SLOVENSKI STANDARD
oSIST prEN ISO 21606:2022

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Zobozdravstvo - Elastomerni pripomočki za uporabo v ortodontiji (ISO/DIS 21606:2021)

Dentistry - Elastomeric auxiliaries for use in orthodontics (ISO/DIS 21606:2021)

Zahnheilkunde - Elastomeres Zubehör für die Kieferorthopädie (ISO/DIS 21606:2021)

Médecine bucco-dentaire - Auxiliaires élastomériques utilisés en orthodontie (ISO/DIS 21606:2021)

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Dentistry — Elastomeric auxiliaries for use in orthodontics

Art dentaire — Auxiliaires élastomères utilisés en orthodontie

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second/third/... edition cancels and replaces the first/second/... edition (ISO #####:####), which has been technically revised.

The main changes compared to the previous edition are as follows:

— xxx xxxxxxx xxx xxxx

A list of all parts in the ISO ##### series can be found on the ISO website.

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.

Introduction

This first edition of ISO 21606 has been developed as a result of the difficulty often encountered by clinicians in making meaningful comparisons between elastomeric auxiliaries using the information currently available from manufacturers and suppliers.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that in assessing possible biological hazards reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Elastomeric auxiliaries for use in orthodontics

1 Scope

This document specifies the requirements and their test methods applicable to all elastomeric auxiliaries used for orthodontics both inside and outside the mouth, in conjunction with fixed and removable appliances. The auxiliaries include orthodontic elastics, orthodontic elastomeric chains, orthodontic thread, orthodontic elastomeric ligatures and orthodontic elastomeric separators.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
orthodontic elastomeric elastic
intra-oral and extra-oral elastomeric ring used to apply forces to orthodontic devices

3.2
orthodontic elastomeric thread
elastomeric thread (may be hollow) of constant cross-section used to apply forces to orthodontic devices

3.3
orthodontic elastomeric chain
interconnected elastomeric rings or a multi-perforated elastomeric band used to apply forces to orthodontic devices

3.4
orthodontic elastomeric ligature
elastomeric ring used to retain wires to orthodontic attachments

3.5
orthodontic elastomeric separator
elastomeric products used to open interproximal spaces between teeth

3.6
link length
L
distance between the centres of the holes of adjacent links of *orthodontic elastomeric chains* (3.3)

Note 1 to entry: See Figure 1.

3.7
test length
length to be tested

Note 1 to entry: The test lengths for different types of elastomeric devices are shown in Figure 1.

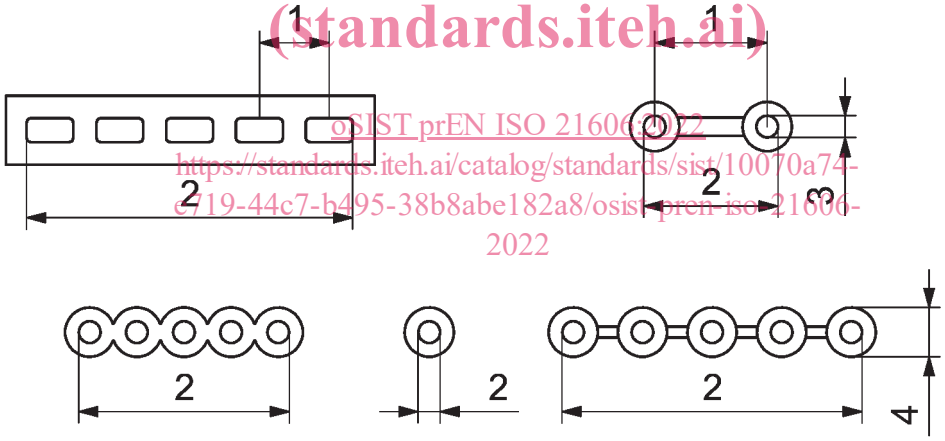
Note 2 to entry: The test length for orthodontic elastomeric chain is five links shown in Figure 1.

Note 3 to entry: The test length for orthodontic elastomeric thread is the length necessary to make over 20 mm loop circumference.

3.8
initial extension force
F_0
force exerted by the elastomeric auxiliary at three times the *test length* (3.7) after *initial extension force* (3.8) to four times the *test length* (3.7)

3.9
24 hour residual force
F_{24}
force exerted by the elastomeric auxiliary at three times the test length at 24 h, after initial extension to four times the test length, and expressed as a percentage of the initial extension force

3.10
ultimate extension
A
extension at break expressed as percentage of the test length



Key
1 link length, L
2 test length
3 inner diameter, D_i
4 outer diameter, D_o

Figure 1 — Test dimensions of elastomeric auxiliaries

4 Requirements

4.1 General

Table 1 summarizes the requirements to be determined for the different elastomeric auxiliaries covered by this International Standard.