INTERNATIONAL STANDARD

ISO 21606

First edition
2007-06-01

Dentistry — Elastomeric auxiliaries for use in orthodontics

Art dentaire — Auxiliaires élastomères utilisés en orthodontie

Reference number
ISO 21606:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21606 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

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 auxillaries 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 International Standard is applicable to all elastomeric auxiliaries including orthodontic elastics, elastomeric bands, chains, links, thread and ligatures used for orthodontics both inside and outside the mouth, in conjunction with fixed and removable appliances.

2 Normative references

The following referenced documents are indispensable for the application 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[1)], *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical use — Specification and test methods*

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

3 Terms and definitions

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

3.1
orthodontic elastics
intra-oral and extra-oral elastomeric rings used to apply forces to teeth

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

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

3.4
orthodontic elastomeric ligatures
elastomeric rings used to retain wires to orthodontic attachments

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

1) To be published. (Replaces ISO 1942, parts 1 to 5)

3.6
link length
L
distance between the centres of the holes of adjacent links of orthodontic elastomeric chains

See Figure 1.

3.7
test length
length of elastomeric units for units under five links;

five links for chains;

20 mm loop circumference for thread;

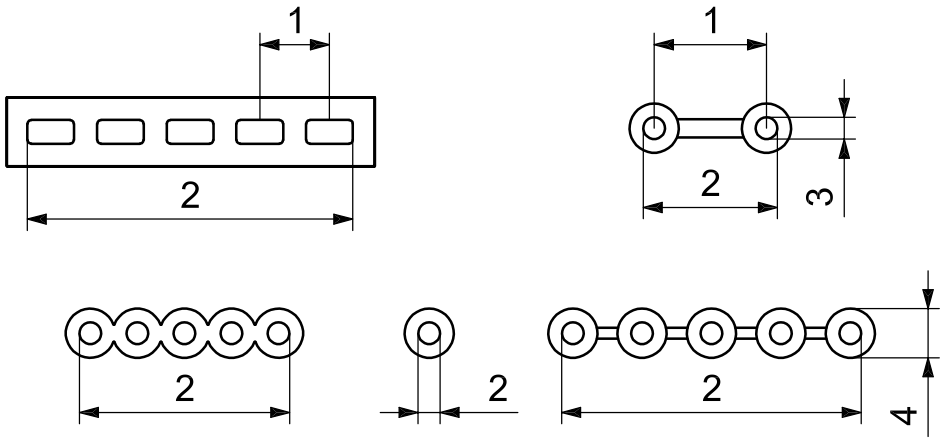
diameter of elastomeric ring without load

See Figure 1.

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

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.

4.2 Dimensions

When determined in accordance with 6.2, the following dimensions of the product shall comply with the ranges stated by the manufacturer.

4.2.1 Inner diameter, D_i, of elastics, chains, ligatures and separators.

4.2.2 Outer diameter, D_o, of threads, chains, ligatures and separators.

4.2.3 Link length, L, of chains.

4.2.4 Cross-section thickness, t, of elastics, chains, ligatures and separators.

4.3 Mechanical properties

4.3.1 Initial extension force

When determined in accordance with 6.3, the initial extension force, F_0, shall be within the range stated by the manufacturer.

4.3.2 24 hour residual force

When determined in accordance with 6.4, the 24 h residual force, F_{24}, shall be within the range stated by the manufacturer.

4.3.3 Ultimate extension

When determined in accordance with 6.5, the ultimate extension, A, of separators shall be within or exceed the range stated by the manufacturer.

Table 1 — Summary of requirements

	Inner diameter D_i	Outer diameter D_o	Link length L	Cross section thickness t	Initial extension force F_0	24 h residual force F_{24}	Ultimate extension A
Elastics	×			×	×	×	
Threads		×			×	×	
Chains	×	×	×	×	×	×	
Ligatures	×	×		×	×	×	
Separators	×	×		×	×	×	×
× = requirement to be determined.							