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Dentistry — Coiled springs for use in orthodontics

Médecine bucco-dentaire — Ressorts hélicoïdaux à usage orthodontique

ICS: 11.060.10

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This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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).

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](#)

ISO 17254 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Introduction

This International Standard has been developed to specify the information provided by manufacturers and suppliers to help clinicians compare coiled springs.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this International Standard, but it is recommended that, for the assessment of possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO 7405.

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Dentistry — Coiled springs for use in orthodontics

1 Scope

This International Standard is applied to coiled springs for use in orthodontic appliances.

This International Standard gives details of methods to compare the physical and mechanical properties of coiled springs, the test methods by which they can be determined, as well as packaging and labelling requirements.

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*

3 Terms and definitions

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

3.1

inner (internal spring) diameter

id

the maximum outside diameter of a tube that could be contained within a coiled spring

Note 1 to entry: See [Figure 1](#).

3.2

outer diameter

od

the maximum inside diameter of a tube within which a coiled spring could be contained

Note 1 to entry: See [Figure 1](#).

3.3

wire cross section dimensions

wd

the cross section dimensions of the wire used to manufacture the spring

Note 1 to entry: See [Figure 1](#).

3.4

unloaded length

l_u

3.4.1

for compression springs, the overall length in the unloaded position

3.4.2

for extension springs, the maximum dimension excluding the hooks, eyelets or connection means in the unloaded position

Note 1 to entry: See [Figure 1](#).

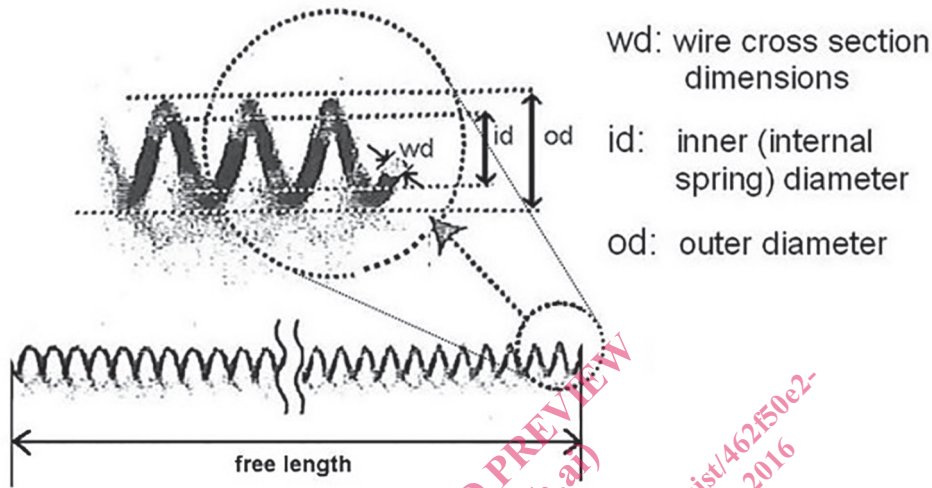


Figure 1 — Coiled Spring Dimensions

3.5
total spring length

l_t
for springs with attachments, the maximum dimension including the hooks, eyelets or connection means in the unloaded position.

3.6
maximum compression

C_{max}
the percentage of the unloaded length of the spring at complete compression

3.7
maximum extension

ϵ_{max}
the lengthening of the spring, in percent, required to produce a permanent deflection of 1 % of the unloaded coil length

3.8
spring load

$L_{80\%max}, L_{60\%max}, L_{40\%max}, L_{20\%max}$
the force exerted by the spring on the return (unloading) cycle following loading to the specified maximum extension or compression at 80 %, 60 %, 40 %, 20 % of the maximum extension or compression

4 Requirements

4.1 General

The manufacturer shall declare the following properties, which, when tested in accordance with the test methods described in [Clause 5](#), shall be within the ranges stated by the manufacturer.

4.2 Dimensions

4.2.1 The following dimensions shall be stated to the nearest 0,01 mm. When determined according to [Clause 5](#), the following dimensions of the product shall comply with the ranges stated by the manufacturer

- a) inner diameter id
- b) outer diameter od
- c) unloaded length l_u
- d) total spring length l_t

4.3 Mechanical properties

4.3.1 Measure the elastic behaviour during unloading

- a) maximum extension ϵ_{\max}
- b) maximum compression c_{\max}
- c) spring load L80%max, L60%max, L40%max, and L20%max of the maximum extension or compression

4.4 Hazardous elements

For the purposes of this International Standard, cadmium, beryllium, and nickel are designated to be hazardous elements and the manufacturer shall state for each the concentrations as a mass fraction expressed as a percentage when each is present greater than 0.1 %.

5 Test methods

5.1 Sampling

Six specimens of a single product from one batch shall be procured for each test.

Measurements shall be made on each dimension of each specimen.

5.2 Dimensions

5.2.1 Apparatus

Measurements shall be taken with calipers, micrometers, optical comparators, or other devices with an accuracy of 0,005 mm.

5.2.2 Measurement procedures

Measure the following to the nearest 0,01 mm: inner diameter, id , outer diameter, od , total length l_t , and unloaded length, l_u , per their respective definitions.

5.3 Mechanical properties

5.3.1 Apparatus

Measurements shall be made using a mechanical testing machine, calibrated for force and deformation at a crosshead rate in the range of 0,5 mm/min to 10,0 mm/min.