

INTERNATIONAL  
STANDARD

ISO  
17254

First edition  
2016-07-15

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## Dentistry — Coiled springs for use in orthodontics

*Médecine bucco-dentaire — Ressorts hélicoïdaux à usage  
orthodontique*



Reference number  
ISO 17254:2016(E)



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# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Requirements</b> .....	<b>3</b>
4.1 General .....	3
4.2 Dimensions .....	3
4.3 Mechanical properties .....	3
4.4 Hazardous elements .....	3
<b>5 Test methods</b> .....	<b>3</b>
5.1 Sampling .....	3
5.2 Dimensions .....	3
5.2.1 Apparatus .....	3
5.2.2 Measurement procedures .....	3
5.3 Mechanical properties .....	4
5.3.1 Apparatus .....	4
5.3.2 Measurement procedures .....	4
5.4 Treatment of results .....	4
<b>6 Packaging and labelling information</b> .....	<b>4</b>
6.1 General requirements .....	4
6.2 Packaging .....	4
6.3 Labelling .....	5
<b>Bibliography</b> .....	<b>6</b>

## 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](http://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](http://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*.

## 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 for the assessment of possible biological or toxicological hazards, reference can be made to ISO 10993-1 and ISO 7405.



# Dentistry — Coiled springs for use in orthodontics

## 1 Scope

This International Standard applies 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

$d_i$

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

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

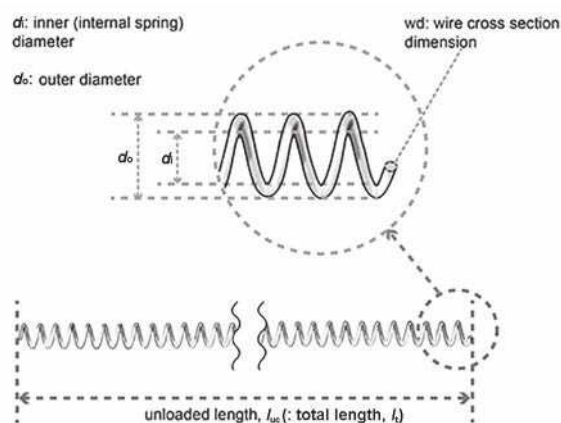


Figure 1 — Coiled Spring Dimensions

### 3.2

#### outer diameter

$d_o$

minimum 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**

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

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

**3.4**  
**unloaded spring length**

$l_{uc}$   
<compression springs> overall length in the unloaded position

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

**3.5**  
**unloaded spring length**

$l_{ue}$   
<extension springs> maximum dimension including the hooks, eyelets or connection means in the unloaded position

Note 1 to entry: See [Figure 2](#).

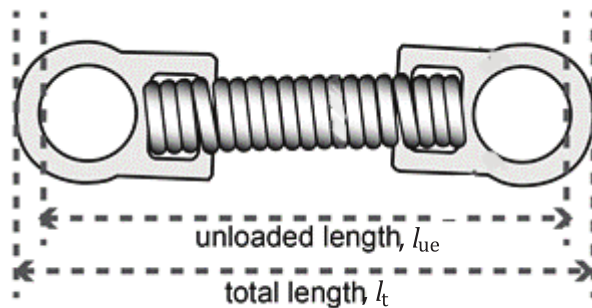


Figure 2 — Coiled Springs Dimensions with Attachments.

**3.6**  
**total spring length**

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

**3.7**  
**maximum compression**

$c_{max}$   
percentage of the spring at complete compression against the unloaded spring length

**3.8**  
**maximum extension**

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

**3.9**  
**spring load**

$L_{80\%max}$ ,  $L_{60\%max}$ ,  $L_{40\%max}$ ,  $L_{20\%max}$   
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  $d_i$
- b) outer diameter  $d_o$
- c) unloaded spring length  $l_{uc}$  or  $l_{ue}$
- d) total spring length  $l_t$

### 4.3 Mechanical properties

**4.3.1** Measure the elastic behaviour during unloading:

- a) maximum extension,  $\varepsilon_{max}$
- b) maximum compression,  $c_{max}$
- c) spring load,  $L_{80\%max}$ ,  $L_{60\%max}$ ,  $L_{40\%max}$ , and  $L_{20\%max}$ , of the maximum extension or compression

### 4.4 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.

## 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,  $d_i$ , outer diameter,  $d_o$ , total length,  $l_t$ , and unloaded spring length,  $l_{uc}$  or  $l_{ue}$ , 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 displacement at a crosshead rate in the range of 0,5 mm/min to 10,0 mm/min.

### 5.3.2 Measurement procedures

**5.3.2.1** Tests shall be performed at  $(23 \pm 2)$  °C except for temperature sensitive springs that shall be tested at  $(36 \pm 1)$  °C.

**5.3.2.2** The crosshead rate shall be in the range of 0,5 mm/min to 10,0 mm/min.

**5.3.2.3** The length of the specimen shall be taken as  $(20 \pm 0,2)$  mm or the unloaded spring length if less than 20 mm.

**5.3.2.4** Determine the following mechanical behaviour of the springs:

- a) maximum extension,  $\epsilon_{\max}$
- b) maximum compression,  $c_{\max}$
- c) spring load,  $L_{80\%_{\max}}$ ,  $L_{60\%_{\max}}$ ,  $L_{40\%_{\max}}$ ,  $L_{20\%_{\max}}$ , of maximum extension or compression

## 5.4 Treatment of results

The test results of each specimen shall be within the manufacturer's specified range in order for the material to comply with the requirements.

## 6 Packaging and labelling information

### 6.1 General requirements

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

- a) 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, and the mass fractions of any hazardous elements as defined in [4.4](#);
- b) the range of each dimension shall be in accordance with [5.2](#);
- c) spring design i.e., Compression (open) or Extension (closed);
- d) the range of each mechanical property shall be in accordance with [5.3.2.4](#).

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

### 6.2 Packaging

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

### 6.3 Labelling

Each package shall be labelled with at least the following information:

- a) the name and address of the manufacturer and, where applicable, of the distributor;
- b) the name or trade name of the spring;
- c) the design of the spring;
- d) the lot number;
- e) the quantity of springs within the package;
- f) a warning for products containing hazardous elements (where appropriate, this information should take the form of symbols).

## Bibliography

- [1] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- [2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*



