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**Sterile, single-use intravascular
catheters over-needle peripheral
catheters**

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In the event of any doubts arising as to the contents,
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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 3223 : 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, single-use intravascular catheters over-needle peripheral catheters

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 10555-5 published in 1996 and Amendment 1 published in 1999 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 in this Standard 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 sterile, single-use catheters (hereafter referred to as “catheters”), intended for accessing the peripheral vascular system.

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

ISO 10555-5:1996 *Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters* and Amendment 1 :1999 (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 3223 : 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 G 4305 : 2005 *Cold-rolled stainless steel plate, sheet and strip*

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

JIS T 0993-1 : 2005 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

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

ISO 594-2 : 1998 *Conical fitting with 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 9626 : 1991 *Stainless steel needle tubing for the manufacture of medical devices and Amendment 1 : 2001*

ISO 10555-1:1995 *Sterile, single-use intravascular catheters—Part 1: General requirements, Amendment 1 : 1999 and Amendment 2 : 2004*

3 Terms and definitions For the purpose of this Standard, the following definitions apply:

3.1 intravascular catheter

flexible tubes intended to be placed into a peripheral vessel (including hydratable intravascular catheter)

3.2 distal end

frontal end of a catheter unit to be inserted in patient, which is the end of patient side viewed from an operator, of the catheter to be inserted

3.3 proximal end, access end

connecting end of a connectable catheter unit, which is the end of operator side viewed from an operator, of the catheter to be inserted

3.4 hub

integrated connector with a catheter or a connector at a proximal end of catheter to be securely connected with the proximal end of catheter

3.5 effective length

length of a catheter capable to be inserted in the body or each length of hydratable catheter of pre-hydration and post-hydration (see figure 1)

3.6 outside diameter

maximum diameter of a catheter capable to be inserted into the blood vessel or a maximum diameter of hydratable catheter of pre-hydration and post-hydration

3.7 hydratable catheter

catheter composed of a material exhibiting clinically significant hydration in contact with an aqueous solution

3.8 post-hydration

condition of the hydratable catheter immersed in an aqueous solution at $(37 \pm 2) ^\circ\text{C}$ for 2 h

3.9 clinically significant hydration

hydrated condition means the state just before post-hydration with 4 mm or 1 % longer effective length, whichever is the shorter, in comparison of those pre-hydration, or a state of 10 % or larger outside diameter post-hydration in comparison to pre-hydration

3.10 needle

assembly comprising a needle tube and a needle hub (see figure 1)

3.11 needle tube

rigid tube with one end sharpened to facilitate entry into body tissue

3.12 needle hub

fitting attached to the needle tube capable to observe flashback when connected with its inner lumen

3.13 vent fitting

fixed or removable fitting permitting venting of air used for restricting or preferably preventing the escape of blood

3.14 catheter unit

assembly comprising the catheter, catheter hub and any integral fittings (see figure 1)

3.15 flashback

blood flow into the needle tube or catheter when it reached blood vessel

3.16 purified water

“purified water” specified in Official Monographs of Japanese Pharmacopoeia (hereafter referred to as “JP”), or water at least equivalent thereto in quality

3.17 endotoxin test water

“water for injection” specified in Official Monographs of JP, or water prepared by the other procedure without reaction at detection limit of Lysate (LAL) reagent used for endotoxin test

4 Configuration and names of each part

The catheter mainly consists of a catheter, a catheter hub, a needle tube and a needle hub. Some may have a winged needle, a vent fitting, an inlet attached to the catheter hub, a mounting unit connecting to a liquid path, a catheter hub attached with a liquid guide tube, a backflow preventive valve, a needle tube with a groove or a hole, a needle tube without hollow, a coated catheter and a needle stick accident preventive tool. Catheters are classified into single-lumen tube or multilumen tubes.

Figure 1 shows an example of typical catheter.

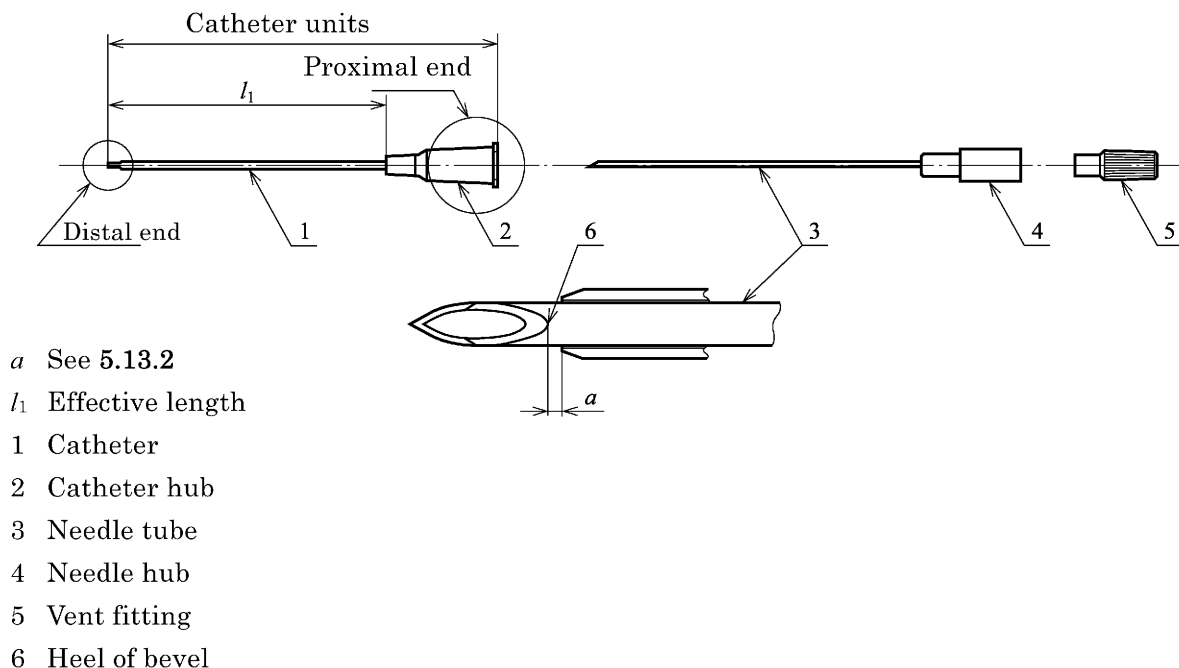


Figure 1 Configuration and names of each part of a catheter (example)

5 Requirements

5.1 General requirements

The catheter shall be sterilized with a validated method and meet 5.2 to 5.13 under sterile conditions. The sterility shall be ensured based on the criteria for validation of sterilization or the criteria equivalent or better to this.

NOTE : For the criteria for validation of sterilization, the criteria for validation of sterilization specified by the Ministry of Health, Labour and Welfare are included.

5.2 Chemical requirements

5.2.1 General

When tested according to 5.2.2, 5.2.3 and 5.2.4, the catheter shall be in conformity with these requirements, or when tested according to an equivalent foreign standard or superiors, it shall meet the standard.

5.2.2 Preparation of test solution and blank test solution

Preparation of test solution and blank test solution shall be as follows.

- a) **Test solution** Immerse 25 catheter units in 250 ml of purified water contained in the suitable vessel made of borosilicate glass. Make the entire surface of catheters as well as the inner wall of catheter hubs contact to the purified water. After keeping the water at temperature of 37^{+3}_0 °C for 2 h, cool it to the room temperature. Remove these catheter units and get back all of water on the external and inner walls of these catheter units into the vessel. The obtained liquid is taken as a test solution.

- b) **Blank test solution** At the same time, purified water without any catheter units is prepared with the same procedure as described above, and the obtained liquid is taken as blank.

5.2.3 pH

The pH difference between the test solution and the blank test solution shall be 1 or lower when determined according to pH Determination in General Test, Process and Apparatus of JP.

5.2.4 Limitations for dissolved metal

When the test solution and the blank test solution are analyzed by atomic absorption spectrophotometry or the equivalent or higher microanalysis method, and the measured value of the test solution is corrected with the measured value of the blank, the test solution shall contain a combined total of 5 mg/L or less of lead, zinc and iron. When the cadmium measurand of the test solution is corrected with the cadmium measurand of the blank, the cadmium content of the test solution shall be 0.1 mg/L or less.

5.3 Biological safety

The biological safety evaluation specified by JIS T 0993-1 shall be performed.

5.4 Endotoxin

Select 10 sets of the catheter units, rinse each catheter unit lumen with 40 ml of running test water for endotoxin at a rate of 10 ml/min, thoroughly wash the outer surfaces of the catheters with the solution and combine the solution to give a test solution. The content of endotoxin shall be less than 0.5 EU/ml by a test according to the endotoxin test in General Test, Process and Apparatus of JP, or comply with the equivalent criteria or superior.

5.5 Surface

No foreign matter shall be observed on the outer surface of the catheter with normal or corrected vision or 2.5-fold magnification. The outer surface of the catheter shall be free from abnormality or defect caused during the production process and damage on blood vessel during use shall be minimum.

When the catheter was coated, no droplet of a lubricant shall be permissible on the outer surface of the catheter by visual examination.

5.6 Resistance to corrosion

No corrosion shall be permissible on the metal part constructing the catheter unit by a test according to Annex A.

5.7 Breaking strength

When tested in accordance with Annex B, the breaking strength of each sample shall be as shown in table 1.

Table 1 Breaking strength of catheter sample

Minimum outside diameter of catheter sample mm	Minimum breaking strength N
≥ 0.55 , < 0.75	3
≥ 0.75 , < 1.15	5
≥ 1.15 , < 1.85	10
≥ 1.85	15
NOTE : No requirement necessary to the breaking strength of catheter with outside diameter of 0.55 mm or less is specified in ISO 10555-1 . The hydratable catheter shall use outside diameter pre-hydration.	

5.8 Airtightness

5.8.1 Leakage under pressure

No leakage of liquid shall be permissible for the catheter hub (if the catheter hub is used in connection with a connecting assembly part or the other part, they shall be connected) under the test according to Annex C.

The hydratable catheter shall be in conformity with the requirements under both conditions of pre-hydration and post-hydration.

5.8.2 Leakage under aspiration

No invasion of air shall be permissible in the hub assembly under aspiration during the test according to Annex D. The hydratable catheter shall be in conformity with the requirements under both conditions of pre-hydration and post-hydration.

5.9 Catheter hub

Whichever the catheter hub and the catheter may be integrated or separated, both shall be female hub, and meet **ISO 594-1** or **ISO 594-2**.

5.10 Flow rate

When tested according to Annex F, the flow rate (representative value) of the catheter unit shall be provided to the user. Determination of flow rate shall be performed both pre-hydration and post-hydration for the hydratable catheter.

5.11 X-ray detectability

It is recommended that catheters be X-ray opaque.

5.12 Multilumen catheters

For multilumen catheters, identification of each lumen shall be apparent to the user.

5.13 Physical requirements

5.13.1 Colour code

The catheter unit shall be colour-coded according to table 2 to indicate the nominal outside diameter of the catheter.

Table 2 Colour coding and corresponding sizes of catheter

Nominal outside diameter of catheter mm	Range of actual outside diameter mm	Colour ^{a) b)}	Gauge ^{c)}
0.6	0.550 to 0.649	Violet	26
0.7	0.650 to 0.749	Yellow	24
0.8, 0.9	0.750 to 0.949	Deep blue	22
1.0, 1.1	0.950 to 1.149	Pink	20
1.2, 1.3	1.150 to 1.349	Deep green	18
1.4, 1.5	1.350 to 1.549	White	17
1.6, 1.7, 1.8	1.550 to 1.849	Gray	16
1.9, 2.0, 2.1, 2.2	1.850 to 2.249	Orange	14
2.3, 2.4, 2.5	2.250 to 2.549	Red	13
2.6, 2.7, 2.8	2.550 to 2.849	Pale blue	12
3.3, 3.4	3.250 to 3.549	Light brown	10
Notes ^{a)} The colour may be opaque or translucent. Suggested colour references for an opacifying process are given in Annex G. ^{b)} The colour coding is usually applied to the catheter hub or to an integral fitting. ^{c)} The use of gauge is optional.			

5.13.2 Catheter unit

The distal end of the catheter shall be tapered for ease of insertion, and shall fit closely to the needle tube. When the needle tube is fully inserted into the catheter unit, the distal end of the catheter shall neither extend beyond the heel of the needle tube bevel nor be more than 1 mm from it (the heel part of needle bevel) (see *a* of figure 1).

5.13.3 Needle tube

- a) **Material** The needle tube shall be made of a rigid material and shall be straight and uniform in cross-section and wall thickness. If stainless steel is used, it shall comply with ISO 9626 or JIS G 4305. The needle tube shall not prevent flashback.
- b) **Needle point of needle tube** When examined by normal or corrected-to-normal vision with $\times 2.5$ magnification, the needle point shall appear sharp and free from feather edges, burrs or hooks.

NOTE: The needle point should be designed to be noncoring. Annex H shows examples of typical needle point geometries

- c) **Needle hub** The needle hub, another feature or a part to be connected to the needle hub shall permit detection of flashback, and shall be designed to communicate with the bore of the needle tube to detect flashback using the lumen of the needle tube. If the needle tube is provided with a removable vent fitting, the needle hub shall terminate in a female fitting with a taper complying with ISO 594-1.
- d) **Strength of union between needle hub and needle tube** When tested in accordance with Annex E, the needle tube shall not be loosened in the needle hub.