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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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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.

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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.

Table 2 — Minimum peak tensile force of tips of length not exceeding 20 mm (for non-silicone PICCs)

Smallest outside diameter of catheter body mm	Minimum peak tensile force N
≥ 0,55 and < 0,75	3
≥ 0,75 and < 1,85	4
≥ 1,85	5

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall conform to ISO 10555-1 and ISO 10555-3 and shall also indicate, for each lumen, whether the lumen is compatible with power injection.

Annex A
(informative)

Rationale and guidance

A.1 General

This annex provides a rationale for tensile requirements for silicone catheters of this document.

A.2 Background

The peak tensile requirements for the catheter shaft and associated junctions were established in 1995 with the first edition of ISO 10555-1 (ISO 10555-1:1995, Table 1). These requirements have remained unchanged since the first edition. Prior to 1995, small-bore silicone PICCs [< 5 Fr (1,67 mm) outer diameter] were present on the market and some of these products are still in use to this day. One of the notable aspects of these small-bore silicone PICCs is that many of these products do not meet the peak tensile requirements, even though some products predate the original publication of ISO 10555-1 by 5 years to 10 years. As such, an assessment of the current state of silicone PICCs on the market was undertaken to determine whether a more appropriate tensile standard was necessary for these products.

A.3 Method

In order to capture an accurate picture of the silicone PICCs currently on the market, a benchmarking of silicone PICCs was conducted. Catheters from 5 different manufacturers were used, ranging in size from 1,98 Fr to 4 Fr (0,66 mm to 1,33 mm), with a requirement that a minimum sample size of N = 10 per catheter configuration be provided for testing. The catheters were tested for shaft tensile and shaft to hub tensile at 3 different manufacturer's laboratories in order to ensure unbiased testing.

A.4 Findings and discussion related to Table 1

The conclusions from the benchmarking testing were that almost all of the silicone catheters tested did not meet the tensile requirements in the first edition of ISO 10555-1 (ISO 10555-1:1995, Table 1), which raises questions about the origins of the tensile requirements and whether silicone catheters on the market in 1995 were adequately considered when developing the tensile requirements. The catheter shaft and shaft to hub tensile data were pooled for each French size, and the 3 Fr (1 mm) and 4 Fr (1,33 mm) catheter data were further analysed to determine an appropriate tensile specification for these two sizes of silicone PICCs. Using a requirement of 95 % CI/95 % reliability, a tensile value that captured 95 % of the tensile values was generated and is shown in Table 1. These values provide an accurate assessment of the tensile performance of silicone PICCs ranging from 3 Fr to 4 Fr (1 mm to 1,33 mm) and create realistic tensile requirements for this size and material of catheter.

Another important conclusion was that the values listed in Table 1 are only applicable to silicone catheters. The main reason for this is that, while silicone has a lower tensile value than other materials commonly used in PICCs (such as polyurethane), silicones have a high elongation at break relative to other materials. PICCs are subjected to a range of forces while they are implanted in the vasculature. However, pure axial forces, i.e. those tested in ISO 10555-1:2013, Annex B, are not readily present except when attempting to remove a catheter where a portion of implanted catheter is adhered to the patient (i.e. fibrin sheath formation, deep vein thrombosis (DVT), etc.). When these conditions are significant enough to provide tensile force during removal, the high elongation of silicone provides a visual cue ("early warning indication") that the catheter is being subjected to higher-than-normal strain and further investigation should be conducted before continuing to remove the catheter.

Bibliography

[1] ISO 11070, *Sterile single-use intravascular introducers, dilators and guidewires*

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