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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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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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 15675:2009), which has been technically revised.

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

1 Scope

This document 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 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 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 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interaction 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*

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 http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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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* (3.1) 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, as a function of time

3.5
plasma-free haemoglobin level
difference between the concentration of plasma-free haemoglobin in a circuit, as a function of time

3.5.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 l of blood

$$NIH\left\{g\ /\ 100\ L\right\} = \Delta fHb \times V \times \frac{100 - Hct}{100} \times \frac{100}{Q \times T}$$

where

ΔfHb is the increase of plasma free hemoglobin concentration (g/L) over the sampling time interval;

V is the circuit volume (L);

Q is the flow rate (L/min);

Hct is the hematocrit (%);

T is the sampling time interval (min)

3.6
white blood cell reduction
percentage reduction of white blood cells contained in a circuit, 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 between $2{,}0 \times 10^{-3}$ Pa·s (2,0 cP), to $3{,}5 \times 10^{-3}$ Pa·s (3,5 cP)

3.9
bubble eliminator
device that can remove bubbles

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3.10
predicate arterial filter
similar arterial filter to the test arterial filter that has previously been approved and used for the same intended clinical use

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 1 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 8637:2010, Figure 1, or a type that complies with ISO 594-2, have been found satisfactory.

NOTE 2 Connectors corresponding to ISO 8637:2010, Figure 3 are considered as one way to comply with this requirement.

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.

The hemolysis results shall be reported as mg/dL and NIH.

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.

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