

SVENSK STANDARD

SS-EN ISO 19023:2018



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Tandvård – Ortodontiska miniskruvar (ISO 19023:2018)

Dentistry – Orthodontic anchor screws (ISO 19023:2018)

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Denna standard är framtagen av kommittén för Tandvård, SIS/TK 327.

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EUROPEAN STANDARD

EN ISO 19023

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2018

ICS 11.060.10

English Version

Dentistry - Orthodontic anchor screws (ISO 19023:2018)

Médecine bucco-dentaire - Vis d'ancrage
orthodontiques (ISO 19023:2018)

Zahnheilkunde - Kieferorthopädische Ankerschrauben
(ISO 19023:2018)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 19023:2018) 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of an identical text or by endorsement, at the latest by August 2018, and conflicting national standards shall be withdrawn at the latest by August 2018.

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The text of ISO 19023:2018 has been approved by CEN as EN ISO 19023:2018 without any modification.

SS-EN ISO 19023:2018 (E)

Introduction

Orthodontic anchor screws for temporary skeletal anchorage of orthodontic appliances are considered as auxiliary orthodontic devices.

Orthodontic anchor screws are medical devices used in dentistry. Unlike implants, such as endosseous dental implants, which are intended to remain permanently inside the bone and where, therefore, osseointegration is desired, orthodontic anchor screws are removed at the end of the orthodontic treatment. Insertion and removal of orthodontic anchor screws require the appropriate instruments and adapters.

This document has been developed as a result of the difficulty often encountered by clinicians to make meaningful comparisons between orthodontic anchor screws using the information currently available from manufacturers and suppliers.

Thus the purpose of this document is to facilitate communication between manufacturers and clinicians which will allow comparison between various orthodontic anchor screws.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document, but it is recommended that, for the assessment of possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO 7405.