INTERNATIONAL STANDARD

ISO 11040-2

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Prefilled syringes —

Part 2:
Plungers and discs for dental local anaesthetic cartridges

Seringues préremplies —

Partie 2: Bouchons-pistons et rondelles d'étanchéité pour cartouches dentaires d'anesthésie locale

Reference number
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Contents

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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.

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.

International Standard ISO 11040-2 was prepared jointly by Technical Committees ISO/TC 76, *Transfusion, infusion and injection equipment for medical use* and ISO/TC 106, *Dentistry*.

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

- *Part 1: Glass cylinders for dental local anaesthetic cartridges*
- *Part 2: Plungers and discs for dental local anaesthetic cartridges*
- *Part 3: Aluminium caps for dental local anaesthetic cartridges*
- *Part 4: Glass barrels for injectables*
- *Part 5: Plungers and plastics rods for injectables*

Annexes A, B and C form an integral part of this part of ISO 11040.

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Prefilled syringes —

Part 2:
Plungers and discs for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the design, dimensions, materials, performance, requirements, marking and test methods for plungers and discs for dental local anaesthetic cartridges intended for single use only.

It applies to primary packs used in direct contact with the drug.

NOTE 1 The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary pack.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 11040 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1994, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD).*

ISO 3302:1990, *Rubber — Dimensional tolerances for use with products.*

ISO 7864:1993, *Sterile hypodermic needles for single use.*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

ISO 8362-5:—[1], *Injection containers for injectables and accessories — Part 5: Freeze drying closures for injection vials.*

ISO 8871:1990, *Elastomeric parts for aqueous parenteral preparations.*

ISO 9997:1990, *Dental cartridge syringes.*

ISO 11040-1:1992, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges.*

ISO 11040-3:1993, *Prefilled syringes — Part 3: Aluminium caps for dental local anaesthetic cartridges.*

3 Classification of types

3.1 Plungers

Plungers shall be classified as follows:

Type A: Plungers without cavities;

Type B: Plungers with one cavity;

Type C: Plungers with two cavities.

1) To be published.

3.2 Discs

Discs shall be classified as follows:

Type A: Trimmed discs;

Type B: Moulded discs.

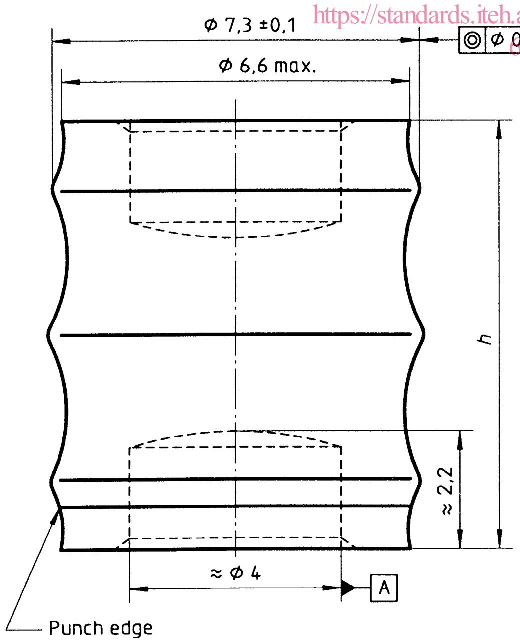
4 Dimensions and designation

4.1 Plungers

4.1.1 Dimensions

The dimensions of plungers shall be as shown in figure 1 and as given in table 1. General dimensional tolerances shall be in accordance with ISO 3302.

Dimensions in millimetres



NOTE — Type C is illustrated.

Figure 1 — Dimensions and configuration of plungers showing positions of cavities

Table 1 — Dimensions of plungers

Dimensions in millimetres

Type1)	h ± 0,25
A	6
B and C	8
1) See 3.1.	

4.1.2 Designation

Plungers shall be designated according to type: the designation shall be expressed as the word "plunger", the number and part of ISO 11040 followed by the abbreviation Pl for plunger and the type letter.

EXAMPLE

A plunger (Pl) of type C (i.e. with two cavities) complying with the requirements laid down in this part of ISO 11040 is designated:

Plunger ISO 11040-2 - Pl - C

4.2 Discs

4.2.1 Dimensions

The dimensions of discs shall be as shown in figure 2. General dimensional tolerances shall be in accordance with ISO 3302.

4.2.2 Designation

Discs shall be designated according to type: the designation shall be expressed as the word "disc", the number and part of ISO 11040 followed by the abbreviation Dc for disc and the type letter.

EXAMPLE

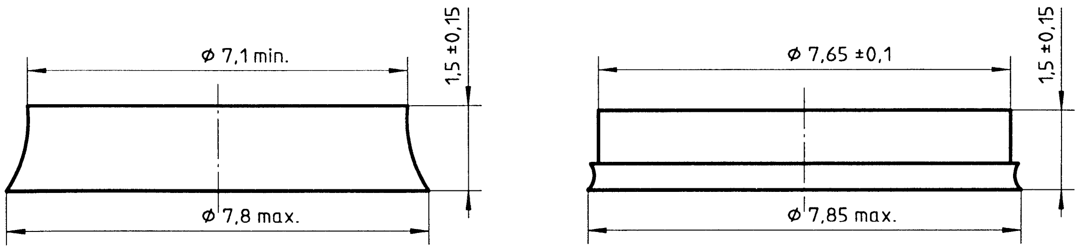
A disc (Dc) of type A (i.e. trimmed) complying with the requirements laid down in this part of ISO 11040 is designated:

Disc ISO 11040-2 - Dc - A

5 Material

Elastomeric materials used for the manufacture of plungers and discs shall be in accordance with the requirements specified in clause 6.

Dimensions in millimetres



a) Type A — Trimmed disc   b) Type B — Moulded disc

Figure 2 — Dimensions and configuration of typical discs

6 Requirements

6.1 Physical requirements

6.1.1 The trimmed part of the disc may be slightly conical and eccentric.

6.1.2 Sprues, if present, shall not protrude beyond the surface of the plunger.

6.1.3 In order to avoid adhesion of the plungers to each other, there shall be spacers as interrupted rings or bridges. The height of the spacers shall not exceed 0,2 mm.

The design of the spacers should be agreed between manufacturer and cartridge assembler.

6.1.4 Discs can be knurled on one or two sides in order to avoid sticking.

6.2 Hardness

The hardness of the rubber parts shall conform to parts previously selected for the intended purpose, when tested in accordance with ISO 48.

The hardness should be agreed between manufacturer and cartridge assembler.

6.3 Fragmentation (coring)

When testing discs for fragmentation in accordance with annex A, not more than three fragments per 50 piercings shall be observed.

6.4 Leakage

When tested according to annex B, no leakage shall be observed.

6.5 Sliding properties

When tested according to annex C, the break-loose force and restarting force shall not exceed 30 N. The force to sustain continuous movement shall not exceed 15 N and there shall be no chattering[2].

6.6 Chemical requirements

The material of the plungers and discs shall not exceed the limits specified in table 2.

6.7 Biological requirements

The elastomeric plungers and discs shall not release any substances which may adversely affect the therapeutic effectiveness of the injectable products, including those substances which may exhibit toxic, pyrogenic or haemolytic reactions.

NOTE 2 Since biological tests are usually required by most of the national Pharmacopoeias or related regulations of health authorities, they are mandatory for producers and users in countries where they exist.

If this is not the case, reference should be made to biological tests, e.g. as described in the United States Pharmacopoeia, European Pharmacopoeia or other Pharmacopoeias.

7 Marking

The package of plungers and discs may be marked with the designation given in 4.1.2 and 4.2.2.

2) Chatter (slip-stick) is the phenomenon of irregular motion of the plunger.

Table 2 — Chemical limits for plungers and discs

Characteristics	Limit	Test method as described in ISO 8871:1990
Reducing matter (oxidizables)	$\leqslant$ 7,0 ml of $c(KMnO_4)$ = 2 mmol/l per 20 ml	Annex C
Heavy metals (calculated as Pb^{2+})	$\leqslant$ 10 µg Pb^{2+}/10 ml	Annex D
Ammonium (calculated as NH_4^+)	$\leqslant$ 20 µg NH_4^+/10 ml	Annex E
Acidity/alkalinity	$\leqslant$ 1,0 ml of c(HCl) or c(NaOH) = 5 mmol/l per 20 ml	Annex G
Residue on evaporation (total solids)	$\leqslant$ 4 mg/100 ml	Annex H
Volatile sulfides (at pH $\approx$ 2)	Coloration of lead acetate paper $\leqslant$ 50 µg Na_2S/20 cm^2 of rubber surface	Annex J
Zinc (calculated as Zn^{2+})	$Zn^{2+} \leqslant$ 30 µg/10 ml	Annex K
Conductivity	$\leqslant$ 40 µS/cm	Annex L
Turbidity	Not exceeding the opalescence of suspension No. 3	Annex M

Annex A
(normative)

Test for fragmentation

A.1 General

The purpose of the test is to measure the relative coring tendency of discs. The test result can be significantly affected by many factors, such as prior processing of the discs, type of crimping device, sealing force, design of the hypodermic needle, its sharpness, the amount of lubrication on the needle, the gauge of the needle, and the keenness of the operator's sight.

In order to obtain comparable results it is necessary to control these variables. Such control is effected by running a parallel test on a sample consisting of similar discs with known fragmentation properties. If the test results are comparable the discs under tests are considered acceptable.

A.2 Principle

Discs to be tested are mounted in cartridge assemblies and pierced with a hypodermic needle. The resulting fragments are collected and counted.

A.3 Apparatus

A.3.1 100 cartridge glass cylinders, according to ISO 11040-1.

A.3.2 Hand-operated capping device and **aluminium caps** with a central hole which fit the glass cylinders used in the test.

A.3.3 Membrane filter set.

A.3.4 Five disposable syringes for single use (e.g. as specified in ISO 7886-1), capacity 10 ml or 20 ml, fitted with a tip for a hypodermic needle.

A.3.5 Five hypodermic needles, with an outer diameter of 0,4 mm, conforming to ISO 7864 and having dimensions as indicated in figure A.1 and table A.1.

Dimensions in millimetres

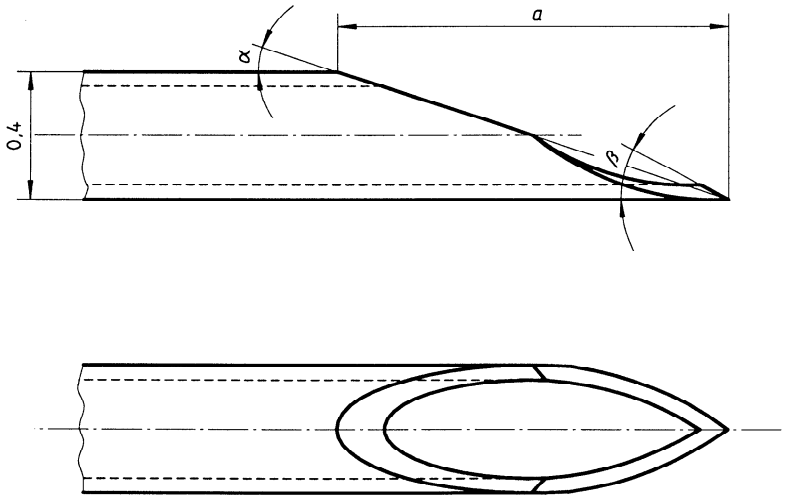


Figure A.1 — Needle point