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Sterile urethral catheters for single use

Sondes urinaires stériles non réutilisables

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Contents

Page

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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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 1616, *Sterile urethral catheters for single use*.

This corrected version of ISO 20696:2018 incorporates the following corrections:

— in Figure A.1, key items 1 and 2 were inverted.

Introduction

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

Sterile urethral catheters for single use

1 Scope

This document specifies requirements and test methods for sterile urethral catheters for single use, with or without a balloon.

This document does not include drainage catheters covered by ISO 20697, e.g. ureteral catheters, nephrostomy catheters, and suprapubic catheters. This document also excludes ureteral stents.

NOTE Ureteral stents are covered in ASTM F1828-97.

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 14971:—[1)], *Medical devices — Application of risk management to medical devices*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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
balloon capacity
volume of liquid to be introduced into the catheter in order to fill the inflation channel and inflate the balloon

3.2
coating
substance applied to the surface of the catheter

3.3
compliant balloon
balloon that continues to expand in size as internal pressure increases

3.4
effective length
L_1
length of the catheter that can be inserted into the body

1) To be published (revises ISO 14971:2007). Stage at time of publication ISO/DIS 14971:2018.

3.5
effective shaft length
L_3
length of non-perforated portion of the catheter excluding the tip, balloon(s), *funnel(s)* (3.6), protective sleeves and/or access port(s)

3.6
funnel
proximal portion of the catheter, which may be connected to a drainage system

Note 1 to entry: See Figures J.1 and J.2.

3.7
intermittent
intended to be removed immediately after emptying the bladder

3.8
non-compliant balloon
balloon that expands to one specific size or size range, even as internal pressure increases

3.9
outer diameter
maximum dimension measured across the cylindrical portion of the shaft

3.10
overall length
L_2
total length from the tip of the catheter to the end of the *funnel* (3.6)

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

[SOURCE: ISO 14971:—, 3.18]

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

[SOURCE: ISO 14971:—, 3.19]

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

[SOURCE: ISO 14971:—, 3.20]

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

[SOURCE: ISO 14971:—, 3.25]

3.15
urethral catheter
tubular device intended for being introduced into the urinary bladder through the urethra in order to provide drainage, drug delivery and/or flushing of the bladder

4 Intended performance

The urethral catheter shall demonstrate the ability to accurately and safely access the intended location. The urethral catheter shall demonstrate the ability to drain urine.

5 General requirements

5.1 Risk management

An established risk management process shall be applied to the design of the device.

Compliance shall be checked by inspection of the risk management file verifying compliance to ISO 14971.

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.

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 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 catheter shall be designated as specified in 5.5.2.

5.5.2 Outer diameter

Unless otherwise specified in another clause 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 ±1 French.

NOTE Additional units can also be given. French size (Fr, Ch, FG) is a nominal dimensional identification of the outer size of urethral catheters; calculated as three times the diameter (in millimetres): Fr = 3 × D (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.

The balloon capacity shall be expressed in millilitres.

5.5.3 Effective shaft lengths

The minimum effective shaft lengths (L_3) shall be as given in Table 1 (see also Figure 1).

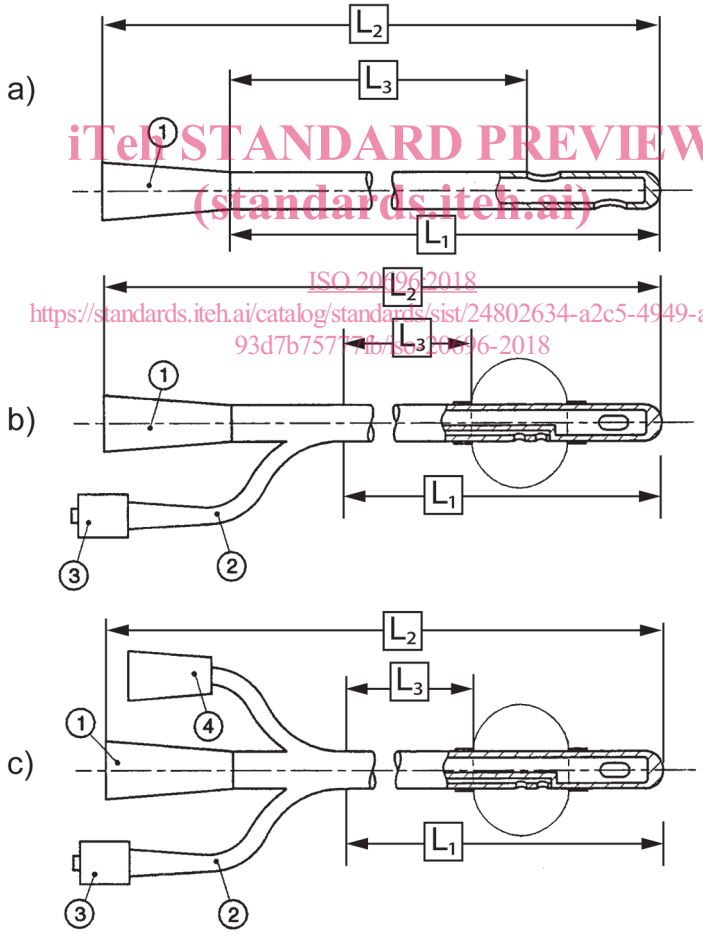
The nominal effective shaft length (L_3) shall be expressed in millimetres, rounded to the nearest millimetre.

NOTE 1 Additional units can also be given.

NOTE 2 Tolerances to the effective length are not specified.

Table 1 — Effective shaft length

Catheter type	L_3 (minimum) mm
Paediatric male	150
Paediatric female	45
Female	60
Male	275
NOTE Shaft dimensions: Shorter sizes can be produced using appropriate risk based clinical justification.	



Key

1 drainage funnel
2 inflation access port
3 valve
4 irrigation access port

L_1 effective length
L_2 overall length
L_3 effective shaft length

Figure 1 — Typical urethral catheters with and without balloon

5.6 MRI compatibility

If applicable, the hazards of urethral catheters in the magnetic resonance environment shall be evaluated by an appropriate method.

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

5.7 Connector

There is no standardized connector. 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 1 A future part of ISO 80369 will address connectors for urethral and urinary applications.

NOTE 2 The funnel is a connecting part, but does not comply with the requirements of ISO 80369-1.

5.8 Sterilization

Urethral 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 Strength

When tested the tip/shaft union and lateral drainage holes shall not show any sign of breaking and neither the tip nor the funnel shall become detached from the shaft.

Compliance shall be checked by the test method in Annex A.

6.2 Connector security

When tested the drainage funnel shall not part from the test connector.

Compliance shall be checked by the test method in Annex B.

6.3 Balloon safety

If present, the balloon shall not leak and shall not occlude the lateral drainage holes.

Compliance shall be checked by the test method in Annex C.

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 specified balloon capacity.

6.4 Catheter inflation lumen integrity and volume maintenance

6.4.1 General

If a balloon is present, choose the appropriate requirement from 6.4.2 and 6.4.3.

6.4.2 Compliant balloon

When deflating the balloon, the percentage of water recovered shall not be lower than the value given in Table 2.

Table 2 — Balloon test volume percentage recovery

Balloon capacity ml	Minimum percentage of volume recovered %
5	55
10	75
20	80
30	80
This document does not specify requirements for balloon capacity of less than 5 ml. These values should be determined by the manufacturer based on risk assessment. Intermediate cases are recommended to comply with the next higher value.	

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

6.4.3 Non-compliant balloon

For 4,0 mm (12 French) and larger catheters, the balloon shall pass through a French size scale no greater than four (4) French larger than the label French size.

This document does not specify requirements for catheter sizes less than 4,0 mm (12 French). These values should be determined by the manufacturer based on risk assessment.

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

6.5 Flow rate

The minimum average flow rates shall be as given in Table 3.

Table 3 — Average flow rates

Designated size		Average flow rate (minimum)	
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	**Drainage lumen** ml/min	**Irrigation lumen** ml/min
2,0	6	10	n.a.[b]
2,7	8	15	n.a.
3,3	10	30	n.a.
4,0	12	50	n.a.
4,7	14	70	25
5,3	16	100	25
6,0	18	100	25
6,7	20	100	25
7,3	22	100	30
8,0	24	100	30
8,7	26	100	30
9,3	28	100	n.a.

NOTE The listed flow rate values are a minimum requirement; clinical flow rate values may be higher.

[a] The Charrière equivalent is given for information.

[b] n.a. = not applicable

Table 3 *(continued)*

Designated size		Average flow rate (minimum)	
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	**Drainage lumen** ml/min	**Irrigation lumen** ml/min
10,0	30	100	n.a.
NOTE The listed flow rate values are a minimum requirement; clinical flow rate values may be higher.			
[a] The Charrière equivalent is given for information.			
[b] n.a. = not applicable			

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

6.6 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 F.

6.7 Kink stability

During placement, the urethral 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 Such as kink stability test method in Annex G.

6.8 Peak tensile force

The minimum peak tensile force of the urethral catheter tubular portion, each junction between catheter component and tubing, and each junction between tubular portions shall be as given in Table 4.

Table 4 — Peak tensile force of urethral catheters

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 using the test method in Annex H.

6.9 Inflated balloon resistance to traction

For 4,66 mm to 8,66 mm (14 French to 26 French) urethral catheters, the balloon shall not pass into or through a funnel-like apparatus, with a size 28 French lumen, representing the bladder outlet and urethra.

This document does not specify requirements for catheter sizes less than 14 French. These values should be determined by the manufacturer based on risk assessment.

Compliance shall be checked using the test method in Annex J.