URGENT: FIELD SAFETY NOTICE

ConMed Corporation WANG™ Transbronchial Aspiration Needles

28 November 2012

ConMed Corporation is sending this communication to provide you with important information concerning a product issue with certain WANG™ Transbronchial Aspiration Needles. All suspect product catalog numbers and lot codes are listed in Attachment I.

These devices were manufactured by ConMed Corporation. ConMed has received complaints of some devices which would not insert properly through the instrument channel of a 2.0mm bronchoscope. ConMed confirmed the complaints. Other than possible difficulty in inserting the device through a 2.0mm scope, ConMed Corporation has no reason to suspect any other issue with the product. Though the potential misfit between the WANG™ Transbronchial Aspiration Needles and the standard instrument channel of a 2.0mm scope does not pose a risk to health, ConMed Corporation has decided to recall the devices listed on Attachment I to the user level. **Therefore, please stop the use of these devices immediately.**

Please review your inventory for any of the devices listed on Attachment I.
We ask that you contact all of those organizations within your facility and any other facilities that you may have supplied or given these affected products to. It is imperative that all end users of these devices receive this notice. **If you have questions, please contact Patricia Cotter, ConMed Recall Coordinator +1 315-624-3237 or fax to +1 315-624-3225 or email wangtban@conmed.com.** You may also contact our Authorized Representative MDSS GmbH situated in Germany via email at info@mdss.com or via phone at +49 511 6262 8630.

If you have any devices listed on Attachment I, please complete Attachment II and return it with the devices to:
ConMed Corporation,
525 French Road, Utica, NY 13502
United States of America
Attn. [redacted]
Return via: FedEx Account # 2919-6855-4

Please process a commercial invoice for the return to the United States referencing your purchase price as a value for Custom's purposes and note on the commercial invoice that the return is for evaluation purposes only. Please include the following information on the invoice, with the returned product:
ConMed FDA Reg. # 1317214
MDL# E531635
510K # K914181
Please do not return used devices.

If you do not have any devices to return, please complete Attachment II, indicating you have no devices and fax it to +1 315-624-3225, Attn: Patricia Cotter.

We apologize for any inconvenience this will cause you or your staff.
The US Food and Drug Administration have been notified of this action. In addition, the appropriate foreign competent authorities have also been notified.

Sincerely,

[redacted]

Patricia Cotter
FSCA Coordinator

ATTACHMENT I
PRODUCT CODES

MEDICAL DEVICE RECALL

Identification of Affected Devices:

Catalog Number	Device Name
MW-222	WANG™ Cytology Needles, Central or Peripheral Regions, 22g x 13mm long needle
MW-322	WANG™ Cytology Needles, Central, Mediastinal and Hilar Regions, 22g x 13mm long needle
SW-121	WANG™ Cytology Needles, Central, Carinal and Mediastinal Regions, 21g x 15mm long needle
SW-221	WANG™ Cytology Needles, Central or Peripheral Regions, 21g x 15mm long needle

Affected lot codes for ALL catalog numbers listed above:

Lot codes for product manufactured to and including the dates listed below:

Catalog Number	Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
MW-222	July 25, 2012	1207251	July 25, 2012	1207251
MW-222	September 17, 2012	1209171	October 15, 2012	1210151
MW-322	September 17, 2012	1209171	October 10, 2012	1210101
SW-121	July 24, 2012	1207241	July 25, 2012	1207251
SW-121	September 17, 2012	1209171	October 8, 2012	1210081
SW-221	September 17, 2012	1209171	September 20, 2012	1209201

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

12 09 17 1

12 09 17 1
- 1 — Manufacturing shift code 1, 2, 3, 4,5,6 or 9
- 17 — Day of the Month
- 09 — Month (September)
- 12 — Year (20**12**)

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)**

Catalog # being returned	Quantity per Box	Quantity of Boxes
MW-222	4/Box	
MW-322	4/Box	
SW-121	4/Box	
SW-221	4/Box	

Have you received any reports of illness or injury related to this product? Yes_____ No__
If yes-please document specific information. Include it when this form is returned to Patricia Cotter.
Return this completed form by fax to: Patricia Cotter at +1 315-624-3225.

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

Charge shipping to: FedEx Acct # 2919-6855-4
Return devices to: ConMed Corporation
525 French Road
Utica, NY 13502 USA
Attn: [redacted]

Your Name:_____
(Please Print)
Signature:_____
Distributor/Hospital :_____ Account #_____
Address:_____
_____
_____
Please complete at least one:
Phone:_____
Fax:_____
Email:_____

Credit will be issued for recall goods being returned