BRITISH STANDARD

BS EN
1617 : 1997

Sterile drainage catheters and accessory devices for single use

The European Standard EN 1617 : 1997 has the status of a British Standard

ICS 11.040.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/27, Medical plastics tubing, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
British Dietetic Association (PENG)
British Surgical Trades Association
Department of Health
Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
Guild of Hospital Pharmacists
Institution of Physics and Engineering in Medicine and Biology
Intensive Care Society
Medical Sterile Products Association
National Association of Theatre Nurses
Royal College of Paediatrics and Child Health
Royal Pharmaceutical Society of Great Britain

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on
15 July 1997

Amendments issued since publication

Amd. No.	Date	Text affected

The following BSI references relate to the work on this standard:
Committee reference CH/27
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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/27 and is the English language version of EN 1617 : 1997 *Sterile drainage catheters and accessory devices for single use*, published by the European Committee for Standardization (CEN).

Cross-references

Publication referred to	Corresponding British Standard
EN 556 : 1994	BS EN 556 : 1995 *Sterilization of medical devices — Requirements for terminally-sterilized devices to be labelled 'Sterile'*
EN 980 : 1996	BS EN 980 : 1997 *Graphical symbols for use in the labelling of medical devices*
EN 1618 : 1997	BS EN 1618 : 1997 *Catheters other than intravascular catheters — Test methods for common properties*

The Technical Committee has reviewed the provisions of prEN 1041, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this British standard.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 6, an inside back cover and a back cover.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1617

February 1997

ICS 11.040.20

Descriptors: Medical equipment, disposable equipment, catheters, definitions, mechanical strength, shock resistance, tests, labelling

English version

Sterile drainage catheters and accessory devices for single use

Sondes et dispositifs accessoires stériles de drainage, non réutilisables

Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung

This European Standard was approved by CEN on 1997-01-10. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A and B form normative parts of this standard.

Annex C is given for information only.

1 Scope

This European Standard specifies requirements for sterile, single use drainage catheters, wound drainage systems and components thereof designed for drainage of fluids to the exterior by means of gravity or negative pressure.

This European Standard does not apply to:

a) catheters of less than 2 mm outside diameter;

b) suction catheters for use in the respiratory tract (see prEN 1733);

c) tracheal catheters (tracheal tubes) (see prEN 1782).

NOTE. Urinary tract catheters are covered in EN 1616.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556	*Sterilization of medical devices — Requirements for medical devices to be labelled 'Sterile'*
EN 980	*Information supplied by the manufacturer for medical devices — Graphical symbols for medical devices*
prEN 1041	*Terminology, symbols and information provided with medical devices — Information provided with medical devices supplied by the manufacturer*
EN 1618 : 1997	*Catheters other than intravascular catheters — Test methods for common properties*

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1 drainage catheter

Tube designed for short or long term percutaneous or surgical insertion into a fluid collection or surgical wound.

3.2 collection device

Bag, bellows, bottle or other container constituting a part of a drainage system designed for collecting liquids and connected to the drainage catheter directly or via a connecting tube.

3.3 drainage system

Drainage catheter and collection device(s) and, where applicable, other accessories such as suction source(s), connecting tube(s), connector(s) or trocar(s).

NOTE. 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.

3.4 connecting tube

Tube designed for the assembly of components of a drainage system.

3.5 trocar

Needle, pointed rod, sleeve or any combination thereof which assists in inserting the drainage catheter into the body tissue or cavity.

3.6 suction source

Self contained device capable of exerting a negative pressure on a drainage catheter or system.

NOTE. The suction source may be the collection device.

4 Requirements

4.1 Kink stability

NOTE. This subclause will be prepared when a test method has been developed.

4.2 Resistance to deformation

The drainage system or any component thereof intended to operate under negative pressure shall not show deformation sufficient to impair the function of the device at the maximum negative pressure stated by the manufacturer.

This shall be determined on the sterilized, ready-for-use product as described in annex A.

4.3 Force at break

4.3.1 *Connections*

When tested according to annex F of EN 1618 : 1997 the minimum force at break for connections shall be as given in table 1.

Table 1. Minimum force at break of connections

Nominal outside diameter (mm)	**Minimum force at break** (N)
2 to 4	5
> 4	15

4.3.2 *Drainage catheters and all other parts of the system*

When tested according to annex B of EN 1618 : 1997 the minimum force at break shall be as given in table 2.

Table 2. Minimum force at break of catheters and other parts of the system	
Nominal outside diameter (mm)	**Minimum force at break** (N)
2 to 4	10
> 4	20

4.4 Radio-detectability

NOTE. This clause will be prepared when a test method has been developed.

4.5 Freedom from leakage

When tested according to annex D of EN 1618 : 1997 neither the drainage system nor any components thereof shall leak at the maximum negative pressure stated by the manufacturer.

4.6 Impact resistance

The collection device shall not leak when tested in accordance with annex B.

The suction source shall not show any loss of vacuum greater than 2 % when tested in accordance with annex B.

4.7 Biocompatibility

The drainage catheter and any other component of the drainage system intended to channel fluid into the patient shall be evaluated for biocompatibility and shall be free from biological hazard.

NOTE. Methods for evaluation for biocompatibility are given in EN 30993.

4.8 Sterility

The device shall comply with EN 556.

4.9 Corrosion test

When tested in accordance with the method given in annex A of EN 1618 : 1997, the test specimen shall not show any evidence of corrosion.

5 Labelling

In addition to the requirements of EN 980 and prEN 1041 the following product-specific details shall be presented on the individual packaging:

a) size of the drainage catheter (i.e. outside diameter expressed in millimetres and length expressed in millimetres or centimetres);

b) radio-detectability if claimed;

c) effective collection capacity of the collection device expressed in millilitres;

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

NOTE. This may be the 'use until date' as defined in prEN 1041.

e) the maximum negative pressure in Pascals (Pa) which the drainage system, or any component thereof supplied separately, can withstand.

NOTE. If the suction source is supplied with the system, this figure is the maximum operating pressure of the suction source.

Annex A (normative)

Test method for resistance to deformation of a drainage system or any components designed to form a part thereof

A.1 Principle

The drainage system or component(s) 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.

A.2 Apparatus

A.2.1 *Water bath*, at (37 ± 2) °C for the drainage catheter.

A.2.2 *Water bath*, at (23 ± 2) °C for other components.

A.3 Procedure

Perform the test on the ready-for-use, sterile product.

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 (**A.2.1**) for not less than 15 min.

Condition other components at 40 % RH to 60 % RH and a temperature of (23 ± 2) °C for not less than 15 min and test immediately after conditioning.

Submit the non-perforated section of the drainage catheter and/or the entire drainage system and/or the individual components thereof (if supplied separately) to the stated negative pressure of the system for 60 s.

Maintain the pressure for at least 60 s. Examine the test specimen by normal or corrected-to-normal vision during the test for evidence of deformation.

Annex B (normative)

Test method for impact resistance of collection device

B.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.

B.2 Apparatus

B.2.1 *A test surface*, which is:

– flat, 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 deformed by more than 0,1 mm when an area of 100 mm^2 is loaded statically with 10 kg 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.

B.2.2 *Means for measuring vacuum*, capable of showing a difference of 1 % of the maximum vacuum.

B.3 Procedure

B.3.1 *Collection device*

Assemble the collection device as for clinical use.

Fill the collection device with water to its collecting capacity. Perform a free fall at an ambient temperature of (23 ± 2) °C from a height of 700 mm onto a hard surface (**B.2.1**). Inspect for leakage by normal or corrected-to-normal vision.

B.3.2 *Suction source*

Assemble the suction source as for clinical use. Ensure the suction source is at the maximum negative pressure and measure and record the pressure. Perform a free fall at an ambient temperature of (23 ± 2) °C from a height of 700 mm onto a hard surface (**B.2.1**). Measure and record the pressure not less than 60 s after impact.

Annex C (informative)

Bibliography

EN 30993 *Biological evaluation of medical devices*

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List of references

See national foreword.

BSI — British Standards Institution

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