INTERNATIONAL STANDARD

ISO 20697

First edition
2018-06

Corrected version
2018-09

Sterile drainage catheters and accessory devices for single use

Sondes et dispositifs auxiliaires stériles de drainage non réutilisables

Reference number
ISO 20697:2018(E)

© ISO 2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

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
Fax: +41 22 749 09 47
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 **1**

4 Intended performance **3**

5 General requirements **3**
5.1 Risk management 3
5.2 Biocompatibility 4
5.3 Detectability 4
5.4 Surface finish 4
5.5 Size designation 4
5.5.1 General 4
5.5.2 Outer diameter 4
5.5.3 Effective length 4
5.5.4 Nominal balloon inflation volume 5
5.6 Connector 5
5.7 MRI compatibility 6
5.8 Sterilization 6

6 Specific requirements **6**
6.1 Kink stability 6
6.2 Corrosion resistance 6
6.3 Resistance to deformation 6
6.4 Peak tensile force 6
6.4.1 Connections 6
6.4.2 Drainage catheters and other accessory devices 7
6.5 Impact resistance 7
6.6 Flow rate 7
6.7 Retention strength 7
6.8 Balloon safety 7
6.9 Drainage catheter inflation lumen integrity and volume maintenance 8
6.9.1 General 8
6.9.2 Compliant balloon 8
6.9.3 Non-compliant balloon 8
6.10 Inflated balloon resistance to traction 8
6.11 Freedom from leakage during aspiration or vacuum 8

7 Information supplied by the manufacturer **9**
7.1 General 9
7.2 Marking on the device and/or packaging 9
7.3 Instructions for use 9

Annex A (informative) **Test method for determining kink stability** **11**

Annex B (normative) **Test method for corrosion resistance** **13**

Annex C (normative) **Test method for resistance to deformation by suction** **14**

Annex D (normative) **Test method for determining peak tensile force of connections** **15**

Annex E (normative) **Test method for determining peak tensile force of drainage catheter** **16**

Annex F (normative) **Test method for impact resistance of collection device** **18**

Annex G (normative) **Test method for determination of flow rate through drainage catheter** **20**

Annex H (informative) **Test method for retention strength** **22**

© ISO 2018 – All rights reserved

Annex I (normative) **Test method for determining balloon safety** **24**

Annex J (normative) **Test method for determining inflation lumen leakage and/or function and/or balloon deflation (drainage catheter with compliant balloon)** **27**

Annex K (normative) **Test method for determining balloon size and deflation reliability (drainage catheter with non-compliant balloon)** **29**

Annex L (normative) **Test method for determining inflated balloon resistance to traction** **31**

Annex M (normative) **Test method for resistance to leakage during aspiration or vacuum** **35**

Bibliography **37**

 © ISO 2018 – All rights reserved

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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This document is based on EN 1617, *Sterile drainage catheters for single use*.

This corrected version of ISO 20697:2018 incorporates the following corrections:

— correction of measurements and units in 6.9.3, 6.10, H.2.2 a) and L.2.1;

— deletion of EN 980 from Bibliography;

— minor editorial changes.

© ISO 2018 – All rights reserved

Introduction

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

© ISO 2018 – All rights reserved

Sterile drainage catheters and accessory devices for single use

1 Scope

This document specifies requirements for sterile, single use drainage catheters, wound and fluid accumulation drainage systems, surgical drainage catheters and their components, where the catheter is placed in a body cavity or wound, surgically or percutaneously, for drainage of fluid or air to the exterior.

The drainage catheter is left to drain naturally or connected to a suction source for faster tissue granulation.

This document is not applicable to:

a) suction catheters;

b) tracheal catheters;

c) urethral catheters;

NOTE See ISO 20696.

d) ureteral stents, biliary stents, and other stents;

NOTE See ISO 14630 and ASTM F1828-97 for stents requirements.

e) drainage catheters placed in digestive tracts percutaneously with gastrostomy technique;

f) neuraxial catheters used for removal of cerebrospinal fluid;

NOTE See ISO 20698.

g) enteral catheters used for removal of solutions or substances from the gastrointestinal tract;

NOTE See ISO 20695.

h) coatings.

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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 80369-1, *Small bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

3 Terms and definitions

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

© ISO 2018 – All rights reserved

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
accessory device
device that is used with the *drainage system* (3.6) for access and/or drainage [e.g. *collection device*(s) (3.3)] and, where applicable, other accessories such as *suction source*(s) (3.16), *connecting tube*(s) (3.4), connector(s), trocar(s), split needle(s)/cannula(s), or introducer(s)

3.2
catheter component
part which is integral with the drainage catheter

EXAMPLE Catheter connectors, securement devices, Heimlich valve.

3.3
collection device
bag, bellows or other portable container designed for collecting liquid

3.4
connecting tube
tube designed for connecting the drainage catheter and *collection device* (3.3), or *collection device* (3.3) and *suction source* (3.15)

3.5
drainage catheter
tube designed for draining fluid or air from a body cavity or a surgical wound

3.6
drainage system
functional assembly of *drainage catheter* (3.5) and *collection device(s)* (3.3) and, where applicable, other accessories such as *suction source(s)* (3.16), *connecting tube(s)* (3.4), connector(s) or trocar(s)

Note 1 to entry: A drainage system may be supplied either in the ready-for-use state or in a state requiring the assembly of some components by the user. Drainage may be achieved either by gravity, by negative pressure generated by an external power source, by manipulation by the user, or by the pre-evacuation of the *collection device* (3.3).

3.7
effective length
L_1
length of the *drainage catheter* (3.5), or pre- and post-hydration lengths of hydratable catheters, that can be inserted into the body

3.8
overall length
L_2
total length from the tip of the *drainage catheter* (3.5) to the end of the *funnel* (3.10)

3.9
effective shaft length
L_3
length of non-perforated portion of the *drainage catheter* (3.5) excluding the tip, balloon(s), *funnel(s)* (3.10), protective sleeves and/or access port(s)

3.10
funnel
proximal portion of the *drainage catheter* (3.5), which may be connected to a *drainage system* (3.7)

© ISO 2018 – All rights reserved

3.11
retention means
physical feature of the *drainage catheter* (3.5) within the body that prevents movement of the drainage catheter out of the body

EXAMPLE Pigtail, suture with pigtail, malecot, balloon.

3.12
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:—, 3.18]

3.13
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.12)

[SOURCE: ISO 14971:—, 3.19]

3.14
risk assessment
overall process comprising a *risk analysis* (3.12) and a risk evaluation

[SOURCE: ISO 14971:—, 3.20]

3.15
risk management file
set of records and other documents that are produced by risk management

[SOURCE: ISO 14971:—, 3.25]

3.16
suction source
self-contained device capable of exerting a negative pressure on a *drainage catheter* (3.5) or system

Note 1 to entry: The suction source may be the *collection device* (3.3).

3.17
trocar
needle, pointed rod sleeve or any combination thereof which assists in passing the *drainage catheter* (3.5) through the body wall

4 Intended performance

The drainage catheter shall demonstrate the ability to accurately and safely access the intended location. The drainage system shall demonstrate the ability to maintain drainage.

If the drainage catheter has retention means, it shall demonstrate the ability to prevent undesired dislodgement. The method of release of retention shall be described in the instructions for use.

5 General requirements

5.1 Risk management

An established risk management process shall be applied to the design of the device and a risk analysis shall be performed.

EXAMPLE ISO 14971.

© ISO 2018 – All rights reserved