
Dentistry — Osteotome

Médecine bucco-dentaire — Ostéotome

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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).

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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](#)

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

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Introduction

Osteotomes are instruments generally used in orthopaedic surgery. However, in dentistry, and more specific, when preparing the implant site for dental implants, certain types of osteotomes are used for bone compaction, sinus floor elevation, and jaw bone cleaving. These types of osteotomes are addressed in this International Standard.

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Dentistry — Osteotome

1 Scope

This International Standard specifies requirements and their test methods for osteotomes used in dentistry for bone compaction, internal sinus floor elevation, and jaw bone cleaving. It also specifies the requirements for their marking and labelling.

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

ISO 6508-1, *Metallic materials — Rockwell hardness test — Part 1: Test method*

ISO 13504, *Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment*

ISO 15087-1, *Dental elevators — Part 1: General requirements*

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

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3 Terms, definitions, and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 13504, ISO 16443 and the following apply.

3.1.1

osteotome

handheld dental instrument designed for bone compaction, internal sinus floor elevation, or jaw bone cleaving

Note 1 to entry: Osteotomes consist of a working tip, a shank, and a handle.

3.1.2

condenser

bone-condenser

handheld dental instrument, with conical shaped *working end* (3.1.5), used for compacting the maxillary bone surrounding the implant socket to improve the primary stability of the implant

3.1.3

chisel

handheld dental instrument designed for cleaving the jaw bone into a buccal and lingual or buccal and palatal bone lamelle in order to insert an implant in between

Note 1 to entry: Chisels can also be used selectively to remove bone for procedures such as grafting and transplantation.

3.1.4

sinutome

handheld dental instrument for performing an internal sinus floor elevation, where the sinus floor is elevated cranially through the oral cavity with different sized instruments

Note 1 to entry: Another term for internal sinus floor elevation is sinus floor elevation according to Summer.

3.1.5

working end

part of the *osteotome* (3.1.1) consisting of a *working tip* (3.1.6) and a shank connected to the *handle* (3.1.7)

3.1.6

working tip

the most frontal area of the instrument which is used for working

3.1.7

handle

area used for holding the instrument during operation

3.1.8

impact surface

backward area of the instrument used for receiving the hitting of the mallet

Note 1 to entry: Another term for mallet is hammer.

3.2 Symbols

The symbols used in Figure 1 to Figure 8 are the following:

L_1 total length;

D_1 diameter or width of the active area;

D_2 maximum diameter at the beginning of the active area.

4 Classification

For the purposes of this International Standard, osteotomes shall be classified according to the shapes into the following types:

- Type 1: sinutome
- Type 2: condenser
- Type 3: chisel

For the purposes of this International Standard, osteotomes shall be classified according to the shape of the shanks into the following forms:

- Form A: straight shank
- Form B: offset shank

5 Shapes

5.1 Sinutome

Working tip: cylindrical

Working area: preferable as shown in detail Z, Figure 3.

Dimensions in millimetres

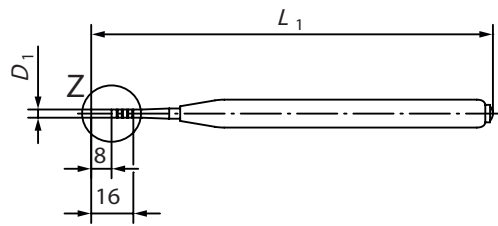


Figure 1 — Type 1, Form A: Sinutome, straight

Dimensions in millimetres

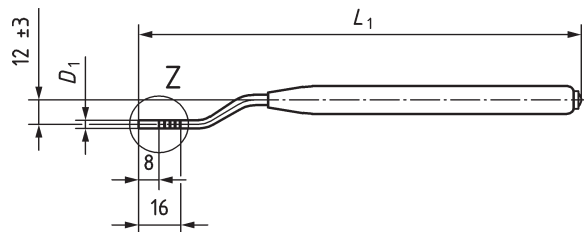


Figure 2 — Type 1, Form B: Sinutome, offset shaped

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- a Plane.
- b Concave.

Figure 3 — Detail Z, working tips of sinutome

5.2 Condenser

Working tip: conical

Working area: preferable as shown in detail Z, [Figure 6](#).

Dimensions in millimetres

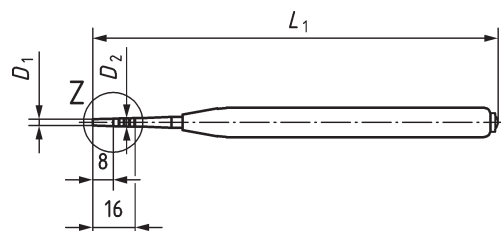


Figure 4 — Type 2, Form A: Condenser, straight