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 ..... **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**

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**

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.

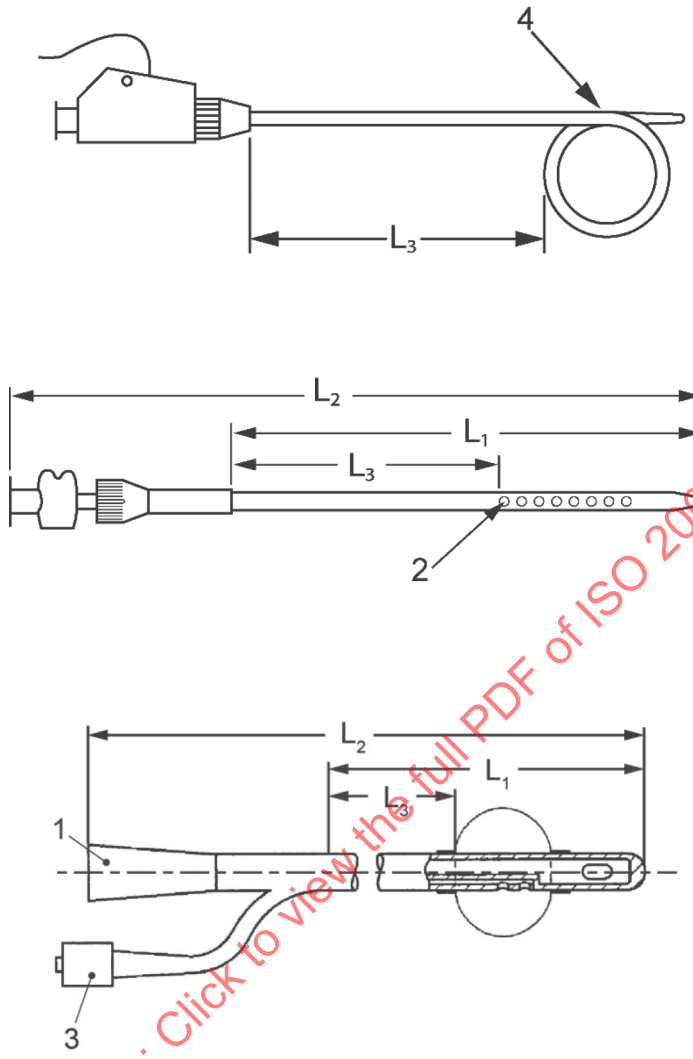
For devices which are not round by design, the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

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.

6.9 Drainage catheter inflation lumen integrity and volume maintenance

6.9.1 General

If a balloon is present, the appropriate requirement from 6.9.2 and 6.9.3 applies.

6.9.2 Compliant balloon

When deflating the balloon, the percentage of water recovered shall not be lower than the value given in Table 3.

Table 3 — Balloon 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 J.

6.9.3 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 drainage 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 K.

6.10 Inflated balloon resistance to traction

For drainage catheters 4,66 mm to 8,66 mm (14 French to 26 French), 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 drainage 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 L.

6.11 Freedom from leakage during aspiration or vacuum

The drainage catheter, accessory devices, or any component(s) designed to form a part thereof, intended to operate under negative pressure shall not leak air during aspiration at the maximum negative pressure as defined by the manufacturer.

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

7 Information supplied by the manufacturer

7.1 General

Units of measurement systems other than those specified may additionally be used.

Marking on all devices shall be durable and legible. Check compliance by inspection and assess durability by use of appropriate test method.

NOTE Appropriate test methods can be ASTM F1842-09 or ASTM F2252-13.

Where appropriate, ISO 11607 (all parts) and EN 1041 should be used and symbols should be made according to ISO 15223-1.

7.2 Marking on the device and/or packaging

NOTE The primary packaging is often transparent. Therefore, for the purposes of this subclause, the combination of marking of the device which is visible through the package and the primary packaging itself are to be considered.

If not practicable on the device itself then marking should be displayed on the primary (individual) packaging, secondary (case) packaging or in the instructions for use.

The primary and/or secondary packaging shall be labelled with the following information at a minimum.

a) Any special storage or handling conditions.

b) An indication that the device is for single use or single patient use. A manufacturer's indication of single use shall be consistent across its range where appropriate.

c) Where appropriate, an indication of whether the device is detectable.

d) If present, effective collection capacity of the collection device expressed in millilitres.

e) The vacuum stability of any pre-evacuated suction source, defined as the date when at least 80 % of the initial negative pressure as stated on the label will remain.

NOTE This can be the "use until date" as defined in EN 1041.

f) Where appropriate, the maximum negative pressure in pascals (Pa) which the drainage system, or any component thereof supplied separately, can withstand (if the suction source is supplied with the system, this value should be the maximum operating pressure of the suction source).

g) Where appropriate, the manufacturer's stated nominal balloon inflation volume.

7.3 Instructions for use

When a separate instruction for use is provided, it shall at least contain information on the following.

a) If the intended purpose of the device is not obvious to the user, the manufacturer shall clearly state it. Where a device is provided with separate instructions for use, this requirement may be omitted from the primary packaging.

b) If the device is intended to be connected to other devices or accessories in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices in order to obtain a safe combination.

c) Any warnings or precautions to take.

d) Date of issue or the revision level of the instructions for use.

e) Where appropriate, an indication that the device is for single use or single patient use. A manufacturer's indication of single use shall be consistent across its range.

f) Where appropriate, the method of cleaning, disinfecting or sterilization necessary prior to use.

g) Where appropriate, known reactions between the drainage catheter and magnetic resonance imaging (MRI) environment.

h) Where appropriate, description of additives or coatings.

i) Any contra-indications, warnings and precautions based on the additive or coating material(s).

j) If the drainage catheter has retention means, instructions for tightening and release of retention.

Annex A
(informative)

Test method for determining kink stability

A.1 Principle

The device is wrapped around incrementally smaller mandrels until a kink is formed.

A.2 Apparatus

A.2.1 Kink fixture, mandrel with incrementally smaller diameters.

NOTE Typical apparatus can be found in Figure A.1.

A.2.2 Calipers.

A.3 Procedure

A.3.1 Select a test piece from the device to be tested. Each tubular portion and each junction between a tubular portion are tested individually.

A.3.2 Place the test pieces to be conditioned in an appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time or a minimum of 2 h. Test in accordance with A.3.3 to A.3.5 immediately after conditioning.

A.3.3 Hold the tubing in both hands, wrap it 180° around a large diameter mandrel to avoid kinking the drainage catheter prematurely.

A.3.4 Continue to wrap the tubing around smaller diameters incrementally until a kink is observed in the tubing.

A.3.5 Once the tubing has kinked, measure the diameter of the mandrel with calipers or record the mandrel diameter.

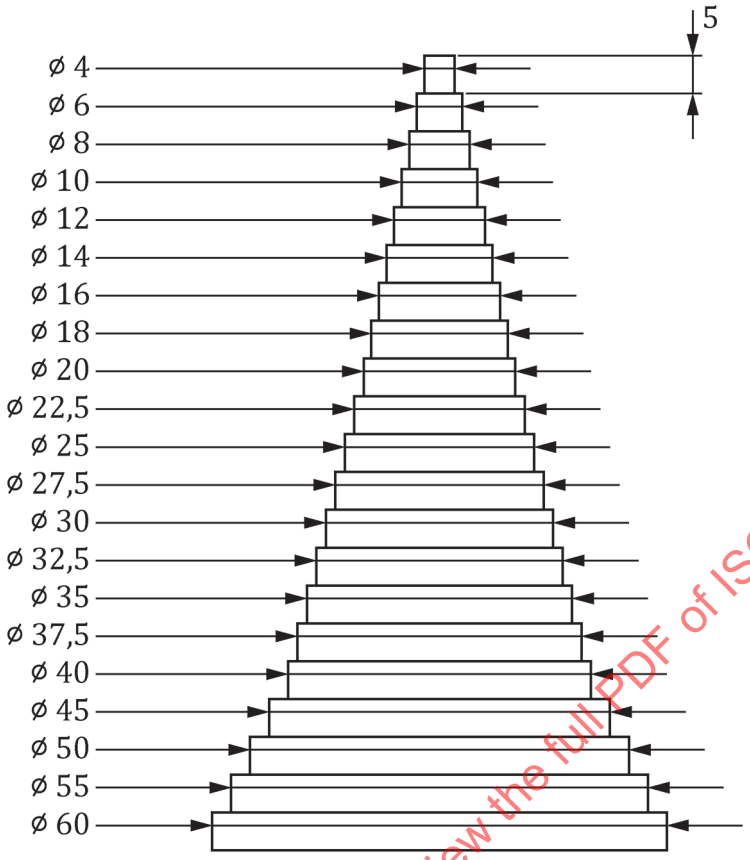
A.4 Test report

The test report shall include the following information:

a) identity of the drainage catheter;

b) the diameter of the mandrel, expressed in millimetres.

Dimensions in millimetres



Key

⌀ mandrel diameter

NOTE 1 Diameter could be engraved on each step.

NOTE 2 The apparatus in the Figure is an example that has been found to be suitable, but is not intended to preclude other sizes of apparatus or other designs from being used, as long as a simple loop is being formed.

Figure A.1 — Apparatus for testing tubing until kinking

Annex B
(normative)

Test method for corrosion resistance

B.1 Principle

The device is immersed in sodium chloride solution, then in boiling distilled or deionized water, and afterwards examined visually for evidence of corrosion.

B.2 Reagents

B.2.1 Saline solution, comprising a solution of analytical reagent grade sodium chloride in freshly prepared distilled or deionized water, [c(NaCl) = 0,15 mol/l].

B.2.2 Distilled or deionized water.

B.3 Apparatus

B.3.1 Borosilicate glass beakers.

B.4 Procedure

B.4.1 Immerse the device in the saline solution (B.2.1) in a borosilicate glass beaker (B.3.1) at (22 ± 5) °C for 5 h.

B.4.2 Remove the test specimen and immerse it in boiling distilled or deionized water (B.2.2) for 30 min.

B.4.3 Allow the water and the test specimen to cool to (37 ± 2) °C, and maintain them at this temperature for 48 h.

B.4.4 Remove the test specimen and allow it to dry at room temperature.

B.4.5 Disassemble specimens that have two or more components, which are intended to be separable in use. Do not strip away or cut open any coatings on metallic components. Inspect the specimen visually for signs of corrosion.

NOTE Additional testing can be performed using alternate durations and temperatures using appropriate risk-based clinical justification.

B.5 Test report

The test report shall include the following information:

a) identity of the device;

b) statement as to whether corrosion occurred during the test.

Annex C
(normative)

Test method for resistance to deformation by suction

C.1 Principle

The drainage catheter, accessory devices, or any component(s) designed to form a part thereof, assembled in a ready-to-use state, are exposed to the negative pressure stated on the label. The test specimen is inspected while under the negative pressure for evidence of deformation.

C.2 Apparatus

C.2.1 **Water bath**, at (37 ± 2) °C.

C.3 Procedure

C.3.1 Perform the test on the ready-for-use product.

C.3.2 Condition those parts of the drainage catheter that are intended for insertion into the body in an atmosphere of 100 % RH or water at a temperature of (37 ± 2) °C (C.2) for not less than 15 min. Condition other components at a minimum of 40 % RH and at a temperature of (22 ± 2) °C for not less than 15 min.

C.3.3 Test immediately after conditioning.

C.3.4 Connect the non-perforated section of the drainage catheter and/or the drainage catheter with accessory devices, and/or the individual components thereof (if supplied separately). Apply the maximum negative pressure as defined by the manufacturer to the system for at least 60 s.

C.3.5 Examine the test specimen by normal or corrected-to-normal vision during the test for evidence of deformation.

C.4 Test report

The test report shall include the following information:

a) identity of the drainage catheter;

b) statement as to whether deformation occurred during the test.

Annex D
(normative)

Test method for determining peak tensile force of connections

D.1 Principle

The connector(s) are assembled in accordance with the manufacturer's instructions. A peak tensile force is applied and the assembled connection is inspected for separation.

D.2 Apparatus

D.2.1 **Tensile testing apparatus**, capable of exerting a force of greater than 15 N.

D.3 Procedure

D.3.1 Assemble the connectors in accordance with the manufacturer's instructions.

D.3.2 Fix the assembled connectors in the tensile testing apparatus. If necessary, use an appropriate fixture to avoid deforming the connectors.

D.3.3 Apply the specified peak tensile force at a testing speed of 500 mm/min.

D.3.4 Inspect the assembled connectors for separation.

D.4 Test report

The test report shall include the following information:

a) identity of the drainage catheter;

b) identity of the connector(s);

c) the specified force applied, in newtons;

d) statement as to whether the connectors separated during the test.

Annex E
(normative)

Test method for determining peak tensile force of drainage catheter

E.1 Principle

Test pieces or the overall length of a drainage catheter are chosen so that each tubular portion, each junction between drainage catheter component and tubing, and each junction between tubular portions is tested. A tensile force is applied to each test piece until the tubing breaks or the junction separates or until a specified force is applied.

E.2 Apparatus

E.2.1 **Water bath**, at (37 ± 2) °C.

E.2.2 **Tensile testing apparatus**, capable of exerting a force of greater than 20 N.

E.3 Procedure

E.3.1 Select a test piece from the drainage catheter to be tested. Include in the test piece the connector, if present, and the junction between segments, e.g. between the tubing and the tip, if present. Exclude distal tips of lengths less than 3 mm from the test piece.

E.3.2 Condition those parts of the drainage catheter that are intended for insertion into the body in an atmosphere of 100 % RH or water at a temperature of (37 ± 2) °C (E.2.1) for not less than 2 h. Condition other components at a minimum of 40 % RH and at a temperature of (22 ± 5) °C for not less than 2 h. Test immediately after conditioning.

E.3.3 Fix the test piece in the tensile testing apparatus. If a connector is present, use an appropriate fixture to avoid deforming the connector.

E.3.4 Measure the gauge length of the test piece, i.e. the distance between the jaws of the tensile testing apparatus or the distance between the connector and the jaw holding the other end of the test piece, as appropriate.

E.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/mm of gauge length (see Table E.1) until the test piece separates into two or more pieces, or until a specified force is applied.

Table E.1 — Examples of conditions for a 20 mm/min/mm strain rate

Gauge length mm	Testing speed mm/min
10	200
20	400
25	500

E.3.6 If testing a drainage catheter that consists of a single tubular portion having regions of different outside diameter, repeat E.3.2 to E.3.5 on test pieces of each different diameter.

E.3.7 Do not perform more than one test on each test piece.

E.4 Test report

The test report shall include the following information:

a) identity of the drainage catheter;

b) the peak tensile force, or the specified force applied, in newtons;

c) outer diameter of each test piece;

d) and if appropriate, the location of the failure.

Annex F
(normative)

Test method for impact resistance of collection device

F.1 Principle

The collection device is submitted to free fall onto a hard surface and is then examined for evidence of damage in the form of leakage or loss of vacuum.

F.2 Apparatus

F.2.1 **Test surface**, which is:

— flat and horizontal, so that no more than two points on its surface differ in level by more than 2 mm;

— rigid, so that it will not be deflected by more than 0,1 mm when an area of 100 mm^2 is loaded statically with 98 N anywhere on the surface;

— sufficiently large that the device under test falls entirely upon its surface;

— has a mass of at least 10 times that of the heaviest device to be tested.

F.2.2 **Means for measuring vacuum**, capable of showing a difference of 2 % of the maximum vacuum.

F.2.3 **Means for occlusion of the inlet/suction port**, where applicable.

F.3 Procedure

F.3.1 Collection device

F.3.1.1 Assemble the collection device as for clinical use.

F.3.1.2 Fill the collection device with water to its collecting capacity. Disconnect the collection device. Occlude the inlet/suction port, where applicable.

F.3.1.3 Perform a free fall at an ambient temperature of (22 ± 5) °C from a height of 700 mm onto a hard surface (F.2.1). Inspect for leakage by normal or corrected-to-normal vision.

F.3.2 Suction source

F.3.2.1 Assemble the suction source as for clinical use. If the device does not have means for self-occluding the inlet/suction port, connect the means for occlusion and occlude the inlet/suction port.

F.3.2.2 Ensure the suction source is at the maximum negative pressure and measure and record the pressure.

F.3.2.3 Perform a free fall at an ambient temperature of (22 ± 5) °C from a height of 700 mm onto a hard surface (F.2.1).

F.3.2.4 Measure and record the pressure not less than 60 s after impact.

F.4 Test report

The test report shall include the following information:

a) identity of the test device(s);

b) for suction sources, the maximum negative pressure at the beginning of the test and the negative pressure after test, expressed in kPa;

c) the statement whether leakage was observed after test.

Annex G
(normative)

Test method for determination of flow rate through drainage catheter

G.1 Principle

Water is allowed to flow through the drainage catheter and the amount of flow is measured either volumetrically or gravimetrically.

G.2 Reagent

G.2.1 Distilled or deionized water, or other clinically relevant media.

G.3 Apparatus

G.3.1 Constant level tank, fitted with a delivery tube and a connector when no test drainage catheter is attached, of providing a flow rate of (525 ± 25) ml/min, and having a hydrostatic head height of (1 000 ± 5) mm.

An example of a suitable apparatus is shown in Figure G.1.

G.3.2 Equipment for collecting and determining the mass or volume of the drainage catheter efflux, to an accuracy of ±1 %.

G.3.3 Timer, for measuring collection time.

G.4 Procedure

G.4.1 Supply the constant-level tank (G.3.1) with media at (22 ± 5) °C. Fit the catheter to be tested to the appropriate connector. If the drainage catheter has a balloon, then the balloon should be inflated to the rated nominal volume prior to testing. Ensure that the drainage catheter outlet is maintained at a hydrostatic head height of (1 000 ± 5) mm.

G.4.2 Flush air from the system by allowing water flow briefly through the drainage catheter.

G.4.3 Start the media flowing through the drainage catheter. Collect the efflux for a measured period of time (not less than 30 s) in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing, taking into account the density of the media.

G.4.4 Perform three determinations on each applicable drainage catheter lumen.

G.5 Expression of results

Calculate the arithmetic average of the three determinations and express it as average flow rate through the drainage catheter, in millilitres per minute. Round the calculated average flow rate to the nearest whole number of millilitres per minute.

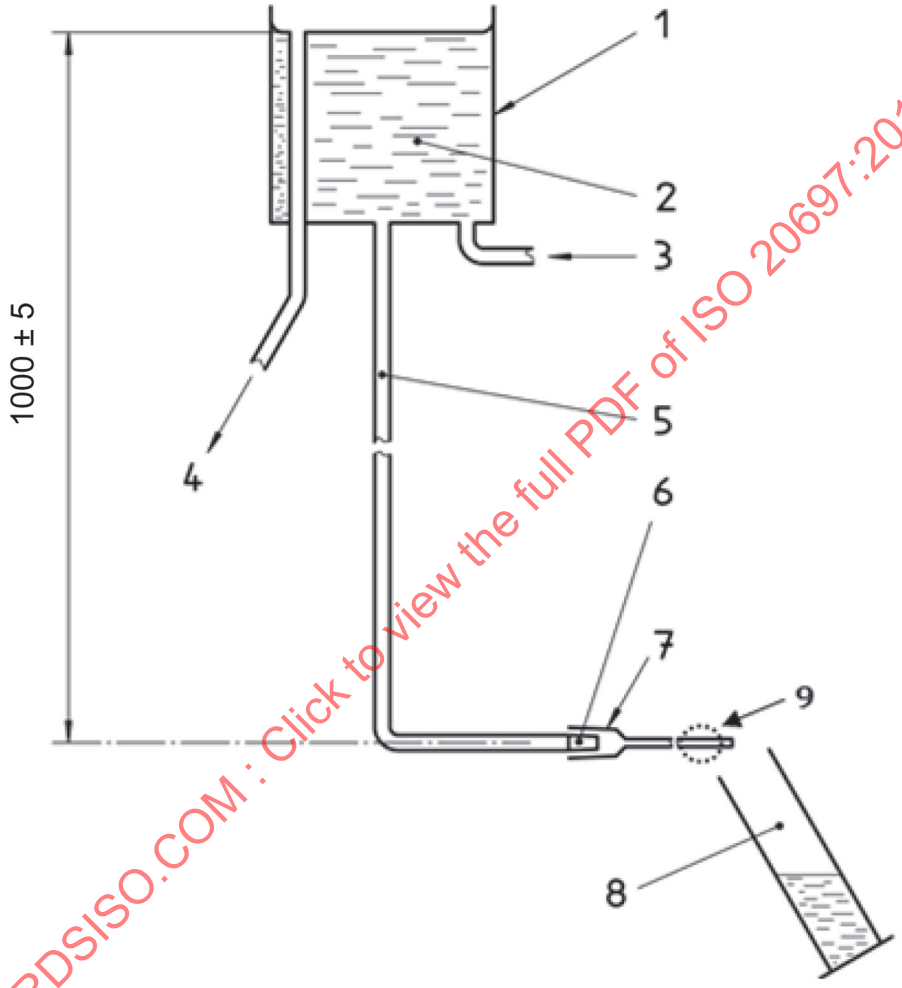
G.6 Test report

The test report shall include the following information:

a) identity of the drainage catheter and the media used for flow rate testing;

b) average flow rate, expressed in millilitres per minute, for each applicable drainage catheter lumen.

Dimensions in millimetres



Key

1 constant-level tank
2 distilled or deionized water
3 inlet
4 overflow
5 delivery tube
6 connector fitting
7 drainage catheter under test
8 collecting/measuring vessel
9 inflated balloon, where appropriate

Figure G.1 — Example of apparatus for determination of flow rate of water through drainage catheter

Annex H
(informative)

Test method for retention strength

H.1 Principle

The peak tensile force is applied to overcome the retention means of the drainage catheter.

H.2 Apparatus

H.2.1 **Tensile testing apparatus**, capable of exerting a force to overcome the retention means of the drainage catheter.

H.2.2 **Plate fixture**, consisting of rigid material with a smooth surface finish, having the following constructional features.

a) Clearance between the outside diameter of the drainage catheter and inside diameter of the plate hole should be present. The plate hole diameter should be 0,33 mm (1 French) larger than the drainage catheter under test.

b) A radius of curvature of 2 mm ± 0,1 mm for all edges adjacent to the hole.

c) A plate thickness of 16 mm ± 0,5 mm.

d) A suitable apparatus with dimensions is shown in Figure H.1.

H.2.3 **Water bath**, at (37 ± 2) °C.

H.3 Procedure

H.3.1 Condition those parts of the drainage catheter that are intended for insertion into the body in an atmosphere of 100 % RH or water at a temperature of (37 ± 2) °C for not less than 2 h. Test immediately after conditioning.

H.3.2 Insert the shaft through the hole of the plate fixture until the retention means is activated and touching as shown in Figure H.1.

NOTE The retention means is prepared in accordance with the manufacturer's instructions.

H.3.3 Fix the test piece in the tensile testing apparatus. If a connector is present, use an appropriate fixture to avoid deforming the connector.

H.3.4 Apply a tensile force at a rate of 100 mm/min until the retention means is completely pulled through the plate or the retention means separates from the device.

H.4 Test report

The test report shall contain the following information:

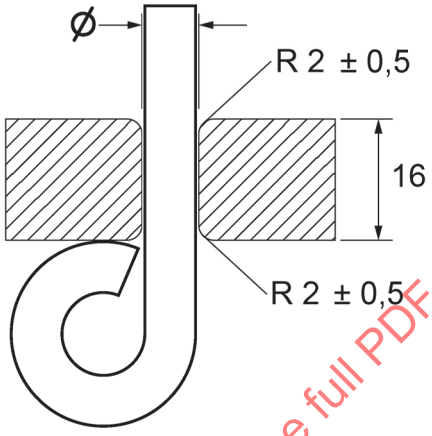
a) the identity of the drainage catheter;

b) the outer diameter of each test piece;

c) the peak tensile force, in newtons;

d) and if appropriate, the location of the failure.

Dimensions in millimetres



Key

Ø plate hole diameter

NOTE The retention means in the figure is an example but is not intended to preclude other designs from being used.

Figure H.1 — Plate fixture

Annex I
(normative)

Test method for determining balloon safety

I.1 Principle

Drainage catheters fitted with balloons may be in position for prolonged periods. Such drainage catheters are therefore immersed for 14 d in simulated urine prior to testing. This step is omitted for drainage catheters without balloons and drainage catheters that are not intended to drain urine. The drainage catheter balloon is inflated with water to the manufacturer's maximum stated capacity. A tensile force is applied to the drainage catheter and the drainage catheter examined visually for occlusion of the lateral drainage holes, if present, by the balloon and leakage from the balloon.

I.2 Reagents

I.2.1 Distilled water or deionized water.

I.2.2 Simulated urine, pH approximately 6,6, of the following composition, the reagents being of recognized analytical grade:

— urea 25,0 g;

— sodium chloride 9,0 g;

— disodium hydrogen orthophosphate anhydrous 2,5 g;

— potassium dihydrogen orthophosphate 2,5 g;

— ammonium chloride 3,0 g;

— creatinine 2,0 g;

— sodium sulphite, hydrated 3,0 g;

— distilled water to 1,0 l.

WARNING — This solution can support microbial growth. There is a strong possibility that large numbers of microorganisms will be present in the solution at the end of the tests described in I.4 and I.3. These procedures should be carried out by trained personnel taking appropriate precautions in the handling of the immersed drainage catheter and the disposal of the contaminated solution.

I.3 Apparatus

I.3.1 Device for suspending the drainage catheter, consisting of a plate of rigid material, having the following constructional features:

a) a hole of diameter of 1 mm greater than that of the nominal size of the drainage catheter under test, with a countersink on the upper surface of the plate;

b) a countersink of 90° included angle of sufficient size to support the base of the balloon of the drainage catheter under test;

c) no sharp edges at the junction of the hole and the countersink.

NOTE To facilitate placement of the drainage catheter under test, the plate can comprise two halves, symmetrical about the centre line of the hole.

I.3.2 Water bath, or other device capable of being controlled at (37 ± 2) °C.

I.3.3 Device for attaching a weight to the drainage funnel or shaft of the drainage catheter, and a series of weights, the combined masses of the attachment device and each mass being as given in Table I.1.

I.3.4 Stopwatch.

Table I.1 — Requirements for load test

Designated size		Minimum mass
Outer diameter mm	Charrière equivalent[a] FG/Ch/Fr	kg
2,7 or less	8 or less	0,3
3,3	10	0,45
4,0	12	0,6
4,7	14	0,7
5,3 to 10,0	16 to 30	1,0

[a] The Charrière equivalent is given for information.

Intermediate cases are recommended to comply with the next higher value.

I.4 Procedure

I.4.1 Inflate the drainage catheter balloon with distilled water to the manufacturer's nominal balloon inflation volume.

I.4.2 Immerse the drainage catheter in the freshly prepared simulated urine (I.2.2) in the water bath (I.3.2) controlled at (37 ± 2) °C, so that the tip and the balloon are completely submerged.

I.4.3 Allow the drainage catheter to remain in the simulated urine for 14 d, then remove the drainage catheter, rinse it with tap water, and dry it. Allow the drainage catheter and contents to come to a temperature of (22 ± 5) °C.

I.4.4 Place the drainage catheter in the suspension device (I.3.1), with the tip uppermost, the balloon resting in the countersink and the shaft protruding from the hole.

NOTE To facilitate placement of the drainage catheter in a single piece suspension device, it might be necessary to either remove the funnels, having first ligatured the drainage catheter shaft, or to drain the balloon, introduce the drainage catheter and then re-inflate the balloon.

I.4.5 Select the weight (I.3.3) appropriate to the drainage catheter under test, as given in Table I.1.

I.4.6 Manually support the weight. Attach the weight to the shaft or drainage funnel of the drainage catheter and gently lower the weight until it is freely suspended from the drainage catheter. Allow it to remain in this position for 1 min.

I.4.7 With the weight in position, visually examine the drainage catheter at the end of a 1 min period for

a) occlusion of the lateral drainage holes, if present, by the balloon, or

b) leakage of water from the balloon.

I.5 Test report

The test report shall contain the following information:

a) the identity of the drainage catheter;

b) whether the lateral drainage holes were occluded by the balloon;

c) whether leakage from the balloon was observed.

Annex J
(normative)

Test method for determining inflation lumen leakage and/or function and/or balloon deflation (drainage catheter with compliant balloon)

J.1 Principle

The drainage catheter balloon and inflation lumen are inflated with water and immersed in simulated urine for 14 d. This step is omitted for drainage catheters that are not intended to drain urine. The balloon is allowed to drain under gravity, and the volume of liquid recovered is measured.

J.2 Apparatus and reagents

J.2.1 **Clamp or similar device**, for suspending the drainage catheter by the tip.

J.2.2 **Appropriate connector**, to connect to the inflation lumen of the device.

J.2.3 **Water bath**, or other device capable of being controlled at (37 ± 2) °C.

J.2.4 **Measuring cylinder**, with accuracy ±1 %, size appropriate to the balloon under test.

J.2.5 **Distilled water**.

J.2.6 **Simulated urine**, of composition given in I.2.2.

J.3 Procedure

J.3.1 Introduce into the drainage catheter balloon, through the valve of the inflation funnel, the volume of distilled water (J.2.5) given in Table J.1.

J.3.2 Completely submerge the drainage catheter in freshly prepared simulated urine (J.2.6) in the water bath (J.2.3), controlled at (37 ± 2) °C for 14 d.

J.3.3 Remove the drainage catheter from the simulated urine, rinse it with tap water and dry it.

J.3.4 Suspend the drainage catheter by the tip using the clamp (J.2.1). Insert the appropriate connector (J.2.2) into the valve of the inflation funnel and allow the contents of the balloon to drain gravimetrically into a measuring cylinder until the flow of liquid stops, or for 15 min, whichever is the shorter period.

J.3.5 If desired, allow the temperature of the liquid in the measuring cylinder (J.2.4) to come to (22 ± 5) °C.

J.3.6 Measure the volume removed from the balloon and calculate the percentage recovered.

Table J.1 — Balloon test capacities

Designated size		Test capacity
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	
2,7 to 3,3	8 to 10	Nominal balloon capacity
4,0 to 4,7	12 to 14	1,2 × balloon capacity
5,3 to 10,0	16 to 30	1,5 × balloon capacity
This document does not specify requirements for balloon test capacities for balloons of less than 2,7 mm outer diameter. These values should be determined by the manufacturer based on risk assessment.		
[a] The Charrière equivalent is given for information.		
NOTE For diameter values falling between two lines, the greater test capacity value applies.		

J.4 Test report

The test report shall contain the following information:

a) the identity of the drainage catheter, including the designated size and balloon capacity;

b) the volume of liquid recovered through the valve, expressed as a percentage of the volume introduced.

Annex K
(normative)

Test method for determining balloon size and deflation reliability (drainage catheter with non-compliant balloon)

K.1 Principle

The outer diameter of the drainage catheter balloon portion is passed through the appropriate French size hole before inflation. The balloon is inflated with distilled water and immersed in water for 7 d. The balloon is then deflated and passed through the appropriate larger diameter hole (French size hole).

K.2 Apparatus and reagents

K.2.1 **French size scale,** with tolerance ± 0,13 mm.

K.2.2 **Distilled water**.

K.2.3 **Water bath**, or other device capable of being controlled at (37 ± 4) °C.

K.2.4 **Syringe with appropriate connector**, to connect to the inflation lumen of the device.

K.2.5 **Force measuring device**, capable of measuring a force greater than 4,5 N.

K.3 Procedure

K.3.1 Carry out the test in an environment at (22 ± 5) °C.

K.3.2 Insert the non-inflated balloon catheter without lubrication through the relevant French size hole using the French size scale (K.2.1) and record.

K.3.3 Inflate the balloon with distilled water to the nominal capacity as defined by the manufacturer.

K.3.4 Submerge the drainage catheter in the water bath (K.2.3) at (37 ± 4) °C for 7 d.

K.3.5 After 7 d, remove the drainage catheter from the bath and place on a clean surface.

K.3.6 Deflate the balloon completely by using a syringe (K.2.4).

K.3.7 The deflated balloon portion of the drainage catheter shall be passed through a French size scale. Record the smallest French size hole that the balloon will pass through without a pulling force greater than 4,5 N (K.3.2).