INTERNATIONAL STANDARD

ISO 10555-4

First edition
1996-06-15

Sterile, single-use intravascular catheters —

Part 4:
Balloon dilatation catheters

Cathéters intravasculaires stériles, non réutilisables —

Partie 4: Cathéters de dilatation à ballonnets

Reference number
ISO 10555-4:1996(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 10555-4 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*

Annex A forms an integral part of this part of ISO 10555. Annexes B and C are for information only.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Sterile, single-use intravascular catheters —

Part 4:
Balloon dilatation catheters

1 Scope

This part of ISO 10555 specifies requirements for balloon dilatation catheters 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 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 definition apply.

3.1 balloon dilatation catheter: Intravascular catheter fitted with a balloon near the distal end, which is introduced into an artery or vein to dilate a part or parts of the vascular system.

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

The position of the balloon shall be radio-detectable when the catheter has been inserted into the body.

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 Designation of nominal size

The nominal size of the catheter shall be designated by the following:

a) the diameter(s) of the inflated balloon(s) or, for multidiameter balloon(s), the diameter of each portion;

b) the effective length of the balloon;

c) the effective length of the catheter;

d) the diameter of the largest guidewire that can be used with the catheter, if applicable.

4.4 Physical requirements

4.4.1 Tip configuration

In order to minimize trauma to vessels during use, the tip of the distal end should be smooth, rounded, tapered or similarly finished.

4.4.2 Freedom from leakage and damage on inflation

When tested as described in annex A, there shall be no leakage or evidence of damage, such as herniation or bursting of the shaft or balloon.

4.4.3 Side holes

The design, number and positioning of side holes should be such as to minimize adverse effects on the catheter and trauma to the tissues.

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) nominal size of the catheter, as designated in 4.3;

b) position(s) of radio-detectable marker(s);

c) maximum balloon inflation pressure, expressed in kilopascals;

d) balloon inflation pressure, expressed in kilopascals, required to achieve the nominal balloon diameter(s).

NOTE 3 Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

Annex A
(normative)

Test for freedom from leakage and damage on inflation

A.1 Principle

The catheter is inflated and deflated a number of times to simulate use *in vivo*. The catheter in an inflated condition is examined for leakage, rupture or herniation.

A.2 Apparatus

A.2.1 Water bath, controlled at (37 ± 2) °C.

A.2.2 Inflation syringe or equivalent device, fitted with a means of measuring pressure with an accuracy of 5 % and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with ISO 594-1, for connection to the catheter.

A.3 Test procedure

A.3.1 Fill the inflation device (A.2.2) with water.

A.3.2 Connect the inflation device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (A.2.1) at (37 ± 2) °C.

A.3.3 Allow the catheter to equilibrate for 2 min. Inflate it to the maximum balloon inflation pressure [see 4.5 c)], holding the inflation pressure for 30 s before deflating. Then deflate the balloon(s). Repeat this procedure eight times.

A.3.4 Inflate the balloon(s) for a tenth time to the maximum balloon inflation pressure and remove the catheter from the water bath, maintaining the balloon(s) in the inflated state.

A.3.5 Inspect the whole catheter for leakage, rupture, herniation, direction of any balloon rupture, and, if rupture occurred, whether fragments were produced.

A.4 Test report

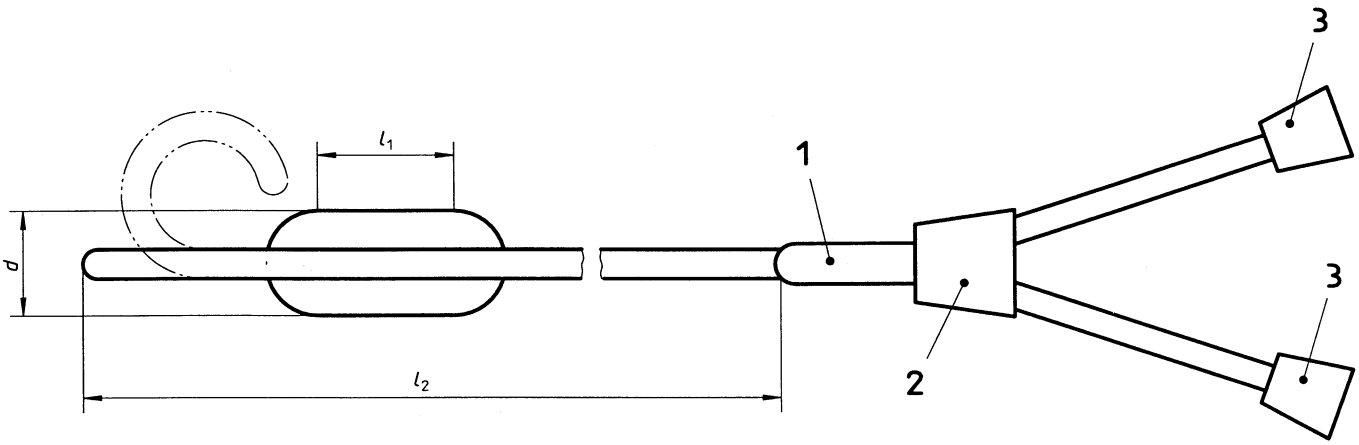
The test report shall include the following information:

a) identity of the catheter;

b) inflation pressure used, expressed in kilopascals;

c) whether leakage occurred from the catheter;

d) whether the catheter shaft or balloon(s) ruptured or herniated, the direction of any balloon rupture, and, if rupture occurred, whether fragments were produced.



Key

d Inflated balloon diameter
l_1 Effective length of the balloon
l_2 Effective length of the catheter
1 Catheter strain reinforcement
2 Junction
3 Catheter hub(s)

NOTE — This drawing shows the designation of dimensions, but the representation of the components is schematic only.

Figure A.1 — Designation of dimensions of balloon dilatation catheter

Annex B
(informative)

Guidance on the selection of balloon materials

The balloon, if it should fail during use, should burst longitudinally and without fragmentation. Consideration should be given to this guideline in the selection of the balloon material and the manner of securing the balloon material to the shaft.

Annex C
(informative)

Bibliography

[1] ISO 11070:—[1], *Sterile, single-use intravascular catheter introducers.*

1) To be published.