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**Tubes and catheters for nephrostomy and
cystostomy**

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Foreword

This Japanese Industrial Standard has been 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 Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3216 : 2012**), which has been technically revised.

However, **JIS T 3216 : 2012** remains valid for three years from the date of public notice of the revision of this Standard.

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Tubes and catheters for nephrostomy and cystostomy

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 20697** : 2018, Edition 1, with some modifications of the technical contents to reflect the conditions unique to Japan.

The 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 catheters used for urethral catheterization, contrast injection or chemical feeding, which are detained in kidney, ureter or bladder after performing percutaneous nephrostomy or cystostomy (hereafter referred to as catheters).

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

ISO 20697 : 2018 *Sterile drainage catheters and accessory devices 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**.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

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

JIS T 0993-1 *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*

JIS T 2107 *Single use surgical scalpel*

JIS T 3242 *The guide wire for non-vascular use*

JIS T 3260 *Dilators*

JIS T 3262 *Introducer needles and introducer catheters*

3 Terms and definitions

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

3.1

shaft

main body of a catheter to be inserted into the body

3.2

hub (connector)

connection between a catheter and other devices

3.3

funnel

female funnel-shaped fitting of a catheter

3.4

tip

tip or its part of a catheter to be inserted into the patient's body, viewed from the operator

3.5

balloon

balloon-like part provided at the shaft of a catheter, which is either for indwelling or expanding

3.6

lateral drainage hole

opening provided at the side face of a catheter

3.7

effective length

length of the catheter that can be inserted into the body (see Figure 1)

3.8

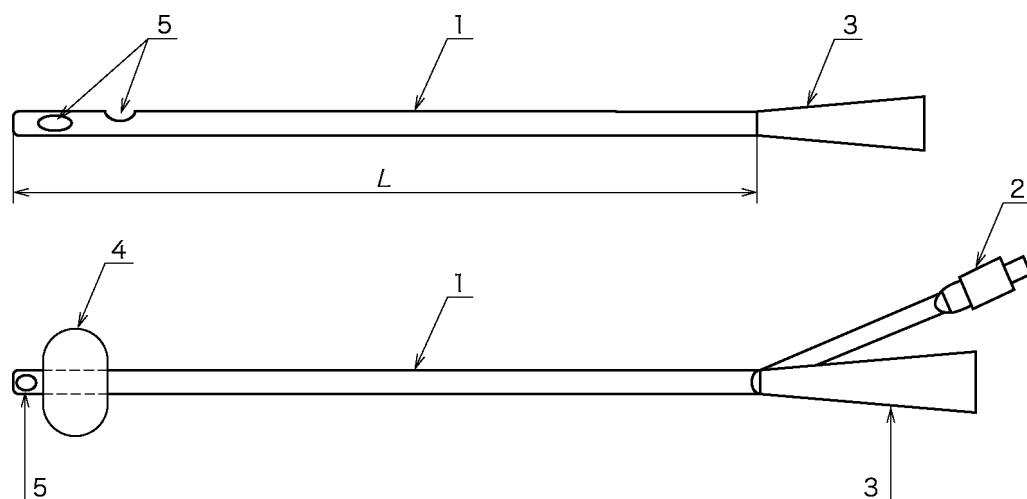
retention means

physical feature of a catheter (e.g. pigtail, malecot, balloon) provided at the tip of the catheter that prevents movement of the catheter out of the body (see Figure 2)

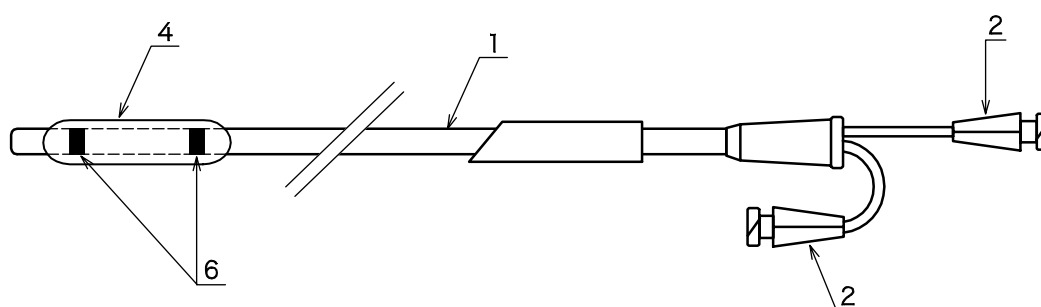
4 Configuration and names of parts

The typical configurations of catheters, along with names of parts, are shown in Figure 1. Balloon catheter of indwelling purposes and that of expanding purposes are illustrated. Configurations of retention means are shown in Figure 2.

Figures 1 and 2 show examples of configuration and names of parts of catheter and examples of shape of retention means, respectively.



a) Indwelling catheter



b) Expanding balloon catheter

- | | |
|-----------|-------------------------|
| 1 shaft | 5 lateral drainage hole |
| 2 hub | 6 marker |
| 3 funnel | |
| 4 balloon | L effective length |

NOTE Catheters may be equipped with the following accessory devices : shape retaining tools such as scalpels, puncture needles, stylets and obturators, or other tools such as dilators (sheaths), guide wires, joint tubes, cocks and fixtures.

Figure 1 Examples of configuration and names of parts of catheters

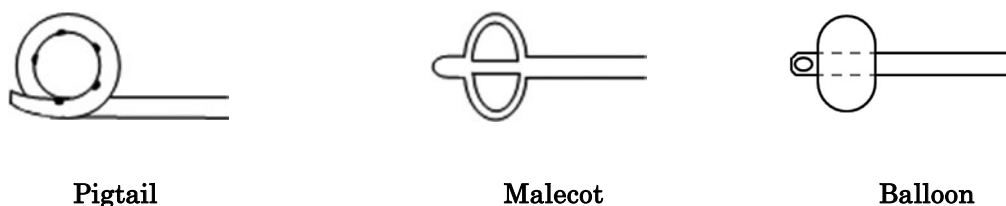


Figure 2 Examples of shape of retention means

5 Requirements

5.1 Appearance and cleanliness

When examined by normal or corrected to normal vision, the external surface of the effective length of the catheter shall appear free from extraneous matter or process defects (flaws, burrs, etc.). If deemed necessary, inspection shall be conducted under a minimum $2.5 \times$ magnification.

5.2 Detectability

The catheter or at least its effective length shall be detectable by X-ray or by other means (ultra-sound, etc.).

5.3 Corrosion resistance

If the catheter and its components use metallic materials which directly or indirectly come into contact with chemical or body fluid, the test shall be performed according to Annex A. If exposed metallic components of the device shows visible signs of corrosion, the extent of corrosion shall be evaluated based on the intended use and risk assessment to confirm the absence of effect on performance and safety of the product.

5.4 Indwelling catheter

5.4.1 Kink stability

The indwelling catheter shall be assessed by the kink stability test according to Annex B and demonstrate its ability to withstand the intended use.

NOTE Other test method than given in Annex B may be used.

5.4.2 Peak tensile force of connections of indwelling catheter

The connections of the indwelling catheter shall be tested according to Annex C and satisfy the minimum peak tensile force given in Table 1. The funnel-shaped connections shall be tested according to Annex D, and withstand the test load without the test connector coming off from the drainage funnel.

Table 1 Peak tensile force of the connections

Outer diameter mm	Minimum peak tensile force N
$2 \geq$	5
2 to 4	5
> 4	15

5.4.3 Peak tensile force of indwelling catheter and other accessory devices

The connections of the indwelling catheter and other accessory devices shall be tested according to Annex E and satisfy the minimum peak tensile force given in Table 2.

Table 2 Peak tensile force of catheters and other accessory devices

Outer diameter mm	Minimum peak tensile force N
2.5	5
2 to 4	10
> 4	20

5.4.4 Safety of indwelling balloon

If the indwelling catheter has a balloon, the change in profile at each end of the uninflated balloon shall have a smooth transition to the shaft.

The balloon shall be capable of approximately symmetrical expansion (the maximum ratio of the distance to the central part of shaft of balloon is less than 4) when filled with water at ambient temperature to its specified balloon capacity. Further, when tested according to Annex F, the balloon shall not leak and if the catheter has lateral drainage holes, shall not occlude the lateral drainage holes.

5.4.5 Volume maintenance of indwelling balloon

If the indwelling catheter has a balloon, the percentage of water recovered when the balloon is inflated and then deflated according to Annex G shall not be lower than the value given in Table 3.

Table 3 Balloon volume percentage recovery

Balloon capacity ml	Minimum percentage of volume recovered %	
	Silicone	Other than silicone
1.5 max.	30	55
3.0	50	55
5.0	55	55
10.0	75	75
20.0	80	80
30.0 min.	80	80
Intermediate cases are recommended to comply with the next higher value.		

5.4.6 Blockage of drainage lumen

The drainage lumen, when the indwelling catheter is immersed in simulated urine for 14 days and water is passed through the drainage lumen, shall be free from blockage and allow free flow of water.

If the indwelling catheter has an irrigation lumen, the same test applies to the irrigation lumen.

5.4.7 Retention strength

If the indwelling catheter has retention means other than a balloon, it shall be tested

according to Annex H by applying a pulling force, and demonstrate its ability to withstand the intended use without dislodgement.

5.5 Expanding balloon catheter

5.5.1 Peak tensile force When pulled at any two positions by the force of 3.9 N, the expanding balloon catheter shall be free from fractures and cracks.

5.5.2 Peak tensile force of the connections When the expanding balloon catheter and hubs are held and pulled by the force of 4.9 N, the catheter shall be free from fractures and cracks.

5.5.3 Pressure resistance When a pressurizer or an infuser is connected to the hub and the balloon is expanded by applying the pressure specified by the manufacturer/supplier, or injecting the volume of air or water specified by the manufacturer/supplier, the balloon shall be free from abnormalities such as burst and leakage.

The pressure or volume as specified by the manufacturer/supplier shall be stated in the accompanying document.

5.6 Accessory devices

5.6.1 Scalpels

The scalpels shall comply with the requirements of Clauses 5, 6, 7 and 8 of JIS T 2107.

5.6.2 Puncture needles

The puncture needles shall comply with the requirements of 5.4 and 5.5 of JIS T 3262.

5.6.3 Guide wires

The guide wires shall comply with the requirements of 5.1 of JIS T 3242.

5.6.4 Dilators

The dilators shall comply with the requirements of 5.4 and 5.5 of JIS T 3260.

6 Biological safety

The catheter shall be assessed for biological safety according to JIS T 0993-1.

7 Sterility assurance

For the catheters to be marked as STERILE, the sterility shall be assured based on the Criteria for Validation of Sterilization or the equivalent or stricter criteria.

NOTE For the validation of sterilization, the Criteria for Validation of Sterilization specified by the Ministry of Health, Labour and Welfare apply.

8 Packaging

8.1 Primary packaging

The primary packaging shall be capable of preventing the ingress of microorganisms