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).

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The following part has been withdrawn and the content has been included in ISO 10555-1: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

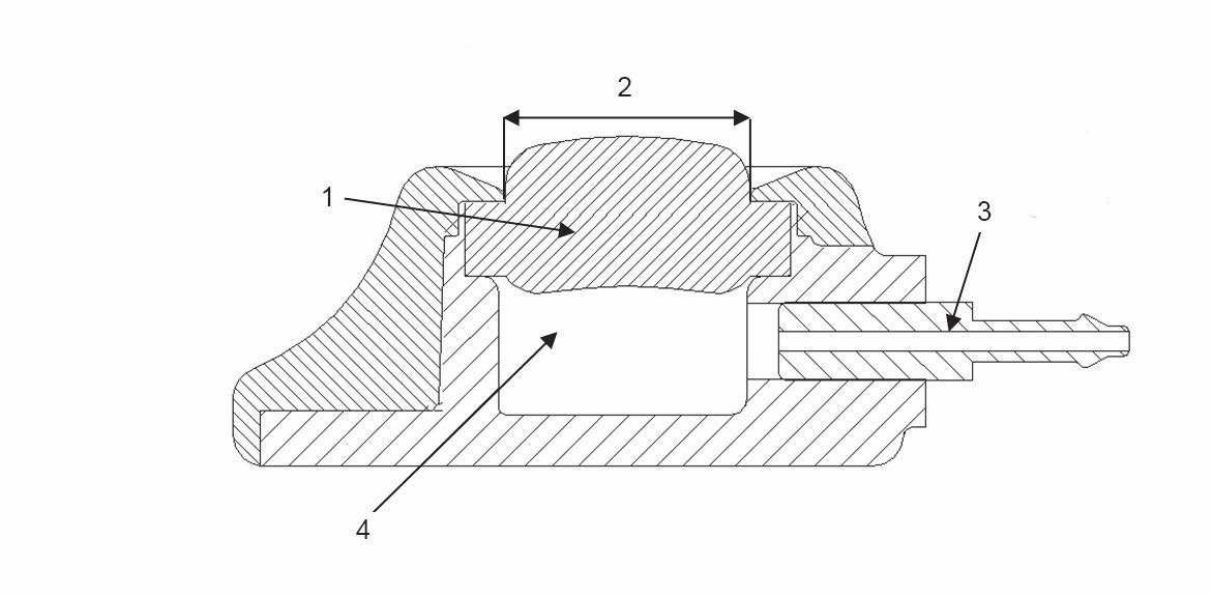
3.8
priming volume of the subcutaneous implanted port
amount of space available in the subcutaneous implanted port to be filled with solution, where the space is comprised of both the reservoir and outlet tube

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

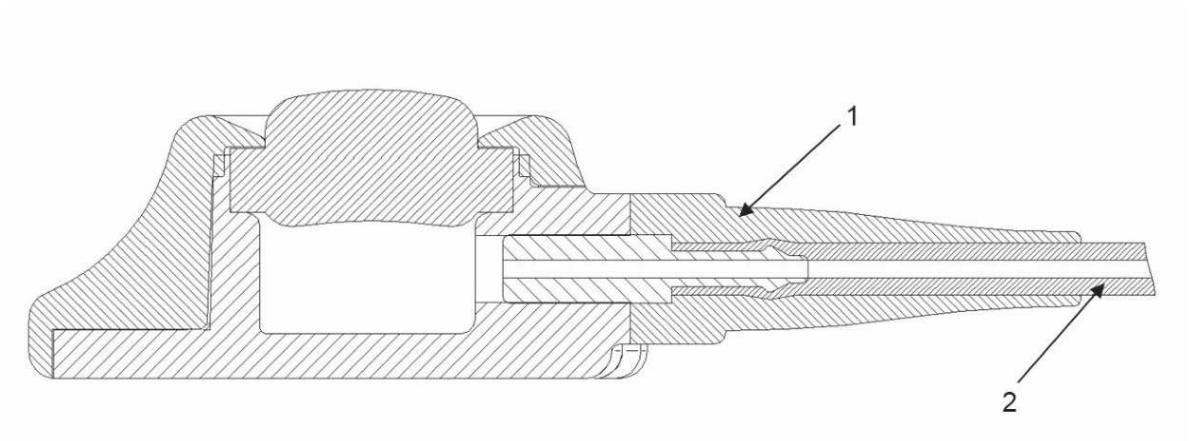
3.12
subcutaneous implanted port
device which permits percutaneous access to the catheter



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.

Annex A
(normative)

Test method for freedom from air leakage

A.1 Principle

Air pressure is applied to the connection and the subcutaneous implanted port to determine if air leakage is found.

A.2 Apparatus

A.2.1 **Leak-proof connector**.

A.2.2 **Syringe**, or constant pressure source.

A.2.3 **Gauge**, capable of measuring up to 300 kPa pressure.

A.2.4 **Fluid-filled**, temperature controlled test chamber.

A.3 Procedure

A.3.1 Bring the test chamber fluid (A.2.4) to a temperature of (37 ± 2) °C, and maintain this temperature throughout the test.

A.3.2 Attach the catheter to the port, if it is a non-connected catheter.

A.3.3 Cut the catheter distal to the port leaving a length of catheter sufficient (max. 10 cm) to allow connection of the pressure gauge and pressure source.

A.3.4 Connect the distal end of the catheter to the pressure source and pressure gauge via a leak-proof connector.

A.3.5 Immerse the subcutaneous implanted port in the temperature controlled test chamber.

A.3.6 Allow the subcutaneous implanted port to reach thermal equilibrium.

A.3.7 Adjust the pressure to a minimum of 200 kPa and wait 2 min.

A.3.8 Examine the assembled subcutaneous implanted port for air leakage (which is a pressure reduction greater than 2,65 kPa in 2 min or if a level of 200 kPa cannot be attained).

A.4 Test Report

The test report shall include the following information:

a) identity of the subcutaneous implanted port;

b) statement whether there is air leakage.

Annex B
(informative)

Determination of flushing volume

B.1 Principle

The subcutaneous implanted port and the catheter are filled with a coloured solution and flushed with successive boli until the colour disappears.

B.2 Reagents

B.2.1 Glycerine.

B.2.2 NaCl 9 g/l.

B.2.3 Patent blue V colourant (λ = 635 nm).

NOTE Patent blue V is an example of a suitable product available commercially. This information is given for the convenience of users of this European Standard and does not constitute an endorsement by ISO (CEN) of this product.

B.3 Apparatus

B.3.1 Non-coring needle.

B.3.2 Syringe.

B.3.3 Spectrophotometer, capable of measuring absorbency at 635 nm.

B.4 Procedure

B.4.1 Prepare 400 ml of NaCl 9 g/l as flushing solution.

B.4.2 Prepare 100 ml of coloured solution (100 ml of 45 % glycerine by weight + 55 % solution NaCl 9 g/l (simulation of blood viscosity) containing 2 mg of patent blue V colourant).

B.4.3 Cut X cm of catheter (e.g. X = 25 cm + outlet tube length) and connect it to the subcutaneous implanted port with the connection according to the manufacturer's instructions for use.

B.4.4 Fill the subcutaneous implanted port and the catheter with sufficient coloured solution.

B.4.5 Flush each subcutaneous implanted port with a 2 ml bolus of flushing solution without shaking it.

B.4.6 Collect the flushed solution in a test tube. Measure the collected solution and repeat flushing and measuring until the coloured solution vanishes by collecting each bolus separately and by indicating the number of successive rinses.

B.4.7 The sum of the boli until the colouring disappears is the flushing volume of the device.

B.5 Test Report

The test report shall include the following information:

a) identity of the subcutaneous implanted port and catheter;

b) total flushing volume expressed in ml;

c) length of catheter expressed in cm.

Annex C
(informative)

Guidance on further characterization testing: Needle penetration and withdrawal

C.1 Principle

The septum is punctured with a non-coring needle and the peak forces of penetration and withdrawal are recorded.

C.2 Apparatus

C.2.1 **Tensile/compression test machine**.

C.2.2 **Fixture**, which holds the needle perpendicular to the subcutaneous implanted port.

C.3 Procedure

C.3.1 Place the test pieces to be conditioned in an appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time. Test in accordance with C.3.2 to C.3.3 immediately after conditioning.

C.3.2 Perform needle penetration force test as follows:

C.3.2.1 Program the test machine with a test speed of 50 mm/min in compression mode.

C.3.2.2 Place the subcutaneous implanted port on the support-plate of the test machine.

C.3.2.3 Insert the fixture which holds the needle perpendicular to the septum surface into the upper jaws.

C.3.2.4 Position the needle just above the puncture surface.

C.3.2.5 Insert needle into the septum of the subcutaneous implanted port such that the needle crosses the septum but does not come into contact with the bottom of the subcutaneous implanted port.

C.3.2.6 Record the peak penetration force.

C.3.3 Perform needle withdrawal force test as follows:

C.3.3.1 Program the test machine with a test speed of 50 mm/min in extension mode.

C.3.3.2 Withdraw the needle completely from the septum of the subcutaneous implanted port.

C.3.3.3 Record the peak withdrawal force.

C.4 Test Report

The test report shall include the following information:

a) identity of the subcutaneous implanted port, diameter and identity of the needle, and presence or not of lubricant on the needle body;

b) peak force of septum penetration and withdrawal.

Annex D
(normative)

Test method for freedom from leakage after multiple punctures

D.1 Principle

Randomly distribute an appropriate number of needle punctures over the effective area of the septum, then the port is leak tested in accordance with Annex A.

D.2 Apparatus

D.2.1 **Apparatus** requested by Annex A.

D.2.2 **Non-coring needles**, recommended by the manufacturer.

D.2.3 **Testing equipment**, for producing punctures.

D.3 Procedure

D.3.1 Bring the test chamber fluid (A.2.4) to a temperature of (37 ± 2) °C, and maintain this temperature throughout the test.

D.3.2 Immerse the subcutaneous implanted port in the temperature-controlled test chamber and allow it to reach thermal equilibrium.

D.3.3 Perform punctures keeping the subcutaneous implanted port in the temperature-controlled test chamber.

The number of punctures should be as follows:

Minimum 1 000 punctures per cm^2 of effective surface area of septum.

If the manufacturer claims resistance to a higher number of punctures, that number shall be considered for this test. Punctures are randomly distributed over the effective surface area of the septum. Ensure that the non-coring needle tip completely passes through the septum at each puncture. Each needle shall be used for a maximum of 50 punctures. Check carefully that the needle tip is not tilted or rocked after exiting the septum; if this occurs, replace the non-coring needle.

D.3.4 Conduct leak test in accordance with Annex A.

D.4 Test report

The test report shall include the following information:

a) identity of tested subcutaneous implanted port and non-coring needles;

b) number of punctures;

c) statement as to whether leakage was observed after punctures.

Annex E
(normative)

Peak tensile force

E.1 Principle

The catheter is connected to the subcutaneous implanted port in accordance with the manufacturer's instructions for use. Tensile force is applied to the connection until the junction separates or the catheter breaks.

E.2 Apparatus

Tensile testing equipment, capable of exerting a force greater than 10 N.

E.3 Procedure

E.3.1 Place the test pieces to be conditioned in an appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time. Test in accordance with E.3.2 to E.3.4 immediately after conditioning.

E.3.2 Tensile speed: 50 mm/min.

E.3.3 Connect the catheter to the subcutaneous implanted port in accordance with the manufacturer's instructions. Fix the test sample in the tensile testing equipment.

E.3.4 Apply the tensile force until the junction separates or the catheter breaks.

E.4 Test report

The test report shall include the following information:

a) identity of the subcutaneous implanted port and the catheter;

b) peak tensile force expressed in newtons.

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