Dentistry - Endodontic instruments - Part 3: Compactors (ISO 3630-3:2021, Corrected version 2023-05)



## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 3630-3:2021 sisaldab Euroopa standardi EN ISO 3630-3:2021 ingliskeelset teksti.

This Estonian standard EVS-EN ISO 3630-3:2021 consists of the English text of the European standard EN ISO 3630-3:2021.

Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.

This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.

Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 23.06.2021.

Date of Availability of the European standard is 23.06.2021.

Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.

The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile <u>standardiosakond@evs.ee</u>.

### ICS 11.060.20

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## EUROPEAN STANDARD

NORME EUROPÉENNE

## **EN ISO 3630-3**

## EUROPÄISCHE NORM

June 2021

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Supersedes EN ISO 3630-3:2015

## **English Version**

# Dentistry - Endodontic instruments - Part 3: Compactors (ISO 3630-3:2021, Corrected version 2023-05)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 3: Compacteurs (ISO 3630-3:2021, Version corrigée 2023-05)

Zahnheilkunde - Endodontische Instrumente - Teil 3: Verdichter (ISO 3630-3:2021, korrigierte Fassung 2023-05)

This European Standard was approved by CEN on 19 April 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 10 May 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## **European foreword**

This document (EN ISO 3630-3:2021) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by December 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 3630-3:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## **Endorsement notice**

The text of ISO 3630-3:2021, Corrected version 2023-05 has been approved by CEN as EN ISO 3630-3:2021 without any modification.

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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

For an explanation of 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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

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 third edition cancels and replaces the second edition (ISO 3630-3:2015), which has been technically revised.

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

- the symbols D,  $d_3$  and  $d_{16}$  in this document have been harmonized with the other parts of the ISO 3630 series:
- 'types' has been changed to 'classes';
- test methods have been improved.

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.

This corrected version of ISO 3630-3:2021 incorporates the following correction: in 5.3.4.1, "200 N" has been changed to "20 N" as follows: "The operative part shall not have any axial movement from the handle when a force of 20 N is applied."

## **Dentistry** — **Endodontic instruments** —

## Part 3:

## **Compactors**

## 1 Scope

This document specifies the requirements and test methods for endodontic compactors (pluggers and spreaders) which are used for the compaction of endodontic filling materials, and also heat-carriers (which are not specified in the other parts of the ISO 3630 series).

This document specifies the requirements for size, marking, product designation, safety considerations, and their labelling and packaging.

## 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 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 terminological databases for use in standardization at the following addresses:

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

#### 3.1

#### compactor

endodontic instrument used manually as a *plugger* (3.2) or *spreader* (3.3) designed to compact filling materials in the root canal system

Note 1 to entry: There are two types: finger (hand) and binangle.

#### 3.2

### plugger

compactor (3.1), used mainly in an apical direction, whose working surface (3.7) is tapered or non-tapered, circular in cross-section and has a flat tip

Note 1 to entry: Figure 1 and Table 1 describe the specific dimensions and characteristics of a plugger.