

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 3216 : 2012

(JMED/JSA)

**Tubes and catheters for nephrostomy
and cystostomy**

ICS 11.040.25

Reference number : JIS T 3216 : 2012 (E)

PROTECTED BY COPYRIGHT

Licensee=Hong Kong Polytechnic University/9976803100
Not for Resale, 07/25/2014 03:05:38 MDT

T 3216 : 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 3216 : 2012, First English edition published in 2013-10

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,
the original JIS is to be the final authority.

© JSA 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

PROTECTED BY COPYRIGHT

Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Composition and names of each part	2
5 Requirements.....	3
5.1 Appearance and cleanliness	3
5.2 Indwelling catheter.....	3
5.3 Expanding balloon catheter.....	4
5.4 Corrosion resistance	5
5.5 Components	5
6 Biological safety	5
7 Assurance of sterility	5
8 Packaging	5
8.1 Primary packaging.....	5
8.2 Secondary packaging	5
9 Labelling.....	5
9.1 Primary packaging	5
9.2 Secondary packaging	6
9.3 Use of symbols	6
Annex A (normative) Test method for safety of connector	8
Annex B (normative) Test method for tensile strength	9
Annex C (normative) Test method for durability of balloon	11
Annex D (normative) Test method for resistance to corrosion	13

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 3216 : 2011** 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 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.

Tubes and catheters for nephrostomy and cystostomy

Introduction

This Japanese Industrial Standard was established in 2005, and has gone through one revision made in 2011 to this day. And it has been revised this time in order to correspond the contents of the standard added thereafter.

Further, no International Standard corresponding to this Standard has been established at this point.

1 Scope

This Standard specifies the tubes and catheters used for urethral catheterization, contrast injection or chemical feeding, which are detained in renal, ureter or bladder after performing nephrostomy or cystostomy through the skin (hereafter referred to as “catheters”).

JIS T 3216 : 2011 may be applied until June 30th, 2015. Moreover, JIS T 3216 : 2005 may be applied until July 28th, 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 and the revisions (including amendments) made thereafter shall not apply.

JIS T 0307 : 2004	<i>Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied</i>
JIS T 0993-1 : 2012	<i>Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process</i>
JIS T 2107 : 2011	<i>Single use surgical scalpel</i>
JIS T 3214 : 2011	<i>Urethral catheters</i>
JIS T 3215 : 2011	<i>Drainage catheters and accessory devices</i>
JIS T 3242 : 2011	<i>The guide wire for non-vascular use</i>
JIS T 3260 : 2007	<i>Dilators</i>
JIS T 3262 : 2007	<i>Introducer needles and introducer catheters</i>
ISO 594-1 : 1986	<i>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1 : General requirements</i>

3 Terms and definitions

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

3.1 shaft

body of catheters to be inserted into the body

3.2 hub (connector)

connecting part between catheters and other devices

3.3 funnel

female funnel-shaped fitting of catheters

3.4 tip part

tip or its part of catheters to be inserted into the patient's body, viewed from operators

3.5 balloon

balloon-like part equipped at a shaft of catheter, which has two types for indwelling and expanding

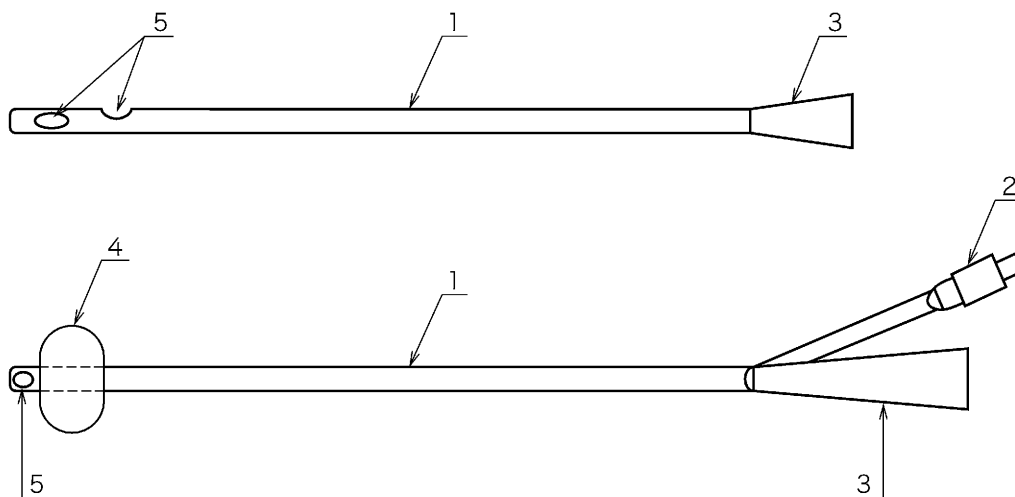
3.6 side hole

hole opening in the side face of catheter

4 Composition and names for each part

The composition and names of each part of typical catheters are as follows. A catheter with balloon has two type for indwelling and for expanding.

Figure 1 shows an example of composition and names for each part of the catheter.



a) Indwelling catheter

Figure 1 Example of composition and names for each part of the catheter