INTERNATIONAL STANDARD

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Cardiovascular implants and extracorporeal systems — Plasmafilters

Implants cardiovasculaires et systèmes extracorporels — Filtres pour plasma

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13960 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 13960:2003), which has been technically revised.

Introduction

This International Standard contains requirements and acceptance criteria (including test methods) for safety related parameters for plasmafilters. Only those requirements that are specific to plasmafilters have been included. Non-specific requirements are covered by references to other International Standards, listed in Clause 2. This International Standard does not cover matters related to toxicity. Such issues are covered in relevant parts of ISO 10993.

Cardiovascular implants and extracorporeal systems — Plasmafilters

1 Scope

This International Standard specifies requirements for sterile, single-use plasmafilters, intended for use on humans.

This International Standard does not apply to the extracorporeal circuits used for plasmapheresis or other extracorporeal blood exchange devices, such as haemodialysers, haemodiafilters, haemofilters, haemoperfusion devices, vascular access devices, oxygenators or active medical devices. This International Standard does not address the replacement fluid.

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 8637, *Cardiovascular implants and artificial organs — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

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 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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: 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*

3 Terms and definitions

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

3.1
blood compartment
part of plasmafilter through which blood is intended to pass

3.2
filtrate compartment
part of plasmafilter through which filtrate flows

3.3
filtration rate
rate at which fluid is removed from the blood compartment across the semipermeable membrane into the filtrate compartment of a plasmafilter

3.4
plasmapheresis
plasma separation
separation of a portion of the whole plasma from formed elements of blood by means of a semipermeable membrane

NOTE Plasmapheresis can also be accomplished through the use of differential centrifugation but this method is not covered by this International Standard.

3.5
plasmafilter
device intended to perform membrane plasmapheresis

3.6
transmembrane pressure
TMP
p_{TM}
mean pressure across the semipermeable membrane

NOTE The transmembrane pressure is given by the following equation:

$$p_{TM} = \frac{p_{BI} + p_{BO}}{2} - p_f$$

where

p_{BI} is the pressure at blood compartment inlet;

p_{BO} is the pressure at blood compartment outlet;

p_f is the pressure at filtrate compartment outlet.

3.7
sieving coefficient
ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in blood

4 Requirements

4.1 Biological characteristics

4.1.1 Biocompatibility

Parts of plasmafilters that will come into direct or indirect contact with blood during their intended clinical use shall be biocompatible with respect to their intended clinical use.

Compliance shall be verified in accordance with 5.2.1.

4.1.2 Sterility and non-pyrogenicity

Blood and filtrate compartments shall be sterile and non-pyrogenic.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 Structural integrity

When tested in accordance with 5.3.1, plasmafilters shall not leak.

NOTE This requirement refers to the external integrity of the devices.

4.2.2 Blood compartment integrity

When tested in accordance with 5.3.2, the blood compartment shall not leak.

4.2.3 Connectors and ports

4.2.3.1 Connections to the blood compartment

Except when plasmafilters and the extracorporeal circuits are designed as an integral system, the dimensions of the blood inlet and outlet connectors of plasmafilters shall be in accordance with ISO 8637.

Compliance shall be verified by inspection.

4.2.3.2 Connection to the filtrate compartment

Except when plasmafilters and their extracorporeal circuits are designed as an integral system, the dimensions of filtrate ports shall be a male 6 % (Luer) taper lock fitting in accordance with ISO 594-2 or dialysis fluid inlet and outlet port in accordance with ISO 8637. Connectors made of semi-rigid materials shall not separate under an axial force of 15 N for 15 s.

Compliance shall be verified by inspection.

4.2.3.3 Volume

When measured in accordance with 5.3.3, the volumes of the blood compartments of plasmafilters shall be within the range of values stated by the manufacturer [see 6.2 d)].

4.2.3.4 Pressure drop

When measured in accordance with 5.3.4, the pressure drop across the blood compartment of the plasmafilter shall be within the range of values stated by the manufacturer [see 6.2 h)].

4.3 Performance characteristics

4.3.1 Filtration rate

When measured in accordance with 5.4.1, the filtration rate shall be within the range of values stated by the manufacturer [see 6.2 g) 1)].