INTERNATIONAL STANDARD

ISO 7885

Second edition
2000-12-15

Sterile dental injection needles for single use

Aiguilles dentaires stériles pour injection, non réutilisables

Reference number
ISO 7885:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 7885:1996), of which it constitutes a technical revision.

The major difference between this edition and the first edition is the introduction of colour coding in accordance with ISO 6009.

Annex A of this International Standard is for information only.

Introduction

This International Standard is closely related to ISO 7864. Requirements for validated sterilization processes are described in International Standards prepared by ISO/TC 198, *Sterilization of health care products.*

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

This International Standard specifies requirements for dental injection needles with metric sizes only. However, attention is drawn to the existence of dental injection needles with imperial threads (see annex A). Manufacturers currently producing needles with imperial thread sizes are requested to change to ISO metric threads; the year 2005 has been set as a target date.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

Sterile dental injection needles for single use

1 Scope

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

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

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 IEC and ISO maintain registers of currently valid International Standards.

ISO 6009:1992, *Hypodermic needles for single use — Colour coding for identification.*

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

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

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

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

ISO 9997, *Dental cartridge syringes.*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.*

3 Terms and definitions

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

3.1
needle unit
the primary container, needle and hub

See Figure 1.

3.2
hardpack
needle unit, consisting of a rigid butt-end sheath and a rigid effective needle sheath, sealed to form a complete unit

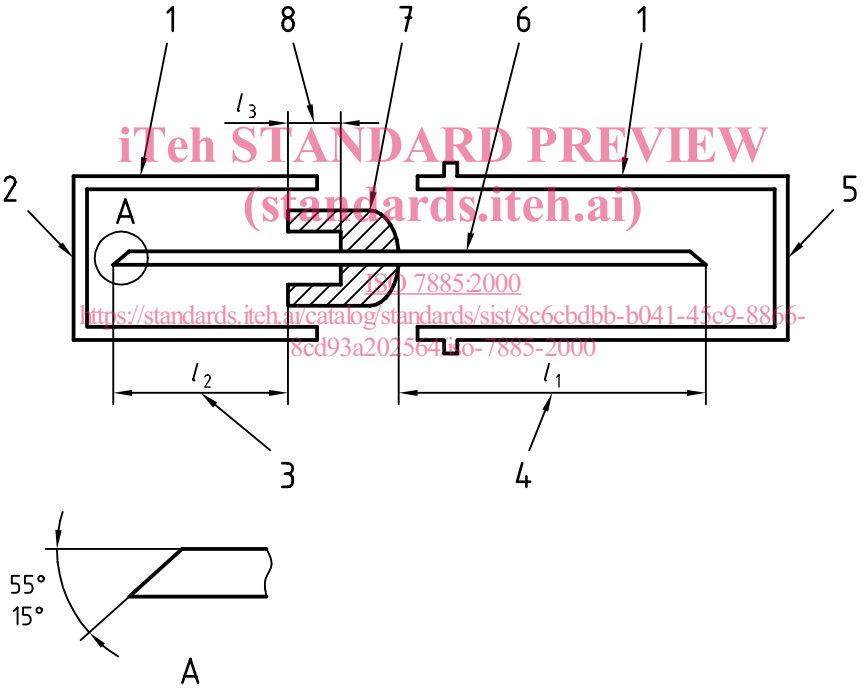
See Figure 1.

3.3
softpack
needle unit, consisting of a preformed plastics tray with a peel-off cover, in which the effective needle length is protected by a rigid sheath

NOTE 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



Key
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)

Figure 1 — Schematic diagram of hardpack

4 Requirements of assembled needle and hub

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

4.2 Limits for extractable metals

Limits and tests for extractable metals shall be in accordance with ISO 7864:1993, clause 6.

4.3 Union between hub and needle

The union between the hub and needle shall not break under a force of 22 N applied at the rate of 1 mm/s in both directions along the needle axis.

4.4 Biocompatibility

See the Introduction for guidance on biocompatibility.

NOTE 1 If freedom from pyrogenic material is required by national legislation, reference to ISO 10993-11 is suggested.

NOTE 2 If freedom from abnormal toxicity is required by national legislation, reference to ISO 10993-1 is suggested.

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 in accordance with ISO 9626 shall be between 0,25 mm and 0,5 mm.

5.2.2 The effective needle length (see l_1 in Figure 1) of the needle tubing 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;

or

b) the rate of water passage through the needle under a hydrostatic pressure not exceeding 1×10^5 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.

Table 1 — Size of stylet to test patency of lumen

Dimensions in millimetres

Nominal outside diameter of needle	Diameter of stylet $^{0}_{-0,01}$
0,25	0,1
0,3	0,11
0,4	0,15
0,5	0,18

6 Requirements of hub

6.1 Compatibility with syringe

6.1.1 General

The hub may be threaded or unthreaded.

6.1.2 Threaded hubs

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.

6.1.3 Unthreaded hubs

If an internal thread is absent, the needle shall be capable of being easily and securely screwed onto the threaded mounting hub as described in 6.1.2.

6.2 Socket depth

The depth of the socket of the hub (l_3 in Figure 1) shall be not less than 5 mm.

6.3 Colour coding

The nominal outside diameter of the needle tubing shall be identified by colour coding in accordance with ISO 6009 (see Table 2 below). This colour coding shall be on the primary container or on the needle hub.

NOTE 1 Attention is drawn to the sets of reference hubs available as reference colour samples (see annex A of ISO 6009:1992)

NOTE 2 The colour zones of opaque colours and the nearest colour samples in a number of colour atlases are given for information in annexes B and C of ISO 6009:1992, respectively.

Table 2 — Colour code

Dimensions in millimetres

Nominal outside diameter of needle	Colour
0,3	yellow
0,4	medium grey
0,5	orange

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.