

# Central Drugs Standard Control Organization

Directorate General of Health Services

Government of India

(Medical Device Division)

Food & Drugs Administration Bhavan,  
Kotla Road, New Delhi.

File No: 31-1303-MD/2013-DC

Date: 21 OCT 2016

## MEDICAL DEVICE ALERT

### DEVICE

JMS Infusion set

The details of product is tabulated as below:

Name of Product	Batch No	Date of Mfg	Date of Expiry	Import License No	Imported by	Mfg by
JMS Infusion set	151125531	2015-11	2020-11	MD-1303-1932	M/s South India Surgical Co. Ltd., 850, Anna Salai, Chennai	M/s JMS Singapore Pte Ltd., 440 Ang Mo Kio Industrial Park 1, Singapore 569620
	151202531	2015-12	2020-12			
	151124531	2015-11	2020-11			
	151201531	2015-12	2020-12			
	151202532	2015-11	2020-11			
	151130531	2015-12	2020-12			
	151127531	2015-11	2020-11			

\* All other batches of JMS Infusion set imported during October 2013 to October 2016, imported with shelf life of 61 months.

### BACKGROUND

JMS Infusion set is intended for the delivery of fluid (medication and nutrients) to patients via an intravenous route. Approval was granted with a shelf life of 3 years based on the documents submitted by the Indian agent/manufacturer.

### PROBLEM

M/s South India Surgical Co. Ltd, New No 117, Old No 65, Ground Floor & First Floor, Wallajah Road, Anna Salai, Chennai – 2 has imported the said product with a shelf life of 61 months; whereas approved shelf life is 3 years by CDSCO.

### ACTION BY

- Medical Directors/Healthcare professionals
- Distributors and the Users

- Staff involved in the management of patients.

## **ACTION**

Form 15 has been issued for the above said product stating not to distribute the stock to further channel.

Recall order has been issued to all the importers.

Healthcare professionals/Distributors/Users are requested not to use or distribute JMS Infusion set bearing shelf life of 61 months.

## **ADVERSE EFFECTS**

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the use of JMS infusion set to the manufacturer, Importer and CDSCO.

## **CONTACTS**

- Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO Kotla Road, New Delhi-110002  
Tel: 91-11-23236975/23236971  
Fax: 91-11-23236973  
Email: dci@nic.in
- M/s JMS Singapore Ptd Ltd, 440 Ang Mo Kio Industrial Park 1, Singapore 569620.  
Tel: +65 6457 1144  
Fax: +65 6459 9564  
Email: jmssin@jmss.com.sg
- M/s South India Surgical Co. Ltd, New No 117, Old No 65, Ground Floor & First Floor, Wallajah Road, Anna Salai, Chennai – 2.  
Tel: +91-44-4219 5555  
Fax: +91-44-4322 7994  
Email: sisco@sisco.in