (3.8) to deliver the thermoplastic obturation material into a root canal system

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.

4.2 Symbols

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

| | |
|-----------|---|
| D | core diameter of the instrument (projected core for paste carriers) measured at the tip |
| d_m | core diameter of the instrument or working part measured from the tip at length l_m |
| d_n | core diameter of the instrument or working part measured from the tip at length l_n |
| d_{op} | core diameter of the instrument or operative part at length l_{op} |
| d_w | core diameter of the instrument or working part measured from the tip at length l_w |
| h | height of barb |
| l_b | tip length, measured from the tip of the broach to the base of the first barb |
| l_m | length for measuring point d_m |
| 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

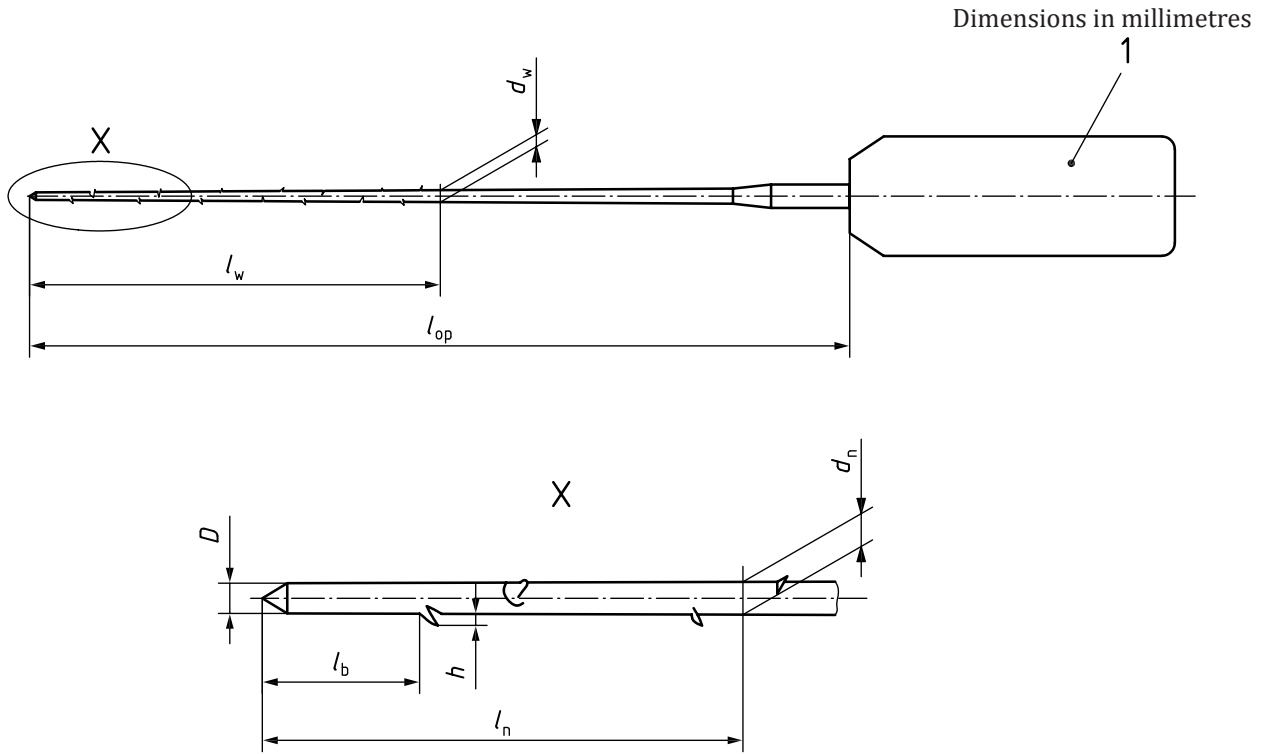
Type 1 instruments shall meet the dimensions and tolerances specified in [Figure 1](#) and [Table 1](#).

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

The working length (l_w) shall be at least 8 mm.

The operative length (l_{op}) shall be at least 20 mm.

There shall be three barbs per millimetre with the first barb starting 1 mm from the tip (l_b).



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

ISO 3630-4:2023

Dimensions in millimetres

| Nominal size | D | Tolerance | l _b min | d _n | Tolerance | d _w | Tolerance | h (±0,02) | Designation by | |
|--------------|------|-----------|-----------------------|----------------|-----------|----------------|-----------|-----------|----------------|-----------------|
| | | | | | | | | | colour | number of rings |
| 020 | 0,12 | ±0,02 | 1 | 0,15 | ±0,02 | 0,22 | ±0,02 | 0,075 | purple | 0 |
| 025 | 0,14 | | | 0,17 | | 0,24 | | 0,085 | white | I |
| 030 | 0,16 | | | 0,19 | | 0,26 | | 0,096 | yellow | II |
| 035 | 0,18 | ±0,03 | | 0,21 | ±0,03 | 0,28 | ±0,03 | 0,105 | red | III |
| 040 | 0,21 | | | 0,24 | | 0,31 | | 0,120 | blue | III I |
| 050 | 0,25 | ±0,04 | | 0,28 | ±0,04 | 0,35 | ±0,04 | 0,140 | green | III II |
| 060 | 0,29 | | | 0,32 | | 0,39 | | 0,160 | black | III III |

5.2.3 Paste carriers — Type 2 instruments

Type 2 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 %.

The 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 and the design of these spirals is left to the discretion of the manufacturer.

Shanks shall be designed in accordance with ISO 3630-1:2019, 5.8.3.2. Test in accordance with ISO 3630-1:2019, 7.6.

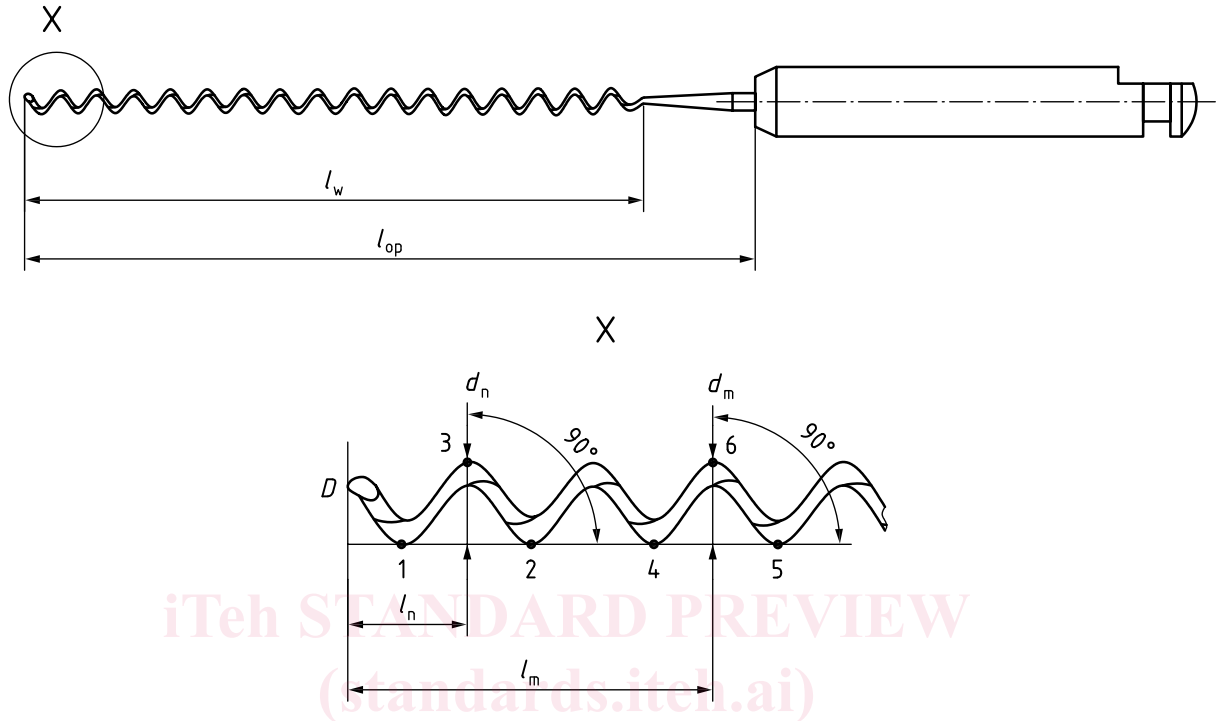


Figure 2 — Paste carriers — Type 2 instruments

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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 | See 7.2.2 | ±0,05 | Red | I |
| 30 | 0,30 | | | Blue | II |
| 35 | 0,35 | | | Green | III |
| 40 | 0,40 | | | Black | IIII |

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.

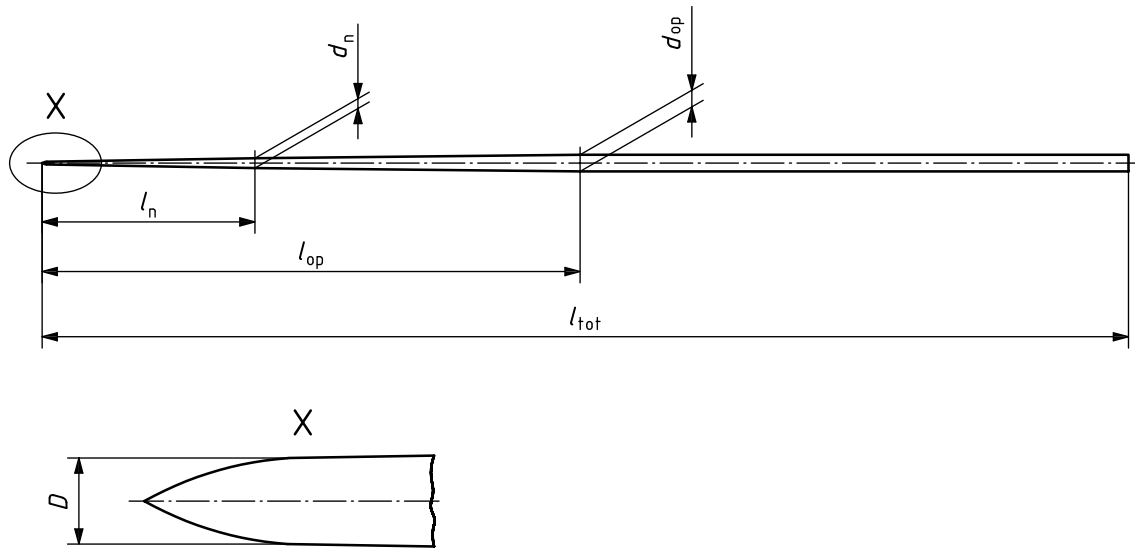


Figure 3 — Explorers and cotton broaches — Type 3 instruments

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

Dimensions in millimetres

| Nominal size | D ±0,02 | d _n at 3 mm ±0,02 | Designation by | |
|--------------|------------|---------------------------------|----------------|-----------------|
| | | | colour | number of rings |
| 12 | 0,12 | 0,20 | White | I |
| 15 | 0,14 | 0,23 | Yellow | II |
| 17 | 0,16 | 0,25 | Red | III |
| 20 | 0,18 | 0,28 | Blue | III I |
| 25 | 0,21 | 0,33 | Green | III II |
| 30 | 0,25 | 0,38 | Black | III III |

The minimum operative length (l_{op}) shall be 25 mm and the total length (l_{tot}) of the instrument shall be $(50 \pm 1,5)$ mm, the maximum operative part (d_{op}) shall be 0,8 mm, and the length for measuring point d_n (l_n) shall be 10,5 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 is at the discretion of the manufacturer.

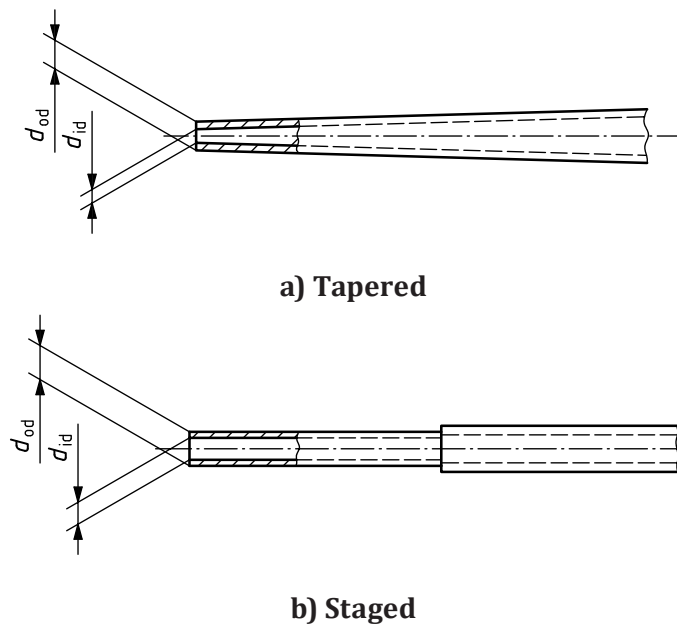


Figure 4 — Cannulae — Type 4 instruments

Table 4 — Dimensions and designations for cannulae — Type 4 instruments

| No. | Size | d_{od} $\pm 0,01$ mm |
|-----|---------|------------------------------|
| 01 | 30Gauge | 0,311 |
| 02 | 28Gauge | 0,362 |
| 03 | 25Gauge | 0,514 |
| 04 | 24Gauge | 0,565 |
| 05 | 23Gauge | 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, explorers, and cotton broaches are tested in accordance with ISO 3630-1:2019, 7.4, the instrument shall not fracture below the value specified in [Table 5](#).

Types 1 and 3 instruments shall not fracture at less than 90° of angular deflection.