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**Blood filters for cardiopulmonary
bypass systems**

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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 3232 : 2005** is replaced with this Standard.

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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, or utility model right 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 or utility model right which has the said technical properties.

Blood filters for cardiopulmonary bypass systems

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 15675** published in 2001 with some modifications of the technical contents in order to harmonize 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 and single-use blood filters and defoaming devices intended for use in cardiopulmonary bypass systems.

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

ISO 15675:2001 *Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems—Arterial line blood filters* (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 3232 : 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)

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

ISO 7199 : 1996 *Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)*

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

3 Terms and definitions

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

3.1 arterial line blood filter

accessory device used as part of the cardiopulmonary bypass system in the arterial blood return line for filtering particles such as blood clots, debris and gas emboli from the blood

3.2 defoaming device

medical device used for defoaming at cardiopulmonary bypass surgery

3.3 blood pathway

paths of the arterial blood filter or defoaming device through which blood passes

3.4 blood

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

3.5 blood cell damage

loss or destruction of cellular components of the blood components

3.6 platelet percentage reduction

percentage reduction of platelets contained in a circuit incorporating an arterial line blood filter or defoaming device, less the percentage reduction in an identical control circuit without an arterial line blood filter or defoaming device, as a function of time

3.7 plasma-free hemoglobin generation

difference between the concentration of plasma-free haemoglobin in a circuit incorporating an arterial blood filter or defoaming device and the concentration in an identical control circuit without an arterial line blood filter or defoaming device, as a function of time

3.8 white blood cell percentage reduction

percentage reduction of white blood cells contained in a circuit incorporating an arterial line blood filter or defoaming device, less the percentage reduction in an identical control circuit without an arterial line blood filter or defoaming device, as a function of time

3.9 filtration efficiency

ability of the arterial line blood filter to remove particles from the blood analogue, expressed as a percentage

3.10 blood analogue

test solution which simulates blood viscosity