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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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