
Dentistry — Cartridge syringes

Médecine bucco-dentaire — Seringues pour cartouches

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 9997:2020](https://standards.iteh.ai/catalog/standards/iso/7c9ea256-3463-4246-adb9-322b9ad881cf/iso-9997-2020)

<https://standards.iteh.ai/catalog/standards/iso/7c9ea256-3463-4246-adb9-322b9ad881cf/iso-9997-2020>



iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 9997:2020](https://standards.iteh.ai/catalog/standards/iso/7c9ea256-3463-4246-adb9-322b9ad881cf/iso-9997-2020)

<https://standards.iteh.ai/catalog/standards/iso/7c9ea256-3463-4246-adb9-322b9ad881cf/iso-9997-2020>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
5 Requirements	2
5.1 General.....	2
5.2 Materials.....	2
5.3 Dimensions.....	2
5.4 Special requirements.....	3
5.4.1 Loading and cartridge size.....	3
5.4.2 Viewing of contents.....	4
5.4.3 Plunger rod.....	4
5.4.4 Aspirating syringes.....	4
5.5 Resistance to reprocessing.....	5
6 Measurement and test methods	5
6.1 Visual inspection.....	5
6.2 Dimensions.....	5
6.3 Secure loading.....	5
6.4 Aspirating test for cartridge syringes of Type 2.....	5
6.4.1 Reagent.....	5
6.4.2 Procedure.....	5
6.4.3 Observation.....	5
6.5 Aspirating test for cartridge syringes of Type 3.....	5
6.5.1 Reagent.....	5
6.5.2 Procedure.....	5
6.5.3 Observation.....	6
6.6 Plunger rod.....	6
6.6.1 Plunger rod movement.....	6
6.6.2 Plunger rod displacement.....	6
6.7 Resistance to reprocessing.....	6
7 Instructions for use	6
8 Marking	7
8.1 Labelling on the unit pack.....	7
8.2 Marking of syringe.....	7
Annex A (informative) Imperial thread sizes	8
Bibliography	9

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:

- the normative references have been updated;
- the requirement for reprocessing has been added in [5.5](#);
- the tolerance for plunger 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. These syringes are of the non-aspirating, 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 which is designed to include a cartridge as a removable part and which can be connected to a dental injection needle

3.4

plunger rod

rigid component which transmits the activating force to the cartridge plunger

3.5

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 (aspiration by force produced by drawing the plunger away from the needle);
- type 3: self-aspirating (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 Materials

Cartridge syringes may be made from metal or have plastic components. The materials are at the manufacturer's discretion provided that all of the requirements of this document shall be met.

Test in accordance with [6.1](#) and [6.7](#).

5.3 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](#).