INTERNATIONAL STANDARD

ISO 15841

Second edition
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Dentistry — Wires for use in orthodontics

Médecine bucco-dentaire — Fils pour utilisation en orthodontie

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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This second edition of ISO 15841 cancels and replaces the first edition (ISO 15841:2006), which has been revised to include a reference to ASTM F2082.

Introduction

As with the first edition, the second edition of this International Standard has been developed to help clinicians compare the wires from different manufacturers and suppliers. In particular, it has been written as a result of the development of new test methods.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this International Standard. For the assessment of possible biological hazards, reference can be made to ISO 10993 and ISO 7405.

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, and packaging and labelling information.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ASTM F2082, *Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery*

3 Terms and definitions

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

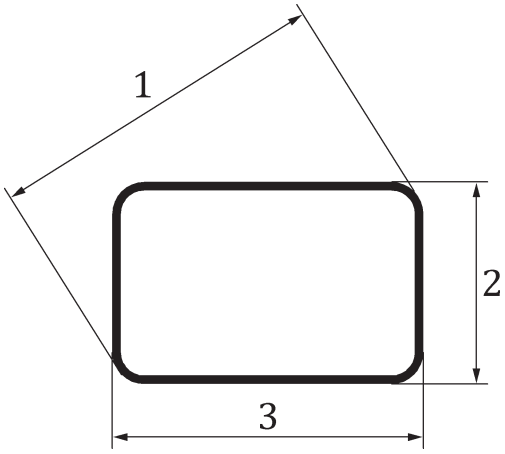
3.1
austenite-finish temperature
T_{af}
temperature at which the metallurgical transformation from the low-temperature martensite phase to the high-temperature austenite phase is completed

3.2
force deflection rate
F_{Δ}
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 dimension(s) in thousandths of an inch without unit designation, in accordance with accepted orthodontic practice

3.4
diagonal
largest cross-sectional dimension of a rectangular wire

Note 1 to entry: See Figure 1.



Key

1 diagonal
2 height
3 width

Figure 1 — Dimensions of cross section of a wire

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
smallest cross-sectional dimension of a rectangular wire

Note 1 to entry: See Figure 1.

3.8
width
larger of the height and width dimensions of a rectangular wire

Note 1 to entry: See Figure 1.

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 displaying nonlinear 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. Austenite-finish temperature shall be determined in accordance with either 6.3.1 or 6.3.2.

5.4 Mechanical properties

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.

5.4.1 Type 1 wires

The modulus of elasticity, 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 force deflection rate, 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

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, when tested in accordance with 6.4.3 shall be stated.

5.5 Hazardous elements

For the purposes of this International Standard, cadmium, beryllium, lead and nickel are designated to be hazardous elements and the manufacturer shall state the concentrations as a mass fraction expressed as a percentage.

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 accuracy of 0,005 mm.

Measurements shall be made on each dimension of each sample.