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## Dentistry — Excavators

*Médecine bucco-dentaire — Excavateurs*



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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)).

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 [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 first edition cancels and replaces the first edition (ISO 13397-4:1997), which has been technically revised. The main changes compared to the previous edition are as follows:

- new shapes have been added — see [Figures 5 to 10](#) and [Table 3](#);
- test values for connection between working end and handle have been reduced from 600 N to 450 N (tensile load) and from 400 Ncm to 0,25 Nm (torque) (see [6.7](#));
- a requirement for UDI-code has been added in [Clause 8](#);
- a requirement for instructions for use has been added in [8.3](#).

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](http://www.iso.org/members.html).

# Dentistry — Excavators

## 1 Scope

This document specifies dimensions and performance requirements for excavators used in dentistry.

## 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 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 21850-1, *Dentistry — Materials for dental instruments — Part 1: Stainless steel*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 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

#### **excavator**

handheld dental instrument for excavating caries

### 3.2

#### **datum point**

section point between the centreline of the *handle* (3.3), at a right angle to the centreline, and the *blade* (3.6)

### 3.3

#### **handle**

area used for holding the *excavator* (3.1) during use

### 3.4

#### **shank**

part of the *excavator* (3.1) that connects the *working end* (3.5) to the *handle* (3.3)

### 3.5

#### **working end**

part of the *excavator* (3.1) after the first bend of the *shank* (3.4) including the working tip