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

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## Foreword

This Japanese Industrial Standard has been established by the Minister of Economy, Trade and Industry 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 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 3243**:2011 is replaced with this Standard.

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# Catheters and tubes designed for the biliary tract

## Introduction

This Japanese Industrial Standard was established in 2005 and has gone through two revisions up to the present. The last revision was made in 2011, and the revision at this time is made to correspond to the improvement of convenience for users derived from changes of the terms, structure of documents, etc.

## 1 Scope

This Standard specifies tubes and catheters designed for the biliary tract and their components. They are inserted into biliary tract [biliary duct (intrahepatic biliary duct, extrahepatic biliary duct), cholecyst, cystic duct, and papilla] or pancreatic duct, in the transduodenal, percutaneous transhepatic, or open abdominal surgery for the purposes of performing the treatment, such as pus discharge, drainage, perforation, expansion of stricture or papilla, prevention of stricture parts, fragmentation, grasp and collection, extraction and purge 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 of the standards (including amendments) indicated below shall be applied.

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

JIS T 0601-2-18 *Medical electrical equipment—Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

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

## 3 Terms and definitions

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

### 3.1 basket catheter

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

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

### 3.2 balloon catheter

catheter provided with the balloon for expansion or collection, to be used to expand stricture parts of biliary duct or duodenal papilla, or to exclude calculus in the biliary tract