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Intravascular catheters — Sterile and single-use catheters —

Part 7: Peripherally inserted central catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables — Partie 7: Cathéters centraux à insertion périphérique

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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

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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 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).

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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

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 7: Peripherally inserted central catheters

1 Scope

This document specifies general requirements and test method for peripherally inserted central catheters (PICC), supplied in the sterile condition and intended for single use, for any application.

It is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

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*

ISO 10555-3, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters*

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
peripherally inserted central catheter
PICC
type of central catheter where the tip resides centrally but the insertion into the vasculature is performed in the peripheral veins (typically upper arm, but other peripheral sites as well)

3.2
outside diameter
largest diameter of the catheter or pre- and post-hydration largest diameters of hydratable catheters along the non-tapered length

Note 1 to entry: The tapered length is the proximal portion of the effective length where the nominal diameter of the catheter is gradually increased (from distal to proximal direction).

4 Requirements

4.1 General

Catheters shall conform to ISO 10555-1, except for the peak tensile force for which the requirements in 4.4 of this document shall apply.

4.2 Distance markings

If the catheter is provided with distance markings, the marking system shall indicate the length of the catheter. From the first mark, the distance between marks shall not exceed 5 cm.

4.3 Lumen markings

For multi-lumen catheters, the identification of each lumen shall be apparent to the user, and for catheters with staggered tips (exit points) the relative position of the distal opening to the tip of the catheter shall be apparent to the user.

4.4 Peak tensile force

4.4.1 General

Test the catheter for peak tensile force in accordance with ISO 10555-1 using the requirement values listed in the following subclauses.

4.4.2 Catheters excluding the tip

a) For catheters not constructed with silicone materials, the peak tensile force of each test piece shall be as given in ISO 10555-1.

b) For catheters constructed with silicone materials, the peak tensile force shall be as given in Table 1.

This document does not specify requirements for peak tensile force for tubing of less than 0,75 mm outside diameter (pre-hydration outside diameter for hydratable intravascular catheters). For those cases, the peak tensile force shall be determined by the manufacturer based on risk assessment.

Table 1 — Peak tensile force of silicone catheter test pieces

Effective outside diameter range of tubular portion of test piece mm	Minimum peak tensile force N
≥ 0,75 and < 1,15	1,6
≥ 1,15 and < 1,85	3,4

NOTE See Annex A for supplementary information.

4.4.3 Tip tensile force

For catheter tips not exceeding 20 mm in length, the minimum peak tensile force of the tip shall be as given in Table 1 for silicone-based catheters and as given in Table 2 for any other material-based catheters when tested in accordance with the method given in ISO 10555-1.

For distal tips of less than 3 mm length, the peak tensile force requirement shall be as given in ISO 10555-1.