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Australian Standard 2696—1984

MEDICAL EQUIPMENT—
SINGLE-USE URETHRAL CATHETERS (STERILE) FOR GENERAL MEDICAL USE

[Title allocated by Defence Cataloguing Authority:
CATHETER, URETHRAL (Sterile, Single-use)]

PUBLISHED BY THE STANDARDS ASSOCIATION OF AUSTRALIA
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The following interests are represented on Committee MD/1:

Australian Chamber of Commerce

Australian Dental Standards Laboratory

Australian Medical Association

Australian Medical Devices and Diagnostics Association

Confederation of Australian Industry

Department of Defence

Department of Veterans Affairs

Department of Health

Hospitals and Hospital Associations

New South Wales Government Stores Department

Pharmaceutical Association of Australia

Representatives of the following interest also participated in the drafting of this standard:

Urological Society of Australasia

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PREFACE

This standard was prepared by the Association's Committee on Hypodermic and Other Equipment for General Medical Use, under the direction of the Medical Materials and Equipment Standards Board.

In the preparation of the standard, account was taken of BS 1695, Catheters, and its draft revision.

The standard applies only to certain types of urinary catheters which are introduced through the urethra, and which are considered to be in widespread general use and 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 committee was aware of the fact that there are problems associated with long term use, compatibility and rigidity of the catheter.

The diagrams illustrate a typical catheter for the purpose of defining the relevant dimensions and terms but the illustrated design of the catheter does not form part of the standard unless specifically stated as such.

Some facilities required for the testing of materials for compliance with this standard are available at the Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067.

An illustrated document describing the various types of catheter referred to in this standard is in process of preparation by the Urological Society of Australasia, and it is envisaged that this will be published in 1984.

CONTENTS

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard

for

MEDICAL EQUIPMENT—SINGLE-USE URETHRAL CATHETERS (STERILE) FOR GENERAL MEDICAL USE

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

NOTES:

1. 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. Advisory information on sampling and assessing compliance with this standard is given in Appendix F.

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

AS 1094 Single-use Syringes (Sterile) for General Medical Use

AS 1600 Conical Fittings with 6 percent (Luer) Taper for Hypodermic and Other Surgical Equipment*

AS 2070 Plastics Materials for Food Contact Use

BS 3574 Recommendations for the Storage of Vulcanized Rubber
United States Pharmacopoeia XIX.

3 CLASSIFICATION. For the purpose of this standard, catheters are classified into two types in acordance with the following:

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

(b) *Type II—Urethral catheters with self-retaining balloon.* Type II classification comprises 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.
   (iv) Gibbon urethral catheters with balloon.

4 DEFINITIONS. For the purpose of this standard, the following definitions apply:

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

4.2 French gauge (also known as Charriere gauge and commonly abbreviated as F, Fr or Ch)—a system indicating the external circumference of the catheter, in millimetres.

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

4.4 Eye—the aperture at the tip end of the catheter.

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 enclosed by the (internal) wall of the catheter.

4.8 Size—the nominal external circumference of the shaft, expressed in millimetres (and commonly referred to as French or Charriere gauge (symbols F, Fr or Ch)).

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, for use as a retention device.

4.14 Nominal capacity of balloon—the minimum balloon capacity at which the catheter is designed to function satisfactorily.

4.15 Rated capacity (maximum) of balloon—the nominal capacity of the balloon or the nominal capacity plus an additional volume designated by the manufacturer.

5 TOLERANCE ON SIZE. When measured 75 mm from the tip end, the external circumference of the catheter shall be in accordance with Table 1, appropriate to the nominal French size and within the tolerances specified therein.

NOTE: For catheters with balloons, the size measurement should not be made over or in close proximity to the balloon.

6 SIZE RANGE. The size range of catheters shall be in accordance with Table 1.

7 MATERIALS.

7.1 General. The catheter shall be made of a suitable plastics material or of natural or synthetic rubber or elastomers, or of a combination of components made from any of these materials, and shall not become soft and sticky or harden excessively when used or during storage prior to use.

*In course of preparation.