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SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

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The following interests were represented on the committee responsible for the preparation of this standard:

Australian Chamber of Commerce

Australian Dental Standards Laboratory

Australian Diabetes Society

Australian Medical Association

Commonwealth and State Departments of Health

Confederation of Australian Industry

Diabetes Federation of Australia

Hospitals and Hospital Associations

New South Wales Government Stores Department

Pharmacy Guild of Australia

AUSTRALIAN STANDARD

SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

AS 1615—1983

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PREFACE

This edition of this standard was prepared by the Association's Committee on Hypodermic Equipment for Insulin Injection under the direction of the Medical Materials and Equipment Standards Committee, to supersede AS 1615—1980.

Unlike the 1980 edition, this standard specifies three sizes of needle, i.e. 0.45 mm, 0.40 mm and 0.36 mm in external diameter and not longer than 20 mm in length, to accommodate the range of needle sizes available to diabetics. Provision has been made for the colour coding of the needle hub, and the labelling requirements have also been changed.

It is recognized that the physical strength of the needle tubing is dependent on composition and tubing dimensions as well as performance tests as required in Clause 5.5. For these reasons, it may be possible to reduce the testing specified in Clause 5.5 in a future revision.

Facilities for testing for compliance with this standard are available at the Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

1 SCOPE. This standard specifies requirements for sterilized individually packed hypodermic needles intended for use once only solely for the injection of insulin. The needle tubes are 0.45 mm, 0.40 mm and 0.36 mm in nominal external diameter.* The needles have the 6 percent (Luer) fitting.

NOTE: Advisory information on sampling and assessing for compliance with this standard is given in Appendix O.

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

AS 1077	Single-use 1 mL Syringes (Sterile) for the Injection of 100 Units per Millilitre Insulin (U-100)
AS 1094	Single-use Syringes (Sterile) for General Medical Use
AS 1157	Methods of Testing Materials for Resistance to Fungal Growth Part 7—Resistance of Papers and Paper Products to Surface Fungal Growth
AS 1386	Cleanrooms and Work-stations
AS 1444	Wrought Alloy Steels—AISI-SAE Standard, Hardenability (H) and Stainless Series
AS 1600	Conical Fittings with 6 percent (Luer) Taper for Hypodermic and Other Surgical Equipment†
AS 1946	Single-use Hypodermic Needles (Sterile) for General Medical Use†
AS 2134	Code of Practice for the Chemical Analysis of Materials by Flame Atomic Absorption Spectroscopy
AS 2506	Wrought Alloy Steels—En Series

and the British Pharmacopoeia, the European Pharmacopoeia and the United States Pharmacopoeia.

3 DESCRIPTION OF NEEDLE. The essential components of the needle are the needle tube and the hub. One end of the needle tube is bonded in the hub; the other end of the needle tube is bevelled and sharpened to form the point. The hub is hollow, forming a socket into which the nozzle of a syringe can be fitted. The space enclosed by the wall of the needle tube is termed the lumen.

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

4.1 Unit—a needle with any sheath attached in accordance with Clause 15.1 and any attached hub cover, as illustrated in Fig. 1.

4.2 Unit pack—a pack containing a single unit.

4.3 Multiple pack—a pack, not being a store pack, containing two or more unit packs.

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

4.5 Water—purified water of the British Pharmacopoeia.

4.6 Needle sheath—the removable protective cover.

4.7 Bore—the internal diameter of the needle tube.

5 REQUIREMENTS FOR NEEDLE TUBE.

5.1 Composition. The needle tube shall be made of stainless steel which is either—

(a) one of the austenitic steels specified in Table 2.2.2 of AS 1444; or

(b) one of the austenitic steels specified in Table 2.1.1 of AS 1444.

5.2 Appearance. When the needle is examined without magnification and with magnification of about 10×—

(a) the needle tube shall appear straight, cylindrical, and of uniform wall thickness;

(b) the outside surface of the needle shall appear smooth and clean and shall exhibit no corrosion, pitting, tool marks, sinks, voids, or stress marks;

(c) the inside surface of the needle tube shall exhibit no corrosion, no extraneous matter other than a film of lubricant, and no obstruction to the flow of liquid; and

(d) the pointed end of the needle tube shall appear sharp and strong, shall exhibit smooth sharpened surfaces on at least three aspects, and shall exhibit no barbs, hooks, feathered edges or other defects.

5.3 Resistance to Corrosion. When the needle is tested in accordance with Appendix A, the needle tube shall not show signs of corrosion.

5.4 Dimensions.

(a) The length of the needle (dimension A in Fig. 1) shall be within ±2 mm of the length stated by the manufacturer, but in any case shall be not longer than 20 mm.

(b) The nominal external diameter and bore shall be in accordance with Table 1.

(c) The angle of the point (angle θ in Fig. 2) shall be not greater than 15 degrees and not less than 9 degrees.

*Formerly 26, 27 and 28 SWG.
†In course of revision.