

ISO 18193:2021 (E)

Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Requirements
4.1	Biological characteristics
4.1.1	Sterility and non-pyrogenicity
4.1.2	Biocompatibility
4.2	Physical characteristics
4.2.1	Blood pathway integrity
4.2.2	Connectors
4.2.3	Kink resistance
4.2.4	Pull strength
4.2.5	External surface
4.2.6	Integrity (corrosion, abrasion, degradation)
4.2.7	Radio-detectability
4.2.8	Distance markings
4.2.9	Lumen markings
4.3	Performance characteristics
4.3.1	Pressure drop
4.3.2	Collapse resistance
4.3.3	Recirculation
4.3.4	Blood cell damage
4.3.4.1	Plasma-free haemoglobin
4.3.4.2	Platelet and white blood cell reduction
4.3.5	Shelf life
5	Tests and measurements for conformity to this document
5.1	General
5.2	Biological characteristics
5.2.1	Sterility and non-pyrogenicity
5.2.2	Biocompatibility
5.3	Physical characteristics
5.3.1	Blood pathway integrity
5.3.1.1	Test liquid
5.3.1.2	Procedure
5.3.2	Connectors
5.3.3	Kink resistance
5.3.3.1	Test liquid
5.3.3.2	Procedure
5.3.4	Pull strength
5.3.4.1	Test liquid
5.3.4.2	Procedure
5.3.5	Integrity (corrosion, abrasion, degradation)
5.3.5.1	Test liquid
5.3.5.2	Procedure
5.3.6	Radio-detectability

- 5.4 Performance characteristics
 - 5.4.1 Pressure drop
 - 5.4.1.1 Test liquid
 - 5.4.1.2 Procedure
 - 5.4.2 Collapse resistance
 - 5.4.2.1 Test liquid
 - 5.4.2.2 Procedure
 - 5.4.3 Recirculation
 - 5.4.3.1 Test liquid
 - 5.4.3.2 Procedure
 - 5.4.4 Blood cell damage
 - 5.4.4.1 Test media
 - 5.4.4.2 Procedure
 - 5.4.5 Shelf life

6 Information supplied by the manufacturer

- 6.1 Information to be given on the cannula
- 6.2 Information to be given on the packaging
 - 6.2.1 Unit container
 - 6.2.2 Shipping container
- 6.3 Information to be given in the accompanying documents
- 6.4 Information to be given in the accompanying documents in a prominent form

7 Packaging

Annex A (informative) Examples of connectors

- A.1 Luer slip fittings
- A.2 Luer lock fittings

Annex B (informative) Test set-up for kink resistance

Annex C (informative) Test set-up for recirculation

Annex D (informative) Test set-up for blood cell damage