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: 31-608-MD/2009-DC (Re. Registration 2011) **Date:** 15 JAN 2014

MEDICAL DEVICE ALERT

DEVICE

Confidence Spinal Cement System

The detail of the recalled products is tabulate below:

Product Code	Product Description					
283910000	Confidence Spinal Cement System 11CC					
Lot Numbers						
CKCC0M	HMDDVB	HLKBM1	HMLCNM	HNDB3T	HLGBFT	HPDBGB
CKCCTP	HMFB6C	HLLBG9	HMMBJ5	HNFBMT	HLGBPH	
HKPBM0	HMFBB5	HLNBD1	HMMBM3	HNGB4Z	HLHBLN	
HLCBGD	HMGBMP	HLNBLK	HMNCC4	HNGB5Y	HLHBT7	
HLDB5F	HMGBTP	HLPBC6	HNCBBJ	HNGBHD	HMHBC8	
HLFBF3	HMGC00	HMBB36	HNCBBK	HNGBHZ	HMHBM2	
HLKBHK	HMKBG6	HMBBG4	HNCBN4	HNHB7N	HMHC28	
HLKBJH	HMKBRJ	HMBCRN	HNCBN5	HNJBHB	HMJB4D	

BACKGROUND

The Confidence Spinal Cement System combines unique highly viscous cement with a novel hydraulic delivery system. The radiopaque Confidence High Viscosity Cement reaches dough- like phase immediately after the cement components have been mixed, without going through a liquid phase. In addition, the viscosity of the Confidence Cement remains relatively constant throughout the entire working time of 8- 10 minutes. The hydraulic delivery system enables a smooth introduction of this highly viscous cement through specially designed introducer needles.

Johnson & Johnson Ltd., issued a notification or 'Field Safety Notice'.

PROBLEM

Voluntary recall has been initiated due to the reason that during injection of cement, (the water in the hydraulic pump leaks past the piston within the pump body resulting in the loss of pressure and inability to continue to inject the cement. This could result in surgical delay which could result in the need for the patient to undergo additional anesthesia as the result of another surgical procedure.

The another reason has been reported that , Firm reported that the cement mixer used to prepare cement for surgery has been identified to not turn properly. The event may be described as the mixer being "Jammed" or "Stuck" and not able to turn which could result in surgical delay in order to prepare another kit or the inability to complete the procedure if an additional kit is not available thereby exposing the patient to additional anesthesia in another surgical procedure.

ACTION BY

- Medical directors/ Healthcare Professionals
- Distributors and the Users
- Staff involved in the management of patients

ACTION

- Johnson & Johnson has ceased distribution of the product while evaluating appropriate corrective and preventive actions.

ADVERSE EFFECTS

There have been no events have been reported resulting in significant delay in procedure, inability to complete procedure or harm to the patients.

Patients and Healthcare professionals are advised to report adverse events suspected to be associated with the Confidence Spinal Cement System to the Manufacturer and CDSCO.

CONTACTS

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