

INTERNATIONAL STANDARD

ISO
10555-1

First edition
1995-06-15

Sterile, single-use intravascular catheters —

Part 1: General requirements

*Cathéters intravasculaires stériles, non réutilisables —
Partie 1: Prescriptions générales*



Reference number
ISO 10555-1:1995(E)

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International Organization for Standardization

Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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

ISO 10555 consists of the following parts, under the general title *Sterile, single-use intravascular catheters*:

- Part 1: *General requirements*
- Part 2: *Angiographic catheters*
- Part 3: *Central venous catheters*
- Part 4: *Balloon dilatation catheters*
- Part 5: *Over-needle peripheral catheters*

Attention is drawn to ISO 11070, which will specify requirements for accessory devices for use with intravascular catheters.

Annexes A, B, C and D form an integral part of this part of ISO 10555. Annex E is for information only.

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Sterile, single-use intravascular catheters —

Part 1: General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

It does not apply to intravascular catheter accessories, which will be covered by a separate standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10555. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10555 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 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*.

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*.

3 Definitions

For the purposes of this part of ISO 10555, the following definitions apply.

3.1 intravascular catheter: Tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes.

3.2 distal end: End of the catheter inserted furthest into the patient.

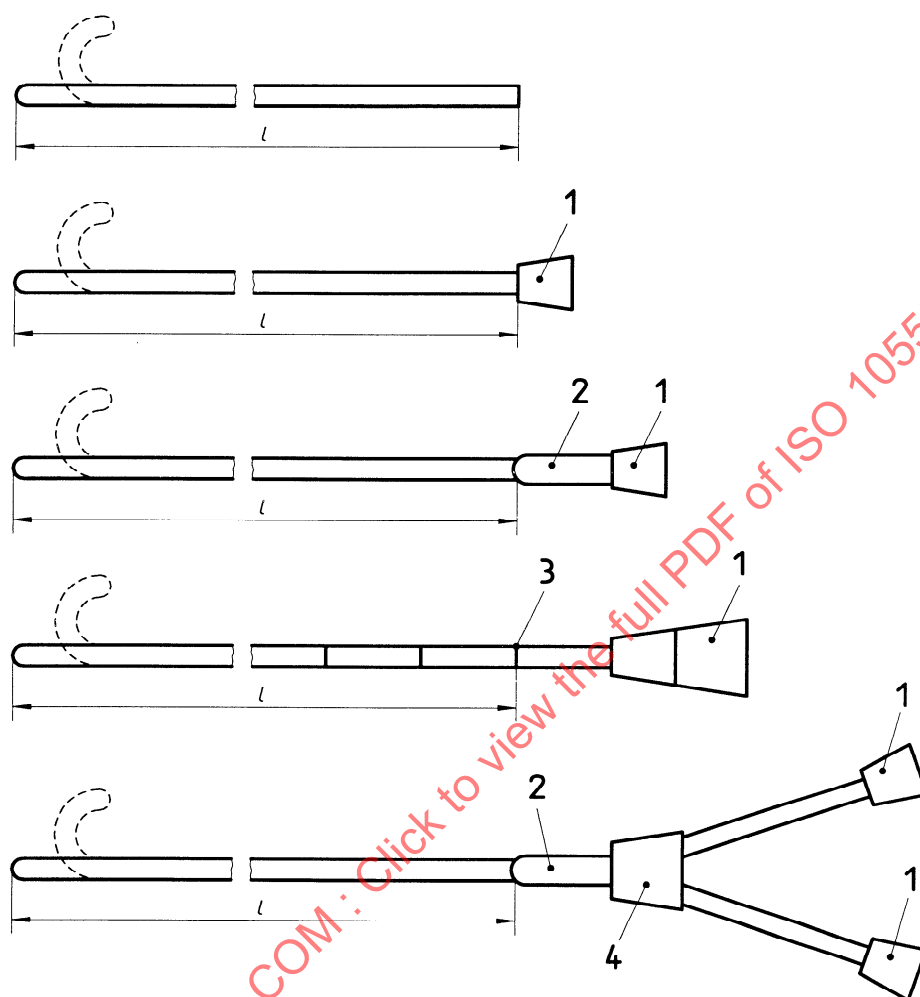
3.3 proximal end; access end: End of the catheter to which connection can be made.

3.4 hub: Connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter.

3.5 effective length, *l*: Length of the catheter that can be inserted into the body. (See figure 1.)

3.6 outside diameter: Maximum diameter of that part of the catheter that can be inserted into the vessel.

3.7 junction: That portion of the catheter that joins one tube to multiple tubes.

**Key**

l = effective length

- 1. catheter hub
- 2. catheter strain reinforcement
- 3. length mark
- 4. junction

Figure 1 — Examples of effective length of catheters

4 Requirements

4.1 General

The catheter shall have been sterilized by a validated method, and shall comply with 4.2 to 4.7 in the sterile condition.

NOTE 1 See ISO 11134, ISO 11135 and ISO 11137 for appropriate methods of sterilization.

4.2 Biocompatibility

The catheter shall be free from biological hazard.

NOTE 2 See ISO 10993-1 for the selection of appropriate test methods.

4.3 Surface

When examined by normal or corrected to normal vision with $\times 2,5$ magnification, the external surface of the effective length of the catheter shall appear free from extraneous matter.

The external surface of the effective length of the catheter, including the distal end, should be free from process and surface defects and should cause minimum trauma to vessels during use.

If the catheter is lubricated, the lubricant should not be visible as drops of fluid on the external surface when the catheter is examined under normal or corrected to normal vision.

4.4 Corrosion resistance

When tested in accordance with the method given in annex A, metallic components of the catheter shall show no signs of corrosion.

4.5 Force at break

When tested in accordance with the method given in annex B, the force at break of each test piece shall be as given in table 1.

4.6 Freedom from leakage

4.6.1 The hub or connection fitting assembly or any other part of the catheter shall not leak liquid when tested in accordance with the method given in annex C.

4.6.2 Air shall not leak into the hub assembly during aspiration when tested in accordance with the method given in annex D.

Table 1 — Force at break of catheter test pieces

Smallest outside diameter of tubular portion of test piece	Minimum force at break
mm	N
$\geq 0,55 < 0,75$	3
$\geq 0,75 < 1,15$	5
$\geq 1,15 < 1,85$	10
$\geq 1,85$	15

NOTE — This part of ISO 10555 does not specify requirements for force at break for tubing of less than 0,55 mm outside diameter.

4.7 Hubs

If the catheter is supplied with either an integral or a separate hub, it shall be a female hub and shall comply with ISO 594-1 and ISO 594-2.

5 Designation of nominal size

The nominal size of the catheter shall be designated as specified in 5.1 and 5.2.

5.1 Outside diameter

Unless otherwise specified in the International Standard for a particular type of catheter, the outside diameter shall be expressed in millimetres, rounded upwards to the nearest 0,05 mm for outside diameters of less than 2 mm, or to the nearest 0,1 mm for outside diameters of 2 mm and greater.

5.2 Effective length

The effective length shall be expressed in a whole number of millimetres for effective lengths of less than 99 mm and in either a whole number of millimetres or a whole number of centimetres for effective lengths of 99 mm and greater.

6 Information to be supplied by manufacturer

The manufacturer shall supply at least the following information. All dimensions given shall be expressed in SI units of measurement.

Units of other measurement systems may additionally be used.

- a) description of the product;
- b) outside diameter;
- c) effective length;
- d) name or tradename and address of manufacturer;
- e) lot designation;
- f) expiry date or use by date;
- g) any special storage and handling instructions;
- h) indication of sterility;
- i) method of sterilization;
- j) indication for single use;
- k) any known chemical and/or physical incompatibilities with substances likely to be used with the catheter;
- l) instructions for use and warnings, as appropriate.

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Annex A

(normative)

Test method for corrosion resistance

A.1 Principle

The catheter is immersed in sodium chloride solution, then in boiling distilled water, and afterwards examined visually for evidence of corrosion.

A.2 Reagents

A.2.1 Saline solution, comprising a solution of analytical reagent grade sodium chloride in freshly prepared distilled water [$c(\text{NaCl}) = 0,15 \text{ mol/l}$].

A.2.2 Distilled or deionized water.

A.3 Apparatus

A.3.1 Borosilicate glass beakers.

A.4 Procedure

Immerse the catheter in the saline solution (A.2.1) in a glass beaker (A.3) at room temperature for 5 h. Re-

move the test specimen and immerse it in boiling distilled water (A.2.2) for 30 min. Allow the water and the test specimen to cool to 37 °C, and maintain them at this temperature for 48 h. Remove the test specimen and allow it to dry at room temperature. Disassemble specimens that have two or more components which are intended to be separable in use. Do not strip away or cut open any coatings on metallic components. Inspect the specimen visually for signs of corrosion.

A.5 Test report

The test report shall include the following information:

- identity of the catheter;
- statement as to whether corrosion occurred during the test.

Annex B

(normative)

Method for determining force at break

B.1 Principle

Test pieces of a catheter are chosen so that each tubular portion, each junction between hub or connector and tubing, and each junction between tubular portions is tested. A tensile force is applied to each test piece until the tubing breaks or the junction separates.

B.2 Apparatus

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

B.3 Procedure

B.3.1 Assemble the catheter in accordance with the manufacturer's instructions. Select a test piece from the catheter to be tested. Include in the test piece the hub or connector, if present, and the junction between segments, e.g. between the tubing and the tip, if present. Exclude distal tips of lengths less than 3 mm from the test piece.

B.3.2 Condition the test pieces in an atmosphere of 100 % relative humidity or water and a temperature of $(37 \pm 2) ^\circ\text{C}$ for 2 h. Test immediately after conditioning.

B.3.3 Fix the test piece in the tensile testing apparatus. If a hub or connector is present, use an appropriate fixture to avoid deforming the hub or connector.

B.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 hub or connector and the jaw holding the other end of the test piece, as appropriate.

B.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/mm of gauge length (see table B.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.

B.3.6 If testing a catheter that consists of a single tubular portion having regions of different outside diameter, repeat B.3.2 to B.3.5 on test pieces of each different diameter.

B.3.7 If testing a catheter that has a sidearm or sidearms,

- repeat B.3.2 to B.3.5 on each sidearm;
- repeat B.3.2 to B.3.5 on a test piece that includes the joint between a sidearm and the adjacent part of that portion of the catheter intended to be introduced into the body;
- repeat B.3.7 b) for each joint.

B.3.8 Do not perform more than one test on any test piece.

Table B.1 — Examples of conditions for 20 mm/min/mm strain rate

Gauge length	Test speed
mm	mm/min
10	200
20	400
25	500

B.4 Test report

The test report shall include the following information:

- identity of the catheter;
- the force at break, in newtons, and outside diameter of each test piece.

Annex C

(normative)

Test method for liquid leakage under pressure

C.1 Principle

The catheter is connected, via a leakproof connection, to a syringe. A hydraulic pressure is applied to the catheter and to the hub assembly, if present, and the catheter tube inspected for leakage.

C.2 Reagent

C.2.1 Distilled or deionized water.

C.3 Apparatus

C.3.1 Reference steel fitting, having a male 6 % (Luer) taper as specified in ISO 594-1.

C.3.2 Leakproof connector, to connect reference fitting (C.3.1) to syringe (C.3.4), fitted with a gauge capable of measuring up to 350 kPa pressure and having a small internal volume.

C.3.3 Connector, to make leakproof connection between syringe (C.3.4) and catheters which do not have hubs.

C.3.4 10 ml syringe, which has passed the tests for leakage past the piston and nozzle as specified in ISO 7886-1.

C.3.5 Means for occluding test specimen, e.g. a clamp.

C.4 Procedure

C.4.1 When testing catheters which have a hub or hubs, if necessary assemble detachable hubs in accordance with the manufacturer's instructions. Con-

nect the hub to the reference fitting (C.3.1) by applying an axial force of 27,5 N for 5 s while applying a twisting action to a value of torque not exceeding 0,1 N·m to give rotation not exceeding 90°, both components being dry. Connect the reference fitting (C.3.1) via the connector (C.3.2) to the syringe (C.3.4).

C.4.2 When testing catheters which do not have hubs, connect the catheter to the syringe (C.3.4) by means of a connector (C.3.3).

C.4.3 Fill the syringe with water (C.2) at (22 ± 2) °C and expel the air. Adjust the volume of water in the syringe to the nominal graduated capacity. Occlude (C.3.5) the test specimen as near the distal end as possible.

C.4.4 Position the apparatus so that the axis of the connection between syringe and catheter is horizontal. Apply an axial force to the syringe so that a pressure of 300 kPa to 320 kPa is generated by the relative action of the piston and barrel. Maintain the pressure for 30 s. Examine the hub assembly, if present, and catheter tube for liquid leakage, i.e. the formation of one or more falling drops of water, and record whether or not leakage occurs.

C.5 Test report

The test report shall include the following information:

- identity of the catheter;
- statement as to whether leakage occurred from the hub assembly, if present, or catheter tube.

Annex D

(normative)

Test method for air leakage into hub assembly during aspiration

D.1 Principle

The hub(s) of the catheter is (are) connected via a reference male conical fitting, to a partially filled syringe. A reduced pressure is applied to the interface of the hub and the reference fitting by withdrawing the syringe plunger, and visual inspection made for the ingress of air bubbles to the syringe.

D.2 Reagent

D.2.1 De-aerated distilled water or de-aerated deionized water.

D.3 Apparatus

D.3.1 Reference steel fitting, as specified in C.3.1.

D.3.2 Leakproof connector, as specified in C.3.2, but without tapping and pressure gauge.

D.3.3 Syringe, as specified in C.3.4.

D.3.4 Means for occluding test specimen, e.g. a clamp.

D.4 Procedure

D.4.1 Assemble detachable hubs in accordance with the manufacturer's instructions. Connect the hub to be tested to the reference fitting (D.3.1) by applying an axial force of 27,5 N for 5 s while applying a twisting action to a value of torque not exceeding

0,1 N·m to give rotation not exceeding 90°, both components being dry.

D.4.2 Connect the reference fitting (D.3.1) via the connector (D.3.2) to the syringe (D.3.3). Seal all valves that are intended to open during aspiration.

D.4.3 Draw into the syringe, through the test specimen and reference fitting, a volume of water (D.2) at $(22 \pm 2) ^\circ\text{C}$ exceeding 25 % of the graduated capacity of the syringe. Avoid wetting the hub/reference fitting union.

D.4.4 Expel the air from the apparatus except for a small air bubble. Adjust the volume of the water in the syringe to 25 % of the graduated capacity. Occlude (D.3.4) the test specimen as close as practicable to the hub.

D.4.5 With the nozzle of the syringe downward, withdraw the plunger to the maximum graduated capacity mark. Hold for 15 s and examine the water in the syringe for the formation of air bubbles, ignoring bubbles formed during the first 5 s.

D.5 Test report

The test report shall include the following information:

- identity of the catheter;
- statement as to whether leakage of air occurred from the hub assembly after the first 5 s.