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ISO 21533

Second edition
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Dentistry — Reprocessable cartridge syringes for intraligamentary injections

Médecine bucco-dentaire — Seringues à cartouche pour injections intraligamentaires, pouvant être retraitées

Reference number
ISO 21533:2018(E)

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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 (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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21533:2003), which has been technically revised with the following changes:

— dosage-wheel design was added;

— clarification of reprocessing was added.

It also incorporates the Technical Corrigendum ISO 21533:2003/Cor.1:2009.

Dentistry — Reprocessable cartridge syringes for intraligamentary injections

1 Scope

This document specifies requirements and test methods for reprocessable cartridge syringes intended for intraligamentary injections.

It specifies requirements for 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 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 1942, *Dentistry — Vocabulary*

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

ISO 9997, *Dental cartridge syringes*

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

3 Terms and definitions

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

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
intraligamentary injection
injection made via the periodontal ligament

3.2
reprocessable cartridge syringe for intraligamentary injections
syringe which can be reprocessed and is specifically designed by the manufacturer for intraligamentary injections and uses a local anaesthetic cartridge

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

3.4
lever
component which delivers the force to the plunger rod

3.5
dosage wheel
part of the syringe system that regulates the volume of solution delivered by using a rotating wheel

3.6
dosage-wheel design
cartridge syringe where the plunger rod is activated by a dosage wheel

3.7
protective sleeve
component which prevents pieces of a fractured cartridge leaving the syringe through the viewing port

3.8
unit pack
pack which contains the syringe

4 Requirements

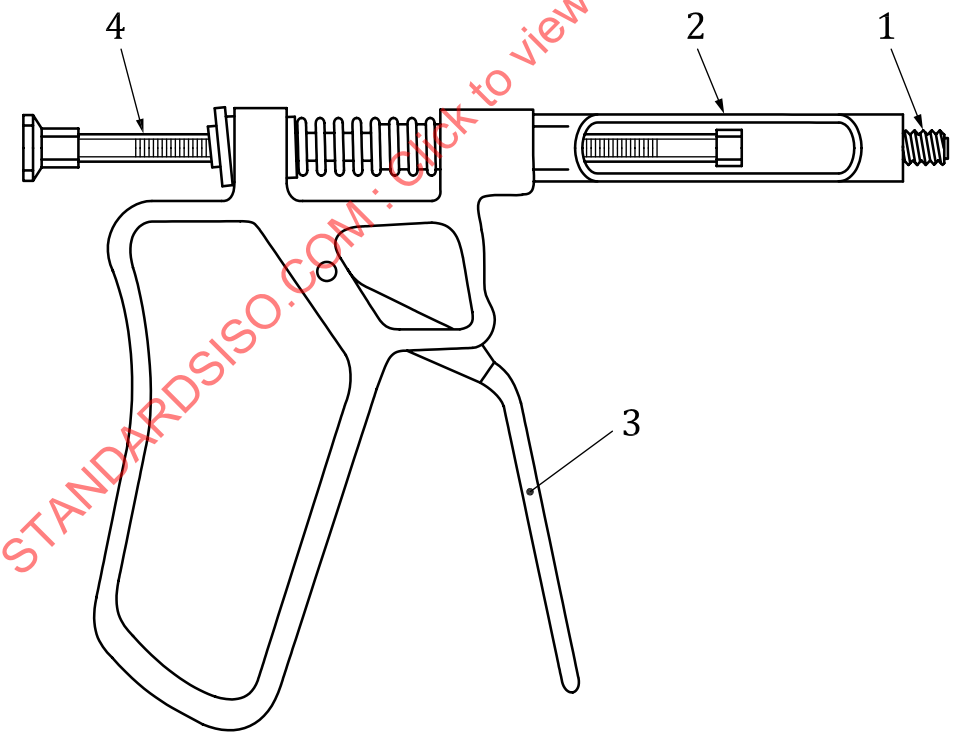
4.1 Design

The design of the cartridge syringe shall be as shown in Figures 1 to 3 of a

a) pistol-grip design,

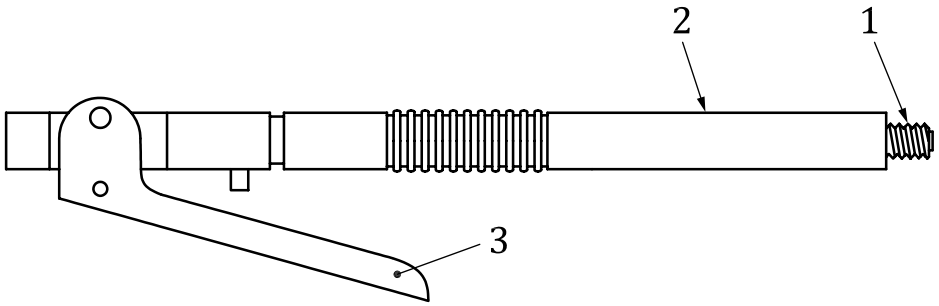
b) pen-grip design, or

c) dosage-wheel design.



Key
1 threaded needle-mounting hub
2 barrel
3 lever
4 plunger rod

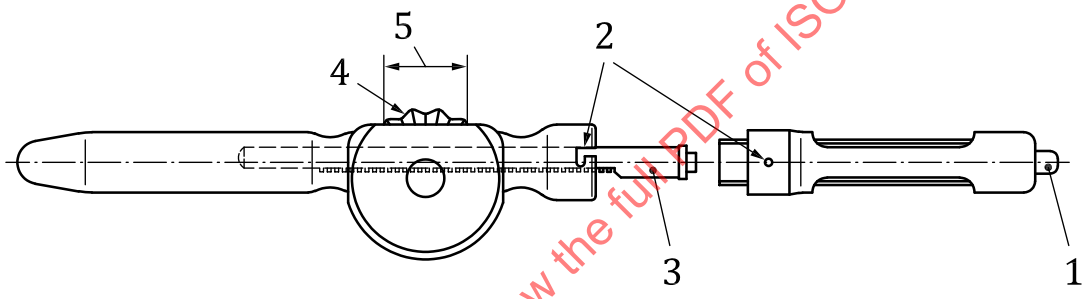
Figure 1 — Pistol-grip design



Key

1 threaded needle-mounting hub
2 barrel
3 lever

Figure 2 — Pen-grip design



Key

1 threaded needle-mounting hub
2 barrel
3 plunger rod
4 dosage-wheel
5 freely accessible area of the dosage-wheel for the activation process

Figure 3 — Dosage-wheel design

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

When 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

When 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 conform to ISO 9997. The length of the plunger rod shall allow maximum travel of the cartridge plunger.

The maximum sideways displacement of the plunger rod shall conform to ISO 9997.

Test according to 5.1.

4.5 Volume of local anaesthetic delivered

The volume of local anaesthetic delivered at each depression of the lever or appropriate rotation of the dosage-wheel shall be within 10 % of the volume claimed by the manufacturer.

Test according to 5.2.

4.6 Protective sleeve

4.6.1 Number of uses

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

Test according to 5.3.

4.6.2 Integrity

The protective sleeve shall retain its integrity during use.

Test according to 5.3.

4.7 Resistance to reprocessing

4.7.1 Syringe

The syringe shall comply with the requirements of 4.2, 4.3, 4.4, 4.5, and in addition shall show no signs of corrosion after 100 reprocessing cycles when tested in accordance with 5.4.

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

4.7.2 Protective sleeve (if supplied)

If the manufacturer states that the protective sleeve can be reprocessed there shall be no visible signs of deterioration and it shall comply with the requirements of 4.6.2 after 100 reprocessing cycles when tested in accordance with 5.4.

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

5 Test methods

5.1 Visual inspection

Conduct visual inspection 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.

5.2.1 Pistol- and pen-grip designs

Depress the lever a sufficient number of times for anaesthetic to be delivered through the needle.

When the anaesthetic delivery is ensured, depress the lever three more times and measure the volume of anaesthetic delivered during each depression. Ensure that the lever returns to its initial position after each depression.

5.2.2 Dosage-wheel design

Rotate the dosage-wheel such that the nominal volume marked on the syringe is delivered, and ensure anaesthetic is being delivered.

When the anaesthetic delivery is ensured, measure the volume delivered for three further successive deliveries.

5.2.3 Record of results

Record the volume of anaesthetic delivered for each test delivery.

5.3 Protective sleeve dislodgement

Prepare the syringe for use as described in 5.2. After anaesthetic delivery is ensured remove the needle and squeeze the lever until the cartridge breaks. Check by visual inspection if the protective sleeve is intact and not damaged.

5.4 Resistance to reprocessing

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

Assess visually for any signs of deterioration as in 5.1. Repeat the tests for 4.2, 4.3, 4.4 and 4.5 for the syringe and 4.6.2 for the protective sleeve.

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

6 Instructions for use

Each syringe shall be accompanied by the following information:

a) indications for use;

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

c) the recommended cartridge size and material;

d) method of assembly and disassembly;

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

f) 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;

g) the volume of anaesthetic solution delivered per depression of the lever or rotation of the dosage wheel;

h) 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) content of the unit pack;

b) name and/or registered trade mark and address of the manufacturer or his authorized legal representative;

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

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

e) details of the needle-mounting thread;

f) 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 reprocessed;

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

i) lot number.

7.2 Marking of syringe

Each syringe shall be permanently marked with:

a) name or registered trade mark of the manufacturer;

b) lot number;

c) where appropriate, markings which specify the volume delivered on rotation of the dosage-wheel.

Annex A
(informative)

Imperial thread sizes

Clause 1 mentions the existence of imperial thread sizes for the needle-mounting threads.

In the interests of patient safety, the imperial thread size used should be $0,216^{\ 0}_{-0,03}$ in ($5,486^{\ 0}_{-0,08}$ mm) with 40 TPI (threads per inch) Whitworth form.