INTERNATIONAL STANDARD

ISO 15841

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Dentistry — Wires for use in orthodontics

Art dentaire — Fils pour utilisation 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.

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*.

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.

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)

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

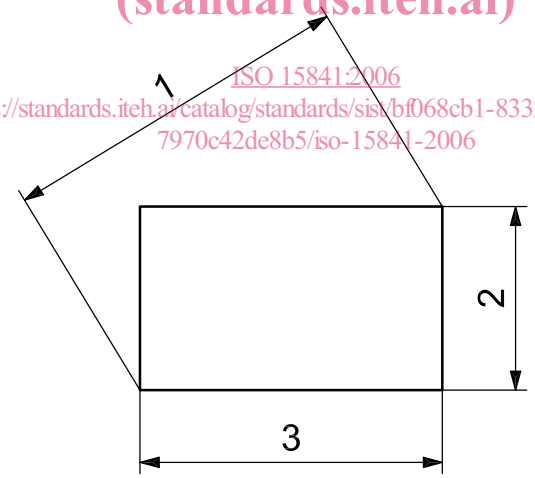
3.6
offset bending force
$F_{S(0,1)}$
force measured at a permanent deflection of 0,1 mm during loading in the bend test

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.

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.