
**Sterile dental injection needles for single
use**

Aiguilles dentaires stériles pour injection, non réutilisables



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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.