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Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation

Implants cardiovasculaires et organes artificiels — Canules pour circulation extracorporelle

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is intended to ensure that cannulae designed to enable extracorporeal circulation (ECC) have been adequately tested for both their safety and function, and that cannulae characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for the evaluation of ECC cannulae. Type test procedures for determination of the cannulae performance and blood cell damage are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of cannulae that suits the needs of the patient.

This document also includes minimum reporting requirements, which allows the user to compare performance characteristics of cannulae of different designs in a standard way.

This document makes reference to other international standards in which methods for determination of characteristics common to medical devices can be found.

Requirements for animal and clinical studies have not been included in this document. Such studies can be necessary for regulatory submissions and/or be parts of a manufacturer's quality system.

This document contains only those requirements that are specific to cannulae. Non-specific requirements are covered by references to other International Standards listed in Clause 2. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation

1 Scope

This document specifies requirements for sterile, single-use cannulae for removal and delivery of patients' blood during cardiopulmonary bypass (CPB) up to 6 h duration, extracorporeal lung assist (ECLA with VV, VAV, or AV cannulation strategies), left or right heart bypass (LHB, RHB), cardiopulmonary support (CPS), extracorporeal life support (ECLS with VA cannulation strategy), extracorporeal carbon dioxide removal ($ECCO_2R$), and other extracorporeal circulation techniques. This standard does not apply to:

— introducers (e.g., guidewires) as addressed in ISO 11070,

— isolated organ perfusion cannulae, and

— intravascular catheters as addressed in ISO 10555-3.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ASTM F640-12, *Standard Test Methods For Determining Radiopacity For Medical Use*

DIN 13273-7, *Catheters for medical use — Part 7: Determination of the x-ray attenuation of catheters; Requirements and testing*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological 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
extracorporeal circulation
blood circulation through an extracorporeal circuit used to support or replace a subject's circulatory and/or gas exchange requirements when the heart and/or lungs are temporarily not capable of functioning normally (e.g. due to lung and/or heart disease) incorporating cannulae, oxygenators, tubing, and/or other devices such as blood pump, arterial filter, reservoir

3.2
cannula
tubular device, single-lumen (3.4) or dual-lumen (3.5), designed to be partially inserted into the cardiovascular system for connection of the patient to the extracorporeal circuit

3.3
blood pathway
portions of the *cannula* (3.2) in contact with blood during the intended clinical use

3.4
single-lumen
cannula (3.2) with one inner lumen used to draw blood from the patient or to return blood to the patient

3.5
dual-lumen
cannula (3.2) with two inner lumens, separated from each other, used to draw blood from and to return blood to the patient

3.6
integral part
part that is connected to the *cannula* (3.2) and that cannot normally be separated by the user

3.7
operating variable
setting of controls that affects the function of the device

3.8
platelet reduction
percentage reduction of platelets contained in a circuit incorporating a *cannula* (3.2)

3.9
plasma free haemoglobin level
concentration of plasma free haemoglobin in a circuit incorporating a *cannula* (3.2)

3.9.1
NIH
normalized index of haemolysis

grams of plasma free haemoglobin released after pumping 100 l of blood

$$N_{ih}\,(g/100\,l) = \Delta f_{Hb} \cdot V \cdot \frac{100 - Hct}{100} \cdot \frac{100}{Q \cdot t} \quad (1)$$

where

N_{ih} is NIH;

Δf_{Hb} is the increase of plasma free haemoglobin concentration (g/l) over the sampling time interval;

V is the circuit volume (l);

Q is the flow rate (l/min);

Hct is the haematocrit (%);

t is the sampling time interval (min).

3.10
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating a *cannula* (3.2)

3.11
blood analogue
test solution which simulates certain blood characteristics relevant for testing, such as viscosity and salinity

3.12
predicate cannula
similar *cannula* (3.2) to the test cannula that is a legally marketed device, recognized-to-be-safe and is used for the same intended clinical use

3.13
distal end
end of the *cannula* (3.2) inserted furthest into the patient

3.14
proximal end
end(s) of the *cannula* (3.2) furthest away from the patient to which connection(s) can be made

3.15
inside diameter
inner diameter of the *cannula* (3.2), measured at the smallest part of the *cannula*

Note 1 to entry: The inside diameter is given in millimetres.

3.16
outside diameter
outer diameter of the *cannula* (3.2), measured at the biggest part of the *cannula* intended for insertion

Note 1 to entry: The outside diameter is given in millimetres.

3.17
effective length
length of the *cannula* (3.2), that can be inserted into the body

Note 1 to entry: The effective length is given in millimetres.

3.18
French size
diameter, D_{fr}, that is three times the normal diameter, D, in millimetres, $D_{fr} = 3D$

3.19
primary packaging
packaging which has direct contact with the device and/or maintains the sterility of the product

3.20
simulated use
use similar to the intended clinical use in an appropriate in-vitro test circuit with a *blood analogue* (3.11) at maximum flow rate as specified by the manufacturer and for the duration specified by the manufacturer for intended clinical use

3.21
vascular model
<single-lumen cannulae> tubular structure of diameter two times the outer diameter of the device under test

3.22
vascular model
<dual-lumen cannulae> simplified vascular model of superior vena cava, right atrium, and inferior vena cava for testing dual-lumen cannulae intended for use as a single *cannula* (3.2), for both venous drainage and return of blood via cannulation of the internal jugular vein

Note 1 to entry: See Annex C.

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The cannula shall be sterile and non-pyrogenic.

Conformity shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

All parts of the blood pathway and all tissue contacting parts of the cannula shall be biocompatible with respect to their intended use.

Conformity shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 Blood pathway integrity

When tested in accordance with 5.3.1, the blood pathway(s) shall not leak.

4.2.2 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.2, allow a secure connection.

Connectors with dimensions as given in the Annex A and fitting to functional gauges and reference steel fittings are a way to comply with this requirement. Performance testing of the connectors shall be performed according to ISO 80369-7:2021, Clause 6, using the reference fittings given in Annex A.

NOTE Connectors of a type that allow connection of tubes with an inner diameter of 4,8 mm, 6,3 mm, 9,5 mm or 12,7 mm, or a type that complies with ISO 8637-1:2017, Figure 1, or a type that complies with ISO 80369-7:2021 have been found satisfactory.

4.2.3 Kink resistance

When tested in accordance with 5.3.3 the cannula shall not kink. Kinking is defined as a deformation of lumen of the device when the bending causes a decrease in flow such that the initial flow through the straight cannula is reduced by more than 50 %.

4.2.4 Pull strength

When tested in accordance with 5.3.4, each cannula shall withstand without disintegration an axial tensile force of a minimum of 15 N or 1,5 times the force possibly occurring during the intended use as determined by the risk assessment of the manufacturer for a duration of 30 s.

4.2.5 External surface

When examined by normal or corrected to normal vision, with a minimum ×2 magnification the external surface of the effective length of the cannula shall appear free from extraneous matter per manufacturer's specification.

The external surface of the effective length of the cannula, including the distal end, shall be free from process and surface defects which could cause trauma to vessels during use or obstruct flow, per manufacturer's specification.

4.2.6 Integrity (corrosion, abrasion, degradation)

When examined in accordance with 5.3.5 by normal or corrected to normal vision, with a minimum ×2 magnification the surface of the cannula shall appear free from corrosion, abrasion, and degradation per manufacturer's specifications.

4.2.7 Radio-detectability

When examined in accordance with 5.3.6 parts of the cannula shall be radio-detectable, if required as determined by the risk assessment.

4.2.8 Distance markings

If the cannula is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks should not exceed 50 mm or a distance determined by risk management.

It is recommended that the distance marks be 10 mm or less apart on that portion of the cannula likely to be of importance to the user in positioning the cannula and monitoring cannula migration.

4.2.9 Lumen markings

If the cannula is not axially symmetric, the position of any side outlets shall be identifiable by the user on the proximal end when the cannula is inserted as defined by the information given by the manufacturer.

For dual-lumen cannulae, the direction of blood flow of each lumen shall be visually identifiable by the user.

4.3 Performance characteristics

4.3.1 Pressure drop

When determined in accordance with 5.4.1, the cannula pressure drop shall be within the range of values specified by the manufacturer.

4.3.2 Collapse resistance

For drainage cannula, when determined in accordance with 5.4.2, the cannula-induced pressure drop shall not increase by more than 50 %.

4.3.3 Recirculation

For dual-lumen cannulae, the percentage of recirculated blood in relation to the blood flow through the extracorporeal circuit shall be within the range of values specified by the manufacturer, when determined in accordance with 5.4.3.

4.3.4 Blood cell damage

4.3.4.1 Plasma-free haemoglobin

When determined in accordance with 5.4.4, the increased concentration of plasma free haemoglobin shall be within the range of values specified by the manufacturer.

The haemolysis results shall be reported as mg/dl and NIH.

4.3.4.2 Platelet and white blood cell reduction

When determined in accordance with 5.4.4, the platelet reduction and the white blood cell reduction shall be within the range of values specified by the manufacturer.

4.3.5 Shelf life

Test results should demonstrate the rated shelf life, as specified by the manufacturer.

5 Tests and measurements for conformity to this document

5.1 General

5.1.1 Tests and measurements shall be performed with final, finished, sterilized devices that are prepared according to the manufacturer's instructions for intended clinical use.

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 Unless otherwise stated, the temperature of test liquids shall be (37 ± 2) °C.

5.1.4 If the relationship between variables is non-linear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 The test or measurement procedures are to be regarded as reference procedures. Other procedures can be accepted, provided that the alternative procedure has been shown to be of comparable precision and reproducibility.

5.1.6 Unless otherwise justified, each test shall be performed using a sufficient number of samples to support a statistical analysis.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Conformity shall be verified by inspection of the manufacturer's documentation on sterilization and pyrogen testing, in accordance with ISO 17665-1, ISO 11135, ISO 11137-1, ISO 14937 and ISO 10993-11, as applicable.

5.2.2 Biocompatibility

Conformity shall be verified by test or by inspection of the manufacturer's documentation on biocompatibility for the finished device, in accordance with ISO 10993-1, ISO 10993-4, and ISO 10993-7, as applicable.

5.3 Physical characteristics

5.3.1 Blood pathway integrity

5.3.1.1 Test liquid

The test liquid shall be water, or other appropriate fluid.

5.3.1.2 Procedure

Using an appropriate test circuit, subject the blood pathway of the device (test both lumens at the same time for dual-lumen cannulae) to a pressure that is 1,5 times the maximum pressure specified by the manufacturer for intended clinical use for the duration specified by the manufacturer for clinical use. Visually inspect the device for leakage of test liquid.

For dual-lumen cannulae, perform an additional test using an appropriate test circuit, subject only the lumen which is intended for the return of blood to the patient, to a pressure that is 1,5 times the maximum pressure specified for this pathway by the manufacturer for intended clinical use for the duration specified by the manufacturer for clinical use. Visually inspect the device for leakage of test liquid.

5.3.2 Connectors

The connection shall be made in accordance with the manufacturer's instructions for use.

Each connection shall withstand a pull force of 15 N for 15 s without separating.

5.3.3 Kink resistance

5.3.3.1 Test liquid

The test liquid for the blood pathway shall be blood or blood analogue with a viscosity of $2{,}0 \times 10^{-3}$ Pa·s (2,0 cP), to $3{,}5 \times 10^{-3}$ Pa·s (3,5 cP).

5.3.3.2 Procedure

Insert device under test into a suitable fluid reservoir in such a way that it allows for unrestricted blood flow through the cannula and for full immersion of the inserted part of the cannula at a worst-case temperature that simulates intended clinical use. For examples of test set-ups, see Annex B. De-air the circuit. Subject the blood pathway to the maximum blood flow rate as specified by the manufacturer while the cannula is completely straight. Set flow direction as specified by the manufacturer. Now bend the cannula around a radius template with a diameter of 4 times the outer diameter of the cannula under test, until minimum 180° enlacement is reached. Alternatively, based on the risk assessment, a

bend radius of 0,8 times the minimum bend radius and 1,2 times the maximum bend angle occurring during intended use may be used. Determine the remaining blood flow rate at a minimum of 10 time points spread appropriately over a test duration at least as long as it is specified by the manufacturer for intended clinical use.

Repeat test at minimal blood flow rate as specified by the manufacturer.

A roller pump shall not be used for this test.

5.3.4 Pull strength

5.3.4.1 Test liquid

The test liquid for the blood pathway shall be blood analogue with a viscosity of $2,0 \times 10^{-3}$ Pa·s (2,0 cP), to $3,5 \times 10^{-3}$ Pa·s (3,5 cP).

5.3.4.2 Procedure

Subject the device under test to simulated use. Immediately thereafter, test as specified:

Test pieces that are integral to the cannula or the entire length of a cannula are chosen so that each tubular portion, each connection between parts or connector and tubular part, and each junction between tubular portions is tested. A pull force of minimum 15 N or 1,5 times the force determined as possible during the intended use by the risk assessment is applied to each test piece for 30 s using appropriate tensile testing apparatus.

NOTE 30 s is the maximum expected time for withdrawing a cannula out of the patient.

Select a test piece from the cannula to be tested. Include in the test piece the hub or connector, if present, and the junction between segments, e.g. between the tubular part and the distal tip.

a) Fix the test piece in the tensile testing apparatus. Use an appropriate fixture to avoid dislodging to achieve a force of minimum 15 N and to avoid deforming the cannula part in the fixture.

b) Apply a pull force of 15 N or 1,5 times the force determined as possibly occurring during the intended use by the risk assessment for 30 s.

If testing a cannula that consists of a single tubular portion having regions of different outside diameter, the test piece should include the smallest diameter.

5.3.5 Integrity (corrosion, abrasion, degradation)

5.3.5.1 Test liquid

The test liquid for the blood pathway shall be blood analogue containing 0,15 mol/l sodium chloride (0,9 %) and with a viscosity of $2,0 \times 10^{-3}$ Pa·s (2,0 cP), to $3,5 \times 10^{-3}$ Pa·s (3,5 cP).

5.3.5.2 Procedure

Subject the device under test to simulated use. Immediately thereafter, an optical inspection for corrosion, abrasion, and degradation shall be performed on all representative integral parts of the cannula.

5.3.6 Radio-detectability

Conformity shall be demonstrated by an appropriate test method, such as ASTM F640-12 or DIN 13273-7.

5.4 Performance characteristics

5.4.1 Pressure drop

5.4.1.1 Test liquid

The test liquid for the blood pathway shall be blood analogue, with viscosity of $3,2 \times 10^{-3}$ Pa·s ± $0,2 \times 10^{-3}$ Pa·s (3,2 cP ± 0,2 cP).

5.4.1.2 Procedure

Subject the device under test to the range of flow rates as specified by the manufacturer for intended clinical use. Measure the pressures on distal and proximal ends.

For dual-lumen cannula, measure the pressure drop for each lumen.

5.4.2 Collapse resistance

5.4.2.1 Test liquid

The test liquid for the blood pathway shall be blood analogue with a viscosity of $2,0 \times 10^{-3}$ Pa·s (2,0 cP), to $3,5 \times 10^{-3}$ Pa·s (3,5 cP).

5.4.2.2 Procedure

Subject the device under test to simulated use and measure the base line pressure drop. Immediately thereafter, subject the device under test to a negative pressure of −6,67 kPa (−50 mmHg) at the distal end at the maximum flow rate specified by the manufacturer and measure the pressure drop induced by the cannula in accordance with 5.4.1. Throughout the testing, the effective length of the device under test shall be subject to a temperature of 37 °C ± 2 °C.

NOTE −6,67 kPa (−50 mmHg) is the negative pressure applied during vacuum assisted venous drainage.

5.4.3 Recirculation

5.4.3.1 Test liquid

The test liquid for the blood pathway shall be water.

5.4.3.2 Procedure

A test circuit incorporating a model of that part of the cardiovascular system intended to be cannulated (for an example of a test set-up, see Annex C), a pump, connecting tubing, and a reservoir shall be assembled. The dual-lumen cannula under test shall be placed in the circuit inside the vascular model according to its intended clinical use. Prime and de-air the circuit prior to the start of testing. By an appropriate method (e.g. thermodeduction, ink, particles) recirculation shall be determined as a percentage of the extracorporeal blood flow. Conduct the test for at least three flow rates to cover the entire range of intended use of the cannula.

Set the flow through the superior vena cava to 40 % of the circuit's flow rate mimicking body circulation (e.g. using a clamp, an additional pump). Typical body circulation flow rates are 0,8 l/min, 3 l/min, and 6 l/min for neonatal, paediatric and adult patients, respectively.

If using particles, these shall have the same density as the test fluid in order to ensure a proper entrainment behaviour. Use 350 to 5 000 particles per millilitre.

Justify test duration for the test method used in order to ensure validity of results.

5.4.4 Blood cell damage

5.4.4.1 Test media

The test liquid for the blood pathway shall be anticoagulated blood.

5.4.4.2 Procedure

Two sets of appropriate, identical circuit components (for examples of test set-ups, see Annex D), shall be assembled. The device under test shall be placed in one of the circuits. A predicate cannula shall be placed in the second test circuit in the same way. Priming and de-airing of the circuits by recirculating with an appropriate solution is recommended before blood is added. The blood pathway test-liquid volumes shall, at the initiation of the test, be within 3 % of each other. The total circuit volume should be chosen to optimize test sensitivity and system noise and shall not exceed 2 l without appropriate justification. All changes in circuit volume during the test shall be documented (e.g. sampling volume and extra fluid added). Perform the test in vitro using the conditions given in Table 1. The predicate device shall be tested under the same conditions.

For testing single-lumen cannulae, the diameter of the cylindrical portion of the test circuit as depicted in Figures D.1 and D.2 shall not exceed two times the outer diameter of the device under test.

For testing dual-lumen cannulae, the rigid egg-shape portion of the test circuit should have a long axis = two times distance between inlet and outlet plus 10 mm and short axis = 1/3 – 1/2 of the long axis as depicted in Figure D.3. Alternatively, the inflow lumen and outflow lumen may be tested independently of each other within the same circuit as depicted in Figure D.4.

If using a roller pump, the pump occlusion shall be adjusted following the manufacturer's standard operating procedure and consistent across all test circuits.

If using a rotary blood pump, pre-load and after-load sensitivity of the pump's rotational speed shall be taken into account and documented. If differences in the pump's rotational speed significantly affect its blood cell damage contribution, the use of additional dynamic controls to account for these differences is recommended.

The sampling schedule shall be in accordance with Table 2. More frequent sampling times are optional. Test duration shall be 6 h.

Table 1 — Conditions for in vitro testing of blood cell damage

Item	Level	Maximum variation
Blood flow rate	the maximum specified by the manufacturer for intended clinical use (see 6.3)	±5 %
Base	0[a]	±5 mmol/l
Blood glucose	10 mmol/l	±5 mmol/l
Haemoglobin	12 g/dl	±1 g/dl

[a] Note that 0 [zero] refers to 24 mmol/l bicarbonate (HCO_3^-).

Table 2 — Sampling schedule

Parameter	Baseline 0 min	Time, after initiation of test min				
		30	90	180	270	360
Plasma free haemoglobin level	X	X	X	X	X	X
White blood cells	X	X		X		X
Platelets	X	X		X		X
Blood gas values pH Base		X		X		X
Haemoglobin/Haematocrit	X	X		X		X
Glucose	X					
Activated clotting time	X	X	X	X	X	X
Temperature	X	X	X	X	X	X
Flow rates	X	X	X	X	X	X
Pressure (inflow and out-flow)	X	X	X	X	X	X
Circuit volume changes	X	X	X	X	X	X

5.4.5 Shelf life

Using a validated method, ageing shall be performed on final, finished, sterilized devices in primary packaging in order to determine nominal shelf life.

6 Information supplied by the manufacturer

6.1 Information to be given on the cannula

The following information shall be given on the cannula:

a) the manufacturer's identification;

b) outer diameter in mm and optional French size;

c) marking of area(s), where clamps might be used, as specified in “Instructions for use";

d) If the cannula is not axially symmetric, the position of any side outlets shall be identifiable by the user on the proximal end.

Additionally, the following information is recommended to be given on the cannula:

— model designation;

— inner diameter in mm and optional French size;

— effective length in mm, as applicable.

6.2 Information to be given on the packaging

6.2.1 Unit container

The following shall be visible through or given on the unit container:

a) the manufacturer's name and address;

b) description of contents;

c) model designation;

d) inner diameter in mm and optional French size;

e) effective length in mm, as applicable;

f) statement on sterility and non-pyrogenicity;

g) expiry date;

h) batch, lot or serial number designation;

i) the words “Read instructions before use”. The symbol may be added before the words “Read instructions before use”. The symbol may be used;

j) any special handling or storage conditions;

k) statement on single use. The symbol may be used.

6.2.2 Shipping container

The following information shall appear on the shipping container:

a) the manufacturer's name and address;

b) description of contents, including number of units;

c) model designation;

d) statement on sterility and non-pyrogenicity;

e) expiry date;

f) any special handling, storage, or unpacking instructions.

6.3 Information to be given in the accompanying documents

Each shipping container shall contain an “Instructions for Use” leaflet with the following information:

a) the manufacturer's address and telephone or telefax number;

b) model designation;

c) required ancillary equipment;

d) instructions on necessary, special, or unique procedures, as applicable;

e) placement, type, and securing of tubing connections;

f) location and purpose of additional entry or exit ports;

g) determination of position of the side outlet when cannula is inserted;

h) procedure of fixation to the patient in order to prevent dislocation;

i) direction of blood flows, as applicable;

j) general operating procedures for normal use;

k) recommended procedure for intraoperative replacement of a cannula, as applicable;

l) maximum and minimum recommended blood flow rates (for each lumen);

m) blood pathway pressure drop(s) at the maximum blood flow rate specified by the manufacturer for intended clinical use;

n) pressure limitation(s) for blood pathway(s);

o) pressure drop / flow curve (determined with blood analogue);

p) area(s), where clamps can be used;

q) if the cannula is provided with distance markings, a description of the marking system;

r) recirculation;

s) statement that the following are available upon request:

   1) sterilization method;

   2) a list of materials of the blood pathway and tissue contact surface;

   3) data related to blood cell damage;

   4) relevant tolerances for data presented.

6.4 Information to be given in the accompanying documents in a prominent form

The following information shall be given, in prominent form, in the accompanying documents:

— pressure limitation(s) for blood pathway(s);

— flow rate limitations for each lumen;

— other device limitations.

7 Packaging

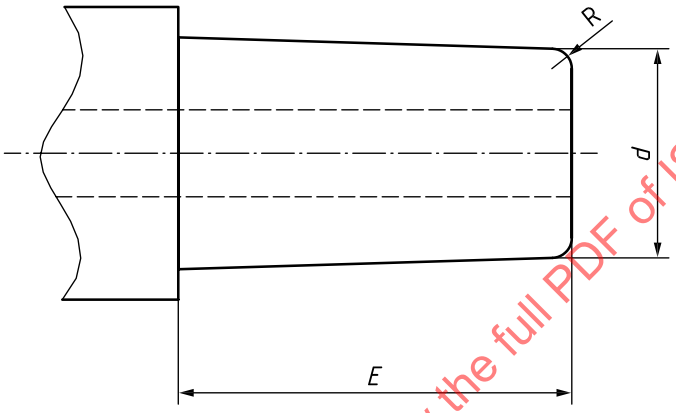
Packaging shall comply with the appropriate requirements of ISO 11607-1 and ISO 11607-2.

Annex A
(informative)

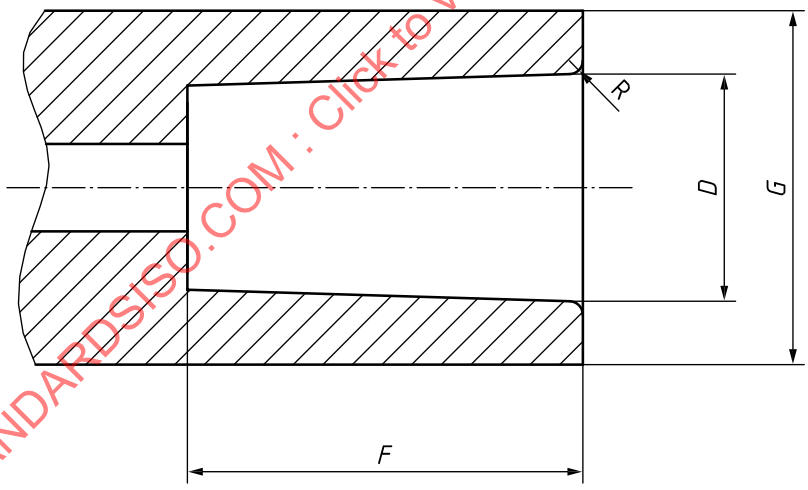
Examples of connectors

A.1 Luer slip fittings

A.1.1 Figures A.1 and A.2 depict Luer slip fittings. For corresponding dimensions, see Table A.1.



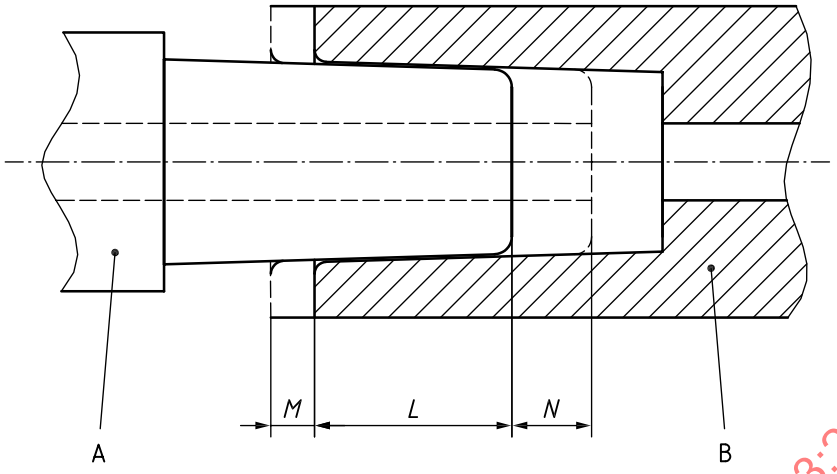
a) Male 6 % (Luer) conical fitting ("male fitting")



b) Female 6 % (Luer) conical fitting ("female fitting")

NOTE See key and dimensions in Table A.1.

Figure A.1 — Typical 6 % (Luer) conical fittings



NOTE See the Key and dimensions in Table A.1.

Figure A.2 — Typical assembly of 6 % (Luer) conical fittings

Table A.1 — Dimensions of 6 % (Luer) conical fittings

Reference			Designation	Dimensions mm	
				rigid material	semi-rigid material
A			Male fitting	N/A	N/A
B			Female fitting	N/A	N/A
Basic dimensions	*d*	min.	Minimum diameter of the end of the male conical fitting (reference diameter)	3,925	3,925
		max.	Maximum diameter at the end of the male conical fitting	3,990	4,027
	D	min.	Minimum diameter at the opening of the female conical fitting	4,270	4,270
		max.	Maximum diameter at the opening of the female conical fitting	4,315	4,315
	E		Minimum length of the male conical fitting	7,500	7,500
	F		Minimum depth of the female conical fitting	7,500	7,500
Other dimensions	*L*[a]		Minimum length of engagement	4,665	4,050
	M[a]		Tolerance for length of engagement of the female conical fitting	0,750	0,750
	N[a]		Tolerance for length of engagement of the male conical fitting	1,083	1,700
	R[b]		Radius of curvature (maximum)	0,5	0,5

[a] Dimensions *L*, *M* and *N* are derived from the basic dimensions.

[b] Or equivalent entry chamfer without any sharp corners.

A.1.2 Gauging test

A.1.2.1 When tested in accordance with A.1.2.4, the conical fitting should satisfy the requirements specified in A.1.2.2 and A.1.2.3.

A.1.2.2 The small end of the male conical fitting should lie between the two limit planes of the gauge and the larger end of the tapered portion should extend beyond the datum plane of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

A.1.2.3 The plane of the maximum diameter at the opening of the female conical fitting should lie between the two limit planes of the gauge. Rocking should not be evident between the gauge and the fitting made of rigid material undergoing test.

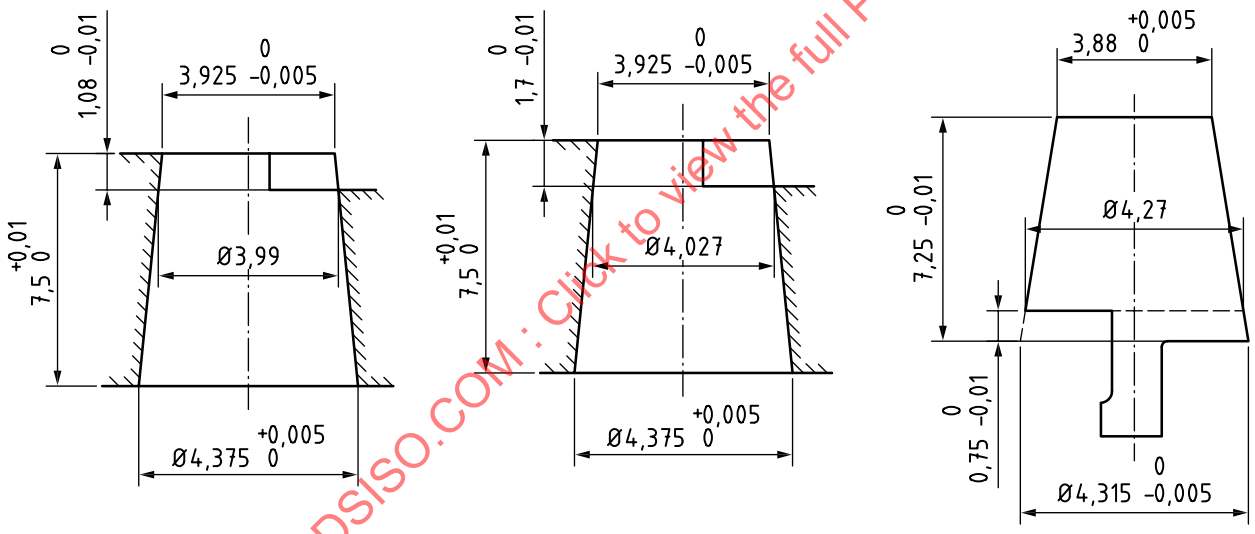
A.1.2.4 The procedure should be carried out as specified in A.1.2.4.1 to A.1.2.4.4.

A.1.2.4.1 Carry out the test using steel gauges as illustrated in Figure A.3.

A.1.2.4.2 Carry out the test at a temperature of (20 ± 5) °C.

A.1.2.4.3 Prior to testing, condition products made from hygroscopic materials at (20 ± 5) °C and (50 ± 10) % relative humidity for not less than 24 h. Conditioning is not required for products made from non-hygroscopic materials.

A.1.2.4.4 Apply the gauge to the conical fitting with a total axial force of 5 N, without the use of torque. Remove the axial load.



a) Gauge for testing rigid male conical fittings **b) Gauge for testing semi-rigid male conical fittings** **c) Gauge for testing female conical fittings of all materials**

NOTE 1 Cone taper (0,06:1).

NOTE 2 Dimensions in millimetres.

Figure A.3 — Gauges for testing 6 % (Luer) conical fittings

A.1.3 Reference steel fittings

A.1.3.1 Figures A.4 and A.5 depict male and female reference steel fittings.

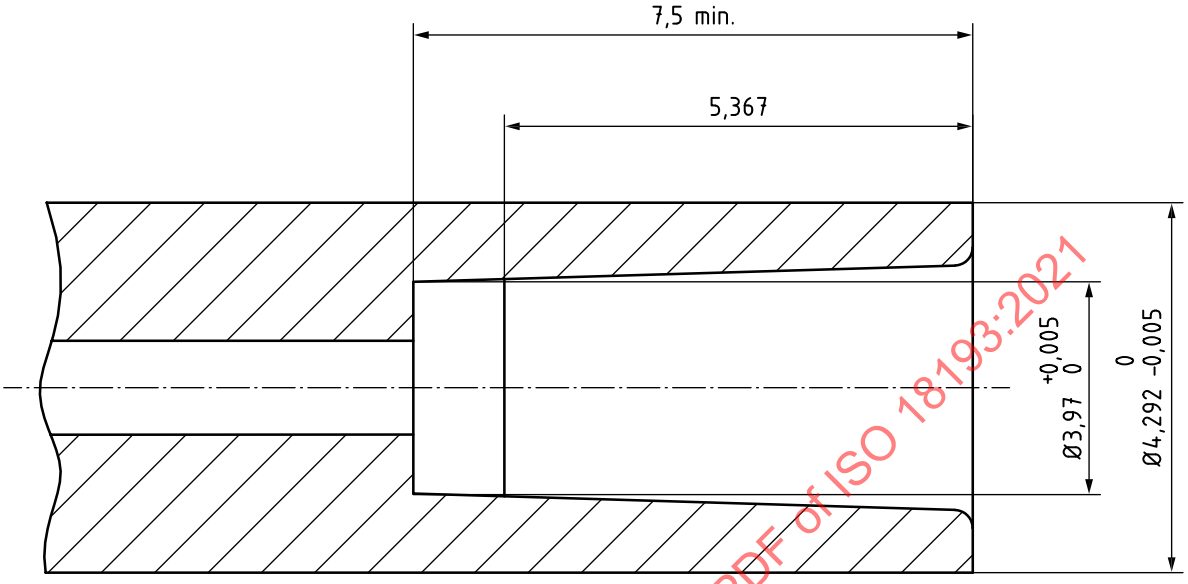


Figure A.4 — Reference steel female conical fitting

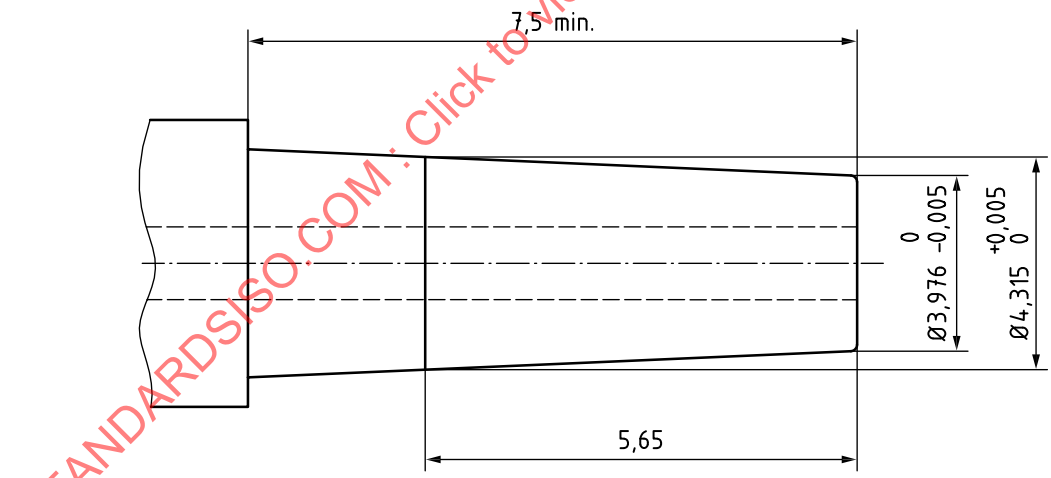


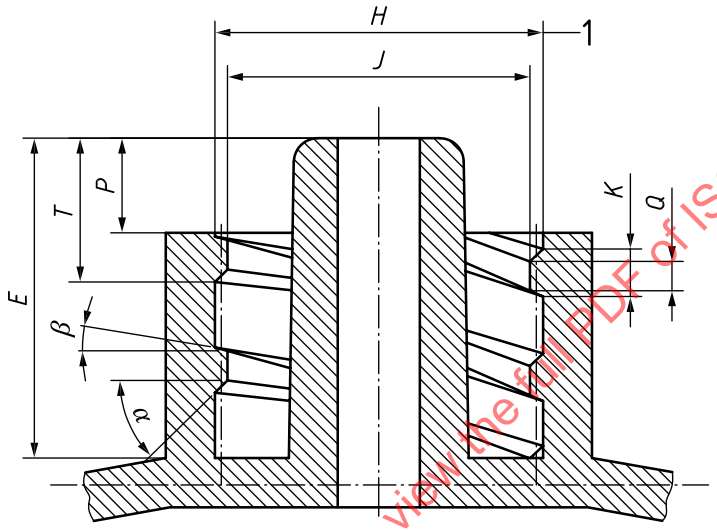
Figure A.5 — Reference steel male conical fitting

A.2 Luer lock fittings

A.2.1 Figures A.6 through A.9 depict Luer lock fittings while Figures A.10 and A.11 depict female reference steel fittings for testing male 6 % (Luer) lock fittings. For corresponding dimensions, see Table A.2.

If a female 6 % (Luer) conical lock fitting as shown in Figure A.8 has lugs in a plane inclined to the axis of fitting, the lugs should form a part of the thread form shown in Figure A.9. In this case, 'V' does not apply.

All outside edges of lug or thread form as shown in Figures A.10 and A.11 should have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

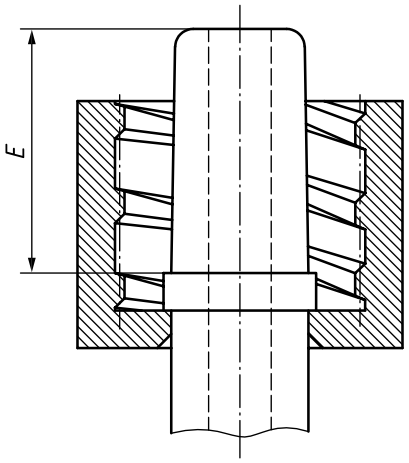


Key

1 double start, right-hand thread of 2,5 mm pitch

NOTE See Key and dimensions in Table A.2.

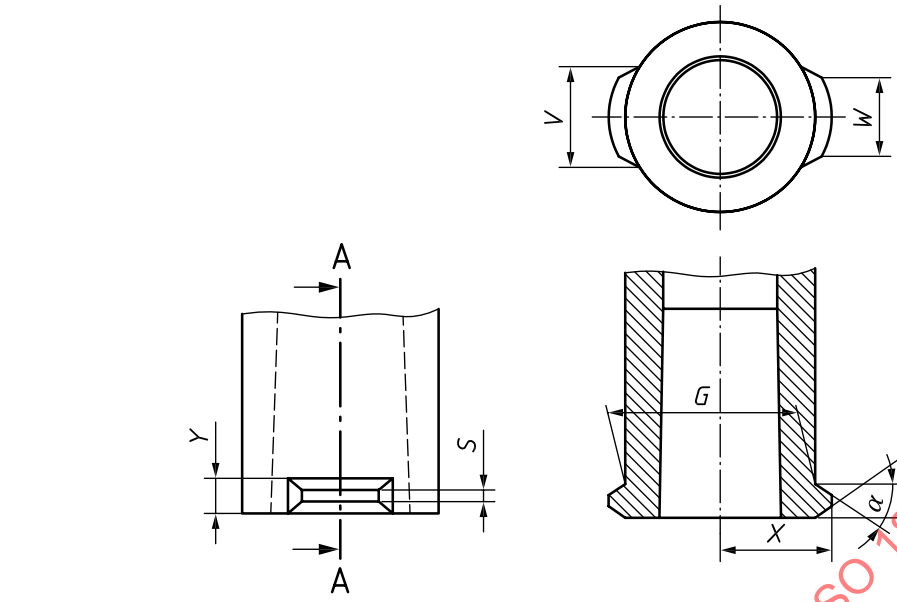
Figure A.6 — Male 6 % (Luer) conical lock fitting with permanently connected internally threaded collar



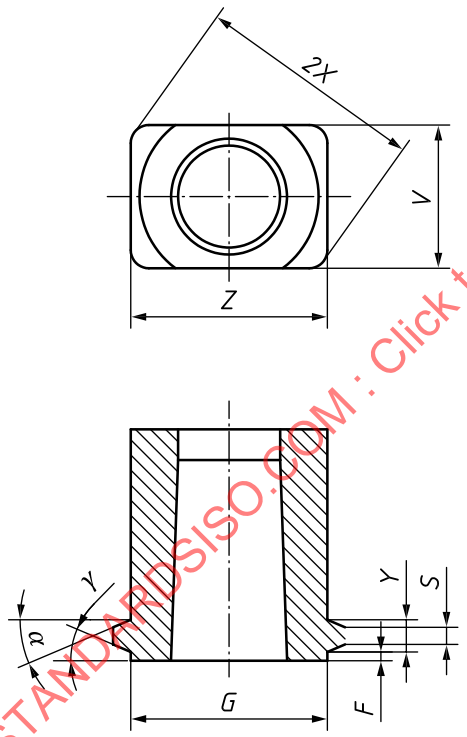
NOTE 1 For other dimensions, see Figure A.6.

NOTE 2 See Key and dimensions in Table A.2.

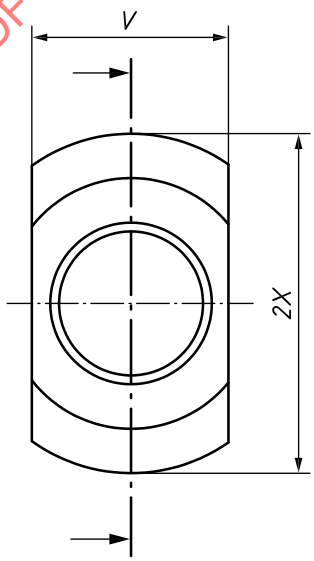
Figure A.7 — Male 6 % (Luer) conical lock fitting with rotatable internally threaded collar



a)



b)



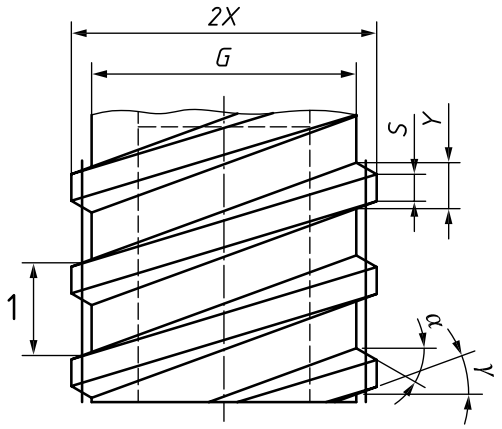
c)

NOTE 1 Variants B and C are intended to be used for the design of rigid fittings only.

NOTE 2 To ensure compatibility with existing rigid fittings, a maximum K = 0,8 mm is preferred.

NOTE 3 See Key and dimensions in Table A.2.

Figure A.8 — Female 6 % (Luer) conical lock fittings with lugs in a plane at right angles to axis of fitting



Key

1 pitch

NOTE 1 For other dimensions, see Figure A.8.

NOTE 2 See Key and dimensions in Table A.2.

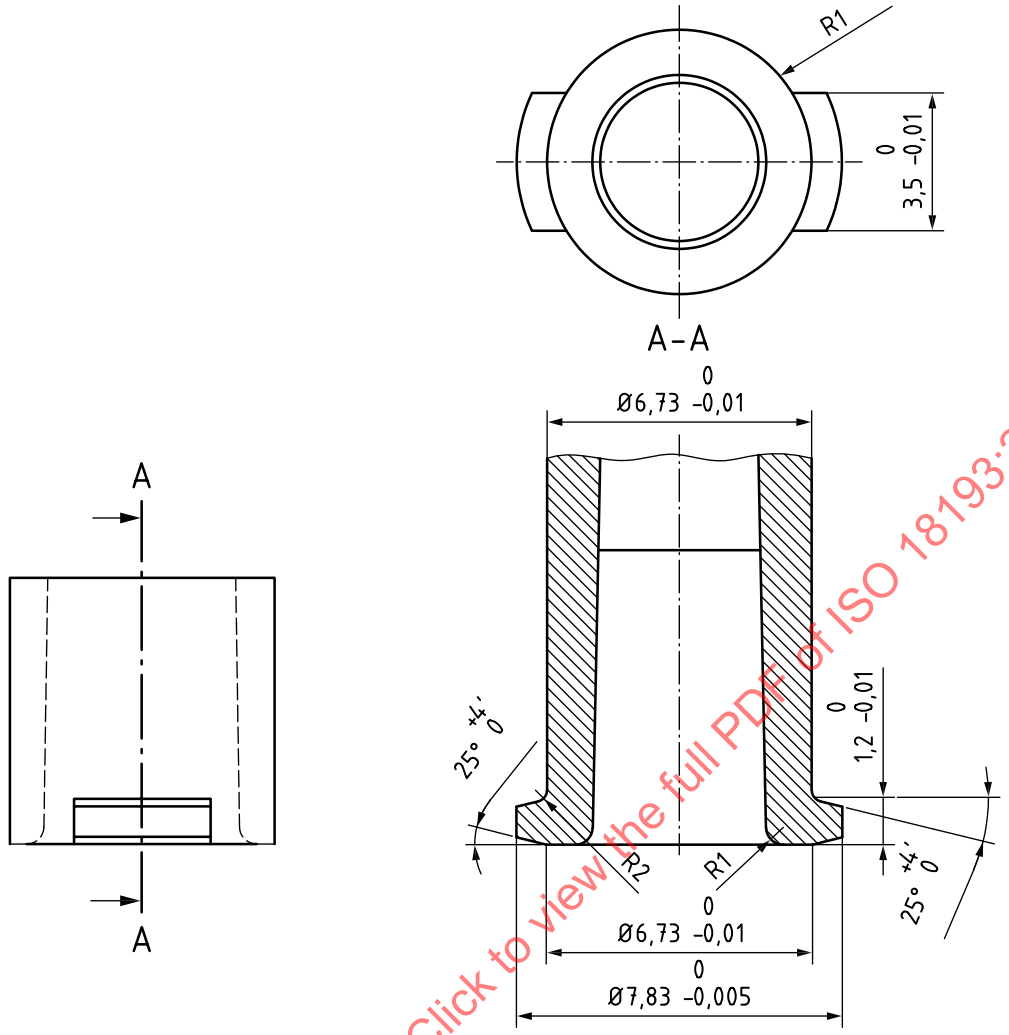
Figure A.9 — Female 6 % (Luer) lock conical fitting with external thread

Table A.2 — Dimensions of 6 % (Luer) rigid conical lock fittings

Symbol	Designation	Dimensions (lengths in millimetres)	
		Figures A.6, A.7, A.8 a) and A.9	Figures A.8 b) and A.8 c)
α	Angle of thread or lug bearing surface against separation with the plane perpendicular to the axis of lock fitting.	$(25^{+5}_{0})°$	$(25^{+5}_{0})°$
β	Minimum angle of internal thread non-bearing surface against separation with the plane perpendicular to the axis of lock fitting.	25°	—
γ	Minimum angle of external thread or lug non-bearing surface against separation with the plane perpendicular to the axis of the lock fitting.	0°	0°
E	Minimum length of male lock fitting.	7,5	—
F	Nominal distance from the face of the fitting to the base of the lug.	—	0,20
G	Maximum outside diameter of female lock fitting at base of lugs or maximum inside diameter of external thread. This diameter should not be increased for a distance from the hub face of 5,5 mm.	6,73	5,7
H	Root diameter of the thread of male lock fitting.	8,0 ± 0,1	—
J	Crest diameter of the thread of male lock fitting.	7,0 ± 0,2	—
K	Maximum thread width of male lock fitting at root.	1	—
P	Minimum projection of nozzle from collar.	2,1	—
Q	Minimum thread crest width of male lock fittings.	0,3	—
S	Lug crest width or thread crest width of female lock fitting with lugs or external thread.	0,3 min.	0,27 max.
T	Maximum distance from tip of male lock fitting to the bottom of first complete thread form of the internal thread.	3,2	—

Table A.2 *(continued)*

Symbol	Designation	Dimensions (lengths in millimetres)	
		Figures A.6, A.7, A.8 a) and A.9	Figures A.8 b) and A.8 c)
V	Maximum chord length at base of lug in a plane at right angles to axis of fitting only, to be measured on a chord of a circle the diameter of which is *J* min. (7,0 mm).	3,5	5,0
W	Minimum chord length at extremity of lug in a plane at right angles to axis of fitting only (*W* should not be greater than *V*).	2,71	—
X	Distance from axis of female lock fitting to extremity of lug.	—	—
2X	Outside diameter across the lugs or external thread.	$7,83^{0}_{-0,1}$	$7,80^{0}_{-0,1}$
Y	Maximum width of base of lug (axial) or thread at base, of female lock fitting to be measured at a point corresponding to an outside diameter equal to *G* (6,73 max.).	1,2	1,30
Z	Width across the lugs at external thread.	—	$6,50^{0}_{-0,1}$
Pitch	Nominal pitch of double-start, right-hand thread of female lock fitting - 5 mm lead.	2,5	—

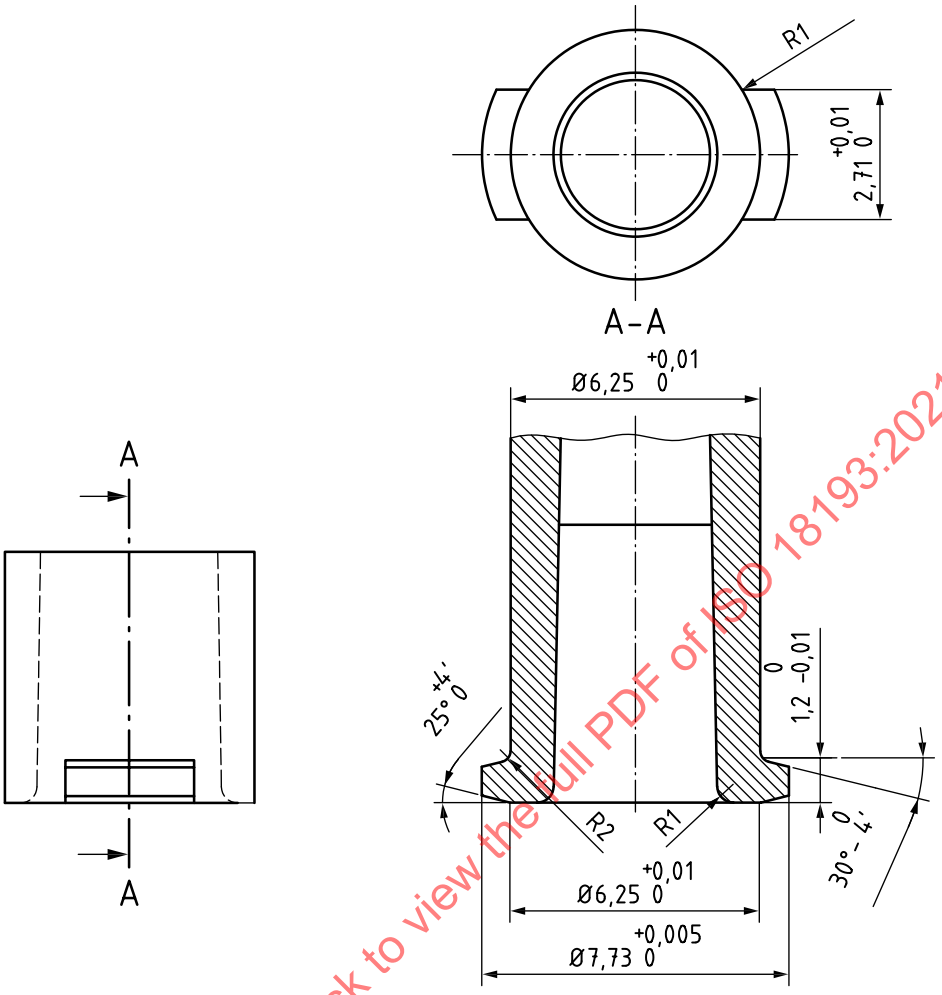


Key

R1 maximum radius 0,5 mm

R2 maximum radius 0,2 mm

Figure A.10 — Female reference conical fitting for testing male 6 % (Luer) lock fittings for leakage, ease of assembly, unscrewing torque and stress cracking



Key

R1 maximum radius 0,5 mm

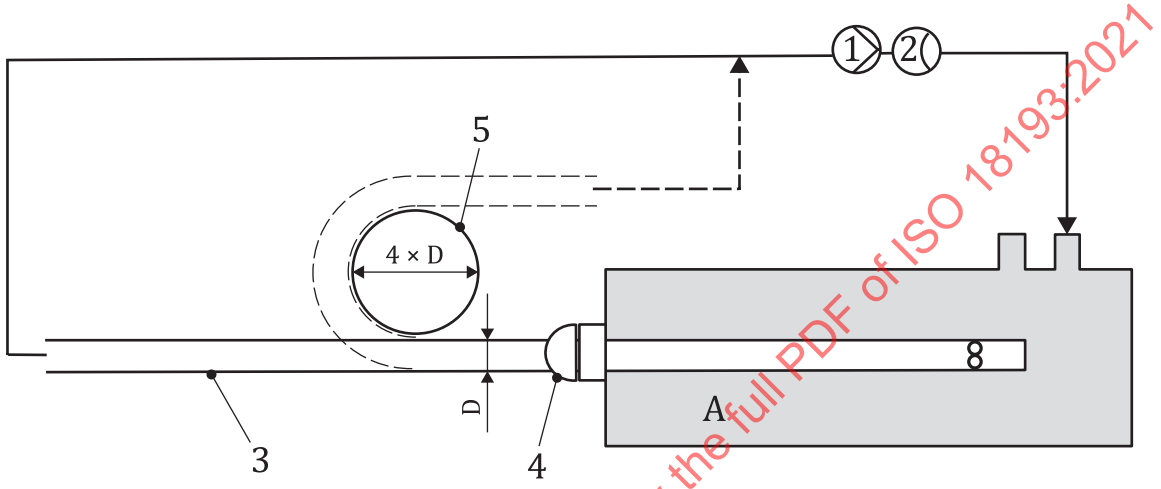
R2 maximum radius 0,2 mm

Figure A.11 — Female reference conical fitting for testing male 6 % (Luer) lock fittings for separation force and resistance to overriding

Annex B
(informative)

Test set-up for kink resistance

B.1 Figure B.1 shows the test-set-up to determine kink resistance in single-lumen drainage cannula in accordance with 5.3.3.

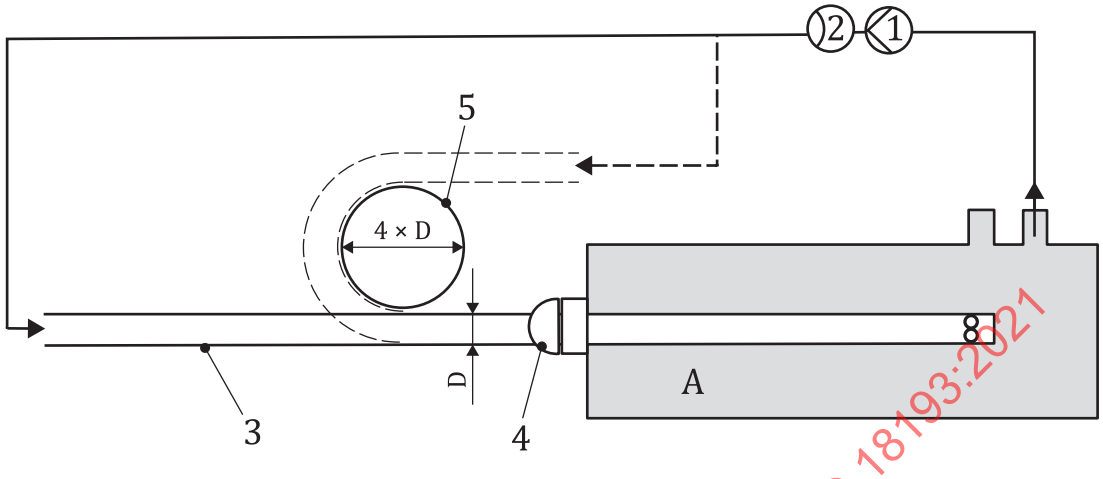


Key

1 rotary blood pump (no roller pump)
2 flow sensor
3 cannula under test with *D* = outer diameter of device under test
4 access port with seal
5 radius template
A reservoir

Figure B.1 — Test set-up to determine kink resistance in single-lumen drainage cannula

B.2 Figure B.2 show a test set-up to determine kink resistance in single-lumen return cannula in accordance with 5.3.3.

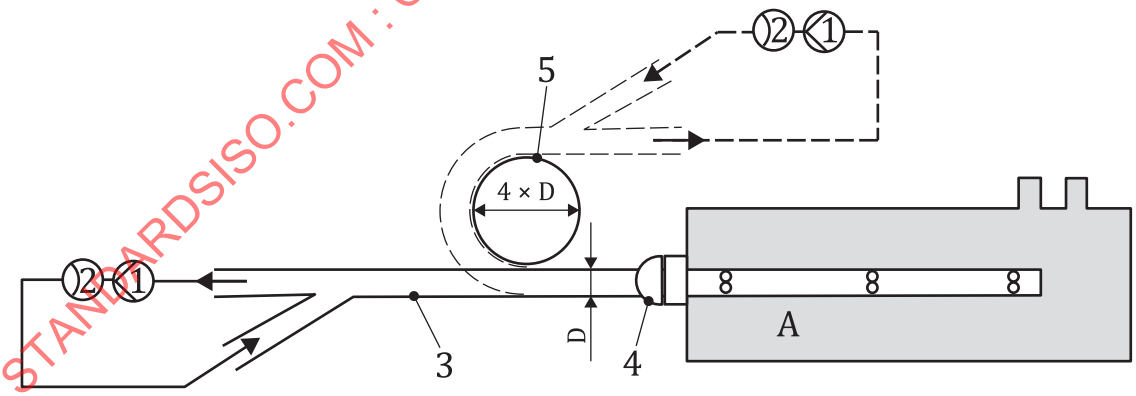


Key

1 rotary blood pump (no roller pump)
2 flow sensor
3 cannula under test with *D* = outer diameter of device under test
4 access port with seal
5 radius template
A reservoir

Figure B.2 — Test set-up to determine kink resistance in single-lumen return cannula

B.3 Figure B.3 shows a test set-up to determine kink resistance in dual-lumen cannula in accordance with 5.3.3.



Key

1 rotary blood pump (no roller pump)
2 flow sensor
3 cannula under test with D = outer diameter of device under test
4 access port with seal
5 radius template
A reservoir

Figure B.3 — Test set-up to determine kink resistance in dual-lumen cannula

Annex C
(informative)

Test set-up for recirculation

C.1 Figure C.1 shows the test set-up for the recirculation test per 5.4.3. The flow from Reservoir A and into Reservoir B represents the flow rate of the *body circulation*. Reservoir C contains the test fluid (e.g. ink, particles, etc.). The recirculation is calculated as

$$R\,(\%) = \frac{C_4}{C_3} \times 100$$

where

R is the recirculation;

C_4 is the concentration of ink, or particles, in Reservoir D;

C_3 is the concentration of ink, or particles, in Reservoir C.