INTERNATIONAL STANDARD

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Dentistry — Reusable cartridge syringes intended for intraligamentary injections

Art dentaire — Seringues réutilisables destinées aux injections intraligamentaires

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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.

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 21533 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Dentistry — Reusable cartridge syringes intended for intraligamentary injections

1 Scope

This International Standard specifies requirements and test methods for reusable cartridge syringes intended for intraligamentary injections.

It specifies requirements for dental cartridge syringes with ISO metric thread sizes, and only intended for intraligamentary injections. However, attention is drawn to the existence of a variety of syringes with imperial thread sizes (see Annex A).

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 1942-3, *Dental vocabulary — Part 3: Dental instruments*

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

ISO 9997, *Dental cartridge syringes*

ISO 11499, *Dental cartridges for local anaesthetics*

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942-3 and the following apply.

3.1
intraligamentary injection
injection made by the dentist via the periodontal ligament

3.2
reusable cartridge syringe intended for intraligamentary injections
syringe used in dentistry which can be resterilized and is specifically designed by the manufacturer for intraligamentary injections and uses a container for local anaesthetics

3.3
unit pack
pack which contains the syringe

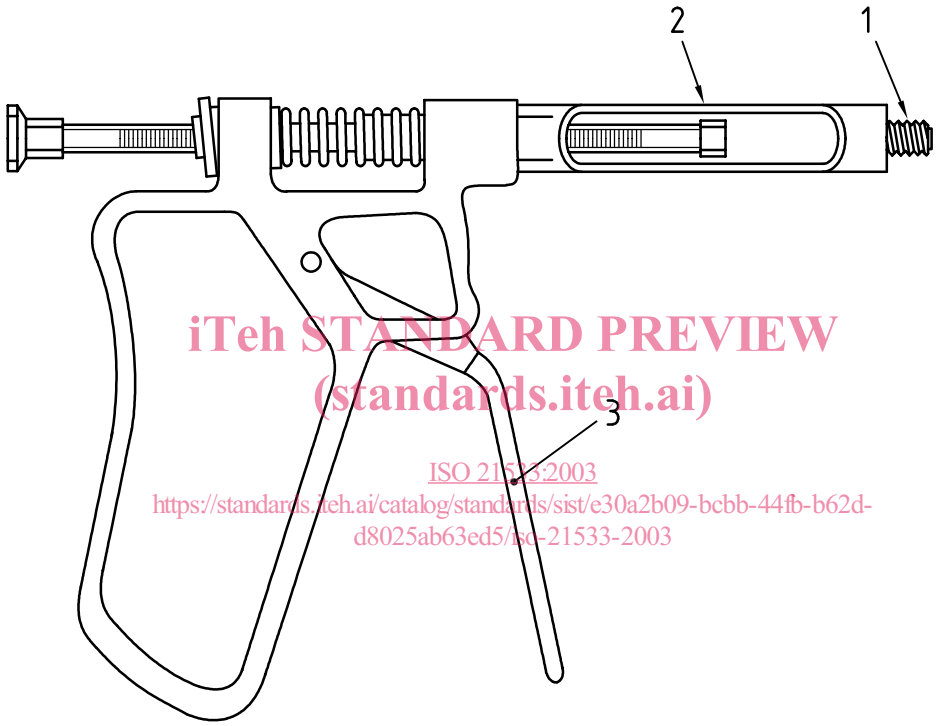
3.4
lever
component which delivers the force to the plunger rod

3.5
protective sleeve
component which prevents pieces of a fractured cartridge leaving the syringe through the viewing port

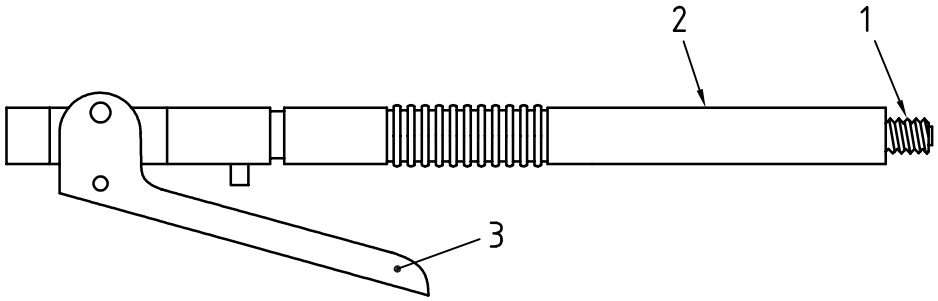
4 Requirements

4.1 Design

The syringe shall be of either a pistol-grip design or a pen-grip design, as shown in Figure 1.



a) Pistol-grip design



b) Pen-grip design

Key
1 threaded needle-mounting hub
2 barrel
3 lever

Figure 1 — Pistol-grip and pen-grip syringe designs

4.2 Barrel

4.2.1 General

The dimensions of the barrel shall conform to ISO 9997.

4.2.2 Loading of the cartridge

4.2.2.1 Syringes without viewing ports

Where a viewing port is not present, the dimensions of the barrel shall permit the loading of a cartridge which conforms to ISO 11499.

4.2.2.2 Syringes with viewing ports

Where a viewing port is present, the dimensions of the barrel shall permit the placement of a protective sleeve and shall permit the loading of a cartridge which conforms to ISO 11499.

4.3 Threaded needle-mounting hub

The dimensions of the threaded needle-mounting hub shall conform to ISO 9997.

4.4 Plunger rod

The diameter of the plunger rod tip shall be $6{,}0^{\ 0}_{-1}$ mm. The length of the plunger rod shall allow maximum travel of the cartridge plunger.

The maximum sideways displacement of the rod shall not exceed 2 mm in any direction from the long axis of the syringe barrel.

Testing shall be carried out in accordance with 5.1 and 5.3.

4.5 Volume of local anaesthetic delivered

When tested in accordance with 5.2, the volume of local anaesthetic delivered at each depression of the lever shall be within 10 % of the volume claimed by the manufacturer.

4.6 Resistance against corrosion, autoclaving and thermal exposure

4.6.1 Syringe

The syringe shall function normally and show no signs of corrosion after the tests in 5.5, 5.6 and 5.7.

4.6.2 Protective sleeve

The protective sleeve, if supplied, shall be either single-use or capable of resterilization.

Test in accordance with 5.4.

If the sleeve is capable of resterilization, it shall fit after testing to 5.5, 5.6 and 5.7 and shall not become dislodged when tested in accordance with 5.4.

5 Test methods

5.1 Visual inspection

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

5.2 Measurement of volume delivered

Prepare the syringe with a glass dental local anaesthetic cartridge conforming to ISO 11499 and a needle conforming to ISO 7885. Depress the lever completely a sufficient number of times for anaesthetic to be delivered through the needle. Depress the lever three more times and measure the volume of anaesthetic delivered during each of these three depressions. Ensure that the lever returns to its initial position after each depression.

5.3 Plunger rod displacement

Remove the syringe barrel and position the plunger rod fully forward in the syringe. Measure the maximum sideways displacement at the front end of the plunger rod tip.

5.4 Protective sleeve dislodgement

Prepare the syringe for use as described in 5.2. Empty the deliverable contents of the cartridge via the needle. Check for dislodgement of the sleeve during the test.

5.5 Boiling-water test

Test the syringe five times as described in ISO 13402.

Visually inspect for compliance with the requirements of 4.6.

5.6 Autoclave test

Test the syringe five times as described in ISO 13402.

Visually inspect for compliance with the requirements of 4.6.

5.7 Dry-heat test

Test the syringe five times as described in ISO 13402.

Visually inspect for compliance with the requirements of 4.6.

6 Manufacturer's information

Each syringe shall be accompanied by the following information:

a) indications for use;

b) instructions for use;

c) information concerning the mechanical advantage produced by the lever;

d) the recommended cartridge size and material;

e) methods of assembly and disassembly;

f) methods of inserting the cartridge and attaching the needle;

g) a statement directing the user to check before use that the barrel and handle are securely connected and that the interchangeable barrel end cap with needle hub (if fitted) is securely in position;

h) the volume of anaesthetic solution delivered per depression of the lever;

i) recommended methods of reprocessing for re-use.

7 Marking

7.1 Marking of unit pack

Each unit pack shall be marked with the following information:

a) the contents of the pack;

b) the name or registered trade mark of the manufacturer;

c) the words “syringe intended for intraligamentary injections” or equivalent;

d) the classification as a pistol-grip or pen-grip design;

e) details of the needle-mounting thread;

f) the size(s) of dental local anaesthetic cartridge(s) to use;

g) if a protective sleeve is supplied, an indication of whether the protective sleeve is single-use or can be resterilized;

h) if a protective sleeve is not supplied, details of the protective sleeve to be used;

i) the lot number.

7.2 Marking of syringe

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