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Australian Standard®

Medical equipment—Single-use urethral catheters (sterile) for general medical use

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STANDARDS AUSTRALIA

This Australian Standard was prepared by Committee HT/1, Hypodermic and Other Equipment for General Medical Use. It was approved on behalf of the Council of Standards Australia on 6 June 1989 and published on 13 November 1989.

The following interests are represented on Committee HT/1:

Australian Chamber of Commerce

Australian Medical Association

Australian Medical Devices and Diagnostics Association

Department of Community Services and Health

Department of Health, N.S.W.

Department of Veterans Affairs

Government Supply Department, N.S.W.

Hospitals and hospital associations

Additional interests participating in preparation of Standard:

Urological Society of Australasia

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PREFACE

This Standard was prepared by the Standards Australia Committee on Hypodermic and Other Equipment for General Medical Use, under the direction of the Health Technology Standards Board to supersede the 1984 edition.

The revision was considered necessary because of practical problems encountered in areas such as sampling, testing and balloon symmetry.

This Standard applies only to certain types of urinary catheters which are introduced through the urethra, which are considered to be in widespread general use, and which have been carefully selected from the large variety currently available. Although other types of catheters may still be used, adherence to the types covered by the Standard would simplify the inventories of manufacturers and hospitals, yet still provide an adequate range for most purposes.

The Standard allows for the use of 'ml', 'cm^3' or 'cc' for expressing the rated balloon capacity (see Clause 10.1(c)) as all types of catheters are presently imported and 'cc' is well understood in the medical industry.

In the preparation of this Standard, account was taken of BS 1695:1986, *Urological catheters,* Part 1: *Specification for sterile, single-use urethral catheters of the Nelaton and Foley types.*

Statements expressed in mandatory terms in Notes to Tables and Figures are deemed to be requirements of this Standard.

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STANDARDS AUSTRALIA

Australian Standard

Medical equipment—Single-use urethral catheters (sterile) for general medical use

1 SCOPE. This Standard specifies requirements for sterile, single-use urethral catheters intended to be introduced through the urethra into the urinary bladder.

NOTE: Materials to be used for the construction of sterile urethral catheters for single-use are not specified in detail as their selection will depend, to some extent, upon the design, process of manufacture and method of sterilization employed by the individual manufacturers.

2 REFERENCED DOCUMENTS. The following documents are referred to in this Standard:

AS
1094 Single-use syringes (sterile) for general medical use
1600 Medical equipment—Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment
1600.1 Part 1: General requirements

BS
5736 Evaluation of medical devices for biological hazards
Part 4: Method of test for intracutaneous reactivity of extracts from medical devices
Part 6: Methods of test for sensitization; assessment of the potential of medical devices to produce delayed contact dermatitis

Therapeutic Goods Order No. 11, Standard for Sterile Therapeutic Goods

3 CLASSIFICATION. For the purpose of this Standard, urethral catheters are classified into two types as follows:

(a) *Type I—Urethral catheters without balloon.* Type I classification includes the following sub-types:
(i) Nelaton, Jaques or other 'ordinary' basically cylindrical urethral catheters.
(ii) Whistle tip urethral catheters.
(iii) Tiemann urethral catheters.

(b) *Type II—Urethral catheters with self-retaining balloon.* Type II classification includes the following sub-types:
(i) Foley type urethral catheters (a Nelaton 'ordinary' basically cylindrical urethral catheter with balloon).
(ii) Whistle tip urethral catheters with balloon.
(iii) Tiemann urethral catheters with balloon.

4 DEFINITIONS. For the purpose of this Standard, the definitions below apply.

4.1 Urethral catheter—a device for the drainage of fluids from the urinary bladder and urethra or for inserting fluids into the bladder.

4.2 French gauge—a designation system indicating the external circumference of the catheter.

NOTES:
1. The French gauge system of measurement is based on the external diameter of the shaft gauged in steps of thirds of a millimetre, the French gauge size being 3 times the external diameter expressed in millimetres.
2. French gauge is also known as Charriere gauge and commonly abbreviated as F, FG, Fr or Ch.

4.3 Tip end—the end of a urethral catheter which is furnished with one or more drainage eyes communicating with the catheter lumens.

4.4 Drainage eye—the aperture at the tip end of the catheter for passage of fluids.

4.5 Shaft—the main length of tubing excluding the tip end.

4.6 Free end—the end of the catheter opposite to the tip end.

4.7 Lumen—the space(s) enclosed by the (internal) walls of the catheter.

4.8 Size—expressed as French gauge (see Clause 4.2) and may include the metric equivalent external diameter of the shaft.

4.9 Unit—the catheter.

4.10 Unit pack—a pack containing a single unit.

4.11 Multiple pack—a pack containing a number of unit packs.

4.12 Store pack—a pack containing one or more multiple packs.

4.13 Balloon—an integral portion of the catheter designed for inflation and deflation, generally for use as a retention device.

4.14 Rated capacity of balloon—the capacity of the balloon or that capacity plus an additional volume designated by the manufacturer.

4.15 'Shall' 'Should' and 'May'—

4.15.1 *Shall*—indicates that a statement is mandatory.

4.15.2 *Should*—indicates a recommendation.

4.15.3 *May*—indicates the existence of an option.

5 SIZE. When determined in accordance with Appendix A, the size of the catheter (dimension '*D*' in Figures 1, 2, 3 and 6) shall be in accordance with Table 1, appropriate to the nominal French gauge size and within the tolerances specified therein.

6 MATERIALS.

6.1 General. The catheter shall be made of a plastics material or of natural or synthetic rubber or elastomer, or of a combination of components made from any of these materials. The catheter shall meet the requirements of this Standard after storage in accordance with the manufacturer's recommended storage conditions.