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## Dentistry — Sinus membrane elevator

*Médecine bucco-dentaire — Sinus membrane éleveurs*

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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 on 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 the following URL: [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 4, *Dental instruments*.

## Introduction

A sinus membrane elevator is a dental instrument used during the placement of dental implants for sinus floor lifting to augment the vertical bone thickness. These types of sinus membrane elevator are addressed in this document.

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# Dentistry — Sinus membrane elevator

## 1 Scope

This document specifies requirements and their test methods for sinus membrane elevators used during the placement of dental implants for sinus floor lifting. It also specifies the requirements for their marking and labelling.

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

ISO 13504:2012, *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 and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 13504:2012 and ISO 16443 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

### 3.1

#### **sinus membrane elevator**

handheld dental instrument designed for lifting or displacing the sinus membrane (floor) by a lateral (external) or vertical approach (crestal) of the maxillary sinus in order to enable bone augmentation for insertion of an implant

Note 1 to entry: A sinus membrane elevator consists of a *working tip* (3.3) and a shank, which is connected to a handle. Instruments may be double-ended.

### 3.2

#### **working end**

part of the sinus membrane elevator consisting of a *working tip* (3.3) and a shank connected to the handle

### 3.3

#### **working tip**

active part of the *working end* (3.2) which will be first to engage bone and the sinus membrane

## 4 Classification

For the purpose of this document, sinus membrane elevators shall be classified according to the approach of sinus floor lifting into the following types:

- Type 1: Lateral/vestibular/external approach;
- Type 2: Vertical/crestal/internal approach.

## 5 Requirements

### 5.1 Material of the working end

The working end of the sinus membrane elevator shall be made of materials in accordance with ISO 13504:2012.

### 5.2 Material for the handle

The material for the handle of the sinus membrane elevator shall be left to the manufacturer's discretion.

### 5.3 Dimensions

The overall length is left to the manufacturer's discretion.

NOTE Overall lengths in excess of 178 mm can cause problems when fitting into trays and cassettes for reprocessing.

### 5.4 Surface finish

The surfaces of the instruments shall be free of visible surface defects when tested in accordance with [6.2](#).

### 5.5 Resistance to reprocessing

There shall be no deterioration or corrosion when tested in accordance with [6.3](#).

### 5.6 Hardness of the working end

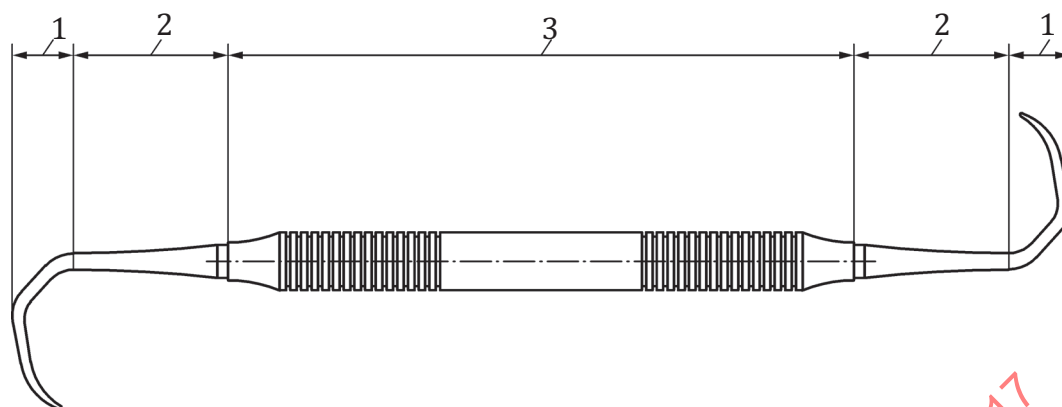
The hardness of the working end for the instrument shall be equal or greater than 480 HV1 or 48 HRC when tested in accordance with [6.4](#).

### 5.7 Connection of shank and handle

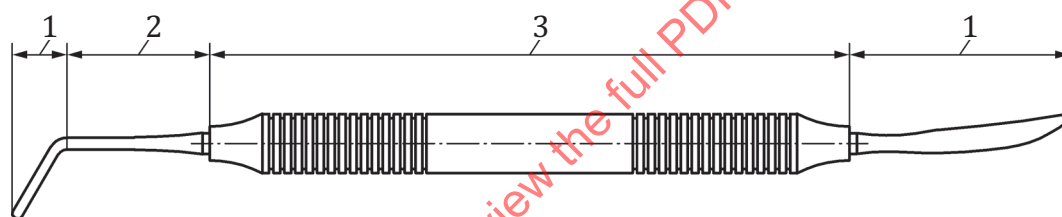
The sinus membrane elevator assembled with the shank and handle shall not loosen when tested at the tensile force and torque as stated under [6.5](#).

### 5.8 Shape of working end

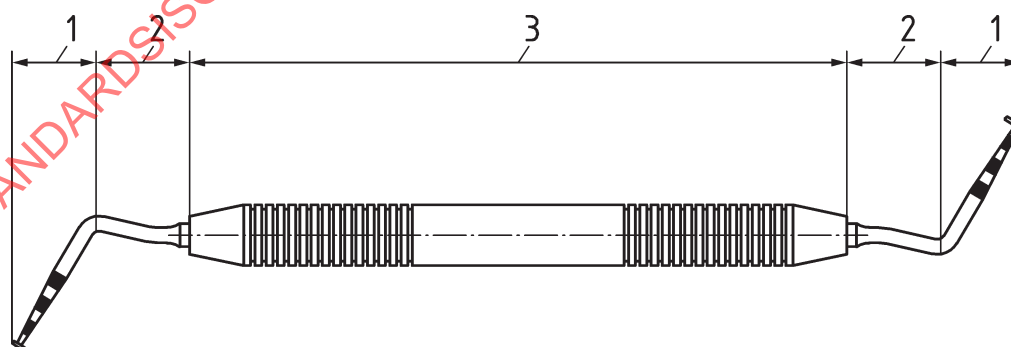
The shape of the working end and working tip is left to the discretion of the manufacturer. [Figures 1 to 3](#) are given as example only. Other designs of working end and working tip are also possible.

**Key**

- 1 working tip
- 2 shank
- 3 handle

**Figure 1 — Example of Type 1****Key**

- 1 working tip
- 2 shank
- 3 handle

**Figure 2 — Example of Type 1****Key**

- 1 working tip
- 2 shank
- 3 handle

**Figure 3 — Example of Type 2**