INTERNATIONAL STANDARD

ISO 21606

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Dentistry — Elastomeric auxiliaries for use in orthodontics

Art dentaire — Auxiliaires élastomères utilisés en orthodontie

Reference number
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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.

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;

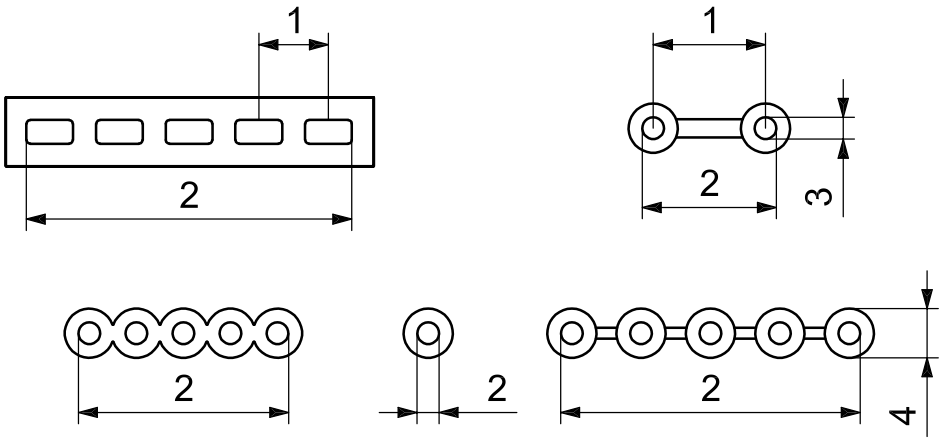
diameter of elastomeric ring without load

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.							

5 Sampling

Samples of a single product shall be prepared for retail sale from the same batch, before their expiry date, and containing enough material to carry out the required tests.

6 Test methods

6.1 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 6.4.2).

6.2 Dimensions

6.2.1 Apparatus

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

6.2.2 Procedure

Select 10 specimens at random and measure the dimensions required on each sample.

6.2.3 Treatment of results

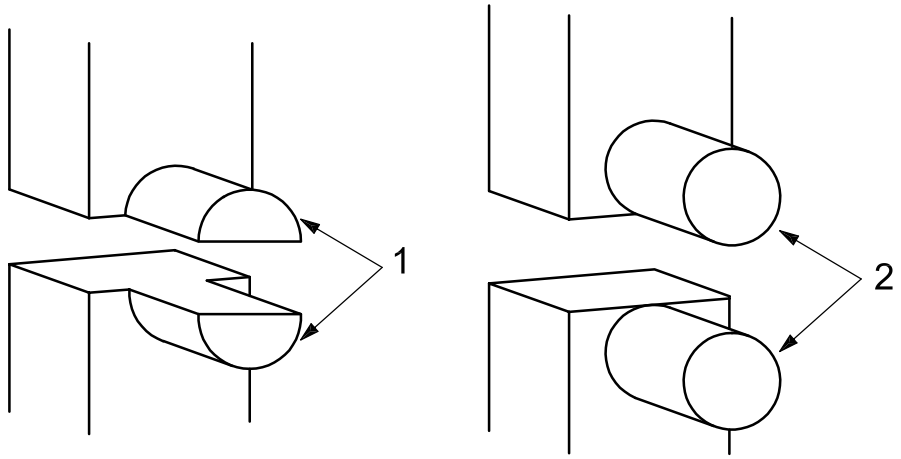
When the dimensions for all 10 specimens are within the manufacturer's stated range, the product is deemed to comply with the requirements of 4.2.

6.3 Initial extension force, F_0

6.3.1 Apparatus

6.3.1.1 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.

6.3.1.2 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 less than 2,0 mm (Figure 2). For all other auxiliaries the radius of the rod shall be 0,5 mm (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 tensile test machine suitable for testing elastomeric auxiliaries

6.3.2 Procedure

Select ten specimens at random and test each specimen. The test lengths are as defined in 3.7, 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.

6.3.3 Treatment of results

When a test specimen breaks during testing, the specimen is considered to have failed the test.

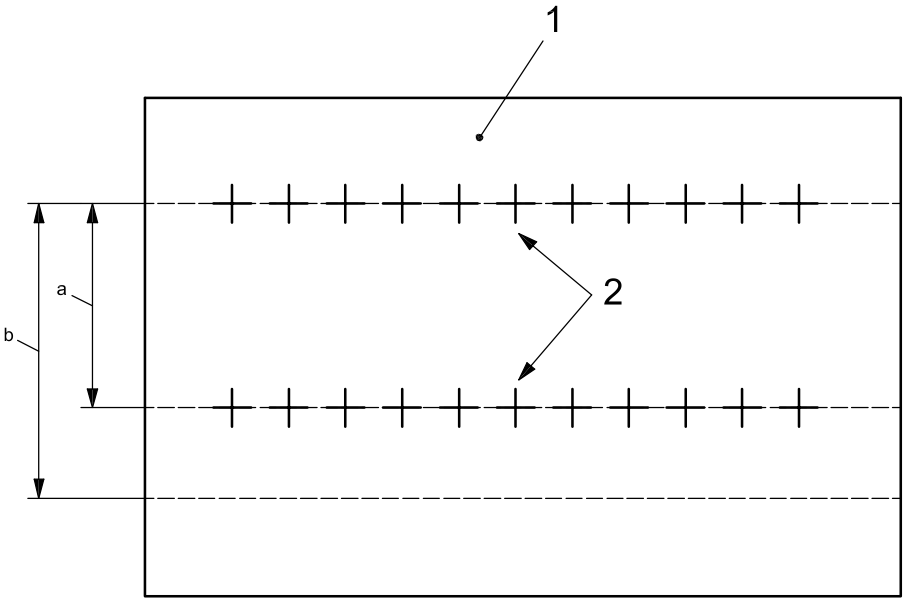
When the values for all ten tested specimens are within the manufacturer's stated range, the material is deemed to have complied with the requirement of 4.3.1.

6.4 24 hour residual force, F_{24}

6.4.1 Apparatus

6.4.1.1 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.

6.4.1.2 Support plate, with pins of 1 mm diameter set at appropriate distances as shown in Figure 3 and which may 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

6.4.2 Procedure

Select ten specimens at random and test each specimen. The test lengths are as defined in 3.7, specified in 4.2 and illustrated in Figure 1.

Apply the initial extensions defined in 6.3.2 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 (Figure 3).

With the extended state of three times the test length applied, the specimens are to be stored on the support in water (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 (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 without relaxation on to the test rod (half-rod or rod shaped on the adaptor [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.

6.4.3 Treatment of results

Where a test specimen breaks during the test, the test specimen is considered to have failed the test.

When the values for all ten specimens are within the manufacturer's stated range, the material is deemed to have complied with the requirement of 4.3.2.

6.5 Ultimate extension, A

6.5.1 Apparatus

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

6.5.2 Procedure

Select ten specimens at random and test each specimen. The test lengths are as defined in 3.7, specified in 4.2 and illustrated in Figure 1.

Place the specimen over the rods of the test apparatus illustrated in Figure 2. Extend the sample at 100 mm/min to fracture and determine the percentage extension at break.

6.5.3 Treatment of results

When the values for all ten samples are within or exceed the manufacturer's stated range, the material is deemed to have complied with the requirement of 4.3.3.

7 Marking, labelling and packaging

NOTE Additional information may be included at the discretion of the manufacturer or as required by legislation.

7.1 General requirements

The manufacturer shall make the following readily available in the catalogue, packaging insert, labelling or other readily accessible means:

a) intended use;

b) material type;

c) ranges of dimensions and of mechanical properties specified in Clause 4.

Adequate containment and protection from contamination during transit and storage shall be provided in accordance with acceptable commercial practice.

7.2 Packaging and labelling

Each package shall be labelled with at least the following information:

a) name and address of the manufacturer and/or distributor;

b) name or trade name of the auxiliary;

c) nominal dimensions or force of the auxiliary;

d) lot number;

e) quantity of auxiliaries;

f) intended use of the auxiliary;

g) expiry date expressed in accordance with ISO 8601;

h) recommended storage conditions.

Bibliography

[1] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

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

[3] ISO 11095, *Linear calibration using reference materials*

ICS 11.060.10

Price based on 8 pages