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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

Reference number
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Foreword

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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.

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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 10555-1:2023, *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

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