INTERNATIONAL STANDARD

ISO 19490

First edition
2017-06

Dentistry — Sinus membrane elevator

Médecine bucco-dentaire — Sinus membrane élevateurs

Reference number
ISO 19490:2017(E)

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Foreword

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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.

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

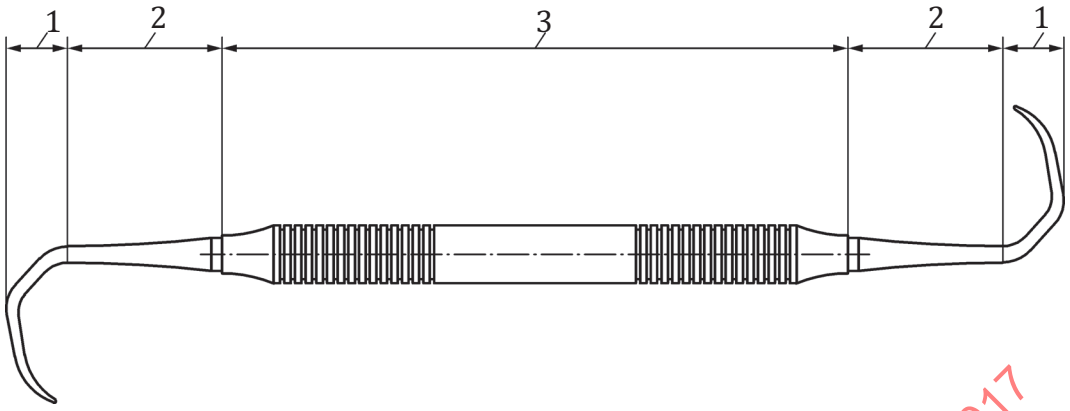
The hardness of the working end for the instrument shall be equal or greater than 480 HV1 or 48 HRC when tested in accordance with 6.4.

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

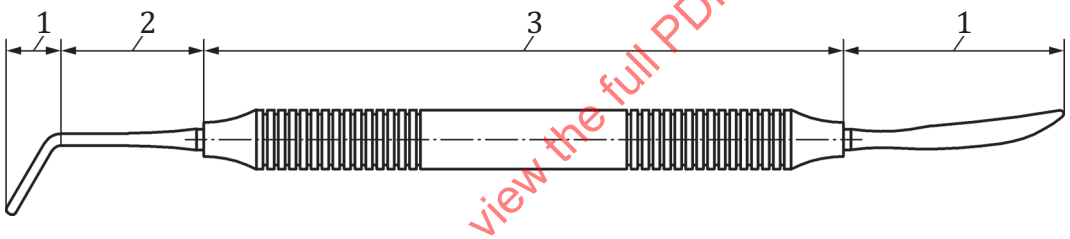
The shape of the working end and working tip is left to the discretion of the manufacturer. Figures 1 to 3 are given as example only. Other designs of working end and working tip are also possible.



Key

1 working tip
2 shank
3 handle

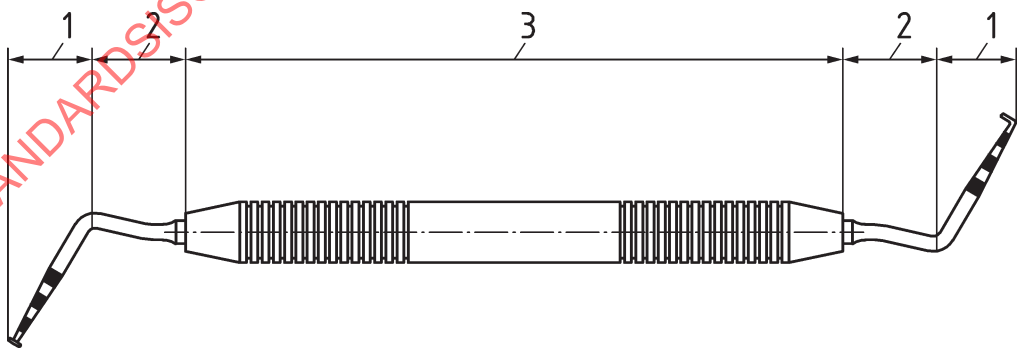
Figure 1 — Example of Type 1



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