INTERNATIONAL STANDARD

ISO 10555-6

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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

Reference number
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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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-thecal, 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

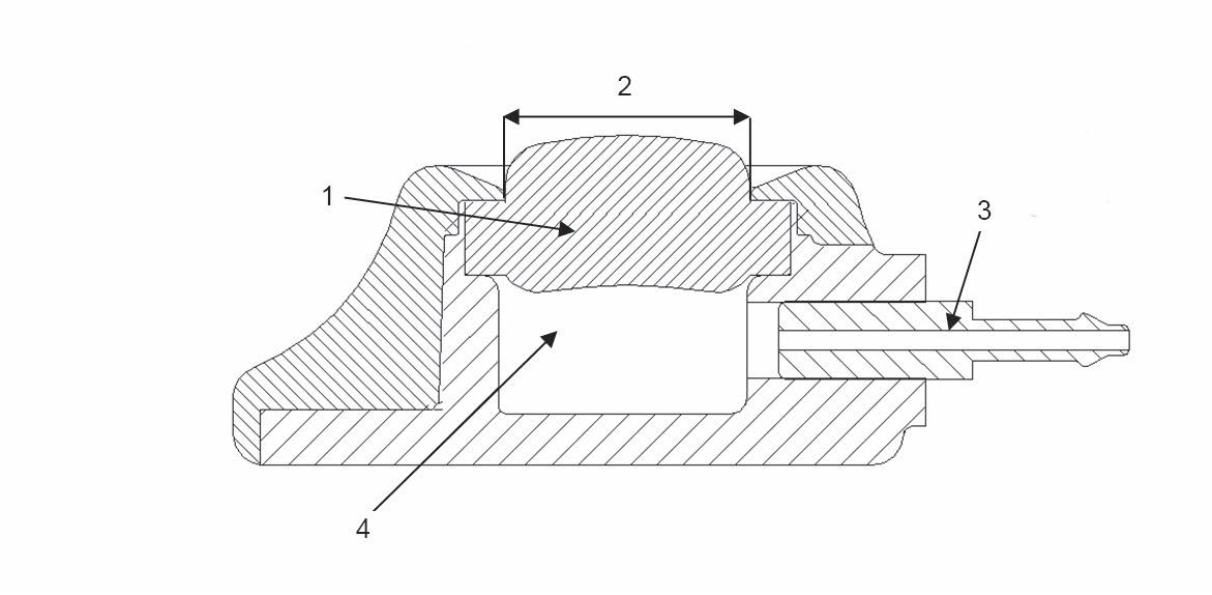
3.8
priming volume of the subcutaneous implanted port
amount of space available in the subcutaneous implanted port to be filled with solution, where the space is comprised of both the reservoir and outlet tube

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

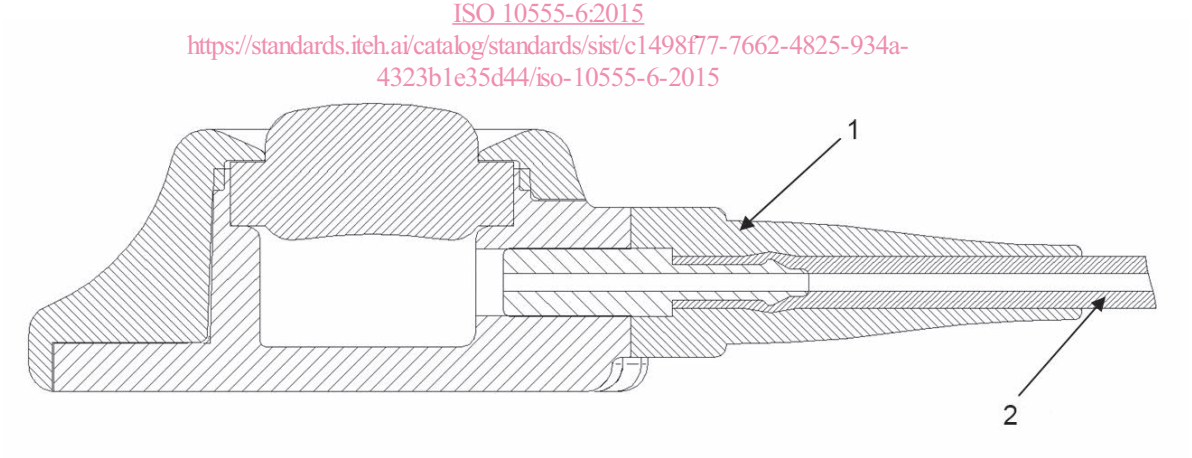
3.12
subcutaneous implanted port
device which permits percutaneous access to the catheter



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.

4.2 Biocompatibility

Subcutaneous implantable port shall be free from biological hazards.

NOTE See ISO 10993-1 for the selection of appropriate test methods.

4.3 Distance markings

If the catheter is provided with distance markings, the marking shall be indicated as follows:

a) for non-connected catheters, indicate distance from the distal end of the catheter;

b) for pre-connected catheters, indicate distance from the proximal end of the catheter.

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.

4.4 Nominal dimensions of the subcutaneous implanted port

If provided, the following measurements shall be expressed in millimetres:

— subcutaneous implanted port dimensions;

— effective surface area of the septum, defined either as the diameter (in case of a circular septum) or as the length and width (in case of other shape) of the septum in nominal dimension.

4.5 Physical requirements

4.5.1 Radio-detectability

The radio-detectability shall comply with ISO 10555-1 and shall include the catheter, subcutaneous implanted port, and connection.

4.5.2 Surface finish

When examined by normal or corrected to normal vision, with a minimum x2,5 magnification, the surface of the subcutaneous implanted port shall appear free from extraneous matter.

4.5.3 Freedom from leakage

The connection or any other part of the subcutaneous implanted port shall not leak air when tested in accordance with the method given in Annex A.

When the test is conducted according to Annex A, the subcutaneous implanted port is considered to leak if the reduction in pressure is greater than 2,65 kPa in 2 min or if a level of 200 kPa cannot be attained.

The septum of the subcutaneous implanted port shall not leak air when tested in accordance with the method given in Annex D.

4.5.4 Flushing volume

The manufacturer shall conduct characterization tests for the flushing volume. A test method is described in Annex B. Any other equivalent method may be used.

4.5.5 Characteristics of the septum

4.5.5.1 Needle penetration and withdrawal force

If tested in accordance with Annex C, the peak force of penetration and withdrawal of a non-coring needle recommended by the manufacturer should be determined.

4.5.6 Characteristics of the connection or the catheter

4.5.6.1 Peak tensile force

For the connection between the port and the catheter, the minimum peak tensile force shall be 5 N when tested in accordance with Annex E.

The minimum peak tensile force of all other parts of the catheter shall comply with ISO 10555-3:2013, 4.4.

4.6 Flow rate

For devices for which flow rate is defined, when tested in accordance with ISO 10555-1:2013, Annex E, the flow rate for each lumen shall be a minimum of 80 % of that stated by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated by the manufacturer for catheters of nominal outside diameter equal to 1,0 mm or greater.

If the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

4.6.1 Subcutaneous implanted ports not indicated for power injection

When tested in accordance with the method given in ISO 10555-1:2013, Annex E, the following modifications shall be made to the test apparatus:

— the male 6 % (luer) taper fitting ISO 10555-1:2013, Figure E.1 component 6 shall be connected to the hub of a non-coring needle;

— the non-coring needle shall be placed through the septum of the subcutaneous implanted port;

— the subcutaneous implanted port shall be connected to the catheter under test (ISO 10555-1:2013, Figure E.1 component 7) following manufacturer instructions;

— an inline pressure transducer shall be connected to the proximal end of the non-coring needle.

The test shall be completed with non-coring needles that characterize the minimum and maximum flow rate under gravity. The needle gauge and length shall be recorded.

4.6.2 Subcutaneous implanted ports indicated for power injection

When tested in accordance with the method given in ISO 10555-1:2013, Annex G, the following modifications shall be made to the test apparatus:

— the locking device (ISO 10555-1:2013, Figure G.1 component 4) shall be connected to the hub of a non-coring needle indicated for power injection;

— the non-coring needle shall be placed through the septum of the subcutaneous implanted port;

— the subcutaneous implanted port shall be connected to the catheter under test (ISO 10555-1:2013, Figure G.1, component 6) following manufacturer instructions.

4.7 Burst pressure of the subcutaneous implanted port and catheter

When tested in accordance with the method given in ISO 10555-1:2013, Annex F, the following modifications shall be made to the test apparatus:

— the locking device fitting (ISO 10555-1:2013, F.2.3 and Figure F.1 component 3) shall be connected to the hub of a non-coring needle according to the appropriate risk-based clinical justification;

— the non-coring needle shall be placed through the septum of the subcutaneous implanted port;

— the subcutaneous implanted port shall be connected to the catheter under test (ISO 10555-1:2013, Figure F.1 component 5) following manufacturer instructions.

4.7.1 Subcutaneous implanted ports not indicated for power injection

When tested in accordance with the method given in ISO 10555-1:2013, Annex F with the above modifications (see 4.7), the burst pressure shall exceed the peak pressure present at maximum flow conditions as determined by 4.6.1.

4.7.2 Subcutaneous implanted ports indicated for power injection

When tested in accordance with the method given in ISO 10555-1:2013, Annex F with the above modifications (see 4.7), the burst pressure shall exceed the peak pressure present at maximum flow conditions as determined by 4.6.2.

5 Magnetic Resonance Imaging (MRI) compatibility

The hazards of subcutaneous implanted ports in the magnetic resonance environment should be evaluated by an appropriate method.

NOTE Such as ASTM F2052, F2213, F2182, and F2119.

6 Information to be supplied by the manufacturer

Information supplied by the manufacturer shall comply with ISO 10555-1 and shall also include the following.

6.1 Marking on the device

Information for product traceability shall be placed on the subcutaneous implanted port by the appropriate method such as direct marking by inkjet or laser.

NOTE A model number and, if applicable, indication for power injection can be added.

This information can be supplied in the form of an identification number or two dimensional symbol specified by GS-1 (Global Standard One) system.

6.2 Primary packaging

The primary packaging shall comply with ISO 10555-1 and shall also contain at least some information on the following:

— indication for power injection.

6.3 Labels for traceability

Three self-adhesive labels shall contain, as a minimum, the following:

— the name of the product and manufacturer;

— designation and item number;

— the batch code, LOT, or serial number.

6.4 Instruction for use

The instruction for use shall comply with ISO 10555-1 and shall also contain at least information on the following:

a) technique for subcutaneous implanted port placement;

b) the nature (generic name) of the constituent materials of the subcutaneous implanted port;

c) priming volume of the subcutaneous implanted port;

d) priming volume of the catheter per 10 cm;

e) if applicable, safety information in the magnetic resonance environment;

f) gravity flow rate in ml/min (power injection flow rate, if applicable, ml/s);

g) if applicable, specifications of the devices required to connect the port to the power injector shall be indicated (e.g. dimensions of non-coring needle, extension lines).

NOTE Units of measurement systems other than those specified in this part of ISO 10555 can additionally be given.