
Prefilled syringes —

Part 2:

**Plunger stoppers for dental local
anaesthetic cartridges**

Seringues préremplies —

*Partie 2: Bouchons-pistons pour cartouches dentaires d'anesthésie
locale*



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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11040-2 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 11040-2:1994), which has been technically revised by:

- aligning this International Standard with the ISO 8871 series;
- separating requirements on plunger stoppers (this part of ISO 11040) and seals; the latter are now completely covered by ISO 11040-3;
- revising Table 1 on dimensions of plunger stoppers;
- revising the requirements on material, hardness, freedom from leakage and sliding characteristics;
- adding requirements on resistance to ageing.

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

- *Part 1: Glass cylinders for dental local anaesthetic cartridges*
- *Part 2: Plunger stoppers for dental local anaesthetic cartridges*
- *Part 3: Seals for dental local anaesthetic cartridges*
- *Part 4: Glass barrels for injectables*
- *Part 5: Plunger stoppers for injectables*
- *Part 6: Plastic barrels for injectables*

Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products. As such, the principles of current Good Manufacturing Practices (cGMP) are applicable to the manufacturing of these components.

Principles of cGMP are described in ISO 15378, and in GMP Guidelines published by the European Community^[5] and the United States of America^[6].

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Prefilled syringes —

Part 2: Plunger stoppers for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the shape, dimensions, material, performance requirements and labelling of plunger stoppers for dental local anaesthetic cartridges intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can be affected significantly by the nature and performance of the primary packaging.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)* [alternative normative reference to ISO 7619-1]

ISO 3302 (all parts), *Rubber — Tolerances for products*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)* [alternative normative reference to ISO 48]

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

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

ISO 11040-3, *Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges*

3 Classification

Plunger stoppers shall be classified as follows:

- Type A: plunger stoppers without cavities;
- Type B: plunger stoppers with one cavity;
- Type C: plunger stoppers with two cavities.