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

Implants cardiovasculaires et organes artificiels — Systèmes de pontage cardio-pulmonaire — Filtres en ligne pour sang artériel

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Contents

Page

Foreword

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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. www.iso.org/directives

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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 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 15674:2009), which has been technically revised.

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

1 Scope

This International Standard specifies requirements for sterile, single-use, arterial blood line 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 referenced documents are indispensable for the application 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 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 within a risk management process*

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*

3 Terms and definitions

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

3.1
arterial blood line 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 blood line filter containing blood during its intended clinical use

3.3
blood cell damage
loss or destruction of cellular components of the blood components

3.4
platelet reduction
percentage reduction of platelets contained in a circuit incorporating an arterial blood line filter, less the percentage reduction in an identical control circuit without an arterial blood line filter, as a function of time

3.5
plasma-free haemoglobin level
difference between the concentration of plasma-free haemoglobin in a circuit incorporating an arterial blood line filter and the concentration in an identical control circuit without an arterial blood line filter, as a function of time

3.6
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating an arterial blood line filter, less the percentage reduction in an identical control circuit without an arterial blood line filter, as a function of time

3.7
filtration efficiency
ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

3.8
blood analogue
test solution which simulates blood viscosity

3.9
bubble eliminator
device that can remove bubbles

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic. Compliance shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

The 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 tolerances 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.

4.3.2 Filtration efficiency

When tested in accordance with 5.4.2, the filtration efficiency of any individual filter shall be at least 80 % when tested with particles that are 20 % larger than the nominal pore size of the filter.

4.3.3 Flow rate capacity

When tested in accordance with 5.4.3, test results will demonstrate the flow rate and pressure limitation(s) to ensure safe and effective performance, as specified by the manufacturer.

4.3.4 Shelf life

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

4.3.5 Air-handling capability

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

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 °C ± 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 shall be regarded as reference procedures. Other procedures can be accepted, provided that the alternative procedure has been shown to be of comparable precision.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Compliance 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 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 × 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 time of use specified by the manufacturer. Visually inspect the device for evidence of water leakage.

5.3.2 Test liquid

The test liquid shall be anticoagulated blood, or water.

The volume of the blood pathway shall be determined as specified by the manufacturer.

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 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 flow rate	The maximum specified by the manufacturer for intended clinical use (see 6.3)	± 5 %
Blood glucose	10 mmol/l	± 5 mmol/l
Haemoglobin	12 g/l	± 1 g/l

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 clotting time	X	X	X	X
Temperature	X	X	X	X
Flow rates	X	X	X	X

5.4.2 Filtration efficiency

5.4.2.1 Test liquid

The test liquid shall be a glycerin solution or water. The test liquid shall contain 350 to 5 000 particles per ml that are 15 % to 25 % larger than the nominal pore size of the filter.

5.4.2.2 Procedure

Pass 500 ml of the test liquid at room temperature (20 °C to 22 °C) through the arterial blood line filter at a flow rate of no less than 100 ml/min and a pressure not exceeding 152 kPa (22 psi) gauge. Determine the pre- and post-filtration mean number of particles. The test shall be performed at the manufacturer's recommended flow rates. Calculate the filtration efficiency, using the readings from the size range of the test particles used for each test sample, by subtracting the post-filtration mean number of particles from the pre-filtration mean, dividing the quotient by the pre-filtration mean number of particles, and multiplying by 100 to obtain a percentage.

5.4.3 Filter flow rate

5.4.3.1 Test liquid

The test liquid shall be anticoagulated blood or a blood analogue.

5.4.3.2 Procedure

Place the device under test in an appropriate test circuit. Set the flow rate at the maximum rated flow and monitor the inlet and outlet pressures across the filter for 6 h. Measure the flow rate using a calibrated flowmeter. Note any pressure changes during the test.