INTERNATIONAL STANDARD

ISO 11040-3

Second edition
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Prefilled syringes —

Part 3: Seals for dental local anaesthetic cartridges

Seringues préremplies —

Partie 3: Rondelles d'étanchéité pour cartouches dentaires d'anesthésie locale

Reference number
ISO 11040-3:2012(E)

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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.

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 11040-3 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 11040-3:1993), which has been technically revised.

ISO 11040 consists of the following parts, under the general title *Prefilled syringes*:

— *Part 1: Glass cylinders for dental local anaesthetic cartridges*

— *Part 2: Plunger stoppers for dental local anaesthetic cartridges*

— *Part 3: Seals for dental local anaesthetic cartridges*

— *Part 4: Glass barrels for injectables and ready-to-use prefillable syringes*

— *Part 5: Plunger stoppers for injectables*

— *Part 6: Plastics barrels for injectables*

The following parts are under preparation:

— *Part 7: Packaging systems for prefillable ready-to-use syringes*

Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products. Therefore, the principles of current good manufacturing practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in ISO 15378 or in the GMP Guidelines published by the European Community and the United States of America.

Prefilled syringes —

Part 3:
Seals for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the shape, dimensions, material, performance requirements and labelling of seals for dental local anaesthetic cartridges intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can be significantly affected by the nature and performance of the primary packaging.

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 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 7885:2010, *Dentistry — Sterile dental injection needles for single use*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

ISO 8871-5:2005, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

ISO 8872, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*

ISO 11040-1, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*

ISO 11040-2, *Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges*

3 Classification

Seals shall be classified as follows:

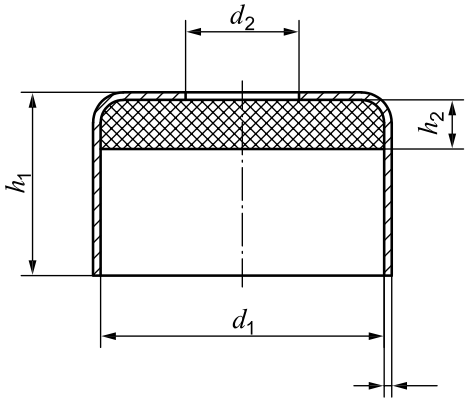
— type A: seals with a mono-layer disc;

— type B: seals with a double-layer disc.

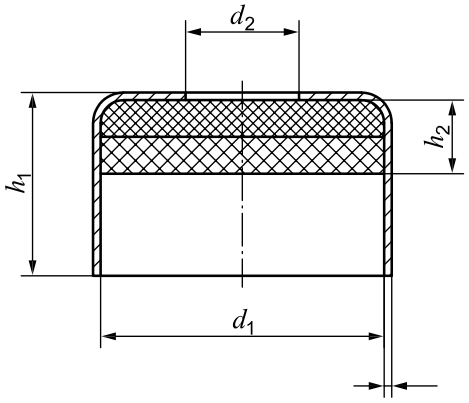
4 Shape and dimensions

4.1 The shape and dimensions of seals shall be as shown in Figure 1 and given in Table 1.

Dimensions in millimetres



Type A: Seal with a mono-layer disc



Type B: Seal with a double-layer disc

Shape and dimensions of seals for dental local anaesthetic cartridges

Dimensions of seals

Dimensions in millimetres

Nominal size	Type	Total cap height[a]	Thickness of disc	Inner cap diameter	Bore diameter
		h_1 ±0,15	h_2 ±0,15	d_1 ±0,05	d_2 ±0,3
7,5	A	4,85 to 4,9	1,3 to 1,5	7,5	3,0
7,5	B	4,85 to 5,3	1,45 to 1,95	7,5	3,0

[a] The height of the seal depends on the thickness and hardness of the disc.

4.2 For type B seals, both single layers shall be continuous. The thickness ratio of the single layers shall be agreed upon between the supplier and user.

4.3 The diameter of the rubber discs shall be such that a sufficient press-fit in the aluminium cap is achieved and that the discs cannot fall out.

4.4 If not otherwise specified, general dimensional tolerances shall be in accordance with ISO 3302-1.

5 Designation

Seals are designated according to their type (see Clause 3 and Figure 1). The designation shall comprise, in the following order, the descriptor “Seal”, a reference to this part of ISO 11040 and the type letter.

EXAMPLE Designation of a seal of type A (i.e. trimmed):

Seal ISO 11040-3 - A

6 Material

6.1 Cap

General requirements for aluminium caps shall be in accordance with ISO 8872. In addition, the cap shall be anodized or suitably lacquered.

6.2 Discs

Discs shall be made from the elastomeric formulation originally tested and approved by the end user. The manufacturer of the discs shall ensure the conformance of each delivery with the type sample and the compliance with previously agreed functional and compendial requirements.

The elastomeric material shall withstand two sterilization cycles when autoclaving in saturated steam at (121 ± 2) °C for 30 min without impairment of its function under conditions of normal use. If other sterilization methods are used, e.g. irradiation, the suitability of the material shall be evaluated.

7 Requirements

7.1 General

The requirements specified in 7.2 to 7.4 constitute minimum requirements concerning the condition of the elastomeric seals on receipt by the user.

7.2 Physical requirements

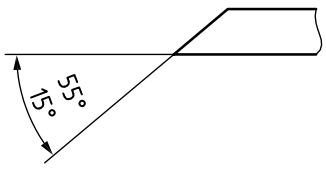
7.2.1 Hardness of the disc

The hardness agreed between the manufacturer and the user shall not differ from the nominal value by more than ±5 Shore A when tested in accordance with ISO 7619-1 on a special test specimen. Alternatively, hardness can be tested on the discs in accordance with ISO 48. If tested according to ISO 48, the microhardness shall not differ by more than ±5 IRHD from the type sample.

The manufacturer should provide suitable test specimens upon request.

7.2.2 Fragmentation

The requirements and test method of ISO 8871-5:2005, 4.2 and Annex B, shall apply, using a needle with an outer diameter of 0,4 mm that conforms to the butt-end requirements in ISO 7885:2010, 5.3.



Schematic representation of butt-end angle

7.2.3 Freedom from leakage

The seal of the cartridge shall show no signs of leakage when tested in accordance with Annex A.

7.2.4 Resistance to ageing

The maximum time between the date of manufacture of the seals and their pharmaceutical use should be agreed upon between the manufacturer and the user.

The seals shall maintain their performance characteristics throughout the entire shelf-life of the medicinal product, which is tested as part of the stability test by the user.

NOTE Ageing depends on storage and handling conditions. A guide to storage of vulcanized rubber is given in ISO 2230.

7.3 Chemical requirements

The requirements of ISO 8871-1 shall apply for the disc.

7.4 Biological requirements

The requirements of ISO 8871-4 shall apply.

Toxicity tests apply to the disc only.

8 Labelling

Packed seals that meet the requirements of this part of ISO 11040 can be labelled with the designation given in Clause 5.

Annex A
(normative)

Leakage test

A.1 Principle

Water-filled cartridges are prepared using the seals to be tested. By means of a suitable device, a force is applied to the seal during a defined time interval. Any observed leakage is recorded.

The leakage tests for seals and plunger stoppers (see ISO 11040-2) can be combined.

A.2 Apparatus

A.2.1 Cartridge cylinders, in accordance with ISO 11040-1.

A.2.2 Seals to be tested.

A.2.3 Plunger stoppers, in accordance with ISO 11040-2.

A.2.4 Suitable equipment, to prepare water-filled cartridges.

A.2.5 Cartridge holder, e.g. as specified in ISO 9997 or ISO 11499.

A.2.6 Pressurizing device, capable of applying a force of (30 ± 1) N.

A.3 Procedure

A.3.1 Take 10 cartridges and fill them with water until they are practically air-free using the seals to be tested.

NOTE The water may be replaced by a coloured solution in order to improve the visibility of the leakage.

A.3.2 Place the first cartridge, mounted in the cartridge holder (A.2.5), into the pressurizing device (A.2.6), and apply a force of (30 ± 1) N for 1 min. Check for leakage at the seal.

SAFETY PRECAUTIONS — Adequate safety measures should be in place to protect the operator.

A.3.3 Repeat the operation described in A.3.2 on the remaining cartridges.

A.4 Expression of results

Report the number of leakages observed at the seal.

Report whether the testing of the seals and plunger stoppers (see ISO 11040-2) has been combined.

Bibliography

[1] ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

[2] ISO 2230, *Rubber products — Guidelines for storage*

[3] ISO 3302-2, *Rubber — Tolerances for products — Part 2: Geometrical tolerances*

[4] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[5] ISO 9997, *Dental cartridge syringes*

[6] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

[8] ISO 13926-2, *Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use*

[9] ISO 15378, *Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP)*

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