International Standard

ISO 19490

Dentistry — Sinus membrane elevator

Médecine bucco-dentaire — Élévateur de membrane sinusienne

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Foreword

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN

This second edition cancels and replaces the first edition (ISO 19490:2017), which has been technically revised.

The main changes are as follows:

— a new reference (ISO 4865-1) has been added to Clause 2;

— a new reference (ISO 17664-1) has been added to Clause 2;

— requirements and test methods have been referenced from ISO 4865-1;

— overall lengths have been reduced from 178 mm to 173 mm;

— a new figure has been added in Type 1 classification;

— marking, labelling and packaging specifications from ISO 4865-1 have been added to Clause 7;

— instruction for use from ISO 4865-1 and ISO 17664-1 have been added to Clause 8.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

A sinus membrane elevator is a dental instrument. It is used during the placement of dental implants for sinus floor lifting to augment the vertical bone thickness. This document addresses these types of sinus membrane elevator.

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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 4865-1:2023, *Dentistry — General requirements of hand instruments — Part 1: Non-hinged hand instruments*

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

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

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

3 Terms and definitions

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

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

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://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 part
part of the *sinus membrane elevator* (3.1) consisting of a *working tip* (3.3) and a shank connected to the handle

3.3
working tip
active part of the *working part* (3.2) which is used to engage bone and the sinus membrane

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