INTERNATIONAL STANDARD

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First edition
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Dentistry — Wires for use in orthodontics

Art dentaire — Fils pour utilisation en orthodontie

Reference number
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Foreword

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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 15841 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

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Introduction

This first edition of ISO 15841 has been developed as a result of the difficulty often encountered by clinicians in making meaningful comparisons between wires using the information currently available from manufacturers and suppliers.

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Dentistry — Wires for use in orthodontics

1 Scope

This International Standard specifies requirements and test methods for wires to be used in fixed and removable orthodontic appliances. It includes preformed orthodontic archwires but excludes springs and other preformed components.

This International Standard gives detailed requirements concerning the presentation of the physical and mechanical properties of orthodontic wires, the test methods by which they can be determined, packaging, and labelling information.

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

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, *Dentistry — Vocabulary*

ISO 6892, *Metallic materials — Tensile testing at ambient temperature*

3 Terms and definitions

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

3.1
austenite-finish temperature
T_{af}
temperature at which the metallurgical transformation from the low-temperature martensite phase to the high-temperature austenite phase is completed

3.2
bending stiffness
S_b
increment of load to produce a unit increment of deflection in the proportional region, expressed in N/mm (e.g. used in the bend test)

3.3
descriptor
code to identify the nominal cross-sectional dimension(s) of a wire in thousandths of an inch without unit designation, in accordance with accepted orthodontic practice (e.g., 16, 18, 17 × 25, 21 × 21)

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3.4
diagonal
largest cross-sectional dimension of a rectangular wire

See Figure 1.

3.5
multistrand wire
orthodontic wire fabricated from two or more individual strands of wire that may be twisted, braided or made into a co-axial wire

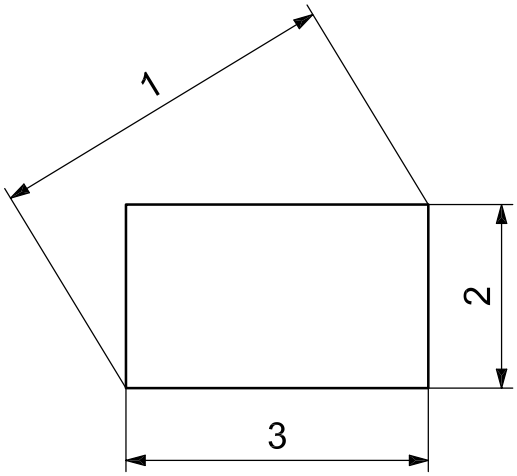
3.6
offset bending force
$F_{S(0,1)}$
force measured at a permanent deflection of 0,1 mm during loading in the bend test

3.7
height
smaller cross-sectional dimension of a rectangular wire

See Figure 1.

3.8
width
larger cross-sectional dimension of a rectangular wire

See Figure 1.



Key

1 diagonal
2 height
3 width

Figure 1 — Dimensions of cross-section of a wire

4 Classification

For the purposes of this document, wires are classified on the basis of their elastic behaviour.

a) **Type 1 wires**: wires displaying linear elastic behaviour during unloading at temperatures up to 50 °C.

b) **Type 2 wires**: wires not displaying linear elastic behaviour during unloading at temperatures up to 50 °C.

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5 Requirements

5.1 General

The manufacturer shall declare the following properties, which, when tested in accordance with the test methods described in Clause 6, shall be within the ranges stated by the manufacturer.

5.2 Dimensions

Each cross-sectional dimension (diameter, width, height and diagonal, as applicable) of the wire shall be stated to the nearest 0,01 mm. For multistrand wires, the dimensions shall be the internal dimensions of a tube that would just contain the wire.

5.3 Austenite-finish temperature

For Type 2 wires, the austenite-finish temperature shall be stated to the nearest 1 °C.

5.4 Mechanical properties

5.4.1 Type 1 wires

When a manufacturer states that different segments of an orthodontic wire have different mechanical properties, the results for each segment shall be tested separately and stated separately.

The elastic modulus, in gigapascals, 0,2 % proof strength, in megapascals, and percentage elongation after fracture when tested in accordance with 6.4.2, shall be stated.

The bending stiffness, in newtons per millimetre, and 0,1 mm offset bending force, in newtons, when tested in accordance with 6.4.3 shall be stated.

5.4.2 Type 2 wires

When tested in three-point bending (see 6.4.3), the force magnitudes measured during unloading at deflections of 3,0 mm, 2,0 mm, 1,0 mm and 0,5 mm and the permanent deflection after unloading shall be stated.

5.5 Hazardous elements

For the purposes of this document, nickel and beryllium are designated to be hazardous elements and the manufacturer must state their percentage concentrations.

6 Test methods

6.1 Sampling

Six specimens of a single product from one batch shall be procured for each test. Where the manufacturer recommends heat treatment prior to clinical use, that heat treatment shall be carried out according to the manufacturer's instructions, before testing.

6.2 Dimensions

Measurement shall be taken using callipers, micrometers, optical comparators or other devices with a precision of 0,005 mm.

Measurements shall be made on each dimension of each sample.

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6.3 Austenite-finish temperature

6.3.1 Apparatus

6.3.1.1 Differential scanning calorimetry apparatus, calibrated to 1 °C.

6.3.2 Procedure

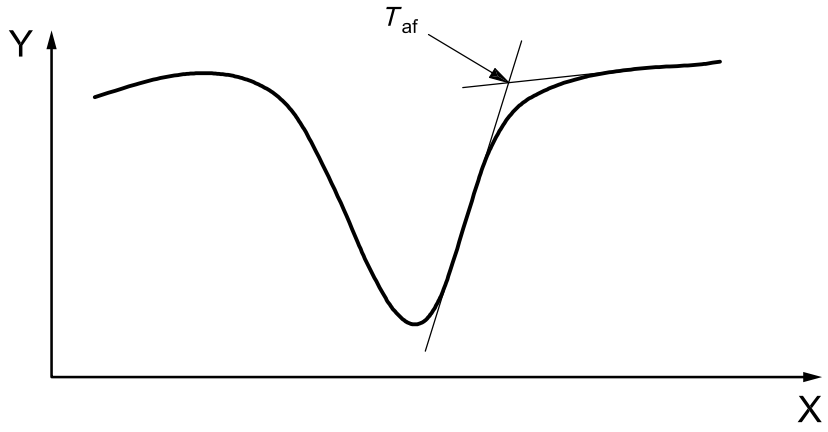
Determine the austenite-finish temperature by differential scanning calorimetry according to the instructions for the instrument.

A heating rate of 10 °C/min shall be used.

Cut specimens to a length suitable for the test instrument.

6.3.3 Determination of austenite-finish temperature

From the curve obtained by differential scanning calorimetry (see Figure 2), the austenite-finish temperature shall be determined from the high temperature side of the valley, as the point of intersection between the tangent drawn at the inflection point and the asymptotic line to the adjacent baseline curve. The intersection of the tangent lines is determined as the austenite-finish temperature, T_{af}, and is reported in degrees centigrade.



Key

X temperature, in degrees centigrade
Y heat flow, in joules per second

Figure 2 — Differential scanning calorimetry curve and interpretation

6.4 Mechanical tests

6.4.1 General

Samples for tensile or bend tests shall be straight. If the wire is delivered coiled, care shall be taken to straighten it. When samples are taken from preformed orthodontic archwires, the samples shall be cut from the straightest section of the archwire.

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6.4.2 Tensile test

6.4.2.1 General

The tests shall be carried out in accordance with ISO 6892 to obtain the elastic modulus, 0,2 % proof strength and percentage elongation after fracture.

6.4.2.2 Apparatus

6.4.2.2.1 Tensile testing apparatus, calibrated for a crosshead rate and force in the range of 0,5 mm/min to 2,0 mm/min.

6.4.2.2.2 Micrometer or equivalent instrument, calibrated to an accuracy of 0,005 mm.

6.4.2.3 Procedure

6.4.2.3.1 The crosshead rate shall be in the range of 0,5 mm/min to 2,0 mm/min.

6.4.2.3.2 The original cross-sectional area, S_0, shall be determined using a micrometer or equivalent instrument (6.4.2.2.2) with an accuracy of 0,005 mm. For products of circular cross-section, the original cross-sectional area may be calculated from the arithmetic mean of two measurements carried out in two perpendicular directions. The original cross-sectional area may also be determined from the mass of a known length and the material's density.

6.4.2.3.3 The original gauge length, L_0, shall be taken as (20 $\pm$ 0,2) mm.

6.4.2.3.4 The distance between the grips of the machine shall be at least (L_0 + 50) mm.

6.4.2.3.5 Determine the percentage elongation after fracture using a measuring device with 0,1 mm resolution.

6.4.2.3.6 Determine the elastic modulus from the slope of the linear portion of the force-deflection diagram.

6.4.2.3.7 Determine the proof strength from the stress-strain diagram at 0,2 % strain.

6.4.3 Bend test

6.4.3.1 Apparatus

6.4.3.1.1 Compression testing apparatus, calibrated for a crosshead rate and force in the range of 0,5 mm/min to 2,0 mm/min.

6.4.3.2 Procedure

6.4.3.2.1 The crosshead rate shall be (7,5 $\pm$ 2,5) mm/min.

6.4.3.2.2 Specimens shall be cut to a minimum length of 30 mm.

6.4.3.2.3 The wires shall be subjected to a symmetrical three-point bend test.

6.4.3.2.4 A span of wire 10 mm between supports shall be used (see Figure 3).

6.4.3.2.5 Deflection shall be carried out with a centrally-placed indenter.

6.4.3.2.6 The radii of fulcrum and indenter shall be (0,10 $\pm$ 0,05) mm.

6.4.3.2.7 Rectangular wires shall be tested in the direction of the height of the wire.

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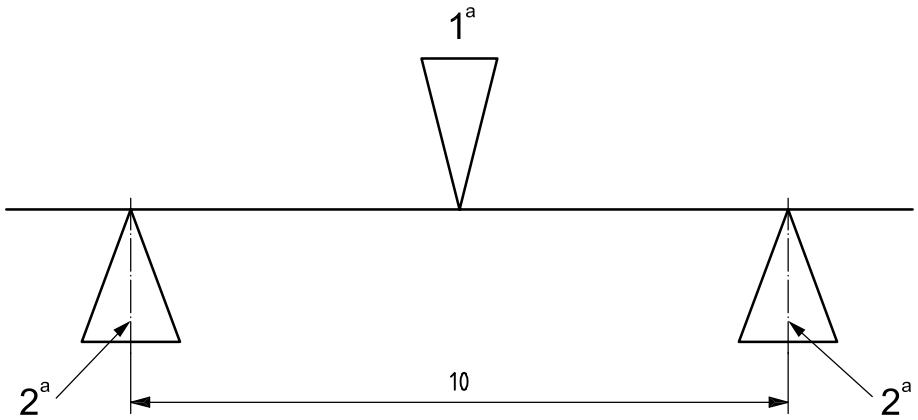
Dimensions in millimetres



Key

1 indenter

2 fulcrum

a The radii of fulcrum and indenter shall be (0,10 ± 0,05) mm.

Figure 3 — Three-point bend test

6.4.3.3 Procedure for Type 1 wires

6.4.3.3.1 Type 1 wires may be tested at room temperature (23 ± 2) °C.

6.4.3.3.2 The wire shall be deflected to a minimum permanent deflection of 0,1 mm.

6.4.3.3.3 Bending stiffness is determined from the force-deflection diagram by calculating the slope of the linear portion of the curve.

6.4.3.4 Procedure for Type 2 wires

6.4.3.4.1 Type 2 wires shall be tested in the range (36 ± 1) °C.

6.4.3.4.2 The wire shall be deflected to 3,1 mm.

6.4.3.4.3 Bending force during unloading is determined from the force-deflection diagram by recording the force readings taken at deflections of 3,0, 2,0, 1,0, and 0,5 mm (see Figure 4).

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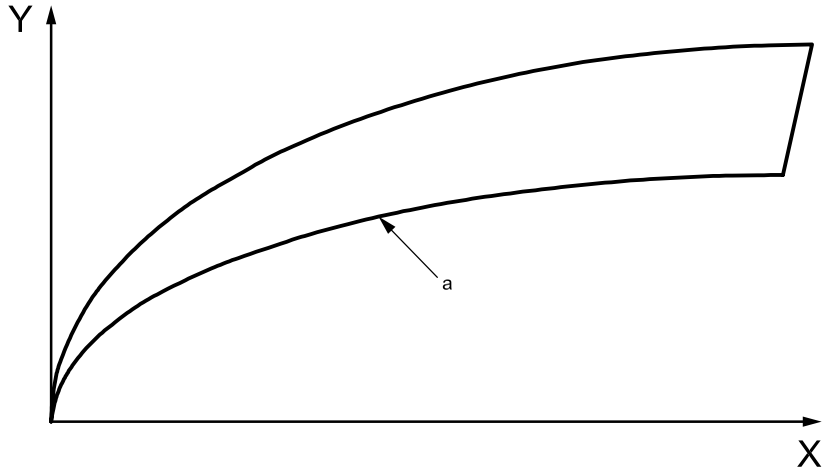

Key

X deflection, in millimetres.

Y force, in newtons.

[a] Results are measured on the unloading curve (lower curve).

Figure 4 — Bend test curve

7 Packaging and labelling information to be provided to the user

7.1 General requirements

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

a) the classification of the wire;

b) the recommended heat-treating procedure for heat-treatable alloys;

c) declaration of chemical composition: the range of composition of the alloy shall include all elements present at concentrations of 0,1 % by mass or greater;

d) the range of each cross-sectional dimension determined in accordance with 5.2;

e) the mechanical properties determined in accordance with 5.4;

f) the austenite-finish temperature where applicable determined in accordance with 5.3.

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

7.2 Packaging

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

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7.3 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 wire;

c) dimensions of wire, in millimetres (additional use of a descriptor is permitted);

d) lot number;

e) the quantity of wires in number, length or weight;

f) the intended use of the wire;

g) for products containing nickel or beryllium, a warning symbol (a triangle with an exclamation point) and the text: “This product contains nickel.” and/or “This product contains beryllium.” shall be included.

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[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*

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