INTERNATIONAL STANDARD

ISO 9997

First edition
1990-11-01

Dental cartridge syringes

Seringues à usage dentaire pour cartouches

Reference number
ISO 9997:1990(E)

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.

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.

International Standard ISO 9997 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

This International Standard specifies requirements for dental cartridge syringes with ISO metric threads only. However, attention is drawn to the existence of a variety of syringes with Imperial threads. Manufacturers currently producing syringes with Imperial threads are requested to change to ISO metric threads and 1992 has been set as a target date.

This page intentionally left blank

Dental cartridge syringes

1 Scope

This International Standard specifies requirements and test methods for re-usable dental cartridge syringes of the aspirating, non-aspirating and self-aspirating types for use with dental local anaesthetics. This Standard does not apply to cartridge syringes having a mechanical-advantage action for creating high pressure.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 261: 1973, *ISO general purpose metric screw threads — General plan.*

ISO 965-1:1980, *ISO general purpose metric screw threads — Tolerances — Part 1: Principles and basic data.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 aspiration: Process by which blood or body fluid is drawn into an anaesthetic cartridge.

3.2 unit pack: Pack containing a dental cartridge syringe and, where appropriate, adaptors.

4 Requirements

4.1 General

4.1.1 Loading and cartridge size

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

Testing shall be carried out in accordance with 5.1.

4.1.2 Viewing

The syringe shall have two opposed viewing ports so that the solution being injected can be observed. One viewing port shall expose more than half the length of the cartridge and shall be positioned so that the stub-end of the needle is visible during use.

Testing shall be carried out in accordance with 5.1.

4.1.3 Needles (and needle mounting)

The syringe shall allow needles of diameters up to 0,65 mm to be used.

Testing shall be carried out in accordance with 5.1.

4.1.4 Plunger

The plunger rod shall be free-moving before and after the tests in 5.4, 5.5 and 5.6. When the rod is pulled fully out of an empty syringe held vertically, the plunger shall be capable of travelling freely and smoothly the whole length under the force of gravity in both vertical directions.

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.

Testing shall be carried out in accordance with 5.1.

4.1.5 Aspirating syringes

Aspirating syringes shall be capable of permitting aspiration at any time during use.

4.1.5.1 Syringes in which aspiration is achieved by deflection of diaphragm in cartridge

After the test, the reagent (5.2.1) shall have aspirated into the cartridge.

Testing shall be carried out in accordance with 5.2.2.

NOTE 1 Some aspirating syringes are intended for use only with cartridges fitted with specially designed rubber pistons. These syringes may not aspirate when used with any other cartridges.

4.1.5.2 Syringes in which aspiration is achieved by means of claw or by connecting plunger rod to cartridge piston by some other means

After the test, the harpoon or threaded portion of the piston rod shall not have disengaged from the piston during these operations.

4.1.6 Needle adaptor

Where a needle adaptor is present, it shall be capable of accommodating needles from 0,3 mm to 0,6 mm nominal diameter (0,65 max. diameter).

Testing shall be carried out in accordance with 5.1.

4.2 Materials

4.2.1 Metal syringes

The parts shall be capable of withstanding repeated sterilization without impairing the function of the syringe and without showing signs of corrosion, for example, blemishes, pittings or discolouration.

Testing shall be carried out in accordance with 5.1 and 5.4 and subsequently 5.5 and 5.6.

4.2.2 Plastic syringes, including metal syringes with plastic parts

The material shall be capable of withstanding repeated sterilization without impairing the function of the syringe and without showing deterioration to the material of construction. The function can be assessed by visual inspection.

Testing shall be carried out in accordance with 5.4 and subsequently 5.5.

Any metal part shall comply with the requirements of 4.2.1.

4.3 Dimensions

The dimensions shall be as specified in figure 1 and shall meet the requirements for screw threads in ISO 261 and ISO 965-1.

5 Test methods

5.1 Visual inspection

Visual inspection shall be conducted at normal visual acuity without magnification.

5.2 Aspirating test for syringes where aspirating is achieved by deflection of diaphragm in cartridge

5.2.1 Reagent

A coloured liquid, for example an aqueous solution of methylene blue with a viscosity of 4 mPa·s (0,04 poise) at 25 °C.

5.2.2 Procedure

Assemble the syringe, cartridge and needle of size 0,4 mm × 35 mm. Depress the plunger 5 mm during 1 s. Release the pressure and then immediately again depress the plunger a further 5 mm during 1 s. Immediately after this second depression immerse the needle in the coloured liquid (5.2.1) and depress the plunger at a rate of 0,5 mm/s for 5 mm and release the pressure.

5.2.3 Observation

Observe whether the requirement of 4.1.5.1 is fulfilled.

5.3 Linkage test for aspirating syringes having claw or means of connecting plunger rod to cartridge piston for aspirating purposes

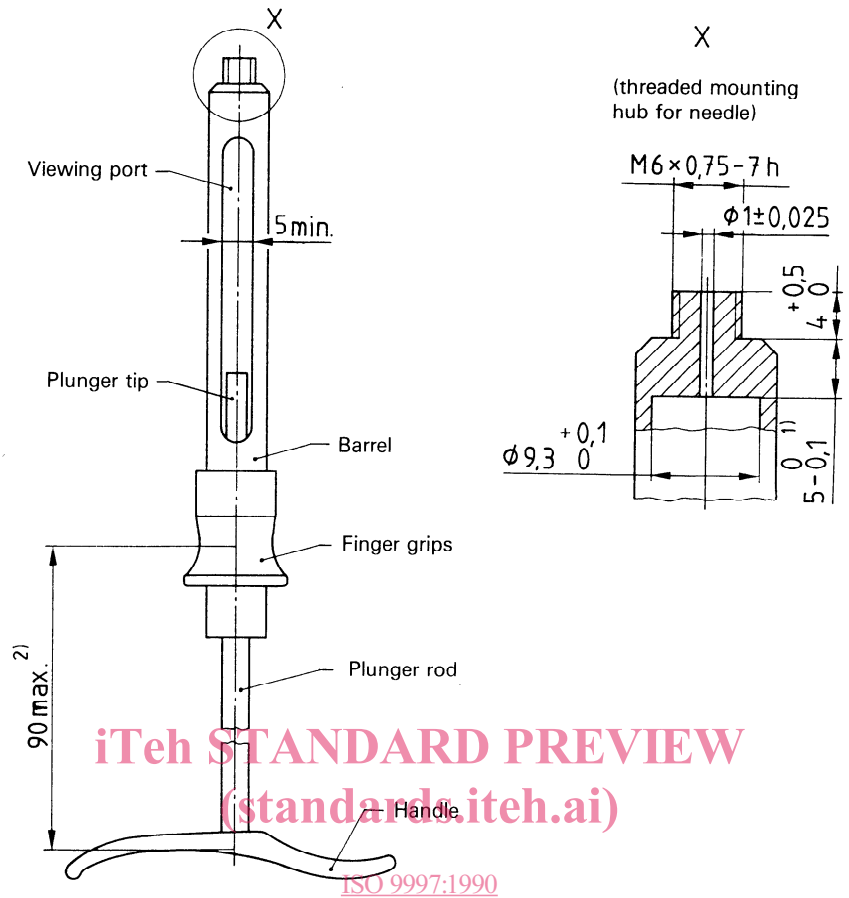
5.3.1 Reagent

A coloured liquid, see 5.2.1.

5.3.2 Procedure

Assemble the syringe, cartridge and needle of size 0,4 mm × 35 mm. Fix the harpoon or threaded portion of the distal end of the piston rod to the piston of the local anaesthetic cartridge in accordance with the manufacturer's instructions. Immerse the needle in the coloured liquid (5.3.1) and depress the piston for 5 mm at a rate of 5 mm/s and then, at the same rate, withdraw it in the opposite direction for a maximum distance of 5 mm. Repeat the test three times with the same local anaesthetic cartridge.

Dimensions in millimetres



1) Dimension includes any aspirating device incorporated at the needle end of the syringe barrel. If no aspirating device is incorporated, dimension shall be reduced to 2^{+1}_{0}.

2) When a full cartridge is mounted.

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

Figure 1 — Dental cartridge syringe

5.3.3 Observation

Observe whether the requirement of 4.1.5.2 is fulfilled.

5.4 Boil test

5.4.1 Reagent

Distilled or deionized water.

5.4.2 Apparatus

A glass or ceramic beaker or a suitable corrosion-resistant stainless steel vessel.

5.4.3 Preparation of sample

Scrub the instrument using soap and warm water, rinse thoroughly with the water (5.4.1) and dry.

5.4.4 Procedure

Immerse the instrument in boiling water (5.4.1) for a minimum of 30 min and allow the instrument to remain cooling in the same water for a further period of 1 h. Then remove the instrument and leave it to stand in air for 2 h.

5.4.5 Assessment of results

Visually inspect (see 5.1) for compliance with the requirements of 4.2.1 or 4.2.2 as appropriate.

5.5 Autoclave test

5.5.1 Apparatus

Autoclave of the non-vacuum type capable of being operated at (136 ± 2) °C and 0,22 MN/m² (2,2 bar).

5.5.2 Procedure

Prepare the sample according to 5.3.3 and place the instrument, unwrapped, in the tray of the autoclave. Using the water (5.3.1), subject the instrument to autoclaving cycles of (3 ± 0,5) min duration at (136 ± 2) °C and 0,22 MN/m² (2,2 bar).

After each cycle, open the door, remove the tray and allow the contents to cool to room temperature.

Perform the cycle five times.

5.5.3 Assessment of results

Visually inspect (see 5.1) for compliance with the requirement of 4.2.1 or 4.2.2 as appropriate.

5.6 Dry heat test (metal syringes only)

5.6.1 Apparatus

Dry heat oven, capable of being operated at (180 ± 5) °C.

5.6.2 Procedure

Prepare the sample according to 5.3.3 and place the instrument in the dry heat oven at (180 ± 5) °C, and after allowing the oven to recover its set temperature, leave it for 30 min.

Remove the instrument from the dry heat oven and allow it to cool to room temperature in air.

Perform the cycle five times.

5.6.3 Assessment of results

Visually inspect (see 5.1) for compliance with the requirement of 4.2.1.

6 Manufacturer's information

Each dental cartridge syringe shall be accompanied by the following information:

a) recommended methods for cleaning and sterilization;

b) method of inserting the cartridge and attaching the needle;

c) method of assembly, if appropriate;

d) technique to be used for aspiration, if applicable.

7 Marking

7.1 Marking of unit pack

Each unit pack (see clause 3) shall be marked with the following information:

a) name or registered trade-mark of the manufacturer;

b) words "dental cartridge syringe";

c) words "aspirating" or "non-aspirating" or "self-aspirating", as appropriate;

d) details of the needle mounting thread;

e) size(s) and type of the cartridge(s) to use with the syringe.

7.2 Marking of cartridge syringe

Each syringe shall be indelibly marked with the name or registered trade-mark of the manufacturer.

UDC 615.473.3:616.314-089.5

Descriptors: dentistry, dental equipment, syringes, specifications, dimensions, tests, marking.

Price based on 4 pages