
**Cardiovascular implants and artificial
organs — Cannulae for extracorporeal
circulation**

*Implants cardiovasculaires et organes artificiels — Canules pour
circulation extracorporelle*

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 18193:2021](https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11ebe9497228/iso-18193-2021)

<https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11ebe9497228/iso-18193-2021>



iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 18193:2021](https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11e9497228/iso-18193-2021)

<https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11e9497228/iso-18193-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	4
4.1 Biological characteristics.....	4
4.1.1 Sterility and non-pyrogenicity.....	4
4.1.2 Biocompatibility.....	4
4.2 Physical characteristics.....	4
4.2.1 Blood pathway integrity.....	4
4.2.2 Connectors.....	4
4.2.3 Kink resistance.....	5
4.2.4 Pull strength.....	5
4.2.5 External surface.....	5
4.2.6 Integrity (corrosion, abrasion, degradation).....	5
4.2.7 Radio-detectability.....	5
4.2.8 Distance markings.....	5
4.2.9 Lumen markings.....	5
4.3 Performance characteristics.....	5
4.3.1 Pressure drop.....	5
4.3.2 Collapse resistance.....	6
4.3.3 Recirculation.....	6
4.3.4 Blood cell damage.....	6
4.3.5 Shelf life.....	6
5 Tests and measurements for conformity to this document	6
5.1 General.....	6
5.2 Biological characteristics.....	7
5.2.1 Sterility and non-pyrogenicity.....	7
5.2.2 Biocompatibility.....	7
5.3 Physical characteristics.....	7
5.3.1 Blood pathway integrity.....	7
5.3.2 Connectors.....	7
5.3.3 Kink resistance.....	7
5.3.4 Pull strength.....	8
5.3.5 Integrity (corrosion, abrasion, degradation).....	8
5.3.6 Radio-detectability.....	8
5.4 Performance characteristics.....	9
5.4.1 Pressure drop.....	9
5.4.2 Collapse resistance.....	9
5.4.3 Recirculation.....	9
5.4.4 Blood cell damage.....	10
5.4.5 Shelf life.....	11
6 Information supplied by the manufacturer	11
6.1 Information to be given on the cannula.....	11
6.2 Information to be given on the packaging.....	12
6.2.1 Unit container.....	12
6.2.2 Shipping container.....	12
6.3 Information to be given in the accompanying documents.....	12
6.4 Information to be given in the accompanying documents in a prominent form.....	13
7 Packaging	13

Annex A (informative) Examples of connectors	14
Annex B (informative) Test set-up for kink resistance	24
Annex C (informative) Test set-up for recirculation	26
Annex D (informative) Test set-up for blood cell damage	29
Bibliography	33

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 18193:2021](https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11ebe9497228/iso-18193-2021)

<https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11ebe9497228/iso-18193-2021>

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.

<https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11e1be9497228/iso-18193-2021>

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.

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 18193:2021](#)

<https://standards.iteh.ai/catalog/standards/iso/2ed84a60-cc3f-4362-a957-11ebe9497228/iso-18193-2021>