INTERNATIONAL STANDARD

ISO 14972

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Sterile obturators for single use with over-needle peripheral intravascular catheters

Obturateurs stériles non réutilisables pour cathéters intravasculaires périphériques à aiguille interne

Reference number
ISO 14972:1998(E)

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 14972 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections,* Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use.*

Annex A forms a normative part of this International Standard. Annex B is for information only.

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Sterile obturators for single use with over-needle peripheral intravascular catheters

1 Scope

This International Standard specifies requirements for obturators, supplied in the sterile condition and intended for single use for plugging over-needle peripheral catheters.

NOTE Attention is drawn to ISO 10555-5, which specifies requirements for over-needle peripheral catheters.

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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1998, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*.

3 Definition

For the purposes of this International Standard, the following definition applies.

3.1
obturator
device designed to be inserted into an over-needle peripheral catheter to plug the lumen of the catheter

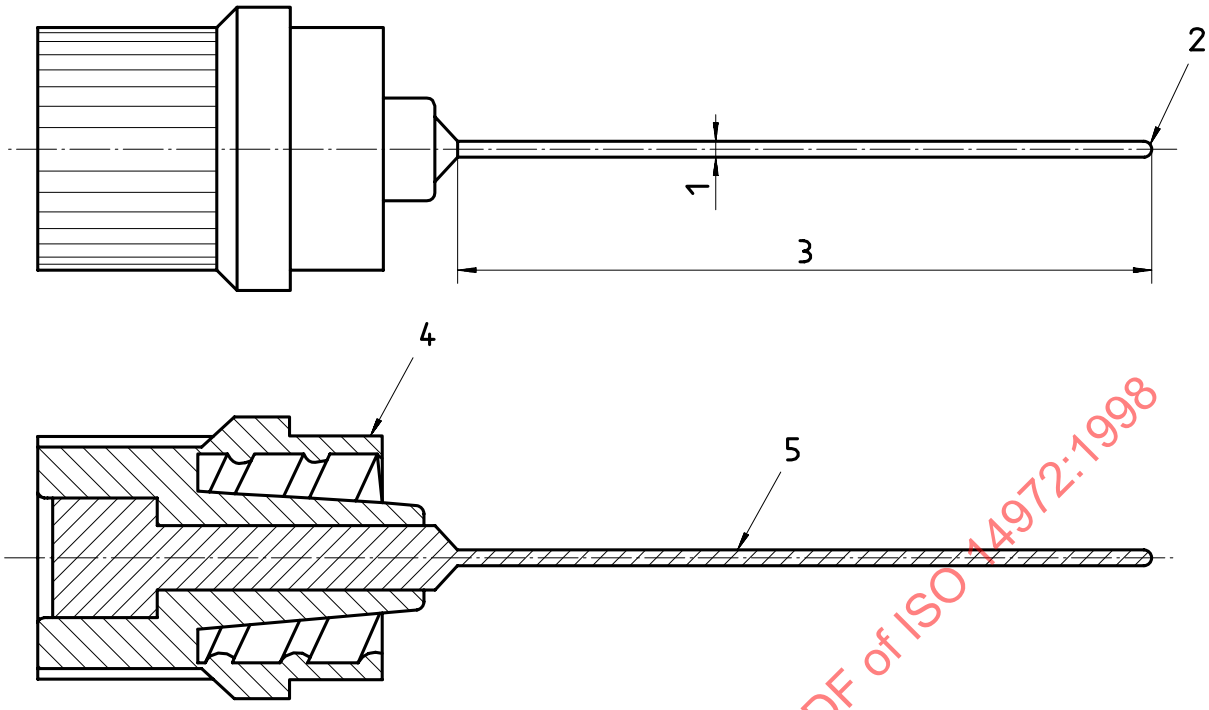
See figure 1.

4 Requirements

4.1 General

The obturator shall have been sterilized by a validated method and it shall comply with the requirements given in 4.2 to 4.10 in the sterile condition.

NOTE See ISO 11134, ISO 11135 and ISO 11137 for appropriate methods of sterilization.



Key

1 Outside diameter
2 Tip
3 Effective length
4 Luer fitting (lock fitting shown)
5 Obturator shaft

Figure 1 — Example of obturator

4.2 Biocompatibility

The obturator shall be free from biological hazard.

NOTE See ISO 10993-1 for the selection of appropriate test methods.

4.3 Surface

When examined by normal or corrected-to-normal vision with 2,5 × magnification, the external surface of the effective length of the obturator shaft shall appear free from extraneous matter.

The external surface and the tip of the obturator shaft should be free from surface defects in order to minimize trauma to vessels during use.

4.4 Force at break

When tested in accordance with the method given in annex A, the force at break of the obturator shall be as given in table 1.

Table 1 — Force at break

Smallest outside diameter of obturator shaft mm	**Minimum force at break** N
≥ 0,35 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	8
≥ 1,85	12

4.5 Luer fitting

The Luer fitting shall comply with ISO 594-1 or ISO 594-2.

4.6 Outside diameter

The outside diameter of the obturator shaft shall be compatible with the inside diameter of the over-needle peripheral catheter(s) with which it is intended to be used in order to plug the lumen of the catheter.

4.7 Effective length

When the obturator is fully inserted into the over-needle peripheral catheter, the tip of the obturator shall either coincide with the tip of the catheter or shall extend from the tip of the catheter by no more than 3,0 mm.

4.8 Colour code

The obturator shall be colour-coded with the colour code of the over-needle peripheral catheter with which it is intended be used.

The colour code shall appear on the unit package unless the colour on the product is visible through the unit package.

4.9 Radio-detectability

It is recommended that obturators be radio-opaque. At present there is no acceptable, validated test method to determine radio-detectability. An approved test method for producing a value of radio-detectability will be established. Until that time, a manufacturer may label the product ‘radio-opaque’ provided this claim can be supported by demonstrating that the manufacturer has an appropriate method for showing radio-opacity.

4.10 Information to be supplied by the manufacturer

The manufacturer shall supply at least the information listed in a) to j). All dimensions given shall be expressed in SI units of measurements.

NOTE Units of other measurement systems may additionally be used.

a) Description of the product.

b) Suitability for use with a specified over-needle peripheral catheter(s).

c) Name or trade name and address of manufacturer.

d) Lot designation.

e) Expiry date or use by date.

f) Any special storage and handling instructions.

g) Indication of sterility.

h) Method of sterilization.

i) Indication for single use.

j) Instructions for use and warnings, as appropriate.

Annex A
(normative)

Method for determining force at break of the obturator

A.1 Principle

Test pieces of an obturator are chosen so that each obturator portion and each junction between the obturator and the Luer fitting is tested. A tensile force is applied to each test piece until the obturator breaks or the junction separates.

A.2 Apparatus

A.2.1 **Tensile testing apparatus**, capable of exerting a force of greater than 15 N.

A.3 Procedure

A.3.1 Select a test piece from the obturator to be tested. Include in the test piece the junction between the obturator and the Luer fitting.

A.3.2 Condition the test pieces in an atmosphere of 100 % relative humidity or water and a temperature of (37 ± 2) °C for 2 h. Test immediately after conditioning.

A.3.3 Fix the test piece in the tensile testing apparatus (A.2.1). Use an appropriate fixture to avoid deforming the obturator or the Luer fitting.

A.3.4 Measure the gauge length of the test piece (i.e. the distance between the jaws of the tensile testing apparatus or the distance between the Luer fitting and the jaw holding the other end of the test piece, as appropriate).

A.3.5 Apply a tensile strain at unit strain rate of 20 mm/min per millimetre of gauge length (see table A.1) until the test piece separates into two or more pieces.

Note the value of the applied tensile force, in newtons, at which separation occurs, and record this value as the force at break.

A.3.6 Do not perform more than one test on each test piece.

Table A.1 — Example of conditions for a 20 mm/min/mm strain rate

Gauge length (mm)	Testing speed (mm/min)
10	200
20	400
25	500

A.4 Test report

The test report shall include the following information:

a) identity of the obturator;

b) the force at break, in newtons, and outside diameter of each test piece.

Annex B
(informative)

Bibliography

[1] ISO 10555-5:1996, *Sterile, single-use intravascular catheters — Part 5: Over-needle peripheral catheters.*

[2] ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

[3] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization.*

[4] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization.*

[5] ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization.*