



JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 3231 : 2011
(JMED/JSA)

**Hard-shell cardiectomy/venous reser-
voir systems (with/without filter) and
soft venous reservoir bags**

ICS 11.040.40

Reference number : JIS T 3231 : 2011 (E)

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Date of Establishment: 2005-03-25

Date of Revision: 2011-07-29

Date of Public Notice in Official Gazette: 2011-07-29

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 3231 : 2011, First English edition published in 2012-01

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.

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Printed in Japan

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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 3231 : 2005** is replaced with this Standard.

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Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 15674** published in 2001 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, extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) surgery (hereafter referred to as “blood reservoirs”).

This Standard applies only to the blood reservoir aspects for multifunctional systems which may have integral components such as blood-gas exchangers (oxygenators), blood filters, defoamers, blood pumps.

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

ISO 15674 : 2001 *Cardiovascular implants and artificial organs—Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags* (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 3231 : 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 T 0993-1 : 2005 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

NOTE : Corresponding International Standard : **ISO 10993-1 : 2003** *Biological evaluation of medical devices—Part 1: Evaluation and testing* (**IDT**)

JIS T 3250 : 2011 *Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

NOTE : Corresponding International Standard : **ISO 8637** : 2004 *Cardiovascular implants and artificial organs—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators* (MOD)

ISO 594-2 : 1998 *Conical fitting with 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2: Lock fittings*

ISO 10993-11 : 2006 *Biological evaluation of medical devices—Part 11: Tests for systemic toxicity*

3 Terms and definitions

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

3.1 hard-shell cardiotomy reservoir

extracorporeal device consisting of rigid walls designed to collect, defoam and filter suctioned blood

3.2 hard-shell venous reservoir

extracorporeal device consisting of rigid walls designed to collect and defoam venous blood

3.3 soft-bag venous reservoir

extracorporeal device consisting of collapsible, pliable walls designed to collect venous blood

3.4 hard-shell cardiotomy/venous reservoir system

extracorporeal device designed to function simultaneously as both a venous reservoir and cardiotomy reservoir

3.5 blood-gas exchanger

medical device designed to supplement, or be a substitute for, the respiratory function of the lung

3.6 blood

heparinized human, bovine or swine blood, whole or diluted with physiological saline solution

3.7 integral part

part that is connected to the blood reservoir or is part of the reservoir system and that cannot normally be separated by the user

3.8 operating variable

setting of controls which affects the function of the device