

Urological catheters

Part 2. Specification for sterile, single-use urethral catheters of the Tiemann, whistle tip, 3-way and haematuria types

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/1, upon which the following bodies were represented:

Association for Spina Bifida and Hydrocephalus
Association of British Health Care Industries
Association of Clinical Pathologists
Association of Continence Advisors
Association of National Health Service Supplies Officers
British Association of Urological Surgeons
British Rubber Manufacturer's Association
British Surgical Trades Association Incorporated
Department of Health
Medical Sterile Products Association
Ministry of Defence
Coopted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 30 September 1990

© BSI 1990

First published January 1951
Second edition April 1981
Third edition, as Part 2,
September 1990

The following BSI references relate to the work on this standard:
Committee reference HCC/1
Draft for comment 87/51138 DC

ISBN 0 580 18847 7

Amendments issued since publication

Amd. No.	Date	Text affected

Amendment No. 1
published and effective from 30 September 1991
to BS 1695 : Part 1 : 1990

Urological catheters
Part 1. Specification for sterile, single-use urethral
catheters of the Nélaton and Foley types

Correction

AMD 6757
September 1991

Table 9. Conditions for preparing extracts for cytotoxicity testing

In the entry for 'Size of test material', delete '0.8 cm²' and substitute '1.5 cm²'.

9109—0.6k—B

HCC/1

Amendment No. 2
published and effective from 15 June 1995
to BS 1695 : Part 2 : 1990

Urological catheters
Part 2. Specification for sterile, single-use urethral catheters of
the Tiemann, whistle tip, 3-way and haematuria types

Revised text

Clause 3 Finish

In line 3, after 'irregularities' insert 'when examined by normal or corrected vision'.

AMD 8660/June 1995

Contents

	Page
Committees responsible	Inside front cover
Foreword	3
Specification	
1 Scope	6
2 Definitions	6
3 Finish	6
4 Freedom from particulate contamination	6
5 Gauge size	6
6 Tip	6
7 Drainage eyes	10
8 Balloon	12
9 Shaft	12
10 Funnels	12
11 Marking of catheters	13
12 Packaging	14
13 Marking of packages	14
14 Biological hazard	15
Appendices	
A Guidance on design and materials	16
B Summary of schedule of performance tests	17
C Method for determining gauge size of catheter	18
D Method for determining the security of the tip to the shaft of the catheter	18
E Method for determining occlusion of drainage eyes and leakage from balloon	19
F Method for determining inflation lumen leakage and/or valve function and/or balloon deflation	21
G Method for determining flow rate of drainage and irrigation lumens	22
H Method for determining the resistance of the drainage lumen of haematuria catheters to collapse or to occlusion under reduced pressure	23
J Method for determining the integrity of the junction between the drainage funnel and the shaft of the catheter	25
K Method for determining the security of fit of the drainage funnel	25
L Method for determining the integrity of the junction between the inflation and irrigation funnels and the shaft of the catheter	26
M Method for determining the security of fit of the irrigation funnel	28
N Symbol for 'Do not re-use'	28
P Method for determining the toxicity of catheters to cells in culture	29

	Page
Tables	
1	Range of catheter sizes 11
2	Balloon test volume percentage recovery 12
3	Balloon capacities 13
4	Tip lengths 13
5	Shaft and funnel dimensions 13
6	Average flow rates 14
7	Requirements for load test 21
8	Balloon test capacities 21
9	Conditions for preparing extracts for cytotoxicity testing 29
Figures	
1	Typical Tiemann catheter without balloon 7
2	Typical Tiemann catheter with balloon 7
3	Typical whistle tip catheter without balloon 8
4	Typical whistle tip catheter with balloon 8
5	Typical 3-way catheter with balloon 9
6	Typical haematuria catheter with balloon 9
7	Typical cross-sectional configurations of catheter shaft and designation of lumen dimensions 10
8	Apparatus and general arrangement for testing security of catheter tip 20
9	Apparatus for flow rate test 22
10	Apparatus and general arrangement for test of resistance of the drainage lumen of haematuria catheters to collapse or to occlusion under reduced pressure 24
11	Test connector and general arrangement for testing security of fit of the drainage funnel 26
12	General arrangement for testing the integrity of the junction between the inflation and irrigation funnels and the shaft of the catheter 27
13	ISO symbol 'Do not re-use,' Registration No. ISO 7000/1051 28

Foreword

This Part of BS 1695 has been prepared under the direction of the Health Care Standards Policy Committee and covers urethral catheters of the Tiemann, whistle tip, 3-way and haematuria types.

BS 1695 was first published in 1950 at the request of the British Association of Urological Surgeons and the Royal College of Surgeons of England in order to standardize the quality and design of the more commonly used types of flexible urinary catheter and to bring uniformity into the gauge system for size and the system of identification marking. BS 1695 was first revised in 1981, when the opportunity was taken to limit the standard solely to sterile catheters for single use, and to introduce requirements for catheters made of plastics materials. BS 1695 was revised again in 1986, when the standard was divided into Parts dealing separately with the main types of catheter, the first to be published being Part 1 which covered Nélaton and Foley catheters. Part 1 was subsequently revised in 1990. Consideration is being given to the preparation of further Parts.

This Part of BS 1695, which is the second Part to be published, applies to Tiemann, whistle tip, 3-way and haematuria catheters and contains requirements for haematuria catheters (of sizes 18 Ch to 24 Ch), this type of catheter not having hitherto been covered by BS 1695.

Some of the other more notable differences between this Part of BS 1695 and the requirements for Tiemann, whistle tip and 3-way catheters that were given in the withdrawn BS 1695 : 1981 are as follows.

(a) A method of assessing the toxicity of the catheter is introduced. In the past, catheters have been implicated in the occurrence of urethral strictures and much research in the UK and abroad has been devoted to establishing any link between urethral strictures and catheter cytotoxicity. Work has been proceeding separately in the Technical Committee responsible for BS 5736 towards developing a suitable test method for cytotoxicity of medical devices. This method has been adopted by the Technical Committee responsible for BS 1695 and a suitable extraction procedure has been developed so as to permit the application of this method to urethral catheters.

A method of test for urinary catheters based on the toxicity of a catheter extract to cells in culture was published in Australian standard AS 2696 : 1984¹⁾. In the UK, BSI Technical Committee HCC/26/1 'Toxicity tests for medical rubber and plastics' has developed a broadly similar method of determining toxicity to cells in culture which is published as BS 5736 : Part 10, although this is not specific to urethral catheters.

BS 5736 : Part 1 suggests that tests for intracutaneous reactivity and sensitization be applied to urinary catheters. There are at present insufficient data to allow numerical acceptance criteria for these properties to be specified in this Part of BS 1695. Therefore, although it is recommended that these tests be performed and the results evaluated by a toxicologist in accordance with BS 5736 : Part 1, performing the tests is not a requirement of this Part of BS 1695.

(b) A number of changes have been made to reflect current practice and usage. The catheter size is designated by both the Charrière gauge size and the equivalent external metric diameter. Regarding Tiemann catheters, the 10 Ch (3.3 mm) size without balloon has been deleted, as have the 15 Ch (5 mm) and 21 Ch (7 mm) sizes with and without balloon, and a 26 Ch (8.7 mm) size has been added. Regarding whistle tip catheters, the 8 Ch (2.7 mm), 9 Ch (3 mm) and 10 Ch (3.3 mm) sizes without balloon have been deleted, as have the 15 Ch (5 mm) and 21 Ch (7 mm) sizes with and without balloon, and 28 Ch (9.33 mm) and 30 Ch (10 mm) sizes have been added. Regarding 3-way catheters, the

¹⁾ Published by the Standards Association of Australia (SAA) and available from BSI Sales Department, BSI, Linford Wood, Milton Keynes MK14 6LE.

15 Ch (5 mm) and 21 Ch (7 mm) sizes have been deleted and a 14 Ch (4.7 mm) size has been added. Improved or additional methods of test have been introduced for the strength and performance of the catheter. The drainage eye dimensions have been revised to allow high flow rates whilst retaining adequate tip rigidity. The standard no longer specifies stylets for use with catheters.

(c) In BS 1695 : 1981, whilst balloon volumes of 3 mL, 5 mL, 20 mL or 30 mL over a range of catheter sizes were specified, no recommendations were given as to the volume of sterile water which, following insertion of the catheter, should be used to inflate the balloon to ensure its retention within the bladder. No account was taken of the volume of the inflation lumen, which represents a significant proportion of the total volume particularly with the smaller balloon sizes. This led to doubt in clinical practice of the actual volume of water which should be used to ensure effective inflation. For example with a 5 mL balloon, the inflation lumen can have a capacity of 2 mL and thus, if 5 mL of water is used to inflate the balloon, the nett fill volume will only be 3 mL. This results in under-inflation of the balloon, with the attendant risk of the catheter failing to remain in the bladder.

In the absence of any instructions on the correct fill-volume in BS 1695 : 1981, either users compensated by using an arbitrarily chosen fill-volume of greater than the balloon capacity, or manufacturers stated on their product labelling the recommended volume to be used for inflation. In the latter case, there have been several examples where a volume range was recommended, leaving it again to the user to make the final choice. In both cases there was a risk of balloon rupture resulting from over-inflation.

This lack of guidance, not unexpectedly, led to confusion amongst users and manufacturers as to the volume necessary for effective inflation, and the opportunity has been taken to clarify the situation.

For the purpose of this Part of BS 1695 the specified balloon capacities that have been selected for correct inflation of the balloon take the volume of the inflation lumen into account (see 2.1). This will ensure effective retention of the catheter in the bladder for purposes of urine drainage and blood clot removal.

Where BS 1695 : 1981 specified a balloon capacity of 5 mL, this revision specifies a capacity of 10 mL. However, owing to the redefinition of 'balloon capacity' to include the volume of the inflation lumen, the capacity (and hence size) of the corresponding balloons in this revision and BS 1695 : 1981 are similar. Indeed, in the case of catheters that were in production in 1981 and in compliance with BS 1695 : 1981, it is expected that no redesign of the balloon will be required. The ratio of the volume of the inflation lumen to that of the balloon in 20 mL and 30 mL balloon sizes is sufficiently small not to necessitate redesigning these balloon sizes, and no change has been made from BS 1695 : 1981. Balloon capacities are required to be stated in the product labelling and these values thus also represent the recommended fill-volume.

For example, a nominal balloon size of 5 mL in accordance with BS 1695 : 1981 would have had a variety of recommended fill volumes stated on the product label. The balloon is now described as a 10 mL balloon, and inflation with 10 mL water will therefore take account of the volume of the inflation lumen, and result in the balloon being adequately inflated for retention purposes.

The catheters should be manufactured and sterilized in accordance with the recommendations given in the *'Guide to good manufacturing practice for sterile medical devices and surgical products'*¹⁾.

¹⁾ Published by the Department of Health and Social Security and available from HMSO, 49 High Holborn, London WC1. ISBN 0 11 320770 0.

Figures 1 to 7 are for the purpose of illustrating the relevant dimensions and terms but do not otherwise form part of this standard.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

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

Specification

1 Scope

This Part of BS 1695 specifies dimensions and performance for sterile, single-use, flexible urethral catheters of the following types:

- (a) urethral catheters with and without balloons, of the following types:
 - (1) Tiemann;
 - (2) whistle tip;
- (b) urethral catheters with balloons, of the following types:
 - (1) 3-way;
 - (2) haematuria.

Other types of urethral catheters, suprapubic and ureteric catheters are not covered by this Part of BS 1695.

NOTE 1. Guidance on design and materials is given in appendix A.

NOTE 2. A schedule of performance tests is given in appendix B.

NOTE 3. The titles of the publications referred to in this Part of BS 1695 are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 1695 the following definitions apply.

NOTE. Designation of dimensions and nomenclature are shown in figures 1 to 7.

2.1 balloon capacity

The volume of liquid to be introduced into the catheter in order to fill the inflation channel and inflate the balloon when *in situ* in the bladder.

2.2 shaft

The tubular portion of the catheter excluding the tip, balloon and the funnel(s).

3 Finish

The shaft of the catheter, the tip, drainage eyes and the balloon shall be smooth and free from surface irregularities.

NOTE. Particular attention should be paid to avoiding design configurations that could cause discomfort to the patient.

4 Freedom from particulate contamination

Catheters shall appear clean and free from extraneous matter when examined by normal or corrected vision.

5 Gauge size

5.1 Gauge size designation

The size of the catheter shall be designated by the Charrière gauge system and by the equivalent nominal external diameter of the shaft expressed in millimetres.

NOTE. The Charrière gauge system of measurement is based on the external diameter of the shaft gauged in steps of thirds of a millimetre, the Charrière gauge size being three times the external diameter expressed in millimetres.

5.2 Gauge size determination

The gauge size of the catheter shall be determined by the method given in appendix C.

5.3 Gauge size range

The range of sizes shall be as given in table 1.

6 Tip

6.1 The tip of the catheter shall be rounded except where a terminal eye is present.

NOTE. The tip may be reinforced by fabric or by other means.

6.2 If the tip of the catheter is produced in a separate production process and subsequently affixed to the shaft, it shall be smoothly blended with the shaft.

When tested by the method given in appendix D the tip shall not become detached from the shaft and neither shall there be any sign of failure of any adhesive bond.