SLOVENSKI STANDARD
oSIST prEN ISO 9997:2019

01-julij-2019

Zobozdravstvo - Dodatek brizgalke (ISO/DIS 9997:2019)

Dentistry - Cartridge syringes (ISO/DIS 9997:2019)

Zahnheilkunde - Ampullenspritzen (ISO/DIS 9997:2019)

Médecine bucco-dentaire - Seringues à usage dentaire pour cartouches (ISO/DIS 9997:2019)

Ta slovenski standard je istoveten z: **prEN ISO 9997**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters
11.060.20	Zobotehnična oprema	Dental equipment

oSIST prEN ISO 9997:2019 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 9997

ISO/TC **106**/SC **4** Secretariat: **DIN**

Voting begins on: **2019-05-03**

Voting terminates on: **2019-07-26**

Dentistry — Cartridge syringes

Médecine bucco-dentaire — Seringues à usage dentaire pour cartouches

ICS: 11.040.25; 11.060.20

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 9997:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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:

— updated Normative References;

— requirement for reprocessing was added in 5.5;

— the tolerance for pluger 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 which are reusable syringes of the aspirating, non-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 with contains a cartridge as removable part

3.3
plunger rod
rigid component which transmits the activating force to the cartridge plunger

3.4
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

  — Type 2a: aspiration by force produced by drawing the plunger away from the needle

  — Type 2b: 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 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.

5.3 Special requirements

5.3.1 Loading and cartridge size

The cartridge shall be capable of being loaded either from the side or from the back (breech 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.

5.3.2 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.

5.3.3 Plunger rod

5.3.3.1 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.

5.3.3.2 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.

5.3.3.3 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.

5.3.4 Aspirating syringes

5.3.4.1 General

Aspirating syringes shall permit aspiration at any time during use.

NOTE 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.

5.3.4.2 Type 2a syringes

When used with a cartridge complying 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.

5.3.4.3 Type 2b syringes

Use a cartridge complying with ISO 11499. After testing, the reagent (6.4.1) shall have been aspirated into the cartridge.

Test in accordance with 6.5.

5.4 Materials

5.4.1 Metal cartridge syringes

The parts shall be capable of withstanding repeated sterilization without impairing the function of the syringe and without showing deterioration of the material of construction.

Test in accordance with 6.1 and 6.7.

5.4.2 Plastics cartridge syringes, including metal cartridge syringes with plastics parts

The material shall be capable of withstanding repeated sterilization without impairing the function of the syringe and without showing deterioration of the material of construction.

Test in accordance with 6.1 and 6.7.

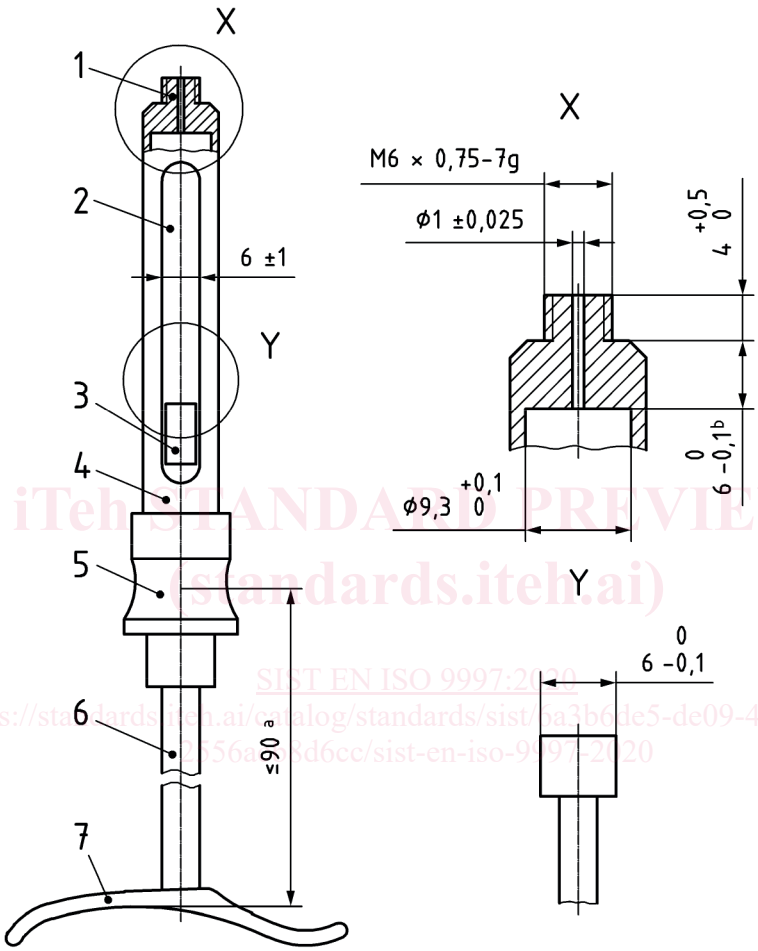
Any metal part shall comply with the requirements of 5.4.1.

5.5 Resistance to reprocessing

The cartridge syringe shall 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.

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