
Dentistry — Reprocessable cartridge syringes for intraligamentary injections

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

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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).

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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

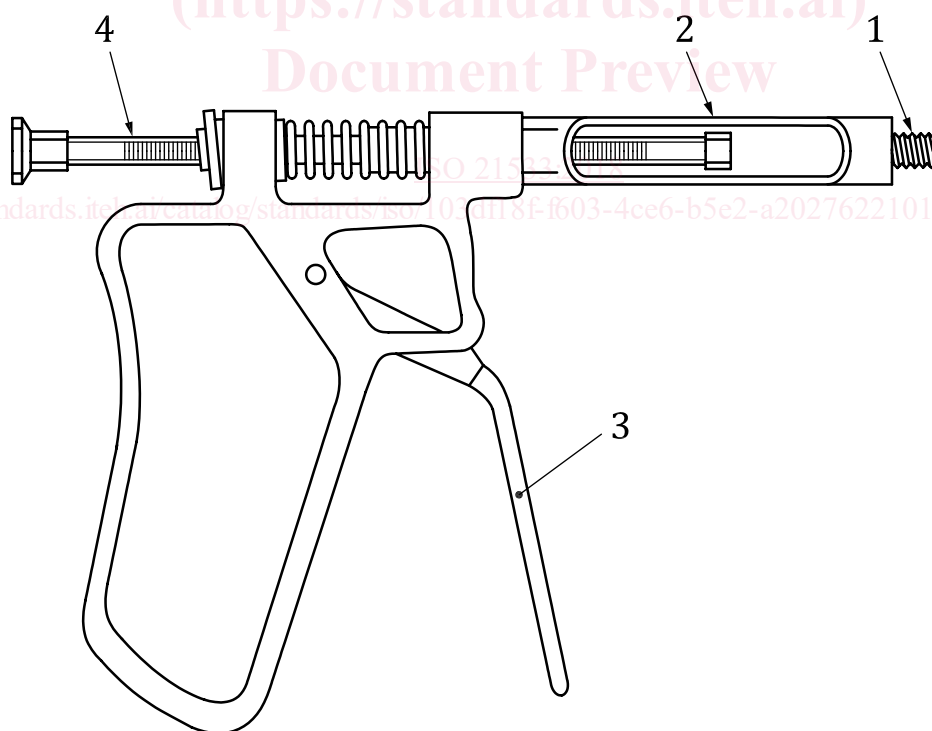
pack which contains the syringe

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