

Urological catheters

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

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the Nélaton and Foley types

Revised text

Clause 3 Finish

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

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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 Nélaton and Foley types. It is a revision of BS 1695 : Part 1 : 1986, which is withdrawn.

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 major types of catheter, the first to be published being Part 1 which covered Nélaton and Foley catheters. The opportunity was taken to designate the catheter size by both Charrière gauge and the metric equivalent, to reduce slightly the range of catheter sizes covered, to revise the drainage eye dimensions so as to allow high flow rates whilst maintaining tip rigidity, to redesignate balloon sizes and fill volumes and to delete requirements for stylets. The changes to balloon size and fill volumes are also incorporated in BS 1695 : Part 2, and a full account of the reasons for the changes is given in the foreword to that standard.

Attention is drawn to BS 1695 : Part 2, which covers Tiemann, whistle tip, 3-way and haematuria catheters. Consideration is being given to the preparation of the further Parts.

The purpose of this revision of BS 1695 : Part 1 is to bring it up-to-date by incorporating the new features introduced in BS 1695 : Part 2 : 1990, the chief of these being the method of assessing the toxicity of the catheter. 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 of 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.

The other differences between this edition and BS 1695 : Part 1 : 1986 are that the tolerance on the external diameter of the catheter has been deleted (being implicit at ± 0.33 mm because of the method of determining size) and that the ISO symbol 'Do not re-use' is optionally permitted on the package labelling.

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

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⁾

Figures 1 and 2 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.

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

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 without balloons, of the Nélaton type;
- (b) urethral catheters with balloons, of the Foley type.

Other types of urethral catheter, 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. 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, 2 and 3.

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 B.

5.3 Gauge size range

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

Table 1. Range of catheter sizes

Designated size		Nominal external diameter	Internal dimensions		
Charrière	Metric equivalent		Minimum cross-sectional area of all shapes of lumen	Minimum diameter of circular lumens	Minimum minor dimension of non-circular lumens ¹⁾
Ch	mm	mm	mm ²	mm	mm
8	2.7	2.66	0.64	0.9	0.9
10	3.3	3.33	0.95	1.1	1.1
12	4.0	4.0	1.54	1.4	1.3
14	4.7	4.66	2.27	1.7	1.6
16	5.3	5.33	3.46	2.1	1.9
18	6.0	6.0	4.91	2.5	2.2
20	6.7	6.66	6.61	2.9	2.5
22	7.3	7.33	9.08	3.4	2.8
24	8.0	8.0	11.94	3.9	3.1
26	8.7	8.66	15.06	4.4	3.4
28	9.3	9.33	18.86	4.9	3.7
30	10.0	10.0	22.90	5.4	4.0

¹⁾ Measured as shown in figure 3. Dimension *x*.