

Australian Standard[®]

**HYPODERMIC EQUIPMENT—
SINGLE-USE NEEDLES
(STERILE) FOR GENERAL
MEDICAL USE**

This Australian standard was prepared by Committee MD/1, Hypodermic and Other Equipment for General Medical Use. It was approved on behalf of the Council of the Standards Association of Australia on 3 January 1984 and published on 1 March 1984.

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Australian Chamber of Commerce
Australian Dental Standards Laboratory
Australian Medical Association
Australian Medical Devices and Diagnostics Association
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PREFACE

This edition of 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, to supersede AS 1946—1976.

The scope of the standard has been extended to cover needles of 0.45, 0.71, 0.90 and 1.25 mm nominal external diameters. Additional appendices deal with tests for particulate contamination, pyrogens and toxicity.

It has not yet been possible to develop an objective performance test for ease of penetration which is also relevant to in-use conditions. This is because the ease of tissue penetration is determined by a number of factors, including needle gauge, whether the needle is siliconized, the point configuration and the degree of drag following penetration of surface membranes.

Although this standard covers single-use needles for general medical use, the standard is also generally applicable to reusable needles for general medical and insulin injection, particularly in regard to physical characteristics. For this reason and the fact that reusable needles are used in very limited numbers, a separate standard for such needles is not deemed necessary.

Certain 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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CONTENTS

| | <i>Page</i> |
|--|-------------|
| SPECIFICATION | |
| 1 Scope | 4 |
| 2 Referenced Documents | 4 |
| 3 Description of Needle | 4 |
| 4 Definitions | 4 |
| 5 Requirements for Needle Tube | 5 |
| 6 Requirements for Hub | 5 |
| 7 Joint of Needle Tube with Hub | 5 |
| 8 Dead Space | 5 |
| 9 Extractable Metals | 7 |
| 10 Pyrogens | 7 |
| 11 Toxicity | 7 |
| 12 Sterilization | 7 |
| 13 Sterility | 7 |
| 14 Particulate Contamination | 7 |
| 15 Packaging | 7 |
| 16 Labelling | 7 |
| APPENDICES | |
| A Method of Testing Needles for Resistance to Corrosion | 9 |
| B Method for Testing Stiffness of Needle | 10 |
| C Method for Testing Resistance of Needle to Bending | 11 |
| D Method for Testing Elastic Recovery of Needle | 13 |
| E Method of Testing Hub for Cleanliness | 15 |
| F Method for Testing Watertightness of Joint Between Needle Tube and Hub | 16 |
| G Method for Testing Strength of Joint Between Needle Tube and Hub | 17 |
| H Method for Determining Dead Space in Needles | 18 |
| J Method for Determining Extractable Metals in Needles | 19 |
| K Method of Testing Needles for Pyrogens | 20 |
| L Method of Testing Needles for Toxicity | 21 |
| N Method of Testing Needles for Particulate Contamination | 25 |
| O Method of Test for Leakage of Unit Pack | 27 |
| P Assessment of Compliance | 28 |

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard

for

HYPODERMIC EQUIPMENT—SINGLE-USE NEEDLES (STERILE) FOR GENERAL MEDICAL USE

1 SCOPE. This standard specifies requirements for sterilized individually packed hypodermic needles intended for use once only. The needle tubes are from 0.45 mm to 1.25 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 P.

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 2070 Plastics Materials for Food Contact Use
- AS 2134 Code of Practice for the Chemical Analysis of Materials by Flame Atomic Absorption Spectroscopy

Munsell Atlas

British Pharmacopoeia

European Pharmacopoeia

United States Pharmacopoeia

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

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 Point—the end of a needle tube which has been bevelled and sharpened for hypodermic use.

4.3 Heel—the position at which the bevelling of the point of the needle tube commences.

4.4 Angle of point—the angle between the linear axis and the line joining the point to the heel of a needle tube.

NOTE: The angle of point is shown as θ in Fig. 2.

4.5 Water—Purified Water as specified in the British Pharmacopoeia.

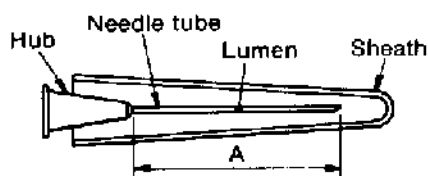


Fig. 1. TYPICAL HYPODERMIC NEEDLE WITH SHEATH, FOR SINGLE USE (DIAGRAMMATIC)

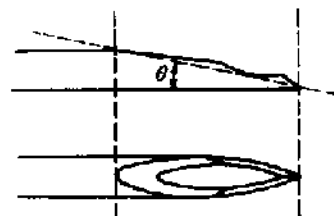


Fig. 2. TYPICAL POINT OF NEEDLE TUBE—ENLARGED VIEW