INTERNATIONAL STANDARD

ISO 10555-5

First edition
1996-06-15

Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

Cathéters intravasculaires stériles, non réutilisables —

Partie 5: Cathéters périphériques à aiguille interne

Reference number
ISO 10555-5:1996(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 10555-5 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*

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

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Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Sterile, single-use intravascular catheters —

Part 5:
Over-needle peripheral catheters

1 Scope

This part of ISO 10555 specifies requirements for over-the-needle peripheral intravascular catheters, intended for accessing the peripheral vascular system, supplied in the sterile condition and intended for single use.

NOTE 1 Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

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 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

ISO 10555-1:1995, *Sterile, single-use intravascular catheters — Part 1: General requirements.*

3 Definitions

For the purposes of this part of ISO 10555, the definitions given in ISO 10555-1 and the following definitions apply.

3.1 peripheral intravascular catheter: Catheter designed for the introduction or withdrawal of liquids or devices into or from the peripheral vascular system.

3.2 needle: Assembly comprising at least a needle tube attached to, and communicating with, a needle hub.

See figure 1.

3.3 needle tube: Rigid tube with one end sharpened to facilitate entry into body tissue.

3.4 needle hub: Fitting attached to the needle tube, providing communication with its bore.

3.5 vent fitting: Fixed or removable fitting permitting venting of air while restricting or preferably preventing the escape of blood.

3.6 catheter unit: Assembly comprising the catheter tube, catheter hub and any integral fittings.

See figure 1.

3.7 flashback: Blood flow into the needle hub.

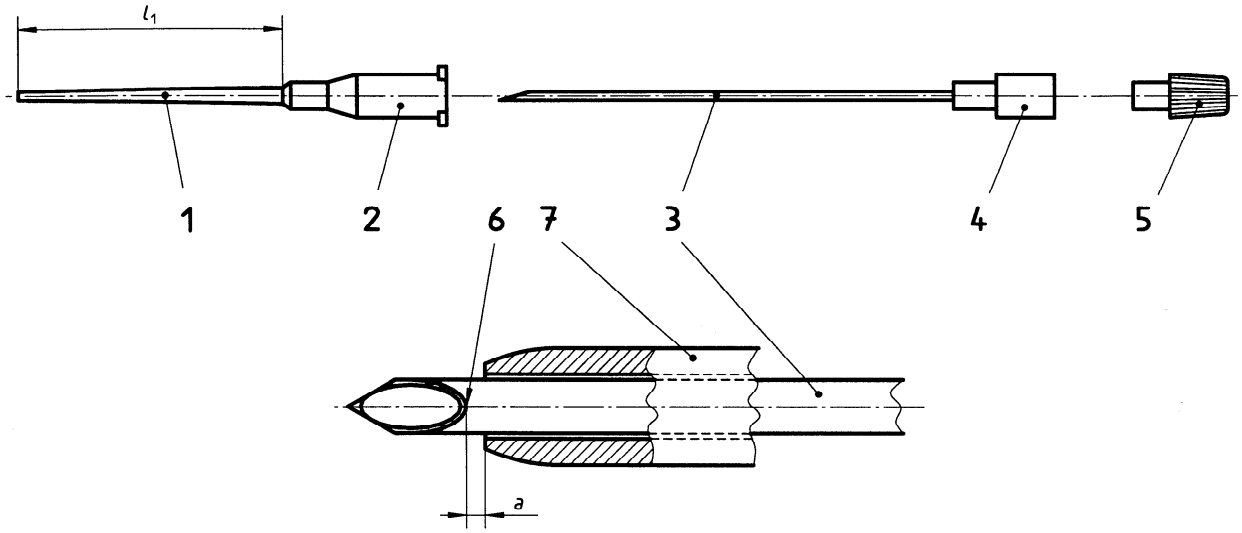
4 Requirements

4.1 General

Unless otherwise specified in this part of ISO 10555, catheters shall comply with ISO 10555-1.

4.2 Radio-detectability

It is recommended that catheters be radio-opaque.



Key

a See 4.4.2; $0 < a < 1$ mm
l_1 Effective length
1 Catheter tube
2 Catheter hub
3 Needle tube
4 Needle hub
5 Vent fitting
6 Heel of bevel
7 Catheter unit

NOTE — Other design features may include wings, injection ports integral with the catheter hub, other means of connecting to the fluid path, protection against accidental needle stick injury, etc. The catheter tube may have a single lumen or multiple lumens.

Figure 1 — Typical over-needle peripheral intravascular catheter

NOTE 2 At the time of publication of this part of ISO 10555, 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 his product "radio-opaque" provided he can support this claim by demonstrating that he has an appropriate method for showing radio-opacity.

4.3 Multilumen catheters

For multilumen catheters, identification of each lumen shall be apparent to the user.

4.4 Physical requirements

4.4.1 Colour code

The catheter unit shall be colour-coded in accordance with table 1 to indicate the nominal outside diameter of the catheter tube.

4.4.2 Catheter unit

The distal end shall be tapered for ease of insertion, and shall fit closely to the needle. When the needle is fully inserted into the catheter unit, the catheter tube shall neither extend beyond the heel of the needle bevel nor be more than 1 mm from it (see dimension a in figure 1).

4.4.3 Needle

4.4.3.1 Material

The needle shall be made of a rigid material and shall be straight and uniform in cross-section and wall thickness. If a steel tube is used, it shall comply with ISO 9626. The fluid pathway in the needle shall be free of unintended obstructions that would prevent flashback.

Table 1 — Colour coding and corresponding sizes of catheter

Nominal outside diameter of catheter tube mm	Range of actual outside diameter mm	Colour[1) 2)]	Gauge[3)]
0,6	0,550 to 0,649	Violet	26
0,7	0,650 to 0,749	Yellow	24
0,8; 0,9	0,750 to 0,949	Deep blue	22
1,0; 1,1	0,950 to 1,149	Pink	20
1,2; 1,3	1,150 to 1,349	Deep green	18
1,4; 1,5	1,350 to 1,549	White	17
1,6; 1,7; 1,8	1,550 to 1,849	Medium grey	16
1,9; 2,0; 2,1; 2,2	1,850 to 2,249	Orange	14
2,3; 2,4; 2,5	2,250 to 2,549	Red	13
2,6; 2,7; 2,8	2,550 to 2,849	Pale blue	12
3,3; 3,4	3,250 to 3,549	Light brown	10

1) The colour may be opaque or translucent. Suggested colour references for opaque materials are given in annex C.

2) The colour coding is usually applied to the catheter hub or to an integral fitting.

3) The use of gauge number is optional.

4.4.3.2 Needle point

When examined by normal or corrected-to-normal vision with × 2,5 magnification, the needle point shall appear sharp and free from feather edges, burrs and hooks.

NOTE 3 The point should be designed to be noncoring. Annex D shows examples of typical needle point geometries.

4.4.3.3 Needle hub

The needle hub or another feature shall permit detection of flashback, and shall be designed to communicate with the bore of the introducer needle tube. If the introducer needle is provided with a removable vent fitting, the needle hub shall terminate in a female fitting with a 6 % (Luer) taper complying with ISO 594-1.

4.4.3.4 Strength of union between needle hub and needle tube

When tested in accordance with annex A, the needle tube shall not be loosened in the needle hub.

4.4.4 Vent fitting

A vent fitting shall be provided.

4.4.5 Flowrate

When tested in accordance with annex B, the flowrate shall be between 80 % and 125 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm, or between 90 % and 115 % of that stated by the manufacturer for catheters of nominal outside diameter 1,0 mm or greater.

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also include the following:

a) flowrate for each lumen;

b) a warning against attempting to re-insert a partially or completely withdrawn needle;

c) on each unit package, the colour code, unless the colour on the product is visible through the unit package.

NOTE 4 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

Annex A
(normative)

Determination of strength of union of needle hub and needle tube

A.1 Principle

A force is applied (successively tensile and compressive) to the needle tube and needle hub and the tube-hub union is then examined for loosening.

A.2 Apparatus

A.2.1 Tensile-testing apparatus, capable of exerting forces of up to 20 N with an accuracy of ± 1 %.

A.3 Test procedure

A.3.1 Condition the needle in an atmosphere of 40 % to 60 % relative humidity and a temperature of (22 ± 2) °C for 2 h immediately before the test.

A.3.2 Clamp the needle tube and the needle hub in the jaws of the tensile-testing apparatus and apply successively, once each, at a rate of 100 mm/min, a tensile and a compressive force of

10 N when testing needles of nominal outside diameter less than 0,6 mm;

20 N when testing needles of nominal outside diameter 0,6 mm or greater.

A.3.3 Examine the union of needle tube and needle hub and record whether the needle tube has been loosened.

A.4 Test report

The test report shall include the following information:

a) identity of the needle;

b) outside diameter of the needle, expressed in millimetres;

c) load applied (i.e. 10 N or 20 N);

d) whether or not the needle tube was loosened in the hub.

Annex B
(normative)

Determination of flowrate through catheter

B.1 Principle

Water is allowed to flow through the catheter and the amount of flow is measured either volumetrically or gravimetrically.

B.2 Reagent

Distilled or deionized water.

B.3 Apparatus

B.3.1 Constant-level tank, fitted with a delivery tube and a male 6 % (Luer) taper fitting complying with ISO 594-1, capable, when no test catheter is attached, of providing a flowrate of (525 ± 25) ml/min, and having a hydrostatic head height of (1 000 ± 5) mm.

An example of a suitable apparatus is shown in figure B.1.

B.3.2 Equipment for collecting and determining the mass or volume of the catheter efflux to an accuracy of ± 1 %.

B.3.3 Timer, for measuring collection time.

B.4 Test procedure

B.4.1 Supply the constant-level tank (B.3.1) with water at (22 ± 2) °C. Fit the catheter to be tested to the male 6 % (Luer) taper fitting.

B.4.2 Start the water flowing through the catheter. Collect the efflux for a measured period of time (not less than 30 s) in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing, assuming that the density of water equals 1 000 kg/m^3.

B.4.3 Perform three determinations on each catheter lumen.

B.5 Expression of results

Calculate the arithmetic average of the three determinations and express it as water flowrate through the catheter, in millilitres per minute. Round the calculated average water flowrate to the nearest whole number of millilitres.

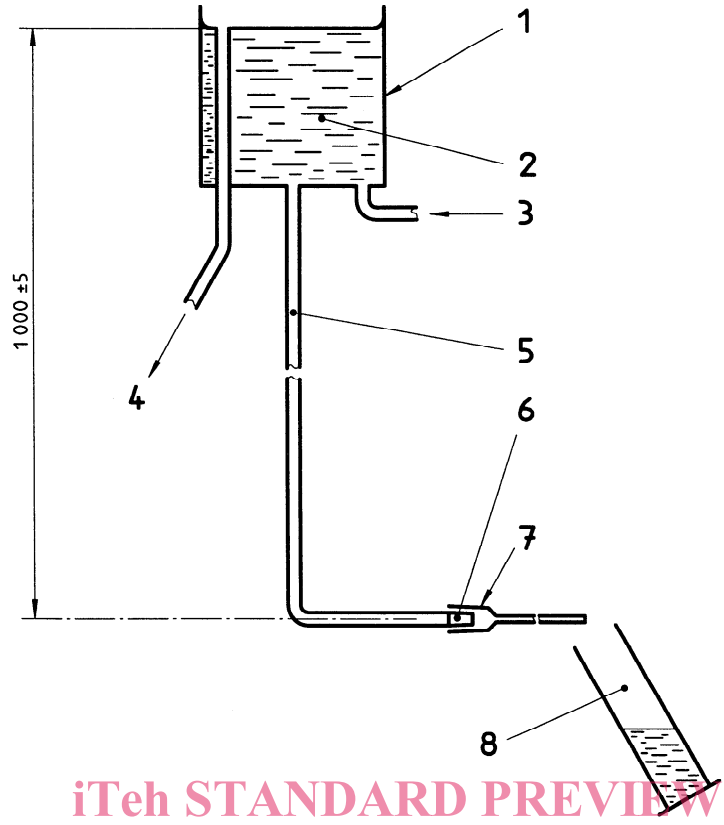
B.6 Test report

The test report shall include the following information:

a) identity of the catheter;

b) average flowrate, expressed in millilitres per minute, for each lumen.

Dimensions in millimetres



Key

1 Constant-level tank
2 Distilled or deionized water
3 Inlet
4 Overflow
5 Delivery tube
6 Male 6 % (Luer) taper fitting
7 Catheter under test
8 Collecting/measuring vessel

Figure B.1 — Example of apparatus for determination of flowrate of water through catheter

Annex C
(informative)

Colours for opaque catheter hubs

Suggested colour references are given for information in table C.1.

Table C.1 — Suggested colours for opaque catheter hubs

Nominal outside diameter of catheter tube mm	Colour code	Munsell Atlas[1]	US Federal Standard 595a[2]	DIN 6164-1[3]	NF X 08-002[4]
0,6	Violet	5 P 6.5/6	—	—	A 2790
0,7	Yellow	3.75 Y 8/14	23 655	1.9; 6.8; 0.7	A 330
0,8; 0,9	Deep blue	2.5 PB 3/8	15 090	16.6; 6.5; 4.2	A 540
1,0; 1,1	Pink	2.5 R 7/6	11 630	8.5; 1.4; 1.5	A 870
1,2; 1,3	Deep green	2.5 G 4/8	14 090	22.6; 6.9; 5.0	A 455
1,4; 1,5	White	N 9.5	27 875	1.0; 0.4; 0.3	A 665
1,6; 1,7; 1,8	Medium grey	N 7	26 231	24.4; 0.2; 3.9	A 630
1,9; 2,0; 2,1; 2,2	Orange	3.75 YT 6/12	12 473	4.5; 6.6; 1.7	A 130
2,3; 2,4; 2,5	Red	7.5 R 4/14	—	7.4; 7.9; 2.7	A 801
2,6; 2,7; 2,8	Pale blue	2.5 PB 7/8	35 190	17.5; 4.4; 2.0	A 590
3,3; 3,4	Light brown	7.5 YR 4.5/6	—	—	A 2030

1) *Munsell Book of* Color. Available from Munsell Color, 2441 N. Calvert Street, Baltimore, MD 21218 USA.

2) US Federal Standard 595a: *Colors,* Volume 1. Available from Superintendent of Documents, US Government Printing Office, Washington DC, 20402 USA.

3) German Standard DIN 6164-1, *DIN Farbenkarte; System der DIN Farbenkarte für den 2°-Normalbeobachter.* Available from Beuth Verlag GmbH, Burggrafenstrasse 6, D-10787 Berlin, Germany.

4) French Standard NF X 08-002, *Collection réduite des couleurs — Désignation et catalogue des couleurs CCR — Étalons secondaires.* (Limited collection of colours. Designation and catalogue of CCR colours. Secondary standards.) Available from AFNOR, Tour Europe, Cedex 7, F-92080 Paris La Défense, France.