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

**Part 6:
Subcutaneous implanted ports**

*Cathéters intravasculaires — Cathéters stériles et non réutilisables —
Partie 6: Chambres à cathéter implantables*

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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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.

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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The following part has been withdrawn and the content has been included in ISO 10555-1: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

Intravascular catheters — Sterile and single-use catheters —

Part 6: Subcutaneous implanted ports

1 Scope

This part of ISO 10555 specifies requirements, performance, and user safety issues related to subcutaneous implanted ports and catheters for intravascular long-term use supplied in sterile condition and intended for single use.

This part of ISO 10555 does not specify requirements, performance, and user safety issues related to non-coring needles.

NOTE Subcutaneous implanted ports are known to be used for indications other than intravascular such as intra-peritoneal, intra-theal, intra-pleural, and epidural access.

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*

ISO 10555-3:2013, *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.

3.1 catheter

single- or multiple-lumen tube allowing access to a point within the body at its distal end

3.2 connection

system connecting the catheter to the subcutaneous implanted port

3.3 effective surface area

area available for puncture by the needle

3.4 flushing volume

volume of solution needed to fully replace one solution from the subcutaneous implanted port and catheter with another

3.5

non-coring needle

needle that does not produce a core when penetrating the septum

Note 1 to entry: Core is a sliver of septum material that can be produced when a needle perforates a septum.

3.6

outlet tube

exit cannula portion of the subcutaneous implanted port that is connected to the catheter

3.7

priming volume

total amount of space available in the subcutaneous implanted port and catheter to be filled with solution

3.8

priming volume of the subcutaneous implanted port

amount of space available in the subcutaneous implanted port to be filled with solution, where the space is comprised of both the reservoir and outlet tube

3.9

priming volume of the catheter

total amount of space available in the effective length of the catheter to be filled with solution

3.10

reservoir

open space below the septum that receives the needle and is in communication with the outlet tube

3.11

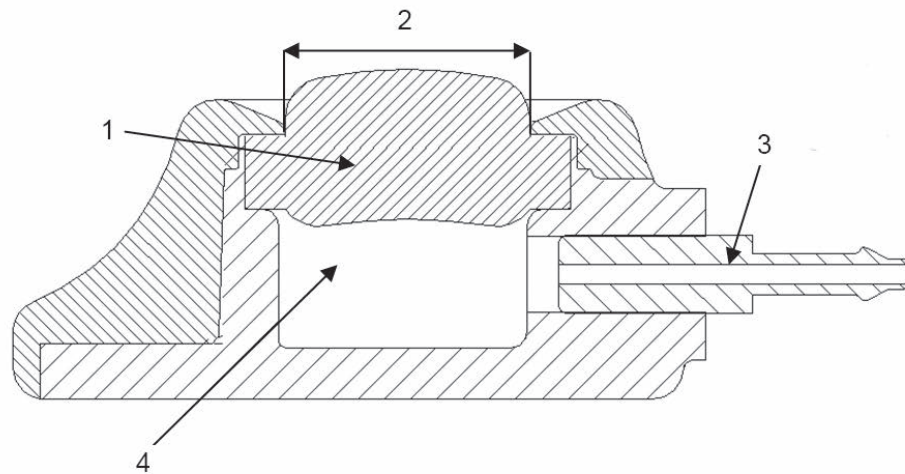
septum

self-sealing membrane through which the needle passes to communicate with the catheter

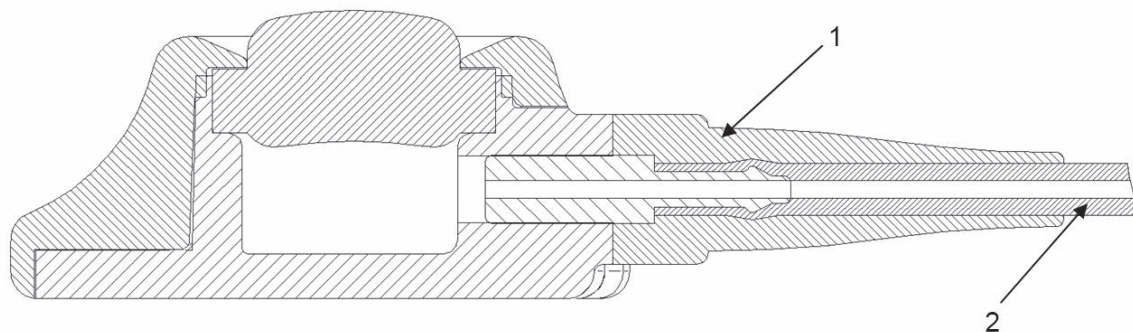
3.12

subcutaneous implanted port

device which permits percutaneous access to the catheter

**Key**

- 1 septum
- 2 effective surface area
- 3 outlet tube
- 4 reservoir

Figure 1 — Subcutaneous implanted port**Key**

- 1 connection
- 2 catheter

Figure 2 — Subcutaneous implanted port connected to a catheter**4 Requirements of the implantable subcutaneous implanted port and catheter****4.1 General**

Unless otherwise specified in this part of ISO 10555, the subcutaneous implanted port and catheter shall comply with ISO 10555-1.