AS 2385—1990

Australian Standard®

Single-use (sterile) infusion sets for general medical use

This Australian Standard was prepared by Committee HT/6, Transfusion Equipment for Medical Use. It was approved on behalf of the Council of Standards Australia on 6 February 1990 and published on 15 October 1990.

The following interests are represented on Committee HT/6:

Australian Chamber of Commerce
Australian Medical Devices and Diagnostics Association
Australian Red Cross Society
Australian Society of Anaesthetists
Department of Administrative Services, N.S.W.
Department of Community Services and Health
Department of Health, N.S.W.
Department of Health, Qld.
Health Department, W.A.
Royal Australasian College of Surgeons
Royal College of Pathologists of Australasia
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PREFACE

This Standard was prepared by the Standards Australia Committee on Transfusion Equipment for Medical Use, under the direction of the Health Technology Standards Board, to supersede AS 2385—1980.

Unlike the previous edition, tests for reducing (oxidizable) matter, metal ions, non-volatile residue, absorbance, haemolytic effects, intracutaneous reactivity and alkylene oxide gas residues are included. The test for toxicity has been replaced by a test for cytotoxicity, the pyrogen test has been altered to allow the use of the *Limulus amoebocyte lysate* (bacterial endotoxins) test, and the requirements for the closure piercing device have been altered. This edition also offers a choice of drip rates.

CONTENTS

FOREWORD

Two types of infusion sets are included in this Standard, one suitable for the administration of blood, blood derivatives and intravenous solutions, and the other for the administration of intravenous solutions only. The set for the administration of blood and blood products requires a piercing device as specified in this Standard to fit the outlet port of a plastics blood container. A simpler and cheaper piercing device would suffice for the set for administering intravenous solutions. Further, the filter for the blood and the solution sets have the same performance characteristics, but the filter for the solution set may be of a much smaller area than that for the blood set.

Wherever possible, stress has been laid on performance requirements rather than dimensional requirements so as to allow as much variation in design as possible without inhibiting innovation. For example, the Standard allows for sets with separate drip chambers and filter chambers and for sets with combined drip and filter chambers.

In regard to the measurement of particulate contamination in giving sets, preliminary investigations have indicated that accuracy of estimation of the number of particles is dependent on a number of experimental variables. Consequently the particulate contamination test described in Appendix I should be considered only as an interim test pending further investigations.

STANDARDS AUSTRALIA

Australian Standard

Single-use (sterile) infusion sets for general medical use

1 SCOPE This Standard specifies requirements for single-use sterile intravenous infusion sets intended for general medical use. It covers sets suitable for blood, blood derivatives and other intravenous fluids in general, and also sets suitable only for use with fluids containing no solid phase. The sets are intended to be restricted to one patient and not to be re-used.

The Standard does not apply to certain types of sets for paediatric use or other sets such as microdrip sets, pump sets and sets fitted with a central venous pressure monitoring device. Requirements for devices for intravenous insertion—whether catheter, needle or cannula—are also not included.

NOTE: The infusion sets covered in this Standard may not be suitable for the administration of platelet concentrates.

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

AS
1094 Single-use syringes (sterile) for general medical use
1444 Wrought alloy steels—Standard and Hardenability (H) Series
1600 Medical equipment—Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment
1600.1 Part 1: General requirements
1946 Hypodermic equipment—Single-use needles (sterile) for general medical use
2134 Recommended practice for chemical analysis by atomic absorption spectrometry
2134.1 Part 1: Flame atomic absorption spectrometry
2134.2 Part 2: Graphite furnace spectrometry
2193 Methods for calibration and grading of force-measuring systems of testing machines
2506 Wrought alloy steels—En series

CK 19 Code of recommended practice for the chemical analysis of materials by ultraviolet visible spectrophotometry

BS
5736 Evaluation of medical devices for biological hazards
Part 4: Method of test for intracutaneous reactivity of extracts from medical devices

British Pharmacopoeia (BP), 1988, Vol 2, Appendix XIVK, pA 183

United States Pharmacopoeia (USP) XXII Monograph 85

Proposed Standard for particulate matter in large volume injections, Therapeutic Goods Act 1972

Therapeutic Goods Order No 11, Standard for sterile therapeutic goods
Guideline on validation of the *Limulus amoebocyte* test as an end-product endotoxin for human and parenteral drugs, biological products and medical devices (FDA), U.S.A.

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

3.1 Set—a single-use sterile intravenous infusion set, including any air-inlet assembly and intravenous injection device provided with the set, but excluding the end protectors.

3.2 Blood set—a set suitable for use with blood, blood derivatives and intravenous fluids in general.

3.3 Solution set—a set suitable only for intravenous fluids containing no solid phase.

3.4 Closure-piercing device—component for perforating the closure of a container of an intravenous fluid and connecting the set to the container.

3.5 Drip chamber—chamber, other than a drip-filter chamber, containing a drip tube and constructed so as to enable the rate of flow of fluid through the set to be observed.

3.6 Filter chamber—chamber, other than a drip-filter chamber, containing a blood or fluid filter.

3.7 Drip-filter chamber—chamber containing a drip tube and a blood or fluid filter, and constructed so as to enable the rate of flow of fluid through the set to be observed.

3.8 Drip tube—tube protruding into a drip chamber or drip-filter chamber at the inlet end.

3.9 Blood filter—porous material placed across a chamber of a blood set to remove clots or aggregates from blood.

3.10 Fluid filter—porous material placed across the liquid pathway of a solution set as a safeguard against the inadvertent use of blood with the set.