INTERNATIONAL STANDARD

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AMENDMENT 1
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Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

AMENDMENT 1

Cathéters intravasculaires stériles, non réutilisables —

Partie 5: Cathéters périphériques à aiguille interne

AMENDEMENT 1

Reference Number
ISO 10555-5:1996/Amd.1:1999(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.

Amendment 1 to International Standard ISO 10555-5:1996 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections,* Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use.*

The purpose of this amendment is to introduce into ISO 10555-5:1996 requirements for the leak-tightness of vent fittings.

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AMENDMENT 1

Page 1, clause 1, Scope

Add the following to the end of the note:

> "and to ISO 14972 which specifies requirements for sterile obturators for use with over-needle peripheral catheters".

Page 3, subclause 4.4.4, Vent fitting

Delete the text and substitute the following:

> "A vent fitting shall be provided. When tested in accordance with annex E, fluid shall not leak out of the vent fitting within 15 s."

Page 10, annex E, Bibliography

Change annex E to annex F.

Add the following reference:

> "[2] ISO 14972:1998, *Sterile obturators for single use with over-needle peripheral intravascular catheters.*"

Page 10

Add the following new annex as annex E.

Annex E
(normative)

Determination of liquid leakage from vent fitting

E.1 Principle

The catheter is connected to a source of simulated blood under hydrostatic pressure. The fluid is allowed to flow into the needle, and the time taken for fluid to leak through the vent fitting is measured.

E.2 Test fluid

E.2.1 Prepare a solution of sodium chloride [0,9 % (M/V)] by dissolving 9 g of reagent grade sodium chloride in distilled or deionized water to make 1 litre of solution.

E.2.2 Prepare the test fluid by mixing 550 ml of sodium chloride solution (E.2.1) and 450 ml of glycerol of USP grade or better.

NOTE To improve the visibility of the solution, a colorant such as red or blue food dye may be incorporated.

E.3 Apparatus

E.3.1 **Constant-level tank**, to provide a hydrostatic head of (400 ± 20) mm, fitted with a delivery tube of inside diameter not less than 3 mm having a clamp or valve and at its end a puncturable membrane (e.g. a latex cap). See figure E.1 for an example of such apparatus.

E.3.2 **Stopwatch**, or similar device.

E.4 Procedure

E.4.1 Supply the constant-level tank (E.3.1) with test fluid (E.2) at (23 ± 2) °C.

E.4.2 Remove all air from the delivery tube and close the clamp or valve.

E.4.3 Insert the tip of the needle tube through the membrane, ensuring that the needle tube is kept horizontal at ± 5 degrees.

E.4.4 Open the clamp or valve so as to allow fluid to enter the needle tube. Measure the time taken for fluid to form the first falling drop at the back of the vent fitting.

E.5 Test report

The test report shall contain at least the following information:

a) the identity of the catheter being tested;

b) the time, in seconds, for the first drop of test fluid to fall.