SLOVENSKI STANDARD
oSIST prEN ISO 10555-4:2023

01-januar-2023

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 4. del: Balonski katetri za širjenje žil (ISO/DIS 10555-4:2022)

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO/DIS 10555-4:2022)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 4: Ballondilatationskatheter (ISO/DIS 10555-4:2022)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 4: Cathéters de dilatation à ballonnets (ISO/DIS 10555-4:2022)

Ta slovenski standard je istoveten z: **prEN ISO 10555-4**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

oSIST prEN ISO 10555-4:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 10555-4

ISO/TC **84**

Secretariat: **DS**

Voting begins on:
2022-11-22

Voting terminates on:
2023-02-14

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

ICS: 11.040.25

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 10555-4:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 medical products and catheters*.

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

The main changes compared to the previous edition are as follows:

— Defined Rated Burst Pressure (RBP) (see 3.2).

— Defined crossing profile (see 3.3), added requirement (see 4.4.5), and created test method (see Annex E).

— 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).

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

— Added informative 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.

Introduction

To be developed, if necessary (not mandatory).

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 terminological 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 comply 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 Where a balloon dilation catheter 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 RBP when tested in accordance with Annex A.

NOTE Longitudinal burst is the desirable balloon burst mode, though other modes may be acceptable with 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, should be evaluated when measuring the outside diameter (see ISO 10555-1).

4.4.6 Balloon removal

Demonstrate 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:####, 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.

NOTE 1 Units of measurement systems other than those specified in this document can additionally be given.

NOTE 2 The crossing profile, expressed in mm, can be given.