INTERNATIONAL STANDARD

ISO 11499

Second edition
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Dentistry — Single-use cartridges for local anaesthetics

Art dentaire — Cartouches à usage unique pour anesthésiques locaux

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11499 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This second edition cancels and replaces the first edition (ISO 11499:1997), which has been technically revised. The following changes have been made:

a) introduction of a colour coding system for the concentration of the anaesthetic agent in single-use cartridges for local anaesthetics;

b) introduction of a colour coding system for the concentration of the vasoconstrictor in single-use cartridges for local anaesthetics.

Introduction

The safe and efficient operation of dental cartridges for local anaesthetics depends on their freedom from leakage, the control of the forces required to initiate and maintain the plunger movement and the absence of large air bubbles.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

Dentistry — Single-use cartridges for local anaesthetics

1 Scope

This International Standard gives specific performance requirements for single-use dental cartridges of 1,8 ml and 2,2 ml nominal capacity for use with local anaesthetics.

It specifies tests for leakage, plunger movement, extractable volume and underfilling, and lists general overall dimensions to ensure that the cartridge will fit dental cartridge syringes complying with ISO 9997.

Labelling requirements are also specified.

NOTE A list of International Standards for certain types of cartridge component is given in the Bibliography

2 Normative references

The following referenced documents are indispensable for the application of this document. 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 9997, *Dental cartridge syringes*

ISO 7885, *Sterile dental injection needles for single use*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

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

3.1
cartridges for local anaesthetics
cartridges containing local anaesthetics designed for use with dental cartridge syringes

4 Requirements

4.1 Freedom from leakage of anaesthetic solution

The filled cartridge shall be free from leakage of anaesthetic solution.

Tests shall be carried out in accordance with 5.4.

4.2 Force required for plunger movement

4.2.1 The force, F_1, to initiate movement of the plunger shall not exceed 30 N.

4.2.2 The force, F_2, to sustain movement of the plunger throughout its effective length shall not exceed 20 N and shall not be less than 2 N.

Tests shall be carried out in accordance with 5.5.

4.3 Underfilling of cartridges

The air bubble in the cartridge shall not be visible below the rim of the aluminium cap.

Tests shall be carried out in accordance with 5.6.

4.4 Biocompatibility

Components of the cartridge in contact with the anaesthetic solution shall neither react with the anaesthetic solution nor release any substances that may adversely affect the therapeutic effectiveness of the injectable products, including those substances which may exhibit toxic, pyrogenic or haemolytic reactions. See Introduction for application of other International Standards.

4.5 Extractable volume

When tested, the extractable volume shall not be less than the capacity stated in 6.1 b) and 6.2 c).

Tests shall be carried out in accordance with 5.7.

4.6 External dimensions of the assembled cartridge

4.6.1 Overall length

The maximum overall length of a 1,8 ml cartridge shall be 65,0 mm.

The maximum overall length of a 2,2 ml cartridge shall be 77,5 mm.

4.6.2 **Overall diameter** (including label if fitted)

The maximum overall diameter shall be 9,0 mm.

4.7 Colour coding

4.7.1 Colour coding shall be at the discretion of the manufacturer

If colour coding is used, it shall comply with the following.

Two indelible coloured bands (Band 1 and Band 2) shall completely encircle the cartridge. Band 1 shall indicate the active anaesthetic ingredient and concentration according to Table 1. Band 2 shall indicate the vasoconstrictor and concentration according to Table 2.

See Figure 1.

Table 1 — Colour coding system for the anaesthetic agent and the concentration in single-use cartridges for local anaesthetics

Local anaesthetic agent and concentration	Colour	PMS [a] colour code
2 % Lidocaine	Red	185 or 186 or 199 or 200
3 % Lidocaine	Purple	266 or 267
2 % Mepivacaine	Brown	477 or 478 or 498 or 499
3 % Mepivacaine	Tan	406 or 407 or 408
3 % Prilocaine	Orange	136 or 137
4 % Prilocaine	Yellow	108 or 109 or 110 or 115 or 116
4 % Articaine	Gold	871 or 872 or 873 or 874 or 875
0,5 % Bupivacaine	Blue	300 or 301

[a] PMS = Pantone matching system.

Table 2 — Colour coding system for the vasoconstrictor and the concentration in single-use cartridges for local anaesthetics

Vasoconstrictor and concentration	Colour	PMS [a] colour code
No vasoconstrictor	White	None
Epinephrine < 1:200 000	Yellow	108 or 109 or 110 or 115 or 116
Epinephrine < 1:100 000 to 1:200 000	Orange	136 or 137
Epinephrine < 1:50 000 to 1:100 000	Brown	477 or 478 or 498 or 499
Epinephrine 1:50 000	Green	347 or 348 or 355 or 356
Levonordefrin	Black	None
Nor-epinephrine 1:100 000	Tan	406 or 407 or 408
Nor-epinephrine 1:25 000	Purple	266 or 267
Octapressin (felypressin)	Blue	300 or 301

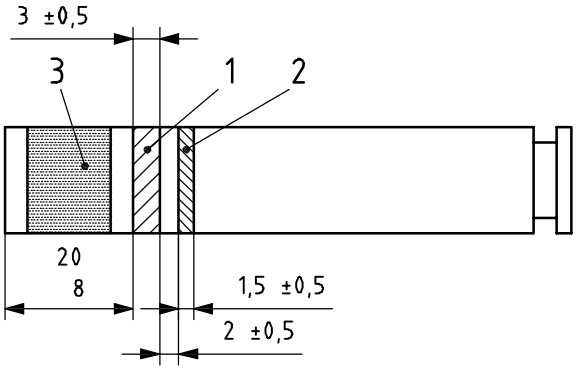
[a] PMS = Pantone matching system.

4.7.2 Positions of colour coding bands

Band 1 shall commence between 8 mm and 20 mm from the plunger end of the cartridge.

Band 2 shall commence at (2 ± 0,5) mm from the cartridge disc end of Band 1.

Dimensions in millimetres



Key

1 band 1 for coding of concentration of anaesthetic agent
2 band 2 for coding of concentration of vasoconstrictor
3 cartridge plunger

Figure 1 — Placement of colour coding bands on cartridge

4.7.3 Dimensions of colour coding bands

Band 1 shall be (3 ± 0,5) mm in width.

Band 2 shall be (1,5 ± 0,5) in width.

5 Test methods

5.1 Sampling

A sample of ten cartridges from the same batch shall be used for each test.

All samples shall pass the test.

5.2 Test conditions

All tests shall be conducted at (23 ± 2) °C.

5.3 Visual inspection

Visual inspection shall be carried out at normal visual acuity without magnification.

5.4 Test for cartridge leakage

5.4.1 Apparatus

5.4.1.1 **Test rig**, to support the cartridge; a suitable test rig is shown in Figure 2.

5.4.2 Procedure

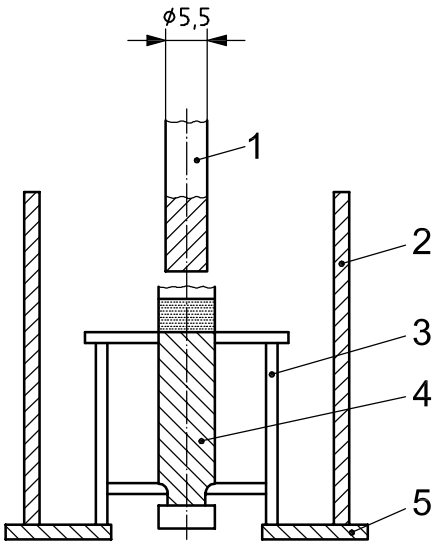
Support the cartridge to be tested in the test rig.

Apply a test force of 60 N axially to a free-fitting round rod that is in contact with the cartridge plunger.

Maintain the force for 1 min and inspect the cartridge for leaks or other failure during this period.

Record any evidence of leakage or other failure of the cartridge.

Dimensions in millimetres



Key

1 rod
2 shatterproof guard, e.g. acrylic cylinder
3 test rig
4 cartridge
5 base

Figure 2 — Apparatus for testing cartridges for leakage of local anaesthetic solution

5.5 Determination of force needed for plunger movement

5.5.1 Apparatus

5.5.1.1 **Machine**, capable of moving the plunger rod of the syringe at a constant velocity of (50 ± 1) mm/min.

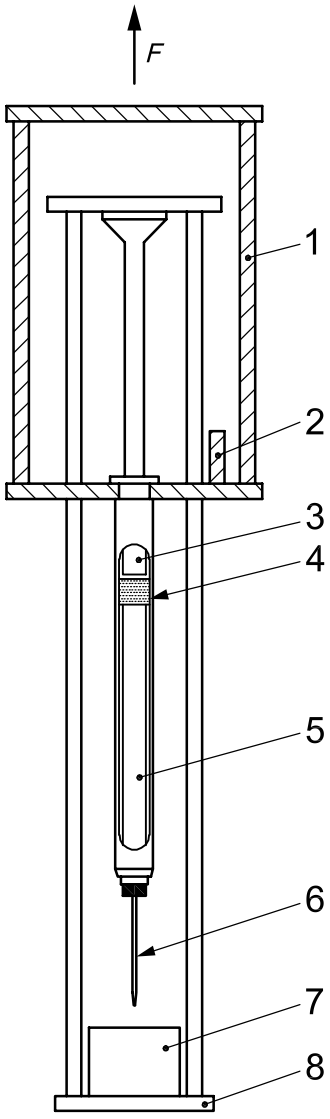
5.5.1.2 **Syringe holder**, capable of mounting a dental cartridge syringe, for example as shown in Figure 3.

5.5.1.3 **Sterile single-use dental injection needle**, 0,4 mm × 35 mm, complying with ISO 7885.

5.5.1.4 **Dental cartridge syringe**, complying with ISO 9997.

5.5.2 Procedure

Place the cartridge to be tested in the syringe and attach the needle (5.5.1.3). Mount the loaded syringe (5.5.1.4) in the syringe holder (5.5.1.2). Operate the testing machine (5.5.1.1) at the rate of 50 mm/min and record the force, F_1, required to initiate movement of the plunger, and the force, F_2, required to sustain movement of the plunger throughout the effective length.



Key

1 syringe holder
2 stop pin
3 plunger rod
4 plunger
5 cartridge
6 needle
7 vessel
8 base, securely fixed

Figure 3 — Apparatus for determining force required for plunger movement of the cartridge

5.6 Size of air bubble

Hold the cartridge vertically with the cap uppermost and tap it on a horizontal surface to dislodge any air bubbles adhering to the side walls. Observe, from a horizontal angle, whether the air bubble is visible below the rim of the cap.

5.7 Extractable volume

5.7.1 Apparatus

5.7.1.1 **Dental cartridge syringe**, in accordance with ISO 9997.

5.7.1.2 **Sterile single-use dental injection needle**, of diameter 0,4 mm, in accordance with ISO 7885.

5.7.1.3 **Suitable container**, graduated in millilitres.

5.7.2 Procedure

Load the cartridge to be tested into the dental cartridge syringe (5.7.1.1) and screw the needle (5.7.1.2) in position. Slowly empty the cartridge into the container (5.7.1.3) and measure the volume of anaesthetic solution extracted.

6 Marking

6.1 Primary container

The marking on the cartridge for local anaesthetics shall include at least the following information:

a) name and/or trademark of manufacturer;

b) minimum extractable volume, in millilitres;

c) active ingredients and their concentrations;

d) colour coding, if used, in accordance with 4.7;

e) lot number (batch code);

f) expiry date;

g) if any component of the cartridge contains natural rubber latex, a statement and/or symbol in accordance with 5.1 of ISO 15223-1:2007 to that effect.

6.2 Secondary container

The labelling on any container for a cartridge for local anaesthetics offered for sale shall include at least the following information:

a) manufacturer's name and address;

b) description of product;

c) minimum extractable volume of each cartridge, in millilitres;

d) nominal capacity of each cartridge, in millilitres;

e) pharmacologically active ingredients and their concentrations;

f) lot number (batch code);

g) expiry date;

h) number of cartridges in container;

i) recommendation for storage;

j) declaration that the product contains a sterile solution for injection;

k) whether or not suitable for diaphragm-method aspiration;

l) if any component of the cartridge contains natural rubber latex, a statement and/or symbol in accordance with 5.1 of ISO 15223-1:2007 to that effect.

Bibliography

[1] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

[2] ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

[3] ISO 11040-1, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*

[4] ISO 11040-2, *Prefilled syringes — Part 2: Plungers and discs for dental local anaesthetic cartridges*

[5] ISO 11040-3, *Prefilled syringes — Part 3: Aluminium caps for dental local anaesthetic cartridges*

[6] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

[7] ISO 21533, *Dentistry — Reusable cartridge syringes intended for intraligamentary injections*

ICS 11.040.10; 11.060.20

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