

Irish Standard I.S. EN ISO 15841:2014

Dentistry - Wires for use in orthodontics (ISO 15841:2014)

I.S. EN ISO 15841:2014

2014-09-06

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This document is based on: Published:

EN ISO 15841:2014 2014-08-20

This document was published ICS number:

under the authority of the NSAI
and comes into effect on:
11.060.10

NOTE: If blank see CEN/CENELEC cover page

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EUROPEAN STANDARD

EN ISO 15841

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2014

ICS 11.060.10

Supersedes EN ISO 15841:2006

English Version

Dentistry - Wires for use in orthodontics (ISO 15841:2014)

Médecine bucco-dentaire - Fils pour utilisation en orthodontie (ISO 15841:2014)

Zahnheilkunde - Drähte für die Kieferorthopädie (ISO 15841:2014)

This European Standard was approved by CEN on 25 July 2014.

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EN ISO 15841:2014 (E)

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EN ISO 15841:2014 (E)

Foreword

This document (EN ISO 15841:2014) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2015, and conflicting national standards shall be withdrawn at the latest by February 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15841:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15841:2014 has been approved by CEN as EN ISO 15841:2014 without any modification.

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INTERNATIONAL STANDARD

ISO 15841

Second edition 2014-08-15

Dentistry — Wires for use in orthodontics

Médecine bucco-dentaire — Fils pour utilisation en orthodontie





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Published in Switzerland

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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.

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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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.

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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, 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_{2f}

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

 $^{F}\Delta$

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.



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