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(JMED/JSA)

**Sterile blood transfusion set**

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## Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3212 : 2005** is replaced with this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, or utility model right which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public or utility model right which has the said technical properties.

# Sterile blood transfusion set

## Introduction

This Japanese Industrial Standard has been prepared based on the third edition of ISO 1135-4 published in 2004 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

## 1 Scope

This Standard specifies the sterile blood transfusion sets for the transfusion of blood preparations such as preserved blood (hereafter referred to as “transfusion sets”) that are ready to use and single-use.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 1135-4:2004 *Transfusion equipment for medical use—Part 4: Transfusion sets for single use* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

JIS T 3212: 2005 may be applied until July 28 in 2014.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

JIS T 0307 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

NOTE : Corresponding International Standard : ISO 15223 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* and Amendment 1 (IDT)

JIS T 0993-1 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

NOTE : Corresponding International Standard : ISO 10993-1: 2003 *Biological evaluation of medical devices—Part 1: Evaluation and testing* (IDT)

JIS T 3209 :2011 *Sterile injection needles*

NOTE : Corresponding International Standard : ISO 7864:1993 *Sterile hypodermic needles for single use* (MOD)

JIS T 3222 : 2011 *Sterile winged intravenous devices*

JIS T 3320 : 2011 *Sterile stopcocks for single use*

ISO 594-1 :1986 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1 : General requirements*

ISO 594-2 :1998 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2 : Lock fittings*

ISO 3696 :1987 *Water for analytical laboratory use—Specification and test methods*

### 3 Terms and definitions

For the purpose of this Standard, the following definitions apply.

#### 3.1 nominal number of drops

number of drops corresponding to 1 ml indicated on cover or container of the transfusion set

#### 3.2 capability to re-seal

property to be free from leakage of liquid when a needle is removed after puncturing the injection site

For non-needle injection site, it means bulb sealing property after removing the male part specified by the manufacturer.

#### 3.3 purified water

purified water specified in Official Monographs of Part II of Japanese Pharmacopoeia or purified water being at least equivalent thereto in quality

#### 3.4 endotoxin test water

water prepared according to water for injection specified in Official Monographs of Part II of Japanese Pharmacopoeia or the other procedures, not responsive to the detection limit of Lysate (LAL) reagent used for endotoxin test

#### 3.5 primary container

packaging directly covering the transfusion sets to keep sterility of the transfusion set

The packaging is relevant to a so-called inner bags if a further secondary container is used. However, some may not keep sterility, in which case a protective cap shall keep sterility inside the transfusion set.

#### 3.6 secondary container

packaging directly covering the primary container and generally containing multiple transfusion sets packaged in the primary container, for example 50 sets

**3.7 bottle needle**

a needle used for piercing the blood preparation container

**3.8 filter**

a filter to filter blood preparations

**3.9 drip chamber**

a tube for observation of drips

**3.10 drip tube**

a part through which the transfusion drips into the drip chamber

**3.11 burette**

a tube made of hard or slightly hard colourless transparent plastic materials, capable of measuring and storing a given quantity of transfusion preparation

**3.12 duct**

a tube introducing blood preparations into the body

**3.13 male and female conical fittings**

parts capable of connection and separation between tools by tapers or other structures

**3.14 protective cap**

a cap for preventing direct contact of a bottle needle and a male conical fitting with ambient for air

**3.15 air-inlet device**

a needle introducing air into the blood preparation container if a hard container is used

**3.16 flow regulator**

a tool for controlling the flow rate of transfusion

**3.17 switching device**

a tool to open or close the lumen of duct

**3.18 injection site**

a part through which drugs are injected during transfusion

**3.19 joint tube**

a tool used for connecting the duct, and the male and female conical fittings, etc.

**3.20 three-way cock**

a drug injection site capable of changing the flow path, which is connected to transfusion set by male and female conical fittings or by other methods

### 3.21 multi-way cock

multiple injection sites capable of changing the flow path, which are connected to transfusion set by male and female conical fittings or by other methods

### 3.22 backflow preventive valve

a valve which prevents backflow of the blood preparation

### 3.23 intravenous needle

a needle for administering a blood preparation by puncturing blood vessel

### 3.24 winged needle

a needle equipped with a wing for administering a blood preparation by puncturing blood vessel, which is connected to transfusion set by male and female conical fittings or by other methods

### 3.25 extension tube

tubular tool used for elongation of duct, which is connected to transfusion set by male and female conical fittings or by other methods

## 4 Configuration

Transfusion set is mainly composed of a bottle needle, a drip chamber (some may be integrated with a bottle needle or equipped with a burette), a duct, a flow regulator, a male conical fitting and a protective cap. In addition, an air-inlet device (some may be integrated with the bottle needle), a filter, an injection site (some may be non-needle system capable of mixing transfusion without using a needle), a three-way cock, a multi-way cock, a backflow preventive valve, an intravenous needle (including a winged needle), an extension tube may be optional.

In addition, the transfusion sets are available in two types: that by gravity feed and that by pump.

Figure 1 illustrates a typical transfusion set, figure 2 illustrates typical components of transfusion set and figure 3 illustrates a typical burette.

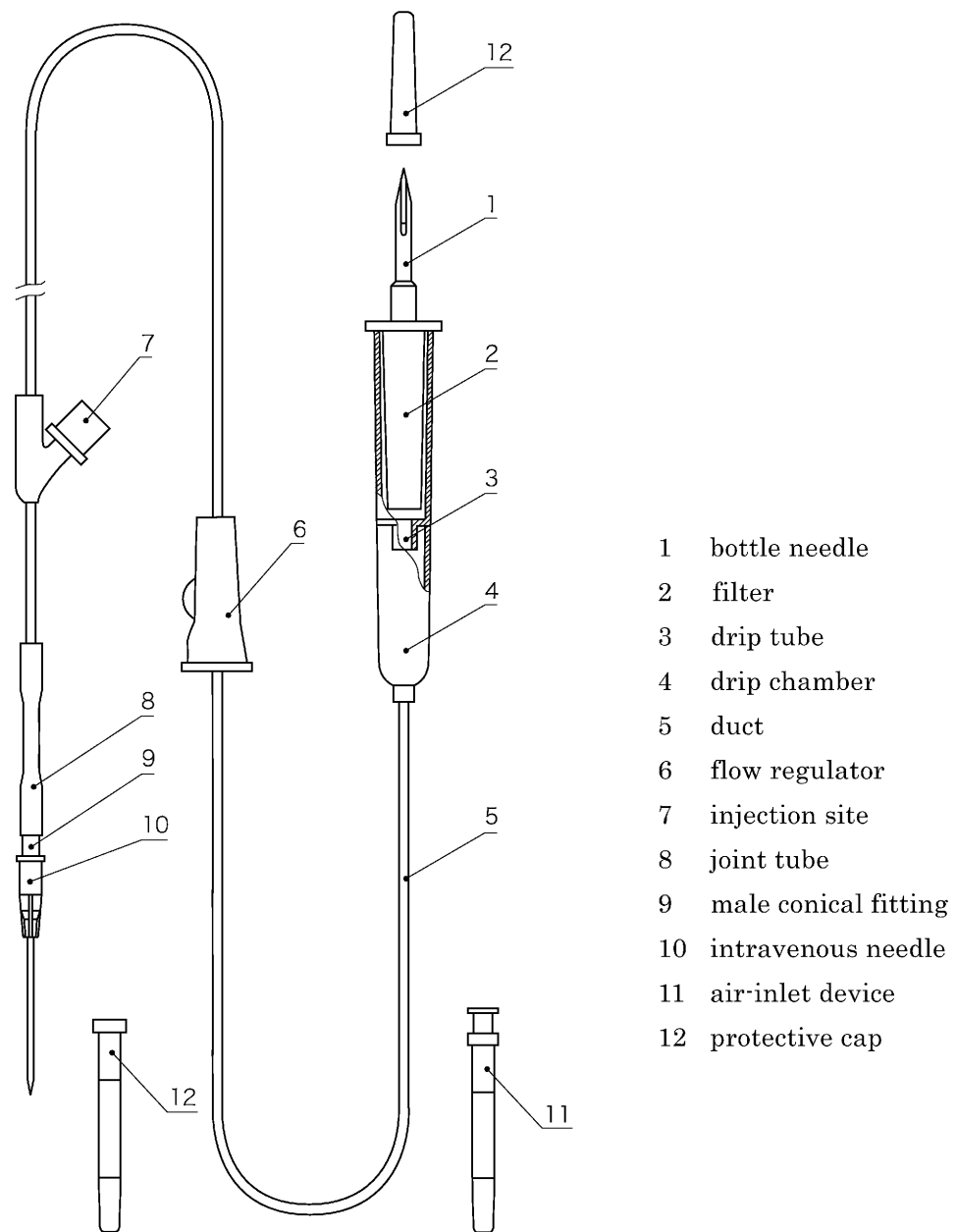
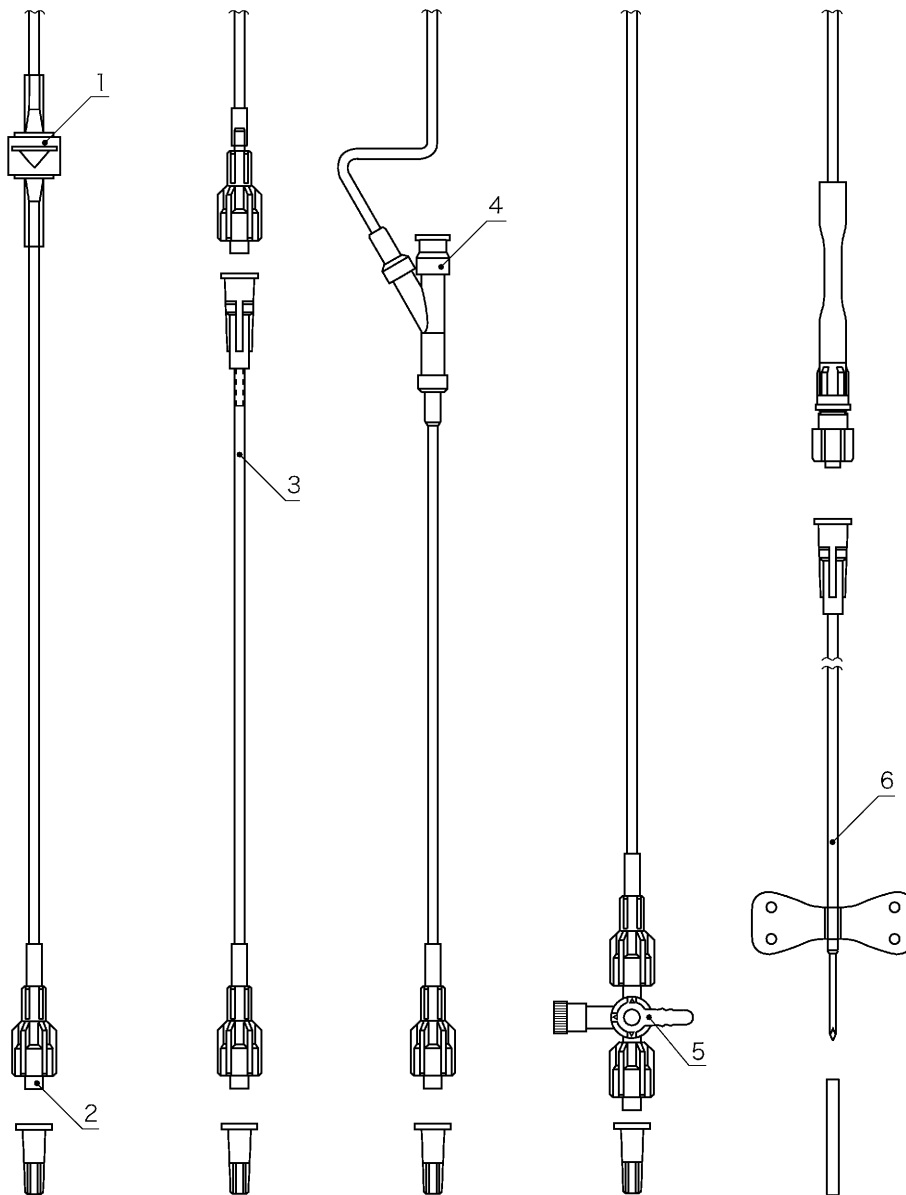


Figure 1 Configuration of typical transfusion set (Example)



- |                             |                                    |
|-----------------------------|------------------------------------|
| 1 backflow preventive valve | 4 injection site (non-needle type) |
| 2 male conical fitting      | 5 three-way cock                   |
| 3 extension tube            | 6 winged needle                    |

**Figure 2 Components (Example)**