BS EN ISO 17937:2015

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Dentistry - Osteotome

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The UK participation in its preparation was entrusted to Technical Committee CH/106/4, Dental Instruments and Equipment.

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Zahnheilkunde - Osteotome (ISO 17937:2015)

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European foreword

This document (EN ISO 17937:2015) 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.

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INTERNATIONAL STANDARD

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Médecine bucco-dentaire — Ostéotome

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

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.

INTERNATIONAL STANDARD ISO 17937:2015(E)

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*

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 palatinal 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

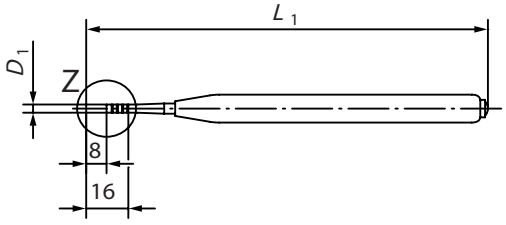


Figure 1 — Type 1, Form A: Sinutome, straight

Dimensions in millimetres

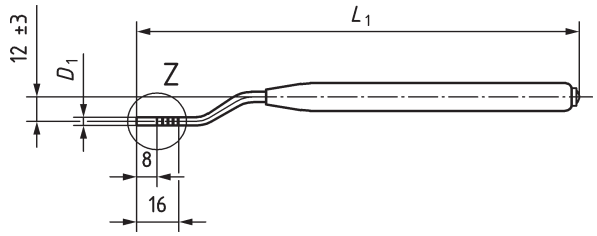
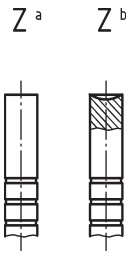


Figure 2 — Type 1, Form B: Sinutome, offset shaped



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

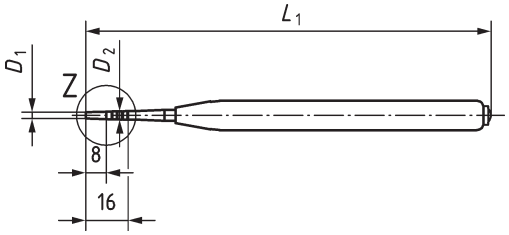


Figure 4 — Type 2, Form A: Condenser, straight

Dimensions in millimetres

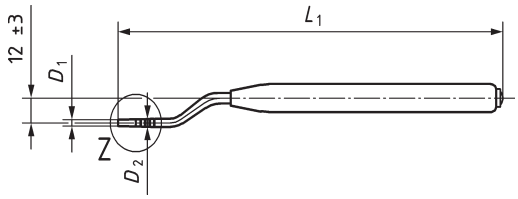
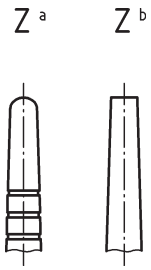


Figure 5 — Type 2, Form B: Condenser, offset



a Convex.

b Plane.

Figure 6 — Detail Z, working tips of condenser

5.3 Chisel

a) Working tip: pointed, straight

Working area: preferable as shown in detail Z, Figure 8.

Dimensions in millimetres

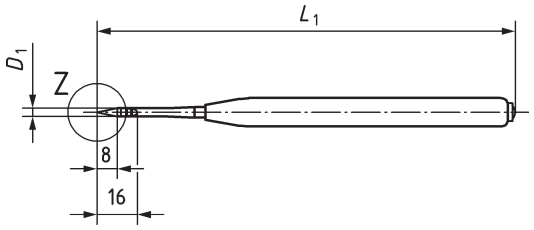
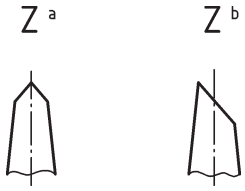


Figure 7 — Type 3, Form A: Chisel, straight with straight working tip



a Straight with doublesided cutting edge/polished section to the point.

b Straight with singlesided cutting edge to the tip.

Figure 8 — Detail Z, working tips of chisel

b) Working tip: pointed, curved or angled

Working area: Preferable as shown in detail Z, Figure 10.

Dimensions in millimetres

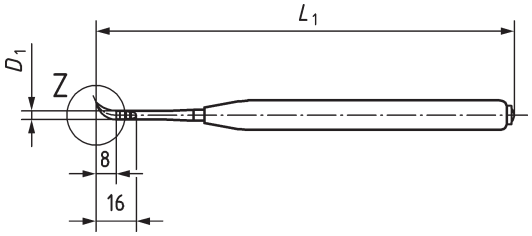
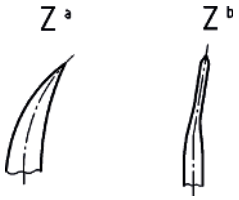


Figure 9 — Type 3, Form A: Chisel, straight with curved or angled working tip



a Curved.

b Angled.

Figure 10 — Detail Z, working tips of chisel

6 Material

6.1 Material of the working end

The materials of the working end of the osteotome shall be in accordance with ISO 13504.

6.2 Material for the handle

The material of the handle of the osteotome shall be in accordance with ISO 13504.

NOTE Some osteotomes consist of a handle with interchangeable working ends.

7 Requirements

7.1 Dimensions

7.1.1 Diameter of the working end (D_1, D_2)

The diameter of the working end shall be within ±0,1 mm of the manufacturer's stated dimensions.

7.1.2 Overall length

The overall length of the osteotome including the handle and the working end shall not exceed 175 mm.

7.2 Marking on the working end

7.2.1 General

Marking shall be marked or carved from the tip of the working end at intervals as per the manufacturer's instructions in 2 mm steps, in order to indicate the depth of introduction of the osteotome into osseous tissue. The length from the working tip to the marking shall be within ±0,1 mm of the manufacturer's dimensions, measuring from the working tip to one of the two marking lines, whichever is nearer to the working tip, and at least the area between 8 mm and 16 mm shall be marked.

7.2.2 Thickness of scale line

The fine scale line or markings used in single dimension shall be visible without magnification.

7.3 Surface finish

The surfaces of the instruments shall be free of visible surface defects when tested in accordance with 8.2.

7.4 Resistance to reprocessing

There shall be no visible signs of deterioration, and the requirement for 7.5 and 7.6 shall be met when tested in accordance with 8.3.

7.5 Hardness of the working end

The hardness of the osteotome shall be equal or greater than 480 HV1 or 48 HRC.

7.6 Connection of shank and handle

The osteotome assembled with the shank and the handle shall not loosen when tested at the tensile force and torque as stated under 8.5.1 and 8.5.2 hereafter. Connection between impact surface and working end shall be from a material which withstands the hammering force.

8 Test method

8.1 Measurement of length and diameter

Measuring devices with the appropriate accuracy shall be used for measurements.

8.2 Test on surface finish

Normal visual inspection shall be conducted without using a magnifying glass.

8.3 Test on resistance to reprocessing

Carry out 100 reprocessing cycles in accordance with the manufacturer's instructions. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning, disinfection, and sterilization. Assess visually for any signs of deterioration of the surface. Repeat the tests for hardness and connection of handle and shank.

8.4 Hardness test

Test the Vickers hardness or Rockwell hardness in accordance with ISO 6507-1 or ISO 6508-1, respectively.

8.5 Connection of shank

8.5.1 Test under tensile force

Apply a tensile force of 1 000 N at the point where the shank is connected to the handle, parallel to the centre of handle for five seconds, in accordance with the method described in ISO 15087-1, Annex C.

8.5.2 Test under torque

Apply a torque of 500 N·cm to the point where the shank is connected to the handle for five seconds, in accordance with the method described in ISO 15087-1, Annex D.

9 Marking, labelling, and instructions for use

9.1 Marking on the osteotome

Marking on the osteotome shall be in accordance with ISO 13504 with the following additional requirements:

a) Scales shall be marked on the surface of device in such a way that the depth of introduction of the osteotome into osseous tissue is legible without magnification by users.

b) Diameter of the working end and the tip of the working end shall be marked on the surface in such a way that it is legible without magnification by users.

9.2 Labelling on the package

Labelling on the package shall be in accordance with ISO 13504.

9.3 Instructions for use

Instructions for use shall be in accordance with ISO 13504 with the following additional requirement:

The description shall include the reprocessing method containing cleaning, disinfection, and sterilization of the osteotome.

Bibliography

[1] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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