INTERNATIONAL **STANDARD**

ISO 3630-3

> First edition 1994-03-01

Dental root-canal instruments —

Part 3:

iTeh Standard pluggers and spreaders

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Instruments pour canaux radiculaires utilisés en art dentaire —

Partie 3: Condenseurs, axial et latéral

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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.

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. We wanted the committees are circulated to the member bodies are circulated to the member bodies as an International Standard requires approval by at least 75 % of the member bodies casting.

International Standard ISO 3630-3 was prepared by Technical Committee ISO/TC 106, Dentistry, Subcommittee SC 4, Dental instruments.

ISO 3630 consists of the following parts, funder the general titles Denta 7b-307d-48e3-root-canal instruments: 9557-0b75cdf93051/iso-3630-3-1994

- Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches
- Part 2: Enlargers
- Part 3: Condensers, pluggers and spreaders

It is anticipated that additional types of instruments will form the subject of additional future parts.

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Introduction

This International Standard covers significant features of hand-operated dental root-canal instruments which are used by the dentist for the mechanical preparation of root canals for treatment. In dentistry these instruments are also referred to as endodontic instruments.

Part 1, in addition to the specific instruments, includes general specifications, requirements and test methods which are applicable to all types of root-canal instruments.

Attention is drawn to the International Standard on a number coding system, ISO 6360, which specifies a 15-digit number for the identification of dental rotary instruments of all types.

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Dental root-canal instruments —

Part 3:

Condensers, pluggers and spreaders

Scope

This part of ISO 3630 specifies requirements and test methods for pluggers and spreaders, used to condense root-canal filling materials. In addition to standard sizes, this International Standard includes a secondary size system referred to as "taper size". These "taper size" sizes are identifiable by tapers S. which vary with instrument size.

9557-0b75cdf93051/iso-36luggers or spreaders.

Definitions

For the purposes of this part of ISO 3630, the following definitions apply. They go beyond those of ISO 1942 by being more precise.

3.1 root-canal filling condenser: Hand instrument the working part of which is cylindrical or tapered, and circular in cross-section. It is designed to condense ISO 3630-3:199the filling material in a root canal in the axial and/or https://standards.iteh.ai/catalog/standards/slateral5directiond-Condensers are commonly used as

Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 3630. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 3630 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-3:1989, Dental vocabulary — Part 3: Dental instruments.

ISO 3630-1:1992, Dental root-canal instruments — Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches.

ISO 6360-1:1985, Dental rotary instruments — Number coding system — Part 1: General characteristics.

ISO 6360-2:1986, Dental rotary instruments - Number coding system — Part 2: Shape and specific characteristics.

- **3.2 root-canal filling plugger:** Hand instrument the working part of which is cylindrical or tapered, circular in cross-section and has a flat tip end. It is designed to compress filling materials in a root canal mainly in an axial direction.
- 3.3 root-canal filling spreader: Hand instrument the working part of which is tapered, circular in cross-section and has a pointed tip end. It is designed to compress filling materials in a root canal mainly in a lateral direction.

Requirements

4.1 Material

The working part and the shank of the instrument shall be made from corrosion-resistant material. The type and the treatment of the material is left to the discretion of the manufacturer.

The handles or shanks shall be made of plastics material or other corrosion-resistant materials at the discretion of the manufacturer.

4.2 Dimensional requirements for standard-type pluggers and spreaders

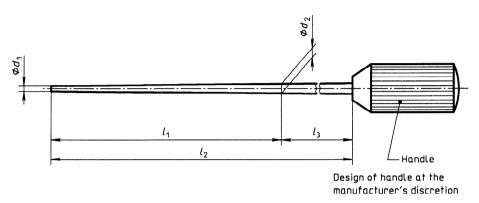
The dimensions are given in millimetres.

The dimensional requirements shall comply with the appropriate tables and figures. Within the dimensional

requirements, variations in shape and design are permitted.

Testing shall be carried out in accordance with ISO 3630-1:1992, subclauses 6.1 and 6.2.

4.2.1 Pluggers



The tip shall be flat and perpendicular to the axis of the instrument. The working part shall be either cylindrical or tapered with a taper of 0,02:1 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 cylindrical.

- d₁ diameter of the working part at the tip end (nominal size)
- d₂ diameter at the end of working part (standards.iteh.ai)
- l_1 length for measuring point d_2 and minimum length of working part
- <u>ISO 3630-3:1994</u>
- length of operative end https://standards.iteh.ai/catalog/standards/sist/4085367b-307d-48e3-
- l₃ neck portion 9557-0b75cdf93051/iso-3630-3-1994

Figure 1 — Plugger

Table 1 — Diameters and designation for standard pluggers

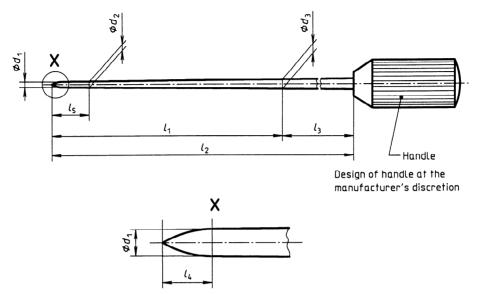
1-11-33				
Nominal size	<i>d</i> ₁	<i>d</i> ₂	Colour	
	± 0,02	± 0,02	designation	
015	0,15	0,47	white	
020	0,20	0,52	yellow	
025	0,25	0,57	red	
030	0,30	0,62	blue	
035	0,35	0,67	green	
040	0,40	0,72	black	
045	0,45	0,77	white	
050	0,50	0,82	yellow	
055	0,55	0,87	red	
060	0,60	0,92	blue	
070	0,70	1,02	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	
130	1,30	1,62	green	
140	1,40	1,72	black	

Table 2 — Lengths

21 25 28 31	ι ₁ min.	<i>l</i> ₂ ± 0,5
	16	25 28

NOTE — Lengths not listed shall be within \pm 0,5 mm of the stated length.

4.2.2 Spreaders



The taper along l_1 is specified by d_2 and d_3 of table 3. The tip end shall be rounded or angled. The neck shall be either continuously tapered, cylindrical or a combination.

- diameter of the projection of the working part at the tip end (nominal size) d_2 diameter at length Is
- (standards.iteh.ai) d_3 diameter at length l_1
- length for measuring point d_3 and minimum length of working part l_1
- length of operative tend/standards.iteh.ai/catalog/standards/sist/4085367b-307d-48e3 l_2 9557-0b75cdf93051/iso-3630-3-1994
- neck portion l_3
- length of tip l_4
- l_5 length for measuring point d_2

Figure 2 — Spreader

Table 3 — Diameters and designation for standard spreaders

otaliaara oproadoro				
Nominal size	d₁ ref.	<i>d</i> ₂ ± 0,02	<i>d</i> 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

Table 4 — Lengths

<i>l</i> ₁ min.	<i>l</i> ₂ ± 0,5	l_{4}	<i>l</i> ₅
16	21 25 28 31	d_1 to $3 \times d_1$	3

NOTE — Lengths not listed shall be within ± 0,5 mm of stated length.

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4.3 Dimensional requirements for taper size pluggers and taper size spreaders

The dimensions are given in millimetres.

The dimensional requirements shall comply with the respective tables and figures in 4.2.1 and 4.2.2 and table 5. Within the dimensional requirements, variations in shape and design are permitted.

Testing shall be carried out in accordance with ISO 3630-1:1992, subclauses 6.1 and 6.2.

Taper size pluggers and taper size spreaders have the nominal sizes for d_1 and taper selected from table 5 at the discretion of the manufacturer.

They have tapers different from standard type instruments.

There is no restriction regarding size. For example if $d_1 = 0.22$ and taper = 0.037, then the size designation would be 022 37.

Taper portion is uniform along the working length.

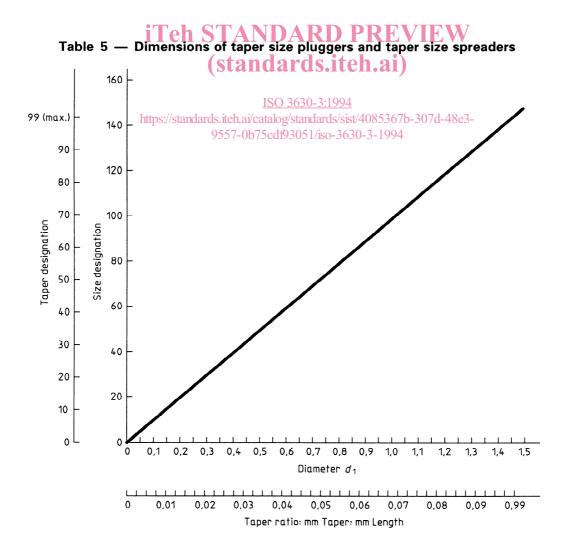
If the working part length, l_1 , is less than 16 mm (see table 5), use the length to the maximum diameter along the taper.

4.4 Pluggers and spreaders fitted in long handles (hand-type instruments)

The symbols and terms in 4.2.1, 4.2.2 and 4.3 also apply to instruments fitted in long handles.

The length and the diameter of the handle shall be at the manufacturer's discretion.

The condensers shall be either straight or bent as shown in figure 3. Length l_1 may be less than 16 mm at the discretion of the manufacturer.



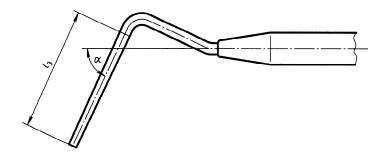


Figure 3 — Bent condenser

The angle α shown in figure 3 shall be consistent within the tolerance as specified in table 6 for any specific size within a brand.

Table 6 — Angle tolerance

Angle range	Tolerance	
α	TA CTANDA	T
α≤ 10°	± 1°	
11° ≤ α ≤ 25°	(s <u>t</u> andar	ds
26° ≤ α ≤ 45°	± 3°	
46° ≼ α	https://standards.iteb.ai/catalog/sta	30- and:

Testing shall be carried out in accordance with 6.1.3.

4.5.3 Handle security

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

Testing shall be carried out in accordance with ISO 3630-1:1992, subclause 6.5.

4.5.4 Surface finish

4.5 Mechanical requirements

4.5.1 Resistance to bending, finger-type instruments

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. The condenser shall be deemed not to comply with this requirement if it fractures or if the permanent set is in excess of the figures stated.

Testing shall be carried out in accordance with 6.1.2.

4.5.2 Resistance to bending, hand-type 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. The condenser shall be deemed not to comply with this requirement if it fractures or if the permanent set is in excess of the figures stated.

9557-0b75cdf93051/iso-3630-3-1994. The operative end shall have a smooth finish when visually inspected under × 4 magnification.

4.5.5 Chemical requirements, corrosion-resistance

Instruments shall not show evidence of corrosion when undergoing one of the corrosion tests specified in ISO 3630-1:1992, subclause 6.6.

4.5.6 Heat-carrier condenser

When instruments are indicated by the manufacturer as being heat-carriers, the instruments shall meet the requirements of 4.5.2.

Testing shall be carried out in accordance with 6.1.3.

5 Sampling

For each test, if not specified differently, more than 90 % of the samples tested shall comply. The sampling plan is as follows:

Test at least 10 instruments of each size to be tested. If all 10 instruments pass, the product passes. If eight