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Sterile drainage catheters and accessory devices for single use

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Foreword

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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).

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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 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.

The committee responsible for this document is ISO/84, *Devices for administration of medicinal products and catheters*

This is a new ISO standard based on EN 1617, *Sterile drainage catheters for single use*.

Introduction

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 ‘Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters’.

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. 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 suction source for faster tissue granulation.

This document does not apply to:

a) suction catheters;

b) tracheal catheters;.

c) uretheral 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;

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

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

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

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:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
accessory devices
collection device(s) (3.3) and, where applicable, other accessories such as *suction source(s)* (3.15), *connecting tube(s)* (3.4), connector(s), trocar(s), split needle(s)/cannula(s), or introducer(s)

3.2
catheter component
any part which is integral with the drainage catheter

EXAMPLE Catheter connectors, securement devices, Heimlich valve, etc.

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
drainage catheter (3.5) and *collection device(s)* (3.3) and, where applicable, other accessories such as *suction source(s)* (3.15), *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 catheter, or pre- and post-hydration lengths of hydratable catheters that can be inserted into the body

3.8
effective shaft length (L_3)
length of non-perforated portion of the catheter excluding the tip, balloon(s), *funnel(s)* (3.9), protective sleeves and/or access port(s)

3.9
funnel
(proximal) portion of the catheter, which may be connected to a drainage system

3.10
retention means
physical feature of the catheter within the body that prevents movement of the catheter out of the body

EXAMPLE Pigtail, suture with pigtail, malecot, balloon, etc.

3.11
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007, 2.16]

3.12
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.11)

[SOURCE: ISO 14971:2007, 2.17]

Note 1 to entry: Risk analysis includes examination of different sequences of events that can produce hazardous situations and harm (see Annex E of ISO 14971:2007)

3.13
risk assessment
overall process comprising a *risk analysis* (3.12) and a risk evaluation

[SOURCE: ISO 14971:2007, 2.18]

3.14
risk management file
set of records and other documents that are produced by risk management

[SOURCE: ISO 14971:2007, 2.23]

3.15
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).

3.16
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. 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 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.

5.4 Surface finish

When examined by normal or corrected to normal vision, the external surface of the effective length of the 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 2,5X magnification.

5.5 Size designation

5.5.1 General

The nominal size of the catheter shall be designated as specified in 5.5.2, 5.5.3 and 5.5.4

5.5.2 Outer diameter

Unless otherwise specified in another part of this document for a particular type of 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 ± 0,33 mm.

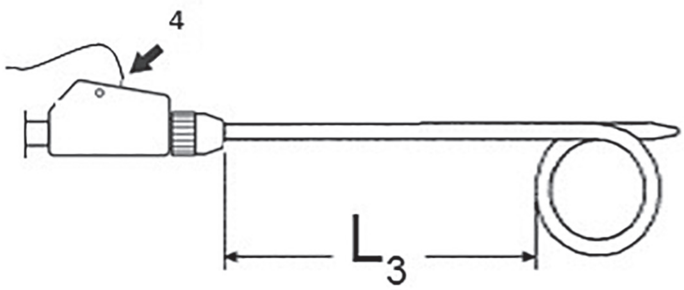
For devices which are not round by design, the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

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

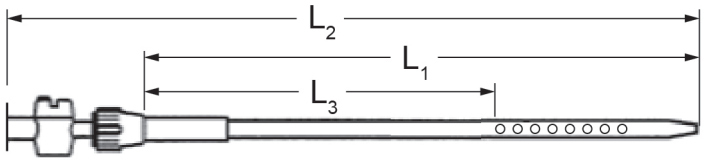
5.5.3 Effective length

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 Tolerances to the effective length are not specified.



a)



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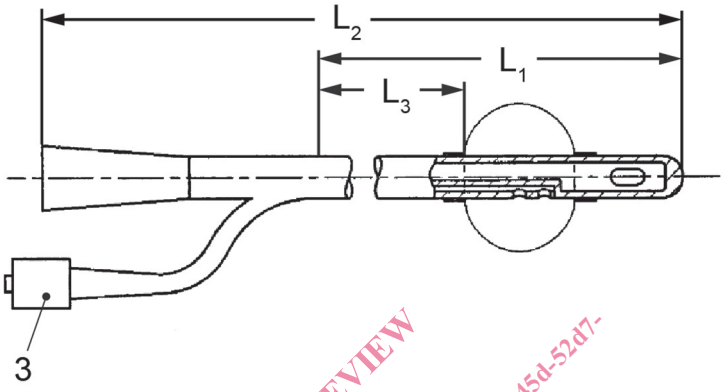

c)

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 ml.

5.6 Connector

There is no standardized connector.

NOTE The funnel (proximal) portion of the catheter is considered to be a connecting part, but is not covered under 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 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 Suggestion to a kink stability test method is shown in Annex A (informative).

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 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 test piece mm	Minimum peak tensile force N
≥ 2 and ≤ 4	5
> 4	15
NOTE 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 catheter component and tubing, and each junction between tubular portions shall be as given in Table 2.

