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 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

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.

Introduction

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

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 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)

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.

Compliance shall be checked by inspection of the risk management file. If clinical studies are performed, these studies shall document measurements taken under conditions for which performance is claimed. The clinical studies shall comply with the requirements of ISO 14155.

5.2 Biocompatibility

The device shall be free from biological hazard in accordance with appropriate testing under ISO 10993-1.

5.3 Detectability

The drainage catheter or at least its effective length shall be detectable by X-ray or by other means (ultra-sound, MRI, etc.), if required by the risk assessment.

NOTE Such as ASTM F640 or DIN 13273-7.

5.4 Surface finish

When examined by normal or corrected to normal vision, the external surface of the effective length of the drainage catheter shall appear free from:

— extraneous matter;

— process and surface defects that may present an unacceptable risk of patient harm.

If deemed necessary based on risk assessment, inspection shall be conducted under a minimum 2,5× magnification.

5.5 Size designation

5.5.1 General

The nominal size of the drainage catheter shall be designated as specified in 5.5.2, 5.5.3 and 5.5.4. Examples of drainage catheters are shown in Figure 1.

5.5.2 Outer diameter

Unless otherwise specified in another part of this document for a particular type of drainage catheter, the outer diameter shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,1 mm. Tolerances on this stated size shall be ±1 French.

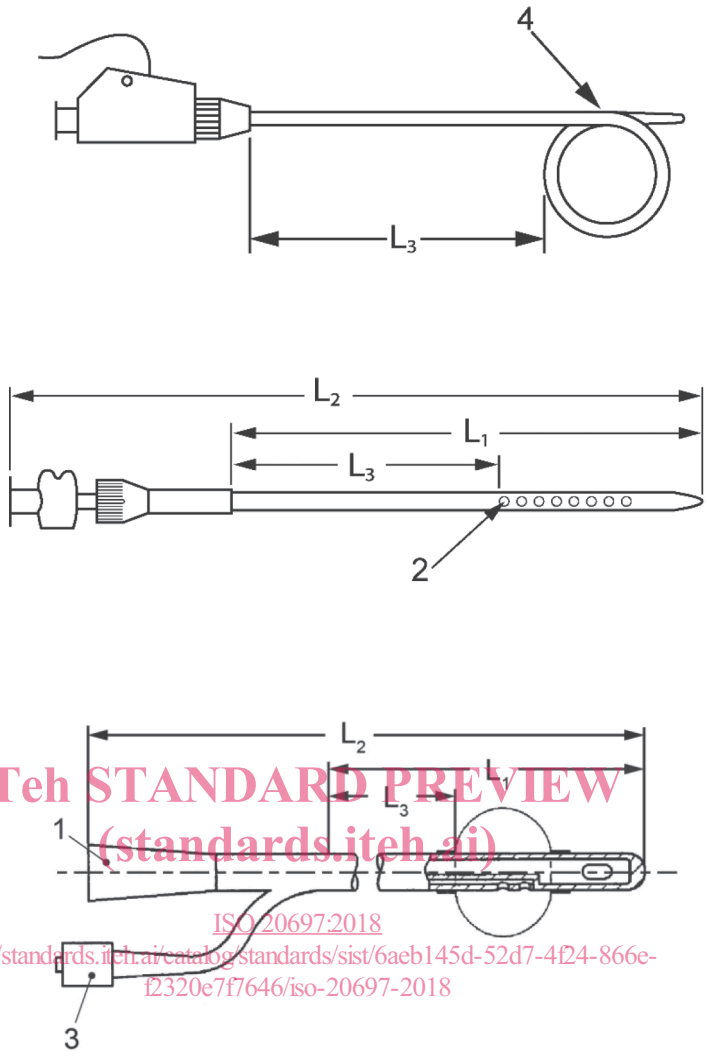
For devices which are not round by design, the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

NOTE French size (FG, Fr, CH) is a nominal dimensional identification of the outer size of drainage catheters; calculated as three times the diameter (in millimetres): Fr = 3 × D (mm).

5.5.3 Effective length

The effective length shall be expressed in millimetres for effective lengths of less than 100 mm, or either in millimetres or centimetres for effective lengths of 100 mm or more.

NOTE This document does not specify tolerances on the effective length.



Key

1	funnel	L_1	effective length
2	lateral drainage holes	L_2	overall length
3	inflation connection	L_3	effective shaft length
4	retention means		

Figure 1 — Examples of drainage catheters

5.5.4 Nominal balloon inflation volume

For devices which have balloons, the nominal balloon inflation volume shall be expressed in millilitres.

5.6 Connector

This document does not specify a standard connector for inclusion in drainage catheters and accessory devices. However, risk of misconnection shall be avoided. This shall be determined by the manufacturer based on risk assessment according to the general requirements of ISO 80369-1.

NOTE The funnel is a connecting part, but does not comply with the requirements of ISO 80369-1.

5.7 MRI compatibility

If applicable, the hazards of drainage catheters and accessory devices in the magnetic resonance environment shall be evaluated by an appropriate method.

NOTE Such as ASTM F2052, ASTM F2213, ASTM F2182, and ASTM F2119.

5.8 Sterilization

Drainage catheters and accessories that are sterile shall comply with international, national or regional standards and shall have a sterility assurance level (SAL) of 10^{-6}.

NOTE See applicable parts of ISO 17665, ISO 11135 and ISO 11137 (all parts) for appropriate methods of sterilization.

6 Specific requirements

6.1 Kink stability

During placement, the drainage catheter shall demonstrate the ability to safely access the intended location. This document does not specify requirements for kink stability testing. Clinically relevant placement value is determined by the manufacturer based on intended use and risk assessment.

NOTE A kink stability test method is shown in Annex A.

6.2 Corrosion resistance

If exposed metallic components of the device could develop visible signs of corrosion that can affect functional performance, the level of corrosion shall be evaluated, with respect to intended use and risk assessment, by subjecting the drainage catheter to the corrosion test described in Annex B.

6.3 Resistance to deformation

The drainage catheter, accessory devices, or any component(s) designed to form a part thereof, intended to operate under negative pressure shall not show deformation (collapse) sufficient to impair the function of the device at the maximum negative pressure as defined by the manufacturer.

Compliance shall be checked according to test method in Annex C.

6.4 Peak tensile force

6.4.1 Connections

The minimum peak tensile force of the external connections between devices recommended by the manufacturer shall be as given in Table 1.

Table 1 — Peak tensile force of the connections

Smallest outer diameter of tubular portion of connected devices mm	Minimum peak tensile force N
≥2 and ≤4	5
>4	15
This document does not specify requirements for peak tensile force for tubing of less than 2 mm outer diameter. These values should be determined by the manufacturer based on risk assessment.	

Compliance shall be checked by using the peak tensile force test method in Annex D.

6.4.2 Drainage catheters and other accessory devices

The minimum peak tensile force of each tubular portion, each junction between drainage catheter component and tubing, and each junction between tubular portions shall be as given in Table 2.

Table 2 — Peak tensile force of drainage catheters and other accessory devices

Smallest outer diameter of tubular portion of test piece mm	Minimum peak tensile force N
≥2 and ≤4	10
>4	20
This document does not specify requirements for peak tensile force for tubing of less than 2 mm outer diameter. These values should be determined by the manufacturer based on risk assessment.	

Compliance shall be checked by using the peak tensile force test method in Annex E.

6.5 Impact resistance

When tested, the collection device shall not leak and the suction source shall not show any loss of vacuum greater than 2 %.

Compliance shall be checked by using the impact resistance test method in Annex F.

6.6 Flow rate

For drainage catheters for which flow rate is claimed, the flow rate for each lumen shall be a minimum of 80 % of that stated by the manufacturer for drainage catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated by the manufacturer for drainage catheters of nominal outside diameter equal to 1,0 mm or greater.

If the flow rate through hydratable catheters is determined, it shall be determined in post-hydration states.

Compliance shall be checked by using the flow rate test method in Annex G.

6.7 Retention strength

If the drainage catheter has retention means other than a balloon, it shall demonstrate the ability to prevent undesired dislodgement. This document does not specify requirements for retention strength testing. Clinically relevant retention value is determined by the manufacturer based on intended use and risk assessment.

NOTE A test method for retention strength is shown in Annex H.

6.8 Balloon safety

If the drainage catheter has a balloon, the balloon shall not leak and shall not occlude the lateral drainage holes.

Compliance shall be checked by using the balloon safety test method in Annex I.

The change in profile at each end of the uninflated balloon should have a smooth transition to the shaft. The balloon should be capable of approximately symmetrical expansion when filled with water at ambient temperature to its nominal balloon inflation volume.