

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 3243 : 2005

(JMED/JSA)

**Catheters and tubes designed for
the biliary tract**

ICS 11.040.25

Reference number : JIS T 3243 : 2005 (E)

PROTECTED BY COPYRIGHT

AVA Documents
Document Sharing Hub

7 S

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization 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, utility model right or application for registration of utility model after opening to the public 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, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

Date of Establishment: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 3243 : 2005, First English edition published in 2005-12

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 2005

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

MT

PROTECTED BY COPYRIGHT

Contents

	Page
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions	1
4 Configuration and name of each part	2
5 Requirements.....	4
5.1 Basket catheter.....	4
5.2 Balloon catheter.....	5
5.3 Drainage tube	5
5.4 Appearance and cleanliness.....	5
5.5 Biological safety.....	5
5.6 Assurance of sterility	5
6 Packaging	6
6.1 Primary packaging	6
6.2 Secondary packaging	6
7 Labelling.....	6
7.1 Primary packaging	6
7.2 Secondary packaging	6
7.3 Use of symbols	7

Catheters and tubes designed for the biliary tract

1 Scope This Japanese Industrial Standard specifies requirements for tubes and catheters designed for the biliary tract and their components, which are inserted through duodenal papilla, skin (percutaneously) or hepatic duct into the biliary tract (cholecyst, cystic duct, biliary duct system), for the purpose of pus discharge, drainage, perfusion, expansion of stricture parts or duodenal papilla, prevention of stricture, and treatments such as fragmentation, grasp and recovery, extraction and removal of calculus.

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions (including amendments) of the standards 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 0601-2-18 *Medical electrical equipment—Part 2-18: Particular requirements for the safety of endoscopic equipment*

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

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

- a) **basket catheter** catheter provided with wire of basket shape at the tip part, and used for fragmentation, grasp and recovery or removal of calculus in the biliary tract

It is used with or without the endoscope, and can be operated by pushing the basket-shaped part out of the sheath by manipulating the hand-operated portion, and can fragment or grip the calculus by putting the basket-shaped part back into the sheath (see figure 1 and figure 2).

- b) **balloon catheter** catheter provided with the balloon for expansion or recovery to expand stricture parts of biliary duct or duodenal papilla, or to ablate calculus in the biliary tract

Some catheters are provided with the wire for incision of duodenal papilla (EST) (see figure 3 and figure 4).

- c) **drainage tube** flexible tube used for pus discharge, drainage, perfusion, splintage or prevention of stricture in the biliary tract

It has the following types : that used for internal stoma, that for external stoma, that for internal and external stoma. The shapes of their side holes and tips are various. Some are provided with the function to prevent dropout (balloon, pigtail, and Malecot, etc.) (see figure 5 and figure 6).

- d) **hand-operated portion** part to grip and operate the catheter (to open and shut the basket, or to bend and stretch the tip of the catheter, etc.)