INTERNATIONAL STANDARD

ISO 21606

Second edition
2022-08

Dentistry — Elastomeric auxiliaries for use in orthodontics

Médecine bucco-dentaire — Auxiliaires élastomériques utilisés en orthodontie

Reference number
ISO 21606:2022(E)

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Published in Switzerland

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Foreword

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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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 21606:2007), which has been technically revised.

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

— subclause 5.1 has been clarified to type test with specification of specimen test quantity;

— subclause 5.5.2 has been clarified with the addition of the word “quickly” to the transfer of specimens from support plate to tensile tester adapters.

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 document 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.

NOTE Auxiliaries include orthodontic elastics, orthodontic elastomeric chains, orthodontic thread, orthodontic elastomeric ligatures and orthodontic elastomeric separators.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this document, 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.

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

ISO 1942, *Dentistry — Vocabulary*

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 given in ISO 1942 and the following apply.

ISO and IEC maintain terminology 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
elastomeric auxiliary
device with elastomeric properties used for transmission of forces including orthodontic *elastics* (3.2), orthodontic *elastomeric chains* (3.4), orthodontic threads, orthodontic *elastomeric ligatures* (3.5) and orthodontic *elastomeric separators* (3.6)

3.2
elastic
intra-oral and extra-oral elastomeric ring used to apply forces to orthodontic devices

3.3
elastomeric thread
elastomeric strand (that can be hollow) of constant cross-section used to apply forces to orthodontic devices

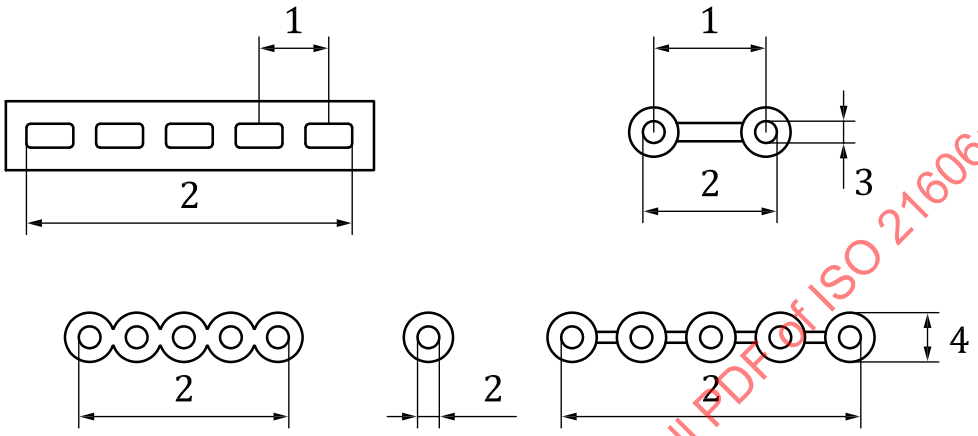
3.4
elastomeric chain
interconnected elastomeric rings or a multi-perforated elastomeric band used to apply forces to orthodontic devices

3.5
elastomeric ligature
elastomeric ring used to retain wires to orthodontic attachments

3.6
elastomeric separator
elastomeric product used to open interproximal spaces between teeth

3.7
link length
L
distance between the centres of the holes of adjacent links of *elastomeric chains* (3.4)

Note 1 to entry: See Figure 1.



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

3.8
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 elastomeric chain is five links shown in Figure 1.

Note 3 to entry: The test length for *elastomeric thread* (3.3) is the length necessary to make over a 20-mm loop circumference.

3.9
initial extension force
F_0
force exerted by the elastomeric auxiliary at three times the *test length* (3.8) after initial extension to four times the test length

3.10
24 h residual force
F_{24}
force exerted by the elastomeric auxiliary at three times the *test length* (3.8) at 24 h, after initial extension to four times the test length, and expressed as a percentage of the *initial extension force* (3.9)

3.11
ultimate extension
A
extension at break expressed as a percentage of the *test length* (3.8)

4 Requirements

4.1 General

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

4.2 Dimensions

When determined in accordance with 5.3, the following dimensions of the product shall comply with the ranges stated by the manufacturer:

a) inner diameter, D_i, of elastomeric elastic, elastomeric chain, elastomeric ligature and elastomeric separator;

b) outer diameter, D_o, of orthodontic elastomeric thread, chain ligature and separator;

c) link length, L, of orthodontic elastomeric chain;

d) cross-section thickness, t, of orthodontic elastomeric elastic, orthodontic elastomeric chain, orthodontic elastomeric ligature and orthodontic elastomeric separator.

4.3 Mechanical properties

4.3.1 Initial extension force

When determined in accordance with 5.4, the initial extension force, F_0, shall be within the range stated by the manufacturer.

4.3.2 24 h residual force

When determined in accordance with 5.5, 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 5.6, the ultimate extension, A, of an elastomeric separator 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
elastic	×			×	×	×	
elastomeric thread		×			×	×	
elastomeric chain	×	×	×	×	×	×	
elastomeric ligature	×	×		×	×	×	
elastomeric separator	×	×		×	×	×	×
Key × : requirement to be determined							

5 Test methods

5.1 Sampling

All tests described in this document are type tests. Type tests shall be made on 10 specimens selected at random from the same batch for retail sale. Each specimen shall be tested. When a test specimen breaks during testing, the specimen is considered to have failed the test. When the values for all 10 tested specimens are within the manufacturer's stated range of 6.1 c), the material is deemed to have complied with the requirements defined in Clause 4.

5.2 Ambient conditions

Force determinations shall be conducted at a temperature of (23 ± 2) °C and relative humidity of (50 ± 10) % (unless otherwise stated, as in 5.5.2).

5.3 Dimensions

5.3.1 Apparatus

Measuring device, with an accuracy of 0,01 mm (e.g. callipers, micrometer, optical comparator or other devices).

5.3.2 Procedure

Measure the dimensions required on each sample.

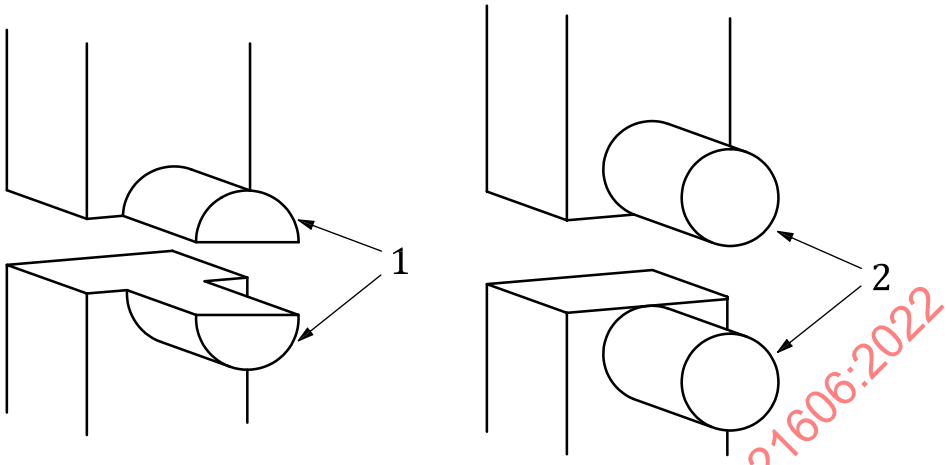
5.4 Initial extension force, F_0

5.4.1 Apparatus

5.4.1.1 Tensile testing machine, capable of a crosshead rate of (100 ± 10) mm/min and an accuracy of 0,1 % for force and 0,1 mm for extension.

5.4.1.2 Test apparatus, that incorporates two half-rods or rods that are parallel to each other and normal to the direction of the force. The radii of the half-rods shall be 0,5 mm for samples with an

inner diameter of less than 2,0 mm (see Figure 2). For all other auxiliaries the radius of the rod shall be 0,5 mm (see Figure 2). This test apparatus is intended to be mounted on the tensile testing machine.



Key

1 test half-rod shape for elastomeric auxiliaries with inner diameter less than 2 mm

2 test rod shape for elastomeric auxiliaries with inner diameter equal to or greater than 2 mm

Figure 2 — Test apparatus for a tensile test machine suitable for testing elastomeric auxiliaries

5.4.2 Procedure

The test lengths are as defined in 3.8, specified in 4.2 and illustrated in Figure 1.

Place the specimen over the rods of the testing apparatus. Extend the sample at a rate of 100 mm/min to 4 × the test length and hold for 5 s. After 5 s, relax extension at 100 mm/min to an extension of 3 × the test length.

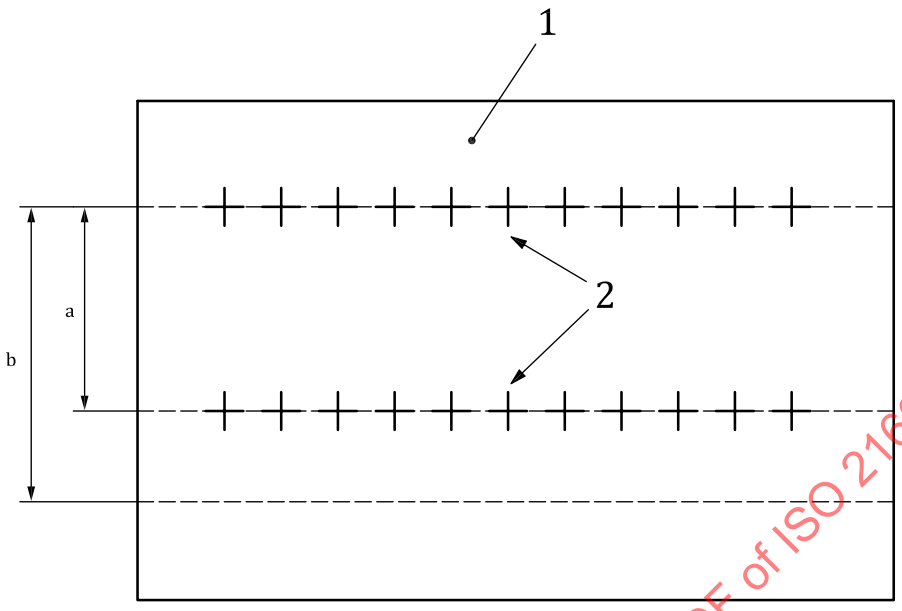
Determine the force exerted in newtons at (30 ± 2) s after reaching the latter extension.

5.5 24 h residual force, F_{24}

5.5.1 Apparatus

5.5.1.1 Tensile testing machine, capable of a crosshead rate of (100 ± 10) mm/min with an accuracy of 0,1 % for force and 0,1 mm for extension.

5.5.1.2 Support plate, with pins of 1 mm diameter set at appropriate distances as shown in Figure 3 and which can be used to extend and then maintain the specimens in the extended condition.



Key

1 plate to support pins

2 location of pins used to extend and then maintain the specimens extended

a Three times test length.

b Four times test length.

Figure 3 — Support plate with test pins for 24 h storing of extended elastomeric auxiliaries in water

5.5.2 Procedure

The test lengths are as defined in 3.7, specified in 4.2 and illustrated in Figure 1.

Apply the initial extensions defined in 3.7, specified in 4.2 for the initial extension force and after determining the initial extension force move the extended elastomeric auxiliaries without any relaxation on to the pins on the support plate (see Figure 3).

With the extended state of three times the test length applied, the specimens shall be stored on the support in water in accordance with ISO 3696:1987, Grade 3 at (37 ± 2) °C for (24 ± 2) h.

Remove the support plate maintaining the extended condition of the auxiliaries and immediately place in water in accordance with ISO 3696:1987, Grade 3 at (23 ± 2) °C for (30 ± 2) min. Then, take the support plate with the auxiliaries out of the water and transfer the specimens quickly on to the test rod (half-rod or rod-shaped on the adaptor [see Figure 2]), positioned apart at three times the test length. Determine the force in newton exerted at (23 ± 2) °C. Calculate the 24 h residual force, F_{24}, as the percentage of the initial extension force, F_0.

5.6 Ultimate extension, *A*

5.6.1 Apparatus

5.6.1.1 Tensile testing machine, capable of a crosshead rate of (100 ± 10) mm/min with an accuracy of 0,1 mm for extension.