INTERNATIONAL STANDARD

**ISO 7885**

First edition
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# Sterile, single-use dental injection needles

*Aiguilles stériles, non réutilisables, pour injections dentaires*



Reference number
ISO 7885:1996(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.

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 7885 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Annex A of this International Standard is for information only.

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# Sterile, single-use dental injection needles

## 1 Scope

This International Standard specifies dimensional and performance requirements for sterile, single-use dental injection needles for dental cartridge syringes for injection of dental local anaesthetics. It does not cover needles for special applications or techniques.

The materials of construction other than those of the needle tubing are not specified.

NOTE 1 This International Standard is closely related to ISO 7864 prepared by ISO/TC 84, *Medical devices for injections*.

This International Standard does not specify requirements for validated sterilization processes.

NOTE 2 ISO/TC 198, *Sterilization of health care products*, is in the course of preparing International Standards for such processes.

This International Standard does not specify colour coding.

NOTE 3 ISO/TC 106 has indicated a preference for the adoption of ISO 6009 colour coding at first revision of the present International Standard.

In some countries national pharmacopoeia or other legally binding regulations may take precedence over this International Standard.

## 2 Normative references

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

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

ISO 9626:1991, *Stainless steel tubing for manufacture of medical devices.*

ISO 9997:1990, *Dental cartridge syringes.*

ISO 10993-1:—[1], *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 10993-11:1993, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity.*

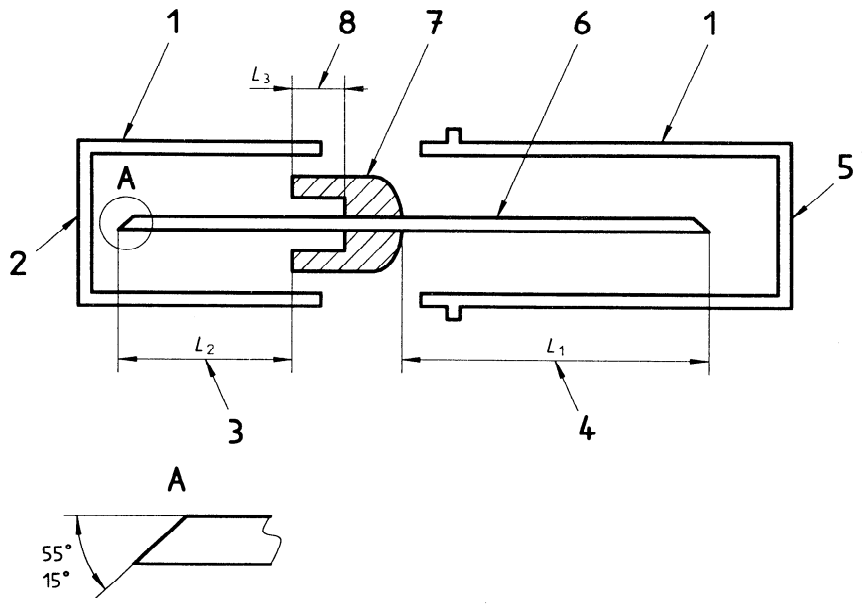
## 3 Definitions

For the purposes of this International Standard, the following definitions apply.

**3.1 needle unit:** Dental needle unit comprising the primary container, needle and hub, as shown in figure 1.

NOTE 4 The terms used to describe the components are given in figure 1.

1) To be published. (Revision of ISO 10993-1:1992)




1 Primary container (two parts)
2 Butt end sheath
3 Butt end length ($L_2$)
4 Effective needle length ($L_1$)
5 Effective needle sheath
6 Needle
7 Hub
8 Socket depth ($L_3$)

NOTE — The primary container of the needle may be hardpack or softpack.



**Figure 1 — Schematic diagram of hardpack**

**3.2 hardpack:** Needle unit, consisting of a rigid butt end sheath and a rigid effective needle sheath, sealed to form a complete unit, as shown in figure 1.

**3.3 softpack:** Needle unit, consisting of a preformed plastic tray with a peel-off cover, in which the effective needle is protected by a rigid sheath.

NOTE 5 A butt end sheath may or may not be present.

**3.4 primary container:** Protective package, hardpack or softpack, for the needle.

**3.5 secondary container:** Container in which primary containers are packed.

## 4 Requirements of assembled needle and hub

### 4.1 Freedom from pyrogenic material

The assembled needle and hub shall satisfy the test for freedom from pyrogenic material specified in ISO 10993-11 or in the European, U.S. or Japanese Pharmacopoeia.

### 4.2 Freedom from abnormal toxicity

The assembled needle and hub shall satisfy the test for abnormal toxicity specified in ISO 10993-1 or in the European, U.S. or Japanese Pharmacopoeia.

### 4.3 Freedom from extraneous matter

The surface of the assembled needle and hub shall be clean and free from extraneous matter when viewed by normal or corrected vision without magnification.

### 4.4 Union between hub and needle

The union of the hub and needle shall not break under a force of 22 N applied as either a push or pull in the direction of the needle axis.

## 5 Requirements of needle tubing

### 5.1 Material

The tubing used for construction of the needle shall comply with ISO 9626.

### 5.2 Dimensions

**5.2.1** The nominal outside diameter of the needle tubing, expressed in millimetres, in accordance with ISO 9626 shall be between 0,3 mm and 0,5 mm.

**5.2.2** The effective needle length (see $L_1$ in figure 1) of the needle tubing, expressed in millimetres, shall be within ± 2 mm of that stated by the manufacturer.

**5.2.3** The size of the needle shall be designated by the nominal outside diameter and the effective needle length, expressed in millimetres, e.g. 0,4 mm × 34 mm.

### 5.3 Butt end

**5.3.1** The angle at the butt end shall be between 15° and 55° when measured through the long needle axis (see figure 1, detail A).

**5.3.2** The butt end length (see $L_2$ in figure 1) shall be between 9,0 mm and 14,0 mm.



### 5.4 Needle point

The needle shall be pointed and when examined under × 2,5 magnification shall appear sharp, free from feather edges, burrs, hooks and/or other defects. The angle of the needle point shall be

— normal point: 12° ± 3°;

— short point: 18° ± 3°.

### 5.5 Patency of lumen

The patency of lumen shall be such that either

a) a stainless steel stylet of the appropriate diameter, selected from the diameters given in table 1, shall pass through the needle;

b) the rate of water passage through the needle under a hydrostatic pressure not exceeding $1 \times 10^5$ Pa shall be not less than 80 % of that of a needle of equivalent outside diameter and length having a minimum inside diameter in accordance with ISO 9626 when tested under the same pressure.

### 5.6 Lubricant

Lubricant on the external surface shall not be visible as droplets of fluid under normal or corrected vision without magnification.

**Table 1 — Size of stylet to test patency of lumen**

Dimensions in millimetres

| Nominal outside diameter of needle | Diameter of stylet $^{0}_{-0,01}$ |
|---|---|
| 0,3 | 0,11 |
| 0,4 | 0,15 |
| 0,5 | 0,18 |

## 6 Requirements of the hub

### 6.1 Compatibility with syringe

If an internal thread is present in the hub, it shall mate with the threaded mounting hub of a cartridge syringe having an external thread of metric form M6 × 0,75 in accordance with ISO 9997 or of Imperial system form 0,218 × 40 T.P.I. (Whitworth form).

### 6.2 Socket depth

The depth of the socket of the hub ($L_3$ in figure 1) shall be not less than 5 mm.

## 7 Requirements of the primary container

**7.1** Each needle shall be supplied in a primary container.

**7.2** The material and design of this container shall ensure

— maintenance of sterility;

— that, once opened, the container shall show clear evidence of having been opened;

— that the effective needle sheath can be used as an aid for attaching the needle to the syringe, without the operator touching the needle.

## 8 Sterility

The dental needle unit shall have been subjected to a validated sterilization process.

## 9 Labelling

The primary or secondary container shall be marked with at least the following information:

a) size of needle (see 5.2.3);

b) name or trademark of manufacturer or distributor;

c) the words "Sterile single-use dental injection needle";

d) ISO graphical symbol for single use, i.e. symbol No.1051 in accordance with ISO 7000;

e) batch or lot number;

f) the words "Do not use if seal is broken";

g) date including year (in accordance with ISO 8601) of sterilization;

h) type of thread.

## Annex A
(informative)

## Bibliography

[1] ISO 6009:1992; *Hypodermic needles for single use — Colour coding for identification.*

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