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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

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10555-4:2013), which has been technically revised.

The main changes are as follows:

— added a definition for balloon rated burst pressure (RBP) (see 3.2);

— added a definition (see 3.3), requirement (see 4.4.5), and created test method (see Annex E) for crossing profile;

— added guidance on endpoint of deflation period (see Annex C);

— defined effective length of the balloon (see 3.4);

— expanded radio-detectability to include detectability by x-ray or by other means (see 4.2);

— within designation of nominal size, added the minimum inner diameter of the introducer, guide catheter, sheath, etc. that can be used with the catheter (see 4.3);

— added requirement (see 4.4.6) and test method (see Annex F) for balloon removal without damage after inflation and deflation;

— added annex for rationale of changes and guidance (see Annex G).

A list of all parts in the ISO 10555 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Intravascular catheters — Sterile and single-use catheters —

Part 4: Balloon dilatation catheters

1 Scope

This document specifies requirements for balloon dilatation catheters supplied sterile and intended for single use.

This document does not specify requirements for vascular stents (see ISO 25539-2).

NOTE Guidance on the selection of balloon materials is given in Annex G.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
balloon dilatation catheter
intravascular catheter fitted with a balloon, which is introduced into an artery or vein to dilate a part or parts of the vascular system

3.2
balloon rated burst pressure
RBP
pressure at which the balloon bursts or leaks with an appropriate safety margin

3.3
crossing profile
maximum outer diameter found between the proximal end of the uninflated balloon and the distal tip of the catheter

3.4
effective length of the balloon
length of the balloon intended to treat the lesion

4 Requirements

4.1 General

Unless otherwise specified in this document, balloon dilatation catheters shall conform with the requirements in ISO 10555-1.

4.2 Detectability of the balloon position

The balloon position shall be detectable by X-ray or by other means (ultra-sound, MRI, etc.).

Detectability shall be demonstrated by an appropriate test method, e.g. the test method specified in ASTM F640-20 or DIN 13273-7.

4.3 Designation of nominal size

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

a) diameter(s) expressed in millimetres (rounded to the nearest 0,1 mm or 0,01 mm) of the inflated balloon(s) or, for multidiameter balloon(s), the diameter of each portion at nominal pressure;

b) effective length of the balloon at nominal pressure(s);

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

d) minimum inner diameter of the introducer, guide catheter, sheath, etc. that can be used with the catheter.

NOTE For stent delivery systems, refer to ISO 25539-2.

4.4 Physical requirements

4.4.1 Balloon rated burst pressure (RBP)

Determine the RBP when tested in accordance with Annex A.

Longitudinal burst is the desirable balloon burst mode, though other modes are acceptable with appropriate justification.

4.4.2 Balloon fatigue; freedom from leakage and damage on inflation

Evaluate the ability of the balloon to withstand 10 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. In cases where 10 repeated inflation cycles are not clinically relevant, the clinically relevant number of cycles including a safety margin can be used when supported by risk assessment. If a number of cycles other than 10 is applied, the test method given in Annex B shall be used but in a revised version adapted to the alternative number of cycles.

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 (balloon compliance)

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

4.4.5 Crossing profile

Determine the crossing profile as described in Annex E.

NOTE The largest diameter over the effective length of the catheter, including the proximal balloon bond, is evaluated when measuring the outside diameter (see ISO 10555-1).

4.4.6 Balloon removal

Demonstrate that the balloon can be removed without damage after inflation and deflation in accordance with the procedure described in Annex F.

4.5 Information to be supplied with the catheter

Information supplied with the catheter shall fulfil the requirements of ISO 10555-1:2023, 6.3 and shall also include the following information:

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

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

c) RBP of the balloon, expressed in kPa;

d) balloon inflation pressure, expressed in kPa, 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.

Units of measurement systems other than those specified in this document should additionally be given if clinically relevant.

NOTE The crossing profile, expressed in mm, can be given.

Annex A
(normative)

Test for rated burst pressure (RBP)

A.1 Principle

The catheter is connected via its hub or proximal end to a pressure generating device which is filled with fluid for inflation. Pressure is applied at a rate that allows accurate detection of burst pressure until catheter balloon leaks or bursts. The burst pressure is recorded, and the RBP of the balloon is determined.

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 Timing mechanism, with specified accuracy of at least ±1 s.

A.2.5 Pressure generating device, fitted with a means of measuring pressure with an accuracy of ±5 % of the reported value while maintaining the inflation pressure and fitted with a male 6 % (Luer) taper for leak proof connection to the catheter.

A.3 Reagent

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

A.4 Test procedure

A.4.1 Fill the pressure generating device (A.2.5) with fluid for inflation (A.3).

A.4.2 The following steps of A.4.2 may be completed in any order.

A.4.2.1 Replace the air in the balloon catheter with fluid for inflation by applying vacuum and allowing the fluid for inflation to return in place of the air. A small amount of air remaining, indicative of normal use, is acceptable.

A.4.2.2 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.4.2.3 Connect the pressure generating device to the catheter under test and immerse at least the balloon portion(s) in the water bath (A.2.2) at (37 ± 2) °C.

A.4.3 Allow the immersed portion of the catheter to equilibrate for a minimum of 2 min.

A.4.4 Inflate the balloon using a pre-determined pressure profile versus time that will allow accurate detection of burst pressure until the catheter bursts or fails. Record the burst pressure, burst mode and location of the burst.

A.4.5 Calculate the RBP.

A.5 Test report

The test report shall include at least the following information:

a) identity of the catheter (e.g. description, lot number, reference part number, etc.);

b) a reference to this document (including its year of publication) and annex;

c) for variable data analysis, the maximum, minimum, mean and standard deviation of the burst pressure, expressed in kPa;

d) RBP, expressed in kPa;

e) all observed burst modes (e.g. longitudinal burst, bond leak etc.) and locations and whether fragments were produced;

f) any deviations from the procedure;

g) the date of test.