INTERNATIONAL STANDARD

ISO 10555-1

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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)

Contents

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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.

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.

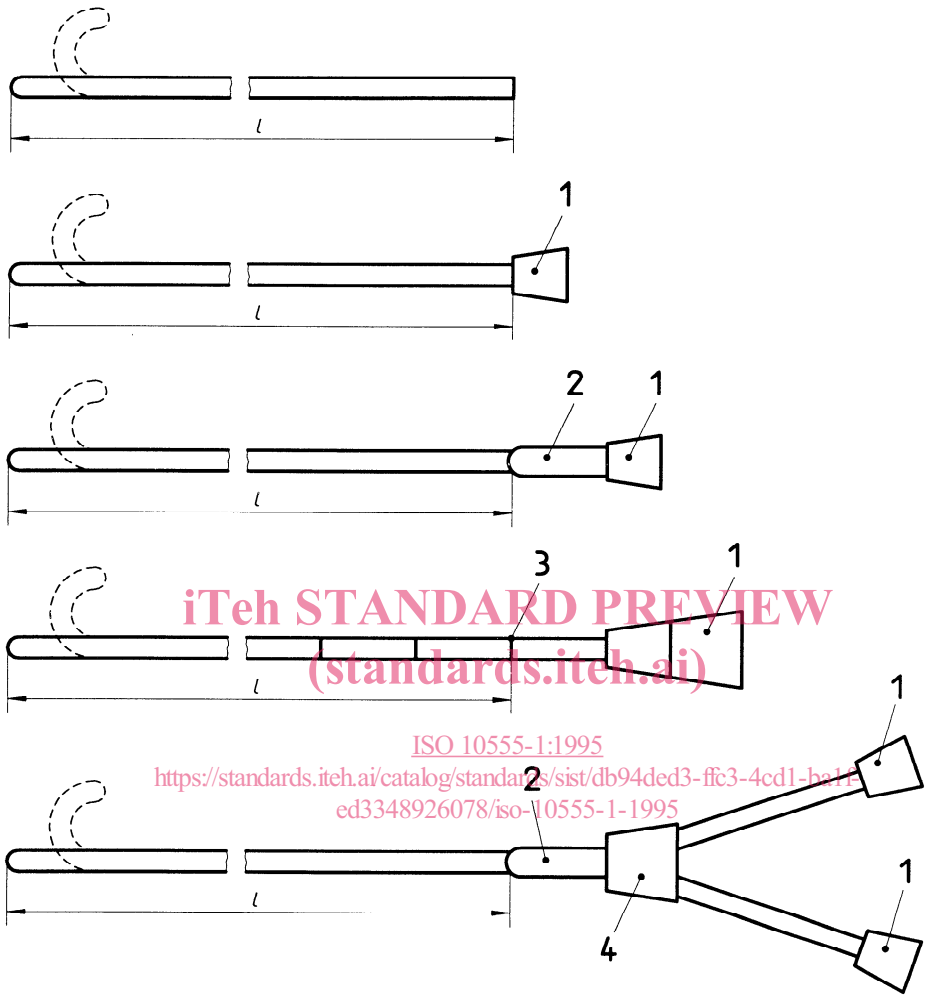
3.3 proximal end; access end: End of the catheter to which connection can be made.

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 × 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 mm	Minimum force at break N
⩾ 0,55 < 0,75	3
⩾ 0,75 < 1,15	5
⩾ 1,15 < 1,85	10
⩾ 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.

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(NaCl) = 0,15 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. Remove 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:

a) identity of the catheter;

b) statement as to whether corrosion occurred during the test.