INTERNATIONAL STANDARD

ISO 3630-3

Second edition
2015-09-01

Dentistry — Endodontic instruments —

Part 3: Compactors: pluggers and spreaders

Médecine bucco-dentaire — Instruments d'endodontie —

Partie 3: Compacteurs axiaux et latéraux

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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).

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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This second edition cancels and replaces the first edition (ISO 3630-3:1994), which has been technically revised with the following changes:

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a) name and definition of "condenser" was changed to "compactor";

b) differentiation between finger instruments and hand instruments was made in Clause 5 and Clause 7;

c) plugger sizes 015 and 020 were deleted from Table 1;

d) reprocessing requirements were added.

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: Compactors: pluggers and spreaders*

— *Part 4: Auxiliary instruments*

— *Part 5: Shaping and cleaning instruments*

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Dentistry — Endodontic instruments —

Part 3:
Compactors: pluggers and spreaders

1 Scope

This part of ISO 3630 specifies requirements and test methods for endodontic instruments used as pluggers and spreaders, used to compact endodontic filling materials not cited in ISO 3630-1, ISO 3630-2, ISO 3630-4, or ISO 3630-5.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

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

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3 Terms and definitions

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

3.1
compactor
instrument whose working part is cylindrical or tapered, and circular in cross-section which is designed to condense the filling material in a root canal in the axial and/or lateral direction

Note 1 to entry: See Figure 3.

3.2
plugger
finger or hand instrument whose working part is cylindrical or tapered, circular in cross-section and has a flat tip end which is designed to compact filling materials in a root canal mainly in an axial direction

Note 1 to entry: See Figure 1

3.3
spreader
finger or hand instrument whose working part is cylindrical or tapered, circular in cross-section and has a pointed tip end which is designed to compact filling materials in a root canal mainly in a lateral direction

Note 1 to entry: See Figure 2.

3.4
heat carrier instrument
hand instrument used for transferring heat to a root canal instrument used for transferring heat to the filling material in a root canal

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3.5
thermomechanical compactor
instrument that may be heated or rotary for compacting obturation material in the root canal

4 Types

For the purposes of this International Standard, endodontic compactors are categorized as Type 1, Type 2, and Type 4 as specified in ISO 3630-1:2008, Clause 4.

5 Classification

The definitions in Clause 3 specify the classification of endodontic compactors and instruments which can be used in a lateral or axial direction or as thermomechanical or heat carrier instrument.

6 Requirements

6.1 Material

The material for the working part of the instrument as well as design of the handle or the shank is left to the discretion of the manufacturer but shall meet the requirements in ISO 3630-1:2008, 5.7.

6.2 Dimensional requirements

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6.2.1 General

The nominal diameter and taper dimensions of the compactors, when stated, shall meet the requirements in ISO 3630-1:2008, Clause 5 except as specified. The instruments shall comply with the appropriate tables and figures. Within the dimensional requirements, variations in shape and design are at manufacturer's discretion.

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Working part length, operative part length, overall length and tip end are left to the discretion of the manufacturer.

The manufacturer shall specify working part length as a minimum and operative part length shall be within 0,5 mm of the length specified. When provided by the manufacturer, the stated overall length shall be within 1,0 mm of the stated length.

6.2.2 Diameters

The diameter designated as d_1 for Type 1, Type 2, and Type 4 instruments is the reference for the nominal size of the instrument, as shown in Figures 1 and 2, when tested as specified in ISO 3630-1:2008, 7.3. The diameter designated as d_1 for Type 4 instruments is the functional diameter. All other dimensions identified in the figures or tables of that International Standard are used for the purpose of calculation of the taper for the working part of Type 2 instruments, the calculation for d_1, and for determination of instrument diameter test locations.

6.2.3 Length

Measure the length in accordance with ISO 3630-1:2008, 7.3.

6.2.3.1 Type 1

Length of working part shall be a minimum of 16 mm. The operative part and overall length shall be left to the discretion of the manufacturer.

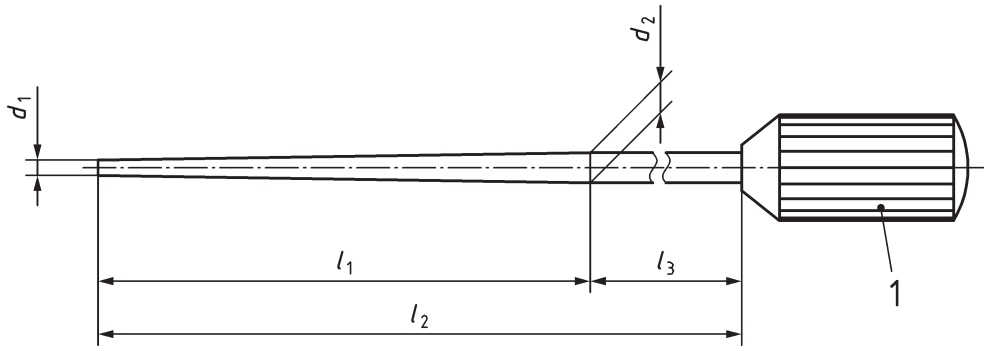
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6.2.3.2 Type 2 and Type 4

The manufacturer shall specify working part as a minimum and operative part length shall be within 0,5 mm of the length specified.

The tip shall be flat and perpendicular to the axis of the instrument. The working part shall be either Type 1 (standard sized), Type 2 (tapered size), or Type 4 (non-tapered) along l_1, based on d_1 and d_2 of Table 1.

The neck shall be either cylindrical or tapered. The diameter d_1 shall not exceed d_2, when non-tapered.



Key

1 handle
d_1 diameter of the working part at the tip end (nominal size)
d_2 diameter at the end of working part
l_1 length for measuring point, d_2, and minimum length of working part
l_2 length of operative end
l_3 neck portion

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Figure 1 — Plugger

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Dimensions in millimetres

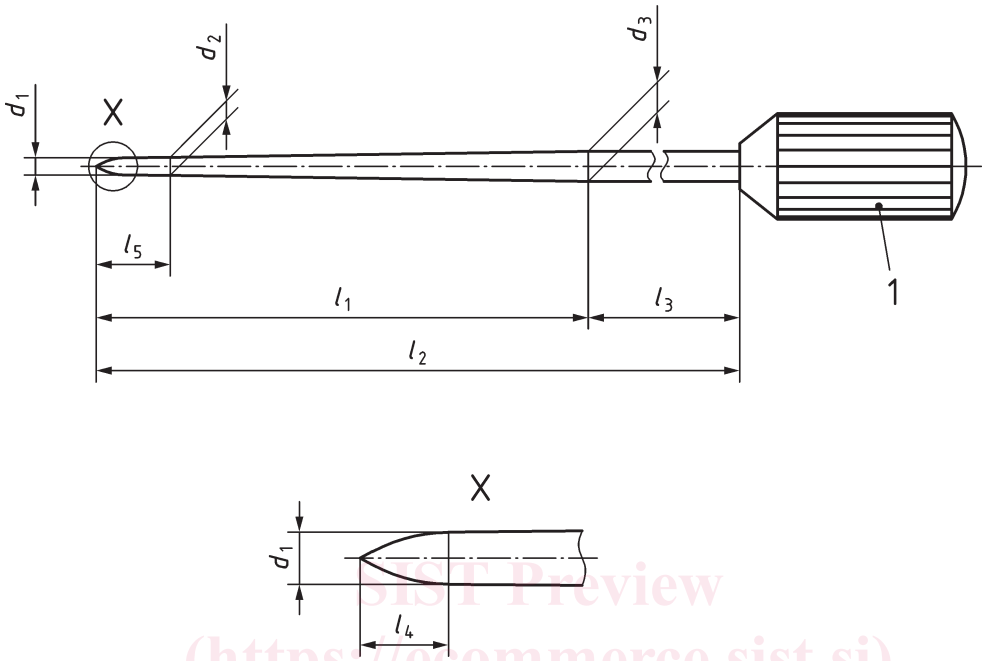
Table 1 — Diameters and designation of pluggers

Nominal size	d_1 ±0,02	d_2 ±0,02	Colour designation
025	0,25	0,57	red
030	0,30	0,62	blue
035	0,35	0,67	green
040	0,40	0,72	black
045	0,45	0,77	white
050	0,50	0,82	yellow
055	0,55	0,87	red
060	0,60	0,92	blue
070	0,70	1,02	green
080	0,80	1,12	black
090	0,90	1,22	white
100	1,00	1,32	yellow
110	1,10	1,42	red
120	1,20	1,52	blue

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Table 1 *(continued)*

Nominal size	d_1 ±0,02	d_2 ±0,02	Colour designation
130	1,30	1,62	green
140	1,40	1,72	black



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Key

1 handle
d_1 diameter of the working part at the tip end (nominal size)
d_2 diameter at fixed length l_5
d_3 diameter at length l_1
l_1 length for measuring point d_3 and minimum length of working part
l_2 length of operative end
l_3 neck portion
l_4 length of tip
l_5 fixed length of 3 mm for measuring point d_2

Figure 2 — Spreader

The taper along l_1 is specified by d_1 and d_2 of Table 2. The neck portion shall be cylindrical, continuously tapered or both. The diameter d_1 shall not exceed d_2, when cylindrical.

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Dimensions in millimetres

Table 2 — Diameters and designation of standard spreaders

Nominal size	d_1 ref.	d_2 ±0,02	d_3 ±0,02	Colour designation
010	0,10	0,16	0,42	purple
015	0,15	0,21	0,47	white
020	0,20	0,26	0,52	yellow
025	0,25	0,31	0,57	red
030	0,30	0,36	0,62	blue
035	0,35	0,41	0,67	green
040	0,40	0,46	0,72	black
045	0,45	0,51	0,77	white

6.2.4 Hand compactors

The symbols and terms in 6.1, 6.2.1, 6.2.2, and 6.2.3 also apply to instruments fitted in handles.

The length and the diameter of the handle shall be at the manufacturer's discretion but the overall length shall not exceed 175 mm.

The compactors shall be either straight or angled as shown in Figure 3. Length l_2 can be less than 16 mm at the discretion of the manufacturer.

The angle, α, shown in Figure 3 shall be within the tolerance as specified in Table 2 for any specific size within a brand.

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Dimensions in millimetres

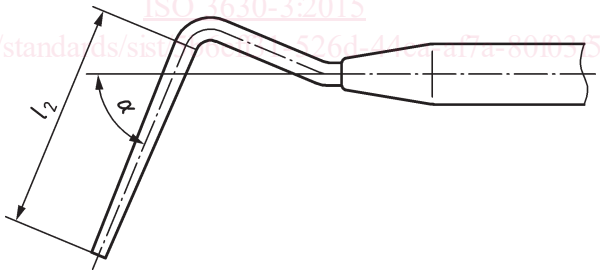


Figure 3 — Binangle compactor

Dimensions in millimetres

Table 3 — Angle tolerance

Angle range α	Tolerance
$\alpha \leq 10°$	±1
$10° < \alpha \leq 25°$	±2
$25° < \alpha \leq 45°$	±3
$\alpha > 45°$	±4

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6.3 Mechanical requirements

6.3.1 Stiffness (resistance to bending), finger compactors

After a deflection of 7°, the handle shall return to its original position on removal of the force; after a deflection of 9°, it shall return to within 2° of its original position. After a deflection of 18°, there shall be no sign of fracture.

Testing shall be carried out in accordance with 8.1.2.

6.3.2 Stiffness (resistance to bending), hand compactors

After a deflection of 15 mm, the handle shall return to its original position on removal of the force; after a deflection of 20 mm, it shall return to within 4,5 mm of its original position. After a deflection of 40 mm, there shall be no sign of fracture.

Testing shall be carried out in accordance with 8.1.3.

6.3.3 Stiffness (resistance to bending), heat carrier instruments

After a deflection of 15 mm, the handle shall return to its original position on removal of the force; after a deflection of 20 mm, it shall return to within 4,5 mm of its original position. After a deflection of 40 mm, there shall be no sign of fracture.

Testing shall be carried out in accordance with 8.1.4.

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6.3.4 Handle security

Handles when affixed to the operative end shall be permanently secured. The instrument shall have no axial movement from the handle and shall not twist within the handle when torque is applied.

Testing shall be carried out in accordance with ISO 3630-1:2008, 7.6.

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6.3.5 Surface finish

The operative end shall have a smooth finish when visually inspected under 4x magnification.

6.4 Resistance to reprocessing

All instruments intended for multiple use shall withstand 100 reprocessing cycles, as defined by the manufacturer's instructions, without deterioration in performance or showing signs of corrosion.

The reprocessing cycle shall include the recommended methods of cleaning, disinfection, and sterilization.

If the manufacturer states a lower number of permitted reprocessing cycles, then this shall be used in place of the 100 stated above.

6.5 Colour coding

When colour coding is included for size or taper, the colour shall comply with ISO 3630-1:2008, 5.2.3, 5.3.6, 5.3.7, 5.4.3, 5.5.3, 5.6.6, and 5.6.7.

7 Sampling

For each test, unless otherwise specified, at least 95 % of the samples tested shall comply. The sampling plan is as follows:

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