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Dentistry — Orthodontic anchor screws

Médecine bucco-dentaire — Vis d'ancrage orthodontiques

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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 SC 1, *Filling and restorative materials*.

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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.

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Dentistry — Orthodontic anchor screws

1 Scope

This document specifies requirements and test methods for orthodontic anchor screws used in orthodontic treatment.

This document gives details of methods to compare physical and mechanical properties of orthodontic anchor screws together with test methods and packaging and labelling information.

NOTE Orthodontic anchor screws are used to provide temporary intraoral skeletal anchorage during orthodontic treatment and are removed at the end of the orthodontic treatment. Similar to endosseous dental implants, they are, therefore inserted into the maxillo-facial bone structures.

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 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ASTM F67, *Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*

ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

ASTM F543-17, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

3 Terms and definitions

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

ISO and IEC maintain terminological 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
orthodontic anchor screw
screw for temporary skeletal anchorage of orthodontic appliances

3.2
shaft
part of the orthodontic anchor screw intended to be inserted into the bone, with at least a threaded portion

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3.3
neck
transgingival section between the shaft and the head of the orthodontic anchor screw

3.4
head
part of the orthodontic anchor screw intended for connection with the orthodontic appliance

3.5
insertion mode
manner of insertion of an orthodontic anchor screw into the bone

4 Symbols and abbreviated terms

The symbols and abbreviated terms illustrated in Figure 1 have the following meaning:

d_1 major thread diameter;

d_2 minor thread diameter;

d_3 largest cross sectional dimension of the anchor screw;

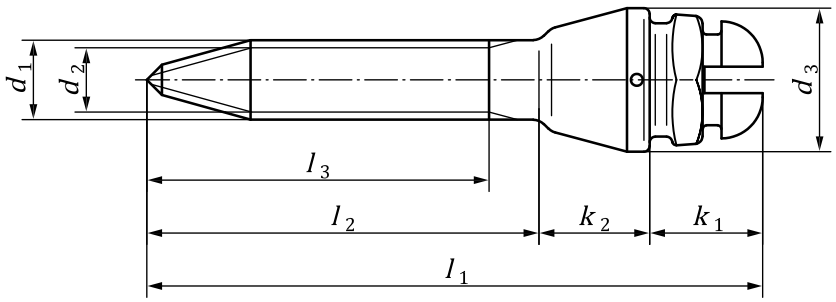
k_1 height of head;

k_2 height of neck;

l_1 overall length;

l_2 shaft length;

l_3 thread length.



NOTE The shape illustrated in Figure 1 is an example, and not a requirement.

Figure 1 — Example for designation of dimensions of orthodontic anchor screw

5 Requirements

5.1 General

The manufacturer shall declare the properties specified in 5.2 to 5.5.

The properties shall be within the ranges stated by the manufacturer.

The properties shall be tested in accordance with the test methods described in Clause 6.

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