

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 3218 : 2012

(JMED/JSA)

Central venous catheters

ICS 11.040.25

Reference number : JIS T 3218 : 2012 (E)

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T 3218 : 2012

Date of Establishment: 2005-03-25

Date of Revision: 2012-07-01

Date of Public Notice in Official Gazette: 2012-07-02

Investigated by: Japanese Industrial Standards Committee
Standards Board
Technical Committee on Medical Equipment

JIS T 3218 : 2012, First English edition published in 2013-11

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
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Printed in Japan

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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 3218 : 2005** is replaced with this Standard.

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Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, applications for a patent after opening to the public, or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, applications for a patent after opening to the public and utility model rights.

Central venous catheters

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 10555-3 published in 1996 with some modifications of the technical contents, reflecting the real conditions in Japan.

The portions with dotted underlines are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with explanations is given in Annex JE. Annex JE is not included in the corresponding International Standard.

1 Scope

This Standard specifies requirements for sterilized central venous catheters which are intended for single use for the purpose of injecting drug solution, collecting blood and/or measuring venous pressure, etc. (hereafter referred to as “catheters”), and guide wire, dilator, introducer needle, introducer tube and sheath introducer which are used for insertion and placement of catheters. However, this Standard does not apply to catheters coated with materials that originated from organisms such as heparin and urokinase in order to bring antithrombogenicity, catheters coated with antibacterial agent in order to have antibacterial effect, or imbition type catheters and catheters with oxygen saturation determination function.

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

ISO 10555-3 : 1996 *Sterile, single-use intravascular catheters—Part 3 : Central venous catheters* (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 3218 : 2005 may be applied until June 30th, 2015.

2 Normative references

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

JIS T 0307 : 2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

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

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 a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2 : Lock fittings*

ISO 7886-1 : 1993 *Sterile hypodermic syringes for single use—Part 1 : Syringes for manual use*

ISO 11070 : 1998 *Sterile, single-use intravascular catheter introducers*

3 Terms and definitions

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

3.1 central venous catheter

intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements

NOTE : The catheter may have a fixation system which is part of the device.

3.2 distal end

end of the catheter to be inserted further into the patient, viewing from operators

3.3 proximal end

end of the catheter on the opposite side of the distal end, which is also referred to as an access end

3.4 hub

connector, which is integrated into catheters, or which is sure to be connected with the proximal end of catheters

NOTE : Connectors on the proximal parts, integrated into dilator, introducer needle or introducer tube, or surely connected with the proximal ends of such devices, are also referred to as hubs.

3.5 effective length (*l*)

length of the catheter which can be inserted in the inside of the body (see figure 1)

3.6 outside diameter

maximum diameter of catheter which can be inserted into blood vessel

3.7 junction

part for connection between catheters and branching tubules

Single-lumen tube can be changed to multilumen tube by using it.

3.8 guide wire

flexible device passing through catheter or dilator in order to make it easy to insert catheter or dilator into blood vessel and indwell them (see figure 2)

NOTE : Guide wires have the following types : the type formed previously like J-shaped guide wire, and the fixed type core guide wire or the movable core wire, as shown in figure 2. Or, some guide wires may be coated with lubricant so as to make the insertion easy.

3.9 dilator

flexible tubular medical devices used for dilation of tissues from percutaneous opening part through blood vessel (see figure 3)

3.10 introducer needle

rigid tube with sharp end used to insert guide wires or catheters into blood vessel (see figure 4)

3.11 introducer tube

a tube that is used generally with an introducer needle passing through a cavity of tube and that is retained by removing an introducer needle after puncture

After insertion of a guide wire, some types of tubes can be torn manually (see figure 4).

3.12 sheath introducer

a medical device used for realizing a route for insertion into a body, that covers a dilator usually to be inserted

It is a flexible tube that can insert a catheter and the like into a body after removing a dilator (see figure 5).

3.13 coil

wire rolled spirally outside the guide wire

3.14 core wire

wire used for internal core for the purpose of making guide wire strong

3.15 safety wire

supplementary wire used for preventing the tip part of a guide wire from dropping out

3.16 tip

extremity of the distal end of the catheter, etc.

4 Configuration and name of each part

The configuration examples and names of each part of typical catheters and introducer kits are shown in figures 1 to 5.

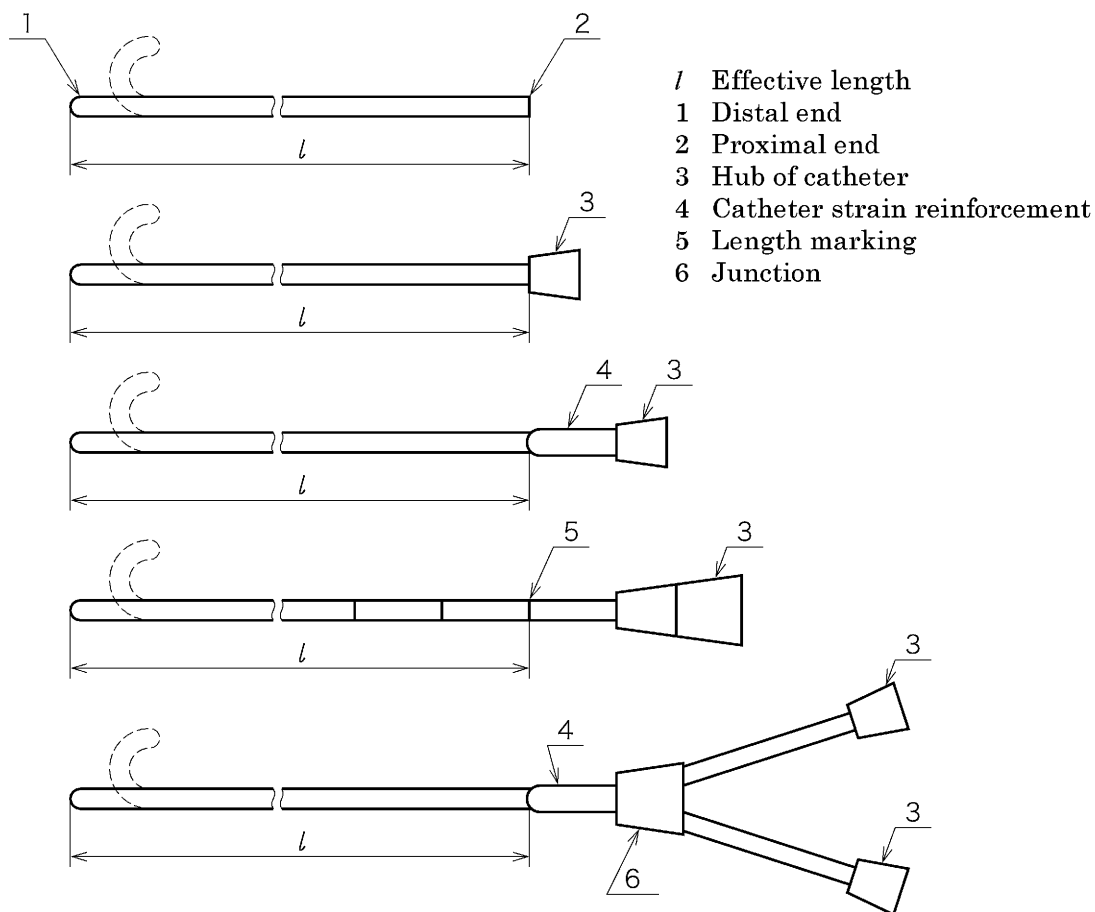


Figure 1 Example of catheter

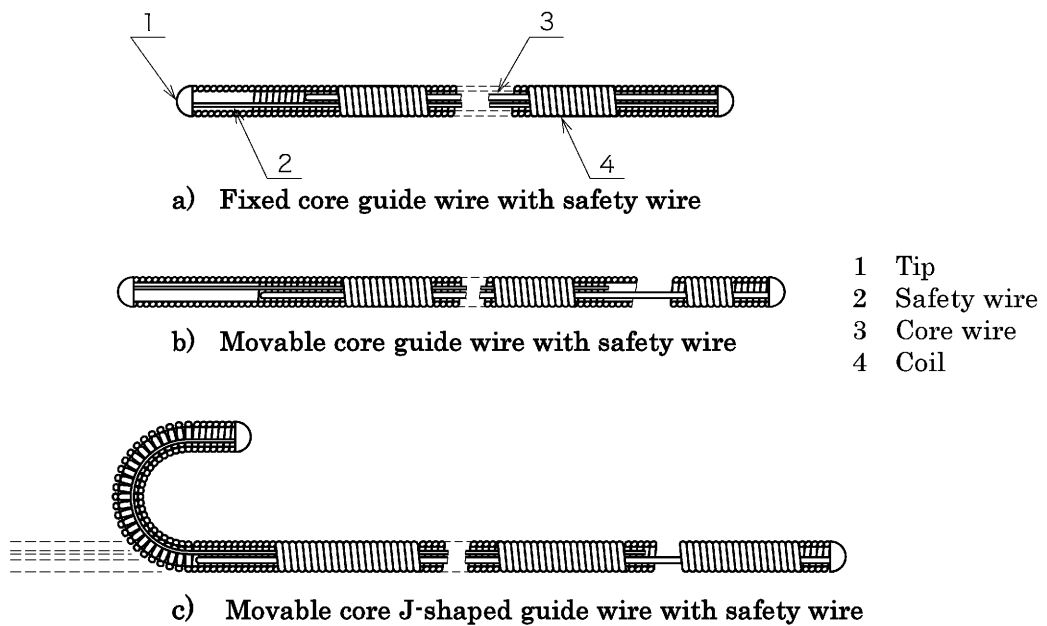


Figure 2 Example of guide wire