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Dentistry — Cartridge syringes

Médecine bucco-dentaire — Seringues pour cartouches

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 9997:1999), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the normative references have been updated;
- the requirement for reprocessing has been added in [5.5](#);
- the tolerance for plunger rod movement has been tightened in [6.6](#).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Cartridge syringes

1 Scope

This document specifies requirements and test methods for cartridge syringes used in dentistry. These syringes are of the non-aspirating, aspirating and self-aspirating types using cartridges with dental local anaesthetics.

This document is not applicable to cartridge syringes having a mechanical-advantage action for creating high pressure.

This document specifies requirements for cartridge syringes with ISO metric thread sizes. However, attention is drawn to the existence of a variety of syringes with imperial thread sizes (see [Annex A](#)).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 261, *ISO general purpose metric screw threads — General plan*

ISO 965-1, *ISO general purpose metric screw threads — Tolerances — Part 1: Principles and basic data*

ISO 1942, *Dentistry — Vocabulary*

ISO 11499, *Dentistry — Single-use cartridges for local anaesthetics*

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

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 11499 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

aspiration

process by which blood or body fluid is drawn into an anaesthetic cartridge

3.2

cartridge

container for local anaesthetics

3.3

cartridge syringe

syringe which is designed to include a cartridge as a removable part and which can be connected to a dental injection needle

3.4

plunger rod

rigid component which transmits the activating force to the cartridge plunger

3.5

unit pack

pack which contains the cartridge syringe

4 Classification

For the purposes of this document, cartridge syringes are classified into the following types:

- type 1: non-aspirating;
- type 2: aspirating (aspiration by force produced by drawing the plunger away from the needle);
- type 3: self-aspirating (aspiration by force produced by the deflection of a diaphragm in the cartridge).

5 Requirements

5.1 General

General requirements for cartridges for dental local anaesthetics as specified in ISO 11499 shall be met.

5.2 Materials

Cartridge syringes may be made from metal or have plastic components. The materials are at the manufacturer's discretion provided that all of the requirements of this document shall be met.

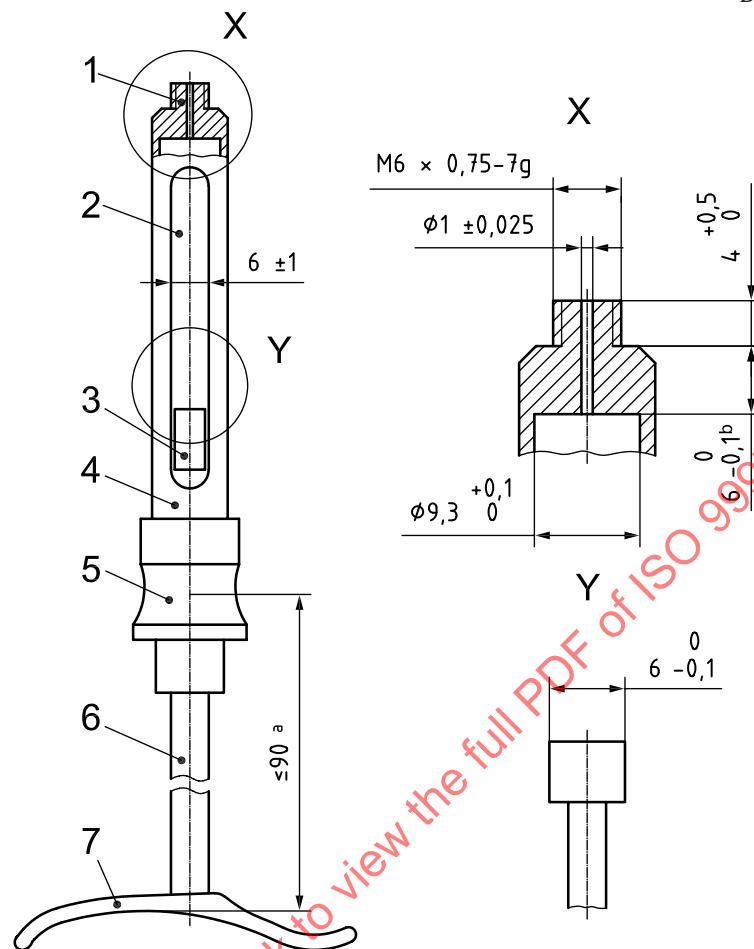
Test in accordance with [6.1](#) and [6.7](#).

5.3 Dimensions

The dimensions for cartridge syringes shall be as specified in [Figure 1](#) and the metric-threaded needle-mounting hub shall meet the requirements for screw threads in accordance with ISO 261 and ISO 965-1.

Test in accordance with [6.2](#).

Dimensions in millimetres

**Key**

- 1 threaded needle mounting hub
- 2 viewing port
- 3 working end of plunger rod
- 4 barrel
- 5 finger grip
- 6 plunger rod
- 7 handle
- a When a full cartridge is mounted.
- b Dimensions include any aspirating device incorporated at the needle end of the syringe barrel. If no aspirating device is incorporated, dimensions shall be reduced to 4^{+1}_0 .

NOTE The design shown is not necessarily preferable to any other design that may exist.

Figure 1 — Cartridge syringe

5.4 Special requirements

5.4.1 Loading and cartridge size

The cartridge shall be capable of being loaded either from the side or from the back (breach type). The cartridge syringe shall permit the appropriate size of local anaesthetic cartridge to be securely held and incapable of being dislodged during use.

Test in accordance with [6.3](#).

5.4.2 Viewing of contents

The cartridge syringe shall allow the solution for injection to be observed, including the result of aspiration.

Test in accordance with [6.1](#), [6.2](#), [6.3](#) and [6.4](#).

5.4.3 Plunger rod

5.4.3.1 Plunger rod design

The cartridge end of the plunger rod shall contain either a permanently attached tip or a means of securing various plunger tips supplied by the manufacturer of the cartridge syringe.

Test in accordance with [6.1](#).

5.4.3.2 Plunger rod movement

The plunger rod shall be capable of travelling freely and smoothly the whole length under the force of gravity in both vertical directions.

Test in accordance with [6.6.1](#).

5.4.3.3 Plunger rod displacement

The maximum sideways displacement of the plunger rod tip shall not exceed 1 mm in any direction from the central axis of the syringe.

Test in accordance with [6.6.2](#).

5.4.4 Aspirating syringes

5.4.4.1 General

Aspirating syringes shall permit aspiration at any time during use.

WARNING — Some aspirating syringes are intended for use only with cartridges fitted with specially designed plungers. These syringes may not aspirate when used with any other cartridges.

5.4.4.2 Type 2 syringes

When used with a cartridge in accordance with ISO 11499, the reagent shall have been aspirated into the cartridge and the harpoon or threaded portion of the plunger rod shall not have been disengaged.

Test in accordance with [6.4](#).

5.4.4.3 Type 3 syringes

Use a cartridge in accordance with ISO 11499. After testing, the reagent (see [6.4.1](#)) shall have been aspirated into the cartridge.

Test in accordance with [6.5](#).

5.5 Resistance to reprocessing

All components of the cartridge syringe shall (including those made of plastic) comply with the requirements of [5.3](#) and [5.4](#), and in addition, shall show no signs of corrosion after 100 reprocessing cycles when tested in accordance with [6.7](#).

If the manufacturer states a maximum number of reprocessing cycles less than 100, this maximum number shall be used instead.

6 Measurement and test methods

6.1 Visual inspection

Carry out visual inspection with normal visual acuity and without magnification.

6.2 Dimensions

Measure the dimensions using a measuring device that is accurate to 1/10 of the tolerance to be measured.

6.3 Secure loading

Place an appropriate size of local anaesthetic cartridge in a cartridge syringe. Move the syringe forward/backward and sideways and assess if the cartridge is securely placed.

6.4 Aspirating test for cartridge syringes of Type 2

6.4.1 Reagent

A coloured liquid, for example an aqueous solution of methylene blue, with a viscosity of 4 mPa.s (0,04 poise) at $(23 \pm 2) ^\circ\text{C}$.

6.4.2 Procedure

Assemble the cartridge syringe, cartridge and needle of dimensions 0,4 mm × 35 mm. Fix the harpoon or threaded portion of the working end of the plunger rod to the plunger of the local anaesthetic cartridge in accordance with the instructions for use. Immerse the needle in the coloured liquid (see [6.4.1](#)) and depress the plunger for 5 mm at a rate of 5 mm/s and then, at the same rate, withdraw the plunger until the reagent appears in the cartridge or for a maximum distance of 5 mm. Repeat the test three times with the same local anaesthetic cartridge.

6.4.3 Observation

Observe whether the requirement of [5.4.4.2](#) is fulfilled after each withdrawal of the plunger.

6.5 Aspirating test for cartridge syringes of Type 3

6.5.1 Reagent

A coloured liquid, as described in [6.4.1](#).

6.5.2 Procedure

Assemble the cartridge syringe, cartridge and needle of dimensions 0,4 mm × 35 mm. Depress the plunger 5 mm during 1 s. Release the force and then immediately again depress the plunger for a further

5 mm for 1 s. Immediately after this second depression, immerse the needle in the coloured liquid (see [6.4.1](#)) and depress the plunger at a rate of 5 mm/s for 5 mm and release the force.

6.5.3 Observation

Observe whether the requirement of [5.4.4.3](#) is fulfilled.

6.6 Plunger rod

6.6.1 Plunger rod movement

Hold the empty cartridge syringe vertically. Move the plunger rod fully out of the syringe, and release. Invert the syringe and repeat the test.

Check if the plunger rod is capable of travelling freely and smoothly, the whole length under the force of gravity in both vertical directions.

If it is capable of travelling freely and smoothly, the whole length, this test is passed.

6.6.2 Plunger rod displacement

Hold the cartridge syringe (without a cartridge) vertically. Move the plunger rod in the fully forward position. Measure any movement at the front end of the plunger rod tip in all directions from the central axis.

If the maximum sideways displacement of the plunger rod tip does not exceed 1 mm, this test is passed.

6.7 Resistance to reprocessing

Carry out 100 reprocessing cycles with the cartridge syringe, in accordance with the manufacturer's instructions for use, in accordance with ISO 17664. The reprocessing cycle shall include the manufacturer's recommended methods of cleaning, disinfection and sterilization.

If the manufacturer states a maximum number of cycles less than 100, use this number of cycles for the test.

Inspect the syringe for any signs of corrosion, pitting, distortion or other surface damage. Repeat the testing for [5.3](#) and [5.4](#).

7 Instructions for use

Each cartridge syringe shall be accompanied by at least the following information:

- a) the indications for use;
- b) the method of inserting the cartridge and attaching the needle;
- c) the method of assembly, if appropriate;
- d) the technique to be used for aspiration, if applicable;
- e) the classification into type "non-aspirating", "aspirating" or "self-aspirating", as appropriate;
- f) if aspirating, the type of aspiration;
- g) the details of the needle-mounting thread;
- h) the size (s) of cartridge(s) to use with the syringe;
- i) the recommended methods of reprocessing for re-use;

- j) if graphical symbols which are not in accordance with ISO 15223-1:2016 are used, they shall be explained in the instructions for use.

8 Marking

8.1 Labelling on the unit pack

If graphical symbols are used in the labelling of the unit pack of a cartridge syringe, these graphical symbols shall be in accordance with ISO 15223-1, if available.

Labelling on the unit pack shall include:

- a) the content of the unit pack;
- b) the name and/or registered trademark and address of the manufacturer or his authorized legal representative;
- c) the words "cartridge syringe";
- d) the classification into type "aspirating", "non-aspirating" or "self-aspirating", as appropriate;
- e) if aspirating, type of aspiration;
- f) the details of the needle-mounting thread;
- g) the size of cartridge for use with the syringe.

NOTE In some countries, national or regional regulations can require a unique device identification-code (UDI-code) labelling on the unit pack.

8.2 Marking of syringe

Each cartridge syringe shall be permanently marked with:

- a) the name or registered trademark of the manufacturer;
- b) a lot number (batch designation).

NOTE In some countries, national or regional regulations can require a UDI-code to be permanently marked on the cartridge syringe.