



## **1. DEVICE/EQUIPMENT:**

Frazier and Poole suction instruments manufactured by ConMed Corporation are single-use devices that may be used during surgery and resuscitation for evacuating fluid, blood and debris.

Conmed are recalling certain product and lot codes (see appendix).

## **2. PROBLEM:**

Previously recalled Frazier and Poole suction instruments, as cited in MDEA(NI)2008-026, have been inspected and re-supplied to customers by Conmed. However, their sterility may be compromised due to an unvalidated method of inspecting the seal on the packaging.

## **3. ACTION BY:**

All nursing, paramedic and supplies department staff.

## **4. ACTION:**

- Identify implicated stock (see list in appendix).
- Quarantine and do not use affected stock.
- Contact ConMed Corporation to arrange return and replacement.

## **5. ONWARD DISTRIBUTION TO:**

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- All wards and departments
- Ambulance trusts
- Day surgery units
- Infection control nurses
- Infection prevention and control directors
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatres
- Independent Health and Social Care Providers
  - Private Hospitals & Clinics, and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Teresa Harris  
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](mailto:tharris@conmed.co.uk)  
[tharris@linvatec.com](mailto:tharris@linvatec.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/084 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

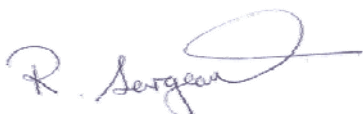
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
20<sup>th</sup> Nov 2008

Action Under Way:  
8<sup>th</sup> Dec 2008

Action Complete:  
29<sup>th</sup> Dec 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

## APPENDIX to MDEA(NI)2008/084



73/74 Shrivenham Hundred Business Park, Swindon, Wilts SN6 8TY  
Tel: 01793 787910 Fax: 01793 784802  
Email: info@conmed.co.uk

### URGENT: DEVICE RECALL

15<sup>th</sup> July 2008

**RE: Frazier and Poole Suction Instruments**

*Please read carefully as there have been previous recalls on similar devices*

ConMed Corporation is sending this communication to provide you with important information concerning a product issue with the Frazier and Poole suction instruments. All suspect product codes are listed in Attachment I. Please review your inventory for any of the devices listed on Attachment I.

These devices were manufactured by ConMed Corporation and were inspected for sterile barrier integrity using a non-validated method of inspection. The company has not been made aware of instances where the pouches are not properly sealed or are unsealed. In no instances has it been reported to the Company that a compromise in the sterile barrier has resulted in illness or injury. Some of the recalled devices were double sterilized. The sterilization method was correct and acceptable. However, the protocol for the use of the double sterilization had not been finalized.

Consequently, we are requesting that these affected devices be removed from both your inventory and from any facility to which you have supplied this product. As a distributor we are asking that you contact all of those facilities to whom you may have supplied these products. It is imperative that all end users of these devices receive this notice.

**Complete and FAX Attachment II and return a copy with the devices.**

**Return to: ConMed Linvatec UK  
73-74 Shrivenham Hundred  
Business Park  
Swindon, Wilts. SN6 8TY**

If you do not have any devices to return, please indicate this on Attachment II and fax it back. Please do not return used disposable devices.

**If you have questions, please contact ConMed Quality Assurance by FAX at 01793 784568 or email [Lbyrne@linvatec.com](mailto:Lbyrne@linvatec.com).**

The US Food and Drug Administration and the appropriate Competent Authorities have been notified of this action. We apologize for any inconvenience this will cause you and your staff.

Sincerely,

Nancy B. Crisino  
Recall Coordinator

www.conmed.co.uk  
Conmed UK is a trading division of Linvatec UK Limited  
Registered Office: 73/74 Shrivenham Hundred Business Park, Swindon, Wilts SN6 8TY  
Registered in England No.3535936

# APPENDIX to MDEA(NI)2008/084

## MEDICAL DEVICE RECALL

### ATTACHMENT I – PRODUCT CODES AND LOT CODES

#### Identification of Affected Devices:

PRODUCT CODE	DESCRIPTION
0031030	BARON FRAZIER, 3 FRENCH, 50/C
0031050	BARON FRAZIER, 5 FRENCH, 50/C
0031070	BARON FRAZIER, 7 FRENCH, 50/C
0031100	SOFT TIP FRAZIER, 10 FR, 40/C
0033080	FRAZIER INSTR, 8 FRENCH, 50/C
0033100	FRAZIER INSTR 10 FRENCH, 50/C
0033110	OLIVE TIP FRAZIER 10 FR, 50/C
0033120	FRAZIER INSTR 12 FRENCH, 50/C
0033180	FRAZIER INSTR 18 FRENCH, 50/C
0035040	POOLE SUCTION INSTRUMENT 50/C

#### For ALL catalog numbers listed above:

Devices that have packaging which exhibits the following lot code information:

- Any of the above devices having a lot code that begins with the letters: UR
- Any of the above devices having a lot code that begins with the letter: E
- Any of the above devices having a lot code that ends with the number: 3

Additionally, the lot codes for Frazier Instrument 10 French listed below are also affected:

Product Code	Lot codes
0033100	0706191
	0706211
	0706221
	0706251
	0706261

Lot codes on boxes and packaging contain a lot code in the following form:

**07 0619 1**

- 07 — Year ( 2007 )
- 06 — Month
- 19 — Day of the Month
- 1 — Manufacturing shift code (1, 2, or 3)



# APPENDIX to MDEA(NI)2008/084

## ATTACHMENT II-EFFECTIVENESS CHECK MEDICAL DEVICE RECALL BUSINESS REPLY FORM

Please check all that apply:

- We DO NOT have any stock of the suspect lots.
- We have notified our accounts to return their stocks of the product to us.
- We are returning: (Complete table below)

PRODUCT CODE	QUANTITY RETURNED
0031030	
0031050	
0031070	
0031100	
0033080	
0033100	
0033110	
0033120	
0033180	
0035040	

Return this completed form by fax to ConMed Quality Assurance at 01793 784568.

If you are returning product, a completed copy of this form MUST be returned with the devices.

**Return devices to:** ConMed Linvatec UK  
73-74 Shrivenham Hundred  
Business Park  
Swindon, Wilts. SN6 8TY

**CHECK ONE:** I request credit \_\_\_\_\_ (for direct consignees ONLY)  
I request No charge replacements \_\_\_\_\_

Have you received any reports of illness or injury related to this product? Yes \_\_\_\_\_ No \_\_\_\_\_

Your Name: \_\_\_\_\_  
(Please Print)

Signature: \_\_\_\_\_

Distributor/Hospital : \_\_\_\_\_

Address: \_\_\_\_\_

Please complete at least one:

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

Email: \_\_\_\_\_

