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(MTJAPAN/JSA)

**Sterile infusion administration set —
Part 4: Sterile infusion sets for single use,
gravity feed**

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Foreword

This Japanese Industrial Standard has been established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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JIS T 3211 series consists of the following 7 parts under the general title *Sterile infusion administration set* :

Part 4 : Sterile infusion sets for single use, gravity feed

Part 5 : Sterile burette infusion sets for single use

Part 8 : Sterile infusion sets for single use with pressure infusion apparatus

Part 9 : Sterile fluid lines for single use

Part 10 : Sterile accessories for fluid lines for single use

Part 11 : Sterile infusion filters for single use

Part 12 : Sterile check valves for single use

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Sterile infusion administration set — Part 4 : Sterile infusion sets for single use, gravity feed

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8536-4** : 2010, Edition 5 and Amendment 1 : 2013 with some modifications of the technical contents to reflect the actual situation in Japan. The amendment to the said International Standard has been compiled in this Standard.

The vertical lines on both sides of the text and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements for single use, gravity feed sterile infusion sets for medical use (hereafter referred to as infusion sets).

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

ISO 8536-4 : 2010 *Infusion equipment for medical use — Part 4 : Infusion sets for single use, gravity feed* and Amendment 1 : 2013 (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**.

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 be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent edition (including amendments) shall be applied.

JIS T 0993-1 : 2012 *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process*

NOTE Corresponding International Standard : **ISO 10993-1** *Biological evaluation of medical devices — Part 1 : Evaluation and testing within a risk management process* (MOD)

JIS T 3209 *Sterile injection needles*

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

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

ISO 14644-1 *Cleanrooms and associated controlled environments — Part 1 : Classification of air cleanliness by particle concentration*

ISO 15223-1 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 : General requirements*

ISO 80369-7 : 2016 *Small-bore connectors for liquids and gases in healthcare applications — Part 7 : Connectors for intravascular or hypodermic applications*

2A Terms and definitions

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

2A.1

nominal number of drops

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

2A.2

self sealing

property of an infusion set to be free from leakage of liquid after its injection site is punctured with a needle and then the needle is pulled out

For a needle-free injection site, it refers to sealing property after the male part of instrument designated by the manufacturer and supplier is pulled out.

2A.3

purified water

purified water listed in Official Monographs Class 2 of the Japanese Pharmacopoeia or that at least equivalent thereto in quality

2A.4

unit container

packaging directly covering an infusion set, which is used for maintaining its sterility

When the infusion set in unit container is further packaged in the shelf or multi-unit container, the unit container is considered as an inner bag.

2A.5

shelf or multi-unit container

packaging directly covering the unit container and generally containing multiple infusion sets, e.g. 50 sets, packaged in the unit container

2A.6

closure-piercing device

needle inserted into an infusion container

2A.7

drip chamber

chamber for observation of drips

2A.8

drip tube

part through which drops fall into the drip chamber

2A.9

burette

tube made of rigid or semi-rigid colourless transparent plastics material, which is capable of measuring and storing a given quantity of fluid

2A.10

tubing

tube which introduces fluid into the body

2A.11

male and female conical fittings

part capable of connection and separation between instruments by a male or female taper or other structures

2A.12

protective cap

cap for preventing a direct contact of a closure-piercing device or a male conical fitting with ambient air

2A.13

air-inlet device

device which introduces air into an infusion container when a hard container is used

2A.14

flow regulator

component which regulates the flow rate of fluid

2A.15

ON/OFF clamp

component used for opening and closing the lumen of tubing

2A.16

fluid filter

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component which catches solid matter in fluid

2A.17

injection site

part for administering other medicines during infusion

2A.18

joint tube

component used for connecting e.g. a tubing, and male and female conical fittings

2A.19

three-way cock

injection site capable of changing the flow path, which is connected to an infusion set by using a conical fitting or other methods

2A.20

multi-way cock

object which has multiple injection sites capable of changing the flow path, which is connected to an infusion set by using a conical fitting or other methods

2A.21

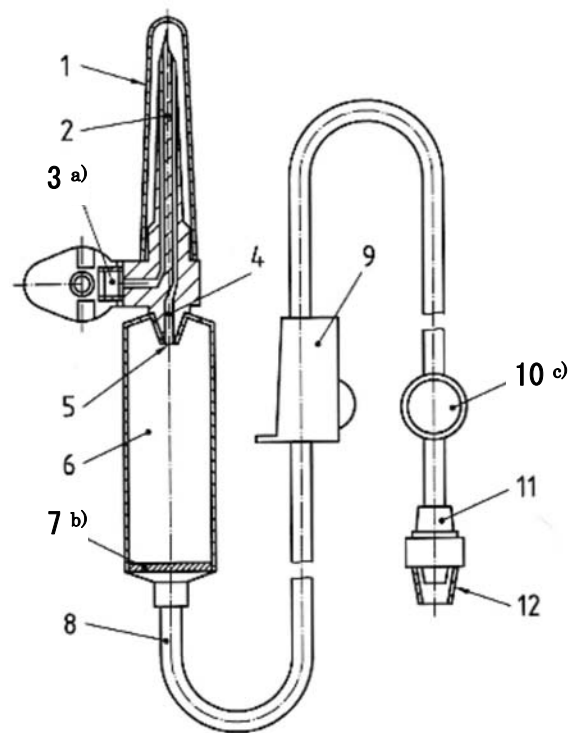
intravenous needle

needle used for injecting fluid into blood vessels

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastic containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1, shall be used for rigid containers.

3.2 The infusion set shall be provided with protective caps to maintain sterility of the closure-piercing device, male conical fitting or needle of the set until the set is used. The air-inlet device shall be provided with a protective cap over the closure-piercing device or needle.



- 1 protective cap of closure-piercing device
- 2 closure-piercing device
- 3 air inlet with air filter and closure
- 4 fluid channel
- 5 drip tube
- 6 drip chamber
- 7 fluid filter
- 8 tubing
- 9 flow regulator
- 10 injection site
- 11 male conical fitting
- 12 protective cap of male conical fitting

Notes ^{a)} Air inlet with air filter is optional.

^{b)} The fluid filter may be positioned at other sites, preferably near the patient access. Generally, the fluid filter used has a nominal pore size of 15 μm .

^{c)} The injection site is optional.

Figure 1 Example of a vented infusion set