URGENT: DEVICE RECALL

November 10, 2006

RE: Frazier and Poole Suction Instruments

ConMed Corporation is sending this communication to provide you with important information concerning a potential sterile barrier issue with the Frazier and Poole suction instruments. All suspect product codes and lot codes are listed in Attachment I.

Devices that were manufactured by ConMed Corporation between October 4, 2001 and October 4, 2006 may have a compromised sterile barrier. The company has 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. Consequently, we are requesting that these devices be removed from both your inventory and from any facility to which you have supplied this product.

Complete Attachment II and return devices immediately to Attn. [redacted] ConMed Corporation, 525 French Road, Utica, NY 13502 USA, using FedEx Account [redacted]. Also include the following Information ConMed FDA Reg.# [redacted] exempt. Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's proposes and note on the commercial invoice the return is for evaluation purposes. ***Please indicate with your returned devices, if you are requesting credit or replacement of the devices.*** Please do not return used disposable devices. 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. If you have questions, please contact [redacted] at +315-624-[redacted] or fax to +315-624-3089 or email [redacted]@mail.conmed.com.

We apologize for any inconvenience this will cause you or your staff.

The US Food and Drug Administration and the appropriate Competent Authorities have been notified of this action.

Sincerely,

[redacted]

[redacted]
Vice President, Quality and Regulatory

ConMed Corporation

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, 20/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

Devices affected were manufactured on the following dates and contain the following lot codes:

Manufactured from: **October 4, 2001** to: **October 4, 2006**
Lot Codes from: **0110041** to: **0610041**

Lot codes on boxes and packaging contain a lot code in the following form:
0409271

04 09 27 1
- 1 – Manufacturing shift code
- 27 – Day of the Month
- 09 – Month
- 04 – Year (2004)

ATTACHMENT II-EFFECTIVENESS CHECK

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 the form by fax to [redacted] at +315-624-3089. If you are returning product, please enclose a copy of this form with the returned devices.

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:_____

Do you request: Credit:_____

No charge replacements:_____