INTERNATIONAL STANDARD

ISO 10555-4

Second edition
2013-06-15

Intravascular catheters — Sterile and single-use catheters —

Part 4: Balloon dilatation catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 4: Cathéters de dilatation à ballonnets

Reference number
ISO 10555-4:2013(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10555-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-4:1996), which has been technically revised. It also incorporates the Technical Corrigendum ISO 10555-4:1996/Cor 1:2002.

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

— *Part 1: General requirements*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

The following part is under preparation:

— *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

— *Part 2: Angiographic catheters*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters, to ISO 25539-2 which specifies requirements for delivery systems if they comprise an integral component of the deployment of the vascular stent, and to ISO 14630.

Intravascular catheters — Sterile and single-use 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.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*[1)]

ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

ISO 10555-1, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10555-1 and the following 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, balloon dilatation 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.

4.3 Designation of nominal size

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

a) diameter(s) expressed in millimetres of the inflated balloon(s) or, for multidiameter balloon(s), the diameter of each portion at recommended pressure;

1) Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

b) effective length of the balloon at recommended pressure;

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

NOTE Where a balloon dilation catheter (see Figure B.1) is used as a stent delivery system, refer to the appropriate standard for stents for designation of nominal size.

4.4 Physical requirements

4.4.1 Balloon rated burst pressure (RBP)

Determine the burst pressure with an appropriate safety margin when tested in accordance with Annex A. Longitudinal failure is the desirable balloon failure mode.

4.4.2 Balloon fatigue; freedom from leakage and damage on inflation

Evaluate the ability of the balloon to withstand repeated inflation cycles to the RBP. When tested as described in Annex B, there shall be no leakage or evidence of damage, such as herniation or bursting of the catheter.

4.4.3 Balloon deflation time

Determine the time required to deflate the balloon from the RBP as described in Annex C.

4.4.4 Balloon diameter to inflation pressure

Determine the relationship between the balloon diameter and the balloon inflation pressure as described in Annex D.

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) RBP of the balloon, expressed in kilopascals;

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

e) guidewire, guide catheter or sheath or introducer compatibility and size recommendations appropriate to the intended clinical use.

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

Annex A
(normative)

Test for balloon rated burst pressure (RBP)

A.1 Principle

The purpose of this test is to determine the RBP of the balloon.

A.2 Apparatus

A.2.1 Recommended guidewire or equivalent.

A.2.2 Water bath, controlled at (37 ± 2) °C.

A.2.3 Leak detection mechanism, e.g. dye in test fluid, pressure drop monitor, flow rate monitor.

A.2.4 Fluid for inflation, e.g. room temperature water or other justified clinically relevant media.

A.2.5 Timing mechanism, with specified accuracy.

A.2.6 Pressure generating device, fitted with a means of measuring pressure with an accuracy of ± 5 % of the reported value and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with ISO 594-1 or ISO 594-2 as applicable, for connection to the catheter.

A.3 Test procedure

A.3.1 Fill the pressure generating device (A.2.6) with fluid for inflation.

A.3.2 If the instructions for use specify that a guidewire should be used during balloon inflation, insert the appropriate guidewire (A.2.1) in the device.

A.3.3 Connect the pressure generating device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (A.2.2) at (37 ± 2) °C.

A.3.4 Allow the catheter to equilibrate for a minimum of 2 min.

A.3.5 Inflate the balloon using a pre-determined pressure profile versus time until the catheter bursts or fails. Record the burst pressure, failure mode and location of the failure.

A.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) mean burst pressure, RBP and maximum, minimum and standard deviation of the burst data, expressed in kilopascals;

c) all observed failure modes.

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

Annex B
(normative)

Balloon fatigue test for freedom from leakage and damage on inflation

B.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.

B.2 Apparatus

B.2.1 Recommended guidewire or equivalent.

B.2.2 Water bath, controlled at (37 ± 2) °C.

B.2.3 Leak detection mechanism, e.g. dye in test fluid, pressure drop monitor, flow rate monitor.

B.2.4 Timing mechanism, with specified accuracy.

B.2.5 Inflation syringe or equivalent device, fitted with a means of measuring pressure with an accuracy of ±5 % of the reported value and maintaining the inflation pressure and fitted with a male 6 % (Luer) taper, complying with ISO 594-1 or ISO 594-2 as applicable, for connection to the catheter.

B.2.6 Compliant tube (if applicable, with a clinically relevant compliance and rationale for use, e.g. when measuring within a stent) of a diameter that represents the recommended vessel diameter for the catheter under test in order to keep the device from moving excessively during inflation cycles.

B.3 Test procedure

B.3.1 Fill the inflation device (B.2.5) with water or other clinically relevant media (selection of media to be justified).

B.3.2 If the instructions for use specify that a guidewire should be used during balloon inflation, insert the appropriate guidewire (A.2.1) in the device.

B.3.3 Connect the inflation device to the catheter under test and immerse at least the whole of the balloon portion(s) in the water bath (B.2.2) at (37 ± 2) °C. If a compliant tube is being used, insert device into the compliant tube.

B.3.4 Allow the catheter to equilibrate for a minimum of 2 min. Inflate it to RBP holding the inflation pressure for a minimum of 30 s before deflating. Then deflate the balloon(s). Repeat this procedure eight times. Observe for leaks.

B.3.5 After a total of 9 times of inflation/deflation according to B.3.4, inflate the balloon(s) further one time to the RBP and remove the catheter from the water bath, maintaining the balloon(s) in the inflated state.