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Australian Standard 2385—1980

SINGLE-USE (STERILE) INFUSION SETS FOR GENERAL MEDICAL USE

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

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

Australian Chamber of Commerce

Australian Dental Standards Laboratory

Australian Red Cross Society

Australian Society of Anaesthetists

Commonwealth and State Departments of Health

Confederation of Australian Industry

Department of Defence

Department of Veterans Affairs

Royal Australasian College of Surgeons

Royal College of Pathologists of Australia

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AUSTRALIAN STANDARD

SINGLE-USE (STERILE) INFUSION SETS FOR GENERAL MEDICAL USE

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PREFACE

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

The standard has been prepared to establish minimum acceptable quality and performance levels for intravenous infusion sets for general medical use and to ensure compatibility of use with containers for blood, blood derivatives and intravenous solutions. The standard does not cover 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.

The committee considered that two types of infusion sets should be included, 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 which must fit the outlet port of a plastics blood container. A simpler and cheaper piercing device would suffice for the set for administration of intravenous solutions. Further, the filter for the blood and the solution sets must have the same performance characteristics, but the filter for the solution set may be of 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 chamber and filter chamber and for sets with combined drip and filter chambers.

The equipment covered by the standard is intended to be restricted to one patient and not be re-used. Attention is also drawn to the fact that the equipment may not be suitable for the administration of platelet concentrates, and that specifications for devices for intravenous insertion, whether catheter, needle or cannula are not included.

In regard to the measurement of particulate contamination of 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 J should be considered only as an interim test pending further investigations.

In the preparation of this standard account was taken of the following publications:

ISO/R1135 Transfusion Equipment for Medical Use

BS 2463 Specification for Transfusion Equipment for Medical Use

New Zealand Department of Health Standard, Disposable Infusion Equipment, March 1974

BS Draft Standard 76/64169 Transfusion Equipment for Medical Use (revision of BS 2463)

This standard requires reference to the following Australian standards:

AS 1077 Single-use Syringes (Sterile) for the Injection of 100 Units per Millilitre Insulin (U-100)

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

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 1615 Single-use Needles (Sterile) for Insulin Injection

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

AS 2070 Plastics Materials for Food Contact Use

AS 2134 Code of Practice for the Chemical Analysis of Materials by Flame Atomic Absorption Spectroscopy

AS 2193 Methods for Calibration and Grading of Force-measuring Systems of Testing Machines

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

AS T25 Rubber Closures for Injectable Products.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard for 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.

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

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

2.1 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.

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

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

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

2.5 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.

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

2.7 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.

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

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

2.10 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.

2.11 Delivery tube — length of flexible tubing connecting the adaptor and a chamber of the set.

2.12 Adaptor — male conical fitting for connecting an intravenous injection device to the set.

2.13 Injection site — section or branch of the set intended for the injection of additives into the fluid pathway.

2.14 Flow regulator — device for controlling and stopping the flow of fluid through the set.

2.15 Connecting tube — flexible tubing other than the delivery tube, connecting components of the set.

2.16 Intravenous injection device — a hypodermic needle or other tubular device for connecting the set to the vein of a patient.

2.17 Air-inlet assembly — device for introducing filtered air into a container of intravenous fluid during the passage of fluid through the set.

2.18 Air filter — material placed across the air pathway of an air-inlet assembly for removing microorganisms from air passing through the assembly.

2.19 Air needle — component of an air-inlet assembly for perforating the closure of a container of intravenous fluid and connecting the assembly to the container.

2.20 End protectors — removable covers protecting the pointed ends and preventing access of microorganisms to the ends and inside of the set.

2.21 Unit — a set with end protectors attached.

2.22 Unit pack — pack containing a single unit.

2.23 Store pack — pack containing two or more unit packs.

3 MATERIALS.

3.1 General. The materials from which the set is made shall, under normal conditions of general medical use—

(a) not have any deleterious effect on blood, blood derivatives, other intravenous fluids, or substances added to blood or intravenous fluids before or during passage through the set; or

(b) not produce any local reaction or general toxic reaction in the recipient of fluids passed through the set; and

(c) comply with the appropriate part(s) of AS 2070 for plastics materials for food contact use. The use of any plastics material not specified by the appropriate parts of AS 2070 for food contact use shall, in the first instance, be referred to the appropriate Regulatory Authority for evaluation. In addition, the plastics materials used shall be able to withstand the sterilization procedure used.

3.2 Liquid Pathway. Any metal in the liquid pathway of the set shall be stainless steel which is either—

(a) one of the martensitic steels specified for the the En 56 series in AS G18 or one of the