BS EN ISO 17254:2016

BSI Standards Publication

Dentistry — Coiled springs for use in orthodontics (ISO 17254:2016)

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2016

ISBN 978 0 580 80474 8

ICS 11.060.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2016.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 17254

August 2016

ICS 11.060.10

English Version

Dentistry - Coiled springs for use in orthodontics (ISO 17254:2016)

Médecine bucco-dentaire - Ressorts hélicoïdaux à usage orthodontique (ISO 17254:2016)

Zahnheilkunde - Spiralfedern für die Kieferorthopädie (ISO 17254:2016)

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European foreword

This document (EN ISO 17254:2016) 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.

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Foreword

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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.

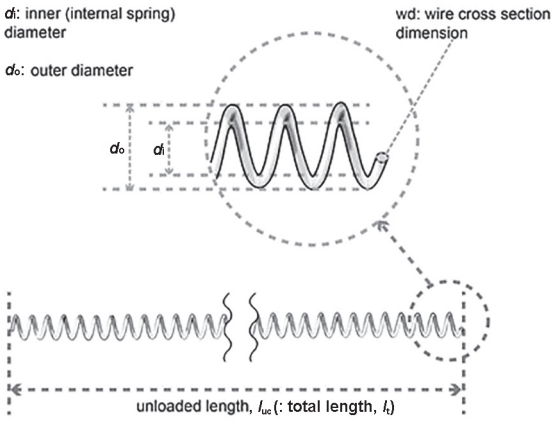

Figure 1 — Coiled Spring Dimensions

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
wd
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.

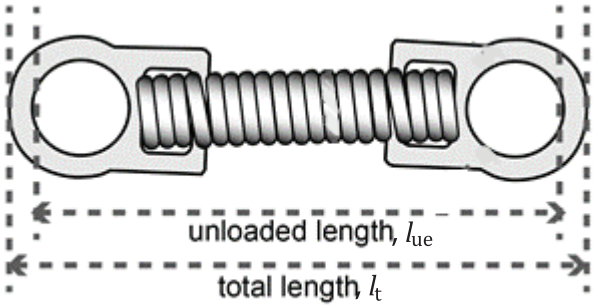

Figure 2 — Coiled Springs Dimensions with Attachments.

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
ε_{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, ε_{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 ± 2) °C except for temperature sensitive springs that shall be tested at (36 ± 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 ± 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, ε_{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*

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