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Sterile infusion administration 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 3211 : 2005 is replaced with this Standard.

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Sterile infusion administration set

Introduction

This Japanese Industrial Standard has been prepared based on the third edition of **ISO 8536-4** published in 2004, the second edition of **ISO 8536-5** published in 2004, and the first editions of **ISO 8536-8**, **ISO 8536-9** and **ISO 8536-10** published in 2004 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions underlined with dots in this Standard are the matters in which the contents of the corresponding International Standards have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies sterile infusion administration sets for infusing infusion solution (hereafter referred to as “infusion sets”) which are ready to use and for single use.

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

ISO 8536-4:2004 *Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed*

ISO 8536-5:2004 *Infusion equipment for medical use—Part 5: Burette infusion sets for single use, gravity feed*

ISO 8536-8:2004 *Infusion equipment for medical use—Part 8: Infusion equipment for use with pressure infusion apparatus*

ISO 8536-9:2004 *Infusion equipment for medical use—Part 9: Fluid lines for use with pressure infusion equipment*

ISO 8536-10:2004 *Infusion equipment for medical use—Part 10: Accessories for fluid lines for use with pressure infusion equipment* (Overall evaluation : 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 3211 : 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 editions of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply. For those without the indication of the year, the most recent edition (including amendments) shall 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 3219 : 2011 *Sterile infusion filter*

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 terms and definitions apply:

3.1 nominal number of drops

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

3.2 resealing property

property of infusion sets to be free from leakage of liquid after its injection site is punctured with a needle and then the needle is drawn back

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

3.3 purified water

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

3.4 endotoxin test water

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

3.5 primary container

packaging directly covering the infusion set to keep sterility of the infusion set, which 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 infusion set.

3.6 secondary container

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

3.7 bottle needle

needle used for piercing the infusion container

3.8 drip chamber

chamber for observation of drops

3.9 drip tube

part through which the infusion drips into the drip chamber

3.10 burette

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

3.11 duct

tube introducing the infusion solution into the body

3.12 male and female conical fittings

part capable of connection and separation between tools by male or female tapers or other structures

3.13 protective cap

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

3.14 air-inlet device

needle introducing air into the infusion container if a hard container is used

3.15 flow regulator

tool which controls the flow rate of infusion

3.16 switching device

tool to open or close the lumen of duct

3.17 filter

filter which traps the solid mass in the infusion preparation

3.18 injection site

part through which drugs are injected during infusion

3.19 joint tube

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

3.20 three-way cock

drug injection site capable of changing the flow path, which is connected to the infusion set by the conical fitting or other method

3.21 multi-way cock

cock having multiple injection sites capable of changing the flow path, which is connected to the infusion set by the conical fitting or other method

3.22 backflow preventive valve

valve preventing backflow of the drug

3.23 intravenous needle

needle puncturing blood vessel and administering a drug through it

3.24 winged needle

needle equipped with a wing for administration of a drug by puncturing blood vessel, which is connected to the infusion set by the conical fitting or other method

3.25 extension tube

tubular tool used for elongation of duct, which is connected to the infusion set by the conical fitting or other method

3.26 infusion filter

a filter removing microorganisms and foreign matters, which is connected to the infusion set by the conical fitting or other method

4 Configuration

Infusion 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, male conical fittings 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 no-needle type capable of injecting without a needle), a three-way cock, a multi-way cock, a backflow preventive valve, an intravenous needle (including winged needle), an extension tube and an infusion filter, etc. may be optional.

In addition, the infusion sets are available in two types: that by gravity feed and that by pump. Figure 1 illustrates a typical infusion set, figure 2 illustrates typical components of infusion set and figure 3 illustrates a typical burette.

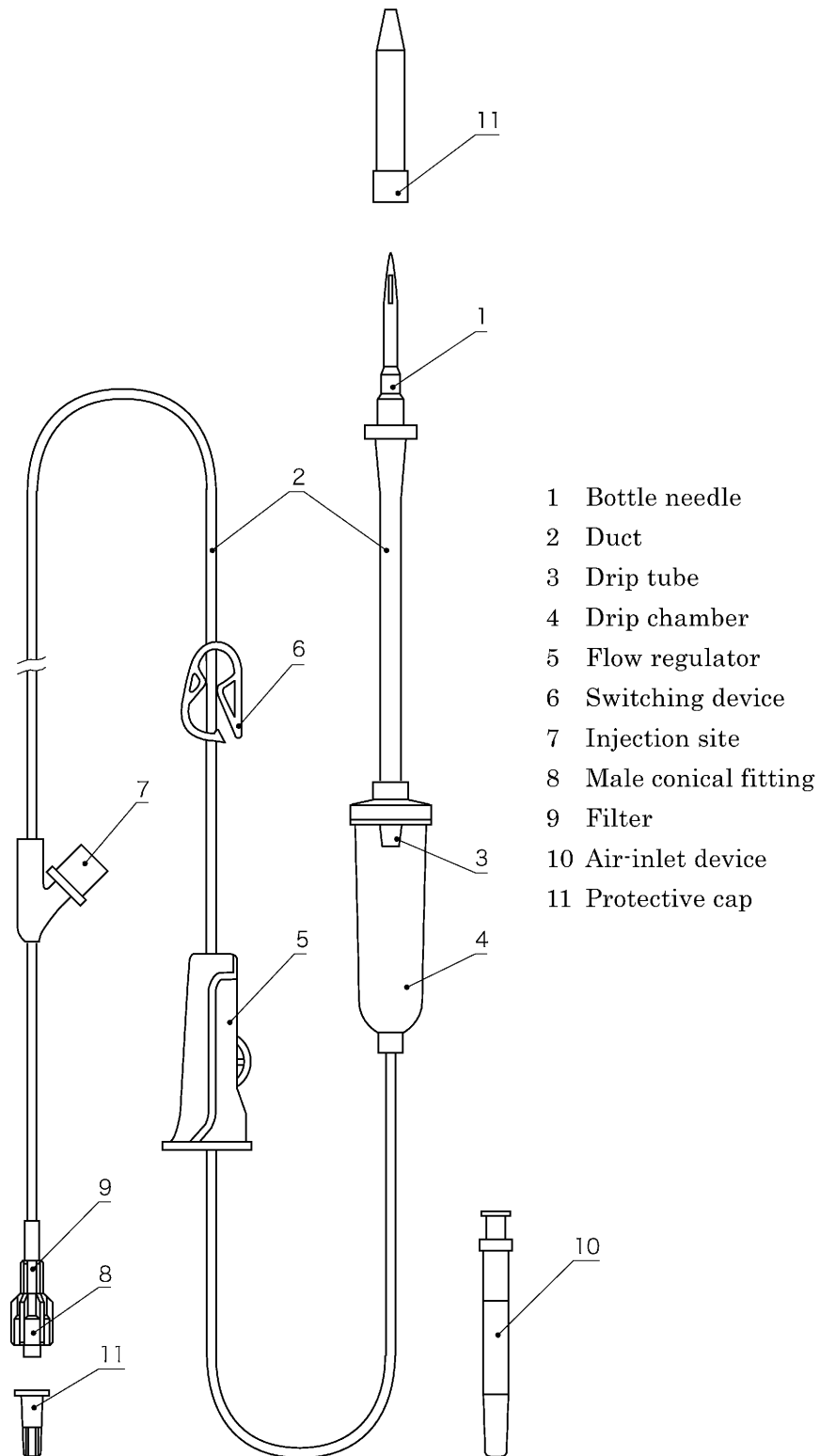
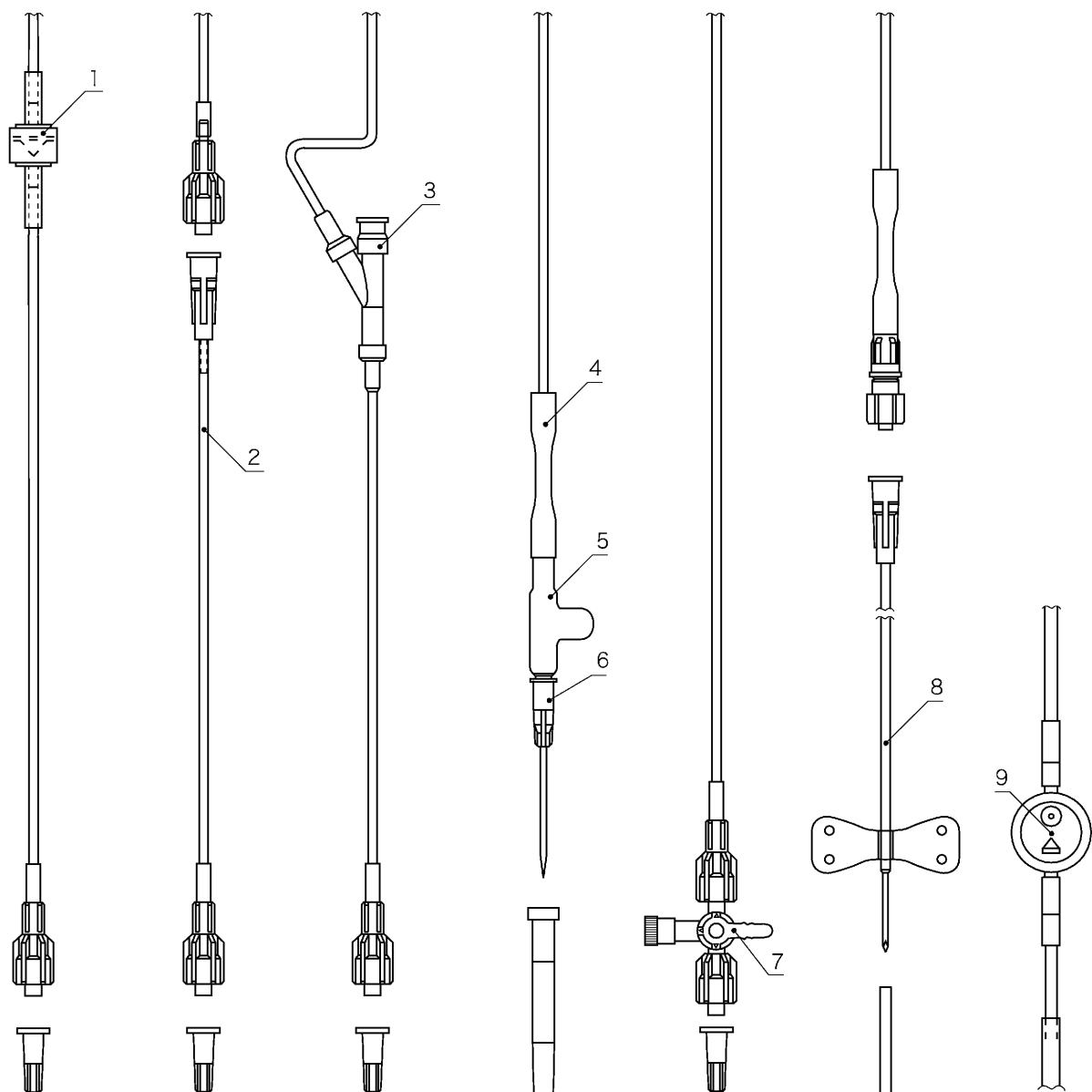


Figure 1 Configuration of typical infusion set (example)



- | | | |
|-----------------------------------|------------------------|-------------------|
| 1 Backflow preventive valve | 5 Male conical fitting | 9 Infusion filter |
| 2 Extension tube | 6 Intravenous needle | |
| 3 Injection site (no needle type) | 7 Three-way cock | |
| 4 Joint tube | 8 Winged needle | |

Figure 2 Components (example)

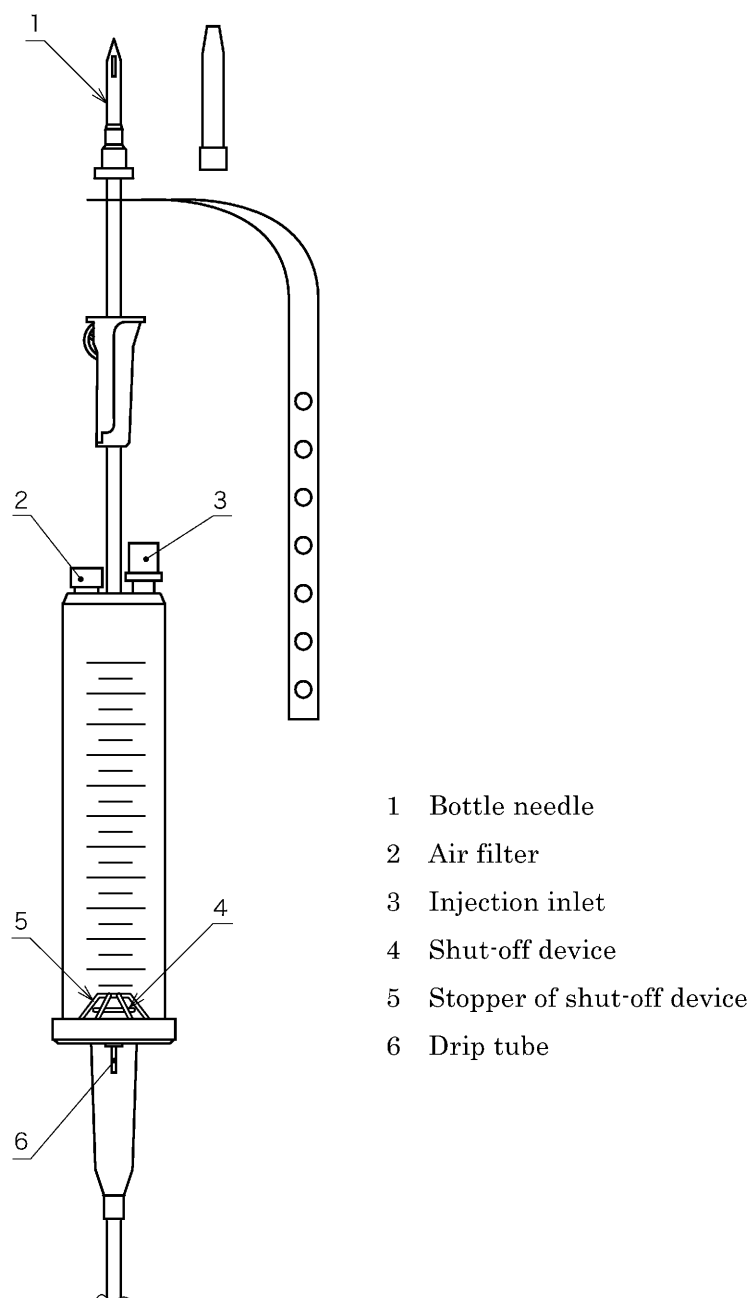


Figure 3 Typical burette (example)

5 Physical requirements

5.1 Particulate contamination

No adhesion of fine particle or foreign matter on the inside is permissible by visual inspection.

5.2 Airtightness

No air leakage shall be observed when the set is placed in water at 20 °C to 30 °C with its tip closed and air at inner pressure of 50 kPa for 15 s is introduced from the tip of bottle needle. In addition, the infusion set for pump shall have integrity sufficient to prevent ingress of microorganisms, and no leakage of air and water is permissible by a test according to A.1.1 and A.1.3 and no invasion of air is permissible by a test according to A.1.2.

5.3 Male and female conical fittings, injection site and joints of joint tube and duct

All connections shall withstand a static tensile force of not less than 15 N for at least 15 s. No water leakage shall be observed in the infusion set for pump at a connection site when tested according to A.2. However, conical fitting used for attachment and removal of intravenous needle, etc. is excluded.

5.4 Bottle needle

- a) No unevenness or damage shall be observed on the outer surface of metal needle tube of the bottle needle and the finished surface shall be smooth. In addition, the outer surface of needle tube made of other than metal materials shall be free from damage and the finished surface shall be smooth.
- b) The bottle needle shall be capable of puncturing the stopper of the infusion container without preliminary puncture.

5.5 Air-inlet device and air filter

The air-inlet device, if any, shall conform to the following specifications.

- a) The air-inlet device shall be provided with an air filter to prevent the ingress of microorganisms.
- b) When the air-inlet device integrated with the bottle needle is inserted into the infusion container, the air admitted into the container shall not become entrained in the liquid outflow.
- c) The air filter shall be fitted so that all air entering the infusion vessel passes through it and that no noticeable reduction of flow rate is caused.
- d) The air-inlet device shall be capable of puncturing the stopper of the infusion container without preliminary puncture.

5.6 Duct

The duct shall be transparent or semi-transparent so that bubbles are observable.

5.7 Filter

For apparatus having a filter, the filter shall have a uniform mesh less than 210 µm.

5.8 Drip chamber and drip tube

The drip chamber, if any, shall conform to the following specifications.