INTERNATIONAL STANDARD

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Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial line blood filters

Implants cardiovasculaires et organes artificiels — Systèmes de pontage cardio-pulmonaire — Filtres sanguins pour la ligne artérielle

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15675 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial line blood filters

1 Scope

This International Standard specifies requirements for sterile, single-use, arterial filters intended to filter and remove emboli, debris, blood clots and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 13485:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001*

ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

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*

3 Terms and definitions

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

3.1
arterial line blood filter
accessory device used as part of the cardiopulmonary bypass system in the arterial blood return line for filtering particles such as blood clots, debris and gas emboli from the blood

3.2
blood pathway
paths of the arterial filter containing blood during its intended clinical use

3.3
blood
heparinized human or bovine blood, whole or diluted with physiological saline solution

3.4
blood cell damage
loss or destruction of cellular components of the blood components

3.5
platelet percentage reduction
percentage reduction of platelets contained in a circuit incorporating an arterial line blood filter, less the percentage reduction in an identical control circuit without an arterial line blood filter, as a function of time

3.6
plasma-free haemoglobin generation
difference between the concentration of plasma-free haemoglobin in a circuit incorporating an arterial blood filter and the concentration in an identical control circuit without an arterial blood filter, as a function of time

3.7
white blood cell percentage reduction
percentage reduction of white blood cells contained in a circuit incorporating an arterial line blood filter, less the percentage reduction in an identical control circuit without an arterial line blood filter, as a function of time

3.8
filtration efficiency
ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

3.9
blood analogue
test solution which simulates blood viscosity

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and nonpyrogenicity

The blood pathway shall be sterile and nonpyrogenic. Compliance shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

Parts of the blood pathway shall be biocompatible with respect to their intended use. Compliance 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 shall not leak.

4.2.2 Blood volume

The volume of the blood pathway shall be within the tolerance specified by the manufacturer (see 6.3).

4.2.3 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.3, allow a secure connection. Connection for accessory ports shall meet the requirements of ISO 594-2.

NOTE Connectors of a type that allows connection of tubes with an inside diameter of 4,8 mm, 6,3 mm, 9,5 mm or 12,7 mm, or a type that complies with ISO 7199, have been found satisfactory.

4.3 Performance characteristics

4.3.1 Blood cell damage

When determined in accordance with 5.4.1, the percentage change (positive or negative) of plasma-free haemoglobin, platelets and white blood cells, shall be within the range of values specified by the manufacturer (see 6.3).

4.3.2 Filtration efficiency

When tested in accordance with 5.4.2, the filtration efficiency of any individual test filter shall be at least 50 % in the range of 40 μm to 100 μm and test results will demonstrate the ability of the filter to remove an average of at least 80 % of the particles in that range.

4.3.3 Flowrate capacity

When tested in accordance with 5.4.3, test results shall demonstrate the flowrate and pressure limitation(s) to ensure safe and effective performance.

4.3.4 Shelf life

When tested in accordance with 5.4.4, test results shall demonstrate the rated shelf life.

4.3.5 Air-handling capability

When tested in accordance with 5.4.5, test results shall demonstrate the air-handling capability.

5 Tests and measurements to determine compliance with this International Standard

5.1 General

5.1.1 Tests and measurements shall be performed with the device in its terminally sterilized form, and 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 ± 1) °C.

5.1.4 If the relationship between variables is nonlinear, 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.

5.2 Biological characteristics

5.2.1 Sterility and nonpyrogenicity

Compliance shall be verified by inspection of the manufacturer's documentation on sterilization and pyrogen testing, in accordance with ISO 11134, ISO 11135, ISO 11137, ISO 14937 or ISO 10993-11, as applicable.

5.2.2 Biocompatibility

Compliance 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 and ISO 10993-7, as applicable.

5.3 Physical characteristics

5.3.1 Determination of blood pathway integrity (sterile final assembly)

Fill the blood pathway of the device with water and subject it to a positive pressure of 1,5 times the manufacturer's rated pressure or, if none is given, to a pressure of 152 kPa (22 psi) gauge and maintain the pressure for 6 h or for the intended use time specified by the manufacturer. Visually inspect the device for evidence of water leakage.

5.3.2 Test liquid

The test liquid shall be heparinized human or bovine blood, or water.

The volume of the blood pathway shall be determined (see 6.3).

5.3.3 Connectors

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

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

5.4 Performance characteristics

5.4.1 Blood cell damage

5.4.1.1 Test media

The test liquid for the blood pathway shall be heparinized human or bovine blood.

5.4.1.2 Procedure

Two sets of appropriate, identical circuit components, including a pump, connecting tubing, a reservoir (as specified by the manufacturer and of suitable size relative to the device under test) and a heat exchanger shall be assembled. The device under test shall be placed in one of the circuits. The blood pathway test-liquid volumes shall, at the initiation of the test, be within 1 % of each other. Perform the test *in vitro* using the conditions given in Table 1.

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

Item	Level	Maximum variation
Blood flowrate	The maximum specified by the manufacturer for intended clinical use (see 6.3) or 6 l/min, whichever is less	± 5 %
Blood glucose	10 mmol/l	± 0,5 mmol/l
Haemoglobin	12 g/dl	± 1 g/dl

The sampling schedule shall be in accordance with Table 2.

Table 2 — Sampling schedule

Parameter	Time after initiation of test (min)			
	Prior to test	30	180	360
Plasma-free haemoglobin	X	X	X	X
White blood cell	X	X	X	X
Platelets	X	X	X	X
Haemoglobin	X	X	X	X
Glucose	X			
Activated coagulation time	X	X	X	X
Temperature	X	X	X	X
Flowrates	X	X	X	X

5.4.2 Filtration efficiency

5.4.2.1 Test liquid

The test liquid shall be a 33 % glycerine solution with a simulated suspension of 350 to 5 000 particles per millilitre in the 40 μm to 100 μm range.

5.4.2.2 Procedure

Pass 500 ml of the test liquid at room temperature (20 °C to 22 °C) through the arterial blood filter at a flowrate of not less than 100 ml/min and a pressure not exceeding 152 kPa (22 psi) gauge. Determine the pre- and postfiltration mean number of particles. A suggested method is contained in 4.2.4 of ANSI/AAMI AT6-1991. Calculate the filtration efficiency, using all readings in the 40 μm to 100 μm test range for each test sample, by subtracting the postfiltration mean number of particles from the prefiltration mean, dividing the quotient by the prefiltration mean number of particles, and multiplying by 100 to obtain a percentage. The test procedure shall be performed using 10 filters.

5.4.3 Filter flowrate

5.4.3.1 Test liquid

The test liquid shall be a blood analogue (test fluid that simulates viscosity).