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RE-USABLE HYPODERMIC NEEDLES FOR GENERAL MEDICAL USE

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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Associated Chambers of Manufactures of Australia
Australian Chamber of Commerce
Australian Dental Standards Laboratory
Australian Institute of Surgical and Dental Technicians
Australian Medical Association
Australian and State Departments of Health
Department of Defence
Department of Repatriation
Hospitals and Hospital Associations
N.S.W. Government Stores Department
Pharmaceutical Association of Australia

This standard, prepared by Committee MD/1, Hypodermic and Other Equipment for General Medical Use, was approved on behalf of the Council of the Standards Association of Australia on 21 June 1976, and was published on 1 January 1977.

To keep abreast of progress in Industry, Australian standards are regularly reviewed. Suggestions for improvements to published standards, addressed to the head office of the Association, are welcomed.

AUSTRALIAN STANDARD SPECIFICATION

RE-USABLE HYPODERMIC NEEDLES FOR GENERAL MEDICAL USE

AS 1945—1976

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PREFACE

This standard was prepared under the direction of the Association's Medical Materials and Equipment Committee as a revision and metrication of AS T42—1969, which it accordingly supersedes.

The standard is one of a series being prepared by the Committee on Hypodermic and Other Equipment for General Medical Use. Other standards in the series are:

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 1679 Glass Syringes (Luer Fitting) for General Medical Use

AS 1946 Single-use Hypodermic Needles (Sterile) for General Medical Use.

In the preparation of this standard, account has been taken of ISO R596, Hypodermic Needles.

The committee responsible for preparing this standard decided that four sizes would be adequate for general use in medical practice. The needles, ranging in size from 0.50 to 1.00 mm (25 to 19 SWG) in nominal external diameter, are mounted with the Luer-lock hub conforming to the requirements of AS 1600.

A standard is being prepared for sharpened hypodermic needle tubing ranging in size from 0.31 to 2.24 mm (30 to 13 SWG). This will ensure that in all specifications incorporating needle tubing, the requirements will be standardized.

In place of the SWG designations of the external diameters in AS T42, this standard has adopted the R20 series of diameters in millimetres as in AS 1153. This avoids the confusion that can arise from expressing nominal diameters in round numbers derived from one-tenth or one-hundredth of the diameter in millimetres. With the change-over from the old SWG designations to the R20 series of diameters, a nominal external diameter of 1.10 mm is an acceptable alternative, until 1 November 1981, to the nominal 1.00 mm diameter specified in Table 1.

A new approach has been made to the values obtained for the test for stiffness. It was found that many of the values previously specified were well beyond the elastic limit and produced a large degree of permanent set. Tests for this standard were performed on a testing machine with automatic graphing. The values for central bending force and maximum deflection in Table 2 have been determined from the elastic limit and in most cases are quite different from those prescribed in previous specifications.

A new appendix has been included describing the method to be used for determining dead space.

Facilities for testing for compliance with this standard are available at the Australian Dental Standards Laboratory, 18 Lonsdale Street, Melbourne, Vic. 3000.

This standard makes reference to the following standards:

AS 1153 Preferred Metric Sizes of Ferrous and Non-ferrous Round Wire for General Engineering Purposes

AS 1444 Wrought Alloy Steels of the AISI-SAE H and Standard Steels Types

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

AS 1679 Glass Syringes (Luer Fitting) for General Medical Use

AS G18 Wrought Alloy Steels of the BS 970 En Series Type.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard Specification for RE-USABLE HYPODERMIC NEEDLES FOR GENERAL MEDICAL USE

1 SCOPE. This specification applies to re-usable hypodermic needles mounted with a Luer (6 percent taper) conical socket*, and ranging in size from 0.50 to 1.00 mm (25 to 19 SWG) in nominal external diameter and intended for general use in medical practice.

2 DEFINITIONS. For the purpose of this specification, the following definitions apply:

Length of needle — the exposed length of the needle tube as measured from the tip of the point to the joint with the hub.

Point (also known as the bevel) — the end of the needle tube which has been bevelled and sharpened.

Angle of point — the angle θ, of the line from the point to the junction of the initial bevel and the full tube diameter, as illustrated in Fig. 1.

Hub (also known as the mount) — the component for attachment of the needle to the syringe.

Bore (also known as the lumen) — the internal cylindrical space in the needle tube.

Unit — a needle which may be protected by a sheath and a cap.

Multiple package — the package which contains a number of units.

3 DESIGNATION AND DIMENSIONS OF NEEDLES. The designation and dimensions of needles in the range appropriate to this specification shall conform to the dimensions given in Table 1. The tolerance on nominal lengths shall be ± 1.0 mm for the 0.50 mm needle size, and ± 1.5 mm for the 0.63, 0.80 and 1.00 mm needle sizes.

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