INTERNATIONAL STANDARD

ISO 13926-2

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1999-04-15

Pen systems —

Part 2:
Plungers and discs for pen-injectors for medical use

Systèmes de stylos-injecteurs —

Partie 2: Bouchons-pistons et rondelles d'étanchéité pour stylos-injecteurs à usage médical

Reference number
ISO 13926-2:1999(E)

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 13926-2 was prepared jointly by Technical Committees ISO/TC 76, *Transfusion, infusion and injection equipment for medical use* and ISO/TC 84, *Medical devices for injections.*

ISO 13926 consists of the following parts, under the general title *Pen systems*:

— *Part 1: Glass cylinders for pen-injectors for medical use*

— *Part 2: Plungers and discs for pen-injectors for medical use*

Annexes A, B and C form an integral part of this part of ISO 13926.

Pen systems —

Part 2:
Plungers and discs for pen-injectors for medical use

1 Scope

This part of ISO 13926 specifies the design, dimensions, material performance requirements and marking of plungers and discs for medical pen systems. It is applicable to primary packs used in direct contact with drugs.

NOTE 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.

This part of ISO 13926 does not apply to laminated or lacquered plungers.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 13926. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 13926 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC 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 8871:1990, *Elastomeric parts for aqueous parenteral preparations.*

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

ISO 13926-1:1998, *Pen systems – Part 1: Glass cylinders for pen-injectors for medical use.*

3 Dimensions and designation

3.1 Dimensions

The plungers shall be type PSF, with dimensions as shown in Figure 1 and given in Table 1, and for discs as shown in Figure 2 and given in Table 2.

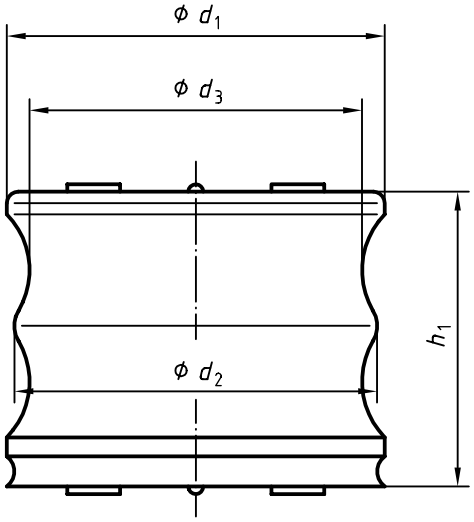
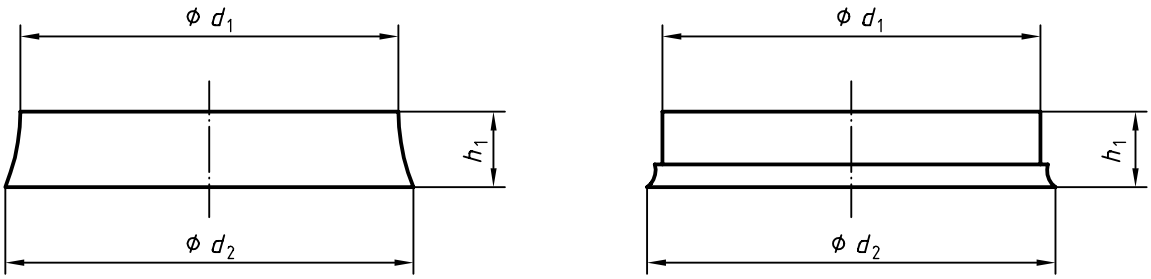


Figure 1 — Dimensions and configuration of plungers for medical pen-injectors

Table 1 — Dimensions of the plunger

Dimensions in milimetres

Nominal volume	Diameter			Height
ml	d_1 ± 0,1	d_2 ± 0,1	d_3 ± 0,15	h_1 ± 0,3
1,5	7,2	6,9	6,4	5,5
2	9,1	8,8	8,3	8,1
2,5	9,6	9,3	8,8	8,7
3	10	9,7	9,2	11,0
4	12,5	12,1	11,7	11
5	12,35	11,95	11,55	11
6	16,6	16,15	15,7	13



Type A
Lined seal

Type B
Moulded disc

Figure 2 — Dimensions and configuration of discs for medical pen-injectors

Table 2 — Dimensions of the disc

Dimensions in millimetres

Nominal volume ml	Type	Diameter		Height
		d_1	d_2	h_1 ± 0,15
1,5	A, B	7,1 min.	7,8 max.	
3	A, B	7,65 ± 0,1	7,85 max.	1,5
4 to 6	B	9,85 ± 0,15	10 max.	

3.2 Designation

Plungers and discs for medical pen systems shall be designated with the appropriate block descriptor followed by a reference to this part of ISO 13926, followed by the type of disc (if applicable), followed by the nominal volume, expressed in millilitres, of the glass cylinder with which it is to be used.

EXAMPLE 1 Designation of a plunger for a glass cylinder with a nominal volume of 1,5 ml complying with the requirements in this part of ISO 13926:

Plunger ISO 13926-2 - 1,5

EXAMPLE 2 Designation of a disc type A for a glass cylinder with a nominal volume of 3 ml complying with the requirements in this part of ISO 13926:

Disc ISO 13926-2 - A - 3

4 Material

The type of elastomeric material used shall be chosen such that the plungers and discs meet the requirements specified in clause 5.

5 Requirements

5.1 Physical requirements

5.1.1 Dimensions

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

The trimmed part of the disc may be slightly conical and eccentric. The trimming edge shall not extend beyond diameter d_2.

Discs may be knurled on one or both sides in order to avoid sticking together in a package.

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

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

5.1.2 Hardness

The hardness shall be agreed between manufacturer and user; hardness shall be determined in accordance with ISO 48.

5.1.3 Fragmentation (coring)

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

5.1.4 Leakage

When testing discs or plungers according to annex B, no leakage of liquid from the glass cylinder shall be observed.

5.1.5 Sliding properties

When testing plungers 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[1)]

5.2 Chemical requirements

The chemical properties of the material of the plungers and discs shall not exceed the limits specified in Table 3.

Table 3 — Chemical limits for plungers and discs

Test	Requirement	Test procedure as described in ISO 8871:1990, annex[a]
Reducing matter (oxidizables)	⩽ 7 ml of $c(KMnO_4)$ = 2 mmol/l per 20 ml	C
Heavy metals (calculated as Pb^{2+})	⩽ 10 µg Pb^{2+}/10 ml	D
Ammonium (calculated as NH_4^+)	⩽ 20 µg NH_4^+/10 ml	E
Acidity/alkalinity	⩽ 1 ml of c(HCl) or c(NaOH) = 5 mmol/l per 20 ml	G
Residue on evaporation (total solids)	⩽ 4 mg/100 ml	H
Volatile sulfides (at pH ≈ 2)	coloration of lead acetate paper ⩽ 50 µg Na_2S/20 cm^2 rubber surface	J
Zinc (calculated as Zn^{2+})	Zn^{2+} ⩽ 30 µg/10 ml	K
Conductivity	⩽ 40 µS/cm	L
Turbidity	not exceeding opalescence suspension number 3	M
a ISO 8871:1990 is under revision at present. Therefore, the requirements specified in this table could change.		

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

5.3 Biological requirements

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

NOTE Since biological tests are usually requested 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, national Pharmacopoeias or ISO 10993 series.

6 Marking

The package of plungers or discs may be marked with a designation in accordance with 3.2.

Annex A
(normative)

Test for fragmentation

A.1 General

The purpose of this test is to measure the coring tendency of discs for glass cylinders of medical pen systems. 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 used, its sharpness, degree of lubrication of the needle, gauge of the needle, and the keenness of the operators's eyesight.

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 similiar discs with known fragmentation properties. If the test results on the control are comparable to previous results, the discs under test are considered acceptable.

NOTE The following fragmentation test method is a test which is only suitable to separate rubber plungers with an acceptable fragmentation behaviour from those with an unacceptable behaviour. It does not simulate daily practice, where for example diabetics pierce a disc with one injection needle several times.

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 in accordance with ISO 13926-1**.**

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), of 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

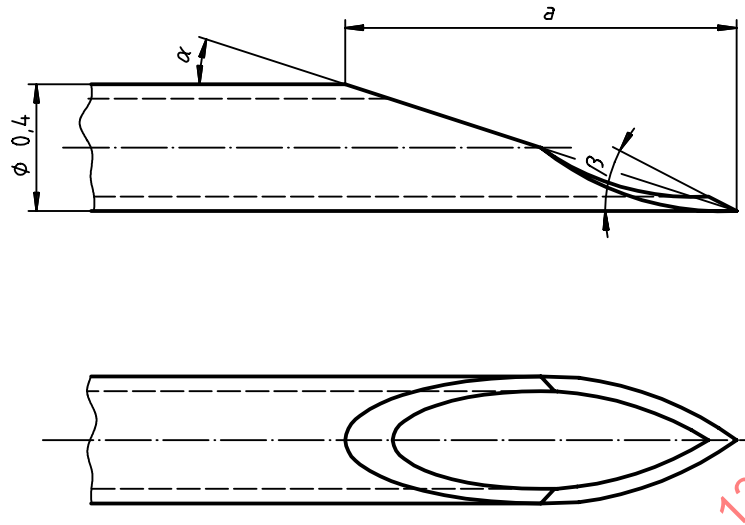


Figure A.1 — Needle point

Table A.1 — Dimensions of the bevel (see Figure A.1)

Bevel type	a mm		α	β
M	min.	max.	nom.	
(medium)	1,35	1,55	≈ 15° 30'	26° ± 1°

A.4 Procedure

A.4.1 Half-fill with water 50 cartridge cylinders, fitted with a plunger, and seal with the discs under test, using an aluminium cap (A.3.2). Repeat this step with 50 comparable cartridges using discs of known fragmentation behaviour. Arrange the two series in two rows as shown in Figure A.2.

A.4.2 Attach a hypodermic needle (A.3.5) to a disposable syringe (A.3.4), filled with water. Remove any water adhering to the needle.

A.4.3 Put cartridge 1 (the first cartridge from the first row) perpendicularly on a firm base, with the disc end pointing upward. Manually pierce the disc with the syringe assembly, holding the syringe in the vertical position.

Inject 1 ml of water into the cartridge.

Withdraw the syringe and remove any water adhering to the needle.

A.4.4 Repeat on cartridge 51 (the first cartridge from the second row).

A.4.5 Repeat operations A.4.3 and A.4.4 on the further cartridges, taking the test objects alternately from the two rows. Ensure that the cartridges from the two rows are kept separate.

After 20 piercings replace the hypodermic needle with a new one.

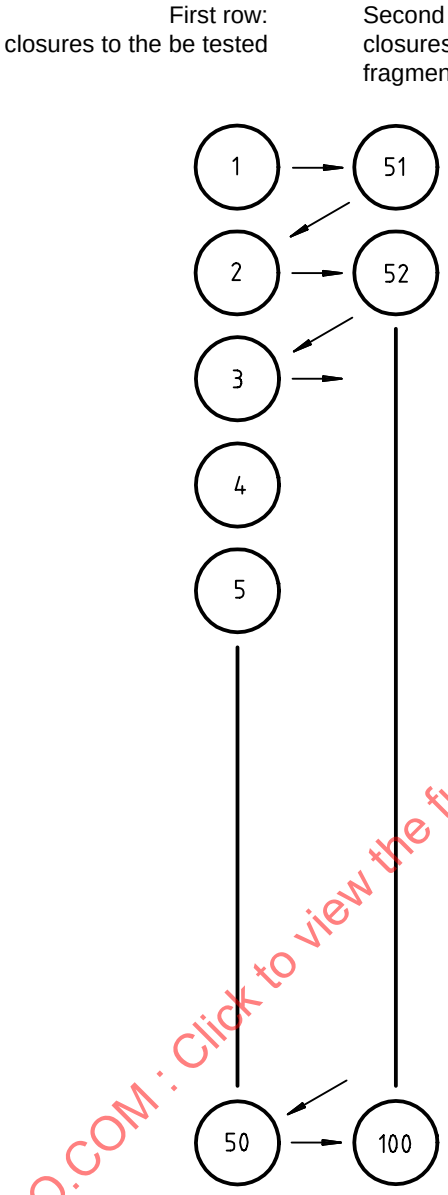


Figure A.2 — Cartridge cylinder sequence for disc fragmentation test

Needle No.[a]	Disc fragmentation test/known combination No.
1	1 51 2 52 3 53 4 54 5 55 6 56 7 57 8 58 9 59 10 60
2	11 61 12 62 13 63 etc.
a Each needle is used for 20 piercings only.	

A.4.6 Remove the discs under test from the cartridge (in the first row). Filter the contents of the cartridge through the same membrane filter. Ensure that no rubber fragments remain in the cartridge. Count and record the number of disc fragments on the filter which are visible to the naked eye at normal visual acuity, without magnification.

A.4.7 Repeat the procedure described in A.4.6 using the cartridges fitted with rubber discs with known fragmentation properties.

A.5 Expression of results

Report the number of disc fragments observed for 50 piercings in each of the two rows.

A.6 Validity

Check the results obtained for the second row for consistency with the known fragmentation behaviour.

In the case of lack of consistency, discard the results from the first row, investigate the cause for the inconsistency, and repeat the test.

Annex B
(normative)

Leakage test

B.1 Principle

Water-filled cartridges are prepared, using the plungers and/or the discs to be tested. By means of a suitable device, a force is applied to the plunger disc during a defined time interval. Any observed leakage is recorded.

B.2 Apparatus

B.2.1 Cartridge cylinders in accordance with ISO 13926-1 with a silicone-treated inner surface.

B.2.2 Aluminium caps in accordance with ISO 11040-3.

B.2.3 An appropriate holder for the cartridges, having a flat area to contact the rubber plunger.

B.2.4 Device enabling a force of 60 N ± 3 N to be transmitted to the mounted plunger, e.g. a suitably adapted version of a tensiometer.

B.3 Procedure

B.3.1 Prepare 10 cartridges, filled with water, and fitted with the plungers and/or discs under test.

B.3.2 Place the first cartridge, mounted in the syringe holder, into the pressurizing device, and apply a force of 60 N to the plunger and/or disc for 1 min.

After this time interval, check for leakage at the plunger and/or the disc.

B.3.3 Repeat the operation described in B.3.2 on the remaining cartriges.

B.4 Expression of results

Report the number of cases in which leakage occurs

a) at the plunger and

b) at the disc.

The outside design, the dimensions and the surface treatment of the plungers/discs used shall be documented.