BS EN ISO 10555-4:2013

BSI Standards Publication

Intravascular catheters — Sterile and single-use catheters

Part 4: Balloon dilatation catheters (ISO 10555-4:2013)

National foreword

This British Standard is the UK implementation of EN ISO 10555-4:2013. It supersedes BS EN ISO 10555-4:1997 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 73020 7

ICS 11.040.25

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2013.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-4

July 2013

ICS 11.040.25

Supersedes EN ISO 10555-4:1997

English Version

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2013)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 4: Cathéters de dilatation à ballonnets (ISO 10555-4:2013)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 4: Ballondilatationskatheter (ISO 10555-4:2013)

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Ref. No. EN ISO 10555-4:2013: E

Foreword

This document (EN ISO 10555-4:2013) has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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

This document supersedes EN ISO 10555-4:1997.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 10555-4:2013 has been approved by CEN as EN ISO 10555-4:2013 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC amended by Directive 2007/47/EEC.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1— Correspondence between this European Standard and Directive 93/42/EEC amended by Directive 2007/47/EEC

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 10555-4
7.3	4.1 4.4
7.5	4.1
8.1	4.1
8.3	4.1
8.4	4.1
9.1	4.1
9.2	4.1 4.2 4.3 4.4
12.7.1	4.1 4.4
12.7.4	4.1
12.8.1	4.1
13.1	4.1 4.5 a)
13.2	4.1
13.3 a)	4.1
13.3 b)	4.1

13.3 c)	4.1
13.3 d)	4.1
13.3 e)	4.1
13.3 f)	4.1
13.3 i)	4.1
13.3 j)	4.1 4.5 b), c), d) and e)
13.3 k)	4.1
13.3 m)	4.1
13.4	4.1
13.6 a)	4.1
13.6 b)	4.1 4.5 a), b) and c)
13.6 c)	4.1
13.6 e)	4.1
13.6 f)	4.1
13.6 g)	4.1
13.6 k)	4.1
13.6 l)	4.1
13.6 n)	4.1
13.6 q)	4.1

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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.

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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.

INTERNATIONAL STANDARD **ISO 10555-4:2013(E)**

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.

B.3.6 Inspect the whole catheter for leakage, rupture, herniation, direction of any balloon rupture, and, if rupture occurred, whether fragments were produced.

B.4 Test report

The test report shall include the following information:

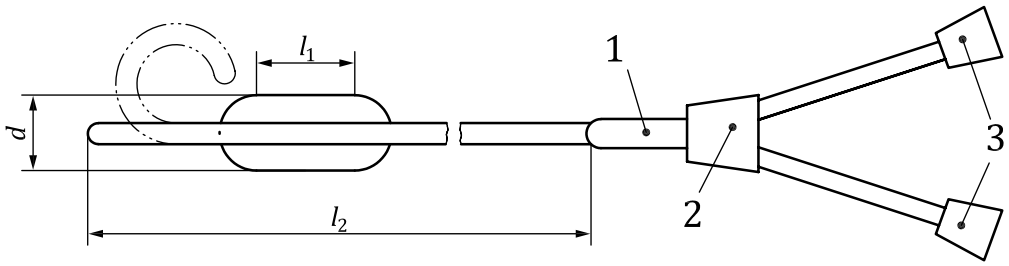
a) identity of the catheter;

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.

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



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 B.1 — Designation of dimensions of balloon dilatation catheter

Annex C
(normative)

Test for balloon deflation time

C.1 Principle

The purpose of this test is to determine the time required to deflate the balloon from the rate burst pressure (RBP) level. This test provides information that might be clinically useful for treatment planning (e.g. potential occlusion time).

C.2 Apparatus

C.2.1 **Recommended guidewire or equivalent**.

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

C.2.3 **Inflation medium**, which is clinically relevant or in accordance with the instructions for use (IFU).

C.2.4 **Timing mechanism**, with a specified accuracy.

C.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.

C.2.6 **Rigid tube** if appropriate, of a diameter that represents the largest recommended vessel diameter for the compliant balloon under test.

C.3 Test procedure

C.3.1 Fill the inflation device (C.2.5) in accordance with the IFU.

C.3.2 Insert the appropriate guidewire (C.2.1) in the device.

C.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 (C.2.2) at (37 ± 2) °C. Insert the device into the rigid tube (C.2.6), if appropriate.

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

C.3.5 Inflate the balloon to the RBP in accordance with the IFU, simulating clinical use.

C.3.6 Deflate the balloon in accordance with the IFU and time (C.2.4) the balloon deflation period to the defined deflation end point.

C.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) maximum, minimum mean and standard deviation of the balloon deflation times, expressed in seconds;

c) definition of the deflation end point;

d) fluid used for inflation;

e) any anomalies observed.

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

Annex D
(normative)

Test for balloon diameter to inflation pressure

D.1 Principle

The purpose of this test is to determine the relationship between the balloon diameter and the inflation pressure.

D.2 Apparatus

D.2.1 Recommended guidewire or equivalent.

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

D.2.3 Fluid for inflation, e.g. room temperature water.

D.2.4 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.

D.2.5 Equipment for measuring balloon diameter with an appropriate accuracy (e.g. micrometer, optical profile projector, laser-micrometer), capable of measuring to 10 % of the specified tolerance or 1 % of the measured value. If a tolerance is specified, the lesser value of the respective percentages shall be used.

D.3 Test procedure

D.3.1 Fill the inflation device (D.2.4) with the fluid for inflation (D.2.3).

D.3.2 Insert the appropriate guidewire (D.2.1) in the device.

D.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 (D.2.2) at (37 ± 2) °C.

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

D.3.5 Inflate the balloon incrementally, allowing the system to stabilize between intervals; pressures should be chosen to determine the balloon diameter at appropriate intervals (e.g. 100 kPa) over the indicated range of diameters.

D.3.6 Measure the diameter of the balloon at each pressure interval at appropriate locations along the length of the balloon; these measurements should be taken immediately after stabilization.

D.3.7 Inflation should not be terminated until the balloon reaches the RBP.

The entire test should be completed rapidly to minimize the effects of viscoelastic behaviour and to better simulate the inflation method used clinically.

D.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) maximum, minimum mean and standard deviation of the balloon diameter, expressed in millimetres, and the associated pressures, expressed in kilopascals.

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

Annex E
(informative)

Guidance on the selection of balloon materials

The balloon, if it should fail during use, should burst longitudinally and without fragmentation. Consider the severity of other failure modes. 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.

Bibliography

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

[2] ISO/TS 12417, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products*

[3] ISO 14630, *Non-active surgical implants — General requirements*

[4] ISO 25539-2, *Cardiovascular implants — Endovascular devices — Part 2: Vascular stents*

[5] CEI 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*[2)]

[6] ISO 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

2) Under preparation.

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