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Dentistry — Single-use cartridges for local anaesthetics

Médecine bucco-dentaire — Cartouches à usage unique pour anesthésiques locaux

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Foreword

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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. www.iso.org/directives

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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 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 11499:2007), which has been technically revised. The following changes have been made:

a) introduction of smaller cartridges of volume 1,0 ml and 1,7 ml;

b) change in force for leakage test.

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 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 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 1,0 ml, 1,7 ml, 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 and ISO 21533.

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 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 7885, *Dentistry — Sterile injection needles for single use*

ISO 9997, *Dental cartridge syringes*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

3 Terms and definitions

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

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

3.2
effective length of the cartridge
the distance travelled by the plunger that expels the extractable volume

3.3
extractable volume
volume of anaesthetic solution which can be delivered when the cartridge is used with a dental cartridge syringe and a dental injection needle

4 Requirements

4.1 Freedom from leakage of anaesthetic solution

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

Test in accordance with 5.4.

4.2 Force needed 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 the effective length shall not exceed 20 N and shall not be less than 2 N.

Test in accordance with 5.5.

4.3 Size of air bubble

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

Test 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 nominal volume stated in 6.1 b) and 6.2 c).

Test in accordance with 5.7.

4.6 External dimensions of the assembled cartridge

4.6.1 Overall length

The maximum overall length of a 1,0 ml cartridge shall be 44,0 mm.

The maximum overall length of a 1,7 ml and 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 Use of colour coding shall be at the discretion of the manufacturer

Colour coding shall be used 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.