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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

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.

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

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;

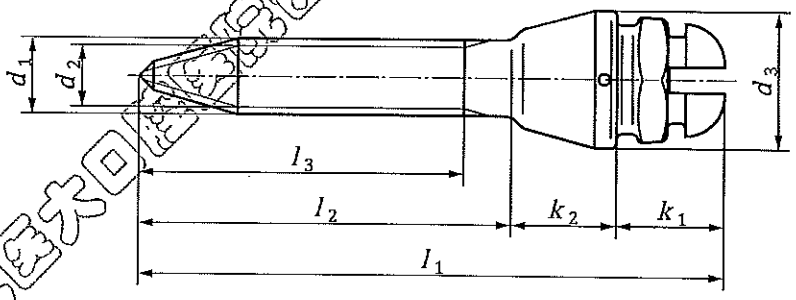
k_1 height of head;

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.

5.2 Materials

The material shall conform to either ISO 5832-2, ISO 5832-3, ASTM F67 or ASTM F136. Otherwise the range of composition of the material shall include all components present at concentrations of 0,1 % by mass or greater.

5.3 Hazardous elements

For the purposes of this document, cadmium, beryllium, lead, and nickel are designated to be hazardous elements and the manufacturer shall state the concentrations as a mass fraction expressed as a percentage.

5.4 Dimensions

The dimensions illustrated in Figure 1, if available, shall be specified by the manufacturer.

The dimensions shall be within the range stated by the manufacturer.

Measure the dimensions in accordance with 6.1.

5.5 Torsional performance

The fracture torque and the insertion torque under worst case conditions shall be specified.

Test in accordance with 6.2 and 6.3.

5.6 Reporting of results

The test results of each specimen shall be within the manufacturer's specified range or tolerance in order for the anchor screw to comply with the requirements.

6 Test methods

6.1 Dimensions

Measurements shall be taken with suitable measuring devices, e.g. calliper, micrometer, or other devices with an accuracy of 0,05 mm.

6.2 Torsional performance – fracture torque

The fracture torque of an orthodontic anchor screw shall be measured with an apparatus according to ASTM F543-17, test method A1.

The maximum torque shall be delivered. The accuracy shall be in accordance with ASTM F543-17.

Five specimens shall be tested.

6.3 Torsional performance – insertion torque

The insertion torque of an orthodontic anchor screw shall be measured with an apparatus according to ASTM F543-17, test method A1. A segment of artificial bone shall be selected as test body to insert the anchor screw. Sawbones® (Sawbones USA, Vashon Island, WA 98070)[1)] is an example of a synthetic bone analogue. Select the material with highest available density to simulate maximum bone density. State the density used and the respective bone density according to ASTM F-1839-08.

1) This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product or supplier named.

The screw shall be inserted following the recommendations of the manufacturer in the instructions for use regarding predrilling.

The maximum torque shall be delivered. The insertion torque shall not be higher than the fracture torque. The accuracy shall be in accordance with ASTM F543-17.

Five specimens shall be tested.

7 Information to be provided to the user

7.1 General requirements

The manufacturer shall provide the following information in an easily accessible manner, e.g. in the catalogue, electronically (e.g. website, DVD) or by other easily accessible means:

a) manufacturer's name and address;

b) commercial name of the orthodontic anchor screw;

c) intended use;

d) major thread diameter;

e) thread length;

f) overall length;

g) applied standard including grade for material, or material composition.

7.2 Instructions for use

Each package of an orthodontic anchor screw shall be accompanied by instructions for use. Alternatively instructions for use may be provided electronically if allowed by national or regional legislation or regulation.

The instructions for use shall include at least the following information:

a) manufacturer's name and address;

b) trade name of the orthodontic anchor screw;

c) intended use;

d) shaft length;

e) major thread diameter;

f) applied standard including grade for material, or material composition;

g) fracture torque;

h) insertion toque;

i) state as delivered (sterile/non-sterile);

j) information as to whether sterilization by the user is required before insertion and how this is to be performed by means of validated methods;

k) insertion mode (pre-drilling/ self-drilling/self-tapping);

l) information regarding the instruments to be used for insertion;

NOTE Usual instruments include gimlets, torque wrenches.

m) date of publication of the instructions for use;

n) warnings and/or advice regarding any precautions to be taken.

7.3 Labelling

The labelling on the package of the orthodontic anchor screw shall include at least the following information:

a) name and address of the manufacturer;

b) where appropriate, name and address of the distributor;

c) commercial name of the orthodontic anchor screw;

d) model number (reference number);

e) lot number (batch designation);

f) number of the orthodontic anchor screws contained;

g) for single-use only;

h) state as delivered (sterile/non-sterile);

i) if delivered sterile: expiration date of sterility, stated in accordance with ISO 8601.

7.4 Packaging

If the orthodontic anchor screw is supplied in a sterile state, its package shall keep the sterilization and shall not allow contamination.

Bibliography

[1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

[4] ASTM F-1839-08, *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments*