
**Intravascular catheters — Sterile and
single-use catheters —**

Part 3:
Central venous catheters

*Cathéters intravasculaires — Cathéters stériles et non réutilisables —
Partie 3: Cathéters centraux veineux*





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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10555-3 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-3:1996), which has been technically revised. It also incorporates the Technical Corrigendum ISO 10555-3:1996/Cor 1:2002.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

- *Part 1: General requirements*
- *Part 3: Central venous catheters*
- *Part 4: Balloon dilatation catheters*
- *Part 5: Over-needle peripheral catheters*

The following part is under preparation:

- *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

- *Part 2: Angiographic catheters*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

Intravascular catheters — Sterile and single-use catheters —

Part 3: Central venous catheters

1 Scope

This part of ISO 10555 specifies requirements for central venous catheters supplied in the sterile condition, and intended for single use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10555-1:2013, *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.

3.1

central venous catheter

intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements

Note 1 to entry: The catheter can have a fixation system which is part of the device.

4 Requirements

4.1 General

Catheters shall comply with ISO 10555-1, except for the peak tensile force (see ISO 10555-1:2013, 4.6), for which the requirements of 4.4 of this part of ISO 10555 shall apply.

4.2 Distance markings

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

It is recommended that the distance marks be 1 cm apart on that portion of the catheter likely to be of importance to the user in positioning the catheter and monitoring catheter migration.

4.3 Lumen markings

For multilumen catheters, identification of each lumen shall be apparent to the user.

4.4 Peak tensile force

For catheters having a tip of softer durometer material or of different construction to the shaft and not exceeding 20 mm in length, the minimum peak tensile force of the tip shall be as given in [Table 1](#) when tested in accordance with the method given in ISO 10555-1:2013, Annex B.

The minimum peak tensile force of all other parts of such catheters shall comply with ISO 10555-1:2013, 4.6.

Table 1 — Minimum peak tensile force of soft tips of length not exceeding 20 mm

Smallest outside diameter of catheter body mm	Minimum peak tensile force N
$\geq 0,550$ and $< 0,75$	3
$\geq 0,75$ and $< 1,85$	4
$\geq 1,85$	5

4.5 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also contain the following:

- a) if the catheter is provided with distance markings, a description of the marking system;
- b) flowrate for each lumen;
- c) maximum guidewire diameter, where applicable;
- d) if applicable, a warning against attempting to withdraw the catheter back through the needle;
- e) at least one recommended cleaning agent.

Units of measurement systems other than those specified in this part of ISO 10555 may additionally be used.

Bibliography

- [1] ISO 11070, *Sterile, single-use intravascular catheter introducers*