Dentistry - Sinus membrane elevator (ISO 19490:2017)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 19490:2017 sisaldab Euroopa standardi EN ISO 19490:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 19490:2017 consists of the English text of the European standard EN ISO 19490:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.06.2017.	Date of Availability of the European standard is 21.06.2017.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Dentistry - Sinus membrane elevator (ISO 19490:2017)

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Zahnheilkunde - Sinusmembranelevator (ISO 19490:2017)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 19490:2017) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 19490:2017 has been approved by CEN as EN ISO 19490:2017 without any modification.

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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 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.

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