



Medical Devices Bureau, Ministry of Health Malaysia
 Level 5, Block E6, Complex E,
 Federal Government Administration Centre,
 62590 Putrajaya, MALAYSIA.
 Tel: 03-8883 2248/2249/2264
 Fax: 03-8888 6184

Medical Device / Equipment RECALL

Date Issued : 25 April 2008

Ref:MDB/R/2008/003

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	Frazier and Poole suction instruments used in surgery. Manufactured by ConMed Corporation .
CLASS	Not Mentioned
USE	Frazier and Poole suction instruments manufactured by ConMed Corporation are single-use devices used during surgery for evacuating fluid, blood and debris. <u>ConMed Corporation is recalling instruments</u> manufactured between October 2006 and August 2007 inclusive. Lot number range: 061004-070731.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	MHRA website, date issued: 9 th April 2008
ALERTING FIRM	ConMed Corporation United Kingdom ConMed Corporation UK 73-74 Shrivenham Hundred Business Park Swindon SN6 8TY Tel: 01793 787 912 Fax: 01793 784 568 E-mail: tharris@conmed.co.uk tharris@linvatec.com

REASON	The sterility of some Frazier and Poole suction instruments may be compromised due to inadequate sealing of their packaging.
SCENARIO IN MALAYSIA	No details available at this moment. Please check whether the device is available and contact the distributor.
ACTION	To all users and healthcare providers having the abovementioned device used in their premises, please identify product codes of affected devices (see attachment). Contact the supplier and: • Identify the affected products.
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	Currently No Information Available
REFERENCES	http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014665 Letter From ConMed Corporation United Kingdom (see attachment)



October 22, 2007

**URGENT – Device Recall
ConMed Corporation – Frazier and Poole Suction Instruments
Catalog Numbers**

**0031030 0033080 0033120
0031100 0031070 0033180
0031050 0033110 0035040
0033100**

Lot No. Range 061004 - 070731

Dear Valued Customer:

ConMed Corporation has become aware of a limited number of Frazier and Poole Suction Instruments which may have an inadequate packaging seal. This seal which is made during the assembly of this product, may be incomplete or not present. Open seals create a situation where the product may become contaminated.

The contaminant, if found, would be the types normally found in dust, dirt, air, human, etc. environments. The risk associated with this type of contamination would be the same or less than the risk of exposing a patient to the general environment.

As a result of our previous action last year, ConMed automated the process for sealing the product pouches. This process was rigorously tested and addressed the issue which required us to recall these products last year.

However, we have found this activity to be ineffective in addressing operator errors. As a result, we have moved the assembly of this product to our corporate headquarters and have changed the packaging to eliminate the potential for this type of situation to reoccur.

ConMed has identified your facility as having received one or more shipments of the products which may be affected. Please review your inventory, then complete and return the attached Field Corrective Action Certificate by 05 November 2007 via fax per the instructions on the second page of this communication.

If you have a product in your inventory and require further information, please contact Teresa Harris at ConMed UK at 01793 787912 between the hours of 8:30 a.m. – 4:30 p.m.), or by e-mail at tharris@linvatec.com.

We would request that you pass this notification on to any individuals/departments within your organization. Please assure that all parties notified maintain awareness of the effected lot range stated on this letter.

Please be aware that ConMed Corporation has notified your National Competent Authority of the Field Safety Notice.

We apologize for this inconvenience and appreciate your assistance with this matter.

Sincerely,

Shawn Riedel
Vice President, Quality Assurance and Regulatory Affairs
ConMed Corporation